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

This standard is issued under the fixed designation F2096; 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 (0.010 in.) 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:*[2]

~~D1898Practice for Sampling of Plastics~~

~~F1327Terminology Relating to Barrier Materials for Medical Packaging~~ 17 Terminology Relating to Flexible Barrier Packaging

3. Terminology

3.1 *Definitions*—General terms relating to barrier materials for medical packaging are found in Terminology ~~F1327~~F17.

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.[3]

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.

[1] This test method is under the jurisdiction of ASTM Committee F02 on Flexible Barrier Packaging and is 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] 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.

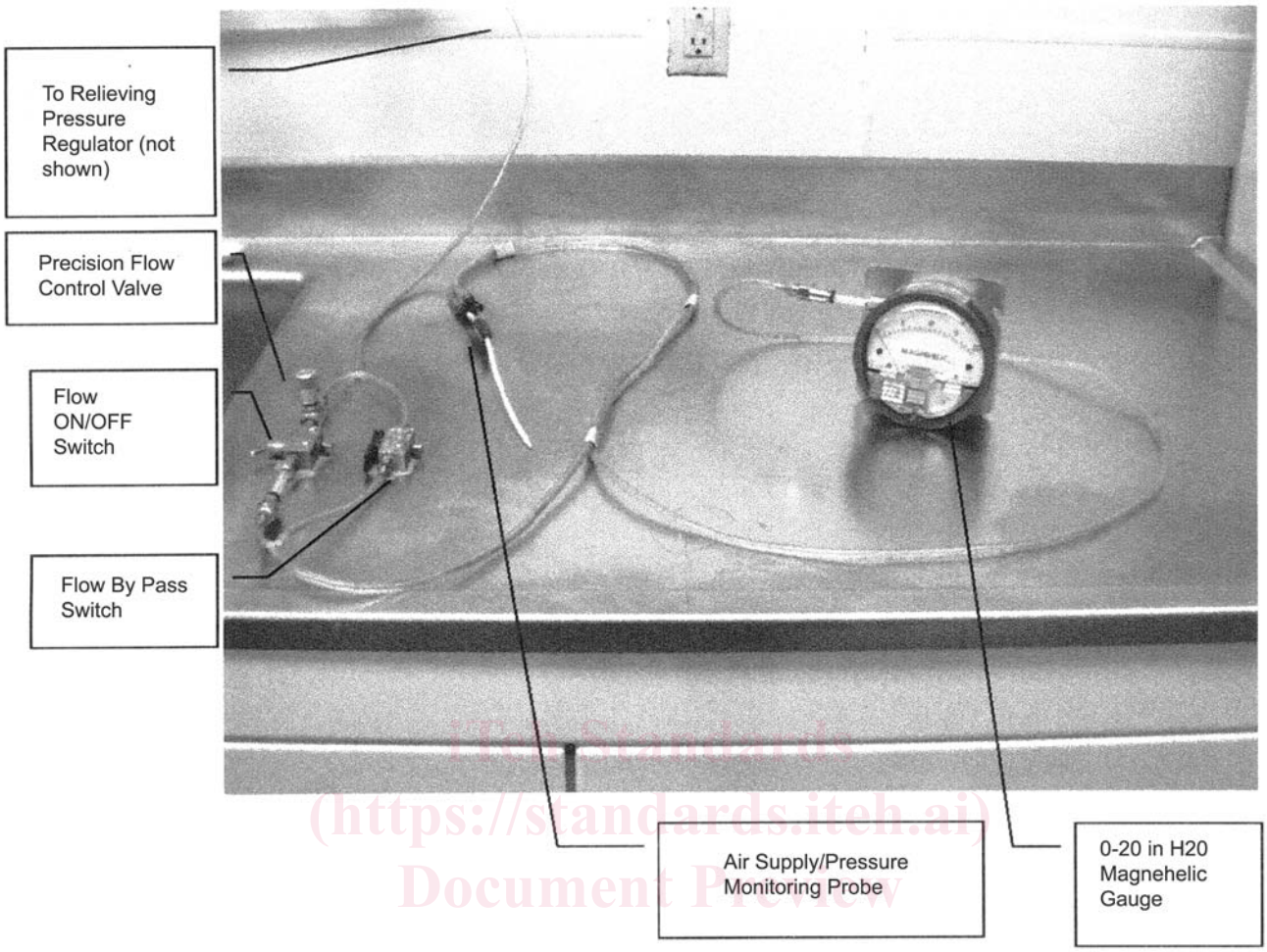

FIG. 1 Sample Test Apparatus

5. Significance and Use

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

5.1 The internal pressurization test method provides a practical way to examine packages for gross leaks.

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~~packages that 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~~or sterile environment, or both, to the product.

5.5 This test method may be used to detect substrate holes and channels.

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).

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.~~ , 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.~~ , adequate to cover the test specimen with approximately 25.4 mm (1 in.) of water.

NOTE 1—It may be beneficial for observation of the test specimen and for interpretation of results to perform the testing in a water container that has at least one transparent side.

7. Sampling

~~7.1The number of test specimens shall be chosen to permit an adequate determination of representative performance. Practice D1898 provides guidance for test speciman selection.~~

7.1 The number of test specimens shall be chosen to permit an adequate determination of representative performance.

8. Conditioning

8.1 No special conditioning of the specimen is required.

9. Procedure

NOTE ~~1—The~~ 2—The establishment of a test pressure in accordance with Annex A1 ~~must be performed prior to initiating the test procedure.~~ must be performed prior to initiating the test procedure. It is recommended that a sample test set-up be provided.

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~~ wherever it is most efficient to ~~the center of~~ observe defects without obscuring any pre-existing defects or creating defects in the inner package ~~as possible.~~ during the puncturing process. 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)~~ 1 in. under water. Start airflow into the package.

NOTE ~~2—It~~ 3—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.

~~9.1.4Thoroughly 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.~~

9.1.4 Thoroughly inspect one side of the package facing upwards for a constant stream of bubbles indicating a specific area of failure (seal channels, pinholes, cracks, tears, and so forth). Then repeat the process by rotating the package 180º so the opposite side of the package is facing upwards. 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.

9.2.2 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~~ wherever it is most efficient to ~~the center of~~ observe defects without obscuring any pre-existing defects or creating defects in the inner package ~~as possible.~~ during the puncturing process. 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.

9.2.3 Insert the air source and pressure monitor into the package. Submerge the package approximately 25.4 mm (1 in.) under water ~~approximately 1 in.~~with the porous part of the package in the up position (if one side is porous) and hold for a minimum of 5 s. Start the airflow into the package.

NOTE ~~3—It~~ 4—It may be helpful to use a fixture to keep the entire package submerged at the proper depth.

9.2.4 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.

~~9.2.5Thoroughly 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.~~

9.2.5 Thoroughly inspect the porous side of the package facing upwards for a constant stream of bubbles indicating a specific area of failure (seal channels, pinholes, cracks, tears, and so forth). Then repeat this process by rotating the package 180º so the opposite side of the package is facing upwards. Inspection time will vary depending on package size.

TABLE 1 Percent Correct by Laboratory and Defect Type

	Defect Type								
	Pouch					Tray			
Laboratory	No Defects	125-µm Channel	250-µm Channel	125-µm Puncture	250-µm Puncture	No Defects	125-µm Puncture	250-µm Puncture	Percent Correct by Laboratory
1	100	100	90	60	80	100	40	90	82.50
2	100	70	90	50	60	90	10	100	71.25
3	80	20	80	60	80	90	60	80	68.75
4	100	70	90	0	0	100	60	100	65.00
5	80	20	100	0	30	100	20	90	55.00
Percent Correct by Defect	92	56	90	34	50	96	38	92	