

INSTRUMENTAL EVALUATION OF THE ACTIVITY  
OF A MEDICAL DEVICE BASED ON  
CAVITATIONAL ULTRASOUND ON  
LOCALIZED FAT

TEST CODE: E0108

SUBMITTED TO: MI

1833421

PRODUCT: —CAVITATIONAL ULTRASOUND DEVICE MEDICELL“



ISO 9001:2000



FINAL REPORT

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OF A MEDICAL DEVICE BASED ON  
CAVITATIONAL ULTRASOUND ON LOCALIZED  
FAT

TEST CODE: E0108

DATE: 17<sup>th</sup> MARCH 2008

SUBMITTED TO: MI 1833421

PRODUCT: CAVITATIONAL ULTRASOUND DEVICE — MEDICELL™

TEST START DATE: JANUARY 13<sup>th</sup> 2008

RESPONSIBLES OF THE STUDY:

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1 STUDY OBJECTIVE

Aim of this study was to evaluate the efficacy of the medical device on subjects with  
localized adiposity on the thighs (trochanteric region).

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## 2 SUMMARY OF THE STUDY METHODOLOGY

The study was conducted on 20 female healthy subjects, age range 18-53 years (mean = 42) whose informed consent had been obtained. In particular volunteers were divided into 2 experimental groups of 10 subjects:

Group I with subcutaneous infiltration -the subjects, before each treatment session, were infiltrated at the level of treated area with 1% carnitine in 20cc of physiological solution (10cc/side).

Group II without infiltration œ the subjects underwent directly to the treatment with the device.

The trial foresaw 4 treatments with the device (1 treatment/week) for a total of 25 minutes: 5 minutes of firming action (device intensity: 70%) followed by 20 minutes of modelling action (device intensity: 80%). Morphometrical (circumferences measurements) and instrumental evaluations (body weight, skinfold caliper) were performed in according to the following scheme:

- T0 (baseline evaluation) : before the 1<sup>st</sup> treatment
- T1 (intermediate evaluation): 1 week after the 1<sup>st</sup> treatment and before 2<sup>nd</sup> treatment
- T4 (final evaluation): 1 week after the 4<sup>th</sup> treatment.

In addition at T0 and T4, for each volunteer, the impedance and the percentage of fat mass were evaluated directly by the device — Advanced Medical Instruments srl“.

## 3 RESULTS

No drop-out occurred, so statistical evaluation of data was carried out, following our internal procedures (descriptive and inferential analysis), on a total of 10 persons for each group. Instrumental results were submitted to statistical parametric test. In particular regarding circumference measurements and skinfold caliper on the treated area:

- for each group; comparison of T1-T4 results vs basal conditions (Anova test for repeated measure followed in case of positivity by Dunnett test)

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-comparison of the 2 groups at equivalent time points (standard two samples t test).

Regarding impedence, fat mass and skinfold caliper on subscapular fold control area

- for each group; comparison of T4 results vs basal conditions (paired T-test).
- comparison of the 2 groups at equivalent times point (standard two samples T test).

### 3.1 Variations in the adiposity

At T0, T1 and T4 visit subjects' weight was recorded. In addition, to assess eventual variations of the fat mass percentage, at T0 (basal visit) and T4 (end of the study) the investigator measured for each subject the impedance (thanks to the medical device — AMI<sup>®</sup>) and the thickness at the level of subscapular untreated control area (with the skinfold caliper). No important variation of subject's weight was noticed at any study time, except for volunteer n° 14 whose weight at T4 was 2,5 kg less than the basal one; in any case these results were not excluded from the statistical analysis because no important variation of the subject's fat mass percentage was found. The measure of the subscapular fold resulted to be more reliable than the impedance measurement; in fact even if any method showed statistically significant differences at any study times and between study groups the measure obtained with the skinfold caliper was more linear for all subject (as showed by the little standard deviation) while the impedance measure showed a wide standard deviation in both group and at all considered study times.

### 3.2 Morphometric evaluations

Circumferences measurements were performed at the level of hips and monilaterally (left or right leg according to a predisposed randomisation list) at the level

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of the III superior of the thigh (greater trochanter), thanks to a specific electro-optical system able to fix the volunteer's position. Morphometrical evaluations at level of the thighs underlined at the end of the treatment a statistically significant reduction of thigh circumference (Dunnett test  $p < 0.05$  T0 vs T4) for both experimental groups (with or without infiltrations) corresponding respectively to 1.43 cm (mean value) for group I and 1.36 cm (mean value) for group II, confirming the significant results obtained just after the first treatment (Dunnett test  $p < 0.05$  T0 vs T1 for both groups). At level of the hips the reduction was even more evident and always statistically significant (Dunnett test  $p < 0.05$  T0 vs T1  $\text{œ}$  T4 for both groups); subjects enclosed in group I reduced on average 1.76 cm after the first session and 3.14 cm at the end of the treatment, while subjects enclosed in group II reduced on average 1.4 cm after the first treatment and 3.26 cm at the end of the study period. No important statistically difference was showed between the 2 groups at any study times.

### 3.3 Skinfold caliper

The skinfold caliper was used to measure the thickness of the skin tissue layer directly on the adipose panniculus were the treatment with —A.M.I." device was performed (mono-laterally on the same leg where circumferences evaluation are taken). On subjects who underwent infiltrations before the treatment the panniculus thickness statistically significant reduced yet after the first session (Dunnett test T0 vs T1  $p < 0.05$  with a reduction percentage of 10.7%). T4 results confirmed this trend with a statistically significant reduction of 14.1% (Dunnett test T0 vs T4  $p < 0.05$ ). Concerning subjects who did not receive infiltrations, the panniculus reduction resulted less important (-2.5%), after the first treatment and it did non achieve a statistically significance. On the contrary at the end of the study period the panniculus was significantly reduced (Dunnett test T0 vs T4  $p < 0.05$ ; -8.6%).

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For the second group the panniculus reduction seems to be less important than the first one, but in any case no statistically important difference was showed between the 2 groups at any study times.

**CONCLUSIONS** Final results showed the treatment with the medical device — Medicell™ determined a clinically relevant and statistically significant reduction of the adipose panniculus in terms of measurement reduction on both treated groups, confirming the results obtained just after a single session. Regarding skinfold caliper measurement, it is possible to notice a more marked reduction of subcutaneous tissue on subjects who underwent subcutaneous infiltrations.

These results concern exclusively the tested medical device and experimental conditions adopted. The present documentation (report, graphs, tables, photographic documentation, experimental procedure and appendices) can be reproduced only integrally for internal use and cannot be divulged (totally or in part) without written consent of DermIng representatives.

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