Report on In-Vitro Characterization and Electrical Safety Testing

of

Prototype Sonotron Device SN. 001
ADM Tronics Unlimited Inc.

Performed by

Instrumentation Systems Center
University of Wisconsin
1500 Johnson Drive
Madison, Wisconsin 53706

James C Houge 11/20/87

James C. Houge, MSBME, PE
Chief Engineer

The output characteristics of the prototype unit were measured to enable comparison with existing standards and currently used electromedical devices. The apparatus consists of a generator unit and an applicator attached by a cable. The generator produces a high voltage signal with a carrier frequency of 434 kilohertz. The carrier is burst modulated virtually 100% at a frequency of 1 kilohertz (see figure 1). The composite signal is conveyed by a coaxial cable to the applicator discharge electrode. The discharge electrode is recessed within the plastic applicator housing a distance of 4 cm. This defines the minimum approach distance between the skin of the subject and the discharge electrode. During application, the generator is keyed on for an interval of 15 seconds. This causes the signal to appear on the discharge electrode and the high voltage (4500 volts peak-to-peak) ionizes the air within the plastic applicator housing as the signal seeks a return path to ground. While the voltage is quite high, a substantial phase difference exists between the time of maximum voltage and maximum current resulting in a relatively small power output. Some of the signal passes through the subject, entering the skin over a 5 cm. diameter area from the corona within the applicator housing. This is shown in figure 2. The measured current passing through the tissue area contacted by the applicator was .022 amperes RMS (root mean square). The measured in-phase voltage across the tissue between the applicator and a ground return electrode was 1.06 volts RMS. This indicates that the power dissipated within the tissue was .023 watts. These measurements were made using beef joints with the approximate geometry and bone/tissue volume and distribution as the human knee. The experimental set up is shown in figure 3. Similar measurements were made using beef tissue sections with geometry and bone/tissue distribution similar to the human finger. These data were very similar to those measured using the knee joint simulation tests.

There is a voltage drop and resulting power dissipation at the interface between the corona within the applicator and the surface of the tissue. The in-phase voltage was measured to be 91 volts RMS with a corresponding power dissipation of 2 watts (see figure 3). This has the effect of heating both the air column within the applicator and the surface of the tissue in contact with the applicator. This temperature rise was measured to be 1.3 degrees C. after a 15 second application of the signal. This effect suggests that a duration of signal application of 15 seconds at a time should limit the temperature rise of the tissue surface to barely perceptible levels. The manufacturer has indicated

that subsequent units will employ an automatic timer to limit the duration of a single application to a 15 second burst.

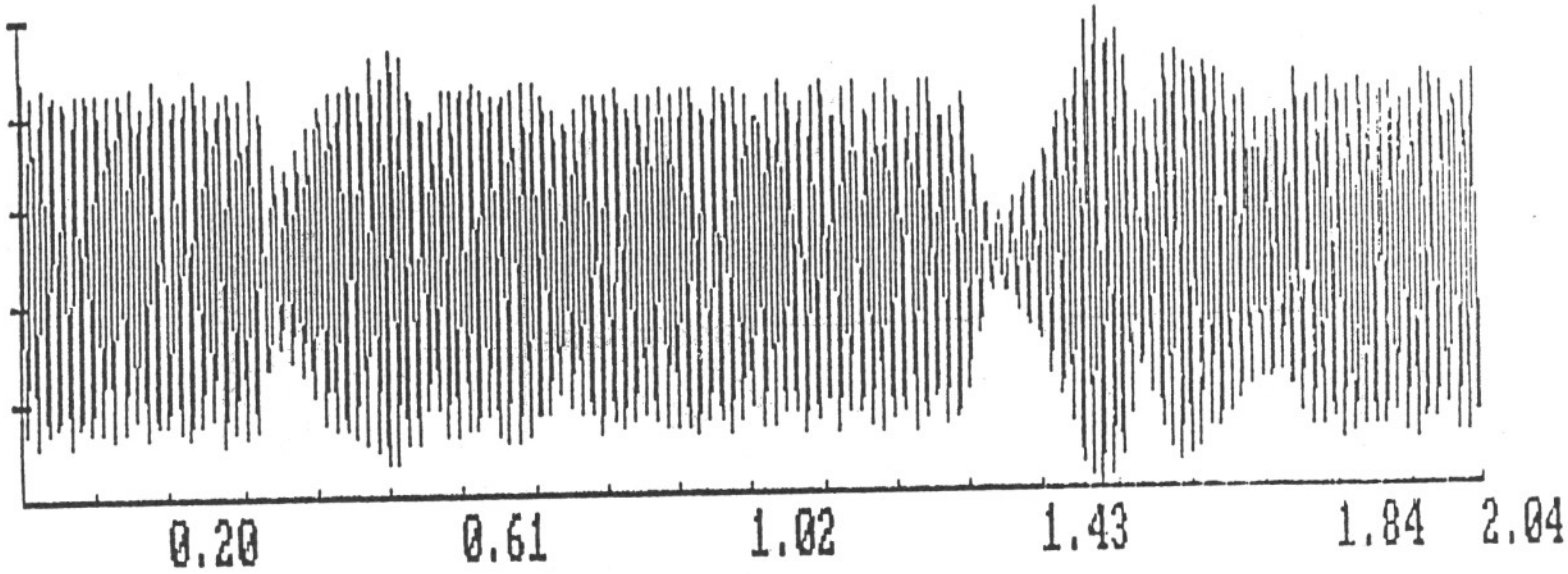
Less than one-third of the current emitted from the applicator passed through the tissue in contact with the tip of the applicator housing. The balance returned to ground by capacitance to other surfaces in the vicinity. These effects were studied by operation of the applicator in a large Faraday cage. The set up for these tests is shown in figure 4. This experiment allowed the total current output of the applicator to ground to be measured. The total current measured during signal operation was .072 amperes RMS. The voltage was measured at the phase angle of maximum current. The total power output from the applicator was calculated to be 6.6 watts. Tests were conducted to determine the maximum current that could return through the handle of the applicator. This would represent the part of the signal that could pass through the operator holding the applicator if he were in direct contact with ground. This current was measured to be .014 amperes RMS, which corresponds to a power dissipation of 1.27 watts.

The signals produced by the apparatus are of the same frequency range as electrosurgical units currently in widespread use. However the currents and corresponding power levels emitted and dissipated in the tissue are far lower, approximately 1/60 for the Sonotron device as compared to a typical electrosurgical unit. The currents measured from the Sonotron device should be below the threshold of perception for the normal range of humans,at these frequencies, as published by Dalziel (ref. 1). The level of measured current returning through the tissue in the simulation tests is sufficiently low that it would probably not even be perceptible by the subject even if he were inadvertently to come in point contact with ground. The very small power measured passing through the tissue suggests that the hazard that exists with electrosurgical units,ie. that of exit burns due to small contact area, should be absent in use of the Sonotron device.

The Sonotron device was subjected to tests to measure the 60 hertz leakage current using a standard test set produced by Ohmic Instruments. Leakage tests were made in off, on and operating modes. Measurements were made in both normal and reversed polarity. The maximum leakage current measured was 80 microamperes, below the maximum of 100 microamperes specified under the ANSI standard(see figure 5).

Summary: A prototype of the Sonotron device was subjected to 60 hertz electrical leakage tests and found to conform to existing ANSI standards for this class of electromedical device.

Tests were also conducted to quantify and classify the output signals. They were found to resemble the frequency spectra of electrosurgical units but with approximately 1/60 the current and power. The signal currents measured in joint tissue simulated applications indicate that the levels should be below the threshold of perception and the power levels small enough to preclude a burn hazard even in the event of inadvertent direct ground contact. These conclusions are valid for both tissue in contact with the applicator tip as well as the operator of the device. These data collected under use as defined by the manufacturer indicate that the Sonotron device could reasonably be regarded as a non significant risk device and eligible for evaluation on human subjects, within a suitable protocol, under the investigational device exemption provisions of the FDA regulations.



TIME IN MILLISECONDS

FIGURE 1

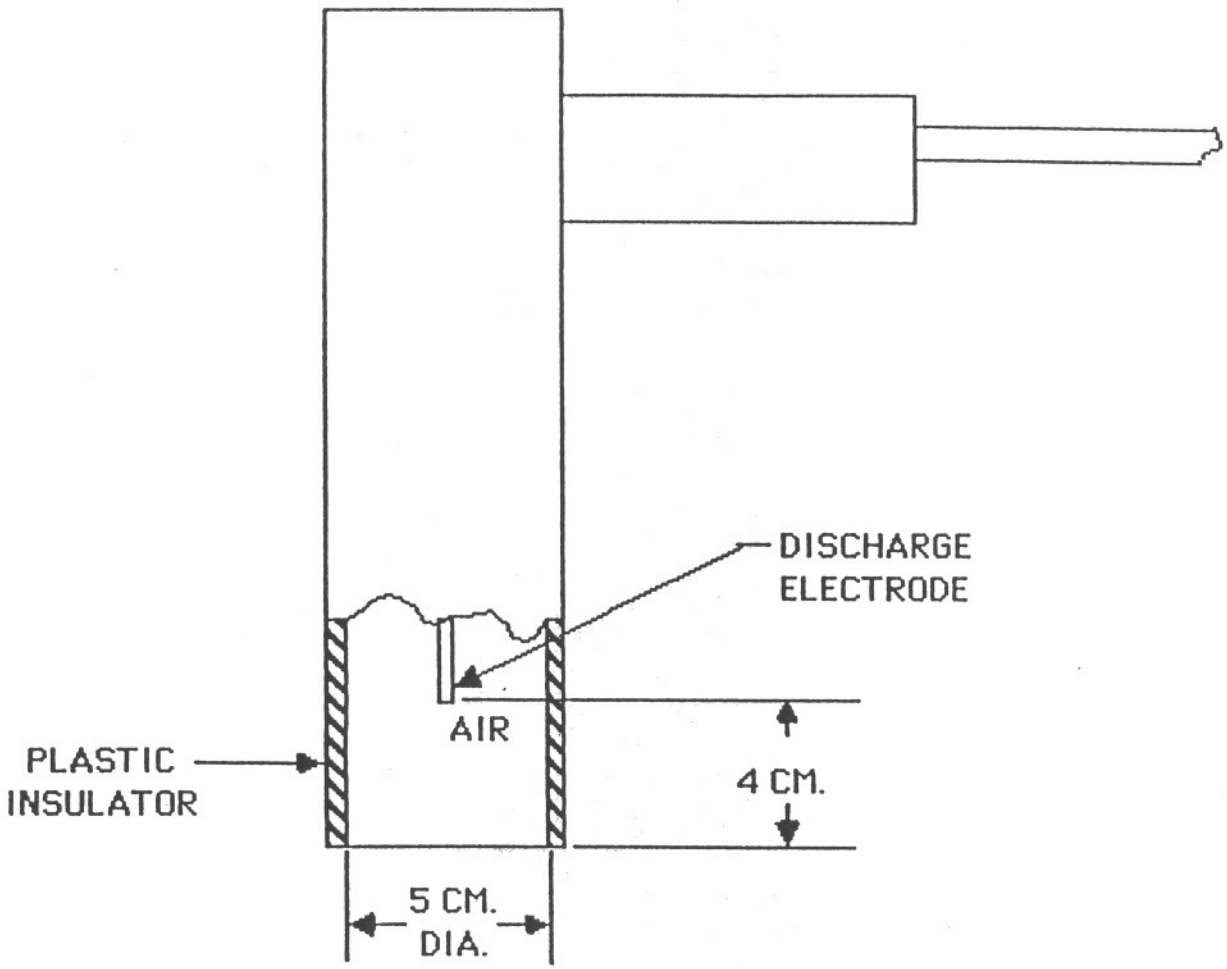


Figure 2

Sonotron Applicator

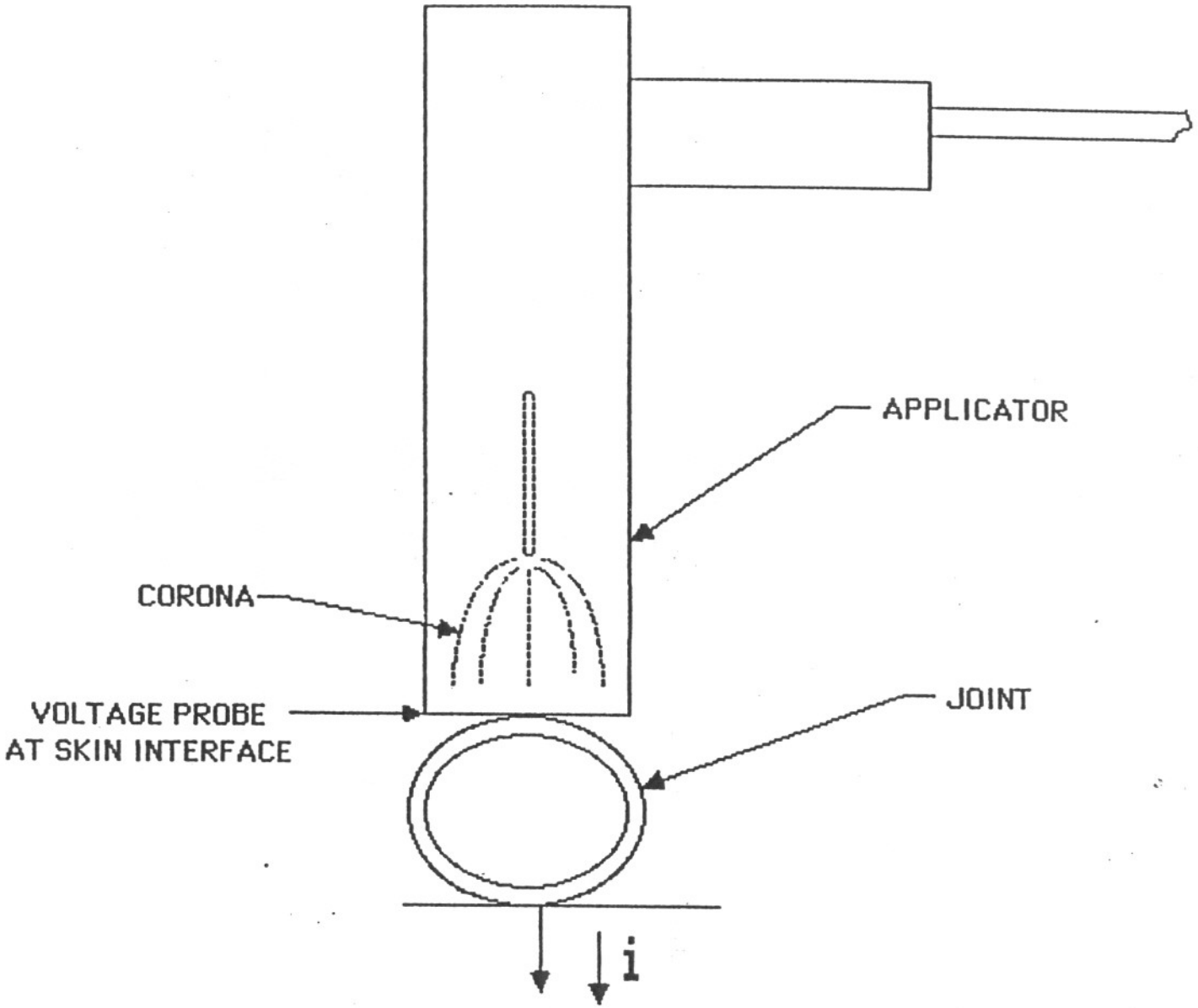


Figure 3

Bone/Tissue Simulator

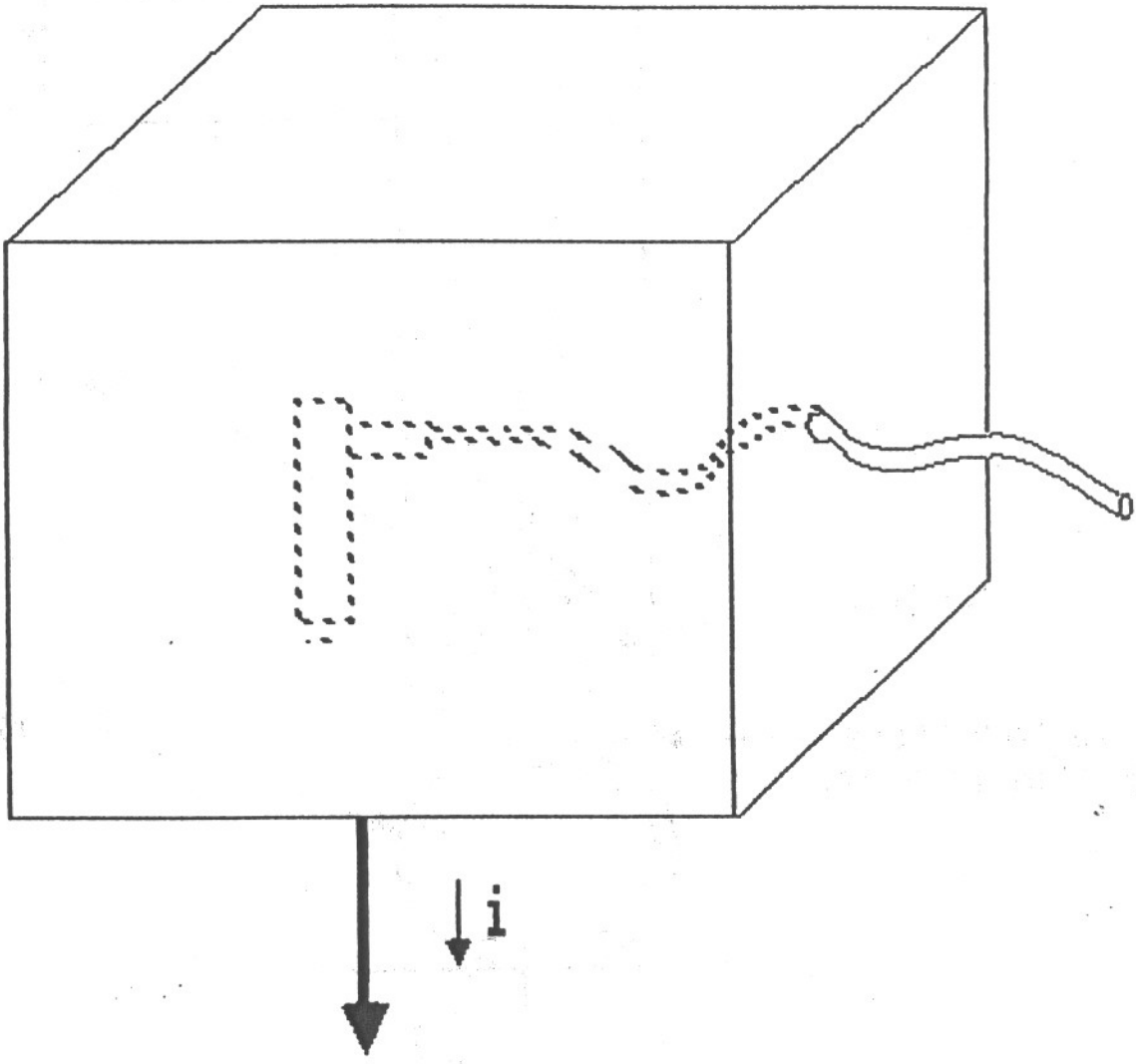


Figure 4

Faraday Cage

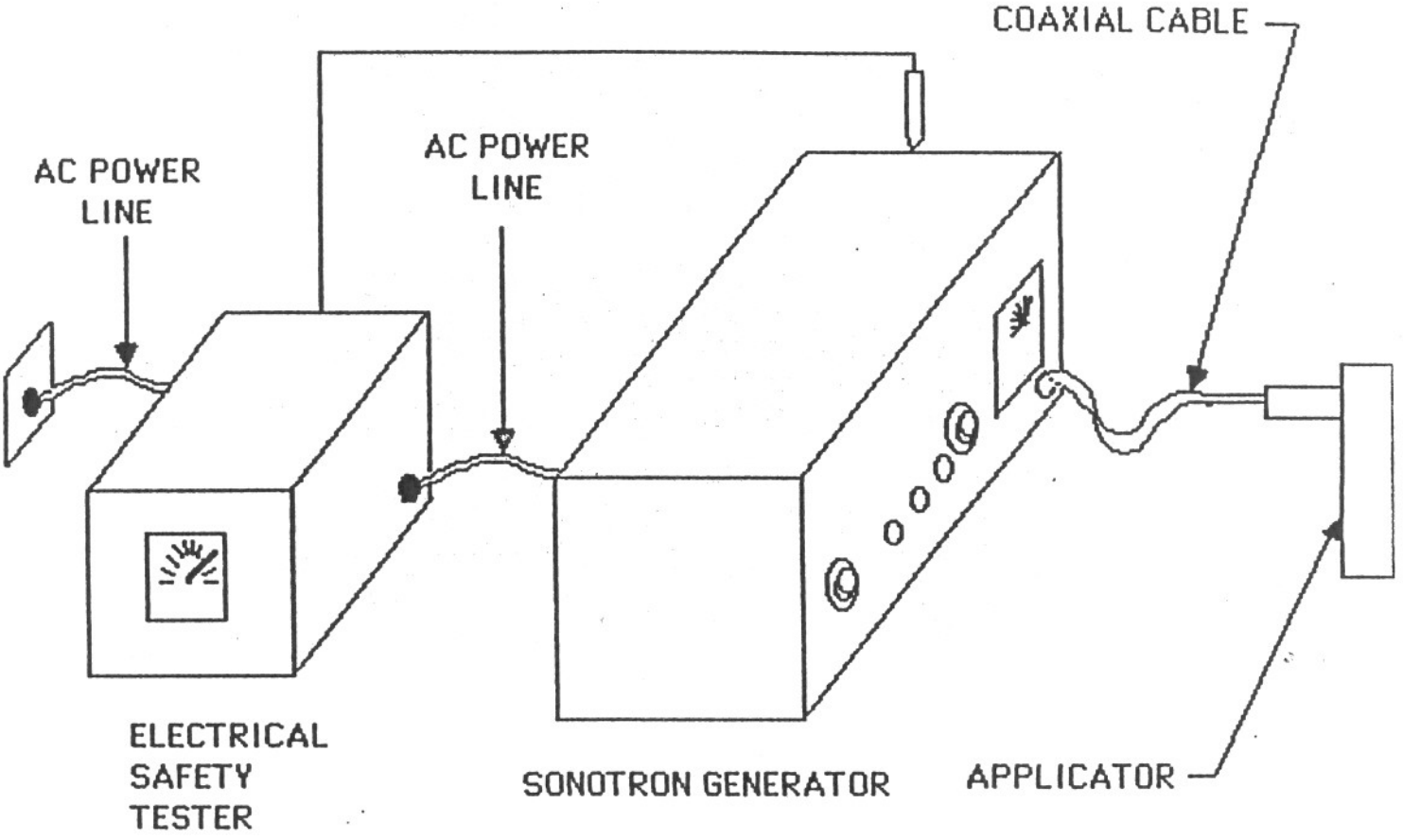
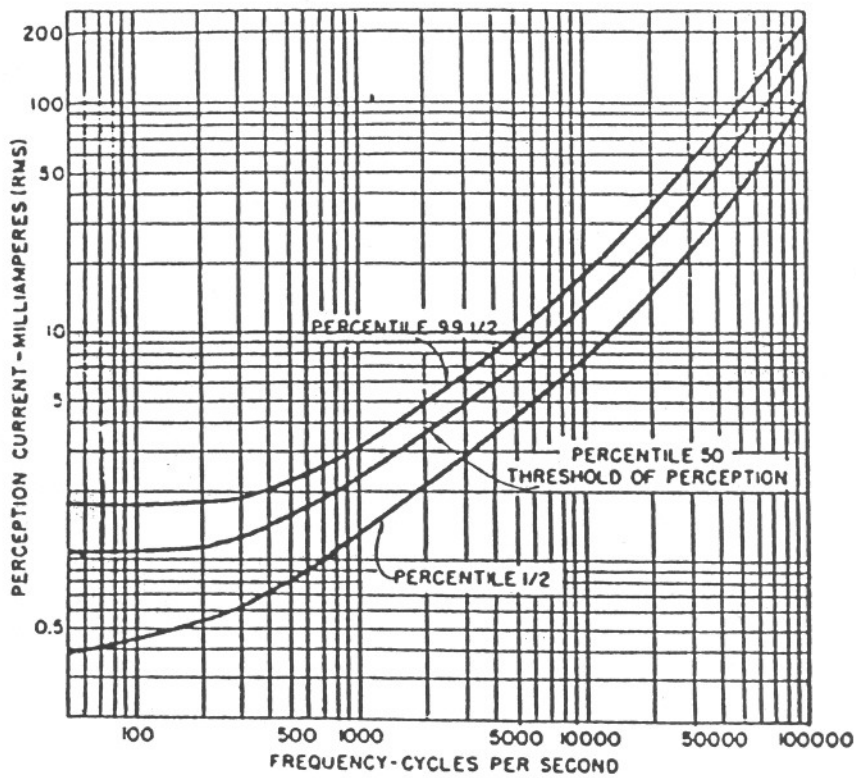


Figure 5

60 Hertz Leakage Measurement



REFERENCE 1

Effect of frequency on threshold of perception current for human subjects, measured with cylindrical hand-held electrodes. Reprinted from C. F. Dalziel, Electric Shock Hazard, in IEEE Spectrum, February, 1972.[5] The same source shows the 50-percentile "let-go" or muscle de-activating currents as 18 mA for frequencies up to 200 Hz, 22 for 1 KHz, and 73 mA for 10 KHz.