

## ZERONA®-Z6 BACKGROUND AND PROTOCOL GUIDE



## CONTENT OVERVIEW

This guide is designed to take you through the proper use of your ZERONA®-Z6 laser. It will cover the Protocol, Proper Placement of Diodes, Measurement Guidelines and Precise Measurements for both men and women.



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## ZERONA®-Z6 TECHNOLOGY & SCIENTIFIC BACKGROUND

#### WHAT IS ZERONA®-Z6?

ZERONA®-Z6 is a new non-invasive body slimming procedure designed to remove fat and slim the body without surgery, pain, or needles. ZERONA®-Z6 allows your clients to continue daily activity without interruption.

#### HOW DOES ZERONA®-Z6 WORK?

ZERONA®-Z6 works by using a patented and clinically proven low-level laser technology. ZERONA®-Z6 emulsifies fat (defined as leakage of the fat out of the cell) within the adipose tissue which is then released into the interstitial space. The excess fat is then passed through the body during its normal course of detoxification.

The ZERONA®-Z6 body slimming procedure was proven though a double-blind, randomized, multi-site, and placebo-controlled study in which patients on average, lost 3.72 inches/ 9.4488 cm from their waist, hips and thighs. These results are dramatic compared to the placebo group, which only lost an average of half an inch.

#### WHY ZERONA®-Z6?

#### FROM THEORY TO THERAPY

- ZERONA®-Z6 utilizes the Erchonia® Laser Scanner.
- Initially designed and FDA cleared for use during liposuction.
- First non-invasive body contouring device with FDA 510(k) Clearance.
- Proven through two level (1), double-blind, randomized, multi-site and placebo-controlled clinical study.
- Study participants lost and average of 3.72 inches/ 9.4488 cm from their waist, hips and thighs after one series of 6 treatments.

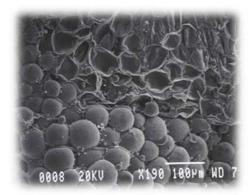


#### FROM PHOTOMODULATION TO PHOTOPOROSIS

- Research began back in 1998 (hand-held).
- Started as an adjunctive device for liposuction.
  - Aim was to reduce post-op discomfort.



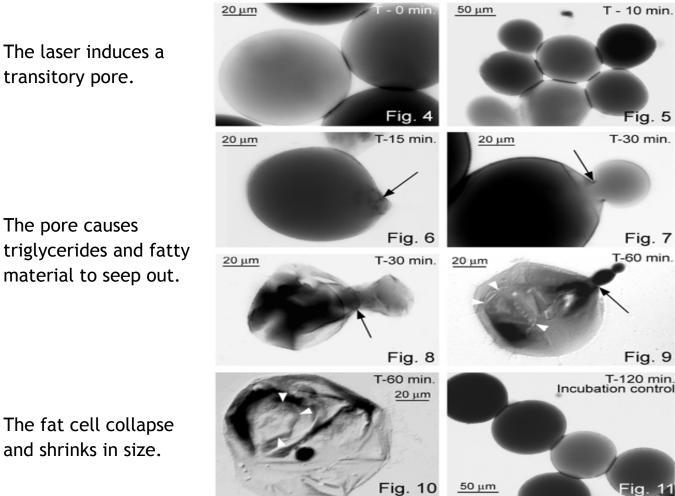




- Histology confirmed release of intracellular fat.
- Hypothesis was that lymphatic system would process the liberated fat.



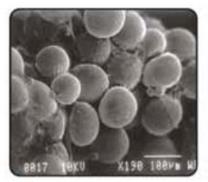
### THE EFFECT OF PHOTOPOROSIS



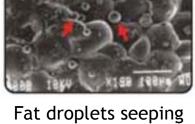
The fat cell collapse and shrinks in size.

RONA<sup>26</sup> Non-Invasive Fat Loss Laser

#### ZERONA®-Z6 TECHNOLOGY BACKGROUND

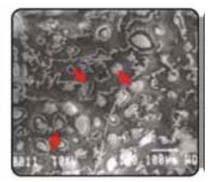


Healthy adipose cells.



across adipose cell

membrane.

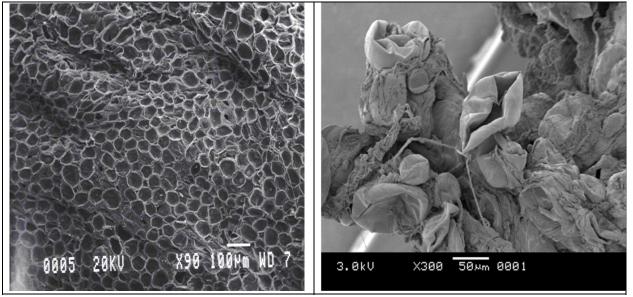


Complete collapse of adipose cellemulsification.

The images above demonstrate the low-level lasers ability to emulsify adipose tissue. These pictures highlight the collapse of the rigid adipose cell and the secretion of triglycerides and fatty acid from the cell.

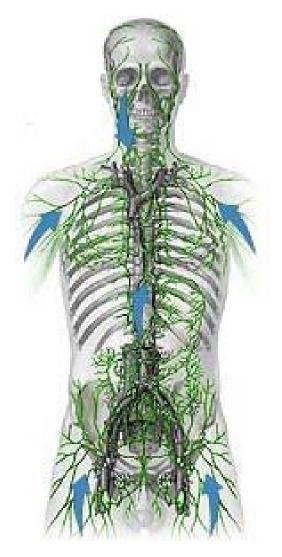
#### THE EFFECT OF PHOTOPOROSIS

The absorption of 635 nm wavelength laser opens a temporary pore, causing seepage of triglycerides into interstitial space.



ERONAZÓ Non-Invasive Fat Loss Laser

#### WHERE DOES THE FAT GO?



- Fat leaves the cell and enters the extracellular space.
- Triglycerides:
  - Are absorbed by the lymphatic system;
  - Transported via afferent lymph vessels to lymph nodes;
  - Broken down by macrophages;
  - Transported to the circulatory system,
    - Used as fuel.

Similar process to natural use of fat as fuel!

Z. E. R. O. N. A<sup>\*</sup> Z6 Non-Invasive Fat Loss Laser

#### WHO IS THE ZERONA®-Z6 FOR?

#### Virtually Everyone!

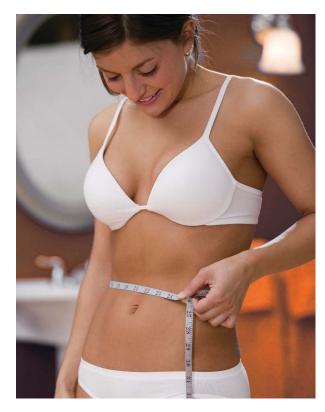
- ✓ NO known side effects.
- ✓ Clients safely treated from 18 up.
- ✓ Male & Female clients.

#### THE IDEAL CANDIDATE

- ✓ Collection of subcutaneous fat;
  - ✓ Not visceral;
  - ✓ Not fibrous (previous surgeries).
- $\checkmark\,$  Healthy, with no current medical condition.
- $\checkmark$  Willing to comply to the program.

ZERONA<sup>26</sup> Non-Invasive Fat Loss Laser





Remove Fat, Reduce Inches

## Slim stubborn fat from:

- Stomach
- Hips
- Thighs
- Buttocks
- Love Handles

ZERO Pain. ZERO Surgery. ZERO Downtime

ZERONA<sup>°Z6</sup>

## WHEN NOT TO USE

The manufacturer of the ZERONA®-Z6 device has provided standard contraindications that must be assessed prior to treating clients. These contraindications are guidelines suggested by the FDA:

- Avoid using the laser over a pregnant uterus.
- Do not treat the face, neck or breast.

There have been no side effects as a result of use of the ZERONA®-Z6 device. There have also been other research studies using Erchonia low level lasers. In these studies, no side effects resulted from or were reported by any participant from use of the device.

The only known or anticipated risks with the use of the laser device is:

- Long-term exposure to laser light could cause damage to eyesight. As a precaution, when you are giving the treatments with the ZERONA®-Z6, ensure that the client wears the special darkened protective glasses to block out the light.
- Avoid using the laser on skin that is infected, burned or cut, as this could cause discomfort or irritation. Wait until the infection, burn or cut has healed before using the laser. If the client has a skin condition, lack of skin sensitivity or are undergoing professional cosmetic treatments, please check with their doctor or clinician before using the laser.
- Laser treatment should not be applied over, or in proximity to (near), cancerous lesions (such as moles and other suspicious skin markings unless known not to be cancerous). There have not been conclusive tests that show whether or not low level laser exposures on or near cancerous lesions do or do not create a serious adverse effect.



The following conditions or medications may affect the client's outcome or weaken fat mobilization or metabolic pathways:

- Steroid medications (may cause weight or girth gain).
- Diabetes (may experience rapid weight or girth gain).
- Metabolic Disorders (may experience rapid weight or girth gain).
- Lymphatic Impairment (fat mobilization may be hindered).
  - Previous abdominoplasty, C-section, liposuction (procedures that have created scar tissue around the treatment site).

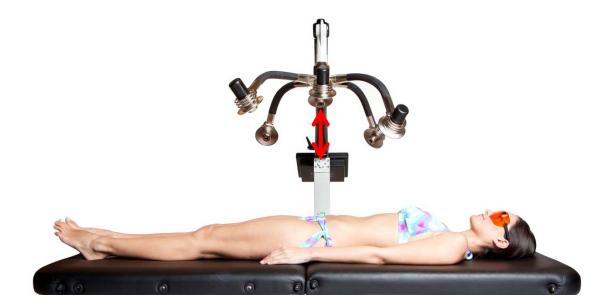
## SUN EXPOSURE, ARTIFICIAL TANNING AND TATTOOS, JEWELRY

The ZERONA®-Z6 635 nm wavelength can safely treat clients who are tan, who are using self-tanners or who have tattoo(s) in the treatment area. Jewelry should be removed if it is in the treatment area to avoid any reflection from the laser light.



## MOVING THE LASER ARM

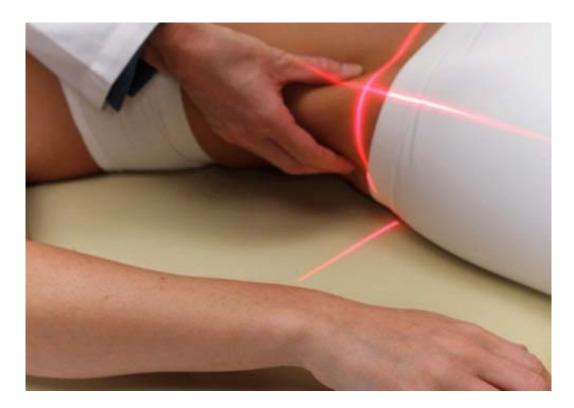
- You should move the arm up and down using the arm, not the diode heads or flex arms. When maneuvering the laser arm, the tension should be adjusted to lock the arm into position.
- Once locked into that position, the arm should remain where placed, ensuring the tension lock is properly activated.





## PROPER DIODE PLACEMENT

Have your client put on the safety glasses and lay on their back. While the client is lying on their back you should check for the areas of the greatest accumulation of fat.



Position the center diodes and adjustable laser arms, no greater than 3-4 inches / 9 cm away from the client's target treatment areas. The goal is to maximize the coverage of the target treatment areas of fat using the line generated beams.

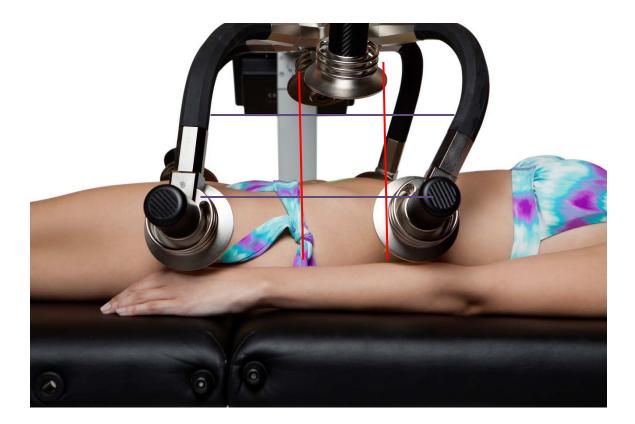
Once positioned, it is important to now locate the area of greatest fatty accumulation midline and laterally. Start by locating the greatest fatty accumulation along the client's midline; this is accomplished by gently palpating the tissue until the largest collection is found. Once the fatty material is located, position the center diodes directly above the fatty accumulation. This step must be carried out for all four diodes ensuring that each diode is carefully positioned over the greatest accumulation of fatty material



It is important to align the diodes so that the line-generated beam reaches the skin's surface at  $90^{\circ}$  or perpendicular.

## ANTERIOR (FRONT) TREATMENT DIODE PLACEMENT

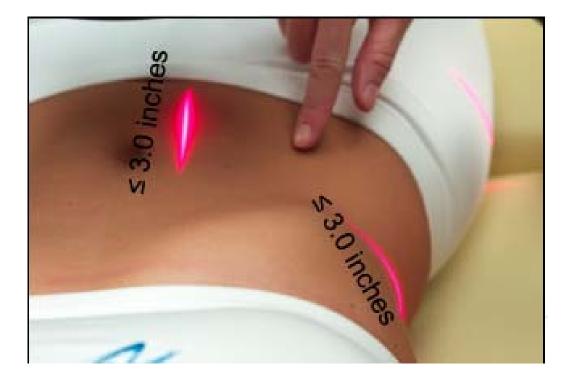
Perpendicular Placement of Diode in Reference to the Treatment Area





#### LINE-GENERATED BEAM PARAMETERS

## 3.0 Inch (7.5 cm) Line-Generated Beams



6 inches (15 cm) separating adjacent Line-Generated Beams



RONA<sup>\* Z6</sup>

Use the palm of your hand to position the adjustable laser heads, shifting the flexible arms to the region of greatest fatty accumulation, as shown.



## ZERONA®-Z6 TREATMENT PROTOCOL

Now that you've positioned the diodes properly in the targeted areas, press the start button to begin. With the lasers on, check the positioning of the heads for coverage of targeted areas. We suggest dimming or turning off the lights to ensure that you have maximized the coverage area.

Once the diodes are positioned properly and the client is comfortable you can leave the room.

Once the first twenty minutes are complete, the lasers will pause and three beeps will emit from the machine.

Return to the room, raise the laser arm off the client, and ask them to roll over and lie on their stomach.



Lower the laser arm over the backside of the client's target area, positioning the center laser diodes in line with an identical position as if the client were lying on their back. Position the center laser diodes and adjustable laser arms, no greater than 3-4 inches / 9 cm away from the client's target treatment areas. The goal is to maximize the coverage of the laser beams to the target treatment areas of fat.

Touch the start button again and check the positioning of the line generated beams to ensure proper positioning.

After the second twenty-minute posterior treatment, the laser will automatically turn off and alert you with three beeps. Return to the room and raise the laser arms off the client. The client can get dressed, leave the office, and resume their daily lives.

#### PRE-TREATMENT CHECKLIST

PRIOR to each treatment, the client should arrive for the treatment with clean, dry skin.

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#### GOLDEN RULES

Proper placement of the ZERONA®-Z6 diodes has been formatted into three basic rules. Each rule plays an important role to ensure proper depth of penetration and stimulation of enlarged fat cells.

	GOLDEN RULES
1	Locate the greatest fat accumulation by palpating the tissue and immediately target with appropriate diode.
2	Ensure the diodes are placed perpendicular to the greatest point of fatty accumulation.
3	Position the diodes 3 to 4 inches from the skin. Additionally, no more than 6.0 inches (15 cm) can separate adjacent line-generated beams.

#### SECONDARY PROTOCOLS

In addition to the ZERONA®-Z6, there are specific secondary protocols that will enhance the body's ability to remove and mobilize the fatty material. Therefore, regardless of client's BMI, it is recommended that all clients selected to participate in a ZERONA®-Z6 treatment regimen follow the secondary protocol parameters:

- Healthy lifestyle
- Hydration
- Lymphatic system stimulation
- Supplements

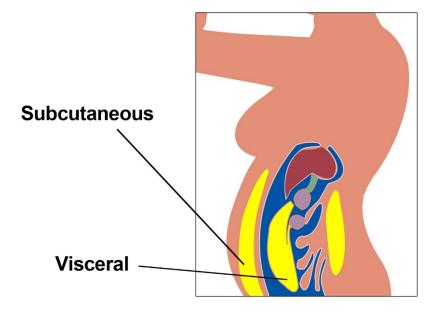


## CLIENT SCREENING



In humans, there are two regions in which adipose tissue is located, *subcutaneously and viscerally*. Subcutaneous fat resides directly beneath the skin while visceral fat is found in the peritoneal cavity around internal organs. Herein lies the important distinction between the two layers of fat; it is the subcutaneous fat layer not the visceral fat layer that the ZERONA®-Z6 targets. The accumulation of fat can result in the expansion of adipocytes within the visceral layer producing a visually undesirable midsection, region. However, based upon the positioning of these adipocytes, which is directly under the abdominal skeletal muscle, the depth is too great for this procedure to be prompting clients to seek the ZERONA®-Z6 as a means to cosmetically correct this. The superficial nature of the subcutaneous fat layer makes it an ideal target for ZERONA®-Z6.

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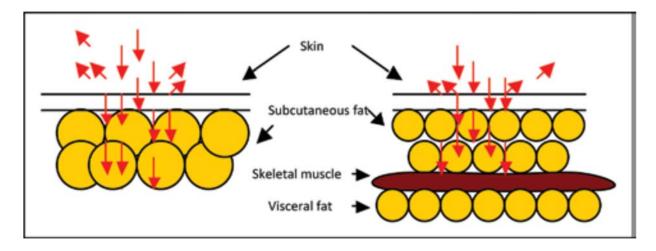


The appearance of enlarged fat cells within the visceral layer may take on the same characteristics as enlarged subcutaneous adipocytes; resulting in a protruding midsection due to the lack of stable abdominal skeletal muscles. To properly determine whether the client possesses an enlarged collection of subcutaneous or visceral fat cells, palpation (pinching) of the area must be performed.

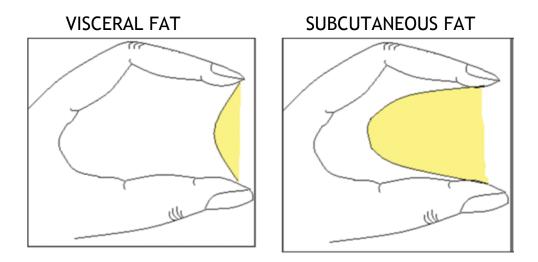
Follow the simple steps below to determine if hypertrophic cells of the subcutaneous zone or visceral zone are resulting in the enlarged mid-section.

- 1. Have the client stand with their arms extended from their side
- 2. Ask the client to contract their abdominal muscles
- 3. Begin to palpate (pinch) the mid-section region
- 4. Observe the firmness of the area





If the area is very firm and a simple pinch does not produce a large volume of tissue between your fingertips, it is safe to assume that the client possesses a significant amount of visceral fat and is not an ideal candidate for the ZERONA®-Z6 Body Slimming procedure.





#### OTHER CLIENT SELECTION CONSIDERATIONS

Another key element in the ZERONA®-Z6 procedure is the processing of the emulsified fat through the lymphatic system. The ability of the client's lymphatic system to effectively process the emulsified fat will have a direct impact on the clinical and aesthetic outcome experienced by the client. One technique that has been successfully utilized to identify clients whose lymphatic systems may not be in the best condition to process the emulsified fat, is to weigh the client before they start Week 1 of the ZERONA®-Z6 procedure protocol (on the next page), and then at the end of Week 1 before they start the ZERONA®-Z6 procedure. If the client has gained weight, then they should not start the ZERONA®-Z6 procedure. You could also encourage the client to repeat the week 1 protocol to see if they can comply and that their body is able to successfully process the emulsified fat.

Prior to starting ZERONA®-Z6, you should recommend that your clients begin to prepare their lymphatic and circulatory systems the week before treatments by starting to take CURVA.

Make sure that your client is willing to commit to keeping ALL scheduled appointments over the treatment period.



## STEPS TO ACHIEVE OPTIMIZING RESULTS

- 1. Supplementation (CURVA<sup>™</sup>)
- 2. Minimum of 64oz of water per day
- 3. Moderate Exercise: a minimum of 15 minutes of walking per day
- 4. Minimize alcohol and caffeine
- 5. Maintain a healthy diet

	Curva®	Moderate Exercise	Hydration	Low Fat Diet & No Alcohol	6 ZERONA®-Z6 Treatments
Week 1	*	*	$\bigstar$	*	
Week 2	*	*	*	*	*
Week 3	*	*	*	*	*
Week 4	*	*	*	*	

By following the recommended protocol, the client will enhance their body's natural detoxification process which will ultimately result in more inches lost.

#### CURVA™

 Proprietary blend of: Niacin, Coleus Forskohlii Root Extract, Commiphora Mukul, Artichoke, Withania Somnifera Root Extract and Holy Basil.



Must be taken morning and night
May cause flushing

ZERONA<sup>26</sup>

#### ADEQUATE HYDRATION

- ✓ Ensures cells function optimally:
  - ✓ 64oz. (8 X 8oz. glasses) consume each day;
  - ✓ Minimize diuretics;
    - ✓ Coffee (will dehydrate the client);
    - $\checkmark$  Alcohol (Toxin, body will eliminate this first).
- ✓ If alcohol or coffee is consumed, an <u>additional</u> 8oz. glass of water should be consumed immediately afterwards.

#### LYMPHATIC SYSTEM MOBILIZATION

- ✓ Mild exercise:
  - ✓ Daily 15-minute walk;
  - Gym (avoid strenuous exercise, putting your body into a cardiovascular state, burning only sugar);
  - ✓ Massages (preferably lymphatic massage).

#### BALANCED NUTRITION

- $\checkmark$  Eat small portions, 5 times a day.
- $\checkmark\,$  Eat whole foods.
- $\checkmark\,$  Never skip a meal.
- $\checkmark$  Have a hearty, healthy breakfast.
- $\checkmark$  Eat your last meal at least 2 hours before bed.
- ✓ Minimize alcohol.



## MEASUREMENT PROTOCOL

Measure the client at the following times:

- 1. Before the first treatment;
- 2. After the last treatment;
- 3. One week after the last treatment.

When taking measurements, you should always make sure that the tape is pulled just tight enough so that the tape isn't sagging but at the same time not too snug.

To take proper measurements, the client should stand with their feet shoulder width apart. Have them relax their muscles. Do NOT let them "suck it in," as this is a typical reflex of most clients.

Document measurements on the Measurement form. You may also want to take before and after photos of your clients. These are both great ways to show your clients their progress!



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## MEASUREMENT AREAS (WOMEN)

Measurement Area (Circumference in Inches)	Reference Point	
Waist	The waist circumference measurement is to be taken such that the tape measure circles around and across the belly button.	
Hips	The hip circumference measurement is to be taken such that the tape measure circles around and across the right and left hips (hip bones).	Hips
Thighs (right and left)	The right and left thigh circumference measurements are to be taken at the area of greatest circumference for each thigh. After the first measurement, write down the distance in inches from the top of each kneecap to the point where you measured the thigh circumference so that you can use this number to be sure all thigh circumference measurements for that client are taken at the same spot as the first time.	Thigh





#### MEASUREMENT AREAS (MEN)

Measurement Area (Circumference in Inches)	Reference Point
Waist	Across the umbilicus.
Flanks	Circumference around "love handles" note distance below umbilicus in inches.



A more specific way to characterize a person's general accumulation of fat besides weight is calculating their body mass index (BMI), which is the calculated ratio of client height and weight. BMI is segmented into the four basic categories:

#### **BMI CATEGORIES**

Underweight	<18.5
Normal Weight	18.5-24.9
Overweight	25-29.9
Obese	≥30



The ZERONA FDA clinical study treated subjects with an overweight BMI (average BMI of 28). Therefore, the standard protocol of six (6) treatments can be successfully administered for individuals of a normal or overweight BMI. Keep in mind that BMI charts do not account for body composition (many athletic people may have a higher BMI due to lean muscle mass which is not fat). You will need to use your best judgment when measuring BMI.

#### MEASUREMENTS

There are core measurements that are segemented based on gender:

Female:	Male:
Waist / Upper Abdomen	Upper Abdomen
Mid-abdomen	Mid-abdomen
Hips	Flanks
Right Thigh	Lower Abdomen
Left Thigh	

However, on the Measurement Form, the measurements are enumerated in a single column.

- Waist/Upper abdomen
- Mid-Abdomen
- Hips/Flanks
- Lower-Abdomen (Men only)
- Right Thigh
- Left Thigh

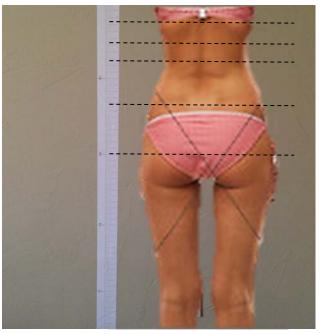
Core measurements must be taken before the first treatment, after the final treatment and one week after the final treatment.



#### MEASUREMENT PROTOCOL

- 1. Have the client stand barefoot or in stocking feet with their feet 12 inches apart for all measurements. Use the same measuring tape each time. The circumference measurements and distance from the floor should be recorded on the Measurement Form.
- 2. Have the client stand adjacent the wall mounted measuring tape and record to the nearest 1/4 inch (1 cm) the distance from the floor on the Measurement Form where the client's greatest points of fatty material are positioned. Mark the point of greatest fatty material using the marking pencil.

Example of Wall Mounted Measure Tape Use to Locate Greatest Points of Fatty Material



- 3. Once the greatest point of fatty material has been identified, its height from the floor should be documented in 1/4 inch or 1 cm increments.
- 4. Have the client raise and cross both arms at chest level, parallel to the floor in an "I Dream of Genie" stance. In this position, clients should hold an inhale breath.



5. For clients, measure the following areas (gender dependent) and document their position in reference to the Wall Mount Height Chart:

Waist/upper abdomen Mid-Abdomen Hips/Flanks Lower-Abdomen (Men only) Right Thigh Left Thigh

Measure the circumference of each area and record to the nearest 1/8 inch or cm.

Hold the tape measure in your left hand with the red button up. Reach around the client's body and secure the end of the tape into the base. Squeeze the red button until the tape hugs the curve of the client's body. Be sure the top edge of the tape measure is level and flush with the white line; not above it. Place the tape measure in a manner that the top edge is beneath the white line made via the marking pencil. Avoid any pinching of the skin with the tape measure.

Record measurements in  $1/8^{th}$  inches (0.1 cm) on the Measurement Form (e.g., 27 1/8, 27 5/8, 33 7/8, etc. or 27.1 cm, 27.4 cm, etc.).



Documenting Wall Mounted Measuring Tape Position of Greatest Points of Fatty Material

BODY MEASUREMENTS			
Measurements	Distance from ground up to marked area		
Date of measurement	01/01/2013		
Weight each measurement date	135 (61.3 kg)		
Waist/Upper Abdomen	29 ¼ (74.3 cm)		
Mid-Abdomen	30		
Hips/Flanks	<b>28</b> <sup>3</sup> ⁄ <sub>4</sub>		
Lower-Abdomen (Men)	N/A		
Right Thigh	<b>25</b> ¼		
Left Thigh	<b>25</b> ¼		



The measurement guide provides a column for all evaluation periods, and it is important that each subsequent evaluation periods have proper measurements reported.

Measurements	Distance from ground up to marked area	Before 1st ZERONA Treatment (BASE)	Final Measurements (one week after Final Treatment)	Total Loss per Measurement Area (BASE minus Final)
Date of measurement	01/01/2013	01/01/2013	01/24/2013	N/A
Weight each measurement date	135	135	132.5	2.5
Waist/Upper Abdomen	<b>29</b> ¼	37 7/8	36 5/8	1.25
Mid-Abdomen	30	36	35 3/8	0.625
Hips/Flanks	<b>28</b> <sup>3</sup> ⁄4	35 3/8	34	1.375
Lower-Abdomen (Men)	N/A	N/A	N/A	N/A
Right Thigh	25 1⁄4	18 7/8	18 5/8	0.250
Left Thigh	25 ¼	17 5/8	17	0.625
Total Inches Lost		183 7/8	178 ½	5.375 (13.65cm)

## COMPLETING MEASUREMENT FORM APPROPRIATELY

Please notice that all sections were completed with either filled in with data points or "N/A." In all, a completed measurement form ensures client data has been properly collected.



## STANDARDIZING PHOTOGRAPHY

#### PHOTOGRAPH ALL CLIENTS

#### ✓ Equipment required:

- ✓ Good quality camera (7M. Pixels or higher);
- ✓ Good quality (external) flash;
- ✓ Tripod;
- ✓ Floor markers.
- ✓ Always use the same:
  - ✓ Room;
    - ✓ Must be dedicated;
    - $\checkmark$  Windows should be draped.
  - ✓ Backdrop;
    - ✓ Must be permanently fixed to the wall;
    - ✓ Preferably blue.
- ✓ Always use consistent:
  - ✓ Lighting no dimmers!

### PHOTOGRAPHY

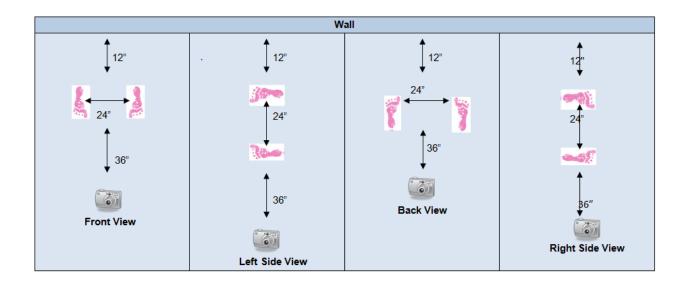
Photographs of the treatment area should be taken before the first treatment and at the post-procedure evaluation (one week after the last treatment). The client should wear the same undergarments for both photo sessions; disposable panties may be used to insure consistency. The client should be standing for all photographs and the photographs must:

• Be taken in proper lighting conditions with flash setting on camera standardized.

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• Use a consistent color backdrop (light blue is recommended).

- Be clear, in sharp focus and show the entire area to be treated.
- Be taken at the same level as the area being photographed.
- Have the client stand 12 inches from the wall with their feet shoulder width apart.
- Have the client raise and cross both arms at chest level, parallel to the floor in a "I Dream of Genie" stance.
- The photographer should stand 36 inches (91 cm) from the client.
- Instruct the client to breathe in and then breathe out. The photographer should take photos of the following views, while the client is breathing out.



# Congratulations on completing the ZERONA®-Z6 Installation and Proper Use Reference Guide. You are now ready to provide great outcomes for your clients with ZERONA®-Z6

It's just that simple...