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Male condoms — Requirements and test methods for condoms made from synthetic materials

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National foreword

This British Standard is the UK implementation of ISO 23409:2011.

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A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Male condoms — Requirements and test methods for condoms made from synthetic materials

Préservatifs masculins — Exigences et méthodes d'essai pour les préservatifs fabriqués en matières synthétiques

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 23409 was prepared by Technical Committee ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*.

Introduction

Synthetic condoms can be made from 100 % synthetic materials or a blend of synthetic materials and natural rubber latex. The material(s) used in synthetic condoms should be validated as constituting a barrier to human immunodeficiency virus (HIV), to other infectious agents responsible for the transmission of sexually transmitted infections (STIs), and to spermatozoa. It is essential that the condoms fit the penis properly, remain on the penis during use, are free from holes and have adequate physical strength so as not to break or tear during use so that the condoms can be deemed to be effective for contraceptive purposes and in order to help prevent the transmission of STIs. It is also important that they be correctly packaged so that they are protected during storage and suitably labelled. All of these issues are addressed in this International Standard.

To be safe, it is essential that the condom and any lubricant, additive, marking materials, dressing, individual packaging material or powder applied to it neither contain nor liberate substances in amounts that are toxic, likely to produce allergies (sensitization), locally irritating or otherwise harmful under normal conditions of storage and use.

Condoms are medical devices. To ensure high quality product, it is essential that condoms be produced under a quality management system using design controls. Reference can be made, for example, to ISO 9001[4], to ISO 14971, and to ISO 13485[8]. Additional guidance can be found in ISO 16038[9].

Condoms are non-sterile medical devices; however, a clean environment is essential to minimize microbiological contamination of the product during manufacturing and packaging.

Condoms can be of the designs given in the following terms, which are not intended to be exhaustive: smooth, textured, parallel-sided, non-parallel-sided, plain-ended, reservoir-ended, dry, lubricated, transparent, translucent, opaque, coloured, preshaped, welded or non-welded.

This International Standard specifies preclinical, clinical, and lot-by-lot physical requirement testing for condoms made from synthetic materials, including condoms made from a blend of synthetic materials and natural rubber latex. Application of lot-by-lot testing requirements becomes relevant only after the preclinical and clinical requirements of this International Standard have been met.

INTERNATIONAL STANDARD ISO 23409:2011(E)

Male condoms — Requirements and test methods for condoms made from synthetic materials

1 Scope

This International Standard specifies the minimum requirements and the test methods applicable to male condoms produced from synthetic materials or blends of synthetic materials and natural rubber latex which are used for contraceptive purposes and to aid in the prevention of sexually transmitted infections.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

ISO 4074, *Natural latex rubber condoms — Requirements and test methods*

ISO/TR 8550 (all parts), *Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for* in vitro *cytotoxicity*

ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223 (all parts), *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied*

ISO 16037, *Rubber condoms for clinical trials — Measurement of physical properties*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 2859-1 and the following apply.

3.1
acceptance quality limit
AQL
quality level that is the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling

[ISO 2859-1:1999, 3.1.26]

3.2
male condom
medical device, intended to cover and to be retained on the penis during sexual activity, used by consumers for purposes of contraception and prevention of sexually transmitted infections

NOTE If a consumer can responsibly consider a device to be a male condom (due to its shape, packaging, etc.) it is considered to be a male condom for the purposes of this International Standard.

3.3
consumer package
package, intended for distribution to a consumer, containing one or more individual containers of condoms

3.4
expiry date
date after which a condom is not suitable for use

3.5
identification number
number, or combination of numerals, symbols or letters, used by a manufacturer on consumer packages to identify uniquely the lot numbers of individual condoms contained in that package, and from which it is possible to trace those lots through all stages of manufacturing, packaging and distribution

NOTE When the consumer package contains only one type of condom, then the identification number can be the same as the lot number. However, if the consumer package contains several different types of condoms, e.g. condoms of different shapes or colours, then the identification number is different from the lot numbers.

3.6
individual container
primary package containing a single condom

3.7
inspection level
relationship between lot size and sample size

NOTE For a description, see ISO 2859-1:1999, 10.1.

3.8
lot
collection of condoms of the same design, colour, shape, size and formulation, manufactured at essentially the same time, using the same process, raw materials of the same specifications and common equipment, and packed with the same lubricant and any other additive or dressing in the same type of individual container

3.9
lot number
number, or combination of numerals, symbols or letters, used by the manufacturer to identify a lot of individually packaged condoms, and from which it is possible to trace that lot through all the stages of manufacture up to packaging

3.10
lot test
test to assess the conformity of a lot

NOTE A lot test may be limited to include only those parameters that can change from lot to lot.

3.11
non-visible hole
hole in a condom that is not visible under normal or corrected vision, but is detected by a suitable water leak test or electrical test

NOTE Suitable tests are specified in this International Standard.

3.12
sampling plan
specific plan which indicates the number of units of product from each lot which are to be inspected (sample size or series of sample sizes) and the associated criteria for determining the acceptability of the lot (acceptance and rejection numbers)

3.13
shelf-life
period from date of manufacture, during which condoms are required to conform to specified requirements for burst pressure, burst volume, freedom from holes, and pack integrity

NOTE Suitable requirements are specified in this International Standard.

3.14
synthetic material
any base material other than 100 % natural rubber latex that is used to make condoms

NOTE This term applies to both condoms made from all synthetic materials and to condoms made from synthetic and latex blends.

3.15
visible hole
hole in the condom that is visible under normal or corrected vision before the condom is filled with water or electrolyte during testing for freedom from holes

3.16
date of manufacture
date of sheath formation or the date the condoms are packed in their individual containers provided that, in the latter case, a maximum period of bulk storage is specified and shelf-life studies have been conducted on condoms that have been subjected to the maximum bulk storage period

3.17
visible defect (other than hole or tear)
broken, missing or severely distorted rim, and permanent creases with adhesion of the film

4 Quality verification

Condoms are mass produced articles manufactured in very large quantities. Inevitably, there is some variation between individual condoms, and a small portion of condoms in each production run that might not meet the requirements of this International Standard. Further, the majority of the test methods described in this International Standard are destructive. For these reasons, the only practicable method of assessing conformity with this International Standard is by testing a representative sample from a lot or series of lots. Basic sampling plans are given in ISO 2859-1. Refer to ISO/TR 8550 for guidance on the selection of an acceptance sampling system, scheme or plan for the inspection of discrete items in a lot. For testing purposes, sampling shall be conducted by lot number, not by identification number.

When ongoing verification is required of the quality of condoms, it is recommended that, instead of concentrating solely on evaluation of the final product, the party concerned also directs their attention to the manufacturer's quality system. In this connection it should be noted that the ISO 9000[3] family and in particular ISO 13485[8] cover the provision of an integrated quality system.

Sampling plans shall be selected to provide an acceptable level of consumer protection. Suitable sampling plans are given in Annexes A and B.

a) Annex A describes sampling plans based on ISO 2859-1 and is most applicable to manufacturers or purchasers assessing the conformity of a continuing series of lots. The full level of consumer protection available depends upon the switch to tightened inspection if deterioration in quality is detected. The switching rules cannot offer their full protection for the first two lots tested, but become progressively more

effective as the number of lots in a series increases. The sampling plans in Annex A are recommended when five or more lots are being tested.

b) Annex B describes sampling plans, based on ISO 2859-1, that are recommended for the assessment of isolated lots. The sampling plans in Annex B provide approximately the same level of consumer protection as those given in Annex A when used with switching rules. It is recommended that these sampling plans be used for the assessment of fewer than five lots, e.g. in cases of dispute, for referee purposes, for type testing, for qualification purposes or for short runs of continuous lots.

c) Handling and storage conditions shall be documented before drawing the samples.

It is necessary to know the lot size in order to derive from ISO 2859-1 the number of condoms to be tested. The lot size varies between manufacturers and is regarded as part of the process and quality controls used by the manufacturer.

5 Lot size

The maximum individual lot size for production is 500 000.

Otherwise, this International Standard does not specify the size of a lot, but it is possible for a purchaser to do so as part of the purchasing contract. Purchasers are encouraged to specify a lot size compatible with the manufacturer's quality management system.

6 Biocompatibility

For any product which is new or which has undergone a significant change to the formulation or manufacturing process, biocompatibility assessments shall be conducted in accordance with ISO 10993-1. Testing for cytotoxicity according to ISO 10993-5, irritation according to ISO 10993-10, and sensitization (delayed contact hypersensitivity) according to ISO 10993-10 shall be conducted. Many synthetic products that have been established as safe, including condoms and medical gloves, can exhibit a positive cytotoxic response when tested according to ISO 10993-5. While any cytotoxic effect can be of concern, it is primarily an indication of potential for *in vivo* toxicity and a condom cannot necessarily be determined to be unsuitable for use based solely on cytotoxicity data. The condom together with the any lubricant, additive, dressing material, or powder applied to it shall be tested. Regulatory bodies might also specify specific local requirements. Accredited laboratories shall be used for the testing. Regulatory bodies might require the results to be interpreted by a qualified toxicologist or other suitably qualified expert. The biological assessment report shall justify that the product is safe under normal conditions of use.

7 Product claims

Condoms meeting the requirements of this International Standard can be used for contraceptive purposes and help protect against sexually transmitted infections. Manufacturers shall justify any additional claims made for their products. If a manufacturer makes a claim relating to improved efficacy or safety then the claim shall be substantiated by clinical investigation. Manufacturers shall make information justifying such claims available to regulatory bodies, notified bodies, and consumer protection authorities.

8 Design

8.1 Retention mechanism

If a mechanism to retain the condom on the penis or an integral bead is required by the condom design, then it shall comply with Clause 14.

8.2 Lubrication

If verification is required of the quantity of lubricant in a package, the method given in Annex C shall be used. The criteria of compliance shall be as agreed between the parties concerned.

The method in Annex C also recovers part of the dressing powder on the condom. An allowance should be made for this when manufacturers or purchasers specify lubricant levels.

8.3 Dimensions

8.3.1 Length

When tested according to the method given in Annex D, taking 13 condoms from each lot, no individual measurement shall be below 160 mm.

8.3.2 Width

When tested by the method given in Annex E, measuring at the narrowest part of the condom in the range of 20 mm to 50 mm from the open end, taking 13 condoms from each lot, no measurement of the width shall deviate from the nominal width stated by the manufacturer by more than ±2 mm.

Where the design of the condom is such that this measurement cannot be made reliably or the narrowest point within the first 50 mm from the open end of the condom is at the bead, the method of measurement shall be provided by the manufacturer.

8.3.3 Thickness

If verification is required of the thickness of a condom, the thickness, determined in accordance with the method given in Annex F, shall be equal to the claimed thickness, subject to a tolerance of:

a) ±0,008 mm for condoms with thickness less than 0,05 mm;

b) ±0,01 mm for condoms with thickness between 0,05 mm and 0,08 mm;

c) ±0,015 mm for condoms with thickness greater than 0,08 mm.

9 Preclinical evaluation

A risk analysis of the product shall be conducted in accordance with ISO 14971. The analysis shall identify safety and efficacy concerns, and shall address at least the areas where the risks are in excess of those encountered with natural rubber latex condoms conforming to ISO 4074.

The barrier properties of the condom shall be established by viral penetration studies using simulated use conditions and a suitable surrogate virus, e.g. bacteriophage phiX 174. Viral penetration properties shall be compared with those of a latex condom that meets the requirements of ISO 4074. A suitable procedure for conducting these studies is given in Annex G. The number of test condoms exhibiting leakage of virus suspension fluid above the detection limit of 2×10^{-6} ml should not be significantly worse than for the control latex condom. Appropriate statistical procedures may be used to analyse the results using a 95 % confidence interval.

Biocompatibility for the finished product and its components shall be established in accordance with the relevant clauses of ISO 10993-1, ISO 10993-5, and ISO 10993-10. Condoms are a surface device with repeated contact with mucosa and possibly compromised tissue surfaces. The tests shall indicate whether the device produces cytotoxicity, sensitization, or mucosal irritation. It is possible for additional testing, e.g. for systemic toxicity in accordance with ISO 10993-11[6], to be required, depending upon the nature of the materials used or to meet local regulatory requirements. If there is a likelihood of systemic absorption of any

components or residuals, mutagenicity testing shall be performed. Regulatory bodies can require the results to be interpreted by a qualified toxicologist or suitably qualified scientist. The biological assessment report shall justify that the product is safe under normal conditions of use.

All data generated in these investigations shall be available to regulatory authorities on request.

The manufacturer shall obtain, and make available on request from regulatory authorities, toxicity data on all the additives and residual monomers, residual solvents and known impurities resulting from the manufacture of the condom. Suitable material safety data sheets are to be supplied as requested for materials used in the manufacture of products in compliance with this International Standard.

10 Clinical (human use) investigations

The manufacturer shall conduct a randomized controlled clinical investigation comparing the synthetic condom to a control condom made from natural rubber latex.

a) Clinical investigations in humans shall be conducted in accordance with local regulatory requirements, as well as ISO 14155.

b) The clinical failure rate (combined slippage and breakage rates) of the synthetic condom shall be non-inferior to the clinical failure rate of the control condom made from natural rubber latex.

c) In order to demonstrate non-inferiority the upper limit of the one-sided 95 % confidence interval for the test condom clinical failure rate minus the control condom clinical failure rate shall be less than or equal to 2,5 %.

   The limit shall be calculated using a method that accounts for the unique characteristics of data such as:

   1) each study participant may contribute data from more than one condom use;

   2) very low event rates.

d) For the control condom, the clinical failure rate shall be less than 4,0 %.

e) The control condom shall be made from natural rubber latex and shall conform to ISO 4074.

f) The physical properties of the natural rubber control condom shall be determined in accordance with ISO 16037.

NOTE See ISO 29943-1[10].

For products in the market prior to the publication of this International Standard, manufacturers may use data from existing clinical investigations. Information on the studies shall be made available to regulatory and governmental authorities upon request.

11 Bursting volume and pressure

Manufacturers shall establish appropriate minimum pressure and volume limits for the specific condom based on the airburst properties of the lot or lots used for the clinical trial. Determine the airburst properties of the lot or lots used in the clinical study using a sample size of at least 2 000 condoms. If more than one lot was used in the clinical study then the sample shall be drawn across all the lots, each individual lot being sampled proportionally to its size. Set the minimum airburst limits at 80 % of the 1,5 percentile values of the airburst volumes and pressures determined above.

For the purposes of this International Standard, the relevant percentile, x, shall be determined by ranking the N data values and taking the value of the nth rank, where

$$n = \frac{Nx}{100} + \frac{1}{2}$$

rounded to the nearest integer (e.g. for $N = 2\,000$, the lower 1,5 percentile is the 31st lowest value).

NOTE 1 Based on data supplied by manufacturers for both synthetic and natural rubber latex condoms, taking 80 % of the 1,5 percentile values provides an adequate tolerance for the long-term lot-to-lot variability seen in normal manufacture.

For products in the market prior to the publication of this International Standard, manufacturers may use existing specifications as established by their regulatory bodies for bursting properties, subject to those specifications being consistent with the above requirements based on a representative sample of the product tested at the time of the clinical trial. Information regarding the establishment of these values shall be made available to regulatory and governmental authorities upon request.

NOTE 2 To ensure that the limits are appropriate, testing can be done by a laboratory accredited to ISO/IEC 17025[32], by an accreditation body, or organization that is a member of the International Laboratory Accreditation Cooperation.

When tested using the methods given in Annex H, the bursting volumes and bursting pressures shall not be less than the minimum values specified above. The compliance level shall be an acceptance quality limit (AQL) of 1,5 for non-conforming condoms. A non-conforming condom is defined as a condom that fails the requirements for volume, pressure or both, or any condom that exhibits obvious leakage.

12 Freedom from holes

When tested by the methods described in Annex J, the compliance level for each lot, for the sum of condoms with visible and non-visible holes and tears, shall be an AQL of 0,25.

13 Stability and shelf-life

13.1 General

Manufacturers shall verify that the condoms comply with the requirements of Clauses 11, 12, and 15 until the end of the shelf-life on the label. Shelf-life claims shall not exceed 5 years.

Data supporting shelf-life claims shall be made available to the appropriate regulatory authorities and direct purchasers upon request.

Before compliance with this International Standard may be claimed, the manufacturer shall provide evidence that:

a) a real-time study as described in 13.2 to determine shelf-life has commenced;

b) pending completion of the real-time study, shelf-life claims as described in 13.3 can be substantiated.

13.2 Procedure for determining shelf-life by real-time stability studies

After testing according to Annex K, the condom shall meet the requirements of Clauses 11, 12 and 15.

If the real-time data indicate a shorter shelf-life than that claimed on the basis of accelerated ageing (13.3), the manufacturer shall notify the relevant regulatory authorities and direct purchasers. The manufacturer shall change the shelf-life claims for the product to the one based on the real-time study. In no case shall the shelf-life exceed 5 years.

For condoms placed on the market based on accelerated stability studies, real-time stability studies shall be completed for the full period of the shelf-life claim.

13.3 Estimating shelf-life based upon accelerated stability studies

Pending the completion of real-time studies, manufacturers shall substantiate the original shelf-life claims. Accelerated stability studies may be used for this purpose.

Further information on stability studies is provided in Annex L. Data generated from such studies should support the claim that the condoms fulfil the requirements in Clauses 11, 12, and 15 for the duration of the shelf-life on the label at $30\,^{+5}_{-2}\,°C$.

14 Visible defects

For visible defects as described in Annex J (J.2.3.3), the compliance level for each lot shall be an AQL of 0,4.

15 Package integrity for individual container

When an individual container comprising one or more flexible laminated films sealed together is tested in accordance with Annex M, it shall pass the test. The compliance level for each test shall be an AQL of 2,5. An AQL of 0,4 shall be applied to individual containers that have visibly open seals.

For other designs of individual containers, the manufacturer shall apply a suitable pack integrity test. The compliance level for each test shall be an AQL of 2,5. The method given in Annex M may be used with suitable adjustment to the level of vacuum applied. Details of the test method shall be provided on request.

16 Packaging and labelling

16.1 Packaging

Each condom shall be packed in an individual container. One or more individual containers may be packed in other packaging such as a consumer package. The individual container, or consumer package or both, shall protect the condom from environmental damage as is appropriate for the product. If condoms are supplied directly to consumers in individual containers then the individual container shall be regarded as a consumer package and shall meet all the labelling requirements.

Any marking medium, such as ink, used on a condom or any part of the package directly in contact with the condom, shall not have a deleterious effect on the condom or be harmful to the user.

Individual containers and any other packaging shall protect the condom from damage during transport or storage. Individual containers and any other packaging shall be designed in such a way that the package can be opened without damaging the condom. The design of the individual container should facilitate easy opening.

Manufacturers shall ensure that each lot complies with the established specification for packaging.

16.2 Labelling

NOTE National or other regulations relating to labelling, e.g. for latex allergy, which could be more stringent, can apply.

16.2.1 Symbols

Any symbols used on packaging, information, and marketing materials shall meet the requirements of ISO 15223.

16.2.2 Individual container

Each individual container shall be indelibly and legibly marked with at least the following information:

a) the identity of the manufacturer or distributor or, if permitted by local regulations, the registered brand or trade mark;

b) the manufacturer's identifying reference for traceability (e.g. the lot number);

c) the expiry date (year and month) — the format of the year shall be in four digits and the format of the month shall be in letters or two digits.

If the individual container is distributed outside a consumer pack within Europe then the CE Mark and address of the manufacturer or European Authorized Representative shall be printed on the individual pack and the requirements of 16.2.4 shall be met.

16.2.3 Consumer package

16.2.3.1 General. Where products are supplied for distribution in consumer packages, the packages shall conform to the requirements of 16.2.3.2 and 16.2.3.3.

16.2.3.2 Consumer package exterior. The outside of the consumer package shall bear at least the following information in at least one of the official languages of the country of destination or as stipulated differently by that country or the purchaser and the seller:

a) a description of the condom, whether it is contoured or has a reservoir, and if it is coloured or textured;

b) the number of condoms contained in the consumer package;

c) the nominal width of the condom;

d) the name or trade name and address of the manufacturer and/or distributor, depending on national and regional requirements;

e) the expiry date (year-month or month-year). If a consumer package contains condoms from different lots, the earliest expiry date shall apply to all condoms;

f) a statement of storage instructions appropriate for the material used;

g) conditions that are impervious to light or other environmental conditions deleterious to the packaging of the condom;

h) whether the condom is lubricated or dry — when a medicinal ingredient is added, it shall be identified and its purpose indicated (e.g. spermicidal), and if the condom or lubricant is fragranced or flavoured, this shall also be stated;

i) the manufacturer's identifying reference for traceability (e.g. the identification number/lot number) — if different types of condoms, e.g. of different colours, are packaged together in the same consumer package, the identification number on the consumer package shall allow the manufacturer to identify uniquely the lot numbers of the individual condoms contained in that package, so that it is possible to trace those lots through all stages of manufacture up to packaging;

j) a statement indicating the type of synthetic material used, and whether the material contains natural rubber;

k) a statement indicating that the condom is for single use;

l) the number of this International Standard (ISO 23409:2010);

m) any other applicable warning as required;

n) if necessary, a statement alerting consumers to any potential allergic reactions as a result of product use.

16.2.3.3 Instructions for use. The outside or the inside of the consumer package, or a leaflet contained within the consumer package, shall bear at least the following instructions for use expressed in simple terms and in at least one of the official languages of the country of destination, if possible supplemented by pictorial representation of the major steps involved or as stipulated differently by that country:

a) the need to handle the condom carefully, including removal from the packaging in order to avoid damage to the condom with fingernails, jewellery, etc.;

b) how and when to put on the condom; mention should be made that the condom should be placed on the erect penis before any contact occurs between the penis and the partner's body so as to assist in the prevention of sexually transmitted infections and pregnancy;

c) the need to stop and check if the user feels the condom slipping or tightening excessively on to the penis because this can lead to breakage;

d) the need to withdraw the penis soon after ejaculation, while holding the condom firmly in place at the base of the penis;

e) the need, if an additional lubricant is desired, to use the correct type of lubricant which is recommended for use with the type of condom concerned;

f) the need to consult a doctor or pharmacist about the compatibility of topical medicines that might come in contact with the condom;

g) advice to seek medical assistance as soon as possible, at least within 72 h should a condom leak or burst during use;

h) advice that if the individual container is obviously damaged to discard that condom and use a new one from an undamaged package;

i) instructions on how to dispose of the used condom;

j) a statement that the condom is for single use — if the condom is reused there might be an increased risk of failure or infection;

k) the number of this International Standard (ISO 23409:2011);

l) the date of issue or the date of the latest revision of the instructions for use.

16.2.4 Condoms not distributed in consumer packages

For condoms that are distributed without a consumer package (e.g. in single foils or strips of foils), it is the responsibility of the organization distributing the condoms to ensure that adequate information is supplied to the user in accordance with local regulations. The individual condom containers shall comply with local labelling requirements. If such condoms are for distribution in Europe, the labelling should be in accordance with the European Medical Device Directive 93/42/EEC[30] as modified by 2007/47/EC[31].

This information may be in the form of leaflets, training sessions, posters, or additional packing added in the distribution chain. For guidance on the content, see 16.2.3.2 and 16.2.3.3.

16.3 Inspection

For each lot, 13 consumer packages and 13 individual containers shall be inspected for conformity. All inspected containers shall conform to the requirements of this International Standard.

Under certain conditions, it might be permissible for the manufacturer or distributor to correct faults associated with packaging and labelling requirements and to resubmit the lot for further conformity testing. Examples include insertion of missing instruction leaflets or the re-packaging of individual containers into entirely new complete consumer packages before placing on the market.

If condoms of the same lot are packed into different consumer packages, then at least one consumer package of each variant should be inspected. The number of packages inspected should not exceed 13, unless the number of variants exceeds 13.

17 Data sheet and test report

17.1 Data sheet

The manufacturer shall make available to all interested parties a data sheet that contains, for each product variant, at least the following information:

a) mean nominal dimensions (length, width, thickness);

b) airburst means and values for volume and pressure with limits based on testing according to Clause 11;

c) materials used in the construction of the condom;

d) nominal quantity and type of lubricant;

e) name and address of manufacturer and contractors (if appropriate);

f) reference to the clinical investigation conducted in accordance with Clause 10.

17.2 Test report

The test report shall contain at least the following information:

a) name and address of the test laboratory;

b) name and address of the client;

c) identification of the test report;

d) identification of the sample (sample size, lot number and lot size);

e) origin of the sample, date of the arrival of the sample in the laboratory, and who has taken the sample;

f) a reference to this International Standard (ISO 23409:2011) and the relevant annexes;

g) a listing of the minimum acceptance requirements for each applicable test (dimensions, freedom from holes, airburst properties, package integrity, visible defects, quantity of lubricant, including measurements and tolerances);

h) description of all deviations from this International Standard;

i) results according to the relevant annexes;

j) measurement error, if available;

k) date of the test report and the signature and title of the person(s) responsible for the report.

Normally it is recommended that condoms used in testing be destroyed after testing. Sometimes condoms need to be kept to demonstrate particular problems. Thus it is important that the condoms be marked or stored in such a way that unintentional use is prevented.

Annex A
(normative)

Sampling plans intended for assessing compliance of a continuing series of lots with sufficient number to allow the switching rules to be applied

A.1 Quality verification

When ongoing verification is required of the quality of condoms, it is suggested that, instead of concentrating solely on evaluation of the final product, the party concerned also directs their attention to the manufacturer's quality system. In this connection it should be noted that the ISO 9000[3] family, and in particular ISO 13485[8], covers the provision of an integrated quality system.

A.2 Sampling plans and compliance levels

If a party wishes to establish, by inspection and testing of samples of the final product, whether a continuing series of lots are in compliance with the requirements of this International Standard, the sampling plans and acceptance criteria given in Table A.1 shall be applied.

Manufacturers may use the plans in Table A.1 or may devise and implement validated alternative quality control methods that result in at least equivalent consumer protection.

When tests are being conducted on fewer than five lots of condoms, the additional protection of the switching rules in ISO 2859-1 is not available and it is recommended that the sampling plans given in Annex B be used to maintain the level of consumer protection.

Table A.1 — Sampling plans and acceptance criteria for a continuing series of lots

Attributes	Inspection level[a]	Acceptance criteria
Dimensions	13 condoms	All samples shall meet the criteria of length of $\geqslant$160 mm and width $\pm$2 mm of stated nominal width
Bursting volume and pressure	General inspection level I	AQL of 1,5 with low value threshold determined by clinical testing (see Clause 11)
Package integrity	Special inspection level S-3	AQL of 2,5
Freedom from holes	General inspection level I but at least code letter M	AQL of 0,25
Visible defects	General inspection level I but at least code letter M	AQL of 0,4
Packaging and labelling	13 consumer packages and 13 individual containers	All shall comply
Quantity of lubricant	13 condoms	As agreed (see 8.2)
Thickness	13 condoms	As agreed (see 8.3.3)

[a] See ISO 2859-1 where relevant.

Applications for these sampling plans include:

a) ongoing production testing and quality control by a manufacturer;

b) ongoing testing by a purchaser for contractual purposes;

c) ongoing inspection by a national authority.

Annex B
(informative)

Sampling plans that are intended for assessing the compliance of isolated lots

Use of the sampling plans given in Annex A for small numbers of lots, i.e. less than five, results in a higher level of consumer risk because the switching rules are not available. In such circumstances the use of larger sample sizes is recommended in order to maintain an acceptable level of consumer protection. The choice of a suitable sampling plan is governed by cost considerations. Larger sample sizes give better discrimination, but at increased cost. Purchasers may, for example, rely upon their experience with a particular supplier when assessing the sample sizes to use for small numbers of lots.

The sampling plans given in Table B.1, when applied to isolated lots, provide approximately the same level of consumer protection as those given in Annex A when used in conjunction with the switching rules. Attention is drawn to the possibility of using double or multiple sampling plans which might reduce the total number of condoms that need to be tested to demonstrate compliance when quality is significantly better than the AQLs.

There is no simple mathematical relationship between the sample size and the lot size. Sample sizes may be increased independently of the lot size to achieve a more reliable estimate of lot quality.

Table B.1 — Sampling plans and acceptance criteria for isolated lots

Attributes	Inspection level[a]	Acceptance criteria
Dimensions	13 condoms	All samples should meet the criteria of length of $\geqslant$160 mm and width $\pm$2 mm of stated nominal width
Bursting volume and pressure	General inspection level I but at least code letter M	AQL of 1,5 with low value threshold determined by clinical testing (see Clause 11)
Package integrity	Special inspection level S-3 but at least code letter H	AQL of 2,5
Freedom from holes	General inspection level I but at least code letter N	AQL of 0,25
Visible defects	General inspection level I but at least code letter N	AQL of 0,4
Packaging and labelling	13 consumer packages and 13 individual containers	All should comply
Quantity of lubricant	13 condoms	As agreed (see 8.2)
Thickness	13 condoms	As agreed (see 8.3.3)

[a] See ISO 2859-1 where relevant.

Applications for these sampling plans include:

a) type testing as part of a certification procedure;

b) cases where the total number of lots being assessed is insufficient to allow the switching rules to be effective;

c) cases of dispute involving isolated lots, e.g. for referee testing.

Annex C
(normative)

Determination of total lubricant for condoms in individual containers

C.1 Principle

The mass loss is determined by removing the lubricant from the pack and condom by washing with a solvent appropriate to the condom material. Washing is carried out either in an ultrasonic bath or by manual agitation. A minimum sample size of 13 condoms is recommended.

C.2 Apparatus and solvent

C.2.1 **Ultrasonic cleaning bath(s)**, or suitable container, e.g. **beaker** and **stirrer**.

C.2.2 **Balance**, accurate to 1 mg.

C.2.3 **Propan-2-ol**, laboratory reagent grade, or other suitable cleaning solvent of laboratory reagent grade depending on the synthetic material used in the test condom. Alternative solvents shall be validated and specified by the manufacturer (hereinafter referred to as “the solvent”). Should alternative solvents be required for either the condom material or the lubricant material, manufacturers shall specify the solvent to be used.

C.3 Procedure

C.3.1 Weigh each individual container to the nearest 1 mg and record the results.

C.3.2 Slit the individual container carefully around three edges and remove the undamaged condom.

C.3.3 Before unrolling the condom cut up one side using scissors, then unroll the condom and wipe it and its individual container free of lubricant as much as possible.

C.3.4 When using the ultrasonic bath, immerse the condom and individual container in the solvent in an ultrasonic bath and wash for 2 min to 10 min. Repeat the washing in clean solvent as many times as necessary to achieve constant mass (within 10 mg) and after drying as specified in C.3.6 and C.3.7.

C.3.5 When washing the condoms manually, immerse the condom and individual container in the solvent in a bath, and wash with manual agitation. Repeat the washing in clean solvent as many times as necessary to achieve constant mass and after drying as specified in C.3.6 and C.3.7.

C.3.6 Remove the condom and individual container from the solvent and wipe to remove excess solvent.

C.3.7 Dry the condom and individual container to constant mass (within 10 mg) at a temperature validated by the manufacturer that is appropriate for the synthetic material being used. The temperature shall not exceed 55 °C.

C.3.8 Weigh each dry condom and individual container to the nearest 1 mg and subtract this result from that found in C.3.1 to give the total quantity of lubricant.

C.4 Accuracy of lubricant recovery

In an interlaboratory study in natural rubber latex condoms, this method was shown to recover about 85 mg more “lubricant” than the amount that was added when the test samples were made. This excess “lubricant” was partly dressing powder, which was also removed by the method.

C.5 Expression of results

The test report shall include the relevant elements of Clause 17, and the amount of lubricant recovered shall be reported to the nearest 50 mg.

Annex D
(normative)

Determination of length

D.1 Principle

The unrolled condom is allowed to hang freely over a graduated mandrel and its length, excluding the reservoir end, is observed and recorded.

D.2 Apparatus

D.2.1 **Mandrel**, with a scale divided into millimetres and having the dimensions shown in Figure D.1, with the zero beginning at the rounded end.

D.3 Procedure

D.3.1 Move the condom inside the individual container such that it is away from the area where the individual container is to be torn. Tear the individual container and remove the condom.

Scissors or other sharp instruments shall not be used to open the individual container.

D.3.2 Unroll the condom, stretch it slightly twice but by no more than 20 mm to smooth out the wrinkles caused by the condom having been rolled up. Lubricants may be removed and suitable powders may be added to avoid sticking.

D.3.3 Put the condom over the mandrel (D.2.1) and let it hang freely, stretched only by its own mass.

D.3.4 Note, to the nearest millimetre, the smallest value of the length of the condom that can be read on the scale outside the open end of the condom.

D.3.5 Condoms subjected to this test may also be used for determination of width.

D.4 Expression of results

The test report shall include the information specified in Clause 17 and the length of each tested condom.

Dimensions in millimetres

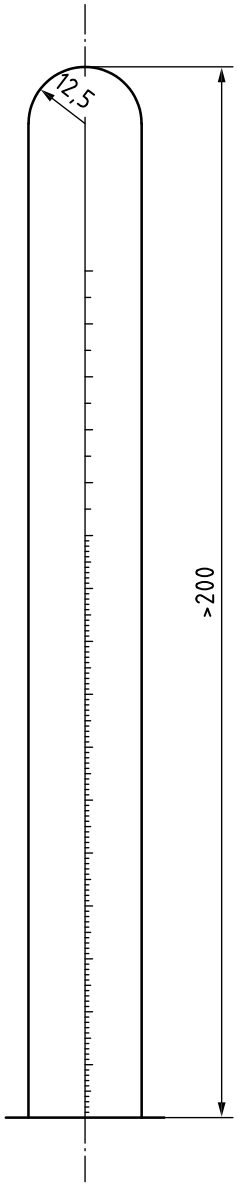


Figure D.1 — Mandrel for determining length of condom

Annex E
(normative)

Determination of width

E.1 Principle

The unrolled condom is allowed to hang freely over the edge of a ruler and its width is observed and recorded.

E.2 Apparatus

E.2.1 **Ruler**, with a scale divided into millimetres.

E.3 Procedure

E.3.1 Move the condom inside the individual container such that it is away from the area where the individual container is to be torn. Tear the individual container and remove the condom.

Scissors or other sharp instruments shall not be used to open the individual container.

E.3.2 Unroll the condom and lay it flat over the edge of the ruler (E.2.1), perpendicular to the condom's axis, allowing it to hang freely. If a lubricated condom does not hang freely, then the lubricant shall be removed and suitable powders may be added to avoid sticking.

E.3.3 Measure, to the nearest millimetre, the width of the condom at a point specified in 8.3.2.

E.3.4 Condoms subjected to this test may also be used for determination of length.

E.4 Expression of results

The test report shall include the information specified in Clause 17 and the width of each tested condom, including the point along the condom at which the measurement was made.

Annex F
(normative)

Determination of thickness

F.1 Principle

This annex describes the test method for determining the thickness of a synthetic condom.

F.2 Apparatus

F.2.1 **Flat-footed micrometer**, **dial** or **digital type**, measurement intervals of not larger than 0,001 mm, with a pressure foot set at (22 ± 5) kPa. The recommended foot diameter is (5 ± 2) mm.

F.2.2 **Scissors**.

F.3 Procedure

F.3.1 Move the condom inside the individual container such that it is away from the area where the individual container is to be torn. Tear the individual container and remove the condom.

Under no circumstances use scissors or other sharp instruments to open the container.

F.3.2 Unroll the condom ensuring that it is not excessively stretched in any direction and wash the condom in propan-2-ol or other suitable solvent to remove lubricants. Dry the condom to a constant mass (± 10 mg).

F.3.3 Cut the condom along its length using scissors and open it out to allow the single wall thickness to be measured.

F.3.4 Zero the micrometer and place the test specimen on the micrometer in order to take the measurement at ±5 mm from the midpoint between the open and closed ends of the condom, excluding the reservoir tip. Read and record the single walled thickness from the micrometer to an accuracy of within ±0,001 mm. Repeat the measurement at two more locations around the circumference, maintaining the same distances between the open and closed ends of the condom. Record the average thickness for each condom and then average the results of all tested condoms.

F.3.5 Repeat F.3.4 (30 ± 5) mm from the open end of the condom, and (30 ± 5) mm from the closed end.

F.4 Expression of results

The test report shall include the elements of Clause 17 and the following information:

a) the individual thickness measurements and average thickness of each condom measured;

b) the average thickness at each of the three locations along the length of the condom [i.e. at (30 ± 5) mm from the closed end, (30 ± 5) mm from the open end and at ±5 mm from the midpoint between the open and closed ends];

c) the average calculated thickness of all the condoms measured.

Annex G
(informative)

Determination of barrier properties using the bacteriophage method

G.1 General

This annex provides the rationale, methodology and the required sensitivity to test the ability of a synthetic condom to act as a barrier to transmission of the etiological micro-organisms of sexually transmitted infections (STIs), including viruses.

A condom is a medical device making a claim that it is effective against STIs and requires that appropriate laboratory tests be performed. Since viruses are the smallest etiological STI agents and include the human immunodeficiency virus (HIV) and hepatitis B virus (HBV), the challenge particle should be a small virus or virus-size particle. Test conditions should account for as many parameters as possible that are considered to be important in real-life conditions. Appropriate choices of challenge particle, solution properties, and test pressure and duration are considered most important and should be included. The barrier properties of a condom may be determined in a static test, i.e. movement of the condom during the test is not required. Choices of parameters that make the *in vitro* test more stringent than expected real-life use are encouraged, with appropriate justification.

The choice of challenge particle has several important aspects. A biological assay might be preferred in general because there should be no “background” level of confounding “signal”, as would be found with radioactively (or otherwise) labelled viruses or virus-like particles.

Surrogate viruses of appropriate size and shape may be substituted for human pathogens. Such surrogates may be bacterial viruses (such as bacteriophages 25 nm to 27 nm in diameter), which are safer, faster and less expensive to use for testing and which can be readily obtained at sufficient titre to provide an adequate challenge concentration. However, in order for the test to be used to demonstrate safety with regard to STIs, the test virus should be smaller than the hepatitis B virus (42 nm diameter), the smallest etiological agent for an STI. For these reasons, the following protocol suggests use of a small bacterial virus as challenge particle.

G.2 Test specimen

G.2.1 Test condoms should be carefully handled so they are not damaged during the test procedure. Gloves should be worn as a precautionary measure to prevent abrasion or puncture by fingernails, jewellery, etc.

G.2.2 Accompanying lubricants and spermicides, if present, should be removed to prevent interference with the test using the method in Annex C. Wash the condom in propan-2-ol or other suitable solvent determined by the synthetic material to remove lubricants without damaging the condom material.

G.3 General requirements

G.3.1 The test consists of filling the condom with virus-containing buffer and determining whether any viruses penetrate that barrier during submersion in collection buffer. Virus penetration is quantified and reported as equivalent volume of challenge suspension needed to account for the amount of virus penetration.

G.3.2 Attach the test condom to an apparatus which:

a) provides a leakproof seal around the top and leaves an appropriate length of test portion available for the virus penetration test (at least 140 mm);

b) provides for restraining of the condom to prevent overexpansion under pressure:

   1) dimensions of the restrainer should allow expansion of the test portion of the condom to a length of 140 mm to 150 mm and a justified circumference depending on the synthetic material tested,

   2) the contour of the restrainer should match that of the condom, including the reservoir tip, if present,

   3) restrainers of the same size and material should be used with the test condoms and with the comparative condoms;

c) provides for exposure of the inside of the condom to aqueous challenge virus suspension;

d) provides for application of pressure to that suspension;

e) allows for submersion of test portion of condom in collection fluid;

f) provides for access to challenge virus suspension inside condom for assay following the test.

G.3.3 Fill the condom with a buffer that complies with the following criteria:

a) has pH approximately 7, salinity of any one of several variations of physiological saline, surface tension less than 0,05 N/m [may be provided by 0,1 % Triton X-100®[1)]];

b) contains the challenge virus at sufficient titre, even at the end of the test (at least 108 pfu/ml, where pfu are plaque-forming units, of a small, approximately spherical virus).

Physiological saline has a lower viscosity than semen and therefore provides a more stringent test. The test may be performed at room temperature (25 ± 2) °C when saline is used.

The bacteriophage phiX 174 may be used as the challenge virus. Other similar challenge bacteriophages may be used but would have to be justified as equivalent to phiX 174.

G.3.4 Place the condom under pressure such that the pressure of the challenge fluid is equivalent to 8 kPa or more (e.g. hydrostatically with an 810 mm column of water or with air or gas pressure.

G.3.5 Place the condom in a collection container with sufficient buffer to allow fluid contact with the test surface of the condom and to collect any virus that penetrates through the condom.

G.3.6 Submerge the filled, pressurized condom (first 140 mm from the closed end, excluding the reservoir tip, if present) in the collection buffer for at least 30 min.

G.3.7 Assay the collection buffer for the challenge virus to determine whether any virus has penetrated the condom and passed into the collection buffer. Mix the collection fluid at the time of assay so that the assay aliquots are representative.

G.3.8 Calculate the equivalent volume of challenge virus penetration needed to account for the amount of virus found in collection buffer.

---

1) Triton X-100® is an example of a suitable product available commercially. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of this product.

G.3.9 Use positive controls to examine items a) to e).

a) Follow the same procedure for the test above using condoms with representative pinholes placed using a small gauge needle of diameter 30 µm. Positive control experiments of the same duration are needed to ensure that the overall test is functioning properly. Condoms with intentional pinholes may be used, although it is recognized that it is difficult to produce small pinholes.

b) Determine whether the challenge virus remained at a stable concentration in the condom during the test. Data from several condoms are needed and should be collected as part of each condom test. The titre of the challenge virus suspension inside the condom at the end of the test is compared to the titre originally placed in the condom. This determines whether and how much the challenge virus titre changes during the test because of interaction with the condom and the test apparatus, or other factors.

c) Determine whether any virus that penetrates the condom remains detectable in the collection buffer over the test period. This can be done by "spiking" the collection buffer with a low level of virus before a mock test (where there is no virus inside the condom and for the same duration) and assaying the titre of the collection buffer at the beginning and end of the mock test. This determines whether and how much the penetrated virus titre changes during the test as a result of interaction with the outside of the condom, the restrainer or the collection container.

d) Increase the starting challenge titre if the stability control or the defections control (or both) indicate the loss of virus titre to compensate for the loss in order to maintain the overall sensitivity of the test.

e) It can be useful to determine via controls (e.g. settle plates) whether contamination caused by aerosolized virus or other leaks can lead to false evidence of virus penetration of the condom.

G.4 Sample size

A minimum of 60 condoms, 20 from each of three lots, should be used in order to determine acceptability. The comparative natural rubber latex condom (20 condoms), meeting the requirements of ISO 4074, to be used in the clinical study are to be tested as a control using steps G.3.2 to G.3.9.

G.5 Detection limits and reporting

G.5.1 Detection limits

G.5.1.1 Assay 1 ml in triplicate (3 ml total).

G.5.1.2 For a 95 % confidence that an assay finds at least one virus when a virus is present [i.e. $p(0) < 0{,}05$], the average number of infectious particles per total volume assayed should be at least three; e.g. there is a 95 % probability that a titre of 1 pfu/ml results in at least one plaque in a 3 ml total assay. Thus, the sensitivity or detection limit of this assay can be claimed as 1 pfu/ml when 3 ml is assayed. Detection limit expressed as volume of challenge virus suspension that penetrated the barrier is probably the most useful measure of test sensitivity. For example, in a real-life risk assessment, the volume of transmitted virus-containing fluid can be translated into infectious units when the titre of a pathogenic virus (in real life) is known. The test procedure should be able to detect 2×10^{-6} ml penetration of the challenge virus suspension. This can be done by using a challenge titre of 1×108 pfu/ml, a collection buffer volume of 200 ml and assaying 1 ml in triplicate from the collection buffer (assuming no loss of virus titre in the challenge buffer nor in the collection buffer). The assay detection limit of 1 pfu/ml is equivalent to penetration by 200 pfu (1 pfu/ml $\times$ 200 ml) or 2×10^{-6} ml (200 pfu divided by 1×108 pfu/ml).

G.5.1.3 Presentation of results for all the test condoms should be presented in a table that includes:

a) the challenge virus titre;

b) the virus titre in the collection buffer;

c) any correction factor for loss of virus (determined in the controls);

d) the calculated challenge volume that penetrated (for the condoms that allowed virus transmission).

The volume of challenge virus suspension needed to account for the virus penetration into the collection buffer can be calculated for each condom by the method presented in G.5.1.2. If some loss of virus titre occurs either inside the condom or outside in the collection container, the calculation should include the appropriate correction for such loss. For condoms that apparently do not allow virus transmission, the detection limit of that particular test should be given, e.g. as 2×10^{-6} ml. Report forms and test results for virus penetration of condom samples should be presented in tabular form, where the data for each condom are individually reported following the requirements of Clause 17.

G.5.2 Reporting

G.5.2.1 Positive control

The report of the results of the positive control experiment should be done using the same reporting format as with virus penetration of test samples.

G.5.2.2 Challenge to virus stability

Results from the test of challenge virus stability should be presented in tabular form, where the data for each condom are individually reported. Necessary items for each test sample are:

a) date test was performed;

b) titre of challenge titre placed inside the condom at the beginning of the test;

c) titre of challenge titre inside the condom at the end of the test;

d) calculated ratio of final to initial titre.

G.5.2.3 Challenge to virus detection

Results from tests to determine the detection of penetrated virus should be in tabular form, where the data for each condom are individually reported. Necessary items for each test sample are:

a) date test was performed;

b) virus titre in collection buffer at the beginning of the test;

c) virus titre in collection buffer at the end of the test;

d) calculated ratio of final to initial titre.

Annex H
(normative)

Determination of the bursting volume and pressure

H.1 Principle

A specified length of the condom is inflated with air, and the volume and pressure required to burst the condom are recorded. Should the inflation device also be used for testing latex condoms, the equipment should be recalibrated using Annex I prior to testing condoms in compliance with this International Standard.

Recommendations on system calibration are given in Annex I.

H.2 Apparatus

H.2.1 Inflation apparatus, e.g. as in Figure H.1, suitable for inflating the condom with clean oil-free and moisture-free air at a specified rate, provided with equipment for measuring volume and pressure and having the following features:

a) a pressure sensor configured such that there is no pressure differential between the condom and the pressure sensor;

b) an apparatus for recording the volume of inflation air delivered, configured such that the volume of air is measured or calculated at the appropriate pressure within the condom and not at the line pressure (which might be higher);

c) a device (test head) for mounting the condom on the machine, with a length limiter having a smooth sphere or hemisphere 25 mm in diameter at its top for hanging the unrolled condom when fixed to the apparatus, and fixed in a position such that when the condom is clamped, the length of the condom, excluding reservoir, remaining for inflation is (150 ± 3) mm;

d) a clamping device for holding the condom and sealing it to the mounting device, e.g. a clamping ring having no sharp edges or protrusions — the clamping ring, test head, and length limiter shall not cause significant stretching of the condom during mounting on the test head;

e) pressure and volume measuring equipment capable of:

   1) a maximum permissible limit of error of ±3 % for volumes greater than 30 % of the expected mean, whatever method is used to measure volume,

   2) measuring the pressure at burst of the condom with a maximum permissible limit of error of ±0,05 kPa.

H.2.2 Clamping device, e.g. a clamping ring having no sharp edges or protrusions. The recommended material of construction is transparent plastic. The clamping ring should not stretch the condom as the clamping ring is placed on to its mount.

When used with an air-inflated cuff mount, the clamping ring should have an internal diameter 36 mm to 40 mm, recommended height 50 mm and extending no more than 3 mm above the air-inflated cuff. The cuff should deflate to such a diameter that the condom freely rolls over it.

H.2.3 **Inflation cabinet**, containing the mounting device, having the facility for viewing the condom during inflation, and of sufficient size to allow the condom to expand freely without being damaged by any part of the cabinet.

H.3 Procedure

H.3.1 Carry out the test under controlled temperature of (25 ± 5) °C and relative humidity (55 ± 10) %.

H.3.2 Move the condom inside the individual container such that it is away from the area where the individual container is to be torn. Tear the individual container and remove the condom.

Scissors or other sharp instruments shall not be used to open the individual container.

H.3.3 Suitable gloves or finger cots shall be worn while handling the condom. In cases of dispute, gloves shall be worn.

H.3.4 Unroll the condom ensuring that it is not excessively stretched in any direction.

The condom may be unrolled directly on to the rod on the test equipment.

H.3.5 Hang the condom on the rod [H.2.1 c)] and affix to the mount (H.2.2). Take care when placing the clamping ring on its mount to avoid damaging or stretching the condom. Inflate with air at a rate of 0,4 dm^3/s to 0,5 dm^3/s (24 dm^3/min to 30 dm^3/min) as validated by the manufacturer. Check to ensure that the condom expands and that there are no obvious leaks.

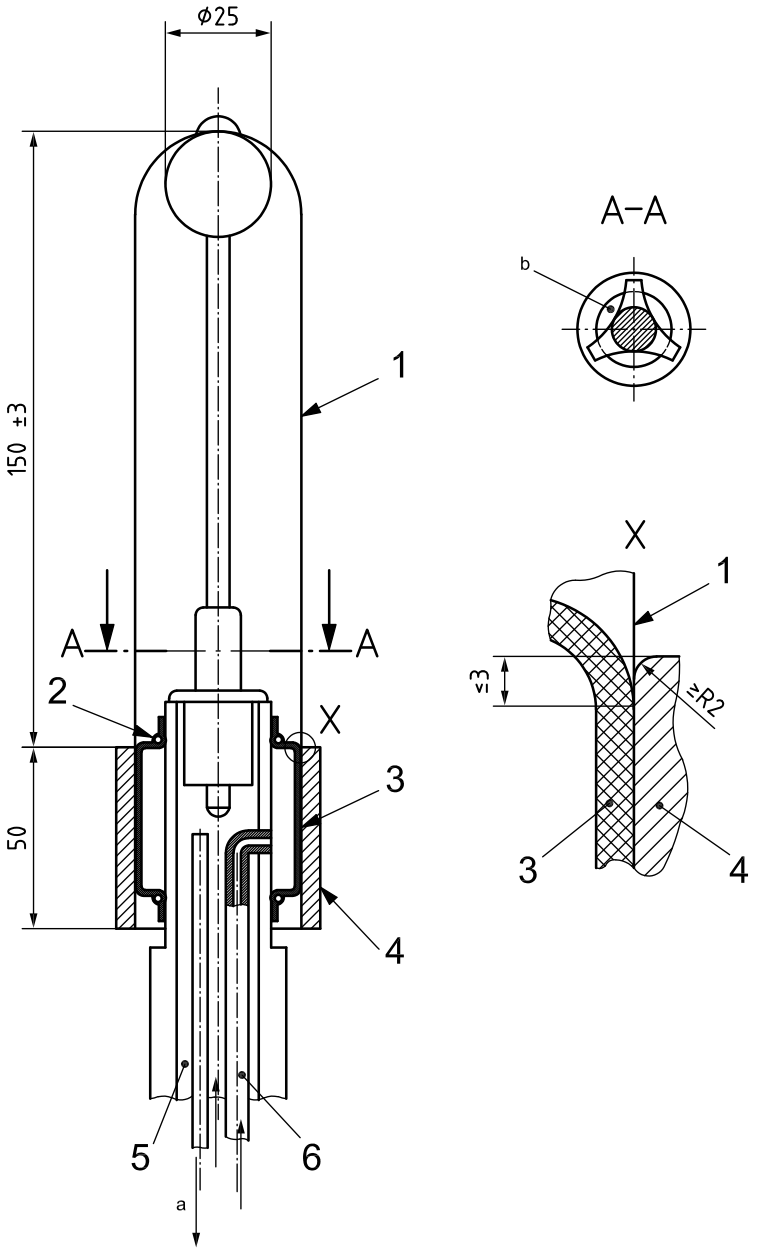
If the condom exhibits an obvious leak, the test should be discontinued because the condom might never burst. The condom should be replaced and the test continued.

H.3.6 If the condom does not leak, measure and record the bursting volume, in cubic decimetres rounded to the nearest 0,1 dm^3 if the minimum burst volume is below 15 dm^3, and to the nearest 0,5 dm^3 if the minimum burst volume is 15 dm^3 or above. The bursting pressure, in kilopascals, shall be rounded to the nearest 0,05 kPa.

H.4 Expression of results

The test report shall include the information specified in Clause 17 and the bursting volume and bursting pressure of each tested condom.

Dimensions in millimetres



Key

1 condom
2 cord
3 flexible expansion cuff
4 clamping collar
5 air inlet for testing
6 air inlet for keeping condom in place

a To pressure-measuring device.
b Areas open for gas flow.

Figure H.1 — Example of a suitable apparatus for determining bursting characteristics

Annex I
(informative)

Calibration of air inflation equipment for determination of burst volume and pressure

I.1 System check algorithm

Due to the diversity of equipment used by different laboratories, it is not practical to define all calibration and verification procedures. It should be noted that equipment regularly used for natural rubber latex condoms can require recalibration to test condoms made from synthetic materials.

The steps described in I.2 to I.10 and presented as a flow diagram in Figure I.1, if performed in order, are an example of suitable system checks for verification, audit and calibration that apply to many systems. The algorithm can require adaption to suit individual equipment configurations. Some systems can benefit from the installation of additional equipment, such as tees, isolating valves or manual control switches, to facilitate system checking.

In-house calibrations should be done at appropriate intervals, or whenever there is a reason to doubt the reading on an instrument.

I.2 Clamp slip force check

This test ensures that the condom length does not vary significantly during inflation and consists of marking a condom as close as possible to the top of the collar, inflating the condom until it is near to burst, bursting it with a pin near the reservoir, and observing whether the mark has moved.

I.3 Inflation length check

This is a measurement, either on the test head or on the length-measuring mandrel, that verifies that 150 mm of condom is being inflated, i.e. that the length limiter is properly set, that the condom is not stretched by the clamping equipment, and that it is not being blown out of position before the clamp grips it.

I.4 Cuff leak check

This is a check that inflated cuffs do not leak air, especially into the condom. If the cuff and the air supply can be actuated separately, it is possible to check the cuff by turning on the air supply, isolating the cuff, and then observing it to see that it is still inflated after 5 min.

I.5 Air supply leak check

This step checks that there are no leaks in the air supply system or the pressure-sensing system that would cause an error in the measured volume.

I.6 Pressure gauge calibration

Pressure gauges or transducers can be checked regularly against a reference meter, connected in parallel with the gauge or transducer. A convenient and accurate reference is a water-tube manometer. The whole range of pressures encountered should be checked, either by placing a variable constriction over the test head or by inflating a condom (or two, one over the other) in stages.

NOTE Some items, such as elimination of leaks, are a prerequisite to others, such as calibration of volume and pressure readings, but others, such as timer checking, inflation length and verification of automatic recording, can be done independently of most other checks.

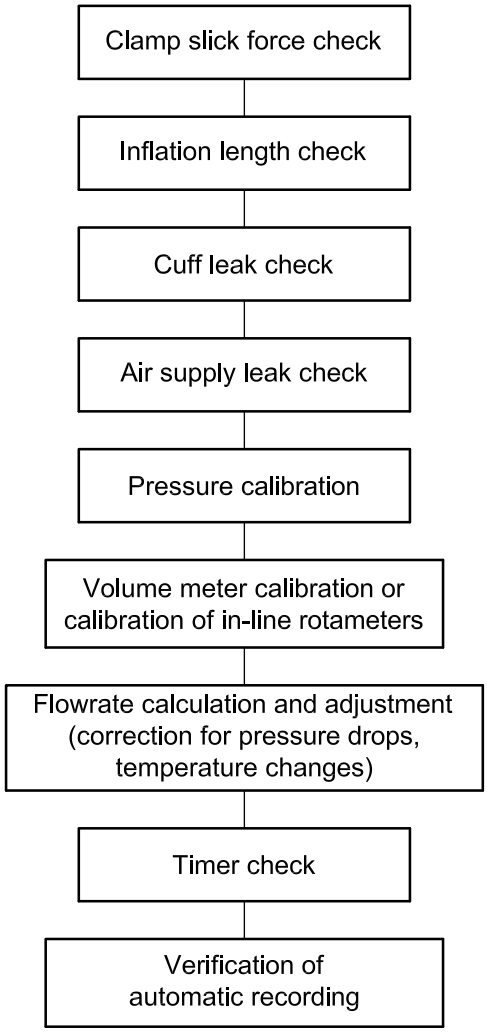


Figure I.1 — List of periodic checks

I.7 Air flow rate adjustment and calibration

If the system relies on timing the inflation and multiplying by the flow rate, the flow rate needs to be known accurately; if, however, total volume is measured, it needs only to be within the stipulated range. It is advisable to set the flow rate around the centre of the allowable range, to allow for fluctuations due to ambient conditions.

Flow rate calibration is conveniently carried out using a suitable variable-area flowmeter (rotameter) calibrated against a certified instrument. Rotameters are simple in construction, having few moving parts, and much of the critical equipment inside the meter is directly visible to the user. Volume meters may also be used.

The calibrating meter should be attached directly to the condom test head, where the condoms are normally mounted. Suitable stands and connecting hoses (with minimal pressure drop) might be necessary. If there is no permanent in-line meter, it is important to verify that the connection of the meter does not alter the flow rate significantly.

Changes in ambient conditions can affect the flow rate slightly, and on systems that rely on elapse of time to burst, flow rate should be checked and recalculated twice daily, and whenever there are major weather changes.

I.8 In-line volume or flow rate meter calibration

For systems equipped with an in-line volume meter (e.g. a diaphragm meter or a turbine meter), the accuracy of the meter can be checked against the rotameter (or other reference meter) cited in I.7. The test defines volume as the quantity of air delivered to the condom, and either it should be measured at the test head, or a correction should be made (using the ideal gas law) for any expansion between the volume meter and the test head. The pressure drop between the volume meter and the test head should be ascertained by a pressure gauge at the volume meter.

In-line rotameters, like calibrating rotameters, are governed by Equation (I.2) (the rotameter equation). A correction should be made for the pressure and temperature under which the rotameter is operating, and for the expansion between the in-line meter and the test head.

I.9 Timer check

Stopwatches or electric timers should be checked against nationally certified timers (e.g. telephone clocks or broadcast time signals).

I.10 Verification of automatic recording

On systems where results (of pressures, volumes or times) are recorded automatically using computers or other equipment, it is necessary to check that the quantities recorded are actually those current at the time of burst. This should be done for each test head in the system. The burst volume (or time, as appropriate to the system) and the burst pressure should be observed for five condoms on each head. The results should be compared with the automatically recorded values.

I.11 Important equations

If a gas experiences a drop in pressure as it flows, it expands. The flow rate and the pressure are related by the ideal gas law:

$$p_1 q_1 = p_2 q_2 \tag{I.1}$$

where

p_1 is the pressure at point 1 in the system;

p_2 is the pressure at point 2 in the system;

q_1 is the volume flow rate at point 1 in the system;

q_2 is the volume flow rate at point 2 in the system.

The reading on a rotameter depends on the pressure and temperature of the gas flowing through it. The true flow rate, q_c, is given by Equation (I.2)

$$q_c = q_m \sqrt{\frac{p_0 \, T_m}{p_m \, T_0}} \tag{I.2}$$

where

q_m is the flow rate indicated;

p_0 is the absolute pressure at which the rotameter is calibrated;

T_0 is the temperature, in kelvins, at which the rotameter is calibrated;

p_m is the absolute pressure when the measurement is being made;

T_m is the temperature, in kelvins, when the measurement is being made.

Annex J
(normative)

Testing for holes

J.1 General

This annex specifies the methods of testing for holes in condoms made of synthetic materials.

J.2 Water leak test

J.2.1 Principle

A condom is filled with a specified volume of water and examined for visible water leakage through the wall of the suspended condom. In the absence of any leakage the condom is then rolled on coloured absorbent paper that is subsequently examined for signs of leakage of water from the condom.

J.2.2 Apparatus and materials

J.2.2.1 **Mounting equipment**, suitable for mounting the condom at its open end, allowing it to be freely suspended, with a means of filling the condom with water while it is suspended. An example of a suitable mount is shown in Figure J.1.

J.2.2.2 **Coloured absorbent paper**.

J.2.2.3 **Rolling device** (optional), incorporating a smooth transparent plate. It may be placed at a fixed height above and parallel to the absorbent paper, where its horizontal movement rolls the condom back and forth. The plate, if used, shall turn the condom through at least one complete revolution, when it is moved through its travel.

J.2.2.4 **Clamping device** (optional), suitable for holding closed the twisted open end of a condom, and preventing it from leaking, without causing damage to the part to be rolled on absorbent paper. An example is a sprung paper clip.

J.2.3 Procedure

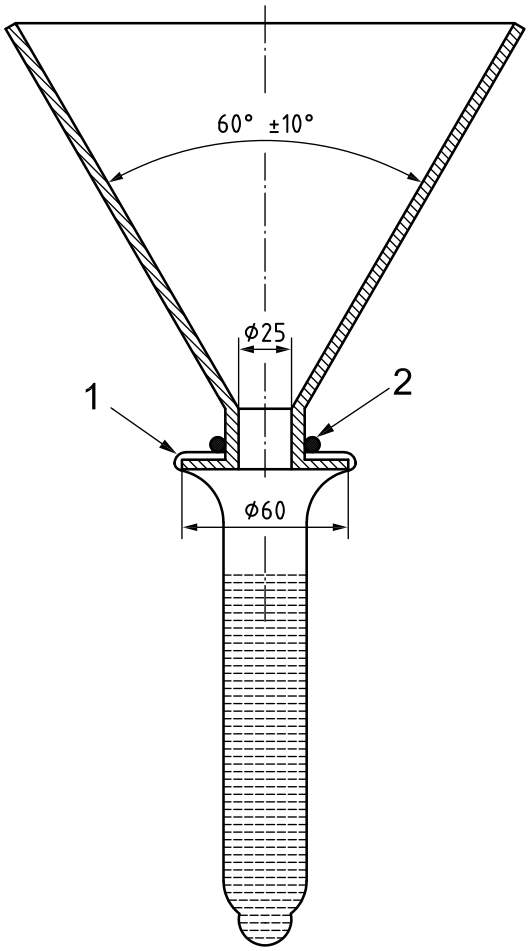
J.2.3.1 Move the condom inside the individual container such that it is away from the area where the individual container is to be torn. Tear the individual container and remove the condom. Scissors or other sharp instruments shall not be used to open the individual container. Wear suitable gloves or finger cots while handling the condom.

J.2.3.2 Unroll the condom ensuring that it is not excessively stretched in any direction. If any hole or tear is noticed, that condom shall be deemed not to be in compliance and further testing of that condom shall be discontinued.

J.2.3.3 Record condoms with other visible defects, namely: broken, missing or severely distorted rims or retention mechanisms, and permanent creases with adhesion of the film.

J.2.3.4 Fit the open end of the condom on to the mount so that the condom is suspended open end upwards.

Dimensions in millimetres



Key

1 well-rounded edge

2 rubber ring

Figure J.1 — Suitable mount

J.2.3.5 Add sufficient water to fill the condom up to a maximum of 300 ml. If it is not possible to get 300 ml of water to be contained within the condom, allow the remainder of the water to form a pressure head within the filling system. The water temperature is to be between 10 °C and 40 °C and make sure that the humidity in the ambient air does not condense on the outside of the condom. Inspect the condom for visible signs of leakage. Deem as failed any condom exhibiting visible signs of leakage from holes located more than 25 mm (determined to an accuracy of 1 mm) from the open end and discontinue the test. Holes found near the open end shall be marked, and measured after the condom is emptied to determine whether they are more than 25 mm from the open end.

J.2.3.6 If there is no visible leakage through the condom after suspension, take hold of the condom by the closed end, and seal the condom, e.g. by twisting it for approximately 1,5 revolutions or by using a suitable plug at a point less than 25 mm from the open end, and remove it from the mount. Hold the end closed with one hand, or with a suitable clamping device (J.2.2.4).

J.2.3.7 Transfer the condom on to a dry sheet of coloured absorbent paper, and roll the closed end around at least one revolution on the paper, keeping the hand applying the motion and pressure at a distance of 25 mm to 35 mm above the paper. Then lay the condom on the coloured absorbent paper, with the axis of the cylinder thus formed parallel to the paper.

J.2.3.8 Roll the condom back and forth at least once for a distance at least equal to the circumference of the condom in its water-filled condition, using one of the two methods below.

a) Manual rolling

During rolling, spread the fingers of the hand so as to distribute the force on the condom as equally as possible. Maintain the hand at a distance of 25 mm to 35 mm above the absorbent paper. Move the hand with respect to the condom so that the condom as a whole is subjected to hand pressure and comes in contact with the absorbent paper.

b) Mechanically assisted rolling

Place the condom on the coloured absorbent paper, and use the rolling device (J.2.2.3) to move the condom through at least one complete revolution.

The condom may be rolled through more than one revolution in order to verify whether there is leakage present. It is intended that the number of revolutions be small, and in no case greater than 10 over both pieces of coloured absorbent paper.

Steps J.2.3.7 and J.2.3.8 may be conducted in any order. For lubricated condoms, the rolling may be done twice on two separate sheets of coloured absorbent paper, to eliminate confusion between marks made by the lubricant and those made by the water.

J.2.3.9 Inspect the coloured absorbent paper for any sign of leakage of water from the condom. Ignore any marks made by the lubricant. Holes found near the open end shall be marked, and their location measured after being emptied to verify that they are more than 25 mm from the open end. Condoms with holes more than 25 mm from the open end shall be deemed not to be in compliance.

NOTE Other test methods including the electrolyte test method may be used for detecting holes in synthetic materials if validated. Not all materials are compatible with the electrolyte test method.

J.3 Electrical test

J.3.1 General

The electrical test method may be used to evaluate condoms made from alternative materials if suitable. The decision to use the electrical method instead of the manual method should be based on validation studies that verify comparable levels of hole detection.

J.3.2 Principle

The condoms are initially screened electrically to detect holes. A condom which has no holes acts as an insulator and allows no current to flow in an electrical circuit. A condom with a hole allows a current to pass.

Condoms which fail the electrical test are then tested by rolling on coloured absorbent paper to confirm the presence or absence of a hole. A decision on whether a condom has a hole or not cannot be made on the basis of the electrical conductivity part of the test alone. The presence of a hole is confirmed by rolling the condom on coloured absorbent paper.

J.3.3 Apparatus and electrolyte

J.3.3.1 **Electric testing equipment**, e.g. as shown in Figures J.2 and J.3.

The parameters are: voltage (10 ± 0,1) V d.c.; resistance (10 ± 0,5) kΩ; accuracy of the voltmeter ±3 mV.

J.3.3.2 **Electrolyte solution**. An aqueous sodium chloride solution, $\rho_{NaCl} = 10$ g/l, at (25 ± 5) °C is recommended, but a solution of suitable electrolyte with equivalent conductivity may be used as an alternative [$\rho_{Na_2SO_4} = (15{,}4 \pm 1{,}0)$ g/l].

J.3.4 Procedure

J.3.4.1 Move the condom inside the individual container such that it is away from the area where the container is to be torn. Tear the container and remove the condom.

In no circumstances, use scissors or other sharp instruments to open the package.

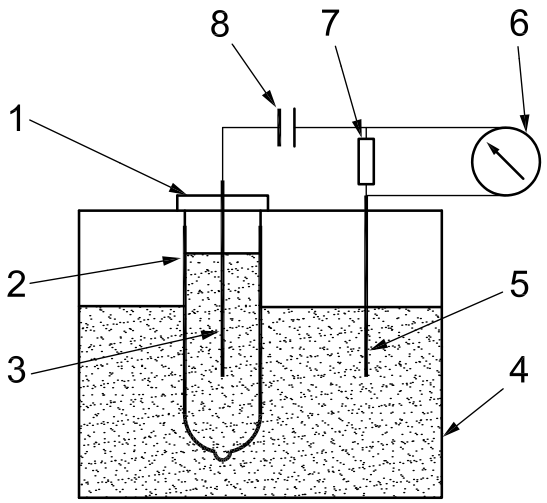
Wear suitable gloves or finger cots while handling the condom.

J.3.4.2 Unroll the condom ensuring that it is not excessively stretched in any direction.

J.3.4.3 Examine the condom visually. Deem any condom which exhibits a visible hole or tear a failure and discontinue the test.

J.3.4.4 Record condoms with visible defects (other than holes and tears).

J.3.4.5 Fit the open end of the condom on to the mount (J.2.2.1) so that the condom is suspended open end upwards.

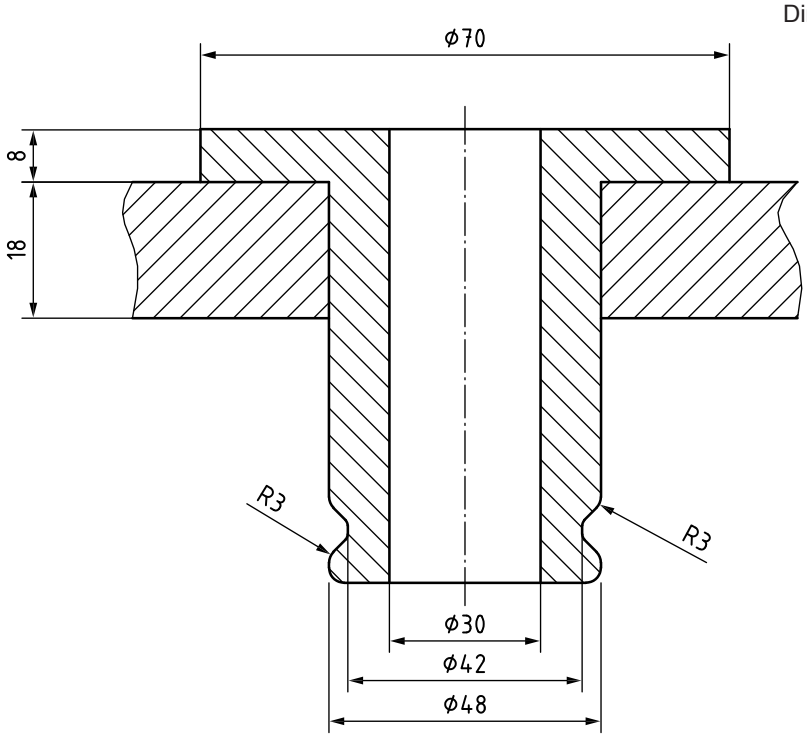


Key

1 support (see Figure J.3)
2 condom filled with electrolyte fixed on support
3 electrode fixed to support
4 container with electrolyte
5 electrodes
6 voltmeter
7 resistor $R = 10$ kΩ
8 voltage source $V = 10$ V d.c. (stable)

Figure J.2 — Schematic diagram of electric testing equipment

Dimensions in millimetres



Key

R3 radius

Figure J.3 — Examples of means of attaching the condom to the support

J.3.4.6 Add (300 ± 10) ml of electrolyte (J.3.3.2) to the condom. Reject any condom that leaks during filling. After all the electrolyte has been added, apply a 10 V d.c. stabilized continuous voltage source in series with a 10 kΩ high precision electrical resistance between the electrode in the container and the electrode inside the condom. Steep the condom in the electrolyte in the container so that all but a minimum of 25 mm from the open end is submerged.

Measure the voltage at the resistor as the condom is steeped in the electrolyte and for up to (10 ± 2) s after maximum immersion. Record the highest voltage observed.

If a voltage equal to or greater than 50 mV is recorded subject the condom to the water test as described in J.3.4.7.

J.3.4.7 Seal the open end of the condom by twisting the condom for approximately 1,5 revolutions and remove the condom from the mount. Remove the excess electrolyte by wiping the condom with a soft cloth or by gentle rolling on absorbent paper. Subject the condom to the water test as described in J.2.3.7 to J.2.3.9.

J.4 Expression of results

The test report shall include elements from Clause 17 and the following particulars:

a) the number of condoms exhibiting a visible hole or tear before mounting on the apparatus and the number of condoms exhibiting a voltage equal to or greater than 50 mV in the case of the electrical test;

b) the number of condoms with observable leaks on the apparatus, which when measured are more than 25 mm from the open end (in the case of the visual test);

c) the number of condoms which showed signs of leakage on rolling, which when measured are more than 25 mm from the open end;

d) the number of condoms with visible defects other than holes or tears, and their nature.

Annex K
(normative)

Determination of shelf-life by real-time stability tests

K.1 Principle

Individual containers of condoms are conditioned at 30^{+5}_{-2} °C for the intended shelf-life period and then tested for conformity with the requirements of Clauses 11, 12 and 15. Small samples are removed and inflation tested periodically to monitor changes during the ageing period.

For the purposes of this International Standard, oven conditioning at 30^{+5}_{-2} °C has been selected to accommodate storage conditions worldwide.

K.2 Procedure

K.2.1 General

After confirming compliance with Clauses 8, 11, 12, 14, and 15, place sufficient condoms in a controlled environment at 30^{+5}_{-2} °C:

a) assess mean and standard deviation of air burst values (32 condoms per interval) at intervals of 1 year or less;

b) carry out tests for conformity with Clauses 11, 12, and 15 at the end of the intended shelf-life, or earlier where warranted by changes in the above data, in accordance with the sampling plans given in Annex B.

Shelf-life shall be confirmed if condoms meet the requirements of Clauses 11, 12, and 15 after storage for a period equal to the intended shelf-life claim.

K.2.2 Testing

K.2.2.1 Test three lots of condoms packed in their respective individual containers for conformity with the requirements of Clauses 8, 11, 12, 14, and 15 using the sampling plans given in Annex B.

K.2.2.2 Condition the condoms at 30^{+5}_{-2} °C. Manufacturers should ensure that precautions are taken to monitor temperatures during the conditioning period and have adequate contingency arrangement in place to respond to any loss of temperature control caused by equipment breakdown or loss of power.

K.2.2.3 Condition sufficient condoms per lot to allow at least 32 condoms to be tested for bursting volume and pressure at intervals of 1 year or less over the duration of the proposed shelf-life period (suggested minimum, 200 condoms). Retain sufficient additional condoms to allow for compliance with Clauses 8, 11, 12, 14, and 15 to be assessed at the end of the proposed shelf-life period using the samples sizes given in Annex B (suggested minimum, 865 condoms).

It is strongly recommended that additional condoms be conditioned as spares in case there is a need for any re-testing or in case additional time points are required.

K.2.2.4 Remove condoms (at least 32 per lot) from the controlled environment at intervals of 1 year or less.

K.2.2.5 Determine bursting volume and pressure according to Annex H.

K.2.2.6 Plot the mean and standard deviation of the bursting pressure and volume against time for each lot.

K.2.2.7 At the end of the proposed shelf-life period, or if the mean and standard deviation of the burst properties as monitored in K.2.2.6 above deteriorate to the point where the condoms might be approaching the limit of complying with the air burst requirements of Clause 11, test sufficient condoms per lot using the sampling plan in Annex B for compliance with Clauses 8, 11, 12, 14, and 15.

NOTE The condoms can be considered to be at risk of approaching the limits of compliance with air burst requirements when the difference between the mean and the limit in Clause 11 is less than $2s$ to $3s$, where s is standard deviation.

K.2.2.8 Assess compliance with Clause 9.

K.3 Confirmation of shelf-life claim

Upon completion of the procedure specified in K.2, the shelf-life claim shall be up to that period, not to exceed 5 years, for which the condoms have complied with the requirements of Clauses 11, 12, 14, and 15.

If the shelf-life marked on the label is more than the confirmed shelf-life, adjust the shelf-life claim and notify the regulatory authorities and direct purchasers.

K.4 Test report

The test report shall include the requirements of H.4 in the form specified by Clause 17 and:

a) the plot of bursting pressure and volume against time, as determined according to K.2.2.6;

b) the number of non-conforming units, as determined according to K.2.2.8;

c) the confirmed shelf-life claim.

Interim test reports shall be made available to appropriate regulatory bodies on request, to document that the real-time study has begun.

Annex L
(informative)

Guidance on conducting and analysing ageing studies

L.1 Principle

Accelerated ageing studies may be used to estimate provisional shelf-life. This annex describes a general protocol that may be used for conducting accelerated ageing studies to estimate shelf-life for market introduction while real-time studies are in progress. It also offers guidelines on analysing these studies to predict shelf-life.

L.2 Background

Before commencing accelerated ageing studies, consideration should be given to the specific mechanisms of degradation that might apply to the type of material from which the condom is made. Some materials, for example, might exhibit excellent resistance to thermal and oxidative degradation, but can be susceptible to rapid degradation by hydrolysis if not protected from moisture. Accelerated ageing studies are usually undertaken at elevated temperatures to increase the rate of degradation, but other potentially important factors, such as humidity, also need to be taken into account.

It should also be recognized that the use of high temperatures can cause effects that are not relevant to the normal ageing processes observed under ambient conditions. For example, some thermoplastic materials can exhibit excessive softening or partial melting at the higher temperatures typically used for accelerated ageing studies on latex condoms. The temperature ranges used for testing synthetic condoms can therefore be more restricted than those used for latex condoms.

L.3 Procedure for conducting accelerated ageing studies

Condition condoms from three production lots in ovens at selected temperatures according to Annex N. At appropriate time intervals, remove samples of condoms from the oven, and determine the air bursting properties according to Annex H. It is recommended that a minimum of four elevated temperatures be used. A minimum of five time points at each temperature is recommended and the study should continue for at least 120 days and preferably 180 days. It is recommended that at least 32 condoms be tested at each time and temperature point.

If the results are to be compared with those for a condom for which real-time stability data are available then equivalent samples of that condom should be conditioned at the same time.

L.4 Analysis of accelerated ageing data to estimate provisional shelf-life

For many materials, shelf-life estimates can be predicted by extrapolation from accelerated ageing studies using the Arrhenius equation. Details of the procedure are given in ISO 11346[7]. The application of the Arrhenius plot should be considered first.

In some cases, it is possible that the Arrhenius plots are not linear. Several approaches to the analysis of non-linear Arrhenius-type plots have been explored, but a consensus method has not been agreed. It should be emphasized that any attempt to extrapolate shelf-life estimates from non-linear Arrhenius plots carries a high level of risk and manufacturers should be conservative about any estimates made under such conditions.

A convenient method of presenting and analysing stability data is to use the time-temperature superposition method to superimpose data from different temperatures on to a single master curve. This method is also described in ISO 11346[7]. In this procedure, the time values for each data point are transformed to equivalent times at a common reference temperature by multiplying the time values by the Arrhenius shift factor, a_T, which is derived from the Arrhenius equation:

$$a_T = \exp\left\{\frac{E_a[(1/T_{ref}) - (1/T_{age})]}{R}\right\} \quad \text{(L.1)}$$

where

E_a is the activation energy;

R is the gas constant [8,314 J/(mol K)];

T_{ref} is the reference temperature, in kelvins;

T_{age} is the ageing temperature, in kelvins.

The reference temperature for condom stability studies is 30 °C.

The physical properties obtained at the various ageing temperatures are plotted against the respective transformed times on a common graph. If the ageing properties transform according to the Arrhenius equation and the correct value is used for the activation energy, then a single master curve is obtained. The properties of the condom after any period of ageing at the reference temperature can be readily read off the resulting curve. Alternatively the shift factor may be determined by using the least squares method to find the best value of a_T to maximize the overlap of the curves or, if the data are plotted on a log time basis, simply by sliding the degradation curves along the log time axis until the best overlap is observed visually.

Yet another method of analysing stability studies is to compare the rates of change of burst properties with those of a condom of similar formulation for which the shelf-life has already been determined by a real-time study.

The results of accelerated ageing data may be analysed using any of the methods described above, any other appropriate method or as stipulated by the manufacturer's regulatory authority. The method chosen should be justified. Manufacturers are not limited to the specific methods described above and are encouraged to investigate these and other methods.

L.5 Test of shelf-life estimates

Once the shelf-life of the condom has been estimated, it is necessary to confirm that condoms selected from three lots comply with the requirements of Clauses 11, 12 and 15 after completion of the thermal challenge equivalent to the proposed shelf-life at 30 °C. Select a set of accelerated ageing conditions equivalent to the estimated shelf-life at the proposed climatic temperature. The ageing conditions should be chosen with a view to replicating the mode of failure at 30 °C that is predicted by the stability study.

Take samples of condoms packaged in individually sealed containers from three lots. The same three lots should be used as for the accelerated ageing study. Condition the samples according to Annex N at the selected ageing temperature for the selected time. Test the samples for compliance with the requirements defined in Clauses 11, 12, and 15.

Annex M
(normative)

Tests for individual container integrity

M.1 General

Individual container integrity refers to the possibility of breaches in sealed individual condom containers that can result in the leakage of lubricant. Such breaches also cause the individual container to be permeable to oxygen or other deleterious substances. However, the test specified in this annex cannot detect leakage due to microporosity or gas permeability of the materials used to construct the individual containers. Consequently, this test may be used only to detect leaks large enough to allow leakage of lubricant.

Several tests are under development. Pending conclusive validation that new tests provide greater sensitivity or consistency, individual container integrity shall be measured according to the following test method using a vacuum level corresponding to (20 $\pm$ 5) kPa absolute pressure.

It is possible that some leaks are not detected by this procedure. Positive pressure inside the condom container after the vacuum is drawn can force the lubricant, if present, to plug small leaks. The size of the leak that can be detected is dependent upon the lubricant and the nature of the packaging material.

M.2 Test method

M.2.1 Apparatus

N.2.1.1 **Vacuum chamber**, capable of withstanding approximately one atmosphere pressure differential, fitted with a vacuum pump, a vacuum gauge and the possibility to inspect the interior during the test.

M.2.2 Reagent

N.2.2.1 **Immersion fluid** (water), treated with a wetting agent (such as dishwashing liquid).

M.2.3 Sampling

Use special inspection level S-3.

M.2.4 Test specimen

Condoms in their individual containers.

M.2.5 Conditioning

The test specimens and test fluid shall be at equilibrium with normal room temperature.

M.2.6 Procedure

Submerge the individual condom containers in water contained in a vessel within the vacuum chamber. The uppermost surface of the containers shall be covered by not less than 25 mm of water. If a dye is added to the water, leakage of water into the container is easier to detect.

Two or more containers may be tested at the same time, provided that they are placed in such a manner that all parts of every container under test can be observed for leakage during the test.

Evacuate the chamber to an absolute pressure of (20 ± 5) kPa. As the vacuum increases, observe the condom containers for leakage in the form of a steady progression of bubbles. Isolated bubbles caused by entrapped air are not considered as leaks. Flexible packaging with little or no headspace cannot be reliably evaluated with this test method.

Hold the vacuum for 1 min. Release the vacuum, remove the lid, and examine the condom containers for the presence of water inside.

M.2.7 Interpretation of results

If there are bubbles indicating leaks in a condom container as the vacuum increases, or when held at specified vacuum, then the specimen fails the test. If the test fluid is visible inside a container, the container fails the test. If there are no bubbles observed indicating leaks, and if no test fluid is visible inside a container, the container passes the test.

M.2.8 Test report

The test report shall include the information specified in Clause 17 and the number of containers with detected leaks.

Annex N
(informative)

Oven treatment for condoms made from synthetic materials

N.1 Principle

Oven treatment is used to condition condoms for shelf-life determination. This annex describes the method for oven treatment.

N.2 Apparatus

Oven, of either type specified in ISO 188[1], and capable of maintaining the temperature conditions specified for the product material. Alternatively, conditioning rooms or chambers may be used provided the specified temperature conditions can be maintained.

Manufacturers should ensure that precautions are taken to monitor oven temperatures during the conditioning period and should have adequate contingency arrangements in place to respond to any loss of temperature control caused by oven breakdown or loss of power.

N.3 Preparation of condoms for test

Before testing, condition condoms in their original individual packages (i.e. remove the individual container from consumer and outer packages before conditioning).

N.4 Procedure

N.4.1 Condition the condoms in an oven at the temperature stipulated for the product.

Mount condoms in such a manner as to minimize direct contact of the specimens with the heated surfaces, especially the base of the oven, thus ensuring even heating of the condoms during oven ageing.

N.4.2 Remove the condoms from the oven after the time stipulated, and keep the packages at (25 $\pm$ 5) °C until tested.

N.4.3 Within 96 h but not sooner than 12 h after removal from the oven, determine bursting volume and pressure according to Annex H.

Bibliography

[1] ISO 188, *Rubber, vulcanized or thermoplastic — Accelerated ageing and heat-resistance tests*

[2] ISO 2230, *Rubber products — Guidelines for storage*

[3] ISO 9000, *Quality management systems — Fundamentals and vocabulary*

[4] ISO 9001, *Quality management systems — Requirements*

[5] ISO 9004, *Managing for the sustained success of an organization — A quality management approach*

[6] ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

[7] ISO 11346, *Rubber, vulcanized or thermoplastic — Estimation of life-time and maximum temperature of use*

[8] ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

[9] ISO 16038, *Male condoms — Guidance on the use of ISO 4074 and ISO 23409 in the quality management of natural rubber latex condoms and synthetic condoms*

[10] ISO 29943-1 [2)], *Condoms — Guidance on clinical studies — Part 1: Male condoms in-use failure modes studies based on self-reports*

[11] ISO/IEC Guide 7, *Guidelines for drafting of standards suitable for use for conformity assessment*

[12] EN 980, *Symbols for use in the labelling of medical devices*

[13] ASTM D3078-02, *Standard test method for determination of leaks in flexible packaging by bubble emission*

[14] ASTM D3767-03, *Standard practice for rubber — Measurement of dimensions*

[15] FREE, M.J., SRISAMANG, V., VAIL, J., MERCER, D., KOTZ, R., MARLOWE, D.E. Latex rubber condoms: Predicting and extending shelf life. *Contraception* 1996, **53**, pp. 221-229

[16] GRIMM, W. Extension of the International Conference on Harmonization tripartite guideline for stability testing of new drug substances and products to countries of climatic zones III and IV. *Drug Dev. Indust. Pharmac.* 1998, **24**, pp. 313-325

[17] GRIMM, W. Storage conditions for stability testing in the EC, Japan and USA; the most important market for drug products. *Drug Dev. Indust. Pharmac*. 1993, **19**, pp. 2795-2830

[18] GILLEN, K.T., CLOUGH, R.L., WISE, J. Extrapolating accelerated thermal-aging results: A critical look at the Arrhenius method. *Polym. Preprints* 1993, **34**, p. 185

[19] BARKER, L.R. Accelerated and long-term ageing of natural rubber vulcanisates. *J. Natur. Rubb. Res.* 1987, **2**, pp. 210-213

[20] BARKER, L.R. Accelerated and long-term ageing of natural rubber vulcanisates — Part 2: Results from ageing tests at 40 °C. *J. Natur. Rubb. Res.* 1990, **5**, pp. 266-274

2) In preparation.

[21] MANDEL, J., ROTH, F.L., STEEL, M.N., STIEHLER, R.D. Measurement of aging of rubber vulcanisates. *J. Res. Nat. Bur. Stand.* 1959, **63C**, pp. 141-145

[22] Division of Life Sciences, Office of Science and Technology, Center for Devices and Radiological Health. *Determining the barrier properties of condoms to viral penetration*. Washington, DC: US FDA, 1994

[23] Center for Devices and Radiological Health, Office of Device Evaluation, Division of Reproductive, Abdominal, Ear, Nose and Throat and Radiological Devices, Obstetrics-Gynecology Devices Branch. *Testing guidance for male condoms made from new material*. Washington, DC: US FDA, 1995. 24 p. Available (2011-01-24) at: http://www.fda.gov/OHRMS/DOCKETS/98fr/3552gd.pdf

[24] World Health Organization. *Preclinical and clinical requirements for approval to market non-latex condoms*. Geneva: WHO, 1997

[25] LYTLE, C.D., ROUTSON, L.B., CYR, W.H. A simple method to test condoms for penetration by viruses. *Appl. Environ. Microbiol.* 1992, **58**, pp. 3180-3182

[26] RETTA, S.M., HERMAN, W.A., RINALDI, J.E., CAREY, R.F., HERMAN, B.A., ATHEY, T.W. Test method for evaluating the permeability of intact prophylactics to viral-size microspheres under simulated physiologic conditions. *Sex. Trans. Dis*. 1991, **18**, pp. 111-118

[27] STEINER, M., TRUSSELL, J., GLOVER, L., JOANIS, C., SPRUYT, A., DORFLINGER, L. Standardized protocols for condom breakage and slippage trials: A proposal. *Am. J. Public Health* 1994, **84**, pp. 1897-1900

[28] CAREY, R.F., HERMAN, W.A., RETTA, S.M., RINALDI, J.E., HERMAN, B.A., ATHEY, T.W. Effectiveness of latex condoms as a barrier to human immunodeficiency virus-size particles under conditions of simulated use. *Sex. Transm. Dis.* 1992, **19**(4), pp. 230-233

[29] TAYLOR, D.J., DOMINIK, R.C. Non-inferiority testing in crossover trials with correlated binary outcomes and small event proportions with applications to the analysis of condom failure data. *J. Biopharmac. Stat.* 1999, **9**(2), pp. 367-377

[30] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. *Off. J. Eur. Union* 1993, **L169**, pp. 1-60. Available (viewed 2011-01-24) at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF

[31] Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market. *Off. J. Eur. Union* 2007, **L247**, pp. 21-55. Available (viewed 2011-01-24) at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:247:0021:0055:en:PDF

[32] ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

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