

# Air quality in healthcare facilities and protected environments Mobile air handling units



Contamination control, safety of care

### Air contamination A major risk to patients at risk

The presence of pathogenic and opportunistic microorganisms in the air poses a risk of hospital-acquired infections, in particular in immunosuppressed patients. In haematology for example, Aspergillus fumigatus is responsible for severe inva-

sive pulmonary infections, most often associated with a high fatality rate. Immunocompetent patients who have undergone major surgery, ICU patients or serious burn victims should also be considered high-risk.

Construction or renovation work generates significant air contamination, which can cause aspergillosis outbreaks. In addition, the development of ultra-resistant microorganisms (tuberiferous bacilli, eHRB, ESBL, MERS-Cov, etc.) is also a concern for practitioners due to their pathogenicity and difficult treatment.





Examples of

airborne microorganisms: Aspergillus fumigatus Acinetobacter baumanii MERS CoV

### Air handling A field regulated by standards and legislation

The air filtration technology has long been used and recognised for its ability to reduce airborne contamination and is subject to a number of standards:

#### Standard NF S90-351: 2013 requires a risk analysis to classify healthcare activities into 4 air-related risk levels such as:

Operating rooms - ICU: Types of activity	Risk class
Orthopaedic prosthetic room, organ transplant, serious burn victims	4
Multi-purpose room, ENT, OPH and other orthopaedics without implants, visceral, cardiovascular surgery	3
Arthroscopy room, haemodynamics	3
Post-operative monitoring room, recovery rooms, movements in operating rooms	2
Multidisciplinary ICU, neonatal resuscitation	2
Hospitalisation: Types of activity	Risk class
Protected wards (haematology), burn victims	4
Haematology (other than protected wards), organ transplant, post-transplant	3
Pharmacy: Types of activity	Risk class
Reconstitution of cytostatic agents, parenteral nutrition production	4
Radiology: Types of activity	Risk class
Interventional imaging	3

Excerpt from table 12 of standard NF S90-351:2013

#### It also defines guide values for stationary air quality performance based on risk classes.

Risk class	Particulate cleanliness class	Particle clearance kinetics	Microbiological cleanliness class	
4	ISO 5	CP 5	M1	
3	ISO 7	CP 10	M10	
2	ISO 8	CP 20	M100	

Excerpt from table 16 of standard NF S90-351:2013

#### Particulate cleanliness classes are specified in standard NF EN ISO 14644-1: 2015

ISO class number	Maximum allowable concentration (particles/m³) of particles with a size equal to or greater than those indicated below					GMP	
(N)	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1 µm	5 µm	attest
1	10						
2	100	24	10				
3	1,000	237	102	35			
4	10,000	2,370	1,020	352	83		
5	100,000	23,700	10,200	3,520	832		A/B
6	1,000,000	237,000	102,000	35,200	8,320	293	
7				352,000	83,200	2,930	С
8				3,520,000	832,000	29,300	D
9				35,200,000	8,320,000	293,000	

#### Special case of IVF laboratories: order of June 2017

The harmful effects of Volatile Organic Compounds (VOC) have been well described in scientific literature for many years. The order of the French ministry of health and solidarity, published in June 2017, defines the particulate cleanliness class of the air in IVF laboratories as ISO8 (class D), while taking into account the toxicity of VOC in the choice of air handling system. While HEPA filters are effective against particles, they have no effect on the chemical contamination of air. They must always be combined with specific VOC adsorption modules such as activated carbon.

#### Aerosol contamination prevention

**airinspace**<sup>®</sup> has developed a comprehensive range of air decontamination units suited to every clinical situation, and has improved on traditional filtration by combining it with other technologies to offer healthcare professionals devices that provide a targeted response to the various air quality challenges in healthcare units.

Numerous clinical studies have shown their efficiency in reducing airborne contamination and preventing infections in vulnerable patients, as illustrated by Gerlinger's study on the **prevention of aspergillosis risk by our PLASMAIR** <sup>(a)</sup> units in haematology patients in intensive care.

During the COVID-19 crisis, as progress was made in the understanding of the epidemic and the means of contamination, the role of contaminated aerosols in the transmission of the virus became apparent, in particular in confined, poorly ventilated or crowded spaces. The use of mobile devices in



these spaces was recommended by the highest scientific and regulatory bodies. In units housing COVID patients, our systems are in place in rooms and corridors to limit cross-contamination. Similarly, in places where masks cannot be worn (dining hall, canteen), their use reduces the risk of contamination while reassuring users.

Furthermore, it is now acknowledged that **a turbulent flow created by properly maintained equipment in the operating room helps achieve sufficient air quality** for most surgical procedures. This follows on various communications from the *Société Française d'Hygiène Hospitalière* (French Hospital Hygiene Society), the French academy of surgery, the recommendations of the American College of Surgeons and Surgical Infection Society and those of the WHO.

You can find out about them in the following pages.

### How to choose a mobile air handling unit?

- Very low noise level.
- Technology suited to the nature of the contaminants to be eliminated.
- No emission of toxic substances.
- Performance confirmed by independent studies and published.
- High flow rate, adapted to the size of the room.
- Simple to use.
- Mobility.
- Easy maintenance.

# IMMUNAIR®/ BIOCAIR®

**Protected environments** 







IMMUNAIR \* connected to a PLASMAIR \* Guardian in a protected room in haematology (top). BIOCAIR \* in a tropical and infectious

diseases unit.

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### Protection unit for immunosuppressed patients 2 variants: Fixed or mobile

- Can be installed in the room with no need for work.
- ISO 5 zone supplied by a PLASMAIR <sup>®</sup> Guardian or Sentinel unit.
- Secure, comfortable space created around the patient's bed.
- Transparent and removable curtains.
- Television (optional).

#### **Applications**

 Haematology: Protection of patients with aplasia or deep immunosuppression.



Fixed Deployable Plenum (FDP) + PLASMAIR<sup>®</sup> Guardian.



Mobile Deployable Plenum (MDP).



Folded Mobile Deployable Plenum (MDP).





## **O BIOCAIR**<sup>®</sup>

#### A unique tailor-made concept

- Tailor-made zone in a standard space (patient's room, pharmacy, laboratory, etc.).
- Positive or negative pressure configuration.
- Clean room partitions.
- Door with controlled leakage flow.
- Controlled by the Wall-i Pilot with possibility of connection to a BMS.
- Backlit ceiling (optional).

#### **Applications**

- Positive pressure: Supplied by a PLASMAIR<sup>®</sup> unit, BIOCAIR<sup>®</sup> is a deployable plenum that:
  - Cares for very fragile patients in haematology, ICU, burn victims in an ISO 6 environment minimum.
  - Laboratories, cytotoxic reconstitution units, cell therapy units.
  - > Office Based Surgery.





- Negative pressure: BIOCAIR<sup>®</sup> becomes an isolation room to:
  - Accommodate infectious patients. The air stream is treated by the **PLASMAIR**<sup>®</sup> unit which destroys pathogenic microorganisms and prevents their dissemination.
  - Create an ISO 8 zone for the installation of class A cabinets needed to prepare cytotoxic drugs, (2007 GMP).



# **PLASMAIR**<sup>®</sup>

Microbiological destruction, HEPA filtration, chemical adsorption







PLASMAIR® range examples: PLASMAIR® Guardian in the operating room (top). PLASMAIR® C2010 in intravitreal

#### Principle of the HEPA-MD technology: 4-stage reactor



#### The standard for air handling in haematology and bone marrow transplant units

- The only mobile air decontamination unit combined with a reduction in Invasive Aspergillosis in haematology (Gerlinger, Infect Control Hosp Epidemiol, 2015).
- More than 15 clinical studies published in peer-reviewed journals (bibliography available upon request).
- Effective retention of microorganisms as assessed by numerous internationally recognised independent laboratories.



Pros	Benefits		
Low-energy cold plasma	Does not create formaldehyde or any other toxic by-product		
Destroys microorganisms	No accumulation of viable microorganisms in the filter No proliferation or release		
H14/U15 filter	High filtration efficiency		
Large filtering area	Large retention capacity and low pressure drop		
Catalyst	No release of toxic by-products		
Activated carbon Retention of Volatile Organic Compounds and odd			
Technology validated by many laboratories	Efficiency demonstrated by independent institutions		





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#### **Applications**

Haematology, bone marrow transplant unit, ICU, serious burn victims, operating rooms, ophthalmology, hospital pharmacy.

### **OPLASMAIR**<sup>®</sup> Guardian

#### Noiseless, high capacity and efficient

- Max flow rate 2,500 m<sup>3</sup>/h.
- Total flora: M1.
- Fungal flora: < 1 CFU/m<sup>3</sup>.
- Particulate cleanliness class:
  - > ISO 7/6 in a room.
  - > ISO 5 under IMMUNAIR®.



Access the menus by simply pressing the icons. 5 languages available.





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C2010

#### Zero footprint and remote controlled

- Max flow rate: 800 m<sup>3</sup>/h.
- Total flora: M10.
- Particulate cleanliness class: ISO 7.



### **PLASMAIR**<sup>®</sup> Sentinel

### The quietest compact unit on the market.

- Max flow rate: 1,200 m<sup>3</sup>/h.
- Total flora: M1.
- Fungal flora: < 1 CFU/m<sup>3</sup>.
- Particulate cleanliness class:
  - > ISO 7/6 in a room.
  - > ISO 5 under IMMUNAIR<sup>®</sup>.



Airflow direction in PLASMAIR<sup>®</sup> Sentinel.



# HEPA Very high-performance microbiological and particulate filtration







Examples of how to use the HEPA range: In a waiting room for patients (top). In a corridor leading to operating rooms.

#### HEPA filters are very high-efficiency filters

HEPA\* filter operating principles: 4 principles for retaining even the smallest particles



- Sieve effect (a few tens of μm): particles with a diameter greater than the distance between 2 fibres cannot pass through.
- Inertia effect (a few μm): particles have too much inertia to accompany the air stream when it curves around a fibre. They continue on their original path and bind to the fibre at the impact point, through physical or electrical adhesion (Van der Waals forces).
- Interception effect (around 1 µm): light particles accompany the air stream around the fibre and are intercepted if they pass within a distance of the fibre that is shorter than their radius.
- **Diffusion effect** (*d* < 1 μm): fine particles are influenced by the Brownian motion of air molecules and bind to the fibres when they touch them.

The efficiency of a filter is the combined efficiency of 4 mechanisms. There is a particle size for which efficiency is minimal. It corresponds with the *Most Penetrating Particle Size (MPPS)*, i.e. the diameter for which particles are retained least efficiently by the filters. This is why the MPPS efficiency values of a filter should always be indicated, knowing that its performance will always be greater for all other particle sizes, including those with a lower diameter.

There are 2 classes of HEPA filter: HEPA H13 and HEPA H14. Their efficiency must be tested in accordance with standard EN 1822. **HEPA H14**  **class filters are ten times more efficient** than HEPA H13 filters.

The filters of airinspace  $^{\otimes}$  air handling units are H14 HEPA filters the MPPS efficiency of which exceeds 99.998%.

In addition, **airinspace**<sup>®</sup> **always uses pleated filter media.** This helps increase the filtering area while minimising footprint. **Pleating can provide up to 100 times more filtering area than a planar filter. airinspace**<sup>®</sup> pleated filters have a very low pressure drop and a long service life (up to 4 years).



#### **Application**

- First contamination reduction phase before protection by our **PLASMAIR**<sup>®</sup> units.
- Treatment of class 2 moderate risk areas (corridor, airlock, etc.).



# **eCHEM** Chemical adsorption









eCHEM range examples: eCHEM Sentinel in IVF cell culture lab (top). eCHEM Cubair

in a biochemistry lab.

#### **eCHEM Range of products** Universal removal of chemicals

- Removal of oxydizing and acid molecules.
- Removal of tVOC.
- Removal of formaldehyde.

#### **Applications**

- Elimination of biocide after room disinfection by automated process.
- Elimination of oxydizing vapors in endoscopes reprocessing labs.
- AMP labs.
- Anatomopathology labs.
- Exposure to organic solvents.

### O eCHEM Sentinel

#### Silent

- 3 activated carbon modules with high adsorption capacity.
- Particle removal.
- Small footprint.



C eCHEM Cubair

#### **Small footprint**

- 5 activated carbon modules.
- 360° airflow.
- Silent.



Air handing examples: Waiting room for patients, operating room corridor, laboratory, ophthalmology, medication reconstitution room, patient's room in haematology, etc.

## airinspace®

Innovation, performance and reliability working with you since 2002

# airinspace® at your service

**Audit:** our teams come from the pharmaceutical industry and clean rooms. They consist of air handling experts who can help you carry out a thorough analysis of your facilities. They provide you with effective, simple solutions tailored to your situation, taking budgetary requirements into account.

**Installation:** once our systems have been delivered, our technical team is at your disposal to present the products to the teams and train them in how to use them. We can ensure the Functional Qualification of all our products.

**Maintenance and customer service:** we have designed our products with maintenance in mind, so that it can be simple and economic. We offer a number of packages and all our agreements are valid through the entire life of the product across the world.

**Warranty:** airinspace<sup>®</sup> offers a 1-year parts and labour warranty across the world (modules and filters excluded).

**Customer support:** any question? A specific requirement? Don't hesitate to call +33 (0)1 30 07 01 01 or email us at: contact@airinspace.com.





ISO 9001 and ISO 13485 certified, attentive to its customers' needs, the multidisciplinary teams of **airinspace**<sup>®</sup> put their skills at your disposal to provide sustainable, quality solutions via its products and services.

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