Designation: F 2227 – 02

Standard Test Method for Non-Destructive Detection of Leaks in Non-sealed and Empty Medical Packaging Trays by CO_2 Tracer Gas Method[1]

This standard is issued under the fixed designation F 2227; 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 pinhole leaks in trays, as small as 50 µm (0.002 in.) in diameter, or equivalently sized cracks, subject to trace gas concentration in the tray, tray design and manufacturing tolerances.

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 1327 Terminology Relating to Barrier Materials for Medical Packaging

3. Terminology

3.1 *General Term Definitions*—For definitions used in this test method, see Terminologies D 996 and F 1327, Sections 3.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *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 trays. The test method provides a qualitative (accept/reject) inspection method to evaluate trays for pinholes and cracks. 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 imperfections such as pinholes or cracks in trays.

5.2 After initial instrument set-up and calibration, the operations of individual tests and test results do not need operator interpretation.

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 and 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.

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 membrane is to seal off the tracer gas transmission out of the top of the open tray.

6.3 *Control Trays*—Calibrated pinholes, or leaks, constructed in control trays 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.

[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.

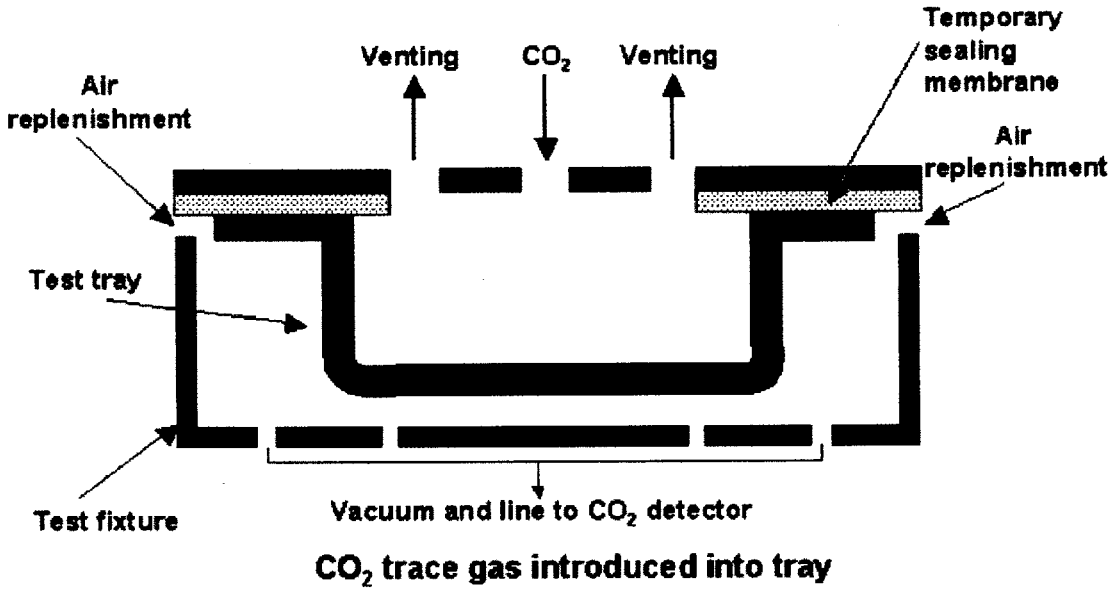

FIG. 1 Schematic of Test Fixture and Test Tray

8.2 *Sealing Membrane*—The sealing membrane must exhibit the correct pliability and tackiness in order to form a gas-tight bond without leaving a residue on the tray-sealing surface after removal from the test fixture.

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 overall system checkout, as well as to establish an initial reference profile for simulated pinhole leaks, and to determine test limits for each different tray geometry to be tested using a specific test fixture. The calibration procedure is performed to establish the sensitivity setting of the instrumentation. It is expected that the calibration procedures be carried out frequently; typically, at least one or more times a day, preferably at the beginning of every shift.

10.2 Refer to the instrument manufacturer's operating instructions regarding preparation of Calibration Standards, Conditioning of Calibration Trays and Instrument Calibration used in establishing baseline settings.

11. Procedure

11.1 Verify that sufficient CO_2 trace gas is available for the tests. Monitor the trace gas supply and functionality of the gas delivery system.

11.2 Select and implement the properly sized test fixture for the trays to be tested. Verify that the instrument and associated test fixture have been calibrated for the trays to be tested. The test fixture is too large when the instrument is unable to detect a calibrated control pinhole leak.

11.3 Adjust the instrument baseline settings determined in calibration.

11.4 Place the tray to be tested into the test fixture making certain that the tray is centered in the fixture and that good sealing contact is made between the tray flange and the fixture incorporated sealing.

NOTE 1—The sealing membrane needs to be clean in order to develop a good seal with the sealing flange of the tray. Laboratory conditions may cause dust or debris to be collected on the sealing membrane. These conditions thus will warrant frequent inspection and cleaning of the sealing membrane with a lint-free cloth soaked with a solvent recommended by the manufacturer of the equipment.

11.5 Close the top cover of the test fixture.

11.6 Start the test.

11.7 Note the pass or fail indicator and record results. Set aside any "failed/defective" trays for further evaluation. Further evaluation should include re-testing of the tray.

11.8 Select another tray and repeat the testing process.

12. Report

12.1 The report shall include the following:

12.1.1 A statement indicating that the tests were performed in accordance with ASTM Standard F 2227, except where noted.

12.1.2 The serial numbers, calibration values and most recent calibration dates for all calibration standards used.

12.1.3 Record the date, time, location, and identification of the apparatus and the operator.

12.1.4 Record the tray type, size, material, product, and traceable identification numbers.