JCE BIOTECHNOLOGY

MANUFACTURER
OF CUSTOMIZED ISOLATION TECHNOLOGY SOLUTIONS
SAFETY AND CONTAMINATION CONTROL

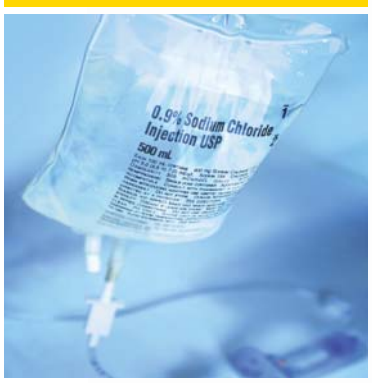
Isolateur Nominat®

N500, N1000, N10-RV4 and ISOLINE® series

For the reconstitution of cytotoxic agents, monoclonal antibodies and sterile preparations

Photos are not binding

Applications
Hospitals & Clinics



www.jcebiotechnology.com

FC-1-10

Pharmacy - Research - Industry

Know-how, flexibility, safety and technological innovation for more than 25 years

Managing contamination has become an issue shared by a growing number of businesses using clean rooms and sterile environments in response to the following problems and considerations:

- Increased safety requirements
- The development of regulatory compliance
- New manufacturing technology requirements
- The transfer of cleanness requirements up and downstream in the production chain, as a part of managing the ultra-cleanness chain
- The search for optimum productivity and a competitive advantage.

JCE BIOTECHNOLOGY, with more than 25 years' experience in the design, manufacture and maintenance of customized isolators and personalized solutions for isolation technology, offers a broad range of equipment and products that comply with the constantly changing regulatory requirements, the specific need of clean rooms and other controlled environments, and the protocols inherent in various activity sectors.

- Isolators
- Bio-decontamination systems
- Transfer airlocks
- Secure RTP (Rapid Transfer Port)-type transfer systems
- Range of accessories and single-use consumables.

JCE BIOTECHNOLOGY

Innovation

Safety

Ergonomics

Flexibility

The Nominat® Concept

JCE Biotechnology has developed a range of specific isolators, designed for the reconstitution of cytotoxic agents, monoclonal antibodies and sterile preparations for Hospitals and Clinics.

The Nominat® series N500, N1000 and Isoline, provides tailored, custom turn-key solution.

JCE Biotechnology's technical offer includes:

- Study and design, manufacturing to order and the installation of the isolator and its accessories
- The air treatment system and H_2O_2 or PAA decontamination of the isolator
- The instrumentation required for the correct operation of the installation
- The qualification of the systems (design, installation, validation of its operation and performances)
- Training of the users following qualification.

JCE BIOTECHNOLOGY

Isolator Nominat® N500/2G series

For the reconstitution of cytotoxic agents, monoclonal antibodies and sterile preparations

Photo not binding

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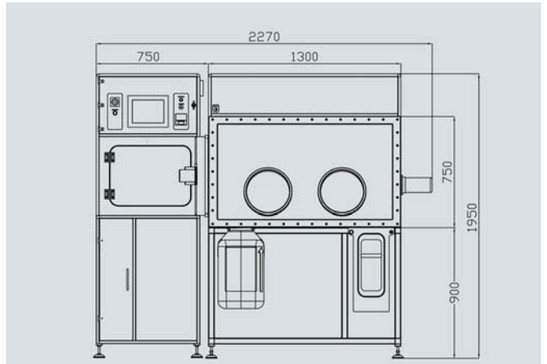
SAFETY AND CONTAMINATION CONTROL

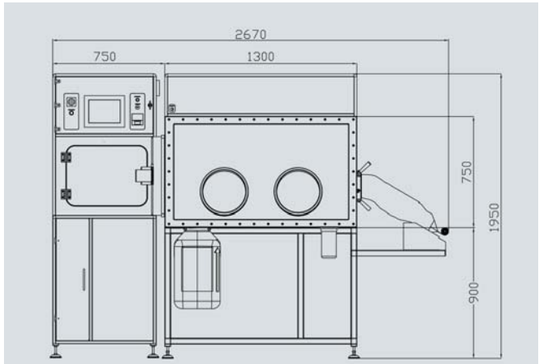
The Nominat® concept N500/2G series

Using these 2 basic configurations, JCE Biotechnology offers you a wide range of isolators, custom developed to suit your needs complete with accessories, to satisfy your specific requirements.



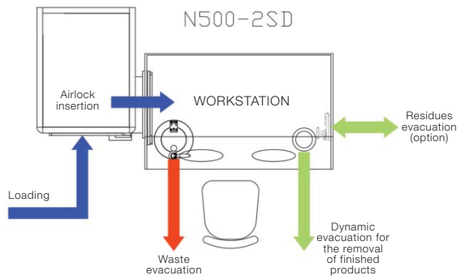
Configuration N500 2SD

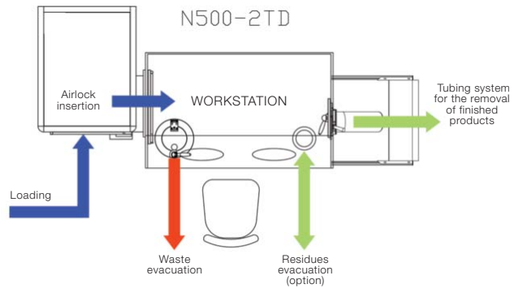
- 1 Nominat insertion airlock
- 1 single station 2 glove handling isolator
- 1 bio-decontamination H_2O_2 or PAA built-in system
- 1 MWS150A® system for the evacuation of solid waste
- 1 secure finished product removal airlock
- Air treatment system: turbulent flow class A when not operating compliant with ISO 14 644-1
- Accessories for monitoring; checking and supervising.



Configuration N500 2TD

- 1 Nominat insertion airlock
- 1 single station 2 glove handling isolator
- 1 bio-decontamination H_2O_2 or PAA built-in system
- 1 MWS150A® system for the evacuation of solid waste
- 1 Tubing system for the removal of finished products
- Air treatment system: turbulent flow class A when not operating compliant with ISO 14 644-1
- Accessories for monitoring; checking and supervising.





Please ask us about other custom-made characteristics and dimensions

JCE BIOTECHNOLOGY

Isolator Nominat® N500/4G series

For the reconstitution of cytotoxic agents, monoclonal antibodies and sterile preparations

Photo non contractuelle

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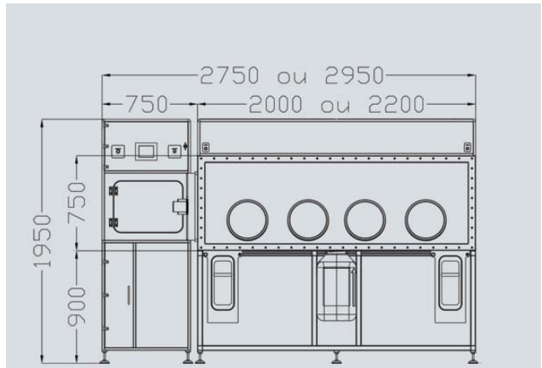
TECHNOLOGY SOLUTIONS
SAFETY AND CONTAMINATION CONTROL

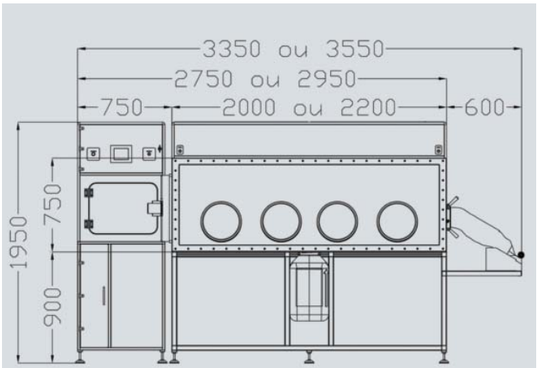
The Nominat® concept N500/4G series

Using these 2 basic configurations, JCE Biotechnology offers you a wide range of isolators, custom developed to suit your needs complete with accessories, to satisfy your specific requirements.



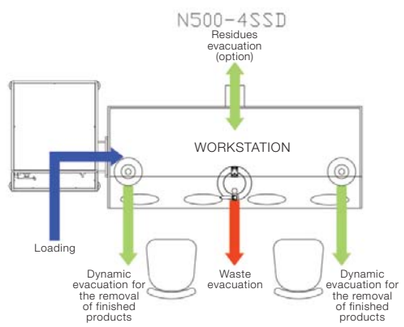
Configuration N500 4SSD

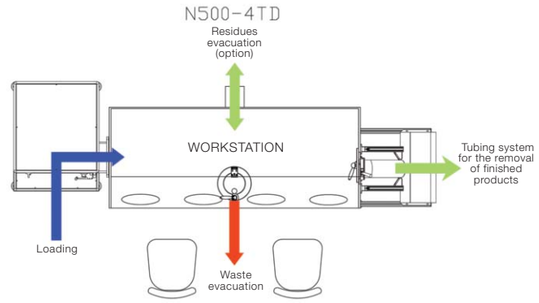
- 1 Nominat insertion airlock
- 1 single station 4 glove handling isolator
- 1 bio-decontamination H_2O_2 or PAA built-in system
- 1 MWS150A® system for the evacuation of solid waste
- 2 secure finished product removal airlocks
- Air treatment system: turbulent flow class A when not operating compliant with ISO 14 644-1
- Accessories for monitoring; checking and supervising.



Configuration N500-4TD

- 1 Nominat insertion airlock
- 1 single station 4 glove handling isolator
- 1 bio-decontamination H_2O_2 or PAA built-in system
- 1 MWS150A® system for the evacuation of solid waste
- 1 Tubing system for the removal of finished products
- Air treatment system: turbulent flow class A when not operating compliant with ISO 14 644-1





Please ask us about other custom-made characteristics and dimensions

JCE BIOTECHNOLOGY

Isolator Nominat® N1000 series

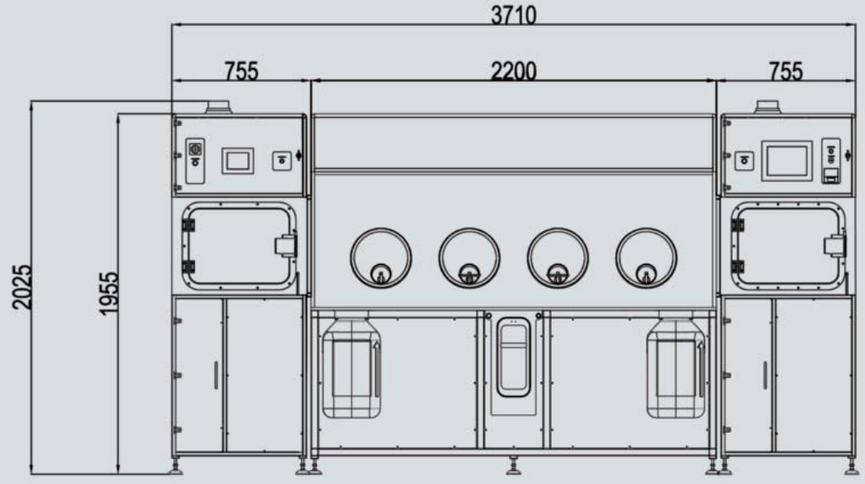
For the reconstitution of cytotoxic agents, monoclonal antibodies and sterile preparations

Photo not binding

MANUFACTURER
OF CUSTOMIZED ISOLATION TECHNOLOGY SOLUTIONS
SAFETY AND CONTAMINATION CONTROL

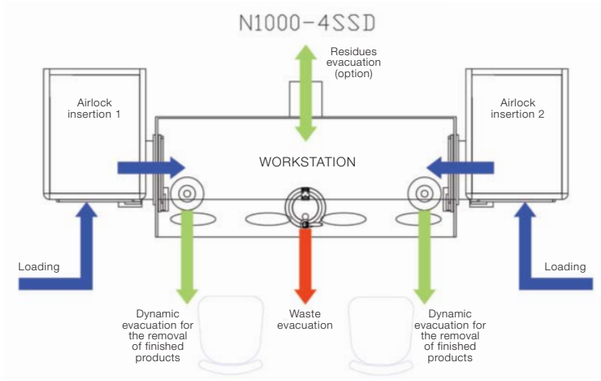
The Nominat® concept N1000 series

Using this basic configuration, JCE Biotechnology offers you a wide range of isolators, custom developed to suit your needs complete with accessories, to satisfy your specific requirements.



Configuration N1000 4SSD

- 2 Nominat® introduction airlock
- 1 handling isolator 4 gloves double station
- 2 H_2O_2 or PAA built in bio-decontamination systems
- 1 MWS150A® system for the evacuation of solid waste
- 2 secure finished product removal airlocks
- Air treatment system: turbulent flow class A when not operating compliant with ISO 14 644-1
- Accessories for monitoring; checking and supervising.



Please ask us about other custom-made characteristics and dimensions

JCE BIOTECHNOLOGY

Nominat® Isolator ISOLINE® series

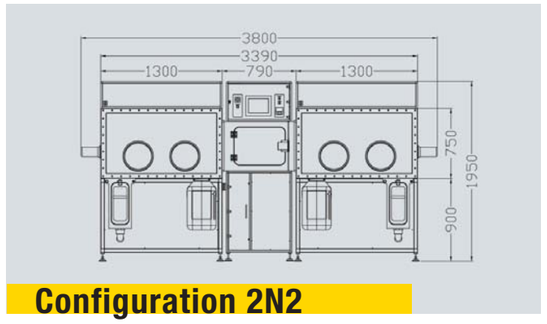
For the reconstitution of cytotoxic agents, monoclonal antibodies and sterile preparations

Photo non contractuelle

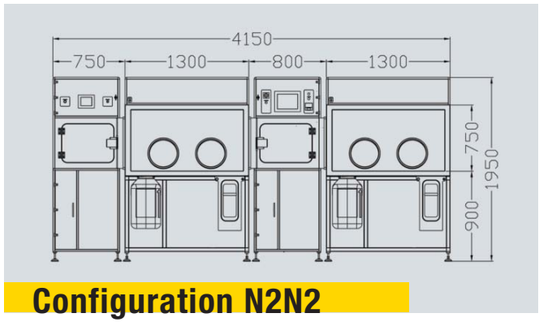
MANUFACTURER
OF CUSTOMIZED ISOLATION
TECHNOLOGY SOLUTIONS
SAFETY AND CONTAMINATION CONTROL

The Nominat® concept ISOLINE® series

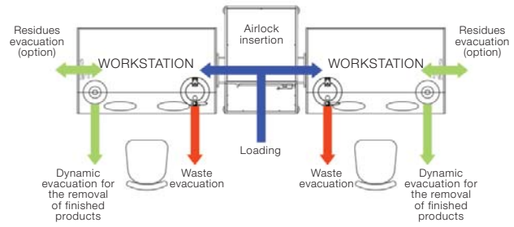
Using these 3 basic configurations, JCE Biotechnology offers you a wide range of isolators, custom developed to suit your needs complete with accessories, to satisfy your specific requirements.

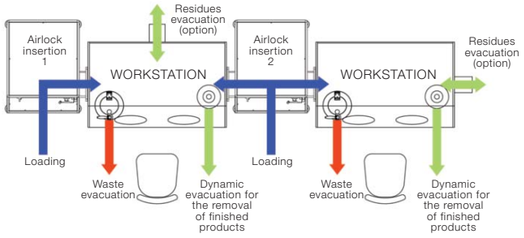


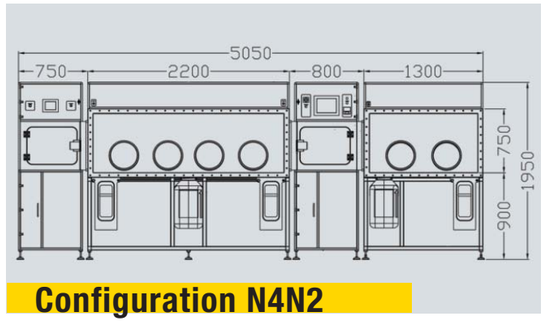
Configuration 2N2



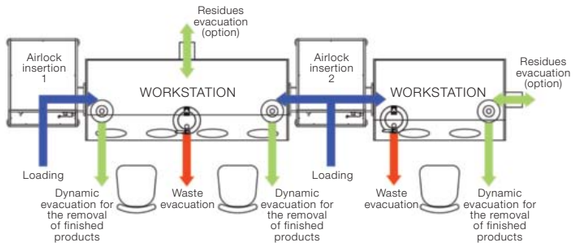
Configuration N2N2







Configuration N4N2



Configurations 2N2 - N2N2 - N4N2

- 1 Nominat® 3 channel insertion airlock with bio-decontamination H_2O_2 or PAA built-in system (on 2N2, N2N2, N4N2 models)
- 1 Nominat® 2 channel insertion airlock with bio-decontamination H_2O_2 or PAA built-in system (on N2N2 and N4N2 models)
- Single station 2 glove or 4 glove handling isolator specifically for cytotoxic agents
- Single station 2 gloves handling isolator specifically for monoclonal antibodies
- Accessories
- MWS150A® system for the evacuation of solid waste for each isolator
- Secure finished product removal airlock for each isolator
- Independent air treatment system for each isolator
- Turbulent flow class A when not operating compliant with ISO 14 644-1
- Accessories for monitoring; checking and supervising.

Please ask us about other custom-made characteristics and dimensions

For secure applications

The quality of the JCE Biotechnology solutions ensures the PREVENTION of all risks of contamination during handling, preparation and transfer.

Lean production mode operation

The configurations ISOLINE® allow on a single manufacturing unit to reconstitute in two independent environments cytotoxic agents or monoclonal antibodies without any risk of cross contamination.
Nominat® bio-decontamination airlocks separate the two clean and sterile atmospheres.
These Nominat® 3 channel airlocks provide access either to the environment dedicated to the cytotoxic agents or to the environment dedicated to the monoclonal antibodies.
The choice of access is made via the supervision touch screen.

- Introduction of the products (active principles, solute pouches, medical equipment….) required for the reconstitutions in each nominative basket (5 to 6 nominative preparations per airlock)
- Selection of the isolator (CYTO/AM) using the supervision touch screen which allows, after the bio-decontamination cycle, access to the dedicated zone.
  Access to the non-dedicated zone is secure and locked.
- Bio-decontamination cycle of 15 to 20' in compliance with the load. Reduction 6 Log on Geobacillus stearothermophilus strain (ATCC7953 or ATCC12980) or PAA (Peracetic acid 4.5%) reduction 6 Log on Bacillus Atropheus strain (ATCC9372)
- Ventilation phase
- Transfer of the products to the isolator selected
- Reconstitution by 1, 2 or 3 preparers (in this reconstitution phase, the airlock may be reloaded and re-sterilised)
- Evacuation of the solid waste via MWS150A® secure evacuation system (rigid or flexible container)
- Evacuation of the finished products via the secure removal airlock
- Option: Management of residues Introduction into the container via the PTS105A door then transfer of the container to an external refrigerated environment at 4/6°C.

Main characteristics of isolators

- Isolator and airlock in PMMA
- Thickness of 10 to 20 mm
- Assembly by polymerisation
- Anodised aluminium panels
- Anodised aluminium base with adjustable legs
- Dimensions: (see technical diagrams with sizes)
- Height of working surface 900 mm
- Centrifugal fan upstream and downstream
- Turbulent flow
- Average extracted air flow rate of 100 to 200 m³/h compliant with configuration
- Renewal rate > 20 Volume/h compliant with configuration
- Operation: Positive or Negative pressure of +/- 50 Pa regulated and adjustable
- HEPA H14 Filtration upstream and downstream of the isolator
- Particle category: Iso 5 when not operating compliant with ISO14 644-1
- Motor-driven valves on the ventilation system
- Leak tightness category 2 compliant with ISO 10 648-2
- Leak rate: 0.5% vol/h at 150 Pa
- Noise level < 65 db compliant with NF EN 12649
- PMMA viewing window. Safety glass in option
- External and internal transfer doors interlocked with inflatable silicone seal
- Handling via 2 or 4 PE/PVC sleeves
- Neoprene gloves 5/10 on front face
- Round shoulder sleeve Diameter 300 mm.

Accessories:

- **Work station lighting**
- Diffused LED > 400 lux, changed externally
- **3 perforated shelves**
- In PMMA
- Removable and adjustable
- **Pouch support rail in stainless steel 316L**
- Adjustable depth
- 5 support hooks
- **Panel connections with 1 electrical socket 2P+earth**
- Seal on pins and socket.

Isolator monitoring

Low concentration external sensor (H_2O_2 version)

- ATI F12 sensor
- Measures to 1 ppm
- 4.20 mA output.

Principle

- Checks and monitors the isolator via IHM Schneider Electric
- Checks and monitors the H_2O_2 or PAA generator
- Reference documents: BPF, European pharmacopoeia in force.

Utilities

- Power supply 230V 50Hz (depending configuration)
- Protection 16A with 300 mA differential circuit breaker (depending configuration)
- Power supply cable 3G2.5 for the isolator
- Shielded power supply 4G2.5 for the extraction unit
- External evacuation Ø 125 mm sealed PVC tube
- RJ45 socket for remote maintenance and information reporting
- Technical compressed air pressure 6 bar.

Traceability

- Constant traceability of all the events using various sensors for the pressure, temperature, hygrometry
- PLC operation which transmits the state of the isolator and airlocks and the management of the doors to a 5", 7" or 10" touch screen
- A USB port or the RJ45 network allows the information to be collected
- the operating system (Windows compatible) we supply allows the data stored on the isolator to be recovered
- Can be exported in Excel format.

At the end of each bio-decontamination or sterilisation cycle, a ticket detailing the parameters is created:

- Name of the equipment
- Batch n° of the sterilising agent
- Date the bottle was opened
- Bio-decontamination number and cycle
- Date and time of cycle start and completion
- Bio-decontamination time
- Rinsing time
- Concentration at end of H_2O_2 rinsing
- Quantity of sterilising agent injected
- End of cycle : passed or failed

- In the event of an anomaly, the information is displayed on the screen: high temperature failing, low temperature failing, valve position failing, fan failing, injected volume failing.
- The detection of these failures stops the bio-decontamination cycle and automatically switches to the ventilation phase.
- The times for the packaging, injection, concentration level after rinsing, upper and lower tank temperature alarms, pressure settings and quantity of sterilising agent may all be adjusted.

Leak-tightness test

- Automatic built-in leak-tightness test
- Pressure drop test
- Category from 1 to 4 compliant with the standard ISO 10 648-2

JCE BIOTECHNOLOGY

Tailor-made

Solutions

&

Specific

Installations

SAS Nominat®

The Nominat® airlock allows any products to be introduced into the isolator (active principles, solutes and medical equipment) required for reconstitutions via a surface bio-decontamination performed either by gaseous diffusion of a peracetic acid solution (PAA) with a concentration of 4.5%, or by the gaseous diffusion of a hydrogen peroxide solution (H_2O_2) with a concentration of 35%.

Operation

The bio-decontamination cycle is performed in a time of 15 to 20' compliant with the load (bio-decontamination 8' and rinsing of 7 to 12') for destruction of 6 Log on a Bacillus Atropheus support (ATTCC 9372) with PAA and Geobacillus Stearothermophilus support (ATCC 7953) with H_2O_2.
This time can be modified and set.

The reference products and labels (dematerialising) are prepared and placed in nominative baskets then placed inside the airlock on the sliding supports.

5 Vertical nominative baskets or 6 Horizontal nominative baskets may be introduced into the airlock. A mix of these baskets can also be used compliant with the principle diagrams and technical characteristics on page 13.

Dimensions

- Introduction airlock: L700 x H415 x W235 mm
- Access height: 1025 mm
- External opening: L350 x H415 mm
- Internal opening: L235 x H415 mm.

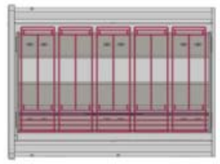
Technical characteristics

- PAA or H_2O_2: bio-decontamination time of 8 minutes*
- Rinsing time: 7 to 12 minutes*
- Rigid opaque PMMA
- Rigid translucent PMMA access door
- Material thickness 10 to 15 mm
- Assembly by polymerisation
- Anodised aluminium panels and chassis
- Chassis mounted on adjustable legs
- Inflatable silicone door seals
- Door interlocking system to prevent any cross opening
- Load capacity of 5 stainless steel baskets with vertical attachment or 6 stainless steel baskets with horizontal attachment
- Baskets on sliding supports
- Turbulent flow centrifugal fan
- Upstream and downstream fans for positive pressure operation
- Adjustable pressure setting
- Average operation flow rate: 50 m^3/h
- Renewal rate: > 100V/h
- HEPA H14 filtration compliant with EN 1822
- Upstream and downstream filtration 1.5P5 99.995%
- Particle category ISO 5 compliant with ISO14644-1
- Leaktigh category 1 to 4 compliant with ISO 10648-2.

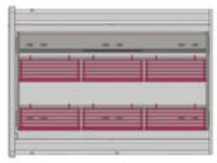
*time can be adjusted to suit load

Examples of load configurations

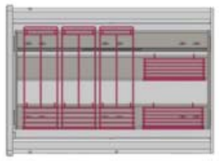
5 single level
ref: ACC 55 01 or double level ref: ACC 55 02 vertical baskets



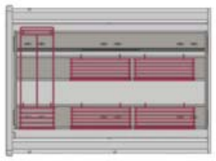
6 flat baskets
Ref: ACC 55 03



3 vertical baskets
+ 2 flat baskets

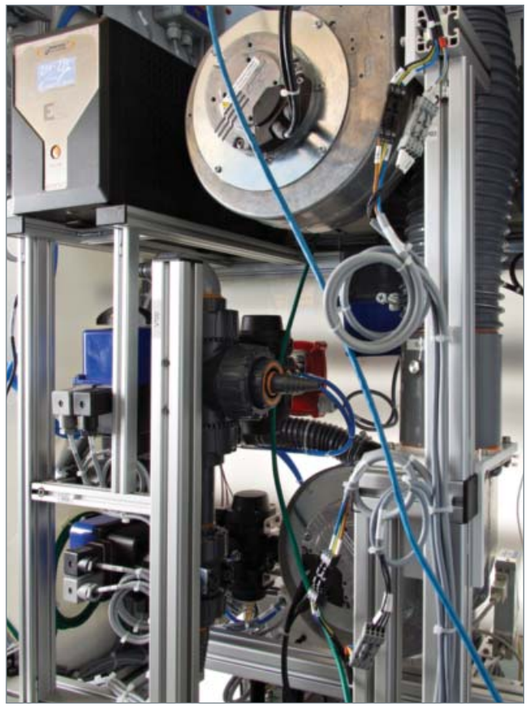


1 vertical basket
+ 4 flat baskets



Bio-decontamination system

Sterilisation or decontamination is a validated process used to ensure that the environment of an isolator or any other sealed system is viably exempt from micro-organisms, by the use of an anti-microbial gas (EN 13 824).



Principle

The sterilisation is a disinfection through the contact of a sterilising agent on the surface of the products inside the isolators or sealed systems and does not have the same sterilisation requirements or characteristics as a medical device (EN 556-1) or medication (European Pharmacopoeia 2002 4th edition). The product used is peracetic Acid (PAA 4.5%) or hydrogen peroxide (H_2O_2 35%).
Surface sterilisation or decontamination is considered as compliant when a reduction of 6 Log of Bacillus Atrophaeus ATCC9372 is achieved for PAA or Geobacillus Stearothermophilus ATCC7953 for H_2O_2.
HEPA filtered air is used as the carrier gas and carries the sterilising agent through the volumes to be sterilised. The surface bio-decontamination is performed by vaporisation of the sterilising agent.

The 4 sterilisation phases

- **Verification phase of the initial conditions**
- **Phase for adjusting the temperature of the evaporation tan**
- **Bio-decontamination phase**
- **Ventilation phase**

The sterilisation or decontamination step may only be carried out once the initial conditions have been met by the user: the products to be decontaminated have been introduced and the doors closed.

Operation

- Introduction of the sterilising agent bottle
- Validation of the batch number and expiry date of the sterilising agent by RFID
- Operator activates the decontamination cycle using the touch screen
- The motor driven valves are closed and opened for the sterilisation cycles
- Conditioning phase
- Bio-decontamination phase
- The sterilising agent is sampled from a 1 liter bottle for H_2O_2 and PAA, using a peristaltic pump and the quantity is measured using a mass flow sensor
- The sterilising agent is then evaporated in a heating tank
- Homogenization phase of air / vapour and bio-decontamination
- Check on relative humidity (H_2O_2)
- When the contact time is reached, the ventilation-filtration system automatically switches to the ventilation phase
- At the end of the ventilation cycle: measure the residual concentration (H_2O_2)
- Validation of the bio-decontamination cycle with a ticket and RJ45 and authorisation to open the door.

Finished products evacuation airlock

Directly connected to the isolator by a sealed flange, this airlock operates permanently with negative pressure.
Its renewal rate > 500 V/h flows through HEPA H14 filters placed upstream and downstream, isolating the volume of sterile air of the isolator and the ambient air where it is located.

Principle

The permanently H14 filtered air flow is evacuated into the ventilation tubes without any external exhaust. A cover with a seal is used to seal the inside of the isolator. A door with an inflatable seal is used to isolate from the exterior.

Operation

- The preparations are placed in sealed radio-sterilised sachets, then introduced into the airlock once the inside cover has been opened.
- When the cover is opened, the air flow from the isolator is sucked into the airlock and evacuated via the external evacuation tubes via the HEPA filtration, thus preventing it from going back into the isolator.
- Once the inside cover has been refitted, a period of 30 seconds (can be modified) permits the airlock to be rinsed thoroughly.
- Once this period is complete, the airlock may be opened.
- The preparation is recovered after the button is pressed, to deflate the seal and open the door.

Evacuation of solid waste

Positioned on the work surface, the secure version of the RTP door system (MWS150A®) is used to evacuate waste without loss of confinement, whilst ensuring the protection of the personnel and the confined zone.

This device may incorporate

- **Flexible PVC containers of 50 or 100 litres**
- **Rigid PE containers of 50 litres**

Operation

The container is ready to use.

- It is radiosterilised at 25 kGy and is connected to the isolator by a quick release coupling on the secure sealed door system MWS150A®.
- Once connected, simply open the inside door of the isolator and fill the container with the waste.
- This IHW (Infectious Healthcare Waste) container can be filled with all types of solid waste (plastic, glass, needles, DM etc…).
- Once it has been filled, close the door and disconnect the container then follow the waste system.

Advantages:

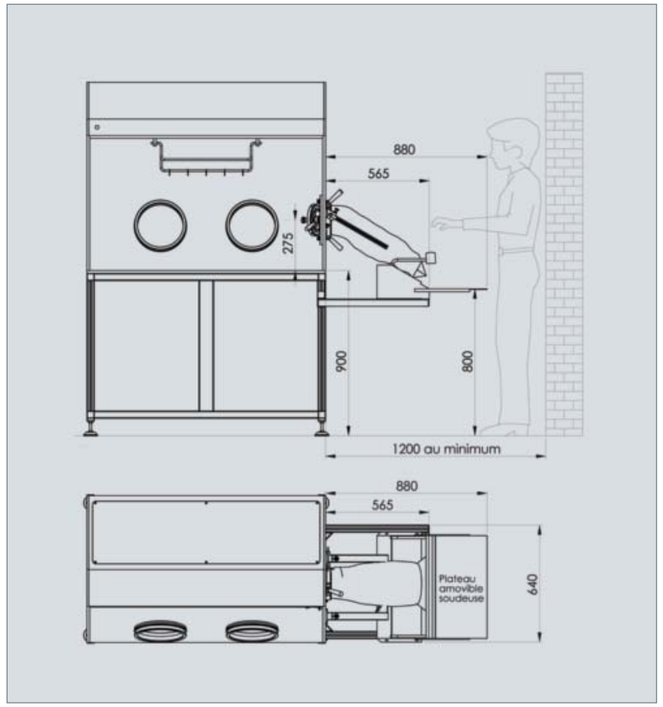
- Complete protection of the preparers
- Simple operation: ready to use
- IHW standards (Infectious Healthcare Waste): NFX30 511, UN3291, UN3249
- No re-packaging before transport
- No Ecobox
- Less handling time
- Incinerable.

Blue container:
- Incineration 1200°C

Yellow container:
- Incineration 850°C

Product removal via tubing

Positioned on the side wall of the isolator, the Tubing system permits the products that have been manufactured and checked to be removed and packaged.



Principle

- Secure door MWS150AT®
- Packaging with PE sheath, length 5 m
- Gamma sterilised to 25 kGy
- Impulse welder
- Double weld length 400 mm
- Magnetic locking.

Operation

- Directly connected to the side wall of the isolator by an Alpha MWS150AT® door, the Tubing system MWS GP5® has a beta door, a PE 100µ sheath that is 5 meters long and gamma sterilised to 25 kGy. The Tubing system has a quick release connector on the Alpha door using the RTP system which avoids contamination of the interfaces.
- Once connected, the operator opens the Alpha door and places the preparation inside the sheath which is naturally positioned at the bottom, then it is welded to seal the product hermetically.
- An impulse welder makes a 400 mm double weld that conservers the integrity of the sheath and the packaging.

Options

Secure residue transfer

Application

- **Secure transfer of the cytotoxic agent residues requiring sterility to be maintained and needing to be kept at a refrigerated temperature in a zone outside of the isolator.**

Principle

- The residues are placed inside a sterilised sealed container introduced via a transfer door then this container is disconnected and placed in a refrigerator at a controlled temperature whilst preserving the integrity of the products and protecting the personnel.

Door characteristics

- Transfer door PTS 105A
- Positioned on side wall, rear wall or work surface of the isolator depending on the models
- Secure locking preventing any opening without
- connection of external accessories
- Materials stainless steel 316L and PVC
- Passage diameter 100 mm
- Silicone seal
- Leak-tightness category 1 compliant with Standard ISO 10648-2.

Container characteristics

- Transfer container CTR105-200
- In PEHD
- Passage diameter 100 mm
- PVC seal
- Leak seal category 1 compliant with Standard ISO 10648-2
- Length 200 mm
- Volume 1.4 litres
- Load capacity 2kg.

Options (continued)

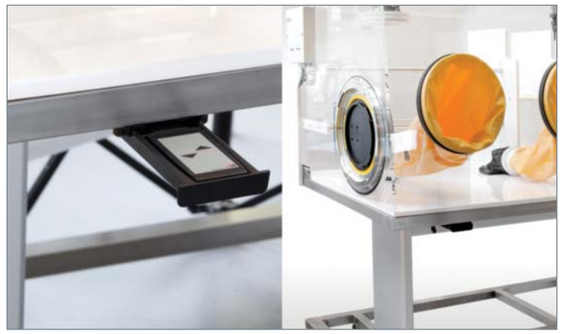
Catalytic System (H_2O_2 version)

H_2O_2 catalyser (transformation into water and oxygen with no residues).

- Can be evacuated into the room
- No external connections required
- Exhaust < 1 ppm checked by low concentration level sensor
- Built-in extraction fan.

Dematerialisation of manufacturing sheets

- 17" or 19" screen
- Mouse
- Bar code scanner or Data Matrix
- Scales for gravimetric check
- Thermal printer



Lifting column

Used to adjust the height of the work surface.
Maximum travel 500 mm limited to 400 mm.
Work surface height adjustable from 820 to 1220 mm.

- Anodised aluminium pillar
- Pillar capacity 3000 N
- Hall effect positioning sensor
- Micro travel limit switch
- Touch button control for raising /lowering.

Front panel

- Open the front panel using a gas actuator
- Safety glass
- Static or inflatable seal
- Secure magnetic closing handle.

Options (continued)

Extraction unit

Compensates pressure drop in the air exhaust piping system.
- Treatment of effluents with active charcoal filter
- Built-in centrifugal fan
- Frequency variator
- Free air flow of 900 m^3/h.

Glove sleeve tester

Automatic testing of gloves and sleeves.
- Built-in compressor
- Test by pressure drop
- Maximum operating pressure 1000 Pa.

Aero-biocollector

Checks the microbiological contamination in the production phase.
Brand and model of the device are URS compliant.
Can be incorporated permanently.
- Petri unit 90 to 100 mm.

Particle counter

Measures the particle concentration in the production phase.
Brand and model of the device based on URS.
Can be incorporated permanently.
- 0.5 µm and 5 µm real time monitoring
- Flow rate of 1 Cubic Foot per Minute
- Analogue or RS232 output

Options (continued)

Inverter

- Protects the network
- Power rating of 2000 VA
- Voltage 230 VAC
- Autonomy of 8’ based on connected load
- Standard CE IEC 61000.

Compressor

- Frequency 50 Hz
- Max. pressure 7 bar
- Max. power supply 2.4 A
- Tank volume of 4 litres
- Noise level 66 dB/1m.

Operator chair

Adjustable seat height from 555 to 785 mm and lift adjustment. Can be adjusted from 2° to 13° and locked in any intermediate position.
- Steel foot rest Ø 460 mm
- Self-locking castors.

Foot rest

Adjustable height, compatible with all types of work station.
- Foot rest pied 450 x 400 ESD
- Main structure made of steel
- Adjustable column in aluminium - PA plate.

Design

Installation

Certification

Performance

Qualification / Validation Services

Testing, qualification and validation of physical and bacteriological processes, isolators, clean rooms and clean areas.
JCE Biotechnology provides proof by demonstrating.

Discover all of JCE Biotechnology's services

Qualification

Operation designed to show that the equipment works correctly and actually delivers the expected results. The validation concept is sometimes expanded to include qualification activities.

Validation

Provides evidence, in compliance with GMP, that the implementation or use of processes, procedures, materials, raw materials, packaging articles or products, activities or systems actually makes it possible to achieve the expected results.

Systems Qualification
Design Qualification

To check that the installations and equipment to be put in place on the basis of the design plans have been correctly designed according to the reference, technical and standards criteria. This also involves defining specifications for the equipment in line with environmental requirements.

Installation Qualification (IQ)

To provide documented proof that the equipment complies with the specifications and to check the presence of related documentation.

Operational Qualification (OQ)

To provide documented evidence that the system operates according to the functional analysis and to the supplier's recommendations.

Performance Qualification (PQ)

To check the performance of the installation within its range of use according to the required operating method.

After-sales

Technical support and maintenance

Reactivity and quality of service.
JCE Biotechnology is there to support you and to guarantee the uninterrupted running of your equipment, by optimising its availability and operability, while keeping within your budget constraints.

Discover all of JCE Biotechnology's services

Technical Support Hotline

Telephone: +33 (0) 470 595 149
Fax: +33 (0) 470 595 141
e-mail: sav@jcebiotechnology.com

We will analyse your requests so as to provide you with an appropriate solution without delay.
When an on-site call-out is necessary, a JCE Biotechnology technician will be sent to you as quickly as possible depending on time constraints and location.
This system allows us to remain proactive and to satisfy our customers.

Service contracts

In addition to the warranty conditions in place following the installation of new equipment, JCE Biotechnology offers a range of preventive and corrective maintenance solutions tailored to your needs, to ensure your equipment operates at full capacity and your costs are kept under control.

Remote maintenance

When putting new equipment into service and depending on the configuration, we will install a device to enable remote-maintenance service of your equipment. For further information on installation and operating conditions please contact us.

JCE BIOTECHNOLOGY

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