TECHNICAL REPORT

ISO/TR 19969

First edition
2018-10

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

Reference number
ISO/TR 19969:2018(E)

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

Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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.

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.

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.

☑

☒

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;

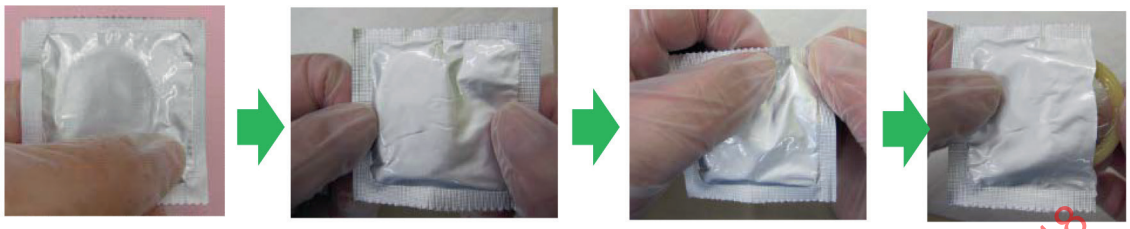
c) clamping device that will hold the condom without slipping until it burst.

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.

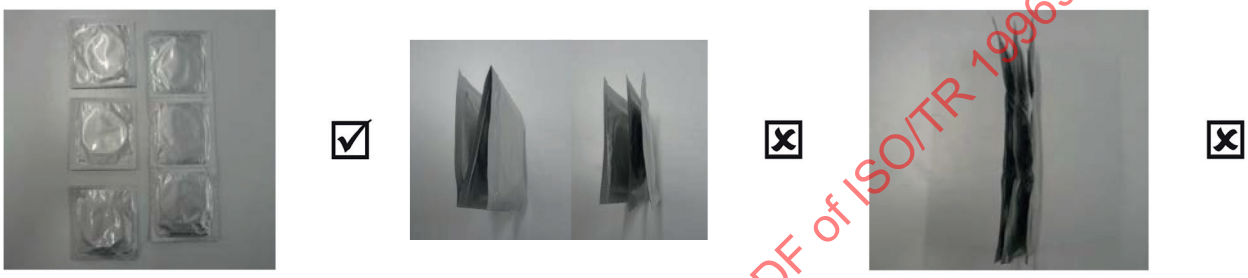
4.2 Protective gloves should be worn while handling and unrolling the condom.

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

4.3 The condom should be moved inside the individual container such that it is away from the area where the container is to be torn. This is to prevent the risk of damaging the condom when the individual container is torn open. Each individual container should be opened separately (see Figure 2).



a) Procedures for unpackaging



b) Appropriate example

(1 strip of individual containers or separate of individual container)

c) Inappropriate example

(a few individual containers)

d) Inappropriate example

(a few strips of individual containers)

Figure 2 — Unpackaging

Scissors or other sharp instruments should not be used to open the individual container. Such instruments could damage the condoms.

4.4 The condom should be tested as soon as possible after removal from the individual container to minimize the impact of any environmental damage caused, for example by exposure to light (particularly UV and fluorescent lights) and ozone.

Testing is preferably started within 1 h, but definitely within 4 h.

4.5 Before each group of tests, it should be confirmed that the surface of the rod or the mandrel is smooth, free from damage or scratches and free from particulate contamination that could damage the condom.

4.6 Condoms that are already rolled are carefully and evenly unrolled over the mandrel using both hands so it fits uniformly on the mandrel (see Figure 3). Extra care should be taken to use minimum stretching and force. Excessive force may cause breakage and incorrect results (see Figure 4).

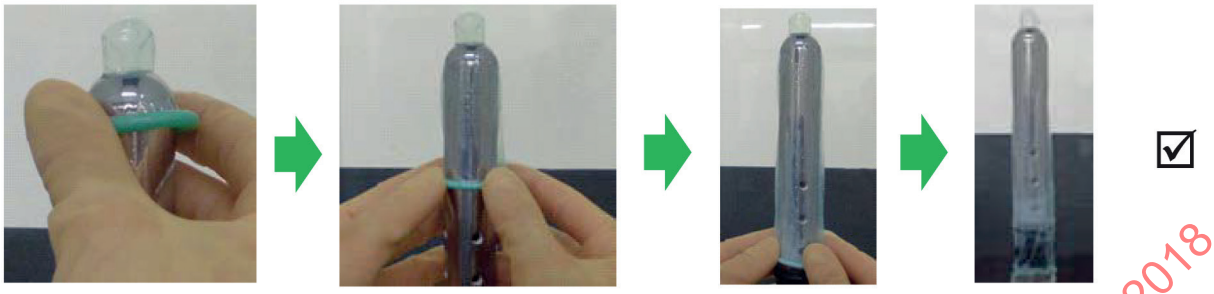


Figure 3 — Direct unrolling on the rod or the mandrel

Figure 4 — Inappropriate example of direct unrolling on the rod or the mandrel

For dry condoms which are not rolled (e.g. in-process samples), the condom may be pulled carefully over the mandrel to position it evenly for testing.

4.7 The external clamping device is set carefully without knocking the condom (see Figure 5).

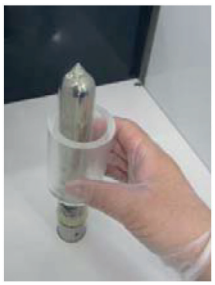


Figure 5 — Setting the external clamping device

5 Sample handling procedure for determining hole test

5.1 Protective gloves should be worn while handling and unrolling the condom to prevent damage caused by finger nails and rough skin. Jewellery such as rings should preferably be removed.

5.2 The condom should be moved inside the individual container such that it is away from the area where the container is to be torn. This is to prevent the risk of damaging the condom when the individual

container is torn open. Each individual container should be opened separately by tearing the container (see Figure 2).

Scissors or other sharp instruments should not be used to open the individual container. Such instruments could damage the condoms.

5.3 The condom should be tested as soon as possible after removal from the individual container to minimize the impact of any environmental damage caused, for example by exposure to light (particularly UV and fluorescent light) and ozone.

Testing is preferably started within 1 h, but definitely within 4 h.

5.4 Two preferred methods of unrolling condoms are recommended based on the studies to minimize damage.

NOTE 1 In some cases, uneven unrolling can cause microscopic damage.

NOTE 2 The two methods are not equally applicable to all types of condom. It might be necessary to establish which one works best for any particular product.

a) Method 1

The condom is gently unrolled onto the index and second finger of one hand. Then, holding the closed end or teat between the thumb and index finger of the other hand, the condom is unrolled by gently repeatedly expanding the two fingers inside the condom while gently pulling the closed end (see Figure 6).

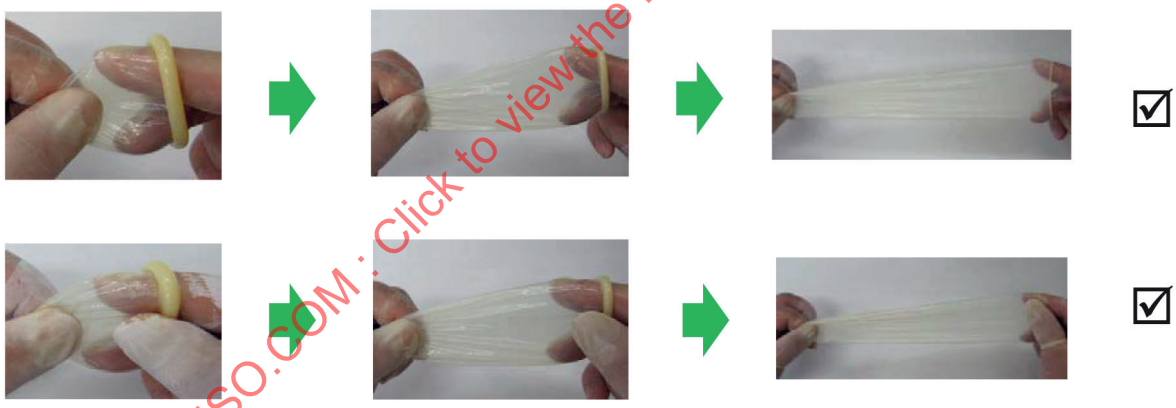


Figure 6 — Unrolling method 1

b) Method 2

A ring is formed with the thumb and index finger of one hand. That hand is placed so the ring is horizontal in front of the person testing with the fingers underneath the condom. With the other hand, the rolled condom is rested on the ring with the teat emerging from the centre of the roll and pointing downwards through the ring. Then, from underneath the ring, the teat is pulled gently to unroll the condom through the ring. An appropriately sized smooth-edged hole in a suitable plastic or metal plate may be used instead of the finger ring if desired (see Figure 7).

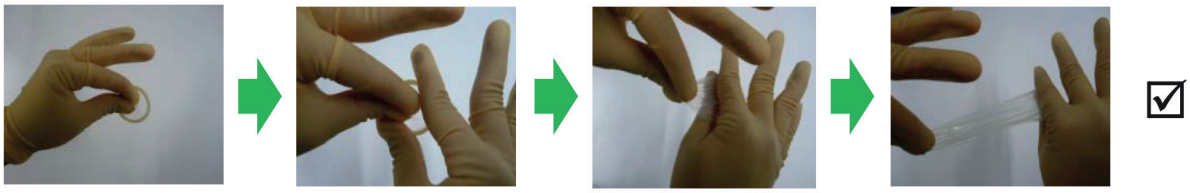


Figure 7 — Unrolling method 2

5.5 The condom is inspected for any visible defects, as described in ISO 4074 and ISO 23409, including broken, missing or severely distorted beads and any visible holes within 25 mm of the bead (including any holes between the bead and the body of the condom). If necessary to remove any temporary creases, air is gently blown into the open end of the condom at about 50 mm from the mouth (i.e. without the lips touching the condom). The closed end is then carefully squeezed between the fingers to seal the air in the condom. The condom should not be stretched. Check the body and closed end of the condom for any visible holes or any permanent creases (see Figure 8).

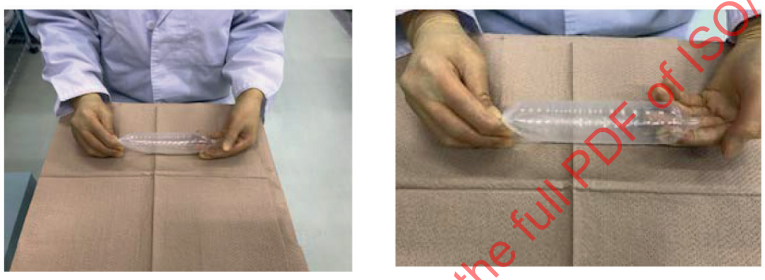


Figure 8 — Visual inspection

5.6 Both hands are used to attach the condom to the mount of the water leak test or electrical test equipment to make sure that it fits uniformly on the mount (see Figure 9). The condom should be stretched as little as possible, i.e. just sufficient to allow the open end to be placed over the mount and not more than 100 % (see Figure 10).

Figure 9 — Attaching the condom sample to the mount of the water leak or electrical test equipment