Glove Integrity Tester

Introduction

In pharmaceutical production, barrier systems like isolators or RABS are essential for protecting both personnel and products. A critical aspect of these systems is the thorough and regular inspection of glove integrity. The glove integrity tester is the key equipment used to assess the sealing of gloves.

GIT-WLAN
（Wireless）

GIT-WLAN02
(Wireless)

GIT-WLAN03
(Wireless)

GIT-MINI02
(Standalone)

Applications

◉ Pharmaceutical and Biotechnology Aseptic Production

GMP Mandatory Requirements:

According to EU GMP Annex 1, glove integrity testing must be performed at defined time intervals, and at least at the beginning and at the end of each production batch.

◉ Food Industry Safety Control

Detection of pinhole defects in food processing gloves, in compliance with HACCP system requirements, to prevent microbial contamination from hands.

◉ High-Risk Industrial Protection

Chemical Industry: Detection of the sealing integrity of acid/alkali-resistant and organic solvent-resistant gloves to prevent chemical permeation and burns.
Nuclear Industry: Verification of the integrity of radiation-protection gloves to minimize the risk of contact with radioactive substances.

◉ Scientific Research and Special Environments

University Laboratory Teaching and Research: Enhancing safety operation standards for laboratory personnel.
Environmental Monitoring / Hazardous Waste Disposal: Protection against corrosive media, in compliance with OSHA, EPA and other regulatory requirements.

Features

Regulatory Compliance

Complies with ISO 14644-7 for repeatable, verifiable testing;
Meets 21 CFR Part 11 for electronic records and signatures;
CE Certified, CNAS Certified

CNAS Certificate

CE Certificate

Glove No. Code

RFID technology automatically identifies the glove number and includes it in the test results

Temperature Monitoring

The high-precision temperature sensor provides an accuracy of ±0.1℃ in detecting temperature differences during testing

Detection Accuracy

Leak rate detection limit can reach 100μm (under certain test parameters and test conditons)

Convenience

2-hour fast charging, universal charging port
Offline testing, exportable PDF reports
Quick port switching

Temperature Sensor

User-friendly interaction

Online calibration

SCADA System

· Data Recording
· Recipe Configuration
· Reporting
· User Management

WIFI router

HMI

WIFI router

· Recipe Development
· Test Start/Activation

Tablet

RFID Identification

Unlimited number of units

RFID Identification

Zone 1

Zone 2

Centralized Glove Testing Strategy

Core Technology:
AI Algorithm Deeply Integrated with Glove Characteristics

Current glove integrity testing mainly uses the pressure decay method, but its accuracy is limited by sensitivity and interference, falling short of pharmaceutical standards. Tailin developed a novel leak detection algorithm based on glove deformation and pressure response. Using dual-control experiments and nonlinear regression, the system compares real-time test curves with reference curves, enabling precise detection of 100μm micropore leaks.
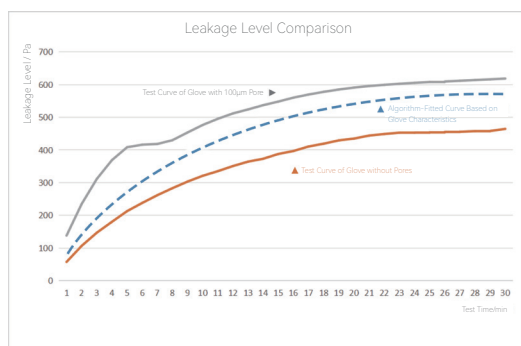
Algorithmic Curve
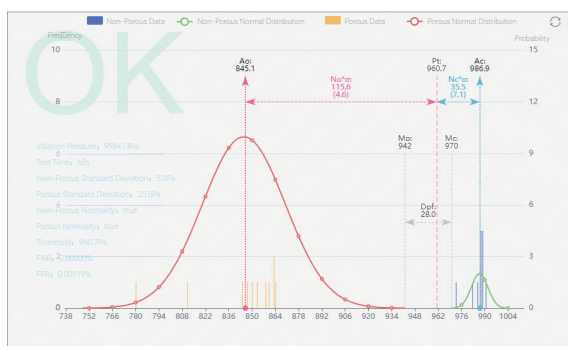
PQ Validation Curve

Yes: ● / No: ●		GIT-MINI02	GIT-WLAN	GIT-WLAN02	GIT-WLAN03
1	Built-in Power & Air Supply	●	●	●	●
2	Built-in Filter	●	●	●	●
3	100-Micron Detection Accuracy	●	●	●	●
4	Replaceable Test Port	●	●	●	●
5	Touch Screen	●	●	●	●
6	Centralized Glove Management	●	●	●	●
7	WIFI/Bluetooth Printing	●	●	●	●
8	Built-in Mini Printer	●	●	●	●
9	Standalone PDF Export	●	●	●	●
10	Audit Trail	●	●	●	●
11	Access Control	●	●	●	●
12	Temperature Monitoring	●	●	●	●
13	Auto Glove ID Recognition	●	●	●	●
14	Clock Synchronization	●	●	●	●
15	1M+ Data Storage Capacity	●	●	●	●
16	PC Data Storage	●	●	●	●
17	Auto Recipe Analysis	●	●	●	●
18	Manual Air Release Valve	●	●	●	●

Software Introduction

The glove integrity management system can simultaneously monitor multiple glove integrity testers online and is capable of integrated online control with the Tailin RTP integrity tester. The system automatically generates batch reports from collected data and supports e-signature technology and audit trail functionality. It is fully compliant with GMP requirements for computer system validation and meets the FDA 21 CFR Part 11 regulations regarding electronic data integrity, e-signatures, and audit trails.

Supports e-signature; Optional e-signature module

Supports recipe customization
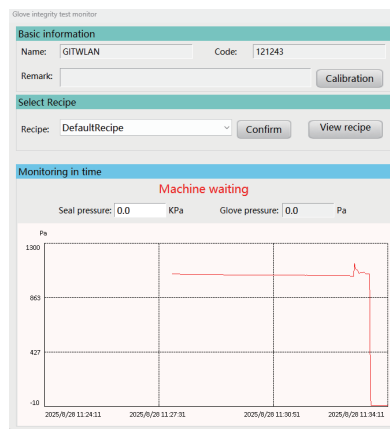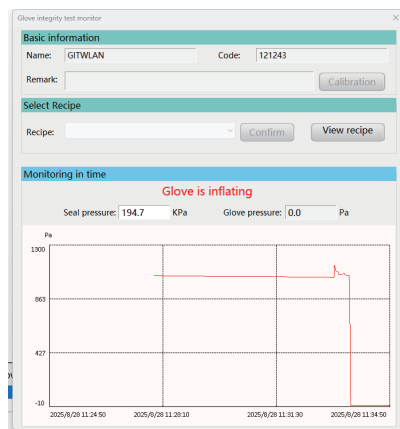
Supports online monitoring of test data
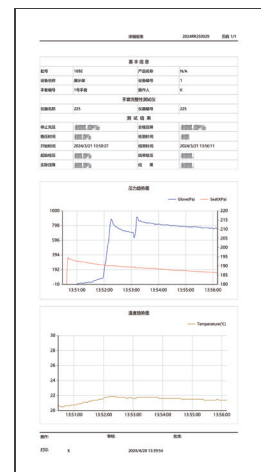
Supports output of detailed reports

Software Functions

- Upper-level control and data acquisition software for easy observation and operation
- Fully automatic monitoring of glove and seal pressure changes
- Wireless PC connection with data transmission
- Monitoring system supports multi-level permission groups
- Self-developed glove testing management system meeting industry needs
- Multiple test setup programs to meet diverse testing needs
- Optional dedicated tablet available
- Unlimited number of glove integrity testers can be monitored simultaneously
- Rigorous data review process in compliance with e-signature requirements

GIT-WLAN03

Main Functions

- **Visualized testing process**
- Compact, portable design for easy use
- Supports quick switching of test ports for different gloves
- Microcontroller-based control with color LCD display
- Built-in air pump, no external compressed air required
- Quick replacement of standard 18650 battery for extended operation
- Up to 8 hours of standby time
- Wireless connection to monitoring system
- RFID technology for automatic glove ID recognition
- Upper-level control and data acquisition software for easy observation and operation
- Ultra-fast inflation system with airtight connection adapter, compatible with all standard and custom glove flanges
- Designed for integrity testing of sleeves/gloves in RABS and isolator systems before or after use
- Clean and user-friendly operation in compliance with GMP standards
- GMP/FDA-compliant design, supporting IOQ and PQ
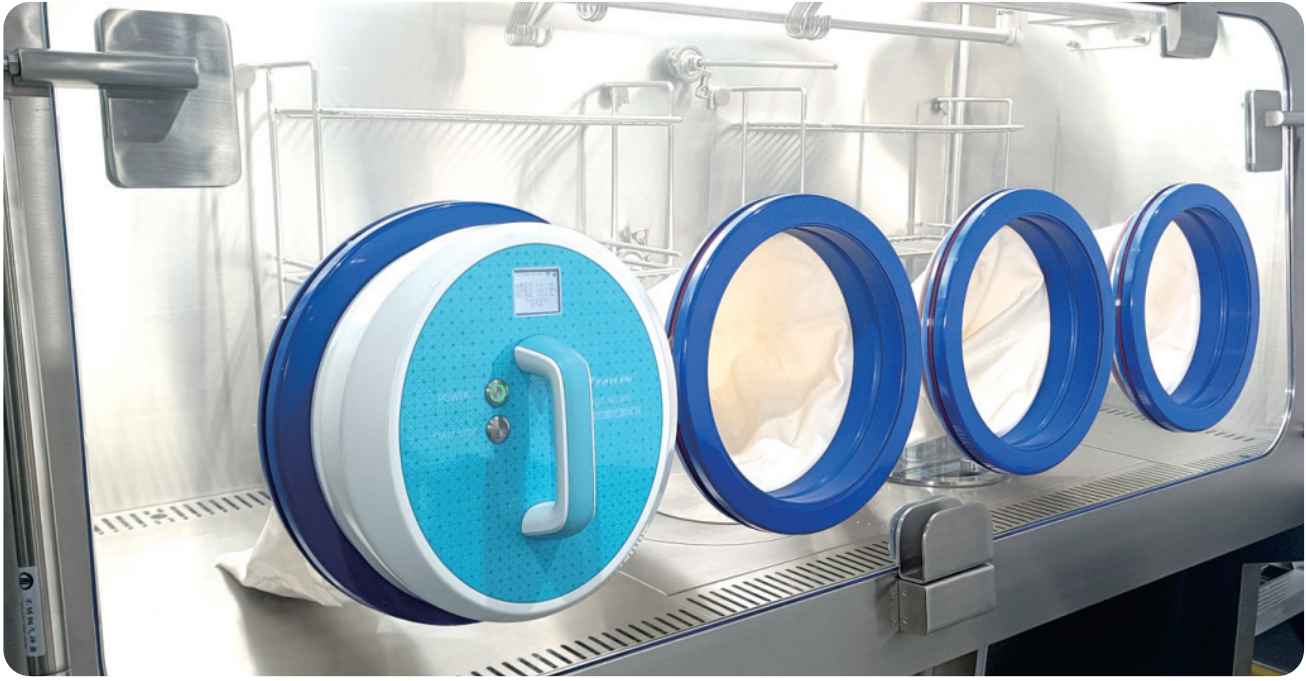- Repeatable and verifiable testing procedures in accordance with ISO 14644-7

Features

- Touchscreen login, user-traceable records
- Test results exportable as PDF directly from the device
- Temperature monitoring for more accurate testing
- Internal/external integrity testing, external mode tests both glove and flange seal
- Wireless PC connection and data transmission, supports third-party server integration
- RFID technology automatically identifies the glove number and includes it in the test results
- Fully automatic monitoring of glove and seal pressure changes
- Monitoring system supports multi-level permission groups
- Self-developed glove testing management system meeting industry needs
- Optional tablet PC for clean room
- Unlimited number of glove integrity testers can be monitored simultaneously
- Rigorous data review process in compliance with e-signature requirements

Technical Parameters

Smallest Detectable Hole	100μm
Single Test Time	≤6min
Temperature Monitoring Accuracy	±0.1℃
Communication	WIFI
HMI	4.3-inch display + 10.5-inch tablet
Dimensions	Φ280mm×125mm
N.W.	≤3kgs
Battery	12V Lithium battery
Continuous Working Time	Fully charged, ≥4 hours
Customized	Glove flange interface can be customized

GIT-WLAN02

Main Functions

- In-situ testing, no sleeve/glove removal
- Compact, portable design for easy use
- **Supports quick switching of test ports for different gloves**
- Microcontroller-based control with color LCD display
- Built-in air pump, no external compressed air required
- Replaceable battery, no need to wait for a recharge
- Up to 8 hours of standby time
- Wireless connection to monitoring system
- RFID technology for automatic glove ID recognition
- Upper-level control and data acquisition software for easy observation and operation
- Ultra-fast inflation system with airtight connection adapter, compatible with all standard and custom glove flanges
- Designed for integrity testing of sleeves/gloves in RABS and isolator systems before or after use
- Clean and user-friendly operation in compliance with GMP standards
- GMP/FDA-compliant design, supporting IOQ and PQ
- Repeatable and verifiable testing procedures in accordance with ISO 14644-7

Features

- Internal/external integrity testing, external mode tests both glove and flange seal
- Wireless PC connection and data transmission, supports third-party server integration
- RFID technology automatically identifies the glove number and includes it in the test results
- Fully automatic monitoring of glove and seal pressure changes
- Monitoring system supports multi-level permission groups
- Self-developed glove testing management system meeting industry needs
- Optional tablet PC for clean room
- Unlimited number of glove integrity testers can be monitored simultaneously
- Rigorous data review process in compliance with e-signature requirements

Technical Parameters

Inflation Pressure	500~2500Pa
Test Time	3min~6min
Pressure Display Resolution	0.1Pa
Smallest Detectable Hole	100μm
N.W.	≈3kg
Dimensions	Φ280mm×150mm
Battery	12V Lithium battery
Power	≤20W
Continuous Working Time	≥4 hours
Communication	WIFI

GIT-WLAN

Main Functions

- In-situ testing, no sleeve/glove removal
- Compact, portable design for easy use
- Microcontroller-based control with color LCD display
- Built-in air pump, no external compressed air required
- Replaceable battery, no need to wait for a recharge
- Up to 8 hours of standby time
- Wireless connection to monitoring system
- RFID technology for automatic glove ID recognition
- Upper-level control and data acquisition software for easy observation and operation
- Ultra-fast inflation system with airtight connection adapter, compatible with all standard and custom glove flanges
- Designed for integrity testing of sleeves/gloves in RABS and isolator systems before or after use
- Clean and user-friendly operation in compliance with GMP standards
- Supporting IOQ and PQ
- GMP/FDA-compliant design
- Suitable for RABS and isolator systems
- Repeatable and verifiable testing procedures in accordance with ISO 14644-7

Features

- Internal/external integrity testing, external mode tests both glove and flange seal
- Wireless PC connection and data transmission, supports third-party server integration
- RFID technology automatically identifies the glove number and includes it in the test results
- Fully automatic monitoring of glove and seal pressure changes
- Monitoring system supports multi-level permission groups
- Self-developed glove testing management system meeting industry needs
- Optional tablet PC for clean room
- Unlimited number of glove integrity testers can be monitored simultaneously
- Rigorous data review process in compliance with e-signature requirements

Technical Parameters

Inflation Pressure	500~2500Pa
Test Time	3min~6min
Pressure Display Resolution	0.1Pa
Smallest Detectable Hole	100μm
Continuous Working Time	≥4 hours
Dimensions	Φ280mm×150mm
N.W.	≈2.6kg
Battery	12V Lithium battery
Power	≤20W
Communication	WIFI

GIT-MINI02

Features

- In-situ testing, no sleeve/glove removal
- Compact, portable design for easy use
- Battery-powered design, no external power required
- Built-in air pump, no external air source required
- Microcontroller-based control with 4.3' touchscreen display
- Good human-computer interaction interface, easy to observe and operate
- Replaceable battery, no need to wait for a recharge
- Up to 8 hours of standby time
- Wireless connection to monitoring system
- RFID technology for automatic glove ID recognition
- Upper-level control and data acquisition software for easy observation and operation
- Designed for integrity testing of sleeves/gloves in RABS and isolator systems before or after use, in compliance with ISO14644-7
- Fully automatic monitoring of glove and seal pressure changes
- Multiple recipe options for various glove testing needs
- RFID technology for automatic glove ID recognition
- Three-level user access control

Technical Parameters

Detection Port Dia	Φ255mm or customized
Input Pressure	>0.2MPa
Inflation Pressure	500~2500Pa
Test time	3min~6min
Pressure Display Resolution	0.1Pa
Smallest Detectable Hole	100um
N.W.	≈2.5kg
Dimensions	Φ280mmx125mm
Battery	12V Lithium battery
Charging Time	4 hours
Power	≤20W
Continuous Working Time	≥4 hours
Data Handling	Online micro-printing, USB export
Data Storage	10000 records

GIT-MINI02

Comparison with GIT-MINI

Model	GIT-MINI02	GIT-MINI
Test Ports	Replaceable	Custom ports, non-replaceable
Test Control	Fully automatic	Manual control
Data Handling	Online micro-printing, USB export	Manual record-keeping
Common Media	Built-in air pump	External air supply
HMI	4.3-inch touchscreen	None
Access Control	three-level access control	None

Charging Trolley

Introduction

The charging Trolley is a dedicated device designed for use with the Glove Integrity Tester. It provides convenient storage and enables easy transport of the tester to the required testing location.

Technical Parameters

Supporting Equipment	With 6 glove integrity testers
HMI	4.3"touch screen + 10.5" tablet
Communication	WIFI
Dimensions(mm)	1210x450x1085
N.W.	≈85kg
Power Supply	220V，50Hz
Power	0.15kW
Options	1. With built-in lithium battery (up to 10 device recharges per full charge) 2. Without lithium battery (real-time power supply during charging only)

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