

Performance Testing – Clinical

A multi-site retrospective analysis has been performed on the records of 77 patients, which demonstrates the efficacy of the device using the Vevazz LED protocol with a 7-minute exposure to the front of the body, 7 minutes to the left side, 7 minutes to the back, and 7 minutes to the right side, with a total of 14 minutes exposure time for each treatment session.

The objective of this study is to retrospectively review existing treatment records at multiple private practice locations in the USA to determine the combined circumferential reduction of the waists, hips and thighs with a single 14 minute treatment session using the subject Vevazz LED product, without benefit of dieting or exercise, in order to establish a baseline of expected outcomes for patients who undertake this procedure and to compare the procedure's effectiveness with non-invasive fat reduction using the Photonica Professional fat reducing low level laser system by Ward Photonics LLC.

The studies differ in that the Ward Photonics LLC protocol was performed four 8-minute treatments.

In order to assure a fair comparison of the measurements with the predicate's measurement schema, the measurements in this study were taken in exact accordance with the Photonica Male Measurement Guide, Female Measurement Guide, Male Measurement Form, and Female Measurement Forms as were used in the clinical trials upon which the predicate's application was approved. Those results were published in *A Retrospective Analysis of the Effects of Red Light Therapy on Body Contouring*.

The same self-tensioning tape measures were used for both studies. As detailed in the Photonica measurement guides and forms, multiple circumferential measurements were recorded for each patient. The measurement reference points are described in the Photonica Male Measurement Guide as quoted here for five measurements:

Back	Circumference at level of nipples
Upper-Abdomen	Distance above umbilicus
Mid-Abdomen	2-3 inches above the umbilicus
Flanks	Circumference around the "love handles"
Lower-Abdomen	Distance from umbilicus

The measurement reference points are described in the Photonica Female Measurement Guide as quoted here for six measurements:

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.

The results of the retrospective analysis are summarized in the table below:

Title of Study:	A Retrospective Analysis of the Effects of Red Light Therapy on Body Contouring.
Study Objective	The objective of this study is to retrospectively review existing treatment records at multiple private practice locations in the USA to determine the combined circumferential reduction of the waist, hips,

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	and thighs with a single 14 minute treatment session using the subject Vevazz LED product, without benefit of dieting or exercise, in order to establish a baseline of expected outcomes for patients who undertake this procedure and to compare the procedure's effectiveness with non-invasive fat reduction using Photonica Professional by Ward Photonics LLC
Number of Sites:	4
Enrollment Size:	77
Patient Population	For the study, 64 of the patients are female (83%) and 13 are male (17%). Females ranged in age from 18 to 77, with an average age of 41.7 years. Males ranged in age from 35 to 68, with an average age of 43.3 years. Overall, patients ranged in age from 18 to 77, with an average age of 42 years.
Study Design	<p>Vevazz LED paddles were positioned directly over the skin with four 7-minute exposures. For males, the paddles were positioned:</p> <ul style="list-style-type: none"> • <u>Front</u>: Over the chest and abdomen, extending 23" toward suprapubic area. • <u>Back</u>: Starting at the top of buttocks, extending 23 inches toward the upper back. • <u>Left</u>: From the left hip area, extending 23 inches toward the left underarm area. • <u>Right</u>: From the right hip area, extending 23 inches toward the right underarm area. <p>For females, the paddles were positioned:</p> <ul style="list-style-type: none"> • <u>Front</u>: From below the bra and extending 23 inches to include the top of the thighs. • <u>Back</u>: Covering the "back" measurement area and extending 23 inches to include the top of the thighs. • <u>Left</u>: The paddles are placed to cover the left "love handle", the outside of the left thigh, and the inside of the right thigh along with the lower abdomen. • <u>Right</u>: The paddles are placed to cover the right "love handle", the outside of the right thigh, and the inside of the left thigh, along with the lower abdomen
Measurements and Timing	<p>Measurements were taken immediately before and after the 14-minute treatment using a self-tensioning tape measure, measurement forms, and instructions (Measurement Guides) exactly as used in the clinical trials for the predicate Photonica Professional.</p> <p>Since measurements were taken immediately before and after the treatment, the observed results are therefore immediate.</p>

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Treatment	<p>The treatments consist of four 7-minute exposures with the 650nm light positioned directly over the skin.</p> <p>Vevazz LED uses large paddles consisting of 28 LEDs in a series/parallel electrical connection. Each LED produces 130 mw/cm² of source power light energy with a wavelength of 650 nm; +/- 25 nm uniformly over the treatment area.</p>																																																		
Results	<p>Inch loss by gender is:</p> <table border="1" data-bbox="574 506 1349 680"> <thead> <tr> <th>Gender</th> <th>Patients</th> <th>Age</th> <th>Inch Loss</th> <th>Std. Dev.</th> </tr> </thead> <tbody> <tr> <td>Males</td> <td>13</td> <td>43.3</td> <td>1 5/8</td> <td>1 2/8</td> </tr> <tr> <td>Females</td> <td>64</td> <td>41.7</td> <td>2 2/5</td> <td>1 6/8</td> </tr> <tr> <td>Total</td> <td>77</td> <td>42.0</td> <td>2 1/80</td> <td>1 1/2</td> </tr> </tbody> </table> <p>Inch loss by treatment site is:</p> <table border="1" data-bbox="574 779 1349 1024"> <thead> <tr> <th>Site</th> <th>Patients</th> <th>Age</th> <th>Inch Loss</th> <th>Std. Dev.</th> </tr> </thead> <tbody> <tr> <td>A</td> <td>8</td> <td>49.1</td> <td>3 4/7</td> <td>1 2/8</td> </tr> <tr> <td>B</td> <td>16</td> <td>48.7</td> <td>1 2/3</td> <td>1 5/8</td> </tr> <tr> <td>C</td> <td>23</td> <td>40.7</td> <td>2 1/2</td> <td>2</td> </tr> <tr> <td>D</td> <td>30</td> <td>37.2</td> <td>2 1/6</td> <td>1 6/8</td> </tr> <tr> <td>Total</td> <td>77</td> <td>43.9</td> <td>2 1/2</td> <td>1 5/8</td> </tr> </tbody> </table> <p>Patients lost a minimum of 1". The maximum lost is 7 1/2".</p> <p>For males, inch loss is computed by adding the inch loss measurements for back, upper-abdomen, mid-abdomen, flanks and lower abdomen.</p> <p>For females, inch loss is computed by adding the inch loss measurements for back, waist, mid-abdomen, hips and thighs.</p>	Gender	Patients	Age	Inch Loss	Std. Dev.	Males	13	43.3	1 5/8	1 2/8	Females	64	41.7	2 2/5	1 6/8	Total	77	42.0	2 1/80	1 1/2	Site	Patients	Age	Inch Loss	Std. Dev.	A	8	49.1	3 4/7	1 2/8	B	16	48.7	1 2/3	1 5/8	C	23	40.7	2 1/2	2	D	30	37.2	2 1/6	1 6/8	Total	77	43.9	2 1/2	1 5/8
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Adverse Events	There were no device-related adverse events																																																		
Substantially Equivalent to Predicate	Vevazz LED achieved an average combined circumferential reduction of the waists, hips, and thighs of 2.5" at one visit using the same measurements schema as in the Photonica Professional study which found an average loss of 3.5" with one 32-minute treatment.																																																		

Further, 100% of patients had clinically significant results at one visit with Vevazz LED, considering that all patients lost at least 1.0" with one treatment. By comparison, traditional liposuction is limited to removal of no more than 500 ml of fat at one surgery, due to the attendant trauma and potential side-effects.

NOTE: While treatment with Vevazz LED immediately reduces the size of subcutaneous fat accumulations exposed to the lights, treatments do not prevent the patients from subsequently gaining weight or increasing the size of the fat accumulations. The durability of the treatment has not been studied or established in follow-up clinical trials with a sufficiently statistically significant sample.

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Tabular Results:
Women:

Provider	First Name	Last Name	Sex	Age	Before Back/Flia Line	After	Loss	Before Waist	After	Loss	Before Abdomen
David Club	Tina	Stocumb	Fe	52	33	32 3/4	1/4	32	31 1/4	3/4	39 1/4
David Club	Stacy	Young	Fe	54	33 1/2	33 1/4	1/4	37 1/2	37	1/2	39 1/2
David Club	Kathy	Arlaud	Fe	44	34 1/4	34	1/4	33 1/4	32 1/2	3/4	37 3/4
David Club	Kelli	Griffin	Fe	52	28 3/4	28 1/2	1/4	29 1/2	29 1/4	1/4	36 1/4
David Club	Amber	Yi	Fe	19	30 1/4	30	1/4	33	32	1	35 3/4
David Club	Cynthia	Koike	Fe	60	33	32 1/2	1/2	33 1/4	33	1/4	37
David Club	Jean	Buffardeau	Fe	77	37 1/2	37	1/2	42 1/2	41 1/2	1	46 1/2
Dr. Kevin C. Carter	Jayla	Palmer	F	18	28 1/2	28 1/4	1/4	28 1/4	28	1/4	33 1/4
Dr. Kevin C. Carter	Jayla	Palmer	F	18	29 days after	27 3/4			27 3/4		
Dr. Kevin C. Carter	Melissa	Palmer	F	46	41 1/2	41 1/4	1/4	47 1/2	47	1/2	53
Dr. Kevin C. Carter	Melissa	Palmer	F	46	29 days after	41			40 1/2		
Dr. Kevin C. Carter	Robin	Harmon	F	51	35 1/2	35 1/4	1/4	37 1/2	37 1/4	1/4	43 1/2
Dr. Kevin C. Carter	Amy	Kemp	F	43	33	33	0	35 1/4	34 3/4	1/2	35 1/2
Dr. Kevin C. Carter	Amy	Kemp	F	43	23 days after	32 1/2			33		
Dr. Kevin C. Carter	Emily	Rinderknecht	F	66	29 1/2	29 1/2	0	28 3/4	28 1/4	1/2	35 1/2
Dr. Kevin C. Carter	Emily	Rinderknecht	F	66	22 days after	29 3/2			28		
Dr. Kevin C. Carter	Susan	Knight	F	45	33 1/4	33	1/4	35 1/2	35 1/4	1/4	39 1/2
Dr. Kevin C. Carter	Susan	Knight	F	45	21 days after	32			33 1/2		
Dr. Kevin C. Carter	Judi	Frizzel	F	55	29 3/4	29 1/2	1/4	29	28 3/4	1/4	34 1/2
Dr. Kevin C. Carter	Judi	Frizzel	F	55	21 days after	29 1/2			28		
Dr. Kevin C. Carter	Carolyn	Carter	F	74	40 1/2	40 1/4	1/4	43 1/2	43	1/2	47
Dr. Kevin C. Carter	Angie	Ellenbecker	F	40	38 1/4	38	1/4	40 1/2	40	1/2	46
Dr. Kevin C. Carter	Mary	Jackson	F	49	33	32 3/4	1/4	38	37 1/2	1/2	45 1/2
Dr. Kevin C. Carter	Lisa	Rosenbaum	F	57	29	29	0	27	26 3/4	1/4	33 1/4
Dr. Kevin C. Carter	Meghan	Palmer	F	23	27 1/4	26 3/4	1/2	26 5/8	26 1/8	1/2	31 3/4
Dr. Kevin C. Carter	Kathy	Austin	F	68	26	25 3/4	1/4	26 1/4	26	1/4	33 1/2
Dr. Kevin C. Carter	Shawna	Winham	F	46	42 1/2	42	1/2	45	44 3/4	1/4	54 1/4
Dr. Kevin C. Carter	Shawna	Winham	F	46	7 days after	40			44 1/2		
Jennifer Allen, DC	Skylar	Perkins	Fe	35	24 5/8	24	5/8	24 7/8	23 1/2	1 3/8	29 3/8
Jennifer Allen, DC	Donna	Bernados	Fe	47	35 5/8	34 7/8	3/4	37 5/8	36 3/4	7/8	48 3/4
Jennifer Allen, DC	Angelina	Tersak	Fe	25	27 1/4	27	1/4	26 7/8	26 1/2	3/8	33 1/2
Jennifer Allen, DC	Elsy	Leistenschneider	Fe	44	36 5/8	35 3/4	7/8	37	36 1/2	1/2	47 1/4
Jennifer Allen, DC	Alexandra	Moore	Fe	26	27 1/8	26 3/4	3/8	26	25 3/4	1/4	32 5/8
Jennifer Allen, DC	Rebecca	Cooper	Fe	35	30 1/2	30 1/8	3/8	27 7/8	26 7/8	1	34 5/8
Jennifer Allen, DC	Kerry	Shewchuk	Fe	41	27 1/8	27	1/8	25 1/8	25 1/8	0	29 1/4
Jennifer Allen, DC	Luanne	Allen	Fe	62	29 1/4	29	1/4	28 5/8	28 1/4	3/8	35
Jennifer Allen, DC	Jini	McCool	Fe	43	29 1/4	28 7/8	3/8	27 1/2	27 1/4	1/4	31 1/8
Jennifer Allen, DC	Alison	Geraci	Fe	34	27	26 1/8	7/8	23 1/4	23 1/8	1/8	28 7/8
Jennifer Allen, DC	Samantha	Keelean	FE	31	26 1/4	27 3/4	1/2	27 1/2	27 1/8	3/8	36 1/8
Jennifer Allen, DC	Samantha	Keelean	FE	31	24 days after	27 3/8			27 1/4		
Jennifer Allen, DC	Brandee	Schamer	Fe	39	30 1/4	30 1/8	1/8	30 1/8	29 1/2	5/8	33 1/2
Jennifer Allen, DC	Brandee	Schamer	FE	39	21 days after	29 5/8			29		
Jennifer Allen, DC	Dawn	Griffis	Fe	51	34 1/2	34 3/8	1/8	32 1/2	32 3/8	1/8	36 1/4
Jennifer Allen, DC	Anne Marie	Fish	Fe	45	29 1/8	28 3/4	3/8	27 1/2	27 3/8	1/8	31 7/8
Jennifer Allen, DC	Kim	Alsop	Fe	50	33 1/4	32 5/8	5/8	34	32 7/8	1 1/8	38 1/2
Jennifer Allen, DC	Stephanie	Hall	Fe	41	24 1/2	24 3/8	1/8	24	23 1/2	1/2	29 1/4
Jennifer Allen, DC	Mary	Geiger	Fe	49	27 1/4	27 1/4	0	26 1/4	26	1/4	30 1/4
Jennifer Allen, DC	Mary	Geiger	FE	49	31 days after	27			26 3/8		
Jennifer Allen, DC	Maggie	Owens	Fe	25	27 7/8	27 7/8	0	26 3/8	26 1/4	1/8	28 7/8
Jennifer Allen, DC	Gin	McClellan	Fe	41	37 1/4	37	1/4	37 1/8	36 1/4	7/8	45 1/4
Jennifer Allen, DC	Yvette	Mauzon	Fe	39	34 1/8	33 7/8	1/4	34 1/4	34	1/4	39 1/4
Theresa Horab	Subject A		F	32	30 1/2	30 1/2	0	32 1/2	32	1/2	36
Theresa Horab	Subject B		F	34	46	45	1	41 1/2	41 1/2	0	51 3/4
Theresa Horab	Subject C		F	38	34 25	34 25	0	30	29 75	1/4	40 25
Theresa Horab	Subject D		F	32	43	42 25	3/4	36	35 5	1/2	45
Theresa Horab	Subject E		F	41	32	31 75	1/4	30 5	30 5	0	33 75
Theresa Horab	Subject F		F	35	45 5	45	1/2	41 25	41 25	0	42 25
Theresa Horab	Subject G		F	35	33 25	33	1/4	29 5	29 25	1/4	30 75
Theresa Horab	Subject H		F		41 5	41 25	1/4	34 75	34 5	1/4	36 5
Theresa Horab	Subject I		F	38	36 75	36 5	1/4	35 5	35 5	0	36 5
Theresa Horab	Subject J		F	24	34	34	0	30 25	30	1/4	31 75
Theresa Horab	Subject K		F	37	41	41	0	38 5	38	1/2	41 75
Theresa Horab	Subject L		F	45	35 5	35 5	0	30 75	30 5	1/4	36 5
Theresa Horab	Subject M		F	41	33 5	33 25	1/4	28 25	28	1/4	29 25
Theresa Horab	Subject N		F	25	36 75	36 5	1/4	32 25	32	1/4	39 25
Theresa Horab	Subject O		F	31	38 25	38	1/4	30 5	30	1/2	36 75
Theresa Horab	Subject P		F	52	44 5	44 25	1/4	54	54	0	55
Theresa Horab	Subject Q		F	27	34 25	34	1/4	29 25	29	1/4	32 25
Theresa Horab	Subject R		F	32	45	44 5	1/2	40 25	39 75	1/2	40
Theresa Horab	Subject S		F	38	47	45 25	1 3/4	48	47	1	48 25
Theresa Horab	Subject T		F	41	30	29	1	31	30 25	3/4	32
Theresa Horab	Subject U		F	20	27 5	27 5	0	25	24 75	1/4	29 25
Theresa Horab	Subject V		F		29 5	29	1/2	29 5	29 5	0	32 5
Theresa Horab	Subject W		F	41	41	39 5	1 1/2	42	40	2	44

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Tabular Results:
Women continued:

After	Loss	Before Hip	After	Loss	Before R. Thigh	After	Loss	Before L. Thigh	After	Loss	Total Loss
38 3/4	1/2	42	41 1/2	1/2	23 3/4	22	1 3/4	22 1/2	21 3/4	3/4	4 1/2
39	1/2	41	40 1/2	1/2	21	20 3/4	1/4	21	20 1/4	3/4	2 3/4
37	1/4	40	39 1/2	1/2	24 1/2	23 1/2	1	23	22 1/2	1/2	3 3/4
35 3/4	1/2	38	37	1	20 3/4	20 1/4	1/2	21 1/2	20 1/2	1	3 1/2
35 1/2	1/4	37	36 1/2	1/2	20 1/4	20	1/4	19 3/4	19 1/2	1/4	2 1/2
36	1	38 3/4	38 1/4	1/2	21	20 3/4	1/4	20 1/2	20 1/4	1/4	2 3/4
46	1/2	47	46	1	20 1/2	18 1/2	2	19 1/2	18	1 1/2	6 1/2
33	1/4	37	37	0	23 1/2	23 1/4	1/4	23	22 3/4	1/4	1 1/4
33			36			23			22 3/4		
52 3/4	1/4	54	53 3/4	1/4	26 1/2	26 1/4	1/4	27 1/2	27 1/4	1/4	1 3/4
52 1/4			50 1/2			26			26 3/4		
43 1/4	1/4	46 1/4	46	1/4	25	24 3/4	1/4	25 1/2	25	1/2	1 3/4
35 1/4	1/4	39 1/4	39	1/4	24 3/4	24 1/2	1/4	25	24 3/4	1/4	1 1/2
34 1/4			38 1/2			24			24 1/2		
35	1/2	36 1/2	36 1/2	0	21 1/2	21 1/4	1/4	21 1/2	21 1/4	1/4	1 1/2
34 3/4			36			21			21		
39 1/4	1/4	42 3/4	42 1/2	1/4	25 1/4	25	1/4	25 1/2	25 1/4	1/4	1 1/2
38 3/4			42			24 1/2			24 3/4		
34 1/4	1/4	36	35 3/4	1/4	20 1/4	20	1/4	20 1/4	20	1/4	1 1/2
33 1/2			35 1/2			19 3/4			19 3/4		
46 1/2	1/2	44	43 3/4	1/4	22 1/2	22 1/4	1/4	22 1/2	22 1/4	1/4	2
45 1/2	1/2	43	43	0	26	25 3/4	1/4	26 1/4	26	1/4	1 3/4
45	1/2	45 1/2	45 1/4	1/4	23	22 3/4	1/4	22 1/2	22 1/4	1/4	2
33	1/4	36 1/2	36 1/2	0	23	22 3/4	1/4	23	22 3/4	1/4	1
31 1/4	1/2	34	33 3/4	1/4	20 3/4	20 1/2	1/4	20 1/2	20 1/4	1/4	2 1/4
33	1/2	37 1/4	37 1/4	0	21	20 3/4	1/4	20 3/4	20 1/4	1/2	1 3/4
54	1/4	55	54 3/4	1/4	30	29 3/4	1/4	30	29 3/4	1/4	1 3/4
54			55			29 3/4			29 1/2		
27 3/4	1 5/8	30 1/8	29 7/8	1/4	17 7/8	17 1/4	5/8	17 7/8	17 1/2	3/8	4 7/8
48	3/4	49	48 3/4	1/4	27 1/4	26 1/2	3/4	26 1/8	25 7/8	1/4	3 5/8
32 1/2	1	34 7/8	34 5/8	1/4	24	23 1/8	7/8	23	22 3/4	1/4	3
46	1 1/4	46 3/4	46 3/8	3/8	27 1/4	26 7/8	3/8	27	26 1/2	1/2	3 7/8
31 1/4	1 3/8	33 3/4	33 1/8	5/8	21 1/8	20 3/4	3/8	21 1/8	20 7/8	1/4	3 1/4
34	5/8	38	37	1	25 3/4	25 1/4	1/2	25 1/2	25 1/4	1/4	3 3/4
28	1 1/4	34 1/4	33 7/8	3/8	22	21 1/8	7/8	22 1/4	21 3/8	7/8	3 1/2
34 3/4	1/4	35 5/8	35 1/2	1/8	19 1/2	19 1/8	3/8	19 1/2	19	1/2	1 7/8
30 3/4	3/8	34	33 1/8	7/8	22 1/2	22 1/4	1/4	22 3/4	22 1/4	1/2	2 5/8
28 1/8	3/4	32	31 7/8	1/8	22 1/8	21 3/4	3/8	22 5/8	21 7/8	3/4	3
35 7/8	1/4	39	38 1/2	1/2	25	24 1/8	7/8	24 1/4	23 1/2	3/4	3 1/4
35 7/8			38								
32 7/8	5/8	37 3/4	37 1/2	1/4	22 1/4	22	1/4	23 5/8	23 1/8	1/2	2 3/8
31 5/8			37								
35 1/4	1	38 1/8	37 5/8	1/2	21 7/8	21 1/8	3/4	22	21 3/4	1/4	2 3/4
31 1/4	5/8	34 1/4	33 5/8	5/8	21 1/8	21	1/8	21	20 7/8	1/8	2
38 1/4	1/4	41 5/8	41 1/4	3/8	23 7/8	23 3/4	1/8	24 1/4	23 3/4	1/2	3
28 1/2	3/4	33 1/2	32 3/4	3/4	18 1/4	17 5/8	5/8	18 1/2	18	1/2	3 1/4
29 7/8	3/8	32 7/8	32 7/8	0	19 5/8	19 3/8	1/4	19 7/8	19 1/2	3/8	1 1/4
29 7/8			33 3/8								
28 1/2	3/8	30 7/8	30 1/4	5/8	21 1/2	21 1/8	3/8	20 1/4	20 1/8	1/8	1 5/8
45	1/4	46 1/4	44 1/2	1 3/4	27 3/8	26 1/2	7/8	27 3/8	26 7/8	1/2	4 1/2
38 1/2	3/4	43 7/8	43 3/8	1/2	30	29 5/8	3/8	30	29 3/4	1/4	2 3/8
35 3/4	1/4	37 3/4	37 3/4	0	23	23	0	22 3/4	22 3/4	0	3/4
51	3/4	53	53	0	33 1/2	32 3/4	3/4	32 1/2	32 1/2	0	2 1/2
39.25	1	41.25	40.25	1	25.25	25	1/4	23.5	23.5	0	2 1/2
44.75	1/4	45	45	0	26.5	26.5	0	27	26.5	1/2	2
33.5	1/4	36.5	36.5	0	32	31.75	1/4	31.5	31.5	0	3/4
42	1/4	49	48.75	1/4	31.25	31	1/4	30	29.75	1/4	1 1/2
30.5	1/4	33.5	33	1/2	31.5	31.25	1/4	31	31	0	1 1/2
36.25	1/4	39.5	39.25	1/4	31	31.75	- 3/4	30.5	30.5	0	1/4
36.25	1/4	34.25	34	1/4	34.5	34.25	1/4	34	34	0	1
31.25	1/2	34.25	34	1/4	30	30	0	30.5	30.5	0	1
41.75	0	41.75	41.75	0	34	34	0	34.25	34	1/4	3/4
36	1/2	40	39.75	1/4	33	32.75	1/4	32.75	32.5	1/4	1 1/2
29.25	0	31	30.25	3/4	20.5	20	1/2	20.5	20.25	1/4	2
39.25	0	39	38.75	1/4	26	25.75	1/4	26.25	26	1/4	1 1/4
36.5	1/4	37.25	37	1/4	25.25	25	1/4	25.5	25.25	1/4	1 3/4
54.75	1/4	57.5	57.25	1/4	29	29	0	29.5	29.25	1/4	1
31.5	3/4	33	33	0	23.23	22.75	1/2	23.25	22.75	1/2	2 2/9
40	0	44.75	44	3/4	44.5	44	1/2			0	2 1/4
48	1/4	48	47	1	21.25	20.25	1	21.25	20	1 1/4	6 1/4
31	1	35	34.5	1/2	17	16.5	1/2	16	16	0	3 3/4
29	1/4	33	32.75	1/4	20.75	20.5	1/4	20.5	20.5	0	1
32	1/2	37	36	1	20.5	20.5	0	20	19.5	1/2	2 1/2
43	1	46	45	1	31	30	1	32	31	1	7 1/2

21 November 2017

Traditional 510k Submission Vevazz LED

Tabular Results:

Men:

Provider	First Name	Last Name	Sex	Age	Before nipple line	After	Loss	Before abdomen upper	After	Loss
David Club	Jason	Redondo	M	35	30.25	30	0.25	33	32	1
Dr. Kevin C. Carter	Rex	Robinson	M	41	34 1/4	34	0.25	32 1/2	32 1/2	0
Dr. Kevin C. Carter	Rex	Robinson	M	41	15 days after		34		30 1/2	
Dr. Kevin C. Carter	Mike	Winham	M	57	43 1/4	42 3/4	0.5	43 1/2	43	0.5
Jennifer Allen, DC	Peter	Helton	M	39	39 1/4	38 7/8	3/8	36 1/4	36	1/4
Jennifer Allen, DC	Robert	Hall	M	44	33 3/4	33 1/2	1/4	28 7/8	28	7/8
Jennifer Allen, DC	Tony	Bernados	M	47	36 3/4	35 3/8	1.375	30 5/8	30 1/8	0.5
Theresa Horab	Subject Y		M	68	38	38	0	37	37	0
Theresa Horab	Subject Z		M	40	43.25	43	0.25	39	39	0
Theresa Horab	Subject AA		M	44	45	45	0	45.25	45	0.25
Theresa Horab	Subject BB		M	32	49.25	49	0.25	46.5	46.25	0.25
Theresa Horab	Subject CC		M	53	40.75	40.75	0	40.25	40	0.25
Theresa Horab	Subject DD		M	44	39.75	39.5	0.25	37.75	37.25	0.5
Theresa Horab	Subject EE		M	19	38.75	38.25	0.5	36	35.75	0.25

Before Abdomen middle (2-3 in above navel)	After	Loss	Before love handles (near navel)	after	loss	Before lower abdomen	after	loss	Total Loss	
35.75	35.5	0.25		37	36.5	0.5	20.25	20	0.25	2.25
31	30 1/2	0.5		32 1/2	32	0.5	33	33	0	1.25
	30 1/4	-30.25			32	-32		33		
42 1/2	42	0.5		41 1/2	41	0.5	39 1/4	39	0.25	2.25
36	35 7/8	1/8		34 1/2	34 1/4	1/4	38 7/8	38 1/2	3/8	1 3/8
30 3/8	29 3/4	5/8		32	31 3/4	1/4	33	32 5/8	3/8	2 3/8
32 1/8	31 3/8	0.75		34 1/8	32 7/8	1.25	35 1/2	34 1/2	1	4 7/8
38	37.5	0.5		39	38.25	0.75	39.25	39	0.25	1.5
40.25	40	0.25		39	39	0	38.75	38.75	0	0.5
47	47	0		49	48.5	0.5	49.5	49	0.5	1.25
48	47.75	0.25		51.5	50.75	0.75	49.5	49.25	0.25	1.75
42	41.5	0.5		41.5	40.75	0.75	39.75	39.25	0.5	2
32.5	32.5	0		32.5	32.5	0	32.5	32	0.5	1.25
35.25	34.5	0.75		37.25	37	0.25	38	37.5	0.5	2.25