Final Report SAM3943i

MECHANICAL CHARACTERIZATION OF SPRINGS OF ANDROPENIS

Study Program: SAM3943

Contract n.: E07/0055.1MI

Sponsor: ANDROMEDICAL S.L.
C/ PROCIÓN, 7
28023 MADRID

Test substance: SPRING OF ANDRO-PENIS

Study Director.....……..... Released on: …….....
(Eng. P. Pescio)

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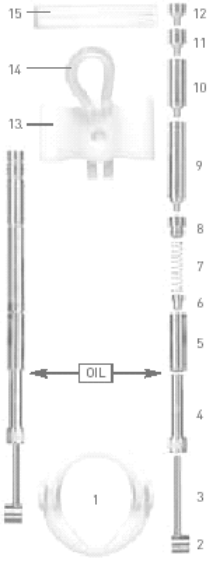
SUMMARY

A study was performed to characterise the springs of ANDRO-PENIS.

The device is constituted of different materials:

1.	Plastic base ring	Plastic
2.	Rod (for the articulated screw)	Metal
3.	Articulated screw	Metal
4.	Adjustable bar screw	Metal
5.	Metal bar	Metal
6.	Screw	Metal
7.	**Spring**	**Metal**
8.	Screw to ground the spring	Metal
9.	Large 4 cm axis	Aluminium alloy
10.	Medium 2 cm axis	Aluminium alloy
11.	Small 0.5 cm axis	Aluminium alloy
12.	Minimum 0.3 cm axis	Aluminium alloy
13.	Superior plastic support	Plastic
14.	Silicone band	Silicon
15.	Andro-Top	Foam



The mechanical properties of the spring (number 7) were determined:
- dimension
- elasticity (the property whereby a solid material changes its shape and size under action of opposing forces, but recovers its original configuration when the forces are removed)

The detailed findings are reported in the section dedicated to “Results”.

INTRODUCTION

This study has been carried on behalf of the Sponsor ANDROMEDICAL S.L. to characterise one components (spring) of the device Andropenis.

This study was performed in the Test Facility Biolab S. p. A. of Vimodrone (MI) – via B. Buozzi, 2 (Italy).

The experimentation started on February 23th, 2007 and ended the same day.

RECORD FILING

The study program and all raw data are filed in Biolab SpA archives for ten years after the issuing of the final report.
No retained sample will be kept.
At the end of the conservation period, the sponsor may request an extension of the conservation of all or part of the substance for a further period, or their restitution. A suitable agreement shall be drafted in this case.

PROCEDURES

All procedures used during this study are recorded in the Biolab Procedures Manual.

TEST SUBSTANCE

The test substance is a device consisting of different parts made of plastic and metallic materials intended to human use in contact with the skin.

Name: ANDRO-PENIS

ANALYSED SAMPLES

The samples are coil compression springs (number 7 in the drawing).

Name: 7. Spring

Description: Spring

Composition declared by the sponsor: n. p.

Acceptance number: 07.4279

Batch: 04/03

Receiving number: R00977.07

Receiving date: February 21th, 2007

The characterisation of the test substance is under Sponsor responsibility.

EXPERIMENTAL PROCEDURE

1- DIMENSION

The spring were measured with a digital gage:

- internal diameter
- exterior diameter of the stem
- exterior diameter of the terminal part
- free length
- length at maximum compression

There was also determined the number of coil.

Each determination were repeated on five samples.

1.1 EQUIPMENT

Digital gage RUPAC

2- ELASTICITY

The samples were compressed at 10 mm/min and the resistance force were recorded.
The test was repeated on five samples.

2.1 EQUIPMENT

Macchina universale di prova Galdabini SUN 1000 (10 kN), 5 kN load cell with SIT certification, software Graphwork 3 for data recordings

RESULTS

Internal diameter *[mm]*		
Sample number	*Top*	*Bottom*
1	4,61	4,61
2	4,62	4,62
3	4,61	4,61
4	4,62	4,62
5	4,59	4,59
MEAN	*4,61*	*4,61*
STD. DEV	*0,01*	*0,01*

Exterior diameter of the stem [mm]	
Sample number	
1	5,61
2	5,59
3	5,61
4	5,61
5	5,62
MEAN	*5,61*
STD. DEV	*0,01*

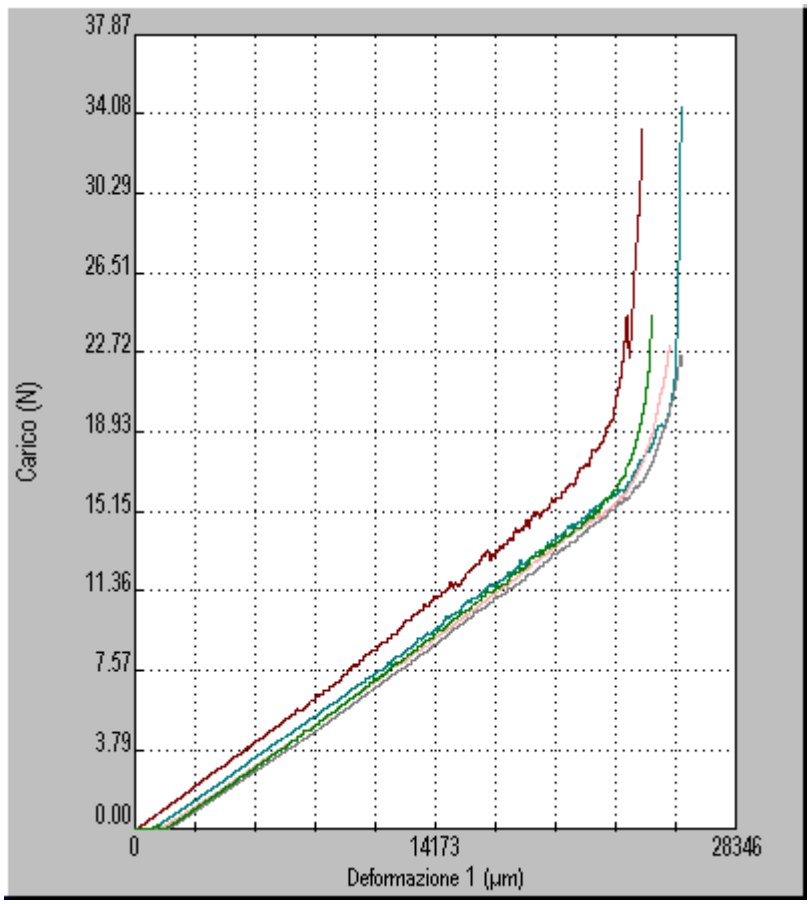
Exterior diameter of the terminal part [mm]	
Sample number	
1	5,83
2	5,85
3	5,82
4	5,84
5	5,85
MEAN	*5,84*
STD. DEV	*0,01*

Free length [mm]	
Sample number	
1	29,32
2	29,46
3	29,11
4	29,37
5	29,41
MEAN	*29,33*
STD. DEV	*0,14*

Length at maximum compression [mm]	
Sample number	
1	5,69
2	5,75
3	5,83
4	5,71
5	5,59
MEAN	*5,71*
STD. DEV	*0,09*

Number of coil [n]	
Sample number	
1	9
2	9
3	9
4	9
5	9
MEAN	*9,00*
STD. DEV	*0,00*

The curve deformation vs elastic force:

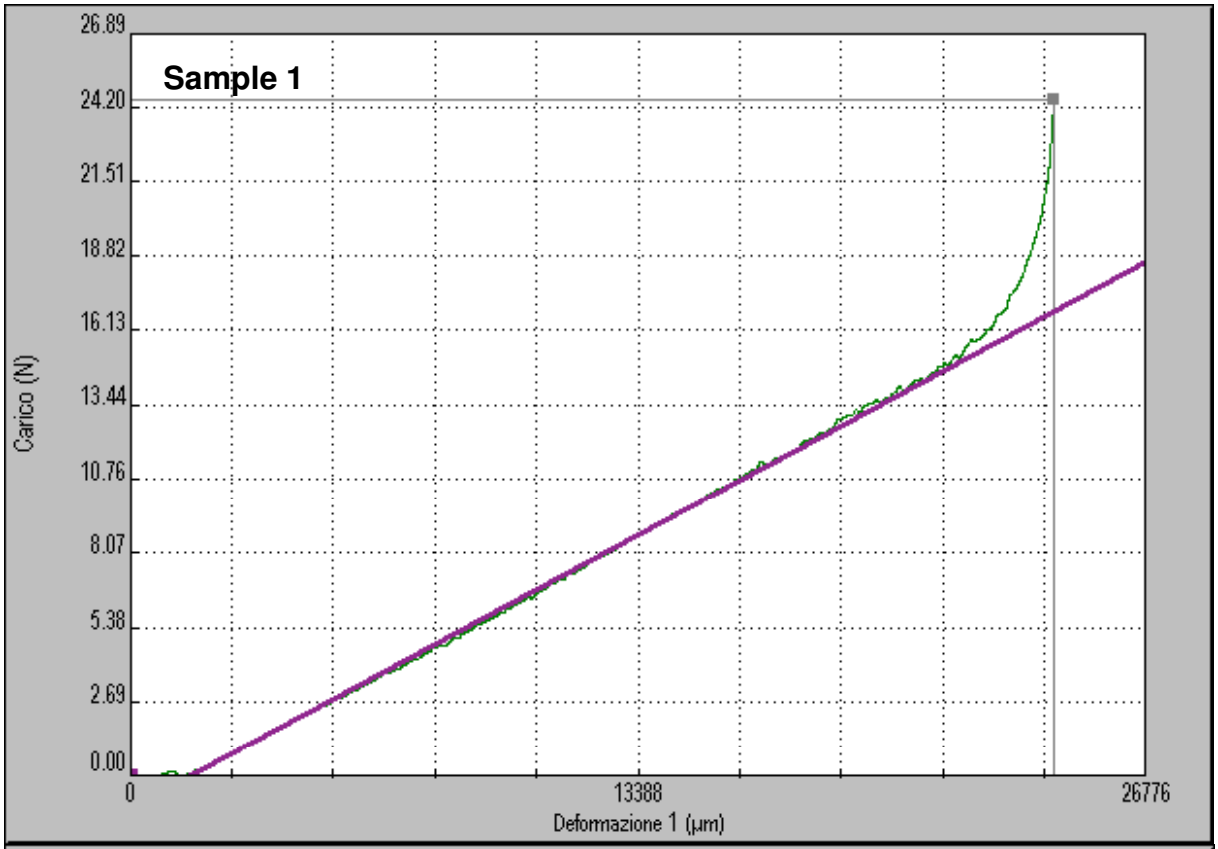


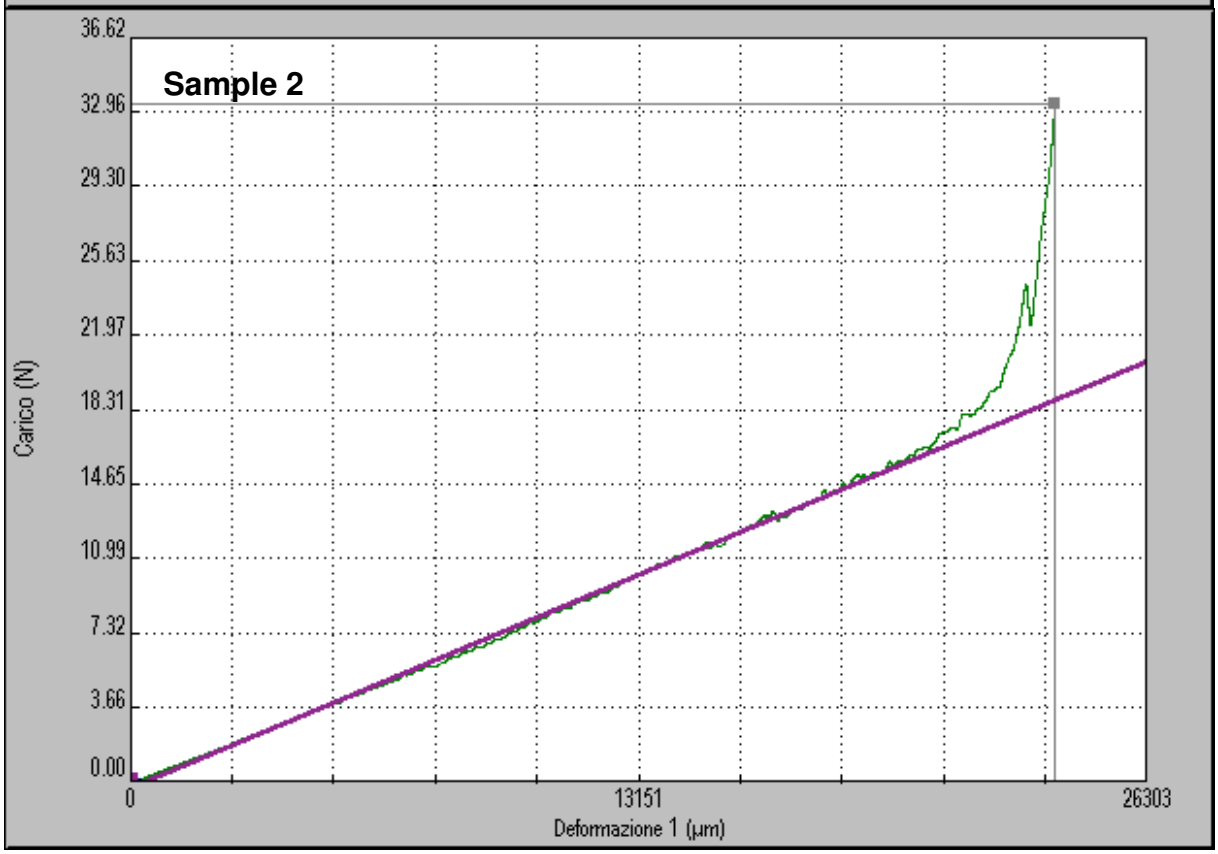
On x axis the deformation in µm; on the y axis the resistance force.

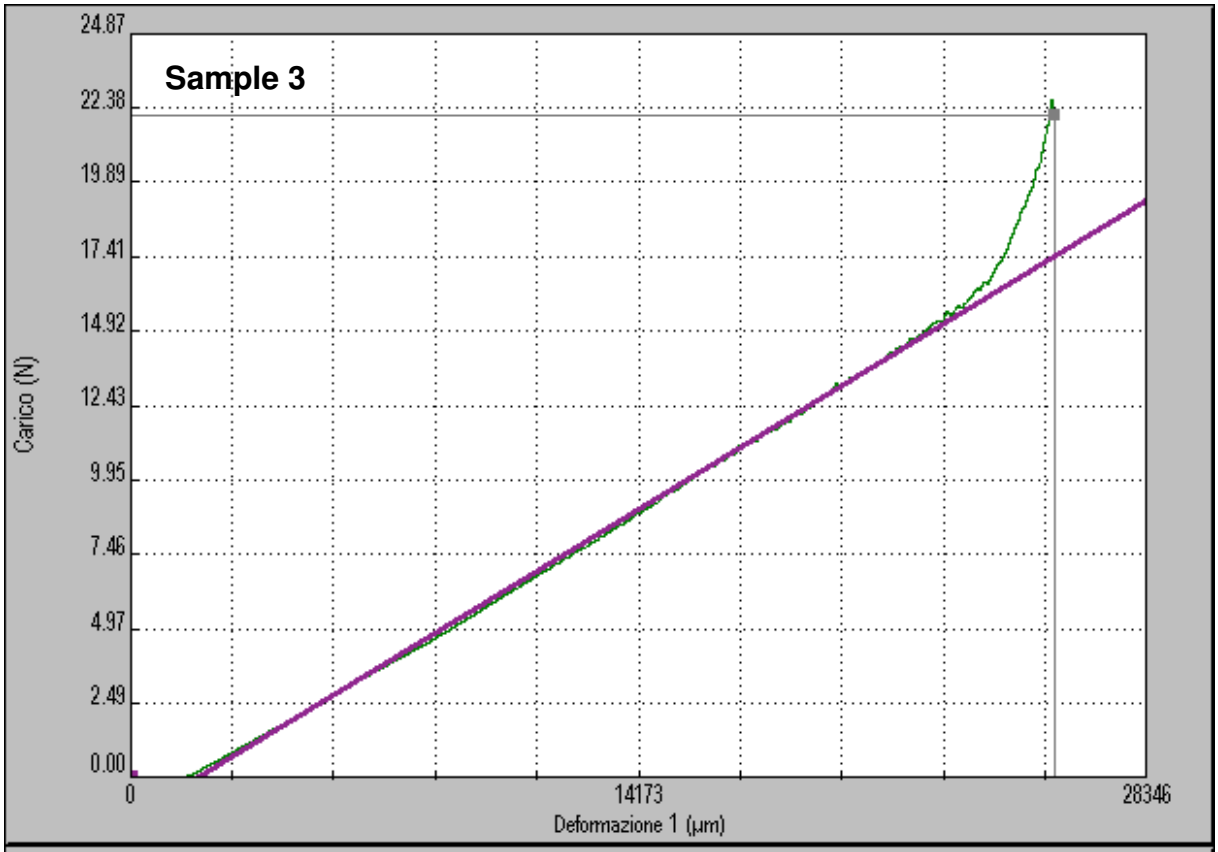
Below each graph with elastic response; the slope of the strait line is the Hook coefficient which identifies the behaviour of a spring:

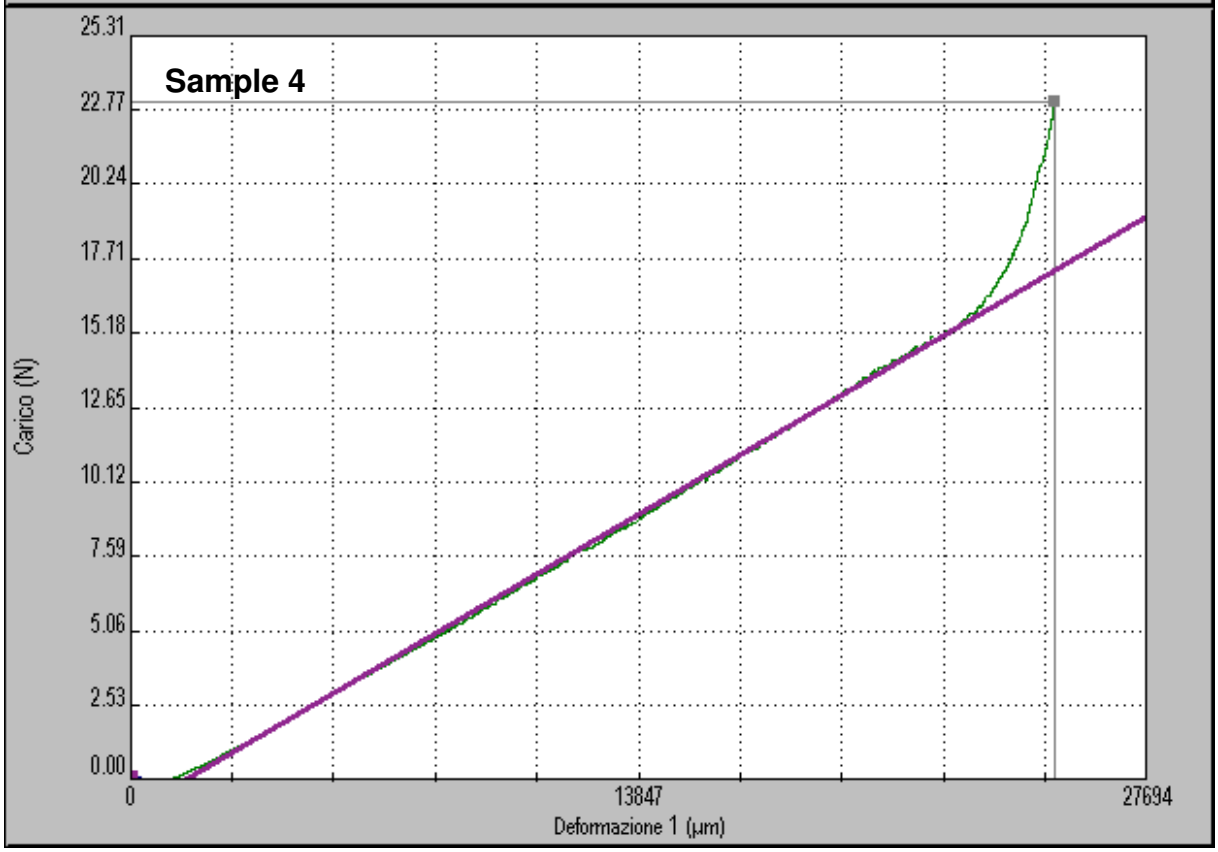
$$F = - K x$$

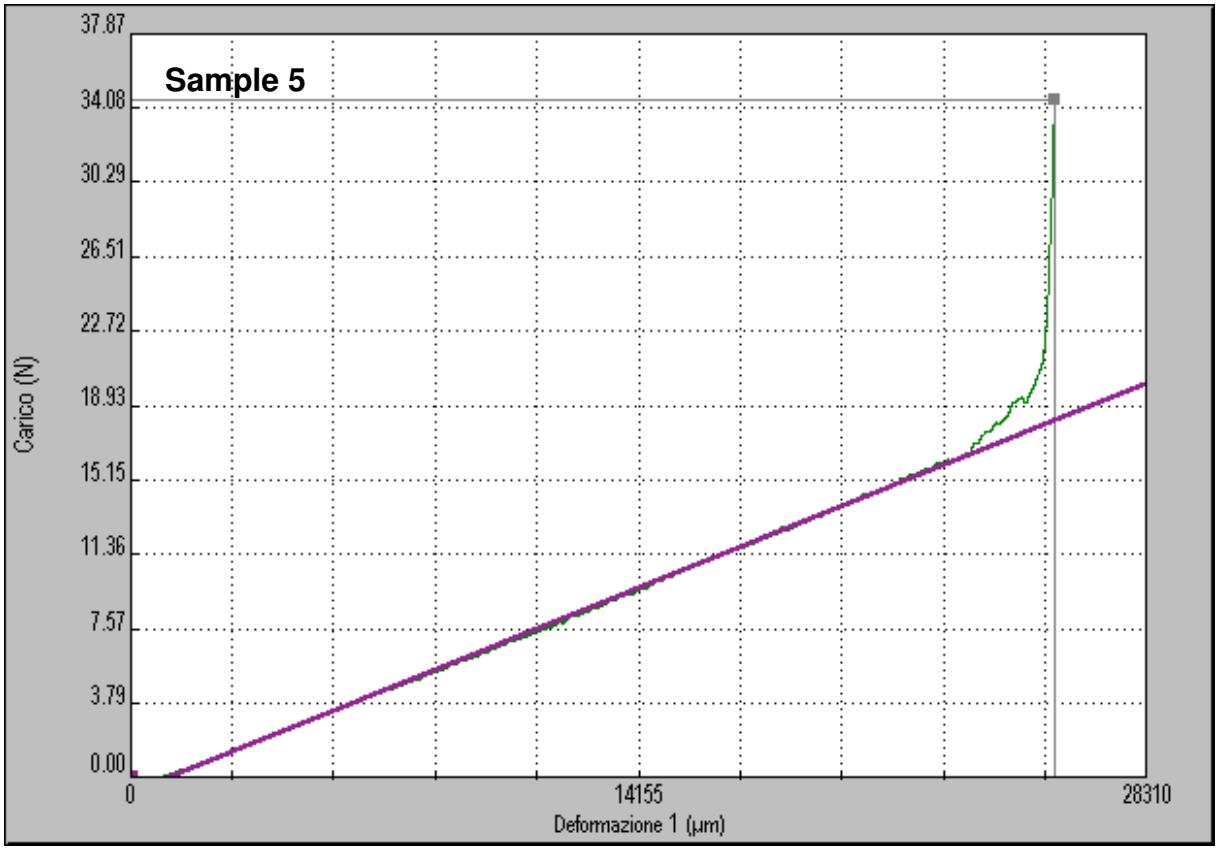
where:
F = resistance force
K = Hook coefficient
x = deformation of the spring
the sign – is introduced because the force is opposite to the deformation.


Sample 1
26.89
24.20
21.51
18.82
16.13
13.44
10.76
8.07
5.38
2.69
0.00
Carico (N)
0
13388
26776
Deformazione 1 (µm)


Sample 2
36.62
32.96
29.30
25.63
21.97
18.31
14.65
10.99
7.32
3.66
0.00
Carico (N)
0
13151
26303
Deformazione 1 (µm)


Sample 3
24.87
22.38
19.89
17.41
14.92
12.43
9.95
7.46
4.97
2.49
0.00
Carico (N)
0
14173
28346
Deformazione 1 (µm)


Sample 4
25.31
22.77
20.24
17.71
15.18
12.65
10.12
7.59
5.06
2.53
0.00
Carico (N)
0
13847
27694
Deformazione 1 (µm)



Hook constant [N/µm]	
Sample number	
1	0,000730
2	0,000797
3	0,000728
4	0,000731
5	0,000735
MEAN	*0,000744*
STD. DEV	*2,96E-05*

CONCLUSIONS

No difference between the analysed samples.