



- ▶ Network all of your Integritest Exacta instruments that feature networking capability
- ▶ Automates 21 CFR Part 11 electronic record keeping
- ▶ Easily share test methods, data and networked resources
- ▶ Secure data transfer and backup
- ▶ Developed and documented according to GAMP 4 guidelines

Integritest[®] Exacta IT3.OP Instrument and Instrument Management Tools

Optimize integrity testing work flow and automate 21 CFR Part 11 record keeping

The Integritest Exacta Instrument IT3.OP and Instrument Management Tools (IMT) create the ideal integrity testing system that will improve productivity through centralized management and reduced redundancy of using stand-alone instruments. Millipore Integritest Exacta Instruments conduct integrity tests, including in-process bubble point, diffusion, and HydroCorr™ tests on a wide range of membrane filter systems. Both hydrophobic and hydrophilic membrane filters are tested with the instrument. Integrity testing is not limited to Millipore filtration devices. Integritest Exacta Instruments conduct filter integrity tests on the upstream side of a filter system, which ensures sterility of the downstream connections.

The Integritest Exacta IT3.OP Instrument and IMT (IT3.OP system) can be integrated into a corporate network, used in an isolated network or the instruments can be used stand-alone.

Networking Capability Simplifies System Management and Optimizes Performance

Taking advantage of the network capability of the IT3.OP System will streamline many processes and save resources.

Increased Process Speed

An IT3.OP system provides the user with the ability to instantly transfer data throughout the organization for faster clearance of product batch after completed test(s).

Administrative Cost Savings

All integrity testing instruments can be managed directly from one central location through network communication. Common network resources are easily accessed and shared throughout the system.

Error Reduction

Only tests relevant to a specific process location can be accessed by the dedicated instrument.

Improved Product Quality

Quality trends can be analyzed from data stored in your organization's central repository.

Electronic Signatures

Sign the test report electronically after each test. The system provides for an electronic signature based on users Windows[®] accounts.

Centralized Data Repository

Test results and backup are all stored in a secured network location.

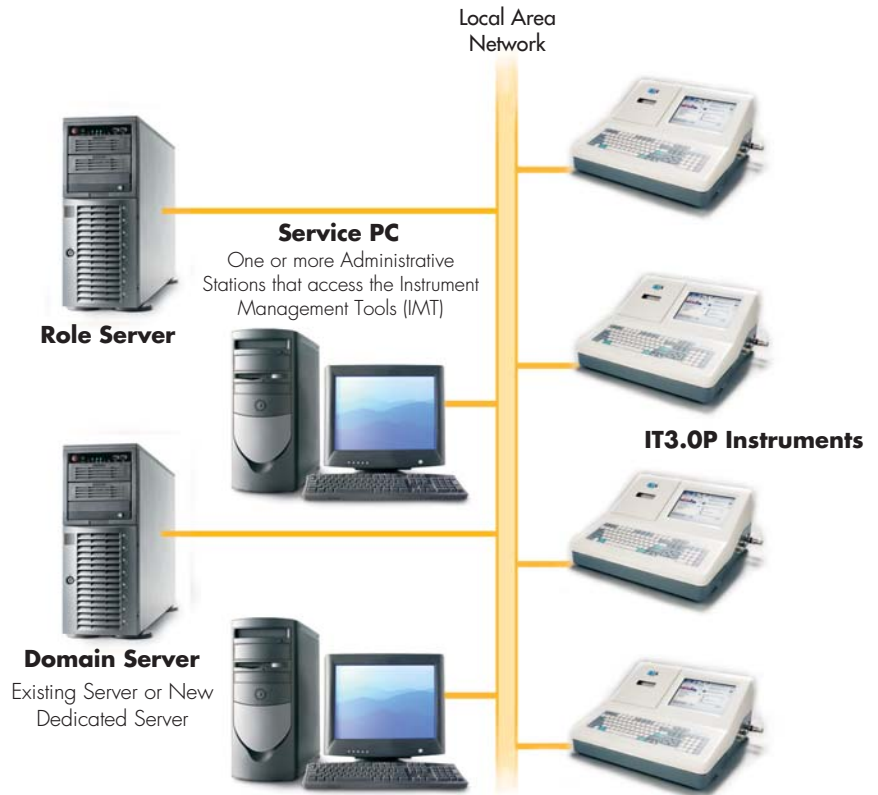
21 CFR Part 11 Compliance Ready

For production operators, supervisors, and validation managers who need to perform on-site filter integrity tests the IT3.OP System meets the technology requirements of 21 CFR Part 11, making it easy to integrate into a Part 11 compliant operation.

Expedite Instrument Validation

When utilizing the network capability you can quickly and easily validate your instruments administration once for all networked instruments. There is no need to validate the administrative functions of each Integrity Testing Instrument as is the case in a non-networked environment.

The IT3.OP System



Centralized administration and networking capability stream-line processes, work-flow and data transfer.

Millipore Integritest Exacta IT3.0P Instrument

Accurate Testing

The system has been designed and qualified to achieve high test accuracy. The software diagnoses and electronically calibrates the transducers and can check the functionality of the computer and pneumatic manifold components.

Easy to Use

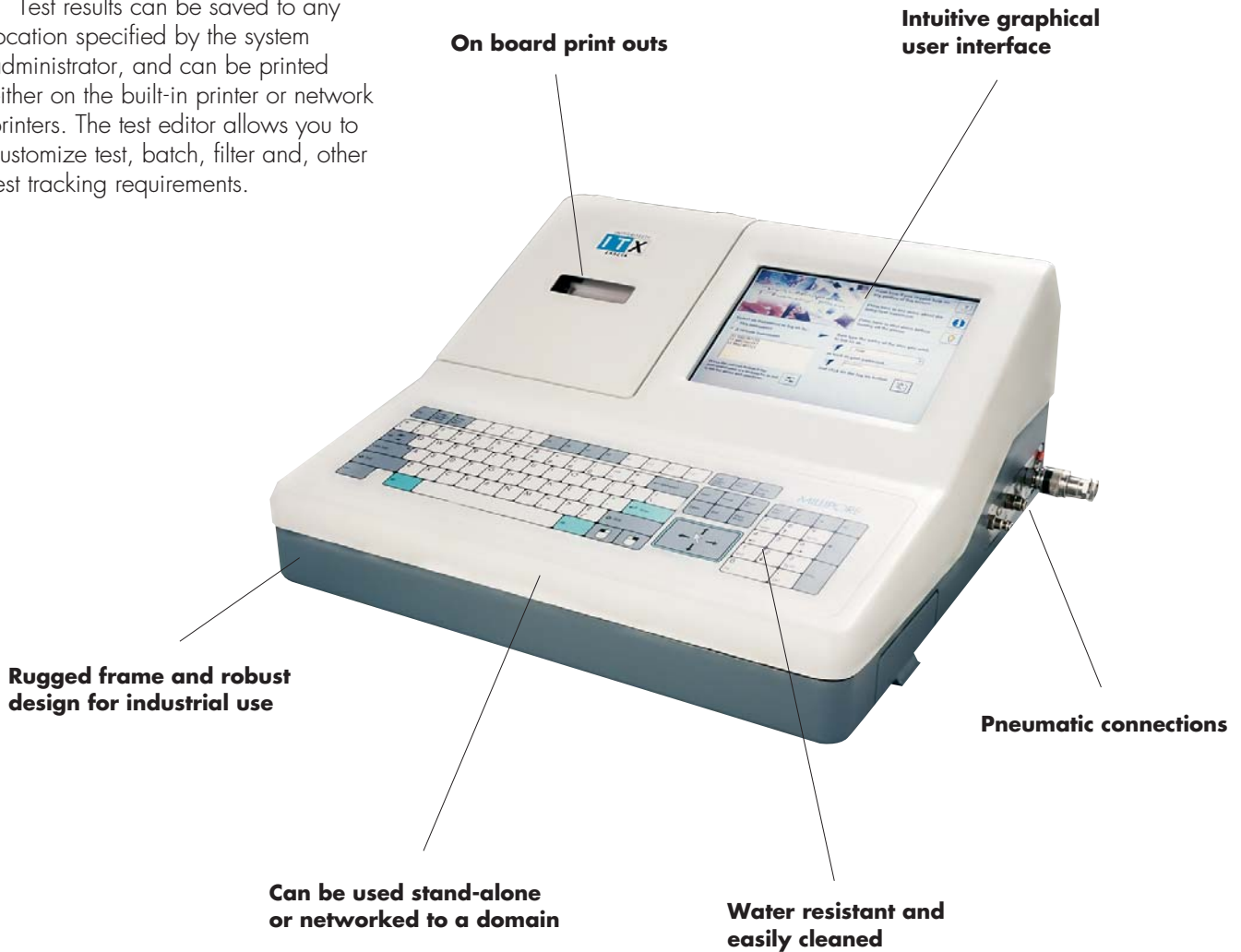
The Integritest Exacta Instrument features a graphical user interface with "point & click" menus and tool-bars. Millipore filter specifications for diffusion, bubble point, and HydroCorr tests are pre-loaded and customer specific filter testing information can easily be added on site.

Test results can be saved to any location specified by the system administrator, and can be printed either on the built-in printer or network printers. The test editor allows you to customize test, batch, filter and, other test tracking requirements.

Durable Construction

The Instrument is enclosed in a water and splash resistant IP54 compliant case with a built-in high efficiency filter that prevents generation of dust by the instrument and allows for clean-room compatibility.

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



Simplify Your Processes with IMT's Networking Capability.

Audit Trail

All changes to user, test, or instrument configuration are logged with the date, time and the name of the person that made the change. Centralized user, test and instrument management using the IMT functionality enables one location to configure multiple instruments at numerous locations.

Regardless of your network configuration, even if the instrument is not networked, instruments with IT3.OP software facilitate regulatory compliance, provide accurate and reproducible filter tests and allow secure management of user access, report data, and instrument settings.

Remote Backup

Historically the default software setting backed up database information to the floppy drive. Depending on the type of backup chosen and the amount of data on the instrument hard drive, this process may require several 3.5 inch floppy disks. You need to store disks in a secure location for retrieval of information for an audit or for restoration to the instrument hard drive.

Now, with IMT networking, the instrument sends the database information to a network location, eliminating the need for floppy disks. If the information needs to be restored, the IT3.OP software searches in the backup location and offers a list of the available files. When a file is selected, the software restores the data in the file from the remote location.

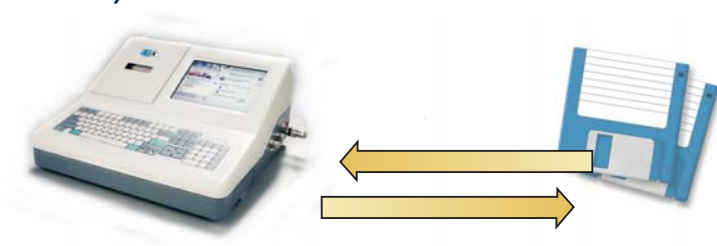
Report Transfer

You can configure the instrument to send completed filter test reports to a network location, such as a central data repository. The IMT sends a checksum file with the report file to verify that the report has not been altered. You can send any test report on the instrument to the central data repository, including archived test reports. Once a test report is successfully transferred, the test data can be removed from the test database to reduce its size.

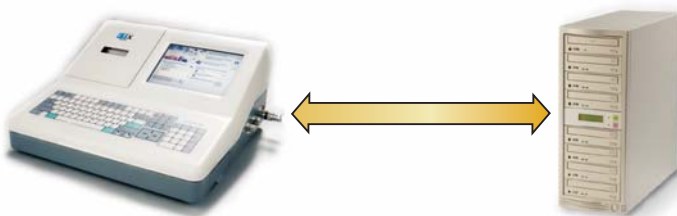


Remote Backup and Recovery

Historically



Now



Electronic Signatures

Electronic signatures can be applied to the reports when they are transferred to the central data repository. The name, date, time, and reason for signature are added to the report. The Instrument Management Tools can be configured to require a single signature, two signatures or no signature. Reports are not transferred to the central data repository until the required signatures are provided. The transferred report files contain the electronic signature information.

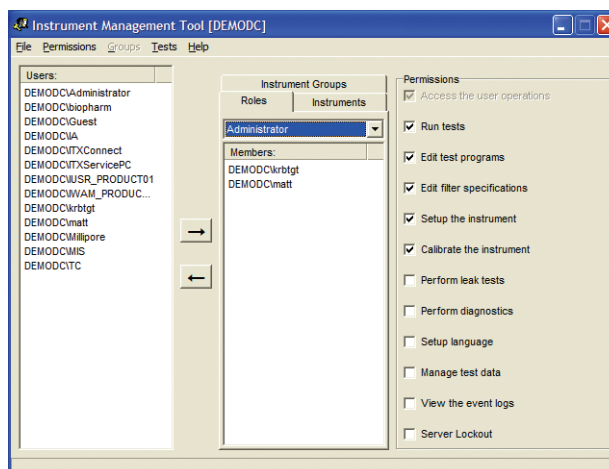
Directly connect the Instrument to a network and retrieve your data.

Improve Productivity

- Shorten processing time by instantly transferring data throughout the organization for quicker clearance of a product batch after a filter integrity test is completed.
- Reduce costs by managing all instruments directly from one location throughout the corporation—even globally—with network communication.
- Reduce errors by password-protecting access of tests for dedicated instruments in specific locations.
- Improve product quality by providing the capability to conduct trend analysis from data stored in your organization's central data repository.
- Provide electronic signatures based on Windows user accounts.

Exacta IT3.OP Instruments can be networked together in a common Ethernet LAN, which increases productivity by taking advantage of an existing network infrastructure. Network integration will not impact the general infrastructure strategy of the existing network. We recommend installing IMT and the instruments on a 21 CFR Part 11 compliant network and then verify compliance with the requirements of 21 CFR Part 11.

Networking allows an administrator to manage user, test, and single or multiple instrument information from a centralized location. A user can create a test on a Service PC in the network domain, and then add it to a group of instruments without having to access each instrument individually. The extent of the productivity gains is largely determined by the number of instruments deployed, their locations, and the state of the existing network.



Easily manage users, instruments, test and security with the Instrument Management tools (IMT).

Centralized User and Instrument Management

Managing user, test, and instrument information is easy with IMT. IMT is accessed from the Service PC desktop.

Centralized user management provides information on all of the accounts on the network domain. This allows you to assign users to various functions on the instrument without having to create IDs or assign passwords. Users assigned to the instrument log in with the same name and password they use elsewhere on the network. Any changes to a user account are applied to all instruments. For example, if a user's domain account is disabled by the MIS department that user will not be able to log in to any of the Integritest Exacta Instruments until the account is re-enabled.

Centralized instrument management allows administrators to configure instruments from the Service PC. Instruments may be consolidated into logical groups that have the same configurations. For example, adding a test to an instrument group adds that test to all instruments within that group.

Centralized Test and Filter Management

Test and filter specifications are managed through the Filter and Test Management Tool (FTMT) which is part of IMT. The FTMT is accessed from the Service PC.

A user can create new test and filter specifications on a single computer and then add them to multiple instruments on the network. This option eliminates the need to program a new test on each instrument saving time and greatly reducing input errors. Central management of test and filter specifications, when utilized properly, ensures that all instruments are using the same revision of the test and filter specifications.

Instrument Operation on a Domain

When an instrument is added to a network domain, it is in Domain mode. In this mode, user and instrument information comes from centrally-managed network computers. The instrument receives information at every successful login when it is connected to the domain.

The network also provides convenient access to the Service Interface controlling all the instruments on the network. Test records may be quickly retrieved from a central data repository.

PAT – Innovative Pharmaceutical Manufacturing and Quality Assurance

The Integritest Exacta version 3.OP is a perfect example of an instrument ready to be installed as part of a Process Analytical Technology (PAT) system. When using an Integritest Exacta version 3.OP, the final result of the filter integrity test (pass/fail) can be directly used by the PAT system to make a decision for the next processing step. As the instrument is integrated with the network that controls the PAT system, the speed of the manufacturing process will be significantly enhanced, without compromising quality control.

Performance Specifications

The Integritest Exacta IT3.OP Instrument has been qualified to the following performance specifications, under typical operating conditions:

Test Accuracy

Test type	Range	Accuracy (error)
Bubble Point	5–90 psi (345-6200 mbar)	≤ 1 psi (70mbar)
Diffusion	Flow rates < 20 mL/min	≤ 1 mL/min at 23 °C
	Flow rates ≥ 20 mL/min	≤ 5% for water ≤ 10% for IPA mixtures
HydroCorr	Flow rates < 0.4 mL/min	≤ 0.02 mL/min
	Flow rates ≥ 0.4 mL/min	≤ 5%

Test Reproducibility (coefficient of variation “CV” or standard deviation “SD”)

Test type	Range	Reproducibility
Bubble Point	5–90 psi (345-6200 mbar)	CV ≤ 10%
Diffusion	Flow rates < 20 mL/min	SD ≤ 2 mL/min
	Flow rates ≥ 20 mL/min	CV ≤ 10%
HydroCorr	Flow rates < 0.4 mL/min	SD ≤ 0.04 mL/min
	Flow rates ≥ 0.4 mL/min	CV ≤ 10%

Operating Conditions

Test type	Range	Reproducibility
Diffusion	47 mm filter discs to 12 round x 30 in. systems	
	TFF systems with diffusion specifications up to 2500 cc/min.	
Bubble Point	47 mm filter discs to 3 round x 30 in. systems	
HydroCorr	47 mm filter discs to 3 round x 30 in. systems	

System Sizing

Error within 5% of an independent measurement (i.e., gravimetric or volumetric).

Operating Specifications

Power Requirement

Electrical: 100–240 Volts AC, 50 or 60Hz

Compressed Gas

System Inlet Pressure: Clean, dry air or nitrogen source of 35–125 psi (2.4–8.5 bar), at least 15 psi (1 bar) greater than the highest test pressure.

System Operating Pressure: 0–100 psig (0–6.9 bar)

Environmental

Storage Temperature: -20 °C to +40 °C, dry

Operating Temperature: 4 °C to +40 °C

Humidity Range: 5% to 95%, non-condensing

Dimensions

Height (nominal): 8 inch (21 cm)

Width (nominal): 19 inch (49 cm)

Depth (nominal): 21 inch (54 cm)

Weight: < 40 pounds (18kg)

Instrument Controls

The Integritest Exacta IT3.OP instrument is controlled by a Pentium processor and features a keyboard with touch-pad mouse and numeric keypad. Full-size keys with tactile response make entering information easy. The ten inch (25 cm) LCD display makes viewing easy. A universal input switching power supply accepts input voltages of 100-240 VAC at frequencies of 50-60 Hz so that the instrument can be used in any country without a voltage converter. A disc drive allows local backup or data transfer.

The ethernet communication port allows for a full network hook-up, enabling data backup and central management of tests and users. It also provides for automatic result distribution and network printing. The inkjet printer prints on 3-inch plain-paper.

Operating System

The IT3.OP instrument uses a customised version of Microsoft Windows XP® Embedded as the operating system and supports multi-lingual user interfaces for both the IMT and instrument.

Languages

All menus, data and help screens, and reports can be displayed in one of several languages including English, French, Spanish, German, Italian and Japanese.

Network Requirements

To install the Integritest Exacta IT3.OP Instrument and IMT over a network, you need a domain controller with Windows 2000 server. To take advantage of the IT3.OP system's 21 CFR compliance ready design, it must be installed on a 21 CFR Part 11 compliant network.

Ordering Information

Description	Catalogue No.
The Integritest Exacta 3.OP Instrument includes instrument loaded with Instrument Management Tool Software (CD with Service Software) and the Users Operating Manual.	XITXACTP130P
The Integritest Exacta 3.OP Upgrade Kit includes a 3.OP hard drive, networking cable assembly, Instrument Management Tool (CD with Service Software) and the Users Operating Manual.	XITXSP173PKT
Users Operating Manual (3.OP)	XITX30PUOM
Administrators Service Manual (3.OP)	XITX30PASM
Validation Guide (3.0)	VG052P
CD For Service PC (Instrument Management Tool)	P88288
Integritest Exacta IT3.OP Instrument Spare Parts and Accessories	
Test Gauge, Calibration Pressure	XITXSP114
Ink Cartridges (3/Pk)	XITXSP105
Paper Rolls (5/Pk)	XITXSP133
Paper Roll Rods (2/Pk)	P80033
Loop-Back Tubing Assembly	XITXLBTA
Inlet Tubing Assembly	XITXSP159
Outlet Tubing Assembly	XITXSP160
Fan Filter	XITXSP110
Inlet Gas Filter	XITXSP111
Printer Cable	XITXSP206
Power Cord 115 V	XITXSP141
Power Cord 240 V	XITXSP142
Main Power Fuse	P80037
Box, Shipping	XITXSP102
Hard Drive w/Software, O/S (3.OP)	XITXSP173P

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