



Integritest® 5 Automatic Filter Test Instrument Services

A wide range of services to support every step of your journey

To help you navigate the highly regulated and complex biopharmaceutical industry, we offer a wide range of comprehensive services to meet your unique manufacturing requirements.

Our range of services can help you save time, lower costs, comply with regulation, and have peace of mind. All our services are performed by experienced personnel who have expertise and knowledge of our equipment.

Service Offerings

- Installation qualification/Operational qualification (IQ/OQ)
- Site acceptance test (SAT)
- Performance qualification support (PQ)
- Network qualification
- Operator training
- System Service Reliance Plans
- Requalification
- Corrective maintenance
- Spare parts

Benefits

- Ensure regulatory compliance
- Enable smooth and successful implementation and integration of system
- Receive direct access to replacement parts
- Ensure consistency and reliability with expert hands-on system training
- Offer optimal solutions for complex projects with tight deadlines

Installation and Qualification

Our installation and qualification services help ensure your equipment is properly installed and functioning per your predefined requirements. All qualification tests are performed by our certified engineers and are based on 25 years of experience to ensure efficiency, safety, and consistency.

Installation Qualification/Operational Qualification (IQ/OQ)

Duration: 2 days per system

Description

Our IQ/OQ service ensures that the installation and operational qualification of your Integritest® 5 system is fully documented. During the IQ/OQ, the system will be tested to ensure that bubble point, diffusion and HydroCORR™ tests can be safely and accurately performed and reproduced.

Includes:

- IQ/OQ protocol
- Documentation verification
- Installation verification
- System configuration
- Calibration verification
- Filter integrity testing
- Error message check
- User access check
- Data management check
- Basic operator training (1 hour)

Filters

A selection of our standard sterilizing-grade filters are used to complete the IQ/OQ testing:

- **Diffusion:** Durapore® 0.22 µm membrane hydrophilic 10" CVGL cartridge or KVGL capsule
- **Bubble point:** Durapore® 0.22 µm membrane hydrophilic 10" CVGL cartridge or KVGL capsule
- **HydroCORR™:** Aervent® 0.2 µm membrane hydrophilic 10" CTGR cartridge or KTGR capsule

Site Acceptance Test (SAT)

Duration: 0.5 day per system

Description

Our SAT tests demonstrate that the system was not impacted by the transportation and installation of the system on site. We verify that the system has been correctly installed, configured and is performing as expected.

Includes:

- SAT protocol writing and execution
- Documentation verification
- Installation verification
- System configuration
- Calibration verification
- Final filter release test

Performance Qualification (PQ)

Duration: 0.3 day per filter application

Description

Our Performance Qualification service ensures that your Integritest® 5 system operates to your specific filter testing applications. The service includes one filter test application per service. Each application purchased will be triple-tested on site for accuracy and reproducibility and results will be documented.

Network Qualification (NQ)

Prerequisites assistance from local IT administrator and configure network is needed

Duration: 1 day per system

Description

The Network Qualification service will document that the Integritest® 5 system functions properly when configured with network applications that are requested on site.

- NQ protocol writing and execution
- System configuration and options
- Test report transfer
- Backup and Restore
- External printer set up
- Configuration management (settings, users and tests)

Integritest® 5 Installation Services Overview and Ordering Information

	Site Acceptance Test (SAT) Verify tester on site	Installation Qualification and Operational Qualification (IQ/OQ) Diffusion, bubble point and HydroCORR™ tests	Performance Qualification (PQ) Filter integrity test to customer specification	Network Qualification (NQ) Network and/or cluster functionality
Duration per system	0.5 day	2 days	0.3 day	1 day
Protocol ready to approve	X	X	X	X
Documentation verification	X	X		
Installation verification	X	X	X	
Operating conditions	X	X		
Unit settings	X	X		
Pressure sensor verification	X	X	X	
Filter test release	1 test			
Diffusion test**		3 tests		
Bubble point test**		3 tests		
HydroCORR™ tests**		3 tests		
Filter test from process range			3 tests***	
Alarm management		X		
User management		X		
Data management		X		
Basic operator training (1 hour)****		X		
IT review and configuration				X

Integritest® 5 Installation Services Overview and Ordering Information (continued)

	Site Acceptance Test (SAT) Verify tester on site	Installation Qualification and Operational Qualification (IQ/OQ) Diffusion, bubble point and HydroCORR™ tests	Performance Qualification (PQ) Filter integrity test to customer specification	Network Qualification (NQ) Network and/or cluster functionality
Network communication				X
NQ protocol writing and execution				X
System configuration and options				X
Test report transfer				X
Backup and Restore				X
External printer set up				X
Configuration management (settings, users and tests)				X
File export & backup		X	X	X

* Per filter application

** With Durapore® 0.22 µm hydrophilic 10" filter (Diffusion and Bubble Point) and Aervent® 0.2 µm hydrophobic 10" filter (HydroCORR™)

*** Per filter

**** No certificate

Support, Maintenance and Requalification Services

Our support services provide everything you need to keep your equipment running smoothly and efficiently. These services cover critical and cGMP required areas such as training, maintenance, and repair.

Operator training

Duration: 2 days per operator

Description

Our operator training is designed for operators and engineers who are responsible for automatic integrity testing of sterilizing filters in the pharmaceutical and biopharmaceutical industries. Using a combination of theory and hands-on instruction, users will learn the key procedures of filter integrity testing, how to read printouts from automatic filter integrity testers and troubleshoot filter-integrity test processes. All current filter integrity tests that apply to all liquid and gas membrane filtration applications, including bubble point, diffusive flow and water intrusion, will be covered.

Includes:

- Course material
- Introduction to sterilizing filtration
- Bubble point and diffusion theory and test methods
- HydroCORR™ theory and test methods
- Troubleshooting filter integrity testing processes
- Training certificate

System Service Reliance Plans

To support you in ensuring optimum equipment uptime and regulatory compliance while mitigating risks, we have developed System Service Reliance Plans, a complete range of services for your equipment. These comprehensive service and support packages allow you to select the coverage level that best fits your needs.

- **Essential Reliance Plan:** includes a selection of preventive maintenance and troubleshooting services

- **Advanced Reliance Plan:** provides higher coverage, with faster response time and priority access to remote and on-site support
- **Total Reliance Plan:** guarantees the highest level of protection for your equipment and our fastest reaction time

For additional details, please refer to the System Service Reliance Plans Data Sheet (**DS7881EN**) available at [SigmaAldrich.com/services-plans](https://www.sigmaaldrich.com/services-plans).

Requalification (ReQ)

Available in selected countries only.

Not available as a stand-alone service - should be executed together with the yearly preventive maintenance visit covered by the System Service Reliance Plan.

Duration: 0.5 days per system

Description

While the maintenance service verifies that your Integritest® 5 system is operational, our requalification service will demonstrate that the system has remained in the qualified state and is compliant with regulations. The requalification within defined time intervals will ensure that your system is qualified throughout its entire lifecycle.

Includes:

- ReQ protocol
- Diffusion test
- Bubble point test
- HydroCORR tests
- System check
- File management

Integritest® 5 Instrument Maintenance and Requalification Services Overview

	Service Reliance Plans (yearly preventive maintenance visit)	Requalification (ReQ)	Workshop Repair Workshop labor and PM	On-site Repair Includes PM labor and travel
Duration per system	0.5 day	0.5 day	Assessment is needed	Assessment is needed
Protocol ready to approve	X	X	X	X
Initial status & software records	X		X	X
Visual inspection	X		X	X
Date & time verification & setting	X		X	X
Leak test	X		X	X
Pressure sensor verification & calibration	X		X	X
Diffusion Test		X		
Bubble Point		X		
HydroCORR tests		X		
Filter test release	X		X	X
Calibration & maintenance date set	X		X	X
System check	X		X	X
File export & backup	X		X	X
Spare parts	Purchased separately		Purchased separately	Purchased separately
Repair labor			X	X
Travel (for on site)/System shipment (for workshop)	X		Excluding shipment back	X
File management		X		

To place an order or receive technical assistance

Please visit

EMDMillipore.com/contactPS

For additional information, please visit

EMDMillipore.com

