Clinical instrumental evaluation of the effect and efficacy of a cosmetic product for the eye contour

TORSTONE SA

RIVOLI

LE REGARD 2.0 SERUM LIFTANT ECLAT

Reference code: lab-01399.9

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Centro di Saggio operante in BPL - Sistema di gestione qualità certificato ISO 9001
Iscritto al Registro Regione Lombardia ai fini dell'autocontrollo alimentare (N 030015309008)
Laboratorio di Prova Accreditato ACCREDIA LAB N 1318L (UNI CEI EN ISO/IEC 17025:2018)
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STUDY DESIGN

1.1. Title

Clinical instrumental evaluation of the effect and efficacy of a cosmetic product for eye contour.

1.2. Aim of the study

The study is aimed to evaluate the effect (short term test) and efficacy (long term test) of a cosmetic product for the eye contour in improving skin radiance, moisturization and profilometry (in terms of decreasing wrinkle depth and improving skin smoothness) both after its first application and after a period of use. Moreover, product ophthalmological tolerability and safety of use are monitored within the study period.
In order to reach this goal, a clinical-instrumental study is carried out on 20 healthy female subjects, aged over 35 and 60 years old, complaining a stressed life-style and clinically showing signs of fatigue in the eye contour together with crow's feet wrinkles. Product effect/efficacy are evaluated 30 minutes (T30min) and 2 hours (T2h) after its first application, in the morning after the first evening-application (T12h) and after 7 (T7) and 28 (T28) days of use by means of non-invasive bioengineering techniques. The instrumental analysis is integrated with the clinical assessment carried out by the Ophthalmologist and by a self-assessment filled in by the enrolled volunteers.

1.3. Tested product

1.3.1. Information provided by the Customer

☒ Product name: **RIVOLI LE REGARD 2.0 SERUM LIFTANT ECLAT Reference code: lab-01399.9**
☒ Way of use: apply twice a day (morning and evening) in the eye contour, gently tapping with the fingertips, from the inside towards the outside.
☒ The tested cosmetic products conform to REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products (recast) (Text with EEA relevance) and to its annexes.
☒ The tested cosmetic product was evaluated for its safety of use on human volunteers (safety assessment).
☒ INCI formula:

AQUA (WATER), COCOS NUCIFERA (COCONUT) OIL, GLYCERIN, CAPRYLIC/CAPRIC TRIGLYCERIDE, HYDROGENATED PHOSPHATIDYLCHOLINE, PROPANEDIOL, UNDECANE, PENTYLENE GLYCOL, BUTYLENE GLYCOL, SODIUM POTASSIUM ALUMINUM SILICATE, BUTYROSPERMUM PARKII (SHEA) BUTTER, PANTHENYL TRIACETATE, SODIUM POLYSTYRENE SULFONATE, CAPRYLYL GLYCOL, TRIDECANE, SORGHUM BICOLOR STALK JUICE, BORON NITRIDE, TITANIUM DIOXIDE (CI77891), XANTHAN GUM, ETHYLHEXYLGLYCERIN, SILICA, NIACINAMIDE, SQUALANE, DIPROPYLENE GLYCOL, GLYCERYL CAPRYLATE, TAMARINDUS INDICA SEED GUM, SYNTHETIC FLUORPHLOGOPITE, DISODIUM ADENOSINE TRIPHOSPHATE, GELLAN GUM, HYDROLYZED OATS, ACETYL RHEUM RHAPONTICUM ROOT EXTRACT, POTASSIUM SORBATE, SODIUM BENZOATE, CERAMIDE NP, TIN OXIDE, TOCOPHEROL

1.4. Ethical requirements

The study is carried out in accordance with the following ethical requirements.

1. All the subjects participating in the study are healthy volunteers of at least 18 years old.
2. All of the subjects participating in the study are selected with the supervision of a dermatologist according to inclusion/not inclusion criteria.
3. Volunteers participation in the study was totally free.
4. All of the subjects participating in the study are informed of the aim and the design of the study.
5. All of the subjects participating in the study are informed of the possible risk involved in the study execution.
6. All of the subjects participating in the study give their informed consent signed at the beginning of the study.
7. Before volunteer exposure to the tested product, all relevant safety information about the product itself and each ingredient were collected and evaluated.
8. All of the study procedures are carried out in compliance with the ethical principles for the medical research (Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and amendments.
9. All of the precautions are taken in consideration in order to avoid excessive skin reactions.
10. If any unexpected/adverse skin reaction occurs, medical investigating specialist evaluates the severity of the reaction (reporting it in the volunteer's data collecting sheet) and proceeds with appropriate therapy.

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1.5. Subjects

1.5.1. Subjects selection

The subjects participating in the study were selected by a board certified Dermatologist from a panel of healthy female volunteers, in accordance with the following inclusion/non-inclusion criteria.

1.5.1.1. Inclusion criteria

- ☑ Healthy female subjects
- ☑ Aged between 35 and 60 years old
- ☑ Caucasian ethnicity
- ☑ Subjects with all skin type (without any specific repartition)
- ☑ Subjects complaining a stressed life-style
- ☑ Subjects clinically showing signs of fatigue in the eye contour and crow's feet wrinkles
- ☑ Commitment to adhere strictly to the information reported in the study information form
- ☑ Commitment not to use for all the study length other topical products with an activity comparable to the products under study
- ☑ Commitment not to expose to the sun/solar lamps during the study period
- ☑ Subjects aware of the test procedure who have signed an informed consent form.

1.5.1.2. Non-inclusion criteria

- ✘ Subjects who do not fit the inclusion criteria
- ✘ Pregnant or nursing women
- ✘ Subjects that have shown allergies to cosmetic products, toiletries, sunscreens and/or topical drugs
- ✘ Subjects with skin pathologies in the test area
- ✘ Subjects under pharmacological treatment (both locally or systemically) that may interfere with the test execution
- ✘ Positive anamnesis for atopy (if this condition interferes with the test execution).

1.5.1.3. Study withdrawal

- ✘ Subjects not respecting the conditions described in the information form
- ✘ Occurrence of accidents, pathologies or conditions which could interfere with the study
- ✘ Subjects who no longer want to participate in the study.

1.6. Study procedure

The study is carried out as follow:

- **T0**: enrollment of 20 subjects according to inclusion/non-inclusion criteria. Instrumental and clinical analysis of the parameters under study (basal evaluation, T0);
- **SHORT TERM TEST**: instrumental evaluation of skin radiance, moisturization, profilometry (wrinkle depth and Ra parameter) and skin pH* after 30minutes (T30min), 2 hours** (T2h) from the first product application and in the morning after the first evening-application (T12). Moreover, digital pictures of the treated area are acquired and volunteers are asked to express their opinion on tested product by answering to a questionnaire.
  *skin pH measurement is performed in order to verify that the product doesn't alter skin conditions.
  **during the first 2 hours after product application, subjects remain in the test facility under controlled temperature and humidity conditions.
- **LONG TERM TEST**: instrumental evaluation of skin radiance, moisturization and profilometry (wrinkle depth and Ra parameter) after 7 (T7) and 28 (T28) days of product use. Moreover, digital pictures of the treated area are acquired and volunteers are asked to express their opinion on tested product by answering to a questionnaire.
  During the long term, product tolerability and safety of use are monitored by an Ophthalmologist.

1.7. Materials and methods

In the sections here below the materials and methods used in this study are reported. All the study procedures are carried out under temperature and humidity controlled conditions (temperature 18-26°C and humidity 50±10%).

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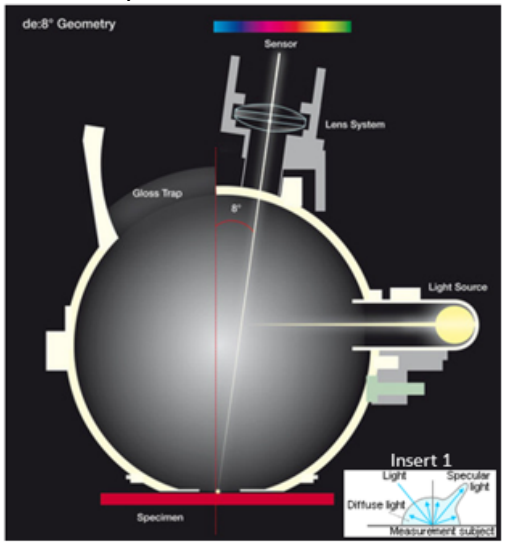
PRODUCT EFFICACY – INSTRUMENTAL EVALUATIONS

1.7.1. Skin radiance – T0, T30min, T2h, T12h, T7, T28

Skin radiance (or skin brightness), is the ability of the skin to reflect the light and it is measured using the gloss parameter (taken using the spectrophotometer/colorimeter CM-700D (Konica-Minolta). The instrument emits diffuse light that reaches the skin through an opening located at the extreme of the lighting sphere. A sensor located at 8 ° compared to the vertical axis of the opening detects then the reflected light and calculates a parameter known as "gloss". The gloss value is used in the management of the brilliance of the colour.
For further information on the principle of the measurement and data analysis see box 1.

Box 1 – Gloss parameter



When light reach a surface it is reflected at the equal but opposite angle from the light source; this is called specularly reflected light. This specular component is reflected as if reflected by a mirror. The light that is not specularly reflected, but scattered in many directions, is called diffuse reflectance (insert 1). The sum of the specular reflectance plus the diffuse reflectance is called the total reflectance. For objects with shiny surfaces, the specularly reflected light is relatively strong and the diffused light is weaker. On rough surfaces with a low gloss, the specular component is weak and the diffused light is stronger. The measuring geometry d: 8° features an optical device which provides diffuse illumination (Ulbricht sphere). The light (Xenon lamp) is projected into a sphere. The interior of the sphere is coated with a white highly reflecting substance (barium sulphate, ceramic, special plastic) which reflects the light manifold. A shutter, an optical element inside the sphere, prevents the directional rays from reaching the measuring sample directly. The sample is positioned at an opening of the sphere and is illuminated from all directions with a close to perfect diffuse light. Through an opening at the top of the sphere the sensor is viewing the surface being measured with an angle of 8° to the vertical. In order to prevent reflection of specular light from the sample surface, the instrument feature a gloss trap. When the trap which is arranged with an angle of -8° to the viewing opening, is open, the light which would otherwise be reflected from the interior wall of the sphere, will be eliminated and can therefore not Illuminate the sample. The relation between directional and diffuse reflection allows calculating the gloss component. The measuring system including gloss is named di: 8° whilst the measuring system excluding gloss is described as de: 8°.

1.7.2. Skin moisturization – T0, T30min, T2h, T12h, T7, T28

The measurement of the skin moisturizing is based on the internationally recognized Corneometer® method. Corneometer® method is based on the dielectric constant of water. The probe shows changes of capacitance according to the moisture content of the measuring object. An electric scatter field penetrates the very first layers of the skin and determines the dielectricity. The used device is a Corneometer CM 825 (Courage+Khazaka, electronic GmbH).

1.7.3. Skin profilometry – T0, T30min, T2h, T12h, T7, T28

Skin surface is quantitatively assessed by Primos 3D (GFMesstechnik GmbH). Primos 3D is a non-contact *in vivo* skin measurement device based on structured light projection. In conjunction with a comprehensive 3-D measurement and evaluation software, the sensor allows to evaluate skin surface properties (i.e. wrinkle depth, volume, roughness etc.). In this study wrinkle depth and Ra parameter (related to skin smoothness) are evaluated. For further information see box. 2.

1.7.4. Skin pH – T0, T2h, T12h

The used instrument is the SKIN pH-METER 905®, Courage + Khazaka GmbH. The measure is based on a combined electrode of high quality, in which both the glass electrode sensitive to H+ and the additional reference electrode are placed in the same site. It is connected to a handle probe containing the measurement electronics. Before the measurements, the SKIN pH-meter® 905 (Courage + Khazaka electronic GmbH) is calibrated using two buffer solutions with known pH (pH 4.01 and 1.7) as reference.
Measurement range: 0 to 12; accuracy: ± 0.1 pH.

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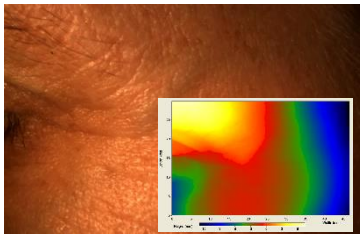
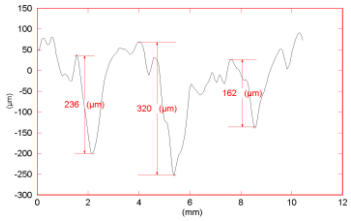
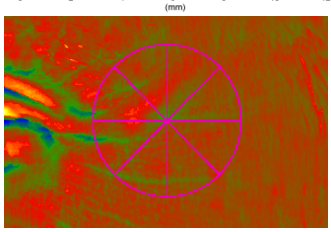
BOX 2 - Skin profilometry by means of Primos 3D analysis



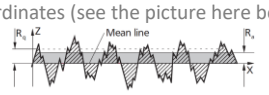
The technique. Primos 3D is a 3D scanner that create a point cloud (set of vertices in a three-dimensional coordinate system) of geometric samples on the surface of the subject. These points are then used to extrapolate the shape of the subject (a process called reconstruction). Like cameras, 3D-scanner have a cone-like field of view, and like cameras, they can only collect information about surfaces that are not obscured. While a camera collects color information about surfaces within its field of view, 3D scanners collect distance information about surfaces within its field of view. The "picture" produced by a 3D scanner describes the distance to a surface at each point in the picture (see the image in the insert).



Calculation of wrinkle depth. It is calculated the height of wrinkles in the sampling lengths: this calculation is done on the sectional picture (wrinkle depth vs. section).



Calculation of roughness. For the calculation of a star roughness, intersections are arranged in a star shape by the program. The calculation of the parameter occurs accordingly to the determination of the line roughness (separate for every star shape arranged intersection). In this study roughness is calculated by the Ra parameter which corresponds to the arithmetic average of the absolute values of the roughness profile ordinates (see the picture here below).



Mathematically Ra is calculated as:

$$R_a = \frac{1}{l}\int_0^l |Z(x)|\, dx$$

1.7.5 Digital macrophotography – T0, T30min, T2h, T12h, T7, T28

Pictures of the treated area are acquired at each experimental monitored check by means of Visioface (Courage+Khazaka). Best cases (3 subjects) are reported in annex 1.

1.7.6. Self-assessment – T30min, T12h, T28

After the first product application, at T12h (in the morning after the first evening-application) and at the end of the study volunteers are asked to express their personal opinion on product efficacy and properties by answering to a questionnaire.

PRODUCT SAFETY: OPHTHALMOLOGICAL TOLERABILITY - T0, T7, T28

Subjects basal condition is evaluated during the first visit. Each enrolled subject is instructed to immediately stop product use if any unwanted side effects occur and to immediately inform the ophthalmologist about any discomforts that may be attributed to the use of the product itself. After 7 and 28 days of product use, the experimenter assesses whether the product is tolerated and is safe, during its use, for the skin and ocular mucous membranes. The following parameters are evaluated (clinically or with the collaboration of the subjects):

- Lacrimation
- Vasodilatation (redness, hyperemia)
- Foreign body sensation
- Photophobia
- Itching and/or burning
- Periocular swelling
- Other

The occurrence of these disorders could mean that the product in question is cause of serious alterations of the ocular mucosa such as: conjunctivitis, keratitis, blepharitis, chemosis, oedema and redness on the external eye area. The intensity of each recorded reaction is classified according to a 5 points score:

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- 0 absent
- 1 very mild
- 2 mild
- 3 moderate
- 4 severe

and described for its duration, frequency and extension.
The onset of alterations to palpebral skin or ocular mucosa is assessed according to the scores shown in Box 3-4.

Box 3

Eyelid skin alterations	
No alteration	**0**
Slight alteration	**1**
Moderate alteration	**2**
Evident alteration	**3**

Box 4

Conjunctival mucosa alterations	
No alteration	**0**
Slight alteration	**1**
Moderate alteration	**2**
Evident alteration	**3**

1.8. Results and Statistics

1.8.1 Results

The Results are reported in their respective units in tables.

1) The mean values are calculated as:

$$m = \frac{\sum_{1}^{n} P}{n} \qquad [1]$$

where:
n is the number of subjects who ended the study
P is the value of the parameter to be analyzed.

2) The mean standard error is calculated as:

$$SEM = \frac{\sqrt{\frac{\sum_{1}^{n}(p_i^2) - \frac{\sum_{1}^{n} p_i^2}{n}}{(n-1)}}}{\sqrt{n}} \qquad [2]$$

3) The mean percentage variations were calculated as:

$$\overline{Var(\%)} = \sum_{1}^{n} \frac{P_T - P_0}{P_0} \qquad [3]$$

where
P_o is the value of the parameter to be analyzed at T0;
P_t is the value of the parameter to be analyzed at monitored experimental times.

All the calculations are done using a Microsoft® Excel.
The results of self-assessment questionnaire are calculated as percentage (%) of subjects who assigned a particular judgment (among those proposed). For each question, the number of subjects related to each judgment is counted → (number of subjects) and then divided by the total number of subjects → % of answers.

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1.8.2. Statistical analysis

The instrumental data are submitted to 2-way Student's test t for paired data. Statistical analysis is carried out by means of a Microsoft® Excel worksheet. The variation is considered statistically significant when p value is <0.05. The statistical analysis foresees the comparison vs T0. Only the data of subjects who ended the study as protocol directed were considered in the statistical analysis.

1.8.3. Interpretation of results

The study here above reported was designed to demonstrate the test product claim(s) in the current framework proposed by Commission Regulation (EU) No 655/2013. Endpoints are measured using techniques currently accepted in the cosmetic field while biases are minimized by procedure(s) standardization according to ISO 9001 Quality Management System. Data are analyzed and interpreted by skilled technician according to both descriptive and inferential statistical analysis procedures. Due to the lack of reference values in the cosmetic field, statistical significance (for instrumental analysis) and percentage of subjects showing an effect (for clinical/sensorial endpoints) are the primary criterion to evaluate the correspondence between the proposed claim(s) and the study output(s). In particular Intragroup (vs. T0) or intergroup (eg. active vs. placebo, treated vs non treated) statistical analysis criterion to reject the null hypothesis (no product effect) is set at p<0.05. For clinical evaluations, the positive effect of the product on the measured parameter is confirmed if more than 50% of the subjects register an improvement. Finally, for the self-assessment questionnaires, the performance and the pleasantness of the product must be perceived by at least 60% of the subjects. Whenever reference values or threshold values exists that values are used to validate product claim(s).

1.9. Start/end date of study

The table here below reports date of beginning and end of the study.

Start date	End date
04/01/2021	02/03/2021

1.10. Report change record

Table here below reports the change log of all approved changes made to the document that make up the course after initial approval.

Rev. no	Date	Description
00	10/03/2021	First release

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SUBJECTS DEMOGRAPHY

n	Vol ID	Age	Skin type	Eyelens wearer	Eyeglass wearer	Sensitive eyes	Sensitive skin	Eye colour
01	C4264M	46	Mixed	No	No	No	No	Brown
02	C0771F	53	Dry	No	No	Yes	Yes	Light blue
03	D2257E	51	Mixed	No	No	Yes	No	Brown
04	P4545P	48	Dry	Yes	Yes	Yes	Yes	Green
05	P4136E	53	Mixed	No	No	No	No	Brown
06	S4242R	48	Dry	Yes	No	No	No	Brown
07	D3610M	53	Mixed	No	No	Yes	Yes	Brown
08	P4482D	56	Dry	No	No	No	No	Light blue
09	M4263R	53	Mixed	No	No	Yes	Yes	Light blue
10	M4866P	57	Dry	No	Yes	Yes	Yes	Green
11	M3423C	56	Dry	No	Yes	Yes	Yes	Light blue
12	Q3572M	58	Dry	No	Yes	Yes	Yes	Green
13	G4599C	50	Mixed	No	Yes	Yes	Yes	Light blue
14	M3754L	49	Dry	No	No	No	No	Brown
15	S4325N	60	Normal	No	Yes	Yes	Yes	Green
16	F4782P	55	Normal	No	Yes	No	No	Brown
17	M4193I	44	Dry	No	Yes	Yes	No	Light blue
18	A3485P	52	Mixed	No	Yes	Yes	Yes	Brown
19	B4848S	60	Mixed	No	Yes	Yes	Yes	Green
20	S4324S	53	Normal	No	Yes	No	No	Brown
	Mean	53	Mixed 40%	Yes 10%	Yes 55%	Yes 65%	Yes 55%	Brown 45%
	Min	44	Dry 45%	No 90%	No 45%	No 35%	No 45%	Light blue 30%
	Max	60	Normal 15%					Green 25%

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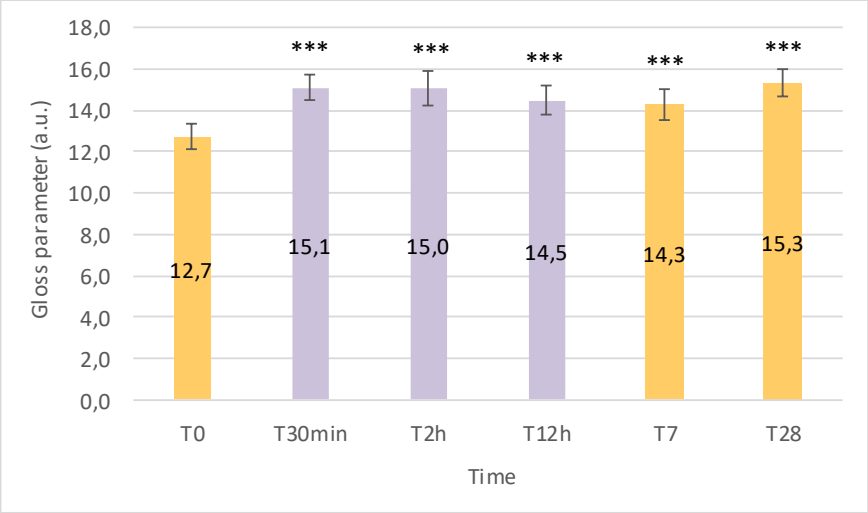
RESULTS
SKIN RADIANCE – GLOSS PARAMETER

TABLE 1. The table below reports the data obtained for each subject taking part in the study for the parameter under study. Data are expressed as arbitrary units (a.u.).

n	Vol ID	T0	T30min	T2h	T12h	T7	T28
01	C4264M	15,60	16,27	15,72	15,84	16,97	19,33
02	C0771F	14,50	14,95	17,98	16,41	14,96	15,58
03	D2257E	12,00	14,38	13,98	16,50	12,26	13,74
04	P4545P	10,76	13,38	13,01	14,17	12,21	14,93
05	P4136E	12,68	14,42	14,40	14,97	14,50	14,65
06	S4242R	10,75	13,94	12,53	11,66	10,23	12,00
07	D3610M	10,33	16,33	12,58	11,47	10,61	12,00
08	P4482D	12,65	13,39	13,49	12,41	13,75	14,31
09	M4263R	13,60	15,54	13,99	13,65	13,20	13,86
10	M4866P	12,70	17,83	14,52	13,05	13,71	13,81
11	M3423C	12,97	15,14	15,84	14,81	15,50	16,14
12	Q3572M	14,06	15,26	15,85	14,93	18,63	19,10
13	G4599C	11,28	12,36	12,63	12,20	13,32	13,70
14	M3754L	16,47	19,38	20,57	20,60	20,40	20,13
15	S4325N	18,91	20,91	25,29	20,56	20,89	21,80
16	F4782P	13,68	14,52	15,60	15,32	18,94	18,63
17	M4193I	9,68	11,39	11,29	10,91	11,30	13,60
18	A3485P	6,65	9,36	8,49	8,87	9,02	9,70
19	B4848S	10,93	14,68	13,75	11,52	11,45	13,67
20	S4324S	14,31	18,60	19,32	19,66	14,03	15,83
	Mean	12,7	15,1	15,0	14,5	14,3	15,3
	SEM	0,6	0,6	0,8	0,7	0,8	0,7
	t-test vs. T0	--	0,000	0,000	0,000	0,000	0,000

% VARIATION VS. T0	T30min	T2h	T12h	T7	T28
	4,3%	0,8%	1,5%	8,8%	23,9%
	3,1%	24,0%	13,2%	3,2%	7,4%
	19,8%	16,5%	37,5%	2,2%	14,5%
	24,3%	20,9%	31,7%	13,5%	38,8%
	13,7%	13,6%	18,1%	14,4%	15,5%
	29,7%	16,6%	8,5%	-4,8%	11,6%
	58,1%	21,8%	11,0%	2,7%	16,2%
	5,8%	6,6%	-1,9%	8,7%	13,1%
	14,3%	2,9%	0,4%	-2,9%	1,9%
	40,4%	14,3%	2,8%	8,0%	8,7%
	16,7%	22,1%	14,2%	19,5%	24,4%
	8,5%	12,7%	6,2%	32,5%	35,8%
	9,6%	12,0%	8,2%	18,1%	21,5%
	17,7%	24,9%	25,1%	23,9%	22,2%
	10,6%	33,7%	8,7%	10,5%	15,3%
	6,1%	14,0%	12,0%	38,5%	36,2%
	17,7%	16,6%	12,7%	16,7%	40,5%
	40,8%	27,7%	33,4%	35,6%	45,9%
	34,3%	25,8%	5,4%	4,8%	25,1%
	30,0%	35,0%	37,4%	-2,0%	10,6%
	20,3%	18,1%	14,3%	12,6%	21,5%
Min	3,1%	0,8%	-1,9%	-4,8%	1,9%
Max	58,1%	35,0%	37,5%	38,5%	45,9%

GRAPH 1. The graph sets out the mean data obtained at each experimental time for the parameter under study. Data are expressed as a mean ± SEM.



COMMENT: a statistically significant improvement of gloss parameter (related to skin brightness) is recorded at each experimental monitored check.

Note: the intra-group statistical analysis (vs. T0) is reported above the error bar in black color.
Legend: * p<0.05; ** p<0.01; *** p<0.001.

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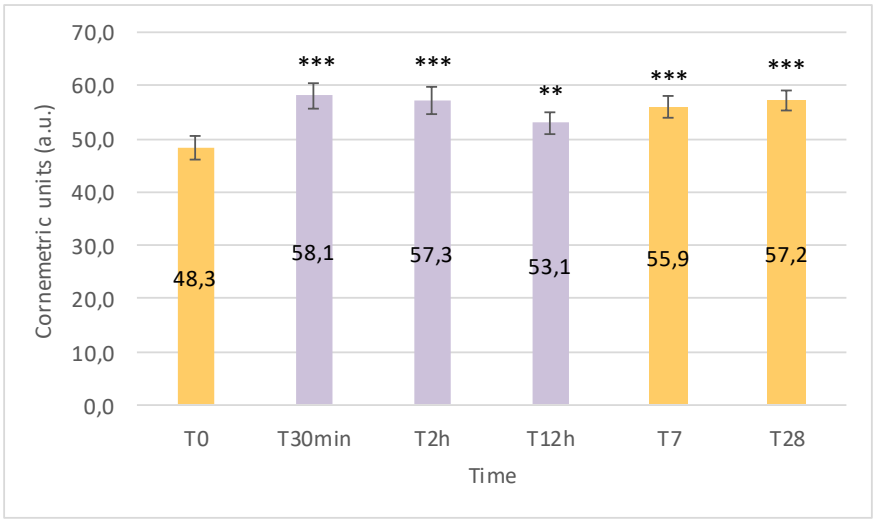
SKIN MOISTURIZATION

TABLE 2. The table below reports the data obtained for each subject taking part in the study for the parameter under study. Data are expressed as corneometric units (a.u.).

n	Vol ID	T0	T30min	T2h	T12h	T7	T28	% VARIATION VS. T0 T30min	T2h	T12h	T7	T28
01	C4264M	47,0	67,4	65,1	51,4	57,6	60,4	43,4%	38,6%	9,4%	22,6%	28,5%
02	C0771F	55,6	67,4	70,5	58,4	63,5	63,8	21,2%	26,8%	5,0%	14,2%	14,7%
03	D2257E	49,2	56,8	53,9	52,3	59,6	60,2	15,4%	9,6%	6,3%	21,1%	22,4%
04	P4545P	60,2	72,6	68,9	68,4	62,8	62,4	20,6%	14,5%	13,6%	4,3%	3,7%
05	P4136E	40,3	50,6	50,3	52,8	57,5	59,3	25,6%	24,8%	31,0%	42,7%	47,1%
06	S4242R	53,9	70,7	69,7	61,5	69,0	70,5	31,2%	29,3%	14,1%	28,0%	30,8%
07	D3610M	55,9	69,9	68,8	62,8	66,9	68,0	25,0%	23,1%	12,3%	19,7%	21,6%
08	P4482D	62,5	71,5	68,4	57,0	65,6	66,0	14,4%	9,4%	-8,8%	5,0%	5,6%
09	M4263R	43,9	49,4	69,3	57,7	56,6	58,1	12,5%	57,9%	31,4%	28,9%	32,3%
10	M4866P	60,2	66,4	64,1	59,0	64,1	65,0	10,3%	6,5%	-2,0%	6,5%	8,0%
11	M3423C	43,6	56,3	55,0	62,7	55,8	54,5	29,1%	26,1%	43,9%	28,0%	25,0%
12	Q3572M	47,7	52,0	49,2	48,7	50,1	52,3	8,9%	3,1%	2,0%	5,0%	9,6%
13	G4599C	31,8	40,4	41,9	37,3	34,7	36,9	27,0%	31,8%	17,2%	9,1%	16,0%
14	M3754L	47,1	55,4	53,6	52,1	59,6	55,8	17,6%	13,9%	10,7%	26,6%	18,5%
15	S4325N	56,2	68,3	63,1	58,8	54,7	60,6	21,6%	12,3%	4,7%	-2,7%	7,8%
16	F4782P	46,1	54,0	50,1	46,0	48,6	47,6	17,1%	8,7%	-0,2%	5,4%	3,3%
17	M4193I	30,7	36,9	38,7	40,0	38,8	43,7	20,4%	26,1%	30,4%	26,5%	42,5%
18	A3485P	32,5	40,4	37,2	33,8	42,5	44,8	24,3%	14,6%	3,9%	30,8%	37,8%
19	B4848S	54,8	64,3	58,9	54,0	57,5	61,5	17,4%	7,5%	-1,4%	5,0%	12,3%
20	S4324S	46,3	50,8	48,3	46,3	52,9	53,0	9,8%	4,3%	0,0%	14,3%	14,5%
	Mean	48,3	58,1	57,3	53,1	55,9	57,2	20,6%	19,4%	11,2%	17,0%	20,1%
	SEM	2,1	2,5	2,4	2,0	2,1	2,0	Min 8,9%	3,1%	-8,8%	-2,7%	3,3%
	t-test vs. T0	--	0,000	0,000	0,002	0,000	0,000	Max 43,4%	57,9%	43,9%	42,7%	47,1%

GRAPH 2. The graph sets out the mean data obtained at each experimental time for the parameter under study. Data are expressed as a mean ± SEM.



COMMENT: a statistically significant improvement of skin moisturization is recorded at each experimental monitored check.

Note: the intra-group statistical analysis (vs. T0) is reported above the error bar in black color.
Legend: * p<0.05; ** p<0.01; *** p<0.001.

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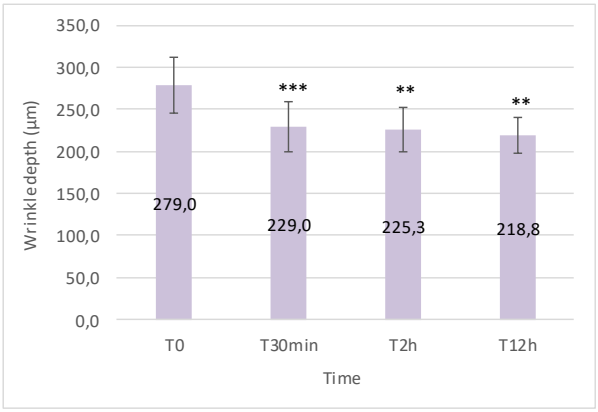
SKIN PROFILOMETRY – wrinkle depth

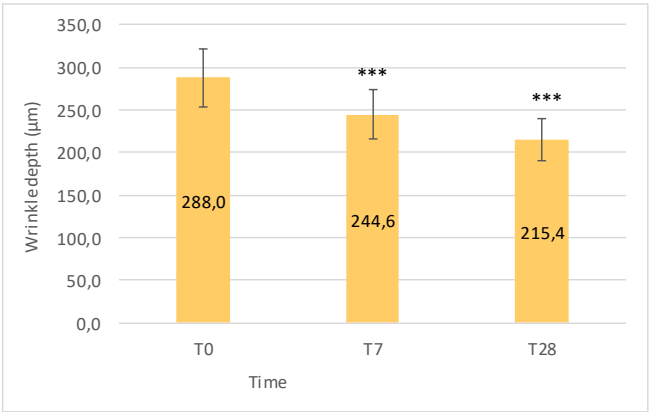
TABLES 3a/b. The table below reports the data obtained for each subject taking part in the study for wrinkle depth parameter. Data are expressed as µm.

n	Vol ID	T0	T30min	T2h	T12h	% VARIATION VS. T0	T30min	T2h	T12h
01	C4264M	281,0	252,7	278,5	276,9		-10,1%	-0,9%	-1,5%
02	C0771F	713,9	621,7	540,6	527,0		-12,9%	-24,3%	-26,2%
03	D2257E	481,6	390,2	343,8	266,2		-19,0%	-28,6%	-44,7%
04	P4545P	258,5	192,8	183,6	167,1		-25,4%	-29,0%	-35,4%
05	P4136E	445,7	479,1	283,1	336,5		7,5%	-36,5%	-24,5%
06	S4242R	354,1	193,6	221,6	252,5		-45,3%	-37,4%	-28,7%
07	D3610M	198,2	154,0	126,1	153,8		-22,3%	-36,4%	-22,4%
08	P4482D	237,3	193,7	153,9	204,3		-18,4%	-35,1%	-13,9%
09	M4263R	287,8	177,6	253,5	182,6		-38,3%	-11,9%	-36,6%
10	M4866P	454,3	315,4	476,6	289,0		-30,6%	4,9%	-36,4%
11	M3423C	232,4	210,4	148,0	170,6		-9,5%	-36,3%	-26,6%
12	Q3572M	265,6	185,0	210,8	257,5		-30,3%	-20,6%	-3,0%
13	G4599C	212,0	183,7	238,8	215,6		-13,3%	12,6%	1,7%
14	M3754L	116,0	127,7	127,3	130,6		10,1%	9,7%	12,6%
15	S4325N	139,9	133,4	126,2	134,9		-4,6%	-9,8%	-3,6%
16	F4782P	126,5	127,6	114,8	111,2		0,9%	-9,2%	-12,1%
17	M4193I	147,0	79,7	108,0	150,0		-45,8%	-26,5%	2,0%
18	A3485P	134,0	122,1	128,2	130,1		-8,9%	-4,3%	-2,9%
19	B4848S	247,8	221,1	237,5	252,8		-10,8%	-4,2%	2,0%
20	S4324S	245,6	218,0	205,5	167,6		-11,2%	-16,3%	-31,8%
	Mean	279,0	229,0	225,3	218,8		-16,9%	-17,0%	-16,6%
	SEM	33,2	29,5	26,3	21,5	Max	-45,8%	-37,4%	-44,7%
	t-test vs. T0	--	0,000	0,001	0,001	Min	10,1%	12,6%	12,6%

n	T0	T7	T28	% VARIATION VS. T0	T7	T28
01	275,0	249,6	217,4		-9,2%	-20,9%
02	722,8	671,7	553,1		-7,1%	-23,5%
03	508,2	378,3	342,5		-25,6%	-32,6%
04	232,0	186,2	159,3		-19,7%	-31,3%
05	464,4	336,5	280,5		-27,5%	-39,6%
06	372,8	267,8	243,6		-28,2%	-34,7%
07	226,2	196,6	162,9		-13,1%	-28,0%
08	253,9	206,3	156,1		-18,7%	-38,5%
09	288,0	194,1	185,3		-32,6%	-35,7%
10	425,8	382,3	375,1		-10,2%	-11,9%
11	290,7	258,6	231,5		-11,0%	-20,4%
12	292,3	270,6	242,1		-7,4%	-17,2%
13	201,7	181,5	175,4		-10,0%	-13,0%
14	121,5	134,3	119,5		10,5%	-1,6%
15	146,2	130,3	117,1		-10,9%	-19,9%
16	126,0	113,7	123,3		-9,8%	-2,1%
17	165,6	151,1	115,2		-8,8%	-30,4%
18	112,7	103,0	105,3		-8,6%	-6,6%
19	267,2	227,2	165,3		-15,0%	-38,1%
20	266,0	252,5	237,2		-5,1%	-10,8%
	288,0	244,6	215,4		-13,4%	-22,8%
	33,7	28,8	24,4	Max	-32,6%	-39,6%
	--	0,000	0,000	Min	10,5%	-1,6%

GRAPH 3a/b. The graph sets out the mean data obtained at each experimental time for the parameter under study. Data are expressed as a mean ± SEM.





COMMENT: a statistically significant decrease of wrinkle depth parameter is recorded at each experimental monitored check.

Note: the intra-group statistical analysis (vs. T0) is reported above the error bar in black color.
Legend: * p<0.05; ** p<0.01; *** p<0.001.

Primos instrumental analysis foresees the overlay and measurement of pictures acquired at different timepoints. In this study, a first analysis has been carried out at the end of the short term test and refers to T0, T30min, T2h and T12h pictures. A second analysis has been carried out at the end of the long term test and refers to T0, T7 and T28 pictures. The analysis procedure carried out with different pictures can determine a slightly different overlay and this explains the difference between T0 values (in short and long term analysis).

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SKIN PROFILOMETRY – Ra parameter

TABLES 3c/d. The table below reports the data obtained for each subject taking part in the study for Ra parameter. Data are expressed as µm.

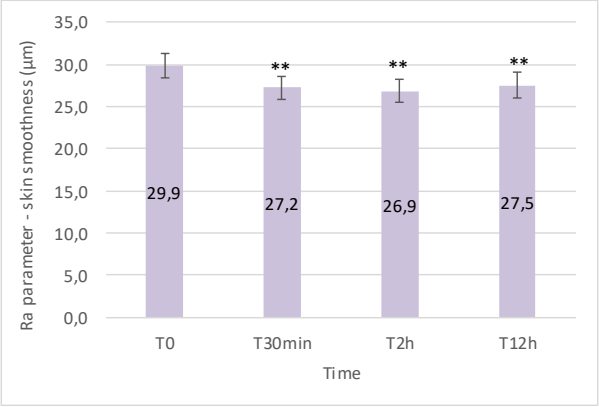
n	Vol ID	T0	T30min	T2h	T12h
01	C4264M	34,5	33,9	38,6	38,3
02	C0771F	33,9	35,2	30,7	35,6
03	D2257E	34,6	22,0	21,2	27,3
04	P4545P	30,1	27,2	24,8	23,8
05	P4136E	25,9	25,6	26,1	24,9
06	S4242R	23,5	21,8	22,6	21,6
07	D3610M	37,0	31,6	23,3	30,6
08	P4482D	34,1	32,1	33,3	31,7
09	M4263R	29,2	24,8	26,0	23,8
10	M4866P	35,4	31,6	30,7	27,7
11	M3423C	30,0	28,0	25,0	24,0
12	Q3572M	20,9	18,1	17,6	16,8
13	G4599C	44,1	40,5	42,1	43,3
14	M3754L	21,7	23,9	21,9	22,9
15	S4325N	26,8	24,8	23,7	23,9
16	F4782P	22,2	23,6	21,6	21,0
17	M4193I	18,2	17,3	18,6	20,0
18	A3485P	27,3	23,5	26,6	23,8
19	B4848S	36,2	28,2	32,0	35,3
20	S4324S	32,4	30,6	30,8	33,7
	Mean	29,9	27,2	26,9	27,5
	SEM	1,5	1,3	1,4	1,5
	t-test vs. T0	--	0,002	0,005	0,005

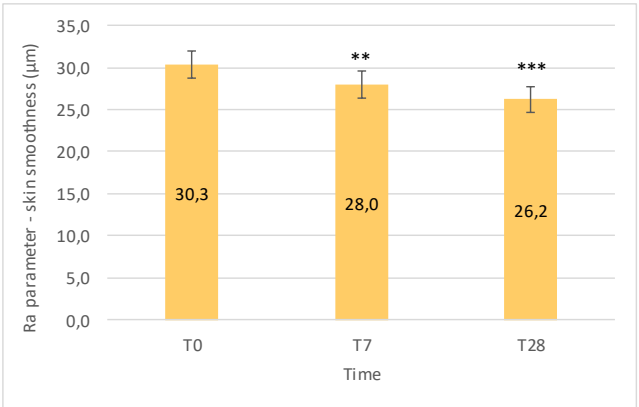
% VARIATION VS. T0	T30min	T2h	T12h
	-1,7%	11,9%	11,0%
	3,8%	-9,4%	5,0%
	-36,4%	-38,7%	-21,1%
	-9,6%	-17,6%	-20,9%
	-1,2%	0,8%	-3,9%
	-7,2%	-3,8%	-8,1%
	-14,6%	-37,0%	-17,3%
	-5,9%	-2,3%	-7,0%
	-15,1%	-11,0%	-18,5%
	-10,7%	-13,3%	-21,8%
	-6,7%	-16,7%	-20,0%
	-13,4%	-15,8%	-19,6%
	-8,2%	-4,5%	-1,8%
	10,1%	0,9%	5,5%
	-7,5%	-11,6%	-10,8%
	6,3%	-2,7%	-5,4%
	-4,9%	2,2%	9,9%
	-13,9%	-2,6%	-12,8%
	-22,1%	-11,6%	-2,5%
	-5,6%	-4,9%	4,0%
	-8,2%	-9,4%	-7,8%
Max	-36,4%	-38,7%	-21,8%
Min	10,1%	11,9%	11,0%

n	T0	T7	T28
01	38,3	39,2	34,6
02	32,8	30,7	28,2
03	38,3	28,1	26,0
04	33,1	26,3	24,3
05	24,5	22,3	21,4
06	24,3	24,6	22,7
07	41,2	35,3	30,9
08	35,7	34,9	33,7
09	27,8	25,3	24,8
10	30,8	29,1	26,1
11	30,0	26,0	24,4
12	20,9	19,0	17,5
13	43,5	42,5	42,0
14	22,6	21,0	19,8
15	27,8	24,9	25,1
16	21,6	20,8	19,5
17	16,8	15,1	14,1
18	31,6	29,4	29,4
19	34,3	35,9	32,2
20	30,8	29,2	27,2
	30,3	28,0	26,2
	1,6	1,6	1,5
	--	0,001	0,000

% VARIATION VS. T0	T7	T28
	2,3%	-9,7%
	-6,4%	-14,0%
	-26,6%	-32,1%
	-20,5%	-26,6%
	-9,0%	-12,7%
	1,2%	-6,6%
	-14,3%	-25,0%
	-2,2%	-5,6%
	-9,0%	-10,8%
	-5,5%	-15,3%
	-13,3%	-18,7%
	-9,1%	-16,3%
	-2,3%	-3,4%
	-7,1%	-12,4%
	-10,4%	-9,7%
	-3,7%	-9,7%
	-10,1%	-16,1%
	-7,0%	-7,0%
	4,7%	-6,1%
	-5,2%	-11,7%
	-7,7%	-13,5%
Max	-26,6%	-32,1%
Min	4,7%	-3,4%

GRAPH 3c/d. The graph sets out the mean data obtained at each experimental time for the parameter under study. Data are expressed as a mean ± SEM.





COMMENT: a statistically significant decrease of Ra parameter is recorded at each experimental monitored check. A decrease of Ra parameter indicates an improvement of skin smoothness; for marketing purposes obtained values can be expressed in absolute values as an improvement of skin smoothness.

Note: the intra-group statistical analysis (vs. T0) is reported above the error bar in black color.
Legend: * p<0.05; ** p<0.01; *** p<0.001.

Primos instrumental analysis foresees the overlay and measurement of pictures acquired at different timepoints. In this study, a first analysis has been carried out at the end of the short term test and refers to T0, T30min, T2h and T12h pictures. A second analysis has been carried out at the end of the long term test and refers to T0, T7 and T28 pictures. The analysis procedure carried out with different pictures can determine a slightly different overlay and this explains the difference between T0 values (in short and long term analysis).

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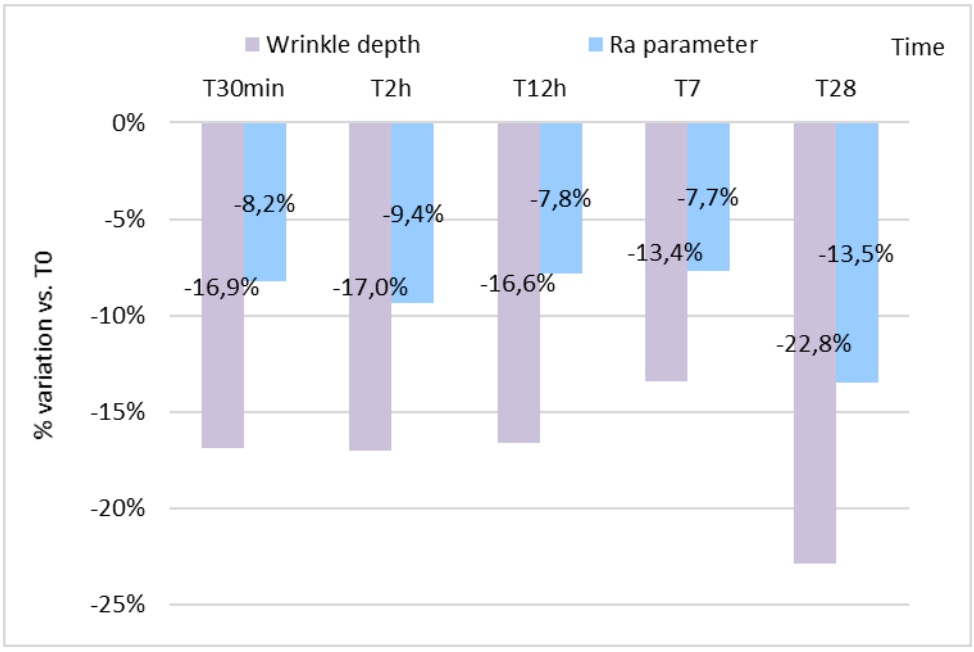
SKIN PROFILOMETRY – Summary

TABLE 3e. The table below summarizes the mean % variation, min/max values and statistical analysis (p-value) obtained for skin profilometry parameters at each experimental monitored check.

		T30min	T2h	T12h	T7	T28
Wrinkle depth	Mean of the % variation vs. T0	**-16,9%**	**-17,0%**	**-16,6%**	**-13,4%**	**-22,8%**
	t-test vs. T0 (p-value)	0,000	0,001	0,001	0,000	0,000
	MAX (maximum variation)	-45,8%	-37,4%	-44,7%	-32,6%	-39,6%
	MIN (minimum variation)	10,1%	12,6%	12,6%	10,5%	-1,6%
Ra parameter (skin smoothness)	Mean of the % variation vs. T0	**-8,2%**	**-9,4%**	**-7,8%**	**-7,7%**	**-13,5%**
	t-test vs. T0 (p-value)	0,002	0,005	0,005	0,001	0,000
	MAX (maximum variation)	-36,4%	-38,7%	-21,8%	-26,6%	-32,1%
	MIN (minimum variation)	10,1%	11,9%	11,0%	4,7%	-3,4%

GRAPH 3e. The graph sets out the mean of the percentage variations obtained at each experimental time for skin profilometry parameters.



COMMENT: a statistically significant decrease of wrinkle depth and Ra parameter is recorded at each experimental monitored check. A decrease of Ra parameter indicates an improvement of skin smoothness; for marketing purposes obtained values can be expressed in absolute values as an improvement of skin smoothness.

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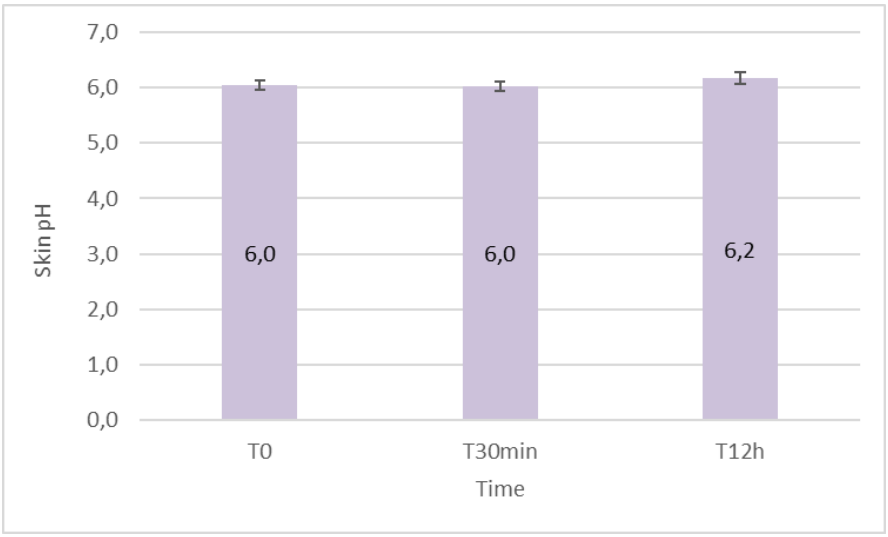
SKIN pH

TABLE 4. The table below reports the data obtained for each subject taking part in the study for the parameter under study. Data are expressed as pH values.

n	Vol ID	T0	T30min	T12h
01	C4264M	6,5	6,4	6,7
02	C0771F	6,4	6,3	6,4
03	D2257E	6,1	6,3	6,5
04	P4545P	6,3	6,3	6,5
05	P4136E	6,3	6,3	6,3
06	S4242R	6,4	6,3	6,5
07	D3610M	6,5	6,4	6,5
08	P4482D	6,4	6,2	6,5
09	M4263R	6,3	6,4	6,4
10	M4866P	6,4	6,3	6,6
11	M3423C	5,8	6,0	7,0
12	Q3572M	6,1	5,9	5,9
13	G4599C	5,9	5,8	5,9
14	M3754L	5,7	5,6	5,8
15	S4325N	5,4	5,4	5,8
16	F4782P	6,1	6,0	5,8
17	M4193I	6,2	5,9	6,0
18	A3485P	5,7	5,6	5,6
19	B4848S	5,0	5,3	5,1
20	S4324S	5,7	5,8	5,7
	Mean	6,0	6,0	6,2
	SEM	0,1	0,1	0,1
	t-test vs. T0	--	0,546	0,103

GRAPH 4. The graph sets out the mean data obtained at each experimental time for the parameter under study. Data are expressed as a mean ± SEM.



COMMENT: 30 minutes after the first application and 12 hours after the first evening-application, tested product doesn't alter the basal skin conditions; pH mean value is almost unvaried.

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PRODUCT TOLERABILITY – OPHTHALMOLOGICAL EVALUATIONS

TABLE 5a. The table below reports the ophthalmological evaluations carried out at baseline.

	Volunteer no	Lacrimation	Vasodilatation	Foreign body sensation	Photophobia	Itching	Stinging eyes	Periocular swelling	Other
	T0								
1	C4264M	0	0	0	0	0	0	0	0
2	C0771F	0	0	0	0	0	0	0	0
3	D2257E	0	0	0	0	0	0	0	0
4	P4545P	0	0	0	0	0	0	0	0
5	P4136E	0	0	0	0	0	0	0	0
6	S4242R	0	0	0	0	0	0	0	0
7	D3610M	0	0	0	0	0	0	0	0
8	P4482D	0	0	0	0	0	0	0	0
9	M4263R	0	0	0	0	0	0	0	0
10	M4866P	0	0	0	0	0	0	0	0
11	M3423C	0	0	0	0	0	0	0	0
12	Q3572M	0	0	0	0	0	0	0	0
13	G4599C	0	0	0	0	0	0	0	0
14	M3754L	0	0	0	0	0	0	0	0
15	S4325N	0	0	0	0	0	0	0	0
16	F4782P	0	0	0	0	0	0	0	0
17	M4193I	0	0	0	0	0	0	0	0
18	A3485P	0	0	0	0	0	0	0	0
19	B4848S	0	0	0	0	0	0	0	0
20	S4324S	0	0	0	0	0	0	0	0

TABLE 5b. The table below reports the ophthalmological evaluations carried out after 7 days of product use (T7).

	Volunteer no	Lacrimation	Vasodilatation	Foreign body sensation	Photophobia	Itching	Stinging eyes	Periocular swelling	Other
	T7								
1	C4264M	0	0	0	0	0	0	0	0
2	C0771F	0	0	0	0	0	0	0	0
3	D2257E	0	0	0	0	0	0	0	0
4	P4545P	0	0	0	0	0	0	0	0
5	P4136E	0	0	0	0	0	0	0	0
6	S4242R	0	0	0	0	0	0	0	0
7	D3610M	0	0	0	0	0	0	0	0
8	P4482D	0	0	0	0	0	0	0	0
9	M4263R	0	0	0	0	0	0	0	0
10	M4866P	0	0	0	0	0	0	0	0
11	M3423C	0	0	0	0	0	0	0	0
12	Q3572M	0	0	0	0	0	0	0	0
13	G4599C	0	0	0	0	0	0	0	0
14	M3754L	0	0	0	0	0	0	0	0
15	S4325N	0	0	0	0	0	0	0	0
16	F4782P	0	0	0	0	0	0	0	0
17	M4193I	0	0	0	0	0	0	0	0
18	A3485P	0	0	0	0	0	0	0	0
19	B4848S	0	0	0	0	0	0	0	0
20	S4324S	0	0	0	0	0	0	0	0

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TABLE 5c. The table below reports the ophthalmological evaluations carried out at the end of the study (T28).

	Volunteer no T28	Lacrimation	Vasodilatation	Foreign body sensation	Photophobia	Itching	Stinging eyes	Periocular swelling	Other
1	C4264M	0	0	0	0	0	0	0	0
2	C0771F	0	0	0	0	0	0	0	0
3	D2257E	0	0	0	0	0	0	0	0
4	P4545P	0	0	0	0	0	0	0	0
5	P4136E	0	0	0	0	0	0	0	0
6	S4242R	0	0	0	0	0	0	0	0
7	D3610M	0	0	0	0	0	0	0	0
8	P4482D	0	0	0	0	0	0	0	0
9	M4263R	0	0	0	0	0	0	0	0
10	M4866P	0	0	0	0	0	0	0	0
11	M3423C	0	0	0	0	0	0	0	0
12	Q3572M	0	0	0	0	0	0	0	0
13	G4599C	0	0	0	0	0	0	0	0
14	M3754L	0	0	0	0	0	0	0	0
15	S4325N	0	0	0	0	0	0	0	0
16	F4782P	0	0	0	0	0	0	0	0
17	M4193I	0	0	0	0	0	0	0	0
18	A3485P	0	0	0	0	0	0	0	0
19	B4848S	0	0	0	0	0	0	0	0
20	S4324S	0	0	0	0	0	0	0	0

TABLE 5d. The table below reports the alterations of eyelids and conjunctival mucosa.

ALALTERATIONS OF EYELID			
Volunteer no	T0	T7	T28
C4264M	0	0	0
C0771F	0	0	0
D2257E	0	0	0
P4545P	0	0	0
P4136E	0	0	0
S4242R	0	0	0
D3610M	0	0	0
P4482D	0	0	0
M4263R	0	0	0
M4866P	0	0	0
M3423C	0	0	0
Q3572M	0	0	0
G4599C	0	0	0
M3754L	0	0	0
S4325N	0	0	0
F4782P	0	0	0
M4193I	0	0	0
A3485P	0	0	0
B4848S	0	0	0
S4324S	0	0	0

ALTERATIONS OF CONJUNCTIVAL MUCOSA			
Volunteer no	T0	T7	T28
C4264M	0	0	0
C0771F	0	0	0
D2257E	0	0	0
P4545P	0	0	0
P4136E	0	0	0
S4242R	0	0	0
D3610M	0	0	0
P4482D	0	0	0
M4263R	0	0	0
M4866P	0	0	0
M3423C	0	0	0
Q3572M	0	0	0
G4599C	0	0	0
M3754L	0	0	0
S4325N	0	0	0
F4782P	0	0	0
M4193I	0	0	0
A3485P	0	0	0
B4848S	0	0	0
S4324S	0	0	0

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SELF-ASSESSMENT

TABLE 6. The table below summarizes the results of the self-assessment questionnaire. The results are expressed as percentage (%) of subjects who expressed the same opinion among those proposed.

GLOBAL APPRECIATION OF THE PRODUCT - AFTER FIRST PRODUCT APPLICATION

No.		Very pleasant	Pleasant	Neither pleasant nor unpleasant	Unpleasant	Very unpleasant	Positive answers
01	What do you think about product aspect?	35,0%	55,0%	10,0%	0,0%	0,0%	90,0%
02	What do you think about product texture?	45,0%	55,0%	0,0%	0,0%	0,0%	100,0%
03	What do you think about product fragrance?	20,0%	40,0%	40,0%	0,0%	0,0%	60,0%
04	What do you think about product spreadability?	30,0%	70,0%	0,0%	0,0%	0,0%	100,0%
No.		Very good	Good	Not good	Bad		Positive answers
05	What do you think about product penetration?	55,0%	45,0%	0,0%	0,0%		100,0%
No.		Silky	Soft	Sticky	Oily		Positive answers
06	What is the after feel on the skin?	50,0%	40,0%	10,0%	0,0%		90,0%
No.		Very good	Good	Not good	Bad		Positive answers
07	What is your overall appreciation of this product?	25,0%	75,0%	0,0%	0,0%		100,0%

EVALUATION OF THE EFFICACY 30 MINUTES AFTER PRODUCT APPLICATION

No.		Intense	Moderate	Slightly	Not at all		Positive answers
08	Have you noticed an amelioration of skin hydration?	0,0%	65,0%	35,0%	0,0%		65,0%
09	Have you felt a tightening effect (lifting effect)?	5,0%	70,0%	20,0%	5,0%		75,0%
10	Have you noticed an amelioration of skin smoothness?	10,0%	45,0%	40,0%	5,0%		55,0%
11	have you noticed an amelioration of skin brightness?	5,0%	55,0%	35,0%	5,0%		60,0%
No.	30min after the application, have you noticed that:	Agree	Moderately agree	Not completely agree	Not agree		Positive answers
12a	Your skin is more moisturized	60,0%	35,0%	5,0%	0,0%		95,0%
12b	Your skin is smoother	35,0%	55,0%	10,0%	0,0%		90,0%
12c	Fines lines and wrinkles are less visible	15,0%	50,0%	35,0%	0,0%		65,0%
12d	Signs of fatigue are less visible and look is fresher	20,0%	50,0%	30,0%	0,0%		70,0%
12e	Your skin is brighter	30,0%	50,0%	20,0%	0,0%		80,0%

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EVALUATION OF THE EFFICACY 12 HOURS AFTER PRODUCT APPLICATION

No.		Intense	Moderate	Slightly	Not at all	Positive answers
13	Have you noticed an amelioration of skin hydration?	15,0%	55,0%	30,0%	0,0%	70,0%
14	Have you felt a tightening effect (lifting effect)?	20,0%	55,0%	20,0%	5,0%	75,0%
15	Have you noticed an amelioration of skin smoothness?	15,0%	35,0%	45,0%	5,0%	50,0%
16	have you noticed an amelioration of skin brightness?	15,0%	40,0%	40,0%	5,0%	55,0%
No.	12 hours after the application, have you noticed that:	Agree	Moderately agree	Not completely agree	Not agree	Positive answers
17a	Your skin is more moisturized	25,0%	65,0%	10,0%	0,0%	90,0%
17b	You skin is smoother	10,0%	80,0%	10,0%	0,0%	90,0%
17c	Fines lines and wrinkles are less visible	5,0%	50,0%	45,0%	0,0%	55,0%
17d	Signs of fatigue are less visible and look is fresher	20,0%	30,0%	50,0%	0,0%	50,0%
17e	Your skin is brighter	25,0%	45,0%	30,0%	0,0%	70,0%

AFTER 4 WEEKS OF APPLICATION, HAVE YOU NOTICED THAT:

No.		Agree	Moderately agree	Not completely agree	Not agree	Positive answers
1a	Your skin is more moisturized	75,0%	20,0%	5,0%	0,0%	95,0%
1b	Your skin is smoother	65,0%	30,0%	5,0%	0,0%	95,0%
1c	Your skin is tightened	40,0%	55,0%	5,0%	0,0%	95,0%
1d	Your skin is firmer	50,0%	40,0%	10,0%	0,0%	90,0%
1e	Fine lines and wrinkles are less visibile	35,0%	55,0%	10,0%	0,0%	90,0%
1f	Signs of fatigue (dark circles and puffiness) are less visibile	35,0%	45,0%	20,0%	0,0%	80,0%
1g	Your skin looks brighter	65,0%	25,0%	10,0%	0,0%	90,0%
1h	Your look appears more relaxed, refreshed and rested	50,0%	40,0%	10,0%	0,0%	90,0%

AFTER APPLICATION, THE FOLLOWING SKIN ISSUES SEEM IMPROVED:

No.		Strongly	Improved	Unchanged	Aggravated	Positive answers
2a	Dehydration	35,0%	60,0%	5,0%	0,0%	95,0%
2b	Dullness	35,0%	50,0%	15,0%	0,0%	85,0%
2c	Tired look	40,0%	40,0%	20,0%	0,0%	80,0%
2d	Fine lines and wrinkles	20,0%	60,0%	20,0%	0,0%	80,0%
No.		Yes	No	--	--	Positive answers
03	When you have used the product, have you felt uncomfortable sensations?	0,0%	100,0%	--	--	100,0%
4a	If YES, have you stopped the application?	0,0%	0,0%	--	--	--
4b	If the treatment has been stopped, has it been stopped for a skin reaction?	0,0%	0,0%	--	--	--
4c	Other reasons?	0,0%	0,0%	--	--	--

Comment: no subjects felt uncomfortable sensations due to product use (no volunteers answered to questions 4a, 4b and 4c).

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CONCLUSION

On the basis of the obtained results, it is possible to conclude that the product:

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LE REGARD 2.0 SERUM LIFTANT ECLAT
Reference code: lab-01399.9

determines a general improvement of the analysed skin parameters both in the short and long term test.
In particular the product determines:

- An increase of gloss parameter by +20.3% 30 minutes after its first application, by +18.1% at T2h, by +14.3% in the morning after the first evening-application (T12h) and respectively by +12.6% and +21.5% after 7 and 28 days of use.
- An increase of skin moisturization by +20.6% 30 minutes after its first application, by +19.4% at T2h, by +11.2% in the morning after the first evening-application (T12h) and respectively by +17.0% and +20.1% after 7 and 28 days of use.
- An decrease of wrinkle depth parameter by -16.9% 30 minutes after its first application, by -17.0% at T2h, by -16.6% in the morning after the first evening-application (T12h) and respectively by -13.4% and -22.8% after 7 and 28 days of use.
- An decrease of Ra parameter (index of an improvement of skin smoothness) by 8.2% 30 minutes after its first application, by 9.4% at T2h, by 7.8% in the morning after the first evening-application (T12h) and respectively by 7.7% and 13.5% after 7 and 28 days of use.

The reported % are referred to the mean variations of the analysed parameters versus T0.
Reported variations are statistically significant variation versus T0.

Tested product **HAS BEEN OPHTALMOLOGICALLY TESTED. IT IS SAFE TO BE USED IN THE PERIOCULAR AREA,** no enrolled volunteers showed any significant alterations on their eyelid skin or eye mucosa during the study period.

Ophthtalmologist

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Data analysis and report

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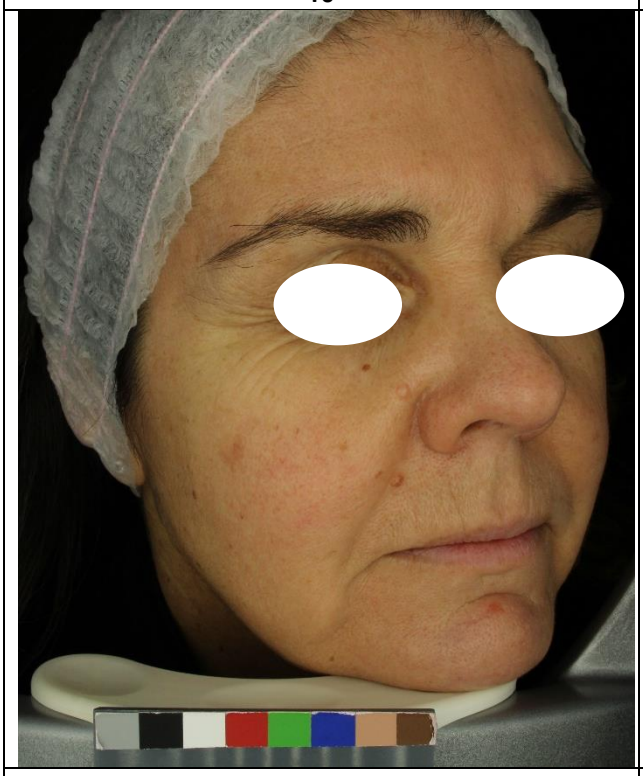
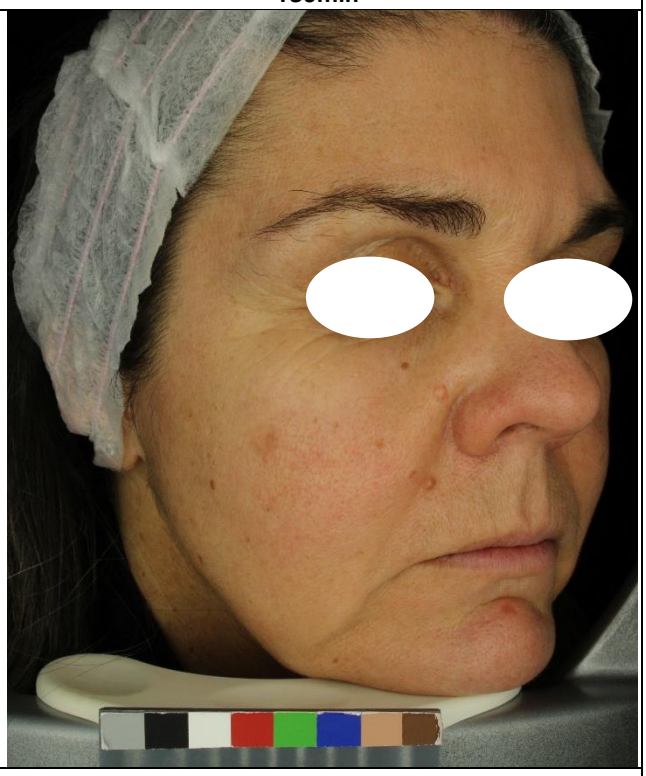
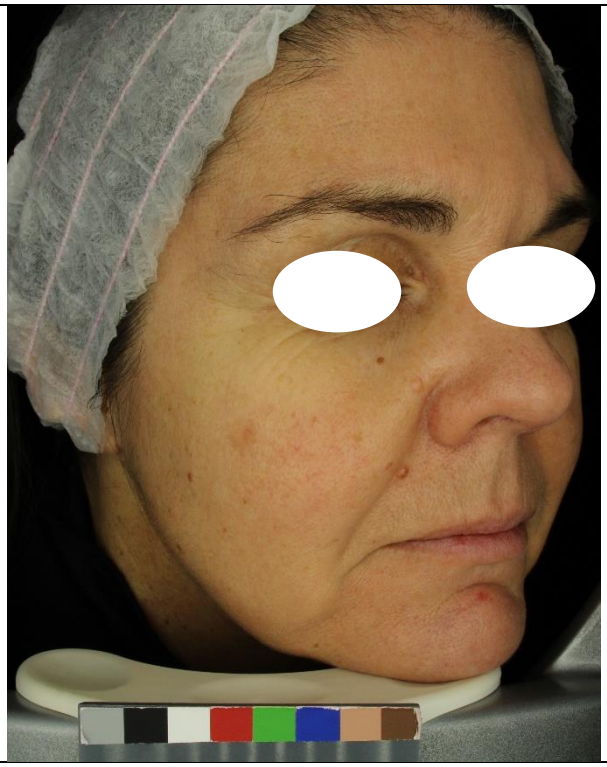
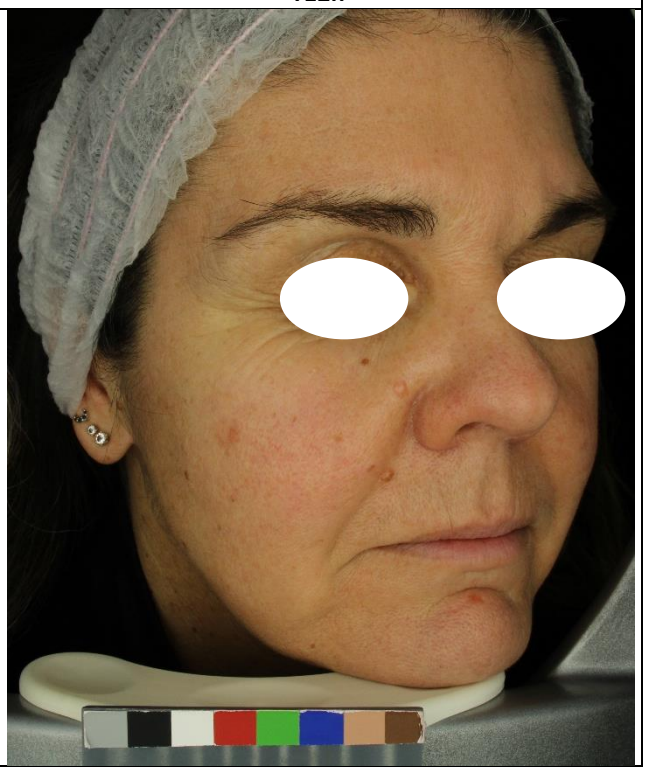
ANNEX 1 – DIGITAL PICTURES

T0	T30min
	
T2h	**T12h**
	

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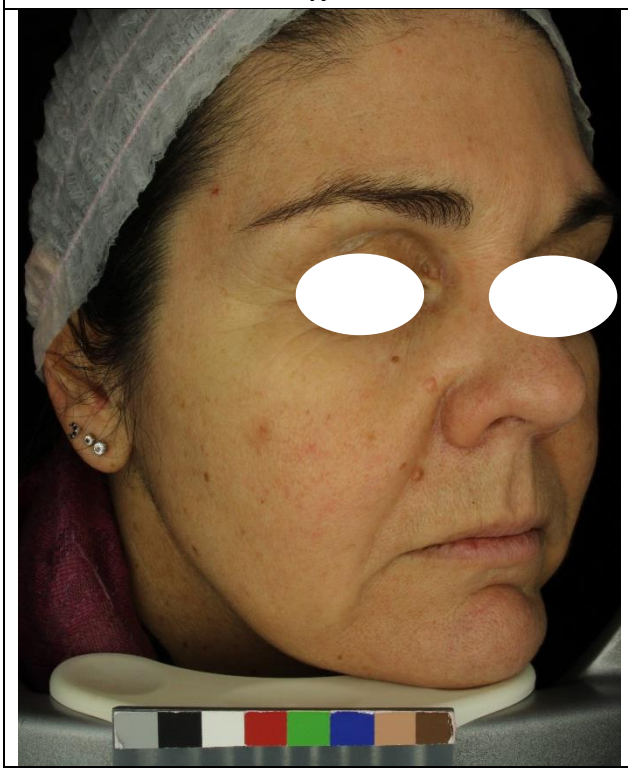
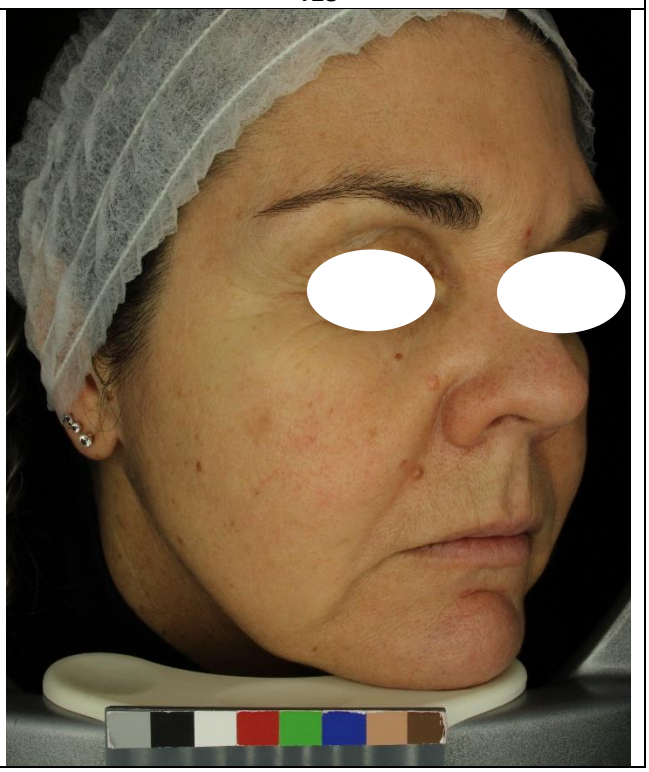
T7	T28
	

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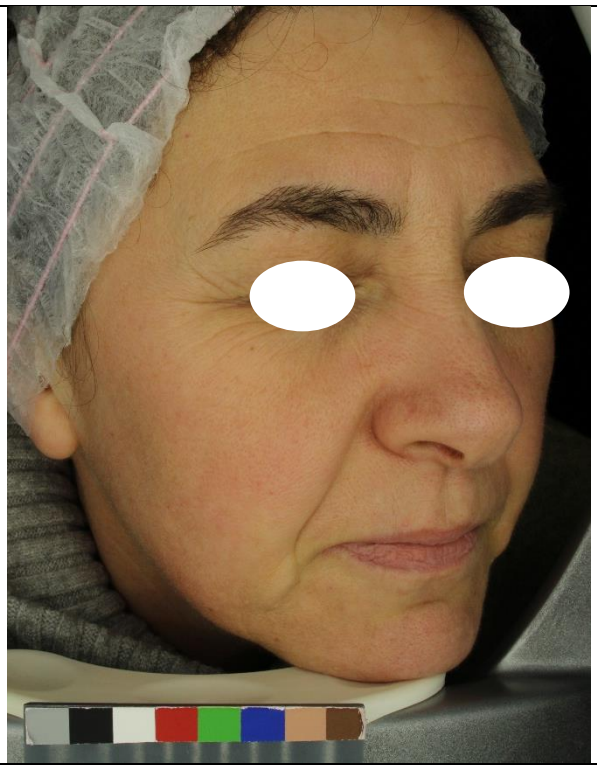
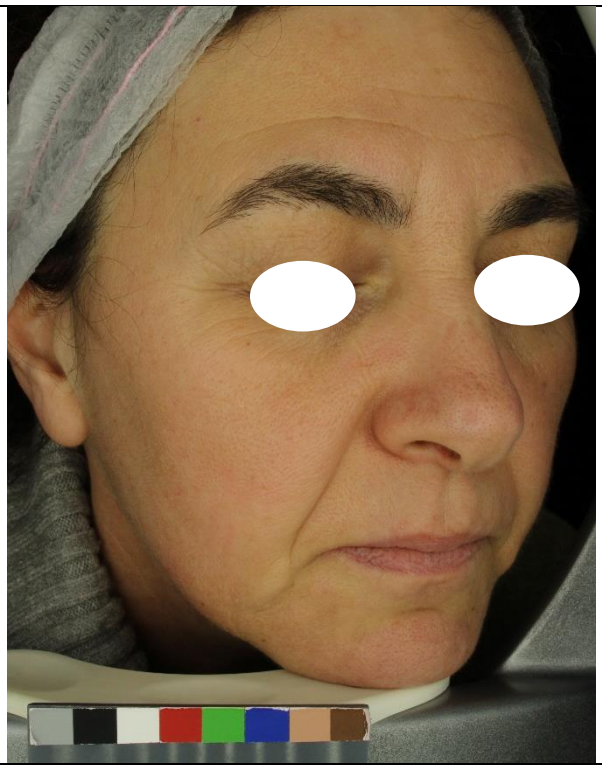
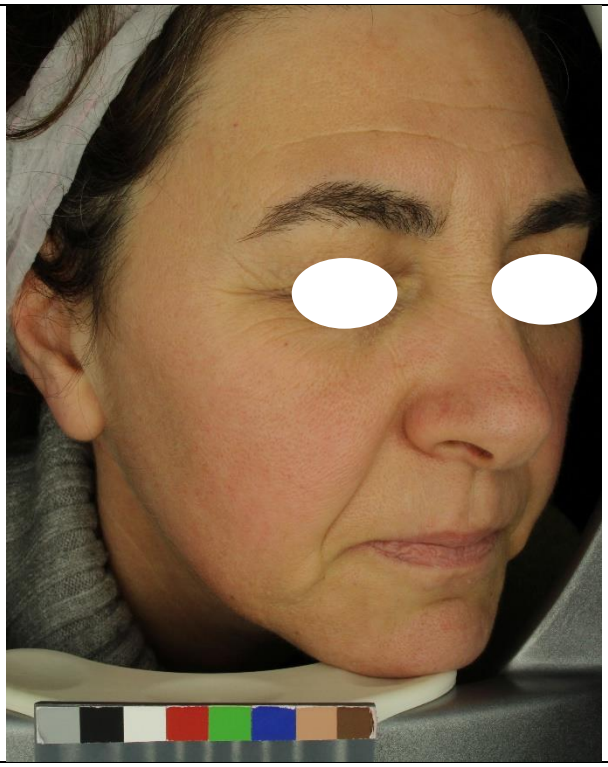
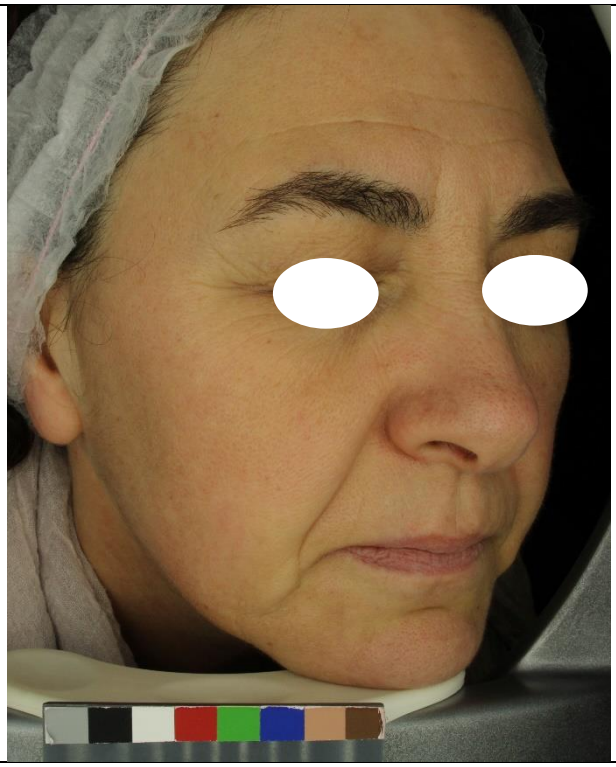
T0	T30min
	
T2h	**T12h**
	

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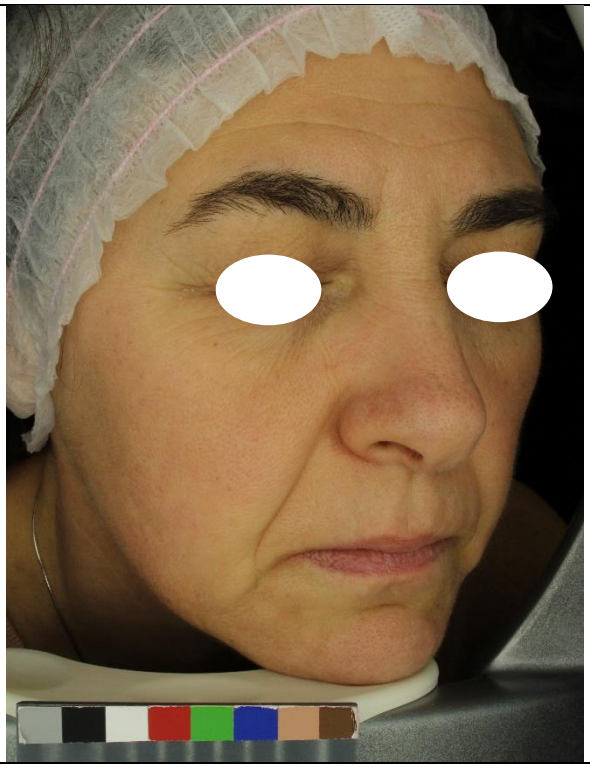
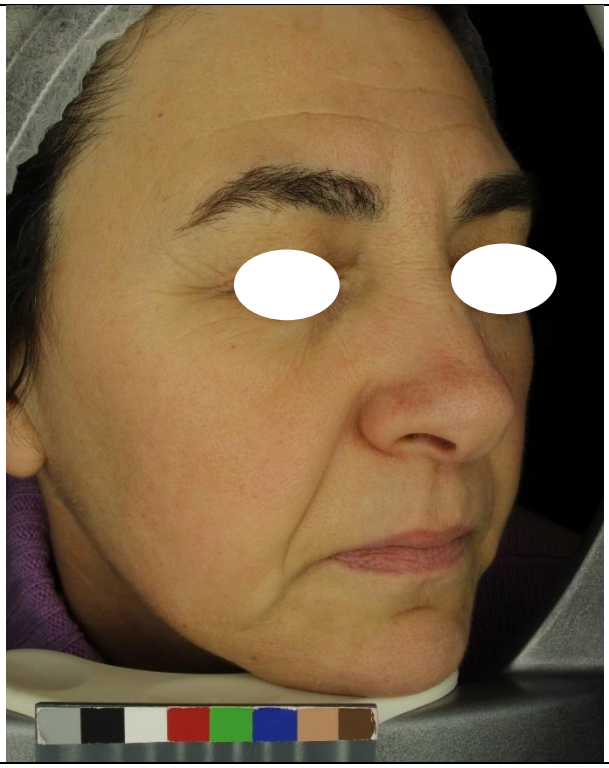
T7	T28
	

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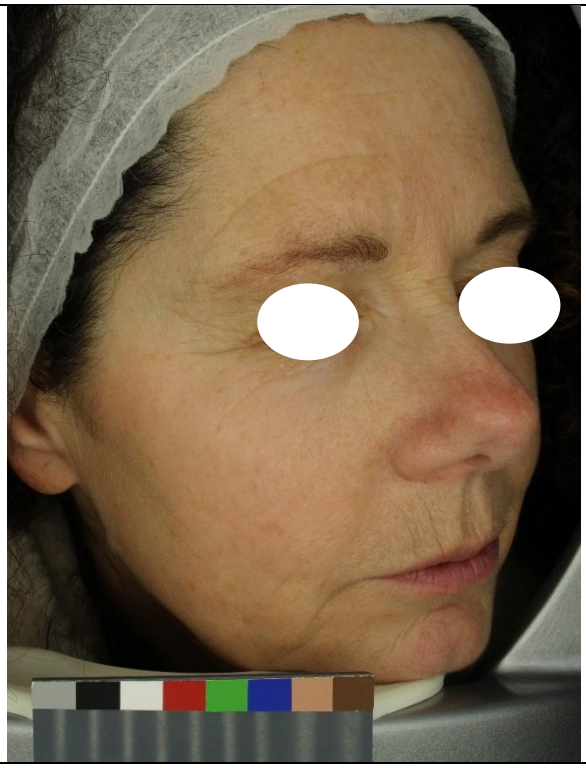
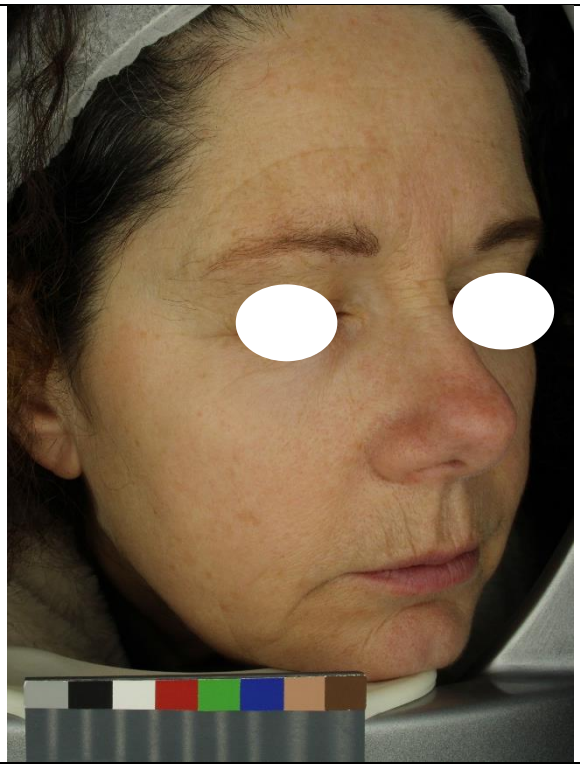
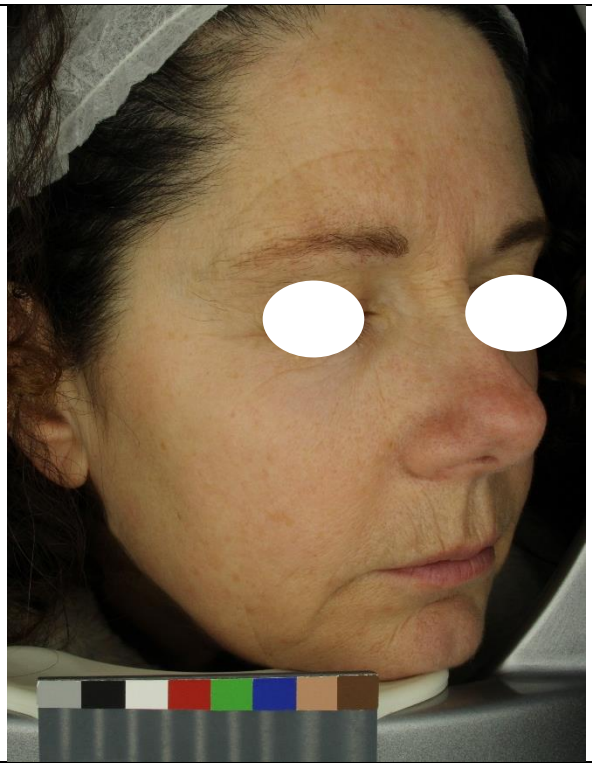
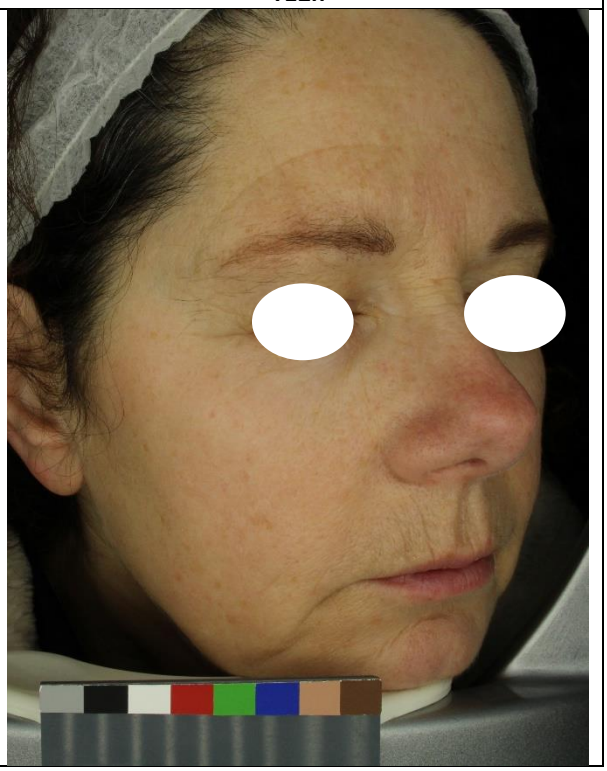
T0	T30min
	
T2h	**T12h**
	

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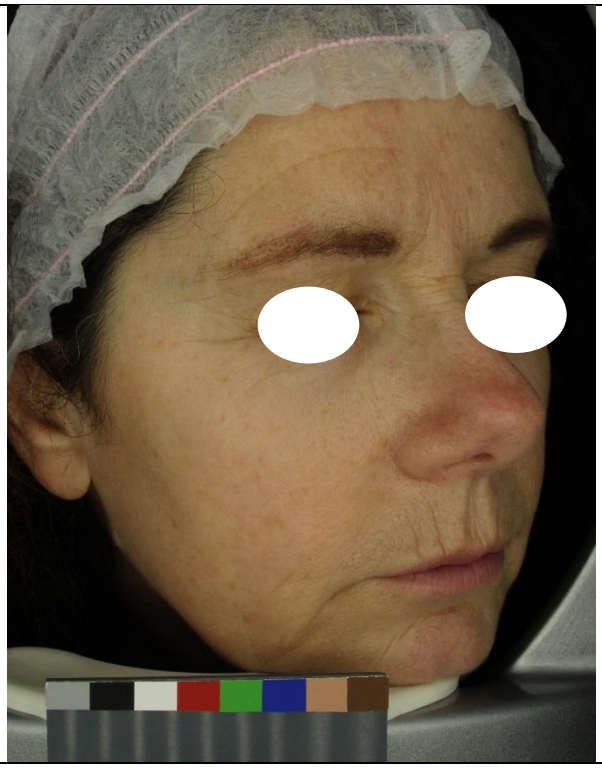
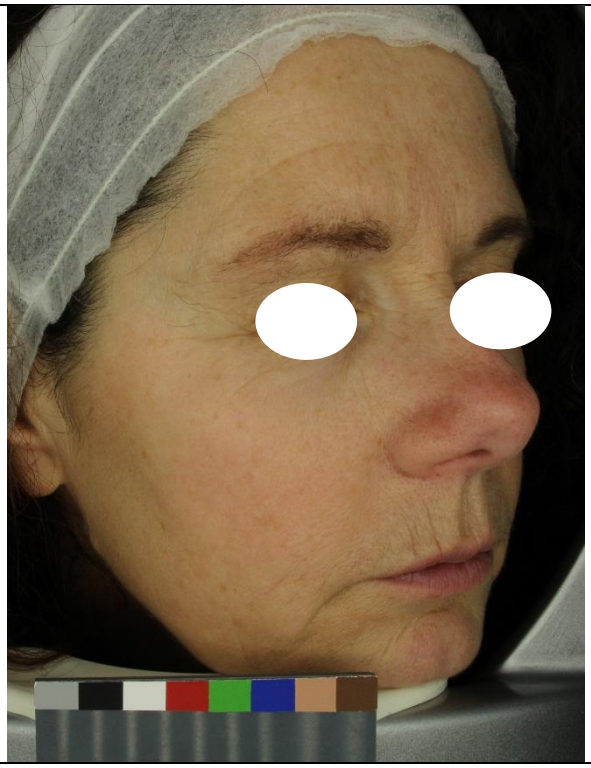
T7	T28
	

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