Designation: D7860 – 14

Standard Test Methods for Measurement of Torque Retention for Child Resistant and Non-Child Resistant Packages with Continuous Thread Closures Using Automated Torque Testing Equipment[1]

This standard is issued under the fixed designation D7860; 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 These test methods evaluate the torque retention of continuous thread closures on containers with matching finishes, for predetermined environmental conditions over time. Methods are defined for both Type I, style "A" push down and turn Type II[2] child resistant and non child resistant type closures.

1.2 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

NOTE 1—The SI unit system is the recommended system.

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:*[3]

D996 Terminology of Packaging and Distribution Environments

D3198 Test Method for Application and Removal Torque of Threaded or Lug-Style Closures

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

D3475 Classification of Child-Resistant Packages

D4169 Practice for Performance Testing of Shipping Containers and Systems

D4332 Practice for Conditioning Containers, Packages, or Packaging Components for Testing

D7386 Practice for Performance Testing of Packages for Single Parcel Delivery Systems

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

3. Terminology

3.1 *Definitions:*

3.1.1 For definitions of general packaging and distribution terms, see Terminology D996.

3.1.2 For definitions of application torque and removal torque, see Test Method D3198.

3.1.3 For Definitions regarding conditioning, see Terminology E41.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *dry torque*—dry torque is defined as applying torque in the absence of lubricant (i.e. product from the container or filling operation) on the threads.

3.2.2 *immediate removal torque*—removal torque that is measured at a stated interval, from 1 to 5 min after closure application.

3.2.3 *torque retention*—a comparison between removal torque at the end of a test period and a predetermined immediate removal torque.

4. Summary of Test Methods

4.1 *Test Method A: Static Evaluation*—At predetermined time intervals, the removal torques of representative samples of a container/continuous thread closure system, previously stored at various environmental conditions, are measured.

4.2 *Test Method B: Dynamic Evaluation*—Practices D4169 and D7386 are used to develop a uniform system of evaluating the ability of primary packages, in the shipping units, to withstand the distribution environment. At the end of predetermined distribution cycles, the removal torques of representative samples of a container/continuous thread closure system are measured.

[1] These test methods are 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.

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[2] For classification of child resistant styles, see ASTM D3475 Standard Classification of Child-Resistant Closures.

[3] 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.

5. Significance and Use

5.1 This test method allows for the measurement of the torque retention properties of container/continuous thread closure systems of various designs, materials, and manufacture, and is suitable for package development and engineering evaluation.

5.2 Each test method can be used for the evaluation of non child resistant container/continuous thread closure systems under controlled conditions such as when the application torque is known and the applied downward force to the closure is zero or for Type I, style "A" push down and turn child resistant container/continuous thread closure systems under controlled conditions such as when the application torque and the applied downward force to the closure is known.

5.3 This test method measures torque retention properties of container/continuous thread closure systems with the use of an automated transducer based torque meter operating at a known rotational velocity (rpm) or known torque ramp.

5.4 This test method is intended for measurement of dry torque only.

6. Apparatus

6.1 *Automated Transducer Based Torque Meter,* with a programmable, fixed velocity or fixed torque ramp rate rotational torque head and digital output that accurately measures within the expected torque range for the particular container/continuous thread closure system to be evaluated. (See Note X for source(s) of equipment.)

6.2 *Torque Calibration Verification Device (Calibrated "Standard"),* is a magnetic type device that produces a repeatable breakaway torque within the expected torque range for the particular container/continuous thread closure system to be evaluated. (A calibrated "standard" is a separate device calibrated to a known set torque value and used for verifying the measuring meter between calibration periods.)

7. Sampling and Test Specimens

7.1 Measure no less than ten test specimens for each torque measurement point per test variable.

7.2 Select previously unused continuous thread closures and containers as test specimens.

7.3 Select a single cap and container mold cavity number combination for testing if possible. A single combination will reduce the variability between samples.

7.4 For torque measurement and analysis of a production line system, sample size should be determined based upon the quantity of mold cavities used to produce the containers and closures used in production.

8. Calibration

8.1 Calibrate transducer based torque meters to a traceable industry recognized traceable standard (e.g. NIST) in accordance with the manufacturer's procedures.

8.2 Verify dynamic calibration of the transducer based torque meter by measuring both the application and removal torque of a calibrated force meter with a torque calibration verification device (calibrated "standard") five times before testing begins. Record results.

9. Conditioning and Preparation of Test Specimens

9.1 Perform test specimen conditioning in accordance with Specification E171 and Practice D4332.

9.2 Fill all of the containers with the specified volume or weight of product, or other materials that yield similar weight and thermal characteristics. See Notes 2 and 3.

NOTE 2—The total quantity of test specimens sampled will depend upon the method selected and the number of environmental storage conditions.

NOTE 3—Given the purpose of the evaluation, empty containers may be used as an option to filled containers for static testing.

10. Procedure (see Note 4)

10.1 *Test A: Static Evaluation Non-Child Resistant Closures:*

10.1.1 Select the minimum application torque for the container/continuous thread system as recommended by the closure manufacturer. (For example, the U.S. Pharmacopoeia, the Society for the Plastics Industry, the Glass Container Manufacturers Institute, or other sources.)

NOTE 4—Under certain conditions of product-filling, storage and distribution, it may be desirable to combine appropriate segments of Test Method A and Test Method B.

10.1.2 Set up torque meter for application torque operation based on manufacturer's procedures.

10.1.3 Place a suitable closure onto the container.

10.1.4 For actuated container clamping type concentric with measuring device, place the container into the machine. For manual style container clamping type, place the container into the machines container holding device in such a manner that the axis of rotation of the closure is concentric with the center of the measuring device.

10.1.5 For positive actuated chuck style, start cycle and tighten the closure to the pre-determined application torque. For manual chuck style, affix the automated machine's rotating measuring device to the closure and tighten the closure to the pre-determined application torque. Record both the pre-determined applied torque and the torque rate or rotation rate of the torque measuring head.

10.1.6 Verify that the machine stopped applying torque at the pre-determined application value. See Note 5.

10.1.7 Apply the balance of the closures or containers to the matching components as directed in 10.1.3, 10.1.4, and 10.1.5.

10.1.8 Store the assembled test specimens as appropriate in accordance with Specification E171 or Practice D4332.

10.1.8.1 Maintain one group of test specimens as a control by storing this group at ambient laboratory conditions. See Note 5.

NOTE 5—The application torque range is usually determined on the basis of the desired removal torque range.

10.1.8.2 Maintain, as appropriate, one or more groups of test specimens at constant temperatures different than ambient laboratory conditions. If desired, cycling at various temperature and relative humidity conditions may be performed.

10.1.9 At the end of each predetermined time period, determine the removal torque for each test sample at ambient laboratory conditions or at the alternative temperature and relative humidity conditions.

10.1.9.1 The following test intervals are recommended: immediate (between 1 and 5 minutes), 24 h, 48 h, 7 days, 14 days, and 28 days. See Note 6.

NOTE 6—Sterilization cycles, if applied, using steam, ethylene oxide, gamma radiation, or other methods are known to affect certain plastics; these effects may influence removal torques.

10.1.10 Set-up machine for removal torque operation based on manufacturers procedures.

10.1.11 Determine the removal torque for each test specimen; for actuated container clamping type concentric with measuring device, place the container into the machine. For manual style container clamping type, place the container in the machine's container holding device in such a manner that the axis of rotation of the closure is concentric with the center of the measuring device.

10.1.12 For positive actuated chuck style, activate machine to remove and measure the cap removal torque from the container. For manual chuck style, affix the measuring device to the container closure and while avoiding contact with the fixed component, activate the machine to remove and measure the cap removal torque from the container. Note the maximum torque required to loosen the closure, the rotation speed or torque rate of the rotating torque measurement device and the dwell time and record these values for the test specimen. See Note 7.

NOTE 7—It is recommended that the same automated torque instrument be used to remove all closures in a given test to reduce possible instrument inconsistencies and their associated variables.

10.1.13 Record the maximum torque required to loosen the closure and the dwell time for each remaining specimen.

10.1.14 Remove the balance of the movable components (normally the continuous thread closures) as directed in 10.1.11 and 10.1.12.

10.2 *Test A1: Static Evaluation -Child Resistant Closures:*

10.2.1 Select the minimum application torque for the container/continuous thread system as recommended by the closure manufacturer. (For example, the U.S. Pharmacopoeia, the Society for the Plastics Industry, the Glass Container Manufacturers Institute, or other sources.)

NOTE 8—Under certain conditions of product-filling, storage and distribution, it may be desirable to combine appropriate segments of Test Method A and Test Method B.

10.2.2 Set up torque meter for application torque operation based on manufacturer's procedures.

10.2.3 Place a suitable closure onto the container.

10.2.4 For actuated container clamping type concentric with measuring device, place the container into the machine. For manual style container clamping type, place the container into the machines container holding device in such a manner that the axis of rotation of the closure is concentric with the center of the measuring device.

10.2.5 Rotate the bottle and cap until the cap's CR outer locking lugs mesh with the inner lugs that allow the cap to be tightened or removed. Activate the CR locking mechanism with sufficient vertical force to prevent slipping of the lugs. Record the vertical downward force.

10.2.6 For positive actuated chuck style, start cycle and tighten the closure to the pre-determined application torque. For manual chuck style, affix the automated machine's rotating measuring device to the closure and tighten the closure to the pre-determined application torque. Record both the pre-determined applied torque and the torque rate or rotation rate of the torque measuring head.

10.2.7 Verify that the machine stopped applying torque at the pre-determined application value. See Note 6.

10.2.8 Apply the balance of the closures or containers to the matching components as directed in 10.1.3, 10.1.4, and 10.1.5.

10.2.9 Store the assembled test specimens as appropriate in accordance with Specification E171 or Practice D4332.

10.2.9.1 Maintain one group of test specimens as a control by storing this group at ambient laboratory conditions. See Note 9.

NOTE 9—The application torque range is usually determined on the basis of the desired removal torque range.

10.2.9.2 Maintain, as appropriate, one or more groups of test specimens at constant temperatures different than ambient laboratory conditions. If desired, cycling at various temperature and relative humidity conditions may be performed.

10.2.10 At the end of each predetermined time period, determine the removal torque for each test sample at ambient laboratory conditions or at the alternative temperature and relative humidity conditions.

10.2.10.1 The following test intervals are recommended: immediate (between 1 and 5 minutes), 24 h, 48 h, 7 days, 14 days, and 28 days. See Note 10.

NOTE 10—Sterilization cycles, if applied, using steam, ethylene oxide, gamma radiation, or other methods are known to affect certain plastics; these effects may influence removal torques.

10.2.11 Set-up machine for removal torque operation based on manufacturers procedures.

10.2.12 Determine the removal torque for each test specimen; for actuated container clamping type concentric with measuring device, place the container into the machine. For manual style container clamping type, place the container in the machine's container holding device in such a manner that the axis of rotation of the closure is concentric with the center of the measuring device.

10.2.13 Rotate the bottle and cap until the cap's CR outer locking lugs mesh with the inner lugs that allow the cap to be tightened or removed. Activate the CR locking mechanism to hold the lugs meshed.

10.2.14 For positive actuated chuck style, activate machine to remove and measure the cap removal torque from the container. For manual chuck style, affix the measuring device to the container closure and while avoiding contact with the fixed component, activate the machine to remove and measure the cap removal torque from the container. Note the maximum torque required to loosen the closure, the rotation speed or

torque rate of the rotating torque measurement device and the dwell time and record these values for the test specimen. See Note 7 regarding instrument inconsistencies and their associated variables.

10.2.15 Record the force required to activate the CR feature, maximum torque required to loosen the closure and the dwell time for each remaining specimen.

10.2.16 Remove the balance of the movable components (normally the continuous thread closures) as directed in 10.2.12 and 10.2.13.

10.3 *Test Method B: Dynamic Evaluation Non-Child Resistant Closure:*

10.3.1 Follow the procedures of Practices D4169 and D7386 for recommendations relevant to the number of test specimens, conditioning, and distribution cycles to be used to evaluate these test specimens.

10.3.2 Follow Section 8 on Calibration for test equipment calibration.

10.3.3 Follow Section 10 on Procedure (Test Method A) for recommendations concerning continuous thread closure application.

10.3.4 Begin evaluation of a selected distribution cycle after immediate removal torque has been determined and before any additional long-term storage, if long-term storage is desired. (Testing may be determined following distribution cycling with removal torques noted.)

10.4 *Test Method B1: Dynamic Evaluation Child Resistant Closure:*

10.4.1 Follow the procedures of Practices D4169 and D7386 for recommendations relevant to the number of test specimens, conditioning, and distribution cycles to be used to evaluate these test specimens.

10.4.2 Follow Section 8 on Calibration for test equipment calibration.

10.4.3 Follow Section 10 on Procedure (Test Method B) for recommendations concerning continuous thread closure application.

10.4.4 Begin evaluation of a selected distribution cycle after immediate removal torque has been determined and before any additional long-term storage, if long-term storage is desired. (Testing may be determined following distribution cycling with removal torques noted.)

11. Report

11.1 Report the following information:

11.1.1 Identification of the test method used.

11.1.2 Identification of the non-child resistant and continuous thread closure and container manufacturer(s), their mold cavity numbers, the material(s) of construction of the closure (including any liner, liner coating, and additional sealing components), and the container (including any coating or annealing agents).

11.1.3 Thread finish and other designation(s) of the non-child resistant and continuous thread closure and the container.

11.1.4 Description of test specimen preparation.

11.1.5 Description of storage conditions.

11.1.6 Description of distribution cycles and handling conditions.

11.1.7 Description of the test area environment.

11.1.8 Number of test replicates.

11.1.9 Application torque range and mean value for each test condition variable.

11.1.10 Removal torque range and mean value for each test condition variable.

11.1.11 Rotational rate or torque rate of the torque measuring device during closure application and removal.

11.1.12 Downward applied force for CR closures if applicable.

11.1.13 Description of the torque instruments used.

11.1.14 Evaluation of comparative results, if appropriate.

11.1.15 Statement that testing was done in accordance with this test method or a description of the difference(s) from this test method.

11.1.16 Calibration Automated Torque Testing Equipment Serial Number or ID, measured results, and date of last calibration.

11.1.17 Calibration “Standard” Serial Number or ID, calibrated value, measured results, and date of last calibration.

11.1.18 Description of chuck style and chuck pressure, if applicable.

12. Precision and Bias

12.1 The precision of this test method is based on an interlaboratory study based on WK30859, Standard Torque Retention for Packages with CT Closures Using Automated Torque Instruments, conducted in 2013. Two laboratories participated in this study. Each of the two labs reported 25 replicate test results for two different bottle / cap combinations, at both 1 RPM and 4 RPM. Every “test result” reported represents an individual determination. Except for the use of only two laboratories, Practice E691 was followed for the design and analysis of the data; the details are given in RR:D10-1017.[4]

12.1.1 *Repeatability (r)*—The difference between repetitive results obtained by the same operator in a given laboratory applying the same test method with the same apparatus under constant operating conditions on identical test material within short intervals of time would in the long run, in the normal and correct operation of the test method, exceed the following values only in one case in 20.

12.1.1.1 Repeatability can be interpreted as the maximum difference between two results, obtained under repeatability conditions that are accepted as plausible due to random causes under normal and correct operation of the test method.

12.1.1.2 Repeatability limits are listed in Tables 1 and 2.

12.1.2 *Reproducibility (R)*—The difference between two single and independent results obtained by different operators applying the same test method in different laboratories using different apparatus on identical test material would, in the long run, in the normal and correct operation of the test method, exceed the following values only in one case in 20.

[4] Supporting data have been filed at ASTM International Headquarters and may be obtained by requesting Research Report RR:D10-1017. Contact ASTM Customer Service at service@astm.org.

TABLE 1 Cap Removal – 1 RPM (in-lbs)

	Average[A] $\bar{x}$	Repeatability Standard Deviation s_r	Reproducibility Standard Deviation s_R	Repeatability Limit r	Reproducibility Limit R	r as % of mean	R as % of mean
Bottle/ Cap Combination A	7.852	0.613	0.613	1.716	1.716	21.9	21.9
Bottle/ Cap Combination B	7.081	0.422	2.307	1.181	6.460	16.7	91.2

[A] The average of the laboratories' calculated averages.

TABLE 2 Cap Removal – 4 RPM (in-lbs)

	Average[A] $\bar{x}$	Repeatability Standard Deviation s_r	Reproducibility Standard Deviation s_R	Repeatability Limit r	Reproducibility Limit R	r as % of mean	R as % of mean
Bottle/ Cap Combination A	7.265	0.718	1.110	2.010	3.108	27.7	42.8
Bottle/ Cap Combination B	7.919	0.368	3.398	1.029	9.515	13.0	120.1

[A] The average of the laboratories' calculated averages.

12.1.2.1 Reproducibility can be interpreted as the maximum difference between two results, obtained under reproducibility conditions that are accepted as plausible due to random causes under normal and correct operation of the test method.

12.1.2.2 Reproducibility limits are listed in Tables 1 and 2.

12.1.3 The above terms (repeatability limit and reproducibility limit) are used as specified in Practice E177.

12.1.4 Any judgment in accordance with statements 12.1.1 and 12.1.2 would normally have an approximate 95% probability of being correct, however the precision statistics obtained in this ILS must not be treated as exact mathematical quantities which are applicable to all circumstances and uses. The limited number of materials tested and laboratories reporting results guarantees that there will be times when differences greater than predicted by the ILS results will arise, sometimes with considerably greater or smaller frequency than the 95% probability limit would imply. The repeatability limit and the reproducibility limit should be considered as general guides, and the associated probability of 95% as only a rough indicator of what can be expected.

12.2 *Bias*—At the time of the study, there was no accepted reference material suitable for determining the bias for this test method, therefore no statement on bias is being made.

12.3 The precision statement was determined through statistical examination of 200 results, from two laboratories, on two bottle / cap combinations. These two combinations were described as the following:

Combination A: Push and Turn Lug Type Child Resistant
Combination B: Continuous Thread

12.3.1 To judge the equivalency of two test results, it is recommended to choose the bottle / cap combination closest in characteristics to the test combination.

13. Keywords

13.1 automated torque measurement; child resistant closure; continuous thread closure; removal torque; retention