

---

# Sonicator® Plus 994

## Instruction Manual



1333 South Claudina Street • Anaheim, CA 92805, U. S. A.  
Toll Free: (800) 854-9305 • Telephone: (714) 533-2221 • FAX: (714) 635-7539  
Web Site: <http://www.mettlerelectronics.com> • Email: [mail@mettlerelectronics.com](mailto:mail@mettlerelectronics.com)

# 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 Plus 994 with respect to the receiver.
- Move the Sonicator Plus 994 away from the receiver.
- Plug the Sonicator Plus 994 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.

Mettler Electronics Corp.  
1333 S. Claudina St.  
Anaheim, CA 92805  
Toll Free: (800) 854-9305  
Or (714) 533-2221

# Table of Contents

Section	Title	Page
<b>1</b>	<b>Introduction</b>	<b>5</b>
1.1	Introduction to the Sonicator Plus 994	5
1.2	Introduction to this Manual	6
1.3	Safety Precautions	6
1.4	Caution	7
1.5	Shipping Damage	7
1.6	Package Contents	7
1.7	Limited Warranty	8
<b>2</b>	<b>Symbol Glossary and List of Abbreviations</b>	<b>9</b>
2.1	Symbol Glossary	9
2.2	Treatment Status Indicator Icons	12
2.3	List of Abbreviations	13
<b>3</b>	<b>Installation</b>	<b>15</b>
3.1	Installation Instructions	15
3.2	EMC Guidance	17
<b>4</b>	<b>Operating Instructions</b>	<b>21</b>
4.1	A Note About Electrodes	21
4.2	General Operating Instructions	22
4.3	General Set-up Procedure	23
4.4	Stimulation Set-up Procedure	24
4.5	Ultrasound Set-up Procedure	28
4.6	Combination Therapy Set-up Procedure	30
4.7	Electrode Positioning	33
<b>5</b>	<b>Indications, Contraindications, Precautions and Adverse Reactions</b>	<b>37</b>
5.1	Indications for Therapeutic Ultrasound	37
5.2	Indications for Neuromuscular Electrical Stimulation	37
5.3	Contraindications for Therapeutic Ultrasound	38
5.4	Contraindications for Neuromuscular Electrical Stimulation	38
5.5	Warnings for Neuromuscular Electrical Stimulation	39
5.6	Precautions for Therapeutic Ultrasound	39
5.7	Precautions for Neuromuscular Electrical Stimulation	40
5.8	Side Effects/ Adverse Reactions for Neuromuscular Electrical Stimulation	41
<b>6</b>	<b>Maintenance and Troubleshooting</b>	<b>43</b>
6.1	Cleaning the Sonicator Plus 994	43
6.2	Routine Maintenance	43
6.3	Troubleshooting the Sonicator Plus 994	43
<b>7</b>	<b>Ultrasound Theory of Operation</b>	<b>47</b>
7.1	Introduction to Ultrasound	47
7.2	Output Levels	50
7.3	Continuous and Pulsed Waves	51
<b>8</b>	<b>References</b>	<b>53</b>
<b>9</b>	<b>Specifications</b>	<b>55</b>
9.1	General Specifications	55
9.2	Ultrasonic Generator Specifications	55
9.3	Ultrasonic Applicator Specifications	57
9.4	Waveform Specifications	58

9.5	Amplitude Modulation Specifications	62
<b>10</b>	<b>Accessories</b>	<b>63</b>
10.1	Ordering Information	63
10.2	Sonicator Plus 994 Accessories	63

# List of Figures

No.	Title	Page
1.1	Sonicator Plus 994	5
3.1	Sonicator Plus 994, Back view – Mains Power Switch, Line Cord connection and Applicator Clamp	16
3.2	Sonicator Plus 994, Front View – Electrode Cable and Ultrasound Applicator Connections	16
3.3	Connecting the Applicator to the Universal Applicator Cable	16
4.1	Front membrane panel and LED indicators	21
4.2	Electrode Sizes and Current Density	22
4.3	Quadpolar Electrode Placement Technique	33
4.4	Bipolar Electrode Placement Technique	34
4.5	Monopolar Electrode Placement Technique	34
4.6	Using the Pencil Electrode	35
7.1	Ultrasound Absorption, Skin	47
7.2	Ultrasound Absorption, Fat	48
7.3	Ultrasound Absorption, Muscle with the Ultrasound Beam Perpendicular to the Muscle Fibers	48
7.4	Ultrasound Absorption, Bone	48
7.5	High Frequency Sound Waves	49
7.6	Ultrasound Application Techniques	50
7.7	Underwater Treatment Technique	50
7.8	Differences Between Transducers	50
9.1	Pulse Waveform – 20% Duty Cycle	56
9.2	Pulse Waveform – 50% Duty Cycle	56
9.3	Continuous Waveform – 100% Duty Cycle	56
9.4	10 cm <sup>2</sup> Applicator (1 MHz) – Three Dimensional Beam Patterns	57
9.5	5 cm <sup>2</sup> Applicator (1 MHz) – Three Dimensional Beam Patterns	57
9.6	5 cm <sup>2</sup> Applicator (3.2 MHz) – Three Dimensional Beam Patterns	58
9.7	1 cm <sup>2</sup> Applicator (3.3 MHz) – Three Dimensional Beam Patterns	58
9.8	Interferential Waveform	58
9.9	Premodulated Waveform	59
9.10	Medium Frequency ( <i>Russian</i> ) Waveform	59
9.11	Biphasic Waveform	60
9.12	High Volt Waveform	60
9.13	Microcurrent Waveform	61

# Section 1: Introduction

## 1.1 Introduction to the Sonicator Plus 994

Thank you for purchasing the Sonicator Plus 994 four-channel combination unit for therapeutic ultrasound and muscle stimulation. The microprocessor controlled Sonicator Plus 994 provides interferential, premodulated, medium frequency, symmetrical biphasic, high volt and microcurrent waveforms with enhanced reliability and ease of use. In addition the Sonicator Plus 994 offers 1 and 3 MHz ultrasound using a variety of interchangeable applicators.

The four-channel Sonicator Plus 994 allows you to utilize up to four different waveforms using four channels simultaneously. You can choose between several different amplitude modulation options such as surge, reciprocation and vector rotation. The interferential and premodulated modes offer frequency modulation as well as a static frequency option.



Figure 1.1 — Sonicator Plus 994

The membrane panel provides both tactile and audio feedback when buttons are pressed. Blinking LED's guide you through the easy setup routine. The new Treatment Status Indicator shows you which stimulation waveform has been chosen for treatment. The status display moves when treatment output is active.

Large, soft-touch control knobs make adjusting power for ultrasound and stimulation easy to accomplish with no guesswork involved. Two LED output displays allow you to monitor two channels simultaneously for two channel or combination treatment protocols. These also allow you to adjust both channels of an interferential protocol simultaneously while monitoring the current.

The Sonicator Plus 994 can provide electrical stimulation only, ultrasound only and combination therapy with the premodulated, biphasic, high volt and medium frequency waveforms. Add the optional treatment cart to create a mobile treatment center for your office.

The Sonicator Plus 994 has been certified by Intertek Testing Services to meet the requirements for ETL Listing per the following standards:

- UL 2601-1-UL Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety Second Edition.
- CSA C22.2 NO 601.1 – 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
- IEC60601-2-10 – Safety of Nerve and Muscle Stimulators

In addition, the Sonicator Plus 994 meets the following standards for radio frequency emissions:

- FCC Part 15-B
- EN-55011 (CISPR-11)

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 before treating patients with the Sonicator Plus 994.

This manual has been written to assist you with the safe operation of the Sonicator Plus 994. It is intended for use by the owners and operators of the Sonicator Plus 994. 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 Plus 994 operates with high voltages. Qualified biomedical technicians with training in ultrasound and neuromuscular stimulator service should perform servicing of the Sonicator Plus 994 or it should be returned directly to the factory. To maximize safety during use, the unit should be plugged into a grounded wall outlet. General safety guidelines for medical electronic equipment should be followed.

To assure compliance with FDA, 21 CFR 1050.10 standards, the ultrasound portion of the Sonicator Plus 994 should be calibrated and safety tested on an annual basis. This service may be obtained from the manufacturer by sending the Sonicator Plus 994 in its original shipping container to Mettler Electronics Corp., 1333 South Claudina Street, Anaheim, CA 92805, ATTN: Service Department. (Telephone toll free: (800) 854-9305, *Alternate telephone number: 1 (714) 533-2221* or by Email: *service@mettlerelectronics.com*) 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.

A service manual for the Sonicator Plus 994 is available from Mettler Electronics Corp. for a small fee. To receive additional information, contact Customer Service using the above numbers or by Email: *mail@mettlerelectronics.com*.

## 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. The electric energy delivered by this device may possibly be lethal. Treatment should be administered only under the direct supervision of a health care professional.

## 1.5 Shipping Damage

Your new Sonicator Plus 994 is shipped complete in one carton. Upon receipt, please inspect the carton and the unit for visible and hidden damage. If you discover any damage, hold all shipping materials, including the carton, and call the shipping agent who delivered the unit. They are responsible for all damage in transit; therefore, all claims should be filed directly with them. The factory will not be responsible for any damage in shipment, nor allow any adjustments unless a proper formal claim has been filed by the receiver against the carrier.

The carton in which your new Sonicator Plus 994 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 warranty repairs are to be performed by Mettler Electronics Corp. or an authorized Mettler Electronics warranty repair center.

## 1.6 Package Contents

Your new Sonicator Plus 994 comes complete with all the necessary components to perform therapeutic ultrasound, neuromuscular electrical stimulation and combination therapy. Below is a list of items that are included in the shipping carton.

1. Sonicator Plus 994
2. Ultrasound applicator, 5 cm<sup>2</sup> at 1 and 3 MHz, (ME 7513), *other applicators available*
3. Hooded, water-proof universal applicator cable, (ME 7392)
4. Sonigel, ultrasound couplant gel, one tube, (ME 1846)
5. Four electrode cable sets, (ME 2260)
6. One single wire electrode cable for combination therapy (ME 2261)
7. Two gray pin to banana adapters, (ME 2027)
8. One package each EZ Trodes, 2" diameter (ME 2221) and 2.75" diameter (ME 2222)
9. One 3.5" x 7" sponge electrode for combination therapy (ME 2004)
10. Detachable U.L. listed, hospital-grade line cord, (ME 7293)
11. Instruction Manual and warranty registration instructions

## 1.7 Limited Warranty

The Sonicator Plus 994 combination unit for neuromuscular electrical stimulation and therapeutic ultrasound is warranted against defects in materials and workmanship for a period of two years from date of purchase. . The Sonicator Plus 994 applicators are warranted against defects in materials and workmanship for a period of one year 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 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.**

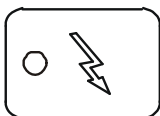
Any legal action brought by the buyer relating to this warranty must be commenced within one year from the date any claim arises and must be brought only in the state or federal courts located in Orange County, California.

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.

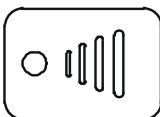


# Section 2—Symbol Glossary and List of Abbreviations

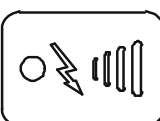
## 2.1 Symbol Glossary



Electrical Stimulation Selector



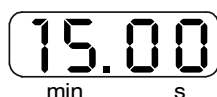
Therapeutic Ultrasound Selector



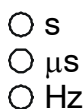
Combination Therapy Selector



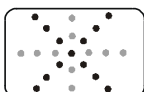
Time display



Time display LED's. Displays treatment time and numeric values for frequency, phase duration, on/off times and alphanumeric error codes.



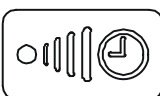
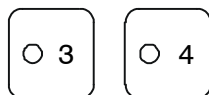
These LED's will illuminate to prompt the clinician to input either time in seconds or microseconds or frequency in Hz. The time or the frequency will be displayed in the numeric time display.



Treatment Status Indicator



Channel display indicator and selector



Ultrasound display indicator and selector



Numeric keypad for time, frequency or phase duration entry.



Starts treatment and stimulation or ultrasound output.



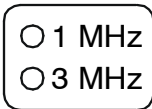
Stops treatment for the treatment displayed in timer window or acts as an "Enter" button during treatment setup.



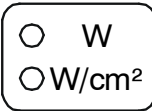
Stops all ultrasound and stimulation output.



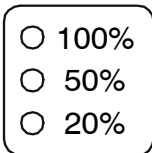
Active ultrasound output indicator on solid when ultrasound output is present, flashing when coupling is inadequate.



Frequency selector for 5 cm<sup>2</sup> 1 and 3 MHz applicator. Displays frequency for all applicators.



Ultrasound output display selector



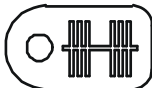
Ultrasound duty cycle selector



Interferential waveform selector — LED is illuminated when this function is activated.



Premodulated waveform selector — LED is illuminated when this function is activated.



Medium frequency waveform selector — LED is illuminated when this function is activated.



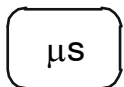
Symmetrical biphasic waveform selector — LED is illuminated when this function is activated.



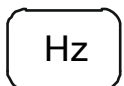
High volt waveform selector — LED is illuminated when this function is activated.



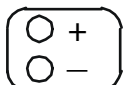
Microcurrent waveform selector — LED is illuminated when this function is activated.



Phase duration control selector — Press this button during a biphasic treatment to display phase duration.



Frequency control selector — Press this button during a stimulation treatment to display frequency.



Polarity selector for high volt and microcurrent waveforms.



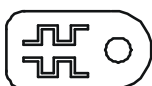
Amplitude modulation (*Vector rotation*), used for interferential waveform only. LED is illuminated when this function is activated.



Continuous stimulation selector



Surge selector to set on and off times



Reciprocation selector, use for channel pairs 1 & 2 or 3 & 4.



Stimulation or ultrasound output displays



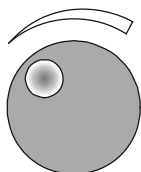
LED's that display the output intensity during a treatment. When the unit is in the "Hold" mode for electrical stimulation, "--- ---" will be displayed. When the unit is in the "Hold" mode for therapeutic ultrasound, the output intensity will be displayed but the "Active Ultrasound Output" indicator will be off and the timer will not be running.



LED indicators are lit to define which output intensity is being displayed in the two windows.



LED indicators are lit to show the measurement units of the output intensity being displayed in the window.



Output intensity control knob, rotate knob clockwise to increase output and counterclockwise to decrease output.



Mains On.



Mains Off.



Attention, consult instruction manual.

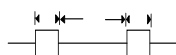


Diagram of Pulsed Mode duty cycle



Type BF Equipment – Class I

IPX0

Not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

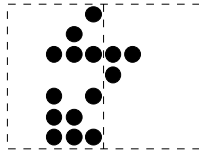
IPX7

Protected against the effects of immersion.

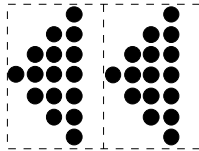


ETL and C-ETL Listed (new logo)

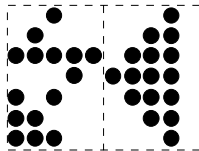
## 2.2 Treatment Status Indicator Icons



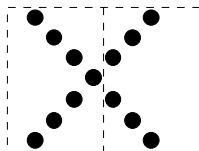
Stimulation selected, waiting for waveform type to be selected.



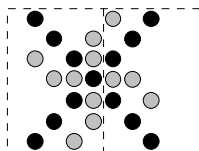
Ultrasound selected



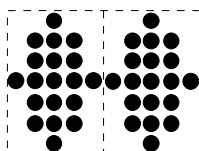
Combination therapy selected, waiting for waveform type to be selected.



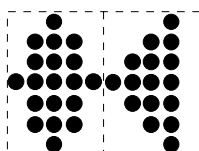
Interferential waveform selected. Display will move to the right when the outputs are active.



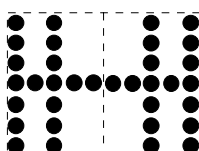
Interferential vector rotation control selected. Display appears to rotate.



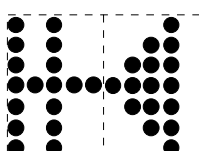
Premodulated waveform selected. Display will move to the right when the outputs are active.



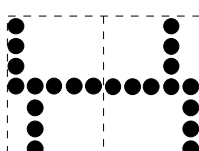
Premodulated waveform selected for combination therapy. Display will move to the right when the outputs are active.



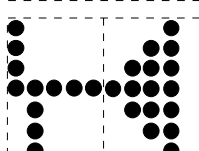
Medium frequency (*Russian*) waveform selected. Display will move to the right when the outputs are active.



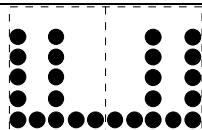
Medium frequency (*Russian*) waveform selected for combination therapy. Display will move to the right when the outputs are active.



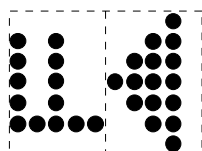
Biphasic waveform selected. Display will move to the right when the outputs are active.



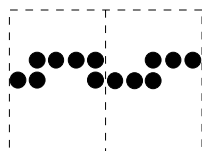
Biphasic waveform selected for combination therapy. Display will move to the right when the outputs are active.



High volt waveform selected. Display will move to the right when the outputs are active.



High volt waveform selected for combination therapy. Display will move to the right when the outputs are active.



Microcurrent waveform selected. Display will move to the right when the outputs are active.

## 2.3 List of Abbreviations

cm <sup>2</sup>	—	Square centimeters
Hz	—	Hertz (pulses per second)
LED	—	Light Emitting Diode
MHz	—	Megahertz (1 × 10 <sup>6</sup> cycles per second)
μA	—	Microampere (1 × 10 <sup>-6</sup> ampere)
μs	—	Microsecond (1 × 10 <sup>-6</sup> second)
mA	—	Milliampere (1 × 10 <sup>-3</sup> ampere)
ms	—	Millisecond (1 × 10 <sup>-3</sup> second)
min	—	Minutes
s	—	Seconds
S/N	—	Serial Number
V	—	Volts
W	—	Watts
W/cm <sup>2</sup>	—	Watts per square centimeter



# Section 3—Installation

## 3.1 Installation Instructions

1. Connect the line cord to the back of the Sonicator Plus 994. (See Figure 3.1)
2. Plug the line cord (ME 7293) into a grounded wall outlet that is rated between 90–240 VAC, 50–60 Hz. Your power supply must match the voltage requirements listed on the serial number label of your device. **Do not connect the Sonicator Plus 994 to a power supply rated differently than that described above.**
3. The line cord comes equipped with a standard 3-prong plug. This plug provides grounding for the Sonicator Plus 994. Do not defeat its purpose by using 3-to-2 prong adapters or any other means of attaching to a wall outlet.
4. Push the hooded, water-proof applicator cable connector (ME 7392) into the round BNC receptacle located on the front of the Sonicator Plus 994. (See Figure 3.2) Connect applicator to universal applicator cable using the BNC connector. (See Figure 3.3) Secure both connectors by rotating them  $\frac{1}{4}$  turn clockwise. To maintain waterproof characteristics of the BNC connectors make sure that all connections are dry before attempting to connect them. ***Please Note:** The applicator model 7513, comes standard with the Sonicator 994. Other applicators that may be used with the Sonicator Plus 994 are the models 7331 and 7310. Verify that the applicator is labeled for use with the Sonicator Plus 994 before attaching it to the unit. This information is contained on the applicator label.*
5. Place the applicator into the applicator clamp. It may be attached to the back as seen in Figure 3.1 or to the side as seen in Figure 1.1.
6. Plug the electrode cables (ME 2260) into the electrode cable connections as seen in Figure 3.2. For combination therapy procedures, plug the single line electrode cable (ME 2261) into the electrode connection for Channel 1.
7. The Sonicator Plus 994 may be susceptible to interference originating from shortwave diathermy units operating in close proximity to it. Avoid operating the Sonicator Plus 994 adjacent to and simultaneously with operating shortwave devices.
8. **Do not use sharp objects to operate the membrane panel switches.** If the tough outer layer of the membrane is broken, moisture may leak into the switches resulting in switch failure.
9. Once you have verified proper functioning of your Sonicator Plus 994, using the instructions in Section 4, please go online to register it at <http://www.mettlerelectronics.com/product-registration/...>

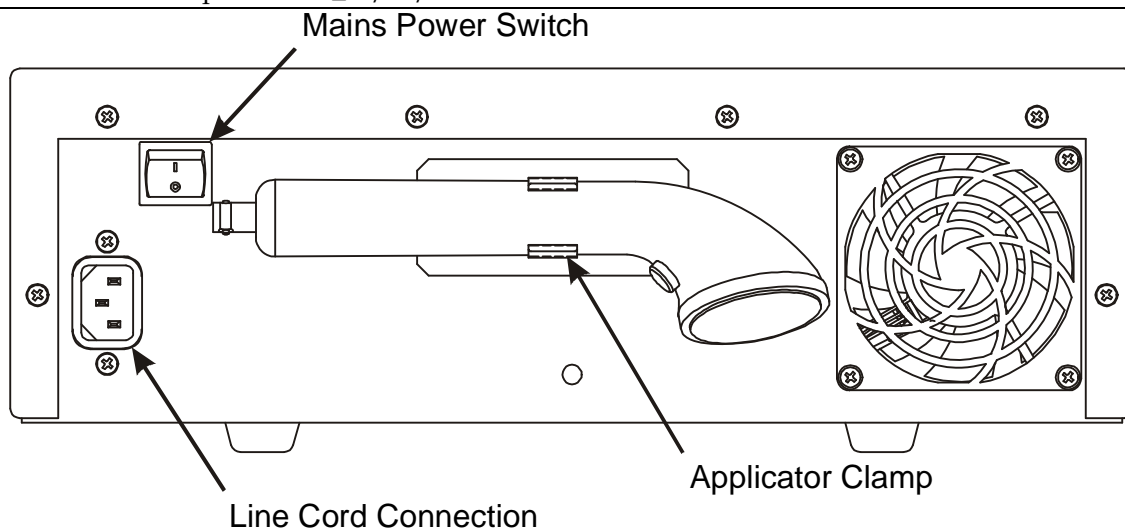


Figure 3.1 – Sonicator Plus 994, Back View –  
Mains Power Switch, Line Cord Connection and Applicator Clamp

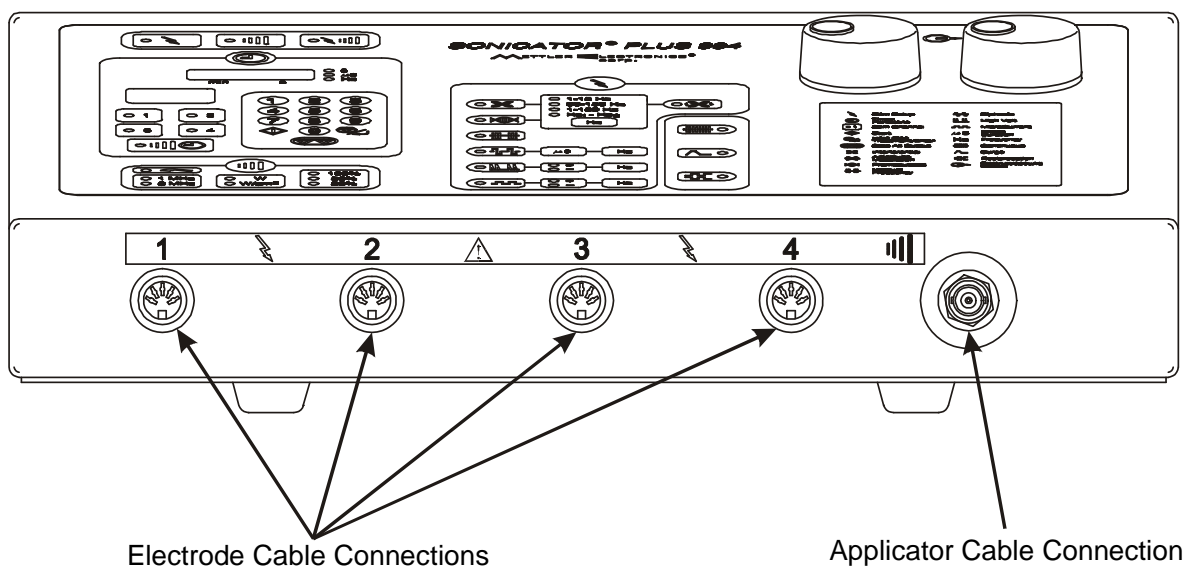


Figure 3.2 – Sonicator Plus 994, Front View –  
Electrode Cable and Ultrasound Applicator Connections

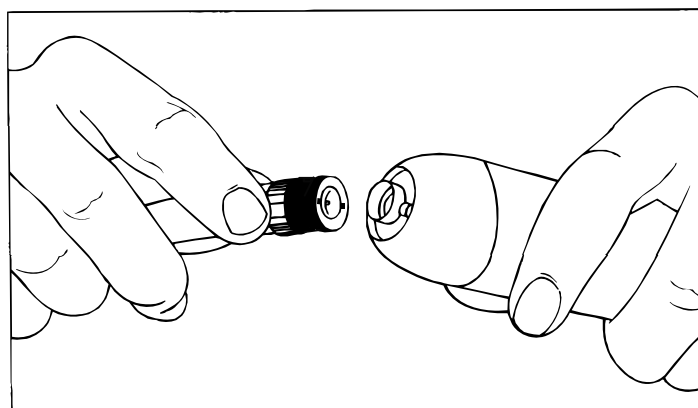


Figure 3.3 – Connecting the Applicator to the Universal Applicator Cable, *line up pegs, push in all the way and rotate 1/4 turn clockwise*



## 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

**WARNING:** The use of accessories, other than those specified, except those supplied or sold by Mettler Electronics Corp., as replacement parts for internal or external components, may result in increased EMISSIONS or decreased IMMUNITY of the Sonicator Plus 994.

<b>Guidance and manufacturer's declaration – electromagnetic emissions</b>		
The Sonicator Plus 994 is intended for use in the electromagnetic environment specified below. The customer or the user of the Sonicator Plus 994 should assure it is used in such an environment.		
<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic environment-guidance</b>
RF emissions CISPR 11	Group 1	The Sonicator Plus 994 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be effected.  The Sonicator Plus 994 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.
RF emissions CISPR 11	Class B	
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 Plus 994 is intended for use in the electromagnetic environment specified below. The customer or the user of the Sonicator Plus 994 should assure that it is used in such an environment.

<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment – guidance</b>
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 Plus 994 requires continued operation during power mains interruptions, it is needed that the Sonicator Plus 994 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 Plus 994 is intended for use in the electromagnetic environment specified below. The customer or the user of the Sonicator Plus 994 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	3 V <sub>rms</sub> 150 kHz to 80 GHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Sonicator Plus 994, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  Recommended separation distance $d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,2\sqrt{P}$ 80MHz to 800 MHz $d = 2,3\sqrt{P}$ 800MHz to 2,5 GHz  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).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>  Interference may occur in the vicinity of equipment marked with the following symbol:  

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.

<sup>a</sup> 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 Plus 994 is used exceeds the applicable RF compliance level above, the Sonicator Plus 994 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Sonicator Plus 994.

<sup>b</sup> 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 Plus 994

The Sonicator Plus 994 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Sonicator Plus 994 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Sonicator Plus 994 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 four stim channels with ultrasound	Reset allowed as long as failure safe

# Section 4—Operating Instructions

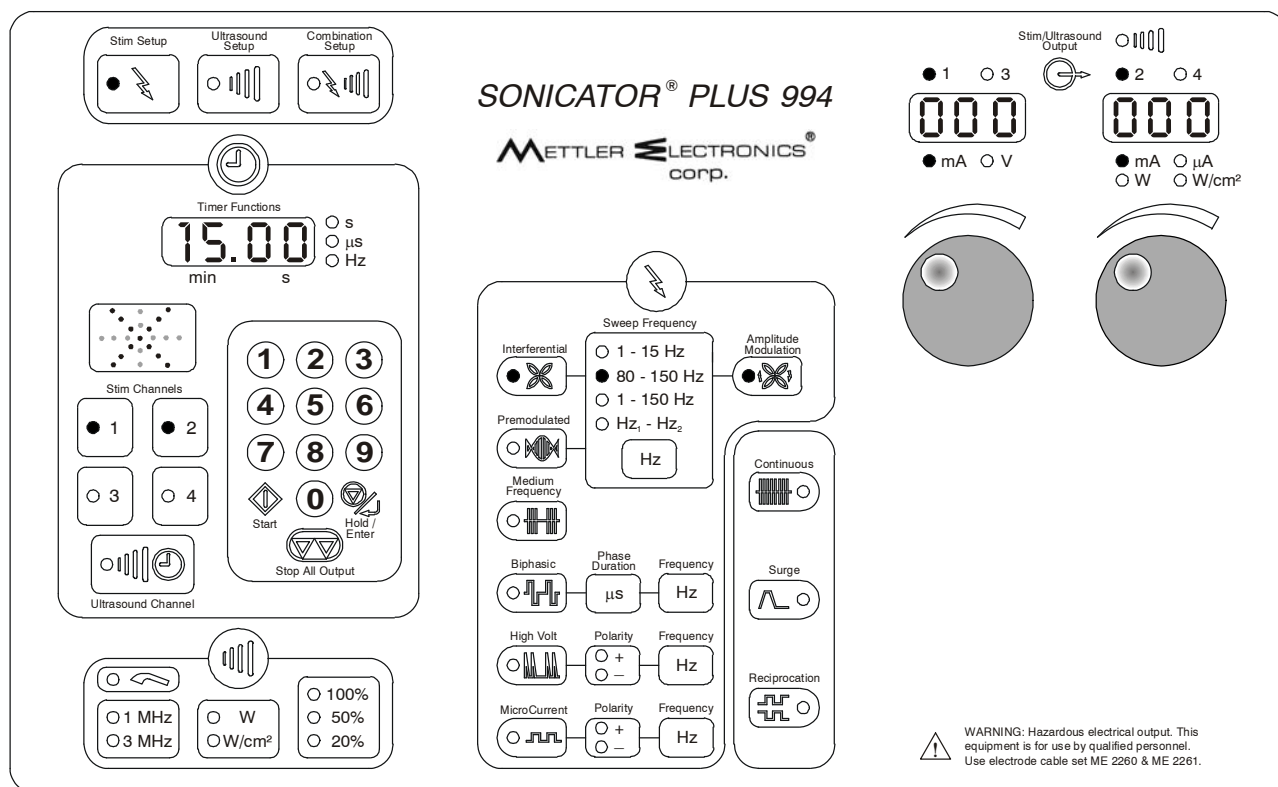


Figure 4.1 – Front membrane panel and LED indicators

## 4.1 A Note About Electrodes

To ensure safe operation of the Sonicator Plus 994 it is recommended that you use Mettler EZ Trode® or V Trode™ self-adhesive electrodes and follow the recommendations listed below:

1. We strongly encourage careful maintenance of the electrode system. This includes the lead wires as well as the pads themselves. Worn cables and/or poor pads (or the wrong sized pads) can have a significant impact upon treatment results.
2. Do not exceed the number of recommended uses listed on the instructions for EZ Trodes or other reusable self-adhesive electrodes.
3. Make sure that the entire surface of the electrode is contacting the patient.
4. Do not use moist hot packs to secure electrodes.
5. To avoid skin irritation due to high current density, do not use electrodes smaller in surface area than the 2" in diameter EZ Trode® self-adhesive electrode (ME 2221).
6. Do not use conductive carbon electrodes with this product.
7. Whenever clinically possible, utilize the largest possible pads to reduce local increases in current density. In situations where small pads are required, use the lowest stimulation intensity necessary to achieve the desired clinical results.

The table below illustrates the relationship between electrode diameter and current density. As you can see the current density increases rapidly when diameter decreases.

Diameter <i>inches</i>	Surface Area <i>Square inches</i>	Current Density <i>mA/sq in (for 10mA)</i>
1.25	1.2	8.2
2.00	3.1	3.2
3.00	7.1	1.4

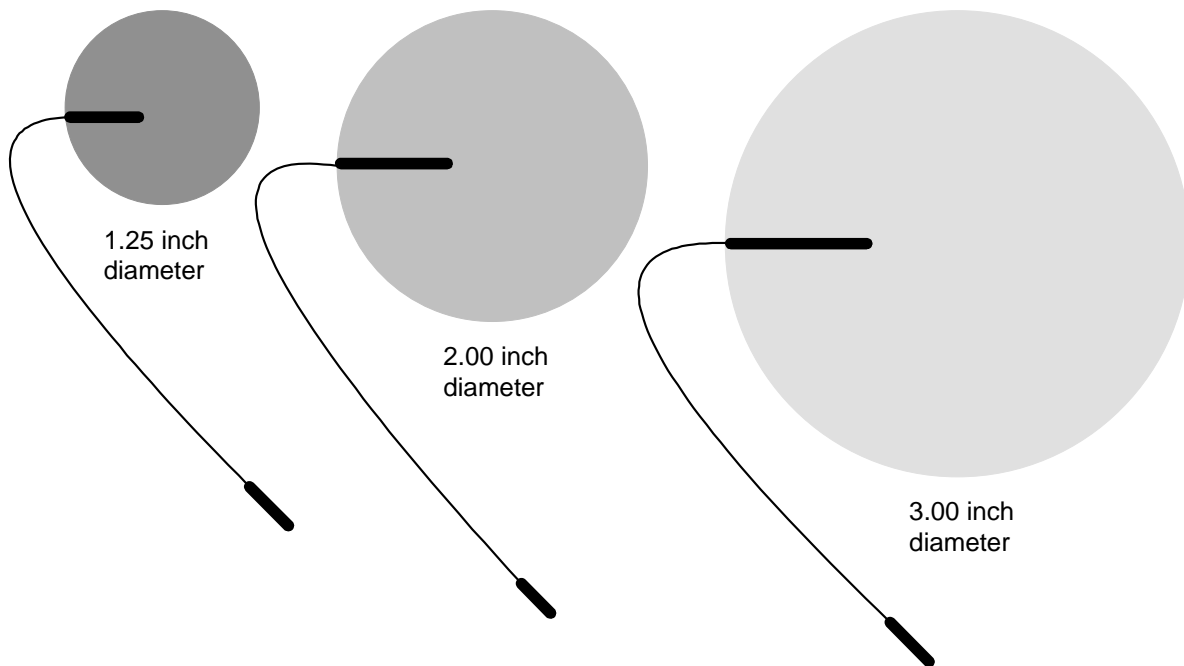


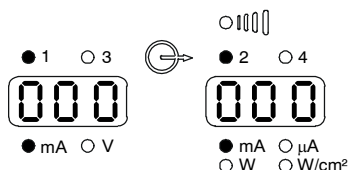
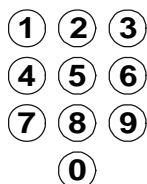
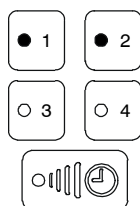
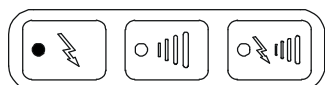
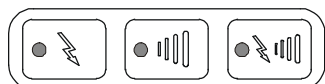
Figure 4.2 – Electrode Sizes and Current Density

## 4.2 General Operating Instructions:

Before you start.

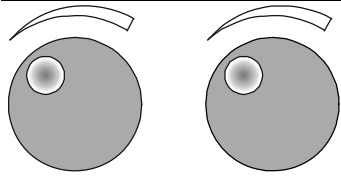
- Review precautions, contraindications and side effects/adverse reactions listed in Section 5.
- Use Mettler Electronics electrodes to ensure safe and effective operation.
- Verify connection of the line cord to a grounded wall receptacle and the Sonicator Plus 994.
- For ultrasound and combination therapy make sure that the applicator is securely connected to the applicator cable and the applicator cable is connected to the Sonicator Plus 994.
- For combination therapy make sure the single line electrode cable (ME 2261) is attached to electrode cable connection for Channel 1 as seen in Figure 3.2. For electrical stimulation connect electrode cables (ME 2260) into the electrode connections for the channels that are going to be used.
- Note: Descriptions of the symbols used on controls are in Section 2.

## 4.3 General Set-up Procedure



1. Turn on the mains power switch by pressing “I” icon on switch.
2. When you first turn the Sonicator Plus 994 on, the LED’s for treatment selectors will flash.
3. Select the treatment you wish to perform: Electrical Stimulation, Ultrasound or Combination Therapy. *You will always start here to begin a new treatment or to start additional treatments.*
4. The green LED indicators will illuminate for the channel(s) or ultrasound treatments that will be active for this session. If you want to run two channels for premodulated, medium frequency or biphasic waveform, press the second button of the channel pair. (#2 if channel 1 selected, #4 if channel 3 is selected)  
  
Indicators will blink for channels that have already been programmed, but are not being programmed currently.  
  
To view the parameters for a channel, whose indicators are blinking, press the blinking channel selector button. You will then be able to view selected treatment parameters, treatment output and time remaining or elapsed.
5. Setup the various treatment parameters specific to the treatment you have selected. *Details are listed below.*
6. Select a treatment time using the numeric keypad. For Ultrasound and Combination Therapy the maximum treatment time is 30 minutes. For Electrical Stimulation the maximum treatment time is 60 minutes. If no treatment time is input, the timer will continue to run until the maximum time elapses.
7. For ultrasound and combination therapy apply gel to the treatment area. For electrical stimulation apply electrodes to the patient.
8. Press the start key to begin treatment.
9. Amber LED indicators for the outputs for electrical stimulation and ultrasound will illuminate when you start a treatment. The numeric display shows the output for the selected channel(s) or ultrasound. The green LED indicators located below the numeric display indicate the output units. Flashing amber LED indicators indicate active channel(s) whose output intensity is not currently displayed. If a channel is not active, the numeric display will show “- - -”.

Flashing amber LED indicators indicate active channel(s) whose output intensity is not currently displayed. If a channel is not active, the numeric display will show “- - -”.



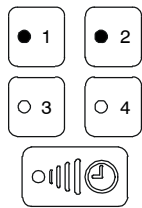
10. Adjust treatment output intensity by rotating the knobs clockwise to increase output and counterclockwise to decrease output.



11. Use this button to stop the treatment output that is currently being displayed by the Sonicator Plus 994. All treatment parameters will still be as you programmed them. For ultrasound, the output intensity will also be remembered. For stimulation, you will be required to readjust the output intensity starting at zero if you resume treatment.

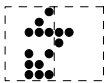


12. Use this button to stop all active treatments. Treatment parameters will still be active so you would be able to resume treatment at any time. For ultrasound, the output intensity will also be remembered. For stimulation, you will be required to readjust the output intensity starting at zero if you resume treatment.



13. After the treatment ends, you can press the channel selector to free up the channel(s) for the next treatment selection. Remove the electrodes from the patient and return them to their package for storage. Remove gel residue from the patient's skin.

## 4.4 Stimulation Set-up Procedure



1. Press the stimulation treatment selector. The Treatment Status Indicator will show you the stimulation icon and all the waveform LED's will begin to blink.



2. Select the stimulation waveform that you would like to use.  
**Interferential** – Channels 1 & 2 or Channels 3 & 4



**Premodulated** – Channels 1, 2, 3 or 4



**Medium Frequency, Russian waveform** – Channels 1, 2, 3, or 4.



**Biphasic** – Channels 1, 2, 3, or 4.



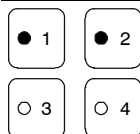
**High Volt** – Channel 1 only



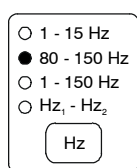
**Microcurrent** – Channel 2 only

**Please Note:** For two-channel operations, the Sonicator Plus 994 works in channel pairs only – Channels 1 & 2 or 3 & 4. Up to four different stimulation protocols may be run simultaneously. The Treatment Status Indicator will show you the icon for the selected waveform.






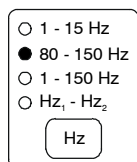
3. For the *interferential* waveform, the Sonicator Plus 994 will automatically pick channel pairs 1 & 2 or 3 & 4. For the *premodulated*, *medium frequency* and *biphasic* waveforms, the next available channel will be selected. If a two-channel treatment is desired pick the second member of the channel pair by pressing its button. Channel 1 is automatically selected for the *high volt* waveform and Channel 2 is automatically selected for the *microcurrent* waveform. If a channel is already in use, you will need to free it up before using these two waveforms. Cancel a treatment setup by pressing the channel selector.
4. Set treatment pulse frequency (Hz), phase duration ( $\mu$ s) and polarity (+ or -) for each waveform.



### Interferential —


Choose from preset frequency modulation programs: 1-15, 80-150 or 1-150 Hz or...

Pick Hz<sub>1</sub>-Hz<sub>2</sub> to set your own static frequency or frequency sweep range. Enter values for each frequency using the numeric keypad followed by the  key. The frequency is displayed in the timer window and the Hz LED is lit.



### Premodulated —

Choose from preset frequency modulation programs: 1-15, 80-150 or 1-150 Hz or...



Pick Hz<sub>1</sub>-Hz<sub>2</sub> to set your own static frequency or frequency sweep range. Enter values for each frequency using the numeric keypad followed by the  key. The frequency is displayed in the timer window and the Hz LED is lit.


### Medium Frequency —

No optional frequency selections



### Biphasic —


The Sonicator Plus 994 stores the value for the phase duration and the frequency for the last Biphasic session. If the value displayed in the timer window is acceptable press the  key. Set  $\mu$ s for the phase duration, 50-300  $\mu$ s. Enter a numeric value followed by the  key.

Set Hz for the frequency, 1-120 Hz. Enter a numeric value followed by the  key.



### High Volt —

Set the treatment polarity. The LED that is lit indicates the red lead wire's polarity.

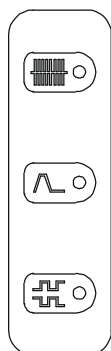
Set Hz for the frequency, 1-120 Hz. Enter a numeric value followed by the  key.

**Microcurrent—**

Set the treatment polarity. The LED that is lit indicates the red lead wire's polarity. Pressing the button twice will allow the polarity to alternate in a biphasic manner. Both LED indicators will be illuminated.

Set Hz for the frequency, 0.5-500 Hz. Enter a numeric value followed by the key, (05 = 0.5 Hz).

5. Set options for amplitude modulation—continuous, surge and reciprocation.



**Continuous**—no amplitude modulation, no On/Off times, (default setting)

**Surge**—Set an On and Off time, 3 seconds Up ramp, 2 seconds Down ramp

**Reciprocation**—Stimulation alternates equally between Channels 1 & 2 or Channels 3 & 4, 1 second Up and Down ramps. May be combined with the Surge option for longer rest times.

**Interferential**—Continuous

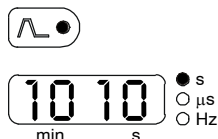
**Premodulated**—Continuous, Surge and Reciprocation

**Medium Frequency, Russian**—Continuous, Surge and Reciprocation

**Biphasic**—Continuous, Surge and Reciprocation

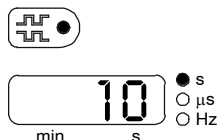
**High Volt**—Continuous and Surge

**Microcurrent**—Continuous

**Surge Mode —**

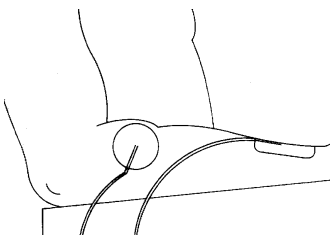
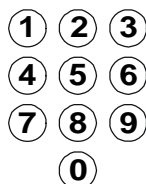
Press Surge selector until you see the On/Off duty cycle that you would like to use. Press the key to accept the values. Preset On/Off choices are 10 10, 10 20, 10 30, 10 40, 10 50 and 10 60.

If you press the Surge selector one more time after “10 60” is displayed, a single number is displayed. This represents the last On time that was programmed. To change the number, use the numeric keypad to enter a new value followed by the key. The Off time is then displayed, enter a new value followed by the key.



**Reciprocation Mode —**

To setup a Reciprocation program you must have stimulation setup for two-channel operation. If Channel 1 is lit, press Channel 2. If Channel 3 is lit, press the Channel 4.

Press the Reciprocation key. Enter a value from 2 to 240 and press the key.



## Surge + Reciprocation –

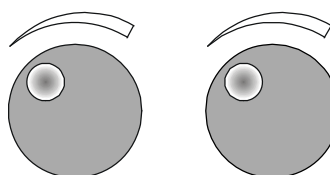
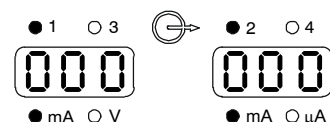
Press Reciprocation key. Press the  key. Press the Surge key until you see the On/Off time you want to use. Press the  key.

- Enter the treatment time using the numeric keypad. The maximum treatment time is 60 minutes. If you do not enter a time, the time will count up during a treatment session, but will not exceed 60 minutes.


- Apply the electrodes to the patient. Attach the electrode cables to the electrodes.



- Press the start key to begin treatment. The waveform will start to move in the treatment status box and the output display will show 0's.

**Please Note:** If you are using the pencil electrode with the microcurrent waveform, you must press the button on top of the pencil electrode to establish contact prior to starting a treatment or a contact error will occur. Once the treatment begins, hold the button down while increasing output intensity.




- Adjust the output intensity by turning the knobs clockwise. The numeric display shows the output in the units indicated by the lit LED below the display for that channel. *Please note:* Adjust the intensity at the peak when the current is on with an amplitude modulation function. Adjust intensity down any time during the On time.

NOTE 1: For the Surge mode, adjust the output intensity for the active channels and then press  to start the Surge cycle. The timer will then begin counting.

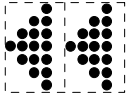
NOTE 2: For the reciprocation mode adjust the intensity for Channel 1 or 3 and then press . Then adjust the intensity for Channel 2 or 4 and press .



- In the interferential mode, press the amplitude modulation (vector rotation) key after the output intensity is adjusted. Adjust intensity Up only at the peak and Down at any time.
- Press the “Hold” key to temporarily suspend treatment. All treatment parameters except output intensity will be retained. Press  to resume treatment and then readjust the output intensity.

12. At the end of a treatment the output intensity will return to zero, the treatment status indicator stops moving and the output displays show “- - - - -”. Remove the electrodes from the patient at this time.

## 4.5 Ultrasound Set-up Procedure



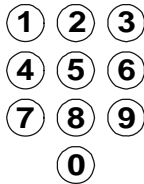
1. Press the ultrasound treatment key. The treatment status indicator will display the ultrasound icon.

2. The green LED indicator will illuminate for the ultrasound treatment. Indicators will blink for channels that have already been programmed, but are not being programmed currently.

To view the parameters for a channel, whose indicators are blinking, press the selector button. You will then be able to view selected treatment parameters, treatment output and time remaining or elapsed.



3. Input treatment time. The maximum treatment time is 30 minutes. If you do not input time the timer will display elapsed time during the treatment and stop at 30 minutes.



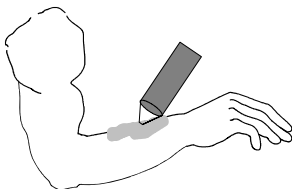
4. If you have the dual frequency 5 cm<sup>2</sup> applicator attached, press this key to select the output frequency. The 10 cm<sup>2</sup> applicator will light up the 1 MHz LED and the 1 cm<sup>2</sup> will light up the 3 MHz LED.



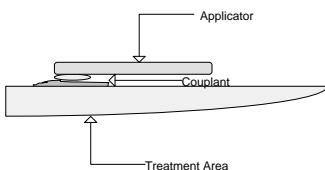
5. Press this key to select either Watts or Watts/cm<sup>2</sup> for the output display.



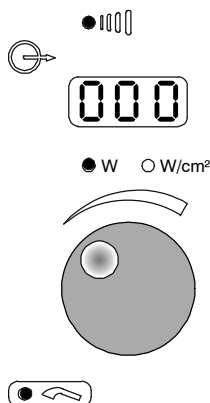
6. Select the duty cycle for the ultrasound from continuous (100%) or pulsed (50% or 20%).




7. Apply a layer of Sonigel (ultrasound couplant gel or lotion) to the treatment area.

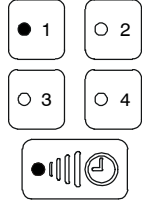
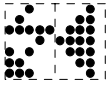


8. Couple the applicator to the treatment area by keeping the entire surface of the applicator in contact with the gel that has been applied to the patient. This will ensure efficient delivery of therapeutic ultrasound to the patient.



9. Press the start key to begin treatment.
10. Adjust the ultrasound power to the desired output intensity, by turning the control knob clockwise to increase intensity and counter-clockwise to decrease it. Remember to couple the applicator to the patient while adjusting ultrasound power. The amber LED marked for ultrasound will indicate that ultrasound is being generated.
11. If the applicator is not in contact with the patient or ultrasound is not being efficiently transmitted to the patient, the LED in the symbol pictured to the left will blink. If inadequate coupling occurs for more than 30 continuous seconds the Sonicator Plus 994 will automatically stop ultrasound output, beep twice and display "E002" in the time display.
12. If you need to temporarily stop treatment press the hold button pictured on the left. Remaining treatment time and selected output power are displayed. Ultrasound power will stop. To resume treatment, press .
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 E002 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 three times. Time and ultrasound power displays will display "0" and ultrasound power will turn off.

## 4.6 Combination Therapy Set-up Procedure



1. Press the combination treatment selector. The Treatment Status Indicator will show you the combination icon and the waveform LED's for Premodulation, Medium Frequency, Biphasic and High Volt will begin to blink.

2. The green LED indicators will illuminate for the ultrasound treatment and Channel 1. Indicators will blink for channels that have already been programmed, but are not being currently displayed.

To view the parameters for a channel, whose indicators are blinking, press the selector button. You will then be able to view selected treatment parameters, treatment output and time remaining or elapsed.

3. Select the stimulation waveform that you would like to use.



**Premodulated**



**Medium Frequency**, *Russian waveform*



**Biphasic**



**High Volt**

**Please Note:** Combination therapy is available with Channel 1 only.

The Treatment Status Indicator displays the icon for the selected waveform plus ultrasound.

4. Set treatment pulse frequency (Hz), phase duration ( $\mu$ s) and polarity (+ or -) for each waveform, if appropriate.

**Premodulated —**

Choose from preset frequency modulation programs: 1-15, 80-150 or 1-150 Hz or...

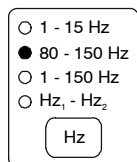
Pick Hz<sub>1</sub>-Hz<sub>2</sub> to set your own static frequency or frequency sweep range. Enter values for each frequency using the numeric keypad followed by the key. The frequency is displayed in the timer window and the Hz LED is lit.


**Medium Frequency —**

No optional selections

**Biphasic —**

The Sonicator Plus 994 stores the value for the phase duration and the frequency for the last Biphasic session. If the value displayed in the timer window is acceptable press the key. Set  $\mu$ s for the phase duration, 50-300  $\mu$ s. Enter a numeric value followed by the key.




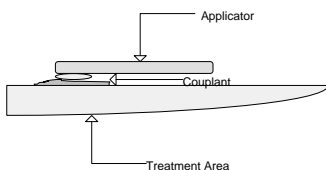
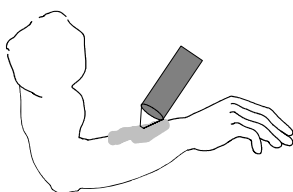
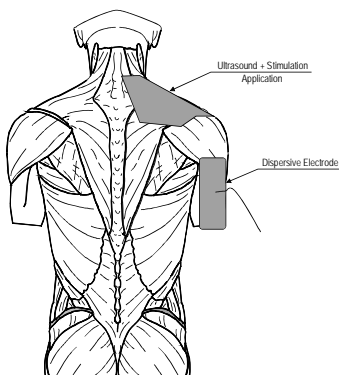
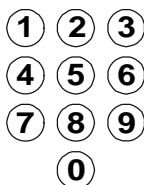
Set Hz for the frequency, 1-120 Hz. Enter a numeric value followed by the  key.



### High Volt—

Set the treatment polarity. The LED that is lit indicates the red lead wire's polarity.

Set Hz for the frequency, 1-120 Hz. Enter a numeric value followed by the  key.

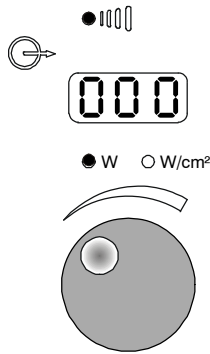


5. Input treatment time. The maximum treatment time is 30 minutes. If you do not input time the timer will display elapsed time during the treatment and stop at 30 minutes.
6. If you have the dual frequency 5 cm<sup>2</sup> applicator attached, press this key to select the output frequency. The 10 cm<sup>2</sup> applicator will light up the 1 MHz LED and the 1 cm<sup>2</sup> will light up the 3 MHz LED.
7. Press this key to select either Watts or Watts/cm<sup>2</sup> for the output display.
8. Select the duty cycle for the ultrasound: continuous (100%) or pulsed (50% or 20%).
9. Apply the dispersive electrode to the patient. Plug the single electrode cable (ME 2261) into channel one. Plug the electrode into the single electrode cable or the red end of a regular electrode cable (ME 2260). **WARNING:** Apply the dispersive electrode in such a manner to prevent transthoracic stimulation.
10. Apply a layer of Sonigel (ultrasound couplant gel) to the treatment area. *Please note: the couplant must also be electrically conductive for combination therapy.*
11. 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.

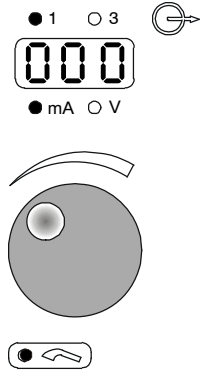




12. Press the start key to begin treatment.




13. Adjust the ultrasound power to the desired output intensity by turning the control knob clockwise to increase intensity and counter-clockwise to decrease it. Remember to couple the applicator to the patient while adjusting ultrasound power. The amber LED marked for ultrasound will indicate that ultrasound is being generated.



14. Adjust the stimulation output to the desired output intensity, by turning the control knob clockwise to increase intensity and counter-clockwise to decrease it.



15. If the applicator is not in contact with the patient or ultrasound is not being efficiently transmitted to the patient, the LED in the symbol pictured to the left will blink. If inadequate coupling occurs for more that 30 continuous seconds the Sonicator Plus 994 will automatically stop ultrasound output, beep twice and display “E002” in the time display.

16. Press the “Hold” key to temporarily suspend treatment. All treatment parameters except stimulation output intensity will be retained. Press  to resume treatment and then readjust the stimulation output intensity.

17. At the end of a treatment the output intensity will return to zero, the treatment status indicator stops moving and the output displays show “- - - 000”. Remove the electrodes from the patient at this time. Wipe any gel residue from the patient’s skin.



## 4.7 Electrode Positioning

### 1. General information

Placement of electrodes may be by the quadpolar, bipolar or monopolar techniques. Proper positioning and contact will insure treatment comfort and efficiency. Electrodes should never be placed in such a manner as to produce current flow through the cardiac area. For safe operation of the Sonicator Plus 994, review contraindications, warnings, precautions and Side Effects/ Adverse Reactions in sections 5.4, 5.5, 5.7 and 5.8 before positioning electrodes.

### 2. Preparation of the skin prior to electrode application

To insure the efficient current conduction necessary for proper treatment, certain preparations must be made. Cleaning or wetting should eliminate any impairment to current conduction on the patient's skin such as an oily or dry surface, or excessive hair coverage. Shaving may be necessary depending upon the density of hair coverage. **Failure to provide for maximum current conduction efficiency could result in skin irritation relating to an increase in current density at the electrode site.**

Using reusable electrodes for longer periods of time than those recommended by the package insert could result in ineffective treatments or cause skin irritation. Care should be taken to ensure application of the total electrode surface area to the patient's skin prior to commencing treatment.

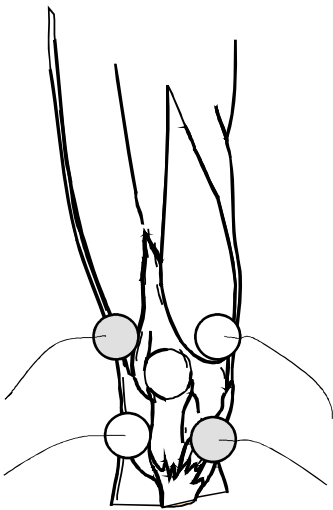


Figure 4.3 – Quadpolar Electrode Placement Technique

### 3. Quadpolar electrode application technique

Quadpolar techniques should be used with the "Interferential" waveform. The electrodes from Channel 1 are placed diagonally from each other. While the electrodes from Channel 2 are placed diagonally across from each other to form an "X" over the treatment area. The zone of maximum interference between the two channels occurs roughly in the center of the "X".

Constantly changing the intensity levels of the two channels will change the interference pattern felt by the patient. Pressing the amplitude modulation key will constantly change the intensity of the outputs of the two channels during treatment, increasing the area covered by the interference pattern.

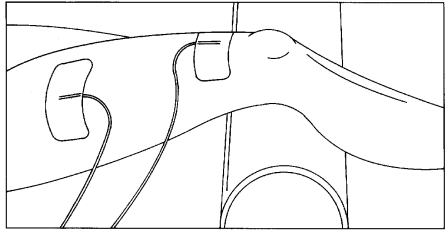


Figure 4.4 — Bipolar Electrode Placement Technique

#### 4. Bipolar electrode placement techniques

Bipolar electrode placement techniques should be used to provide stimulation to larger muscle groups, such as the quadriceps or the hamstrings. The symmetrical waveforms of the “Premodulated”, “Medium Frequency” and “Biphasic” waveforms are usually applied to the body using the bipolar technique.

Equal size electrodes are placed at each end of the muscle or muscle group. Current concentration is over the entire length of that muscle or muscle group and is especially effective on weak musculature. Electrode placement should be at opposite ends of the limb or muscle group. Care should be taken to insure that electrodes are not placed too close together which could produce current concentration along the edges of the pads. This is the so-called “edging effect” which can cause patient discomfort. The figure on the left shows a pad set up for stimulation of the quadriceps.

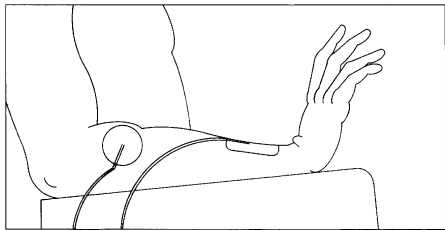


Figure 4.5 — Monopolar Electrode Placement Technique

#### 5. Monopolar electrode application techniques

Monopolar techniques may be used with the “High Volt”, “Microcurrent”, “Premodulated”, “Medium Frequency” and “Biphasic” waveforms. The smaller, active, electrode (black and negative) is placed over the muscle motor point. In treatments designed to relieve pain, the active electrode is placed over the painful area. The larger, dispersive, electrode (red and positive) is placed on the same side of the body at some point distal to the active electrode. The dispersive pad is generally three to four times larger than the active electrode so that current density is too low to cause muscle contractions under the dispersive electrode. Never place the dispersive electrode over the antagonist muscle.

The monopolar electrode placement technique has been found to be especially useful for muscle stimulation of the upper extremities and small muscle groups. This technique helps concentrate the stimulation effect on the muscle under the smaller electrode. The figure on the left illustrates one possible electrode placement for muscle stimulation of the forearm.

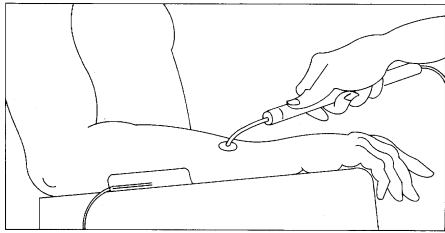


Figure 4.6 — Using the Pencil Electrode

## 6. Using the pencil electrode

The pencil electrode is used for the stimulation of small muscles or painful areas. It is also useful to help identify the exact motor point of a muscle or muscle group. The pencil electrode may be used with the “Premodulated”, “Medium Frequency” or “Biphasic” waveforms.

Attach the pencil electrode to the black electrode cable using a pin to banana adapter. Attach the red electrode cable to a dispersive pad. Apply dispersive electrode in such a manner to prevent transthoracic stimulation.

Pressing the switch located on the pencil electrode will allow treatment currents to be delivered to the patient. Four tips of different sizes are included with the pencil electrode. The figure on the left shows an application of the pencil electrode.

**Please Note:** *If you are using the pencil electrode with the microcurrent waveform, you must press the button on top of the pencil electrode to establish contact prior to starting a treatment or a contact error will occur. Once the treatment begins, hold the button down while increasing output intensity.*



## 7. Additional information about electrode placement:

Motor point charts are available as guides from Mettler Electronics Corp. These points may vary from patient to patient, and at time of injury, may vary in the same patient. “Functional Electrical Stimulation - A Practical Clinical Guide” by Benton, Baker, Bowman and Walters: published by Rancho Los Amigos of Downey, California is an excellent guide for electrode placement for muscle stimulation. “Clinical Transcutaneous Electrical Nerve Stimulation” by Mannheimer and Lampe is a good source for electrode placement techniques for pain management.



# Section 5—Indications, Contraindications, Precautions and Adverse Reactions

## 5.1 Indications for Therapeutic Ultrasound

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 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 Indications for Neuromuscular Electrical Stimulation

The application of pulsating electric currents to the body via electrodes elicits responses from nerves, which conduct pain sensation and muscle contraction information.

Stimulation of sensory fibers will help block pain while the stimulation of motor fibers will generate pulsatile contractions of the muscle groups innervated by the nerves being stimulated.

Based on this information, some of the indications for use are as follow:

1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain (*Interferential, Premodulated and Microcurrent waveforms*)
2. Temporary relaxation of muscle spasm, *all waveforms except Microcurrent*
3. Prevention of post-surgical phlebo-thrombosis through immediate stimulation of calf muscles, *all waveforms except Microcurrent*
4. Increase of blood flow in the treatment area, *all waveforms except Microcurrent*
5. Prevention or retardation of disuse atrophy in post-injury type conditions, *all waveforms except Microcurrent*
6. Muscle re-education, *all waveforms except Microcurrent*
7. Maintaining or increasing range of motion, *all waveforms except Microcurrent*

## 5.3 Contraindications for Therapeutic Ultrasound

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 epiphyseal areas (bone growth centers) of the bones of growing children.

## 5.4 Contraindications for Neuromuscular Electrical Stimulation

1. Electrical neuromuscular stimulation should not be administered to individuals who are or may be pregnant.
2. Do not stimulate a patient who has a cardiac demand pacemaker.
3. Patients with implanted electronic devices should not be subjected to stimulation.
4. Placement of electrodes across the chest laterally or anterior/posterior creates a possible hazard with cardiac patients and is therefore not recommended. Do not use transthoracically in any mode. Great care should be exercised in applying the electrical stimulus current to any region of the thorax because the stimulus current may produce cardiac arrhythmia. In patients with known heart disease, electrical stimulation should be used only after careful physician evaluation and patient instruction.
5. Place electrodes in such a way to avoid stimulation of the carotid sinus (neck) region.
6. Patients with arterial or venous thrombosis, or thrombophlebitis are at risk of developing embolisms when electrical stimulation is applied over or adjacent to the

vessels containing the thrombus. If a patient has a history of deep vein thrombosis, even many years past, the affected area should not be stimulated.

7. Do not use over swollen, infected, or inflamed areas. Do not place electrodes over skin eruptions.
8. Fresh fractures should not be stimulated in order to avoid unwanted motion.
9. Do not apply stimulation transcranially (through the head).
10. Do not use on cancer patients.
11. Stimulation should not be applied immediately following trauma or to tissues susceptible to hemorrhage.
12. Positioning electrodes over the neck or mouth may cause severe spasm of the laryngeal or pharyngeal muscles. These contractions may be strong enough to close the airway or cause difficulty in breathing.
13. Do not apply stimulation for undiagnosed pain syndromes until etiology is established.
14. Do not apply electrodes directly over the eyes or inside body cavities.
15. Do not use electrical stimulation in conjunction with high frequency surgical equipment or microwave therapy systems.

## 5.5 Warnings for Neuromuscular Electrical Stimulation

1. Electrical stimulation is ineffective for pain of central origin.
2. Electrical stimulation must be applied by a physician or other qualified practitioner and should be used for only the prescribed purposes.
3. Electrical stimulation is of no curative value.
4. Electrical stimulation is a symptomatic treatment and as such suppresses the sensation of pain, which could serve as a protective mechanism.
5. The safety of electrical stimulators for use on children has not been determined. Keep out of reach of children.
6. Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when electrical stimulation is in use.

## 5.6 Precautions for Therapeutic Ultrasound

1. Ultrasound should not be applied in areas of reduced sensation or circulation. 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 Plus 994 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 bleeding disorders. Examples of these are hemophilia, post acute trauma, long term steroid therapy, cumiden or heparin therapy.
5. Moving technique of the applicator should be used when applying therapeutic ultrasound at intensities greater than  $0.5 \text{ W/cm}^2$  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 Plus 994, should be adequately grounded and safety tested to insure safe operation with the Sonicator Plus 994.
8. The use of therapeutic levels of ultrasound may delay or prevent callous formation in a healing fracture.

## 5.7 Precautions for Neuromuscular Electrical Stimulation

1. Care should be taken in the treatment of patients receiving another type of electrotherapeutic treatment (such as conventional TENS) or having indwelling electrodes, lead wires, or transmitters (for electrophrenic pacing or cerebellar or urinary bladder stimulation). Stimulation currents should not cross the lead wires or electrodes.
2. It is advisable to insulate patients, preferably by use of a wooden treatment table or one that is completely padded by non-conductive material. Do not allow the patient to touch any grounded metal during a treatment.
3. Limit treatment intensity to 50 mA (50 V) or less, when using small electrodes (2" X 2", pencil or smaller), to reduce the chance of thermal burns due to high current density. *Avoid current densities exceeding  $2 \text{ mA/cm}^2$  when using this device.*
4. Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
5. Avoid placing electrodes directly over open wounds since current density tends to concentrate in these areas.
6. Use extreme caution when treating desensitized areas or on patients who may not be able to report discomfort or pain.
7. Use caution in applying electrical stimulation over areas where there is a loss of normal skin sensation.
8. Adequate precautions should be taken in the case of persons with suspected or diagnosed epilepsy.
9. Patients should not be left unattended during any treatment.



10. Care should be taken following recent surgical procedures when muscle contraction may disrupt the healing process.
11. Do not apply electrical stimulation over the menstruating uterus.
12. The long-term effects of chronic electrical stimulation are unknown.
13. Effectiveness for pain management is highly dependent upon patient selection by a person qualified in the management of pain patients.
14. Turn on the Sonicator Plus 994 before applying electrodes to the patient.

## **5.8 Side Effects/Adverse Reactions for Neuromuscular Electrical Stimulation**

1. Skin irritation and burns beneath the electrodes have been reported with the use of electrical muscle stimulators.
2. Possible allergic reactions to tape, gel or electrodes may occur.



# Section 6—Maintenance and Troubleshooting

## 6.1 Cleaning the Sonicator Plus 994

1. The Sonicator Plus 994 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. Follow the EZ Trode package insert for the use and care of the electrodes supplied with the Sonicator Plus 994.
3. For routine cleaning of the electrode cables use soap and water. Thoroughly dry after cleaning.
4. Use soap and water for routine cleaning of the Sonicator Plus 994 applicators. When disinfection is necessary, use a disinfectant such as a 10% bleach solution. Rinse the applicator thoroughly after disinfection to remove any residue. The Sonicator Plus 994 applicator *is neither autoclavable nor gas sterilizable*.

## 6.2 Routine Maintenance

1. Standard medical electrical safety checks should be performed annually by qualified biomedical engineers or technicians trained to perform these procedures.
2. Inspect electrode cables and associated connectors for damage.
3. To assure accurate performance of the Sonicator Plus 994, calibration verification of ultrasonic output should be performed on an annual basis.
4. Inspect treatment head for cracks, since they may allow ingress of conductive fluid(s).
5. Inspect treatment head cables and associated connectors for damage.
6. Avoid rough handling of the treatment head, since it is critical to the safe and effective application of therapeutic ultrasound and relatively fragile.

## 6.3 Troubleshooting the Sonicator Plus 994

Symptom	Action
1. Nothing lights when main power switch is turned on.	Is line cord connected to outlet? Does the outlet have power? Unit may require servicing if none of the above resolve the problem.

- |                                     |   |
|-------------------------------------|---|
| 2. "E001" displayed in Time window. | Check applicator cable connections to make sure they are securely attached to the Sonicator Plus 994 and the applicator and the rings are turned fully clockwise to lock connectors.  |
| 3. "E002" displayed in Time window. | There is insufficient ultrasound coupling. Use gel or lotion labeled for therapeutic ultrasound coupling. Resume treatment after applying proper couplant. See number 13 on page 25 of this manual for additional information on efficient coupling of ultrasound to the patient.   |
| 4. "E003" displayed in Time window. | The Sonicator Plus 994 cannot tune to the applicator transducer. Turn unit off and then on and try to begin another ultrasound treatment. If the error code persists, the applicator and/or the Sonicator Plus 994 require servicing.   |
| 5. "E004" displayed in Time window. | There is a malfunction in the power output circuitry for ultrasound. Turn unit off and then on and try to begin another ultrasound treatment. If the error code persists, the Sonicator Plus 994 requires servicing.  |
| 6. "E005" displayed in Time window. | There is a malfunction in the power output circuitry for ultrasound. Turn unit off and then on and try to begin another ultrasound treatment. If the error code persists, the Sonicator Plus 994 requires servicing.  |
| 7. "E60_" displayed in Time window. | There is an output voltage error for electrical stimulation. If powering unit OFF and restarting does not remove error, the unit requires servicing.  |
| 8. "E70_" displayed in Time window. | <p>If E7 occurs during the treatment the patient connection impedance may be increasing because the electrodes are drying out or lifting from the patient.</p> <p>If E7 occurs when the output is first being adjusted, it may mean the electrodes or cables are not making a good circuit. Check cable and electrode connections and make sure electrodes are making good contact with the patient.</p> <p>In the continuous treatment modes the output voltage is reduced while the unit monitors the impedance of the patient connection. If the unit is in amplitude modulated modes, such as recip or surge, this patient connection error causes the unit to go into the HOLD mode.</p> |

All patient connection errors should be investigated to determine their cause.

9. "E80\_" displayed in Time window.

An output overcurrent has been detected. Current exceeded 70 mA RMS for interferential, 55 mA for premodulated, and medium frequency or 105 mA peak for biphasic.

Reposition electrodes farther apart. Remove any moisture or gel from between the electrodes and try again. If error persists even without a patient connection or load, unit requires servicing.

10. "E90\_" displayed in Time window.

Output error for electrical stimulation has been detected. Remove electrode cables from unit and turn OFF and then ON. Replace electrode cables onto unit. Reprogram treatment and try starting treatment session again.

If powering unit OFF and restarting does not remove error, the unit requires servicing.

11. "F1\_" displayed in Time window.

There has been a communication error between the microprocessors. If powering unit OFF and restarting does not remove error, unit requires servicing.

12. "F2\_" displayed in Time window.

There has been a relay test error – If powering unit OFF and restarting with all the electrode cables removed does not remove error, the unit requires servicing.

13. "F3\_" displayed in Time window.

There has been a power supply error – If powering unit OFF and restarting does not remove error, the unit requires servicing.

If problem is not addressed above, or if additional troubleshooting guidance is desired, call (800) 854-9305.

The distributor who sold the Sonicator Plus 994 should be able to assist you with a loaner unit during warranty service.



# Section 7—Ultrasound

## 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 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.

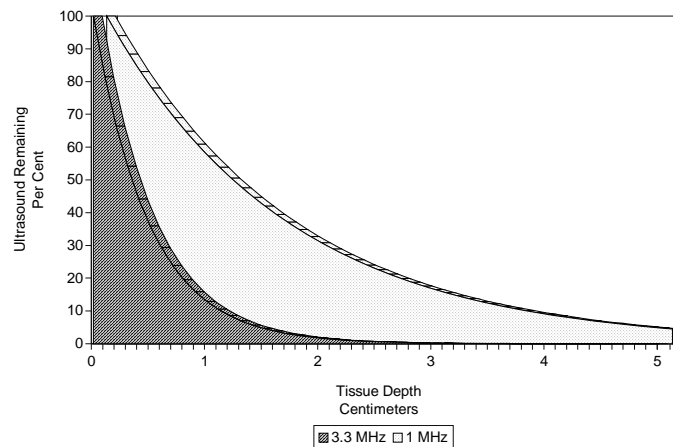


Figure 7.1 – Ultrasound Absorption, Skin

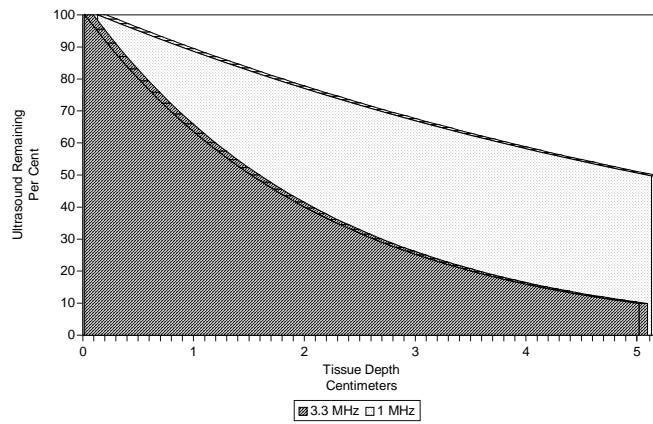


Figure 7.2— Ultrasound Absorption, Fat

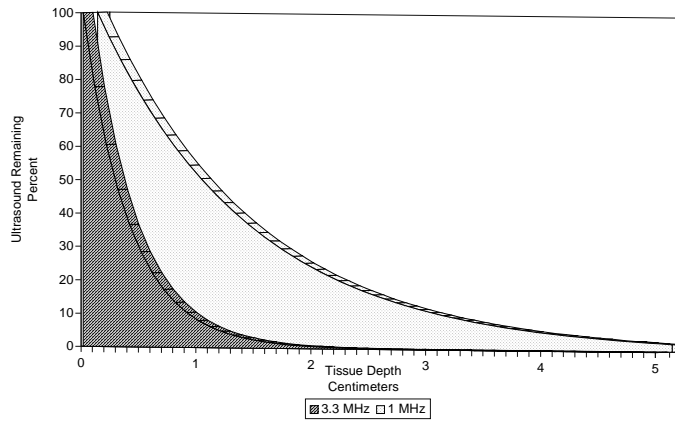


Figure 7.3— Ultrasound Absorption, Muscle with the Ultrasound Beam Perpendicular to the Muscle Fibers

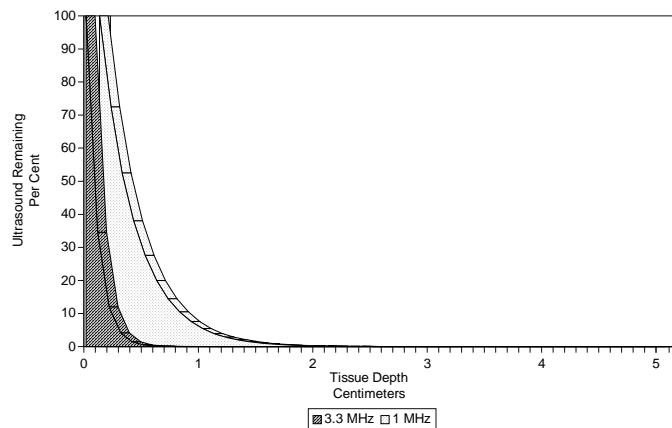
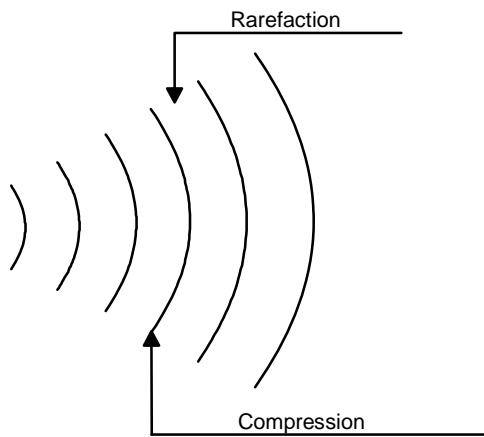


Figure 7.4— Ultrasound Absorption, Bone

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.





Areas of compression and rarefaction of the molecules form high frequency sound waves. 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 Plus 994 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.

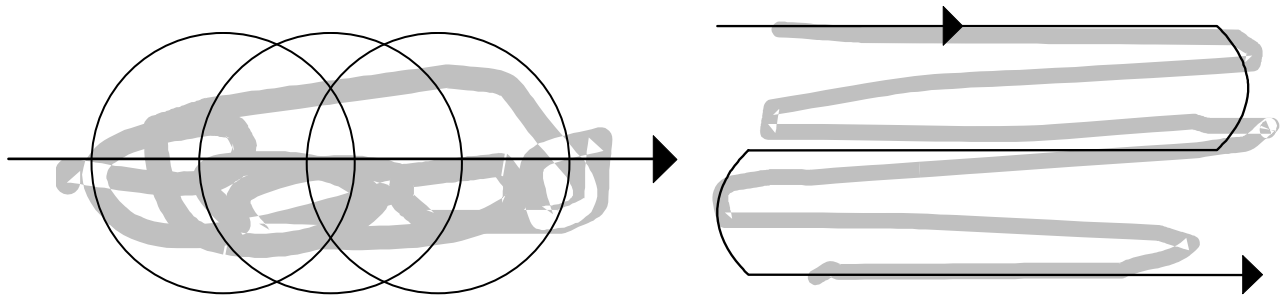


Figure 7.6—Ultrasound Application Techniques

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  $\frac{1}{2}$  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.

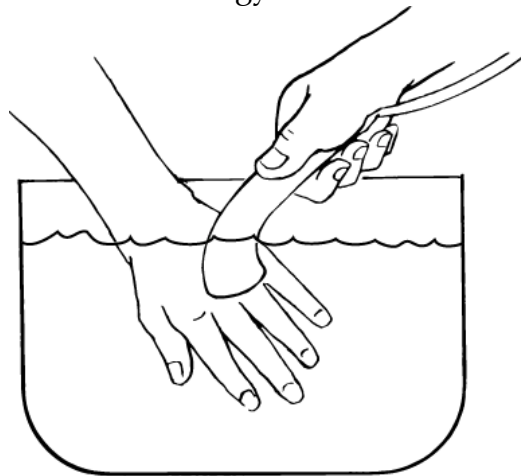


Figure 7.7 Underwater Treatment Technique

## 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.

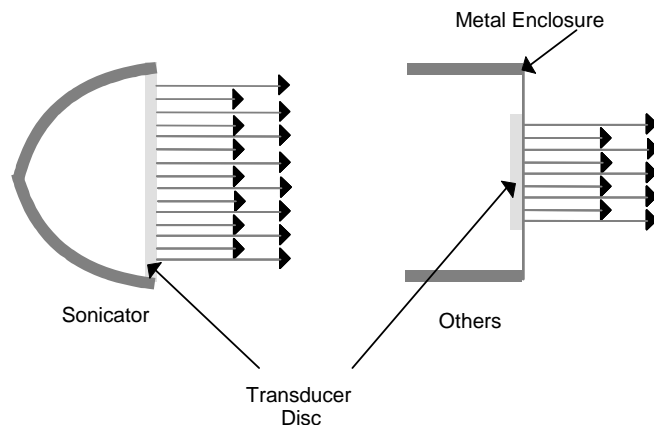


Figure 7.8 Differences Between Transducers

Intensity Setting (W/cm <sup>2</sup> )	ERA (cm <sup>2</sup> )	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 varied appreciably. We caution the user to consider this since units of different manufacture are available in many departments. 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 cm<sup>2</sup> 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 seems 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 Plus 994 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 a pulse frequency of 100 Hz with either a pulse width of 2 milliseconds and 8 milliseconds between pulses for the 20% duty cycle or 5 milliseconds and 5 milliseconds between pulses for the 50% duty cycle. In the pulse mode, peak power is displayed.



# Section 8—References

1. Baker, L.L., Bowman, B.R., and McNeal, D.R.: "Effects of Waveform on Comfort During Neuromuscular Electrical Stimulation", *Clinical Orthopedics and Related Research*, No. 233, pp. 75-85, August, 1988.
2. Belcher, J.: "Interferential Therapy", *N.Z. Journal of Physiotherapy*, 6:29-34, 1974.
3. Benton, L., et al.: *Functional Electrical Stimulation – A Practical Guide*, Rancho Los Amigos Hospital, 1981.
4. Bowman, B.R. and Baker, L.L.: "Effects of Waveform Parameters on Comfort During Transcutaneous Neuromuscular Electrical Stimulation", *Annals of Biomedical Engineering*, Vol. 13, pp. 59-74, 1985.
5. Brooks, M.E., Smith, E.M., and Currier, D.P.: "Effect of Longitudinal Versus Transverse Electrode Placement on Torque Production by the Quadriceps Femoris Muscle during Neuromuscular Electrical Stimulation", *JOSPT*, 11:11, pp. 530-534.
6. De Dominico, G.: *New Dimensions in Interferential Therapy, A Theoretical and Clinical Guide*, Reid Medical Books, Sydney, 1987.
7. De Dominico, G.: "Motor Stimulation with Interferential Currents", *Australian Journal of Physiotherapy*, 31:225-230, 1985.
8. De Dominico, G.: "Pain Relief with Interferential Therapy", *Australian Journal of Physiotherapy*, 28:14-18, 1982.
9. DeLitto, A. and Snyder-Mackler, L.: "Two Theories of Muscle Strength Augmentation Using Percutaneous Electrical Stimulation", *Physical Therapy*, (70:158-164), 1990
10. Dyson, M.: "Mechanisms Involved in Therapeutic Ultrasound". *Physiotherapy*, March 1987, Vol. 73:3, pp. 116- 120.
11. Electrotherapy Standards Committee of the Section on Clinical Electrophysiology of the American Physical Therapy Association. *Electrotherapeutic Terminology in Physical Therapy*, APTA, 1990.
12. Ganne, J. M. "Interferential Therapy", *Australian Journal of Physiotherapy*, 22:101-110, 1976.
13. Hayes, K.W.: *A Manual for Physical Agents*, Appleton & Lange, 1993.
14. Hecox, B., Mehreteab, T.A. and Weisberg, J.: *Physical Agents – A Comprehensive Text for Physical Therapists*, Appleton & Lange, 1994.
15. Kahn, J.: *Principles and Practice of Electrotherapy*, Churchill Livingstone, 1987.
16. Killian, C.B.: "Electrical Stimulation Overview, Introduction to High Frequency Stimulation", *Stimulus*, 1986.
17. Kottke, F.J., Stillwell, G.K. and Lehman, J.F., eds.: *Krusen's Handbook of Physical Medicine and Rehabilitation*, W.B. Saunders Company, 1982.
18. Low, J. and Reed, A.: *Electrotherapy Explained – Principles and practice*, Butterworth-Heinemann, 1994.

19. 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.
20. Jorgenson, S. P. "Interferential Therapy", *ACA Journal of Chiropractic*, 23:12, 28-30, 1986.
21. Kahn, Joseph.: *Principles and Practice of Electrotherapy*, Churchill Livingstone, New York, 1987.
22. Kottke, F.J.; Stillwell, G.K.; and Lehman, J.F. ed. *Krusen's Handbook of Physical Medicine and Rehabilitation*. W.B. Saunders Co., Philadelphia, 1982.
23. Mannheimer, J.S. and Lampe, G.N: *Clinical Transcutaneous Electrical Nerve Stimulation*, F. A. Davis Company, 1984.
24. Michlovitz, S.L. and Wolf, S.L., ed. *Thermal Agents in Rehabilitation*, F.A. Davis Co., Philadelphia, 1990.
25. Nelson, R.M. and Currier D.P.: *Clinical Electrotherapy*, Appleton and Lange, 1991.
26. Nikolova, L.: *Treatment with Interferential Current*, Churchill Livingstone, 1987.
27. Nyborg, W.L. and Ziskin, M.C., ed. *Biological Effects of Ultrasound*. Vol. 16 of *Clinics in Diagnostic Ultrasound*, Churchill Livingstone, New York, 1985.
28. Prentice, W.E.: *Therapeutic Modalities in Sports Medicine*, Times Mirror/Mosby College Publishing, 1990.
29. Reid, D.C. and Cummings, G.C.: "Efficiency of Ultrasound Coupling Agents". *Physiotherapy*, Vol. 63:8, 1977, pp. 255- 257.
30. Savage, B. *Interferential Therapy*, Faber and Faber, Boston, 1984.
31. Schwann, H.P. and Carstensen, E.L.: "Advantages and Limitations of Ultrasonics in Medicine". *JAMA* 5:52 Vol. 149, 1952, pp. 121-125.
32. Selkowitz, D.M.: "Improvement in Isometric Strength of the Quadriceps Femoris Muscle After Training with Electrical Stimulation", *Physical Therapy*, (65:186–196), 1985.
33. Snyder–Mackler, L. and Robinson, A. J., eds.: *Clinical Electrophysiology, Electrotherapy and Electrophysiologic Testing*, Williams and Wilkins, 1989.
34. Starkey, C.: *Therapeutic Modalities for Athletic Trainers*, F. A. Davis Company, 1993.
35. Wadsworth, H. and Chanmugam, A.P.P.: *Electrophysical Agents in Physiotherapy – Therapeutic and Diagnostic Use*, Science Press, Marrickville NSW 2204 Australia, 1983.
36. 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.
37. Wilkie, C. D. "Interferential Therapy", *Physiotherapy*, 55: 503-506, 1969.
38. Wolf, S.L., ed.: *Electrotherapy*, Churchill Livingstone, New York, 1981.

This manual has been written as a guideline for the correct use of the Sonicator Plus 994. Reading the above references will provide a more complete understanding of the correct use of therapeutic ultrasound, neuromuscular stimulation and combination therapy.

# Section 9—Specifications

## 9.1 General Specifications:

Input:	90–240 VAC, 50–60 Hz, 2.3 Amp Nom.
Certification:	The Sonicator Plus 994 complies with the ultrasound performance standards set forth in the Code of Federal Regulations, Title 21 (Food and Drugs), Part 1050.10
Year 2000 Compliant	Yes
Weight:	10.7 pounds
Dimensions:	5 in (H) x 14.5 in (W) x 10 in (D)
Operating Temperature:	+50°F to +104°F
Humidity:	Operating, 30% to 75% Relative Humidity at 104°F Nonoperating, 5 to 95% Relative Humidity, non-condensing
Storage Temperature:	-40°F to 167°F
Timer Accuracy:	±0.5 minutes 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:	60 minutes–electrical stimulation 30 minutes–ultrasound or combination therapy
Treatment Timer:	Treatment time counts down to zero when a time is set, or up to 60 or 30 minutes when no time is set. The digital timer indicates time in minutes and seconds. The timer also indicates the remaining or elapsed treatment time during the “Hold” period.

## 9.2 Ultrasonic Generator Specifications:

Frequency:	1.0 MHz ±10% 3.2 MHz ±10% 3.3 MHz ±10%
Modes:	Continuous Pulsed – 20% duty cycle Pulsed – 50% duty cycle
Pulse Repetition Rate:	100 Hz ±20%
Pulse Duration:	2 msec ±20%, 20% duty cycle 5 msec ±20%, 50% duty cycle
Temporal Peak/ average intensity ratio:	5:1 ±20%, 20% duty cycle 2:1 ±20%, 50% duty cycle

Maximum output power:	22 W with a 10 cm <sup>2</sup> applicator, (ME 7310) 11 W with a 5 cm <sup>2</sup> applicator, (ME 7513) 2.2 W with a 1 cm <sup>2</sup> applicator (ME 7331)
Maximum intensity:	2.2 W/cm <sup>2</sup> with all applicators
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, 3.2 or 3.3 MHz sine wave pulses are modulated with square wave pulses. The power level is adjusted by varying the pulse amplitude. The pulse waveforms are shown below:

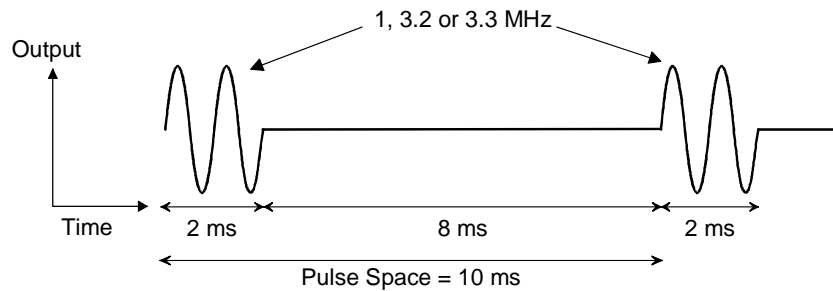


Figure 9.1 – Pulse Waveform – 20% Duty Cycle

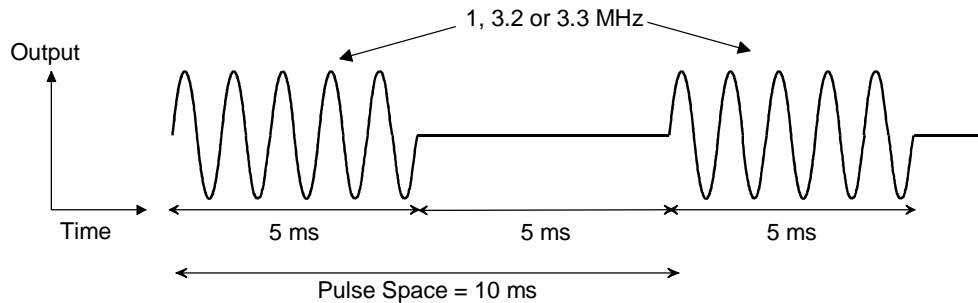


Figure 9.2 – Pulse Waveform – 50% Duty Cycle

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:

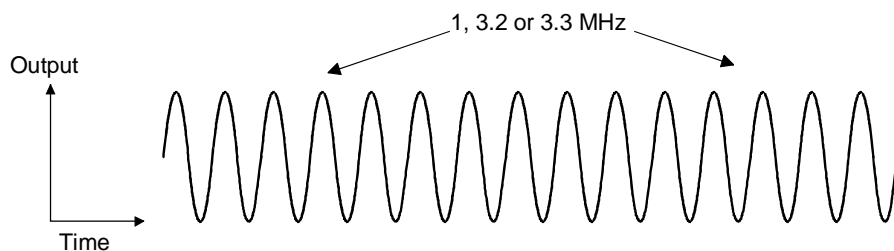


Figure 9.3 – Continuous Waveform



## 9.3 Ultrasonic Applicator Specifications:

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

Individual Applicator Specifications:

Applicator Part Number	Frequency	Effective Radiating Area
ME 7310	1 MHz $\pm 10\%$	10 cm <sup>2</sup> $\pm 20\%$
ME 7331	3.3 MHz $\pm 10\%$	1 cm <sup>2</sup> $\pm 20\%$
ME 7513	1 or 3.2 MHz $\pm 10\%$	5 cm <sup>2</sup> $\pm 20\%$

Maximum Beam

Non-Uniformity Ratio: 6:1

Spatial Pattern:

The applicator produces a collimated (cylindrical) beam with an area of 1, 5 or 10 cm<sup>2</sup>, measured 5 mm from the ceramic disc surface when the radiation is emitted into the equivalent of an infinite medium of distilled water at 30° C.

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 9.3, 9.4, 9.5 and 9.6.

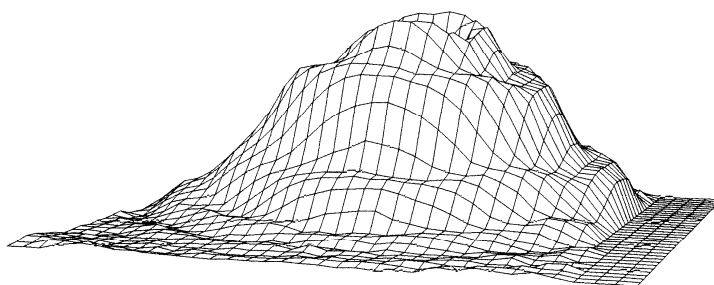


Figure 9.4—10 cm<sup>2</sup> Applicator (1 MHz), ME 7310,— Three Dimensional Beam Pattern

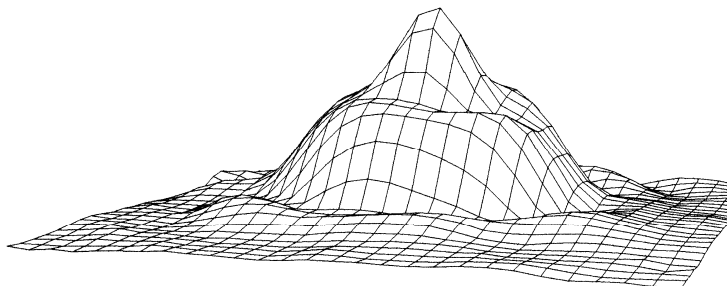
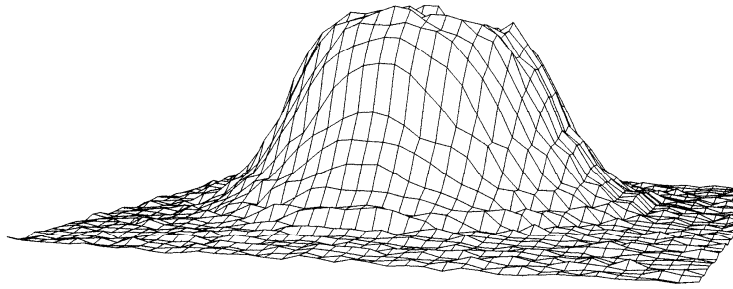
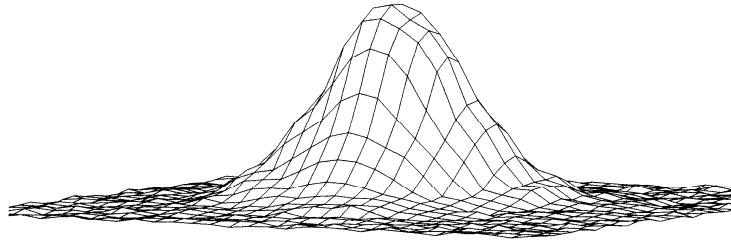
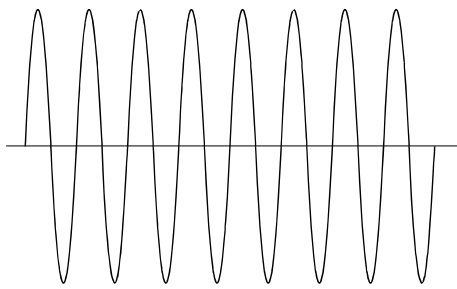


Figure 9.5—5 cm<sup>2</sup> Applicator (1 MHz), ME 7513,— Three Dimensional Beam Pattern

Figure 9.6—5 cm<sup>2</sup> Applicator (3.2 MHz), ME 7513,— Three Dimensional Beam PatternFigure 9.7—1 cm<sup>2</sup> Applicator (3.3 MHz), ME 7331,— Three Dimensional Beam Pattern

## 9.4 Waveform Specifications:

### Interferential Mode

Figure 9.8—Interferential  
Waveform

---

Waveform Type:	Sinewave
Polarity:	None
Volts:	0–65 volts RMS, 1 Kohm load
Current:	0–65 mA RMS, 1 Kohm load
Average current at maximum intensity and frequency:	65 mA RMS
Maximum current density under 2" diameter electrode.	3.2 mA/cm <sup>2</sup>
Frequency:	Channel 1 = 4000 Hz Channel 2 = 4000 to 4250 Hz variable frequency sine wave
Frequency Modulation:	1–15 Hz 80–150 Hz 1–150 Hz xx–xx Hz, xx=any value from 1 to 250 Hz
Phase Duration:	125 µs
Available Amplitude Modulation Options:	Vector rotation
Available Channels:	Channel pairs 1 & 2 or 3 & 4

---

## Premodulated Mode

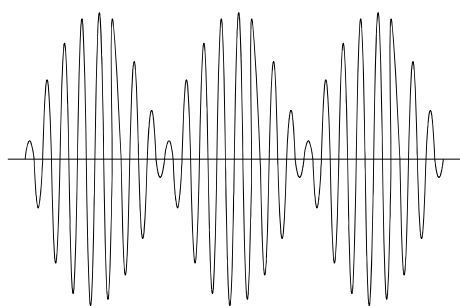


Figure 9.9 — Premodulated Waveform

Waveform Type:	Amplitude modulated sine wave
Polarity:	None
Volts:	0–50 volts RMS, 1 Kohm load
Current:	0–50 mA RMS, 1 Kohm load
Average current at maximum intensity and frequency:	50 mA RMS
Maximum current density under 2" diameter electrode.	2.5 mA/cm <sup>2</sup>
Frequency:	4,000 Hz
Frequency Modulation:	1–15 Hz 80–150 Hz 1–150 Hz xx–xx Hz, <i>xx=any value from 1 to 250 Hz</i>
Phase Duration:	125 $\mu$ s internal sine wave 4–1,000 ms beat envelope
Available Amplitude Modulation Options:	Continuous Surge Reciprocation
Available Channels:	All

## Medium Frequency Mode

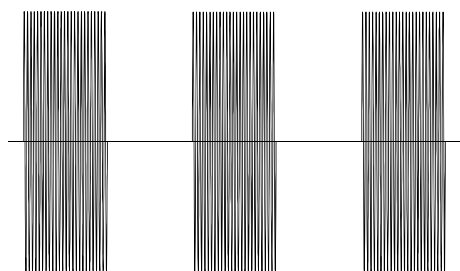


Figure 9.10 — Medium Frequency (*Russian*) Waveform

Waveform Type:	Burst modulated sine wave
Polarity:	None
Volts:	0–50 volts RMS, 1 Kohm load
Current:	0–50 mA RMS, 1 Kohm load
Average current at maximum intensity and frequency:	50 mA RMS
Maximum current density under 2" diameter electrode.	2.5 mA/cm <sup>2</sup>
Frequency:	2500 Hz, Burst at 10 ms on and 10 ms off
Frequency Modulation:	No
Phase Duration:	200 $\mu$ s

Available Amplitude	
Modulation Options:	Continuous Surge Reciprocation
Available Channels:	All

## Biphasic Mode

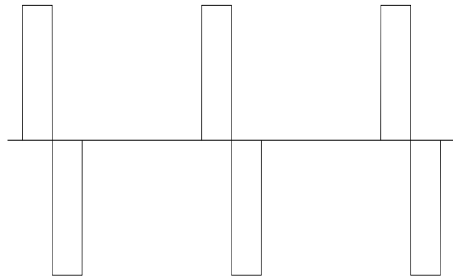


Figure 9.11 – Biphasic Waveform

Waveform Type:	Symmetrical biphasic square wave
Polarity:	None
Volts:	99 volts peak, 1 Kohm load
Current:	0 –99 mA peak, 1 Kohm load
Average current at maximum intensity and frequency:	7.2 mA
Maximum current density under 2" diameter electrode.	0.36 mA/cm <sup>2</sup>
Frequency:	1–120 Hz
Frequency Modulation:	No
Phase Duration:	50–300 $\mu$ s
Available Amplitude	
Modulation Options:	Continuous Surge Reciprocation
Available Channels:	All

## High Volt Mode

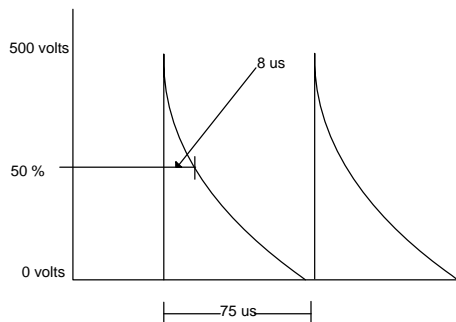


Figure 9.12 – High Volt Waveform

Waveform Type:	Monophasic twin peak
Polarity:	Positive or negative
Volts:	500 volts peak, 1 Kohm load
Current:	0 –500 mA peak, 1 Kohm load
Average current at maximum intensity and frequency:	1.2 mA at 120 pps with 1 Kohm load
Maximum current density under 2" diameter electrode.	0.06 mA/cm <sup>2</sup>
Frequency:	1–120 Hz

Frequency Modulation:	No
Phase Duration:	8 $\mu$ s at 50% Vmax
Polarity:	Positive or negative
Available Amplitude	
Modulation Options:	Continuous Surge
Available Channels:	Channel One only

## Microcurrent Mode

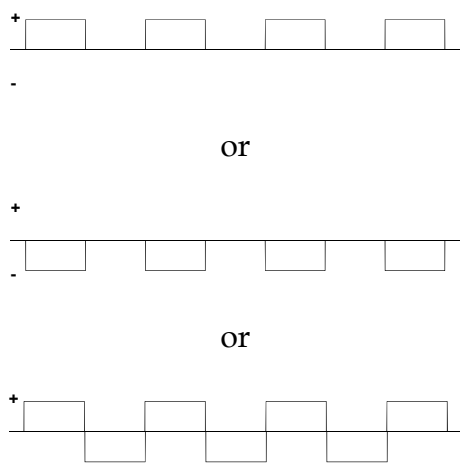


Figure 9.13 – Microcurrent Waveform

Waveform Type:	Monophasic or biphasic square wave
Polarity:	Positive or negative or biphasic pulses
Volts:	1 Volt peak, 1 Kohm load
Current:	10-990 $\mu$ A peak, 1 Kohm load
Average current at maximum intensity and frequency:	445 $\mu$ A
Maximum current density under 2" diameter electrode.	24.4 $\mu$ A/cm <sup>2</sup>
Frequency:	0.5-500 Hz
Duty Cycle:	50%
Frequency Modulation:	No
Pulse Duration:	1-2000 ms
Available Amplitude	
Modulation Options:	Continuous
Available Channels:	Channel Two only

## 9.5 Amplitude Modulation Specifications:

<b>Vector rotation:</b>	<i>Interferential Mode Only,</i>
	-50% amplitude modulation in anti phase with an eight second modulation period.

<b>Surge Mode:</b>	<i>Premodulated, Medium Frequency and Biphasic Pulsed Modes</i>
--------------------	---

Up ramp:	3 seconds
Down ramp:	2 seconds
Preset on/off times:	10 seconds on, 10 seconds off 10 seconds on, 20 seconds off 10 seconds on, 30 seconds off 10 seconds on, 40 seconds off 10 seconds on, 50 seconds off 10 seconds on, 60 seconds off
Programmable On time:	1-240 seconds
Programmable Off time:	1-240 seconds

<b>Reciprocation mode:</b>	<i>Premodulated, Medium Frequency and Biphasic Pulsed Modes</i>
----------------------------	---

Up and down ramps:	1 second, <i>reciprocation only</i>
Reciprocation time:	2-240 seconds, (On time = off time)
Combine with Surge:	Use up and down ramps of surge program Use on/off times of surge program.

# Section 10—Accessories

## 10.1 Ordering Information:

Therapy products and accessories are available from Mettler Electronics authorized Distributors. For information regarding either Mettler products or a distributor near you, please call toll free, (800) 854-9305 or phone (714) 533-2221 in areas outside the continental United States. Ask for Customer Service. Mettler Electronics is open from 7 AM until 5 PM Pacific Time for your convenience.

## 10.2 Sonicator Plus 994 Accessories

Catalogue #	Item Description
109	Rugged padded tote bag for carrying a Sonicator Plus 992 or 994 or Sys*Stim 294 along with its accessories complete with shoulder strap.
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)
1860	Sonigel clear gel couplant in tubes for therapeutic ultrasound and muscle stimulation, (4 cases of 12 x 9.5 oz. tubes)
1861	Sonigel clear gel couplant in bottles for therapeutic ultrasound and muscle stimulation, (4 cases of 12 x 250 ml bottles)
1863	Sonigel Lotion, 1 gallon with pump and pour off bottle
1864	Sonigel Lotion, 4 X 1 gallon individually packaged
2000	4 Sponge electrodes (2" x 2")
2001	24 Sponge inserts (2" x 2")
2002	4 Sponge electrodes (4" x 4")
2003	24 Sponge inserts (4" x 4")
2004	1 Sponge electrode (3.5" x 7")
2005	12 Sponge inserts (3.5" x 7")
2006	1 Sponge electrode (8" x 10")
2007	12 Sponge inserts (8" x 10")
2008	4 Electrode straps (24")
2009	4 Electrode straps (48")
2023	Pencil electrode set with push button stimulation control, (includes handle, 4 different sizes of stainless steel spot electrode tips, and carrying case)
2027	Pin to banana adapter plug set to be used with ME 2260 or 2261 electrode cables. Four each, gray.

2030	Bifurcation cable set, 2 cables, one red and one black, pin termination
2221	EZ Trode – 2" diameter round self-adhering, reusable electrodes with lead wires; case of ten packages (four electrodes/pkg.)
2222	EZ Trode – 2.75" diameter round self-adhering, reusable electrodes with lead wires; case of ten packages (four electrodes/pkg.)
2223	EZ Trode – 2" x 5" self-adhering, reusable electrodes with lead wires, case of 10 packages (2 electrodes/pkg.)
2224	EZ Trode – 2" square self-adhering, reusable electrodes with lead wires, case of 10 packages (2 electrodes/pkg.)
2260	Electrode cable for the Sonicator Plus 994 with pins
2261	Single cord electrode cable for the Sonicator Plus 994 for combination therapy
2702	V Trode –2" diameter round electrodes with lead wires, case of ten packages (four electrodes/pkg.)
2703	V Trode –2.75" diameter round electrodes with lead wires, case of 10 packages (four electrodes/pkg.)
2704	V Trode –2" x 4" oval electrodes with lead wires, case of 10 packages (four electrodes/pkg.)
2705	V Trode –2" square electrodes with lead wires, case of 10 packages (four electrodes/pkg.)
7293	Detachable U.L. listed, hospital-grade line cord
73	Three-shelf mobile cart for all Sonicator Plus products. Holds unit on the top shelf with lower shelves for accessories.
7310	Sonicator 716, 730, 992 and 994 applicator (10 cm <sup>2</sup> / 1 MHz)
7331	Sonicator 730, 992 and 994 pencil style applicator (1 cm <sup>2</sup> / 3.3 MHz)
7392	Hooded, water-proof universal applicator cable for the Sonicator Plus 930, 992 and 994
7513	Sonicator Plus 930, 992 and 994 applicator (5 cm <sup>2</sup> / 1 or 3.2 MHz)