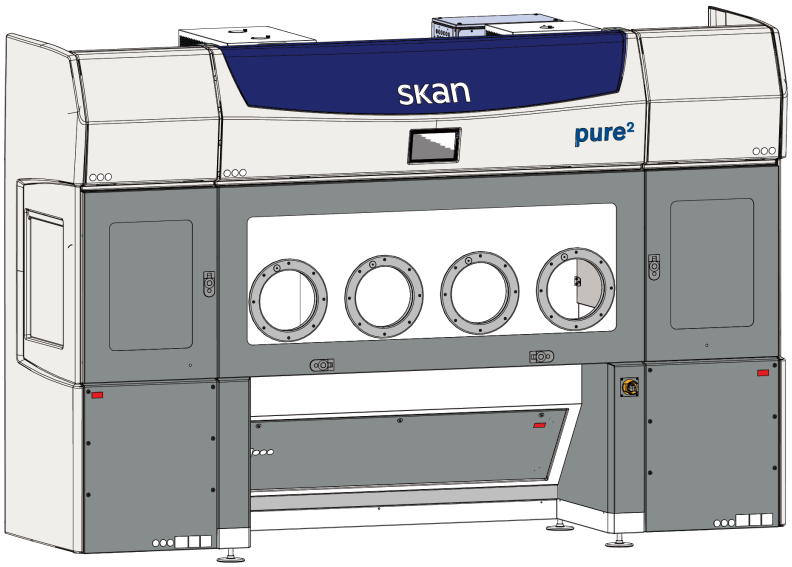
SKAN pure²

Glue nameplate here !



Operating manual

EN

Original

466146_G

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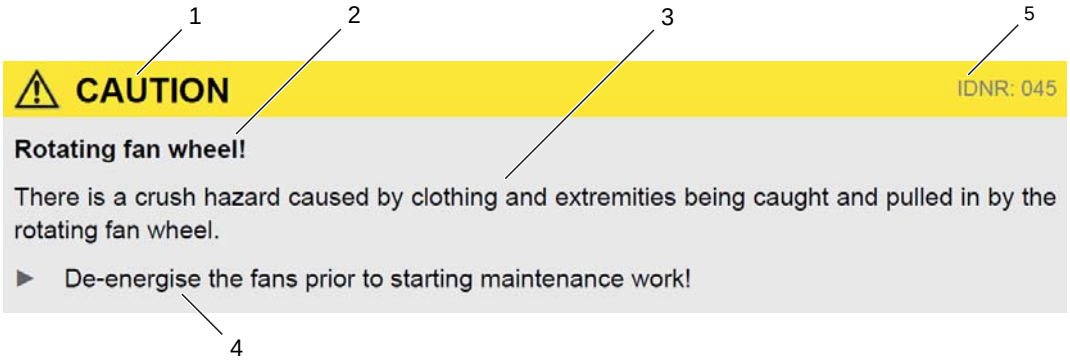
Table of contents

1 Version control

Version	Initials	Description / Changes made	Valid from
A	schwla1	First version for release.	19.09.2023
B	schwla1	Formal error in the versioning. No changes.	06.02.2024
C	schwla1	Update of the name plate and technical data.	29.04.2024
D	schwla1	Update chapter "Alarm list and description".	18.06.2024
E	schwla1	Update chapter "Access rights".	14.08.2024
F	schwla1	Update chapter "Intended use". Update chapter "Impermissible use".	04.10.2024
G	schwla1	Update chapter "Access rights". New group / level: 3	release

2 Layout and display of warnings

This document contains warnings alerting you to existing hazards. Warnings in this document are structured as follows:



1 Signal word
2 Type and source of the hazard - description of the existing hazard
3 Harmful incident (accident) which occurs/could occur when measures/prohibitions are not complied with
4 Measures/prohibitions which allow the harmful incident (accident) to be prevented
5 Identification number of the cross-reference to internal risk assessment

The **signal word** indicates:

- How severe the consequences of the harmful incident could be;
- How probable occurrence of the harmful incident (accident) is should measures/prohibitions not be complied with.

Signal word	Explanation
DANGER	If measures/prohibitions for preventing a harmful incident are not complied with, a harmful incident (accident) resulting in death or extremely severe injuries will occur. High probability of the harmful incident occurring.
WARNING	If measures/prohibitions for preventing a harmful incident are not complied with, a harmful incident (accident) resulting in death or extremely severe injuries could occur. Medium probability of the harmful incident occurring.
CAUTION	If measures/prohibitions for preventing a harmful incident are not complied with, a harmful incident (accident) with minor or medium injuries could occur. Low probability of the harmful incident occurring.
NOTICE	If measures/prohibitions for preventing a damaging incident (accident) are not complied with, damage to property will occur.

3 Service and information address

Address:	SKAN AG Kreuzstrasse 5 CH-4123 Allschwil
General phone:	+41 61 485 44 44
Service phone Isolators: (Industrial division)	+41 61 485 44 00
Service phone laboratory equipment: (Lab division)	+41 61 485 45 55
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4 Document validity

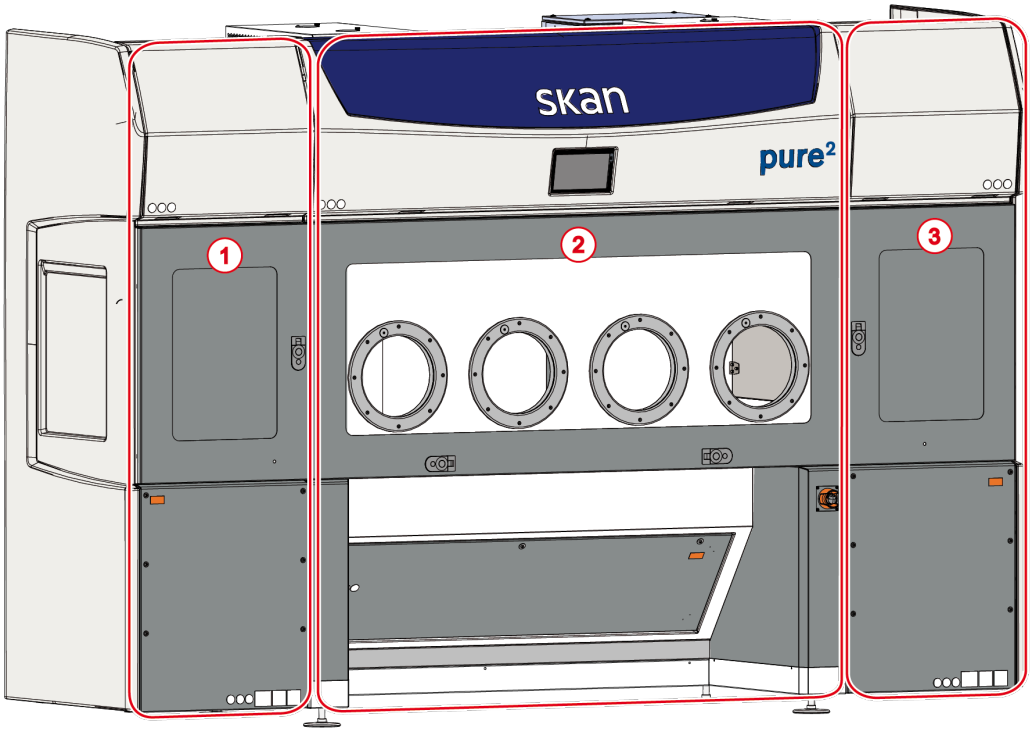
This document describes the options specific to the SkanPURE isolator.

The drawings / illustrations do not show the exact configuration of the isolator on site. They are exemplary to explain the operation and functionalities of the isolator.

5 Introduction

The SKANPURE is an isolator designed for a 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.

The SKANPURE consists optionally of a left airlock for material transfer (1), the main chamber (2) and optionally of a right airlock (3) for material transfer.



6 Information for your safety

6.1 Residual risks

The machines of SKAN AG are designed, built and tested according to the latest state of the art, in compliance with the applicable standards and regulations, and offer high operational safety and reliability. Nevertheless, improper transportation, assembly, operation, maintenance, disassembly and removal of the systems can pose hazards for persons and property.

Warning and safety messages in the operating manual, as well as warning signs and instruction labels on the system, informs about hazards that cannot be eliminated through design measures (residual risks).

- Read and observe the operating manual document that is relevant to you and your job.
- For your safety, observe all safety messages and warnings in the operating manual specific for the machine.
- Observe all warning signs and instruction labels on the machine.

6.2 Minimum qualifications for machine operators

Errors during operation can lead to unforeseeable hazards and risks.

► The machines of SKAN AG shall only be operated by trained persons who have been instructed in the operation of SKAN machines.

6.3 Decontamination of the machine with hydrogen peroxide (H_2O_2)

In case of contact (touch, ingestion, inhalation) with hydrogen peroxide (H_2O_2), serious damage to health can result!

1. When decontaminating the machine, be sure to observe the safety sheet on hydrogen peroxide (H_2O_2).
2. Observe the legal regulations when handling hydrogen peroxide (H_2O_2)!
3. Check the machine regularly according to the maintenance schedule for integrity (leaks).
4. After each decontamination cycle it is recommended to perform a residual H_2O_2 concentration measurement inside the decontaminated area (e.g. by using Dräger tubes).

6.4 Unexpected release of hydrogen peroxide (H_2O_2)

Damage to health due to inhalation of hydrogen peroxide (H_2O_2)!

The power supply for the TLV (Threshold Limit Value) sensor is provided by the isolator's integrated control cabinet. If the isolator is switched off or the power supply of the isolator fails, the TLV sensor is no longer supplied with power, which means that it can no longer measure the hydrogen peroxide concentration of the ambient environment. Alarming by the TLV sensor is no longer possible in this condition.

1. Ensure that only trained personnel are in the clean room as soon as the isolator is switched off or the power supply of the isolator fails!
2. Observe the safety sheet for hydrogen peroxide!
3. When changing H_2O_2 bottle, wear appropriate personal protective equipment!
4. Ensure that the power supply to the TLV sensor is restored as soon as possible!

6.5 Operating media of the plant, as well as substances handled and generated during the production process

Operating media of the plant, as well as substances handled and generated during the production process, can pose health hazards.

1. Observe the material safety data sheets (MSDS) of substances with which you might get into contact during operation of the plant.
2. Protect yourself against possible hazards by wearing appropriate personal protective equipment (PPE).
3. Observe the valid legal regulations and recommendations when handling the plant's operating media.
4. Observe the valid legal regulations and recommendations when handling the substances used and generated during the production process.

6.6 Only process toxic and biohazardous substances after taking into account the utilised filters (systems)

If toxic or biohazardous substances are processed in the isolator, these have to be completely trapped by the utilised filters (systems). This alone can prevent these substances from escaping the isolator, and thus prevent exposure of humans and the environment to these substances!

1. Make sure that only such microbiological substances, organisms, etc., are processed in the isolator, which it is possible to trap with the utilised filters (systems);
2. Observe the intended use of the isolator! Only process such substances in the isolator for which it has been approved.

6.7 Operating machine components of other manufacturers

Components or devices may be built into the machines of SKAN AG that are not constructed and marketed by SKAN AG. Information regarding safety as well as information on the operation of these components can be found in the document at hand as well as in the original operating manuals of the component manufacturer.

▶ Also observe the original operating manual of the component manufacturers when operating the machine. The original operating manual can be found in the **appendix to the instruction handbook**.

6.8 Manual cleaning of the working chamber and of the entire system

During manual cleaning of the working chamber and of the entire system, possible dangers and risks shall be considered. They may result from reactions of materials that might remain in the working chamber, with the agents used for cleaning and disinfecting, as well as the surfaces to be cleaned and the ambient atmospheric conditions (temperature, humidity, etc.).

⚠ CAUTION

Cleaning utensils/materials can be ignited by hot components!

Fire hazard.

► After you finish your cleaning work, remove all cleaning utensils/materials out of the isolator.

▶ Find out what are the potential dangers and risks to which you may be exposed to, during the manual cleaning of the working chamber and of the entire system! Take appropriate precautions (wear personal protective gear, etc.)!

6.9 Using cleaning and disinfection agents

Cleaning and disinfection agents can have substances that are hazardous to health, are highly flammable and can form explosive mixtures.

- Observe the safety instructions and safety data sheets of the cleaning and disinfection agents used.
- During cleaning and disinfection tasks, adhere to the applicable output rates for the cleaning and disinfection agents used.
- In systems with integrated heat sources, do not use cleaning and disinfection agents that contain alcohol.
- Observe the additional information on cleaning and disinfection agents.

6.10 Flow visualisation in the containment

During comprehensive flow visualisation when using organic fluids, the media used for visualisation can deposit in the suspended matter filters of the circulation zone. Possible consequences are:

✓ Increased pressure loss through the HEPA/ULPA filters (circulation zone);
✓ Reduced H_2O_2 concentration during the decontamination in the work chamber;
✓ Reduced decontamination effect of the decontamination (increased D-value);
✓ Extended aeration times.

NOTICE

Irreversible damage to the HEPA/ULPA filter when using glycerin or triethylene glycol (TEG) for flow visualisation!

► Use neither glycerin nor triethylene glycol (TEG) for flow visualisation.
► For flow visualisation use fog generators with fog fluids approved for flow visualisation in clean rooms.

For flow visualisation SKAN recommends:

► *Fog generator: FlowMarker®*
► *Fog fluid: SAFEEX®-FLOWMARKER FOG FLUID*

When you have made flow visualisations in the containment:

1. Clean all accessible surfaces manually;
2. Aerate the containment for at least 72 hours or exchange the recirculated air filter of the containment;
3. Conduct at least three decontamination cycles to remove any deposits and soiling on the air-ducting systems.

6.11 Power interruption

If there is a sudden power interruption, all doors of the unit should be immediately closed.

It is recommended to use a UPS (Uninterruptible Power Supply) with the equipment. With this it is possible to switch off the unit in a safe way. Then the doors should be closed and in operating mode "Plant OFF" the [Shut Down] button should be selected. (Shut down procerur is discribed in ➦ *Chapter 17.3 'Switching off the machine and the controller' on page 41*.)

If power interruption occurred during H_2O_2 decontamination, it is recommended to check the residual concentration in the unit, before opening the unit.

It is always recommended, to have the H_2O_2 TLV sensor powered independently of the unit, to ensure functional H_2O_2 monitoring although the power to the unit is interrupted.

⚠ WARNING

If power interruption occurred during the H_2O_2 decontamination, a residual concentration of H_2O_2 will be in the unit!

► All doors should be kept closed until the Emergency aeration is completed after the restart!

6.12 Sudden power recovery or manual restart of the system after a power failure

Crushing injuries by movement of electrically driven system components when power is suddenly restored, or a manual restart of the system is performed, after a power failure.

- Beware of sudden power restoration after a power failure!
- Take appropriate precautions when power is restored not by the independent (general) electric network. Take appropriate precautions before turning the system on again!

6.13 Regular maintenance of the machine

The operational safety and reliability of the machine depends on trouble-free functioning of all protective equipment.

- Perform maintenance work and inspections at the intervals specified in the maintenance plan.

6.14 Maintenance work on pneumatic machine components

There is risk of crush injuries caused by sudden movements of pneumatically-powered machine components.

- Lock and secure the pressure air supply against being switched on again unintentionally.

6.15 Maintenance work on electrically operated machine components

There is risk of crush injuries caused by sudden movements of electrically powered machine components.

- Always de-energise electrical machine components before starting maintenance work.
- Lock the power supply / voltage source against being switched on unintentionally.
- Take suitable precautions when the machine is switched on again (avoiding danger from suddenly starting up fans or moving flaps when power is returned).

6.16 Checking the machine for leak-tightness (leak test)

If the machine is not gastight, H_2O_2 could escape from the working chamber during decontamination.

With the manual leak test, after service and maintenance work, you can check whether the machine is sealed gas-tight and can hold pressure.

▶ Perform a manual leak test, after each service and maintenance work!

6.17 Minimum qualifications for maintenance and service personnel

Errors during maintenance and installation work can lead to unforeseeable hazards and risks.

- The machines of SKAN AG shall only be serviced and repaired by trained maintenance and service personnel who have been instructed in the maintenance of SKAN machines.

6.18 Troubleshooting

Rectifying malfunction of the machine can be dangerous. Improper rectifications of malfunctions of the machine (troubleshooting) can lead to impairment of the machine functionality as well as unforeseeable hazards.

- Only conduct troubleshooting measures if you have the appropriate specialised knowledge.
- If you have any questions, please contact the Service department of SKAN AG.

6.19 Maintenance work on components of the decontamination system

When performing maintenance on components of the decontamination system, there is a risk of chemical burns, eye injuries as well as serious damage to health due to touching, swallowing or inhaling hydrogen peroxide.

- Observe the safety data sheet for hydrogen peroxide.
- Wear personal protective equipment appropriate to your maintenance work.

6.20 Replacement of machine components

Replacing machine components with spare parts of a different type or from a different manufacturer can lead to system malfunctions and impairment of the machine output with unforeseeable hazards.

- Only use spare parts with identical specifications (identical type and manufacturer) as per spare parts list to replace system components.

6.21 Using the transfer shelf in the airlock

For the transfer of liquids in closed containers, such as gas bottles or infusion bags, these should be placed in a suitable tray on the shelves to catch any spillages.

Recommended stainless steel trays 1.2L resistant to H_2O_2 from Carl Roth Laborbedarf (order no. YH71.1) or comparable product.

6.22 Disposal

Improper disposal of the machine or machine components can cause hazards to humans and the environment.

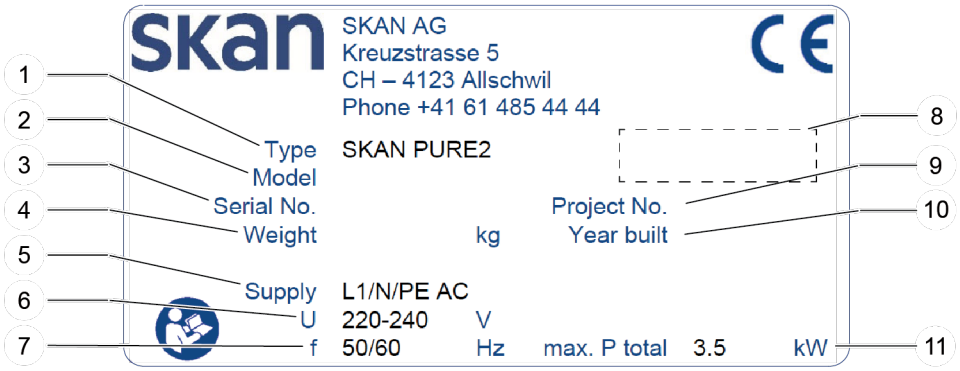
- Dispose of the machine or machine components in compliance with the pertinent laws, regulations and directives.

7 Machine conformity

The machine declaration of conformity is provided with the equipment.

8 Machine identification

The machine is identified by the machine's nameplate. The nameplate is mounted on the left, below the isolator door.



1 Type designation of the machine
2 Model designation, possibly variant of the machine;
Safety-relevant operating parameters only with specification according to DIN 12980
3 Serial number
4 Weight of the machine in "kg"
5 Characteristic values of the supply system
6 Voltage range of the machine in "V"
7 Frequency range of the machine in "Hz"
8 Text field depending on the valid standard for country of operation resp. additional information:
- for UL: "In accordance with UL61010-1"
- for EU DIN 12980: "IfZ nach DIN 12980:2017 / V_{av}=0.25m/s, P=-60Pa"
9 Project number - Skan internal number
10 Year of construction
11 Maximum total power of the machine in "kW"

9 Information on machine use

9.1 Intended use

The machine is suitable for:

- Processing / manufacturing of aseptic pharmaceuticals and products
- Processing / manufacturing of toxic pharmaceuticals and products (CMRs)
- Pharmaceutical mixing at low levels (combination, mixing, modifying ingredients to create individual medications for patients)
- Applications in which manual filling machines are integrated in the isolator
- Installation in an EMC-controlled environment

9.2 Overview of the production process

The machine offers a mechanical separation between the controlled room environment and the inner environment (work chamber) in which the pharmaceutical product is processed. The inner environment of the machine makes it possible to process the pharmaceutical products in accordance with the application and product requirements.

The machine provides 'Grade A' cleanroom conditions in accordance with EC guidelines. This means that ISO class 5 (acc. to SN EN ISO 14644-1) is achieved in the work chamber on the inner, freely accessible surfaces.

An automatic decontamination system is integrated in the machine. This ensures a surface decontamination and its maintenance on all internal work surfaces, transfer openings and connections.

9.3 Impermissible use

The machine **is not suitable**:

- For use as an isolator for filling of substances with explosive properties;
- For use as an isolator for filling of dusts and powders;
- For use as an isolator for filling of hydrogen peroxide-sensitive substances;
- For use as an isolator in which hydrogen peroxide-sensitive components or materials are installed;
- For operation in potentially explosive areas pursuant to 1999/92/EC Appendix 1;
- For vaporisation of hydrogen peroxide (H_2O_2) for a purpose that is not part of a surface decontamination within the scope of the intended use;
- For installation in a household-like environment.

10 Technical data

10.1 Supply media

The precise specifications of the needed supply media can be found in the documents Pure Supply Connections.

10.2 Dimensions and weight

Identification	Value
Dimensions	See machine layout
Weight	See nameplate on front page of this document

10.3 6.3 Environmental conditions

Identification	Value
Environmental Temperature	10-24 °C
Humidity	20-65 % rH
Altitude	max. 2000m above sea level

10.4 Electrical connection and consumption values

Identification	Value
Mains (supply)	L / N / PE AC L1 / L2 / PE AC (USA/CA only)
Operating voltage	220 V-240 V
Frequency	50 Hz / 60 Hz
Max. input power	* max. 3.5 kW
Nominal current	* max. 15 A
Control voltage	24 V DC
Overvoltage category	Intended for connection to an electrical supply network of overvoltage category II.
Degree of pollution	2 according to IEC 61010-1
Protection against intrusion (IP class)	20 according to IEC 61010-1

* Maximum values valid in case of a complete assembly with airlocks and all configuration options included.
Local electrical installation must consider maximum load of the unit and comply to current regulations.

Please find the current consumption values on the machine's nameplate on the front page of this document.

Plug socket

The plug sockets are powered and connected by the operator!

The plug socket must be secured in accordance with the applicable local regulations.

DANGER

Even when the machine is switched off, these sockets are still under dangerous voltage!

Danger to life and death by electrocution!

- ► Avoid contacting of energised parts!
- ► Before maintenance and service work disconnect the power supply to the sockets!
- ► If you are unsure, please contact the Service department of Skan!

10.5 Ground connection

When connecting the system, the local regulations must be observed.

For safety reasons, an additional grounding of the system must be carried out professionally. For this purpose, screw terminals (PE/green/yellow) are also available in the electric box. These must be connected to the grounding of the building using a suitable cable or strand with a cross-section of at least 6 mm^2.

10.6 Pneumatic connection values

Identification	Value
Pneumatic connection (supply)	6 - 10 bar, 22 Nm^3/h, 8 mm Festo plug, ISO 8573-1:2010 Class 1.3.1

10.7 Sound pressure level and light intensity

Identification	Value
Sound pressure level	< 65 db(A) acc. to EN 12469: 2000 < 60 db(A) acc. to DIN 12980: 2017
Light intensity	> 800 lx, 300 mm above ground of the work chamber

10.8 Decontamination process values

Identification	Value
Consumption of H_2O_2	Main chamber: about 15 ml Airlock: about 7.5 ml

The specified values are estimates and can still change because of the cycle development; the specified values are valid for the entire decontamination.

10.9 Work chamber process values

Identification	Value (production)	Value (decontamination cycle)
Cleanroom class	A	n.a.
Differential pressure	Aseptic: 60 Pa Toxic: -60 Pa	During Conditioning and Holding phase: 0 Pa. During Aeration: acc. value (production).
Temperature	n.a.	17-28 °C
Relative air humidity	n.a.	< 25% start decontamination
Air velocity	0.2 - 0.3 m/s according DIN 12980 0.36 - 0.54 m/s according GMP Annex 1	n.a.

10.10 Airlock process values

Identification	Value (production)	Value (decontamination cycle)
Cleanroom class	A	n.a.
Differential pressure	Aseptic: 40 Pa Toxic: -40 Pa	During Conditioning and Holding phase: 0 Pa. During Aeration: acc. value (production).
Temperature	n.a.	17-28 °C
Relative air humidity	n.a.	n.a.
Air velocity	0.2 - 0.3 m/s according DIN 12980 0.36 - 0.54 m/s according GMP Annex 1	n.a.

11 Specification hydrogen peroxide 35%

Use hydrogen peroxide (H_2O_2) in the SKANPure only in original containers and with the following specification.

Observe the safety data sheet of the product used.

Supplier:	Solvay
Specification:	H_2O_2 INTEROX SG-35%
Item number (Solvay):	SG-35
Container:	Plastic bottle, black, 1 litre or 2.5 litre

If other product use is required, it needs to be according to the recommendation of SKAN.

12 Features

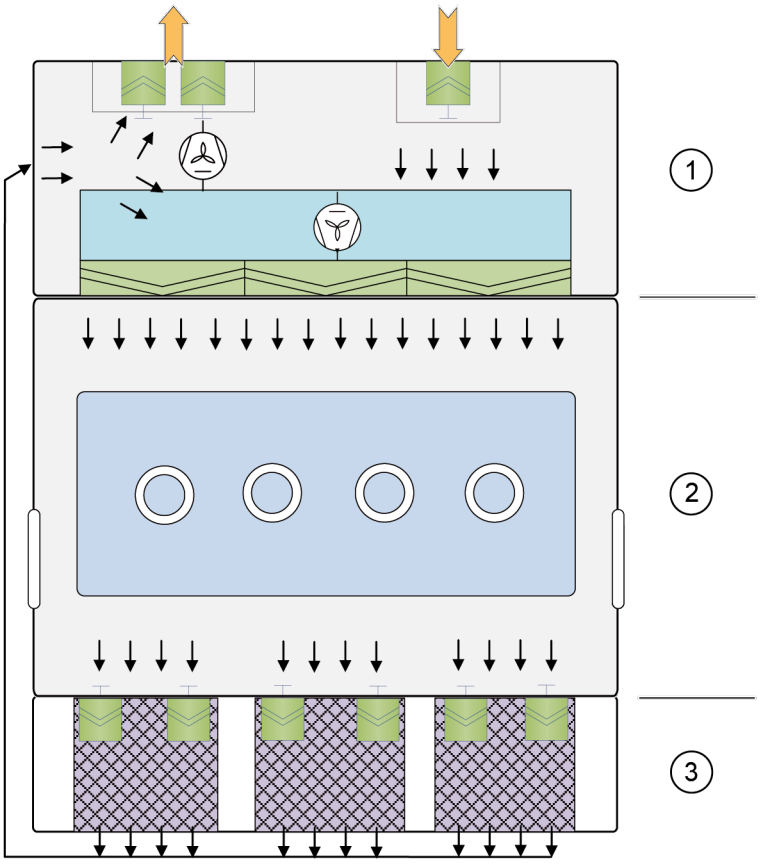
12.1 Zone concept

12.1.1 Main chamber zone concept

To assure proper function of the main work chamber, it is sealed off from the environment during the production (isolator doors are closed, intake and exhaust air is separated by HEPA filters).

For the main chamber three zones are defined for production (see the following figure). Each zone demonstrates specific properties and requirements with respect to:

- The filtered air (single HEPA filtered or double HEPA filtered);
- The decontamination status, if decontamination is required (decontaminated or not decontaminated).



1 **Intake and exhaust air zone:**
- not classified area
- HEPA filtered

2 **Main chamber:**
- classified area
- double HEPA filtered
- decontaminated (if decontamination required)

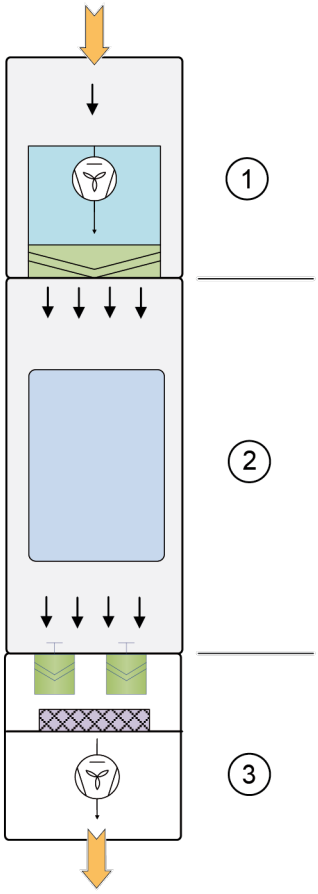
2 **Circulated air zone:**
- not classified area
- HEPA filtered

12.1.2 Airlock zone concept

To assure proper function of the airlock, the airlock chamber is sealed off from the environment during the production (doors are closed, intake and exhaust air is separated by HEPA filters).

For the airlock two zones are defined for production (see the following figure). Each zone demonstrates specific properties and requirements with respect to:

- The filtered air (single HEPA filtered or double HEPA filtered);
- The decontamination status, if decontamination is required (decontaminated or not decontaminated).



1 **Intake air zone:**
- not classified area
- not HEPA filtered

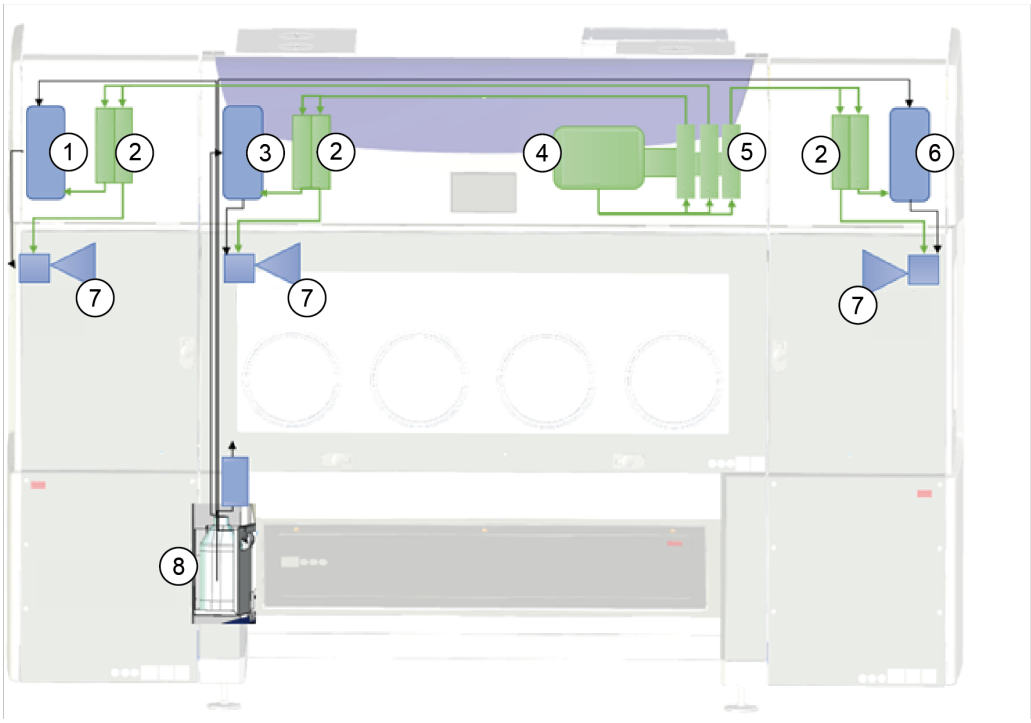
2 **Airlock chamber:**
- classified area
- HEPA filtered
- decontaminated (if decontamination required)

3 **Exhaust air zone:**
- not classified area
- HEPA filtered

12.2 SKANPURE® decontamination system

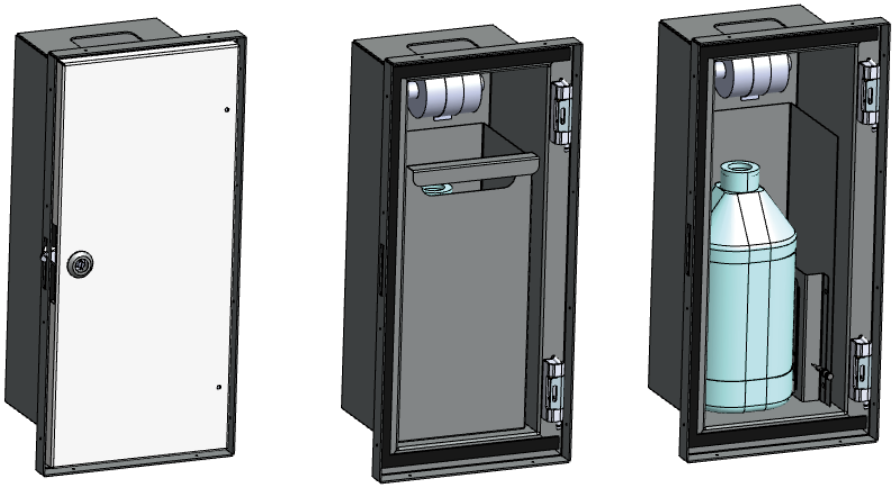
The SKANPURE® ensures a defined reduction of the microbial contamination on the surfaces in the isolator using nebulized Hydrogen Peroxide (H_2O_2). SKANPURE® is a process for the application of H_2O_2 surface decontamination in a sealed system.

12.2.1 SKANPURE® main components



1 Cloud dosing system - Left airlock
2 Filter system of the cloud
3 Cloud dosing system - Main chamber
4 Main pneumatic system
5 Valves of the pneumatic system
6 Cloud dosing system - Right airlock
7 Spray nozzles
8 H_2O_2 Station with storage bottle

12.2.2 H_2O_2 Station



The H_2O_2 Station of the SKANPURE® Decontamination system is situated at the lower part of the isolator and collects the initial supply of aqueous H_2O_2 solution. The complete H_2O_2 Station unit is integrated in a separate housing. The bottle is connected with tubes to each Cloud. An active-carbon based filter is placed inside the H_2O_2 Station connected to an outlet on the cap of the bottle. It ensures that gaseous H_2O_2 escaping the bottle is decomposed.

A low limit sensor is placed inside the H_2O_2 station to detect if enough H_2O_2 is available for a complete decontamination.

⚠ WARNING

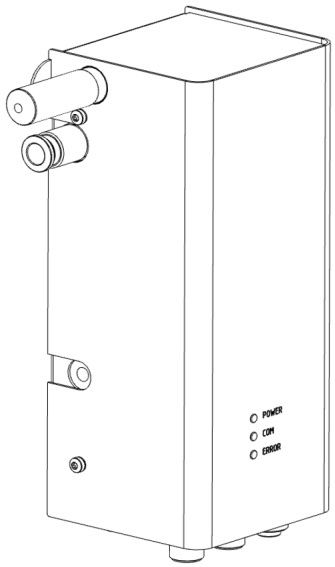
The Cloud station is used to storrage and provide peroxide (H_2O_2) for the decontamination process!

Touching, swallowing or inhaling hydrogen peroxide can cause chemical burns, eye injuries and other damage to health.

- ► Observe the safety sheet for hydrogen peroxide.
- ► Only use hydrogen peroxide in accordance with the specifications provided here.
- ► Use hydrogen peroxide in the original containers only.
- ► When performing maintenance activities at the Cloud station, wear appropriate personal protective equipment.
- ► When replacing components, use only spare parts compliant with the spare parts list.

12.2.3 Cloud dosing system

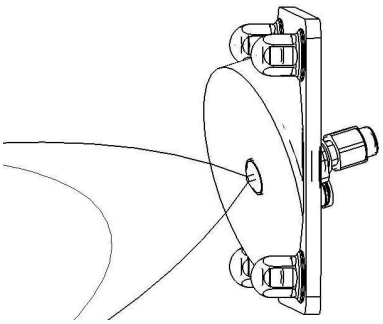
The SKANPURE® Cloud system is used to provide the correct amount of H_2O_2 with the correct dosing rate for the decontamination process. The SKANPURE® Clouds are mounted close to each of the SKANPURE® spray nozzle. The correct amount of H_2O_2 is calculated using the Cloud.



Details of the Cloud functionality and installation are described in the quickstart guide.

12.2.4 SKANPURE® spray nozzle

The SKANPURE® decontamination system makes use of a so called SKANPURE® nozzle (external mixing type) which is located outside the isolator chamber and sprays into the chamber. The gas flow supports distributing the fog in the whole chamber and over time, the droplets vaporize and the H_2O_2 ends up in vapor phase.



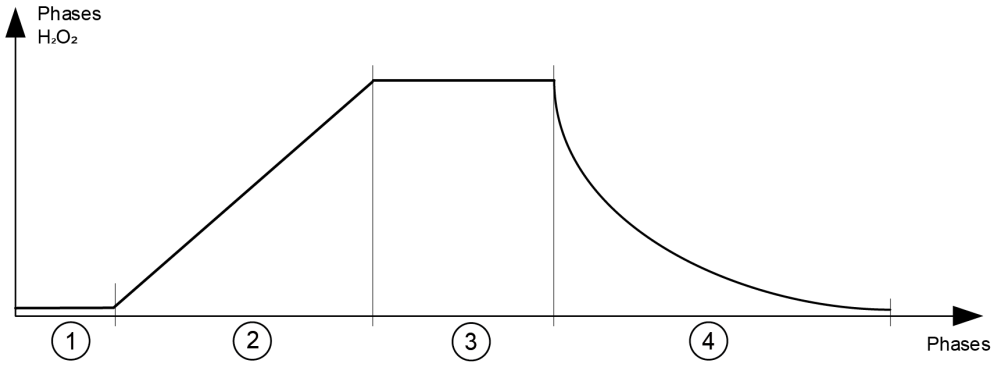
12.2.5 Pneumatic Air Supply

The Pneumatic Air contains of valves, filters and tubes. The Pneumatic Air is needed for the dual phase SKANPURE® nozzle. The high pressure of the pneumatic air is directly expanded externally of the SKANPURE® nozzle and thus vaporizes the H_2O_2 leaving the nozzle. Additionally the air is used to distribute the H_2O_2 in the isolator. For the drying purpose and for the leak test the same air supply through the SKANPURE® nozzle is used.

12.2.6 SKANPURE® decontamination process

During the H_2O_2 surface decontamination, the desired microbial reduction is achieved by the release of H_2O_2 into the chamber and the induction of the lethal dose over time. The SKANPURE® process deserves specific hardware and sequences. During the decontamination cycle of the Pure system, hydrogen peroxide is distributed directly via the SKANPURE® spray nozzles into the isolator.

The H_2O_2 surface decontamination is generally implemented in four stages:



- **Phase 1: Preconditioning**

  The necessary starting conditions for decontamination are created in the decontamination system during the Preconditioning phase. The SKANPURE® mainly dries the unit down to appropriate humidity conditions and the H_2O_2 line to the Clouds are filled.
- **Phase 2: Conditioning**

  During the Conditioning phase, the dosage of gaseous H_2O_2 required to achieve the desired decontamination effect is generated in the airlock chamber. For this purpose a defined quantity of H_2O_2 from aqueous solution is nebulized directly into the chamber of the isolator.
- **Phase 3: Holding**

  During the Holding phase, the isolator is exposed to the applied H_2O_2 dose over a defined time.
- **Phase 4: Aeration**

  During the Aeration phase the flushing of isolator with HEPA filtered fresh air, ensures that the maximum residual H_2O_2 concentration [ppm] required in the chamber is achieved. The air vented out of the isolator is decomposed through catalytic converter before it is reintroduced through the HEPA Filter into environment.

12.2.7 Tests before commissioning

Leak tightness of the system at defined test pressure

The leak tightness of the containment system for which the SKAN Cloud is used has to be determined at a defined test pressure before the commissioning. The test procedure, in particular the maximum permissible leak rate, needs to be determined by the plant integrator in the course of a risk analysis. Aspects such as health hazards and poor decontamination effect due to volatile (escaping from the airlock chamber during the decontamination) hydrogen peroxide aerosols need to be taken into account thereby. The test procedure has to be determined and carried out in accordance with ISO 10648-2 "Containment enclosures -- Part 2: Classification according to leak tightness and associated checking methods".

Correct positioning of the H_2O_2 station

The correct positioning of the dosing station needs to be checked before the commissioning. The positioning of the H_2O_2 station must conform to the specifications for technical installation conditions for a safe plant operation.

Guarantee of defined compressed air supply for H_2O_2 station and SKANPURE® nozzles

The compressed air supply of the H_2O_2 station and the SKANPURE® nozzles must be checked before commissioning. Care must be taken to ensure that the required compressed air in terms of quality, quantity and pressure is guaranteed for plant operation.

Test sequence

Before performing a decontamination sequence of the SKAN pure2, the user has to perform successful test sequence of the Cloud.

For every change of the liquid in the bottle of the H_2O_2 station, when any tubing is changed or when parameters of the Cloud have changed, a successful test sequence has to be performed to ensure proper operation of the Cloud.

12.3 H_2O_2 TLV Sensor

The H_2O_2 low concentration measurements of the surrounding room provide an indicative measurement of the H_2O_2 gas concentration [ppm] at any time and triggers an alarm when the allowed Threshold Limit Value (TLV = 0.5 ppm) exceeds. The Pure² is only delivered optionally with separately powered TLV sensor. Each unit however includes a dry contact for connecting a TLV sensor.

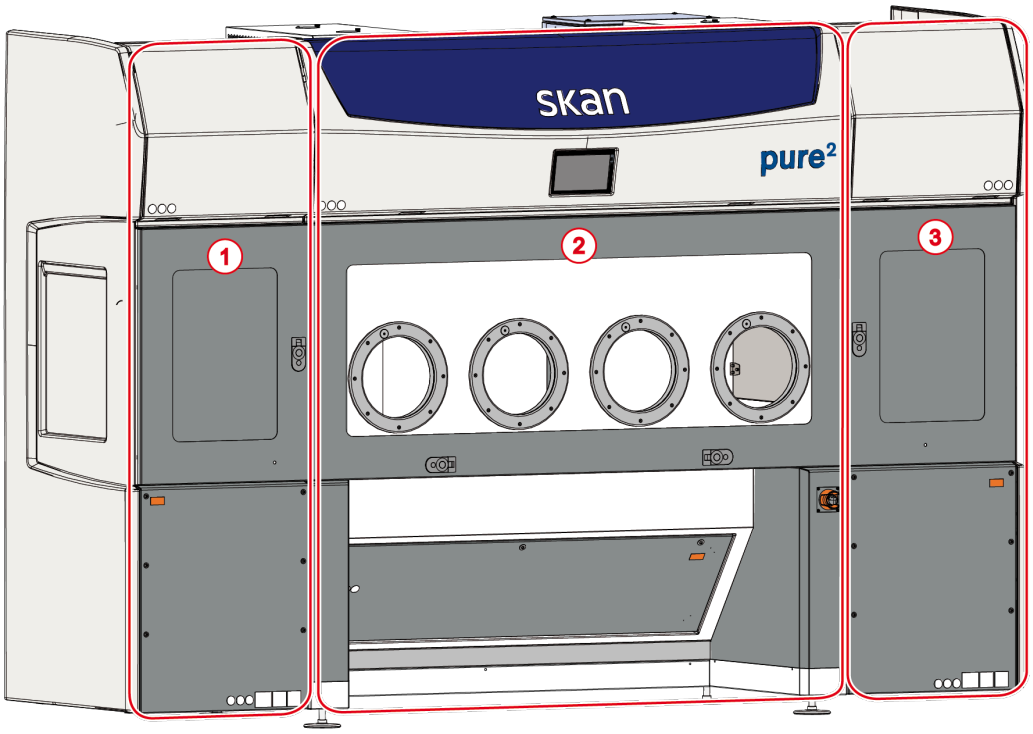
It is always recommended to have an independently powered H_2O_2 TLV sensor located close to the operator at the isolator.

13 Machine layout

13.1 Machine sections and process elements

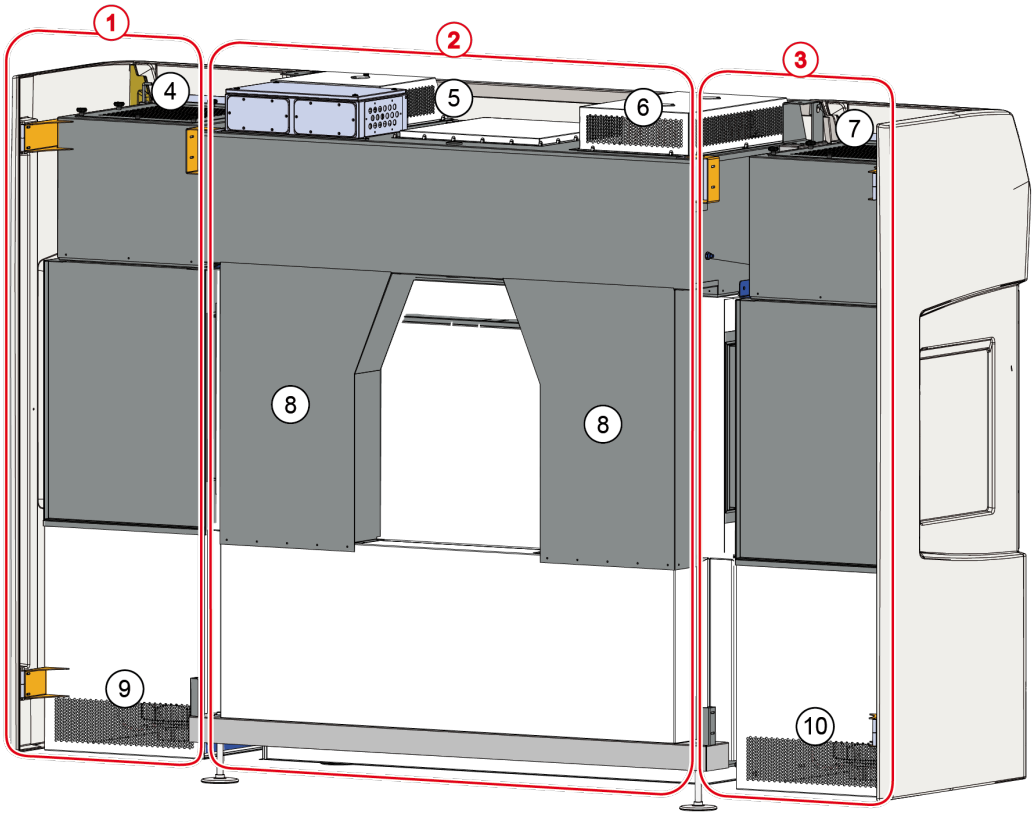
The machine can be divided into machine sections on the basis of its functional units. The machine sections and their most important process elements are shown on the following diagrams:

13.1.1 Front view



1 Left airlock
2 Main chamber
3 Right airlock

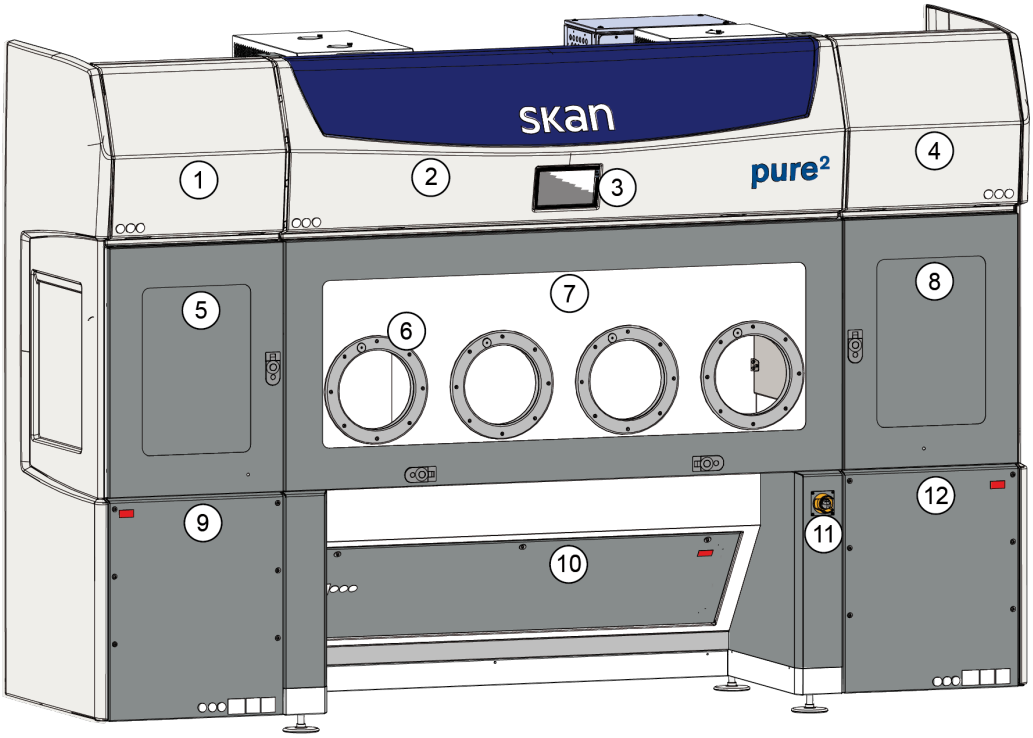
13.1.2 Back view



1 Left airlock
2 Main chamber
3 Right airlock
4 Intake air - Right airlock
5 Intake air - Main chamber
6 Exhaust air - Main chamber
7 Intake air - Left airlock
8 Return air channels - Main chamber
9 Exhaust air - Right airlock
10 Exhaust air - Left airlock

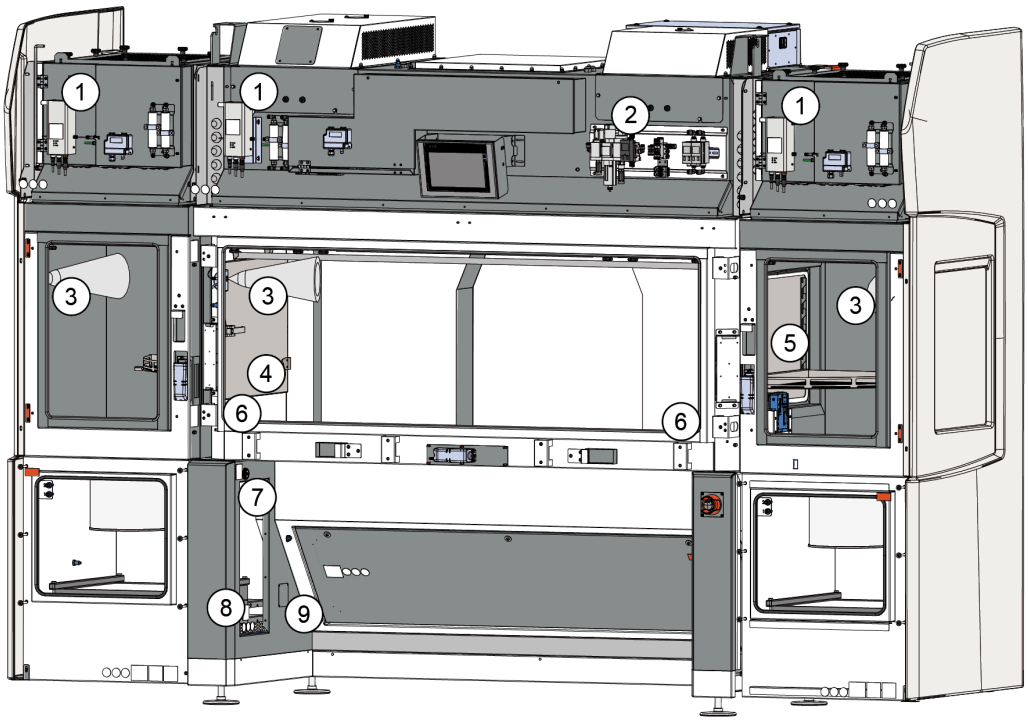
13.2 Important operating and display elements

13.2.1 Front view - doors closed



1 Left airlock
2 Main chamber
3 Operating panel (HMI)
4 Right airlock
5 Front door - Left airlock
6 Glove ports (exemplary)
7 Front door - Main chamber
8 Front door - Right airlock
9 FiPa service cover - Left airlock
10 FiPa service cover - Main chamber
11 Emergency button
12 FiPa service cover - Right airlock

13.2.2 Front view - doors open



1 SKAN® cloud
2 Pneumatic air supply
3 SKANPURE® spray nozzle
4 Transfer door - Left airlock
5 Transfer door - Right airlock
6 Power plug inside isolator
7 USB port
8 H_2O_2 station
9 Power plug outside isolator

14 Operator's position and hazard area

When operating the machine, the following areas shall be taken into consideration:

- **Operator's position**

  The operator's position is the area of the machine that shall be accessed by the operator for operating and controlling the machine within the scope of the intended use.

  For persons in this area, there is a slight injury risk, such as striking or crushing of limbs by careless opening or closing of the doors to the work chamber.

  This area shall be entered for operating the machine only under the condition that all information in the manual at hand, as well as the safety signs of the machine, is observed.

- **Hazard area**

  In the hazard area, there is an increased risk of injury such as crushing or severing of limbs by moving machine parts or electrical shock from current-carrying components.

  The hazard area of the machine encompasses the complete service area of the machine for maintenance and repair work, as well as that area of the machine that is defined as hazard area by the machine operator.

  This area shall **not** be entered!

Operator's position and hazard area can be defined only in coordination with the operation or the operational readiness of the machine or other devices needed for the work process.

Operator's position and hazard area shall always be defined by the machine operator, taking into account all possible dangers that result from the joint operation of isolator and other devices needed for the work process; the operator's position and the hazard area shall be separate from each other.

15 Commissioning the machine

Commissioning the machine shall only be done by SKAN AG or by technicians trained and authorised by SKAN AG. Adjustments of any component (e.g. airflow velocity) without the consent of SKAN could cause cross contamination and destroy products.

16 Visual and audible signalling of malfunctions and status of the machine

A current machine malfunction is indicated as follows:

- Red illumination of all chambers;
- Acoustic warning signal;
- Alarm message on the control panel;
- Dedicated machine reaction depending on type of alarm or STATE in which the alarm occurred;
- Acoustic warning signal when power is interrupted.

17 Start-up and shut down the machine

17.1 Switching on the machine

Prerequisites:

✓ A safe starting up of the machine is ensured (no persons in the machine's hazard area for example);
✓ Front doors are closed;
✓ Transfer doors are closed;

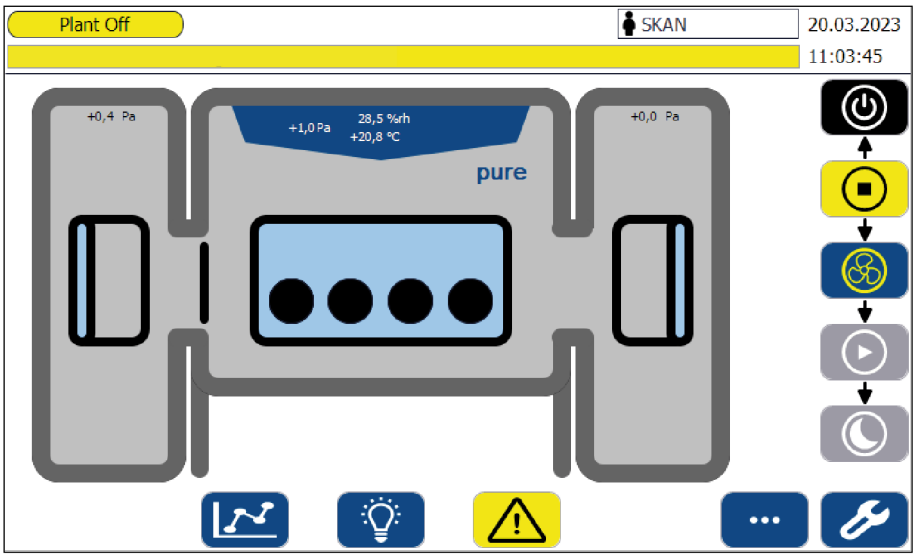
1. Turn the main switch of the machine to ON.
   ➡ The machine's power supply is switched on.
   ➡ The software starts.
   ➡ Compressed air is switched on and the signalisation is checked.
   ➡ The "Initialisation" screen appears on the control panel:

➡ The Initialisation and testing phase is finished:

If initialisation fails, the Reboot and Settings buttons appear on the control panel for further service activities.

In this case, please locate the fault and restart the machine resp. consult Skan Service.

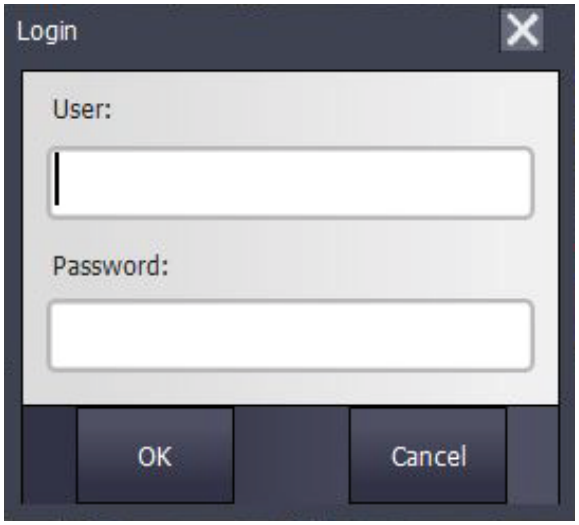
2. Touch the [Main page] button  at the bottom of the operating screen.
   ➡ The main overview operating screen appears:



3. You will be asked to login on the operator panel screen.

17.2 Login / Logout

1. Touch the "Login input field" at the top right of the operating screen.
   ➡ A pop-up window with user name and password appears:



2. Enter your access data and confirm with [OK].
   ➡ You are free to start work with the isolator.

17.3 Switching off the machine and the controller

✓ Front doors are closed;
✓ Transfer doors are closed;
✓ The machine is in plant modeOFF

NOTICE

Irreversible damage to the main board software functions due to interrupted / uncontrolled shut down.

► The machine is always connected to the mains power supply. The mains shall never be turned off in any other state than “Plant OFF”

1. Switch off the machine at the control panel:

   Touch the [Machine OFF] button  at the right side of the operating screen.

   ➡ The "Shutdown" screen appears on the control panel:

   ➡ The Shutdown phase is finished:

If shutdown is finished, the Reboot button appears on the control panel.
If required, you may reboot the machine.

2. Turn the main switch of the machine to OFF.
   - ➡ The system's controller is shut down.
   - ➡ The machine's power supply is switched off.

18 Control panel

18.1 Language of the operator panel screen

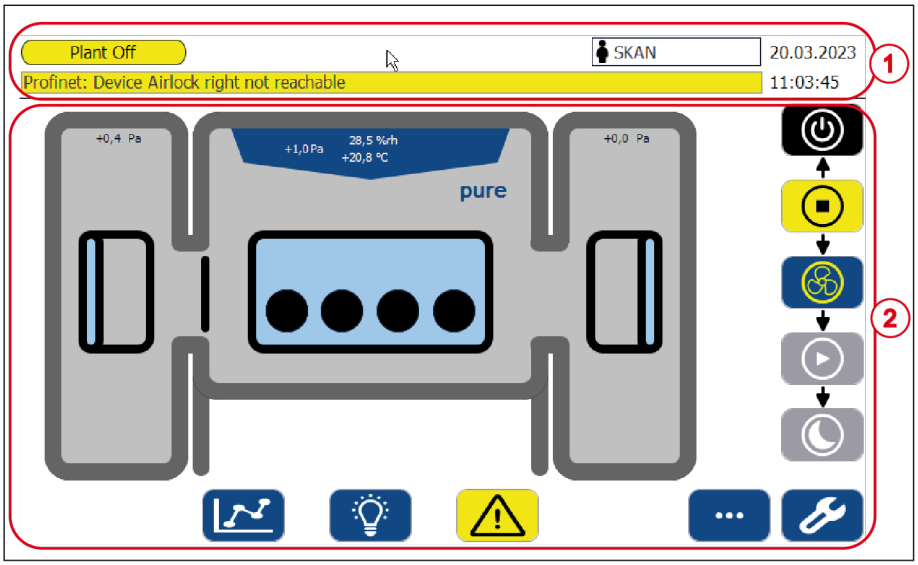
Available language of the operator panel screen is ****english****

Language settings are not possible on the operator panel screen.

18.2 Structure of the operator panel screen

After the machine is turned on, the initialisation phase has been completed and the [Main page] button  was touched, the main operator panel screen is shown on the control panel.

There are non-menu-dependent (permanent) and menu-dependent (local) screen areas:



Item	Designation
1	Permanent screen (non-menu-dependent screen)
2	Local screen (menu-dependent screen)

18.2.1 Permanent screen

The permanent (non-menu-dependent) screen area shows the display and functional elements listed in the following:

- Current machine mode
- Last alarm message
- Login input field
- Date and time

18.2.2 Local screen

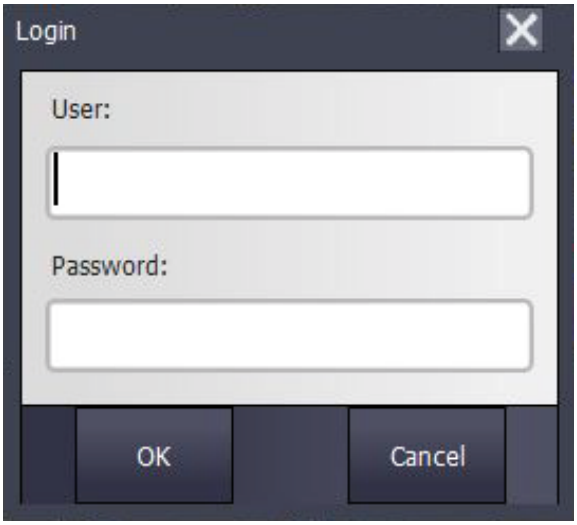
The local (menu-dependent) screen area shows the display and functional elements listed in the following:

- Menu bar: Buttons to switch the main menus and if available the submenus
- Menu-specific control keys and indicators.
- Status of components, current values and the alarm messages, manual control buttons and much more.

18.3 Login and logout function

18.3.1 Manual login

After touching the "Login input field" at the top right of the operating screen, a pop-up window will prompt the user to enter a user name and password:



When the user name and password entered are correct, operation of the system will be enabled within the scope of the access rights defined for the respective user.

Entering a wrong password 9 times will lead to the user being blocked.

To release a blocked user, administrator rights are required.

18.3.2 Manual logout

After touching the "Login input field" at the top right of the operating screen, a pop-up window will prompt the user to enter a user name and password: *******

After a defined period of time (logout time), the control panel automatically sets the password level to 0. The period of time before automatic logout occurs totals **** 10 min.

18.3.3 Screen keyboard

The screen keyboard appears automatically as soon as a text or numerical entry by the user is required.

19 Access rights and user administration

19.1 Access rights

The control panel is equipped with access control for data and functionality. For this purpose, data and function access on the control panel are assigned to specific user levels in the corresponding password levels.

It is possible to handle different users with individual passwords. For each user group, different levels of rights are defined.

A password level with a higher degree of access has the right to execute all actions from those users with lower password levels.

The following table (access matrix) shows the monitored functions and specific access rights and password levels:

Group name	VIEWER	OPERA-TOR	SUPER-VISOR	SUPER-VISOR + DATA MOVE	ADMINIS-TRATOR	PURE-ADMIN	SKAN
Group number / Level	**0**	**1**	**2**	**3**	**7**	**8**	**9**
Password definition by	customer	customer	customer	customer	customer	PURE-ADMIN	SKAN
Current values	x	x	x	x	x	x	x
Trends	x	x	x	x	x	x	x
Light on / off		x	x	x	x	x	x
Machine operation on Overview screen		x	x	x	x	x	x
Alarm handling (Acknowledging)		x	x	x	x	x	x
Start / stop decontamination		x	x	x	x	x	x
Maintenance (incl. manual operation)			x	x	x	x	x
Switch language			x	x	x	x	x
Change of batch name while batch is running			x	x	x	x	x
Cloud test sequence			x	x	x	x	x
Reset Emergency mode			x	x	x	x	x
Change light and buzzer settings			x	x	x	x	x
Start / stop leak test			x	x	x	x	x
Change parameter of leak test				x	x	x	x

Group name	VIEWER	OPERA-TOR	SUPER-VISOR	SUPER-VISOR + DATA MOVE	ADMINIS-TRATOR	PURE-ADMIN	SKAN
Group number / Level	**0**	**1**	**2**	**3**	**7**	**8**	**9**
Password definition by	customer	customer	customer	customer	customer	PURE-ADMIN	SKAN
Download copy of alarm & messages list				x	x	x	x
Up- / Download user management				x	x	x	x
Move of Archive and Reports				x	x	x	x
User administration					x	x	x
Cloud manual valve movement					x	x	x
Change pure configuration (avalable parts)					x	x	x
Change parameters on HMI					x	x	x
Up-/download parameter file with checksum					x	x	x
End / reload runtime (access to windows)					x	x	x
Access to restricted files on SD-Card (e.g. audit files, archives, etc.)					x	x	x
Up-/download parameter file without checksum						x	x
Change additional Cloud parameters						x	x
Set time zone on PLC						x	x
Set concentration mode & report settings on particle counter						x	x
Set auxiliary inputs & outputs						x	x

19.2 User administration

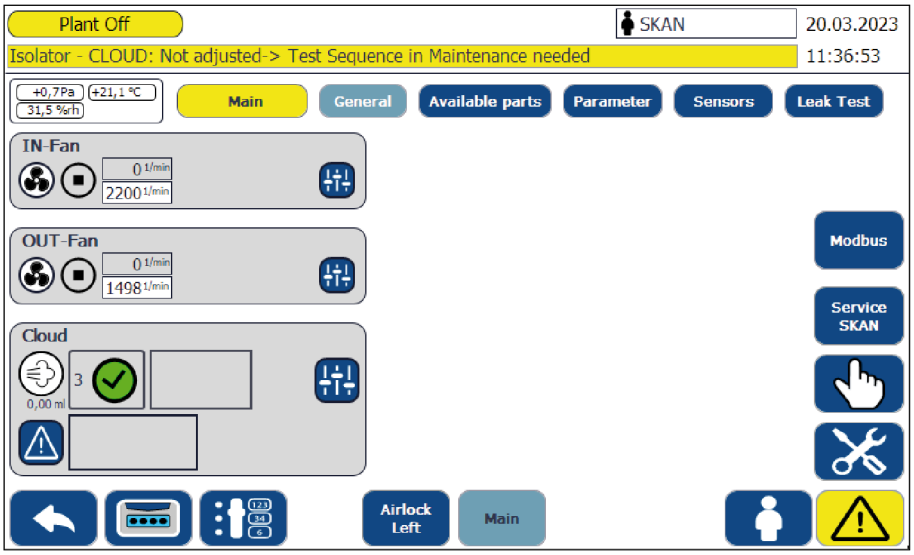
In the user administration menu you can:

- Create, change or delete users;
- Assign and change user-specific passwords.

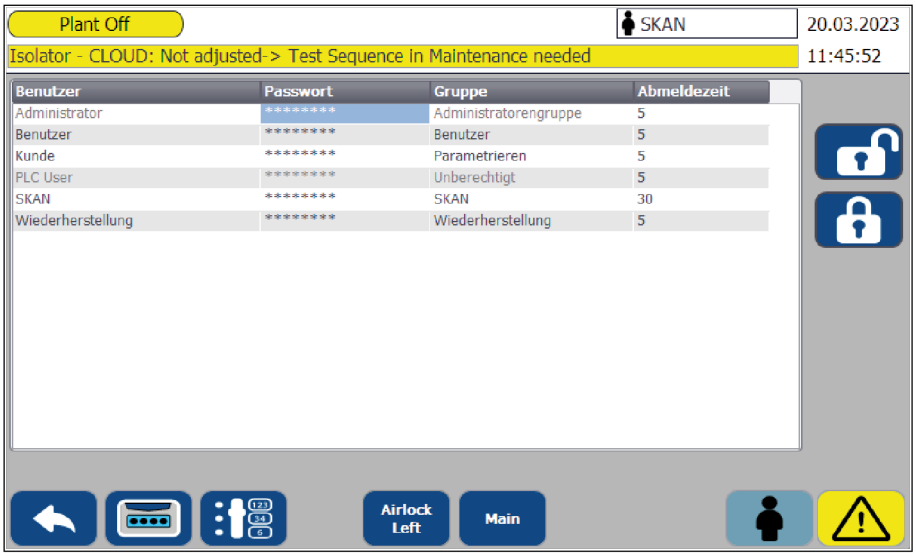
On the "User management" operating screen the following information are displayed:

- User name;
- Password: possibility to change the current user password;
- Group: user group;
- Logoff time: automatic logoff after this time is elapsed (in min);
- Login / Logoff.

1. Touch the [Settings] button  at the bottom right of the operating screen.
   ➡ The "Generall settings" operating screen appears:



2. Touch the [User administration] button at the bottom right of the operating screen.
   ➡ The "User administration" operating screen appears:



To remove a user, simply edit his username and clear the field. By pressing enter, the user will be removed.

To add a new user, touch the screen below the last username in the list to enter.

OPERATOR can only change his own password and logoff time.

20 Emergency

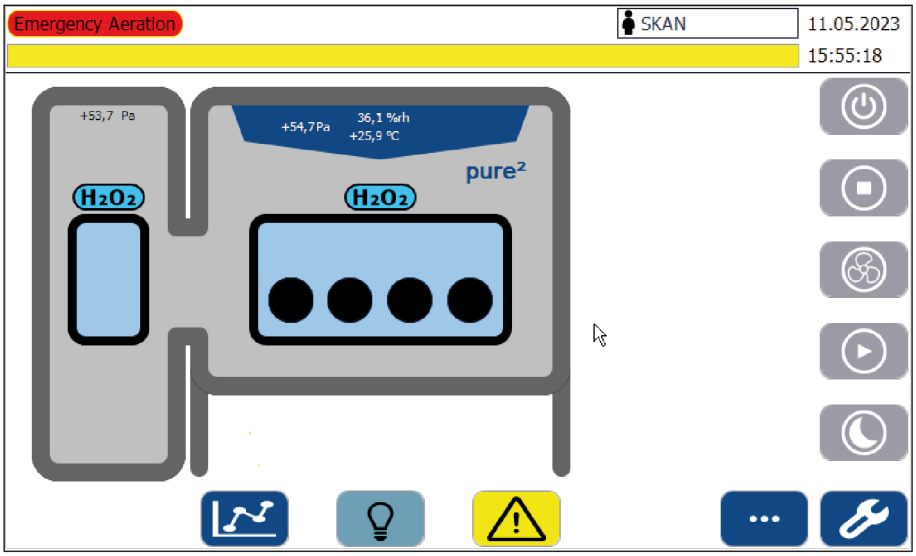
If the emergency stop button is pressed, the machine switches in Emergency mode.

In emergency mode all possibly moving parts integrated with the system stop.

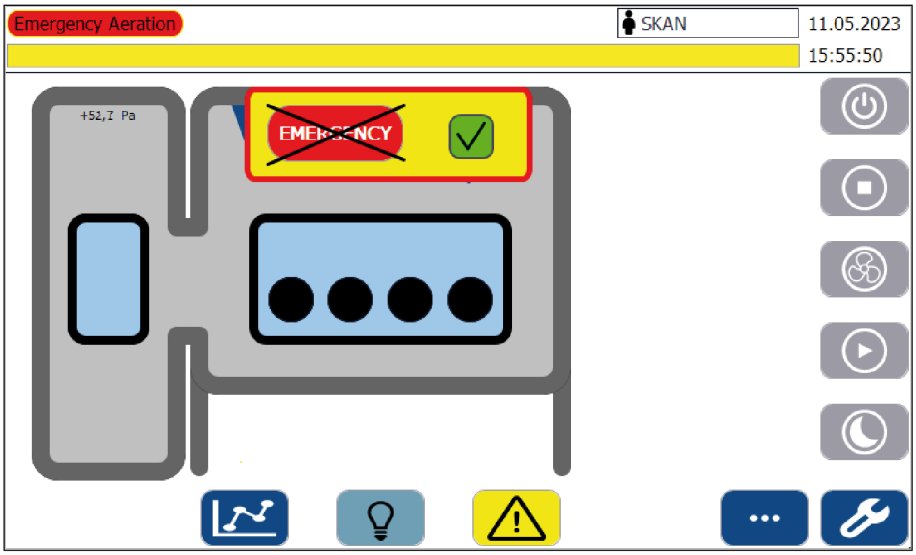
The compressed air supply is switched off immediately and a corresponding alarm message is generated.

If there is no H_2O_2 in the working chamber, the system switches automatically into plant OFF

If there is H_2O_2 in the working chamber, the decontamination and dosing of H_2O_2 is aborted and the system switches automatically into Aeration. You cannot interrupt the aeration process. Please wait until the aerating process has ended!



End of Aeration a confirmation prompt appears.



► Touch the [Confirmation] button  to end emergency mode.

➡ Emergency mode is finished.

To restart the system after an emergency stop:

- The causes of the emergency stop i.e. all machine component faults, must be eliminated completely.
- Release of the emergency stop button.
- Acknowledge the current error message (see chapter Alarm handling).

You can switch the system manually in plant ON or OFF.

21 Operating the system

21.1 Switching the lighting on and off

The lighting for the working chamber can be switched on and off together for the main chamber and airlock from the "Main page" operating screen.

The lighting also has a signalling function. If an alarm is active or the isolator switches to emergency mode, the lighting changes automatically to red. During decontamination or aeration after an emergency, the lights automatically switch to blue.

The lighting for the working chamber cannot be switched on in the following machine modes.

- *Shut down*
- *Decontamination*

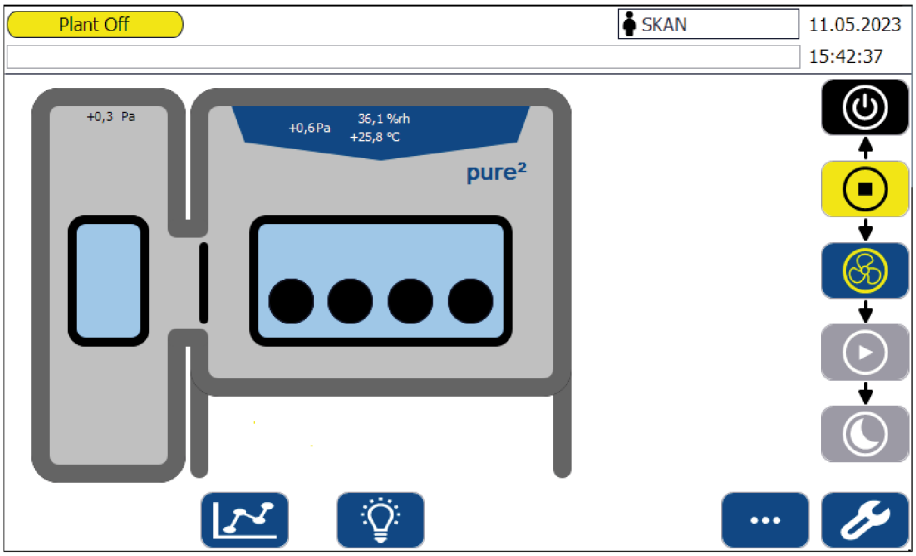
Prerequisites:

✓ The machine is switched on at the main switch and the initialisation ist terminated.

1. *If the "Main page" operating screen is not active:*

   Touch the [Main page] button  at the bottom left of the operating screen.

   ➡ The "Main page" operating screen appears:



2. *When the conditions for switching on the light are present, the [Lighting] button at the bottom of the operating screen is active. To switch the lighting on:*

   Touch the [Lighting] button  :

   ➡ The lighting of the machine is switched on;

   ➡ The [Lighting] button changes its colour to light blue.

3. *To switch the lighting off:*

   Touch the [Lighting] button  again.

   ➡ The lighting of the machine is switched off;

   ➡ The [Lighting] button changes its colour to dark blue.

21.2 Switching the machine on and off at the control panel

Machine is switched on and off from the "Main page" operating screen.

21.2.1 Plant ON - Switching the machine on

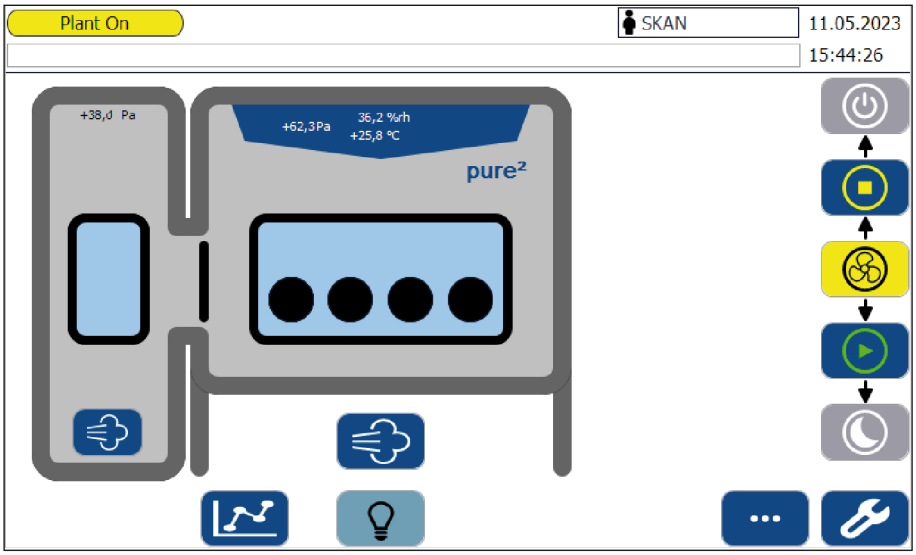
✓ The machine is in plant mode OFF;

▶ Touch the [Machine on] button  at the right side of the operating screen.

➡ The machine is switched on.

➡ The [Machine on] button changes its colour to yellow.

➡ The fans are started up.



21.2.2 Plant OFF - Switching the machine off

✓ The machine is in plant mode ON;

1. Touch the [Machine off] button  at the right side of the operating screen.

   ➡ You will be asked to login again on the operator panel screen.

2. Enter your access data and confirm with [OK].

   ➡ The machine is switched off.

   ➡ The [Machine off] button changes its colour to yellow.

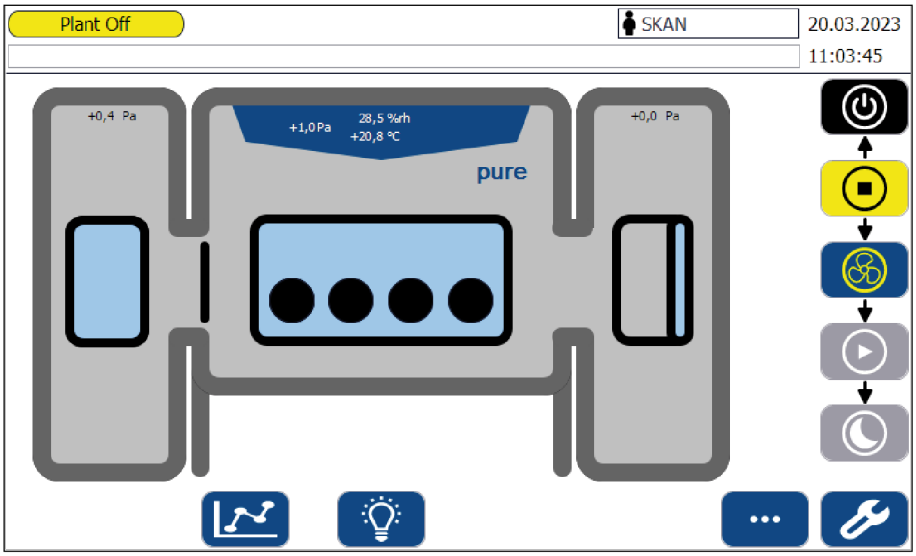
   ➡ The fans are shutting down.

21.3 Opening and closing the front doors

Doors of the machine may only be opened when the doors interlocks are released on the operating screen.

The status of the doors is indicated accordingly on the "Main page".

Ex. In the following picture there is an isolator with airlocks on both sides, the left airlock door is locked (door is closed on the picture), the right airlock door is released (door is open on the picture):



The doors can be opened and closed from the "Main page" operating screen.

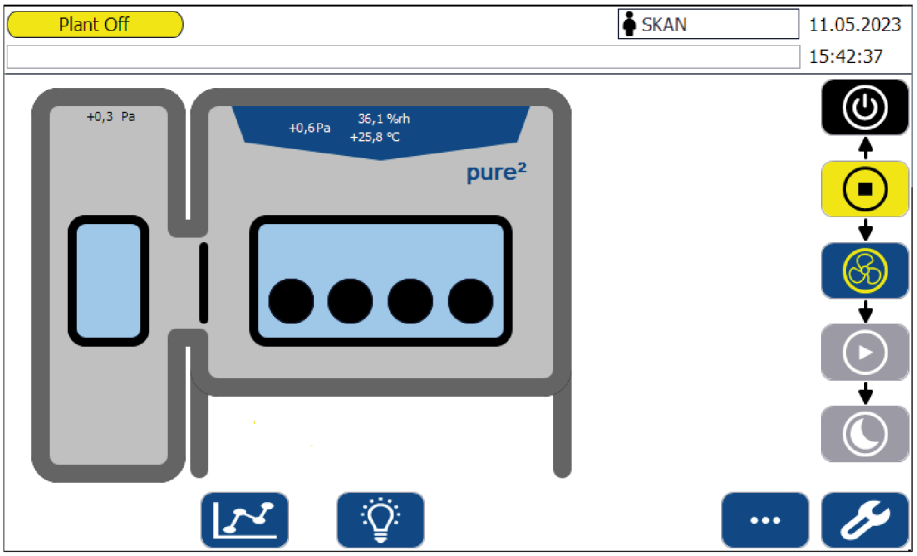
21.3.1 Open the front door

Prerequisites:

✓ The transfer door(s) is closed;

The machine is in one of the following plant modes:

✓ Plant OFF
✓ Plant ON
✓ MAINTENANCE
✓ CLEANING



1. *Open the left airlock door*:

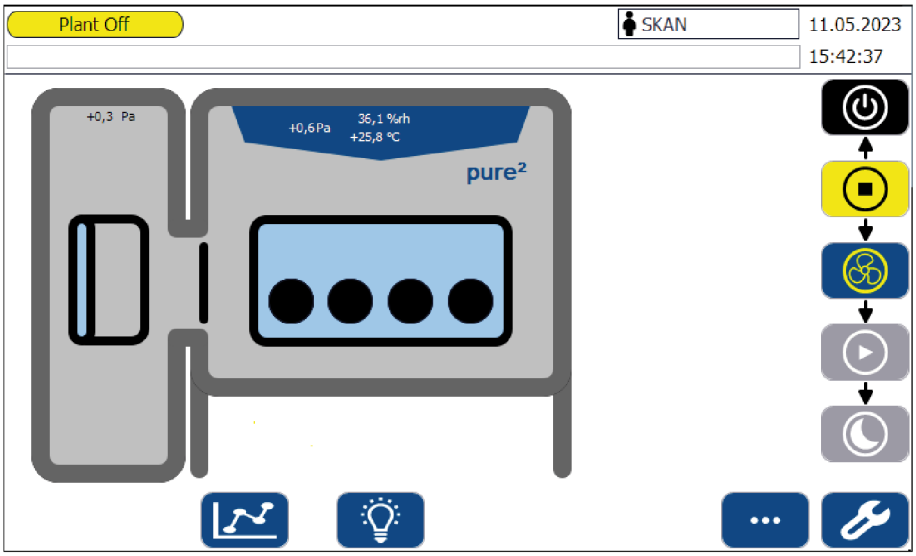
   Touch the left airlock door on the "Main page"

2. *If you operate the system in negative pressure and biologically active substances are being processed, you are requested to perform a cleaning of the chamber.*

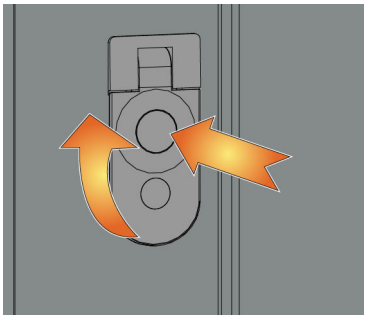
   Carry out the cleaning of the chamber according to internal cleaning procedures.

   Close the transfer door after cleaning the airlock chamber.

   ➡ The doors interlock is released;



3. After releasing the door on the operating screen, open the mechanical hinge by pushing the button in the middle of the hinge and by pulling open the door.



➡ You are free to open the door.

To open the isolator door or the right airlock door proceed in a similar way as described above for the left airlock door.

21.3.2 Close the front door

Prerequisites:

✓ The transfer door(s) is closed;

The machine is in one of the following plant modes:

✓ Plant OFF
✓ Plant ON
✓ MAINTENANCE
✓ CLEANING

⚠ CAUTION

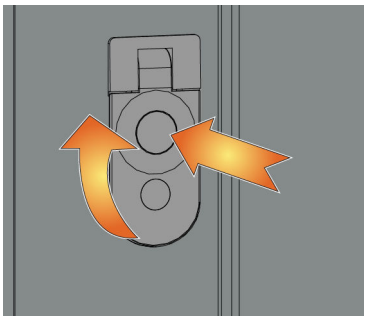
Heavy glass doors!

Crushing and injuring of body parts.

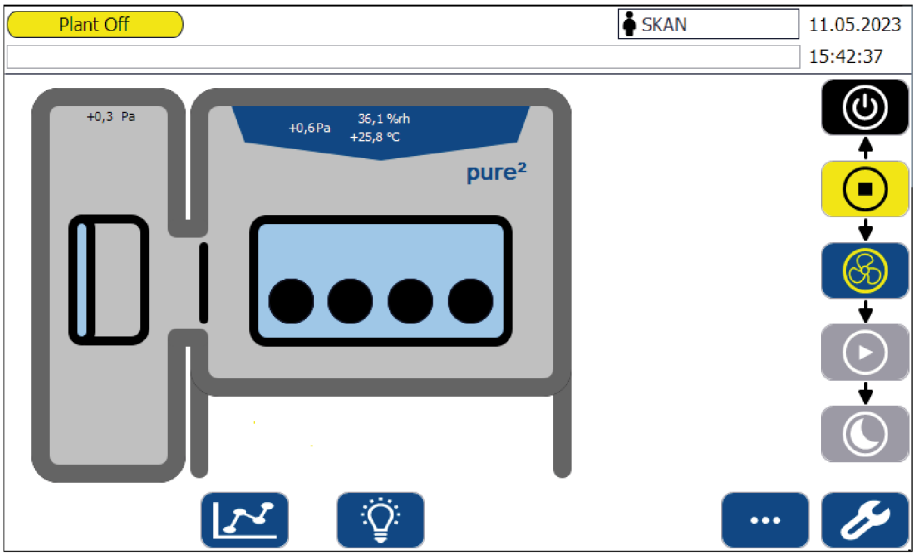
► Take proper care when opening and closing the glass doors.
► Open and close gas pressure spring-supported doors only with the aid of attached handles or with the aid of the integrated shoulder rings (glove ports).
► Do not allow other persons to be present in the opening/closing area of the doors.

1. *Close the left airlock door*:

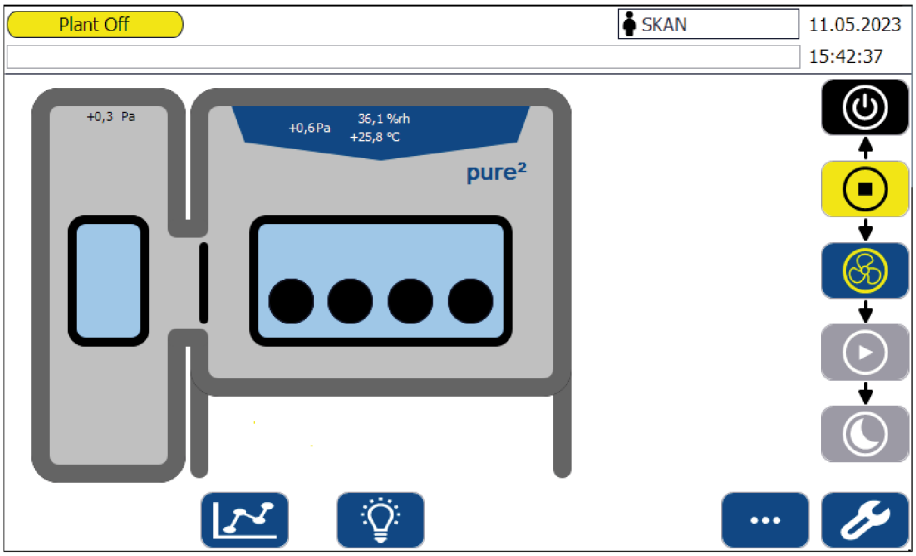
   Close the airlock front door. Lock it by pushing the button in the middle of the hinge and closing it completely.



➡ The airlock door is closed.



2. Touch the left airlock door on the "Main page"
   ➡ The doors interlock is locked;



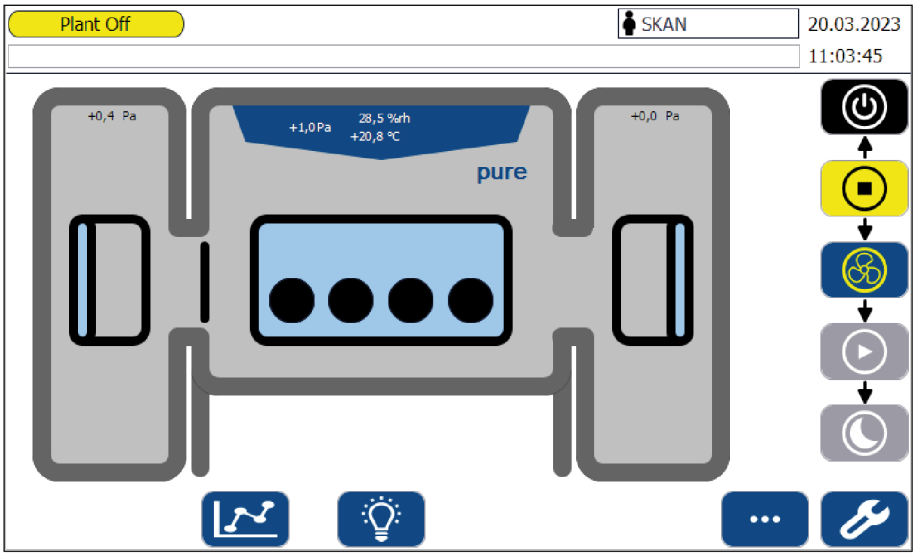
To close the isolator door and the right airlock door proceed in a similar way as described above for the left airlock door.

21.4 Opening and closing the transfer door

Transfer doors of the machine may only be opened when the doors interlocks are released on the operating screen.

The status of the doors is indicated accordingly on the "Main page".

Ex. In the following picture there is an isolator with airlocks on both sides, the left airlock transfer door is locked (transfer door is closed on the picture), the right airlock transfer door is released (transfer door is open on the picture):



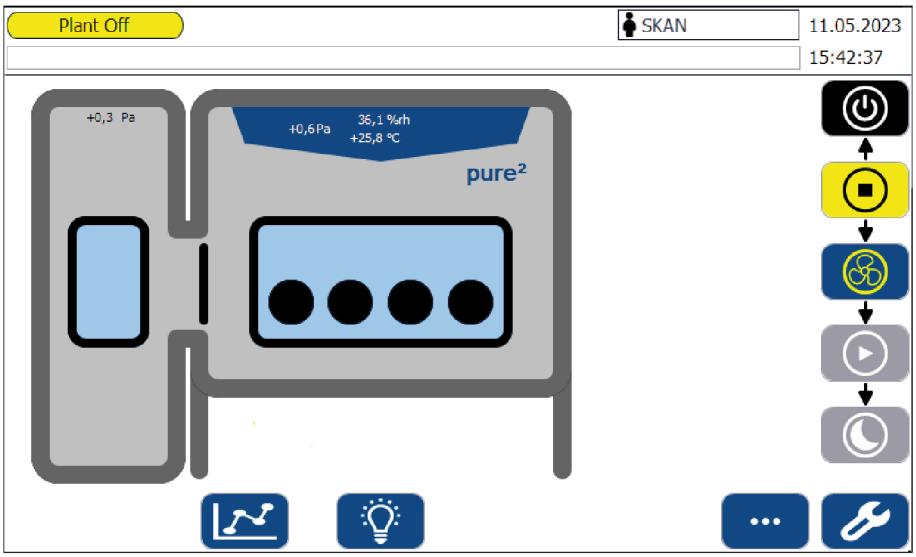
The transfer doors can be opened and closed from the "Main page" operating screen.

21.4.1 Open the transfer door

Prerequisites:

The machine is in one of the following plant modes:

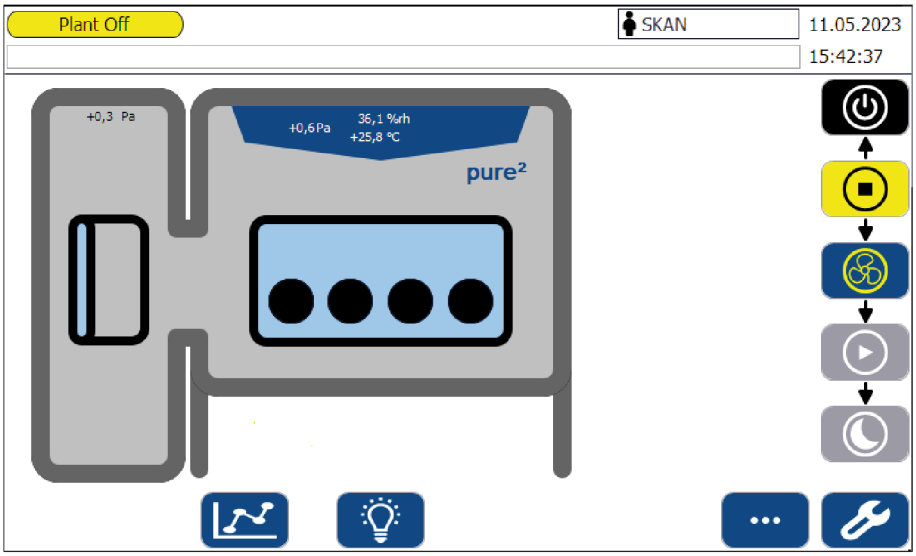
- ✓ Plant OFF
- ✓ Plant ON
- ✓ PRODUCTION in **overpressure**, if the chambers on both sides of the transfer door are decontaminated;
- ✓ PRODUCTION in **negative pressure**, if the front doors of the chambers on both sides of the transfer door are closed and locked;
- ✓ MAINTENANCE
- ✓ CLEANING



► *Open the left transfer door*:

Touch the left transfer door on the "Main page"

➡ The transfer doors interlock is released;



➡ You are free to open the transfer door.

➡ In **negative pressure** operation, the airlock chamber is contaminated after opening the transfer door.

To open the right transfer door proceed in a similar way as described above for the left transfer door.

21.4.2 Close the transfer door

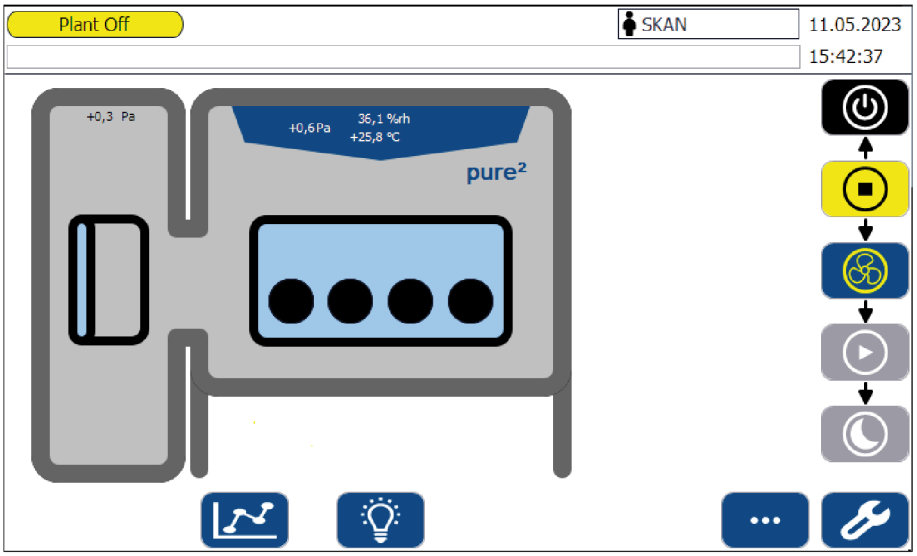
Prerequisites:

The machine is in one of the following plant modes:

✓ Plant OFF

✓ Plant ON

✓ PRODUCTION
✓ MAINTENANCE
✓ CLEANING



1. **⚠ CAUTION**

   The transfer dood must be closed manually.

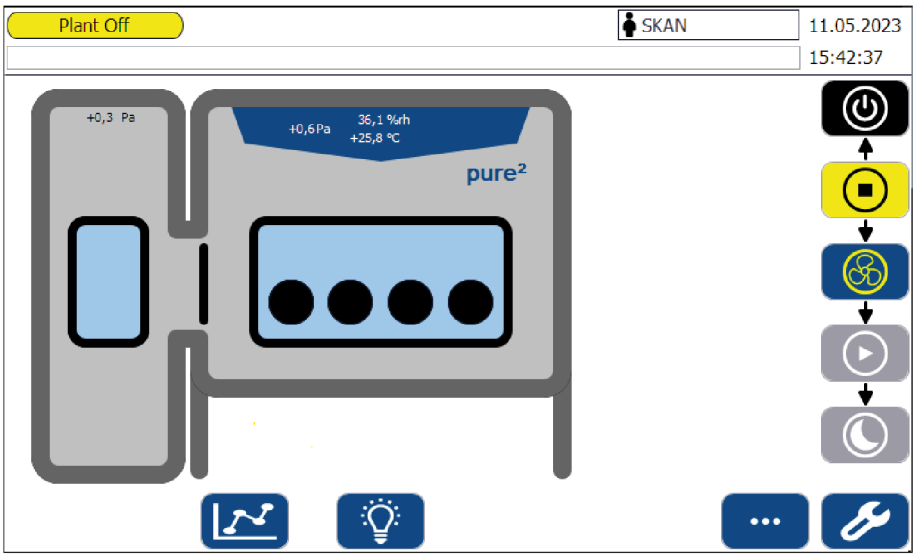
   Crushing hazard!

   ► Close the transfer door carefully!

   Close the left transfer door.

2. Touch the left transfer door on the "Main page"

   ➡ The doors interlock is locked;



To close the right transfer door proceed in a similar way as described above for the left transfer door.

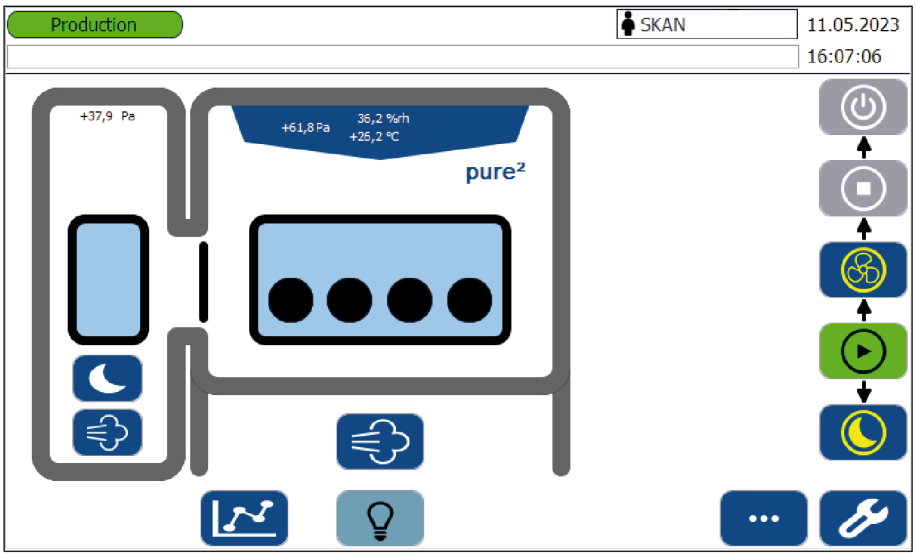
21.5 Current values

Current measuring values and setpoints of fans or clouds can be displayed in the operating screen.

1. *If the "Main page" operating screen is not active:*

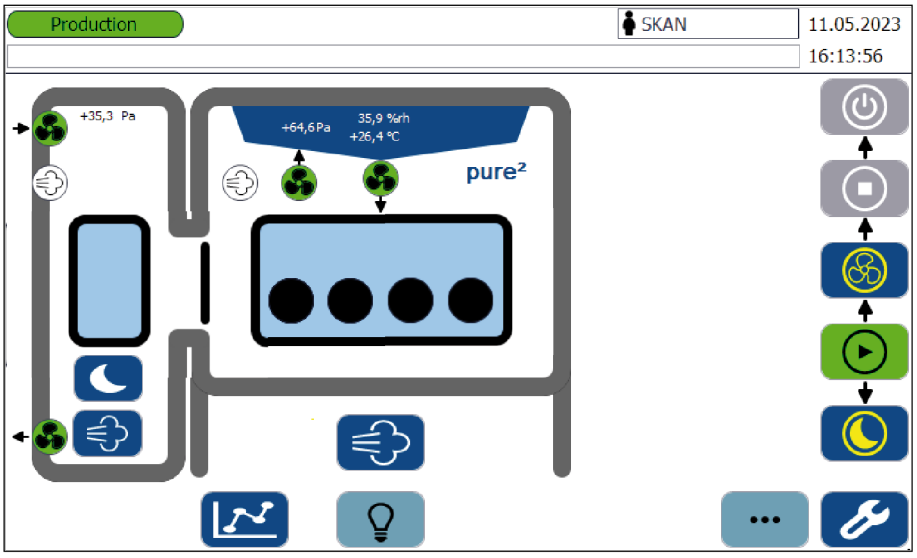
   Touch the [Main page] button  at the bottom left of the operating screen.

   ➡ The "Main page" operating screen appears:



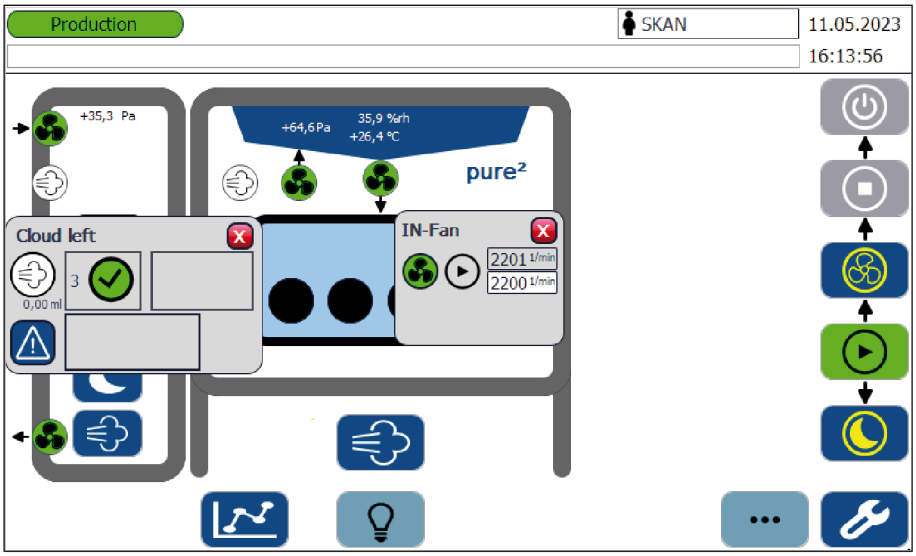
2. Touch the [Display devices] button  at the bottom right of the operating screen.

   ➡ The devices are shown in the main page:



3. Touch the "Fan" icon  or the "Cloud" icon  to display the corresponding actual values.

   ➡ The corresponding actual values pop-up windows appears:



4. Touch the [Cancel] button  to close the pop-up windows.

21.6 Decontamination

If the machine is contaminated, a decontamination of the isolator chambers is started.

First, if the isolator and the airlock are contaminated, a so-called combined decontamination is started. This ensures that the gasket(s) of the transfer door(s) between the isolator and airlock is decontaminated. During decontamination, the transfer door is open so that the gasket can be aerated with H_2O_2. Here the air flow from the isolator into the airlock is ensured by the airflow concept.

After loading the airlock, the airlock chamber is contaminated. To transfer material into the isolator chamber a decontamination of the airlock is required.

You can always repeat the procedures of loading, decontaminating and material transfer of the airlock without needing to decontaminate the isolator work chamber

⚠ CAUTION

During decontamination, hydrogen peroxide (H_2O_2) evaporates in the machine!

Chemical burns, eye injuries, fainting and death can result when contacting the hydrogen peroxide vapour.

- ► Close all openings of the work chamber (e.g. tri-clamps, mouseholes).
- ► Observe the safety data sheet for hydrogen peroxide.

! NOTICE

Only surfaces that can be completely purged with hydrogen peroxide vapour can be decontaminated!

Insufficient decontamination due to covered or dirty surfaces.

- ► Clean rough surfaces (e.g. surfaces of gloves and sleeves) before you start decontamination.
- ► Make sure that all surfaces are free of greasy and oily contamination.
- ► Make sure that no surfaces are covered in the work chamber during decontamination.

The scope of decontamination, the requirement for decontamination before and/or after production, as well as the start confirmation of decontamination, were set during machine setup on the basis of the intended use and processed products.

You can take changes to the decontamination parameters in the Cloud settings menu / Settings --> General --> Cloud ... .

21.6.1 Starting combined decontamination

Prerequisites:

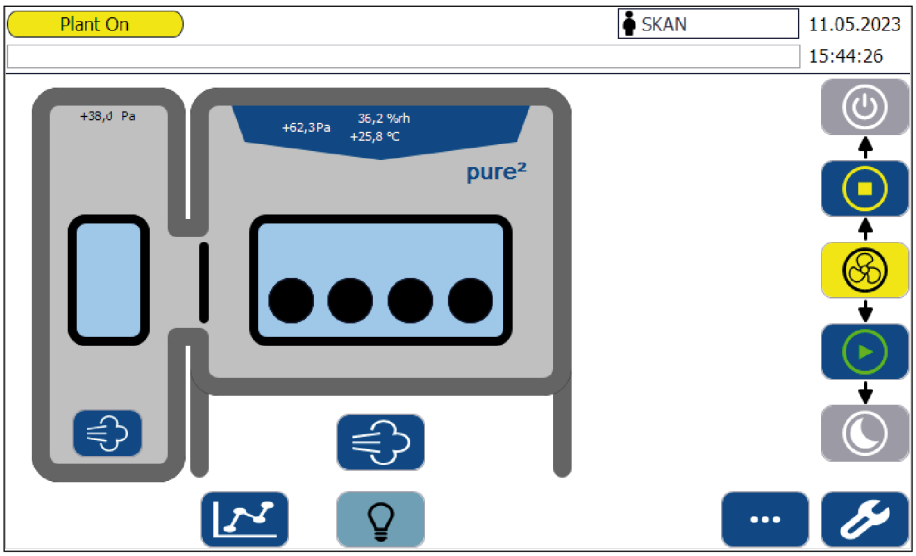
- ✓ The isolator is in plant mode ON or PRODUCTION;
- ✓ The front doors are closed the doors interlocks are locked ;
- ✓ The transfer door is open.
- ✓ The parameters of the decontamination are defined and qualified by a cycle development;
- ✓ All transfer systems (e.g. rapid-transfer ports) are prepared for the decontamination;
- ✓ All gloves are checked for leak-tightness;
- ✓ All gloves are stretched in the working chamber (for instance, by using glove stretchers);
- ✓ All surfaces in the working chamber are thoroughly cleaned;

✓ There is no active critical alarm message;
✓ The amount of hydrogen peroxide (H_2O_2) filled in the H_2O_2 supply bottle is sufficient for decontamination;
✓ The working chamber is free of flammable or explosive substances, gases and vapours that can lead to dangerous reactions with hydrogen peroxide.

1. *If the "Main page" operating screen is not active:*

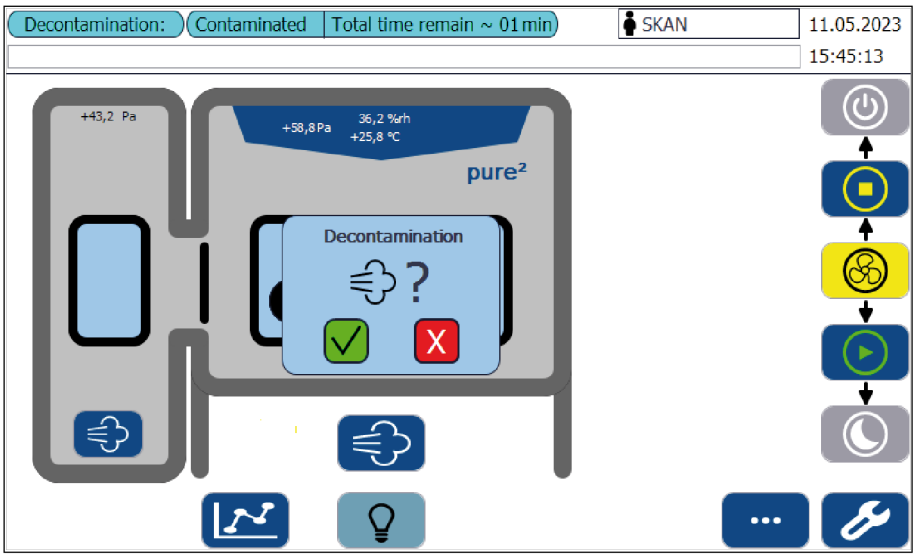
   Touch the [Main page] button  at the bottom left of the operating screen.

   ➡ The "Main page" operating screen appears:



2. Touch the [Decontamination] button  at the bottom middle of the operating screen.

   ➡ The confirmation prompt *"Decontamination ?"* appears, depending on the valid settings.

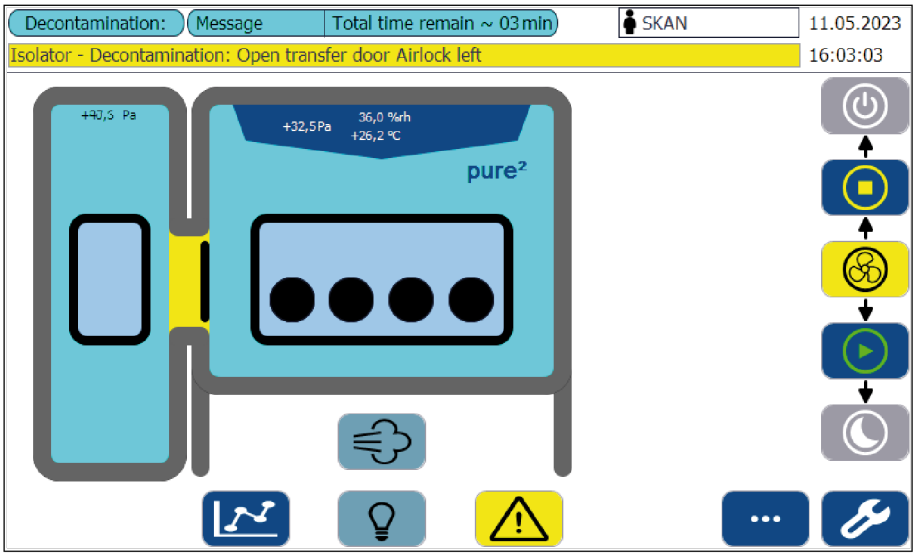


3. Touch the [Confirmation] button  to start decontamination.

4. *If the transfer door is closed:*

   You are requested to open the transfer door.

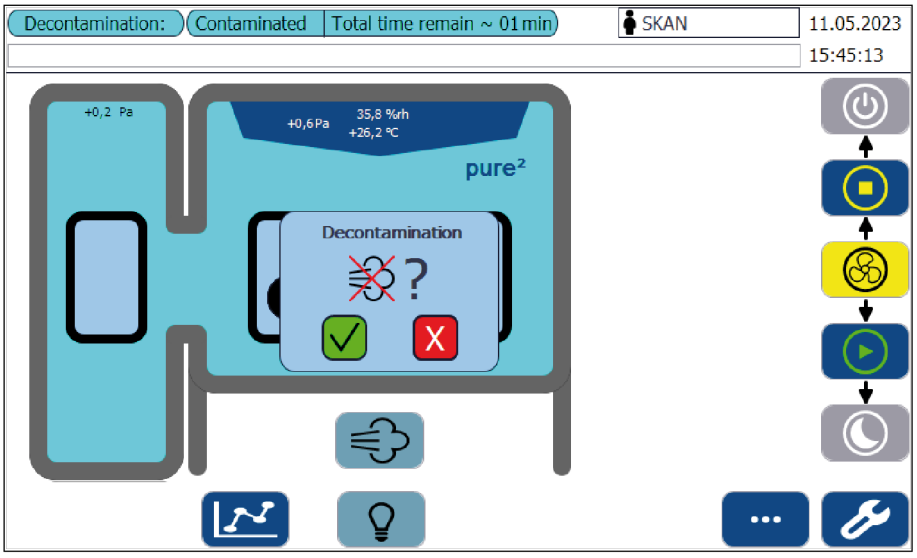
   ➡



5. Open the transfer toor.

6. Touch the [Decontamination] button  at the bottom middle of the operating screen again.

   ➡ The confirmation prompt *"Decontamination ?"* appears, depending on the valid settings.

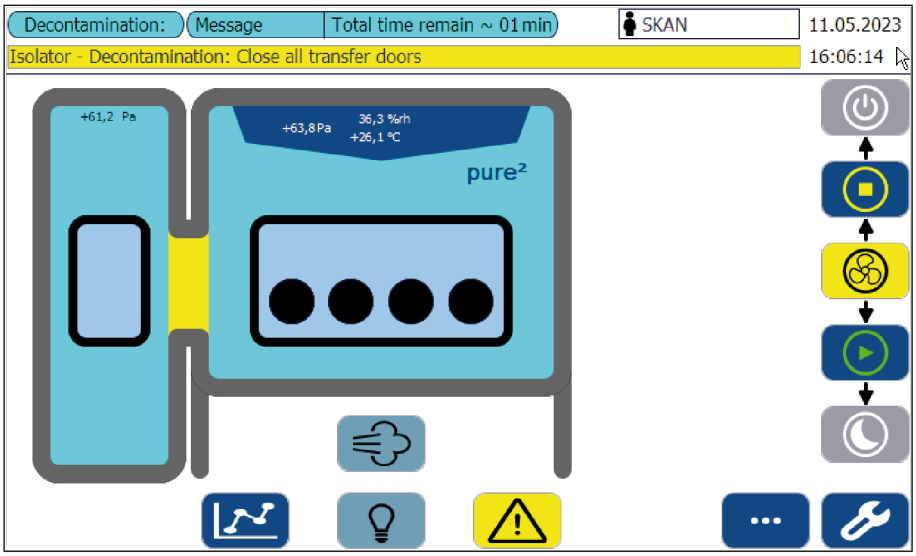


7. Touch the [Confirmation] button  to start decontamination.

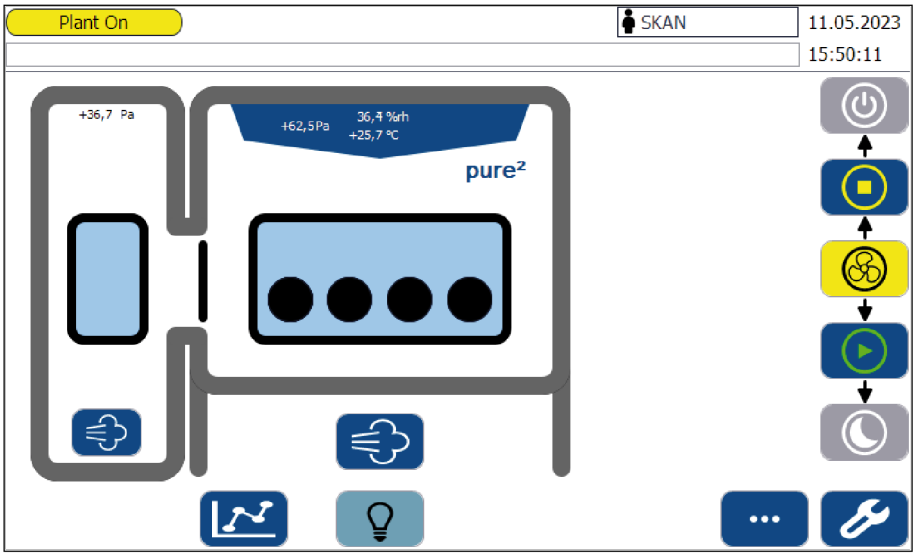
   ➡ Decontamination starts;

   ➡ The blue lighting in the chambers indicates that the decontamination is in progress;

8. At the end of the decontamination you are requested to close the transfer door.



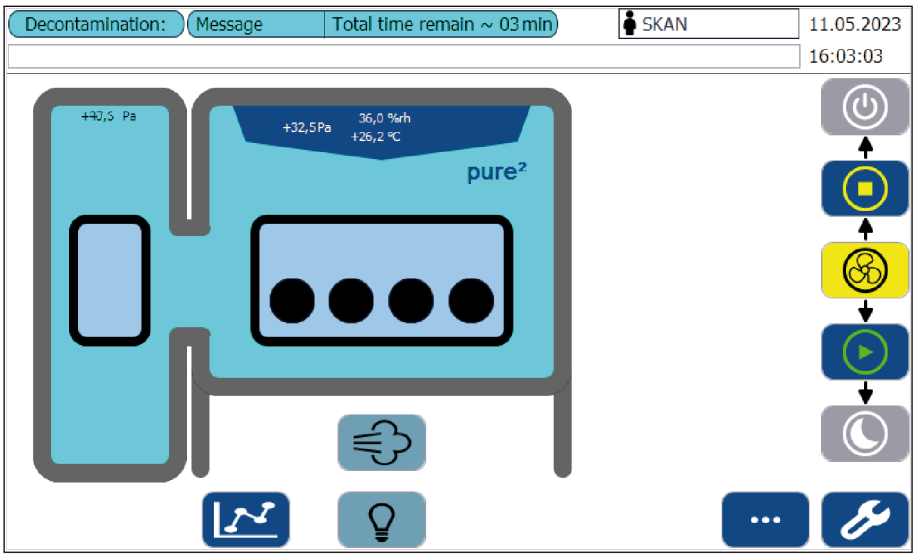
9. Close the transfer toor.
   - The decontamination is finished.
   - The blue lights in the chambers is turned off;
   - The decontaminated status of the chamber is shown on the control panel with a white chamber background.



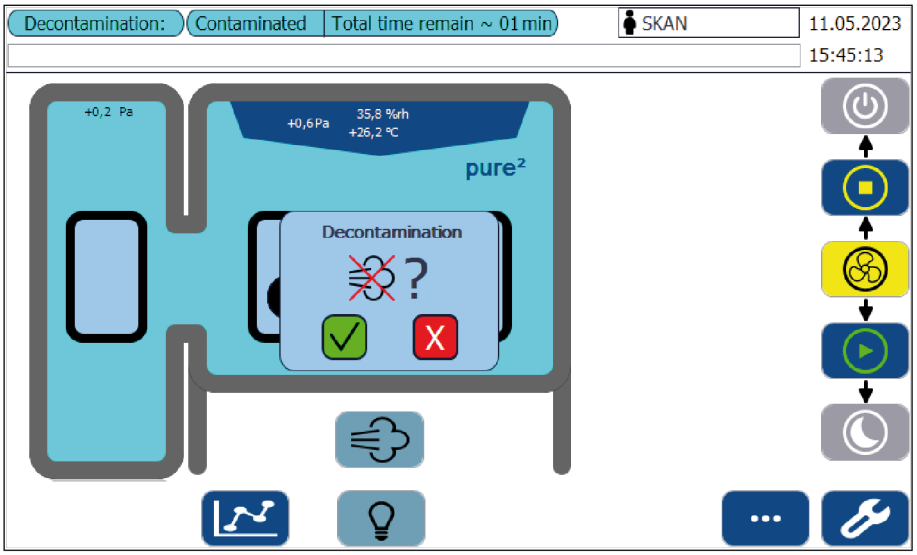
   - Once the decontamination has successfully finished, the machine automatically switches back to machine mode before decontamination: ON or PRODUCTION.

21.6.2 Aborting the combined decontamination

✓ The decontamination was started, the machine is in plant mode DECONTAMINATION;



1. Touch the [Decontamination] button  at the bottom middle of the operating screen again.
   ➡ The confirmation prompt *"Decontamination ?"* appears.



2. Touch the [Cancel] button  to abort decontamination.
   ➡ The decontamination is cancelled;
   ➡ A corresponding alarm message is generated;
   ➡ The working chamber is aerated with fresh clean air; you cannot interrupt the aeration process.
   Please wait until the aerating process has ended!

21.6.3 Starting the decontamination of the airlock

Prerequisites:

- ✓ The isolator is in plant mode ON or PRODUCTION;
- ✓ The transfer door is closed.
- ✓ All the required materials were loaded into the airlock chamber.
- ✓ The front door is closed the doors interlock is locked ;
- ✓ The parameters of the decontamination are defined and qualified by a cycle development;
- ✓ All surfaces in the working chamber are thoroughly cleaned;
- ✓ There is no active critical alarm message;
- ✓ The amount of hydrogen peroxide (H_2O_2) filled in the H_2O_2 supply bottle is sufficient for decontamination;
- ✓ The working chamber is free of flammable or explosive substances, gases and vapours that can lead to dangerous reactions with hydrogen peroxide.

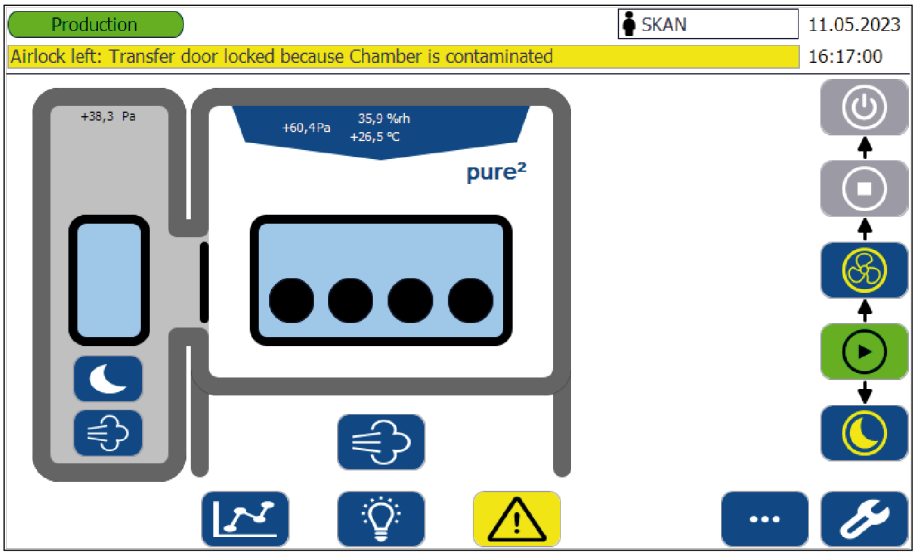
After loading the airlock, the airlock chamber is contaminated. To transfer material into the allready decontaminated isolator chamber a decontamination of the airlock is required.

You can always repeat the procedures of loading, decontaminating and material transfer of the airlock without needing to decontaminate the isolator work chamber

1. *If the "Main page" operating screen is not active:*

   Touch the [Main page] button  at the bottom left of the operating screen.

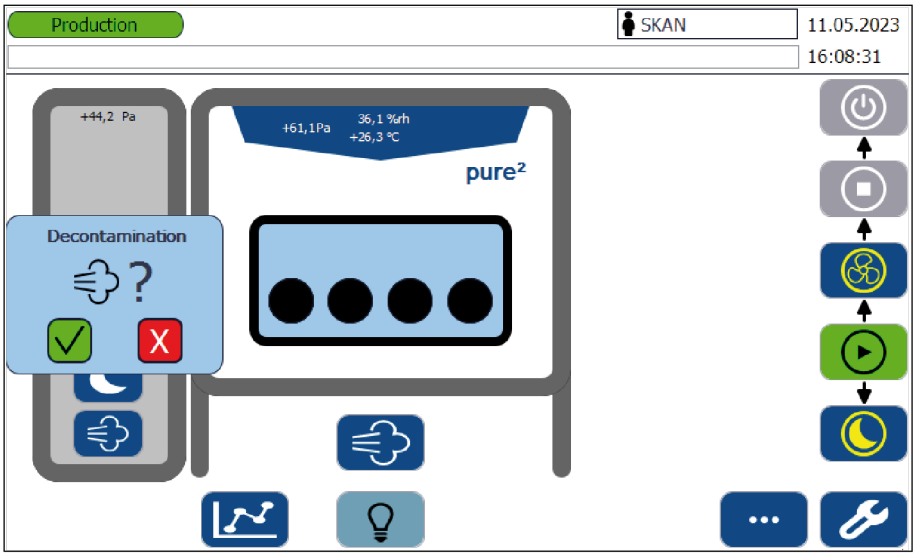
   ➡ The "Main page" operating screen appears:



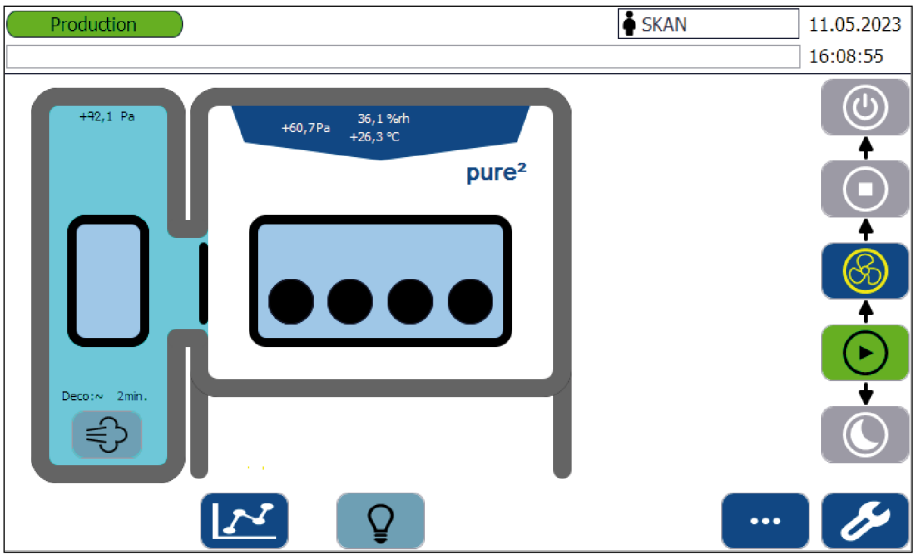
   The isolator chamber is decontaminated and the airlock is after loading closed and contaminated.

2. Touch the [Decontamination] button  at the the left side (in the airlock chamber) of the operating screen.

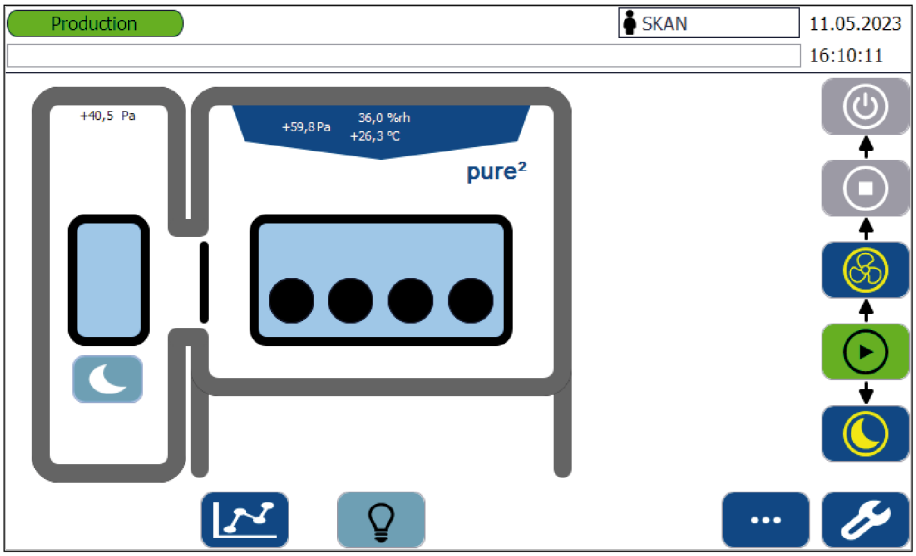
   ➡ The confirmation prompt *"Decontamination ?"* appears, depending on the valid settings.



3. Touch the [Confirmation] button to start decontamination.
   - ➡ Decontamination starts;
   - ➡ The blue lighting in the airlock chamber indicates that the decontamination is in progress;

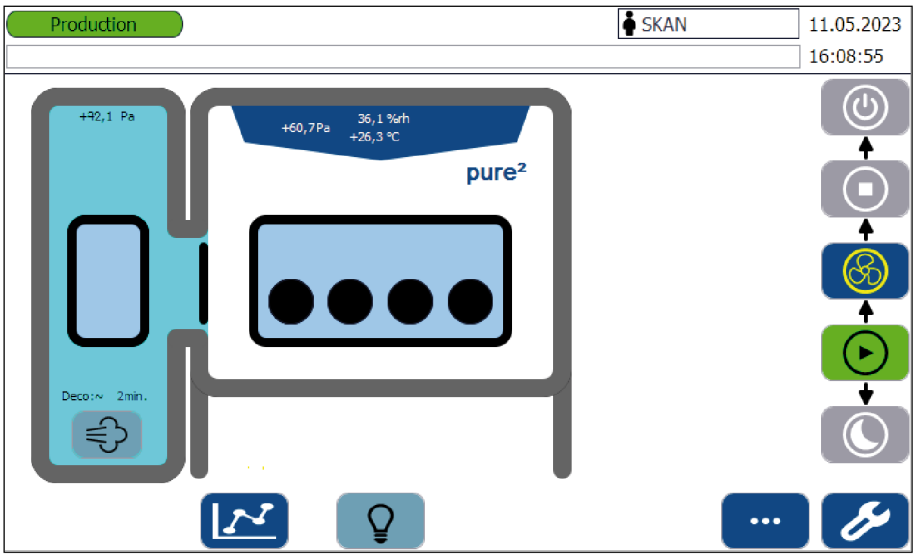


4. If the decontamination is finished:
   - ➡ The blue lights in the airlock chamber is turned off;
   - ➡ The decontaminated status of the airlock chamber is shown on the control panel with a white chamber background.


Production
SKAN
11.05.2023
16:10:11
+40,5 Pa
+59,8 Pa
36,0 %rh
+26,3 °C
pure²

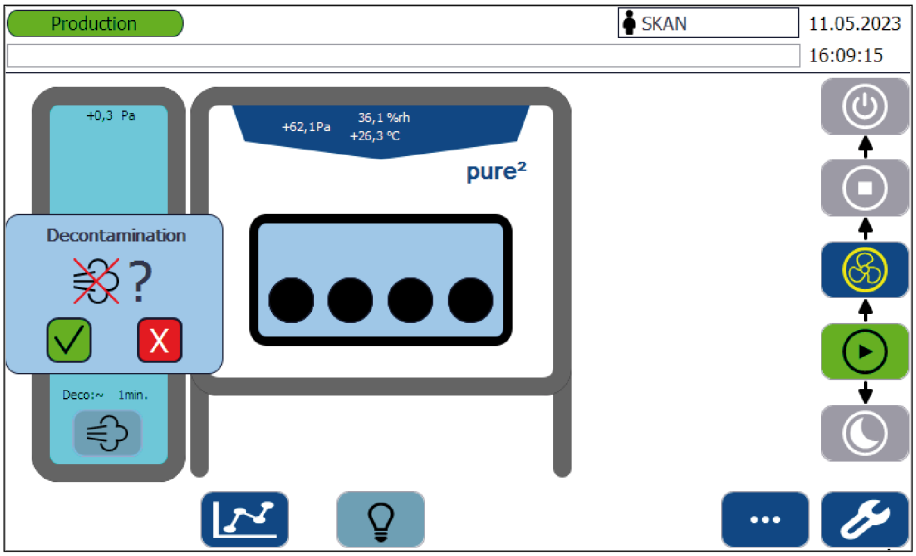
21.6.4 Aborting the decontamination of the airlock

✓ The decontamination of the airlock was started;



1. Touch the [Decontamination] button  at the the left side (in the airlock chamber) of the operating screen.

   ➡ The confirmation prompt *"Decontamination ?"* appears.



2. Touch the [Cancel] button  to abort decontamination.

   ➡ The decontamination is cancelled;

   ➡ A corresponding alarm message is generated;

   ➡ The airlock chamber is aerated with fresh clean air; you cannot interrupt the aeration process.
   Please wait until the aerating process has ended!

21.6.5 Airshower airlock

Prerequisites:

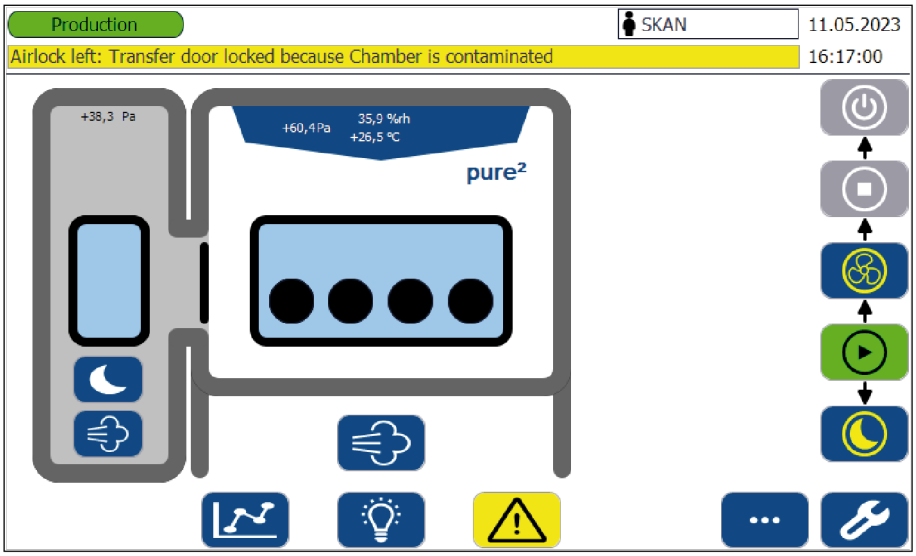
✓ The isolator is in plant mode ON or PRODUCTION;
✓ The transfer door is closed.
✓ All the required materials were loaded into the airlock chamber.
✓ The front door is closed the doors interlock is locked ;
✓ All surfaces in the working chamber are thoroughly cleaned;
✓ There is no active critical alarm message;

To transfer material into or from the allready decontaminated isolator chamber as an alternative to decontamination an airshower can be started.

1. *If the "Main page" operating screen is not active:*

   Touch the [Main page] button  at the bottom left of the operating screen.

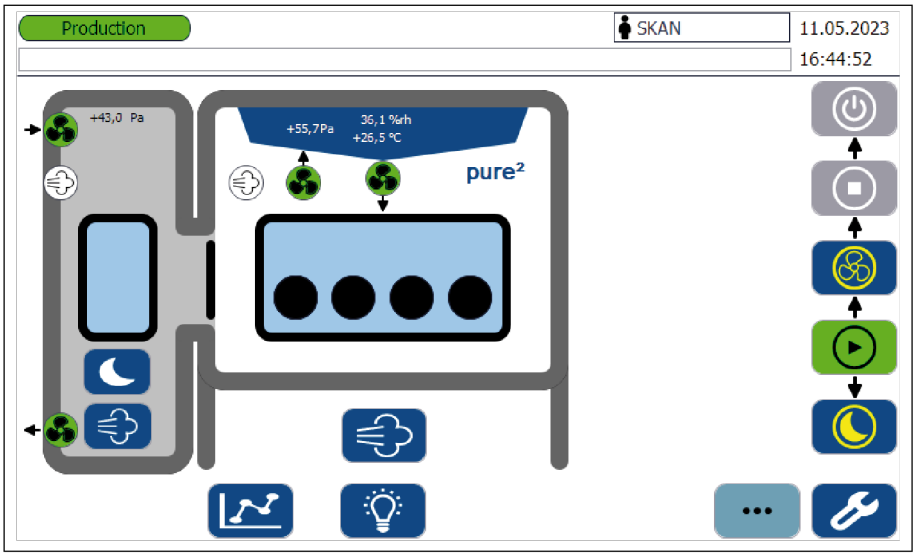
   ➡ The "Main page" operating screen appears:



   The isolator chamber is decontaminated and the airlock is closed and contaminated.

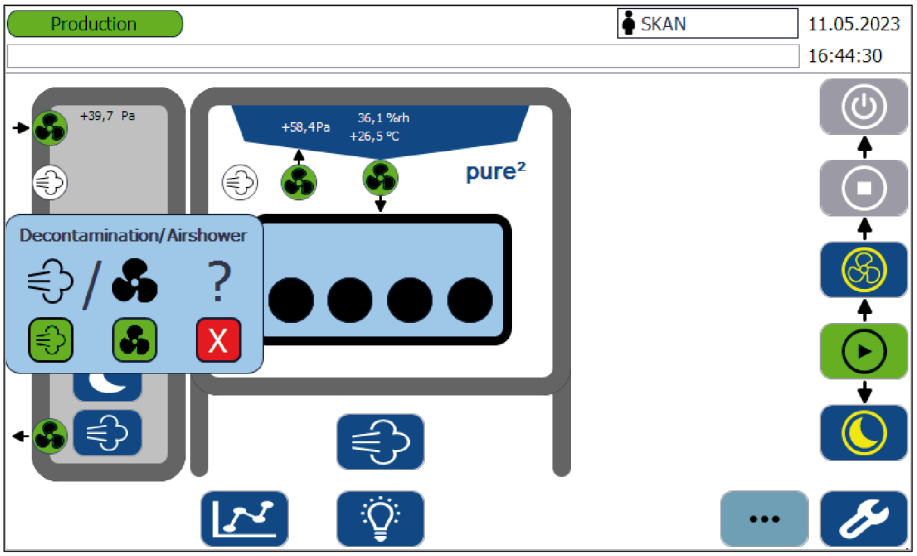
2. Touch the [Display devices] button  at the bottom right of the operating screen.

   ➡ The devices are shown in the main page:



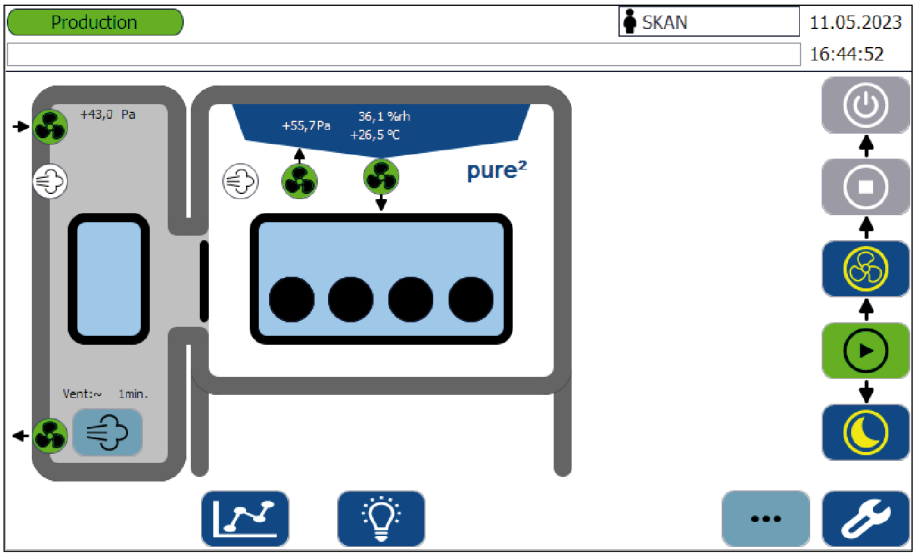
3. Touch the [Decontamination] button  at the the left side (in the airlock chamber) of the operating screen.

   ➡ The confirmation prompt *"Decontamination/Airshower ?"* appears, depending on the valid settings.



4. Touch the [Confirmation-Airshower] button  to start the airshower of the airlock chamber.

   ➡ The airshower starts;



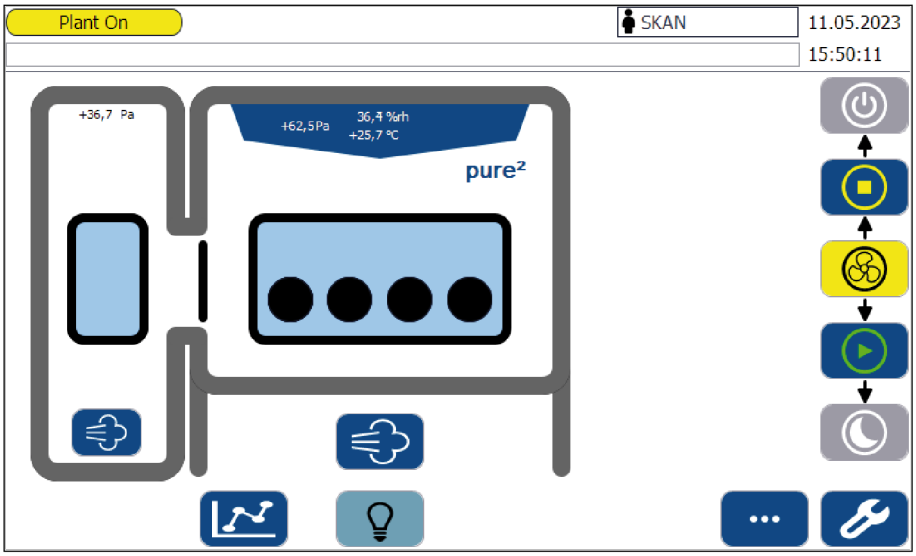
5. If the airshower process is finished:

   ➡ You are free to transfer materials from airlock into the isolator chamber or the other way.

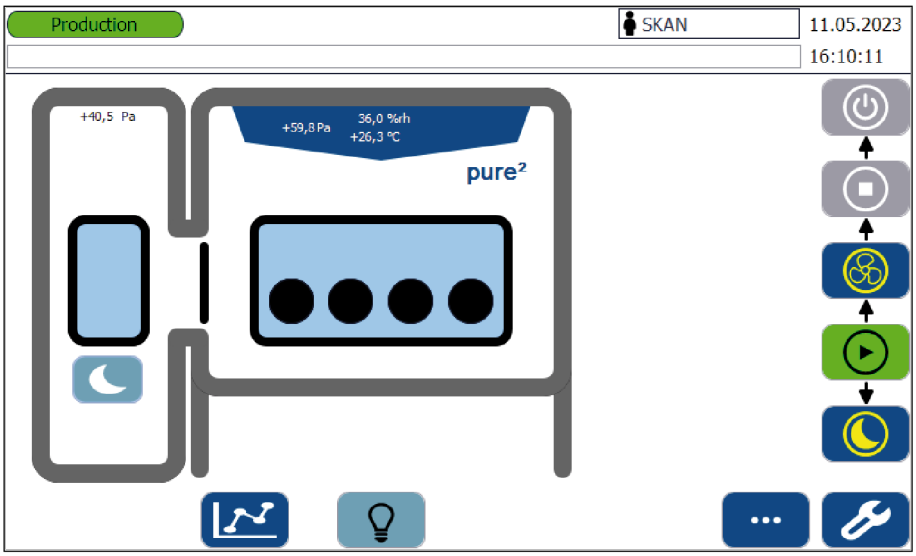
21.7 Production

Prerequisites:

✓ The front doors are closed;
✓ The machine is plant modes ON
✓ The machine is decontaminated or not depending on the settings on the basis of the intended use and processed products.



1. Touch the [Production] button  at right side of the operating screen.
   ➡ The machine changes in plant mode PRODUCTION



2. *If you would like to leave machine mode PRODUCTION (open doors for example):*

   Touch the [Plant ON] button  at right side of the operating screen.
   ➡ The machine changes in plant mode ON.

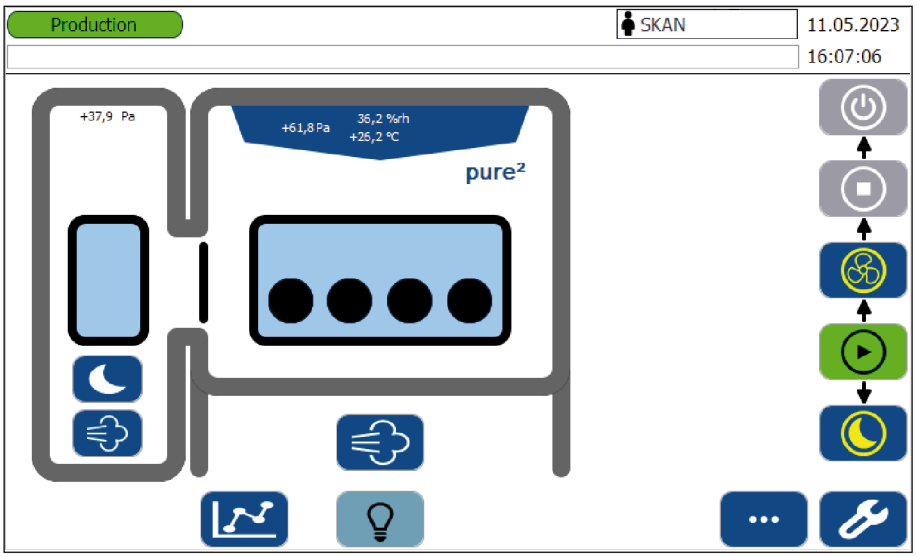
21.8 Standby

If you do not use the isolator for a certain time but want to keep the decontaminated status of the chamber, you can switch to standby mode. In standby mode, the doors remain closed and the fans run slower.

Prerequisites:

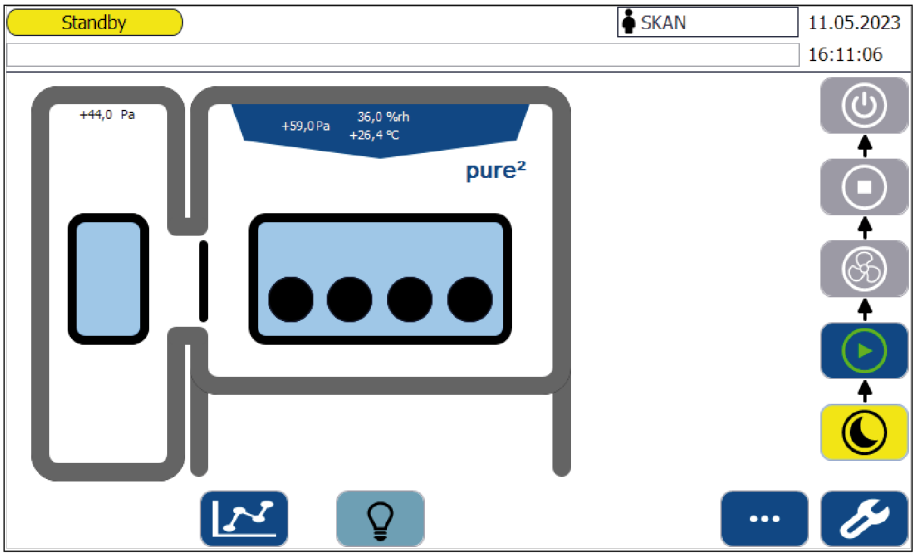
✓ The machine is plant modes PRODUCTION

✓ The machine is decontaminated or not depending on the settings on the basis of the intended use and processed products.



1. Touch the [Standby] button  at right side of the operating screen.

   ➡ The machine (isolator and airlock) changes in plant mode STANDBY

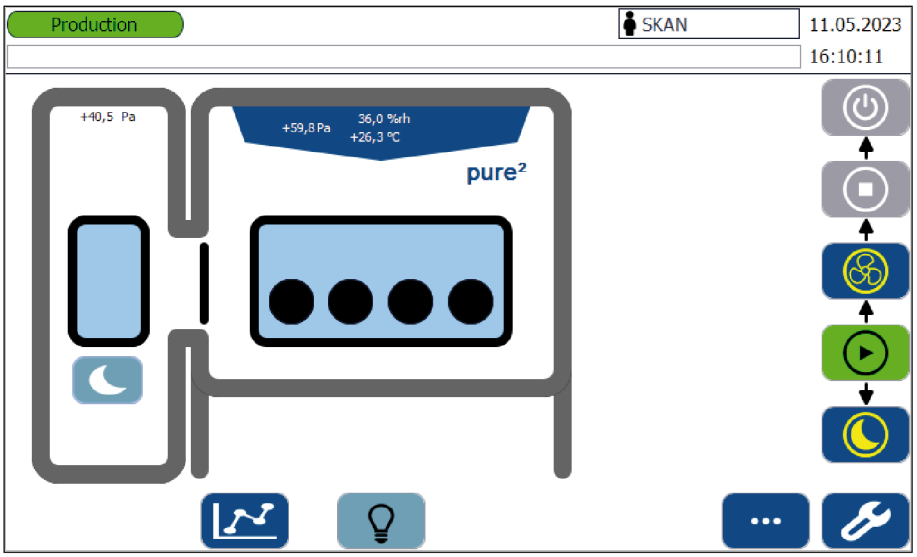


   ➡ The status of the chamber is maintained during standby mode and the front doors remain closed.

2. *If you would like to switch **only the airlock** in STANDBY:*

   Touch the [Standby] button  at the the left side (in the airlock chamber) of the operating screen.

   ➡ The airlock changes in plant mode STANDBY.



3. *If you would like to switch the airlock to mode Production again:*

   Touch the [Standby] button  at the the left side (in the airlock chamber) of the operating screen again.

4. *If you would like to leave machine mode STANDBY (isolator and airlock) :*

   Touch the [Production] button  at right side of the operating screen.

   ➡ The machine changes in plant mode PRODUCTION.

   ➡ The fans run with the set values.

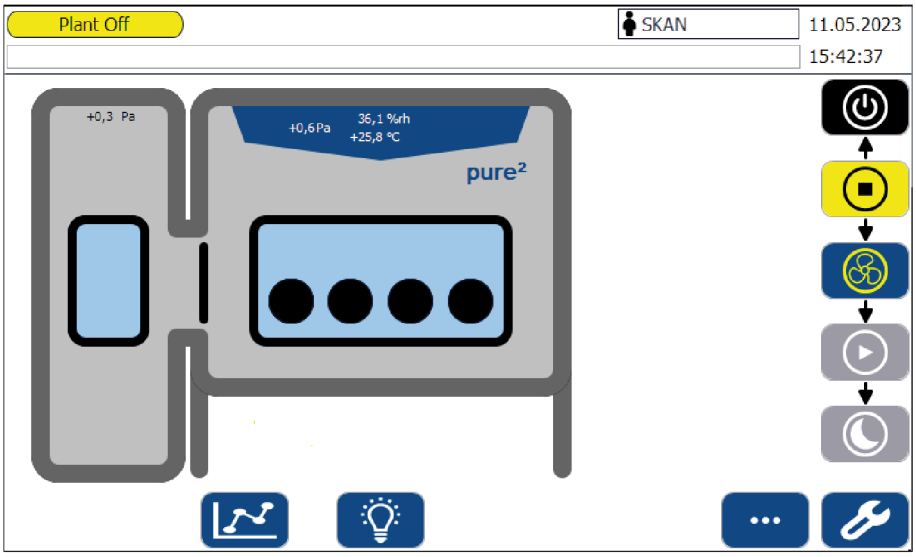
22 Trends

Different measurement values are displayed in their time dependence in the main menu "Trends".

1. *If the "Main page" operating screen is not active:*

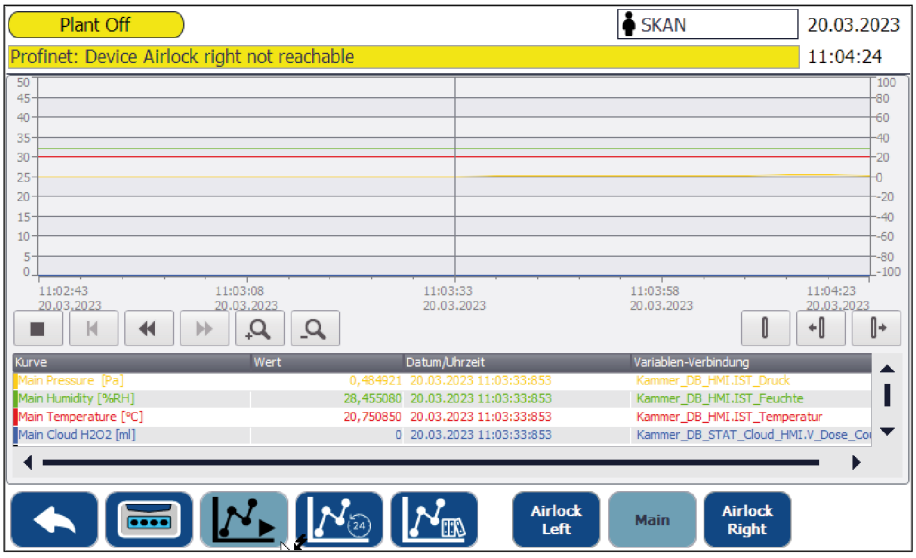
   Touch the [Main page] button  at the bottom left of the operating screen.

   ➡ The "Main page" operating screen appears:



2. Touch the [Trends] button  at the bottom left of the operating screen.

   ➡ The "Trends" operating screen appears:



3. Touch the machine part buttons at the bottom of the operating screen to see the trends of the required machine parts (depending on the configuration of your system):

   - Airlock left;
   - Main chamber;
   - Airlock right;

4. Touch the trend type buttons at the bottom of the operating screen to see the evolution of the values in the required time window. You can select between 3 different recording options:
   - Daily;
   - Long therm;
   - Archiv;

   ➡ The trends window with the set parameters appears.

23 Alarm handling

The system generates an alarm message (fault message) every time a machine fault occurs, which is displayed in the alarm message window of the permanent screen.

There are three different kind of messages:

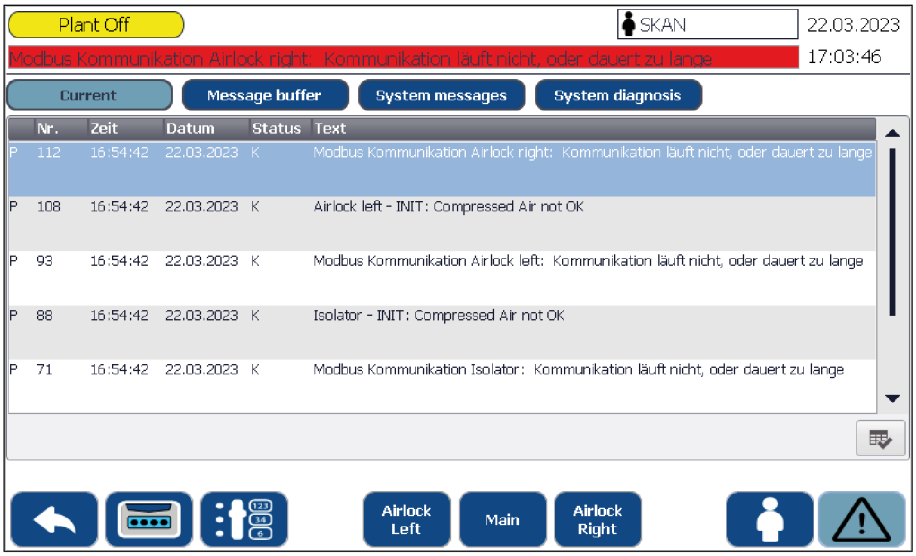
- Alarms - colored in red - have to be acknowledged;
- Warning messages - colored in yellow - without acknowledgement;

Alarms are continuously logged and can be reviewed at audits.

The last alarm or warning is displayed in the alarm messages window of the permanent screen. All others unknowledged messages can you see in the Alarm menu.

1. Touch the [Alarms] button  at the bottom right of the operating screen.

   ➡ The "Alarms" operating screen appears:



2. Touch the available submenu buttons at the top of the operating screen to see the "Message buffer", "System messages" or System diagnosis".

   In the "Current message list" you will find all current unknowledged alarms or warnings.

3. Eliminate the reason of the fault.

4. Touch the [Acknowledgement] button  at the bottom right of the operating screen.

   ➡ All alarm messages are confirmed.

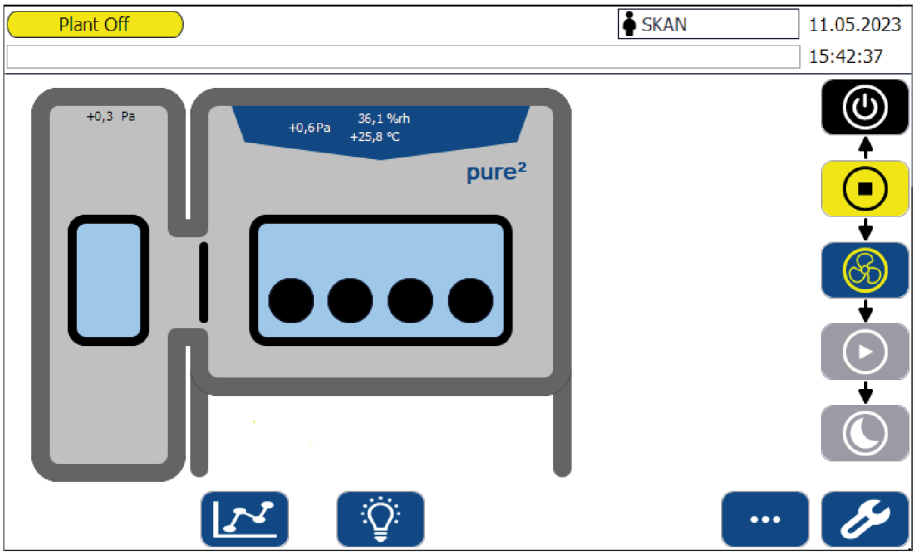
   Once acknowledged the alarms will disappear from this list.

24 Settings

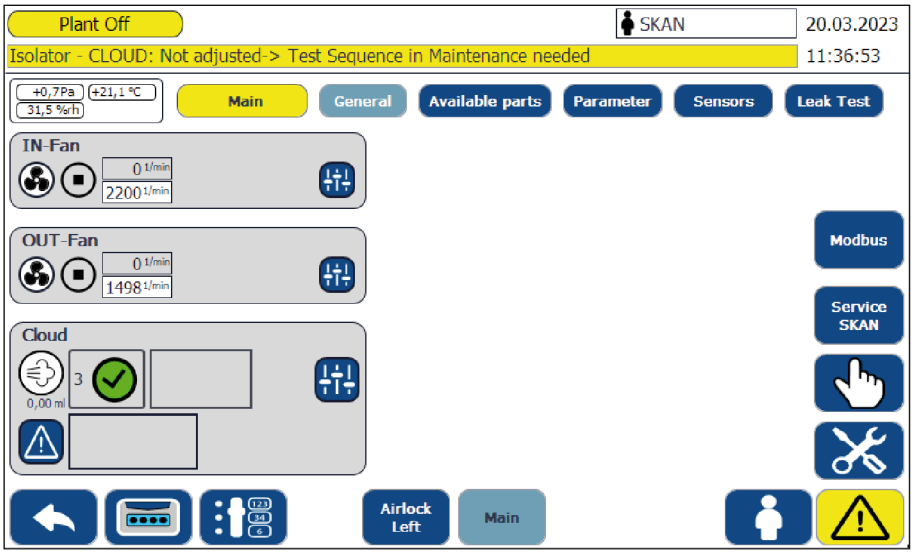
24.1 Loading / save parameters

If you are logged in with a sufficiently high password level, you may download the current software and therefore all settings of the system as a backup before carrying out service work, or install new software with valid system settings.

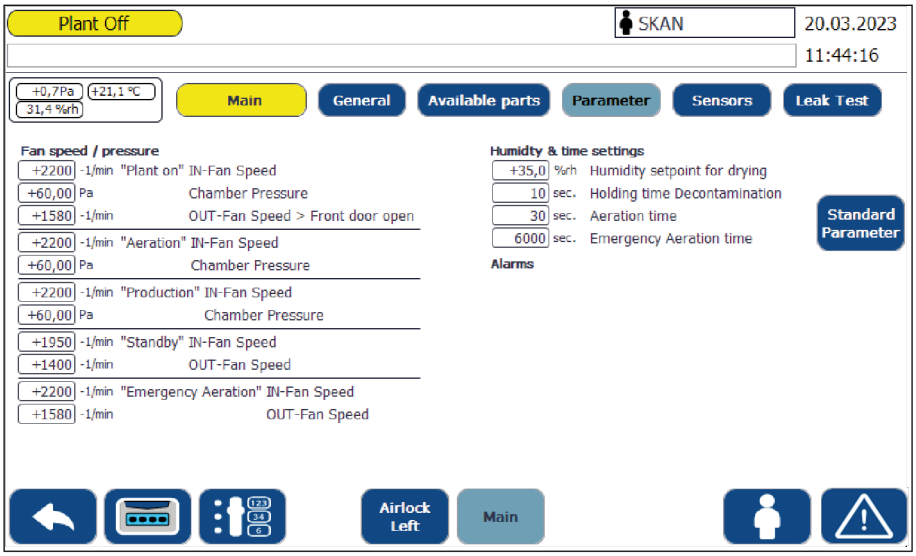
✓ The machine main switch is on and the system ist started up.



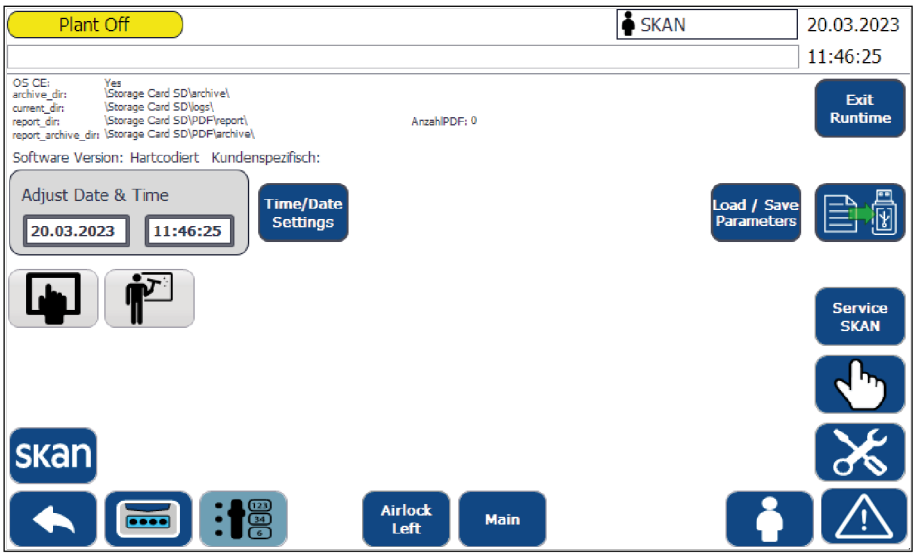
1. Connect the medium where you would like to save the backup copy or perform the installation.
2. Touch the [Settings] button  at the bottom right of the operating screen.
   ➡ The "Generall settings" operating screen appears:



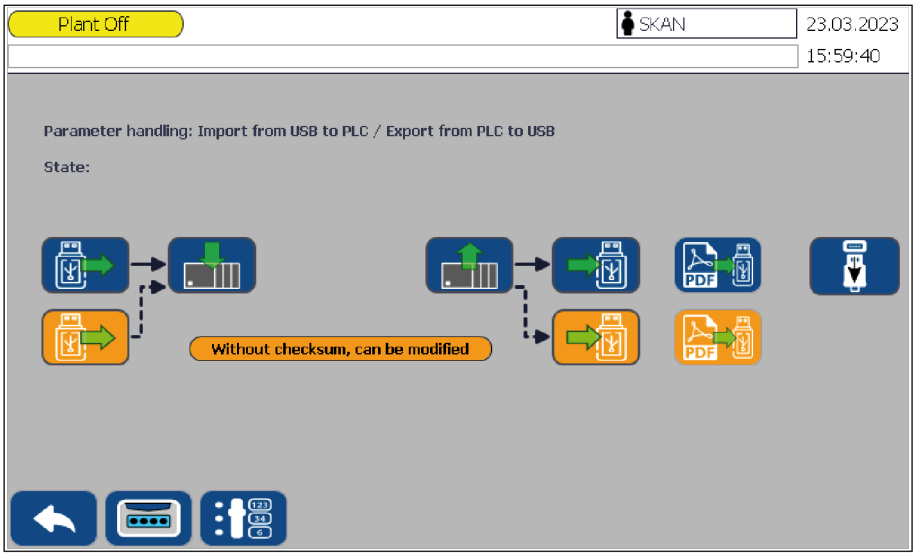
3. Touch the [Parameter] button at the top right of the operating screen.
   ➡ The "Parameter" operating screen appears:



4. Touch the [Features] button  at the bottom left of the operating screen.
   ➡ The "System settings" operating screen appears:



5. Touch the [Load / Save Parameters] button left of the operating screen.
   ➡ The operating screen to import / export to / from USB appears:



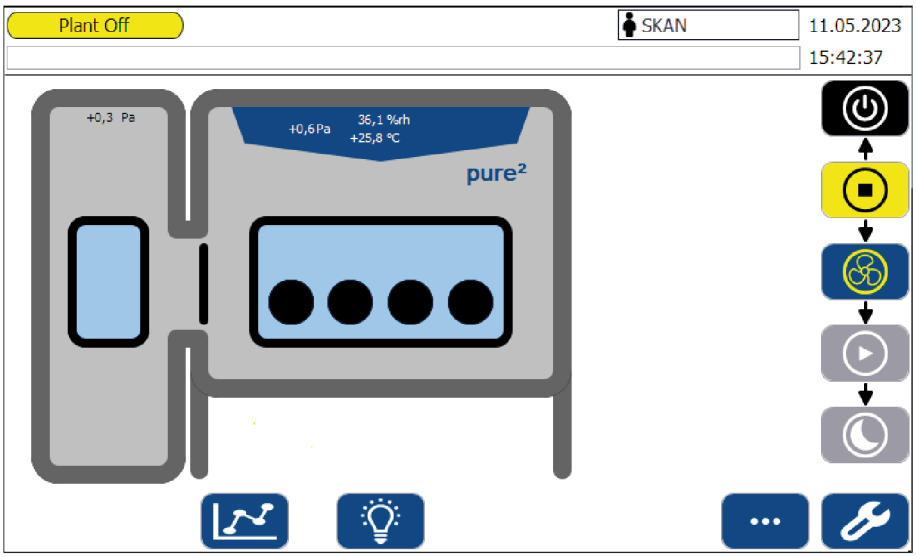
➡ The operating screen to import / export to / from USB appears:

The orange buttons are only visible for Skan maintenance personal.

6. Touch the corresponding buttons to import or export the software to or from PLC.
7. *Exit the "Settings" menu:*

   Touch the [Main page] button  at the bottom left of the operating screen.

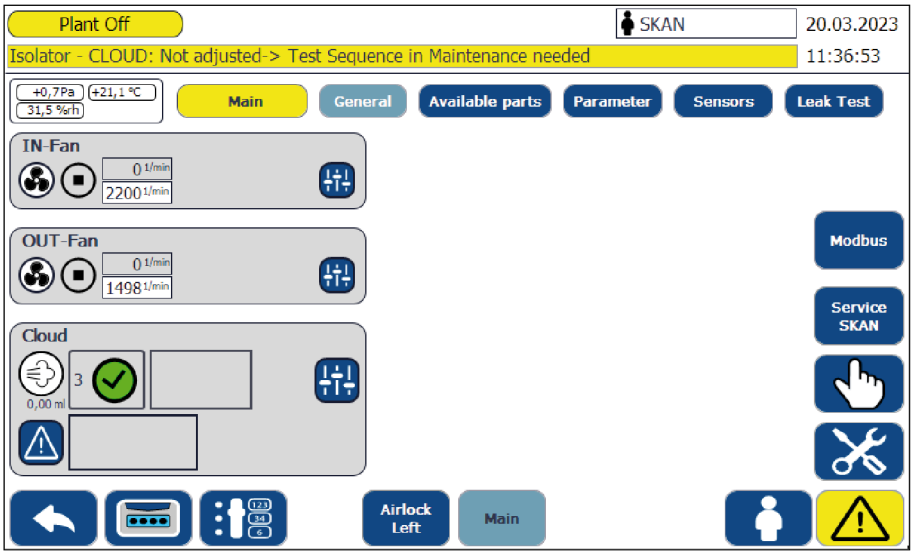
   ➡ The "Main page" operating screen appears:



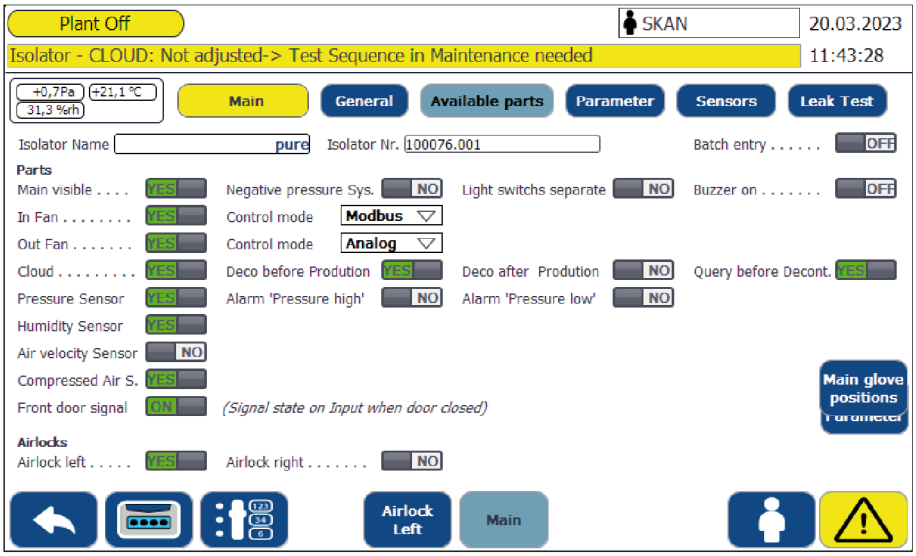
24.2 Software settings

1. Touch the [Settings] button  at the bottom right of the operating screen.

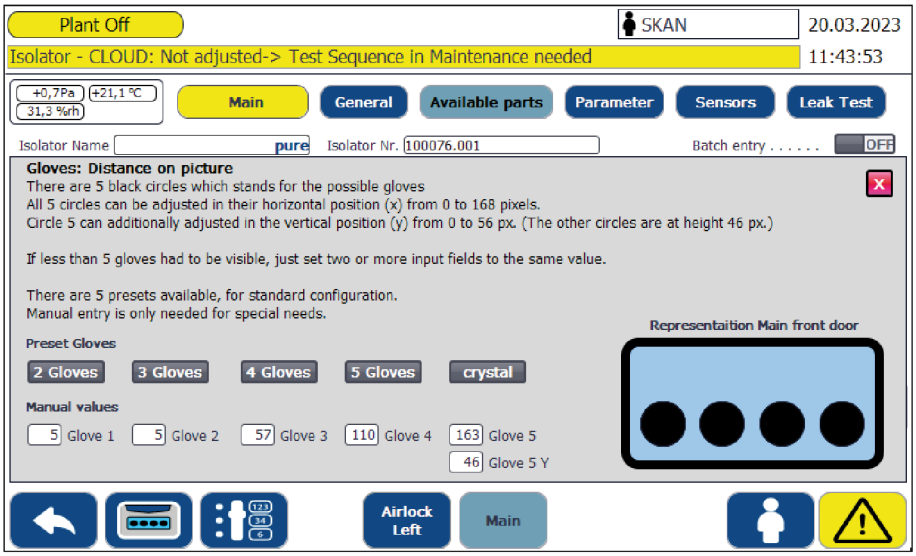
   ➡ The "Generall settings" operating screen appears:



2. Touch the [Available parts] button at the top middle of the operating screen.
   ➡ The "Available parts" operating screen appears:.



3. Select the machine compartment in the menu bar what you would like to make the settings for.
4. Perform the configuration settings required for your machine compartment.
5. Select the "Main" machine compartment in the menu bar.
6. Touch the [Main glove positions] button at the right side of the operating screen.
   ➡ The configuration operating screen for the main front door appears:



7. Set the visualisation and the position of the gloves.

25 Maintenance

25.1 Checking the system for leak-tightness (Leak test)

With the manual leak test, after service and maintenance work, you can check whether the machine is sealed gas-tight and can hold pressure.

NOTICE

A leak test should be performed regularly by trained personnel.

- ► After service / and maintenance activities.
- ► A leak test of the entire system must be carried out at least weekly under the normative requirements of DIN 12980.

NOTICE

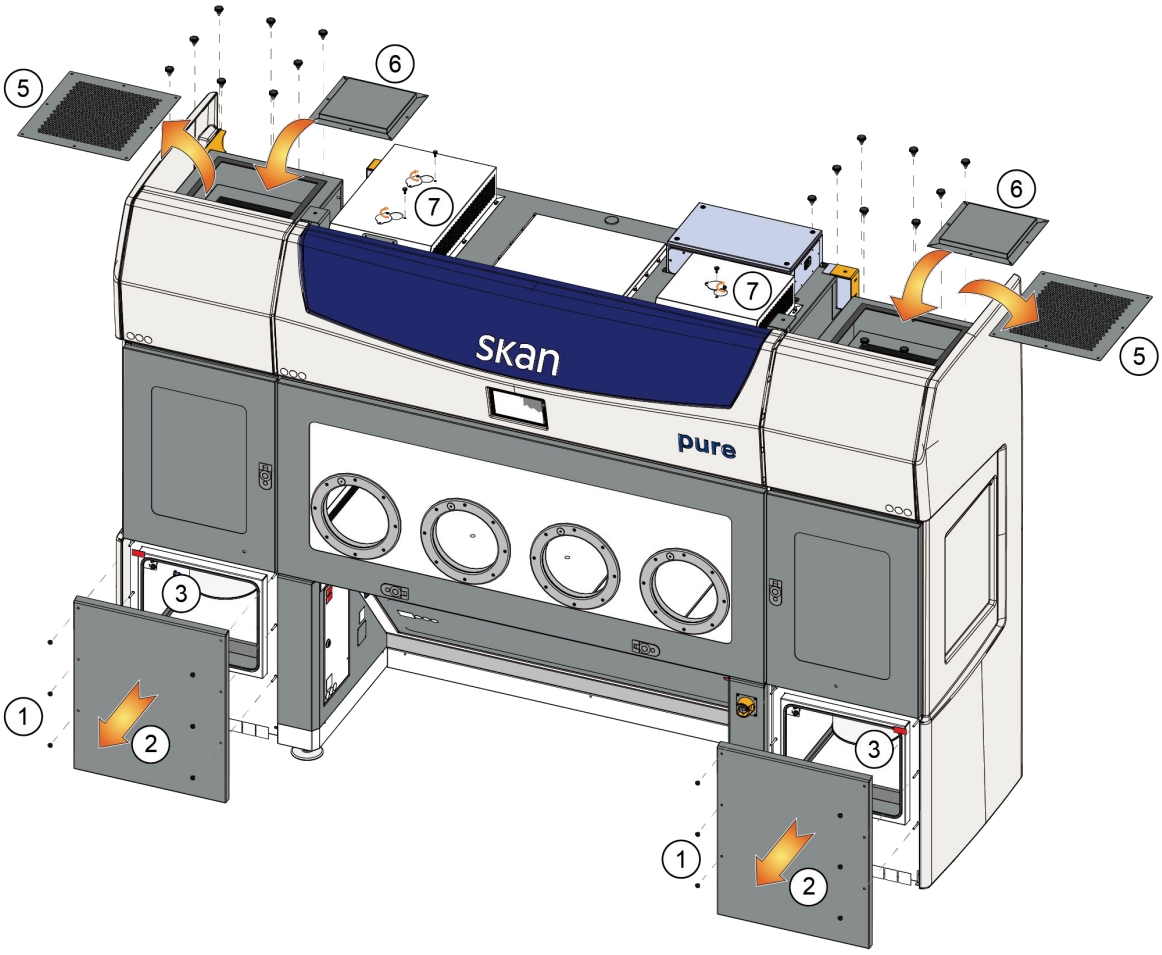
A leak test is not capable of detecting small holes and/or cracks in the gloves or sleeves!

Contamination hazard.

- ► Check the integrity of the glove port regularly. Use a validated test method.
- ► When operating the unit under the normative requirements of the DIN 12980, a leak test of the glove system must be carried out at least once per working day, using a validated procedure.

25.1.1 Preparation for the manual leak test

Before starting the manual leak test, the unit must be prepared for the test according to this chapter.



1. Remove the six screws of the airlock base frame revision lid.
2. Remove the revision lid.
3. Manually close the FiPas by using the appropriate tool.

➡ *For detailed information and safety instruction refer to separated FiPa filter cartridge instruction.*

4. Close the isokinetic probe (Option) with the suitable lid.
5. Remove the of the intake air fan of the airlock (left and right - depending on the configuration of your system).
6. Instead of the protective grid mount the corresponding metal sheet cover.
7. Open the round plates of the top FiPa exhaust housing and FiPa intake.
8. Close the FiPas with the appropriate tool.

   ➡

For detailed information and safety instruction refer to separated FIPA filter cartridge instruction.

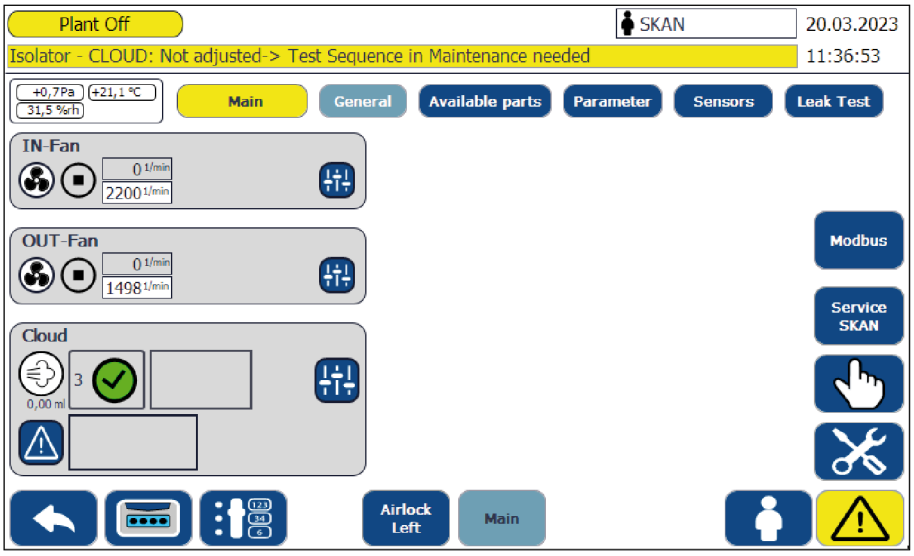
9. Open the transfer door.
10. Close the mouse hole cover (only applicable for the option LAF)

    ➡ After finishing the preparation, the user can start a manual leak test.

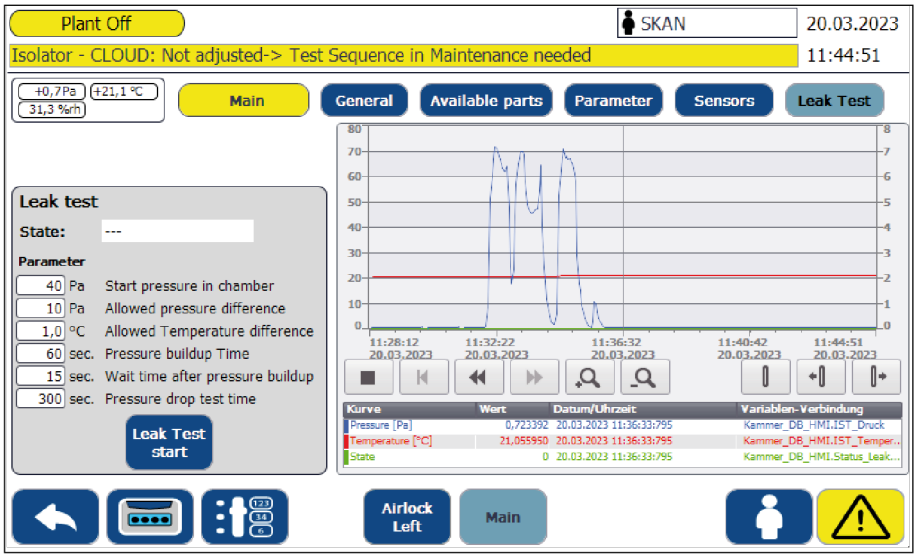
25.1.2 Starting the manual leak test (test in overpressure)

✓ The front doors are closed
✓ The transfer doors are open.
✓ The isolator is in machine mode ON.

1. Touch the [Settings] button  at the bottom right of the operating screen.
   ➡ The "Generall settings" operating screen appears:



2. Touch the [Leak Test] button at the top right of the operating screen.
   ➡ The "Leak Test" operating screen appears:.



3. Touch the [Leak test start] button.
   ➡ message appears “Close all openings”.
4. Check that all openings are closed.

5. Confirm by touching the [OK] button.
   ➡ Leak test starts.
   Text field shows “leak test is running”.
   The [abort leak test] button is enabled.
6. Afterwards the unit shows either “Leak Test successful” or “Leak Test Failed”.
7. Further operator input is required e.g. to start a new Leak test or to return back to normal action.

25.1.3 Cancelling the manual leak test (test in overpressure)

▶ Touch the [ABORT LEAK TEST] button.
   ➡ Manual leak test is cancelled.
   Corresponding advisory message shows.
   The unit switches back to state 23 Special. Further operator input is required e.g. to start a new Leak test.

25.1.4 Returning back to normal operation

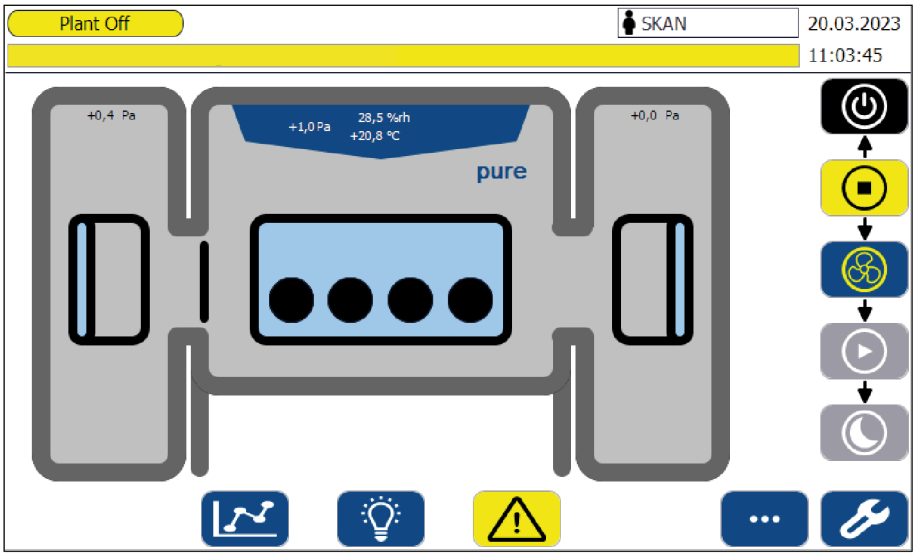
⚠ CAUTION

Crush hazard when closing the end cover and when inserting the FiPa filter cartridge!

Fingers can be crushed when closing the end cover or inserting the cartridge!

► Do not reach into the locking mechanism when closing the cartridge.
► Do not reach into the inlet opening area when inserting the filter cartridge.

1. To return back to normal operation, the user has to put the elements described in preparation for the manual leak test back to the initial position.
2. *Exit the "Settings" menu:*
   Touch the [Main page] button  at the bottom left of the operating screen.
   ➡ The "Main page" operating screen appears:


Plant Off
SKAN
20.03.2023
11:03:45
+0,4 Pa
+1,0 Pa
28,5 %rh
+20,8 °C
+0,0 Pa
pure

25.1.5 Starting the manual leak test (test in negative pressure)

When using the system under the requirements of DIN 12980, the leak test of the main chamber and the airlock chamber(s) should be carried out at least weekly.

The limit values are defined in accordance with class 4 of ISO 10648-2:1994-12, with a leak rate of maximum 10% volume content per hour, at twice operating pressure

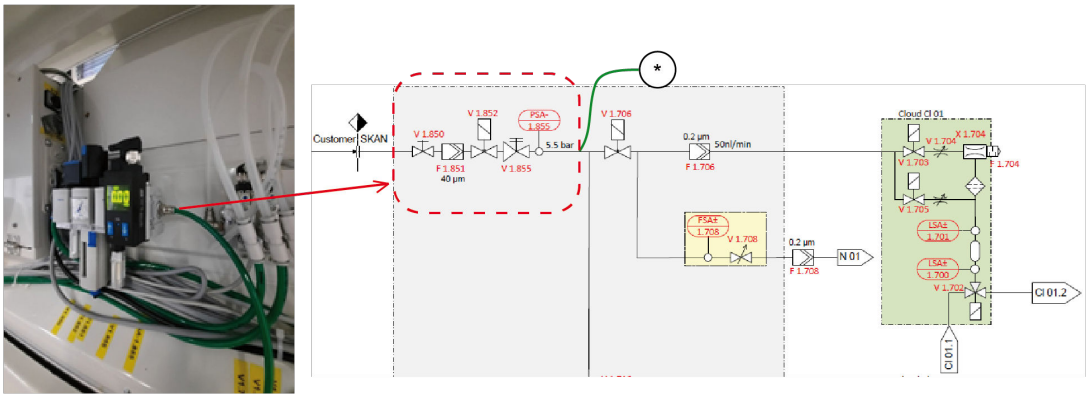
Chamber	Volume [l]	Lake rate 10 % in [l/h]	[l/min]
airlock	394	39	0.7
4 gloves main chamber	2.100	210	3.5
4 gloves + 1 x airlock	2.494	249	4.2
4 gloves + 2 x airlock	2.888	289	4.8
2 gloves main chamber	1.530	153	2.6
2 gloves + 1 x airlock	1.924	192	3.2
2 gloves + 2 x airlock	2.318	232	3.9

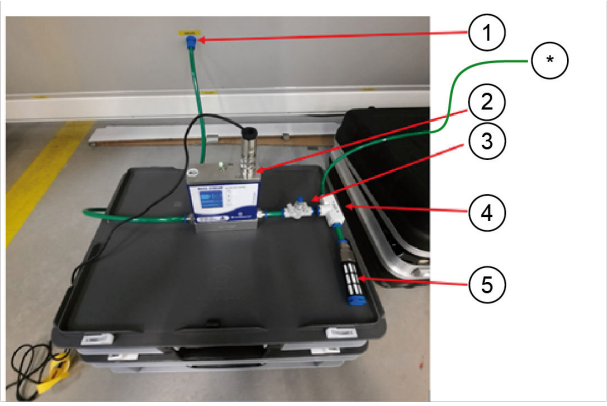
Test installation

✓ Test preparations as described previously at the beginning of this chapter.
✓ The isolator is in machine mode OFF.
✓ The corresponding front doors and transfer doors are closed.

1. Connect the compressed air supply to the venturi nozzle:

➡





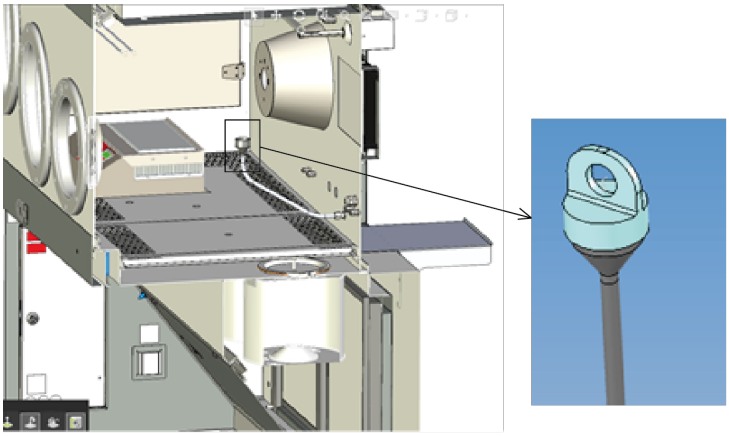
1 DEHS connection
2 Flowmeter: Type: Bronkhorst MF-227, Range: 0.5 - 10 l/min
3 Needle valve: Type Festo GR-QS-8
4 Venturi nozzle: Type Festo VN-14-L-T4-PQ2-VQ3-RQ3, Max 90 l/min
5 Silencer: Type Festo U 1/4

2. Open the service door above the main chamber and open the valve V 1.852 manually at the main pneumatic system.
3. With the needle valve adjust the pressure to -120Pa at the test installation.
4. Read the air flow at the Flowmeter at least as three times in an interval of one minute.

25.2 Microbiological environment monitoring

25.2.1 Isokinetic probe for particle counter without decontamination loop

Optionally, a particle counter can be connected directly to the isokinetic probe in the working chamber. Before the decontamination cycle, the isokinetic probe must be tightly closed with the supplied lid.



⚠ CAUTION

During decontamination, hydrogen peroxide (H_2O_2) in the machine!

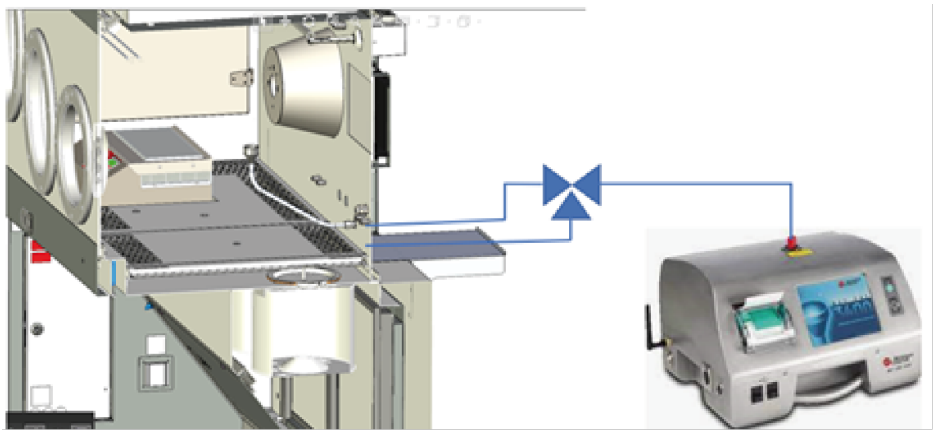
Chemical burns, eye injuries, fainting and death can result when contacting the hydrogen peroxide.

- ► Close all openings of the work chamber.
- ► Observe the safety data sheet for hydrogen peroxide.

► Close the isokinetic probe before each decontamination!

25.2.2 Isokinetic probe for particle counter with decontamination loop

The particle counter is connected directly to the 3/2-way valve.
In PRODUCTION, the valve is opened automatically. The particle counter is then directly connected to the isokinetic probe in the working chamber. In all other modes is the valve position in "Deco Loop". Here, the isokinetic probe and the valve is decontaminated with hydrogen peroxide.



26 Using the glove port

26.1 Information on use

Observe the following notes when using the glove port:

⚠ CAUTION

Insufficient person protection if glove port system is defective!

Poisoning and environmental contamination if toxic gases or substances leak.

- ► Check the integrity of the glove port system regularly. Use a validated test method.
- ► Do not use sharp-edged tools during work.
- ► Do not wear jewellery on your hands; work without a wristwatch.
- ► Do not work with long or sharp fingernails.
- ► Wear a second pair of gloves when working with toxic substances.

If there are rapid movements in the glove port, there could be pressure fluctuations in the work chamber, which can lead to an alarm reaction of the machine.

Be conscious therefore of calm, clean-room compliant movements when you are working with the glove port.

26.2 Basic design of the shoulder ring

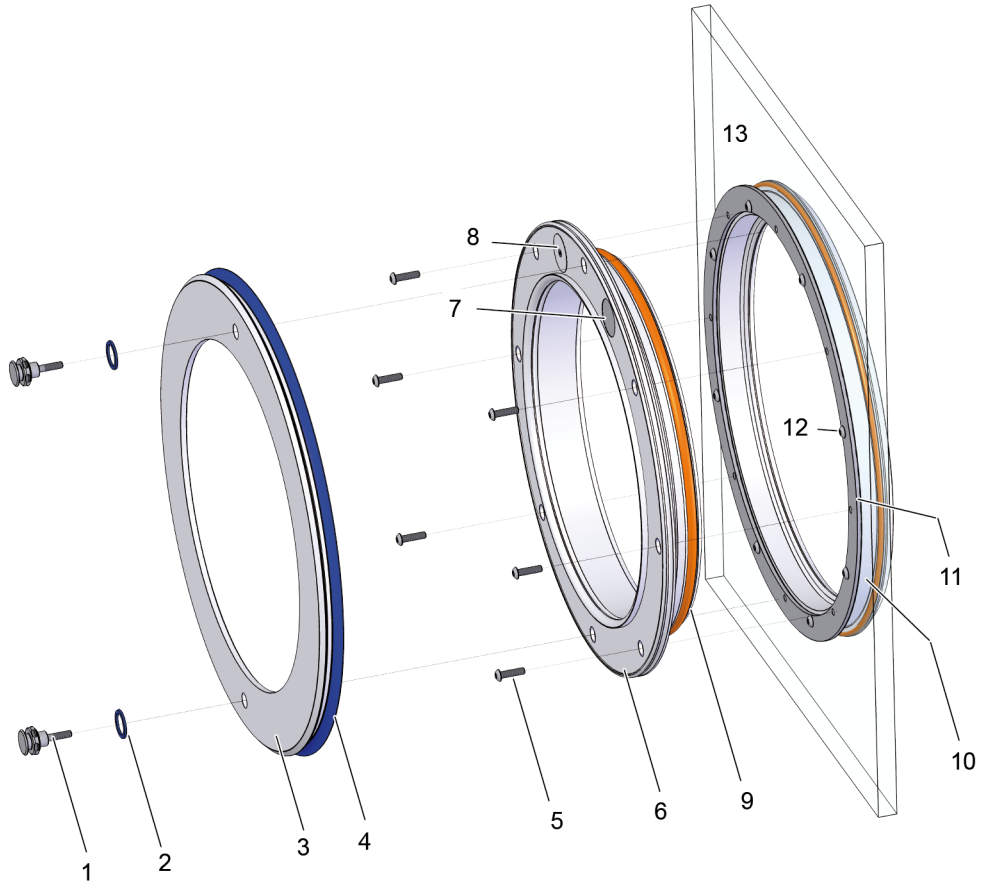
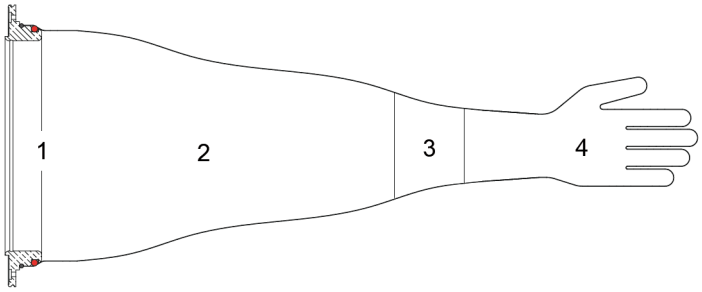


Fig. 1: V3 Shoulder ring - basic design

1 SKAN fitting screw for shoulder rings, M5
2 Sealing ring
3 Cover ring
4 Sealing profile
5 M5 pan-head screw with hexagon socket
6 Inner ring
7 Labelling plate
8 RFID tag
9 O-ring, round cord D8
10 Outer ring, with round cord D4
11 Stainless steel flange with PVC washer
12 M5 pan-head screw with hexagon socket
13 Single pane

26.3 Replacing the two-piece glove

The two-piece glove consists of a sleeve (2) and a glove (4). These are connected to each other via the glove ring (3).



1 Inner ring
2 Sleeve
3 Glove ring
4 Glove

If you are using or have used toxic and/or active substances in the working chamber, ensure that the following measures have been taken before changing the glove:

- Cleaning/decontamination of the glove surfaces on the working chamber side
- Cleaning/decontamination of the working chamber
- Inactivation of toxic and active substances in the working chamber

WARNING

Gloves and surfaces in the work chamber can potentially be contaminated!

There is a danger of poisoning and environmental contamination with toxic substances.

► Clean and decontaminate the glove surface on the work chamber side of the gloves before you begin with the glove exchange.
► Clean and decontaminate the work chamber before you begin with the glove exchange.
► Inactivate toxic and active substances in the work chamber before you begin with the glove exchange.

CAUTION

No protective barrier between the work chamber and the surrounding during the glove exchange!

Product contamination! Contamination of the work chamber.

► Remove or protect all substances within the work chamber that are at risk of getting contaminated before you begin with the glove exchange.

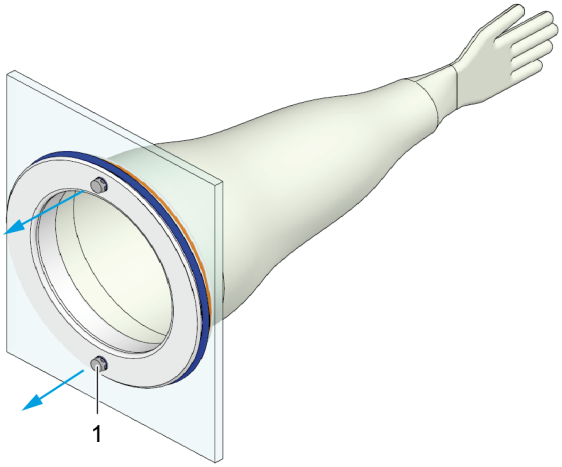
✓ Universal spanner with adjustment range of at least 22 mm (WAF21) or open-end spanner WAF21
✓ Tool for Allen screws, size 3
✓ Torque wrench (calibrated; torque range 1 Nm - 10 Nm)
✓ System status "off"
✓ Replacement glove/sleeve according to spare parts list

▶ For a glove change without a sleeve change see ➦ *Chapter 26.4 'Replacing the glove on the glove ring' on page 108*

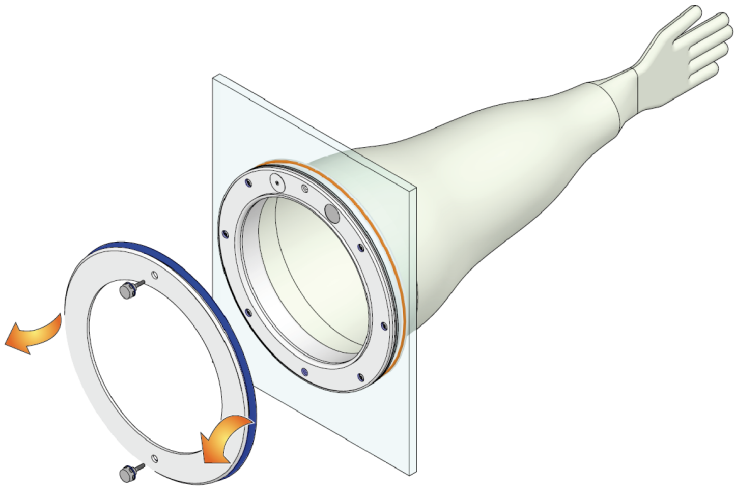
26.3.1 Disassembling the inner ring

Before replacing the two-piece glove, you shall dismantle the inner ring from the shoulder ring.

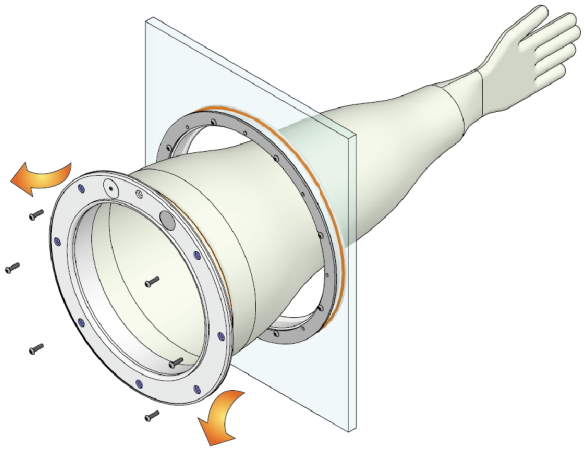
1. Loosen and remove the two fitting screws (1) that fasten the cover ring to the inner ring.



2. Grasp the cover ring with both hands sideways in the profile groove at the level of the two orange arrows. Pull evenly on the ring until it detaches from the flange of the inner ring.

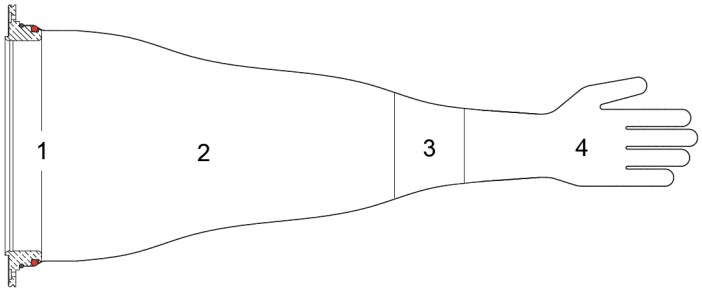


3. Loosen and remove all the pan-head screws that fix the inner ring to the outer ring. Remove the inner ring with the glove from the opening.
   ➡



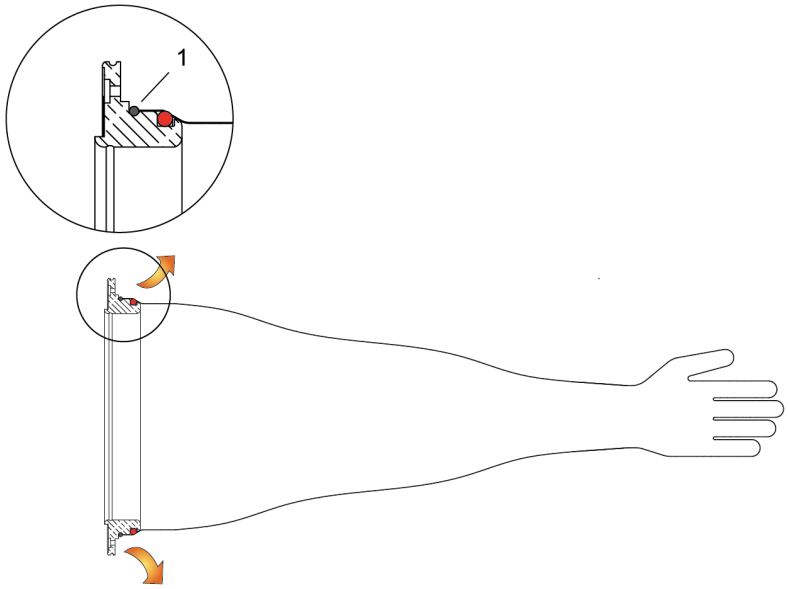
26.3.2 Disassembling the sleeve

The sleeve (2) is dismantled from the inner ring (1) and the glove ring (3).



1. Loosen the rolled rim (1) from the profile groove of the inner ring and slip it off.

➡



2. Roll the O-ring of the sleeve into the free groove on the glove ring.

➡

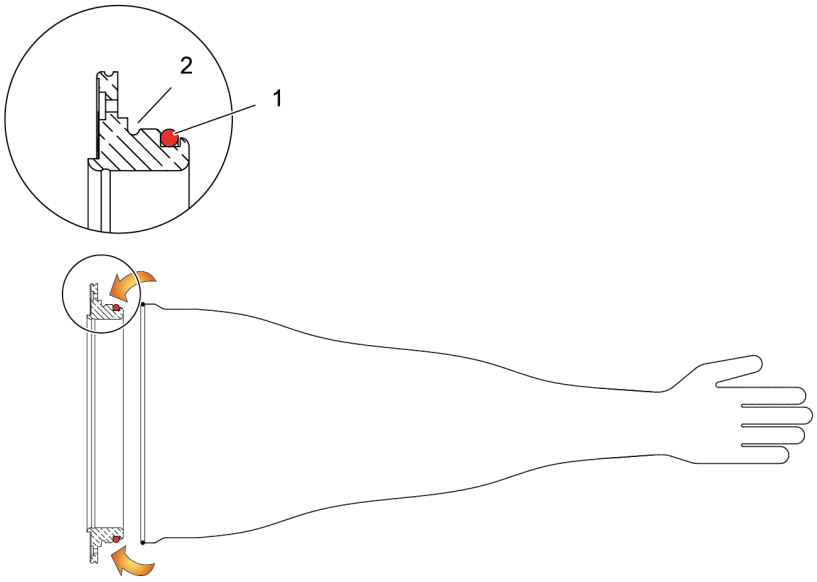
3. Pull the sleeve off the glove ring.

26.3.3 Assembling the sleeve

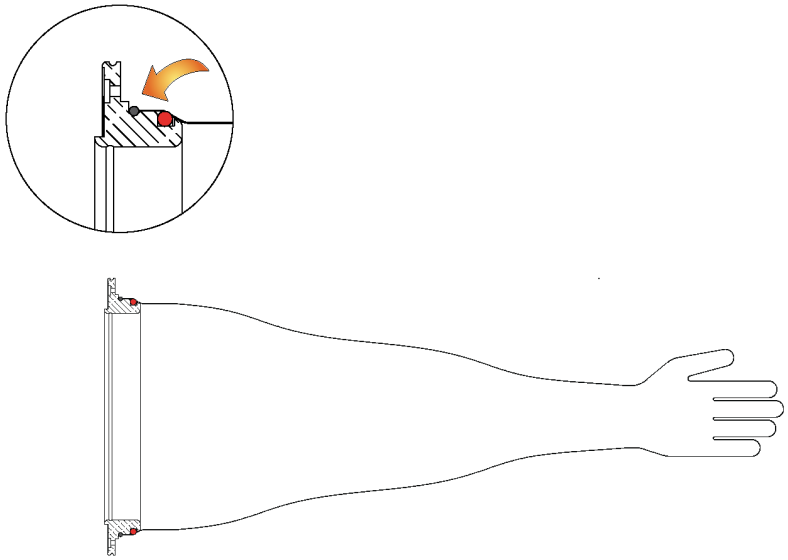
The sleeve is mounted on the inner ring and the glove ring.

1. Slip the rolled rim of the new sleeve over the inner ring of the shoulder ring. Pay attention to the vertical alignment of the glove part. Pull the rolled edge further over the O-ring (1) to the profile groove (2). Make sure that the rim is in the profile groove.

➡



➡



2. Pull the new sleeve on to the glove ring.

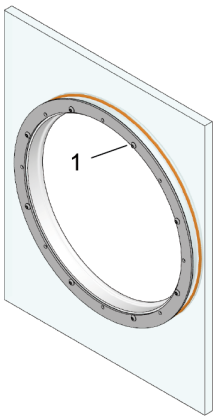
3. Roll the O-ring of the sleeve from the glove ring back on to the sleeve.

26.3.4 Assembling the inner ring

1. Before assembling the glove system, check all M5 pan-head screws (1) on the outer ring for tight fit. Observe the maximum tightening torque:

   Ma (max) = 2.0 Nm (1.48 ft x lb)

   ➡

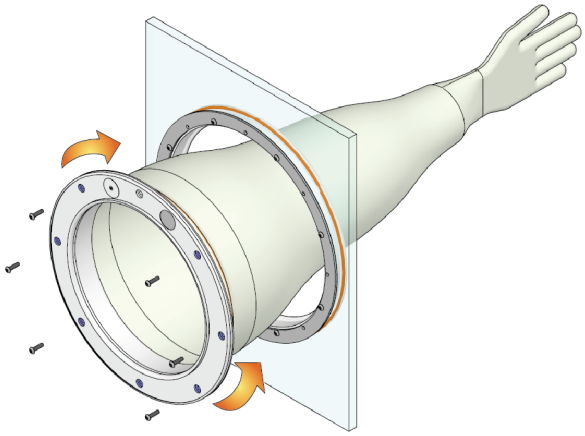


2. Insert the inner ring with the mounted glove system into the outer ring.

NOTICE

Make sure that the inner ring is correctly aligned.

➡

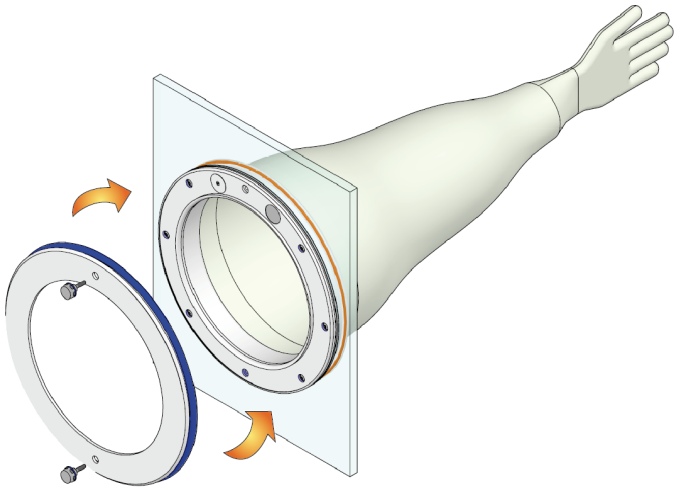


3. Fasten the inner ring by screwing in all pan-head screws on the outer ring evenly. Tighten the screws evenly in a crosswise sequence, in several passes, up to the maximum tightening torque:

   Ma (max) = 1.8 Nm (1.33 ft x lb)

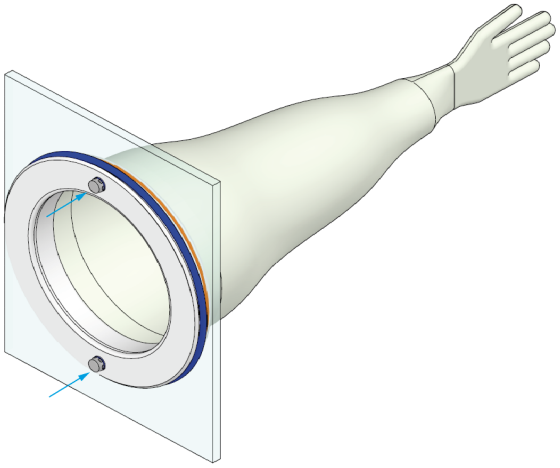
4. Press the cover ring onto the mounting flange of the inner ring until it engages.

   ➡



5. Secure the cover ring with the two fitting screws WAF21 and tighten the screws to 1.8 Nm (1.33 ft x lb).

   ➡



6. Check the newly mounted glove port for leaks.

26.4 Replacing the glove on the glove ring

⚠ WARNING

Gloves and surfaces in the work chamber can potentially be contaminated!

There is a danger of poisoning and environmental contamination with toxic substances.

- ► Clean and decontaminate the glove surface on the work chamber side of the gloves before you begin with the glove exchange.
- ► Clean and decontaminate the work chamber before you begin with the glove exchange.
- ► Inactivate toxic and active substances in the work chamber before you begin with the glove exchange.

⚠ CAUTION

No protective barrier between the work chamber and the surrounding during the glove exchange!

Product contamination! Contamination of the work chamber.

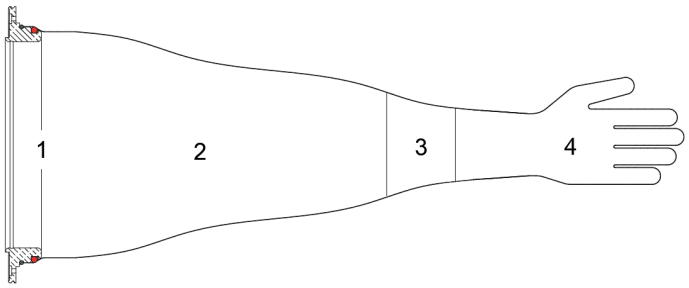
- ► Remove or protect all substances within the work chamber that are at risk of getting contaminated before you begin with the glove exchange.

If you use or have used toxic and/or active substances in the work chamber, make sure that the following measures have been taken prior to a glove exchange:

- Cleaning and decontamination of the glove surface on the work chamber side
- Cleaning and decontamination of the work chamber
- Inactivation of poisonous and active substances in the work chamber

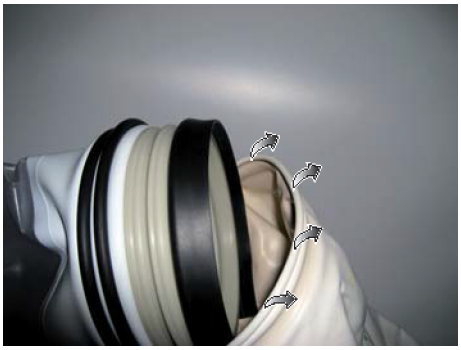
26.4.1 Disassembling the glove

1. The glove (4) is removed from the glove ring (3).



2. Roll the O-ring of the glove in the free groove on the glove port.

3. Pull the glove off the glove port.



26.4.2 Assembling the glove

1. Pull the new glove onto the glove port.

➡

2. Roll the O-ring of the glove from the glove port back onto the sleeve.

➡

26.5 Changing gloves during operation

A glove can be exchanged even without the disassembly of shoulder ring and sleeve.

NOTICE

The isolator can become contaminated due to faulty glove exchange or existing leaks in the gloves!

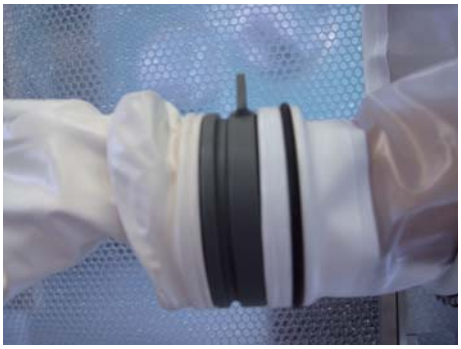
Product contamination.

► Please note that maintaining the protection/sterility barrier cannot be ensured comprehensively for the duration of the glove exchange during this exchange method.

1. Transfer a new glove into the work chamber of the machine.
2. Stretch the glove to be exchanged in the isolator.

3. Roll the O-ring of the glove from the glove port onto the glove.

4. Roll the outer edge of the glove from the inner groove of the glove port into the glove-sided outer groove.



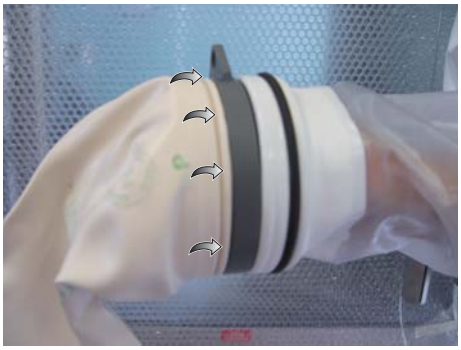
➡ Outer edge of the glove into the outer, glove-sided groove of the glove port.

5. Hold the glove port firmly and pull the glove to be exchanged into the sleeve.

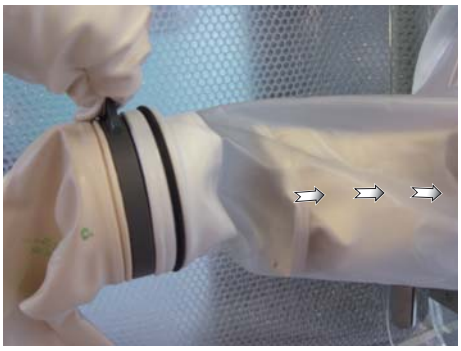
➡ Glove to be exchanged in the sleeve.

6. Pull the new glove over the glove to be exchanged.

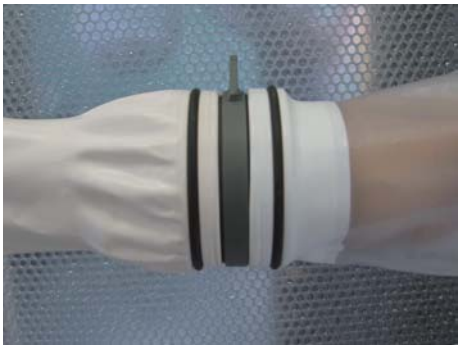
7. Roll the outer ring of the glove to the inner, glove-sided groove of the glove port.



8. Remove the glove to be exchanged by pulling it from the glove port through the sleeve to the outside.



9. Secure the new glove with the O-ring. Roll the O-ring over the glove to the inner, glove-sided groove of the glove port.



➡ Glove port with new glove.

27 Glove system according DIN 12980

According to the normative use of SKAN pure² to DIN 12980, the following points must be observed:

DANGER

Danger due to active substances!

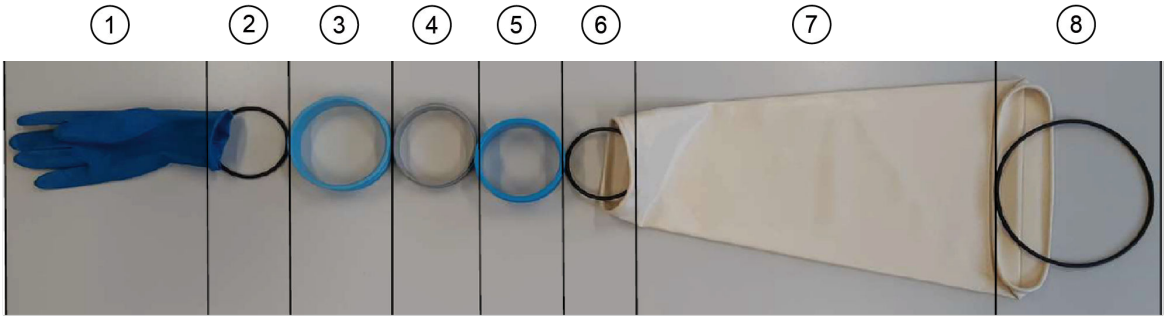
Working with active substances inside the unit can endanger the health of the operator.

- ► Only use glove systems that meet the requirements for Category III PPE (complex PPE) in ac-cordance with PPE Regulation (EU) 2016/425.
- ► Gloves and sleeves must be tested with regards to their resistance to permeation and penetration.

Replacement of the gloves and sleeves are described in the previous chapter.

27.1 Quick-change system for gloves

The following picture shows the glove change system, the structure of the SKAN two-piece glove port:



1 Glove
2 Gloves O-ring
3 Outer sleeve ring
4 Lip seal
5 Inner sleeve ring
6 Sleeves O-ring
7 Sleeve
8 O-ring

The figure shows the glove changing system from Berner Safety (https://www.berner-safety.de/media/8344/berner-zytostatika-isolator-schutzhandschuhwechsel.pdf) on a sleeve from Jung Rubber Tec.

Skan recommends the use of tested protective gloves type Berner Manu L from size 8.5.

Please ask SKAN Customer Service for article numbers and prices.

28 Check for chafing, cracks and leaks

1. When using the SKAN pure² under normative requirements in accordance with DIN 12980, a leak test on the glove system must be carried out at least once per working day using a validated procedure, e.g. with the SKAN Wireless GloveTester (WirelessGT).
2. Check the glove for chafing, cracks and leaks. Use a validated test method.

If you find damage (wear, cracks or leaks) to components of the glove port, replace the damaged components and check the glove port again.

We recommend to perform the glove integrity test (leak test) with the SKAN Wireless Glove Tester (WirelessGT®).

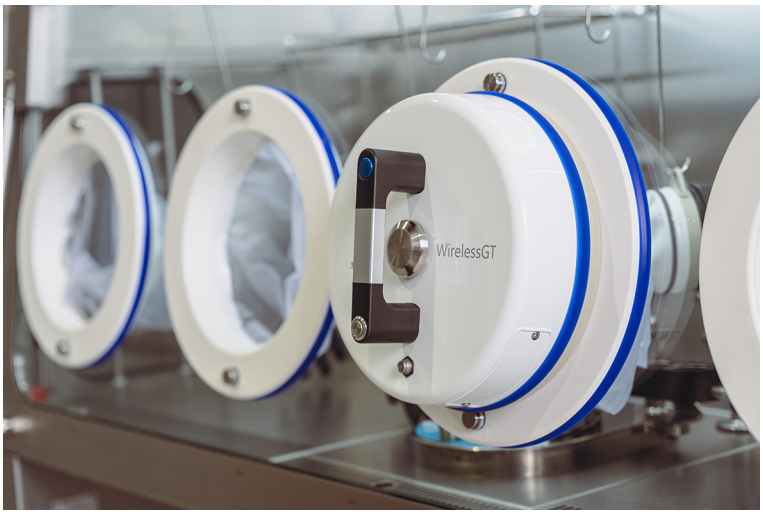


Fig. 2: SKAN WirelessGT ® installed

29 Cleaning and disinfection agents

29.1 Information for your safety

⚠ CAUTION

Cleaning and disinfection agents with highly flammable properties!

Danger of explosion and burns!

- ► If effective ignition sources are present, refrain from using alcoholic cleaning agents and disinfectants in the working chamber or other limited areas of the system! Effective ignition sources may include: Electric arcs or sparks in electrical equipment, hot surfaces of integrated heat sources, static charging of unearthed components.
- ► Adhere to the applicable output rates for cleaning and disinfection agents.
- ► Observe the warning messages on the packaging of the cleaning and disinfection agents used.
- ► Observe the safety data sheets of the cleaning and disinfection agents.

⚠ CAUTION

Cleaning and disinfection agents with properties that are hazardous to health!

Irritation to skin and eyes. Poisoning.

- ► Observe the warning messages on the packaging of the cleaning and disinfection agents used.
- ► Observe the safety data sheets of the cleaning and disinfection agents.
- ► Wear appropriate personal protective equipment (PPE) when cleaning and disinfecting.

29.2 Notes on material and component-specific compatibility

NOTICE

Cleaning agents containing hypochlorite and cleaning agents with strong acids and highly concentrated halogenated solutions attack stainless steel surfaces!

Corrosion and oxidation of stainless steel surfaces.

- ► Do not use cleaning agents containing hypochlorite for stainless steel surfaces.
- ► Do not use cleaning agents with strong acids for stainless steel surfaces.
- ► Do not use highly concentrated halogenated solutions as cleaning agents for stainless steel surfaces.

Tab. 1: Material and component-specific compatibility towards cleaning agents

Assembly group / Component	Suitable cleaning agents	Important information
Acrylic and plexiglass panes	Plastic cleaners for acrylic and plexiglass products	Do not use any cleaning agents that contain alcohol, acetone, chloramine or carbon tetrachloride.
EPDM seals	Sterile low-particle silicone wiping cloths (e.g. Klerwipe™- CR made by Shield Medicare)	
Glass panes	Glass cleaner	
Stainless steel surfaces	Soapy water 70% ethanol solution 70% propanol solution Cleanroom wiping cloths Chromium steel cleaner	Do not use cleaning agents containing hypochlorite, cleaning agents containing strong acids or highly concentrated halogenated solutions.
Plastic surfaces as long as not acrylic and Plexiglas panes	Soapy water 70% ethanol solution 70% propanol solution Cleanroom wiping cloths Plastic cleaners	

Tab. 2: Material and component-specific compatibility towards disinfection agents

Assembly group / Component	Suitable disinfection agents
Acrylic and plexiglass panes	P3-topax 91 (Ecolab Schweiz GmbH) P3-topactive OKTO (Ecolab Schweiz GmbH) Divosan forte VT6 (Diversey) Tego 2000 VT25 (Diversey)
EPDM seals	70% ethanol solution 70% propanol solution Mikrozid® AF liquid (Schülke & Mayr GmbH Deutschland)
Glass panes	70% ethanol solution 70% propanol solution Mikrozid® AF liquid (Schülke & Mayr GmbH Deutschland)
Stainless steel surfaces	70% ethanol solution 70% propanol solution Mikrozid® AF liquid (Schülke & Mayr GmbH Deutschland)
Plastic surfaces as long as not acrylic and plexiglass pane	70% ethanol solution 70% propanol solution Mikrozid® AF liquid (Schülke & Mayr GmbH Deutschland)

The table doesn't provide information about the effective spectrums of the listed disinfection agents.

30 Troubleshooting machine malfunctions

Troubleshooting malfunctions of the machine requires comprehensive knowledge of the machine, in particular regarding the functional relationships of the machine components. Before troubleshooting measures are taken, you must determine which hazards can occur in association with the planned measures or the manipulation of the machine. Measures or manipulations for the machine that could result in danger to personal safety or the environment may not be performed.

⚠ WARNING

Improper rectifying of machine malfunctions can lead to unforeseeable risks!

This poses a hazard to personal safety and the environment.

- ► Rectifying machine malfunctions shall be performed only by trained technicians.
- ► When troubleshooting, always wear personal protective equipment that is appropriate for the expected hazards.

If questions or uncertainties arise during troubleshooting or rectifying malfunctions, please contact SKAN service.

30.1 Alarm list and description

ID	Location - Name	Description
128	General - QISA 1.831: TLV Sensor Alarm	TLV Sensor sees H_2O_2 higher than allowed threshold limit value.
127	General - PSA 1.855: Compressed Air pressure too low.	Used to alarm if sensor value lower than allowed range.
129	General - PSA 1.855: Compressed Air sensor failure	Used to alarm if sensor value higher than allowed range.
160	General - Lost communication with HMI	Used for alarming if connection cable is disconnected.
159	General - Network storage not reachable for file export!	Used for alarming if network storage not available.
95	Airlock left - CLOUD: Not adjusted --> Test Sequence in Maintenance needed	After an airlock left Cloud error, please provide a Test Sequence in maintenance.
100	Airlock left - IN-FAN: Warning - speed deviation	Used for alarming if the value deviate from the setpoint.
104	Airlock left - OUT-FAN: Warning - speed deviation	Used for alarming if the value deviate from the setpoint.
84	Airlock left - Pressure too high --> actual value [Pa], upper limit [Pa]	Used for alarming if pressure higher than the permitted value.
85	Airlock left - Pressure too low --> actual value [Pa], lower limit [Pa]	Used for alarming if pressure lower than the permitted value.

ID	Location - Name	Description
157	Airlock left - Pressure too high during H_2O_2 cycle	Used for alarming if pressure higher than the permitted value.
86	Airlock left - Air velocity too high --> actual value [m/s], upper limit [m/s]	Used for alarming if air velocity higher than the permitted value.
87	Airlock left - Air velocity too low --> actual value [m/s], lower limit [m/s]	Used for alarming if air velocity lower than the permitted value.
126	Airlock left (LAF): Alarm Airspeed [m/s]	Airlock left (LAF) airspeed alarm
164	Airlock left - Manual termination of the decontamination/airshower	Used for alarming if manual termination of the decontamination/airshower.
168	Airlock left - Transfer door left/right opened during decontamination	Used for alarming if airlock transfer door opened unintentionally.
167	Airlock left - Front door opened during decontamination	Used for alarming if airlock front door opened unintentionally.
111	Airlock right - CLOUD: Not adjusted-> Test Sequence in Maintenance needed	After an airlock right Cloud error, please provide a Test Sequence in maintenance
115	Airlock right - IN-FAN: Warning - speed deviation	Used for alarming if the value deviate from the setpoint.
119	Airlock right - OUT-FAN: Warning - speed deviation	Used for alarming if the value deviate from the setpoint.
57	Airlock right - Pressure too high --> actual value [Pa], upper limit [Pa]	Used for alarming if pressure higher than the permitted value.
59	Airlock right - Pressure too low --> actual value [Pa], lower limit [Pa]	Used for alarming if pressure lower than the permitted value.
158	Airlock right - Pressure too high during H_2O_2 cycle	Used for alarming if pressure higher than the permitted value.
81	Airlock right - Air velocity too high --> actual value [m/s], upper limit [m/s]	Used for alarming if air velocity higher than the permitted value.
82	Airlock right - Air velocity too low --> actual value [m/s], lower limit [m/s]	Used for alarming if air velocity lower than the permitted value.
125	Airlock right (LAF) - Alarm Airspeed [m/s]	Airlock right (LAF) airspeed alarm
165	Airlock right - Manual termination of the decontamination/airshower	Used for alarming if manual termination of the decontamination/airshower.

ID	Location - Name	Description
170	Airlock right - Transfer door left/right opened during decontamination	Used for alarming if airlock transfer door opened unintentionally.
169	Airlock right - Front door opened during decontamination	Used for alarming if airlock front door opened unintentionally.
131	Main - CLOUD: Not adjusted -> Test Sequence in Maintenance needed	After a main chamber Cloud error, please provide a Test Sequence in maintenance
135	Main - IN-FAN: Warning - speed deviation	Used for alarming if the value deviates from the setpoint.
139	Main - OUT-FAN: Warning - speed deviation	Used for alarming if the value deviates from the setpoint.
89	Main - Pressure too high --> actual value [Pa], upper limit [Pa]	Used for alarming if pressure higher than the permitted value.
90	Main - Pressure too low --> actual value [Pa], lower limit [Pa]	Used for alarming if pressure lower than the permitted value.
91	Main - Air velocity too high --> actual value [m/s], upper limit [m/s]	Used for alarming if air velocity higher than the permitted value.
92	Main - Air velocity too low --> actual value [m/s], lower limit [m/s]	Used for alarming if air velocity lower than the permitted value.
162	Main - LAF Mousehole opened during decontamination	Used for alarming if Mousehole opened unintentionally.
161	Main - Transfer door airlock (left/right) closed during decontamination	Used for alarming if airlock transfer door closed unintentionally.
163	Main - Manual termination of the decontamination/airshower	Used for alarming if manual termination of the decontamination/airshower.
166	Main - Front door opened	Used for alarming if main front door opened unintentionally.

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