

CONFIDENTIAL

REPORT: OBJECTIVATION STUDY

SPONSOR : **INDUSTEX**

INVESTIGATIONAL
PRODUCT : **VIBRATONE**

CLINICAL STUDY : EVALUATION OF THE EFFICACY OF AN
INVESTIGATIONAL PRODUCT, AFTER 2 WEEKS OF
APPLICATIONS, UNDER THE NORMAL CONDITIONS OF
USE BY 15 ADULT VOLUNTEERS

PROTOCOL : N° E060202PE, of August 28th, 2006

REPORT : N° E060202RD7, of October 30th, 2006

Study Monitor:
Mrs. M^a Mercé ARMENGOL
Marketing Manager
INDUSTEX
Paseo San Gervasio, 87 bajos
08022 BARCELONA

Director of the Study:
Mr. Badr RAIS
Ph.D. in Biochemistry and
Cell Biology
I.E.C. Espagne
C/ Caspe, 104, Bajos
08010 BARCELONA

28 pages's document

INSTITUT D'EXPERTISE CLINIQUE
ESPAGNE

REPORT

**CLINICAL STUDY FOR THE EVALUATION OF THE EFFICACY OF
AN INVESTIGATIONAL PRODUCT, AFTER 2 WEEKS OF
APPLICATIONS, UNDER THE NORMAL CONDITIONS OF USE BY 15
ADULT VOLUNTEERS**

"Clinical Objectivation Test"

Sponsor (Person who requested the study) :

- Company Name: INDUSTEX
- Study Monitor: Mrs. M^a M. ARMENGOL, Marketing Manager

Clinical Research Facilities:

- Company Name: I.E.C. Espagne
Calle Caspe - 104 Bajos
08010 BARCELONA
- Director of the Study: Mr. B. RAIS, Ph.D. in Biochemistry and Cell Biology

Investigational product: VIBRA TONE

Study request: Protocol n° E060202PE, of August 28th, 2006

Report: n° E060202RD7, of October 30th, 2006

Study timetable:

- Start of the study : September 12th, 2006
- End of observations : September 26th, 2006
- End of study (signature of final report by Investigator) : October 30th, 2006

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TABLE OF CONTENTS

AUTHENTICATION	5
PERSONNEL INVOLVED IN THE REALISATION OF THE STUDY	6
SUMMARY	7
QUALITY CONTROL	10
1. STUDY OBJECTIVE	11
2. STUDY RELEVANCE	11
3. INVESTIGATIONAL PRODUCT	12
3.1. Designation.....	12
3.2. Identification code numbers for the study	12
3.3. Description.....	12
3.4. Analytical control	12
3.5. Packaging.....	12
3.6. Quantities supplied and date of receipt	12
3.7. Storage.....	12
4. VOLUNTEERS	13
4.1. Principle of recruitment, selection and inclusion	13
4.2. Inclusion criteria	13
4.3. Non-inclusion criteria	14
4.4. Prohibition and restriction	15
4.5. Number of volunteers	15
4.6. Recording.....	15
5. CLINICAL STUDY (EXPERIMENTAL DESIGN)	16
5.1. Environmental conditions.....	16
5.2. Specific clinical examination	16
5.3. Instrumentation, evaluations and questionnaires.....	16
5.3.1. Weights.....	16
5.3.2. Measurements by technician	16
5.4. Planning of the study	17
5.5. Data analysis and interpretation of the results.....	17
6. REGULATIONS, CONFIDENTIALITY AND LEGAL FORMALITIES	18
6.1. Regulations	18
6.2. Confidentiality	18
6.3. Legal formalities.....	18
6.3.1. Information and informed consent.....	18
6.3.2. Data recording and archiving	19
7. PROTOCOL COMPLIANCE	20
8. RESULTS AND DISCUSSION	21

8.1. Volunteers.....	21
8.2. Experimental measurements and appraisals	21
8.3. Appraisal of cutaneous acceptability of the investigational product by the volunteers.....	21
8.4. Appraisal of the acceptability, efficacy and cosmetics qualities of the investigational product by the volunteers	22
9. CONCLUSION	23
APPENDIX 1	25
TABLE I : Volunteers' characteristics.....	26
TABLE II : Centimetric measurements	27
FIGURE I : Appraisal of the investigational product by volunteers after 2 weeks of applications	28

AUTHENTICATION

The study subject of the present report was conducted under my responsibility, in compliance with the experimental protocol, the procedures of the Clinical Research Facility and the regulations of the Good Clinical Practices.

All the observations and the numerical data obtained during this study are reported in the present document. After reading, I certify that these data are an accurate reflection of the obtained results.

I have read this report and I agree with its content.

Badr RAIS
Study Director

PERSONNEL INVOLVED IN THE REALISATION OF THE STUDY

<p><u>I.E.C. Manager:</u> Name: J.P. GUILLOT, D.E.S.S. Senior Toxicologist - Pharmacologist (Eurotox Registered Toxicologist) Address: Route de Bibost 69690 Bessenay - France ☎ : (33) 4.74.70.93.39</p>	<p><u>General Manager I.E.C. Espagne</u> Name: B. RAIS Ph.D. in Biochemistry and Cell Biology Address: Calle Caspe, 104 Bajos 08010 Barcelona ☎ : 93.512.45.59</p>
<p><u>Management Assistant:</u> Name: M.E. NAVARRO, DALF diploma Address: Caspe, 104 Bajos 08010 Barcelona ☎ : 93.511.10.92</p>	<p><u>Quality Auditor:</u> Name: A. RADI BENJELLOUN, Graduate in Microbiology and Drugs Control Diploma Address: Calle Caspe, 104 Bajos 08010 Barcelona ☎ : 93.511.10.92</p>
<p><u>Study Director:</u> Name: B. RAIS Ph.D. in Biochemistry and Cell Biology Address: Calle Caspe, 104 Bajos 08010 Barcelona ☎ : 93.511.10.49</p>	<p><u>Technicians</u> Names: G. BRIONES, J.C. ALONSO Address: Calle Caspe, 104 Bajos 08010 Barcelona ☎ : 93.246.92.18</p>
<p><u>Study Monitor:</u> Name: M^a M. ARMENGOL Address: INDUSTEX Paseo San Gervasio, 87 bajos 08022 Barcelona ☎ : 93.254.71.00</p>	

INSTITUT D'EXPERTISE CLINIQUE ESPAGNE
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Head office: Caspe, 104, bajos, 08010 BARCELONA Tel.: (34) 932 469 218 - Fax: (34) 932 469 219

SPONSOR:
INDUSTEX

INVESTIGATIONAL PRODUCT:
VIBRA TONE

OBJECTIVATION STUDY

SUMMARY

REDUCING EFFECT

**CLINICAL STUDY FOR THE EVALUATION OF THE EFFICACY OF A
INVESTIGATIONAL PRODUCT, AFTER 2 WEEKS OF APPLICATIONS,
UNDER THE NORMAL CONDITIONS OF USE BY 15 ADULT
VOLUNTEERS**

VOLUNTEERS

20 volunteers from both sexes were recruited for this study, taking into account the inclusion and non-inclusion criteria, as well as the prohibition and restriction concepts defined for the study.
15 from them came to I.E.C. Espagne and were accepted to participate on the study.

Analysis of results was made over a panel of 15 volunteers, whose physical characteristics are summarised on the following table:

Volunteers	Body skin nature	Sensitivity of the body	Mean Body Mass Index	Healthy subject with history of atopy
Number : 15 Women : 9 (60%) Men : 6 (40%) Mean age : 37 Min age : 22 Max age : 48	. Normal : 13 (86%) . Dry : 2 (14%)	2 (14%)	27.37 ± 2.53	1 (6%)

PROTOCOL

For the inclusion on the study, volunteers were weighted and sized in order to calculate their B.M.I. (Body Mass Index). The measurements centimetres of the abdominal, buttock and thigh perimeter was done by circular measurements of the central area (zone of the maxim concentration of oily mass) of each volunteer and was performed with a tape-measure (in centimeters) using a maintaining device enabling to mark-off the measurement areas with accuracy and reproducibility throughout the whole study. Measurements (expressed in centimeters) were done using a tape measure, on the standing up volunteer's position (feet position to be marked off), using a height gauge, enabling to define with accuracy a line around the areas, on which is applied the tape measure.

The applications of the vibrator belt were realized by volunteers at home, with 30 minutes daily session.

The determination of the mean values of the centimeter measurements obtained at each time point of the study D1 (before applications) and D14 (after 2 weeks of applications) and for each area, by the calculation of the means and the standard deviations (Sd – scores) of individual data, allows determine the existence of statistical significant differences between the obtained values.

RESULTS AND CONCLUSION

Analysis of the results obtained revealed on the whole:

- **As regard its objective efficacy**, after 2 weeks of applications; it was assessed by measuring abdomen, buttock and thigh perimeter in centimetres and the weight in kilograms from each volunteer at D1 and D14 of applications of the vibrator belt at their home.

Results obtained for the investigational product on the 15 volunteers are showed as following:

Homogeneity of variance and normality of distribution verified the all of cases.

* MESURES OF WEIGHT (n=15)

It has been observed a statistically significant decrease of the weight of 0.91 kg after of 2 weeks of applications of the investigational product, with regard to the initial values.

	D1	D14	Δ D1-D14 days	Probabilidad p : efecto producto “ t “ de student
Weight (kg)	76.67 ± 9.75	75.77 ± 9.82	0.91 ± 0.75	0.009

In grey: probability p (Paired Student "t" test, "two-tail", signification: $p < 0.05$) above the differences (ΔD1 –D14 days).

* **CENTIMETRIC MEASUREMENTS** ($n=15$)→ At thighs level

It has been observed a statistically significant decrease of the thighs perimeter of 1.12 cm after of 2 weeks of applications of the investigational product, with regard to the initial values.

→ At buttocks level

It has been observed a statistically significant decrease of the buttocks perimeter of 2.12 cm after of 2 weeks of applications of the investigational product, with regard to the initial values.

→ At abdomen level

It has been observed a statistically significant decrease of the abdomen perimeter of 2.43 cm after of 2 weeks applications of the investigational product, with regard to the initial values.

	THIGH (cm)	BUTTOCKS (cm)	ABDOMEN (cm)
D1	62.10 ± 5.72	103.75 ± 7.20	95.20 ± 7.28
D8	60.98 ± 5.49	101.63 ± 6.92	92.77 ± 7.28
Δ D1 –D14 days	1.12 ± 0.90	2.12 ± 1.29	2.43 ± 1.07
Probability p: reducing effect Student “ t “ test	<i>0.00</i>	<i>0.00</i>	<i>0.00</i>

In grey: probability p (Paired Student “t” test, “two-tail”, signification: $p < 0.05$) above the differences (ΔD1–D14 days).

In conclusion, the applications of the product “VIBRA TONE” during 2 weeks, under normal conditions of use, by 15 volunteers of both sexes, with ages between 22 and 48 years, and a BMI between 24 and 30, have shown a statistically significant decrease of the weight and thigh, buttocks and abdomen perimeter, as regard to the initial values.

Barcelona, October 30th, 2006

**B. RAIS
Ph.D. in Biochemistry
and Cell Biology
General Manager**

This study have been done at the INSTITUT D'EXPERTISE CLINIQUE ESPAGNE, presided by Mr. J.P. GUILLOT, Toxicology Specialist (Eurotox Registered Toxicologist)

QUALITY CONTROL

This study was conducted in conformity with the standard operating procedures of the Clinical Research Centre, the general procedures of I.E.C. Espagne, the signed protocol and the general principles of the Good Clinical Practices published by I.C.H. (CPMP/ICH/135/95).

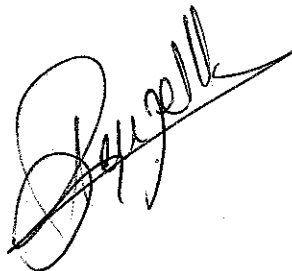
The control of the clinical studies is carried out periodically. It is designed to ensure that all critical phases (investigational product applications and examinations or measurements) of a particular study type are controlled, at least once a quarter, for the studies carried out during this time period. Dates of these controls and study type concerned are given below.

The results of these controls were reported to the Investigator and to the General Management.

Types of study	Dates of controls	Dates of reports to the Investigator	Dates of reports to the General Management
. Identical study :	12 September 2006	12 September 2006	12 September 2006
. Others :	PEU 27 July 2006 TUCR 04 October 2006	PEU 27 July 2006 TUCR 04 October 2006	PEU 27 July 2006 TUCR 04 October 2006

This report has been controlled by I.E.C. Espagne Quality Unit, it is an accurate account of the procedures followed, and accurately records the raw laboratory data generated in this study.

	Dates of control	Dates of report to the General Management
Report (vs. compiled data) :	30 October 2006	30 October 2006



Signature:

Amina RADI
Quality Auditor

Date: 30 October 2006

1. STUDY OBJECTIVE

To assess the efficacy of a cosmetic investigational product by measures of weight and centimetric measurements, after 2 weeks of applications, under the normal conditions of use, by 15 adult volunteers.

2. STUDY RELEVANCE

The appreciation of the reducing effect of the investigational product is based on centimetric measurements of the thigh, buttocks and abdominal perimeter performed at D1 (before the applications) and D14 (after 2 weeks of applications), a clinical specific and adapted evaluation by a trained assessor, under the normal conditions of use, in volunteers presenting a BMI included between 24 and 30.

3. INVESTIGATIONAL PRODUCT

3.1. Designation:

VIBRA TONE

3.2. Identification code number for the study: E060202 062002

3.3. Description:

Each pack sample contain: belt with remote control, transformer, bag of transport and instruction manual.

3.4. Analytical control:

It was under the responsibility of the Study Monitor to determine the identity, the physical-chemical characteristics and any other criteria which could allow identification of the investigational product batch.

For this type of study, no analytical dosage was made and neither stability, nor absorption of the investigational product was evaluated by I.E.C. Espagne.

3.5. Packaging:

The belt pack was delivered in a bag.

3.6. Quantity supplied and date of receipt:

30 samples received on August 30th 2006.

3.7. Storage:

A sample of the investigational product will be kept in our facilities for four months as of the date of despatch of the final report. From this date on, and with no contrary advice of the Study Monitor, the investigational product will be destroyed.

4. VOLUNTEERS

4.1. Principle of recruitment, selection and inclusion

The procedure for recruitment, selection and inclusion of the panellists who accepted to collaborate in this study, after informed consent, was elaborated to give them clear and precise information, allowing them to appreciate the aim and the consequences of their consent.

This procedure included, in particular:

- a preliminary interview during the objective and the protocol of the study were explained to the panellists, the study timetable, the compensation modes, as well as the possible benefits, the constraints linked to the study and the foreseeable risks even in case of stop of the study before its normal end ;
- the signature of an informed consent statement by the panellist: he could thus make his decision completely free taking the conditions proposed into account;
- the notification of the take over of the panellist by the insurance in civil liability subscribed independently by the Sponsor and I.E.C. Espagne, once the panellist has been definitively admitted for study by the Investigator.

The panellists recruited for this study were selected by the person responsible for recruitment and selection on the basis of the inclusion and non-inclusion criteria, as well as the prohibition and restriction concepts defined in the protocol.

The final inclusion of the panellists was determined by the Investigator, Study Director, from a pre-study medical auto-questionnaire and from a clinical medical examination specific to the study, performed just before the start of treatment.

4.2. Inclusion criteria

- Origin: Caucasian.
- Sex: both.
- Age: from 18 to 50 years old.
- Weight: included within the limits of the scale proposed by the Metropolitan Insurance Company
- **At request of Sponsor, the volunteers should have a Body Mass Index (B.M.I.: Weight (kg)/Size (m)²) included between 24 and 30.**
This criterion was verified by the Investigator at definitive admission of the volunteer.
- Health condition: it corresponds to the selection criteria defined in the procedures of I.E.C. Espagne, in order to eliminate, as much as possible, the volunteers incurring risks or presenting with redhibitory affections for the clinical studies performed by Institut d'Expertise Clinique. These criteria are evaluated on the basis of questionnaires and clinical examinations listed in the protocol.
- Volunteers having a stable weight since three months at least (maximum variation of 1.5 Kg).
- Volunteers able to prove a fixed abode.
- Social cover: the volunteers shall be affiliated to a social security cover.

- Understanding of the Spanish language: Spanish-speaking volunteers, able to read the documents they are presented with and to hold to what they are explained.
- Female volunteers: having regular menstruations, but out of the menstrual period during the study.
- Accepting not to be or to go on a diet and not to follow aesthetic slimming treatments (massage, thalasso therapy ...) other than specified by the trial.

4.3. Non-inclusion criteria

- Volunteers not presenting with the above-mentioned inclusion criteria.
- Volunteers having participated in a cutaneous or peri-ocular local acceptability test during the last 2 weeks and/or to sensitization trial during the last 3 months and/or a photo-sensitization or photo-irritation study during the last 4 months.
- Volunteers deprived from liberty by a judiciary or administrative decision, sick volunteers in emergency situation.
- Under age or of age volunteers protected by law, as well as those admitted in sanitary or social facilities, ever since the research can be performed in another manner.
- Volunteers refusing to give their agreement by signing the informed consent statement.
- Volunteers having undergone organ excision (kidney, lung, spleen, liver), an organ transplant, a skull concussion with extended loss of consciousness since less than 5 years ago or with present after-effects.
- Volunteers either pregnant or breastfeeding mothers, or not using medically acceptable contraceptive methods during the last 3 months.
- Volunteers in period of menopause and subject to phenomenon of sudden flush.
- Volunteers having:
 - . *the following disorders*: cardio-vascular, pulmonary, digestive, neurological, psychiatric, genital, haematological, endocrine, having a redhibitory aspect for the study concerned ;
 - . *an immunological deficit*;
 - . *a background of drug intolerance* (local or general anaesthetics) ;
 - . *a skin disease*, and in particular: urticaria, oedema, eczema, recurrent herpes, herpes zoster having erupted less than 3 months before, pityriasis versicolor, common acne with a sudden rise of inflammation or nodular or cystic acne, psoriasis, ichthyosis, lichen planus, chronic lupus erythematosus, cheloid scars, severe pigmentary disorders (vitiligo, chloasma, multiple lentigines, numerous or congenital naevi, especially if they are of large size), hyperhidrosis, dorsal hyperpilosity, very strong perspiration ;
 - . *a febrile illness*: more than 24 hours of fever within the 8 days prior to the first application of the investigational product.
- Volunteers having had or being in the course of a long-term treatment with, in particular, antihistamine, steroids, beta blockers (including collyrium) and/or desensitization.
- Volunteers having applied or intending to apply cosmetic or pharmaceutical products (except the usual cleanser) on the cutaneous areas concerned 3 days before the beginning of the study and on the starting day of the trial.

- Volunteers having followed or intending to follow a slimming treatment or a treatment for blood circulation by oral or cutaneous route during the last two weeks or by physical methods (liposuction, ionophoresis, lymphatic draining...) during the last two months to the cutaneous areas concerned by the study.

- Volunteers smoking more than 10 cigarettes a day.

4.4. Prohibition and Restriction

Aspirin, products containing aspirin, anti-inflammatory drugs or antihistaminic or systemic steroids by general route, are forbidden throughout the duration of the study (except paracetamol). No other cosmetic shall be applied on the thighs and buttocks during the study except the usual cleansing product. The investigational product shall not be applied the evening before each visit at I.E.C. Espagne.

4.5. Number of volunteers

This study was performed in 15 exclusive adult volunteers.

Justification: "15" was the number requested by the Sponsor.

4.6. Recording

The volunteers were registered in the order of their inclusion, this being made progressively as they arrived.

5. CLINICAL STUDY (EXPERIMENTAL DESIGN)

5.1. Environmental conditions

The whole study was performed under the environmental conditions of specific relative temperature and humidity, controlled and identical for each volunteer. The measurements and evaluations were performed in a room completely air-conditioned.

The ambient temperature was maintained at $21 \pm 1^\circ\text{C}$.

5.2. Specific clinical examination

For their inclusion on the study, volunteers were weighted and sized in order to calculate their B.M.I. (Body Mass Index). The centimetric measurements abdominal, buttock, arm and thigh perimeters were done by circular measurements of the central area (zone of the maxim concentration of oily mass) of each volunteer and were performed with a tape-measure (in centimeters), using a maintaining device enabling to mark-off the measurement areas with accuracy and reproducibility throughout the whole study. Measurements (expressed in centimeters) were done, on the standing up volunteer's position (feet position to be marked off), using a height gauge enabling to define with accuracy a line around the areas, on which is applied the tape measure.

The applications of the vibrator belt were realized by volunteers at home, with 30 minutes daily session.

The determination of the mean values of the centimetric measurements, obtained at each time point of the study D1 (before applications) and D14 (after 2 weeks of applications) and for each area, by the calculation of the means and the standard deviations (Sd – scores) or standard errors on the mean (SEM – measurements) of individual data, allows determine the existence of statistical significant differences between the obtained values.

5.3. Instrumentation, evaluations and questionnaires

5.3.1. Weights

With the aim to verify the stability of the corporal mass of the volunteers, each panellist was weighed at each time point of the study, with the help of the electronic scales “TEFAL”. The considered precision of ± 100 g corresponds with defined characteristics by manufacturer.

5.3.2. Measurements by technician

The measurements centimetres of the abdominal, buttock, arm and thigh perimeter was done by circular measurements of the central area (zone of the maxim concentration of oily mass) of each volunteer, were performed with a tape-measure (in centimeters), using a maintaining device enabling to mark-off the measurement areas with accuracy and reproducibility throughout the whole study. Measurements (expressed in centimeters) were done, on the standing up volunteer's position (feet position to be marked off), using a height gauge enabling to define with accuracy a line around the areas, on which is applied the tape measure.

5.4. Planning of the study

ACTIONS	D1	D14
Admission by I.E.C. Espagne staff (inclusion and non-inclusion criteria).	X	
Measurements of weight, size and abdominal, buttock and thigh perimeter of each volunteer by a technician.	X	X

5.5. Data analysis and interpretation of results

The centimetric measurements of the abdominal, buttock and thigh perimeter performed at D1 and D14 of applications of the vibrator belt were performed. The determination of the mean values of the centimetric measurements obtained at each time point of the study D1 (before applications) and D14 (after 2 weeks of applications) and for each area, by the calculation of the means and the standard deviations (Sd – scores) of individual data, allows determine the existence of statistical significant differences between the obtained values.

Checking of the homogeneity of variances and the normality of distributions respectively was done by the Levene test and by the Kolmogorov-Smirnov test (significativity: $p < 0.05$). Data obtained were then processed using a paired Student "t" test ("two-tail", significativity: $p < 0.05$) in case of homogeneity of variances and normality of distributions, for measurements; or paired Wilcoxon test ("two-tail", significativity: $p < 0.05$) in case of heterogeneity of variances or non normality of distributions; doing possible to compare the values obtained after the device application of the study to the initial measurements.

The synthesis of this analysis, as well as the global appraisal of the efficacy, enabled interpretation of the results, according to the type of product and to the effect searched by the Study Monitor.

6. REGULATIONS, CONFIDENTIALITY AND LEGAL FORMALITIES

6.1. Regulations

This study, without any direct therapeutical finality for the panellist was performed in agreement with the most recent recommendations of the World Medical Association (Declaration of Helsinki - 1964, amended in Tokyo, 2004). This study also complies with the provisions of the law relative to the protection of subjects participating in clinical research protocols in Spain and with current Good Clinical Practices (GCP).

6.2. Confidentiality

Any information regarding the health condition of the volunteers and the results of the clinical examinations, performed before the start of treatment, for their recruitment, their selection and inclusion, are submitted to the rules of the medical secrecy: in no case, this information will be given to the Sponsor with their identity.

To ensure preservation of the volunteers' anonymity, those were identified by a code number using 5 letters, corresponding to the first 3 letters of their surname, then the first 2 letters of their first Christian name, and for the study, by a number corresponding to their inclusion order in the test.

At the end of the study, the page called "Volunteer Identification Form", in which are mentioned particularly the name and address of the volunteer, was taken from the laboratory notebook and destroyed.

"The Investigators and any person who collaborated in the studies are sworn to professional secrecy especially as regards the nature of the investigational products, the studies, the persons on test and the results obtained".

6.3. Legal formalities

6.3.1. Information and informed consent

An information sheet was given to each volunteer, in order to inform her/him of, in particular:

- the aim of the research, its methodology and its duration ;
- the possible benefits, the constraints linked to the study and the foreseeable risks, even in case of stop of the research before its end ;
- the non-inclusion period, the amount of the compensation, the possibility to personally check the exactitude of the data contained in her medical file and their subsequent destruction.

This information allowed the volunteer to sign an informed participation consent, with full knowledge of the facts.

6.3.2. Data recording and archiving

All hand-written data were immediately transcribed in laboratory notebooks constituted, paginated and fastened before the start of the study.

All raw data are kept in the archives of I.E.C. Espagne for 10 years, at the following address:

. I.E.C. Espagne, Calle Caspe, 104 Bajos, 08010 Barcelona - España

Once this period is over, the Sponsor is contacted regarding its archives. No archive destroying will be done without the written agreement from the Sponsor.

7. PROTOCOL COMPLIANCE

No incident which could have affected the quality or the interpretation of the results obtained was observed.

8. RESULTS AND DISCUSSION

8.1. Volunteers

20 volunteers from both sexes were recruited for this study, taking into account the inclusion and non-inclusion criteria, as well as the prohibition and restriction concepts defined for the study.

15 from them came to I.E.C. Espagne and were accepted to participate on the study.

Analysis of results was made over a panel of 15 volunteers, whose physical characteristics are listed in the following table and table I of appendix.

Volunteers	Body skin nature	Sensitivity of the body	Mean Body Mass Index	Healthy subject with history of atopy
Number : 15 Women : 9 (60%) Men : 6 (40%) Mean age : 37 Min age : 22 Max age : 48	. Normal : 13 (86%) . Dry : 2 (14%)	2 (14%)	27.37 ± 2.53	1 (6%)

8.2. Experimental measurements

Results of the means and standard deviations of individual measurement data of abdomen, buttock, and thigh perimeter in centimetres and the weight in kilograms at D1 and D14 of applications of the vibrator belt application are presented in the table II of appendix. Statistical differences are also noted. No spontaneous complementary remarks have been made by the technician.

8.3. Appraisal of cutaneous acceptability of the investigational product by the volunteers

After 2 weeks of application of the product, the volunteers have not observed any indicative sign of intolerance.

However 9 volunteers indicated have observed, during the study, the clinical following signs:

Vol. n°	Kind of reaction	Intensity	Location	Duration	Period de appearance
02	Prickling	Very slight	Legs, buttocks and abdomen.	While I have the belt worn	During all the study
03	Prickling and redness	Slight	abdomen	10 minutes	After each application
04	Prickling and redness	Slight	abdomen	A seconds	The first week
06	Prickling	Very slight	Legs	30 minutes	After each application
08	Prickling and redness	Slight	Legs and abdomen	A seconds	After each application
09	Prickling and redness	Marked	abdomen	A minutes	After each application
13	Prickling and redness	Marked	abdomen	A minutes	After each application
14	Prickling and redness	Slight	abdomen	2 minutes	After each application
15	Prickling	Slight	Abdomen	2 minutes	The first days

8.4. Appraisal of the acceptability, efficacy and cosmetics qualities of the investigational product, by the volunteers

From the panellist's answers to the questionnaire filled in after 2 weeks of study, a majority of positive answers were revealed for the following criteria (in % of panellist's subjects questioned):

. pleasant to very pleasant product	74%
. product suitable for the volunteer's skin type	87%
. pleasant to very pleasant sensations	60%
. seem comfortable modify the velocity of vibration	93%
. no sensation of oppression	100%
. no sensation of excessive hot	100%
. skin is more firm	54%
. sensation of relax	73%
. product very good to good	54%
. comfortable to use	82%
. easy of use	100%
. effective to reduce volume	67%
. to recommend to family o friend	73%
. figure of the body is more redesigned	73%
. reduction of accumulations of localized fatty	74%
. reduction of volume	73%
. purchase intention	53%

A more moderate evaluation was attributed to the following criterion:

. skin is more elastic	27%
. skin is more smooth	34%
. skin is more moist	13%
. skin is more tonic	27%
. skin texture has improved	40%
. reduction of skin orange aspect	47%

9. CONCLUSION

Homogeneity of variance and normality of distribution verified the all of cases.

* MESURES OF WEIGHT (n=15)

It has been observed a statistically significant decrease of the weight of 0.91 kg after of 2 weeks of applications of the investigational product, with regard to the initial values.

	D1	D14	Δ D1-D14 days	Probabilidad p : efecto producto “ t “ de student
Weight (kg)	76.67 ± 9.75	75.77 ± 9.82	0.91 ± 0.75	0.009

In grey: probability p (Paired Student "t" test, "two-tail", signification: $p < 0.05$) above the differences (ΔD1 –D14 days).

* CENTIMETRIC MEASUREMENTS (n=15)

→ At thighs level

It has been observed a statistically significant decrease of the thighs perimeter of 1.12 cm after of 2 weeks of applications of the investigational product, with regard to the initial values.

→ At buttocks level

It has been observed a statistically significant decrease of the buttocks perimeter of 2.12 cm after of 2 weeks of applications of the investigational product, with regard to the initial values.

→ At abdomen level

It has been observed a statistically significant decrease of the abdomen perimeter of 2.43 cm after of 2 weeks applications of the investigational product, with regard to the initial values.

	THIGH (cm)	BUTTOCKS (cm)	ABDOMEN (cm)
D1	62.10 ± 5.72	103.75 ± 7.20	95.20 ± 7.28
D8	60.98 ± 5.49	101.63 ± 6.92	92.77 ± 7.28
Δ D1 –D14 days	1.12 ± 0.90	2.12 ± 1.29	2.43 ± 1.07
Probability p: reducing effect Student “ t “ test	0.00	0.00	0.00

In grey: probability p (Paired Student "t" test, "two-tail", signification: $p < 0.05$) above the differences (ΔD1–D14 days).

In conclusion, the applications of the product “VIBRA TONE” during 2 weeks, under normal conditions of use, by 15 volunteers of both sexes, with ages between 22 and 48 years, and a BMI between 24 and 30, have shown a statistically significant decrease of the weight and thigh, buttocks and abdomen perimeter, as regard to the initial values.

APPENDIX

TABLE I

VOLUNTEERS' CHARACTERISTICS

<i>Vol N° 01, 02,...</i>	<i>Sex M or F</i>	<i>Age</i>	<i>Body Skin Nature (1)</i>	<i>Initial Weight (Kg)</i>	<i>Height (m)</i>	<i>BMI</i>
01	F	38	Dry	64	1.64	23.80
02	F	22	Normal	70.4	1.6	27.50
03*	F	25	Normal	63.4	1.6	24.77
04(s)	F	45	Dry	63.3	1.6	24.73
05*	F	44	Normal	73.9	1.59	29.23
06	F	42	Normal	76.3	1.58	30.56
07	F	48	Normal	77.1	1.7	26.68
08	F	22	Normal	95	1.73	31.74
09	F	44	Normal	73.5	1.66	26.67
10	M	45	Normal	81.6	1.765	26.19
11*(s)	M	43	Normal	83.6	1.83	24.96
12	M	31	Normal	72.4	1.7	25.05
13	M	29	Normal	92.1	1.73	30.77
14	M	35	Normal	86.3	1.72	29.17
15	M	42	Normal	77.2	1.64	28.70
MEAN				76.67	1.67	27.37

* : "atopic" volunteer

(s): sensitive

TABLA II

MEASURES OF WEIGHT, CENTRIMETRIC MEASUREMENTS
(mean and standard deviation as regard the mean – S.E.M. – n=15)

VOL.	WEIGHT (Kg)			THIGH (cm)			BUTTOCKS (cm)			ABDOMEN (cm)		
	D1	D14	D1-D14	D1	D14	D1-D14	D1	D14	D1-D14	D1	D14	D1-D14
1	64	63.4	0.6	59	57.5	1.5	94.2	93.5	0.7	95	92	3
2	70.4	68.3	2.1	66	63.5	2.5	113	109	4	92	91	1
3	63.4	62.8	0.6	64	61.5	2.5	102.5	98.5	4	79.5	76	3.5
4	63.3	61.8	1.5	56	55.5	0.5	96	92.5	3.5	94	91.5	2.5
5	73.9	74.3	-0.4	64	63.5	0.5	107	104	3	102	97.5	4.5
6	76.3	74.3	2	66	64.5	1.5	109	105.5	3.5	94	90.5	3.5
7	77.1	76.4	0.7	65	62	3	101.5	100.5	1	93	90.5	2.5
8	95	94.6	0.4	76	75	1	122	120	2	113	109.5	3.5
9	73.5	72.8	0.7	68	67.5	0.5	108	107	1	96	93.5	2.5
10	81.6	81.4	0.2	57	56.5	0.5	100	97.5	2.5	94.5	92	2.5
11	83.6	82.5	1.1	55.5	54.8	0.7	101.5	99	2.5	94	92.5	1.5
12	72.4	71	1.4	56.5	55.5	1	97.5	96.5	1	88.5	86.5	2
13	92.1	90.1	2	62.5	62	0.5	104.5	102.5	2	96.5	95	1.5
14	86.3	85.9	0.4	59	59	0	101	101	0	103	102.5	0.5
15	77.2	76.9	0.3	57	56.4	0.6	98.5	97.4	1.1	93	91	2
MEAN	76.32	75.77	0.91	62.10	60.98	1.12	103.75	101.63	2.12	95.20	92.77	2.43
St. Dev.	10.02	9.82	0.75	5.72	5.49	0.90	7.20	6.92	1.29	7.28	7.28	1.07
P**	-	-	0.009	-	-	0.000	-	-	0.000	-	-	0.000

*statistically significant difference

**p: probability determined by T Student test ($p < 0.05$)

FIGURA I

APPRAISAL OF THE INVESTIGATIONAL PRODUCT BY VOLUNTEERS AFTER 2 WEEKS OF APPLICATIONS

