BIODECONTA

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Glove Integrity Testing System

GISTOOL

www.biodeconta.com

Hardware advantages

Glove Integrity Testing System **GISTOOL**

Pressure decay test | Different performance versions are available | Circle mouth quick release patent | Sensor metering mode | RFID identification at the ring entrance

Replaceable removable battery | The minimum detection pore size is 100 μm | Wifi/Lora wireless connection | USB data export

The Biodecorta Glove Integrity Tester GISTOOL is a product in China that excels in both performance and appearance. On the basis of fully referring to the relevant provisions of GMP and ISO 14644-7 Appendix E.5, this product is tested using the pressure attenuation method. At present, the product versions are the basic version of GISTOOL-50 glove integrity testing system, the upgraded version of GISTOOL-100 glove integrity testing system, and the brand new version of GISTOOL-150 glove integrity testing system for users to choose from.

Host accessories

The product configuration is fully equipped

1. Device host
2. Customized Ring Mouth (Quick Disassembly Patent)
3. Server, tablet, router
4. Charger, aviation case, user manual, trolley

Matching gloves

Meet customer customization needs

1. Main manufacturers:PIERCAN、NORTH（HONEYWELL）、RotAdler
2. Main materials: CSM (Hypalon), nitrile
3. Main dimensions: 7 inches, 8 inches, 10 inches, 12 inches
4. Ring type: circular, elliptical
5. Assembly method: formal or reverse

The product is easy to operate and does not require additional software installation

Fully meet customer needs with comprehensive functional configuration

Glove integrity test **GISTOOL**
Focused on sterile isolation devices

Multi level permission management | Meet audit tracking requirements | Visual testing | electronic signature | User Rating Management

Glove lifecycle management | Customize test parameters | Customized glove ring mouth

According to GB/T25915.7-2010/ Research and development of ISO 14644-7:2004 standard

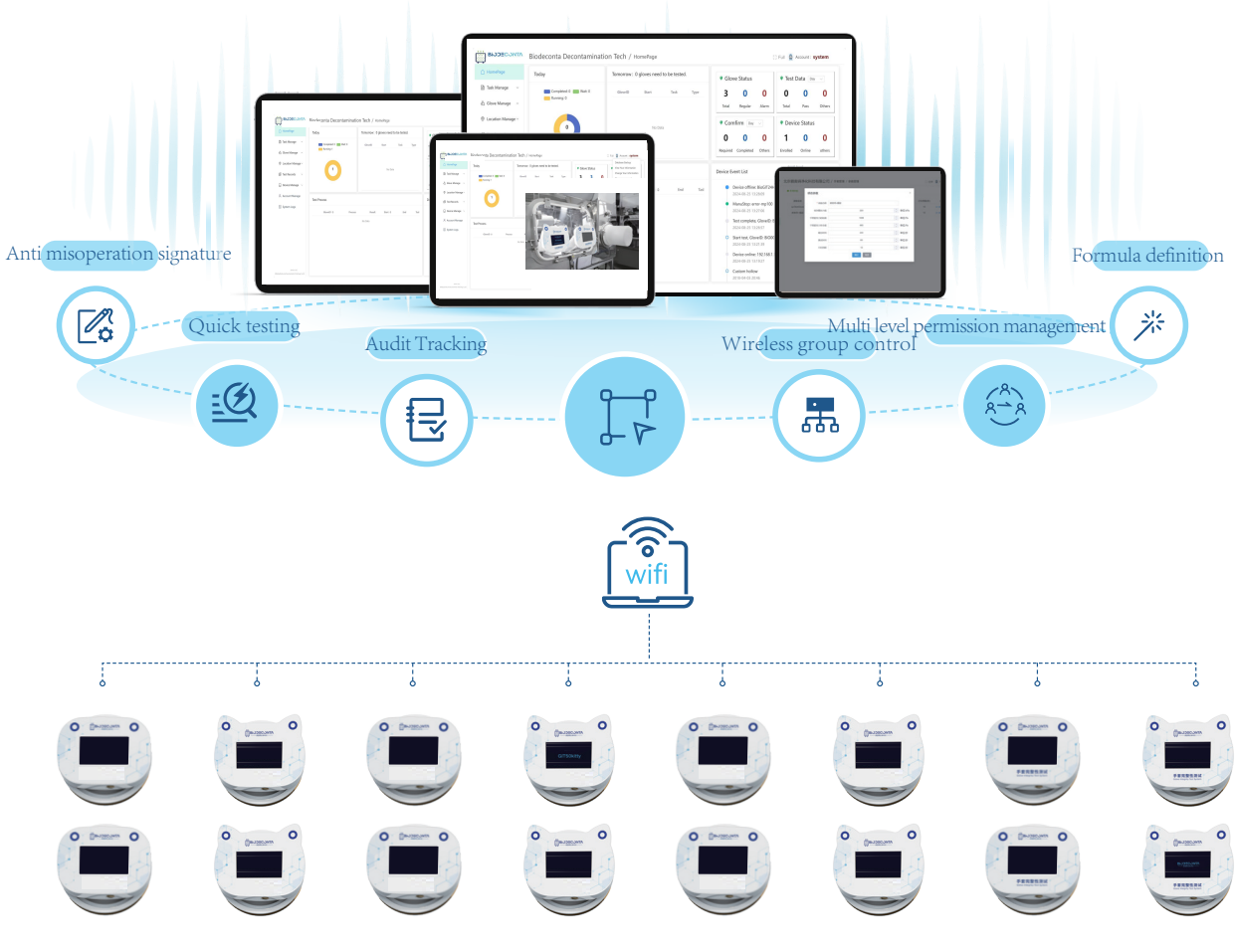
The software complies with 21CFR part 11 Requirements for electronic record and electronic signature authentication

Capable of performing IOQ and PQ validation

Compliant with FDA/GMP and other regulations Computer System Verification Requirements

According to the requirements of ISO 14644-7, Repeatable and verifiable testing programs

Wireless group control design
Support 200 or more devices to work simultaneously



Basic version

Glove Integrity Testing System

GISTOOL-50

Dual mode of single machine and group control

NTC Lite Test Core

Customized flange

7-inch capacitive touch color large screen

The Biodecorta glove leak detector GISTOOL-50 is the preferred choice for glove testing in sterile production environments in China. It is equipped with a high-performance battery and air pump, and can operate independently in any location.

The USB interface is convenient for printing data at any time. It has dual modes of single machine and group control, which can be expanded as needed, and also has RFID recognition function to meet the networking needs of 200+devices. Customizable flange size to meet customer needs. As a basic version, GISTOOL-50 is cost-effective and provides a professional level testing experience.

PRODUCT FEATURES

Simplicity is not simple
Equipped with USB interface, print data anytime

High performance testing
Using the core NTC Lite test component in normal mode
Can detect 300 μ m aperture

RFID identification
Automatically identify connections to meet the networking needs of over 200 devices

Product specifications
280 × 230 × 75cm, 3.0kg (excluding glove sealing flange)

Optional Accessories
Optional differential pressure sensor metering accessory

Customized flange
Customizable flange size

Single machine, group control dual-mode
It can be used in standalone mode or expanded to group control mode at any time

Stable and excellent
Equipped with high-precision differential pressure sensor 0.2%

Integrated design
Built in air pump, the exquisite whole machine is integrated to complete the entire process of inflation testing

High performance battery
Equipped with high-performance batteries to maintain long-term operation

Upgrade version

Glove Integrity Testing System

GISTOOL-100

NTC-GO testing core | Detachable battery | Single machine/group control dual-mode | Patent quick release flange

Sensor metering mode | Minimum detection aperture of 100 μm | Lightweight and convenient

The Biodecorta glove leak detector GISTOOL-100 stands out in the rigorous fields of aseptic production and scientific research with its high level of leak detection professionalism. We strictly adhere to GMP and ISO 14644-7 Appendix E.5 standards, and accurately use pressure attenuation method for testing to ensure that every test result is true and reliable. The wireless group control version is designed to be very powerful, capable of controlling over 200 devices simultaneously and supporting multi workshop and multi glove testing management. The data storage is compatible with all mainstream databases on the market, which is conducive to the integration of enterprise systems. As an upgraded version of the GISTOOL series, GISTOOL-100 is launched at a more affordable basic price while improving quality, significantly reducing budget investment for customers.

PRODUCT FEATURES

Accurate and reliable
Standard sensor measurement mode ensures long-term precision and stability of the equipment, with an accuracy of up to 0.2%

Patent quick release
Patent quick release ring mouth design, convenient and quick replacement of ring mouth

Excellent performance
New generation NTC-GO detection core, minimal detection,The aperture can reach 100 μm

Single machine/group control mode
It can be used in standalone mode or expanded to group control mode at any time

RFID identification
Automatically identify connections to meet the networking needs of over 200 devices

High performance battery
Detachable and quick to replace battery, maintaining long-term continuous operation

Product specifications
245 × 180 × 130cm, 2.2kg (excluding glove sealing flange)

New version

Glove Integrity Testing System

GISTOOL-150

Extremely lightweight

Wifi LoRa dual-mode channel

NTC-G01 test core

Temperature and humidity compensation function

Sensor metering mode

Patent quick release flange

The Biodecorta glove leak detector GISTOOL-150 has excellent leak detection capabilities in sterile production environments in China. Its built-in high-precision sensor is extremely accurate, and the parameter compensation function ensures stable test data.

The NTC-GO detection core has superior performance, with a minimum detection aperture of 100 μ m. The patented quick release ring flange design is practical, can be quickly replaced, and supports customization to meet different needs. The new version brings customers an unprecedented experience, whether in terms of testing efficiency, accuracy, or operational convenience, it will make customers feel its unique value and help the safety guarantee of sterile production environments reach new heights.

PRODUCT FEATURES

Ultimate precision
Built in high-precision sensors and parameter compensation function ensure stable test data
Accuracy can reach 0.2%

Patent quick release
Quickly replace the flange of the ring mouth and support customized ring mouth

Excellent performance
New generation NTC-GO detection core, minimal detection
The aperture can reach 100 μ m

Wireless group control
The wireless group control version can simultaneously control more than 200 devices

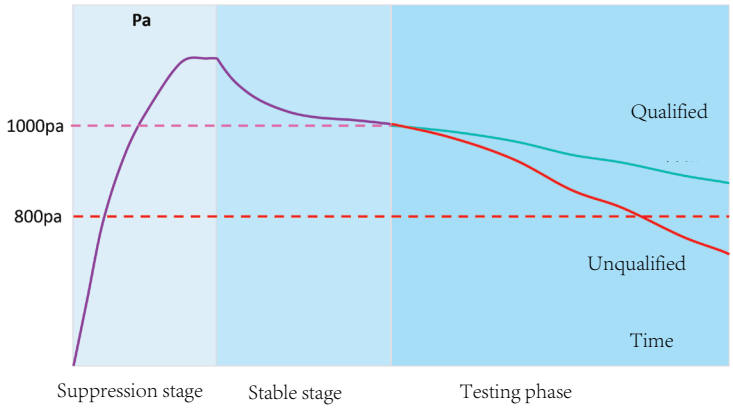
RFID identification
Automatically identify connections to meet the networking needs of over 200 devices

High performance battery
Detachable and quick to replace battery, maintaining long-term continuous operation

Product size
220×180×145cm; 220 × 165 × 145cm, ≤ 1.8kg (excluding glove sealing flange)

Principle of pressure attenuation method

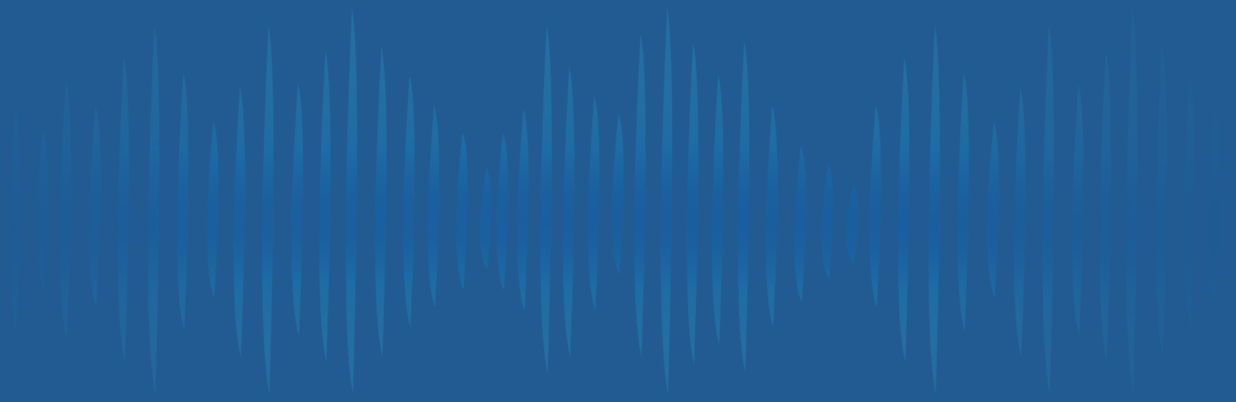
GISTOOL uses pressure decay detection method to inflate gloves with its built-in inflation pump. After the internal pressure reaches the set value, the stabilization process begins. After the pressure is maintained, the test begins when the pressure drops to the starting value. If the pressure drops within the standard range within a certain period of time, it indicates that the gloves are well sealed and the test result is qualified; Otherwise, it is considered unqualified.



Glove Integrity Testing System

GITSTOOL-50/100/150

Product parameters	GISTOOL-50	GISTOOL-100	GISTOOL-150
Group control function	Support, can synchronously control ≥ 200 devices	Support, can synchronously control ≥ 200 devices	Support, can synchronously control ≥ 200 devices
Communication method	WIFI	WIFI、LoRa（Customizable）	WIFI、LoRa（Customizable）
Multi level permissions	Support, customizable permission range	Support, customizable permission range	Support, customizable permission range
Audit Tracking	Yes	Yes	Yes
Operation screen	7-inch touch screen, capacitive screen	7-inch touch screen, capacitive screen	5-inch touch screen, capacitive screen
Operation method	Local and group control dual mode	Local and group control dual mode	Group control mode
RFID	Yes	Yes	Yes
Glove cavity test pressure	0-2500Pa	0-2500Pa	0-2500Pa
Glove cavity pressure resolution	0.1pa	0.1pa	0.1pa
Accuracy of pressure sensor	0.2%F.S	0.2%F.S	0.2%F.S
Measurement range of pressure sensor	0-2500pa	0-2500pa	0-4000Pa
Working environment	Temperature: 0~50℃; Relative humidity: 5%~90% RH (non condensing)		
Storage temperature	RH (non condensing) temperature: 0-60℃; Relative humidity: 5%~90% RH (non condensing)		
Product size	280×230×75cm	245×180×130cm	220×180×145cm；220×165×145cm（K）
Product weight	3.0kg（Sealed flange without gloves）	2.2kg（Sealed flange without gloves）	≤ 1.8kg（Sealed flange without gloves）
Glove ring flange	Size customization	Size customization (patented quick release)	Size customization (patented quick release)
Qualification certification	EN61326-1:2013；EN61000-3-2:2014；EN61000-3-3:2013	EN61326-1:2013；EN61000-3-2:2014；EN61000-3-3:2013	EN61326-1:2013；EN61000-3-2:2014；EN61000-3-3:2013
Testing time	≤ 8 minutes (the test duration can be adjusted before testing, and the preparation time is about 5 minutes)	≤ 8 minutes (the test duration can be adjusted before testing, and the preparation time is about 5 minutes)	≤ 8 minutes (the test duration can be adjusted before testing, and the preparation time is about 5 minutes)
Battery	Built in battery	External replaceable	Built in replaceable
Continuous working time	≥ 3 H	≥ 3 H	≥ 3 H
Detection accuracy (minimum aperture)	100 μm	100 μm	100 μm
Power	<10W	<10W	<10W
Sensor metering mode	Yes	Yes	Yes
Efficient filtration	No	Yes	Yes



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