# Sonicator<sup>®</sup> Plus 994 Specifications

| General Specifications:                 |  |
|---|--|
| Input:                                  | 90–240 VAC, 50–60 Hz, 2.3 Amp. Nom.  |
| Certification:<br>Domestic model        | The Sonicator Plus 994 complies with the ultrasound performance standards set forth in the Code of Federal Regulations, Title 21 (Food and Drugs), Part 1050.10 and IEC 601-2-5, 1 <sup>st</sup> Ed., 1984   |
| ETL and C-ETL Listed:<br>Domestic model | Model ME 994 (9801427)   |
| Classification:<br><i>CE model</i>      | Protective Class I Equipment<br>Type BF Equipment<br>Enclosed equipment without protection against ingress of<br>water.<br>Equipment not suitable for use in the presence of a<br>flammable anesthetic mixture with air or with nitrogen oxide                               |
| Year 2000 Compliant                     | Yes  |
| U.S. Patent Numbers:                    | U.S. and foreign patents applied for and granted including U.S. Patent Numbers 4,966,131 and 5,095,890.  |
| Weight:                                 | 10.7 pounds<br>4,9 kg  |
| Dimensions:                             | 5 in (H) x 14.5 in (W) x 10 in (D)<br>12.7 cm (H) x 36.8 cm (W) x 25.4 cm (D)  |
| Operating Temperature:                  | +50°F to +104°F<br>+10°C to +40°C  |
| Humidity:                               | Operating, 30% to 75% Relative Humidity at 104°F (40°C)<br>Nonoperating, 5 to 95% Relative Humidity, non-condensing  |
| Storage Temperature:                    | -40°F to 167°F<br>-40°C to 75°C  |
| Storage Humidity:                       | Storage, 30% to 90% Relative Humidity at 40° C, Non-<br>condensing   |
| Storage Pressure:                       | 700-900 mB   |
| Environmental Disposal:                 | The device contains lead in the form of solder used to<br>produce electrical contact between components. To avoid<br>adverse environmental impact, utilize a disposal facility that<br>performs complete incineration of the device at a temperature<br>in excess of 1000°C. |
|   | The shipping materials are fabricated of cardboard and may<br>be disposed of with other paper products.  |

| Treatment timer:                               |  |
|--|--|
| Timer Accuracy:                                | <ul> <li>±0.5 minutes for times less than 5 minutes</li> <li>±10% for times from 5 to 10 minutes</li> <li>±1.0 minute for times greater that 10 minutes</li> </ul>   |
|  | ±5%, CE specification  |
| Maximum Treatment Time:                        | 60 minutes-electrical stimulation<br>30 minutes-ultrasound or combination therapy  |
| Treatment Timer:                               | Treatment time counts down to zero when a time is set, or up<br>to 60 or 30 minutes when no time is set. The digital timer<br>indicates time in minutes and seconds. The timer also<br>indicates the remaining or elapsed treatment time during the<br>"Hold" period.              |
| Ultrasonic Generator Specific                  | ations:  |
| Frequency:                                     | 1.0 MHz ±5%<br>3.2 MHz ±5%<br>3.3 MHz ±5%  |
| Modes:   | Continuous<br>Pulsed—20% duty cycle<br>Pulsed—50% duty cycle   |
| Modulation:                                    | 100%   |
| Modulation Waveform:                           | Rectangular  |
| Pulse Repetition Rate:<br>Modulation Frequency | 100 Hz ±20%  |
| Pulse Duration:<br>Modulation Period           | 2 msec ±20%, 20% duty cycle<br>5 msec ±20%, 50% duty cycle   |
| Temporal Peak/ average intensity ratio:        | 5:1 ±20%, 20% duty cycle<br>2:1 ±20%, 50% duty cycle   |
| Maximum output power:                          | <ul> <li>22 W with a 10 cm<sup>2</sup> applicator, (ME 7310)</li> <li>11 W with a 5 cm<sup>2</sup> applicator, (ME 7513)</li> <li>2.2 W with a 1 cm<sup>2</sup> applicator (ME 7331)</li> </ul>  |
| Maximum intensity:                             | 2.2 W/cm <sup>2</sup> with all applicators   |
| Indication accuracy:                           | ±20% (for any level above 10% of maximum)  |
| Output description:                            | The output waveform is continuous or pulsed as programmed<br>by the membrane panel control. In the pulse mode the 1, 3.2<br>or 3.3 MHz square wave pulses<br>are modulated. The power level is adjusted by varying the<br>pulse amplitude. The pulse waveforms are shown<br>below: |



Figure 3.2—Pulse Waveform—50% Duty Cycle

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



Figure 3.3—Continuous Waveform

#### Ultrasonic Applicator Specifications:

Piezoelectric discs:

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

| Γ                    | <b>Applicator Part Number</b> | Frequency   | Effective Radiating Area  |
|----------------------|-------------------------------|---|---|
| =                    | ME 7310                       | 1 MHz ±5%   | 10 cm <sup>2</sup> ±10%   |
|                      | ME 7331                       | 3.3 MHz ±5%   | $1 \text{ cm}^2 \pm 10\%$   |
|                      | ME 7513                       | 1 or 3.2 MHz ±5%  | $5 \text{ cm}^2 \pm 10\%$   |
| Maximur<br>Non–Uni   | n Beam<br>formity Ratio:      | 6:1   |   |
| Maximur<br>Intensity | n Effective<br>Ratio:         | 2:1   |   |
| Spatial Pa           | attern:                       | The applicator produc<br>an area of 1, 5 or 10 cr<br>disc surface when the<br>of an infinite medium | es a collimated (cylindrical) beam $m^2$ , measured 5 mm from the ceran radiation is emitted into the equivalent of distilled water at 30° C. |
|                      |                               |   |   |

Individual Applicator Specifications:

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 3.3, 3.4, 3.5 and 3.6.



Figure 3.4—10 cm<sup>2</sup> Applicator (1 MHz), ME 7310,—Three Dimensional Beam Pattern



Figure 3.5—5 cm<sup>2</sup> Applicator (1 MHz), ME 7513—Three Dimensional Beam Pattern



Figure 3.6—5 cm<sup>2</sup> Applicator (3.2 MHz), ME 7513—Three Dimensional Beam Pattern



Figure 3.7—1 cm<sup>2</sup> Applicator (3.3 MHz), ME 7331—Three Dimensional Beam Pattern

# Waveform Specifications: Interferential Mode

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

#### **Premodulated Mode**



Figure 3.9—Premodulated Waveform

|   | A 1º/ 1 11/1                     |
|---|----------------------------------|
| Waveform Type:                          | Amplitude modulated              |
|   | sille wave                       |
| Polarity:                               | None                             |
| Volts:                                  | 0-50 volts RMS, 1 Kohm load      |
| Current:                                | 0-50 mA RMS, 1 Kohm load         |
| Average current at<br>maximum intensity | 50 mA RMS                        |
| Maximum current<br>density under        | 50 HII Y KWIS                    |
| 2" diameter electrode:                  | 2.5 mA/cm <sup>2</sup>           |
| Frequency:                              | 4,000 Hz                         |
| Frequency Modulation:                   | 1–15 Hz                          |
| 1 2                                     | 80–150 Hz                        |
|   | 1–150 Hz                         |
|   | xx–xx Hz,                        |
|   | xx=any value from<br>1 to 250 Hz |
| Phase Duration:                         | 125 μs internal sine wave        |

| 4–1,000 ms | beat envelope |
|------------|---------------|
|------------|---------------|

| Available Amplitude<br>Modulation Options: |  |
|--|--|
|  |  |

Continuous Surge Reciprocation

Available Channels: All

## Medium Frequency Mode



Figure 3.10—Medium Frequency (*Russian*) Waveform

|   | Waveform Type:                       | Burst modulated sine wave                   |
|---|--------------------------------------|---|
|   | Polarity:                            | None  |
|   | Volts:                               | 0-50 volts RMS, 1 Kohm load                 |
|   | Current:                             | 0-50 mA RMS, 1 Kohm load                    |
|   | Average current at maximum intensity |   |
| n | and frequency:                       | 50 mA RMS                                   |
| ) | Maximum current<br>density under 2"  |   |
|   | diameter electrode.                  | $2.5 \text{ mA/cm}^2$                       |
|   | Frequency:                           | 2500 Hz, Burst at<br>10 ms on and 10 ms off |
|   | Frequency Modulation:                | No  |
|   | Phase Duration:                      | 200 μs                                      |
|   | Available Amplitude                  |   |
|   | Modulation Options:                  | Continuous                                  |
|   |                                      | Surge                                       |
|   |                                      | Reciprocation                               |
|   | Available Channels:                  | All   |
|   |                                      |   |

## Biphasic (TNS) Mode

|   | Waveform Type:   | Symmetrical biphasic square wave |
|---|--|----------------------------------|
|   | Polarity:  | None                             |
|   | Volts:   | 99 volts peak, 1 Kohm load       |
|   | Current:   | 0 –99 mA peak,<br>1 Kohm load    |
| Figure 3.11—Biphasic <i>(TNS)</i><br>Waveform | Average current at<br>maximum intensity<br>and frequency:  | 7.2 mA                           |
|   | Maximum current<br>density under 2"<br>diameter electrode. | 0.36 mA/cm <sup>2</sup>          |
|   | Frequency:   | 1–120 HzzHz                      |
|   | Frequency Modulation:                                      | No                               |

|                          | Phase Duration:                      | 50–300 μs                                  |
|--------------------------|--------------------------------------|--|
|                          | Available Amplitude                  | ·  |
|                          | Modulation Options:                  | Continuous                                 |
|                          |                                      | Surge                                      |
|                          |                                      | Reciprocation                              |
|                          | Available Channels:                  | All  |
| High Volt Mode           |                                      |  |
|                          | Waveform Type:                       | Monophasic twin peak                       |
| 500 volts                | Polarity:                            | Positive or negative                       |
|                          | Volts:                               | 500 volts peak, 1 Kohm load                |
| 50 %                     | Current:                             | 0–500 mA peak, 1 Kohm load                 |
|                          | Average current at                   | -  |
|                          | maximum intensity                    |  |
| 0 volts                  | and frequency:                       | 1.2 mA at 120 pps with<br>1 Kohm load      |
| Figure 3.12—High Volt    | Maximum current                      |  |
| Waveform                 | density under 2"                     |  |
|                          | diameter electrode.                  | $0.06 \text{ mA/cm}^2$                     |
|                          | Frequency:                           | 1–120 HzzHz                                |
|                          | Frequency Modulation:                | No   |
|                          | Phase Duration:                      | 8 μs at 50% Vmax                           |
|                          | Polarity:                            | Positive or negative                       |
|                          | Available Amplitude                  |  |
|                          | Modulation Options:                  | Continuous                                 |
|                          |                                      | Surge                                      |
|                          | Available Channels:                  | Channel One only                           |
| Microcurrent Mode        |                                      |  |
|                          | Waveform Type:                       | Monophasic or biphasic square wave         |
| -<br>or                  | Polarity:                            | Positive or negative or<br>biphasic pulses |
|                          | Volts:                               | 1 Volt peak, 1 Kohm load                   |
|                          | Current:                             | 10-990 µA peak, 1 Kohm load                |
|                          | Average current at maximum intensity |  |
| Figure 3.13—Microcurrent | and frequency:                       | 990 μA                                     |
| Waveform                 | Maximum current                      |  |
|                          | density under 2"                     |  |
|                          | diameter electrode.                  | $24.4 \ \mu A/cm^2$                        |
|                          | Frequency:                           | 0.5-500 Hz                                 |
|                          | Duty Cycle:                          | 50%zHz                                     |
|                          | Frequency Modulation:                | No   |
|                          | Pulse Duration:                      | 1-1000 ms                                  |

|                         | Available Amplitude<br>Modulation Options:   | Continuous   |
|-------------------------|--|--|
|                         | Available Channels:  | Channel Two only   |
|                         |  |  |
| Amplitude Modulation Sp | ecifications:  |  |
| Vector rotation:        | Interferential Mode On   | ly   |
|                         | -50% amplitude modula<br>anti phase with an eig  | ation in<br>ht second modulation period.                       |
| Surge Mode:             | Premodulated, Medium Free  | quency and Biphasic (TNS) Pulsed Modes                         |
| Up ramp:                | 3 seconds  |  |
| Down ramp:              | 2 seconds  |  |
| Preset on/off times:    | 10 seconds on, 10 secon<br>10 seconds on, 20 secon<br>10 seconds on, 30 secon<br>10 seconds on, 40 secon<br>10 seconds on, 50 secon<br>10 seconds on, 60 secon | nds off<br>nds off<br>nds off<br>nds off<br>nds off<br>nds off |
| Programmable On time:   | 1-240 seconds  |  |
| Programmable Off time:  | 1–240 seconds  |  |
| Reciprocation mode:     | Premodulated, Medium Free  | quency and Biphasic (TNS) Pulsed Modes                         |
| Up and down ramps:      | 1 second, reciprocation  | e only   |
| Reciprocation time:     | 2-240 seconds, (On tim   | ne = off time)   |
| Combine with Surge:     | Use up and down ramp   | s of surge program   |
|                         | Use on/off times of surg   | ge program.  |
| Two timer option:       | No   |  |