

# **Efficacy of beautytek treatment (Breast and Upper Leg) Pre-Trial Results**

## **Abstract**

The efficacy of the beautytek treatment was investigated by testing several skin-physiological parameters. Three female test persons (aged approx. 30, 40, and 50 years) received treatments of the breast and upper leg, whereby the left side was treated 12 times whereas the right side was treated only during the last 6 sessions. After treatment a moderate to substantial improvement of measured parameters was observed. The beautytek treatment was particularly beneficial in reducing the undulation of the sub-skin area in the upper leg strongly indicating the reduction of and improvement in cellulite. In general the test results confirm that all test persons benefited from the beautytek treatment in the treated regions. The trial was conducted as a pre-trial for a planned main study documenting the effectiveness of beautytek treatments.

## **Aim of study**

For several years the beautytek method has been applied in cosmetic institutes. Frequently a scientific prove of its effectiveness has been mandated by users, potential buyers and regulatory bodies. Currently only attempts of systematic scientific investigations of its efficacy exist [1]. Therefore a prospective scientific study was planned aimed to document the efficacy of beautytek related treatments.

- according to a well defined treatment regiment
- applied to certain selected body areas
- tested by relevant parameters common in experimental dermatology
- comparing untreated and treated time intervals for control purposes.

In order to assess the suitability and relevance of parameters, the magnitude of treatment induced changes, and the structure and extend of the study (number of test persons, cost) a pre-trial of three test persons was conducted and is documented below.

## **Methods**

Three healthy female volunteers, aged approx. 30, 40 and 50 years, were recruited, consulted about the intend of the study, and their consent obtained. Table 1 contains the personal data of the test persons. The treatment was carried out by 'neosoma', an aesthetic institute located in Cologne, Germany (Heidelind Latz, Dr. Norbert Arndt) during March and April of 2003.

| <b>Test person</b> | <b>Age (years)</b> | <b>Weight (kg)</b> | <b>Height (m)</b> |
|--------------------|--------------------|--------------------|-------------------|
| SE                 | 31                 | 88                 | 1,71              |
| CG                 | 42                 | 69                 | 1,68              |
| BW                 | 47                 | 56                 | 1,70              |

*Table 1: Personal data of test persons*

The test persons were treated during

### Cycle 1

6 treatments on the left side of the body,  
with an initial treatment of the upper leg and a subsequent treatment of the female breast in the same session, and during

### Cycle 2

6 treatments on both sides of the body  
with an initial treatment of both upper legs and subsequent treatment of the breast in the same session.

During the treatments the usual electrolytes CEL 236 and CEL 231 were applied to the upper leg and breast respectively. ACT-treatments were carried out in all test persons starting with the 6<sup>th</sup> treatment during 4 sessions on both upper legs. All treatments followed the regular regiment of the beautytek-program using the regular probes.

Before the first, after the 6<sup>th</sup> and after the 12<sup>th</sup> session digital photographs were obtained by neosoma showing a frontal and lateral view of the treated body areas.

Skin irritations or other external symptoms were not observed throughout the duration of the study. Test persons did not report any abnormal physical or other noticeable conditions.

The measurement of skin-physiological parameters were carried out at the Institute for Experimental Dermatology at the University Witten-Herdecke in Witten, Germany (Director Prof. Dr. med. H. Tronnier) and were under guidance of Mrs. Priv. Doz. Dr. Ulrike Heinrich. The tests itself were performed by laboratory technologist Mrs. Cornelia Wibusch.

Tests were done

- before the 1<sup>st</sup> treatment
- after the 6<sup>th</sup> treatment (cycle 1) and
- after the 12<sup>th</sup> treatment (cycle 2).

During the tests the following parameters were recorded and evaluated:

#### Capillary Perfusion

Determination of capillary perfusion using the laser Doppler flow meter measuring the mean flow velocity of capillary blood in parts of the treated skin area.

#### Elasticity of Skin (Cutometer)

Determination of suction pressure required to draw a skin plexus into a cavity mold. By measuring the maximum pressure, time of pressure rise, and time of pressure drop the parameters elasticity R6, the viscoelastic properties of skin, and the elasticity R7, the biological elasticity were derived.

#### High Resolution Ultrasound Imaging (B-Scan)

Using a 20 MHz ultrasound probe skin structures were displayed to a maximum depth of 7 mm at a resolution of 0.05 mm. Ultrasound images were evaluated by a special software algorithm determining the area of interest in sub-skin structures. This area is related to the occurrence of cellulite and is supposed to show a decrease with progressing treatment (smoothing effect, reduction of “orange peel skin”).

#### Infrared-Thermography

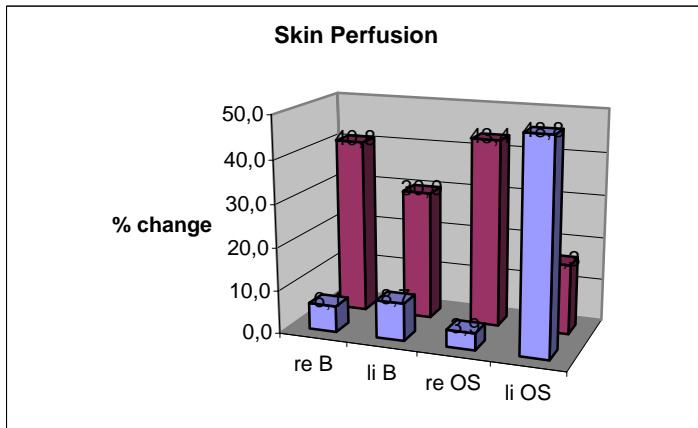
Measurement of superficial skin temperature by determining infra red radiation.

#### SELS-Test (Surface Evaluation of Living Skin)

Profilometric investigation of skin surface by high resolution digital photography determining the parameters roughness, scaling, smoothness, and wrinkles using special automated software algorithms.

### **Results**

The graphs given below show changes of measured parameters after the 6<sup>th</sup> treatment (left side treated, right side untreated) and after the 12<sup>th</sup> treatment (left side had obtained 12 treatments, right side 6 treatments only)



Capillary skin perfusion

The left upper leg shows a marked and the left breast a moderate increase in skin perfusion after the 6th treatment. After the 12<sup>th</sup> treatments capillary perfusion is further enhanced in both breasts and the right, formerly untreated leg but is decreased in the left leg as compared to values after the 6<sup>th</sup> treatment.

Fig. 1: Skin perfusion measured by laser

Doppler flowmetry,

OS = upper leg, B = breast, re = right side, li = left side

Front row columns indicate relative changes after 6 treatments, back row columns indicate relative changes after 12 treatments, whereby left side was treated 12 times while right side received only 6 treatments. Treatments on the right side began together with the 7<sup>th</sup> treatment of the left side.

Elasticity, viscoelastic properties, R6 (Cutometer)

In both treated body areas (upper leg and breast) an improvement of viscoelastic properties can be observed in average. Negative values in R6 reflect improved skin condition.

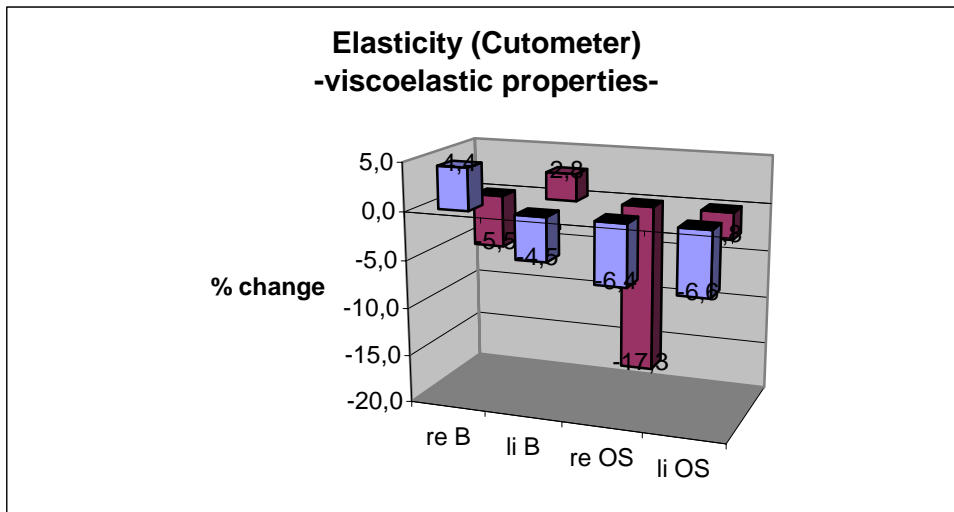


Fig. 2: Elasticity, viscoelastic properties R6 (Cutometer)

Elasticity, bioelastic properties, R7 (Cutometer)

In both treated body areas (upper leg and breast) an improvement of bioelastic properties can be observed in average. Positive values in R7 reflect improved skin condition.

In particular, marked differences between treated and untreated sides can be seen after 6 treatments, being equilibrated with the second treatment cycle.

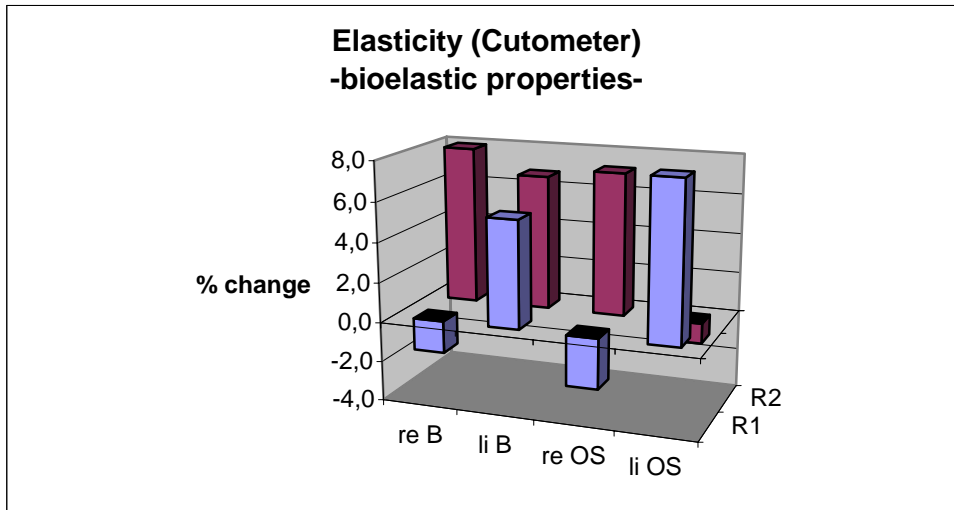


Fig. 3: Elasticity, bioelastic properties R7 (Cutometer)

Ultrasound imaging

As expected no noticeable differences of the parameter ‘Area’ were observed in the breast. In contrast a substantial improvement was reached during treatment of both upper legs. After the first treatment cycle of 6 treatments a marked difference between treated and untreated side was obtained (30% reduction in Area), equilibrated after the 2<sup>nd</sup> treatment cycle.

The reduction of area, i.e. reduced undulation of sub-skin layers, is related to a decrease in cellulite (also refer to Appendix, Fig. 8).

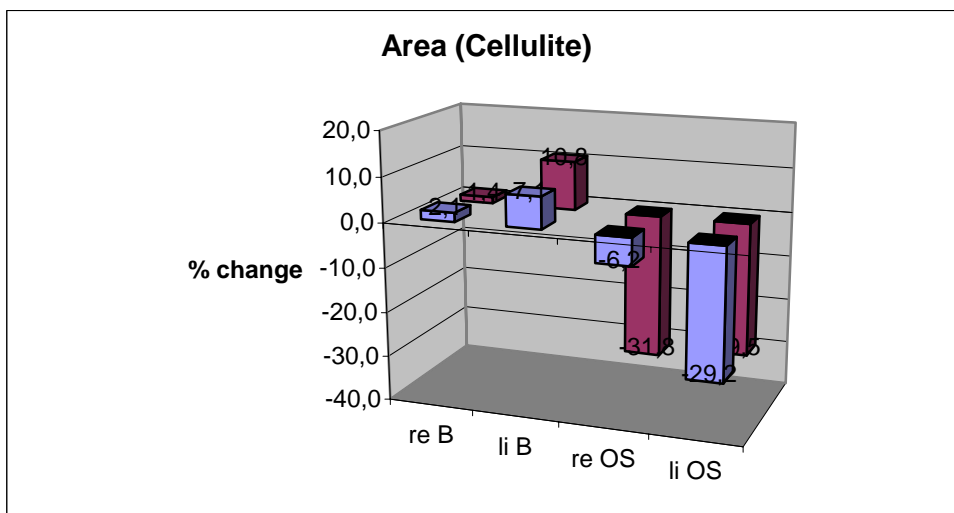


Fig. 4: ‘Area’ indicating area of sub-skin layers determined by high resolution ultrasound imaging

Thermography

No noticeable changes were observed in this parameter.

SELS-Test

In general a moderate to marked improvement was observed in the parameters roughness, scaling, smoothness, and wrinkling; only in the left breast no improvement in skin scaling occurred.

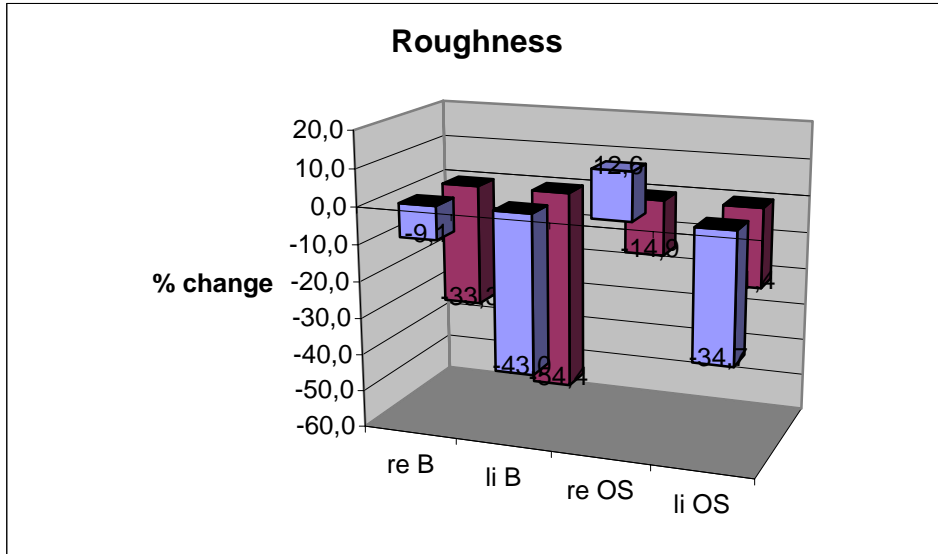


Fig. 5: Changes in skin roughness as determined by the SELS test method.

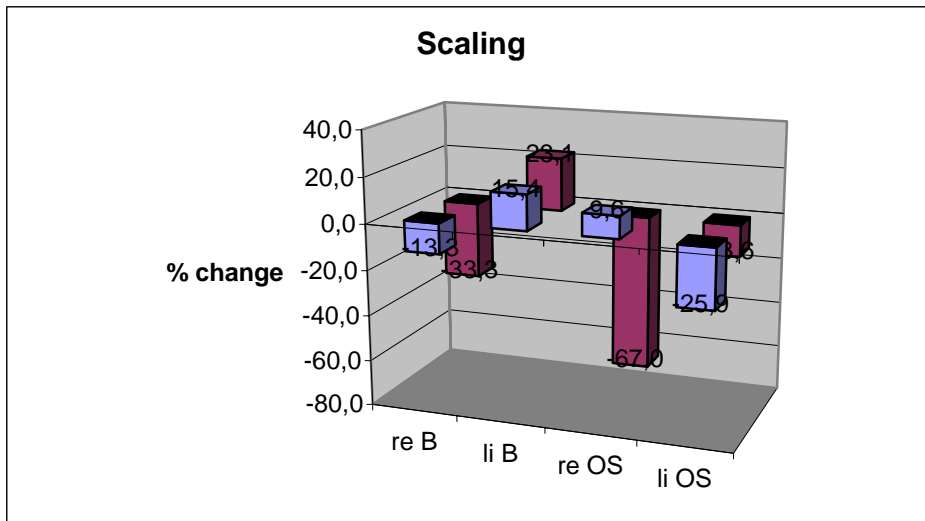


Fig. 6: Changes in skin scaling as determined by the SELS test method.

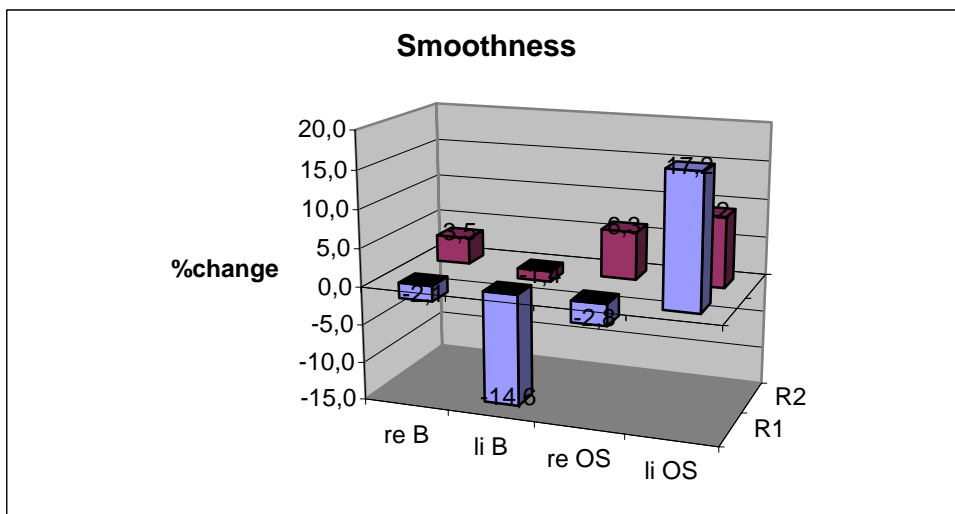


Fig. 7: Changes in skin smoothness as determined by the SELS test method.

## Subjective Results

### Test person SE:

The breast looked floppy, pendulous, and worn out on both sides after seven months of breast feeding in twins. Post treatment the breast looked and felt firm, shaped and lifted. According to the test person the breast was comparable to pre-birth conditions.

Post treatment the circumference of thighs was reduced by 4 cm each; the total body weight was 4 kg lower.

### Test person CG:

After breast feeding of three children the breast was extremely pendulous and wrinkly. At the end of the treatment the breast looked firmer and showed a natural curvature in supine position; wrinkles were markedly less visible. Although not treated, the abdomen showed an increased firmness.

On the upper legs a tightening and smoothing effect could be observed. Cellulite was visibly reduced.

### Test person BW:

Pre treatment the breast was tubular, floppy, and very pendulous, a pre-existing condition since the test person was 18. The breast also showed strong wrinkling. Post treatment a marked reduction in wrinkles on both breasts was seen.

The upper legs showed a tightening of skin and a complete reduction in cellulite.

All three test persons reported a very noticeable increase in leg perfusion after the treatment. (One of the treated women called this “a new livelihood in my legs”).

## Discussion

The efficacy of the beautytek treatment was evaluated by measuring different skin-physiological parameters. Superficial skin temperature did practically not change after the treatment. This result is not surprising as the test takes superficial temperature and does not reach deeper skin structures. Furthermore the test was not carried out immediately after the treatment but one to several days later. The result is also consistent with the intention of the beautytek treatment not to cause skin irritation or other complications of skin surface which could be enhanced by a rise in skin temperature over a longer period of time. The measurement of skin temperature immediately or a few hours after the treatment could be more meaningful. Logistic required the test procedure to take place one or several days after the treatment. Empirical observations suggest that the beautytek treatment reaches an optimum between several hours and several days after treatment. Therefore the time interval between end of treatment and tests was chosen, most likely picking peak or near-peak results.

The most impressive reaction was obtained in the parameter ‚Area‘. Its reduction correlates well with a decrease of cellulite. After the treatment of the upper leg a marked improvement was recorded in this parameter. During the treatment cycle though, no further decrease of Area was seen in the left upper leg. We view this result as a consequence of the initially unilateral treatment: Mainly the previously untreated right leg side benefited from the energy dissipated during the second treatment cycle.

Considering the skin structure of the breast, the Area remained practically unchanged in this part of body. SELS parameters did not substantially contribute to prove treatment effectiveness. Except for roughness, SELS data showed particularly little effect in the female breast.

By comparing treated and untreated sides, test results suggest that the treatment extends well beyond the treated region effecting neighboring parts of the body. The treatment of two regions, breast and legs in one session, is not in agreement with standard beautytek treatment rules requiring only one region to be treated at one time. Logistic and cost considerations proposed the current study protocol but may have contributed to diminished test results in each of the regions.

The low number of test persons does not allow for statistical significance. Therefore an interpretation of results validating the beautytek treatment efficacy in general must be considered carefully. Tendencies

and trends though can be derived. Taking the widely varying skin structure into account, transfer of the obtained results to other parts of the body should be expressed with caution.

Undoubtedly though the test results strongly suggest that all test persons benefited from the beautytek treatment in the treated regions.

Literature:

[1] Dorittke, Wahlen, Höning d'Orville, Kardorff. Eine beachtenswerte Methode in der Lifestyle-Medizin: Beautytek. (A Remarkable Method in Life-Style Medicine: Beautytek.) Kosm Med. 2002,4: 213

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Performance of beautytek treatment:

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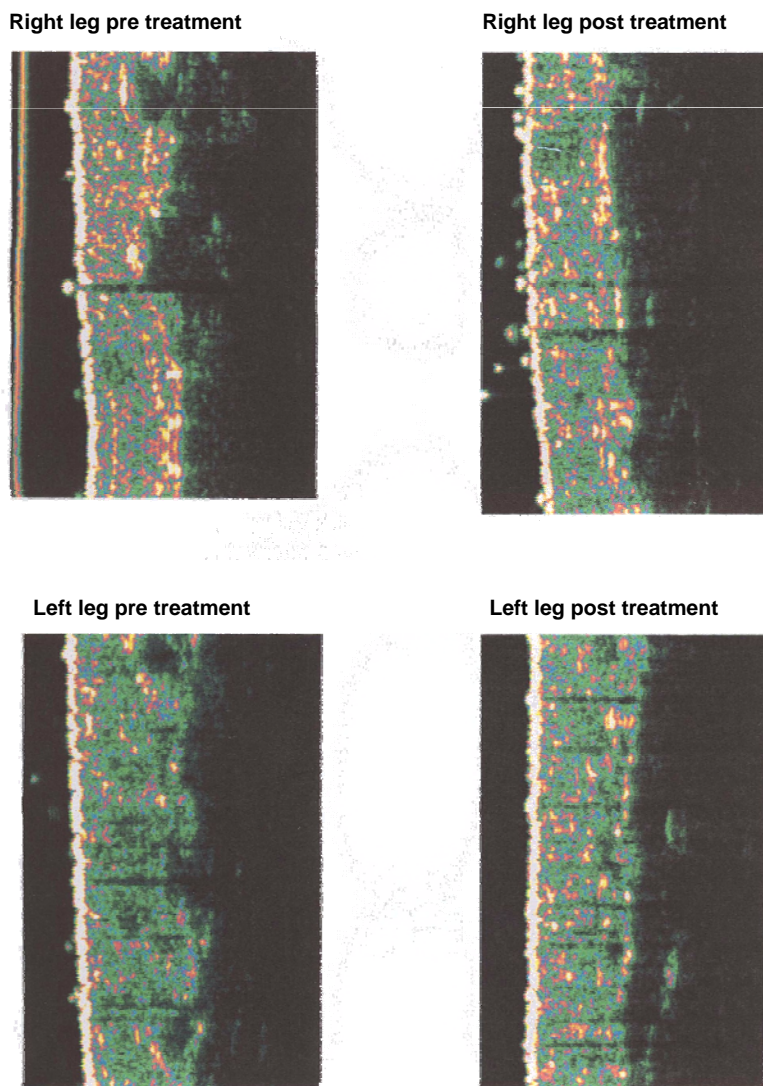
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## Appendix

### Example of high resolution ultrasound images in test person SE



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*Fig.: 8: Ultrasound scans of upper leg with determination of „Area“. Images show skin surface on left side and undulation of lower skin layer on right side. Area determines the region between these border lines. beautytek treatment reduces undulation of lower structure as seen in right images.*

Table of measured data

m0= Initial values before treatment

m1 = Values after 6 treatments

m2= Values after 12 treatments

| <b>Skin perfusion</b>           |       | m0    | m1    | m2    |
|---------------------------------|-------|-------|-------|-------|
| Right breast                    | re B  | 9,8   | 10,4  | 13,8  |
| Left breast                     | li B  | 8,0   | 8,7   | 10,4  |
| Right upper leg                 | re OS | 7,6   | 7,9   | 10,9  |
| Left upper leg                  | li OS | 8,0   | 11,9  | 9,3   |
| <b>Elasticity (viscoelast.)</b> |       | m0    | m1    | m2    |
| Right breast                    | re B  | 0,183 | 0,191 | 0,173 |
| Left breast                     | li B  | 0,176 | 0,168 | 0,181 |
| Right upper leg                 | re OS | 0,173 | 0,162 | 0,143 |
| Left upper leg                  | li OS | 0,181 | 0,169 | 0,176 |
| <b>Elasticity (biological)</b>  |       | m0    | m1    | m2    |
| Right breast                    | re B  | 0,745 | 0,733 | 0,804 |
| Left breast                     | li B  | 0,667 | 0,703 | 0,712 |
| Right upper leg                 | re OS | 0,711 | 0,693 | 0,762 |
| Left upper leg                  | li OS | 0,683 | 0,737 | 0,676 |
| <b>Ultrasound (Area)</b>        |       | m0    | m1    | m2    |
| Right breast                    | re B  | 0,956 | 0,976 | 0,969 |
| Left breast                     | li B  | 0,916 | 0,981 | 1,015 |
| Right upper leg                 | re OS | 1,592 | 1,494 | 1,086 |
| Left upper leg                  | li OS | 1,639 | 1,160 | 1,155 |
| <b>Thermography °C</b>          |       | m0    | m1    | m2    |
| Right breast                    | re B  | 31,5  | 32,1  | 32,7  |
| Left breast                     | li B  | 32,1  | 32,0  | 32,4  |
| Right upper leg                 | re OS | 29,9  | 29,4  | 30,0  |
| Left upper leg                  | li OS | 29,5  | 29,2  | 29,8  |
| <b>SELS (roughness)</b>         |       | m0    | m1    | m2    |
| Right breast                    | re B  | 0,66  | 0,60  | 0,44  |
| Left breast                     | li B  | 1,14  | 0,65  | 0,52  |
| Right upper leg                 | re OS | 0,87  | 0,98  | 0,74  |
| Left upper leg                  | li OS | 0,98  | 0,64  | 0,77  |
| <b>SELS (scaling)</b>           |       | m0    | m1    | m2    |
| Right breast                    | re B  | 0,15  | 0,13  | 0,10  |
| Left breast                     | li B  | 0,13  | 0,15  | 0,16  |
| Right upper leg                 | re OS | 0,94  | 1,03  | 0,31  |
| Left upper leg                  | li OS | 0,81  | 0,60  | 0,70  |

| <b>SELS (smoothness)</b> |       | m0    | m1    | m2    |
|--------------------------|-------|-------|-------|-------|
| Right breast             | re B  | 23,41 | 22,93 | 24,23 |
| Left breast              | li B  | 28,04 | 23,94 | 27,65 |
| Right upper leg          | re OS | 25,84 | 25,12 | 27,46 |
| Left upper leg           | li OS | 23,01 | 26,96 | 25,13 |
| <b>SELS (wrinkling)</b>  |       | m0    | m1    | m2    |
| Right breast             | re B  | 43,96 | 44,22 | 42,94 |
| Left breast              | li B  | 45,78 | 44,28 | 44,88 |
| Right upper leg          | re OS | 39,11 | 38,13 | 36,18 |
| Left upper leg           | li OS | 46,00 | 44,25 | 45,00 |

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