ISOPRIME
Optimized for common aseptic applications

A rigid-wall isolator
optimized for common aseptic applications

Getinge's isolators maintain an enclosed and sterile environment for aseptic operations.

Versatile, the ISOPRIME is suitable for all major sterile applications from aseptic filling and repackaging of sterile components, to sterility testing, compounding, preparation of medical drugs and devices, and more. 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.

Our isolators are compatible with our full range of DPTE® transfer solutions to ensure safe and efficient trans fer without breaking containment.

Two types of ventilation to maintain aseptic conditions

With the ISOPRIME, 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 and traceability

ISOPRIME offers a Siemens PLC for process control and monitoring. The control system is equipped with a 10" color touch panel PC with an intuitive user interface for easy navigation, operation, and parameter monitoring. The reports are generated in PDF and can be transferred to a network server, a USB flash drive, or sent to a network printer.

User access is easily managed and adapted to your needs using a non-pyramidal structure. Authorized users can adjust process parameters according to the unique requirements of a specific process. The system allows you to choose up to two signatories.

ISOPRIME is FDA 21 CFR Part 11 compliant in accordance with the PLC capabilities.

Simple and clean design

1. Meet various aseptic process requirements with Unidirectional Airflow (UDAF) or Engineered Turbulent Flow (ETF) ventilation

2. User-friendly Siemens HMI providing connectivity and traceability

3. Safe and easy access to the chamber and hatch thanks to their door opening upwards

4. Effective bio-decontamination with Steritrace, a built-in bio-decontamination unit

5. Customizable service plate flexible and retrofitable to your needs

6. Full control of the system performance with integrated and optional monitoring devices

Maintenance

Easy in-house maintenance

- Save time and effort during the maintenance with a direct and easy access to the electrical cabinet.

- At Getinge, we offer comprehensive support whenever you need it.
  An optional integrated module allows Getinge's team to safely execute software updates and investigations remotely.

- Save space by reducing the clearance area for maintenance by using the ISOPRIME front, right, top accesses.

Integrated bio-decontamination

Hydrogen Peroxide Vapor (HPV) is a proven sterilant commonly used in the pharmaceutical industry. It is generated from liquid Hydrogen Peroxide (H_2O_2) from a bottle placed in a receptacle on the isolator. The bottle is fitted with an RFID (Radio Frequency Identification Device) to improve and ensure traceability, quality, and batch number management.

Getinge H_2O_2 generator checks the validity of the HPV bottle, and the lot number is recorded in the process batch report. The integrated H2O2 generator ensures safe operations and reliable processes.

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. The ISOPRIME provides the means to bio-decontaminate the isolator working chamber, the hatch, or both chamber and hatch simultaneously.

Accessoires and options

Integrated monitoring devices

- H_2O_2 sensors for concentration monitoring
- H_2O_2 sensors for operator safety
- Active air sampler
- Non viable particle
- Wireless glove leak tester (GLT)

Shelving solutions

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

Other typical accessories

- Hanging bars with hooks
- Service plate with DPTE® alpha ports, tri-clamp passthroughs, cable glands, etc.
- Integration of peristaltic pump for membrane filtration
- Sleeve extenders with finger separators
- Integrated UPS (Uninterruptible Power Supply)
- and many more accessories ...

Sterile applications

Multipurpose and tailored solutions

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

Cell culture, cell and gene therapy

Transfer and repacking of sterile components, closures, etc.

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

Transfer or bio-decontamination isolator (can be mobile)

Assembly and preparation of medical devices

Reactor or vessel charging isolator

Small batches fill and finish

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

Personalized medicine

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 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)

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

ISOTEST Isolator
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

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.

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