



Automatic Integrity Test

Instrument Qualification

On-site Validation for Installation Qualification (IQ) and Operational Qualification (OQ)

- ▶ Determine the correct testing for your instrument
- ▶ Provide test protocols, data and reports
- ▶ Provide on-site protocol execution, assistance and operator training
- ▶ Provide recommendations for PQ and maintenance of the instrument

Millipore performed extensive product qualification testing of the automatic integrity testers prior to market release. This testing included validating independent hardware, software and integrated system testing. Despite this level of qualification, however, it is recommended that the end user qualify automatic integrity testing instruments used for critical measurements in the environment in which they are used.

Qualification of automatic integrity testing instruments can be complicated and time consuming, especially to those unfamiliar with the instrument. Millipore validation engineers, familiar with the operation, can provide on-site assistance with performing Installation Qualification (IQ) and Operational Qualification (OQ). As part of this service, Millipore provides protocols and a comprehensive final report documenting all testing and results. Recommendations are made for testing worst-case and normal operating conditions of the instrument and on-going preventative maintenance. Let Millipore's years of filtration and process optimization experience save you time and resources.

Regulatory Compliance

Filter integrity testing is a critical step in the production of sterile drug products and is required by regulatory bodies worldwide. The United States Food and Drug Administration's Guidance on Sterile Drug Products Produced by Aseptic Processing recommends post-use integrity testing to check for leaks or filter damage. Millipore's automatic integrity testers allow users to measure integrity values accurately with a minimum of operator intervention.

Current GMP's for Finished Pharmaceuticals require process validation. Process validation is defined as "establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality characteristics." The key elements in process validation are equipment and process qualification. As equipment used in production of sterile drugs that provide required process data, automatic integrity testers require validation.

Test Procedure

The user should formally receive the unit according to their facility's standard procedures, and fill out the Millipore filter matrix to help determine the filters to be used in OQ testing. A standard test protocol is submitted to the client for review and approval. When both Millipore and the client sign the protocol, then on-site testing will be scheduled. A standard report, which summarizes test data, is submitted to the client at the completion of testing.

What You Need to Have to Begin

- The catalog number and test specifications of all filters typically tested
- Samples of each type of non-Millipore filter tested
- Millipore automatic integrity tester which has been installed in its use location and in working order

Ordering Information

Description	Catalogue No.
Qualification for Integritest® Exacta Instrument	VSERVIQOQ
Qualification for Integritest 4 Instrument	VSERVIT4Q
On-site Preventative maintenance, training, operation assistance or calibration services	VSERVLABR

How to Request Automatic Integrity Tester Qualification Services

To request on-site qualification or to get information on other validation services, call your Millipore Applications Specialist or the Millipore office nearest you. In the U.S. and Canada, call toll-free 1-800-MILLIPORE (1-800-645-5476).

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