Millipore®
Filtration, Separation
& Preparation

Integritest® 5: Integrity assurance with ease and confidence

Accurately and reliably verify the integrity of your filters and processing equipment with the portable, easy to implement, and automated Integritest® 5. The Integritest® 5 delivers a simple and intuitive user experience, while providing optional depth of flexibility to fit your process.

Benefits

- Robust unit protects against water and dust entry, and automatically checks calibration
- Improved test algorithm reduces test time and simplifies test creation
- Intuitive software includes help screens available for every step
- Flexible displays, run information, and test collections to suit your process
- Standard model offers all networking functions, including multi-unit management and synchronization

MilliporeSigma

Compliance

Improved test speed while maintaining high accuracy

For bubble point tests, the proven tangent method is used to maximize readings from stable portions of the filters' profiles

See more in Feature Details on following pages

Designed to support GMP and 21 CFR p11 compliance

User access rights can be controlled, data integrity is ensured, and a full audit trail is available. Single or double, manual or electronic signatures are all supported

See more in Feature Details on following pages

Reliability

Prevent water and dust entry with IP54 rating

Eliminate setup mistakes with errorless quick connectors

Protect against liquid back-flow issues with sensor feedback, float valve and more

See more in Feature Details on following pages

Remove contamination concerns with cleanable, replaceable Housing Interface Module

Stay informed of calibration issues with automatic self-check

Usability

Queue tests and pre-enter run information to save time

See more in Feature Details in following pages

Convenient on-board printer

Thermal printer paper removes particulate generation concerns and the need for ink, and stays legible for over 12 years or after exposure to water and alcohol.

See more in Feature Details on following pages

Streamlined screens that are easy to learn

Designed for an operator to quickly learn to run tests and print reports. Test creation offers step by step guidance

Accessible help for every screen and search function just where you need it.

Various human input

Control with the touch screen, even with plastic gloves

Attach a mouse and/or keyboard if you prefer via USB or Bluetooth

Flexibility

Organize tests into collections and users into groups for easy access, management and security

Reduce risk of human error by assigning tests to specific users

See more in Feature Details on following pages

Pick the information you want to see with the highly configurable display and reports

See more in Feature Details on following pages

Choose regional settings such as language or date/time format

Integration

Save time by synchronizing tests, users, and settings on all instruments

Connect to a router, then enter the instrument cluster name and a file path. Make edits only once, and everything stays synchronized. Easy

Never lose data and settings by centrally storing reports, backups, and more

Set folder paths to store your files on a network location

Use your corporate single sign on with Windows® Active Directory users on the instrument

Stay secure and compliant to your corporate Information Technology rules

See more in Feature Details in following pages

Supports Wifi, Bluetooth, USB printers and barcode scanners for data input

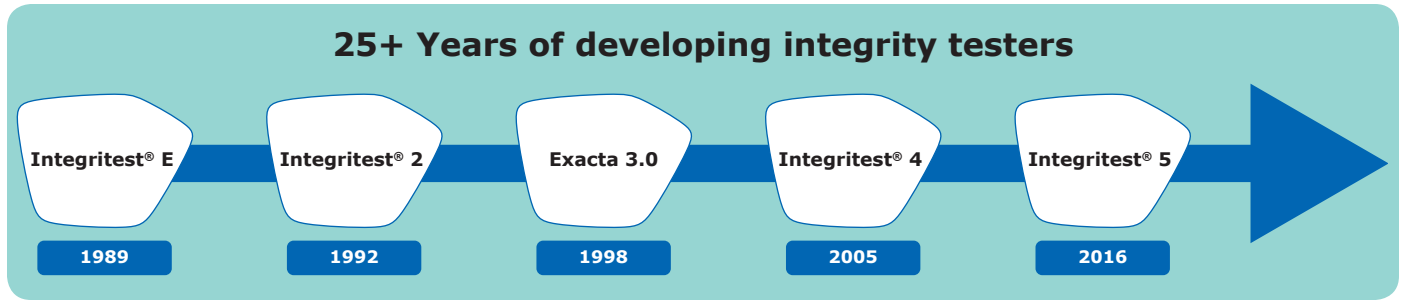802.11a/b/g/n/ac wireless Ethernet and dual band support, 2.4GHz adn 5GHz

Wi-Fi CERTIFIED by the Wi-Fi Alliance

Dual Mode Bluetooth 2.1, 2.1 + EDR, 3.0, 3.0 + HS, 4.0 (BLE)

Supports wired Ethernet up to 1 Gbit/s

Supported by a Knowledgeable, Responsive, Global Partner

25+ Years of developing integrity testers

Integritest® E	Integritest® 2	Exacta 3.0	Integritest® 4	Integritest® 5
1989	1992	1998	2005	2016

History and experience matter. We introduced the first commercial automated integrity tester over 25 years ago. We were the first to automate sizing, and we developed the first water intrustion test- HydroCorr™. We know filters. We know integrity testing.

Feature detail

Compliance: integrity test instruments, bubble point tangent method, and improved test speed

The Integritest® 5 takes precise pressure measurements and cknown internal volumes to derive flow rates. Upstream volumes are found by measuring pressure changes from releasing precise quantities of gas. The instrument then measures the pressure decay, and based on the upstream volume, calculates the final flowrate for diffusion and HydroCorr™ water intrusion tests. This flowrate is compared with the test specification for the integrity conclusion.

Bubble point and pressure hold tests follow a similar method of monitoring pressure drops but provide the necessary pressure results instead. Bubble point tests use the tangent method, and takes several pressure decay measurements at different applied pressures to map the filter's integrity profile. Stable diffusive flow is achieved at lower pressures, and stable convective flow is achieved at higher pressures. By mapping the profile of the filter through both types of flow, the instrument can accurately calculate the intersection of these curves to find the actual bubble point of the filter. This also reduces emphasis on measurements in the volatile portion of the curve.

The Integritest® 5 improves on test speed by optimizing the algorithm. For example, for diffusion tests, the instrument reads through fluctuations and ends the test as soon as a stable, accurate result is achieved. For bubble point tests, the instrument identifies optimum points to take measurements based on test parameters and ongoing readings, which reduces the number of measurements needed to reliably map the filters' profile and return an accurate result.

Reliability: back-flow ingress prevention with cleanable Housing Interface Module

Sometimes even despite the best training, process, and equipment, liquid backflow into the system can occur as a natural result of working with fluids, pressurized equipment, and human error. High precision instruments like filter integrity testers can be affected by fluid ingress and may require disruptive repair, so the Integritest® 5 has been designed to eliminate this problem.

As a preventive technique, all exhaust steps are monitored by a pressure sensor to check that the housing or capsule is fully exhausted and depressurized before opening valves leading into the instrument. This prevents the condition of a lower instrument pressure causing air and possible fluids to be pushed into the instrument. During other steps of a test run, this pressure sensor also monitors for pressure drops within the instrument and will react to imminent fluid blow back by quickly switching to the exhaust flow path. As a final line of defense, the Housing Interface Module (HIM) incorporates a float valve that will seal against rising fluid. Even in emergency cases of power loss or compressed gas loss, the instrument will protect itself by springing valves shut.

If contamination is a concern to you, the HIM's flow path is validated to be fully cleanable. Simply remove the HIM, attach the cleaning accessory, and use the cleaning instructions found in the user guide.

If your process conducts pre-use, post-sterilization integrity testing and you assess that cross-contamination between products or processes is a risk, it is even possible to keep specific HIMs to be used separately.

Compliance: signatures, users, and audit trails

The Integritest® 5 supports single and double signatures, in either manual or electronic forms. Appropriate space and fields are provided for manual signatures. Electronic signatures follow all regulations to help you stay 21 CFR part 11 compliant. A username and password are required to sign, and all necessary information are automatically provided, such as name, date, time, and even a configurable standard message that the user signs to. Signatures cannot be transferred, removed, or altered.

Usernames and passwords restrictions, such as length, can be restricted with the same rules as Windows®. There are five roles that are assigned on the instrument with increasing access rights.

The Integritest® 5 application automatically loads up and prevents any access to the underlying Windows® operating system. This ensures a robust platform that prevents accidental or untrained changes that may hinder operation.

The Auditor tool logs all actions, results, and edits, along with the timestamp of occurrence. Electronic records and test data are protected from alteration.

Usability: test queue and preview

Tests can be added to a queue list to help you save time when testing multiple filters. When a test is running, you can pick or search for the tests you need next and add them to the queue. Run information for tests, such as batch number and filter serial number, can also be entered ahead of time when you're waiting for the previous test to finish.

Flexibility: highly configurable groupings and security

Simple usability has been a guiding principle in designing the Integritest® 5. However, there is a depth of configurability with optional features should you need it.

If you have many tests, separate them into Collections to add structure and find them more easily. For example, you can create a Collection with all tests for Durapore® filters, or tests used in a certain suite, or tests for your newest product.

Tests in a Collection can be secured to limit access, and reduce human error. If only one team is trained to run tests on alcohol-wetted filters, secure those tests in a Collection and only let that group of users see and access those tests. Securing Collections this way also prevents operators from running the wrong test, since the tests that aren't relevant to them are hidden from view.

To help manage this security, Users can be assigned to Groups. If a Group of operators was just trained to run a new Collection of tests, just add the access rights to the Group instead of each individual.

Flexibility: highly configurable display

Pick the information to see. It may be easier to identify your test by the filter manufacturer instead of by the test type. Or choose to view and sort test reports by batch number, and the name of the user who ran the test.

Many headings are also fully configurable, such as choosing to add a Collection description, or specifying the fields to enter as run information. Choose the information to enter, and whether it is required.

Reports can also be configured to show and print the information you want to see. This keeps it relevant to your process and more easily understood, which reduces mistakes.

Integration: powerful cluster synchronizations and networking

Settings, Users, and Tests can be published from one instrument to keep a Cluster of instruments synchronized. This simplifies and saves time on managing tests, users, and configurations across multiple instruments. The fastest setup only uses a router connection and a shared folder within the instrument. The rest of the instrument Cluster can then be set to update from that folder. If you then edit a test or create a new user on the Master IT5, all instruments in the Cluster will pull this information and update accordingly. Even a USB memory stick can be used if a router isn't available.

A network shared folder can increase availability of the Cluster synchronization data, and can also be used for other exported data such as auto-backups and reports. If you need certain instruments to have different settings, such as a local printer or a different report repository, you can assign specific settings to a subgroup of instruments within a Cluster. Test Collections can also have instrument based security to control which instruments can run which tests.

Integration: domain and corporate Information Technology compliance

Domain users are supported to simplify user management by using corporate user ID and password. Authentication uses standard Windows® functions and registration mechanisms, and roles are then defined in the IT5 application.

To keep computers and networks protected, Information Technology (IT) departments often need to enforce strict rules. The Integritest® 5 makes it easier to connect to your corporate network and helps you maintain security by being a fully installable Windows® application. This means the IT department can place their standard, approved operating system and applications on the instrument's computer, and the Integritest® 5 software can be run on top of this secure image.

Similarly, you can install the Integritest® 5 software on an office PC if you prefer not to centrally manage your instrument Cluster from a Master instrument.

Description	Part Number
Integritest® 5 Instrument (North American power cable included)	IT5INS001
Power Cord Japan	P83066
Power Cord Australia, NZ	P83067
Power Cord UK, IE, HK, SG	P83068
Power Cord Western Europe AT, BE, FR, FI, DE, GR, NO, NL, PL, PT, ES, SE	P83069
Power Cable Argentina	PWRCABLEAR
Power Cable Brazil	PWRCABLEBR
Power Cable China	PWRCABLECN
Power Cable Denmark	PWRCABLEDK
Power Cable Italy	PWRCABLEIT
Power Cable Switzerland	PWRCABLECH
Power Cable South Africa, India, Pakistan	PWRCABLEZA
Power Cable South Korea	PWRCABLEKR
Power Cable Taiwan	PWRCABLETW

Services

Qualification services help you minimize regulatory risks, save qualification time, and maximize your process efficiency. Preventive maintenance services help you keep your equipment running, increase production time, and save emergency repair costs over the long term.

Our services are provided by trained engineers, application scientists and system designers with unique knowledge of the equipment and years of experience.

By using our services, you can benefit from

- Unrivaled access to parts and testing equipment
- Up-to-date training, service protocols and practices
- A better understanding of your equipment thanks to our global installed base
- Service protocols and reports that meet industry and regulatory expectations

Our on-site calibration and maintenance services offers the least disruption to your workflow and process.

Please consult our Equipment Installation, Qualification and Maintenance brochure for more information.

To Place an Order or Receive Technical Assistance

In the U.S. and Canada, call toll-free 1-800-645-5476

For other countries across Europe, please visit:
www.emdmillipore.com/offices

For Technical Service visit:
www.emdmillipore.com/techservice