

Ward Photonics

ULTRASLIM CERTIFICATIONS

Independent laboratory testing, bench testing, animal testing, IRB clinical trials, international standards accreditations, and U. S. patents awarded for the UltraSlim® include:

- FDA Clearances K160880, K150336, and K202361.
- FDA Good Manufacturing Practices
- ISO13485:2016
- ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories.
- Complies with ISO14971:2019
- IEC 62471:2006 Photobiological safety of lamps and lamp systems.
- IEC 60601-1-2:2007 Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests.
- IEC 60601-2-57:2011, Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetics.
- IEC 60601-1:2012 reprint Medical Electrical Equipment - Part 1 General Requirements for Basic Safety and Essential Performance.
- ANSI/AAMI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 - Part 1 General Requirements for Basic Safety and Essential Performance.
- ISTA 3A Shipping & Handling (ASTM) testing.
- Toxikon Animal Testing 14-00947-N1 Non-GLP Report.
- Bench Testing "Comparison of Red Light Transmission Through Skin and Subcutaneous Fat" (comparison with low-level laser lipolysis).
- ClinicalTrials.gov (NCT02867150), with Summary Report, "A Retrospective Analysis of the Effects of Red Light Therapy on Body Contouring"
- Manufactured subject to US Patents No. 9,044,595 B2, 9,498,641 B2, and 9,808,314.

A close-up photograph of the UltraSlim device, showing a white top panel with the brand name 'UltraSlim' in red script. Below the panel is a blue surface densely packed with numerous small, circular light-emitting diodes (LEDs) arranged in a grid pattern.

UltraSlim

TECHNICAL SPECIFICATIONS

Power Density: 240,000 mW total, 1600 mW per diode, with 150 light emitting diodes.

Treatment Area: 56cm x 41cm (2,294cm²)

Output Intensity: 262.5 mW/cm² at 2",
105 mW/cm² at 6.7"

Treatment Time: 8 or 20 minutes

Standard Dose: 126 J/cm²

Wavelength: 635nm +/- 2nm

Electrical: 300 W, 110Vac, 3A, 60Hz
(Standard American Outlet)

Dimensions: 5.5 ft x 2 ft x 2 ft

Weight: 115 lbs (52 kg) on Wheels

CLINICAL RESULTS

Average Fat Loss/Visit: 3 1/2" 1,580.2ml of fat

Minimum Fat Loss/Visit: 1 5/8" 716.6ml of fat

Maximum Fat Loss/Visit: 10" 4,608.2ml of fat

(NCT02867150)

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