Designation: D7257 – 06 (Reapproved 2011)

Standard Test Method for Automated Shelling Two-Piece Child-Resistant Closures That Are Activated by Two Simultaneous Dissimilar Motions[1]

This standard is issued under the fixed designation D7257; 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 test method covers the measurement of the force required to separate (or "shell") the snap-fitted outer cap from the inner cap of Type IA, IB, or IC child-resistant closures. See Practice D3475.

1.2 This test method is an alternative to Test Method D3481, a manual test procedure.

1.3 This test method does not measure the force required to separate parts of a child-resistant closure system that were originally "screwed-on" instead of "snapped-on" (for example, pull a cap over or through continuous or multi-start threads when the cap was originally screwed on).

1.4 The values stated in inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.

1.5 *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]

D3474 Practice for Calibration and Use of Torque Meters Used in Packaging Applications

D3475 Classification of Child-Resistant Packages

D3481 Test Method for Manual Shelling Two-Piece Child-Resistant Closures That Are Activated by Two Simultaneous Dissimilar Motions

E105 Practice for Probability Sampling of Materials

E122 Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process

3. Terminology

3.1 *Definitions:*

3.1.1 *shelling fixture or bracket*—a metal bracket that attaches to a two-piece, child-resistant closure and pries an outer cap from an inner cap. The bracket is shaped to simulate the prying action of a child's teeth. See Fig. 1.

3.1.2 *drive cable*—a non-extensible cable attached from the shelling fixture to a tensile strength measuring device to provide the cap shelling force.

3.1.3 *lifting notch*—indentation on the shelling fixture that lifts the outer cap off the inner cap during the test. See detail A in Fig. 1.

4. Summary of Test Method

4.1 This test method measures the force required to pry the outer cap off the inner cap using a fixture having a contact point under the tip of the skirt of the outer cap and leverage being placed on that point and the top of the cap. This procedure is used where a pivotal prying force can be successfully used to separate the components of the closure system, thereby disabling the child-resistant function.

5. Significance and Use

5.1 This test method of applying force may be used as a standard test to compare the characteristics of a given design of container/child-resistant closure system with a standard or to compare the characteristics of container/child resistant closure systems differing in construction.

5.2 It may be used to simulate certain manipulations that may be expected to occur in protocol testing (such as, prying with the teeth, or objects in the room, biting, and pulling with the teeth).

5.3 This test may be used to establish performance specifications. Shelling force may vary with cap application torque,

[1] This test method is under the jurisdiction of ASTM Committee D10 on Packaging and is the direct responsibility of Subcommittee D10.32 on Consumer, Pharmaceutical, Medical, and Child Resistant Packaging.

Current edition approved Aug. 1, 2011. Published November 2011. Originally approved in 2006. Last previous edition approved in 2006 as D7257 –06. DOI: 10.1520/D7257-06R11.

[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.

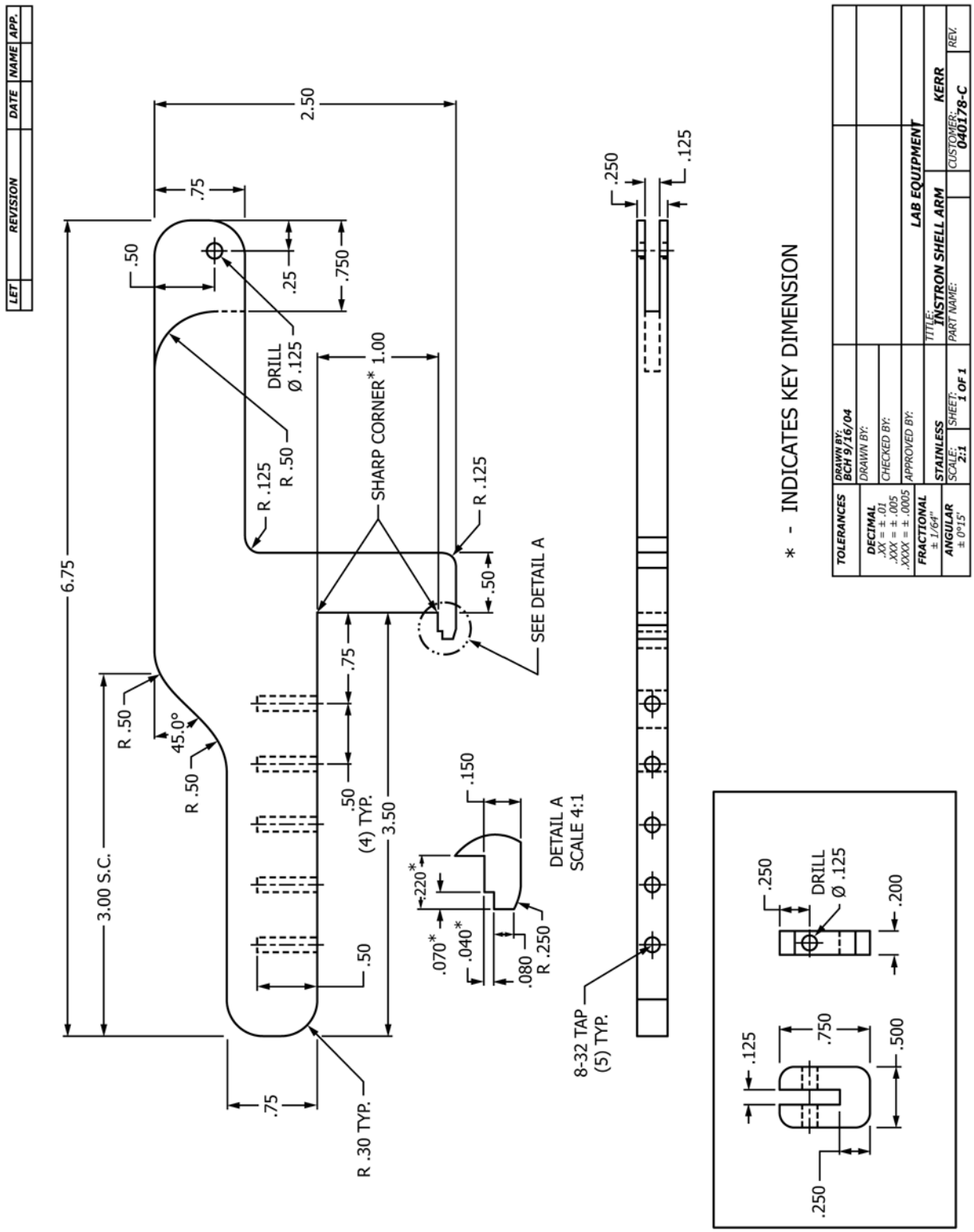

FIG. 1 Shelling Bracket

bottle design, and other factors. Consequently where precise comparative results are desired, these factors must be carefully controlled.

6. Apparatus

6.1 *Testing Machine*—A testing machine of the constant-rate-of-crosshead-movement with vertical orientation type and comprising essentially the following:

6.1.1 *Fixed Member*—A fixed or essentially stationary grip capable of holding a suitable bottle finish for the cap to be tested. The fixed grip should be the lower grip.

6.1.2 *Movable Member*—A movable, top member carrying a second grip.

6.1.3 *Grip*—A grip for holding the shelling bracket cable can be either the fixed or self-aligning type.

6.2 *Attachments, Fixtures, and so forth* (see Fig. 1):

6.2.1 *Cap Holding Fixture,* with one contact point under the top of the outer cap skirt and the other point contacting the top of the cap. The distance between the two contact points should be 34 mm or approximately 1⅜ in. (in accordance with page 19 of the Krogman study) or to the farthest side of the cap if less than 34 mm.

6.2.2 *Non-extensible Cable,* to be attached to the movable member of the testing machine. The cable should be marked in such a manner that the same length of cable will be attached to the tensile tester and shelling bracket for all samples being tested.

6.2.3 *Bottle Fixture*—A standard GPI bottle finish, with corresponding finish to the closure(s) being tested.

7. Sampling, Test Specimens, and Test Units

7.1 The number of samples will depend on the desired purpose for which the test is being conducted. However, for a given set of samples, sufficient measurements should be taken in accordance with established statistical sampling procedures in order to obtain consistent results.

7.1.1 Refer to Practices E105 and E122 for more specific information.

7.2 Performance normally should be based on a test of not less than ten representative specimens of a given type selected at random.

8. Conditioning

8.1 Preconditioning is not necessary unless it is required to simulate a particular storage environment.

8.2 If special conditions are not required, components may be stored for a minimum of 24 h at 23 ± 2°C (73.4 ± 3.4°F) and 50 ± 5 % relative humidity.

9. Procedure

9.1 Apply all closures to be tested to the appropriate container fixture at a specified and uniform torque.

NOTE 1—Specifying the application torque is necessary for test consistency as the physical relationship/interlocking between the inner and outer closure can change at different application torque levels. Torque meters should be calibrated as referenced in Practice D3474.

9.2 Attach the shelling fixture drive cable to the movable member of the tensile tester and raise the grip so that the fixture is suspended freely. Zero the load sensor or note the weight of the fixture to subtract it from the shelling force measurements later.

9.3 The load cell of the tensile test should be directly above the cap on the container fixture.

9.4 After the closure has been applied, attach the container fixture to the fixed member of the tensile testing machine.

9.5 Position the body of the shelling fixture onto the closure so that the fixture is horizontal and lifting notch is under the outer cap.

9.6 Set the tensile tester for a travel speed of 15 in./min (381 mm/min) and start the tensile tester.

9.7 Allow the tensile tester to run until the outer cap has been pried from the inner cap, unless an alternative end point is desired.

NOTE 2—Some closure systems lose their child resistance before the outer cap is completely removed from the inner cap. For this reason an appropriate test endpoint should be chosen for a given closure.

9.8 The maximum force measured to reach the test end point shall be recorded as the shelling force.

10. Report

10.1 The report shall include the following:

10.1.1 Name, number and date of procedure used,

10.1.2 Gross description of container/child-resistant closure system under test; its complete structural specifications; kind of material; size and style of closure and bottle finish including thread type; manufacturer and lot number; date of receipt or other identification of the specific batch being evaluated,

10.1.3 Description of the exact test equipment and procedure that were used to obtain the test results, including the contact point location of the shelling bracket (see 6.2.1),

10.1.4 Table showing the maximum shelling force for each test, and

10.1.5 Statement that the test was made in accordance with ASTM Test Method D7257. Any and all deviations from the recommended procedure should be noted.

11. Precision and Bias

11.1 *Precision*—The repeatability standard deviation has been estimated for three packages based on testing conducted in one laboratory. One package had a within-laboratory standard deviation of 0.3 lbf or 7.31 % of the average. A second package had a standard deviation of 0.41 lbf, 8.36 % of the average shelling force. The standard deviation of a third package was 0.52 lbf, 25.8 % of the shelling force average. Other packages may have different repeatability values.

11.2 *Bias*—No justifiable statement can be made on the bias of this test method since a true value cannot be established by an accepted referee method.

12. Keywords

12.1 shelling; two simultaneous dissimilar motions; Type IA child-resistant closure; Type IB child-resistant closure; Type IC child-resistant closure