EHRET

Labor- und Pharmatechnik

WORK STATION ISOLATORS -positive pressure

Pharmaceutical Technology

WORK STATION ISOLATORS
positive pressure

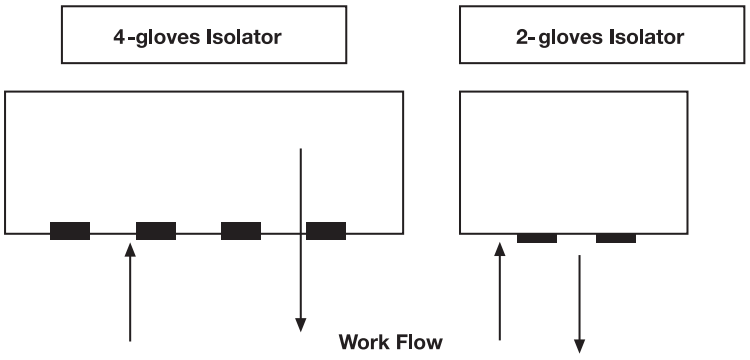
2/4–glove, class A, laminar / turbulent flow, positive pressure, H_2O_2 – sterilizable, modular construction
Isolator technology must be seen as a high security concept in the cleanroom technology, since additional essential security features can be achieved:

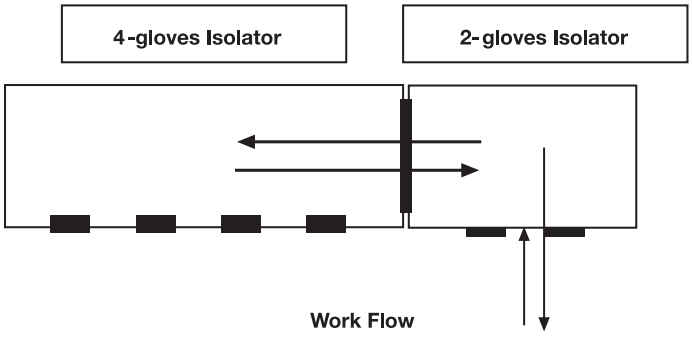
- Consequential separation of personnel and process
- Disengagement of the circulated airflow inside the isolator from the ventilation of the workplace
- Possibility of a highly efficient microbiological decontamination (SAL 10^{-6})
- Overflow principle, pressure differences and physical separation all in one
- The legislator supports this argumentation by demanding lower classes of cleanliness for the surrounding room of isolators than for cleanrooms

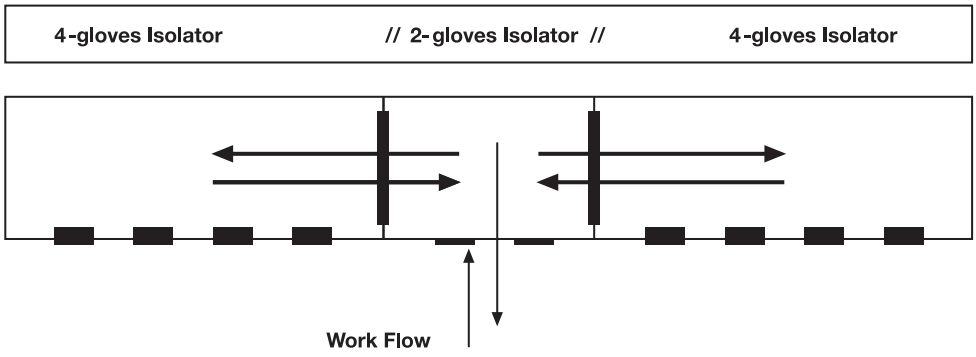
Application examples: Sterility tests and small amount production; Transfill – Weighing – Dosing

- Highest product protection and effective personnel protection by a high static isolator tightness and dynamic tightness under positive pressure operation
- Production isolators can be located in ambiences of class D or class C
- Sterility test isolators can be installed in an access controlled but unclassified surrounding
- For sterility tests of aseptically produced medication the isolator technology is used most common in order to increase the quality of the microbiological results of the sterility tests. Therefore the so-called „false positives“ can be eliminated by the use of isolator technology
- Not least reasonable economical cost reduction can be achieved, depending on the existing cleanroom equipment of the user

Modular construction and configuration examples:







Technical Information Work Station Isolators

Technical data standard Work Station Isolators		
Positive pressure - Laminar Flow Isolators		
Specification as per: In operation mode „At Rest“ at particle size 0,5 µm		
US CFR 209E-ENGLISH	Class 100	
US CFR 209E-SI-metrical system	Class M 3,5	
EU GMP-Annexe 1	Class A	
ISO 14644-1	ISO 5	
Unidirectional airflow in the chamber, recirculating	vertically, unidirectional	vertically unidirectional
Air speed [m/s] 300 mm below the distribution grid	0,45 ± 20%	0,45 ± 20%
Positive pressure – Turbulent Flow Isolators		
Specification as per: in operation mode „At Rest“ at particle size 0,5 µm		
US CFR 209E-ENGLISH	Class 10 000	
US CFR 209E-SI-metrical system	Class M 5,5	
EU GMP - Annexe 1	Class B	
ISO 14644-1	ISO 7	
Airflow in the chamber	turbulent	turbulent
Isolator-Type	**2-glove isolator**	**4-glove isolator**
Differential pressure in the work chamber [Pa]	+50 up to +150	+50 up to +150
Exhaust air duct; outer diameter [mm]	100	100
Supply / exhaust air volume [m^3/h]	approx. 150	approx. 150
Noise level dB[A]	65	65
approx. dimensions W x H x D [mm]	1100 x 2800 x 980	2035 x 2800 x 980
approx. chamber dimensions W x H x D [mm]	1094 x 994 x 794	1995 x 895 x 794
Work space height above the floor [mm]	900	900
Weight [kg]	approx. 400	approx. 900
No. of arm openings/clear diameter [mm]	2/270	4/270
Chamber illumination [LUX]	800	800
Connected power [Volt/Hz/Watt] without optional electric sockets	230/50/450	230/50/800
Compressed air of pharmacy quality required [inflatable door gasket]	6 bar	6 bar

Standard equipment= • Option= o

Housing/Chamber/Support frame		Control/Regulation/Sensors	
Housing/Lining: stainless steel AISI 304, visible surface brushed, Ra ≤ 1,2 µm	•	Switch cabinet stainless steel AISI 304	•
Chamber: stainless steel AISI 316 L or AISI 316 Ti, Ra ≤ 0,8 µm	•	Siemens S7-300 control CPU 3152-DP, with Siemens operator panel OP 17	•
Chamber: All corners/edges radius 20mm rounded	•	All parameters controlled by PLC: automatic LF* and pressure control, pre-programmed leak tight test, night reduction, door lock of the front visor and an optional transfer door. Alarm on low LF* and low pressure. [*=Only on LF-Isolator]	•
Support frame: stainless steel AISI 304, square tube, separable for positioning	•		
Constructive preparation for modular extension with further standard isolators	O	Sensors: 1x pressure gauge for differential pressure 1x airflow sensor with LF-isolators	•

Visor/Sleeves/Gloves/Illumination		Interface/optional sensors	
Folding front visor, sloped by 7°, with gas struts, safety glass pane [15mm], with inflatable gasket, safety lock	•	Connections for sterilizing unit, pneumatically controlled gassing valves and H_2O_2 piping	•
With modular extension: transfer swing doors, horizontal straight, safety glass pane [15mm] with inflatable gasket, with logical lock	O	Sensors: Temperature and humidity, rest O_2, air sampler, continuous particle monitoring with fully automatic decontamination-loop	O
Arm openings, diameter 270 mm, round, with shoulder rings. Divetex sleeves with textile insert and Hypalon gloves size 8, thickness 0,4 mm.	•	Interface: CIP-system, work floor drain, TriClamps, valves for N_2-O_2 gassing, validation opening	O
One-piece glove/sleeve system	O		
Illumination, approx. 800 Lux inside the work chamber	•		

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Filter		Further options	
Supply air HEPA-Filter H 14, 99,995% in MPPS	●	H_2O_2-decontamination systems, H_2O_2-OEL, LC and HC sensors, catalyst	O
Exhaust air HEPA-Filter H 14, 99,995% in MPPS	●	Leak tight test system for gloves and sleeves	O
Circulation air HEPA-Filter with LF Isolators, H 14, 99,995% in MPPS	●	Orbital sample shelve systems, rotating, one-hand operation	O
All filters with DEHS test ports, accessible from the front	●	DPTE®-S double-door transfer system	O
Filter monitoring of all filters with differential pressure manometers	O	All equipment for sterility testing: Millipore Steritest Equinox – pump system	O
Filter monitoring of all filters with pressure sensors	●	1CFR part11 conform data manager with audit trail	O

Supply and exhaust air flaps		Rules conformity	
Supply and exhaust air valves with motor drive, with position feedback signal, electro-magnetically controlled via PLC	●	Considered: DIN EN ISO 14644, FDA, GMP, cGMP, PIC/s; tested as per GMP / VDI 2083-3, DIN EN ISO 14644-3, VDE 701/ EN 60400/EMV 61000, CE-mark	●

		Documentation	
		Standard documentation GAMP-4 compliance basic documentation and extended GAMP-4 compliance documentation	O

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