SAFETY CODE – 25

SHORT-WAVE DIATHERMY

GUIDELINES FOR LIMITING RADIOFREQUENCY EXPOSURE

Environmental Health Directorate
Health Protection Branch

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PREFACE

This document provides guidelines for the operation of short-wave diathermy devices to minimize exposure of the operators to radiofrequency radiation emitted by these devices. These safety guidelines do not govern exposure of the patient for therapeutic purposes as prescribed by a physician. The safety guidelines are intended for instruction and guidance of persons employed in Federal Public Service departments and agencies, as well as those coming under the jurisdiction of the Canada Labour Code. The guidelines may also assist provincial autho-rities having responsibility for controlling the installation and use of radiation emitting devices.

The document was prepared by the Radiation Protection Bureau in cooperation with the Bureau of Medical Devices and Federal Provincial Subcommittee on Radiation Surveillance.

Interpretation and further details of the recommendations of this safety code may be obtained from the Non-Ionizing Radiation Section, Radiation Protection Bureau, Environmental Health Directorate, Health Protection Branch, Ottawa, Ontario K1A 0L2.

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1. INTRODUCTION

Short-wave diathermy is used in medical therapy to produce local heating in tissue through the conversion of electromagnetic energy into thermal energy. This therapeutic modality has been in use since the mid-thirties, and since 1947 has been almost exclusively conducted at 27 MHz, one of the frequencies allocated for industrial, scientific and medical uses.

A Canada-wide survey of non-ionizing radiation emitting medical devices conducted in 1977 indicated that approximately the same number of short-wave diathermy devices and ultrasonic therapy devices were in use in hospital clinics, and that there were about ten times more short-wave (27 MHz) than microwave (2.45 GHz) diathermy units in use(1,2). Approximately the same total number of patients treated were treated by ultrasound and short-wave diathermy in all facilities (hospitals, physiotherapy, chiropractic and sports clinics).

Comprehensive measurements of the intensities of stray fields around short-wave diathermy devices(3) indicated that there is a potential for operator exposure in excess of the levels recommended by the Federal government(4).

Exposure to high intensity radiofrequency (RF) radiation can cause adverse health effects. It is essential, therefore, that such exposures be eliminated.

The purpose of these guidelines is to provide general advice to the operators of short-wave diathermy devices, that would assist them in limiting their exposure to RF radiation. Sample data on the RF field intensities for common treatments are given, and methods of measuring the exposure are described. Only a brief summary of reported biological effects is given. For a more comprehensive review other publications should be consulted(5-8).

2. BIOLOGICAL EFFECTS OF RF EXPOSURE

Electromagnetic radiation at the frequency of operation of short-wave diathermy (27 MHz) is known to produce various biological effects. The interactions and the biological effects produced at this frequency are not in any way frequency specific(7), and a broader base including the effects of other radiofrequencies should be considered. As a matter of fact, exposure of a human being at 27 MHz is well modelled in terms of expected biological effects by exposure of a small rodent to a much higher frequency, following the rules of physical scaling(9). Exposure to RF radiation can result in effects that are benign, beneficial (e.g., short-wave diathermy treatment) or potentially harmful. The brief review that follows is limited to effects that are potentially harmful, and against which protection is sought through adherence to exposure standards.

The interaction of RF and microwave radiation with living systems, including human beings, is a complex function of many parameters. Biological responses are due to the electromagnetic fields inside the biological body rather than to the external fields. The electrical properties (permittivity) of the living system and its geometry determine the amount of radiation reflected, transmitted and absorbed for a given exposure field. The exposure field is characterized by the frequency, intensity, polarization (direction) and type e.g., a plane wave, a fringe (leakage) field, the near-field of a radiator.

The interactions of RF fields with living systems can be considered on a macroscopic or microscopic (molecular, cellular) level. On the molecular level, two basic mechanisms govern the interactions. These are space charge polarization at lower RF frequencies and field-induced rotation of polar molecules at higher RF and microwave frequencies(5). The space charge polarization is due to travelling charge carriers, i.e., ions whole movement is affected by the applied field. Polar molecules i.e., molecules having an uneven spatial distribution of charges, such as water and proteins, experience a torque when placed in an electric field. Both of these mechanisms are of a relaxation character. In moderate fields only a relatively small number of charges or molecules is actually affected by the field (moved toward, or aligned with, the direction of the applied field). The movements are hindered by the thermal motion of molecules and charges, and the kinetic energy undergoes a conversion into the thermal energy. In these interactions the electromagnetic energy is converted into kinetic energy of molecules, and subsequently converted into thermal energy.

Quite a different mechanism underlies some specific inter-actions of extremely low frequencies (ELF) (below 100 Hz) and RF fields amplitude modulated at ELF frequencies(7), e.g., changes in calcium efflux. The fact that these interactions occur is well established, but their mechanisms are still not fully understood. These interactions are very sensitive to the frequency (ELF) and amplitude of the exposure field, as well as other variables, e.g., species[7].

Quite apart from the interaction mechanisms involved, biological effects are related to the intensities of the fields within the living body, not to the external intensity of an exposure field. The internal fields are a complex function of exposure conditions and other parameters. The internal fields are frequently described in terms of the specific absorption rate (SAR) which expresses the rate of energy absorption (e.g., at a given location, or averaged over the whole body) and is proportional to the square of the internal electric field intensity. The proportionality constant depends on the electrical properties of the tissue. The average SAR for a while body, far-field (far away from the radiator) exposure depends on the field frequency, intensity, direction, subject-to-source configuration, subject's size and shape, and presence of other objects particularly metal objects in the immediate vicinity. There are no simple methods of directly measuring the average SAR, but its approximate value can be calculated (it can be measured for animals, but the test animal has to be sacrificed). When exposure occurs in the far-field (plane-wave propagation), it has been shown[5], that for a given size and shape of a biological body, there is a frequency at which maximum amount of RF power is absorbed in the exposed body (Figure 1). This frequency is called the resonant frequency.

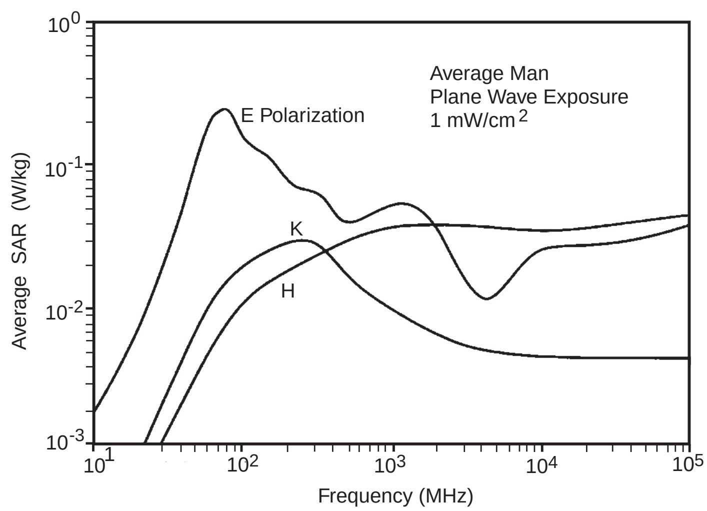

Figure 1 – Average specific absorption rate for an average man exposed to 1 mW/cm^2 plane wave. E polarization denotes the electric field parallel to the body, H denotes the magnetic field parallel to the body and K denotes the wave moving from head to toes or toes to head.

Not only does the maximum absorption occur at this frequency, but in a range of frequencies around it the distribution of the absorbed power in the body is highly nonuniform. Increased absorption occurs in various places inside the body, resulting in so-called “hot spots”. For human beings maximum energy absorption takes place between 30 and 100 MHz, depending on the body size and the environment. For an average man isolated from ground the frequency of the maximum absorption is about 80 MHz. For small experimental animals this frequency is much higher, e.g., for a rat, 900 MHz, for a mouse, 2000 MHz.

Very little is known about the average SAR and the SAR distribution for partial-body exposures close to the radiation source, such as may be the case for operator exposures in short-wave diathermy leakage fields. Calculations and experiments for other, not entirely dissimilar exposures, indicate that the whole-body average SAR for exposures in the near-field is less than the whole-body average SAR for exposures of the equivalent intensity in the far-field. The nonuniformity of SAR distribution is certainly further accentuated in partial-body exposures.

Biological effects of RF exposure have been investigated in various animals. There appears to be a consensus among scientists that the great majority of the effects of exposure to RF and microwave radiation, excepting those resulting from ELF modulated fields, are thermal in nature. This statement, however, should not be taken simplistically. The effects of RF induced heating are significantly different from the effects caused by other modalities of heating. Three distinctive features of RF and microwave induced heating are: various depths of penetration, the existence of internal “hot spots” and the rapidity of heating. The induction of nonuniformities in the temperature of various parts of the brain may cause alterations whole extent and implications have not yet been fully recognized.

The thermogenic effects of RF or microwave energy have been well documented and recently summarized[10]: (a) biological effects due to thermoregulatory response occur when an animal is thermally loaded at a rate equal to its basal metabolic rate (BMR);

(b) numerous behavioral and endocrine effects, and cardiac and respiratory changes for SARs below the BMR, are manifestations of physiological responses to mild thermal stress; (c) the thermal stress resulting from about twice the BMR, when maintained over long periods of time, leads to significant physiological effects, and (d) the responses to thermal load from pulsed fields appear to be the same as the responses to cw fields of the same average power.

The effects on two organs, the eye and the gonads, that are particularly susceptible to heat, have been extensively investigated(5). Microwave radiation at frequencies above 800 MHz can produce injury to the eye. The type of injury depends on the frequency, e.g., millimetre waves can produce keratitis. Cataracts develop after a sufficiently long exposure to power densities above 100 mW/cm^2. The effects on the testes result from high intensity fields and thermal injury.

Studies to investigate whether microwaves produce genetic effects have been performed on bacteria, flies, various plant and animal cells and tissue cultures. The results of the studies did not yield any reliable or systematic evidence that RF or microwaves can induce any mutation in living systems other than through induction of heat; it is known that the rate of induction of mutations increases with increasing temperature.

Studies of effects of RF exposure on mammalian teratogenesis indicate that there is a dose-response relation between the effects and the absorbed dose. Only intense fields that result in significant heating are associated with a reliable induction of teratogenesis.

No cardiovascular disturbances occur as the result of exposure to electromagnetic fields at relatively low levels (below 10 mW/cm^2). Some cardiovascular responses may result from the effects on the nervous system.

The effects of RF and microwave exposure on the central nervous system and on behaviour have been the most controversial subject in the field of biological effects of microwave radiation. In the USSR and some Eastern European countries it was asserted that exposure to low-level radiation (frequently referred to as "athermal") resulted in reversible neurasthenic disorders[5,6]. These observations have not been confirmed by the Western researchers. It has been clearly shown, however, that RF exposure can disrupt animal behaviour. The threshold value of the SAR for the effect has been established. Recent studies of possible synergistic effects of RF exposure and various drugs have produced a highly inconsistent picture, with synergy for some drugs, a weakening effect for others or no interrelation.

Most of the aforementioned biological effects (except cataracts) can be caused by exposure of humans to 27 MHz, when the radiation is of sufficient intensity and duration.

These and numerous other biological effects together with their biophysical basis have been considered in establishing protection standards[5,8,10]. Analysis of the scientific data base and criteria used in establishing the Canadian recommendation are given elsewhere[5].

3. RECOMMENDED MAXIMUM EXPOSURE LEVELS IN CANADA

Short-wave diathermy devices operate predominantly at a frequency of 27 MHz. The maximum levels recommended by Safety Code - 6[4] for "occupational exposure" of workers in federal establishments at these frequencies are as follows:

(i) For whole- or partial-body exposure (including extremities – hands and arms, feet and legs) averaged over a one-minute period

(rms) electric field intensity	300 V/m
(rms) magnetic field intensity	0.8 A/m
power density	25 mW/cm^2

(ii) For whole- or partial-body exposure excluding extremities averaged over a one-hour period

(rms) electric field intensity	60 V/m
(rms) magnetic field intensity	0.16A/m
power density	1 mW/cm^2

(iii) For a whole- or partial-body exposure (excluding extremities) for periods of exposure longer than 1 minute, but shorter than 1 hour, the maximum time, t (minutes), that a person can be exposed to the field must not exceed

$$t = 60/W,$$

where W (mW/cm^2) is the equivalent plane-wave power density. The equivalent plane-wave power density corresponding to the electric field intensity E (V/m) and the magnetic field intensity H (A/m) is:

$$W = E^2/3770,$$
$$W = 37.7\ H^2$$

(iv) For exposure of the extremities averaged over a one-hour period

(rms) electric field intensity	200 V/m
(rms) magnetic field intensity	0.5 A/m
power density	10 mW/cm^2

(v) For exposure of the extremities for periods longer than 1 minute, but shorter than 1 hour, the maximum time, t (minutes), that extremities can be exposed to the field must not exceed

$$t = 600/W$$

where W (mW/cm^2) is the equivalent plane-wave power density.

4. TYPICAL RF FIELDS CLOSE TO DIATHERMY DEVICES

There is some variety in designs of short-wave diathermy devices, and probably more diversified designs will be introduced in the future, however, certain common features can be distinguished. A diathermy device consists of an applicator, RF generator, and control console. The applicator, also called an electrode, applies RF energy to a certain portion of a patient's body. The RF generator is usually housed in the control console, although there are designs where it is incorporated into the applicator. RF power is delivered from the generator to the applicator by two cables forming an unshielded two-wire transmission line.

Two basic types of electrodes (applicators) are in use, the capacitor-type and the inductor-type such as a "pancake" coil or diplode. The heating mechanism and profile are somewhat different for the two types(11). In the case of capacitive electrodes, tissue heating is basically due to the RF electric field, while for inductive electrodes (coils), heating occurs by eddy currents induced in tissue by the magnetic field. The other field is also present, but at a much lower intensity.

The stray fields close to the applicator, but outside the treatment area, are relatively strong and highly irregular(3,12). High intensity fields are also produced near the cables. The radiation field close to the short-wave diathermy applicator is of the near-field type, so that the intensities of the electric and magnetic field are not at a constant ratio of 377 as they are for the far-field. There is no simple formula to predict the intensities of stray fields, except that the higher the power setting the stronger they are, if all other parameters (e.g., electrode placement) remain unchanged.

The typical range of intensities of the stray electric and magnetic fields around the diathermy cables is shown in Figure 2.

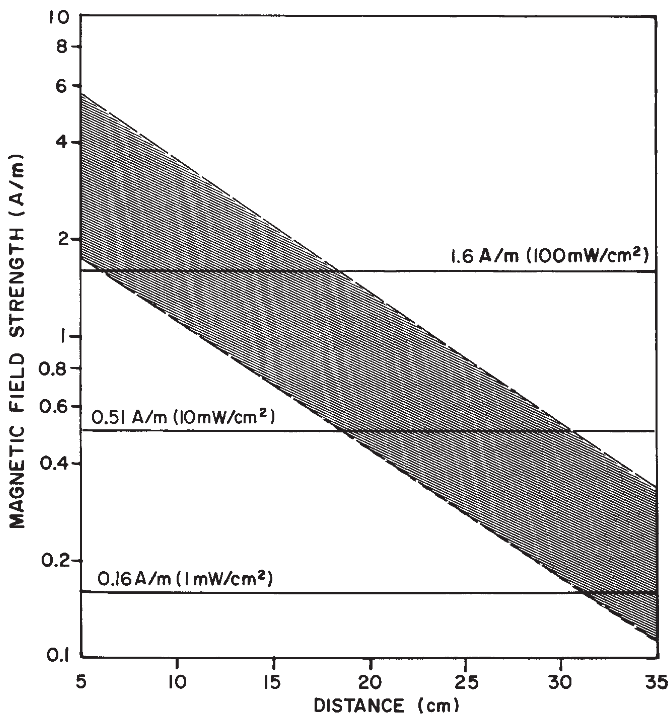

Figure 2a – The range (shaded area) of the magnetic field intensities around cables of the short-wave diathermy device for various types of electrodes and typical power settings.

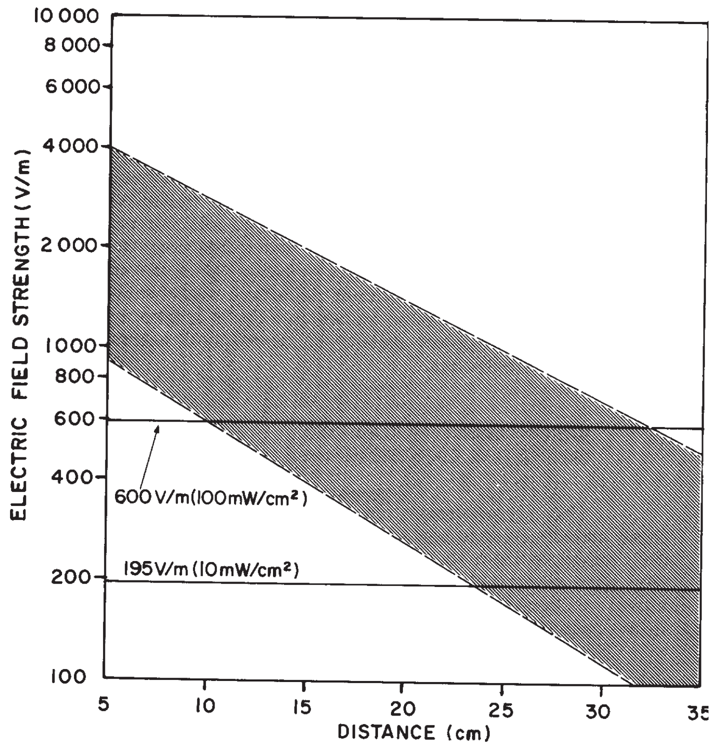

Figure 2b – The range (shaded area) of the electric field intensities around cables of the short-wave diathermy device for various types of electrodes and typical power settings.

The intensities of the fields around the electrodes depend on the electrode type and design, power setting, part of patient being treated, and placement of the electrode over the area being treated. The intensity decreases with distance away from the electrodes. The intensities are always highest in the plane of the applicator and are less above and below this plane for a given distance. However, disturbances to the stray field pattern can be introduced by large metal objects, e.g., a metal bed. In most treatment protocols, for properly placed electrodes, the intensities of the fields drop to below an equivalent power density of 1 mW/cm^2 at a distance of less than 1m[3,12]. A significant departure was observed for the treatment configuration shown in Figure 3, where fields with an equivalent power density of 10 mW/cm^2 extended to 1 m from the electrodes.

5. SAFE USE GUIDELINES – CONTROL OF OPERATOR EXPOSURE

The recommendations provided here address only those aspects of safe use that are specific to radiofrequency (RF) exposure from short-wave diathermy devices, and do not deal with electrical safety rules. The recommendations are aimed at keeping the operator exposure to RF within the limits recommended in Canada.

5.1 Care of Equipment

(a) Short-wave diathermy devices should be thoroughly examined at least yearly to ensure that all the parts are in good working order. Particular care should be taken to ensure that cables and electrodes are not cracked or burned, and the hinges of the applicator (electrode) support are working properly.

(b) The operation of electrodes should only be tested when they are placed over a tissue phantom such as a plastic container with physiological solution. Power must not be switched to the electrodes unless they are properly applied to a patient or the tissue phantom.

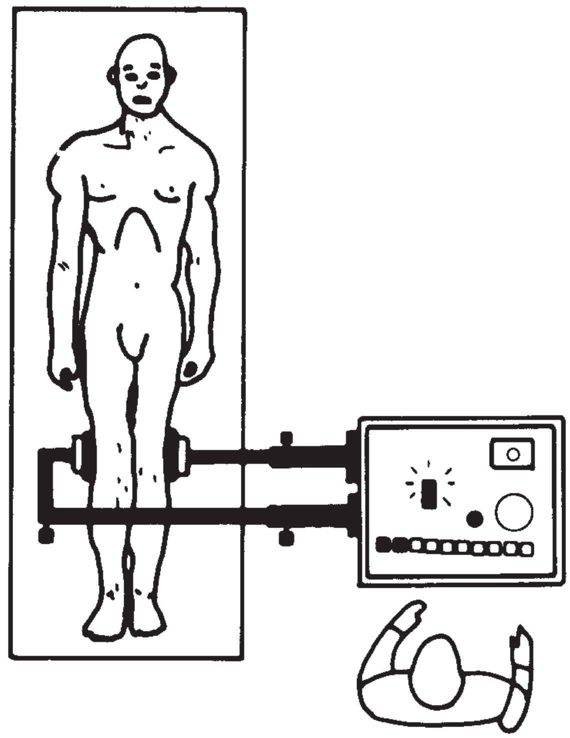

Figure 3 – The diathermy treatment configuration producing high intensity stray fields.

(c) Manufacturer's instructions on equipment care should be followed, and whenever there are any doubts whether the device operates properly, a qualified person should be called in to test the device.

5.2 Use of Equipment

Operators of short-wave diathermy devices should minimize potential exposure to RF radiation. To maintain exposures within the recommendations of the Federal government:

(a) Short-wave diathermy devices should be used only for treatments prescribed by a physician.

(b) The electrodes should be carefully placed over the treatment area. Minimizing the gaps between the electrodes and patient or towels helps to limit stray RF radiation.

(c) The RF power should be turned on only after the electrodes are in place.

(d) The operator should remain at least 1 m from the electrodes and 0.5 m from the cables during the treatment. Short duration excursions closer to the electrodes or cables are permitted, but only when necessary.

(e) No metal beds or chairs should be used during short-wave diathermy treatments. Other large metal objects should be kept at least 3 m from the electrodes and cables, when the short-wave device is in operation.

Care must be taken to ensure that the patient does not receive any unnecessary exposure to tissues other than those prescribed for treatment. To minimize such exposure:

(a) The applicator should be carefully placed to conform to the treated area as closely as possible.

(b) The cables leading to the applicator should not be placed in the vicinity of the patient's nonprescribed tissue.

(c) A patient-operated safety switch should always be operational, so that the patient can terminate the treatment.

(d) The patient should remove all metal objects.

If the patient has metal or other implants which may interact with RF energy, the physician must be aware of this before prescribing the treatment. Unless specifically recommended by the patient's physician after risk benefit considerations, the patient with implants must not be treated by short-wave diathermy.

(e) Patients with cardiac pacemakers should only be treated if recommended by their physician. The diathermy operator should remain in the treatment room or be able to observe the patient during the whole treatment duration.

(g) No pregnant patient should receive short-wave diathermy treatment in any area of the body which is likely to result in exposure of the fetus.

To avoid fire hazard, cables and electrodes should be kept away from flammable materials, as stray RF fields can heat such synthetic materials as nylon, polyvinyl chloride (PVC), polyethylene terephthalate (PET) and combinations of cotton with synthetics. Further information concerning thermal hazards associated with short-wave diathermy devices can be obtained from the Bureau of Medical Devices, Environmental Health Directorate, Health Protection Branch, Ottawa, Ontario K1A 0L2.

Short-wave diathermy devices should only be operated by a qualified nurse, medical practitioner or physiotherapist who has taken a course in the use of such devices.

6. RF RADIATION MEASUREMENTS

The need to measure stray RF fields around a short-wave diathermy device may arise when new electrodes or even complete devices are introduced, especially when the devices operate at high power (above 500 W). For instance, some RF diathermy devices used for cancer treatment operate at such high powers, and the design of the applicators may be such that intense stray fields are produced at greater distances(13). In such cases, an RF survey should be carried out to determine a safe working distance for the operator.

The following general recommendations on RF radiation surveys should be followed:

(a) The electrode should be positioned over a test treatment area of an appropriate phantom, e.g., a manikin filled with saline solution, or a patient receiving a prescribed treatment.

(b) If an output power indicator is provided, a low power setting should be used and the measurement results extrapolated to higher power settings assuming the power setting control operates linearly. For instance, if for a power setting of 100 W the electric field intensity at 1 m from the applicator is 15 V/m, and the treatment power setting is 400 W, then the electric field intensity at 1 m will be $\sqrt{\frac{400}{100}}\ 15 = 30$ V/m. (This level should be compared with the recommended maximum exposure of 60 V/m. In this case the operator is within safe limits at a distance of 1 m from the applicator).

(c) When an RF survey is performed, the electric and the magnetic field should be measures and their intensities compared against the standard.

(d) Instruments having isotropic sensing elements should be used for RF surveys, as the field direction is not known. Examples of suitable instruments include*: for the electric field, Holaday,

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* This does not constitute a statement of an official recommendation or endorsement of the products mentioned.

model HI3001, HI3002, HI3004, Narda, model 8609, for the magnetic field, Holaday, model HI-3002, Narda, model 8602, 8603, 8607 or 8608 with probe 8631 or 8633, or model 8609.

(e) The measurements should be done in the plane of the applicator and the plane of the cables.

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