



## PACKAGE TEST CARTRIDGES: HEALTHCARE APPLICATIONS

### Integrity and shelf life are critical.

Permeation testing, the process of determining the rate at which air (i.e. oxygen), moisture, or chemicals pass through materials, is a cornerstone of healthcare product safety. It plays a vital role in ensuring the integrity of medical devices, protective equipment and packaging materials, ultimately safeguarding both healthcare professionals and patients.

The integrity of packaging is crucial for maintaining the sterility and potency of products. By evaluating the barrier properties of packaging materials, manufacturers can select those that effectively prevent the ingress/egress of moisture, oxygen and other contaminants that could degrade the quality of the enclosed products.



Packaged syringes

### Benefits

Utilizing test cartridges to analyze packaging for specific healthcare applications allows the user to characterize their barriers faster, easier, and with increased accuracy. Various healthcare applications require understanding how much moisture leaves or enters a system. For example, how much moisture leaves a drug delivery system (e.g. syringe) from the manufactured product, or the volume of moisture infiltrating drug blister packs throughout environmental challenges along the supply chain. Fast accurate data allows products to be released with high confidence quite expediently while eliminating costly product recalls.

- Faster results than traditional gravimetric test methods
- Increased accuracy and detection sensitivity
- Easier sample prep and test setup
- Test moisture barrier of packaging directly off manufacturing line

# BLISTER CARTRIDGES DETERMINING MOISTURE BARRIER PROPERTIES

## Egress analysis

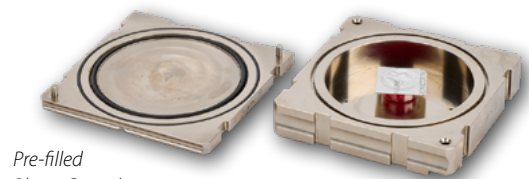
Typically, testing for what enters through packaging is desirable, although various applications must quantify what leaves a system. Egress analyses are common in the healthcare industry. Questions regarding how much moisture leaves a pre-filled syringe drug delivery system, or how long will this bag of saline be good for? These situations call for unique test set-ups that have not always been the easiest or most repeatable due to historical prep challenges. Utilizing the capture vessel cartridges allows easy reproducible egress testing. With five different options, this optimizes testing efficiency by selecting the best size limiting dead volume for optimal test throughput.

### Pre-filled Blister Cartridge (egress analysis): Determine blister moisture barrier.

The pre-filled blister cartridges were specifically designed for our film permeations analyzers to determine the amount of moisture leaving small-sized sealed systems (i.e. egress). Either by injecting water into the vial or blister cavity, or quantifying the moisture leaving a liquid medication dose, these deeper (or increased volume) cartridges allow multiple samples to be placed within a sealed impermeable chamber to analyze the moisture barrier properties of the system. This allows users to simulate real world challenges along the supply chain.

#### Benefits

- Facilitates egress testing, used to understand what leaves a package.
- Testing one or multiple pre-filled samples
- Analyzing whole system (i.e. egress)
- Easier, faster and more accurate than historical test methods
- No external gas supply required as the desired permeant is present in the pre-filled samples



Pre-filled Blister Cartridge

### Capture Vessels (egress analysis): Egress testing for medical packaging systems.

These larger capture vessels accommodate a wide range of samples such as saline bags, air bladders to carbonated bottles. The four sizes allow optimization of the sample volume/dead volume ratio for increased test efficiency.

#### Benefits

- Facilitates egress testing, used to understand what leaves a package.
- Characterize moisture barrier properties of 'systems' (e.g. saline bags to syringes)
- Four sizes to accommodate multiple sample types
- Facilitates easier testing versus drilling holes and epoxying purge lines
- Analyze water vapor transmission (WVTR) of medical solutions (i.e. products)
- No external gas supply is required as the desired permeant is present in pre-filled samples



4x2 Capture Vessel



4x12 Capture Vessel

# BLISTER CARTRIDGES DETERMINING MOISTURE BARRIER PROPERTIES

## Ingress analysis

Many medications, medical devices or healthcare solutions are sensitive to the amount of light, oxygen, carbon dioxide or moisture entering a packaging system. Proper characterization of barrier properties is critical for understanding the shelf life a product will have along the supply chain. Ingress permeation testing focuses on what chemical gas types enter a package at a specific set of environmental conditions. Sterility, product integrity and regulatory compliance are key to ensuring the product's quality, safety and efficacy.

### Empty Blister Cartridge (ingress analysis): Determine blister moisture barrier.

The blister cartridges were specifically designed for challenging blister cavities with precise % RH as well as 100% RH. During early stages of blister manufacturing, it's important to evaluate how barrier levels change after the raw plastic sheeting is formed into a blister dome. These offer the versatility to quantify water vapor transmission rate for both the cavity and the sealed system.

### Blister Benefits

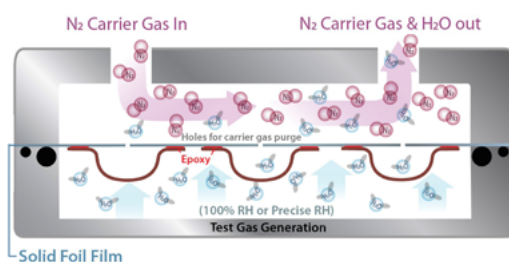
- Ability to determine blister moisture properties at precise % RH
- Testing one or multiple empty blisters
- Analyzing whole blister system (i.e. ingress)
- Easier, faster and more accurate than historical gravimetric (USP 671)
- Reversible for 100% RH or 0-90% RH testing



### Testing Blister Cavities without Foil Backing

A blister package consists of two main components — the dome and the backing sheet — sealed together to form a complete system. Before the blister is filled with a product, you may want to evaluate the empty sealed blister.

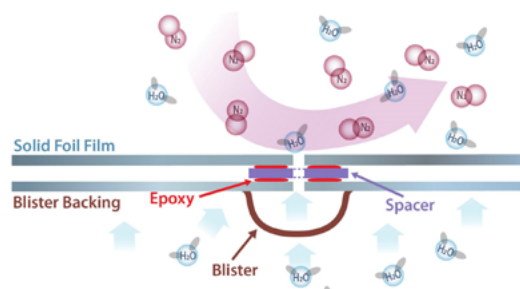
- You will need a foil mask with holes well within the blister dome(s). Epoxy the perimeter of the blister cavities on top of the solid foil film.
- Ensure only the convex sides of the blisters are exposed to test gas and fit within the o-ring diameter of the test cell.
- Orient the convex side of the blister to the test gas and run like a film using package units.



### Testing Blister Systems with Foil Intact

With the cartridge and mask setup, testing empty blister samples is as easy as testing film samples. The Empty Blister Test Cartridge may be used with any MOCON® Next Generation Film Analyzer, such as the OX-TRAN® 2/22 or AQUATRAN® 3.

- Poke a small hole into a blank foil, as well as into the backing of your blister sample. This allows the carrier gas to sweep the interior of the sealed blister.
- Seal the bottom of the backing to the mask using a spacer and a bead of epoxy. A washer is used to create space between the backing and the solid foil film (see figure).
- Ensure the convex side of the dome is exposed to the test gas when placing foil within test cell.



# CHOOSING A CARTRIDGE BASED ON YOUR APPLICATION NEEDS

## Applications

Choosing the optimal permeation solution for your unique medical application is critical for ensuring the safety, quality, and efficacy of your product. Our testing expertise allows barrier characterization for the following applications:

- Blister packs
- Ampoules and vials
- Blood bags
- Foil pouches for medical devices
- Drug bottles
- Saline bags and wraps
- Wound dressings
- Syringe systems



Sodium chloride IV bags

## How to choose the best cartridge for your samples

To determine the correct healthcare test cartridge for specific test needs, the following questions must be asked:

1. Testing films or packages? What is the transmission level?
2. Permeation ingress or egress testing? If egress testing, what size are the samples and what is the permeation level?
3. If blister testing, what size are the blisters and what is the permeation level? Multiple blisters may be needed to produce a readable signal, depending on the sensitivity of the permeation analyzer being used.

Answering the above questions is helpful, although for optimal testing best practices, send samples in for a free pre-sales test evaluation by our Permeation Application Scientist.

Cartridge	Internal Dimensions	Part Number	Instrument
Pre-filled Blisters	3.1" Ø x 0.650" tall (7.87 x 1.44 cm)	Precise RH: 054-575	AQUATRAN® models 3 and 3/34; PERMATRAN-W® 3/34
Empty Blisters	3.0" Ø x 0.57" tall (7.62 x 1.44 cm)	Precise & 100% RH: 054-126	OX-TRAN® 2/12, 2/22; AQUATRAN® 3, 3/34; PERMATRAN® 3/34
Capture Vessels	4" Ø x 2" tall (10.2 x 5.1 cm)	054-591 each / 054-592 (set of 4)	PackRack®, 2/48, 2/40, 3/40
	4" Ø x 12" tall (10.2 x 30.5 cm)	054-593 each / 054-592 (set of 4)	
	6" Ø x 4" tall (15.2 x 10.2 cm)	054-595 each / 054-594 (set of 4)	
	6" Ø x 18" tall (15.2 x 45.7 cm)	054-597 each / 054-598 (set of 4)	

## Our experts listen to your needs and offer customized solutions

AMETEK MOCON continually expands our extensive cartridge line based on customer testing requirements to ensure accurate and consistent test results. With over 55 years of industry experience behind the designs, our interchangeable cartridges address general industry challenges as well as specific customer requests.

