

IMPORTANT DIFFERENCES AND SIMILARITIES BETWEEN IEC ULTRASOUND
THERAPY STANDARD AND FDA ULTRASOUND THERAPY STANDARD
(Not inclusive)

IEC [60601-2-5 (current) which references 61689 (1996)]

FDA [1978]

GENERAL

Application

FDA: Applies to any applicator (transducer) shape and multiple crystal applicators

IEC: Applies only to single, plane circular transducers

Beam Shape

FDA: Differentiates diverging, collimating, focusing beams

IEC: Diverging, collimating, convergent beams (no highly focused beams allowed - see below)

Beam Area

FDA: In any plane sum of points where intensity is > 5 % of peak intensity

IEC: In any plane minimum area encompassing 75% of total energy in plane x correction factor.

Effective Radiating Area (ERA) - beam area at applicator face

FDA: Measured at 5 mm from face. Very susceptible to problems finding spatial peak in near field.
Method can accommodate strange shaped applicators.

IEC: Determined by measuring Beam Areas at four distances from applicator and extrapolating back to surface. Tends to give smaller but more reproducible area values than FDA.

Modulation

FDA: Considered modulated if peak pressure amplitude of modulating wave is greater than 1.05 x the r.m.s. pressure amplitude.

IEC: Same

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LIMITS

Effective Intensity (EI) - defines average intensity at transducer surface (power/ERA)

FDA: No limit. (For focused beams defined at focal surface.)

IEC: Maximum $\leq 3.0 \text{ W/cm}^2$. (Tends to be higher than by FDA methods due to smaller ERA.)

BNR (Beam nonuniformity ratio) - defines spatial peak to effective intensity

FDA: No limits to BNR

IEC: $BNR \leq 8$ (This limits 'hot spots' in field and also precludes focused beams)
(Note: For ideal circular plane piston source, $BNR = 4$)
(Note: This limit, together with effective intensity limit \Rightarrow spatial peak temporal average intensity
($I_{spta} \leq 24 \text{ W/cm}^2$)

Applicator Temperature

FDA: Doesn't mention
IEC: Max Temperature rise $\leq 16 \text{ K}$

Leakage ultrasound

FDA: Doesn't mention
IEC: Max. Intensity $\leq 100 \text{ mW/cm}^2$

Timer (automatic shutoff)

FDA: Accuracy specified, but no limit
IEC: Same accuracy but 30 minutes max allowed

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INDICATORS

FDA: Meter or calibrated control for **average power and effective intensity** (continuous wave conditions) and **temporal maximum power and temporal max. effective intensity** (modulated waveform). Accuracy 20%. Also indicator for **pulse duration and repetition rate** if variable. Indicator "when and only when" power is applied to the transducer.
IEC: Same for **power and intensity** for continuous and modulated waveforms. Accuracy 20%. Pulse characteristics have to be given in accompanying literature for each modulation setting. No visual indicator required when transducer energized.

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SPECIFICATIONS (on applicator, generator or literature)

FDA: If not variable and indicated by meter or control then requires frequency, ERA, max BNR, applicator type (divergent, focusing, collimating), focal length and focal area if focused, description if modulated, pulse duration, pulse repetition rate, temporal max EI/EI. Also general maintenance, safety and installation information.
IEC: The same except also requires max. total power output and I_{spta} .