

**GETINGE ISOTEST
CONTAMINATION PREVENTION
DURING STERILITY TESTING**



STERILITY TESTING IN ISOLATORS

“Separative devices provide assured protection in varying levels by utilizing physical or dynamic barriers, or both, to create separation between operation and operator. Isolators are allowed to get a controlled environment with the operator physically inside but biologically outside” (ISO 14644-7)

According to the Pharmacopoeias (USP<71>), Sterility Testing is the last mandatory control to be performed on sterile drugs and ophthalmic products before their release for patients. It must be performed avoiding the risk of both false positive and false negative results. A false positive result causes added work for the busy QA/QC laboratory and adds significant costs as it delays or

prevents release of the product for sale. A false negative result could place a non sterile product on the market, with the potential liability issues that this entails. The features and protocols of the ISOTEST avoid these two risks and provide smooth, routine and efficient control of the entire Sterility Testing process.



- Sterility testing in an isolator reduces the number of false positives to almost zero. A false positive means doing another test, i.e. spending more time and money while the manufactured lot is waiting. It may also lead to the loss of a batch of product which was not contaminated.
- Getinge ISOTEST is an isolator specifically designed and produced for sterility testing of the majority of injectable products. Naturally, the time it takes to perform the test cannot be compressed, but the process itself can. This is the case for the Getinge ISOTEST, where the continuous work flow, easy access, short bio-decontamination cycle etc. helps to cut testing time, increasing productivity.
- The ISOTEST can be used for 1 or 2 operators, where both have good access to the hatch and can simultaneously work with two different methods inside the isolator (with membrane and/or Steritest™/Sterisart™ and/or direct inoculation methods and/or Rapid Microbiology Method.)
- The daily workload can be between 10 to 40 tests (per shift).
- The circulation of samples will be made with minimum time between production and testing.
- ISOTEST, being a completely closed system, improves the operator protection against potency of both samples and filters.
- Using an isolator means that the surroundings can be a conventional room with restricted access. resulting in lower running costs compared to a clean room.
- Simplified egress of canisters, filtrate and waste with no loss of environment integrity.



DESIGNED SPECIFICALLY FOR THE APPLICATION

Traceability

Important parameters are monitored and may be recorded; they can be either directly sent to a printer (option) or stored on a remote PC (option).

- The process is always controlled by the operator.
- Security for both the operator and the patient.
- Data exchange table available on ethernet network.

Validated process

Validated process due to new integrated H₂O₂ sterilizer STERITRACE II:

- Integrated: cost effective, reliable, no additional equipment to manipulate and maintain (no dessiccant), only one user interface to control both the isolator and the sterilizer. H₂O₂: no odor, easy to monitor during the validation process.
- Validation is easier, increased productivity as a result of the minimized cycle times.

Leak tightness

Automatic leak testing procedure for the bio-decontamination airlock and for the whole work area.

- Leak tightness is guaranteed.
- High protection of operator and environment.

Siemens PLC Controller And Touchscreen Display

Both the isolator and integral Getinge Steritrac II HPV sterilizer are controlled by a single Siemens PLC control system. This assures repeatable, reliable operation. The Siemens PLC is an industry standard and has communication capabilities for remote monitoring.

- The operator control panel is a colour touchscreen, which provides access to the PLC for parameter setting (by authorized persons) and critical parameter monitoring. Alarms are also clearly presented on the display.
- The single, easily navigated operator panel assure simple operation, minimized errors, and maximized productivity.



H₂O₂ bottle with RFID chip

- Dedicated GETINGE H₂O₂ bottle with RFID chip
- Full traceability: lot number, expiration date, and remaining H₂O₂ level in the bottle.
- High security, safe and easy manipulation.
- No residue.

Stainless steel & glass structure

The structure of the isolator is made of 316L stainless steel and glass

- More reliability, longer life cycle.
- Cost effectiveness (10 year amortization).
- Shorter bio-decontamination process.

Specially designed for the sterility test application

Conceptual design for sterility testing, with a continuous workflow and optimized ergonomic operation.

- The organization of the workflow is dedicated to sterility testing.
- Faster process, higher productivity and more ergonomic for the operator.

Replaceable gloves

Gloves are replaceable without breaking containment. These may be replaced in-process, saving time, maximizing productivity.

Different types of sterility tests can be performed using the Getinge ISOTEST

Can be used with membrane and/or Steritest™/Sterisart™ and/or direct inoculation methods and/or Rapid Microbiology Method.

- Less isolators are needed in the facility.
- Cost saving.

External waste collection system with DPTE® beta bag

Placed in two trolleys under the isolator: one for liquid waste (20 liter) and one for solid waste (100 liter), with egress in the middle of the work area inside the isolator.

- Waste can immediately be removed from the isolators working space, easy to access, easy and safe to remove. No loss of isolator integrity and no risk of sample / environment contamination.
- Efficiency: only one operator required to replace the bag.
- Clean working space inside the isolator.



DPTE® Technology – A Crucial Success Factor

While providing significant safety and contamination control benefits, placing a physical barrier between the process and the user introduces operational challenges: how to move material into and out of an isolator without breaking the sterile containment?

Fortunately this is nothing new for Getinge. Many years ago, La Calhène developed a system that has become an industry standard worldwide. The DPTE® Port System was originally developed for the nuclear industry where Getinge La Calhène remain a key supplier.

Widely known as an Alpha-Beta or RTP port, it is now used for a wide variety of applications in the pharmaceutical industry where contaminated, toxic and-or sterile material needs to be transferred without compromising the integrity of the contained environment.

Read more at www.getinge.com

MONEY, SPACE AND TIME SAVER



A MAJOR STEP FORWARD TOWARDS THE ZERO FALSE POSITIVE: GETINGE ISOTEST

- Designing and maintaining of a sterile working space between two HEPA filters.
- Biological separation of the operator from working space.
- Bio-decontamination of the volume of the isolator, and the outside of: utensils, culture media and samples.
- Ingress & egress of any material without breaking integrity / sterility of isolator.
- Can be used with membrane and/or Steritest™/ Sterisart™ and/or direct inoculation methods and/or Rapid Microbiology Method.
- 10-year life cycle plan thanks to stainless steel and glass design.
- Optimized air flow management for both positive pressure control and aeration phase make the Getinge ISOTEST one of the most energy efficient in the market.
- Conventional room with restricted access only.
- Mock-up study have been carried out to optimize ergonomics and logistics for the flow of components.
- Surface including space for operators and for loading & unloading: 20 m² foot print maximum.
- The Clean Dry Air conditioning and aeration system of the Steritrace II allows a compact design with no external additional requirements (desiccant cartridge, regenerator, etc).
- Workstation always “Ready to Test”, due to the bio-decontamination transfer hatch and DPTE® transfer systems for canisters and waste.
- Bio-decontamination of the load in the transfer hatch is fast (30 to 45 min) thanks to integrated Steritrace II and big number of air change per hour (aeration).
- Easy transfer from transfer hatch to workstation thanks to internal mobile cart and stainless steel baskets.

FAQ – Design Criteria Questions Answered

Airflow Regime Design

Getinge has developed a ventilation system specially adapted to the sterility testing application.

While not requiring the characteristics used in production, the sterility testing environment must guarantee total surface bio-decontamination and prevention of cross contamination. Furthermore, all surfaces of the isolator have to be easily accessible for monitoring and cleaning.

The engineered turbulent flow provided by Getinge provides full access to contained surfaces, with no hidden areas (return air-duct, filter faces, etc).

It optimizes the flow during bio-decontamination, with no covered surfaces that may not be exposed to the bio-decontamination vapor, such as the underside of shelves. Turbulence is necessary to assure complete surface vapor bio-decontamination.

Getinge, with our un-matched experience acquired over many years, and our substantial installed base, is confident in providing the industry with the best and most cost effective system available for sterility testing.

ACCESSORIES, CONSUMABLES, CONTINUOUS SUPPORT AND SERVICE

Our Philosophy

Getinge's aim is not only to provide high quality, industry leading, reliable equipment, our objective is to be your chosen partner within specific application areas of Infection and control and Contamination Prevention.

Our products and services are available globally, provided and supported by 27 Getinge sales and service companies and a network of more than 65 authorized distributors. We presently distribute and support our products locally in more than 100 countries.



Our Scope of Supply

In addition to the Getinge ISOTEST isolator, we can also provide:

- Installation, commissioning and qualification.
- Routine maintenance and periodic validation.
- Training, via our professional Academy.
- A wide range of accessories, including baskets, racks, glove and port testing equipment.
- Spare parts, delivered rapidly from our regional distribution centers.
- Consumables, incl. pouches, Dispobags™, gloves & sleeves, steriliant, filters, baskets.



RELATED PRODUCTS FROM GETINGE FOR THE QUALITY ASSURANCE LABORATORY

Getinge: a unique supplier

Getinge can take care of virtually all your needs for contamination prevention in the Quality Assurance Laboratory. We supply:

- Pharmaceutical steam generators.
- Laboratory washers & sterilizers.
- Custom hardwall and flexible film isolators for manipulation and transfer, including autoclave interface isolators.

Consult Getinge for details.





COMPLETE SOLUTIONS FOR CONTAMINATION PREVENTION

Getinge is the world's leading provider of solutions for effective cleaning, disinfection and sterilization in the healthcare and life science sectors. We are dedicated to helping our customers provide maximum productivity in the most cost-efficient way. We do this by offering well thought through and customized solutions. This means that we are with our customers all the way from architectural planning and education to traceability and support – with complete solutions, long-term commitment and global presence. Getinge – Always with you.

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GETINGE GROUP

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GETINGE GROUP is a leading global provider of products and systems that contribute to quality enhancement and cost efficiency within healthcare and life sciences. We operate under the three brands of ArjoHuntleigh, GETINGE and MAQUET. **ArjoHuntleigh** focuses on patient mobility and wound management solutions. **GETINGE** provides solutions for infection control within healthcare and contamination prevention within life sciences. **MAQUET** specializes in solutions, therapies and products for surgical interventions, interventional cardiology and intensive care.