

Integritest® 5 Instrument

Catalog Number: IT5INS001

Includes:

- North American power cord
- TTU International Power Cable, IP54
- Male Staubli to 1.5" TC End Cap
- Male Staubli to 3/4" TC End Cap
- Inlet Tubing Assembly
- Outlet Tubing Assembly
- Internal Printer Paper (3 pack)
- CE Declaration of Conformity
- Certificate of Quality
- Operator and Equipment Safety Guide
- Quick-start Guide



Power Cable:

Please order your local power cable in addition to the instrument.

Power Cable by Country	Catalog Number
Power Cord North America (included in IT5INS001)	P83065
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 Switzerland	PWRCABLECH
Power Cable China	PWRCABLECN
Power Cable Denmark	PWRCABLEDK
Power Cable Italy	PWRCABLEIT
Power Cable South Korea	PWRCABLEKR
Power Cable Taiwan	PWRCABLETW
Power Cable South Africa, India, Pakistan	PWRCABLEZA

Materials Of Construction

- Polyurethane tubing
- Stainless steel
- Aluminum chassis
- Solid state silicon device
- Lithium battery
- Copper wire
- Piezo-electronic polymer

The flow path does not contain animal content.

Design Properties

Physical Characteristics

Height: 9.1 inches (23.1 cm)

Width: 15.4 inches (39.1 cm)

Depth: 17.0 inches (43.2 cm)

Weight: 10.5 kg

Hardware

- Pressure regulators and sensors
 - Inlet pressure regulator (voltage controlled, 2 to 105 psig)
 - Tank Pressure Sensor (Gauge transducer, 0 to 102 psig)
 - Housing Pressure Sensor (Absolute transducer, 0 to 117 psia)
- Internal tank (predetermined gas volume reference)
 - Stainless steel cylinder tank (500 cc nominal)

UI Computer

- Computer operating system: Windows® 10
- Computer solid state drive \geq 64GB nominal
- Computer RAM: \geq 4GB, shared with video
- Computer CPU: AMD Embedded G-Series, 1.6 GHz or faster

UI Display

- Tilt angle (screen face of system): 20° (stand down); 34° (stand up)
- Display type: Color active matrix TFT LCD, LED backlighting, projected capacitive touch interface
- Display size: 10.1 in nominal diagonal
- Display resolution: 1024 × 600 pixels (WSVGA)
- Display Viewing angle: $\pm 45^\circ$ typical (90° total), horizontal; -15° +35° typical (50° total), vertical

Printer

- Printer type: Direct thermal
- Print Speed Up to 5.2 Lines per Second
- Serial data input
- 3 in. Plain Paper

Test Module Controller

- Windows® CE operation systems
- I/O board with built-in A/D and D/A converters

Main Power Supply

- 100-240 Vac; 50/60Hz

Pneumatic Ports

- Staubli male connector for pressure inlet supply
- Rectus male connector for upstream filter connection
- Female tube connector for pneumatic exhaust

Communication Ports

- 2 USB communication
- 1 RJ45 Ethernet port

Software Design Properties

User role access rights

- Operators: run tests, print reports, and sign reports
- Supervisors: Operator + sign reports as the second electronic signature (optional)
- Service: Operator + editing, settings, tools, and calibration
- Instrument managers: Service + sign reports as the second electronic signature (optional)
- Administrators: Instrument manager + Windows® access

Multi-Language UI Support

- Chinese Simplified
- English
- French
- German
- Italian
- Japanese
- Korean
- Portuguese
- Spanish

Performance Properties

Operational

The instrument is designed to operate in a pharmaceutical manufacturing plant, including designed to support wet rooms and clean room standards for low particulate levels.

- Ambient Temperature: 1 to 40 °C.
- Ambient Humidity: 50% at 40 °C to 80% at 31 °C non-condensing
- Altitude: –80 to 2000 meters
- Atmospheric pressure: Hardware has been designed so that atmospheric pressure fluctuation of ± 0.1 inches water does not provide a false positive test result.
- Ingress Protection Rating: The instrument is compliant to IP54
- Noise level: 24 dB average, 65 dB maximum during exhaust step at 1m from front of instrument

Non-Operational

- Ambient Temperature: -20 to 60 °C
- Ambient Humidity: 10% to 90% non-condensing
- Shipping Validation: meets ISTA 2A packaged products partial simulation testing requirements
- External surfaces are compatible with the following sanitizing agents:
 - Hydrogen peroxide (3%)
 - Quaternary Ammonium Compounds (0.2%)
 - Formaldehyde (37%)
 - Alcohol (isopropyl alcohol) (70%)
 - Sodium Hypochlorite (NaOCl) (5.2%)
 - Sodium Hydroxide (NaOH) (2%)
 - Spor-Klenz®

Tests

Test accuracy (at standard and stable conditions):

Test type	Range	Accuracy
Diffusion	Flow rates < 20 mL/min (water)	± 1 mL/min
	Flow rates ≥ 20 mL/min (water)	± 5%
	Flow rates < 20 mL/min (alcohol)	± 2 mL/min
	Flow rates ≥ 20 mL/min (alcohol)	± 10%
Bubble Point	5 – 90 psig	± 1 psig
Bubble Point Asymmetric	5 – 90 psig	± 5 psig
HydroCorr™ Test	Flow rates < 0.4 mL/min	± 0.02 mL/min
	Flow rates ≥ 0.4 mL/min	± 5%
Virus Diffusion	Flow rates < 20 mL/min	± 2 mL/min
	Flow rates ≥ 20 mL/min	± 10%
Pressure Hold	Pressure drops < 1 psig	± 0.05 psig
	Pressure drops ≥ 1 psig	± 5%

Test reproducibility (coefficient of variation, CV or standard deviation, sn-1):

Test type	Range	Accuracy
Diffusion	Flow rates < 20 mL/min	sn-1 ≤ 2 mL/min
	Flow rates ≥ 20 mL/min	CV ≤ 10%
Bubble Point	5 – 90 psig	CV ≤ 10%
HydroCorr™ Test	Flow rates < 0.4 mL/min	sn-1 ≤ 0.04 mL/min
	Flow rates ≥ 0.4 mL/min	CV ≤ 10%
Virus Diffusion	Flow rates < 20 mL/min	sn-1 ≤ 2 mL/min
	Flow rates ≥ 20 mL/min	CV ≤ 10%
Pressure Hold	Pressure drops < 1 psi	sn-1 ≤ 0.1 psi
	Pressure drops ≥ 1 psi	CV ≤ 10%

The Integritest® 5 Instrument operates within the listed specifications for:

Test Type	Configuration Range	Operating Range
Diffusion	47 mm disks – 12 round × 30" systems	Diffusion rate: 0.5 – 600 mL/min Test pressure: 5 – 95 psig
Bubble Point	13 mm disks – 3 round × 30" systems	Test pressure: 5 – 90 psig
HydroCorr™ Test	47 mm disks – 3 round × 30" systems	Test pressure: 5 – 90 psig Flow rate: 0.01 – 10 mL/min
Virus Diffusion	25 mm disks – 12 round × 30" system	Diffusion rate: 0.5 – 600 mL/min Test pressure: 5 – 95 psig
Pressure Hold	0.1 – 100L without pre-pressurization	Test pressure: 5 – 60 psig

Operational Requirements

Electrical

- 100-240 Vac; 50/60Hz
- Fuse type 2A, 5×20 mm

Gas Supply

- Clean dry air
- Maximum inlet pressure: 120 psi
- Minimum inlet pressure: 15 psi greater than the test pressure is recommended

Spare Part Numbers

Description	Part Number
Male Staubli to 3/4" TC End Cap	IT5SP0001
3/8" Barb Filter Test Accessory Kit	IT5SP0002
Housing Interface Module (HIM) Assembly	IT5SP0003
Housing Interface Module (HIM) Cleaning Fixture	IT5SP0004
Adapter Kit, 9/16 HB, 5/8 HB, 1/4 NPTM	IT5SP0005
Male Staubli to 1.5" TC End Cap	IT5SP0006
TTU International Power Cable	IT5SP0007
Inlet Tubing Assembly	IT5SP0008
Outlet Tubing Assembly	IT5SP0009
Calibration Token	IT5SP0010
Fuse Glass 2A 250VAC 5×20MM	IT5SP0012
Cover, Tube Storage	IT5SP0013
F1 Filter Assembly, Water Trap	IT5SP0014
Inline Pneumatic Filter Assy	IT5SP0015
Ancillary material kit - Collection of all Power Cords, Hoses, etc. that comes standard with Integritest® 5 Instrument	IT5SP0016
Packaging Kit - Spare Set of Shipping Boxes/Foam	IT5SP0017
Transport Kit - Hard-shell-type carrying case	IT5SP0018
Spare Part, Integritest Thermal Paper	XIT4TPRTP3
Spare Tubing, 100 ft	XITXSP180

Regulatory Information

Copyright information

- Microsoft® License agreement: The Integritest® 5 Instrument includes a Microsoft® license, which pertains to the Microsoft® operating system.

Regulatory and Safety:

- The Integritest® 5 instrument was developed and validated according to GAMP5 Guidelines.
- Designed to support 21 CFR Part 11 compliance, the Integritest® 5 instrument captures electronic data and allows the data to be printed, but protects against access and manipulation by the end user. An Integritest® 5 test report should be printed, signed and dated immediately after test completion and used for regulatory activities. Reports and signatures cannot be altered. By validating the system and implementing procedural controls, the Integritest® 5 instrument can be implemented and operated in compliance with FDA regulations.
- This product is CE marked to self-declare compliance to the applicable European directives through the use of EN compliance standards. Please refer to the products Declaration Of Conformity for further details.
- This product meets the electrical safety requirements for North America through the application of UL/CSA 61010-1 3rd edition for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General requirements. The product has also been evaluated to the international equivalent IEC 61010-1 3rd edition standard.
- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. EMC part: CFR Title 47 Part 15 subpart B Class A for USA; ICES-003, issue 5, Class A for Canada and IEC as certified according CB scheme (registration number DE3-30198) 61326-1:2013; EN55011 2009/2010 A1 class A for EU
- This device is an unintentional radiator. Please be aware that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

For additional information, please visit **MerckMillipore.com**.
To place an order or receive technical assistance, please visit
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MerckMillipore.com

Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt, Germany

