



DASITGROUP



GloveFAST Cyto Technical Sheet

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1. Foreword

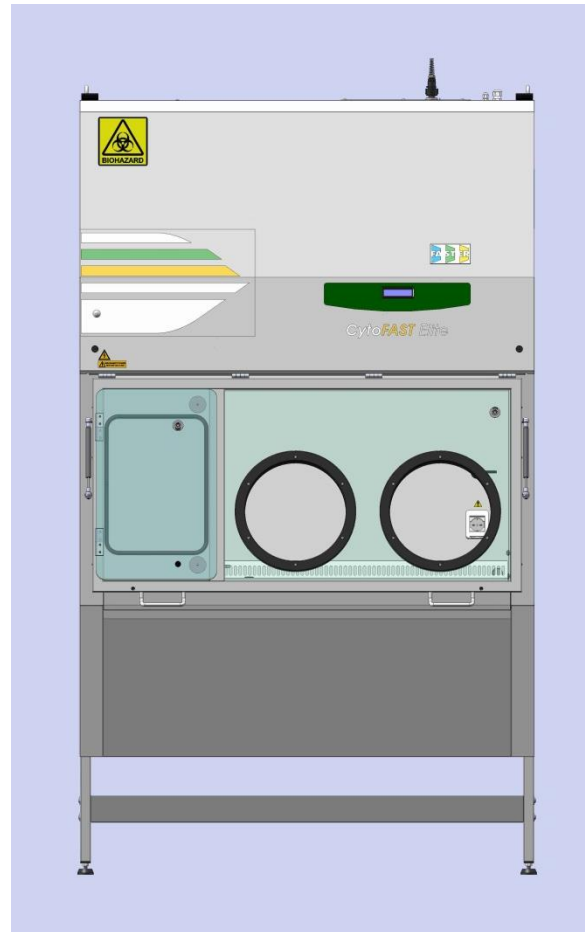
GloveFAST *Cyto* is an isolator system primarily conceived for the reconstitution of anti-neoplastic drugs. It works in negative pressure delivering triple protection to the operator, environment and the product as well. The gloves installed on the frontal screen provide for a physical separation of the products manipulated delivering superior safety for the operators. GloveFAST *Cyto* can be used as well for the handling of pathogens belonging to any group according to EN 12469:2000 and anytime the process involves the handling of cytotoxic or hazardous chemicals. The unit is equipped with triple level of HEPA filtration.

2. Applications

GloveFAST *Cyto* can be variously used in hospital oncology centers for drugs preparation and any time an high and proven grade of protection for the operators are required.

In particular, the isolator is qualified for the following applications:

- > preparation of anti-neoplastic chemotherapies,
- > manipulation of cytotoxic and cytostatic drugs,
- > manipulation of etiologic agents with proven and active pathogenicity on humans and animals,
- > handling of pathogen compounds in high concentration and mutagen agents,
- > oncogenic virus,
- > microbiology, virology and cell cultures
- > recombinant DNA applications



3. Construction

The body carcass is made in cold rolled epoxy painted steel painted with Alesta® Dupont antimicrobial coating. The internal surfaces are made in AISI 304 stainless steel as well as the work surfaces of the transfer hatch and main chamber with Scotch Brite finishing. All the corners are smooth. The whole isolator can be optionally supplied fully made in AISI 304 or AISI 316 stainless steel Scotch-brite finishing.

4. Screens

Frontal screen of the main chamber is made with a glare free safety glass 8mm thickness, the front outer door of the hatch is made of safety glass 10mm thickness, while the inner sliding door is made of PMMA. Left and right side glasses of the isolator body are made with tempered 6mm thickness glasses. The frontal screen of the main chamber can be totally opened for cleaning or maintenance purposes by means of two handles installed for this scope. A couple of gas springs keep the glass in open position whenever needed. The tightness of the frontal screen is achieved by proven-tight gasket and screws pressing the gasket.

5. Gloves and sleeves

The unit is equipped with 300mm/250mm rounded Polyethylene flanges with O-Ring system for gloves positioning. The gloves are made in neoprene material and separated by means of sleeves made in CSM. Gloves and sleeves are connected with POLYETHYLENE clamps and bands.

6. Hatch doors system

Transfer hatch doors are controlled with electro-magnetic type. The external and internal doors are temporized. The internal door is made in PMMA material and the opening is enhanced with a top/down sliding system.

7. Technical Specifications

	GloveFAST Cyto 2-4-2	GloveFAST Cyto 2-5-2	GloveFAST Cyto 2-6-4
<ul style="list-style-type: none"> Overall dimensions (w x d x h) 	1350 x 882 x 2345mm	1655 x 882 x 2345mm	1960 x 882 x 2345mm
<ul style="list-style-type: none"> Internal Useful dimensions (w x d x h) 	(852 + 316) x 580 x 740mm	(1157 + 316) x 580 x 740mm	(1462 + 316) x 580 x 740mm
<ul style="list-style-type: none"> Transfer tray surface dimensions (w x d) 	290 x 300mm	290 x 300mm	290 x 300mm
<ul style="list-style-type: none"> Useful sliding top/down opening from the transfer hatch chamber into the main chamber 	290mm	290mm	290mm
<ul style="list-style-type: none"> Construction materials 	<ul style="list-style-type: none"> › Body carcass made in cold rolled epoxy painted steel coated with Alesta Dupont antimicrobial coating 	<ul style="list-style-type: none"> › Body carcass made in cold rolled epoxy painted steel coated with Alesta Dupont antimicrobial coating 	<ul style="list-style-type: none"> › Body carcass made in cold rolled epoxy painted steel coated with Alesta Dupont antimicrobial coating
	<ul style="list-style-type: none"> › Internal working volume surface fully made in AISI 304 stainless steel 	<ul style="list-style-type: none"> › Internal working volume surface fully made in AISI 304 stainless steel 	<ul style="list-style-type: none"> › Internal working volume surface fully made in AISI 304 stainless steel
	<ul style="list-style-type: none"> › Work surfaces either of the main chamber and of the sliding transfer tray made in AISI 304 stainless steel 	<ul style="list-style-type: none"> › Work surfaces either of the main chamber and of the sliding transfer tray made in AISI 304 stainless steel 	<ul style="list-style-type: none"> › Work surfaces either of the main chamber and of the sliding transfer tray made in AISI 304 stainless steel
<ul style="list-style-type: none"> Motor-blowers 	<ul style="list-style-type: none"> › Main LAF centrifugal double-inlet external rotor motor-blower 	<ul style="list-style-type: none"> › Main LAF centrifugal double-inlet external rotor motor-blower 	<ul style="list-style-type: none"> › Main LAF centrifugal double-inlet external rotor motor-blower
	<ul style="list-style-type: none"> › Centrifugal double-inlet external rotor Exhaust motor-blower 	<ul style="list-style-type: none"> › Centrifugal double-inlet external rotor Exhaust motor-blower 	<ul style="list-style-type: none"> › Centrifugal double-inlet external rotor Exhaust motor-blower
<ul style="list-style-type: none"> Screens 	<ul style="list-style-type: none"> › Frontal tempered 8mm glass 	<ul style="list-style-type: none"> › Frontal tempered 8mm glass 	<ul style="list-style-type: none"> › Frontal tempered 8mm glass

• Flanges and Gloves	> Side tempered 6mm glasses	> Side tempered 6mm glasses	> Side tempered 6mm glasses
	> Transfer hatch internal and external Plexiglass screens	> Transfer hatch internal and external Plexiglass screens	> Transfer hatch internal and external Plexiglass screens
• Electrical outlet	> 2 x Rounded 300mm POLYETHYLENE flanges	> 2 x Rounded 300mm POLYETHYLENE flanges	> 4 x Rounded 200mm POLYETHYLENE flanges
	> 2 x Neoprene gloves	> 2 x Neoprene gloves	> 4 x Neoprene gloves
• Electrical provisions	No.01 IP 66 electrical outlet	No.02 IP 66 electrical outlet	No.02 IP 66 electrical outlet
• Noise level	Volt free contact	Volt free contact	Volt free contact
• Lighting Level	<54 dB(A)	<57 dB(A)	<57 dB(A)
• Power	No.02 36W fluorescent tube delivering more than 1000Lux at work surface level	No.02 36W fluorescent tube delivering more than 1000Lux at work surface level	No.02 36W fluorescent tube delivering more than 1000Lux at work surface level
• Weights	230V – 50Hz – 10A	230V – 50Hz – 10A	230V – 50Hz – 10A
• Packing details	315Kg net weight – 380Kg gross weight	350Kg net weight – 400Kg gross weight	400Kg net weight – 480Kg gross weight
• Cleanliness of air	Carton box suitable for overseas shipment 1470x900x2200mm	Carton box suitable for overseas shipment 2060x900x2200mm	Carton box suitable for overseas shipment 2060x900x2200mm
• Downflow, Exhaust Filter, Inlet Filter and Filter under work surface Type	ISO 3 according to ISO 14644-1		
	ULPA filter with integral metal frame and filter frame gaskets; fully compliant with EN 1822 (H14) and IEST-RP-CC001.3 requirements (each cabinet has individual downflow, exhaust filters and inlet filters.)		

8. Filtration

The filtration of the equipment is provided by n.05 H14 HEPA filters with specifications as listed in the table below:

	Filter type	Efficacy	Compliance
MAIN	Double low pressure drop Dihedral main H14 HEPA filters located below the work surface - 530x287x400mm - 238x287x400mm	<ul style="list-style-type: none"> • 99.995% MPPS (EU) • >99.999% for particles between 0.1 and 0.3 microns 	<ul style="list-style-type: none"> • CEN EN 1822 (EU) • IEST-RP-CC001.3 / CC007 / CC034.1 (USA)
PASS BOX	Low pressure drop Dihedral main H14 HEPA filters located below the work surface - 238x287x400mm	<ul style="list-style-type: none"> • 99.995% MPPS (EU) • >99.999% for particles between 0.1 and 0.3 microns 	<ul style="list-style-type: none"> • CEN EN 1822 (EU) • IEST-RP-CC001.3 / CC007 / CC034.1 (USA)
LAF	Low pressure drop LAF H14 HEPA filter delivering class ISO 5 (GMP Grade A) in laminar flow condition within the working and transfer chambers	<ul style="list-style-type: none"> • 99.995% MPPS (EU) • >99.999% for particles between 0.1 and 0.3 microns 	<ul style="list-style-type: none"> • CEN EN 1822 (EU) • IEST-RP-CC001.3 / CC007 / CC034.1 (USA)
INLET	Low pressure drop inlet H14 HEPA filter located on the top of the isolator. Replacement of this filter is from the top. – 305x457x69mm	<ul style="list-style-type: none"> • 99.995% MPPS (EU) • >99.999% for particles between 0.1 and 0.3 microns 	<ul style="list-style-type: none"> • CEN EN 1822 (EU) • IEST-RP-CC001.3 / CC007 / CC034.1 (USA)
EXHAUST	Low pressure drop exhaust H14 HEPA filter located on the top of the isolator – 457x610x69mm	<ul style="list-style-type: none"> • 99.995% MPPS (EU) • >99.999% for particles between 0.1 and 0.3 microns 	<ul style="list-style-type: none"> • CEN EN 1822 (EU) • IEST-RP-CC001.3 / CC007 / CC034.1 (USA)

9. Tightness of the body carcass

The body carcass tightness is classified in Class 3 according to ISO 14644-7 and ISO 10648-2 with an hourly leakage rate minus than 16Pa per minute starting from an operating pressure of 150Pa of pressure. The unit performances declared as defined by ISO 14644-7.

10. Air flow speed

Operational air flow speed is factory set to 0,40m/s both in the main and the transfer chamber. Half-speed reduction is available as well set to 0,25m/s. Alternative set-points are available upon request.

11. Operating pressure

The unit works with operative negative pressure set to -75Pa

12. Alarms

The unit automatically controls operational parameters and provide for audio and visual alarms in case of:

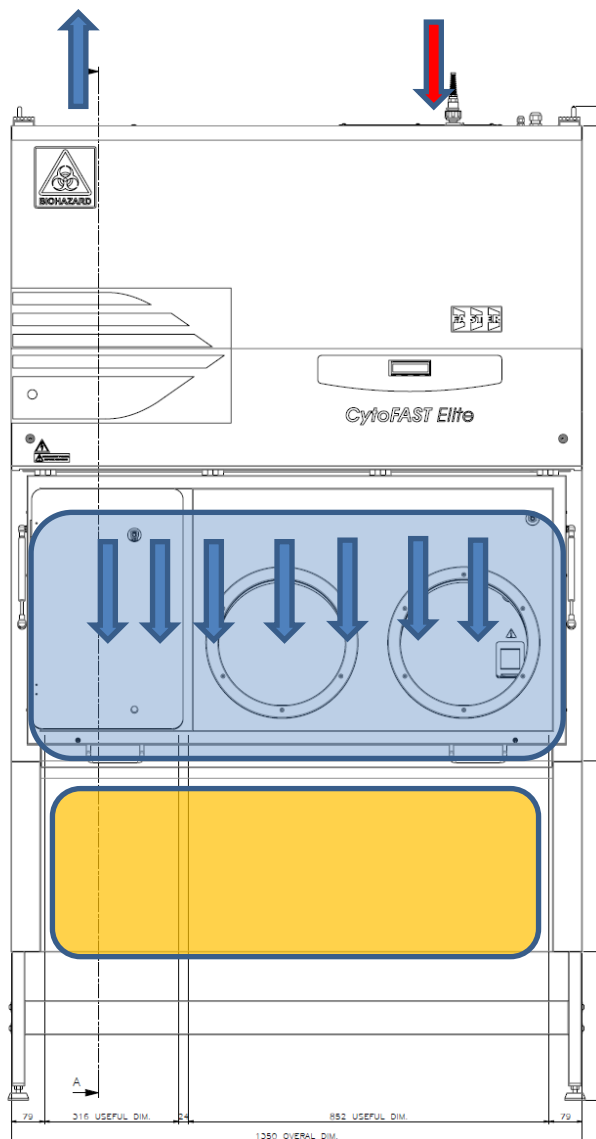
- out of range or incorrect laminar airflow velocity and internal pressure
- incorrect position of frontal glass
- saturation of HEPA filters
- end of life-cycle of UV lamp (if fitted)
- blockage in the exhaust duct
- fan-motor malfunction
- power failure






13. Air flow diagram

Environment air enters into the close isolator system from the inlet H14 HEPA filter positioned on top of the unit. The HEPA filtered air is then pulled down-wards in laminar flow condition prior to being filtered again by the second stage of H14 HEPA filtration.

As the closed system is in negative pressure, the air is recirculated and filtered by the main H14 HEPA filters located below the work surface (third stage of filtration). The air is then partially recirculated into the main chamber and partially exhausted from the top where is located the fourth stage of H14 HEPA filtration. Air delivered either in the transfer hatch and the main chamber is in laminar flow conditions.



AIR FLOW PATTERN	
	Environment Air
	Sterile Air in laminar flow condition
	Contaminated Air with cytotoxic compounds

14. Available option

GloveFAST Cyto can be supplied equipped with the following options available:

- Construction fully made in AISI 304L or AISI 316 stainless steel
- Double ATV DN150 electric gauge for automatic pressure decay test.
- Hanging rails for bags
- Back side wall LCD screen window (screen not included)
- Anti-blowback valve
- Automatic adjustable height supporting stand (work surface height from 770mm to 1070mm)
- Internal circuit for hydrogen peroxide generators connection
- Special right side panel including provision for waste bag

15. Standards compliances

GloveFAST Cyto comply to the following Standards:

GloveFAST Cyto - Compliances -	
FILTRATION	<ul style="list-style-type: none">• EN 1822 (EU)• IEST-RP-CC00 1.3 / 007 / 034.1 (USA)
AIR CLEANLINESS	<ul style="list-style-type: none">• ISO 14644-1
ISOLATORS	<ul style="list-style-type: none">• ISO 10648 2• Annex 1 to GMP• ISO 14644-7
ELECTRICAL SAFETY	<ul style="list-style-type: none">• IEC 61010-1 (Europe / Worldwide)• UL 61010-1 (USA)
CYTOTOXIC and MICROBIOLOGICAL COMPOUNDS HANDLING	<ul style="list-style-type: none">• DIN 12980:2017 – EN 12469:2000