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Ihre Nachricht vom	Ihr Zeichen	Unser Zeichen	Datum
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Specialist doctors' dermatological report on the

OPTICAL 3D-MEASUREMENT OF THE SURFACE OF THE SKIN

Quantitative evaluation of the roughness of the surface of the skin with the calculation of standardised skin roughness parameters according to DIN 4768 ff.

Designation of the preparation:

CREME EDELWEISS ANTI-AGEING
Marque Athanor Lot No: A-421010

Client:	**Belidis Sàrl** **Rue des Artisans 4** **CH – 2830 Courrendlin**
Test persons:	20 test subjects, all with healthy skin
Test concentration:	Preparation undiluted
Test period:	4 weeks
Test area:	face

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1. AIM OF THE TESTS

It was the aim of this test to carry out a precise investigation of the preparation as regards the subjects' tolerance according to clinical dermatological test criteria. In addition, the depth of wrinkles was examined before and after the period of application by means of optical 3D measurement.

The test subjects could seek advice every day from the dermatologist present at the test about objective and subjective changes to their skin.

Before the start of the application test, all the test subjects underwent a dermatological examination. Every test subject then applied the Preparation Creme Edelweiss Anti-Ageing every day in the morning and the evening to the test area according to the instructions.

Daily checks of the skin condition could be made as required by the dermatologist involved with the test.

Optical 3D measurements followed before and after 4 weeks.

2. OPTICAL 3D MEASUREMENT WITH PRIMOS

2.1. Introduction

3D measurement and evaluation of the surface of human skin is an important task in dermatological examinations for both medical and cosmetic purposes. For precise diagnoses, therapeutic decisions or even for the evaluation of progress in medical or cosmetic treatment, precise knowledge of the 3D surface of the skin is an important aid. Measurement of the 3D profile of the surface of the skin can be carried out by taking impressions of the skin (casts) or by direct in-vivo measurement.

2.2. Measurement procedures

With the PRIMOS optical 3d measuring device, the so-called digital stripe projection technique is used as the optical measurement procedure. In this measurement method a pattern of parallel stripes is projected onto the surface of the skin and recorded by means of a system of image lenses on the CCD chip of a camera.

The 3D measurement effect is achieved because the slightest differences in the height of the surface of the skin deflect the projected parallel stripes so that these deflections represent a qualitative and quantitative measurement of the profile of the skin. This is recorded by the CCD camera, digitalised and transferred to the measurement and evaluation computer for the quantitative evaluation. In the evaluation, mathematical algorithms are applied which were originally developed and used for the high-precision optical measurement of optical and precision mechanical components and can now be used effectively in optical 3D measurement of the skin in order to build a high-precision 3D profile of the surface of the skin.

The PRIMOS optical 3D skin measuring device (derived from **P**haseshift **R**apid **I**n vivo **M**easurement **O**f **S**kin) is distinguished by the use of digital light or stripe projection together with the digital processing of the signal. The digital light projection used is based on developments in micromirror projectors which were made and brought to the market by Texas Instruments, Dallas in the nineties.

The compact version of the PRIMOS optical 3D skin measurement system used here consists of an optical measurement head (with an integrated micromirror projector, projection and recording optics and a CCD recording camera), a measurement and evaluation computer and a tripod for the device for the free spatial movement of the optical measurement head to allow the recording of various areas of the skin. Another element of the PRIMOS device is a

measurement and evaluation software package which handles the recording and evaluation of the surface of the skin.
With the PRIMOS device, both recording of measurements of the profile of the skin's surface completely without contact and the measurement of impressions is possible. Each method of taking measurements has its advantages and disadvantages. With the inexperienced taking of impressions, the slightest mechanical disturbance to the surface of the skin can lead to changes in the 3D microstructure. Direct in vivo measurement of the skin gives problems of "blurring" by the test subject as well as the vegetative nervous movements described below. Both types of measurement recording can lead to different results in the assessment of the skin's roughness or smoothness.

2..3. High-precision area identification
The surface of human skin is, depending on the circulation and the vegetative nervous system, subjected to constant movement. Furthermore, there is the risk with the examination of areas of the body which are difficult to approach (e.g. lips, eyelids or even wrinkles around the eyes) that there will be slight movements or changes in position of the surface of the skin during measurement. Such changes can, depending on the stage in the recording (illumination stage) cause different levels of disturbance. Large movements can make the set of 3D data completely unusable. A series of slight movements during the measurement recording are relatively easy to identify in the set of raw data. Errors resulting from microscopically small movements of the areas of skin under examination during the measurement recording are often recognised only with difficulty and risk falsifying the measurement results obtained from the surface of the skin.
Optical 3D skin measurements are carried out with the aim of discovering the effect of a cosmetic or medical treatment on the surface of the skin. This aim of the examinations requires that the skin surface can be quantitatively and qualitatively precisely measured before and after the treatment. Since the surface of human skin shows a very uneven microstructure, it is particularly important for the measurement of skin smoothness that the measurement is taken from precisely the same area of the skin before and after the treatment or during the treatment procedure. Despite the fact that judging by eye leads one to believe that a practically identical area is being measured, the reported roughness measurements of the skin can show major differences due to, for instance, slight lateral displacement. With the aim of eliminating the sources of error mentioned during optical 3D skin measurement, a very precise area identification method was developed for the PRIMOS device which finally makes it possible to fix the measurement position on the surface of the skin before and after treatment with a precision of 1/10 of a pixel which, using a field of measurement of 10 x 8 mm^2 and a camera with 640 x 480 pixels, corresponds to a precision of positioning of approx. 1 μm. The achievement of high-precision area identification in video real time during the recording of the measurement occurs in the following two stages and consists of a high-precision computer-aided area identification (matching) during the evaluation of the sets of 3D measurement data.

- For the immediate identification of an area during the recording, the procedure is such that the camera images of the final and start positions with which the areas to be treated will be compared are first loaded into the measuring computer. Then the live imaging of the skin area now to be measured by PRIMOS is started and the two images are superimposed. The simplest case would be where the start area serves to overlay the current live image. As practical experience has shown, it is very difficult to make a positive visual match of the

two images i.e. the current live image and the reference image. In order to remove this difficulty, a methodical approach was chosen. In this approach five points are calculated in the reference image on the basis of distinctive structures and these points are shown with different coloured circles on the monitor of the PRIMOS device. The corresponding positions of these circles are shown simultaneously on the current live image as squares of the same colours. The task during the recording of the measurements is now to bring the circles closely into line with the corresponding squares by means of slight movement of the area of the skin or of the field measured.
If this is completely successful, then the precision of positioning is approx. 2 camera pixels and the recording of the measurement can be carried out.
• As experimental investigations have shown, the above-mentioned identification of areas in video real time is not yet adequate for high-precision measurements especially for the effect of cosmetics on smoothness of the skin or in the development of wrinkles around the eyes.
With the aim of increasing the accuracy of measurement significantly again and being able to record and evaluate the finest structural variations, yet another software-aided area identification system was developed. To carry out this high precision matching procedure, the reference area is loaded into the left window of the matching software and each skin surface to be compared with this into the right window.

To identify the variations between the start (reference) condition and the currently measured condition to be compared, two different procedures can be chosen either separately or simultaneously. On the one hand, profile sections can be laid over the two main profiles which can be automatically placed exactly in the same position thanks to the high-precision matching of the main profiles.
A further possibility for the evaluation of the very precisely positioned surfaces of the skin before and after a course of treatment is the recording and comparison of roughness parameters which are obtained from the reference profile and the measured profile.

2.4. Materials used

In the measurement of casts (evaluation of impressions of the skin made with silicon), measurement errors due to body movements can be avoided. The casting material (silicon for precision casting, silicon-based [Polysiloxan condensation-bonding]) high viscosity, corresponds to DIN 13913 A 2, ISO 4823 Type 1 Cat.B, colour: white. The physical characteristics are as follows: deformation under pressure: 1 to 4 %, residual pressure deformation: less than 2 % (in accordance with DIN 13913), variation in size: less than –0.45 % (in accordance with DIN 13913 and ISO 4823).
The casting material is produced immediately before use. 2.5 cm of universal hardener paste are added to 12ml of casting silicon. After 45 seconds of mixing time, the substance is spread evenly without pressure over the area of the skin and hardens in 2 to 3 minutes. This now flexible cast is carefully removed from the surface of the skin and fixed flat on a glass plate with a layer of adhesive containing no solvents.

2..5. Evaluation

For a particular density of points selected for the x and y axes, a computer program draws a realistic three-dimensional image of the relief of the skin on a colour screen. As the next step the measurement data stored in the computer are processed and then evaluated. This analysis consists of the following stages:

1. Generation of a roughness profile from the surface relief by alignment and filtering
2. Calculation of standardised roughness parameters (DIN 4768 ff.)

With the PRIMOS software the changes in structure of the epidermis can be classified quantitatively with the aid of various standardised surface measurement parameters in accordance with DIN (Deutsche Industrie Norm, German industrial standards) and ISO (International Standards Organisation). The calculations are carried out by reference to the relevant DIN standards, and long-wave profile elements are removed as required by polynomials. Wave filters and Gauss filters can also be used as required. The star roughness used here serves to provide a measurement of the dependence on the angle for the roughness parameters in the direction of the greatest height variations. The profile sections are grouped into a star shape. The most useful surface measurement parameters that can be applied here to assess skin structures are the following:

1. R_a	The arithmetic mean of the absolute values of all profile ordinates within the entire measured section (l_m) after (digital) filtering out of variations in form and the rougher sections of the undulation.
2. R_z	(DIN) from the greatest individual roughness depth measurements of five adjacent individual measurements of equal length of the (digitally) filtered profile.
3. R_q	Quadratic mean value of the variation of the roughness profile within the measurement section of a (digitally) filtered profile.
4. R_{max}	The greatest individual roughness depth occurring Z_1 of the (digitally) filtered profile within the entire measured section (l_m) in determining R_2 (DIN).
5. R_{3z}	The arithmetic mean of the 5 lowest individual roughness measurements R_{z1} to R_{z5}. The lowest individual roughness is defined as the vertical distance between the third highest profile peak and the third deepest profile trough within the individual measured section l_e of the (digitally) filtered roughness profile, where vertical and horizontal minimal values must be ignored.
6. R_{3zm}	The greatest value in R_{zi} occurring in determining R_{3z} within the entire measured section.
7. R_p	The distance between the highest point and the median line within the measured section of a (digitally) filtered profile.
8. R_2	(ISO) Sum of the median values of the absolute heights relative to the median line of the five highest and five deepest profile points recorded within the measured section.
9. R_e	Sum of the absolute median values of the height of the profile peaks and the depths of the profile troughs.
10. S_m	Arithmetic mean of the distance between the cut-off points of the unused ends of the profile recording and a numerical threshold running parallel to the median line of the reference section I_m S=1/n S S_j=(S1+S2+S3+Sn)/n.
11. W_e	The height of the profile within the measured section of the wave I after filtering out the roughness.
12. F.D.	Fractal dimension: 1 < FD < 3. Finer definition in e.g. "Surface Topography", Vol. 1, Issue 2, June 88, p.143 ff. To simplify, it can be said that the smaller the value, the greater the smoothness.

2.6. Literature:

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3. RESULTS OF THE EXAMINATIONS

3.1. Dermatological examinations

1. Before the start of the application test, all test subjects showed a healthy skin in the application area. No other pathological skin-changes were observable.
2. During the application test, none of the 20 test subjects showed any pathological skin changes in the test area. No allergic or irritative skin reactions were observed. There were no interruptions to the test. Specialist medical treatment of the skin was not needed in any case.
3. After the end of the application test, no test subject showed any allergic or irritative skin reactions in the test area in the final dermatological examination. The named preparation was tolerated very well and led to no undesirable changes in the skin of any of the test subjects.

3.1.1. List of test subjects

Test subject no.	Name	Sex	Age
1	K. L.	70	w
2	N. T.	39	w
3	D. T.	66	w
4	J. T.	41	w
5	I. T.	46	w
6	A. V.	42	w
7	Ch. H.	45	w
8	G. A.	67	w
9	S. O.	39	w
10	S. A.	37	w
11	U. Sch.	45	w
12	H. K.	34	w
13	S. N.	37	w
14	R. F.	49	w
15	I. S.	45	w
16	H. S.	45	w
17	M. R.	30	w
18	H. W.	30	w
19	A. H.	42	w
20	A.L.	37	w

3.2. Results of the optical 3D measurement of the surface of the skin

The individual test results are attached to the report.

3.3. Summary of the changes before and after 4 weeks of application
The Rz-DIN values in the test area are compared before and after 4 weeks and in the relative change (with negative values indicating an improvement).

Test subject no.	before	after 4 weeks	Difference	rel. Change as %
1	151,9	113,4	-38,5	-25,3456221
2	183,0	100,6	-82,4	-45,0273224
3	111,2	103,6	-7,6	-6,83453237
4	120,6	94,51	-26,09	-21,6334992
5	133,4	97,98	-35,42	-26,5517241
6	108,8	93,59	-15,21	-13,9797794
7	135,5	87,83	-47,67	-35,1808118
8	103,9	98,16	-5,74	-5,52454283
9	129,7	111,9	-17,8	-13,7239784
10	146,0	110,2	-35,8	-24,5205479
11	144,1	114,4	-29,7	-20,610687
12	134,4	84,54	-49,86	-37,0982143
13	136,9	122,8	-14,1	-10,2994887
14	157,8	118,5	-39,3	-24,904943
15	150,6	103,9	-46,7	-31,0092961
16	163,6	106,6	-57	-34,8410758
17	142,9	106,5	-36,4	-25,4723583
18	123,7	136,1	-12,4	10,0242522
19	191,3	100,7	-90,6	-47,3601673
20	133,4	126,0	-7,4	-5,54722639
AVERAGE	**140,135**	**106,5905**	**-33,5445**	**-22,2720783**

The improvement in the roughness of the skin as a result of the **Preparation CREME EDELWEISS ANTI-AGEING** amounted on average to 22,27,%.

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4. ASSESSMENT OF THE TEST RESULTS

20 test subjects in all tolerated the above-mentioned **Preparation CREME EDELWEISS ANTI-AGEING** without problems according to dermatological clinical criteria in an four-week test. There were no instances at all of undesirable changes, and certainly no pathological ones, to the skin in the test area.

The extended optical 3D-measurements of the surface of the skin with determination of the roughness of the skin in accordance with DIN 4768 ff showed after 4 weeks of application an average improvement in the roughness of the skin of 22,27 %.

In summary, it can be concluded from a dermatological point of view that Preparation **CREME EDELWEISS ANTI-AGEING** was tolerated very well by clinical dermatological criteria and led to a significant improvement in the roughness of the skin as defined by DIN Standard 4768 ff. The average improvement in roughness of the skin after 4 weeks of application was 22,27 %.

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