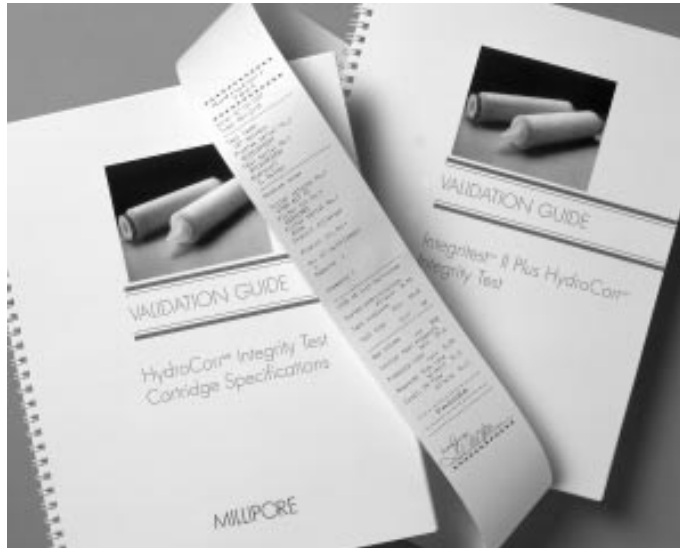


The HydroCorr™ Integrity Test

■ Water-based integrity test for hydrophobic filters



Description

The HydroCorr test is a highly sensitive water-based integrity test for hydrophobic membrane filters. This test provides an advantage over traditional integrity testing methods that require alcohol. In the past, hydrophobic filter integrity testing has consisted of diffusion and bubble point tests conducted on filters wet with alcohol or alcohol/water mixtures. Due to contamination concerns, most alcohol integrity tests were conducted off line, making it impossible to test a filter in place after steaming. Another drawback to alcohol-based integrity testing is the high cost associated with purchasing, handling, storing, and disposing of alcohol. Because the HydroCorr test uses only water and there is minimal flow through an integral filter, it can be conducted as a preuse test, in place, after steaming. This capability decreases the risk of processing a batch of product using a nonintegral filter.

Advantages

- No alcohol required
 - eliminates special handling requirements
 - eliminates safety concerns
 - no additional expense
- In situ test
 - can test gas filters post steam-in-place
 - tests process filter housings and fittings
- Validatable test
 - cartridge specifications correlated to bacterial retention test
 - simultaneous referee test available for on-site IQ/OQ

Millipore's water-flow integrity test (the HydroCorr test) meets FDA requirements for integrity tests of sterilizing-grade cartridges. The HydroCorr test specifications are correlated to the bacterial challenge test.

Theory

The HydroCorr test is based on the fact that liquid is repelled by the pores of hydrophobic filters through surface tension and capillary forces. The minimum pressure required to force liquid into the largest pores is called the water-intrusion pressure. The water-intrusion pressure is analogous to a hydrophilic bubble point and is a measure of pore diameter.

Water-Intrusion Pressure Formula

$$P = \frac{-4k\sigma\cos\theta}{d}$$

where

P = intrusion pressure

d = pore diameter

k = membrane shape correction factor

$\cos\theta$ = cosine of contact angle

σ = surface tension

The HydroCorr test is conducted at a pressure below the water-intrusion pressure. For integral filters, there is minimal flow of water through the membrane. This minimizes downstream contamination. And, since the membrane does not wet out, the filter can be used immediately after testing, with little or no filter drying required. When water flow is measured in an integral filter during the HydroCorr test, it is due primarily to the compression of the pleated filter structure caused by pressurizing the filter. This does not damage the filter.

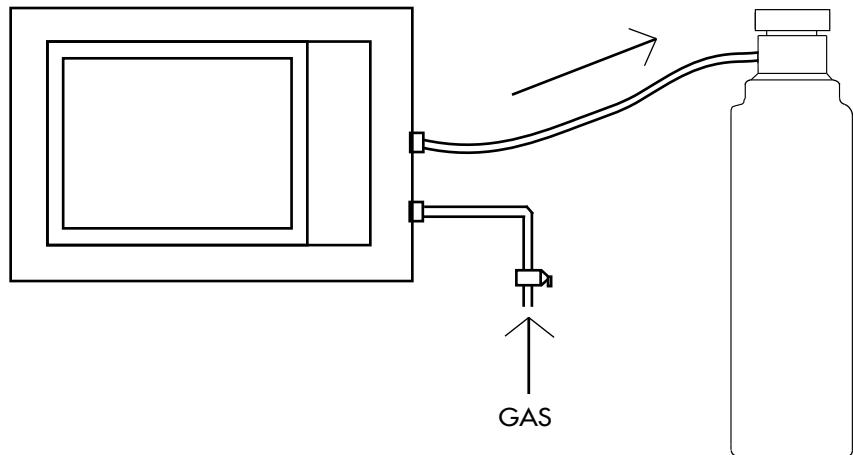


Automatic Test Procedure

The HydroCorr test can be conducted on the Integritest II and Integritest II Plus automatic integrity testing systems. All that is required is to use the appropriate HydroCorr test software (see Ordering Information).

1. Install a dry filter in a housing and fill the filter housing with clean water.
2. Program the test parameters into the instrument for the filter system being tested.
3. Connect a compressed-air supply to the instrument, the instrument to the filter, then run the test.
4. The Integritest II/II Plus system will adjust to the appropriate test pressure and maintain pressure on the system until the filter has stabilized. It will automatically determine the water-flow value and indicate whether the filter passed or failed. The test will take 20 minutes for most cartridges.
5. If the filter is integral, drain water from the upstream of the housing and use the filter immediately.

AUTOMATIC INTEGRITY TESTER



Ordering Information

Description	Catalogue No.
Integritest II Plus HydroCorr test diskette, 1.4 MB	XEIPWF000
Integritest II HydroCorr test diskette, 720 KB	XEITWF000
HydroCorr integrity test operator's manual	P35007

Millipore Worldwide

To Place an Order or Receive Technical Assistance

For additional information call your nearest Millipore office.

In the U.S. and Canada, call toll-free **1-800-MILLIPORE (1-800-645-5476)**

In the U.S., Canada and Puerto Rico, fax orders to **1-800-MILLIFX (1-800-645-5439)**

On the Internet
<http://www.millipore.com>



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