

Electric Hole Tester (EHT)

Now Also Available with Tip Challenge Mode

Valendor introduces a new EHT with excellent hole detection ability and efficiency. All integrated in a tester requiring a minimum of space.

The Electric Hole Tester is designed for reliable and less operator-dependent testing of holes on condoms according to the international condom standard ISO 4074:2002 Annex K.3. The electric method is now also adopted by WHO.

IMPROVED HOLE DETECTION ABILITY

Valendor's research and innovations has resulted in this extraordinary machine, which combines several new features, added to the traditional electric hole tester. The new EHT offers flexibility to select the mode of test to suit the products and customer's need. Holes that have been difficult to detect with the water leak method and/or with the standard electric test method can now be easily detected by Valendor's new EHT. By using filling volumes from 200ml to 400 ml, combined with the unique Tip Challenge mode, guarantees that no holes are missed in the preliminary electric screening. The EHT also gives information about the location of the hole. On the other hand, since all holes shall be confirmed by manual rolling, the EHT screening method will in no way affect the acceptance/ rejection criteria according to the relevant standards.



TESTING EFFICIENCY

Since the condoms are automatically removed from the holders after the test, Valendor's Electric Hole Tester is more than 100% faster than conventional electric hole testers. For instance, testing a sample of 315 pcs takes less than 25 minutes. As a result the number of testers required as well as the number of operators will be reduced. Saves investment and operational labour costs.

TESTING PROCEDURE

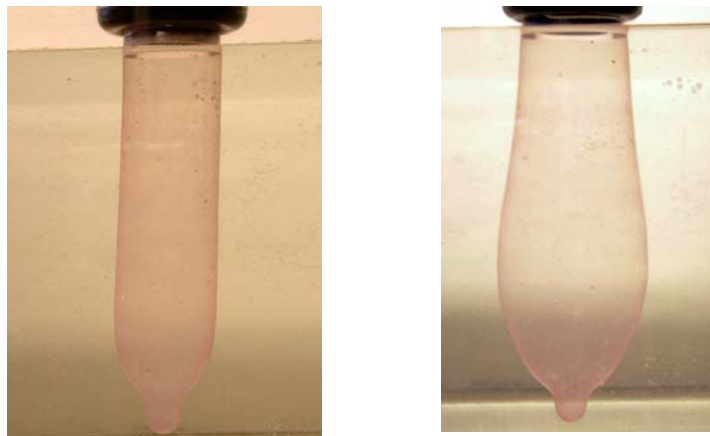
The operator places the condom on the mount and starts the automatic testing sequence of each individual condom. The condom will be submerged in the electrolyte container below and measured for leaks after 10 seconds. If the reading is less than 50 mV, the condom is automatically removed from the holder. After loading the first condom the operator continues

with loading number 2, 3 and 4. When loading of number 4 is completed, the first test probe is ready for a new condom and then number 2 etc.

In case the electrical reading indicates a hole, the condom remains on the holder and can be removed by the operator to verify the possible hole by rolling the condom on absorbed paper.

STANDARD AND FORCED EXTENSION TEST

By filling the condom with more than 200 ml (preferably 400ml) of electrolyte, a controlled forced extension of the submerged condom is achieved. This enables the latex to stretch and holes, not detectable in the "Standard Test", will be detected using this method. The "Forced Extension Test" is performed in the same manner as the "Standard Test"



There is a clear difference in the stretching of the submerged condoms. Standard test with 200 ml (left) and Forced Extension with 400 ml (right).

TIP CHALLENGE MODE

The Tip Challenge mode is designed particularly for testing condoms with thicker wall in the tip and closed end. The design and the shape of a normal condom support the closed end and prevent the latex film to stretch equally to the parallel sides when a condom is filled with fluid. If there are tiny holes in the closed end, these might be kept closed by the latex film when the filled condom is submerged in the electrolyte and thereby preventing the holes to be detected.

The Tip Challenge will stop the submerging movement and let the filled condom hang high enough for only the tip to be submerged in the electrolyte. This will allow the filled volume of water to "challenge" the tip, since most of the water filled in the condom will stretch the closed end of the condom. This will stretch the latex film of the tip and thereby facilitate detection of holes in this area.



Tip Challenge with 400 ml

When should Tip Challenge be used?



Article No. 1101 & 1102, 2004-04

- The Tip Challenge Mode can be used in all testing, since it will not affect the acceptance and rejection criteria.
- If you are manufacturing condoms with thicker wall in the tip and closed end, the Tip Challenge Mode is highly recommended.
- The "Tip Challenge Test" is an outstanding tool for process validation and in the R&D process.

Test data acquisition, analysis, display and storage

All test data are displayed in real-time on a computer monitor. The voltage reading for each individual condom is saved in data file simultaneous with the reading as well. That means that no data will be lost in case of power failure. The system produces automatically a test certificate including the name and logo of the laboratory (if desired), all particulars as specified in ISO 4074 as well as the position of the hole. Or any special requests specified by the laboratory. The test data can be exported for further analysis.

Valendor's testing software is fully compatible with Microsoft Office. (Excel, Word, Access).

Specifications	
Voltage supply	(10 ± 0.5) V
Leak detection threshold	(50 ± 1) mV
Dimensions:	
Length	900 mm
Width	300 mm
Height	1700 mm

VALENDOR reserves the right to modify this specification in part or as a whole.



Article No. 1101 & 1102, 2004-04

Re: Application of ISO 4074 Annex L, Testing for holes

The procedure for Electrical Test specifies (in L.3.3.6) the condom to be filled with 200 +/- 10 ml electrolyte.

Proposal to amendment:

An amendment of the current standard has been proposed in order to replace 200 +/- 10 ml electrolyte with: *at least 200 ml electrolyte*.

The current wording 200 +/- 10 ml limits the volume of electrolyte that can be used.

By limiting the filling volume to 200ml, (which in sensitivity correspond with the acceptance criteria for the verification by manual rolling) means that there is 50% chance of detecting/not detecting holes of the size corresponding to the intended acceptance limit.

To use electrolyte volumes above 200 ml will in no way make the requirement in the standard more stringent, because the final accepted/rejected criteria is still determined by the manual rolling and not using the outcome of the preliminary electrical test. Increasing the filling volume to 400 ml improves the reliability of the test.

Application of filling volume of 400 ml:

The general opinion among experts within standardisation and condom quality (among others Dr. Bill Potter, CEN PL) is, that the use of higher filling volumes (i.e. 400ml) is not in violation with the standard, since the electrolyte volume in the preliminary electric screening doesn't affect the acceptance criteria.

However, would the authority concerned, contrary to all expectation, require the use of 200 +/- 10 ml filling volume, you can always re-test the condoms indicating holes at 400ml, using 200ml filling volume. The tricky question in this case may be whether to perform the final test on a condom indicating hole at 400ml but not at 200ml.

Jarmo Gustavsson
Managing Director