



**The Effect of the Fat Freezer System on  
Total Body Appearance, Mid-Section Girth, Body Fat Mass  
& Weight Loss for Normal, and Overweight Men and Women**

**Fat Freezer System  
A Pilot Study**

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A division of DETUAG Testing Centers.

With Measurement Approval & Statistical Analysis by Dr. Bob  
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Study Term per Participant: 8 Weeks

|          |          |
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**Study Sponsor: FREEZE N FIT INC.**

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## Abstract

35 subjects were accepted to participate in the Fat Freezer Fitness System study. Out of the 35 subjects initially accepted, 26 participants completed the Study. 23 female and 3 male subjects completed the 8 week test period. These subjects were examined to assess the effects of utilizing the Fat Freezer System.

Before the study, the accepted subjects were to have already been wanting to stay in shape or get into better shape yet having the dilemma of not losing the desired fat mass from the lower front of the abdomen – pouch area – and or from the side flank area AKA the love handles. Maintenance or loss desired in these target areas is difficult due to the higher percentage of fat tissue stored in these areas.

The subjects followed the study protocol for a total of eight (8) weeks. The subjects were measured at the start of the program and at the completion of 8 weeks to determine the effects that the FAT FREEZER SYSTEM produces on total body appearance with a focus on measured and visual result at target areas, body fat mass and total body weight loss. In addition, user satisfaction after 8 weeks of following the system was documented.

The Statistically Significant results of the study showed a plan of action utilizing the FAT FREEZER SYSTEM to be an effective body shaping and body mass maintenance intervention strategy for the busy individual.

Statistics across the majority of the group resulted in target area reductions. For the twenty six participants the average reduction was 7.3 pounds of body mass weight lost in 8 weeks and actual body fat mass had an average decrease of nearly 5 pounds (4.97).

The use of the tested FAT FREEZER SYSTEM led participants to a measurable and visual loss across the targeted data points of total mass, fat mass and size in the 8 week time period. The core finding of the study was that with ongoing compliance with the FAT FREEZER SYSTEM a user could expect to experience continued and consistent results including target area reductions, body shaping, along with weight loss on users with weight to lose.

## INTRODUCTION:

We live in a society which celebrates the appearance of healthy, lean and toned bodies. However, according to the World Health Organization nearly 2 billion people are obese or overweight.<sup>1</sup> Obesity has been reported to shorten the life span by an average of 8 to 10 years compared to people at normal weight.<sup>2</sup> Most people know that eating healthfully and regular exercise is the best way to lose body fat and tone body muscle yet many simply aren't motivated to exercise and eat healthfully enough in order to generate and maintain a leaner more healthful body mass. Many complain that even if they do try, for a short period, they have difficulty trimming down specific target areas such as the belly pouch or the love handles and therefore have a 'why bother' attitude - give up and continue to gain fat mass.

Hence a system that works in conjunction with exercise and a healthful diet with an additional component that can reduce targeted stubborn fat stores and enhance body shaping efforts beyond diet and exercise alone would be a system society could benefit from.

This additional component of the tested system, a Cryolipolysis device, is said to work on the basis that fat cells are more vulnerable to energy extraction. The system device was designed to cool fat cells allowing a user to 'target' stubborn fat stores in localized areas creating a new motivation to get in better shape.



The Manufacturer states: "The system freezes targeted cells without affecting the surrounding tissue. It breaks and kills the particular cells in your problem area through the application of the right degree of cold. The dead cells leave the body naturally through your lymphatic system. It is a non-invasive procedure, which destroys targeted cells and disposes them safely and naturally. It results to a sleeker, more sculpted figure."

Not only is the link between weight loss and controlled healthful eating a well-established area of research so is the link between weight loss and exercise.<sup>3</sup> It's already well understood that weight and fat mass loss is a normal result of healthful eating embracing a reduced calorie diet and regular exercise.<sup>4</sup> Correspondingly, it is also well accepted that with weight and fat mass loss reductions, girth size (i.e. measured at the mid-section) also reduces.<sup>5</sup> In addition, studies show that using a Cryolipolysis device can be effective at reducing specific localized areas of the body.<sup>6</sup>

In our recent study a system incorporating, general exercise, healthful eating and Cryolipolysis device use, known to the study subjects as the Fat Freezer System, has been shown to provide advantages for mid-section reduction, fat loss, and weight loss.

## Product (System)

### 1. Fat Freezer Device:

The Fat Freezer device is a machine intended for use by adults desiring to decrease subcutaneous fat deposits in specific areas of the body. Controlled cold lipolysis (cryolipolysis) is used for the breakdown of adipocytes (a cell specialized for the storage of fat) by immediate and delayed-induced apoptosis (the death of cells that occurs as a normal and controlled part of an organism's growth or development). When it comes to stubborn excess body fat removal and contouring - liposuction is considered the high standard however studies indicate, Cryolipolysis can be an effective option for those interested in nonsurgical procedures. The method involves controlled application of cooling within the temperature range of +5 to -11 °C for the targeted reduction of fat cells to reshape the contours of the body.<sup>6,7</sup> The degree of exposure to cooling causes cell death of subcutaneous fat tissue, without apparent damage to the overlying skin.<sup>6,10</sup>

The manufacturer of the Fat Freezer device states the unit mimics the temperature range shown to be effective “through the application of the right degree of cold.”

**2. Fat Freezer Healthful Meal Plan:** A meal plan recommending a minimum average daily base of 1200 calories and a main rule to simply eat more if hungry. Shopping list was also included and plan was to be repeated weekly.

**3. Regular General Exercise:** The Fat Freezer System workout program instructed participants to exercise in the Fat Freezer System target heart rate zone for no less than 30 min up to 50 minutes 3 days per week on average. This information allowed the participants to easily mimic the exertion level and duration anywhere they wanted on any type of cardio machine or aerobics class they preferred or even while walking. The compliance workouts provided at the Testing Center were very basic beginner level general cardio moves one would find in any beginner fitness class. Testing Center workouts were for 50 minutes while keeping heart rates in the preferred zone of 60% to 80% of Fat Freezer System recommended Heart Rate zone for approx. 30 minutes. Test subjects were instructed to follow the formula while exercising at home and to participate in facility exercise compliance sessions no less than 1 time per week.

The Fat Freezer System was designed to offer a realistic and practical way to easily and efficiently diminish body fat in stubborn fat store areas such as the lower abdomen known as ‘belly pouch’ and the fat stores on the sides of the body above the hip bone known as the ‘love handles’.

### SUBJECTS:

26 subjects attended measurement and photo day at the 8 week mark of the study, 23 women and 3 men.-The initial characteristics/measurements for the subjects were the following:

| Subject # | Gender | Age | Height | Weight | BMI |
|-----------|--------|-----|--------|--------|-----|
| 1         | M      | 58  | 6'4    | 206    | 26  |
| 2         | F      | 52  | 5'6    | 151    | 24  |
| 3         | F      | 60  | 5'7    | 136    | 21  |
| 4         | F      | 57  | 5'5    | 127    | 21  |
| 5         | F      | 65  | 5'2    | 124    | 22  |
| 6         | F      | 55  | 5'9    | 149    | 22  |
| 7         | F      | 34  | 5'9    | 177    | 27  |
| 8         | F      | 64  | 4'10   | 110    | 23  |
| 9         | F      | 37  | 5'2    | 117    | 22  |

|    |   |    |      |       |    |
|----|---|----|------|-------|----|
| 10 | F | 57 | 5'5  | 138   | 23 |
| 11 | M | 59 | 5'6  | 175   | 28 |
| 12 | F | 35 | 5'2  | 125   | 23 |
| 13 | M | 54 | 5'9  | 189.5 | 28 |
| 14 | F | 45 | 5'4  | 117   | 21 |
| 15 | F | 56 | 5'7  | 137   | 22 |
| 16 | F | 25 | 5'2  | 140   | 26 |
| 17 | F | 53 | 5'6  | 141   | 23 |
| 18 | F | 39 | 5'3  | 133   | 24 |
| 19 | F | 48 | 5'5  | 128   | 22 |
| 20 | F | 63 | 5'1  | 121   | 23 |
| 21 | F | 60 | 5'0  | 140   | 27 |
| 22 | F | 34 | 5'7  | 155   | 24 |
| 23 | F | 41 | 5'2  | 136   | 25 |
| 24 | F | 39 | 4'11 | 124   | 24 |
| 25 | F | 50 | 5'6  | 161.2 | 26 |
| 26 | F | 64 | 5'7  | 148   | 23 |

As can be noted above, those that completed the 8 week study initially represented a spectrum of ages and fitness levels, with ages ranging from 25 years to 65 years, and Body Mass ranging from 21 to a high of 28. The National Institute of Health defines overweight as having a Body Mass Index of 25 to 29 and obese as 30 or more. The above characteristics indicate the group represented mostly midline normal and overweight when beginning the program.

## **METHODS:**

### **Screening Visit**

At the Screen/Baseline Visit (day 1), the following was performed:

1. Consent and releases were explained and obtained.
2. Subject questionnaire were completed containing subject name, contact information, weight loss/gain history, and pertinent medical history.
3. Site Investigator or Group Coordinator reviewed questionnaire for completion of information and signature and answered all questions by subject. The Group Coordinator made the final decision for inclusion or exclusion of a subject into the User Group.
4. Subject "before" photos were taken and subjects were weighed and measured.
  - a. Hip girth measurement
  - b. Midsection girth measurement (Belly)
  - c. Body Fat Skinfold measurement x 2
  - d. Left thigh measurement
  - e. Height
  - f. Weight
  - g. Body Fat %
  - h. Body Fat Mass

7. Each subject was provided a Subject Package including:

- A. User's product directions
- B. Meal plan with shopping list

- C. User Group Directions and exercise instructions
- D. Copy of Informative Consent and release

8. During regular group compliance sessions subjects were asked at the 8 week mark to evaluate any change with respect to their current level of satisfaction with their weight, body shape and product use.

The FAT FREEZER SYSTEM consisted of 1) The Fat Freezer Device 2) The Fat Freezer Meal Plan & Healthful eating tips 3) The Fat Freezer recommended general cardio exercise zone 3 times weekly.

Participants were given the following instructions:

1. Abide by the Meal Plan and tips
2. Participate in general cardio approx. 3 times per week keeping heart rate in stated target zone for approx. 20 to 30 min.
3. Use Fat Freezer device as recommended in package

### **Exercises and Training Regimen;**

The workout program for the Fat Freezer System instructed participants to exercise in the Fat Freezer System target zone for no less than 30 min up to 50 minutes 3 days per week on average. This information allowed the participants to easily mimic the exertion level and duration anywhere they wanted on any type of cardio machine or aerobics class they preferred or even while walking. The compliance workouts provided at the Testing Center were very basic beginner level general cardio moves one would find in any beginner fitness class. Testing Center workouts were for 50 minutes while keeping heart rates in the preferred zone of 60 to 80% of HMR for approx. 20 to 30 minutes. Test subjects were instructed to follow the formula while exercising at home and to participate in facility compliance sessions no less than 1 time per week.

The Fat Freezer System Target Heart Rate Zone is calculated by finding the Fat Freezer System recommended maximum heart rate and subtract age from 220. For example, a 45 years old would subtract 45 from 220 to get a maximum heart rate of 175. In order to keep heart rates mostly in the moderate zone we now subtract 4 from 175 and get a Fat Freezer System maximum heart rate of 171.

With the calculated Fat Freezer maximum heart rate, calculate the individualized Fat Freezer System heart rate exercise zone of 60 to 80%.

Participants were able to take the easy to follow instructions and apply it to their home workouts while doing any exercise including bouncing on a mini trampoline, using a bike, or elliptical, or even walking.

### **Fat Freezer Healthful Meal plan & Eating Tips**

The Fat Freezer System meal plan tips were designed to be a practical, doable approach to improving eating habits and to support and initiate healthy fat loss.

Subjects were provided instructions to follow their Fat Freezer System meal plan tips including healthful eating consisting of 4 to 5 healthful meals a day found in the Fat Freezer System Meal Plan.

- *Always start with breakfast – remember your metabolism doesn't really kick in until after 1<sup>st</sup> real meal.*
- *Drink a minimum of a glass of water within 20 minutes of waking up. Adequate morning hydration can get things moving through you more quickly and efficiently.*
- *No Alcoholic beverages. Not one serving is less than 100 calories and lets be honest – not many of us only have 1. If you have 3 or 4 alcoholic drinks, at minimum, you have ingested and extra 300 to 600 calories not including your meal.*

- *Coffee and tea OK without fatty creams, milk or sugar/sweeteners*
- *Avoid FALSE sweeteners*
- *Limit or omit sugars – and remember – sugar is not fat but it IS Highly fat promoting.*
- *Omit white starches such as rice, bread and pasta. White starches such as bread convert in the body to sugar for immediate energy release however if the sugar/energy is not released it will convert in the body to fat. Many researchers now believe that white starches such as that in bread, rice and pasta is a major reason for obesity in America today.*
- *After breakfast make sure to fuel the body every 2.5 to 3 hrs.*
- *Get in the mindset that food is fuel and you need the cleanest and highest quality to regularly fuel your body.*
- *Every now and then its ok to have a cheat meal that you enjoy but EVERY Now and then NOT every day or even every other day.*
- *Water should be your liquid of choice. water water every day with a goal of no less than 1 gal.*
- *Omit soda and juices – remember sugar is not fat but extremely fat promoting.*
- *Have an apple Approx. 15 to 20 minutes before lunch and before dinner. The fiber in the apple will fill you a little before your meals causing you to consume less calories than usual during each meal.*

*[1] Di Lorenzo C, Williams CM, Hajnal F, Valenzuela JE. "Pectin delays gastric emptying and increases satiety in obese subjects." Gastroenterology. 1988 Nov;95(5):1211-5.*

*[2] Conceicao de Oliveira M, Sichieri R, Sanchez Moura A. "Weight loss associated with a daily intake of three apples or three pears among overweight women." Nutrition. 2003 Mar;19(3):253-6.*

The Fat Freezer System healthful eating tips emphasized whole foods. Alcoholic beverages, soda, juice, sugars, sodium and saturated fats were to be limited or excluded. The Fat Freezer System meal plan and tips works to allow an individual to more successfully adhere to in essence a calorie restriction of their previous eating habits by simply supplying the user with more healthful lower calorie options promoting healthful daily meal habits.

# The Fat Freezer System Meal Plan and Shopping List:

|  | Day 1  | Day 2   | Day 3   | Day 4   | Day 5   | Day 6   | Day 7  |
|--|--|---|---|---|---|---|--|
| <b>B</b><br><b>R</b><br><b>E</b><br><b>A</b><br><b>K</b><br><b>E</b><br><b>T</b> | Scrambled Eggs<br>* 8 oz. or more, water<br>* 1/2 banana<br>* 1 scrambled egg white, 1 scrambled egg with yolk.  | Orange Chicken<br>* 8 oz. or more, water<br>* 1/2 an orange<br>* 1/2 cup shredded chicken breast, warm or cold – yes for breakfast.   | Smoothie<br>* 1/2 cup plain fat free yogurt<br>* 1/2 a banana<br>* 3 frozen pineapple slices<br>* 1 tsp. coconut flavor<br>* 8 oz. or more, water                       | Scrambled Eggs<br>* 8 oz. or more, water<br>* 1/2 a banana<br>* 1 scrambled egg white, 1 scrambled egg with yolk.   | Orange Chicken<br>* 8 oz. or more, water<br>* 1/2 an orange<br>* 1/2 cup shredded chicken breast, warm or cold – yes for breakfast.   | Smoothie<br>* 1/2 cup plain fat free yogurt<br>* 1/2 a banana<br>* 3 frozen pineapple slices<br>* 1 tsp. coconut flavor<br>* 8 oz. or more, water                       | Scrambled Eggs<br>* 8 oz. or more, water<br>* 1/2 a banana<br>* 1 scrambled egg white, 1 scrambled egg with yolk.  |
| <b>S</b><br><b>M</b><br><b>A</b><br><b>K</b>                                     | *1 cup fat free flavored yogurt<br>* 8 oz. or more, water  | * 1 large apple<br>* 8 oz. or more, water   | * 1 large orange<br>* 8 oz. or more, water  | *1 cup fat free flavored yogurt<br>* 8 oz. or more, water   | * 1 large apple<br>* 8 oz. or more, water   | * 1 large orange<br>* 8 oz. or more, water  | *1 cup fat free flavored yogurt<br>* 8 oz. or more, water  |
| <b>L</b><br><b>M</b><br><b>E</b><br><b>N</b><br><b>T</b>                         | Spicy Chicken & Pasta<br>* 1/2 cup spinach pasta (the green colored pasta)<br>* 1/2 cup chicken breast chopped<br>* 5 TBS fat free salsa<br>* 8 oz. water<br>* 1/2 of an apple | Cruachy Turkey Salad<br>* 1/2 cup cooked broccoli<br>* 1/2 bag dry BAKED Ramen Noodles - boiled<br>* 1/2 bag dry BAKED Ramen Noodles crunched up<br>* 1/2 cup snow peas<br>* 1 orange chopped<br>* 3 thin slices of peppered turkey lunch meat chopped.<br>* 1 tsp. lite sesame seed dressing, or vinaigrette.<br>* 8 oz. water | Chicken Sandwich<br>* 2 slices whole wheat toast<br>* 1/2 chicken breast<br>* 1 slice low fat cheddar cheese<br>* 10 large spinach leaves<br>* Mustard<br>* 8 oz. water | Peanut Butter Pasta<br>* 1/2 cup angel hair pasta - cooked<br>* 1 TBS. low fat peanut butter<br>MIX peanut butter in with warm pasta so it melts.<br>* 1/2 cup broccoli<br>* 1/2 of an apple<br>* 8 oz. water | Cruachy Turkey Salad<br>* 1/2 cup cooked broccoli<br>* 1/2 bag dry BAKED Ramen Noodles - boiled<br>* 1/2 bag dry BAKED Ramen Noodles crunched up<br>* 1/2 cup snow peas<br>* 1 orange chopped<br>* 3 thin slices of peppered turkey lunch meat chopped.<br>* 1 tsp. lite sesame seed dressing, or vinaigrette.<br>* 8 oz. water | Chicken Sandwich<br>* 2 slices whole wheat toast<br>* 1/2 chicken breast<br>* 1 slice low fat cheddar cheese<br>* 10 large spinach leaves<br>* Mustard<br>* 8 oz. water | Spicy Chicken & Pasta<br>* 1/2 cup spinach pasta (the green colored pasta)<br>* 1/2 cup chicken breast chopped<br>* 5 TBS fat free salsa<br>* 8 oz. water<br>* 1/2 of an apple |

## Fat Freezer System weekly Meal Plan Shopping List:

- 6 pack eggs
- 8-10 oz. Plain Fat Free Yogurt
- 8-10 oz. non-fat Cottage Cheese
- 3 – Fat free yogurt – any flavor
- 1 lb. sliced turkey – Peppered Turkey Breast – thinly sliced from the deli
- 5 slices low fat cheddar cheese – also from the deli
- 1 small container Coconut Extract
- 1 small container Cinnamon (powdered)
- Jerk Seasoning
- 1 small loaf low fat whole wheat bread – make sure the first ingredient is WHOLE WHEAT.
- 1 small bag of slivered almonds
- 2 ready bags of spinach – like the salad in a bag, but ONLY spinach
- 1 small bag spinach pasta – the green colored pasta
- 1 small bag angel hair pasta
- 1 small container of low fat peanut butter
- 1 Small container of fat free salsa
- 1 small bottle vinaigrette salad dressing
- 1 small bottle fat free ranch salad dressing
- 1 small bottle lite sesame seed salad dressing
- 1 small bottle mustard
- 2 bags BAKED Ramen Noodles
- 4 medium sized bananas
- 8 oranges
- 4 small tangerines
- 1 bag of seedless grapes
- 1 bunch of celery
- 6 mushrooms
- 6 asparagus
- 2 bunches/stalks of broccoli
- 4 large apples
- 1 small container of strawberries – at least 12 strawberries
- 1 bag frozen chicken breasts – at least 5-6 in a bag
- 1 – 16 oz. bag frozen pineapple slices
- 1 can pineapple slices in lite syrup or juice
- 1 lbs. LEAN ground turkey
- Water – about 48 oz. per day

|  | Day 1  | Day 2   | Day 3   | Day 4   | Day 5   | Day 6   | Day 7   |
|--|--|---|---|---|---|---|---|
| <b>S</b><br><b>M</b><br><b>A</b><br><b>K</b>             | * 1 cup strawberries<br>* 8 oz. water  | * 1 large banana<br>* 8 oz. water   | * 1 large orange<br>* 8 oz. water   | * Large handful leafy spinach<br>* 8 oz. water  | * 1 cup strawberries<br>* 8 oz. water   | * 1 large orange<br>* 8 oz. water   | * Large handful leafy spinach<br>* 8 oz. water  |
| <b>L</b><br><b>M</b><br><b>E</b><br><b>N</b><br><b>T</b> | Summer Salad<br>* 3 oz. chopped chicken breast<br>* 1/2 cup grapes<br>* 1/2 cup strawberries<br>* 1/2 cup celery – sliced<br>* 1/2 cup pineapple slices<br>* 1 TBS non-fat ranch dressing<br>* 8 oz. water | Spinach Salad<br>* 1 cup spinach leaves<br>* 2 tangerines, chopped<br>* 5 almonds<br>* 4 thin slices of peppered turkey lunch meat – chopped<br>* 1/2 cup cooked broccoli<br>* 1 tsp. lite sesame seed dressing or vinaigrette<br>* 8 oz. water | Jamaican Jerk<br>* 1/2 lb. ground turkey<br>* 3 mushrooms sliced<br>* 1 cup celery chopped<br>* 2 TBS. Jamaican Jerk Seasoning<br>* 1 cup spinach<br>* 2 tsp. lite vinaigrette<br>MIX all ingredients together<br>* 8 oz. water | Chicken and Veggie's<br>* 3 oz. grilled chicken breast – shredded<br>* 1/2 cup cooked broccoli<br>* 3 cooked asparagus<br>* 1 thin slice sharp cheddar cheese<br>* 1/2 cup seedless grapes<br>* 8 oz. water | Spinach Salad<br>* 1 cup spinach leaves<br>* 2 tangerines, chopped<br>* 5 almonds<br>* 4 thin slices of peppered turkey lunch meat – chopped<br>* 1/2 cup cooked broccoli<br>* 1 tsp. lite sesame seed dressing or vinaigrette<br>* 8 oz. water | Jamaican Jerk<br>* 1/2 lb. ground turkey<br>* 3 mushrooms sliced<br>* 1 cup celery chopped<br>* 2 TBS. Jamaican Jerk Seasoning<br>* 1 cup spinach<br>* 2 tsp. lite vinaigrette<br>MIX all ingredients together<br>* 8 oz. water | Chicken and Veggie's<br>* 3 oz. grilled chicken breast – shredded<br>* 1/2 cup cooked broccoli<br>* 3 cooked asparagus<br>* 1 thin slice sharp cheddar cheese<br>* 1/2 cup seedless grapes<br>* 8 oz. water |
| <b>S</b><br><b>M</b><br><b>A</b><br><b>K</b>             | * 1/2 cup plain fat free yogurt with 5 almonds<br>* 8 oz. water  | * 1/2 orange<br>* 8 oz. water   | * 3 frozen pineapple slices<br>* 1/2 cup plain fat free yogurt with 5 almonds<br>* 8 oz. water  | * Large handful leafy spinach<br>* 5 almonds<br>* 8 oz. water   | * 1/2 cup plain fat free yogurt with 5 almonds<br>* 8 oz. water   | * 1/2 orange<br>* 8 oz. water<br>* 1/2 cup plain fat free yogurt with 5 almonds   | * 3 frozen pineapple slices<br>* 8 oz. water  |

- TIPS:**
- Every meal should include at least 8 oz. of water.
  - MAIN RULE: if hungry – eat more from the block. This is the minimum for each.
  - Lunch is to be finished no later than 1:30pm. If lunch is eaten after 1:30pm, pasta, or any white carb portion is to be deleted.

daily caloric intake, as well as protein measured in grams.

| Day 1                              | Day 2                              | Day 3                              | Day 4                            | Day 5                              | Day 6                            | Day 7                             |
|------------------------------------|------------------------------------|------------------------------------|----------------------------------|------------------------------------|----------------------------------|-----------------------------------|
| 1191.3 Calories<br>72.1 g. Protein | 1204.3 Calories<br>48.2 g. Protein | 1286.3 Calories<br>83.9 g. Protein | 1284 Calories<br>71.1 g. Protein | 1374.3 Calories<br>58.7 g. Protein | 1231 Calories<br>84.4 g. Protein | 971.3 Calories<br>77.2 g. Protein |

## Fat Freezer Device Use:

The participants were given the following instructions when using the Fat Freezer Device:

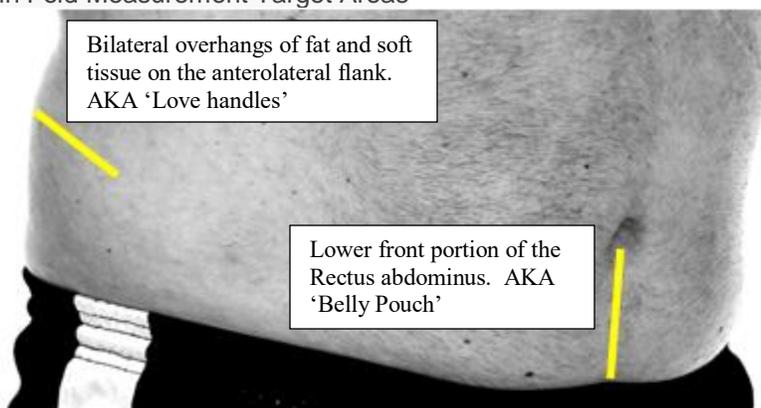
1. Loop the end of the Velcro belt around the handle of one of the Fat Freezer device.
2. Apply a protective pad on a study target area of the body. Ie Flanks (love handles) and lower front abdomen (belly pouch).
3. Carefully place the Fat Freezer device (metal cooling plate) over the included protective membrane.
4. Wrap the Velcro belt firmly around the body part and apply the other end around the opposite loop and attach the Fat Freezer firmly.
5. A green light turns on after pressing the '30' or '60' button to confirm the device is working properly.

6. When desired time is reached the Fat Freezer device will beep and shut off.
7. Gently massage the area of the body using circular motions for at least 2 minutes after use.
8. Wait 4 weeks before applying the Fat Freezer to the same area.

### Data Collection Methods

Measurement protocol was approved by Dr. Bob Girandola Ed.D, a Department of Kinesiology Associate Professor at the University of Southern California. The protocol was administered by Eddie Gaut, Director of Research at the DETUAG Testing Center. Height and weight were measured utilizing a medical scale. Body fat composition was measured utilizing an Omron electrical impedance body fat tester model number HBF -300. Circumference girth measurements were taken by Detuag Testing Center Director of Research using the specialized tension regulated MyoTape body tape measure with consistent tension and common points of reference to reduce measurement variability. The same researcher took all measurements to reduce measurement variability. 2 target areas were also measured with the Accu-Measure® skin fold caliper as an attempt to measure localized result in the specific fat store areas targeted by the Fat Freezer Device. As seen in Fig 1. below the skin fold calipers were used to target the area of the bilateral overhangs of fat and soft tissue on the anterolateral flank and the lower front portion of the Rectus Abdominus. Accu-Measure® Body Fat Testers have gold standard accuracy to within 1.1% of underwater weighing results. In this study the calipers were used simply as an accurate tool to measure thickness of skinfold pinch in mm at the target sites of the device. By using this method we can determine if actual body fat diminished, stayed the same or accumulated in these target areas.

Figure: 1  
Skin Fold Measurement Target Areas



### Objectives:

The key objectives of this study are to:

- 1) Capture Before and After photos
- 2) Capture Before and After measurements
- 3) Determine if compliance, with complete Fat Freezer System for 8 weeks, can make a change in physical appearance of the body with a focus on target areas of bilateral overhangs of fat and soft tissue on the anterolateral flank AKA 'love handles' and the lower front of Abdominal wall - AKA belly pouch.
- 4) Determine if compliance to the tested Fat Freezer System generates statistically significant results.
- 5) Determine what protocol elements can be used, changed or added for future studies.

### Procedures

Prior to beginning the program all subjects were measured according to the methods previously described. The subjects were instructed to initiate the FAT FREEZER SYSTEM on the same day. Subjects were instructed to

continue with the System for a total period of 8 weeks. At the conclusion of the 8 weeks the subjects were measured and photographed again for the same parameters.

**RESULTS:**

Subject compliance rate decreased by the 8 week mark of the test, in that 26 of 35 test subjects continued through the 8 week program. Subjects dropped out of the program or were disqualified due to lack of motivation in continuing compliance. However the number of dropouts did not affect the results conclusions.

On average, the 26 test subjects lost nearly 1 pound (.9125) of measured body mass per week over 8 weeks.

The Majority of measured subjects experienced a midsection circumference loss and the average loss was 1.15 inches for 26 test subjects.

**Table 1 – Average Reductions for 26 subjects after 8 weeks**

| MEASUREMENT   | AVERAGE STARTING | AVERAGE AFTER 8 wks. | AVERAGE REDUCTION at 8 wks. |
|---|------------------|----------------------|-----------------------------|
| Body weight lbs.  | 142.6            | 135.3                | 7.3                         |
| Midsection (inches)   | 33.33            | 32.18                | 1.15                        |
| Fat Mass lbs.   | 41.09            | 36.12                | 4.97                        |
| Love Handle Caliper Skin fold pinch Test mm<br>Target area: left flank          | 44.5             | 34.46                | 10.04                       |
| Belly Pouch Caliper Skin fold pinch Test mm<br>Target area: front lower abdomen | 23.7             | 19.8                 | 3.9                         |

As seen in Table 1, and as expected, body mass weight loss and fat mass parameters also saw reductions across the group. Average weight loss achieved for the 26 was 7.3 pounds during the 8weeks. What was even more impressive was that body fat mass across the group went down by 4.97 lbs., corresponding to an average of .62lbs. pounds of actual FAT mass lost per participant per week after 8 weeks or 68% of the weight lost from 26 subjects was actual body fat.

As also seen in Table 1 when the Fat Pinch caliper was used on the target area known as the love handle an average reduction of 10.04 mm of pinch-able fat was documented. This reduction corresponds with the overall satisfaction of System use seen in Table 2 and the visual changes seen in many of the subjects before and after comparison photos.

During the study, participants completed a number of questionnaires - the 8 week answers to which are summarized below and in Table 2.

As seen in Table 2:

- At 8 weeks a combined total of 88.5% subjects either ‘Agreed’ or ‘Strongly Agreed’ they will continue to use the Fat Freezer Device after the study is complete.

- At 8 weeks a combined total of 61.5% subjects either ‘Agreed’ or ‘Strongly Agreed’ the Fat Freezer Device made their tummy diminish more quickly than previous exercise and diet plan alone.
- At 8 weeks a combined total of 88.5% subjects either ‘Agreed’ or ‘Strongly Agreed’ the Fat Freezer Device made their love handles diminish more quickly than their previous exercise and diet plan alone.
- At 8 weeks a combined total of 92.3.5% subjects either ‘Agreed’ or ‘Strongly Agreed’ they would recommend this complete System to others who need to target overall body shape.

**Table 2**  
**8 WEEK Questionnaire Summary of Study Subjects**

| Question  | Strongly Agree          | Agree            | Neutral        | Disagree            | Strongly Disagree            |
|---|-------------------------|------------------|----------------|---------------------|------------------------------|
| <b>1. I will continue to use the Fat Freezer Device after the study is complete.</b>                                      | 18                      | 5                | 2              | 0                   | 0                            |
| <b>2. The Fat Freezer Device made my tummy diminish more quickly than my previous exercise and diet plan alone.</b>       | 9                       | 7                | 9              | 1                   | 0                            |
| <b>3. The Fat Freezer Device made my love handles diminish more quickly than my previous exercise and diet plan alone</b> | 9                       | 14               | 2              | 1                   | 0                            |
| <b>4. I would recommend this complete System to others who need to target overall body shape.</b>                         | 12                      | 12               | 1              | 1                   | 0                            |
| <b>5. I would recommend the Fat Freezer device to others who need to target love handles and belly pouch.</b>             | 15                      | 9                | 2              | 0                   | 0                            |
| <b>6. At 8 weeks I notice a positive result from using the Fat Freezer System</b>   | 13                      | 11               | 2              | 0                   | 0                            |
| <b>QUESTION:</b>  | <b>Highly Satisfied</b> | <b>Satisfied</b> | <b>Neutral</b> | <b>Dissatisfied</b> | <b>Strongly Dissatisfied</b> |
| <b>1. At 8 weeks how satisfied are you with your results from the Fat Freezer device only?</b>                            | 12                      | 8                | 6              | 0                   | 0                            |
| <b>2. At 8 weeks how satisfied are you with the Fat Freezer System?</b>   | 16                      | 8                | 2              | 0                   | 0                            |

Also as seen in Table 2:

- At 8 weeks a combined total of 92.3% subjects either 'Agreed' or 'Strongly Agreed' they would recommend the Fat Freezer device to others who need to target love handles and belly pouch.
- At 8 weeks a combined total of 92.3% subjects either 'Agreed' or 'Strongly Agreed' they notice a positive result from using the Fat Freezer System.
- At 8 weeks a combined total of 77% were 'Satisfied' or 'Highly Satisfied' with their results from the Fat Freezer Device.
- At 8 weeks a combined total of 92.3% were 'Satisfied' with their results from the Fat Freezer System.

### **Statistical Analysis:**

Statistics is the method of showing that the differences found would be the same if another similar group of subjects were tested. Normally, what is accepted in comparing fat loss equipment or programs is  $P < 0.05$  (95 out of 100) or  $P < 0.01$  (99 out of 100). Meaning that 95 or 99 times out of 100 we would obtain the same results with any other small group of subjects.

1. Body Weight changes: For  $N = 26$  Body weight Pre testing was 142.6 lbs. and weight Post testing was 135.3 lbs. an 5 % weight loss and statistically significant result with  $P < 0001$
2. Belly Girth Inch changes: Pre = 33.3 inches; Post = 32.2 inches and change is a 3.3% drop which is also significant with  $P < 0001$
3. Fat mass changes; Pre = 41.1 lbs.; Post = 36.1, drop is 12% of fat, and statistically significant as well.  $P < 0001$
4. Skin Fold: Belly: pre 23.7; Post 19.8 a percent decrease of 16% and statistically significant as well.
5.  $P < 0001$
6. Skin fold Love handles: Pre 44.5; Post 34.5 % decrease of 22% and statistically significant as well.  $P < 0001$ .

We found statistical significance for fat loss, weight loss, belly inch loss, and caliper fat pinch loss in the Fat Freezer System Study.

The statistics show (T Test) the losses to be Significant. This means a majority of users with weight, inches and excess body fat to lose could expect similar results generated in this study.

### **DISCUSSION:**

This study was on the Fat Freezer System incorporating 3 different components all known to eliminate body fat in various ways. More research will need to be done in order to determine how much fat loss each component of the system contributed to loss at the target areas. At minimum, as a next step, a longer term control arm to this Pilot study would be recommended in order to compare the full Fat Freezer System use to Fat Freezer device use only. It would also be recommended that a DEXA body composition scan, currently one of the most reliable and clinically/medically accepted body composition tests, be used to determine even the smallest of body composition changes in specific localized zones targeted by the Fat Freezer device.

### **CONCLUSIONS:**

The combination of all the components of the FAT FREEZER SYSTEM, led to a measurable loss across data points in the 8 week time period with Statistically Significant results. The statistical analysis (T Test) shows the

losses to be significant. This means an absolute majority of users with a midline normal to overweight BMI can expect similar results generated in this study

The overall results of the study are consistent with other prior research regarding effective mid-section and weight loss intervention strategies, in that it was fully anticipated that the FAT FREEZER SYSTEM would produce reductions in weight, fat mass, and size.<sup>8</sup> The magnitude of the FAT FREEZER SYSTEM was consistent with results experienced in other studies including healthful eating and exercise as components.

In the 8 week period the system produced a statistically significant average weight loss for 26 participants of nearly 1 pound per week (.9125) pounds/week compared to 1-2 pounds being the typical range of other researched strategies which included diet and exercise.<sup>9</sup>

The Fat Freezer System study targeted specific areas for the Fat Freezer device to be used. The front belly pouch and the love handles. For the statistically significant majority of the test subjects the target areas, of the Fat Freezer Device, did diminish by measurement and visually in photographs.

A core finding of this study is that the FAT FREEZER SYSTEM is a realistic and practical way to manage, maintain or reduce body mass weight, fat mass, and waist size with the added bonus of Cryolipolysis to potentially assist in the targeting of the stubborn fat store areas of the lower front abdomen AKA belly pouch and the flank AKA love handle. With ongoing compliance with the FAT FREEZER SYSTEM, a majority of users can be expected to generate continued results because subjects will have achieved a sense of motivation and accomplishment in a short duration via exercise and a healthful meal plan and future potential of diminishing stubborn target areas via the device, thus re-enforcing the value of continuing with the FAT FREEZER SYSTEM for achieving longer term body composition and Fat Freezer System target reductions in fat mass as well as achieving long term midsection girth reductions.

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