

# *Hydration and TEWL Study for a Light Therapy Treatment over a Period of 14 days*

## *Final Report Study N° 09B-0108*

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*This report is composed of 17 pages including appendices (4 pages).*

***February 5<sup>th</sup>, 2009***

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## **STUDY OBJECTIVE**

To evaluate cutaneous Hydration and Trans-Epidermal Water Loss (TEWL) after use of a light therapy treatment device over a period of 14 days.

## **PROTOCOL**

### **1. Ethics Committee**

This procedure and associated documents were reviewed and approved by an Ethics Committee on November 12<sup>th</sup>, 2008 prior to the commencement of the study. The Ethics Committee is an independent organization whose responsibility is to ensure the protection of the rights, security and well-being of the volunteers participating in the study.

### **2. Duration**

The study was carried out from January 8<sup>th</sup> through January 23<sup>rd</sup>, 2009.

### **3. Investigation Site**

Evalulab Inc. located at 5475 rue Paré, Suite 206, Mont-Royal, Quebec, Canada.

### **4. Personnel**

The study was conducted by Andrea Sebesten, B. Sc. (investigator).

### **5. Test Device**

Upon reception, the test device was registered in the "Receptions Book" and assigned a code followed by storage at ambient humidity and temperature in an area allocated for this purpose.

12 devices of **"Tanda Regenerate Anti-aging Light Therapy Treatment"**  
Evalulab Lot: 081209.CS.01

*"Tanda Regenerate Anti-aging Light Therapy Treatment" is a hand-held device that uses 660 nm red LED light which is thought to aid in skin cell regeneration and thus improvement in the signs of skin aging.*

### **6. Quality Assurance**

Good Clinical Practices (GCP) are defined by the totality of the pronouncements put in place for ensuring the quality and authenticity of the trials and the obtained data on one hand and the respect for ethics on the other.

The investigator records data in individual Case Report Forms for each volunteer. The data entry is made in black ink. In case of errors or omissions, the entries are crossed out and initialled by the investigator.

All recorded data is validated by the investigator, who assumes responsibility for the quality of work presented and verifies that all gathered data is in agreement with the protocol.

The records obtained during the study will be kept by Evalulab Inc. for a period of 2 years.

### **7. Statistical Analysis**

Statistical analysis was carried out on all pertinent parameters. Differences in results before and after the test were assessed for statistical significance using the Student's *t* test.

## **8. Adverse Events or Serious Adverse Events**

Volunteers were asked to immediately communicate any reactions to Evalulab. Tolerance to the test device was evaluated based on observed reactions and their degree of severity, as well as on their reproducibility from one volunteer to another.

An "Adverse Event" is defined as any noxious and unintended response observed in a volunteer testing a product, which does not necessarily have a causal relation with the test device or the treatment in question.

The risks for adverse events associated with this test may vary amongst the volunteers. Volunteers may be subject to cutaneous discomforts such as rash (intense redness), cracking, exfoliation effect, dryness or even pain if the test products are strongly irritant or if the volunteer is particularly sensitive to the products. Volunteers may also develop an allergic sensitisation to the test products or to its components.

The term "Serious Adverse Event" refers to any untoward medical occurrence, related or not to the test products that may lead to death, persistent or significant disability, that requires hospitalization or prolongation of a hospitalization period or that provokes invalidity, significant or permanent incapacity, or that translates to congenital anomaly or malformation.

## **9. Amendment to Protocol**

There were no amendments to the protocol.

## **10. Hydration and TEWL Study**

### **• Type of Study**

Monocentric, open-ended, meaning the evaluator, volunteers, and sponsors alike, were aware of the nature of the test material.

### **• Volunteers**

#### Recruitment of volunteers:

A total of 12 healthy female volunteers were recruited.

#### Informed Consent Form:

All volunteers had to sign and date the Informed Consent Form explaining the conditions of the study, the risks involved and briefly describing the product to be tested.

#### Confidentiality:

Participation of the volunteers in this study is confidential. The information gathered in the course of the study was recorded in individual case report forms, that are numerically coded and do not contain the names of the volunteers.

Only the employees of Evalulab, auditors of the sponsor and regulatory bodies (FDA, Health Canada and Ethics Committee) may have access to the confidential information.

### Inclusion Criteria:

1. Volunteers of the feminine sex, in good health, 21 years or older,
2. With normal to dry/dehydrated skin producing hydration readings under 40 units, as determined by Corneometer® at the first visit to the lab,
3. Who accept to discontinue use of skin care products on the test area for the duration of the study and at least 3 days before the start of the study,
4. Who have no prior experience with Tanda Regenerate device,
5. With skin phototype I, II or III based on the Fitzpatrick Classification,
6. Cooperating in the study, able to be monitored at each visit, aware of the demands and duration of the controls, thus allowing perfect adherence to the established protocol,
7. Who have read, signed and dated the Informed Consent Form upon full knowledge of the risks involved with the study,
8. Who use a method of contraception (contraceptive pill, condoms, spermicidal creams, an intra-uterine device (IUD), abstinence ...).

### Exclusion Criteria:

1. Women with history of skin irritation or allergies to the type of product to be tested specifically those with a history of hypersensitivity or allergy to light, or topical products (body washes, soaps, hydrating creams, anti-aging products ...) or in general, with allergies to certain food, to certain chemical products, to jewellery...,
2. Stricken with a critical or progressive illness (asthma, diabetes, cancer, immunological deficiency...),
3. With a history of light activated medical problems such as light triggered seizure disorders or migraine headaches,
4. On medication or having taken medication in the last 7 days prior to the beginning of the study or have had skin therapies in the last 14 days prior to the beginning of the study that could affect skin characteristics or could bias the study (antibiotics, steroids, antihistamines, drugs which may cause light sensitivity,...),
5. Who have taken oral retinoids (Accutane) within 6 months prior to the beginning of the study,
6. Who have initiated treatment with hormones including estrogen, progesterone, or oral contraceptives for 12 weeks or less, immediately preceding study entry or who intend to discontinue hormonal therapy during the study,
7. With a history of dermal anomalies (eczema, topical dermatitis, psoriasis) or stricken with skin anomalies on the areas to be tested which could interfere with the results of the study (scar, mole...),
8. Who have had any cosmetic procedures within 2 months of baseline visit and during the study period (chemical peel, microdermabrasion, laser, botox, fillers) on the tested area,
9. Who frequent tanning salons or foresee exposure to the sun during the study,
10. Who abuse alcohol, drugs or/and tobacco,
11. Who are undergoing another clinical study,
12. Women who are pregnant, lactating or expecting to become pregnant during the study.

## • Test Methods

### Hydration Evaluation by Corneometer®

Epidermal moisture of the stratum corneum can be assessed by non-invasive in vivo instrumental testing methods based on the electric properties of the skin, the electrical capacitance. The stratum corneum is a dielectric corpus and all changes in its hydration status are reflected by changes in the electric capacitance, expressed in arbitrary units by Corneometer®.



Hydration measurements were taken with Corneometer® CM825 (Courage & Khazaka, Germany) equipped with a 49 mm<sup>2</sup> probe. The probe was gently pressed against the skin (a pressure of 3.56 N) and the capacitance was recorded.

### TEWL Evaluation by Tewameter®:

The skin is the primary protection for the body. Trans-Epidermal Water Loss (TEWL) is the most important parameter for evaluating the efficacy of the skin water barrier.

In normal, healthy and intact skin, the barrier function is effective and water loss rates are very low. If the barrier is compromised due to pathological, physical or chemical damage, the water loss rates increase indicating the degree of the damage. In contrast, reduction in TEWL is an indicator of high barrier film integrity.

Monitoring TEWL over time allows measurement of responses to a given treatment as a determination of the effectiveness of various prophylactic strategies that could be used to prevent injury, and thus to protect skin.

Tewameter® TM 300 (Courage & Khazaka, Germany) measures the water evaporation at the skin surface. Measurement of water evaporation is based on the diffusion principle in an open chamber:

$dm/dt = -D \times A \times dp/dx$  where:

A = surface in m<sup>2</sup>,

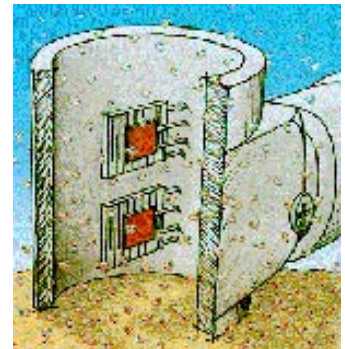
m = water transported (in g),

t = time (h),

D = diffusion constant (=0.0877 g/m.h (mm Hg),

p = vapor pressure of the atmosphere (mmHg),

x = distance from skin surface to point of measurement (m).



## • Experimental Design

On the first visit (D0) the volunteers were scheduled to arrive at the laboratory at least two hours after taking their shower, and without having applied any skin care products on their lower legs at least 3 days before the commencement of the study.

Hydration measurements of the lower legs were taken to assess inclusion / exclusion criteria.

After verification of the inclusion/exclusion criteria, and signing of the Informed Consent Form explaining the conditions of the test, the risks involved and a description of the device to be tested, each volunteer was given the test device, a follow-up sheet to be completed after every use and a self-evaluation questionnaire to be completed after 14 days of treatment.

During the same visit each volunteer was instructed to use the test device as follows:

1. Unpack the Tanda Professional Light Therapy device and all accessories.
2. Firmly place the device in its recharging stand and plug the power adapter into the base of the recharging stand and the other end into a power outlet.
3. Ensure orange charging light is on and fully charge the device (about 2 hours).
4. Press the orange button once.
5. When the light flashes green, the device is ready to begin a treatment.
6. Place light in contact with skin, directly over the area to be treated.
7. Each treatment cycle is three minutes. An audible beep will sound every 30 seconds during the treatment cycle. Two quick beeps will indicate when the cycle is complete.
8. Treatment cycles: Use for 6 minutes on the test area daily.
9. Store the device in its stand.

After explaining the functioning and the precautions to be taken during the use of the device, each volunteer was provided with an instruction sheet, supplied by the study sponsor.

The use of all skin care products on the lower legs (except for regular cleansing products) was prohibited during the study. Changes regarding the brand of their regular cleansing products were not permitted during the entire length of the study.

The study was conducted in a laboratory room with controlled temperature ( $24^{\circ}\text{C} \pm 2$ ) and relative humidity ( $36\% \pm 2$ ). After 20 minutes of stabilisation in the laboratory room, hydration measurements using a Corneometer® and Trans-Epidermal Water Loss (TEWL) measurements using a Tewameter® were taken on 2 predetermined sites of each volunteer's lower leg. One of these sites served as control, and the other site was considered as the test site. The distribution of the control and the test site on the right or the left lower leg was made at random in order to reduce systemic errors related to anatomical differences between volunteers (see Table I in Appendices). Volunteers were to use the device on the test site 6 minutes per day.

Furthermore, measurements taken at D0 were repeated at D7 and D14 in the same manner as described above. At day 7, the volunteers had to return with their completed daily logs and device. At D14, the volunteers had to return their completed daily logs, self-evaluation questionnaires and device. The daily logs (use diaries) were intended for verification of the volunteers' adherence to the protocol.

All observations and measurements were recorded for each volunteer in their respective Case Report Forms.

In addition to the observations made and recorded by Evalulab, the volunteers were encouraged to observe and report to Evalulab any immediate or delayed reactions such as redness, irritation, itching and/or other sensations on the application site.

## RESULTS

All individual data collected from the self-evaluation questionnaires are presented in Table II in the Appendices.

A summary of each section for which results were obtained is provided below, with a discussion.

### 1. Device Acceptance

- Participation

A total of 12 female volunteers (Average Age = 55.8) were recruited to participate in the study and completed the study. The profile of each volunteer is presented in Figure 1.

**Figure 1: Volunteer profile**

No.			Initials	Age	Skin Phototype	Sex
01	-0108-01-	001	LV	58	II	F
01	-0108-01-	002	DJ	51	II	F
01	-0108-01-	003	EM	58	III	F
01	-0108-01-	004	DB	60	III	F
01	-0108-01-	005	MG	60	III	F
01	-0108-01-	006	IL	47	II	F
01	-0108-01-	007	JD	45	III	F
01	-0108-01-	008	RS	62	III	F
01	-0108-01-	009	DM	55	III	F
01	-0108-01-	010	ES	59	III	F
01	-0108-01-	011	FR	59	III	F
01	-0108-01-	012	RE	56	III	F

- Tolerance

No "Adverse Events" or "Serious Adverse Events" were observed by the investigator, during the entire length of the study.

All data for tolerance collected from the self-evaluation questionnaires completed by the volunteers are presented in Table II in the Appendices.

As part of the questionnaire, the volunteers were to judge treatment tolerance by selecting none, slight, moderate, or high for each of the intolerance criteria. The list of intolerance criteria and the responses expressed as the percentage of volunteers responding in each category after two weeks of treatment are provided in Figure 2 below.

**Figure 2. Overall scores for tolerance at day 14**

Criteria	"None"	"Slight"	"Moderate + High"
Redness	100%	0%	0%
Tightening	100%	0%	0%
Skin flaking	100%	0%	0%
Other	100%	0%	0%
Stinging	92%	8%	0%
Burning sensation	83%	17%	0%

There were reports of "Slight" discomforts such as burning sensations (17%) and stinging (8%) during daily use of the device.

However, the results overall indicate that the treatment was well tolerated by the majority of the participants.



## 2. Device Efficacy (Qualitative Survey)

The purpose of the self-evaluation questionnaires was to assess the volunteers' perceptions of the efficacy of the test device after 14 days of use.

- **Perception of Device Efficacy**

To assess the perception of the efficacy of the test device at D14, the volunteers were to complete questions pertaining to immediate improvement in hydration and comfort of the skin, softness, smoothness, more nourished appearance, calming effect, improvement in hydration at D14, diminished tightening sensation and discomfort caused by dry skin at D14. The responses for each criteria expressed as "A lot", "Moderately", and "Slightly" have been combined and summarized as total percentage of positive responses for each parameter in Figure 3.

All scores for performance collected from the self-evaluation questionnaires completed by the volunteers are presented in Table II in the Appendices.

**Figure 3. Overall scores for performance at day 14**

Criteria	"A lot + Moderately"	"Slightly"	Total
Softer skin at D14	50%	50%	100%
Improved hydration at D14	42%	58%	100%
Smoother skin at D14	50%	42%	92%
More nourished appearance at D14	33%	50%	83%
Diminished discomfort caused by dry skin at D14	33%	50%	83%
Immediate improvement in hydration	50%	25%	75%
Diminished tightening sensation at D14	33%	42%	75%
Immediate improvement in comfort of skin	50%	17%	67%

Pooling all the positive answers (Total) together, all of the volunteers said they had softer skin on the test site at D14. The same percentage of participants noted an improvement in hydration on the test site at D14. A total of 92% of the volunteers considered their skin was smoother on the test site at D14. Eighty-three percent (83%) of the volunteers considered their skin had a more nourished appearance on the test site at D14 and experienced a decrease in the discomfort sensation caused by dry skin at D14.

From the results presented in Figure 3, it is shown that a total of 75% of the volunteers observed a reduction in tightening sensations on the test site at D14.

The perception regarding immediate improvement in hydration and skin comfort was very good with a high percentage of positive responses as follows:

Fifty-percent (50%) of the volunteers indicated "A lot" or "Moderate" improvement in hydration right after using the device. Another 25% observed a "Slight" improvement in the same criteria, totalling 75% positive responses.

Fifty-percent (50%) of the volunteers indicated "A lot" or "Moderate" improvement in skin comfort on the test site right after using the device. Additionally, 17% observed a "Slight" improvement in the same criteria, resulting in a total of 67% positive responses.

Not shown in the Figure 3 are the responses to several additional questions at the completion of the study concerning the device's calming effect, overall performance, recommendation, and purchase of the test device if sold at a competitive price.

Overall scores for the criteria "I find that the device had a calming effect on my skin" indicated that 50% of the volunteers considered that the device had a calming effect on the skin.

The overall performance was rated moderately: 50% (combining "Very effective" and "Effective") of the participants considered that the treatment was effective. Sixty-seven percent (67%) of the volunteers would recommend the treatment to others, and the same percentage of participants would consider purchasing the device.

- **Comments**

The complete list of all the comments expressed by the volunteers about the treatment is presented in Table III in the Appendices.

None of these comments need to be underscored or discussed at any length.

### 3. Device Efficacy (Quantitative Assay)

- **Hydration Results over a period of 14 days**

Individual results for hydration measurements expressed as arbitrary units are presented in Table IV in the Appendices. Statistical analysis is also provided in the same table.

Figure 4 shows the average hydration results obtained for the control and the test site on 12 volunteers at each time of measurement.

**Figure 4 - Average hydration results (arbitrary units) at each time of measurement**

Evolution of Hydration average compared to control at each time of measurement	D0	D7	D14
Control	21.67	21.25	21.08
Tanda Regenerate Anti-aging Light Therapy	21.75	22.92	24.33

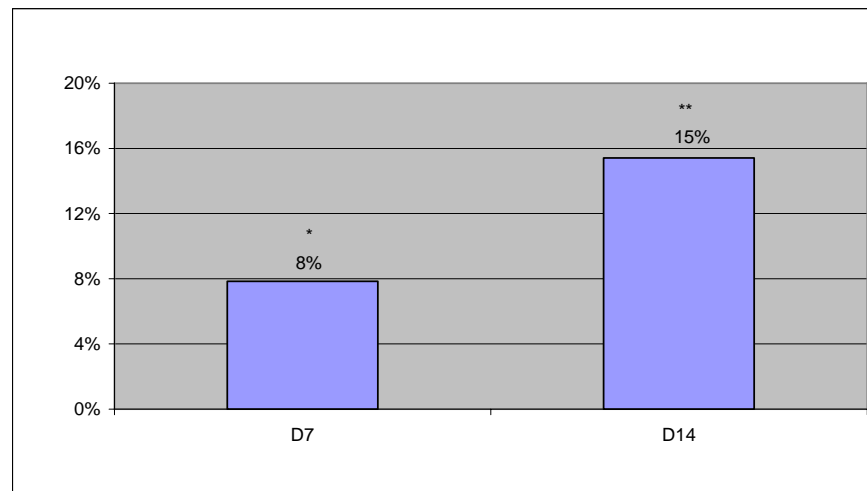
The hydration results for the control site were low and remained constant throughout the study.

At D0, no significant difference can be observed between the control and the test site.

The treatment significantly increased skin hydration ( $p<0.05$ ) at D7 when compared to the average of the results obtained from the control site at the same time of measurement. This trend was maintained up to D14, with a level of significance ( $p<0.01$ ) when compared to the average of the results obtained from the control site.

The corresponding hydration evolution, in percentages and based on the abovementioned average results, is presented in Figure 5. This evolution demonstrates the differences between the average measurements from the test device site and those from the control site.

**Figure 5. Evolution of Hydration after use of the test device at D7 and D14 when compared to control (in %)**



(Statistical Significance, \* =  $p<0.05$ , \*\* =  $p<0.01$ )

Statistical analysis of the data revealed that the test device had a significant effect on hydration at D7 and was maintained at D14 when compared to the control, respectively by 8% and 15%.

- **TEWL Results over a period of 14 days**

Individual results for TEWL readings expressed as  $\text{g}/\text{hm}^2$  are presented in Table V, in the Appendices. Statistical analysis is also provided in the same table. It is important to note that TEWL decreases as the skin barrier function against moisture loss is improved.

Figure 7 shows the average TEWL results for the control and the test site on 12 volunteers at each time of measurement.

**Figure 7 - Average TEWL results ( $\text{g}/\text{hm}^2$ ) at each time of measurement**

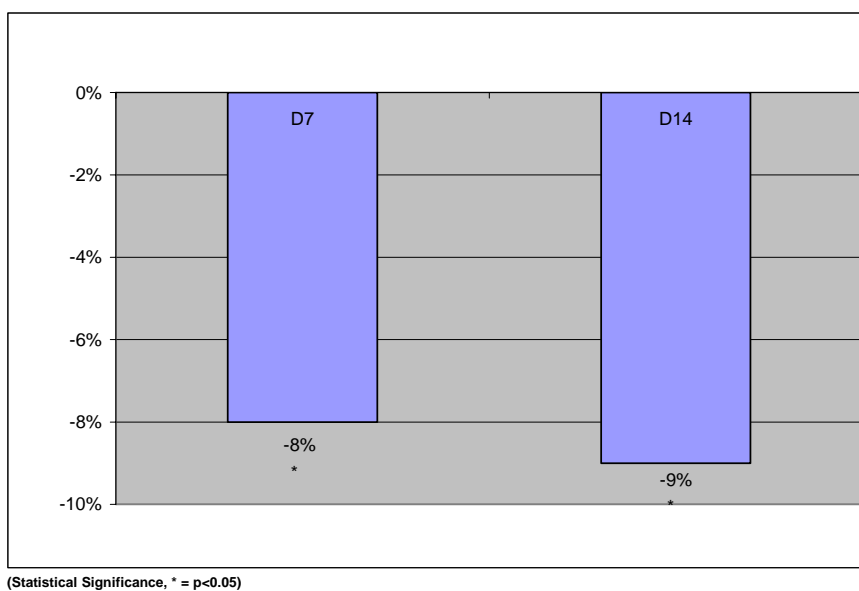
Evolution of TEWL average compared to control at each time of measurement	D0	D7	D14
Control	11.69	11.68	12.15
Tanda Regenerate Anti-aging Light Therapy	11.78	10.75	11.03

The TEWL results for the control site remained almost constant throughout the study. At D0, no significant difference is observed between the control and the test site.

The treatment significantly decreased TEWL during the entire length of the study ( $p < 0.05$ ) when compared to average results obtained from the control site at the same time of measurement.

The corresponding TEWL evolution, in percentages and based on the abovementioned average results, is presented in Figure 8. This evolution demonstrates the differences between the average measurements from the test device site and those from the control site.

**Figure 8. Evolution of TEWL after use of the test device at D7 and D14 when compared to control (in %)**



The evolution of the TEWL level of the skin on the test site at D7 reveals that the device significantly decreased TEWL by 8% when compared to the average of the results obtained from the control site.

In addition, it can be noted that this trend was maintained up to D14 (TEWL reduced by 9%).

## CONCLUSION

The objective of this study was to evaluate the cutaneous Hydration and Trans-Epidermal Water Loss (TEWL) after use of a device called "Tanda Regenerate Anti-aging Light Therapy" over a period of 14 days. The study was carried out by taking measurements on 12 healthy female volunteers.

Comments from the volunteers regarding the device were very positive.

The treatment significantly increased skin hydration at D7 ( $p < 0.05$ ) and D14 ( $p < 0.01$ ), by 8% and 15% respectively, when compared to the average of the results obtained from the control.

With regard to TEWL, significant differences with  $p < 0.05$  were observed for the test device at D7 and D14 when results were compared to the average of the results obtained from the control site at the same time of measurement. The TEWL decreased by 8% at D7 and by 9% at D14.

The device seems to have interesting properties, recognized by the volunteers and demonstrated by the measurements taken, for improving the state of the skin, notably the hydration and Trans Epidermal Water Loss. Anti-aging claims will need to be verified by further study.

I, the undersigned, Andrea Sebesten, declare that this study was conducted under my supervision, in accordance with the principles of "*Good Clinical Practices*". The recorded results show exactly and completely the raw data of the study.



Signature  
Andrea Sebesten, B. Sc.  
Investigator, Laboratory Director

Mont-Royal - February 5<sup>th</sup>, 2009.

I the undersigned, Elisabeth Fiquet, declare that the information provided in this report reflects in a complete and exact manner the results obtained during the study.



Signature  
Elisabeth Fiquet, M. Sc  
Quality Assurance Director, President

Mont-Royal - February 5<sup>th</sup>, 2009

## APPENDICES

**Table I - Randomization Table for 14 days Hydration & TEWL Study**

<b>Vol. No.</b>	<b>Treated Lower Leg</b>	<b>Non-Treated Lower Leg</b>
001	Right	Left
002	Left	Right
003	Right	Left
004	Left	Right
005	Right	Left
006	Left	Right
007	Right	Left
008	Left	Right
009	Right	Left
010	Left	Right
011	Right	Left
012	Left	Right

Table II - Scores for Tolerance and Performance at day 14

**TOLERANCE**

0=None, 1=Slight, 2=Moderate and 3=High

Criteria	001	002	003	004	005	006	007	008	009	010	011	012
Redness	0	0	0	0	0	0	0	0	0	0	0	0
Stinging	0	0	0	0	0	0	0	0	1	0	0	0
Tightening	0	0	0	0	0	0	0	0	0	0	0	0
Burning sensation	0	1	0	0	0	0	0	0	1	0	0	0
Skin flaking	0	0	0	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0	0	0	0

**PERFORMANCE**

3=A lot, 2=Moderately, 1=Slightly and 0=Not at All

Criteria	001	002	003	004	005	006	007	008	009	010	011	012
Immediate improvement in comfort of skin	3	1	0	0	2	1	2	3	0	2	2	0
Immediate improvement in hydration	2	2	0	1	2	1	2	1	0	2	2	0
Softer skin at D14	3	2	1	1	1	2	2	1	1	3	2	1
Smoother skin at D14	3	2	1	1	1	2	2	1	0	3	3	1
More nourished appearance at D14	2	1	1	1	0	1	2	0	1	3	3	1
Improved hydration at D14	2	2	1	1	1	1	2	1	1	3	2	1
Diminished tightening sensation at D14	2	1	1	1	0	1	2	0	0	3	2	1
Diminished discomfort caused by dry skin at D14	2	1	1	1	0	1	2	0	1	3	2	1

Y=Yes, N=No

Criteria	001	002	003	004	005	006	007	008	009	010	011	012
Calming effect	Y	Y	N	N	N	N	Y	Y	N	Y	Y	N

3=Very Effective, 2=Effective, 1=Not Really Effective and 0=Not at All Effective

Criteria	001	002	003	004	005	006	007	008	009	010	011	012
Global Performance	3	2	1	1	1	1	2	1	2	3	2	1

3=Strongly agree, 2=Somewhat agree, 1=Somewhat disagree and 0=Fully disagree

Criteria	001	002	003	004	005	006	007	008	009	010	011	012
Recommendation	3	2	2	0	1	1	2	2	2	3	2	0

2=Certainly, 1=Maybe and 0=Certainly not

Criteria	001	002	003	004	005	006	007	008	009	010	011	012
Purchase at competitive price	2	1	1	0	0	0	2	1	1	2	2	0

Table III - Comments for the test product at day 14

Vol.	Negative comments	Positive comments
01-1209-001	-	The device is really easy to use. It does not require a lot of time per day. My skin is really soft.
01-1209-002	Not effective enough. Sometimes I felt like a "heating" sensation on my skin.	-
01-1209-004	...but these differences did not last a long time and were not significant.	I noticed that my skin was slightly softer and slightly more hydrated right after using the device...
01-1209-005	... this feeling disappeared a few hours later.	Right after application my skin was softer and smoother to touch, but ...
01-1209-007	I think this device should be tested on a bigger surface of the skin to obtain more precise results.	-
01-1209-008	... it had covered a bigger surface of the skin.	I would recommend this device to others, if...
01-1209-009	The surface where I used the device was too small for me to really observe a change.	-
01-1209-010	-	I am very satisfied with the results obtained.
01-1209-011	-	I do not know if my skin is more hydrated, but I know that my skin is softer and that the brown spots diminished. My skin seems less dry.

**Table IV - Individual Hydration Results for the test device and control expressed as arbitrary units with Statistical Analysis over a period of 14 days**

Volunteer	Tanda Regenerate Anti-aging Light Therapy		
	D0	D7	D14
1	16	18	20
2	23	28	27
3	22	22	28
4	27	29	28
5	22	21	20
6	23	26	27
7	18	19	22
8	16	15	15
9	24	27	29
10	19	22	25
11	22	20	20
12	29	28	31
Mean	<b>21.75</b>	<b>22.92</b>	<b>24.33</b>
Stdev	<b>4.00</b>	<b>4.58</b>	<b>4.83</b>
Stat. Signif. compared to D0		0.09	0.01
Stat. Signif. compared to D7			0.04

Volunteer	Control		
	D0	D7	D14
1	17	17	16
2	24	26	26
3	23	22	26
4	28	29	27
5	23	21	17
6	21	21	24
7	17	18	17
8	15	13	14
9	21	20	20
10	20	19	23
11	24	21	17
12	27	28	26
Mean	<b>21.67</b>	<b>21.25</b>	<b>21.08</b>
Stdev	<b>3.98</b>	<b>4.59</b>	<b>4.74</b>
Stat. Signif. compared to D0		0.36	0.55
Stat. Signif. compared to D7			0.84

Evolution of Hydration average compared to control at each time of mesurement	D0	D7	D14
Control	21.67	21.25	21.08
Tanda Regenerate Anti-aging Light Therapy	21.75	22.92	24.33
% Improvement of Hydration (test vs. Control)	0%	8%	15%
t test	0.86	0.03	0.00

(Statistical Significance, Blue: p<0.01, Red: p<0.05, Green: p<0.1)



**Table V - Individual TEWL Results for the test device and control expressed as g/hm<sup>2</sup> with Statistical Analysis over a period of 14 days**

Volunteer	Tanda Regenerate Anti-aging Light Therapy		
	D0	D7	D14
1	10.18	7.08	6.98
2	7.01	9.88	9.51
3	11.46	11.51	10.78
4	9.78	10.29	9.13
5	14.34	13.66	13.32
6	13.69	14.21	15.56
7	15.64	12.37	13.62
8	12.33	8.88	10.41
9	9.08	8.90	9.86
10	12.01	9.26	9.86
11	16.10	15.01	14.08
12	9.78	7.92	9.26
Mean	<b>11.78</b>	<b>10.75</b>	<b>11.03</b>
Stdev	<b>2.78</b>	<b>2.58</b>	<b>2.53</b>
Stat. Signif. compared to D0		0.09	0.16
Stat. Signif. compared to D7			0.34

Volunteer	Control		
	D0	D7	D14
1	10.31	9.29	10.26
2	7.60	8.80	10.46
3	11.11	11.16	11.84
4	9.64	9.23	9.44
5	13.36	13.53	14.69
6	13.61	16.35	13.22
7	15.47	13.53	13.60
8	11.81	10.58	12.10
9	9.22	9.95	10.31
10	12.54	11.79	12.55
11	15.83	16.57	15.67
12	9.74	9.39	11.66
Mean	<b>11.69</b>	<b>11.68</b>	<b>12.15</b>
Stdev	<b>2.55</b>	<b>2.74</b>	<b>1.90</b>
Stat. Signif. compared to D0		0.99	0.22
Stat. Signif. compared to D7			0.27

Evolution of TEWL average compared to control at each time of measurement	D0	D7	D14
Control	11.69	11.68	12.15
Tanda Regenerate Anti-aging Light Therapy	11.78	10.75	11.03
% Improvement of TEWL (test vs. Control)	1%	-8%	-9%
t test	0.45	0.03	0.02

(Statistical Significance, Red: p<0.05, Green: p<0.1)