skan

Multipurpose isolator pure

skan.com/puresolutions

BUCH HOLM

Together always one step ahead

SKAN is a Swiss company and a global market and technological leader for isolators, cleanroom devices, and decontamination processes for the aseptic production of biopharmaceutical substances. SKAN's core competency is the design and development of process isolators for the aseptic filling of biopharmaceutical products. Furthermore, the company offers its customers process support, services, and consumables.

SKAN's technology and innovation leadership is based on a unique combination of specialist knowledge in the areas of ventilation technology, air conditioning, sterilisation, software programming that must be validated in a pharmaceutically compliant manner, microbiology and chemistry. It is also experienced when it comes to regulatory requirements and production competency.

With its state-of-the-art products and services, SKAN focuses on markets with the highest regulatory requirements in the health sector. These are mainly situated in Europe, North America, Japan, South Korea, and Singapore. In these markets, every third vaccine that is produced in an isolator is filled in a SKAN isolator. SKAN also sells its products in emerging markets such as China, India and Brazil. If the pharmaceutical companies there wish to export to Europe or North America, they also have to fulfill the same strict legal regulations.

SKAN's expertise and innovative energy is the result of long years of trusting relationships with blue-chip (bio)pharmaceutical companies and leading research laboratories worldwide. SKAN's products and services are decisive for the success of its customers. For this reason, the company profits from high market entry barriers. Thanks to the experts at our in-house laboratories who research innovative solutions for isolator technology, SKAN can fulfill even the most complex customer requirements.

As well as investing in technological improvements and expanding production capacity, SKAN has always worked closely with its customers and developed qualification strategies that guarantee fast process approvals by the authorities. A comprehensive support programme is available so that the customer receives optimal care during the entire product life cycle. This is guaranteed by a worldwide service network comprising in-house and external specialists.

pure – the essence of an isolator

Your needs

- Cost-effective cGMP Grade A, ISO 5 containment that eliminates full cleanroom requirements
- Wide range of applications
- Fast and automated decontamination cycles with H_2O_2
- Excellent ergonomics and working conditions
- Compliance with current regulatory and standard requirements

Our solutions

- pure is suitable for aseptic and aseptic-toxic processes
- Closed containment ensures safe handling conditions even when working with high potent products
- Fast and safe H_2O_2 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
- Worldwide professional 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 to GAMP 5 CAT 4
- Batch reporting
- All operational, service and maintenance access from the front to allow installation against the wall
- Easy assembly, installation and access through standard doorways and elevators

Our experience – your advantage

In the pure, SKAN combines its extensive knowledge of life science and laboratory safety solutions with isolator technology.

Versatile

The pure offers a wide range of applications, from pharmaceutical-biotech laboratories to hospital and clinical pharmacies, from compounding to cell culture and
genetics, from animal and research industries to medicine. Common areas of use include:

- 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 and Gene Therapy

Standards & certifications

- CB Scheme according to IEC 61010-1:2010 that complies with international mutually accepted IECEE standards of product safety for electrical devices. Tested, certified and controlled by accredited testing laboratory Eurofins Product Service GmbH.
- According to standard DIN 12980:2017-05 that complies with German Product Safety Act (ProdSG§22). Tested, certified and controlled by accredited testing laboratory TÜV NORD CERT GmbH.
- Machinery Directive 2006/42/EC
- EMC Directive 2014/30/EC
- EN 12469 (performance criteria for microbiological safety cabinets)
- ISO 14644-3/7 (Test Methods / clean air hoods, gloveboxes, isolators and mini-environments)

Features

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

skanfog® H_2O_2 micro-nebulization
skanfog® technology guarantees a fast, reproducible and validated decontamination cycle and material transfer.

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

H_2O_2 dosing unit
Commercially available 35 % hydrogen peroxide (H_2O_2) 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 %.

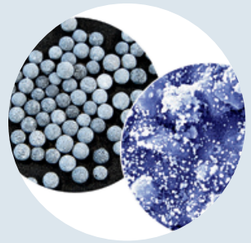
Outer housing and design
ABS polymer, a widely used, durable and resistant standard material for outstanding laboratory design.

Space-saving design
The isolator's compact design allows it to be moved through standard doorways and elevators. All access operations can be performed from the front side. The isolator can be installed against the wall.

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

Glove testing system
SKAN glove testing system optionally available.

SKAN nanox® catalyst
The SKAN patented nanox® catalyst technology optimizes aeration time and removes the need to connect the pure isolator to the HVAC system. Integrated one-through catalytic decomposition of H_2O_2 (<99.99 %) reduces air use thanks to direct air exchange with the room environment.



Innovative decontamination solution

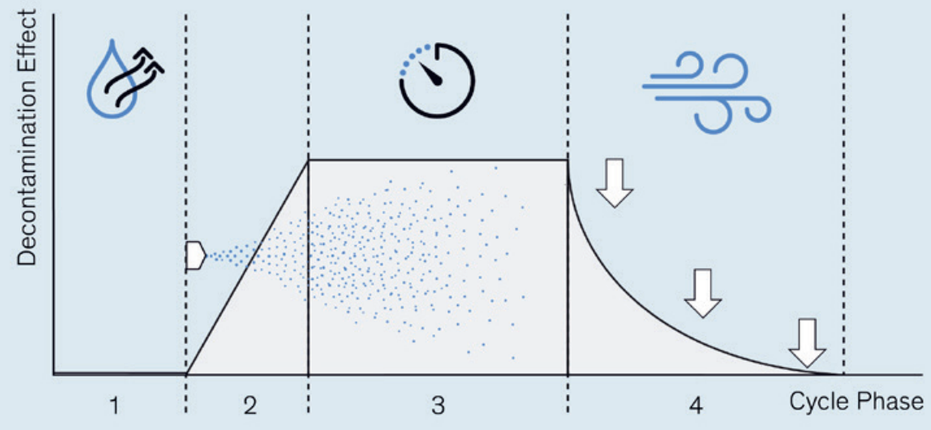
skanfog®

The 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. In moderate concentrations, nebulized H_2O_2 can also be used without concern as to toxicity, corrosion and persistence. Scientific studies have shown that a total kill of a $10e^6$ population of the test organism Geobacillus stearothermophilus can be qualified and reproduced.

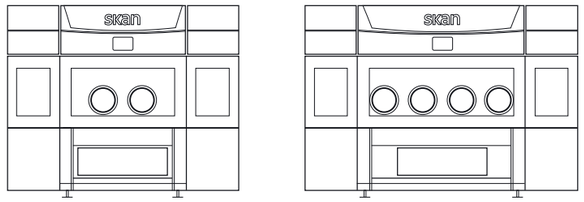
Fast decontamination cycle

The decontamination process is divided into three phases:

- In the conditioning phase, the required amount of H_2O_2 is micro-nebulized into the containment area.
- This is followed by a well-defined dwell time, which ensures the desired decontamination efficacy.
- In the aeration phase, the decontaminated containment area is aerated by means of a catalytic loop.



Technical data



Type		2 glove working chamber (with 2 airlocks)	4 glove working chamber (with 2 airlocks)
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”
Work surface height	[mm] [ft]	970 3’-2”	970 3’-2”
H_2O_2 type	[L] / [%]	2.5 / 35	
Operating pressure	[Pa]	-60 or +60 (specify when ordering)	
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 of working chamber	Type	Stainless steel AISI 316L (EN 1.4404) surface roughness ≤ 0.8 µm	
Material of body housing	Type	ABS polymer	
Material of window	Type	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_2O_2 catalyst	Type	Patented SKAN nanox®	
Control system	Type	Embedded control system with 10” color touch screen control panel, GAMP 5 CAT 4	
Interfaces	Type	USB	
Light	[lx]	Min. 800 inside the working chamber	
Pneumatic air supply	[bar] / [Nm^3 / h]	6 - 10 / 7.5 - 22, class 1.3.1 (according to 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

- ⟶ Independent hydrogen peroxide sensor (TLV) for room installation
- ⟶ Multi-piece stainless steel rack & shelves
- ⟶ SKAN glove testing system WGT 2
- ⟶ Glove stretchers
- ⟶ Air velocity sensor in the working chamber
- ⟶ Environmental monitoring for airborne microorganisms (handheld) and airborne particles (preinstalled mechanical interface)
- ⟶ Secure RTP (rapid transfer port) transfer systems
- ⟶ Qualification & validation services (IQ / OQ)
- ⟶ Microbiological qualification (MBQ)
- ⟶ Further options available upon request

According to GMP Annex 1 air speed can be set to 0.45 m / s (+/ -20%). In the case of non-GMP applications, air speed will be set to 0.25 m / s.
Contact (skin contact, ingestion, inhalation) with hydrogen peroxide (H_2O_2) can lead to serious health problems! It is recommended to use an independent H_2O_2 TLV sensor for room monitoring.
If the maximum threshold value (TLV) is exceeded, the sensor alarm signal can be transmitted to the controller of the pure.

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