Problems of condom supplies to High altitude locations

1. The issue: Several supplies that have been made to high altitude locations such as Quito have shown signs of leaks. However, when tested for seal integrity all the batches pass.
2. The problem appears to be one of slow seepage through micro channels in the seal area, compounded by the differential pressure between the inside of the foil packs and the ambient areas.

1. The primary pack comprises of a pack of 57x55 mm with a laminate of layers of plastic/aluminium foil/plastic seal layer. These could be 3/4 layers. The seal layer could be of different composition depending on the supplier.

2. 48 strips of 3 packs are then stacked vertically in a gross box (144 condoms), soon after the foiling is completed. The batches are then inspected and tested by an independent agency prior to shipment. The independent agency also tests for package integrity. The time from primary packaging to shipment could take 4-6 weeks. Sea transport could take 4-8 weeks depending on location. Air shipments could take a week to ten days.

1. After receipt of product at the high altitude location and storage, it was found that the gross boxes showed damp patches due to silicone oil seepage. Consequently, the customers were reluctant to accept the product claiming seal integrity failure. However, when product from these batches was tested in the laboratory for seal integrity, they passed.

Points to note:

1. The foil packs are packed soon after foiling and the packs are packed vertically. Under these conditions lubricant does not have much time to migrate over the condom and is likely to pool at the bottom of the pack. This could influence the seepage at the bottom.
2. A study to check the lubricant migration in the pack has been done and results are available.
3. The material of the seal layer also needs to be investigated.
4. Since it appears that this is not a seal failure but only seepage through probable micro channels, this is an area for further investigation.
5. Will increasing the sealing width make a difference???
6. The differential pressure which is exerting pressure on the seals is due to air in the pack. Is it possible to reduce the quantum of air in the pack?? It was noticed that the pack from a rotary machine appeared to have less air. The Doeka style machines may have more air since the foil layers are separated to allow the pincer and lube feeding tube to enter the gap.
7. It should be noted that rectangle packs with smaller cavities have less air in them.

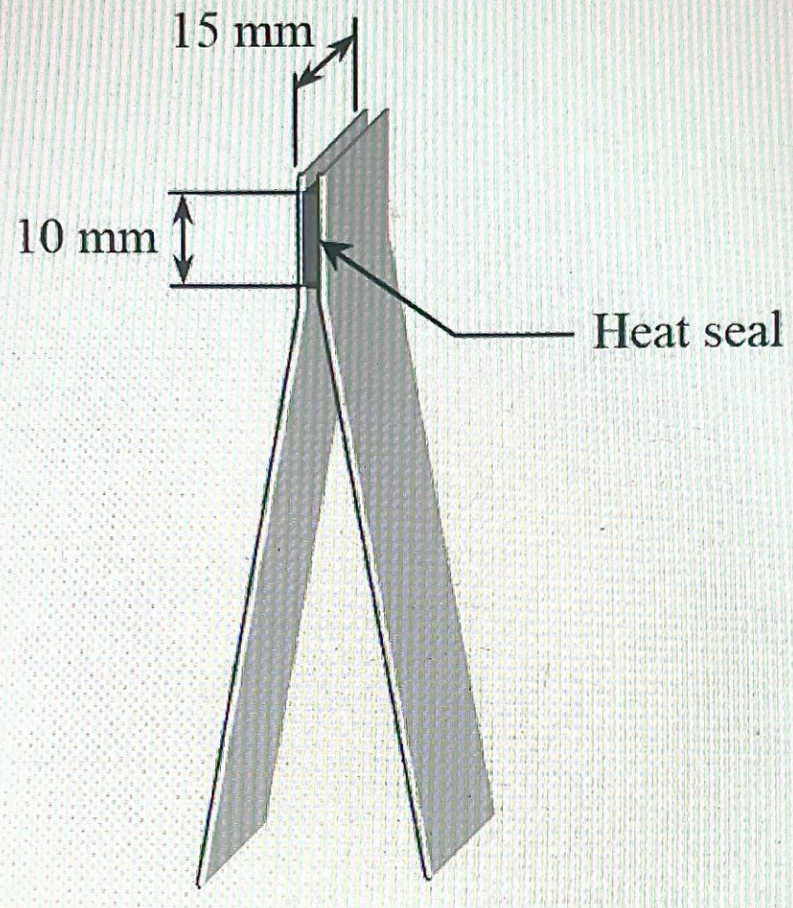


Figure 1: Heat-seal dimensions

Testing of Heat-seals

After the heat-seals were produced, it were allowed to condition at room temperature for at least 40 hours to achieve chemical stabilization. Aging of heat-seal was necessary as the strength of seal may change in time, which may due to the memory of polymer, or thermophysical properties of polymer as the heat-seal samples undergo melting and cooling processes 10. In practice, packaging goods are aged through storage before being used by the consumer. Therefore, heat-seals made in this study were aged for at least 40 hours before tested.

The strength of heat-seal is often determined by measuring the force required to pull apart the pieces of which have been sealed together, ether in a dynamic or static load test 14. In this study, the sample was peeled apart at room temperature in tensile tester of model MICRO 350, using a 100 N load cell. Each leg of the test specimen

Study to minimise leakage/seepage of condom packs at high altitudes.

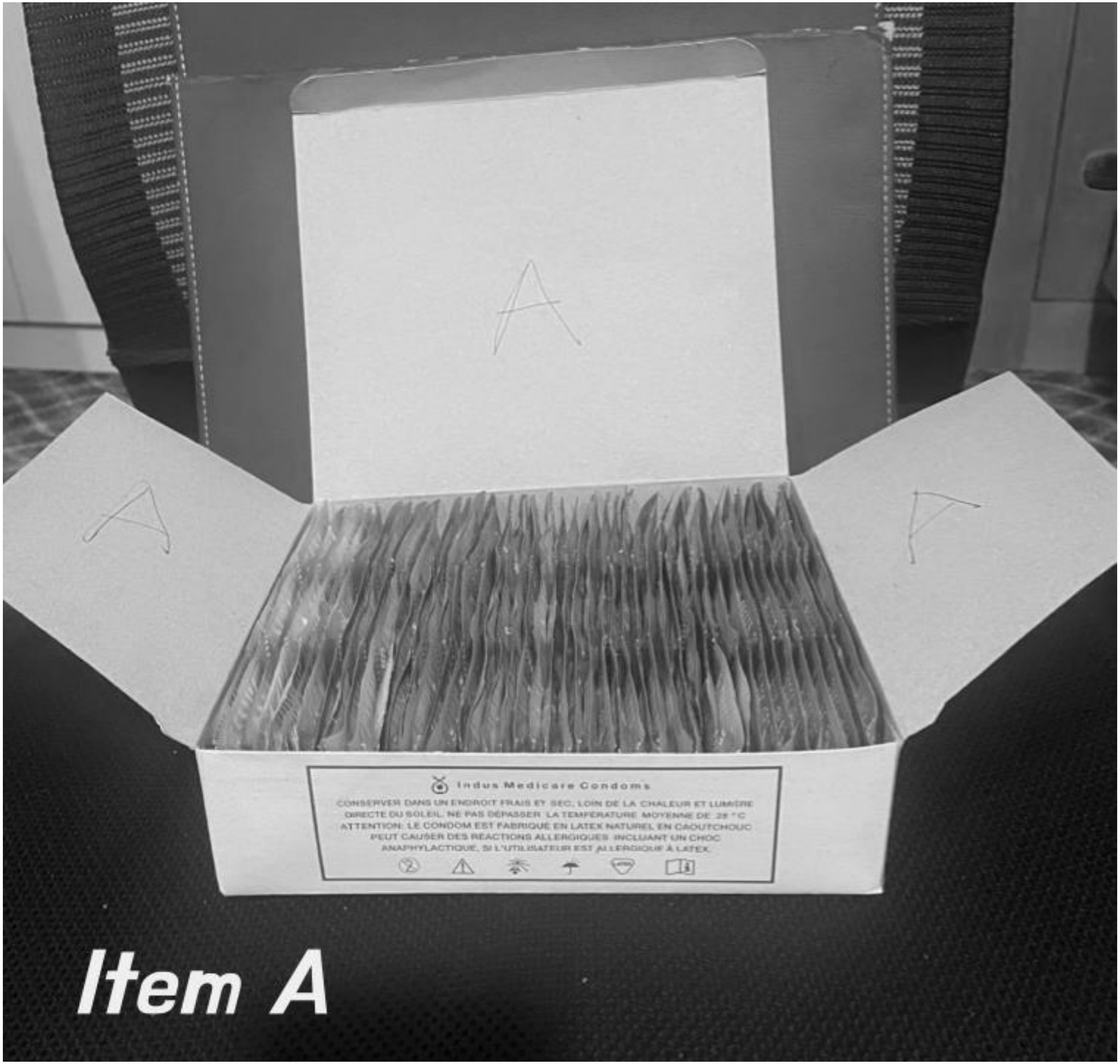
1. Lab study to estimate the increase in pack thickness at different altitudes: Completed.
2. Calculation of differential pressure at different altitudes: Completed.
3. Compare the different methods of packing in the secondary (gross box.):-
   - A. Current method is 48 strips of 3s placed vertically. (Photo A)
   - B. Place flat strips of 3s in 4 rows and 12 high. (Photo B)
   - C. Place flat strips of 3s in 4 rows and 12 high with expansion space. (Photo C)

Procedure of test: Box **A** and **B** to be taped tight to prevent expansion, simulating the actual conditions in a Master carton. item **C** need not be taped as the condom packs will be allowed to expand in the box.

Boxes to be lined with tissue paper prior to packing.

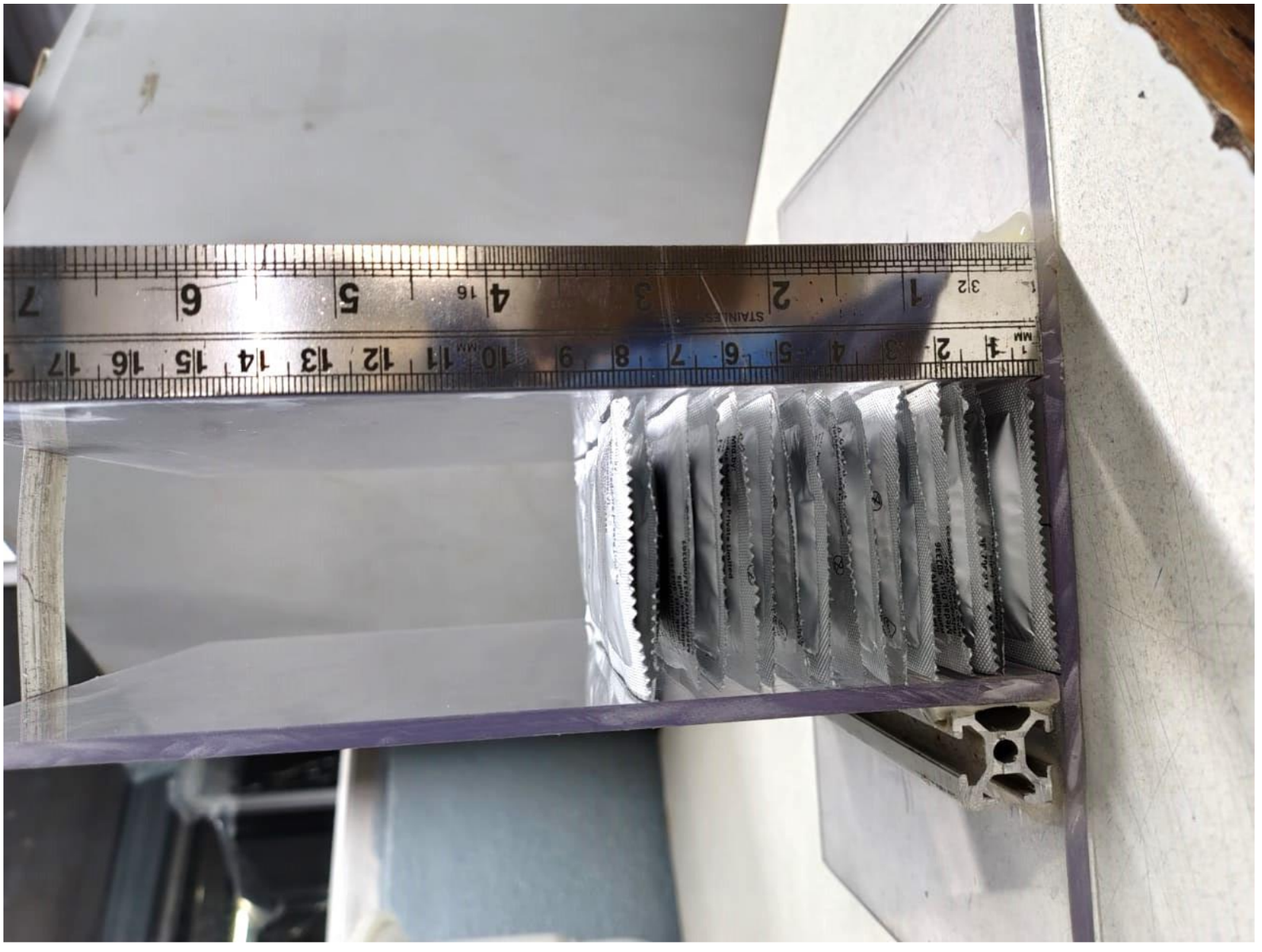
The gross boxes will be placed in the vacuum chamber and exposed a vacuum equivalent to 57 kpa (15000 ft altitude) for 6-8 hours.

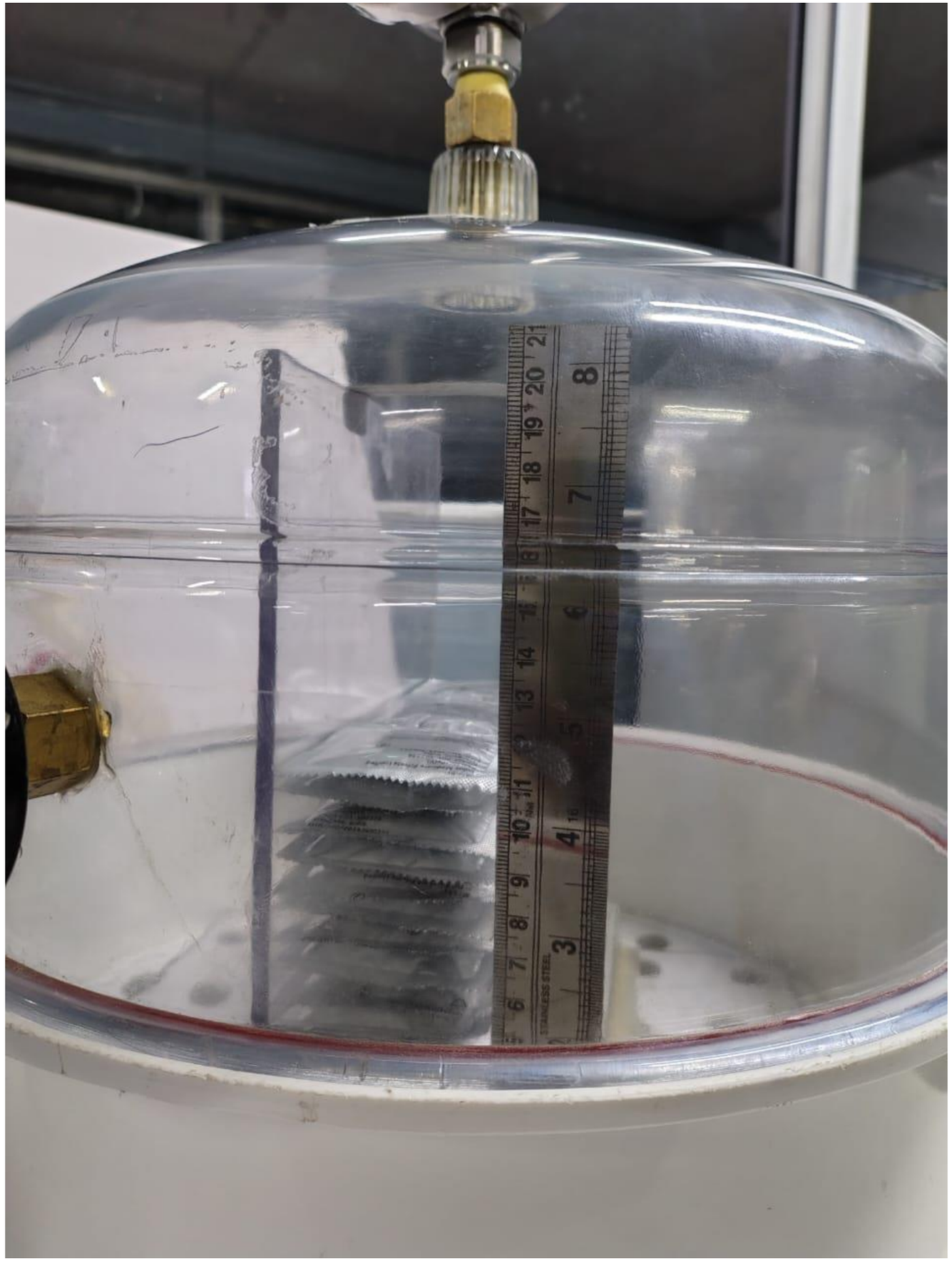
After 6-8 hours boxes opened to check for any seepage.


A
A
A
Indus Medicare Condoms
CONSERVER DANS UN ENDROIT FRAIS ET SEC, LOIN DE LA CHALEUR ET LUMIÈRE DIRECTE DU SOLEIL. NE PAS DÉPASSER LA TEMPÉRATURE MOYENNE DE 28 °C
ATTENTION: LE CONDOM EST FABRIQUÉ EN LATEX NATUREL EN CAOUTCHOUC PEUT CAUSER DES RÉACTIONS ALLERGIQUES INCLUANT UN CHOC ANAPHYLACTIQUE. SI L'UTILISATEUR EST ALLERGIQUE À LATEX.
Item A


B
B
B
Item B


Item C





Pressure calculations for foil packs subject to altitude differences.

1. Absolute Pressures. Kg/sqcm.

Sea Level	1.03
500m	0.955
2500m	0.797
3048m (10000 ft.) Quito.	0.711
11500m (37000 ft) equivalent to 20 kpa	0.22

2. Load on foil/seal area assuming pack **not allowed to expand.**

a. Differential pressure (0-2134m/7000ft) 1.03-0.797= 0.233 kg/sq cm
Load on unsealed (cavity) surface (one side) 0.233x4.5x4.5 = 4.72 kgs
Load on both sides 4.72x2 = 9.44 kgs

Load per seal length of 15mm 9.44x15/180 = **0.7866 kgs**

b. Differential pressure (0-3048m/10,000ft): 1.03-0.711 = 0.319 kg/sq cm
Load on the unsealed foil surface area (one side): 0.319x4.5x4.5 = 6.46 Kgs
Load on both sides: 6.46x2 = 12.92 kgs

Load per seal length of 15 mm : 12.96x15/180 = **1.08 kgs**
(ref peel strength test)

c. Differential pressure (0-11500m/37500ft): 1.03-0.22 = 0.81kgs/sq cm.

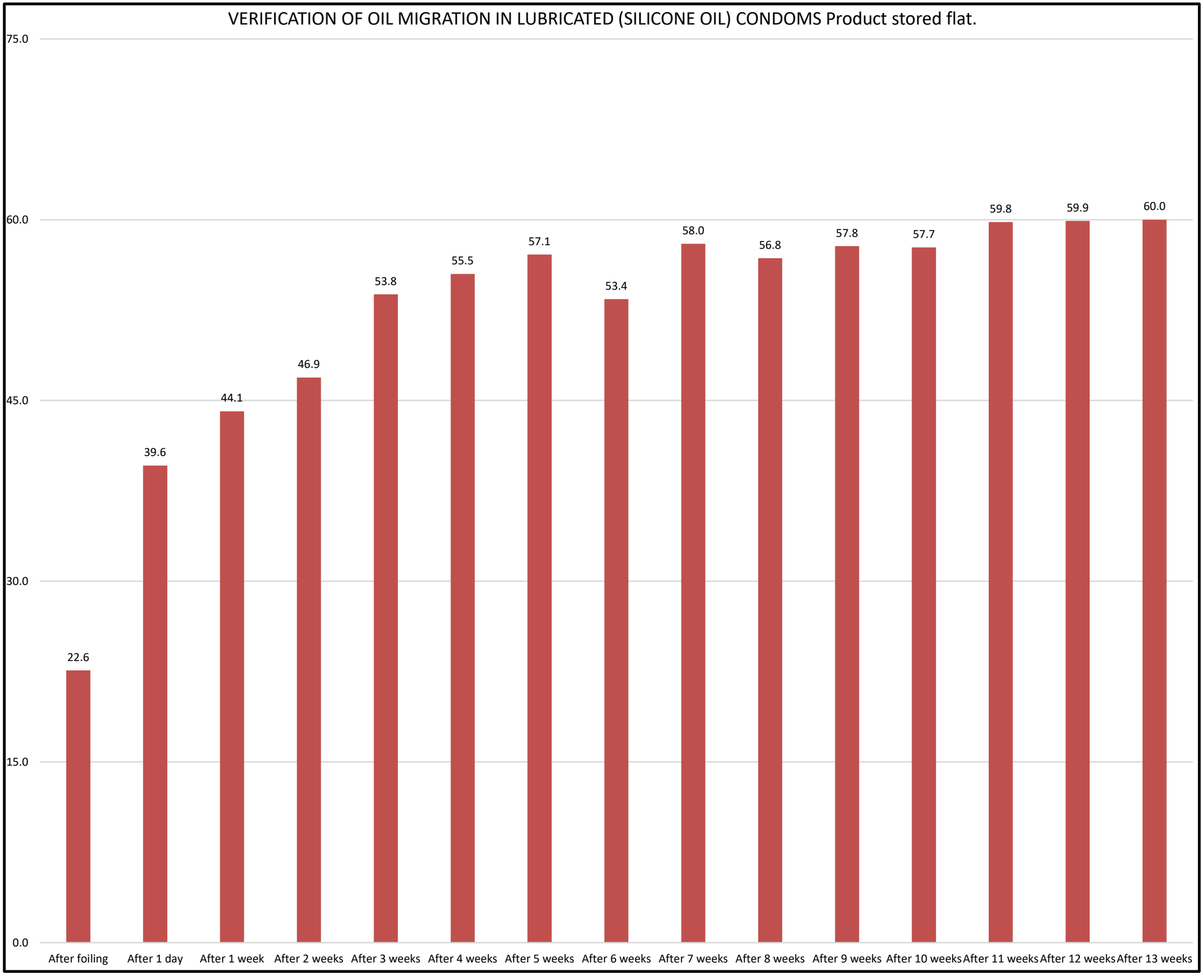
load on the unsealed foil surface area (one side): 0.81x4.5x4.5 =16.4 kgs
load on both sides: 16.4x2= 32.8 kgs

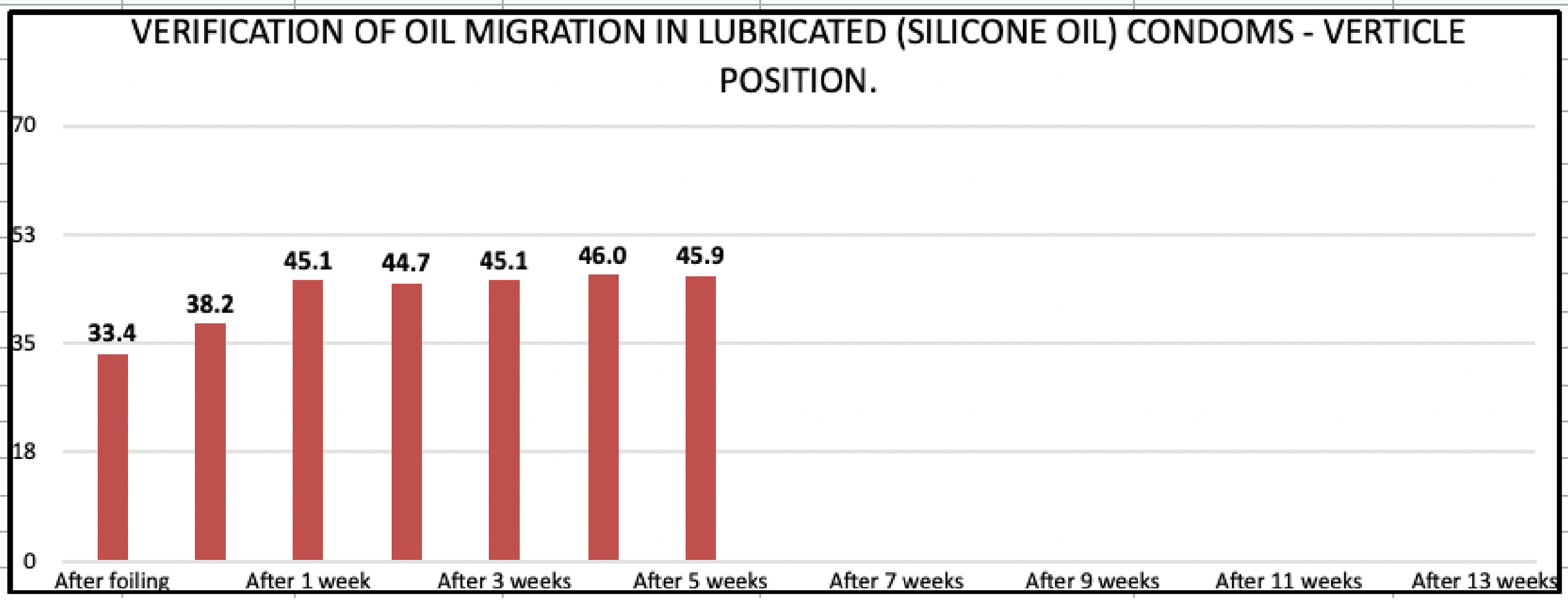
Load per seal length of 15 mm: 32.8x15/180 = **2.733 kgs**.

Questions:

1. What happens when 48 packs are confined in a box next to each other and all trying to expand under low pressures???
2. Will it help to go to a different box size : 4 strips x 36 =144 or 4 x 25 = 100???
3. Do the leaks occur due to peeling of the laminate or is the leak through capillaries in the seal area???

Note: Calculations based on standard pack size of 57x55mm with cavity of 45x45mm


VERIFICATION OF OIL MIGRATION IN LUBRICATED (SILICONE OIL) CONDOMS Product stored flat.
75.0
60.0
45.0
30.0
15.0
0.0
22.6
39.6
44.1
46.9
53.8
55.5
57.1
53.4
58.0
56.8
57.8
57.7
59.8
59.9
60.0
After foiling
After 1 day
After 1 week
After 2 weeks
After 3 weeks
After 4 weeks
After 5 weeks
After 6 weeks
After 7 weeks
After 8 weeks
After 9 weeks
After 10 weeks
After 11 weeks
After 12 weeks
After 13 weeks


VERIFICATION OF OIL MIGRATION IN LUBRICATED (SILICONE OIL) CONDOMS - VERTICLE POSITION.
% Migration
70
53
35
18
0
33.4
38.2
45.1
44.7
45.1
46.0
45.9
After foiling
After 1 week
After 3 weeks
After 5 weeks
After 7 weeks
After 9 weeks
After 11 weeks
After 13 weeks

S no.	Dimension (mm)	Altitude(feet)	Absolute Pressure (kPa)	Vacuum (mmHg)	No. of Pieces	Initial Reading(mm)	Final Reading after expansion	Average bulging per piece in mm	Average Initial height piece (mm)	Final Reading piece (mm)	Deviation %	% Difference
1	55 x 57 (static)	7000	78	139	16	82	91	0.6	5.1	5.7	11.0	28.0
		10000	70	199			114	2.0		7.1	39.0	39.0
		15000	57	297			138	3.5		8.6	68.3	
2		7000	78	139	12	59	67	0.7	4.9	5.6	13.6	28.8
		10000	70	199			84	2.1		7.0	42.4	32.2
		15000	57	297			103	3.7		8.6	74.6	
3	55 x 57 (Rotary)	7000	78	139	16	76	86	0.6	4.8	5.4	13.2	21.1
		10000	70	199			102	1.6		6.4	34.2	22.4
		15000	57	297			119	2.7		7.4	56.6	
4		7000	78	139	12	54	62	0.7	4.5	5.2	14.8	22.2
		10000	70	199			74	1.7		6.2	37.0	25.9
		15000	57	297			88	2.8		7.3	63.0	
5	70 x 30	7000	78	139	16	80	91	0.7	5.0	5.7	13.8	10.0
		10000	70	199			99	1.2		6.2	23.8	27.5
		15000	57	297			121	2.6		7.6	51.3	
6		7000	78	139	12	60	66	0.5	5.0	5.5	10.0	11.7
		10000	70	199			73	1.1		6.1	21.7	26.7
		15000	57	297			89	2.4		7.4	48.3	

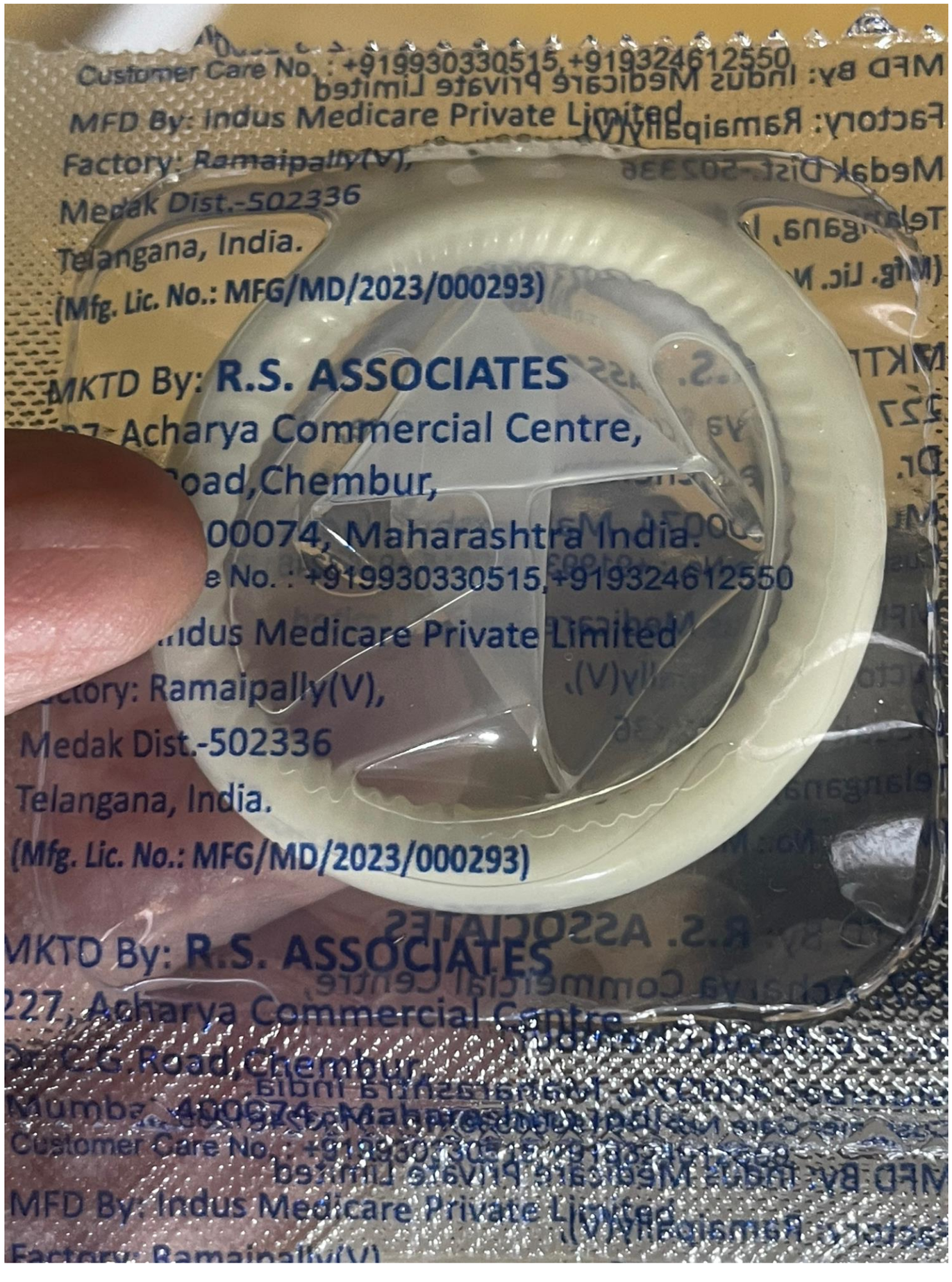
Date : 08.08.2024

5	70 x 45	7000	78	139	16	81	92	0.7	5.1	5.8	13.6	14.8
		10000	70	199			104	1.4		6.5	28.4	33.3
		15000	57	297			131	3.1		8.2	61.7	
6		7000	78	139	12	61	67	0.5	5.1	5.6	9.8	16.4
		10000	70	199			77	1.3		6.4	26.2	26.2
		15000	57	297			93	2.7		7.8	52.5	

Foil Pack sizes vs

Pack Size	cavity size mm	seal width mm	area of pack sq cm	Area of cavity sq cm	Total Seal area sq cm	Reduction in area wrt to normal		Internal loading at 7000ft/ 2134 m, kgs	Load per seal length of 15mm. kgs	Internal loading at 10000 ft 3048 m	load per seal length of 15mm, Kgs	Internal loading at 15000 ft 4570 m	load per seal length of 15 mm kgs
						Reduction WRTto A %							
57x55	45x45	4-5	31.35	20.25	11.10			9.44	0.877	12.92	1.08	18.1	1.5
70x30	53x20	7-8/4-5	21.00	10.6	10.4	33.0		4.93	0.506	6.76	0.69	12.06	1.24
70x40	54x28	7-8/4-5	28.00	15.12	12.85	10.68		7.04	0.64	9.65	0.88	17.16	1.48
60x40*	50x30	5/5	24.00	15.00	9.00	23.44		7.0	0.656	9.57	0.90	13.86	1.30
70x35*	55x25	7.5/5	24.50	13.75	10.75	21.85		6.4	0.60	8.77	0.82	14.14	1.33

Note: Pressurisation in aircraft usually at 6000-7000 ft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