



Labor- und Pharmatechnik



WORK STATION ISOLATORS - negative pressure



Pharmaceutical Technology



EHRET LIFE SCIENCE SOLUTIONS

EHRET – WORK STATION ISOLATORS

negative pressure

2/4-glove, class A, laminar / turbulent flow, negative pressure, H₂O₂ – sterilizable, modular construction

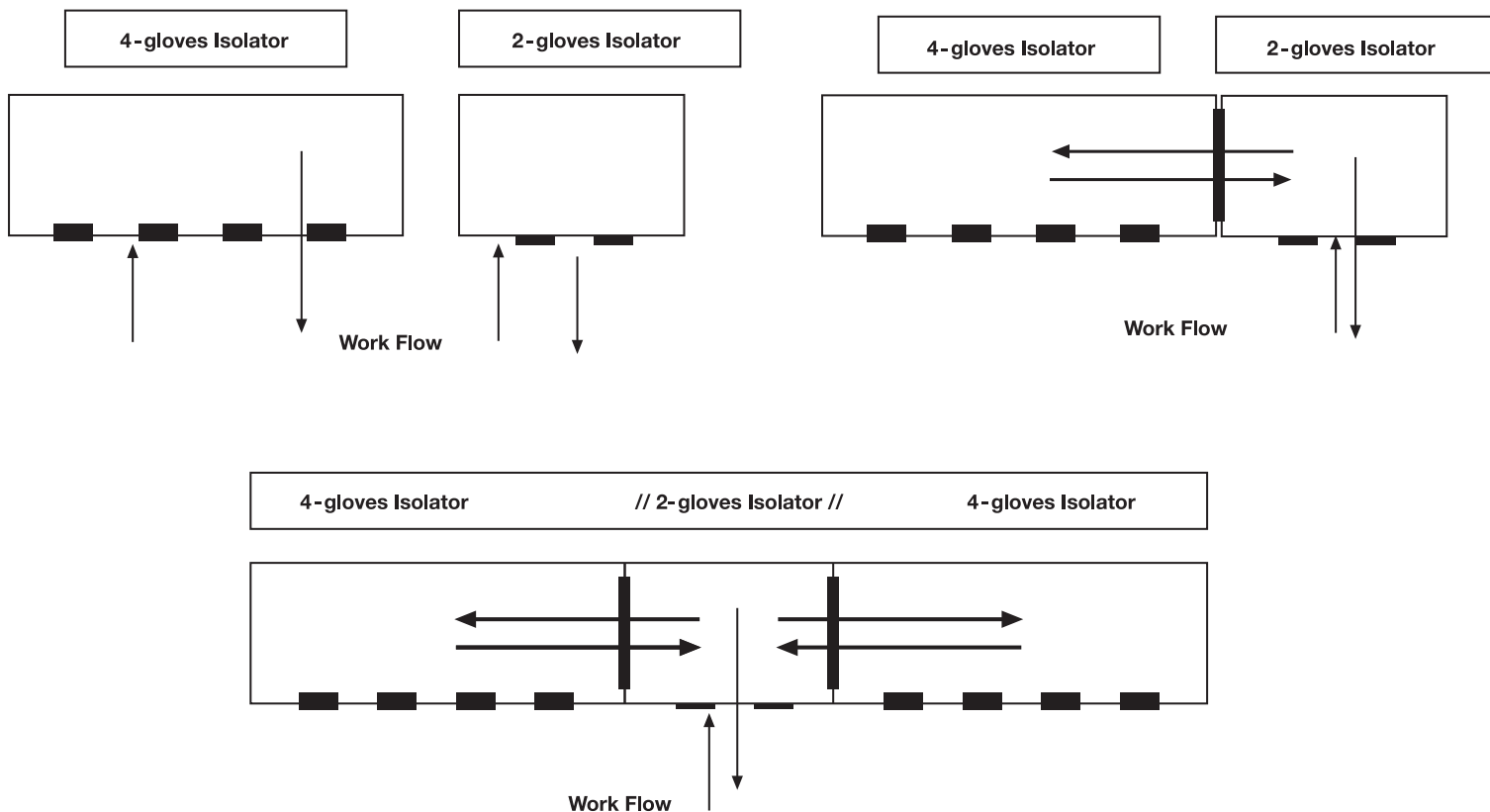
Isolator technology must be seen as a high security concept in the cleanroom technology, since additional essential security features can be achieved:

- 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)
- Negative pressure against the ambience, overflow principle 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: Small production of toxins and cytostatic drugs; Treatment – Transfill – Weighing – Dosing – Encapsulation

- Highest personnel protection and effective product protection by a high static isolator tightness and dynamic tightness under negative pressure operation
- Production isolators can be located in ambiances of class D or class C
- Considerably higher operator protection than with a workbench
- Not least reasonable economical cost reduction can be achieved, depending on the existing cleanroom equipment of the user
- Filter exchange possible under low contamination risk
- Clean-in-place (CIP) system possible

Modular construction and configuration examples:



Technical Information Work Station Isolators

Technical data standard Work Station Isolators		
Negative 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%
Negative 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
Tightness following ISO 10648, class 3, maximum hourly leakage rate 1%	●	●
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 = ○

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 315 2-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 LF-Isolator]	●
Support frame: stainless steel AISI 304, square tube, separable for positioning	●		
Additional Filter-in-Bag system in the return air channel serving as contamination protection and for filter exchange at low contamination risk	○	Connection to an existing process control technique, or an existing or optionally offered monitoring system	○
Constructive preparation for modular extension with further standard isolators	○	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 ₂ O ₂ piping	●
With modular extension: transfer swing doors, horizontal straight, safety glass pane (15mm) with inflatable gasket, with logical lock	○	Sensors: Temperature and humidity, rest O ₂ , air sampler, continuous particle monitoring with fully automatic decontamination-loop	○
Arm openings, diameter 270 mm and 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	○
One-piece glove /sleeve system	○		
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 ₂ O ₂ - decontamination systems, H ₂ O ₂ -OEL, LC and HC sensors, catalyst	○
Exhaust air HEPA-filter H 14, 99,995% in MPPS	●	Orbital sample shelve systems, rotating, one-hand operation	○
Circulation air HEPA-filter with LF Isolators, H 14, 99,995% in MPPS	●	DPTE®-S double-door transfer system	○
All filters with DEHS test ports, accessible from the front	●	All equipment for sterility testing: Millipore Steritest Equinox-pump system	○
Filter monitoring of all filters with differential pressure manometers	○	21CFR part11 conform data manager with audit trail	○
Filter monitoring of all filters with pressure sensors	○		

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	○

