Integritest® 4 Series

Automated Filter Integrity Test Instruments and Central Instrument Management Tool Software

- ▶ Portable, easy to use

- ▶ Reliable, accurate measurements

- ▶ Fast testing improves productivity

- ▶ Network model is 21 CFR Part 11 compliance ready

- ▶ Centralized administration with IMT software

- ▶ Available in multiple languages

Easy-to-use, portable, networkable,* and fully-automated integrity test systems that offer reliable, repeatable measurements fast

The Integritest 4 instrument is an easy-to-use, portable, fully-automated integrity test system. Available in either a standalone or networkable configuration, the Integritest 4 instrument offers reliable and repeatable integrity test data. The intuitive touch screen user interface streamlines the test while the accelerated testing capability provides users with more time for processing. On-site calibration support and diagnostic capability minimizes downtime, saving time and money. Leveraging a proven test algorithm, the Integritest 4 instrument performs bubble point, diffusion, enhanced bubble point, and HydroCorr^SM (Millipore water-based test for hydrophobic filters) tests on a wide range of filters including disks, cartridges and TFF filters, virus, and asymmetric membrane filters.

The rugged, ergonomic design of the system enables users to easily carry the Integritest 4 instrument to any site. The standalone configuration enables users to print the results on the onboard printer.

The networked configuration enables users to quickly perform an integrity test, print the results on a shared network printer and automatically store test reports on a network data repository.

DATA SHEET

*Integritest 4N only

The Integritest 4N networkable configuration enables users to print results directly to any networked printer via Ethernet connection. The Integritest 4N instrument is 21 CFR Part 11 compliance ready for electronic records and electronic signatures, improving productivity and facilitating record keeping.

Easy to Use

The Integritest 4 instrument features a graphical user interface with touch-screen menus and intuitive icons for faster testing, enabling more effective use of production equipment and resources. Millipore and customer specific filter testing information can be easily entered on-site. Test results can be printed using the built-in printer. Printed test results can be customized to include operator, batch, or other desired data.

- Intuitive, multilingual graphical user interface
- 10-inch touch-screen color SVGA display with active matrix
- Pivoting base for easy adjustment of display angle
- Bar code input for easy filter identification and data entry*
- Utilizes market-leading Windows XP® embedded operating system
- Customized interface based on operational roles
- Context-based online help

Accurate, Reliable Results

The instrument has been designed and qualified to achieve high test accuracy. To ensure correct performance, the software automatically checks the functionality of the computer and pneumatic manifold components prior to each test. User programmable test parameters allow for more case specific testing when needed for analysis.

Rugged Industrial Design

The exterior surfaces can be easily wiped clean with alcohol or bleach. Instrument-grade inlet and outlet connections on the pneumatic manifold assembly minimize leaks, providing accurate results.

- Compact industrial design with quick-connect ports for easy set up
- External valve array prevents back flow of fluids into the instrument
- Modular hardware design allows for easy servicing on location
- Durable, onboard printer produces a printout that does not fade, even when wet
- Easily field calibrated for routine maintenance and record keeping

Sound Algorithm

The Integritest 4 instrument uses a software algorithm to determine the bubble point of a filter. The accuracy of this algorithm is key to proving that your filter is integral. Our algorithm is based on a mathematically proven tangent method. Unlike other solutions on the market today, it extrapolates the accurate portion of a flow curve while avoiding dependencies on the volatile portions. This, in combination with an event-based capture of the flow curve, gives you the most reliable, sustainable method of bubble point testing.

- Supports all traditional tests such as bubble point and diffusion
- Optional accelerated test allows you to quickly obtain accurate, repeatable results
- Accurate, reliable testing for asymmetric bubble point
- Programmable prepressurization for properly testing multilayer virus removal filters
- New pressure hold test to test vessels, valves, equipment and pipework

*Requires external bar code reader

Networkable Configuration

Leveraging the built-in networking capability of the Integritest 4N instrument together with the Windows XP® tool kit, users can share a networked printer for central printout of test reports. The software also enables electronic signatures for sign-off of test reports, which can be transferred to a central data repository for the backup of all Integritest 4N instrument test reports. The Integritest 4N instrument can also support wireless Ethernet communication eliminating the need to physically plug the unit into the network.

21 CFR Part 11 Compliance Ready

The Integritest 4N software meets the technical requirements of FDA regulation 21 CFR Part 11 for electronic records and electronic signatures.

Increase Process Speed

When integrated into a network, final filter integrity test results are uploaded into the main control system enabling an immediate stop/go decision, improving the pharmaceutical production process without compromising quality control.

Central Instrument Management Tool Software

Centralized instrument management and automated electronic recordkeeping
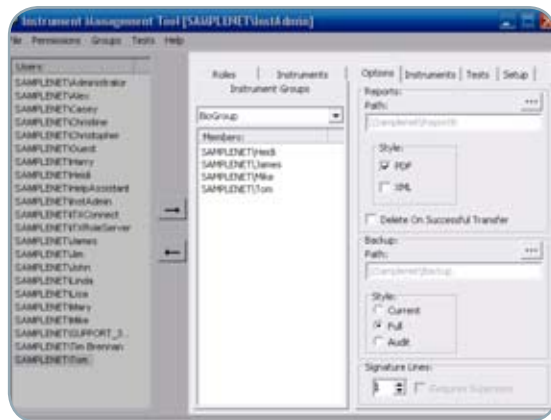
The ability to manage remote instruments via a networked PC, streamlines operations as well as optimizing integrity testing consistency and reliability throughout manufacturing.

The Integritest 4N Central Instrument Management Tool (Central IMT) software allows centralized management of all Integritest 4N instruments integrated to a network domain, improving manufacturing and system administrator productivity .

The Integritest 4N Central IMT software enables system administrators to:
- Manage Users
  - Assign users to instruments
  - Define user roles
  - No need to create user IDs or assign passwords*
  - Track password* changes
- Manage Integritest 4N Instruments
  - Add or change test definitions
  - Define report formats
  - Track the addition and deletion of users*
- Manage Filter Test Reports
  - Define data repository location
- Automatically download setups when Integritest 4N instruments are logged onto the network
- Organize instrument groups
- Automatically generate remote backups
  - Periodically
  - Information for instrument recovery and event logs
- Security
  - Domain controller assigned user names

Assign Instruments and Users to Logical Groups

- Users are selected from the domain of users provided by the domain controller
- Tests are assigned to defined instruments in the group
- An instrument tab lists all the instruments added to the Central IMT software. All checked instruments are part of the group.
- Report transfer, remote backup and electronic signature parameters are assigned to a group of instruments

*The central IMT software uses the same ID and password used to log onto a company's network domain.

Consistent, Effective and Reliable Integrity Tester Instrument Management

Centralized user and instrument management of all Integritest 4N test systems enhances testing consistency and repeatability. Central IMT allows a user in one location to access and configure multiple instruments in several locations. A test can be entered on one PC and added to a group of Integritest 4N instruments without having to access each instrument individually. A password change on one instrument automatically propagates to all instruments on the same network when a domain controller is used.

Figure 1. The Integritest 4N systems can be connected to a network printer and a central data repository.

Hub

Printer

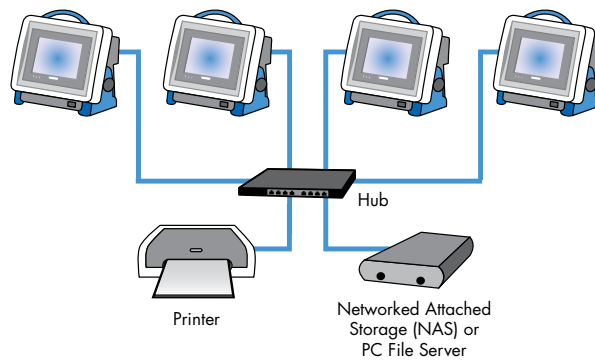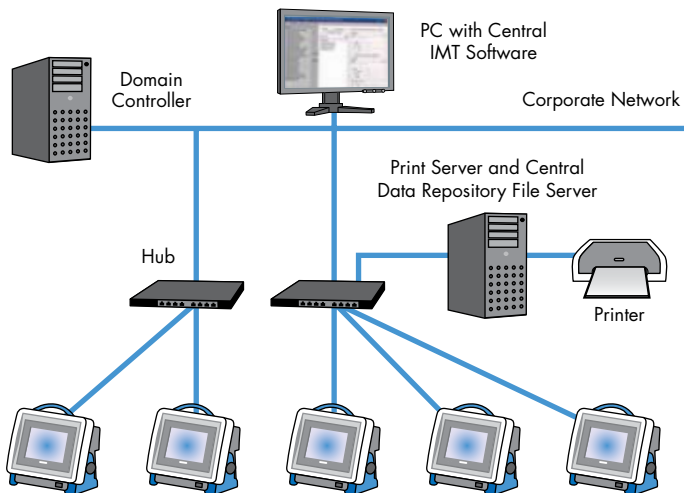Networked Attached
Storage (NAS) or
PC File Server

Figure 2. The Integritest 4N systems can also be networked to a domain-controlled Local Area Network (LAN).

PC with Central
IMT Software

Domain
Controller

Corporate Network

Print Server and Central
Data Repository File Server

Hub

Printer

Available Expedited Instrument Validation Service

The Integritest 4 instrument was developed and validated according to the GAMP Guide for Validation of Automated Systems. Validation reports are available for review during an on-site audit. The Integritest 4 instrument can be validated on-site using a validation protocol customized for you and executed by a Millipore Access® Services team.

Comprehensive Services and Support

Access Services is available to conduct installation, calibration and validation on-site. Millipore offers a proven validation protocol that tests the range of filters and tests used in a facility. Millipore Service Representatives offer factory or on-site maintenance and repair services.

The Requirement of Integrity Testing

Regulatory agencies require integrity testing of sterilizing grade filters as well as the integrity of process critical filters, such as bioburden reduction filters, which directly affect product quality. For production operators, supervisors, and validation managers who need to perform on-site filter integrity tests, the Integritest 4 instrument is a solution that is easy to learn and gives you the confidence and assurance you need for your test results. Users can conduct bubble point, diffusion, enhanced bubble point, HydroCorr and pressure hold tests on disk, cartridge and TFF filters, virus, and asymmetric membrane filters.

Specifications

Test Accuracy (at standard, stable conditions)

Test Type	Range	Accuracy
Diffusion (Standard and Accelerated)	Flow rates < 20 mL/min Flow rates ≥ 20 mL/min (water) Flow rates ≥ 20 mL/min (alcohol)	≤ 1mL/min ≤ 5% ≤ 10%
30 Second Diffusion*	Flow rates < 20 mL/min Flow rates ≥ 20 mL/min	≤ 2 mL/min ≤ 15% /−10%
Bubble Point (BP) Standard	345–6205 mbar (5–90 psig)	≤ 68.9 mbar (1 psig)
Bubble Point Asymmetric	345–6205 mbar (5–90 psig)	< 344.7 mbar (5 psig)
Accelerated BP Hydrophilic PVDF	345–6205 mbar (5–90 psig)	≤ 137.9 mbar (2 psig)
Accelerated BP Hydrophobic PTFE	345–6205 mbar (5–90 psig)	≤ 206.8 mbar (3 psig)
HydroCorr	Flow rates < 0.4 mL/min Flow rates ≥ 0.4 mL/min	≤ 0.02 mL/min ≤ 5%
Virus Diffusion	Flow rates < 20 mL/min Flow rates ≥ 20 mL/min	≤ 2 mL/mi ≤ 10%
Pressure Hold	Pressure drops < 68.9 mbar (1 psig) Pressure drops ≥ 68.9 mbar (1 psig)	≤ 3.5 mbar (0.05 psi) ≤ 5%

*Used in accelerated enhanced bubble point and asymmetric enhanced bubble point tests.

Test Reproducibility (at standard, stable conditions)

Coefficient of variation (CV) or standard deviation (sn−1)

Test Type	Range	Reproducibility
Diffusion*	Flow rates < 20 mL/min Flow rates ≥ 20 mL/min	sn−1 ≤ 2 mL/min CV ≤ 10%
All Bubble Point Tests	345–6205 mbar (5–90 psig)	CV ≤ 10%
HydroCorr	Flow rates < 0.4 mL/min Flow rates ≥ 0.4 mL/min	sn−1 ≤ 0.04 mL/min CV ≤ 10%
Virus Diffusion	Flow rates < 20 mL/min Flow rates ≥ 20 mL/min	sn−1 ≤ 2 mL/min CV ≤ 10%
Pressure Hold	Pressure drops < 68.9 mbar (1 psi) Pressure drops ≥ 68.9 mbar (1 psi)	sn−1 ≤ 6.9 mbar (0.1 psi) CV ≤ 10%

*Diffusion reproducibility is not specified for the 30 second diffusion test.

Test Specifications

Test Type	Configuration Range	Operating Range
Diffusion*	47 mm disks – 12 round x 30 in. systems Capsules to TFF systems	Diffusion rate: 1 – 750 mL/min Test pressure: 345–6550 mbar (5–95 psig)
Bubble Point (All Except Accelerated Hydrophobic)	47 mm disks – 3 round x 30 in. systems	Test pressure: 345–6205 mbar (5–90 psig)
Accelerated Hydrophobic Bubble Point	47 mm disks – 1 round x 30 in. systems	Test pressure: 345–6205 mbar (5–90 psig)
HydroCorr	47 mm disks (Aervent-50) – 3 round x 30 in. systems	Test pressure: 345–6205 mbar (5–90 psig) Flow rate: 0.01 – 10 mL/min
Virus Diffusion	25 mm disks – 3 round x 30 in. systems	Diffusion rate: 1 – 600 mL/min Test pressure: 345–6550 mbar (5–95 psig)
Pressure Hold	Up to 12 round x 30 in. systems	Test pressure: 345–6550 mbar (5–95 psig)

* Pneumatic flow rate is at least 2500 mL/min at 5516 mbar (80 psi). The operating range claim of 750 mL/min is based upon the qualification testing of a 12 x 30-inch filter configuration. However, the maximum physical capacity of the pneumatic module is 2500 mL/min, which enables integrity testing of large TFF systems.

Specifications (continued)

Power Requirements

Voltage	90–264 volts AC, 50/60 Hz
Current rating	3.5 amps

Compressed Gas

Inlet pressure	Clean, dry air or nitrogen source of 2.4–8.2 bar (35–120 psi) at least 1.03 bar (15 psi) greater than the highest test pressure
Operating pressure range	0.34–7.03 bar (5–102 psig)

Environmental

Storage temperature	−20 to 80 °C
Operating temperature	1 to 40 °C
Humidity	5 to 95%, non-condensing

Nominal Dimensions

Height	37.2 cm (14.6 in.)
Width	41.6 cm (16.4 in.)
Depth	25.4 cm (10.0 in.)
Weight	< 15 kg (32 lb)

Computer

Software operating system	Windows XP embedded
Port 1	5-pin DIN connector for service access
Port 2	PS/2 Bar code reader input
Port 3*	RJ45 for Ethernet connection

*Integritest 4N only

System Attributes

	Integritest 4* Instrument	Integritest 4N Instrument	Integritest 4N Used with PC Central IMT Software
Comprehensive library of integrity testing modes that include diffusion (standard, accelerated/virus); bubble point (standard/asymmetric/accelerated; enhanced BP; HydroCorr test; pressure hold	●	●	●
Intuitive, multilingual, easy to use 10.4 in. SVGA touch user interface	●	●	●
Rugged, portable industrial design	●	●	●
Developed according to GAMP 4 Guidelines	●	●	●
Network Ready		●	●
Ethernet printer support		●	●
Remote Integritest 4N database backup with Networked Attached Storage (NAS) or networked server PC		●	●
Automatic filter test report transfer and storage on a central repository with a NAS or networked PC when electronic signature requirements are met		●	●
Meets the technical requirements of 21 CFR Part 11		●	●
From a networked PC: – Add or change network definitions – Define users and user permissions – Track additiom and deletions of users – Track changing of passwords – Organize instruments into groups			● ● ● ● ●

* The Integritest 4 can be upgraded to an Integritest 4N instrument. Contact Millipore for details.

Ordering Information

Description	Catalogue No.
Integritest 4 Standalone Instrument**	XIT4 S00 01
Integritest 4N Instrument**	XIT4 N00 01
Integritest 4 External Valve Array	XIT4S PEVA 01
Integritest 4 Field Calibration Kit	XIT4SP FCA 01
Integritest 4 Printer Paper (3 pack)	P83071
Integritest 4 Printer Ribbon Cartridge (3 pack)	P83075
Integritest 4N Central IMT Software	XIT4N CIMT 01
Integritest 4 Inlet Tubing with Dessicant Air Filter	P83076

** Includes power cord, external valve array and operators manual

To Place an Order or Receive Technical Assistance

In the U.S. and Canada, call toll-free
1-800-MILLIPORE (1-800-645-5476)
In the U.S., Canada and Puerto Rico, fax orders
to **1-800-MILLIFX (1-800-645-5439)**
Outside of North America contact your local office.
To find the office nearest you visit **www.millipore.com/offices**
Internet: **www.millipore.com**
Technical Service: **www.millipore.com/techservice**

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