skan

pure²

Features

Operating mode
Operating modes are visible by different colored internal lighting (white, blue, red).

Airlock
The airlock is equipped with a shelf and can be placed to the left, right or on both sides of the isolator.

Space-saving design
The working chamber is available in two sizes, with either two or four glove ports.
The compact design means it will fit through standard doors and in lifts.
All operation and maintenance openings are accessible from the front.

H_2O_2 station
Fully integrated decontamination system in each chamber. Commercially available hydrogen peroxide (H_2O_2) 35% can be stored safely in the isolator. Micro-nebulisation guarantees fast, reproducible decontamination cycles which can be validated.

H14 HEPA FIPA filter cartridge
Patented SKAN technology for safe, simple filter changes.
The pure^2 isolator comes with double HEPA H14 filters, each with a filtration efficiency of 99.995 %.

Display

9" Siemens color touch screen with local user administration. The Siemens controller represents the current industry standard, including trend monitoring, batch log creation and optional audit trail.

Housing and design

ABS polymer – a widely used, strong and durable standard material for exceptional design in the laboratory.

Glove test

The custom-configured SKAN glove testing system is available as an option. Glove ports compatible with WirelessGT2.

nanox catalytic converter

nanox catalytic converter technology reduces aeration time and allows autonomous operation without having to connect to the building's air exhaust system.
Built-in catalytic decomposition of H_2O_2 (<99.99%) allows direct exchange with ambient air.

Our experience – your advantage

SKAN combines extensive knowledge of laboratory safety cabinets and isolators.

Standards and certification

- CB scheme in accordance with IEC 61010-1:2010, meeting international, mutually recognised IECEE standards for product safety for electrical equipment. Tested, certified and monitored by certified body Eurofins Product Service GmbH.
- GS mark for the type examination under DIN 12980:2017-05 in accordance with the requirements of the German Device and Product Safety Act (ProdSG, section 22). Tested, certified and monitored by certified body TÜV NORD CERT GmbH.
- Machinery Directive 2006/42/EC
- EMC Directive 2014/30/EC
- EN 12469 (performance criteria for microbiology safety cabinets)
- ISO 14644-3/7 (test methods / clean air hoods, glove boxes, isolators and mini-environments)

More information

Applications

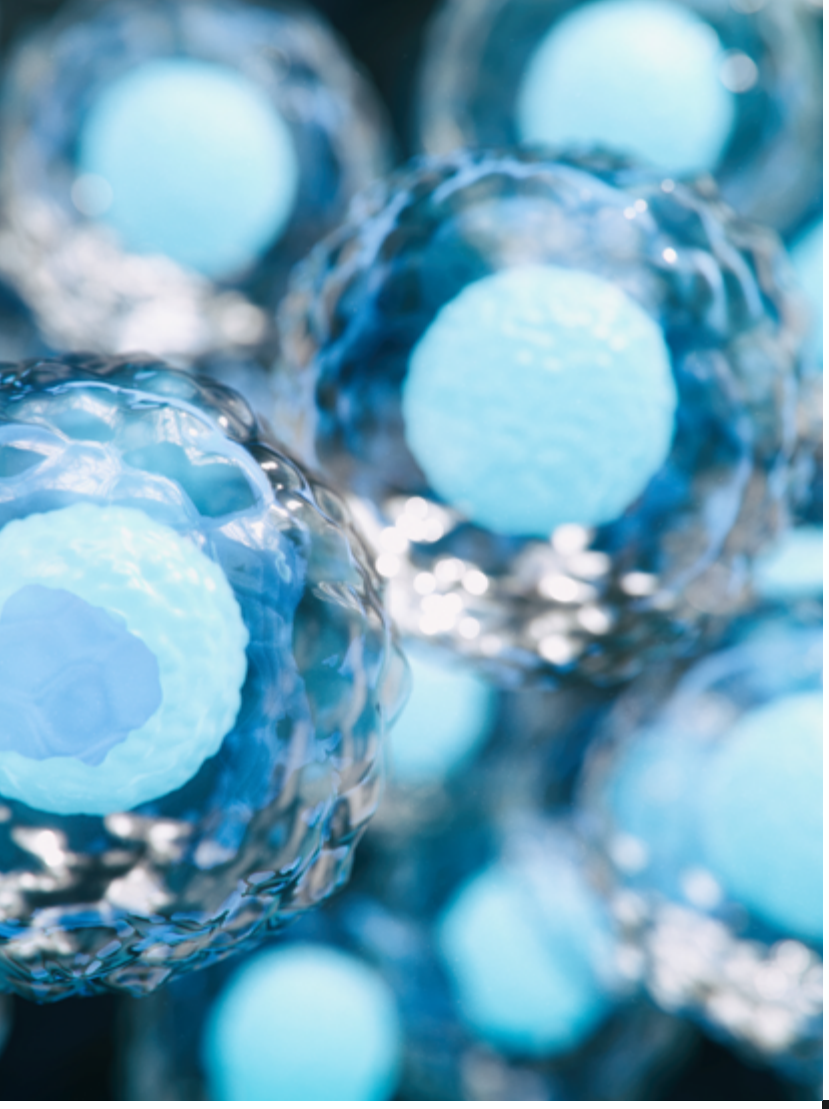
- Cell and Gene
- Sterility testing
- Biosafety
- Pharmaceutical manufacture

Sterility testing

- Plug-and-play design
- Working chamber corresponds to GMP Grade A / ISO 5 with unidirectional-airflow
- Optional integration of sterility testing pump (Millipore or Sartorius)
- FDA 21 CFR Part 11 compliance through Siemens controller

Biosafety

- Systematic protection against hazards when processing biological agents
- Safe and complete containment thanks to the selectable negative pressure operation
- Assured operator and environmental protection, with optional H_2O_2 decontamination
- Reduction of microbiological load



Cell and Gene

- Flexibly adapts to your work and manu facturing process
- Suitable for fast material transfer when processing cell cultures
- Assured operator and environmental protection, with optional H_2O_2 decontamination
- Contamination protection through GMP-compliant unidirectional air flow

Pharmaceutical manufacturing

- Suitable for aseptic and aseptic-toxic applications (e.g. CMR substances)
- Improved patient safety through compliance with GMP requirements
- Complies with GMP and FDA 21 CFR Part 11 for processing electronic data records
- Optional configuration for the integration of filling equipment

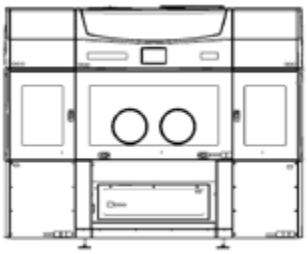
pure^2 specifications

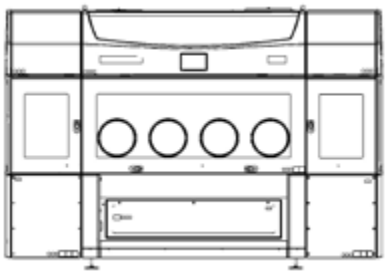
Your requirement

- Safe containment system corresponds to GMP Grade A / ISO 5 with unidirectional airflow
- Wide range of applications
- Fast, automated H_2O_2 decontamination
- Compliance with applicable regulatory and standards requirements
- Excellent ergonomics and working conditions combined with maximum safety

Our Solution

- The pure isolator is intended for aseptic and aseptic-toxic applications
- Sealed containment system provides safety even when working with high-risk or highly potent products
- Faster, safer H_2O_2 decontamination cycle thanks to patented skanfog technology
- Spacious airlock and fast transfer increase productivity
- Thanks to the built-in SKAN nanox catalytic converter, no connection to the building's air exhaust system is required
- Simple plug-and-play installation process
- Modular, space-saving design
- Worldwide service and support network through subsidiaries and partners





Type		2-glove working chamber	4-glove working chamber
External dimensions [w x d x h] with 2 airlocks	[mm] [ft, in]	2811×955×2277 9'-3" × 3'-2" × 7'-6" (see diagram above)	3301×955×2277 10'-10" × 3'-2" × 7'-6" (see diagram above)
External dimensions [w x d x h] with 1 airlock	[mm] [ft, in]	2196 × 955 × 2277 7'-2" × 3'-2" × 7'-6"	2683 × 955 × 2277 8'-8" × 3'-2" × 7'-6"
External dimensions [w x d x h] working chamber alone	[mm] [ft, in]	1581 × 955 × 2277 5'-1" × 3'-2" × 7'-6"	2065 × 955 × 2277 6'-8" × 3'-2" × 7'-6"
Working area [w x d x h]	[mm] [ft, in]	1410×715×629 4'-8" × 2'-4" × 2'-1"	1895×715×629 6'-3" × 2'-4" × 2'-1"
Height of work surface	[mm] [ft, in]	970 3'-2"	970 3'-2"
H_2O_2 type	[L] / [%]	Standard: 1.0 / 35, optional: 2.5 / 35	
Operating pressure	[Pa]	-60 or +60 (please specify when ordering)	
Air velocity Downflow laminar airflow	[m/s]	0.45 +/- 20% 0.25 (standby)	
Air consumption isolator / airlock	[m^3/h]	500–650 400–750	
Working area material	Type	Stainless steel AISI 316L (EN 1.4404) Ra ≤ 0.8 µm	
Housing material	Type	ABS polymer	
Window material	Type	Double-glazed safety glass	
Exhaust (double filtration)	Type, filter class	HEPA H14 filtration (SKAN FiPa) (standalone operation, connection to building's air exhaust system not required)	
Airlock filter	Type, filter class	Intake air HEPA H14 filter plate / exhaust air HEPA H14 SKAN FIPA	
H_2O_2 catalytic converter	Type	SKAN nanox®, patented SKAN technology	
Operation	Type	Built-in controller with 9" colour touch screen, GAMP 5 Category 4	
Interfaces	Type	USB	
Illumination	[lx]	> 800 in the working chamber	
Air supply pressure	[bar] / [Nm^3/h]	6–10 / 7.5–22, class 1.3.1 (as per ISO 8573-1:2010)	
Sound level	db (A)	max. 65	
Power supply (single phase)	[VAC] / [Hz] / [W]	220 - 240 / 50 - 60 / max. 3800	
Gloves	Type	Standard: 1-part gloves (butyl) Optional: 2-part gloves (butyl glove, CSV cuff) / glove change system	

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