

GISTOOL Glove Integrity Testing System

GISTOOL-50 / 100



Product Overview

The GISTOOL series by Biodeconta is an advanced glove integrity testing solution engineered for aseptic manufacturing and cleanroom environments. Fully compliant with GMP requirements and ISO 14644-7 Annex E.5, the system employs the pressure decay method to deliver precise, repeatable test results.

With wireless group control, the GISTOOL system supports an unlimited number of connected devices, enabling centralized management across multiple workshops and facilities. Enterprise groups with multiple plants can deploy a single software platform to manage all sites independently. Data storage is compatible with all mainstream databases for seamless enterprise system integration.

The GISTOOL product line offers two models to meet varying operational requirements:

GISTOOL-50

Standard configuration for essential glove integrity testing



GISTOOL-100

Enhanced configuration with extended detection capabilities



GISTOOL Series Highlights

Both GISTOOL models share a common set of core advantages that deliver European-grade performance at a highly competitive price point.

Key Features

► **Accurate & Reliable**

Accuracy of $\pm 0.2\%$ F.S. for standard technical expression.

► **Excellent Performance**

Minimum detectable aperture of 100 μm (GISTOOL-100) / 200 μm (GISTOOL-50, 100 μm optional)

► **RFID Identification**

Automatic device identification via RFID for seamless networking with unlimited connected units.

► **External Calibration Interface**

Both models feature a built-in external differential pressure sensor calibration port, allowing convenient connection to third-party pressure calibration equipment for on-site verification.

► **Patented Quick Release**

Patented quick-release flange design enables tool-free glove port adapter changeover in seconds.

► **Single / Group Control Mode**

Flexible standalone or group control operation. Scale from a single unit to an unlimited fleet across multiple facilities.

► **Standard BL22 High-Performance Battery**

widely available for convenient replacement

► **GTM Glove Lifecycle Management**

The GTM (Glove Test Management) software delivers full lifecycle glove tracking, including physical attributes (brand, model, material), installation compliance records (replacement dates, reasons), and historical test reports — enabling streamlined regulatory compliance and data management.

Software & Compliance

The GISTOOL series is powered by a Browser/Server (B/S) architecture, delivering enterprise-grade software capabilities with 21 CFR Part 11 compliance built in.

Software Architecture	B/S (Browser/Server)
Installation	Server-based
User Permissions	Multi-level, customizable permission range
Electronic Signature	Yes
Data Storage	Server-based
Data Recovery	Automatic backup
Map Editing	Yes
Alarm Module	Yes
Audit Trail	Yes
Glove History Tracking	Yes
Password Policy	Yes
Batch Report	Yes
Auto Upload (after disconnecting)	Yes
21 CFR Part 11	Compliant
Aperture PQ Test	Yes
Built-in Calibration	External only (GISTOOL-50) / Built-in + External (GISTOOL-100)

Testing Methodology

GISTOOL employs the pressure decay detection method. The built-in inflation pump pressurizes the glove cavity to the configured set point. Following a stabilization period, measurement begins once pressure stabilizes at the defined start value.

If the measured pressure decay remains within the acceptable threshold during the test window, the glove integrity is confirmed and the result is recorded as PASS. If the decay exceeds the threshold, the result is recorded as FAIL, indicating a potential leak.

Technical Specifications Comparison

Parameter	GISTOOL-50	GISTOOL-100
Group Control Function	Supported, unlimited devices	Supported, unlimited devices
Communication Method	WIFI	WIFI, LoRa (Optional)
Multi-level Permissions	Support, customizable	Support, customizable
Audit Tracking	Yes	Yes
Operation Screen	7-inch capacitive touch	7-inch capacitive touch
Operation Method	Local + Group control	Local + Group control
RFID	Yes	Yes
Glove Cavity Test Pressure	0–2000 Pa	0–2000 Pa
Pressure Resolution	0.1 Pa	0.1 Pa
Sensor Accuracy	0.2% F.S.	0.2% F.S.
Sensor Stability	≤ 0.5%/yr	≤ 0.5%/yr
Pressure Sensor Range	0–2000 Pa	0–2000 Pa
Seal Pump Max	0.25 MPa	0.25 MPa
Min. Detection Aperture	200 μm(100 μm Optional)	100 μm
Working Environment	0–50°C; 5%–90% RH	0–50°C; 5%–90% RH
Storage Temperature	0–60°C; 5%–90% RH	0–60°C; 5%–90% RH
Dimensions (mm)	280×230×75	245 ×180 ×130
Weight	1.8 kg	1.6 kg
Glove Ring Flange	Size customization (patented quick release)	Size customization (patented quick release)
Battery	External replaceable lithium	External replaceable lithium
Continuous Working Time	≥ 4 hours	≥ 4 hours
Testing Time	≤ 8 min (+ ~5 min prep/200 μm)	≤ 8 min (+ ~5 min prep/200 μm)
Power	< 10 W	< 10 W
Sensor Metering Mode	Yes	Yes
Efficient Filtration	No	Yes (Optional)
Quick Release	Yes (Patented)	Yes (Patented)
Mode Switch	No (Optional)	Yes
Certification	EN61326-1:2013; EN61000-3-2:2014; EN61000-3-3:2013/CE/FCC	EN61326-1:2013; EN61000-3-2:2014; EN61000-3-3:2013/CE/FCC