



The unique solution for a pure environment

SKANFOG® PURE, the essence of an isolator

SKAN

SKAN, founded in 1968, is one of the pioneer companies in the field of cleanroom equipment and manufacturing of isolators for the pharmaceutical and biotech industries.

Innovative products, client specific solutions as well as an efficient service organization have made SKAN a worldwide market leader and an important partner of the industry and research laboratories.

Your Needs

- Cost effective Grade A, ISO 5 containment that eliminates full cleanroom requirements
- Wide application range
- Fast and automated decontamination cycles by H₂O₂
- Excellent ergonomics and working conditions
- Compliance to current regulatory and standards requirements

Our Solutions

- SKANFOG® PURE: An aseptic and aseptic-toxic working isolator
- Closed containment provides a safe handling condition also when working with high potent products
- Fast and safe H₂O₂ decontamination cycles with the patented SKANFOG® technology
- Large and fast airlock to improve isolator productivity
- No connection to HVAC required due to integrated SKAN NANOX® catalyst system
- Easy to install "plug and play" solution
- Modular, space saving design
- A worldwide reputable service and after-sales support through our branch offices or partners



Outstanding Features

- Working chamber and airlock in stainless steel
- Smooth and easy to clean working surface
- Selectable positive or negative pressure operation
- Maintains cGMP cleanroom class A, ISO 5 standards
- User-friendly 10" color touch screen control panel
- Mainboard and software engineered according GAMP 5
- Batch reporting
- All operational, service or maintenance access from the front so to install against the wall
- Easy assembly, installation and access through standard doorways and elevators

Our Experience – Your Advantage

SKANFOG® PURE combines the broad knowledge about life science and laboratory safety solutions with isolator technology.

Versatile

SKANFOG® PURE offers a wide application range from pharmaceutical-biotech laboratories to hospital and clinical pharmacies, from compounding operation to cell culture and genetics, from animal and research industries to medical field. Common fields are:

- Carcinogenic, mutagenic or reprotoxic substances (CMR)
- Total parenteral nutrition (TPN)
- Intravenous solution (IV)
- Cytotoxic
- Virostatic
- Anti-neoplastic chemotherapy
- Pathogenic microbiology/viruses
- Transformed DNA
- Small scale aseptic pharma production
- Cell cultures
- Quality control
- Cell therapy

Standards & Certifications

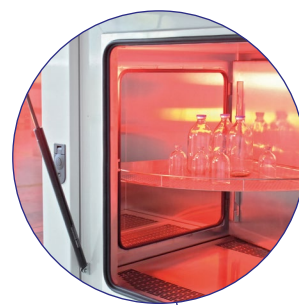
SKANFOG® PURE is certified according to the latest standards, i.e.

- Machinery Directive 2006/42/EC
- EMC Directive 2014/30/EC
- EN 12469 (performance criteria for microbiological safety cabinets)
- DIN 12980 (laboratory installations – safety cabinets and gloveboxes for cytotoxic substances and other CMR drugs)
- ISO 14644-7 (clean air hoods, gloveboxes, isolators, mini-environments)
- CB-Scheme test certificate according IEC 61010-1, complies to UL 61010-1



Alarm indicator

In the event of an alarm, the chamber light turns to red for a convenient visible alert.



Space saving design

The compact design allows the bringing-in through standard doorways and elevators. All access operations can be performed from the front side. The isolator can be installed against the wall.

Airlocks

The airlock (equipped as a standard with a shelf) can be available on the right, on the left or on both sides of the isolator.



H₂O₂ dosing unit

Commercially available 35 % hydrogen peroxide (H₂O₂) bottles can be safely stored in the isolator.

SKAN FIPA Filter cartridge HEPA H14

Patented SKAN technology for safe and easy filter change. Double HEPA H14 filtration with retention rate of 99,995 %.



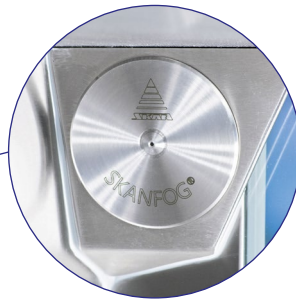
HMI

User-friendly 10" color touch screen control panel.

Outer housing and design

ABS polymer as widely used, durable and resistant standard material for outstanding laboratory design.

PURE



SKANFOG® H₂O₂ micro-nebulization

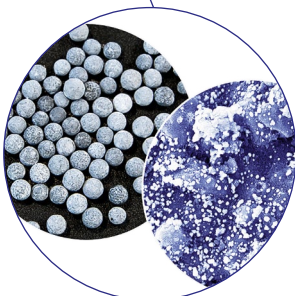
SKANFOG® technology guarantees a fast, reproducible and validated decontamination cycle and material transfer.

Working chamber size

Two working chamber sizes available, either with two or four glove ports.

Glove leak test

SKAN glove leak tester optionally available.



SKAN NANOX® catalyst

The SKAN patented NANOX® catalyst technology provides the optimization of aeration time and allows the possibility to place the SKANFOG® PURE isolator with no connection to the HVAC system. Integrated one-through catalytic decomposition of H₂O₂ (<99.99%) allows an air saving operation by direct air exchange with the room environment.

Innovative Decontamination Solution

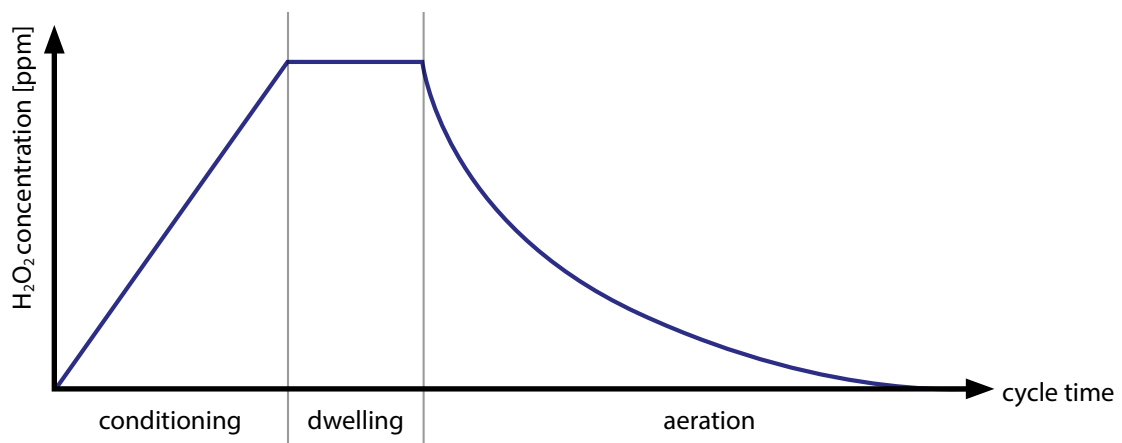
SKANFOG®

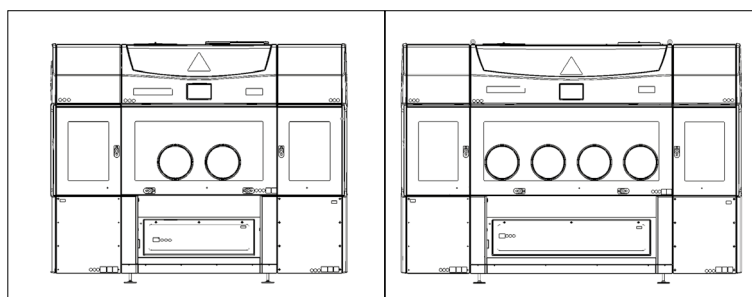
SKANFOG® decontamination process is a decontamination technology based on the micro-nebulization of hydrogen peroxide (H_2O_2). Compared with conventional wiping, it simplifies and enhances both procedure and validation. Moreover, nebulized H_2O_2 in moderate concentrations can be used without concern regarding toxicity, corrosion and persistence. Scientific studies have shown that a total kill of a 10^6 population of the test organism *Geobacillus stearothermophilus* can be qualified and reproduced.



Fast decontamination cycle

The decontamination process is divided in three phases: In the conditioning phase, the required H_2O_2 amount is micro-nebulized into the containment. A well-defined dwelling time follows and comprehensively ensures that the desired decontamination efficacy will be accomplished. In the aeration phase, the decontaminated containment is aerated by means of a catalytic loop.





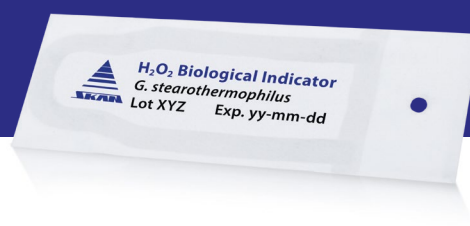
Technical data (chamber + 2 airlocks)		2 gloves SKANFOG® PURE isolator	4 gloves SKANFOG® PURE isolator
Complete system [wxdxh]	[mm] [ft]	2811 × 955 × 2277 9'-3" × 3'-2" × 7'-6"	3300 × 955 × 2277 10'-10" × 3'-2" × 7'-6"
Useful chamber [wxdxh]	[mm] [ft]	1410 × 715 × 629 4'-8" × 2'-4" × 2'-1"	1895 × 715 × 629 6'-3" × 2'-4" × 2'-1"
Max. height of load	[mm] [ft]	970 3'-2"	970 3'-2"
H ₂ O ₂ type	[L] / [%]	2.5 / 35	
Operation pressure	[Pa]	-60 or +60 (tbd at order)	
Air velocity down flow	[m/s]	0.45 +/- 20 % 0.25 (Standby)	
Air consumption isolator	[m ³ /h]	max. 500	max. 650
Air consumption airlock	[m ³ /h]	400 - 750	
Material working chamber	Type	Stainless steel AISI 316L (EN 1.4404) surface roughness ≤ 0.8 μm	
Material body housing	Type	ABS polymer, RAL 9016	
Material window	Type	6 mm double safety glass	
Exhaust (double filtered)	Type, filter class	SKAN FIPA HEPA H14 filtered (independent, no exhaust duct needed)	
Filter type to airlock	Type, filter class	Intake HEPA H14 plate filter / Exhaust SKAN FIPA H14 filtered	
H ₂ O ₂ catalyst	Type	Patented SKAN NANOX®	
Control system	Type	Embedded control system with 10" color touch screen control panel, GAMP 5 CAT 3	
Interfaces	Type	USB	
Light	[lx]	Min. 800 inside the chamber	
Pneumatic air supply	[bar] / [Nm ³ /h]	6 - 10 / 7.5 - 22, class 1.3.1 (acc. ISO 8573-1:2010)	
Noise level	db (A)	Max. 65	
Power supply (single phase)	[VAC] / [Hz] / [W]	220 - 240 / 50 - 60 / max. 3800	
Gloves	Type	Standard: 1-piece gloves (butyl) Options: 2-piece gloves (butyl gloves, CSV sleeves) / Glove changing system	
Available options		<ul style="list-style-type: none"> • Independent hydrogen peroxide sensor (TLV) for room installation • Multi piece stainless steel rack & shelves • SKAN glove tester • Glove stretchers • Air velocity in chamber optional • Environmental monitoring for viable (handheld) and non-viable particles (mechanical interface pre-installed) • Secure RTP (rapid transfer port) transfer systems • Qualification & validation services (IQ/OQ) • Microbiological qualification (MBQ) • Further options available upon request 	

WirelessGT

The innovative glove leak testing system without tubes and wires: it's better to be wireless.

SKAN BI®

The biological indicator for H₂O₂ decontamination: designed for outstanding performances.



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