

Integritest® Exacta Integrity Instrument

- Easy to validate, highly accurate, easy-to-use automatic integrity tester for the regulated biopharmaceutical industry



Regulatory agencies such as the FDA, EMEA and MCA require integrity testing of sterilizing-grade filters. For production operators, supervisors, and validation managers who need to perform on-site filter integrity tests, Millipore's Integritest Exacta Integrity Instrument provides the highest level of confidence in the regulated biopharmaceutical industry. The Integritest Exacta is designed to comply with the FDA regulation 21 CFR Part 11. Users can conduct bubble point, diffusion, enhanced bubble point and HydroCorrSM (water-based test for hydrophobic filters) tests on disk, cartridge and TFF filters.

Complete Validation

- Designed for compliance with the FDA regulation 21 CFR Part 11 (Electronic Records; Electronic Signatures).
- Final System Qualification (FSQ) includes testing on a wide range of actual disk, cartridge, and TFF filters.
- Software meets or exceeds industry software standards and Millipore's software quality assurance plan.
- The Integritest Exacta (ITX) instrument can be validated on-site to conform to cGMP standards for software and computer validation.

Accurate

- Test processes and algorithms have been designed and qualified to achieve high test accuracy (bubble point error ≤ 1 psi, diffusional flow rate error ≤ 1 mL/min).
- Software for diagnosing and electronically calibrating the transducers and automatically checking the functionality of the computer and pneumatic manifold components is included.

Easy to Use

- The ITX features a graphical user interface with "point & click" menus and toolbars, based on the Microsoft NT[®] operating system.
- Millipore filter specifications for diffusion, bubble point, and HydroCorr tests are pre-loaded. Other filter testing information can easily be added on site.
- Test results can be printed either on the built-in printer or via the parallel port to any Windows[®] compatible external printer.
- Context-sensitive help screens provide instruction on demand.
- Test results are saved to a local database and can be searched by the test, batch number or date.
- Test editor screen fields can be customized to include operator, batch, or other desired data.

Industrial Design

- Rugged case.
- Water and splash resistant (IP54 compliant).
- Clean room compatible—built-in high efficiency filter prevents generation of dust by the instrument.
- Easy wipe design with surfaces compatible with alcohol, bleach and dilute sodium hydroxide.

Pneumatics

Pressure regulators

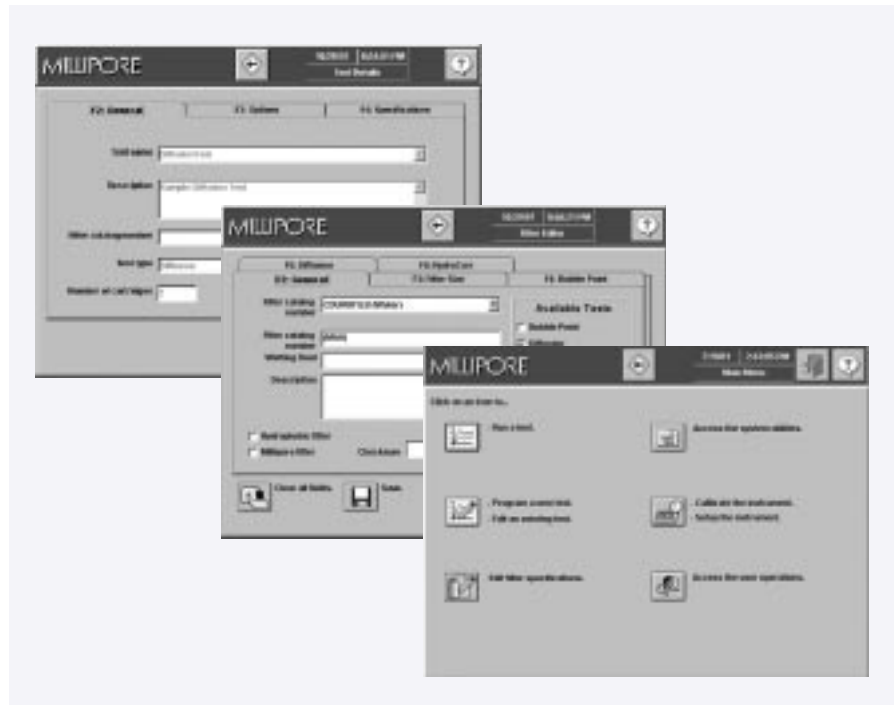
The electronic inlet pressure regulator self-regulates inlet gas pressure up to 100 psi (6.5 bar). Simply hook it up to facilities air (or regulated nitrogen/air tank) and the ITX will regulate the pressure depending upon the test pressure required. Inlet gas will be cleaned and dried by the purifier that is part of the tubing assembly.

Valves

A solenoid feed valve, solenoid tank select valve, external pneumatic exhaust pilot valve and pneumatic exhaust valve all control pressurization of the filter housing. This provides automatic control of pressurized air to instrument and to housing. All Exacta valves are chosen to ensure maximum tightness for improved accuracy. Direct attachment to the manifold minimizes the risk of leaks which improves accuracy due to less "noise" in the pressure decay value.

The ITX can be set up to relieve housing pressure in two ways:

1. The housing pressure can be vented from the exhaust valve as located within the pneumatic manifold assembly.
2. The exhaust valve can be located remotely from either the ITX instrument and/or the housing. This can be advantageous for clean room applications or explosion proof areas. In this setup, the housing pressure can be vented to a different location.



Internal tank

The internal reference tank has a tightly controlled gas volume. This ensures accuracy in the final flow rate calculation.

Pressure Transducers

Highly accurate absolute pressure transducers enable the pressure decay values to be accurately determined, translating into accurate flow rates for diffusion, bubble point, enhanced bubble point and HydroCorr tests.

Computer

- Pentium processor.
- Full function membrane keyboard with touchpad mouse and numeric keypad is easy to clean. Full-size keys with tactile response makes entering information easy.
- 10" (25 cm) active color matrix LCD 640 x 480 screen with VGA output is a bright, large color screen that makes viewing test information easy.
- Universal input switching power supply accepts input voltages of 100-240 VAC at frequencies of 50-60 Hz. The ITX can be used in any country without a voltage converter.

- 3.5" (1.4 MB) floppy disc drive allows saving to diskette for backup or data transfer.
- Built-in hard disk drive permits test software, filter specifications, and filter test results to be stored easily.
- Instrument-grade inlet and outlet connections on the pneumatic manifold assembly minimize leaks, providing more accurate results.
- Ethernet communication port allows data backup and recipe administration.
- The inkjet printer prints results on 3" plain-paper.
- Parallel port, DB 25 pin, permits connection to an external printer.

Operating System

The Integritest Exacta Integrity Instrument uses Microsoft NT as the operating system and is available in either Pan-European or Japanese versions.

Integrity Test Software

The Integritest Exacta test software has the capability to run diffusion, bubble point, enhanced bubble point and HydroCorr tests and can test hydrophilic and hydrophobic filters. The integrity test software features a graphical user interface to program and run integrity tests. Test information can be saved after programming the specifications.

Languages

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

Test Specifications

The Integritest Exacta Integrity Instrument has pre-loaded specifications for Millipore filters, which are automatically imported with a selected filter when programming diffusion, bubble point, enhanced bubble point and HydroCorr tests.

Operational Requirements

Electrical

100-240 Volts AC, 50 or 60 HZ

Compressed Gas

System Inlet Pressure:

Clean, dry air or nitrogen source of 35–125 psi (2.4–8.6 bar), but at least 15 psi (1.0 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

Accessories

The following accessories are included with the ITX:

- Operating Manual
- Certificate of Quality
- Tubing assembly, inlet, with air filter
- Tubing assembly, outlet, with 2-way instrument valve and water trap
- Tubing Loop-Back Assembly
- Plain paper rolls (5 pack)
- Paper Roll Rod
- Power cords, 110V European and cable ending in a standard female computer-style connection
- Inkjet Cartridge (3 pack)
- Millipore Software license agreements
- Registration Return Envelope

Regulatory Compliance



CE Requirements

The Integritest Exacta Integrity Instrument, complies with the following directives and standards:

89/336/EEC, EMC Directive

- EN 50082-1:1992
Electromagnetic compatibility, generic residential, commercial and light industrial immunity standard
- EN 55011:1991
Group 1 Class B ISM emission requirements
- EN 55022:1998
Class A emission requirements
- EN 61000-3-2:2000
EMC limits for harmonic current emissions
- EN 61000-3-3:1995
EMC limitation of voltage fluctuations and flicker
- IEC 801-2
Electrostatic Discharge
- IEC 801-3
Radiated RF
- IEC 801-4
Fast Transient Burst



73/23/EEC, Low Voltage Directive

- EN61010:1993
Safety requirements for electrical equipment for measurement, control, and laboratory use
- The testing simulates a typical operating environment. Testing is performed to assess compliance with EMC-harmonized standards for emissions, immunity, and low-voltage (safety). The Integritest Exacta Integrity Instrument is shipped with a Declaration of Conformity (self-certification) to the EMC Directives.

Physical Characteristics

Height (nominal):

8 inches (20 cm)

Width (nominal):

19 inches (48 cm)

Depth (nominal):

21 inches (53 cm)

Weight:

< 39 pounds (18 kg)

Specifications

The ITX has been qualified to the following performance specifications, under typical operating conditions:

Test Accuracy

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

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

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

The ITX will operate within the listed specifications for the following test configurations, under typical operating conditions:

Test type	Configuration Range	Considerations
Diffusion	47 mm disks 12 round x 30" systems	Maximum diffusion rate: 2500 mL/min at 40 psi (2760 mbar)
	Capsules to TFF systems	Test pressure: 5–90 psi (345-6200 mbar) Minimum diffusion rate: 1 mL/min
Bubble Point	47 mm disks	Test pressure 5–90 psi (345-6200 mbar)
	3 round x 30" systems	Granularity: bubble point intervals < 0.5 psi (30 mbar)
HydroCorr	47 mm disks (Aervent 50) 3 round x 30" systems	Test pressure 5–90 psi Flow rate: 0.01–100 mL/min

System Sizing

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

Ordering Information

Description	Catalog No.
Integritest Exacta	XITX ACT P1
Integritest Exacta Japanese Version	XITX ACT P2
Printer Inkjet cartridges (3 pack)	XITX SP1 05
Fan Filter	XITX SP1 10
Inlet Air Filter	XITX SP1 11
Reference Pressure Equipment	XITX SP1 14
Thermo Plug	XITXTP
Loop-Back Tubing Assembly	XITXLBTA
Printer Paper Rolls (5 pack)	XITX SP1 33
Rods (2 pack)	P80033
Housing Temperature Sensor	XITX SP1 54
Inlet Tubing Assembly	XITX SP1 59
Outlet Tubing Assembly	XITX SP1 60
Operating System (English)	XITX SP1 71P
Operating System (Japanese)	XITX SP1 74P
Inlet/Outlet Tubing	XITX SP1 80
Network Cable	XITX SP1 94
Serial Cable	XITX SP1 96
External Printer Cable (parallel)	XITX SP2 06
Shipping box	XITX SP1 02
O&M Manuals:	
English	XITX SP1 21P
French	XITX SP1 22P
Spanish	XITX SP1 23P
Italian	XITX SP1 24P
German	XITX SP1 25P
Japanese	XITX SP1 26P

To Place an Order or Receive Technical Assistance

For additional information call your nearest Millipore office:

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)**

Internet: www.millipore.com

Tech Service:

www.millipore.com/techservice

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