

SynchroSonic ***U/50****



User's Guide

Amrex[®]
electrotherapy equipment
a division of Amrex-Zetron, Inc.

*Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner licensed by the law of the state in which he practices to use or order the use of this device.

SynchroSonic U/50 User's Guide

Revised August 1998

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SynchroSonic®
QuickConnect™
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Thank you. . .

for selecting the Amrex SynchroSonic U/50. We believe that you will find this instrument to be versatile, dependable and user friendly. The SynchroSonic U/50 provides the widely used therapeutic modality of ultrasound. The ultrasound may be applied separately or may be combined with electrical stimulation simultaneously through the ultrasound transducer using an external Electrical Stimulator.

Your SynchroSonic U/50 has been manufactured by a group of dedicated, highly trained employees who exemplify the sixty year Amrex tradition of manufacturing therapeutic equipment of the highest quality while supporting you with prompt, courteous customer service.

Upon receipt of your SynchroSonic U/50, verify your accessories against the enclosed check list. Promptly return the postage paid Registration Card to Amrex. Save the original shipping carton and all packing materials.

Please carefully review this User's Guide prior to operating the SynchroSonic U/50. Should you have questions regarding your new purchase, or need assistance, telephone Amrex Technical Services at (800) 221-9069.

Limited Warranty

Amrex-Zetron, Inc. (Manufacturer) warrants each instrument it manufactures to be free from defects in material and workmanship under normal use and service for a period of two (2) years from the date of purchase. This two year warranty extends only to the original purchaser and shall not apply to batteries, fuses, accessories or any instrument which has been subjected to misuse, neglect, accident or abnormal conditions of operation.

There is a one (1) year warranty on the ultrasound transducer and cable.

The Manufacturer's obligation under this warranty is limited to repairing or replacing, at the Manufacturer's option, any instrument returned to the factory within two (2) years from the date of purchase. If the Manufacturer determines that the product fails to conform to this warranty due to misuse, alteration or abnormal condition of operation, including evidence that nonauthorized personnel have attempted to repair the device, the instrument will be repaired at customers expense. This warranty is exclusive and in lieu of all other warranties, expressed or implied, including but not limited to any other warranty of merchantability or fitness for any particular purpose. Manufacturer shall not be liable for any special, incidental or consequential damages, whether in contract, tort or otherwise.

Service and Shipping Information

Amrex Technical Services has a representative to assist you should your equipment require service or repair. It is necessary to obtain a Return Merchandise Authorization (RMA) number before returning equipment to the factory for warranty repair. Call our representative toll free (800) 221-9069. Damage, resulting from repairs made outside the factory, is not covered under the warranty.

To maintain compliance with FDA, 21 CFR 1050.10 Performance Standards, your Amrex ultrasound must be calibrated and safety tested on an annual basis. Amrex strongly recommends that servicing be referred to the factory. Call toll free (800) 221-9069.

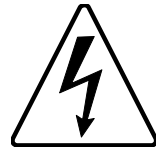
Save the original shipping carton and all packing materials to safely return Amrex equipment to the factory for service; repair; annual calibration, electrical and mechanical safety check. All accessories, including the ac line cord, must be included with the returned instrument. The customer is responsible for all freight charges. The Manufacturer shall assume NO responsibility for damage in transit.

Contraindications—Warnings—Precautions

THIS INSTRUMENT OPERATES ON 120 VOLTS AC, 60 Hz. (unless otherwise indicated on the unit) AND MUST BE PROPERLY GROUNDED FOR SAFETY. The three wire power cord with "hospital grade" plug should be connected to a GROUNDED AC wall receptacle. It is the personal responsibility and obligation of the user to insure that this instrument is properly connected to the AC POWER source before use.



Warning—Risk of burns and fire. DO NOT use near conductive material such as metal bed parts or innerspring mattresses. Renew electrode cables upon evidence of deterioration. Use of controls, adjustment, or performance of procedures, other than those specified herein, may result in hazardous exposure to ultrasonic energy.



Ultrasound—Contraindications

Ultrasound should not be used in the following areas: transcerebrally; near the heart or reproductive organs; over viscera, eyes, ears, the spinal column, malignancies, the joint capsule in arthritic conditions either acute or subacute, or over total joint replacements. Ultrasound should not be used in cases of: cardiac pacemakers, pregnancy, implants, malignant or benign tumors, multiple sclerosis, arteriosclerosis or weakened blood vessels, hemophilia, thrombosis and thrombophlebitis either acute or subacute. Neither should ultrasound be used over bone in growing children, where the skin suffers from any sensory impairment, nor in the area of the carotid sinus nerves, visceral plexus or large autonomous ganglion.

Ultrasound—Precautions

Excessive doses of ultrasound can cause damage to tissue. Periosteal pain is an indication of excess intensity. Should this occur, reduce the power and/or move the transducer more quickly over the area being treated.

Any bleeding tendency is increased by heating because of the increase in blood flow and vascularity of the heated tissues. Care should be used in treating patients who have bleeding disorders.

Electrical Muscle Stimulation—Contraindications

- Contraindicated for patients with cardiac demand pacemakers.
- Should not be used on cancer patients.

Electrical Muscle Stimulation—Warnings

- Long term effects of chronic electrical stimulation are unknown.
- Safety has not been established for the use of electrical muscle stimulation during pregnancy.
- Adequate precautions should be taken in the case of persons with suspected heart problems.
- Adequate precautions should be taken in the case of persons with suspected or diagnosed epilepsy.
- Do not stimulate over the carotid sinus nerves, especially in patients with a known sensitivity to the carotid sinus reflex.
- Severe spasm of the laryngeal and pharyngeal muscles may occur when the electrodes are positioned over the neck or mouth. The contractions may be strong enough to close the airway or cause difficulty in breathing.
- Electrical muscle stimulators should not be applied transcranially.
- Electrical muscle stimulators should not be used over swollen, infected or inflamed areas or skin eruptions.
- Caution should be used in the transthoracic application of electrical muscle stimulators in that the introduction of electrical current into the heart may cause arrhythmias.
- Electrical muscle stimulators should be kept out of the reach of children.

Electrical Muscle Stimulation—Precautions

Precautions should be observed:

- When there is a tendency to hemorrhage following acute trauma or fracture.
- Following recent surgical procedures when muscle contraction may disrupt the healing process.
- Over the menstruating uterus.
- Where sensory nerve damage is present by a loss of normal skin sensation.

Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or the conductive medium. The irritation can usually be reduced by use of an alternate conductive medium or alternate electrode placement.

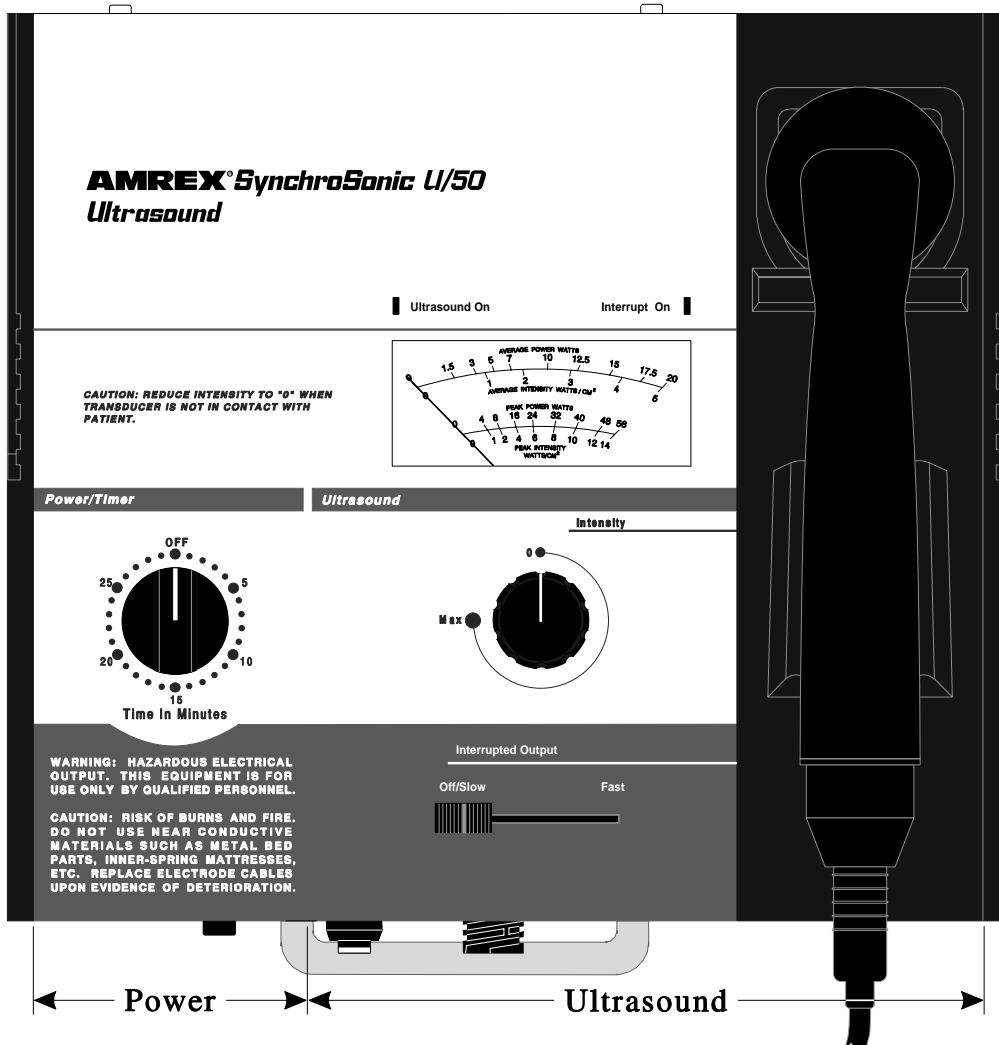
Skin irritation and burns beneath the electrodes have been reported with the use of electrical muscle stimulators.

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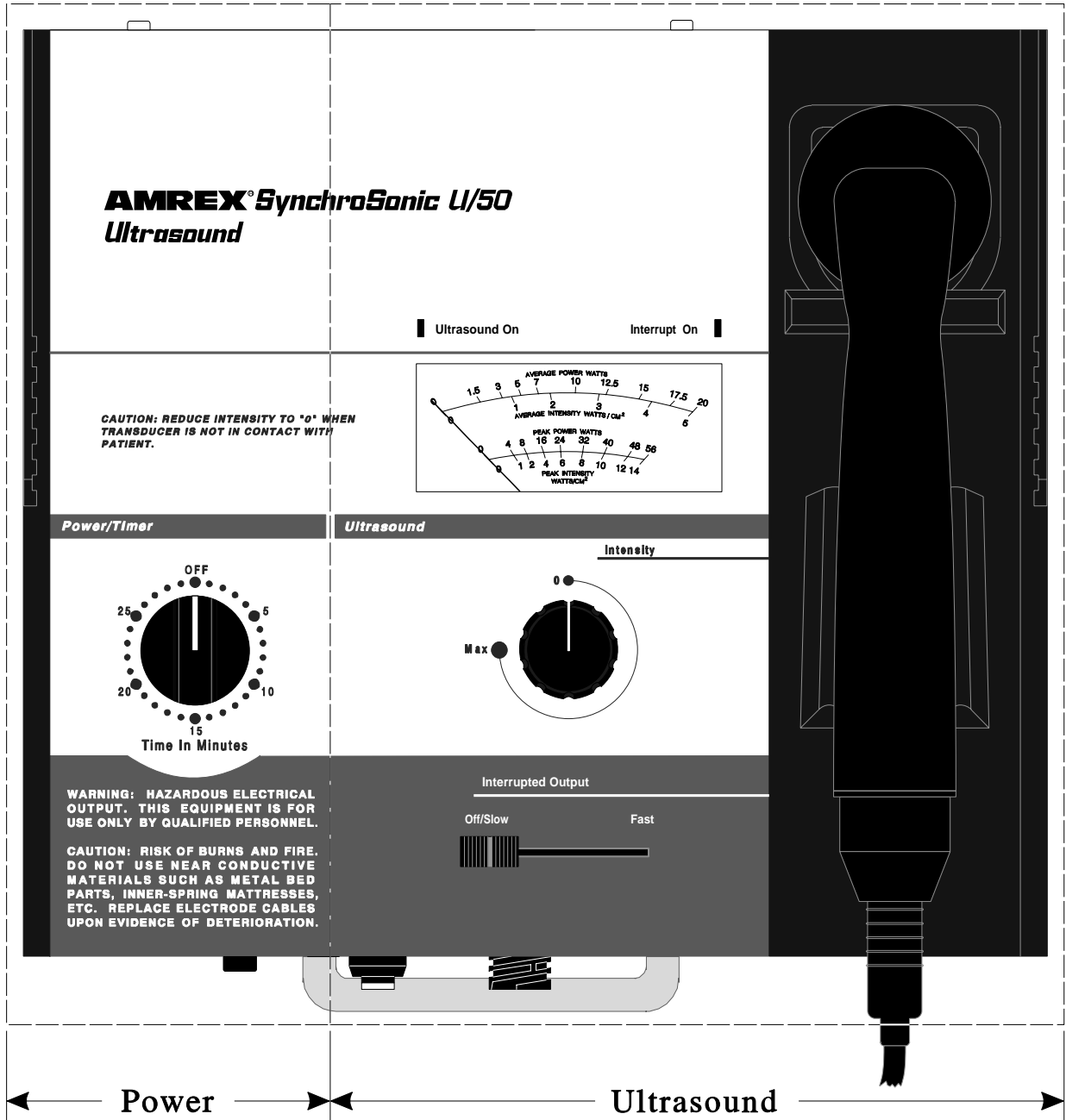
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Overview

The layout of the U/50 panel is logically arranged into two major sections. These sections are, from left to right: Power and Ultrasound.



In the illustration below, dashed lines surround each of the U/50's sections. A brief description of each section follows the illustration, and Parts 2 and 3 of this manual contain detailed descriptions.



Power Section

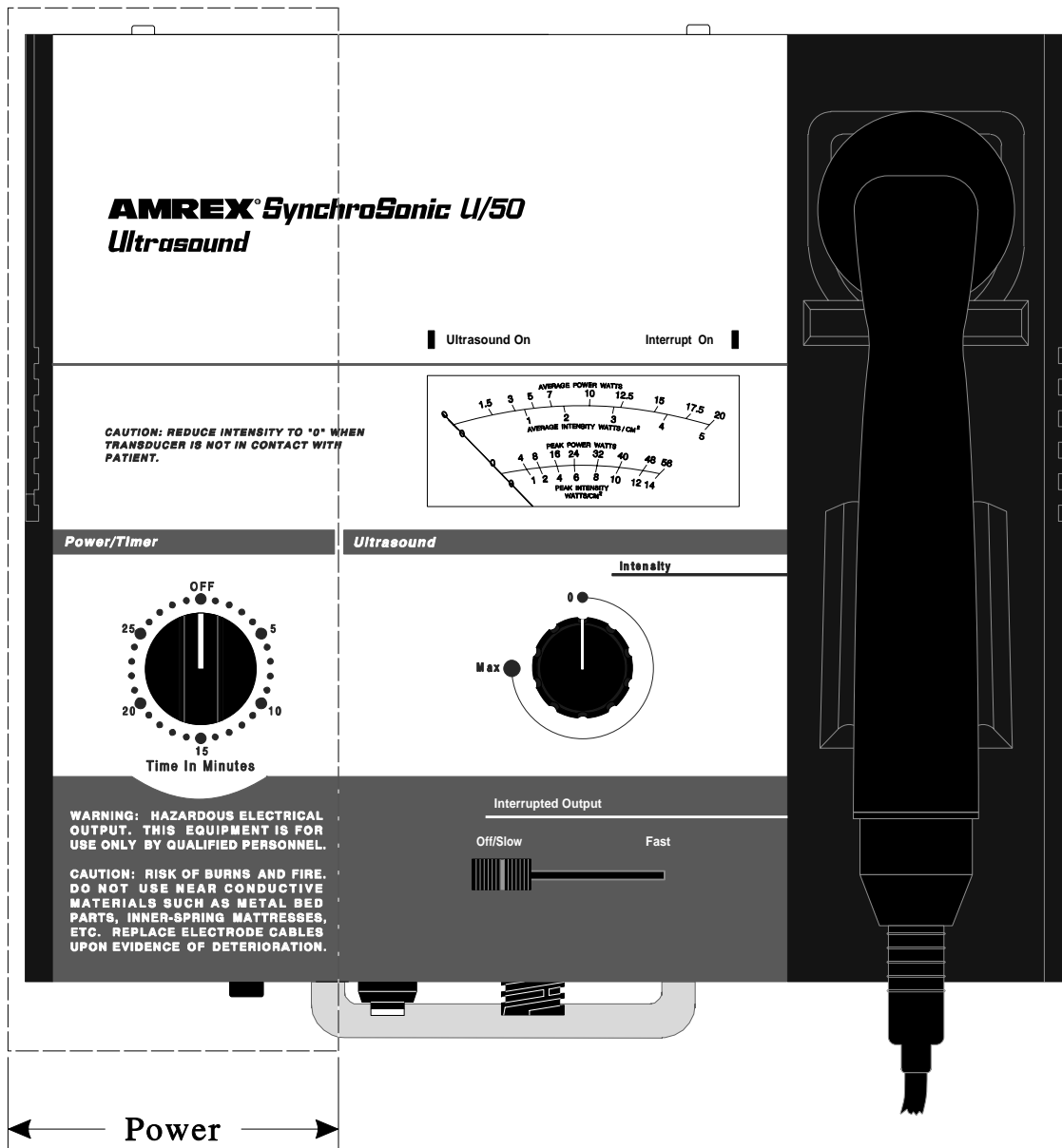
Use the Power Section to activate the main ac power and set the treatment duration. When the treatment is complete the power will shut off and a bell will sound.

Ultrasound Modality Section

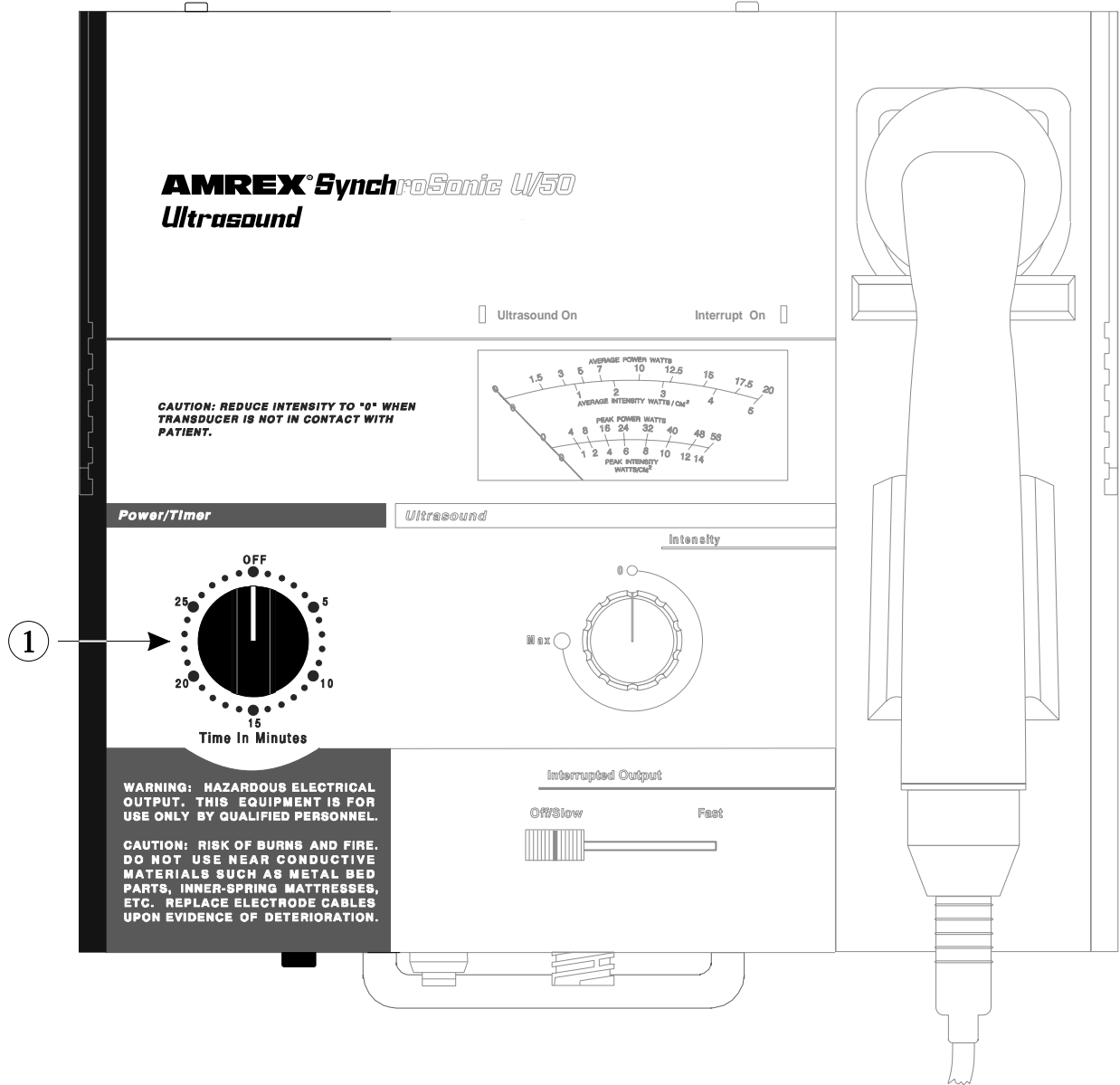
Set the intensity and monitor the output of ultrasonic energy with the controls, connectors and meter dial in this section of the panel. Select either non-interrupted output or a specific interrupted rate using the Interrupted Output slide control. Combine Ultrasound output with an external Electrical Stimulator using the Combination Mode switch.

Power Section

In the illustration below, dashed lines surround the U/50's power section.



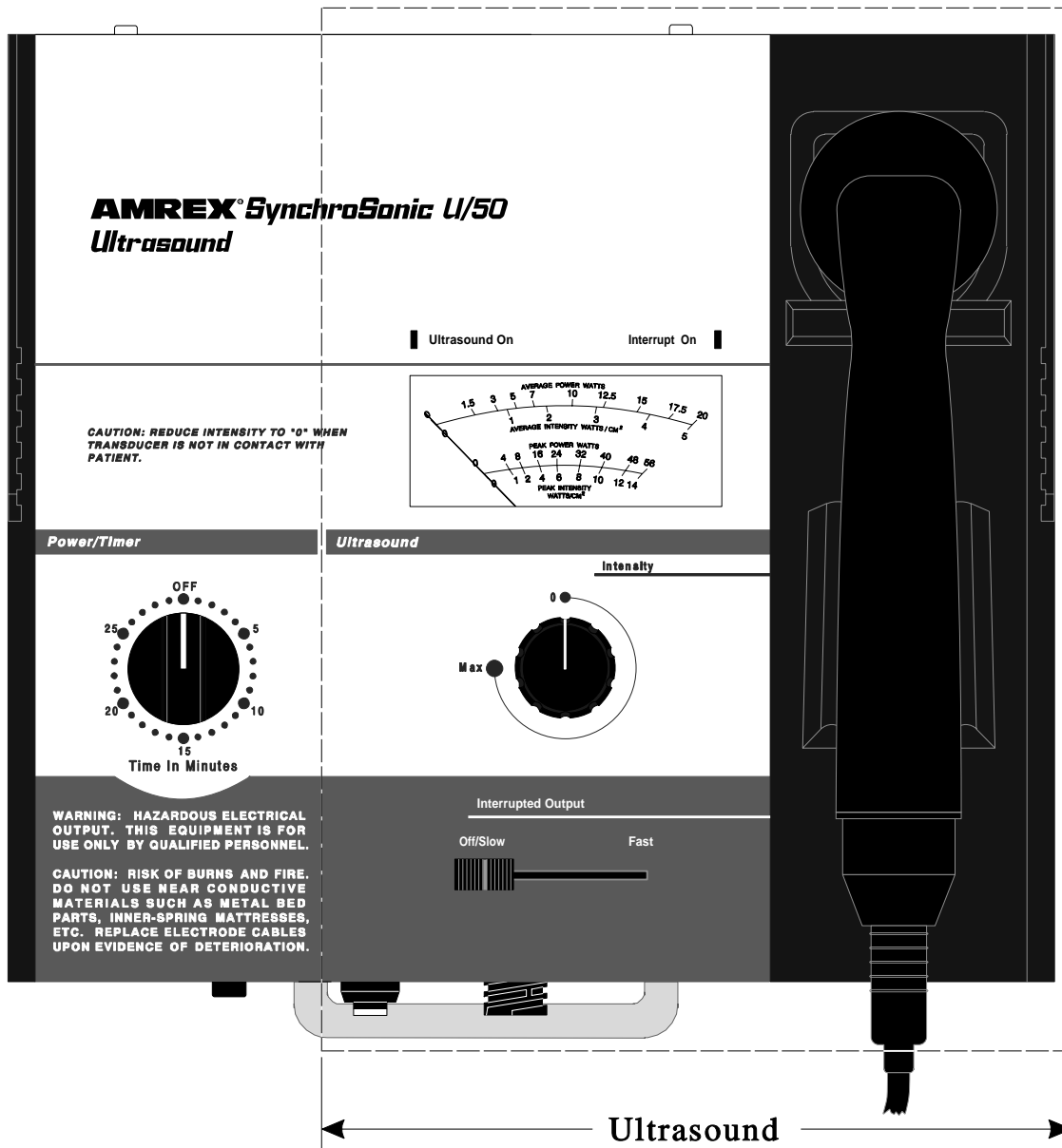
The power section of the U/50 panel is depicted below. Item referenced with circled number (1) is explained on the following page.



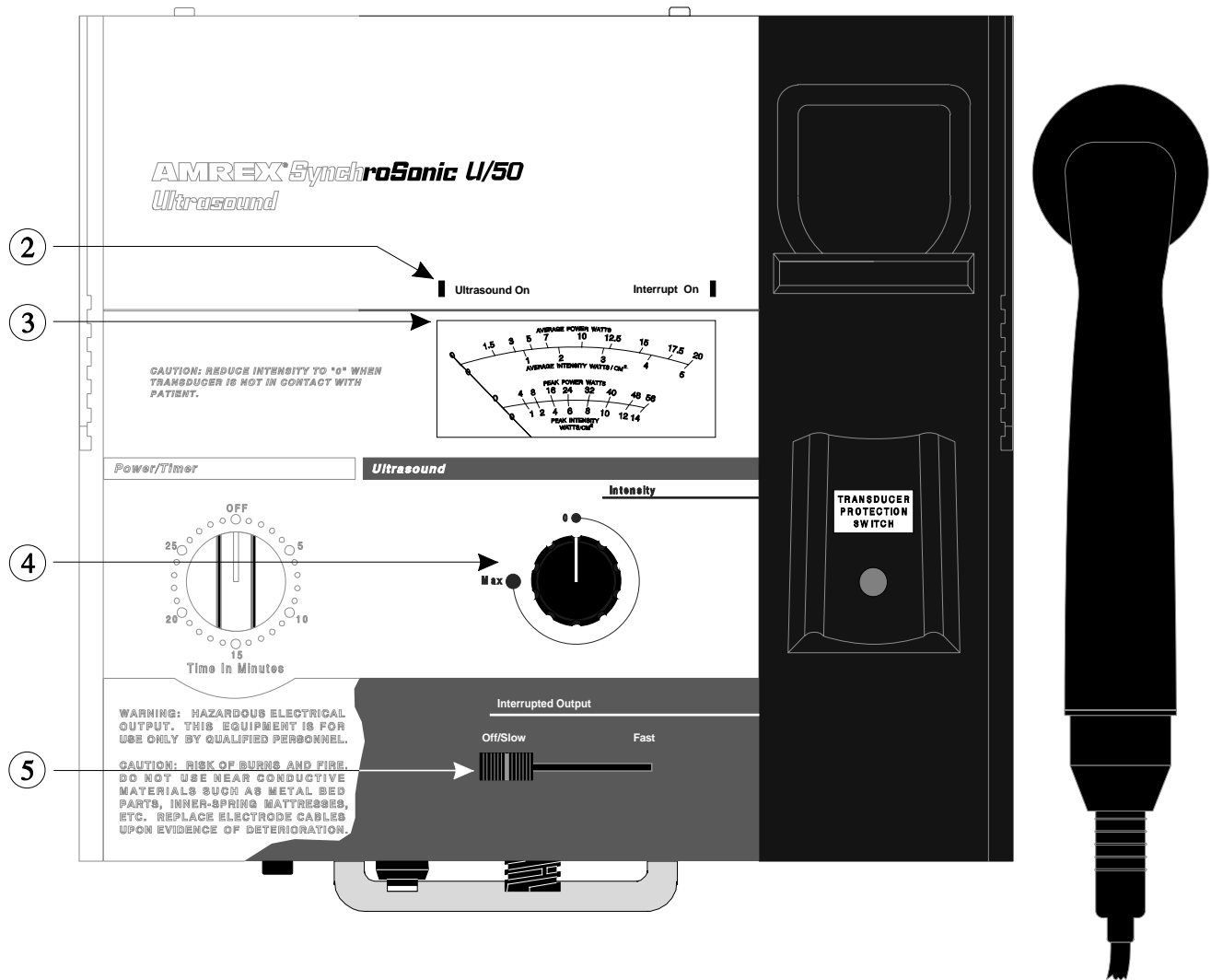
- 1. POWER/TIMER:** Controls the main ac power as well as the timer for treatment. Turn the *Power/Timer* knob clockwise past the 10 minute mark and then set it to the desired treatment time. The *Ultrasound On* indicator light (located above the upper left corner of the ultrasound meter) will illuminate. The ac power will shut off and a bell will sound when treatment is completed. To initiate early shut off, turn the *Power/Timer* knob counterclockwise to the Off position. The ac power will shut off and a bell will sound.

Ultrasound Modality

In the illustration below, dashed lines surround the U/50's ultrasound section.



The ultrasound section of the U/50 panel is depicted below. Items referenced with circled numbers (2 - 5) are explained on the following page.



2. ULTRASOUND ON INDICATOR LIGHT

3. ULTRASOUND METER: Consists of four scales:

Average Power Watts Refers to the total watts applied to the patient. Has a range of 0 to 20 watts.

Average Intensity Watts/CM² Refers to the power density or watts per square centimeter. Has a range of 0 to 5 watts/cm².

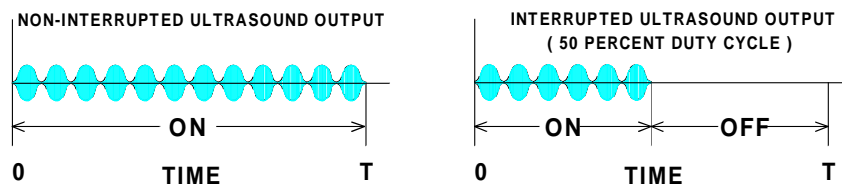
Peak Power Watts Refers to output at 120 Hz amplitude modulated.

Peak Intensity Watts/CM² Refers to the power density or watts per square centimeter at 120 Hz amplitude modulated.

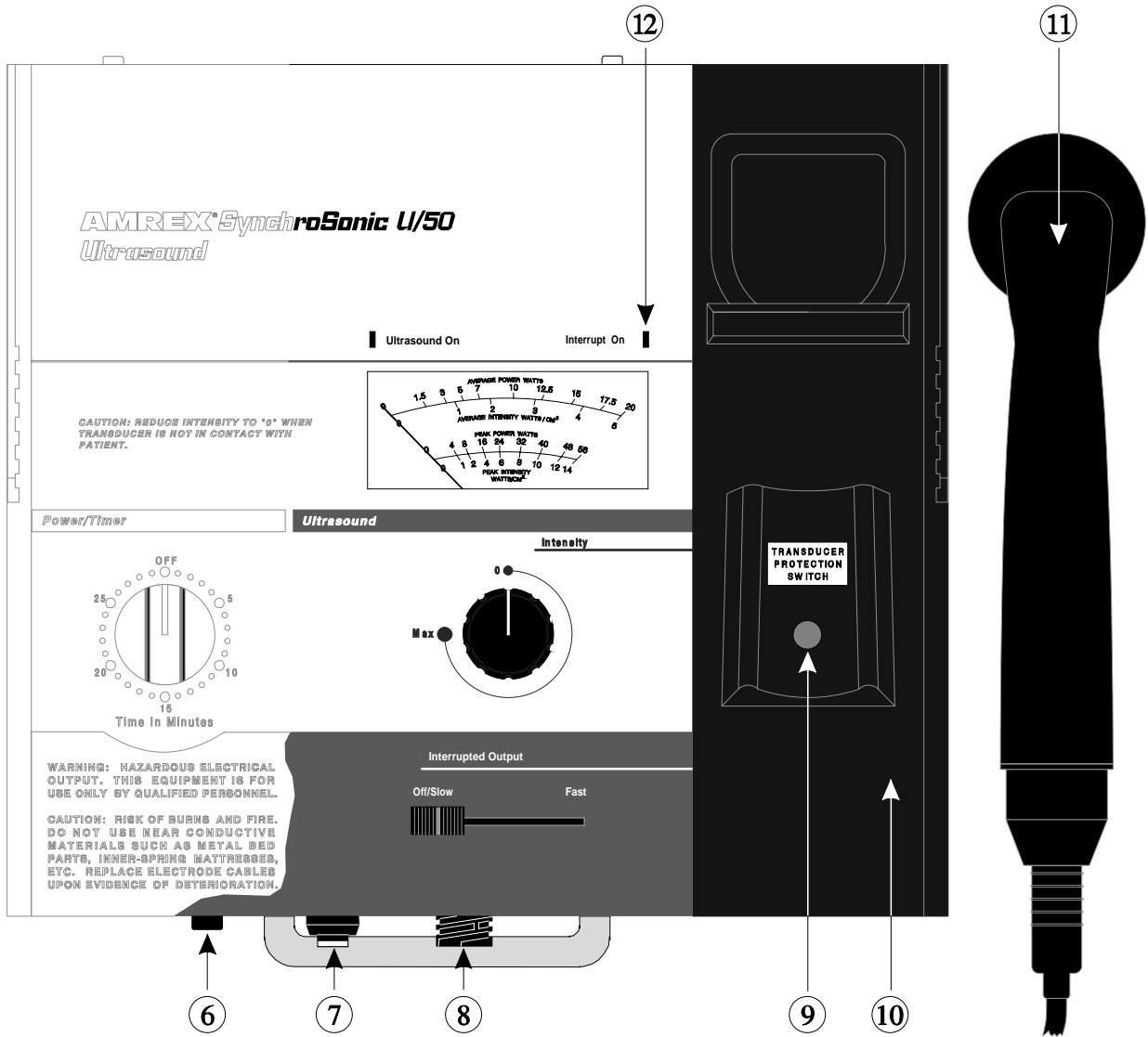
4. ULTRASOUND INTENSITY CONTROL: Regulates output from 0 to Max as displayed on the Ultrasound Meter dial.

5. ULTRASOUND INTERRUPTED OUTPUT SLIDE CONTROL: Provides a variable selection of interrupted output. When the slide switch is in the *Off* position, the output will be non-interrupted. As the control is moved to the right, the *Interrupt On* indicator light (located above the upper right corner of the ultrasound meter) will illuminate and the interrupted rate will increase. The approximate duration is 3½ to 1½ second intervals, 50% duty cycle. When the control is returned to the *Off* position, the *Interrupt On* indicator light will turn off and the interrupted rate will stop.

ULTRASOUND WAVEFORM
AMPLITUDE MODULATED AT 120 Hz.



The ultrasound section of the U/50 panel is depicted below. Items referenced with circled numbers (6 – 12) are explained on the following page.





6. **STIMULATOR INPUT JACK:** Provides for connection to an external UL Listed Amrex Low Volt AC Muscle Stimulator, Model MS322.
7. **COMBINATION MODE SWITCH:** Provides for external Amrex MS322 Low Volt AC Muscle Stimulator output and ultrasound to be applied simultaneously through the ultrasound transducer. In the *Off* position, only ultrasonic energy is obtained through the transducer even though the stimulator may still be active.
8. **ULTRASOUND OUTPUT TRANSDUCER CONNECTOR:** Provides for connection to an Amrex *Ultrasound Transducer*. The ***Transducer Cable Fault Alarm System*** detects improper transducer cable connection and/or transducer cable damage. If a transducer cable is improperly connected or damaged, an audible signal will be emitted from the generator, the "Interrupt On" light will illuminate and the ultrasound meter will display "0" output. Ultrasound output will cease until the transducer cable is properly connected to the generator or, if damaged, replaced.
9. **TRANSDUCER PROTECTION SWITCH:** When the transducer is placed in the cradle, the ultrasonic energy will automatically shut off **AND** when the transducer is removed from the cradle, the ultrasonic energy will resume **IF:** the *Ultrasound Intensity* control is not set at the "0" position, the treatment period has not been completed and the bell has not sounded.
10. **ULTRASOUND TRANSDUCER CRADLE**
11. **ULTRASOUND TRANSDUCER**

Note: Only Use The Transducer(s) Assigned To This Generator. Transducer serial number is located on the Transducer and on the Generator Label.
12. **INTERRUPT ON INDICATOR LIGHT**

U/50 General Operation and Application Procedures

General Operation

1. Connect the U/50's ac power cord to the U/50's ac receptacle and plug the "Hospital Grade" connector to a properly grounded 120Vac, 60Hz receptacle.
2. Connect the assigned ultrasound transducer to the generator's *Ultrasound Output Transducer Connector* and place the handle in the transducer cradle.
3. Reduce the *Ultrasound Intensity* control to "0" and set the *Ultrasound Interrupted Output* slide control at the Off position.
4. Prepare a contact medium at and around the treatment site with a liberal coating of Amrex Conductance and Coupling Gel.
5. Turn the *Power/Timer* knob and set it to the desired treatment time.

Note: When the treatment time is less than ten (10) minutes, turn the *Power/Timer* knob clockwise past the ten (10) minute mark and then set it back to the desired time. The *Ultrasound On* indicator light (located above the upper left corner of the ultrasound meter) will illuminate. Allow one (1) minute for the ultrasound modality to warm-up.

6. Verify that the *Ultrasound Intensity* control is set at the "0" position before removing the transducer from the cradle and placing the transducer faceplate on the prepared treatment site.
7. Slowly increase the *Ultrasound Intensity* control to the desired output level as indicated on the ultrasound meter dial. If desired, adjust the *Ultrasound Interrupted Output* slide control now. When the *Ultrasound Interrupted Output* slide control is adjusted, the *Interrupt On* indicator light (located above the upper right corner of the ultrasound meter) will illuminate and the *Ultrasound Meter* indicator will rise and fall indicating interrupted cycles provided the transducer is not in the ultrasound cradle.

8. When treatment is completed, the ac power will shut off and a bell will sound. To initiate early shut off, turn the *Power/Timer* knob counterclockwise to the Off position. The ac power will shut off and a bell will sound. Reduce the *Ultrasound Intensity* control to "0" position and thoroughly clean the transducer faceplate before placing the transducer in the transducer cradle.

Application of Ultrasound

Therapeutic ultrasound provides for increased cell permeability as well as micro-massage. Analgesic and thermal effects occur when ultrasound is applied to the nerve root and primary treatment site.

Ultrasonic energy is transmitted by means of an applicator, or transducer, applied directly to the skin. Since ultrasonic energy will not be efficiently transmitted through air, a conducting medium (water or gel) must be used between the transducer and skin tissue. Amrex Conductance and Coupling Gel is recommended. This gel is excellent for ultrasonic energy transmission as well as conductance for application of electrical muscle stimulation. The Amrex transducer utilizes a polished aluminum faceplate. Coupling agents other than Amrex Conductance and Coupling Gel may cause a discoloration or "pitting" of the aluminum.

Apply a generous amount of gel to the area being treated. Place the transducer in contact with the skin surface BEFORE increasing the output intensity. Move the transducer in a slow, rotary or stroking motion.

If the area to be treated is an irregular surface that does not allow proper soundhead contact, the AMREX transducer may be utilized for underwater therapy. Immerse the area to be treated and the transducer maintaining approximately one inch distance between the area being treated and the faceplate. To insure proper transmission of ultrasonic energy, brush away air bubbles if they appear on the soundhead's faceplate.

At the conclusion of the treatment, thoroughly clean the transducer faceplate before placing the transducer in the Cradle. Always return the Ultrasound Intensity control to "0" when the transducer is not in contact with the patient to avoid serious damage to the transducer crystal and generator.

Caution

Excessive doses of ultrasound can cause damage to tissue. Periosteal pain is an indication of excess intensity. If this occurs, the power should be reduced and/or move the transducer more quickly over the area being treated. The *Interrupted Output* mode may also be utilized to reduce heat build up in tissue and for the mechanical effect of ultrasound on tissue

Adverse Effects - Shortwave Diathermy Interference

It is extremely important for the physiotherapist to have a clear understanding of the potential danger involved in the use of a ultrasound device in close proximity to an active shortwave diathermy unit.

A medical shortwave diathermy unit is a very powerful transmitter of radio energy, the larger ones having an output of 500 watts. Any ultrasound device with external leads, in close proximity to a shortwave unit, is likely to be affected by interference. This interference may be in the form of sparking between electrodes or between the leads and the device casing. The leads connecting the ultrasound device to the patient can act as an aerial and collect the radio frequency energy from the shortwave unit. This could interfere with the operation of the ultrasound unit or affect internal functions of the device. Or, it could result in the patient experiencing some unusual "surges" of current. There is no significant electrical radiation from a ultrasound device.

The increasing electronic sophistication of physiotherapeutic equipment is likely to mean that this problem is going to become more obvious. The minimum safe operating distance is difficult to determine since local factors must be considered. At least two or three meters is needed between the nearest parts of either instrument, including the cables and electrodes. The ultrasound device does not need to be plugged into a power supply to be affected by interference from a shortwave unit. Some very old types of shortwave generators seem to produce more interference than others which compounds the problem even further. With some shortwave units, the distance between devices of at least three meters may still be inadequate.

In practice, shortwave diathermy units and ultrasound units should be placed and operated as far away from each other as possible. It may be necessary to screen off all shortwave units from other equipment or to have fully screened rooms in which shortwave diathermy equipment can be operated without risk of interfering with other sensitive equipment. This is often difficult in a small practice where space is at a premium. In such cases, the units may have to be operated at different times, not simultaneously. In all cases, it would be very dangerous to give shortwave diathermy and ultrasound treatment to a patient simultaneously.

Any patient who reports a sudden, unexplainable "surge" in output may be experiencing the effects of shortwave interference.

Ultrasound—Indications

Ultrasound delivered to the body using an efficient coupling provides deep heating effects to body tissues. When therapeutic ultrasound is delivered to the body at intensities capable of generating a deep tissue temperature increase, some or all of the following effects may occur:

- Pain relief
- Reduction of muscle spasm
- Increase in collagen elasticity or extensibility
- Increase in blood flow
- Increase in soft tissue elasticity
- Increase in enzyme activity
- Mild inflammatory response which can help resolve chronic inflammatory processes

Some of the general conditions for which ultrasound has been used as an adjunctive therapy are:

- Increase range of motion of contracted joints using heat and stretch techniques
- Treatment of chronic bursitis, epicondylitis and tenosynovitis
- Reflex Sympathetic Dystrophy as in shoulder-hand syndrome or Sudeck's atrophy
- Treatment of plantar warts
- Chronic arthritis
- Back pain from lumbago, coccygodynia, radiculitis, sciatica, spondylitis deformans and others
- Reduction of postoperative pain, phantom pains and pain from intercostal neuralgia

Ultrasound—Contraindications

Ultrasound should not be used in the following areas: transcerebrally; near the heart or reproductive organs; over viscera, eyes, ears, the spinal column, malignancies, the joint capsule in arthritic conditions either acute or subacute, or over total joint replacements. Ultrasound should not be used in cases of: cardiac pacemakers, pregnancy, implants, malignant or benign tumors, multiple sclerosis, arteriosclerosis or weakened blood vessels, hemophilia, thrombosis and thrombophlebitis either acute or subacute. Neither should ultrasound be used over bone in growing children, where the skin suffers from any sensory impairment, nor in the area of the carotid sinus nerves, visceral plexus of large autonomous ganglion.

Ultrasound—Precautions

Excessive doses of ultrasound can cause damage to tissue. Periosteal pain is an indication of excess intensity. Should this occur, reduce the power and/or move the transducer more quickly over the area being treated.

Any bleeding tendency is increased by heating because of the increase in blood flow and vascularity of the heated tissues. Care should be used in treating patients who have bleeding disorders.

The Ultrasound Transducer

It is important to maintain the transducer. Care should be taken to avoid sharply bending or twisting the cable. Cable life depends on frequency of use as well as on proper handling. If it becomes necessary to replace the standard cable, the transducer and the generator must be returned to the factory.

Damage to the crystal may result from overheating. When not in use, always return the transducer to the cradle and reduce the Ultrasound Intensity control to "0".

The transducer incorporates a machined aluminum faceplate and conductance mediums other than Amrex Conductance and Coupling Gel may cause a discoloration or "pitting" of the aluminum. Use standard alcohol when cleaning the faceplate.

Note: Only Use The Transducer(s) Assigned To This Generator. Transducer serial number is located on the Transducer and on the Generator Label.

Transducer Cable Fault Alarm System

Detects improper transducer cable connection and/or transducer cable damage. If a transducer cable is improperly connected or damaged, an audible signal will be emitted from the generator, the "Interrupt On" light will illuminate and the ultrasound meter will display "0" output. Ultrasound output will cease until the transducer cable is properly connected to the generator or, if damaged, replaced.

For Amrex models equipped with a standard transducer: The generator and transducer must be returned to the factory for repair and calibration, electrical and mechanical safety check.

For Amrex models equipped with the Amrex "QuickConnect System" and less than one (1) year since the last ultrasound calibration: The transducer cable may be replaced on site.

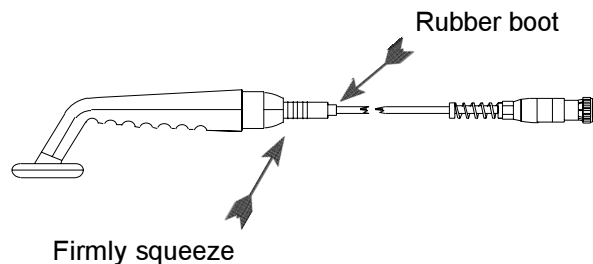
For Amrex models equipped with the Amrex "QuickConnect System" and more than one (1) year since the last ultrasound calibration: Amrex strongly recommends that the generator and transducer be returned to the factory for repair and calibration, electrical and mechanical safety check.

QuickConnect Transducer Cable System (Optional Feature)

The “QuickConnect System” enables the practitioner to quickly and easily replace the transducer cable in the office or clinic. Only transducer cables equipped with the Amrex “QuickConnect System” may be replaced in this manner.

To REMOVE the Cable from the Transducer Handle:

1. Verify that the *Power/Timer* knob is turned counterclockwise to the Off position.
2. Reduce the *Ultrasound Intensity* control to "0" position and thoroughly clean the transducer faceplate before placing the transducer in the transducer cradle.
3. Disconnect the assigned ultrasound transducer from the generator's *Ultrasound Output Transducer Connector* and remove the handle from the transducer cradle.
4. Firmly squeeze the rubber boot and pull away from the transducer handle.



To INSTALL the Cable:

5. Slide the rubber boot down the replacement cord to expose the connector.
6. Grip the metal ring lined area of the connector and firmly push it into the transducer handle. A snap sound will indicate proper installation.
7. Slide the rubber boot up the cord, over the connector and into the transducer handle.

Note: The QuickConnect cable *must* be properly connected to the transducer handle before immersion in water.

8. Connect the assigned ultrasound transducer to the generator's *Ultrasound Output Transducer Connector* and place the handle in the transducer cradle.

To order a “QuickConnect System” cable replacement, telephone Amrex Customer Service at (800) 221-9069 and refer to Amrex Part Number P27-DCA.

To upgrade your unit to include the “QuickConnect System,” send the transducer and the generator with your request for Amrex Part Number P2-RETRO, to Amrex, 641 East Walnut Street, Carson, California 90746.

Dual Transducers (Optional Feature)

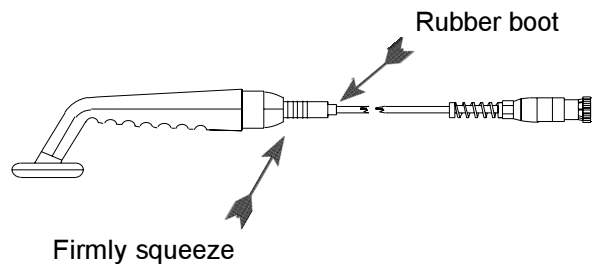
Dual transducers enable the practitioner to select an alternate transducer to provide a wider range of flexibility for therapeutic applications. The standard size transducer provides maximum coverage for stimulation therapy while the smaller size transducer is ideal for treating outer extremities.

Only Amrex generators equipped with dual transducers may be exchanged in this manner.



To Change from One Assigned Amrex Transducer to Another:

1. Verify that the *Power/Timer* knob is turned counterclockwise to the Off position. Reduce the *Ultrasound Intensity* control to "0" position and thoroughly clean the transducer faceplate before placing the transducer in the transducer cradle.
2. Reduce the *Ultrasound Intensity* control to "0" position and thoroughly clean the transducer faceplate before placing the transducer in the transducer cradle.
3. Disconnect the assigned ultrasound transducer from the generator's *Ultrasound Output Transducer Connector* and remove the handle from the transducer cradle.
4. Firmly squeeze the rubber boot and pull away from the transducer handle.



5. Slide the rubber boot down the cord to expose the connector.
6. Grip the metal ring lined area of the connector and firmly push it into the alternate transducer handle. A snap sound will indicate proper installation.
7. Slide the rubber boot up the cord, over the connector and into the alternate transducer handle.

Note: The QuickConnect cable *must* be properly connected to the transducer handle before immersion in water.

8. Connect the assigned alternate ultrasound transducer to the generator's *Ultrasound Output Transducer Connector* and place the handle in the transducer cradle.

U/50 Combination Mode

The Ultrasound modality may be combined with an Electrical Stimulator for simultaneous application through the ultrasound transducer. This technique involves using a large electrode pad and the ultrasound transducer. The transducer soundhead will become the active electrode which will transmit both ultrasound and electrical stimulation. Combination modes require specific control settings and pad arrangements.



Ultrasound Combined With MS322 Low Volt AC Muscle Stimulator

Control Settings and General Operation

1. Connect the U/50's ac power cord to the U/50's ac receptacle and plug the "Hospital Grade" connector to a properly grounded 120Vac, 60Hz receptacle.
2. Connect the MS322's ac power cord to the MS322's ac receptacle and plug the "Hospital Grade" connector to a properly grounded 120Vac, 60Hz receptacle.
3. Connect the assigned ultrasound transducer to the generator's Ultrasound Output Transducer Connector and place the handle in the transducer cradle.
4. Connect the dispersive pad to an Output jack on the MS322. Connect one end of the patient lead to the remaining Output jack on the MS322 and the other end to the Stimulator Input jack on the U/50.
5. Reduce the Ultrasound Intensity control to "0" and set the Ultrasound Interrupted Output slide control at the Off position.
6. Depress the U/50 Combination Mode switch to the Off position (color indicator will not be visible).

7. Reduce the MS322 Intensity control to the 0/Reset position enabling the audible "click". Set the Output Mode selector to Tetanize. Set the Pulse/Surge Rate control at the slow position.
8. Prepare a contact medium at and around the treatment sites with a liberal coating of Amrex Conductance and Coupling Gel. Properly secure the thoroughly moistened dispersive pad insuring that the entire conductive area of the pad makes full contact. The conductive area of the dispersive pad must be at least twice the area of the transducer faceplate.
9. Turn the U/50 Power/Timer knob and set it to the desired treatment time. Note: When the treatment time is less than ten (10) minutes, turn the Power/Timer knob clockwise past the ten (10) minute mark and then set it back to the desired time. The Ultrasound On indicator light (located above the upper left corner of the ultrasound meter) will illuminate. Allow one (1) minute for the ultrasound modality to warm-up.
10. Turn the MS322 Power/Timer knob and set it to the desired treatment time.

Note: When the treatment time is less than ten (10) minutes, turn the Power/Timer knob clockwise past the ten (10) minute mark and then set it back to the desired time. The Stimulator On indicator light (located to the right of the Power/Timer knob) will illuminate.
11. Verify that the MS322 Intensity control is set at the 0/Reset position.
12. Depress the U/50 Combination Mode switch to the On position (color indicator will be visible).
13. Verify that the Ultrasound Intensity control is set at the "0" position before removing the transducer from the cradle and placing the transducer faceplate on the prepared treatment site.
14. Slowly increase the Ultrasound Intensity control to the desired output level as indicated on the Ultrasound Meter dial. If desired, adjust the Ultrasound Interrupted Output slide control now. When the Interrupted Output slide control is adjusted, the Interrupt On indicator light (located above the upper right corner of the ultrasound meter) will illuminate and the Ultrasound Meter indicator will rise and fall indicating interrupted cycles provided the transducer is not in the ultrasound cradle. Stimulator output is unaffected.
15. Slowly increase the Stimulator Intensity control to the desired output level. Select an alternate Output Mode, Pulsation or Surge, and adjust the Pulse/Surge Rate control if so desired.
16. When treatment is completed, the ac power will shut off and a bell will sound. To initiate early shut off, turn the Power/Timer knob counterclockwise to the Off position. The ac power will shut off and a bell will sound. Reduce the Stimulator Intensity control to the 0/Reset position enabling the audible "click". Reduce the Ultrasound Intensity control to "0" position and thoroughly clean the transducer faceplate before placing the transducer in the transducer cradle. Thoroughly clean the pad(s) with warm water and dispose of the used cloth cover(s).

Application of Electrical Muscle Stimulation

Electrical muscle stimulation, high voltage or low voltage ac, is usually applied through carbon type pad electrodes with disposable cloth covers, or sponge type pad electrodes. The *Flextrode System* has been designed for the application of electrical stimulation with the use of carbon type electrodes.

The *Flextrode* pad electrode must be used with the *Flextrode* disposable cloth cover. The cloth cover provides added hygienic protection and increased conductance to the patient. To obtain maximum conductivity, it is important to properly prepare the *Flextrode* pad electrode and cloth cover before application of electrical muscle stimulation.

The *Flextrode* pad electrode and cloth cover assembly must be completely and thoroughly moistened by immersing it in water. Apply a generous amount of Flextrode Conductive Spray to the moistened cloth cover. If the Flextrode Conductive Spray is not desired, apply a generous amount of Amrex Conductance and Coupling Gel to the thoroughly moistened *Flextrode* cloth cover. A generous amount of Flextrode Conductive Spray or Amrex Conductance and Coupling Gel is required to insure good conductivity. Thoroughly clean pad(s) with warm water after each treatment and dispose of the used cloth cover(s).

Important

It is the personal responsibility and obligation of the user to verify that patient cords and electrode pads show no evidence of deterioration prior to patient application. When such evidence exists, replace the cords or electrodes. Never sharply bend or twist the cords. Loose connections or broken cords can cause poor conductance and possible discomfort to the patient.

Should the patient complain of low stimulation output, no output or sudden irregular increases in output, immediately discontinue treatment. Check for the following: secure cord connections; proper electrode contact with the patient; electrode wear or lack of cleanliness. Replace patient cords and/or pad electrodes that show any evidence of deterioration.

Adverse Effects - Shortwave Diathermy Interference

It is extremely important for the physiotherapist to have a clear understanding of the potential danger involved in the use of a ultrasound device in close proximity to an active shortwave diathermy unit.

A medical shortwave diathermy unit is a very powerful transmitter of radio energy, the larger ones having an output of 500 watts. Any ultrasound device with external leads, in close proximity to a shortwave unit, is likely to be affected by interference. This interference may be in the form of sparking between electrodes or between the leads and the device casing. The leads connecting the ultrasound device to the patient can act as an aerial and collect the radio frequency energy from the shortwave unit. This could interfere with the operation of the ultrasound unit or affect internal functions of the device. Or, it could result in the patient experiencing some unusual "surges" of current. There is no significant electrical radiation from a ultrasound device.

The increasing electronic sophistication of physiotherapeutic equipment is likely to mean that this problem is going to become more obvious. The minimum safe operating distance is difficult to determine since local factors must be considered. At least two or three meters is needed between the nearest parts of either instrument, including the cables and electrodes. The ultrasound device does not need to be plugged into a power supply to be affected by interference from a shortwave unit. Some very old types of shortwave generators seem to produce more interference than others which compounds the problem even further. With some shortwave units, the distance between devices of at least three meters may still be inadequate.

In practice, shortwave diathermy units and ultrasound units should be placed and operated as far away from each other as possible. It may be necessary to screen off all shortwave units from other equipment or to have fully screened rooms in which shortwave diathermy equipment can be operated without risk of interfering with other sensitive equipment. This is often difficult in a small practice where space is at a premium. In such cases, the units may have to be operated at different times, not simultaneously. In all cases, it would be very dangerous to give shortwave diathermy and ultrasound treatment to a patient simultaneously.

Any patient who reports a sudden, unexplainable "surge" in output may be experiencing the effects of shortwave interference.

Electrical Muscle Stimulation—Indications

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increased local blood circulation
- Muscle reeducation
- Maintenance of or increase in range of motion
- Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis

Electrical Muscle Stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

Electrical Muscle Stimulation—Contraindications

- Contraindicated for patients with cardiac demand pacemakers.
- Should not be used on cancer patients.

Electrical Muscle Stimulation—Warnings

- Long term effects of chronic electrical stimulation are unknown.
- Safety has not been established for the use of electrical muscle stimulation during pregnancy.
- Adequate precautions should be taken in the case of persons with suspected heart problems.
- Adequate precautions should be taken in the case of persons with suspected or diagnosed epilepsy.
- Do not stimulate over the carotid sinus nerves, especially in patients with a known sensitivity to the carotid sinus reflex.
- Severe spasm of the laryngeal and pharyngeal muscles may occur when the electrodes are positioned over the neck or mouth. The contractions may be strong enough to close the airway or cause difficulty in breathing.
- Electrical muscle stimulators should not be applied transcranially.
- Electrical muscle stimulators should not be used over swollen, infected or inflamed areas or skin eruptions.
- Caution should be used in the transthoracic application of electrical muscle stimulators in that the introduction of electrical current into the heart may cause arrhythmias.
- Electrical muscle stimulators should be kept out of the reach of children.

Electrical Muscle Stimulation—Precautions

Precautions should be observed:

- When there is a tendency to hemorrhage following acute trauma or fracture.
- Following recent surgical procedures when muscle contraction may disrupt the healing process.
- Over the menstruating uterus.
- Where sensory nerve damage is present by a loss of normal skin sensation.

Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or the conductive medium. The irritation can usually be reduced by use of an alternate conductive medium or alternate electrode placement.

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

Specifications

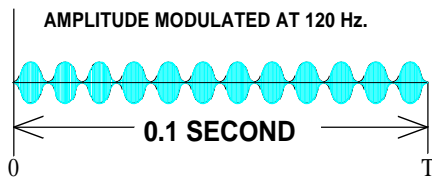
Input Power Requirements

Line Voltage 120 Vac, 60 Hz
 (Special voltages available on request)
 Current 1 A
 Line Leakage < 50 μ A
 UL Listed Medical Equipment 65T1
 CSA Approved Risk Class 2G - LR91512

Ultrasonic Generator

(Complies with FDA Regulation 21 CFR 1050.10 and FCC Regulations)

Frequency 1.0 MHz \pm 5%
 Waveform amplitude modulated
 at 120 Hz \pm 1%



Pulse Duration 8 ms \pm 1%
 Output Mode variable interrupted
 and non-interrupted
 Output Power 0 to 20 W total \pm 20%
 0 to 5 W/cm² \pm 20%

Temporal Peak/Temporal
 Average Intensity 2.8:1 \pm 20%

Treatment

Timer variable from 0 to 30 min
Timer Accuracy
 < 5 min \pm 1 min
 5 to 10 min \pm 10%
 > 10 min \pm 1 min

Applicator (Transducer)

Crystal Material barium-titanate
 Applicator Beam Type collimating
 Frequency 1.0 MHz \pm 5%
 ERA 4 cm² \pm 20%
 BNR 5.5:1 max

Label Abbreviations

Mod Model Number
 Gen Generator, all Amrex
 Ultrasound Models
 F Frequency
 Area Effective Radiating Area, ERA
 Type (coll.) Collimating
 BNR Beam Nonuniformity Ratio

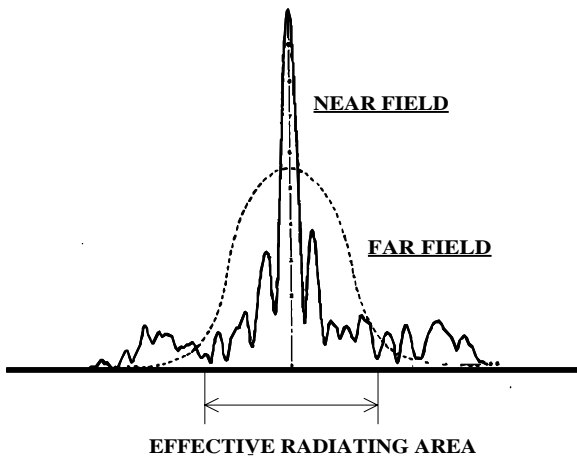
Instrument

Overall Dimensions 11½" W x 11" D
 x 7" H
 Weight (including transducer) 12 Lbs
 Shipping Weight 17 Lbs

Cleaning Instructions

1. Disconnect the power supply.
2. Use mild soap with a lightly moistened cloth.
3. Air dry before using.

Sound Pressure Level



Spatial Pattern

The applicator produces a collimated (cylindrical) beam with an area of 4 cm² as measured 5 mm from the faceplate surface when the radiation is emitted into the equivalent of an infinite medium of distilled, degassed water 30° C, and with line voltage variations in the range of ± 10% of the rated value.

The beam of the applicator is circular in all planes parallel to the applicator face. If a cross section is taken through the axis of the beam, the pattern varies with distance from the face. A few inches from the face (far field), it is a single smooth bell shaped curve. Nearer the face (near field), the pattern varies more due to phase cancellations.

Service and Shipping Information

Amrex Technical Services has a representative to assist you should your equipment require service or repair. It is necessary to obtain a Return Merchandise Authorization (RMA) number before returning equipment to the factory for warranty repair. Call our representative toll free (800) 221-9069. Damage, resulting from repairs made outside the factory, is not covered under the warranty.

To maintain compliance with FDA, 21 CFR 1050.10 Performance Standards, your Amrex ultrasound must be calibrated and safety tested on an annual basis. Amrex strongly recommends that servicing be referred to the factory. Call toll free (800) 221-9069.

Save the original shipping carton and all packing materials to safely return Amrex equipment to the factory for service; repair; annual calibration, electrical and mechanical safety check. All accessories, including the ac line cord, must be included with the returned instrument. The customer is responsible for all freight charges. The Manufacturer shall assume NO responsibility for damage in transit.

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