Designation: F 2096 – 02

Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)[1]

This standard is issued under the fixed designation F 2096; 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 detection of gross leaks in medical packaging. Method sensitivity is down to 250 µm with an 81 % probability (see Section 11). This test method may be used for tray and pouch packages.

1.2 The sensitivity of this test method has not been evaluated for use with porous materials other than spunbonded polyolefin or with nonporous packaging.

1.3 This test method is destructive in that it requires entry into the package to supply an internal air pressure

1.4 The values stated in SI units are to be regarded as the standard. The values given in parentheses are for information only.

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:*

D 1898 Practice for Sampling of Plastics[2]

F 1327 Terminology Relating to Barrier Materials for Medical Packaging[3]

3. Terminology

3.1 *Definitions*—General terms relating to barrier materials for medical packaging are found in Terminology F 1327F 1327.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *breathing point pressure*, *n*—pressure at which permeation of air through the porous material begins.[4]

4. Summary of Test Method

4.1 The package is inflated underwater to a predetermined pressure. The package is then observed for a steady stream of air bubbles indicating a failure area.

4.2 The sensitivity of this test method is dependent on the differential pressure and method of pressurization. Establishment of a test pressure for each package material/size is critical for obtaining repeatable results (see Annex A1 for the procedure on establishing test pressure). Inadequate pressurization of the package can significantly reduce the sensitivity of this test method. Higher differential pressures will increase the test sensitivity. However, excessive pressurization of the package may rupture seals or cause misinterpretation of bubble patterns emanating from porous packaging. This may result in an erroneous conclusion regarding the presence or absence of package defects. While not required, use of a bleed-off control valve in line with the pressure monitoring device, will aid in stabilizing the test pressure, and help eliminate excessive pressurization of the package (see Fig. 1).

4.3 Two different test methods are presented for the testing of porous and nonporous packaging. The key difference between the test methods (as described in Annex A1) is in allowing time for the water to saturate the porous material.

5. Significance and Use

5.1 The internal pressurization test method provides a practical way to examine packages for gross leaks, which may render the product non-sterile.

5.2 This test method is extremely useful in a test laboratory environment where no common package material/size exists.

5.3 This test method may apply to very large or long packages, which do not fit into any other package integrity test method apparatus.

5.4 This test method may be used as a means to evaluate package integrity. Package integrity is crucial to consumer safety since heat sealed packages are designed to provide a contamination free and sterile environment to the product.

6. Apparatus

6.1 *Pressure Delivery System*, with pressure monitoring gage, and bleed-off control valve, capable of delivering air at a pressure of 0-50 mbar (0-20 in. H_2O).

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[1] This test method is under the jurisdiction of ASTM Committee F02 on Flexible Barrier Materials and is the direct responsibility of Subcommittee F02.60 on Medical Packaging.

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[2] *Annual Book of ASTM Standards*, Vol 08.01.

[3] *Annual Book of ASTM Standards*, Vol 15.09.

[4] All porous packaging by definition will permit the passage of air. At a given internal pressure it will therefore exhibit an emanating stream of air bubbles dependent on the pore size. A stream of bubbles identified at a lower internal pressure than the breathing pressure point may indicate a defect in the packaging.

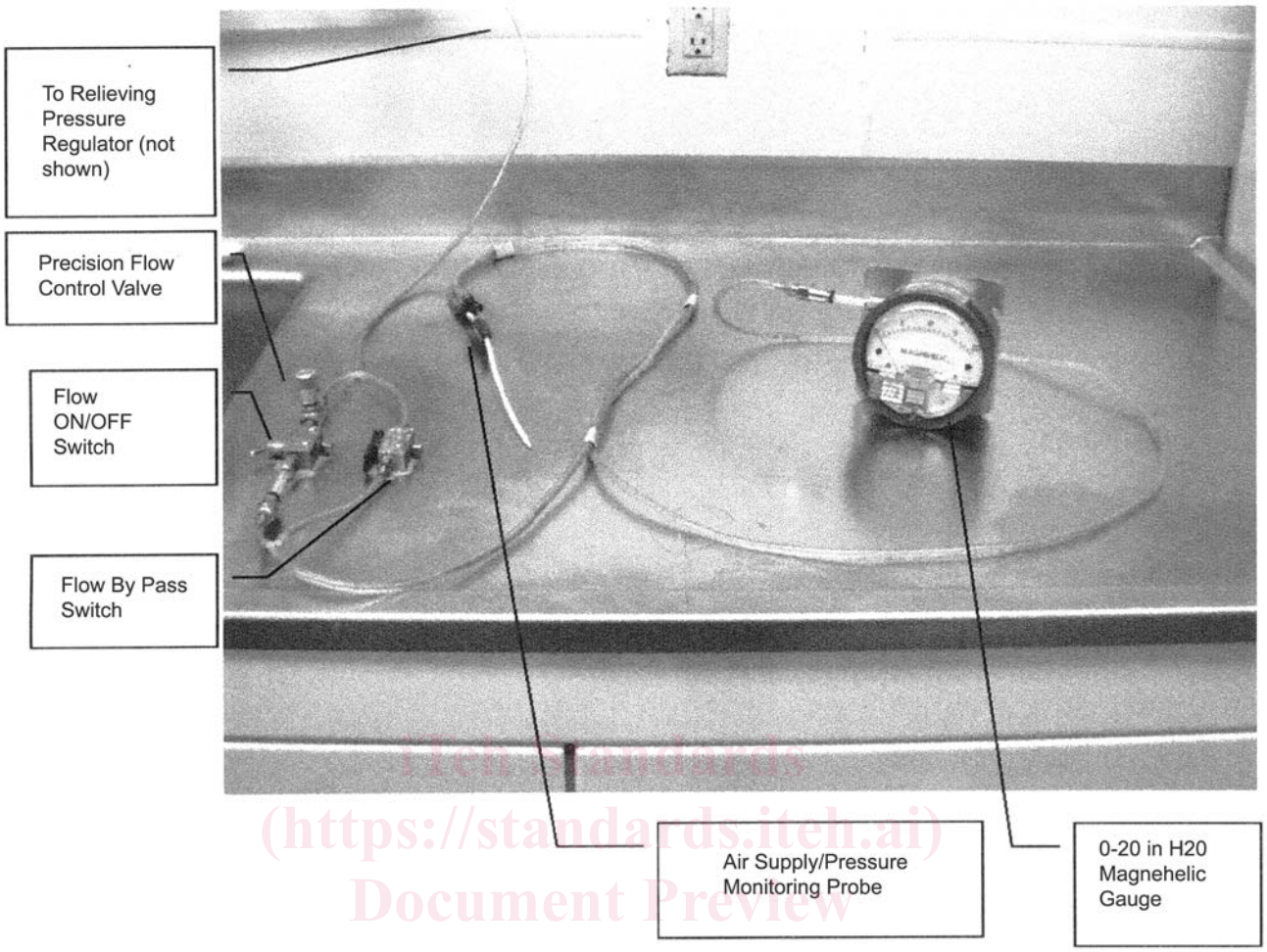

FIG. 1 Probability of Rejection-Combined Laboratory Results

6.2 *Device for Puncturing Package*, (for example, small slotted screwdriver or other appropriate device) to allow insertion of air source and pressure monitoring device.

6.3 *Water Container*, adequate to cover the test specimen with approximately one (1) in. of H_2O.

7. Sampling

7.1 The number of test specimens shall be chosen to permit an adequate determination of representative performance. Practice D 1898D 1898 provides guidance for test speciman selection.

8. Conditioning

8.1 No special conditioning of the specimen is required.

9. Procedure

NOTE 1—The establishment of a test pressure in accordance with Annex A1 must be performed prior to initiating the test procedure.

9.1 *Test Method A—Procedure for Nonporous Packaging*:

9.1.1 Create a hole in the package using a puncturing device (for example, small slotted screwdriver or other appropriate device) for inserting the air source and pressure monitor into the control sample. Create the hole as close to the center of the package as possible. The hole size should allow insertion of the air source and pressure monitor with minimal air leakage. Use tape or a rubber disk as a septum over the puncture site to seal the insertion site if necessary.

9.1.2 Insert the air source and pressure monitor into the test specimen. Submerge the package under water approximately one (1) in. Start airflow into the package.

NOTE 2—It may be helpful to use a fixture to keep the entire package submerged at the proper depth.

9.1.3 Adjust the airflow and bleed-off valve as necessary to slowly inflate the package to a value equal to or greater than the minimum test pressure as established in accordance with Annex A1. Adjust the bleed-off valve and pressure regulator as necessary to maintain constant pressure.

9.1.4 Thoroughly inspect the package for a constant stream of bubbles indicating a specific area of failure (seal channels, pinholes, cracks, tears, and so forth). Inspection time will vary depending on package size.

9.1.5 Remove the package from water and mark any observed area(s) of failure.

9.2 *Test Method B—Procedure for Porous Packaging*:

9.2.1 Apply blocking agent to samples if required in accordance with A1.1.2.4.