
# The unique solution for a pure environment

SKANFOG® PURE, the essence of an isolator

Together always one step ahead

# SKANFOG® PURE

## 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.

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### Your Needs

- Cost effective Grade A, ISO 5 containment that eliminates full cleanroom requirements
- Wide application range
- Fast and automated decontamination cycles by $H_2O_2$
- 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 $H_2O_2$ 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
- 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

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

## Versatile

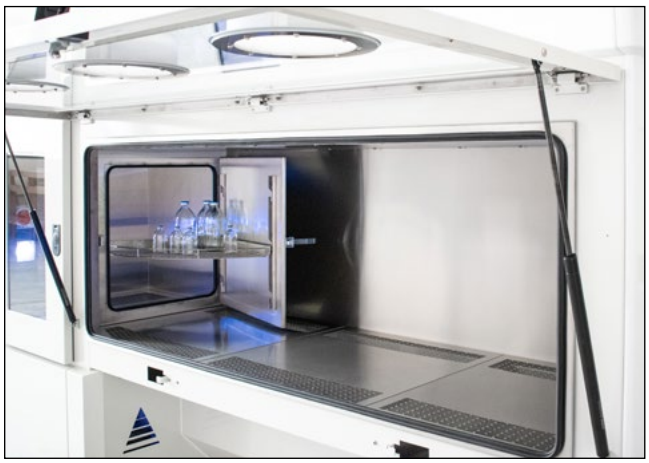
SKANFOG® PURE offers a wide application range from pharmaceutical-biotech laboratories to hospital and clinical pharmacies, from compounding operation to cell culture and genetics, from animal and research industries to medical field.  Common fields are:

- 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 and Gene

## 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)
- cTUVus certified

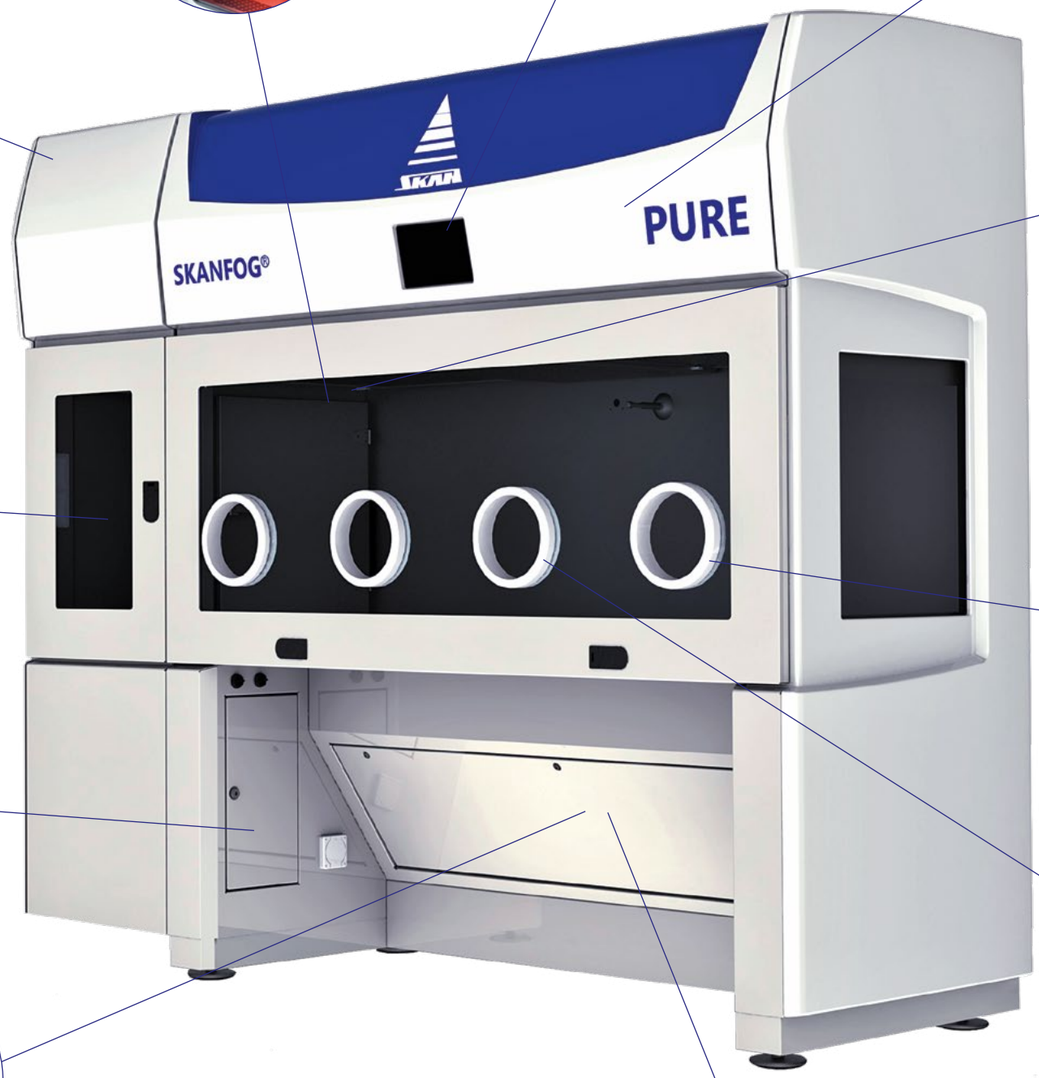


**Alarm indicator**
In the event of an alarm, the chamber light turns to red for a convenient visible alert.

**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.

**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.




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

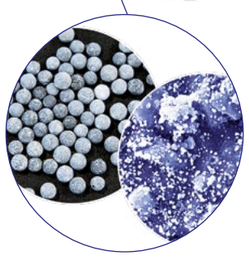
**Airlocks**
The airlock (equipped as a standard with a shelf) can be available on the right, on the left or on both sides of the isolator.

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

**$H_2O_2$ 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 %.

**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 $H_2O_2$ (<99.99 %) allows an air saving operation by direct air exchange with the room environment.

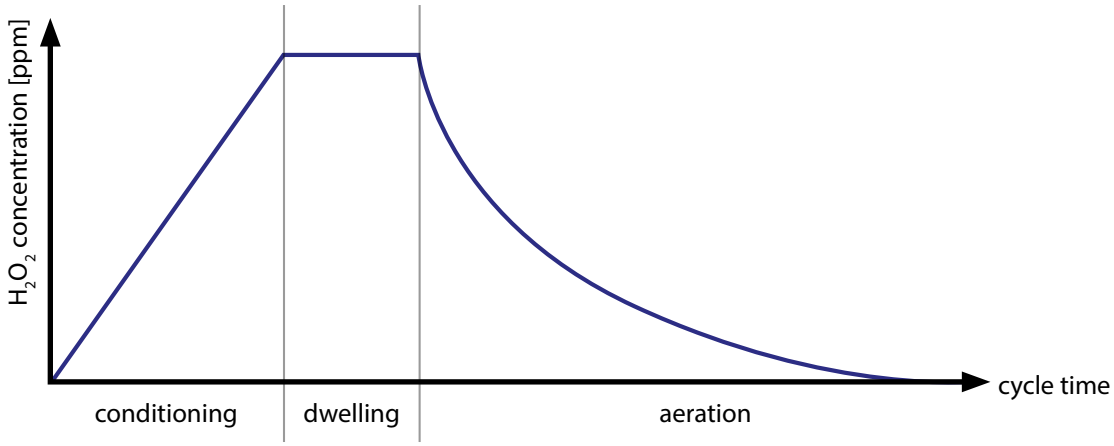
# Innovative Decontamination Solution

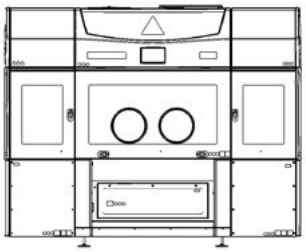
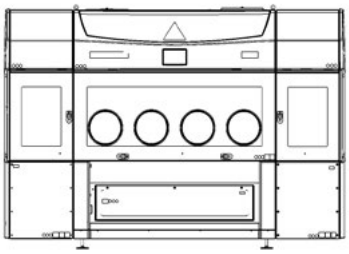
## SKANFOG®

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 10e6 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]<br>[ft] | 2811 × 955 × 2277<br>9′-3″ × 3′-2″ × 7′-6″ | 3300 × 955 × 2277<br>10′-10″ × 3′-2″ × 7′-6″ |
| **Useful chamber [wxdxh]** | [mm]<br>[ft] | 1410 × 715 × 629<br>4′-8″ × 2′-4″ × 2′-1″ | 1895 × 715 × 629<br>6′-3″ × 2′-4″ × 2′-1″ |
| **Max. height of load** | [mm]<br>[ft] | 970<br>3′-2″ | 970<br>3′-2″ |
| **$H_2O_2$ type** | [L] / [%] | 2.5 / 35 | |
| **Operation pressure** | [Pa] | -60 or +60 (tbd at order) | |
| **Air velocity down flow** | [m / s] | 0.45 + / - 20 % | |
| **Air consumption isolator / airlock** | [$m^3$ / h] | 550…650 / 300…550 | |
| **Material working chamber** | Type | Stainless steel<br>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 | |
| **$H_2O_2$ catalyst** | Type | Patented SKAN NANOX® | |
| **Control system** | Type | Embedded control system with 10″ color touch screen control panel, GAMP 5 | |
| **Interfaces** | Type | USB | |
| **Light** | [lx] | Min. 800 inside the chamber | |
| **Pneumatic air supply** | [bar] / [$Nm^3$ / h] | 6-10 / 10 | |
| **Noise level** | db (A) | Max. 60 | |
| **Power supply** | [VAC] / [Hz] / [W] | 230 / 60 / max. 3000 | |
| **Gloves** | Type | Standard: 1-piece gloves (butyl)<br>Options: 2-piece gloves (butyl gloves, CSV sleeves) / Glove changing system | |
| **Available options** | • Independent hydrogen peroxide sensor (TLV) for room installation<br>• Multi piece stainless steel rack & shelves<br>• SKAN glove tester<br>• Glove stretchers<br>• Air velocity in chamber optional<br>• Environmental monitoring for viable (handheld) and non-viable particles (mechanical interface pre-installed)<br>• Secure RTP (rapid transfer port) transfer systems<br>• Qualification & validation services (IQ / OQ)<br>• Microbiological qualification (MBQ)<br>• Further options available upon request | | |

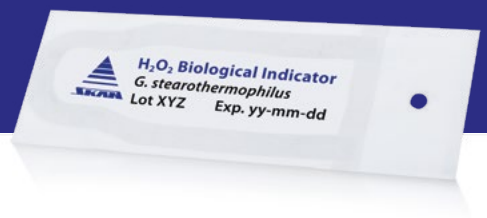
According GMP Annex 1 air speed can be set to 0.45 m / s (+ / -20%). In case non GMP application air speed will be set to 0.25 m / s.
Contact (skin contact, ingestion, inhalation) with hydrogen peroxide ($H_2O_2$) can lead to serious health problems! It is recommended to use an independent $H_2O_2$ TLV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

**WirelessGT**

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

**SKAN BI®**

The biological indicator for $H_2O_2$ decontamination: designed for outstanding performances.


**SKAN AG**
Binningerstrasse 116
4123 Allschwil
Switzerland
Phone +41 61 485 44 44
info@skan.ch
www.skan.ch

**SKAN Stein AG**
Rüchligstrasse 296
CH-4332 Stein
Switzerland
Phone +41 62 873 18 41
info.stein@skan.ch

**SKAN Deutschland GmbH**
Nickrischer Straße 2
02827 Görlitz/Hagenwerder
Germany
Phone +49 358 223 789 0
de.info@de.skan.ch

**SKAN US, Inc.**
7409 ACC Blvd., Suite 200
Raleigh, NC 27617
USA
Phone +1 919 354 638 0
sales@us.skan.ch

**SKAN Japan**
5194-6 Katsurenhaebaru,
Uruma-shi, Okinawa 904-2311,
Japan
Phone +81 989 349 922
info@skan.ne.jp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