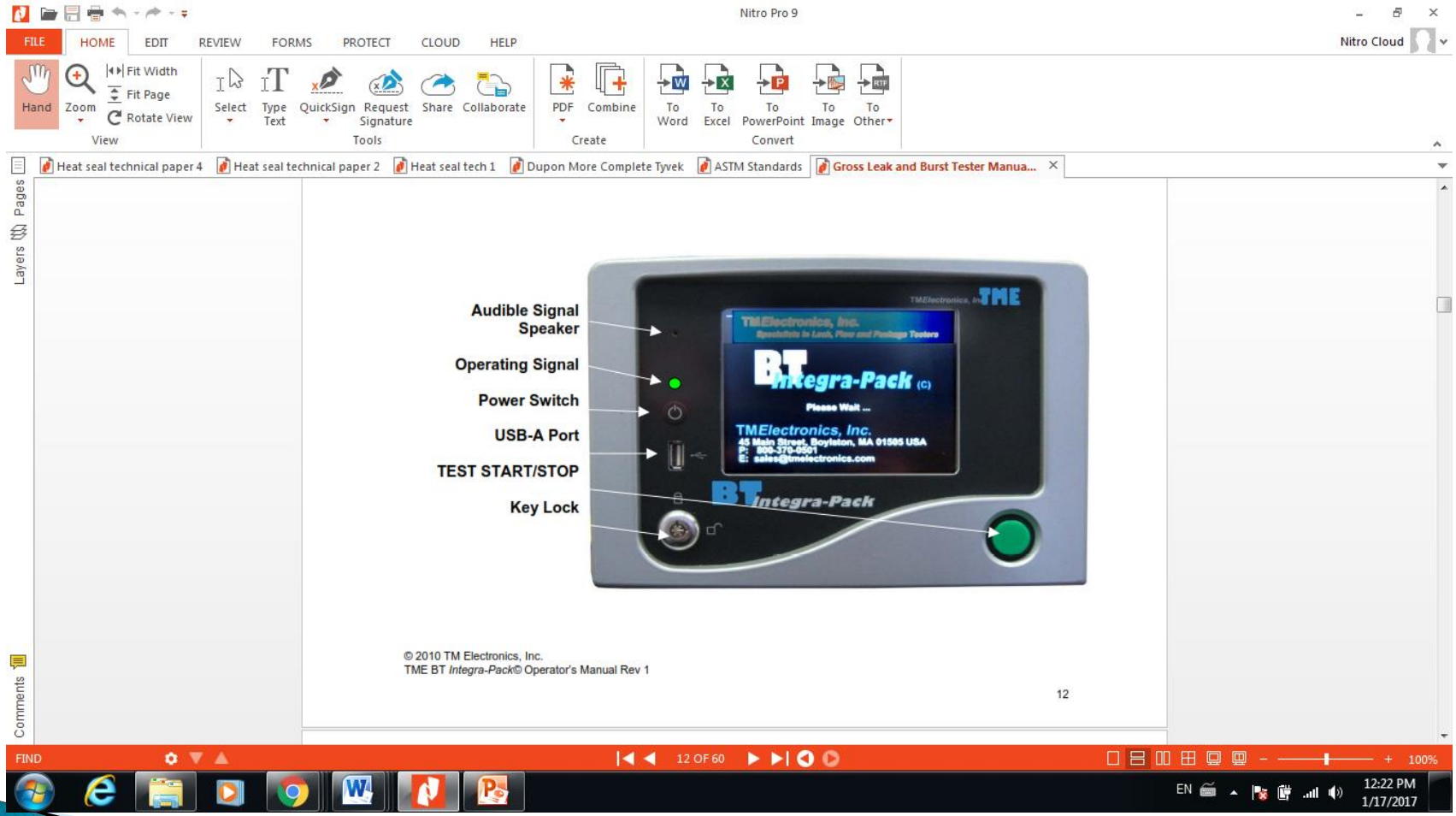
Seal and Medical Device Testing

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

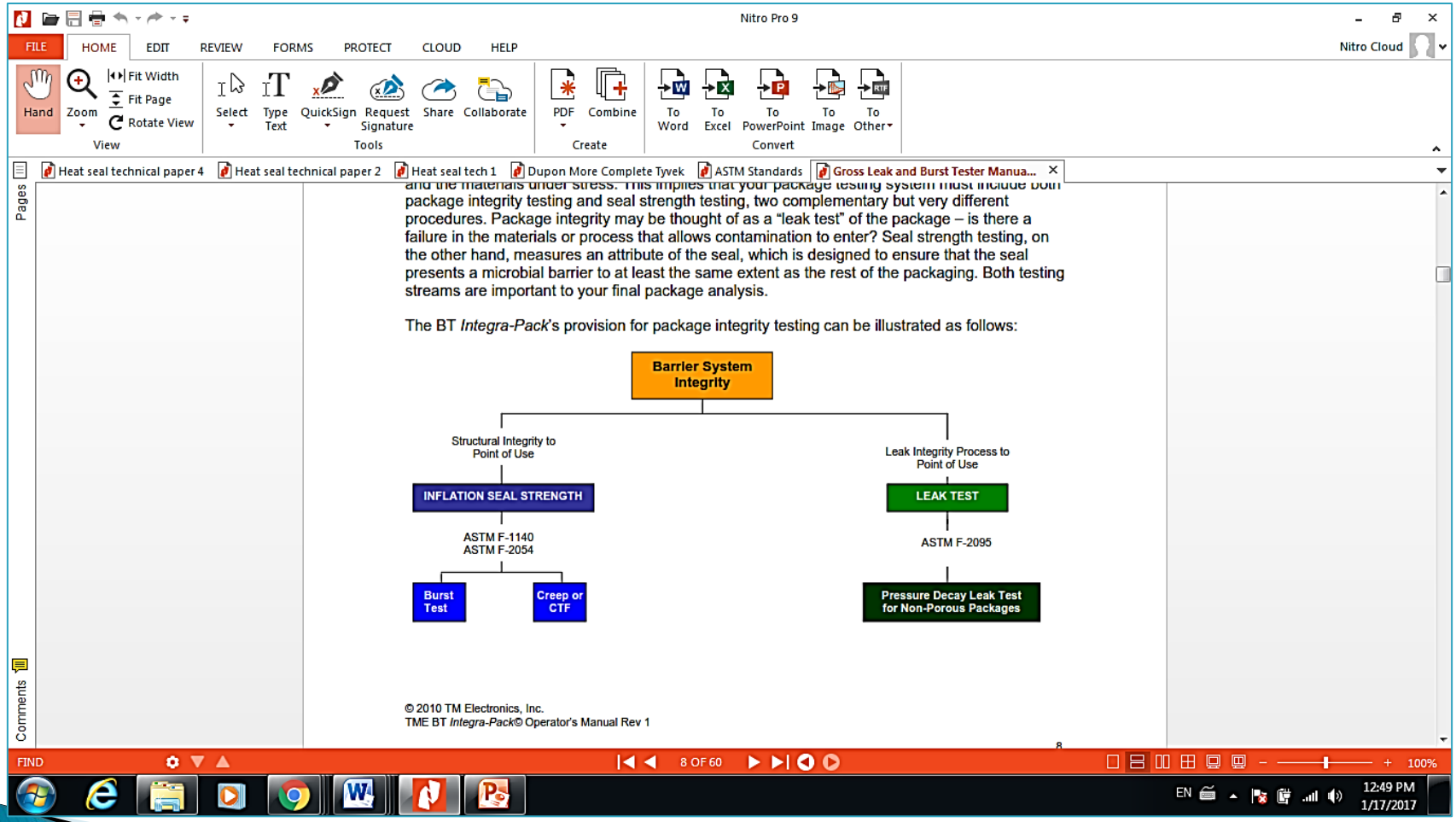
A BT-Integra-Pack Package Tester.



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



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.

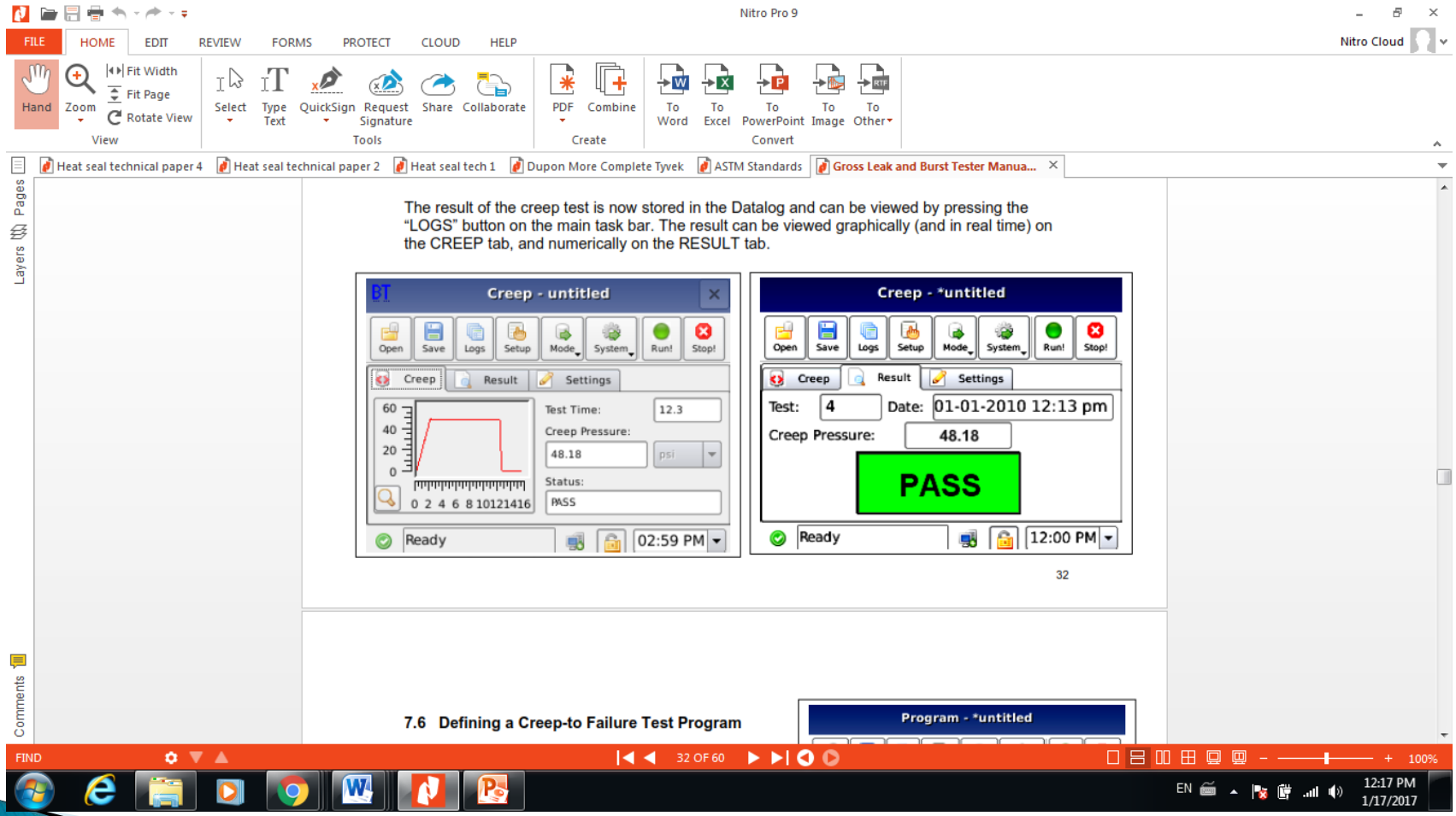
ASTM F2096-11 and ASTM F88/F88M-15 Standards

- 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 ASTMF88/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



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.