CUSTOMER: .....

REFERENCE: .....

ISOCYT FREJA
Rigid wall compounding Isolator for centralized safe reconstitution of injectable cytotoxic drugs

SPECIFICATION

PRODUCT SPECIFICATION
The ISOCYT FREJA is a leaktight enclosure, equipped with means of transfer and manipulation which keeps an enclosed environment allowing a cross protection between the operator and the product, against microbiological and chemical contamination, without compromising the environment.

APPLICATION
Isolator for bi-directional protection in reconstitution of injectable cytotoxic drugs.
The repetitive handling of cytotoxic products can affect the health of nurses during reconstitution and administration. To prevent this, in many cases the reconstitutions are centralized in protected areas of hospital pharmacies.
An isolator is the method of choice to get the best control without jeopardizing either the personnel/environment or the sterile quality of final product. “Just In Time” 2 operator ISOCYT FREJA, in addition to the usual comfort of Getinge La Calhène isolators, gathers features to provide an optimal cross protection.

KEY FEATURES
- 316L or European equivalent stainless steel isolator shell, with integrated H_2O_2 bio-decontamination airlock and Dynamic Output Port
- One glass window where four shoulder rings are mounted, allowing operation inside the sterile environment
- 304 L stainless steel welded supporting frame
- Two ergonomic footrests for the operators
- Non-glare lighting of work area
- Ventilation system capable of 40 air changes per hour for work station with a positive or negative pressure.
- Control system:
  - Fully automatic control command PLC system (Siemens)
- Single inlet and outlet HEPA filters
- 2 x 2 glove working station isolator
- Central Dynamic Output Port (accessible to both operators)
- Manipulation by gloves (changeable without breaking the leaktightness) mounted on sleeves
- Transfer system using DPTE® systems and doors

Due to continued product improvement, system configurations and specifications may change without notice.

ERGONOMICS AND COMFORT
Ergonomics and comfort are key points of Getinge-La Calhène isolators. These aspects have been taken into account for ISOCYT FREJA’s design, and more particularly in the following elements:
- Chair (optional)
- Footrest
- Specially shaped sleeves
- DPTE® transfer system
- Bio-decontamination airlock
- Isolator dimensions
- Accessories

QUALITY STATEMENT
Confidence of clients in the Getinge Group is our 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 ISOCYT FREJA complies with the following standards:
Electrical requirement
- Directive n° 2004/108/CEE (CEM)
- Directive n° 2006/95/CEE (BT)

Glove regulations
- Directive n° 89/686/EEC (PPE)

Automation regulation
- GAMP 5 procedures, current guidelines are followed in all our documentation and validation support materials.
- 21CFR Part 11 capable in accordance to the PLC capabilities

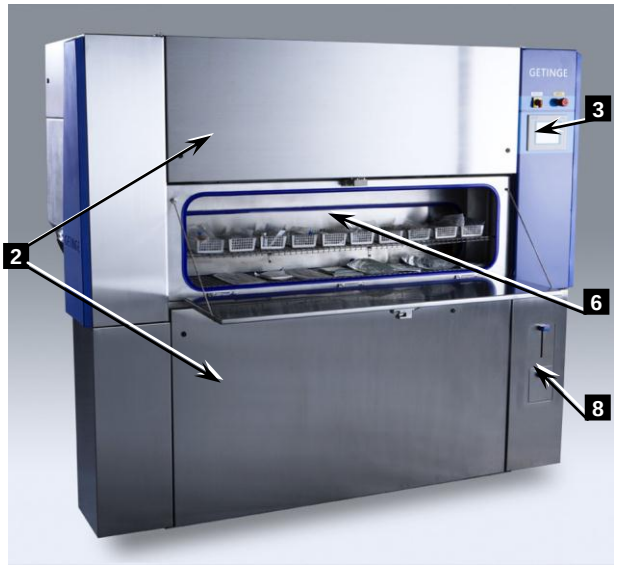
❑ - Denotes optional feature - Check boxes as required.
- Commercial specifications only.
- Pictures and drawings non contractual.

DESCRIPTION

PRODUCT DESCRIPTION

The ISOCYT FREJA is composed of 8 parts:

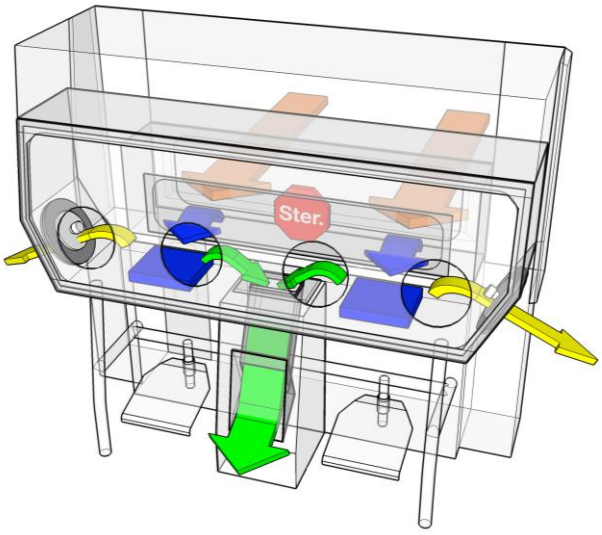
- Work station **1**
- Ventilation / filtration **2**
- Control system **3**
- Manipulation system **4**
- Waste Transfer DPTE® port **5**
- Bio-decontamination airlock **6**
- Dynamic Output Port **7**
- Steritrace II - Integrated H_2O_2 sterilizer **8**



PRINCIPLE OF OPERATION

Example of Working procedure

- The pharmacist converts the prescriptions into formulations
- The formulations are individually loaded in indivual baskets and transferred in the bio-decontamination airlock
- The leaktightness of the airlock is tested before starting the validated H_2O_2 bio-decontamination cycle
- After completion of the bio-decontamination cycle, the baskets are transferred to the already bio-decontaminated work station
- When all the baskets are in the work station, a new bio-decontamination cycle can be started in the airlock with a second series of baskets
- The operators do the reconstitutions, throw away the waste in the laterally located DPTE® and put each preparation in a zip pouch before egress through the Dynamic Output Port
- Each reconstitution is labelled and quality controlled
- The drug is then stored in an appropriate transfer box and shipped before being administered to the patient



Product loading
Bio-decontamination phase
Waste
Product preparation
Final product outlet

DESIGN FEATURES

Design features and material definition conform to the specifications listed below.

Stainless steel isolator shell

Work station, bio-decontamination airlock, and Dynamic Output Port

The system is constructed from solid, high quality, stainless steel (type 316 L or European equivalent).
Surfaces are polished to facilitate cleaning (Ra = 0.8 µm) in accordance with EN ISO 1302.

One glass window with four shoulder rings

- The window is made of transparent tempered glass in accordance with the standard EN 12150 (impact resistance).

Ventilation / filtration with PLC regulation

Bio-decontamination airlock

It comprises two modules (Air inlet and outlet modules):

Air inlet module with:

- Inlet pre-filter
- Inlet air blower (air flow rate)
- Motorized DN 80 isolation ball valve with a position detector
- Stainless steel filter housing with connection for filter integrity testing
- 99.995 % MPPS HEPA filter (H14)

Air outlet module with:

- 99.995 % MPPS HEPA filter (H14)
- Stainless steel filter housing with connection for filter integrity testing
- Motorized DN 80 isolation ball valve with a position detector
- Extraction air blower (pressure)

Airlock capacity:

- 12 to 24 baskets depending on the size of baskets used.

Work station and Dynamic Output Port

It comprises two modules (Air inlet and outlet modules):

Air inlet module with:

- Inlet pre-filter
- Inlet air blower (air flow rate)
- Motorized DN 80 isolation ball valve with a position detector
- Stainless steel filter housing with connection for filter integrity testing
- 99.995 % MPPS HEPA filter (H14)

Air outlet module with:

- 99.995 % MPPS HEPA filter (H14)
- Stainless steel filter housing with connection for filter integrity testing
- Motorized DN 80 isolation ball valve with a position detector
- Extraction air blower

Work station capacity (DO version):

- 16 to 32 baskets depending on the size of baskets used.

Liquid H_2O_2 main injection circuit

- H_2O_2 bottle with RFID chip
- Dosing pump
- Vaporizer

Inlet circuit of vaporized H_2O_2

H_2O_2 for bio-decontamination airlock

- Motorized DN 50 isolation butterfly valve with a position detector

Work station and Dynamic Output Port

- Motorized DN 50 isolation butterfly valve with a position detector

Oulet circuit of vaporized H_2O_2

H_2O_2 for bio-decontamination airlock, work station and Dynamic Output Port

- Recirculation blower
- Motorized DN 50 isolation butterfly valve with a position detector
- Butterfly valve DN 25 for pressure control

Control system

Full automatic control PLC system:

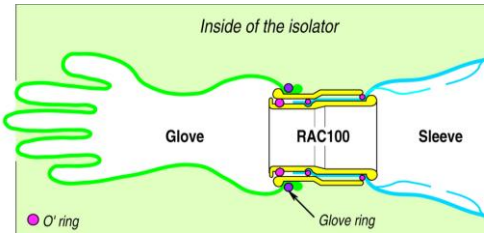
PLC and operator interface:

- Full automatic leak test before bio-decontamination
- Automatic transition between phases
- Adjustable phases parameters
- Status, alarms and parameter display
- Access control by password
- Automatic phase report
- Fully automatic bio-decontamination cycles

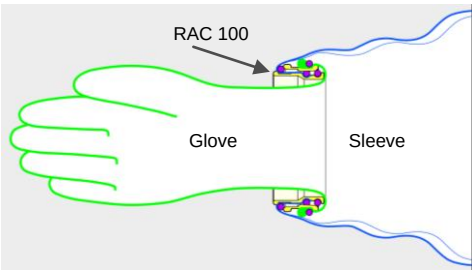
Printer (option):

- Report print out
- Date – time – start – end of each phase
- Pressure data max – min – scale – temperature
- H_2O_2 bio-decontamination report

Manipulation system
Manipulation inside the isolator is done through comfortable and secure glove-sleeve assemblies.



(enclosure under positive pressure)



(enclosure under negative pressure)

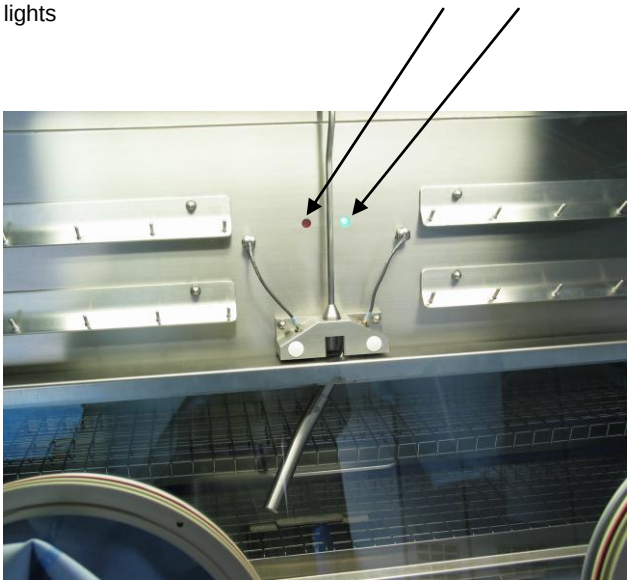
DPTE®-XS 190 transfer system
Note: a detailed description of the DPTE® function is available on request.
DPTE®-XS 190 transfer systems are mounted on the side walls. Where a connection of a DPTE®-DispoBag and/or DPTE®-Tubing is needed.

DPTE®-XS 190:
The DPTE®-XS 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 HDPE.
A J3L lip seal is mounted onto the Alpha door.

Bio-decontamination airlock (external and internal door)
An external door with maintains the leaktightness between airlock and outside. An internal door maintains the leaktightness between airlock and work station. Green and red lights indicate to the operators if they are allowed to open the internal door. Both doors are locked locked with a solenoid interlock during the bio-decontamination phases.

External door with a solenoid interlock

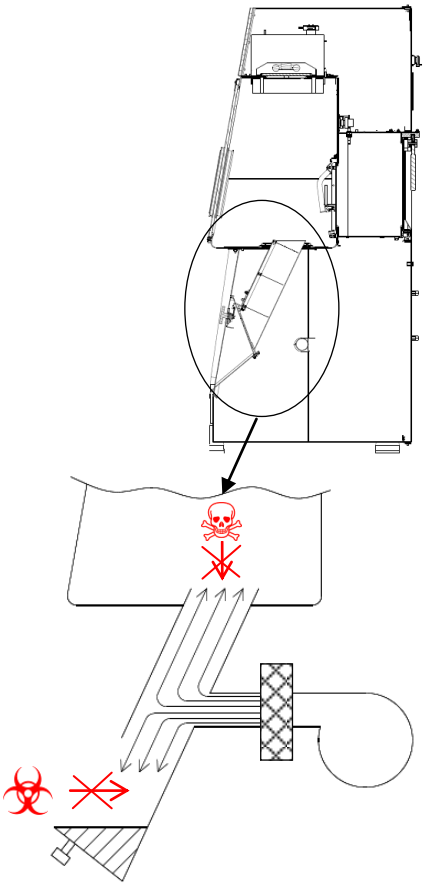
Internal door with a solenoid interlock with red and green lights



Dynamic Ouput Port

An external door with a solenoid interlock maintains the leaktightness between dynamic ouput and outside.

The integrated Dynamic Output Port allows continuous egress of the preparations from the work station. For a specific management of air flows, it protects the operator (no output of chemical contamination) and the product (no entry of contamination from the room to the inside of the isolator).



Steritrace II - Integrated H_2O_2 sterilizer

The isolator contains the integrated H_2O_2 sterilizer Steritrace II for the bio-decontamination of:

- The work chamber
- All loads entered through the bio-decontamination airlock

It works with Hydrocyde H_2O_2 bottles (refer to the consumable sheet).

The main phases of a bio-decontamination cycle are:

- Dehumidification
- Injection phase
- Aeration using the inlet and outlet air blower of the isolator

Hydrogen Peroxide Vapor (H_2O_2) is a well established, proven chemical sterilant.

The different materials used in the manufacture of the isolators are compatible with the bio-decontamination agents (H_2O_2). The resistance of any other material used inside the isolator should be tested beforehand.

Bio-decontamination, Sterile and Sterilization

In a healthcare context, decontamination is a means of rendering material safe to handle. Contaminants may be hazardous chemicals or biological agents. Bio-decontamination is a means of removing biological agents.

- Sterilization is one of several bio-decontamination processes.
- ”Sterile” is defined as a complete absence of living organisms. As microbial destruction is a logarithmic function, it is not absolute, but the accepted level to define a product ’sterile’ is a log-6 reduction (a sterility assurance level, or SAL, of 10^{-6}.)

Injectable products must be ”Sterile”. To render an injectable drug ”sterile”, it must be either terminally sterilized (e.g autoclaved after packaging), or must be produced in an aseptic environment.

In “aseptic processing” the drug is sterilized (e.g. by filtration), and the packaging is presterilized. The environment for the packaging must be controlled to prevent opportunity for contamination.

An isolator optimally separates the preparation environment from the external surroundings. An isolator may be readily bio-decontaminated to reduce the bio-burden, and may be maintained in this condition (through appropriate transfer technologies) for extended periods. It is more practical to achieve this in an isolator compared to a clean room, hence, the achievable SAL is higher for aseptic processing in an isolator compared to a clean room. Product sterility may be assured.

Typically, bio-decontamination of the environment is performed at an SAL of 10^{-6} (sterile), but 10^{-4} is sometimes allowed for operational efficiency purposes.

Getinge’s Steritrace II is capable of providing a sterilization process for an isolated environment and we refer to it as an ”integrated H_2O_2 sterilizer”.

Getinge will as standard provide a bio-decontamination process at an SAL of 10^{-6}. However, clients may, based on a risk assessment, decide to decontaminate at a lower level (e.g. 10^{-4}) HPV bio-decontamination is superior to other bio-decontamination techniques (such as alcohol wipedown) as it is repeatable, validatable and not dependent on manual procedure.

ORDERING

ORDERING

Description

Use the description below to select the appropriate models.

ISOCYT FREJA XX Y

Range Name

DO - Dynamic Output Port
TR - Tubing system with one operator right side
T2 - Tubing system with two operators

P - Positive pressure
N - Negative pressure

CONFIGURATION SELECTION

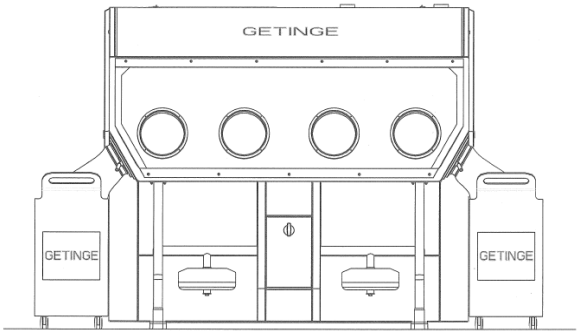
The user can choose to use as an output either a Dynamic Output Port (standard) or a Tubing system. If a the latter is chosen, the Dynamic Output Port it still present, but its external door remains closed at all time.

Configuration

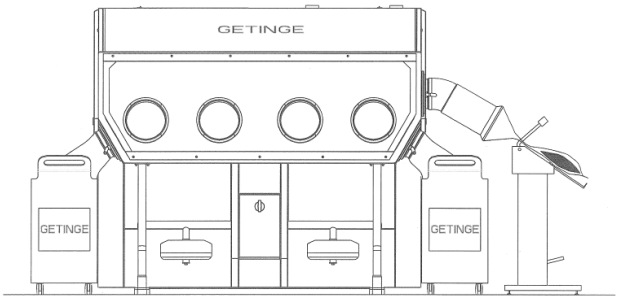
- ☐ **DO** - Dynamic Output Port
- ☐ **TR** - Tubing system with one operator-right side
- ☐ **T2** - Tubing system with two operators

Regulation type

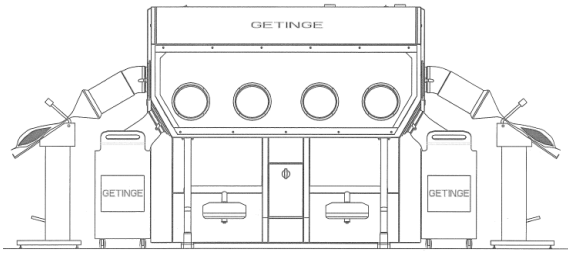
- ☐ **P** - Positive pressure
- ☐ **N** - Negative pressure



DO - Dynamic Output Port



TR - Tubing system for one operator-right side



T2 - Tubing system for two operators

DIMENSIONS (refer to the details in the "dimensions" section)

OPTION LIST

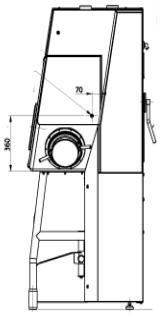
- ☐ FREJA «Tracker Software»
- ☐ Cable «FREJA Tracker»(with 20 m of ethernet cable)
- ☐ Printer (with 30 m of USB cable)

CONSUMABLES (refer to the product sheet n° 108)

ACCESSORIES (see items pages 8 and 9)

- ☐ Stainless Steel Basket (240 x 240 mm)
- ☐ Stainless Steel Basket (240 x 180 mm)
- ☐ Stainless Steel Basket (240 x 120 mm)
- ☐ Basket separators (120 mm)
- ☐ Basket separators (180 mm)
- ☐ Basket separators (240 mm)
- ☐ Hook for pouches
- ☐ H_2O_2 probe – room for one isolator
- ☐ H_2O_2 probe – room for several isolators
- ☐ Set of 2 handles for connection (DPTE®-DispoBag, multipurpose container)
- ☐ Set of 2 handles for connection (DPTE®-Tubing 190)
- ☐ Ergonomic seat (standard)
- ☐ Ergonomic seat (comfort)
- ☐ Sleeve support
- ☐ Trolley for DPTE®-DispoBag
- ☐ Welding machine (Tubing system only)
- ☐ Preparation trolley
- ☐ 5 magnets to maintain the manufacturing sheets
- ☐ Standard cable glands
- ☐ Customized cable glands *(*)*
- ☐ Autotransformer
  Other voltages.....

2 PG11 stainless steel cable glands for cable Ø 5.5 to 12 mm symmetrically positioned



(*) The customized location of the cable glands implies the establishment of a contractual document between both parties.

Isocyt FREJA configuration guide

	Included				
	Config DO	***Config TR***	***Config T2***	***Required***	***Comment***
Freja Tracker software license	No	No	No	One of the 2 options is recommended	A PC computer is required (not included). In case of several isolators, 1 license is needed (all isolators are connected to the same PC computer). The PC must have as many Ethernet plugs and RJ 45 cables as isolators. The software installation should be done at the factory on the PC previously provided by the customer.
Printer	No	No	No		For real time printed phase reports (not stored in the isolator) ; this option does not need a PC computer (direct connection between the isolator and the printer).
Stainless steel baskets	12 baskets 240 x120 mm	12 baskets 240 x120 mm	12 baskets 240 x120 mm	/	3 sizes available: (240 x 120 mm) or (240 x 180 mm) or (240 x 240 mm) Recommended: baskets for 3 batches (1 batch in the isolator, 1 in the airlock and 1 outside) Maximum number of baskets in airlock : 24 (240 x 120 mm) or 18 (240 x 180 mm) or 12 (240 x 240 mm).
Baskets Separator	10 (120 mm) 10 (240 mm)	10 (120 mm) 10 (240 mm)	10 (120 mm) 10 (240 mm)	/	Useful to create compartments in the basket.
Hook for pouch	6	6	6	/	Recommended to hang the pouches in the isolator.
H_2O_2 probe – room for one isolator	No	No	No	One of the 2 options is recommended	Recommended in case of one isolator. Please check your local regulations to determine if this probe is mandatory.
H_2O_2 probe – room for several isolators	No	No	No		Recommended in case of several isolators. Please check your local regulations to determine if this probe is mandatory.
Multipurpose container (standard version)	2	3	4	max.10 connections	Required for bio-decontamination of DPTE® seals. Can be used also as a container for emergency or for temperature sensitive drugs.
Multipurpose container (intensive version)	No	No	No	Intensive use	
Set of 2 handles removable for DPTE®DispoBag and multipurpose container	1	1	1	/	The handles are needed to connect: DPTE®-DispoBag, and the multipurpose container (standard version).
Set of 2 handles removable for DPTE®Tubing	0	1	1	/	The handles are needed to connect: DPTE®-Tubing
Ergonomic seats	No	No	No	/	Recommended: 2 seats
Sleeve support	4	4	4	/	Required for proper biodecontamination of gloves and sleeves.
Trolley for DPTE®-DispoBag	No	No	No	Recommended	Two trolleys per isolator are recommended as they protect the DPTE®-DispoBag and facilitate the transportation of the full bag.
Welding machine for DPTE®-Tubing	No	1	2	/	The welding machine is included not needed in DO configuration.

Isocyt FREJA configuration guide

	Included				
	Config DO	***Config TR***	***Config T2***	***Required***	***Comment***
Preparation trolley	No	No	No	Recommended	In order to maximize the productivity, one loading trolley per isolator is recommended.
Magnets (batch of 5)	1	1	1	/	Allow to maintain the individual sheets for preparation on the window.
POCT key	1	1	1	/	Allow to open the container to sterilize it in the airlock.
DPTE®-DispoBag	3 DispoBags	3 DispoBags	3 DispoBags	/	The DPTE®-DispoBag provides the user with the highest level of protection Consumption : Average 200 reconstitutions per DispoBag (approx. 1 week 1/2 for 50 reconst. / day).
DPTE®-Tubing 190	No	1	2	/	Average consumption: 300 preparations / tubing.
Ready to Fit Neoprene gloves, size 7	10 gloves	10 gloves	10 gloves	/	Size 7 is the most common size.
Ready to Fit Neoprene gloves, size 8	No	No	No		Use size 8 for operators with larger hands.
Sleeve PVC, model 1	No	No	No	/	4 sleeves (model 1 or model 2) are required. Recommendation: change the 4 sleeves at least once a year ; it is also recommended to have a few sleeves in stock in order to be able to replace quickly a defective sleeve.
Sleeve PVC, model 2	4 sleeves	4 sleeves	4 sleeves		
FREJA-Bag	1000 pouches (200 x 350 mm) + 1000 pouches (200 x 450 mm)	1000 pouches (200 x 350 mm) + 1000 pouches (200 x 450 mm)	1000 pouches (200 x 350 mm) + 1000 pouches (200 x 450 mm)	/	The zip pouches are needed in DO configuration only. Consumption: 1 pouch / reconstitution. 3 sizes available.
Hydrocyde H_2O_2 bottle	1 box of 12 bottles	No	No	/	Consumption: approx. 8 to 12 cycles per bottle in the bio-decontamination airlock, approx. 3 cycles in the whole isolator (these figures may change according to the particular loads and requirements of the customer).
"Cleanpak" cleansing wipe	1 "cleanpak	No	No	/	"Cleanpak"= 20 sterile wipes. Consumption : 2-3 wipes to clean the whole isolator.

PROCESS FEATURES AND OPTIONS

FREJA Tracker Software

- Record of electronic data reports of each phase in a secured database
- Display of these reports, with key data such as:
  - Date, time, serial number, parameter values (mean, standard deviation, min, max) alarms (if any) and phase status (ok/not ok)
- The parameters recorded include:
  - Pressure, temperature, duration of each sub-step, H_2O_2 injection rates, air flow, relative humidity
- Printed reports
- Connection to several ISOCYT FREJA
- Virtually unlimited database capacity (more than 10.000 working days)

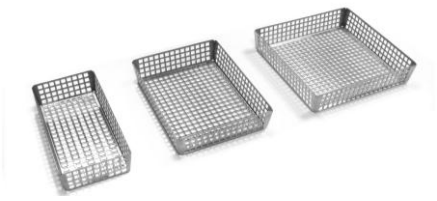
PC minimum configuration

- Computer: Intel Pentium or compatible, 166 MHz or higher
- Memory 512 MB
- Windows XP
- Hard disk space: 40 GB
- Drive CD-ROM
- Ethernet connection – 1 dedicated card (this card can not be shared with another network)

ACCESSORIES

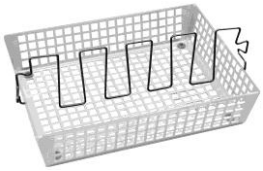
Basket	**Item:** 33531C (240 x 240 mm) 33569C (240 x 180 mm) 33570C (240 x 120 mm)

The baskets are used to place the loads in the bio-decontamination airlock (syringes, needles, vials, transfer sets, pouches, etc.) They allow the user to transfer easily the loads from the airlock to the isolator. When they are empty, they can be piled up and transferred back to the airlock. The baskets are made of 316 L stainless steel or European equivalent.



Baskets separators	**Item:** 35746C (120 mm) 35747C (180 mm) 35748C (240 mm)

The separators allow compartments to be made in stainless steel baskets in order to properly maintain some items during bio-decontamination. They come in batches of 10. They are made of 316L stainless steel.



Hook for pouch	**Item:**18894C

Hooks allow pouches to be suspended in the isolator. They are made of 316L stainless steel.

H_2O_2 probe – room for one isolator	**Item:** 26750C

The H_2O_2 probe is designed to monitor the H_2O_2 concentration in the room, for an increased protection of the operators. If the level is higher than an alarm threshold, an alarm is activated and the probe sends the information to the isolator in order to stop the bio-decontamination cycle (if it were in progress) and switch to emergency aeration.
When several Isocyt Freja are used in the same room, one probe per isolator is required. For this reason, this model is recommended when there is only one isolator in a room.

H_2O_2 probe – room for several isolators	**Item:** 34203C

The H_2O_2 probe with integrated alarm is another way of monitoring H_2O_2 levels in a room. It is recommended particularly if there are several Isocyt Freja in the same room, because only one probe is then required. When the alarm threshold is exceeded, the probe triggers its integrated sound and visual alarm.

Set of 2 handles DPTE®-DispoBag and multipurpose container	**Item:** 35502C

The handles are designed for an easy connection and disconnection of the DPTE®-DispoBag, the multipurpose container.

Set of 2 handles DPTE®-Tubing 190	**Item:** 20296C

The handles are designed for an easy connection and disconnection of the DPTE®-Tubing 190.

Ergonomic seat	**Item :** 33134C (standard) 33904C (comfort)

ISOCYT FREJA's ergonomic seat is composed of a seat and a back with sealed stuffing covered with vinyl. Surfaces are smooth and prevent particle deposit while facilitating cleaning. In addition the Comfort model meets the requirements of continued use in clean rooms. This non-slipping seat is antistatic. Lastly, thanks to a back with a permanent point of contact, the vertebral column is automatically supported in a straight position, for a great working comfort.

Comfort version

Standard version

Sleeve support	**Item:** 19422C

For the positive pressure version of ISOCYT FREJA, the gloves tend to be folded up by the pressure when they are not used. This could cause some folded surfaces not to be properly bio-decontaminated. In order to avoid this phenomenon, a sleeve support is placed in each glove, from the outside of the isolator. It allows the whole surface of the glove to be exposed to the sterilant.

Magnets (supplied by batch of 5)	**Item:** 35348C

Magnets allow to maintain the individual sheets for preparation on the frame of the isolator window.

Trolley for DPTE®-DispoBag	**Item:** 32685C

The trolley for DPTE®-DispoBag protects the bag when it is connected to the isolator. Thanks to it rollers, it allows the user to easily transfer the full bag for disposal. It has 3 out of 4 faces, so that it is not necessary to lift the full and heavy bag for removing it from the trolley.

Transparent trolley in PMMA allowing to visualize the filling level of the bag.

Welding machine for DPTE®-Tubing system	**Item:** 6007001665 (230V) **Item:** 6007001666 (115V)

The welding machine is made of from solid, high quality, stainless steel. The welding machine consists of a double-seal welder and a cutter to cut the liner between the two weldings. It allows both to isolate the product to be transferred and to preserve the containment inside the isolator.

Preparation trolley	**Item:** 34276C

This trolley allows baskets to be prepared in advance and facilitates loading in the bio-decontamination airlock which maximises productivity. It can hold up to 12 baskets (240 x 240 mm format). It is made of 304L stainless steel.

SERVICES

ISOCYT FREJA isolator is inspected before shipment.
This operation is carried out by our Inspection Department.and validated by our Quality Department.

☐ Hospital Qualification (work on customer site):
According to the Good Manufacturing Practices in a hospital, a production installation has to be qualified.
The objective of the Hospital Qualification is to constitute the written evidence, by means of a defined protocol, that the operating performance of the equipment in its final environment conforms to the specification.

Documentation

Standard:

- DPTE® manual: NTA 3003/55
- DPTE® Beta manual: NTA 3003/38
- Parameters file: 3785-209-51
- Isolator identication form
- List of spare parts
- Installation manual
- User manual
- Technical manual
- Statement of conformity
- Certificate of Calibration (sensor, sensor and transmitter)
- Language:
  - ☐ French
  - ☐ English

Option list:

☐ Other language: .....

☐ Software package GAMP 5

- Detail Design Specification (DDS)
- Software validation package

PACKING AND OPTIONS

Packaging identification

- Item reference
- Quantity
- Assembly

Packing method

- The ISOCYT FREJA isolator will be packed according to the agreed method of shipment

Storage conditions

- Storage temperature: 5°C to 40°C

SHIPPING OPTIONS

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

SPECIFICATIONS

- Operating pressure *(production)*:
  +40 Pa ± 10 Pa (positive pressure)
  -40 Pa ± 10 Pa (negative pressure)
- Operating pressure *(bio-decontamination)*:
  +60 Pa ± 10 Pa
- Isolator classification
  Iso 5 as per standard ISO 14644-1 part 1
- Inlet air change rate (100 % fresh air):
  40 volume per hour for work station (free extraction new filters).
  700 volume per hour for bio-decontamination airlock (free extraction new filters) only during aeration phase
- Leaktightness specifications *(value at factory test):*
  0.5 % vol/h at 150 Pa
- Filtration level:
  ≥ 99.995 % *(MPPS efficiency)*
- Equivalent sound pressure at 1 m:
  Maximum: ≤ 75 dBA
  Typical :
  - aeration : 64 dBA
  - production : 51 dBA

  Note: noise may vary depending on the environment (size of rooms, furniture, extraction system …)
- Type of flow:
  Turbulent flow
- Volume of the isolator (values given for information):
  Work station: 0.8 m^3
  Bio-decontamination airlock: 0.21 m^3
  Dynamic ouput: 0.013 m^3
- Isolator protection index:
  IP 20
- Weight unit:
  650 kg for DO version
- Compatible earthing system:
  IT, TT, TN
- Breaking capacity:
  IT earthing system:3 kA (double default).
  TT/TN earthing system: 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:
  Emission: EN 61000-6-4, 2007 issue
  Immunity: EN 61000-6-2, 2006 issue

REQUIREMENTS

- Temperature:
  Between 20 °C and 24 °C (stable)
  Recommended: 22 °C
- Air extraction:
  - Standard configuration: Refer to detailed specifications in the installation manual
  - Specific configuration: contact Getinge
- Climatic resistance:
  20 to 70 % relative humidity without condensation
  Recommended: 40 to 60 %
- Maximun acceptable load:
  Working station: The maximum load on the working area is 100 kg (evenly distributed)
  Bio-decontamination airlock: 40 kg

Compressed air

Dry & clean compressed air with the following characteristics:

- Pressure: 3 bar < P < 10 bar
- Dew point: < - 20°C
- Compressed air flow rate (continuous) : 15 Nm^3/h
- Filtration: 5 µm

Quick release coupling (Staubli –RBE 06)
coupling : Groove Ø12 or female 3/8 G (connection close to the ceiling).

Electrical

- Tension
  AC 207 to 244 V, 48 to 63 Hz / single-phase current
- Maximum amperage:
  16 A
- Power:
  Maximum: 3.7 kVA
  Typical : 1.4 kVA (without equipment connected)
  Heat loss: < 300 W
- Power supply:
  Cable of 10 m with European plug (connected to the power switch of the isolator).
  - H_2O_2 alarm cable
    Dry contact – customer cable
  - USB connection for printer
  - Ethernet connection (for a PC with FREJA Tracker)
  - Connection to H_2O_2 probe (analog connection)

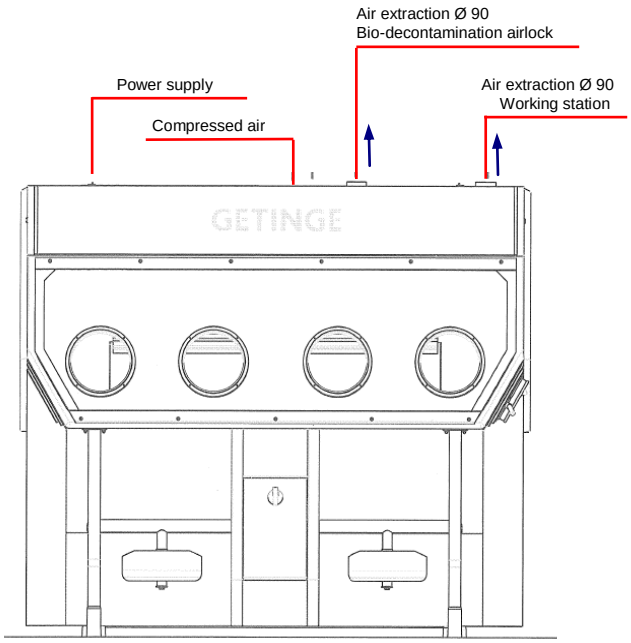
  Note
  - Power supply avalaible in technical casing of isolator 4 A (total).
  - 6 plugs with 2 phases + earth – 230 Volts.
  - 3 additional power supplies avalaible (230 V) on a screw terminal block.

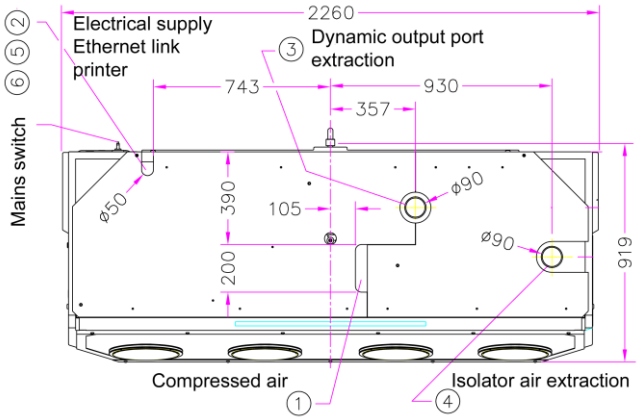
Characteristics of the isolator room

- Minimum recommended: ISO 8 environment
- 2 air extractions are needed for each isolator

Warning: the position of the utilities in the room must be agreed between the customer and Getinge. Getinge compliance with the specifications for the extractions is essential for the correct functioning of the equipment.

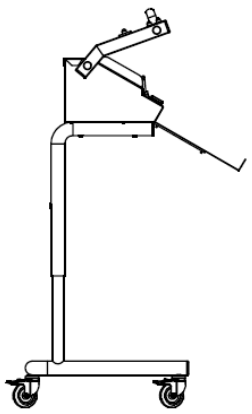
ISOCYT FREJA





Welding machine
DPTE®Tubing

220V/230 V – 50/60 Hz 420w
Cable length: 2.2 m
Plug type: European
Weight: 39Kg



GLOSSARY

DPTE® Safety Double Door Transfer System: The safest method for introducing and removing sterile and or for toxic material without breaking containment.

DPTE®-DispoBag: System allowing to evacuate waste without any risk of contamination of the operator and the environment.

DPTE®-Tubing: The tubing outfeed system has been designed to allow dynamic sterile tranfer of materials or products from the inside of the isolator to the outside, in a semi continuous way without breach of containment.

RFID: Radio Frequency Identification

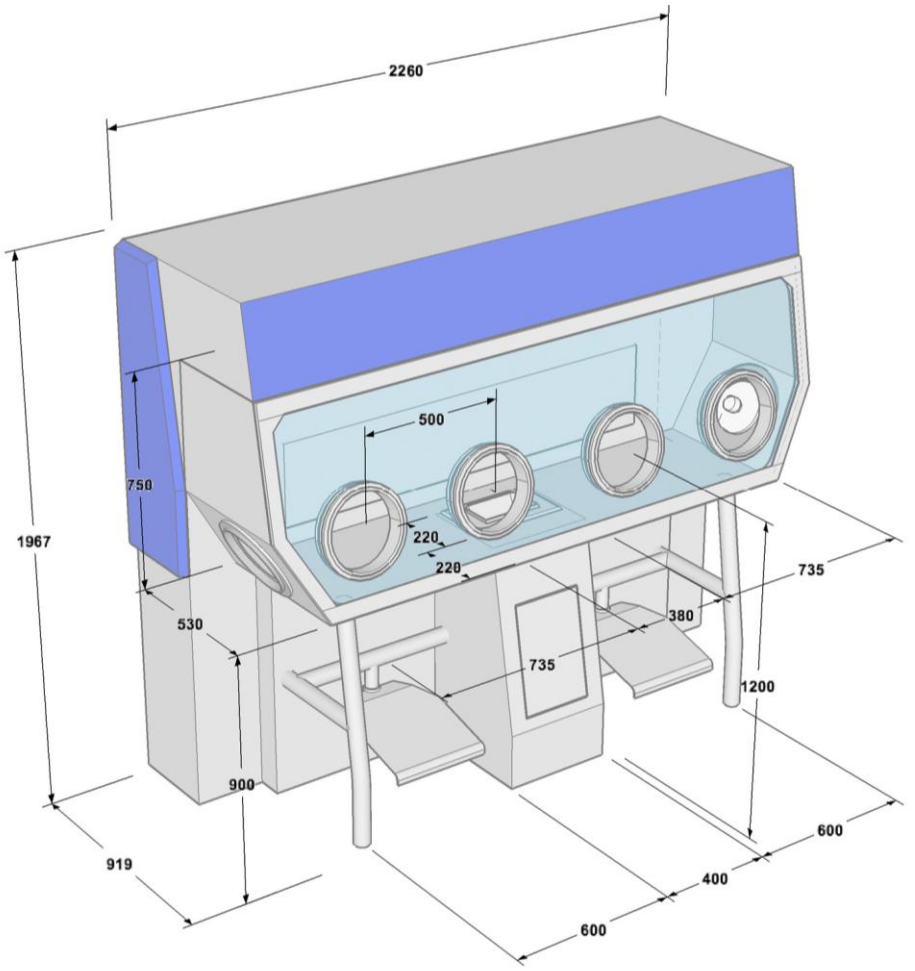
EMC: ElectroMagnetic Compatibility

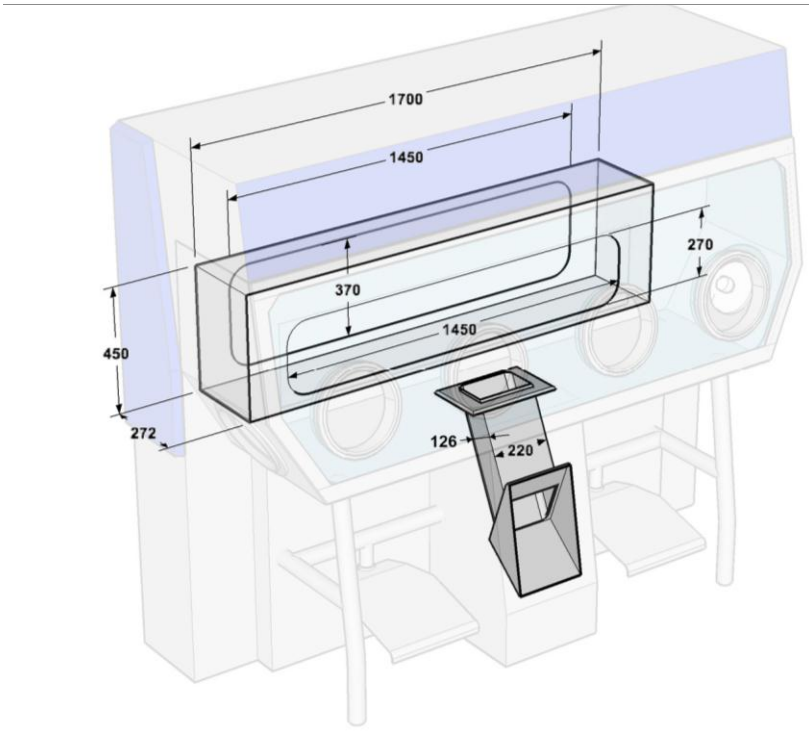
LV: Low voltage

PPE: Personal protective equipment

PC: Personal Computer

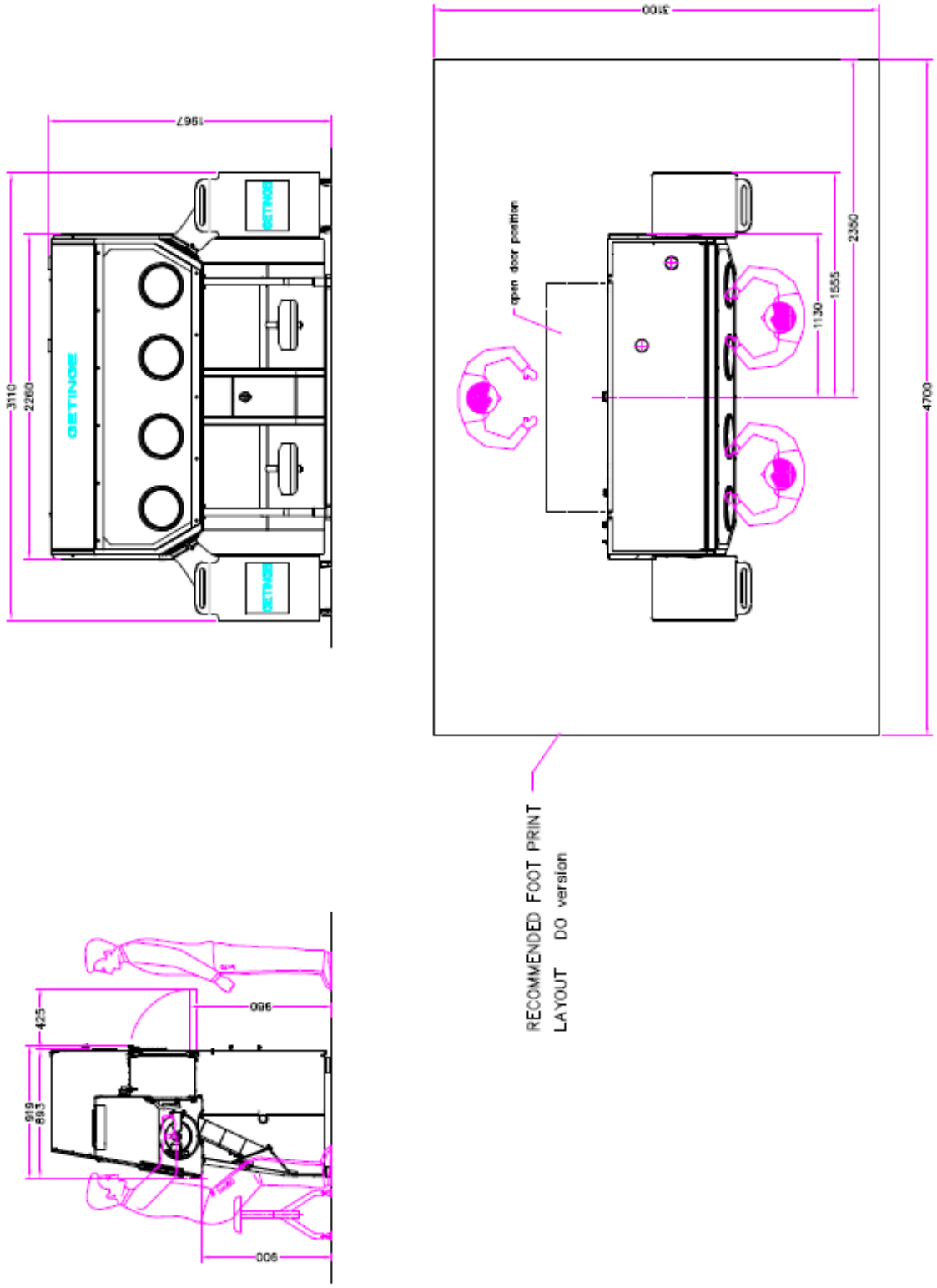
DIMENSIONS (mm)





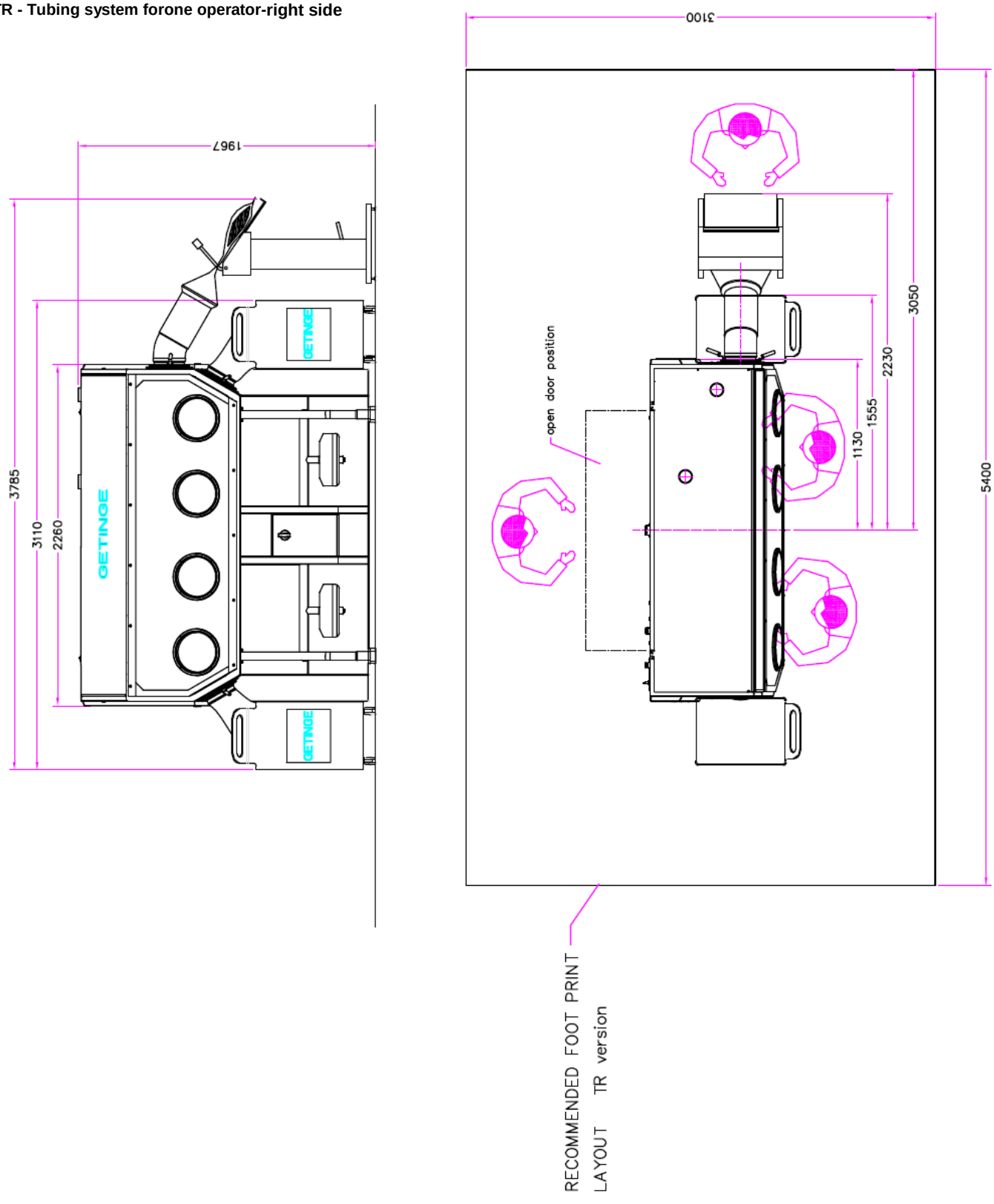
DIMENSIONS (mm)

DO - Dynamic Output Port



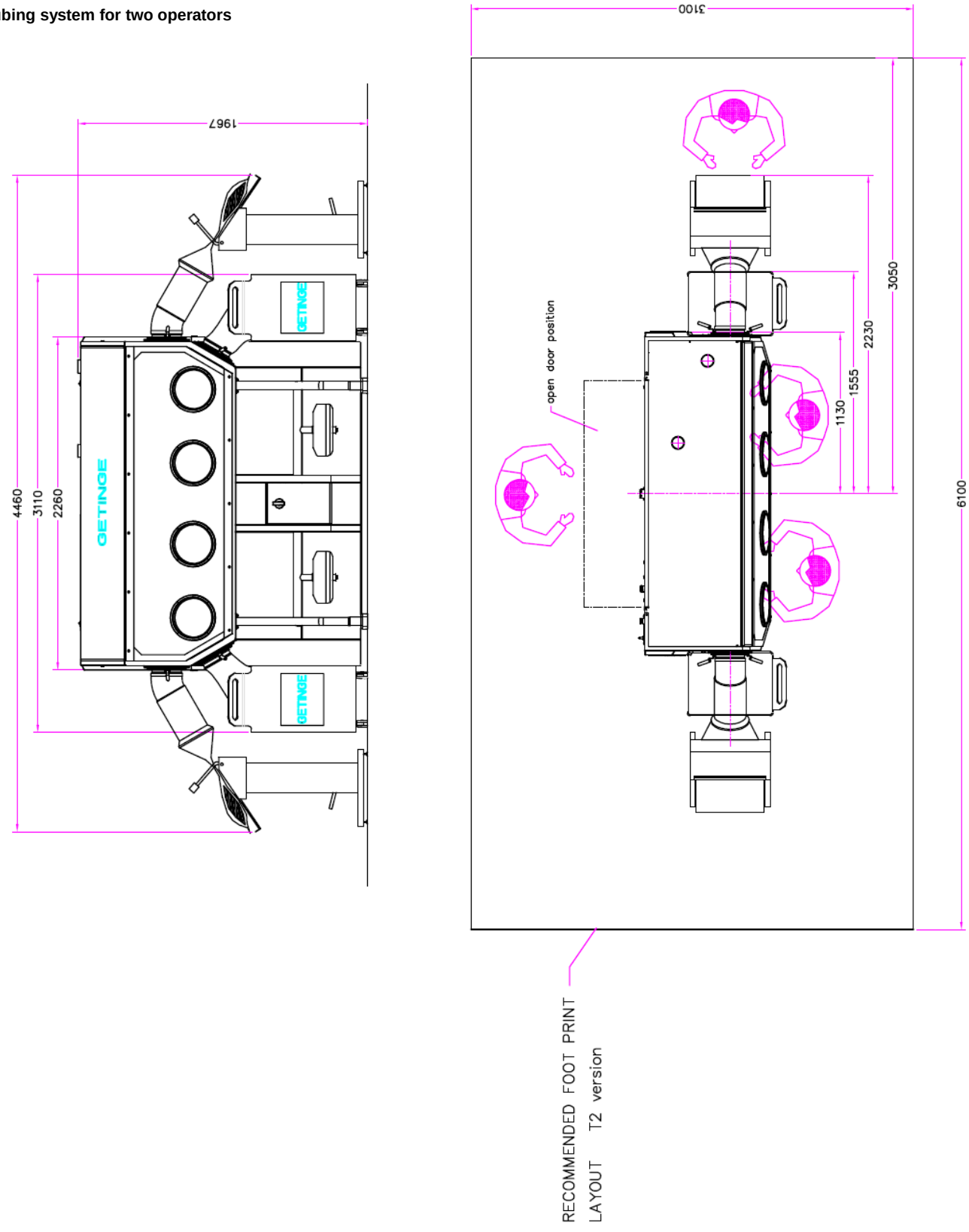
DIMENSIONS (mm)

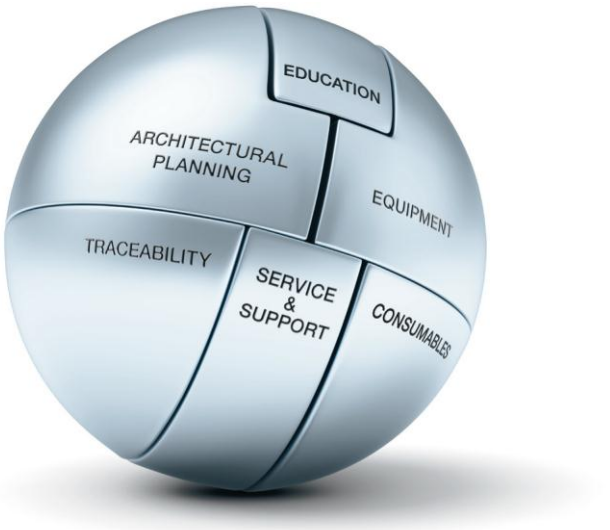
TR - Tubing system forone operator-right side



DIMENSIONS (mm)

T2 - Tubing system for two operators





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 theway 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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