

Sonicator[®] 740

Instruction Manual

 **M**ETTTLER  **E**LECTRONICS[®]
corp.

FCC Frequency Interference Statement

Warning:

This equipment generates and uses radio frequency energy, and if not installed and operated in strict accordance with the manufacturer's instructions, may cause radio frequency interference.

Notice 1:

This equipment has been verified to comply with the specifications in Part 18 of FCC Rules, which are designed to provide reasonable protection against radio frequency interference. However, there is no guarantee that interference will not occur in a particular installation.

Notice 2:

If this equipment is found to be the source of radio frequency interference, which can be determined by turning the equipment off and on, the user should try to correct the interference by one or more of the following measures:

- Reorient the receiving antenna (as applicable).
- Relocate the Sonicator with respect to the receiver.
- Move the Sonicator away from the receiver.
- Plug the Sonicator into a different outlet than the receiver.
- If necessary, the user should consult with the dealer or manufacturer for additional suggestions. (The user may find FCC's "Interference Handbook" helpful. It is available from the U.S. Government Printing Office, Washington, D.C. 20402, Stock No. 004-000-00450-7.)

Notice 3:

The manufacturer is not responsible for any interference caused by unauthorized modification to this equipment.

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Section 1: Introduction

1.1 Introduction to the Sonicator 740

Thank you for purchasing the Sonicator 740 therapeutic ultrasound device from Mettler Electronics Corp. The microprocessor controlled Sonicator 740 provides therapeutic ultrasound with enhanced reliability and ease of use. An optional rechargeable battery is available to free you from depending on wall power. The Sonicator 740 automatically self-tunes to the ultrasound applicator to ensure accurate delivery of ultrasound.

The Sonicator 740 has a standard 5 cm² applicator at 1 and 3.2 MHz. An additional two applicators are included with the 740x. These additional applicators are: 10 cm², 1 MHz and 1 cm², 3.3 MHz. The 5 and 10 cm² applicators are contoured for easy ultrasound application. The pencil-shaped 1 cm² applicator is ideal for delivering ultrasound to hard-to-reach and small treatment areas. All applicators attach to the Sonicator 740 using the same universal applicator cable.

The Sonicator 740 produces ultrasound in continuous and 10, 20 and 50% pulsed modes for maximum treatment flexibility. The back-lit liquid crystal display (LCD) informs the practitioner about treatment status. Time and ultrasound output intensity are actively displayed during a treatment. The “ultrasound active” indicator on the display alerts the operator when ultrasound is being delivered by the applicator. An additional LED on the applicator itself lights when ultrasound is being delivered and flashes when there is a problem with coupling.

Large controls on the silicone rubber keypad provide one touch entry for treatment parameters. An audible tone provides you with further reinforcement that a selection has been made. Error conditions are prominently shown on the display as well as all treatment parameters.



Figure 1.1—Sonicator 740 with all the available applicators

The Sonicator 740 has been certified by Intertek Testing Services to meet the requirements for ETL Listing per the following standards:

- UL 60601-1 Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety Second Edition.
- CAN/CSA C22.2 NO 601.1-M90 - Medical Electrical Equipment - Part 1: General Requirements for Safety General Instruction No 1; Supplement 1; 1994 R(1997)
- IEC60601-2-5 - Safety of Ultrasonic Therapy Equipment

In addition, the Sonicator 740 meets the following standards for radio frequency emissions:

- FCC Part 18
- IEC/EN 60601-1-2

Mettler Electronics Corp. has been certified by VTT Expert Services LTD to be compliant with EN ISO 13485:2003 and MDD 93/42/EEC Annex II requirements. In addition, Mettler is certified by DQS Medizinprodukte GMBH to be compliant with ISO 13485:2003 (CMDCAS) Canadian Medical Device requirements.

1.2 Introduction to This Manual

Read the contents of this manual prior to treating patients with the Sonicator 740.

This manual has been written to assist you with the safe operation of the Sonicator 740. It is intended for use by the owners and operators of the Sonicator 740. The goal of this manual is to direct the correct operation and maintenance of this unit.

The specifications and instructions presented in this manual are in effect at the time of its publication. These instructions may be updated at any time at the discretion of the manufacturer.

1.3 Safety Precautions

The Sonicator 740 operates with high voltages. Servicing of the Sonicator 740 should be performed by qualified biomedical technicians with training in ultrasound service or it should be returned directly to the factory. To maximize safety during use, the unit should be plugged into a grounded wall outlet of proper voltage only unless operating with optional battery power.

To assure compliance with FDA, 21 CFR 1050.10 standards, the Sonicator 740 should be calibrated and safety tested on an annual basis.

This service may also be performed by qualified biomedical engineers or technicians trained in ultrasound calibration.

NOTE: All warranty repairs must be performed by Mettler Electronics Corp. or by a service facility authorized by Mettler Electronics to perform warranty repair work.

1.4 Caution

Federal law restricts the sale of this device to, or on the order of a physician, dentist, veterinarian or any other practitioner licensed by law of the state in which he practices.

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy. Treatment should be administered only under the direct supervision of a health care professional.

1.5 Shipping Damage

Your new Sonicator 740 is shipped complete in one carton. Upon receipt, please inspect the carton and the unit for visible and hidden damage. If any damage is discovered, hold all shipping materials, including the carton, and call the shipping agent who delivered the unit.

The carton in which your new Sonicator 740 was received is specially designed to protect the unit during shipping. Please retain all shipping materials in the event that you will need to return your unit for servicing. NOTE: All repairs must be performed by Mettler Electronics Corp. or by a service facility authorized by Mettler Electronics to perform repair work.

1.6 Package Contents

Your new Sonicator 740 comes complete with all the necessary components to perform therapeutic ultrasound. Below is a list of items that are included in the shipping carton.

1. Sonicator 740
2. A Sonicator 740 ultrasound applicator: 5 cm², 1 and 3.2 MHz (ME 7413); *The Sonicator 740x also includes the following additional applicators: 10 cm², 1 MHz (7410) and 1 cm², 3.3 MHz (7431).*
3. Detachable, hospital grade line cord, (ME 7293)
4. Universal applicator cable, (ME 7391)
5. One trial-size tube of Sonigel
6. Instruction Manual
7. An optional battery (ME 7401) may also be included in this package if ordered at the time of purchase. Additionally, it may be ordered separately at any time.

1.7 Limited Warranty

The Sonicator 740 generating unit is warranted against defects in materials and workmanship for a period of two years from date of purchase. The Sonicator 740 applicators and applicator cable are warranted against defects in materials and workmanship for a period of one year from date of purchase. The battery is warranted against defects in materials and workmanship for a period of 90 days from date of purchase. During the applicable warranty period Mettler Electronics Corp. will, at its discretion, either repair or replace the Product without charge for these types of defects.

For service under this warranty, the Product must be returned by the buyer within the applicable warranty period to Mettler Electronics Corp. **Shipping charges to and from Mettler Electronics Corp. under this warranty must be paid by the buyer. The buyer must also include a copy of the sales receipt or other proof of the date of purchase. If the Product is returned without proof of the date of purchase, it will be serviced as an out-of-warranty product at Mettler Electronics Corp.'s prevailing service rates.**

Alteration, misuse, or neglect of the Product voids this warranty. Except as specifically set forth above, Mettler Electronics Corp. makes no warranties, express or implied, including without limitation any implied warranty of merchantability or fitness for a particular purpose, with respect to the Product. If any implied warranties apply as a matter of law, they are limited in duration to one year.

Mettler Electronics Corp. shall not be liable for any indirect, special, consequential or incidental damages resulting from any defect in or use of the Product.

Any legal action brought by the buyer relating to this warranty must be commenced within one year from the date any claim arises and must be brought only in the state or federal courts located in Orange County, California.

Some states do not allow limitations on how long an implied warranty lasts, or the exclusion or limitation of incidental or consequential damages, so the above limitations or exclusions may not apply to the buyer. This warranty gives the buyer specific legal rights, and the buyer may also have other rights which vary from state to state.

Section 2—Symbol Glossary and List of Abbreviations

2.1 Symbol Glossary



Time symbol



Output symbol

MIN

Minutes

SEC

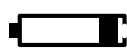
Seconds



Ultrasound active when this symbol is shown on the display. This symbol blinks when coupling is inadequate.



Battery symbol when the Sonicator 740 is running off the battery and the unit is unplugged from the wall. Bars indicate degree of charge. Battery symbol will be absent if the battery is not installed. (1 bar= 0-25%, 2 bars = 26-50%, 3 bars= 51-75% and 4 bars = 76-100%)



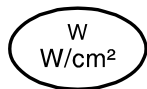
Battery almost empty symbol. The outline of the battery will begin blinking on and off when it is time to recharge the battery.



Sets duty cycle to continuous (100%) or pulsed (10%, 20% or 50%) ultrasound output.

%

Duty cycle for pulsed or continuous ultrasound.



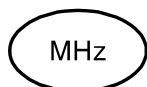
Sets output display to watts or watts per square centimeter.

W

Watts

W/cm²

Watts per square centimeter



Sets output frequency for 5cm² applicator, either 1 or 3 MHz.

MHz

Megahertz






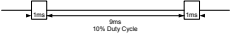


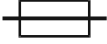










Increases or decreases treatment time.



Increases or decreases ultrasound output intensity or power.



Starts treatment, ultrasound output activated.

	Temporarily stops treatment while maintaining treatment parameters. Ultrasound output stopped.
	Power On
	Power Off
	Symbol for 10% duty cycle on serial number label
	Symbol for 20% duty cycle on serial number label
	Symbol for 50% duty cycle on serial number label
	Fuse symbol
	Alternating current (AC)
	Refer to instruction manual for directions.
	Non-ionizing radiation
	Type B Equipment
IPX0	Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
IPX7	Protected against the effects of immersion, applicator only.
	Recycle the rechargeable lithium ion battery.
	Rechargeable lithium ion battery, dispose of separately from other trash.
	UL Recognized Component Mark
	Tested to comply with FCC standards
	CE mark on battery
	ETL and C-ETL Listed

2.2 List of Abbreviations

BNR	–	Beam Non-uniformity Ratio
cm ²	–	Square centimeters
Coll	–	Collimating
ERA	–	Effective Radiating Area
MHz	–	Megahertz (millions of cycles (10 ⁶) per second)
LCD	–	Liquid Crystal Display
LED	–	Light Emitting Diode
W	–	Watt(s)
W/cm ²	–	Watt(s) per square centimeter

Section 3—Installation

3.1 Installation Instructions

1. If you have chosen the optional battery pack, install the battery as seen in Figures 3.4 and 3.5.
2. To install the optional battery first remove the power cord. Then, remove the screws located on the back panel of the Sonicator 740 on either side of the specification label using a Phillips screw driver, Figure 3.4.
3. Place the battery into the compartment as shown in Figure 3.5. Avoid depressing any of the buttons on the keypad while inserting the battery. Turning the unit on its side while installing the battery will keep the pressure off the buttons. If a button is depressed when the battery is being installed a continuous beep will alert the user of this condition. To stop the alarm, remove the battery and reinstall it.
4. Close the battery compartment lid and reattach it by tightening the Phillips head screws.
5. Connect the line cord to the back of the Sonicator 740. (See Figure 3.1)
6. Plug the line cord into a grounded wall outlet that is rated at 100-240 VAC 50/60 Hz. Your mains power supply must match the voltage requirements listed on the serial number label of your device. **Do not connect the Sonicator 740 to a power supply rated differently than that described above.**

The unit comes equipped with a grounded line cord. This plug provides grounding for the Sonicator 740. Do not defeat its purpose by using adapters or any other means of attaching to a wall outlet.

7. If the optional battery is installed, it will begin charging as soon as the line cord is plugged into the wall and the Sonicator is turned on using the switch on the back of the unit. The charging status will be displayed on the display. Full charging takes up to four hours. The unit may be used while it is charging.
 8. Push the applicator cable connector into the round BNC receptacle located on the bottom of the Sonicator 740 by lining up the slots with the pegs, pushing in all the way and rotating the ring $\frac{1}{4}$ turn clockwise. Connect applicator to universal applicator cable using the same technique. To maintain waterproof characteristics of the BNC connectors make sure that all connections are dry before attempting to connect them, Figure 3.6.
 9. Place the 5 or 10 cm² applicator into its receptacle. Line up the metal disc on the applicator with the floating magnet on wall of the applicator receptacle and secure on the applicator hook, Figure 3.3. A separate receptacle is located on the back of the unit for the 1 cm² applicator. Place it crystal-side-in, into the holder. (Figure 3.1)
 10. Once you have verified proper functioning of your Sonicator 740, using the instructions in Section 4, please register the warranty for your Sonicator 740.
-
10. **Warning:** The Sonicator 740 may be susceptible to interference originating from shortwave diathermy units operating in close proximity to it. Avoid operating the Sonicator 740 adjacent to and simultaneously with operating shortwave devices.
 11. **Warning:** If the integrity of the external protective conductor in the installation or its arrangement is in doubt, the Sonicator 740 should be operated using the battery.
 12. **Do not use sharp objects to operate the silicone rubber keypad controls.** If the tough outer layer of the control is broken, moisture may leak into the unit resulting in switch and main board failure.
 13. The optional battery pack may only be used in the Sonicator 740. Do not attempt to use other batteries than Mettler part number ME7401. Additional precautions for handling the optional battery include:
 - Do not store the Sonicator 740 for long periods with the battery installed.
 - Keep the Sonicator 740 plugged into the mains to assure full battery charge when needed.
 - Do not ship the Sonicator 740 with the battery installed.
 - Avoid shorting the battery
 - Do not immerse in water.

- Do not disassemble or deform the battery
- Do not expose the battery to fire.
- Do not dispose of the battery in fire.
- Avoid excessive physical shock or vibration.
- Keep out of the reach of children.
- Never use a battery that appears to have suffered abuse.
- Lithium ion batteries are recyclable.
- Regulations for disposal vary for different countries. Dispose of in accordance with local regulations.



Figure 3.1 – Back side view of unit – mains power switch, line cord connection, banana jack for combination therapy and 1cm² applicator holder

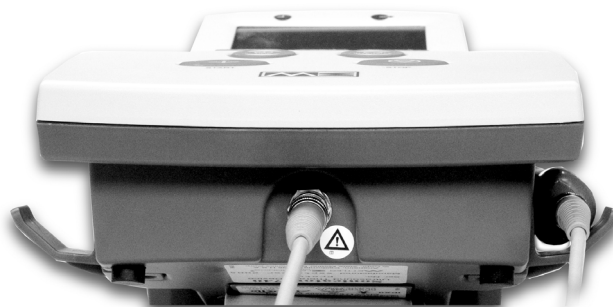


Figure 3.2 – Front side view – Applicator cable connection



Figure 3.3 – Side View – Applicator cradle with floating magnet and hook



Figure 3.4—Bottom view – Battery door



Figure 3.5 – Installing the Battery

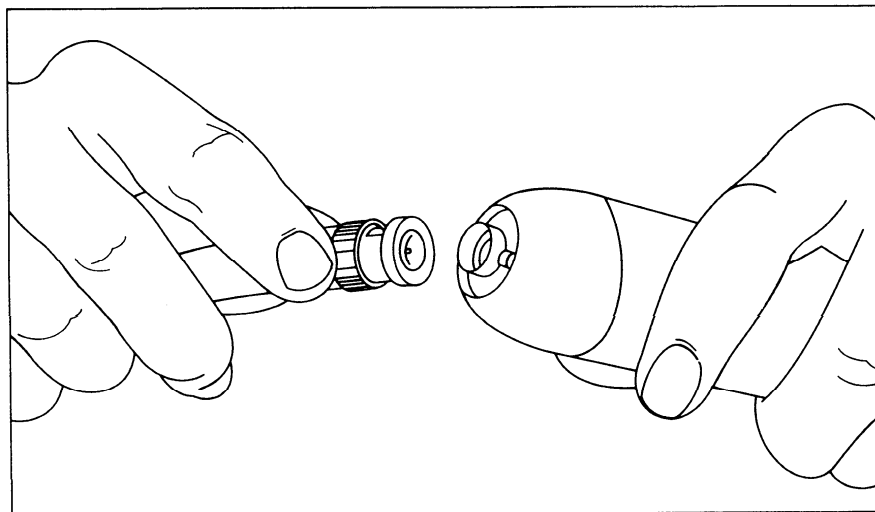


Figure 3.6—Connecting the Applicator to the Universal Applicator Cable, line up pegs, push in all the way and rotate the ring ¼ turn clockwise

3.2 EMC Guidance

CAUTION: Medical Electrical Equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the following tables.

Portable and mobile Radio Frequency (RF) communications equipment can affect Medical Electrical Equipment.

Accessories: Hospital Medical grade power cord of a maximum length of 120 inches or 3 meters

WARNING: The use of accessories, other than those specified, except those supplied or sold by Mettler Electronics Corp., Incorporated as replacement parts for internal or external components, may result in increased EMISSIONS or decreased IMMUNITY of the Sonicator 740.

Guidance and manufacturer's declaration – electromagnetic emissions


The Sonicator 740 is intended for use in the electromagnetic environment specified below. The customer or the user of the Sonicator 740 should assure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The Sonicator 740 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be effected.
RF emissions CISPR 11	Class B	The Sonicator 740 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Applicable	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Sonicator 740 is intended for use in the electromagnetic environment specified below. The customer or the user of the Sonicator 740 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Sonicator 740 requires continued operation during power mains interruptions, it is needed that the Sonicator 740 be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The Sonicator 740 is intended for use in the electromagnetic environment specified below. The customer or the user of the Sonicator 740 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 GHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Sonicator 740, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80\text{MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800\text{MHz to } 2.5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Sonicator 740 is used exceeds the applicable RF compliance level above, the Sonicator 740 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Sonicator 740.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Sonicator 740

The Sonicator 740 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Sonicator 740 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Sonicator 740 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

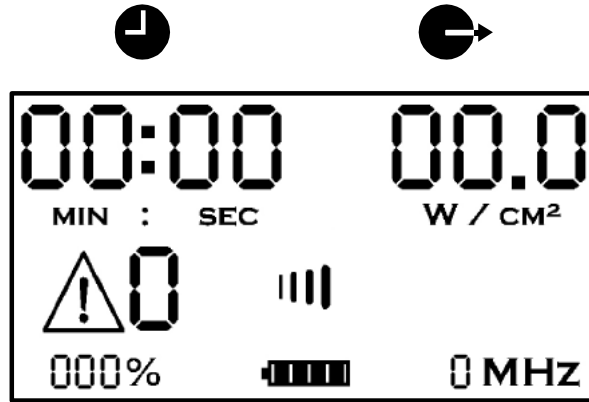
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration

No.	Mode Of Operation	Essential Performance Degradation Allowed
1	Unit tested to 230 VAC for CE Unit tested to 120 VAC for US/Canada	Unit designed to be failure safe in abnormal condition
2	Unit has one ultrasound output channel	Reset allowed as long as failure safe

Section 4—Operating Instructions



Sonicator® 740

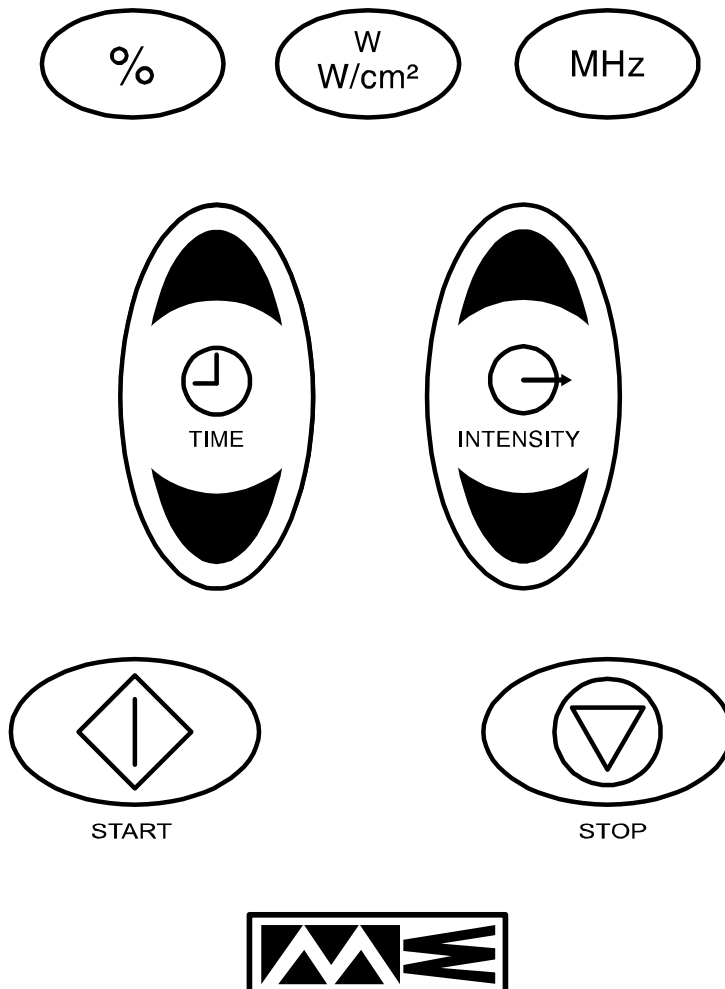
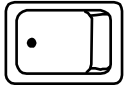


Figure 4.1 – Control panel and display

4.1 General Operating Instructions:

Before you start:

- a) Review precautions and contraindications in Section 5.
- b) Verify connection of the line cord to a grounded wall receptacle and the Sonicator 740 or that the battery is charged.
- c) Check the universal applicator cable connections to the Sonicator 740 and to the applicator of choice to assure secure connection.
- d) Note: Descriptions of the symbols used on controls are in Section 2.



1. Turn on the mains power switch by pressing the dot on the switch.



2. When the battery symbol shows one bar remaining and the battery outline begins to flash, plug in the wall and leave the unit on to recharge the battery. There may not be enough power remaining to complete your treatment. Please note: you can use the Sonicator 740 while it is recharging.



3. Select the desired treatment time by pressing the up arrow on the time control. Only whole minutes can be selected. Treatment times up to 30 minutes may be set. Time is displayed on the LCD. *You can also start a treatment without inputting time. The time will count up and output will stop after 30 minutes.*



4. Select either continuous or pulsed ultrasound by pressing the **%** key. The LED indicator on the key will illuminate when a selection is made.



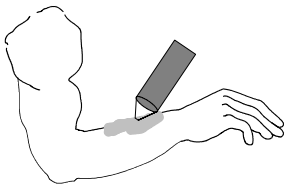
5. Select either watts (W) or watts per square centimeter (W/cm²) using the **W W/cm²** key. The LCD display will show the units of measure that have been selected.



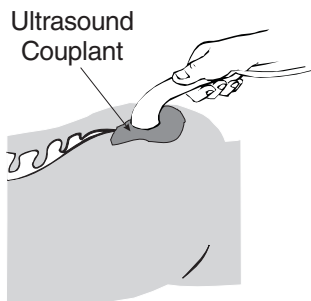
6. Select either 1 or 3 MHz using the **MHz** key when you are using the 5 cm² applicator. The 10 cm² applicator is fixed at 1 MHz and the 1 cm² applicator is fixed at 3 MHz.



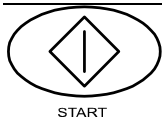
7. Adjust the ultrasound power to the desired intensity using the intensity Up/Down arrows. Pressing the up or down arrow momentarily will increase or decrease the ultrasound power in 0.1 W or W/cm² increments. Holding an arrow down will rapidly raise or lower the ultrasound power. You may also complete this step after you have started the treatment.



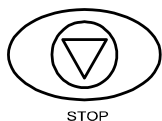
8. Apply a layer of ultrasound couplant gel to the treatment area.



9. Couple the applicator to the treatment area by keeping the entire surface of the applicator in contact with the gel that has been applied to the patient. This will ensure an efficient delivery of therapeutic ultrasound to the patient.



10. Press the start key to begin treatment.



11. If you need to temporarily stop treatment press the stop key pictured on the left. Remaining treatment time and set intensity will be displayed. Ultrasound power will stop and the indicator showing output on the display will go out. To resume treatment press the start key pictured in number 10 above.




12. If the applicator is not in contact with the patient or ultrasound is not being efficiently transmitted to the patient, the ultrasound symbol pictured will blink. The blue LED in the applicator 5 or 10 cm² handle will blink if contact is lost.



13. If inadequate coupling occurs for more than 30 continuous seconds the Sonicator 740 will automatically cease ultrasound output, beep twice and display the symbol to the left.

13. **Notes on coupling:** Failure to efficiently transmit therapeutic dosages of ultrasound to the patient can be caused by the following:

- a) Treatment of an irregular area where it is impossible to keep the applicator surface in contact with the gelled patient area. In this case you can try to use a little more gel or perform underwater treatment, if the treatment area is submersible in water.
- b) An inappropriate couplant is being used. Only materials that efficiently transmit ultrasound should be used for therapeutic ultrasound applications. Some creams and oil-based preparations are not efficient ultrasound couplants. If you use these materials the coupling indicator LED may blink and  may be displayed.
- c) Areas of heavy body hair will trap air beneath the hair and prevent ultrasound transmission. Shaving the treatment area prior to treatment or thoroughly wetting the area prior to the application of couplant will result in more efficient transmission of ultrasound.


14. When the set treatment time has elapsed, the unit beeps. Time will be "0" and ultrasound power display will show the set power. The ultrasound power will turn off.

4.2 Combination Therapy Using the Sonicator 740

Application of simultaneous therapeutic ultrasound and electrical neuromuscular stimulation can be accomplished using the Sonicator 740 with any Sys*Stim® electrical neuromuscular stimulator from Mettler Electronics Corp.

In this technique, the applicator delivers the ultrasonic energy and becomes the active electrode for muscle stimulation. Follow the instructions below to administer combination therapy.

Instructions for Combination Therapy:

Combination therapy may be performed by plugging any Sys*Stim muscle stimulator active lead wire (black) into the banana jack located on the back of the Sonicator 740, (Figure 3.1). Use a pin-to-banana adapter to convert the pin end of lead wire so that it will fit into the banana jack on the unit. The banana jack is identified by the symbol: 


The dispersive lead wire (red) is connected to a dispersive electrode which is applied to the patient to complete the electrical circuit. When the electrical output is generated by the stimulator, it will be passed through the metal ring on the applicator head by means of this connection.

Please review all neuromuscular electrical stimulation precautions and contraindications listed in the Sys*Stim instruction manual before proceeding with combination therapy.

The timer on the Sonicator will control the length of time ultrasound is delivered. The Sys*Stim timer is placed into timer bypass during combination therapy. Press "Start" on the Sonicator 740 and "Start" on the

Sys*Stim muscle stimulator to begin treatment. The intensity of electrical stimulation is adjusted on the muscle stimulator, while ultrasound intensity is adjusted on the ME 740. When the selected time has completed on the Sonicator 740, press “Hold” on the Sys*Stim muscle stimulator before removing the applicator from the patient. This will turn off the stimulation output to the applicator.



Figure 4.2 Combination Therapy Connections – Banana jack is located above the  symbol.

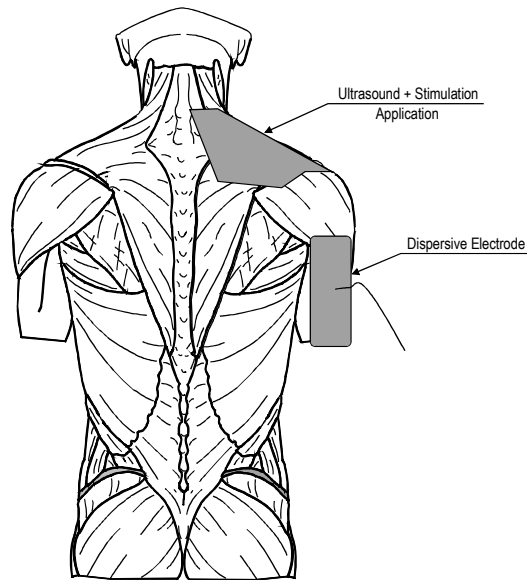


Figure 4.3 – Combination Therapy Example

Section 5—Indications, Contraindications and Precautions

5.1 Indications

Ultrasound delivered to the body using an efficient couplant provides deep heating effects to body tissues. Ultrasound delivered at a frequency of 1 MHz penetrates to a depth of approximately 5 centimeters while ultrasound at a frequency of 3.3 or 3.2 MHz penetrates tissue to a depth of approximately 1–2 cm.

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:

1. Pain relief
2. Reduction of muscle spasm
3. Localized increase in blood flow
4. Increase range of motion of contracted joints using heat and stretch techniques.

5.2 Contraindications

1. Therapeutic ultrasound should not be applied over the pregnant or potentially pregnant uterus. Therefore, therapeutic ultrasound should not be applied over the uterus unless specific assurance can be attained from the patient that she is not pregnant.
2. Patients who have cardiac pacemakers should be protected from direct ultrasound exposure over the thorax to protect the lead wires and pacer from such exposure.
3. Therapeutic ultrasound should not be applied to the eye.
4. Applications of therapeutic intensities of ultrasound should be avoided over the heart.
5. Neoplastic tissues or space occupying lesions should not be exposed to ultrasound.
6. Ultrasound should not be applied to the testes to avoid increases in temperature.
7. Areas of thrombophlebitis should not be treated with therapeutic ultrasound due to the increased possibility of clotting or dislodging a thrombus. Conditions where this might occur are deep vein thrombosis, emboli and severe atherosclerosis.
8. Tissues previously treated by deep x-ray or other radiation should not be exposed to therapeutic ultrasound.
9. Ultrasonic treatment over the stellate ganglion, the spinal cord after laminectomy, subcutaneous major nerves and the cranium should be avoided.
10. Do not treat ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand and tissue necrosis might result.
11. Ultrasound should not be applied over the bone growth centers until bone growth is complete.

5.3 Precautions

1. Ultrasound should not be applied in areas of reduced sensation or circulation or over anesthetic areas. Patients having reduced sensation will not be able to notify the practitioner of discomfort if ultrasound intensities are too high. Patients with compromised circulation may have an excessive heat buildup in the treatment area.
2. Operators should not routinely expose themselves to therapeutic ultrasound. The applicator handles for the Sonicator 740 have been designed to allow the practitioner to perform underwater treatments without exposing the hands to ultrasound.
3. If a patient complains of periosteal pain (deep, achy pain) during ultrasonic treatment, intensity should be reduced to a comfortable level.
4. Any bleeding tendency is increased by heating because of the increase in blood flow and vascularity of the heated tissues. Care, therefore, should be used in treating patients with therapeutic ultrasound who have hemorrhagic diatheses or bleeding disorders.
5. Moving technique of the applicator should be used when applying therapeutic ultrasound at intensities greater than 0.5 W/cm^2 to assure even exposure of tissues to ultrasound.
6. Heating of the joint capsule in acute or subacute arthritis should be avoided.
7. Electric treatment tables or whirlpools which may come in contact with the patient during a treatment with the Sonicator 740 should be adequately grounded and safety tested to insure safe operation with the Sonicator 740.
8. The use of therapeutic levels of ultrasound may delay or prevent callous formation in a healing fracture.

Section 6—Maintenance and Troubleshooting





6.1 Cleaning the Sonicator 740 and its ultrasound applicator

1. The Sonicator 740 can be wiped off with a damp cloth. The power cord should be disconnected from the unit before this is done. In the case of stubborn dirt a gentle household cleaner can be sprayed on the cloth and then wiped on the unit. If this method is used, remove any cleaner residue with a damp cloth. Do not spray cleaner into the vents of the unit.
2. Use soap and water for routine cleaning of the Sonicator 740 applicator. When disinfection is necessary, wipe with a disinfectant such as a 10% bleach solution. Rinse the applicator thoroughly after disinfection to remove any residue. The Sonicator 740 applicator *is neither autoclavable nor gas sterilizable*.

6.2 Routine Maintenance

1. To assure accurate performance of the Sonicator 740, calibration verification of ultrasonic output should be performed on an annual basis.
2. Standard medical electrical safety checks should be performed annually by qualified biomedical engineers or technicians trained to perform these procedures.
3. Inspect treatment head for cracks, since they may allow ingress of conductive fluid(s).
4. Inspect treatment head cables and associated connectors for damage.
5. Avoid rough handling of the treatment applicator, since it is critical to the safe and effective application of therapeutic ultrasound and relatively fragile.

6.3 Troubleshooting the Sonicator 740

Symptom	Action
1. Nothing lights when mains power switch is turned on.	Is the battery installed? If it is, it may require charging. Plug unit into wall outlet and turn on. If unit comes on observe battery icon to see if it charged. If there is no battery installed verify that the line cord is connected to the outlet? Is the line cord securely connected to the Sonicator 740? Is there power to the outlet? Unit may require servicing if none of the above resolves the problem.
2. A continuous beep occurs when the battery is installed.	A button on the keypad has been pressed while the battery was installed. To stop the alarm, remove the battery and reinstall it. Please note: turning the unit on its side while installing the battery will keep the pressure off the buttons.
3.  1	Check applicator cable connections to make sure they are securely attached to the Sonicator 740 and the applicator and the locking rings are turned fully clockwise to lock connectors.
4.  2	There is insufficient ultrasound coupling. Use gel or lotion labeled for therapeutic ultrasound coupling. Resume treatment after applying proper couplant. See number 13 in section 4 of this manual for additional information on efficient coupling of ultrasound to the patient.
5.  3	The Sonicator 740 cannot tune to the applicator transducer. Try a different applicator. Press "Stop" to clear error. If error does not repeat with the new transducer, the old transducer needs servicing. If error repeats with the new transducer, the unit needs servicing.
6.  4	There is a malfunction in the power output circuitry. The Sonicator 740 requires servicing.

7.  **5**

Output power is not within output tolerances. To attempt to clear this error: unplug the unit from the wall outlet, remove the battery, reinstall the battery and plug the unit back in. Turn the unit back on and attempt to restart the unit. If the error is not resolved, the Sonicator 740 requires servicing.

8.  **6**

Battery is over temperature. Unplug the unit from the wall outlet and remove or replace the battery.

Section 7—Theory of Operation

7.1 Introduction to Ultrasound

Ultrasound is a form of acoustical vibration occurring at frequencies too high to be perceived by the human ear. The limit for the audible range is at about 20 kHz. Frequencies above this level are considered ultrasound. The range 700 kHz to 1, 1 MHz appeared during early investigative work to be best suited to clinical applications. Most therapeutic ultrasound devices operate at frequencies within this range. Recent studies have been conducted utilizing a frequency of 3 MHz. Since 3 MHz allows ultrasound transmission only 1/3 the depth of 1 MHz, it has been used for the treatment of more superficial structures.

Figures 7.1, 7.2, 7.3 and 7.4 illustrate the relative depths of penetration of 1 and 3.3 MHz. Since the body is actually composed of a variety of tissues, the depth of penetration will depend on the amount of each tissue in the path of the ultrasound beam. Quite frequently, the presence of bone in the ultrasound beam will be the limiting factor in determining the actual depth to which the ultrasound beam will reach. This is best illustrated in Figure 7.4. In the fingers and toes, ultrasound can pass around the bone to the opposite surface of the digit. In this case, if the intensity is high enough, the patient may report heat or discomfort on the surface opposite the ultrasound application.

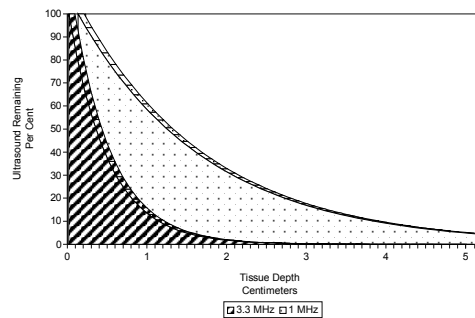


Figure 7.1 – Ultrasound Absorption, Skin



Figure 7.2 – Ultrasound Absorption, Fat

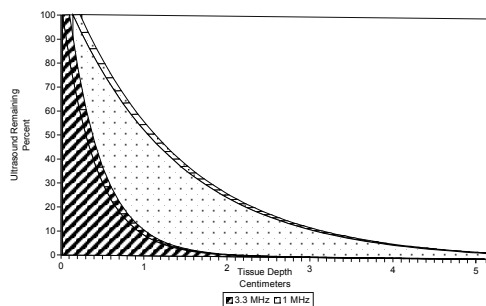


Figure 7.3 – Ultrasound Absorption, Muscle with the Ultrasound Beam Perpendicular to the Muscle Fibers

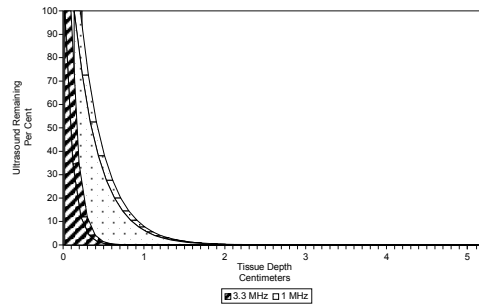
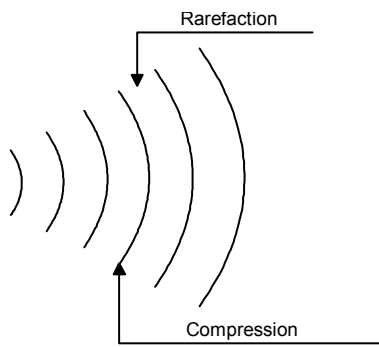


Figure 7.4—Ultrasound Absorption, Bone

The physics of ultrasound and audible sound are similar, except for frequency. Both travel as longitudinal waves through a conducting medium. Ultrasound waves can be propagated in a gaseous, liquid, or solid medium, but not in a vacuum.



High frequency sound waves are formed by areas of compression and rarefaction of the molecules. Ultrasound exhibits certain beaming properties and can be reflected, refracted, scattered or absorbed. In passing through media, it is attenuated and the absorbed energy is transformed into heat. The attenuation coefficient for longitudinal waves in liquid and soft tissues is high, producing the phenomenon at bone surfaces known as selective heating.

Figure 7.5—High Frequency Sound Waves

Clinical ultrasound is produced through the reverse piezoelectric effect. Electricity is carried from a radio frequency source to an electrode in contact with the surface of a specially cut crystal. The electrical charges applied to the crystal surface produce mechanical vibrations, or the so-called reverse piezoelectric effect.

The crystal may be natural or synthetic and may be salt, quartz, polycrystalline or ceramic. When this crystal is in resonance with the driving oscillator, optimum conversion from electrical to mechanical energy is achieved. The Sonicator 740 uses a barium titanate ceramic for all of its transducers.

Ultrasonic power is expressed in watts (W), or watts per square centimeter (W/cm^2). Average intensity (W/cm^2) is obtained by measuring the total output of the applicator (in watts) and then dividing it by the size of the effective radiating area of the applicator. The effective radiating area is different from the overall dimension of the applicator face.

Ultrasound waves need a medium for their transmission and that is accomplished by using a proper coupling agent. This coupling layer between the transducer and body surface will assist in the propagation of the mechanical vibrations and prevent loss of transmission.

Once the coupling agent is applied to the body surface, the applicator placed in contact, and the desired output selected in total watts, or watts per square centimeter, the technique of application is by means of circular or stroking movement. In the circular method, the sound head of the applicator is moved in slow and circular overlapping movements. In the stroking, or "paintbrush" method, slow back and forth strokes are used, again with slight overlapping. Motion with either technique should be slow enough to insure proper energy absorption yet fast enough to eliminate excessive amounts of absorption that could produce periosteal pain. Some references recommend that the treatment area covered by this moving technique be two to three times the effective radiating area of the transducer for every five minutes of exposure.

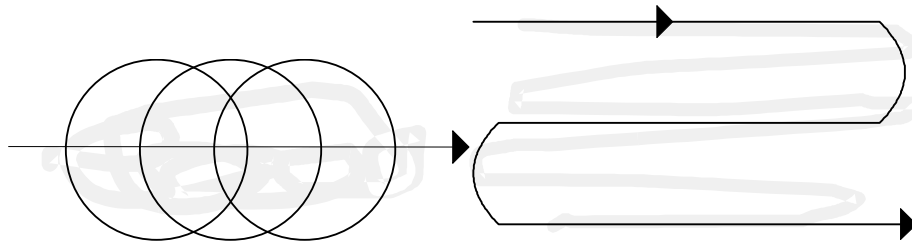


Figure 7.6—Ultrasound Application Techniques

On occasion, irregular surfaces of the body are treated (hands) and may offer a poor surface for proper sound head contact. The underwater technique may be used for these applications. The part to be treated and the sound head are submerged in water and the sound head is moved over the area, keeping the head ½ to 1 inch away from the area of treatment. As air bubbles appear on the surface of the sound head they should be wiped away to insure proper transmission of energy.

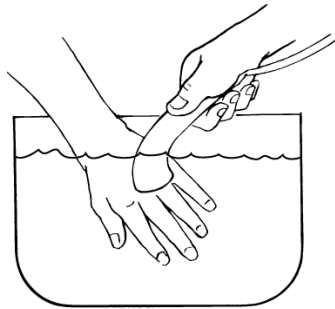


Figure 7.7 Underwater Treatment Technique

7.2 Output Levels

The differences between transducers of varying radiating areas are shown below. The chart is a calculation of power output for these applicator crystals with different radiating areas.

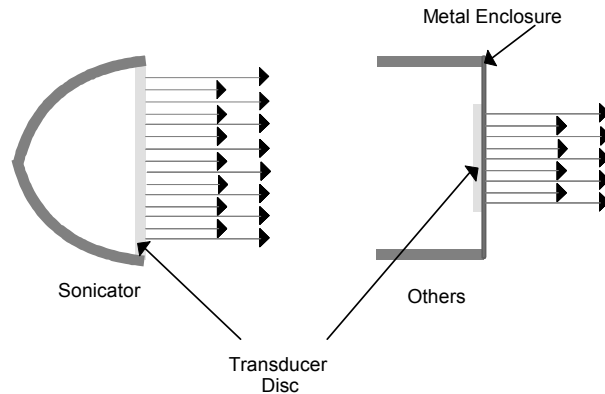


Figure 7.8 Differences Between Transducers

Intensity Setting (W/cm ²)	ERA (cm ²)	Effective Power Produced (W)
1.5	1	1.5
1.5	5	7.5
1.5	10	15.0

You will note, though the intensity setting remained constant, the amount of energy delivered varies appreciably. We caution the user to consider this since units of different manufacture may be available in your facility. If watts per square centimeter is used as the prescribed intensity setting, the effective watts delivered will not remain constant.

By keeping these considerations in mind as well as the size of the area to be treated, selection of the proper sized applicator can be made. In general the larger 10 cm² applicator should be used to treat large areas. Remember to always check the labeling for the effective radiating area of the applicator when selecting treatment intensities. Some applicator treatment surfaces may appear larger than their actual effective radiating area.

7.3 Continuous and Pulsed Waves

Ultrasound may be applied in either continuous or pulsed waveform. Advocates of pulsed beam applications suggest the approach reduces the thermal effects while accenting the mechanical. Wulff in his paper titled "Reduction of Thermic Effect of Ultrasound Dosages by the Use of Pulsed Ultrasound Energy", reported, " the use of pulsed ultrasound energy permits accurately controlled reduction of total ultrasound intensities employed in therapy." He recommended the use of rectangular pulses and stated, "The biologic response reactions of the sonated tissue seem to continue during the sound free intervals provided that a ratio between pulse duration and free interval of 1:4 is maintained." Laboratory research being conducted by Dyson and associates in England seems to indicate beneficial non-thermal effects of ultrasound. However, clinical studies have not been conducted to thoroughly corroborate this evidence.

The Sonicator 740 provides both continuous and pulse wave capabilities. The continuous mode is on more than 95% of the time and has an unmodulated wave. The pulse settings have pulse frequencies of 100 Hz with pulse widths of 1, 2 or 5 milliseconds and 9, 8 or 5 milliseconds between pulses. On time to total time is 1:10, 1:5 or 1:2. The duty cycles are 10%, 20% or 50% and the on time to off time ratio for the 20% duty cycle is 1:4. In the pulse mode, peak power is displayed.

Section 8—References

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 2. Griffen, J.E. and Karselis, T.C.:*Physical Agents for Physical Therapists*, C.C. Thomas, Springfield, IL, 1978, pp. 225- 227.
 3. Jaskoviak, P.A. and Schafer, R.C. *Applied Physiotherapy – Practical Clinical Applications with Emphasis on the Management of Pain and Related Syndromes*, Associated Chiropractic Academic Press (A.C.A.), 1986.
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 9. Reid, D.C. and Cummings, G.C.: "Efficiency of Ultrasound Coupling Agents". *Physiotherapy*, Vol. 63:8, 1977, pp. 255- 257.
 10. Schwann, H.P. and Carstensen, E.L.: "Advantages and Limitations of Ultrasonics in Medicine". *JAMA* 5:52 Vol. 149, 1952, pp. 121-125.
 11. *Wadsworth, H. and Chanmreyam, A.P.P., *Electrophysical Agents in Physical Therapy*. Science Press; Marrickville N.S.W., 1983.
 12. Warron, C.G.; Koblanski, J.N.; and Sigelmann, R.A.: "Ultrasound Coupling Media: Their Relative Transmissivity". *Arch Phys Med Rehab*, Vol. 57, 1976. pp. 218-222.
- * Excellent overviews of therapeutic ultrasound. Extensive bibliographies can provide more in-depth information if needed.

This manual has been written as a guideline for the correct use of the Sonicator 740. Reading the above references will provide a more complete understanding of the correct use of therapeutic ultrasound.

Section 9—Specifications

9.1 General Specifications:

Input:	100–240 VAC, 50/60 Hz, 1.0 amperes maximum
External Fuse:	1.0 A, 250 V, GDC/S506 5 x 20 mm time delay 2 x T1.0 AL250 V
Optional Battery:	Rechargeable Smart Lithium Ion Battery Pack rated at 10.8V and 4.8Ah.
Certification:	The Sonicator 740 complies with the ultrasound performance standards set forth in the Code of Federal Regulations, Title 21 (Food and Drugs), Part 1050.10.
ETL and C-ETL Listed:	Model ME 740 (9801427)
Classification:	Protective Class I Equipment and Internally Powered Equipment Type B Equipment Enclosed equipment without protection against ingress of water. Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with nitrogen oxide.
Treatment timer Indicator:	The digital timer indicates time set in minutes and seconds prior to the start of treatment and treatment time remaining during treatment or when treatment is temporarily suspended. If no treatment time is set the timer will count up to 30 minutes and then treatment will stop.
Accuracy:	±0.5 minute for times less than 5 minutes ±10% for times from 5 to 10 minutes ±1.0 minute for times greater than 10 minutes
Maximum treatment time:	30 minutes
Size:	13.5 in (L) x 9.5 in (W) x 7 in (H)
Weight:	3.75 pounds without battery 4.5 pounds with battery
Temperature:	
Operating:	50°F to 104°F
Non-Operating:	-40°F to 167°F
Humidity:	Operating, 30% to 75% Relative Humidity at 104°F Non-Operating, 5% to 95% Relative Humidity, non-condensing

9.2 Ultrasonic Generator Specifications:

Frequency:	1.0 MHz ±10% 3.2 MHz ±10% 3.3 MHz ±10%
Modes:	Continuous Pulsed 10, 20 and 50% Duty cycle
Pulse repetition rate:	100 Hz ±5% (Pulse Mode)
Pulse duration:	1, 2 or 5 msec ±5%
Temporal peak/average intensity ratio:	10:1, 5:1 and 2:1 ±5%

Maximum output power: 22 W with a 10 cm² applicator, (ME 7410)
 11 W with 5 cm² applicator, (ME 7413)
 2.2 W with a 1 cm² applicator (ME 7431)

Maximum intensity: 2.2 W/cm²

Indication accuracy: ±20% (for any level above 10% of maximum)

Output description: The output waveform is continuous or pulsed as programmed by the membrane panel control. In the pulse mode the 1.0, 3.2 or 3.3 MHz is pulse modulated. The power level is adjusted by varying the pulse amplitude.

The pulse waveform is shown below:

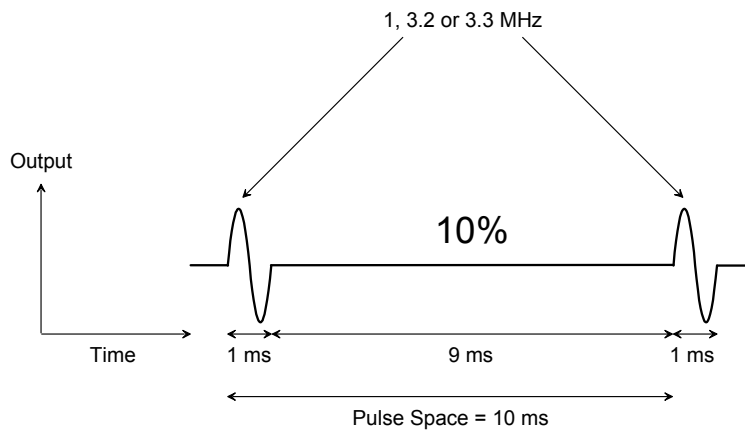


Figure 9.1—10% Pulse Waveform

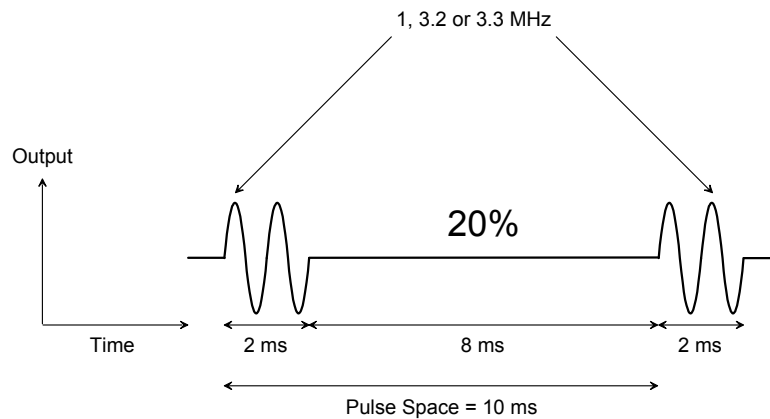


Figure 9.2—20% Pulse Waveform

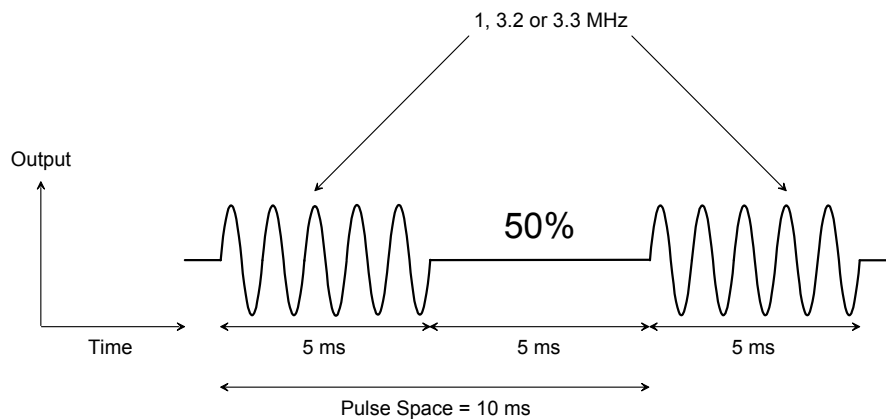


Figure 9.3—50% Pulse Waveform

In the continuous mode, the power is on at least 95% of the time the timer is running. The continuous mode waveform is shown below:

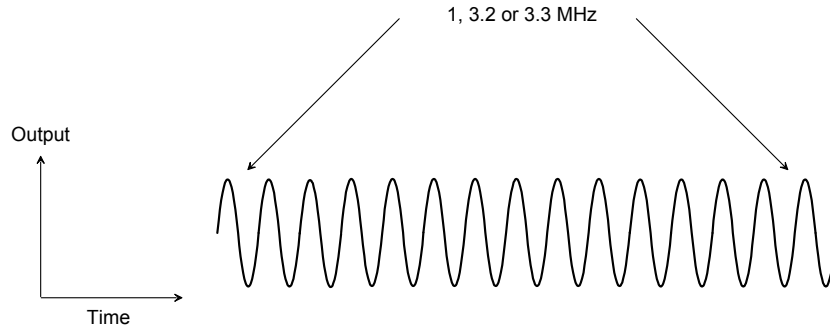


Figure 9.4—Continuous Waveform

9.3 Ultrasonic Applicator Specifications:

Piezoelectric discs: The output transducer utilizes a barium titanate disc with a specially coated face.

Individual Applicator Specification:

Applicator Part Number	Frequency	Effective Radiating Area
ME 7413	1 MHz \pm 10%	5 cm ² \pm 20%
ME 7413	3.2 MHz \pm 10%	5 cm ² \pm 20%
ME 7410	1 MHz \pm 10%	10 cm ² \pm 20%
ME 7431	3.3 MHz \pm 10%	1 cm ² \pm 20%

Beam type: Collimating

Maximum beam non-uniformity ratio: 6:1

Spatial Pattern: The applicator produces a collimated (cylindrical) beam with an area of 1, 5 or 10 cm², measured 5 mm from the ceramic disc surface when the radiation is emitted into the equivalent of an infinite medium of distilled, degassed water at 30° C, and with line voltage variations in the range of the rated value.

The beam of the applicator is circular in all planes parallel to the applicator face. A few inches from the face, it is a single smooth bell-shaped curve. Nearer the face the pattern varies more due to phase cancellations. Sample curves measured in the far field from the surface are shown in Figures 9.5, 9.6, 9.7 and 9.8.

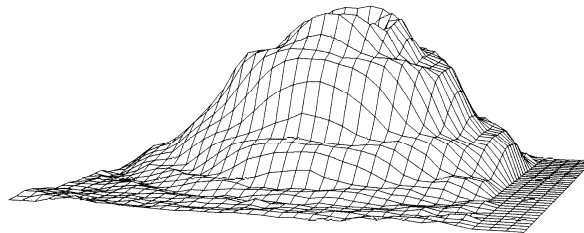


Figure 9.5—10 cm² Applicator (1 MHz), ME 7410,— Three Dimensional Beam Pattern

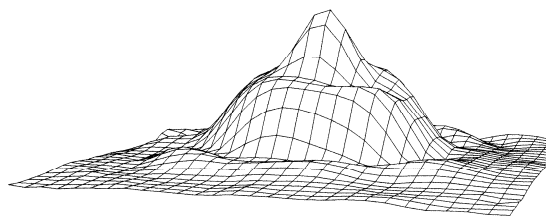


Figure 9.6—5 cm² Applicator (1 MHz), ME 7413,— Three Dimensional Beam Pattern

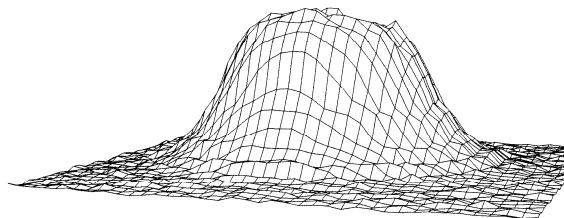


Figure 9.7—5 cm² Applicator (3.2 MHz), ME 7413,— Three Dimensional Beam Pattern

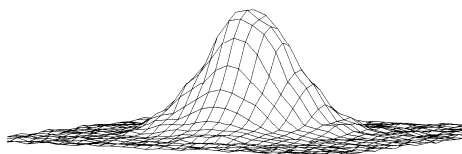


Figure 9.8—1 cm² Applicator (3.3 MHz), ME 7431,— Three Dimensional Beam Pattern

Section 10—Accessories

10.1 Ordering Information:

10.2 Sonicator 740 Accessories

Catalogue #	Item Description
110	Travel bag— Ideal for carrying the Sonicator to the patient. Holds one Sonicator 740 and its accessories
1844	Sonigel— salt free colloidal water couplant, case of 12, 9.5 oz. tubes
1851	Sonigel clear gel couplant, (12 x 250 ml)
1852	Sonigel clear gel couplant, (1 x 5 liters)
1853	Sonigel clear gel couplant, (4 X 5 liters)
1863	Sonigel Lotion with Aloe Vera, 1 gallon with pump and pour off bottle
1864	Sonigel Lotion with Aloe Vera, 4 X 1 gallon individually packaged
7293	Detachable U.L. listed, hospital-grade line cord, <i>domestic</i>
7391	Universal applicator cable
7401	Optional battery pack
7413	Sonicator 740 ultrasound applicator; 5 cm ² , 1 MHz or 3.2 MHz
7410	Sonicator 740 ultrasound applicator; 10 cm ² , 1 MHz
7431	Sonicator 740 ultrasound applicator; 1 cm ² , 3.3 MHz
73	Mobile cart— Can hold any Sonicator therapeutic ultrasound with the Sys*Stim 226, side by side. It has two additional shelves to hold supplies.

