

CPG Sec. 397.100 Accuracy Requirements for Indication of Temporal-Maximum Ultrasonic Power, 21 CFR 1050.10(c)(1)(ii)

BACKGROUND:

The subject paragraph of the Ultrasonic Therapy Performance Standard requires that units having an amplitude-modulated (pulsed) output waveform provide an indication of the temporal-maximum ultrasonic power and intensity. The requirement also states that the sum of the errors in the indications of temporal-maximum ultrasonic power and ratio of the temporal-maximum to temporal-average intensities may not exceed + 20% for all emissions greater than 10 percent of the maximum emission.

This accuracy requirement was specified in this way, i.e., as a sum of errors, in order to relate the error in the indication to the uncertainty in measurement of the temporal-average power. In the current state-of-the-art, the measurement of temporal-average power can be made with greater accuracy (e.g., by radiation force techniques) than the measurement of temporal-maximum power, which currently must rely on hydrophone measurements. Furthermore, many ultrasonic therapy devices are capable of operating in either the pulsed or continuous mode; since the production testing of such devices would include measurement of the temporal-average power (to calibrate the continuous mode), it is logical to relate the calibration of the pulsed mode to the same measurement.

The actual wording of this section of the standard has caused some confusion among users and manufacturers. The *Center for Devices and Radiological Health* intends to formally amend the standard so that the requirement will be stated more clearly. The amendment process requires a certain amount of time; for the interim period, the Agency policy regarding the calibration of the pulsed mode will be as specified below.

POLICY:

The intent regarding the calibration of the pulsed mode can be stated as follows: The temporal-maximum power and intensity must be indicated, and the ratio of temporal-peak to temporal-average intensities must be specified. For a given setting of the output control, the indicated

temporal-maximum power divided by the ratio of intensities will yield a value for temporal-average power. This calculated value must agree with the measured value of the temporal-average power, for the same setting of the output control, to within + 20 percent. This policy will guide the *CDRH's* compliance testing, and should guide manufacturers in production testing. Manufacturers and interested parties will be notified when the proposed amendment is published for comment and when the formal amendment process has been completed.

Material between asterisks is new or revised

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