



# 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
- Preventive maintenance (PM)
- 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<br>Test (SAT)<br>Verify tester on site | Installation Qualification<br>and Operational<br>Qualification (IQ/OQ)<br>Diffusion, bubble point and<br>HydroCORR™ tests | Performance<br>Qualification (PQ)<br>Filter integrity test to<br>customer specification | Network<br>Qualification (NQ)<br>Network and/or<br>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,<br>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 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

## Preventive Maintenance (PM)

Duration: 0.5 days per system

### Description

Maintenance is the most cost-effective and critical component to ensuring the best performance of your system. Regular maintenance reduces repair costs, increases uptime, and calibration and preventive maintenance programs are required by Regulatory Authorities. During your maintenance visit, certified Field Service Engineers will verify your equipment using established protocols, and any necessary adjustments or parts replacement will be performed.

### Includes:

- PM protocol
- Leak test
- As-found and As-left pressure sensor verification
- System check
- Wear and tear parts replacement

## Corrective Maintenance (CM)

### Description

If your system experiences an issue and needs repair we offer corrective maintenance services both in our workshops and at your site. Spare parts are available to be purchased separately (Please see the Integritest® 5 instrument specification sheet for more details on spare parts and accessories.)

## Integritest® 5 Instrument Maintenance Services Overview

|   | Preventative Maintenance (PM) | Workshop Repair<br>Workshop labor and PM | On-site Repair<br>Includes PM labor and travel |
|---|-------------------------------|--|--|
| Duration per system                                 | 0.5 day                       | Assessment is needed                     | Assessment is needed                           |
| Protocol ready to approve                           | 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  |
| Filter test release                                 |                               | X  | X  |
| Calibration & maintenance date set                  | X                             | X  | X  |
| System check  | X                             | X  | X  |
| File export & backup                                |                               | 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  |

## To place an order or receive technical assistance

Please visit

[EMDMillipore.com/contactPS](https://EMDMillipore.com/contactPS)

For additional information, please visit

[EMDMillipore.com](https://EMDMillipore.com)

