Designation: F 2228 – 02

Standard Test Method for Non-Destructive Detection of Leaks in Medical Packaging Which Incorporates Porous Barrier Material by CO_2 Tracer Gas Method[1]

This standard is issued under the fixed designation F 2228; 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 non-destructive test method detects leaks in non-porous rigid thermoformed trays, as well as the seal between the porous lid and the tray. The test method detects channel leaks in packages as small as 100 µm (0.004 in.) diameter in the seal as well as 50 µm (0.002 in.) diameter pinholes, or equivalently sized cracks in the tray, subject to trace gas concentration in the package, package design and manufacturing tolerances.

NOTE 1—This test method does not claim to challenge the porous (breathable) lidding material. Any defects that may exist in the porous portion of the package will not be detected by this test method.

1.2 The values stated in SI units are to be regarded as standard units. Values in parentheses are for information only.

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:* [2]

D 996 Terminology of Packaging and Distribution Environments

F 17 Terminology Relating to Flexible Barrier Materials

F 1327 Terminology Relating to Barrier Materials for Medical Packaging

3. Terminology

3.1 *General Term Definitions*—For definitions used in this standard, see Terminologies D 996, F 17, and F 1327.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *basal flow*—transverse transport of trace gas across the seal due to gas flow within the plane of the porous barrier material as well as flow between the porous barrier and the temporary gasketing. This is an expected property of the porous barrier material and does not represent a leak. Experimentally, this flow may be thought of as noise, which will always be present, to some degree, during testing and must be accounted for.

3.2.2 *trace gas*—a compound selected solely for use to identify leakage flow.

4. Summary of Test Method

4.1 This test method utilizes CO_2 sensing techniques in the detection of a CO_2 trace gas to quantify leaks in medical packaging, which incorporates porous barrier material. This test method provides a qualitative (accept/reject) inspection method to evaluate packages for pinhole, crack and channel leaks. Further information on the "Leak Test Theory" may be found in Annex A1.

5. Significance and Use

5.1 Harmful biological or particulate contaminants may enter the package through incomplete seals or imperfections such as pinholes or cracks in the trays.

5.2 After initial instrument set-up and calibration, the operations of individual tests and test results do not need operator interpretation. The non-destructive nature of the test may be important when testing high value added products.

5.3 Leak test results that exceed the permissible threshold setting are indicated by audible or visual signal responses, or both, or by other means.

5.4 This non-destructive test method may be performed in either laboratory or production environments. This testing may be undertaken on either a 100 % or a statistical sampling basis. This test method, in single instrument use and current implementation, may not be fast enough to work on a production packaging line, but is well suited for statistical testing as well as package developmental design work.

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

6. Apparatus

6.1 *Non-destructive Trace Gas Leak Detection Apparatus*—The apparatus' test fixture consists of three major elements and is shown in Fig. 1.

6.2 *Sealing Membrane*—The purpose of the sealing membrane is to seal off the tracer gas transmission, normal to the porous lid surface. However, the membrane does not completely control the transmission of tracer gas basal flow in the transverse direction.

6.3 *Control Packages*—Packages with calibrated capillary channel leaks as well as packages with calibrated pinholes in the tray constructed for instrument calibration as well as for test procedure verification.

6.4 *Test Fixture*—Apparatus, which must be designed to ensure detection of a calibrated leak.

7. Preparation of Apparatus

7.1 The test apparatus is to be started, warmed-up, and made ready according to the manufacturer's specifications. The instrument must be operated in an environment as described in the instrument's user manual.

8. Reagents and Materials

8.1 *CO_2 Trace Gas Cylinder and Regulator*—A cylinder of "Commercial" or "Bone Dry" grade carbon dioxide with a minimum of 206.84 kPa (30 psi) pressure is required for calibration and testing.

8.2 *Sealing Membrane*—The temporary sealing membrane must exhibit the correct pliability and tackiness in order to form a gas-tight bond with the porous lidding materials during the testing process, and must release at the end of the test without damaging the porous lid or the edge seal.

8.3 *Sealing Membrane-induced Damage*—During the process of membrane selection for a specific package design and configuration, inspect the packages for the following indications of membrane-induced damage after the membrane is removed from the package:

8.3.1 Sticky residue remaining on the porous barrier material at the end of the test cycle.

8.3.2 Fibers from the porous barrier material remaining on the sealing membrane at the end of the test cycle.

8.3.3 Visible changes to the texture or structure of the porous lidding material at the end of the test cycle, under microscope or other magnified examination.

8.3.4 Damage to the printed information on the porous barrier. The adhesive of the sealing membrane may lift off the ink from the barrier.

8.3.5 Failure of the package to release from the sealing membrane at the end of the test cycle.

8.3.6 Damage to the seal incurred on removal of the membrane from the package.

9. Hazards

9.1 As the test fixture is closed, it may present pinch-point hazards.

9.2 CO_2, although inert and non-toxic, can cause danger of suffocation if it is allowed to displace oxygen. Thus it is recommended that the spent carbon dioxide be naturally vented away from the test area and that adequate ventilation be provided.

10. Calibration and Standardization

10.1 Before any measurements are made, the apparatus must be calibrated. The calibration procedure is used for

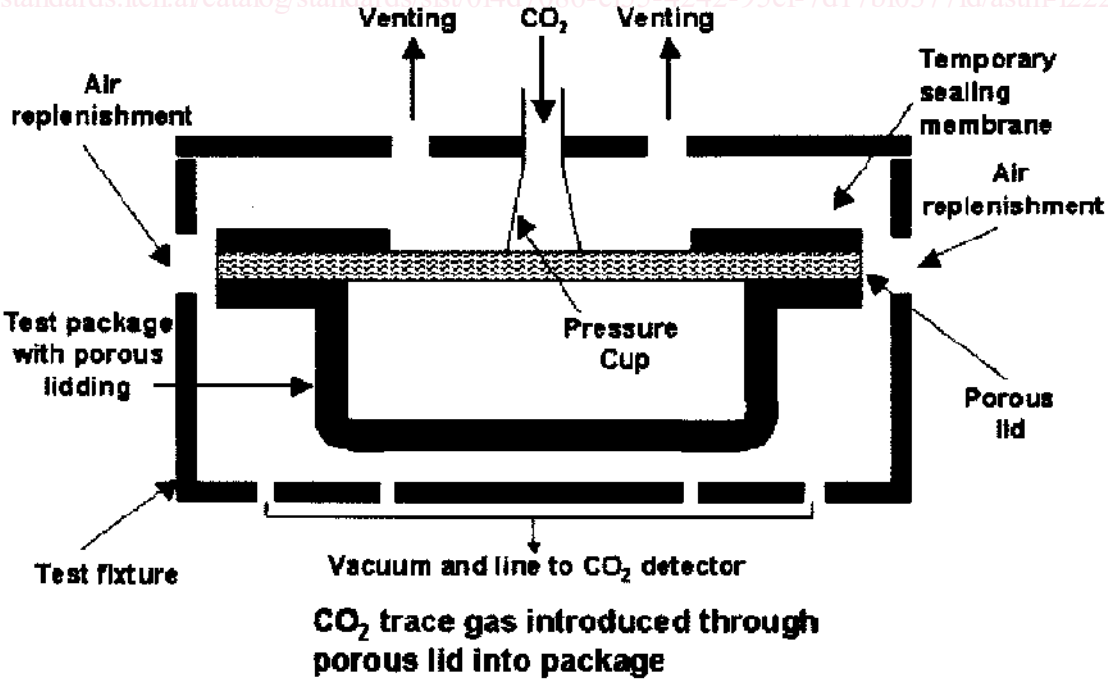

FIG. 1 Schematic of Test Fixture and Test Package