ISOTEST
Two-person isolator
for optimized workflows

GETINGE ✳

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 sterilant. 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.

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

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.

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 sterilezone to another through a non-sterile zone, with leak-tight, risk-free reconnection.

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.

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.

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-S Isolator
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

ISOFLEX Isolator
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)
  - Unidirectional Air Flow (UDAF)

ISOPRIME Isolator
Optimized for common aseptic applications

The ISOPRIME is the ideal solution for customers with modular rigid-wall isolator requirements that combine high-quality, versatility and continuous operations at a competitive price point.

- Operator-friendly access
- Direct access for maintenance
- Cost effective solution
- Two types of ventilation to maintain aseptic conditions:
  - Engineered Turbulent Flow (ETF)
  - Unidirectional AirFlow (UDAF)

GETINGE ✷

With a firm belief that every person and community should have access to the best possible care, Getinge provides hospitals and life science institutions with products and solutions aiming to improve clinical results and optimize workflows. The offering includes products and solutions for intensive care, cardiovascular procedures, operating rooms, sterile reprocessing and life science. Getinge employs over 10,000 people worldwide and the products are sold in more than 135 countries.