Sonicator® Plus 920

Instruction Manual

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IR9–67 Rev. F_07/02/12

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Section 1: Introduction

1.1 Introduction to the Sonicator Plus 920

Thank you for purchasing the Sonicator Plus 920 two-channel combination unit for therapeutic ultrasound and muscle stimulation. The microprocessor controlled Sonicator Plus 920 provides interferential (4-pole), premodulated (2-pole interferential), medium frequency (Russian), EMS, high volt, TENS, microcurrent and direct current (DC) waveforms. In addition the Sonicator Plus 920 offers 1 and 3 MHz ultrasound using a dual frequency 5.5 cm² applicator. An optional 0.9 cm² applicator at 1 and 3 MHz is also available.

The two–channel Sonicator Plus 920 allows you to utilize up to two different waveforms using two channels simultaneously. You can choose between several different amplitude modulation options such as the surge, reciprocation and vector sweep. The interferential and premodulated modes offer frequency modulation as well as a static frequency option.

Figure 1.1— Sonicator Plus 920

The Sonicator Plus provides both a membrane panel and a touch-sensitive screen to allow you to quickly set up treatments. 90 treatment setups allow you to quickly set up a treatment that is already in the memory, plus you customize any of these programs with your own treatment protocol.

The Sonicator Plus 920 can provide electrical stimulation only, ultrasound only and combination therapy with the premodulated, TENS, high voltage, microcurrent and DC waveforms. Add one of the two optional treatment carts to create a mobile therapy center for your office.

The Sonicator Plus 920 has been certified by Intertek Testing Services to meet the requirements for ETL Listing per the following standards:

- IEC 60601-1:1988/A1:1991/A2:1995 (UL60601-1:2003), IEC60601-1-1: 2000 Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety.
- IEC 60601-1:1988/A1:1991/A2:1995 (CAN/CSA C22.2 NO 601.1, 1-M-90) – Medical Electrical Equipment – Part 1: General Requirements for Safety
- IEC60601-2-5:2000 – Safety of Ultrasonic Physiotherapy Equipment
- IEC60601-2-10: 1987/A1:2001– Safety of Nerve and Muscle Stimulators
- ISO14971:2007, CAN/CSA ISO13485 – Risk Management
- CMDR/SOR98-282

In addition, the Sonicator Plus 920 also meets the following standards for radio frequency emissions and immunity:

- IEC60601-1-2: 2007
- FCC Part 18: 2003

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 920.

This manual has been written to assist you with the safe operation of the Sonicator Plus 920. It is intended for use by the owners and operators of the Sonicator Plus 920. 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. To ensure that you receive important updates to this manual or announcements about this product, please register the warranty for your Sonicator Plus 920 on line at http://www.mettlerelectronics.com/product-registration/.

- The operating manual is required for safe use of the unit. If you lend or transfer the unit to another party such as a facility, be sure to provide this manual with the unit.
- Carefully read the Safety Precautions before operating the unit. Follow the precautions given.
- To prevent injury to the operator or patient or property damage, the manual uses the following terms and symbols to represent varying levels of danger. Make sure you understand what these symbols mean before reading the manual.

⚠DANGER Improper handling may result in a high risk of death or serious injury.

⚠WARNING Improper handling may result in a risk of death or serious injury.

⚠CAUTION Improper handling may result in injury or property damage.

Calls attention to Danger, Warning, or Caution items

This particular symbol means "Electric Shock Hazard."

Indicates an action to be avoided.

This particular symbol means: "Do Not Disassemble."

Indicates a mandatory action.

This particular symbol means "Remove the plug from the power outlet."

1.3 Safety Precautions

⚠WARNING

The Sonicator Plus 920 operates with high voltages. Qualified biomedical technicians with training in ultrasound and neuromuscular stimulator service should perform servicing of the Sonicator Plus 920 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 the FDA, 21 CFR 1050.10 ultrasound standard, the ultrasound portion of the Sonicator Plus 920 should be calibrated and safety tested on an annual basis. This service may be obtained from the manufacturer by sending the Sonicator Plus 920 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*) 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 920 is available from Mettler Electronics Corp. for a nominal charge.

1.4 Caution

⚠CAUTION

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

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

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. The stimulus delivered by this device may be sufficient to cause electrocution. Electrical current above 25 μC must not flow through the thorax because it may cause a cardiac arrhythmia.

1.5 Shipping Damage

Your new Sonicator Plus 920 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 proper formal claim has been filed by the receiver against the carrier.

The carton in which your new Sonicator Plus 920 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 920 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 920
2. Large ultrasound applicator, 5.5 cm² at 1 and 3 MHz, (ME 9201)
3. Sonigel, ultrasound couplant gel, one sample tube, 100 ml, (ME 1846)
4. Two electrode cable sets, (ME 2266)
5. One package V Trodes, 2" diameter (ME 2702))
6. Two 4"x 4" sponge electrodes, (ME2002)
7. Two pin to banana adapters, (ME 2027)
8. Detachable U.L. listed, hospital–grade line cord
9. Instruction Manual on a CD ROM

1.7 Limited Warranty

The Sonicator Plus 920 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 920 applicator is 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, Control Descriptions and List of Abbreviations

2.1 Symbol Glossary

Increase intensity button

Decrease intensity button

"Pause" treatment button pauses treatment for all either channel one or two but retains set treatment parameters and remaining treatment time. Adjust intensity to resume treatment.

Stop treatment button stops all output and resets all treatment parameters to their default settings.

Time symbol

Increase parameter value control

Decrease parameter value control

Go to the configuration menu

Load a protocol

Save a treatment protocol

Go back a step

Accept a setting

C H Channel

US Ultrasound tab

COMBO Combination tab

4-Pole Interferential

2-Pole Interferential (Premodulated)

Electrical Muscle Stimulation

Russian


TENS


High Voltage

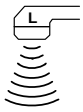

Direct Current (DC)


Ultrasound treatment

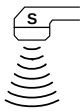

Combination treatment

Large ultrasound applicator plugged in

Small ultrasound applicator plugged in



Large ultrasound applicator active



Small ultrasound applicator active


Carrier frequency for 4-pole and 2-pole interferential and EMS


Beat frequency for 4-pole and 2-pole interferential and EMS


Duty cycle for Russian mode

Set pulse width

Set twin pulse width for high voltage


Set individual pulse width for high voltage


Positive polarity

Negative polarity

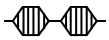

Bipolar

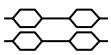

Vector sweep mode

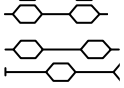

Continuous mode


Burst mode

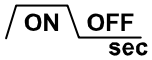

Frequency modulation mode


Surge mode


Surge mode, 2 channels


Reciprocation (Alternate) mode


Frequency sweep range



Set on / off times


Electrode symbol

Using gel for ultrasound treatment

OTM	Using cream for ultrasound treatment
L	Large (~5.5 cm²) ultrasound applicator plugged in.
S	Small (0.9 cm²) ultrasound applicator plugged in.
w/cm²	Watts per square centimeter selected for intensity display.
Watt	Watts selected for intensity display.
Freq.	Select ultrasound frequency (1 or 3 MHz)
	Select ultrasound duty cycle (5, 10, 20, 30, 40, 50 or 100%)
	Mains On.
	Mains Off.
	Attention, consult instruction manual.
	Diagram of Pulsed Mode duty cycles
	Type BF Equipment—Class I
	Non–ionizing radiation
	Read the information in the instruction manual.
IPX0	Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
IPX7	Protected against the effects of immersion.
C ETL US LISTED Intertek 3123653 Classified	ETL and C–ETL Listed

2.2 Control Descriptions

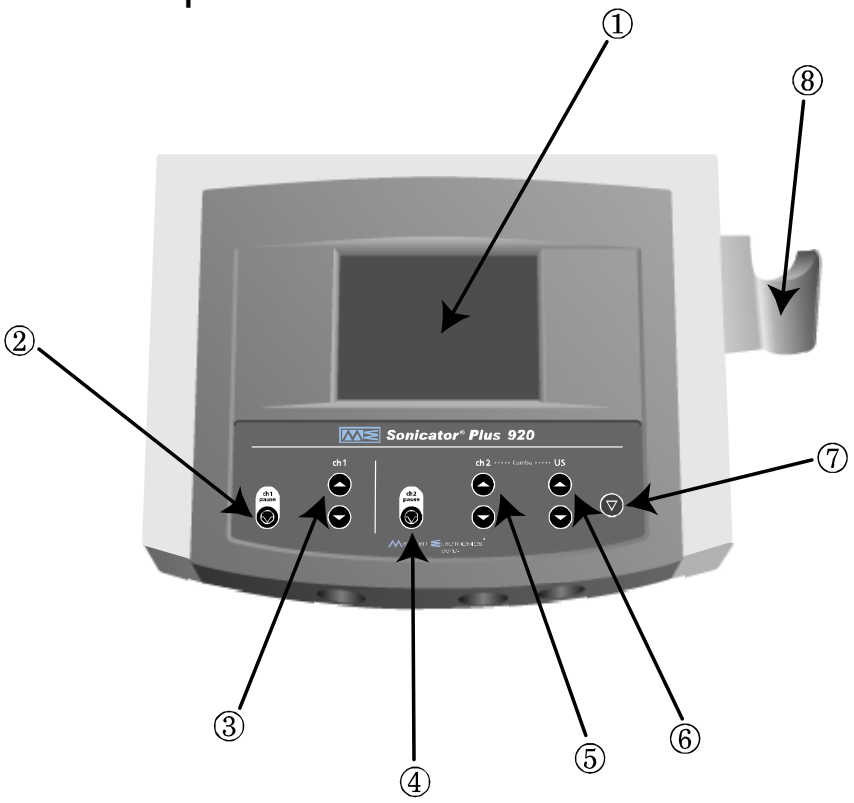


Figure 2.1— Sonicator Plus 920, top view

1. Touch-screen LCD
2. CH1 pause control
3. CH1 intensity controls
4. CH2 pause control
5. CH2 intensity controls
6. Ultrasound intensity controls
7. Stop control
8. Ultrasound applicator cradle

2.3 List of Abbreviations

CH	—	Channel
cm²	—	Square centimeters
COMBO	—	Combination
Hz	—	Hertz (pulses per second)
LCD	—	Liquid crystal display
LED	—	Light Emitting Diode
MHz	—	Megahertz (1 x 10^6 cycles per second)
µs	—	Microsecond (1 x 10^{-6} second)
mA	—	Milliampere (1 x 10^{-3} ampere)
ms	—	Millisecond (1 x 10^{-3} second)
min	—	Minutes
sec	—	Seconds
S/N	—	Serial Number
US	—	Ultrasound
W	—	Watts
W/cm²	—	Watts per square centimeter

Section 3—Installation

3.1 Installation Instructions

⚠CAUTION

1. When installing the unit, pay attention to the following:
   - Install the unit beyond the reach of possible water splashes.
   - Install the unit where it will not be adversely affected by atmospheric pressure, temperature, humidity, sunlight, dust, ventilation, salt air, sulfur, or other such harmful substances.
   - Protect the unit against instability, vibration, or impact (including during transportation).
   - Do not leave the unit in locations with combustible airborne materials such as combustible anesthetic gases mixed with oxygen, nitrogen suboxide and air, or combustible disinfecting agents or cleaning agents mixed with air.
   - Do not install the unit where chemical products are stored or where gases may be emitted.
   - To avoid accidents due to damage to the main unit and accessories, keep the unit away from flames or fire.
   - If you are not going to use the unit for an extended period of time, remove the power cord from the wall outlet.
2. The Sonicator Plus 920 may be susceptible to interference originating from shortwave diathermy units operating in close proximity to it. Avoid operating the Sonicator Plus 920 adjacent to and simultaneously with operating shortwave devices. Keep at least 5 feet (1.5 m) away from operating shortwave diathermy devices.
3. Connect the line cord to the back of the Sonicator Plus 920. (See Figure 3.1) Make sure that the power switch is in the Off position.
4. Grasp the plug of the line cord (ME 9203) and insert it into a grounded wall outlet that is rated between 100–240 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 920 **to a power supply rated differently than that described above.**
5. The line cord comes equipped with a standard 3–prong plug. This plug provides grounding for the Sonicator Plus 920. Do not defeat its purpose by using 3–to–2 prong adapters or any other means of attaching to a wall outlet.
6. Line up the key at the top applicator cable connector with the slot on the round receptacle located on the front of the Sonicator Plus 920. (See Figure 3.2) The side with the arrow on it is up so you can see it. Please note: only ultrasound applicators labeled for use on the Sonicator Plus 920 (9201 and 9202) should be used, others are unacceptable. To avoid malfunctions or accidents, do not handle the ultrasound applicator roughly.
7. Place the applicator onto the applicator cradle. (See Figure 3.3)
8. Plug the electrode cables (ME 2266) into the electrode cable connections as seen in Figure 3.2. Each cable has an arrow on it. Place the arrow facing up and then press into the connector.
9. **Do not use sharp objects to operate the membrane panel switches or touch screen.** If the tough outer layer of the membrane is broken, moisture may leak into the switches resulting in switch failure. Using objects other than finger tips may damage the screen.
10. Once you have verified proper functioning of your Sonicator Plus 920, using the instructions in Section 4, please register the warranty for your Sonicator Plus 920 on line at *http://www.mettlerelectronics.com/product-registration/*.

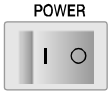
Figure 3.1— Sonicator Plus 920, Back View—
Mains Power Switch and Line Cord Connection

Figure 3.2— Sonicator Plus 920, Front View—
Electrode Cable and Ultrasound Applicator Connections

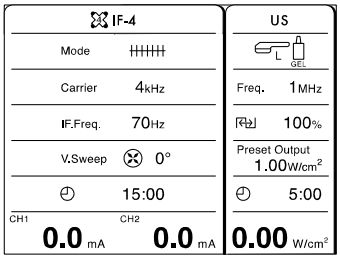
Figure 3.3—Sonicator 920 with ultrasound applicator cradle

3.2 Customizing the Optional Settings

The Sonicator Plus 920 has a number of options that the user can set to regulate the volume of the buzzer and determine the lighting of the LCD screen. This section will guide you through the process.

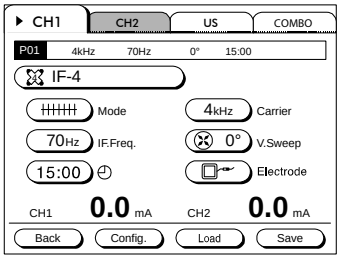


1. Turn on the mains power switch by pressing "**I**" icon on switch.

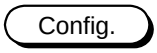


2. When you first turn the Sonicator Plus 920 on, the default parameters for each of the two stimulation channels and the ultrasound channel are displayed. (The original default stimulation program is for interferential.

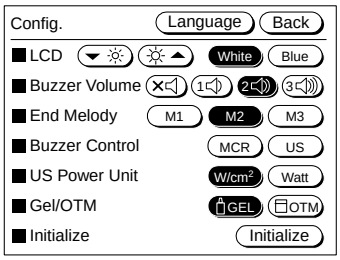
3. Press any one of the channel selectors at the top of the screen.



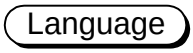
4. You will then see the setup for that channel.



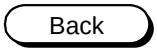
5. Press the "Config." button on the touch screen panel.



6. You will then see the "Config." screen. After you are done with setting the various options you will always press "Back" and the Sonicator Plus 920 will save your changes to memory so that the next time you turn on the unit it will remember your custom settings.



7. Touching the "Language" key allows you to select one of 11 languages for the menus: English, German, French, Italian, Spanish, Portuguese, Finnish, Swedish, Turkish, Greek, or Chinese. Once you select the desired language, press the back key to return to the "Config." Menu.



8. Press the "Back" key to return to the setup menu.

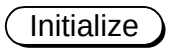
9. To select the desired volume for the buzzer, press any one of the four selectors.

10. Use the "M" selectors to pick one of three end-of-treatment sounds. You will hear your selection, when you press the selector.

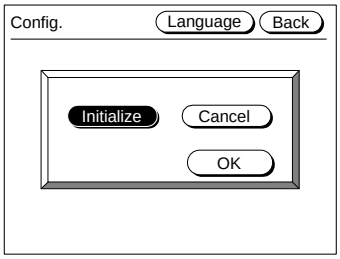
11. You can determine whether you will get beeps when you lose contact for either microcurrent (MCR) or ultrasound (US). You will get a submenu asking whether you want the beep on or off for that kind of treatment.

12. Use this selector to determine the units in which you would like to see ultrasound output displayed.

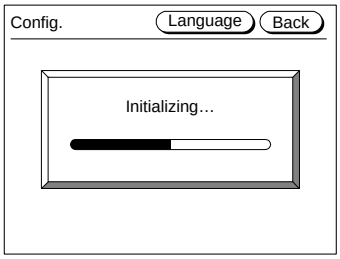
13. Use this selector to tell the Sonicator Plus 920 whether you are using an ultrasound gel (GEL) or some other less efficient couplant (OTM).



14. The “Initialize” key will erase all the initial settings and stored programs and reset the unit to the factory-set values. Do not initialize the system if you wish to preserve your stored treatment program settings.



15. This is the initialization screen. Press “Cancel” and then “OK” if you do not wish to reset all of the user-controlled settings.



16. When you press “Initialize” and then “OK” the initialization begins. When it is complete, the unit will reset itself, beep twice and return to the startup menu.

3.3 EMC Guidance

- Medical electronic devices are designed to ensure electromagnetic compatibility (EMC). These devices must be installed and used in accordance with the EMC information provided in the following section.
- Portable and mobile RF communications devices may affect medical electronic devices.
- Cable lengths:
  1) Ultrasound probe (L): 5.9 feet, (1.8 m)
  2) Electrode cable: 6.9 feet, (2.1 m)
  3) Power supply cord: 8 feet, (2.44 m)
  4) Ultrasound probe (S): 5.9 feet, (1.8 m)
  5) HV/DC probe: 6.9 feet (2.09 m)
- If accessories other than those supplied as spare parts by the manufacturer are used, the emission of this instrument may increase and immunity may be reduced.
- Do not place this instrument next to or on top of another device when using it. If it has to be placed next to or on top of another device, check that this instrument and the device function properly before use.

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., Incorporated as replacement parts for internal or external components, may result in increased EMISSIONS or decreased IMMUNITY of the Sonicator Plus 920.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Sonicator Plus 920 is intended for use in the electromagnetic environment specified below. The customer or the user of the Sonicator Plus 920 should assure it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	This unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	This unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The Sonicator Plus 920 is intended for use in the electromagnetic environment specified below. The customer or the user of the Sonicator Plus 920 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air		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	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line (s) to line (s) ±2 kV line (s) to earth		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		Mains power quality should be that of a typical commercial or hospital environment. If the user of the Sonicator Plus 920 requires continued operation during power mains interruptions, it is needed that the Sonicator Plus 920 be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	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 920 is intended for use in the electromagnetic environment specified below. The customer or the user of the Sonicator Plus 920 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Sonicator Plus 920, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 GHz	3 Vrms	$d = 1.2\sqrt{P}$
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, [a] should be less than the compliance level in each frequency range.[b] 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.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Sonicator Plus 920 is used exceeds the applicable RF compliance level above, the Sonicator Plus 920 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 920.

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

Recommended separation distances between portable and mobile RF communications equipment and the Sonicator Plus 920

The Sonicator Plus 920 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Sonicator Plus 920 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Sonicator Plus 920 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 two stimulation channels with ultrasound	Reset allowed as long as failure safe

Section 4—Operating Instructions

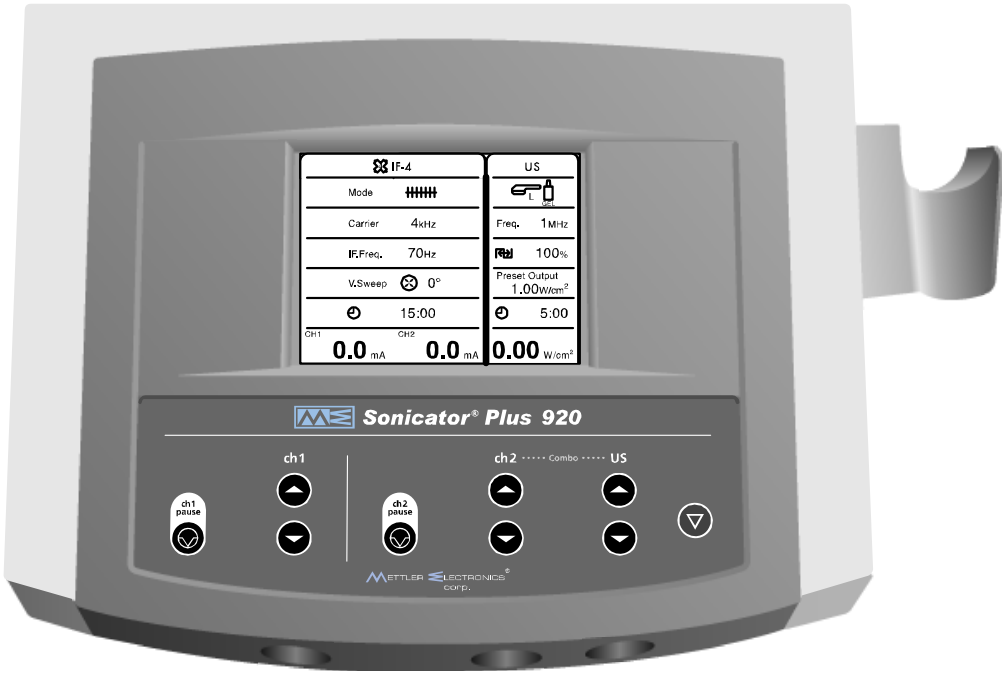


Figure 4.1—Membrane panel and touch-sensitive screen

4.1 A Note about Electrodes

To ensure safe operation of the Sonicator Plus 920, 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 V 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 over the electrodes.
5. To avoid skin irritation due to high current density, do not use electrodes smaller in surface area than the 2" in diameter V Trode self-adhesive electrode (ME 2702).
6. Do not use conductive carbon electrodes with this product.
7. Do not use self-adhesive electrodes with the Direct Current mode. Use sponge type electrodes with plain tap water moistening the sponges.
8. 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 that the current density increases rapidly when diameter decreases.

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

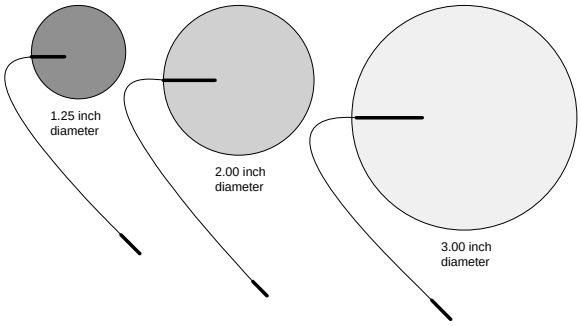


Figure 4.2—Electrode Sizes and Current Density

4.2 General Operating Instructions:

Before you start...

a) Review precautions, contraindications and side effects/adverse reactions listed in Section 5.

b) Use Mettler Electronics electrodes to ensure safe and effective operation.

c) Verify connection of the line cord to a grounded wall receptacle and the Sonicator Plus 920.

d) For ultrasound and combination therapy make sure that the applicator is securely connected to the Sonicator Plus 920. Use only applicators designated for use with this product. (9201 and 9202)

e) For combination therapy, make sure the electrode cable marked with a "4" is attached to electrode cable connection for Channel 2. Plug your dispersive electrode into the red-tipped lead wire marked "combo". The black tipped lead wire is not connected to anything.

f) For electrical stimulation, connect electrode cables (ME 2266) into the electrode connections for the channels that are going to be used. There is an arrow on the top of the connector which always faces up when you plug in the cable.

g) For waveforms that have polarity such as DC, microcurrent and high voltage, the black-tipped electrode cable with the black stripe on the cable is negative. The side with the red-tipped lead wire with no black stripe is positive.

h) The Sonicator Plus 920 will retain in memory the last treatment performed on any stimulation channel or on ultrasound.

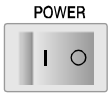
i) If you attempt to increase the stimulation intensity without electrodes connected to the patient, you will get a double beep, the intensity does not increase and the time will not begin to count down. Check whether the electrodes are properly attached before using the Sonicator Plus 920.

j) The unit responds to the button pressed first. If another button is pressed while one button is still depressed, the first operation continues. Release the first button, and then press the button you want to activate next.

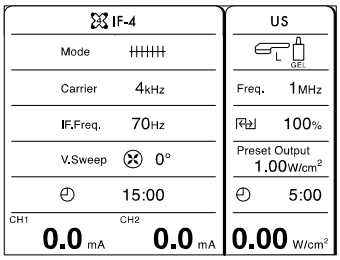
k) Make sure that the electrodes are not touching each other before starting a treatment. If you attempt to turn up the output when electrodes are too close or touching, the intensity will not go up and the timer will not start. As soon as the problem is corrected, the Sonicator Plus 920 will begin to respond to the intensity control button.

l) Note: Descriptions of the symbols used on controls are in Section 2.

4.3 Quick Set-up for Electrical Stimulation

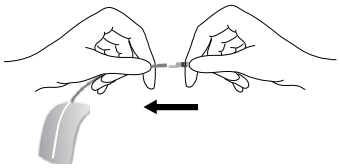


1. Turn on the mains power switch located on the back of the unit by pressing "**I**" icon on switch.

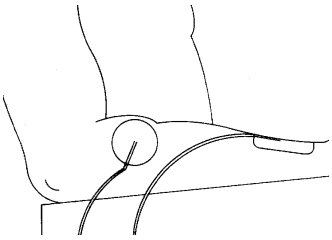


2. When you first turn the Sonicator Plus 920 on, the default parameters stimulation and ultrasound are displayed.

3. Plug in the stimulation cables into the receptacles marked "ch1" and "ch2".



4. Plug the cable into the electrode.



5. Stick the electrodes on the patient. You will need two electrodes for each channel.

6. If the treatment that you want to run is displayed, adjust the intensity and start treatment for the stimulation channel that you are using by pressing the "Up" arrow for that channel on the control panel.

7. If you attempt to adjust the intensity of a channel with no electrodes stuck on the patient the intensity display will not go up and the treatment will not start. If you lose contact while the treatment is running, "CH1 Error1" will be displayed. If the electrode cable is broken or the electrode is not making good contact with the patient, you will have similar symptoms.

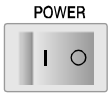
CH1 Error 1

8. To clear an error press the "pause" key for the affected channel and then you can attempt to restart the treatment by adjusting the intensity up after you have resolved the problem.

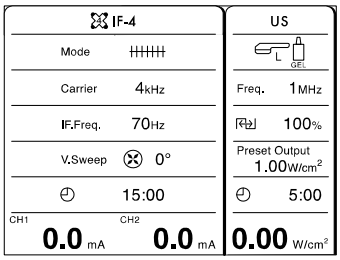
9. Pressing "pause" will stop that specific channel and not change all of the parameters including remaining treatment time.

10. Pressing "stop" on the control panel will stop output on all channels and on ultrasound. Treatment time will reset to the originally requested value.

4.4 Quick Set-up for Therapeutic Ultrasound

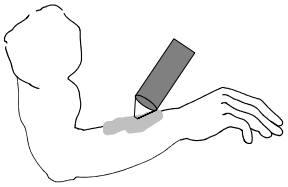


1. Turn on the mains power switch located on the back of the unit by pressing "**I**" icon on switch.

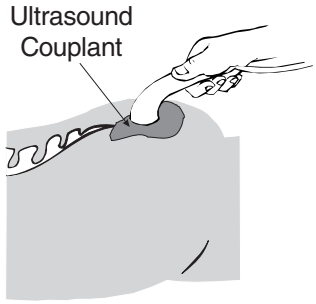


2. When you first turn the Sonicator Plus 920 on, the default parameters for each of the two stimulation channels and the ultrasound channel are displayed.

3. For ultrasound, plug the ultrasound applicator into the receptacle labeled "US".



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

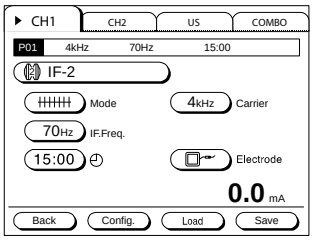


5. Couple the applicator to the treatment area by keeping the entire surface of the applicator in contact with the gel that has been applied to the patient. This will ensure an efficient delivery of therapeutic ultrasound to the patient. Green LEDs on either side of the applicator will light when coupling is achieved.

6. Adjust the intensity level for the ultrasound. If you just press the "US" intensity control once, the preset output intensity will be delivered.

7. If you hear an intermittent beeping sound or the indicator light on the applicator goes out, there is inadequate coupling to the patient. Reapply gel and treatment will resume again when coupling is established.

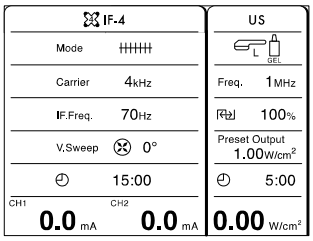
8. Pressing "Stop" on the control panel will stop output on all channels and on ultrasound, but will not reset the treatment parameters to their default values. Treatment time will also display remaining time on the timers. If channels 1 and/or 2 are running, return the treatment intensity to "0.00" and all ultrasound output will stop.



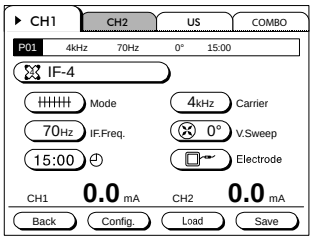
9. At this point you may adjust any of the treatment parameters or just go to the next step.

10. Adjust the intensity of the channel that you are using and start treatment by pressing the "Up" arrow on the control panel.

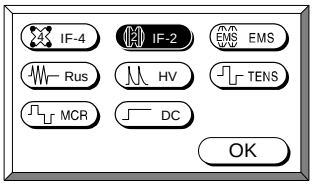
4.5 Using Saved Programs



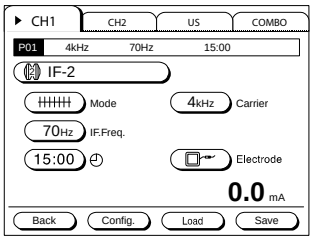
11. Pick the channel that you want to use by pressing the touch screen.



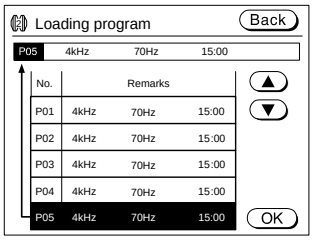
12. Once the treatment setup screen is displayed you can change the waveform by pressing the waveform selector on the screen.



13. Pick the waveform that you wish to use and then press ok. *Please note: There are stored programs for each of the waveforms, ultrasound and combination therapy.*

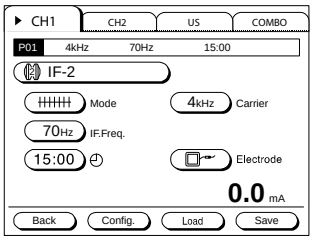


14. Press the "Load" button.



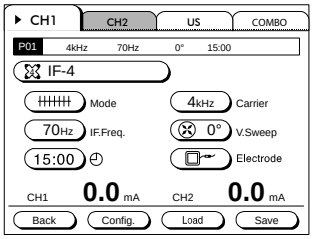
15. Press the program that you would like to use.

16. When the program that you would like to use is highlighted, press "OK".

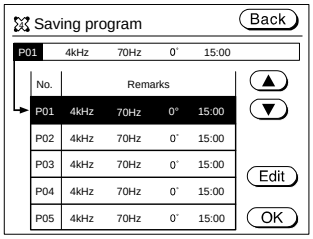


17. This symbol will be displayed next to the waveform to indicate the Preset or user-defined "Free" program that has been selected.

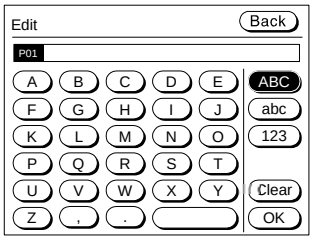
4.6 Saving a Treatment Protocol



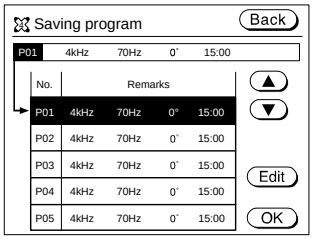
1. Choose the channel you want to use. Then, set the treatment parameters that you would like to retain in memory in the treatment setup mode. Press the "Save" button to go to the screen where you will save the protocol.



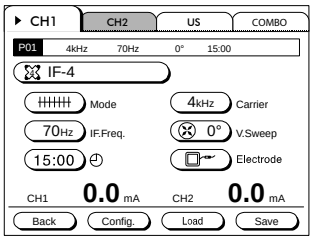
2. Press the line number where you would like to save the protocol. Press "Edit" to add a remark.



3. Use the key board to add text that describes the protocol that you are saving. Press "OK" when you see the text that best describes the protocol that you are saving. Pressing "Clear" will back up the cursor to retype a letter or number. Pressing "Back" will send you back to the previous screen.



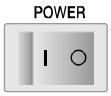
4. The text you input will show in the program space that you are saving into. Pressing "OK" will enter save that protocol into the program space that you have selected.



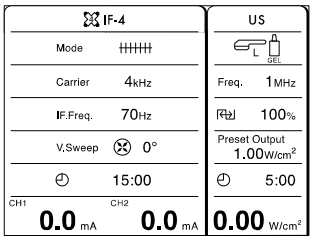
5. You will then go back to the treatment screen and you can then use the protocol or program a new one.

6. Adjust the intensity and start treatment for the channel that you are using by pressing the "Up" arrow on the control panel.

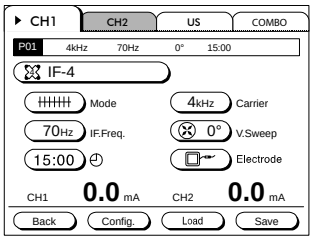
4.7 4-Pole Interferential Stimulation Set-up Procedure



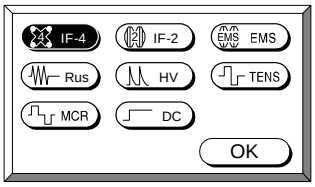
1. Turn on the mains power switch located on the back of the unit by pressing "**I**" icon on switch.



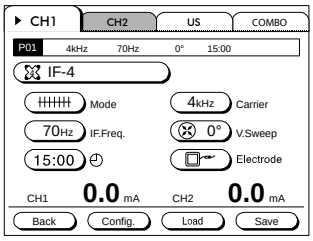
2. When you first turn the Sonicator Plus 920 on, the default parameters for each of the two stimulation channels and the ultrasound channel are displayed. Once you have used the unit, it will remember the last treatments that you completed.



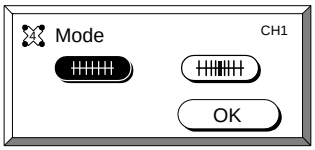
3. On the touch screen, press the channel key of the channel you would like to run interferential therapy. For this mode you will need 2 channels, so simply pressing the CH1 or CH2 selector will pick the one you want. If IF-4 (Interferential) is not displayed, press the waveform button on the screen.



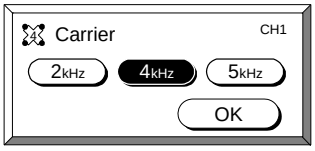
4. Press the "IF-4" button on the touch screen display to highlight it and then press "OK".



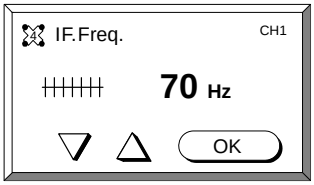
5. You can then change any of the five additional parameters shown by the buttons on the screen.



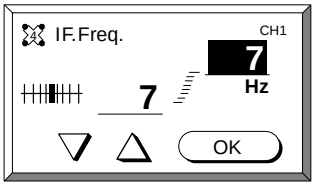
6. Select the mode by pressing the symbol that describes what you want to do, either continuous or modulated frequency. Press "OK" to select the option and return to the treatment screen.



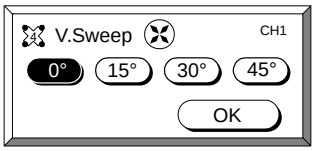
7. Press the Carrier button and select whichever carrier frequency that you would like to use. Press "OK" to accept the value and return to the treatment screen.



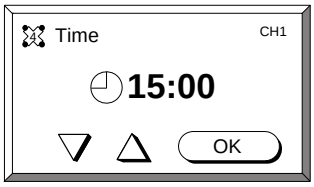
8. Adjust the IF frequency by pressing the "IF. Freq." button on the treatment screen. If continuous is selected, the top screen will be displayed. Use the up and down arrows to adjust the frequency and then "OK" when you are finished.



If frequency modulation is selected, the lower screen will be displayed. Press the lower number or the upper number to adjust the frequency modulation sweep range. Use the arrows to raise or lower the values and then press "OK" when you are finished.

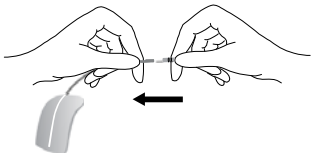


9. Select the Vector Sweep angle by pressing the "V. Sweep" button and the value that you would like to use. Press "OK" to accept the value and return to the treatment screen.

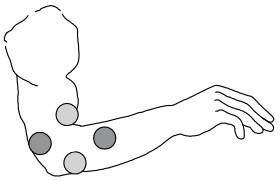


10. Select the treatment time by pressing the up and down buttons and then the up and down arrows on the touch screen display. You can choose from 1-60 minutes. Press "OK" to accept the value and return to the treatment screen.

11. Plug two electrode cables into channels 1 & 2.



12. Plug the cables into four electrodes.



13. Stick the electrodes on the patient. You will need two electrodes for each channel, four in total.

14. Adjust the intensity and start treatment for either channel 1 or 2 by pressing the "Up" arrow on the control panel. The other channel in the channel will go up simultaneously. The maximum intensity is 100 mA peak.

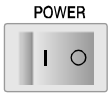
CH1 Error 1

15. If you attempt to adjust the intensity of a channel with no electrodes stuck on the patient you will get an "Error 1". You will also get this message if the electrode cable is broken or the electrode is not making good contact with the patient. Output will stop.

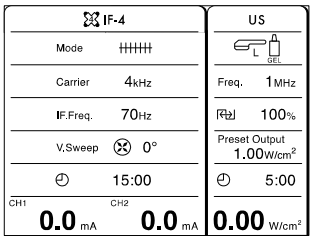
16. To clear an error press the "Pause" key for the affected channel will allow you to correct the problem with electrode contact. Once the electrodes are secure, you can then adjust the intensity up again.

17. Pressing "stop" on the control panel will stop output on all channels and on ultrasound. Treatment time will reset to the originally requested value.

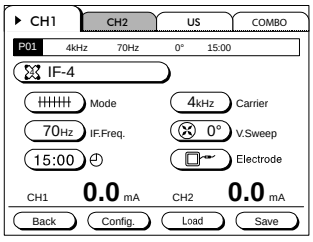
4.8 2-Pole Interferential Stimulation Set-up Procedure



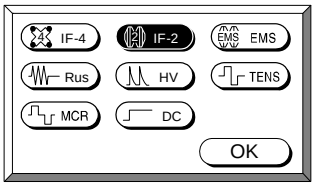
1. Turn on the mains power switch located on the back of the unit by pressing "**I**" icon on switch.



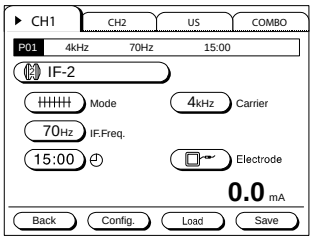
2. When you first turn the Sonicator Plus 920 on, the default parameters for each of the two stimulation channels and the ultrasound channel are displayed. Press the channel that you would like to use.



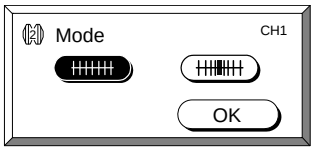
3. Press the waveform button to change the waveform to go to the waveform selection screen.



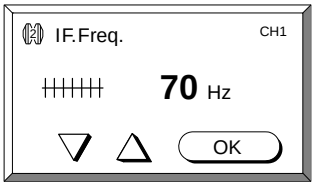
4. Press the "IF-2" button on the touch screen display to highlight it and then press "OK".

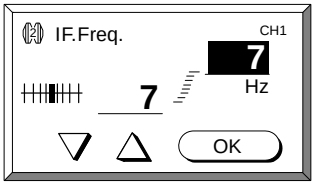


5. Press any of the four additional buttons on the screen to select which parameters you would like to change. Press "OK" to select the option and return to the treatment screen.



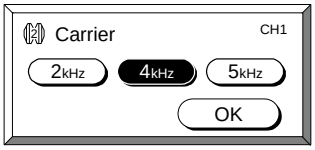
6. Select the mode by pressing the symbol that describes what you want to do, either continuous or modulated frequency. Press "OK" to select the option and return to the treatment screen.





7. Adjust the IF frequency by pressing the "IF. Freq." button on the treatment screen. If continuous is selected, the top screen will be displayed. Use the up and down arrows to adjust the frequency and then "OK" when you are finished.

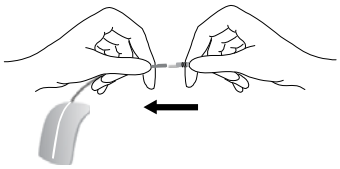
   If frequency modulation is selected, the lower screen will be displayed. Press the lower number or the upper number to adjust the frequency modulation sweep range. Use the arrows to raise or lower the values and then press "OK" when you are finished.



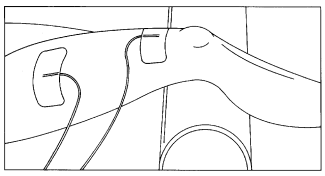
11. Press the Carrier button and select whichever carrier frequency that you would like to use. Press "OK" to accept the value and return to the treatment screen.

12. Select the treatment time by pressing the up and down buttons and then the up and down arrows on the touch screen display. You can choose from 1-60 minutes. Press "OK" to accept the value and return to the treatment screen.

8. Plug one electrode cable into the channel corresponding to the channel that you have programmed.



10. Plug the cable into two electrodes.



11. Stick the electrodes on the patient. You will need two electrodes.

12. Adjust the intensity and start treatment for the channel that you are using. The maximum intensity is 100 mA peak.

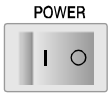
18. If you attempt to adjust the intensity of a channel with no electrodes stuck on the patient you will get an "Error 1". You will also get this message if the electrode cable is broken or the electrode is not making good contact with the patient. Output will stop.

CH1 Error 1

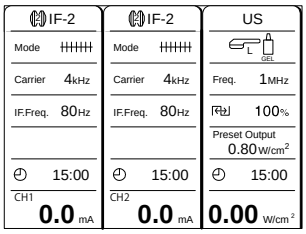
19. To clear an error press the "Pause" key for the affected channel will allow you to correct the problem with electrode contact. Once the electrodes are secure, you can then adjust the intensity up again.

20. Pressing "stop" on the control panel will stop output on all channels and on ultrasound. Treatment time will reset to the originally requested value.

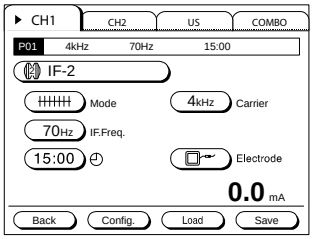
4.9 EMS Stimulation Set-up Procedure



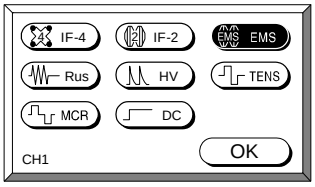
1. Turn on the mains power switch located on the back of the unit by pressing "**I**" icon on switch.



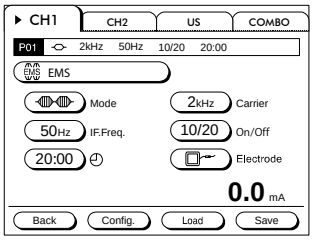
2. When you first turn the Sonicator Plus 920 on, the stored parameters for each of the two stimulation channels and the ultrasound channel are displayed. Press the channel key for the channel that you would like to run.



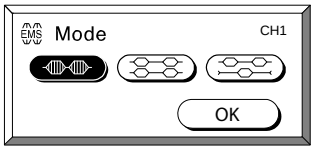
3. Press the waveform button to change the waveform to go to the waveform selection screen.



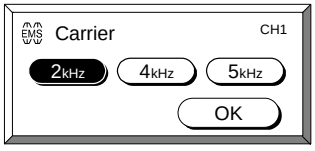
4. Press the "EMS" button on the touch screen display to highlight it and then press "OK".



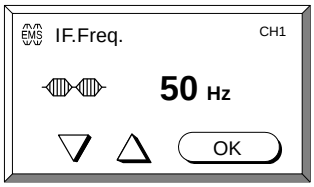
5. Press any of the five additional buttons on the screen to select which parameters you would like to change.



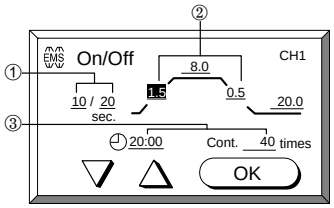
9. Select the mode by pressing the symbol that describes what you want to do: 1-channel surge, 2-channel surge or reciprocation. Press "OK" to select the option and return to the treatment screen.



6. Select the carrier frequency by pressing the symbol on the left then pressing the up and down arrows on the touch screen display. You can choose from 2, 4 or 5 kHz. Press "OK" to select the option and return to the treatment screen.



7. Select the beat frequency by pressing the symbol on the left then pressing the up and down arrows on the touch screen display. You can choose from 20-250 beats. Press "OK" to select the option and return to the treatment screen.



8. To change the On, Off and Ramp times or the number of cycles: Press the corresponding key to open the sub window and change the parameters.

   ①Touch to select the value of On-time or Off-time, and set the new value using the up and down arrows. * *This setting automatically changes the number of cycles.*

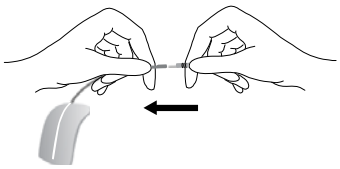
   ②To change the Ramp-up time, Ramp-down time, or Hold time, touch to select the value you want changed and set the new value using the up

and down arrows. * *The Ramp-up time, Ramp-down time, and Hold-time can be specified within the range of the On-time.*

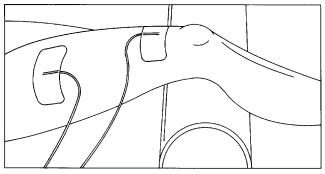
③ To set the treatment time or the number of muscle contractions, touch to select the value you want changed, and set the new value using the up and down arrows. * *This setting automatically changes the respective values.* Press "OK" to select the option and return to the treatment screen.

9. Select the treatment time by pressing the up and down buttons and then the up and down arrows on the touch screen display. You can choose from 1-60 minutes. Press "OK" to accept the value and return to the treatment screen.

10. Plug one electrode cable into the channel corresponding to the channel that you have programmed.



12. Plug the cable into two electrodes.



13. Stick the electrodes on the patient. You will need two electrodes.

14. Adjust the intensity and start treatment for the channel that you are using. The maximum intensity is 100 mA peak.

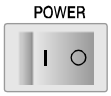
CH1 Error 1

15. If you attempt to adjust the intensity of a channel with no electrodes stuck on the patient you will get an "Error 1". You will also get this message if the electrode cable is broken or the electrode is not making good contact with the patient. Output will stop.

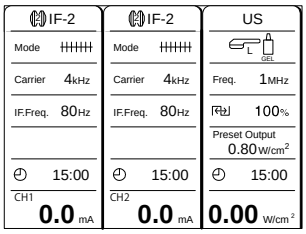
16. To clear an error press the "Pause" key for the affected channel will allow you to correct the problem with electrode contact. Once the electrodes are secure, you can then adjust the intensity up again.

17. Pressing "stop" on the control panel will stop output on all channels and on ultrasound. Treatment time will reset to the originally requested value.

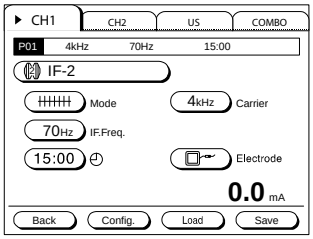
4.10 Russian Stimulation Set-up Procedure



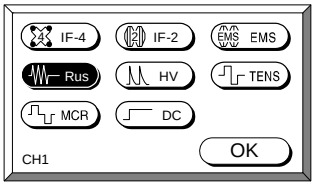
1. Turn on the mains power switch located on the back of the unit by pressing "**I**" icon on switch.



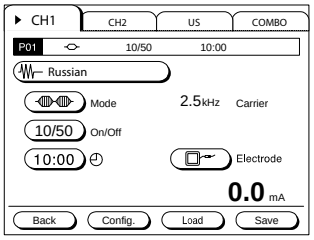
2. When you first turn the Sonicator Plus 920 on, the stored parameters for each of the two stimulation channels and the ultrasound channel are displayed. Press the channel key for the channel that you would like to run.



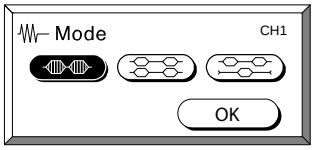
3. Press the waveform button to change the waveform to go to the waveform selection screen.



4. Press the "Rus" button on the touch screen display to highlight it and then press "OK".

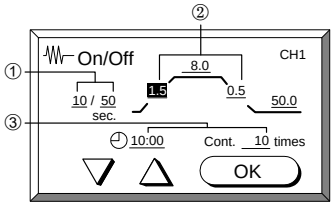


5. Press any of the three additional buttons on the screen to select which parameters you would like to change.



6. Select the mode by pressing the symbol that describes what you want to do: 1-channel surge, 2-channel surge (co-contraction) or reciprocation (alternate). Press "OK" to select the option and return to the treatment screen.

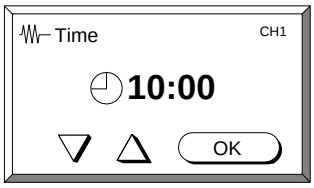
7. To change the On, Off and Ramp times or the number of cycles: Press the corresponding key to open the sub window and change the parameters.



①Touch to select the value of On-time or Off-time, and set the new value using the up and down arrows. * *This setting automatically changes the number of cycles.*

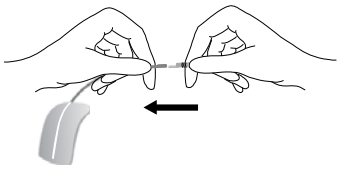
②To change the Ramp-up time, Ramp-down time, or Hold time, touch to select the value you want changed and set the new value using the up and down arrows. * *The Ramp-up time, Ramp-down time, and Hold-time can be specified within the range of the On-time.*

③ To set the treatment time or the number of muscle contractions, touch to select the value you want changed, and set the new value using the up and down arrows. * *This setting automatically changes the respective values.* Press "OK" to select the values and return to the treatment screen.

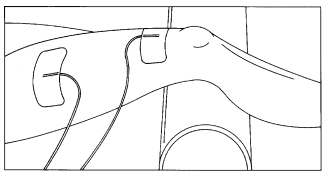


8. Select the treatment time by pressing the up and down buttons and then the up and down arrows on the touch screen display. You can choose from 1-60 minutes. Press "OK" to accept the value and return to the treatment screen.

7. Plug one electrode cable into the channel corresponding to the channel that you have programmed.



8. Plug the cable into two electrodes.



9. Stick the electrodes on the patient. You will need two electrodes.

10. Adjust the intensity and start treatment for the channel that you are using. The maximum intensity is 100 mA peak.

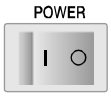
CH1 Error 1

11. If you attempt to adjust the intensity of a channel with no electrodes stuck on the patient you will get an "Error 1". You will also get this message if the electrode cable is broken or the electrode is not making good contact with the patient. Output will stop.

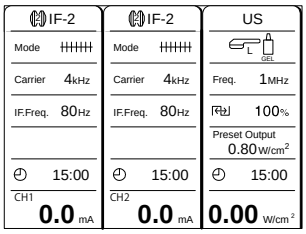
12. To clear an error press the "Pause" key for the affected channel will allow you to correct the problem with electrode contact. Once the electrodes are secure, you can then adjust the intensity up again.

13. Pressing "stop" on the control panel will stop output on all channels and on ultrasound. Treatment time will reset to the originally requested value.

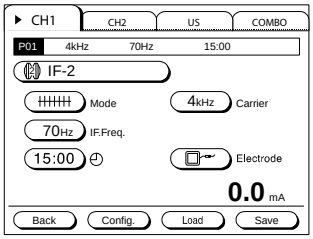
4.11 High Voltage Stimulation Set-up Procedure



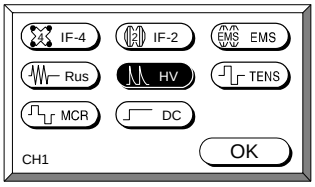
1. Turn on the mains power switch located on the back of the unit by pressing "**I**" icon on switch.



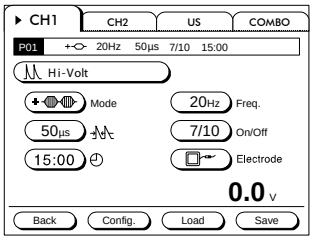
2. When you first turn the Sonicator Plus 920 on, the stored parameters for each of the two stimulation channels and the ultrasound channel are displayed. Press the channel key for the channel that you would like to run.



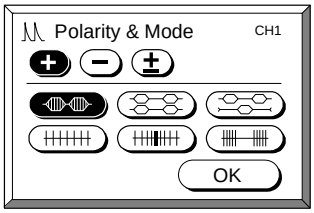
3. Press the waveform button to change the waveform to go to the waveform selection screen.



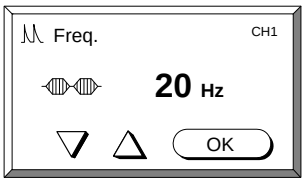
4. Press the "HV" button on the touch screen display to highlight it and then press "OK".

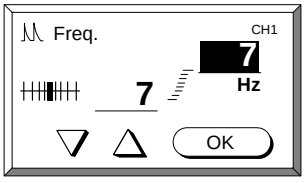


5. Press any of the five additional buttons on the screen to select which parameters you would like to change.



6. Select the mode by pressing the symbol that describes what you want to do. You can select the polarity and; 1-channel surge, 2-channel surge (co-contraction), reciprocation (alternate), continuous, frequency modulation or burst options. Press "OK" to select the options and return to the treatment screen.

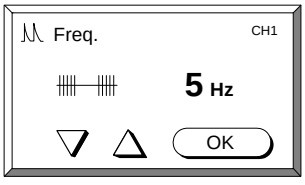


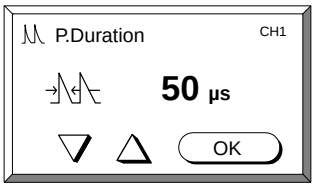


7. Adjust the pulse frequency by pressing the "Freq." button on the treatment screen. If continuous is selected, the top screen will be displayed. Use the up and down arrows to adjust the frequency and then "OK" when you are finished.

   If frequency modulation is selected, the middle screen will be displayed. Press the lower number or the upper number to adjust the frequency modulation sweep range. Use the arrows to raise or lower the values and then press "OK" when you are finished.

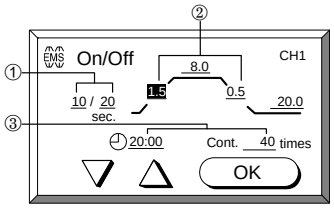
   If burst mode is selected, the lower screen will be displayed. You can select a burst mode frequency from 1 to 7 bps. Use the arrows to raise or lower the values and then press "OK" when you are finished.





8. Adjust the pulse width by pressing the "µs" button on the touch screen. Use the up and down arrows to adjust the value and then press "OK" when you are finished.

9. If you have chosen an amplitude modulation option: change the On, Off and Ramp times or the number of cycles: Press the corresponding key to open the sub window and change the parameters.



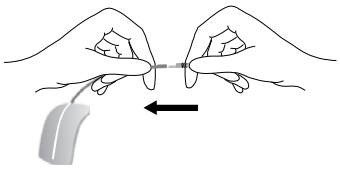
①Touch to select the value of On-time or Off-time, and set the new value using the up and down arrows. * *This setting automatically changes the number of cycles.*

②To change the Ramp-up time, Ramp-down time, or Hold time, touch to select the value you want changed and set the new value using the up and down arrows. * *The Ramp-up time, Ramp-down time, and Hold-time can be specified within the range of the On-time.*

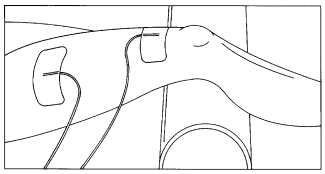
③ To set the treatment time or the number of muscle contractions, touch to select the value you want changed, and set the new value using the up and down arrows. * *This setting automatically changes the respective values*. Press "OK" to select the option and return to the treatment screen.

10. Select the treatment time by pressing the up and down buttons and then the up and down arrows on the touch screen display. You can choose from 1-60 minutes. Press "OK" to accept the value and return to the treatment screen.

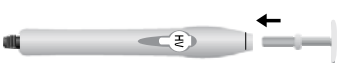
11. Plug one electrode cable into the channel corresponding to the channel that you have programmed.



12. Plug the cable into two electrodes.

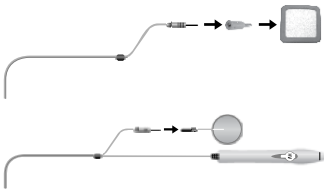


13. Stick the electrodes on the patient. You will need two electrodes.



14. You may also use the High Voltage Probe. First snap in the electrode size that you want to use for your application.

15. Place the sponge over the disc and then cover with the fabric cover to hold the sponge in place. Moisten with tap water. Press the button on the high voltage probe when you want to deliver stimulation.



16. Use either a self-adhesive electrode or the sponge electrode supplied with the high voltage probe as a dispersive electrode. Secure a sponge electrode to the patient with a Velcro strap.

17. Adjust the intensity and start treatment for the channel that you are using. The maximum intensity is 150 volts peak.

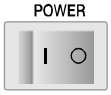
CH1 Error 1

18. If you attempt to adjust the intensity of a channel with no electrodes stuck on the patient you will get an "Error 1". You will also get this message if the electrode cable is broken or the electrode is not making good contact with the patient. Output will stop.

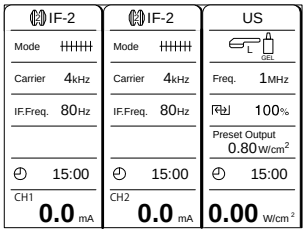
19. To clear an error press the "Pause" key for the affected channel will allow you to correct the problem with electrode contact. Once the electrodes are secure, you can then adjust the intensity up again.

20. Pressing "stop" on the control panel will stop output on all channels and on ultrasound. Treatment time will reset to the originally requested value.

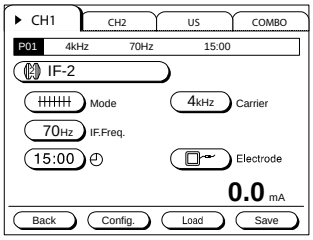
4.12 TENS Stimulation Set-up Procedure



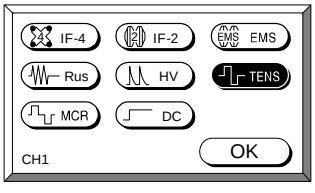
1. Turn on the mains power switch located on the back of the unit by pressing "**I**" icon on switch.



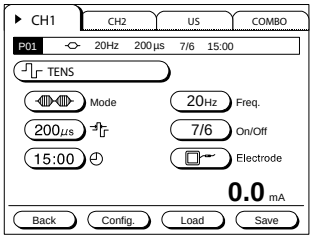
2. When you first turn the Sonicator Plus 920 on, the stored parameters for each of the two stimulation channels and the ultrasound channel are displayed. Press the channel key for the channel that you would like to run.



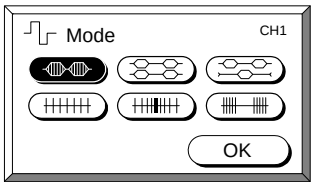
3. Press the waveform button to change the waveform to go to the waveform selection screen.



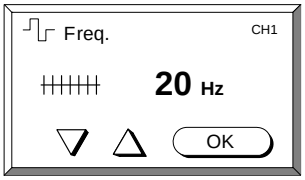
4. Press the "TENS" button on the touch screen display to highlight it and then press "OK".



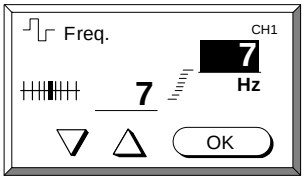
5. Press any of the five additional buttons on the screen to select which parameters you would like to change.



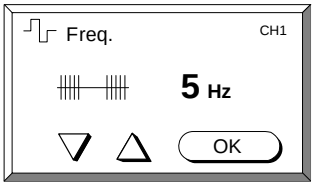
6. Select the mode by pressing the symbol that describes what you want to do. You can select 1-channel surge, 2-channel surge (co-contraction), reciprocation (alternate), continuous, frequency modulation or burst options. Press "OK" to select the options and return to the treatment screen.



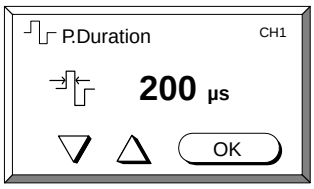
7. Adjust the pulse frequency by pressing the "Freq." button on the treatment screen. If continuous is selected, the top screen will be displayed. Use the up and down arrows to adjust the frequency and then "OK" when you are finished.



If frequency modulation is selected, the middle screen will be displayed. Press the lower number or the upper number to adjust the frequency modulation sweep range. Use the arrows to raise or lower the values and then press "OK" when you are finished.

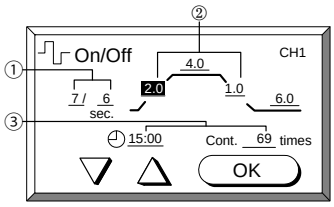


If burst mode is selected, the lower screen will be displayed. You can select a burst mode frequency from 1 to 7 bps. Use the arrows to raise or lower the values and then press "OK" when you are finished.



8. Adjust the pulse width by pressing the "µs" button on the touch screen. Use the up and down arrows to adjust the value and then press "OK" when you are finished.

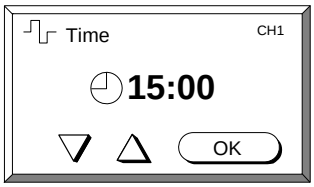
9. If you have chosen an amplitude modulation option: change the On, Off and Ramp times or the number of cycles: Press the corresponding key to open the sub window and change the parameters.



①Touch to select the value of On-time or Off-time, and set the new value using the up and down arrows. * *This setting automatically changes the number of cycles.*

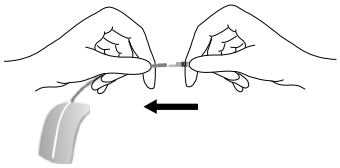
②To change the Ramp-up time, Ramp-down time, or Hold time, touch to select the value you want changed and set the new value using the up and down arrows. * *The Ramp-up time, Ramp-down time, and Hold-time can be specified within the range of the On-time.*

③ To set the treatment time or the number of muscle contractions, touch to select the value you want changed, and set the new value using the up and down arrows. * *This setting automatically changes the respective values.* Press "OK" to select the option and return to the treatment screen.

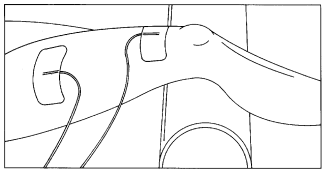


10. Select the treatment time by pressing the up and down buttons and then the up and down arrows on the touch screen display. You can choose from 1-60 minutes. Press "OK" to accept the value and return to the treatment screen.

11. Plug one electrode cable into the channel corresponding to the channel that you have programmed.



12. Plug the cable into two electrodes.



13. Stick the electrodes on the patient. You will need two electrodes.

14. Adjust the intensity and start treatment for the channel that you are using. The maximum intensity is 100 mA peak.

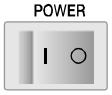
CH1 Error 1

15. If you attempt to adjust the intensity of a channel with no electrodes stuck on the patient you will get an "Error 1". You will also get this message if the electrode cable is broken or the electrode is not making good contact with the patient. Output will stop.

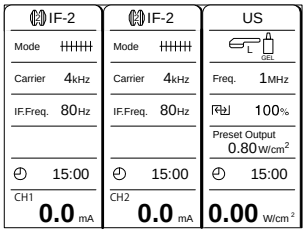
16. To clear an error press the "Pause" key for the affected channel will allow you to correct the problem with electrode contact. Once the electrodes are secure, you can then adjust the intensity up again.

17. Pressing "stop" on the control panel will stop output on all channels and on ultrasound. Treatment time will reset to the originally requested value.

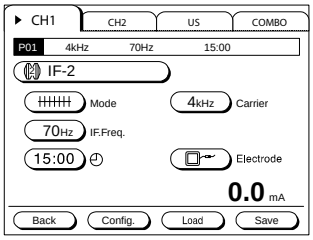
4.13 Microcurrent Stimulation Set-up Procedure



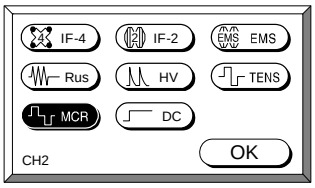
1. Turn on the mains power switch located on the back of the unit by pressing "**I**" icon on switch.



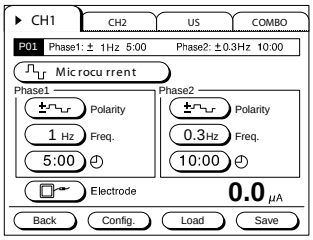
2. When you first turn the Sonicator Plus 920 on, the stored parameters for each of the two stimulation channels and the ultrasound channel are displayed. Press the channel key for the channel that you would like to run.



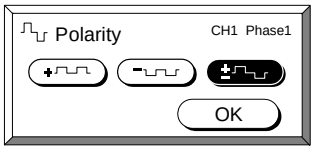
3. Press the waveform button to change the waveform to go to the waveform selection screen.



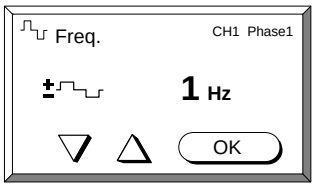
4. Press the “MCR” button on the touch screen display to highlight it and then press “OK”.



5. Press any of the six additional buttons on the screen to select which parameters you would like to change. You can program two treatment phases with different parameters for microcurrent. The optional fields are the same for each phase of the treatment, but may have different parameters.



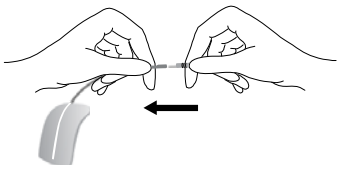
6. Select the polarity by pressing the polarity button. Press the polarity that you would like to set and then “OK” when you are finished.



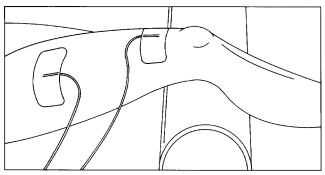
7. Adjust the pulse frequency by pressing the “Freq.” button on the treatment screen. If continuous is selected, the top screen will be displayed. Use the up and down arrows to adjust the frequency and then “OK” when you are finished.

8. Select the treatment time by pressing the up and down buttons and then the up and down arrows on the touch screen display. You can choose from 1-60 minutes. Press “OK” to accept the value and return to the treatment screen.

9. Plug one electrode cable into the channel corresponding to the channel that you have programmed.



10. Plug the cable into two electrodes.



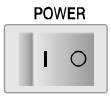
11. Stick the electrodes on the patient. You will need two electrodes.

12. Adjust the intensity and start treatment for the channel that you are using. The maximum intensity is 100 mA peak.

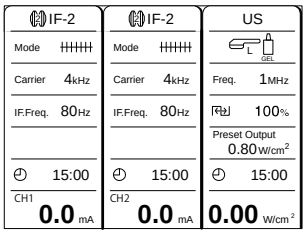
13. To momentarily stop this channel use the “Pause” key for this channel. Once you are ready to resume, adjust the intensity up again.

14. Pressing "stop" on the control panel will stop output on all channels and on ultrasound. Treatment time will reset to the originally requested value.

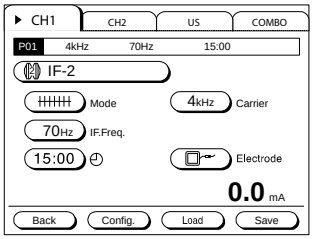
4.14 DC Stimulation Set-up Procedure



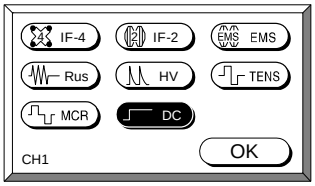
1. Turn on the mains power switch located on the back of the unit by pressing "**I**" icon on switch.



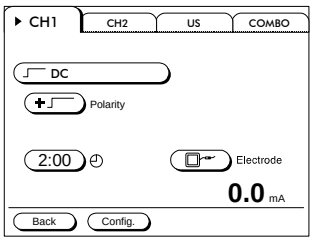
2. When you first turn the Sonicator Plus 920 on, the stored parameters for each of the two stimulation channels and the ultrasound channel are displayed. Press the channel key for the channel that you would like to run.



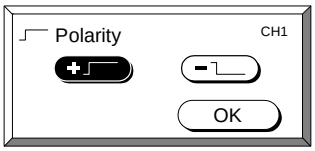
3. Press the waveform button to change the waveform to go to the waveform selection screen.



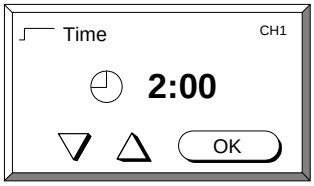
4. Press the "HV" button on the touch screen display to highlight it and then press "OK".



5. Press any of the two additional buttons on the screen to select which parameters you would like to change.

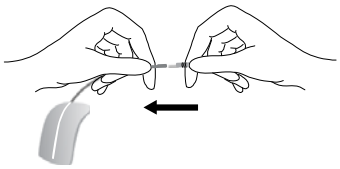


6. Select the polarity by pressing either the "+" or "-"button. Press "OK" to accept the polarity and return to the treatment screen.

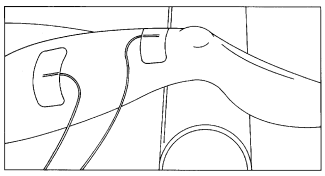


7. Select the treatment time by pressing the up and down buttons and then the up and down arrows on the touch screen display. You can choose from 1-60 minutes. Press "OK" to accept the value and return to the treatment screen.

8. Plug one electrode cable into the channel corresponding to the channel that you have programmed.



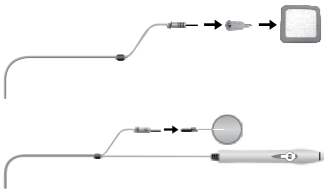
9. Plug the cable into two electrodes.



10. Use sponge electrodes with DC current. Self-adhesive electrodes will be permanently ruined if you attempt to use them. Moisten the sponges with tap water.

11. You may also use the High Voltage Probe. First snap in the electrode size that you want to use for your application.

12. Place the sponge over the disc and then cover with the fabric cover to hold the sponge in place. Moisten with tap water. Press the button on the high voltage probe when you want to deliver stimulation.



13. Use a sponge electrode supplied with the high voltage probe as a dispersive electrode. Secure a sponge electrode to the patient with a Velcro strap.

14. Use caution when applying direct current since it can be extremely irritating and can even cause burns if not applied properly. The maximum intensity with this waveform is 20 mA. When you use the high volt probe, intensity will be limited to 2 mA to prevent high current densities.

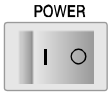
CH1 Error 1

15. If you attempt to adjust the intensity of a channel with no electrodes stuck on the patient you will get an "Error 1". You will also get this message if the electrode cable is broken or the electrode is not making good contact with the patient. Output will stop.

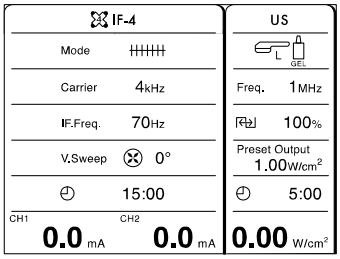
16. To clear an error press the "Pause" key for the affected channel will allow you to correct the problem with electrode contact. Once the electrodes are secure, you can then adjust the intensity up again.

17. Pressing "stop" on the control panel will stop output on all channels and on ultrasound. Treatment time will reset to the originally requested value.

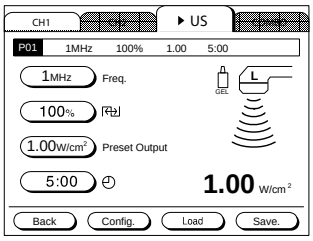
4.15 Therapeutic Ultrasound Setup Procedure



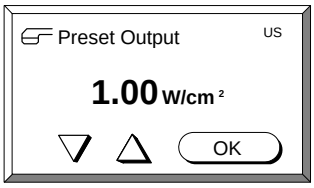
1. Turn on the mains power switch located on the back of the unit by pressing "**I**" icon on switch.



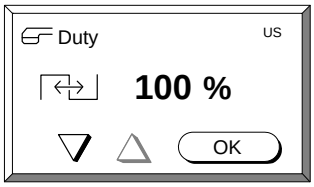
2. When you first turn the Sonicator Plus 920 on, the default parameters for each of the two stimulation channels and the ultrasound channel are displayed. Press the tab at the top labeled "US" to see in detail all of the options



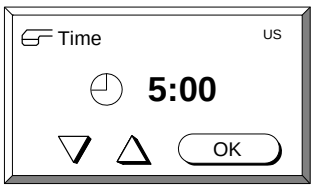
3. There are four options that on the left side of the screen that you can change.



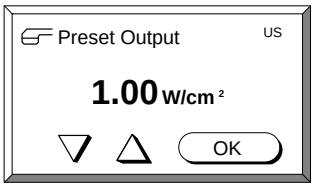
4. Press the "MHz" button to change from 1 to 3 MHz Use the arrow keys to change the value and press "OK" to accept the displayed value.



5. Press the "%" button to the duty cycle for the pulsed ultrasound. Use the arrow keys to change the value and press "OK" to accept the displayed value.

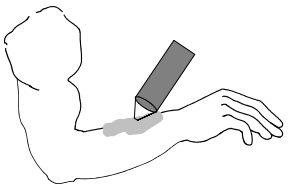


6. Select the treatment time by pressing the up and down buttons and then the up and down arrows on the touch screen display. You can choose from 1-30 minutes. Press "OK" to accept the value and return to the treatment screen.

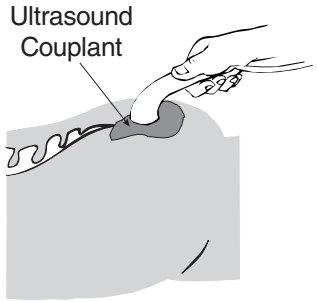


7. Adjust the preset output by pressing the up and down arrow keys to raise or lower the output. Press "OK" to accept the value and return to the treatment screen.

8. For ultrasound, plug the ultrasound applicator into the receptacle labeled "US".



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



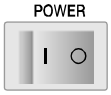
10. Couple the applicator to the treatment area by keeping the entire surface of the applicator in contact with the gel that has been applied to the patient. This will ensure an efficient delivery of therapeutic ultrasound to the patient. Green LEDs on either side of the applicator will light when coupling is achieved.

11. Adjust the intensity level for the ultrasound. If you just press the "US" intensity control once, the preset output intensity will be delivered. You can then raise or lower the output intensity by using the arrow keys labeled "US".

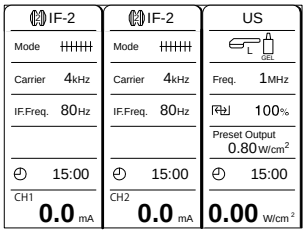
12. If you hear an intermittent beeping sound or the indicator light on the applicator goes out, there is inadequate coupling to the patient. Reapply gel and treatment will resume again when coupling is established.

13. Pressing "Stop" on the control panel will stop output on all channels and on ultrasound, but will not reset the treatment parameters to their default values. Treatment time will also display remaining time on the timers. If channels 1 and/or 2 are running, return the treatment intensity to "0.00" and all ultrasound output will stop.

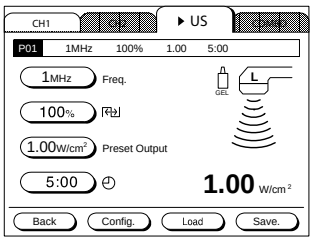
4.16 Combination Therapy Setup Procedure



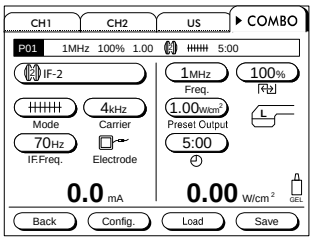
1. Turn on the mains power switch located on the back of the unit by pressing "**I**" icon on switch.



2. When you first turn the Sonicator Plus 920 on, the default parameters for each of the two stimulation channels and the ultrasound channel are displayed. Press the tab at the top labeled "US" to see in detail all of the options



3. Press the "COMBO" button to display the options available for combination therapy. Channel



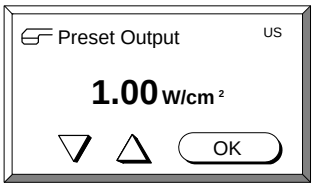
4. This screen shows all of the options available for ultrasound and electrical stimulation. Press the waveform button to change the stimulation waveform for combination therapy.

5. Press the waveform button to select the waveform that you would like to use. Choose from IF-2, high volt, TENS, microcurrent or DC continuous. Press "OK" when you are finished.

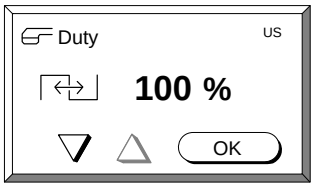
6. For high voltage, TENS and 2-pole interferential waveforms select the Mode, either continuous or frequency modulation. For the high voltage and TENS waveforms the burst mode is also available. For microcurrent, high volt and DC, you set the polarity. Microcurrent and high volt also have a bipolar mode. Press "OK" when you are finished.

7. Set the pulse duration for high voltage or TENS

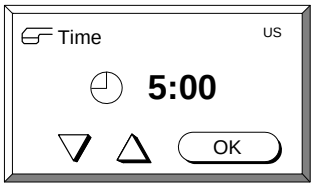
8. For the continuous, frequency modulated and burst modes input the treatment frequency.



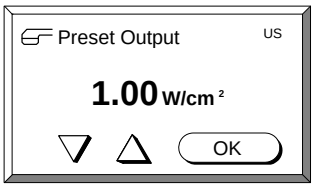
9. Press the "MHz" button to change from 1 to 3 MHz Use the arrow keys to change the value and press "OK" to accept the displayed value.



10. Press the "%" button to the duty cycle for the pulsed ultrasound. Use the arrow keys to change the value and press "OK" to accept the displayed value.

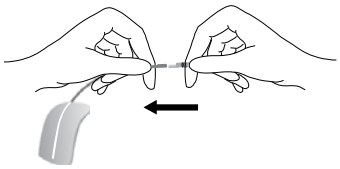


11. Select the treatment time by pressing the up and down buttons and then the up and down arrows on the touch screen display. You can choose from 1-30 minutes. Press "OK" to accept the value and return to the treatment screen.



12. Adjust the preset output by pressing the up and down arrow keys to raise or lower the output. Press "OK" to accept the value and return to the treatment screen.

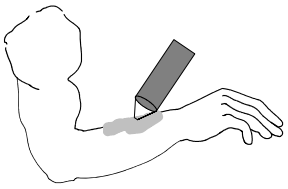
13. For ultrasound, plug the ultrasound applicator into the receptacle labeled "US" and plug the electrode cable into.



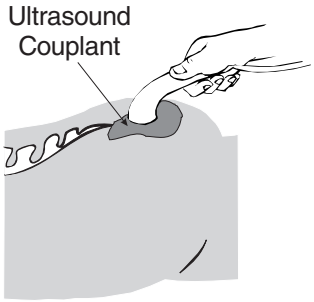
14. Plug red-tipped cable end into one electrode. If it is an original cord set #4, the red-tipped end will be marked with "Comb.".

15. Apply the dispersive electrode to the patient.

⚠WARNING Apply the dispersive electrode in such a manner to prevent transthoracic stimulation.



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



17. 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. Green LEDs on either side of the applicator will light when coupling is achieved after treatment is initiated.

18. Adjust the intensity level for the ultrasound. If you just press the "US" intensity control once, the preset output intensity will be delivered. You can then raise or lower the output intensity by using the arrow keys labeled "US". Then adjust the stimulation intensity.
19. If you hear an intermittent beeping sound or the indicator light on the applicator goes out, there is inadequate coupling to the patient. Reapply gel and treatment will resume again when coupling is established.

20. Pressing "Stop" on the control panel will stop output on all channels and on ultrasound, but will not reset the treatment parameters to their default values. Treatment time will also display remaining time on the timers. If channels 1 and/or 2 are running, return the treatment intensity to "0.00" and all ultrasound output will stop.

4.17 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 920, review contraindications, warnings, precautions and Side Effects/Adverse Reactions in sections 5.6, 5.7, 5.9 and 5.10 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.

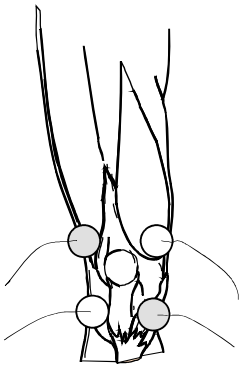


Figure 4.3—Quadpolar Electrode Placement Technique

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.

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 "EMS" and "Russian" waveforms are usually applied to the body using the bipolar technique.

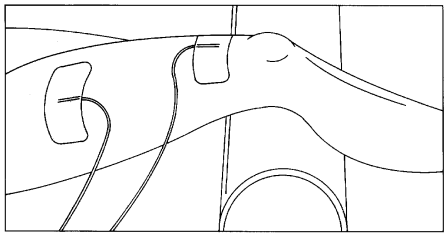


Figure 4.4—Bipolar Electrode Placement Technique

   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 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.

5. Monopolar electrode application techniques

   Monopolar techniques may be used with the "High Voltage"and "TENS" waveforms. The smaller, active, electrode 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 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.

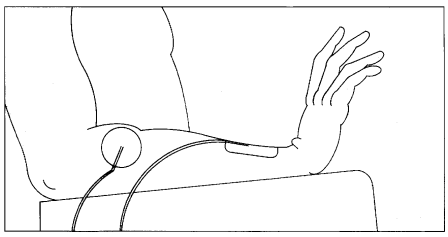


Figure 4.5—Monopolar Electrode Placement Technique

   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.

6. 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.

Section 5—Indications, Contraindications, Precautions and Adverse Reactions

5.1 Indications for Therapeutic Ultrasound

Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as;

1. Relief of pain, muscle spasms and joint contractures:
2. Relief of pain, muscle spasms and joint contractures that may be associated with:
   - Adhesive capsulitis
   - Bursitis with slight calcification
   - Myositis
   - Soft tissue injuries
   - Shortened tendons due to past injuries and scar tissues
3. Relief of pain, muscle spasms and joint contractures resulting from:
   - Capsular tightness
   - Capsular tightening

5.2 Indications for Pain Management

4-Pole Interferential, 2-Pole Interferential, TENS and Microcurrent waveforms

1. Symptomatic relief of chronic intractable pain
2. Post-traumatic pain
3. Post-surgical pain

5.3 Indications for Neuromuscular Stimulation

EMS, TENS, Hi Volt and Russian waveforms

1. Relaxation of muscle spasms
2. Increase local blood circulation
3. Prevention or retardation of disuse atrophy
4. Muscle re-education
5. Maintaining or increasing range of motion
6. Immediate post surgical stimulation of calf muscles to prevent venous thrombosis

5.4 Indications for Muscle Spasm

DC *(Direct Current)* waveform

1. Relaxation of muscle spasm

5.5 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. Do not apply therapeutic ultrasound over a healing fracture.
12. Ultrasound should not be applied over the epiphyseal areas (bone growth centers) of the bones of growing children.

5.6 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 transcerebrally (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 or shortwave therapy systems.

5.7 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.

5.8 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 920 have been designed to allow the practitioner to perform underwater treatments without exposing the hands to ultrasound.
3. If a patient complains of periosteal pain (deep, achy pain) during ultrasonic treatment, intensity should be reduced to a comfortable level.
4. Any bleeding tendency is increased by heating because of the increase in blood flow and vascularity of the heated tissues. Care, therefore, should be used in treating patients with therapeutic ultrasound who have hemorrhagic diatheses or bleeding disorders.
5. Moving technique of the applicator should be used when applying therapeutic ultrasound at intensities greater than 0.5 W/cm² 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 920 should be adequately grounded and safety tested to insure safe operation with the Sonicator Plus 920.

5.9 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. Added safety is provided if the patient cannot touch any grounded metal parts.
3. Limit treatment intensity to 50 mA (50 V) or less, when using small electrodes (2" diameter), to reduce the chance of thermal burns due to high current density. Avoid current densities exceeding 2 mA/cm² when using this device.
4. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
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. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
14. Effectiveness for pain management is highly dependent upon patient selection by a person qualified in the management of pain patients.
15. The Sonicator Plus 920 should be used only with electrode cables and electrodes recommended for use by Mettler Electronics Corp.
16. Turn on the Sonicator Plus 920 before applying electrodes to the patient.

5.10 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 920

1. The Sonicator Plus 920 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 V Trode package insert for the use and care of the electrodes supplied with the Sonicator Plus 920.
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 920 applicator. Rinse the applicator thoroughly after disinfection to remove any residue. You can disinfect the stainless steel part of ultrasound applicator, with a cloth moistened with an approximately 70% alcohol solution. The Sonicator Plus 920 applicator *is neither autoclavable nor* gas sterilizable.

6.2 Routine Maintenance

1. To assure accurate performance of the Sonicator Plus 920, calibration verification of ultrasonic output should be performed on an annual basis. Refer to the Maintenance Manual for guidance on this procedure.
2. Standard medical electrical safety checks should be performed annually by qualified biomedical engineers or technicians trained to perform these procedures.
3. Inspect electrode cables and associated connectors for damage.
4. Inspect ultrasound applicator for cracks, since they may allow ingress of conductive fluid(s). The ultrasound probe is waterproof and should never be disassembled, since doing so may degrade its waterproofing or the performance of the transducer, resulting in electric shock. (IPX7)
5. Inspect the applicator cable and its connector for damage.
6. The applicator is an integral part of delivering safe and effective therapeutic ultrasound. Avoid rough handling of the ultrasound applicator since it is relatively fragile and can be damaged if dropped or otherwise abused.
7. Never open the Sonicator Plus 920. Doing so may lead to malfunctions or accidents.
8. Do not damage, break, modify, bend forcibly, tug on, twist, or bundle the electrode cord. If a heavy object is placed on the cord or it is pinched or modified, the cord may be damaged, resulting in fire, electric shock, or other accident.
9. When cleaning the unit, do not wipe using paint thinner, gasoline, kerosene, polishing powder, hot water, or chemicals to prevent discoloration of the main unit and probes. Wipe with a cloth soaked in cold water or lukewarm water and forcefully wrung.
10. If you plan to use a unit that has been left standing for some time, always check to ensure that the unit functions normally and safely.

6.3 Troubleshooting the Sonicator Plus 920

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 resolves the problem.
2. CH 1 Error 1	Appears when the current flow is interrupted (e.g., an electrode is detached from the treatment area or if there is a break in the electrode cable). The display also indicates which channel is affected. Check the electrode cable connections to make sure that they are connected. Make sure both electrodes are attached to the cables and to the patient. Try fresh electrodes and or cables to resolve this problem. Press either the error message or "Stop" to reset the treatment after checking the electrodes. Then readjust the treatment intensity by pressing the "Up" arrow to begin the treatment again.
3. CH 1 Error 2	Appears when the current level increases suddenly (e.g., the electrode is partly detached from the treatment area or moved out of position). Reattach the electrodes firmly. Press either the error message or "Stop" to reset the treatment after resolving the cause of the error. Then readjust the treatment intensity by pressing the "Up" arrow to begin the treatment again.
4. Error 3	Appears when a problem occurs in the ultrasound applicator. Check the ultrasound applicator for damage and replace if necessary. Make sure that it is firmly connected to the Sonicator Plus 920. Press either the error message or "Stop" to reset the treatment after resolving the cause of the error. Then readjust the treatment intensity by pressing the "Up" arrow to begin the treatment again.
5. Error 4	Appears when an internal connection is disconnected or similar problem has occurred. Remove the electrodes from the patient. Turn off power, and then turn back on. If the error is not resolved, the Sonicator Plus 920 requires servicing.

If problem is not addressed above, or if additional troubleshooting guidance is desired, call (800) 854-9305 or email our service department at *service@mettlerelectronics.com*.

The distributor who sold the Sonicator Plus 920 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.

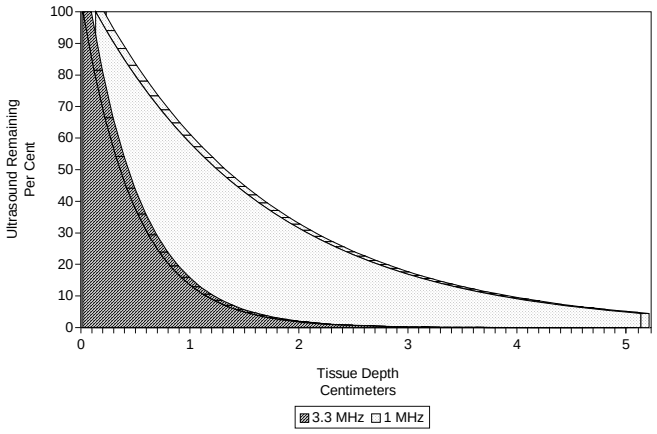


Figure 7.1—Ultrasound Absorption, Skin

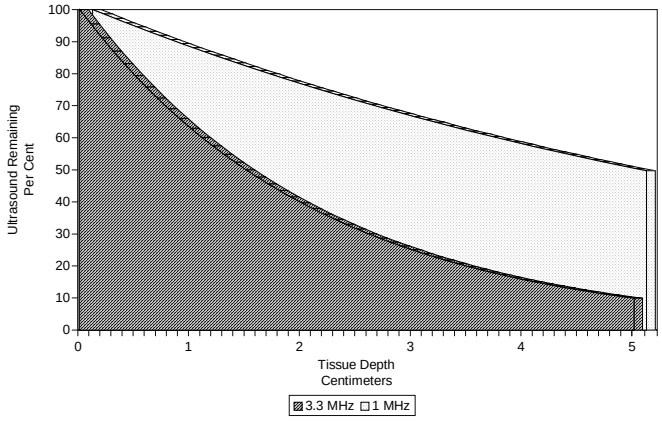


Figure 7.2—Ultrasound Absorption, Fat

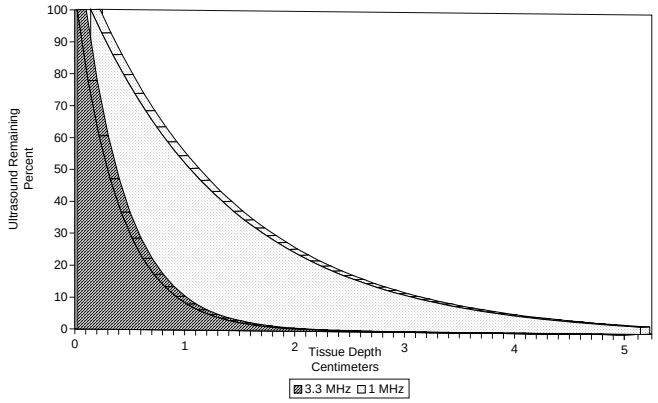


Figure 7.3—Ultrasound Absorption, Muscle with the Ultrasound Beam Perpendicular to the Muscle Fibers

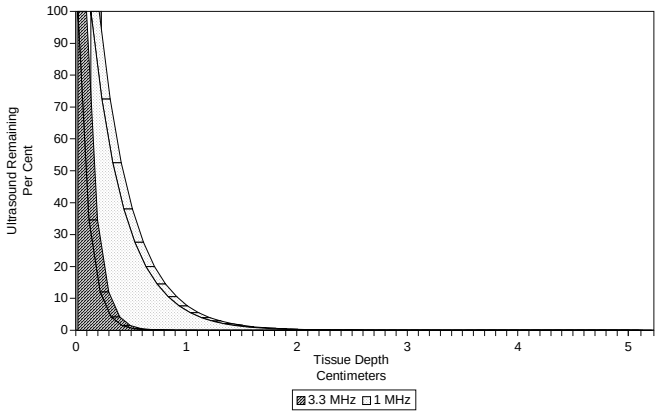
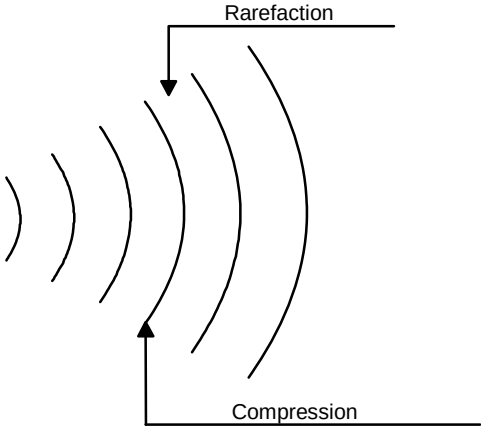


Figure 7.4—Ultrasound Absorption, Bone

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 920 uses a silicon dioxide (SiO_2 ceramic for its transducers.

Ultrasonic power is expressed in watts (W), or watts per square centimeter (W/cm²). Average intensity (W/cm²) 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 ERA (effective radiating area) is indicated on the label of each Mettler applicator. Please note: the ERA is different from the overall dimension of the applicator face.

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

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

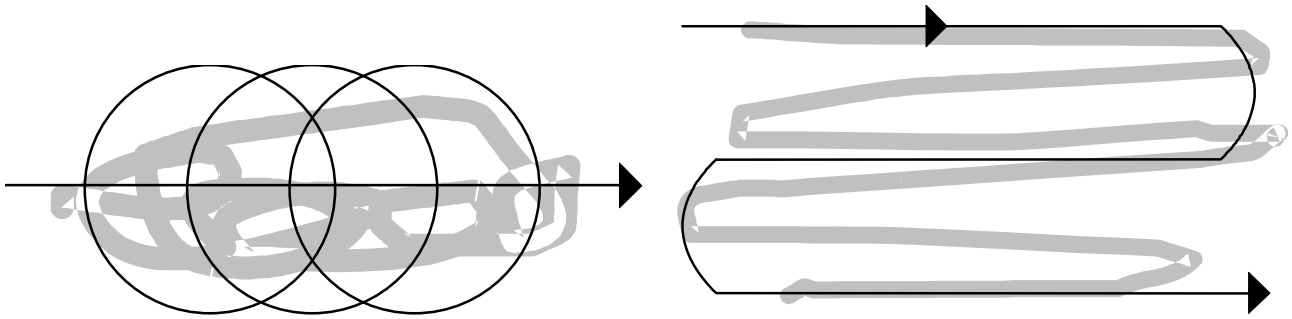


Figure 7.6—Ultrasound Application Techniques

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

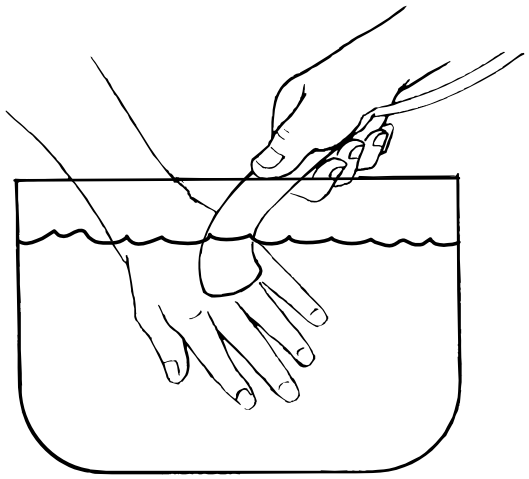


Figure 7.7 Underwater Treatment Technique

Section 8—References

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This manual has been written as a guideline for the correct use of the Sonicator Plus 920. 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:	100-240 V ~ 50/60 Hz, 95 VA
Certification:	The Sonicator Plus 920 complies with the ultrasound performance standards set forth in the Code of Federal Regulations, Title 21 (Food and Drugs), Part 1050.10
ETL and C-ETL Listed:	Model ME 920
Weight:	11 pounds
Dimensions:	4.9 in (H) x 13.6 in (W) x 10.5 in (D)
Operating	
Temperature:	+50°F to +104°F
Relative Humidity:	30 to 75 %
Atmospheric Pressure:	700 to 1060 hPa
Storage	
Temperature:	14°F to 140°F
Relative Humidity:	30 to 95%
Atmospheric Pressure:	700 to 1060 hPa
Transportation	
Temperature:	14°F to 140°F
Relative Humidity:	30 to 95%
Atmospheric Pressure:	700 to 1060 hPa
Timer Accuracy:	± 3%
Maximum Treatment Time:	60 minutes–electrical stimulation 30 minutes–ultrasound or combination therapy
Treatment Timer:	Treatment time counts down to zero. The digital timer indicates time in minutes and seconds. The timer also indicates the remaining treatment time during the "Hold" period.

9.2 Ultrasonic Generator Specifications:

Frequency:	1.0 MHz ±5% 3.0 MHz ±5%
Modes:	Continuous Pulsed—5, 10, 20, 30, 40 and 50% duty cycle
Pulse Repetition Rate:	100 Hz ±20%
Pulse Duration:	0.5, 1, 2, 3, 4 and 5 msec ±20%
Temporal Peak/ average intensity ratio:	20:1, 10:1, 5:1, 3.3:1, 2.5:1 and 2:1 ±10%
Maximum output power:	11 W (100%) with large applicator, 1 MHz, (ME 9201) 16.5 W (pulsed) with large applicator, 1 MHz, (ME 9201) 12 W (100%) with large applicator, 3 MHz, (ME 9201) 18 W (pulsed) with large applicator, 3 MHz, (ME 9201) 1.8 W (100%) with small applicator, 1 MHz, (ME 9202) 2.7 W (pulsed) with small applicator, 1 MHz, (ME 9202) 1.6 W (100%) with small applicator, 3 MHz, (ME 9202) 2.4 W (pulsed) with small applicator, 3 MHz, (ME 9202)

Maximum intensity: 2.0 W/cm² (100%)
3.0 W/cm² (pulsed mode)

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 or 3 MHz sine wave pulses are modulated. The power level is adjusted by varying the pulse amplitude. The pulse waveform shown below represents all the available pulsed options. The frequency remains the same while the on and off times vary.

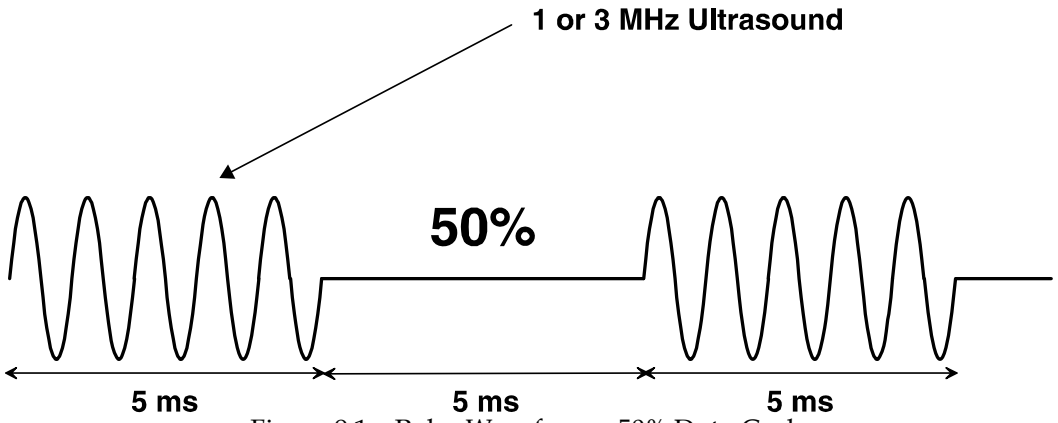

Figure 9.1—Pulse Waveform—50% Duty Cycle

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:

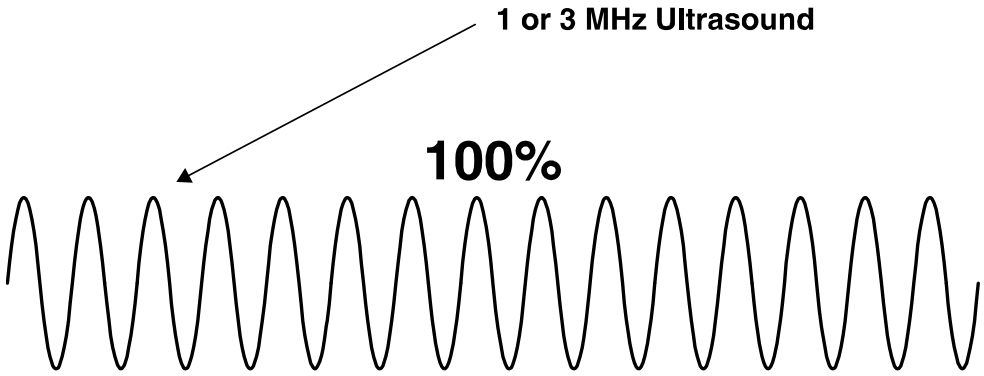

Figure 9.2—Continuous Waveform

9.3 Ultrasonic Applicator Specifications:

Individual Applicator Specifications:

Applicator Part Number	Frequency	Effective Radiating Area	Maximum Beam Non-Uniformity Ratio	Type
ME 9201	1 MHz ±5%	5.5 cm² ±20%	4.6:1	Collimated
ME 9201	3 MHz ±5%	6.0 cm² ±20%	4.2:1	Collimated
ME 9202	1 MHz ±5%	0.9 cm² ±20%	4.7:1	Divergent
ME 9202	3 MHz ±5%	0.8 cm² ±20%	4.7:1	Collimated

Spatial Pattern:

The applicator produces a collimated (cylindrical) beam with an area listed, 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 through 9.6.

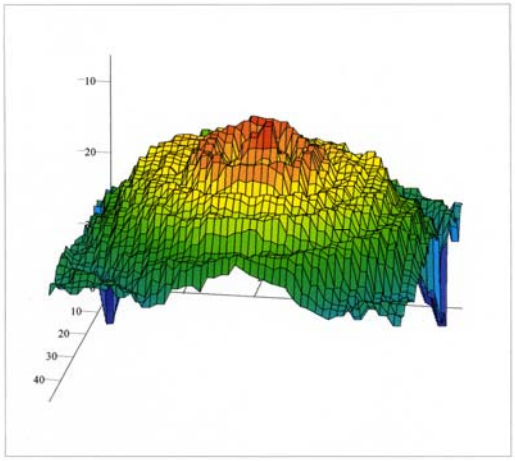

Figure 9.3—Large Applicator (1 MHz), ME 9201—Three Dimensional Beam Pattern

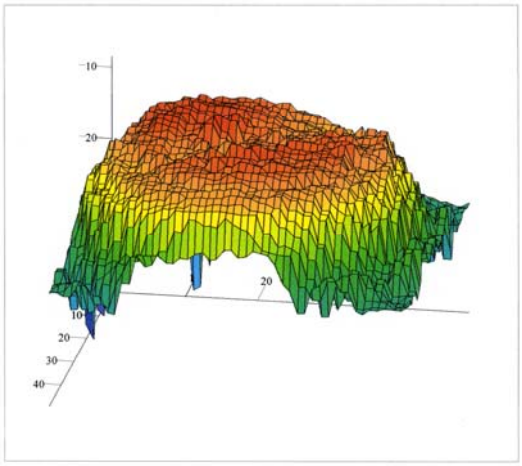

Figure 9.4—Large Applicator (3 MHz), ME 9201—Three Dimensional Beam Pattern

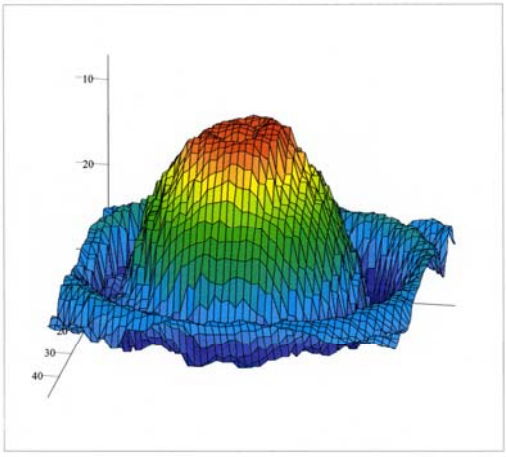

Figure 9.5—Small Applicator (1 MHz), ME 9202—Three Dimensional Beam Pattern

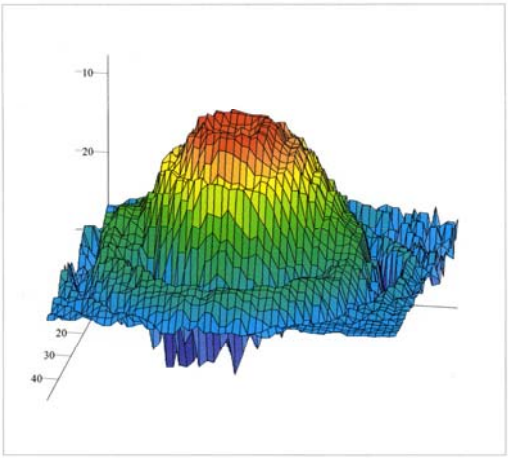

Figure 9.6—Small Applicator (3 MHz), ME 9202—Three Dimensional Beam Pattern

9.4 Waveform Specifications:

4-Pole Interferential Mode

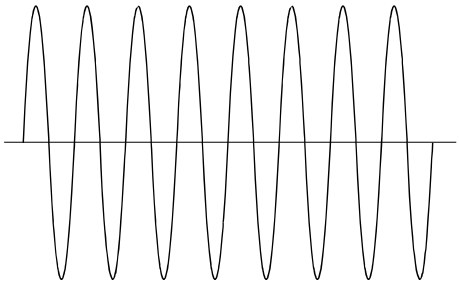

Figure 9.7—4-Pole Interferential Waveform

Waveform Type:	Sinewave
Polarity:	None
Maximum Voltage:	50 V ±20% (Peak value, 500Ω load)
Current:	0–100 mA peak, 500Ω load
Carrier Frequency:	2 kHz, 4 kHz, 5 kHz
Interference frequency	1-250 beats
Frequency Modulation:	1 to 10 in 1-beat steps, and 10 to 250 in 10-beat steps. *(For Sweep: Min. frequency → Max. frequency)*
Vector sweep angle:	0, 15, 30, 45 degrees
Available Channels:	Channels 1 & 2 together

2-Pole Interferential (Premodulated)

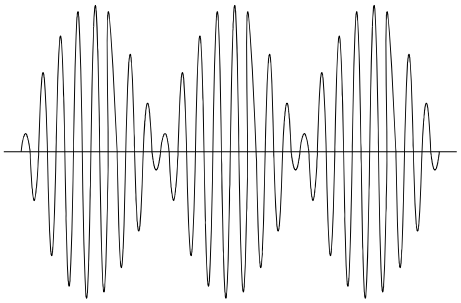

Figure 9.8—2-Pole Interferential Waveform

Waveform Type:	Amplitude modulated sine wave
Polarity:	None
Maximum Voltage:	50 V ±20% (Peak value, 500Ω load)
Current:	0–100 mA peak, 500Ω load
Carrier Frequency:	2 kHz, 4 kHz, 5 kHz
Interference frequency	1-250 beats
Frequency Modulation:	1 to 10 in 1-beat steps, and 10 to 250 in 10-beat steps. *(For Sweep: Min. frequency → Max. frequency)*
Available Channels:	All

EMS Mode

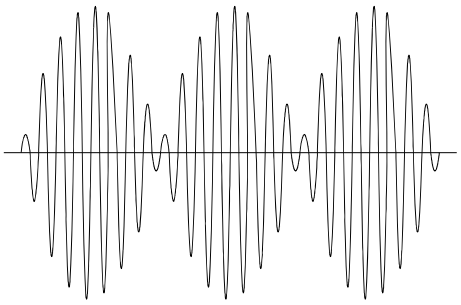

Figure 9.9—EMS Waveform

Waveform Type:	Amplitude modulated sine wave
Polarity:	None
Maximum Voltage:	50 V ±20% (Peak value, 500Ω load)
Current:	0–100 mA peak, 500Ω load
Carrier Frequency:	2 kHz, 4 kHz, 5 kHz
Interference frequency	20 to 250 beats in 10 beat steps
Amplitude Modulation Options:	Independent, Simultaneous, Alternate
On-time	1 to 30 sec (In 1-sec steps) *(includes ramp-up, hold and ramp-down times)*
Off-time	1 to 99 sec (In 1-sec steps)
Ramp-up Time	0 to 3 sec (In 0.5-sec steps)
Hold Time	0 to 30 sec (In 0.5-sec steps)
Ramp-down time	0 to 3 sec (in 0.5-sec steps)
Contraction	1 to 1,800 times
Available Channels:	All, (1 & 2 or 3 & 4 for simultaneous or alternate)

Russian Mode

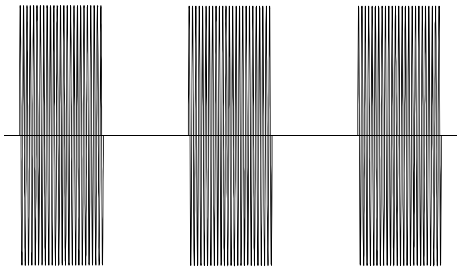

Figure 9.10—Russian Waveform

Waveform Type:	Burst modulated sine wave
Polarity:	None
Maximum Voltage:	50 V ±20% (Peak value, 500Ω load)
Current:	0–100 mA peak, 500Ω load
Frequency:	2500 Hz, Burst at 50 bps 10 ms on and 10 ms off
Available Amplitude Modulation Options:	Independent, Simultaneous, Alternate
On-time	1 to 30 sec (In 1-sec steps) *(includes ramp-up, hold and ramp-down times)*
Off-time	1 to 99 sec (In 1-sec steps)
Ramp-up Time	0 to 3 sec (In 0.5-sec steps)
Hold Time	0 to 30 sec (In 0.5-sec steps)
Ramp-down time	0 to 3 sec (in 0.5-sec steps)
Contraction	1 to 1,800 times
Available Channels:	All

Hi Volt Mode

Figure 9.11— Hi Volt Waveform

Waveform Type:	Monophasic twin peak
Polarity:	Positive, negative or both
Voltage:	0 to 150 V±20% (Peak value, 500Ω load)
Maximum Current:	300 mA peak, (Peak value, 500Ω load)
Phase Duration:	10 to 80 µs (In 10-µs steps)
Frequency:	Constant：0.5 to 200 Hz Burst: 60 Hz (Fixed) Sweep：1 to 200 Hz Independent, Simultaneous, Alternate: 20 to 200 Hz
Frequency Modulation:	Constant, Burst, Sweep
Burst frequency *2	0.5 to 7 Hz (0.5, 0.7 Hz, 1 to 7 Hz (In 1-Hz steps)).
Available Amplitude Modulation Options:	Independent, Simultaneous, Alternate
On-time *1	1 to 30 sec (In 1-sec steps) *(includes ramp-up, hold and ramp-down times)*
Off-time *1	1 to 99 sec (In 1-sec steps)
Ramp-up time *1	0 to 3 sec (In 0.5-sec steps)
Hold time *1	0 to 30 sec (In 0.5-sec steps)
Ramp-down time *1	0 to 3 sec (In 0.5-sec steps)
Contraction *1	1 to 1,800 times
Available Channels:	All

*1: May be set only in Independent, Simultaneous, or Alternate mode.

*2: This frequency to be set only in Burst mode.

TENS Mode

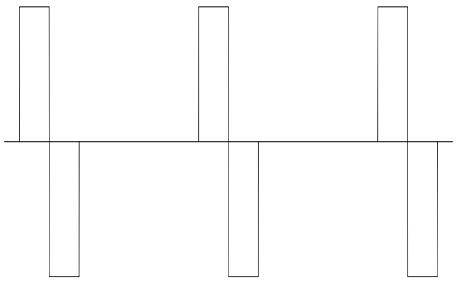

Figure 9.12—TENS Waveform

Waveform Type:	Biphasic square
Polarity:	None
Maximum Voltage:	50 V ±20% (Peak value, 500Ω load)
Current:	0 –100 mA peak, 500Ω load
Phase Duration:	50 to 300 µs (In 10-µs steps)
Frequency:	Constant： 0.5 to 250 Hz Burst: 100 Hz (Fixed) Sweep： 1 to 250 Hz Independent, Simultaneous, Alternate: 20 to 250 Hz
Frequency Modulation:	Constant and Sweep
Burst frequency *2	0.5 to 7 Hz (0.5, 0.7 Hz, 1 to 7 Hz (In 1-Hz steps)).
Available Amplitude Modulation Options:	Burst, Independent, Simultaneous, Alternate
On-time *1	1 to 30 sec (In 1-sec steps) *(includes ramp-up, hold and ramp-down times)*

Off-time *1	1 to 99 sec (In 1-sec steps)
Ramp-up time *1	0 to 3 sec (In 0.5-sec steps)
Hold time *1	0 to 30 sec (In 0.5-sec steps)
Ramp-down time *1	0 to 3 sec (In 0.5-sec steps)
Contraction *1	1 to 1,800 times
Available Channels:	All

*1: May be set only in Independent, Simultaneous, or Alternate mode.

*2: This frequency to be set only in Burst mode.

Microcurrent Mode

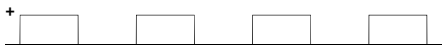

Figure 9.13—Microcurrent Waveform

Waveform Type:	Mono- or Bi-phasic square
Polarity:	Plus, minus or both
Maximum Voltage:	0.375 V ±20% (Peak value, 500Ω load)
Current:	0 to 750 µA peak, 500Ω load
Phase Duration:	Duty fixed at 50%
Frequency:	0.3 to 400 Hz (0.3, 0.5, 0.7, 1-10: set in 1 Hz increments, 10-400: set in 10 Hz increments)
Available Channels:	All

Direct Current Mode

Waveform Type:	Continuous DC
Polarity:	Plus or minus
Maximum Voltage:	10 V ±20% (500Ω load)
Current:	0 to 20 mA peak, 500Ω load
Available Channels:	All

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. You can also reach our Customer Service Department via email at *mail@mettlerelectronics.com*.

10.2 Sonicator Plus 920 Accessories

Catalogue #	Item Description
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 with Aloe Vera, 1 gallon with pump and pour off bottle
1864	Sonigel Lotion with Aloe Vera, 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")
2027	Pin to banana adapter plug set to be used with ME 2260 or 2201 electrode cables. Four each, gray.
2221	EZ Trode – 2" diameter round self–adhering, reusable electrodes with lead wires; case of ten packages (four electrodes/pkg.)
2222	EZ Trode – 3" 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 ten packages (four electrodes/pkg.)
2266	Electrode cable for the Sonicator Plus 920

2267	Optional high volt / DC probe, pin-to-banana adapter and 3 ½" x 7" sponge electrode for the Sonicator Plus 920
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.)
73	Three-shelf mobile cart for all Sonicator Plus products. Holds unit on the top shelf with lower shelves for accessories.
97	Sturdy stainless steel cabinet with a platform for Mettler electrotherapy products and three shelves with a plastic door with two locking wheels.
9201	Sonicator Plus 920, applicator (~5.5 cm^2/ 1 or 3 MHz)
9202	Sonicator Plus 920 applicator (~0.9 cm^2/ 1 or 3 MHz)