

ABSTRACT

CLINICAL/INSTRUMENTAL STUDY

**Evaluation of anti-wrinkle and anti-ageing
Efficacy of an aesthetic treatment for skin
By 42 Collagen Bodywave**

**Study carried out at FARCODERM
In co-operation with
UNIVERSITY OF PAVIA**

COLLAGEN BODYWAVE / Vita Skin Booster

**QUADRA
MEDICAL srl**



KEY PERSONNEL

Cliente / Customer

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Centro di Dermo Cosmesi per il benessere / Dermocosmesis Wellness Center

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Light Therapy

Professional light therapy innovation.

Light therapy is process in which a specific wavelength of light is projected onto the skin. The light causes chemical reactions in the target area, which excite cells to increase cellular performance, and could be useful for treat skin aging, rejuvenate skin, eliminate acne and skin spots. The key to light therapy is the wavelength of light, as different colours (wavelengths) produce different chemical reactions within the cells increased cellular activity in specific cells [1].

Originally **discovered by NASA** about 40 years ago to stimulate plant growth [2]. Red Light Therapy was also found to encourage cell repair and healing of injuries incurred by astronauts while in space. Even in a zero gravity environment, where cell growth is normally very slow, this red light energy was shown to stimulate the metabolism in muscle and bone as well as skin and subcutaneous tissue.

Recently, Quadra Medical introduced a new treatments which rely on the therapeutic effects of light at wave-lengths of visible light. Light therapy has shown strong efficacy for the treatment of wrinkles, sun damage, uneven skin tone, rosacea and inflammatory acne, because have the ability to increase energy inside cells which helps to speed up the healing process [3-7].

Light Therapy is safe, **non-invasive**, and no post-treatment is required. It **does not emit any ultraviolet rays**, nor does it cause dryness or discomfort.

Red light therapy (633nm)

Improving skin quality.

Red light (wavelength of 633nm) is able to penetrate the skin to a depth of 8 – 10mm. This penetration triggers the body to make collagen and elastin, and to generate new capillaries. The result of **more collagen and elastin is firmer, tighter-looking skin**, and the result of new capillaries is **more circulation, which increases wound-healing and scar tissue reducing benefits**. The complete action of the Red Light are:

1. **Increases circulation and the formation of new capillaries [8]**. This brings an **immediate healthy glow** to the skin, and paves the way for you to maintain a more youthful and healthier appearance, as new capillaries mean more oxygen and nutrients to each skin cell every day.

2. **Increases lymph system activity**. This reduces swelling and puffiness. These results would also be noticed after the first and each subsequent treatment. Again, this paves the way for less puffiness in the future as the lymph system is actually made more efficient over time, resulting in healthier skin overall.

3. **Stimulates the production of collagen and fibroblasts**. Collagen is what is responsible for the elasticity, firmness, and fullness of your skin. The increased production of collagen and fibroblasts is what will smooth out your fine lines and wrinkles, smooth the texture of the skin, and reduce pore size over time. **Collagen cells grow slowly, so be patient, and expect to see “before and after” results at about three months of consistent treatment.**

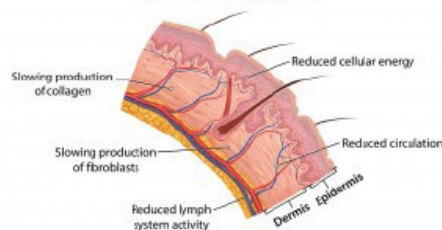
4. **Causes the release of ATP, or raw cellular energy**. This provides energy to the cells to make the most of the additional blood, oxygen, nutrients, detoxification, growth, and repair already initiated by your red light therapy treatments.

Red Light Therapy result

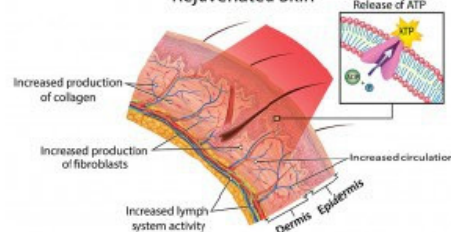
Red Light Therapy is extremely effective for:

- Anti-aging: stimulation of collagen and elastin fibres in the deeper layers of the dermis gives a visible smoothing effect on wrinkles, plumps the skin and improves skin elasticity, suppleness and firmness
- Creates a healthy glow about your face
- Smooths overall skin tone
- Speeds the healing of blemishes, like acne [9] and rosacea
- Reduces redness, flushing, and broken capillaries
- Fades scars and stretch marks
- Brings more moisture to your skin

Stressed or Aging Skin



Rejuvenated Skin



Light Therapy skin treatment is safe

The light therapy is non-invasive, non-abrasive, does not cause skin inflammation and does not require any special post treatment procedures. It is recommended that protective goggles be used during treatments for precautionary reasons. If you accidentally look at the neon tubes, no harm will be done but never stare into the direct line of light for extended intervals of time.

The red and green light therapy is considered a safe, easy and gentle skin rejuvenation and whitening technology however the following precautions should always be taken:

- Do not use if pregnant, epileptic or taking cortisone or steroid injections
- Do not use on open sores, wounds or infected areas

Light therapy has been **thoroughly researched and proven to be safe and effective** by hundreds of studies all over the world.

In fact **FDA**, said that **“Red Light”** at 633nm and **“Green Light”** at 525 nm have a **“non-significant risk”** status and is completely safe for the eyes.

Study of two-year clinical trial of NASA evidenced that the red light could improving also the lives of cancer patients [11].

How long last the results?

Results vary depending on the skin type, and depending on the age, the length of treatment and the original conditions being treated. Skin rejuvenation is a dynamic process. If maintenance treatments are discontinued, natural expression lines will gradually return over the course of time, at which point re-treatment can be put in place.

However the following is a guideline for the frequency of exposure and corresponding expected results both for 42 Collagen BodyWave and 42 Whitening BodyWave:

Age	Frequency	Best Results At	Maintenance
25 - 35	2 times per week	3-6 weeks	1 time per month
35 - 55	2 times per week	4-8 weeks	1 time per month
55 +	2 times per week	8 weeks	1 time per month

Vibration Plate

Beauty Vibro Plate^{PLUS} is a new generation pulsating vibration plate.

The plate alternates between working time with resting time, just like a workout at the gym for better results. From the pulsating vibration plate of the oscillation Beauty Vibro Plate plus bone structures are strengthened, the burning of calories is increased, the central and peripheral nervous system is stimulated, there is an increase in the secretion of certain important hormones.

The oscillating programs are 3:

- . Anticellulite (Anticell)
- . Slimming (Slim)
- . Toning (Toning)



Scientific and experimental testing [12-13-14-15] demonstrated that the vibrating plates, in particular the **BEAUTY VIBRO PLATE^{PLUS}** with pulsating vibration is extremely efficient in giving:

- increased peripheral micro-circulation
- improved lymphatic drainage
- oxygenating and revitalizing of the connective tissue
- strengthening of the bone structure
- increased secretions of some important hormones
- increased metabolism and the burning of calories
- stimulation to the central and peripheral nervous system

There are 3 procedures in the treatment: Anticell, Slimming and Toning. They are sessions of oscillating pulsating frequency.

ANTICELL

From the very first exercise the vibrations at low pulsating frequency emitted by the oscillating plate guarantee:

- a feeling of wellbeing thanks to the messaging effect to the spinal cord and large muscle groups
- an increase of the peripheral microcirculation
- an effective treatment to combat cellulite

SLIMMING

The vibrations medium pulsating frequency emitted by the oscillating plate give:

- a physical workout will consequent calorie burning
- a slimming workout specifically for buttocks and thighs
- an increase of the basal metabolism which contributes to the breaking down of accumulated adipose fat.

TONING

The vibrations at a more elevated pulsating frequency emitted by the oscillating plate allows:

- a more rapid muscle use
- increased strength and toned and reenergized feeling
- intense workout
- a better blood circulation

Cosmetic product for Light Therapy

Light Activator

Light Activator enhances the penetration of Red Light at 633nm (Collagen Light Therapy) and Green Light at 525nm (Whitening Light Therapy) into the skin. Improves skin quality and gives a new vitality to the skin by promoting the production of collagen and elastin while inhibits the production of melanin. It is developed for both the treatments.

Direction for use: apply on clean skin before each session of Light Therapy. Spray from a distance of 20 centimetres on the face, neck, décolleté and in all the body. It is very important for obtain good result. Please remember to includes this product in a complete program.

ACTIVE INGREDIENTS:

Oxi 229-BT: activates and reactivates the tissutal regeneration connected to the light Therapy through a significant stimulation of cell respiration and has a soothing action on the skin.

Arbutin: more effective, faster, and safer approach to promoting skin lightening and an even skin tone on all skin types. Arbutin blocks epidermal melanin biosynthesis by inhibiting enzymatic oxidation of tyrosine and minimizes liver spots.

Matrixyl™: a revolutionary ingredient to fight wrinkles, it reduces the appearance of wrinkles. It stimulates fibroblasts to synthesize collagen, elastin, fibronectin and glycosaminoglycans, restoring skin pattern and epidermal-dermal junction to reduce wrinkles.

Hyalo-oligo™: it covers skin surface avoiding dermal water loss and above all deeply penetrates into the horny layer of your skin, moisturising it from inside and filling wrinkles and lines in a visible way.

Kombuchka: with "lipofilling" effect it offers a non-invasive natural way to smoother, younger, more radiant skin; it protects the integrity of collagen and elastin which are essential for maintaining youthful skin.

Liftensyl®: tightening "Flash Effect". Immediate efficacy of the reduction of visible wrinkles and fine line, plus the sensation of comfort and softness.

Vitamin E: the best anti-oxidant, anti-radicals, derma-protective, hydrating. It is also used for its anti-age properties. The cellular membrane avoids oxidative degradation of fat acids which are the base of the same membranes.

Vitamin C: helps collagen synthesis, the protein penetrates into the deepest levels of the skin providing plasticity to tissues. Also elastic and refreshing effect.

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AIM OF THE STUDY

The aim of this study is to evaluate the *anti - wrinkle* and *anti - ageing* efficacy of a specific aesthetic total body treatment by vertical equipment **42 COLLAGEN BODYWAVE**.

In order to reach this goal the following skin parameters were measured:

- Skin moisturizing;
- Skin elasticity;
- Skin profilometry;
- Digital photo;
- Clinical evaluation

METHOD DESCRIPTION

The study is performed as follows:

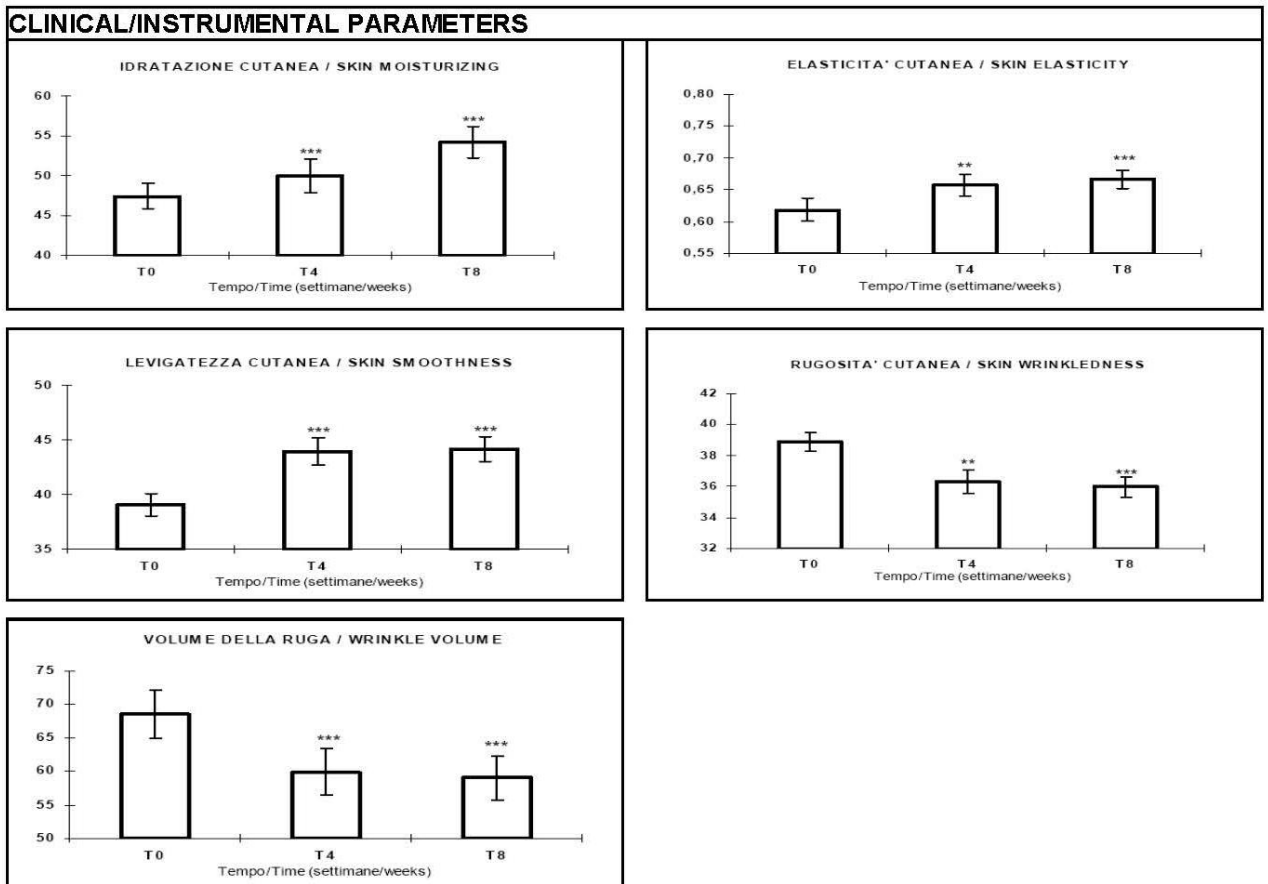
- enrolment of 20 female subjects aged between 40 and 60 years who were divided into two experimental groups:
 - GROUP A - 10 subjects who used 42 COLLAGEN BODYWAVE
 - GROUP B - 10 subjects who used 42 COLLAGEN BODYWAVE in association with daily application of VITA SKIN BOOSTER ELIXIR e VITA SKIN BOOSTER CREAM;
- Evaluation of the treatment efficacy using the vertical equipment 42 COLLAGEN BODYWAVE by red light ($\lambda= 633\text{nm}$). The treatment **includes 3 sessions of 15'** each during 8 weeks;
- Evaluation of the clinical/instrumental parameters after **4 and 8 weeks of treatment**. The monitored area is: face skin.

RESULT OF CLINICAL/INSTRUMENTAL PARAMETERS

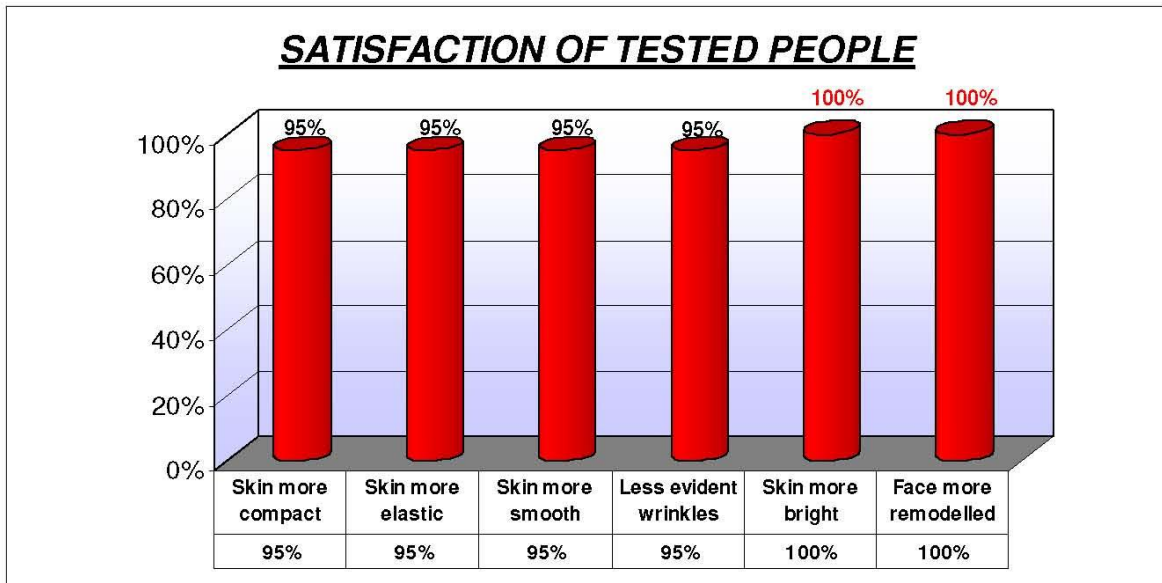
All of clinical/instrumental parameters evaluated, **skin moisturizing, skin elasticity, skin smoothness, skin wrinkleless and skin volume**, have underline a **very good improvement** after the full treatment by 42 COLLAGEN BODYWAVE in association with the cosmetics products VITA SKIN BOOSTER ELIXIR e VITA SKIN BOOSTER CREAM

PARAMETRI STRUMENTALI / INSTRUMENTAL PARAMETERS	T4	T8
idratazione cutanea % vs T0 skin moisturizing % vs T0	19,3%	24,7%
elasticità cutanea % vs T0 skin elasticity % vs T0	8,2%	10,3%
levigatezza cutanea % vs T0 skin smoothness % vs T0	11,7%	15,1%
rugosità cutanea % vs T0 skin wrinkleness % vs T0	-6,4%	-7,0%
volume della ruga % vs T0 wrinkle volume % vs T0	-19,7%	-20,2%

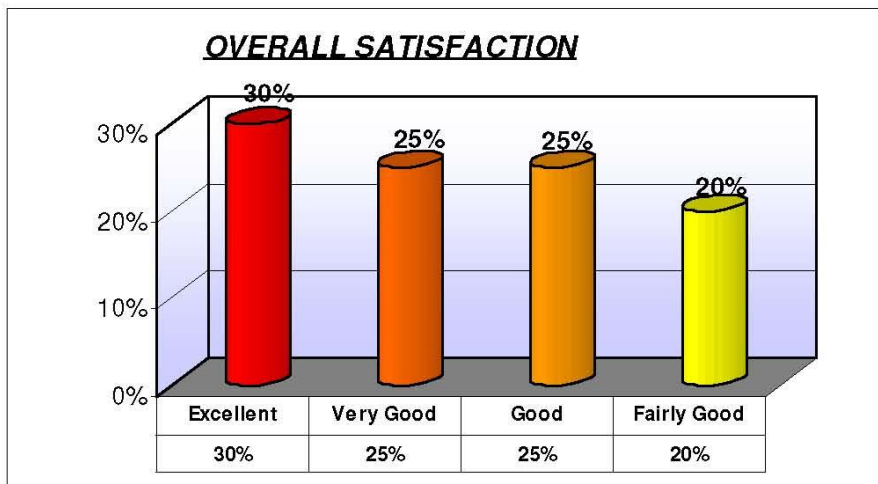
The charts below, illustrate the variation of clinical/instrumental parameters in 3 different time, before the treatment (T0), after 4 weeks (T4) and at the end (T8). Respect the start condition all the parameters show a **positive variation highly significant** express by 3 stars, that are the maximum possible result.



SUBJECTS EVALUATION RESULT



All people tested expressed an extremely positive opinion regarding the **improvement of skin compactness, skin elasticity, skin smoothness** and regarding the **reduction of skin wrinkle**. **100% of the subject indicated that their skin is brighter and their face reshaped and younger.**



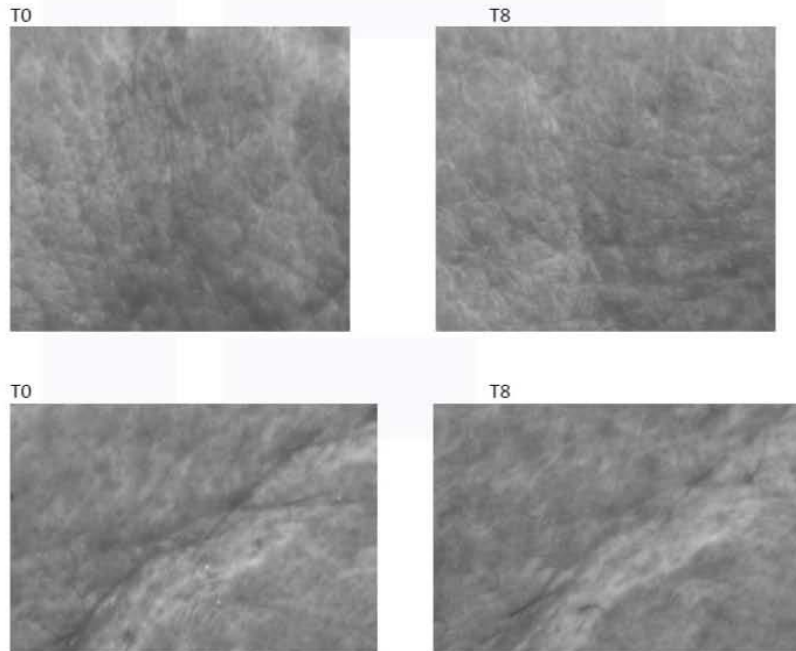
The final satisfaction of all subjects at the end of the treatments expressed in terms of judgement a very good value:

- **30% EXCELLENT**
- **25% VERY GOOD**
- **25% GOOD**
- **20% FAIRLY GOOD**

VISIBLE RESULT

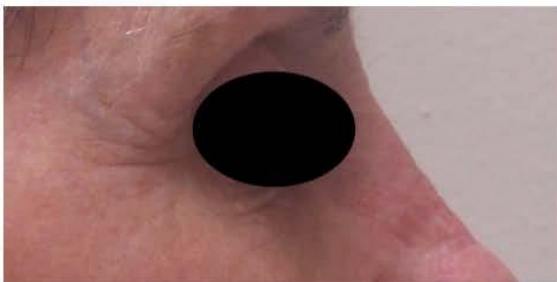
The Visioscan images report skin surface before and after the treatments 42 COLLAGEN BODYWAVE in association with VITA SKIN BOOSTER ELIXIR e VITA SKIN BOOSTER CREAM.

As you can note the skin appears more lifted and the wrinkles attenuated.



The images show the results of 8 weeks 42 COLLAGEN BODYWAVE treatment in association with daily application of VITA SKIN BOOSTER ELIXIR e VITA SKIN BOOSTER CREAM treatment. **As you can notice there is both a positive effect in the reduction of wrinkles visibility and an aesthetic improvement of the skin face that appears more smoothed, compact and brighter.**

T0 (Before the treatment)



T8 (After 8 weeks of treatment)



T0 (Before the treatment)



T8 (After 8 weeks of treatment)



CONCLUSION

The instrumental and clinical data show the efficacy of both treatments (group A: 42 COLLAGEN BODYWAVE and group B: 42 COLLAGEN BODYWAVE in association with VITA SKIN BOOSTER ELIXIR E VITA SKIN BOOSTER CREAM) in the improvement of the **skin trophism as showed by the improvement in skin moisturization and elasticity.**

The **skin appears more compact** and the wrinkles are attenuated.

The efficacy of the treatment in the skin wrinkledness is confirmed by the subjects participating in the study (GROUP A and GROUP B) that have judged it good.

The skin appearance is improved after the treatment: skin appears **more compact and brighter.**

Further observations:

- No anti-aging equipment in the market is based on a scientific study so complete and depth, carried on by a well-known institution like FARCODERM, in co-operation with Pavia University.
- No anti-aging equipment in the market has proven so clear results, positive and consistent in terms of:
 - instrumental analysis
 - perception of the participants in the study
 - the proceedings of the dermatologist who has seen the participants in the study
 - photographic vision
- All the people have found the treatment very pleasant and commitment to conduct all meetings required by the study is considered appropriate having regard to the results obtained and the degree of satisfaction achieved by the end of treatment.
- All the subjects appreciated the technological innovation that characterizes 42 COLLAGEN BODYWAVE.
- The study highlights the non-invasive treatment and the absence of side effects during or after treatment. All 20 people have completed treatment.
- The only equipment in the industry to carry on a Treatment which is at the same time Total Body, Anti-aging and slimming at once and automatically, without any operator. It works effectively on wrinkles, face, décolleté, hands, feet and stretch marks.

Reference:

- [1] E. M. Vinck, B. J. Cagnie, M. J. Cornelissen, H. A. Declercq, and D. C. Cambier, *Laser Med. Sci.* 18, 95 (2003) [DOI: 10.1007/s10103-003-0262-x].
- [2] Effect of NASA light-emitting diode irradiation on wound healing. *J Clin Laser Med Surg.* 2001 Dec; 19(6):305-14.
- [3] Light-emitting Diode Phototherapy at 630nm Increases Local Levels of Skin-homing T-cells in Human Subjects, Shin-ichiro Takezaki et al.: *Nippon Med Sch* 2006; 73 (2) -
- [4] The Photobiology of LED Phototherapy. R. Glen Calderhead, MSc, DrMedSci, FRSM.
- [5] NASA space technology shines new light on healing. *Marshall Star* Vol. 41/No. 16
- [6] The NASA Light-Emitting Diode Medical Program, Progress in Space Flight and Terrestrial Applications Harry T. Whelan, M.D. et al.
- [7] Laser Photostimulation of collagen production in healing rabbit Achilles tendons. G. Kesava Reddy et al.
- [8] <http://www.ncbi.nlm.nih.gov/pubmed/?term=LLLT+OR+Low+level+laser+therapy+OR+Photobiomodulation+AND+circulation>
- [9] Red Light LED Phototherapy for Acne Vulgaris in Patients with Skin Phototype IV. Seung Yoon Lee, MD, Chung Eui You, MD, and Mi Youn Park, MD, PhD
- [10] Wound Healing Effect of 525 nm Green LED Irradiation on Skin Wounds of Male Sprague Dawley Rats. Min-Woo Cheon and Yong-Pil Park Department of Biomedical Engineering, Dongshin University, Naju 520-714, Kore
- [11] <http://www.nasa.gov/topics/nasalife/features/heals.html>
- [12] The effects of vibration loading on adipose stem cell number, viability and differentiation towards bone-forming cells. *J. R. Soc. Interface* (2011) 8, 1736–1747 doi:10.1098/rsif.2011.0211
- [13] Vibration Exposure and Biodynamic Responses during Whole-Body Vibration Training. ANDREW F. J. ABERCROMBY, WILLIAM E. AMONETTE
- [14] VibroRollage: effects of vibrations on aesthetical problems caused by cellulite to improve psycho-physical balance Studies from Preventive Medicine Dpt. of the "Second University" Naples. 2003
- [15] Cellulite: evaluations on different methodologies of treatment. Abstract from EMEA Paris 2005 A.M. Forenza MD

Documents



QUADRA MEDICAL srl



DICHIARAZIONE DI CONFORMITA'
DECLARATION OF CONFORMITY

Il sottoscritto, rappresentante il seguente costruttore
The undersigned, representative of the following manufacturer

"QUADRA MEDICAL srl"
Via Strada Cartigliana, 143/B – 36061 Bassano del Grappa (Vi) – ITALY

DICHIARA che l' apparecchiatura descritta in appresso:
DECLARES that the product:

Descrizione: **Apparecchiatura verticale per il trattamento estetico della pelle**
Modello: **42 COLLAGEN BODYWAVE**

Description: **Vertical unit for skin aesthetical treatment**
Model: **42 COLLAGEN BODYWAVE**

è conforme alle disposizioni legislative che traspongono le seguenti Direttive:

- direttiva 2004/108 CE (Direttiva EMC) e successivi emendamenti
- direttiva 2006/95 CE (Direttiva Bassa Tensione) e successivi emendamenti

is in accordance with the following Directives:

- 2004/108 EC Directive (EMC Directive) and subsequent amendments
- 2006/95 EC Directive (Low Voltage Directive) and subsequent amendments

e che sono state applicate tutte le norme e/o specifiche tecniche di seguito indicate
and that all the following standards have been applied

- EN 55015 2000-08 - EN 55015/A1 2001-12 - EN 55015/A2 2002-10
- EN 61000-3-2: 2006-04
- EN 61000-3-3: 1995-01 - EN 61000-3-3/A1: 2001-06 - EN 61000-3-3/A2/IS1: 2005-11
- EN 61547: 1995-09 - EN 61547/A1: 2000-12
- EN 60335-2-27 - EN 60335-2-27/A1 - EN 60335-2-27/A2

Ultime due cifre dell'anno in cui è affissa la marcatura CE: **09**
Last two figures of the year of the CE marking:

Luogo: **Bassano del Grappa (Vi) - Italy**
Place

Data: **09 / 02 / 2010**
Date

Il Presidente

The CEO

Sig./Mr. Fabio Durighel



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Patent

Minutes of Filing
Patent Application
For INDUSTRIAL INVENTION

Number of request: TV2010A000082

CCIAA of deposit: TREVISO

Date of deposit: 03/06/2010

DESCRIPTION

Technical field of the invention

The invention is related to a device for skin treatments for aesthetic or medical use. Apparatus for the treatments of skin thought bio-stimulation by means of radiation, comprising one or more low or high pressure discharge emitters of Visible incoherent light without UV components which are adapted to irradiance the skin to Bio-stimulated it.

Protocollo n°/Record no°:	FU.04.C.L_2009/150
data/date:	30/04/2009

Allegato 3

SCHEDA INFORMATIVA



Gent.le Signora,

La invitiamo a partecipare ad uno studio finalizzato a valutare l'efficacia anti-rughe di un trattamento estetico (42 COLLAGEN BODYWAVE).

Dear Mrs.,

we invite You to take part to a study aimed at evaluating the anti-wrinkle efficacy of a aesthetic treatment 842 COLLAGEN BODYWAVE).

Rischi e Benefici / Risks and Benefit

RISCHI - Tutti i prodotti da sottoporre a studio sono stati valutati per la loro sicurezza d'uso su soggetti umani. Al meglio delle nostre conoscenze non ci si attendono rischi di media/grave entità.

BENEFICI - È possibile che durante lo studio Lei registri un miglioramento (ad es. diminuzione della visibilità delle rughe, aumento dell'idratazione cutanea) della cute del viso. La informiamo sin da adesso della temporaneità dei risultati (se ottenuti).

RISKS - The product to be tested was evaluated for its safety of use by human subjects. To the best of our knowledge no side effects of medium/serious degree are expected to occur.

BENEFIT - It is possible that during the study period You can notice an improvement of the skin conditions (for example: decrease of wrinkle visibility, increase of skin moisturizing). We inform You about the temporaneity of the results (if obtained).

Modalità d'uso/applicazione dei prodotti / Products' use/application

VITA SKIN BOOSTER ELIXIR: applicare, massaggiando fino ad assorbimento al mattino sulla cute deterosa ed asciutta del viso.

VITA SKIN BOOSTER CREAM: applicare, massaggiando fino ad assorbimento al mattino e alla sera sulla cute deterosa ed asciutta del viso.

VITA SKIN BOOSTER ELIXIR: apply on the face with a soft massage until the product is completely absorbed, once a day, in the morning .

VITA SKIN BOOSTER CREAM : apply on the face with a soft massage until the product is completely absorbed, twice a day, in the morning and evening.

Confidenzialità dei dati clinici / The clinical data are strictly confidential

E' possibile che durante o al termine dello studio, funzionari della Società che ha promosso lo studio o funzionari delle Autorità Sanitarie debbano esaminare la sua cartella clinica.

Questi risultati potranno anche essere pubblicati. In ogni caso Lei non sarà mai indicato per nome se non assolutamente necessario e che anche in questo caso solo a persone soggette, come noi, al segreto professionale. Tutte le informazioni che saranno raccolte in questo studio resteranno comunque del tutto confidenziali e Lei non potrà essere identificato da queste informazioni.

During or at the end of the test the promoters of the survey or some Health officers may have to examine your case file. The results could also be published . In any case your name will never be mentioned, unless if absolutely necessary and also in this case only to people - who like us - are subject to professional secrecy. All information gathered in the survey will remain strictly confidential and you won't be identified from it.

Cosa succederà se lei dovesse decidere di non partecipare allo studio? / What happens, if you decide not to take part in the test?

La Sua decisione di prendere parte a questo studio deve essere assolutamente volontaria, non deve sentirsi in nessun modo obbligata a partecipare.

Se Lei decidesse di non partecipare allo studio non andrà incontro a nessun provvedimento da parte nostra né perderà alcuno dei benefici che le sono stati garantiti. Se Lei dovesse interrompere il trattamento prima del termine dello studio non andrà incontro a nessun provvedimento da parte nostra né perderà alcuno dei benefici che le sono oggi garantiti.

Tuttavia, in caso Lei decidesse di interrompere lo studio, Le chiediamo di informare rapidamente il suo medico.

Da parte nostra ci riserviamo la facoltà di sospendere il trattamento nel qual caso i controlli clinici dimostrassero che non Le sta giovando i benefici attesi.

Your decision to take part in the test must be absolutely voluntary, you must not feel forced to. If you decide not to take part, you will neither run into any inconvenience nor lose any benefit which you enjoy at the inclusion time. If you decide to interrupt the treatment before its end, you can do it any time and you will neither run into any inconvenience nor lose any benefit you enjoy now. However, if you decide to interrupt it, you should inform your physician promptly. We ourselves reserve the right to interrupt the test if we detect it isn't good for you.

Lei ha il diritto di porre le richieste di chiarimento che ritiene opportune, sia ora che durante tutto il periodo di studio, rivolgendosi direttamente a:

You can ask for an explanation before, during and after the treatment directly to:

Dottor / Specialist _____ Telefono / Phone _____

che la seguirà per tutta la durata dello studio
who will attend you throughout the treatment

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Protocollo n°/Record no°:	FU.04.C.L_2009/150
data/date:	30/04/2009

-
- ▶ Il risultato del test citato nel presente rapporto si riferisce esclusivamente al prodotto testato ed alle particolari condizioni sperimentali impiegate nel test.
 - ▶ The result(s) cited in this present report only refer(s) to the tested sample and to the particular experimental conditions hereby described.
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