Notice

·If you have any questions, please contact our person in charge.

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PURETEC CO., LTD.

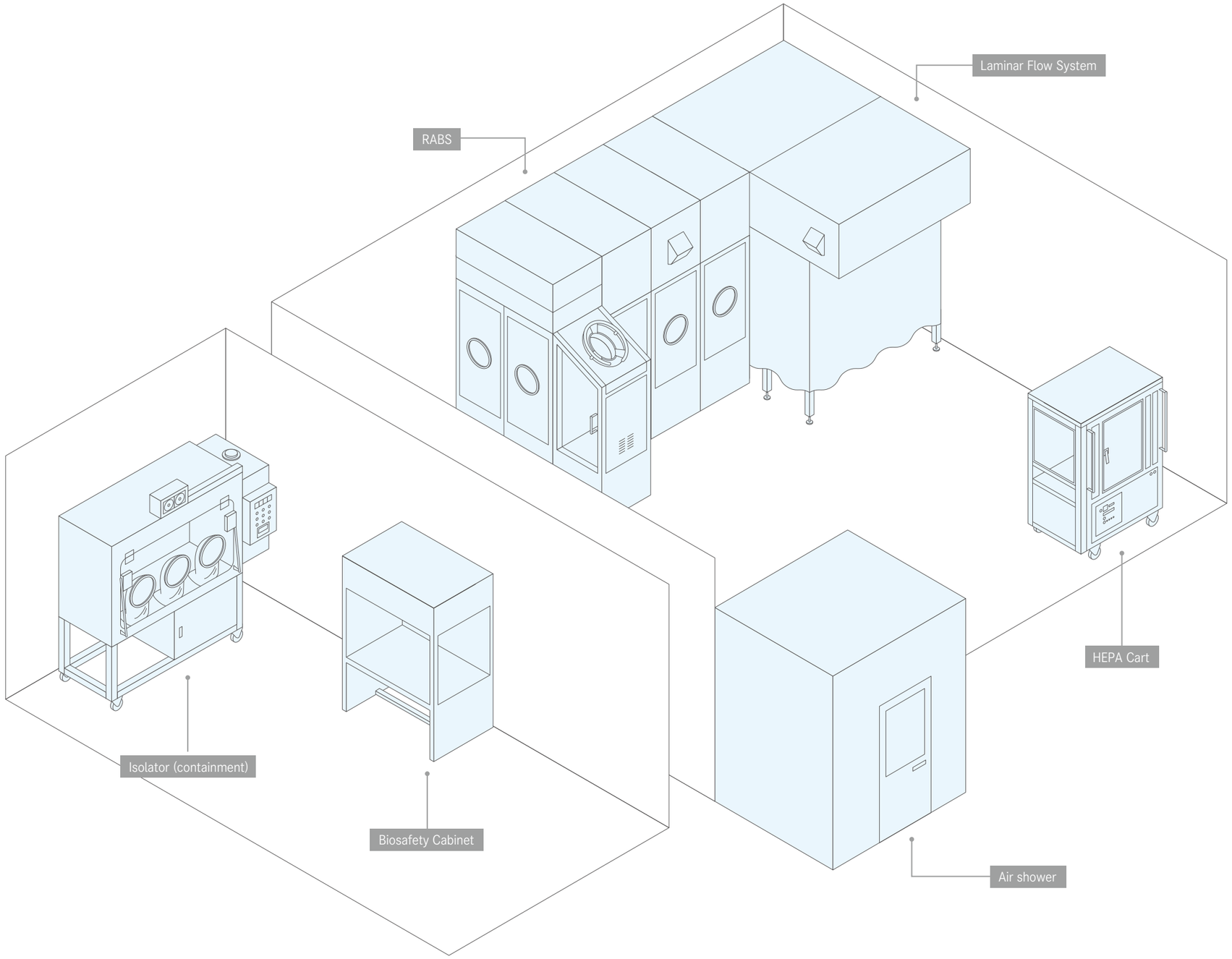
MIRAPRO GROUP

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
Isolator (containment) ····· P07
CLOSE-RABS ····· P09
OPEN-RABS ····· P10
Laminar Flow System ····· P11
HEPA Cart ····· P13
Clean Room Air Conditioning System ····· P14
Air Shower ····· P15
Other Systems ····· P16
Validation Service ····· P17
History/Business Office ····· P18

Performance and Cleanliness Classification

Airtightness

Environment of Clean Room Grade **A**

Internal Environment Grade **A**

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)

STEP 1

Inquiry

Please feel free to contact us first.
Our technical sales personnel are cognizant of the technology and will serve you from first contact through after-sales maintenance.
We are also waiting for your preliminary consultations before consideration of introduction.

STEP 2

Hearing

Please inform us of the environment and conditions that are necessary to offer the equipment most appropriate to meet your needs and settle your problems.

Purpose / Specification / Condition / Scope of Application etc.

If you have any questions or require more specialized knowledge, our technical sales personnel or technical staff can visit the site directly and conduct surveys.

STEP 3

Proposal of Plan/Estimate

Propose a plan and an estimate.

- Design (temperature and humidity, air volume, structure, strength, space, etc.)
- Estimate
- Estimate specifications
- Planed drawing, etc.

STEP 4

Contract

In some cases, conduct final confirmation of the specifications through mockups after the order is confirmed.

- Mock-up
- Confirmation of the specifications (Specifications, Drawings, IQ/OQ protocol)

STEP 5

Designing and Production

Carry out detailed designings for each part based on the confirmed plan.
Manufacture the parts based on the drawings thereof.

STEP 6

Assembly

We gather the parts and assemble the equipment in our own factory.
We also conduct factory inspections, test running, and FAT (Factory Acceptance Test).

- Factory Assembly
- Factory Inspection
- FAT (Factory Acceptance Test)

STEP 7

Carry-in and Installation

Carry the equipment to its actual operating site, assemble, and installation.

- Transport
- Carry in
- Assemble, installation
- IQ (Installation Qualification)
- OQ (Operational Qualification)
- Confirm Bio-decontamination performance
- Completed documents

STEP 8

Maintenance

We will conduct periodic validation to maintain your systems.

- Retrospective validation
- Inspection and Repair

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

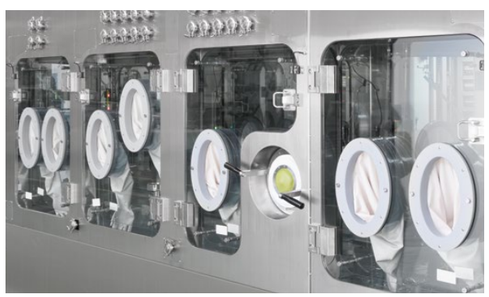
Internal Environment — Grade A

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

Manufacture of Aseptic products

↓

Filling machine + Isolator

Sterility test

↓

Isolator for Sterility test

For external Bio-decontamination machine

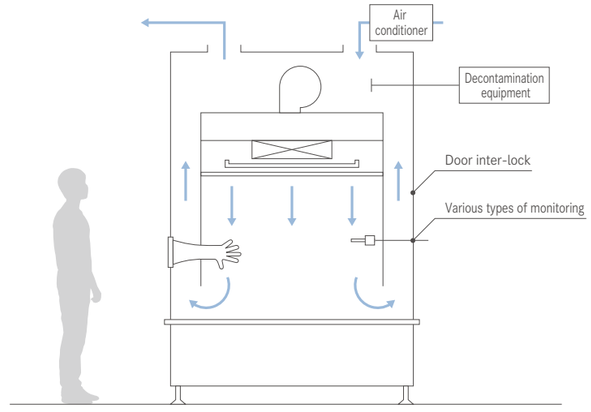
↓

Transfer isolator

For special environment

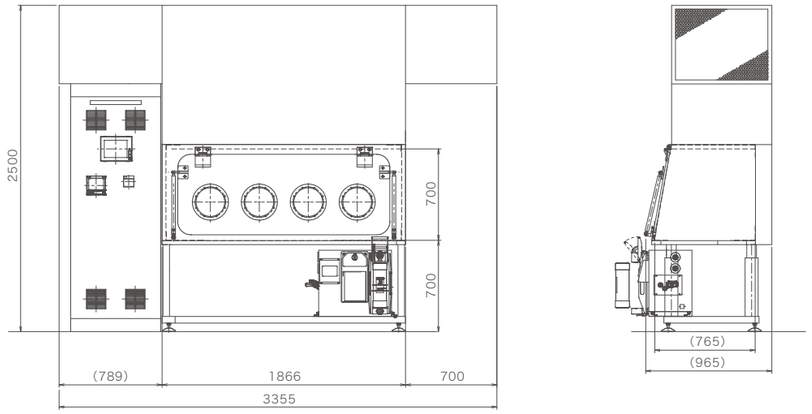
Low oxygen / low humidity, etc.

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

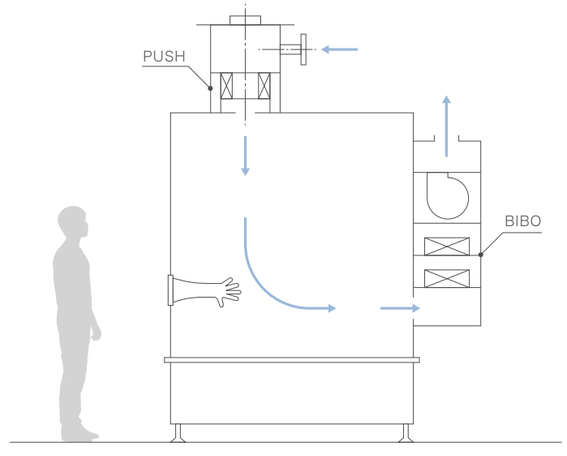
Vial filling line Sterilization+Containment

Application case

Options can be added upon request

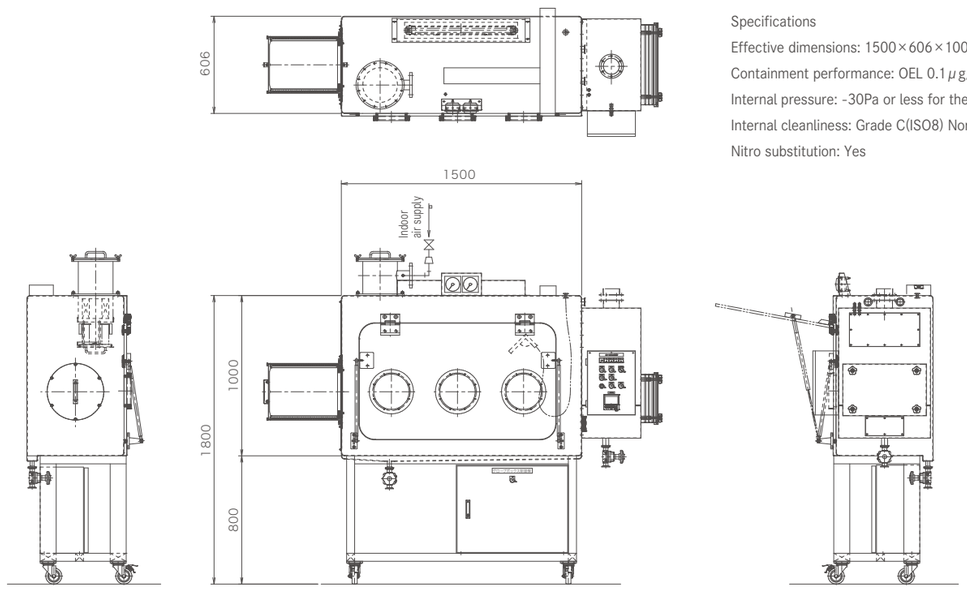
- Supply HEPA: Push type
- Exhaust HEPA: BIBO type
- Low internal humidity
- Nitrogen substitution
- WIP specifications
- Door seal: Pneumatic-seal
- Glove port: Round / Oval
- Material input /output: RTP, PassBox, Bagout Port

Construction case



Specifications case

Weighing isolator



Specifications
Effective dimensions: 1500×606×1000 H
Containment performance: OEL 0.1 μg/m³
Internal pressure: -30Pa or less for the installation room
Internal cleanliness: Grade C(ISO8) Non-working
Nitro substitution: Yes

R A B S

Restricted Access Barrier System

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

C L O S E - R A B S

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

Environment of Clean Room — Grade B

Internal Environment — Grade A

Access to the process area using gloves

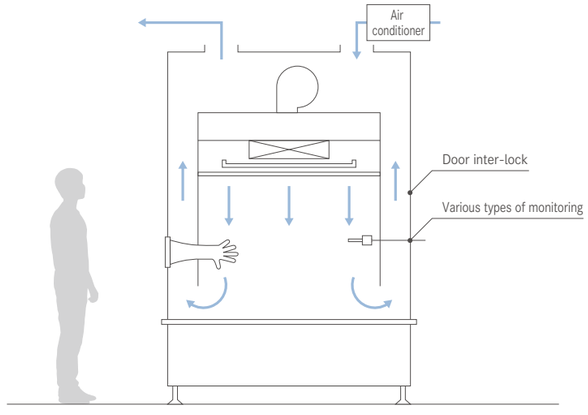
*Physical access limitations / Elimination of human-related pollution sources

Structures / Specifications

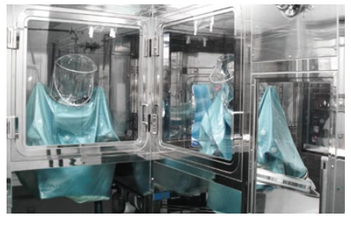
- Pillar + Kasten type or welding integrated structure
- Door Seal: Packing or Pneumatic-seal
- Internal circulation mechanism (W-wall type / return duct type)
- Internal decontamination itself or not
- AHU added or supply / exhaust by customer

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

O P E N - R A B S

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

Environment of Clean Room — Grade B

Internal Environment — Grade A

Access to the process area using gloves

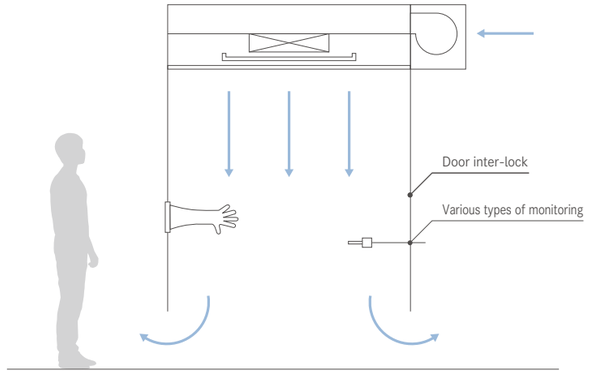
*Physical access limitations / Elimination of human-related pollution sources

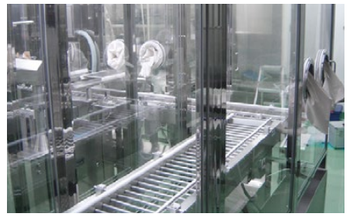
Structures / Specifications

- Pillar + Kasten type
- No internal decontamination itself
- Add mechanical locking mechanism to the laminar structure
- Attach glove ports

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

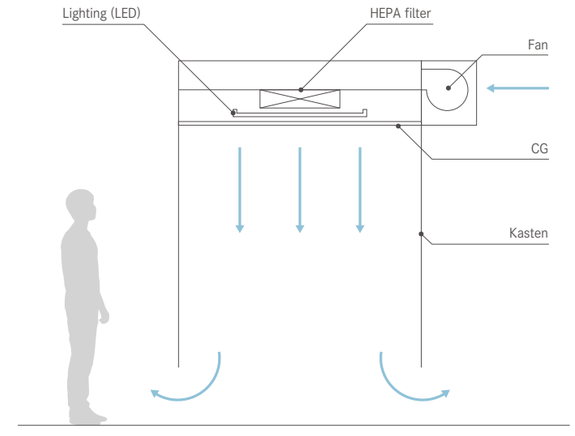
Laminar Flow System

Laminar Flow System for Conveyors

Merits of CG

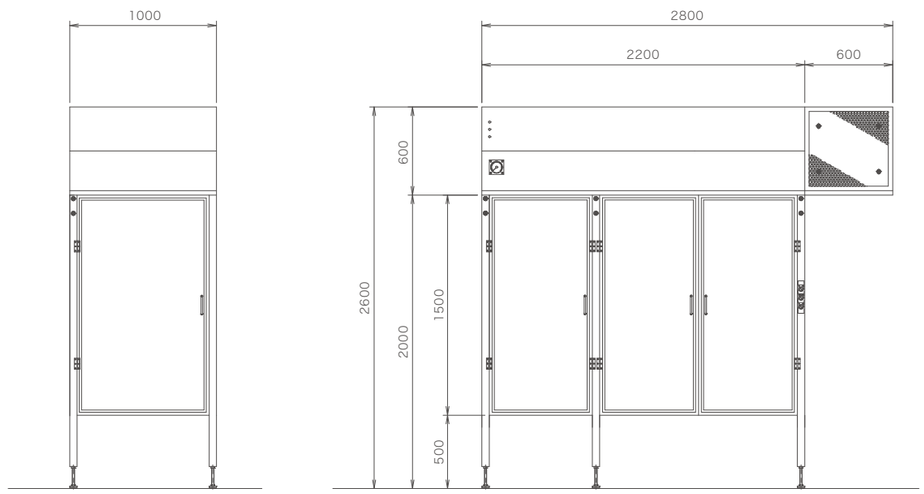
- Excellent distribution of air velocity
- Suppress fluctuation of air velocity
- High Flexibility
- Built-in lighting is possible

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

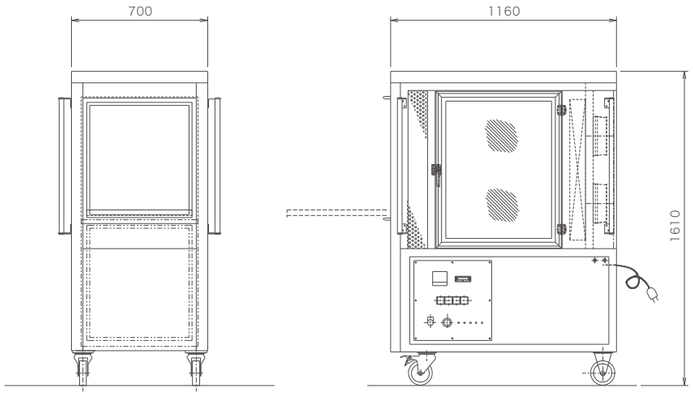
Environment of Clean Room — Grade B ~ D

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



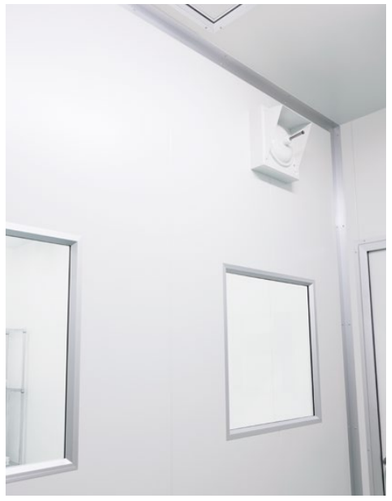
Specifications
Blowout air velocity: 0.45m/s ±20%
Cleanliness class: ISO5
Material: Body SUS304 (Internal: Polishing·
Exterior: Polishing)
Partition: Antistatic polycarbonate
Door: Side ... Opening door
Front ... Up and down slide
Internal: Slide table
Accessories: HEPA differential pressure gauge,
PAO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

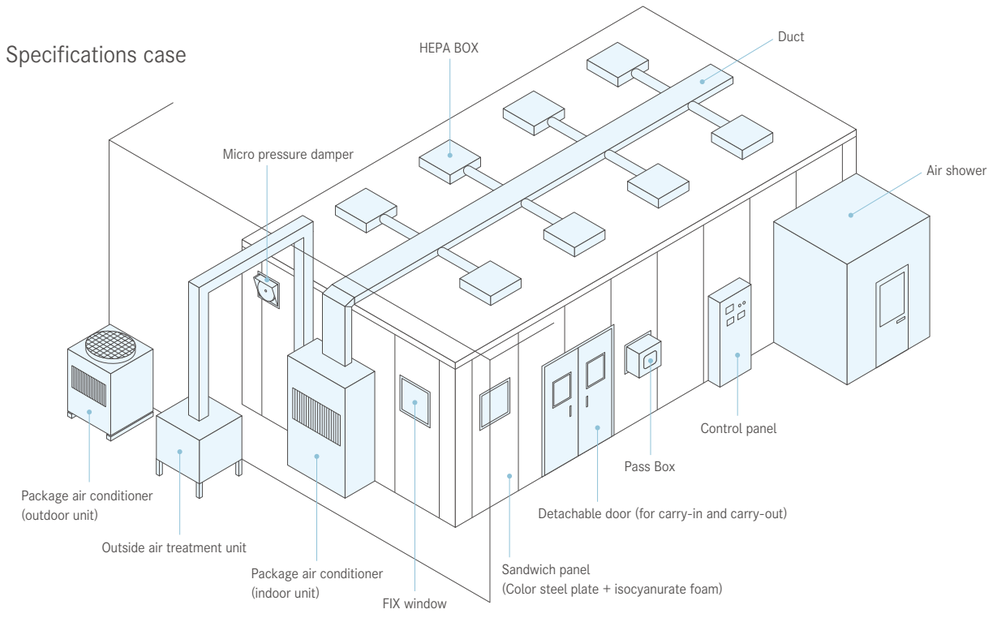


1. Economical design
A plan with reduced cost is possible by combining abundant clean room devices, such as CG.

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



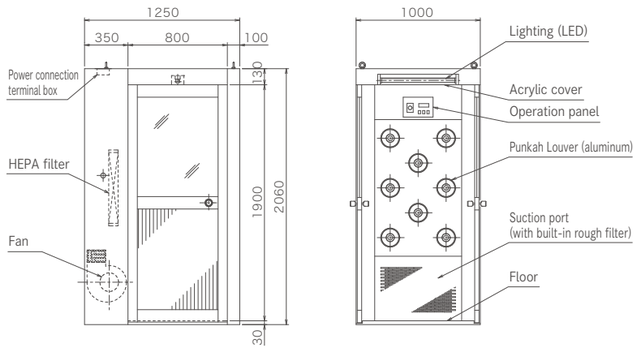
AIR SHOWER

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

Air shower for workers

Specifications case

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



Standard Specifications / Type

Model		AS-1000AA	AS-1000BB	AS-1500AA	AS-2000BB
Dust collection efficiency		99.97% or more for 0.3μm 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	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			
Blowout	Type	Single blowing	
		Double blowing	
		Combination with ceiling blowing	
Door	Manual		Slide type Swing type Single-opening Double-opening
	Automatic		
	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
② L dimension (mm)
③ A: Single blowing B: Double blowing
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

OTHER SYSTEMS

Propose the best clean system according to your intended purpose

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.

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.

Validation master plan

▼

Basic design

▼

Validation protocol

▼

IQ·OQ

▼

Create a final validation report

Basic plan	· Formulation of validation master plan, Basic design · Execution system, assignment · Basic policy · Schedule settings
Basic design, implementation of the design	· Create the validation master plan · Conduct design validation · Support the creation of SOP
Installation Qualification <IQ>	· Create IQ protocol · Conduct IQ / Conduct calibration · Prepare an IQ Report
Operational Qualification <OQ>	· Create OQ protocol · Conduct OQ · Prepare an OQ Report

Validation items	
Examples of IQ items	· Equipment structure inspection · Equipment rotation check · Control device calibration · Duct inspection, etc.
Examples of OQ items	· Air volume measurement · Temperature measurement · Humidity measurement · Differential pressure measurement · Cleanliness measurement · Leakage inspection · Illuminance inspection · Airflow inspection etc.

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.

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