



Trial Report

**EVALUATION OF THE EFFECT OF BIOFREEZE®
ON CUTANEOUS TEMPERATURE**

Test under medical control

*Monocentric study, without direct individual benefit, controlled, randomized, in simple blind
(investigator masked) in intra-individual versus initial state*

Beginning: 09/06/2005

Ending: 23/06/2005

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Ref. Sponsor: NA

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SIGNATURES

	Date	Signature
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Aurélie JOURDAN <i>Project Manager</i> DERMEXPERT		
Catherine TOMKIEWICZ <i>Quality Assurance Manager</i> DERMEXPERT		

DermExpert insures the quality of the collected data and guarantees that the study took place under the responsibility of the Main Investigator for the medical follow-up.

If there is no query concerning this report in the two weeks following its submission, it will be considered as definitive.

For further analysis or reporting, DermExpert reserves the right to invoice the client in function of requests made.

SUMMARY OF THE STUDY AND RESULTS

1. SUMMARY OF THE STUDY

This study is to define the effect of a medical device, **Biofreeze**[®], on the cutaneous temperature with two different concentrations. It is a type I device, for external use which acts by purely mechanical and non-pharmacological action.

The volunteers to be included are men and women 18 to 65 years presenting a healthy skin on the level of the forearms

The study lasted one day, for two hours, with measurements every 5 minutes (i.e. a maximum of 25 measurements).

The cutaneous temperature measurement is made with an infrared thermometer on the 5 zones every 5 minutes during a maximum of 2 hours starting from the end of the product application.

Measurements cease at the time of return to a normal cutaneous temperature of the 2 treated zones.

Measurements are carried out in a room with a controlled and constant temperature.

2. SUMMARY OF RESULTS

- Effect of the product

There is no significant difference between the products A and B.

However, there is a difference between product A and the witness ($p=0,0082$) and between the product B and the witness ($p=0,0109$).

- Relation dose-effect

The analysis of the dose-effect shows that there is a significant difference between two dosages of 5 and 10 mg/cm² ($p=0,0059$).

There is no significant difference between the temperatures of the zones treated by an amount of 5 mg/cm² of product A or product B and the untreated witness zone ($p=0,1371$).

However, the temperature of the zone treated with a dose of 10 mg/cm² is significantly lower than that of the witness zone ($p=0,0002$).

- Tolerance

Three cutaneous intolerances were noted.

METHODOLOGY

Calendar	Beginning: 09/06/2005 Ending: 23/06/2005
Study Phase	III, medical device, without direct individual benefit Site agreement: 10622 H
Study type	Monocentric study, cross-over, controlled, randomized, versus initial state Open for treated zone and untreated zone, blind for the 2 menthol concentrations
Objectives Principal	Study of efficacy of Biofreeze [®] on the cutaneous temperature
Secondary	Evaluation of the tolerance of Biofreeze [®]
Study Products	<p>Product A: Biofreeze[®] Concentration 1 Route and method of administration: Topic Posology:</p> <ul style="list-style-type: none"> ▪ Single application, standardized quantity (5 mg/cm²) ▪ Single application, standardized quantity (10 mg/cm²) <p>Treated zone: Front forearm (2 zones)</p> <p>Product B: Biofreeze[®] Concentration 2 Route and method of administration: Topic Posology:</p> <ul style="list-style-type: none"> ▪ Single application, standardized quantity (5 mg/cm²) ▪ Single application, standardized quantity (10 mg/cm²) <p>Treated zone: Front forearm (2 zones)</p> <p>A 5th untreated zone on a front forearm will serve as witness.</p>
Authorized products	Possibility of washing the studied zone with water 2 hours before the visit. No topical product on the front forearm the day of the visit.
Population: - Number of subjects - Numbers of group - Numbers of center	33 1 1
Selection Criteria Criteria of inclusion	1 - Men and women, 2 - Age: 18 to 65 years, 3 - Normal distribution of hair on the level of the front forearms,

<p>Criteria of non inclusion</p>	<p>4 - Healthy skin on the level of the forearms, 5 - Last wash with water without soap 2 hours before the visit, 6 - Written informed consent obtained, 7 - For who the investigator considers that the compliance will be correct, 8 - Covered by a social security system in accordance with the article L1121-11 of the Public Code of Health relating to biomedical research.</p> <p>1 - Pregnancy or breast feeding in progress, pregnancy under consideration during the study, 2 - Allergy known to the product tested (menthol, camphor...) or topical products in general, atopic subjects, 3 - Any dermatological affection on the level of the front foreman in progress or finished in less than one month, 4 - Systemic affection under or finished in less than 3 months likely to influence the evolution of the studied cutaneous state, 5 - Any dermatological treatment, in particular local corticoids, on the level of the front forearm, in progress or finished in less than one month, 6 - Use on the forearm of exfoliants or scrubs products, or of massage gloves in the 3 days preceding the study, 7 - Use of a topical product on the front forearm the day of the visit, 8 - Serious pathology, 9 - Subject in period of exclusion or participant in a cosmetic or therapeutic test.</p>
<p>Criteria of evaluation</p> <ul style="list-style-type: none"> - Primary criterion - Secondary criterion 	<p>Cutaneous temperature measurements using an infrared thermometer.</p> <p>Clinical examination for the local tolerance.</p>
<p>Plan of study</p>	<p><i>For the detail, see the table on page 7</i></p>

CHRONOLOGY OF EXAMINATIONS AND VISITS

	A Single visit		
	H0	H0+ 5 mn ⁽¹⁾	H0+ 2 H
Demographic information	X		
Medical antecedents	X		
Previous and concomitant treatments	X		
Clinical examination	X		
Collection of consent	X		
Inclusion / non-inclusion criteria	X		
Cutaneous temperature measurements on the 5 zones	X	X ⁽¹⁾	X
Application of the products	X		
Adverse events		X	X
Final report ⁽²⁾			X

⁽¹⁾: a cutaneous temperature measurement will be carried out on the 5 zones, **every 5 minutes during a maximum of 2 hours, starting from the end of the product application** = A maximum of 25 measurements.

Measurements will stop when the cutaneous temperature of the 4 treated zones returns to the normal cutaneous temperature (3 identical consecutive measurements, at 5 minutes of interval).

⁽²⁾: At H0+2h if ending normally or at any time if leaving the study prematurely.

RESULTS

1. STUDIED POPULATION

Number of volunteers included:	33
Numbers of withdrawal:	1
Population analyzed:	32 volunteers: mean age 39,0 ± 12,0 years

The volunteers were included in the study after oral and written information, signature of consent for participation, and after medical examination (verification of the inclusion criteria).

Volunteer n°14 did not test the 10 mg/cm² dosage.

There is no significant difference when this subject is included or not in the analysis; the statistician decided not to include this subject in the statistical analysis.

The analysis includes 32 volunteers.

The individual data are presented in appendix of the report.

2. STATISTICAL PLAN

The description and the analysis of the population included and the enumeration of the withdrawals of study were carried out.

Statistical analysis was performed (significance level of 5%), by analysis of variance or T test of Student for quantitative variables and by Chi² test for the qualitative variables.

Data of local tolerance were described with descriptive statistics.

All individual results are in appendix n° 5.

3. RESULTS OF CUTANEOUS TEMPERATURE

This study is considered as being a plan in crossover because the temperature measurements are repeated in time (crossover means that each volunteer is his own witness). All subjects must have the same number of measurements; but certain subjects were not stabilized at the end of 6 measurements, so these additional values cannot be taken into account in the analysis.

Measurement 1 is the basic measurement for each zone, i.e. the temperature of the zone before application of the product, when the subject arrives in the laboratory.

Measurements are taken in an air-conditioned room, the basic temperature of the skin (before treatment) cannot be reached again at the end of measurements.

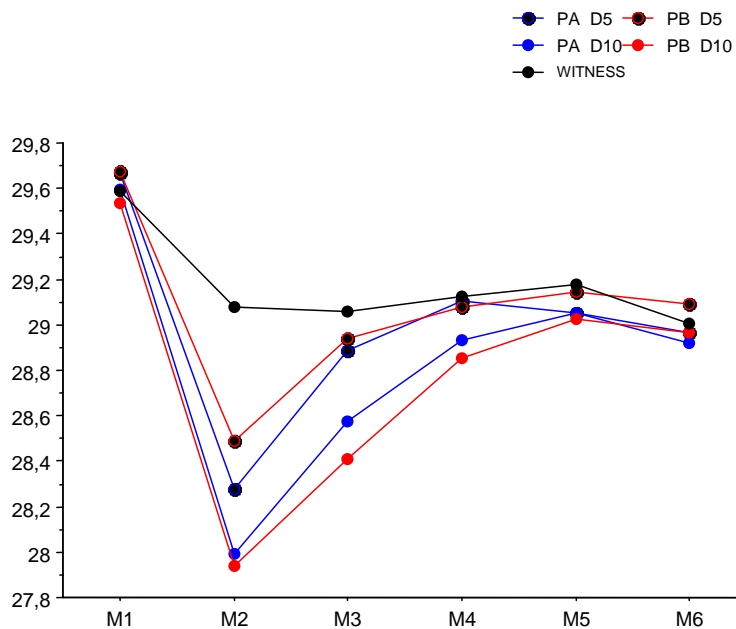
3.1. Descriptive statistics Product, Dose (mean \pm standard deviation)

❖ Dose 5 mg/cm² (D5)

	Witness (N=32)	Product A (N=32)	Product B (N=32)
Measure 1	29,6 \pm 0,9	29,7 \pm 0,7	29,7 \pm 0,8
Measure 2	29,1 \pm 1,1	28,3 \pm 1,1	28,5 \pm 1,2
Measure 3	29,1 \pm 1,0	28,9 \pm 1,0	28,9 \pm 1,2
Measure 4	29,1 \pm 1,1	29,1 \pm 1,0	29,1 \pm 1,1
Measure 5	29,2 \pm 1,1	29,1 \pm 1,0	29,1 \pm 1,1
Measure 6	29,0 \pm 1,1	29,0 \pm 1,1	29,1 \pm 1,2

❖ Dose 10 mg/cm² (D10)

	Witness (N=32)	Product A (N=32)	Product B (N=32)
Measure 1	29,6 \pm 0,9	29,6 \pm 0,9	29,5 \pm 0,9
Measure 2	29,1 \pm 1,1	28,0 \pm 1,3	27,9 \pm 1,4
Measure 3	29,1 \pm 1,0	28,6 \pm 1,2	28,4 \pm 1,2
Measure 4	29,1 \pm 1,1	28,9 \pm 1,1	28,9 \pm 1,1
Measure 5	29,2 \pm 1,1	29,0 \pm 1,0	29,0 \pm 1,1
Measure 6	29,0 \pm 1,1	28,9 \pm 1,1	29,0 \pm 1,1

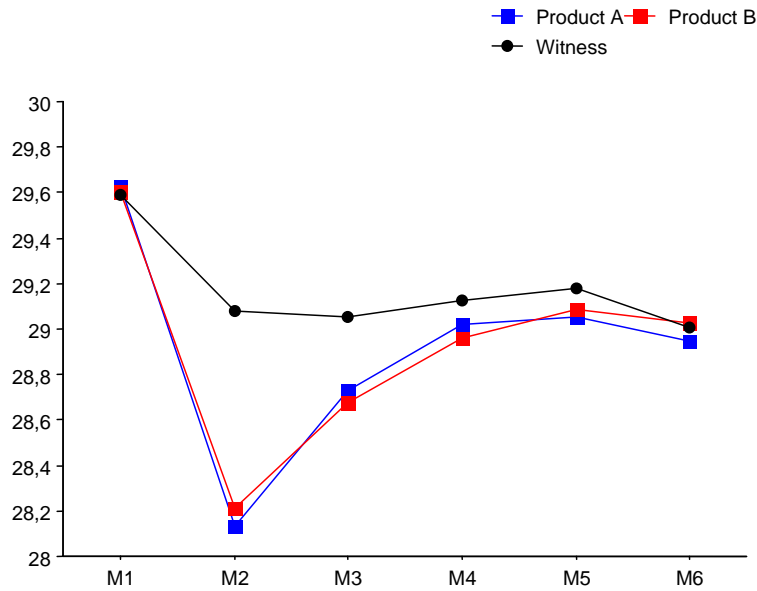


PA D5 = Product A with 5 Mg - PA D10 = Product A with 10 Mg
 PB D5 = Product B with 5 Mg - PB D10 = Product B with 10 Mg

Graph N°1: Evolution of the cutaneous temperature according to products A and B with two different dosages

3.2. Results of the analysis

3.2.1. Effect of the product

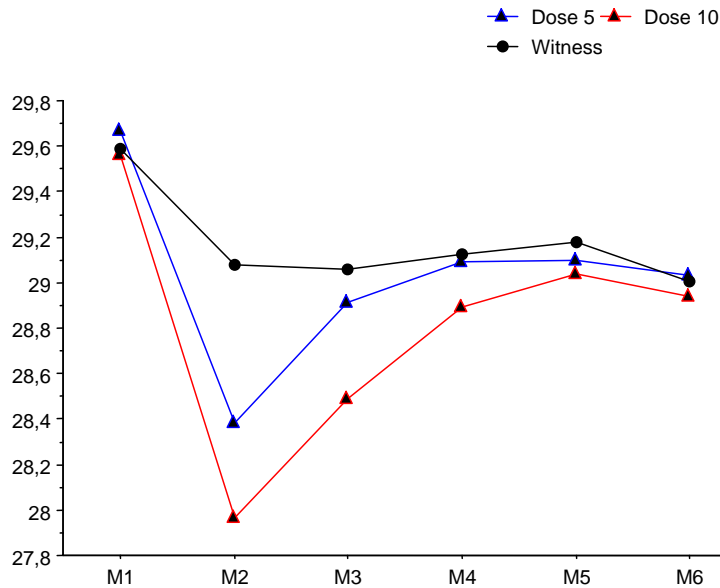


Graph N°2: Effect of product – Comparison between products A and B

There is no significant difference between the products A and B (Dosages merged).

On the other hand, there is a difference between
 - the product A and the witness ($p=0,0082$) and
 - the product B and the witness ($p=0,0109$).

3.2.2 Relation dose-effect



Graph N° 3: Evolution of the cutaneous temperature according to the dosage of products A and B

The analysis of the dose-dependant effect makes it possible to note that there is a significant difference between 2 dosages of 5 and 10 mg/cm² (p=0,0059).

There is no significant difference between the temperatures of the zones treated with an amount of 5 mg/cm² and the untreated witness zone (p=0,1371).

To be noted that the temperature of the zone treated with an amount of 10 mg/cm² is significantly lower than that of the witness zone (p=0,0002).

4. TOLERANCE

Subjects 24, 28 and 30 presented cutaneous intolerances.

4.1. Time of appearance and frequency

Subjects 28 and 30 presented an intolerance after 30 minutes whereas the subject 24 reacted after 25 minutes. The frequency is the same for the 3 subjects (1).

For subject 30, intolerance still occurs at the end of the study.

None of these intolerances required particular treatment.

4.2. Descriptions and intensity

The 3 subjects had redness, erythema. Subjects 24 and 28 felt heating whereas subject 30 felt prickling. The subject 24 described an intensity 1, the 2 others describe an intensity 2. Subjects 24 and 30 had a feeling of irritation and the subject 28 a feeling of discomfort.

4.3. Imputability

The investigator considers that the imputability was certain (= 4) for subjects 24 and 28 and probable (= 2) for subject 30.

For the 3 subjects, it is an isolated element: the erythema is limited to the treated zone, it did not spread.

5. ADVERSE EVENTS

No adverse event took place during this study.

APPENDICES

- Appendix 1: Protocol
- Appendix 2: Information note and informed consent form
- Appendix 3: CRF
- Appendix 4: Description of the technique used
- Appendix 5: Data acquisition of the study
- Appendix 6: Statistical Report

This report is composed of 12 pages, without the appendices.

**APPENDIX 1:
PROTOCOL**

**APPENDIX 2:
INFORMATION NOTE AND INFORMED CONSENT FORM**

**APPENDIX 3:
CRF**

**APPENDIX 4:
DESCRIPTION OF THE TECHNIQUE USED**

MEASUREMENTS OF CUTANEOUS TEMPERATURE

A cutaneous temperature measurement is carried out on the 5 zones, **every 5 minutes during a maximum of 2 hours, starting from the end of the product application** = A maximum of 25 measurements.

Measurements will stop when the cutaneous temperature of the 4 treated zones returns to the normal cutaneous temperature (3 identical consecutive measurements, at 5 minutes of interval).

The normal cutaneous temperature does not correspond to the basic measurement because measurements are carried out in air-conditioned room, the skin temperature is obviously reduced.

These measurements will be carried out using an infrared thermometer in a room with a controlled and constant temperature ($20 \pm 2^{\circ}\text{C}$).

**APPENDIX 5:
DATA ACQUISITION OF THE STUDY**

**APPENDIX 6:
STATISTICAL REPORT**

**EVALUATION OF THE EFFECT OF BIOFREEZE®
ON THE CUTANEOUS TEMPERATURE**

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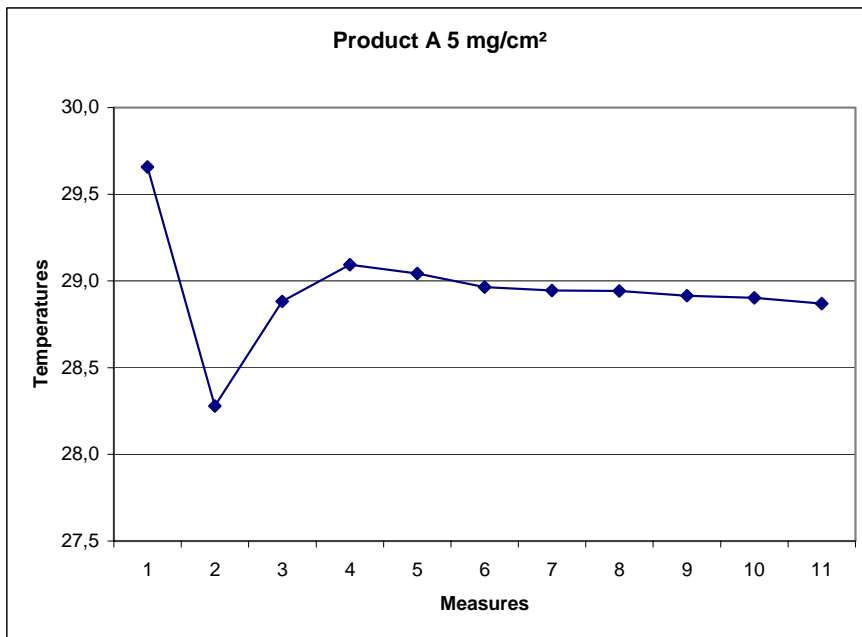
1 RESULTS OF THE CUTANEOUS TEMPERATURE

Results were extrapolated to fill in the following tables: when the results are stabilized for a volunteer, the value of the last measurement is deferred for the following measurements (even if in actuality measurement was not taken).

Product A 5mg/cm ²											
N° vol	1	2	3	4	5	6	7	8	9	10	11
01	29,5	28,3	29,1	29,1	29,7	29,4	29,4	29,4	29,4	29,4	29,4
02	29,8	28,7	29,4	29,2	29,2	29,0	29,0	29,0	29,0	29,0	29,0
03	30,4	30,1	29,5	29,5	29,6	28,6	28,6	28,6	28,6	28,6	28,6
04	30,1	28,5	29,4	29,2	29,2	29,1	29,0	29,0	29,0	29,0	29,0
05	28,8	29,2	29,7	29,2	28,6	28,2	28,2	28,2	28,2	28,2	28,2
06	28,4	26,8	27,6	27,4	27,4	27,4	27,4	27,8	27,8	27,8	27,8
07	30	28,0	28,8	29,0	29,5	29,1	29,2	29,2	29,3	29,2	29,2
08	28,8	27,8	28,0	28,8	28,8	28,8	28,9	28,9	28,9	28,9	28,9
09	29,8	29,3	29,8	29,1	28,8	29,2	28,8	28,8	28,8	28,8	28,8
10	29	27,0	27,8	28,0	28,4	27,9	27,4	28,4	27,9	27,9	27,9
11	30,5	28,4	29,6	30,0	29,8	29,6	29,6	29,6	29,6	29,6	29,6
12	29,0	27,8	28,4	28,4	28,1	27,4	27,8	28,2	27,8	27,5	27,5
13	28,8	27,6	27,9	27,7	27,7	27,7	27,7	28,0	28,0	28,0	28,0
14	29,4	28,4	28,8	28,7	28,8	28,8	28,2	28,2	28,2	28,2	28,2
16	30,0	28,5	29,0	29,3	29,7	29,7	30,0	29,7	29,7	29,7	29,7
17	30,1	27,1	29,1	29,6	29,9	30,1	29,8	30,0	30,0	30,0	30,0
18	30,7	30,0	29,9	29,9	30,0	30,0	30,0	30,0	30,0	30,0	30,0
19	30,2	28,1	29,4	29,4	29,4	29,4	29,4	29,4	29,4	29,4	29,4
20	30,4	29,1	30,0	30,4	30,0	30,1	30,0	29,6	29,6	29,6	29,6
21	30,1	29,7	29,8	30,0	29,1	29,3	29,4	29,1	29,1	29,1	29,1
22	28,6	26,1	26,8	27,3	27,0	27,0	27,0	27,0	27,0	27,0	27,0
23	29,5	27,1	27,6	28,0	28,0	27,8	27,8	27,8	27,8	27,8	27,8
24	29,0	27,2	27,8	27,9	27,5	27,4	27,4	27,4	27,4	27,4	27,4
25	28,7	26,6	27,4	27,9	27,7	28,1	28,1	27,8	27,7	27,7	27,7
26	30,0	27,3	27,8	28,2	28,1	27,7	27,4	27,5	27,5	27,5	27,5
27	29,5	26,9	28,3	28,8	28,8	28,6	28,8	28,3	28,3	28,3	28,3
28	30,3	30,0	30,6	31,0	31,1	31,1	31,2	31,2	31,2	31,2	31,2
30	30,5	29,8	30,6	30,6	30,6	30,7	30,7	30,7	30,7	30,7	30,7
31	30,7	29,4	29,6	30,4	29,9	30,1	30,2	30,0	30,0	30,0	30,0
32	28,1	27,3	27,7	28,2	28,2	29,1	29,1	29,1	29,1	29,1	29,1
33	29,5	28,9	29,1	29,5	29,9	29,8	29,8	29,9	29,9	29,9	29,9
34	30,4	28,6	28,6	29,4	29,3	29,0	29,2	28,6	28,6	28,6	27,5
35	30,1	29,6	30,2	31,0	30,6	30,6	30,7	30,7	30,7	30,7	30,7

29 subjects had more than 6 measurements.
 24 subjects had more than 7 measurements.
 11 subjects had more than 8 measurements.
 8 subjects had more than 9 measurements.
 3 subjects had more than 10 measurements.

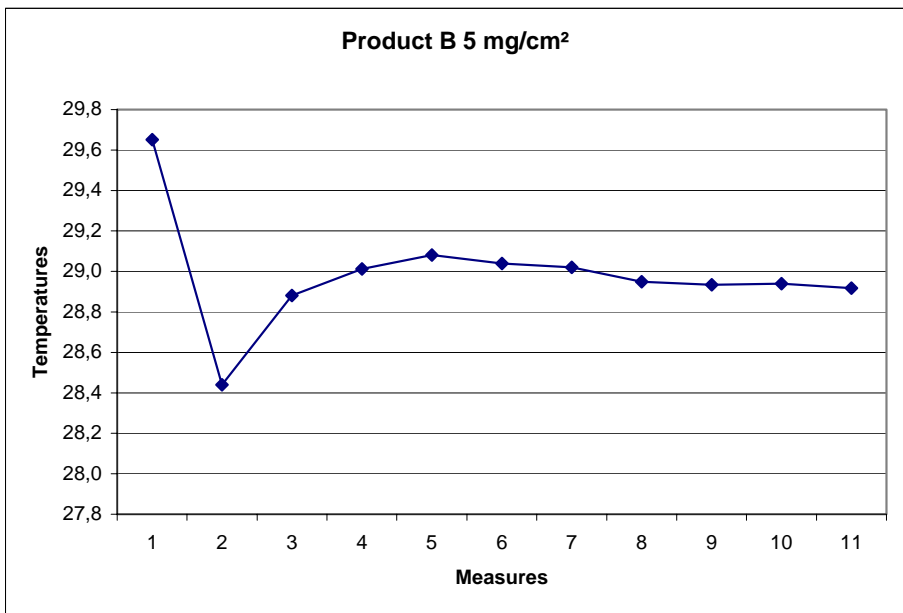
Product A 5mg/cm ²											
N° vol	1	2	3	4	5	6	7	8	9	10	11
Average	29,7	28,3	28,9	29,1	29,0	29,0	28,9	28,9	28,9	28,9	28,9



Product B 5mg/cm ²											
N° vol	1	2	3	4	5	6	7	8	9	10	11
01	29,6	27,8	28,7	28,7	29,1	28,8	28,8	28,8	28,8	28,8	28,8
02	29,7	28,6	28,7	29,3	29,3	29,2	29,2	29,2	29,2	29,2	29,2
03	30,5	28,8	29,4	29,0	29,3	29,0	29,0	29,0	29,0	29,0	29,0
04	29,8	28,5	29,0	29,2	29,0	29,2	29,0	29,0	29,0	29,0	29,0
05	29,3	29,5	29,2	29,3	29,3	29,3	29,3	29,3	29,3	29,3	29,3
06	28,4	26,6	27,4	27,3	27,3	27,3	27,2	27,3	27,3	27,3	27,3
07	30	28,7	29,6	29,3	29,5	29,1	29,3	29,4	29,4	29,4	29,4
08	28,8	27,8	28,5	28,9	29,0	28,9	29,0	29,0	29,0	29,0	29,0
09	30,3	29,6	30,0	28,9	29,1	29,5	29,0	29,0	29,0	29,0	29,0
10	28,4	27,7	28,0	28,8	28,5	28,1	28,1	28,0	28,0	28,0	28,0
11	29,4	29,3	28,7	28,5	29,1	28,0	29,1	29,1	29,1	29,1	29,1
12	29,0	27,5	27,5	27,8	27,8	26,9	27,3	27,0	26,8	26,8	26,8
13	28,7	27,1	28,0	28,0	27,7	27,6	27,8	27,8	27,8	27,8	27,8
14	29,0	26,9	27,0	27,0	27,0	27,4	27,4	27,4	27,4	27,4	27,4
16	29,9	28,8	29,6	29,4	29,9	30,1	30,1	30,0	30,0	30,0	30,0
17	30,7	28,6	29,5	29,9	30,2	30,7	30,2	30,2	30,2	30,2	30,2
18	30,8	30,9	30,9	31,0	30,9	30,9	30,9	30,9	30,9	30,9	30,9
19	30,0	28,0	28,5	28,7	29,6	29,7	29,7	29,6	29,6	29,6	29,6
20	30,4	28,8	29,6	30,5	30,0	30,3	30,1	29,6	29,6	29,6	29,6
21	30,8	29,0	30,2	30,2	30,2	30,0	30,0	29,4	29,4	29,4	29,4
22	28,4	25,2	26,0	26,6	26,4	26,4	26,4	26,4	26,4	26,4	26,4
23	29,0	27,6	27,6	27,7	27,9	27,9	27,9	27,9	27,9	27,9	27,9
24	28,9	26,6	26,9	27,6	27,3	27,1	27,1	27,1	27,1	27,1	27,1
25	28,8	27,1	27,5	27,9	28,3	28,7	28,4	28,0	27,9	27,9	27,9
26	29,9	28,9	29,8	29,0	29,5	29,0	29,0	29,0	28,9	29,0	29,0
27	30,1	28,6	29,3	29,1	29,1	29,0	29,0	28,4	28,4	28,4	28,4
28	30,1	29,4	29,8	30,7	30,6	30,7	30,7	30,7	30,7	30,7	30,7
30	30,5	29,8	30,5	30,6	30,6	30,6	30,6	30,6	30,6	30,6	30,6
31	30,7	29,3	29,8	29,9	29,9	29,9	30,0	29,9	29,9	29,9	29,9
32	27,9	28,0	28,2	28,4	28,3	29,0	29,0	29,0	29,0	29,0	29,0
33	29,5	29,9	29,6	29,9	29,8	29,5	29,5	29,3	29,3	29,3	29,3
34	30,4	28,7	28,8	28,9	29,4	28,8	28,5	28,7	28,6	28,7	28,0
35	30,8	30,9	31,3	31,4	30,8	31,7	31,1	31,3	31,3	31,3	31,3

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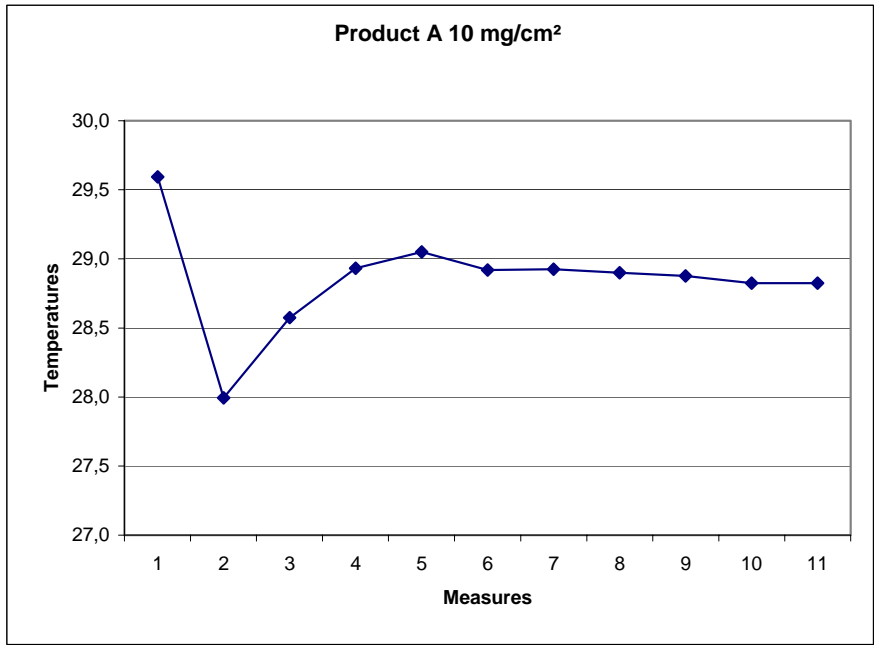
Product B 5mg/cm ²											
N° vol	1	2	3	4	5	6	7	8	9	10	11
Average	29,7	28,4	28,9	29,0	29,1	29,0	29,0	28,9	28,9	28,9	28,9



Product A 10mg/cm ²											
N° vol	1	2	3	4	5	6	7	8	9	10	11
01	29,3	27,1	28,2	28,1	27,7	27,7	27,7	27,7	27,7	27,7	27,7
02	29,8	28,1	27,7	28,7	28,8	28,7	28,7	28,7	28,7	28,7	28,7
03	29,7	28,4	27,8	29,1	28,8	29,3	29,3	29,3	29,3	29,3	29,3
04	30,1	27,8	28,7	29,0	29,1	29,0	29,0	29,0	29,0	29,0	29,0
05	28,3	26,6	28,1	27,9	27,9	27,9	27,9	28,0	27,9	27,9	27,9
06	29,1	26,5	27,3	28,1	28,6	28,3	28,0	28,0	28,0	28,0	28,0
07	30,2	28,9	29,3	29,5	30,0	29,4	29,4	29,8	29,2	29,2	29,2
08	28,9	27,6	28,1	28,8	29,2	29,3	29,3	29,3	29,3	29,3	29,3
09	30,3	29,1	29,8	29,2	29,2	29,2	29,0	29,0	29,0	29,0	29,0
10	28,8	27,5	27,7	28,8	28,6	27,6	28,2	28,2	28,2	28,2	28,2
11	28,4	28,1	28,7	28,7	28,7	28,1	28,7	28,7	28,7	28,7	28,7
12	29,2	27,7	27,3	27,7	27,5	27,5	27,5	27,1	27,2	26,6	26,6
13	28,8	27,1	27,7	27,9	28,0	27,2	28,0	28,1	28,1	28,1	28,1
14											
16	29,9	28,7	29,4	29,3	29,8	29,8	29,6	30,0	30,0	30,0	30,0
17	30,9	29,1	29,6	30,1	30,5	30,8	30,5	30,4	30,4	30,4	30,4
18	31,0	30,8	30,8	30,8	30,5	30,5	30,5	30,5	30,5	30,5	30,5
19	28,1	27,0	28,3	29,1	29,1	29,1	29,1	29,1	29,1	29,1	29,1
20	30,7	29,4	30,2	30,6	30,4	29,9	29,8	29,4	29,4	29,4	29,4
21	30,7	28,4	30,0	30,0	29,9	29,6	29,5	28,9	28,9	28,9	28,9
22	27,5	24,6	25,1	26,4	26,8	26,7	26,7	26,7	26,7	26,7	26,7
23	29,0	26,6	27,1	27,4	27,8	27,8	27,8	27,8	27,8	27,8	27,8
24	29,3	27,0	27,2	28,0	27,8	27,8	27,8	27,8	27,8	27,8	27,8
25	29,3	27,3	28,2	28,5	28,8	28,9	29,0	28,3	28,0	28,0	28,0
26	30,2	27,6	29,3	28,4	28,9	28,8	28,4	28,4	28,5	28,4	28,4
27	29,3	27,5	27,8	28,3	28,4	28,4	28,4	28,0	28,0	28,0	28,0
28	30,6	29,1	29,4	30,3	30,6	30,6	30,6	30,6	30,6	30,6	30,6
30	30,3	30,2	30,1	30,2	30,3	30,3	30,3	30,3	30,3	30,3	30,3
31	30,8	28,8	29,7	29,9	29,8	29,9	29,9	29,9	29,9	29,9	29,9
32	28,4	27,1	28,0	28,7	28,8	29,0	29,0	29,0	29,0	29,0	29,0
33	29,2	28,3	28,6	28,5	29,4	28,8	29,2	29,5	29,5	29,5	29,5
34	30,2	27,7	28,2	28,7	29,0	28,6	28,0	28,5	28,5	27,6	27,6
35	30,7	30,1	31,0	31,1	30,9	30,9	30,8	30,8	30,8	30,8	30,8

28 subjects had more than 6 measurements.
 24 subjects had more than 7 measurements.
 11 subjects had more than 8 measurements.
 8 subjects had more than 9 measurements.
 3 subjects had more than 10 measurements

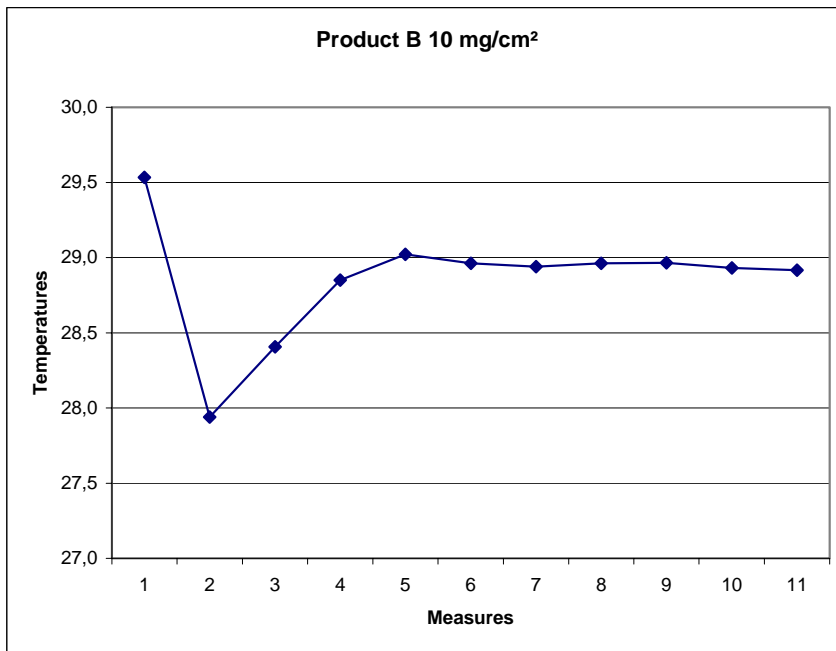
Product A 10mg/cm ²											
N° vol	1	2	3	4	5	6	7	8	9	10	11
Average	29,6	28,0	28,6	28,9	29,1	28,9	28,9	28,9	28,9	28,8	28,8



Product B 10mg/cm ²											
N° vol	1	2	3	4	5	6	7	8	9	10	11
01	29,8	28,7	27,5	28,3	28,5	28,7	28,8	28,8	28,8	28,8	28,8
02	29,1	27,3	27,4	28,1	28,1	27,9	27,9	27,9	27,9	27,9	27,9
03	29,9	27,6	27,8	28,9	28,8	29,1	29,1	29,1	29,1	29,1	29,1
04	29,8	28,7	27,5	28,3	28,5	28,7	28,8	28,8	28,8	28,8	28,8
05	29,0	27,2	28,3	28,5	28,4	28,3	28,1	28,1	28,1	28,1	28,1
06	29,0	26,3	27,4	27,7	28,2	28,0	28,0	27,7	27,7	27,7	27,7
07	29,3	27,7	28,4	29,4	29,6	30,0	29,5	30,0	30,0	30,0	30,0
08	28,8	28,0	28,3	28,9	29,1	29,1	29,4	29,4	29,4	29,4	29,4
09	31	28,0	28,9	29,5	29,8	29,2	29,0	29,0	29,0	29,0	29,0
10	29,2	28,0	27,7	28,2	28,4	28,4	28,0	28,5	28,5	28,2	28,2
11	29,8	28,9	29,6	29,6	29,7	29,6	29,6	29,6	29,6	29,6	29,6
12	29,4	27,6	27,4	27,4	27,3	27,3	27,3	27,0	27,3	26,5	26,5
13	28,4	26,5	27,3	27,7	28,4	27,3	28,2	28,9	28,9	28,9	28,9
14											
16	30,2	28,9	29,8	29,2	29,6	29,8	29,7	30,0	30,0	30,0	30,0
17	29,8	29,3	29,8	29,9	30,0	29,8	30,0	30,0	30,0	30,0	30,0
18	30,9	31,1	30,3	30,3	30,0	30,1	30,1	30,1	30,1	30,1	30,1
19	29,6	27,7	28,0	28,9	29,3	29,3	29,3	29,3	29,3	29,3	29,3
20	30,1	28,3	29,4	30,6	30,4	30,4	30,0	30,0	30,0	30,0	30,0
21	31,1	28,1	29,3	29,8	29,7	29,4	28,8	28,5	28,5	28,5	28,5
22	27,7	24,7	25,4	25,7	26,2	26,1	26,2	26,2	26,2	26,2	26,2
23	27,7	25,0	26,8	27,5	27,7	27,7	27,7	27,7	27,7	27,7	27,7
24	29,5	27,3	27,5	28,2	27,9	27,6	27,6	27,6	27,6	27,6	27,6
25	28,7	29,6	27,7	28,0	28,9	28,5	28,6	28,1	28,0	28,0	28,0
26	29,1	27,0	28,3	28,5	27,9	27,9	27,9	28,0	27,9	27,9	27,9
27	29,2	27,1	28,1	28,2	28,4	28,3	28,3	28,1	28,1	28,1	28,1
28	30,6	29,9	30,4	31,0	31,0	31,0	31,1	31,1	31,1	31,1	31,1
30	30,3	29,2	30,3	30,4	30,4	30,5	30,5	30,5	30,5	30,5	30,5
31	30,6	28,4	29,4	29,4	29,7	30,2	30,1	30,1	30,1	30,1	30,1
32	28,4	26,7	27,9	29,0	29,0	29,0	29,0	29,0	29,0	29,0	29,0
33	29,2	28,4	28,7	28,9	29,4	29,5	29,4	29,7	29,7	29,7	29,7
34	29,3	26,7	27,8	28,6	29,4	29,3	29,3	29,2	29,2	29,2	28,7
35	30,6	30,2	30,6	30,6	31,0	30,8	30,8	30,8	30,8	30,8	30,8

28 subjects had more than 6 measurements.
 24 subjects had more than 7 measurements.
 11 subjects had more than 8 measurements.
 8 subjects had more than 9 measurements.
 3 subjects had more than 10 measurements

Product B 10mg/cm ²											
N° vol	1	2	3	4	5	6	7	8	9	10	11
Average	29,5	27,9	28,4	28,9	29,0	29,0	28,9	29,0	29,0	28,9	28,9



N° vol	Witness										
	1	2	3	4	5	6	7	8	9	10	11
01	29,7	29,7	28,8	29,1	28,7	28,7	28,7	28,8	28,8	28,8	28,8
02	29,5	29,2	29,0	29,3	29,4	29,0	29,0	29,0	29,0	29,0	29,0
03	30,2	29,7	29,2	29,2	29,2	29,2	29,2	29,2	29,2	29,2	29,2
04	29,8	29,3	29,0	28,9	28,8	28,7	28,8	28,8	28,8	28,8	28,8
05	27,4	27,5	28,5	28,3	28,2	27,9	27,9	27,9	27,9	27,9	27,9
06	28,8	27,7	27,6	27,8	27,9	27,8	27,6	27,3	27,3	27,3	27,3
07	29,8	29,4	29,4	29,3	29,6	29,0	29,0	29,0	29,0	29,0	29,0
08	28,7	28,8	28,4	28,9	28,9	29,0	28,9	28,9	28,9	28,9	28,9
09	31	30,0	29,7	29,6	29,8	28,8	28,8	28,8	28,8	28,8	28,8
10	28,3	28,7	28,3	27,8	28,7	28,2	27,6	28,2	27,7	28,1	27,9
11	30,4	29,7	30,0	30,3	30,0	30,0	30,0	30,0	30,0	30,0	30,0
12	28,5	28,5	28,8	28,5	28,5	28,6	28,6	28,5	28,0	27,7	27,7
13	29,3	27,1	27,3	27,5	27,5	27,1	28,2	28,4	28,4	28,4	28,4
14	29,7	28,9	28,5	28,3	28,4	28,7	28,6	28,6	28,6	28,6	28,6
16	30,1	30,5	29,1	29,5	29,3	29,5	29,7	29,5	29,5	29,5	29,5
17	29,8	30,1	29,8	29,7	29,8	29,4	29,6	29,3	29,6	29,6	29,6
18	30,9	30,8	30,3	30,2	30,2	30,2	30,2	30,2	30,2	30,2	30,2
19	30,0	29,3	29,5	29,5	30,1	29,7	29,7	29,7	29,7	29,7	29,7
20	30,3	30,0	30,2	30,4	30,4	30,3	30,2	29,4	29,4	29,4	29,4
21	31,1	29,1	29,8	30,3	30,3	29,6	29,6	29,5	29,4	29,4	29,4
22	27,9	26,3	26,3	26,2	25,9	25,9	25,9	25,9	25,9	25,9	25,9
23	29,2	27,7	28,0	28,2	28,1	28,0	28,0	28,0	28,0	28,0	28,0
24	29,1	27,5	28,0	28,3	27,8	27,9	27,9	27,9	27,9	27,9	27,9
25	28,9	28,6	28,9	28,6	29,2	28,2	28,7	28,1	27,9	27,9	27,9
26	29,7	28,6	28,6	28,4	28,5	28,3	28,2	28,2	28,3	28,2	28,2
27	29,0	28,5	28,4	28,3	28,2	28,2	28,4	28,2	28,2	28,2	28,2
28	30,7	30,6	30,6	31,0	31,1	31,1	31,2	31,2	31,2	31,2	31,2
30	30,4	30,4	30,6	30,6	30,7	30,7	30,7	30,7	30,7	30,7	30,7
31	30,8	30,4	30,5	30,1	30,2	30,2	29,9	29,9	29,9	29,9	29,9
32	28,4	28,6	28,6	29,0	28,8	29,2	29,2	29,2	29,2	29,2	29,2
33	29,4	29,0	28,8	29,5	29,9	29,9	29,8	29,7	29,7	29,7	29,7
34	29,8	29,2	29,6	29,0	29,3	29,3	28,6	28,3	28,3	27,7	27,7
35	29,9	30,1	30,2	30,7	30,7	30,6	31,0	30,8	30,8	30,8	30,8

29 subjects had more than 6 measurements.
 24 subjects had more than 7 measurements.
 11 subjects had more than 8 measurements.
 8 subjects had more than 9 measurements.
 3 subjects had more than 10 measurements

Witness											
N° vol	1	2	3	4	5	6	7	8	9	10	11
Average	29,6	29,1	29,0	29,1	29,2	29,0	29,0	28,9	28,9	28,9	28,9

