

## **ABSTRACT CLINICAL/INSTRUMENTAL STUDY**

**Efficacy evaluation of an aesthetic treatment  
For brightening skin tone and skin spots  
By 525 Whitening Bodywave**

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

**WHITENING BODYWAVE / Nano Spray / Home Use**

**QUADRA  
MEDICAL srl**



Protocollo n°/Record no°: **FU.04.C.L\_2009/150**data/date: **30/04/2009**

## KEY PERSONNEL

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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.

## Green light therapy (525nm)

*Improving skin Brightening.*

Whitening Light Therapy Technology is designed to **reduce hyper-pigmentation and sun damage**, giving the feel and appearance of a **softer, even-toned, brighter more luminous complexion [10]**. The light at 525nm penetrate into the basal layer of the dermis. It therefore helps lighten freckles and age spots promoting an overall clear and radiant skin.

Green light affects the melanocytes (the cells that produce the melanin, which is the pigmentation in the bottom layer of the epidermis), reducing its production. Over time, spots simply fade away for a younger looking, rejuvenated, and more even complexion.

### Green Light Therapy result

Green Light Therapy is extremely effective for:

- reduces Hyperpigmentation through penetration of the basal layer
- prevents the formation of freckles and evens out skin tone
- regulates melanin production and corrects age spots
- preventing the formation of new brown spots
- clear softer, more luminous looking skin
- eliminating the redness
- positive effect with regulating bacterial and sebaceous gland activity, both of which lead to acne.

## 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<sup>PLUS</sup> 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<sup>PLUS</sup>** 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

## **AIM OF THE STUDY**

The aim of this study is to reduce the skin's imperfections and the appearance of uneven pigmentation focalizing the efficacy of a specific aesthetic total body treatment by vertical equipment which emits green light at 525 nm **WHITENING LIGHT TREATMENT** and **PROFESSIONAL WHITE SPRAY & CARE TECHNOLOGY** (Biolight Lotion) and **BRIGHTENING MIRACAL LINE** (On The Go White, Luminescent Day, Luminescent Night, Luminescent Serum)

## **METHOD DESCRIPTION**

• The method used: 20 female subjects aged between 30 and 60 years who were divided into three experimental groups:

○ **GROUP B :**

- 7 subjects
- **WHITENING LIGHT TREATMENT** (by green light ( $\lambda = 525$  nm)), includes 3 sessions of 15' each during 8 weeks:

- **PROFESSIONAL WHITE SPRAY & CARE TECHNOLOGY** with Biolight Lotion includes 3 sessions after each session of **WHITENING LIGHT TREATMENT**, during 8 weeks.

Application : spray Biolight Lotion on the face, neck and also on the body, for give an immediate whitening effect. Dry well with the gun air option. Repeat the application if necessary.

- **BRIGHTENING MIRACLE LINE** ( On the go white , Luminescent day cream, Luminescent night cream, Luminescent serum)

Application : Morning : After cleansing every morning, apply Luminescent Serum on spot or darker area of eyes. Apply Luminescent Day then spray On The Go White all over face and neck.

Night : Use Luminescent Serum on spot area of eyes Then, use Luminescent night all over clean face and neck every night.

○ **GROUP B :**

- 7 subjects
- **WHITENING LIGHT TREATMENT** (by green light ( $\lambda = 525$  nm)), includes 3 sessions of 15' each during 8 weeks:

- **BRIGHTENING MIRACLE LINE** ( On the go white , Luminescent day cream, Luminescent night cream, Luminescent serum)

Application : Morning : After cleansing every morning, apply Luminescent Serum on spot or darker area of eyes. Apply Luminescent Day then spray On The Go White all over face and neck.

Night : Use Luminescent Serum on spot area of eyes Then, use Luminescent night all over clean face and neck every night.

○ **GROUP C:**

- 6 subjects
- **PROFESSION WHITE SPRAY & CARE TECHNOLOGY** with Biolight Lotion includes 3 sessions after each session of WHITENING LIGHT TREATMENTS. during 8 weeks.

Application : spray Biolight Lotion on the face, décolleté and also on the body, for give an immediate whitening effect. Dry well with the gun air option. Repeat the application if

necessary.

- **BRIGHTENING MIRACLE LINE** (On the go white , Luminescent day cream, Luminescent night cream, Luminescent serum)

**Application :**

Morning : After cleansing every morning, apply Luminescent Serum on spot or darker area of eyes. Apply Luminescent Day then spray On The Go White all over face and neck.

Night : Use Luminescent Serum on spot area of eyes Then, use Luminescent Night all over clean face and neck every night.

○ **GROUP D:**

- 6 subjects
- **BRIGHTENING MIRACLE LINE** ( On the go white , Luminescent day cream, Luminescent night cream, Luminescent serum)

**Application :**

Morning : After cleansing every morning, apply Luminescent Serum on spot or darker area of eyes. Apply Luminescent Day then spray On The Go White all over face and neck.

Night : Use Luminescent Serum on spot area of eyes Then, use Luminescent Night all over clean face and neck every night.



## **INSTRUMENTAL AND CLINICAL EVALUATION**

### **SKIN WHITENING - Clinical grades**

The Clinical evaluation was based on score report on 1-100 scale, the higher the scale the darker is the skin express by a dermatologist.

### **SKIN WHITENING – Instrumental coordinates CIELab**

Before the beginning of the treatment ( $T_0$ ), treated areas have been photographed with the instrument KODAK EasyShare Z740 digital camera MedicalSCOPE microcamera HR and acquisition software MedicalSCOPE v. 1.0.6 – company FastBrain Engineering srl Photographic monitoring of treated areas were repeated in subsequent periods of study ( $T_4$  e  $T_8$ ).

Pictures were subjected to computerized colometric analysis. The colour was expressed through system of coordinates CIELab through three numerical values:  $L^*$  (luminance),  $a^*$  (erythema),  $b^*$  (pigmentation), by software: Corel Photo-Paint X3, vers. 13.0.0.576

For evaluation of a whitening effect, we base our interpretation of 1 parameters:  $L^*$  (luminance): that represents the relative brightness from total darkness ( $L^*=0$ ) to absolute white ( $L^*=100$ )

### **CONSUMER EVALUATION – Questionnaire**

10 questions after 4 and 8 week of treatments, for understand the efficacy of the treatment.

### **PHOTOS – Face and spots**

## RESULT GROUP A

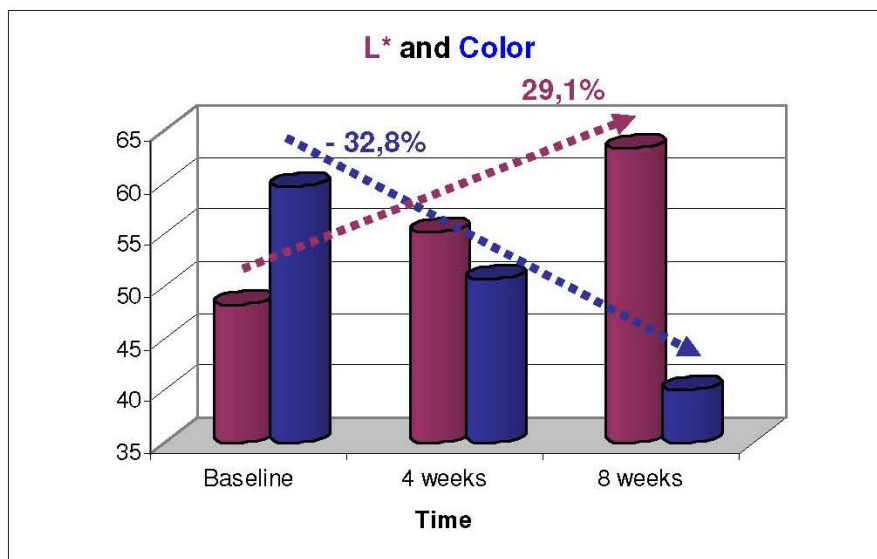
GROUP A	
3 TIMES A WEEK	WHITENING LIGHT TREATMENTS Green light ( $\lambda = 525 \text{ nm}$ )
3 TIMES A WEEK	PROFESSIONAL WHITE SPRAY & CARE TECHNOLOGY <b>BIOLIGHT LOTION</b>
2 TIMES EVERY DAY	HOME USE <b>ON THE GO WHITE</b> <b>LUMINESCENT DAY CREAM</b> <b>LUMINESCENT NIGHT CREAM LUMINESCENT SERUM</b>

### SKIN WHITENING – COLOR - Clinical grades




The results represented in the graph compare the whitening attribute of the complete treatment made for 2 month Clinical scores are reported on 1-100 scale, the higher the score the darker skin. As can be seen substantial change are observed after 4 weeks of treatment with a lightening of 14,8%. After 8 weeks even more whitening is observed with scores decreasing to 32,8% in skin darkness.

### SKIN WHITENING - coordinates CIELab

Objective measurements of change in skin color during the treatment were obtained on the face. A significant decrease in skin color was observed after 4 weeks and 8 weeks. After 8 weeks a 29,1% change was observed in L\* value. No significant in a\* and b\* values were observed indicating that the color change was a general lightening effect and did not result in increase irritation or change in green or red values in skin. The brighter is the skin, the higher are the L\* parameter.



## CONSUMER EVALUATION – Questionnaire

ATTRIBUTES	POSITIVE OPINION	
	After 4 weeks	After 8 weeks
Dull complexion is reduced	 89%	 97%
Yellowish appearance is reduced	 80%	 88%
The appearance of age spots is reduced	 75%	 85%
Evenness of skin tone	 79%	 91%
The skin looks more translucent	 76%	 95%
The skin looks brighter	 86%	 97%
The skin looks moisturized	 76%	 89%
The skin is smoother	 75%	 90%
The skin texture looks more refined	 78%	 87%
The treatments leaves a healthy looking skin	 82%	 95%

## PHOTOS – Face and spots



## RESULT GROUP B

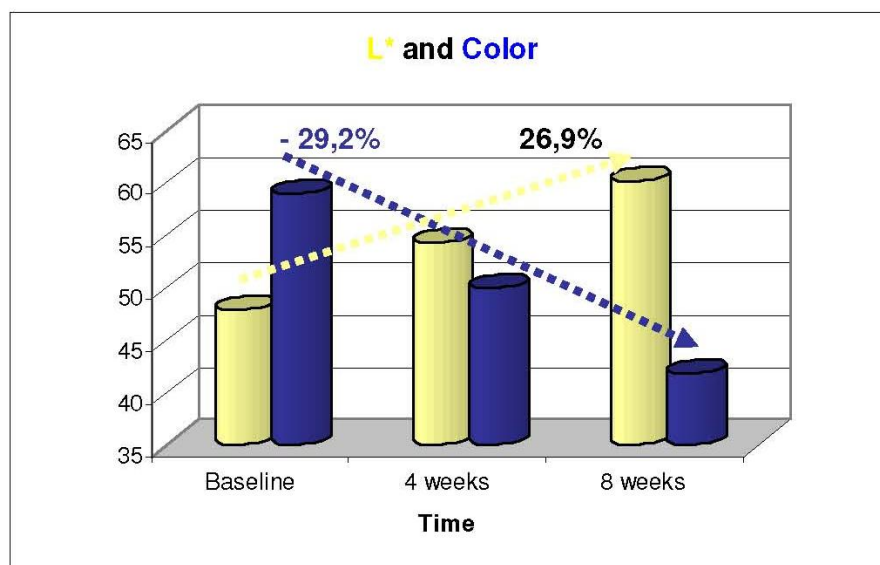
GROUP B	
3 TIMES A WEEK	WHITENING LIGHT TREATMENTS Green light ( $\lambda = 525 \text{ nm}$ )
2 TIMES EVERY DAY	HOME USE <b>ON THE GO WHITE</b> <b>LUMINESCENT DAY CREAM</b> <b>LUMINESCENT NIGHT CREAM</b> <b>LUMINESCENT SERUM</b>

### SKIN WHITENING – COLOR - Clinical grades

The results represented in the graph compare the whitening attribute of the complete treatment made for 2 month Clinical scores are reported on 1-100 scale, the higher the score the darker skin. As can be seen substantial change are observed after 4 weeks of treatment with a lightening of 15,28%. After 8 weeks even more whitening is observed with scores decreasing to 29,2% in skin darkness.





















### SKIN WHITENING - coordinates CIELab

Objective measurements of change in skin color during the treatment were obtained on the face. A significant decrease in skin color was observed after 4 weeks and 8 weeks. After 8 weeks a 26,9% change was observed in L\* value. No significant in a\* and b\* values were observed indicating that the color change was a general lightening effect and did not result in increase irritation or change in green or red values in skin. The brighter is the skin, the higher are the L\* parameter.





**CONSUMER EVALUATION – Questionnaire**

ATTRIBUTES	POSITIVE OPINION	
	After 4 weeks	After 8 weeks
Dull complexion is reduced	 86%	 92%
Yellowish appearance is reduced	 80%	 86%
The appearance of age spots is reduced	 75%	 83%
Evenness of skin tone	 75%	 89%
The skin looks more translucent	 70%	 90%
The skin looks brighter	 68%	 89%
The skin looks moisturized	 73%	 89%
The skin is smoother	 68%	 88%
The skin texture looks more refined	 67%	 79%
The treatments leaves a healthy looking skin	 74%	 95%

**PHOTOS – Face and spots**



# RESULT GROUP C

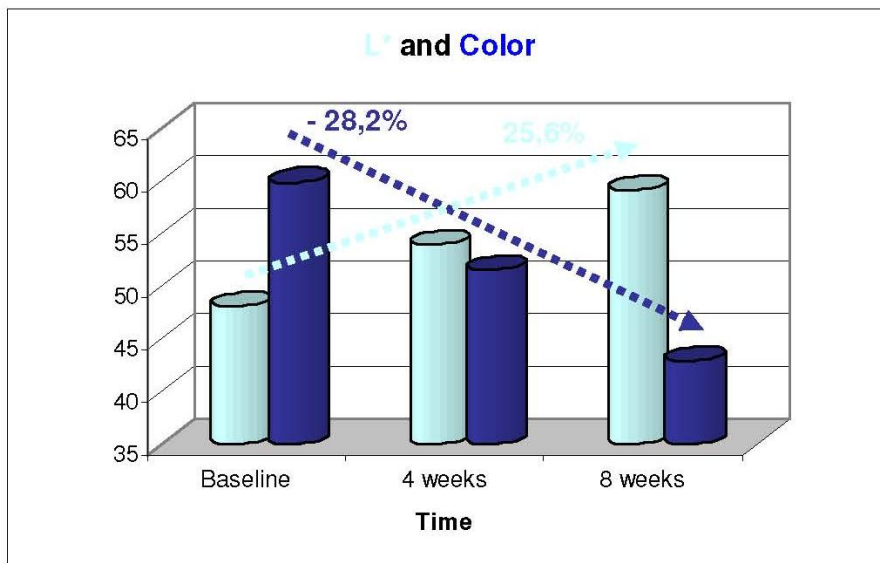
GROUP C	
3 TIMES A WEEK	PROFESSIONAL WHITE SPRAY & CARE TECHNOLOGY BIOLIGHT LOTION
2 TIMES EVERY DAY	HOME USE ON THE GO WHITE LUMINESCENT DAY CREAM LUMINESCENT NIGHT CREAM LUMINESCENT SERUM

## SKIN WHITENING – COLOR - Clinical grades

The results represented in the graph compare the whitening attribute of the complete treatment made for 2 month Clinical scores are reported on 1-100 scale, the higher the score the darker skin. As can be seen substantial change are observed after 4 weeks of treatment with a lightening of 14,1%. After 8 weeks even more whitening is observed with scores decreasing to 28,2% in skin darkness.












## SKIN WHITENING - coordinates CIELab

Objective measurements of change in skin color during the treatment were obtained on the face. A significant decrease in skin color was observed after 4 weeks and 8 weeks. After 8 weeks a 25,6% change was observed in L\* value. No significant in a\* and b\* values were observed indicating that the color change was a general lightening effect and did not result in increase irritation or change in green or red values in skin. The brighter is the skin, the higher are the L\* parameter.





## CONSUMER EVALUATION – Questionnaire

ATTRIBUTES	POSITIVE OPINION	
	After 4 weeks	After 8 weeks
Dull complexion is reduced	 84%	 90%
Yellowish appearance is reduced	 77%	 84%
The appearance of age spots is reduced	 75%	 85%
Evenness of skin tone	 75%	 89%
The skin looks more translucent	 70%	 90%
The skin looks brighter	 68%	 91%
The skin looks moisturized	 80%	 89%
The skin is smoother	 68%	 87%
The skin texture looks more refined	 65%	 79%
The treatments leaves a healthy looking skin	 74%	 93%

## PHOTOS – Face and spots



## RESULT GROUP D

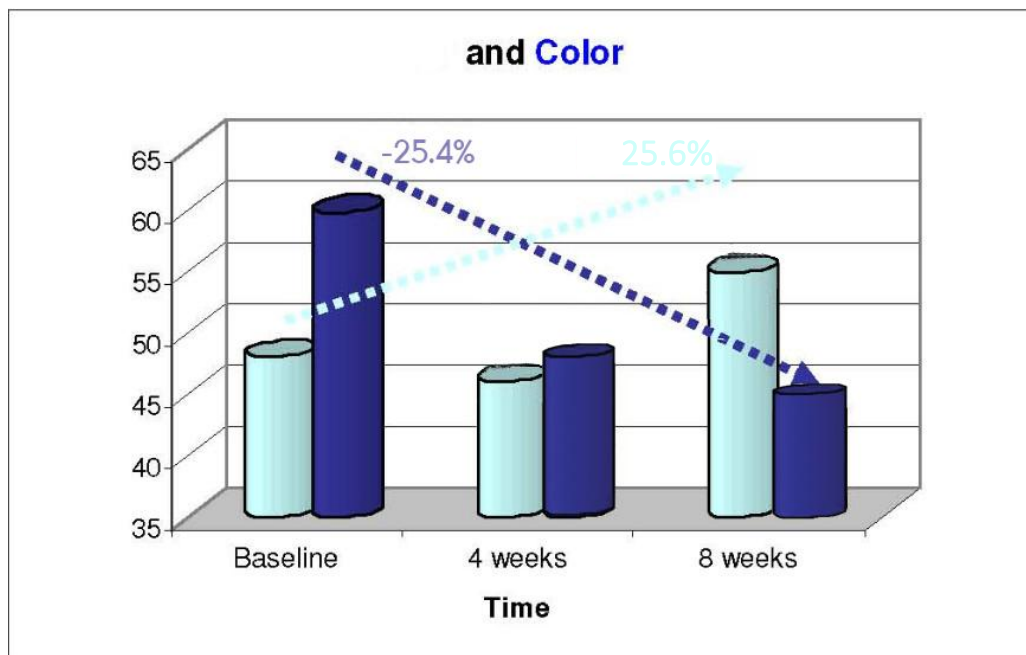
GROUP D	
3 TIMES A WEEK	PROFESSIONAL WHITE SPRAY & CARE TECHNOLOGY BIOLIGHT LOTION
2 TIMES EVERY DAY	HOME USE ON THE GO WHITE LUMINESCENT DAY CREAM LUMINESCENT NIGHT CREAM LUMINESCENT SERUM

### SKIN WHITENING – COLOR – Clinical grades

The results represented in the graph compare the whitening attribute of the complete treatment made for 2 month Clinical scores are reported on 1-100 scale, the higher the score the darker skin. As can be seen substantial change are observed after 4 weeks of treatment with a lightening of 11.3%. After 8 weeks even more whitening is observed with scores decreasing to 25.4% skin darkness.

### SKIN WHITENING – coordinates CIELab

Objective measurements of change in skin color during the treatment were obtained on the face. A significant decrease in skin color was observed after 4 weeks and 8 weeks. After 8 weeks a 21.7% change was observed in L\* value. No significant in a\* and b\* values were observed indicating that the color change was a general lightening effect and did not result in increase irritation or change in green or red values in skin. The brighter in the skin, the higher are the L\* parameter.



# CONCLUSIONS

## EFFICACY EVALUATION OF AN AESTHETIC TREATMENT FOR BRIGHTENING SKIN TONE AND SKIN SPOTS

ALL THE THREE AESTHETIC TREATMENT:

- **GROUP A :**
  - WHITENING LIGHT TREATMENTS, GREEN LIGHT ( $\lambda=525\text{NM}$ )
  - PROFESSIONAL WHITE SPRAY & CARE TECHNOLOGY, BIOLIGHT LOTION
  - HOME USE, ON THE GO WHITE, LUMINESCENT DAY CREAM, LUMINESCENT NIGHT CREAM, LUMINESCENT SERUM
- **GROUP B :**
  - WHITENING LIGHT TREATMENTS, GREEN LIGHT ( $\lambda =525\text{NM}$ )
  - PROFESSIONAL WHITE SPRAY & CARE TECHNOLOGY, BIOLIGHT LOTION
- **GROUP C :**
  - PROFESSIONAL WHITE SPRAY & CARE TECHNOLOGY, BIOLIGHT LOTION
  - HOME USE, ON THE GO WHITE, LUMINESCENT DAY CREAM, LUMINESCENT NIGHT CREAM, LUMINESCENT SERUM
- **GROUP D :**
  - HOME USE, ON THE GO WHITE, LUMINESCENT DAY CREAM, LUMINESCENT NIGHT CREAM, LUMINESCENT SERUM

HAVE HELPED TO HIGHLIGHT IN EVERY THREE GROUPS (A, B, C, AND D) A SIGNIFICANT EFFECTIVENESS IN INCREASING SKIN BRIGHTNESS, DECREASING THE EVIDENCE OF SKIN HYPER-MELANOSIS AND THE SENILE YELLOWISH BROWN PLAQUE AND PIGMENT CAN EVIDENTLY BE DIMINISHED.

THE CLINICAL GRANES EVIDENCE AS CAN BE SEEN SUBSTANTIAL CHANGE ARE OBSERVED AFTER 4 WEEKS AND MORE EVIDENCE AFTER 8 WEEKS AF THE FOUR TREATMENTS.

THE STRUMANTAL ANALISIS OF L\* PARAMETER REVEAL A SIGHIFICANT INCREASE IN SKIN BRIGHTNESS IN EVERY FOUR TREATMENTS, MORE EVIDENCE IN GROUPA.

THE CONSUMER EVALUATION UNDERLINE THAT A HIGH NUMBERS OF CONSUMER EXPESSED A POSITIVE OPTION OF ALL THE PARAMENTERS.

IN ALL THE FOUR TREATMENTS SHOW EFFECTS ON SKIN PARAMETERS LIKE GLOSSINESS, FOLDS AND WRINKELS, SMOOTHNESS, MOISTURIZED AND ELASTICITY, SHOW BENEFICIAL EFFECTS ON OVERALL SKIN APPEARANCE.

ALL VOLUNTEERS, COMPLETED THE TEST. NONE OF THE VOLUNTEERS EXPRESSED PHENOMENON OF INTOLERANCE TO THE TREATMENT.

## 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) -
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- [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, Korea
- [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. Foreza 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"**  
**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 WHITENING BODYWAVE**

*Description:* **Vertical unit for skin aesthetical treatment**  
*Model:* **42 WHITENING 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*

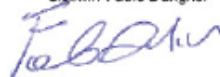
- EN 55015 2000-08 - EN 55015/A1 2001-12 - EN 55015/A2 2002-10
- EN 61000-3-2: 2006-04
- EN 61000-3-3: 1995-01 - EN 61000-3-3/A1: 2001-06 - EN 61000-3-3/A2/S1: 2005-11
- EN 61547: 1995-09 - EN 61547/A1: 2000-12
- EN 60335-2-23: 2003-06

Ultime due cifre dell'anno in cui è affissa la marcatura CE: **10**  
*Last two figures of the year of the CE marking:*

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

Data: **15 / 06 / 2010**  
*Date*

Il Presidente / CEO  
Sig. Mr. Fabio Durighel



## 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*

Farcoderm srl

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## Documents

FARCODERM is an European Expertise Network dedicated to Wellness and Beauty.

- We are a company providing all the services to assess security, safety, tolerability, sensory aspects, efficacy of cosmetic products (skin care, hair care, make-up, solar care, personal care), nutritional products and medical devices.
- Acting as a close partner to your R&D and Marketing divisions, we provide our support and expertise for the realization of your scientific projects by:
  - Performing in-vitro, ex-vivo and in-vivo studies,
  - Proposing standard assays and designing innovative protocols,
  - Testing both your finished products and raw materials.



## The University of Pavia : Since 1361

The University of Pavia is one of the oldest universities in Europe. An edict issued by King Lotharius quotes a higher education institution in Pavia as already established in 825. This institution, mainly devoted to law studies, was then chosen as the main education centre for northern Italy. Enlarged and renovated by the Duke of Milan, Gian Galeazzo Visconti, it became the University of the Duchy, officially established as a Studium Generale by Emperor Charles IV in 1361.

Alessandro Volta (1745-1827) is only one of a large group of famous professors who taught at the University of Pavia. Today the University boasts 24,000 students, both from Italy and from overseas. In 2013, 4,408 students graduated and 639 obtained a post-graduate qualification.

Today Pavia is a Research University, offering a wide variety of disciplinary and interdisciplinary teaching organized in 18 Departments and has study programmes at all levels: Bachelor's degrees, single-cycle Masters degrees, research degrees, speciality schools and level I and II Masters degrees.

**Research is carried out in departments, institutes, clinics, centres, and laboratories in close association with public and private institutions, enterprises and companies.**

The University of Pavia is in a way unique not only because of its prestigious historical origins and top quality achievements, but also due to its leading and promoting role in the so-called "Pavia System", characterized by 20 colleges and residences where thousands of students can live, study and play sports. The oldest residences, named Collegio Borromeo and Collegio Ghislieri, were built in the 16th century; more recently other colleges for male and female students were founded through both public and private initiatives.





## **THAT'SO ASIA REGIONAL OFFICE**

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