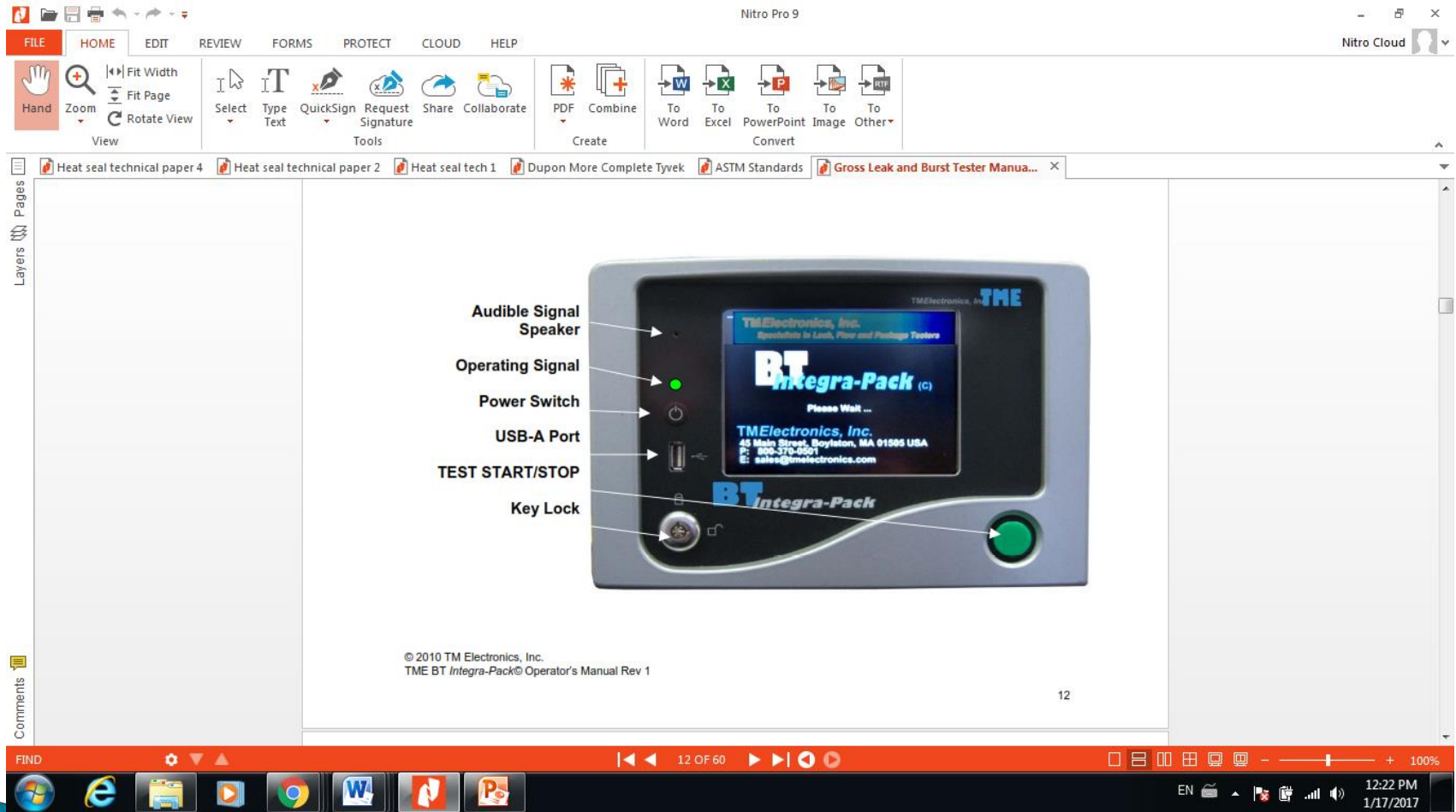


Seal and Medical Device Testing

Rationale for Testing
ASTM Test Standards
ASTM F88/F88M and ASTM F2096

A BT-Integra-Pack Package Tester.



Rationale for Testing

- ▶ Once the polymer film has been transformed into a medical packaging device, following heat sealing, these must be tested.
- ▶ The test methods are used to validate the devices' ability to maintain product integrity.
- ▶ This means neither seals nor material should have a leak.
- ▶ This means seal and material tensile strength are adequate throughout product life cycle.

Barrier System Integrity Tests

Nitro Pro 9

FILE HOME EDIT REVIEW FORMS PROTECT CLOUD HELP

Hand Zoom Fit Width Fit Page Rotate View

Select Type Text QuickSign Request Signature Share Collaborate

PDF Combine To Word To Excel To PowerPoint To Image To Other

Heat seal technical paper 4 Heat seal technical paper 2 Heat seal tech 1 Dupon More Complete Tyvek ASTM Standards Gross Leak and Burst Tester Manua...

Pages

and the materials under stress. This implies that your package testing system must include both package integrity testing and seal strength testing, two complementary but very different procedures. Package integrity may be thought of as a "leak test" of the package – is there a failure in the materials or process that allows contamination to enter? Seal strength testing, on the other hand, measures an attribute of the seal, which is designed to ensure that the seal presents a microbial barrier to at least the same extent as the rest of the packaging. Both testing streams are important to your final package analysis.

The BT *Integra-Pack*'s provision for package integrity testing can be illustrated as follows:

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graph TD; A[Barrier System Integrity] --> B[Structural Integrity to Point of Use]; A --> C[Leak Integrity Process to Point of Use]; B --> D[INFLATION SEAL STRENGTH]; D --> E["ASTM F-1140  
ASTM F-2054"]; E --> F[Burst Test]; E --> G[Creep or CTF]; C --> H[LEAK TEST]; H --> I[ASTM F-2095]; I --> J[Pressure Decay Leak Test for Non-Porous Packages];
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Comments

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ASTM Test Standards

- ▶ Several ASTM standards are available to test and validate the seals and substrate material of medical packaging devices.
- ▶ These tests may be conducted prior to and following sterilization, as well as after accelerated or real-time aging.
- ▶ The FDA accepts the results of such tests, when evaluating a medical device during the PMA or 510(K) approval process.
- ▶ Some of the standards used for this purpose follow:

ASTM Test Standards

- ▶ ASTM F2096-11: Gross Leak Test
- ▶ ASTM F88/F88M-15: Seal Strength Test
- ▶ ASTM 3039-15: Dye Penetration Test
- ▶ ASTM F1140/1140M-13: Unrestrained Burst
- ▶ ASTM F2054/2054M-13: Restrained Burst
- ▶ ASTM D6653/D6653M-13: Altitude Test
- ▶ ASTM F1980-16: Accelerated Aging
- ▶ ETC.

ASTM F2096-11 and ASTM F88/F88M-15 Standards

- ▶ ASTM F2096-11 and ASTM F88/F88M-15, the Bubble and Seal Strength Tests are two key tests.
- ▶ ASTM F2096-11 is used to detect gross leaks in packaging(seal or material), with a sensitivity down to 250µm.
- ▶ ASTM F88/F88M-15 is used to measure the strength of seals in flexible barriers.

ASTM F2096-11 and ASTM F88/F88M-15 Standards

- ▶ To perform either tests, first, enough samples are collected to allow for a high confidence interval.
- ▶ Conditioning follows sampling for the case of ASTM F88/F88M-15.
- ▶ The conditioning of specimens is done in accordance with and as stipulated in the ASTM F88/F88M-15 standard.

Bubble Test: Creep Test Window of BT-Integra-Pack Test

The screenshot displays the Nitro Pro 9 software interface. The top menu bar includes FILE, HOME, EDIT, REVIEW, FORMS, PROTECT, CLOUD, and HELP. The toolbar contains various icons for editing, viewing, and creating documents. The document titled "Heat seal technical paper 4" is open, showing a text block that reads: "The result of the creep test is now stored in the Datalog and can be viewed by pressing the 'LOGS' button on the main task bar. The result can be viewed graphically (and in real time) on the CREEP tab, and numerically on the RESULT tab."

Two windows are overlaid on the document:

- Creep - untitled**: This window has tabs for Creep, Result, and Settings. The Creep tab shows a graph with a red line representing a creep test. The Result tab shows the following data: Test Time: 12.3, Creep Pressure: 48.18 psi, Status: PASS. The window is labeled "Ready" and shows the time 02:59 PM.
- Program - *untitled**: This window has tabs for Creep, Result, and Settings. The Creep tab shows the following data: Test: 4, Date: 01-01-2010 12:13 pm, Creep Pressure: 48.18. A large green box with the word "PASS" is displayed. The window is labeled "Ready" and shows the time 12:00 PM.

The bottom status bar shows the page number 32 OF 60 and the time 12:17 PM on 1/17/2017.

ASTM F2096–11: Bubble Test I: How it is Performed

- ▶ A minimum test pressure is first established for the tests as outlined in annex A1 of the ASTM F2096–11 standard.
- ▶ The test specimen is then inflated to the test pressure while submerged under about an inch of water.
- ▶ The specimen is then observed for a steady stream of bubbles, indicating a failure.
- ▶ The location of the failure, if a failure occurs, is noted and marked.

ASTM F2096–11: Bubble Test II: Interpretation of Test Results

- ▶ A package may fail the bubble test due to:
- ▶ A Defective Seal. A defective seal is one with: Channels, pinholes, tear, delamination, etc. and represent a possible path for contaminating entities like microbes.
- ▶ These defects may be traced back to the seal formation process– excessive temp, longer than necessary dwell time, higher than required pressure, contaminants on the sealing surface, etc.

ASTM F2096-11: Bubble Test II: Interpretation of Test Results

- ▶ Seal Channels are the main sources of leaks in seals.
- ▶ Channels may form in seals due to:
 - ▶ The sealing temperature set too high.
 - ▶ The sealing pressure and dwell time set too high.
 - ▶ The presence of contaminants on the sealing area during sealing.

Tensile Strength Test: A Tensile Strength Tester



ASTM F88/F88M-15: Seal Strength Test I: How it is Performed

- ▶ Seal strength test is used to measure the strength of seals in flexible barrier materials.
- ▶ Following the sampling, conditioning and preparation of the test specimens, these are pulled one at a time with a tensile testing machine until failure occurs.
- ▶ The specimens should be an inch wide, while the separation rate of the jaws of the tensile testing machine can be between 8 to 12 in/min, for three possible test techniques.

ASTM F88/F88M-15: Seal Strength

II: Interpretation of Test Results

- ▶ The result of the test in alphanumeric and/or graphic format as well as the mode of failure is obtained for each sample tested.
- ▶ The maximum force, the average force, energy to cause seal separations per specimen are pertinent test information.
- ▶ Plots include: force vs clamp separation of each specimen, used in calculating the average seal strength of the specimen.
- ▶ Statistical analysis is performed on the data, to obtain parameters such as: mean, range and standard deviation. These can be used to validate or modify the sealing process.

ASTM F88/F88M-15: Seal Strength

II: Interpretation of Test Results

- ▶ A number of failure modes are possible with the seal strength test. These include:
 - ▶ Adhesive Peel
 - ▶ Cohesive Peel
 - ▶ Delamination
 - ▶ Material Elongation
 - ▶ Peel with Elongation
 - ▶ Material Break or Tear in seal area or at seal edge
 - ▶ Material Break or Tear, remote from the seal

ASTM F88/F88M-15: Seal Strength

II: Interpretation of Test Results

- ▶ An adhesive or cohesive peel failure implies: The tensile strength of the seal is lower than that of the material. This occurs when the seal is formed at a temperature lower than the plateau initiation temperature of the sealant.
- ▶ A Delamination, or Tearing failure implies: The tensile strength of the seal is higher than that of the material. This occurs when the seal is formed at or above the plateau initiation temperature.