

# Testing for Freedom From Holes – Practical Issues Based on Experience with ISO 4074:2002

## Background

ISO 4074:2002 specifies two methods for testing for freedom from holes. Annex L clause L.2 describes the water leak test in which 300ml of water is placed in each condom. Holes are detected by allowing the condom to hang whilst full of water and then by rolling it, still containing 300ml of water, on absorbent paper. Any leakage of water observed either during hanging or when the condom is rolled indicates the presence of a hole in the condom.

Clause L.3 describes the electrical test. Essentially the condoms are screened initially by determining whether an electrical current can flow across the film when the condom is filled with 200ml of electrolyte and immersed in an electrolyte bath. The electrical current is detected by determining the voltage rise across a resistor. If the voltage exceeds 50mV then the condom is deemed potentially defective. A confirmatory test is conducted by increasing the volume of electrolyte and/or water within the condom to 300ml and rolling it on absorbent paper as per the water leakage test described above. Only when the presence of a hole is confirmed by the rolled water leakage test is the condom deemed to be non-compliant.

In principle the two tests are considered to be equivalent since the presence of a hole is determined by exactly the same criterion, namely the detection of a leak when the condom is rolled on absorbent paper. This is only true however if the electrical test is able to detect all the holes that can be found by rolling. If this is not true then the test as described in Annex L.3 may understate the number of non-complying condoms in a sample.

The equivalence of the two test methods, along with other methods, was investigated in a major inter-laboratory study funded by the EU (Contract No MAT1-CT 940050). The conclusion of the study was:

*“The main outcome of this project was that the Rolled Water Test and European Electrical Test confirmed by Rolled Water Test gave consistent results which were more reliable than the other three methods. There is no important difference between the results of the Rolled Water Test or the European Electrical Test confirmed by the Rolled Water Test in terms of repeatability and reproducibility or within the limits of our ability to determine, false positives or false negatives. Both methods should be permitted in standards with the choice made by individual laboratories”*

This conclusion may need to be reconsidered in the light of recent experience with the two tests.

## Practical Issues Reported With the Tests

During audits and inspections of manufacturing facilities and test laboratories along with trouble shooting investigations when the test results have been challenged the following issues have been identified with the two test methods.

1. The way in which the rolling water test is conducted varies significantly from laboratory to laboratory. The individual methods used to roll the condom appear to result in substantial differences in the amount of stretching the film experiences. It is possible that some of the techniques used may be more or less efficient at detecting non-complying condoms but there is at present no data to support or reject this position. The view has also been expressed that in some circumstances the length of the hanging period can affect the ease with which small holes can be identified (longer hanging periods make it easier to find small holes) but again there is no data at present to support this.
2. Questions have been raised about whether the use of a rolling device, which is optional according to clause L.2.2.3, gives equivalent results to rolling by hand. One laboratory reports that the force required to squeeze the condom such that the device is 30mm above the absorbent paper is over four times that required than when rolling by hand. Again there is no data to substantiate whether or not the use of a rolling device gives equivalent results to hand rolling.
3. Several laboratories have reported that the electrical test when conducted with 200ml of electrolyte as specified in clause L.3 fails to detect known holes in certain types of condoms and at specific locations. Clearly if true this could lead to a significant understatement of the number of non-complying condoms when this test is used.
4. It may be possible to improve the reliability of the electrical by making a number of changes to the protocol. These include but are not limited to increasing the electrolyte volume, increasing the voltage, increasing the hanging period prior to immersion in the electrolyte bath, adopting a double immersion protocol and/or introducing a two stage testing protocol such that the teat and closed end is tested first when the condom is only partially immersed, followed by complete immersion and testing as normal.
5. The modifications described in 4 above should reduce the risk of the electrical screening test failing to reject any non-conforming condoms but it is likely that the changes may also increase the risk of conforming condoms being incorrectly rejected at this stage of the test. Nevertheless any conforming condoms incorrectly rejected by the electrical test should still pass the rolled water test and be accepted.
6. In principle, assuming that the electrical phase of the test is capable of detecting all non-conforming condoms, the electrical and water tests should be equivalent since the presence of a hole in both cases has to be confirmed by the rolled water test using 300ml of water or electrolyte. In practice, however, the technician has much more time to look for a hole when using the electrical test procedure since only 5 or 6 condoms at most will be subject to inspection whereas when the water test is used the whole sample, typically 315 condoms, has to be examined. For this reason the electrical test may be more effective at detecting very small holes, particularly if changes are made to improve the sensitivity of the electrical phase of the test.

## Supporting Evidence

It is acknowledged that at present there is very little data to support the points raised above. A summary of two limited studies showing how changes to the electrical test protocol can affect the outcome are appended. A direct comparison across 14 lots of condoms comparing the outcome of a modified electrical test and the standard hang and roll water test is shown in the table below. Laboratory A used the electrical test, modified by using 400ml of electrolyte and allowing the tip of the condom to hang in the electrolyte for 6 seconds before full immersion, whereas Laboratory B used the water test exactly as described in Annex L Clause L.2. In both cases the presence of a hole was detected or confirmed by the rolling water test using 300ml of water or electrolyte.

Results for Laboratory A Confirmed Holes per Sample of 315 Using Electrical Test (400ml Electrolyte and “Tip Challenge” Protocol)	Results for Laboratory B Confirmed Holes per Ample of 315 Using Water Test With Rolling
4	1
9	0
7	0
9	2
13	2
13	1
4	4
13	2
6	5
6	1
8	6
4	3
6	3
11	3

The difference between the total number of holes summed across all lots for each laboratory is highly statistically significant ( $\chi^2 = 44.5$ ,  $p < 0.001$ ). The Wilcoxon signed rank test applied to the differences between the paired results also confirmed that the results from each laboratory were highly statistically significantly different. Clearly the electrical test, as modified by Laboratory A, detected far more non-complying condoms than did the standard water test with this specific type of condom despite the fact that in both cases the final test for confirming the presence of a hole was identical. Although these results suggest that there is a difference between the two test procedures other factors, such as poor lot and therefore sample homogeneity, may have contributed to the outcome.

## Discussion

The most comprehensive comparison completed to date comparing the electrical and water tests is the EU inter-laboratory study. Although the overall view was that the two tests were broadly equivalent when the results were averaged across all condom types some potentially important differences emerge when individual types of condoms are considered. For example, for deliberately punctured silicone lubricated

condoms the detection rate of the water test was approximately twice that of the electrical test (47.67% versus 22.04%). For silicone lubricated condoms with what were described as “natural holes” (these were condoms that had failed electronic testing during manufacture) the detection rate for the water test was ca 29% higher than for the electrical test (39.39% versus 30.49%). Similarly for normal production, silicone lubricated condoms of good quality the level of holes detected by the water test was again ca 29% higher than for the electrical test but the actual percentages of non-complying condoms were very small and this difference may not be of any statistical importance (0.18% versus 0.14%). Given the increasing importance of silicone as the lubricant of choice for condoms the implications of these results should be considered in more detail. The study itself was very complex and these top line results may not be statistically significant..

Although the data presented in this document support the position that it may be possible to improve the sensitivity of the electrical test, this is not the intention behind bringing the information to the attention of ISO/TC 157. What is of most importance is the possibility that the two tests for freedom from holes specified in ISO 4074:2002 may not be equivalent for all condom types. This position is supported by feedback from several laboratories and by the results for silicone lubricated condoms reported in the EU study. If true, then this is clearly unacceptable.

This document also emphasises the point that changes made to the electrical test can affect the final outcome despite the fact that the rolled water test remains the final arbiter of the presence or absence of a hole. No particular recommendations are being made in relation to the selection of one test over the other, nor concerning the specific modifications that were made to the electrical test. The recommendation is that more work needs to be done to investigate the equivalence of the two tests as currently specified in ISO 4074:2002.

W D Potter

July 2004

## Appendix: Additional Data

The two studies reported below are limited in scope and size but they do give some indication of how changes in the protocol for the electrical test may affect the outcome.

In the first study 20 condoms were selected at random from one lot. Of these 10 were punctured at the base of the tip using a sharp needle (diameter 0.55 mm) and a piece of hard plastic as an anvil. The remaining 10 condoms were punctured at a point 50 mm from the open end. These condoms were subjected to the electrical test using the following protocol:

1. The condoms were subjected to the electrical conductivity test as described in Annex L Clauses L.3.3.1 to L.3.3.6 using 200 ml of electrolyte but subject to one significant deviation from the standard protocol; the electrolyte was added to the condom as it was being immersed into the electrolyte bath.
2. The same condoms were then subject to the electrical conductivity test as described in Annex L Clauses L.3.3.1 to L.3.3.6 using 400 ml of electrolyte (again the electrolyte was added as the condoms were being immersed).
3. The same condoms were then subjected to the electrical conductivity test as described in Annex L Clauses L.3.3.1 to L.3.3.6 using 400 ml of electrolyte but this time the condoms were only partially immersed in the electrolyte bath then held for 6 seconds (this is called the “Tip Challenge” test). The condoms were then fully immersed and the test voltage applied

A non-conforming condom was defined as one for which the voltage exceeded 50mV at any stage during the test. The results are summarised in the table below.

Test	Non-conforming Condoms Found	
	At Tip	50 mm from Open End
Electrical test with 200 ml electrolyte	1/10	8/10
Electrical test with 400 ml electrolyte	4/10	10/10
Electrical test with 400 ml electrolyte and “Tip Challenge”	8/10	10/10

As can be seen from the table the ability of the test to detect condoms with known punctures increased as the volume of electrolyte is increased and the “Tip Challenge” test was used. Even when the “Tip Challenge” method was employed the rate of detection of punctured condoms at the tip is only 80%. The detection rate at the tip with 200 ml of electrolyte was particularly poor although this may have due to the deviation from the standard protocol noted above. Other factors may have contributed to the increase in sensitivity seen with the different procedures, for example progressive hydration and or stretching of the condoms as the different tests were performed

In a related study 315 condoms were drawn from on lot and subjected to the following sequence of tests (these condoms were not deliberately punctured):

1. All condoms were tested using the water test as defined in Annex L Clause L.2 of ISO 4074:2002 with the exception that the test was terminated after the hanging stage (Clause L.2.3.5). This was done since it was felt that rolling could damage the condoms for subsequent tests but it is recognised that the hanging test may not have found all the holes present.
2. The same condoms were then subjected to the electrical conductivity test as described in Annex L Clauses L.3.3.1 to L.3.3.6 using 200 ml of electrolyte (again there was a deviation from the standard protocol in that the electrolyte was added to the condom as it was being immersed).
3. The same condoms were then subject to the electrical conductivity test as described in Annex L Clauses L.3.3.1 to L.3.3.6 using 400 ml of electrolyte.
4. The same condoms were then subjected to the electrical conductivity test as described in Annex L Clauses L.3.3.1 to L.3.3.6 using 400 ml of electrolyte and the “Tip Challenge” test as described above.
5. In the above tests condoms for which the voltage exceeded 50 mV were noted as potential non-compliers and inspected for evidence of holes whilst still full of electrolyte but were not subject to rolling as described in Clauses L.2.3.7 to L.2.3.9.
6. After the final test any condom that had failed the electrical test (voltage exceeded 50 mV) but where a hole could not be detected by inspection was subjected to the rolling test using 300ml of water.

The outcome of the study is reported in the table below.

Test	Non-conforming Condoms Found	Comment
Water test (hanging only)	1/315	
Electrical test with 200 ml electrolyte	0/315	The defective condom found in hanging water test was not detected by the electrical test
Electrical test with 400 ml electrolyte	6/315	5 holes were verified by observation of visual leakage
Electrical test with 400 ml electrolyte and “Tip Challenge”	12/315	11 holes were verified by observation of visual leakage 1 hole was verified by rolling

It can be concluded from the above results that for this particular type of condom the electrical test using 200 ml of electrolyte did not detect any holes including the one found by the hanging water test. The deviation from the standard protocol, i.e. immersing the condom in the electrolyte bath concurrently with adding the electrolyte to the condom, may have contributed to the lack of sensitivity in this instance. Using 400 ml of electrolyte together with the “Tip Challenge” test detected the highest number of condoms with holes. It is probable that had the rolled water test been used

initially (rather than just the hanging test) more holes would have been found. Continuing hydration and repeated stretching of the condoms as the tests were performed sequentially may also have contributed to the increased detection rate.