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Designation: D 3492 – 03

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.

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

1. Scope

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

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

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

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

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

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

2. Referenced Documents

2.1 *ASTM Standards:*

D 412 Test Methods for Vulcanized Rubber 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]

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

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

Current edition approved Aug. 10, 2003. Published Septemeber 2003. Originally approved in 1976. Last previous edition approved in 1997 as D 3492–97.

[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 (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

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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.

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

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

4.2.1 *Procedures for Dimensional Test*:

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

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

4.2.1.3 *Thickness*—Measure the thickness of condoms dried at room temperature for a minimum of 16 h after any dressing materials have been removed with water or isopropanol. Measure the wall thickness at three points, 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 with the pressure of the foot thickness gage at 22 ± 5 kPa. When a condom is textured, measure the thickness in the nontextured area. Report the measurements to the nearest 0.01 mm.

4.2.1.4 *Precision and Bias*—This precision and bias has been prepared in accordance with Practice D 4483. Refer to this practice for terminology and other statistical details. The precision results in this precision and bias give an estimate of the precision for this test method. The precision parameters should not be used for acceptance or rejection of the material, as this data is specific to this round robin and may not be representative of other lots, materials or laboratories. Users of this test method should apply the principles outlined in Practice D 4483 to their laboratory and materials or between specific laboratories. The principles of 4.2.1.5 would then be valid for such data. Tables 3 and 4 are based on an interlaboratory study conducted in 2001 in accordance with Practice D 4483 involving three male latex condom materials (A–"thin", B–regular, C–"thicker"), ten laboratories, two locations on the condom (open end–150 mm from the shoulder, closed end–30 mm from the shoulder) with two replicates per location taken on the same day. Therefore, $p = 10$, $q = 3$, and $n = 2$. The measurement technique as defined in Practice D 3767 was used.

TABLE 2 Dimensional Requirements

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

TABLE 3 Open End Thickness

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

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

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

TABLE 4 Closed End Thickness

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

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

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

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

(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 of 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 4.2.1.4 and 4.2.1.5 would have an approximate 95 % (0.95) probability of being correct.

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

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

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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, and

w = nominal flat width in millimetres of the shank portion of the condom measured 70 ± 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 Table 5 and Table 6 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. (**Warning—**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 Table 5 and Table 6 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.)

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.

TABLE 5 Burst Pressure

NOTE 1—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 6 Burst Volume

NOTE 1—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.

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 Section 10.2 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.).

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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.

9. Keywords

9.1 condoms; contraceptives; prophylactic; rubber

ANNEXES

(Mandatory Information)

A1. DETERMINATION OF LENGTH

A1.1 Purpose

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

A1.2 Principle

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

A1.3 Equipment

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

A1.4 Procedure

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

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

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

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.

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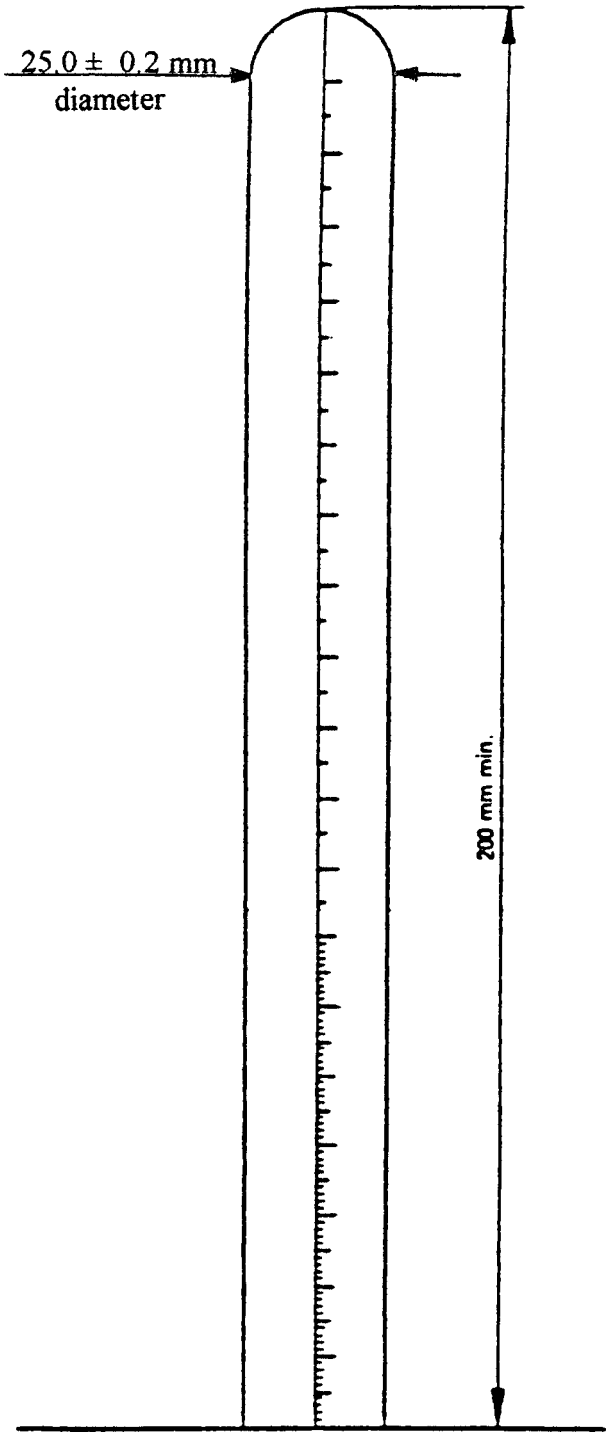

FIG. A1.1 Mandrel for Determining Length of Condom

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