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Guidance on sample handling for determination of bursting volume and pressure, and testing for freedom from holes for male condom

Mode opératoire de préparation pour les méthodes d'essai d'éclatement et d'essai de résistance au trou des préservatifs de faible épaisseur

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 157, *Non-systematic contraceptive and STI barrier prophylactics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Recent analyses of male condom samples from different manufacturers that have failed the freedom from holes test suggest that some of the holes observed in the samples are caused by damage when the samples are being prepared for testing in the laboratory. There have also been reports of incorrect results when testing condoms for bursting volume and pressure caused by poor handling of the condoms, for example by excessively stretching the samples when mounting them on the burst testing apparatus. This leads to the development of a guidance for preparation procedures of test samples or test pieces such as test for holes and bursting volume and pressure.

An interlaboratory study comparing the results for tests for freedom from holes and burst properties from different laboratories has been completed. Thin natural rubber latex condoms and polyurethane condoms were used in this study. The study identified various handling procedures that could lead to incorrect results. Based on this study, a set of standardized handling procedures have been developed to minimize the risk of incorrect results being obtained.

This document describes these standardized handling procedures which are designed to minimize unintentional damage to the condoms during sample preparation and testing procedure in the laboratory. It is expected for the procedures described in this document to improve the reproducibility of test results between laboratories. This document helps improve the precisions of mechanical testing for male condoms as specified in ISO 4074 and ISO 23409.

The guidance given in this document is intended for laboratory testing only. It is not intended for condom users and should not be included in the instructions for use for condom users.

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Guidance on sample handling for determination of bursting volume and pressure, and testing for freedom from holes for male condom

1 Scope

This document gives guidance on the procedures for sample preparation for determining bursting volume and pressure and testing male condoms for freedom from holes.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
individual container
primary package containing a single condom

3.2
lubricant
material which is applied to lubricate the surface of the condom and make it easier to unroll

3.3
protective gloves
gloves to protect the condom from handling damage

EXAMPLE Seamless gloves (e.g. non-sterile medical examination glove).

3.4
rod or mandrel
device used to support the condom during bursting volume and pressure

3.5
external clamping device
clamp which holds the condom to permit it to be inflated without leaking

3.6
coloured absorbent paper
water absorbing paper used during water leakage test to examine the condom sample is free from pinhole

Note 1 to entry: See 5.9 and Figure 1.

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a) Appropriate example



b) Inappropriate example
adhesive tape stuck on the absorbent paper

Figure 1 — Coloured absorbent paper

3.7
mount
part of the water leakage testing device with appropriate diameter according to type and material of the condom used to mount condom sample

4 Sample handling procedure for determining bursting volume and pressure

4.1 Before commencing testing of a new material, the following should be checked:

a) pressure transducer range is appropriate to the products;

b) pressure transducer is calibrated over the range of pressure expected;

c) clamping device that will hold the condom without slipping until it burst.

Abnormal or unexpected results, such as those outside the normal or expected range, or outside the calibrated operating range should be investigated and noted before results are reported.

4.2 Protective gloves should be worn while handling and unrolling the condom.

It is recommended for seamless gloves (e.g. non-sterile medical examination glove) to be worn.

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