RABS
RESTRICTED ACCESS BARRIER SYSTEM

RABS Tecninox designs and manufactures RABS – Restricted Access Barrier System – suitable to isolate areas intended for critical procedures such as pharmaceutical production lines.

The main purpose of this comparmentalisation is to contain the particulate propagation within the isolated area, protecting both the environment and the operator who works through gloves positioned on the RABS glass.

This comparmentalisation is not hermetic: a low depression maintains powders inside the isolated area (dynamic containment).

RABS – RESTRICTED ACCESS BARRIER SYSTEM

- **RABS for enhanced cleanroom contamination control** by creating a physical barrier between the process critical areas and the surrounding operators.
- **Operations:** personnel can intervene through the gauntlets fixed of the RABS perimetral walls
- **RABS doors:** access door to process area can be opened under well-defined SOPs, door opening has to be recorded as well as the operator in the process control system and after these operations all the product present in the critical area has to be rejected and a deep surface cleaning operation has to be performed.

ASEPTIC PROCESS APPLICATIONS:

Aseptic filling: Uni Directional Air Flow Isolators are used to fill vials, syringes, and other containers with sterile products.

Aseptic compounding: Uni Directional Air Flow Isolators are used to compound sterile products, such as IV solutions and chemotherapy drugs.

Sterility testing: This testing is conducted by direct inoculation or membrane filtration methods, and it is generally performed in a Uni Directional Air Flow isolator designed for this kind of application.

ATMP manufacturing: Uni Directional Air Flow Isolators are an essential part of the manufacturing process for ATMPs. The unit is designed to be bio-decontaminated and to control temperature and Relative Humidity of the isolator chamber environment.

PROCESS CONTAINMENT APPLICATIONS NEGATIVE DIFFERENTIAL PRESSURE

Raw material sampling: HPAPI sampling of performed in our turbulent flow isolator capable to contain all handled powders up to OEB 6. The unit works in a negative differential pressure environment and can be bespoke designed according to the inlet raw material containers as well as sampled materials and waste exit.

Process batch preparation - dispensing: the isolator design for this kind of process is dictated from the raw material inlet devices and dispensed materials outlet from the isolator enclosure. Sacrificial sleeve interfaces, Material Ari Lock, Rapid Transfer Ports, Continuous liner, dual split butterfly valves can be integrated within the isolator chamber.

HEALTHCARE APPLICATIONS

Aseptic Product Compounding – Positive Pressure: isolator units can operate in a positive differential pressure to provide a safe and clean work environment for compounding of non-hazardous drug preparations.

- IV admixtures
- TPN formulation and compounding
- R&D

Aseptic Toxic Product Compounding – Negative Pressure: isolator units have to operate in a negative differential pressure while providing a safe and clean working environment for compounding of hazardous drug preparations.

- Chemotherapy
- Hazardous Drug Handling
- R&D

Aseptic Handling of Biological Agents – Negative Pressure: isolator units have to operate in a negative differential pressure while providing a safe and clean working environment for aseptic handling of biological agents.

- Cell, Cell Culture, Stem Cell processing, Allogenic Cell Therapy
- Monoclonal Antibody production
- Bio-Hazardous handling of biological agents up-to level 4 (WHO laboratory safety manual, 4th edition)
- Virus and vaccine research and manufacturing
- R&D.

Description	2 Gloves	3 Gloves	4 Gloves	5 Gloves	MAL 2 Gloves
Unit Supplied Quantity	1	1	1	1	1
Overall dimensions (WxDxH) mm	1420x850x2350	1870x850x2350	2320x850x2350	2770x850x2350	900x850x2350
Work area dimensions (WxDxH) mm	1050x690x800	1500x690x800	1950x690x800	2400x690x800	800x690x800
Weight (kg)	340	490	635	780	260
Voltage Supply	400-440 VAC 50/60 Hz	400-440 VAC 50/60 Hz	400-440 VAC 50/60 Hz	400-440 VAC 50/60 Hz	400-440 VAC 50/60 Hz
Phases	3P + N + E	3P + N + E	3P + N + E	3P + N + E	3P + N + E
Power (kW)	0,5	0,75	1	1,25	0,2
Noise level (dB)	≤ 75 db	≤ 75 db	≤ 75 db	≤ 75 db	≤ 75 db
Lighting ± 10% (Lux)	500	500	500	500	500