

# 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 services to meet your unique manufacturing requirements.

Our services can help you save time, lower costs, and comply with regulation. All services are performed by our global experts who have intimate knowledge of our equipment, backed by decades of experience.

## Service Offerings

- Installation Qualification/Operational Qualification (IQ/OQ)
- Site Acceptance Test (SAT)
- Performance Qualification support (PQ)
- Network qualification
- Operator training
- System Service Reliance Plans
- Spare parts

## Benefits

- Ensure regulatory compliance
- Enable successful implementation and integration of your integrity testing system
- Ensure consistency and reliability with expert hands-on system training
- Receive direct access to replacement parts



## 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 services ensure 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" cartridge or capsule
- **Bubble point:** Durapore® 0.22 µm membrane (hydrophilic), 10" cartridge or capsule
- **HydroCORR™:** Aervent® 0.2 µm membrane (hydrophobic), 10" cartridge or capsule

## Site Acceptance Test (SAT)

Duration: 0.5 day per system

#### Description

Our SAT tests demonstrate that transportation and system installation had no impact on the system's performance. 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)

Assistance from local IT administrator to configure the 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

	<b>Site Acceptance Test (SAT)</b> Verify tester on site	<b>Installation Qualification and Operational Qualification (IQ/OQ)</b> Diffusion, bubble point, and HydroCorr™ tests	<b>Performance Qualification (PQ)</b> Filter integrity test to customer specification	<b>Network Qualification (NQ)</b> 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
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 and 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 and Maintenance 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 ensure optimum equipment uptime and regulatory compliance while mitigating risks, we have developed System Service Reliance Plans; a complete range of services for your systems and equipment. These comprehensive service and support packages allow you to select a coverage level that best fits your needs. The Essential Reliance Plan includes a selection of preventive maintenance and troubleshooting services while the Advanced Reliance Plan provides higher coverage, with faster response time and priority access to remote and on-site support.

#### Coverage Level

Services	Details	Level of Protection	
		Advanced Reliance Plan	Essential Reliance Plan
<b>System Eligibility</b>		<b>&lt;15 years</b>	<b>All ages</b>
<b>Preventive Maintenance (PM) visit</b>	1 PM visit (labor and travel included) <sup>(a)</sup>	✓	✓
<b>Preventive Maintenance (PM) spare parts kit</b>	Yearly preventive maintenance spare parts kit	✗	✗
<b>Traceable and auditable documentation</b>	Full service report	✓	✓
<b>Spare parts storage assessment</b>	Spare parts advisory service (first year only)	✓	✓
<b>Asset tagging solution</b>	QR code sticker and cards to quickly and easily identify your system and contact us	✓	✓
<b>Remote troubleshooting</b>	Priority remote support on system and software <sup>(b)</sup> —phone and email	24h <sup>(e)</sup>	✓
	Priority remote support on system and software <sup>(b)</sup> —smart glasses and remote connection <sup>(c)</sup>	 ✓ <sup>(f)</sup> 	✗
<b>On-site troubleshooting</b>	On-site support—response time	Within 5 days <sup>(g)</sup>	No engagement on response time
	Troubleshooting/repair visit (labor and travel included)	1 per year (no carry over)	Billable services
<b>Spare parts</b>	Spare parts for repair <sup>(d)</sup>	15% discount <sup>(h)</sup>	10% discount <sup>(h)</sup>

 = Smart Glasses

 = Remote connection

(a) Maintenance kit to be purchased separately prior to service.

(b) Support provided via phone and email and limited to 10 cases per year and 30 h of investigation. Software update not included in Service Reliance Plans.

(c) Only for suitable systems and if the connection is tested upfront with customer.

(d) Best effort is aimed at supplying spare parts and/or find equivalent over the system's lifetime, but no guarantee of availability over time.

(e) 24h from the customer's requests, to our service team returning the call. May vary depending on customer's location.

(f) Smart glasses eligibility: for number of service plans  $\geq 3$  large systems and  $\geq 5$  small systems (Integristest® 5 System, Mobius® MIX System, Mobius® Power MIX System). 1 pair of smart glasses per customer. Additional pair will be charged.

(g) Five business days for Advanced, from the time when it is agreed that a troubleshooting visit is necessary.

(h) Discount on list price.

## Integritest® 5 Instrument Maintenance Services Overview

	System Service Reliance Plans (Preventive Maintenance yearly visit)	Workshop Repair Workshop labor and PM	On-site Repair Includes PM labor and travel
Duration per system	0.5 day	Assessment needed	Assessment needed
Protocol ready to approve	X	X	X
Initial status and software records	X	X	X
Visual inspection	X	X	X
Date and time verification and setting	X	X	X
Leak test	X	X	X
Pressure sensor verification and calibration	X	X	X
Filter test release	X	X	X
Calibration and maintenance date set	X	X	X
System check	X	X	X
File export and 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

For additional information, please visit  
[EMDMillipore.com/Systems-Services](https://EMDMillipore.com/Systems-Services)

