Designation: F2878 – 10

Standard Test Method for Protective Clothing Material Resistance to Hypodermic Needle Puncture[1]

This standard is issued under the fixed designation F2878; 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.

INTRODUCTION

Occupational exposures to bloodborne pathogens (BBP) caused by needlestick injuries are a concern for healthcare professionals, law enforcement officers, first responders and others.

Transmission of diseases such as Human Immunodeficiency Virus (HIV) and Hepatitis C (Hep C) as a result of percutaneous needlestick injuries have been documented worldwide. These diseases can lead to life-long chronic health problems and possibly death.

Work practice safety procedures, including the use of personal protective equipment (PPE) such as gloves, aprons, and sleeves, are used to diminish the risk of occupational exposure to BBP's through needlestick injury.

The purpose of this standard is to measure relative hypodermic needle puncture resistance offered by various materials based on the conditions specified within the standard. This standard does not attempt to simulate all use conditions. A number of variables which impact puncture resistance are not addressed by this standard. For example, stiffness of backing materials, presence of lubricants, and tension on the specimen may all impact puncture resistance, but are not considered by this standard.

This standard defines three common hypodermic needles to evaluate puncture resistance. Through development of this standard, it has been observed that needle diameter has an effect on puncture resistance. Therefore needles of various diameters have been specified. Users of this method may specify testing with one or more of the needles defined within the standard.

The hypodermic needles referenced have been selected with consideration to three main points:

(*1*) As needle gauge increases the load required to puncture materials taken from commonly available hypodermic needle resistant PPE increases. The performance is not linear and therefore relatively large gauge (21 g) and small gauge (28 g) needles are provided to better understand a material's performance against one end of the spectrum or the other.

(*2*) Certain end-use applications are concerned with protection from either large gauge needles or small gauge needles. For example, police officers searching suspected intravenous drug users are most commonly at risk of injury from fine gauge needles (28 g), but not large gauge needles. Whereas, workers inoculating poultry on commercial farms may be concerned with large gauge needles (21 g), but not small gauge needles.

(*3*) Certain materials are optimized to resist either large gauge or small gauge needles and testing against the other would not be useful. Other materials may be engineered for resistance to the full breadth of the gauge spectrum. For example, in applications, such as healthcare, where a broad range of needle gauges are expected, testing against both ends of the spectrum allows for a better understanding of robustness.

[1] This test method is under the jurisdiction of ASTM Committee F23 on Personal Protective Clothing and Equipment and is the direct responsibility of Subcommittee F23.20 on Physical.

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1. Scope

1.1 This test method is used to determine the force required to cause a sharp-edged puncture probe (hypodermic needle) to penetrate through protective clothing material. The standard describes three test probes that may be used: 21-, 25-, or 28-gauge needles.

1.2 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

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:*[2]

D1776 Practice for Conditioning and Testing Textiles

D1777 Test Method for Thickness of Textile Materials

D2000 Classification System for Rubber Products in Automotive Applications

D2582 Test Method for Puncture-Propagation Tear Resistance of Plastic Film and Thin Sheeting

E4 Practices for Force Verification of Testing Machines

F1342 Test Method for Protective Clothing Material Resistance to Puncture

3. Terminology

3.1 *Definitions:*

3.1.1 *protective clothing material, n*—any material or combination of materials used in an item of clothing for the purpose of isolating parts of the wearer's body from a potential hazard.

3.1.2 *hypodermic needle, n*—a hollow bore stainless steel cylinder with a beveled tip used to penetrate the skin by cutting; often used in conjunction with a syringe for injecting or withdrawing fluids.

4. Summary of Test Method

4.1 A material specimen is placed in a support assembly (see Fig. 1) that is affixed to the upper or lower arm, depending on machine configuration, of a tension testing machine. Some materials have different performance based on which face is presented toward the needle. Care should be taken when mounting to ensure the needle initiates puncture on the desired face. When reporting results include which side was facing the needle.

4.2 A pointed puncture probe of set dimensions is mounted to the penetrometer stand and the whole assembly is attached to the compression cell of the tension testing machine.

4.3 The puncture probe which is positioned perpendicular to the specimen is moved at a constant velocity until the tip of the probe perforates the backside of the material specimen.

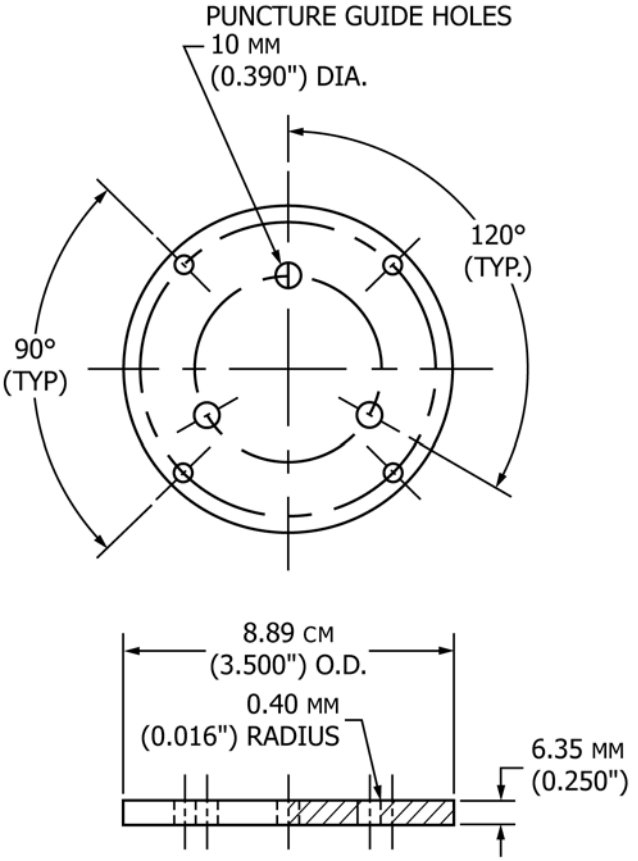


FIG. 1 Specimen Support Assembly (Two needed)

4.4 The maximum force required to puncture the material specimen is measured by the compression cell.

4.4.1 The average of twelve test replicates is reported as the puncture resistance.

5. Significance and Use

5.1 This test method evaluates puncture resistance of protective clothing materials which may include: plastics or elastomeric films, coated fabrics, flexible materials, laminates, leathers or textile materials.

5.1.1 This test method uses hypodermic needles with specified dimensions as puncture probes.

5.1.2 This test method evaluates puncture resistance of protective clothing materials, perpendicular to the material's surface and with no supporting structure under/behind the material specimen.

5.1.3 Evaluation of puncture resistance for snag-type puncture should be performed in accordance with Test Method D2582.

5.1.4 Evaluation of puncture resistance for non-cutting puncture should be performed in accordance with Test Method F1342.

6. Apparatus

6.1 *Thickness Gauge,* suitable for measuring thickness to the nearest 0.01 mm, as specified in Test Method D1777 shall be used to determine the thickness of each protective clothing specimen tested.

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

6.2 *Testing Machine,* shall meet the following criteria:

6.2.1 It shall be capable of holding the specimen securely between the two clamps.

6.2.2 A machine capable of providing load versus elongation data until point of rupture shall be used.

6.2.3 The error of the machine shall not exceed 1 % at any reading within its loading range. Refer to Practices E4 for determining accuracy of the apparatus

6.2.4 It shall be outfitted with a compression cell. The testing machine may be configured with the compression cell on the upper arm. The compression cell shall have a range sufficient to penetrate the specimen.

6.3 *Hypodermic Needle Puncture Probes General Description:*

6.3.1 All probes shall be fabricated from 304 stainless steel with a Rockwell C Hardness of 35 to 40.

6.3.2 All probes shall be: three-facet, regular bevel, regular wall hypodermic needles. Technicians may select from the following gauges:

6.3.2.1 28 gauge, 12.7-mm needle length (see Fig. 2a)

6.3.2.2 25 gauge, 25.4-mm needle length (see Fig. 2b)

6.3.2.3 21 gauge, 38.1-mm needle length (see Fig. 2c)

6.3.2.4 Becton Dickinson model numbers BD 309309 (28g, ½-in. long), BD305125 (25g, 1-in. long) and BD 305167 (21g, 1½-in. long) have been found to be suitable, though needles from other sources which conform to the general description (6.3.1-6.3.2) and perform within the range described in the lot validation table below may be used.

6.4 A total of twelve puncture probes, selected from needle lots that have been validated, are required (one for each puncture measurement) to conduct the test.

6.5 *Specimen Support Assembly* shall consist of two flat metal specimen support plates that clamp together so the sample specimen is held tightly between them. Care should be taken to lay specimens flat in the assembly without distortion or tension on the specimen. It shall also consist of a machine interface plate that can be connected to the testing machine. There should be enough distance to allow for at least 25 mm of travel of the probe. The plates should be closed tightly on the specimen to reduce slipping/shifting of the material between the plates during testing to the greatest extent possible.

6.5.1 Each plate shall have one or more puncture guide holes measuring 10 to 25.4-mm diameter. Ideally, for efficiency in testing, the plates may have three 10-mm diameter puncture guide holes. The holes should be spaced equally on the plate with each hole forming the points of a 60° equilateral triangle centered on the plates as shown in Fig. 2.

6.5.2 The two specimen support plates shall be connected to the testing machine using a machine interface plate.

NOTE 1—Needle holders which allow the hub of the needle to be slipped over the end of the needle holder for a tension fit and needle holders with a screw down chuck (as used on a dissecting needle) which require the needle to be cut from the hub and inserted into the end clamp have both been used successfully.

6.6 It is important to ensure the needle mounting technique being used securely holds the needle at a 90º angle relative to the surface of the test specimen throughout the test procedure. The clamp or mounting post should allow the proper length of the needle to remain exposed during testing. (see 6.3.2.1 – 6.3.2.4)

6.7 Calibration Material shall be: polychloroprene film, Thickness 1.57 ± 0.05 mm (0.062 in.), hardness (Shore A) 50 ± 5, tensile strength 1200 psi min, ultimate elongation 300 % min, specific gravity 1.4.

6.7.1 Specification for calibration material is based on Trelleborg Coated Systems US, Inc. (formerly Reeves Brothers) part number: REEVES NS 5550.[3]

7. Test Specimen

7.1 Four square test specimens, 8.9 by 8.9 cm each, shall be prepared. Cut holes through the specimens to accommodate specimen support assembly fasteners.

[3] The sole source of supply of the material known to the committee at this time is Gindor, Inc. of Goshen, IN, Tel: 574–642–4004, http://www.gindor.com. If you are aware of alternative suppliers, please provide this information to ASTM International Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee,[1] which you may attend.

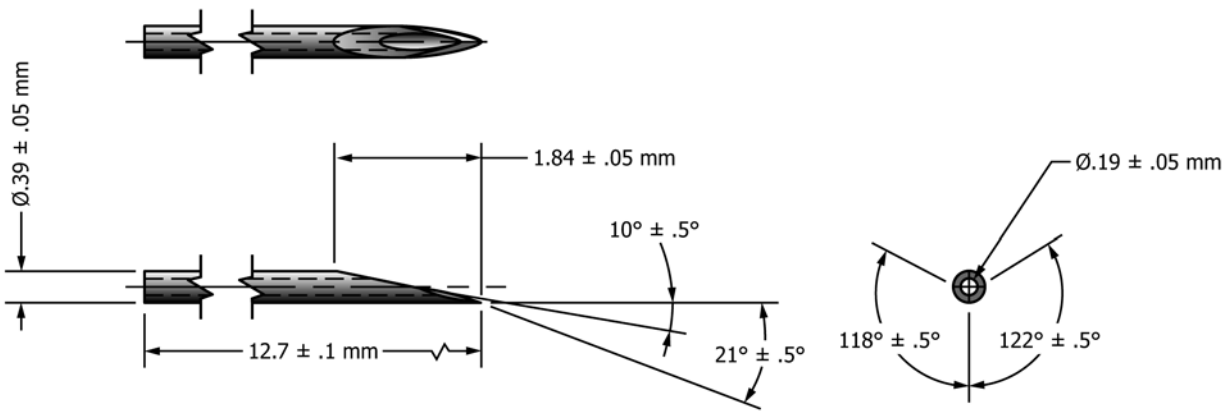
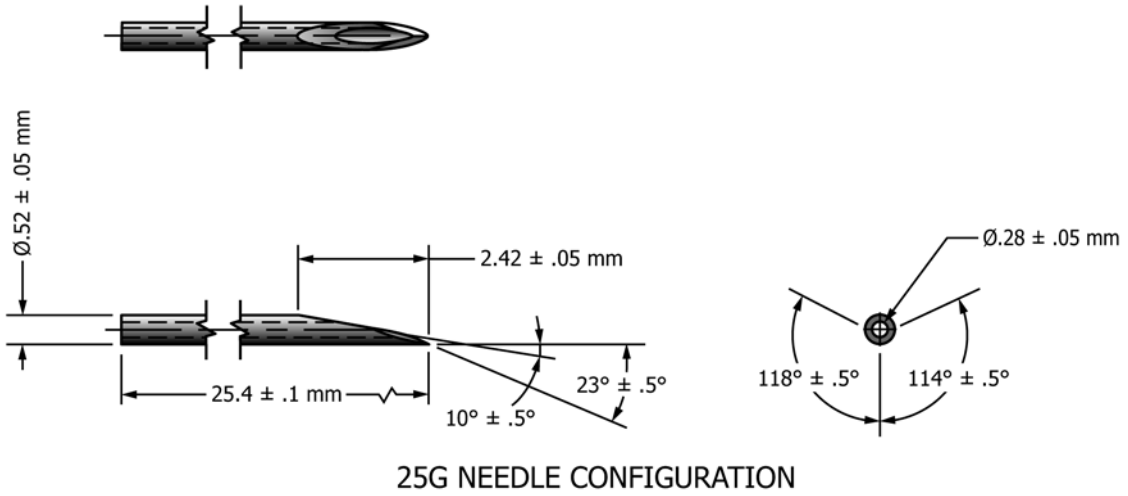
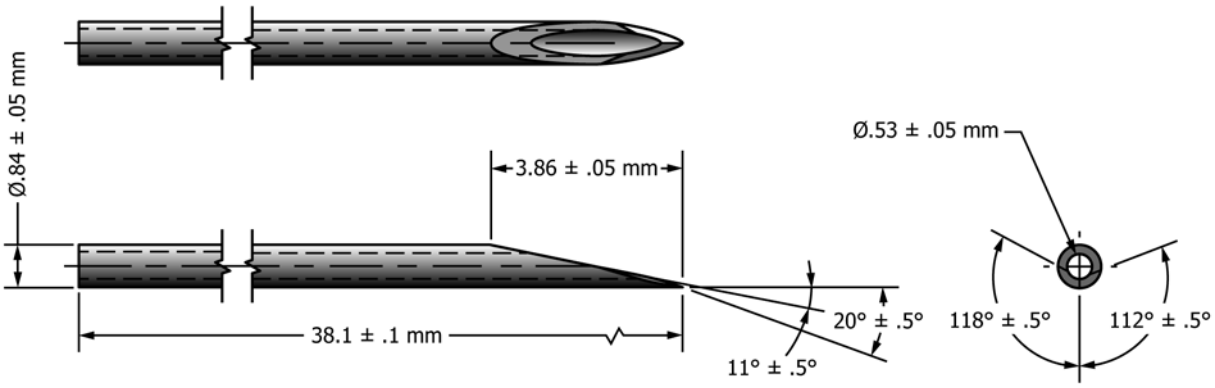


FIG. 2 (a) Needle-tip Geometries (28G Needle Configuration)



25G NEEDLE CONFIGURATION

FIG. 2 (b) Needle-tip Geometries (25G Needle Configuration) *(continued)*



21G NEEDLE CONFIGURATION

FIG. 2 (c) Needle-tip Geometries (21G Needle Configuration) *(continued)*

7.2 Test specimens should be conditioned prior to testing in accordance with Practice D1776.

8. Calibration

8.1 Each lot of hypodermic needles shall be validated.

8.2 Needle lot validation procedure

8.2.1 Identify manufacturer's lot number on the needle packaging.

8.2.2 Randomly select seven needles from the same manufacturing lot and conduct seven puncture measurements on the calibration material as described in Section 9.

8.2.3 If the average of the puncture measurements fall within the range specified on Table 1, needles from this lot are acceptable for data collection and reporting. If the average of the puncture measurements does not fall within the range specified in Table 1, needles from this particular lot can not be used to conduct this test.

TABLE 1 Lot Validation Table for Needles

Needle Gauge	Avg. Peak Force Target (N)	Tolerance (±)	Standard Dev. (max)
28	0.822	0.189	0.105
25	1.134	0.17	0.115
21	1.538	0.251	0.158

9. Procedure

9.1 Measure the thickness of each specimen to the nearest 0.01 mm and record.

9.2 Mount the material specimen to be tested in the support assembly. Mark the two plates and take care that the holes are aligned prior to testing to avoid damaging the penetrometer and plates.

9.3 Attach the material support assembly to the upper or lower arm of the test apparatus depending on machine configuration.

9.4 Position a fresh needle (from a lot of needles validated as described in Section 8) on the compression cell of the test apparatus. Compression test machines require the cross head to travel some distance before reaching the set velocity. Ensure the tip of the needle is set back far enough from the surface of the test specimen to allow the cross head to build up to the desired velocity prior to impacting the test specimen.

9.5 Set the testing machine in operation, but stop it when the penetrometer has been driven through the sample specimen. The penetrometer shall have a velocity of 500 mm/min under load conditions and shall be uniform at all times.

9.6 Record the maximum force registered by the indicating device to the nearest 0.01 N.

9.7 If the needle buckles prior to penetration, record the peak force loaded on the specimen prior to buckling.

9.8 After the first test is complete, dispose of the used needle in a puncture proof sharps disposal container, mark the spot on the test specimen where the puncture occurred, mount a fresh needle, and repeat the test.

9.8.1 Multiple punctures may be conducted on a single test specimen. When conducting multiple punctures, ensure holes from previous punctures are located outside of the puncture guide hole.

9.9 Conduct a total of twelve puncture resistance measurements. The same type of needle (21, 25, or 28 gauge) should be used in each of the twelve measurements.

10. Report

10.1 Report the following information:

10.1.1 Describe the type of material tested including the thickness of each specimen to the nearest 0.01 mm and which side of material was facing needle. Calculate and report the average thickness.

10.1.2 Report the gauge, manufacturer, part number and lot number for needles used in the test including length protruding from the clamp or hub.

10.1.3 Report the maximum force required for each puncture to the nearest 0.01 N in all twelve test replicates.

10.1.4 Calculate and report the average and standard deviation of puncture force required to penetrate the material. Include copies of the stress strain curves with labeling.

11. Precision and Bias

11.1 *Precision*—The precision of this test method is being determined. Needles should be used only once to insure that each puncture resistance measurement uses a needle with the correct unaltered geometry.

11.2 *Bias*—Since there is no accepted reference material suitable for determining the bias for the procedure in this test method for measuring needle puncture resistance of protective clothing materials, bias has not been determined.

12. Keywords

12.1 hypodermic; needle; needle resistance; needlestick; prick; protective clothing materials; puncture; puncture resistance; stick