

## Automatic Integrity Test Instrument Qualification: On-site Validation for Installation Qualification (IQ) and Operational Qualification (OQ)

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. Let Millipore's years of filtration and process optimization experience save you time and resources with an inclusive Installation Qualification (IQ) and Operational Qualification (OQ) service offering.

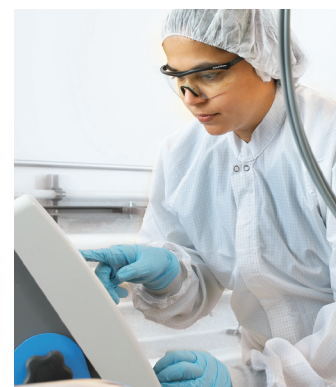
- Determine the correct testing for your instrument
- Provide test protocols, data and reports
- Provide on-site protocol execution, assistance and operator training
- Provide recommendations for PQ and maintenance of the instrument

### 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 GMPs 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 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 customized test protocol is submitted to the client for review and approval. On-site testing will be scheduled upon the client's approval of the protocol. A standard report, which summarizes test data, is submitted to the client at the completion of testing.

## MILLIPORE'S ON-SITE VALIDATION FOR IQ AND OQ INCLUDES:

- A project dedicated validation coordinator for project planning and protocol generation.
- Protocols for each unit that are customized to validate your range of use of the instrument. Our protocols are designed to meet your needs. Your coordinator works with your filter list to provide a robust validation package to ensure regulatory compliance.
- All travel related costs for IQOQ execution.
- A Millipore Validation Engineer to execute protocol at your site. Our Validation Engineers are Integrity Testing Subject Matter Experts fully trained in the manual reference techniques used to complete OQ.
- Validation of the network functionality to ensure CFR21 Part 11 compliance.
- All calibrated equipment and Millipore filters that are required for validation activities.
- Review of all generated data; an IQOQ Summary Report is provided.
- Concise IQOQ binder containing Approved Protocol, Original Data, Approved Summary Report.

## 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

## 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)**.



[www.millipore.com/offices](http://www.millipore.com/offices)

**ADVANCING LIFE SCIENCE TOGETHER™**  
**Research. Development. Production.**

Millipore, Integritest and Access are registered trademarks of Millipore Corporation. The M mark and Advancing Life Science Together are trademarks of Millipore Corporation. Lit. No. SDS1008EN00 Rev. B 12/08 Printed in U.S.A. BP-GEN-08-01230 © 2008 Millipore Corporation, Billerica, MA 01821 U.S.A. All rights reserved.