

TheraSound EVO

OPERATION MANUAL



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Congratulations on the purchase of your Richmar TheraSound EVO.

Richmar warrants that your TheraSound EVO is free of defects in material and workmanship. This warranty shall remain in effect for three (3) years* from the date of the original end user purchase. If this Product fails to function during the warranty period due to a defect in materials or workmanship, Richmar or the selling dealer will repair or replace the respective Product without charge.

All product repairs must be performed by Richmar.

Any modifications or repairs performed by unauthorized centers or groups will void this warranty.

To qualify for warranty coverage, your product must be registered with Richmar within ten (10) days of purchase in one of the following ways:

- Using the online form at richmarweb.com/warranty-registration
- Mailing in the completed warranty card included with the device

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

This warranty does not cover:

1. Replacement parts or labor furnished by anyone other than Richmar, the selling dealer, or a certified service technician.
2. Defects or damage caused by labor furnished by someone other than Richmar, the selling dealer, or a certified service technician.
3. 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 Manual.

RICHMAR SHALL NOT BE LIABLE IN ANY EVENT FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES

Some locations 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 Richmar or the selling dealer under this warranty:

1. A claim must be made within the warranty period to Richmar or the selling dealer.
2. Please contact Richmar's Technical Service Department at:
Phone: 1-888-549-4945
Email: technicalsupport@richmarweb.com

This warranty gives you specific legal rights and you may also have other rights which vary from location to location. Richmar 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 FINES FOR A PARTICULAR PURPOSE.

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*Applcators and any related accessories have a one year warranty.

This manual is written to ensure the proper and safe operation of the TheraSound EVO. It contains general information regarding replacement parts, operation, safety precautions and maintenance. In order to maximize safety, efficiency and the life of your TheraSound EVO, please read this manual thoroughly and follow all instructions prior to operating the unit.

Specifications and instructions put forth in this manual are in effect at the time of publication; however, due to Richmar's policy of continued product improvement, changes may be made to these specifications and instructions at any time without obligation on the part of Richmar.

SYMBOLS GLOSSARY

Declaration of Conformity:

Richmar declares that the TheraSound EVO complies with following normative documents:
IEC60601-1, IEC60601-2-22, IEC60825-1

PRECAUTIONARY INSTRUCTIONS

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

 **DANGER**

Possible safety issues that could be imminently hazardous and could result in death or serious injury.

 **WARNING**

Possible safety issues that could cause serious injury and/or equipment damage.

 **CAUTION**

Possible safety issue that could have the potential to cause minor to moderate injury or damage to equipment.

THERAPEUTIC ULTRASOUND

Richmar Ultrasound devices are indicated to produce therapeutic deep heat for the following conditions:

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

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

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. Where the skin suffers from any sensory impairment.
8. Over areas of malignancies.
9. In the area of visceral plexus and large autonomous ganglion.
10. Over the thoracic area if the patient is using a cardiac pacemaker.
11. Over a healing fracture.
12. 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 diasthesis.
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).

WARNING

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.

INITIALIZATION

To operate the device, make sure that the power cord is plugged into the power receptacle on the back of the unit. The power receptacle is located on the rear of the device, next to the On/Off switch. Turn the switch to the "I," or On position. The device should then activate.

NOTE: Ensure that an Ultrasound Applicator is connected into the back of the device. If NO Applicator is installed, the LCD displays will illuminate "88" and the unit will not respond to any user key inputs.

The TheraSound will then go through a quick diagnostic check where some letters and numbers appear on the display. This is normal. After the diagnostic check blue digits will appear in the time and intensity windows.

TREATMENT SETUP

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" area.
- Set the intensity by using the **+** or **-** buttons in the "Intensity" area.
- With all parameters set, apply coupling agent to the treatment area. Place transducer onto the treatment area.

NOTE: Treatment Intensity can be toggled between W/cm² and Watts by pressing the Select button to the right of the Intensity adjustment buttons.

- Press the **▶** button and the "Time" indicator will start to flash. This indicates that the treatment is running and time is counting down. Notice that the "Ultrasound Active" indicator is now illuminated indicating that the unit is now delivering ultrasound output.

PAUSING TREATMENT

NOTE: 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 **⏸** 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 **▶** 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 **▶** 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.

NOTE: 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 **▶** button to begin.

COMBINATION TREATMENT

Richmar's TheraSound EVO ultrasound is designed to be connected to any Richmar clinical muscle stimulator (i.e. Winner EVO ST4), thus enabling the user to provide combination therapy to patients.

To connect the TheraSound unit to a stimulator, simply plug an electrode lead from the stimulator into the Combo Input on the rear of the TheraSound, to the left of the applicator port. The electrode connected

to the channel's other output, along with the soundhead of the TheraSound, will complete the circuit to provide stimulation.

CAUTION

When using a combination treatment, note that both faces of the "Therapy Hammer" transducer will output stimulation.

Please **DO NOT** touch the metal portion of the Therapy Hammer not in use, while doing therapy, as it could cause potential shock or harm.

CLEANING

DISINFECTING RECOMMENDATIONS

To disinfect the soundhead between therapy treatments, Richmar recommends using a disinfectant cleaner for ultrasound. OSHA

addresses the need for prudent infection control (OSHA Instruction CPL 2-2.33C) to include decontamination of equipment between patients.

THERASOUND EVO, FRONT



THERASOUND EVO, REAR



USER INTERFACE

1. Ultrasound Intensity Select
2. Ultrasound Frequency Select
3. Start/Stop
4. Applicator Select
5. Duty Cycle Select
6. Treatment Time Select

7. Pause Treatment
8. Intensity Measurement Toggle
9. On/Off Switch

CONNECTION PORTS

10. Electrical Power Entry Module
11. Ultrasound Applicator Port
12. Combo Input

EVO ULTRASOUND APPLICATOR OPTIONS

1. 5 cm² Applicator

The 5 cm² Applicator is a dual-frequency (1 MHz and 3 MHz) ultrasound applicator with an output range from 0-10 watts

2. 10 cm² Applicator

The 10 cm² Applicator operates at 1 MHz only with an output range from 0-20 watts or 0-2.0w/cm².

3. Hammer Applicator (5 cm² & 2 cm²)

The Hammer Applicator is a dual-frequency (1 MHz and 3 MHz) ultrasound applicator. The 5 cm² transducer provides an output range from 0-10 watts and the 2 cm² transducer will provide and output range of 0-4 watts.

4. Autosound Applicator

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



THERASOUND EVO

PROBLEM


POSSIBLE SOLUTION

Device fails to power ON.

Check to verify that the power cord is fully plugged into the power entry module below the AC switch on the rear of the device.

Verify that the power cord is plugged into the AC wall outlet

Check the fuse to verify that it has not blown.

 **CAUTION**

To ensure personal safety, unplug the unit before checking the fuse

Ultrasonic Active LED fails to illuminate

Verify applicator cord is firmly connected into applicator connection port on rear of the device.

Display reads "HEAD"
The "HEAD" warning is a safety feature wherein the soundhead temperature shuts off to avoid overheating. This warning occurs when the soundhead overheats, usually due to an un-coupled or poor coupling situation.

Turn the device off for 3-4 minutes to allow it to reset and turn it back on again and begin treatment. If the "HEAD" warning is still displayed, please call the factory

When using the Hammer Applicator, check that the soundhead in use is selected for output. Be sure to use an adequate amount of coupling gel or lotion specifically designed for ultrasound treatment.

OUTPUT TROUBLESHOOTING

Richmar suggests that ultrasound output be tested once a week. To do this, turn on the device and start a treatment at 100 % output. The outputting head should be facing up towards the user. Pour some water on the soundhead and increase the intensity. If the device is outputting ultrasound, the water should cavitate, or bubble, on the soundhead.

 **CAUTION**

DO NOT operate the ultrasound in an "unloaded" condition for more than one minute at intensities greater than 1.0 W/cm². It is possible that the transducer may overheat and damage the unit.

ULTRASOUND SERVICE INFORMATION

Richmar recommends that all Richmar ultrasound therapy products be returned to the factory or to a Richmar Authorized Service Center for service or calibration. It is recommended that the device be calibrated annually or when any major component has been changed.

TECHNICAL SPECIFICATIONS



THERASOUND EVO SPECIFICATIONS

Dimensions	9.5"W x 12"D x 6.25"H
Weight	5.6 lbs
Power Input	115 VAC at 1.0 Amp / 230 VAC at 0.5 Amp at 50/60 Hz.

ULTRASOUND APPLICATOR SPECIFICATIONS

5 CM APPLICATOR

Soundhead ERA	5 cm ²
Frequency	1 MHz & 3 MHz
BNR	5.5:1 maximum
Output	0-2 w/cm ² (0-10 watts +/- 15 %)

10 CM APPLICATOR

Soundhead ERA	10 cm ²
Frequency	1 MHz
BNR	5.5:1 maximum
Output	0-2 w/cm ² (0-20 watts +/- 0 %/-25 %)

HAMMER APPLICATOR

Soundhead ERA	2 cm ² & 5 cm ²
Frequency	1 MHz & 3 MHz
BNR	5.5:1 maximum
Outputs	2 cm ² =0-2.0w/cm ² (0-4 watts +/- 15 %) 5 cm ² =0-2.0w/cm ² (0-4 watts +/- 15 %)

HAMMER APPLICATOR

Soundhead ERA	3.5 cm ² - treatment area of 14 cm ²
Frequency	1 MHz, 3 MHz, or 1 & 3 MHz chain
BNR	5.5:1 maximum
Ultrasound Output	0-2.0 w/cm ²

NOTE: Autosound 3 MHz and 1 & 3 MHz chain are limited to 1.5 W/cm²

APPLICATOR TYPE

The ultrasonic radiation fields produced by Richmar 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 Richmar applicator is labeled to provide the user with information on its applicable parameters. The following abbreviations are used on the label.

GEN: The Richmar 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.

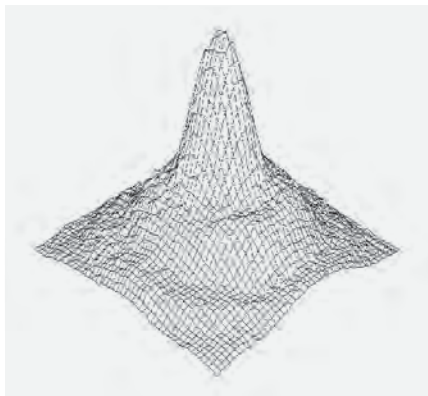
NEAR FIELD/ FAR FIELD

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 0.5 cm from the transducer face.

NEAR FIELD DISTRIBUTION

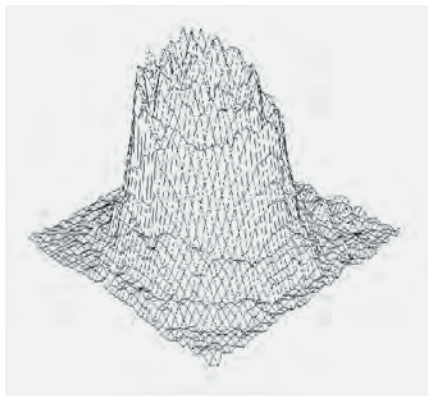
Beyond this point, the beam has a more uniform intensity and is called the “far field”. Below is shown the far field distribution at 16 cm from the transducer face.



NEAR FIELD DISTRIBUTION

FAR FIELD DISTRIBUTION

The preceding descriptions apply for radiation emitted into the equivalent of an infinite medium of distilled, degassed water at 86 °F (30 °C) and with line voltage variations in the range of +/-10 % of the rated value.



FAR FIELD DISTRIBUTION

TRANSDUCER PARAMETERS AND TOLERANCES

Therapy Hammer EVO Ultrasound Applicator (2 cm²/ 5 cm²)

Therapy Hammer ultrasound applicators have both a 2 cm² and 5 cm² transducer. The Effective Radiating Area (ERA) for both of these transducers is +/- 25 % with a Beam Non-uniformity Ratio (BNR) of 5.5:1 or less. Both transducers can operate with frequencies of 1 MHz or 3 MHz +/- 10 %.

5 cm² EVO Ultrasound Applicator

The ERA if the 5 cm² EVO Ultrasound Applicator is +/- 25 % with a BNR of 5.5:1 or less. This applicator can operate with frequencies of 1 MHz or 3 MHz +/- 10 %.

10 cm² EVO Ultrasound Applicator

The ERA tolerance of the 10 cm² EVO Ultrasound Applicator is + 0 / - 25 % with a BNR of 5.5:1 or less. This applicator can operate with a frequency of 1 MHz +/- 10 %.

AutoSound EVO Ultrasound Applicator

The AutoSound EVO Ultrasound Applicator uses four 3.5 cm² transducers that fire in sequence for 1 second each, starting with the transducer furthest from the cord. Each of these transducers operate with an ERA tolerance of +/- 25 % and a BNR of 5.5:1 or less. This applicator can operate with frequencies of 1 MHz, 3 MHz, or a 1 MHz – 3 MHz Sweep within a tolerance of +/- 10 %.

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 +/- 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 1 MHz or 3 MHz of 2.5 milliseconds in duration. Depending upon the Richmar 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 TO PULSES

% DUTY CYCLE	PULSES/SECOND
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 an allowable 6 % error in the wattmeter, which for the pulsed mode does not exceed +/-14 % allowing 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 Richmar 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:

$$Rtpa = (1/\text{Duty}):1$$

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 TO PULSES

% DUTY 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.

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, 5 cm² Transducer

Spatial Average = (1.75 Watts)/(5 cm²) = 0.35 Watts/cm²

The pulse width (On time) of all Richmar 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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