

CLEAN SAFETY INTELLIGENT TECHNOLOGY

ortner
cleanrooms unlimited



Cleanliness
made in Austria

Guiding principle



Cleanroom Process Management



We thereby create pure and high-quality production processes for safe end products for our customers. This is our contribution as a European company to securing our competitiveness.

Cleanroom solutions



We develop and manufacture systems and technologies for the creation of particulate and microbiological cleanliness to meet cleanroom requirements in a wide range of industries.

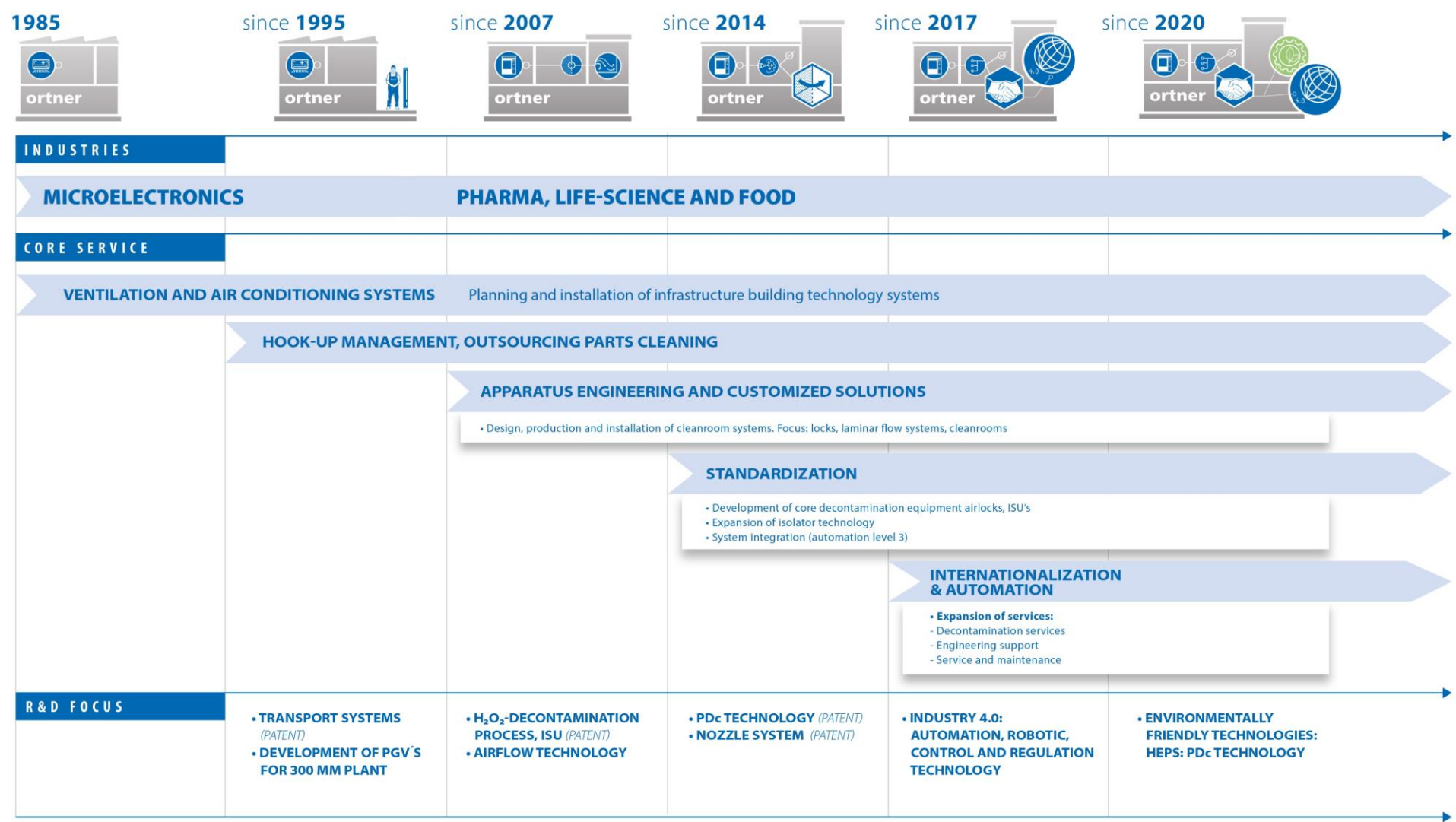
Cleanroom integration



As a system supplier for air lock and decontamination processes, we integrate our systems and technologies into the customers' production processes.



The phases in our development



Product portfolio

LockLine

- Material air locks
- Personnel air locks



IsoLine

- Isolator systems
- RABS & barrier systems



DecoLine

- H₂O₂ generator technology
- CH₂O generator technology
- Fumigation nozzles
- Additional equipment



FlowLine

- Laminar flow systems
- Atmos pure systems



LabLine

- Additional laboratory equipment



Service

- Decontamination services
- Service
- Part cleaning outsourcing
- Hook-up management

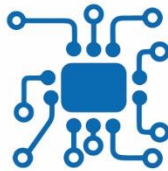


We are system supplier

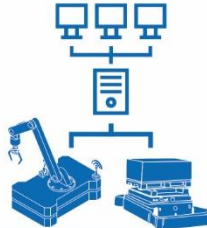
ortner
cleanrooms unlimited



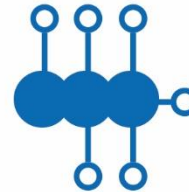
Hardware



Software



Industry 4.0



Process engineering



Validation

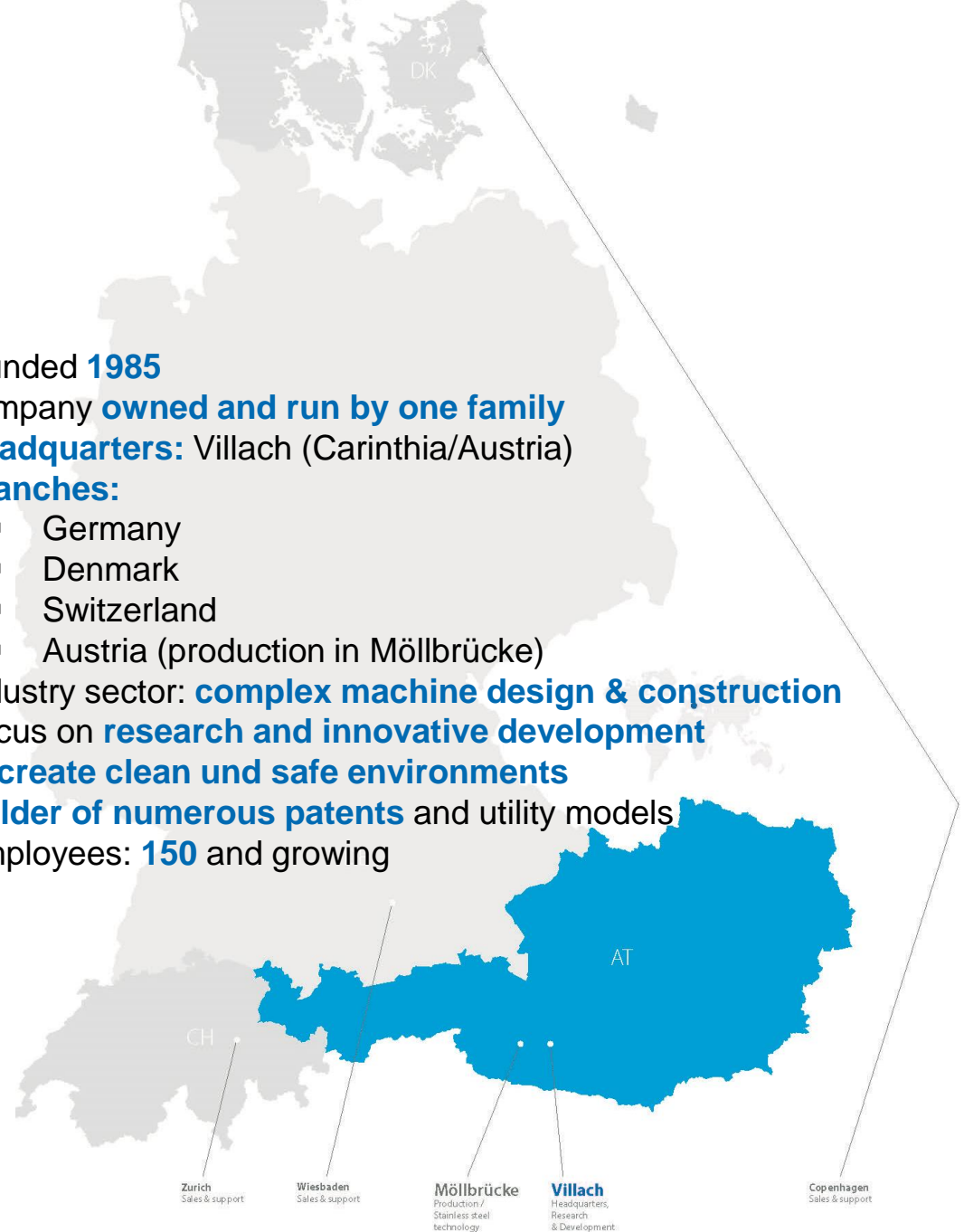


Service/maintenance

Facts & Figures



- founded **1985**
- company **owned and run by one family**
- **Headquarters:** Villach (Carinthia/Austria)
- **Branches:**
 - Germany
 - Denmark
 - Switzerland
 - Austria (production in Möllbrücke)
- Industry sector: **complex machine design & construction**
- Focus on **research and innovative development to create clean und safe environments**
- **Holder of numerous patents** and utility models
- Employees: **150** and growing



We act sustainably

Our commitment and obligation to assume a leading role in the field of sustainability is deeply embedded in our values. The principle of sustainability is the foundation of every single one of our processes.

Select SDG targets that we are committed to:



Promote education



Secure growth
and full
employment



Produce sustainable
products



Protect the
environment

OUR VALUES



Stability

We believe in the value of a handshake, are credible, reliable, and responsible.



Independence

We are flexible and have no fear of contact.



Clarity

As a family-run company we are down-to-earth and straightforward.



Spirit of innovation

As a technology company, we live – besides our passion for technological solutions – from a high degree of innovation.



Headquarters Villach | Carinthia

ortner
cleanrooms unlimited

R&D

Technology

Project development

Service &
maintenance

Administration

Outsourcing

Production Möllbrücke | Carinthia

ortner
cleanrooms unlimited

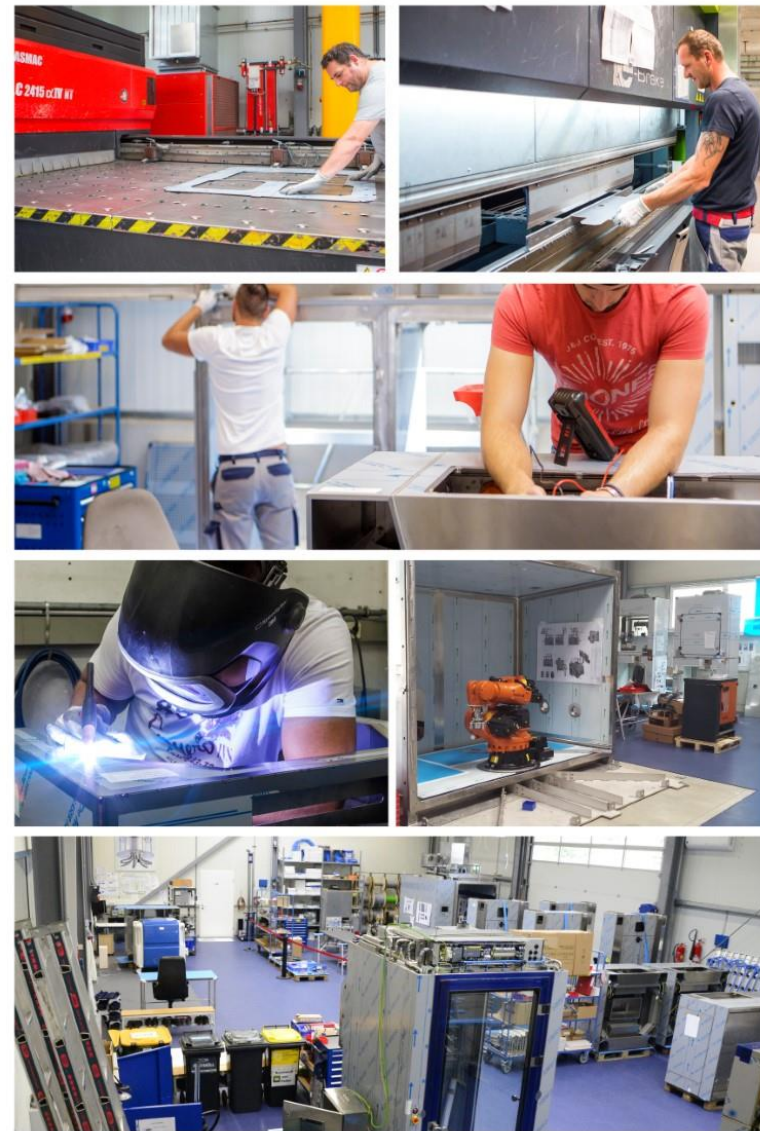
We manufacture in Austria for good reasons:

Quality

Highest
qualification

Flexibility
&
Variety

Sustainability







Core technologies

CORE TECHNOLOGY

H₂O₂ decontamination technology

For more than 15 years, Ortner has worked intensively on **gaseous room decontamination using H₂O₂** (hydrogen peroxide).



LOG6 decontamination
at room temperature



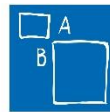
Validated process
reduces security risks



Sensitive products
can be treated (e.g.
electronics)



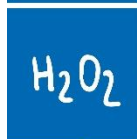
Short decontamination
time < 15 min.
is attainable



Accepted by many
authorities as a
standard process



No danger
of explosion



Safe & environmentally friendly

The decomposition of H₂O₂
does not produce toxic residues
(splitting into **water** and **oxygen**)



Bacteria

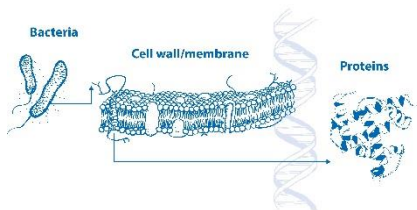


Spores



Viruses

$$E0 = +1,78 [V] \text{ H}_2\text{O}_2/\text{H}_2\text{O}$$



High personnel safety



Technology for H₂O₂ decontamination

For special requirements to decontaminate complex surfaces in rooms, air locks and ventilation systems, there is a broad portfolio of systems:



Gas generators
“ISUs”

Nozzle systems

Additional equipment
“mobile H₂O₂ cat.”

Decontamination
locks

Integrated H₂O₂ unit
(e.g. in an isolator)

Decontamination Services

ortner
cleanrooms unlimited

H2O2

DECONTAMINATION SERVICES

1. Engineering Support

- Decontamination concept (fumigation concept)
 - System optimization/upgrades
- Decontamination test/material resistance test
 - Leakage test
- Flow and gas concentration simulations
 - Consulting
 - Planning
 - Expert assessments

2. Cycle development & cycle validation

3. Room Decontamination

4. Microbiology Support

5. Training

6. Equipment rental

7. Equipment maintenance



CORE TECHNOLOGY

PDc-Technology

ortner
cleanrooms unlimited



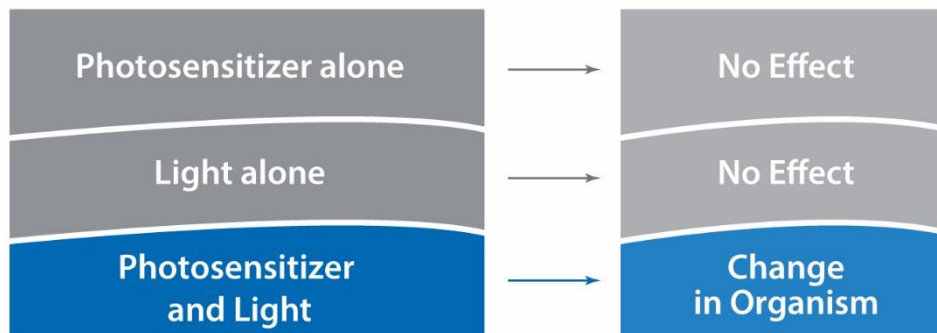
Photodynamics is a reaction of a dye to a special wavelength of light.

Formation of highly reactive oxygen radicals

- Reaction with **undesired germs**
- Result: **Germ elimination**

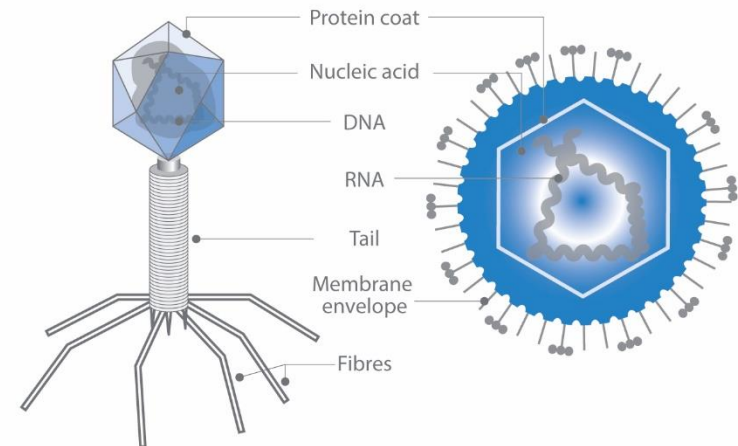
- ✓ **not dangerous for humans**
- ✓ Possibility to decontaminate people in the working environment → **Transmission of germs by humans is minimized**

Photosensitizer



The cell structures of viral and bacterial membranes are destroyed by oxidation

Bacteriophage



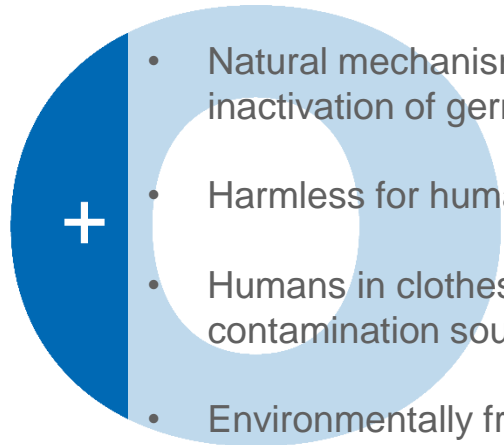
CORE TECHNOLOGY

PDc-Technology

ortner
cleanrooms unlimited



The **Photodynamic Disinfection certified Technology (PDcT)** is a newly developed and patented process by Ortner for the effective **microbiological inactivation of germs** on surfaces.

- 
- Natural mechanism for microbiological inactivation of germs up to Log 3
 - Harmless for humans
 - Humans in clothes can be controlled as contamination sources
 - Environmentally friendly technology
 - Performance results scientifically tested

PDcT results have been **scientifically verified by independent institutes:**
(based on studies by the Fraunhofer Gesellschaft IPA Institute)

Safety for people

- ✓ Good skin compatibility
- ✓ Proven reactive oxygen species in the ROS test



Fraunhofer
TESTED[®]
DEVICE
Ortner Reinraumtechnik
PDS-Schleuse
Report No. OR 1501-747



**Innovations-
und Forschungspreis
des Landes Kärnten
2015**

ECONOVIVUS



HOUSKAPREIS | 2016
PRIVAT
STIFTUNG

PDc technology with a wide range of applications

ortner
cleanrooms unlimited



Healthcare



Research & Lab



Food Processing



PDc-Cleanroom
Clothing



PDc-Wardrobe
System



PDc-Personnel
Air Lock



PDc-Textile Air
Duct System



Selected products for the **pharmaceutical and life-science industry**

Decontamination Locks



Personnel Air Lock



Material Air Lock

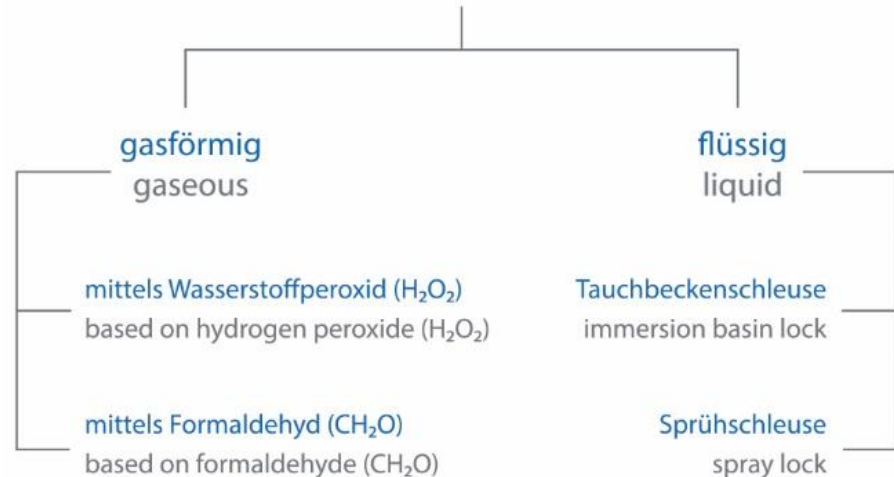
Decontamination is the generally applicable term for the removal of dangerous contamination from persons, objects or unprotected surfaces.

When selecting the appropriate decontamination method, the user can choose from a **wide range of procedures**.



LockLine

Dekontaminationsschleuse Decontamination locks



Personnel Air Locks



JET-Personnel Air Showers



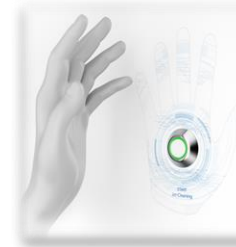
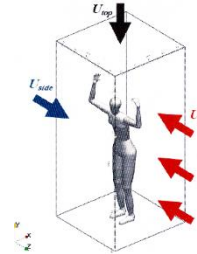
PDc-Personnel Air Showers



Personnel Wet Showers

JET-Personnel Air Shower

A **certified** personnel air lock with integrated JET-nozzle technology for a **validatable** and **highly efficient physical particle cleaning of surfaces**.



- Combination of laminar displacement flow & JET air nozzle system guarantees cleaning success
- The posture of the person is monitored by sensors
- Process sequence is visualized on a display
- Cleaning results have been tested and confirmed by renowned institute (Fraunhofer)
- Plug & Play and factory-qualified system



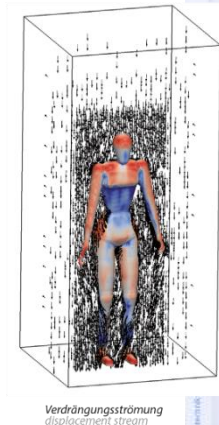
Fraunhofer
TESTED[®]
DEVICE
Ortner Reinraumtechnik
PDS-Schleuse
Report No. OR 1501-747

PDc-Personnel Air Shower

Thanks to the integrated **photodynamic decontamination technology**, the **certified personnel lock** guarantees **microbiological decontamination of surfaces in addition to physical cleaning**.

+

- Two functions in one device: microbiological and particulate surface decontamination
- Microbiological germ reduction up to 98%
- Combination of laminar displacement flow & JET air nozzle system guarantees cleaning success
- The posture of the person is monitored by sensors
- Process sequence is visualized on a display
- Plug & Play and factory-qualified system



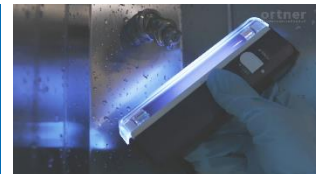
Fraunhofer
TESTED®
DEVICE
Ortner Reinraumtechnik
PDS-Schleuse
Report No. OR 1501-747

Personnel Wet Shower

The personnel wet shower serves as an **effective barrier to the controlled exit of personnel in protective clothing from contamination areas and** ensures a high level of personal protection. The wet shower is especially **suitable when handling hazardous substances.**



- Automatic chamber cleaning process
- Freely adjustable rinsing time
- Validatable cleaning by riboflavin test
- Easy maintenance
- Plug & Play and factory-qualified system



Validatable cleaning

Material Air Locks



H₂O₂ decontamination



Spray decontamination



Transfer hatches



H₂O₂ Decontamination Lock

The H₂O₂ decontaminable material air locks **are suitable for aseptic transfer or for the transfer of heat-labile material.**

5 liter H₂O₂ container for **several decontamination cycles**

Pull-out pharmacy cabinet for **easy maintenance**

+

- Easy integration through standardized compact design
- Accelerated gas injection and withdrawal through innovative nozzle system
- Mutually interlocked air lock doors
- Factory-qualified system incl. factory-performed decontamination test run



Spray Air Locks

For areas where **particularly fast cycle times** (within a few minutes) or different products are required, **decontamination with liquid media is a good alternative**.

Immersion lock basins → for products that generally do not float upward.
Downstream drying process necessary.

Spray locks → the advantages of an immersion basin lock (e.g. short cycle times) plus the advantage of easy determination and validation of different cycles.

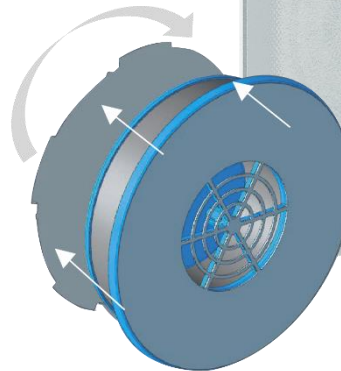
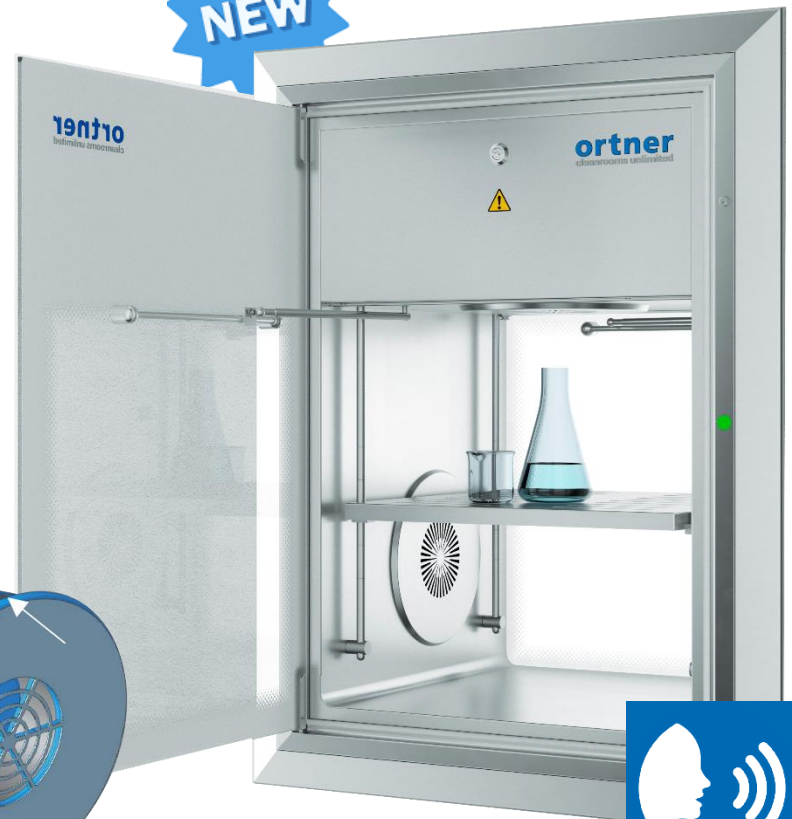
Disadvantage: The spray pattern must be precisely developed and is a very complex matter.



Transfer Hatch Comfort S6

The **Comfort S6 transfer hatch** is designed → as an independent unit with a self-sufficient ventilation system and so needs no ventilation infrastructure

THE NEW GENERATION
TRANSFER HATCHES



- Automatic “one-finger” door opening
- Self-sufficient ventilation system
- New operating concept with optional voice control
- Easy change filter system
- Settings via WLAN
- Simple assembly



Voice control

Active and Passive Transfer Hatches

Specially designed for **ISO cleanroom classes from level 4 and GMP class from B** for **efficient infeed and outfeed** of different materials and products. The **advanced ventilation concept** within the air lock ensures **perfect cleanliness directly at the product**.

+

- Standard supply and exhaust air filter holder
- Double wall construction
- Optional second sealing level
- Flushing times freely adjustable
- Easy to clean
- Execution also as radiation, fire protection and disinfection lock (UVC)

Active	Passive
✓	
✓	✓
✓	✓
✓	
✓	✓
✓	✓



Transfer Hatch Combi – Active L

Suitable for **material infeed and outfeed of sterile goods** within the scope of cleanroom class B, optionally extendable to clean room class A with a laminator.

The lower air lock reaches cleanroom classes B-C via a **shadow ventilation system** and is designed for raw materials, auxiliary materials or waste.



- Structure: Profile frame / double wall construction
- Optional second sealing level
- Resistant to commercially available disinfectants
- Easy to clean
- Flushing times freely adjustable



Active L

H₂O₂ Gas Generators: Interactive Superinduce Unit (ISU)

The ISU is one of the most powerful H₂O₂ gas generator units on the market.



ISU 1.0

variable
up to 100 m³/h



ISU 2.0

variable
up to 350 m³/h



ISU integrated

variable
up to 100 m³/h



ISU Stationary

variable
up to 600 m³/h

Volume flow

Max. room size

can be used
**up to approx.
50 m³**

can be used
up to approx. 500 m³

variable

can be used
≥ 800 m³

ISU mobile

The ISU, one of the most modern and advanced **H₂O₂ generation facilities**, **interacts** – through various channels – with different infrastructure systems, plants or devices.

Gas flow can be generated either “**intensively highly concentrated**” or “**gliding continuously**” (= superinduction effect).



- Powerful preheating function
- Variable air flow up to 350 m³/h
- Powerful built-in catalyzer
- External nozzle control
- Shorter decontamination cycles
- Intuitive user interface (red/green/blue)
- Uncomplicated maintenance



ISU Stationary

A large system for complex and high-performance decontamination processes.

+

- The system is monitored and controlled by a superordinate process control system
- Decontamination is performed fully automatically and is logged by the system
- The size of the system allows enormous volumes of space to be decontaminated

Special features:

- Room volume: > 800 m³
- H₂O₂ reservoir: 65 L
- Vaporizer: up to 18g H₂O₂/min



Nozzle Systems

An **even H_2O_2 gas distribution** in the room and in all facilities is particularly important for safe and validatable decontamination processes and **supports the success of the decontamination.**

+

- Patented system designed according to state-of-the-art CFD simulation
- Unique shape causes a high impulse current
- Shape and control ensure that the room air circulates in the shortest possible time
- Positive influence for free rinsing processes and desorption performance

- Rating: 1x130 m³/h, max. up to 800 m³/h



Mobile H₂O₂ Catalyzer

For **fast decomposition of hydrogen peroxide** – if, for example, materials sensitive to H₂O₂ must be decontaminated.

+

- Accelerates the decomposition of hydrogen peroxide gas in a room after the decontamination process is complete
- Recirculation mode: Gas is sucked in via a built-in catalyzer, thus reducing the H₂O₂ concentration in the room.
- Short and cost-efficient process

The necessary **ventilation time at e.g. 1000 m³ room volume is reduced by up to 50%.**



DECONTAMINATION Use Cases

ROOM DECONTAMINATION

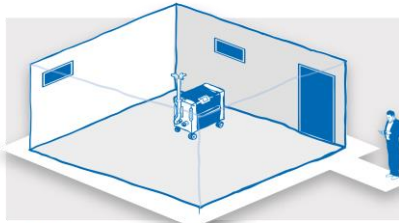


fig. 1)

ISU Mobile
with surface-mounted nozzle in the room
Process control from outside via tablet

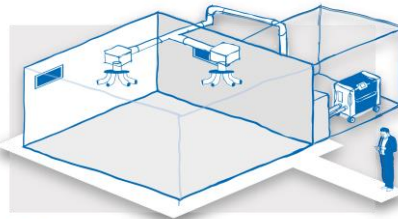


fig. 2)

ISU Mobile
(in the technical area)
Room decontamination via the
gassing nozzle Compact or Light

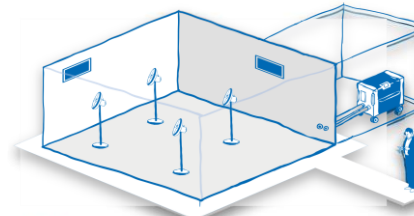


fig. 3)

ISU Mobile
(in the technical area)
Room decontamination via wall ducts,
free-standing fans in the room for gas
distribution

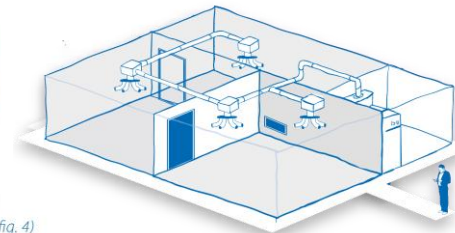


fig. 4)

ISU Stationary
(large-scale facility)
Decontamination of several rooms with
automated processes via pipelines to the
Compact or Light gassing nozzle

SYSTEM DECONTAMINATION

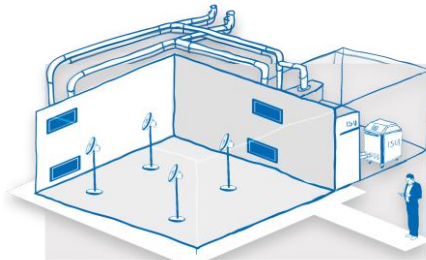


fig. 5)

ISU Stationary
ISU Dispense
Room decontamination
via the ventilation system

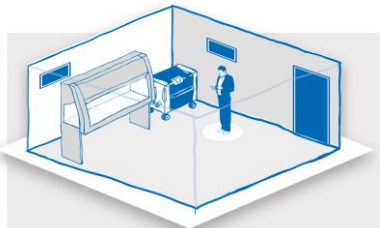
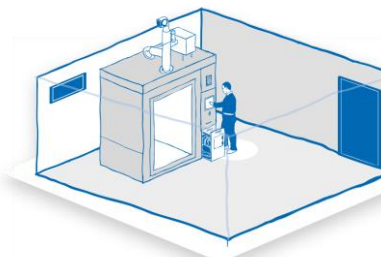
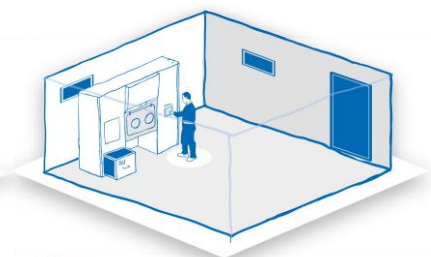


fig. 6)

Safety Cabinet
ISU Mobile
The two systems are connected
with the gas supply pipes



H₂O₂ Lock
ISU integrated
(ISU integrated)
or ISU Mobile



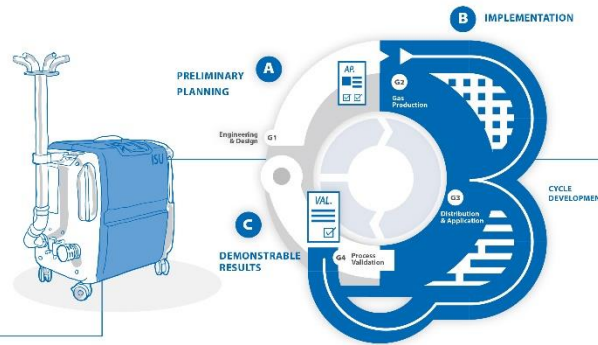
Isolator
ISU integrated
(installed in the isolator)
or ISU Mobile

Procedure of H₂O₂ room decontamination

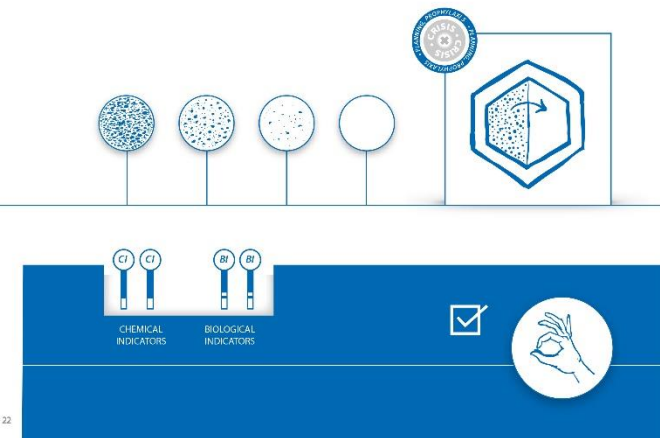
A: Pre-planning



B: Cycle development



C: Result/verification



- Site evaluation
- Room preparation

- Start of cycle
- Cycle monitoring
- Release measurement
- Evaluation of effectiveness of the cycle
- Optimization of the cycle
- Reproducibility of the cycle
- Room release

- Evaluation of bio-indicators
- Documentation

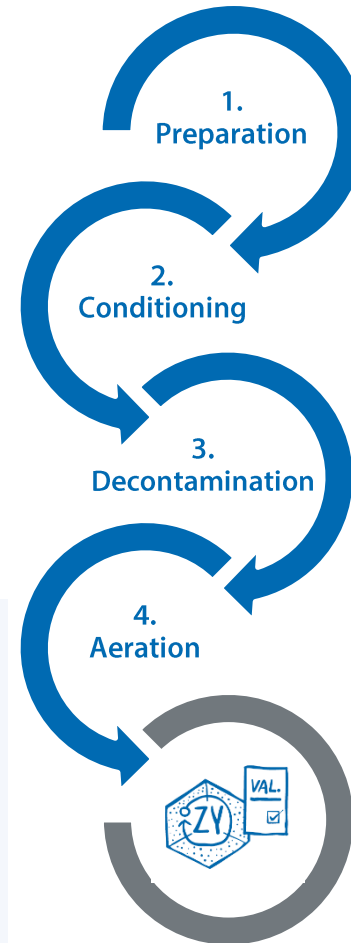
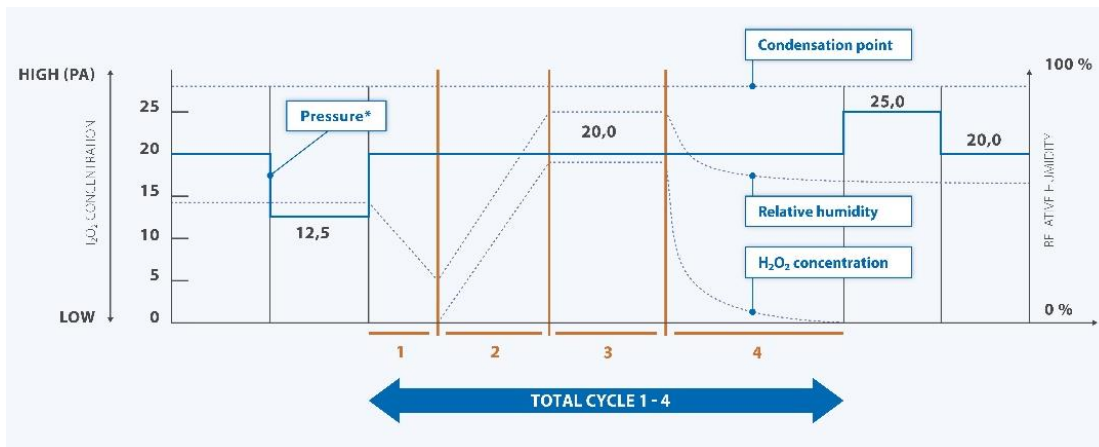
Cycle development & validation

The success of a decontamination procedure depends, among other things, on **air humidity**, **H₂O₂ concentration**, **gas exposure time** and **temperature**.

Several measuring runs are carried out to determine the cycle times.

A decontamination cycle...

- ✓ serves for effective and successful decontamination
- ✓ defines the quantity of the evaporated H₂O₂
- ✓ defines the duration of the decontamination process



Four phases of cycle development

Cycle validation

is carried out after successful cycle development (= **three decontaminations** based on bio-indicators give optimally analogous results).

Remote monitoring via tablet

Additional safety:

The decontamination process can be monitored outside the hazardous area and, if necessary, can be interrupted and resumed in a controlled manner without exposing the operating personnel to danger.



Barrier technology: Isolator Systems

ortner
cleanrooms unlimited



Modularity



Energy efficiency



Safety



Decontamination



Logging



Automation



Cytostatics and
Aseptic Isolators



Sterility Test
Isolators

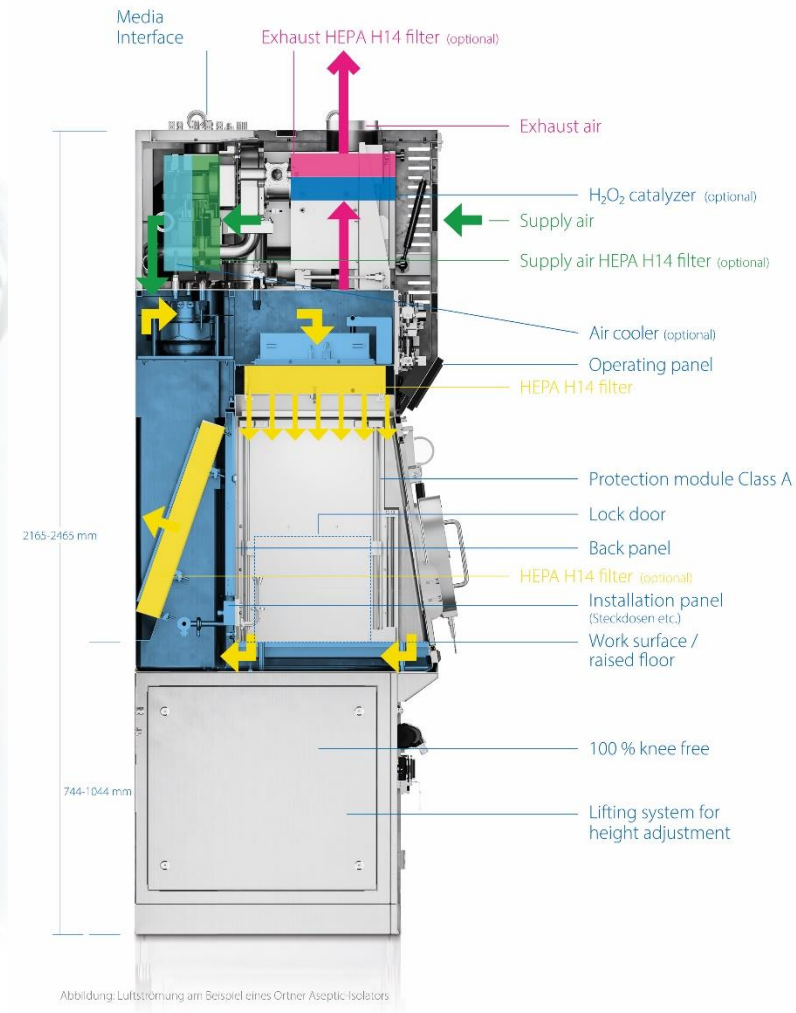


Containment
Isolators



Automated Isolator
Solutions

Air Flow Principle of an Isolator



Aseptic and Cytostatic Isolators

Can be used for **product** and/or **personal** protection.
Tightness of the entire system corresponds to class 4.

+

- Fully automatic integrated H₂O₂-decontamination incl. logging (up to LOG 6)
- Decomposition of H₂O₂ by build-in catalyzer
- H₂O₂ locks for the inward and outward transfer
- Easy loading and unloading thanks to sliding doors
- Interior chamber design adaptable to the interior design
- Low noise level of <60 dB (A)
- Network-capable: User administration, remote access, time synchronization



Sterility Test Isolators

For sterility testing of samples of pharmaceutical products.



- Fully automatic integrated H₂O₂-decontamination incl. logging (up to LOG 6)
- Automated environment & particle monitoring
- Fully integrated glove and insulator leak test according to ISO 14644-7
- Electrical height adjustment for sitting and standing operation
- Low noise level of < 60 dB (A)
- Logging via OPC client
- Network-capable: User administration, remote access, time synchronization



Containment Isolators

For use in the manufacture of products to prevent the release of hazardous substances in the form of powdered articles through the air during production.



- Automated WIP process with rotation and mist nozzles
- Automated leak test
- Integrated supply and exhaust air
- Validatable purification (riboflavin test)
- Low noise level of <60 dB (A)
- Network-capable: User administration, remote access, time synchronization



Automated Isolator Solutions

Isolators with integrated robot technology are a suitable solution for the production and processing of cytostatics or other critical products (API).

Containment isolator

Tightness overall system

Seal class 4

under DIN EN ISO 14644-7:2004 (D) and
ISO 10648-2:1994 (E)

Aeration systems

including dehumidification and drying of
containment

Conformity

complete system FDA- and GMP-compliant

Wash process

design self-emptying

Containment cleaning

by robots

Lock technology

all locks with separate pressure control

Robot technology

Robot

6-axis robot





<https://youtu.be/Si9ZtlIGdOk>



Integration of **Industry 4.0**

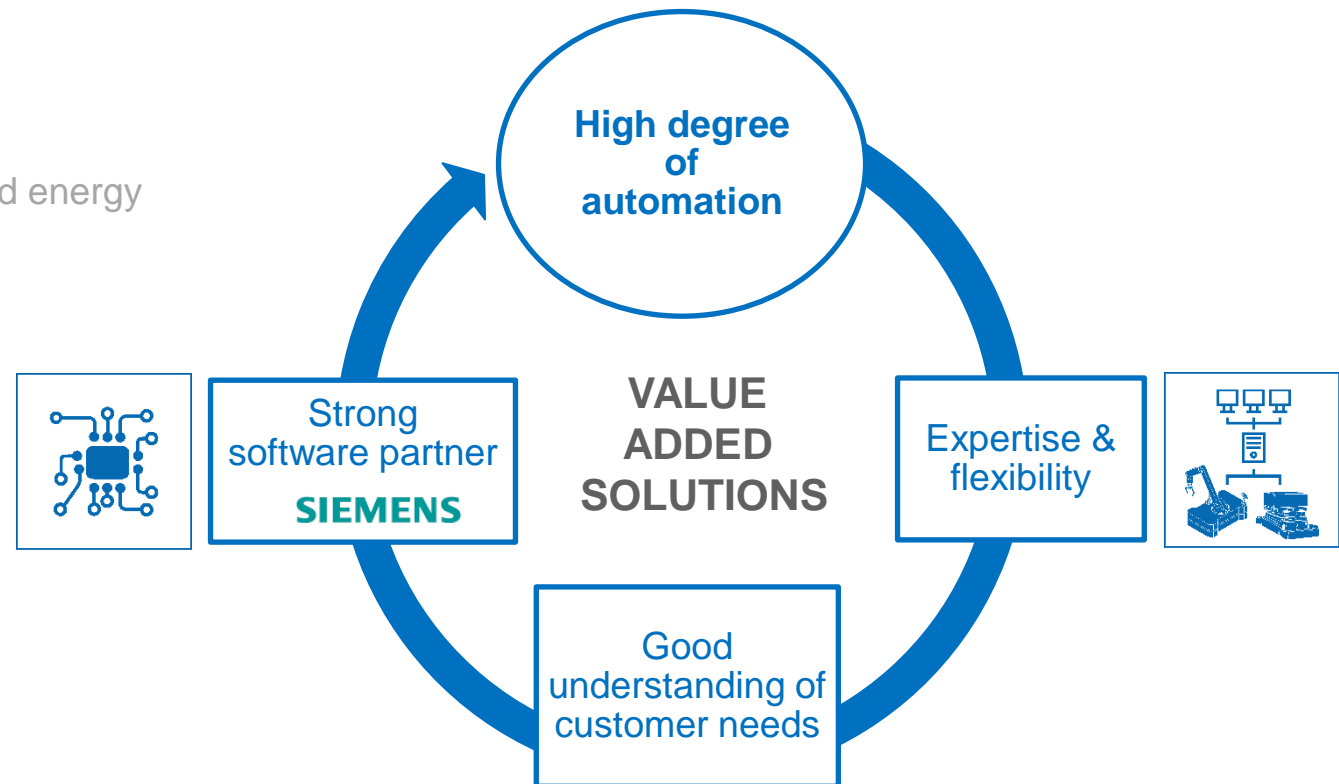
We are the problem solvers

Solving technological challenges is one of our strengths

When designing our systems, we attach **great importance to integration capability**.
Ortner systems can be fully integrated into building management systems and are therefore **easy to network, monitor, operate, maintain or solve technical problems**.

The advantages:

- Improved user comfort
- Increased productivity
- Increased operating and energy efficiency

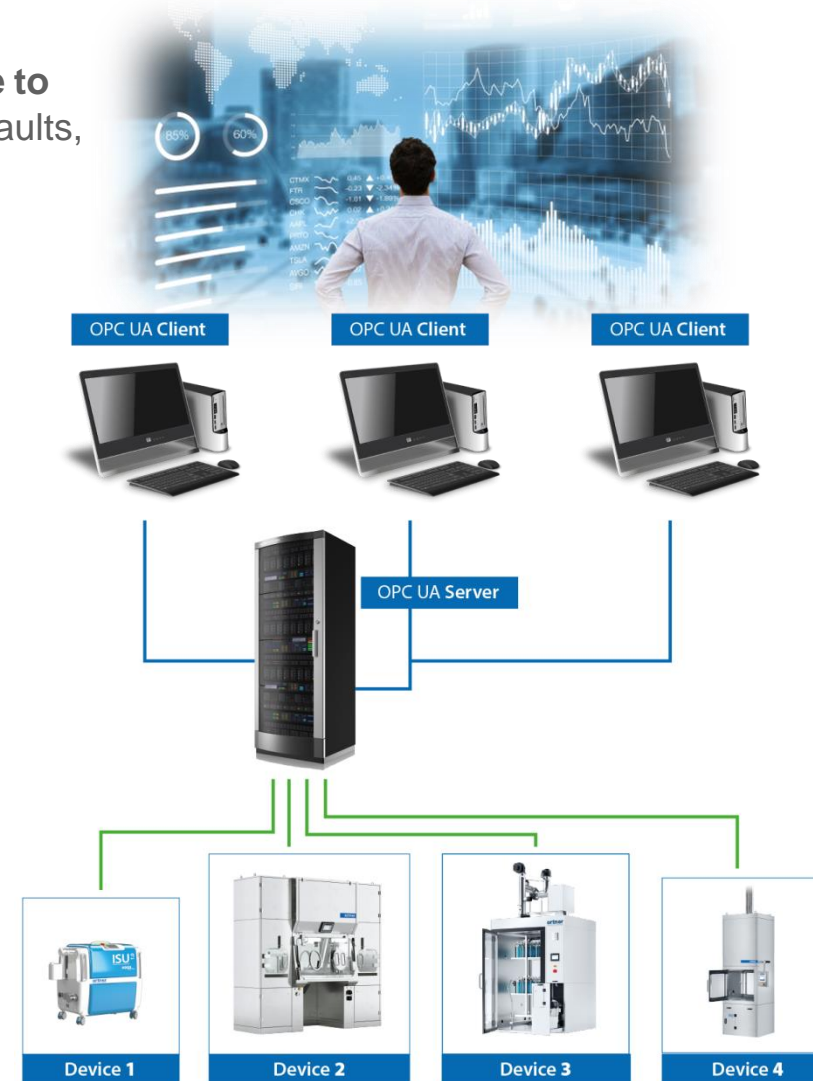


Provision of machine data

All of our systems are equipped by default with a **modern OPC-UA interface**, so that the **machine data is available to the operator in real time** (e.g. running times, interruptions, faults, energy consumption, measured data, etc.).

The advantage:

- **Increase in productivity**
By analyzing machine data, the production processes are evaluated and optimized



Increased safety through dual control principle

Isolator systems equipped with a **CCTV camera system** make the entire production process safer, easier, more effective and more economical.

The CCTV camera system serves as an **additional control** for e.g. the production of cancer drugs – **to be able to check the production process afterwards**:

The critical steps in the process are recorded, stored and, if necessary, made up for.



Best Practice example

Needs of the customer:

Automated material transport and H₂O₂ decontamination in the multi-storey research laboratory

Our solution:

To control the material flow through the zones without contact and automatically, the entire processes were redesigned and the H₂O₂ air locks adapted to requirements. This enables the H₂O₂ locks to communicate with the driverless transport and building management system: all doors function automatically and the entire decontamination process starts automatically.



The H₂O₂ locks open automatically and initiate the decontamination process automatically.

The advantages:

- Higher productivity
- Safe and reliable
- Cost saving

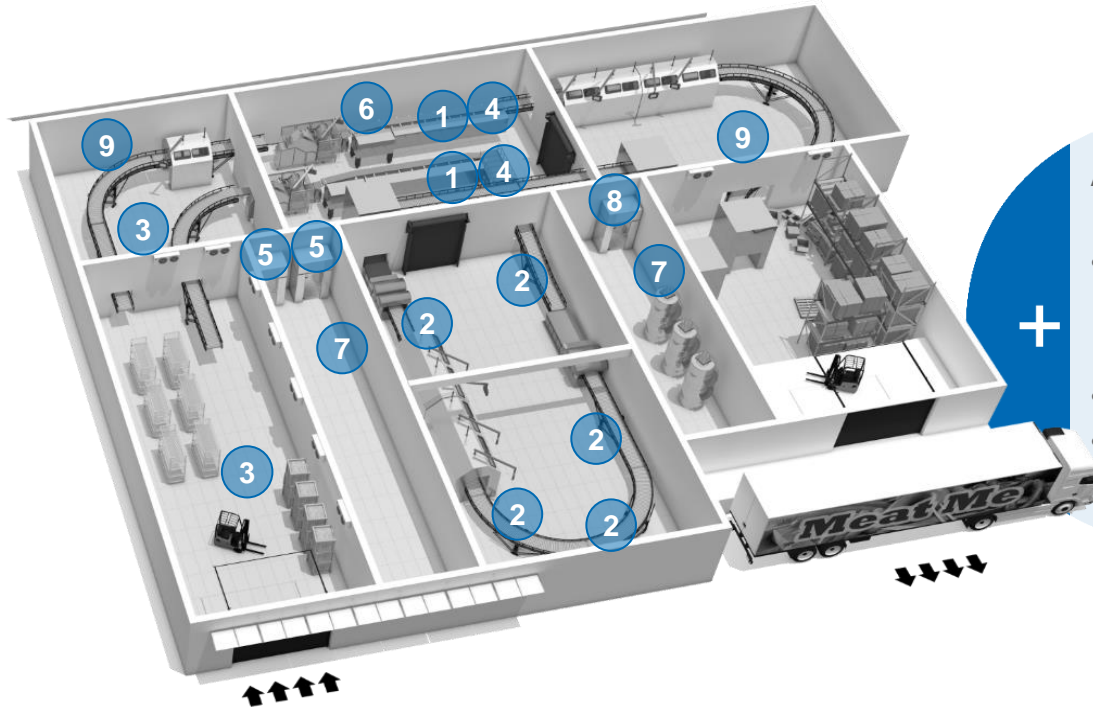
<https://youtu.be/gEqM3O1MBA>





Selected products for the **food industry**

Areas of application (example meat industry)



Advantages for the industry:

- extended shelf life with no chemical preservatives and no additional thermal processes
- Increased product safety
- CFU < 1

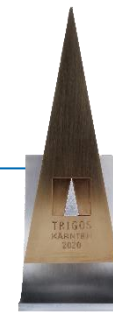


Laminarflow DecAx

The system is specially designed to avoid microbiological recontamination by means of an integrated disinfection unit.

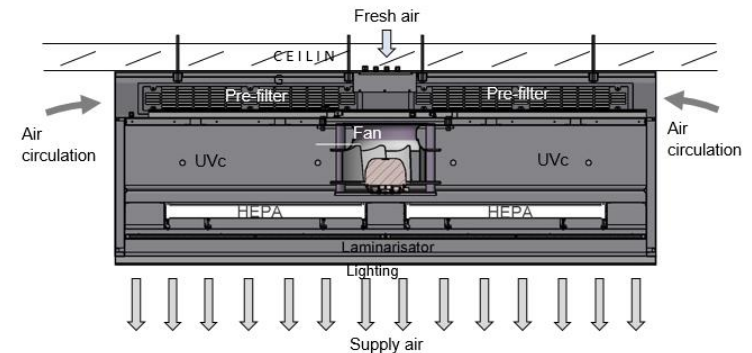
+

- CFU < 1 directly in proximity to the product due to hurdle technology
- Microbiological safety through HEPA filter and surface disinfection
- Very long filter service life
- Plug & Play and factory-qualified system



Kategorie „Social Innovation & Future Challenges“

ortner
cleanrooms unlimited



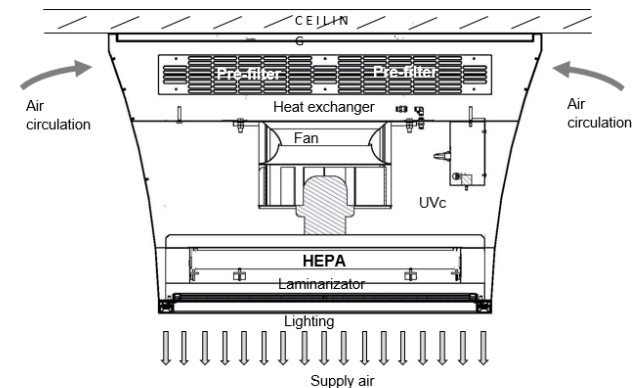
Atmos pus systems – Aseptic FFU

Selective protection concept: Filtering of particles and germs via HEPA filter and microbiological surface disinfection by integrated UV-c unit.



+

- CFU < 1 through point-source air flow
- Microbiological safety through filtration and surface disinfection
- Optimized indoor air quality in the entire area
- Very long filter service life
- Plug & Play and factory-qualified system

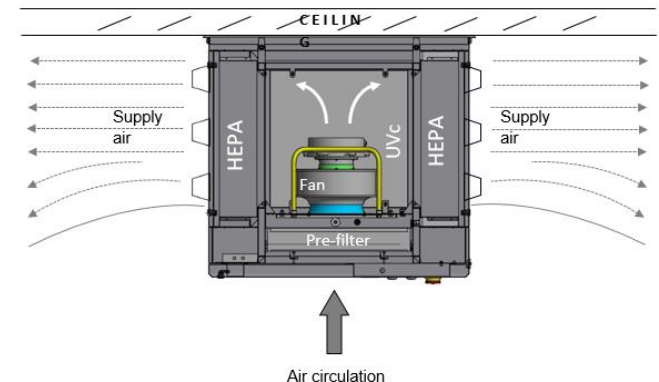


Hygienic Cube

The **self-sufficient unit serves** for permanent air circulation. Thanks to the dilution principle it is ideal for **operational areas of small and large room volumes**.

+

- CFU < 50/100 m³ room volume achievable
- Microbiological safety thanks to integrated UV-C sterilization
- Selective air discharge on one, two, three or four sides
- Plug & Play and factory-qualified system

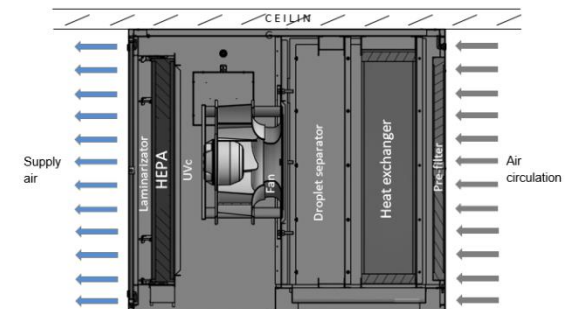


Hygienic Forced Air Cooler

ortner
cleanrooms unlimited

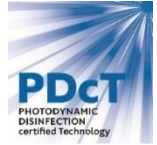
Designed as a room protection concept, it works on the principle of low-turbulence mixed flow. Ideal for cold rooms up to cooled production rooms.

- CFU < 50/100 m³ room volume achievable
- Microbiological safety thanks to integrated UV-c sterilization
- Optimized flow pattern – ideal cooling air distribution with reduced turbulence
- Plug & Play and factory-qualified system



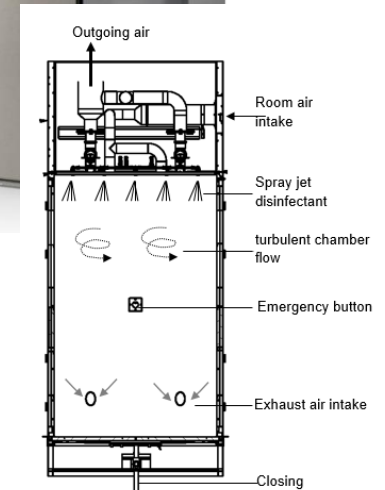
Spray Air Lock

Spray decontamination to introduce the pre-formed goods contamination-free into pre-production, smoking or storage areas and thus eliminate the risk of cutting-edge contamination.



+

- Germ reduction down to log 4 is possible (depending on loading condition and medium)
- Optimal disinfectant distribution thanks to special nozzle technology
- Fast cycle times (depending on load) from 5 to 15 minutes
- Plug & Play and factory-qualified system



Thank you for your attention

Ortner Reinraumtechnik GmbH
Uferweg 7, A-9500 Villach
Tel.: +43 (0) 4242 311 660-0

www.ortner-group.com

View Newsletter

<https://www.ortner-group.com/en/newsletter.php>