ISOTEST
Rigid wall sterility test isolator

SPECIFICATION

PRODUCT SPECIFICATION
The Isotest is a leaktight enclosure equipped with means of transfer and manipulation which keep enclosed environment allowing a cross protection operator/product against microbiological and chemical contaminations without compromising the environment.

APPLICATION
According to the Pharmacopoeias, 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 lab 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 the protocols of the Isotest avoid these two risks and provide smooth, routine and efficient control of the entire Sterility Testing process.

KEY FEATURES
- 316L stainless steel isolator shell and bio decontamination airlock shell,
- Two glass windows on which are mounted three shoulder rings allowing to operate inside the sterile environment,
- 304 L stainless steel welded supporting frame,
- Two ergonomical footrest the operators,
- Two external lightings in the housing ventilation,
- Ventilation system capable of 40 air changes per hour for work station with a positive pressure of 40 ± 10 Pa (adjustable), and of 400 air changes per hour for bio-decontamination hatch with a positive pressure of 60 ± 10 Pa (adjustable),
- Control system: - Full automatic control command PLC system (Siemens),
- Single inlet and outlet HEPA filters,
- A 2 x 3 opposite glove working station isolator,
- Manipulation by gloves mounted on sleeves (changeable without breaking the sterility) with sleeve support for bio decontamination,
- Transfer systems using DPTE® double door systems and doors with inflatable gaskets.

QUALITY STATEMENT
Confidence in the Getinge group is the most important quality criteria. This must be the hallmark of all our external and internal commitments, activities and products. Products and services supplied by Getinge must conform to the agreed terms and expectations to ensure recommendations for further business. The achievement of these quality goals is the basis for continued competitive and successful enterprise.

STANDARDS & CODES
The Isotest complies with all appropriate standards, codes and directives relevant to the region of installation. The equipment is manufactured according to industry requirements and standards. A declaration this matter is available on request.
Electrical regulations
- Directive n° 89/336/EEC amended 92/31/EEC,
- Directive n° 73/23/EEC.
Glove regulations
- Directive n° 89/686/EEC.
Automation regulation
- GAMP4 procedures, current guidelines are followed in all our documentation and validation support materials.
- 21CFR Part 11 compliant in accordance to the PLC capabilities.

- Denotes optional feature - Check box as required.
- Commercial specifications only.
- Pictures and drawings non contractual.
DESCRIPTION

PRODUCT DESCRIPTION

The isotest is composed of 6 parts:

- Containment enclosure
- Ventilation / filtration
- Control system
- Manipulation system
- Transfer system
- H₂O₂ sterilizer

PRINCIPLE OF OPERATION

Working procedure:

- All the necessary samples, media and equipment for one or several tests are placed in a perforated stainless steel trolley before loading them into the input lock-chamber.
- The leaktightness of the input lock-chamber is tested before starting the validated H₂O₂ bio-decontamination cycle.
- After its completion and a control of the level of concentration of H₂O₂ in the lock-chamber the trolley is introduced in the already H₂O₂ bio-decontaminated work station (average is one bio-decontamination per month).
- The operator(s) proceeds to perform the test after retracting the empty trolley to the input lock-chamber.
- Each of the two canisters (per test) is put on the appropriate canister support according to the temperature of its incubation.
- The canister support is removed through the sealed sterile sleeve of DPTE® Tubing.
- The canisters can either stay in their sealed sleeve to go to the incubator or can be packed off.
- The result is evaluated after 14 days of incubation.
Advantage
No false positive:
- ISOTEST is a leaktight free-standing bio-decontaminated isolator made of polished 316L stainless steel which includes:
  - An input lock-chamber for the bio-decontamination of the surfaces of samples, media and equipment used for the test before entering the isolator,
  - A face-to-face work station for one or two operators working through sleeves and Ready-to-Fit sterile gloves,
  - Each work station can be equipped with a Millipore Equinox Steritest pump and a DPTE® transfer system for the waste (the second workstation may alternately be configured for direct inoculation testing).
  - The pre-sterilized DPTE®-Dispobag collects the filtrate and the solid waste with a chemical protection of the environment and a microbiological protection of the test,
  - The DPTE®Tubing sealed sleeve protects the isolator, the environment and the Steritest canisters during transfer to the incubator.

No false negative:
ISOTEST is bio-decontaminated with H$_2$O$_2$. The concentration of residues in the isolator does not result in any change in the growth of bacteria during bacteriostasis and fungistasis tests.
The rapid process / reduced time for H$_2$O$_2$ vapour bio-decontamination of the input lock-chamber (for a 10$^4$ to 10$^6$ Spore Log Reduction (SLR)) does not allow or induce any adverse effect on positive samples.

BASIC DESIGN FEATURES
Design features and material definition conform to the specification listed below, unless specifically mentioned as optional.

Containment enclosure
It comprises two main parts:
- 316L stainless steel isolator shell and bio decontamination airlock shell,
- Two glass windows on which are mounted three shoulder rings.

Stainless steel isolator shell and bio decontamination airlock shell
The isolator shell and bio decontamination airlock shell are constructed from solid, high quality, stainless steel (type 316L or European equivalent).
Surfaces are polished to facilitate cleaning (Ra 0,5 µm and Ra 0,8 µm) in accordance with ISO 1302 norm.

Two glass windows on which are mounted three shoulder rings
Tailgate
The front face of the isolator is equipped with an hinged window, supported by two jacks.
Window
- The glass is made of tempered glass transparent securit.
The back face of the isolator is equipped with a fixed window.

Ventilation / filtration with PLC regulation
Bio-decontamination hatch:
It comprises two modules (Air inlet and outlet modules):
Air inlet module (inlet air) with:
- Inlet pre-filter PRV 200,
- Inlet air blower V 133 non leaktight (air flow rate),
- Motorized DN 80 isolation ball valve in PVC,
- Stainless steel filter housing with pass-through for Emery testing,
- 99,995% MPPS HEPA filter 3P6.
Air outlet module (extraction) with:
- 99,995% MPPS HEPA filter 3P6,
- Stainless steel filter housing with pass-through for Emery testing,
- Motorized DN 80 isolation ball valve in PVC,
- Leaktight extraction air blower V 133 (pressure).

Work station:
It comprises two modules (Air inlet and outlet modules):
Air inlet module (inlet air) with:
- Inlet pre-filter PRV 160,
- Inlet air blower G2D 120 non leaktight (air flow rate),
- Motorized DN 80 isolation ball valve in PVC,
- Stainless steel filter housing with pass-through for Emery testing,
- 99,995% MPPS HEPA filter 3P3.
Accessories for H$_2$O$_2$ vapour
- Circulation fans for good distribution.
Air outlet module (extraction) with:
- 99,995% MPPS HEPA filter 3P3,
- Stainless steel filter housing with pass-through for Emery testing,
- Motorized DN 80 isolation ball valve in PVC,
- Leaktight extraction air blower G2D 120 (pressure).

Ventilation / filtration H$_2$O$_2$:
It comprises two modules (H$_2$O$_2$ inlet and outlet modules):
H$_2$O$_2$ inlet module with:
- DN 32 pneumatic diaphragm valve,
- Position detector,
H$_2$O$_2$ outlet module (extraction) with:
- DN 32 pneumatic diaphragm valve,
- Position detector,

Control system
Full automatic control command PLC system:
PLC and operator interface:
- Full automatic leak test before bio decontamination,
- Automatic transition between phases,
- Adjustable phases parameters,
- Status, alarms and measurements displaying,
- Access control by password.
• Automatic phase report,
• \( \text{H}_2\text{O}_2 \) full automatic control command by isolator.

**Printer (option):**
• Report print out,
• Date – time – start – end of each phase,
• Pressure data max – min – scale – temperature,
• \( \text{H}_2\text{O}_2 \) bio decontamination report.

**Manipulation system**
Manipulation inside the isolator is done through glove-sleeve assemblies. Gloves are available in various sizes and various materials such as neoprene, Hypalon® or neoprene / Hypalon® double dipping. The sleeves are made of Hypalon® (various materials available).

The standard is:
• Hypalon® sleeve,
• Ready to fit - Glove Neoprene (T7 size).

**Ready to fit Gloves**
Particle free & sterile ELS gloves in individual packaging. The shape of the ELS glove has been specifically designed to work in isolator allowing a glove interchange without breaking the leaktightness of the isolator.

The “Ready to fit” ELS Glove provides improvement for better use in a sterile isolator:
• Double rotor-cleaning and drying in an ISO class 5 room to eliminate the particles,
• Individual double packaging,
• Beta beam sterilization with a Sterility Assurance Level (SAL) greater than \( 10^{-6} \) according to the European Pharmacopoeia (EP) 4th edition § 2.6.1,
• Identification with a batch number and expiration date. The assembly of the glove onto the sleeve is done using a cuff ring called RAC100, which is used to test the integrity of the glove using the GLT (Glove Leak Tester) and for replacement of the glove without breaking the sterility.

Gloves supplied by GETINGE-La Cathène are EC certified.

It comprises two parts:
• DPTE®-S 190 transfer system
• Dummy container

**DPTE®-S 190 transfer system:**
The DPTE®-S 190 is completely interlocked and allows safe connection/disconnection of the DPTE® Beta part.
The alpha flange is constructed from solid, high quality, stainless steel (type 316L or European equivalent).
The Alpha door is manufactured of high molecular weight HDPE.

A J3L lip seal made of PVC (polyvinyl chloride) is mounted onto the Alpha door.

**Dummy container:**
The DPTE®-S 190 are supplied with a dummy container for easier bio decontamination of the seal surface areas.
The dummy container is manufactured of high molecular weight HDPE.

A J3L lip seal made of PVC (polyvinyl chloride) is mounted onto the beta flange.

**Transfer system (hatch door and intermediate door).**
A rectangular doors with an inflatable gasket and air & electric interlock maintain the leaktightness between hatch/ outside and hatch / work station during the bio decontamination phases.

It comprises four main parts:
• Door
• Inspection window
• Inflatable gasket/detector
• Tracks (only for intermediate door)

**Door:**
The door is made of polypropylene PP with stainless steel hinges (type 316L or European equivalent).

**Inspection window:**
The inspection window is made of polymethyl methacrylate PMMA.

**Inflatable gasket/detector:**
The inflatable gasket is made of silicone and air & electric lock (detector) maintain the leaktightness between hatch/ outside and hatch / work station during the bio decontamination phases.

**Track (only for intermediate door):**
The tracks are fixed on the door to guide the trolley.
Hatch door

Intermediate door

Transfer system (tri-clamps and cables glands)
The tri-clamps and cables glands are manufactured from solid, high quality, stainless steel (type 316L or European equivalent). The two tri-clamps are located in the work station on the tubing outfeed side (air sampling connection and cable of the particle counter for example).

H₂O₂ sterilizer
The isolator is designed and equipped to be bio-decontaminated using H₂O₂ hydrogen peroxide (vapour). The chemical bio decontamination concerns the bio decontamination of surfaces only. The different materials used in the manufacture of the isolators are compatible with the bio decontamination agents. The resistance of any other material used for the isolator must be approved beforehand.

- The sterilizer operates in closed loop.
- Pressure regulation in the isolator during the bio decontamination cycle is ensured by the sterilize.
- Bio decontamination agents: H₂O₂ at 35%
- Bio decontamination mode: Evaporation
- Fluid required: None
- Operating principle: Closed loop
- Others: Integrated catalytic converter

Sterility testing
The steritest Equinox is a transfer pump which is used with Steritest devices, allowing to check the sterility of drugs from various packaging formats.

Accessories
- Sterility testing pump
- DPTE-DispoBag®
- Tubing system
- Transfer trolley / baskets

- Optimization of operator’s ergonomics
- Automatic closing of the pump head
- Pump with high flow
- SOP’s on program

DPTE-DispoBag®
When practicing sterility testing in isolator there is a need to safety transfer samples, analytical equipment, culture media and rinsing solution. The solid waste (empty containers, blisters…) as the liquid waste (filtrates) must be egressed from the isolator without interfering with the analysis and without any risk of chemical and biological cross contamination with the environment. DPTE-DispoBag® for waste is a gamma sterilised 190 DPTE-BetaBag® designed to ease the collection and the sorting of waste during sterility testing. As all DPTE® systems they allow a leaktight cross protection between operator and environment.

DPTE-DispoBag® Liquid/Solid
- The egress of solid/liquid waste is done through a 190 DPTE® transfer system with Capacity of 20L of liquid & 50L of solid polyurethane gamma sterilized bags.
- This unit provides protection for both liquid and solid filtrate.
- The sterile, ready to use DPTE-DispoBag® are manufactured and individually controlled as are all DPTE-BetaBag® products in ISO class 7.
Trolley and Liquid / Solid
A dedicated trolley is available for easier removal.

- The trolley is made of stainless steel and the containers are made of Polyethylene.

Tubing system™
The tubing outfeed system has been designed to allow dynamic sterile transfer of materials or products from the inside of the isolator to the outside, in a semi continuous way without breach of containment.
The tubing outlet uses the DPTE® system and the method of operation is the same as for a standard container.
The assembly of tube and DPTE® is sterilized by radiation.
The big advantage of this transfer system is the ease of dismounting and interchange ability.
It comprises two parts:
- Tubing 1
- Welding machine 2
- Canister holder 3

Tubing
DPTE® tube equipped with sterile sleeve (the assembly tube and DPTE® 190 is sterilized by radiation) made of polyethylene of a length 40 meter and width 400 mm (flat).

Welding machine
Welding machine and frame are made of stainless steel. The work station consisting of a double-seam welder and Cutter.
Thanks to its system of two parallel welds, the double-seam welder fitted with cutter, allows both to isolate the product to be transferred and to preserve containment inside the isolator. The sleeve is accurately cut between the 2 seams using the cutter.

Canister holder
Holder used to keep in position the canisters before being remove into the DPTE tubing for incubation.
It comprises one part:
Holder 1

Holder
The holder is made of polyethylene (dimension 183x120x15 mm).

Transfer trolley
Transfer of material component to the working station is done through a bio decontamination hatch equipped with a mobile trolley. The baskets, containing the necessary elements for each test, are put on this mobile trolley and can be suspended in the work station.
It comprises two parts:
- Mobile trolley 1
- Baskets 2

Mobile trolley
Mobile trolley is constructed from solid, high quality, stainless steel (type 316L or European equivalent).

Baskets
Baskets are constructed from solid, high quality, stainless steel (type 316L or European equivalent).
Four baskets (240x160x370mm)
One basket (650x240x440mm).
ORDERING

Description
Use the description below in combination with the capacity table to select the appropriate models.

Example Model: ISOTEST C

Range Name
Installation style

INSTALLATION STYLE SELECTION

Working configuration
- Configuration A (1) One sterility testing, (2) two DPTE® S 190 and one DPTE-DispoBag®, (3) one tubing system.
- Configuration B (1) One sterility testing, (2) two DPTE® S 190 and one DPTE-DispoBag®, (3) one tubing system.
- Configuration C (1) Two sterility testing,(2) four DPTE® S 190 and two DPTE-DispoBag®, (3) two tubing system.

MANIPULATION

- Hypalon® sleeve
- Ready to fit - Glove Neoprene (T7 size)

DIMENSIONS (Detail see page 8)

OPTION LIST

- Containment enclosure
- Perforated shelves (600 x 208 mm 3 levels)

- Control system
- SCADA System (INTOUCH)

- Printer (with SCADA System)
- Printer (without SCADA System)
- Drager probe H₂O₂ – 0 ppm / 5 ppm - operator protect
- Drager probe H₂O₂ – 0 ppm / 50 ppm - residual monitorage
- Drager probe H₂O₂ – 0 ppm / 2000 ppm- sterilisation monitorage

MANIPULATION SYSTEM

- Sleeve - PVC / DIVETEX
- Ready to fit Glove – Neoprene

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- Neoprene glove

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<td>T8</td>
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- Neoprene / Hypalon glove

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- Hypalon glove

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H₂O₂ sterlizer

- Dry air regenerator for deshidification (for reusable cartridge)
- Reusable cartridge (can be regenerated)

FRAME (DISMANTLED PARTS)

- To access during the installation of the isolator (clearance door minimum: 2.04m)

PROCESS FEATURES AND OPTIONS

Perforated shelves (600 x 208 mm)
The 3 level perforated shelves is manufactured of stainless steel (type 316L). It allowsinstalling loads in the isolator in order to optimize their bio-decontamination.(for A or B configuration only).

SCADA System (INTOUCH)

PC equipped with one software which can:
- Control command as operator interface,
- Audit-trail,
- Electronic record data reports,
- Safety access,
- Trend historical,
- Printer,
- Possibility to control three units.
DIMENSIONS
(diagrams)
SERVICES

Check

Standard:
Isotest isolator is inspected before shipment. This operation is carried out by our Inspection Quality Department following the inspection plan. The inspection plan describes the manufacturing process and inspection. It gives the input and output data of the different phases of the product manufacturing and inspection. Inspections sheets are signed by the Inspection Quality Department and the Quality Internal Validation Department.

Option:
FAT with dedicated protocol (Factory Acceptance Test), written according to GETINGE-La Calhène format and test procedures. The protocol is sent to the customer for approval before test execution.

Documentation

Standard:
- English language
- French language
- Operating file including (following general goods-in acceptance testing procedure):
  - General description (Piping Instrumentation Diagram),
  - Assembly drawing(s) and parts list(s),
  - Electrical file(s),
  - Technical documents (component data sheet),
  - User manual(s),
  - Inspection notes,
  - Certificates (material certificate main parts and the calibration certificates of the equipment used during the test),
  - Acceptance reports.

Option list:
- Other language: ............................
- Factory Acceptance Testing (included the standard documentation in place of the inspection notes)
- Software package
  - Detail Design Specification (DDS),
  - Software validation package.

PACKING AND OPTIONS

Packaging identification
- Item reference,
- Quantity,
- Assembly.

Packaging method
- The Isotest isolator will be packed according to the agreed kind of shipment.

Storage conditions
- Normal storage temperature (16°C and 24°C).

SHIPPING AND OPTIONS

☐ Shipping by air
☐ Shipping by sea
☐ Shipping by road (distribution service)
☐ Shipping by road (direct carriage)

INSTALLATIONS

Limits of use / specification
- Operating pressure (production):
  +40 Pa ± 10 Pa.
- Operating pressure (bio-decontamination):
  +60 Pa ± 10 Pa.
- Temperature (production):
  Between 18°C and 24°C.
- Climatic resistance:
  20 to 70 % relative humidity without condensation.
- Environment classification at rest:
  M 3.5 as per standard FS 209 E or Iso 5 as per standard ISO 14644-1.
- Inlet air change rate (100 % fresh air):
  40 per hour for work station (free extraction new filters).
  400 per hour for bio-decontamination hatch (free extraction new filters).
- Leaktightness specifications (value at factory test):
  0.5 % vol/h at 150 Pa.
- Filtration level:
  ≥ 99.995 % (MPPS efficiency).
- Equivalent sound pressure:
  ≤ 75 dBa.
- Type of flow:
  Turbulent flow.
- Volume of the isolator (Values given for information only):
  Work station: 1,32 m³
  Bio-decontamination hatch: 0,41 m³
- Isolator protection index:
  IP 20.
- Volume of load to be bio-decontaminated in the hatch:
  150 Liters.

Operating limits
- Temperature range:
  0°C / + 50°C.
- Maximum pressure tests:
  - 250 Pa / + 250 Pa.
- Load unit:
  600 Kg.
Electrical
- Power supply: AC 207 to 244 V, 48 to 63 Hz.
- Number of phases: 1.
- Amperage: 16 A.
- Power: 3.68kW.
- State of compatible neutral: IT, TT, TN.
- Breaking power:
  State of IT neutral: 3 KA (default double).
  State of TT / TN neutral: 20 kA.
- Testing voltage (standard test):
  As per EN 61 010-1, 2001 issue.
  Classification of II excess-voltage, degree of pollution 2.
- Electrical safety device:
  As per EN 61 010-1, 2001 issue.
- Electromagnetic compatibility:
  EN 55011, 1998 issue,
  EN 55011, 1999 issue A1,
  EN 55011, 2002 issue A2.

UTILITY REQUIREMENTS
Characteristics of the isolator room
- Recommended air change rate per hour: 5 minimum.
- Independent rejection of the sterilizing agent to the building for each isolator.

Isotest isolators

H₂O₂ sterilizer
- Detector of hydrogen peroxide (H₂O₂),
- Evacuation for the regeneration phase,
- Mains plug: 230V / 50Hz / 20 A.

ACCESSORIES
List of spare parts

<table>
<thead>
<tr>
<th>Item Description</th>
<th>Code</th>
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<tbody>
<tr>
<td>Basket (240x160x370mm)</td>
<td>27928</td>
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<tr>
<td>Basket (650x240x440mm)</td>
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<tr>
<td>Beta door Ø 190 made of high density polyethylene</td>
<td>11942</td>
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<tr>
<td>Canister holder</td>
<td>27887</td>
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<td>Circle profil gasket EPDM</td>
<td>18222</td>
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<td>DPTE ®-S-Transfer system</td>
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<td>Dry air regenerator for desuhdification (for reusable cartridge)</td>
<td>29562</td>
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<td>Heat sealing machine</td>
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<td>HEPA filter 300 x 300 mm</td>
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<td>HEPA filter 300 x 600 mm</td>
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<td>Hypalon® sleeve</td>
<td>16285C</td>
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<td>Inflatable gasket of intermediate door and hatch door</td>
<td>24386</td>
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<td>J3L 190 E PVC for DPTE® beta flange 190 for false container</td>
<td>21819</td>
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<td>Kit for replacing the J3L lipseal including one device for replacing the J3L lipseal, procedure of replacement, particle-free cleaning paper and silicone bottle</td>
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<tr>
<td>Liquid/Solid DPTE-DispoBag®</td>
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<td>Membrane filter 0,2 µm</td>
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<td>Prefilter PRV160</td>
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<td>Prefilter PRV200</td>
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<td>Pressure switch of inflatable gasket</td>
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<td>Proximity switch of hatch door</td>
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<td>R48 O’ ring (for RAC 100)</td>
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GLT
The glove in an isolator constitutes the weakest link in the containment barrier. GLT system allows “in situ” glove testing without breaking the absolute barrier and thereby stopping the exploitation.
Simple and rapid to operate (approximately 6 minutes to test one glove), the equipment is capable of detecting a glove perforation not visible to the naked eye (detect Ø 40 µm pin hole).
The standard equipment is designed for use with GETINGE La Calhène glove cuff ring system (type RAC 100).

In this picture, a GLT.

GLOSSARY
Closed loop: The sterilizer ensures the inlet and outlet of the sterilizing agent in the enclosure.
Divetex: PVC coated material specially adapted to be used with an isolator.
DPTE-DispoBag®: System allowing to evacuate solid and liquid waste during sterility testing without any risk of contamination with the environment.
DPTE® Transfer system: Safety double door transfer system. The safest method for introducing and removing sterile and or for toxic material without breaking containment.
DPTE® Tubing: System allows to transfer materials outside of the isolator in a semi continuous way as a standard container.
EP: European Pharmacopoeia
GLT: Glove Leak Tester
Hypalon®: Synthetic elastomer compatible with H₂O₂
Open loop: The sterilizer ensures the inlet of the sterilizing agent, the isolator extraction system ensures the outlet.
PLC System: Control command system for regulation of ventilation and filtration
SCADA: Supervisory Control And Data Acquisition
H₂O₂ sterilizer: Sterilizer using hydrogen peroxide (H₂O₂) in closed loop.
Getinge provides complete solutions for effective and efficient cleaning, disinfection and sterilization in the healthcare and life science sectors. Our know-how comprises everything from architectural planning, production and handling equipment, to systems for full traceability of sterile goods. Our commitment covers expert advice, training and long-term technical support.