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# Sonicator® 716

## Maintenance Manual



**M**ETTLER **M**LECTRONICS®  
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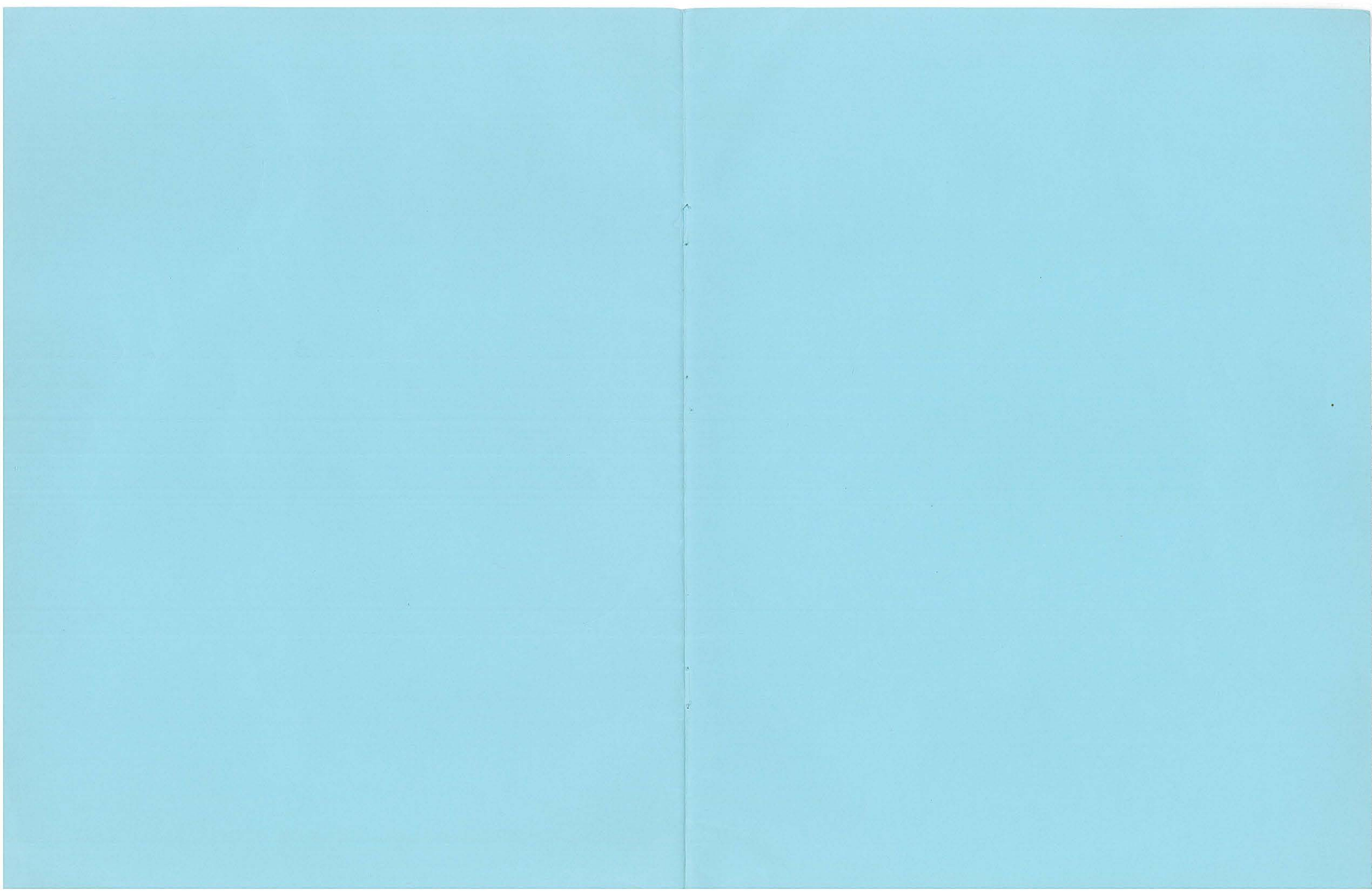
1333 South Claudina Street  
Anaheim, CA 92805  
U.S.A.

Toll Free: (800) 854-9305 • Phone: (714) 533-2221 • FAX: (714) 635-7539

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## Appendix C—Parts List

<u>Parts Location</u>	<u>Description</u>	<u>Part Number</u>
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### Main Assemblies, PC Boards & Cables

	Power Supply PC Board Assembly	QR1-02
	Display PC Board Assembly	QR1-01
	Membrane Switch	HG1-17

	Back Housing Assembly with Stud (Domestic)	QR2-07
	Handle	WKR2-03
	Internal Coax Cable Assembly	QR1-13
	Internal DC Power Cable Assembly	QR1-08
	Fuses, 0.6 Amp. (Domestic)	FB1-13
	Power Cord, 10 foot hospital grade	ME 7293

Applicator	(10 cm <sup>2</sup> , 1 MHz) Parts	
	10 cm <sup>2</sup> , 1 MHz Applicator, complete	ME 7310
	Crystal Ring Assembly, 10 cm <sup>2</sup> x 1 MHz	QN1-09
	Applicator Handle Assembly	QR3-01
	O-Ring, 1.487"	KF1-12
	Universal applicator cable	ME 7391

# Sonicator<sup>®</sup> 716

## Maintenance Manual

**METTLER ELECTRONICS<sup>®</sup>**  
corp.

1333 S. Claudina Street  
Anaheim, California 92805 U.S.A.  
Call toll free: (800)-854-9305  
or call: (714)-533-2221  
FAX: (714) 635-7539

May, 1997

IR7-20

## FCC Frequency Interference Statement

### WARNING:

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

### NOTICE 1:

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

### NOTICE 2:

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

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

### NOTICE 3:

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

## Appendix B— Ultrasound Applicator Repair

1. Figure B.1 shows the ME 7305 applicator top assembly. It is representative of the Sonicator 716 applicator.
2. Applicator components include: transducer ring assembly and handle assembly.
3. Replacement crystal ring and applicator handle assemblies may be installed by Mettler authorized repair facilities only. (Unauthorized repairs void warranty provisions.)
4. Applicators may be returned to the factory Service Department for repair if desired.

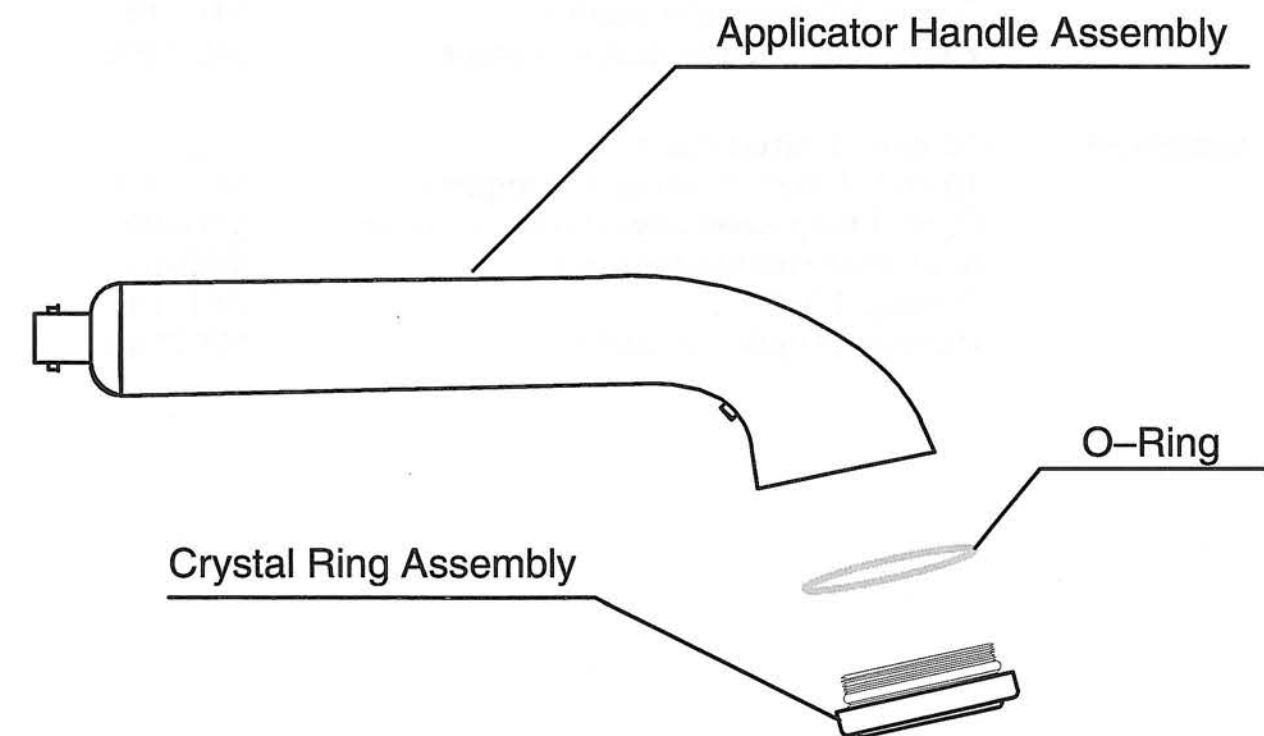


Figure B.1—Applicator Top Assembly

## Appendix A—Measuring Ultrasound Power Output

OHMIC Instruments ultrasound power meters, UPM-series, are traceable to National Institute of Science and Technology (NIST) standards. The UPM-DT-1 is recommended as first choice for measuring applicator output.

Whatever instrument is chosen to make these measurements, some basic principles apply to all. Degassed water must be the medium for ultrasound. Water used in ultrasound power meters must be degassed to less than 4 ppm (dissolved oxygen) for reliable results and adherence to FDA measurement requirements.

Mettler Electronics Corp. developed a good method for degassing water using a canning technique involving a pressure cooker and Mason jars. This is easier than boiling water for 30 minutes and transferring it to plastic bottles while still hot, then placing the bottles in a refrigerator. If interested in this method, send a request to the Mettler QA Department.

Also, when measuring ultrasound output, insure accurate placement of the applicator face over the center of the power meter target. If off center, the target will be moved around by ultrasound resulting in unstable readings.

Ultrasound output measurements should be taken in a stable environment, i.e., no air conditioning drafts across the power meter surface, and no vibrations shaking the power meter mechanism. These influences cause unstable readings and reduce reading repeatability.

Insure the power meter is zeroed between readings to verify a stable reference.

Finally, it is recommended that three sets of readings be taken and the average determined to obtain a more accurate representation of device performance. This helps minimize the effects of measurement variables.

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## Section 8—Troubleshooting Guide

### 8.1 No Lights When Main Power Turned On

- Check line cord connected to line supply.
- Check line cord securely connected to Sonicator 716.
- Check line fuses on power supply board.
- Check line supply.

### 8.2 Ultrasound Output Indicator Blinks

- Check applicator cable connection.
- Applicator connector should be pushed into the case connector and locking ring engaged.
- Try another applicator – if light comes on, original applicator may need repair.

### 8.3 Error Codes

The Sonicator 716 is equipped with internal diagnostics designed to facilitate operator troubleshooting. An error code (Err) is displayed in the TIMER DISPLAY if a problem is detected by the microprocessor. Error codes are:

#### Error code 1 (Err1):

The Sonicator 716 is unable to detect the presence of an applicator. Check the applicator cable connection. The plug should be pushed into the connector and turned. If Err1 still is displayed in the timer window, install a different applicator. If the display returns to normal (no error code) the applicator may need repair.

#### Error code 2 (Err2):

The applicator has been operating with an inadequate load for thirty consecutive seconds. The timer stops and output goes to zero.

Error code 3 (Err3): *— Possible F3 OR F4 BLOWN*  
Indicates improper self-tuning. Install another applicator. If this resolves the error condition, the replaced applicator may need repair. If the error code is still present with the alternate applicator, return the Sonicator 716 and its applicator to the factory for repair.

#### Error code 4 (Err4)

Usually indicates a shorted output stage. Power must be recycled to clear the display. Turn off main power and turn it back on. If condition persists, replace the Display Board.

#### Error code 5 (Err5)

Return unit to factory for service.

*RECONNECT BOARDS  
US CABLE SHORTED*

## Limited Warranty

The Sonicator 716 generating unit is warranted against defects in materials and workmanship for a period of two years from date of purchase. The Sonicator 716 applicators and applicator cable are warranted against defects in materials and workmanship for a period of one year from date of purchase. During the applicable warranty period Mettler Electronics Corp. will, at its discretion, either repair or replace the Product without charge for these types of defects.

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

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

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

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

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

## Section 7—Routine Maintenance

- 7.1 Clean the Sonicator 716 with a damp cloth. Remove the line cord plug from the wall before cleaning. Use a gentle household cleaner, sprayed on the cloth, for stubborn dirt. If this method is used, remove any cleaner residue with a clean damp cloth.
- 7.2 Disinfect applicators with an appropriate disinfectant. Rinse the applicator thoroughly after disinfection to remove any residue. Applicator and cables ARE NOT autoclavable. Do not immerse the BNC connector on either end of the cable in any fluid unless it is securely connected to its mating connector.



6.2.3.5. Press "Continuous" key. The Continuous LED should come on and the output should return to 100%.

#### 6.2.4 Contact:

Remove the applicator from the wattmeter. The Power LED should begin blinking. The unit should beep twice and Err2 appear in the TIME LED's in 30 seconds (6 seconds for IEC units).

#### 6.2.5 Disconnect Test:

Press Go. Disconnect the applicator from the unit. The unit will beep twice, enter HOLD, and display Err1. Reconnect the applicator.

### 6.3 Burn In:

6.3.1 Turn power off. Reassemble the unit.

6.3.2 Set the ultrasound output to maximum in pulse mode.

6.3.3 Run the unit for 29 minutes.

6.3.4 After Burn-in repeat 6.2.2.1 and 6.2.4.

### 6.4 Safety Tests:

Apply 3000 VAC for 1 second (from the gnd pin on the plug to the blades).

6.4.1 Monitor HV supply current for any evidence of breakdown indicated by current spikes in reading.

6.4.2 Leakage Test: 100 uA RMS Max-Chassis; 50 uA RMS Max from Applicator ring

6.4.3 Ground Resistance: Check the resistance from the gnd pin on the plug to the ultrasound applicator ring. Resistance should be less than 0.5 ohms.

### 6.5 Request for Feedback

Valuable customer feedback is lost when field repairs are made without reporting problems to the factory. Mettler Electronics Corp. is determined to provide quality products at reasonable prices. To meet that commitment we need to know how products are performing in the field. Field engineers and technicians performing checks are requested to report problems to the factory Service or QA Department so that appropriate action is taken to prevent problem recurrence.

## Section 1—Introduction

### 1.1 The Manual

This manual is intended to aid qualified biomedical engineers and technicians in testing, servicing, and repairing Sonicator 716's. It contains an equipment description, operating procedures, theory of operation, test procedures, specifications, and troubleshooting tips.

This manual is current as of its publication. Mettler Electronics Corp. may, however, make improvements as required. To receive manual changes, send your name and address to:

Mettler Electronics Corp.  
Service Manual Changes  
1333 S. Claudina Street  
Anaheim, CA 92805.

### 1.2 The Sonicator 716

The Sonicator 716 is a microprocessor-controlled device providing continuous or pulsed ultrasound. It delivers 1 MHz ultrasound through interchangeable 10 cm<sup>2</sup> applicators of the same type. Verify calibration when you install a new applicator.

One 10 cm<sup>2</sup> applicator is shipped with each generator. Applicators are sealed to facilitate underwater treatments, and are repaired by returning them to a Mettler Electronics Corp. authorized service facility.

The membrane control panel has clearly labeled key pads that produce audible feedback when activated. LED timer and output displays are large and bright.

Verify conformance to specifications at least yearly.

### 1.3 Precautions

1. The Sonicator 716 operates with high voltages. Servicing should be performed by qualified ultrasound technicians or the unit should be returned to the factory for service.
2. The internal circuit boards are not designed to be serviced at the component level because of the extensive use of surface mount circuitry. Any attempt at replacing a surface mount component will result in damage to the board. Replace entire circuit board assemblies only!
3. For maximum safety, plug the Sonicator 716 into a grounded wall outlet of proper voltage only. Follow general safety practices for medical electronic equipment.
4. The Sonicator 716 requires 115 VAC, 50/60 Hz primary power.  
DISCONNECT THE LINE SUPPLY CORD PRIOR TO DISASSEMBLY OF THE

UNIT. Line supply voltage is present on primary components exposed by removing the back cover.

5. Use calibrated test equipment in good working order.
6. USE OF CONTROLS OR ADJUSTMENTS, OR PERFORMANCE OF PROCEDURES OTHER THAN THOSE SPECIFIED IN THIS MANUAL AND IN THE Sonicator 716 INSTRUCTION MANUAL, MAY RESULT IN HAZARDOUS EXPOSURE TO ULTRASONIC ENERGY.
7. Do not operate the Sonicator 716 in close proximity to operating shortwave or microwave diathermies.
8. Replace line fuses with specified type and rating only, to avoid risk of fire or other damage.
9. Do not operate the membrane control panel with pointed objects such as pencils, pens, or tools.
10. Make sure all connectors are tight with all pins making good contact when reassembling the unit after service.
11. As a prescription device, the Sonicator 716 may be sold only to, or on the order of, a physician, physical therapist, or other practitioner licensed by the state in which he/she practices.

## 1.4 Labels

Each medical device must be uniquely identified for traceability and device history. This is accomplished with serial numbered labels unique to each device.

Product labels provide performance data, and must remain on the device at all times. Preserve label integrity during repair and servicing when actions such as removing access covers could cause label damage.

Please include model and serial numbers when requesting service assistance from the factory.

*For units with Rev A or B software:*

6.1.6.3 Press "1". Measure the frequency at TP7. It should be less than 930 kHz.

6.1.6.4 Press "3". Measure the frequency at TP7. It should be at least 1060 kHz.

*For units with Rev C or D software:*

6.1.6.5 Press "1". Measure the frequency at TP7. It should be less than 930 kHz.

6.1.6.6 Press "2". Measure the frequency at TP7. It should be at least 1060 kHz.

6.1.6.7 Press "Hold" to exit the VCO Diagnostic

## 6.2 Ultrasound Tests:

### 6.2.1 Output Waveform:

Connect the applicator to the unit with a BNC "T" connector. Connect a 10x scope probe to the BNC connector. Place the applicator in the watt meter. Zero the watt meter. Press Go. Set power to 5 Watts indicated on the unit. Verify that the output waveform is a smooth sine wave.

### 6.2.2 Output Power:

6.2.2.1 Test the unit as required below and record results:

<u>Watts: Indicated</u>	<u>Watts: Measured (<math>\pm 20\%</math>)</u>
4.0	3.2 – 4.8
15.0	12.0 – 18.0
22.0	17.6 – 26.4

6.2.2.2 Turn the variac down to 103 VAC, 60 Hz.

6.2.2.3 Set power to the maximum Watts indicated on unit. Power should measure as specified in 6.2.2.1. Record power.

6.2.2.4 Turn the variac up to 126 VAC, 60 Hz.

6.2.2.5 Verify that the power remains as specified in 6.2.2.1.

6.2.2.6 Return the variac to 115 VAC.

### 6.2.3 Pulse Test:

6.2.3.1. Set scope for 20v/div. and 2 mS/div.

6.2.3.2. Press Go.

6.2.3.3. Press the "Pulse" key. The Pulse LED should come on.

6.2.3.4. Verify output waveform is 2 ms on and 8 ms off. (20% tolerance on measurements)

### 6.1.3 Main Bd: Power Up Check:

- 6.1.3.1 Turn power on. The time display should show "Err1", and power display should show "00.0". The Watts and Continuous LEDs should be lit.

### 6.1.4 Keybd Test:

- 6.1.4.1 To enter Diagnostic Mode press and release the "Hold" and "Continuous" keys at the same time. When in Diagnostic Mode the displays will show all zeros and the six green LEDs will flash.
- 6.1.4.2 Press "1" and then "Go".
- 6.1.4.3 Press 0 - 9 and verify the numbers appear in the TIME LEDs.
- 6.1.4.4 Press "W", "W/cm<sup>2</sup>", Continuous & Pulse. Verify each LED lights as the switch is pressed.
- 6.1.4.5 Press the Up arrow and verify the Power LEDs increment.
- 6.1.4.6 Press the Down arrow and verify the Power LEDs decrement.
- 6.1.4.7 Press "Hold" to exit the Keyboard Diagnostic.

### 6.1.5 Display Test:

- 6.1.5.1 Press "2" and then "Go" to start the Display Diagnostic.
- 6.1.5.2 The right most LED will show the Diagnostic chosen, while all other LEDs will continually count from 0-9 then A-F.
- 6.1.5.3 Verify that the 7 segment LEDs are all of uniform brightness.
- 6.1.5.4 Press "Hold" to exit the Display Diagnostic.

### 6.1.6 VCO Test

- 6.1.6.1 Before running the VCO test, determine the software revision of the microprocessor. Press "0" and then press "Go". The minutes digits in the Time display will show the numeric equivalent of the software revision letter. (Rev A=01:00, Rev Z=26:00. Record the software version and then press "Hold" to exit this test.
- 6.1.6.2 Press "3" and then "Go" to start the VCO Diagnostic. This diagnostic puts out several reference voltages for the VCO adjustment. This adjustment is made at the factory and this step is provided to verify the adjustment.

## Section 2—Equipment Description

### 2.1 Equipment Layout

The Sonicator 716 has two printed circuit boards, one ultrasonic applicator, a membrane control panel, a main power switch, top and bottom enclosures, miscellaneous hardware and wire harnesses. A block diagram is shown in Fig. 2.1.

#### Display Board

The Display Board contains a display decoder, four 7-segment light emitting diodes (LED's) for treatment time indication, three 7-segment LED's for output power indication, and five individual (green) LED's for control status information. This board also contains the microprocessor circuitry, the VCO, the RF power output stage, and a matching network. Ultrasound RF energy is coupled out through a BNC connector to a short cable that connects to a bulkhead BNC connector at the case bottom. The front panel membrane switch is connected to this board by means of a zero insertion force connector.

#### Power Supply Board

Power Supply Board inputs: Filtered mains power

Main Board outputs: +5, +12, and up to + 40 VDC.

The power supply board contains a transformer that steps down the incoming line voltage and applies it to rectifiers to produce raw DC that is down regulated by three terminal regulators. A high frequency switching power supply is programmed to produce the variable voltage that is supplied to the power output stage on the Display Board. This voltage is under the control of the microprocessor and is determined by the desired power output setting. The DC output voltages are available at a header at the top of the board assembly. A short multiconductor cable connects to the Display board.

#### Applicators

A single 10 cm<sup>2</sup> applicator connects to the Sonicator 716. This applicator is used on the Sonicator 716 and 730. Applicators connect to generators with a double shielded coaxial universal applicator cable having a BNC connector at both ends.

#### Other Components

The membrane panel, main power rocker-type switch, and applicator BNC connector are mounted to the top enclosure.

Subassemblies are interconnected with wire harnesses and matched connectors. Connectors cannot be mated to incorrect plugs without excessive force or obvious error.

All wiring and connections in the primary circuit are UL recognized. The primary circuit is all the components and interconnections on the primary winding side of the power transformer.

Software in the microcontroller is an additional component requiring the same controls in manufacturing, processing, and changing as other components.

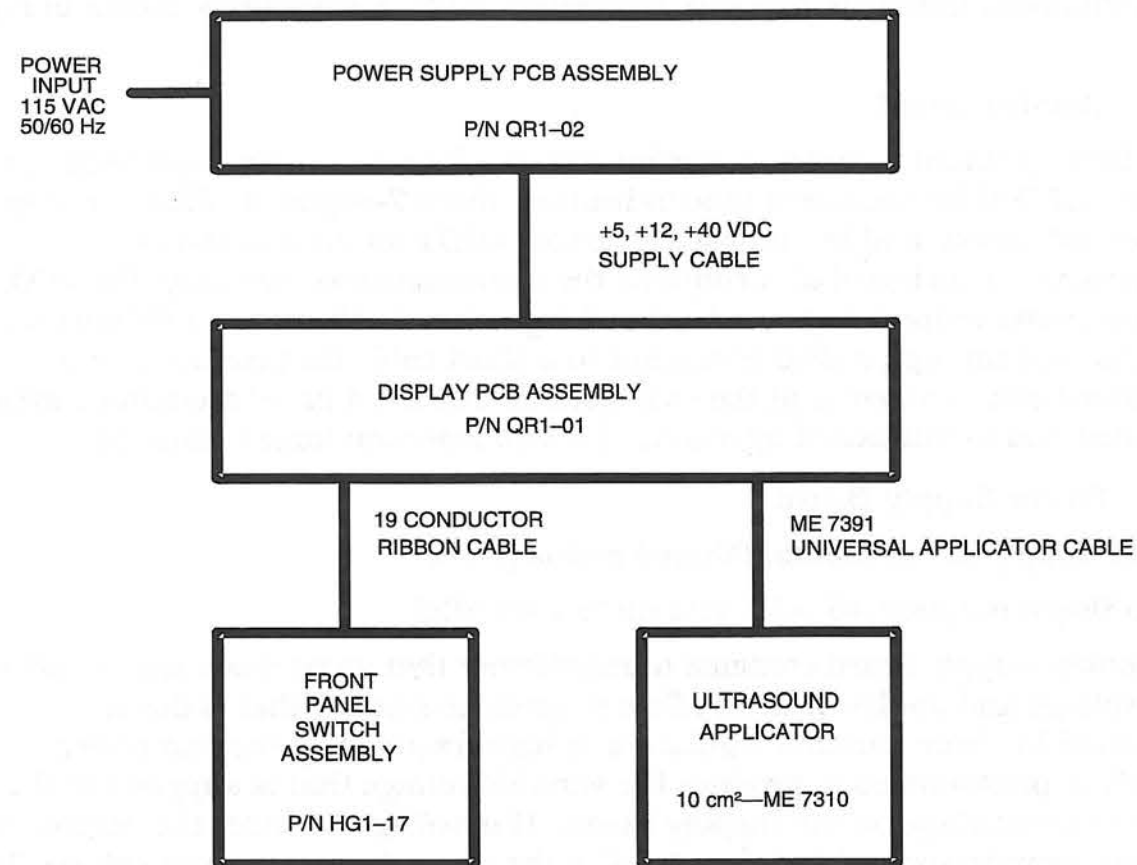


Figure 2.1—Sonicator 716 Block Diagram

## 2.2 Theory of Operation

### Display Board Circuitry

The display circuit uses a seven segment LED display IC on the Display Board to provide segment drive for four time display digits, three power display digits, and five individual status LED's. Data to be displayed is written directly from the microcontroller on the Main Board to the display controller IC.

The microprocessor controls the operation of the Sonicator 716 via instructions stored in internal EPROM. These are not field alterable and are programmed into the instrument at the manufacturing plant. Input and output ports of the microprocessor are connected to a display driver, a VCO, the membrane switches, and the current return sense resistors via appropriate interface circuitry. The drive to the RF power output stage is controlled by the

# Section 6—Performance and Safety Testing

### Equipment Required:

DVM, Dual Channel Scope, one 10x probe, Frequency Counter, Ohmic Power Meter, Ammeter, Leakage Current Tester, Hipot Tester, Variac, BNC "T" connector

### Before Testing Units:

1. Review Safety Instructions in Section 1.
2. Review Operating Instructions in Section 5.
3. Review Keyboard Symbol Definitions in Section 3.

## Procedure:

### 6.1 Basic Functional Tests:

6.1.1 Visual Check: Look at the case exterior for any obvious signs of mechanical damage or cracks in the housing. Inspect the power and applicator cables for any signs of fraying, failing insulation, or other mechanical damage. Inspect the applicator handle, the crystal face, and the ring assembly for any signs of mechanical damage. Open the case by removing the four screws in the case back panel. Inspect the inside for signs of any visible damage. Note that all the cables are attached at both ends.

Check primary wiring and fuses. Verify Fuses, 600 mA.

#### 6.1.2 Power Supply Test:

6.1.2.1 Disconnect the Power Supply cable at J1 on the Display Bd. Connect the unit to a variac. Adjust variac for 115 VAC out. Turn on power. Check for proper power supply voltages on the Power Supply Bd.

+40v PS Bd J1-2 to J1-5 (38 to 42)

+12v PS Bd J1-2 to J1-4 (11.7 to 12.3)

+5v PS Bd J1-2 to J1-3 (4.8 to 5.2)

6.1.2.2 Turn power off. Reconnect the Power Supply cable to J1.

ultrasound couplants. If you use these materials the coupling indicator LED may blink and Err2 may be displayed.

- c) Areas of heavy body hair will trap air beneath the hair and prevent ultrasound transmission. Shaving the treatment area prior to treatment or thoroughly wetting the area prior to the application of couplant will result in more efficient transmission of ultrasound.

12. When the set treatment time has elapsed, the unit beeps. Time and ultrasound power displays will display "0" and ultrasound power will turn off.

microprocessor which monitors the return current and adjusts the DC supply voltage to the output stage to determine output power.

#### Power Supply Board Circuitry

Primary power is applied to the Power Supply Board through a line filter, then to the power switch, fuses, and then to the power transformer on the PCB. Transformer secondaries return to the PCB where they are rectified and filtered. Two of these filtered voltages are fed to regulators to provide regulated +5 VDC and +12 VDC for control electronics. The third output is provided by a switching power supply and produces filtered, regulated, nominal +40 VDC used to power the ultrasound output stage.

#### Applicators

Components: transducer ring assembly; handle; spring contact; ground contact identification resistor; strain relief; and wire assembly terminated in a BNC connector.

The transducer is a piezoelectric ceramic disc fastened to a stainless steel threaded ring. The ring may be removed from the applicator for replacement at a Mettler Electronics Service Center and provides access to the internal wire assembly. The BNC connector wire assembly and spring and ground contacts in the applicator handle provide a signal path from the universal applicator cable to the transducer element.

The handle is an injection molded polymer. It is threaded to accept the transducer ring assembly at one end and a strain relief the BNC connector at the other end.

The universal applicator cable interconnects the applicator to the generator. It is detachable via a BNC connector at both ends. The type, length, and shielding of the cable are critical to the proper operation of the unit. This item must be replaced in its entirety, so any replacement cable assembly must be supplied by Mettler.

Applicators are designed to be repairable. The ultrasound crystal ring assembly should only be replaced at an authorized Mettler Electronics Corp. service facility. Any damage to the applicator handle, requires replacement of the entire applicator handle assembly.

## 2.3 Specifications

### Generator

Input:	115 VAC $\pm 10\%$ , 50/60 Hz, 0.6 ampere (max.)
Fuses:	0.6 A /250V for 115 VAC
Frequency:	1 MHz $\pm 5\%$
Pulse repetition rate:	100 Hz $\pm 20\%$ (Pulse Mode)
Pulse duration:	2 msec ( $\pm 20\%$ )
Temporal peak/ Average intensity ratio:	5:1 ( $\pm 20\%$ )
Maximum output power:	22 Watts
Maximum intensity:	2.2 W/cm <sup>2</sup>
Indication accuracy:	$\pm 20\%$ (for any level above 10% of maximum).

U.S. Patent Nos. 4,966,131 and 5,095,890

### Output:

The output waveform is continuous or pulsed as programmed by the membrane panel control. In PULSE mode the 1 MHz sinusoidal output is square wave pulse-modulated. The power level is adjusted by varying the pulse amplitude. The pulse waveform is shown below.

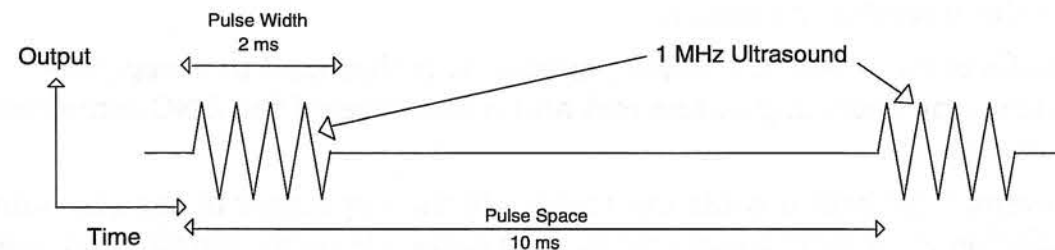


Figure 2.2 Pulse Waveform.

In the continuous mode (CW), the power is on all the time the timer is running. The effects of the self-tuning one second frequency sweep may be detected when using sensitive output measuring instruments. The continuous mode waveform is shown below:

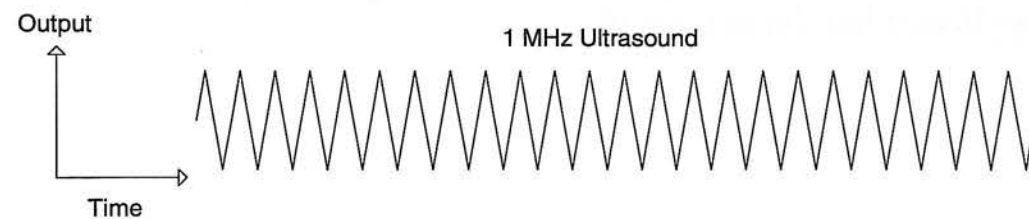
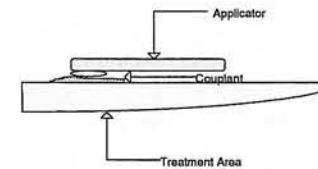
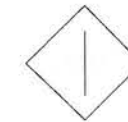


Figure 2.3 Continuous Wave Waveform.

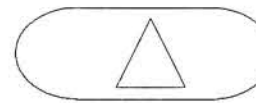
Please note: A decrease in power level may be observed once a second during the retune and diagnostic cycle.



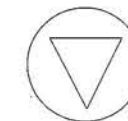
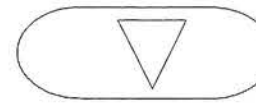
6. Couple the applicator to the treatment area by keeping the entire surface of the applicator in contact with the gel that has been applied to the patient. This will ensure an efficient delivery of therapeutic ultrasound to the patient.



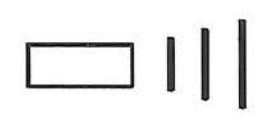
7. Press the button pictured to the left to begin treatment.



8. Adjust the ultrasound power to the desired intensity using the Up/Down arrows. Pressing an Up/Down arrow momentarily will raise or lower the ultrasound power in 0.1 W or W/cm<sup>2</sup> increments. Holding an arrow down will rapidly raise or lower the ultrasound power. Remember to couple the applicator to the patient while adjusting ultrasound power.



9. If you need to temporarily stop treatment press the button pictured on the left. Remaining treatment time and "00.0" will be displayed. Ultrasound power will stop. To resume treatment press the button pictured in number 7 above.



10. This LED indicator is ON solid when ultrasound output is being delivered to a patient. If the applicator is not in contact with the patient or ultrasound is not being efficiently transmitted to the patient, the LED in the symbol pictured to the left will blink. If inadequate coupling occurs for more than 30 continuous seconds the Sonicator 716 will automatically cease ultrasound output, beep twice and display "Err 2" in the time display.

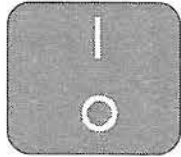
11. Notes on coupling: Failure to efficiently transmit therapeutic dosages of ultrasound to the patient can be caused by the following:

- a) Treatment of an irregular area where it is impossible to keep the applicator surface in contact with the gelled patient area. In this case you can try to use a little more gel or perform underwater treatment, if the treatment area is submersible in water.
- b) An inappropriate couplant is being used. Only materials that efficiently transmit ultrasound should be used for therapeutic ultrasound applications. Some creams and oil based preparations are not efficient

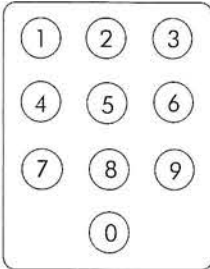
## 5.1 General Operating Instructions:

Before you start.

- Review precautions and contraindications in Section 5.
- Verify connection of the line cord to a grounded wall receptacle and the Sonicator 716.
- Check the applicator cable connection to the Sonicator 716 to assure secure connection.
- Note: Descriptions of the symbols used on controls are in Section 3.



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



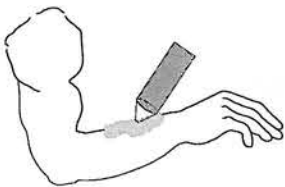
- Select the desired treatment time by pressing a number(s) on the numeric keypad. Unit beeps when a button is pressed. Only whole minutes may be selected. Treatment times from 1 to 29 minutes are valid. Time is displayed in the time window.



- Select either continuous (|||||) or pulsed (—||—||—) ultrasound by pressing the appropriate button. The LED indicator on the button will illuminate which selection is made.



- Select either Watts (**W**) or Watts per square centimeter (**W/cm<sup>2</sup>**) as the units of measure for ultrasound power that will be displayed. The LED indicator on the button will illuminate which selection is made.



- Apply a layer of Sonigel (ultrasound couplant gel) to the treatment area.

### Applicators

Frequency:	1 MHz $\pm$ 5%
Effective Radiating Area:	10 cm <sup>2</sup> $\pm$ 20%
Beam type:	Collimating
Maximum BNR:	6:1

**Spatial Pattern:** The applicator produces a collimated (cylindrical) beam with an area of 10 cm<sup>2</sup> as measured 5 mm from the applicator face when radiating into the equivalent of an infinite medium of distilled, degassed water at 30° C, and with line voltage variations in the range of  $\pm$ 10% of the rated value.

The applicator beam 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. A sample curve as measured in the far field is shown in the following figure.

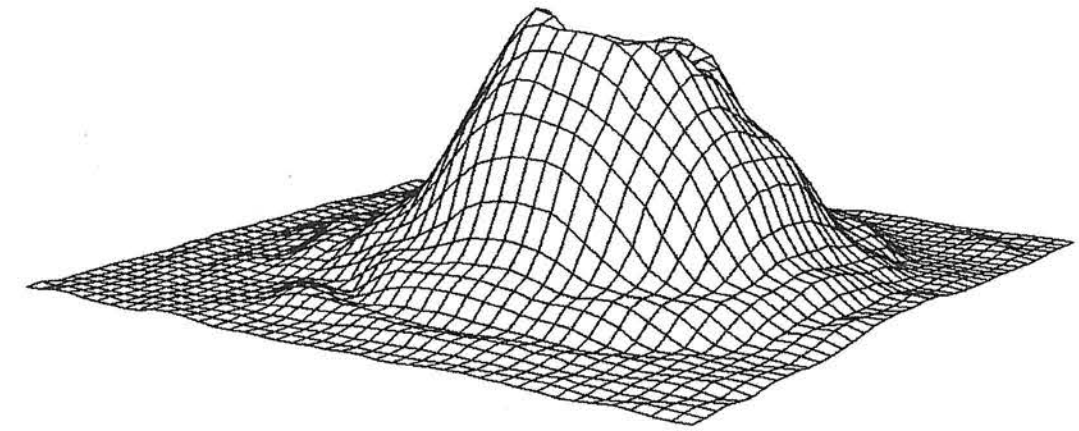


Figure 2.4—10 cm<sup>2</sup> Applicator

### Treatment Timer

Indicator:	The digital timer indicates time set in minutes and seconds prior to the start of treatment and treatment time remaining during treatment or when treatment is temporarily suspended.
Accuracy:	$\pm$ 0.5 minute for times less than 5 minutes $\pm$ 10% for times from 5 to 10 minutes $\pm$ 1.0 minute for times greater than 10 minutes
Maximum treatment time:	29 minutes

Certification

The Sonicator 716 complies with the ultrasound performance standards set forth in the Code of Federal Regulations, Title 21 (Food and Drugs), Subpart 1050.10, F.C.C. Part 18, and U.L. 544

# Section 5—Operating Instructions

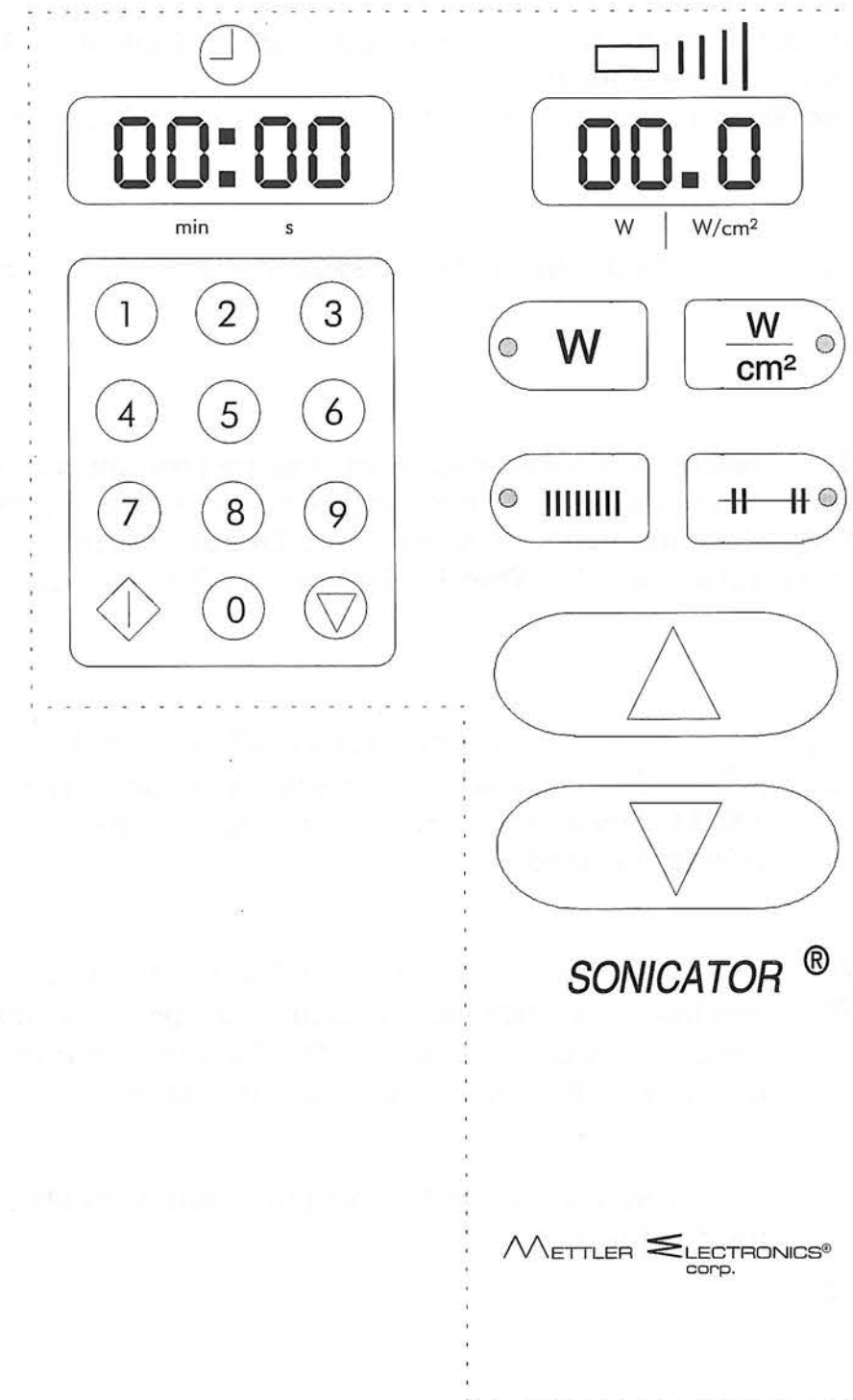


Figure 5.1—Front membrane panel and LED indicators



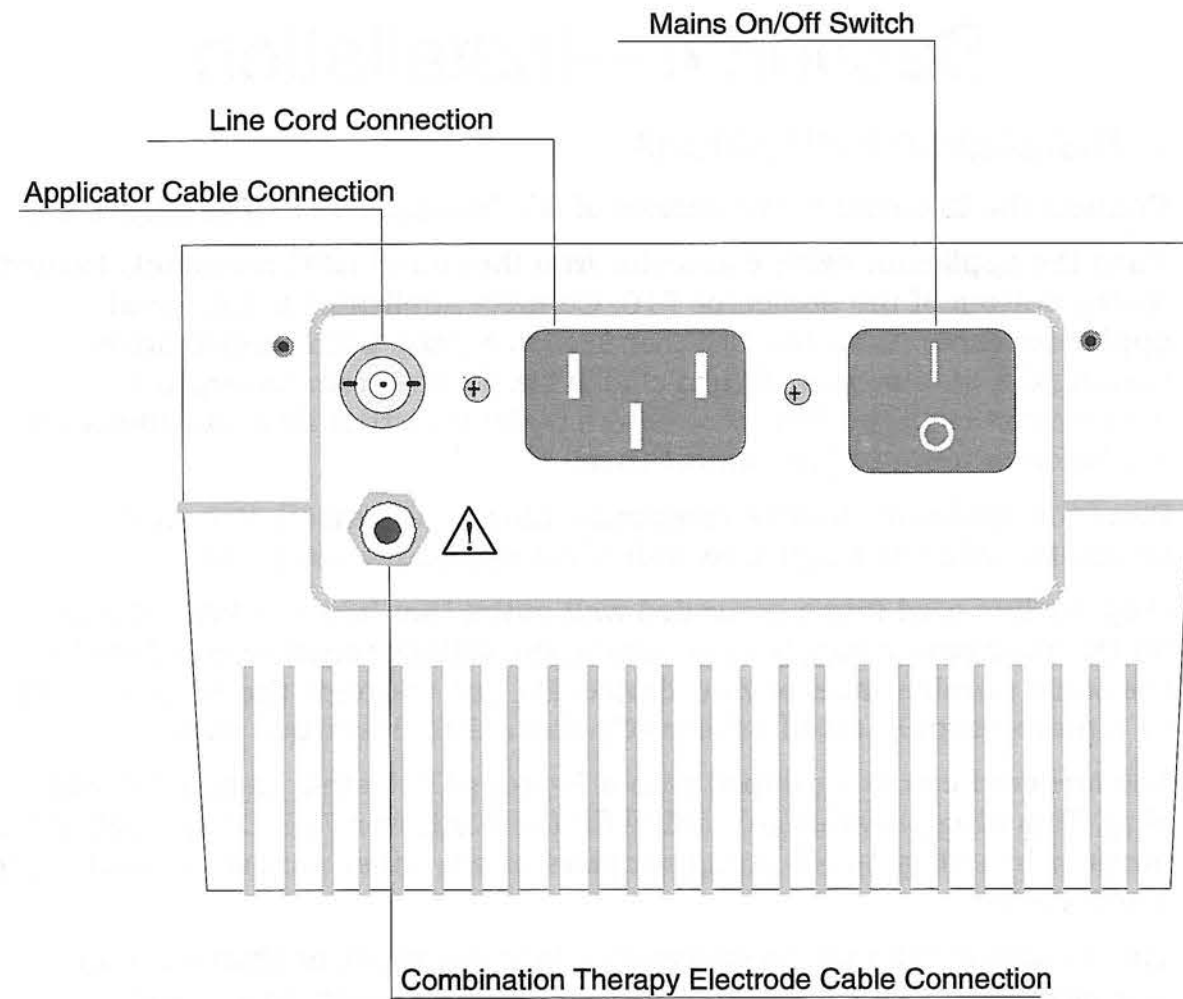


Figure 4.1—Sonicator 716, Bottom view—Main Power Switch and Line cord, Applicator Cable and Combination Therapy Electrode Cable Connections

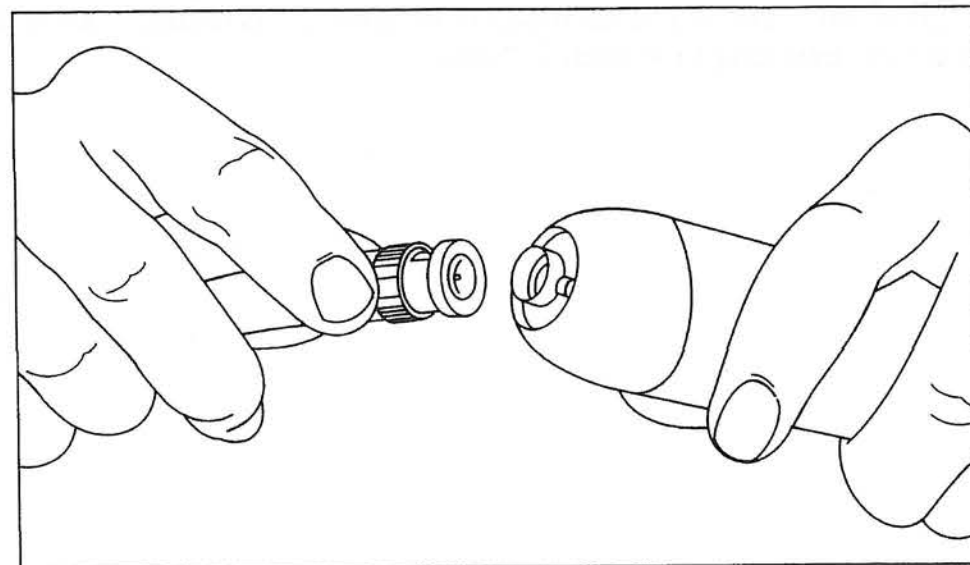






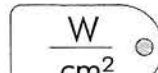
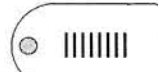
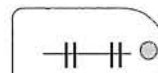
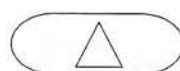


Figure 4.2—Connecting the Applicator to the Universal Applicator Cable

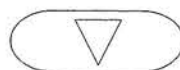
## Section 3—Symbol Glossary and List of Abbreviations

### 3.1 Symbol Glossary

-  Time
- min Minutes
- s Seconds
-  Numeric keypad for time entry.
-  Starts treatment, ultrasound output activated.
-  Temporarily suspends treatment, maintains treatment parameters, ultrasound output stopped.
-  Ultrasound active when LED indicator lit. LED blinks when coupling is inadequate.
- W Watts
- W/cm<sup>2</sup> Watts per square centimeter
-  Selects display in Watts. Watts selected when LED indicator lit.
-  Selects display in Watts per square centimeter. Watts per square centimeter selected when LED indicator lit.
-  Selects continuous wave ultrasound output. Continuous wave ultrasound output selected when LED indicator lit.
-  Selects pulsed ultrasound output (2 ms On, 8 ms Off). Pulsed ultrasound selected when LED indicator lit.



Increases ultrasound output.



Decreases ultrasound output.



Mains On.



Mains Off.



Refer to instruction manual for directions.

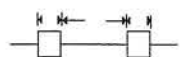


Diagram of Pulsed Mode duty cycle

### 3.2 List of Abbreviations

Area	—	Effective Radiating Area in square centimeters (cm <sup>2</sup> )
BNR	—	Beam Non-uniformity Ratio
cm <sup>2</sup>	—	Square centimeters
Coll	—	Collimating
ERA	—	Effective Radiating Area in square centimeters (cm <sup>2</sup> )
Freq	—	Frequency
Gen	—	Generator
Hz	—	Hertz (cycles per second)
LED	—	Light Emitting Diode
MHz	—	Megahertz (1,000,000 Hz)
S/N	—	Serial Number
VCO	—	Voltage Controlled Oscillator
W	—	Watt(s)
W/cm <sup>2</sup>	—	Watt(s) per square centimeter

## Section 4—Installation

### 4.1 Installation Instructions

1. Connect the line cord to the bottom of the Sonicator 716. (See Figure 4.1)
2. Push the applicator cable connector into the round BNC receptacle located on the bottom of the Sonicator 716. Connect applicator to universal applicator cable using the BNC connector. Secure both connectors by turning the outside ring ¼ turn clockwise. To maintain waterproof characteristics of the BNC connectors make sure that all connections are dry before attempting to connect them.
3. Place the applicator into its receptacle. Line up the metal disc on the applicator with the magnet on wall of the applicator receptacle.
4. Plug the line cord into a grounded wall outlet that has 115 VAC ±10%, 60 Hz. Your power supply must match the voltage requirements listed on the serial number label of your device. Do not connect the Sonicator 716 to a power supply rated differently than that described above.

The line cord comes equipped with a 3-prong UL Listed, Hospital Grade plug. This plug provides grounding for the Sonicator 716. Do not defeat its purpose by using 3-to-2 prong adapters or any other means of attaching to a wall outlet.

5. The Sonicator 716 may be susceptible to interference originating from shortwave diathermy units operating in close proximity to it. Avoid operating the Sonicator 716 adjacent to and simultaneously with operating shortwave devices.
6. Do not use sharp objects to operate the membrane panel switches. If the tough outer layer of the membrane is broken, moisture may leak into the switches resulting in switch failure.