# Winner EVO Series OPERATION MANUAL





## **CAUTION**

The operator should read and be familiar with the precautions and operation of this device prior to beginning treatments.

This device is not designed to be connected with any electrical equipment or accessories unless manufactured and/or approved by Rich-Mar. This includes whirlpools, lead cords, probes, self-adhesive electrodes and carbon electrodes NOT manufactured by Rich-Mar.

## 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.

For continued protection against fire hazard, replace fuses ONLY with those of the same type and rating.

This equipment should always be grounded. Grounding reliability can only be achieved when the equipment is connected to an equivalent marked, "Hospital Grade."

This device should be kept out of the reach of children.

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# 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 funtion 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 Thrity (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 unarthorized centers or groups will void this warranty.

The warranty period for certain accessories is 90 days. These 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 / FAX(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 MERCHANT ABILITY OR FINESS FOR A PARTICULAR PURPOSE.

# WINNER EVO SERIES

## **FRONT VIEW**

## WINNER EVO COMBO

## WINNER EVO STIM



- 1. Ultrasound User Interface
- 2. E-Stim User Interface
- 3. Intensity Knob
- 4. 2 or 4 Channel Output

- 5. E-Stim User Interface
- 6. Intensity Knob
- 7. 2 or 4 Channel Output

# WINNER EVO SERIES

## **REAR VIEW**

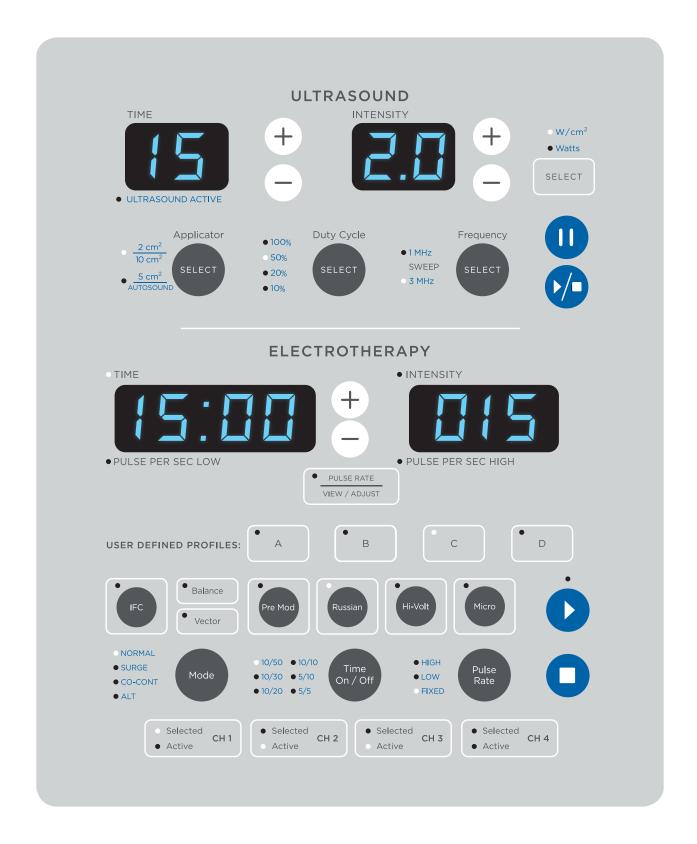


- 1. Ultrasound Applicator Cradle
- 2. Laser/Light Module (optional)
- Ultrasound Applicator Plug (CM units)
   Cooling Fan
- 4. Combo Mode Stim Lead Jack

- 5. Unit Power Module with ON/OFF Switch
- 6. Electrical Stim Lead Cord Test Jack

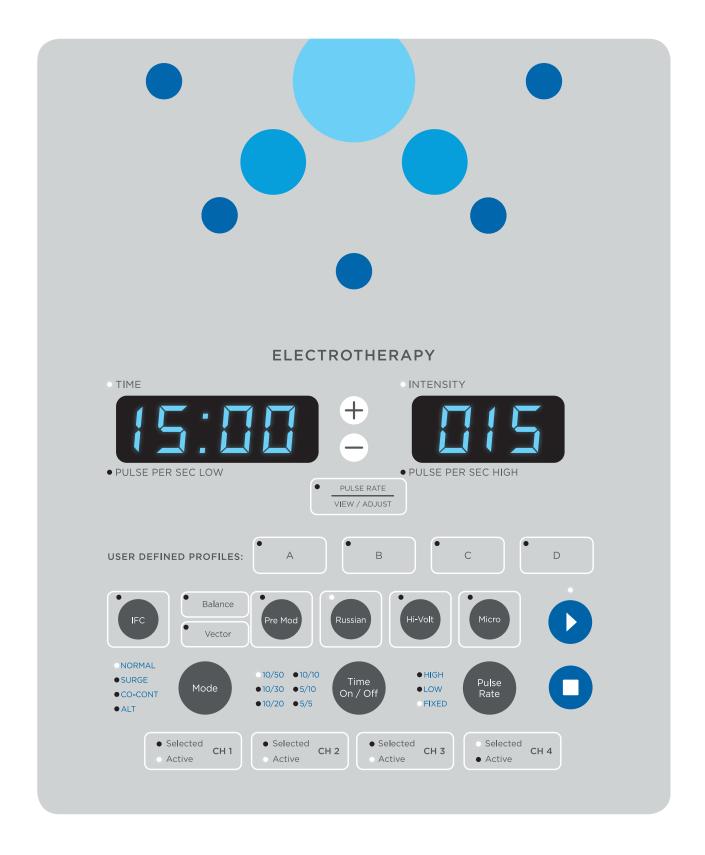
# **USER INTERFACE**

## Winner EVO Combo

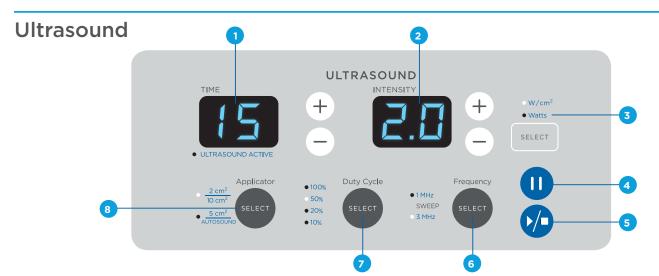


# **USER INTERFACE**

## Winner EVO Stim

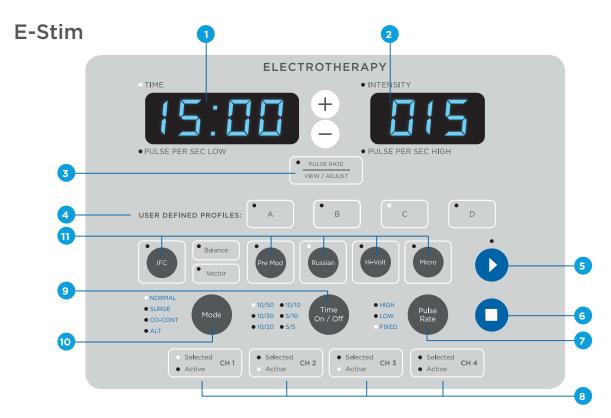


## **USER INTERFACE**



- 1. Time Display and Adjust
- 2. Ultrasound Intensity Display and Adjust
- 3. W/cm or Watts Display Select
- 4. Ultrasound Pause/Resume

- 5. Ultrasound Start/Stop
- 6. Ultrasound Frequency
- 7. Ultrasound Duty Cycle
- 8. Applicator Select



- 1. Time Display and Adjust
- 2. Intensity Display
- 3. Pulse Rate Adjust
- 4. User Defined Profiles
- 5. Start Treatment
- 6. Stop Treatment

- 7. Pulse Rate Select
- 8. Channel Select
- 9. Time ON/OFF Select
- 10. Mode Select
- 11. Stim Output Modality Select

#### Introduction

The Winner units are products that resulted from dedication to research and development. The Winner units offer the most flexible treatment possibilities in a convenient, easy-to-use package. This manual is meant to familiarize the user with the controls, operations, waveforms and ultrasound therapies available in the Winner units. The simple control of the unit allows the user to master the unit's vast capabilities more quickly and easily.

### **User Interface**

The Winner units use a straight forward control panel with each waveform therapy and parameter clearly labeled. Each button requires only light pressure to be activated. You should also hear an audible beep each time a button is pressed. LED lights illuminate indicating the availability and/or selection of particular parameters. The large and bright LED numerical displays show treatment time, intensity and pulse rates.

### **Power Switch**

This power switch turns the unit on and off and is located on the rear side of the unit. "I" represents the on position and "O" represents the off position.

## Winner Operation Overview

The Winner Series offers a variety of different devices to fit your therapy needs:

The CM4 models are four-channel, multi-therapy stimulationultrasound combination units. The Winner CM2 models are the two channel combination version.

The ST4 is a four-channel multi-waveform stimulator, and the ST2 is a two-channel version.

The Winner units will output any one of the following waveforms:

Quadpolar IFC (Classic Interferential) Premod IFC (Bipolar Interferential)

Russian

Hi-Volt

Microcurrent

Depending upon the waveform in use, any one of the following treatment modes can also be used:

Normal output

Surge output

Co-Contraction output

Alternating channel output

NOTE: For more information on outputs, see the

"Waveforms" section.

The Winner CM4 and CM2 can also provide 1MHz and 3MHz ultrasound frequencies.

Note: For more information, see the "Ultrasound" section.

### **Electrical Stimulation**

Once the device is turned on, you will notice that the green LED lights in the Waveforms (Quadpolar IFC, Pre-Mod IFC, Russian, HiVolt and Micro) and the Therapy Profiles are blinking. This is to indicate that the unit is on and ready for treatment. It is also a quick reference to determine if the device is in the Easy Therapy Profile mode or Advanced Therapy Profile mode (see Therapy Profile section for more information).

\* If no treatments are running and no buttons are pressed the device will go into a "sleep mode" where the LEDs will not blink on the stimulator side. Simply press any button to re-activate the stimulator.

### To Start a Stim Treatment

Press the button of the desired Waveform or Therapy Profile. Once you do this you will notice that the device has selected the first available channel(s). For example, if you turn on the device and press the Pre-Mod IFC button, the green LED next to Selected in the Ch. 1 button will illuminate. This indicates that the treatment will output from Ch. 1 and you should use that lead cord to apply the electrodes, or you can now select the CHANNEL you want to use by first pressing that channel's button.

You will then notice that the Waveform/Profile LEDs are blinking. You then select the waveform or profile you would like to use by pressing it's button.

However you have selected to begin your treatment (either picking the waveform first or the channel button first) you will then notice that certain LEDs have been illuminated indicating that they are currently selected. Using the example above of Pre-Mod IFC, the LEDs are lit next to Normal, a High pulse Rate and 15:00 minutes of treatment time. You can change any of these parameters by pressing the appropriate button(s) noticing that the LED lights change too. Once the desired parameters are displayed, the Winner devices will prompt you to set Intensity by flashing the Adjust LED light underneath the Intensity dial. As you set the desired intensity level, you will notice that the green Active light is illuminated in the Ch. 1 button to indicate that current is being output. Once the desired intensity level has been set press the Start/Accept button and the time begins counting down.

NOTE: When using Quadpolar IFC one of the channel pair's Selected light will blink. If you balance the treatment then the intensity display will be different between the two channels. Whichever channel's Selected light is constantly illuminated will display its intensity level.

## **Running Concurrent Stim Treatments**

The Winner units have either four independent stimulation channels (CM4 and ST4 models) or two independent stimulation channels (CM2 and ST2 models). This allows you to treat four or two different sites or patients at the same time with completely different treatment parameters. To start a concurrent stim treatment press the desired waveform or Therapy Profile or channel for the second treatment. If you pressed the Waveform or Profile button the green Selected LED light in the Ch. 2 button should now be illuminated. If you pressed a channel button than that channel's Selected LED should be illuminated.

You will also notice that the green Selected LED light on Ch. 1 went out but its green Active LED light is still illuminated. This means that there is a treatment currently on Ch. 1 but its parameters are not selected for display. If you pressed the waveform or Profile button the treatment parameters on Ch.2 are now displayed. If you pressed a channel button you now need to select the waveform or Profile you want to use and its parameters will be displayed. Any adjustments can now be made to the parameters for this second treatment. Then, set Intensity and press the Start/Accept button to begin the treatment time countdown. NOTE: If the Quadpolar IFC therapy waveform is selected, it requires both channels one and two or channels three and four and will subsequently set the same intensity level on both channels. Once the intensity levels are set in Quadpolar IFC and the Start/Accept button has been pressed, you have the option of Balancing the output by pressing the Balance button. When pressed, the green LED light on the Balance button will illuminate and the green Adjust LED light will illuminate under the intensity dial. Use the dial to balance the patient's sensation. You will see only the selected channel's intensity level increase or decrease, but understand that as it increases, the other Quad IFC channel's intensity decreases proportionately. Once the balance has been completed, press the Start/Accept button.

### **To View Stimulation Treatment**

If you are running two or more concurrent stim treatments, you will only see one treatment's parameters at a time. Press the desired channel button to illuminate its Selected LED light. You will then see all the parameters for that particular channel's treatment. Whichever channel button you press will activate the Selected LED and display that treatment's parameters.

## **To Stop a Stimulation Treatment**

If you only want to stop a single treatment without affecting the other treatments, press and hold the desired channel button and the stimulation Stop button at the same time.

NOTE: If you just press the stimulation's Stop button it WILL STOP ALL STIM TREATMENTS.

### **Waveform Parameter Options**

Waveform choices include Quadpolar IFC, Pre-Mod IFC, Russian, Hi-Volt (Monophasic), and Microcurrent.

Quadpolar IFC will only output classic Interferential current in a Normal mode and it requires both Ch.1 and Ch. 2 or Ch. 3 and Ch. 4 (if applicable). The Balance button allows for better patient sensation balance if that button is selected - as you increase or decrease intensity on the selected channel it will do the opposite on the other channel in the pair. Quadpolar IFC also allows you to turn an amplitude modulating Vector on or off. The Vector provides a soothing massage effect and also helps to lessen patient accommodation. The Pulse Rate available is either the High, Low or a Hi-Lo combination.

*Pre-Mod IFC* will output pre-modulated, two-pad Interferential current in any of the desired Modes (Normal, Surge, Co-Cont and Alternating). The Vector can be turned on or off in the Normal mode. The Pulse Rates available in the Normal mode are High, Low, and Hi-Lo scan. If the Surge, Co-Contraction, or Alternating mode is selected, only the Fixed Pulse Rate is available. Any of the six On/Off timing options are available in the Surge or CoCont modes. In the Alternating mode the 10/10 or the 5/5 timing cycles are available.

**Russian and Hi-Volt-** Both waveforms are available in any of the Modes (Normal, Surge, Co-Cont, and Alternating). The Fixed Pulse Rate is only available for Russian.

\* The Hi-Volt Pulse Rates available in the Normal mode are High, Low, and Hi-Lo scan. If the Surge, Co-Contraction, or Alternating mode is selected, only the Fixed Pulse Rate is available. Any of the six On/Off timing options are available in the Surge or Co-Cont modes. In the Alternating mode, the 10/10 or the 5/5 timing cycles are available.

**NOTE:** The Hi-Volt in the Winner is a non-dispersive style. This means that for each channel, one of the electrodes is positive and the other is negative. When using the Hi-Volt waveform, the *red pin is positive* and the *white pin is negative*.

*Microcurrent* will only output in a Normal mode and its Pulse Rate is only available as a Fixed output.

## **Stimulation Modes**

Depending upon the waveform selected, the user can choose from Normal, Surge, Co-Contract and Alternating modes.

*Normal Mode* is basic continuous, un-interrupted output of the selected waveform.

Surge Mode is a single channel of output that is interrupted in an "on/off" method of a certain time, in seconds, of output followed by a certain time, in seconds, of no output. For example, if Surge mode is selected and the "10/20" option is selected, this means that for 10 seconds there will be output to the set intensity level followed by 20 seconds of zero output. The cycle continues until treatment time expires.

\* NOTE: There is a built-in ramp up time of three seconds in the "on" time and a ramp down of one second in the "off" time.

**Co-Contraction Mode** is the same as the Surge mode except that it will concurrently run two channels, either 1 and 2 or 3 and 4, to the same "on" and "off" time. Independent intensity levels can be set.

Alternating Channel Mode will alternately turn one channel "on" and then a second channel "on" as soon as the first channel goes into the "off" time. For example, in an Alt mode both Ch. 1 and Ch. 2 will be used. If the "10/10" option is selected in the Time On/Off then, after intensity levels have been set for each channel and treatment started, Ch. 1 will be "on" for 10 seconds. Once Ch.1 goes "off", Ch. 2 will be "on" for 10 seconds. This alternating will continue until treatment time expires.

## To Adjust Stimulation Intensity during Treatment

Intensity can be adjusted during treatment, even during the off cycle in Surge or Alternating modes, simply by pressing the desired Channel button.

*Normal mode intensity adjustment-* When in Normal Mode, you will notice that the light in the Start/Accept button is flashing. Once the level is adjusted, press Start/Accept and the user will be prompted to do the same for channel two, if applicable.

# Timing Mode Intensity Adjustment- Surge, Co-Cont & Alt Surge Mode Intensity Adjustment

In the Surge mode, press the Channel button and you will notice that the Start button is blinking. Press the Start button to access a change in intensity as a safety feature. You will then notice that the time has stopped counting down and the channel's Active LED is illuminated. Make your intensity adjustment and press the Start button when finished. The timing cycle will now start over. This process is done as a safety feature so that you cannot increase intensity during the "off" cycle.

## Co-Contract or Alternating Modes Intensity Adjustment

These modes use two channels so you need to press the button for the Channel that you want to adjust. Once you do this, notice that the Start button is blinking. You cannot change the intensity until you press the Start button. Press the Start button and the treatment's other channel Active LED goes out, the selected channel's Active LED illuminates, and the Timer stops counting down. Make your intensity adjustment and press the Start button when finished. The timing cycle will now start over. This process is done as a safety feature so that you cannot increase intensity during the "off" cycle.

## **Stimulation Pulse Rates**

Depending upon the waveform selected, the user can use either a Scan (High, Low or Hi-Lo) or a Fixed pulse rate. Once the type of pulse rate has been selected (High, Low, Hi-Lo or Fixed), press the Pulse Rate View/Adjust button. If a Scan is selected, the low end of the Scan will be displayed in the Stim Time display but note that the Pulse 1 light is illuminated. The high end of the Scan will be displayed in the Stim Intensity display but note that the Pulse 2 light is illuminated now. At this point you can make adjustments to either end of the Scan by using the up/down arrows for Pulse 1 and the dial for Pulse 2. Once the Pulse Rate has been selected press the Start/Accept button.

*The High Scan and Low Scan* will make a complete cycle through the selected pulse rate range in 30 seconds. For example, if a 100-120 scan is selected it will start at 100 Hz and scan up to 120Hz and back down to 100Hz every 30 seconds.

*The High-Low Scan* pulse rate mode will split the treatment time in half with the first half using the High pulse rate scan and the second half using the Low pulse rate scan.

To set up a Hi-Lo pulse rate scan set the High scan and then the Low scan and select the Hi-Lo Pulse Rate. Follow these steps:

- -Press the Pulse Rate button and select High pulse rate.
- -Press the Pulse Rate View Adjust button and set the desired High scan.
- -Press the Pulse Rate View button again. -Press the Pulse Rate Mode button to select the Low pulse rate. -Press the Pulse Rate View Adjust button and set the desired Low scan.
- -Press the Pulse Rate View button again.
- -Now press the Pulse Rate Mode button until the High-Low is selected (both LEDS will be lit for High and Low.
- -Set time and intensity and begin treatment.
- \* The LED of the pulse rate that is currently running in the High-Low scan will be constantly lit and while the other scan's LED will be blinking.

Example: You start a treatment in the High-Low Scan and the High LED is constant and the Low LED is blinking. This indicates the that High scan is currently outputting. You can verify this by pressing the Pulse Rate View Adjust.

### Fixed Pulse Rate

If Fixed pulse rate is selected and the Pulse Rate View/Adjust button has been pressed, the pulse rate is displayed in the Stim Time display and the Pulse 1 light is illuminated. Make adjustments to the fixed pulse rate by using the up/down arrows or the dial. After selecting Pulse Rate press the Pulse Rate View/Adjust button.

## **Stimulation Treatment Time**

Treatment time for the Winner stimulation is adjustable from 199 minutes. You can adjust treatment time in one minute increments at any time by pressing the increase or decrease buttons below the treatment time during the displayed treatment.

# Setting Waveform Defaults and Therapy Profiles Waveform Defaults-

To set particular parameters so that they are defaults for a Waveform button, select the Waveform and set all the parameters as desired: Treatment time, Mode, Time On/ Off (if applicable) and Pulse Rate. Once all parameters are selected, set the Intensity and PRESS AND HOLD THE START/ ACCEPT BUTTON UNTIL YOU HEAR TWO CLICKS AND A LONG TRILL. When this occurs, it has stored those displayed parameters as the default for that waveform. Repeat this process for each waveform. For example, if you wanted to change the Pre-Mod defaults to a Surge treatment:

- Press the PreMod IFC button,
- Select the Surge Mode,
- Select the 10/10 Timing Cycle.
- Press the Pulse Rate View Adjust and set a 65 Hz pulse rate and press the Pulse Rate View Adjust again
- Set the Treatment Time for 8 minutes.
- Turn the dial to set the intensity and PRESS AND HOLD THE START BUTTON UNTIL YOU HEAR TWO CLICKS AND A LONG TRILL.

Now, whenever you press the PreMod IFC button, it will come up with the above treatment.

## Therapy Profiles -

The Winner devices will allow you to use either the Easy Therapy Profile mode or the Advanced Therapy Profile mode. The Easy Therapy Profile mode allows you to set a total of four different therapies so you can start a treatment with one touch. The Advanced Therapy Profile mode will allow you to have *four different profiles for each waveform*, giving you a total of 20 Therapy Profiles. If the device is in the Easy Therapy Profile mode, the Profile

LEDs will blink along with the waveform LEDs when the device is first powered on.

If the device is in the Advanced Therapy Profile mode, *the Profile LEDs will not blink* when the device is first turned on. To switch from one Therapy Profile mode to another, turn the device off, press and hold any of the Therapy Profiles, and turn the device on. You should hear a series of beeps and notice that the Profile LEDs are now in the opposite mode.

## Easy Therapy Profile Mode Set-Up

To set a Profile in the Easy mode, press the desired Profile button (A, B, C, or D) TWICE. Then, select the desired waveform and all its parameters. Set the intensity and PRESS AND HOLD THE START/ACCEPT BUTTON UNTIL YOU HEAR TWO CLICKS AND A LONG TRILL. This indicates that the treatment is stored under that Therapy Profile and can be accessed by pressing that Profile button. You may want to name and note the treatment on the included Easy Mode Profile Reference card under Waveforms/ Profiles.

## **Easy Therapy Profile Use**

Once you have set your Easy Profiles, simply press the desired Profile (A, B, C, or D). The LED for that Profile should illuminate along with the waveform and parameters of the treatment. Simply set the intensity level and press start to begin the treatment.

Advanced Therapy Profile Mode Set-Up To set a Profile in the Advanced mode, first press the waveform and then press the desired Profile (A, B, C or D). For example, press Quadpolar then profile A. You will see that there is a treatment default already programmed. To change the treatment, simply select the parameters you want for that waveform profile, set intensity and PRESS AND HOLD THE START/ACCEPT BUTTON UNTIL YOU HEAR TWO CLICKS AND A LONG TRILL. This indicates that the treatment is saved as a profile for that waveform. You may want to name and note the treatment on the included waveform specific Profile Reference card. Use the Advanced Mode Profile Reference cards. In this case, it would be the Quad/Pre-Mod card. There are also cards for Russian/Hi-Volt and Micro/Support.

## **Advanced Therapy Profile Use**

Once you have set your Advanced Profiles, simply press the desired waveform and then the desired Profile (A, B, C, or D). The LED for that Profile should illuminate along with the waveform and parameters of the treatment. Simply set the intensity level and press start to begin the treatment.

#### Lead Cord Tester

The Winners have a set of lead jacks on the left side of the unit. Plug in your lead cord and touch the tips together. You should hear a beep to let you know your leads are good. If you hear no beep then you need to replace your lead cord.

## **Ultrasound - CM Models Only**

The ultrasound function of the Winner CM4 and CM2 is very easy to use. Once the machine is turned on, the last treatment's parameters will be displayed. If this is the desired treatment set the intensity with its up/down arrows and press the Start button.

The Ultrasound Active light illuminates and the Time is blinking indicating that ultrasound is being output and time is counting down.

\*NOTE: Be sure to use Aloe-Sound Lotion as a coupling agent and place the appropriate soundhead on the patient. Remember to always move the soundhead, approximately 4cm/second either in a circular or back and forth motion. If you want to change ultrasound parameters select from the following list:

- > Transducer
- ➤ Frequency
  Select from 1MHz or 3MHz. Remember that the lower the frequency, the deeper the penetration, if intensity levels are equal. 1MHz is a lower frequency than the 3MHz.
- ➤ Ultrasound Wattage (Output)

  The Winner will display output in either W/cm² or Watts. Select the output display by pressing the Select button next to the intensity up/down arrows.
- ➤ Duty Cycle Pulsed outputs can be selected from 10%, 20% or 50%, or 100%.
- > Treatment Time Select the desired treatment time between 1 and 99 minutes.

# **To Adjust Ultrasound Parameters During Treatment**You can adjust Treatment Time, Intensity, Transducer, Duty Cycle and Frequency at any time during the treatment by using the appropriate control.

## **To Pause an Ultrasound Treatment**

Once an ultrasound treatment is running, pause it by pressing the Pause/Resume button. The time will stop flashing, the Ultrasound Active light will go out and the Intensity will start flashing - indicating a paused treatment. To resume treatment, press the Pause/ Resume button.

**CAUTION**: Do not operate the soundhead in an unloaded condition (without Aloe-Sound coupling Lotion/Gel and patient contact). This can cause the transducer to get very hot and may cause unrepairable damage.

**NOTE**: When administering an ultrasound treatment, be sure that the treatment area of the patient has an ample quantity of Rich-Mar Aloe-Sound Lotion or Gel Plus 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.

## Combo - CM Models Only

The Winner CM4 and CM2 units allows the user to combine a stim treatment with an ultrasound treatment by emitting stimulation and ultrasound through the soundhead at the same time

Quick and easy "self-jacking" can be accomplished by taking the lead cord from the stim channel you want to use and plug the desired lead tip into the special ultrasound jack for combination therapy.

- Plug the lead cord into the red jack of whatever channel you are using for stim.
- Apply the electrode to the desire lead tip (figure 2) and put it on the patient.
- Then, plug the pin end of the other side of the lead into the small silver stim jack on the right side of the ultrasound cable (figure 3). This makes the soundhead function as that electrode.
- Apply the Aloe-Sound Coupling Lotion or Gel to the site and apply the soundhead to the patient. This completes the stimulation circuit(figure 4) and the stimulation component of the treatment may now be set up.

Once the parameters are selected, set the stim intensity level. The patient should feel the stimulation. Set the ultrasound parameters making sure to move the soundhead once you are outputting ultrasound (Ultrasound Active light comes on). You are now providing a combination therapy treatment.

All Rich-Mar Ultrasound Applicators can be used in the Combo mode.

\* Therapy Hammer Applicator shown in pictures.

**NOTE:** Both contraindications for ultrasound **and** stimulation should be observed when using the device in combination.



Figure 1



Figure 2



Figure 3



Figure 4

# **Electrical Stimulation Site Preparation, Electrode Attachment, and Maintenance Guidelines**

 Know the stimulation characteristics, indications, and contraindications of the desired waveform. For most patients, the Micro amperage current will be subsensory. 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 therapies, be sure that the intensity is set to a comfortable level.

## NOTE: 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.
- 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.

## **Carbon Electrode Information**

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.

## **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.

### **Carbon Electrode Maintenance**

Rich-Mar Corporation recommends that your carbon electrodes be replaced annually.

## **Recommended Electrode Types**

Rich-Mar Corporation recommends the use of our self-adhesive electrodes with this device.

SuperStim or MultiStim self-adhesive will provide the proper conductive properties.

## FOR MORE INFORMATION ON RICH-MAR ELECTRODES, CONTACT YOUR LOCAL RICH-MAR DEALER or THE RICH-MAR SALES DEPARTMENT at 1-888-549-4945

## **Patient Lead Cord Maintenance**

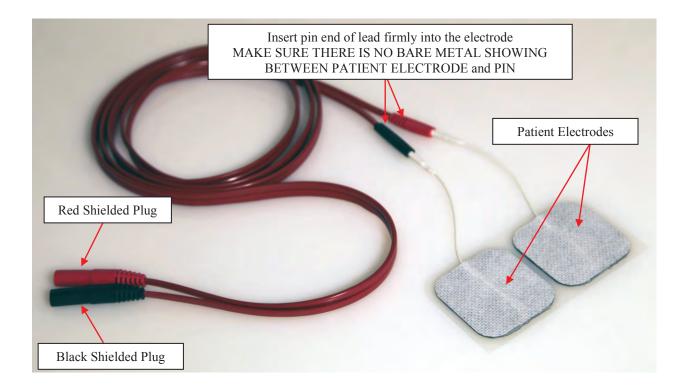
Rich-Mar Corporation recommends that your patient lead cords be replaced annually. Please note that your patient lead cords bear a label with a space provided to write in the date that the lead cord was put into service ("Date in Service"). There is also a space to write in the replacement due date ("Replace 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.

## Patient Electrode Connection

Plug shielded ends of lead cord into the output jacks on the device (red end into red jack and white end into white jack for each channel)



# Rich-Mar Muscle Stimulator Indications for Treatment

## Contraindications and Warnings for Quadpolar IFC, Pre-Mod IFC, Hi-Volt (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 malignant lesions. This includes cancer patients.
- 3) Over the cartoid sinus area. 4) Trancerebrally. 5) Over the pregnant uterus.

## Warnings

- 1) The long-term effects of chronic electrical stimulation are unknown.
- Adequate precautions should be taken when stimulation is used on persons with suspected heart problems.
- Adequate precautions should be taken when stimulation is used on persons with suspected or diagnosed epilepsy.
- 4) Severe spasm of the laryngeal and pharangeal muscles may
- occur when the electrodes are positioned over the neck or mouth. The contractions may be strong enough to close the
- 6) airway or cause difficulty in breathing.
- 7) Electrical stimulation should not be used in electrically sensitive areas.
- 8) Electrical muscle stimulation (EMS) should not be used over swollen, infected, or inflamed areas of skin eruptions (e.g., phlebitis, thrombo phlebitis, varicose veins).
- 9) Caution should be used in the transthoracic application of electrical muscle stimulation (EMS) in that the introduction of
- 10) electrical current into the heart may cause arrythmias.
- 11) Electrical muscle stimulation (EMS) devices should be kept out of the reach of children.
- 12) Safety has not been established for use of electrical stimulation during pregnancy.
- 13) This device should be used only under the continued supervision of a physician.
- 14) 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 Rich-Mar 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.
- Following recent surgical procedures when muscle contrac-
- 3) tions may disrupt the healing process.
- 4) Over the menstruating uterus.
- When sensory damage is present by a loss of normal skin sensation.
- 6) When using this device at current outputs above 40mA, extra caution should be observed to avoid 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 cartoid sinus area.
- 4) Trancerebrally.
- 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.
- The user MUST keep the device out of the reach of children.

### **Precautions**

- 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. **NOTE:** Both contraindications for ultrasound *and* stimulation should be observed when using the device in combination.

#### Waveforms

The Winner units represent the most sophisticated electrical waveform generation ever developed in electrotherapy. The waveforms are software generated by an extremely sophisticated computer that resides in each Winner unit.

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. Hi-Volt (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. Microcurrent provides subsensory stimulation.

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 50Hz 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 Winner units have been programmed to have the most common treatment options as factory waveform default settings. However, the Winner units are designed to provide the most sophisticated and customized treatments imaginable.

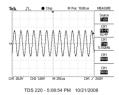
Helpful Hint: If you desire further information regarding waveform descriptions, recommended reading to supplement this section is ELECTROTHERAPEUTIC TERMINOLOGY in Physical Therapy, published by the American Physical Therapy Association. For more information, contact the APTA, 1111 North Fairfax Street,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

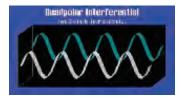
## **Quadpolar Interferential (four pads)**

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 Winner stimulators can provide 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 Winner stimulators produce 5000Hz sine waves from channel one and produce between 5000 and 5200Hz sine waves and channel two. Channels one and two operate in concert to treat one site. The user may select a fixed "beat" or pulse rate between zero and 200. The user may also select a scan setting which scans between a low "beat" and a high "beat" setting.

## **Quadpolar Interferential Parameters:**

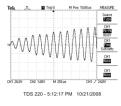
- Carrier Frequency: 5000Hz
- ➤ Beat Frequency Fixed: 0-200Hz
- ➤ Beat Frequency Scan Low: 0Hz to 200Hz
- ➤ Beat Frequency Scan High: 0Hz to 200Hz
- > Vector Options: On or Off
- Alternating Rate:\* Not Available
- Surge Rates: \* On: Not Available, Off: Not Available
- Ramp On: Fixed 3 Seconds
- Ramp Off: Fixed 1 Second

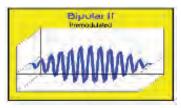
**Quadpolar Interferential** The Total Output Current = 50mA rms. The meter shown on the display of the Winner units is listed as rms current. To convert rms to peak current, multiply rms by 1.414. Examples are given below.

Meter Reading (rms)	
Milliamps (ma)	Peak Current Conversion
5	7.1
10	14.1
15	21.3
20	28.2
25	35.4
30	42.4
35	49.5
40	56.6
45	63.6
50	70.7

### **Pre-Mod IFC Interferential**

Pre-Mod IFC Interferential operates with a carrier frequency but it is premodulated within the Winner stimulators. This enables a single channel (two-electrode) system to be used. Pre-Mod IFC Interferential can select a pulse rate or a "beat" frequency between five and 200Hz.





## **Pre-Mod IFC Interferential Parameters:**

Carrier Frequency: 5000HzBeat Frequency Fixed: 2-200Hz

Beat Frequency Scan Low: 2Hz to 200Hz
 Beat Frequency Scan High: 2Hz to 200Hz

Vector Options: On or Off

Surge and Co-Cont rates: 5/5, 5/10, 10/10, 10/20, 10/30, 10/50 "on/off" Seconds

➤ Alternating Rate: 5/5 and 10/10 "on/off" Seconds

Ramp On: Fixed 3 SecondsRamp Off: Fixed 1 Second

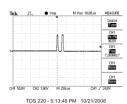
## **Pre-Mod IFC Interferential**

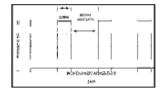
The Total Output Current = 50mA rms. The meter shown on the disply of the Winner units is listed as rms current. To convert rms to peak current, multiply rms by 2.34 (1.414/.707). Examples are given below:

Meter Reading (rms) Milliamps (ma)	Peak Current Conversion
5	11.7
10	23.4
15	35.1
20	46.8
25	58.7
30	70.1

## Hi-Volt (Monophasic)

The Winner stimulators also have the capability to produce a Hi-Volt Symmetric Square-Wave Monophasic stimulation having two equal positive phases per pulse. This results in a net charge effect. The polarity of monophasic will be positive for the red pin for each channel and negative for the white pin. Total Output Current for the Hi-Volt = 200 mA.





## **Hi-Volt (Monophasic) Parameters:**

> Carrier Frequency: Not Applicable

Pulse Rate: 2-200Hz Fixed
Scan Low: 2Hz to 200Hz
Scan High: 2Hz to 200Hz

Phase Duration: 50uSInterphase Interval: 100uS

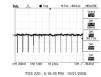
Surge and Co-Cont rates: 5/5, 5/10, 10/10, 10/20, 10/30, 10/50 "on/off" Seconds

➤ Alternating Rate: 5/5 and 10/10 "on/off" Seconds

Ramp On: Fixed 3 SecondsRamp Off: Fixed 1 Second

## **Micro Current**

Micro current is a pulsed waveform that produces 50mS phases from 1-1000 pulses-per-second. The phases alternate from positive to negative every 2.7 seconds. The amplitude is adjustable from zero to 1000mA.







### **Microcurrent Parameters:**

Carrier Frequency: Not Applicable

➤ Pulse Rate: Fixed .3-1000Hz

➤ Phase Duration: 50mS

Interphase Interval: Dependent upon pulse rate

Positive/Negative Interval: 2.7 seconds

> Alternating Rate: Not Applicable

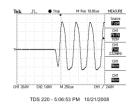
Surge Rates: Not Applicable

Ramp On: Not Applicable

Ramp Off: Not Applicable

## Russian

Total Output Current = 50 mA rms. Russian is a 2500Hz timemodulated waveform having a sinusoidal frequency that is burst modulated at 50% duty. Russian is available in normal, surge, co-contraction and alternating modes.





## **Russian Parameters:**

Carrier Frequency: 2500Hz

➤ Beat Frequency: Fixed 5-200Hz

➤ Pulse Rate: 5-200Hz Fixed

Surge and Co-Cont rates: 5/5, 5/10, 10/10, 10/20, 10/30, 10/50 "on/off" Seconds

➤ Alternating Rate: 5/5 and 10/10 "on/off" Seconds

Vector Options: Not Available

Ramp On: Fixed 3 seconds

Ramp Off: Fixed 1 seconds

## **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.

**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.

## **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 diastheses.
- 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 unrepairable damage may occur to the transducer in an unloaded state.

## Introduction

The Rich-Mar Winner CM Series are designed to provide therapy professionals with the best technology at affordable prices. The Winner CM Series products and accessories offer the most flexible treatment possibilities in a convenient, easy-to-use package. This manual is meant to familiarize the user with the controls, operations, and ultrasound therapies available on the Winner CM Series units. The simple control of the units allows the user to master the units' vast capabilities quickly and easily.

## **Operation**

NOTE: Ensure that an Ultrasound Applicator is connected into the back of the unit. If NO Applicator is installed, the 7-segment displays will indicate all 8's and the unit will not respond to any user key inputs.

To operate the unit, make sure that the power cord is plugged into the power receptacle on the back of the unit. The power receptacle is located below the On/Off switch. Turn the switch to the "1," or on position. The device should then activate. The Therasound unit will then go through a quick diagnostic check where some letters and numbers appear on the display. This is normal. After the diagnostic check green digits will appear in the time and intensity windows. To set up a treatment, select the parameters desired by pressing their corresponding buttons. A beep will sound every time a button is pressed on the device. Select the duty cycle (100%, 50%, 20%, or 10%) by pressing the Duty Cycle Select button. Then select the desired treatment time by pressing the "+" or "-" buttons in the "Time Set" area. Select how the intensity will be displayed, either in W/cm<sup>2</sup> or Watts, by pressing the Select button in the "Intensity" area. Set the intensity by using the "+" or "-" buttons in the "Intensity" area.

Once all treatment parameters have been set as desired, apply ultrasound-coupling lotion or gel to the patient and place the transducer on the patient. Press the "Start" button and the "Time" indicator will start to flash. This indicates that the treatment is running and time is counting down. Notice that the green "Ultrasound Active" indicator light is now illuminated indicating that the unit is now delivering ultrasound output wave forms.

Please note that any treatment parameter may be modified or changed while the device is operating simply by pressing the button corresponding to the parameter to be changed.

To pause treatment, press the "Pause" button. Time will stop flashing and the intensity will begin to flash.

Notice that the "Ultrasound Active" indicator light is no longer illuminated, indicating that the treatment has been Paused and the unit is no longer delivering ultrasound output wave forms.

To resume treatment, press the "Resume" button and the time will flash and the "Ultrasound Active" indicator will once again illuminate.

When the treatment time ends, a loud beep will sound and time will stop flashing and revert to the last treatment time entered. The intensity will revert to zero and the ultrasound active light will extinguish. To stop a treatment, press the "Stop" button. Time will stop flashing and revert to the last treatment time entered. Intensity will revert to zero and the "Ultrasound Active" light will extinguish.

Recently used parameters, with the exception of the output intensity, will remain saved as the default parameters after a treatment ends. To use the same treatment again, enter the desired intensity and press the "Start" button to begin.

## Winner CM Series Ultrasound Plug & Play Applicators

The Winner CM Series will both accept the new Rich-Mar "Plug & Play" series Ultrasound Applicators as listed below:

## 5cm<sup>2</sup>Applicator

The  $5 \text{cm}^2$  Applicator is a dual-frequency (1MHz and 3MHz) ultrasound applicator with an output range from 0 - 10 Watts.

## 10cm<sup>2</sup>Applicator

The  $10\text{cm}^2$  Applicator operates at 1MHz only with an output range from 0-20 Watts or  $0-2.0\text{W}/\text{cm}^2$ .

## Hammer Applicator (5cm<sup>2</sup> & 2cm<sup>2</sup>)

The Hammer Applicator is a dual-frequency (1MHz and 3MHz) ultrasound applicator. The 5cm<sup>2</sup> transducer provides an output range from 0-10 Watts and the 2cm<sup>2</sup> transducer will provide an output range of 0-4 Watts.

## Autosound Applicator - EVO Devices Only

The Autosound Applicator is a dual-frequency (1MHz and 3MHz) "Hands Free" style applicator. At 1 MHz Output selected, the Autosound Applicator will deliver 0-7 Watts and at 3 MHz Output, the Autosound Applicator will deliver 0-5 Watts of power.

# **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 (4 parts per million of oxygen).

## 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**

Rich-Mar recommends that the device be calibrated a minimum of once per year.

## 10cm<sup>2</sup>Applicator

You need to complete only the 1 MHz portion.

## 5cm<sup>2</sup>Applicator

You need to complete both the 5cm @ 1 MHz and the 5cm@3 MHz portions.

## Hammer Applicator (5cm<sup>2</sup> & 2cm<sup>2</sup>)

You need to complete both the 5cm @ 1MHz, 5cm @ 3MHz, 2cm @ 1MHz, and 2cm @ 3MHz portions.

## **Tuning Frequency and Setting Voltage**

## 5cm @ 1MHz

- 1) Install the 5cm soundhead into the wattmeter making sure that only the face of the transducer is submerged. Zero the wattmeter.
- 2) Hold down the Start/Stop switch and turn on the unit. The software version should appear on the screen.
- 3) Let off the Start/Stop switch and the frequency will appear on the screen for 5cm@1MHz. Find the frequency peak and add 5kHz.

## Note: Normal range of operation is 930 to 960.

4) Press Start/Stop switch and the voltage will appear. Set maximum output to 10 watts.

## 5cm @ 3MHz

- 1) Press the Start/Stop switch.
- 2) Find the frequency peak for 5cm @3MHz and add 7kHz.

# Note: Normal range of operation is 3050 to 3150.

3) Press the Start/Stop switch and the voltage will appear. Set maximum output to 10 watts.

## 2cm @ 1MHz

- 1) Press the Start/Stop switch.
- 2) Find the frequency peak for 2cm @ 1MHz and add 5kHz.

## Note: Normal range of operation is 950 to 980.

3) Press the Start/Stop switch and the voltage will appear. Set maximum output to 4 watts.

## 2cm @ 3MHz

- 1) Press the Start/Stop switch.
- 2) Find the frequency peak for 2cm @ 3MHz and add 5kHz.

# Note: Normal range of operation is 3050 to 3150.

3) Press the Start/Stop switch and the voltage will appear. Set maximum output to 4 watts.

## Tuning Frequency and Setting Voltage cont.

## 10cm @ 1MHz

- 1) Install the 10cm soundhead into the wattmeter making sure that only the face of the transducer is submerged. Zero the wattmeter.
- 2) Hold down the Start/Stop switch and turn on the unit. The software version should appear on the screen.
- 3) Let off the Start/Stop switch and the frequency will appear on the screen for 10cm@1MHz. Find the frequency peak and add 5kHz.

## Note: Normal range of operation is 900 to 950.

1) Press Start/Stop switch and the voltage will appear. Set maximum output to 20 watts.

## **Autosound "Hands Free" Applicator**

\* Due to the complexity of this procedure and the tooling required, it is recommended that the Autosound Applicator be returned to Rich-Mar for calibration purposes.

## **Cleaning Recommendations**

To disinfect the soundhead(s) between therapy treatments, Rich-Mar recommends using an Ultrasound Disinfectant. OSHA address the need for prudent infection control (OSHA Instruction CPL 2-2-44C) to include decontamination of equipment betweem patients.

## Changing the Voltage from 115V to 230V

WARNING: RISK OF ELECTRICAL SHOCK.

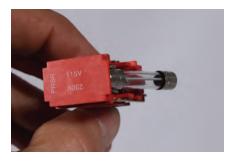
Unplug unit prior to changing the voltage from 115 to 230.



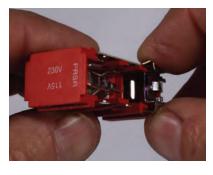
1. After unplugging the unit, open the outlet cover with a flathead screwdriver by inserting it into the notch as shown above.



2. Once the outlet cover is open, insert the flathead screwdriver into the notch on the red voltage converter as shown above.



3. Holding the regulator so that 115V is right-side up, remove the 1amp slow blow fuse from the right side.



4. Rotate the regulator until 230V is right-side up. Remove the clip from the right-hand side and insert *two* .5amp slow-blow fuses, one on each side.



5. SAVE THE CLIP AS IT IS NEEDED TO SWITCH BACK TO 115V. After correct fuses are inserted into each side, insert the regulator into the slot with 230V reading right-side up as shown above.



6. Finally, close the outlet cover, ensuring that the desired voltage appears through the window in the outlet cover. Also be sure to use an adapter for the AC plug to suit local wall outlets in use.

## 115V to 230V Quick Check

- Take out 1amp slow blow fuse and remove clip on back of 230V side.
- , SAVE CLIP
- , Insert two .5 amp slow blow fuses.
- , Insert regulator with 230V appearing through the window in outlet cover.

## Changing the Voltage from 230V to 115V

WARNING: RISK OF ELECTRICAL SHOCK. Unplug unit prior to changing the voltage from 230 to 115.



1. After unplugging the unit, open the outlet cover with a flathead screwdriver by inserting it into the notch as shown above.



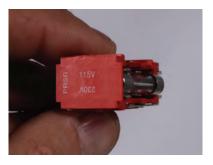
2. Once the outlet cover is open, insert the flathead screwdriver into the notch on the red voltage converter as shown above.



3. Remove the two .5 amp slow blow fuses from the voltage regulator.



4. Hold the regulator so that 230V is right-side up. Insert the clip into the right-hand side of the regulator.



5. Rotate the regulator so that 115V is right-side up and insert one 1 amp slow blow fuse into the right side. Insert the regulator into the slot in the unit with 115V reading right-side up.



6. Close the outlet cover, ensuring that 115V appears through the window in the outlet cover. Also be sure to use an adapter for the AC plug to suit local wall outlets in use.

## 230V to 115V Quick Check

Take out the two .5 amp slow blow fuses. INSERT THE CLIP INTO THE RIGHT HAND SIDE OF THE 230V REGULATOR

- , Insert one 1 amp slow blow fuse.
- , Insert regulator with 115V appearing through the window in outlet cover.

## **Trouble Shooting**

Rich-Mar Corporation takes pride in its Technical Support Hotline: 1-888-549-4945. We have an outstanding staff ready to take your calls and help with diagnosing and troubleshooting problems. You can also access service manuals and information on our website, www.richmarweb.com under the "Service" tab. Listed below are several options for troubleshooting the Winner units. Since there are microprocessor "computers" driving the Winner Devices, they may occasionally lock up. Although this will rarely occur, if the machine seems to "lock up" or if the display seems odd at all, turn the machine off for a moment and then turn it on again. If you are having any consistent quality problems please call your local distributor for service.

## WARNING

Prior to opening your Winner device for service or repair, please obtain the procedure from www.richmarweb.com or by contacting the factory. Failure to use this procedure may result in damage to the unit!

## **Winner CM Specifications**

## **Dimensions:**

Clinical devices = 12 1/2"W x 16 "D x 9 1/2 "H Portable devices = 20" W x 16 D x 7 1/2" H

## Weight:

CM4 Models = 13 lbs CM2 Models = 12 lbs CM4P Models = 26 lbs CM2P Models = 25 lbs

Power Input: 115/230VAC at 60/50 Hz Power Consumption: 110 Watts Fuse: 1.5 Amp / 250VAC Line Leakage: Less than 50μA

## **Winner ST Specifications**

## **Dimensions:**

Clinical devices = 12 1/2" W x 16" D x 9 1/2" H Portable devices = 20" W x 16 D x 7 1/2" H

## Weight:

ST4Models = 11 lbs. ST2 Models = 10 lbs. ST4P Models = 24 lbs ST2P Models = 23 lbs.

**Power Input:** 115/230VAC at 60/50 Hz

**Power Consumption:** 110 Watts **Fuse:** 1.0 Amp / 250VAC **Line Leakage:** Less than 50μA

## Winner Accessories

The accessories that come standard with the Winner units, as well as the optional accessories available for the unit, are listed below. Their part numbers are included for easy reordering.

## Standard Accessory Package for Winner Series CM4 and ST4

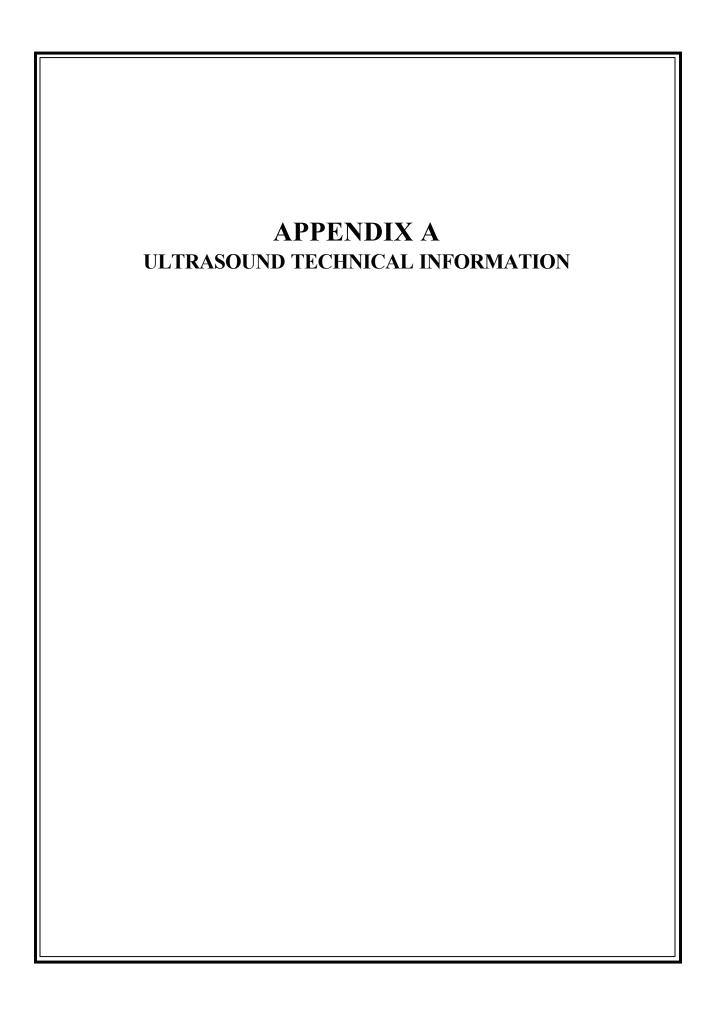
- 2 White pin lead cord (P/N: C1718A)
- 2 Red pin lead cord (P/N: C1719A)
- 1 MultiStim 2.0" x 2.0" self-adhesive electrodes (P/N: 201-123)

## CM2 and ST2

- 1 White pin lead cord (P/N: C1718A)
- 1 Red pin lead cord (P/N: C1719A)
- 1 MultiStim 2.0" x 2.0" self-adhesive electrodes (P/N: 201-123)

## CM models only

16 oz. bottle of lotion (P/N: A1904)



# **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.

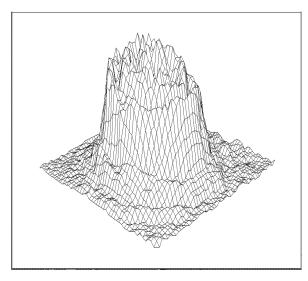
BNR: The Beam Nonuniformity Ratio.

Type: Coll-means collimating applicator.

## Near Field/ Far Field:

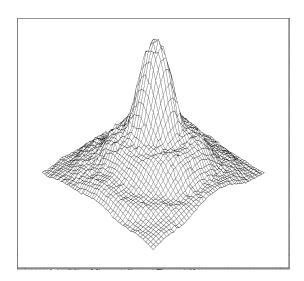
If measurements are made of the sound intensity along the central axis of the beam produced by the applicator, the intensity distribution shows maxima and minima near the applicator and then a gradual decline beyond the last maximum intensity.

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**

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  $30^{\circ}$ C and with line voltage variations in the range of  $\pm 10\%$  of the rated value

## **Transducer Parameters and Tolerances:**

10cm² / 5cm² /Hammer (5cm² & 2cm²) Applicators
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 Beam-Nonuniformity-Ratio (BNR) of any Rich-Mar transducer is 5.5:1 or less.

# Transducer Parameters and Tolerances: Autosound Applicator

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, three and a half (3.5), or two square centimeters, depending upon the size of the transducer being used. The tolerance for the ERA is +/-25% on the 2, 3.5 and 5 square centimeter transducers. The tolerance for the 10 square centimeter transducers is +0. -25%.

The Beam-Nonuniformity-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 or three 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  $\pm 14\%$  allowing for a 6% error in the wattmeter, which equals  $\pm 20\%$ .

## **Pulsed Mode**

When operated in the pulsed mode, the generator produces a square-wave burst of sinusoidal waveform of 1MHz or 3MHz of 2.5 milliseconds in duration. Depending upon 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 = .95, 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 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

Rtpa = 1.05:1

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

% Duty Cycle	Rtpa
(Indicated on front panel of device)	
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.

```
Temporal Average = (Duty) x (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)

```
Spatial Average = (Temporal Average)/(ERA)
Example, 5 Watts, 35% Duty, 5cm<sup>2</sup> Transducer
```

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

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:

Pulse width (On time) = 2.5mS

Off time = [2.5-2.5(%Duty cycle)]/(%Duty cycle)

Where %Duty cycle is represented as a decimal.

Please see the following example for computing the

Off time for a 10% Duty cycle:

Off time=[2.5-2.5(0.10)]/(0.10)=22.5 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.

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## Manufactured for:



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