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Respilon Membranes S.R.O.

Ref. product: P.2413-P.2421 MASKS

CLINICAL EVALUATION OF ANTIWRINKLE EFFECT OF "RESPIBEAUTY PROGRAM"

FINAL REPORT - INF.1122.20.10

DATE – July 27th, 2022

Respilon membranes S.R.O.

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Product:
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BIONOS BIOTECH, S.L.
For the following activites of:
To perform efficacy studies on products from the cosmetic and food industries. To perform biological diagnostic Assays.
Is in accordance with the requirements of the standard ISO 9001:2015
INITIAL CERTIFICATION DATE: 12/02/2021
THIS CERTIFICATE IS VALID UNTIL: 11/02/2024

MINISTÈRE DE L'ENSEIGNEMENT SUPÉRIEUR, DE LA RECHERCHE ET DE L'INNOVATION

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EXECUTIVE SUMMARY

GOAL

To assess the antiwrinkles effect of **"RespiBeauty Program"** after topical application in 20 volunteers for 7 days.

METHODOLOGY

Twenty volunteers, aged between 40 and 65 years old, with visible signs of wrinkles on forehead. Each volunteer applied the product on the face according to client's instructions. Forehead wrinkles were measured using Bio 3D Structured-light scanner. The measurements were carried out before (D0) and 7 days (D7) from the beginning the treatment. Finally, volunteers filled in a self-assessment questionnaire (use test) at the end of the treatment (D7). Dermatological surveillance was included in the study.

RESULTS

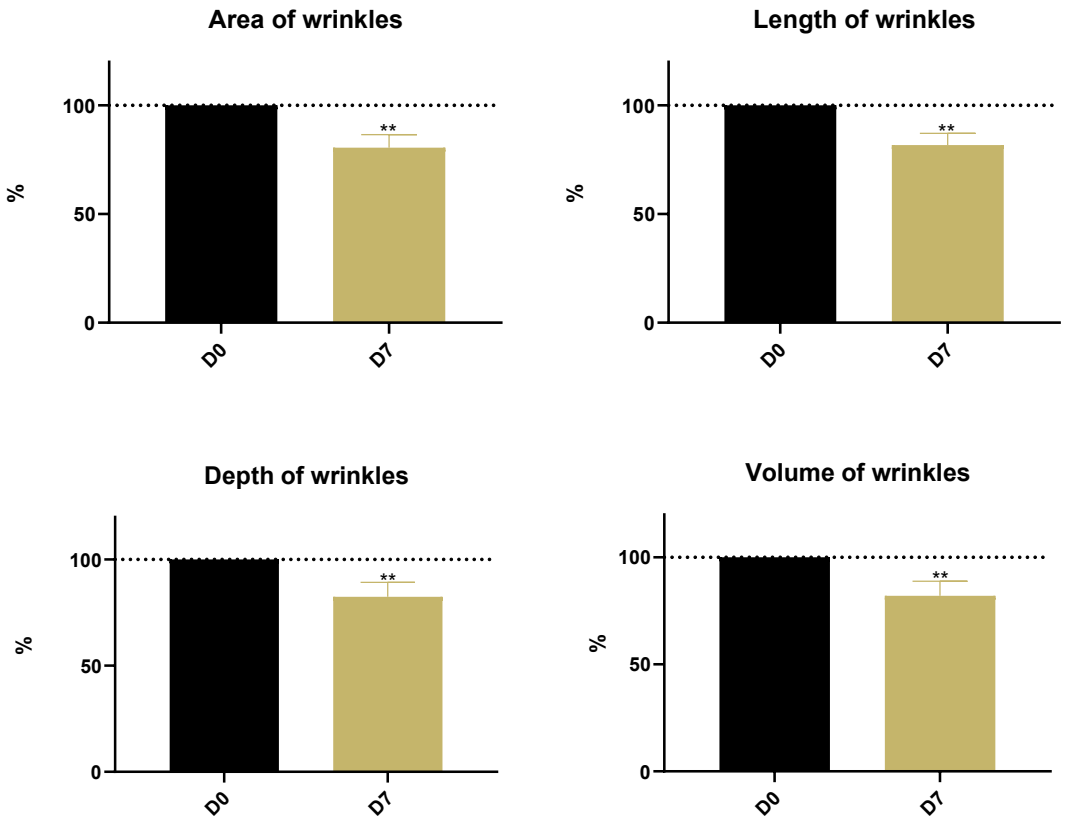
Results of the Bio3D Structured-light Scanner were analyzed to assess the total area, length, depth and volume of forehead wrinkles that the software recognized in the Region of Interest (ROI). All values were normalized to the corresponding levels at basal values.

Results showed a statistically significant reduction of forehead wrinkles' area upon treatment with "**RespiBeauty Program"** of **19.44 ± 6.02 %** after 7 days. Regarding the length of forehead wrinkles, a significant reduction by **18.24 ± 5.34 %** was observed after 7 days. On the other hand, a significant reduction by **17.50 ± 6.79 %** was observed after 7 days, after the quantification of forehead wrinkles' depth

When evaluating wrinkles' volume, results showed a statistically significant reduction upon treatment with "**RespiBeauty Program"** of **17.92 ± 6.72 %** after 7 days**,**

With regard to the self-assessment questionnaire the treatment got an overall acceptance average of 66% after 7 days of treatment with "**Respibeauty Program**" Specifically, positive evaluations (overall acceptance ≥ 80 %) were obtained for 1 out of 5 parameters regarding the cosmetic attributes, 2 out of 11 regarding the cosmetic effectiveness, and 1 out of 3 parameters regarding the consumer opinion.

Regarding the skin compatibility and acceptability, none of the volunteers showed any skin acceptability problem or manifested a cutaneous reaction during the treatment.



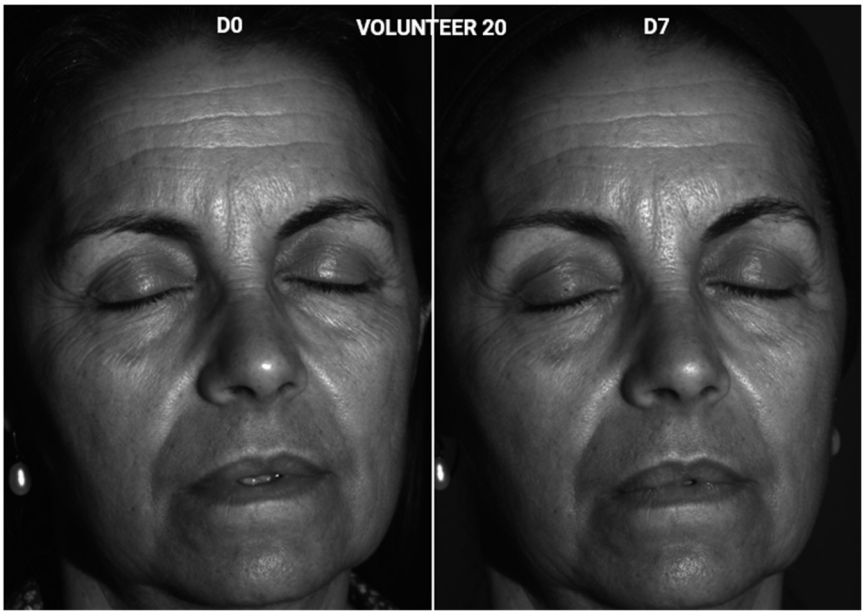


Figure 1. . Graphical representation of normalized parameters measured (%) before (D0) and after 7 days (D7) of treatment. The Mean and Standard Error of the Mean (SEM) are shown. Asterisks indicate significant differences as follows; * p-value < 0.05, ** p-value < 0.01, *** p-value< 0.001, **** p-value < 0.0001..// Below, macroscopic images of the volunteer 20 throughout the assay.

CONCLUSION

The goal of this study was to assess the antiwrinkle effect of "**Respibeauty Program"** after topical application in 20 volunteers for 7 days. In conclusion, this clinical study shows that "**Respibeauty Program**" significantly reduces the area, length, depth and volume of **forehead wrinkles**.

Finally, regarding skin compatibility, the treatment showed good cutaneous acceptance and may claim "**Dermatologically Tested", "Clinically Tested"** and "**Tolerance Tested**".

1 Title

Clinical evaluation of antiwrinkle effect of "RespiBeauty Program"

2 Product tested

The tested samples were received in Bionos Biotech on 24/06/2022 at room temperature, and labelled as indicated:

PRODUCT TESTED	PRODUCT CODE
Face mask 1	P.2413
Face mask 2	P.2414
Face mask 3	P.2415
Face mask 4	P.2416
Face mask 5	P.2417
Face mask 6A	P.2418
Face mask 6B	P.2419
Face mask 7 A	P.2420
Face mask 7 B	P.2421

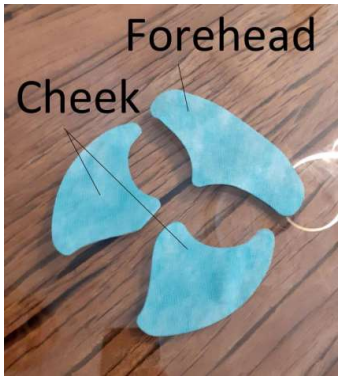


Figure 2: P2413 -P2421: RespiBeauty Program

Samples were stored at room temperature in our facilities and delivered to the volunteers before the start of the treatment.

3 Registration dates

- **Study begins**: 24/06/2022
- **Study ends:** 27/07/2022
- **Experimental phase begins:** 04/07/2022
- **Experimental phase ends:** 11/07/2022
- **Dates of measurements:** 1st 04/07/2022 – 2nd 11/07/2022

4 Platform

Twenty volunteers self-applied home routine following client's instructions.

5 Material and Methods

5.1 Wrinkles and roughness assessment

A **Structured-light 3D scanner** is a 3D scanning device measuring the three-dimensional shape of an object using projected light patterns and a camera system [*Borko Furht, 2008*]. Projecting a narrow band of light onto a three-dimensionally shaped surface produces a line of illumination that appears distorted from other perspectives than that of the project and can be used for geometric reconstruction of the surface shape (light section).

The evaluation of three-dimensional (3D) shapes by means of optical sensors has an increasing importance in number of applications because of the intrinsic noncontact nature of the measurement and the possibility of reducing the measurement time with respect to contact probes. Typical applications in the industrial field are production quality control, both in the microrange and in the macrorange [*Docchio et al., 1999*], the digitalization of free-shape surfaces in the reverse engineering process, and a number of 3D computer vision problems [*Poussart and Laurendeau, 1989*]. More recently, they have been successfully used in other fields, such as archeology, for measuring and preserving cultural heritage and in entertainment and 3D virtual reality frameworks [*Rioux et al., 1997*].

A number of publications now exist on the optical techniques developed for 3D measurement, both of the passive and the active nature. In passive methods, no controlled source of light is necessary. Surface reflectance, stereo disparity and camera motion are examples of techniques based on this passive approach. However, the main drawback is represented by the high computation effort needed to get deep information.In active methods, use of a pattern of radiation simplifies the problem of depth measurement. Interferometric and more techniques achieve very accurate measurements over small depth ranges [*Kuwamura and Yamaguchi, 1997*], time-of-flight methods are suitable for medium and long distances and triangulation-based methods match the short-distance interval. Within this frame, the systems based on the scanning of coherent light are widely used [*Rioux, 1984*], as well as whole-field profilometers, based on the projection of structured-light. A number of pattern projection schemes belong to this last category and differ from each other in the coding used to express the light directions. It has been developed a technique that combines two methods for the

projection and the demodulation of bidimensional patterns of light, known as the gray-code and the phase-shift methods [*Sansoni et al., 1999*]. The resulting technique, hereafter called GCPS (Gray-code and Phase-shift) has been integrated into a prototype for 3D vision developed to achieve a system that performs at optimal accuracy and speed over a wide typology of objects.

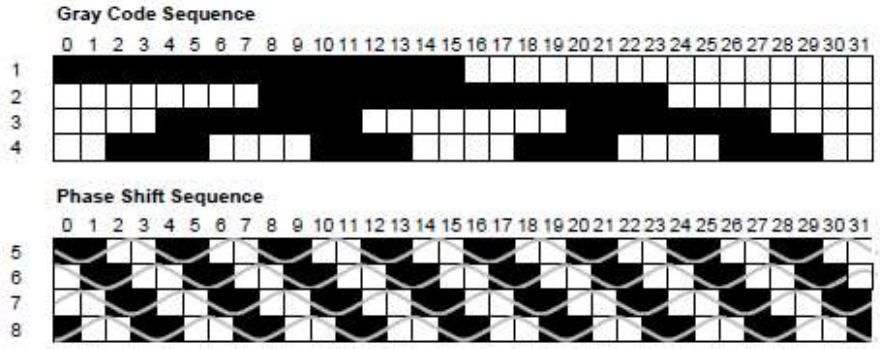


Figure 3. Representation of Gray code and Phase shift patterns.

The gray-code technique allows the unique description of 2 different directions of projection by means of the well-known one-distance gray code. The number of the directions of projection that can be unequivocally defined equals the number of the code words, thus, the larger this number, the wider the non-ambiguity height range. On the other hand, as each projection direction is associated with a code word, but not further decomposed, the measurement resolution is rather low [*Sansoni et al., 1997*]. With the phase-shift approach, the directions of projection are coded by phase values. Because the phase is continuously distributed within its range of non-ambiguity, a theoretically infinite height resolution can be obtained, actually limited only by the errors that are due to gray-level quantization and noise. On the other hand, the range of non-ambiguity is limited to the interval 0-2, and this fact strongly reduces the height range [*Sansoni et al., 1997*].

The combination of gray code and phase shift in GCPS has been proposed by several authors to exploit the positive features of each method and compensate for their drawbacks [*Krattenthaler et al., 1993*]. In principle, the latter is used to increase the information given by the former by adding a fractional contribution to the code words that identify each direction of projection. Consequently, the measurement performance is strongly improved as to the resolution and the range of the measurement.

Two major methods of stripe pattern generation have been established: Laser interference and projection. The laser interference method works with two wide planar laser beam fronts. Their interference results in regular, equidistant line patterns. Different pattern sizes can be obtained by changing the angle between these beams. The method allows for the exact and easy generation of very fine patterns with unlimited depth of field. Disadvantages are high cost of implementation, difficulties providing the ideal beam geometry, and laser typical effects like speckle noise and the possible self-interference with beam parts reflected from objects. Typically, there is no means of modulating individual stripes, such as with Gray codes.

On the other hand, the projection method uses incoherent light and basically works like a video projector. Patterns are usually generated by passing light through a digital spatial light modulator, typically based on one of the three currently most widespread digital projection technologies, transmissive liquid crystal, reflective liquid crystal on silicon (LCOS) or digital light processing (DLP) modulators, which have various comparative advantages and disadvantages for this application.

A typical measuring assembly consists of one projector and at least one camera, as shown in Figure 4. For many applications, two cameras on opposite sides of the projector have been established as useful.

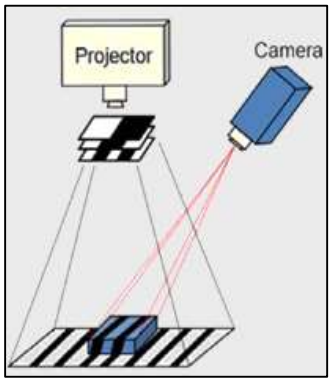


Figure 4. Schematic representation of the Bio3D Structured-light Scanner set up.

In Bionos Biotech, we have developed the **Bio3D Structured-light Scanner**, a 3D digitalization system based on structured-light fringe projection (gray code + phase shift method), which works at 290 images per second, reducing the effects of movement and getting a higher resolution that current systems in the market. The 3D information obtained is analysed with specific software, developed internally to perform different

quantifications of skin surface and profile [*Groves et al., 2014*].

The projector used is a high-performance and high-reliability device, with a very small size that uses DLP technology and a high-power white LED light source with a frame rate of 290 fps. The camera used is based on a 1.3 Mpixels CMOS sensor with GigE Interface for high-speed optical metrology applications. The purpose of using these devices is to synchronize camera and projector to work at a frame rate of 290 fps, and in this way, be able to scan the scene in a time less than 0.15 sec. This scanning speed allows to maintain the precision of the method (> 0.1 mm) in the 3D reconstruction of *in vivo* objects.

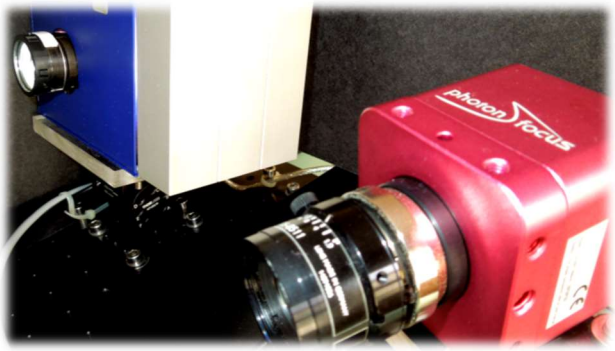


Figure 5. Image from part of Bio3D Structured-light device used in this assay.

2D images from the face (forehead) are processed in order to assess the effects of the treatment on area, length, depth and volume of wrinkles. State comparatives can be performed before and after a cosmetic or clinical treatment, through specific software, in order to estimate the level of improvement in each of the volunteers.

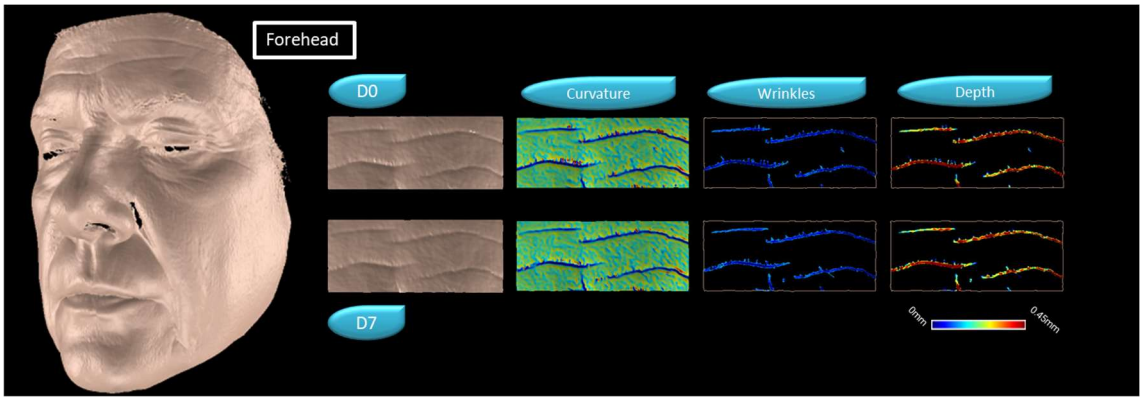


Figure 6., 3D reconstructions from the face area were obtained after image processing through specific software, ROI selected for analysis and images used for data acquisition

From the whole 3D reconstruction, a Region of Interest (ROI) is selected in which the wrinkles analysis will be carried out. The analysis performed is a curvature analysis. The curvature of a point belonging to a surface is a measurement directly related to the geometry of the surrounding area of that determined point. The curvature is the inverse of the sphere's radius that best fits with the surrounding area of that assessed point. In Figure 6, it is shown the concept of curvature.

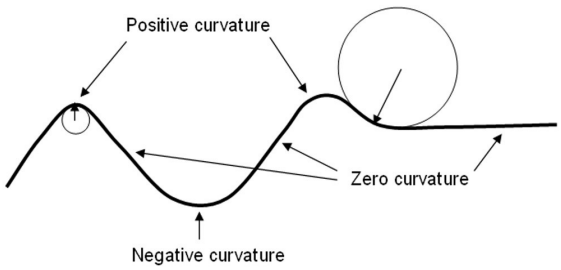


Figure 7. Schematic representation about curvature, interpreted as the inverse of the sphere's radius that best fits with the surrounding area of the assessed point.

5.2 Procedure

In this assay, the effect of **"Respibeauty Program"** after 7 days of treatment was assessed in 20 human volunteers, through quantification of forehead wrinkles using Bio 3D Structured-light scanner. The measurements were carried out before (D0) and 7 days (D7) from the beginning the treatment. Finally, volunteers filled in a self-assessment questionnaire (use test) at the end of the treatment (D7). Dermatological surveillance was included in the study.

USE CONDITIONS

The product was self-applied by the volunteers once a day (morning) for the first 5 days, and twice a day (morning and evening) on days 6 and 7, in face area, following the follow instructions:

"1. Open the package with dry hands.

2. Gently remove masks from the package. Avoid contact with moisture (i.e. water, moist hands)

3. Remove the white non-woven textile from the top of the forehead mask. Be sure active layer

(white paper-like structure) is not sticked to it and stays on the blue layer.

4. Wet the forehead with water (tap water, water in spray, mineral water) and place with dry fingers the mask on forehead covering whole T zone.

5. Wait for 5-10s to let the mask soak into the skin. Remove the blue cover non-woven from T-zone. Let the material to soak into you skin and massage in any leftovers.

6. Repeat the process with left cheek mask – be sure not touching the active layer with wet fingers.

7. Remove the white non-woven from left cheek mask. Be sure active layer (white paper-like structure) is not sticked to it and stays on the blue layer.

8. Wet the left cheek with water (tap water, mineral water) and place with dry fingers the mask on cheeks covering the contour of eye and Crows feet.

9. Wait for 5-10s to let the mask soak into the skin. Remove the blue cover non-woven from face. Let the material to soak into you skin and massage in any leftovers.

10. Remove the white non-woven from right cheek mask. Be sure active layer (white paper-like structure) is not sticked to it and stays on the blue layer.

11. Wet the right cheek with water (tap water, mineral water) and place with dry fingers the mask on cheeks covering the contour of eye and Crows feet.

12. Wait for 5-10s to let the mask soak into the skin. Remove the blue cover non-woven from face. Let the material to soak into you skin and massage in any leftovers.

13. Massage the left-overs to the skin with your fingers.

14. The masks is not removed or washed after use – you can put on make-up"

PANEL

The panel represents the susceptible population to use the product.

Inclusion criteria were:

- Female, 40 to 65 years of age.
- In good general health (physical, mental, and social well-being, not merely the absence of disease/infirmity)
- Presence of visible wrinkles on forehead
- Understanding and signature of Informed Consent (copy of original Informed Consent is shown in **Attachment 6).**

On the other hand, the criteria of exclusion were:

- Allergy or reactivity to some of the components of the product, or a product with a similar category than tested one.
- Recent surgery in the experimental area.
- Relevant cutaneous marks in the experimental areas, which could interfere with the measurements (scars, sunburns, etc.).
- In-use relevant pharmacological or hormonal treatment.
- Presence of skin diseases or melanomas.
- Forecast of change of routine or relevant way of life, during the period of study.
- Nursing, pregnant, or planning to become pregnant during the study according to subject self-report.

VOLUNTEERS

The number of volunteers according to the client's needs was 20. Volunteer's data is found in **Attachment 1.**

The self-assessment questionnaire was filled up by the 20 volunteers who completed the treatment. Raw data and additional comments from the volunteers are shown in **Attachment 4.**

STUDY OBLIGATIONS

Obligations imposed on volunteers were the following:

- To respect the conditions of use.
- Do not use other facial products during the study period.
- To maintain those hygiene and cosmetics habits that do not interfere with the assigned skin care routine.
- Do not include any new cosmetic or nutricosmetic product in their daily routine.

INFORMED CONSENT

Informed consent was obtained from each volunteer prior to initiating the study describing reasons for the study, possible adverse effects, associated risks and potential benefits of the treatment, and their limits of liability. The panelists signed and dated the informed consent document to indicate his authorization to proceed and acknowledge his understanding of the contents before the start of the study. The informed consent model is shown in **Attachment 6.**

IMAGE AND PERSONALITY RIGHTS

The sponsor (Respilon membranes S.R.O.) may use the pictures from all the volunteers included in the study, for internal discussion of the results.

The sponsor (Respilon membranes S.R.O.) can make commercial and marketing use of the pictures from the volunteers who gave the consent to transfer their image and personality rights (for this specific study), according to the information shown in the table of **Attachment 1** (Volunteer's data).

The sponsor (Respilon membranes S.R.O.) can make commercial and marketing use of the pictures from the volunteers who did NOT give the consent to transfer their image and personality rights (for this specific study), according to the information shown in the table of Volunteer's data (**Attachment 1**), if they are able to assure the impossibility to recognize the person (e.g. using a black bar to completely cover the area of the eyes to avoid full personal recognition).

ETHICS

The study protocol is in accordance with the Scientific Committee on Consumer Safety (SCCS) guidance. It meets all international standards for research studies involving human subjects, the Good Clinical Practices (ICH-GCP), and World Medical Association. It has been conducted pursuant to the Declaration of Helsinki (1864), with the amendments of Tokyo (1975), Venice (1983), Hong Kong (1989), and Seoul (2008).

CHECKING OF THE ACCEPTABILITY

The subjects were requested to note every day any reaction observed, and sensation of discomfort felt. An examination of the experimental area under standard daylight source was performed by the responsible technician, the same days of the technical measurements.

Together with the clinical examinations performed during the treatment, each subject was questioned by the responsible technician about the possible sensations of discomfort they felt, at the end of the study.

5.3 Statistical analysis

For wrinkles assessment, different images were used, and one experimental value was obtained from the region of interest (ROI) selected, for each timepoint.

All technical values obtained before (D0) and after 7 days (D7) with treatment were normalized to the basal values before the treatment (D0) and expressed as a percentage. Averaged value for each condition and error bars indicating the standard error of the mean (SEM) are shown. The normalization method used increases the statistical power as it suppresses random variation between subjects [*Walpole et al., 2002*].

Data collected before (Basal, D0) and after 7 days (D7) of the treatment were subjected to One sample Wilcoxon test for statistical significance.

6 Results

6.1 Evaluation of wrinkles

Results of the Bio3D Structured-light Scanner were analyzed to assess the total area, length, depth and volume of forehead wrinkles that the software recognized in the Region of Interest (ROI). All values were normalized to the corresponding levels at basal values. Raw data of measurements of Bio3D are shown in **Attachment 2.** Original images for each of the volunteers before and over the treatment are included in a digital file and detailed in **Attachment 5**.

Results showed a statistically significant reduction of forehead wrinkles' area upon treatment with **"RespiBeauty Program"** of **19.44 ± 6.02 %** after 7 days. Regarding the length of forehead wrinkles, a significant reduction by **18.24 ± 5.34 %** was observed after 7 days. On the other hand, a significant reduction by **17.50 ± 6.79 %** was observed after 7 days, after the quantification of forehead wrinkles' depth (Figure 8 and Table 1).

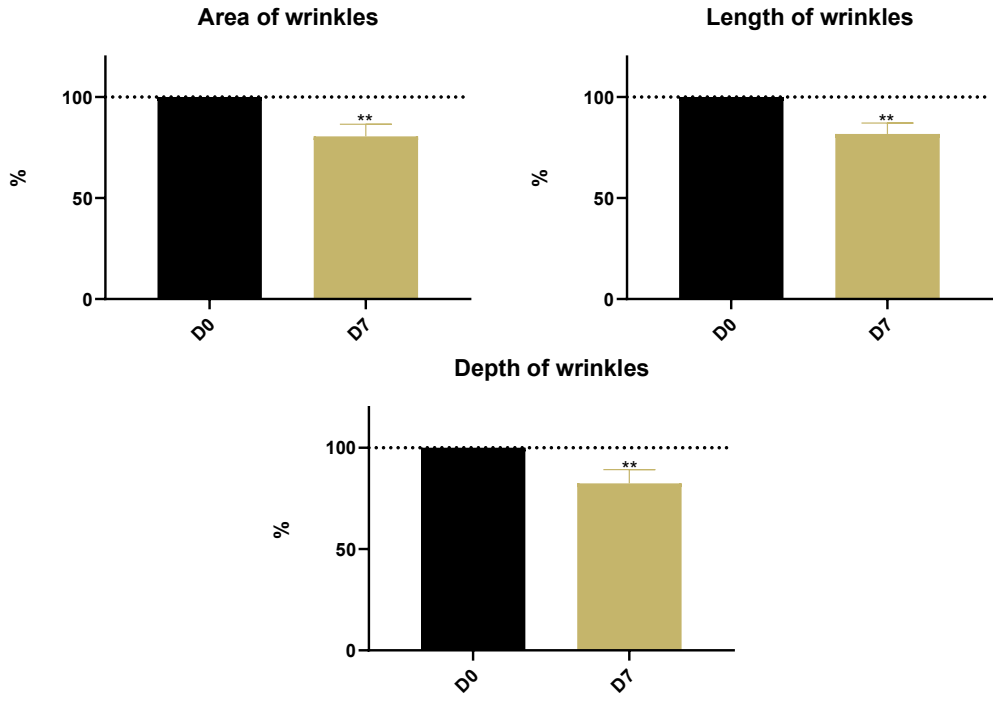


Figure 8. Graphical representation of the normalized area, length and depth of forehead wrinkles before (D0) and after 7 days (D7) of treatment. The Mean and Standard Error of the Mean (SEM) are shown. Asterisks indicate significant differences as follows; * p-value < 0.05, ** p-value < 0.01, *** p-value< 0.001, **** p-value < 0.0001.

Area of wrinkles	
Multiple comparisons test	D7 vs. D0
Mean Diff,	**-19.44**
Significant?	**Yes**
Adjusted P Value	**0.0049**
Length of wrinkles	
Multiple comparisons test	D7 vs. D0
Mean Diff,	**-18.24**
Significant?	**Yes**
Adjusted P Value	**0.042**
Depth of wrinkles	
Multiple comparisons test	D7 vs. D0
Mean Diff,	**-17.5**
Significant?	**Yes**
Adjusted P Value	**0.0083**

Table 1. Statistical analysis of results shown in Figure 8.

When evaluating wrinkles' volume, results showed a statistically significant reduction upon treatment with "**RespiBeauty Program**" of **17.92 ± 6.72 %** after 7 days**,** (Figure 9 and Table 2).

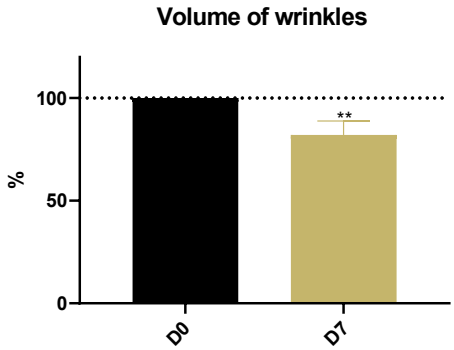


Figure 9. Graphical representation of the normalized volume of forehead wrinkles before (D0) and after 7 days of treatment. The Mean and Standard Error of the Mean (SEM) are shown. Asterisks indicate significant differences as follows; * p-value < 0.05, ** p-value < 0.01, *** p-value< 0.001, **** p-value < 0.0001.

Volume of wrinkles	
Multiple comparisons test	D7 vs. D0
Mean Diff,	**-17.92**
Significant?	**Yes**
Adjusted P Value	**0.0083**

Table 2. Statistical analysis of results shown in Figure 9.

The complete results of the statistical analysis are shown in **Attachment 3.**

6.2 Self-Assessment questionnaire

The efficacy of the treatment was subjectively evaluated using a test (self-assessment questionnaire) right ay day 56.

For the **self-assessment questionnaire**, opinions are given according to parameters from 1 to 5 (1 = Totally Disagree / 2 = Disagree / 3 = Not agree nor disagree / 4 = Agree / 5 = Totally Agree). For positive impressions, satisfaction was considered when volunteers scored parameters from 4 to 5. Complete results for each volunteer are shown in **Attachment 4**.

Results from the **self-assessment questionnaire after 7 days** of treatment (D7) are shown in the following table:

	QUESTIONNARIE AT THE END	AVERAGE	1	2	3	4	5	% Satisfied
COSMETIC ATTRIBUTES	1.The texture of the product is pleasant.	**4**	1	0	7	6	6	60
	2. Product absorption is fast.	**4**	2	2	0	4	12	**80**
	3. The perfume of the product is pleasant.	**4**	0	0	12	3	5	40
	4. The colour of the product is nice.	**4**	1	0	4	6	9	75
	5. The application of the product is easy.	**3**	2	3	4	6	5	55
COSMETIC EFFECTIVENESS	6. The contour of my face appears smoothed.	**4**	2	0	2	8	8	**80**
	7. My fine lines and wrinkles appear to be minimized.	**4**	1	3	3	10	3	65
	8. My skin is hydrated	**4**	1	1	4	8	6	70
	9. My skin looks younger	**4**	1	1	6	9	3	60
	10. My skin is firmer	**4**	0	2	7	5	6	55
	11. My skin is smoother	**4**	0	0	3	11	6	**85**
	12. My skin seems more radiant	**4**	1	0	5	9	5	70
	13. My skin seems more flexible (elastic)	**4**	1	0	9	6	4	50
	14. The treatment unifies the skin tone.	**3**	0	2	9	7	2	45
	15. The treatment brightness my skin	**4**	0	2	3	9	6	75
	16. The treatment improves visually the quality of my skin	**4**	0	0	6	9	5	70
CONSUMER OPINION	17. I am satisfied with the treatment received	**4**	0	0	4	8	8	**80**
	18. I would use the treatment again.	**4**	1	1	3	6	9	75
	19. I would recommend the treatment.	**4**	1	1	4	5	9	70

A relevant percentage of volunteers (≥ 80 %) considered that:

- Product absorption is fast
- The contour of their face appears smoothed.
- Their skin is smoother
- They are satisfied with the treatment received

Taken together, the self-assessment questionnaire indicated an overall acceptance average of 66% after 7 days of treatment with "**Respibeauty Program**" Specifically, positive evaluations (overall acceptance ≥ 80 %) were obtained for 1 out of 5 parameters regarding the cosmetic attributes, 2 out of 11 regarding the cosmetic effectiveness, and 1 out of 3 parameters regarding the consumer opinion.

7 Discussion and conclusions

The goal of this study was to assess the anti-wrinkle effect of "**Respibeauty Program"** after topical application in 20 volunteers for 7 days. In conclusion, this clinical study shows that "**Respibeauty Program**" significantly reduces the area, length, depth and volume of **forehead wrinkles**.

Finally, regarding skin compatibility, the treatment showed good cutaneous acceptance and may claim "**Dermatologically Tested", "Clinically Tested"** and "**Tolerance Tested**".

8 References

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9 Registry and Regulation

The final report, the raw data and the assay protocol have been saved in computer format, and a copy on paper. All the information provided from the Client, volunteers and generated by Bionos Biotech will be considered as *confidential*. The information about materials, reagents and protocols adopted by Bionos Biotech SL during the assays is confidential and will not be shared with third parts.

This study was performed under principle of Good Clinical Practices (International Recommendations ICH Topic E6, CPMP/ICH/135/95 of May 1st, 1996, European Parliament and Council Guideline 2001/20/CE – DOCE OF May 1st 2001).

Based on **Article 20 or Regulation (EC) No 1223/2009** on cosmetic products (CPR), **Commission Regulation (EU) No 655/2013** established EU harmonised common criteria in order to assess whether or not the use of a claim is justified.

Experimental studies include (but are not limited to) studies *in silico*, *in vitro*, *ex-vivo*, with instrumental or biochemical methods, studies conducted on volunteers, investigator evaluations, sensory evaluations, etc. Different types of experimental studies can be used to provide data on the performance of cosmetic products. Such studies should comprise methods which are reliable and reproducible. The studies should follow a well-designed and scientifically valid methodology according to best practices. The criteria used for evaluation of product performance should be defined with accuracy and chosen in accordance with the aim of the test. The experimental aspect of studies calls for reliance on knowledge and awareness of statistical principles in the design and analysis of the study, e.g. in terms of number of subjects, test samples, etc. This is necessary in order to ensure that the studies achieve scientifically and statistically valid conclusions.

Studies conducted on volunteers should follow ethical principles and products tested should have been assessed as safe. Human studies should be conducted on the target population where necessary and be defined by strict inclusion/exclusion criteria.

Products may bear claims that relate to the nature of experimental studies. Consumer expectations regarding these claims may vary depending, in particular, upon the presentation of the claim and its specific context. However, in all circumstances, consumers will expect that such claims are made only when the effects tested are favourable:

- The claim "tolerance tested" means that the product underwent tests under the supervision of a scientifically qualified professional intended to study its tolerance on a target group and that the results of those tests show that the product was

well tolerated by this group.

- The claim "tested under medical supervision" indicates that the product underwent tests conducted under the supervision of a medically qualified professional, such as a medical doctor or a dentist. Depending on the presentation of the claim, it may, for (example, refer to a specific efficacy of the product or to skin tolerance.
- The claim "dermatologically tested" implies that the product was tested on humans under the supervision of a dermatologist. Depending on the presentation of the claim, it may, refer to a specific efficacy or tolerance of the product. Consumer self-perceptions studies are not appropriate to support such claims. The same logic would apply to a claim referring to any other medical discipline.
- The claim "clinically tested" refers to expertise, process or conditions under which the tests were carried out. "Clinically tested" means that the product was tested on humans under the supervision of a medically qualified professional or another scientifically qualified professional according to a clinical protocol or in a clinical setting.

The treatments tested in this **study 1122.20.10** may claim:

- **"Dermatologically tested".**
- "**Tolerance tested**".
- "**Clinically tested**".

A critical point for the validity of consumer tests is the wording of the questionnaire. The questions and proposed answers should be clear enough to be unequivocally understood by participants. The answers scale should be well balances (e.g., same number of positive and negative answers (a nominal, ordinal or visual analogical notation scale may be used)) and not capable of influencing the answer.

Special attention should be paid to the wording of questions for which responses will be used to substantiate the claim: the claim should be directly substantiated by the results related to the relevant question without any questionable interpretation.

Data processing and the interpretation of results should be fair and should not overstep the limits of the test's significance. Data recording, transformations, and representation in tabular or graphical form should be transparent or clearly explained if complex. It should not be designed to overstate the effect(s) measured. Appropriate statistical analysis of the data should be performed.

Attachments

Attachment 1: Volunteers data

Nº Volunteer	ID Volunteer	Age	Gender	Type of skin	Transfer of image and personality rights
1	2333	65	Female	Combination	No
2	2292	45	Female	Combination	Yes
3	2334	51	Female	Combination	Yes
4	2128	58	Female	Combination	Yes
5	2308	57	Female	Dry	Yes
6	2141	50	Female	Combination	Yes
7	2311	59	Female	Dry	Yes
8	2310	49	Female	Combination	Yes
9	2312	49	Female	Combination	Yes
10	2211	59	Female	Dry	Yes
11	2174	41	Female	Combination	Yes
12	2322	58	Female	Combination	Yes
13	2323	42	Female	Dry	Yes
14	2244	65	Female	Combination	Yes
15	2269	57	Female	Combination	Yes
16	2309	55	Female	Dry	Yes
17	2228	55	Female	Dry	Yes
18	2298	47	Female	Dry	Yes
19	2335	54	Female	Dry	Yes
20	2201	58	Female	Dry	Yes

Attachment 2: Raw data – Bio3D

	WRINKLES RAW DATA									
	Area (mm2)			Length (mm)			Depth (mm)			Volume (mm3)		
	0	7 d		0	7 d		0	7 d		0	7 d	
V01	106,23	105,12		164,20	163,78		1247,31	1130,43		31,60	27,85	
V02	42,85	25,91		116,50	73,62		106,58	59,07		2,21	1,27	
V03	60,79	31,13		188,27	84,21		400,21	224,94		7,61	4,44	
V04	28,54	26,47		71,44	69,23		150,79	146,38		3,31	3,13	
V05	35,50	25,50		104,55	82,23		209,73	139,08		4,21	2,57	
V06	28,70	22,47		56,15	48,72		138,04	108,00		2,97	2,33	
V07	46,53	35,63		121,68	100,05		185,25	166,17		3,78	3,38	
V08	62,11	21,14		160,21	57,93		165,68	53,13		3,37	1,06	
V09	2,11	3,13		5,72	7,38		12,04	19,32		0,26	0,42	
V10	25,18	26,79		85,78	87,81		188,60	205,65		3,23	3,57	
V11	57,73	55,25		131,39	113,88		235,24	236,35		5,25	5,33	
V12	67,42	57,76		204,19	163,67		438,23	376,19		8,54	7,63	
V13	11,18	8,41		35,24	26,48		57,19	44,37		1,07	0,85	
V14	32,37	41,76		99,08	127,28		198,78	280,36		3,88	5,30	
V15	39,36	24,11		107,11	67,61		127,31	69,67		2,69	1,56	
V16	5,66	4,79		18,62	14,50		21,09	18,80		0,41	0,38	
V17	26,12	13,32		89,48	45,85		138,73	76,63		2,48	1,37	
V18	4,03	2,77		10,17	9,45		15,71	12,35		0,33	0,23	
V19	30,35	24,91		91,29	79,63		171,57	133,52		3,53	2,74	
V20	59,37	35,09		116,62	84,80		493,10	267,88		10,97	5,71	

	RELATIVE TO DAY 0									
	Area (mm2)			Length (mm)			Depth (mm)			Volume (mm3)		
	0	7 d		0	7 d		0	7 d		0	7 d	
V01	100,00	98,96		100,00	99,74		100,00	90,63		100,00	88,13	
V02	100,00	60,47		100,00	63,19		100,00	55,42		100,00	57,41	
V03	100,00	51,21		100,00	44,73		100,00	56,21		100,00	58,33	
V04	100,00	92,75		100,00	96,91		100,00	97,08		100,00	94,59	
V05	100,00	71,83		100,00	78,65		100,00	66,31		100,00	61,20	
V06	100,00	78,29		100,00	86,77		100,00	78,24		100,00	78,46	
V07	100,00	76,57		100,00	82,22		100,00	89,70		100,00	89,36	
V08	100,00	34,04		100,00	36,16		100,00	32,07		100,00	31,34	
V09	100,00	148,34		100,00	129,02		100,00	160,47		100,00	159,85	
V10	100,00	106,39		100,00	102,37		100,00	109,04		100,00	110,36	
V11	100,00	95,70		100,00	86,67		100,00	100,47		100,00	101,56	
V12	100,00	85,67		100,00	80,16		100,00	85,84		100,00	89,33	
V13	100,00	75,22		100,00	75,14		100,00	77,59		100,00	80,11	
V14	100,00	129,01		100,00	128,46		100,00	141,04		100,00	136,36	
V15	100,00	61,26		100,00	63,12		100,00	54,73		100,00	58,00	
V16	100,00	84,63		100,00	77,87		100,00	89,15		100,00	92,89	
V17	100,00	51,00		100,00	51,24		100,00	55,24		100,00	55,31	
V18	100,00	68,73		100,00	92,92		100,00	78,61		100,00	69,49	
V19	100,00	82,08		100,00	87,23		100,00	77,82		100,00	77,53	
V20	100,00	59,10		100,00	72,71		100,00	54,33		100,00	52,05	

Attachment 3: Raw data - Statistical Analysis

One sample Wilcoxon test		
Area of Wrinkles		
	D0	D7
Theoretical median	100	100
Actual median	100	77,43
Number of values	20	20
Wilcoxon Signed Rank Test	Samples with equal values	
Sum of signed ranks (W)		-146
Sum of positive ranks		32
Sum of negative ranks		-178
P value (two tailed)		**0,0049**
Exact or estimate?		Exact
P value summary		**
Significant (alpha=0.05)?		**Yes**
How big is the discrepancy?		
Discrepancy		-22,57
Descriptive statistics		
	D0	D7
Number of values	20	20
Minimum	100	34,04
25% Percentile	100	60,67
Median	100	77,43
75% Percentile	100	94,96
Maximum	100	148,3
Range	0	114,3
Mean diff D0-D7		**-19,44**
Mean	100	80,56
Std. Deviation	0	26,92
Std. Error of Mean	0	6,02
Lower 95% CI of mean	100	67,96
Upper 95% CI of mean	100	93,16
Sum	2000	1611

One sample Wilcoxon test		
Length of Wrinkles		
	D0	D7
Theoretical median	100	100
Actual median	100	81,19
Number of values	20	20
Wilcoxon Signed Rank Test	Samples with equal values	
Sum of signed ranks (W)		-148
Sum of positive ranks		31
Sum of negative ranks		-179
P value (two tailed)		**0,0042**

Exact or estimate?		Exact
P value summary		**
Significant (alpha=0.05)?		**Yes**
How big is the discrepancy?		
Discrepancy		-18,81
Descriptive statistics		
	D0	D7
Number of values	20	20
Minimum	100	36,16
25% Percentile	100	65,57
Median	100	81,19
75% Percentile	100	95,91
Maximum	100	129
Range	0	92,86
Mean diff D0-D7		**-18,24**
Mean	100	81,76
Std. Deviation	0	23,87
Std. Error of Mean	0	5,34
Lower 95% CI of mean	100	70,59
Upper 95% CI of mean	100	92,93
Sum	2000	1635

One sample Wilcoxon test		
Depth of Wrinkles		
	D0	D7
Theoretical median	100	100
Actual median	100	78,43
Number of values	20	20
Wilcoxon Signed Rank Test	Samples with equal values	
Sum of signed ranks (W)		-138
Sum of positive ranks		36
Sum of negative ranks		-174
P value (two tailed)		**0,0083**
Exact or estimate?		Exact
P value summary		**
Significant (alpha=0.05)?		**Yes**
How big is the discrepancy?		
Discrepancy		-21,58
Descriptive statistics		
	D0	D7
Number of values	20	20
Minimum	100	32,07
25% Percentile	100	55,62
Median	100	78,43
75% Percentile	100	95,47
Maximum	100	160,5
Range	0	128,4

Mean diff D0-D7		**-17,50**
Mean	100	82,5
Std. Deviation	0	30,38
Std. Error of Mean	0	6,79
Lower 95% CI of mean	100	68,28
Upper 95% CI of mean	100	96,72
Sum	2000	1650

One sample Wilcoxon test		
Volume of Wrinkles		
	D0	D7
Theoretical median	100	100
Actual median	100	79,29
Number of values	20	20
Wilcoxon Signed Rank Test	Samples with equal values	
Sum of signed ranks (W)		-138
Sum of positive ranks		36
Sum of negative ranks		-174
P value (two tailed)		**0,0083**
Exact or estimate?		Exact
P value summary		**
Significant (alpha=0.05)?		**Yes**
How big is the discrepancy?		
Discrepancy		-20,72
Descriptive statistics		
	D0	D7
Number of values	20	20
Minimum	100	31,34
25% Percentile	100	58,08
Median	100	79,29
75% Percentile	100	94,17
Maximum	100	159,9
Range	0	128,5
Mean diff D0-D7		**-17,92**
Mean	100	82,08
Std. Deviation	0	30,06
Std. Error of Mean	0	6,72
Lower 95% CI of mean	100	68,02
Upper 95% CI of mean	100	96,15
Sum	2000	1642

Attachment 4: Raw data from self-assessment questionnaire

	QUESTIONNARIE AT THE END																			
	Volunteer	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
COSMETIC ATTRIBUTES	1.The texture of the product is pleasant.	3	5	4	3	1	5	3	4	3	5	3	4	4	4	5	3	3	5	4	5
	2. Product absorption is fast.	1	5	1	4	5	5	2	2	5	5	5	4	5	5	5	5	4	5	4	5
	3. The perfume of the product is pleasant.	3	5	4	3	3	5	3	3	3	5	5	4	3	3	3	4	3	3	3	5
	4. The colour of the product is nice.	1	5	4	4	3	5	3	4	5	5	5	5	3	4	5	4	4	5	3	5
	5. The application of the product is easy.	5	5	4	3	2	5	2	1	1	3	5	3	5	4	4	3	2	4	4	4
COSMETIC EFFECTIVENESS	6. The contour of my face appears smoothed.	1	5	5	5	1	5	4	4	5	5	3	5	4	4	4	3	4	5	4	4
	7. My fine lines and wrinkles appear to be minimized.	3	5	4	4	1	4	4	2	5	4	2	4	4	3	4	2	4	5	3	4
	8. My skin is hydrated	3	5	4	5	1	5	3	4	5	5	4	3	2	4	4	3	4	5	4	4
	9. My skin looks younger	4	5	4	4	1	4	3	3	5	4	3	4	4	3	4	2	3	5	3	4
	10. My skin is firmer	5	5	3	3	3	5	3	4	5	4	2	2	5	3	4	3	3	5	4	4
	11. My skin is smoother	4	5	3	5	3	5	3	4	5	5	4	4	4	4	4	4	4	5	4	4
	12. My skin seems more radiant	1	5	5	5	3	4	4	4	5	4	3	4	4	3	4	3	3	5	4	4
	13. My skin seems more flexible (elastic)	4	5	3	4	1	5	3	3	5	4	3	3	3	3	3	3	4	5	4	4
	14. The treatment unifies the skin tone.	4	5	3	3	3	4	3	4	5	4	2	3	3	4	3	2	3	4	3	4
	15. The treatment brightness my skin	4	5	4	4	3	5	4	4	5	5	2	4	3	4	5	2	3	5	4	4
	16. The treatment improves visually the quality of my skin	3	5	3	4	3	5	4	4	5	5	3	4	4	3	4	3	4	5	4	4
CONSUMER OPINION	17. I am satisfied with the treatment received	3	5	4	4	3	5	3	4	5	5	4	5	4	4	5	3	4	5	4	5
	18. I would use the treatment again.	3	5	4	5	1	5	3	4	5	5	3	5	4	4	5	2	4	5	4	5
	19. I would recommend the treatment.	3	5	4	5	1	5	3	4	5	5	3	5	4	4	5	2	3	5	4	5

Attachment 5: Images

All images are enclosed in a digital file, together with this report, with the following folder structure:

1122.20.10 PHOTOS

- **MACROSCOPIC PHOTOS**
  - **V01**
    - V01 D0_ D7 FRONT 1122. tif
    - V01 D0_ D7 LEFT 1122.tif
    - V01 D0_ D7 RIGHT 1122.tif

- **BIO3D WRINKLES**
  - **V01**
    - Arrugas.jpg
    - Frontal_0_7.tif

Attachment 6: Informed Consent

Bionos
Testing Efficacy

FT-W-05_5

INFORMACIÓN Y AUTORIZACIÓN DE PARTICIPACIÓN EN EL ENSAYO	
Código de Protocolo: 1122.20.10	Promotor: Respilon Membranes S.R.O.
Fecha de la versión: 04/07/2022	Investigador Principal: Dr. Jose Luis Mullor Sanjosé Dra. Adela Serrano Gimeno
Centro: Bionos Biotech S.L.	

CONSENTIMIENTO INFORMADO

Yo, _____ con DNI, _____

- He comprendido la información que se me ha facilitado.
- He podido hacer preguntas sobre el estudio.
- He recibido suficiente información sobre el estudio.
- Comprendo que mi participación es voluntaria.

AUTORIZACIÓN DE CESIÓN DERECHOS DE IMAGEN:

Al amparo de lo dispuesto en la Ley Orgánica 1/ 1982, de 5 de Mayo, de protección civil del derecho al honor, a la intimidad personal y familiar y a la propia imagen, como parte del estudio citado y en la hipótesis de una futura explotación publicitaria de los productos testados. El cedente autoriza a Bionos, al Promotor, y a aquella persona por cuya cuenta intervenga el Promotor, la reproducción y difusión de las mencionadas imágenes, o partes de las mismas con las siguientes condiciones:

- La cesión se efectúa a título gratuito; el cedente no recibe contraprestación alguna a cambio de la cesión de sus derechos de imagen.
- El promotor únicamente podrá identificarme por mi código de voluntario y no tendrá acceso a mis datos personales.
- Para marketing/ publicidad, con la única salvedad y limitación de aquellas utilizaciones o aplicaciones que puedan atentar al derecho al honor en términos previstos en la Ley orgánica 1/1982.

PROTECCIÓN DE DATOS

De conformidad con lo establecido en la Ley Orgánica 3/2018 de 5 de Diciembre, de Protección de Datos Personales y Garantía de los Derechos Digitales (LOPDGDD), así como el Reglamento General (UE) 2016/679 del Parlamento Europeo y del Consejo de 27 de Abril de 2016 relativo a la Protección de Datos de las personas físicas, le informamos que sus datos personales como voluntario a los ensayos que realiza este laboratorio, entre los que se encuentran los relativos a su salud, serán tratados de manera lícita, leal, transparente, adecuados, pertinente y limitados a lo necesario en relación a los fines descritos y por los cuales fueron obtenidos, este laboratorio adoptara toda las medidas tanto técnicas, organizativas como personales para el correcto cumplimento de las obligaciones que la citada normativa impone al Responsable del Tratamiento.

Así pues, le informamos que el Responsable del tratamiento es **BIONOS BIOTECH, S.L.** con **CIF B98508039**, domicilio en la **Avda. Fernando Abril Martorell 106. Hospital la Fe (Torre A – Planta 1ª) - 46026 Valencia, Registro Sanitario N.º 22043**, sus datos serán tratados con la finalidad de su participación voluntaria en los ensayos clínicos que realiza este laboratorio, para ello le informamos que usted deberá cumplimentar previamente en formato papel o electrónicamente (según sea cada cuestionario y/o determine la empresa) los documentos necesarios para su participación en dicho ensayo y en los que se le ha informado de todo el tratamiento que se le va a realizar a falta de la información que a continuación le solicitamos y que pasará a formar parte de la documentación denominada "Historia Clínica", relativo a usted y al ensayo en el que va a participar.

Le comunicamos que de acuerdo con la normativa vigente en materia de protección de datos podrá ejercer sus derechos así como revocar el consentimiento prestado para el tratamiento de los mismos, dirigiendo su petición a la dirección arriba indicada o por correo electrónico a la dirección dpo@bionos.es, sus datos serán conservados mientras exista una relación con este laboratorio o mientras el ensayo en el que ha participado este abierto y posteriormente durante el tiempo necesario para cumplir con las obligaciones según la Ley General de Sanidad y la Ley 41/2002 de Autonomía del Paciente, le informamos que para el tratamiento de sus datos este laboratorio ha obtenido su consentimiento expreso, además queremos informarle que sus datos considerados como de **"categoría especial"** podrán ser tratados cuando los mismos sean necesarios para fines de medicina preventiva, diagnósticos médicos, prestación de asistencia medico sanitarias y/o servicios de asistencia sanitaria, sobre la base del Derecho de la Unión o de los Estados miembros o **en virtud de un contrato y que se realice por un profesional sanitario sujeto al secreto profesional o por otra persona sujeta asimismo a una obligación equivalente de secreto.**

De la misma manera le informamos que con la finalidad del seguimiento, de una mayor eficacia en nuestros estudios y en definitiva una correcta prestación de nuestros servicios a nuestros clientes, este laboratorio deberá realizar fotos y/o videos, con la finalidad de evaluar los tratamientos realizados a sus voluntarios (antes, durante y después) del mismo, estas imágenes serán utilizadas para la mejora en beneficio de nuestros ensayos, sobre procedimientos y/o procesos de trabajo relacionados con nuestra actividad, sus datos (imágenes, fotos y/o videos), serán usadas exclusivamente para las finalidades indicadas y cumplirán con lo dispuesto en la Ley Orgánica 1/1982, de 5 de mayo, de protección civil del derecho al honor, a la intimidad personal y familiar y a la propia imagen y el Reglamento General (UE) 2016/679 del Parlamento Europeo y del Consejo de 27 de Abril de 2016 relativo a la Protección de Datos de las personas físicas y/o normativa vigente.

Así mismo le informamos que sus datos personales no serán cedidos a terceros, salvo que exista una obligación legal asumible por el Responsable del tratamiento, también queremos informarle que los datos relativos a los ensayos realizados incluyendo las (imágenes, fotos y/o videos), forman parte de la documentación necesaria sobre el mismo, así como la documentación relativa al (tratamiento, seguimiento, información, estudios y metodologías empleadas..), esta información será cedida y tratada por nuestros clientes con la finalidad de la mejora de su producto y el análisis de los resultados de los ensayos, ambas entidades cumplimos con los más altos procedimientos y estándares en referencia a los datos obtenidos (seguridad y control de los mismos), aplicamos las medidas técnico- organizativas más adecuadas al tratamiento que realizamos, por ello le solicitamos nos marque la casilla como que usted queda informado de todo lo relacionado con el tratamiento de datos que realiza **BIONOS BIOTECH, S.L.** para terceros en relación a los ensayos en los que usted se ha presentado voluntariamente.

Si desea plantear una reclamación en relación al tratamiento de sus datos por parte de esta clínica, le informamos que puede ponerse en contacto con la Agencia Española de Protección de datos, C/ Jorge Juan, 6 28001-Madrid – www.agpd.es

Autorizo al Promotor del estudio a usar mi imagen/registros audiovisuales:

SI ☐ NO* ☐

* Rechazar el uso de mi imagen para fines comerciales no prohíbe mi participación en el estudio.

Apruebo la presente autorización.

Firmado en Valencia _____/_____/_____ .....

Autorizo al Promotor del estudio a usar mi imagen/registros audiovisuales.

COPIA PARA EL VOLUNTARIO

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