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Технические характеристики на изотестеры ISOFLEX-S, настенные модульные изоляторы ISOTEST, ISOFLEX-R, тестеры герметичности перчаток GLT компании GETINGE

ISOTEST

Two-person isolator for optimized workflow

Efficient and reliable workflows

Double work station increases productivity for sterility testing

Optimize your sterility testing workflows to maximize throughput. The ISOTEST isolator facilitates a continuous testing process instead of a batch process, eliminating unproductive time between batches.

Sterility testing is the last mandatory control performed on sterile drugs, components, and medical devices before their release for administration to patients. The ISOTEST isolator provides the completely closed system necessary to avoid the risk of false positive results. You can rely on ISOTEST to provide a controlled environment and optimal workflows for reliable sterility testing.

ISOTEST can also be used for cytotoxic or TPN (Total Parenteral Nutrition) reconstitution, compounding of drugs and many other aseptic applications.

Dual-operator access optimizes workflows

Two operators can have simultaneous access to the chamber and the load inside the hatch. They can work with the same or different sterility testing methods inside the isolator. The system can be used with any combination of closed or open membrane filtration, direct inoculation methods, and rapid microbiology methods (RMM).

Minimize downtime for improved throughput

The ISOTEST isolator supports continuous testing instead of a batch process, eliminating unproductive downtime between batches. Short bio-decontamination cycles and the capacity for dual operations combine for a throughput rate of up to 40 tests per 8-hour shift (based on an average test size of 20 ml containers/vials).

Effective bio-decontamination

With ISOTEST, you can bio-decontaminate the total volume of the unit; the hatch can be included, or bio-decontaminated separately. Bio-decontamination happens quickly for high productivity, often within 30-45 minutes.

The integrated bio-decontamination unit uses Hydrogen Peroxide Vapor (HPV) as steri-lant. The generator is controlled by the same PLC as the unit for simplified and reliable operations.

Validated process control and traceability

Both the isolator and integral bio-decontamination unit are controlled by a single Siemens PLC control system. Reports are sent to an integrated printer or remote PC (option). Data and reports can be stored in the built-in FDA 21 CFR part 11 compliant SCADA and in the customer network (option).

The color touchscreen control panel is intuitive and easy to operate. Through the HMI, authorized users can set process parameters that operators can easily monitor during the process.

Integrated bio-decontamination: Steritrace

The built-in bio-decontamination unit uses Hydrogen Peroxide Vapor (HPV), a proven sterilant commonly used in the pharmaceutical industry. It is generated from liquid Hydrogen Peroxide (H_2O_2) from a bottle fitted with an RFID (Radio Frequency Identification) device, that is placed in a receptacle on the isolator. The generator checks the validity of the HPV bottle and the batch number is recorded in the process report. Steritrace is controlled by the same PLC as the isolator unit, thus minimizing components and enabling validation and maintenance of a single piece of equipment.

Manipulation devices

Application-specific options for comfort and safety

Getinge isolators can use different manipulation systems to match the process to the operator's hand. The Glove-Sleeve offers protection and easy maintenance. An O-ring system allows the glove to be replaced without breaking sterility.

Minimize contamination risk with Getinge´s wireless Glove Leak Tester (GLT)

Ensure a safe production and process control with the paperless Glove Leak Tester that enables seamless in-situ glove testing. Wireless, paperless and pipeless, the GLT allows for accurate and repeatable testing for glove and sleeve integrity, i.e. detecting perforations not visible to the naked eye.

Glove Leak Tester (GLT) shown on demo display

Continuous workflow, easy access, and fast bio-decontamination help increase productivity.

DPTE® Transfer Systems

Application-specific options for comfort and safety

DPTE® Alpha

The core of the DPTE® transfer system is the Alpha port; a secure interlock enables totally safe connections and disconnections. The DPTE® system allows material to be moved from one sterile zone to another through a non-sterile zone, with leak-tight, risk-free reconnection.

DPTE-BetaBag®

The DPTE-BetaBag® is a combination of a DPTE® Beta part and a bag for the safe transfer of sterile products or waste material. The DPTE-BetaBag® single-use range is designed for fast contamination-free transfer to maintain high-speed production, increase flexibility and minimize validation costs.

DPTE® Beta Containers

Stainless steel or plastic DPTE® Beta Containers allow for safe transfer into and out of a barrier system. Autoclavable, stainless steel and plastic inserts enable you to sterilize and transfer tools etc.

Safe and efficient waste handling

A dual-waste DPTE-BetaBag® allows for safe removal of liquid and solid waste from the isolator. The DPTE® system provides egress from inside the isolator chamber while maintaining isolator integrity; there is no risk of sample or environmental contamination. It's a useful solution for handling cytotoxic waste.

Other standard isolator solutions from Getinge

ISOFLEX Isolators

A modular, rigid-wall isolator

The ISOFLEX isolator protects the product against contamination during aseptic operations such as sterility testing. The rigid-wall isolator maintains an enclosed and sterile environment throughout transfer, manipulation, and bio-decontamination.

- Modular design for flexible use
- Validated process control and traceability
- Two types of ventilation to maintain aseptic conditions: Engineered Turbulent Flow (ETF) and Unidirectional AirFlow (UDAF)

ISOFLEX-S Isolators

A transparent, flexible-wall isolator

The ISOFLEX-S isolator has transparent semi-rigid plastic walls that provide a panoramic view of the working area. Isoflex-S isolators combine the robustness of a 316L stainless steel working base with the comfort of working with glove sleeves on a flexible wall.

- Flexible and mobile
- User-friendly operations
- Modular design
- Validated process control and traceability
- Cost effective solution

A transparent softwall isolator

Your panoramic view of the working area

Regulatory agencies require sterility testing of pharmaceutical products to ensure sterile batch. ISOFLEX-S Isolators provide a safe controlled environment that is cost effective for reliable testing procedures.

When sterility testing pharmaceutical products, there is no room for error. Modular ISOFLEX-S Isolators are designed for flexible, user-friendly operation that delivers accurate, reproducible results.

The ISOFLEX-S isolator has transparent semi-rigid plastic walls for comfortable work with clear visibility.

ISOFLEX-S

Work in comfort with clear visibilit

Flexible and mobile

Castors allow the ISOFLEX-S isolator to easily move and connect to other isolators or filling lines using Getinge's patented DPTE® system. With its integrated Hydrogen Peroxide (H_2O_2) generator, it can also be used as a mobile bio-decontamination unit.

User-friendly operations

The flexible wall allows operators to push and pull the soft canopy for comfort and accessibility. Transparent PVC provides a panoramic view and 360° visibility of the working area, tools and components. The base is constructed from robust, polished 316L stainless steel for easy and efficient cleaning and solidity.

Modular design

ISOFLEX-S is available in three- or four-glove configurations. The three-glove isolator (1.5m long) is designed for one operator and offers a large storage capacity. The four-glove configuration (2m long) provides working capabilities for two operators simultaneously. The DPTE® Transfer System can be installed in the base of the isolator and at both ends, instead of the standard lateral doors hence increasing contamination control.

Validated process control and traceability

Both the isolator and integral bio-decontamination unit are controlled by a single Siemens PLC control system. Reports are sent to an integrated printer or remote PC (option). Data and reports can be stored in the built-in FDA 21 CFR part 11 compliant SCADA and in the customer network (option).

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Manipulation devices

Application-specific options for comfort and safety

Getinge isolators can be provided with different application-specific manipulation systems that match the process inside the isolator to the operator's hand. The Glove-Sleeve offers protection and easy maintenance. An O-ring system allows the glove to be replaced without breaking sterility. The system is designed for use with the paperless Glove Leak Tester (GLT) for seamless in-situ glove testing. This provides a complete package that is safe, comfortable, practical, and able to be validated for regulatory compliance.

A robust 316L stainless steel working base combined with the comfort of glove sleeves and a flexible, fully transparent wall.

DPTE® Transfer Systems

Application-specific options for comfort and safety

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A dual-waste DPTE-BetaBag® allows for safe removal of liquid and solid waste from the isolator. The DPTE® system provides egress from inside the isolator chamber while maintaining isolator integrity; there is no risk of sample or environmental contamination. It's a useful solution for handling cytotoxic waste.

Other standard isolator solutions from Getinge

ISOFLEX Isolators

A modular, rigid-wall isolator

The ISOFLEX isolator protects the product against contamination during aseptic operations such as sterility testing. The rigid-wall isolator maintains an enclosed and sterile environment throughout transfer, manipulation, and bio-decontamination.

- Modular design for flexible use
- Validated process control and traceability
- Two types of ventilation to maintain aseptic conditions: Engineered Turbulent Flow (ETF) and Unidirectional AirFlow (UDAF)

ISOTEST Isolators

Efficient and reliable sterility testing processes

ISOTEST is an isolator designed for sterile applications, including sterility testing of sterile drugs, components, and devices. Continuous workflow, easy access, and fast bio-decontamination help to increase productivity.

- Dual workstation with capacity to combine two test methods
- Optimized workflow
- Minimize downtime for improved throughput
- Effective bio-decontamination
- Validated process control and traceability

A modular, rigid-wall isolator

The answer to your daily needs for aseptic processing

Protect against contamination during sterile applications. ISOFLEX Isolators maintain an enclosed and sterile environment for aseptic operations.

In biopharmaceutical production, healthcare and many other markets, it's critical to create and maintain aseptic conditions throughout transfer, manipulation, and bio-decontamination. The modular, rigid-wall ISOFLEX Isolator offers the flexibility you want, with the process controls that you require.

A large front glass window can be easily opened for fast and ergonomic loading. ISOFLEX is compatible with our full range of DPTE® Transfer Solutions to ensure safe and efficient transfer without breaking containment.

ISOFLEX

Multi-purpose and tailored to your process

Two types of ventilation to maintain aseptic conditions

With the ISOFLEX, choose from unidirectional or turbulent airflow to meet various process requirements. In this sealed, operator-free environment with control over sources for contamination entry (HEPA filters, transfer ports), Engineered Turbulent Flow (ETF) is sufficient to maintain sterile conditions. However, for aseptic applications where it is important to ensure that non-viable particles are rapidly swept away from critical areas, unidirectional airflow (also known as UDAF, LAF, Laminar flow) is appropriate to meet Grade A/ISO 4.8. When handling sterile APIs, a HEPA filter with safe changeover is available as an option.

Validated process control & traceability

ISOFLEX offers either a Siemens or Rockwell Allen Bradley PLC for process control and monitoring. Both control systems are equipped with a 19" color touch panel PC with an intuitive user interface for easy navigation, operation, and parameter monitoring. User access is easily managed and adapted to your needs using a non-pyramidal structure.

ISOFLEX provides standard, Windows 10 based, built-in SCADA for central supervision of process performance. Authorized users can adjust process parameters according to the unique requirements of a specific process. Batch reports can be digitally stored locally or in the user's network. The system allows you to choose up to 2 signatories. ISOFLEX is fully FDA 21 CFR Part 11 and GMP Annex 11 capable and compliant.

A modular design maximizes flexibility

Configured to your specific needs, today and tomorrow

Modular design for flexible use

The modular design of the ISOFLEX allows the isolator to be configured and to evolve according to your specific needs. Three-glove versions are available for a single operator, while four-glove versions allow two operators to work simultaneously.

Bio-decontamination hatches can be added at one or both ends of the isolator. HMI can be positioned on the left or right side depending on your need or site constraints.

Easy to install and upgradable

3-glove UDAF ISOFLEX

3-glove ETF ISOFLEX

3-glove ETF ISOFLEX with hatch and (H2O2) catalytic converter

4-glove ETF ISOFLEX with hatch and (H2O2) catalytic converter

4-glove ETF ISOFLEX with hatch

4-glove ETF ISOFLEX with integrated Glove Leak Tester (GLT)

Stand Alone Wireless Glove Leak Tester (GLT)

Operator centered design

- The large front window can be safely and easily opened for fast and ergonomic loading.
- The workstation is height adjustable (option) to meet the needs of people with different heights and work preferences.
- The user-friendly HMI swivels and is height adjustable for ease of use.
- The workstation is illuminated with LEDs for clear visibility.
- The light stays on while the front window is opened to ease the loading and cleaning process.
- The lighting will change colors depending on the isolator's status.

Accessories and options

Bio-decontamination alternatives

When it comes to bio-decontamination, the ISOFLEX provides the means to bio-decontaminate the isolator working chamber, the hatch, or both chamber and hatch simultaneously. The integrated H_2O_2 generator ensures safe operations and reliable processes. The unit is controlled by the same interface as the isolator and provides full traceability of H_2O_2 bottles.

Integrated monitoring devices:

- H_2O_2 sensors for operator safety
- Active air sampler
- Non viable particle
- Wireless Glove Leak Tester (GLT)

Shelving solutions:

- Basic shelves
- Modular shelves
- Hatch shelves and baskets: space saving and no risk of surface contamination transfer.

Connectivity and reporting:

- Isolator connected to customer network
- User Management with connection to Active Directory
- Periodical back-up of SQL data base
- Data integrity
- Use of network printer
- Traceability with archived batch reports on network

Other typical accessories:

- Dismountable hanging bars with hooks
- Service plate with tri-clamp passthroughs and cable glands
- H_2O_2 catalytic converters
- Integration of peristaltic pump for membrane filtration
- Sleeve extenders with finger separators
- And many more accessories...

Sterile applications

Multipurpose and tailored solutions

Sterility testing or quality control (membrane filtration, direct inoculation, rapid method)

Transfer or Biodecontamination isolator (can be mobile)

Transfer, repacking of sterile components, closures, etc.

Aseptic processing (assembly of processes, parts preparation, etc.)

Reactor or vessel charging isolator

Assembly, preparation of medical devices

Small batches Fill and Finish

Cell culture, cell & gene therapy

Personalized medicine

Compounding (Total Parenteral Nutrition TPN, Intravenous IV solution, cytotoxic reconstitution...)

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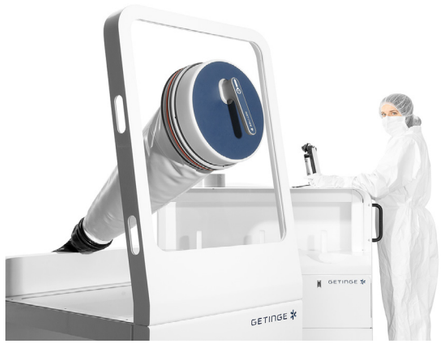
- Flexible and mobile
- User-friendly operations
- Modular design
- Validated process control and traceability
- Cost effective solution

Wireless Glove Leak Tester (GLT)

In-situ glove testing for complete integrity with traceability

Adhere to stricter regulations

In addition to underlining the importance of selecting isolator gloves with good mechanical and chemical resistance, the internationally recognized guidelines* stipulate that Glove Integrity Testing needs to be included in Standard Operating Procedures – and that gloves must be tested for leakage prior to each production batch.
To make this easier, Getinge has developed the new wireless Getinge GLT (Glove Leak Tester) that enables seamless in-situ glove testing.



Getinge's GLT

Gloves constitute the most vulnerable link in the containment barrier. Wireless, paperless and pipeless, the new GLT allows for accurate and repeatable testing for glove and sleeve integrity – i.e. perforations not visible to the naked eye.

- Full traceability compliant to FDA 21 CFR part 11 and EU annex 11
- A modern tool compliant to international guidelines*
- Wireless and pipeless (no cables and pipes between the remote head and the main unit)
- Based on pressure decay method with easy application, micro-pumps on board

- HMI available either with external tablet or with onboard version, integrated (through SCADA) for Getinge isolators

* European Commission, EudraLex, Volume 4, EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use, Annex 1, Manufacture of Sterile Medicinal Products, December 2017 (draft for comment)
FDA Aseptic Processing Guidance
PIC/S Pharma Inspection Convention Cooperation Scheme, Section 9.5.3

Security at your fingertips

Minimize contamination risk with the new Glove Leak Tester (GLT)

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