

Research

IRB Clinical Trials: Fat Reduction

In 2016 multi-site clinical trials ([NCT02867150 at ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02867150)), researchers documented that UltraSlim® Professional provides the results that so many of your patients want:

Immediate Results. All patients lost fat immediately -- without dieting, exercise, drugs, or surgery.

Dramatic Fat Loss At Each Visit. Patients lost an average of 1,580cc of fat in just 32 minutes (3.5" combined waist, hips, and thighs). During one visit!

Works For Everyone. Every patient had clinically significant losses at each visit, ranging from 717cc to 4,608cc (1 5/8" to 10" from the waist, hips, and thighs).

Durability. Patients seen at follow-up had lost an additional 1 1/8" of fat during the week following treatment. With UltraSlim®, patients lose the fat permanently through a natural bodily function known as "lipolysis", whereby the contents of their fat cells are excreted primarily in their waste.

IRB Clinical Trials: Cellulite and Fat Reduction

In 2016 multi-site clinical trials ([NCT03647748 at ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03647748)), researchers documented that UltraSmooth® is second only to UltraSlim® Professional for fat reduction (average losses of 3.9" 14 days post-treatment) and UltraSmooth® also significantly improves the appearance of cellulite noninvasively.

IRB Clinical Trials: Effects of a Red/Gold/IR LED Combination Light on Reduction of Fat

We are currently sponsoring clinical trials ([NCT04525573 at ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04525573)) as an open-label evaluation of the effects of a red/gold/IR LED combination light on the reduction of fat. The results shall be compared to previous results from a comparator UltraSlim® device utilizing only red LED monotherapy for the non-invasive reduction in fat layer for body contouring.

IRB Clinical Trials: Treatment of Lung Inflammation

We are currently sponsoring clinical trials ([NCT04524715 at ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04524715)) to determine if a reduction of pneumonic inflammation occurs after treatment with our investigational device applying red-light technology in the respiratory system of patients suffering from acute viral pneumonia.

Accreditations

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

- [IEC 60601-1:2012](#) reprint Medical Electrical Equipment - Part 1 General Requirements for Basic Safety and Essential Performance.
- [IEC 60601-1-2:2007](#) Medical electrical equipment. General re-quirements 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.
- [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.
- [IEC 62471:2006](#) Photobiological safety of lamps and lamp systems.
- [ISTA 3A](#) Shipping & Handling (ASTM) testing.
- [Toxikon Animal Testing 14-00947-NI](#) Non-GLP Report.
- FDA Good Manufacturing Practices.
- [FDA Clearances K160880, K150336, K180338, and K202361.](#)
- Manufactured subject to [US Patents No. 9,044,595, 9,498,641, 9,808,314, and 10,946,210.](#)
- [FDA-cleared, ISO 13485 certified devices](#) - the global standard for medical excellence.

Patents and Trademarks

The United States Patent and Trademark Office has awarded our inventors U.S. Patents No.: [9,044,595](#), [9,498,641](#), [9,808,314](#), and [10,946,210](#) and has accepted our pending [U.S. Patent Application No.: 63/074,790](#) for respiratory treatments.

- System and method for reducing lipid content of adipocytes in a body, US patent 9,044,595
- Fat reducing device and method utilizing optical emitters, US patent 9,498,641
- Fat reducing device and method utilizing optical emitters, US patent 9,808,314
- Cellulite and fat reducing device and method utilizing optical emitters, US patent 10,946,210
- Respiratory Treatment Device And Method Utilizing Optical Emitter, US patent 63/074,790

- Cellulite And Fat Reducing Device And Method Utilizing Optical Emitters, EU patent 14860875.5
- DISPOSITIVO Y MÉTODO PARA REDUCIR LA GRASA CORPORAL MEDIANTE LA UTILIZACIÓN DE EMISORES ÓPTICOS, [Colombian patent NC2019/0004085](#)
- DISPOSITIVO Y MÉTODO PARA REDUCIR LA GRASA CORPORAL MEDIANTE LA UTILIZACIÓN DE EMISORES ÓPTICOS, [Mexican patent MX/a/2019/004642](#)
- MÉTODO DE REDUÇÃO DO CONTEÚDO DE LIPÍDIOS DE ADIPÓCITOS SUBCUTÂNEOS, [Brazilian patent BR 11 2019 008187 9](#)

[We also have patents issued or pending in 146 other countries.](#)

The United States Patent and Trademark Office has also awarded several registered trademarks, including UltraSlim® and UltraSmooth®.

Our patents, trademarks, and other intellectual property are held by Blue Water Innovations, LLC.

MDSAP certification