



Designation: **F2227–02 (Reapproved 2007) F2227 – 13**

Standard Test Method for Non-Destructive Detection of Leaks in Non-sealed and Empty Medical Packaging Trays by CO₂ Tracer Gas Method¹

This standard is issued under the fixed designation F2227; 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

[D996 Terminology of Packaging and Distribution Environments](#)

[F1327 Terminology Relating to Barrier Materials for Medical Packaging](#) (Withdrawn 2007)³

3. Terminology

3.1 *General Term Definitions*—For definitions used in this test method, see Terminologies [D996](#) and [F1327](#), 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 CO₂ sensing techniques in the detection of a CO₂ 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](#). [fe3-41b1-9756-163a48848512/astm-f2227-13](https://doi.org/10.1520/F2227-02R07-10.1520/F2227-13)

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.

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.

Current edition approved ~~April 1, 2007~~ Aug. 1, 2013. Published ~~May 2007~~ September 2013. Originally approved in 2002. Last previous edition approved in ~~2002~~ 2007 as [F2227–02](#):[F2227–02](#) (2007). DOI: [10.1520/F2227-02R07-10.1520/F2227-13](https://doi.org/10.1520/F2227-02R07-10.1520/F2227-13).

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 The last approved version of this historical standard is referenced on www.astm.org.

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 *CO₂ 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 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 CO₂, 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.

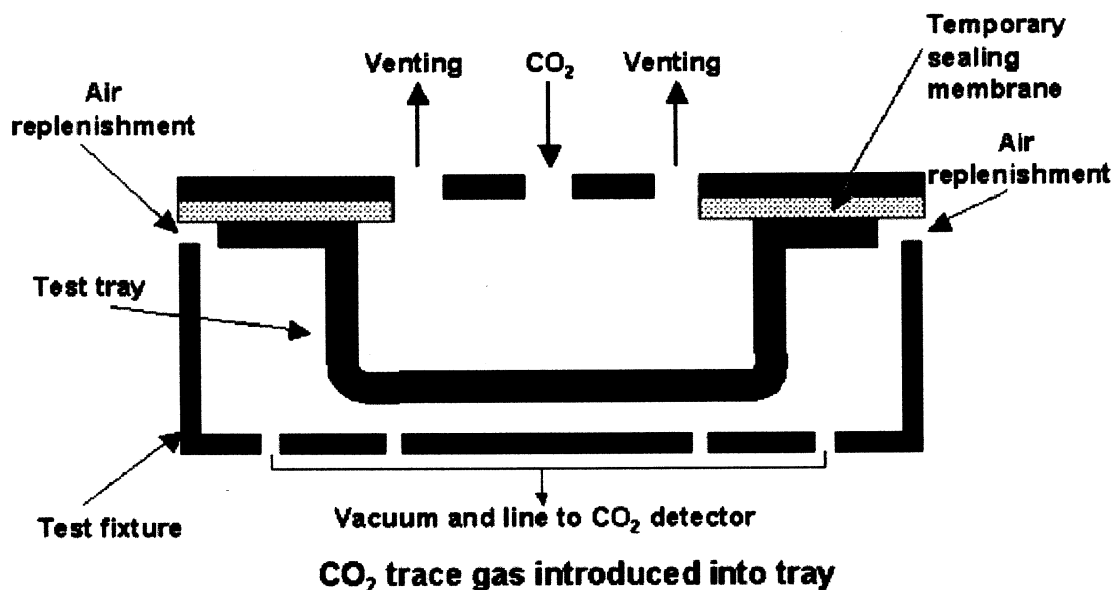


FIG. 1 Schematic of Test Fixture and Test Tray