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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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## 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](http://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](http://www.iso.org/patents)).

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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](http://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](http://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](#).