

(4) If any test is performed in an enclosure, the enclosure shall be not less than 0.227 cubic meter (8 cubic feet).

(5) Any lamp designed to be operated only in a specific fixture or luminaire that the lamp manufacturer supplies or specifies shall be tested in that fixture or luminaire. Any other lamp shall be tested with no reflector or other surrounding material.

[44 FR 52195, Sept. 7, 1979, as amended at 53 FR 11254, Apr. 6, 1988]

PART 1050—PERFORMANCE STANDARDS FOR SONIC, INFRASONIC, AND ULTRASONIC RADIATION-EMITTING PRODUCTS

AUTHORITY: 21 U.S.C. 351, 352, 360, 360e-360j, 360hh-360ss, 371, 381.

§ 1050.10 Ultrasonic therapy products.

(a) *Applicability.* The provisions of this section are applicable as specified herein to any ultrasonic therapy product for use in physical therapy manufactured on or after February 17, 1979.

(b) *Definitions.* The following definitions apply to words and phrases used in this section:

(1) *Amplitude modulated waveform* means a waveform in which the ratio of the temporal-maximum pressure amplitude spatially averaged over the effective radiating surface to the root-mean-square pressure amplitude spatially averaged over the effective radiating surface is greater than 1.05.

(2) *Applicator* means that portion of a fully assembled ultrasonic therapy product that is designed to emit ultrasonic radiation and which includes one or more ultrasonic transducers and any associated housing.

(3) *Beam cross-section* means the surface in any plane consisting of the points at which the intensity is greater than 5 percent of the spatial-maximum intensity in that plane.

(4) *Beam nonuniformity ratio* means the ratio of the temporal-average spatial-maximum intensity to the temporal-average effective intensity.

(5) *Centroid of a surface* means the point whose coordinates are the mean values of the coordinates of the points of the surface.

(6) *Collimating applicator* means an applicator that does not meet the definition of a focusing applicator as specified in paragraph (b)(15) of this section and for which the ratio of the area of at least one beam cross-section, whose centroid is 12 centimeters from the centroid of the effective radiating surface, to the area of the effective radiating surface is less than two.

(7) *Continuous-wave waveform* means a waveform in which the ratio of the temporal-maximum pressure amplitude spatially averaged over the effective radiating surface to the root-mean-square pressure amplitude spatially averaged over the effective radiating surface is less than or equal to 1.05.

(8) *Diverging applicator* means an applicator that does not meet the definition of a collimating applicator or a focusing applicator as specified in paragraphs (b) (6) and (15) of this section.

(9) *Effective intensity* means the ratio of the ultrasonic power to the focal area for a focusing applicator. For all other applicators, the effective intensity is the ratio of the ultrasonic power to the effective radiating area. Effective intensity is expressed in watts per square centimeter ($W\text{ cm}^{-2}$).

(10) *Effective radiating area* means the area consisting of all points of the effective radiating surface at which the intensity is 5 percent or more of the maximum intensity at the effective radiating surface, expressed in square centimeters (cm^2).

(11) *Effective radiating surface* means the surface consisting of all points 5 millimeters from the applicator face.

(12) *Focal area* means the area of the focal surface, expressed in square centimeters (cm^2).

(13) *Focal length* means the distance between the centroids of the effective radiating surface and the focal surface, for a focusing applicator, expressed in centimeters (cm).

(14) *Focal surface* means the beam cross-section with smallest area of a focusing applicator.

(15) *Focusing applicator* means an applicator in which the ratio of the area of the beam cross-section with the smallest area to the effective radiating area is less than one-half.

(16) *Generator* means that portion of a fully assembled ultrasonic therapy

product that supplies electrical energy to the applicator. The generator may include, but is not limited to, a power supply, ultrasonic frequency oscillator, service controls, operation controls, and a cabinet to house these components.

(17) *Maximum beam nonuniformity ratio* means the maximum value of the beam nonuniformity ratio characteristic of a model of an ultrasonic therapy product.

(18) *Operation control* means any control used during operation of an ultrasonic therapy product that affects the ultrasonic radiation emitted by the applicator.

(19) *Pressure amplitude* means the instantaneous value of the modulating waveform, and is $p_1(t)$ in the expression for a pressure wave, $p(t)=p_1(t) p_2(t)$, where $p(t)$ is the instantaneous pressure, $p_1(t)$ is the modulating envelope, and $p_2(t)$ is the relative amplitude of the carrier wave normalized to a peak height of one. All are periodic functions of time, t , at any point in space. The period of $p_1(t)$ is greater than the period of $p_2(t)$.

(20) *Pulse duration* means a time interval, expressed in seconds, beginning at the first time the pressure amplitude exceeds the minimum pressure amplitude plus 10 percent of the difference between the maximum and minimum pressure amplitudes, and ending at the last time the pressure amplitude returns to this value.

(21) *Pulse repetition rate* means the repetition frequency of the waveform modulating the ultrasonic carrier wave expressed in pulses per second (pps).

(22) *Service control* means any control provided for the purpose of adjustment that is not used during operation and can affect the ultrasonic radiation emitted by the applicator, or can alter the calibration or accuracy of an indicator or operation control.

(23) *Ultrasonic frequency* means the frequency of the ultrasonic radiation carrier wave, expressed in Hertz (Hz), kilohertz (kHz), or megahertz (MHz).

(24) *Ultrasonic power* means the total power emitted in the form of ultrasonic radiation by the applicator averaged over each cycle of the ultrasonic radiation carrier wave, expressed in watts.

(25) *Ultrasonic therapy product* means:

(i) Any device intended to generate and emit ultrasonic radiation for therapeutic purposes at ultrasonic frequencies above 16 kilohertz (kHz); or

(ii) Any generator or applicator designed or specifically designated for use in a device as specified in paragraph (b)(25)(i) of this section.

(26) *Ultrasonic transducer* means a device used to convert electrical energy of ultrasonic frequency into ultrasonic radiation or vice versa.

(c) *Performance requirements.* The requirements of this paragraph are applicable to each ultrasonic therapy product as defined in paragraph (b)(25) of this section when the generator and applicator are designated or intended for use together, or to each generator when the applicator(s) intended for use with the generator does not contain controls that affect the functioning of the generator.

(1) *Ultrasonic power and intensity—(i) Continuous-wave waveform operation.* A means shall be incorporated to indicate the magnitudes of the temporal-average ultrasonic power and the temporal-average effective intensity when emission is of continuous-wave waveform. The error in the indication of the temporal-average ultrasonic power shall not exceed ± 20 percent for all emissions greater than 10 percent of the maximum emission.

(ii) *Amplitude-modulated waveform operation.* A means shall be incorporated to indicate the magnitudes of the temporal-maximum ultrasonic power and the temporal-maximum effective intensity when the emission is of amplitude-modulated waveform. The sum of the errors in the indications of the temporal-maximum ultrasonic power and the ratio of the temporal-maximum effective intensity to the temporal-average effective intensity specified in paragraph (d)(3)(ii) of this section shall not exceed ± 20 percent for all emissions greater than 10 percent of the maximum emission.

(2) *Treatment time.* A means shall be incorporated to enable the duration of emission of ultrasonic radiation for treatment to be preset and such means shall terminate emission at the end of the preset time. Means shall also be incorporated to enable termination of emission at any time. Means shall be

incorporated to indicate the magnitude of the duration of emission (expressed in minutes) to within 0.5 minute of the preset duration of emission for setting less than 5 minutes, to within 10 percent of the preset duration of emission for settings of from 5 minutes to 10 minutes, and to within 1 minute of the preset duration of emission for settings greater than 10 minutes.

(3) *Pulse duration and repetition rate.* A means shall be incorporated for indicating the magnitudes of pulse duration and pulse repetition rate of the emitted ultrasonic radiation, if there are operation controls for varying these quantities.

(4) *Ultrasonic frequency.* A means shall be incorporated for indicating the magnitude of the ultrasonic frequency of the emitted ultrasonic radiation, if there is an operation control for varying this quantity.

(5) *Visual indicator.* A means shall be incorporated to provide a clear, distinct, and readily understood visual indicator when and only when electrical energy of appropriate ultrasonic frequency is being applied to the ultrasonic transducer(s).

(d) *Labeling requirements.* In addition to the labeling requirements in part 801 and the requirements of §§1010.2 and 1010.3 of this chapter, each ultrasonic therapy product shall be subject to the applicable labeling requirements of this paragraph.

(1) *Operation controls.* Each operation control shall be clearly labeled identifying the function controlled and, where appropriate, the units of measure of that function. If a separate control and indicator are associated with the same function, then labeling the appropriate units of measure of that function is required for the indicator but not for the control.

(2) *Service controls.* Each service control that is accessible without displacement or removal of any part of the ultrasonic therapy product shall be clearly labeled identifying the function controlled and shall include the phrase "for service adjustment only."

(3) *Generators.* (i) Each generator shall bear a label that states: The brand name, model designation, and unique serial number or other unique identification so that it is individually

identifiable; ultrasonic frequency (unless there is an operation control for varying this quantity); and type of waveform (continuous wave or amplitude modulated).

(ii) Generators employing amplitude-modulated waveforms shall also bear a label that provides the following information: Pulse duration and pulse repetition rate (unless there are operation controls for varying these quantities), an illustration of the amplitude-modulated waveform, and the ratio of the temporal-maximum effective intensity to the temporal-average effective intensity. (If this ratio is a function of any operation control setting, then the range of the ratio shall be specified, and the waveform illustration shall be provided for the maximum value of this ratio.)

(4) *Applicators.* Each applicator shall bear a label that provides the following information:

(i) The brand name, model designation, and unique serial number or other unique identification so the applicator is individually identifiable;

(ii) A designation of the generator(s) for which the applicator is intended; and

(iii) The ultrasonic frequency, effective radiating area, maximum beam nonuniformity ratio, type of applicator (focusing, collimating, diverging), and for a focusing applicator the focal length and focal area.

(5) *Label specification.* Labels required by this paragraph shall be permanently affixed to or inscribed on the ultrasonic therapy product; they shall be legible and clearly visible. If the size, configuration, or design of the ultrasonic therapy product would preclude compliance with the requirements of this paragraph, the Director, Center for Devices and Radiological Health, may approve alternate means of providing such labels).

(e) *Tests for determination of compliance—(1) Tests for certification.* Tests on which certification pursuant to §1010.2 of this chapter is based shall account for all measurement errors and uncertainties. Such tests shall also account for increases in emission and degradation in radiation safety that occur with age.

(2) *Test conditions.* Except as provided in §1010.13 of this chapter, tests for compliance with each of the applicable requirements of this section shall be made:

(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 transducers 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."

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