

# ***A Retrospective Analysis of the Effects of Red Light Therapy on Body Contouring***

**Abstract:** *This multi-site clinical study finds that Photonica Professional™ achieves an average combined circumferential reduction of the waist, hips, and thighs of 3.5" at one visit using the same measurements schema as in the Zerona® study which found an average loss of 3.6" with seven office visits over three weeks. Further, 98% lost 2.0" or more at the first visit with Photonica Professional.*

**Photonica Professional™**

Ward Photonics LLC  
1980 N. Atlantic Avenue, Suite 1030  
Cocoa Beach, Florida 32931

## **Photonica Professional™**

**Abstract:** *This multi-site clinical study finds that Photonica Professional™ achieves an average combined circumferential reduction of the waist, hips, and thighs of 3.5" at one visit using the same measurements schema as in the Zerona® study which found an average loss of 3.6" with seven office visits over three weeks. Further, 98% lost 2.0" or more at the first visit with Photonica Professional.*

### **1. BACKGROUND**

There is a great demand to be slimmer and many people resort to cosmetic surgical procedures to become thinner, with more aesthetically appealing body contours. Others turn to non-invasive slimming technologies that destroy the fat cells with ultrasound, microwaves, heat, cold, or radio frequency radiation. Whether the fat cells are surgically removed or destroyed with a non-invasive technology, there are substantial risks to the patient, including damage to the surrounding tissue, nerves, blood vessels, lymphatics, and collagen fibers. These procedures may be accompanied with blood loss, loss of nerve sensitivity, and post-procedure recovery, often accompanied by a great deal of inflammation, bruising and pain. Once fat cells are removed or destroyed, subsequent weight gain cannot be normally distributed throughout the body's fat cells, inevitably resulting in dysmorphic fat accumulations in the subcutaneous and/or visceral fat.

Body contouring with red light therapy is safer than other procedures, offering non-invasive permanent fat removal by temporarily opening the fat cells and draining the contents using the body's natural process of lipolysis. There is no damage to tissue, no pain, no downtime, and no other negative outcomes. Since no cells are removed or destroyed, subsequent weight gain can be normally distributed throughout the body's fat cells,

Zerona and Photonica Professional use 635nm red light technology to cause lipolysis in subcutaneous fat. Zerona uses low-power lasers (US Patent 8932338) and Photonica Professional uses high-power, ultra-narrow bandwidth LEDs (US Patent 9044595). The primary difference between laser and non-laser light is that all of a laser's power is focused on a single point as a beam of "coherent" light. Lasers must therefore operate at extremely low power to avoid tissue damage. While low-level lasers like Zerona are safe on the skin and present a risk of tissue damage only to the eyes, higher power lasers can burn through steel. Photonica Professional does not present a risk to the eyes or any body tissue, and is therefore safer than lasers.

Zerona uses 5 lasers with 17.5mW each (87.5mW total power), all focused on five scanning pinpoints. Photonica Professional uses 150 custom LEDs with 1,600mW each (240,000mW total power) uniformly disbursed over an area approximately 23" by 17". Studies with porcine cadavers demonstrate that although the coherent light of the lasers is 107.5 times more efficient at penetrating the skin and delivering photonic energy to the fat cells, Photonica Professional emits 840.0 times more power, more than overcoming the transdermal inefficiency of its non-coherent light and delivers 7.8 times more photonic energy (Luminous Flux as measured in Lux) to the subcutaneous fat cells to biomodulate the lipolysis process:

	<b>Zerona</b>	<b>Photonica Professional</b>
Standard Dose Emitted To The Skin	0.06 J/cm <sup>2</sup>	50.4 J/cm <sup>2</sup>
Luminous Flux To The Subcutaneous Fat Cells	40.0 lx	313.6 lx

The design for Zerona is based on Dr. Rodrigo Neira's groundbreaking research and Erchonia's clinical trials<sup>1</sup> from May 2007 to June 2008 with 67 patients aged 18–65 in which they found that 3.6" circumferential reduction could be achieved with 17.5mW lasers, but incorrectly concluded that the non-coherent *"LED did not generate a statistically significant reduction in the circumference measurement in inches."* It appeared to be settled science in many publications 2009–2011 that lipolysis would not occur with LEDs, but occurred only with the coherent light of a certain type of laser.



The design for Photonica Professional is based on the subsequent research of Terry J. Ward, M.H.A., who in 2011 discovered that the published research and clinical trials were fundamentally flawed and that he could achieve greater results with his non-laser lights than had been published by Jackson, et al. Ward concluded that "light is light" and was awarded a patent for his non-invasive fat removal method and machine, which uses LEDs with 2,742 times more total power than Zerona and 19,200 times more power than the LED system studied in the Zerona clinical trials.

The Zerona treatment consists of a 20-minute exposure with five scanning lasers on the front of the patient and then 20 minutes on the back of the patient, with a total of 40 minutes exposure time for each treatment session. Sessions were scheduled three times a week for two weeks and "after" measurements were taken a week after the last treatment session, at the seventh office visit.

The treatment protocol considered here with Photonica Professional is referred to as "UltraSlim Cold Light®" and consists of an 8-minute exposure to the front, 8 minutes to the left side, 8 minutes to the back, and 8 minutes to the right side, with a total of 32 minutes exposure time for each treatment session. Since results are immediate, all before and after measurements are taken at the same treatment session.

## 2. OBJECTIVE

The objective of this study is to retrospectively review existing treatment records at multiple private practice locations in the United States of America to determine the combined circumferential reduction of the waist, hips, and thighs with a single 32-minute treatment session using the subject Photonica Professional product, without benefit of dieting or exercise, in order to establish a baseline of expected outcomes for patients who undertake this patented procedure and to compare the procedure's effectiveness with non-invasive fat reduction using the Zerona scanning low-level laser system by Erchonia Corp.

## 3. STUDY DESIGN/PATIENTS AND METHODS

**Retrospective Review:** A 100% sample of 58 patient records was taken in November 2015 from two private-practice locations for the initial treatment of their 29 most recently admitted patients to receive the specified red light therapy for body contouring in 2015. This sample size of 58 patient treatment records compares favorably with Zerona's treatment of 35 patients in the cited comparison of Zerona and a "sham" LED system.

**Ethics:** All patients gave informed consent for the procedure and no patient was denied service or offered a placebo treatment.

<sup>1</sup>Jackson, Robert F.; Dedo, Doug D.; Roche, Greg C.; Turok, David I.; Maloney, Ryan J. (2009). "Low-Level Laser Therapy as a Non-Invasive Approach for Body Contouring: A Randomized, Controlled Study". *Lasers in Surgery and Medicine* 41 (10): 799–809. doi:10.1002/lsm.20855. PMID 20014253.

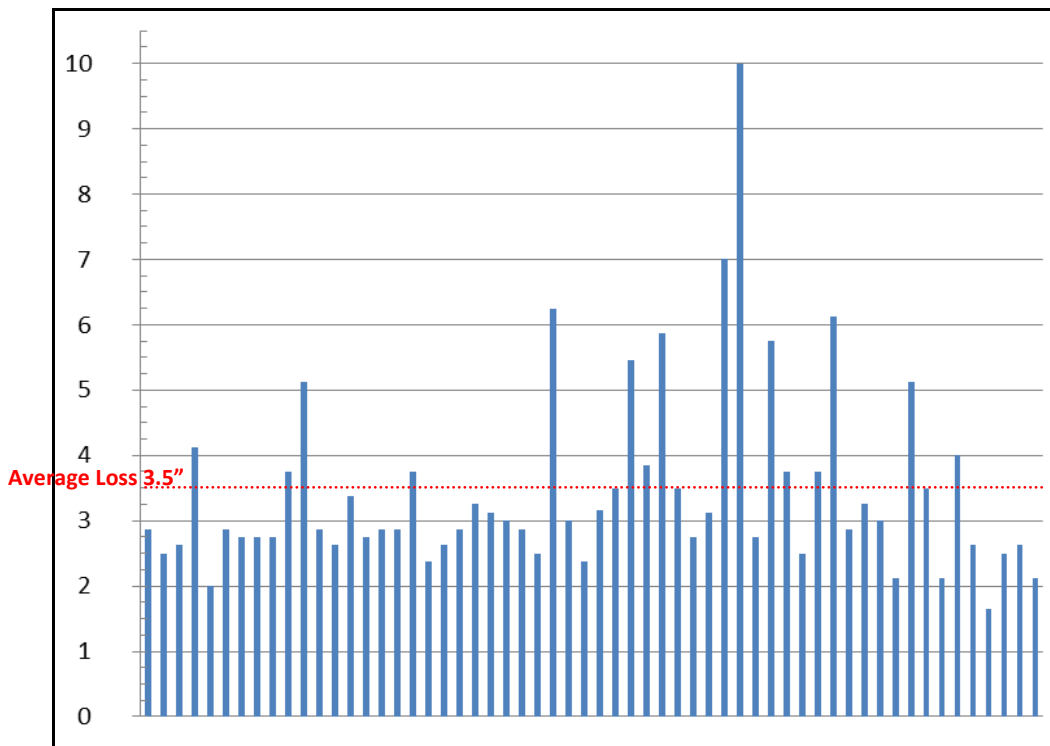
Exemption: This research involves the analysis of existing data and other materials where the data can be collected such that individual subjects cannot be identified in any way.

Methods: All patients were measured using the schema used for the Zerona circumferential reduction 2007-2008 clinical trials, with six measurements for females and five for males. Excluded from treatment were any individuals under age 18, any who were pregnant or trying to become pregnant, any with diminished liver or kidney capacity, any with active cancer, and any with a photosensitive condition or medication. Of the 58 patient records sampled, 46 were for females aged 18-74 years and 12 were for males aged 25-67 years. Although many patients receive multiple treatments, reported here are results achieved at the first visit.

Treatment: All participants received four eight-minute exposures with the Photonica Professional. Reduction in the total combined inches of circumference measurements of the waist, hip and bilateral thighs from immediately before and after the treatment was assessed.

Results: Participants demonstrated an overall reduction in total circumference across all three sites of 3.5 inches. As shown below in Chart 1 and in Table 1, one of the participants lost 1 5/8" (1.7%) and the other 57 participants (98.3%) lost 2" to 10" at the initial treatment. Females lost an average of 3/8" more than the males.

**CHART 1: Combined Inch Loss At The First Visit With Photonica Professional**



#### 4. PRODUCT

**Model: Photonica Professional**

**Description:** The **Photonica Professional** is an FDA-cleared non-invasive light therapy system that is based on emitting a specific type of red light using high-frequency constant current switching to modulate power to an array of high-power, ultra-narrow bandwidth Light Emitting Diodes ("LEDs").

The red light implements biochemical reactions in the skin which increase the skin's collagen and elastin, thereby reducing the appearance of lines, wrinkles, and fine lines while also treating benign vascular and

pigmented lesions, such as but not limited to solar lentigines, sun spots, liver spots and age spots. For the FDA-cleared indications for use (K150336), the treatment time is 20 minutes per exposure.

The special red light is also known to reduce the lipid content of adipocytes (“fat cells”) from targeted regions of a patient’s body. Knowledge of this side-effect is used by some physicians for off-label fat removal. This retrospective analysis examines records for 58 patients who received off-label treatments using the FDA-cleared device, but with treatment times of 8 minutes instead of 20.

Terry J. Ward, M.H.A., a Zerona laser expert, and Heidi Araya, a NASA scientist, were awarded a patent by the United States Patent and Trademark Office (US 9,044,595) for their breakthrough method of permanent fat removal without dieting or exercise, using only the non-invasive red light therapy with Ward’s invention. The special red light works by applying sufficient energy to release intracellular fat into the interstitial space. The released intra-cellular fat is then removed through the body’s natural functions.

Prior unpublished studies have shown that patients lost 2” to 10” combined from their waist, hips, and thighs, with an average loss of 3.4” and over 98% of patients losing at least two inches of fat in only 32 minutes, without diet or exercise. The current study is intended for public release.

Although the coherent light from lasers is more efficient at penetrating the skin due to its concentration on a single pinpoint, upon contact with the subcutaneous fat, the light scatters and becomes non-coherent in the adipose tissue. The Photonica Professional starts with non-coherent light, which requires more power because it is less efficient at penetrating the skin, but allows it to safely deliver 7.8 times more photonic energy (luminous flux) to the fat cells without tissue damage as would occur with coherent laser light of that intensity.

Zerona delivers all of its energy to a single point on the skin and uses scanning to distribute the power. At the point on the skin where the laser is focused, the laser is some 500,000 times more powerful than the light from Photonica Professional, but because Zerona moves the active pinpoint with a scanner, the total photonic energy (luminous flux) delivered to the fat cells is much lower than with Photonica Professional.

Zerona is 248.25 times more efficient at penetrating the skin, delivering 739.78 lx/mW/cm<sup>2</sup> to the fat cells while the Photonica Professional delivers only 2.98 lx/mW/cm<sup>2</sup>. Photonica Professional compensates for lower efficiency by using a stronger irradiance.

Photonica Professional consists of a main control unit, LED panel, and cable connections. The main control unit contains the main input, fuses, power supply, control circuits, Start button, and Minutes selector switch.

The power switch has a failsafe system that ensures the voltage from a wall socket can never come in contact with the user. A hospital-approved isolation transformer is mounted on the base of the medical pole cart and also supports the main control unit and the light fixture, with an articulated arm. System operation is preset. The unit operates at a wavelength of approximately 635nm, with a total power output of approximately 300 watts.

This technology is based on high-power, ultra-narrow bandwidth LEDs in the red spectrum. Due to a 60° lens on each LED, there is very little variation in light output across the treatment area.



The device is intended for prescription use by a physician or their staff in an office environment or health facility.

## **5. MEASUREMENTS**

To assure a fair comparison with the Zeronia clinical trials, all patients were measured using the schema used for the 2007-2008 Zeronia circumferential reduction clinical trials, with six measurements for females and five for males.

Shown below are Figures 1 through 6:

Figure 1: Zeronia Female Measurements Guide

Figure 2: Zeronia Female Measurement Form

Figure 3: Zeronia Male Measurements Guide

Figure 4: Zeronia Male Measurement Form

Figure 5: UltraSlim Female Measurement Form

Figure 6: UltraSlim Male Measurement Form

As shown in these figures, the “UltraSlim” measurement forms record the same parametric data in the same 1/8” increments as used for the Zeronia clinical trials.

FIGURE 1: Zerona Female Measurements Guide



## Female Measurements Guide

- ▶ Each patient is measured prior to the first treatment and after the 6th. If the patient has lost a minimum of 3.0 inches (cumulative from the measurement areas indicated below) after the 6th treatment, they are to return approximately one week later for the FINAL MEASUREMENT. If the patient has not lost a minimum of 3.0 inches then another 3 treatments will be provided and scheduled every other day over the next week.
- ▶ All measurement data must be obtained at the same point on the body. It is critical that appropriate Reference Points are used to ensure accurate and consistent results.
- ▶ The individual taking measurements must make sure the measuring tape is flush to the skin, pulled snugly and is level to the ground at both front and back.
- ▶ Patients should stand with feet placed shoulder-width apart and relax their muscles before measuring. You can also use "colored tape" to mark the floor so the patient's feet are always in the same position and the same distance apart. Note: Also avoid letting the patient "suck in" their tummy when measuring – this is a common reflex.
- ▶ Patients should wear the same undergarments when taking each measurement (two piece bathing suit or bra and panties).
- ▶ To ensure consistency, SBMI Protocol requires that all measurements are obtained in relation to a standardized Reference Point (i.e. how far below umbilicus is hip measurement, or how far above the kneecap for thigh measurement).
- ▶ To ensure the diodes (or arms) are the same distance from the body for each treatment, a measurement between the center diode to the umbilicus must be taken and recorded. The distance from the diodes to the body should not exceed 8 inches, however closer is better, as long as the tail feathers of the diode lights touch or intersect.
- ▶ Using this Reference Point system is key in allowing you to re-measure the same area to document the real change in circumference after treatment. Change in circumference will vary from patient to patient.

Below is a summary of Exact Measurement Areas  
& Reference Points.

Measurement Area (Circumference in Inches)	Reference Point
Back	Circumference where fat is under bra and note distance in inches above the umbilicus
Waist	2-3 inches above umbilicus (note distance)
Mid-Abdomen	2-3 inches below the umbilicus (note distance)
Hips	Note distance below umbilicus
Thighs (right and left)	Greatest circumference, then note distance from top of kneecap

**Note:** Patients also lose inches from many areas not measured and in between measured areas.





**FIGURE 2: Zerona Female Measurement Form**

## Female ZERONA® Measurement Form

Practice Name \_\_\_\_\_ Physician Name \_\_\_\_\_

PATIENT INFORMATION			
Patient Name		Patient Number	
Age		Height	
City	State	Zip Code	

ZERONA PATIENT MEASUREMENT RESULTS						Limited Guarantee Treatments		
Measurements	Reference Point	Distance from Reference Point	Before 1st ZERONA Treatment (BASE)	After 6th ZERONA Treatment (6th)	One Week After 6th Treatment	After 9th ZERONA Treatment (9th)	After 12th ZERONA Treatment (12th)	Total Loss per Measurement Area (BASE minus FINAL)
Date of Measurement								
Weight Each Date								
Diode Distance	Diode Head to Umbilicus							
Back	Base of Bra							
Waist	Umbilicus							
Mid-Abdomen	Umbilicus							
Hips	Umbilicus							
Right Thigh	Top of kneecap							
Left Thigh	Top of kneecap							
<b>Total Inches Lost</b>								
Patient Initials								
Medical Professional Initials								

ADDITIONAL SYSTEMIC MEASUREMENT RESULTS						Limited Guarantee Treatments		
Measurements	Reference Point	Distance from Reference Point	Before 1st ZERONA Treatment (BASE)	After 6th ZERONA Treatment (6th)	One Week After 6th Treatment	After 9th ZERONA Treatment (9th)	After 12th ZERONA Treatment (12th)	Total Loss per Measurement Area (BASE minus FINAL)
Neck								
Right Arm	Elbow							
Left Arm	Elbow							
Right Knee	Kneecap (center)							
Left Knee	Kneecap (center)							
<b>Total Systemic Inches Lost</b>								
<b>GRAND TOTAL INCHES LOST</b>								
Patient Initials								
Medical Professional Initials								

- You must start and finish your six treatments in two weeks. Each of the six treatments cannot be more than 72 hours apart.
- You must come back for your final measurement approximately 7 days after your final treatment.

**Email completed forms weekly to: [clientservices@sbmi.com](mailto:clientservices@sbmi.com) or fax to 888.684.8144**

Patient Signature \_\_\_\_\_

Medical Professional Signature \_\_\_\_\_



FIGURE 3: ZERONA Male Measurements Guide



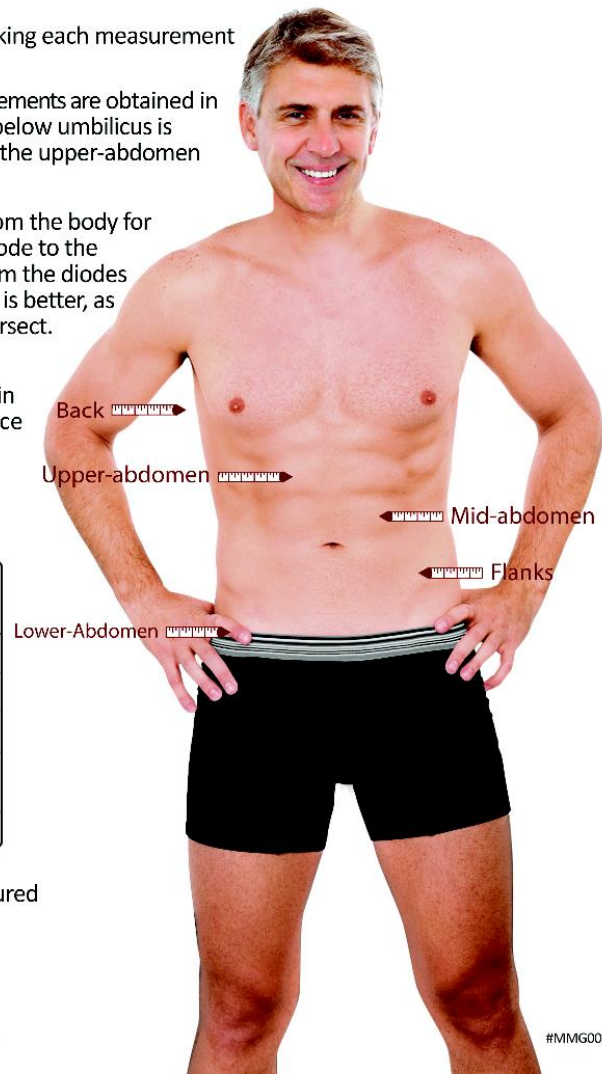
## Male Measurements Guide

- ▶ Each patient is measured prior to the first treatment and after the 6th. If the patient has lost a minimum of 3.0 inches (cumulative from the measurement areas indicated below) after the 6th treatment, they are to return approximately one week later for the FINAL MEASUREMENT. If the patient has not lost a minimum of 3.0 inches then another 3 treatments will be provided and scheduled every other day over the next week.
- ▶ All measurement data must be obtained at the same point on the body. It is critical that appropriate Reference Points are used to ensure accurate and consistent results.
- ▶ The individual taking measurements must make sure the measuring tape is flush to the skin, pulled snug and is level to the ground at both front and back.
- ▶ Patients should stand with feet placed shoulder-width apart and relax their muscles before measuring. You can also use “colored tape” to mark the floor so the patient’s feet are always in the same position and the same distance apart. Note: Also avoid letting the patient “suck in” their tummy when measuring – this is a common reflex .
- ▶ Patients should wear the same undergarments when taking each measurement (bathing suit or undergarments).
- ▶ To ensure consistency, SBMI Protocol requires that all measurements are obtained in relation to a standardized Reference Point (i.e. how far below umbilicus is flank measurement, or how far above the umbilicus for the upper-abdomen measurement).
- ▶ To ensure the diodes (or arms) are the same distance from the body for each treatment, a measurement between the center diode to the umbilicus must be taken and recorded. The distance from the diodes to the body should not exceed 8 inches, however closer is better, as long as the tail feathers of the diode lights touch or intersect.
- ▶ Using this Reference Point system is key in allowing you to re-measure the same area to document the real change in circumference after treatment. Change in circumference will vary from patient to patient.

Below is a summary of Exact Measurement Areas & Reference Points.

Measurement Area (Circumference in Inches)	Reference Point
Back	Circumference at level of nipples
Upper-Abdomen	Distance above umbilicus
Mid-Abdomen	2 - 3 inches above the umbilicus
Flanks	Circumference around “love handles”; note distance below umbilicus in inches
Lower-Abdomen	Distance from umbilicus

**Note:** Patients also lose inches from many areas not measured and in between measured areas.



**FIGURE 4: ZERONA Male Measurement Form**

## Male ZERONA® Measurement Form

Practice Name \_\_\_\_\_ Physician Name \_\_\_\_\_

PATIENT INFORMATION		
Patient Name	Patient Number	
Age	Height	
City	State	Zip Code

ZERONA PATIENT MEASUREMENT RESULTS						Limited Guarantee Treatments		
Measurements	Reference Point	Distance from Reference Point	Before 1st ZERONA Treatment (BASE)	After 6th ZERONA Treatment (6th)	One Week After 6th Treatment	After 9th ZERONA Treatment (9th)	After 12th ZERONA Treatment (12th)	Total Loss per Measurement Area (BASE minus FINAL)
Date of Measurement								
Weight Each Date								
Diode Distance	Diode Head to Umbilicus							
Back	Across Nipples							
Upper-Abdomen	Umbilicus							
Mid-Abdomen	Umbilicus							
Flanks	Umbilicus							
Lower-Abdomen	Umbilicus							
<b>Total Inches Lost</b>								
Patient Initials								
Medical Professional Initials								

ADDITIONAL SYSTEMIC MEASUREMENT RESULTS						Limited Guarantee Treatments		
Measurements	Reference Point	Distance from Reference Point	Before 1st ZERONA Treatment (BASE)	After 6th ZERONA Treatment (6th)	One Week After 6th Treatment	After 9th ZERONA Treatment (9th)	After 12th ZERONA Treatment (12th)	Total Loss per Measurement Area (BASE minus FINAL)
Neck								
Right Arm	Elbow							
Left Arm	Elbow							
Right Knee	Kneecap (center)							
Left Knee	Kneecap (center)							
<b>Total Systemic Inches Lost</b>								
<b>GRAND TOTAL INCHES LOST</b>								
Patient Initials								
Medical Professional Initials								

- You must start and finish your six treatments in two weeks. Each of the six treatments cannot be more than 72 hours apart.
- You must come back for your final measurement approximately 7 days after your final treatment.

Email completed forms weekly to: [clientservices@sbmi.com](mailto:clientservices@sbmi.com) or fax to 888.684.8144

Patient Signature \_\_\_\_\_

Medical Professional Signature \_\_\_\_\_

**UltraSlim**  
Cold Light

1-800-345-4381  
Info@MyUltraSlim.com

<b>Name</b> <i>(Last, First, M.I.):</i>	<b>Phone:</b>
<b>Home Address :</b>	<b>Email:</b>
<b>Location of Services:</b>	

[illegible]

UltraSlim<sup>®</sup>  
Cold Light<sup>™</sup>

1-800-345-4381  
Info@MyUltraSlim.com

<b>Name</b> <i>(Last, First, M.I.):</i>	<b>Phone:</b>
<b>Home Address :</b>	<b>Email:</b>
<b>Location of Services:</b>	

[illegible]

## 6. DATA

**Table 1: Before and After Measurements At The First Treatment Visit With Photonica Professional**

Age	Gender	Before Measurements						Total	After Measurements						Total	Loss	Mean	Min	Max
25	Male	46 7/8	42 5/8	41 1/2	42 1/2	44 1/2		218	46 3/8	42 1/4	40 7/8	41 7/8	43 3/4		215 1/8	2 7/8			
41	Male	46	42 7/8	41 1/2	44	44 1/4		218 5/8	45 5/8	42 3/8	41	43 3/8	43 3/4		216 1/8	2 4/8			
49	Male	38 5/8	36 7/8	34 1/2	37	38 3/8		185 3/8	38 1/4	36 1/2	33 7/8	36 3/8	37 3/4		182 6/8	2 5/8			
67	Male	51	49 1/2	53 7/8	56 1/4	52 7/8		263 1/2	49 3/8	49	53 1/4	55 1/2	52 1/4		259 3/8	4 1/8			
45	Male	38 1/8	35 1/4	34	36 1/8	36 3/4		180 1/4	37 7/8	34 7/8	33 5/8	35 5/8	36 1/4		178 2/8	2			
35	Male	38 5/8	36 3/4	33 1/8	32 7/8	33 3/4		175 1/8	38	36 1/4	32 1/2	32 1/4	33 1/4		172 2/8	2 7/8			
49	Male	44 7/8	42 5/8	38 7/8	38 3/4	39		204 1/8	44 3/8	42	38 3/8	38 1/8	38 1/2		201 3/8	2 6/8			
36	Male	43 7/8	40 3/4	38 7/8	42 3/8	42 1/2		208 3/8	43 1/4	40 1/8	38 1/2	41 3/4	42		205 5/8	2 6/8			
58	Male	46 7/8	48 3/8	48	47	47 7/8		238 1/8	46 1/4	47 7/8	47 3/8	46 1/2	47 3/8		235 3/8	2 6/8			
25	Male	39 3/4	36 1/2	37	39	39 1/4		191 1/2	39 3/8	36 1/8	36 1/2	38	37 3/4		187 3/4	3 6/8			
55	Male	46 1/4	45 1/8	44 1/4	45 1/4	45 3/4		226 5/8	44 1/2	44 1/8	43 1/2	44 1/2	44 7/8		221 1/2	5 1/8			
34	Male	44 1/4	43 5/8	41 1/2	45 1/8	44 5/8		219 1/8	43 7/8	43 5/8	40 7/8	44 1/4	43 5/8		216 1/4	2 7/8			
43.3	Total Lost 12 Males															37	3 1/8	2	5 1/8
43	Female	35 3/8	37 1/4	42 3/8	44 5/8	28	28	215 5/8	35	36 3/4	41 3/4	44 1/8	27 5/8	27 3/4	213	2 5/8			
51	Female	39 3/4	39 5/8	41 3/4	45 7/8	28 5/8	28	223 5/8	39	39 1/8	41 1/8	45 1/8	28 1/4	27 5/8	220 2/8	3 3/8			
54	Female	33	33 5/8	34 1/2	37 7/8	38		177	32 1/2	33	34	37 1/4	37 1/2		174 2/8	2 6/8			
45	Female	29 1/4	31 1/2	34 1/2	35 5/8	21 1/2	21 5/8	174	28 3/4	31 1/8	34	35	21 1/8	21 1/8	171 1/8	2 7/8			
67	Female	35 1/2	36 3/8	37	41 1/2	25 1/4	25 5/8	201 1/4	35	35 7/8	36 1/2	40 7/8	24 7/8	25 1/4	198 3/8	2 7/8			
42	Female	36 1/8	39 5/8	42 1/8	42 7/8	26	25 7/8	212 5/8	35 5/8	39	41 5/8	42 1/4	25	25 3/8	208 7/8	3 6/8			
28	Female	31 5/8	30 3/8	33 1/2	35 7/8			131 3/8	31	29 7/8	32 7/8	35 1/4			129	2 3/8			
38	Female	30 1/2	30 3/4	31 7/8	32			125 1/8	30 1/8	30	31 1/8	31 1/4			122 4/8	2 5/8			
18	Female	32	30 1/2	35 3/4	38 5/8	24 5/8	24 3/4	186 1/4	31 1/2	30 1/8	35 1/8	38	24 1/4	24 3/8	183 3/8	2 7/8			
60	Female	34 3/8	35 3/4	38 7/8	40 7/8	25 7/8	26	201 3/4	33 7/8	35 1/8	38 1/4	40 1/8	25 1/2	25 5/8	198 4/8	3 2/8			
52	Female	31 7/8	33 7/8	36 1/4	37	14	13 7/8	166 7/8	31 3/8	33 1/8	35 5/8	36 1/2	13 5/8	13 1/2	163 6/8	3 1/8			
47	Female	34 7/8	33 1/2	35 1/4	37 7/8	13	12 1/2	167	34 1/2	32 7/8	34 3/4	37 1/4	12 5/8	12	164	3			
35	Female	27 7/8	27 3/8	30 3/4	33 1/2	22 3/8	22 7/8	164 3/4	27 1/2	26 7/8	30	33	22	22 1/2	161 7/8	2 7/8			
36	Female	35 5/8	35 1/4	38 1/4	38 1/2	30 1/4	30 1/2	208 3/8	35 1/8	34 7/8	37 3/4	38 1/8	29 7/8	30 1/8	205 7/8	2 4/8			
30	Female	33	34 1/4	37 1/2	39 1/4	27 7/8	28 5/8	200 1/2	32 1/8	32 7/8	36 1/8	37 3/4	27 3/8	28	194 2/8	6 2/8			
36	Female	37 7/8	36 3/4	39	40 7/8	26 1/2	25 7/8	206 7/8	37 3/8	36 1/8	38 1/2	40 1/4	26 1/8	25 1/2	203 7/8	3			
38	Female	43 7/8	45 1/4	46 3/4	49	27 1/2	26 1/2	238 7/8	43 1/4	44 3/4	46 3/4	48 1/2	27 1/8	26 1/8	236 4/8	2 3/8			

35	Female	49	51 3/8	58 7/8	63 2/3			223	48 3/8	50 3/4	58	62 5/8			219 6/8	3 1/8			
40	Female	38 3/4	39 1/4	42 3/4	44 1/8	26 3/8	27 1/2	218 3/4	38 1/4	38 5/8	42 1/8	43 3/8	25 7/8	27	215 2/8	3 4/8			
55	Female	30 7/8	40 1/3	38 3/4	26	26		162	30 1/2	37 7/8	37 3/4	25 1/4	25 1/8		156 4/8	5 4/8			
35	Female	35	35 1/2	38 2/5	41 1/2	26	27	203 3/8	34	34 7/8	37 7/9	40 1/2	25 7/8	26 1/2	199 1/2	3 7/8			
34	Female	38 1/8	43 3/8	45 7/8	43	28 1/4	27 1/8	225 3/4	38	39 1/4	45 1/8	42 5/8	27 3/4	27 1/8	219 7/8	5 7/8			
48	Female	36 1/8	36 5/8	41 1/4	44 5/8	26 3/4	28 1/4	213 5/8	35 1/4	36 1/4	41	44	26 1/4	27 3/8	210 1/8	3 4/8			
30	Female	34 1/2	33 5/8	39	44	24 7/8	26 1/8	202 1/8	34 3/8	33 1/4	38 3/4	43	24	26	199 3/8	2 6/8			
74	Female	35 3/4	37 1/4	39 3/8	40 1/8	21 1/8	20	193 5/8	34 7/8	36 7/8	38 1/2	39	20 1/4	21	190 1/2	3 1/8			
32	Female	32 1/2	31 1/2	36 1/2	37 1/8	22 7/8	22 7/8	183 3/8	30 7/8	30	34	36 1/2	23	22	176 3/8	7			
54	Female	32 3/8	34 7/8	38 7/9	38 7/8	23 5/8	23 5/8	192 1/7	29 7/9	31 3/8	36 1/2	38 1/2	23	23	182 1/7	10			
43	Female	30 3/4	32 5/8	37	38 1/2	22 5/8	22 3/8	183 7/8	30 5/8	30 7/8	36 1/2	38 1/2	22 1/2	22 1/8	181 1/8	2 6/8			
30	Female	38 1/8	43 3/8	45 7/8	43	28 1/4	27 7/8	226 1/2	38	39 1/4	45 1/8	42 5/8	27 7/8	27 7/8	220 3/4	5 6/8			
51	Female	36 1/8	37 1/8	42	39	22 3/8	22 3/4	199 3/8	35 7/8	36 1/8	41 1/2	38	21 7/8	22 1/4	195 5/8	3 6/8			
45	Female	28 1/8	27 1/8	31	34 3/8	20 1/2	21	162 1/8	27 1/4	26 3/8	30 3/4	34 3/8	20 1/8	20 3/4	159 5/8	2 4/8			
19	Female	31 7/8	34	38 1/4	43 1/2	26 1/2	26 7/8	201	31 7/8	30 7/8	37 7/8	42	26 1/2	26 1/2	195 5/8	5 3/8			
41	Female	31 1/4	29	32	36 7/8	20 7/8	21 1/2	171 1/2	30 1/2	28	31 7/8	33 1/2	20 1/2	21	165 3/8	6 1/8			
28	Female	46 1/8	49 3/4	52 3/4	53 1/8			201 3/4	46	48 1/2	51 3/4	52 5/8			198 7/8	2 7/8			
31	Female	29 3/8	29 1/2	31	35 1/2	21 1/2	21 3/4	168 5/8	28 7/8	28 1/2	31	34 3/8	20 7/8	21 3/4	165 3/8	3 2/8			
35	Female	30	30 7/8	35	38 7/8	24 1/2	24 1/2	183 3/4	29 7/8	30	34 7/8	38 1/4	23 7/8	23 7/8	180 3/4	3			
49	Female	30 1/2	29 7/8	36	34	20 1/2	21 5/8	172 1/2	30	29	36	33 7/8	20 1/2	21	170 3/8	2 1/8			
54	Female	31	30 1/2	34	35 1/2	20	21	172	30 1/2	29 7/8	34	34	20	20 1/4	168 5/8	3 3/8			
24	Female	51 1/8	55 1/2	59	61	62 1/8		288 3/4	50 1/4	55 1/8	58 1/4	60 3/8	61 1/4		285 1/4	3 4/8			
53	Female	32	32 1/2	38 1/2	36 3/4	20 3/8	20 5/8	180 3/4	31 5/8	32 1/4	38	36 1/2	20	20 1/4	178 5/8	2 1/8			
50	Female	33 3/4	42 1/8	24 3/4	22 1/2	24 3/8	22 1/2	170	33 1/2	41 1/8	24 1/4	21 3/8	24 1/8	21 5/8	166	4			
51	Female	39 3/8	41 5/8	43 1/2	44 5/8	46 5/8		215 3/4	39 3/8	41	42 7/8	43 7/8	46		213 1/8	2 5/8			
40	Female	32 3/4	34 5/8	37 3/4	40 7/8	24 1/8	24 1/8	194 1/4	32 1/2	34 1/4	37 3/8	40 1/4	24 1/8	24 1/9	192 3/5	1 5/8			
37	Female	34 1/4	39 1/8	24 1/2	24 1/4	23	23 1/8	168 1/4	34	38 5/8	23 7/8	23 3/4	22 3/4	22 3/4	165 3/4	2 4/8			
54	Female	33 1/4	31 5/8	34 7/8	37 5/8	12 1/2	12 5/8	162 1/2	33	30 3/4	34 3/8	37 3/8	12 1/8	12 1/4	159 7/8	2 5/8			
50	Female	30 5/8	33 5/8	35 3/8	36 1/2	21 5/8	21 1/4	179	30	33 3/8	35 1/8	35 3/4	21 1/2	21 1/8	176 7/8	2 1/8			
42.2	Total Lost 46 Females															162 6/8	3 4/8	1 5/8	10
43.3	Total Lost 58 Patients															199 6/8	3 4/8	1 5/8	10

## 6. ANALYSIS

Since the patient records were a random sample of the patients treated at the reporting clinics, the demographics reflect the clinics' caseload:

46 of the patients are female (79%) and 12 are male (21%)

Females ranged in age from 18 to 74, with an average age of 42.2 years

Males ranged in age from 25 to 67, with an average age 43.3 years

Overall, patients ranged in age from 18 to 74, with an average age 43.3 years

As shown in Table 2, females lost an average of 3 ½", with a range of 1 5/8" to 10.0". Males lost an average of 3 1/8", with a range of 2.0" to 5 1/8". Overall, patients lost an average of 3 ½", with a range of 1 5/8" to 10.0" lost at the first treatment visit:

**TABLE 2: Summary of Inches Lost By Gender**

	Total	Females	Males
Patients	58	46	12
Average Inch Loss	3 1/2	3 ½	3 1/8
Minimum Inch Loss	1 5/8	1 5/8	2
Maximum Inch Loss	10	10	5 1/8

As shown in Table 3, fully 81% of patients lost between 2" and 4", while 18% lost more than 4" and 2% lost less than 2" at the first treatment visit:

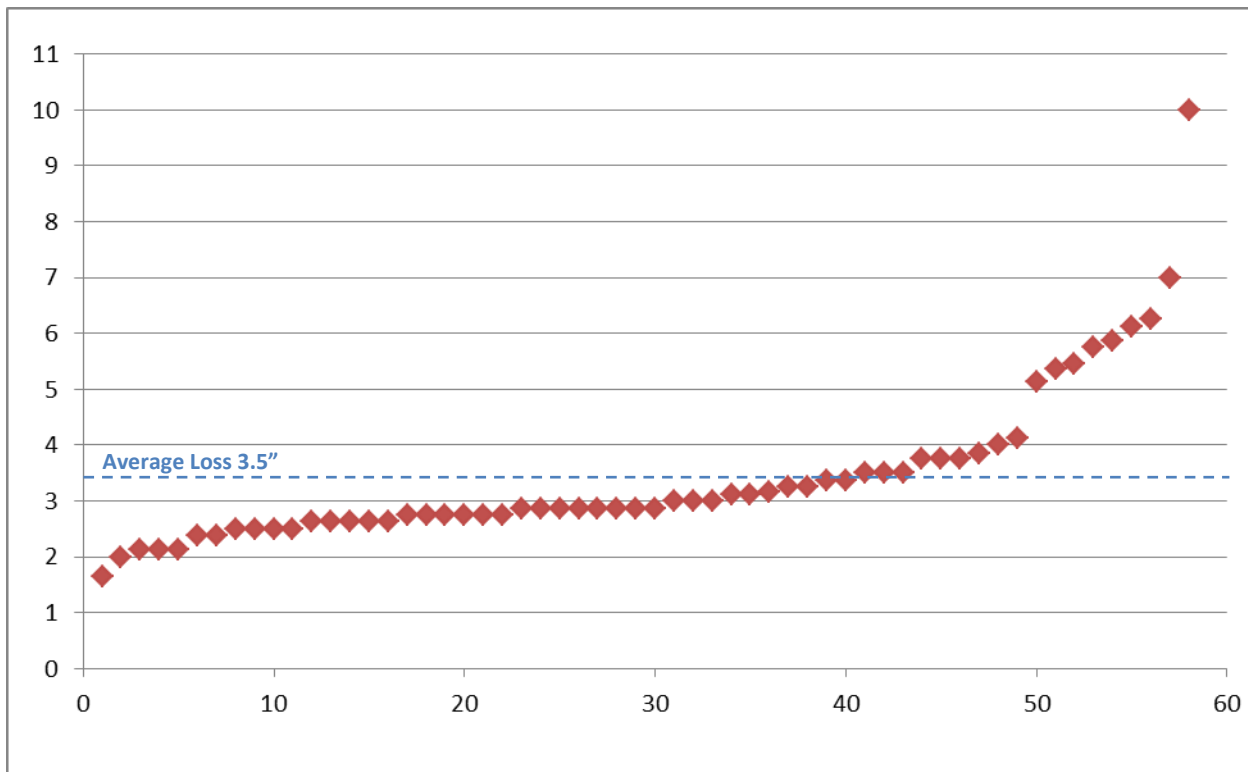
**TABLE 3: Inches Lost By Gender**

Inch Loss	Total		Females		Males	
<2"	1	2%	1	2%	0	0%
2-3"	32	55%	23	50%	9	75%
3-4"	15	26%	14	30%	1	8%
4-5"	1	2%	0	0%	1	8%
5-6"	5	9%	4	9%	1	8%
6-7"	3	5%	3	7%	0	0%
10+"	1	2%	1	2%	0	0%

By gender, Table 3 shows that 80% of females and 83% of males lost between 2" and 4" at their initial treatment visit.

As shown in Chart 2, 31% of patients (18 of 58) lost more than the average loss of 3.5":

**CHART 2: Inches Lost In Ascending Order**



## 7. FINDINGS

Photonica Professional achieves an average combined inch loss of 3.5" at the first visit, with 98% of patients losing more than 2" at one treatment visit.

These results compare favorably with the combined inch loss of 3.6" reported for Zerona with 6 treatments and 7 office visits over 3 weeks.

## 8. CONCLUSION

Red light therapy is a safer alternative for body contouring than surgical procedures or noninvasive procedures which remove or destroy fat cells. Also, Photonica Professional is safer and more effective than laser-based red light therapy systems such as Zerona.

Ward Photonics LLC should apply for FDA clearance for circumferential reduction of the waist, hips, and thighs as an additional Indication For Use, with treatment exposures of 8 minutes rather than the 20-minute exposures used for the indications for use cleared by FDA in 2015.

## 9. ACKNOWLEDGMENTS

Mr. Ward had full access to the clinical data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis; however, Mr. Ward was not at any time involved in the collection and transcription of data from the source medical records. Mr. Ward is Managing Director for Ward Photonics LLC and the inventor of the patented treatment procedure studied.

The participants received services from Mobile Laser Slimming, LLC doing business as UltraSlim, with 29 served at its clinic location in Orlando, Florida and 29 treated at its clinic in Cocoa Beach, Florida. Access to the



patient records and the transcription of the data to Excel spreadsheet files were provided by Mobile Laser Slimming, LLC doing business as UltraSlim. Ward nor any member of the Institutional Review Board had contact with any of the participants in the study. The sponsor of the clinical trial, Ward Photonics LLC, manufactured the devices used in these clinical trials. The role of the sponsor was simply to build the treatment devices and to summarize the data provided by the clinics in their Excel spreadsheet files.

The supervising Institutional Review Board had full access to the clinical data in the study and was not compensated for their time. The IRB membership was not involved in the writing of this manuscript, however, they read, edited, and approved this piece prior to its release.



Signature

Terry J. Ward, M.H.A.

March 9, 2016

\_\_\_\_\_  
Date