



# ***OMNISOUND<sup>®</sup> 3000E PRO***

## ***Ultrasound Therapy System***

### **User Manual**

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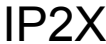








## OMNISOUND® 3000E PRO

ACP manufactures a premier line of rehabilitation technologies to assist health care professionals with improved outcomes and quality-of-life for Patients. The ACP product line includes Pain Control Systems, Muscle Stimulators, Interferential Therapy, Therapeutic Ultrasound, Pulsed Shortwave Diathermy devices, and advanced Therapeutic Exercise Systems. Our **MEGAPULSE®**, **NEUROPROBE®**, **OMNISTIM®**, **OMNISOUND®**, **OMNIBAND®**, **OMNITEST®**, **OMNICYCLE®**, and **OMNIVR®** represent the most recent world wide advances available for therapeutic application of electromedical devices and other rehabilitation technology.

ACP is internationally recognized for its contribution to research in the development of medical applications for therapeutic rehabilitation. The Company sponsors and conducts research at leading health care institutions and major universities throughout the world.

## SYMBOLS ON THE PRODUCT

Symbol	Used for	Symbol	Used for
	Serial number		Type BF medical device per: IEC 60601
	Date of manufacture		Manufacturer
	Caution, consult accompanying documents		Caution, electrical precautions
	Remote Control connection		CE mark of confidence compliant to MDD (93/42/EEC)
	Connection Electrode Cable		Classification against intrusion of water, dust, accidental contact of a body part.
	Proper disposal required. Do not dispose of with regular household waste. Follow state and/or local regulations.		Alternating current device.
	Observe the user manual		Consult instructions for use
	Protect the product from humidity		ON / OFF push button

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## ULTRASOUND INDICATIONS & CONTRAINDICATIONS

**CAUTION:** Federal law restricts this device for sale or use by, or on the order of, a Practitioner licensed by the laws of the state in which he/she practices to use or order the use of the device.

Please notice that Accelerated Care Plus cannot provide medical advice. If you have specific medical questions, please contact your healthcare professional.

### Indications

The Omnisound Pro is indicated for:

- Relieving pain
- Decreases joint stiffness and contractures
- Reduction of muscle spasm
- Increases local circulation
- Relief of pain, muscle spasms, and joint contractures that may be associated with: adhesive capsulitis, bursitis with slight calcification, myositis, soft tissue injuries, shortened tendons due to past injuries and scar tissues
- Relief of sub-chronic, chronic pain and joint contractures resulting from: capsular tightness, capsular scarring

### Contraindications

- Patients with an implanted medical device other than a pacemaker.
- Near brain, cervical ganglia, spine, laminectomy sites (can cause spinal-cord heating)
- Near the reproductive organs
- Total hip arthroplasties with methylmethacrylate or high density polyethylene
- Arthroplasties—the effect on bony ingrowth arthroplasties is not well defined; for this reason the most prudent course is avoiding ultrasonic therapy over these areas
- **Note:** There is no contraindication to the application of Ultrasound over metal implants.
- Over or near bone growth centers until bone growth is complete
- Over the thoracic area if the patient is using a cardiac pacemaker
- In an area of the body where a malignancy is known to be present
- In an area of the body where infectious disease is present
- Blood vessels in poor condition should not be treated as the vessel walls may rupture as a result of the exposure
- Patients suffering from cardiac disease should not receive treatment over the cervical ganglia, the stellate ganglion, the thorax in the region of the heart, or the vagus nerve, as a reflex coronary vasospasm might result. Only low intensities and short treatment times should be used if these patients are treated in other areas since the stimulation of practically any afferent autonomic nerve (especially the vagus nerve) in the body may cause a change in cardiac rate
- Patients with thrombophlebitis or other potentially thromboembolic diseases (such as DVT) should not be treated since a partially disintegrated clot could result in an obstruction of the arterial supply to the brain, heart or lungs
- Over a healing fracture
- Over the eye
- Over the pregnant uterus

- Over ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand
- Over areas of recent bleeding or hemorrhage
- Over areas of active tuberculosis

## ULTRASOUND WARNINGS & PRECAUTIONS

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### Warnings

- Do not operate this device until the User Manual, including all Indications for Use, Contraindications, Warnings and Precautions, have been carefully read and understood.
- Operation of this device or placement of lead wires, probes, pads and electrodes in close proximity (less than 5 feet) to an operating shortwave or microwave diathermy unit may produce instability in the device output or burns at the treatment site. Since the patient may not feel the 27 MHz frequency, they lack the protective sensation and tissue burns could result. Short-wave field could potentially damage or reset medical devices in close proximity to the drum applicator.
- Treatment should not be applied over the carotid sinus nerves, (located in the anterior neck triangle), including, stellate ganglion, vagus nerve, or laryngeal or pharyngeal muscle. Particular care should be taken for patients with a known sensitivity to the carotid sinus reflex, as carotid sinus stimulation may alter blood pressure and cardiac contractility.
- Do not apply treatment over heart. Thermal/sub-thermal treatment may affect organ function.
- Treatment should not be applied when high fever is present.
- Do not apply over the lumbar or abdominal region, or over the uterus during menstruation as therapy may temporarily increase menstrual flow.
- Treatment should not be applied directly over external stimulator systems.
- The treatment head should be moved continuously during treatment to avoid discomfort and burns.
- An appropriate coupling medium should be employed in order to ensure energy transmission to the tissue.

### Precautions

- Application site and settings should be based on the guidance of the prescribing practitioner.
- All equipment and accessories should be kept out of the reach of children or unqualified persons.
- Do not connect this device to any wall outlet that has not been properly grounded, or to any electrically non-isolated medical device.
- Use only ACP specified accessories and/or supplies with ACP devices. Do not use any power cords, or power supplies, other than the ones provided or specified for this device. Use of any other power supply could seriously damage the device and will void the warranty.
- When cleaning the device, never immerse them or wash them with water. See the infection control section in this manual for cleaning instructions. Devices should not be submerged in water or other liquids.

- Failure to follow the manufacturer's prescribed maintenance for this device may lead to device failure and transient or unreliable performance. State and federal survey and JCAHO require all equipment to be maintained and calibrated according to the manufacturer recommended schedules.
- A potential electric shock hazard exists once the device outer casing has been in part, or fully, removed. Only qualified service personnel should perform Service and repairs. Warranty will be voided if the outer casing has been removed or tampered with.
- Inspect and cleanse the skin prior to application. Following treatment check the skin for evidence of irritation or burns, and if present, treat as appropriate. If the patient has, or complains of, skin irritation following treatment; shorten the treatment time on the next treatment session, or use an alternative type of therapy or applicator placement.
- Gradually increase the output intensity/power to required dose or patient tolerance while monitoring the device display.
- Caution should be taken with patient exhibiting psychological or physical hypersensitivity to the therapeutic treatment. Several attempts should be made to place them at ease so that their confidence and cooperation can be gained during the treatment.
- The treatment area should be checked from time to time, and if there is evidence of, or if the patient complains of, pain or overheating during treatment, adjust the output downward until it is tolerated by the patient. If the patient continues to complain of pain or overheating, discontinue the treatment and shorten the treatment time on the next treatment session, or use an alternative type of therapy or applicator placement.
- Do not apply treatment directly over/under hot or cold packs. Caution is recommended when treatment follows the application of hot or cold therapy, which may alter the patient's sensation. Application of thermal agents over areas of impaired circulation should be performed with caution as the circulation may be insufficient to heat or cool the tissue, altering the patient's perception of warmth and pain, and burns or tissue necrosis may result from subsequent treatment.
- Treatment should not follow the application of medicated patches, salves, or creams. The presence of electrical stimulation may be altered by the presence of these materials on the patient's skin. Some medications can alter the patient's sensation. Heat can also increase the absorption of medication and may be contraindicated. If there is a medical necessity to perform such treatments, these patients should be monitored diligently during application.
- Caution should be used when applying thermal ultrasound over areas of body where circulation is impaired, or which lack normal sensation. Absent or diminished sensation should be avoided or, if unavoidable, treated with caution. Establishment of acceptable intensity levels for desensitized areas may be related to the intensity levels tolerated on normal skin in opposite or related body parts.
- Do not connect this device to any electro medical equipment for combination therapy except the Omnistim® family of electro stimulators.
- Do not immerse any part of the operator's body into the water bath during underwater techniques since the long-term biophysical effects of ultrasonic energy exposure have not been evaluated.
- Over acute skin conditions such as eczema, dermatitis, etc.



## THE OMNISOUND® 3000E PRO

### Delivery of the Omnisound® 3000E Pro

Upon receipt of your Omnisound® inspect the shipping container and contents for any obvious or concealed damage. All ACP products are packaged carefully for rapid, safe delivery. We guarantee delivery in perfect condition to the postal or delivery services. However, any damage or loss incurred during transportation or delivery is the postal or Delivery Company's responsibility. If damage or loss to the product and/or container is obvious or suspected, appropriate notation must be made on the signed freight bill at the time of delivery. All damage claims should be promptly filed with the delivering carrier and must be initiated by the addressee where the package was to be delivered. Retain the original shipping container and inserts for validation of damage claim or use at a later date.

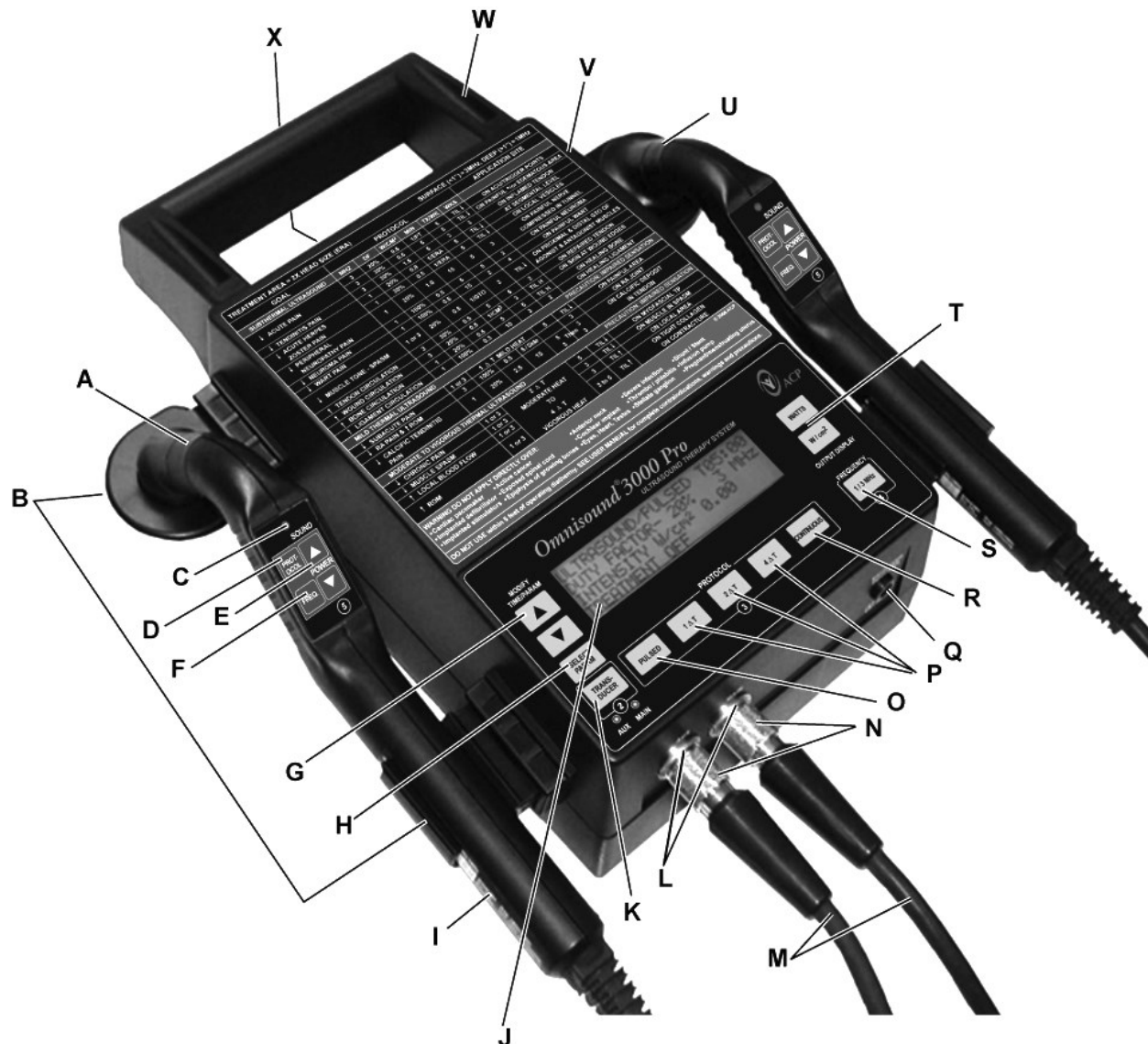
**NOTE:** *The purpose of this manual is to acquaint you with the Omnisound® operating features and functions. In order to avoid any misunderstanding, please read the manual carefully before attempting to assemble or operate the Omnisound®. If questions remain unanswered, contact your ACP sales representative or call 1-800-350-1100 or internationally call 1-775-685-4000.*

### Introduction

Welcome to the Omnisound® 3000E Pro, the system that redefines therapeutic ultrasound. While conceiving and designing the Omnisound® 3000E Pro, ACP set out to overcome the limitations of ordinary ultrasound devices. Here are just a few of the functions we developed that make the Omnisound® 3000E Pro truly the future of ultrasound therapy:

- **Controlled Depth of Penetration** - The Omnisound® 3000E Pro enables you to treat soft tissue injuries, superficially with 3 MHz and instantly at the push of a button, treat deeper injuries with 1 MHz - without switching transducers.
- **Two Transducer Sizes** - Our 2cm<sup>2</sup> and 5cm<sup>2</sup> heads offer optimum flexibility in treatment and are automatically enabled as you change from one to the other.
- **Fully Adjustable Transducer Head** - A comfortable, consistent contact can be maintained during any surface or underwater application because the transducer head rotates to any degree angle from 0 to 360°.
- **Microprocessor Controlled Digital Screen** - Easy-to-read digital screen offers accurate indications of all treatment parameters plus the calibration date, assist screens, automatic self-test, Effective Radiating Area (ERA) and Beam Non-uniformed Ratio (BNR).
- **Continuous and Pulsed Modes** - Variable duty factors offer a choice between 5, 10, 20, 25, 33, 50 and 100% applications for optimum flexibility in all phases of treatment.
- **Delta T Temperature Mode** - Automatic dose control system helps to assure consistent tissue heating.
- **Finger Tip Control** - You no longer have to return to the ultrasound unit to alter output intensity. Just push the switch on the transducer.
- **Combination Therapy** - Interconnect port allows combination therapy with the Omnistim® family of electro stimulators.
- **Excellent BNR and ERA** - Our superior BNR and ERA makes for highly uniform and comfortable applications.
- **Over Heating Temperature Sensing Monitor** - A coupling monitor indicates when the transducer head is overheated and the power is shut down automatically.
- **Automatic Self-Test with Problem Identification** - Allows accurate evaluation and documentation of unit functionality . . . before you begin treatment.

## Controls and Functions

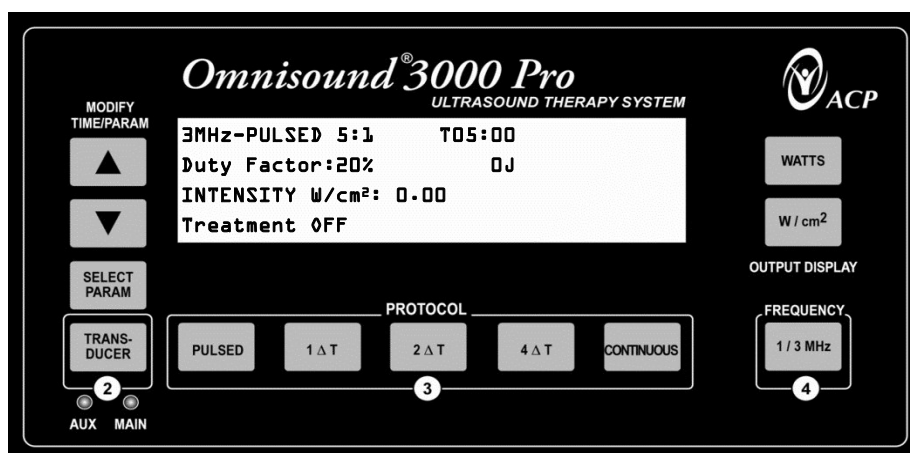


- A. Two transducers are standard: 2cm<sup>2</sup> and 5cm<sup>2</sup> transducers, both operable at 1 or 3 MHz.
- B. Transducer clamps, which are used to hold the transducers when not in use.
- C. Active transducer LED is on continuously to show which transducer is selected. The LED flashes on and off when transducer is over heated.
- D. PROTOCOL selection button on the transducer handle can be used to select the desired treatment protocol.
- E. The POWER button on the transducer handle is used to increases and decreases ultrasound output level.
- F. The FREQUENCY select button on the transducer handle is used to select either 1MHz (deep tissue penetration) or 3MHz (superficial tissue penetration).
- G. The MODIFY TIME/PARAMETER up/down buttons are used to increase treatment time in 1 minute intervals or decrease time in 30 seconds intervals. Timer may be adjusted during operation. The up/down arrows are also used to modify other selected parameters.
- H. The SELECT PARAMETER button is used to select the appropriate coupling medium.

- I. The TRANSDUCER LABEL lists the transducer's serial number, beam non-uniformity ratio (BNR), effective radiating area (ERA), and other information.
- J. The digital SCREEN displays information on selected treatment parameters.
- K. This button selects the transducer to be used for treatment (Main or Aux).
- L. Transducer plug-in receptacle for connecting the transducers to the unit.
- M. Transducer cables.
- N. The transducer cable connector which is inserts into the transducer plug-in receptacle for connection of the transducer to the unit.
- O. Button used to select the PULSED output modes: Pulsed at 5, 10, 20, 25, 33, or 50%.  
**NOTE:** Default is set at 20%, and then changes sequentially from 5% through 50%.
- P. These buttons set the output in Delta T mode (either 1ΔT, 2ΔT, or 4ΔT).
- Q. Input port for the shrouded pin to banana adapter (*Item No. 2503036*) connecting a lead wire from electro stimulator for combination therapy.
- R. Button used to select 100% Duty Factor for CONTINUOUS Ultrasound output.
- S. FREQUENCY button used to select 1MHz for deep tissue penetration or 3MHz for superficial tissue penetration during treatment.
- T. Pressing this button changes the display to show output in Watts or Watts/cm<sup>2</sup>.
- U. Each transducer head (2 or 5cm<sup>2</sup>) adjusts to any angle from 0 to 360°.
- V. I/O Toggle button. Press "I" in to turn on the AC line power. Toggle "O" to turn off the AC line power.
- W. Solid carrying handle for easy transport of the equipment.
- X. This is the general CAUTION LABEL for the Ultrasound unit, located on bottom of the unit. This label also contains data regarding the machine including the unit Serial Number.

## Default Operating Screen

When the power button is pressed, the following screen appears (default screen):



## Factory Settings

### Auto Test System

The Omnisound® 3000E Pro system contains the most advanced automatic testing system of any ultrasound system available. The microprocessor system enables the unit to provide high level auto-diagnostics while displaying corrective action programs to the clinician. Every time you turn on the Omnisound® 3000E Pro the system performs a sequence of automatic tests.

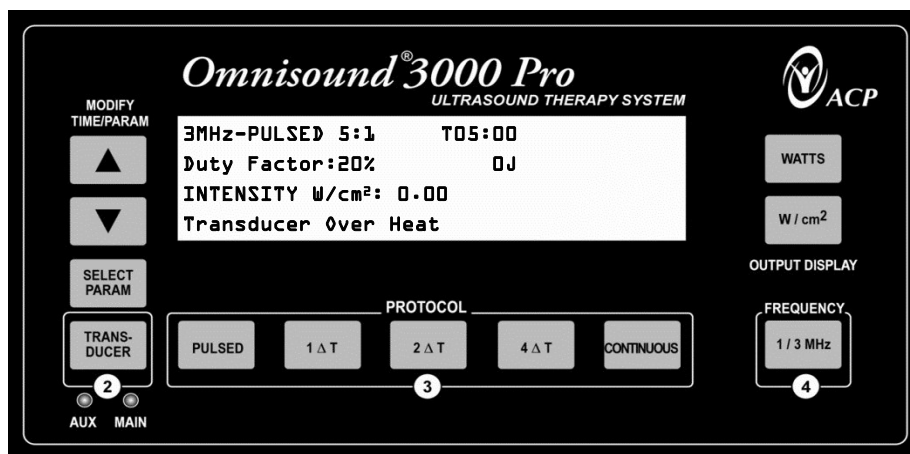
1. The system verifies that the transducer is connected. If it is not, a warning message is displayed informing the user to turn off the system and connect the transducer to the Main output connector. If both transducers are connected the default is to the transducer plugged in to the Main output connector.
2. After a transducer is detected, the system will perform an automatic self-test.
3. The transducer cable is dynamically tested.
4. Omnisound® 3000E Pro transducers contain their calibration data in the transducer handle.
5. When all systems pass the auto test, the main screen will appear automatically, and the microprocessor will allow user access and treatment protocol selection.

When the transducer output is switched from Main to Aux output with the transducer select switch, the auto retest screen will start up to ensure proper function of the Omnisound® 3000E Pro system to the new transducer.

### Additional Tests/Warnings

If the sensor in the transducer head detects a temperature over 47°C (116.6°F), the word "Over Heat" will flash on the display and the unit will emit three "beeps." The unit will become inoperable and the treatment time will be temporarily frozen until such time as the temperature drops to the proper level.

When the sensor checks the temperature and finds that it has returned to the proper level, the unit will emit two "beeps," and the word "Over Heat" will disappear and the display screen will return to normal. The user may then press START to continue the treatment with the existing parameters. Alternatively, the treatment time and intensity may be reset before pressing START to recommence the treatment.



**NOTE:** Make sure that the output is switched OFF when the transducer is not in use. Temperature will rise rapidly if the output is switched ON and the transducer is not in contact with the skin.

## Power Supply Operation

Omnisound® 3000E Pro is a line power only device. It is not intended for use with batteries.

## Operational Sequence

### Connection of the Transducer

Select the desired transducers (2cm<sup>2</sup> or 5cm<sup>2</sup>) for use with the Omnisound® 3000E Pro. Position the transducer cable plugs so that the 12 prongs align correctly with the 12 receptor holes in the transducer cable MAIN socket or AUX socket. This can be accomplished quickly by placing the inside key at the 12 o'clock position. Insert the transducer cable plugs into the transducer cable sockets and turn the knurled cuff of the plug clockwise many times until the threaded barrel of the plug is no longer visible. The transducers should now be firmly attached to the Omnisound® 3000E Pro generator.

### Connecting Line Power

Insert the three-prong hospital grade plug of the AC line cord into a wall outlet supplying a 100 - 240 volt, alternating current, 47-63 Hertz frequency. Plug in the other end (female connector) into the supplied AC power supply. Insert the power supply output connector into the receptacle on the Omnisound® 3000E Pro generator located under the carrying handle. After the transducers are connected the power may be applied by pressing the red switch located on the right side of the Omnisound® 3000E Pro generator.

### Transducer Controls / Operation

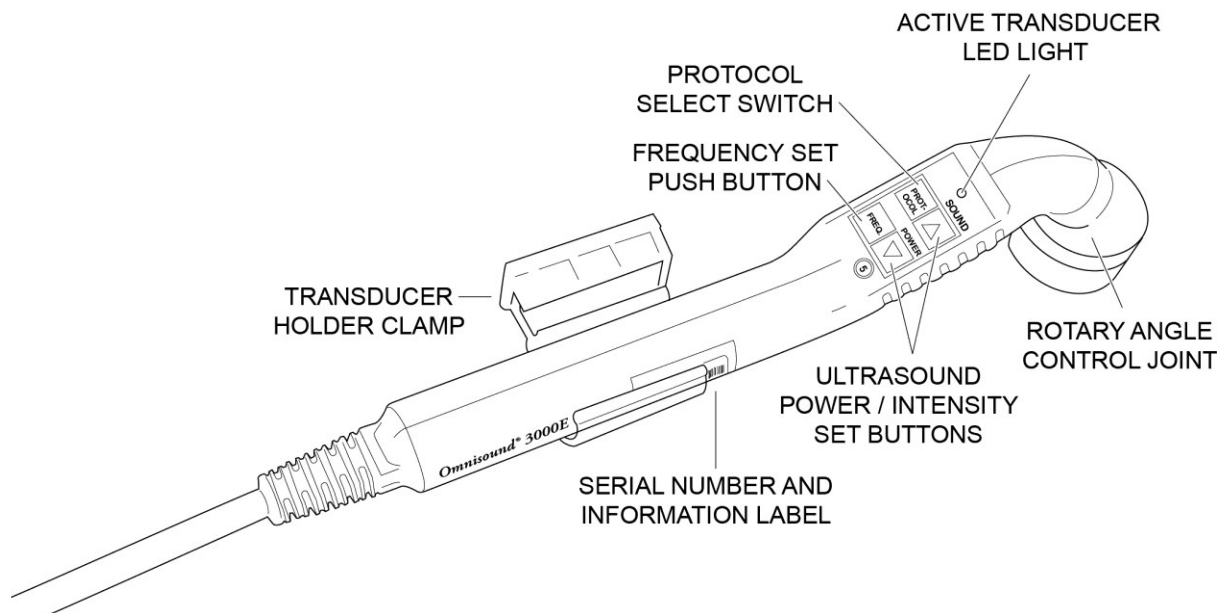
The Omnisound® 3000E Pro transducers are available in two sizes, 2 cm<sup>2</sup> and 5 cm<sup>2</sup>. Each transducer may be operated at 1 or 3 MHz operating frequencies, which control the depth of penetration. A unique feature of Omnisound® 3000E Pro transducers is the fully adjustable transducer angle. To adjust transducer angle hold the transducer in one hand while adjusting the transducer head to the desired position. The transducer should not be stressed when it reaches the end of its movement range to avoid damage of the rotary joint. ACP transducers are fully waterproof and may be used with underwater techniques. It is recommended that the handle is held by the operator without direct contact to the water, to avoid exposure.

The Omnisound® 3000E Pro transducers are individually calibrated to the Omnisound® 3000E Pro Generator with which it is manufactured and is intended for use only with that generator. This is ensured by identifying the serial number of generator with which the transducer is intended for use on the transducer label.

The Omnisound® 3000E Pro transducer contains a complete workstation which allows you to set output directly on the transducer handle. The "power up" and "power down arrows" allow setting of the power or intensity of the ultrasound beam. The timer starts when the power up arrow is released from a zero output starting position. The timer stops (holds) when the output is reset to zero with the power down arrow. This can be used if you are interrupted during treatment and you wish to maintain initial treatment time. A continuous tone will be heard while adjusting output power up or down.

**NOTE:** *Output power is automatically decreased to zero upon frequency change.*

## Transducer Controls and Functions



**OMNISOUND® 3000E PRO TRANSDUCER**

## TREATMENT GUIDELINES

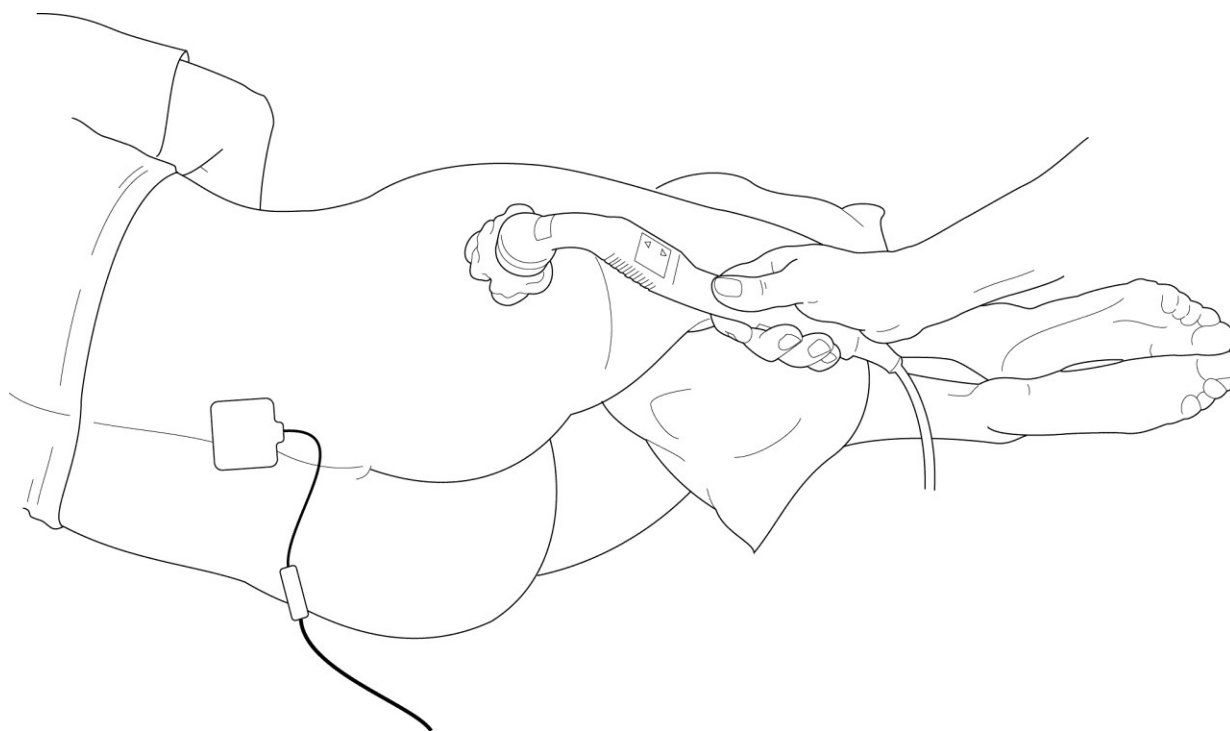
### Application Techniques

The following guidelines should be followed when applying ultrasound for therapeutic treatment.

1. Thorough cleansing of the treated area for removal of oils, creams, dirt, and sweat will ensure more uniform delivery of ultrasonic energy across the skin. After cleansing, an inspection and evaluation of the skin's integrity and sensation should be done prior to treatment.
2. Test the patient's skin in the desired treatment area for sensory response prior to the application of ultrasound therapy. If areas of anesthesia or lack of temperature sensitivity are found, use caution and low doses (sub-thermal). Care should be exercised with these patients, as they may not detect damaging thermal effects.
3. Use the minimum effective dosage (including power and exposure time). If more therapy is required a longer time at a lower output is recommended. Avoid using maximum power levels. For example, a typical comfortable output should be 0.5 - 1.0 W/cm<sup>2</sup>.
4. Apply coupling medium plentifully to the area to be treated. As the superficial skin temperature increases, more gel may be added to cool the skin while performing the treatment. Use underwater technique for the smaller joints where effective coupling is not possible. The water temperature should be slightly warmer than the target tissue temperature.
5. When using ultrasound a moving head technique is recommended to avoid the build up of "Hot Spots" or standing waves which might lead to tissue damage.
6. Reduce the output power if the patient complains of pricking sensations, "pins and needles" or painful temperature changes. Induced pain is also a good indication that the dosage level is too high. This sensation may indicate periosteal heating and should be avoided as significant tissue damage may occur under prolonged treatment application.
7. Proper personnel training on use of ultrasound and the equipment is essential in order to ensure high standards of therapy.
8. Avoid operator exposure to the ultrasonic field.

## Connection for Combination Therapy

Select one of the Omnistim® family of electro stimulators for use with the Omnisound® 3000E Pro. Choose the appropriate lead wire from the electro stimulator and separate the two tip pins. Take the positive (red) tip pin and insert it into the desired type and size of electrode, making certain that the electrode chosen is larger than the transducer head size. This will allow the transducer to remain as the active electrode. Attach the self-adhesive electrode to the patient's body. Take the negative (black) tip pin and insert it into the shrouded pin to banana adapter (*Item No. 2503036*). Insert the adapter into the interconnect port of the Omnisound® 3000E Pro. Now the Omnisound® 3000E Pro transducer head will receive the designated output from the electro stimulator. Keep in mind that all treatment parameters for electro stimulation (output intensity, frequency, treatment time, etc.) must be controlled from the electro stimulator. However, all ultrasound treatment parameters will be controlled from the Omnisound® 3000E Pro. Apply a liberal amount of conductive gel to the patient's body and begin combination therapy through the Omnisound® 3000E Pro transducer head.





## INFECTION CONTROL EQUIPMENT AND PRINCIPLES OF USE

### Definitions

- **Barrier Film** – One-time use, disposable plastic film for use over touch/operator surfaces of equipment to reduce risks of cross-contamination and need for high level disinfection of equipment between patients.
- **Germicidal Disposable Wipe** – Low level and/or intermediate level disinfectant germicidal disposable wipe for use on electrotherapeutic devices and accessories.
- **Plastic Lead Wire Sleeve** – Barrier to be used on lead wires, covering the junction of lead wire and electrode wire.
- **Transducer Cover** - Barrier to be used between the transducer and skin - gel interface.

### Universal Precautions – Body Substance Isolation

Universal Precautions (UP) must be implemented in the care of all patients to protect employees from occupational exposure to blood borne pathogens. Personal protective equipment (gloves, masks, gowns) should be available and worn by staff when occupational exposure to blood, body fluids containing blood, semen and vaginal secretions is likely to occur. Health care workers with exudating lesions or weeping dermatitis should refrain from all direct patient care and from handling patient care equipment until the condition resolves. Equipment must be cleaned/disinfected and protective barriers used when appropriate.

### Cleaning / Disinfecting of the Omnisound® 3000E Pro

Modality equipment shall be cleaned / disinfected per facility infection control policy. ACP recommends the following guidelines:

### Cleaning and Low Level Disinfection

**This is a recommended daily housekeeping practice to keep the equipment clean and free of contaminants which could contribute to transmission of infection. The following practices are recommended for use when treating intact skin without the presence of physiologic fluids such as blood and urine.**

- Clean equipment daily with ACP germicidal wipes. At the end of the day, wipe common contact surfaces, such as control panel and ultrasound transducer, with germicidal disposable wipe and allow to air dry. This technique will inactivate *M. tuberculosis* as well as most bacteria and viruses. This will also facilitate removal of organic material contaminants from equipment.
- Clean ultrasound transducers with ACP germicidal wipes after each patient use.

## Intermediate Level Disinfection

This method is recommended to keep the equipment clean and free of contaminants when used between patients for treatment of non-intact skin or incontinence management, where there is an increased risk of patient cross-contamination.

- After each use, clean common contact surfaces, such as control panel and ultrasound transducer, with ACP germicidal wipes.
- With a second ACP germicidal cloth, wipe again leaving surfaces wet for at least 5 minutes. Allow the surface to air dry before patient use.
- Barriers should also be used on the equipment for treatment of non-intact skin or incontinence management. This technique will inactivate *M. tuberculosis* as well as most bacteria and viruses.

## Use of Barriers - Intermediate Level Disinfection

The use of an all-purpose barrier film provides surface protection from cross-contamination resulting from a variety of applications. This procedure should be used whenever dealing with non-intact skin or the chance of coming in contact with bodily fluids. Barrier film is designed to cover any surface that may be touched during a patient treatment to help prevent cross-contamination. Barrier film is for single-use only. The film is discarded after each patient treatment. The procedure for use is as follows:

1. Wash hands.
2. Apply intermediate level disinfection prior to barrier application.
3. Select and cut with clean scissors a length of plastic barrier film to fit over the operatory surfaces of the Omnisound® 3000E Pro unit.
4. Select and cut with clean scissors a 2-foot length of plastic sleeve and slide it over the ultrasound handle and cable.
5. Apply ultrasound gel into plastic transducer cover. Apply plastic cover snugly, ensuring no air spaces between the transducer, gel, and plastic cover. Pull plastic cover over transducer handle and securing plastic sheath with rubber band ring.
6. Prepare any items which may come in contact with the therapist during treatment, such as pens, assessment tools, cart handles, etc.
7. Don gloves.
8. Perform Ultrasound treatment.
9. After treatment, remove gloves and wash hands.
10. Don clean gloves and remove plastic barrier film from Omnisound® 3000E Pro and discard.
11. Remove plastic sleeve from cable by sliding it over the transducer head, and discard.
12. Carefully remove plastic transducer cover in an inside-out manner, ensuring the outside of the plastic cover does not come in contact with the transducer. Discard.
13. Intermediate level disinfect the Omnisound® 3000E Pro unit prior to the next treatment application.



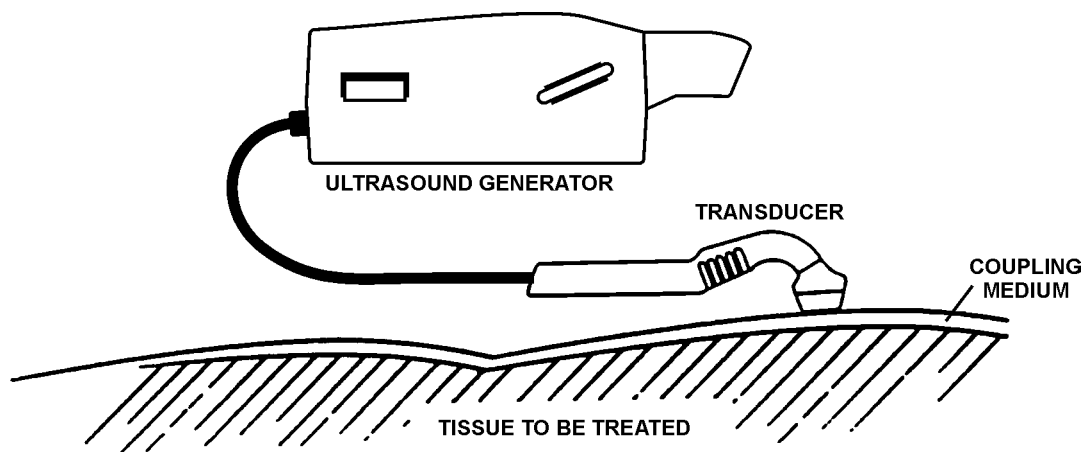
## MODES OF OPERATION

### History

The use of ultrasound in physical medicine dates back to the late 1930's (Pohlman, et al, 1939). After the Second World War, great interest was shown in this technique and many technical papers were presented. By 1955, the council on Physical Medicine and Rehabilitation of the American Medical Association recommended the technique as an adjunctive therapy for the treatment of pain, soft tissue injury and joint dysfunction, including osteoarthritis, peri-arthritis, bursitis, tenosynovitis and a variety of musculoskeletal syndromes. Ultrasound therapy is currently used on a very frequent basis in physical medicine. The Omnisound® 3000E Pro ultrasonic therapy system provides the clinician with an accurately calibrated ultrasound source capable of operating in pulsed or continuous modes at 1.0 MHz or 3.0 MHz for therapeutic applications.

### Theory of Operation

Ultrasonic therapy devices generally consist of a generator and a transducer. The generator produces the electrical drive output to the transducer and provides measurement of its ultrasonic output. The transducer converts the electrical energy from the generator into mechanical vibrations, known as ultrasonic vibrations. These vibrations are then coupled to the patient's tissue via a coupling medium such as ultrasonic gel, water or mineral oil. When electro stimulation is used simultaneously with ultrasound through the transducer the coupling medium must also be conductive.



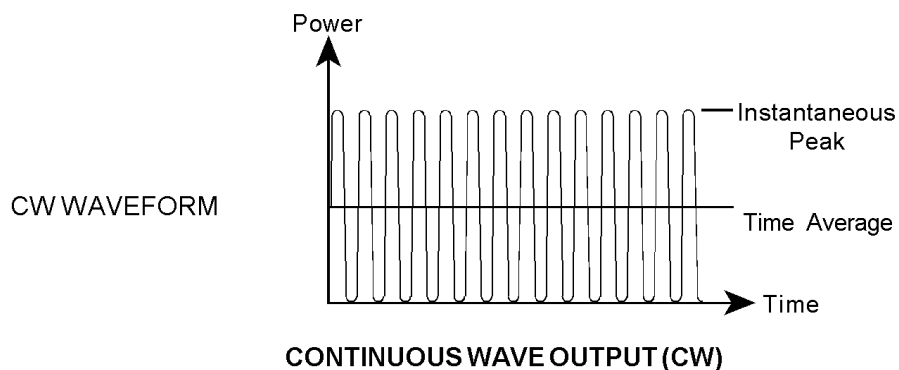
#### SCHEMATIC REPRESENTATION OF A TYPICAL ULTRASOUND GENERATOR

Typically therapeutic ultrasound generators operate in the 500 kHz to 3.5 MHz range. The frequency of the ultrasonic wave will determine the absorption by the tissue and thus the penetration of the beam in the tissue. Output intensities of 0.1 - 3 watts/cm<sup>2</sup> are typically applied for therapeutic purposes in pulsed or continuous wave modes.

## Temporal Variation of Ultrasonic Output

### Continuous Wave Output

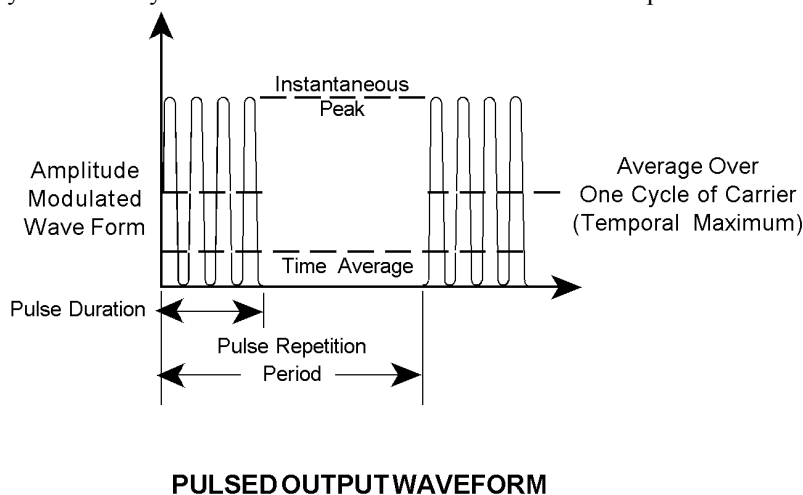
Ultrasonic output may be produced on a continuous basis or may be pulsed. Ultrasonic power is measured in watts, which are a measure of the total power emitted in the form of ultrasonic radiation by the applicator, averaged over each cycle of the ultrasonic radiation carrier wave. The power may also be expressed in watts/cm<sup>2</sup>, which gives the output in watts for each square centimeter of effective radiating area on the transducer surface. The effective radiating area is a measurement of the surface area of the transducer, which produces more than 5 percent of the maximum intensity in the near ultrasound field measured at 5mm from the transducer surface. It should be noted that the effective radiating area does not generally cover the entire surface area of the transducer (effective radiating surface) and varies with the crystal frequency when operated at different crystal harmonics.



In continuous wave mode (cw) the time average power is defined as the temporal average power and is 50 percent of the peak instantaneous power. When the ultrasound unit is calibrated with a power measurement device it is generally measured in the continuous wave mode.

### Pulsed Wave Output

Ultrasound devices may also produce pulsed or discontinuous waveforms. These outputs are generally square wave in shape. The output of pulsed ultrasound is defined as the average output over one cycle of the carrier, rather than the average over time (time average). This measurement is referred to as the Temporal Maximum power. By defining the output in this way, Average power (temporal average) may be calculated by multiplying the Temporal Maximum by the duty factor. Duty factor is the ratio of on time to total time for pulsed waveforms.



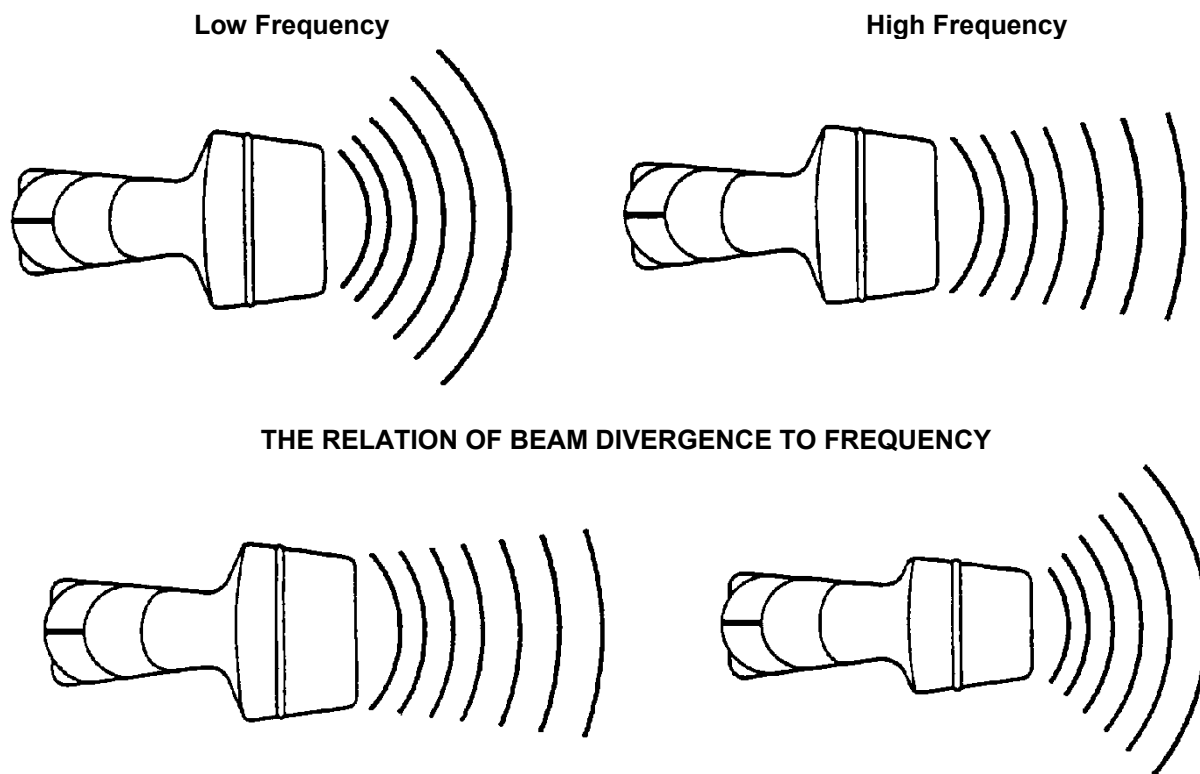
The Omnisound® 3000E Pro offers duty factors in pulsed mode of 50, 33, 25, 20, 10 and 5 percent. Decreasing duty factor will decrease the average ultrasonic power which will lower the thermal effect of the beam on the tissue. The pulse duration is preset at 2 milliseconds. The system produces square wave output in pulsed mode. Average power or intensity may be calculated by taking the digital power meter reading and multiplying it by the duty factor.

## Beam Characteristics, Power, and Intensity Measurement

Intensity is a quantity used to establish exposure level to the ultrasound beam. It is measured in watts per square centimeter of effective radiating surface. Ultrasound applicators do not generally produce beams of perfectly uniform intensity over the surface of the transducer. Thus the measurement represents an average for the effective radiating surface area.

### Beam Divergence

The beam divergence of an ultrasonic therapy applicator is related to the frequency of the ultrasound and the size of the source (applicator). The lower the ultrasound frequency, the greater the beam divergence. Conversely, the smaller the source diameter, the greater the beam divergence.

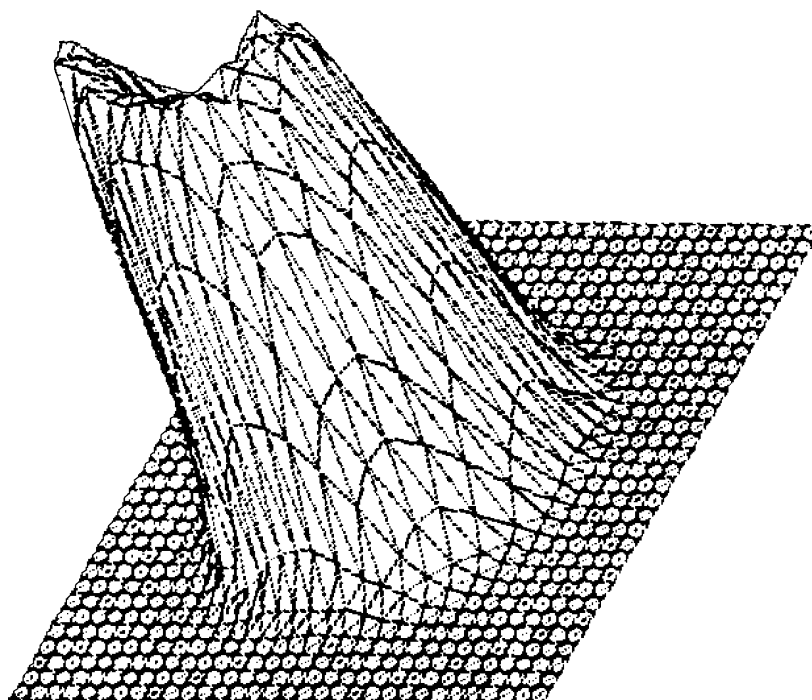


## THE RELATION OF BEAM DIVERGENCE TO SOURCE DIAMETER

In general, the output of a piston radiator (typical ultrasonic therapy applicator) is more complex than the above since the source does not produce a uniform field over its surface. As the ultrasound leaves the transducer the beam size remains relatively constant (although there is non-uniformity). This is followed by a region with a more uniform field. These areas are known as the near and far fields.

Ultrasound has an excellent ability to penetrate deeply, primarily due to its small beam divergence (Schwan, 1958). A typical beam scan of an applicator is presented below.

Model Number: 3000E Pro  
Serial Number: 2945  
Frequency: 1 or 3 MHz  
Test Date: 2/1/04  
ERA: 5.0 cm<sup>2</sup>  
BNR: 2.75:1



## Beam Non-Uniformity Ratio

Beam non-uniformity ratio is defined as the ratio of temporal - average spatial - maximum intensity to the temporal average effective intensity as measured at 5mm from the transducer surface. The typical range for most commercially obtainable transducers is between 3 to 1 and 10 to 1. BNR can be useful in comparing one unit to another for field uniformity. One should keep in mind that the spatial maximum intensity in watts/cm<sup>2</sup> is equal to the calibrated intensity on the output display multiplied by the BNR, i.e.: if 1 W/cm<sup>2</sup> was registering on the output display and the BNR was 7:1 the maximum intensity in the tissue would equal 7 watts/cm<sup>2</sup> at certain portions of the field. This should be kept in mind when determining output dosage. It is also important to maintain continuous movement of the head for these reasons.

## Output Power and Exposure Time

The total power for a given amount of treatment time determines the total energy transferred to the tissue. One should note that if one uses different ultrasonic generators with differing effective radiating areas, one should use the total power measurement not the intensity measurement in order to correlate the settings on the units. Times must also be accurate in order to assure proper treatment dosage. The Omnisound® 3000E Pro systems use a quartz controlled microprocessor based digital timer, which operates in minutes and seconds to an extremely high degree of accuracy. Care should be taken when applying therapy to move the head continuously over the desired treatment area.

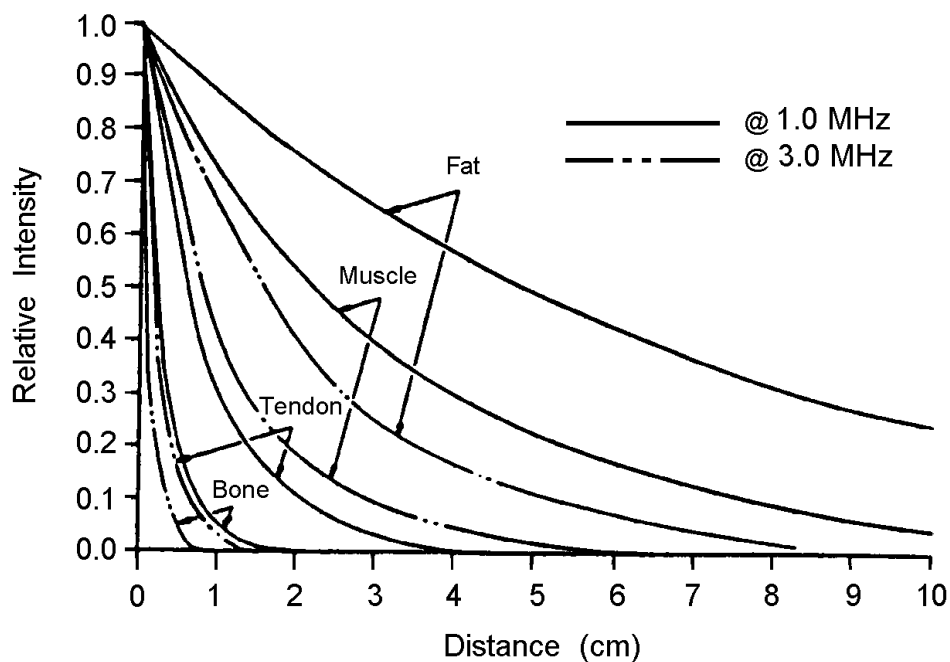
## Monitoring of Delivered Power or Intensity

The Omnisound® 3000E Pro power meter displays the ultrasonic power level to be delivered to the patient under proper coupling conditions. First apply an ultrasound couplant to the treatment area. The output control (up power arrow) should then be increased to the desired power or intensity level. Power should be reduced prior to decoupling to avoid overheating of the transducer when used. The thermal shutdown system is provided on all Omnisound® 3000E Pro transducers to prevent thermal damage to the transducer. Appropriate warnings will be displayed on the main operating screen should this occur. Power may be restored when the head is properly re-coupled to the patient or following cool-down should overheating occur. If little coupling is occurring in the treatment area due to the size of the area, underwater application technique may be indicated. It is poor practice to allow continuous overheating of the transducer.

## Ultrasound Transmission and Absorption

When ultrasonic energy is applied to the tissue it is absorbed in varying degrees. This absorption of energy can increase tissue kinetic energy leading to increased temperature or the formation of cavitations or acoustic micro streaming.

It is known that different tissue types absorb ultrasound differently and for this reason the modality has the ability to selectively treat certain tissues due to their greater energy absorption. The absorption coefficient describes the degree of absorption by the tissue and is approximately equal to the frequency in the 1-4MHz range. For this reason, ACP uses both 1.0 and 3.0MHz ultrasonic outputs using an exclusive feedback control system through its treatment transducer. The use of these two frequencies allows greater or less attenuation of the beam, for example, 1.0MHz penetrates approximately 3 times more than 3.0MHz ultrasonic beams. This may be helpful in selecting intensity and time for ultrasonic therapy applications. Due to this reason the patient will generally experience much faster heating with 3MHz ultrasound and dosage or treatment time may have to be reduced to avoid overheating of the tissue.





## Temperature Mode of Operation / Delta T Mode

In order to achieve repeatable thermal effects of ultrasound in tissue the dosage of the ultrasound beam must be carefully controlled. This involves accurate determination of the treatment area, couplant to be used, frequency of operation, BNR and the desired temperature increase required to achieve appropriate therapeutic effects in the tissue.

LEHMAN and other investigators have categorized the effects of ultrasound on tissue as being of a mild or 1 degree C increase, moderate or 2 degree C increase or vigorous or 4 degree C heating effect above the baseline tissue temperature of 37.5 degrees C. Typically vigorous heating is used to treat connective tissue contracture and scar tissue while moderate and mild heating are used in pain control, sub acute and chronic inflammatory conditions and for muscle spasm reduction.

The patented Delta T mode of the Omnisound® 3000E Pro is a proprietary software system that is used in conjunction with the ultrasound system to ensure consistent dosimetry.

To use the system proceed as follows:

1. After the unit has completed self-test and the default screen appears depress the 1, 2 or 4 degree Delta T protocol button.
2. Select the couplant being used, if other than ultrasound gel, by using the select parameter switches (normally this is not used when ultrasound gel is selected).
3. Select the frequency of 1 or 3MHz.

**NOTE:** 3MHz is the default frequency so if the depth is less than 1" or 2.5cm for the target tissue then you will not need to change the frequency. If the depth is greater than 1", select the 1MHz frequency.

4. To start the treatment, supply adequate couplant, apply the transducer to the patient and increase the power. As you do so you will notice that the timer will change from 15 minutes to a lower value. This will only occur if the dose is sufficient to reach the desired temperature within the treatment time. Adjust the output intensity - typically to a range of 0.5W/cm<sup>2</sup> to 1W/cm<sup>2</sup> is used based on patient comfort. The treatment time will automatically adjust based on the power setting chosen to provide the correct dosage. As the power is increased the time decreases and vice versa. If the patient experiences any discomfort decrease the power by a small amount (0.1 - .2W/cm<sup>2</sup>) and note if the pain is reduced. If so continue the treatment. The treatment time will automatically increase to compensate for the decreased power level. Repeat again if the sensation is still too hot following the reduction of power.

**NOTE:** The delta T mode of operation is calibrated for muscle not in proximity of bone. If the ultrasound application at 3MHz is within 1 cm of bone the 2 degree delta T mode will heat at a rate of 4 degrees, or the 1 degree delta T mode will heat at 2 degrees. Within .5cm proximal to bone, the 1 degree Delta T mode will heat at 4 degrees due to the reflexion of the ultrasound field from the bone back into the overlying tissue.

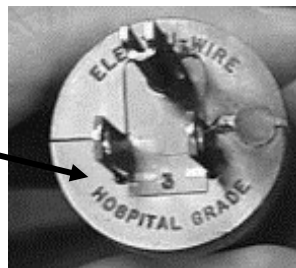
5. The temperature display shows the projected temperature increase over time based on the selected parameters for treatment. Although it does not represent actual temperature it should be a close approximation if the treatment is correctly applied.
6. Use a slow (approximately 1cm per second) linear or circular motion with the transducer. The treatment area should be restricted to two of the transducer sizes, which approximates 2 effective radiating areas (ERA). This is absolutely mandatory if the correct relationships in the calculation equations are to be met.
7. When the treatment is complete the timer will beep, the output will power down. To treat another area of 2 ERA simply push the up power control on the transducer and the mode will be set up automatically at the originally set default parameters. To change the defaults select a new protocol from the front panel switches.

## TROUBLESHOOTING

The following table lists machine problem symptoms and possible areas to check for the problem causes. If these suggested measures do not correct the machine malfunction, call your ACP Customer Support representative.

PROBLEM	CAUSE	REMEDY
BROKEN CABLE message is displayed on the unit	<ul style="list-style-type: none"> <li>Transducer may not be connected properly.</li> <li>Unit may have problem with transducer or cable.</li> </ul>	<ul style="list-style-type: none"> <li>Check if transducer is plugged-in correctly. If not, plug-in transducer and re-start unit.</li> <li>If error message was on and transducer was connected properly, please contact the Service Center for assistance.</li> </ul>
TRANSDUCER OVER HEAT message is displayed on the unit	<ul style="list-style-type: none"> <li>Transducer output is too high and/or the couplant is inadequate. This error occurs during treatment. When this message is displayed, the output is automatically terminated. The unit is in "locked" condition until the transducer temperature is reduced. At that point the unit resets.</li> </ul>	<ul style="list-style-type: none"> <li>Check if appropriate couplant was used, and if it was used in sufficient quantity and with proper technique. Improper use of couplant will result in unit overheating.</li> <li>If the couplant was applied appropriately and in sufficient quantity, contact the Service Center.</li> </ul>
TRANSDUCER NOT PRESENT message is displayed on the unit	<ul style="list-style-type: none"> <li>Transducer may not be connected properly.</li> </ul>	<ul style="list-style-type: none"> <li>Check if transducer is plugged-in correctly. If not, plug-in transducer and re-start unit.</li> <li>If properly re-connecting the transducer does not resolve the problem, please contact the Service Center for assistance.</li> </ul>
Unit will not power on	<ul style="list-style-type: none"> <li>Power cord not plugged in to the unit or AC outlet</li> </ul>	<ul style="list-style-type: none"> <li>Verify the electrical cord has a molded <b>HOSPITAL GRADE</b> plug (see below)</li> <li>Verify if power cord is connected as appropriate</li> <li>Verify AC outlet is functional</li> </ul>
Unit will not start	<ul style="list-style-type: none"> <li>Output power not increased.</li> </ul>	<ul style="list-style-type: none"> <li>Select FREQUENCY, DUTY FACTOR, and OUTPUT POWER</li> </ul>
Cannot change settings	<ul style="list-style-type: none"> <li>Treatment in progress</li> </ul>	<ul style="list-style-type: none"> <li>Stop treatment, adjust, and restart</li> </ul>
Patient feels surging or spiking sensation	<ul style="list-style-type: none"> <li>Absent, inadequate, or improper conductive medium interface</li> <li>Treatment output intensity is too high.</li> </ul>	<ul style="list-style-type: none"> <li>Replace with correct and adequate conductive medium</li> <li>Reduce output intensity</li> </ul>
Patient cannot detect output	<ul style="list-style-type: none"> <li>Failure of transducer(s), or conductive medium interface</li> <li>Failure of Omnisound® 3000E Pro</li> <li>Patient may have compromised sensation tolerance.</li> </ul>	<ul style="list-style-type: none"> <li>Use Omnisound® 3000E Pro output test to determine if unit has failed or is operating incorrectly.</li> <li>Check for patient sensation in the treatment area.</li> </ul>

Identify the "HOSPITAL  
GRADE" marking on the  
power plug



### Omnisound® Output Test:

1. Turn the unit to "ON."
2. Select the 3.0 MHz frequency and set DUTY FACTOR to CONTINUOUS.
3. Submerge the transducer head in a water bath and turn OUTPUT POWER to maximum.
  - For a 5 second period remove and submerge the transducer head continuously from the water bath.
  - After 5 seconds hold the transducer head out of the water pointed away from you.
  - You should see what appears to be a fine water spray (mist) emanating from the head. This would indicate normal operation.
  - If you do not see what appears to be a fine water spray (mist) coming off the head, there is no ultrasound output, and may require service. If this is the finding, contact the ACP Customer Support. All ultrasound repairs should be done by ACP Service Center personnel.
4. After this test immediately turn OUTPUT POWER to the off position.

## Calibration

If clinicians are to give prescribed therapeutic doses of ultrasound with reasonable accuracy, the machine used is required to meet the equipment performance standard (21 CFR 1050.10) instituted by the Food and Drug Administration. Periodic calibration of treatment parameters having a direct influence on the physiological effect of ultrasound on tissue, i.e., ultrasound power output, and time accuracy, is a major part of this regulation. It is suggested, therefore, that the Omnisound® 3000E Pro be verified at least once yearly. The Omnisound® 3000E Pro calibration must also be verified after it has been serviced or repaired. Routine recalibration may be performed through the screen calibration system available by pushing the calibration key of the main run screen. An Ohmic UPMDT-10 or 30 may be used to perform recalibration. Please follow the directions on the calibration screens to perform this procedure. It is recommended that recalibration be performed by qualified service personnel.

Due to the sophisticated nature of the Omnisound® 3000E Pro, ACP requires that all service work be performed at its service facility or by a qualified ACP field technician or authorized service center.

## Service Center

For repair or service of ACP Products and accessories, please call (800) 350-1100 and follow the prompts. Normal hours of operation are 6:00am to 5:00pm Pacific Standard Time. After hours, please leave a message and a technician will return your call during the next scheduled workday.

## SPECIFICATIONS

GENERAL:			
Dimensions:	4" (10.2 cm) H x 11" (27.9 cm) W x 12" (30.5 cm) D		
Weight:	8.5 lbs (3.8 kg)		
Operating Power:	120/240VAC; 50/60Hz; 50W		
Display System:	Super Twist LCD full character display with adjustable contrast /viewing angle.		
System Architecture:	CMOS integrated micro-controller with on board memory and instruction set.		
ULTRASOUND GENERATOR:			
Frequency:	1 MHz ± 10% or 3 MHz ± 10%		
Indication Accuracy:	± 20% for all levels greater than 1 watt.		
Output Display:	Shows total Watts or Watts/cm <sup>2</sup> during the Accuracy +/- 20% for all levels greater than 1 watt.		
Pulsed Mode:	Output is continuous or pulsed. In pulsed mode output is 100% square wave modulated. Power level is adjusted with intensity control which controls pulse amplitude.		
Continuous Mode:	Output is on as long as the timer has time remaining and the output control is turned up.		
Delta T Mode:	Output time is calculated based on treatment intensity to achieve a 1, 2, or 4 <sup>o</sup> C temp increase in 2 x ERA muscle tissue load.		
RTPA	Duty Factor	Pulse Duration	Pulse Repetition Rate
	± 20%	± 20%	
1:1	100%	continuous	continuous
2:1	50%	2 ms	250Hz
3:1	33%	2 ms	165Hz
4:1	25%	2 ms	125Hz
5:1	20%	2 ms	100Hz
10:1	10%	2 ms	50Hz
20:1	5%	2 ms	25Hz
ULTRASOUND APPLICATOR:			
Piezoelectric Disk:	Lead zirconate titanate		
Frequency:	1 MHz ± 10% or 3 MHz ± 10%		
ERA/BNR:	<b>Effective Radiating Area (ERA) and Beam Non-Uniformity Ratio (BNR):</b>		
		<b><u>1MHz 2cm<sup>2</sup></u></b>	<b><u>1MHz 5cm<sup>2</sup></u></b>
	ERA	1.75 ± 60%	5.0 ± 50%
	BNR	< 5:1	< 5:1
	Nominal	2.5:1	3.0:1
		<b><u>3MHz 2cm<sup>2</sup></u></b>	<b><u>3MHz 5cm<sup>2</sup></u></b>
	ERA	1.75 ± 60%	5.0 ± 50%
	BNR	< 5:1	< 5:1
	Nominal	2.5:1	3.0:1
PATIENT SAFETY SYSTEMS:			
Activation:	Patient safety hand control shuts down output. Output modality may not be changed during operation. Output levels are reset to zero at the start and completion of treatment.		
MISC:			
Treatment Programs:	Output intensity is gradually increased during treatment from 0 to 20% automatically in a linear manner over the duration of the treatment when the anti-adaptation mode is selected. The amount of the increase is user programmable.		
Certificates and Approvals:	Devices are designed to meet or exceed all safety requirements of a medical device in its class per IEC 60601 and CSA C22.2 No. 601.1		

**Caution:** Federal law restricts this device to sale by or on the order of a physician (or other health practitioner licensed by their State). ACP reserves the right to change technical specifications and product availability without notice.

## Effective Radiating Area (ERA) and Beam Non-Uniformity Ratio (BNR)

### SPATIAL PATTERN

The applicator produces a collimated cylindrical beam when measured at 5mm from the radiating surface with distilled degassed water 30°C with line voltage variations of  $\pm 10$  percent of rated value for the 5cm<sup>2</sup> transducer at 1 and 3MHz and the 2cm<sup>2</sup> transducer at 3MHz. At 1MHz the 2cm<sup>2</sup> transducer produces a diverging beam. The graph on the following page is representative of a three dimensional plot of the beam at 5mm from the transducer surface.

### POWER AND INTENSITY

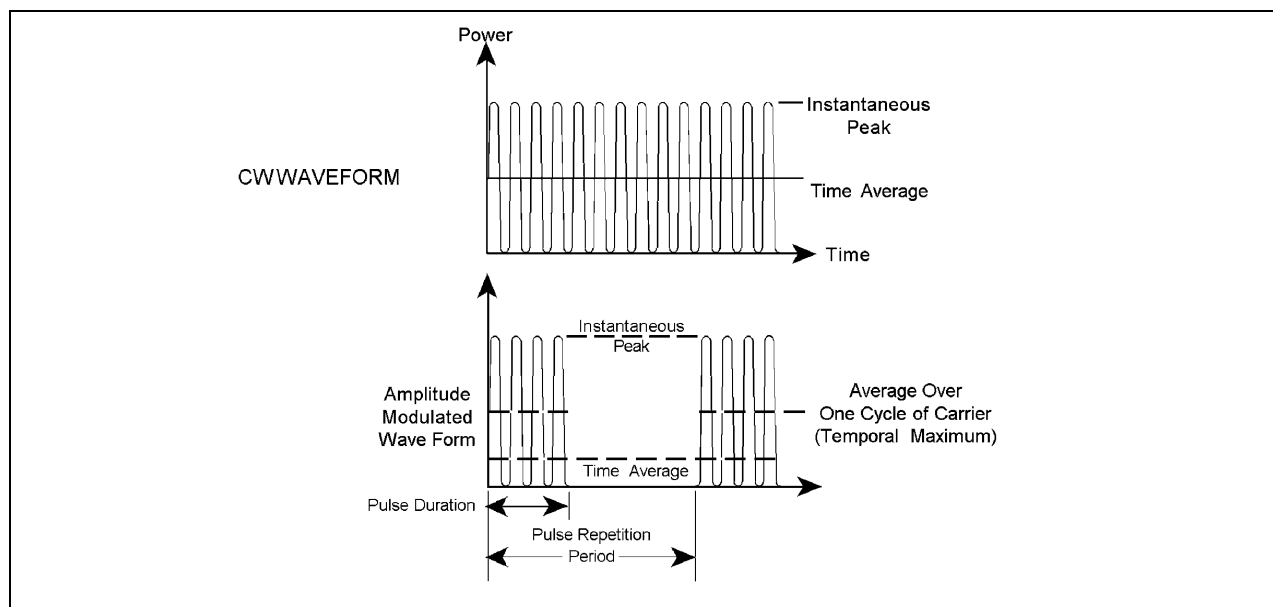
Output Power	2cm <sup>2</sup>	5 cm <sup>2</sup>	
1MHz	0-3W	0-9W	Nominal
3MHz	0-3W	0-6W	Nominal
Output Intensity	2cm <sup>2</sup>	5 cm <sup>2</sup>	
1MHz	0-2W/cm <sup>2</sup>	0-1.8W/cm <sup>2</sup>	Nominal
3MHz	0-2W/cm <sup>2</sup>	0-1.2W/cm <sup>2</sup>	Nominal

### CERTIFICATION

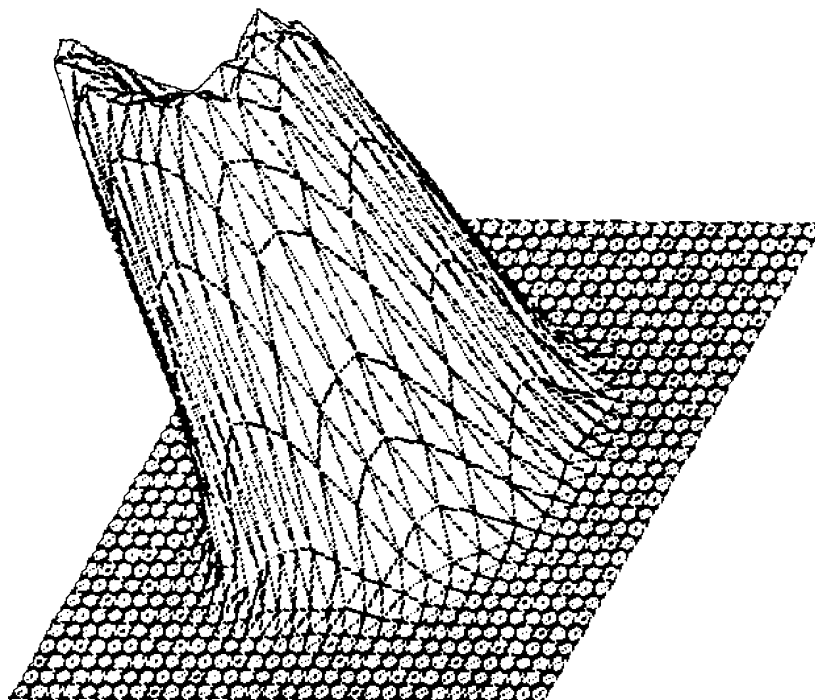
The Omnisound® complies with the ultrasound performance standards as set forth in 21 CFR 1050.10. Patented in USA Nos.: 5,086,788; 5,413,550; D 315,958; other patents pending.

### ABBREVIATIONS

<b>RTPA</b>	MAX/AVG INTENSITY RATIO, Ratio of Temporal-Maximum Effective Intensity to the Temporal-Average Effective Intensity	<b>MHz</b>	Megahertz
<b>Gen</b>	Generator	<b>cm<sup>2</sup></b>	Square Centimeter
<b>S/N</b>	Serial Number	<b>CW</b>	Continuous Wave
<b>Freq.</b>	Frequency	<b>W</b>	Watts
<b>BNR</b>	Beam Non-Uniformity Ratio	<b>W/cm<sup>2</sup></b>	Watts per Square Centimeter
		<b>P.P.S.</b>	Pulses per Second
		<b>ERA</b>	Effective Radiating Area
		<b>Coll.</b>	Collimating



**ACP ULTRASONIC THERAPY APPLICATOR  
INTENSITY IMAGE AT 5mm FROM TRANSDUCER SURFACE**



Model Number:	3000E
Serial Number:	2945
Frequency:	1 or 3 MHz
Test Date:	2/1/04
ERA:	5.0 cm <sup>2</sup>
BNR:	2.75:1

## STANDARD AND OPTIONAL ACCESSORIES

ITEM	ITEM NO.	DESCRIPTION
	<b>1203000E</b>	<b>OMNISOUND® 3000E PRO ULTRASOUND THERAPY SYSTEM</b> 1 MHz and 3 MHz low BNR Portable Ultrasound with Delta T dose control  <b>Shipping Weight: 8 lbs (3.6 kg)</b>
ITEM	ITEM NO.	DESCRIPTION
	<b>57422</b>	Line Power Supply, 12V – 48V (no CE)
	<b>19856</b>	AC Line Power Cord, Hospital Grade
	<b>PAD-12</b>	Shrouded Pin to Banana Adapter
	<b>46059</b>	Medium Transducer, 5cm with Crystal
	<b>85569</b>	Small Transducer, 2cm with Crystal
	<b>48777</b>	Omnisound® 3000E Pro User Manual

## Infection Control Supplies

ITEM	ITEM NO.	DESCRIPTION
	<b>52479</b>	Barrier Film for Surfaces, Infection Control, 4" x 6" perforated sheets – 1200 sheets/roll
	<b>66431</b>	Barrier Film for Surfaces, Infection Control, 6" x 9" perforated Sheets – 1200 sheets/roll
	<b>50593</b>	Barrier Film - for Surfaces, Infection Control, 12" x 14" perforated Sheets – 800 sheets/roll
	<b>63574</b>	Barrier Tubing 3" x .004 High Clarity – 1,200 ft. roll
	<b>55536</b>	Super Sani-Cloth® Wipes, Single Use Packets (50 pkt/bx)
	<b>44425</b>	Super Sani-Cloth® Wipes, Tub (160 wipes/tub)
	<b>96849</b>	Sani-Cloth® Wipes w/ Bleach, Tub (75 wipes/tub)
	<b>45539</b>	Ultrasound® Gel – 250 ml bottle
	<b>32060</b>	Ultrasound® Gel – 5L container
	<b>30354</b>	Ultrasound® Probe Covers (25/box)



## STANDARD LIMITED PRODUCT WARRANTY

*The warranty information provided in this section is applicable only to products purchased from ACP, directly or through an authorized dealer. This section does not apply to leased products. The terms of maintenance and repair of any leased products are detailed in the separately executed agreement between the parties.*

### Warranty Coverage

This warranty provides coverage, for Equipment purchased, against manufacturer's defects in material and workmanship, and extends to the original owner of the product during the warranty period for that product. Only those items returned to the ACP Service Center within the warranty period, and also within thirty (30) days after notification to ACP of the defect, shall be eligible for repair under the Standard Limited Product Warranty. Buyer is responsible for shipping cost associated with sending the Equipment to the ACP Service Center. ACP shall ship Equipment to Buyer after repair at no cost to the Buyer provided repair is deemed to be under warranty. ACP may, at its discretion and only for valid warranty claim, repair or replace any part(s) that prove to be defective during the warranty period.

### Warranty Exclusion

Any and all warranty coverage will be void if any of the following have occurred:

1. The product contains repairs or replacement parts not furnished by ACP.
2. The product is damaged resulting from misuse or negligence.
3. The product has been tampered with and/or altered, including serial number alteration.

Note: Use of the Equipment with accessories and/or supplies not approved by ACPL for use with the Equipment may void the warranty if such accessory or supply item caused damage to the Equipment.

### Warranty Period

The following coverage is provided at no additional cost to the Buyer:

**New Equipment / Product.** Products purchased as new from ACP are warranted against manufacturer's defects in material and workmanship for a period of one (1) year from the date of purchase.

**Refurbished Equipment / Product.** Products purchased specifically as Refurbished Equipment are warranted against manufacturer's defects in material and workmanship for a period of six (6) months from the date of purchase.

**Accessories.** All accessories for ACP equipment / products are warranted against manufacturer's defects in material and workmanship for a period of three (3) months from the date of purchase.

### Warranty Validation

The following information needs to be provided to the ACP Customer Support representative prior to the product being returned under warranty coverage:

1. Buyer name or account number as it appears under the "Bill TO" on the ACP or recognized ACP Dealer invoice.
2. Invoice Date and Number.
3. Model number, description, and serial number of equipment.
4. Detailed description of the problem.

## Return of Defective Equipment

Any Equipment returned to the ACP Service Center under warranty coverage must have the Warranty coverage validated and must receive authorization from ACP Customer Support prior to being received at the Service Center.

Shipping charges, insurance, and any other costs incurred in sending product to ACP Service Center is the responsibility of the customer and will not be refunded. ACP shall cover the shipping charges and related costs to return the unit to the customer, provided repair is deemed to be under warranty.

ACP is not responsible for any loss or damage to the Equipment prior to receipt at the ACP Service Center. Equipment returned for warranty service must be shipped complete with all accessories (except for manuals), in its original packing or equivalent so as not to be damaged while in transit.

**Note:** Any Equipment sent to the ACP Service Center that is not covered by the ACP Limited Product Warranty is subject to a minimum service and handling fee.

### **IMPORTANT:**

**DO NOT SHIP THE EQUIPMENT TO ACP SERVICE CENTER WITHOUT FIRST SECURING AUTHORIZATION TO DO SO. PLEASE CALL CUSTOMER SERVICE AT (800)-350-1100 FOR AUTHORIZATION. EQUIPMENT SENT IN WITHOUT AUTHORIZATION FROM ACP CUSTOMER SUPPORT WILL NOT BE ACCEPTED.**

### **Returned Materials Shipping Address:**

**Accelerated Care Plus  
Attn: ACP Service Center  
4999 Aircenter Circle, Suite 103  
Reno, NV 89502**