

CUSTOMER:

REFERENCE:

SOFT WALL HALF-SUIT ISOLATOR

Half-Suit Isolator

European version

PRODUCT SPECIFICATION

SPECIFICATION

The Getinge-La Calhène Half-Suit Isolator (SWB) are leaktight enclosures equipped with means of transfer and manipulation that keeps an enclosed environment. This allows cross protection of the operator/product against microbiological and chemical contamination without compromising the environment.

Half suit is conceptually an extension of the glove sleeve concept applied to the entire upper body. This allows the operator to be physically inside the isolator, while being micro-biologically outside. The obvious benefit is a much wider ergonomic range compared to glove-sleeves. The materials of construction insure the maximum dexterity and comfort to the user.

APPLICATION

Half-Suit Isolators allow aseptic operations such as sterility testing, aseptic formulation and filling, etc.

KEY FEATURES

- 316L stainless steel base
- Transparent flexible PVC canopy (0.3 mm thickness)
- 304 L stainless steel welded supporting frame on lockable casters
- Ventilation system capable of more than 20 air changes per hour, and positive pressure of $+30 \pm 10$ Pa (adjustable)
- Control system:
 - Manual command with automatic pressure control "PARIS 1" type
 - Automatic PLC control (Siemens)
- Single inlet and outlet HEPA filters
- Manipulation is carried out by one Half-Suit with gloves (changeable without breaking the sterility)
- Half-Suit support for bio decontamination (optional)
- Transfer system using DPTE® double door systems and access doors

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 Half-Suit Isolator complies with all appropriate standards, codes and directives relevant to the region of installation. The equipment is manufactured according to industry requirements and standards.

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 (optional), 21CFR Part 11 and current guidelines are followed in all our documentation and validation support materials.
- 21CFR Part 11 capable in accordance to the PLC capabilities

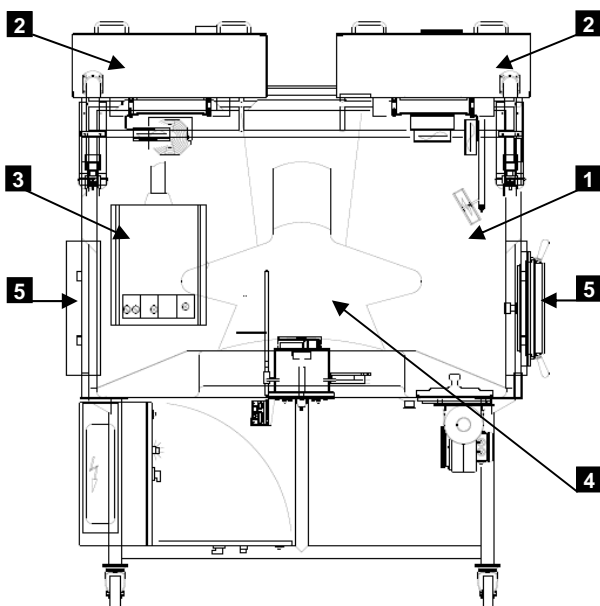
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- ☐ - Denotes optional features - Check boxes as required.
 - Commercial specifications only.
 - Pictures and drawings non contractual.

DESCRIPTION

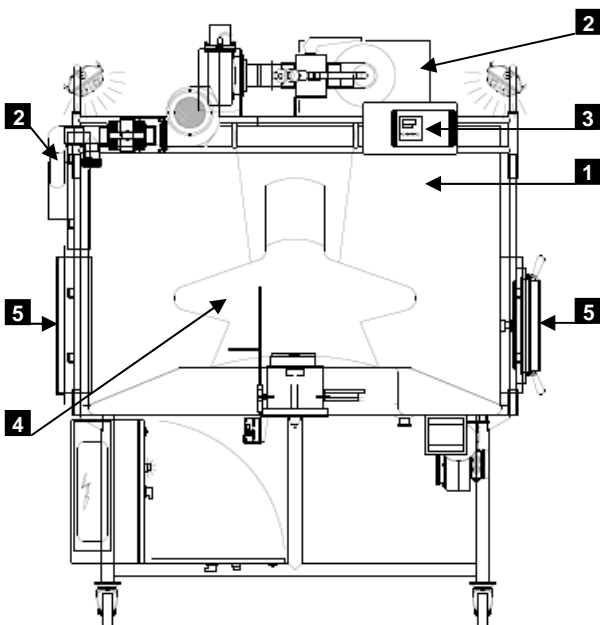
PRODUCT DESCRIPTION

The Half-Suit Isolator is composed of 5 parts:

- Containment enclosure **1**
- Ventilation / filtration **2**
- Control system **3**
- Manipulation system (s) **4**
- Transfer system (s) **5**



A Half-Suit Isolators with PLC control system.



A Half-Suit Isolators with "PARIS 1" control system.

PRINCIPLE OF OPERATION

All the surfaces and the atmosphere of a Half-Suit isolator can be bio-decontaminated using a chemical process (either using hydrogen peroxide or peracetic acid).

Half-Suit isolators allows aseptic operations such as sterility testing, and manual filling formulation.

The operator can operate inside the sterile environment using manipulation systems while remaining outside.

BASIC DESIGN FEATURES

Design features and material definition are listed below, unless specifically mentioned as optional.

Containment enclosure

Comprised of three main parts:

- Stainless steel base,
- Stainless steel welded structure,
- Transparent flexible PVC canopy.

Stainless steel base

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

Surfaces are polished to facilitate cleaning (Ra 0.5 µm in accordance with ISO 1302 standards).

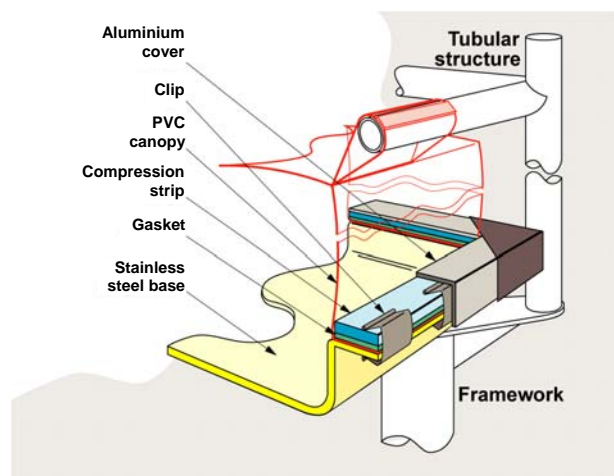
Stainless steel welded structure

Frame and structure are constructed from solid, high quality, stainless steel (type 304L or European equivalent).

Surfaces are polished to facilitate cleaning (Ra 0.8 µm in accordance with ISO 1302 standards except for welding).

Transparent flexible PVC canopy

The canopy is manufactured of transparent flexible PVC (polyvinyl chloride) of 0.3 mm thickness, with viewing windows, attached to the stainless steel base.



Ventilation / filtration with PLC type regulation

Comprised of two modules (Air inlet and outlet modules):

Air inlet module (inlet air) with:

- Inlet pre-filter
- Inlet air blower (air flow rate)
- Motorized DN 80 isolation valve in PVC
- Stainless steel filter housing with connection for integrity testing
- 99.995% MPPS HEPA filter 3P6
- Motorized DN 40 sterilizing agent inlet valve in PVC, for hydrogen peroxide H₂O₂ and peracetic acid

Accessories for H₂O₂ generator connection

- Mixing fans for good distribution

Air outlet module (extraction) with:

- 99.995% MPPS HEPA filter 3P6
- Stainless steel filter housing with connection for integrity testing
- Motorized DN 80 isolation valve in PVC
- Extraction air blower (pressure)
- Flexible pipe 90mm, 5 meter long

Accessories for H₂O₂ generator connection

- Motorized DN 40 sterilizing agent outlet valve in PVC
- Solenoid valve for pressure tapping

Accessories for peracetic acid PA

- Motorized DN 20 sterilizing agent by-pass valve in PVC

Ventilation / filtration with "PARIS 1" type regulation

Comprised of two modules (Air inlet and outlet modules):

Air inlet module (inlet air) with:

- Inlet pre-filter
- Inlet air blower (air flow rate)
- DN 50 isolation valve in PVC (with sensor proximity switch only VHP)
- Stainless steel filter housing with connection for integrity testing
- 99.995% MPPS HEPA filter 3P3

Accessories for hydrogen peroxide H₂O₂,

- Inlet connection for H₂O₂ generator with DN 40
- Mixing fans for good distribution

Accessories for peracetic acid PA generator connection

- One inlet PA

Air outlet module (extraction) with:

- 99.995% MPPS HEPA filter 6P6
- Stainless steel filter housing with connection for integrity testing
- DN 80 isolation valve in PVC (with sensor proximity switch only VHP)
- Flexible pipe 90mm, 5 meter long

Accessories for H₂O₂ generator connection

- DN 40 sterilizing agent outlet valve in PVC (with sensor proximity switch only VHP)

- Mixing fans for good distribution

Accessories for peracetic acid PA generator connection

- Sterilizing agent outlet by-pass valve in PVC

Control system

Automatic PLC control:

PLC and operator interface:

- Full automatic leak test before bio-decontamination or during production
- Automatic transition between phases
- Adjustable modes and parameters
- Status, alarms and data display
- Access control by password
- Automatic phase report
- VHP® full automatic control command by isolator

Printer:

- Report print out
- Date – time – start – end of each phase
- Pressure data max – min – scale – temperature

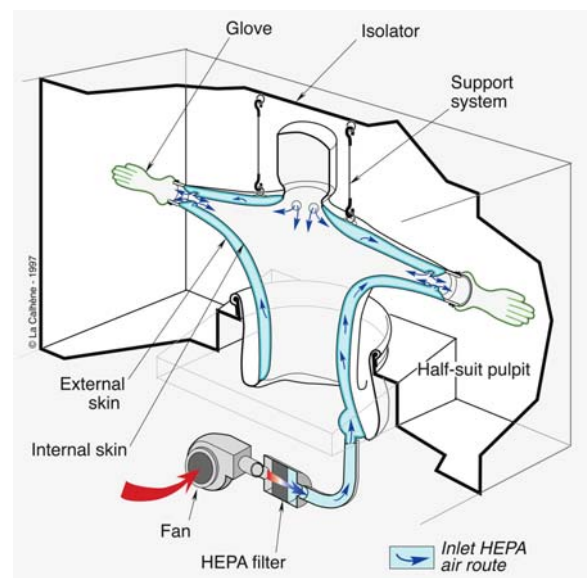
Manual command with automatic pressure control PARIS 1:

- Adjustment of the set pressure
- Display of the measured pressure
- High and low pressure alarm, with strobe and buzzer

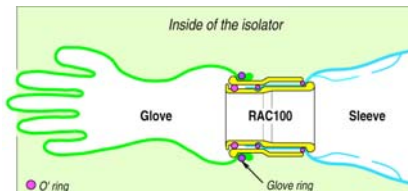
Manipulation system

Half suit

The manipulation inside the isolator is done through half suit. The half suit is manufactured with polyester/PVC double skin construction, for better protection of both operator and isolator environment. It is equipped with panoramic vision helmet and ventilation system that provides fresh air to the helmet and sleeve area. The half suit is simple and efficient seal, the attachment system to the isolator insures reliable leaktightness and easy changeover.



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 Calhène are EC certified.



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 isolators allowing a glove interchange without breaking the leak-tightness of the isolator.

The "Ready-to-fit" ELS Glove provides improvement for aseptic processing:

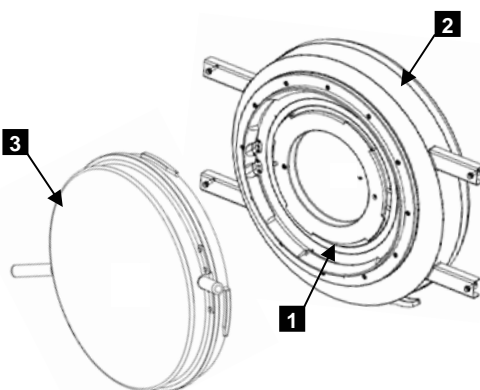
- Particle free (glove drum cleaned in classified area)
- Individual double packaging
- Beta beam sterilization with a Sterility Assurance Level (SAL) greater than 10^{-6} according to the European Pharmacopoeia (EP) 4th edition § 2.6.1
- Identification with a batch number and expiration date

Transfer system (DPTE®-S transfer system)

DPTE®-S transfer system mounted on a Ø 565 support.

It including:

- DPTE® transfer system (alpha part) **1**
- Ø 565 support **2**
- Dummy container (beta part) **3**



DPTE®-S transfer system:

The DPTE®-S 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 density HDPE.

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

Ø 565 support:

The Ø 565 support is manufactured from solid, high quality, stainless steel (type 316L or European equivalent).

Dummy container:

The DPTE®-S are equipped with a dummy container for easier bio-decontamination of the seal surface areas.

The dummy container is manufactured with a high density HDPE.

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

Transfer system (access doors)

The conventional door allows to load or unload easily the isolator.

It including:

- Ø 565 door **1**
- Clamp band **2**
- End cap **3**

Ø 565 door:

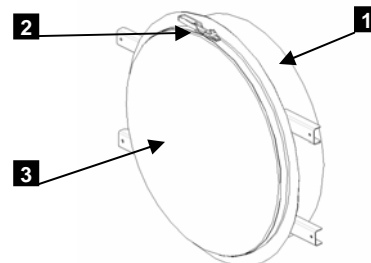
The Ø 565 door is manufactured from solid, high quality, stainless steel (type 316L or European equivalent).

Clamp band:

The clamp band is manufactured from solid, high quality, stainless steel (type 304L or European equivalent).

End cap:

The End cap is manufactured of transparent flexible PVC (polyvinyl chloride) of 0.3 mm thickness.



Transfer system (Service plate)

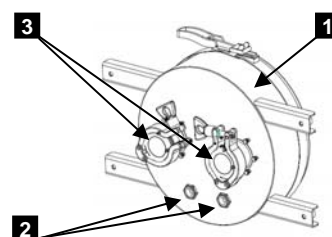
The service plate is manufactured from solid, high quality, stainless steel (type 316L or European equivalent).

Equipped with two compression fittings and two tri-clamps (air sampling connection and cable of the particle counter).

The service plate is located in front of the operator.

It including:

- Service plate **1**
- Compression fittings **2**
- Tri-clamps **3**



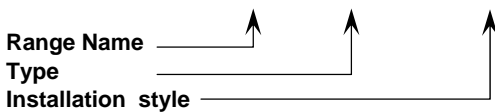
ORDERING

ORDERING

Description

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

Example Model: ISO SWB DS PLC VHP® A F



INSTALLATION STYLE SELECTION

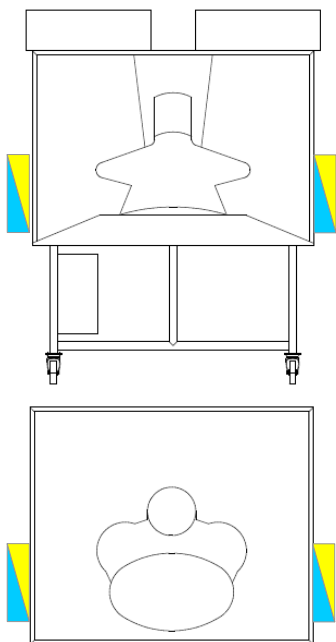
Control system

- PLC
- PARIS 1

Sterilizer interface

- hydrogen peroxide H₂O₂ – mobil VHP® M100S
- hydrogen peroxide H₂O₂ – mobil VHP® 1000ED
- Peracetic acid PA - MAN

Transfer system



DPTE®-S transfer system

Right hand side		Left hand side	
<input type="checkbox"/>	DPTE®-S Ø 270 (A)	<input type="checkbox"/>	DPTE®-S Ø 270 (B)
<input type="checkbox"/>	DPTE®-S Ø 350 (C)	<input type="checkbox"/>	DPTE®-S Ø 350 (D)

Conventional door

- Right hand side (E)
- Left hand side (F)

Manipulation

- Half suit with ready-to-fit - Glove Neoprene (T7 size)

DIMENSIONS (Detail see page 10 and 11)

OPTION LIST (Detail see page 6)

Containment enclosure

- 1 1/2" drain extraction drain on base
- 1 Hanging bar with hooks
- Wire shelves (600 x 300 mm 3-level)
- Lath floor
- Serving floor

Control system

- Temperature probe (for "PARIS 1" type only), included in PLC
- Drager probe H₂O₂ – 0 ppm / 5 ppm -Surrounding room safety
- Drager probe H₂O₂ – 0 ppm / 50 ppm -residual monitoring
- Drager probe H₂O₂ – 0 ppm / 2000 ppm-sterilization monitoring
- Digital recorder
- Paper recorder
- Lighting (for "PARIS 1" type only), included in PLC
- Stainless steel electrical cabinet (type 304L or European equivalent - "PLC" type only)
- UPS (uninterruptable power supply)
- Autotransformer
- Other voltages:

Manipulation system

- Half suit extender for bio-decontamination
- Ready-to-fit Glove – Neoprene

Size	3/10	5/10
T7	<input type="checkbox"/>	Standard
T8		<input type="checkbox"/>

- Ready to fit Glove – Neoprene / Hypalon glove

Size	5/10
T7	<input type="checkbox"/>
T8	<input type="checkbox"/>
T9	<input type="checkbox"/>

- Neoprene glove

Size	3/10
T7	<input type="checkbox"/>
T8	<input type="checkbox"/>
T9	<input type="checkbox"/>

- Hypalon glove

Size	3/10
T7	<input type="checkbox"/>
T8	<input type="checkbox"/>
T9	<input type="checkbox"/>

Transfer system

- Ø 565 door HDPE (for "PARIS 1" type only)
- Fluid platine HDPE (for "PARIS 1" type only)
- DPTE®-S Ø 190 located on the base for waste (liquid & solid)

Sterility testing

- Equinox pump integral (Millipore)

Other size

- 2 Half suit Isolators

PROCESS FEATURES AND OPTIONS

1 1/2" drain"extraction drain on base

The 1 1/2" drain permits to evacuate liquids and spills.

Hanging bar with 12 hooks (x1)

The hanging bar with hooks are manufactured of stainless steel (type 316L).

Wire shelves (600 x 300 mm)

3-level stainless steel shelves for article storage and proper positioning during bio-decontamination.

Lath floor

The lath floor is manufactured of stainless steel. It allows installing loads on the base in order to optimize bio-decontamination.

Serving hatch

The serving hatch is manufactured of stainless steel (type 316L). It allows easy transfer of the loads from the transfer isolator to the working unit.

UPS

Keep the isolator's functional modes in case of power cut-off "Uninterruptible Power Supply" (UPS).

Autotransformer

- Getinge-La Calhène can supply an autotransformer for other voltages than 230V
- The isolator must be connected using a 2P+T standard power outlet connected to earth and protected against excess currents

Manipulation system

Half suit supports for bio-decontamination. The half suit support optimize the positioning during the bio-decontamination phase (limit hidden surfaces). This device also inhibits the introduction of person in the isolator during the bio-decontamination.

Transfer system

Access doors / Ø 565 support:

The access doors and Ø 565 support can be manufactured of high density HDPE instead of 316L.

Service plate:

The service plate can be manufactured of high density HDPE instead of 316L.

DPTE®-S Ø 190:

The DPTE®-S is equipped with a dummy container for easier sterilization of the seal surface areas.

Sterility testing

The special designed Equinox is integrated to the floor of the isolator. The option package includes pump, integration and wiring.

Other size

2 Half suit Isolators

Overall dimension (mm): **3000 (w) x 2500 (h) x 2000 (d)**



SERVICES

Check

Standard:

Half-Suit Isolator are 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 provides input and output datas 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 the validation protocol (Factory Acceptance Test), written according to GETINGE-La Calhène format and test procedure. 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)
 - Standard functional specification
 - 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)
- GAMP4 documentation package (Isolator + VHP)
- Detail Design Specification (DDS)
- Software validation package
- GAMP4 documentation (SCADA)
- Detail Design Specification (DDS)
- Software validation package

PACKING AND OPTIONS

Packaging identification

- Item reference
- Quantity
- Assembly

Packing method

- The Half-Suit Isolator will be packed according to the agreed 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*):
+30 Pa \pm 10 Pa
- Operating pressure (*bio-decontamination*):
+60 Pa \pm 10 Pa
- Temperature (*production*):
Between 16°C and 24°C
- Temperature (*bio-decontamination*):
Room temperature \pm 2°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:
20 minimum per hour (*free extraction new filters*)
- Leaktightness specifications (*value ex-works*):
0.1 % vol/h at 100 Pa

- Filtration level:
 \geq 99.995 % (*MPPS efficiency*)

- Equivalent sound pressure:
 \leq 75 dBa

- Type of flow:
Turbulent flow

- Volume of the isolator (Values given for information only):
Half-Suit Isolators: 2,7 m³

- 2 Half-Suit Isolator: 4 m³

- Isolator protection index:
IP 20

- Weight unit:
Half-Suit Isolator: 360 Kg
2 Half-Suit Isolator: 500 Kg

- Maximum acceptable load:
Half-Suit Isolator and 2 Half-Suit Isolator : 75 Kg/m²

Operating limits

- Temperature range:
0°C / + 50°C

- Maximum mechanical load:
- 50 Pa / + 200 Pa

Electrical

- Power supply:
AC 170 to 264 V, 48 to 63 Hz

- Number of phases:
1/2

- Amperage:
9.3 A

- Power:
2139 VA

- State of compatible neutral:
IT, TT, TN

- Breaking power:
State of IT neutral: 10KA
State of TT / TN neutral: 20 kA

- Testing voltage (*standard test*):
As per EN 61 010-1, 1995 issue,
Classification of II excess-voltage, degree of pollution 2

- Electrical safety device:
As per EN 61 010-1, 1995 issue

- Electromagnetic compatibility:
EN 50 081-2, 1992 issue

- EN 50 082-2, 1995 issue

- EN 61000-4-3, 1997 issue

- EN 61000-4-6, 1997 issue

- EN 61000-4-4, 1995 issue

- EN 61000-4-2, 1995 issue

- EN 55011, 1991 issue

UTILITY REQUIREMENTS

Characteristics of the isolator room

- Independent exhaust of the sterilizing agent to the building for each isolator

Half-Suit Isolator

- Mains plug: 230V / 16A

Sterilizer

VHP® M100S or 1000ED (hydrogen peroxide H₂O₂):

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

MAN (Peracetic acid PA):

- Medical quality compressed air set at 3 bars minimum
- Mains plug: 230V / 50Hz / 1A

ACCESSORIES

List of spare parts

Description	Part number
24 V indicator light (yellow)	19750
24 V leak-tight buzzer	19751
Adhesive for flexible PVC and vinyl	2884C
Canopy	Depending of option (refer to its n°)
Clamping band made of stainless steel Ø 450 (filter housing)	639C
Clamping band made of stainless steel Ø 565	6322C
Clamping band made of stainless steel Ø 662	11163
Clamping band made of stainless steel Ø 880 (half suit)	8713C
DPTE®-S-Transfer system	Following the product sheet DPTE®-S (FP 200)
HEPA filter 300 x 300 mm	6603C
HEPA filter 300 x 600 mm	18518C
HEPA filter 600 x 600 mm	6604C
Indicator cloth	6294C
ISOP filter for half suit	2581C
Kit for replacing the J3L lipseal including one device for replacing the J3L lipseal, procedure of replacement, particle-free cleaning paper and silicone bottle	23024C
Long supporting elastic band for hanging half suit	18408C
Membrane filter 0,2 µm	6599 C
Neoprene rubber band ES 450	6629C

Neoprene rubber band ES 565	6630C
Neoprene rubber band ES 800x500	7812C
Neoprene rubber band ES 880	6632C
Prefilter PRV160 for PARIS1	4643C
PVC cape for Ø 565 - 30/100	6593C
Reels of thermal paper of the printer	21160
Repair kit for canopy	630C
Short supporting elastic band for hanging half suit	18479C
TLD 36/840 lamp	16856

RELATED & OTHER APPROPRIATE PRODUCTS DESCRIPTION

Depending on the application, the glove isolators can be used as:

Transfer isolator

- To bio-decontaminate the equipment, which is introduced into the work station isolator

Half-Suit Isolator

- To perform operations such as sterility testing, aseptic formulation and filling, etc



Transfer isolator.

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 quick 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).



GLT.

Bio-decontamination of an isolator

One of main characteristics of an isolator system is its capability to be bio-decontaminated and to keep a germ-free environment with whatever operation or transfer performed.

In some cases, the isolator is bio-decontaminated after each process, in order to eliminate potential biohazard.

Bio-decontamination of an isolator is performed by contact of a gas or vapor form a sterilant, generated by a stand-alone or integrated device. Getinge-la Calhène has experience with several suppliers.

All isolators for aseptic and bio-hazard operation are equipped with connections that can accommodate the bio-decontamination device selected.

Getinge-la Calhène has participated in the development and integration of multiple bio-decontamination systems. Some have been developed for specific applications, like bio-decontamination cycles for large filling isolator suites.

Bio-decontamination can be obtained from various chemical sterilants.

There are 2 main types of apparatus:

- Vapor generator for hydrogen peroxide H₂O₂ (VHP®)
- Vapor generator for peracetic acid PA (MAN)



Vapor generator for hydrogen peroxide H₂O₂ (VHP®)



Vapor generator for peracetic acid PA (MAN)

GLOSSARY

Transfer Isolator: Leak tight volume used for the bio-decontamination and the transfer of a work load

Half-Suit Isolator: Leak tight volume where operations such as sterility testing, aseptic formulation and filling, etc. are performed.

SWB type: Isolators with transparent soft wall canopy, with a stainless steel base (SWB)

VHP® M 100S: H₂O₂ vapor generator for small volume

VHP® 1000ED: H₂O₂ vapor generator for large volume

MAN: Sterilizer using Soproper in open loop

Open loop: The decontamination system provides the input of the agent, the isolator extraction system ensures the extraction

Closed loop: The decontamination system ventilation system recirculates the agent in the enclosure

Hypalon: Synthetic elastomer compatible with H₂O₂

Polyester PVC coat: PVC coated jersey, for operator comfort

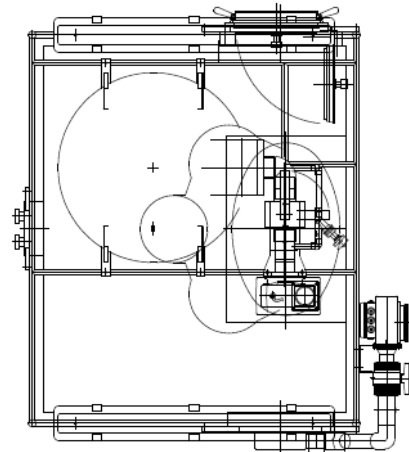
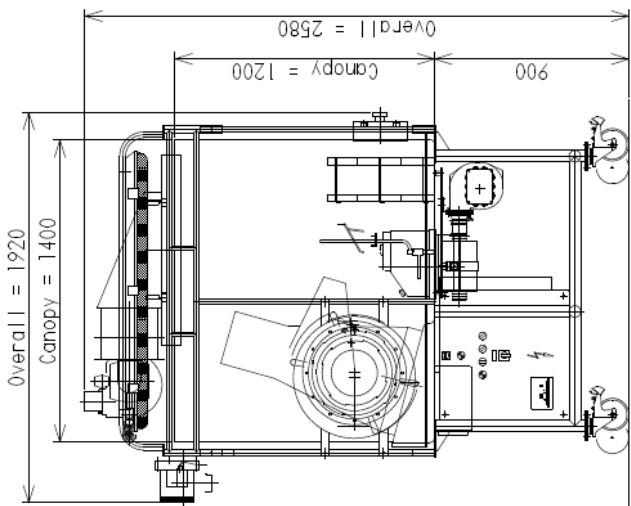
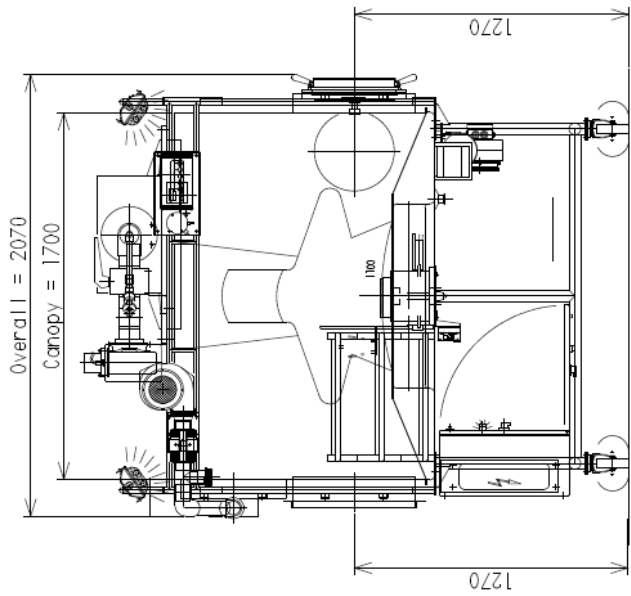
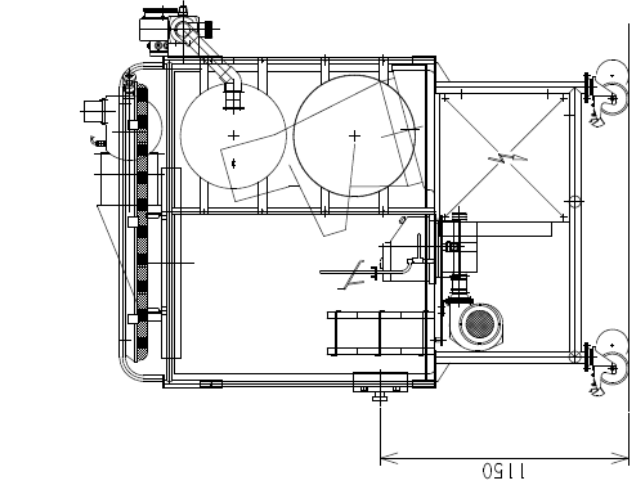
DPTE® BETA: Container flange / container door / container body assembly. Mobile part of the DPTE® system (for example a container)

GETINGE

DIMENSIONS

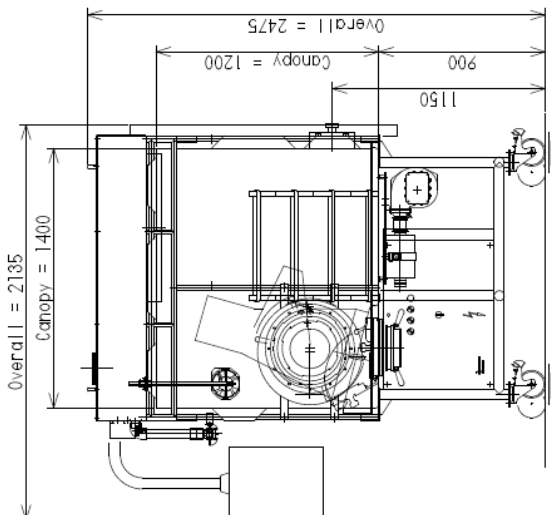
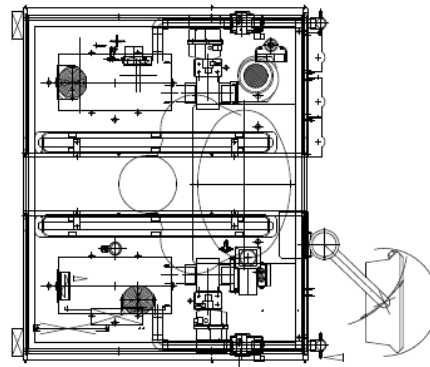
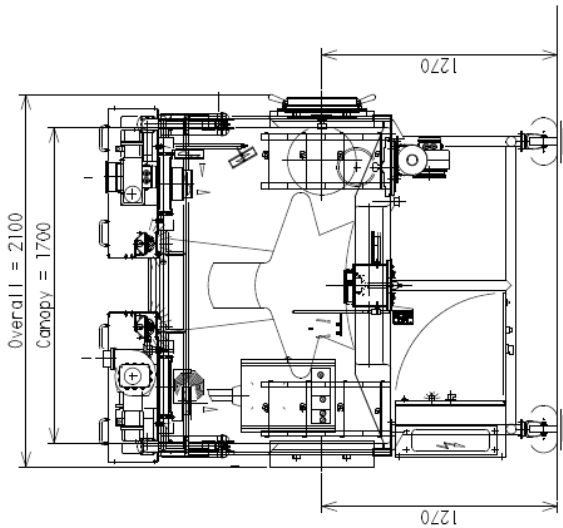
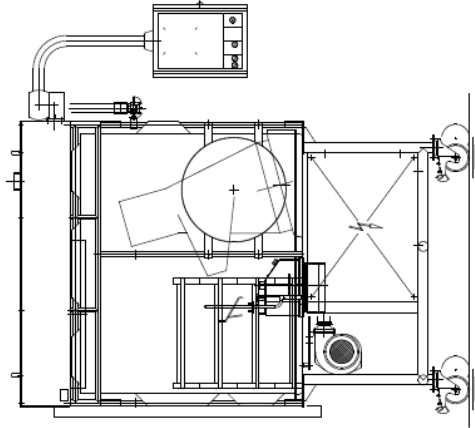
(diagrams)

*Half-Suit Isolators with
"PARIS 1" control system*



GETINGE

DIMENSIONS (diagrams) *Half-Suit Isolators with PLC control system*





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.

GETINGE

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