

A Study of the Effectiveness of Electric Hole Test on Natural Latex Condoms Using Different Filling Volumes

Background

ISO 4074:2002 specifies two methods for testing for freedom from holes. The Water Leak Test also known as Hang and Roll Test described in Annex L clause L.2 and the Electric Test described in Annex L, clause L.3.

The Electric Test is used to pre-select samples to use in the final verification of holes using the rolling method described in clause L.2 but without the hanging procedure. Only when the presence of a hole is confirmed by the rolled water leakage test is the condom deemed to be non-compliant.

The two tests are considered to be equivalent since the presence of a hole is determined by the detection of a leak when the condom is rolled on absorbent paper as described in clause L.2. This is only true if the electrical test is able to detect all the holes that can be found by the Hang and Roll method.

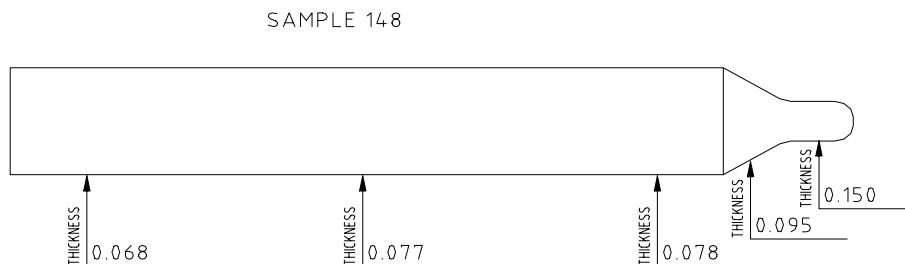
Trials made at Valendor Laboratory and at other laboratories indicate that the electric method with 200 ml filling volume is not able to detect all the holes that would be detected in the Hang and Roll Test.

The Study

The objective of the study was to compare the Electric Test using 200 ml filling volume, alternative 400 ml filling volume with the Hang and Roll Test described in clause L.2.

The study was made on 20 condoms with holes made by sharp pin and hard plastic as anvil. Ten of the condoms were punctuated in the shoulder area (between the tip and parallel sided part of the condom), ten condoms were punctuated 50 mm from the open end.

The thickness profile of the condom appears from the illustration below.



The test was repeated several times using the same condoms, alternating 200ml and 400ml filling volumes.

The performance of the equipment was validated using reference condoms before and after each test.

The hang and roll test according to ISO 4074 L.2 was performed as second test after the first electric test with 200 ml filling volume.



After six repeated tests (three with 200ml and three with 400ml) a verification of holes was made by mechanically assisted rolling (without previous hanging) according to ISO 4074 L.2.3.7 to L.2.3.9.

Results

The results are given in Table 1. The numbers in the cells is the voltage measured in mV. For technical reasons maximum value that can be displayed is approximately 465 mV.

The table also gives detection rates for each individual condom with repeated test at 200ml respective 400ml.

Detection rates and hole indication rates for each test of the 20 (10 with shoulder holes + 10 with body holes) condoms are given in the table. All readings above 2mV are considered as hole indications (readings 1 and 2 mV are considered as “noise” in the system).

The outmost right-hand column explores the results when using Valendor’s Electric Hole Tester (EHT) in Tip Challenge Mode. In the Tip Challenge mode the voltage is first checked when the condom is hanging in the air and only the closed end is in contact with the electrolyte in the tank below. After the first check in the Tip Challenge Mode, the condom is fully submerged and the voltage is checked a second time.

Comments and observations

The size of the made holes in this study may be smaller than usually found in the same type of trials. However, the objective of the study was to compare the methods in the area where the sensitivity matters. The made holes were also found in all 20 samples and 19 (or 95%) of the 20 condoms didn’t meet the acceptance criteria when tested according to ISO 4074 Annex L, clause L.2 (the hang and roll test).

The results of this study shall not be interpreted as an indication that the electric method as described in ISO 4074 clause L.3 would miss the most of the holes in condoms. Holes in condoms are rare and holes of the size equal or near the acceptance level stated in ISO 4074 probably only occurs in a very small number of condoms.

However, this study clearly demonstrates that the electric method with 200 ml filling volume, when applied to certain condoms, has very serious limitations to detect holes that can be detected by the hang and roll method.

When the electric test was conducted with 400 ml filling volume, the detection rate (for this specific condom) increased from 17% to 37% for holes in the shoulder area and from 10% to 90% for holes located 50 mm from the open end.

When the Tip Challenge Mode was used with 400 ml filling volume, the detection rate for holes in the shoulder area increased to 90% (100% of the holes confirmed in the hang and roll test). The detection rate for holes 50 mm from the rim also increased, but this result is considered as random, since the Tip Challenge Mode does not affect the hole detection in the parallel sided part of the condom.

Note! The percentages given above also include the condom that was found to meet the acceptance criteria in the hang and roll test.

It should be noted that the rolling in the hang and roll test was done using a rolling device described in clause L.2.2.3. The force required squeeze the condom to 30 mm was approximately 12 N. The force required to press half of the condom to 30 mm and let the other part expand freely in all directions, which may be the case at manual rolling, was only 3-4 N. Therefore, the number of holes detected by manual rolling may have been less than was the case in this study. On the other hand, the pressure inside the immersed condom filled with only 200 ml electrolyte and supported by electrolyte from outside is probably less than the pressure caused by manual rolling. This makes the detection of smaller holes in specific condoms haphazard with the electric method as currently described in ISO 4074 L.3.



To increase the reliability of the electric test originally introduced in Europe, the current standard has been amended to include a visual inspection of the condom before it is immersed.

Considering that the filling volume in the hang and roll test is 300 ml and the minimum hanging time before inspection is one minute, it can be expected that the electric method would require higher volume to have the same detection ability during the hanging part of the test, since there is no minimum hanging time stated in the electric test. This study also clearly demonstrate that the visual inspection alone is not able to detect smaller holes, either with 300 ml filling volume, as practised in the hang and roll test and therefore neither with 200 ml as is the case in the electric test.

Other observations

The results in this study show that the detection rate in the electric test will not increase when the test is repeated. However, some condoms may contain a large number of micro holes and indicate holes in the electric test. In those cases the voltage measured may increase when the test is repeated and exceed 50 mV, but the condom will still pass the rolling test.

Validation of EHT method

VALENDOR LABORATORY

Sample ID: 148 Date: 2004-09-04 --- 2004-09-11
 Lot No.: xxxxx Tested by: jg

Holes made by sharp pin and hard plastic as anvil

| # | Hole location | ISO 4074 L.3 200ml | re-test 200ml | 2nd re-test 200ml | 400ml | re-test 400ml | 2nd re-test 400ml | ISO 4074 L.2 Hang&Roll --- full test | Hang & Roll -- hole detected after hanging | Hang & Roll -- hole detected at rolling | Hole detected by rolling with extra pressure | Hole verified after electric test by rolling - no hanging | Detection rate with 200ml | Detection rate with 400ml | Detection rate with 400 and Tip Challenge |
|----|---------------|--------------------|---------------|-------------------|-------|---------------|-------------------|--------------------------------------|--|---|--|---|---------------------------|---------------------------|---|
| 1 | shoulder | 456 | 2 | 2 | 456 | 455 | 6 | Y | Y ¹⁾ | | | Y | 33% | 67% | 455 |
| 2 | shoulder | 3 | 2 | 2 | 455 | 4 | 4 | Y | Y | | | Y | 0% | 33% | 455 |
| 3 | shoulder | 2 | 2 | 2 | 45 | 3 | 4 | N | N | N | Y | N | 0% | 0% | 21 |
| 4 | shoulder | 2 | 2 | 2 | 3 | 3 | 6 | Y | N | Y | | Y | 0% | 0% | 455 |
| 5 | shoulder | 1 | 2 | 2 | 455 | 4 | 455 | Y | Y | | | N | 0% | 67% | 455 |
| 6 | shoulder | 396 | 2 | 2 | 3 | 3 | 455 | Y | N | Y | | Y | 33% | 33% | 455 |
| 7 | shoulder | 2 | 2 | 2 | 3 | 455 | 3 | Y | Y ¹⁾ | | | Y | 0% | 33% | 455 |
| 8 | shoulder | 456 | 7 | 455 | 455 | 455 | 3 | Y | Y ¹⁾ | | | Y | 67% | 67% | 455 |
| 9 | shoulder | 455 | 2 | 2 | 4 | 4 | 455 | Y | N | Y | | Y | 33% | 33% | 455 |
| 10 | shoulder | 2 | 2 | 2 | 3 | 4 | 455 | Y | Y | | | Y | 0% | 33% | 248 |
| 11 | 50 fr rim | 2 | 2 | 2 | 347 | 455 | 455 | Y | N | Y | | Y | 0% | 100% | 455 |
| 12 | 50 fr rim | 2 | 14 | 57 | 455 | 92 | 455 | Y | N | Y | | Y | 33% | 100% | 455 |
| 13 | 50 fr rim | 2 | 2 | 2 | 455 | 455 | 455 | Y | N | Y | | Y | 0% | 100% | 455 |
| 14 | 50 fr rim | 2 | 2 | 2 | 455 | 455 | 455 | Y | N | Y | | Y | 0% | 100% | 452 |
| 15 | 50 fr rim | 2 | 2 | 106 | 455 | 455 | 455 | Y | N | Y | | Y | 33% | 100% | 455 |
| 16 | 50 fr rim | 2 | 2 | 2 | 455 | 3 | 455 | Y | N | Y | | Y | 0% | 67% | 455 |
| 17 | 50 fr rim | 8 | 2 | 2 | 455 | 455 | 455 | Y | N | Y | | Y | 0% | 100% | 455 |
| 18 | 50 fr rim | 2 | 2 | 293 | 455 | 455 | 455 | Y | N | Y | | Y | 33% | 100% | 455 |
| 19 | 50 fr rim | 2 | 2 | 2 | 455 | 4 | 28 | Y | N | Y | | Y | 0% | 33% | 110 |
| 20 | 50 fr rim | 2 | 2 | 2 | 455 | 455 | 455 | Y | N | Y | | Y | 0% | 80% | 455 |

For Individual Tests

| | | | | | | |
|-----------------------|-----|-----|-----|------|------|------|
| Found shoulder holes | 40% | 0% | 10% | 40% | 30% | 40% |
| Found body holes | 0% | 0% | 30% | 100% | 80% | 100% |
| Indicated shoulder ho | 50% | 10% | 10% | 100% | 100% | 90% |
| Indicated body holes | 10% | 10% | 30% | 100% | 100% | 100% |

Summary for method

| | | | |
|-------------------------|-----|------|------|
| Found shoulder holes | 17% | 37% | 90% |
| Found body holes | 10% | 90% | 100% |
| Indicated shoulder hole | 23% | 100% | 100% |
| Indicated body holes | 17% | 100% | 100% |

1) Hole detected visually after more than three minutes hanging