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Standard Test Methods for Pressure Decay Leak Test for ~~Nonporous~~ Flexible Packages With and Without Restraining Plates[1]

This standard is issued under the fixed designation F 2095; 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.

ϵ^1 NOTE—Added research report reference to Section 11 editorially in March 2008.

1. Scope

1.1 These test methods cover the measurement of leaks in nonporous film, foil, or laminate flexible pouches and foil-sealed trays, which may be empty or enclose solid product. If product is enclosed, seals or surfaces cannot be in contact with water, oils, or other liquid.

1.2 These test methods will detect leaks at a rate of 1×10^{-4} sccs (standard cubic centimetres per second) or greater, in flexible packages. The limitation of leak rate is dependent on package volume as tested.

1.3 The following test methods are included:

1.3.1 *Test Method A*— Pressure Decay Leak Test for ~~Nonporous~~ Flexible Packages Without Restraining Plates

1.3.2 *Test Method B*— Pressure Decay Leak Test for ~~Nonporous~~ Flexible Packages With Restraining Plates

1.4 These test methods are destructive in that they require entry into the package to supply an internal pressure of gas, typically air or nitrogen, although other gases may be used. The entry connection into the flexible package must be leak-tight.

~~1.5~~

1.5 For porous packages, see 9.3.

1.6 *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:*~~

~~D1898 Practice for Sampling of Plastics~~ ASTM Standards: [2]

D 4332 Practice for Conditioning Containers, Packages, or Packaging Components for Testing

E 177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E 691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

F 17~~Terminology Relating to Flexible Barrier Packaging~~

~~F1327Terminology Relating to Barrier Materials for Medical Packaging~~ Terminology Relating to Flexible Barrier Packaging

2.2 *Other Document:*

~~ANSI/AAMI/ISO 11607Packaging for Terminally Sterilized Medical Devices~~ ANSI/AAMI/ISO 11607–1:2006 Packaging for Terminally Sterilized Medical Devices—Part 1: Requirements for Materials, Sterile Barrier Systems, and Packaging Systems[3]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *integrity*—the unimpaired physical condition of the package. This implies that there are no leaks in the seals or body materials.

3.1.2 *leak*~~—See Terminology F1327~~—See Terminology F 17.

~~[1] These test methods are under the jurisdiction of ASTM Committee F02 on Flexible Barrier Materials and are the direct responsibility of Subcommittee F02.40 on Package Integrity.~~

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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.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

3.1.3 *nonporous*—types of materials that are not purposely designed to transfer gases through their matrix.

3.1.4 *restraining plates*—plates of rigid material, for example, aluminum, that are used to restrict the movement of the package during inflation.

3.1.5 *seal*—See Terminology F 17.

3.1.6 *standard cubic centimetre per second (sccs)*—the flow rate of a gas (air) at standard conditions of 20°C (68°F) and 101.3 kPa (14.7 psig) (1 atmosphere or 760 mm Hg).

3.1.6.1 *Discussion*—Conditions may be varied depending on the source of data. Always check the definition being used.

4. Summary of Test Method

4.1 Detection of leak paths in flexible packages that have nonporous material surfaces and seals can be accomplished by pressurization of the package to a fixed pressure, shutting off the pressure and connecting a pressure transducer. Observed changes in pressure indicate the presence of leakage paths in the package seals or pinholes in the surfaces. This leak may be represented in decay pressure units or calculated leak rate units. To accomplish this technique, a leak-tight measuring path must be available between the package interior volume and the pressure transducer (see Fig. 1).

NOTE 1—The coating used on porous barrier films will mask defects (pin-holes) in/through the porous material but not defects in the seals.

4.2 Restraining plates may be used to limit the volume of the pressurized package. Because the sensitivity of these test methods is dependent in part on the internal volume of the package, the effect of restraining plate use is to increase the sensitivity of the test (see Fig. 2). See Appendix X1 for further discussion of the effects of restraining plates on these test methods.

5. Significance and Use

5.1 These test methods provide a rapid, simple to apply method to detect small leaks in flexible package seals or walls at the leak rate level of greater than 1×10^{-4} ~~sces, thus providing a measure of package integrity.~~ sccs, thus providing a measure of package integrity. Porous barrier film packages made non-porous with an impermeable film forming coating may demonstrate lateral leakage through the barrier material. Verification of leakage differences from background leakage must be included in validation methods. The use of calibrated hole sizes or orifices may be appropriate to determine leakage sensitivity or barrier integrity for these materials.

5.2 While theoretical leak rate sensitivity can be established by calculation, the test measurement is in pressure units and the measuring instrument must be calibrated, certified, and verified with these units.

5.3 The pressure decay method of leak testing is a physical measure of package integrity. When testing medical packaging which must conform to ISO ~~11607~~11607–1: 2006 standards, it may necessary to verify the results of the pressure decay test method with other sterile package integrity test methods.

5.4 Test Method A allows packages to be pressurized without restraint. In Test Method A the pouch, tray, or other type package will contain a volume of air defined by its mechanical configuration and its ability to resist internal pressure applied. This test method requires that the package reach a stable volume configuration (stop stretching) to make a measurement.

5.5 Test Method B allows the use of rigid restraining plates against the walls of the package to limit its volume and stabilize the package volume.

6. Apparatus

6.1 *Test Method A*:

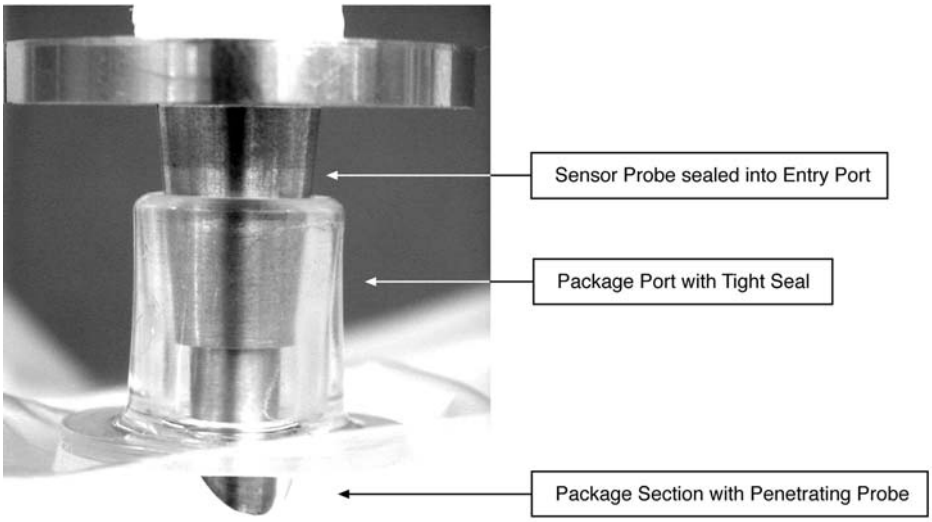

FIG. 1 Leak-Tight Entry System

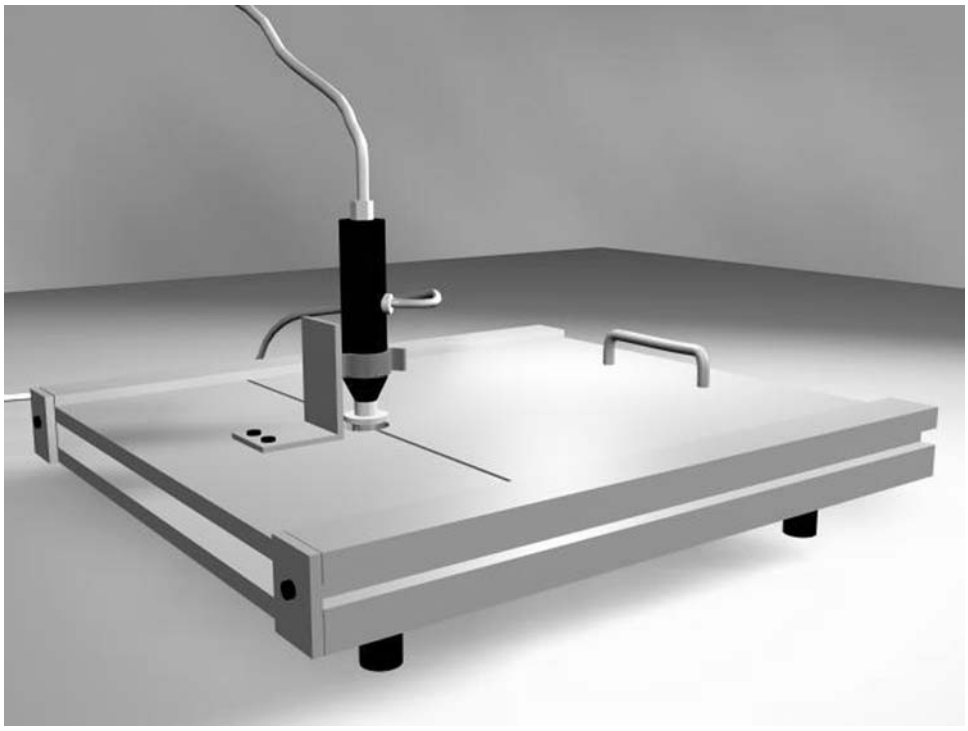

FIG. 2 Restraining Fixture with Leak-Tight Entry System

6.1.1 A measuring instrument that provides the following:

6.1.1.1 A means to detect pressure changes with sufficient sensitivity to achieve theoretical leak rates in the package specification;

6.1.1.2 Automatic timer controls to pressurize the package to a preset pressure, hold the pressure for a set time, and provide a time period during which pressure change data can be taken;

6.1.1.3 A means to set pressure;

6.1.1.4 A means of holding and displaying the pressure change inside the package at the end of the test cycle;

6.1.1.5 A means (optional) to set pressure decay limits for a test method and alert the operator if the limit is exceeded.

6.1.2 A means to enter the package in a leak tight manner so that an inflation pressure can be applied to the package and changes in internal pressure can be sensed.

NOTE ~~1—It~~ 2—It is important to verify the leak integrity of the entry means so that it does not contribute to the pressure changes sensed during testing.

6.2 *Test Method B—Using Restraining Plates*:

6.2.1 The measuring instrument shall have the characteristics described in 6.1.1.1-6.1.1.5.

6.2.2 Parallel, rigid plates are required. An ability to adjust plate separation is desirable. The surface of the plates should provide limited porosity in order to prevent blocking of pinhole leaks in the walls (see Fig. 2).

NOTE ~~2~~3—Several techniques have been used to provide a means to prevent blocking or lowering of the leak rate in package material walls in contact with the plates. These techniques include the use of semi-porous plastic, scoring of plate surfaces and use of screen-type materials.

6.2.3 A means to enter the package in a leak-tight manner so that an inflation pressure can be applied to the package and changes in internal pressure can be sensed.

NOTE ~~3—It~~ 4—It is important to verify the leak integrity of the entry means so that it does not contribute to the pressure changes sensed during testing.

7. Sampling

~~7.1The sample size is chosen to permit an adequate determination of representative performance. Practice D1898 provides guidance to test specimen selection.~~

7.1 The sample size is chosen to permit an adequate determination of representative performance.

7.2 Sample identification should be made prior to testing to allow the operator to refer to specific test samples, if necessary. Record information such that test results and anomalies are identifiable back to the individual specimens.

8. Conditioning

8.1 Package samples should be conditioned to obtain the same temperature conditions as exist for the test apparatus. Since measured pressure change is also a function of temperature, then the samples must be at a stable temperature. Most testing will occur at standard laboratory conditions of 23 ± 2°C (73 ± 4°F) and 50 ± 5 % relative humidity. Other conditions should be recorded at the time of the test.