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From the Office of the President

February 7, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

To Whom It May Concern:

We are writing with regard to the notice published in the Federal Register on Monday, January 24, 2000 regarding the Direct Final Rule to amend various device regulations to reflect current American Society for Testing and Materials citations.

We are very pleased that FDA is updating its references to three ASTM methods:

- D1415-68 Test Method for Rubber Property – International Hardness to D1415-88
- D412-68 Tension Test of Vulcanized Rubber to D412-97
- D3492-83 Standard Specification for Rubber Contraceptives (Condoms) to D3492-96

The purpose of this letter is to let you know that D412 and D3492 have both been revised again. The following are the reasons for the latest revisions. We are requesting that FDA reference the most current version of each of these standards.

Rationale for changes to D412-97 Standard Test Methods for Volcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers – Tension to **D412-98A** Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers-Tension

The title was changed because the term *Thermoplastic Rubber* is not defined by the ASTM terminology standard D1566 Standard Terminology Relating to Rubber, and has been removed from D1418 Standard Practice for Rubber and Rubber Latices-Nomenclature. The term is not in common usage in journals or other literature.

The scope was changed to include a statement that methods A and B, which already appear in the standard, do not produce identical results.

The first two sentences of Note 4 were deleted because the wording is redundant to that which appears in the section just prior to the note.

Metric values were added in a separate table from the USCM values because dies used in each system would not produce the same results on the same specimen. The report section was modified to require that the type of dye used to test the samples be recorded.

The scope was changed to limit the test method to "vulcanized thermoset" to avoid confusion, redundancy and inconsistency with the current literature.

Contact: ~~Peter Surette (781) 826-5600~~

C1

99N-4955

Rational for changes to D3492-96 Standard Specification for Rubber Contraceptives (Male Condoms) to **D3492-97** Standard Specification for Rubber Contraceptives (Male Condoms)

Air Burst Test Accuracy—The change on the accuracy requirement for air burst testing was adopted. The equipment accuracy will now be ±5% for burst volume (previously ±0.2dm^3) and ±2% for burst pressure (previously ±0.05 kPa). Also the rounding requirement for air burst volume will be the nearest 1 liter (dm^3) (previously 0.5 dm^3). All of the above were done to reflect the accuracy of the test equipment.

Thickness Measurement—It was agreed to change the method for determining the location of the three points on a condom for measuring thickness. The current standard states "Measure the wall thickness at three points, 10 ± 5mm from the open, 30 ± 5mm from the closed end, and at the mid-distance between these two points." A proposal to change this to 30 ± 5mm, 90 ± 5mm and 150 ± 5mm from the closed end was approved. All the locations for the 3-point measurement of thickness in the above (Section 4.2.1.3) are specified for clarity.

Storage of condoms—Section 7.2 will be changed to read "latex condoms should be stored in sealed containers, in dry areas at temperatures 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." This gives a specific storage temperature.

In section 3.1, the words "good quality" will be deleted as the requirement is for rubber latex to conform to ASTM D1076. The phrase "good quality" in Section 3.1 of D3492-96 was removed in the D3492-97 edition as natural rubber latex conforming to Spec. D1076 is already a good quality latex.

In table 1 the AQL for leakage will be changed from 0.4 to 0.25 to make the requirement more stringent.

Figure 1 (mandrel for determining length of condoms) will have the width dimension express as 25.0 ± 0.2mm (currently expressed as a radius of 12.5 ± 0.5mm) to make the requirement more simple to meet.

Contact: Kok-Kee Hon, (703) 941-7656

Two copies of each of the new standards are enclosed. If you have any questions, please do not hesitate to contact me or the contacts listed above. My telephone number is 610-832-9687. Thank you for your consideration.

Sincerely yours,

Kathleen Kono

Kathleen Riley Kono
ASTM Washington Representative

Cc: Phil Chao, FDA
Rob Allen, ASTM

Designation: D 412 – 98a

Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension[1]

This standard is issued under the fixed designation D 412; 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 Department of Defense.

1. Scope

1.1 These test methods cover procedures used to evaluate the tensile (tension) properties of vulcanized thermoset rubbers and thermoplastic elastomers. These methods are not applicable to ebonite and similar hard, low elongation materials. The methods appear as follows:

Test Method A—Dumbbell and Straight Section Specimens
Test Method B—Cut Ring Specimens

NOTE 1—These two different methods do not produce identical results.

1.2 The values stated in either SI or non-SI units shall be regarded separately as normative for this standard. The values in each system may not be exact equivalents; therefore each system must be used independently, without combining values.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

D 1349 Practice for Rubber—Standard Temperatures for Testing[2]

D 1566 Terminology Relating to Rubber[2]

D 3182 Practice for Rubber—Materials, Equipment and Procedures for Mixing Standard Compounds and Preparing Standard Vulcanized Sheets[2]

D 3183 Practice for Rubber—Preparation of Pieces for Test Purposes from Products[2]

D 3767 Practice for Rubber—Measurement of Dimensions[2]

D 4483 Practice for Determining Precision for Test Method Standards in the Rubber and Carbon Black Industries[2]

E 4 Practices for Force Verification of Testing Machines[3]

2.2 *ASTM Adjunct:*

Cut Ring Specimens, Method B (D 412)[4]

2.3 *ISO Standards:*

ISO 37 Rubber, Vulcanized and Thermoplastic Determination of Tensile Stress-Strain Properties[5]

3. Terminology

3.1 *Definitions:*

3.1.1 *tensile set*—the extension remaining after a specimen has been stretched and allowed to retract in a specified manner, expressed as a percentage of the original length. (D 1566)

3.1.2 *tensile set-after-break*—the tensile set measured by fitting the two broken dumbbell pieces together at the point of rupture.

3.1.3 *tensile strength*—the maximum tensile stress applied in stretching a specimen to rupture. (D 1566)

3.1.4 *tensile stress*—a stress applied to stretch a test piece (specimen). (D 1566)

3.1.5 *tensile stress at-given-elongation*—the stress required to stretch the uniform cross section of a test specimen to a given elongation. (D 1566)

3.1.6 *thermoplastic elastomers*—a diverse family of rubber-like materials that unlike conventional vulcanized rubbers can be processed and recycled like thermoplastic materials.

3.1.7 *ultimate elongation*—the elongation at which rupture occurs in the application of continued tensile stress.

3.1.8 *yield point*—that point on the stress-strain curve, short of ultimate failure, where the rate of stress with respect to strain, goes through a zero value and may become negative. (D 1566)

3.1.9 *yield strain*—the level of strain at the yield point. (D 1566)

3.1.10 *yield stress*—the level of stress at the yield point. (D 1566)

4. Summary of Test Method

4.1 The determination of tensile properties starts with test pieces taken from the sample material and includes the preparation of the specimens and the testing of the specimens.

[1] These test methods are under the jurisdiction of ASTM Committee D-11 on Rubber and are the direct responsibility of Subcommittee D11.10 on Physical Testing.

Current edition approved July 10, 1998. Published August 1998. Originally published as D 412 – 35 T. Last previous edition D 412 – 98.

[2] *Annual Book of ASTM Standards*, Vol 09.01.

[3] *Annual Book of ASTM Standards*, Vol 03.01.

[4] Detailed drawings are available from ASTM Headquarters, 1916 Race St., Philadelphia, PA 19103. Order Adjunct No. PCN 12-404121-20.

[5] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

Specimens may be in the shape of dumbbells, rings or straight pieces of uniform cross-sectional area.

4.2 Measurements for tensile stress, tensile stress at a given elongation, tensile strength, yield point, and ultimate elongation are made on specimens that have not been prestressed. Tensile stress, yield point, and tensile strength are based on the original cross-sectional area of a uniform cross-section of the specimen.

4.3 Measurement of tensile set is made after a previously unstressed specimen has been extended and allowed to retract by a prescribed procedure. Measurement of "set after break" is also described.

5. Significance and Use

5.1 All materials and products covered by these test methods must withstand tensile forces for adequate performance in certain applications. These test methods allow for the measurement of such tensile properties. However, tensile properties alone may not directly relate to the total end use performance of the product because of the wide range of potential performance requirements in actual use.

5.2 Tensile properties depend both on the material and the conditions of test (extension rate, temperature, humidity, specimen geometry, pretest conditioning, etc.); therefore materials should be compared only when tested under the same conditions.

5.3 Temperature and rate of extension may have substantial effects on tensile properties and therefore should be controlled. These effects will vary depending on the type of material being tested.

5.4 Tensile set represents residual deformation which is partly permanent and partly recoverable after stretching and retraction. For this reason, the periods of extension and recovery (and other conditions of test) must be controlled to obtain comparable results.

6. Apparatus

6.1 *Testing Machine*—Tension tests shall be made on a power driven machine equipped to produce a uniform rate of grip separation of 500 ± 50 mm/min (20 ± 2 in./min) for a distance of at least 750 mm (30 in.) (see Note 1). The testing machine shall have both a suitable dynamometer and an indicating or recording system for measuring the applied force within ±2 %. If the capacity range cannot be changed for a test (as in the case of pendulum dynamometers) the applied force at break shall be measured within ±2 % of the full scale value, and the smallest tensile force measured shall be accurate to within 10 %. If the dynamometer is of the compensating type for measuring tensile stress directly, means shall be provided to adjust for the cross-sectional area of the specimen. The response of the recorder shall be sufficiently rapid that the applied force is measured with the requisite accuracy during the extension of the specimen to rupture. If the testing machine is not equipped with a recorder, a device shall be provided that indicates, after rupture, the maximum force applied during extension. Testing machine systems shall be capable of measuring elongation of the test specimen in minimum increments of 10 %.

NOTE 2—A rate of elongation of 1000 ± 100 mm/min (40 ± 4 in./min) may be used and notation of the speed made in the report. In case of dispute, the test shall be repeated and the rate of elongation shall be at 500 ± 50 mm/min (20 ± 2 in./min).

6.2 *Test Chamber for Elevated and Low Temperatures*—The test chamber shall conform with the following requirements:

6.2.1 Air shall be circulated through the chamber at a velocity of 1 to 2 m/s (3.3 to 6.6 ft/s) at the location of the grips or spindles and specimens maintained within 2°C (3.6°F) of the specified temperature.

6.2.2 A calibrated sensing device shall be located near the grips or spindles for measuring the actual temperature.

6.2.3 The chamber shall be vented to an exhaust system or to the outside atmosphere to remove fumes liberated at high temperatures.

6.2.4 Provisions shall be made for suspending specimens vertically near the grips or spindles for conditioning prior to test. The specimens shall not touch each other or the sides of the chamber except for momentary contact when agitated by the circulating air.

6.2.5 Fast acting grips suitable for manipulation at high or low temperatures may be provided to permit placing dumbbells or straight specimens in the grips in the shortest time possible to minimize any change in temperature of the chamber.

6.2.6 The dynamometer shall be suitable for use at the temperature of test or it shall be thermally insulated from the chamber.

6.2.7 Provision shall be made for measuring the elongation of specimens in the chamber. If a scale is used to measure the extension between the bench-marks, the scale shall be located parallel and close to the grip path during specimen extension and shall be controlled from outside the chamber.

6.3 *Dial Micrometer*—The dial micrometer shall conform to the requirements of Practice D 3767 (Method A). For ring specimens, see 14.10 of these test methods.

6.4 *Apparatus for Tensile Set Test*—The testing machine described in 6.1 or an apparatus similar to that shown in Fig. 1 may be used. A stop watch or other suitable timing device measuring in minute intervals for at least 30 min, shall be provided. A scale or other device shall be provided for measuring tensile set to within 1 %.

7. Selection of Test Specimens

7.1 Consider the following information in making selections:

7.1.1 Since anisotropy or grain directionality due to flow introduced during processing and preparation may have an influence on tensile properties, dumbbell or straight specimens should be cut so the lengthwise direction of the specimen is parallel to the grain direction when this direction is known. Ring specimens normally give an average of with and across the grain properties.

7.1.2 Unless otherwise noted, thermoplastic rubber or thermoplastic elastomer specimens, or both, are to be cut from injection molded sheets or plaques with a thickness of 3.0 ± 0.3 mm. Specimens of other thickness will not necessarily give comparable results. Specimens are to be tested in directions both parallel and perpendicular to the direction of flow in the mold. Sheet or plaque dimensions must be sufficient to do this.

7.1.3 Ring specimens enable elongations to be measured by

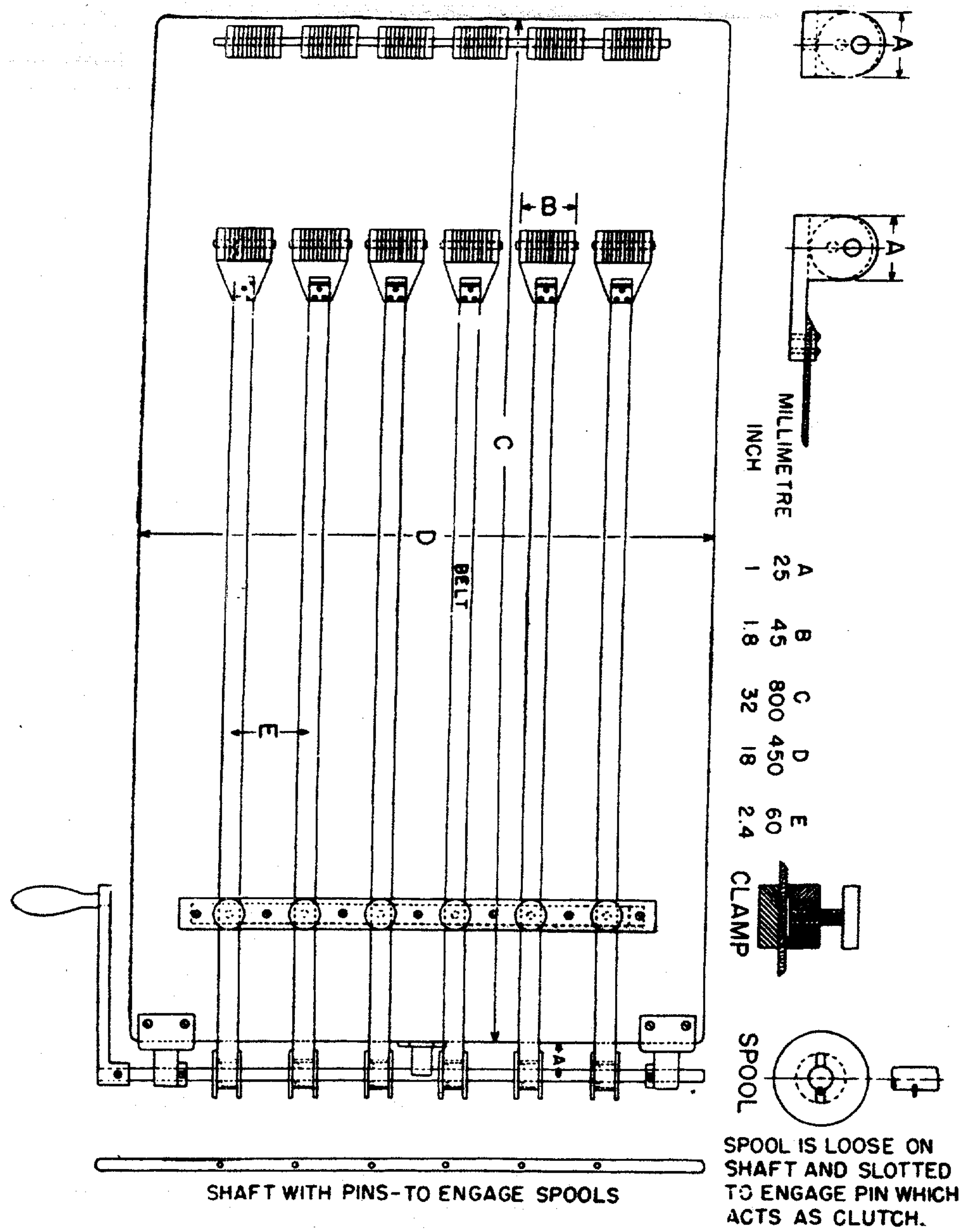


FIG. 1 Apparatus for Tensile Set Test

grip separation, but the elongation across the radial width of the ring specimens is not uniform. To minimize this effect the width of the ring specimens must be small compared to the diameter.

7.1.4 Straight specimens tend to break in the grips if normal extension-to-break testing is conducted and should be used only when it is not feasible to prepare another type of specimen. For obtaining non-rupture stress-strain or material modulus properties, straight specimens are quite useful.

7.1.5 The size of specimen type used will be determined by the material, test equipment and the sample or piece available for test. A longer specimen may be used for rubbers having low ultimate elongation to improve precision of elongation measurement.

8. Calibration of the Testing Machine

8.1 Calibrate the testing machine in accordance with Procedure A of Practice E 4. If the dynamometer is of the strain-gage type, calibrate the tester at one or more forces in addition to the requirements in Sections 7 and 18 of Practice E 4. Testers having pendulum dynamometers may be calibrated as follows:

8.1.1 Place one end of a dumbbell specimen in the upper grip of the testing machine.

8.1.2 Remove the lower grip from the machine and attach it, by means of the gripping mechanism to the dumbbell specimen in the upper grip.

8.1.3 Attach a hook to the lower end of the lower specimen grip mechanism.

8.1.4 Suspend a known mass from the hook of the lower specimen grip mechanism in such a way as to permit the mass assembly to temporarily rest on the lower testing machine grip framework or holder (see Note 2).

8.1.5 Start the grip separation motor or mechanism, as in normal testing, and allow it to run until the mass is freely suspended by the specimen in the upper grip.

8.1.6 If the dial or scale does not indicate the force applied (or its equivalent in stress for a compensating type tester) within specified tolerance, thoroughly inspect the testing machine for malfunction (for example, excess friction in bearings and other moving parts). Ensure that the mass of the lower grip mechanism and the hook are included as part of the known mass.

8.1.7 After machine friction or other malfunction has been removed, recalibrate the testing machine at a minimum of three points using known masses to produce forces of approximately 10, 20 and 50 % of capacity. If pawls or rachets are used during routine testing, use them for calibration. Check for friction in the head by calibrating with the pawls up.

NOTE 3—It is advisable to provide a means for preventing the known mass from falling to the floor in case the dumbbell should break.

8.2 A rapid approximate calibration of the testing machine may be obtained by using a spring calibration device.

9. Test Temperature

9.1 Unless otherwise specified, the standard temperature for testing shall be 23 ± 2°C (73.4 ± 3.6°F). Specimens shall be conditioned for at least 3 h when the test temperature is 23°C (73.4°F). If the material is affected by moisture, maintain the relative humidity at 50 ± 5 % and condition the specimens for at least 24 h prior to testing. When testing at any other temperature is required use one of the temperatures listed in Practice D 1349.

9.2 For testing at temperatures above 23°C (73.4°F) preheat specimens for 10 ± 2 min for Method A and for 6 ± 2 min for Method B (see Note 3). Place each specimen in the test chamber at intervals ahead of testing so that all specimens of a series will be in the chamber the same length of time. The preheat time at elevated temperatures must be limited to avoid additional vulcanization or thermal aging.

NOTE 4—**Precaution:** In addition to other precautions, suitable heat or cold resistant gloves should be worn for arm and hand protection when testing at other than 23°C (73.4°F). A mask for the face is very desirable for high temperature testing to prevent the inhalation of toxic fumes when the door of the chamber is open.

9.3 For testing at temperatures below 23°C (73.4°F) condition the specimens at least 10 min prior to testing.

TEST METHOD A—DUMBBELL AND STRAIGHT SPECIMENS

10. Apparatus

10.1 *Die*—The shape and dimensions of the die for preparing dumbbell specimens shall conform with those shown in Fig. 2. The inside faces in the reduced section shall be perpendicular to the plane formed by the cutting edges and polished for a distance of at least 5 mm (0.2 in.) from the cutting edge. The die shall at all times be sharp and free of nicks (see Note 4).

NOTE 5—The condition of the die may be determined by investigating the rupture point on any series of broken (ruptured) specimens. Remove such specimens from the grips of the testing machine, stack the joined-together specimens on top of each other, and note if there is any tendency for tensile breaks to occur at the same position on each of the specimens. Rupture consistently at the same place indicates that the die may be dull, nicked, or bent at that location.

10.2 *Bench Marker*—The two marks placed on the specimen and used to measure elongation or strain are called "bench marks" (see Note 5). The bench marker shall consist of a base plate containing two raised parallel projections. The surfaces of the raised projections (parallel to the plane of the base plate) are ground smooth in the same plane. The raised projection marking surfaces shall be between 0.05 and 0.08 mm (0.002 and 0.003 in.) wide and at least 15 mm (0.6 in.) long. The angles between the parallel marking surfaces and the sides of the projections shall be at least 75°. The distance between the centers of the two parallel projections or marking surfaces shall be within 1 % of the required or target bench mark distance. A handle attached to the back or top of the bench marker base plate is normally a part of the bench marker.

NOTE 6—If a contact extensometer is used to measure elongation, bench marks are not necessary.

10.3 *Ink Applicator*—A flat unyielding surface (hardwood, metal, or plastic) shall be used to apply either ink or powder to the bench marker. The ink or powder shall adhere to the specimen, have no deteriorating effect on the specimen and be of contrasting color to that of the specimen.

10.4 *Grips*—The testing machine shall have two grips, one of which shall be connected to the dynamometer.

10.4.1 Grips for testing dumbbell specimens shall tighten automatically and exert a uniform pressure across the gripping surfaces, increasing as the tension increases in order to prevent slippage and to favor failure of the specimen in the straight reduced section. Constant pressure pneumatic type grips also are satisfactory. At the end of each grip a positioning device is recommended for inserting specimens to the same depth in the grip and for alignment with the direction of pull.

10.4.2 Grips for testing straight specimens shall be constant pressure pneumatic, wedged, or toggle type designed to transmit the applied gripping force over the entire width of the gripped specimen.

11. Specimens

11.1 *Dumbbell Specimens*—Whenever possible, the test specimens shall be injection molded or cut from a flat sheet not less than 1.3 mm (0.05 in.) nor more than 3.3 mm (0.13 in.) thick and of a size which will permit cutting a specimen by one of the standard methods (see Practice D 3182). Sheets may be prepared directly by processing or from finished articles by cutting and buffing. If obtained from a manufactured article, the specimen shall be free of surface roughness, fabric layers, etc. in accordance with the procedure described in Practice D 3183. All specimens shall be cut so that the lengthwise portion of the specimens is parallel to the grain unless otherwise specified. In the case of sheets prepared in accordance with Practice D 3182, the specimen shall be 2.0 ± 0.2 mm (0.08 ± 0.008 in.) thick died out in the direction of the grain. Use Die C, Fig. 2 (unless otherwise noted) to cut the

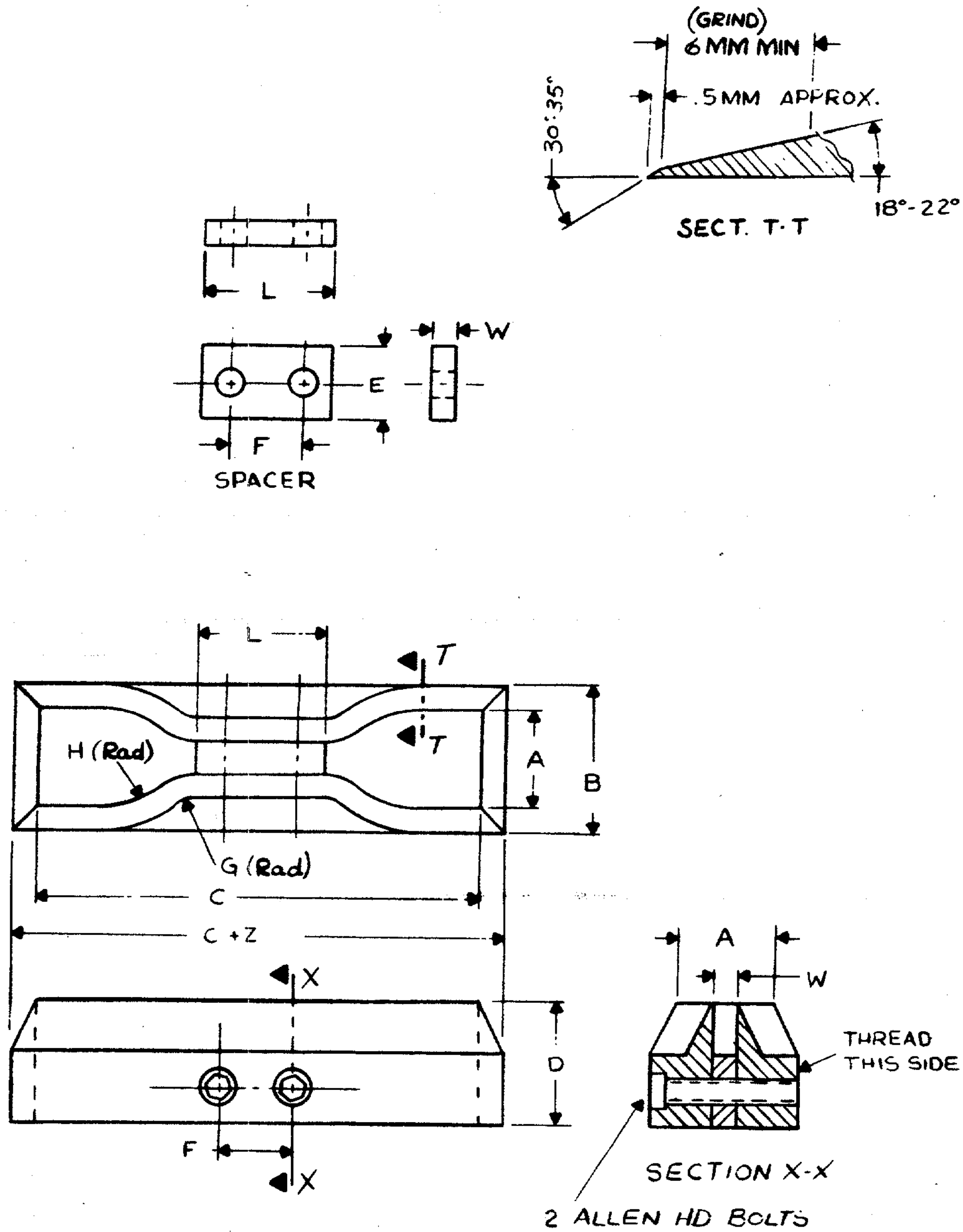


FIG. 2 Standard Dies for Cutting Dumbbell Specimens

specimens from the sheet with a single impact stroke (hand or machine) to ensure smooth cut surfaces.

11.1.1 *Marking Dumbbell Specimens*—Dumbbell specimens shall be marked with the bench marker described in 10.2, with no tension on the specimens at the time of marking. Marks shall be placed on the reduced section, equidistant from its center and perpendicular to the longitudinal axis. The between bench mark distance shall be as follows: for Die C or Die D of Fig. 2, 25.00 ± 0.25 mm (1.00 ± 0.01 in.); for any other Die of Fig. 2, 50.00± 0.5 mm (2.00 ± 0.02 in.).

11.1.2 *Measuring Thickness of Dumbbell Specimens*—Three measurements shall be made for the thickness, one at the center and one at each end of the reduced section. The median of the three measurements shall be used as the thickness in calculating the cross sectional area. Specimens with a difference between the maximum and the minimum thickness exceeding 0.08 mm (0.003 in.), shall be discarded. The width of the specimen shall be taken as the distance between the cutting edges of the die in the restricted section.

11.2 *Straight Specimens*—Straight specimens may be prepared if it is not practical to cut either a dumbbell or a ring specimen as in the case of a narrow strip, small tubing or narrow electrical insulation material. These specimens shall be of sufficient length to permit their insertion in the grips used for the test. Bench marks shall be placed on the specimens as described for dumbbell specimens in 11.1.1. To determine the cross sectional area of straight specimens in the form of tubes, the mass, length, and density of the specimen may be required. The cross sectional area shall be calculated from these measurements as follows:

Dimensions of Standard Dumbbell Dies[A] (Metric Units)

Dimension	Units	Tolerance	Die A	Die B	Die C	Die D	Die E	Die F
A	mm	±1	25	25	25	16	16	16
B	mm	max	40	40	40	30	30	30
C	mm	min	140	140	115	100	125	125
D	mm	±6[B]	32	32	32	32	32	32
D-E	mm	±1	13	13	13	13	13	13
F	mm	±2	38	38	19	19	38	38
G	mm	±1	14	14	14	14	14	14
H	mm	±2	25	25	25	16	16	16
L	mm	±2	59	59	33	33	59	59
W	mm	±0.05, −0.00	12	6	6	3	3	6
Z	mm	±1	13	13	13	13	13	13

[A]Dies whose dimensions are expressed in metric units are not exactly the same as dies whose dimensions are expressed in U.S. customary units. Dies dimensioned in metric units are intended for use with apparatus calibrated in metric units.
[B]For dies used in clicking machines it is preferable that this tolerance be± 0.5 mm.

FIG. 2 a *(continued)*

Dimensions of Standard Dumbbell Dies[A] (U.S. Customary Units)

Dimension	Units	Tolerance	Die A	Die B	Die C	Die D	Die E	Die F
A	in.	±0.04	1	1	1	0.62	0.62	0.62
B	in.	max	1.6	1.6	1.6	1.2	1.2	1.2
C	in.	min	5.5	5.5	4.5	4	5	5
D	in.	±0.25[B]	1.25	1.25	1.25	1.25	1.25	1.25
D-E	in.	±0.04	0.5	0.5	0.5	0.5	0.5	0.5
F	in.	±0.08	1.5	1.5	0.75	0.75	1.5	1.5
G	in.	±0.04	0.56	0.56	0.56	0.56	0.56	0.56
H	in.	±0.08	1	1	1	0.63	0.63	0.63
L	in.	±0.08	2.32	2.32	1.31	1.31	2.32	2.32
W	in.	±0.002, −0.000	0.500	0.250	0.250	0.125	0.125	0.250
Z	in.	±0.04	0.5	0.5	0.5	0.5	0.5	0.5

[A]Dies whose dimensions are expressed in metric units are not exactly the same as dies whose dimensions are expressed in U.S. customary units.
[B]For dies used in clicking machines it is preferable that this tolerance by± 0.02 in.

FIG. 2 b *(continued)*

$$A = M/DL \quad (1)$$

where:

A = cross-sectional area, cm^2,
M = mass, g,
D = density, g/cm^3, and
L = length, cm.

NOTE 7—A in square inches = A (cm^2) × 0.155.

12. Procedure

12.1 *Determination of Tensile Stress, Tensile Strength and Yield Point*—Place the dumbbell or straight specimen in the grips of the testing machine, using care to adjust the specimen symmetrically to distribute tension uniformly over the cross section. This avoids complications that prevent the maximum strength of the material from being evaluated. Unless otherwise specified, the rate of grip separation shall be 500 ± 50 mm/min (20 ± 2 in./min) (see Note 7). Start the machine and note the distance between the bench marks, taking care to avoid parallax. Record the force at the elongation(s) specified for the test and at the time of rupture. The elongation measurement is made preferably through the use of an extensometer, an autographic mechanism or a spark mechanism. At rupture, measure and record the elongation to the nearest 10 %. See Section 13 for calculations.

NOTE 8—For materials having a yield point (yield strain) under 20 % elongation when tested at 500 ± 50 mm/min (20 ± 2 in./min), the rate of elongation shall be reduced to 50 ± 5 mm/min (2.0 ± 0.2 in./min). If the material still has a yield point (strain) under 20 % elongation, the rate shall be reduced to 5 ± 0.5 mm/min (0.2 ± 0.002 in./min). The actual rate of separation shall be reported.

12.2 *Determination of Tensile Set*—Place the specimen in the grips of the testing machine described in 6.1 or the apparatus shown in Fig. 1, and adjust symmetrically so as to distribute the tension uniformly over the cross section. Separate the grips at a rate of speed as uniformly as possible, that requires 15 s to reach the specified elongation. Hold the specimen at the specified elongation for 10 min, release quickly without allowing it to snap back and allow the specimen to rest for 10 min. At the end of the 10 min rest period, measure the distance between the bench marks to the nearest 1 % of the original between bench mark distance. Use a stop watch for the timing operations. See Section 13 for calculations.

12.3 *Determination of Set-After-Break*—Ten minutes after a specimen is broken in a normal tensile strength test, carefully fit the two pieces together so that they are in good contact over the full area of the break. Measure the distance between the bench marks. See Section 13 for calculations.

13. Calculation

13.1 Calculate the tensile stress at any specified elongation as follows:

$$T_{(xxx)} = F_{(xxx)}/A \quad (2)$$

where:

$T_{(xxx)}$ = tensile stress at (xxx) % elongation, MPa (lbf/in.^{2}),
$F_{(xxx)}$ = force at specified elongation, MN or (lbf), and
A = cross-sectional area of unstrained specimen, m^2 (in.^{2}).

13.2 Calculate the yield stress as follows:

$$Y_{(stress)} = F_{(y)}/A \quad (3)$$

where:
$Y_{(stress)}$ = yield stress, that stress level where the yield point occurs, MPa (lbf/in.^{2}),
$F_{(y)}$ = magnitude of force at the yield point, MN (lbf), and
A = cross-sectional area of unstrained specimen, m^2 (in.^{2}).

13.3 Evaluate the yield strain as that strain or elongation magnitude, where the rate of change of stress with respect to strain, goes through a zero value.

13.4 Calculate the tensile strength as follows:

$$TS = F_{(BE)}/A \quad (4)$$

where:
TS = tensile strength, the stress at rupture, MPa (lbf/in.^{2}),
$F_{(BE)}$ = the force magnitude at rupture, MN (lbf), and
A = cross-sectional area of unstrained specimen, m^2 (in.^{2}).

13.5 Calculate the elongation (at any degree of extension) as follows:

$$E = 100[L - L_{(o)}]/L_{(o)} \quad (5)$$

where:
E = the elongation in percent (of original bench mark distance),
L = observed distance between bench marks on the extended specimen, and
$L_{(o)}$ = original distance between bench marks (use same units for L and $L_{(o)}$).

13.6 The breaking or ultimate elongation is evaluated when L is equal to the distance between bench marks at the point of specimen rupture.

13.7 Calculate the tensile set, by using Eq 5, where L is equal to the distance between bench marks after the 10 min retraction period.

13.8 *Test Result*—A test result is the median of three individual test measurement values for any of the measured properties as described above, for routine testing. There are two exceptions to this and for these exceptions a total of five specimens (measurements) shall be tested and the test result reported as the median of five.

13.8.1 *Exception 1*—If one or two of the three measured values do not meet specified requirement values when testing for compliance with specifications.

13.8.2 *Exception 2*—If referee tests are being conducted.

TEST METHOD B—CUT RING SPECIMENS

14. Apparatus

14.1 *Cutter*—A typical ring cutter assembly is illustrated in Fig. 3. This is used for cutting rings from flat sheets by mounting the upper shaft portion of the cutter in a rotating housing that can be lowered onto a sheet held by the rubber holding plate as shown in Fig. 4.

14.1.1 *Blade Depth Gage*—This gage consists of a cylindrical disk having a thickness of at least 0.5 mm (0.02 in.) greater than the thickness of the rubber to be cut and a diameter less than the inside diameter of the specimen used for adjusting the protrusion of the blades from the body of the cutter. See Fig. 3.

14.2 *Rubber Holding Plate*—The apparatus for holding the sheet during cutting shall have plane parallel upper and lower surfaces and shall be a rigid polymeric material (hard rubber, polyurethane, polymethylmethacrylate) with holes approximately 1.5 mm (0.06 in.) in diameter spaced 6 or 7 mm (0.24 or 0.32 in.) apart across the central region of the plate. All the holes shall connect to a central internal cavity which can be maintained at a reduced pressure for holding the sheet in place due to atmospheric pressure. Fig. 4 illustrates the design of an apparatus for holding standard sheets (approximately 150× 150 × 2 mm) during cutting.

14.3 *Source of Reduced Pressure*—Any device such as a vacuum pump that can maintain an absolute pressure below 10 kPa (0.1 atm) in the holding plate central cavity.

14.4 *Soap Solution*—A mild soap solution shall be used on the specimen sheet to lubricate the cutting blades.

14.5 *Cutter Rotator*—A precision drill press or other suitable machine capable of rotating the cutter at an angular speed of at least 30 rad/s (approximately 300 r/min) during cutting shall be used. The cutter rotator device shall be mounted on a horizontal base and have a vertical support orientation for the shaft that rotates the spindle and cutter. The run-out of the rotating spindle shall not exceed 0.01 mm (0.004 in.).

14.6 *Indexing Table*—A milling table or other device with typical x-y motions shall be provided for positioning the sheet and holder with respect to the spindle of the cutter rotating device.

14.7 *Tensile Testing Machine*—A machine as specified in 6.1 shall be provided.

14.8 *Test Fixture*—A test fixture as shown in Fig. 5 shall be provided for testing the ring specimens. The testing machine shall be calibrated as outlined in Section 8.

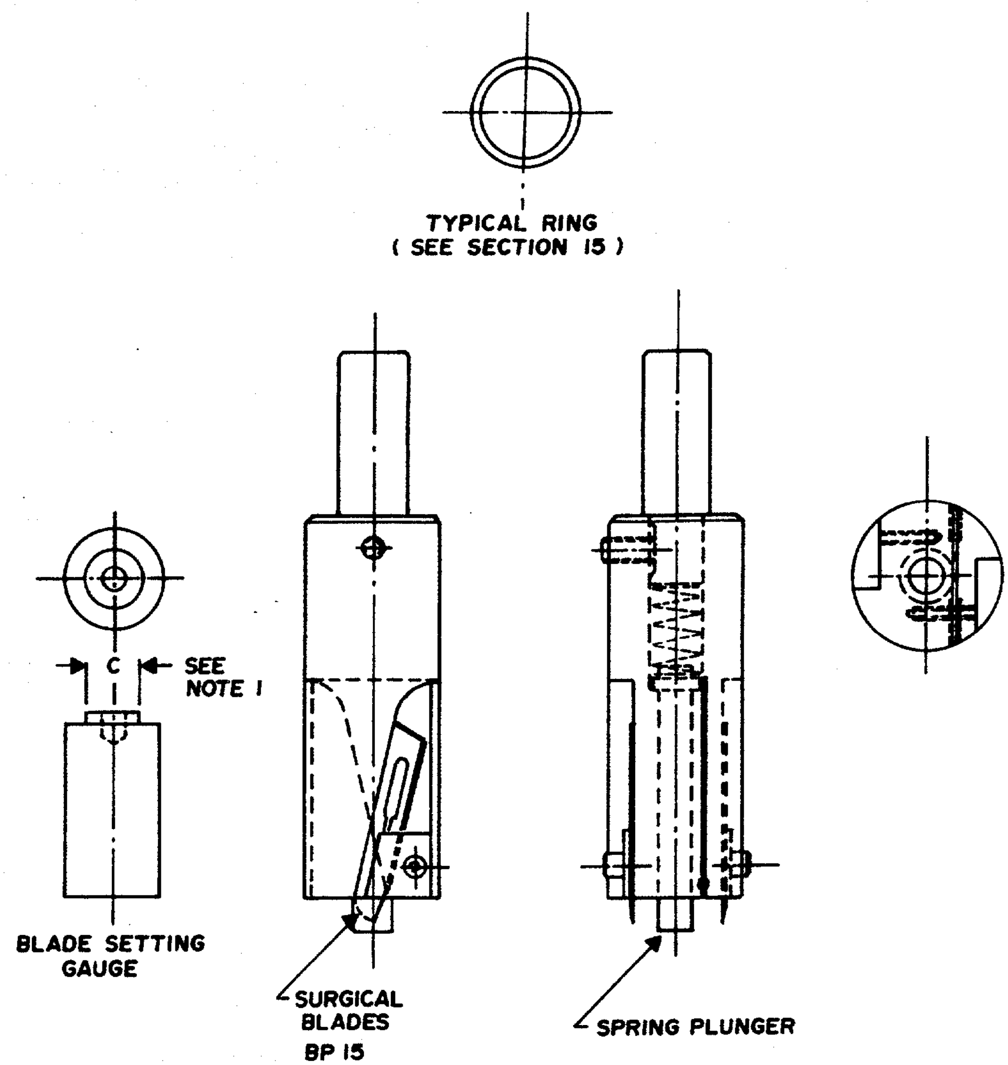
14.9 *Test Chamber*—A chamber for testing at high and low temperatures shall be provided as specified in 6.2.

14.9.1 The fixtures specified in 14.8 are satisfactory for testing at other than room temperature. However at extreme temperatures, a suitable lubricant shall be used to lubricate the spindle bearings.

14.9.2 The dynamometer shall be suitable for use at the temperature of test or thermally insulated from the chamber.

14.10 *Dial Micrometer*—A dial micrometer shall be provided that conforms to the requirements of Practice D 3767.

14.10.1 The base of the micrometer used to measure the radial width shall consist of an upper cylindrical surface (with its axis oriented in a horizontal direction) at least 12 mm (0.5 in.) long and 15.5± 0.5 mm (0.61 ± 0.02 in.) in diameter. To accommodate small diameter rings that approach the 15.5 mm (0.61 in.) diameter of the base and to avoid any ring extension in placing the ring on the base, the bottom half of the



NOTE 1—Dimension *C* to be 2 mm (0.08 in.) less than the inside diameter of the ring.

FIG. 3 Typical Ring Cutter Assembly

cylindrical surface may be truncated at the cylinder centerline, that is, a half cylinder shape. This permits placing small rings on the upper cylindrical surface without interference fit problems. Curved feet on the end of the dial micrometer shaft to fit the curvature of the ring(s), may be used.

15. Ring Specimen

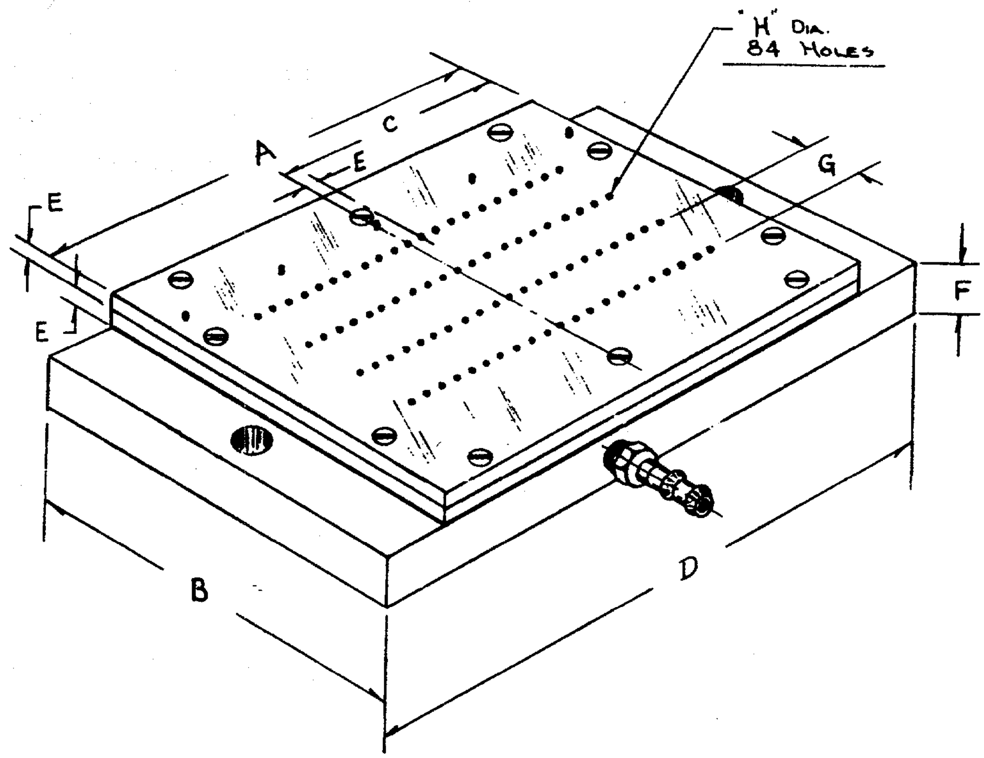
15.1 *ASTM Cut Rings*—Two types of cut ring specimens may be used. Unless otherwise specified, the Type 1 ring specimen shall be used.

15.1.1 *Ring Dimensions*:

	mm	in.
Type 1		
Circumference (inside)	50.0 ± 0.01	2.0 ± 0.004
Diameter (inside)	15.92 ± 0.003	0.637 ± 0.001
Radial width	1.0 ± 0.01	0.040 ± 0.0004
Thickness, minimum	1.0	0.040
maximum	3.3	0.13
Type 2		
Circumference mean	100.0 ± 0.2	4.0 ± 0.0004
Diameter (inside)	29.8 ± 0.06	1.19 ± 0.0001
Radial width	2.0 ± 0.02	0.08 ± 0.0008
Thickness, minimum	1.0	0.04
maximum	3.3	0.13

15.2 *ISO Cut Rings*—The normal size and the small size ring specimens in ISO 37 have the following dimensions given in mm. See ISO 37 for specific testing procedures for these rings.

	Normal	Small
Diameter, inside	44.6 ± 0.2 mm	8.0 ± 0.1 mm
Diameter, outside	52.6 ± 0.2 mm	10.0 ± 0.1 mm
Thickness	4.0 ± 0.2 mm	1.0 ± 0.1 mm



Dimension	mm	in.	Dimension	mm	in.
A	178	7.0	F	19	0.75
B	152	6.0	G	23	0.90
C	89	3.5	H	1.5	0.062
D	229	9.0			
E	6	0.25			

FIG. 4 Rubber Holding Plate

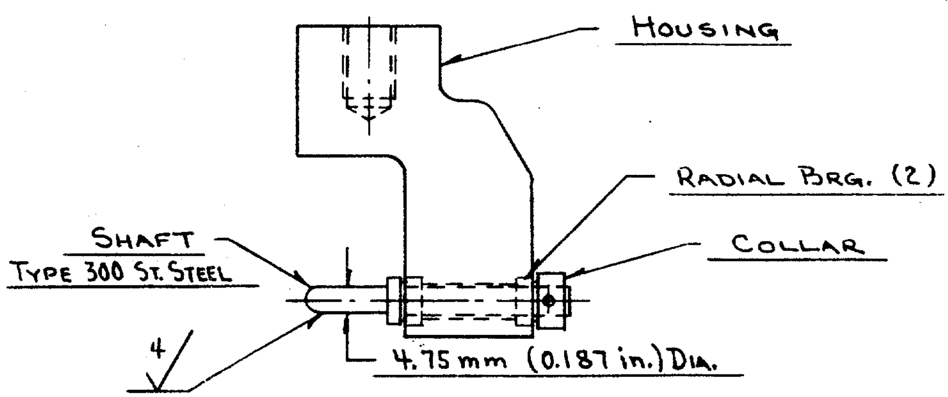


FIG. 5 Assembly, Ring Tensile Test Fixture

15.3 *Rings Cut from Tubing*—The dimensions of the ring specimen(s) depend on the diameter and wall thickness of the tubing and should be specified in the product specification.

15.4 *Preparation of Cut Ring Specimens*—Place the blades in the slots of the cutter and adjust the blade depth using the blade depth gage. Place the cutter in the drill press and adjust the spindle or table so that the bottom of the blade holder is about 13 mm (0.5 in.) above the surface of the holding plate. Set the stop on the vertical travel of the spindle so that the tips of the cutting blades just penetrate the surface of the plate. Place the sheet on the holding plate and reduce the pressure in the cavity to 10 kPa (0.1 atm) or less. Lubricate the sheet with mild soap solution. Lower the cutter at a steady rate until it reaches the stop. Be sure that the blade holder does not contact the sheet. If necessary, readjust the blade depth. Return the spindle to its original position and repeat the operation on another sheet.

15.5 *Preparation of Ring Specimens from Tubing*—Place the tubing on a mandrel preferably slightly larger than the inner diameter of the tubing. Rotate the mandrel and tubing in a lathe. Cut ring specimens to the desired axial length by means of a knife or razor blade held in the tool post of the lathe. Lay thin wall tubing flat and cut ring specimens with a die or cutting mechanism having two parallel blades.

15.6 *Ring Dimension Measurements*:

15.6.1 *Circumference*—The inside circumference can be determined by a stepped cone or by "go-no go" gages. Do not use any stress in excess of that needed to overcome any ellipticity of the ring specimen. The mean circumference is obtained by adding to the value for the inside circumference, the product of the radial width and π (3.14).

15.6.2 *Radial Width*—The radial width is measured at three locations distributed around the circumference using the micrometer described in 14.10.

15.6.3 *Thickness*—For cut rings, the thickness of the disk cut from the inside of the ring is measured with a micrometer described in Practice D 3767.

15.6.4 *Cross-Sectional Area*—The cross-sectional area is calculated from the median of three measurements of radial width and thickness. For thin wall tubing, the area is calculated from the axial length of the cut section and wall thickness.

16. Procedure

16.1 *Determination of Tensile Stress, Tensile Strength, Breaking (Ultimate) Elongation and Yield Point*—In testing ring specimens, lubricate the surface of the spindle with a suitable lubricant, such a mineral oil or silicone oil. Select one with documented assurance that it does not interact or affect the material being tested. The initial setting of the distance between the spindle centers may be calculated and adjusted according to the following equation:

$$IS = [C_{(TS)} - C_{(SP)}]/2 \quad (6)$$

where:

IS = initial separation of spindle centers, mm (in.),
$C_{(TS)}$ = circumference of test specimen, inside circumference for Type 1 rings, mean circumference for Type 2 rings, mm (in.), and
$C_{(SP)}$ = circumference of either (one) spindle, mm (in.).

Unless otherwise specified the rate of spindle separation shall be 500 ± 50 mm/min (20 ± 2 in./min) (see Notes 7 and 8). Start the test machine and record the force and corresponding distance between the spindles. At rupture, measure and record the ultimate (breaking) elongation and the tensile (force) strength. See Section 17 for calculations.

NOTE 9—When using the small ISO ring, the rate of spindle separation shall be 100 ± 10 mm/min (4 ± 0.4 in./min).

16.2 *Tests at Temperatures Other than Standard*—Use the test chamber described in 6.2 and observe the precautionary statement in Note 2. For tests at temperatures above 23°C (73.4°F), preheat the specimens 6 ± 2 min at the test temperature. For below room temperature tests cool the specimens at the test temperature for at least 10 min prior to test. Use test temperatures prescribed in Practice D 1349. Place each specimen in the test chamber at intervals such that the recommendations of 9.2 are followed.

17. Calculation

17.1 Stress-strain properties for ring specimens are in general calculated in the same manner as for dumbbell and straight specimens with one important exception. Extending a ring specimen generates a nonuniform stress (or strain) field across the width (as viewed from left to right) of each leg of the ring. The initial inside dimension (circumference) is less than the outside dimension (circumference), therefore for any extension of the grips, the inside strain (or stress) is greater than the outside strain (or stress) because of the differences in the initial (unstrained) dimensions.

17.2 The following options are used to calculate stress at a specified elongation (strain) and breaking or ultimate elongation.

17.2.1 *Stress at a Specified Elongation*—The mean circumference of the ring is used for determining the elongation. The rationale for this choice is that the mean circumference best represents the average strain in each leg of the ring.

17.2.2 *Ultimate (Breaking) Elongation*—This is calculated on the basis of the inside circumference since this represents the maximum strain (stress) in each leg of the ring. This location is the most probable site for the initiation of the rupture process that occurs at break.

17.3 Calculate the tensile stress at any specified elongation by using Eq 2 in 13.1.

17.3.1 The elongation to be used to evaluate the force as specified in Eq 2 (13.1), is calculated as follows:

$$E = 200[L/MC_{(TS)}] \quad (7)$$

where:

E = elongation (specified), percent,
L = increase in grip separation at specified elongation, mm (in.), and
$MC_{(TS)}$ = mean circumference of test specimen, mm (in.).

17.3.2 The grip separation for any specified elongation can be found by rearranging Eq 7, as given below:

$$L = E \times MC_{(TS)}/200 \quad (8)$$

17.4 Calculate the yield stress by using Eq 3 in 13.2.

17.5 Evaluate the yield strain as given in 13.3. Since yield strain may be considered to be an average bulk property of any material, use the mean circumference for this evaluation.

17.6 Calculate the tensile strength by using Eq 4 in 13.4.

17.7 Calculate the breaking or ultimate elongation as follows (see Notes 9 and 10):

$$E = 200/[L/IC_{(TS)}] \quad (9)$$

where:

E = breaking or ultimate elongation, percent,
L = increase in grip separation at break, mm (in.), and
$IC_{(TS)}$ = inside circumference of ring test specimen, mm (in.).

17.8 The inside circumference is used for both types of rings, see 15.1.1 for dimensions. Use the inside diameter to calculate the inside circumference for Type 2 rings.

NOTE 10—Eq 8, Eq 9, and 10 are applicable only if the initial setting of the spindle centers is adjusted in accordance with Eq 7.

NOTE 11—The user of these test method should be aware that because of the different dimensions used in calculating (*1*) stress at a specified elongation (less than the ultimate elongation) and (*2*) the ultimate (breaking) elongation (see 20.1 and 20.2), it is possible that a stress at a specified elongation, slightly less (4 to 5 %) than the ultimate elongation cannot be measured (calculated).

18. Report

18.1 Report the following information:

18.1.1 Results calculated in accordance with Section 13 or 17, whichever is applicable,

18.1.2 Type or description of test specimen and with Section 13 which type of die, either U.S. Customary Units or Metric Units, was used.

18.1.3 Date of test,

18.1.4 Rate of extension if not as specified,

18.1.5 Temperature and humidity of test room if not as specified,

18.1.6 Temperature of test if at other than 23 ± 2°C (73.4 ± 3.6°F) and

18.1.7 Date of vulcanization, preparation of the rubber, or both, if known.

19. Precision and Bias

19.1 This precision and bias section has been prepared in accordance with Practice D 4483. Refer to Practice D 4483 for terminology and other statistical details.

19.2 The precision results in this precision and bias section give an estimate of the precision of these test methods with the materials used in the particular interlaboratory program as described below. The precision parameters should not be used for acceptance/rejection testing of any group of materials without documentation that the parameters are applicable to those particular materials and the specific testing protocols that include these test methods.

19.3 *Test Method A (Dumbbells)*:

19.3.1 For the main interlaboratory program a Type 1 precision was evaluated in 1986. Both repeatability and reproducibility are short term, a period of a few days separates replicate test results. A test result is the median value, as specified by this test method, obtained on three determination(s) or measurement(s) of the property or parameter in question.

19.3.2 Three different materials were used in this interlaboratory program, these were tested in ten laboratories on two different days.

19.3.3 For the main interlaboratory program cured sheets of each of the three compounds were circulated to each laboratory and stress-strain (dumbbell) specimens were cut, gaged, and tested. A secondary interlaboratory test was conducted for one of the compounds (R19160). For this testing, uncured compound was circulated and sheets were cured at a specified time and temperature (10 min at 157°C) in each laboratory. From these individually cured sheets, test specimens were cut and tested on each of two days one week apart as in the main program. The main program results are referred to as "Test Only" and the secondary program results are referred to as "Cure and Test."

19.3.4 The results of the precision calculations for repeatability and reproducibility are given in Tables 1 and 2, in ascending order of material average or level, for each of the materials evaluated and for each of the three properties evaluated.

19.3.5 The precision of this test method may be expressed in the format of the following statements that use what is called an "appropriate value" of *r*, *R*, (*r*), or (*R*), that is, that value to

TABLE 1 Type 1 (Test Only) Precision on Method A Die C Dumbbell Test Specimens

NOTE:
Sr = repeatability standard deviation.
r = repeatability = 2.83 times the square root of the repeatability variance.
(r) = repeatability (as percentage of material average).
SR = reproducibility standard deviation.
R = reproducibility = 2.83 times the square root of the reproducibility variance.
(R) = reproducibility (as percentage of material average).

Material	Average	Within Laboratories			Between Laboratories		
Part 1 Tensile Strength, MPa:							
		Sr	*r*	*(r)*	*SR*	*R*	*(R)*
1. N18081	9.88	0.200	0.568	5.75	0.293	0.829	8.40
3. E17074	15.38	0.467	1.323	8.60	0.482	1.366	8.88
2. R19160	25.70	0.436	1.235	4.80	1.890	5.351	20.82
Pooled Values[A]	16.99	0.385	1.090	6.42	1.102	3.120	18.37
Part 2 Percent Elongation:							
		Sr	*r*	*(r)*	*SR*	*R*	*(R)*
3. E17074	156.3	6.304	17.842	11.41	11.481	32.492	20.78
2. R19160	510.4	11.471	32.464	6.36	21.243	60.120	11.77
1. N18081	591.6	17.810	50.402	8.52	27.198	76.972	13.01
Pooled Values[A]	419.4	12.761	36.114	8.61	20.999	59.427	14.16
Part 3 Stress at 100 % Elongation, MPa:							
		Sr	*r*	*(r)*	*SR*	*R*	*(R)*
1. N18081	1.17	0.053	0.151	12.96	0.061	0.1744	14.92
2. R19160	2.01	0.050	0.142	7.10	0.274	0.7755	38.62
3. E17074	9.08	0.489	1.385	15.25	0.738	2.0910	23.02
Pooled Values[A]	4.09	0.285	0.808	19.79	0.456	1.2915	31.60

[A]No values omitted.

TABLE 2 Type 1 (Cure and Test) Precision on Method A Die C Dumbbell Test Specimens[A]

NOTE 1:
Sr = repeatability standard deviation.
r = repeatability = 2.83 times the square root of the repeatability variance.
(r) = repeatability (as percentage of material average).
SR = reproducibility standard deviation.
R = reproducibility = 2.83 times the square root of the reproducibility variance.
(R) = reproducibility (as percentage of material average).

NOTE 2:
N18081—highly extended, low durometer CR (Neoprene).
R19160—high tensile NR.
E17047—moderately filled EPDM.

Part 1 Tensile Strength, MPa:

Material	Average	Within Laboratories			Between Laboratories		
		Sr	*r*	*(r)*	*SR*	*R*	*(R)*
1. R19160	26.0	0.613	1.73	6.66	1.74	4.95	19.0

Part 2 Percent Elongation:

Material	Average	Within Laboratories			Between Laboratories		
		Sr	*r*	*(r)*	*SR*	*R*	*(R)*
1. R19160	526.9	13.32	37.7	7.15	19.6	55.70	10.5

Part 3 Stress at 100 % Elongation, MPa:

Material	Average	Within Laboratories			Between Laboratories		
		Sr	*r*	*(r)*	*SR*	*R*	*(R)*
1. R19160	1.83	0.072	0.205	11.21	0.226	0.641	34.5

[A]Seven laboratories participated in this cure and test program.

be used in decisions about test results (obtained with the test method). The appropriate value is that value of *r* or *R* associated with a mean level in Tables 1-4 closest to the mean level under consideration at any given time, for any given material in routine testing operations.

19.3.6 *Repeatability*—The repeatability, *r*, of this test method has been established as the appropriate value tabulated in Tables 1 and 2. Two single test results, obtained under normal test method procedures, that differ by more than this tabulated *r* (for any given level) must be considered as derived from different or nonidentical sample populations.

19.3.7 *Reproducibility*—The reproducibility, *R*, of this test method has been established as the appropriate value tabulated in Tables 1 and 2. Two single test results obtained in two different laboratories, under normal test method procedures, that differ by more than the tabulated *R* (for any given level) must be considered to have come from different or nonidentical sample populations.

19.3.8 Repeatability and reproducibility expressed as a percentage of the mean level, (*r*) and (*R*), have equivalent application statements as above for *r* and *R*. For the (*r*) and (*R*) statements, the difference in the two single test results is expressed as a percentage of the arithmetic mean of the two test results.

19.3.9 *Bias*—In test method terminology, bias is the difference between an average test value and the reference (or true) test property value. Reference values do not exist for this test method since the value (of the test property) is exclusively defined by the test method. Bias, therefore, cannot be determined.

TABLE 3 Type 1 Precision—Test Method B (Rings)

NOTE:
Sr = repeatability standard deviation.
r = repeatability = 2.83 times the square root of the repeatability variance.
(r) = repeatability (as percentage of material average).
SR = reproducibility standard deviation.
R = reproducibility = 2.83 times the square root of the reproducibility variance.
(R) = reproducibility (as percentage of material average).

Tensile Strength (MPa)							
Material	Average	Within Laboratories			Between Laboratories		
		Sr	*r*	*(r)*	*SR*	*R*	*(R)*
5. MATL 5	11.5	0.666	1.885	16.3	1.43	4.06	35.3
6. MATL 6	12.7	0.274	0.775	6.0	0.83	2.35	18.5
1. MATL 1	14.6	0.367	1.040	7.1	0.40	1.15	7.9
4. MATL 4	15.0	0.553	1.565	10.4	3.03	8.59	57.2
2. MATL 2	20.3	1.293	3.660	18.0	2.47	6.99	34.4
3. MATL 3	22.3	1.556	4.405	19.6	1.55	4.40	19.6
Pooled Values[A]	15.9	0.942	2.666	16.7	1.87	5.31	33.3

[A]No values omitted.

TABLE 4 Type 1 Precision—Test Method B (Rings)

NOTE:
Sr = repeatability standard deviation.
r = repeatability = 2.83 times the square root of the repeatability variance.
(r) = repeatability (as percentage of material average).
SR = reproducibility standard deviation.
R = reproducibility = 2.83 times the square root of the reproducibility variance.
(R) = reproducibility (as percentage of material average).

Ultimate Elongation, %							
Material	Average	Within Laboratories			Between Laboratories		
		Sr	*r*	*(r)*	*SR*	*R*	*(R)*
1. MATL 1	322.1	15.25	43.18	13.40	33.4	94.7	29.4
2. MATL 2	445.4	11.35	32.12	7.21	34.1	96.6	21.7
4. MATL 4	509.4	27.44	77.65	15.24	51.1	144.8	28.4
5. MATL 5	545.0	2.91	8.25	1.51	56.3	159.5	29.2
6. MATL 6	599.7	12.91	36.55	6.09	14.0	39.6	6.60
3. MATL 3	815.8	16.25	45.99	5.63	90.6	256.5	31.4
Pooled Values[A]	539.6	16.54	46.82	8.67	48.2	136.4	25.2

[A]No values omitted.

19.4 *Test Method B (Rings)*:

19.4.1 A Type 1 precision was evaluated in 1985. Both repeatability and reproducibility are short term, a period of a few days separates replicate test results. A test result is the mean value, as specified by this test method, obtained on three determinations or measurements of the property or parameter in question.

19.4.2 Six different materials were used in the interlaboratory program, these were tested in four laboratories on two different days.

19.4.3 The results of the precision calculations for repeatability and reproducibility are given in Tables 3 and 4, in ascending order of material average or level, for each of the materials evaluated.

19.4.4 Repeatability, *r*, varies over the range of material levels as evaluated. Reproducibility, *R*, varies over the range of material levels as evaluated.

19.4.5 The precision of this test method may be expressed in the format of the following statements that use what is called an "appropriate value" of *r*, *R*, (*r*), or (*R*), that is, that value to be used in decisions about test results (obtained with the test method). The appropriate value is that value of *r* or *R* associated with a mean level in Tables 1-4 closest to the mean level under consideration at any given time, for any given material in routine testing operations.

19.4.6 *Repeatability*—The repeatability, *r*, of this test method has been established as the appropriate value tabulated in Tables 3 and 4. Two single test results, obtained under normal test method procedures, that differ by more than this tabulated *r* (for any given level) must be considered as derived from different or nonidentical sample populations.

19.4.7 *Reproducibility*—The reproducibility, *R*, of this test method has been established as the appropriate value tabulated in Tables 3 and 4. Two single test results obtained in two different laboratories, under normal test method procedures, that differ by more than the tabulated *R* (for any given level) must be considered to have come from different or nonidentical sample populations.

19.4.8 Repeatability and reproducibility expressed as a percentage of the mean level, (*r*) and (*R*), have equivalent application statements as 19.3.6 and 19.3.7 for *r* and *R*. For the (*r*) and (*R*) statements, the difference in the two single test results is expressed as a percentage of the arithmetic mean of the two test results.

19.4.9 *Bias*—In test method terminology, bias is the difference between an average test value and the reference (or true) test property value. Reference values do not exist for this test method since the value (of the test property) is exclusively defined by the test method. Bias, therefore, cannot be determined.

20. Keywords

20.1 elongation; set after break; tensile properties; tensile set; tensile strength; tensile stress; yield point

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

This standard is issued under the fixed designation D 3492; 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.

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.

2. Referenced Documents

2.1 *ASTM Standards:*

D 412 Test Methods for Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers—Tension[2]

D 573 Test Method for Rubber—Deterioration in an Air Oven[2]

D 1076 Specification for Rubber—Concentrated, Ammonia Preserved, Creamed, and Centrifuged Natural Latex[2]

D 3078 Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission[3]

D 3767 Practice for Rubber—Measurement of Dimensions[2]

E 691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method[4]

2.2 *Other Document:*

ANSI/MIL-STD 105E Sampling Procedures and Tables for Inspection by Attributes[5]

3. Materials and Manufacture

3.1 Condoms shall be manufactured from natural rubber latex conforming to Specification D 1076.

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.

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

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.

4.2 *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, 30 ± 5 mm, 90 ± 5 mm and 150 ± 5 mm from the closed end. The thickness measuring device shall conform to that specified in Practice D 3767, Test Method A. When a condom is textured, measure the thickness in the

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.

[1] This specification is under the jurisdiction of ASTM Committee D-11 on Rubber and is the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

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[2] *Annual Book of ASTM Standards*, Vol 09.01.

[3] *Annual Book of ASTM Standards*, Vol 15.09.

[4] *Annual Book of ASTM Standards*, Vol 14.02.

[5] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

TABLE 2 Dimensional Requirements

Minimum Length, mm	Maximum Width, mm	Minimum Thickness, mm
160	54	0.03

nontextured area. Report the measurements to the nearest 0.01 mm.

4.2.1.4 *Precision and Bias*—The precision and bias of measuring condom dimensions are as specified in Practice D 3767.

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. 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 D 412.

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 D 573. 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.

4.3.2 *Precision and Bias*—The precision and bias associated with the tensile strength and ultimate elongation of male condoms are as specified in Test Methods D 412.

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:

$$V_{min} = 0.00592(w^2) \quad (1)$$

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 mm ± 5 mm from the open end.

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

4.4.3 *Precision and Bias:*

4.4.3.1 Tables 3 and 4 are based on an interlaboratory study conducted in 1992 in accordance with Practice E 691 involving six condom lots tested by six laboratories. For each lot, all the samples were prepared at one source but the individual specimens were prepared at the laboratories that tested them. Each test result was the average of 80 individual determinations. Each lab obtained two test results for each condom lot.

NOTE 4: **Caution**—The explanations of r and R in 4.4.3.2 are only intended to present a meaningful way of considering the approximate precision of this test method. The data in Tables 3 and 4 should not be rigorously applied to the acceptance or rejection of condom lot, as those data are specific to the round robin and may not be representative of other lots, conditions, materials, or laboratories. Users of this test method should apply the principles outlined in Practice E 691 to generate data specific to their laboratory and materials, or between specific laboratories. The principles of 4.4.3.2 would then be valid for such data.

TABLE 3 Burst Pressure

NOTE—all values in kPa units.

Condom Lots	Average	S_r [A]	S_R [B]	r [C]	R [D]
A	1.86	0.19	0.20	0.53	0.56
B	1.87	0.24	0.25	0.63	0.72
C	1.76	0.18	0.19	0.50	0.53
D	1.75	0.20	0.21	0.56	0.60
E	1.84	0.26	0.26	0.73	0.75
F	1.71	0.19	0.20	0.53	0.56

[A] S_r is the 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 4 Burst Volume

NOTE—all values in dm^3 units.

Condom Lots	Average	S_r [A]	S_R [B]	r [C]	R [D]
A	37.3	4.6	5.4	13.0	15.3
B	30.5	3.3	3.9	9.3	11.1
C	38.4	5.2	6.0	14.7	16.9
D	37.9	5.6	6.3	15.7	17.9
E	28.4	4.8	5.1	13.7	14.5
F	37.8	6.1	6.6	17.2	18.8

[A] S_r is the 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.

4.4.3.2 *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 averages (medians/other function) from testing X number of specimens, the following definitions are applicable:

(*a*) *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 for that material.

(*b*) *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.

(*c*) Any judgement in accordance with 4.4.3.1 and 4.4.3.2 would have an approximate 95 % (0.95) probability of being correct.

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

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. The test method is described in Annex A3.

4.5.2 *Precision and Bias*—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.

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 D 3078 with the pressure reduced at least 50.8 kPa (15 in. of Hg) below atmospheric pressure. The inspection requirements of Paragraph 8.2 of Test Method D 3078 are not required. Package integrity requirements are stated in Table 1.

6. Labeling

6.1 Each condom package (individual or retail) shall be marked legibly and include the name or trademark of the manufacturer.

6.2 The retail package shall contain either the uncoded date of manufacture or expiration date, which shall be marked as such.

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

7. Storage

7.1 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 Latex condoms should be stored in sealed containers in dry areas at 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.

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.

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.

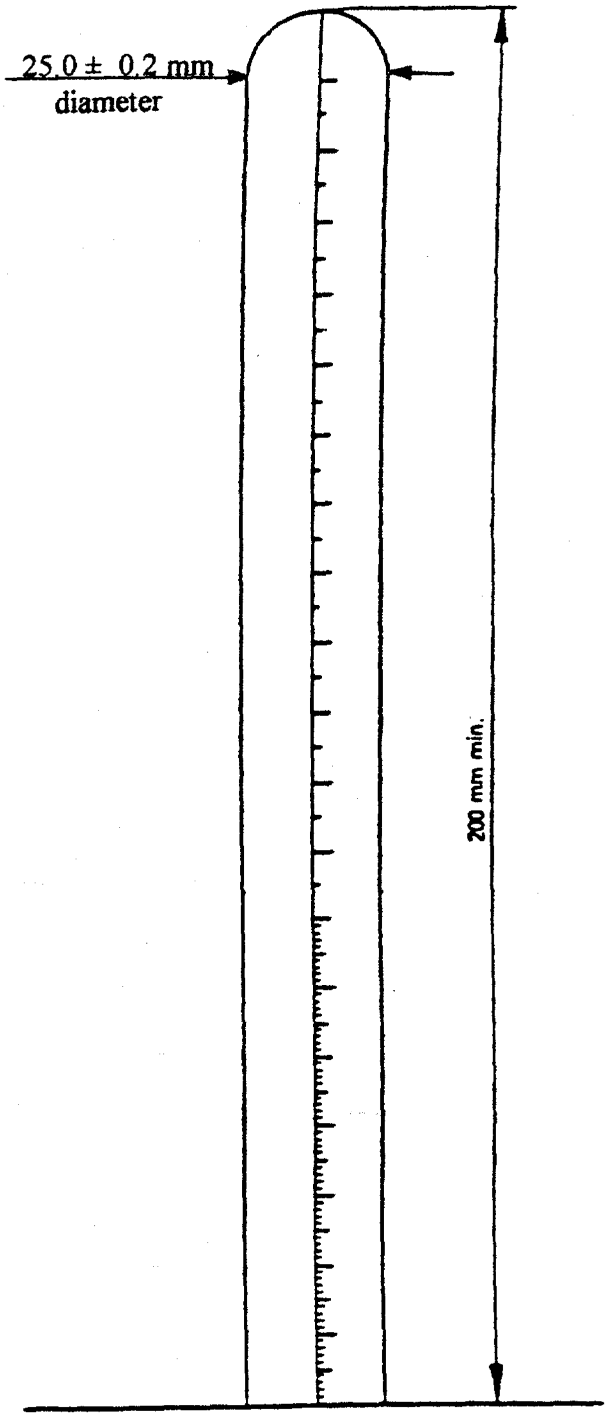


FIG. A1.1 Mandrel for Determining Length of Condom

A2. AIR BURST TESTING OF CONDOMS

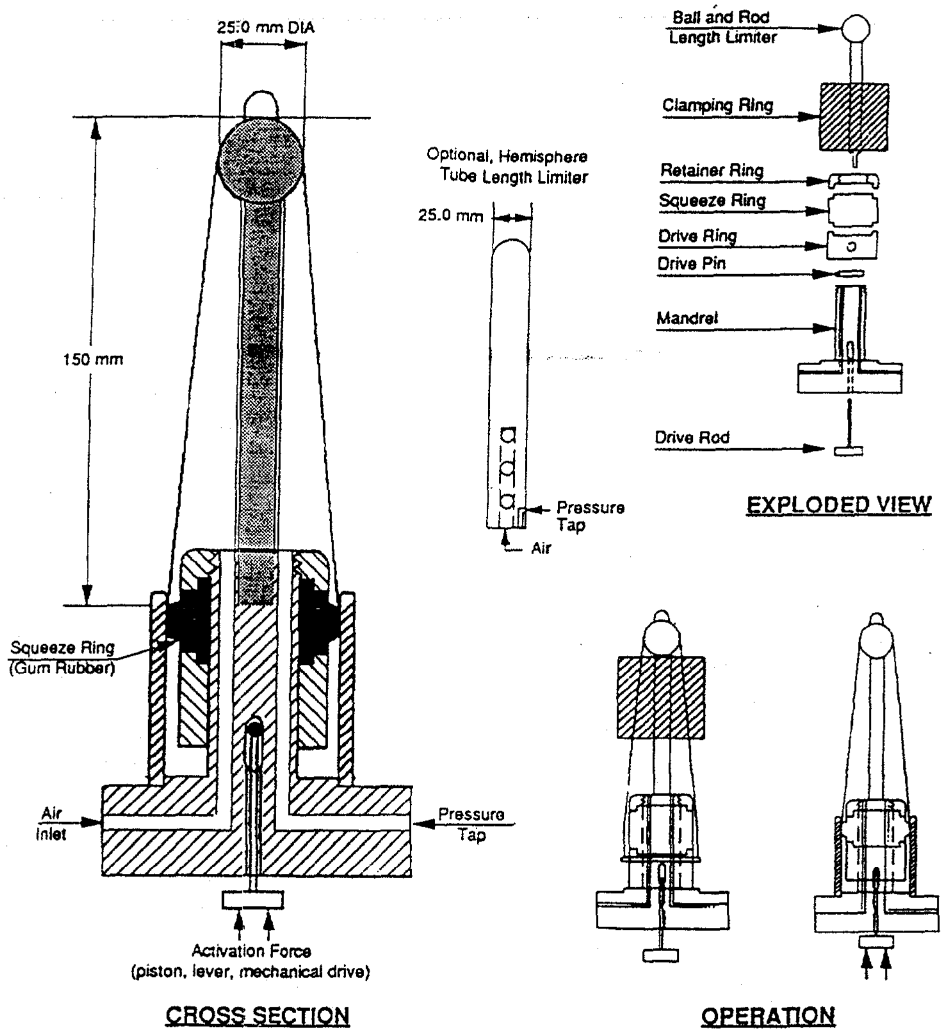
A2.1 Principle

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.

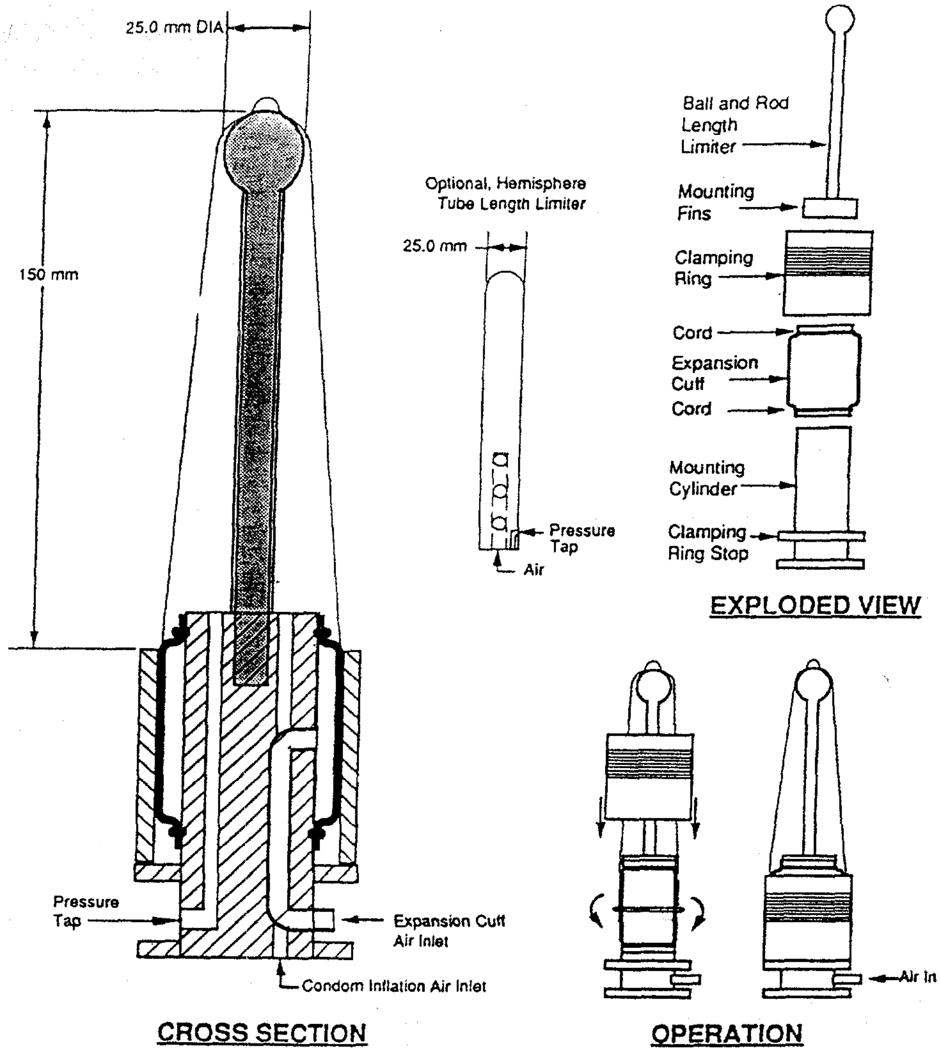
A2.2.2 Suitable mount for clamping the condom to the apparatus without damaging or stretching the condom. The mount shall be equipped with a rod of sufficient length to ensure that the length of condom tested, excluding reservoir (if any), is 150 ± 3 mm. The rod shall terminate in a smooth sphere 25 mm in diameter for hanging the unrolled condom when fixed to the apparatus. Examples of suitable mounts are shown in Figs. A2.1 and A2.2. Additional information related to the validation of the air burst testing apparatus is provided in Appendix A2.



NOTE—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 150 ± 3 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



NOTE—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 150 ± 3 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

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 5—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.

A3. LEAKAGE TEST

A3.1 Test Principle

A3.1.1 Experience has shown that the water leak test is most sensitive when the condom is filled while hanging vertically, its top is closed off, and the condom is placed in a horizontal position while it is examined for leaks. With this technique, the internal pressure over the entire condom surface is approximately uniform.

A3.2 Test Apparatus

A3.2.1 A filling apparatus with suitability 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. If the condom is not removed from the device for inspection, the apparatus must also seal the end of the condom against water overflow without the introduction of an air headspace as the condom is positioned horizontally as in A3.3.5.

A3.3 Procedure

A3.3.1 A properly trained and qualified operator will:

A3.3.1.1 Carefully remove the condom from the package, being sure to hold the condom while it is still inside the package in such a manner that during the opening of the package, the packaging material does not damage or cut the condom. Remove the condom, and if rolled, unroll the condom to its fullest length.

A3.3.1.2 Carefully stretch the condom's rim and affix (place) it on the filling apparatus.

A3.3.1.3 Fill each condom to be tested with 300 ± 25 cm^3 of water whose temperature is not less than 20°C nor greater than 40°C. 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.

A3.3.1.4 Close off the top of the condom. If the condom is not removed from the device for inspection, the apparatus must also seal or permit manual sealing of the open end of the condom against water overflow without the introduction of an air headspace as the condom is positioned horizontally as in A3.3.5.

NOTE 6—Recent surveys of the marketplace have found products within the scope of this specification that will not readily contain the 300 cm^3 of water as required for this test. To evaluate these products for leakage, manual extension of the condom to allow filling with the 300 cm^3 or pressurization of the condom to a uniform pressure of 1.6 kPa is allowed.

A3.3.1.5 Manually raise the closed end of the freely hanging condom (for example, in the cupped palm of one hand) through an angle of $90 \pm 10°$, that is, until it is horizontal. Inspect the entire surface of the condom for evidence of leakage.

A3.3.1.6 If leakage is noted in the upper region of the condom near the rim, mark the spot. Remove the condom from the funnel fixture. Empty the water. Measure the distance from the marked spot of the leak to the rim.

A3.4 Interpretation of Results—see 4.5.1.

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 D 412. Experience with the tensile testing of condoms has resulted in several refinements to the methods of specimen preparation described in Test Methods D 412. It has been demonstrated during interlaboratory studies of this test procedure that the hand or mallet cutting of specimens, as allowed by Test Methods D 412, 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 7—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 8—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 9—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.

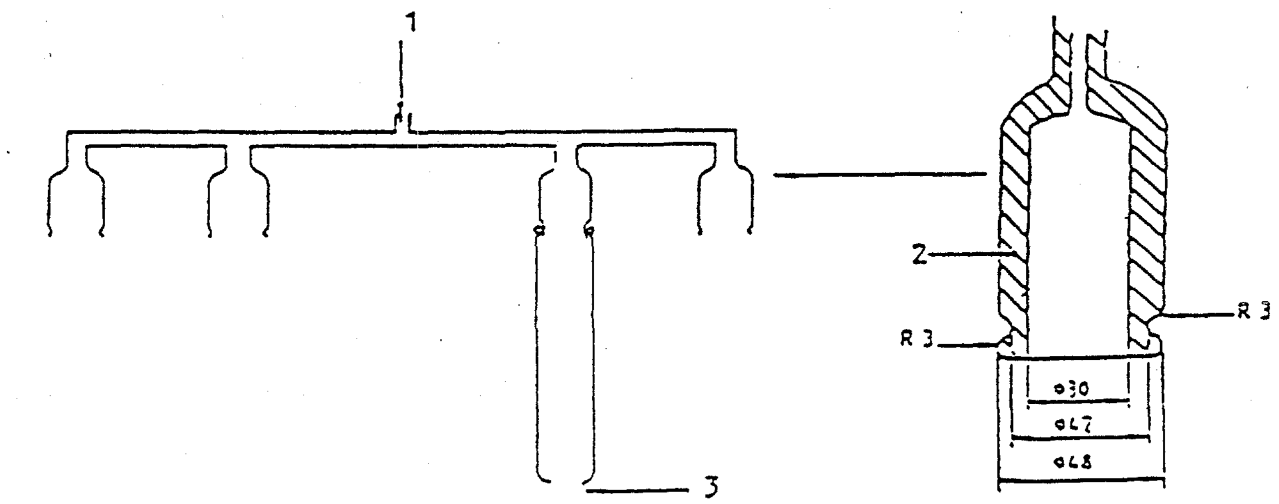
NOTE 10—Steps X1.4.1.4 through X1.4.1.8 are applicable to lubricated condoms only.

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 11—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



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

FIG. X1.1 Condom Drying Apparatus

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 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:

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

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:

$$E = 100\,\frac{(2D + G - C)}{C} \qquad (3)$$

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.

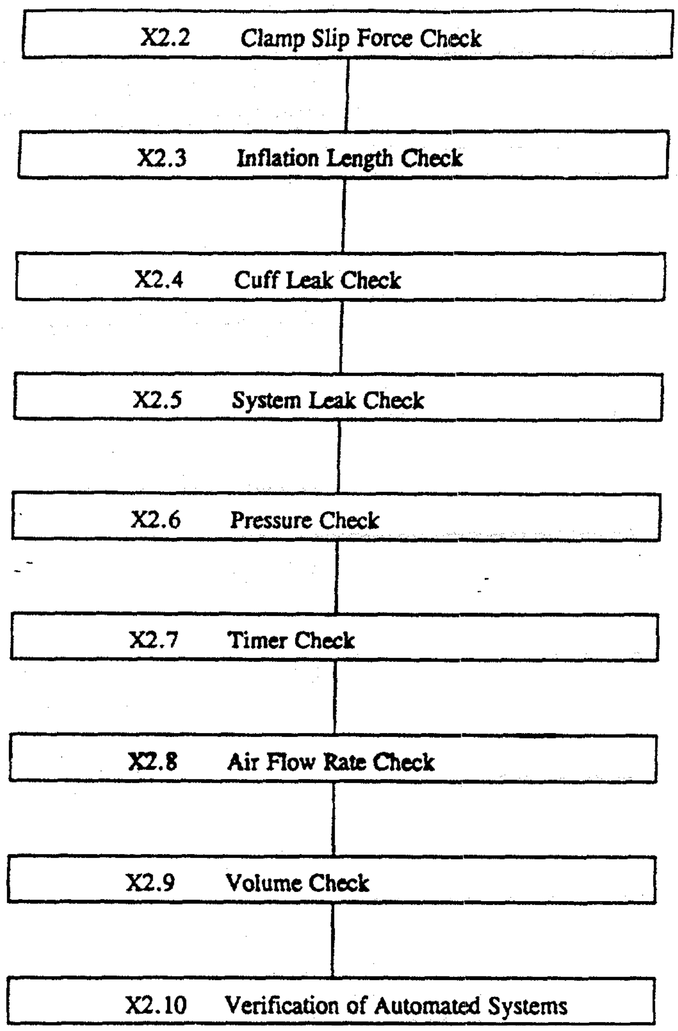
X2.2.2 Install a condom on the clamp and mark the condom with a fine-tipped felt pen at the edge of the clamp. Place a second condom over the outside of the first condom and outside the clamping ring. Do not place the second condom inside the clamp. Inflate the condom to at least 2.5 kPa and observe 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 150 mm ± 3 mm. 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 of 147 to 153 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).

X2.4 Cuff Leak Check

X2.4.1 For systems having an inflated cuff, there is a



NOTE—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

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 (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 0–3 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 0.4–0.5 dm^3/s (24–30 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 12—The rotameter must be placed at the air inlet to the condom.

$$Q = q_R \sqrt{\frac{P_R \times T}{T_R \times P}} \tag{4}$$

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:

$$V = Qt\left(\frac{P_{bar}}{P_{bar} + P_{burst}}\right) \quad (5)$$

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.

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