Designation: F2878 – 19

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 BBPs 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 is expected, testing against both ends of the spectrum allows for a better understanding of robustness.

1. Scope

1.1 This test method is used to determine the force required to cause a sharp-edged hypodermic needle to penetrate through protective clothing material. The standard describes three needles 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D1776/D1776M Practice for Conditioning and Testing Textiles

D1777 Test Method for Thickness of Textile Materials

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

E4 Practices for Force Verification of Testing Machines

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

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

F1342/F1342M Test Method for Protective Clothing Material Resistance to Puncture

3. Terminology

3.1 *Definitions:*

3.1.1 *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.

3.1.2 *penetration, n*—when the beveled tip of the needle has passed through the specimen as defined in 4.3.

3.1.3 *penetrometer, n*—a material tester or similar device consisting of a movable crosshead with accurate speed control, a load cell used in compression, a needle holder, and a specimen holder. The needle holder should be attached to the load cell in such a way as to accurately determine the load during the needle penetration of the specimen, holding the needle parallel to the crosshead motion and perpendicular to the specimen to be tested. The specimen holder should be mounted rigidly with respect to the crosshead motion and present the specimen perpendicular to the needle.

3.1.4 *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.

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 penetrometer or material testing device. 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 needle of set dimensions is mounted to the needle holder which is attached or can be attached to the load cell of the penetrometer or material testing device.

4.3 The needle is positioned perpendicular to the specimen and is moved at a constant velocity until the tip of the needle penetrates through the backside of the material specimen. The needle length visible through the back of the test specimen shall be at least 2.21 mm for a 28-G needle, 2.90 mm for a 25-G needle, and 4.62 mm for a 21-G needle.

4.4 The maximum force required to penetrate the specimen is measured by the load cell.

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

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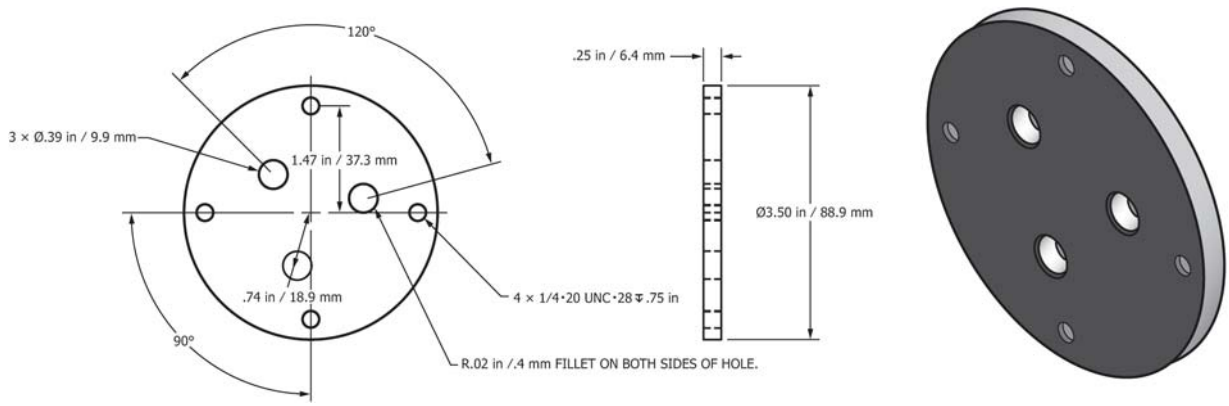
[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.



NOTE 1—Holes are 1 in. from edge.

FIG. 1 Example of a Specimen Support Assembly (Two Needed)

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 needle 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/F1342M.

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.

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

6.2.1 The specimen holder shall be capable of holding the specimen securely between the two plates.

6.2.2 A penetrometer or material testing device shall be used that is capable of providing load-versus-displacement data for facing surface contact through needle penetration.

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 load cell used in compression. The testing machine may be configured with the load cell on the upper arm. The load cell shall have a range sufficient to measure the force necessary for needle penetration of 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 309420 or 329461 (28 G by ½ in.), 305125 (25 G by 1 in.), and 305167 (21 G by 1½ in.) have been found to be suitable, though needles from other sources which conform to the general description (6.3.1 and 6.3.2) and perform within the range described in the lot validation table below may be used.

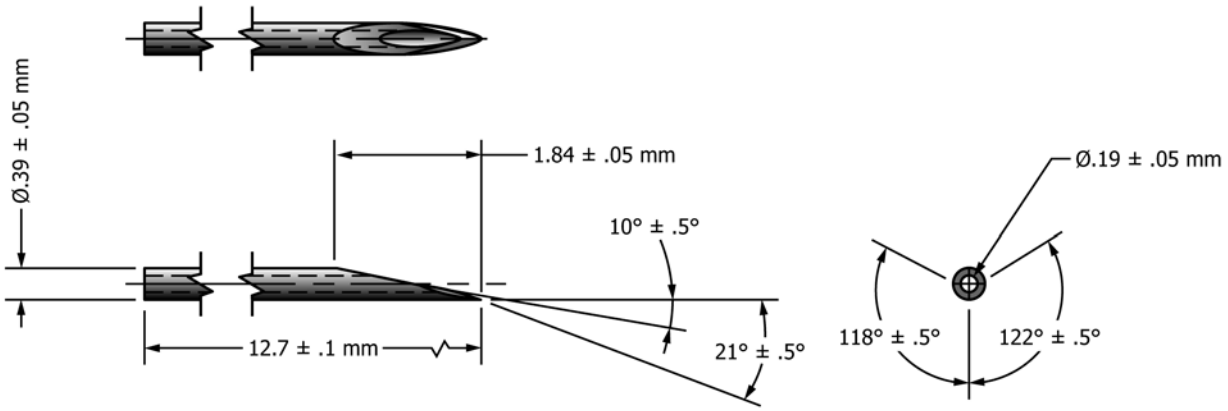
6.4 A total of twelve needles, selected from needle lots that have been validated, are required (one for each puncture measurement) to conduct the test.

6.5 *Specimen Support Assembly* shall consist of two flat metal specimen support plates that clamp together so the specimen is held tightly between them. Care should be taken to lay the specimen 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 needle. The plates should be closed tightly on the specimen to reduce, to the greatest extent possible, slipping/shifting of the material between the plates during testing.

6.5.1 Each plate shall have one or more puncture guide holes measuring 10 mm in diameter. Ideally, the guide hole diameter would be 10 mm with an edge radius of 0.4 mm. (See Fig. 1.) 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. 1.

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



28G NEEDLE CONFIGURATION

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