



INTEGRITY TESTER SYSTEM



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ISOLATOR | STERILE TRANSFER CABIN
INTEGRITY TESTER | MICROBIAL CONSUMABLES

INTELLIGENT WIRELESS GLOVE INTEGRITY TESTER



Product Introduction

Gloves are the weakest link in a protective barrier isolation system and are the most critical part of an aseptic filling line because they come into direct contact with the operator and are a major source of potential contamination.

GTS enables wireless, paperless and ductless wireless testing for accurate and repeatable testing of glove and cuff integrity, i.e. detecting perforations not visible to the naked eye.

Product Features

- ▶ Wireless connection with PC, inspection data can be transmitted wirelessly.
- ▶ Complies with 21CFR Part 11 certification requirements for electronic records and electronic signatures.
- ▶ Complies with computerized validation with audit trail capabilities.
- ▶ Data can be made non-modifiable and can be integrated into production reports in real time.
- ▶ Administrator, processor, operator three levels of user rights, to meet the GMP computer rights management requirements.
- ▶ RFID radio frequency scanning code, glove code automatic identification, without manual input.
- ▶ It can realize group control of multiple equipments and simultaneous start/stop control of single or multiple equipments with real-time fault alarm.
- ▶ Built-in lithium-ion battery, wireless external power supply.
- ▶ Built-in micro air pump, no need for external compressed air.
- ▶ Equipped with military standard triple-proof tablet PC, it can be operated with gloves, which is safe and meets the requirements of clean room.
- ▶ Formulation management, different brands or different thicknesses of gloves can be set up according to the data provided by the manufacturer or the manufacturer of the isolation device test method.
- ▶ Replaceable test flanges, different cuff opening sizes just need to change the test flange, no need to change the test unit.



Stand-alone glove testing system



Group control glove testing system

Safety At Your Fingertip



Comply with GB/T25915.7-2010/ISO 14644-7:2004/2020 edition of Pharmacopoeia (ChP) and other laws and regulations.



Gloves can be tested for integrity and traceability in situ.



Minimize the risk of contamination with the new Glove Leak Tester (GTS).

Technical Parameters

▶ Maximum set inflation pressure for glove cavity	2000Pa	▶ Testing time	5~8min
▶ Maximum inflatable pressure of the seal	0.2MPa	▶ Weights	4.0kg/unit
▶ Continuous working time	8h	▶ Internal battery	12V lithium ion battery
▶ Pressure display resolution	0.1Pa	▶ Charging time	≤4h

*1 to N group control smart glove integrity test system can be configured according to the actual needs.

INTELLIGENT WIRELESS GLOVES/RTP INTEGRITY TESTER



Product Introduction

The wireless glove/RTP integrity testing system meets the requirements of the new 2023 GMP guidelines/G-B/T25915.7-2010/ISO 14644-7:2004/2020 edition of the Pharmacopoeia and other regulatory requirements, is powerful and easy to operate.

The wireless glove integrity test end and the wireless transmission device integrity test end can be connected to the same set of control management software at the same time for operation and data recording to ensure data integrity, software.

The system meets the requirements of 21CFR part11 electronic records and electronic signatures.

GTS-WLAN Wireless Glove Integrity Tester (Test Side)

Product Introduction

Gloves are the weakest link in a protective barrier isolation system and are the most critical part of an aseptic filling line because they come into direct contact with the operator and are a major source of potential contamination.

GTS enables wireless, paperless and ductless wireless testing for accurate and repeatable testing of glove and cuff integrity, i.e. detecting perforations not visible to the naked eye.



Stand-alone glove testing system

Product Features

- ▶ Wireless connection with PC, inspection data can be transmitted wirelessly.
- ▶ Complies with 21CFR Part 11 certification requirements for electronic records and electronic signatures.
- ▶ Complies with computerized validation with audit trail capabilities.
- ▶ Data can be made non-modifiable and can be integrated into production reports in real time.
- ▶ Administrator, processor, operator three levels of user rights, to meet the GMP computer rights management requirements.
- ▶ RFID radio frequency scanning code, glove code automatic identification, without manual input.
- ▶ It can realize group control of multiple equipments and simultaneous start/stop control of single or multiple equipments with real-time fault alarm.
- ▶ Built-in lithium-ion battery, wireless external power supply.
- ▶ Built-in micro air pump, no need for external compressed air.
- ▶ Equipped with military standard triple-proof tablet PC, it can be operated with gloves, which is safe and meets the requirements of clean room.
- ▶ Formulation management, different brands or different thicknesses of gloves can be set up according to the data provided by the manufacturer or the manufacturer of the isolation device test method.
- ▶ Replaceable test flanges, different cuff opening sizes just need to change the test flange, no need to change the test unit.

Technical Parameters

▶ Maximum set inflation pressure for glove cavity	2000Pa	▶ Testing time	5~8min
▶ Maximum inflatable pressure of the seal	0.2MPa	▶ Weights	4.0kg/unit
▶ Continuous working time	8h	▶ Internal battery	12V lithium ion battery
▶ Pressure display resolution	0.1Pa	▶ Charging time	≤4h

TTS-WLAN Wireless Transmission Unit Integrity Tester (Test Side)

Product Introduction

Wireless and pipeless integrity tester for DPTE® Alpha and Beta containers.

The TTS allows you to check the integrity of the DPTE® system before or after a product's production cycle during the confined transfer of material in and out of an isolator or isolator in other classified environments, or between processes during storage in sterile containers. The TTS allows for wireless, paperless, and tubeless wireless testing for accurate and repeatable testing of the integrity of Alpha and Beta containers, i.e., detecting perforations that are not visible to the naked eye. invisible perforations.

Product Features

- ▶ Wireless connection with PC, inspection data can be transmitted wirelessly.
- ▶ Complies with 21CFR Part 11 certification requirements for electronic records and electronic signatures.
- ▶ Complies with computerized validation with audit trail capabilities.
- ▶ Data can be made non-modifiable and can be integrated into production reports in real time.
- ▶ Administrator, processor, operator three levels of user rights, to meet the GMP computer rights management requirements.
- ▶ It can realize group control of multiple equipments and simultaneous start/stop control of single or multiple equipments with real-time fault alarm.
- ▶ Built-in lithium-ion battery, wireless external power supply.
- ▶ Built-in micro air pump, no need for external compressed air.
- ▶ Equipped with military standard triple-proof tablet PC, it can be operated with gloves, which is safe and meets the requirements of clean room.
- ▶ Formulation management, different brands or different thicknesses of gloves can be set up according to the data provided by the manufacturer or the manufacturer of the isolation device test method.
- ▶ Replaceable test flanges, different cuff opening sizes just need to change the test flange, no need to change the test unit.

Technical Parameters

▶ Maximum set inflation pressure for glove cavity	±5000Pa	▶ Testing time	3min
▶ Maximum inflatable pressure of the seal	0.2MPa	▶ Weights	4.0kg/unit
▶ Continuous working time	8h	▶ Internal battery	12V lithium ion battery
▶ Pressure display resolution	0.1Pa	▶ Charging time	≤4h



Group Control Glove/RTP Test System

SINGLE USE SYSTEM INTEGRITY TESTING SYSTEM



Product Introduction

As disposable technology becomes more prevalent in the pharmaceutical industry, disposable systems including e.g., reservoir bags, disposable bioreactors, cell factories, etc., require a higher level of assurance of the integrity of the single-use systems (SUS) used in the processing steps of raw materials and drug products.

Disposable systems may be damaged in the manufacturing process, transportation or operation, integrity testing of disposable systems before use can achieve "early detection of problems" and reduce the risk of product obsolescence, in the use of the disposable system after the end of the waste disposal of disposable systems before the integrity test to confirm the integrity of the disposable system throughout the entire production process, used to support the release of the product.

Single-Use System (SUS) integrity testing is necessary when products have the potential for liquid leakage and microbial invasion.



- Comply with the 2020 version of the drug and other laws and regulations, the 2023 new version of the GMP guidelines and other laws and regulations.
- Enhance regulatory compliance and accelerate drug production capacity to ensure market availability.
- Allows integrity and traceability testing of disposable systems.



- Minimize the risk of contamination by using disposable system integrity testers. Improve operator safety.
- Avoid process downtime and batch losses and prevent the risk of loss of high value products in the commercial phase.

The current worldwide requirements for integrity testing of disposable systems are as follows (for information only).

Country/geography	File	Pre-use integrity testing		Post-use integrity testing
		Pre-sterilization	Post-sterilization	
EU	Regulations	Unnecessary	Mandate	Mandate
WHO	Regulations	Unnecessary	Mandate	Mandate
Japan	Regulations	Unnecessary	Mandate	Mandate
USA	Regulations	Optional (based on risk control)		Mandate
	Guide	Optional (based on risk control)		Mandate
China	Regulations	Not mentioned		Mandate
	Guide	Optional (Based on risk control)		Mandate
South Korea	Regulations		Mandate	Mandate
India	Regulations		Mandate	Mandate

BTS-P50/100 Single-use System Integrity Tester

Product Features

- ▶ Operation screen selection 10.4" large industrial-grade color touch PC, the operation of the use of more comfortable and smooth.
- ▶ Each test port can work independently, can simultaneously test the same or different models and specifications of the disposable system, and each port has an independent data report.
- ▶ Complies with 21CFR Part 11 certification requirements for electronic records and electronic signatures.
- ▶ Compliance with computerized validation requirements with audit trail functionality.
- ▶ Complies with GAMP5 regulatory requirements.
- ▶ Data entry is made easier and safer with barcode/2D code scanners.
- ▶ Drain function after the completion of the test: after the completion of the test through the active pumping, will be disposable system residual gas, rapid exhaust off.
- ▶ Administrator, processor, operator three levels of user rights, to meet the GMP computer rights management requirements.
- ▶ Longer print retention period with needle printers instead of thermal printing.
- ▶ Detailed electronic test report in PDF format can be output, including temperature and pressure change curves for the entire test cycle, with better data integrity.
- ▶ Recipe management, different brands or different disposable systems can be set up with different test recipes according to the test parameters provided by the manufacturer.
- ▶ Modular design, optional detector air supply system module, to achieve the use of no compressed air environment.
- ▶ A complete package of validation documents to provide users with the most reliable support.



Technical Parameters

▶ Measurement range	Test pressure: 0.3KPa~30KPa	▶ Power supply requirements	AC220V, 10A
	Pressure drop: 0.03KPa~30KPa		▶ Maximum power
▶ Measurement accuracy	±0.1%FS	▶ Dimension	Detection system 560×430×280mm(WxDxH) Air supply system 560×430×190mm(WxDxH)
▶ Operating environment	Ambient temperature: 15°C~35°C		▶ Maximum operating pressure
	Ambient humidity: 5~95%RH	▶ Minimum Input Pressure	0.4MPa
▶ Operating screen	Configuration: Industrial Panel PC		▶ Weights
	Size: 10.4" TFT LCD	▶ Detection accuracy	
	Waterproof rating: IP65		

BTS-P10 Single-use System Integrity Tester

Product Features

- Operation screen selection 10.1" large color touch screen, the operation of the use of more comfortable and smooth.
- With 1or2 test ports to enhance testing efficiency.
- Each test port can work independently, and can test the same or different models and specifications of disposable systems at the same time, and each port has independent test data.
- A scanning gun can be used to scan the barcode or QR code of the product to be measured to get the information of the product to be measured, which makes data entry easier and safer.
- With logging, recipe selective download function.
- Compliance with regulatory requirements.
- Drain function after the completion of the test: after the completion of the test through the active pumping, will be disposable system residual gas, rapid exhaust off.
- Administrator, processor, operator three levels of user rights, to meet the GMP computer rights management requirements.
- Longer print retention period with needle printers instead of thermal printing.
- Electronic test reports can be output in PDF format.
- Recipe management, different brands or different disposable systems can be set up with different test recipes.
- Compact design, small size and weight, space-saving and easy to carry.
- The metal casing can be cleaned and wiped with various disinfectant solutions.
- A complete package of validation documents to provide users with the most reliable support.



Technical Parameters

➤ Number of test ports on a single host	1or2 test Ports	➤ Power Supply	AC 220V,50Hz
➤ Sensor Accuracy	0.1%FS	➤ Power	120W
➤ Detection Accuracy	≥30μm	➤ Weights	18kg
➤ Test Range	0~10kPa	➤ Dimension	315×420×385mm(WxDxH)
➤ Air Input Pressure	0.4~0.6Mpa		