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DECONTAMINATION SOLUTIONS FROM ORTNER

YOUR SAFETY IN QUALIFIED HANDS.

Complete. Diverse. Clean.

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cleanrooms unlimited

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JOSEF ORTNER
CEO Ortner Group

WELCOME THE "DECON TEAM"!

The world is changing – and we are changing with it. For over 30 years, Ortner has been continuously developing clean room technology through permanent research and development activities. Because microorganisms don't rest, Ortner doesn't either: viruses, bacteria, and spores adapt constantly. This is why we are constantly developing our technologies and processes further to be able to answer new questions with innovative answers.

CHANGE WITH KNOWLEDGE

Our answers are state-of-the-art technologies. We pay particular attention to broad applicability so that the entire industry can derive the greatest benefit possible from our technologies.

The focus lies on cooperation in the field of research and knowledge transfer. Together with our strong network of research partners, we develop innovative topics – and we are happy to pass on the newly acquired knowledge for the benefit of all. Because our technologies are not a well-kept secret, but help to overcome challenges in society.

FOCUS ON SAFETY

We handle your specialized and sometimes even critical projects, which require extensive expertise and many years of experience. The goal of mastering these constantly new tasks drives us forward in our commitment to research and innovation. This enables us to constantly acquire new knowledge and consolidate the experience we have gained.

This brochure shows the complexity and interrelationships of decontamination. The focus is always on safety for persons and the environment. Different technologies offer different approaches to solutions – but they must not be forgotten: The human being is the most important decision-maker in the field of clean room technology.

IMPRINT

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OVERVIEW.

ortner
DECON
TEAM

THE CHALLENGE
The Decontamination.

Focus on your safety

Decontamination ensures that harmful microorganisms – whether bacteria, viruses, or spores – are eliminated.

This removal of hazardous contaminants is a decisive task in clean room technology, and the areas of application for this process for the elimination of microorganisms are numerous: From the pharmaceutical industry to research facilities, safety laboratories, and healthcare. The primary goal is always to prevent hazards to human health and the environment. Numerous technologies are used to achieve this goal. To make optimal use of this diversity, reliable specialist knowledge is required.

THE SOLUTION:
Ortner Technology & Expertise

A variety of solutions:

Ortner Reinraumtechnik GmbH has been on the market for over 30 years and offers a wide range of chemical and physical decontamination and sterilization processes:
Hydrogen peroxide, formaldehyde, photodynamics, UV-C radiation, chlorine dioxide, ethylene oxide, alcohols, and much more.

The advantage:

Ortner offers complete solutions for a wide range of decontamination challenges – whether they are individual objects, rooms, or entire buildings.
Equipped with the latest technology and many years of expertise, the Ortner team designs tailor-made solutions and accompanies the process from start to finish. This ensures high security and simultaneously saves both time and resources.

AREAS OF APPLICATION

- Pharmaceutical sector
- Safety laboratories
- Research and animal husbandry
- Healthcare and hospitals

Safe and environmentally friendly:
H_2O_2 decontamination

The Ortner Principle: Every technology has its own legitimacy, because no technology can do everything. Which decontamination and sterilization process is used depends on the specific application. The emphasis is therefore put on H_2O_2 decontamination – disinfection by hydrogen peroxide in evaporated form. This technology scores in two decisive criteria when comparing methods: **The easy applicability for the users, as well as its environmental friendliness.**

ROOM DECONTAMINATION SERVICES

THE VERSATILITY:
Ortner products and services

GAS GENERATORS

ADDITIONAL EQUIPMENT

CUSTOMIZED REQUIREMENTS

ISU
Hydrogen peroxide gas generator

Genny
Formaldehyde gas generator

High-turbulence nozzle systems

ISU
Dispense

Mobile H_2O_2 catalyst

ISU
Stationary

THE BIG PICTURE

Overview.

"Research as the foundation"

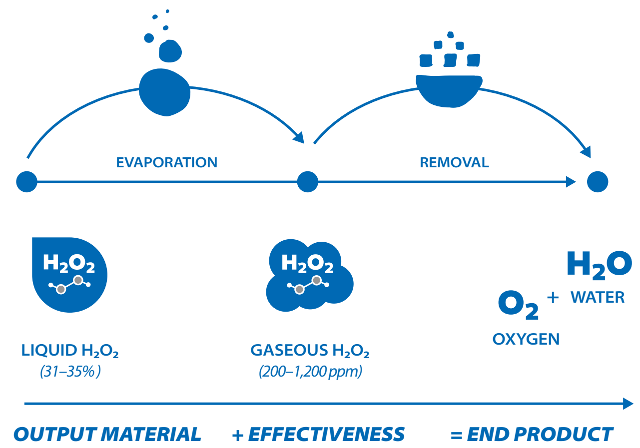
The complexity of decontamination: to understand and control the entirety of the H_2O_2 decontamination process, a broad spectrum of knowledge is required. In-depth knowledge of physics and chemistry is just as important as extensive microbiological expertise. An expertise which requires intensive research activities and a constant drive for innovation.

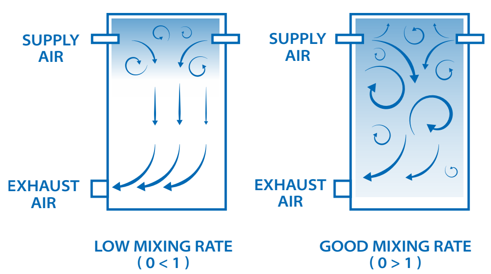
For decades we have been involved in the entire process of decontamination technology on a scientific basis. The many years of research work with renowned institutions in science and research are proving successful. Through the detailed analysis in the field of gaseous decontamination, personal safety and process validation, Ortner is able to design the entire decontamination process and put it into practice: the engineering of the fluid mechanics, proper gas generation, the best distribution systems, and the most efficient cycle development.

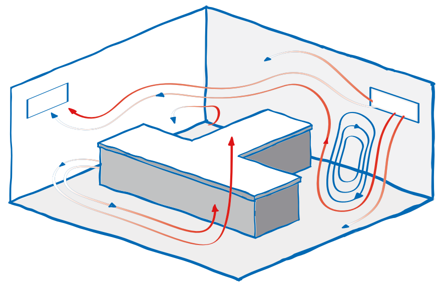
The most important research partners are:

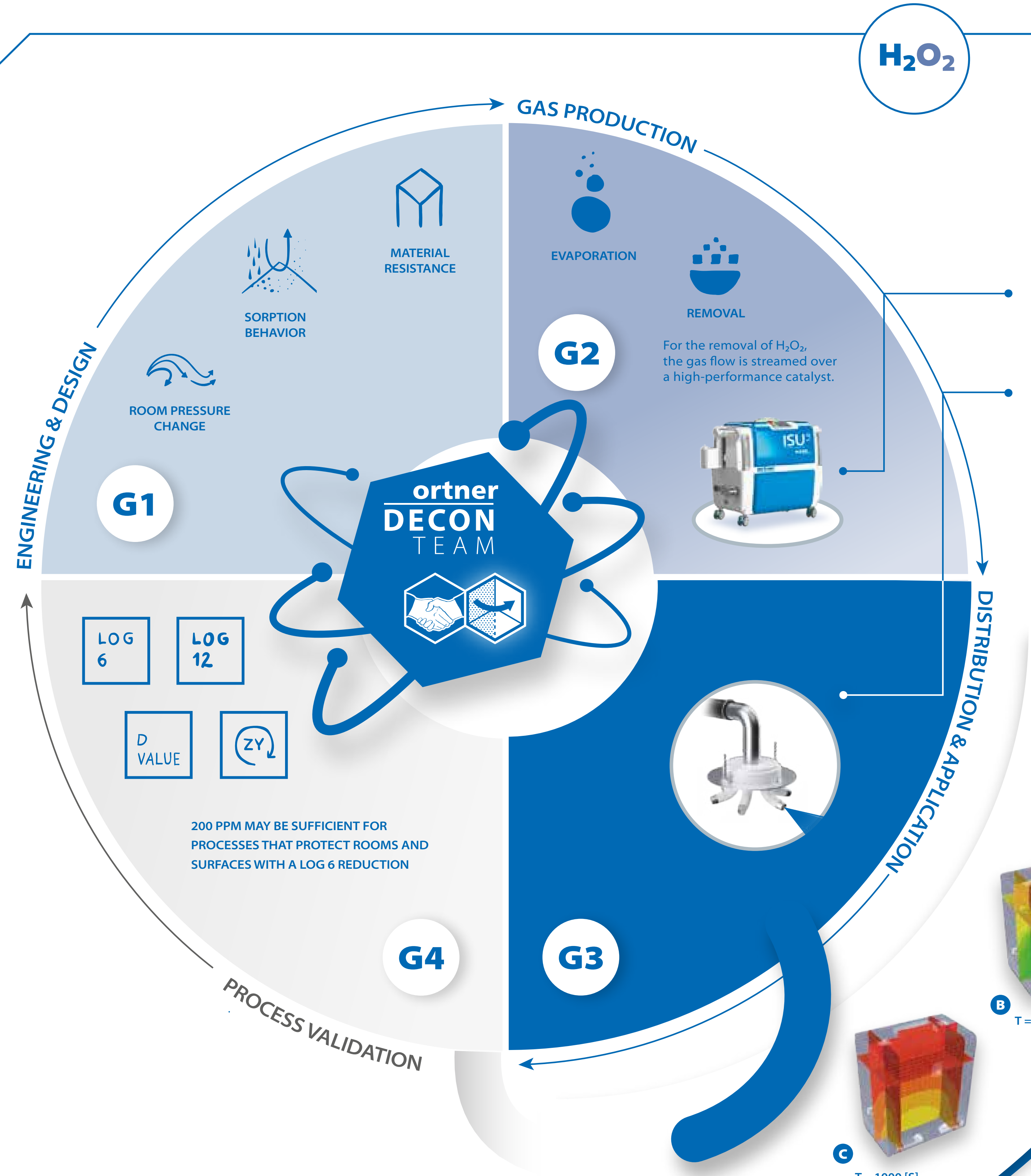
- Graz University of Technology, Institute for Environmental Biotechnology
- Research Center Pharmaceutical Engineering GmbH Graz, Institute of Process and Particle Technology
- Carinthian Tech Research AG
- Silicon Austria Labs (SAL)

THE H_2O_2 DECONTAMINATION PROCESS









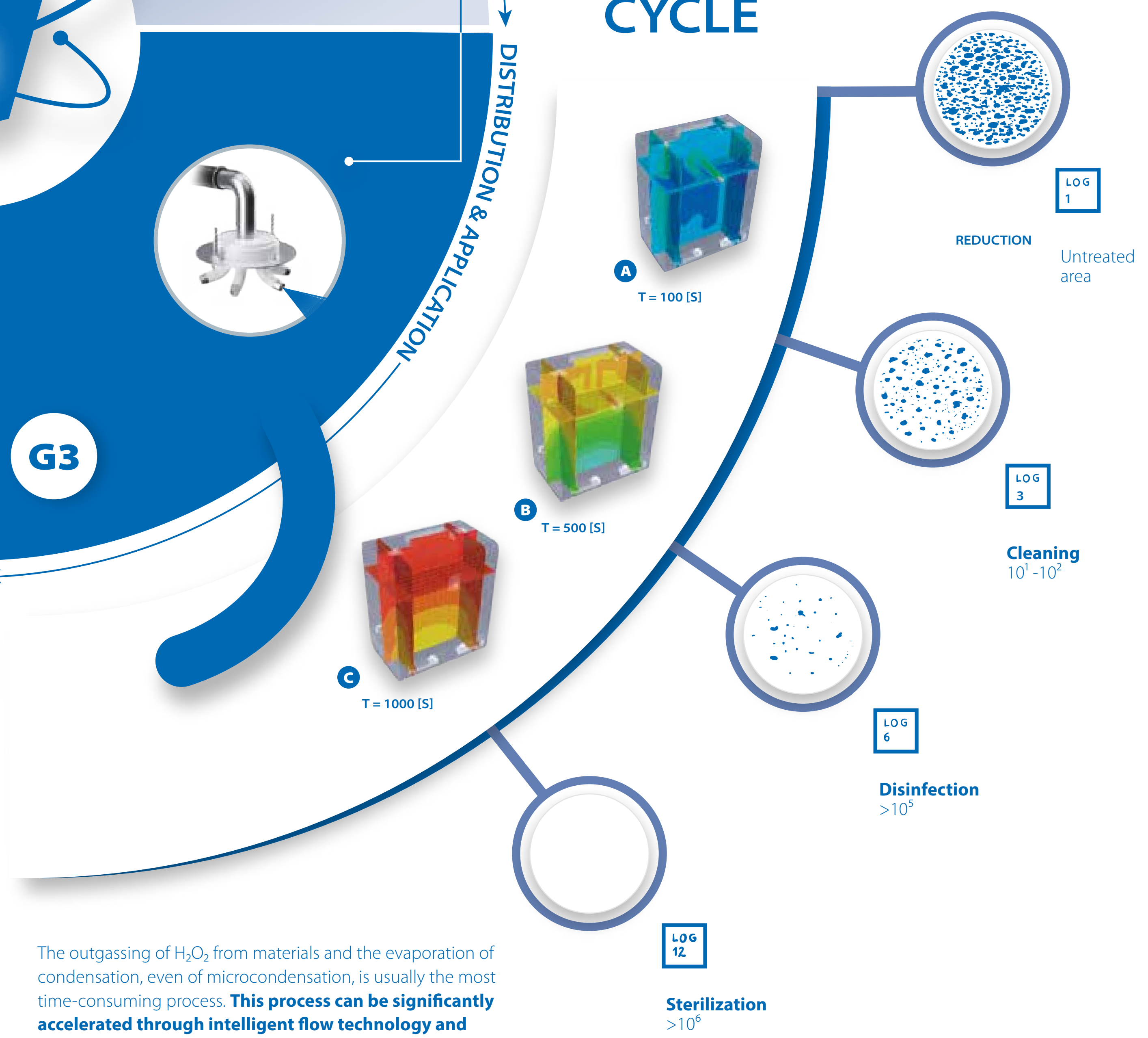
Hydrogen peroxide

- Hydrogen peroxide has a lower partial pressure than water and therefore takes longer than water to evaporate.
- Low gas pressure requires a higher boiling point.
- The gas rises due to the increased evaporation temperature.
- The room is filled with gas from top to bottom.
- Optimum mixing ratios can be achieved by higher intake speeds and air turbulence. Turbulence is an advantage during the influence phase.

With the ISU generator system, both "single loop" and "dual loop" processes can be run. The generator sucks in air from the room or chamber and continuously enriches the gas flow with H_2O_2. Thanks to the high gas flow volume and high external fan pressure, external systems and plants can be supplied effectively.

Uniform gas distribution or concentration distribution is of particular importance for safe and verifiable processes and has an enormous influence on the success of decontamination. Well planned and verified gas introduction and optimal introduction technology are basic prerequisites for avoiding damage. Special nozzle systems are used for this purpose.

CYCLE



FLOW SIMULATION

Each area of the room shall be within a turbulent airflow range. Very complex decontamination conditions can be calculated and simulated in advance using CFD (flow simulation).

The outgassing of H_2O_2 from materials and the evaporation of condensation, even of microcondensation, is usually the most time-consuming process. **This process can be significantly accelerated through intelligent flow technology and temperature increase.**

Ortner's expertise is based on three key factors that make us the central point of contact for all decontamination challenges.

1

ADVANTAGE OF KNOWLEDGE

The company's in-depth knowledge of H_2O_2 and CH_2O procedures ensures that we carry out decontamination processes safely, quickly, and professionally. It is crucial for our decontamination team always to keep an eye on **"THE BIG PICTURE"** to be able to deliver the best results.

Lateral thinking is the decisive key to success: Thus, we incorporate the knowledge of numerous special fields and research results and integrate them into our work. We have developed modern, state-of-the-art decontamination technologies from this.

2

FULL SERVICE PARTNER

As a full-service provider, we take on all the tasks that arise during a decontamination project – including project planning, cycle development, decontamination, validation, and documentation. **You receive all the necessary services from a single source.**

3

EXPERT STATUS

Successfully solving special and unusual challenges is our strength. Many years of experience, pioneering work in the field of decontamination, and extensive knowledge make us specialists. No matter what challenge you face: **Ortner seeks out and discovers an agreeable solution. This is due to the company's approach and way of thinking, the spirit of research, and the cooperation with scientists from different fields.**

DECONTAMINATION SERVICES
from Ortner.

To enable you to fully benefit from our decontamination solutions and products, we offer a range of services.

DECONTAMINATION SERVICES

1. Engineering Support

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

2. Cycle development & cycle validation

3. Room Decontamination

4. Microbiology Support

5. Training

6. Generator Rental

7. Maintenance of Equipment

ortner DECON TEAM

ORTNER SERVICES

Decontamination services

1. Engineering Support

Decontamination concept:

We support external companies in a wide range of issues relating to room decontamination. For example, we design decontamination concepts for companies that develop laboratories. We also assist operators of safety laboratories with the preparation of decontamination concepts. These services are offered regardless of whether the actual decontamination is carried out by Ortner or not.

System optimization/Upgrades:

We offer support in updating your systems to the latest state-of-the-art. The goal is to make decontamination processes safer, faster, and more efficient by optimizing existing systems. For systems that have been in operation for several years, this can be done by updating the sensors or installing new fans or doors. This service is not only offered for Ortner products, but also for third-party products.

Test decontamination/ Material resistance:

A single test decontamination of a room can be useful in different cases. This applies in particular to areas that have not yet been decontaminated.

Material compatibility tests show whether and to what extent materials are H_2O_2-resistant. Ortner tests the material resistance of products and materials on behalf of manufacturers and customers.

Leakage test:

It is particularly important to check the air-tightness of a room before putting it into operation. A test is mandatory, especially for safety laboratories that operate under negative pressure and must demonstrate a high level of air-tightness. Test decontamination provides information as to whether the room to be gassed is completely sealed. If the meters indicate that gas is leaking, the leak is repaired and the room retested.

Flow and gas concentration simulations:

A simulation of decontamination brings decisive advantages: in the event of uncertainties or complex tasks, a simulation improves the planning and reduces the cycle development. Possible damages can also be excluded at the same time. Financial aspects also support this simulation: the cost of repairing the damage is usually many times higher than the cost of the simulation. It can also provide information on whether, for example, one or two nozzles must be used in the decontamination process.

A flow simulation can be carried out on a PC: the geometry and properties of the room are programmed accordingly and the decontamination is then simulated. This ensures that the gas reaches every corner of the room. Alternatively, non-toxic fluid vapor can be emitted directly into the room, and the video recordings can be used to analyze whether all points in the room can be reached evenly during decontamination.

Consulting:

A. PLANNING
B. EXPERT ASSESSMENTS
C. EXPERTISE

Our tasks also include assessments, expert opinions, and on-site consulting. On request, we prepare analyses of required technologies for planners, laboratories, and other parties, or prepare expert opinions on clean-room requirements for rooms, systems, and processes. All information, expert opinions, and assessments are carried out by our decontamination experts.

2. Cycle Development and Cycle Validation

Ortner provides various additional services as part of the cycle development and validation process:

- **TEMPERATURE MEASUREMENT**
- **H_2O_2 CONCENTRATION MEASUREMENT**
- **HUMIDITY MEASUREMENT**

Mobile devices are used to measure whether a constant temperature, humidity, or H_2O_2 concentration exists everywhere in the room or system. Ortner has a measuring system that can check all three values simultaneously. In this way, possible critical points in the room can be identified quickly.

3. Room Decontamination

Room decontamination
Our qualified DECON team ensures that decontamination requirements – from the smallest room to the machine and to large buildings – are fully met. Equipped with state-of-the-art technology and many years of expertise, the DECON team ensures fast and efficient decontamination in the shortest possible time.

Contract decontamination
If you need decontamination only once or rarely, and if decontamination can be scheduled, contract decontamination is recommended. You do not need to have any equipment at your disposal for this type of operation. The Ortner team provides the necessary equipment and manpower, regardless of whether it is for the decontamination of a room or a facility.

4. Microbiology Support

Ortner carries out the necessary measures and evaluations itself – from incubation in the incubator to the determination of biological contamination. At the same time, we work very closely with certified laboratories to provide you with comprehensive security.

5. Training

The handling of H_2O_2 and other chemicals requires an exact knowledge transfer. To be able to carry out decontamination properly and safely, you or your employees will be extensively trained on the system. In addition to this system training, Ortner offers general decontamination training, if required.

6. Generator Rental

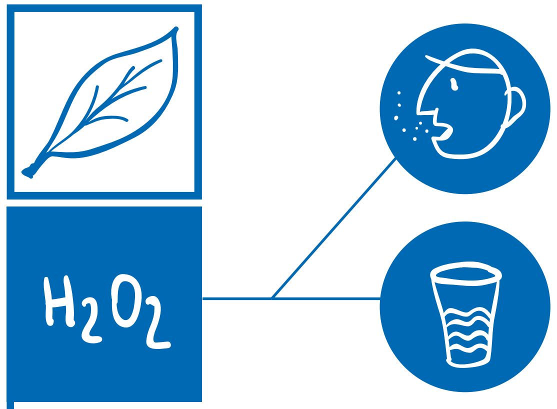
Ortner's modern mobile H_2O_2 generator systems can be rented if required. The powerful gas generators have nozzles on top, allowing even rooms without integrated connections to be decontaminated. Rental is possible only after extensive training.

7. Maintenance of Installations

The maintenance of the gas generators and systems is relatively simple and uncomplicated. Ortner's service team carries out these activities within the framework of maintenance contracts, or on request. The ISU generator should be serviced and calibrated once a year and the H_2O_2 sensors recalibrated every six months.

OUR CORE TECHNOLOGY:
The H_2O_2 decontamination

Safe & environmentally friendly



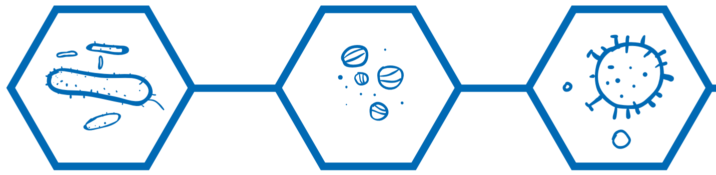
Whenever possible, Ortner relies on the innovative H_2O_2 decontamination method: a modern and viable method for almost all applications.

The decomposition of H_2O_2 does not produce toxic residues
(splitting into water and oxygen)

Rooms/clean rooms
(laboratories, intensive care units, pharmacies, homes, animal husbandry…)

Machines, installations, devices
(locks, chambers, safety workbenches, bottling machines, sewage systems, containers, freeze dryers, autoclaves…)

Air conditioning and ventilation systems, exhaust air/supply air filters, fans



Bacteria **Spores** **Viruses**

Working principle:

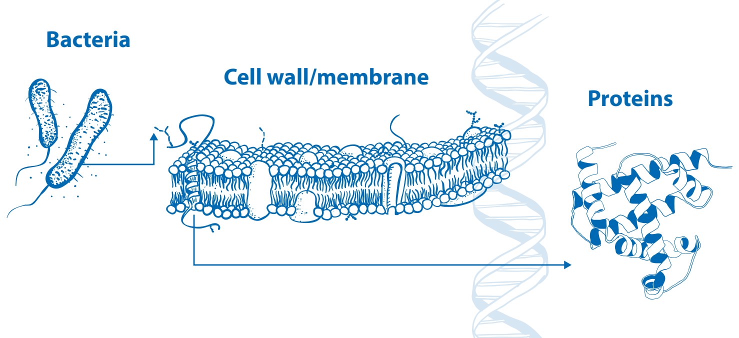
The biocidal effect of hydrogen peroxide results from its high oxidation capacity and, due to the formation of free radicals, leads to rapid efficacy against most microorganisms.

H_2O_2 attacks in different ways, e.g. on the bacterial cell, the cell wall, or the cytoplasm, as well as the DNA/RNA. In the process, envelope proteins of the microorganism are altered and thus denatured. Denaturation leads to impaired metabolic ability and ultimately to the death of the microorganism.

This procedure demonstrates extensive effectiveness against bacteria, fungi, viruses, and spores.

Hydrogen peroxide is a strong oxidizing agent

$$E0 = +1.78\ [V]\ H_2O_2/H_2O_2$$



ZY	D VALUE	LOG 6	LOG 12

LOG 6 means: Of 1,000,000 microorganisms, only a maximum of 1 microorganism remains alive after decontamination.

- **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**

ARGUMENTS FOR H_2O_2 DECONTAMINATION:

Manual spray disinfectants and conventional decontamination methods are increasingly being replaced by the hydrogen peroxide decontamination method.

THE REASONS:

1 SAFE & EFFECTIVE

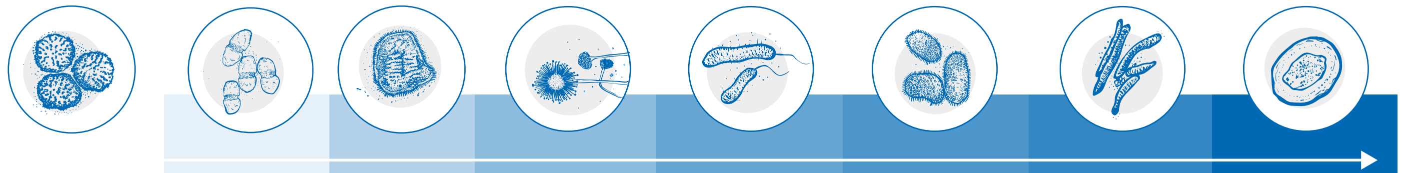
- Effective alternative to formaldehyde, peracetic acid
- High biological efficacy (up to LOG6 reduction)
- Environmentally friendly (decomposes to oxygen and water)
- Low material stress
- Most materials are resistant or at least conditionally resistant to H_2O_2

2 FAST & EVALUABLE

- Short D-values, short degassing times
- Validated process reduces security risks
- Approved by RKI, FDA, MCA, and others

3 WIDE RANGE OF APPLICATIONS

- In isolators, material locks, etc., also for temperature-sensitive devices and materials
- Highly effective room decontamination even of rooms that are part of larger clean room areas
- Most electronic devices can be decontaminated

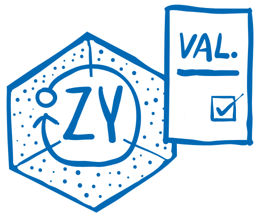


Viruses with Lipid Envelope (LIPOPHIL)	Gram-Positive Bacteria	Large Viruses Without Envelopes	Fungi	Gram-Negative Vegetative Bacteria	Viruses Without Lipid Envelope (HYDROPHIL)	Mycobacteria	Bacterial Spores
Orthomycoviridae *(Influenza, Influenza A2)* Paramycoviridae *(Newcastle)* Herpesviridae *(Pseudorabies, Herpes Simplex)* Rhaboviridae *(Vesicular stomalitis)* Toga / Flawviridae *(Hog cholera, BVD)*	Entercoccus faecium Entercoccus aureus Staphylococcus aureus Lactobacillus casei Listeria monocytogenes Legionella pneumophilia	Adenovirus *(Adenovirus 2)* Poxviridae *(Vaccinia)*	**Molds** Aspergillus niger Aspergillus terrus Fusarium oxysporum Penicillium crysogenum **Yeasts** Candida parapsilosis Saccharomyces cerevisiae Rhodotorula glutinis	Pseudomonas aeruginosa Burkholdia cepacia Serratia marcesens Escherichia coli Escherichia coli O157 Proteus vulgaris Salmonella choleraesuis	Parvoviridae *(mouse and canine parvovirus* *Piccornaviridae* *(Polio Type 1, Swine vesicular virus, Rhinovirus 14)* Reoviridae *(Blue-tongue, Avian exanthema)*	Mycobacterium smegmatis Mycobacterium terrae Mycobacterium bovis Mycobacterium tuberculosis Nocardia lactamdurans	Bacillus stearothermophilus Bacillus-pumilus Bacillus subtilis Bacillus anthracis Bacillus cereus Bacillus circulans Clostridium sporogenes Clostridium botulinum Clostridium tetani

H_2O_2 RESISTANCE

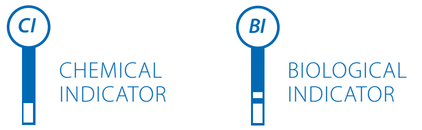
CYCLE DEVELOPMENT:
Calculated precisely.

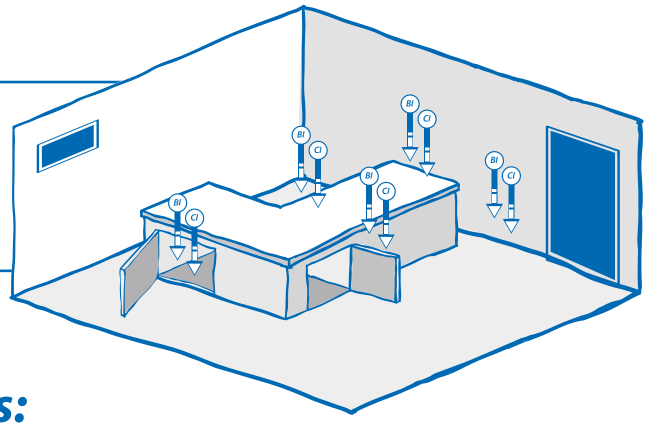
Cycle development is at the heart of any decontamination process and critical to its success. It is a statistical method to adjust the decontamination process ideally to the environmental conditions and the respective room condition.



Professional cycle development encompasses:

- **A** THE CODEVELOPMENT OF THE POSSIBLE LOADING SITUATION
- **B** THE DETERMINATION OF RISKS, RISK ZONES SUCH AS COLD SPOTS, MATERIAL PROPERTIES, ETC.
- **C** THE DETERMINATION OF WORST CASE POINTS
- **D** THE DESIGN OF CHEMICAL AND BIOLOGICAL INDICATORS AND THE INTERPRETATION OF RESULTS
- **E** THE AVOIDANCE OF CONDENSATE AT CRITICAL POINTS
- **F** DETERMINATION OF THE SHORTEST POSSIBLE CYCLE TIME (CALCULATION OF THE D-VALUE FOR EACH TEST LOCATION) (OPTIONAL)
- **G** CFD SIMULATION AT PROJECT START (OPTIONAL)





LOG6 germ reduction in focus:

In the case of H_2O_2 decontamination, a reduction of LOG6 is achieved during cycle development. Proof of successful decontamination is provided by the biological indicators used in cycle development. (The highly resistant bacterial spores of Geobacillus stearothermophilus are used as a control element). By calculating the D-value (= decimal reduction time) it can then be extended to a theoretical reduction of LOG12.

D WERT | LOG 6 | LOG 12

A cycle development is divided into four phases:

1 PREPARATION

To avoid condensation, the air in the room is pre-dried.

- Removal of moisture to a certain degree
- Heating of the evaporator to the desired temperature
- Heating piping system
- **KPI = low relative humidity**

2 CONDITIONING

The H_2O_2 solution is evaporated and introduced into the room via the gas nozzles or gas supply lines.

- Build-up of the H_2O_2 concentration near the dew point
- To avoid condensation at all points
- **KPI = highest H_2O_2 concentration within the shortest possible time**

3 DECONTAMINATION

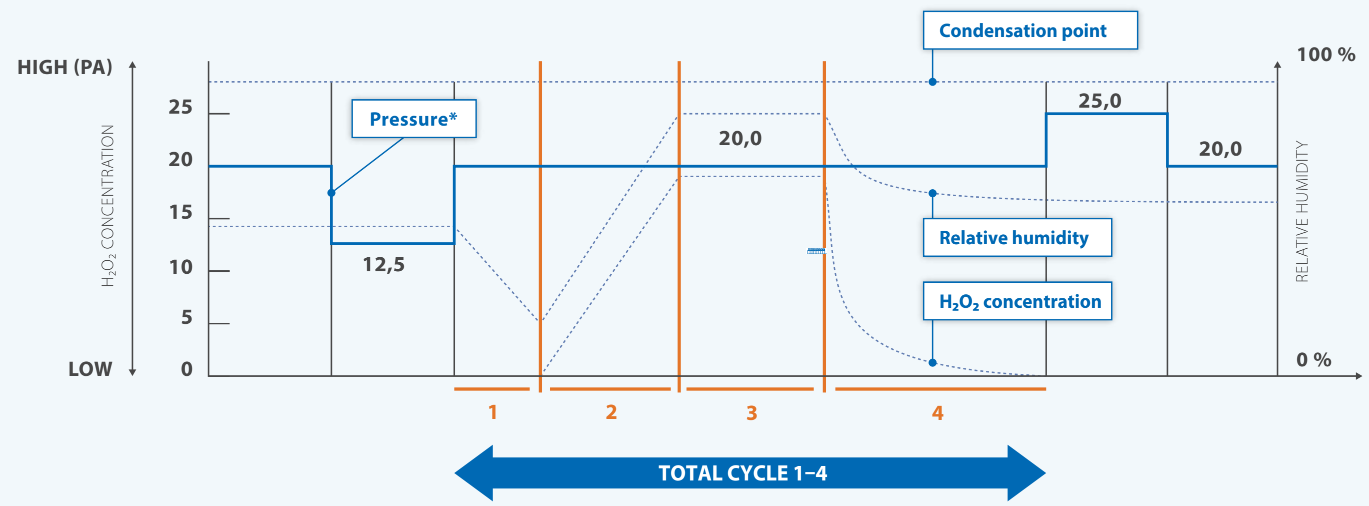
The H_2O_2 concentration is maintained at a desired concentration level and the gas is evenly distributed throughout the room by fans.

- Determination of the exposure time until the LOG6 reduction is reached
- Maintaining concentration with no further increase
- **KPI = LOG6 decontamination at all locations**

4 AERATION

The H_2O_2 gas is decomposed into water and oxygen by a catalyst in an environmentally friendly and residue-free way.

- Safe removal of H_2O_2
- High turbulent air flow
- **KPI = threshold limit value of ≤ 0.5 ppm**



Cycle optimization:

The success of decontamination depends, among other things, on air humidity, H_2O_2 concentration, gas exposure time, and temperature. Several measurements are carried out to determine the cycle times.

BIO-INDICATORS | ***CHEMICAL-INDICATORS*** | ***GAS CONCENTRATION*** | ***AIR HUMIDITY*** | ***TEMPERATURE CURVES***

Cycle validation:

Cycle validation occurs after successful cycle development. Triple decontamination (fumigation) using bio-indicators will, at best, produce similar results. Ortner uses certified biological indicators to validate the H_2O_2 decontamination process: they contain a magenta-colored indicator ink that reacts to hydrogen peroxide vapor.

Logging:

Each completed decontamination cycle is logged in the ISU system. The decontamination protocol serves as proof of the successful execution of the decontamination process and contains all relevant cycle data. Audit trail files can also be generated. These document every change to the system parameters.

ortner
cleanrooms unlimited

PRACTICAL EXPERIENCE

Procedure for H_2O_2 decontamination

ortner DECON TEAM

Everything a decontamination expert has to master…

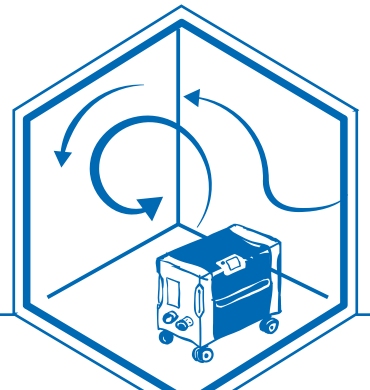
"My professional motto: There's always a way! What connects me to Ortner is above all my curiosity and thirst for research:** again and again we are confronted with new challenges in decontamination. No matter how complex the challenge may be, together with my team, I always look for the best solution – safety for humans, animals, and the environment is always in focus. I have taken this responsibility seriously since the beginning of my many years at Ortner. More than 15 years ago I was involved in the construction of the first Ortner air lock with decontamination technology. Since then, a lot has happened technologically, but the goal has remained the same: to make the daily work of our customers safer and easier."

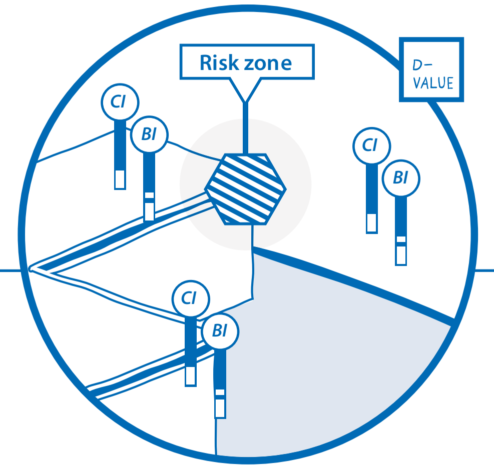
ROLAND KOLLER
ORTNER DECON-TEAM

PRACTICAL EXPERIENCE

Procedure for H_2O_2 decontamination

EVERYTHING A DECONTAMINATION EXPERT HAS TO MASTER...





BIO & CHEMICAL INDICATORS

A PRELIMINARY PLANNING

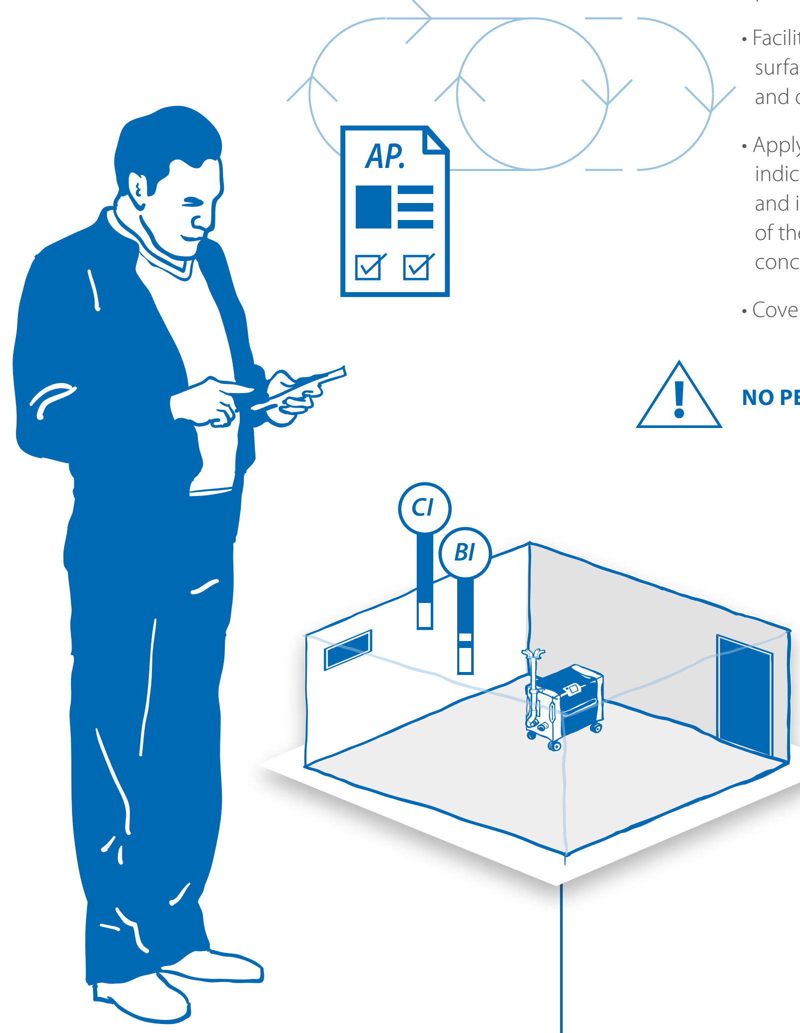
1. SITE EVALUATION

- **Which microorganisms or toxic substances are (possibly) present?**
- **What is the infrastructural situation?**
- **What is or could be contaminated?**
- **Are there any special requirements or needs?**
- **What factors are involved in the project?**
- **Are there any legal requirements?**
- **What does the desired timeframe look like?**

2. ROOM PREPARATION

- Switch off the ventilation of the room to be decontaminated or seal the supply air and exhaust air outlets.
- Close or cover the doors and all other openings. There can be no air exchange with the outside.
- Avoid large temperature differences on surfaces. Condensation may form on cold surfaces.
- Remove absorbent materials from the rooms. These can absorb larger quantities of H_2O_2, which leads to a longer degassing phase.
- Facilities and equipment shall be prepared in such a way that all surfaces can be easily reached by H_2O_2 gas. Open cabinet doors and drawers.
- Apply chemical and biological indicators. The position of the indicators results from the structural conditions of the room and its equipment. Critical points result from the investigations of the relative humidity and temperature distribution and gas concentration measurement.
- Cover the door with masking before starting the cycle.

NO PERSONNEL MAY REMAIN IN THE ROOM



TEMPERATURE MEASUREMENT

H_2O_2 CONCENTRATION MEASUREMENT

HUMIDITY MEASUREMENT

B IMPLEMENTATION/ CYCLE DEVELOPMENT

3. START OF THE CYCLE

a) Preparation
b) Conditioning
c) Decontamination
d) Aeration

4. CYCLE MONITORING

The important parameters influencing the success of decontamination are measured and controlled during the cycle.

- H_2O_2 concentration
- Temperature
- Humidity

5. RELEASE MEASUREMENT

The H_2O_2 concentration must be **<0.5–1 ppm** before the room can be re-entered or material brought in.

6. EVALUATION OF THE EFFECTIVENESS OF THE CYCLE

a) Chemical and biological indicators will be evaluated.
b) Biological indicators are incubated at 55 °C for seven days.

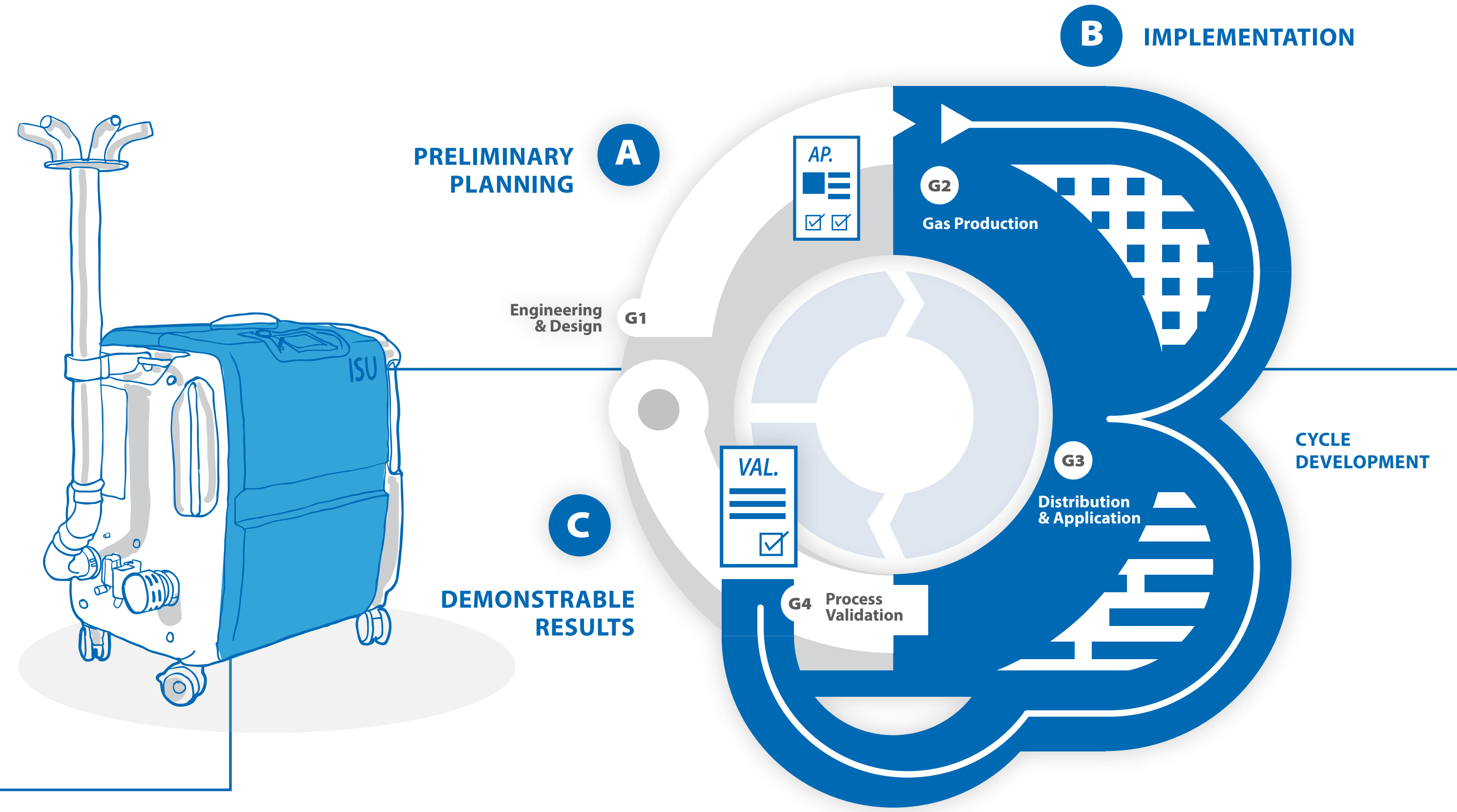
7. CYCLE OPTIMIZATION

A cycle is optimized based on the evaluation of biological indicators, gas concentration, air humidity, and temperature curves.

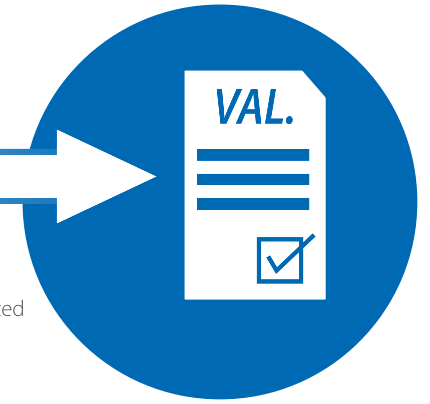
8. REPRODUCIBILITY OF THE CYCLE

Can be checked on the basis of the measurement.

9. ROOM RELEASE



C RESULTS/ EVIDENCE



Proof of successful decontamination is provided by the bio-indicators used in cycle development. The elimination by LOG6 levels of the bio-indicators used at all designated positions shows the effectiveness of the procedure.

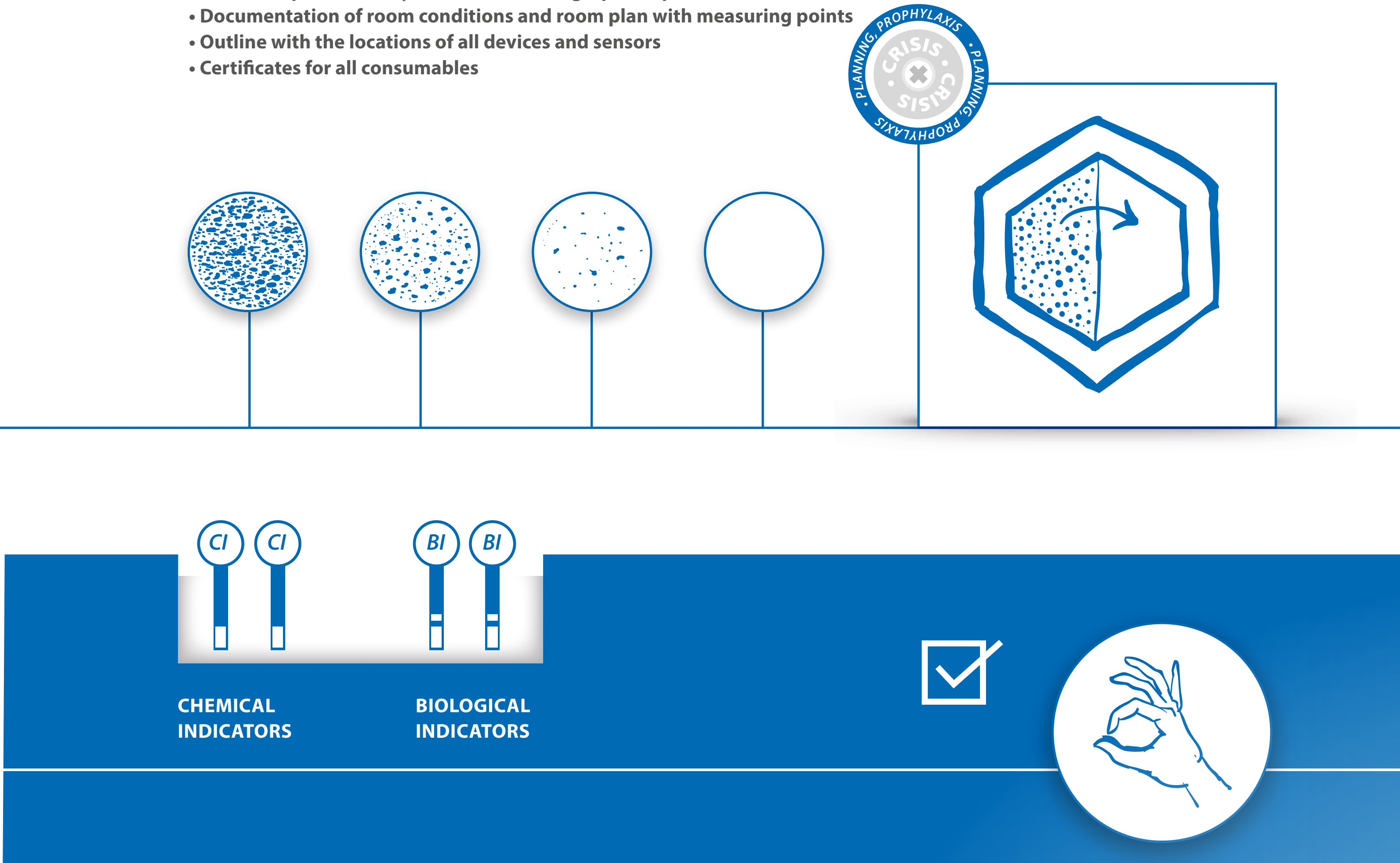
10. DOCUMENTATION

Finally, a full report is drawn up or the positive results confirmed.
The report shall contain, among others:

- **Meter results of bio-indicators**
- **Visual documentation of the execution of the cycle**
- **Raw data of measurement results**
- **Results of performed cycle data and their graphic representations**
- **Documentation of room conditions and room plan with measuring points**
- **Outline with the locations of all devices and sensors**
- **Certificates for all consumables**

LOG 6

LOG 12



CHALLENGES OF

H_2O_2 decontamination

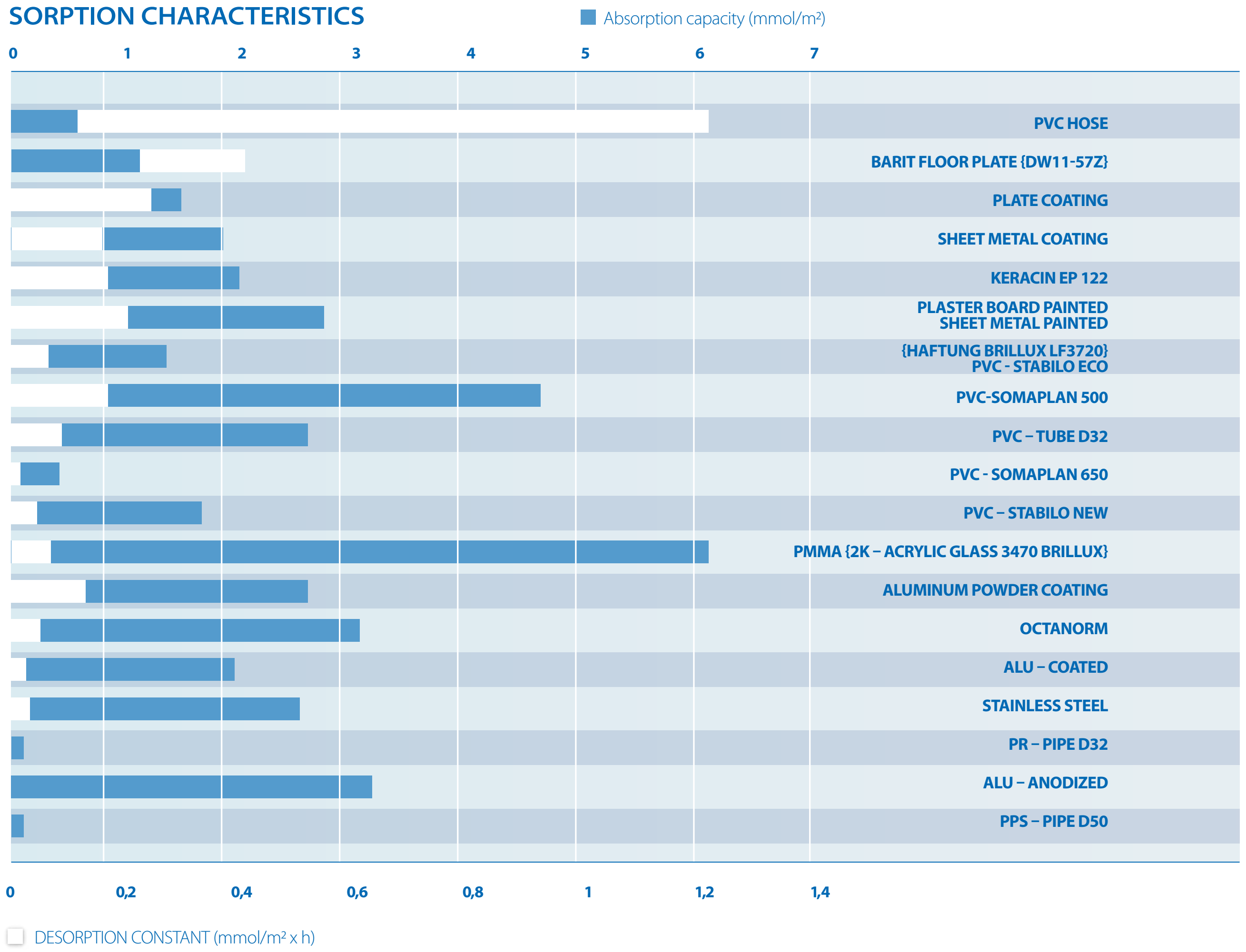
H_2O_2 decontamination is establishing itself as a “clean alternative” in the clean room technology sector. But even this innovative technology has challenges to master – the largest are always the rooms to be decontaminated themselves. Ortner offers them the best possible service with its well-founded expertise.

Sorption characteristics:

The significance of the materials
Once H_2O_2 gas is inseparably connected to the humidity, unavoidable adsorption and desorption of materials that absorb moisture is created. It is crucial to know the sorption behavior of different materials precisely. Only in this way the H_2O_2 technology can be used safely and successfully. Materials in the room to be decontaminated must therefore be precisely taken into account in the decontamination planning and in the cycle development.

The challenge
Many materials absorb moisture quickly but release it again much more slowly. This can be especially important for the cycle duration.

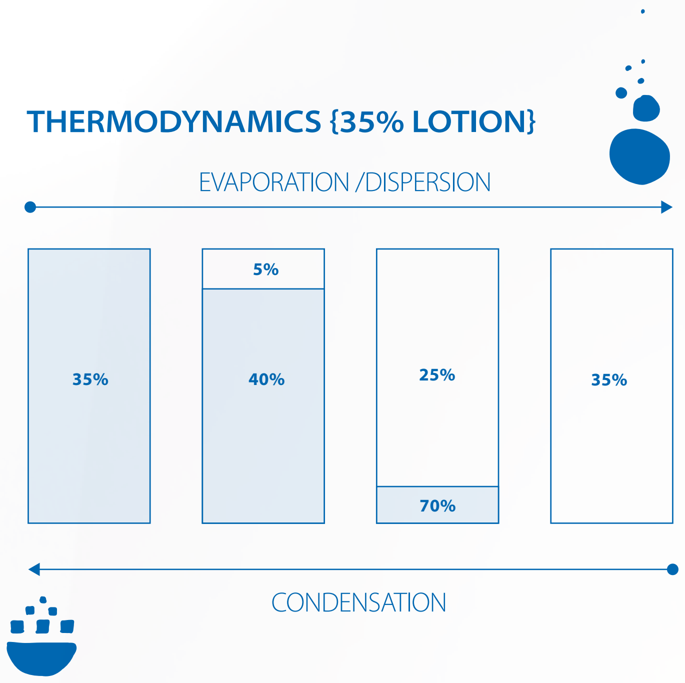
Avoiding damage
High air volumes or gas flow volumes during introduction reduce the risk enormously. Short cycle times and possibly lower H_2O_2 concentrations can reduce the risk to a minimum.



Condensate avoidance as the top priority

Due to the different partial pressure between H_2O_2 and water, the evaporation behavior and the condensation behavior differ considerably. Frequently, there is an increase and change in the H_2O_2 concentration in the condensate. Condensate concentrates during the process and can lead to surface damage.

Condensation: H_2O_2 condenses only when the surface temperature falls below the dew point. Essentially there are only three ways of avoiding condensate:



1. Avoiding cold surfaces
This can be done by heating the system.

2. High air flow and turbulences
Applying turbulent flow to risk zones in a room is an effective solution to avoid condensation formation. High air volumes and high flow velocities in air ducts counteract the formation of condensate.

3. Lowering the relative humidity
By evaporating H_2O_2, even if the total amounts are relatively small, the humidity is increased. Lowering the relative humidity during evaporation can be done by dehumidifying the raw air or by mixing the hot vapor air with adequate amounts of room air.

The decontamination cycle is decisive for avoiding condensation. Special flow techniques can be used to prevent or effectively remove condensation.

The generator used, on the other hand, has no effect on condensate formation: whether the condensate is precipitated or not is a physical result and is generator-independent.

CHALLENGES OF

H_2O_2 decontamination

DRY VERSUS WET— IT'S ALL ABOUT PHYSICS

Wet or dry processes depend exclusively on the cycle development and physical conditions in the room or chamber.

DRY PROCESSES

Dry processes depend primarily on humidity, temperature and pressure. Particular attention is required in the design and cycle development for possible cold bridges (surface temperatures of materials).

Dry processes can be carried out more gently and at the same time with a higher gas concentration, which reduces cycle times.

Dehumidification of the air at good climatic conditions (rH approx. 50%) is not absolutely required. Dehumidification is advisable or necessary if:

A) VERY SHORT PROCESS TIMES ARE DESIRED
B) HIGH CONCENTRATIONS ARE REQUIRED
C) THE RELATIVE HUMIDITY IN THE ROOM OR CHAMBER IS HIGH (e.g. > 60 % rH)

The process of dehumidification of the air normally has only limited benefit for the decontamination cycle, except in the case of special requirements.

WET PROCESSES

Wet processes may be disruptive or irrelevant, intentionally or unintentionally. H_2O_2 condensate is corrosive and difficult to break down. The breakdown process can be accelerated by increasing the air volume or temperature or by lowering the humidity. Condensate precipitation can be avoided or reduced through strong air movements (turbulent flow).

D-VALUE *

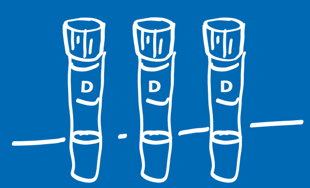
* *(= decimal reduction time, destruction value)*

The D-value is the time that is required to complete the process under precisely defined conditions, e.g. at a certain temperature, to reduce the initial concentration of a certain population of microorganisms by a power of ten, i.e. by 90%.

This time depends strongly on the type or strain of the microorganism, the temperature and other conditions – especially water activity, pH and ionic strength. That means, each microorganism has its own D-value.

For H_2O_2 decontamination, bio-indicators with Bacillus stearothermophilus as a highly resistant test germ are usually used.

LOG 6   LOG 12



Determining the D-value
This is used to determine the "decontamination value", i.e. the time period during which a biological indicator is inactivated in a quantitative region according to a series of experimental data. **"Limited Holcomb-Spearman-Karber Method."**

This method is used to determine in advance the theoretical mean time in which a biological indicator in a quantitative region is inactivated or not, i.e. shows positive or negative growth. To carry out this procedure, an impact time must be evaluated in advance. This is subdivided into several equal time periods and all three time periods of the survival curve must be covered:

- **the survival time** (all survive)
- **the survival kill window** (mixed)
- **as well as the kill time** (all die off) **of the biological indicator**

We use this scientific method to:

- **verify the bio-indicators used**
- **to determine the D-value for each test location of a load**

This is a type of incoming goods inspection by BI and is compared with the D-value of the vendor. The biggest advantage is a reliable determination of the shortest possible cycle time.

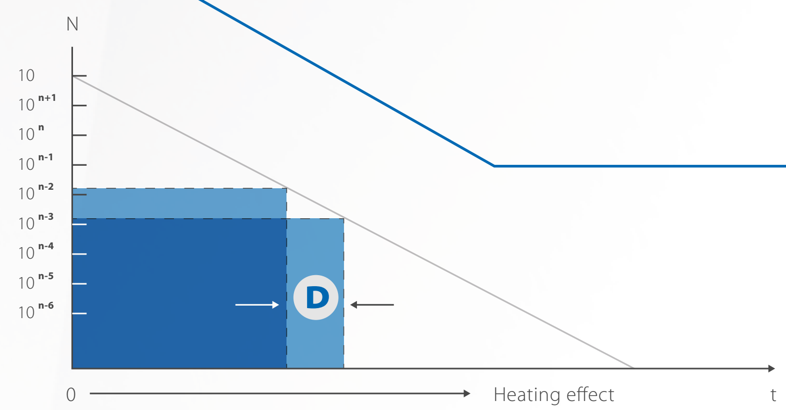


Fig: Survival curve incl. table with D-values

Germ	Temperature	Time {D-Value}
Staphylococcus aureus	80 °C	2 sec.
Bacillus stearothermophilus	121.1 °C	4–5 min.
Mesophilic Spore Formers (Endospores)	130 °C	1 min.
Spores of Geobacillus stearothermophilus	121 °C	1.5–2.5 min.
Spores of Geobacillus stearothermophilus	115 °C	approx. 18 min.
Listeria monocytogenes	71.7 °C	3.3 sec.

DECONTAMINATION
Use Cases

ROOM DECONTAMINATION

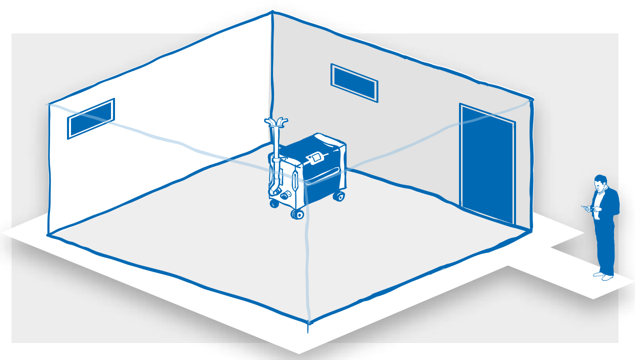


Fig. 1)

ISU Mobile
with surface-mounted nozzle in the room

Process control from outside via tablet

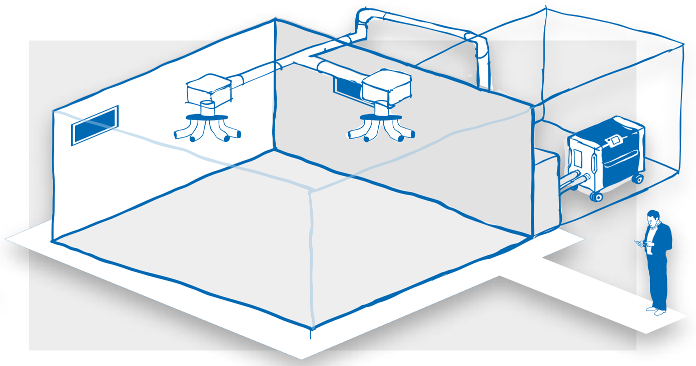


Fig. 2)

ISU Mobile
(in the technical area)

Room decontamination via the gassing nozzle Compact or Light

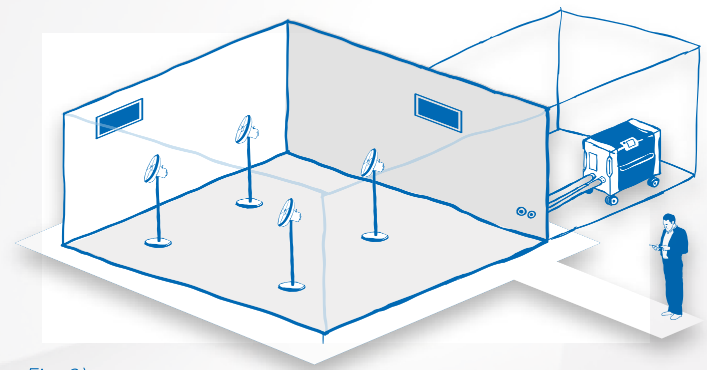


Fig. 3)

ISU Mobile
(in the technical area)

Room decontamination via wall ducts, free-standing fans in the room for gas distribution

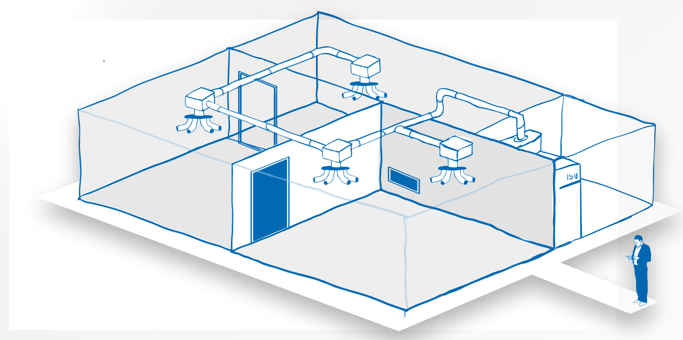


Fig. 4)

ISU Stationary
(large-scale facility)

Decontamination of several rooms with automated processes via pipelines to the Compact or Light gassing nozzle

SYSTEM DECONTAMINATION

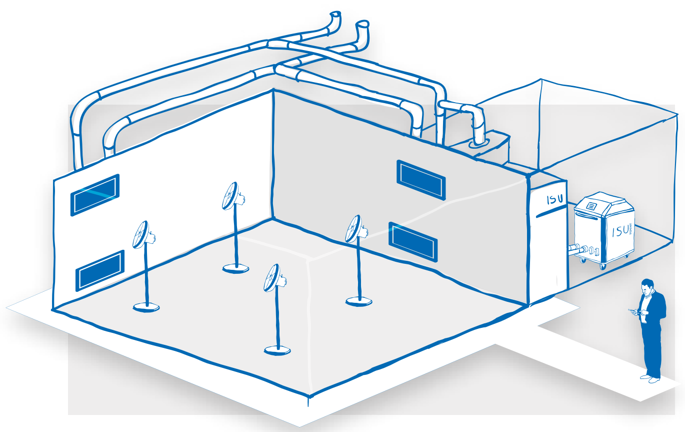


Fig. 5)

ISU Stationary
ISU Dispense

Room decontamination via the ventilation system

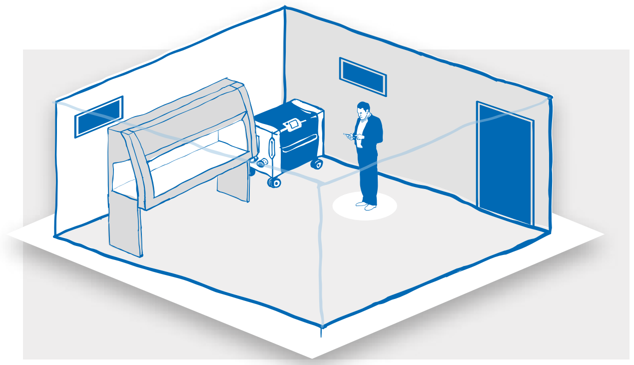


Fig. 6)

Safety Cabinet
ISU Mobile

The two systems are connected with the gas supply pipes

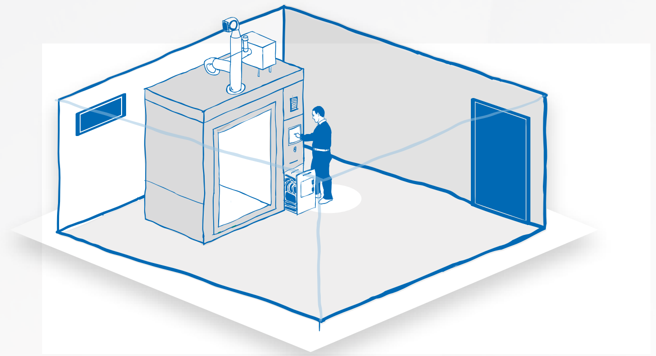


Fig. 7)

H_2O_2 Lock

ISU integrated
(installed in the lock)

or ISU Mobile

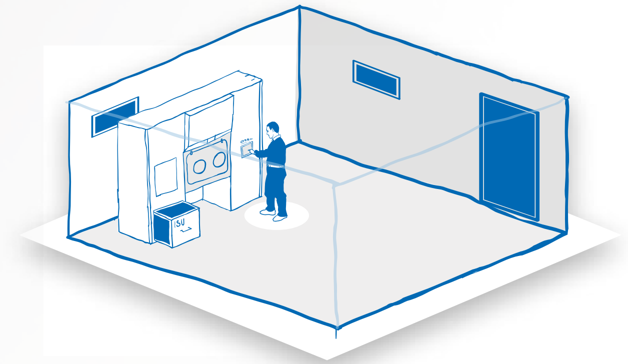


Fig. 8)

Isolator

ISU integrated
(installed in the isolator)

or ISU Mobile

ISU Mobile

H_2O_2 Gas Generator

ISU
1.0

ISU
2.0

ADDITIONAL OPTIONS:

- **HC sensor, LC sensor**
- **H_2O_2 Catalyst with H14 filter**
- **Gassing nozzle attached**
- **Comfort display module for remote control via WLAN**
- **Audit trail**

The **Ortner PLUS**

+

- Powerful evaporation module
- Integrated heater module, e.g. for: heating of air ducts, including numerous interfaces for system integration and communication with external system controls
- Suitable for open and closed-loop processes
- Suitable for effective decontamination processes for room volumes up to 500 m^3
- Automatically controlled volume flow up to 350 m^3/h
- 5 liter H_2O_2 container (ISU 2.0), 1 liter (ISU 1.0)

Smart. It is possible to operate the ISU Mobile with another control unit (e.g. from another workstation or outside the room to be decontaminated). All operating states of the system, all actual values of the sensors, the process lines, all alarms, and the current cycle data are provided via the LAN interface. The operator can select and start a cycle externally via the LAN interface.

Technical data

	ISU 1.0	ISU 2.0
Casing	plastic (ABS)	plastic (ABS)
Power consumption	3.5 kW / 12.5 A	6 kW / 14 A
Voltage	230 VAC or 3 × 400 VAC/50 Hz/N/PE	230 VAC or 3 × 400 VAC/50 Hz/N/PE
Fan	electronic speed control	electronic speed control
Control unit	Siemens S7 1200	Siemens S7 1200
Storable cycles	1–10 (optionally expandable)	1–10 (optionally expandable)
Pump	high-precision dosing pump +/– 1%	high-precision dosing pump +/– 1%
Pump service life	10,000 operating hours	10,000 operating hours
Scale	0 - 1,500 g	0 - 6,000 g
Signalization	process signaling (red/green/yellow)	process signaling (red/green/yellow)
Injection rate	1 – 10 g/min	1 – 10 g/min
Room temperature	0 – 40°C	0 – 40°C
Airflow volume	variable up to 100 m^3/h	variable up to 350 m^3/h
Hose connections	DN 32 Tri-Clamp	DN 80 Tri-Clamp
Touch panel	TP 700 Comfort (color)	TP 700 Comfort (color)
H_2O_2 reservoir	up to 1 liter (technically pure H_2O_2)	up to 5 liters (technically pure H_2O_2)
Room volumes	applicable up to approx. 50 m^3	applicable up to approx. 500 m^3
Internal piping	stainless steel	stainless steel
Weight	approx. 130 kg	approx. 200 kg
Swivel casters	swivel casters with directional lock	swivel casters with directional lock

Model	Overall dimensions W x H x D mm		
ISU 1.0 925-030-000-000-06	**1,120**	**1,040**	**660**
ISU 2.0 925-020-000-000-06	**1,260**	**1,290**	**780**

The ISU *(Interactive Superinduce Unit)* **is one of the most powerful H_2O_2 gas generators on the market.** It is used for decontamination with hydrogen peroxide.

The ISU communicates interactively (also with external systems) **and can network or combine different systems or devices.** Due to its high performance, it is possible to reliably decontaminate facilities and rooms of different sizes and with different volumes.

The system can be used as a stand-alone device in various sizes and designs and has mobile or stationary variants.

1 | Decontamination of special transport containers for shipping animals

2 | H_2O_2 decontamination of safety cabinets

3 | Room decontamination of BSL laboratories

4 | ISU Mobile with nozzle attached

5 | Additional security: users can monitor the process outside the hazardous area and, if necessary, interrupt and resume a decontamination process in a controlled manner without exposing the operating personnel to danger.

Nozzle systems

Light nozzle

Nozzle Compact

- **Each nozzle element can be controlled individually**
- **Each individual nozzle outlet can be opened or closed separately by nozzle cycles**
- **Due to the timing and orientation of the blasting, difficult room geometries can be ideally flowed through**

ADDITIONAL OPTIONS:

(light & compact nozzles)

- **Corner nozzle set design**
- **Ceiling installation kit**
- **Cover element**
- **The gas flow exits all nozzles simultaneously and evenly**

Attached nozzle

The **Ortner PLUS**

+

- Uniform distribution of the gas concentration in the entire room including niches
- Special design causes a high pulse current. This results in a high induction power and depth of the gas flow
- Can be integrated in all common ceiling grids (compact nozzle & light nozzle)
- Positive influence on free rinsing processes and desorption performance

Technical data

Light nozzle
Nozzles: 6 nozzle elements
Projection distance: approx. 6 m, round
Connection diameter: DN 100
Air output: max. up to 800 m³/h

Compact nozzle
Nozzles: 6 nozzle elements
Throw distance: 2 x 15 m
Connection diameter: DN 100
Air output: 1 x 130 m³/h, max. up to 800 m³/h
Electrics: control of valve terminal
Valve block 2 bar pneumatic cylinder
Material/color: plastic, white

Attached nozzle
Nozzles: 6 nozzle elements
Throw distance: 2 x 15 m
Air output: 1 x 130 m³/h, max. up to 800 m³/h
Material/color: plastic, white

Model (in mm)	Nozzle LIGHT	Nozzle COMPACT
Diameter	**450**	**450**
Height, straight version	> 150	> 400
Height, angled version	250	370

Compact nozzle
For safe and verifiable decontamination processes, it is particularly important to distribute the H_2O_2 gas evenly throughout the room and all facilities. Ortner's decontamination nozzles have been designed as a patented system based on state-of-the-art CFD simulation. They are designed as mobile or stationary units and are used for uniform and fast gas distribution. The nozzle has six outlet nozzles, arranged in a circle, to distribute the air enriched with H_2O_2 optimally in the room. An ideal solution even for complex room decontamination.

1 | The shape:
Not only does the shape of the nozzle cause induction and turbulence, but so does the positioning and the angular position, which guarantees a high depth effect and prevents condensation.

2 | The current:
Due to the high intake speed and the induction effect, the room air is pushed into a roller movement. With the change in cycle, a reverse flow is created, pushing the gas into niches and exposed places.

3 | The effect:
With the controllable nozzles, individual diffusers can be put into action sustainedly or only briefly. This allows, for example, long corridors (up to approx. 25 m) to be well gassed with a nozzle system, or the gas flow to be directed through an open door.


1


2


3

Additional equipment
ISU Dispense
Distribution and amplifying unit

ISU Dispense is designed for all applications where an H_2O_2 generator is already present, but the power of the generator is not sufficient for room decontamination on a larger scale.
It is a distribution and amplifier unit and can be used for all commercially available generator types. It communicates interactively. Due to the variably adjustable volume flows of up to 400 m³/h and to the process variety, decontaminations can be realized via nozzle systems and over long distances, as well as via ventilation systems. The system has been specially developed for the decontamination of large room volumes.

It is designed as a modular system and can be equipped with a wide variety of components and thus ideally adapted to the respective operator requirements. The integrated formulation management makes it easy to access and manage developed cycles.

ADDITIONAL OPTIONS:

- **HC sensor**
- **H14 sensor**
- **H_2O_2 catalyst**
- **Powder-coated housing**
- **Automatic room and chamber clearance measurement for release for use**

The **Ortner PLUS**

- Integrated heater module, e.g. for heating air ducts
- Suitable for control of pulsed nozzle systems
- Safe decontamination processes through condensate avoidance
- Volume flow variable up to 400 m³/h
- Comprehensive interfaces for system integration and communication with external system controls
- Combinable with all commercially available generator types

Technical data

ISU Dispense

Casing
stainless steel 1.4301
Power consumption
4.8 kW without external generator
Voltage
230 VAC or 3 x 400 VAC/50 Hz/N/PE
Current
12 A without external generator
Fan
electronic speed control
Control unit
Siemens S7 1200
Storable cycles
1–10 (optionally expandable)
Signalization
signal light (red/green/yellow)
Room temperature
0 – 40°C
Airflow volume
variable up to 400 m³/h
Hose connections
DN 80 Tri-Clamp
Hose connection for external generator
Kamlok 1 1/2"
Touch panel
KTP 700
Max. room size
applicable up to approx. 500 m³
(depending on external generator power)
Internal piping
stainless steel
Swivel casters
swivel casters with directional lock
LC sensor
OEL value monitoring

1 | With the aid of the amplifier unit, even large areas can be decontaminated successfully and quickly.

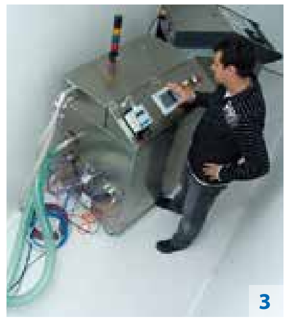
2 | The integrated formulation management makes it easy to access and manage developed cycles.

3 | Due to the variably adjustable volume flows of up to 400 m³/h and to the process variety, decontamination can also be done via ventilation systems.

4 | Designed as a modular system, the ISU Dispense can be equipped with a wide variety of components and thus ideally adapted to the respective operator requirements.


1


2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4

Additional equipment
Mobile H_2O_2 catalyst

The mobile H_2O_2 catalyst is used for accelerated degradation of hydrogen peroxide gas in a room after a completed decontamination process.
The H_2O_2 dismantling process becomes shorter and thus more cost-efficient with the H_2O_2 catalyst used. The unit operates in recirculation mode and sucks in the gas via a built-in catalyst, thus reducing the H_2O_2 concentration in the room. The device is operated via a touch panel and the signalling via LED signal lighting. The start and stop function of the system can be easily controlled via a timer or optionally via a time input, as well as via a potential-free contact. The rollers enable easier and free manipulation of the equipment in the room.

ADDITIONAL OPTIONS:
- **Circulation mode via bypass**
- **WLAN interface to external**

Our latest development
ISU Stationary

Safety through innovation.

THE ISU STATIONARY HAS BEEN SPECIALLY DESIGNED FOR APPLICATIONS WHERE POWERFUL AND COMPLEX DECONTAMINATION PROCESSES ARE REQUIRED.

Automation
The system is monitored/controlled via a higher-level process control system.
Automated process execution, visualization, registration and monitoring of the measured process values, calibration, as well as user management and data transmission complete the range of functions.

Visualization
The system is operated via touch panels.
The main panel is located directly on the ISU station. The second panel is located outside the room where the system is located. The H_2O_2 decontamination process is started from this panel.

Logging
All parameters are set during cycle development and cycle validation by Ortner. The decontamination is fully automatic and is logged by the system.
After a H_2O_2 decontamination process has been completed, a decontamination protocol is printed. It can be output directly to a printer or saved as a PDF file. The decontamination protocol contains all cycle-relevant data as well as a printout of the fault message list if faults have occurred.

Gas distribution
The ISU system can be connected via a pipe system to a varying number of decontamination nozzles and decontamination outlets.

Sensors
To monitor the H_2O_2 decontamination process, selected parameters are monitored or checked using sensors.

Service mode
The service mode is used for maintenance and calibration of the sensors and can be activated from the touch panel.

Special Features:

The dimension of the system makes it possible to decontaminate an enormous volume of space simultaneously:

- **ROOM VOLUME: ≥ 800 M³**
- **H_2O_2 RESERVOIR: 65 L (15 L TO 100 L POSSIBLE)**
- **VAPORIZER: UP TO 18G H_2O_2/MIN**

Compact nozzle (with nozzle cycle)

- Each individual nozzle outlet can be opened or closed by nozzle cycles.
- To achieve the required volume flow, the air flow velocity at a distance from the nozzle outlet was calculated in advance.

1. Via intelligent nozzle systems, air volumes of 350 m³/h can be introduced into the rooms.
2. Both the nozzle cycles and the gas-tight flaps in the individual decontamination lines can be controlled via the ISU system.
3. An emergency stop button is installed directly on the system. This ensures a controlled stop of the ISU stationary in an emergency.

Individual Solutions

**Special conditions often require special solutions.
The constant new challenges in the field of decontamination are the best stimuli for the continuous further development of processes and application technology.**

Challenging tasks, coupled with the innovative drive of our employees and the support of universities and research centers, mean that our equipment, processes, and technologies are constantly being further developed. The result is modern, customer-oriented decontamination solutions that are seamlessly integrated into the customer's existing production processes and that make workflows much more effective and safer.

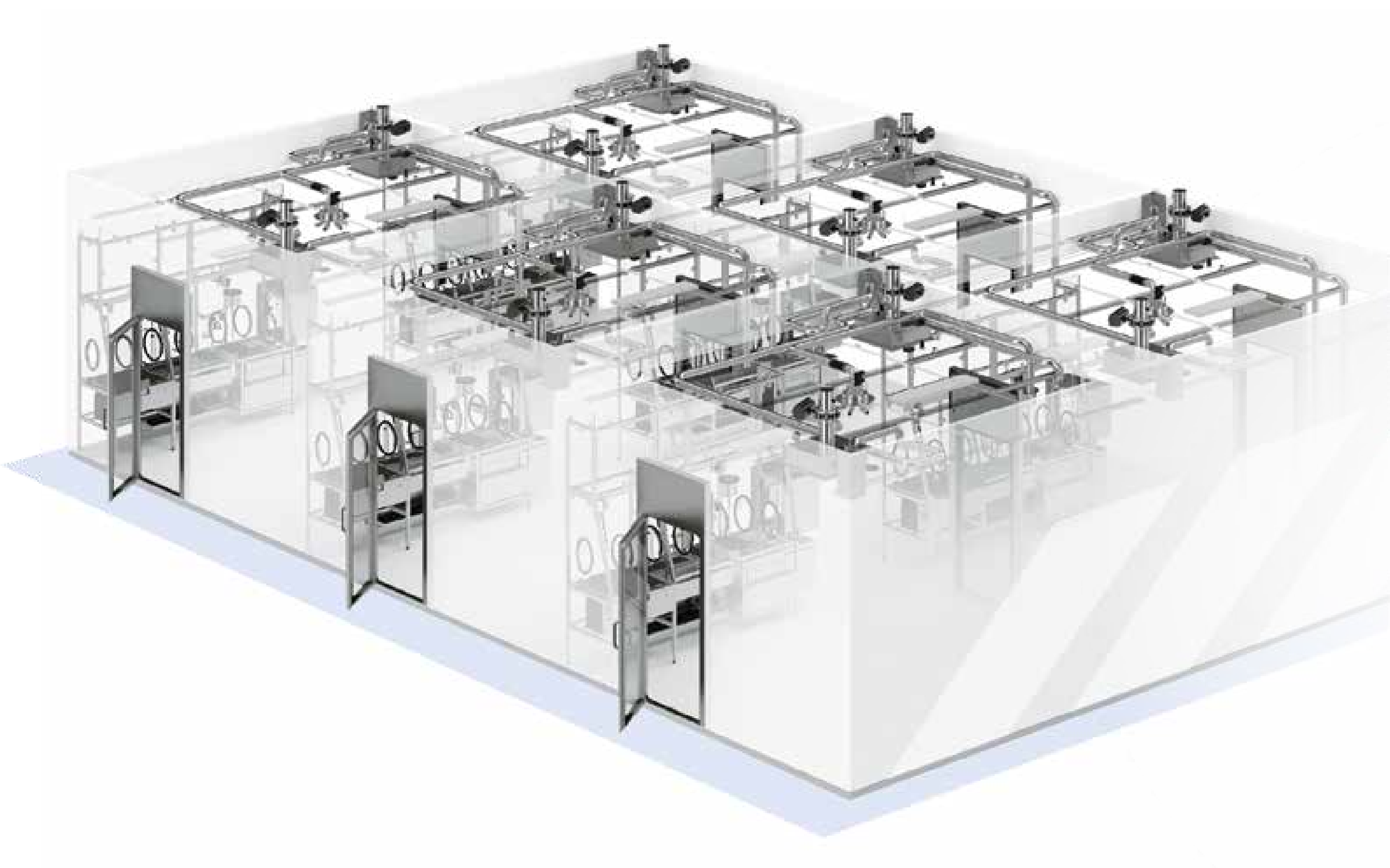
FULLY AUTOMATIC DECONTAMINATION OF ROOM GROUPS

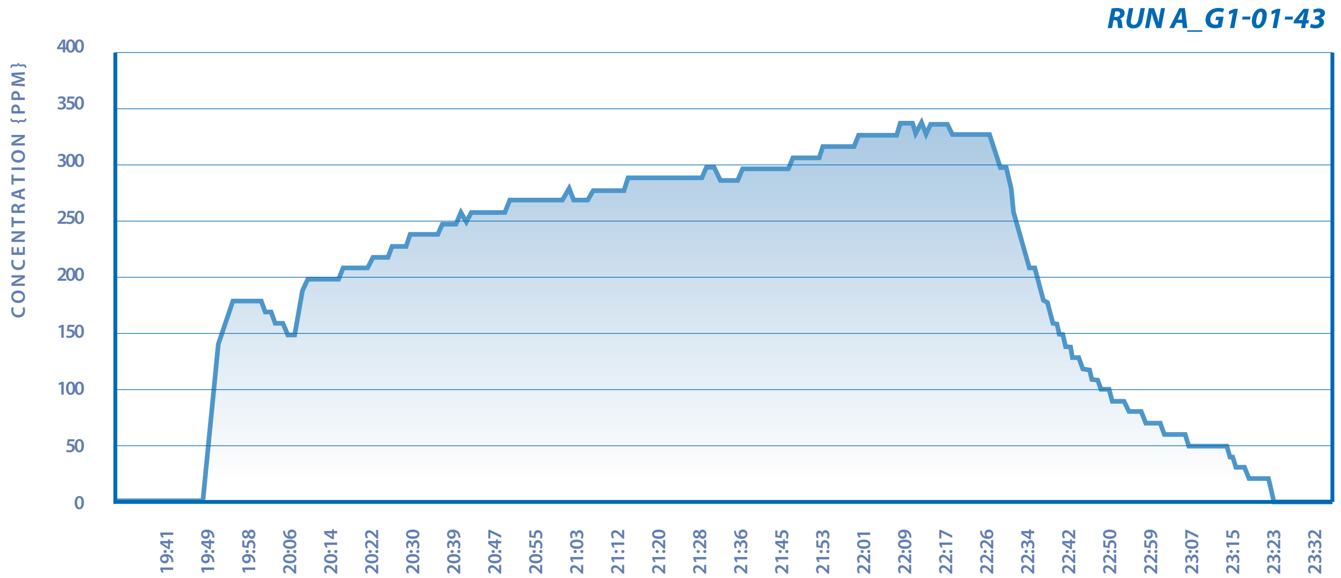
Complex technology, not the status quo

Development and integration of a fully automated decontamination system to decontaminate several rooms in parallel or serially. The H_2O_2 generator system is positioned outside the clean rooms and supplies the individual rooms centrally, according to developed and validatable cycles. Effective processes can be developed regardless of room size, room geometry, or installed equipment. Such complex tasks require not only technically superior decontamination systems, but also a high level of process engineering, understanding of microbiology, and a lot of intuition. CFD-supported simulations also offer more security in conceptual design and planning.

In addition to stationary H_2O_2 evaporation generators with special measurement and monitoring technology, gas injection and application technology are the greatest challenges. Via heated gas pipes, the H_2O_2 gas mixture is transported over long distances without condensation to the feeding points. Gas injection via installed standard ventilation systems is fundamentally possible, but requires powerful amplification systems such as ISU Dispense. As a rule, however, this insertion is problematic, as it can lead to very long cycles and surface damage, and it should therefore be avoided as much as possible. The "six jet nozzles", which can be used to fulfill almost all requirements, have proven to be the ideal insertion technique. The entire system is controlled centrally, and every system and room condition as well as the valve positions are monitored. This ensures that data is available to the user in real time.

A fully automated decontamination system, which is positioned outside the clean rooms, centrally supplies the individual rooms.





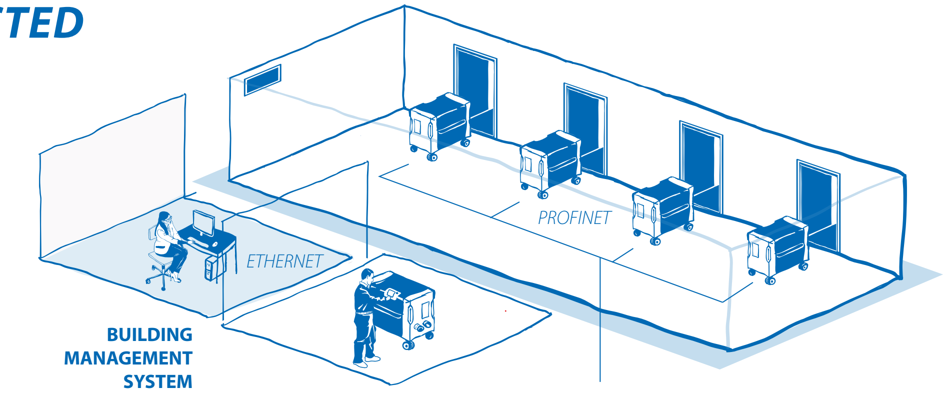
A calculation program, with which room decontamination can be simulated even under difficult conditions, was developed in cooperation with the Graz University of Technology.

Individual Solutions

GENERATOR-INTERCONNECTED OPERATION

A network of systems for a concept

In an ISU network operation, several ISU gas generators can be used in parallel and controlled by an ISU master system. An ISU generator takes over the "master function" and controls all other ISU stations that function as "slaves". All ISU generators used in interconnected operation communicate intelligently with each other: The generators connected to the master system via ProfiNet perform the same, or their own functions, in parallel, e.g. decontamination process monitoring or nozzle control.



TIME SAVING
The interconnected operation can be extended almost indefinitely. Room sizes of over 1,000 m³ can also be decontaminated in a reasonable time.

EASY TO USE
In an ISU interconnected operation, one of the generators is defined as the "master". The user controls only the master module. The information from the other generators in the network ("slaves") is passed on to the user via the master generator.

INCREASED SAFETY
While the decontamination process is still in progress, the surrounding rooms of the room being decontaminated can also be monitored. Three LC sensors can be managed per ISU generator, which can be installed in adjacent rooms. Thus, unwanted leakage of H_2O_2 or an unwanted concentration in these rooms can be detected and reported immediately.

FLEXIBILITY
The definition of the "master" generator can be freely selected. Each of the generators in the network can act both as master and slave. The master module can be controlled remotely via its own tablet or via the customer's network.

H_2O_2 DECONTAMINATION OF COLD SURFACES

Challenges of the procedure and the conceptual design

As a rule, it is assumed that gaseous H_2O_2 decontaminations take place under normal room conditions (20 °C) and at a humidity of approx. 40 to 50 % rH. There are special cases where components and rooms with low temperatures <10 °C have to be decontaminated. In this case, condensate precipitation is usually unavoidable. To decontaminate rooms in this condition means that the materials and equipment must be resistant to concentration of H_2O_2 and the influence of humidity must be carefully checked. In addition, longer cycle times must be expected. Special techniques, such as highly turbulent flushing using sorption-dehumidified supply air, or an effective catalyst improve the process and help prevent damage. In locks, these processes can be made faster, safer, and more effective. In both cases it is necessary to bring the H_2O_2 concentration to a maximum and to dry up the condensate as quickly as possible.

Condensation on the bottles during transport from the cool room to the air lock

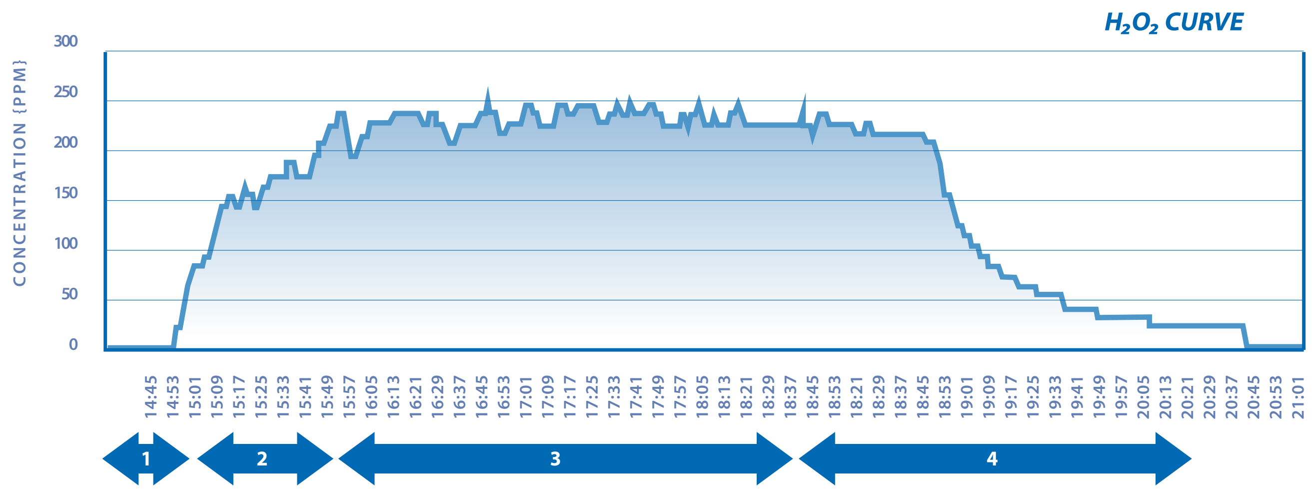
Drying phase of the condensate before H_2O_2 decontamination

H_2O_2 decontamination lock in the exit area

LOW-CONCENTRATION DECONTAMINATION PROCESSES

Less is sometimes more

In the first years since the H_2O_2 application for decontamination in clean rooms, it was common practice to develop decontamination cycles with very high concentrations—and this opinion is still prevalent today. Concentrations > 800 ppm, sometimes up to 1,000 ppm, were, and are, not uncommon. It is a misconception to assume that concentration is the only decisive factor for effective and short cycle times. Material damage or increased absorption are often the negative effects. Especially due to the scientific studies (primarily Graz University of Technology, RCPE Research Center Pharmaceutical Engineering, CTR Carinthian Tech Research, etc.) and the innovative ability of individual experts and users have proven that LOG6 decontaminations of lower concentrations, e.g. 180 to 250 ppm, can be achieved at any time. Experienced cycle developers and decontamination experts can develop material-friendly processes with the right equipment.

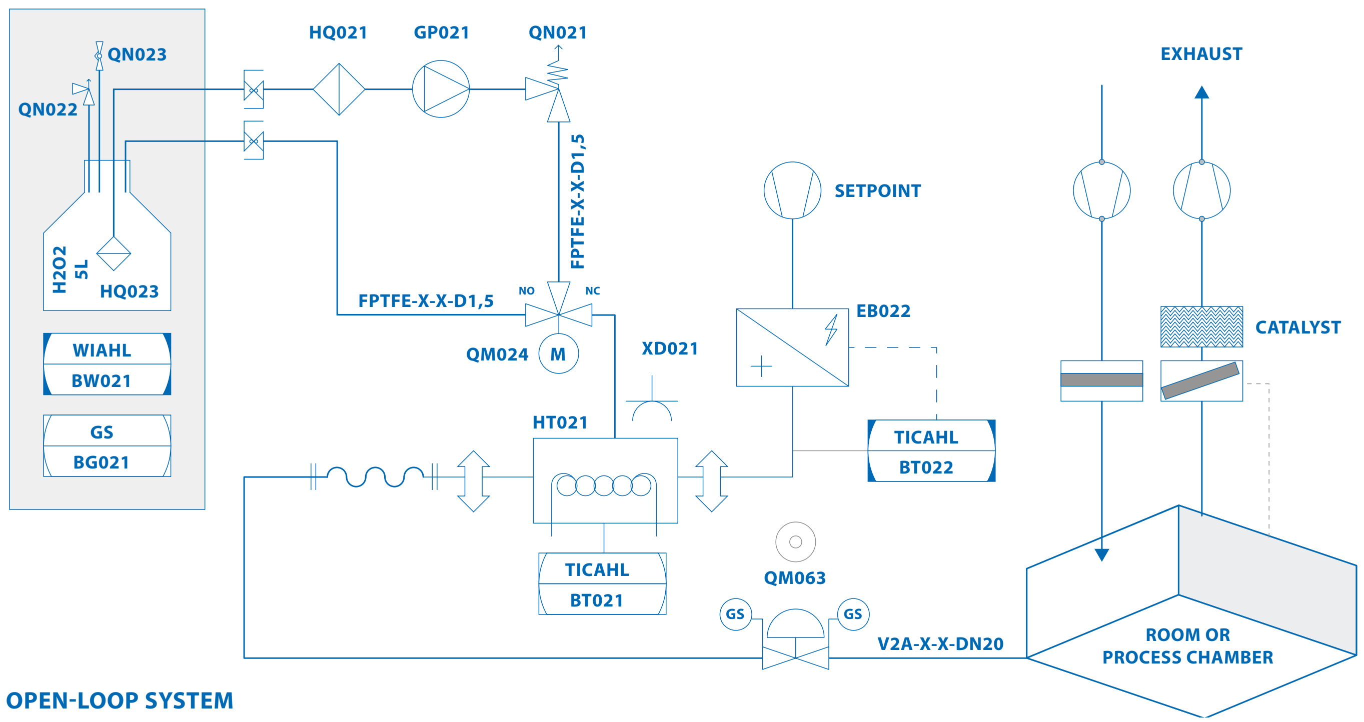


General knowledge

Whether a room decontamination is carried out in an "open-loop" or "closed-loop" procedure is a question of safety. Each case must be investigated individually.

OPEN-LOOP

An open-loop system is a process state in which all supply air connections are tightly sealed and the exhaust air or exhaust air connections remain open. The pressure p in the room either adjusts to the system pressure of the exhaust air system, or a neutral pressure according to the environment is created.



OPEN-LOOP SYSTEM

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ADVANTAGE

Open-loop systems can also be used in rooms or chambers that are not very dense. The environment is not jeopardized or affected. For this reason, the majority of all H_2O_2 decontamination processes are carried out using the open-loop method.

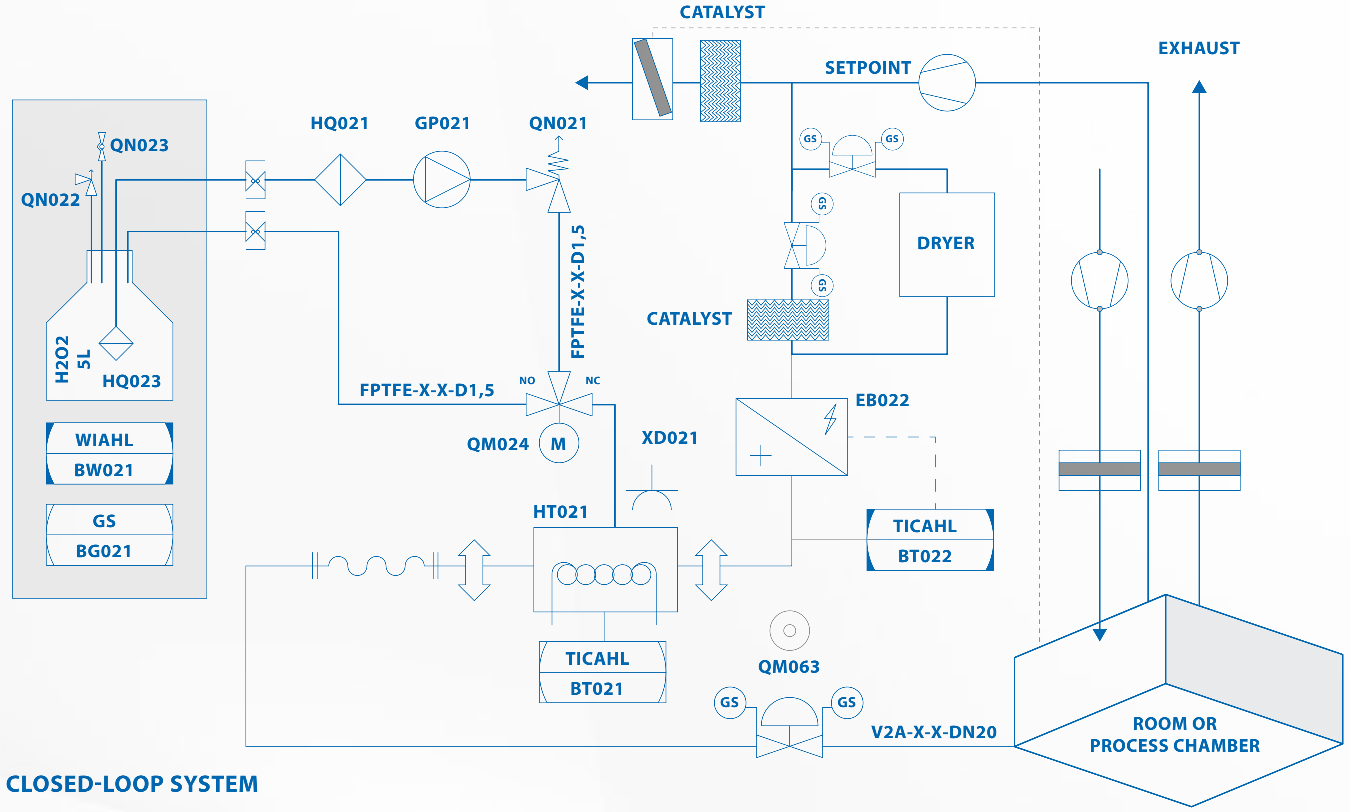
DISADVANTAGE

In rooms or chambers that are supplied via a circulating air or mixing system, open-loop processes cannot be used or can be used only to a limited extent.

Regardless of the location of the H_2O_2 generator, the generator injects the gas quantity into the partially open system (supply air or exhaust air open) and sucks the same quantity back in as recirculation gas. The room pressure does not change because of the mass increase of the evaporated liquid. The supply air butterfly valve opens after the cycle is completed.

CLOSED-LOOP

A closed-loop is a process state in which all supply air and exhaust air connections in the room or chamber are tightly closed. The pressure in the room adjusts itself to an uncontrolled pressure, depending on the environment.



CLOSED-LOOP SYSTEM

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ADVANTAGE

Closed-loop processes can be used with room systems or chambers that do not have an exhaust air system. The prerequisite is that the H_2O_2 dismantling takes place in the generator. Closed-loop processes are also used for very critical investment structures or where risk potential is extreme.

DISADVANTAGE

Due to the increase in pressure, H_2O_2 can escape into the environment. In rooms or systems with e.g. process exhaust air, machine extraction or other connections, all systems must be sealed tightly.

Irrespective of the location of the H_2O_2 generator, the generator blows the gas volume into the closed system (supply or exhaust air open) and extracts the same volume again as the circulating gas volume. The room pressure changes slightly due to the increase in mass of the evaporated liquid quantity. At the end of the cycle, the supply and exhaust air dampers are reopened.

CH_2O decontamination

A NECESSARY PROCEDURE FOR CERTAIN APPLICATIONS

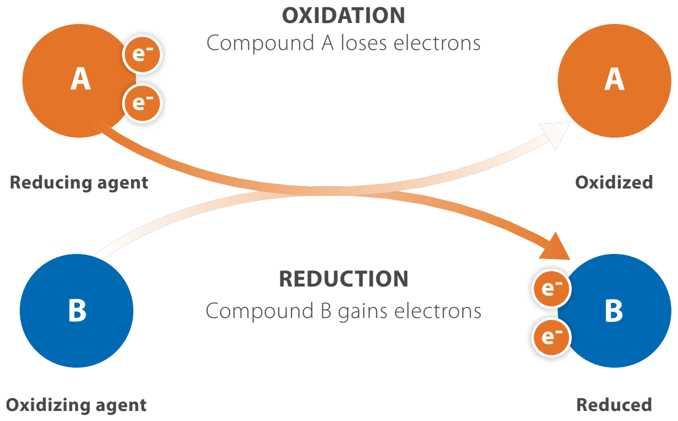
In comparison to hydrogen peroxide decontamination, decontamination with formaldehyde is more dangerous and complex, and the associated safety and regulatory processes are more complicated. In some areas, however, it is absolutely necessary and prescribed by the authorities.

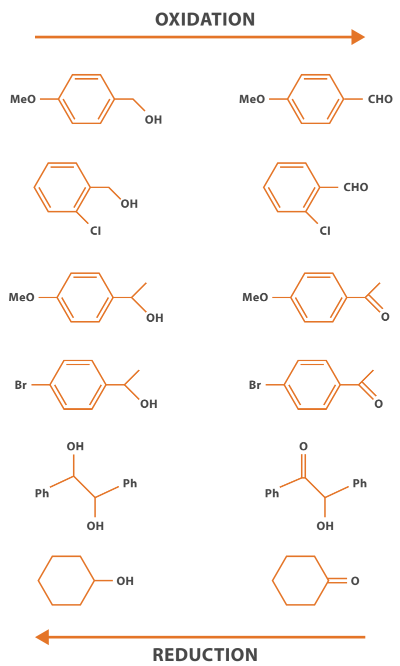
For many special applications, such as foot-and-mouth disease, or the occurrence of certain viruses for which there is still no documented proof of effectiveness of the H_2O_2 technology, this is still the only practical procedure:

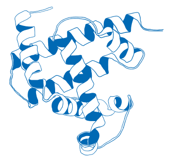
- **LABORATORY ANIMAL HUSBANDRY**
- **HIGHER SAFETY AREAS**
  (biosafety level laboratory)
- **QUARANTINE AREAS**
- **NICHE AREAS**
  (e.g. hatcheries or equivalent livestock holdings)

Working principle:

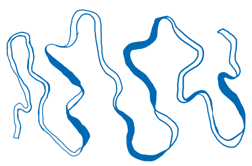
The biocidal effect results from the high reduction capacity of formaldehyde and leads to the denaturation of envelope proteins of the microorganism.







Active (functioning) protein



Denatured Protein

Pros & Cons of formaldehyde decontamination:

ADVANTAGES
- good germ reduction (sterility)
- active against bacteria, viruses, fungi
- RKI-accepted procedure

VS.

DISADVANTAGES
- toxic process
- very long cycle times
- extensive and strict legal requirements

STATE-OF-THE-ART CH_2O DECONTAMINATION

Genny – formaldehyde gas generator

Genny 1.0
Formaldehyde
Gas Generator

The Genny systems are the first decontamination generators on the market that enable safe and monitored room decontamination with formaldehyde from outside via suitable ventilation systems.

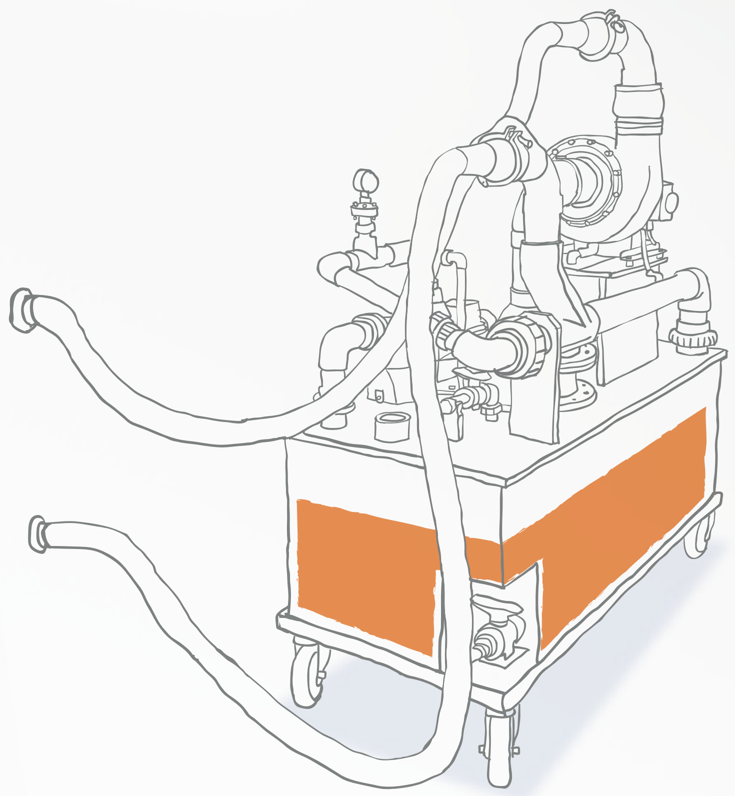
The generator communicates interactively (as well as with external systems). Due to the variably adjustable volume flows of up to 350 m^3/h and the process variety, decontaminations can be realized via nozzle and ventilation systems and over long distances.

Neutralization can take place using ammonia or via residue-free chemisorption. Larger quantities of formalin can be vaporized via external reservoir expansion.

Degradation of formaldehyde after decontamination:

Formaldehyde is a hazardous substance that must be disposed of accordingly.
As a result of the latest developments in the field of formaldehyde degradation, it is now possible to neutralize formaldehyde without ammonia. This completely eliminates the need for time-consuming cleaning, and the process is also more environmentally friendly and more person-friendly.

- **via chemisorption system**
  After decontamination, the gas is neutralized by a chemisorption system.
- **via scrubber system**
  One of the latest innovations in formaldehyde technology was developed by Ortner. The gas is scrubbed out via an air scrubber system. This eliminates the need for annoying cleaning and makes handling much easier.



Scrubber system

FAQs
FREQUENTLY ASKED QUESTIONS

HARDWARE

What are the differences (advantages/ disadvantages) between cold and hot atomization?

In cold atomization, the active ingredient is finely atomized using ultrasonic atomizers. The room air absorbs the microdroplets, which raises the air humidity. In the case of longer operating times and in the absence of room air distribution systems, saturation occurs in the vicinity of the atomizer unit, and marginal droplet precipitation may occur. To avoid this and/ or to achieve a good room admission, it is advisable to distribute the gas flow, e.g. by means of stationary fans. Droplets on surfaces can lead to massive damage or to long cycle times.

In hot gas atomization, H_2O_2 is dripped onto a heating plate in a generator. The H_2O_2 changes immediately into a gas (water vapor state). The H_2O_2 water vapor and gas mixture is blown out of the generator via a fan and brought into the room. Due to the thermal effect of the hot gas, uncontrolled flows, and thus also damage, can occur in rooms. A room partitioning is also recommended here.

Core statement: both procedures have their advantages and disadvantages, and thus their justification. It always depends on the respective application and technology.

How many people are required to operate an ISU?

The ISU is designed and built to be very easy to use: one person is enough.

Where must the ISU be positioned during the decontamination process?

The generator can be installed indoors or outdoors. The ideal location depends on the specific application. The diagram on page 24–25 provides an overview.

Up to what room volumes can an ISU be used in?

The maximum room volume depends on the geometry and load of the room to be decontaminated - e.g. whether the room is empty or filled with machines. The bandwidth therefore reaches up to approx. 500 m³.

SOFTWARE

Which protocols are generated and can they be printed?

At the end of each completed decontamination cycle, the ISU generates a decontamination protocol in the form of a PDF file. The file is stored in a defined location. These can be printed or sent as required, for example. The decontamination protocol serves as proof for the successful execution of the decontamination process and contains all relevant cycle data. Audit trail files can also be generated. These document every change to the parameters of the system.

Can several ISUs be interconnected?

The interconnection of several ISUs is possible. This is a "interconnected operation". Two or even ten ISUs, for example, can be interconnected. Such an integrated operation makes sense if larger areas have to be decontaminated at the same time in a decontamination process. How it works: One ISU acts as master, the others as slaves. The operator must communicate only with the master ISU. The advantage: The minimal effort required for control helps to save costs. More information—see page 36.

DECONTAMINATION PROCESS
(FUMIGATION PROCESS)

What are the differences as opposed to formaldehyde decontamination?

Disinfection by hydrogen peroxide is predominantly preferred in the industry: H_2O_2 has an advantage with its ease of use, safety, effectiveness, environmental friendliness, and good material compatibility. Disinfection with formaldehyde is more dangerous because it is toxic and more complex, but in some areas, it is absolutely necessary and required by regulation (e.g. foot-and-mouth disease)

Is decontamination with H_2O_2 dangerous?

Provided that the safety regulations and application guidelines are correctly observed, decontamination with H_2O_2 is not dangerous. However, limit values must not be exceeded, as very precise values apply when handling liquid H_2O_2 security measures.

How long does cycle development take?

The duration of the development of a decontamination cycle influences the operator's specifications with regard to the maximum permissible decontamination duration, the room condition, the maximum permissible concentration, the materials in the room, the equipment and fittings, and much more.

When must a new cycle be developed?

Quite simply: as soon as something is changed in the area to be decontaminated. For example, if something is taken out of the room or placed in it, the room is enlarged or partitioned, or if the load is changed in the H_2O_2 lock. Because every change has an effect on the cycle.

How long does the decontamination process take?

A multitude of factors are decisive here. The most important are the size of the room, the ventilation options, and the room volume. The time ranges from approx. 20 minutes for a smaller lock to several hours for a large room.

At what room temperature is decontamination possible?

Normally, standard decontamination processes take place in rooms with normal temperatures of approx. 18 °C to 25 °C. From a purely physical point of view, however, there are hardly any limits to the process: decontamination can also take place in colder and warmer rooms. The decontamination processes must then be adapted to the respective temperature, and factors such as the formation of condensate must also be taken into account, especially at low temperatures.

Is there a list of material compatibilities?

Component manufacturers occasionally announce an H_2O_2 resistance in their data sheets. General material compatibility lists show whether and to what extent materials are H_2O_2-resistant. Different research institutes provide such lists. Ortner also carries out ongoing material tests on behalf of manufacturers and therefore also has such a resistance list.

Which indicators are used and where can I get them?

Chemical indicators are used for cycle development and rapid detection. Biological indicators serve as evidence that decontamination was successful. The use of test indicators is required by law. Such indicators are offered by various companies, including Mesa Labs. This is a 5 mm stainless steel shell on which – depending on the LOG level to be achieved – a different number of spores is applied. At one LOG6 level, about one million spores are applied. The particularly resistant spore Geobacillus stearothermophilus serves as a test indicator for H_2O_2 decontaminations.

How much H_2O_2 is consumed during decontamination ?

The consumption depends on the size of the room and can range from about ten grams for a quick lock to five liters for a large room.

Is it true that FMD viruses can also be inactivated with H_2O_2?

So far, successful inactivation of the foot-and-mouth disease virus (FMD virus) has not been scientifically proven. For this reason, decontamination with formaldehyde is still mandatory.

SERVICE/MAINTENANCE

How often must the ISU be serviced?

The ISU device should be serviced and calibrated once a year and the H_2O_2 sensors recalibrated every six months. Maintenance also depends on the duration of use. In general, the maintenance of the ISU is relatively simple and not very time-consuming.

MISCELLANEOUS

When does the purchase of an ISU pay off and what alternatives are there?

The profitability of acquiring an ISU depends on the frequency and urgency of its use. If decontamination is required only once or rarely, and if this can be planned in advance, or if shorter waiting times are not relevant, contract decontamination services are recommended. If, on the other hand, the ISU is needed more often or at very short notice, a break-even calculation should be drawn up and the purchase calculated.

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