




Notice

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 **PURETEC CO., LTD.**  **MIRAPRO GROUP**

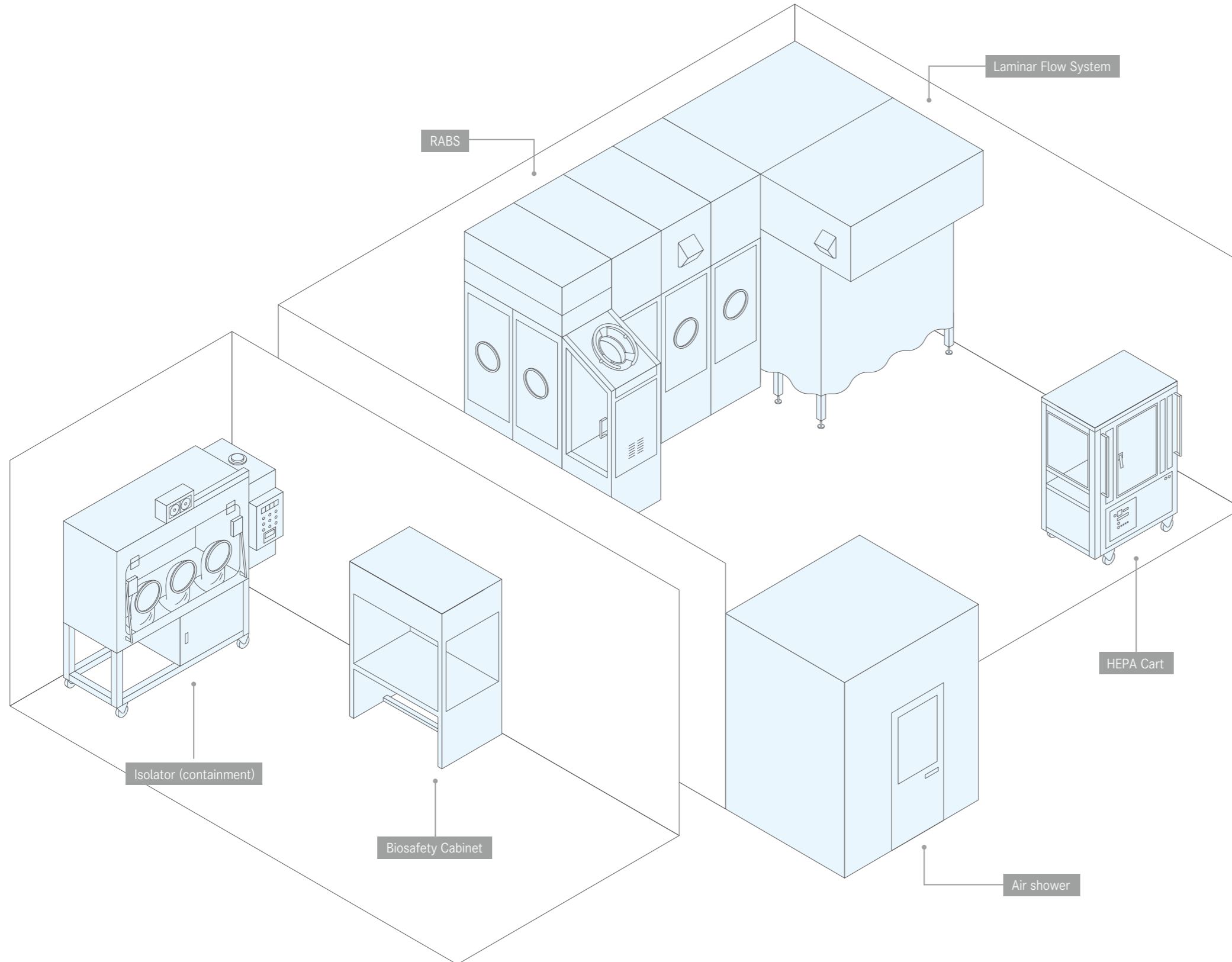
Design for Clean Air  
 **Clean Air Technology**



## Propose advanced systems × user's perspective Provide the clean space that you are searching for

Puretec's clean room air-conditioning systems and isolator systems, boasting the highest-level performance in the industry, are adopted in a variety of fields, including pharmaceuticals, medical devices, food, hospitals, precision instruments, and electronic components.

Our knowledgeable and experienced staff will propose a custom-made clean space to suit your needs.



## Clean Air Technology

- Installation Process ..... P03
- Isolator (positive pressure type) ..... P05
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## Performance and Cleanliness Classification



- Airtightness** | The degree of airtightness inside the system, or the presence or absence of airtightness.
- Environment of Clean Room** | The environmental grade of the suitable installation room.
- Internal Environment** | The internal environmental grade to be achieved after installation of the system.

### Cleanliness Classification

ISO14644-1	FDA guidance for sterile products manufacture	EU-GMP Annex1	Microbiological Methods
ISO Class 5	100	Grade A	Grade A
ISO Class 6	1,000	—	—
ISO Class 7	10,000	Grade B	Grade B
ISO Class 8	100,000	Grade C	Grade C
ISO Class 9	—	Grade D	Grade D

\*Compared by in operation  
\*Quantity of particles of 0.5 μm or more per cubic feet

# Installation Process

From inquiry to after-sales-and-follow-up service (an example)



**Please entrust us with design to after-sales-and-follow-up service.**

We provide services from design through to after-sales-and-follow-up service. Even for product requirements that we have not experienced before, we will strive to propose the best for our customers based on our long-standing experience and abundant accomplishments. Please contact us first. Since we own measuring devices at our company, we will take the responsibility for validation and maintenance afterwards.





# ISOLATOR

Isolator (positive pressure type)

A high-quality isolator system based on state-of-the-art technology and rich know-how

A barrier system under complete laminar flow.  
A closed apparatus with a capsule structure, ensuring protection from cross contamination.

Airtightness



Environment of Clean Room

Grade **C** or **D**

Internal Environment

Grade **A**

### Access to the process area using gloves

\*Physical access limitations / Elimination of human-related pollution sources

### Structures / Specifications

- Welding integrated structure
- Door-seal type Pneumatic-seal type
- Internal circulation type (W-wall type / return duct type)
- Internal environment monitoring



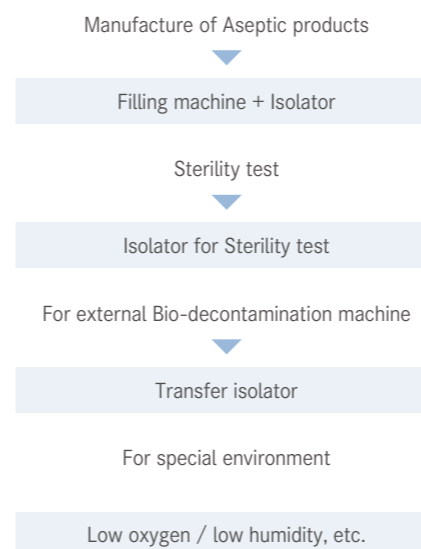
Vial filling line Sterilization



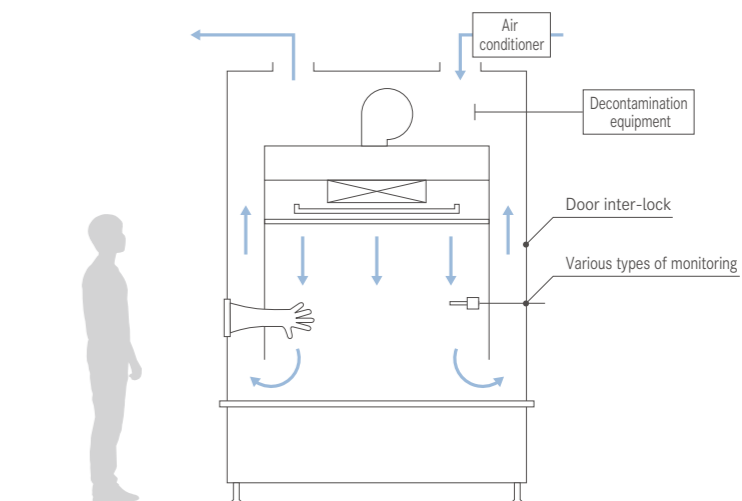
Mock-up



### Application case

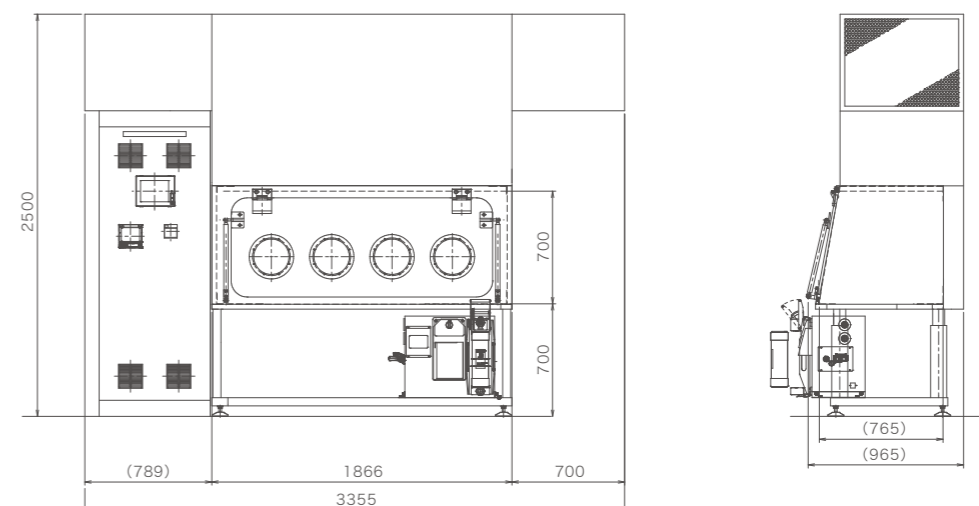


### Construction case



### Specification case

#### Isolator for Sterility test



#### Specifications

- Blowout method: Unidirectional flow
- Blowout air velocity: 0.45m/s ±20%
- Internal pressure: +25Pa(design pressure)
- Monitoring items: Internal pressure / temperature / humidity

- Door: reinforced glass
- Internal temperature and humidity: Arbitrary
- Required utility: Power 3φ200V 3kW
- Compressed air 0.5MPa 3L/min(maximum)



# ISOLATOR

Isolator (Containment)

Containment Isolator which protects the environment and workers and improve workability.

Containment Isolator ensures the safety of the operator when handling hazardous substances and prevents the leakage of hazardous substances into the surrounding environment.

Airtightness



Environment of Clean Room

Grade **C** or **D**

Internal Environment

Grade **A** ~ **D**

Access to the process area using gloves

\*Contain the internal materials to prevent effect on human body

### Structures / Specifications

- Welding integrated structure
- Door seal type Pneumatic-seal type
- One pass or circulation type
- Internal environment monitoring



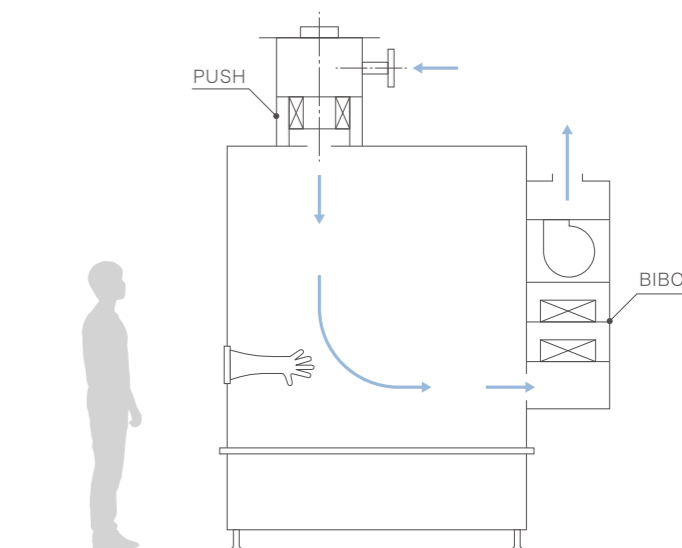
Vial filling line Sterilization + Containment

### Application case

Options can be added upon request

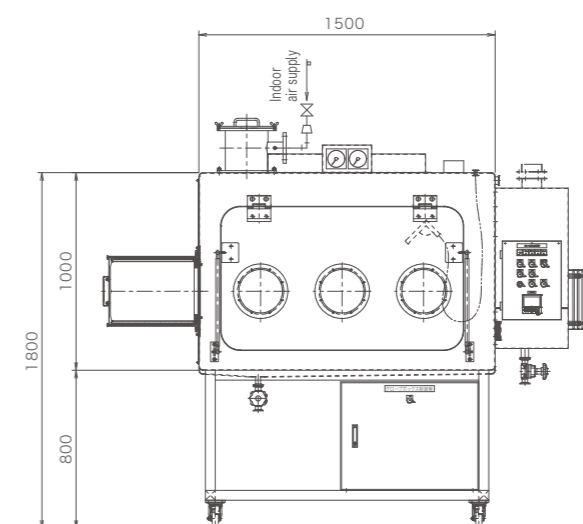
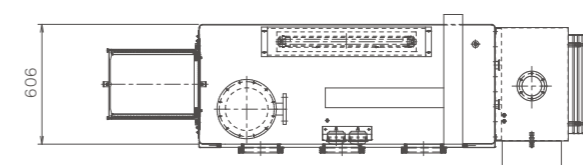
- Supply HEPA: Push type
- Exhaust HEPA: BIBO type
- Low internal humidity
- Nitrogen substitution
- WIP specifications
- Door seal: Pneumatic-seal
- Glove port: Round / Oval
- Material input /output: RTP, PassBox, Bagout Port

### Construction case

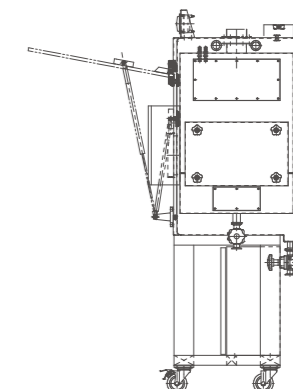


### Specifications case

#### Weighing isolator



- Specifications
- Effective dimensions: 1500×606×1000 H
  - Containment performance: OEL 0.1 μg/m<sup>3</sup>
  - Internal pressure: -30Pa or less for the installation room
  - Internal cleanliness: Grade C(ISO8) Non-working
  - Nitro substitution: Yes




# RABS

Restricted Access Barrier System

We can offer proposals to suit a wide variety of needs with our abundant accomplishments.

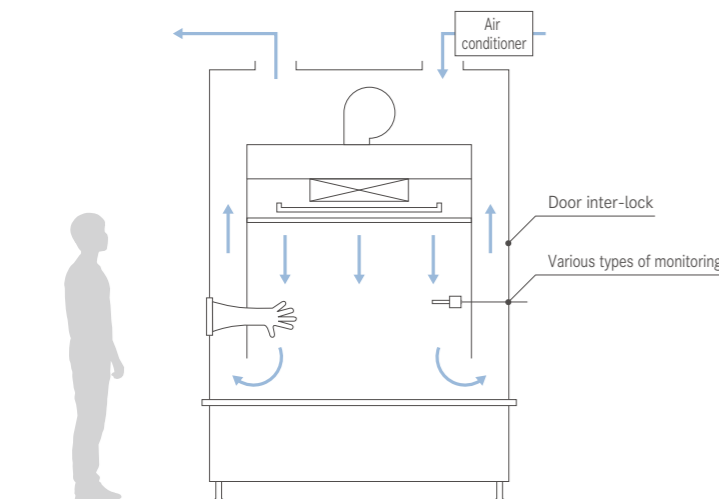
## CLOSE-RABS

Close-RABS is an intermediate structure between isolator and laminar flow system. It has less contamination risk than laminar flow system and a lower price than isolator.

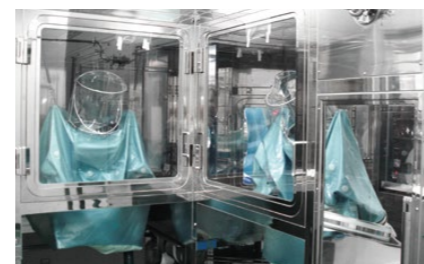
Airtightness		Access to the process area using gloves	<small>*Physical access limitations / Elimination of human-related pollution sources</small>
Environment of Clean Room	Grade <b>B</b>	<b>Structures / Specifications</b>	
Internal Environment	Grade <b>A</b>	<ul style="list-style-type: none"> <li>- Pillar + Kasten type or welding integrated structure</li> <li>- Door Seal: Packing or Pneumatic-seal</li> <li>- Internal circulation mechanism (W-wall type / return duct type)</li> <li>- Internal decontamination itself or not</li> <li>- AHU added or supply / exhaust by customer</li> </ul>	

### Construction case

CLOSE-RABS for filling machine



CLOSE-RABS for filling machine




Half-Suit Type CLOSE-RABS

**Specifications**  
 Blowout method: Unidirectional flow  
 Blowout air velocity: 0.45m/s ±20%  
 Internal positive pressure: +25Pa(design pressure)

**Monitoring items:** air velocity / internal pressure / humidity  
**Partition:** Kasten (Polycarbonate with SUS frame)  
**Internal circulation mechanism:** W-wall type

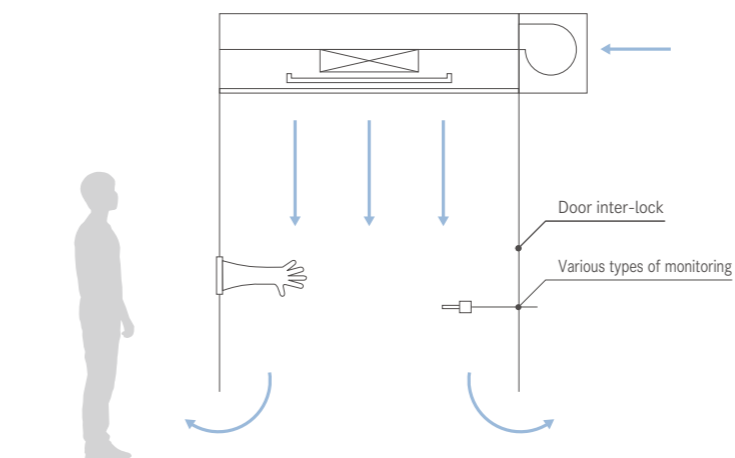
## OPEN-RABS

Open-RABS is an intermediate structure between isolator and laminar flow system. It has less contamination risk than laminar flow system and a lower price than isolator.

Airtightness		Access to the process area using gloves	<small>*Physical access limitations / Elimination of human-related pollution sources</small>
Environment of Clean Room	Grade <b>B</b>	<b>Structures / Specifications</b>	
Internal Environment	Grade <b>A</b>	<ul style="list-style-type: none"> <li>- Pillar + Kasten type</li> <li>- No internal decontamination itself</li> <li>- Add mechanical locking mechanism to the laminar structure</li> <li>- Attach glove ports</li> </ul>	

### Construction case

OPEN-RABS for filling machine



OPEN-RABS for filling



OPEN-RABS for filling machine + transportation

**Specifications**  
 Blowout method: Unidirectional flow  
 Blowout air velocity: 0.45m/s ±20%  
**Monitoring items:** air velocity  
**Partition:** Kasten(Polycarbonate with SUS frame)





# LAMINAR FLOW

Laminar Flow System

Boasts the highest-level lamination properties and realizes excellent air velocity distribution by placing CG\*

An ideal clean air system that obtains stable airflow with superior laminar flow properties. Necessary sizes and shapes can be made regardless of the filter sizes.

Airtightness



Environment of Clean Room

Grade **B**

Internal Environment

Grade **A**

CG is placed for the blowout surface

\*CG: An airflow creation device in sterile products process jointly developed with Zellweger Luwa AG and a pharmaceutical company (CIBA-GEIGY).

### Structures / Specifications

- Pillar + Kasten type
- Body: SUS 304
- Partition: Kasten (Polycarbonate with SUS frame) or vinyl curtain
- Installation method: Self-supporting (pillar) or suspending



Laminar Flow System

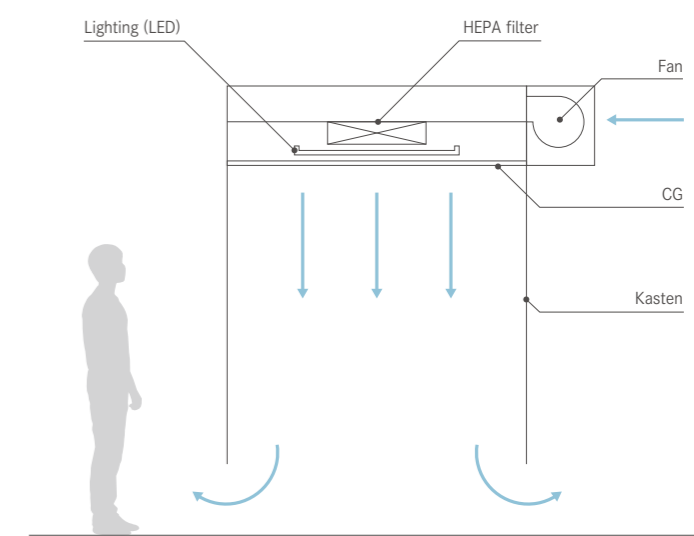


Laminar Flow System for Conveyors

### Merits of CG

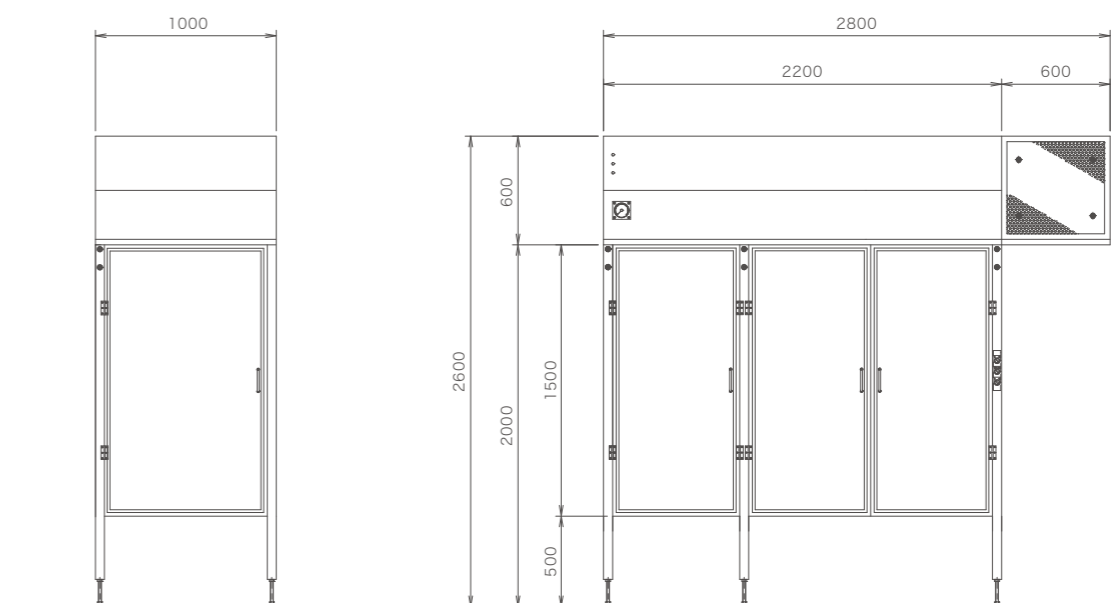
- Excellent distribution of air velocity
- Suppress fluctuation of air velocity
- High Flexibility
- Built-in lighting is possible

### Construction case



### Specifications case

#### Laminar Flow System



#### Specifications

- Blowout method: Unidirectional flow
- Blowout air velocity: 0.45m/s ± 20%
- Partition: Kasten (Polycarbonate with SUS frame)

# HEPA CART

A clean environment can be maintained with a rechargeable battery during transportation.

Maintain a positive pressure, transport and store products under a clean environment.



**Airtightness**

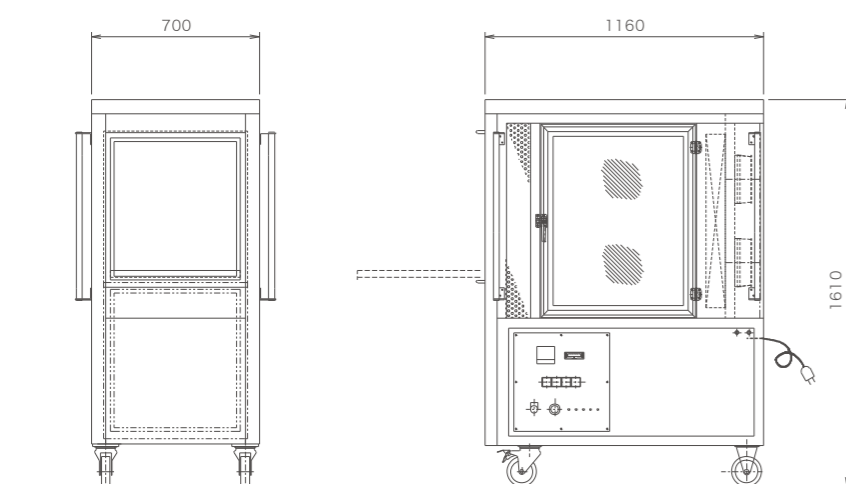
**Environment of Clean Room** Grade **B** ~ **D**

**Internal Environment** Grade **A**

Options can be added upon request

- Blowout direction: Vertical or horizontal
- Partition: Polycarbonate (with SUS frame), vinyl curtain, etc.
- Caster: Conductive wheel
- Inside: Slide table, two-stage table
- Electric assist type

## Specifications case



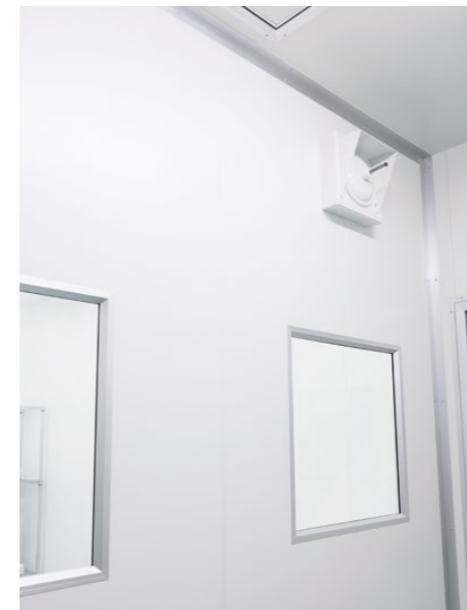
**Specifications**  
 Blowout air velocity: 0.45m/s ±20%  
 Cleanliness class: ISO5  
 Material: Body SUS304 (Internal: Polishing, Exterior: Polishing)  
 Partition: Antistatic polycarbonate  
 Door: Side ... Opening door  
 Front ... Up and down slide  
 Internal: Slide table  
 Accessories: HEPA differential pressure gauge, PAO input port · Measuring port

**Operating time**  
 100V power supply: Continuous operation  
 Battery operation: 1.0hour  
 Battery charging time: 2.0hours  
 \*However, at battery initial performance,  
 Power cord (5m) automatic winding method

# Clean Room Air Conditioning System

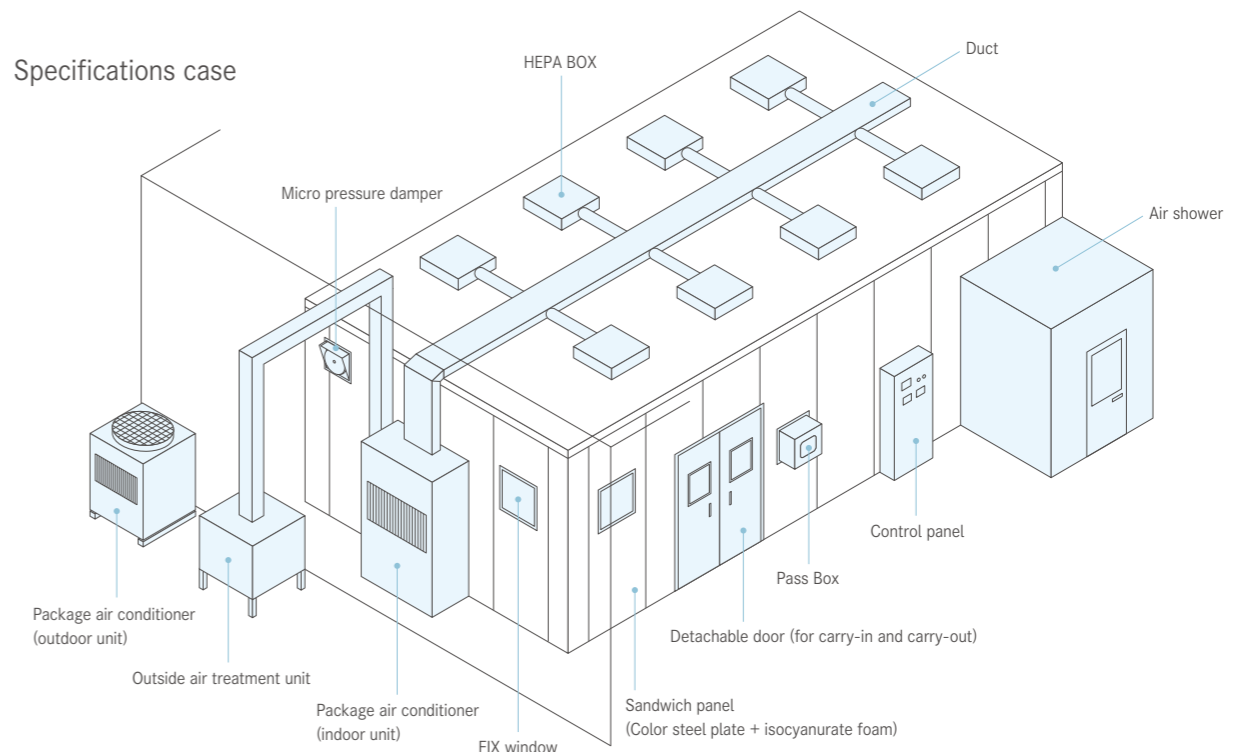
Design and construct a clean room in consideration of the environment and energy saving

For a variety of industries such as electronic industries, of semiconductors and liquid crystals as well as precision equipment, pharmaceuticals, medical devices, food, film, nonwoven fabrics, and hospitals.



- 1. Economical design**  
A plan with reduced cost is possible by combining abundant clean room devices, such as CG.
- 2. Short delivery time**  
Construction with short delivery time is possible owing to the standardized panel structure. Also, a wide variety of panels, doors, etc., are available.
- 3. Energy saving**  
Air conditioning load is reduced by placing heat-insulation panels. Energy saving is possible.

## Specifications case





# AIR SHOWER

# OTHER SYSTEMS

Design according to requirements of body size, operation method, various options, etc.

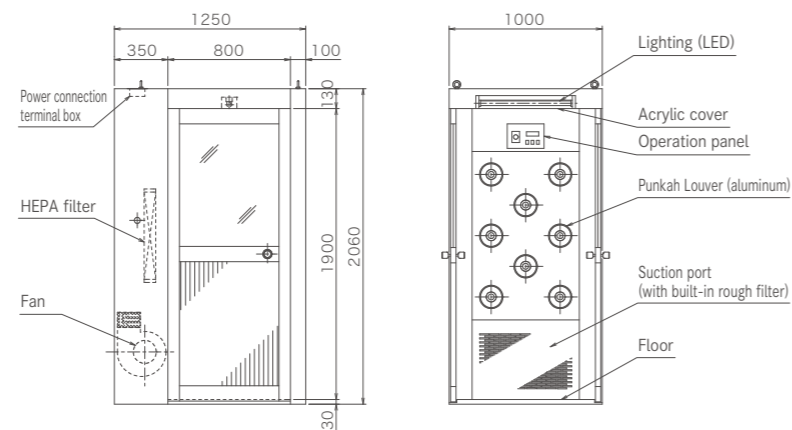
Propose the best clean system according to your intended purpose



Air shower for workers

## Specifications case

Standard type air shower for workers (AS-1000AA)



Dry Heat Sterilizer

Full automatic operation in various modes.  
Secure sterilization and drying process are guaranteed.  
Highly reliable equipment with various safety devices.



Clean Bench

The dimensions of the body, cleanliness, materials for the body, etc., are all custom-designed and custom-made.

## Standard Specifications / Type

Model	AS-1000AA	AS-1000BB	AS-1500AA	AS-2000BB
Dust collection efficiency	99.97% or more for 0.3 μm PAO particles			
Dust collecting filter	Prefilter: Washable nonwoven fabric		Main filter: HEPA filter	
Blowout air velocity (50Hz/60Hz)	Approximately 23/25 m/s			
L dimension of the body	1000mm	1500mm	1500mm	2000mm
Blowout nozzle	8 pieces	16 pieces	8 pieces	32 pieces
Body	Bonderized steel plate with melamine baking finishing			
Effective dimension of the clearance	800mm			
Start-up method	Timer interlock	Photoelectric switch		
	Continuous	Manual changeover switch		
Lighting	20W		40W	
Power consumption (W)	470/640	940/1180	470/640	1880/2360

Category	Type	
Blowout	Single blowing	
	Double blowing	
	Combination with ceiling blowing	
Door	Manual	Slide type
	Automatic	Swing type
		Single-opening
		Double-opening
	Air Curtain	
Direction of entry and exit	Go straight	
	L-type (rectangular)	
	T-type (three-way door)	
Floor	Yes	Flat type
		Grating type
	Non	Use the existing floor
Start of air blowing	Photoelectric switch	
	Pushbutton switch	
Explosion proof	Non-explosion-proof (standard)	
	Improved explosion resistance	
	Explosion-proof	

## Explanation of Model

AS	-	1000	A	A	① Air shower	③ A: Single blowing	B: Double blowing
					② L dimension (mm)	④ A: Manual door	B: Automatic door

- Other models are also available.  
We will design the size and operation method upon request.
- Options are as follows.  
Air curtain / Electromagnetic lock / Interphone / Ceiling blowing



Mothproof booth

Entry of insects and foreign substances is prevented by the supply of clean air through a filter and positive pressurization within the equipment.  
Airtight doors, a cleaning function within the equipment, are designed and constructed upon request.



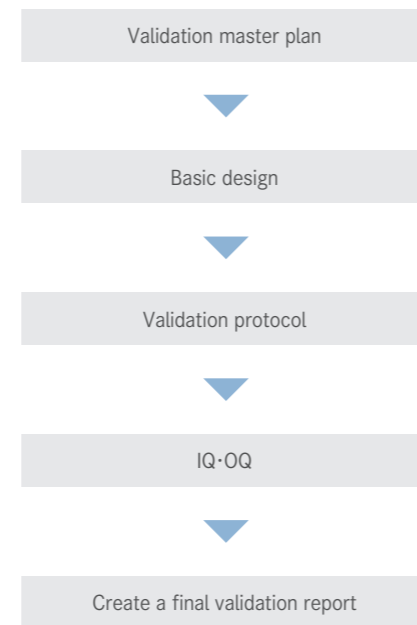
Simplified Clean Booth

Clean booth compliant with ISO6 to 8.  
For various purposes such as cleaning of one block of a factory.

# VALIDATION SERVICES

Validation services are provided to meet various standards based on the newest information.

Various validation services relating to a clean room are provided to meet revised standards of GMP, FDA, WHO-GMP, EU-GMP, PIC/S, etc., based on the latest information by utilizing our abundant experiences and worldwide network. In the final report, we will formulate an improvement plan and an air conditioning improvement plan, and conduct construction work accordingly.



Basic plan	<ul style="list-style-type: none"> <li>Formulation of validation master plan, Basic design</li> <li>Execution system, assignment</li> <li>Basic policy</li> <li>Schedule settings</li> </ul>
Basic design, implementation of the design	<ul style="list-style-type: none"> <li>Create the validation master plan</li> <li>Conduct design validation</li> <li>Support the creation of SOP</li> </ul>
Installation Qualification <IQ>	<ul style="list-style-type: none"> <li>Create IQ protocol</li> <li>Conduct IQ / Conduct calibration</li> <li>Prepare an IQ Report</li> </ul>
Operational Qualification <OQ>	<ul style="list-style-type: none"> <li>Create OQ protocol</li> <li>Conduct OQ</li> <li>Prepare an OQ Report</li> </ul>

Validation items	
Examples of IQ items	<ul style="list-style-type: none"> <li>Equipment structure inspection</li> <li>Equipment rotation check</li> <li>Control device calibration</li> <li>Duct inspection, etc.</li> </ul>
Examples of OQ items	<ul style="list-style-type: none"> <li>Air volume measurement</li> <li>Temperature measurement</li> <li>Humidity measurement</li> <li>Differential pressure measurement</li> <li>Cleanliness measurement</li> <li>Leakage inspection</li> <li>Illuminance inspection</li> <li>Airflow inspection etc.</li> </ul>

## History

- ▶ March 1980 Began sales of gas adsorbent PureLite by the Development Group of Chemical Business Division of Nippon Chemical Industrial Co., Ltd.
- ▶ April 1994 Established Nippon Puretec Co., Ltd., in Koto-ku, Tokyo, wholly owned by Nippon Chemical Industrial Co., Ltd.
- ▶ June 1994 Opened the headquarter office in Chiyoda-ku, Tokyo.
- ▶ July 1995 Opened the R&D Technical Center in Koto-ku, Tokyo.
- ▶ September 2003 Acquired ISO 9001 certification.
- ▶ November 2006 Acquired all issued stocks of Luft Technologies (former Luwa Japan) Ltd.
- ▶ November 2009 Opened the Kyushu Sales Office.
- ▶ October 2012 Merged with Luft Technologies Ltd. (Our company is the surviving company.)
- ▶ April 2015 Moved the headquarters to Nagoya.
- ▶ October 2021 Became a 100%-owned subsidiary of MIRAPRO Co., Ltd.
- ▶ October 2021 Changed corporate name to Puretec Co., Ltd.

## History of former Luft Technologies Ltd.

- ▶ March 1967 Established Nippon Luwa Ltd.
- ▶ September 1985 Changed the company name to Luwa Japan Ltd.
- ▶ July 1997 Became a 100%-owned subsidiary of Zellweger Luwa AG.
- ▶ November 2006 Became a 100%-owned subsidiary of Nippon Puretec Co., Ltd.
- ▶ November 2010 Changed the company name to Luft Technologies Ltd.
- ▶ October 2012 Merged with Nippon Puretec Co., Ltd.



## Business Office

### Headquarters / Nagoya Office

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