Designation: D3492 – 16

Standard Specification for Rubber Contraceptives (Male Condoms)[1]

This standard is issued under the fixed designation D3492; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

This standard has been approved for use by agencies of the U.S. Department of Defense.

1. Scope

1.1 This specification covers the minimum requirements for individually packaged male condoms made from natural rubber latex and intended for single use. This specification does not cover the specifications for lubricants or other dressing materials that may be applied to condoms except as noted in 3.2.

1.2 This specification is intended to assist buyers in obtaining condoms of consistent quality. The safe and proper use of condoms is excluded from the scope of this specification.

1.3 The applicability of this specification is as a design guideline and a reference test specification. It is not intended to be a routine quality control specification for condom manufacturing operations.

1.4 The annexes in this specification include important information, such as that on apparatus or materials, that is a mandatory part of the specification but too detailed for inclusion in the main text.

1.5 The appendixes in this specification contain information intended to provide guidance only and are not a mandatory part of the specification.

1.6 It shall be the responsibility of the manufacturer for any condom design that falls outside the specifications of this standard to determine testing methodology and substantiate the appropriateness of that methodology to assure the quality of the condoms to the purchaser and to the government regulatory authority having jurisdiction.

1.7 Regulatory bodies may require additional information, such as clinical data, to support the condom sizes subject to this standard.

1.8 The values stated in SI units are to be regarded as the standard. The values given in parentheses are for information only.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

D573 Test Method for Rubber—Deterioration in an Air Oven

D1076 Specification for Rubber—Concentrated, Ammonia Preserved, Creamed, and Centrifuged Natural Latex

D3078 Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission

D3767 Practice for Rubber—Measurement of Dimensions

D4483 Practice for Evaluating Precision for Test Method Standards in the Rubber and Carbon Black Manufacturing Industries

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

2.2 *ISO Standard:*[3]

ISO 4074 Natural Latex Rubber Condoms – Requirements and Test Methods

ISO 10993 Biological Evaluations of Medical Devices

2.3 *Other Document:*[3]

ANSI/MIL-STD 105E Sampling Procedures and Tables for Inspection by Attributes

3. Materials and Manufacture

3.1 Condoms shall be manufactured from natural rubber latex conforming to Specification D1076.

3.2 The condoms and any dressing materials applied to them shall not liberate substances that are known to be toxic, sensitizing, locally irritating, or otherwise harmful to the general population under normal conditions of use.

NOTE 1—Natural rubber latex products are known to cause irritation or sensitivity in a small proportion of the user population.

[1] This specification is under the jurisdiction of ASTM Committee D11 on Rubber and is the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

NOTE 2—Condom lubricants that contain Nonoxynol 9 spermicide are known to cause irritation in a small proportion of the user population.

NOTE 3—ISO 10993 contains methods to evaluate the biocompatibility of natural rubber latex condoms.

4. Requirements

4.1 *General:*

4.1.1 *Sampling*—Samples will be selected randomly from the defined "lot." The sampling plan must conform to the requirements listed in Table 1.

4.1.2 *Sample Handling*—To avoid inadvertent damage, operators must wear rubber gloves, finger cots, or other suitable hand/finger covers and exercise reasonable caution in handling the packet or condom in order to minimize the possibility of damage during the testing procedure.

4.1.3 *Process Controls*—Manufacturers may use process control tests to determine condom properties. Finished condoms shall be used for qualification and referee tests.

4.1.4 *Lot*—A collection of condoms of the same design, color, shape, size, and formulation manufactured continuously, using the same process, raw materials, or the same specification, common equipment, and packaged with the same lubricant and any other additives or dressing in the same type of individual container. The maximum lot size shall be 500 000 condoms.

4.2 *Dimensions*—Condoms shall meet the requirements listed in Table 2.

4.2.1 *Procedures for Dimensional Test:*

4.2.1.1 *Length*—Measure the length of the condom to the nearest 1 mm, using the method described in Annex A1.

4.2.1.2 *Width*—Measure to the nearest 0.5 mm the width of the condom laid flat at a distance 30 ± 5 mm from the open end.

4.2.1.3 *Thickness*—Measure the thickness of condoms dried at room temperature for a minimum of 16 h after any dressing materials have been removed with water or isopropanol. Measure the wall thickness at three points per the table below. The thickness measuring device shall conform to that specified in Practice D3767, Test Method A with the pressure of the foot thickness gage at 22 ± 5 kPa. When a condom is textured, measure the thickness in the nontextured area. Report the measurements to the nearest 0.01 mm.

Condom Length (mm)	Thickness Measurement Points from Closed End (±5 mm)
125 – 135	20, 60, 100
136 – 160	25, 75, 125
160+	30, 90, 150

4.3 *Tensile Properties*—This part of the specification specifies a method for determining the breaking force, tensile strength, and ultimate elongation of rubber contraceptives.

TABLE 1 Quality Inspection Requirements[A]

Characteristic	Inspection Level	AQL
Condom		
Dimensions	S-2	4.0
Air burst properties	I	1.5
Leakage	I	0.25
Package		
Package integrity	S-3	2.5

[A] ANSI/MIL-STD 105E.

TABLE 2 Dimensional Requirements

	Nominal Length (mm)[A,B]	Nominal Flat Width (mm)[C,D]	Thickness (mm)
Minimum	125	45	0.03
Maximum	210	60	N/A

[A] The length of the condom shall be measured excluding the reservoir tip if any.
[B] No length measurement shall deviate from the nominal length stated by the manufacturer by more than ±10 mm.
[C] No width measurement shall deviate from the nominal width stated by the manufacturer by more than ±2 mm.
[D] For condoms having a shaped profile about the closed end, the width of the profile, when laid flat, shall be not more than 75 mm.

There are no breaking force, tensile strength, or elongation requirements for condoms given in this specification.

4.3.1 *Procedures for Tensile Properties*—Breaking force, tensile strength, and ultimate elongation. Test methods are presented in Appendix X1 and Test Methods D412.

4.3.1.1 *As Is*—Condoms that are less than 12 months old and have not been subjected to accelerated aging.

4.3.1.2 *Accelerated Aging*—Heat condoms to be aged in their primary packages at 70 ± 2°C for 166 ± 2 h in accordance with Test Method D573. Determine tensile properties not less than 16 h or not more than 96 h after heating. Manufacturers may use process control tests to determine suitable shelf life, but accelerated aging at 70°C for 166 h shall be used for qualification tests and referee tests.

4.4 *Air Burst Properties*—Condoms shall conform to the requirements of 4.4.1 for pressure and 4.4.2 for volume.

4.4.1 *Pressure*—When tested as described in Annex A2, the bursting pressure shall not be less than 1.0 kPa.

4.4.2 *Volume*—When tested as described in Annex A2, the bursting volume shall not be less than that as calculated by the following equation:

$$V_{min} = 0.00003947 W^2 L \quad (1)$$

where:

V_{min} = minimum burst volume in dm^3, rounded to the nearest 1 dm^3,
W = nominal flat width in millimetres of the shank portion of the condom measured 70 ± 5 mm from the open end, and
L = inflation length of the condom in millimetres.

NOTE 4—Cubic decimetre (dm^3) is equivalent to litre (L).

NOTE 5—If the length of the condom is 125 to 135 mm, then the inflation length is 100 mm. If the length of the condom is 136 to 160 mm, then the inflation length is 125 mm. If the length of the condom is 161 to 210 mm, then the inflation length is 150 mm.

4.5 *Leakage:*

4.5.1 *Criteria*—Condoms that burst during the test or show any evidence of leakage in the test area, including seepage, microdroplets, squirters, etc., not including leakage at a distance of 25 mm (1 in.) or less from the open end, will be considered failures.

4.5.2 The "Hang-and-Squeeze" test method described in Annex A3 is recommended; however, when the purchaser specifies by the contract or purchase order, the "Hang-and-Roll" test method described in ISO 4074 may be used by the manufacturer in place of the method described in Annex A3.

5. Packaging

5.1 Unless otherwise specified, packaging shall be in accordance with the manufacturer's commercial practice.

5.2 Condom packages shall be tested in accordance with Test Method D3078 with the pressure reduced at least 50.8 kPa (15 in. of Hg) below atmospheric pressure. The inspection requirements of Section 10.2 of Test Method D3078 are not required. Package integrity requirements are stated in Table 1.

6. Labeling

6.1 Each condom package (individual primary package and retail package) shall be marked legibly.

6.1.1 Each condom package (individual primary package and retail package) shall include the name or trademark of the product.

6.1.2 Each condom package (individual and retail) shall include the statement, "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions."

6.2 The condom primary package (a.k.a. "wrapper" or "foil") and the retail package shall display the expiration date, which shall be marked as such, for example, "Exp."

6.2.1 The expiration date, which shall be interpreted as the last day of the month indicated, shall be displayed as the month and year of expiry using either a numeric or alphabetic month, preceded or followed by the numeric year designation, for example: 01/2010 or Jan 2010 or 2010/01 or 2010 Jan.

6.2.2 The expiration date shall be determined as specified in Annex A4.

6.2.3 Each condom package shall also include the name and place of business of manufacturer, packer, or distributor; statement of identity ("latex condom"); lot number and expiration date; and, if appropriate, country of origin (for example, "Made in _____").

6.3 The retail package label shall include the intended uses, appropriate warning statements, and declaration of net quantity of contents.

6.3.1 The retail package label may also contain information regarding the description of the condom (for example, nominal width, length, texture, shape, etc.).

6.3.2 Appropriate directions for use shall be included on the retail package or separately in a package insert.

6.3.3 Local labeling requirements take precedence over the labeling requirements listed in the standard but are not a part of the standard.

6.3.3.1 For packaged condoms intended for sale within the USA, each condom package (individual and retail) shall accord to the specifications set forth by the USFDA.

6.3.3.2 For packaged condoms intended for export from the USA, each condom package (individual and retail) shall accord to the specifications of the foreign purchaser and not be in conflict with the laws of the country to which it is intended for export.

7. Storage

7.1 During production, processing, and packaging, condoms shall not be allowed to come into contact with oil-based antiseptics, phenols and their derivatives, petroleum-based products, or other material harmful to rubber.

7.2 In-process bulk unpackaged latex condoms should be stored in appropriate closed containers in dry areas at a temperature below 40°C (104°F). Storage for short periods of time above this temperature will not be harmful to product. They should be kept away from direct sources of heat and ultraviolet light.

8. Quality Assurance

8.1 When specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements.

9. Keywords

9.1 condoms; contraceptives; prophylactic; rubber

ANNEXES

(Mandatory Information)

A1. DETERMINATION OF LENGTH

A1.1 Purpose

A1.1.1 Annex A1 specifies a method of determining the length of rubber condoms.

A1.2 Principle

A1.2.1 Free hanging of the unrolled condom over a graduated mandrel (Fig. A1.1) and observation of its length, the teat excluded.

A1.3 Equipment

A1.3.1 A mandrel with a scale divided into millimetres and having the dimensions shown in Fig. A1.1.

A1.4 Procedure

A1.4.1 Unroll the condom and smooth out the wrinkles resulting from the condom having been rolled up.

A1.4.2 Put the condom over the mandrel and let it hang freely, stretched only by its own mass.

A1.4.3 Note, to the nearest millimetre, the length of the condom as indicated on the scale outside the open end of the condom.

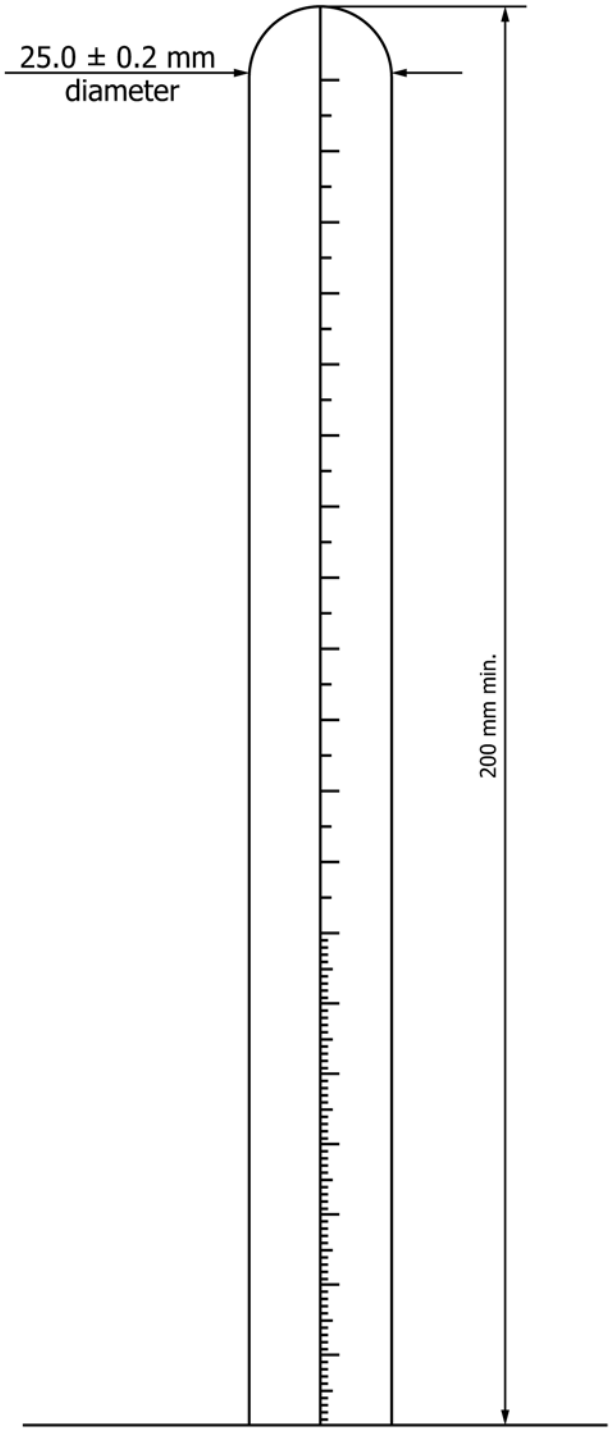


FIG. A1.1 Mandrel for Determining Length of Condom

A1.5 Test Report

A1.5.1 Report the following information:

A1.5.1.1 Identification of the sample,

A1.5.1.2 Length noted in accordance with A1.4.3, and

A1.5.1.3 Date of testing.

A2. AIR BURST TESTING OF CONDOMS

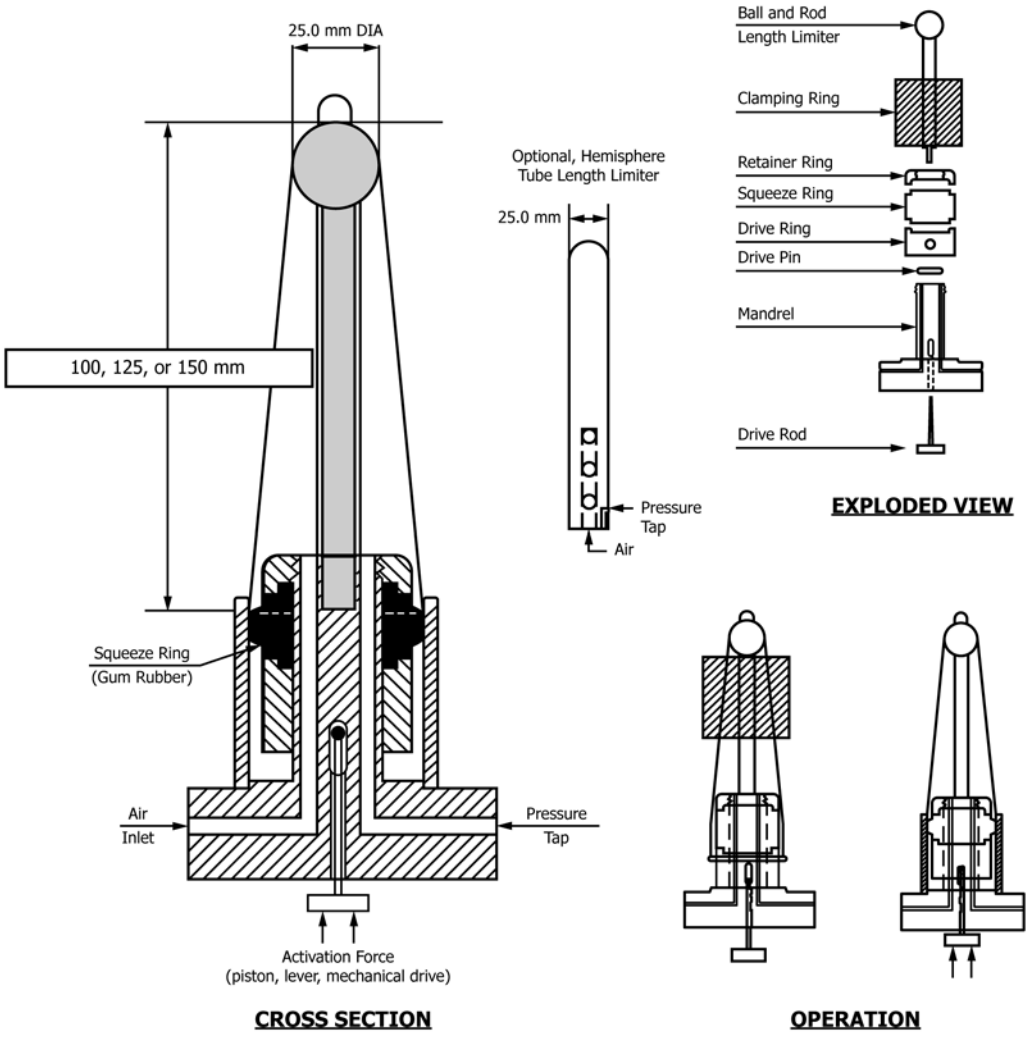
A2.1 Principle

A2.1.1 A constant length of condom is inflated with air, and the volume and pressure at the moment of bursting is recorded.

A2.2 Equipment

A2.2.1 Apparatus capable of inflating the condom with clean, oil-free air at a specified rate and provided with equipment for measuring volume inside the condom to an accuracy of 5 % and pressure inside the condom to an accuracy of 2 %, respectively. It must be configured to measure the pressure within the condom and not at the air inlet line pressure, which may be different.

A2.2.2 Suitable mount for clamping the condom to the apparatus without damaging or stretching the condom. The mount shall be equipped with a rod of sufficient length to ensure that for condoms >160 mm, the length of condom tested, excluding reservoir (if any), is 150 ± 3 mm. If the length of the condom is 136 to 160 mm use a rod and an inflation length of 125 mm. If the length of the condom is 125



NOTE 1—Other designs for a mechanical clamp system are feasible. This drawing is intended only as an example of one of the possibilities. In any design of this type of system the important criteria are:

(1) Pressure tap configured such that there is no pressure drop between the condom and the pressure tap.
(2) Length of condom that is free to expand is 100, 125, or 150 mm.
(3) Sphere at top of length limiter is 25.0 ± 0.2 mm diameter.
(4) Clamping ring does not pull condom down the cylinder as it is lowered.

FIG. A2.1 Example of Condom Mount for Air Inflation Testing—Mechanical Clamp

to 135 mm use a rod and an inflation length of 100 mm. (See Fig. A2.1 and Fig. A2.2.)

A2.3 Procedure

A2.3.1 Carry out the test under controlled conditions of temperature (25 ± 5°C).

A2.3.2 Unroll the condom onto the rod without stretching, but ensure that the condom is draped smoothly. Place the unrolled condom on the mount. Seal it to the system and ensure that air cannot leak through the seal or from the system during inflation.

A2.3.3 Inflate the condom with air at a constant rate of 0.4 to 0.5 dm^3/s (24 to 30 dm^3/min).

NOTE A2.1—The flow rate referred to is that under pressure and temperature conditions prevailing at the opening that leads into the condoms.

A2.3.4 If the condom leaks, discontinue the test. In the analysis of the test results, such behavior does not constitute a sample test. Replace the sample if this occurs.

A2.3.5 If the condom does not leak, measure and record the bursting volume in cubic decimetres rounded to the nearest 0.5 dm^3, and the bursting pressure in kilopascals rounded to the nearest 0.1 kPa.

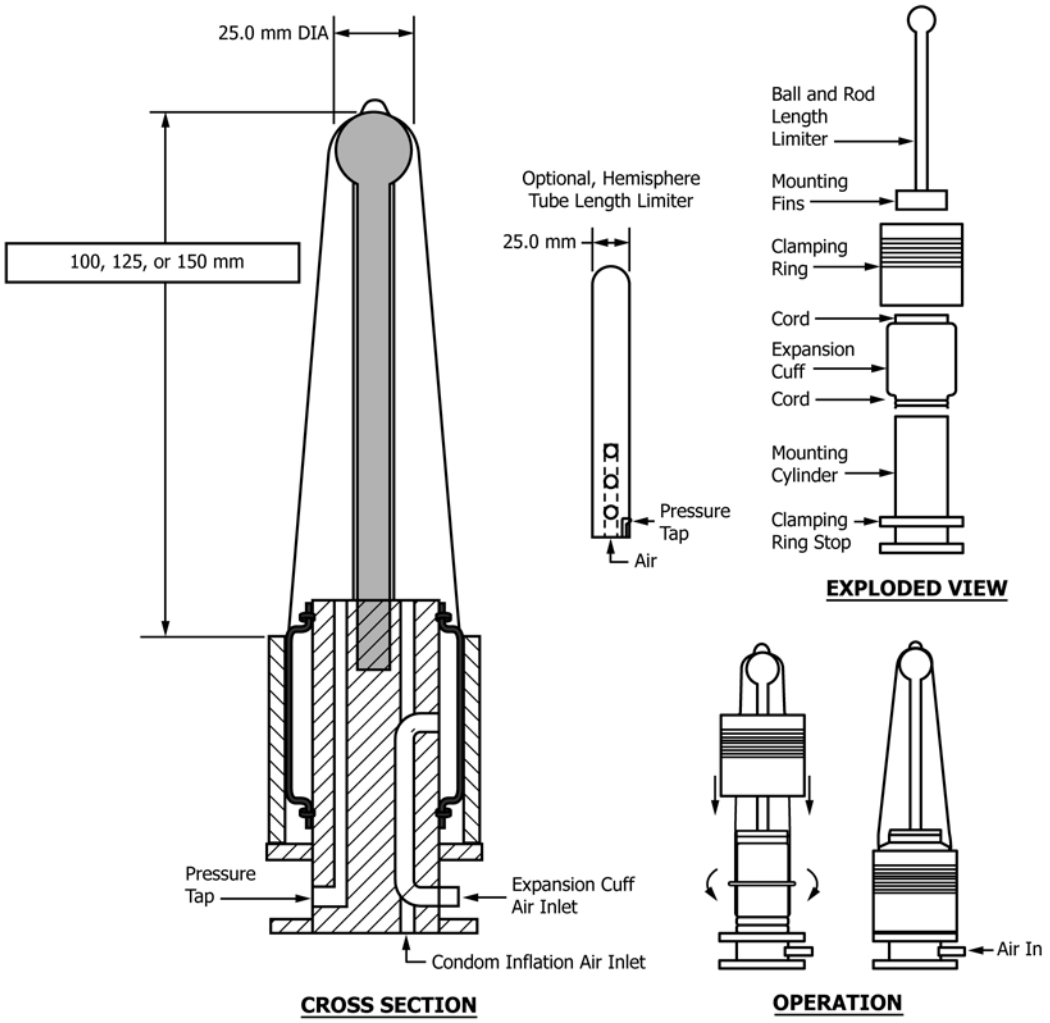
A2.4 Test Report

A2.4.1 Include at least the following particulars in the test report:

A2.4.1.1 Identification of sample,

A2.4.1.2 Bursting volume and bursting pressure of each condom tested, and

A2.4.1.3 Date of testing.



NOTE 1—Other designs for an air-operated clamp system are feasible. This drawing is intended only as an example of one of the possibilities. In any design of this type of system the important criteria are:
(1) Pressure tap configured such that there is no pressure differential between the condom and the pressure tap.
(2) Length of condom that is free to expand is 100, 125, or 150 mm.
(3) Sphere at top of length limiter is 25.0 ± 0.2 mm diameter.
(4) Expansion cuff deflates to a diameter such that the condom rolls freely over it.

FIG. A2.2 Example of Condom Mount for Air Inflation Testing—Air-Inflated Cuff

A3. LEAKAGE TEST

A3.1 *Test Principle*—Experience has shown that the water leak test is most sensitive when the condom is filled with water while hanging vertically, its top is closed off, and the condom is moved into horizontal positions and squeezed while it is examined for leaks.

A3.2 *Test Apparatus*—A filling apparatus with a suitably smooth-finished funnel fixture whose design permits the condom under test to hang unsupported, that is, with the closed end not touching the surface below while being filled with water, should be used.

A3.3 *Procedure*—Only a properly trained and qualified operator will conduct this procedure while wearing gloves or finger cots.

A3.3.1 To open the packet or package, slide the condom to one side of the packet. Gently hold the condom inside the packet in such a manner that during the opening of the packet, the packaging material does not damage or cut the condom. Tear the opposite side of the packet enough to carefully remove the condom keeping the packet intact, if rolled, unroll the condom to its fullest length. (Under no circumstances will scissors or any sharp instrument be used to open a condom.)

A3.3.2 Carefully stretch the condom rim and affix (place) it on the filling apparatus using two hands. (Fig. A3.1).

A3.3.3 Fill each condom to be tested with water per the table below. The temperature of the water shall not be less than 10°C nor greater than 40°C. Condom width is as measured in 4.2.1.2.

Condom length (mm)	Condom width (mm) Water Volume (cm^3)		
	45 to 49.5	50 to 55.5	56 to 60
125 to 135	150	200	250
136 to 160	200	250	300
160+ mm or longer	300	300	300

A3.3.4 Gently tap the condom to remove air bubbles from the inner surface of the condom (Fig. A3.2). Allow the condom to hang freely for not less than 1 min. Inspect the entire surface of the water-filled area of the condom for evidence of leakage. If a leak is detected, gently wipe the condom with a suitable low or lint-free laboratory grade paper or cloth towel to dry the surface. Use a water resistant permanent marker to circle the area of the defect. If there is no evidence of leakage, continue examining the condom.

A3.3.5 Gently squeeze the closed end and gently force the water to the top of the condom in a ball (Fig. A3.3) examining all surfaces for leaks. Lift the condom to a 45° angle so as to look at the back side of the condom for leaks.

A3.3.6 Release the ball of water, and gently roll the condom around in your hands so that the condom twists closed near the top (open end) to prevent water from escaping. Now gently force the water back to the closed end (Fig. A3.4).

NOTE A3.1—If you squeeze too hard and roughly force the water up, the condom will pop off the nozzle.

A3.3.7 Use the water to inflate the reservoir fully with about 20 mL of water (Fig. A3.5). Care should be used not to over distend the reservoir end during squeezing. At this point the "pinky" finger of the hand will be positioned such that it is at the last wide point of the condom before the nipple, even with the end of the shoulder. Turn the condom in an upward position to check for holes.

A3.3.8 Holding the closed end of the condom, gently force the water back to the top of the condom. Carefully examine the entire surface of the condom for holes (Fig. A3.5).

A3.3.9 If any leakage is noted during the inspection mark the location with a water-resistant permanent marker (Fig. A3.6).

FIG. A3.1 Leakage Test

FIG. A3.2 Leakage Test

FIG. A3.3 Leakage Test

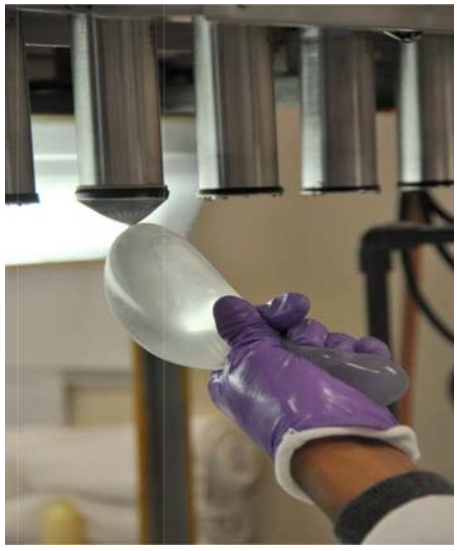


FIG. A3.4 Leakage Test

A3.3.10 Remove the condom from the funnel fixture. Empty the water. If a leak is marked in the upper region of the condom near the rim, measure the distance from the marked spot of the leak to the rim. Leakers within 25 mm (1 in.) from the rim will not be classified as defective for conformance to the water leakage AQL.

A3.4 *Interpretation of Results*—See 4.5.1.

FIG. A3.5 Leakage Test

FIG. A3.6 Leakage Test

A4. EXPIRATION DATE TESTING

A4.1 Only products that are found to conform to the requirements of Section 4 of this specification shall be entered into the expiration date testing of this annex.

A4.2 The expiration date must be supported by data demonstrating physical and mechanical integrity of the product after three discrete and representative lots of the product have been subjected to each of the following conditions:

A4.2.1 Storage of unpackaged bulk product for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the packaged product at 70 ± 2°C for 7 days (followed by room temperature equilibration for 24 h);

A4.2.2 Storage of unpackaged bulk product for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the packaged product at a selected temperature between 40 and 50 ± 2°C for 90 days; and

A4.2.3 Storage of unpackaged bulk product for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the packaged product at a monitored or controlled temperature between 15 and 30°C for the lifetime of the product (real time storage).

A4.3 If all of the products tested after storage at temperatures as described in paragraphs A4.2.1 and A4.2.2 of this annex pass the manufacturer's physical and mechanical integrity tests, the manufacturer may label the product with an expiration date of up to 5 years from the date of product packaging.

A4.4 If the extrapolated expiration date under paragraphs A4.2.1 and A4.2.2 of this annex is used, the labeled expiration date must be confirmed by physical and mechanical integrity tests performed at least annually and at the end of the stated expiration period as described in paragraph A4.2.3.

A4.5 If any of the testing performed at least annually and at the end of the stated expiration period following real time storage described in paragraph A4.2.3 of this annex fails to confirm the extrapolated expiration date, the manufacturer must, at that time, relabel subsequently produced product to reflect the actual shelf life.

A4.6 Initial testing of finished packaged final product shall conform to the sample plan.

APPENDIXES

(Nonmandatory Information)

X1. PREPARATION AND TESTING OF RING-STYLE TEST SPECIMENS FOR THE TENSILE TESTING OF CONDOMS

X1.1 Purpose

X1.1.1 The purpose of Appendix X1 is to provide information on the preparation of the ring-type tensile specimens supplementary to that provided in Test Methods D412. Experience with the tensile testing of condoms has resulted in several refinements to the methods of specimen preparation described in Test Methods D412. It has been demonstrated during interlaboratory studies of this test procedure that the hand or mallet cutting of specimens, as allowed by Test Methods D412, results in consistently lower tensile strength values and considerably greater experimental variability.

X1.2 General

X1.2.1 The importance of cutting properly prepared ring-type test specimens for the tensile testing of condoms cannot be overemphasized. Every effort must be made in the training of personnel and the selection of equipment to ensure that the test specimen is clean cut and that the cut across the width of the condom is made at a right angle to the condom's length. The use of guides for the selected sample cutting equipment to ensure the condom is placed at right angles to the cutting die is recommended. In addition, the region selected for cutting should be inspected carefully prior to cutting to ensure that the resulting ring specimen is free of film flaws.

X1.3 Equipment

X1.3.1 *Die*—A device having parallel cutting edges spaced 20 ± 0.1 mm apart and having a length of at least 70 mm designed so that the cutting edges may be replaced or honed periodically to maintain the die's sharpness.

X1.3.2 *Cutter*—A mechanical press or other apparatus that ensures that the die's cutting edges will move in a straight vertical direction to the anvil (cutting surface).

NOTE X1.1—Experience has shown that a mechanical press operating at a minimum vertical cutting speed of not less than 500 mm/s (20 in./s) and constructed so that the die may be attached to the arbor will result in more uniform specimens. As an alternative, a mallet and die can be used for sample cutting. However, this method is not recommended since the quality of the sample produced is greatly affected by the skill of the technician and the technique used.

X1.3.3 *Anvil (Replaceable Cutting Surface)*—The anvil must be a flat surface large enough to support a replaceable backing material that will permit the die to cut cleanly through the test specimen with minimal damage to the die's cutting edge. The cutting die shall not cut over previous cutting scars in the backing material.

NOTE X1.2—Experience has shown that 3 mm (0.125 in.) thick high density polyethylene (HDPE), polyvinylchloride (PVC), rubber, and polyethylene-coated cardboard are acceptable backing materials. Hard-pressed cardboard also has been used successfully, but care must be taken to ensure that the die cutting edge is not damaged. A wide variety of materials produce good results if they meet the basic requirements of being smooth, flat, and firm. When cutting specimens, excessive penetration of the cutting surface should be avoided. If considerable penetration is required to cut the sample, the cutting surface is not sufficiently firm or the die is not sufficiently sharp.

X1.3.4 *Unrolling Mandrel*—A device made of suitable material (smooth and cleanable) that will permit the condom to be unrolled, if necessary, and sized so that the condom is not stretched during its removal.

X1.3.5 *Solvents*—Water or isopropyl alcohol, or both, to be used to remove lubricant, if required.

X1.3.6 *Towel*—A soft laboratory grade absorbent material to be used to remove lubricant, if required.

X1.3.7 *Dressing Material*—Virgin talc, corn starch or silica, or both, (fragrance-free) to be used to assist drying and avoid stickiness during handling and cutting.

X1.3.8 *Condom Drying Apparatus*—An example of suitable apparatus for drying the condom after removal of the lubricant is shown in Fig. X1.1.

X1.4 Method

X1.4.1 *Condom Preparation:*

X1.4.1.1 Carefully remove the condom from the package, being sure to hold the condom while still inside the package in such a manner that during the opening of the package, the packing material does not damage or cut the condom.

X1.4.1.2 Carefully unroll the condom to its full length.

X1.4.1.3 Cut off the reservoir portion at the shoulder area. For round end condoms, cut just below the round end.

X1.4.1.4 Individually dip each lubricated condom into laboratory grade anhydrous isopropyl alcohol (IPA). For aqueous-based lubricants, water can be used. The condom should be held by the ring when dipping.

X1.4.1.5 In a second container containing IPA or water, again individually dip each condom (if necessary).

X1.4.1.6 Subsequently dip each condom in an IPA/dressing material slurry by submersion and gently mixing. Constant stirring of the slurry is required.

NOTE X1.3—All solutions must be changed when necessary.

X1.4.1.7 Dry the condom (reservoir removed) using a suitable apparatus (see X1.3.8) for a minimum of 15 min. Remove any excess dressing material by wiping.

X1.4.1.8 Lay the condoms flat on a bench top surface covered with towels and allow to air dry at ambient temperature for a minimum of 16 h. The condoms must be covered in some manner during this period.

NOTE X1.4—Steps X1.4.1.4 through X1.4.1.8 are applicable to lubricated condoms only.

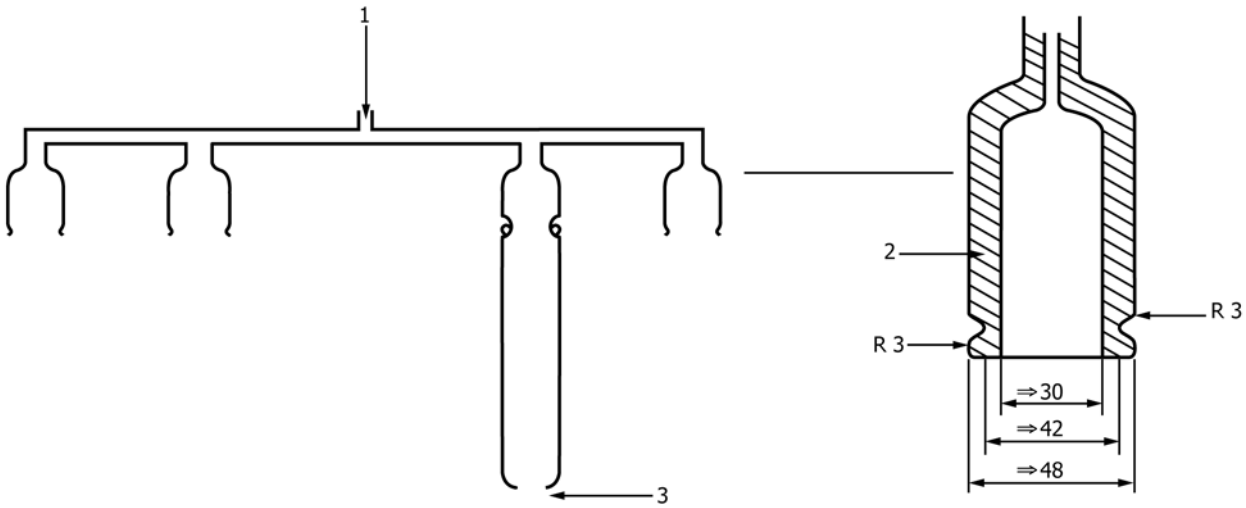
X1.4.2 *Ring Specimen Preparation*—Lay the condom on the replaceable cutting surface, making sure that it is flat and free of folds and wrinkles.

NOTE X1.5—The cutting die shall not cut over the previous cutting scars in the backing material.

X1.4.2.1 *Smooth Surface Condoms*—Cut the ring specimen in the region approximately 80 mm from the open end of the condom. Care should be taken to ensure that the cutting edges of the die are parallel to the "width" of the condom and perpendicular to the "length" of the condom.

X1.4.2.2 *Textured Surface Condoms*—Cut the ring specimen in a region free of texture and at least 5 mm from the nearest texture or the rim. Care should be taken to ensure that the cutting edges of the die are parallel to the "width" of the condom and perpendicular to the "length" of the condom.

X1.4.2.3 *Form-fitting Condoms*—Cut the ring specimen in a region free of shaping, that is, in a region in which the edges



NOTE 1—Oil-free, moisture-free compressed air supply.
NOTE 2—Suitable material, for example, glass.
NOTE 3—Reservoir removed.

FIG. X1.1 Condom Drying Apparatus

of the condom are parallel to and at least 5 mm from the end of the shaping or the rim. Care should be taken to ensure that the cutting edges of the die are parallel to the "width" of the condom and perpendicular to the "length" of the condom.

X1.4.2.4 *Other Styles of Condoms*—Cut the ring specimen in the region approximately 80 mm from the open end of the condoms, if free of texture or shaping, or in any other region consistent with the intent of forming a ring specimen that, when tested, will yield information consistent with assessing product quality.

X1.4.3 *Inspection:*

X1.4.3.1 Examine the ring specimens for evidence of damage, for example, nicks, or tears along the cut edges, or flaws in the film. Discard any ring specimen determined to be unsuitable and replace with a newly cut specimen from a freshly opened condom prepared as described in X1.4.1.

X1.4.3.2 Condition all tensile test specimens, if not already conditioned, for not less than 3 h at 25 ± 5°C and at 50 ± 5 % relative humidity. Test at 25 ± 5°C.

X1.4.4 *Dimensions of Tensile Specimen:*

X1.4.4.1 For each specimen, measure the thickness to the nearest 0.01 mm. Discard any specimen if the three measurements differ by more than 0.02 mm. Record the mean for the thickness.

X1.4.4.2 Lay the specimen flat. For each specimen, measure the distance between the two folded edges to the nearest 0.5 mm. Multiply the measurement by 2 to obtain the circumference of the ring specimen.

X1.4.5 *Tensile Tester*—Use a tensile tester with a range of approximately 100 N and a speed of 8.5 ± 0.8 mm/s (500 mm/min). Use roller grips at least 20 mm in length and 15 ± 1 mm in diameter that rotate on low friction bearings. If desired, rotate one roller grip mechanically at a rate of approximately one revolution in 6 to 10 s.

X1.4.6 *Procedure*—If necessary, lubricate the roller surfaces with any rubber lubricant, for example, silicon oil, talc, etc., that does not affect natural rubber. Place the specimen over the rollers and start the tester. Record the force and separation of roller centers at break.

X1.4.7 *Calculations:*

X1.4.7.1 Calculate the tensile strength as follows:

$$T = \frac{F}{2\,WD} = 0.025\,\frac{F}{D} \qquad \text{(X1.1)}$$

where:

T = tensile strength, MPa,
F = breaking force, N,
W = width of ring, 20 mm, and
D = mean single wall thickness, mm.

X1.4.7.2 Calculate the elongation at break as follows:

$$E = 100\,\frac{(2D + G - C)}{C} \qquad \text{(X1.2)}$$

where:

E = elongation at break, %,
D = distance between centers of rollers at break, mm,
G = circumference of one roller, mm, and
C = circumference of the specimen, mm.

X1.4.8 *Test Report*—Report the following information:

X1.4.8.1 Identification of the sample,

X1.4.8.2 Breaking force, ultimate tensile strength, and elongation for each tested condom, and

X1.4.8.3 Date of testing.

X2. AIR INFLATION EQUIPMENT FOR THE DETERMINATION OF BURSTING VOLUME AND PRESSURE: AN EXAMPLE OF SYSTEM CALIBRATION

X2.1 General

X2.1.1 Due to the diversity of equipment used by different testing laboratories, it is not practical to define all calibration procedures. However, a general outline (Fig. X2.1) of system calibration techniques and descriptions of some widely applicable procedures are warranted in order to minimize interlaboratory variance. These checks should be carried out before new equipment is commissioned, after a modification or repair, and periodically at pre-established intervals in accordance with good laboratory practice.

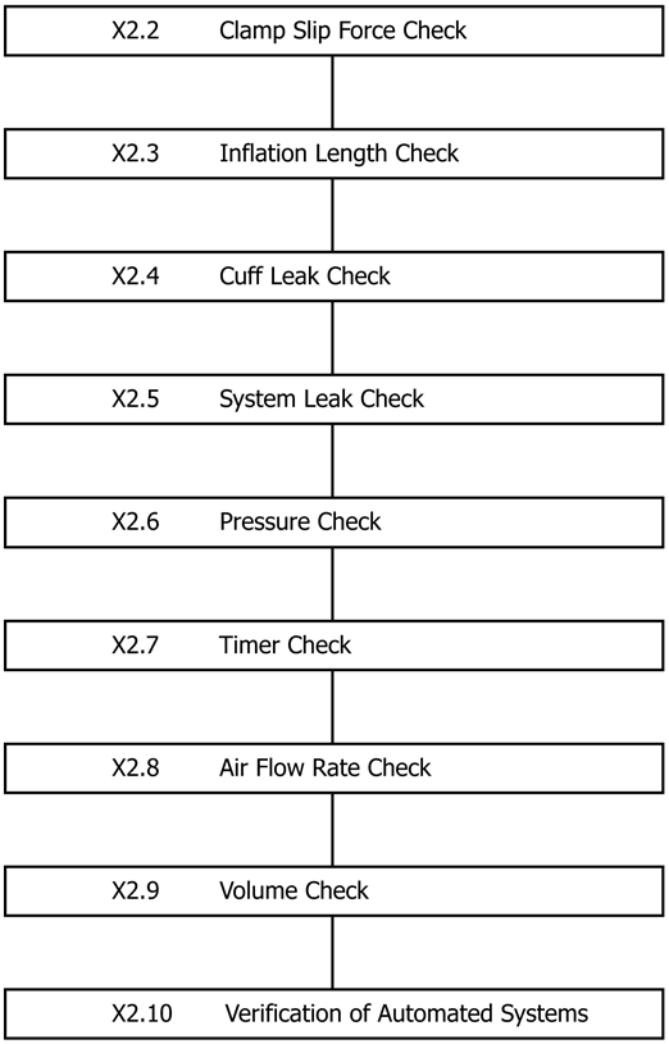
X2.2 Clamp Slip Force Check

X2.2.1 A clamp slip force test ensures that the condom length does not vary during inflation. Clamp slip force checks should be carried out with standard, lubricated, untextured condoms.

X2.2.2 Install a condom on the clamp and mark the condom with a fine-tipped felt pen at the edge of the clamp. Place a second condom over the outside of the first condom and outside the clamping ring. Do not place the second condom inside the clamp. Inflate the condom to at least 2.5 kPa and observe whether the mark has moved. If there has been movement of the mark away from the clamp, repair or replace the clamp. If no slippage is seen, proceed to the inflation length check (X2.3).

X2.3 Inflation Length Check

X2.3.1 The specified length of condom to be inflated is 100 to 150 ± 3 mm depending on overall length of the condom (see table below). To verify this length, mount a condom on each clamp. Mark the condom with a fine-tipped felt pen as close as possible to where it is gripped by the clamp. Remove the condom and place it on a standard length-measuring mandrel with a tip diameter of 25 mm. Read and record the length at the mark. If any measurement is outside the range given in the table below ±3 mm, check the clamping mechanism to determine if the clamp is stretching or interfering with the condom. Make corrections, or replace the clamping mechanism, and then repeat the inflation length check. If inflation length is within specifications, proceed to the cuff leak check (X2.4).



NOTE 1—Some items, such as leak checks, are a prerequisite to others, such as volume and pressure checks, but others, such as timer check and inflation length check, can be done independently of most other checks.

FIG. X2.1 Systems Calibration Techniques

Condom Length (mm)	Inflation Length (mm)
125 – 135	100
136 – 160	125
160+	150

X2.4 Cuff Leak Check

X2.4.1 For systems having an inflated cuff, there is a possibility that air could leak from the cuff into the condom while the cuff is still clamping effectively.

X2.4.2 If there is an isolation valve between the cuff and the air supply, isolate the cuff and then observe to see that the cuff is still inflated after 5 min.

X2.5 System Leak Check

X2.5.1 Inflate two condoms one over the other to approximately 20 dm^3 (about 40 s inflation time), and turn off the air supply. Record the height of the condom. Recheck the height after 10 min. If the change in height of the condom is over 50 mm, repeat the test with two other condoms. If there is still a significant height reduction, check the system for air leaks. If the condom height remains within 50 mm of the initial height, proceed to the pressure check (see X2.6).

X2.6 Pressure Check

X2.6.1 Pressure gages or transducers should be checked regularly against a reference meter. A convenient and accurate reference is a water-tube manometer. The water in the manometer should be clean and the zero should be checked prior to each use.

X2.6.2 First check gage or transducer reading for zero. Connect the manometer in parallel with the pressure gage or transducer. Pressurize the system over the range of 0 to 3 kPa, and compare the pressure of the gage or transducer to the manometer.

X2.6.3 If the gage or transducer gives a reading within 0.05 kPa of the manometer, then the calibration is acceptable.

X2.7 Timer Check

X2.7.1 Stopwatches or electric timers should be checked against nationally certified timers (for example, telephone clocks or broadcast time signals).

X2.8 Air Flow Rate Check

X2.8.1 This check is to ensure that the air flow rate is within the specifications 0.4 to 0.5 dm^3/s (24 to 30 dm^3/min) when ambient pressure or temperature changes.

X2.8.2 Calibration of air flow rate is most conveniently carried out using a suitable variable area flowmeter (rotameter) calibrated against a nationally or internationally certified displacement flowmeter. Once the rotameter has been calibrated against a known standard, the actual flow rate can be calculated using the following equation:

NOTE X2.1—The rotameter must be placed at the air inlet to the condom.

$$Q = q_R \sqrt{\frac{P_R \times T}{T_R \times P}} \qquad \text{(X2.1)}$$

where:

Q = actual air flow rate (dm^3/s),
q_R = reference air flow rate (dm^3/s) obtained from certified rotameter conversion chart,
P_R = reference absolute pressure (kPa) at the rotameter inlet when the rotameter was calibrated against a certified meter (sum of barometric pressure and gage inlet pressure),
T_R = temperature (°K) of air flowing through the rotameter when it was calibrated against a certified meter,
P = absolute pressure (kPa) at the rotameter inlet when determining air flow rate (barometric pressure and gage inlet pressure), and
T = temperature (°K) of air passing through the rotameter when determining air flow rate.

X2.9 Volume Check

X2.9.1 *In-line Volume Meter*—For systems equipped with an in-line volume meter, the meter can be checked against a rotameter or other certified volume meter.

X2.9.1.1 A rotameter can be placed in-line with the volume flowmeter, and the reading on the volume meter can be compared with the product of the true flow rate (as calculated in X2.8) and a fixed time of calibration, for example, 60 s. The pressure at the inlet to the rotameter and at the volume flowmeter must be the same or a correction must be made (using the perfect gas law) for any expansion between the volume flowmeter and test head.

X2.9.2 *Air Flow Rate Multiplied by Time*—For systems that use air flow rate multiplied by time to determine the burst volume, a correction factor must be used for the compressibility of the gas. The following equation will provide the actual air volume inside the condom at the time of burst:

$$V = Qt\left(\frac{P_{bar}}{P_{bar}+P_{burst}}\right) \quad (X2.2)$$

where:

V = burst volume (dm^3),
Q = actual air flow rate (dm^3/s) (see X2.6),
t = time to burst (s),
P_{bar} = barometric pressure (kPa), and
P_{burst} = condom pressure at burst (kPa).

X2.10 Verification of Automated Systems

X2.10.1 On systems where results (for example, volume, inflation time, and pressure) are recorded automatically, it is necessary to check that all parameters recorded are actually those at the time of burst. This must be done for each test head in the system.

X2.10.2 Manually calculate the burst volume using the calculation outlined in X2.9.2. A stopwatch should be used to record the inflation time to the nearest 0.1 s. Inflation time is defined as the period from which the air flow begins to inflate the condom to the burst moment. Compare the manually calculated burst volume to the automated burst volume. If the results are significantly different, the automated system inflation time and flow rate calculation should be checked.

X2.10.3 For systems using a volume flowmeter, the computer output should be checked against the meter reading. The burst pressure should be manually recorded and compared against the automated readout. If the pressure is significantly different, refer to X2.6 for pressure check.

X3. PRECISION AND BIAS STATEMENTS FOR TEST METHODS

X3.1 Dimension: Precision and Bias

X3.1.1 This precision and bias has been prepared in accordance with Practice D4483. Refer to this practice for terminology and other statistical details. The precision results in this precision and bias give an estimate of the precision for this test method. The precision parameters should not be used for acceptance or rejection of the material, as this data is specific to this round robin and may not be representative of other lots, materials or laboratories. Users of this test method should apply the principles outlined in Practice D4483 to their laboratory and materials or between specific laboratories. The principles of X3.1.2 would then be valid for such data. Table X3.1 and Table X3.2 are based on an interlaboratory study conducted in 2001 in accordance with Practice D4483 involving three male latex condom materials (A–"thin", B–regular, C–"thicker"), ten laboratories, two locations on the condom (open end–150 mm from the shoulder, closed end–30 mm from the shoulder) with two replicates per location taken on the same day. Therefore, p = 10, q = 3, and n = 2. The measurement technique as defined in Practice D3767 was used.

TABLE X3.1 Open End Thickness

NOTE 1—All values in microns (0.001 mm).

Material	Average	S_r [A]	S_R [B]	r [C]	R [D]
A	61.8	0.8	5.3	2.3	14.8
B	62.2	0.8	4.6	2.3	12.8
C	80.8	1.0	7.0	2.7	19.6

[A] S_R is within-laboratory standard deviation of the average (median/other function).
[B] S_r is the between-laboratory standard deviation of the average (median/other function).
[C] r is the within-laboratory repeatability limit = 2.8 S_r.
[D] R is the between-laboratory reproducibility limit = 2.8 S_R.

TABLE X3.2 Closed End Thickness

NOTE 1—All values in microns (0.001 mm).

Material	Average	S_r [A]	S_R [B]	r [C]	R [D]
A	77.2	0.4	3.9	1.1	11.0
B	82.2	0.7	6.0	2.1	16.7
C	114.4	1.3	8.7	3.5	24.3

[A] S_R is within-laboratory standard deviation of the average (median/other function).
[B] S_r is the between-laboratory standard deviation of the average (median/other function).
[C] r is the within-laboratory repeatability limit = 2.8 S_r.
[D] R is the between-laboratory reproducibility limit = 2.8 S_R.

X3.1.2 *Concept of r and R*—If S_r and S_R have been calculated from a large enough body of data for test results that were averaged (medians/other function) form testing X number of specimens, the following definitions are applicable:

X3.1.2.1 *Repeatability (r)*—Comparing two test methods for the same material obtained by the same operator using the same equipment on the same day. The two test results should be judged not equivalent if they differ by more than the r value of that material.

X3.1.2.2 *Reproducibility (R)*—Comparing two test results for the same material obtained by different operators using different equipment on different days. The two test results should be judged not equivalent if they differ by more than the R value for that material.

X3.1.3 Any judgment in accordance with X3.1.1 and X3.1.2 would have an approximate 95 % (0.95) probability of being correct.

X3.1.4 There are no recognized standards by which to estimate bias of this test method.

TABLE X3.3 Burst Volume (Litres)

	Average[A]	Repeatability Standard Deviation	Reproducibility Standard Deviation	Repeatability Limit	Reproducibility Limit
	$\bar{X}$	s_r	S_R	r	R
178 ± 3 mm	41.28	3.04	3.57	8.51	10.00
143 ± 3 mm	32.35	2.80	3.64	7.84	10.20
131 ± 3 mm	26.28	2.04	3.07	5.71	8.60

[A] The average of the laboratories' calculated averages.

TABLE X3.4 Burst Pressure (kPa)

	Average[A]	Repeatability Standard Deviation	Reproducibility Standard Deviation	Repeatability Limit	Reproducibility Limit
	$\bar{X}$	s_r	S_R	r	R
178 ± 3 mm	2.15	0.12	0.13	0.35	0.37
143 ± 3 mm	2.09	0.26	0.26	0.72	0.74
131 ± 3 mm	2.29	0.28	0.30	0.80	0.84

[A] The average of the laboratories' calculated averages.

TABLE X3.5 Length (mm)

	Average[A]	Repeatability Standard Deviation	Reproducibility Standard Deviation	Repeatability Limit	Reproducibility Limit
	$\bar{X}$	s_r	S_R	r	R
178 ± 3 mm	179.9	2.1	2.5	5.9	7.0
143 ± 3 mm	145.3	1.8	2.4	4.9	6.8
131 ± 3 mm	133.1	2.3	3.1	6.5	8.6

[A] The average of the laboratories' calculated averages.

TABLE X3.6 Width (mm)

	Average[A]	Repeatability Standard Deviation	Reproducibility Standard Deviation	Repeatability Limit	Reproducibility Limit
	$\bar{X}$	s_r	S_R	r	R
178 ± 3 mm	52.9	0.2	0.6	0.7	1.7
143 ± 3 mm	52.8	0.2	0.6	0.6	1.6
131 ± 3 mm	52.8	0.3	0.6	0.9	1.8

[A] The average of the laboratories' calculated averages.

X3.2 Tensile Properties: Precision and Bias

X3.2.1 The precision and bias associated with the tensile strength and ultimate elongation of male condoms are as specified in Test Methods D412.

X3.3 Air Burst Properties: Precision and Bias[4]

X3.3.1 The precision of this test method is based on an interlaboratory study conducted in 2014. Ten laboratories participated in the study, testing three different condom types for four properties. Every analyst was instructed to report as many as 80 replicate test results for each material in this study. Practice E691 was followed for the study design and analysis.

X3.3.1.1 *Repeatability (r)*—The difference between repetitive results obtained by the same operator in a given laboratory applying the same test method with the same apparatus under constant operating conditions on identical test material within short intervals of time would in the long run, in the normal and correct operation of the test method, exceed the following values only in one case in 20.

(1) Repeatability can be interpreted as maximum difference between two results, obtained under repeatability conditions, that is accepted as plausible due to random causes under normal and correct operation of the test method.

(2) Repeatability limits are listed in Tables X3.3-X3.6.

X3.3.1.2 *Reproducibility (R)*—The difference between two single and independent results obtained by different operators applying the same test method in different laboratories using different apparatus on identical test material would, in the long run, in the normal and correct operation of the test method, exceed the following values only in one case in 20.

(1) Reproducibility can be interpreted as maximum difference between two results, obtained under reproducibility conditions, that is accepted as plausible due to random causes under normal and correct operation of the test method.

[4] Supporting data have been filed at ASTM International Headquarters and may be obtained by requesting Research Report RR:D11-1111. Contact ASTM Customer Service at service@astm.org.

(2) Reproducibility limits are listed in Tables X3.3-X3.6.

X3.3.1.3 The above terms (repeatability limit and reproducibility limit) are used as specified in Practice E177.

X3.3.1.4 Any judgment in accordance with statements X3.3.1.1 and X3.3.1.2 would have an approximate 95 % probability of being correct.

X3.3.2 *Bias*—At the time of the study, there was no accepted reference material suitable for determining the bias for this test method, therefore no statement on bias is being made.

X3.3.3 The precision statement was determined through statistical examination of 5394 test results, from a total of ten laboratories, on three condom types.

X3.3.4 To judge the equivalency of two test results, it is recommended to choose the material closest in characteristics to the test material.

X3.4 Leakage: Precision and Bias

X3.4.1 No statement is made concerning the precision or bias of determining leakage in condoms since the result states merely whether there is conformance to the criteria specified.