

GloveFAST Cyto Pharma

Cytotoxic Isolators



LABORATORY AND
INDUSTRIAL EQUIPMENT

GloveFAST Cyto Pharma

Faster Isolators for cytotoxic applications

GloveFAST Cyto Pharma is the latest isolator of FASTER cytotoxic isolators.

Mainly conceived and designed for cytotoxic reconstitution and chemotherapy preparations typically performed in hospital pharmacies or in Aseptic compounding units inside the hospitals, this unit finds applications also in the pharmaceutical and chemical fields when it comes to development of new toxic agents or API.



RANGE OF APPLICATIONS processing of

- Chemotherapy preparation
- Cytotoxics (CMR)
- Any other toxic active agents

ECO CONTROLLING SYSTEM - ENERGY EFFICIENCY TECHNOLOGIES FOR A LOW ENVIRONMENTAL IMPACT

The new ECS® microprocessor uses the latest innovative methods of integrated management of all the principal functions of ventilation and filtration - self-regulating the ventilation system by compensating for the increased pressure drops of the filters and restoring power balance.

Combining the use of DC motors, dimmable LED lights and certified low pressure-drop filters, the new ECS® controlling system optimizes power consumption, reducing CO₂ emissions into the environment.

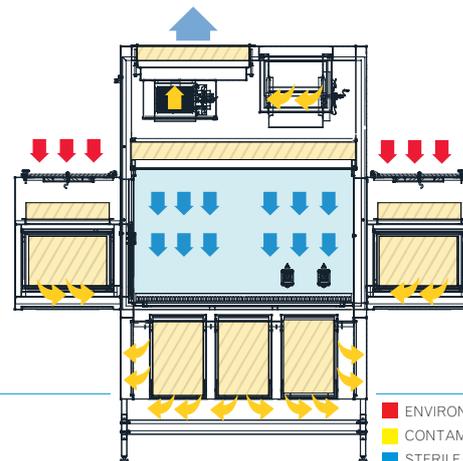


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SAFETY WITHOUT COMPROMISES

Faster GloveFAST Cyto Pharma cytotoxic isolators are negative pressure devices which separate a pharmaceutical process or activity both from the operator and the surrounding environment when it comes to reconstitution of lyophilized drugs and toxic materials handling. **Faster GloveFAST Cyto Pharma** units secure from contamination assuring an healthy and safe environment for the operators with a cost-efficient solution. Primarily conceived for safe aseptic handling of hazardous materials such as preparation and handling of **cytotoxic drugs, manipulation of antineoplastic chemotherapeutics and CMR**. **Faster GloveFAST Cyto Pharma** is a negative isolator in **Class 2** as per **ISO14644-7** with leak rate level measured in **16 Pa/minute** with a real unidirectional airflow providing a **Class ISO 3** in terms of cleanliness level according to **ISO 14644-1** or **EC GMP Grade A**, isolating the operator and the environment from the process and its constituent parts. **Faster GloveFAST Cyto Pharma** are widely used in hospital pharmacies and oncology clinics for compounding of chemotherapy agents or IV admixtures that can be harmful to pharmacy personnel.



WORKING PRINCIPLES

Room air is aspirated from the top of the transfer hatches through an H14 HEPA filter and pushed into the working area of the pass boxes. The air is then pass through a second H14 HEPA filter located at the back of the transfer hatches and then in the return channel where it is mixed with the air coming from the main filter under the work surface. The pressurized air into the plenum is then pushed through the downflow H14 HEPA filter to provide laminar flow and clean

conditions in the work chamber. From here, through the slots of the work surface, it goes into the main H14 HEPA filter under the work surface and then in the return channel located at the back of the work chamber. Part of the air is exhausted through the exhaust H14 HEPA filter creating the negative pressure condition (which protects operator and environment) and part is recirculating in the work chamber.

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DIMMABLE LED LIGHTS

allowing power consumption reduction and adjustable to fit different users needs.

THE BEST FILTRATION EVER

Differently from many other units available in the market for the same type of use, the unit delivers a unidirectional Laminar Flow thanks to a H14 HEPA filters (High Efficiency Particulate Air) covering the entire work area and to 7° sloped front and back.

The transfer hatches are also filtered by means of an inlet G4 prefilter and 2 HEPA filters H14 while the main filtration stage is represented by the sloped H14 filters located underneath the work surface able to trap cytotoxic contamination.

Finally the air is filtered a last time by the H14 filter located at the top of the unit.

UNMATCHED NOISE LEVEL

With most of the competitors sounding extremely loud, GloveFAST Cyto Pharma offers an incredibly low noise level.

The on field experience proved that the decommissioning of competitors' isolators and installation of the new GloveFAST Cyto Pharma brings to a substantial reduction of the noise level in the room.



ROUND GLOVEPORTS The front visor is equipped with either 2 or 4 integrated glove ports of 300/250 mm diameter allowing great comfort to the user especially during cleaning operations.

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MAIN FEATURES

IP 66 ELECTRICAL SOCKETS

2 x IP 66 electrical sockets for total protection against liquid splashes.



SMOOTH SURFACE

without crevice as per GMP requirements.



REMOVABLE WORK SURFACE

Work Surface in stainless steel AISI 316L is easily removable for routine cleaning and disinfection procedures. As standard supplied with spill retaining solid work surface, perforated/solid in one piece or sections are available on request.

Work chamber entirely made of stainless steel 304.

INCREASED SPACE FOR LEGS

The innovative system of third filter bank made of H14 HEPA/ULPA filters beneath the work surface, increases the space for operator's knees (> 480 mm) giving extreme comfort to the operator.

BAG-OUT SYSTEM

The main filters under the work surface are conceived to be disposed off in a standard 60lt waste bin according to the latest version of DIN 12980:2017 Standard. The bag-out System offers a safe and easy replacement of the main filters under work surface which can be intact passed through the side hatch without having to open the front visor in full respect of engineers and environment protection as per DIN 12980:2017 Standard.



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CONSTRUCTIONS FEATURES

CONSTRUCTION

Full body of the unit and transfer hatches made in epoxy painted steel coated with Alesta® Dupont anti-microbial painting. Full AISI 304L stainless steel body carcass and hatches available as option.

WORKING SURFACES

Fully made in AISI 316L stainless steel with scotch brite finishing.

Back and side walls in AISI 304L stainless steel.

TRANSFER HATCHES

GloveFAST Cyto Pharma transfer hatches are D2 type according to ISO 14644-7.

The hatches are fitted with an outer door and a top lid made of safety opaque glass.

Inner and outer hatch doors are interlocked.

Separated timers for loading and unloading hatches can be set as per customer request.



FILTRATION

Filtration is provided by seven levels of absolute filters H14 HEPA/ULPA with typical efficiency of 99.995% MPPS according to CEN EN 1822 as well as 99.999% conforming to IEST-RP CC00 1.3 USA. All the filters are low pressure drop certified H14 HEPA/ULPA filters.

DEHS RAPID TEST PORTS

The Isolator is fitted with a number of test ports allowing the HEPA filters to be tested individually.

SLEEVE+GLOVES

The polyethylene glove ports of 300 mm/250 mm host a CSM sleeves connected to neoprene gloves by means of PVC cuff ring.

Glove and sleeve can be replaced separately thus saving money for the end user.



AIR QUALITY

Air cleanless in Class ISO 3, according to ISO 14644-1

Vertical, unidirectional flow (laminar flow) in the work zone is 0,45 m/s. Inflow velocity in case of sleeve breeching is $\geq 0,7$ m/s (as per ISO 14644-7).

GLASSES

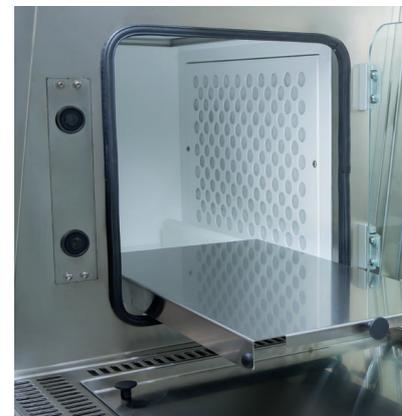
Front window made of 8 mm safety glass is framed in an aluminum frame. Internal and external transfer hatch doors are made of safety glass. The frontal view-screen is slanted with top hinges and gas struts that allow full opening for loading and unloading of bulky tools.



TRANSFER HATCHES SLIDING WORK SURFACE

Stainless steel AISI 316L sliding tray in each transfer hatch ease the transfer of materials inside/outside the working volume.

The trays are removable for sterilization processes in autoclave.



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THE USER-FRIENDLY
PRACTICAL
KEYBOARD



AUDIO VISUAL ALARMS PROVIDED FOR

- out of range laminar airflow velocity
- low operating pressure
- saturation of H14 HEPA/ULPA filters
- blockage in the exhaust duct
- motor malfunction
- power failure
- leak rate test failure

ECS® MICROPROCESSOR BASED MONITORING SYSTEM:

full status report provided on the 2-line digital display via the new generation microprocessor which controls control all functions and automatically compensate motor power reduction that may happen due to the progressive clogging of the filters, ensuring that steady laminar flow velocity and safety are kept.



THE USER-FRIENDLY PRACTICAL KEYBOARD

and the rear-lit LCD will continuously display all required data keeping the user constantly informed of the cabinet working conditions in particular:

- display of laminar airflow velocity
- display of inside and outside temperature
- display of residual lifetime of H14 HEPA/ULPA filters, UV Lamp (if fitted)
- display of total number of hours of operation
- display of saturation level of H14 HEPA/ULPA filters
- operating pressure
- motors power



COMPLIANCE

FILTRATION	AIR CLEANLINESS	CONTAINMENT	ELECTRICAL SAFETY	SAFETY CABINETS, GLOVE BOXES FOR CYTOTOXIC SUBSTANCES AND OTHER CMR DRUGS
EN 1822/ IEST-RP-CC00 1.3	ISO 14644-1	ISO 14644-7	EN 61010-1/ IEC 61010-1	DIN 12980:2017

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TOP QUALITY

- Air quality in grade A (unidirectional Laminar Flow) as per EU-GMP Guide within the entire work zone
- Easy cleaning of inner and outer surface
- Automatic pressure decay test (via optional ATV valve) with results of the test stored in the isolator back up memory.
- Negative operating pressure (-75Pa) with laminar airflow and actively regulated blowers
- Aseptic glove-changing system
- Easy monitoring of all parameters, test and maintenance
- Ergonomically designed for easy operation, good visibility and high operators' comfort
- High air-change rate within the work zone and the transfer hatches for rapid clean-up of contaminated air
- Foot switch controlled inner doors



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HANDS FREE

Inner and outer doors of the transfer hatches are hinged and operate by means of footswitch. As option, an electrical vertically sliding system can be provided for inner doors.

The outer doors open from left to right or viceversa (depending on which hatch). As option and in the 3 way hatch they can be opened upwards.



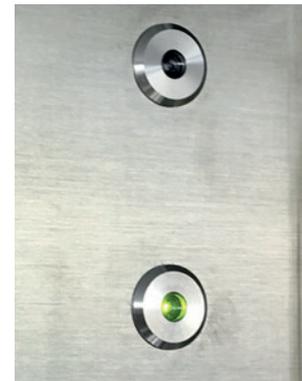
standard hinged
inner door



electrical sliding
inner door
(optional)



foot switch



LED indicators
for inner hatch
door status in the
internal back wall

POWER IS NOTHING WITHOUT CONTROL

The diagram illustrates the RemoteFAST remote control system. It shows a 'Customer' workstation on the left and a 'Service' workstation on the right. A wireless signal icon connects the two workstations, indicating remote communication. The Customer workstation is a blue desk with a monitor and keyboard. The Service workstation is a computer monitor and keyboard on a desk.

The optional remote control (RemoteFAST) allows FASTER service engineer to monitor isolator's functions as well as making preliminary diagnosis in the event of breakdown.

This allow local service engineers to visit customer site with the solution already in their pocket.

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OPTIONAL

OPTIONAL EXTRAS

The list of optional extras available for GloveFAST Cyto Pharma is quite wide. The most common are listed here below:

- Compressed air, vacuum and nitrogen service taps
- H₂O₂ pipework for connection to most common brands of VHP generators like Steris, Bioquell with specific communication protocols developed
- Electrically operated adjustable support stand
- Easy-Change Cuff Ring System (Push/Push)
- Single hatch version
- Electrical inner hatch doors
- Active charcoal filter
- Stainless steel hanging rail with six hooks
- 19" cleanroom touch screen
- Isokinetic probe for particle monitoring
- Display of hatch pressure
- CCTV for documented/traceable process
- Glove/sleeve test disc with digital manometer
- RJ 45/RS 232/USB Interface ports
- Temperature and humidity sensors
- Sealed monitor screen in the backwall
- Multi-functional touch-display (size 7")
- Intercom
- Rapid hatch configuration
- ATV valve on top of the unit for automatic leak rate test
- ATV valves on the hatches in replacement of the standard lids for automatic leak rate test
- Inflatable gaskets for superior isolation during VHP decontamination



SAFETY EVERY DAY

Automatic Pressure Decay Test:

If the ATV valve has been included in the isolator configuration, **users can be everyday sure that the isolator is fully compliant with the expectations and ready to work in full safety**, without having to wait the next preventive maintenance.

In case the pressure decay is higher than the set threshold the display will show "Pressure Test Fail".

In case the pressure decay is lower than the set threshold the display will show "Pressure Test Pass".





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CUSTOM MADE SOLUTIONS

with H₂O₂-Rapid-Gassing-Hatch and attached Cytotoxic Safety Workbench

A wide range of customization is available, from cytotoxic line combining a cytotoxic isolator to a cytotoxic cabinet to inflatable gaskets or integration with DPTE ports for safe waste of contaminated materials or rapid gassing hatch.



TECHNICAL SPECIFICATION



Description	GloveFAST Cyto Pharma			
	2-4-2	2-5-4	2-6-4	
<i>Isolator dimensions</i>	<i>Unit</i>			
Outer dim. (WxDxH) complete	mm	2510x870x2300	2815x870x2300	3120x870x2300
Inner dim. (WxDxH) work chamber	mm	1192x580x740	1497x580x740	1802x580x740
Gloves material	Neoprene			
Sleeves material	CSM			
Sleeve dimensions	Dimensions at wrist 90 mm-Glove port Ø 300/250 mm			
<i>Electrical connection & weight</i>				
Weight (approx. kg)		550	580	620
Lighting level (Lux)			≥ 2000	
Noise level (dB(A))		≤ 53	≤ 55	≤ 58
<i>Working parameters</i>				
Operating pressure			-75 Pa	
Downflow air speed			0,45 m/s	
Exhaust Flow rate			300 m ³ /h	



Striving everyday to improve our environmental performance, Faster developed environmental procedures are founded on three guiding principles:

Protect the Environment for present and future generations manufacturing low energy consumption equipments

Reduce risks and improve efficiencies

Introduce improved technology and processes



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