Final Report SAM2818I

MECHANICAL CHARACTERIZATION

Study Program No:

SAM2818

Contract:

E05/0137.4MI

Sponsor:

ANDROMEDICAL S.L. Mar Mediterràneo, 19 28220 Majadahonda MADRID – (ES)

Test substance:

ANDRO-PENIS

Alemendro hadici ... Date of issue: 18/10/05 Study Director: (Ing A.Radici)

This report cannot be partially reproduced without written permission of the Laboratory

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.

biolab	Centro di Saggio	Versione: Pagina: Data stampa:	SAM28181 Italiano 10 di 15 18/10/2005
The following cha A 2% offset has	arts are representative of the behavio	ur of the materi	al.



Stress/strain chart of silicone band probes

BIOLAB S.p.A. VIA B. BUOZZI, 2 - 20090 VIMODRONE (MI) - 🕿 02/708415.31 🏐 02/2504333 - E-mail: biolab.milano@biolab.it

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 (<i>penis length</i>) [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