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(i) For all possible combinations of adjustments of the controls listed in the operation instructions.

(ii) With the ultrasonic radiation emitted into the equivalent of an infinite medium of distilled, degassed water at 30 °C for measurements concerning the ultrasonic radiation.

(iii) With line voltage variations in the range of ±10 percent of the rated value specified by the manufacturer.

(3) *Measurement parameters.* Measurements for determination of the spatial distribution of the ultrasonic radiation field shall be made with a detector having dimensions of less than one wavelength in water or an equivalent measurement technique.

(f) *Informational requirements*—(1) *Servicing information.* The manufacturer of an ultrasonic therapy product shall provide or cause to be provided to servicing dealers and distributors, and to others upon request, at a cost not to exceed the cost of preparation and distribution adequate instructions for operations, service, and calibration, including a description of those controls and procedures that could be used to increase radiation emission levels, and a schedule of maintenance necessary to keep equipment in compliance with this section. The instructions shall include adequate safety precautions that may be necessary regarding ultrasonic radiation exposure.

(2) *User information.* The manufacturer of an ultrasonic therapy product shall provide as an integral part of any user instruction or operation manual that is regularly supplied with the product, or, if not so supplied, shall cause to be provided with each ultrasonic therapy product, and to others upon request, at a cost not to exceed the cost of preparation and distribution:

(i) Adequate instructions concerning assembly, operation, safe use, any safety procedures and precautions that may be necessary regarding the use of ultrasonic radiation, and a schedule of maintenance necessary to keep the equipment in compliance with this section. The operation instructions shall include a discussion of all operation controls, and shall describe the effect of each control.

(ii) Adequate description of the spatial distribution of the ultrasonic radiation field and the orientation of the field with respect to the applicator. This will include a textual discussion with diagrams, plots, or photographs representative of the beam pattern. If there is more than one ultrasonic transducer in an applicator and their positions are not fixed relative of each other, then the description must specify the spatial distribution of the ultrasonic radiation field emitted by each ultrasonic transducer and present adequate examples of the combination field of the ultrasonic tranducers with regard to safe use. The description of the ultrasonic radiation field shall state that such description applies under conditions specified in paragraph (e)(2)(ii) of this section.

(iii) Adequate description, as appropriate to the product, of the uncertainties in magnitude expressed in terms of percentage error, of the ultrasonic frequency effective radiating area, and, where applicable, the ratio of the temporal-maximum effective intensity to the temporal-average effective intensity, pulse duration, pulse repetition rate, focal area, and focal length. The errors in indications specified in paragraphs (c)(1) and (c)(2) of this section shall be stated in the instruction manual.

(iv) A listing of controls, adjustments, and procedures for operation and maintenance, including the warning ''Caution—use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.''

[43 FR 7166, Feb. 17, 1978, as amended at 45 FR 16483, Mar. 14, 1980; 53 FR 11255, Apr. 6, 1988]

SUBCHAPTER K [RESERVED]