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August 31, 2020

IDE FINAL REPORT

U.S. FDA IDE Number: G180219
Protocol Name: Effect of low frequency high intensity ultrasound on subject waist circumference reduction
Protocol Number: 005-00036-8
Device name: Ultimate Contour Mini
Device indication(s) for use: Application of ultrasound for non-invasive waist circumference reduction

Report Prepared by:

Robert Larsen
CAO Group, Inc.

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Appendix A: Independent Monitor Reports

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1. STUDY PARTICIPANTS

1.1. Sponsor:

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1.2. Institutional Review Board (IRB):

University of Utah Institutional Review Board
75 South 2000 East
Salt Lake City, Utah 84112
File Number: IRB_00113587
Approved: 30 Oct 2019
Approval Expires: 5 Aug 2020
There has been no change in the IRB during the course of this study.

1.3. Independent Study Auditor / Monitor:

Core Compliance, LLC
63 E 11400 S, #249
Sandy, Utah 84070
Contact: Terence Rarick, Lead Monitoring Consultant

1.4. Number of Investigational Sites: 1

Cosmetic Surgery Happiness, Inc., dba Just the Right Curves
7525 S Union Park Avenue
Midvale, UT 84047
Number of investigators: 1 Principal investigator and 5 sub-investigators
Principal Investigator: M. Kirk Moore, MD
Sub-investigators: Layne A. Hermansen, DO
Anne M. Hutchinson, MD
Melinda M. Midgley, MD
John M. Sanders, DO
Linda Brown-Trudel, MD

All investigators operated at the study site listed above.

Articles published from data collected from this study: No publications have been made from data collected from this study.

2. EXECUTIVE SUMMARY

A single-site, single arm study was undertaken to evaluate the effectiveness and safety of using low frequency ultrasound in the frequency range of 35-45kHz to achieve disruption of sub-dermal adipose tissue in the abdominal region of adults. The study utilized the Ultimate Contour Mini device for this purpose. The treatment consisted of one application of the device for 30 minutes at its highest setting, with a total of three treatments applied to the subject, spaced approximately one week apart. Measurements were made of the subject's waist circumference using a constant-tension tape measure. Assessment was made of the subjects immediately after each treatment, and at 1 week, 4 weeks, and 12 weeks following the final treatment to identify any safety concerns, interactions, or effects that may result from the treatments. Subject's were provided with questionnaires prior to the treatments, after the treatments, and at the 12-week follow-up to assess the subjects' impressions regarding effectiveness.

A total of 52 subjects commenced treatments and a total of 42 subjects completed the study. For those that completed the study, a reduction of waist circumference of 2.0 inches on average was measured. The target reduction amount for study success was set at 1.0 inches, with a ±0.25 inch cumulative uncertainty. The 2.0 inches on average was seen to hold constant at the 1-week and 4-week follow-up visits. Subjects felt that the treatments achieved some success and felt some improvement regarding their body image, but identified that either additional treatment regimens using this device, or other methods of reducing their waist circumference, were still needed.

Some subjects identified that during the treatments the device handpiece felt warm to the skin but was tolerable. Some also indicated they could hear, or experienced, a ringing or buzzing sensation in their ears. This was mostly tolerated well although two subjects chose to stop participation because this issue was too uncomfortable to them. Some redness and skin discomfort was noted, but generally self-resolved without any intervention except for one subject who required application of hydrocortisone to address a rash that had developed, which may have been instigated by the study device although medications this subject was taking may have contributed. One subject observed what was described as "fatty urine" after the first treatment, and one subject reported constipation two days after a treatment.

A slight adjustment was needed to the devices to stabilize the temperature sensing of the handpieces. The study protocol had to be adjusted relative to the 12-week follow-up assessment due to the existence of the COVID-19 pandemic and restrictions on the interaction and movement of people. The 12-week assessment was performed via video phone call and the waist circumference measurement at this visit was omitted.

This study supports a conclusion that the device is effective in reducing the waist circumference of a subject using low-frequency ultrasound. Some effects are noted with most of these effects being mild and tolerable, and most were already anticipated. Some additional precautions and information are recommended to be added to the device Instructions for Use relative to the perceived warmth of the handpiece, the possibility of 'hearing' the ultrasound, possible vertigo after the treatment, possible constipation, and precaution that individuals taking rosuvastatin may be more susceptible to developing a rash or itch.

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3. STUDY PROTOCOL

3.1. INDIVIDUAL TREATMENT SESSION

Prior to the Treatment:

- The subject was scheduled to arrive at the study site to undergo a treatment.
- The date of the treatment and the time of arrival were documented in the treatment session record.
- During the first treatment only: The subject was given the WaistQ-Pre survey to fill out.
- The assigned pre-treatment investigator measured the waist circumference of the subject and documented this in the Pre-Treatment record, with the measurements made by the blinded assessment clinician as described in the Measurement Tools and Methods section of the protocol.
- Prior to Treatments 2 and 3, the subject was asked for the study diary, and the pre-treatment investigator reviewed the diary and the subject's previous post-treatment Anticipated Effects, and Adverse Event forms if any, and discussed with the subject the items that were recorded about any abnormal body functions or observations that may have been relevant to the treatment. If any were indicated, these were documented in the subject's record. Additional records were made by the investigator as to whether past events and observations were resolved or still unresolved.
- The subject was then moved to the treatment area.

Application of the Treatment:

- The treatment clinician prepared the subject for treatment by displacing clothing from the treatment area, which is the abdominal area from the bottom of the sternum to the iliac crest.
- The subject was instructed to lie down on their back on the treatment table.
- The treatment clinician turned on the Ultimate Contour Mini device and set it to the indicated parameters for this study: Time Setting of 30 minutes; Intensity Setting of 4.
- The treatment oil/fluid, a massage oil with a cottonseed or grapeseed oil base, was applied to the subject's skin over the area intended for treatment.
- The treatment clinician applied the treatment handpiece to the subject's skin in the intended treatment area.
- The treatment clinician pressed the Activation button on the Ultimate Contour screen to begin energy emissions from the handpiece.
- The treatment clinician moved the handpiece along the skin with slight pressure to the handpiece to maintain contact with the skin, moving in circular, orbital motions approximately twice the diameter of the handpiece diameter, and progressively advancing in a linear direction from one edge of the treatment zone to the other in an overall back-and-forth approach.
- The treatment clinician continued application of the handpiece until either the proscribed 30 minutes had expired, or the subject indicated to halt the treatment due to discomfort.
- Once energy emissions cease, the handpiece was removed from the skin, and the treatment oil cleaned off from the skin.
- The subject replaced their clothing and moved back to the assessment room.

Post-Treatment Assessment:

- The Post-Treatment assessing investigator observed the treated area for any redness, edema, swelling, or other indications specifically called for in the Anticipated Effects treatment record. The subject was asked for any unexpected sensations, for example sensations of high heat or of a "pins and needles"

tingling effect in the tissue. These anticipated effects were documented in the treatment session record. Un-anticipated effects were recorded in the Adverse Event form.

- The subject was presented with the Stanford Pain Scale chart and asked to rate their overall pain and discomfort during the treatment. This was documented in the treatment session Assessment record.
- A waist circumference measurement of the abdominal region was made using the constant-tension tape measure. This measurement was recorded in the Post-Treatment Measurement record.
- Following the first treatment, the subject was provided with a study diary form, and instructed to document in the diary any unusual sensations, events, or bodily responses and to bring the form with them for the next visit.
- At the final treatment session only, the subject was provided with the WaistQ-Post survey to fill out.
- The subject was then scheduled for the next study session, and then excused.

3.2. FOLLOW-UP

- The subject was scheduled for and arrived at the study site at time points approximately 1, 4, or 12 weeks after the final treatment.
- The date of the visit and the time of arrival were documented in the Post-Assessment Measurement and Anticipated Effects forms.
- At the 1-week visit, the subject filled out the WaistQ-Post survey. At the 12-week follow-up, the WaistQ-12 survey was filled out.
- The subject was asked for the study diary, and the investigator reviewed the diary and discussed with the subject the items that were recorded about any abnormal body functions or observations that may have been relevant to the treatment. If any were indicated, these were documented in the subject record. The investigator also reviewed observations and adverse events documented in previous sessions and discussed these with the subject. If applicable, additional records were made by the investigator as to whether past events and observations had been resolved or were still unresolved.
- At the 1-week and 4-week follow-up visits, the subject was provided with the study diary form, and instructed to document in the diary any unusual sensations, events, or bodily responses and to bring the form with them for the next visit. The subject was then scheduled for the 4-week or 12-week follow-up visits as appropriate.
- At the 12-week follow-up, additional review was made of the subject's Medical History and Medication forms and any new content for these forms is noted therein and discussed with the subject. If the 12-week follow-up visit was concluded and the Adverse Event form indicated any unresolved adverse results for the subject, additional follow-up was scheduled as appropriate until all adverse results were concluded.

4. STUDY SUBJECTS

4.1. Schedule of Subject Enrollment

Table 1 below indicates the cumulative number of subjects for each indicated category:

Date	(A) Subjects Scheduled	(B) Subjects Interviewed	(C) Subjects Excluded	(D) Subjects Enrolled (A-C)	(E) Subjects Treated	(F) Subjects Dropped Out	(G) Subjects Continuing/ Concluding Study (D-F)
6 Jan 2020	25	24	1	24	24	0	24
8 Jan 2020	50	49	2	48	48	3	45

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Date	(A) Subjects Scheduled	(B) Subjects Interviewed	(C) Subjects Excluded	(D) Subjects Enrolled (A-C)	(E) Subjects Treated	(F) Subjects Dropped Out	(G) Subjects Continuing/ Concluding Study (D-F)
10 Jan 2020	54	53	2	52	52	3	49
13 Jan 2020	54	53	2	52	52	3	49
15 Jan 2020	54	53	2	52	52	6	46
20 Jan 2020	54	53	2	52	52	6	46
22 Jan 2020	54	53	2	52	52	6	46
27 Jan 2020	54	53	2	52	52	10	42
29 Jan 2020	54	53	2	52	52	10	42
18 Feb 2020	54	53	2	52	52	10	42
19 Feb 2020	54	53	2	52	52	10	42
21 Feb 2020	54	53	2	52	52	10	42
26 Feb 2020	54	53	2	52	52	10	42
27 Feb 2020	54	53	2	52	52	10	42
4 Mar 2020	54	53	2	52	52	10	42
13 Apr 2020	54	53	2	52	52	10	42

Table 1. Schedule of subject enrollment.

4.2. Summary

Total subjects scheduled to participate (A): 54
Total subjects enrolled (D): 52
Total subjects completing all elements of the protocol (G): 42

Exclusions (C): Subject #5 did not complete the enrollment and interview process and chose not to enroll. Subject #31 did not meet the minimum Body Mass Index value for participation in the study.

Dropouts (F): Subjects #6 and 15 indicated that the ultrasound energy could be heard in their ears, causing enough discomfort that they felt the possible benefit of the treatment was not worth the discomfort. Subjects # 10, 13, 16, 19, 37, 47, 52, and 54 all cited scheduling or personal conflicts that prevented them from traveling to the study cite to continue participation.

5. STUDY DEVICES

5.1. Device Traceability

Number of devices delivered to the study site: 5 – Serial numbers 000143, 000144, 000145, 000146, 000147

Disposition of Devices: 5 units were returned to the custody of the sponsor, although 1 unit – 000147 – was then quickly exported out of the United States for laboratory assessment by an interested party located outside the U.S.

5.2. Device Changes

The investigators reported during the first day of treatments that one of the units was providing a notification that the ultrasound hand piece was approaching temperature limits set for the device. Subsequent evaluation of the particular unit and handpiece by the sponsor found that the handpiece was operating within allowed temperatures when the device generated the notification. The temperature measurements were made using an NIST traceably calibrated thermometer (Fluke Model 50S) with a Type K thermocouple. The thermocouple was affixed to the center of the transducer face using thermally conductive tape. The device was set at the maximum setting (Level 4) and set for 40 minutes duration. A starting point of approximately 25-26°C was observed (ambient temperature). The handpiece was activated and the temperature observed. The handpieces were not placed on a human subject or in a water tank bath but were left exposed to the air. Of the handpieces tested, (2 out of 4 available), the warning screen was observed to appear at between 10-11 minutes into the treatment cycle. At this time, the handpieces were observed to measure between 41.2 to 41.6°C. Subsequent testing was done on the handpiece in a 37°C bath (simulating the human body) with the thermocouple applied to the transducer. The testing showed the transducer surface did not exceed 44.0°C after 30 minutes of operation at Intensity Level 4, and the temperature was noted to be 44.2°C after 40 minutes of operation at Level 4 (the maximum operational settings of the device).

A modification to the ultrasound handpiece was made, consisting of applying a 10k ohm resistor across the signal leads of the handpiece thermistor. This served to stabilize the temperature signal reported back to the microprocessor in the device. This adjustment is considered to be temporary and is presently not intended to be incorporated to the final version of the device as provided to the market. Additional testing and evaluation shall be done to confirm that the thermistor sensor signals are correctly processed by the device software relative to the established safety limits.

6. SUMMARY OF RESULTS

6.1. Study Progress

IDE Approval Under the present protocol: 5 Nov 2019

Recruitment Commenced: 5 Nov 2019

Treatments Commenced: 6 Jan 2020

Treatments Concluded: 22 Jan 2020

Follow-up Assessment Concluded: 13 Apr 2020

Dataset Lockdown: 28 Apr 2020

At this time, the activities indicated in the study protocol have been completed. All treatments have been applied, and all follow-up assessments have been performed for those participants who have chosen to continue with the study to its end, subject to the adjustment to the final follow-up owing to the COVID-19 pandemic and restrictions on in-person contact.

6.2. Summary Statistics

A total sample size of a minimum of 40 subjects was established for this study. This number was based on

$$n = \frac{2 \cdot (Z_\alpha + Z_\beta)^2 \cdot \sigma^2}{d^2}$$

where:

Z_α = 1.96, based on a confidence of P=0.05 (false rejecting of a true null hypothesis),
Z_β = 0.84, based on a power of 80% (failure to reject a false null hypothesis),
d = 1.0 inch reduction in waist circumference as a meaningful/successful change in measurement,
σ = 1.50 inches, based on the evidence presented by a published study[5] under similar treatment parameters and conditions reporting a typical response of 0.75 inches through the umbilical region and assuming some of the population may not respond at all.

The resulting calculation gave a minimum study population size of 37. Accounting for possible attrition and adding a generous margin of safety, a recruitment size of 50 individuals was established. A total of 42 study subjects successfully completed the study, so the minimum of necessary study subjects was satisfied.

All indicated values that follow are based on the 42 study subjects who completed the study. All study records were transcribed from physical documents to an electronic spreadsheet to aid in statistical analysis and assessment. An individual who was independent of the study audited the transcription for data integrity, and identified only a minor condition where subject comments were recorded as “0”, and the electronic database documented these responses as “None”. This information was not involved in the statistical analysis and was added to the electronic record for informational purposes only. A copy of the electronic database was also provided to the study monitor for auditing. Study data is now presented.

Gender – Male: 8; Female: 34
Race – Caucasian: 32; Hispanic/Latino: 4; Asian: 1; Not Specified: 5

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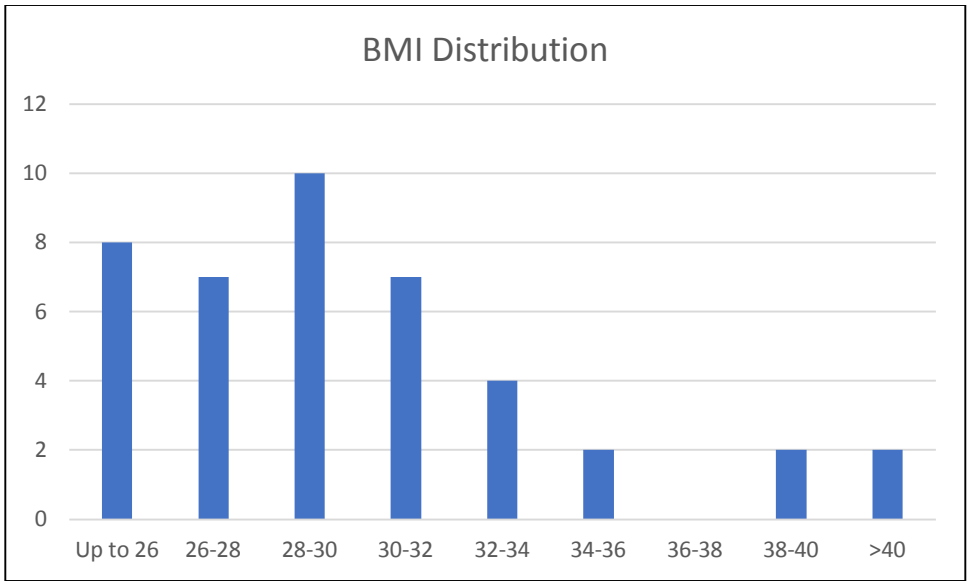
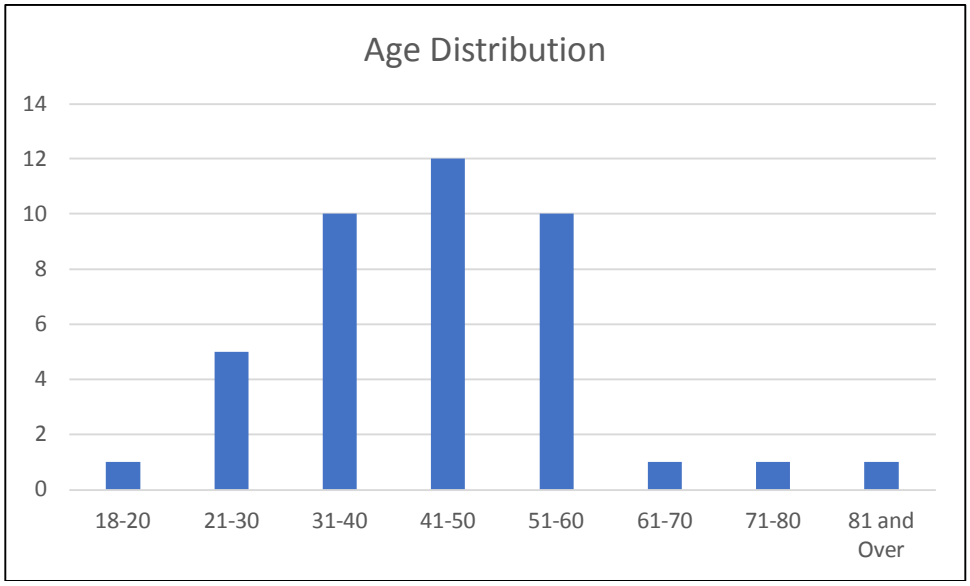


BMI – Average: 29.95; Low: 25.06; High: 44.39

Figure 1. Distribution of study subjects by BMI score.



Age: Average: 44.5; Youngest: 20; Oldest: 81; Not Specified: 1

Figure 2. Distribution of study subjects by age.

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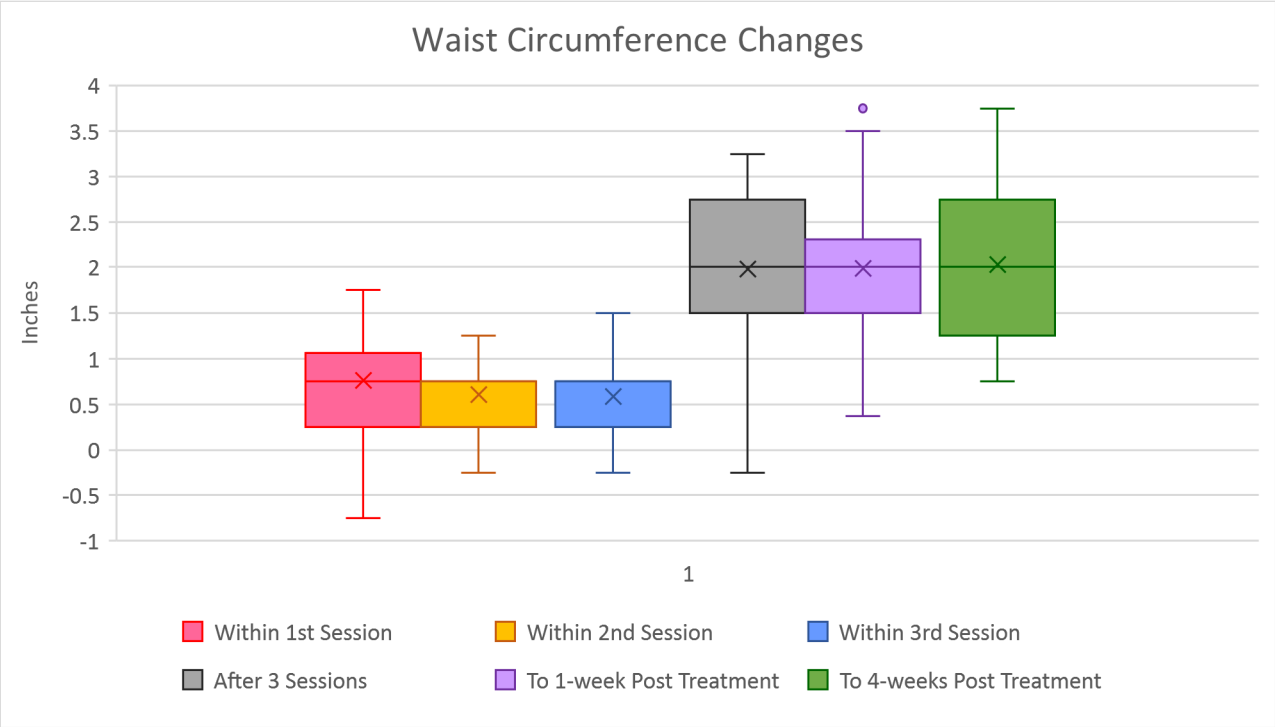

Figure 3. Distribution of data for change in waist measurement.

Consistent with the protocol, measurements were made of the subject's waist circumference:
The subject's circumference was measured using a Gulick II (Model: 67020, Country Technology, Inc., Gay Mills, Wisconsin) tape measure with constant-tension feature that is factory-calibrated by the manufacturer. The process of obtaining a measurement was as follows:

a) The area of the body was exposed (in this case lifting up the shirt to expose the abdominal region).
b) The subject was informed to stand straight and to breathe normally, but to focus on steady shallow breaths.
c) The clinician applied the tape measure by locating the top of the hip bone (iliac crest) and positioning the tape just above this bony landmark, just where one finger can fit between the iliac crest and the lowest rib.
d) The clinician ensured that the tape measure is positioned horizontally, parallel to the floor.
e) The measurement was taken at the end of normal expiration.
f) At a signal from the clinician the subject paused at the conclusion of an exhale, at which point the clinician pulled the tape until the constant-tension feature was enabled. The clinician then observed the measurement value and documented this value in the treatment record.

The data presented in Figure 3 shows statistical information about the change in waist circumference at the different time-points in the study. For each subject, comparison was made:

a) The change in waist circumference before and after the first treatment session.
b) The change in waist circumference before and after the second treatment session.
c) The change in waist circumference before and after the third treatment session.
d) The change in waist circumference comparing the measurement before the first treatment session and after the third treatment session.
e) The change in waist circumference comparing the measurement before the first treatment session and 1 week after the third treatment session.

f) The change in waist circumference comparing the measurement before the first treatment session and 4 weeks after the third treatment session.

The resulting difference values for the 42 subjects who completed the study were then subject to the following statistical analysis.

Within the 1st Treatment:
- Average circumference reduction: 0.76 inches
- Largest circumference reduction: 1.75 inches
- Smallest circumference reduction: -0.75 inches (circumference increase)
- Standard deviation: 0.52 inches

Within the 2nd Treatment:
- Average circumference reduction: 0.61 inches
- Largest circumference reduction: 1.25 inches
- Smallest circumference reduction: -0.25 inches (circumference increase)
- Standard deviation: 0.38 inches

Within the 3rd Treatment:
- Average circumference reduction: 0.59 inches
- Largest circumference reduction: 1.50 inches
- Smallest circumference reduction: -0.25 inches (circumference increase)
- Standard deviation: 0.36 inches

Before 1st Treatment to after 3rd Treatment:
- Average circumference reduction: 1.98 inches
- Largest circumference reduction: 3.25 inches
- Smallest circumference reduction: -0.25 inches (circumference increase)
- Standard deviation: 0.83 inches

Before 1st Treatment to 1 week after 3rd Treatment:
- Average circumference reduction: 1.99 inches
- Largest circumference reduction: 3.75 inches
- Smallest circumference reduction: 0.375 inches
- Standard deviation: 0.80 inches

Before 1st Treatment to 4 weeks after 3rd Treatment:
- Average circumference reduction: 2.03 inches
- Largest circumference reduction: 3.75 inches
- Smallest circumference reduction: 0.75 inches
- Standard deviation: 0.77 inches

The primary study objective was to determine if the effectiveness of the device, established as achieving a minimum 1.0 inch reduction in waist circumference at a point 12 weeks after the last treatment was administered. As indicated in the section of this report regarding protocol deviations, the measurement at the 12 week point could not be obtained due to the COVID-19 pandemic and restrictions on movement and

activities applied to reduce the pandemic. Although it is not reliable to extrapolate a trend with a total of only three data points, it is noted that at the 4-week follow-up that the average change in circumference is nearly constant for those three data points, with the standard deviation tightening within the study subjects as time progresses and the worse-performing study subject seeing an improved reduction in waist circumference.

Review of the data shows there was not consistency as to which study subject recorded the largest reduction in waist circumference or the least reduction (or increase) in waist circumference in each of the six comparison sets. Evaluating the data for change in circumference within the first treatment session, only one individual (Subject #38) recorded an increase in waist circumference after the treatment. There is no indication in the treatment records of any unusual circumstances during this treatment for this subject, and at the present time there is not a plausible explanation for this result. Within the other comparison sets, values of -0.25 inch waist reduction are shown as the least favorable outcome. When performing the waist measurement, investigators were instructed to identify the nearest ¼ inch mark on the tape measure and document this value in the record. This presents a measurement accuracy of ±0.125 inches. Comparing two measurements then provides a cumulative datapoint uncertainty of ±0.25 inches. A difference of waist circumference of -0.25 inches would then fall within that cumulative uncertainty and could just as likely to be a difference of 0 inches.

After the third treatment session, the overall change in waist circumference is shown to be nearly exactly 2 inches. As indicated, the primary study objective was to achieve 1.0 inches of reduction. Even considering the cumulative measurement uncertainty of ±0.25 inches, the study data support a determination that the device does achieve at least 1 inch of waist circumference reduction. Correlation analysis between the subject's BMI rating and the six measurement comparison sets shows no correlation between the study subject's BMI and the extent of waist circumference reduction. Correlation analysis between the subject's gender and the six measurement comparison sets shows no correlation between gender and the extent of waist circumference reduction. Correlation analysis comparing reported medication use or medical history of a subject to the six measurement sets shows some slightly positive correlation between waist reduction within the 2nd and 3rd treatment sessions and those reporting use of medications or a documented medical history. However, this effect is not seen in the data set of before 1st treatment and after the 3rd treatment, or the data set at the 1-week and 4-week follow-ups. Thus the impact or influence of medications being taken or previous medical history is not regarded as significant relative to the reduction in waist circumference provided by this device.

6.3. Study Subject Perception

Prior to experiencing the first treatment, each subject was provided with a short survey (WaistQ-Pre) meant to gauge their perception about their body image and abdominal appearance, and their expectations regarding the treatment. A similar survey was again provided at the 1-week follow-up visit (WaistQ-Post) and again at the 12-week follow-up visit (WaistQ-12Wk), these surveys also gauging the subject's perception about their body image and abdominal appearance, and how the treatments aligned with their expectations. For this section of the report, an abbreviation system shall be used to refer to the survey number and the question within that survey. As examples, the question in the WaistQ-Pre survey about how the subject felt about showing their waist in public would be an abbreviation of "1-9", and the question in the WaistQ-12Wk survey about how the subject thoughts on the effectiveness of the treatment would be an abbreviation of "3-3".

Prior to treatments, subjects reported little or no discomfort with the dermal layers of their waist region (1-1), and not being overly concerned or proud of their general appearance (1-4) or how well their clothes fit (1-8). Subject responses were moderate about the anticipated effectiveness of the treatment (1-2) and the treatment meeting their expectations (1-3). Subjects did express concern about showing their waist region in public (1-9). Most subjects indicated a feeling of importance in reducing their waist (1-11) and the majority had tried some other methods previously to reduce their waist circumference (1-10).

Following the treatments, subjects reported a slightly better condition relative to the itchiness or discomfort of their skin with 3 subjects reporting slight discomfort before the treatments (1-1), and only 1 subject reporting slight discomfort after the treatments (2-1 and 3-1), but not the same subject on both follow-up surveys. Subjects recall experiencing some skin discomfort during the treatments (2-2 and 3-2), but the more favorable responses at the time the surveys were completed (2-1 and 3-1) suggest that the subject's experience with skin discomfort improve after the treatments. Regarding the perceived effectiveness of the treatment, subjects had a more negative opinion about the effectiveness a week after treatments were concluded (2-3), but this sentiment improved at the 12-week follow-up (3-3) when asked the same question, return to values similar to the expectation prior to the treatment (1-2). A similar dip is seen relative to how well the treatment met expectations (1-3, 2-4, and 3-4).

Subject comfort about how they look saw a slight improvement at the 1-week follow-up (2-5), but the perception at the 12-week follow-up (3-5) returned to similar levels as prior to treatment (1-4). This same result is seen in how the subjects perceived their acceptance by others, showing a slight improvement at the 1-week follow-up (2-8) compared to the pre-treatment (1-7) and 12-week follow-up (3-8). The surveys don't show much difference regarding comments the subjects received from others about their appearance and the positivity of those comments (1-5, 1-6, 2-6, 2-7, 3-6, and 3-7). The subjects' comfort level in their clothes showed an improvement during the course of the study, with 22 responding positively before treatment (1-8), increasing to 27 positive responses at the 1-week follow-up (2-9) and improving again to 34 positive responses at the 12-week follow-up (3-9). The subject's level of comfort in showing their waist region did not change much immediately after the treatments (2-10), with only 4 individuals providing a positive response at this point compared with 5 subjects giving a positive response prior to the treatments (1-9). However, this response improved with 10 subjects indicating a positive response to showing their waste at the 12-week follow-up (3-10).

When asked if the subjects would recommend the treatment to others, only 12 responded favorably at the 1-week follow-up (2-11), but that response improved to 21 subjects responding positively at the 12-week follow-up. When asked if they need to undergo the procedure again, a vast majority indicated they would at both follow-up surveys (2-12 and 3-12) with scores of 31 and 30, respectively. When asked if the subject would try other waist-reduction methods after experiencing this treatment, a vast majority indicated they definitely or probably would (2-13 and 3-13) with combined results of 32 and 30, respectively.

In summary, subjects in this study were not terribly concerned about their present physical state, although they recognized a need to and a desire to improve that. Subjects reported a slight improvement to the itchiness or irritation of their skin in the abdominal area, and considerable improvement in being self-conscious of showing their waist in public and in how well they felt their clothes fit. The treatments did not meet expectations as well as expected immediately following the treatment regimen, but this feeling abated over time. The subjects' willingness to recommend the treatment reflects a similar improvement

over time. Subjects indicated they would be willing to undergo this procedure again, but at the same time most indicated they would also seek other solutions.

7. PROTOCOL DEVIATIONS

1) Initial monitoring activities of study records by the sponsor discovered that the post-treatment assessment of one subject among those sampled indicated that the post-treatment assessment for anticipated effects was performed by a sub-investigator rather than the principal investigator. This was contrary to the protocol which indicates that the principal investigator is the only person authorized to perform the post-treatment assessment. The principal investigator was promptly notified of this deviation. Subsequent monitoring visits by the sponsor found that for the particular subject in question, and for all other subject records sampled, subsequent post-treatment assessment was performed only by the principal investigator - consistent with the protocol. Review of the records for the particular subject in question showed that the subsequent post-treatment assessment performed by the principal investigator did not note any adverse effects or extent of anticipated effects more extreme as compared to the post-assessment record that was documented by the sub-investigator during the first treatment.
2) During the first monitoring visit by the sponsor, examples of documentation were identified where the principal investigator had not signed the respective forms. This was promptly brought to the attention of the principal investigator, where the principal investigator indicated that he "had simply not noticed the signature fields on those forms". Subsequent monitoring visits reviewed the specific examples found and sampled additional records, and found that these forms have been signed by the principal investigator.
3) The study protocol provided for follow-up assessments of the study subjects at 1 week, 4 weeks, and 12 weeks after the final treatment. The timing of the 12-week follow-up was such that this follow-up was to occur around the middle of April 2020. During this time period, the COVID-19 pandemic was occurring, to the extent that stay-at-home and social distancing orders were in place by federal, state, and county agencies. Relative to this situation, the protocol for the 12-week follow-up was altered such that instead of having the study subject visit the study site, the investigator arranged for a video phone call with the study subject. This allowed the investigator to visual examine the treatment area on the subject, and ask the follow-up questions provided for in the form, and to follow-up with any previous outstanding effects or adverse events. This alteration of the protocol prevented capture of the waist circumference measurement of the study subject. The absence of this data limits the determination of long-term efficacy of the treatment. This change in protocol still adequately addresses ensuring the continued safety of the study subject in harmony with the protocol. The WaistQ-12 subject perception survey was emailed to the study subjects, who then emailed back the completed surveys.
4) The protocol originally indicated that the WaistQ-Post satisfaction survey would be administered following the third treatment, and again at the 1-week and 4-week follow-up visits. This survey was only administered once, at the 1-week follow-up visit. Administration of this survey immediately after the third treatment did not provide enough time for the effects of the treatment regimen to fully settle in or provide opportunity for the subject to fully evaluate and consider their impression of the results. Similarly, it was felt that if the survey were administered at the 4-week assessment, the responses would not be appreciably different from results of the survey at the 1-week follow-up relative to the additional effort needed from the subject to complete the survey.

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8. RISK ANALYSIS

8.1. Unanticipated Effects and Adverse Events

A total of two Adverse Event forms were utilized during the course of this study. Each is now discussed.

Subject #22 – Skin Rash

Adverse Event	Start Date	Stop Date	Severity	Relationship	Action Taken	Outcome of AE	Expected?	SAE?
Skin Rash	21-Jan-2020	23-Jan-2020	1	3	5 Hydrocortisone	1	2	2

After the third treatment session, this subject reported the onset of a skin rash a day after this treatment. The record does not detail the portion of the body where the rash occurred but identifies that the rash is probably related to the study (Relationship = 3). The report indicates the event is unanticipated (Expected? = 2) and indicates that this is a Serious Adverse Event (SAE = 2). The indication by the investigator that this event is unanticipated is incorrect as this condition is discussed in Section 8.3.5.1 on Surface Risks of this report, and that the possibility of blistering, swelling, edema, erythema, purpura, or aggravation of existing dermal conditions were presented in the study protocol and discussed in the subject's Informed Consent document. The indication that this event is an SAE may not be accurate given that the severity is marked as "1" (Mild), no medical intervention was sought or needed, and the condition was declared as resolved within 2 days. The record shows the event was resolved (Outcome of AE = 1), and the principal investigator signed-off on this adverse event as resolved on 11 March 2020.

Review of this subject's personal information shows a number of medications and nutritional supplements were documented in the Medications form. Two of the medications that may have contributed to the event are rosuvastatin and methenamine. Rosuvastatin, under the brand name of Crestor, is an HMG-CoA reductase inhibitor meant to reduce cholesterol has reported effects of worsening diabetes. The overall influence of this medication on lipid and glycolic metabolism could be significant as anticipated effects of this treatment include influences on liver function and aggravation of diabetic conditions, to the extent that these were identified as exclusion criteria. Methenamine is specifically indicated for bacterial reduction in the context of urinary tract infections. A noted side-effect of this medication is inflammation, redness, and itchiness, although these symptoms are usually seen around the mouth and throat considering that the medication is taken orally. Follow-up was made with this subject, who reported no instances of a rash before or after the treatment sessions of this study.

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Subject #46 – Constipation

Adverse Event	Start Date	Stop Date	Severity	Relationship	Action Taken	Outcome of AE	Expected?	SAE?
Constipation	12-Jan-2020	13-Jan-2020	1	2	5 Miralax	1	2	2

Two days after the first treatment session, this subject reported the occurrence of constipation. Although not documented in the Adverse Event form, the Subject Diary for this study subject provides additional detail that the event happened for the entire day of Jan 12 and half the day of Jan 13 and the subject scored the severity of the event as "Moderate'. The record indicates this condition is possibly related to this study (Relationship = 2). The report indicates the event is unanticipated (Expected? = 2) and indicates that this is a Serious Adverse Event (SAE = 2). There are no indications that this event happened after the second or third treatments. The subject did not report use of any medications or past medical history that may be implicated in this event. The indication that this event is an SAE may not be accurate given that the severity is marked as "1" (Mild), no medical intervention was sought or needed, and the condition was declared as resolved within a day. The record shows the event was resolved (Outcome of AE = 1), there is no further report of the event after additional treatments were applied or reported in the follow-up visits, and the principal investigator signed-off on this adverse event as resolved on 11 March 2020. It is recommended that the Instructions for Use for this device include a precaution that constipation may occur as a result of the treatment.

8.2. Summary of Documented Anticipated Effects

Subject #	Treatment #	Treatment Date/Time	Anticipated Effect	Date of Resolution, or plan for Resolution
2	1	1/6/2020; 0900hrs	"Complained of buzzing in ears during treatment; Fine afterwards"	1/13/2020 [NOTE: There is no indication in the records that this subject complained of the same issue during subsequent treatments.]
3	1	1/6/2020; 0900h	"Ears ringing from ultrasound, tolerated well."	1/13/2020 [NOTE: There is no indication in the records that this subject complained of the same issue during subsequent treatments.]
3	2	1/13/2020; 0950h	[Post-treatment assessment recorded a Pain Level score of '1', and a Tingling Sensation score of '1'].	1/20/2020 [The Post-treatment assessment recorded a Pain Level score of '0', and

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Subject #	Treatment #	Treatment Date/Time	Anticipated Effect	Date of Resolution, or plan for Resolution
				a Tingling Sensation score of '0' following the third treatment].
8	1	1/6/2020; 1200h	"Pt. got red and experienced some pain. That was helped by changing from lines to circles on his back. (+ more oil.)"	1/27/2020 [Principal investigator noted no issues or concerns, and scored anticipated concerns all marked as 0]
8	2	1/13/2020; 1117h	"Last time he was bothered more by the heat of the treatment, this time he said he had decided to adjust to it more." "No issues during treatment except annoying to ears and warm skin."	1/27/2020 [Principal investigator noted no issues or concerns, and scored anticipated concerns all marked as 0]
8	3	1/20/2020; 1100h	"Less painful than previous"	1/27/2020 [Principal investigator noted no issues or concerns, and scored anticipated concerns all marked as 0]
10	2	1/13/2020; 1210h	"Didn't like the heat"	1/20/2020 [NOTE: There is no indication in the records that this subject complained of the same issue during the last treatment.]
11	3	1/20/2020; 1200h	"c/o vertigo x few minutes"	1/27/2020 [Principal investigator noted no issues or concerns, and anticipated concerns all marked as 0 during the 1-week follow-up.]
15	1	1/6/2020; 1440h	"Some pain in ears from procedure"	1/6/2020 Subject indicated they are exceptionally sensitive to sounds and felt the potential benefit of the treatment was not worth the discomfort in their ears. Subject elected to discontinued participation.
18	2	1/13/2020; 1530h	"Wand started buzzing - whistling, went away, was about minutes 22-27"	1/13/2020 [This particular device was used on previous and subsequent subjects the same day, and on previous and subsequent days, and no further report of this issue on this unit or any other unit.]

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Subject #	Treatment #	Treatment Date/Time	Anticipated Effect	Date of Resolution, or plan for Resolution
22	3	1/20/2020; 1535h	"Oil left purple residue / stain on clothing, sheets."	1/27/2020 [Principal investigator noted no issues or concerns, and anticipated concerns all marked as 0 during the 1-week follow-up.]
29	1	1/8/2020; 1056h	"Pre was less - pts abd circumference & fat made it easy to pull tighter. I did not pull tighter."	1/15/2020 [NOTE: There is no indication in the records that this subject complained of the same issue during subsequent treatments.]
29	3	1/22/2020; 1027h	"No probs except grease on shirt last time and a little today"	1/27/2020 [Principal investigator noted no issues or concerns, and anticipated concerns all marked as 0 during the 1-week follow-up.]
30	1	1/8/2020; 1050h	"Ringing in ears"	1/15/2020 [NOTE: There is no indication in the records that this subject complained of the same issue during subsequent treatments.]
30	2	1/15/2020; 0953	"Subject states she noticed the evening of her 1st treatment, her urine appeared "fatty". Also mild headache evening of treatment, discomfort less than 1, resolved on own."	1/22/2020 [NOTE: There is no indication in the records that this subject complained of the same issue during the final treatment or 1-week follow-up visit.]
32	3	1/22/2020; 1120h	"Stretch marks got a little red" "Feels she definitely lost fat, sees a 'line' indentation."	1/27/2020 [Principal investigator noted no issues or concerns, and anticipated concerns all marked as 0 during the 1-week follow-up.]
36	1	1/8/2020; 1245h	"No ringing in ears or erythema (Like most had ringing and erythema that resolved when wand removed)"	1/15/2020 [NOTE: There is no indication in the records that this subject complained of the same issue during subsequent treatments.]
46	1	1/10/2020; 1545h	[Post-treatment assessment recorded a Pain Level score of '1'].	1/15/2020 [The Post-treatment assessment recorded a Pain Level score of '0' following the second and third treatments].
51	1	1/10/2020; 1542h	"Felt warm, almost too warm but able to tolerate w/o	1/15/2020

Subject #	Treatment #	Treatment Date/Time	Anticipated Effect	Date of Resolution, or plan for Resolution
			problem + complete procedure" [Post-treatment assessment recorded a Pain Level score of '1', and a Numbness score of '1'].	[NOTE: There is no indication in the records that this subject complained of the same issue during subsequent treatments. The Post-treatment assessment recorded a Pain Level score of '0' and a Numbness score of '0' following the second and third treatments]

Table 2. Summary of reported anticipated effects.

8.3. Discussion of Anticipated Risks

A discussion of the risks and benefits of the study device is now provided. This discussion addresses the purpose and use of the device itself, as well as anticipated risks associated with this device. Familiarity with the study protocol, device labeling regarding description of the device, the proposed mechanism of action, and the device's intended use is presumed within the context of this risk analysis and the discussed anticipated effects.

8.3.1. DEVICE RISKS

The delivery of ultrasound energy for the indicated purpose and at the ultrasound frequency have been previously evaluated and published by other individuals, and these references are provided at the end of this report.

8.3.1.1. ELECTRICAL SHOCK

A risk exists that the operator or the subject may experience an electrical shock, owing that the device is an electrically active device and obtains power from a wall outlet. This is of particular concern where the portion of the device that contacts the subject is a metal surface and may provide electrical connection to the device.

This risk is mitigated in that the device has been designed to, and has been certified compliant to, the recognized consensus standard of IEC 60601-1, 3rd Edition. Testing and certification was performed by an independent third party, Intertek Testing Services. In meeting the requirements of this standard, which is intended to provide protection to the subject and operator against a variety of hazards including electrical shock, the operator and subject are afforded acceptable protection against this risk. Accordingly, the possibility for this risk occurring is extremely low, and should the risk happen the possible severity is low and momentary.

During the study, observation was made that one device was heard to make an unpredictable buzzing or rattling sound during use. Examination of the device by the sponsor found that a mechanical component within the handpiece had come loose and was responsible for the noise. Re-securing the component eliminated the noise and no further issues were reported with this device.

8.3.1.2. THERMAL INJURY

A risk exists that the operator or the subject may experience excessive temperatures, owing that the device uses electrical energy to create ultrasound energy, and that this activity is less than 100% efficient so that heat is generated. This heat may be present within the device itself and may also be present in the applicator handpiece where the ultrasound transducer is located. Where the device is to be held by the operator for up to 40 minutes, and the metal surface of the handpiece in contact with the subject for up to 40 minutes, this is a notable risk.

This risk is mitigated in that the device has been designed to, and has been certified compliant to, the recognized consensus standard of IEC 60601-1, 3rd Edition. Testing and certification was performed by an independent third party, Intertek Testing Services. In meeting the requirements of this standard, which is intended to provide protection to the subject and operator against a variety of hazards including excessive temperatures where the device's primary intended function is not accomplished through application of heat, the operator and subject are afforded acceptable protection against this risk.

Additionally, the device has been designed to incorporate a thermal sensor within the handpiece which sends temperature data to the device. If excessive temperatures are measured, the device is designed to immediately halt the ultrasound emissions and not allow resuming emissions until the temperature has lowered to a safe level. An alteration of the temperature sensor was made, with the effect of dampening/stabilizing the temperature signal to the processor. Possible risk is that the software is less responsive to changes in temperature. The severity of this risk is minimal as treatment records indicate no aggravated complaints or issues related to the treatment experience after the modification was applied.

Treatment data indicates that subjects may feel the warmth of the handpiece, and there may be some relationship between the method and technique of application, and the heat sensation that is experienced. A total of 4 complaints were identified during the course of the study related the perceived warmth or heat of the handpiece. Three of these complaints were from the same one study subject (#8). Of these three instances, 2 of the 3 treatments were applied by one clinician, while the third treatment was applied by a different clinician. Two different devices were used over these three events on this one subject, with the clinician performing two of the treatments using two different devices. There is not information to support a correlation beyond that of this particular subject. The subject did not document any current medications or previous medical history that may increase susceptibility to feeling heat or warmth from the handpiece. Although the device was tested and found compliant to IEC standards for medical devices, which includes allowable temperatures for portions not intended to deliver heat, the number of comments and observations about the warmth of the hand piece supports that the IFU should be amended to include information to the user that the hand piece may feel warm and to advise the subject that they may experience this. Although the device was tested and found compliant to IEC standards for medical devices, which includes allowable temperatures for portions not intended to deliver heat, the number of comments and observations about the warmth of the hand

piece supports that the IFU should be amended to include information to the user that the hand piece may feel warm and to advise the subject that they may experience this.

8.3.2. SOFTWARE INTEGRITY

A risk exists that the operator may select device settings that could be harmful to the subject, or the device may direct ultrasound emissions contrary to what the operator has selected.

This risk is addressed in a number of ways:

- The embedded programming of the device includes an initialization checksum as well as a watchdog routine to monitor software activities. If either mechanism detects an anomaly, a fault condition is generated which halts ultrasound emissions and prevents further use of the device until the device is powered down.
- The device is programmed to allow selection of ultrasound emissions at only four levels, which are assigned a simple numerical identifier (i.e. "1, 2, 3, or 4"). The device design ensures emissions at the highest level are consistent with the maximum energy output as indicated in the device labeling. Internal verification tests have demonstrated that the ultrasound emissions are ±15% of the labeled value. It is acknowledged that study will employ the device at the highest emission intensity (Level 4), but the application time shall be for 30 minutes which is less than the device maximum emission time of 40 minutes.
- The device design provides for a number of ways to prevent continued emissions to the subject in the event of a software error. These include removing the handpiece from the subject, enabling an emergency stop button located on the device, pressing the screen to Stop the emissions, turning off the main power switch on the unit, or disconnecting the power cord from the unit or from the wall outlet.

The combination of these efforts reduce the potential risk to the subject to a low level. Should the risk occur, the device fault mechanism and the variety of methods to stop further emissions to the subject provide for a lower severity of risk to the subject.

8.3.3. OPERATOR ERROR

A risk exists that the subject may experience excessive treatment, owing to the operator being unfamiliar with the device or selecting inappropriate settings.

This risk is mitigated in that the user interface has been designed to be extremely simple. The device provides only two parameters that the operator needs to select from: Emission intensity and treatment time. Each of these parameters has only four choices. In the case of Intensity, the operator selects from a Level 1, Level 2, Level 3, or Level 4 with 1 being the lowest level and 4 being the highest. For the Time setting, the operator selects from 10, 20, 30 or 40 minutes of treatment duration. Intensity settings for this

device are substantially lower than the energy levels applied in the published references (see Tonucci), where some mild yet anticipated adverse interactions were noted.

Once the operator has made these selections, a button is pressed to ready the device for emissions. One more button press is needed to activate the ultrasound emissions. When the device is placed in the ready condition or is emitting energy, the device does not allow the operator to change the Intensity and Time settings. Additionally, if the operator forgets to place the device into a standby status following a treatment, the programming automatically places the device into the standby status after 4 minutes of device inactivity.

The combination of these efforts reduce the potential risk to the subject to a very low level. Should the risk occur, the severity of risk to the subject is low since the maximum possible output of this device is substantially lower than levels reported in the published literature.

8.3.4. ELECTROMAGNETIC INTERFERENCE

A risk exists that the operator or the subject may experience adverse health conditions, owing that the device is an electrically active device with circuitry and obtains power from a wall outlet. This is of particular concern where the device may emit electromagnetic energy or fields that may disrupt other medical equipment in the vicinity, or may disrupt implanted active devices within the operator or subject.

This risk is partially mitigated in that the device has been designed to, and has been certified compliant to, the recognized consensus standard of IEC 60601-1-2, 3rd Edition. Testing and certification was performed by an independent third party, DNB Engineering. In meeting the requirements of this standard, which is intended to provide protection to the subject and operator against a variety of hazards resulting from radiated and transmitted emissions, the operator and subject are afforded acceptable protection against this risk.

Notwithstanding this level of mitigation, the risk still exists to individuals who have implanted active devices. To further mitigate the risk, exclusion is provided in the study for such individuals and cautions are indicated in the device's operator's manual about this risk. Combined, the possibility for this risk occurring is low, and should the risk happen the possible severity is low except for individuals with implanted active devices, in which case the risk remains at a moderate level.

No reports of electromagnetic interference were documented during the study.

8.3.5. APPLICATION RISKS AND BENEFITS

The risks associated with the application of this device are separated into two topics: Safety-related risks, and Efficacy-related risks. These are addressed in turn.

8.3.5.1. Surface Risks

A risk exists that the application of the indicated frequency and intensity of ultrasound for the indicated durations may cause contact tissue interactions. These include blistering, swelling, edema, erythema, purpura, aggravation of existing dermal conditions, changes in pigmentation, or weakening and/or compromise of wounds.

Existing publications utilizing ultrasound energy at the same frequency indicate these risks are a real concern and have been observed. To help in mitigate this risk, the present device is operated at a substantially lower intensity level than devices used in the published references. It is reasonable to expect that the lower intensity of this investigational device should reduce the severity of such conditions and results compared to what was reported in the published studies. Treatment data to date indicates that some erythema and purpura may occur, but these are determined to be of minor severity, with all instances resolving within a week after being observed.

Treatment data indicate that operator technique may influence the extent of negative surface tissue response. Of particular concern is the speed at which the handpiece is moved along the skin surface, and the adequate use of massage oil to support conduction. The Instructions for Use should be reviewed and updated to include clearer illustration or description of the application technique that will help mitigate negative surface responses.

An observation was noted in once instance where the subject was indicating some discomfort and the treating clinician observed some redness of the treatment area. The clinician noted that they changed the method of handpiece movement from a back-and-forth search pattern type approach to moving the handpiece in circular, orbital motions and progressively moving the handpiece over the treatment area – along with application of more treatment oil – alleviated the situation. The timing of the complaint is examined. This was the third subject that the particular clinician had treated that day, but no similar complaints among the 5 remaining subjects treated by the clinician that day. This was the second use of the particular device on the particular day, but no similar complaints among the 5 remaining subjects treated using that particular device for the remainder of that day. It should be noted that the study subject that had this issue reported was subject #8, who is discussed previously under the Thermal Injury section.

The other surface tissue risks identified appear to be mitigated with some certainty as there have been no reports of blistering, swelling, or alteration of pigmentation. One subject did note a discoloration of stretch marks in the treatment area.

8.3.5.2. Target Tissue Risks

The intended purpose of this device is to disrupt sub-dermal adipose tissue via a proposed mechanism of ultrasound cavitation within the tissue. The proposed mechanism is that the cavitation causes cell rupture. The ruptured contents are then evacuated by the body's existing lymphatic mechanisms and

the material is metabolized and/or eliminated from the body. The risk is somewhat mitigated in that this device is operating at a lower intensity than what has been employed in other published studies. Since this is the intended function and purpose of the device, the remaining risk to the target tissue is duly recognized.

8.3.5.3. Deep Structure Risks

Potential risks and concerns exist where the ultrasound energy may propagate beyond the target tissue and be absorbed by underlying structures, such as bone or organs. Verification testing shows that the ultrasound energy is focused at a depth of 6mm from the surface of the handpiece, and that most of the energy is contained within a distance up to about 12mm from the surface of the handpiece. The risk is somewhat mitigated in that this device is operating at a lower intensity than what has been employed in other published studies. However, published studies indicate a potential of propagation resulting in subjects reporting pain or discomfort from bony areas beneath the treatment area. The overall risk is still regarded as moderate since it is unknown as to what extent the reduction of intensity in this investigational device will reduce the incidence or severity of pain or discomfort within underlying structures. The frequency at which these risks occur will be a function of the subject's anatomy, in particular the extent of sub-dermal adipose tissue that lies between the device handpiece and the internal body structures. Since this aspect is variable relative to the types of subjects who participate, control of this variable is limited, although the study does provide for exclusion of subjects with a Body Mass Index below 25. This exclusion should prevent participation by subjects who would have a lesser amount of sub-dermal adipose tissue and thus help to mitigate this risk.

Another risk is for subjects with implanted articles, whether or not active. These articles may absorb the ultrasound energy, and either propagate the energy or convert it to heat, ore be compositionally or structurally compromised by the energy. This risk is mitigated in that persons with implants in or near the treatment area are excluded from the study. Additionally, persons with implants in or near the treatment area are contraindicated in the device labeling.

8.3.5.4. Systemic Risks

Risks exist relative to the impact on systemic health. These are noted in the published literature as potential changes to blood glucose levels as well as concerns over susceptibility of individuals who are already immuno-compromised. Published studies report increases in blood glucose and lipid levels, which would support the proposed mechanism of action. For individuals who present or at risk of insulin resistance, use of this device presents an elevated risk to these individuals. This risk is discussed in the informed consent form and in the device labeling. Study data supports the possibility of increased lipids in the urine. One subject in this study reported an appearance of “fatty urine” after the first treatment. This subject did not note the same condition after subsequent visits and no other reports of this issue were received.

Immuno-compromised individuals, such as those who are currently ill, undergoing chemotherapy, or have a condition that presents a weakened immune response may be at greater risk for further compromise as the proposed mechanism of clearance would divert immune resources towards clearing the ruptured adipose tissue, resources not available to ward off infection or support resistance to other existing or potential stressors. This risk is mitigated in that persons with compromised immune responses are excluded from the study and are contraindicated in the device labeling.

Since the frequency of ultrasound employed for this device is centered around 37kHz, this frequency is closer to the range of human hearing, as compared to other devices on the market. Treatment data indicates that some subjects may hear the transducer or experience a ringing in the ears. For some subjects, this sensation may be substantial enough to cause discomfort in the ear and possible vertigo by disrupting the subject's middle-ear equilibrium. The treatment data indicate that the ringing is reported to stop when the treatment concluded. With the one instance of vertigo reported, subjects should be advised to wait a few minutes after treatment before getting up and walking. This should be ordinarily inherent as the subject should still be lying on the treatment bed having the treatment oil cleaned off. The device Instructions For Use should be updated to reflect this precaution regarding potential vertigo. Devices used in the study were re-evaluated and found to still be operating within design parameters, with ultrasound output measured at 37±1 kHz among the devices.

Although the limit of human hearing of sound conducted through the air is generally regarded as 20 – 20kHz, research from as early as 1948 addresses the phenomenon of bone-conducted ultrasound, whereby ultrasound energies are conducted through the skeletal structure. There is possibility that the emitted ultrasound from this device could be conducted through the soft tissue to underlying bone, which is then conducted up to the cochlear structure in the ear. Example references of such studies are listed at the end of this report. These studies have established that conducted ultrasound can be perceived in the ear as 'sound' up to ranges of 100kHz -120kHz, and that subjects perceive the conducted ultrasound as equivalent to higher frequency open-air sounds in the 8-14kHz range. However, these studies were conducted by placement of transducers on the skull or head region and may not be translatable to explaining the observed phenomenon. The exact mechanism of action has not been definitively determined by this research.

Follow-up assessment was performed for those subjects who reported the audible buzzing sensation, by having these subjects undergo an audiology test performed by an independent third-party licensed audiologist. With the exception of one subject (#3), these tests demonstrated that the subjects do not have any substantial hearing loss, or any correlation in reduced hearing capacity that would suggest that this device induces damage to hearing. In the case of Subject #3, the audiology report showed some significant hearing loss int eh upper frequencies. However, this subject authorized release of an audiology test performed prior to participation in the study that shows identical hearing responses as those obtained in the post-treatment assessment. This evidence further supports that use of this device is not likely to lead to hearing damage. Since a significant number of subjects experienced this condition, the Instructions for Use for the device should be reviewed and amended to address this possibility.

8.3.5.5. Fetal/Nursing Risks

Risks exist relative to the impact of this frequency and intensity of ultrasound on developing embryos and fetuses. This ultrasound energy may prevent, disrupt, or alter the rate of development in the unborn in ways that cannot be understood or anticipated. Such impacts could result in premature mortality of the fetus, of the born child, or have permanent impacts on the entire life of the individual. Additionally, changes in blood glucose levels or levels of other blood or lymphatic constituents may be captured in breast milk that would then be passed along to the nursing child. Alterations in these levels in breast milk could have impact to the health of the child in unknown ways.

This risk is mitigated in that women who were nursing, or who were or may have become pregnant during the course of this study were excluded from the study. Additionally, women who are nursing or are or may become pregnant are contraindicated in the device labeling.

8.3.5.6. Population Risks

Risks exist in that certain segments of the subject population may have risk ratings at higher levels for some of the other risks described herein, relative to other segments of the population. Persons with certain existing or past conditions, women who are nursing or are or may become pregnant, persons with implants, and persons with limited sub-dermal adipose tissue are already addressed within this document. At this time, there are not any foreseen differences in risk with regards to subject gender. A risk does exist relative to youth in that young persons may desire pursuing this treatment without having the cognitive ability to fully understand the risks involved or to fully consider other methods available for reducing waist circumference. Additionally, youth may be more susceptible to misconceptions about body image and to peer pressure, which may affect a full and rational decision regarding this treatment. This risk is mitigated in that individuals under the age of 18 are excluded from the study. Additionally, individuals under the age of 18 are contraindicated in the device labeling.

There is concern that differences in skin tone, with a basis in differences in ethnicity, may produce differing results. At this time, there are not any anticipated factors or reasons to suggest that such may be the case. It is not expected that different skin pigmentation will react to or interfere with ultrasound energy transmission differently. The published literature does not report the breakdown of skin tones and/or ethnicity, and there does not seem to be discussion as to whether variations in skin contribute to differences in safety or efficacy of similar devices. A risk of hypo or hyperpigmentation is acknowledged, and the extent or severity of such may be a function of the skin tone. During the course of this study, the majority of study subjects were Caucasian. However, a few individuals of other ethnicities did participate. Among these participants, there were no reports of effects or issues with skin response to the treatment. The overall reduction in waist circumference of these individuals does not appear as outliers in the measurement data, ranging from 1.5 to 2.75 inches of circumference reduction.

In the absence of definitive and published studies that this sponsor is aware of, there is not sufficient evidence to exclude any particular ethnicities or skin tones from use of the device.

8.3.6. EFFICACY RISKS

A risk exists in that the device and treatment regimen as proposed in this study will not render results to support a conclusion that the device effectively reduces a person's waist circumference. This risk has as its basis that the combination of lower frequency and lower intensity are not well understood as to the effect on adipose tissue. There is possibility that this device and treatment have no effect on adipose tissue, or have an effect that does not meet a subject's expectations for an acceptable reduction in waist circumference.

The risk of a lack of efficacy is negligible, in that subjects with a large, or perceived-to-be-large, waist circumference are not immediately at risk for death or serious injury because of the large waist circumference. A large waist circumference, in and of itself, is not regarded as a disease or condition, although it often serves as a symptom of a disease or condition. In the event that the device and treatment proved ineffective, participation in this study did not preclude the subject from further treatment through a number of other available methods, among those being exercise, diet management, and a number of clinical procedures currently employed. As discussed in the Data Analysis section, the results of this study yielded a 2 inch reduction in waist circumference, on average, and the device proved to be effective in accomplishing its intended purpose.

Another risk existed in that the results of the study may not be translatable to the general population. This would have at its root a low number of participants in the study, such that results seen in those who do participate may not be representative of the results the overall population may experience. This risk was mitigated to some extent by enrolling a quantity of participants to where a total of 42 completed the study. This study did provide for a reasonable representation of age groups within the inclusion criteria. Considering that this is still a fairly small number of subjects, and the ethnicity of the subjects was vastly Caucasian, there is still possible risk of differing results relative to the ethnicity of the subject.

Single-way ANOVA analysis of the results between men and women does indicate a statistical significance in the way men and women respond to the treatment, with indication that men do not obtain as much waist circumference reduction as women. The 8 men who completed the study averaged 1.875 inches of reduction while women averaged 2.066 inches. This result is not compounded by the relative obesity of the subjects, considering that the men had an average BMI of 32.45 going into the study and the women had an average BMI of 29.36. This may indicate a difference in treatment response between men and women.

8.4. BENEFITS

The benefits offered by the device and proposed treatment method are that it presents a method of achieving a rapid and noticeable reduction in waist circumference that is not surgically invasive. Some methods available to achieving the same results include diet and exercise. These methods can take weeks and longer to achieve noticeable results, and often the subject loses motivation to maintain the regimen

even when noticeable results are achieved. Other methods tend be surgically invasive, and although some methods may achieve rapid and noticeable results, the risks of infections or complications from surgically invasive procedures could have serious and possibly permanent impacts on the subject or prevent the subject from pursuing such procedures, all of this notwithstanding significant costs usually associated with surgical procedures and over all treatment. Other devices are known that utilize ultrasound to achieve reduction in waist circumference. These devices operate at higher intensities and/or higher ultrasound frequencies. In this study, the device has demonstrated effectiveness by reducing a subject's waist circumference by an average of 2.0 inches. The subject surveys support that this result is noticeable by the subject.

9. OTHER STUDY CHANGES

No other changes occurred relative to the study that are not already documented in this report

10. FUTURE PLANS

At present, the device has 510(k) clearance under K171052 for a radio frequency feature and use. The sponsor utilized the results of this study to support a 510(k) application to add to the device the indication declared at the start of this report, namely: Application of ultrasound for non-invasive waist circumference reduction. The sponsor submitted this application with receipt acknowledged by the U.S. FDA on June 3, 2020.

11. REFERENCES

1. Atluri, P. , et al. "Clinical effects of noninvasive ultrasound therapy for circumferential reduction." *Am J Cosmetic Surg,* **Vol. 29 No. 2 (Jun 2012),** pp. 114-120.

2. Coleman, W.P. III, Coleman, W.P. IV, Weiss, R.A., Kenkel, J.M., Ad-El, D.D., and Amir, R. "A Multicenter Controlled Study to Evaluate Multiple Treatments with Nonthermal Focused Ultrasound for Noninvasive Fat Reduction." *Dermatol Surg,* **Vol. 41 No. 1 (Jan 2017),** pp. 50-57.

3. Corso, J. F. "Bone-conduction thresholds for sonic and ultrasonic frequencies*." The Journal of the Acoustical Society of America*, **35(11) (1963),** 1738-1743.

4. Deatherage, B.H., L.A. Jeffress, H.C. Blodgett. "A note on the audiblility of intense ultrasonic sound." *Journal of the Acoustical Society of America*, **26 (1954),** p. 582.

5. Dieroff, H.G., H. Ertel. "Some thoughts on the perception of ultrasound by man." *Advances in Otorhinolaryngology***, 209 (1975**), pp. 277-290.

6. Dunlap, S.A., M.L. Lenhardt, A.M. Clarke. "Human skull vibratory patterns in audiometric and supersonic ranges." *Otolaryngol Head Neck Surg,* **99 (1988),** pp. 389-391.

7. ELdesoky, M.T.M., Abutaleb, E.E.M., and Mousa, G. S. M. "Ultrasound cavitation versus cryolipolysis for non-invasive body contouring." *Australasian J Dermat,* **Vol. 57, No. 4 (Nov 2016),** pp. 288-293.

8. Gavreau, V. "Audibillite de sons de frequence elevee." *Comptes Rendus,* **226 (1948),** pp. 2053-2054.

9. Haeff, A.V., C. Knox. "Perception of ultrasound." *Science*, **139 (1963),** pp. 590-592.

10. Hausswirth, C., Marguet, L.A., Nesi, X., and Slattery, K. "Two weeks of High Intensity Interval Training in Combination with a Non-Thermal Diffuse Ultrasound Device Improves Lipid Profile and Reduces Body Fat Percentage in Overweight Women." *Front Physiol,* **Vol. 10, No. 3 (Oct 2019),** pp. 1307.

11. Kirikae, I. "An experimental study on the fundamental mechanism of bone conduction." *Acta Otolaryngol Suppl,* **145 (1959),** pp. 1-111.

12. Lenhardt, M.L., R. Skellett, P. Wang, A.M. Clarke. "Human ultrasonic speech perception." *Science*, **253 (1991),** pp. 82-85.

13. Lenhardt, M.L. "Ultrasonic hearing in humans: applications for tinnitus treatment." *Int. Tinnitus J*, **9 (2003)**, pp. 69-75.

14. Mohammadzadeh, M., et al. "Reduction in measures of adiposity using a combination of radio frequency and ultrasound cavitation methods." *Eur J Integrative Med,* **Vol. 8, No. 3 (Jun 2016),** pp. 313-316.

15. Okamoto, Y., S. Nakagawa, K. Fujimoto, M. Tonoike. "Intelligibility of bone-conducted ultrasonic speech." *Hearing Research,* **208 (2005),** pp. 107-113.

16. Pugliese, D., Maiorano, E., and Pascone, M. "Histopathological features of tissue alterations induced by low frequency ultrasound with cavitation effects on human adipose tissue." *Intl J Immunopath and Pharmac,* **Vol. 26 No. 2 (Apr 2013),** pp. 541-547.

17. Pumphrey, R.J. "Upper limit of frequency for human hearing." *Nature,* **166 (1950),** p. 571.

18. Staab, W., T. Polashek, J. Nunley, et al. "Audible ultrasound for profound losses." *Hear Rev,* **2 (1998),** pp. 28 - 36.

19. Tonndorf, I. "A new concept of bone conduction." *Arch Otolaryngol*, **87 (1968),** pp. 49- 54.

20. Tonucci, L. B., Mourão, D. M., Ribeiro, A. Q., and Bressan, J. " Noninvasive body contouring: Biological and aesthetic effects of low-frequency, low-intensity ultrasound device." *Aesth Plast Surg,* **Vol. 38, No. 5 (Oct 2014),** pp. 959-967.

21. Yamashita, A., T. Nishimura, Y. Nagatani, T. Okayasu, T. Koizumi, T. Sakaguchi, H. Hosoi. "Comparison between bone-conducted ultrasound and audible sound in speech recognition." *Acta Otolaryngologica: Supplementum*, **562 (2009),** pp. 34-39.

Clinical Study Report:

Descriptive Study of Efficacy of Low-Frequency, High-Intensity Ultrasound for Reduction in Subdermal Adipose Layers

Study Type:	Clinical trial with Medical Device (MD)
Study Categorization:	Clinical investigations or other studies of medical devices, risk category A
Study Registration:	The study is intended to be registered on the (automatically through this application) and register (ClinicalTrials.gov) 42 CFR 11.10
Study Identifier:	Identification Numbers: NCT# 04206384
Sponsor, Sponsor-Investigator or Principal Investigator:	Sponsor: CAO Group, Inc. Rob Larsen-Regulatory Affairs Manager CAO Group, Inc. 4628 West Skyhawk Drive West Jordan, UT 84084 Ph: 801-256-9282 Principal Investigator: Dr. M. Kirk Moore, MD
Third-Party- Monitor the study Trial Statistician-Manage the data collection & data entry	Observer/ Trial Statistician- Core Compliance, LLC. Terence Rarick-Director of Operations/Consultant 63 E 11400 S, #249 Sandy, Utah 84070
Investigational Product:	Ultimate Contour Body Sculpting Device
Protocol Version and Date:	Protocol ID: 005-00036-8, 15 October 2019

Signature Page(s)

The monitor of this study (Trial Statistician) have approved the protocol version 01 (dated 04.16.2020) and confirm hereby to conduct the study according to the protocol. (21 CFR 812.3) norm if applicable and the 42 CFR 11.10 legally applicable requirements.

Site Location
Cosmetic Surgery Happiness, Inc
Dr Kirk Moore
7525 Union Park Ave
Midvale, Utah 84047

Date: January 6th 2020

Trial Statistician: Core Compliance, LLC. Terence Rarick

X Terence Rarick

Monitoring Party
Trial Statistician

Local Principal Investigator at study site:
I have read and understood this trial protocol and the trial study protocol,

Site Cosmetic Surgery Happiness, Inc	Cosmetic Surgery Happiness, Inc Dr Kirk Moore 7525 Union Park Ave Midvale, Utah 84047
Principal investigator	Dr. M. Kirk Moore

Signature:

5.4.2020

Date:

Table of Contents

STATEMENT OF COMPLIANCE

(1) All personnel involved in the conduct of this study have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.]

1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:

Descriptive Study of Efficacy of Low-Frequency, High-Intensity Ultrasound for Reduction in Subdermal Adipose Layers

Study Description:

A randomized, blinded comparison of waist circumference reduction of an active test group vs. a placebo control in adults.

Objectives:

The purpose of this study is to evaluate principally the effectiveness, and secondarily the safety, of external application of lower frequency ultrasound to the waist/abdominal region of adults to achieve a reduction of adipose cells/tissues in the subcutaneous region. The application of higher frequency (200kHz to 3MHz) ultrasound for this purpose has previously been demonstrated and such devices have received clearance for treatment in the United States. The question remains whether application of ultrasound at a lower frequency (35kHz to 45kHz) can achieve comparable results without introducing any new or elevated risks to the patient. This study seeks to answer this question

Endpoints:

The study has a fixed endpoint of three (3) treatment sessions and three follow-up visits per patient, to the extent that a sufficient quantity of patients have completed the study. Given that a gap of 6-8 days will exist between treatments, the scheduling of patients will be staggered as necessary to best utilize investigator and equipment resources, with the overall course of the study treatments is not expected to exceed 6 weeks of total study time.

The follow-up visits are mandated to occur at intervals of one, four, and twelve (12) weeks from the date of final treatment. Once all patient treatments are completed, analysis of the data shall be performed by the sponsor (and reviewed by an independent statistical resource) to determine the extent of success in achieving the primary and secondary objectives.

Study Population:

The population for this study shall consist of adults age 18 and over. Recruiting

	efforts shall focus on obtaining a reasonably even number of male and female patients and to include patients exhibiting a body mass index (BMI) of 25 or higher. No concern or focus will be given regarding the ethnicity of the patients, although a wide range of ethnicities would be beneficial. Patients will be evaluated relative to the inclusion and exclusion criteria indicated below. A recruitment target of a total of 50 patients is established. During recruitment, each candidate will be assigned a test subject number for identification purposes
Phase:	Development Phase: Performance Validation
Description of Sites/Facilities Enrolling Participants:	All testing conducted under this investigation will be performed at a single site, an existing dermatology practice located inMidvale, Utah. This setting is representative of the medical office environment under which the device would be used in the market Consistent with this setting, patients will be scheduled for treatment and upon arrival have the procedure performed, along with appropriate pre-treatment and post-treatment assessment and instructions, and then allowed to depart. The principal investigator for this study will be Dr. Kirk Moore. Dr. Moore has no contractual or financial relationship with the sponsor or with the specification developer. Additional research staff, in the persons of medical staff and assistants already present at the study site, shall assist with the performance of this study. **Participants-** Age equal to or above 18. Body Mass Index ≥ 25.
Description of Study Intervention:	Indication Studied: Application of ultrasound for non-invasive waist circumference reduction.

1.2 SCHEMA

Flow diagram

Prior to Enrollment	During selection, the patient's gender, age, height, weight, and ethnicity will be documented. The patient shall be provided with information regarding the treatment and the risks and benefits associated with the treatment and provided with and asked to sign the informed consent. consent is then provided to the patient
Visit 1 Time Point	Individual Treatment Session (approximately 70 minutes) The patient is scheduled to arrive at the study site to undergo a treatment. • The date of the treatment and the time of arrival will be documented in the treatment session record. • During the first treatment only: The patient is given the Q-Pre-Survey to fill out. • The assigned pre-treatment investigator measures the waist circumference of the patientand documents this in the Pre-Treatment record, with these measurements being made by the blinded assessment clinician as described in the Measurement Tools and Methods • Prior to Treatments 2 and 3, the patient will be asked for the study diary, and the pre-treatment investigator shall review the diary and the patient's previous post-treatment Anticipated Effects and Adverse Event forms and discusses with the patient the items that are recorded about any abnormal body functions or observations that may be relevant to the treatment. If any are indicated, these will be documented in the patient record. Additional record shall be made by the investigator as to whether past events and observations have been resolved or are still unresolved. • The patient is moved to the treatment area.
Visit 2 Time Point	Application of the Treatment (approximately 45 minutes): • The treatment clinician prepares the patient for treatment by displacing clothing from the treatment area, which is the abdominal area from the bottom of the sternum to the iliaccrest. • The patient lies down on their back on the treatment table. • The treatment clinician turns on the Ultimate Contour Mini device and sets it to theindicated parameters for this study: Time Setting of 30 minutes; Intensity Setting of 4. • The treatment oil/fluid, a massage oil with a cottonseed or grapeseed oil base, is applied to the patient's skin over the area intended for exposure. • The treatment clinician applies the treatment handpiece to the patient's skin in the intended treatment area. • The treatment clinician presses the Activation button on Ultimate Contour screen to begin energy emissions from the handpiece. • The treatment clinician begins moving the handpiece along the skin with slight pressure to the handpiece to maintain contact with the skin, moving in circular, orbital motions approximately twice the diameter of the handpiece diameter, and progressively advancing in a the linear direction from one edge of the treatment zone to the other in an overall back-and-forth approach. • The treatment clinician continues application of the handpiece until either the proscribed 30 minutes has expired, or the patient indicates to halt the treatment due to discomfort. • Once energy emissions cease, the handpiece is removed from the skin, and the treatment oil is cleaned off from the skin. • The patient replaces clothing and is moved back to the assessment room.

Visit 3 Time Point	Post-Treatment Assessment (approximately 15 minutes): • The Post-Treatment assessing investigator observes the treated area for any redness, edema, swelling, or other indications specifically called for in the Anticipated Effects treatment record. The patient is asked for any unexpected sensations, for example sensations of high heat or of a "pins and needles" tingling effect in the tissue. These anticipated effects are documented in the treatment session record. Un-anticipated effects are recorded in the Adverse Event form. • The patient is presented with the Stanford Pain Scale chart and asked to rate their overall pain and discomfort during the treatment. This is documented in the treatment session record. • A waist circumference measurement of the abdominal region is made using the constant- tension tape measure. This measurement is recorded in the Post-Treatment Measurement record. • The patient is provided with a study diary form, and instructed to document in the diary any unusual sensations, events, or bodily responses and to bring the form with them for the next visit. • At the final treatment session only, the patient is provided with the Q-Post Survey to fill out. • The patient is then scheduled for the next study session, and then excused.
Follow Up	**Final Assessments** FOLLOW-UP (approximately 15 minutes): • The patient is scheduled for and arrives at the study site at the appropriate time points 1, 4, or 12 weeks after the final treatment. • The date of the visit and the time of arrival will be documented Post-Assessment Measurement and Anticipated Effects forms. • For the 1-week and 4-week visits, the patient fills out the WaistQ-Post Survey. For the 12-week follow-up, the WaistQ-12 Survey is filled out. The patient will have their waist circumference measured and documented by an investigator assigned to the post-treatment measurement and assessment activity, as described in the Measurement Tools and Methods section of this protocol. The patient will be asked for the study diary, and the investigator shall review the diary and discuss with the patient the items that are recorded about any abnormal body functions or observations that may be relevant to the treatment. If any are indicated, these will be documented in the patient record. The investigator will also review observations and adverse events documented in previous sessions and discuss these with the patient. Additional record shall be made by the investigator as to whether past events and observations have been resolved or are still unresolved. • For the 4-week or 12-week follow-up visits, the patient is provided with a study diary form, and instructed to document in the diary any unusual sensations, events, or bodily responses and to bring the form with them for the next visit. The patient is then scheduled for the 4-week or 12- week follow-up visits as appropriate. • At the 12-week follow-up, additional review is made of the patient's Medical History and Medication forms and any new content for these forms is noted therein and discussed with the patient. If the 12-week follow-up visit is concluded and Adverse Event forms indicate any unresolved adverse results for the patient, additional follow-up is scheduled as appropriate until all adverse results are concluded.

1.3 SCHEDULE OF ACTIVITIES (SOA)

Procedures	Screening Day -7 to -1	Enrollment/Baseline Visit 1, Day 1	Study Visit 2 Day 14 +/-1 day	Study Visit 3 Day 28 +/- 1 day	Final Study Visit 4 Day 44 +/-1 day
Informed consent					
Pre-Waist Survey Form					
Adverse Event Log					
Safety Monitoring Log					

2 INTRODUCTION

2.1 STUDY RATIONALE

The purpose of this study is to evaluate principally the effectiveness, and secondarily the safety, of external application of lower frequency ultrasound to the waist/abdominal region of adults to achieve a reduction of adipose cells/tissues in the subcutaneous region. The application of higher frequency (200kHz to 3MHz) ultrasound for this purpose has previously been demonstrated and such devices have received clearance for treatment in the United States. The question remains whether application of ultrasound at a lower frequency (35kHz to 45kHz) can achieve comparable results without introducing any new or elevated risks to the patient. This study seeks to answer this question

2.2 BACKGROUND

All testing conducted under this investigation will be performed at a single site, an existing dermatology practice located in Lehi, Utah. This setting is representative of the medical office environment under which the device would be used in the market. Consistent with this setting, patients will be scheduled for treatment and upon arrival have the procedure performed, along with appropriate pre-treatment and post-treatment assessment and instructions, and then allowed to depart. The principal investigator for this study will be Dr. Kirk Moore. Dr. Moore has no contractual or financial relationship with the sponsor or with the specification developer. Additional research staff, in the persons of medical staff and assistants already present at the study site, shall assist with the performance of this study.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWNPOTENTIAL RISKS

During selection, the patient's gender, age, height, and ethnicity will be documented. The patient shall be provided with information regarding the treatment and the risks and benefits associated with the treatment and provided with and asked to sign the informed consent. A copy of the informed consent is then provided to the patient.

Details of the treatment protocol

STUDY STAFF

- Principal Investigator - (Dr. Kirk Moore) Licensed medical doctor. Discuss patient adverse interactions, and directly observe patient adverse interactions following treatment; Supervise overall execution of the study protocol, including study documentation;
- Treatment Clinician - Directly trained by sponsor in the use and application of the device. Licensed medical doctor. Responsible for application of the device to the patient. This staffshall not be permitted to serve as Assessment staff.
- Assessment Clinician - Directly trained by sponsor in the use and application of the measurement tool to be used for this study. Licensed medical doctor. Responsible formeasuring the patient's waist circumference and documenting such in the patient record. This staff shall not be permitted to serve as Treatment staff.
- Clerical Staff - Directly trained by the sponsor on the study protocol and the use and management of forms associated with this study. Minimum of a high school diploma. Responsible for receiving patients at arrival and scheduling next visits, and for providing and collecting study records from each of the clinicians. May also assist with organization ofstudy records.

2.3.2 KNOWN POTENTIAL BENEFITS

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		

The primary objective of this study is to determine if the application of lower frequency (35kHz to 45kHz) ultrasound energy to the waist/abdominal region of the human body is capable of effecting a reduction in the amount of subcutaneous adipose cells and/or tissue to an amount of at least 1 inch and to a statistically significant level. Determination of the reduction in this adipose tissue is achieved via measurement of the body circumference that includes the abdominal area that was treated, and comparing measurements prior to the initial treatment with measurements after the entire treatment regime is concluded. Per the proposed clinical mechanism of action, the disrupted tissue is cleared by the lymphatic system which facilitates excretion or elimination of the disrupted tissue contents. Having been eliminated, the patient should exhibit a reduction in waist circumference. For this objective to be successfully achieved, a reduction in waist circumference of at least one inch must be demonstrated at a point of 12 weeks after the last of three treatment sessions has been applied..	The primary endpoint is *the* reduction in the amount of subcutaneous adipose cells and/or tissue to an amount of at least 1 inch and to a statistically significant level.	
Secondary		
The secondary objective of this study is to assess the safety of this device. Assessment is made by having the patient rate the treatment experience and report any symptoms, side effects, or associated abnormal conditions. Additional assessment is made by the investigators to qualitatively confirm if visually detectable abnormal conditions (example: edema) are presented following the treatment. Success is determined by whether the patients indicate that any discomfort experienced during the treatment, and following the treatment that are directly attributable to the treatment, along with an absence of side-effects or abnormal conditions directly attributable to the treatment, create a risk/benefit condition where the benefit of treatment is regarded to outweigh the risks and temporary discomfort. Quantitatively, the benefit is regarded to outweigh the risk when: 1) No patients report a pain rating of 4 or higher on the Stanford Pain Scale, 2) No	The secondary endpoint(s)*are* treatment experience and report any symptoms, side effects, or associated abnormal conditions	*Endpoints have been validated in*

patients exhibit any side effects or abnormal conditions at the conclusion of the final treatment, and 3) No patient who was included in the Test group reports that the treatment regimen was unsuccessful.		
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4 STUDY DESIGN

4.1 OVERALL DESIGN

4.1.1 Device Description and Settings

The Ultimate Contour device is a portable device that consists of a single central unit which houses all of the device electronics. The device features a fold up touchscreen that shows the device's operating condition and allows the operator to select the device's functional parameters. A single external, detachable power cord connects the device to an ordinary electrical outlet. The device contains an internal power supply that is auto switching to the input voltage and input frequency (100-240VAC, 50- 60Hz). The device include a single, permanently attached output cable. The operator attaches the ultrasound treatment hand piece to the end of the output cable. The device is designed to allow application of RF energy via separate specifically designed hand pieces, but the application of RF energy is not within the scope of this study. The device is capable of sensing if a hand piece is attached and to identify which hand piece is attached, in order to prevent any inappropriate power from reaching the hand piece or prevent the device from being configured in an inappropriate manner.

After attachment of the hand piece, the operator selects which treatment type (US or RF) is to be done. The device then presents only two parameters for operator to adjust: the duration of the treatment, and the relative intensity of the applied energy. The duration can be selected from 10, 20, 30, or 40 minutes duration. The intensity is selected from a comparative rating Level of "1, 2, 3, or 4", with Level 4 being the maximum energy level the device can output and Levels 1 through 3 being at staggered levels less than the maximum. Once the settings are selected, the operator places the device into a Ready state. At this point,

the hand piece is placed in contact with the skin and the operator presses a button on the screen to activate the hand piece. The unit applies energy to the hand piece at the selected intensity Level and the unit begins to count down from the selected time duration. Generally, the operator allows the device to operate until the selected time elapses, at which point the device automatically returns to the Ready state and beeps to inform the operator the cycle is complete. The operator may also stop the treatment at any time, either by pressing the stop button on the screen or activating a separate emergency stop button located on the device. During treatment, the device monitors the temperature of the hand piece (and by contact, the temperature of the skin) via temperature sensors located in the hand piece and in direct contact with external metal surfaces of the hand piece that contact the skin. If excessive temperature is measured, the device halts operation of the hand piece. For the purposes of this study, the device will be set at a treatment time of 30 minutes and an intensity level of 4.

Adjunctive activities associated with the treatment will also be performed. These included conversation with the patient about what to expect during the individual treatments and overall outcomes of the entire regimen, as well as instructions to the patient at the conclusion of the study regarding care and proper lifestyle habits. All of these adjunctive activities are described in the operator's manual for the device, and the clinicians will be instructed on the presence of these consultative activities in the manual and the execution of these activities for the purposes of this study.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

This study is designed as a single-arm study. All eligible candidates shall be enrolled to undergo treatment by the device according to the procedure and protocol that are discussed herein. This approach is consistent with other studies that have been done with similar devices where the primary objective of waist circumference reduction was also intended.

5 STUDY POPULATION

The population for this study shall consist of adults age 18 and over. Recruiting efforts shall focus on obtaining a reasonably even number of male and female patients and to include patients exhibiting a body mass index (BMI) of 25 or higher. No concern or focus will be given regarding the ethnicity of the patients, although a wide range of ethnicities would be beneficial. Patients will be evaluated relative to the inclusion and exclusion criteria indicated below. A recruitment target of a total of 50 patients is established. During recruitment, each candidate will be assigned a test subject number for identification purposes.

5.1 INCLUSION CRITERIA

5.1.1 Inclusion/Exclusion with discussion of rationale; address both sexes and race allowance vs. availability

Inclusion in the study consisted of the following criteria:

- Age equal to or above 18.
- Body Mass Index ≥ 25.

5.2 EXCLUSION CRITERIA

Exclusion from the study consisted of the following criteria:

- Age equal to or below 17.
- Body Mass Index < 25.
- Open sores, wounds, or otherwise compromised skin in the treatment area
- History of keloid formation, hypertrophic scarring, or abnormal/delayed wound healing.
- Known or suspected pregnancy, or active nursing.
- General systemic conditions of arteriosclerosis or heart disease, anemia, aortic aneurysm, or hypertension.
- Liver conditions such as hyperlipidemia, hepatitis, liver disease, or abnormal liver function
- Diabetes or blood-glucose sensitivity
- Any prior invasive cosmetic surgery to the waist or abdominal area, such as liposuction.
- Hernias or diastasis recti within the treatment area.
- Concurrent, or within the last 6 months, participation in any clinical trial for another device or drug.
- Existing bacterial or viral infections (influenza, rhinovirus, hepatitis, pneumonia, tuberculosis, and the like)
- Presence of acne vulgaris, herpes zoster, psoriasis vulgaris, or similar skin conditions in the treatment area.
- Any type of cosmetic treatment to the target area within the last 6 months.
- Implanted active medical device anywhere in the subject, or metallic or polymeric implants in the vicinity of the treatment area.
- Currently undergoing, or recently underwent, chemotherapy or radiation treatment.
- Per the investigator's discretion, any physical or mental condition which may compromise the patient's safety or welfare.
- Failure to complete the study as outlined.

The primary rationale for the exclusion criteria that were identified is to ensure that any existing health conditions that may be adversely impacted by the use of this device are not aggravated or made worse. Additionally, exclusion of women who are pregnant or nursing is viewed as an appropriate precaution to prevent any possible complications to the fetus or nursing child that cannot presently be anticipated. For women who enroll for the study, a urine-based pregnancy test (Pregnancy hCG Test Strips, by Pregmate) shall be administered to determine if the subject is pregnant.

A secondary rationale for these exclusions is that the conditions and situations listed in the exclusions may contribute to a change in weight, skin condition, or the patient's response to the ultrasound energy which may obscure the resultant data and make it more difficult to objectively assess if the study objectives have been met. The exclusion of persons age 17 and under primarily is a matter of responsible consent and the prospective patient being capable of making an informed and rationale decision regarding the possible risks and benefits of the treatment, as well as being in a legally permissible status to elect a medical procedure on their own behalf.

The study will be conducted at a single existing medical clinic: Just the Right Curves, 7525 Union Park Ave., Midvale, UT 84047, with recruiting efforts being made in the immediate vicinity of this location.

During selection, the patient's gender, age, height, and ethnicity will be documented. The patient shall be provided with information regarding the treatment and the risks and benefits associated with the treatment, and provided with and asked to sign the informed consent. A copy of the informed consent is then provided

to the patient.

5.3 SCREEN FAILURES

5.4 STRATEGIES FOR RECRUITMENT AND RETENTION

RECRUITMENT/SCREENING (total time of activity, 2-3 weeks):

- Advertisement shall be made in social media channels regarding the study. This method is thought to be appropriate to bring the study to the attention to prospective participants located in the vicinity close to the study site.
- An appointment is made with a prospective patient, where the candidate is evaluated according to the inclusion and exclusion criteria, and medical history and medications. The purpose and protocol of this study are discussed, any candidate questions or concerns are addressed, and the consent form is presented. The candidate may sign the consent form at this time, or arrange for time to further review their participation. Women participating in the study who are of child- bearing age or capable of becoming pregnant shall take a pregnancy test. Patient Information, Medical History, and Medication forms are presented for the patient to populate.
- Recruitment continues until 50 included candidates are identified and consent obtained on those candidates.
- A candidate is accepted to participate after the following are confirmed by the principal investigator:
    - The Informed Consent Form is signed
    - The Patient Information Form is completed and the patient is not excluded due to any of the indicated criteria
    - The Medical History and Medication forms are populated and reviewed to ensure the candidate does not meet any of the exclusion criteria or other circumstances that may put the candidate at elevated risk by participating.

6 STUDY INTERVENTION

6.1 ADMINISTRATION OF TREATMENT

TREATMENT (total time of activity, 14-18 weeks - 4-6 weeks for the 1st, 2nd, and 3rd treatment applications, and 12-14 weeks following the 3rd treatment for follow-up visit):

Individual Treatment Session (approximately 70 minutes)
Prior to the Treatment (about 10 minutes):

- The patient is scheduled to arrive at the study site to undergo a treatment.
- The date of the treatment and the time of arrival will be documented in the treatment session record.
- During the first treatment only: The patient is given the Q-Pre Survey to fill out.
- The assigned pre-treatment investigator measures the waist circumference of the patient and

documents this in the Pre-Treatment record, with these measurements being made by the blinded assessment clinician as described in the Measurement Tools and Methods section of this protocol.

- Prior to Treatments 2 and 3, the patient will be asked for the study diary, and the pre-treatment investigator shall review the diary and the patient's previous post-treatment Anticipated Effects and Adverse Event forms and discusses with the patient the items that are recorded about any abnormal body functions or observations that may be relevant to the treatment. If any are indicated, these will be documented in the patient record. Additional record shall be made by the investigator as to whether past events and observations have been resolved or are still unresolved.
- The patient is moved to the treatment area.

Application of the Treatment (approximately 45 minutes):

- The treatment clinician prepares the patient for treatment by displacing clothing from the treatment area, which is the abdominal area from the bottom of the sternum to the iliac crest.
- The patient lies down on their back on the treatment table.
- The treatment clinician turns on the Ultimate Contour Mini device and sets it to the indicated parameters for this study: Time Setting of 30 minutes; Intensity Setting of 4.

The treatment oil/fluid, a massage oil with a cottonseed or grapeseed oil base, is applied to the patient's skin over the area intended for exposure.

- The treatment clinician applies the treatment handpiece to the patient's skin in the intended treatment area.
- The treatment clinician presses the Activation button on the Ultimate Contour screen to begin energy emissions from the handpiece.
- The treatment clinician begins moving the handpiece along the skin with slight pressure to the handpiece to maintain contact with the skin, moving in circular, orbital motions approximately twice the diameter of the handpiece diameter, and progressively advancing in a linear direction from one edge of the treatment zone to the other in an overall back-and-forth approach.
- The treatment clinician continues application of the handpiece until either the proscribed 30 minutes has expired, or the patient indicates to halt the treatment due to discomfort.
- Once energy emissions cease, the handpiece is removed from the skin, and the treatment oil is cleaned off from the skin.

The patient replaces clothing and is moved back to the assessment room.

6.2 PREPARATION/HANDLING/STORAGE/ACCOUNTABILITY

6.2.2 TRAINING

- The sponsor shall review the education and experience of personnel proposed as study staff.
- The principal investigator and staff shall be trained by the sponsor regarding the proper use of the device and the details of the study protocol.

6.2.3 PRODUCT STORAGE

6.2.4 PREPARATION

CIRCUMEFERENCE

The patient's circumference will be measured via use of a Gulick II (Model: 67020) tape measure with constant-tension feature that is factory-calibrated by the manufacturer. The process of obtaining a measurement proceeds as follows:

1. The area of the body is exposed (in this case lifting up the shirt to expose the abdominal region).
2. The patient is informed to stand straight and to breathe normally, but to focus on steady shallow breaths.
3. The clinician applies the tape measure by locating the top of the hip bone (iliac crest) and positioning the tape just above this bony landmark, just where one finger can fit between the iliac crest and the lowest rib.
4. The clinician ensures that the tape measure is positioned horizontally, parallel to the floor.
5. Measurement is taken at the end of normal expiration.

At a signal from the clinician the patient is to pause at the conclusion of an exhale, at which point the clinician pulls the tape until the constant-tension feature is enabled. The clinician then observes the measurement value and documents this value in the treatment record.

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

Blinding for this study shall primarily be at the level of the study investigators, whereby the investigator performing the treatment shall not be the same as the investigator who makes the pre-treatment assessment, who is not the same as the clinician performing the post-treatment assessment of the patient for immediate adverse effects. In other words, at any given time while a patient is present at the study site, there will be a minimum of three clinicians present at the site, and each respective clinician shall be assigned to one of the three activities (pre-assessment, treatment, or post-assessment) for the duration of that day's activities. Patient forms shall be designed such that dedicated forms are provided for each of these three activities, and the forms of any one particular activity (for example, the pre- treatment assessment) are not provided to or made available during the other activities of the patient's visit (ex. provided during the post-treatment assessment).

6.4 STUDY INTERVENTION COMPLIANCE

Adherence to the protocol will be assessed by documenting study visits.

6.5 CONCOMITANT THERAPY

7 STUDY INTERVENTIONDISCONTINUATIONAND PARTICIPANTDISCONTINUATION/WITHDRAWAL

8 STUDY ASSESSMENTS AND PROCEDURES

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8.1 EFFICACY ASSESSMENTS

Efficacy & Safety variables, including collection of adverse event data and anticipated adverse reactions

Efficacy

Input variables related to the determination of efficacy include the patient's age, gender, ethnicity, height, and weight (to determine the relative extent of obesity). Study output variables collected during this trial included the change in patient waist circumference as a primary indicator. Capture and collection of patient images may be useful for informational purposes, but are not a requirement of this study and shall not be used for any data analysis or study conclusions.

Monitoring

The study shall be monitored in the following manner:

- Training and Initial Inspection: The sponsor shall visit the study site and shall conduct an inspection of the site to determine that the site is adequate and appropriate for the activities described in this protocol. In particular, attention shall be given to ensuring that separation of treatment and the two assessment activities are accommodated to ensure patient and staff blinding is maintained, and that patient safety is ensured. Training shall be conducted for the investigators and staff regarding the study protocol, methods of measurement, and operation of the device.
- Informed Consent: The sponsor shall obtain copies of the signed informed consent forms prior to delivery of study devices.
- Surprise Inspection: At least twice during the course of study treatments, an independent third-party shall conduct a surprise inspection of the study site while treatments are being conducted, to review that the protocol is being followed, confirm that protection of human subjects is being employed, and ensure that treatment records are properly filled and maintained. Since the total duration of the device treatment period is anticipated to be only 4-6 weeks, the mandated 2 surprise visits are considered appropriate. If records or actions of investigation staff are found to be inconsistent, additional site inspections and possible additional training shall be employed.
- Collection of devices and records: Once all device treatments are completed, the sponsor shall retrieve the study devices and obtain copies of all treatment records. The sponsor shall review the patient records, and make especial note of adverse interactions contained in the records.
- Follow-up Records: At the conclusion of the follow-up visits, the sponsor shall collect the patient records from the follow-up visit. The sponsor shall compare and confirm that all adverse interactions that have been documented have been resolved at this point. If any adverse interactions are still unresolved, the sponsor shall work with the investigator to continue follow- up with the affected patients to achieve resolution.
- Audit of the Records: An independent third-party shall perform a sampling review of the study records during the surprise visits, and shall conduct a full audit of all study records at the conclusion of the study. This audit shall include quality control verification of data uploaded to electronic format. The audit shall confirm that all indicated adverse effects, whether anticipated or not, have been followed through to conclusion and such conclusions are documented in the Case Record Forms.

Post-Treatment Assessment (approximately 15 minutes):

- The Post-Treatment assessing investigator observes the treated area for any redness, edema, swelling, or other indications specifically called for in the Anticipated Effects treatment record. The

patient is asked for any unexpected sensations, for example sensations of high heat or of a "pins and needles" tingling effect in the tissue. These anticipated effects are documented in the treatment session record. Un-anticipated effects are recorded in the Adverse Event form.

- The patient is presented with the Stanford Pain Scale chart and asked to rate their overall pain and discomfort during the treatment. This is documented in the treatment session record.
- A waist circumference measurement of the abdominal region is made using the constant-tension tape measure. This measurement is recorded in the Post-Treatment Measurement record.
- The patient is provided with a study diary form, and instructed to document in the diary any unusual sensations, events, or bodily responses and to bring the form with them for the next visit.
- At the final treatment session only, the patient is provided with the Q-Post Survey to fill out.

The patient is then scheduled for the next study session, and then excused.

FOLLOW-UP (approximately 15 minutes):

- The patient is scheduled for and arrives at the study site at the appropriate time points 1, 4, or 12 weeks after the final treatment.
- The date of the visit and the time of arrival will be documented Post-Assessment Measurement and Anticipated Effects forms.
- For the 1-week and 4-week visits, the patient fills out the WaistQ-Post Survey. For the 12-week follow-up, the WaistQ-12 Survey is filled out.

  The patient will have their waist circumference measured and documented by an investigator assigned to the post-treatment measurement and assessment activity, as described in the Measurement Tools and Methods section of this protocol. The patient will be asked for the study diary, and the investigator shall review the diary and discuss with the patient the items that are recorded about any abnormal body functions or observations that may be relevant to the treatment. If any are indicated, these will be documented in the patient record. The investigator will also review observations and adverse events documented in previous sessions and discuss these with the patient. Additional record shall be made by the investigator as to whether past events and observations have been resolved or are still unresolved.
- For the 4-week or 12-week follow-up visits, the patient is provided with a study diary form, and instructed to document in the diary any unusual sensations, events, or bodily responses and to bring the form with them for the next visit. The patient is then scheduled for the 4-week or 12- week follow-up visits as appropriate.
- At the 12-week follow-up, additional review is made of the patient's Medical History and Medication forms and any new content for these forms is noted therein and discussed with the patient. If the 12-week follow-up visit is concluded and Adverse Event forms indicate any unresolved adverse results for the patient, additional follow-up is scheduled as appropriate until all adverse results are concluded.

DATA ANALYSIS AND FINAL REPORTS (approximately 2-3 weeks)

- Once all study participants have concluded the 12-week follow-up, unless participants are unable to be contacted or unwilling to participate in the follow-up, and all adverse interactions have a documented conclusion, analysis of the study data shall be conducted according to the Data Analysis section below.
- Data documented in the physical study records are populated into electronic spreadsheets.
- Data integrity is validated, and then data analysis is performed.

Once data analysis is complete, final study reports shall be prepared, presenting the results of the study.

8.2 SAFETY AND OTHER ASSESSMENTS

Input variables related to safety are reflected in the exclusion criteria. Primary among these is the effect the ultrasound treatment has on existing illnesses or conditions. There is concern that the delivered energy could adversely affect these conditions, making the patient's overall status worse. Other input variables for safety include the effect on localized tissue directly exposed to the ultrasound, as well as possible systemic effects that may occur.

Output data collected for safety include the patient's assessment of pain or discomfort experienced during or following the treatment, and questioning regarding any observations about systemic health that the patient may make during the overall trial. Any such comments or concerns from the patient are documented in the patient treatment records. Additionally, observations by the clinician about localized tissue response and patient general behavior were collected if any occurred and made part of the patient record.

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.3.1 DEFINITION OF ADVERSE EVENTS (AE)

8.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS (SAE)

If any adverse events occur, such will be immediately reported to the principal investigator who will assess the events and make determinations about whether the study should be halted or modified, or whether the participant should be excluded from further participation in the study. The study sponsor shall also be notified of the adverse event and of the principal investigator's assessment and decision regarding any action towards the participant or the study.

8.3.3 CLASSIFICATION OF AN ADVERSE EVENT

Anticipated adverse responses include:

- Localized inflammation, edema, and elevated temperature of the treatment area: Based on the proposed mechanism of action, the application of ultrasound and the disruption of cells could result in a localized increase in tissue temperature, accompanied by increased blood circulation through the insulted tissue.
- Localized pain or discomfort: The action of ultrasound of this frequency and intensity on nerve cells is not well understood. The same mechanism of action could trigger nervous cell responses interpreted by the brain as a pain response. The disruption and cavitation of adjacent adipose cells could also trigger a pain response.
- Possible system disruption: The applied ultrasound energy is intended to provide localized energy at the typical depth of tissue where sub-dermal adipose cells are found. The ultrasound energy could continue to propagate further into the body, reaching gastro-intestinal organs beneath the treated area. In generalized terms, there could be disruptions to digestive processes resulting from exposure to the ultrasound energy.
- Possible elevation of blood glucose levels: The disruption and lysis of adipose cells may release an increased amount of glycogen into the blood stream. Patients who present with diabetes or pre-diabetes or who are susceptible to variations in blood glucose levels may experience side- effects

consistent with elevated glucose levels wherein they are unable to metabolize and/or process the glucose products adequately.

- Possible pigmentation changes of the skin: The action of ultrasound on the skin may alter the amount or chemical nature of pigments in the skin, causing discolorations relative to the surrounding skin.
- Possible aggravation of surgically compromised or wounded tissue: The action of ultrasound on tissue that has been disrupted, such as through surgical procedures, previous wounds, or previously or presently inflamed tissue, could create mechanical stresses on the wound boundaries an possible overcome connective tissues across the wound boundaries, resulting in re-opened or inflamed sites.
- Possible increased compromise of immuno-suppressed patients: Patients who are or have recently experienced systemic procedures or conditions that weaken or suppress the immune system may be further weakened as a result of this treatment, as the process is expected to utilize immune responses to clear away the treated sub-cutaneous tissues.

8.3.3.1 SEVERITY OF EVENT

8.3.3.2 RELATIONSHIP TO STUDY INTERVENTION

8.3.3.3 EXPECTEDNESS

8.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

Describe how AEs and SAEs will be identified and followed until resolved or considered stable. Specify

Sequence and duration of study period

Patients will be scheduled according to each one's availability for the first of three treatment sessions. After each particular treatment, the patient will be scheduled for the next visit, with it being preferred that subsequent treatments occurring between 6-8 days into the future of the present treatment. Each patient is to receive 3 treatment sessions, with each session featuring the same device settings and conditions of application relative to which study group the patient is assigned to. Overall, the study treatments are anticipated to take about 6 weeks to accomplish. The patient is recalled 1 week, 4 weeks, and 12 weeks after the last treatment for follow-up evaluation.

8.3.5 ADVERSE EVENT REPORTING

8.3.6 SERIOUS ADVERSE EVENT REPORTING

8.3.7 REPORTING EVENTS TO PARTICIPANTS

8.3.8 EVENTS OF SPECIAL INTEREST

8.3.9 REPORTING OF PREGNANCY

PREGNANCY
Women who enroll in the study shall be administered an over-the-counter pregnancy strip test to determine if the candidate is pregnant. The test strip to be used in the study is branded as the "Pregnancy hCG Test Strip", distributed by Pregmate located in Ft. Lauderdale, Florida. This product is demonstrated with a detection threshold of 25 IU/L and an accuracy level of 98%. This product features a control indicator to demonstrate validity of the test strip, and a results indicator – if the second indicator appears, this is a results of "pregnant". If the indicator does not appear, this is a results of "not-pregnant". Results of the test must be indicated on the

8.4 UNANTICIPATED PROBLEMS

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8.4.1 DEFINITION OF UNANTICIPATED PROBLEMS (UP)

8.4.2 UNANTICIPATED PROBLEM REPORTING

8.4.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

Unanticipated problems affecting the study or study participants will be reported to subjects by the primary investigator as soon as they are known.

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

9.2 SAMPLE SIZE DETERMINATION

A total sample size of a minimum of 40 patients was established for this study. This number is based on

$$n = \frac{2 \cdot (Z_a + Z_{f3})^2 \cdot a^2}{d^2}$$

where:
Z_α = 1.96, based on a confidence of P=0.05 (false rejecting of a true null hypothesis),
Z_β = 0.84, based on a power of 80% (failure to reject a false null hypothesis),

d = 1.0 inch reduction in waist circumference as a meaningful/successful change in measurement,

σ = 1.50 inches, based on the evidence presented by a published study[5] under similar treatment parameters and conditions reporting a typical response of 0.75 inches through the umbilical region and assuming some of the population may not respond at all.

The resulting calculation gives a population size of 37. Accounting for possible attrition and adding a generous margin of safety, a recruitment size of 50 individuals is arrived at. Review of the data analysis shall be conducted by an independent entity to confirm the handling and calculation of data, and the conclusions drawn from the data regarding statistical significance.

9.3 POPULATIONS FOR ANALYSES

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

9.4.2 ANALYSIS OF THE PRIMARY EFFICACY ENDPOINT(S)

9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

9.4.4 SAFETY ANALYSES

9.4.5 BASELINE DESCRIPTIVE STATISTICS

9.4.6 PLANNED INTERIM ANALYSES

9.4.7 SUB-GROUP ANALYSES

9.4.8 TABULATION OF INDIVIDUAL PARTICIPANTDATA

9.4.9 EXPLORATORY ANALYSES

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

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10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

10.1.2 STUDY DISCONTINUATION AND CLOSURE

10.1.3 CONFIDENTIALITY AND PRIVACY

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

10.1.5 KEY ROLES AND STUDY GOVERNANCE

10.1.6 SAFETY OVERSIGHT

10.1.7 CLINICAL MONITORING

10.1.8 QUALITY ASSURANCE AND QUALITY CONTROL

10.1.9 DATA HANDLING AND RECORD KEEPING

Data quality assurance

Patient and study data will be documented on physical, printed patient treatment session sheets. The

completed sheets will be provided to the sponsor, who has the responsibility of uploading the data into electronic files for statistical analysis and processing. Calculations made from the data will be conducted in the electronic files, and the accuracy of calculations provided by the electronic spreadsheets shall be relied on. The clinicians and those who participate in the data collection will not have access to the electronic files, calculations, or analyses. Electronic data management tools are also employed to perform the statistical analysis of the key data.
Accuracy of the measurements made by the tape measure are verified by the sponsor. This is confirming the calibration status of the device via the manufacturer's certificate of calibration, as well as verification by measuring rigid metal cylinders with the device and comparing the measurements with NIST traceable calibrated calipers to measure the sample diameter from which the circumference can be calculated.
Where patients discontinue participation in the study, or key data is not documented properly on the treatment sheets, data from such patients shall not be incorporated in the statistical analysis of the data.

10.1.9.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Statistical methods planned, including handling data exclusion, analysis of sub-groups if any

Any patient that did not conclude all three treatments shall be excluded from the analysis. If there are fewer than 37 patients remaining after the study concludes and exclusions are applied, than no analysis shall take place and additional study subject enrolled until a minimum of 40 completed participants exist. In the event that a patient concludes at least one treatment session, but afterwards discontinues participation in the study, the presence of the patient in the study shall be acknowledged for data analysis purposes. Missing data for such acknowledged participants shall be fulfilled by inserting the least favorable result obtained realized from among all test subjects who did complete the study.
Statistical analysis shall then proceed on the fully populated study data.

Primary analysis shall consist of applying the Anova single-factor acceptance test evaluating the change in waist circumference based on the data collected by the tape measure. A confidence of P=0.05 shall be applied. The results of this data shall be directly applied to determining if the primary objective of the study has been met.

A correlation analysis shall be applied to all variable data recorded, as well as key calculations from the data, to identify any potential two-way connections or relationships between sets of data. Any correlations scoring a magnitude of 0.85 or greater shall be discussed and if appropriate, Anova single-factor analysis applied to determine if there is statistical significance to the relationship and any statements that might be supported by the data. Of primary interest is any impact the starting BMI might have on the amount of change, and any impact that gender may impart to the outcome.

10.1.9.2 STUDY RECORDS RETENTION

10.1.10 PROTOCOL DEVIATIONS

10.1.11 PUBLICATION AND DATA SHARING POLICY

10.1.12 CONFLICT OF INTEREST POLICY

10.2 ADDITIONAL CONSIDERATIONS

Not applicable.

10.3 ABBREVIATIONS

10.4 PROTOCOL AMENDMENT HISTORY

The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale. A Summary of Changes table for the current amendment is located in the Protocol Title Page.

Version	Date	Description of Change	Brief Rationale
005-00036-4	8 Aug 2018	Initial Approval	Initial Approval
005-00036-8	4 Nov 2019	Remove control group, chane in study site and principal investigator	Compliance of a control group was anticipated to be extremely difficult to provide meaningful data; Previous PI and site bowed out due to liability concerns

11 REFERENCES

- Atluri, P. , et al. "Clinical effects of noninvasive ultrasound therapy for circumferential reduction." *Am J Cosmetic Surg,* **Vol. 29 No. 2 (Jun 2012),** pp. 114-120.

- ELdesoky, M.T.M., Abutaleb, E.E.M., and Mousa, G. S. M. "Ultrasound cavitation versus cryolipolysis for non-invasive body contouring." *Australasian J Dermat,* **Vol. 57, No. 4 (Nov 2016),** pp. 288-293.

- Mohammadzadeh, M., et al. "Reduction in measures of adiposity using a combination of radio frequency and ultrasound cavitation methods." *Eur J Integrative Med,* **Vol. 8, No. 3 (Jun 2016),** pp. 313-316.

- Pugliese, D., Maiorano, E., and Pascone, M. "Histopathological features of tissue alterations induced by low frequency ultrasound with cavitation effects on human adipose tissue." *IntlJ Immunopath and Pharmac,* **Vol. 26 No. 2 (Apr 2013),** pp. 541-547.

- Tonucci, L. B., Mourão, D. M., Ribeiro, A. Q., and Bressan, J. " Noninvasive body contouring: Biological and aesthetic effects of low-frequency, low-intensity ultrasound device." *Aesth Plast Surg,* **Vol. 38, No. 5 (Oct 2014),** pp. 959-967.

Data and Safety Monitoring (DSM) Report for Single-Site Studies

-Open Session-

Report Cover Page

Protocol Title/number:	Effect of low frequency high intensity ultrasound on patient waist circumference reduction 005-00036-8
Principal Investigator (PI):	Dr. M. Kirk Moore, MD
Meeting date:	October 2019
Date of Report:	April 13, 2020
Data as of:	April 27, 2020
Prepared by:	Terence Rarick Lead Monitoring Consultant Core Compliance, LLC 63 E 11400 S, #249 Sandy, Utah 84070

Signature Page(s)

The monitor of this study (Trial Statistician) have approved the Data Monitoring Report version 02 (Dated 05.01.2020)

Trial Statistician: Core Compliance, LLC. Terence Rarick Lead Consultant

Site Location
Cosmetic Surgery Happiness, Inc
Dr Kirk Moore
7525 Union Park Ave
Midvale, Utah 84047

Date May 1st, 2020

X Terence Rarick

Monitoring Party
Trial Statistician

Table of Contents

Milestone Timeline

Study Type

☐ Interventional, specify type of Intervention (check more than one if applicable):

☐ Drug ■ Device ☐ Biological/Vaccine ☐ Procedural/Surgery
☐ Radiation ☐ Behavioral ☐ Genetic ☐ Dietary Supplement
☐ Combination Product ☐ Diagnostic Test ■ other, *specify*:_____

☐ Non-interventional

Data and Safety Monitoring (DSM) Report Milestone Timeline		**Comments** (If any of the information has changed since the time of the last report, please explain. For any milestone dates that have changed, specifically related to enrollment targets, please note the previous date and the reason for change. Recruitment target milestone changes must be discussed with the and Monitoring Body)
Project Period Jan 6, 2020 – April 13, 2020		
Trial Registered on ClinicalTrials.gov <Insert date (i.e., 11/2019) the trial was registered on the ClinicalTrials.gov website. Date should be no later than 21 calendar days after enrolling the first participant>		
Initial IRB Approval Date 4 Nov 2019		
Regulatory Clearances Date 26 Nov 2019		

Anticipated Site Agreements Signature Date Clinical Study-Ultimate Contour Body Sculpting Device- Page 1 Signature Page Sponsor, Lead Investigator, Statistical Investigation Agreeement2_Kirk Moore	Dates executed	
Actual Site Agreements Signature Date <Insert the actual date of the signature on the first site's agreement and note the site to which the date corresponds >	Aug 29th, 2019 Jan 6th 2020	
Study Commencement Date Descriptive Study of Efficacy of Low-Frequency, High-Intensity Ultrasound for Reduction in Subdermal Adipose Layers	Jan 6th 2020	
Study Opened to Enrollment <Insert the date when the study was opened to recruitment>	November 26th, 2019	
Planned Enrollment Number <Insert target number of participants to be enrolled. This is the number of participants required per protocol (this number will be compared to the "Actual Number Enrolled"). This number is expected to remain unchanged, unless a protocol amendment changes this required number and is approved by the . A history of the changes should be noted in the comments section.>	Target number -56 Actual number- 54	
Enrollment Definition <Insert how enrollment is defined as stated in your study protocol (i.e., enrolled = consented and randomized)>	**Recruitment** Recruiting shall consist of about 50 patients, with a target of at least 40 patients completing the study. Should patients drop out of the protocol such that 37 patients are not achieved at the end of the study, additional patients shall be recruited to achieve the target number	

Target Enrollment Start Date <Insert planned date (i.e., mm/yyyy) for the first participant enrolled>	October 15th, 2019 See Enrollment Graph attachment	
Actual Enrollment Start Date* <Insert date the first participant was enrolled>	Jan 6th 2020	

Target 25% Enrolled Date <Insert planned date (i.e., mm/yyyy) for when 25% of the participants will be enrolled>		
Actual 25% Enrolled Date* <Insert the actual date (i.e., mm/yyyy) when 25% of the participants were enrolled>		
Target 50% Enrolled Date <Insert planned date (i.e., mm/yyyy) for when 50% of the participants will be enrolled>		
Actual 50% Enrolled Date* <Insert the actual date (i.e., mm/yyyy) when 50% of the participants were enrolled>		
Target 75% Enrolled Date <Insert planned date (i.e., mm/yyyy) for when 75% of the participants will be enrolled>		
Actual 75% Enrolled Date* <Insert the actual date (i.e., mm/yyyy) when 75% of the participants were enrolled>		
Target 100% Enrolled Date <Insert planned date (i.e., mm/yyyy) for the last patient enrolled>		
Actual 100% Enrolled Date* <Insert date the last participant was enrolled>	January 10th 2020	
Target Last Visit Date <Insert planned date for the last participant visit (i.e., mm/yyyy); last patient out>	March 2020	
Actual Last Visit Date* <Insert date for the last participant visit>	April 13th 2020	
On-protocol Duration (per participant) – e.g., 24 months <Insert the planned length of time each participant will be on protocol, starting with enrollment	October 15th 2019 March 1st 2020	

and ending with the last follow-up visit>		
Intervention Duration **(per participant) – e.g., 6 weeks <Insert the planned length of time the intervention will be administered to each participant per the protocol>	Jan 6th, 2020 April 13th, 2020	
Interim Analysis Planned <Insert planned date (i.e., mm/yyyy) for the interim analysis>	Treatment 1-Jan 11th 12th 2020 Treatment 2-Jan 16th-19th 2020 Treatment 3-Jan 23-25th 2020	
Interim Analysis Completed <Insert date (i.e., mm/yyyy) when the interim analysis was completed>	April 22nd 2020	
Interim Analysis Reviewed by Data and Safety Monitoring Board <Insert date (i.e., mm/yyyy) when the interim analysis was reviewed by the safety monitoring board>	April 22nd 2020	
Target Database Lock <Insert planned date (i.e., mm/yyyy) for the database lock once all data queries have been completed>	April 24th, 2020	
Actual Database Lock* <Insert date the database was locked>	May 1st, 2020	
Target Primary Analysis Complete <Insert planned date (i.e., mm/yyyy) for the analysis of the primary outcome measure(s) to be completed>	?	
Actual Primary Analysis Complete* <Insert date the analysis of the primary outcome measure(s) was completed>	May 1st 2020	
Target Secondary Analysis Complete <Insert planned date (i.e., mm/yyyy) for the analysis of the		

secondary outcome measure(s) to be completed>		
Actual Secondary Analysis Complete* <Insert date the analysis of the secondary outcome measure(s) was completed>		
Trial results Posted on ClinicalTrials.gov <Insert date the results were posted on the ClinicalTrials.gov website no later than 1 year after the "primary completion date" of the trial. Date of final data collection for the primary outcome measure>	Date:	
Target Final Study Report Completed Date <Insert planned date (i.e., mm/yyyy) when the final (or draft) report/manuscript that describes the study and its findings is expected to be available>	Date: May 15th, 2020	
Actual Final Study Report Completed Date* <Insert date (i.e., mm/yyyy) the final (or draft) report/manuscript that describes the study and its finding was completed>	Date:	
Data Sharing – Submission to Repository <Insert date (i.e., mm/yyyy) when data were submitted and specify location submitted, if applicable>	Date:	

*****Insert 'not applicable' until milestone is reached.
** Insert 'not applicable' for studies without an intervention duration (i.e., surgical or observational studies)

Executive Summary

Study Overview Since the Last Monitoring Body Meeting	*Provide a summary of enrollment and important events since the last Monitoring Body meeting/report. The date through which the enrollment and safety data are provided should be indicated in this section.*
Overall Study Status	• Provide status of sites (e.g., IRB approval, whether recruitment has begun, timeframe for IRB approval/enrollment start) • 56 participants screened • 54 participants enrolled • 0 of participants awaiting treatment • 0 of participants in follow up • 42 of participants completed the protocol • 12 participants discontinued from study/follow up not ongoing
Stopping Rules ***{Use terminology that matches the protocol throughout this report}***	Provide information on whether any participants have met stopping rules since the previous Monitoring Body review.
Safety Summary	• 1 adverse event have occurred in 2 subjects • 5 new adverse events are being reported since the previous Monitoring Body report • There have been no additional serious adverse events since the last Monitoring Body meeting • Of the 10 adverse events, all were considered either mild or moderate • Only one adverse event was deemed related to the intervention
Protocol Deviations and Action Taken	0 protocol deviations associated with 0 subjects have been reported. deviation – the 12-week follow-up was conducted over video chat and no waist measurement was made, due to COVID-19

	• None of the deviations have impacted subject safety. • The protocol deviations did not meet the IRB's reporting requirements
Summary of Protocol Changes and New Requests for Protocol Changes	Did not determine any changes

Study Administration

Recruitment and Participant Status:

Figures and Tables

Figure 1: Enrollment: Overall Study Status

Data as of Oct 13th, 2019

Date of report: May 1st, 2020

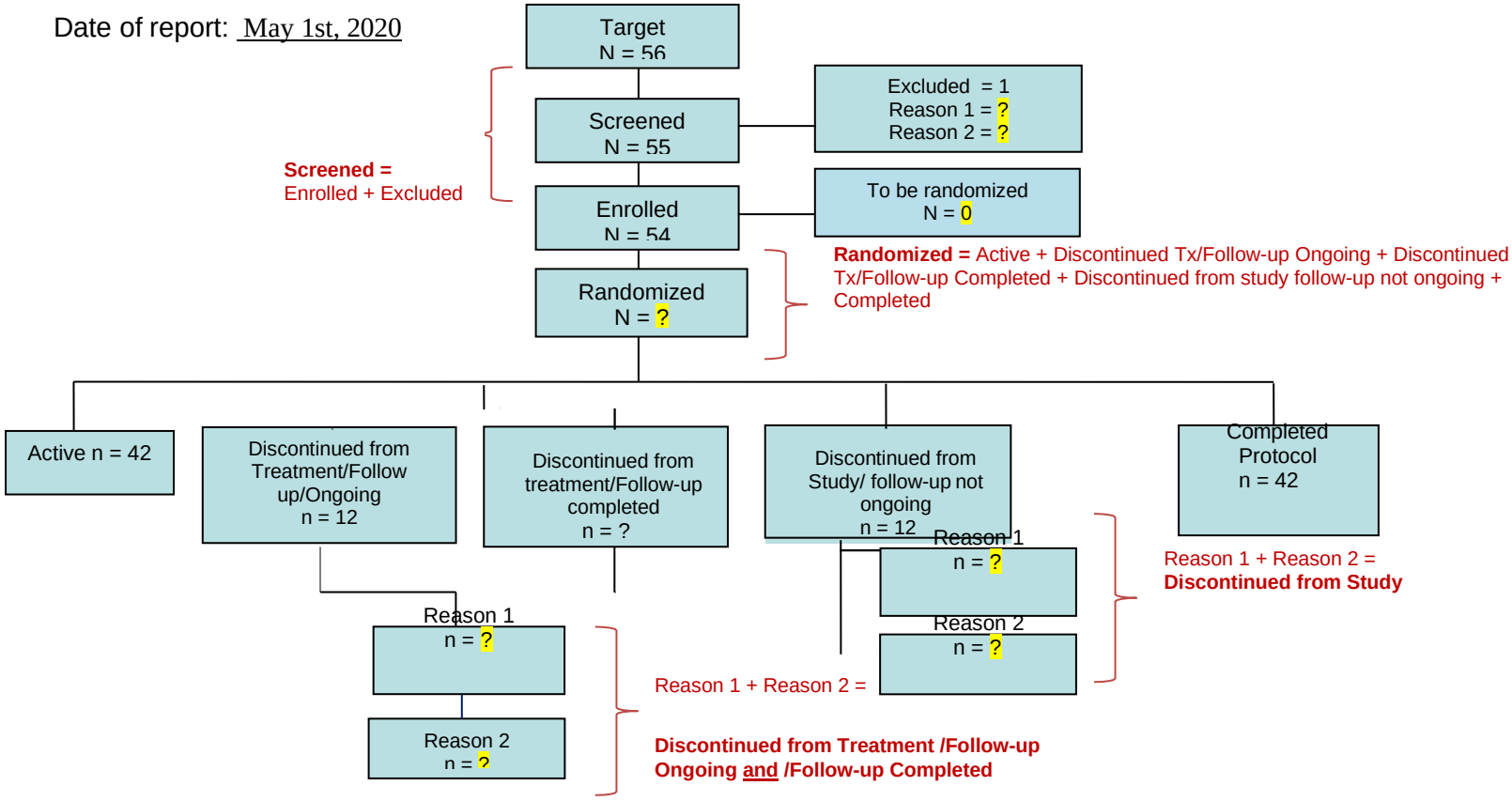
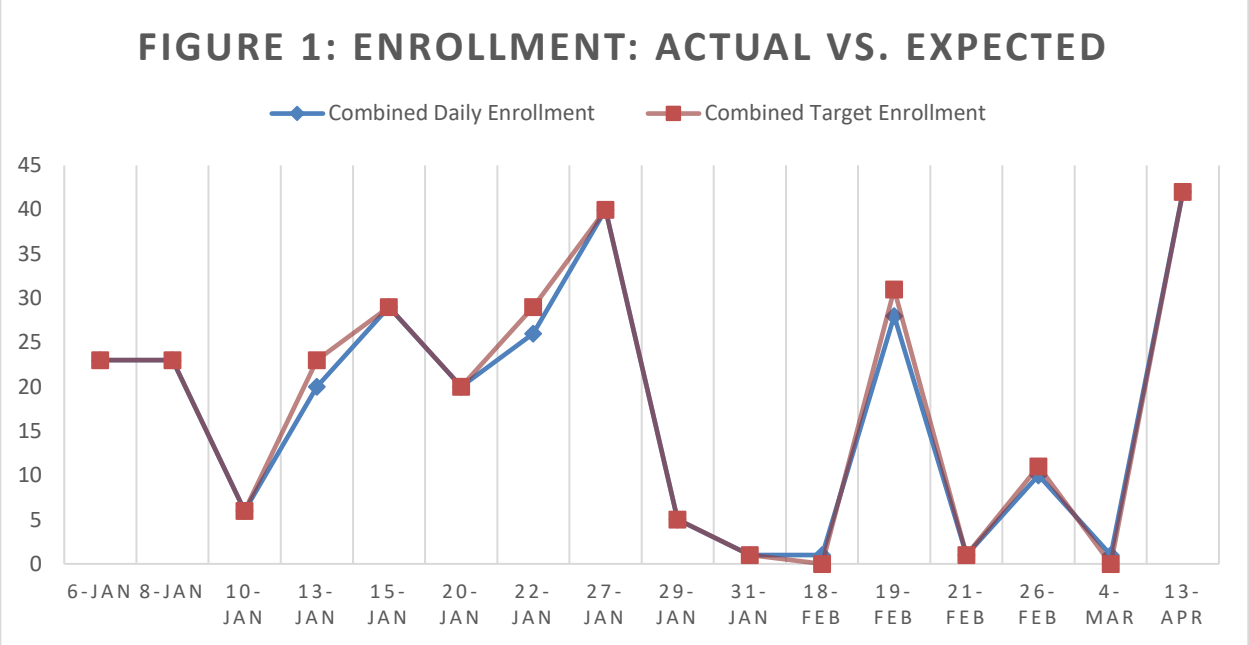


Figure 2: Enrollment: Actual vs. Expected

All Sites - Aggregate

Data as of: January 2020

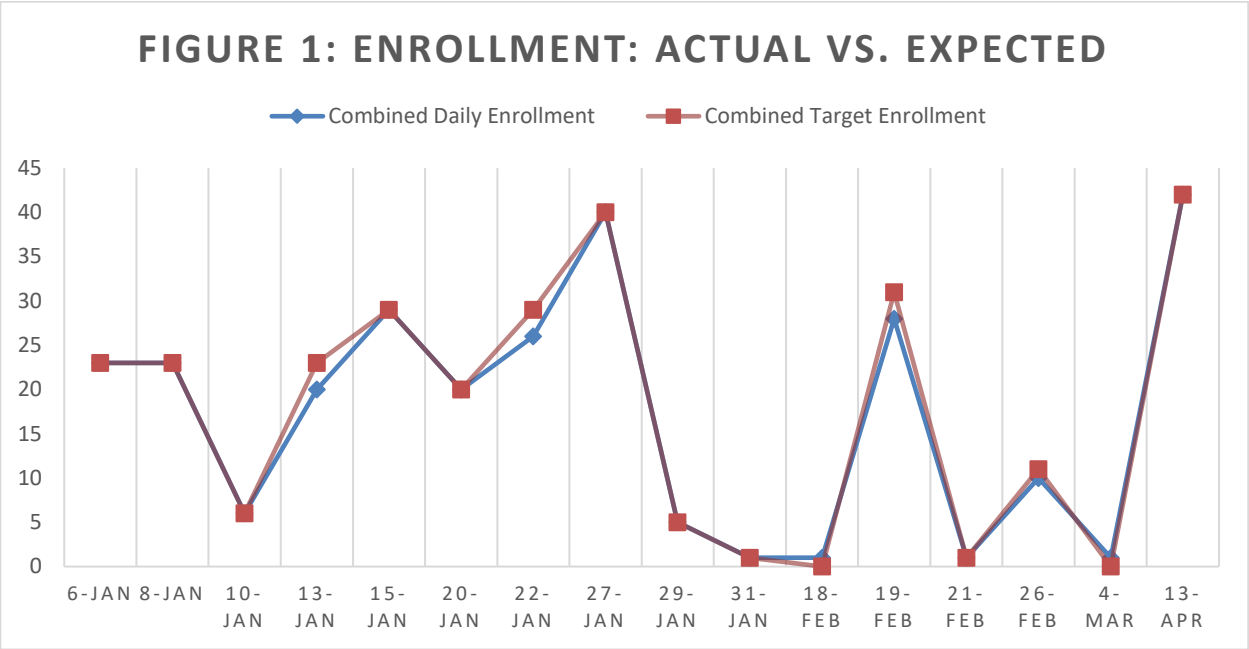
Date of report: April 2020



Time Period	Expected Number of Participants (cumulative)	Actual Number of Participants (cumulative as of April 13 2020)
Jan 6	24	23
Jan 8	48	46
Jan 10	46	52
Jan 13	52	49
Jan 15	49	49
Jan 20	49	49
Jan 22	49	46
Jan 27	46	46
Jan 29	46	46
Jan 31	46	46
Feb 18	46	46
Feb 19	46	42
Feb 21	42	42
Feb 26	42	42
Mar 4	42	42
Apr 13	42	42
Totals	**42**	**42**

Numbers should be displayed **cumulatively**, adding the number of participants from the previous month(s) to each new row.

SITE:7525 Union Park Ave Midvale, Utah 84047



Time Period	Expected Number of Enrolled Participants (cumulative)	Actual Number of Enrolled Participants (cumulative as of 4/13/2020)
Jan 6	24	23
Jan 8	48	46
Jan 10	46	52
Jan 13	52	49
Jan 15	49	49
Jan 20	49	49
Jan 22	49	46
Jan 27	46	46
Jan 29	46	46
Jan 31	46	46
Feb 18	46	46
Feb 19	46	42
Feb 21	42	42
Feb 26	42	42
Mar 4	42	42
Apr 13	42	42
Totals	**42**	**42**

Table 1: Participant Enrollment Status

Data as of: Oct 13th, 2019

Date of report: April 28, 2020

	Treatment 1		Treatment 2		Total	
	n	%*	n	%*	n	%*
Enrolled	54	98		100		100
Active	51	94				
Completed Protocol	51	94				
	n	%**	n	%**	n	%**
Discontinued from Treatment/Follow-up Ongoing	2	98		100		100
Reason 1 ****						
Reason 2						
	n	%***	n	%***	n	%***
Discontinued from Treatment/Follow-up Completed		100		100		100
Reason 1						
Reason 2 Other (specify):						
	n	%***	n	%***	n	%***
Discontinued from Study/Follow-up Not Ongoing		100		100		100
Reason 1						
Reason 2						

** % of participants who are enrolled.*

*** % of participants who have discontinued treatment, but continued to be followed as part of the study. For some protocols, it is important to distinguish between participants who withdrew early from the study and those who discontinued treatment but may or may not still be followed.*

**** % of participants who have discontinued the study and are no longer being followed.*

***** Reasons should be customized with items relevant to the study protocol.*

Table 2: Screen Failures by Site

Data as of: April 13th, 2020

Date of report: May 1st, 2020

Reasons*	Site 1		Site 2		Total	
	n	%	n	%	n	%**
Reason 1						0
Reason 2						0
Total Screened						0
Total Screen Failures						0

*****Reasons should be customized with items relevant to the study protocol.*

******** *% of the total number screened; the number of screen failures should be equivalent to the total number of participants screened minus the total number of participants enrolled.*

Table 3: Demographics by Site

Data as of: Jan 6th, 2020

Date of report: April 28, 2020

Characteristics*		Treatment 1 n (%)	Treatment 2 n (%)	Treatment 3 n (%)	Total n (%)	Target (n%) (from target enrollment table in grant)
Total Enrolled:		52	49	46		
Gender	Male	10	9	8		
	Female	42	40	38		
Ethnicity	Hispanic or Latino	5	4	4		
	Not Hispanic or Latino	40	38	36		
	Missing	7	7	6		
Race	American Indian/Alaska Native	0	0	0		
	Asian	1	1	1		
	Black or African American	0	0	0		
	Native Hawaiian or Other Pacific Islander	0	0	0		
	White	39	37	35		
	More than one race	0	0	0		
	Missing	7	7	6		
Education	Grade School	N/A				
	High School or equivalent					
	Some college, no degree					
	College degree					
	Graduate degree					
	Doctoral					
Age	18 - 24	4	4	4		
	25 - 34	13	11	9		
	35 -44	10	10	9		
	45 - 54	13	13	13		
	55 +	11	10	10		

Table 4: Key Baseline Characteristics by Site

Data as of: April 13, 2020

Date of report: May 1st 2020

Characteristics*		Site 1 n (%)	Site 2 n (%)	Site *i* n (%)	TOTAL n (%)
Body Mass Index	Below 18.5	0	Only measured once		
	18.5 – 24.9	0			
	25.0 – 29.9	34			
	30.0 and Above	18			
Descriptive Study of Efficacy of Low-Frequency, High-Intensity Ultrasound for Reduction in Subdermal Adipose Layers Total Score	Mean				
	Standard Deviation				
	Median				
	Minimum				
	Maximum				

***** *Characteristics should be customized with items relevant to the study protocol (e.g., stratification variables); the items listed are only examples.*

Table 5: Study Duration for All Participants

Data as of: April 13, 2020

Date of report: May 1st 2020

Time in Study* Total n=	Expected** n (%)	Actual*** n (%)
Treatment 1	54	52
Treatment 2	52	49
Treatment 3	49	46
Completed Study	49	42

***** *Should be customized to visit schedule and can be shown by visits, days, weeks, months, or treatment periods.*

****** *Number of participants expected to complete each study milestone.*

******* *Number of participants who completed each study milestone.*

Study Administration

Data Quality Tables

Table 6: Summary of Missed Visits by Site

Data as of: April 13, 2020

Date of report: May 1st 2020

Missed Visits	Treatment 1 n (%)	Treatment 2 n (%)	Treatment 3	Total n (%)
Number of Completed Participants	52	49	46	88
Number of Participants Missing Visits	2	5	8	17
Number of Missed Visits	2	5	8	17
Average Number of Missed Visits for Completed Participants				

{This table should display the number of participants missing visits and the number of actual missed visits divided by those who are currently active on the protocol and those who completed.}

Table 7: Summary of Case Report Forms (CRFs) Completed by Site

Data as of: April 13, 2020

Date of report: May 1st, 2020

CRFs*	Site 1			Site 2		
	Number of CRFs Expected	**Number of CRFs Completed**	**% of Missing CRFs**	**Number of CRFs Expected**	**Number of CRFs Completed**	**% of Missing CRFs**
Demographics						0
Medical History	56					
Vital Signs						
etc.						
All (total)						

***** *The CRFs listed should be customized with items relevant to the study protocol; the CRFs listed are examples but are not required.*

Safety Assessments for All Participants:

Tables and Listings

Table 8: Incidence of Adverse Events by Body System and Preferred Term

Data as of: _____

Date of report: _____

Body System and Preferred Term*	Total n=		
	n_i**	(%)***	Events****
Overall			
Body System 1***			
Preferred Term 1			
Preferred Term 2			
etc.			
Body System 2			
Preferred Term 1			
Preferred Term 2			
etc.			
Body System 3			
etc.			

Table 9: Severity of Adverse Events by Preferred Term

Data as of: _____

Date of report:_____

Preferred Term*	Total n=		
	Mild	Moderate	Severe
	n** (%)***	n (%)	n (%)
Preferred Term 1			
Preferred Term 2			

**For each preferred term, sort by most common event in descending order of incidence.*

***Number of participants experiencing a certain severity of an adverse event where each participant is counted only once at highest level of severity.*

****% of participants experiencing a certain severity of an adverse event.*

Listing 1: Adverse Events by Site

Data as of: _____

Date of report: _____

Treatment	Participant ID	Age	Gender	Event Term	AE Onset Date	AE Stop Date	Study Intervention Onset Date	Study Intervention Stop Date	Relationship*	Participant discontinued from intervention?	Expected (Y/N)	Severity**	Outcome***	Serious (Y/N)
1	2	45	F	Buzzing Ears	Jan 6							1	Recovered w/o treatment	N
1	3	49	M	Ears Ringing	Jan 6							1	Recovered w/o treatment	N

***** *Relationship should be specifically defined for each study (i.e., Relationship to intervention, Relationship to study drug, etc.) The following are commonly used categories: Definitely, Probably/Possibly, Not Related*

****** *The following are commonly used categories: Mild, Moderate, Severe.*
******* *Outcome:*

Recovered, without treatment
Recovered, with treatment
Still Present, no treatment
Still Present, being treated
Residual effect(s) present-no treatment
Residual effect(s) present-being treated
Subject died

Listing 2: Serious Adverse Events by Site*

Data as of: _____

Date of report: _____

Site	Participant ID	Age	Gender	Event Term	Study Intervention Duration**	Study Intervention Start Date	Study Intervention Stop Date	SAE Onset Date	SAE Stop Date or Ongoing	Relationship to Study***	Expected? (Yes/No)	Outcome ****	Unanticipated Problem?***** (y/n)

** This listing can be sorted by SAE Description or by Participant ID.*
*** The number of days on study treatment at the onset of the SAE.*
**** Relationship should be specifically defined for each study (i.e., Relationship to intervention, Relationship to study drug, etc.) The following are commonly used categories: Definitely, Probably/Possibly, Not Related.*
***** Outcome:*

Recovered, without treatment
Recovered, with treatment
Still Present, no treatment
Still Present, being treated
Residual effect(s) present-no treatment
Residual effect(s) present-being treated
Subject died

******The incident must meet the following criteria to qualify as an Unanticipated Problem:*

- *was unexpected in terms of nature, severity, or frequency*
- *is definitely or possibly related to participation in the research*
- *suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized*

NOTE: All AEs in Listing 1 that have been designated as an SAE ("Y") should also be included on this Listing.

Listing 3: Deaths by Site

Data as of: _____

Date of report: _____

Site	Participant ID*	Gender	Age	Date Enrolled	Date of Death	Study Intervention Start Date	Study Intervention Stop Date	Cause of Death	Relationship **

***** *It is expected that individuals will be listed on Listing 1: Adverse Events, Listing 2: Serious Adverse Events and the more detailed Listing 3: Deaths by Site.*

****** *The following are commonly used categories for relationship: Definitely, Probably/Possibly, Not Related.*

Table 10: Laboratory Test Results Summary*

Data as of: _____

Date of report: _____

Laboratory Test	Study Visits							----------Change from Baseline----------				
		n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Test 1	Screening												
	Visit 1												
	Visit 2												
	Visit 3												
	Visit 4												
Test 2	Screening												
	Visit 1												
	Visit 2												
	Visit 3												
	Visit 4												
etc…	Screening												
	Visit 1												
	Visit 2												
	Visit 3												
	Visit 4												

** Table may include lab test results that are clinically significant, as defined by the protocol, or ALL lab test results.*

Table 11a - 11i: Laboratory Test Results Summary by Site*

Data as of: _____

Date of report: _____

----------Change from Baseline----------

Laboratory Test**	Study Visits												
		n	Mean	SD	Median	Min	Max	n	Mean	SD	Median	Min	Max
Test 1	Screening												
	Visit 1												
	Visit 2												
	Visit 3												
	Visit 4												
Test 2	Screening												
	Visit 1												
	Visit 2												
	Visit 3												
	Visit 4												
Etc…	Screening												
	Visit 1												
	Visit 2												
	Visit 3												
	Visit 4												

** One table for each site.*

*** Table may include lab test results that are clinically significant, as defined by the protocol, or ALL lab test results.*

Listing 4: Clinically Significant Abnormal Lab Values by Site

Data as of: _____

Date of report: _____

Site	Participant ID	Study Visit	Lab Test	Baseline Result	Current Result	% Change from Baseline	Normal Range

{Lab tests that are deemed clinically significant as specified in the study protocol should be listed along with baseline result and normal range as stated by the study lab.}

Listing 5: Unanticipated Problems

Data as of: _____

Date of report: _____

Site	Date UP Identified	Date of UP incident	UP Description*	Subject ID (or describe group affected)**	Action taken*** (1 -10, include all that apply)	Action taken, specify	SAE? (yes/no)	Reported to the IRB? (yes/no)	IRB action required? If yes, describe response from IRB (attach correspondence, if necessary)

{The incident must meet the following criteria to qualify as an Unanticipated Problem:

- *was unexpected in terms of nature, severity, or frequency*
- *is definitely or possibly related to participation in the research*
- *suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized}*

**Describe harm or potential harm that occurred to subject(s), whether the incident is resolved, and whether the subject(s) remains in the study. If the Unanticipated Problem is a serious adverse event, submit this form and complete the Serious Adverse Event form.*

***If the Unanticipated Problem affects a particular group in the study, please identify that group, i.e., subjects in Treatment Group A, subjects enrolled before May 1, 2020, etc. If a group of individuals affected is across more than one treatment group, it may not be possible to complete this field.*

****Action taken with the study as a result of the Unanticipated Problem? (include all that apply)*

1- No action
2- Revise protocol to eliminate apparent immediate hazards to subjects
3 - Modification of inclusion or exclusion criteria to mitigate newly identified risks
4 - Implementation of additional procedures for monitoring subjects
5 - Suspension of enrollment of new subjects
6 - Notify currently enrolled subjects
7- Suspension of research procedures in currently enrolled subjects
8 - Modification of consent documents to include a description of newly recognized risks (site and/or study wide)
9 - Provision of additional information about newly recognized risks to previously enrolled subjects
10 – Other, specify

Listing 6: Protocol Deviations

Data as of: _____

Date of report: _____

Site	Participant ID	Deviation Date	Deviation Description*	Deviation Category**

***Deviation Description - record what occurred and why. For example, an expired drug was used by a new coordinator who did not check the expiration date. The description should also include remedies taken. In this case, the participant/subject was called to return the drug and was issued unexpired medication.*

****Deviation Category – provide a category of the protocol deviation description. Example deviation categories include: Randomization of ineligible participant; Failure to obtain consent; Participant seen outside window of follow-up; Not reporting serious adverse event.*

Clinical Study Type

☐ Drug ■ Device ☐ Biological/Vaccine ☐ Procedural/Surgery
☐ Radiation ☐ Behavioral ☐ Genetic ☐ Dietary Supplement
☐ Combination Produce ☐ Diagnostic Test

Protocol Title/number:	Effect of low frequency high intensity ultrasound on patient waist circumference reduction 005-00036-8
Principal Investigator (PI): **Auditor/Monitor:** **Data Collection Responsibility:** **Scheduling Coordinator:**	Dr. M. Kirk Moore, MD Terence Rarick, Core Compliance LLC Lane Hermansen, Linda Brown, Melinda Midgely, Anne Hutchinson, John Sanders Austin Meadors
1st Sample Inspection date:	January 6th 2020
2nd Sample Inspection date:	January 13th 2020
Address of Site:	7525 Union Park Ave, Midvale, UT 84047

Clinical Monitoring	Clinical site monitoring is conducted to ensure quality control verification of data that the reported for trial data are accurate, complete, and verifiable, and that the conduct of the trial is in compliance with the currently approved protocol/amendments

Data Collection Patient Information:	Patient # Age Gender Ethnicity Height (in) Weight (lbs) BMI Med Hist Form Available? Medications Form Available? Informed Consent on File? Candidate Accepted? Medications Medical History Medical History
Treatment Session #1	Treatment Date Pre-Assessment Time Pre-treat Circumference (in) Pre-Treat Comments Pre-Treat Investigator Treatment Time Unit S/N Treatment Comments Treatment Investigator Anticipated Effects Time Pain Rating Brusing Rating Erythema/ purpura Rating Edema/ Swelling Rating Numbness Rating Tingling Rating Blistering Rating Anticipated Effects Comments Post-Assessment Time Post-treat Circumference (in) Post-Treat Comments Post-Treat Investigator
Treatment Session #2	Treatment Date Pre-Assessment Time Pre-treat Circumference (in) Pre-Treat Comments Pre-Treat Investigator Treatment Time Unit S/N Treatment Comments Treatment Investigator Anticipated Effects Time Pain Rating Brusing Rating Erythema/ purpura Rating Edema/ Swelling Rating Numbness Rating Tingling Rating Blistering Rating Anticipated Effects Comments Post-Assessment Time Post-treat Circumference (in) Post-Treat Comments Post-Treat Investigator

Treatment Session #3	Treatment Date Pre-Assessment Time Pre-treat Circumference (in) Pre-Treat Comments Pre-Treat Investigator Treatment Time Unit S/N Treatment Comments Treatment Investigator Anticipated Effects Time Pain Rating Brusing Rating Erythema/ purpura Rating Edema/ Swelling Rating Numbness Rating Tingling Rating Blistering Rating Anticipated Effects Comments Post-Assessment Time Post-treat Circumference (in) Post-Treat Comments Post-Treat Investigator
Week 1 **Follow Up Visit**	Follow-Up Date Follow-Up Time Follow-Up Circumference (in) Brusing Rating Erythema/ purpura Rating Edema/ Swelling Rating Numbness Rating Tingling Rating Blistering Rating Follow-Up Comments Follow-Up Investigator
Week 4 **Follow Up Visit** **Post Treatment**	Follow-Up Date Follow-Up Time Follow-Up Circumference (in) Brusing Rating Erythema/ purpura Rating Edema/ Swelling Rating Numbness Rating Tingling Rating Blistering Rating Follow-Up Comments Follow-Up Investigator
Week 12 **Follow Up Visit** **Post Treatment**	Follow-Up Date Follow-Up Time Follow-Up Circumference (in) Brusing Rating Erythema/ purpura Rating Edema/ Swelling Rating Numbness Rating Tingling Rating Blistering Rating Follow-Up Comments Follow-Up Investigator Adverse Effects Concluded

<table>
<tr><td>Surveys</td><td>
<table>
<tr><th>Pre Waist-Q Survey Avail.?</th><th>Post Waist-Q Survey Avail.?</th><th>12wk Waist-Q Survey Avail.?</th></tr>
</table>
</td></tr>
<tr><td>Protection of Human Subjects
Date: Jan 6th 2020</td><td>
Monitor/Observer evaluated & ensured;

The patient is given the Q-Pre-Survey to fill out.
Assigned test subject number for identification purposes
The assigned pre-treatment investigator measures the waist circumference of the patient and documents this in the Pre-Treatment record, with these measurements being made by the blinded assessment clinician as described in the Measurement Tools and Methods

Monitor/Observer Documented the following-

Subjects will be recruited – Q-Pre-Survey completed
Description of informed consent – witnessed completed
Ensuring necessary medical/professional intervention for adverse events- Observed pre-treatment investigators-MM & LB
Documented the Serious Adverse Events Risk to subjects- Documented in treatment comments
Ensured the data was protected and kept confidential- observed data was inputted in separate room and access control measures

</td></tr>
<tr><td>Samples Protection Adverse Events
Date: Jan 6th 2020</td><td>
<table>
<tr><th>Treatment Date</th><th>Pre-Assessment Time</th><th>Pre-treat Circumference (in)</th><th>Pre-Treat Comments</th><th>Pre-Treat Investigator</th><th>Treatment Time</th><th>Unit S/N</th><th>Treatment Comments</th><th>Monitor Data Security</th></tr>
<tr><td>6-Jan-2020</td><td>9:00</td><td>42.50</td><td>None</td><td>MM</td><td>9:00</td><td>000144</td><td>Complained of buzzing in ears during treatment; Fine afterwards</td><td>Consent form signed
Access to designated; Data collectors</td></tr>
</table>
</td></tr>
</table>

	6-Jan-2020	9:00	46.00	None	LB	9:00	000143	Ears ringing from ultrasound, tolerated well.	Consent form signed Access to designated Data collectors

Quality Control verification of data Recruitment & Screening Date: Jan 6th 2020

Visit reminder checklists; data entry, clinical site monitoring reports; chart review tools
Monitor reviewed the data collectors input customer data into the following;

- Master Spreadsheet-*Study 005-00036-8_RAW DATA*
- The Informed Consent Form is signed
- The Patient Information Form was completed, and the patient is not excluded due to any of the indicated criteria
- The Medical History and Medication forms were populated and reviewed to ensure the candidate does not meet any of the exclusion criteria or other circumstances that may put the candidate at elevated risk by participating.

Samples Date Jan 6th 2020

Patient #	Age	Gender	Ethnicity	Height (in)	Weight (lbs)	BMI	Med Hist Form Available?	Medications Form Available?	Informed Consent on File?	Candidate Accepted?	Medications	Medical History	Monitoring Validation	Monitoring Tool
1	30	F	White	70	201.4	28.89	Y	Y	Y	Y	N	N	TR	Checklist

	2	45	F	White	73	230.2	30.37	Y	Y	Y	Y	Diltiazem Asprin Vitamin D	Vent. Tachycardia	TR	Checklist
	3	49	M	White	75	259	32.37	Y	Y	Y	Y	N	Deviated septum	TR	Checklist

QA Monitoring to Individual Treatment Sample Session Date Jan 13th, 2020

Monitor reviewed the following protocol was followed;

- The patient schedules
- The date of the treatment and the time of arrival was documented in the treatment session record.
- During the first treatment only: The patient is given the Q-Pre-Survey to fill out.
- The assigned pre-treatment investigator measures the waist circumference of the patient and documents this in the Pre-Treatment record, with these measurements being made by the blinded assessment clinician as described in the Measurement Tools and Methods section of this protocol.
- Prior to Treatments 2 and 3, the patient will be asked for the study diary, and the pre-treatment investigator shall review the diary and the patient's previous post-treatment Anticipated Effects and Adverse Event forms and discusses with the patient the items that are recorded about any abnormal body functions or observations that may be relevant to the treatment. If any are indicated, these will be documented in the patient record. Additional record shall be made by the investigator as to whether past events and observations have been resolved or are still unresolved.
- The patient is moved to the treatment area.

All activities above were audited and monitored and followed- Monitor/Observer - ☒

Samples Administration of Treatment Protocol Date: Jan 13th 2020	Observed **Principal Investigator (PI):** Dr. M. Kirk Moore, MD Followed established protocol Visually observed & documented checklist of Admin Treatment ***All activities above were audited and monitored and followed-*** Monitor/Observer - ☒
Audit Report Summary of Study Records	• 1 adverse event have occurred in 2 subjects • 5 new adverse events are being reported since the previous Monitoring Body report • There have been no additional serious adverse events since the last Monitoring Body meeting • Of the 10 adverse events, all were considered either mild or moderate • Only one adverse event was deemed related to the intervention

The Sponsor Investigator and (Observer) monitoring the study and (Trial Statistician) have approved the protocol version 01 and confirm hereby to conduct the study according to the protocol, (21 CFR 812.3) norm if applicable and the 42 CFR 11.10 legally applicable requirements.

Monitor/Trial Statistician:

7525 Union Park Dr. Midvale, UT

Place/Date	Jan 6th 2020	Signature	Terence Rauch
Place/Date	Jan 13th 2020	Signature	Terence Rauch