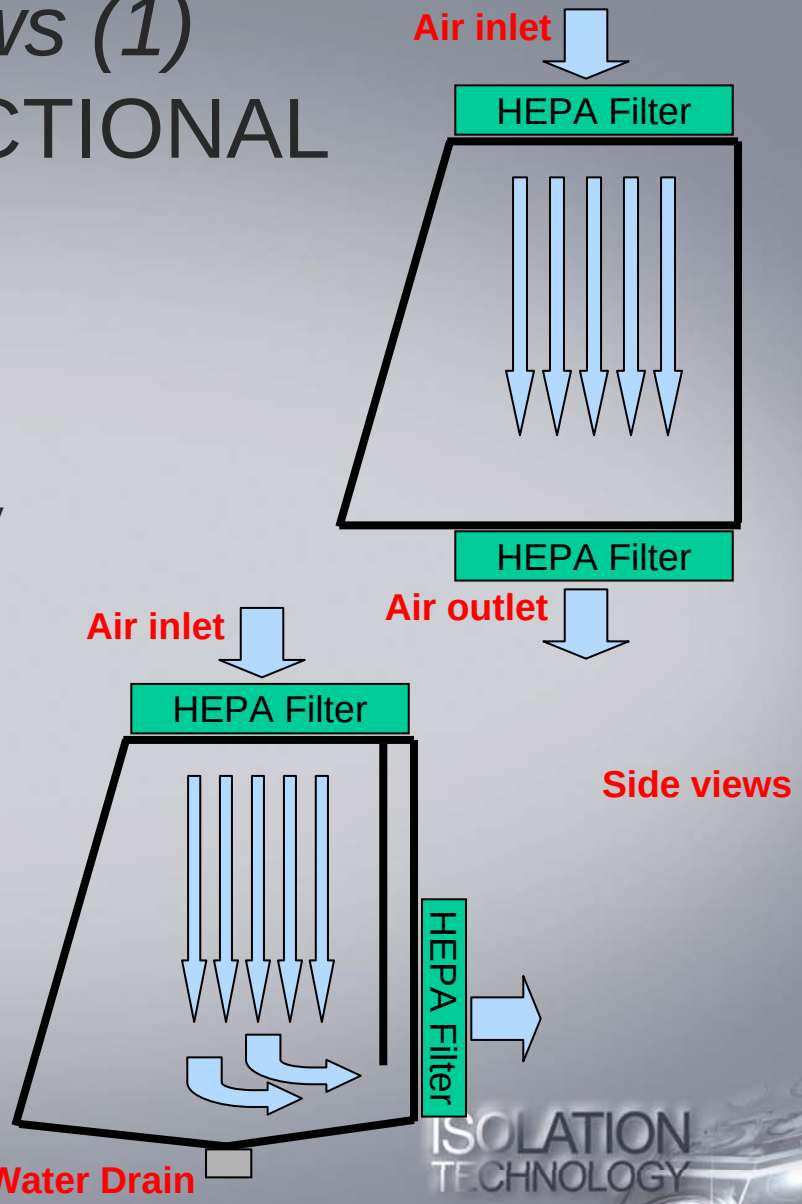
Different Airflows

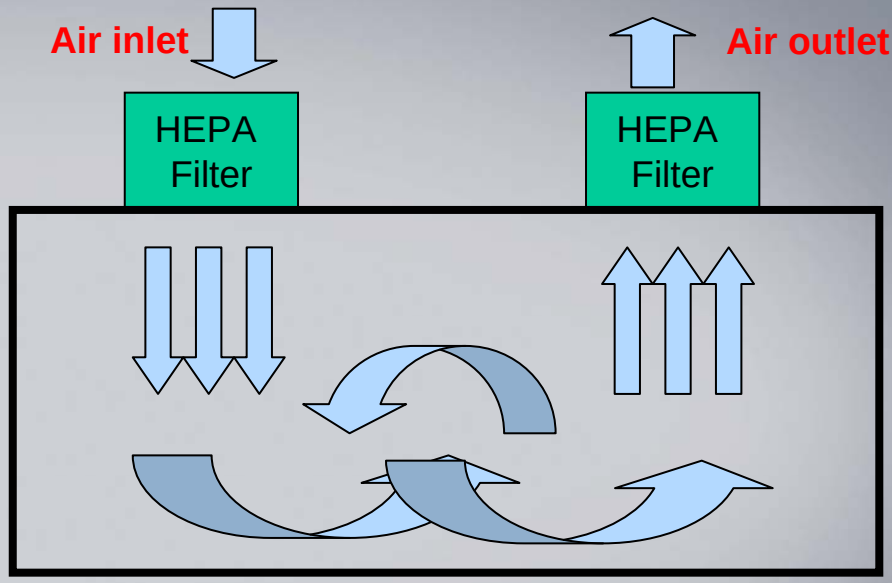
Air flows (1) UNIDIRECTIONAL

- **Unidirectional Flow (also called Laminar Flow):**
  - 0.45 m/s ±20% air speed
  - Fastest “ambient class” recovery time
  - Excellent with powder (in that case a top-down flow must be adopted
  - The huge amount of air to be handled must be taken into consideration



Air flows (2)
TURBULENT

- Turbulent flow:
  - 20 – 40 air changes per hour
  - Higher “ambient class” recovery time than with the Unidirectional Flow, due to the lowest volume of air used
  - Excellent for transportable or small size Isolators
  - Excellent when an inert gas (Nitrogen, Argon…) must be used in alternative to the normal Air
  - Some areas can remain dirty (non reached by the air flow)

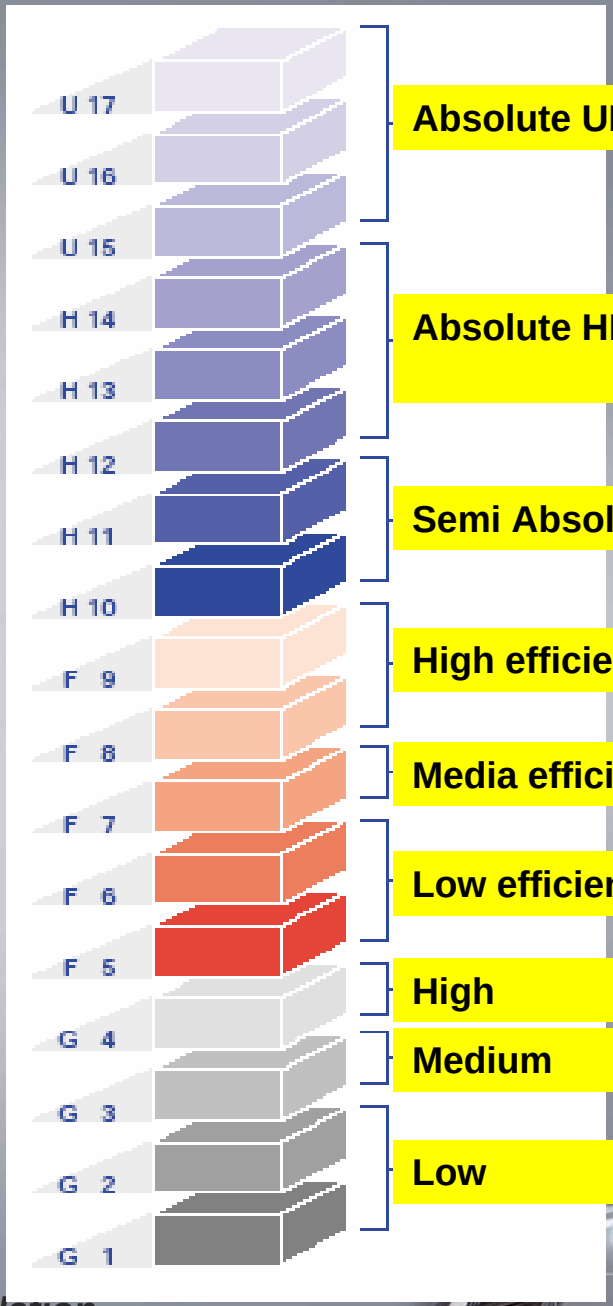


Front view

HEPA and ULPA Filters

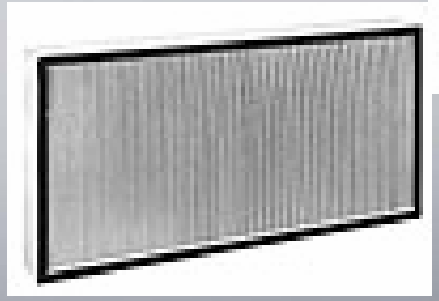
Classification CEN EN 1822

Class	Efficiency % with MPPS method	
	Global Efficiency	Minimum value of localized efficiency
H10	≥ 85	-
H11	≥ 95	-
H12	≥ 99.5	97.5
H13	≥ 99.95	99.75
H14	≥ 99.995	99.975
U15	≥ 99.9995	99.9975
U16	≥ 99.99995	99.99975
U17	≥ 99.999995	99.9999



HEPA and ULPA Filters (2)

- Different shapes and sizes available: squared, rectangular and cylindrical
- Different flow capacity expressed in m^3/hour



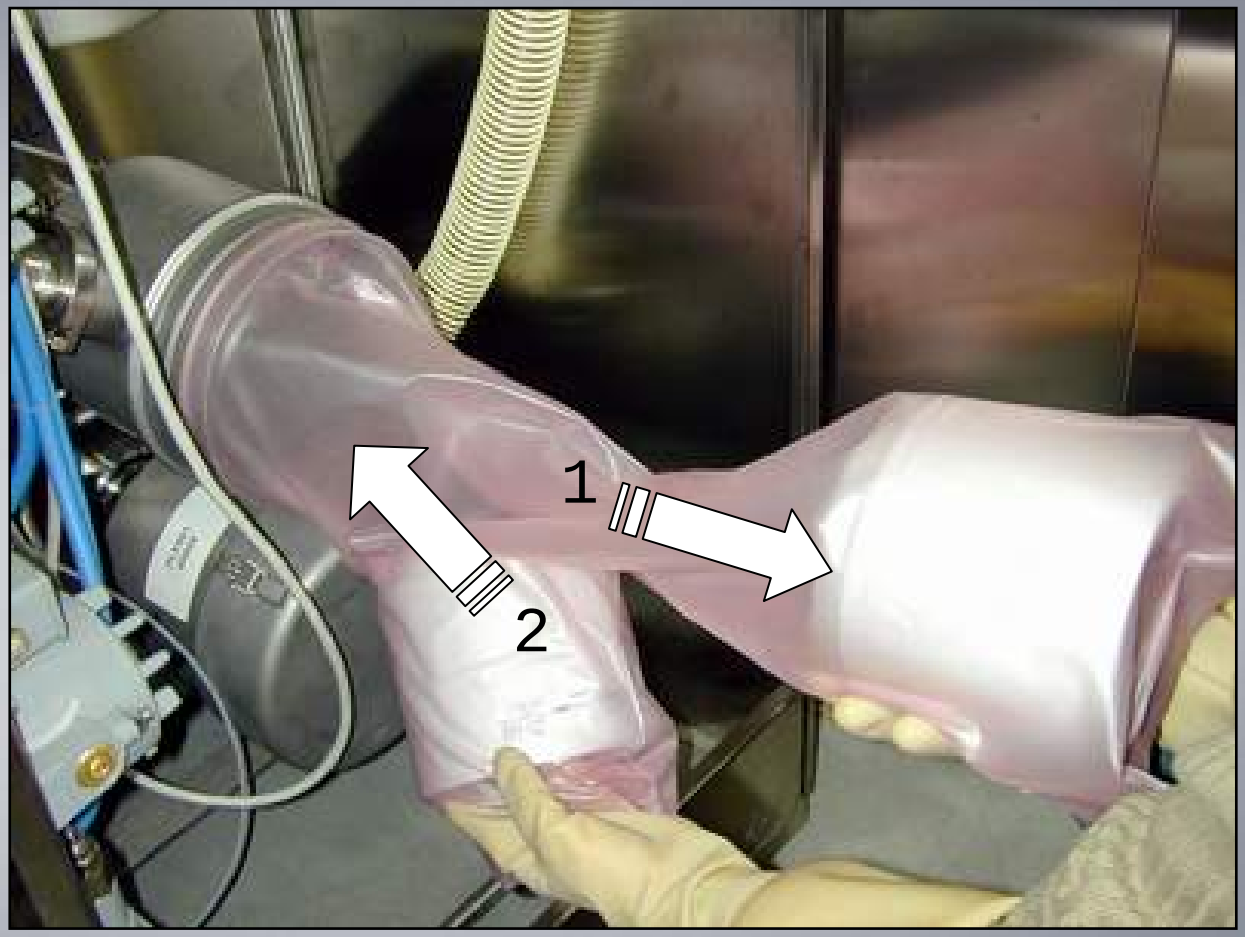
Internal cartridge filter (HEPA) for turbulent air flow

Internal rectangular panel filter (HEPA) for unidirectional air flow

ISOLATION TECHNOLOGY

External HEPA Filter with stainless steel case
(Bag In / Bag Out replacement system)

ISOLATION TECHNOLOGY



(Bag In / Bag Out Filter Replacement System)

ISOLATION TECHNOLOGY

External Rectangular Filter bag-in/bag-out

ISOLATION TECHNOLOGY

External Rectangular Filter Replacement (Bag In / Out System)

External Canister

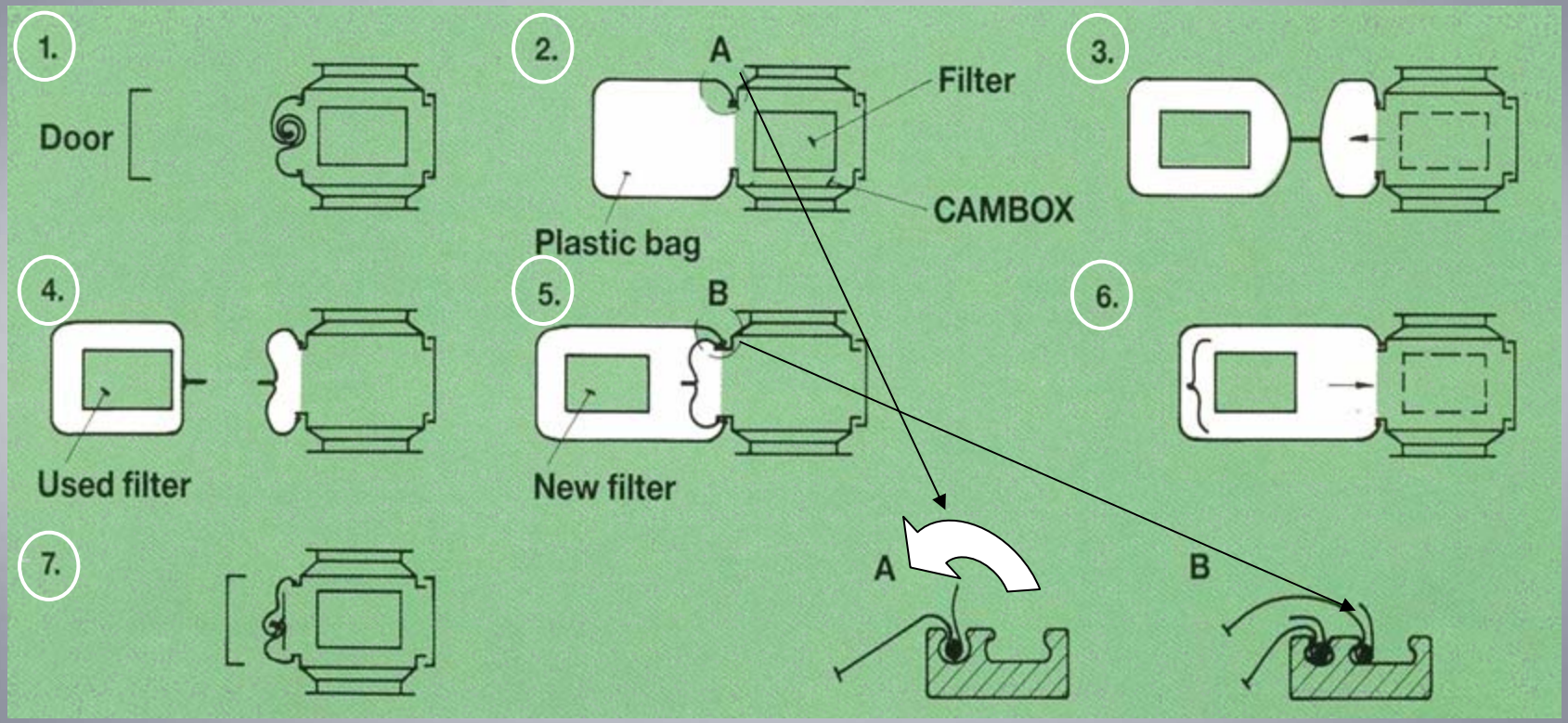
Safe Filter Removal with containment bag

Positioning of a new filter

Door closing

ISOLATION TECHNOLOGY

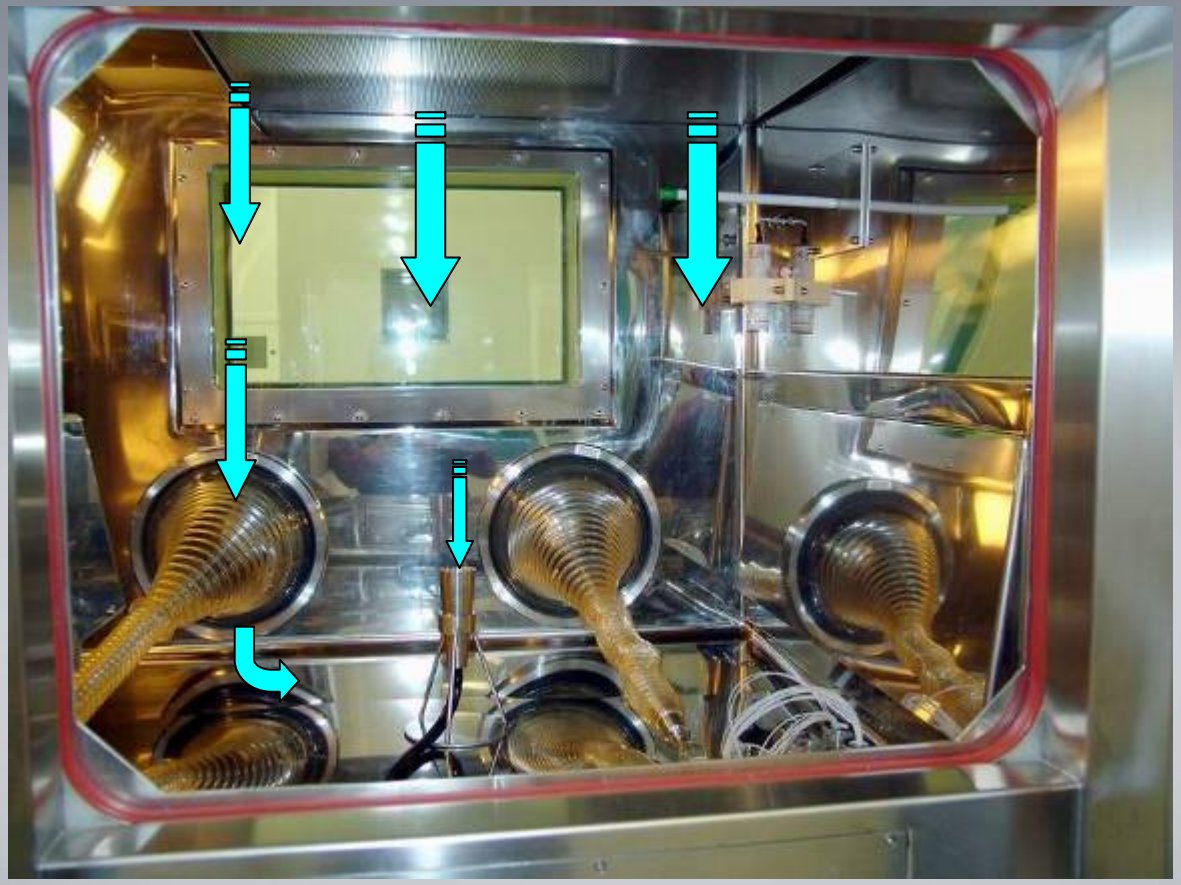
Replacement Scheme
(Bag In / Out System)



ISOLATION TECHNOLOGY

Dwyer pressure gauges to constantly check filter status / obstruction

UNIDIRECTIONAL (Laminar) Air Flow

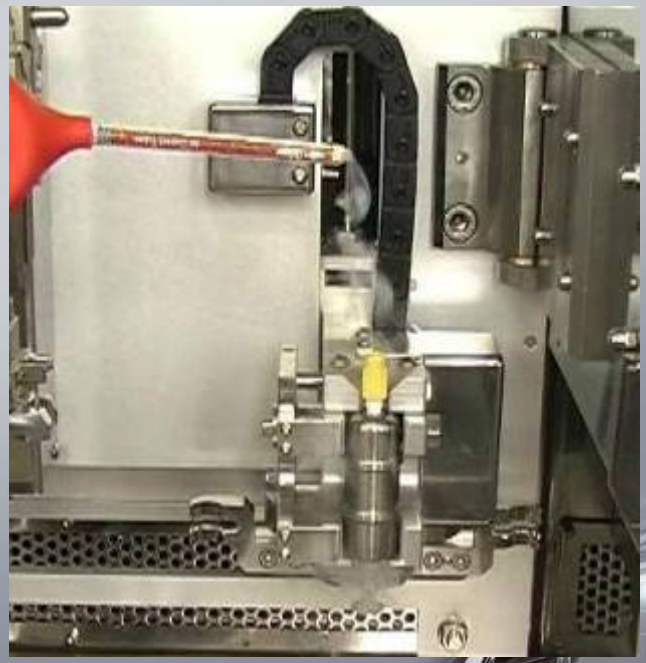


- UNIDIRECTIONAL air Flow allows a constant cleaning of the working area;
- it creates a barrier between different environments protecting the critical operation in sterile condition;
- allows to work in negative pressure to protect the operator and the surrounding environment or positive pressure to protect the product inside the glove box keeping the ambient cassified, avoiding contact with contaminated airborne particles.
- can handle bigger air volumes and allows quick class recovery.

Visual Verification of the Unidirectional flow (Smoke test)

This test is made to verify the unidirectional flow

Verification of the critical working zone constantly cleaned by the unidirectional flow.



Verification of unidirectional air flow rate

- This test is made to check the compliance of the unidirectional air flow wich has to respect a velocity included between 0,36 and 0,54 m/s near the working zone.
- Air flow rate for isolators can be even lower (EC-GMP Annex1-2003)

ISOLATION TECHNOLOGY

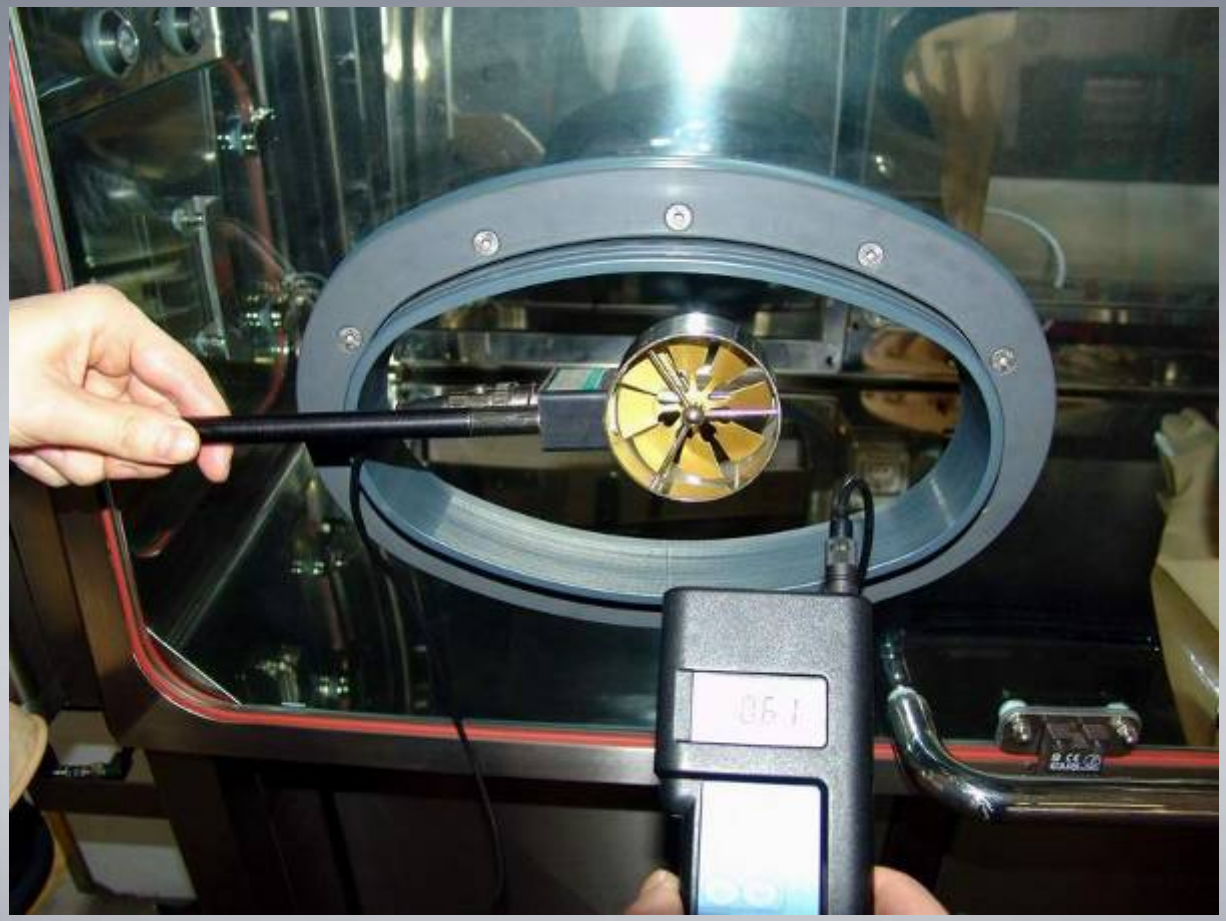
Smoke test (for Turbulent air flow)

Smoke introduction inside the isolator box with ventilation interruption. The test begins activating the ventilation.

Visual Inspection of the time necessary for the complete smoke extraction.

ISOLATION TECHNOLOGY

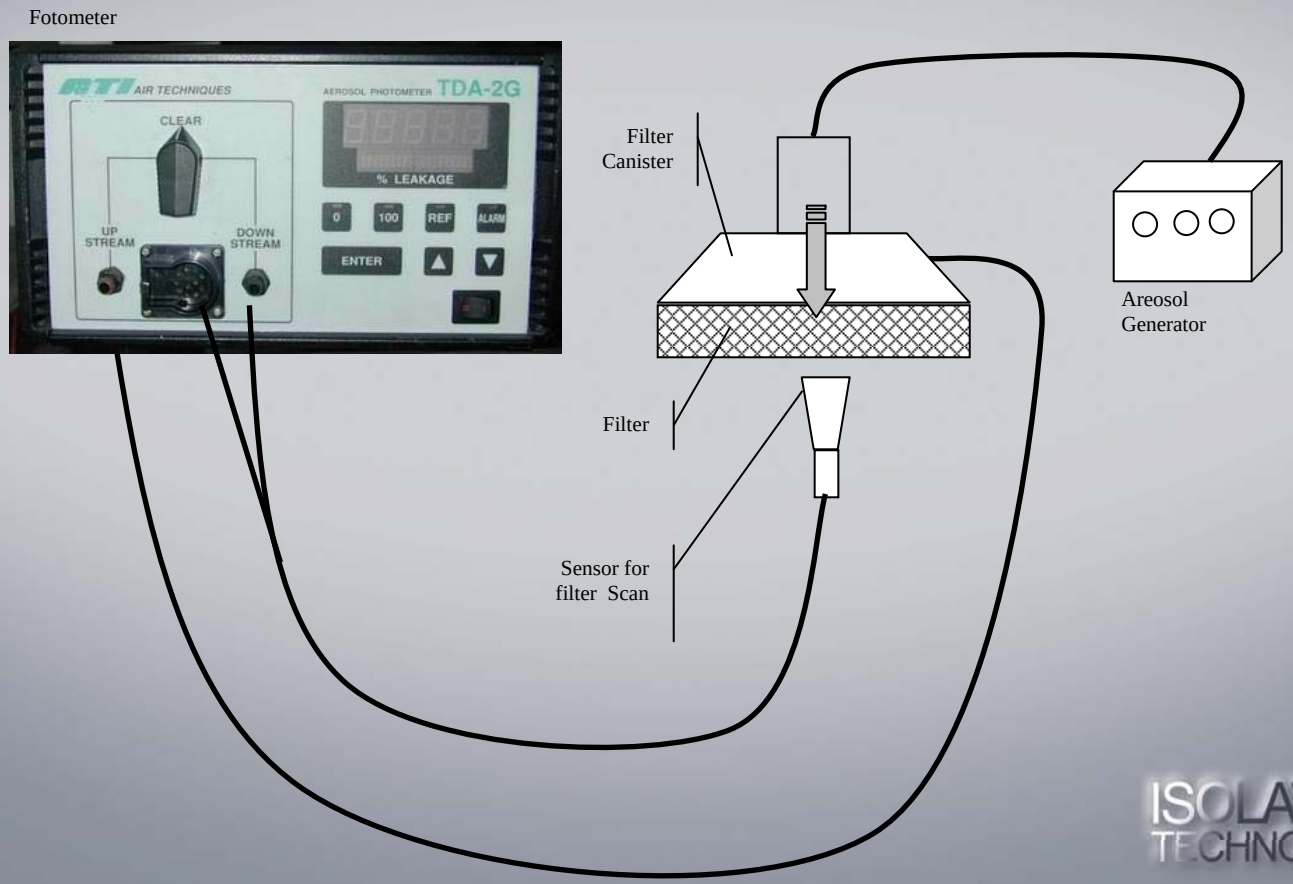
Glove Breach test



This test is made to verify that in the worst case (accidental glove removal) isolator is able to guarantee a correct air flow (originating outside the box and coming inside it in case of underpressure) with a mininum rate of 0,5 m/s (reference value according to ISO 14644-7:2004).

Verification of Filter Integrity

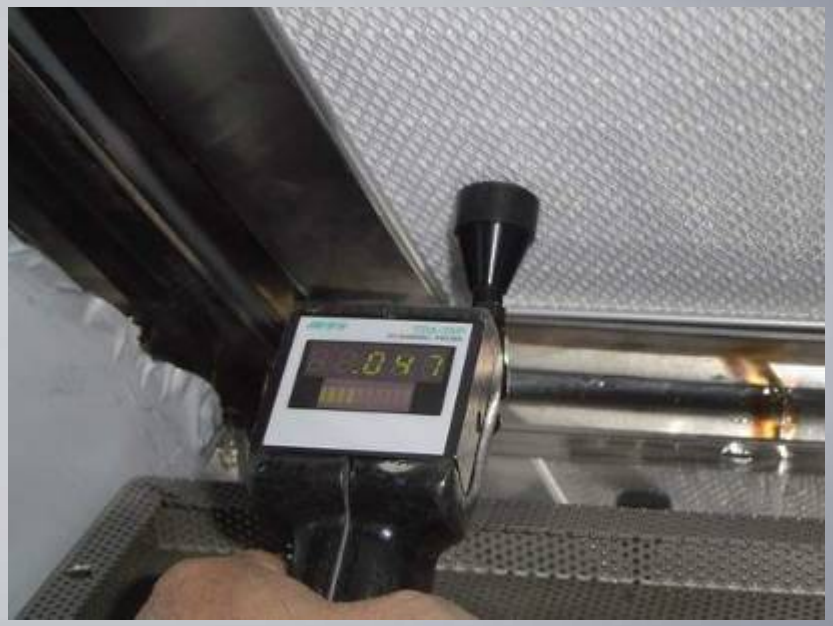
Scheme of test execution



ISOLATION TECHNOLOGY

Verification of Filter Integrity

Potential filter leackage is tested. The filter is scanned on its complete surface. Also the filter gaskets are tested.



Defective Filter with punctual leackage on the surface.

ISOLATION TECHNOLOGY

Classification of a clean area

Clean-room or clean area: is a special room or area where the concentration of air-borne particles is controlled. It is constructed in such a way as to reduce the introduction, generation and retention of particles within the area.

Classification: Level (or the process of specifying or determining the level) of air-borne particulate cleanliness applicable to a clean-room or clean zone, expressed in terms of an ISO Class N, which represents maximum allowable concentrations (in particles per cubic meter of air) for considered size of particles

Example: the concentration limit for ISO class 5 is 3520 particles/m^3 air, considering particles with a size of Ø 0.5 μm.

LIMITS OF PARTICLE CONCENTRATION
(0.5 μm)

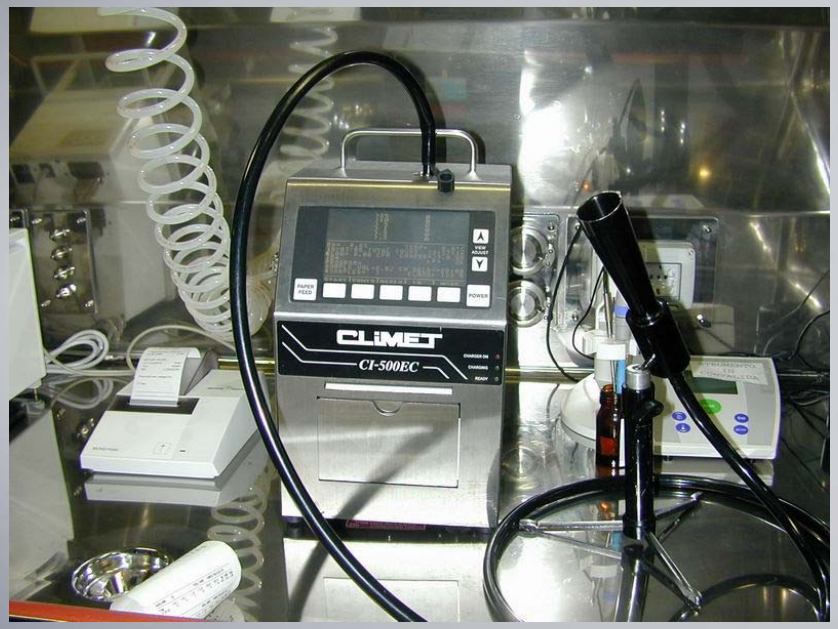
ISO class	ISO 14644-1	FS 209E	FS 209E CLASS
1	==	==	==
2	4	==	==
3	35	35,3	1
4	352	353	10
5	**3 520**	**3 530**	**100**
6	35 200	35 300	1 000
7	352 000	353 000	10 000
8	3 520 000	3 530 000	100 000
9	35 200 000	==	==

“GMP” particle correspondence:

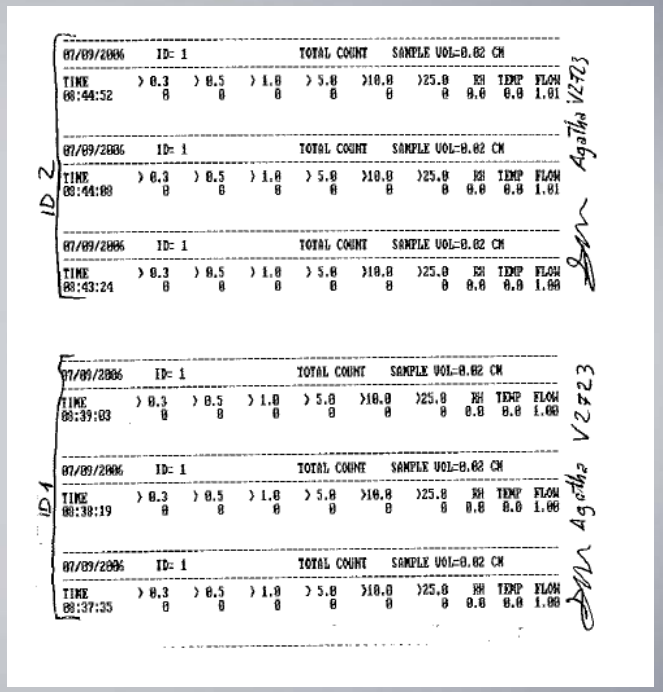
Grade A and B correspond to class 100, M 3.5, ISO 5
Grade C corresponds to class 10000, M 5.5, ISO 7
Grade D corresponds to class 100000, M 6.5, ISO 8

Note: the GMP classification does not only refer to the particle contamination, but also to microbiological contamination, which can be achieved by sanitization and/or sterilization.

Verification of air particle concentration



Particle Counting Test



07/09/2006 ID: 1 TOTAL COUNT SAMPLE VOL=0.02 CM

TIME	>0.3	>0.5	>1.0	>5.0	>10.0	>25.0	RH	TEMP	FLOW
08:44:52	0	0	0	0	0	0	0.0	0.0	1.01

07/09/2006 ID: 1 TOTAL COUNT SAMPLE VOL=0.02 CM

TIME	>0.3	>0.5	>1.0	>5.0	>10.0	>25.0	RH	TEMP	FLOW
08:44:08	0	0	0	0	0	0	0.0	0.0	1.01

ID 2 Agatha V2723

07/09/2006 ID: 1 TOTAL COUNT SAMPLE VOL=0.02 CM

TIME	>0.3	>0.5	>1.0	>5.0	>10.0	>25.0	RH	TEMP	FLOW
08:43:24	0	0	0	0	0	0	0.0	0.0	1.00

07/09/2006 ID: 1 TOTAL COUNT SAMPLE VOL=0.02 CM

TIME	>0.3	>0.5	>1.0	>5.0	>10.0	>25.0	RH	TEMP	FLOW
08:39:03	0	0	0	0	0	0	0.0	0.0	1.00

07/09/2006 ID: 1 TOTAL COUNT SAMPLE VOL=0.02 CM

TIME	>0.3	>0.5	>1.0	>5.0	>10.0	>25.0	RH	TEMP	FLOW
08:38:19	0	0	0	0	0	0	0.0	0.0	1.00

ID 1 Agatha V2723

07/09/2006 ID: 1 TOTAL COUNT SAMPLE VOL=0.02 CM

TIME	>0.3	>0.5	>1.0	>5.0	>10.0	>25.0	RH	TEMP	FLOW
08:37:35	0	0	0	0	0	0	0.0	0.0	1.00

Test report


COMECER
www.comecer.com/isolation