

Example Policy for the Integrity Test for Daily Verification of Heat-sealing Device and Self-Sealing Pouches

NOTE: This document is an example of a policy that may be instituted in a health-care facility for the actual policy in a facility must be based on variables, logistics, and risk-assessments that are specific to your facility.

Subject: Peel Pouch Daily Integrity Test

Department: CPD, CSSD, SPD, SPA, MDRD, dental, medical, and other offices using a heat sealer to package items in peel pouches.

Approved By: [Approved by Dept Supervisor/Manager]

Effective: [Enter the date when it goes into effect]

Revised: November 2021

Purpose: To monitor the seal quality of the heat-sealing device to ensure the peel pouch barrier is intact.

Policy: Inspect and test any heat-sealing device with the pouch integrity test to ensure proper seal of peel pouch sterile barrier systems and test self-sealing pouches. The pouch integrity tests will be conducted every day that a heat-sealing device is used for paper/poly and Tyvek[®]/poly pouches with a push indicator dye test. This test is to be done per the manufacturer's instructions for use (IFU)¹, and the test results will be documented according to facility policy for documentation of performance quality tests.

Rationale: There are many reasons why electrical/mechanical devices may fail. Failures of such devices are not always evident to the end user. Additionally, the ability of a staff member to identify problems with the equipment will be widely variable based on the individual's experience and attention to detail. Performing a standardized, daily test of the equipment will help any end user to identify whether the equipment/product is functioning properly.

Standard and Professional Society Recommendations:

ANSI/AAMI ST90:2017 (3.19) defines performance qualification (PQ) as a process of obtaining and documenting evidence that the equipment (installed and operated in accordance with operational procedures) consistently performs in accordance with predetermined criteria and, thereby, yields product meeting its specification.²

ANSI/AAMI ST90:2017 (7.1), regarding equipment used to process medical equipment, states the following:

The healthcare organization shall plan and develop processes for incorporating new devices, equipment, and materials necessary for effectively and safely processing medical devices. This plan shall be consistent with the requirements of the other quality system processes and communicated with other departments as necessary.

In planning for new devices, equipment, and material, the healthcare organization shall specify:

- a) Quality controls, quality assurance checks, and safety objectives for the device, equipment, or material
- b) Processes, documents, inspection requirements, test activities, and necessary resources
- c) Criteria for acceptance and rejection in accordance with device, material, or equipment manufacturer recommendations.
- d) Records needed to provide evidence that the planning processes and new device, equipment, or material meet the predetermined requirements.³

Procedure:

Pouch Seal Integrity Test (IFU)

Sealing Process Test:

To test the integrity of the seals for heat-seal and self-seal pouches:

1. Check temperature on heat-sealing unit.
2. Set temperature between 120 °C – 130 °C for sealing Tyvek®/poly pouches, unless otherwise indicated by your Tyvek®/poly pouch manufacture's IFU.
3. *With gloves on*, place push indicator dye test (model # TPS-001) for Tyvek® pouches inside a Tyvek® pouch with the pointed side of the indicator dye test pointing toward the open-end of the pouch.
4. Seal the pouch.
5. Place the pouch on a cleanable surface, as ink may leak through the pouch and stain surfaces underneath.
6. Push indicator dye test inside the pouch by sliding three fingers in the direction of the arrow of the push indicator until it breaks.
7. Once the ink has been expelled from the push indicator dye pack, pick up the pouch and make sure the dye is reaching the entire seal of the pouch.
8. Examine visually for any dye leaking through the sealed part of the pouch.
9. If you do not see any tunneling of the ink (through the seal), this indicates that the seal is good.
 - a. Test is finished
 - b. Document your results according to your hospital policy.
10. If you do see tunneling of the ink through the seal of the pouch:
 - a. Document test results

- b. Notify your supervisor
 - c. Follow your hospital policy for reporting equipment failure.
11. Retry the test following the steps above.

Once the test passes for your Tyvek[®]/poly pouch, test the paper/poly pouch seal:

1. Set the temperature on the heat-sealing unit to 160 °C – 180 °C for sealing paper/poly pouches.
2. *With gloves on*, place push indicator dye test (model # PS-001) for paper/poly pouches inside a paper/poly pouch with the pointed side of the indicator dye test pointing toward the open end of the pouch.
3. Seal the pouch.
4. Place the pouch on a cleanable surface, as ink may leak through the pouch and stain surfaces underneath.
5. Push indicator dye test inside the pouch by sliding three fingers in the direction of the arrow of the push indicator until it breaks.
6. Once the ink has been expelled from the push indicator dye pack, pick up the pouch and make sure the dye is reaching the entire seal of the pouch.
7. Examine visually for any dye leaking through the sealed part of the pouch.
8. If you do not see any tunneling of the ink (through the seal), this indicates that the seal is good.
 - a. Test is finished
 - b. Document your results according to your hospital policy.
9. If you do see tunneling of the ink through the seal of the pouch:
 - a. Document test results
 - b. Notify your supervisor
 - c. Follow your hospital policy for reporting equipment failure.
10. Retry the test following the steps above.

Principle:

The dye in this test provides the user with a visual indicator to determine the quality of a heat-sealed peel pouch.

Range Of Application:

For paper/poly heat-sealed pouches and Tyvek[®]/poly heat-sealed pouches.

Interferences:

If dye leaks through the heat-seal, an item inside the pouch could interfere with the heat-sealing device, or a problem may exist with the heat-sealing device—requiring service.

Storage:

Store at room temperature.

Shelf Life:

Expiration date provided on each container of pouch seal integrity tests.

Responsibility:

The department manager (or their designee) is responsible for ensuring proper training/competency of staff, compliance with this policy, and documentation related to this performance qualification test of the department heat-sealer.

- Ensure all Pouch Seal Integrity Test(s) are documented correctly by reviewing records daily or each day a test is taken/performed.
- Ensure that corrective action is taken on any failed test before the heat-sealer is put back in service.

Pouch Seal Integrity Test Log Sheet

Equipment name _____ Equipment Serial number # _____

Date Tested	Tester's Initials	Lot number	Heat Seal/Self-Seal	Paper-Poly/Tyvek®	Pass/Fail	Action Comment

Sample Competency for Pouch Integrity Test Policy to test the seal integrity of the seals for heat-seal and self-seal pouches

Name: _____

Competency Statement: Complies with policy and procedure for testing lumened/channeled items and endoscopes for residual moisture.

Key:

1 = Performs independently and consistently. Asks for assistance in new situations.

2 = Performs with minimal guidance and direction. Asks for assistance when necessary.

3 = Performs with maximal guidance and direction. Preceptor dependent. Consistently needs assistance.

Comments: _____

Competency Achieved: _____ **Date:** _____

Evaluator: _____

Learner: _____

Critical Behavior	1	2	3
1. Set/check temperature is in the correct range for the peel pouch product being used. (120 °C – 130 °C for Tyvek®, 160 °C – 180 °C for paper).			
2. Collect materials needed for integrity test: a) PPE b) Integrity test pack c) Peel pouch product.			
3. Don gloves.			
4. Place seal integrity test in peel pouch (with arrow pointing toward open end of pouch) being sure to use proper test for type of pouch. a) PS-001 for paper/poly pouches b) TPS-001 for Tyvek®/poly pouches			
5. Seal the pouch.			
6. Place pouch on cleanable surface.			
7. Push the indicator dye pack with your fingers in the direction of the arrow until the dye bursts from the package.			
8. Pick up package and ensure that dye reaches entire seal.			
9. Identify any dye leaks in the seal.			
10. Document results per facility policy.			

11. Report any failed dye test findings per facility policy.			
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References:

¹ Healthmark Industries. (2019). Instruction Instructions for Use: Pouch Seal Integrity Test.

Healthmark.info. http://www.healthmark.info/SterilizationProducts/HeatSealers/Pouch_Seal_Integrity_Test_IFU_.pdf

² Association for the Advancement of Medical Instrumentation. (2017). ANSI/AAMI ST90:2017. (Section 3.19., p 5). AAMI.

³ Association for the Advancement of Medical Instrumentation. (2017). ANSI/AAMI ST90:2017. (Section 7.1., p 13). AAMI.