Final Report SAM2818I

MECHANICAL CHARACTERIZATION

Study Program No: SAM2818

Contract: E05/0137.4MI

Sponsor: ANDROMEDICAL S.L.
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Test substance: ANDRO-PENIS

Study Director: ..... Date of issue: .....
(Ing A.Radici)

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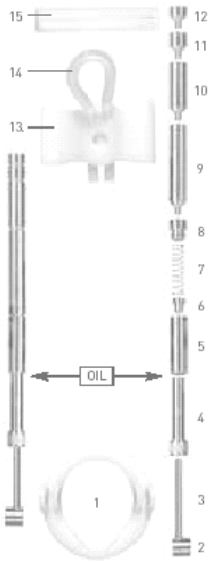
SUMMARY

A study was performed on the test substance ANDRO-PENIS to determine its mechanical properties, in order to identify possible problems which could verify during the device use.

In particular the following test have been performed:



1. Resistance to tensile stress of silicone band (id. 14): determination of stress before breakage, determination of stress/strain curve of this component when submitted to a tensile stress.
2. Creep at constant stress test of the silicone band (id. 14): a constant stress was applied for 6 hours in order to simulate device's behaviour in use.
3. Determination of required load to pull away the silicone band (id. 14) from superior plastic support (id.13), while the silicone band is fully inserted in it.
4. Relaxation at constant deformation test on the spring (id. 7), performed on spring/metal bar (id. 2-3-4-5-6-7-8-9) complex: a constant compression was applied in order to simulate device's behaviour in use.
5. Determination of stress-strain curve of spring/metal bar complex (id. 2-3-4-5-6-7-8-9) when submitted to a compression stress.
6. Determination of tensile load developed by the device in several different configurations, obtained by combination of the following parameters:
    a. base length (penis length)
    b. device's length
    c. silicone band diameter

The detailed result are reported in the section *"Results".*

INTRODUCTION

On behalf of Sponsor ANDROMEDICAL S.L. a study was performed on samples of ANDRO-PENIS. The study is finalised to give a mechanical characterization of the device and its components.

The study was performed in Biolab Assay Centre, Vimodrone (MI), Via B. Buozzi n. 2.

The study started on September 5th 2005 and ended on October 18th, 2005.

FILING

All raw data and a copy of the final report and possible revisions will be kept in the archives of Biolab S.p.A. for a period of 10 years after the issue of the final report.
The control sample of the test substance has not been stored.
At the end of the storing period the Sponsor, upon drafting a suitable contract, may request an extension of the conservation of all or part of the substances for a further period or their substitution.

PROCEDURES

The procedures used in the study are documented in the Procedure Handbook of Biolab S.p.A.

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

TESTED SAMPLE

The analysed sample, representative of the test substance, is identified as follows:

Denomination: ANDRO-PENIS

Identification: 05.16494

Receiving no.: R03758.05

Receiving date: August 22th, 2005

EXPERIMENTAL PROCEDURE

Equipment

All the mechanical assays were performed using the following equipment:
- Macchina universale di prova Galdabini SUN 1000 (10 kN), 10 kN load cell with SIT certification, parallel steel clamps with resin inserts, software Graphwork 3 for data recordings

1. Resistance of tensile stress of silicone band

The test was performed on tube section 10 cm long; the probes were inserted into the clamps in order to leave an about 8-9cm free length. The probes were pre-stressed in order to allow a correct alignment and thus a correct reading of the parallel length. Then, a 300 mm/min constant rate tensile stress was applied until the probe broke apart.
Load and elongation values before breakage were logged, the test was repeated on five probes.

2. Creep test on the silicone band

The test was performed on tube section 10 cm long; the probes were inserted into the clamps in order to leave a 8cm free length.
The probes were stressed with a constant rate tensile stress until the load was 32N, then the load was kept constant at that value for 6 hours.
The test was repeated on three probes.

3. Determination of pull-away load on silicone band

The test was performed on the silicone band fully inserted in the superior plastic support.
The plastic support was clamped and the silicone band pulled downward using a hook until the silicone band slipped off from the support.
The maximum load before band pulling away was logged; the test was repeated on three probes.

4. Relaxation test on spring

The test was performed on the spring/metal bar complex; the probes were inserted into the clamps; then they were stressed with a constant rate compression stress until the elongation of the spring was 6mm, then the deformation was kept constant for 6 hours. The test was repeated on three probes.

5. Determination of stress-strain curve on spring/metal bar complex

The test was performed on the spring/metal bar complex; the probes were inserted into the clamps; then a 10 mm/min constant rate compression stress was applied until the spring get to its limit when the test ended.

6. Determination of tensile load developed by the device

The test was performed on the complete device.
Holding firmly the plastic base ring, a metal bar has been introduced in the band, in order to simulate user's penis. Then the tensile strength developed on the silicone band has been logged.
The test has been repeated on different configurations: the parameters changed are the following:

- base length. This value represents the penis length, as it is when measured below the glans: this one is the point where the user would close the silicone band.
- device's length, measured from the lower part of the plastic ring to the upper part of the metal axis
- silicone band diameter, two different extension, the former narrower, the latter larger.

RESULTS

1. Resistance of tensile stress of silicone band

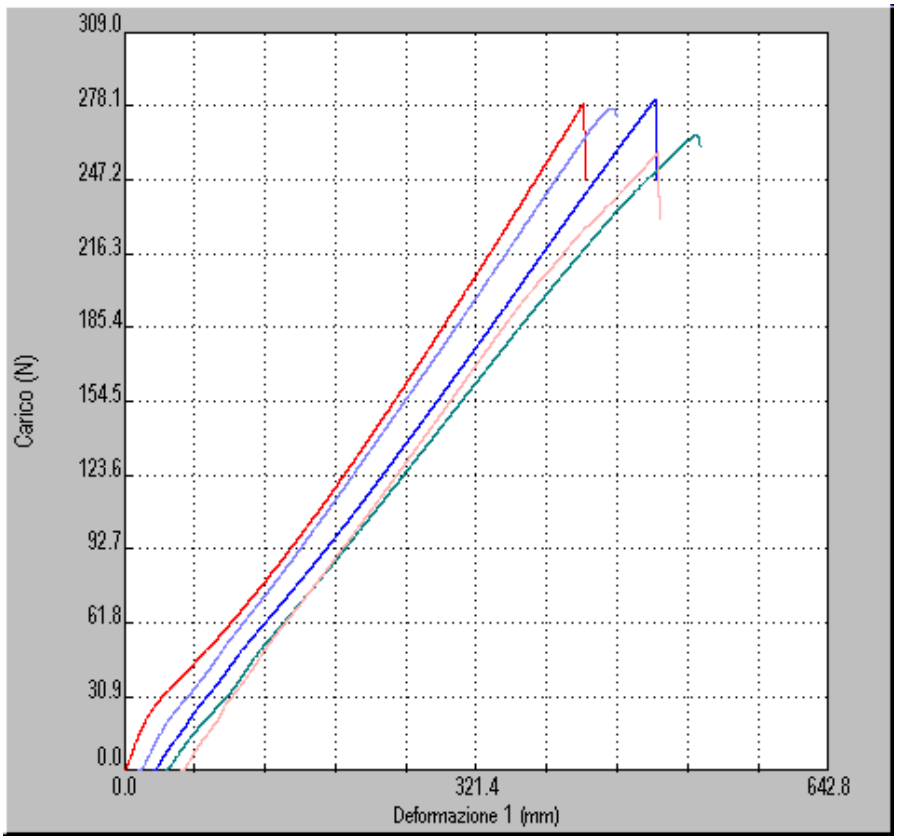
In the following table are reported load and extension at componenent breakage.

probe	load before breakage [N]	free initial lenght [mm]	strain before breakage [mm]	extension % before breakage
1	258,45	80,00	436,91	646,14
2	265,95	90,00	486,99	641,10
3	280,95	90,00	460,50	611,67
4	273,95	90,00	436,31	584,79
5	279,10	94,00	420,72	547,57
Mean	**271,68**	**88,80**	**448,29**	**606,25**
Std-Dev	9,41	5,22	25,88	41,04
RSD%	**3,46**	**5,87**	**5,77**	**6,77**

Data reported in the table above have been obtained by challenging the probes with a constant rate tensile stress (v = 300 mm/min).

The specifications of the analyzed components report a maximal deformation before breakage of no less than 500%, therefore all the samples analyzed must be considered perfectly in accordance with the existing regulation.

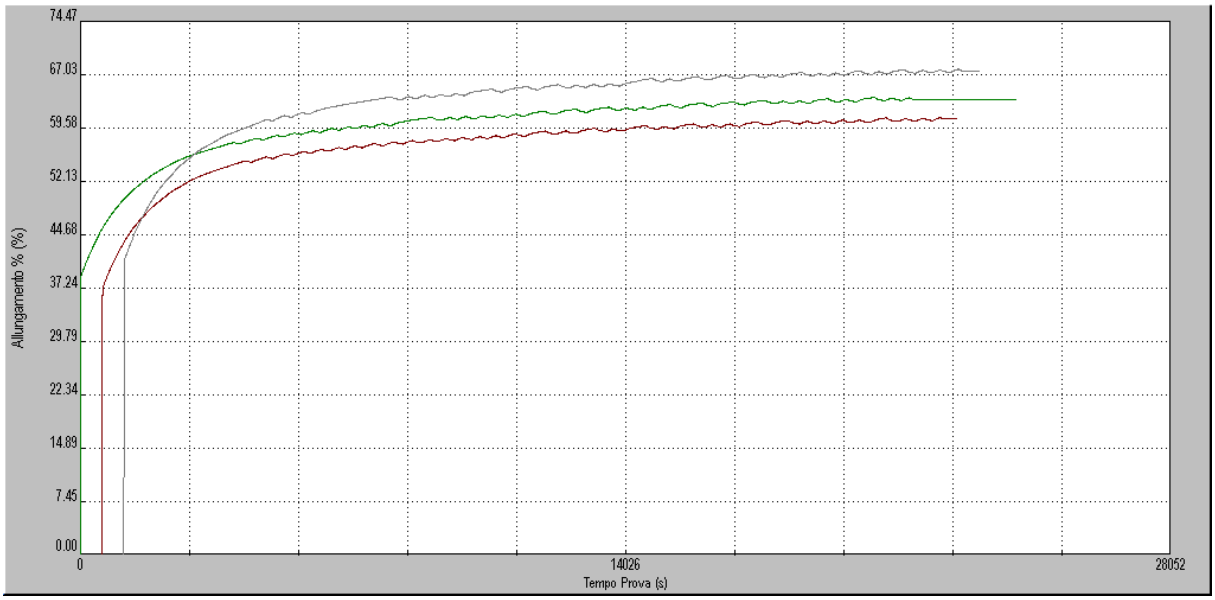
The following charts are representative of the behaviour of the material.
A 2% offset has been inserted between the different curves in order to distinguish the overlapping ones.



Stress/strain chart of silicone band probes

2. Creep test on the silicone band

The test gave no evidence of anomalous behaviours: at constant load the extension slowly grow up to an asymptote at about 60-70%.
The following charts are representative of the behaviour of the material when submitted to the creep test.
No significant permanent deformation were detected in the probes after the test.



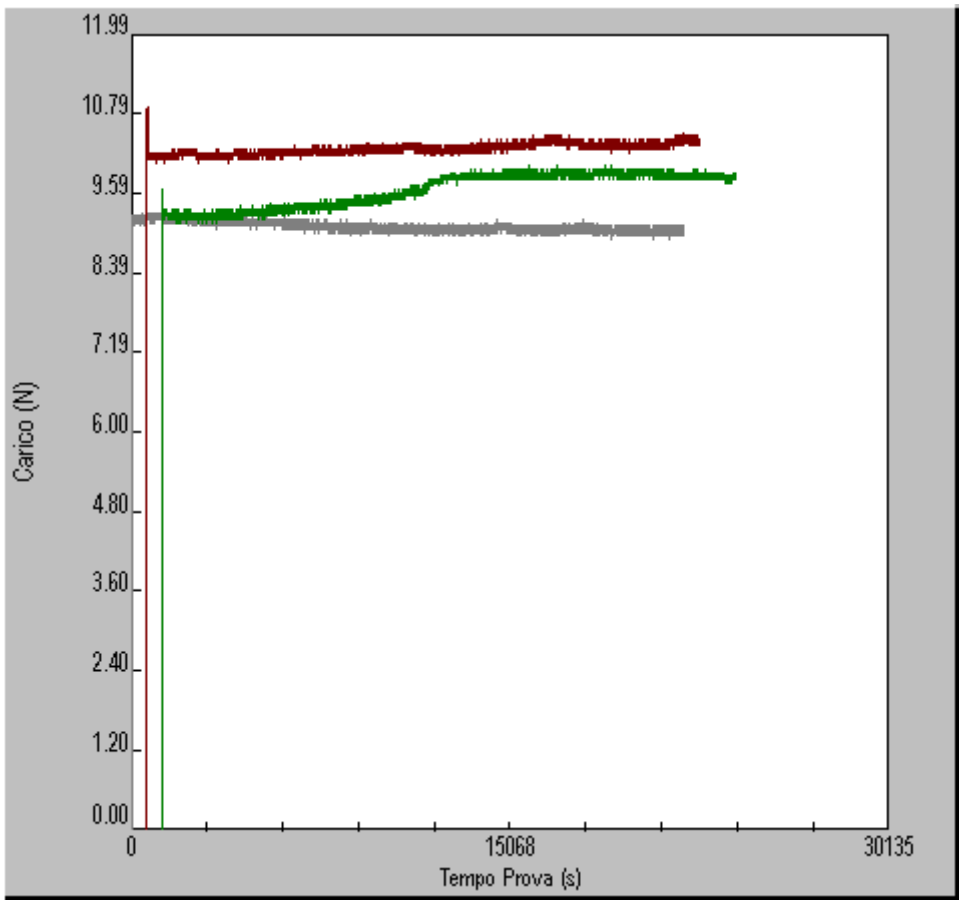
On the Y axis, the probe extension% , on the X axis the testing time

3. Determination of pull-away load on silicone band

When tested as described in “Experimental procedure” section, the mean value obtained from three sample tested was 65N.
It can be stated that this value is greater than any reasonable force observable during the normal use.

4. Relaxation test on spring

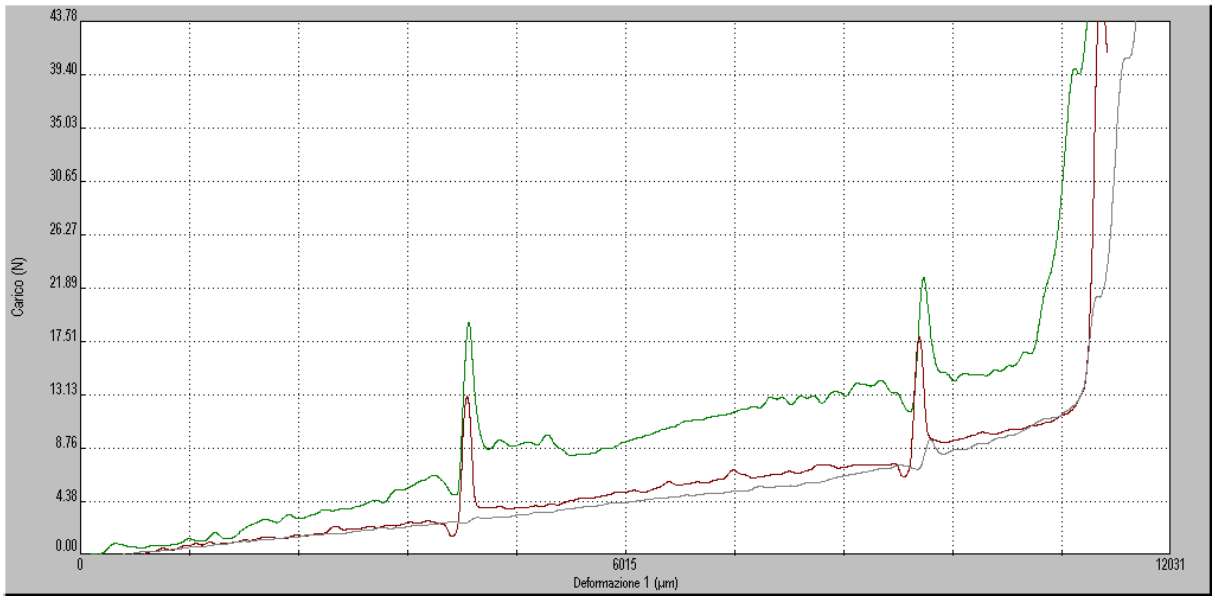
The test gave no evidence of anomalous behaviours.
The following charts are representative of the behaviour of the material when submitted to the creep test.



On the Y axis, the load needed for hold a constant deformation , on the X axis the testing time

5. Determination of stress-strain curve on spring/metal bar complex

The following charts are representative of the behaviour of the material.
In the complete there would be two springs parallel working, so the developing load in the device would be two times the one of one spring.
The specifications of the analyzed components report an elastic coefficient of about 0.6 mm/N, which is confirmed by the obtained results.



This chart show the load/deformation linear relation in the spring; the elastic coefficient is about 0.6 mm/N.
The peaks in curves are due to no perfect lubrication of the springs.

6. Determination of tensile load developed by the device

In the following table are reported the tensile strength developed by the device in different configurations.
It can be stated that, when working in a reasonable range of length, tensile stress is independent from device length and base length; it seems to depend only from the difference between these two values.
Differences in values obtained with silicone band in narrow or large configuration are probably due to silicone elasticity.

Changing parameters:

- base length. This value represents the penis length, as it is when measured below the glans: this one is the point where the user would close the silicone band.
- device's length, measured from the lower part of the plastic ring to the upper part of the metal axis
- silicone band diameter, two different extension, the former narrower, the latter larger.

Device length [cm]	**Base length (*penis length*) [cm]**	**Silicone Band**	**Developed load [N]**
11	7,0	large	2,45
11	7,0	narrow	2,00
11	6,5	large	4,80
11	6,5	narrow	4,50
11	6,0	large	5,80
11	6,0	narrow	5,40
13	8,0	large	5,80
13	8,0	narrow	5,25
13	9,0	large	2,55
13	9,0	narrow	2,15
15	9,5	large	6,80
15	9,5	narrow	6,40
15	10,5	large	3,10
15	10,5	narrow	2,75