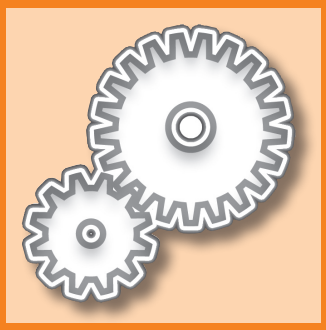

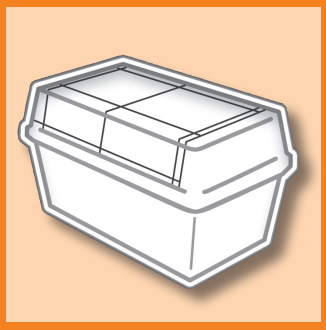

CAGE PROCESSING
in Animal Facilities
properly done

New
7th edition
2025

AK
KAB

Arbeitskreis
Käfigaufbereitung
(Working Group for Cage
Processing)
7th edition 2025

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CAGE PROCESSING in Animal Facilities

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Arbeitskreis Käfigaufbereitung (AK KAB)

(Working Group for Cage Processing)

7th issue 2025

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We would like to express our gratitude to all former AK KAB members, who have not been mentioned above; for their efforts to create and continuously enhance the AK KAB brochure.

Inhalt

1 Introduction

In animal facilities, a wide range of different items including cages, cage lids, wire grids, bottles, bedding, feed, transport trolleys, steam sterilization containers, work clothes, and other equipment needs to be processed. Technical quality is essential for a safe and efficient processing procedure. It is also important that the selected systems are user-friendly, and all individual components interact smoothly. Usually, a centrally located wash-up area (processing center) is the place where the processing is done.

Automatic processing is generally preferred to manual washing as it is more efficient and provides better options for standardization and monitoring. Whilst this brochure provides some information on manual washing, its focus is on automated processing to reflect this preference.

Considering the complexity of processing combined with potential interface issues, standardizing the procedure and defining constructional requirements of processing systems is vital. They underpin the high hygienic standards required for the above-mentioned items.

When designing cages, the first and most crucial factor to consider is the animal. Further requirements are defined by occupational health aspects and economically efficient workflows. Since the predominant biomedical research models are rodents and rabbits, this brochure puts its emphasis on items especially designed for these species.

In the meantime, the working group for cage processing has also dealt with the processing of aquatic housing systems. As the requirements and the resulting recommendations differ considerably from cage processing, these have been published in a separate booklet of the working group on cage processing entitled “FISH TANK PROCESSING in Animal Facilities properly done” in the 1st edition 2020.

The AK KAB has made it its aim to provide a manufacturer-neutral guideline for planning, procuring, and operating processing systems and single processing components, and thus wish to address planners, manufacturers, and operators alike.

The following chapters provide information on:

- Cage processing cycles
- Processing goods requirements
- Cage processing procedure
- Constructional requirements
- Operation and operating
- Performance evaluation checks for cleaning systems
- Ecological requirements
- Potential mistakes, defects and material damages
- Literature, standards, publications
- Terms / definitions

In the 2nd edition of this brochure, the AK KAB has added the chapters “4.6 Reduction of microorganisms on heat-sensitive items by means of hydrogen peroxide (H_2O_2) / peracetic acid (PAA)” and “7. Performance evaluation checks for washing systems”. In the 3rd edition, all of chapter 7 has been revised, and the guidelines for checking washed water bottles for cleanliness have been completed.

The 4th edition received a complete revision and update, emphasizing on chapter “4.2 Emptying components”; “4.4 Filling components”, and “9.6 Problems during treatment of the bottle drinking nipples.

Focus of the new 5th edition was the state-of-the-art update of chapter „4 Cage processing procedure “. Chapter 4.5.2 “Special requirements on the process validation”, was added to specify sterilization-requirements and the new part 12 “Appendix: Self-declaration concerning checkable properties of washers“ should further on help during purchase decision phases.

In the 6th edition, the text was adapted, and the chapters were revised according to the latest state of the art. In chapters 4.5 and 4.6, for example, the further developments in chamber dimensions for sterilizers and H_2O_2 material locks were updated. In chapters 4.5 and 6.11, supplementary instructions for periodic checks of sterilization and cleaning results were included to ensure the system functions according to the recommendations of the AK KAB. In chapter 7.4, the inspection of the rinsing performance of a washer was described in more detail and supplementary acceptance criteria were defined. Chapter 7.8 now also contains information on the

possible review and evaluation of the processes according to certain sustainability criteria. Chapter 9 contains further information on changes to plastic materials, steam sterilization of goods in sterilization bags and the possibility of recycling measures for discarded processed goods.

The 7th edition has been adapted and revised in accordance with the latest state-of-the-art.

The new edition focuses particularly on all aspects related to sustainability. Sustainability is examined holistically using the three-pillar model of economic, ecological, and sociocultural aspects. The previous Chapter 8, “Ecological Requirements,” has therefore been expanded and renamed accordingly. At the same time, aspects related to sustainability have been added to the relevant chapters.

To accommodate the continuously changing ecological and sociocultural conditions, further adjustments are planned for future editions.

Chapter 4.5 adds requirements for steam sterilization in laboratories that work with biological materials belonging to higher risk groups (e.g., classification of the SARS-CoV-2 (COVID) virus in risk group R3). In addition, technical features have been added (e.g. connection of the sterilizer to an on-site cooling circuit, liquid sterilization with natural cooling, standby function/sleep mode) that are useful for sustainability reasons.

You will find information on legal restrictions, regulations, work safety aspects, as well as on the guidelines of the Gesellschaft für Versuchstierkunde / Society of Laboratory Animal Science (GV-SOLAS) in the respective chapters.

Note: This version is the translation of a German brochure. Therefore, it refers to the cage processing procedures and normative standards that are usually given in Germany.

2 Cage Processing Cycles

The following figure shows the interaction of components and functions when cages are processed in the wash-up area:

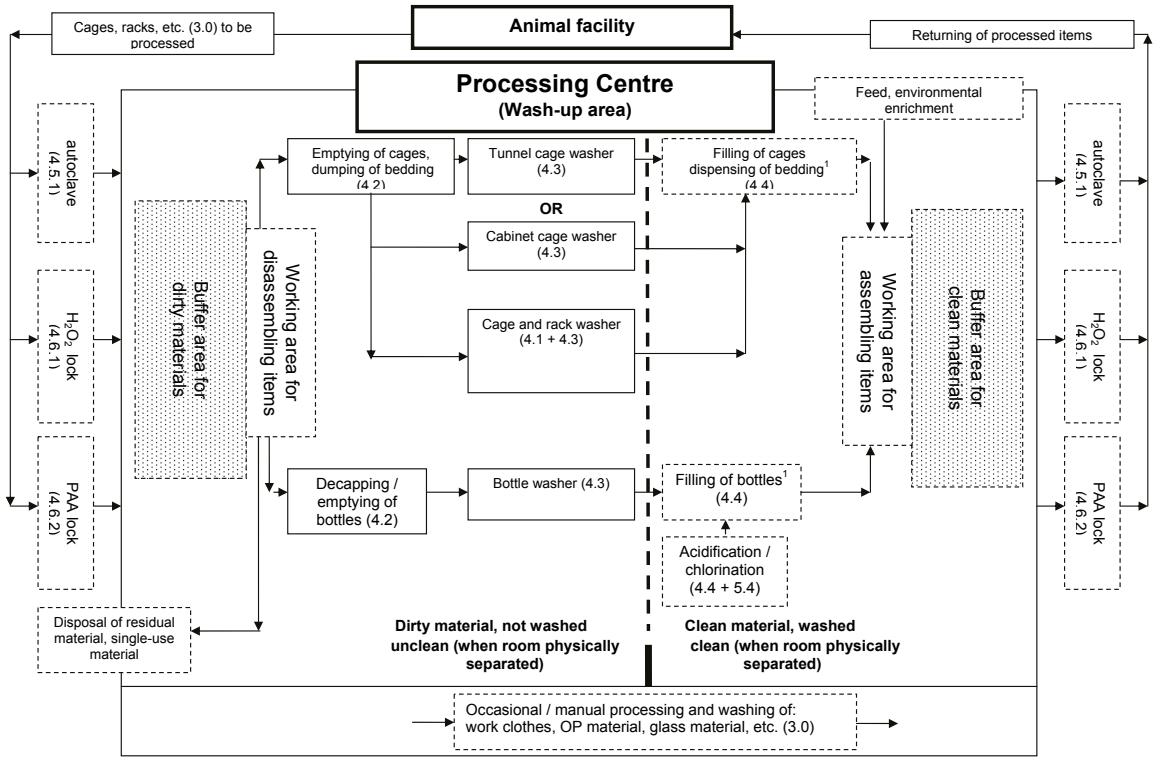


Fig. 2-1: Treatment process cycle

Note: Dotted boxes may or may not be included in the process cycle as shown. Either immediately after cleaning or immediately after introduction within the animal housing area.

The material flow shown can, as before, be carried out manually, but can also be partially or fully automated. Both the decreasing number of available workers and the increasing requirements regarding occupational safety (see also information sheet B 012 Laboratory animal husbandry) are strong and continuous drivers for the automated design of processing processes.

At this point, reference is made to the possible use of digital systems with sensors and artificial intelligence within the animal husbandry area, which enable cages to be changed as needed and can thus significantly reduce the volume of the material flow and the goods to be processed. This can significantly increase the sustainability of the operation and optimize the design of the scullery and the material locks in terms of layout, space requirements and equipment. The latter is particularly suitable for the increasing number of existing buildings that need to be renovated.

3. Requirements for Items to be Processed

Following the description of the processing cycle (Chapter 2), the items to be processed in this procedure are described below. The goods and their materials as well as information on selection and design are presented. Automatic processing will be the focus.

3.1 Product overview

Below you will find a list of items commonly used for automatic processing:

Table 3-1

Plastics	Stainless Steel
Cage base for rodents	Metal cages
Filter hoods (with filter sheet) for open cages	Wire lids and wire floors
(Filter) hoods for IVC cages	Dividers
Airflow components for IVC systems	Bottle caps
Drinking bottles	Drinking valves for AWS systems
Card holders	Card holders
Cage base and waste trays for rabbits Environmental enrichment (can be made of wood)	Cage racks for open cage systems
Supply and transport containers for feed / bedding	Cage racks for IVC systems, including electronics and sensors, if suitable for cleaning and sterilization
Metabolic cages	Airflow components for IVC systems
Injection tubes	Storage and transport racks
Crates for water bottles and accessories	Mobile work and laboratory benches
	Supply and transport containers for feed / bedding
	Food hoppers
	Crates for water bottles and accessories

Note: Other than shown in this table, it may be necessary to process the above-described items manually for either technical reasons (specialty cages) or economic reasons (low utilization or lack of funding).

Usually, the following (heat-sensitive) items undergo manual processing only (please refer to chapters 4.5 and 4.6):

Table 3-2

IVC fan units
Electronic components on blower units or IVC cage racks, such as computers, room monitoring systems, etc., which cannot be processed mechanically.
Animal cage changing stations
Ventilated cabinets for animal cages
Biosafety cabinets
Bedding disposal stations

Listed below are optional items for animal facilities. Information on processing them can be found in other publications, for example in “Instrumenten-Aufbereitung im Veterinärbereich richtig gemacht, (grüne Broschüre)”, “Proper Maintenance of Instruments in Veterinary Surgeries” (green brochure), please refer to chapter 10:

Table 3-3

Endoscopes
Surgical instruments
Textiles
Glass material
Components for automatic watering systems
Operating tables
Computer
Microscopes
Power tools

3.2 Materials for processing

The requirements for the material to be processed depend heavily on the individual circumstances. These can vary greatly in terms of mechanical, thermal and chemical resistance as well as the frequency of material handling.

The common materials and their most important properties are described below:

3.2.1 Plastics

The following plastics are generally used:

- Polycarbonate (e.g. Makrolon®)
- Polysulfone
- Polyetherimide
- Polyphenylsulfone
- Polypropylene
- Polystyrene
- Polyphenylene oxide (e.g. Noryl®)
- Composite materials (e.g. fiberglass reinforced material, Trespa® or Polyphthalamides (PPA))
- Various materials for wheels and castors (see chapter 4.1)

In rodent cages, mostly polycarbonate, polysulfone, polyetherimide, and polyphenylsulfone are used. The table below indicates the individual characteristics of these plastics:

Table 3-4

	Steam sterilizable up to1	Remarks
Polycarbonate	121 °C	• transparent, clear, or slightly tinted • regular autoclaving may cause degradation of material (please refer to chapter 9) • Alkaline residues may cause problems (please refer to chapter 9)
Polysulfone	134 °C	• transparent, slightly tinted • suitable for frequent autoclaving • physically and chemically high-resistant • unsuitable rinse aids may cause problems (please refer to chapter 9)
Polyetherimide	143 °C	• transparent, amber-coloured • suitable for frequent autoclaving • Physically and chemically very high-resistant

Polyphenylsulfone	143 °C	• transparent, slightly tinted • suitable for frequent autoclaving • Physically, chemically and mechanically very high-resistant

Note: The above-mentioned data is meant to be a rough guideline. For product-specific questions, please refer to the manufacturers' instructions.

The following advice might be useful:

- When steam sterilizing filled water bottles made of polycarbonate, a temperature lower than 121 °C is recommended (e.g. 118 °C) in order to avoid deformation. It is also possible to prolong the autoclaving time (please refer to chapter 4.5.1.2, table 6-3, and chapter 9.4).
- When transferring cages with dirty bedding out of a barrier area by means of autoclaving, the cages should be made of either polysulfone, polyetherimide, or polyphenylsulfone (please refer to chapter 4.5.1). This also applies to cages filled with highly resinous bedding (please refer to chapter 9.1).
- When autoclaving and where the release of bisphenol A is not permitted or wanted, processing items made of polycarbonate is to be avoided.

3.2.2 Stainless steel

Stainless steel is often used and well suited for processing items in animal facilities. Usually, so-called "V2A-steels" are used (1.4301 / AISI 304). What is essential, in all cases, is the machining and working of the steel, especially the pre-machining and finishing of welds and surfaces.

Stainless steel, however, can be damaged when in contact with chlorines (e.g. hydrochloric acid, please refer to chapter 9.5).

3.3 Information on item design

You will find a detailed description of required cage dimensions in the guidelines of the GV-SOLAS and the Appendix A of the European Council, ETS 123 (please refer to chapter 10). Therefore, dimensions will not be discussed here. Please note, however, the following advice regarding the design of items for processing:

- Sharp edges are dangerous for humans and animals; they can be avoided by careful deburring.
- Cavities are difficult to clean and should be avoided, for example, hollow section structures should be fully welded.
- In the case of air ducts (e.g. IVC cage racks with ventilation pipes), their inner sides must be accessible during cleaning by proper arrangement and function of the spray nozzles of the washer
- "Cavities" should be avoided, without causing functional limitations
- A joint-free design is recommended to avoid dirt traps (hygiene) and capillary action (drying).
- Flat surfaces are recommended for easy cleaning and drying.
- Ergonomic aspects should be considered, for example the use of 18 bottle crates instead of 36 bottle crates, crates made of plastic or the use of height-adjustable cage changing stations.
- Items should be stackable for effective use of transport and storage space.
- The design of the items should be maintenance-friendly, for example filters and other components that require regular maintenance should be easily accessible.

4 Cage Processing Procedure

4.1 Transport and storage systems

Usually, in order to be washed and sterilized, all items need to be transferred out of and back into the animal housing area. The items are moved constantly and therefore they should be easily transported in all areas (animal rooms, hallways, processing center) and usually need to be able to be temporarily stored. Hence, the same system should be used inside and outside the animal housing area. The items are moved with so-called transport and storage trolleys that pass through the same washing and if applicable steam sterilization pro-

cess parallel to the other items. This should be considered when planning the capacity and design of washers and sterilizers.

Furthermore, during planning it must be checked whether the use of driverless transport and storage systems (e.g. AGV – Automated Guided Vehicle) makes sense for the transport routes of the goods to be processed.

Below you will find a description of general requirements, some examples of transport and storage trolleys, as well as design, construction and materials.

4.1.1 General requirements for transport and storage systems

To ensure a smooth workflow, transport and storage systems used in animal facilities should meet the following requirements:

- Transport and storage trolley systems should match the total facility layout (doors, lifts, washers, sterilizers, and locks) as well as the items to be processed (please refer to chapter 3).
- For better planning, the capacity required for transport, storage, and steam sterilization should be examined in advance. When selecting suitable transport and storage trolleys, the manufacturers of those should be contacted for assistance.
- They should be easy, convenient and safe to handle for a single person.
- They should also be able to undergo the same washing and steam sterilization process as the items to be processed and should be resistant to the applied detergents and disinfectants (please refer to chapter 9).
- The trolley systems should be designed for universal use, for storage, transport, and loading of sterilizer and lock. An optional function might be that they can be used as work benches. The advantages are as follows: after being washed, there is no need for the items to be transferred to another trolley for steam sterilization. Hence, the number of different trolley types can be reduced. If the available sterilizers and locks are not designed for floor level access, special small loading trolleys can be used as well.

4.1.2 Examples of commonly used transport and storage systems

Table 4-1

Types	**Common dimensions (H x W x D in mm)**	**Transport and storage of**
Universal transport / storage trolley	1500–1900 x 500–600 x 1000–1500	various items, e.g. stacked open cage bases and wire lids, or closed cages, etc. feed and / or bedding bags water bottles in crates; accessories
Special cage transport / storage trolley	1500–1900 x 500–1000 x 1000–1500	closed cages; allows for a safe and contamination-free transport of specific cage types
Special bottle transport / storage trolley	1500–1900 x 500–700 x 1000–1500	water bottles in suitable crates made of stainless steel or plastic; stable design adequate for the required capacity
Special feed transport / storage trolley	1500–1900 x 500–600 x 1000–1500	feed in suitable containers (racks, perforated metal shelves, etc.)

Fig. 4-1: Examples of universal transport / storage trolleys

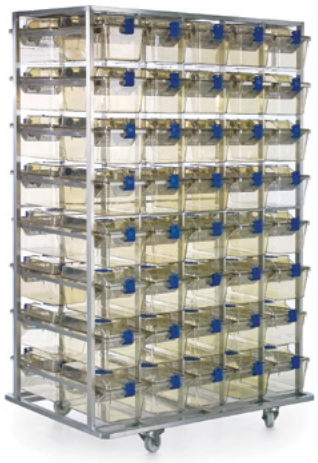


Fig. 4-2: Example of the special cage transport / storage trolley

Fig. 4-3: Special transport / storage trolley for cage bases

Fig. 4-4: Examples of a special bottle transport / storage trolley, for stainless steel and / or plastic bottle racks

Fig. 4-5: Example of special feed transport / storage trolley

4.1.3 Materials

Due to high mechanically, thermally, and chemically induced material strain, especially during washing and steam sterilization, stainless steel is a material often used and well suited (please refer to chapter 3.2.2) for transport and storage trolleys.

For wheels and fenders (collision protection), the following plastics are adequate.

- Glass-fiber reinforced Nylon® (soft, smooth running)
- Bakelite® (harder, louder rolling noise, but thermally more resilient)
- Polyphenylsulfone (very high thermal and chemical resistance, durable and high stability, smooth running).

4.1.4 Design and construction

Depending on their type of use, the following important aspects should be considered when designing transport and storage systems:

- Wheels and fenders must be thermally and chemically resistant to avoid degradation during washing, disinfection, and steam sterilization.
- The total structure, and wheel structure in particular, need to withstand the process-induced stress during washing, disinfection, and steam sterilization (maximum stress must be calculated).
- Perforated and / or inclined surfaces are recommended to minimize water puddles during washing and / or steam sterilization and to make items easily accessible for steam.
- Height-adjustable shelves ensure flexible use.
- Special bottle trolleys (e.g. with open bars instead of closed sides) allow for better ventilation and achieve a faster regulation of the temperature balance during steam sterilization (heating-up, cooling-down).
- Wheels, handbrakes, and fenders, as well as other movable parts (wear and tear parts) should be easy to replace.
- In case elevators are used for transportation, king-sized wheels are required (diameter 100 mm or more) to avoid getting stuck in the gap between elevator and floor. Huge gaps should be avoided because of job safety and for wheels protection.

In addition, please pay attention to the information given on design in chapter 3.3.

4.2 Emptying components

To minimize the amount of dirt being carried over to the washing chamber, drinking bottles and cage bases need to be emptied prior to being washed as described in chapter 4.3. There are different ways of emptying cages and bottles. Generally, cage bases are emptied of dirty bedding, possibly mixed with disposable enrichment products and feeding pellets. In bottles, there is usually just water residue left.

Below you will find a description of components that allow for a convenient, efficient, and most important, safe emptying of cages and bottles.

4.2.1 Cage emptying

4.2.1.1 Hygienic and work safety aspects

Dirty bedding can pose several potential health hazards: Danger of infections caused by exposure to animal excrements, as well as the risk of generating allergens caused by proteins of dander, hair and excrements.

The dust of certain wood types can also cause allergies. Some of these wood dusts are even classified as carcinogenic (please refer to chapter 4.4.1.5).

Another important aspect to consider is the strain on the human musculoskeletal system. Constant repetitive work like manual dumping of cages often leads to muscular tensions and chronic afflictions of the back, neck and shoulder area.

The impact of repetitive working processes on operating staff like manual emptying of cages and the preventive measures (arrangement of the cages, installation of automatic systems like robots) have been investigated in scientific studies (see publications chapter 10).

4.2.1.2 Handling of dirty bedding

When handling cages, gloves, suitable respiratory masks, and suitable work clothes should always be worn. Transport trolleys with cages to be emptied as described in chapter 4.1 should be moved adjacent to the empty station and locked there.

Environmental enrichment that is to be reused and / or is unsuitable for the bedding disposal system must be removed before a cage is emptied, unless the disposal system is adequately dimensioned for these articles or equipped with a suitable shredder. If there is excrement or bedding left after a cage has been emptied and knocked off, it should be removed with a soft scraper. This leads to better cleaning results and less dirt being carried over to the washer.

Separate waste disposal must be provided for any contaminated protective clothing (e.g. gloves, respiratory masks, hair nets, overalls, etc.).

4.2.1.3 Design of bedding disposal stations

For a convenient, staff-friendly workflow, unnecessary stacking and moving of items should be avoided. Therefore, it is recommended to set up the disposal station in line with the washer to aid workflow. Avoiding major torso twists and long transport distances is not only ergonomic, but also timesaving. There should be sufficient room for temporary storage of stacked cages. This room can either be created by considering the space adjacent to the disposal station or by using side tables.

Size: Ergonomic heights are set between approximately 800 and 900 mm, depending on the local situation. Reasonable dimensions of a dumping area often range between 800 x 800 and 1000 x 1000 mm (L x W), depending on the dimensions of the cages used.

Structure: The disposal station or elements connected to the waste collection bin or conveyor tube should have sealed surfaces to avoid dirt traps. A grid, bar, or similar device allows for an easy knocking out and setting down of cages. For a convenient cleaning, such devices should be detachable.

Material: Stainless steel (material 1.4301 / AISI 304 or higher grade) offers a major advantage regarding durability and cleaning.

Cleaning: Disposal stations should be easy to clean and need to be designed accordingly. General cleaning should be done daily and intensive cleaning weekly (either manually or automatically, depending on the design).

Components for shredding and disposal of environmental enrichment / feed pellets:
Depending on the design of the disposal station, solutions for shredding the enrichment and feeding pellets (e.g. shredder) must be taken into consideration. The purpose is to avoid clogging of subsequent parts of the processing system (e.g. press or conveyor tube). Functional reliability of a shredding unit and its suitability for the products to be shredded should also be considered.

Most importantly of course, such supplementary equipment must be safe to handle for the operating staff. Thus, openings must be safe and designed to prevent particles from escaping or being ejected (please refer to Regulation (EU) 2023/1230, formerly known as Directive 2006/42/EC).

Components for preventing dust and allergens:
Taking measures to avoid dust and allergen exposure is most important for the health protection of the operating staff (refer to TRGS 906 & TRGS 553 or local equivalent). Such measures should be taken for every exposed area (e.g. disposal station, collection bins for bedding, dust, and waste in general). In addition to technical and / or organizational dust prevention, an efficient particle reduction can be achieved with a suitable suction device and should be preferred to personal protective equipment (e.g. respiratory masks). The following particle suction devices are technically possible:

- Negative pressure between emptying- and bedding collection room (in cases of funnel with large chute)
  → Less effective, high requirements on the ventilating system and relocation of the dust problem
- Rim extraction system at the emptying station
  → Less effective
- Small or large suction hood (“crossflow hood”)
  → Highly effective, reasonable costs of purchase
- LAF-tent solution (down flow)
  → Highly effective, high space requirements and high costs of purchase

Above-mentioned devices should guarantee a strong and effective front air barrier (air suction into the work aperture at operator level), to avoid the release of aerosols during cage emptying (referring to “Requirements of Cage Changing Stations”, TRBA 120 or local equivalent).

Components for automation: The use of anthropomorphic robots, which have been used in industry for many years, brings significant ergonomic advantages, especially when many similar goods must be processed. On the one hand, the necessary constant throughput is ensured, and on the other hand, the workload on employees is reduced and they are protected from allergens, dust and odors.

Note:
The use of low dust bedding can already make a significant contribution. Allergens, such as animal hair, dander etc. are not reduced by this.

4.2.1.4 Options for emptying cages - advantages / disadvantages

In the table, below you will find options for a manual, semi-automatic, and fully automatic emptying of cages:

Table 4-2

	Variant	Advantages	Disadvantages
Manual systems (without dust suction)	Direct emptying into disposal bags or containers	Cost-effective; can be realized in existing systems; flexible	Time-consuming; high dust exposure; unpleasant smell; low capacity
Manual systems (with suitable dust suction devices)	Emptying via emptying hopper into a disposal room beneath;	No manual transportation of waste bedding from the wash-up area (timesaving); reduced fine dust exposure; less unpleasant smell; high capacity	Can usually not be realized within an existing system; dust exposure in the disposal room;
	Emptying cabin where cage contents are emptied into disposal bags or containers, with suitable dust suction device	Reduced fine dust exposure	Time-consuming (limited ergonomics); unpleasant smell; low capacity
Semi-automatic systems	Emptying hopper or emptying cabin with pneumatic bedding conveyance into an external collection bin	No manual moving of items from wash-up area (timesaving); reduced fine dust exposure; less unpleasant smell; high capacity	Complex retrofitting into an existing building; relatively cost-intensive
Fully automatic systems	Fully automatic emptying with help of robots or machines with pneumatic waste conveyance into an external collection bin	Constant throughput, timesaving; ergonomically beneficial; reduced fine dust exposure; less unpleasant smell; high capacity; reduced staff possible	High costs of purchase requires space; limitations possible due to necessary standardization; high maintenance; requires skilled personal

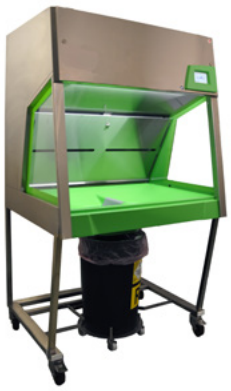


Fig. 4-6: Example of a manual system: emptying cabin where cage contents are emtied into disposal bags or containers, with suitable dust suction device

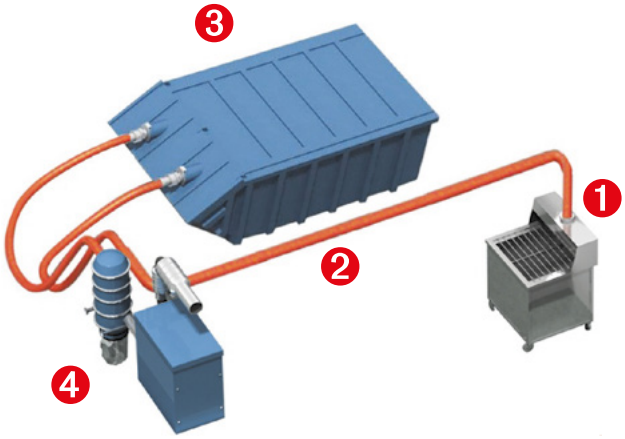


Fig. 4-7: Example of a semi-automatic system: Discharge hopper or cabin (1) with pneumatic litter feed via pipework (2) into an external container (3); vacuum generator and dust filter (4)

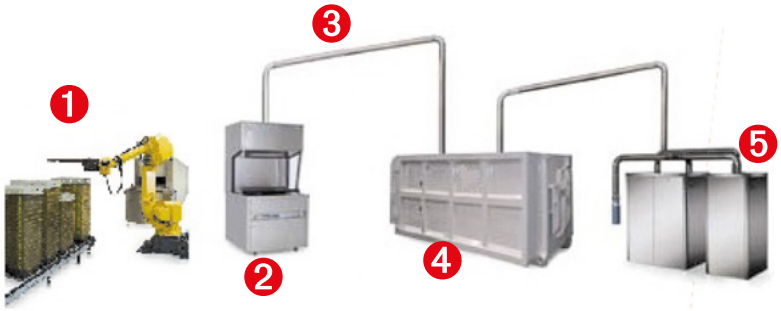


Fig. 4-8: Example of a fully automatic system: Emptying of the cage bases by robot or automatic machine (1) into the discharge hopper (2), with pneumatic conveying via pipework (3) into an external container (4); vacuum generator and dust filter (5)

4.2.2 Emptying drinking bottles

Before drinking bottles can be washed, the bottle caps must be removed from the bottle necks. The open bottles will then be inserted into their crates and the crates turned over to remove residual liquids. After that the washing chamber will be loaded with the bottles neck down.

4.2.2.1 Design of bottle emptying stations

For a convenient, staff-friendly workflow, unnecessary stacking and moving of items should be avoided. Hence, the emptying machine should be set up in a way that the washer can be loaded right after the bottles have been opened and emptied. Avoiding major torso twists and long transport distances is not only ergonomically reasonable, but also timesaving. Therefore, emptying stations can be designed and arranged “in a line” as part of the entire bottle processing station.

Size: Ergonomic working heights are set between 800 and 900 mm. Reasonable dimensions depend on the bottle crate design. There should also be enough room for temporary storing of bottle crates.

Structure: To collect residual liquids the emptying unit should be equipped with a sink of sufficient size. In addition, the sink’s dimensions should allow enough space to hold baskets for collecting the bottle caps. The workspace should allow for convenient handling and moving bottle crates.

Material: Stainless steel (material 1.4301 / AISI 304 or superior grade) offers a major advantage regarding durability and cleaning.

Cleaning: Emptying stations should be easy to clean and be designed accordingly. General cleaning should be done daily and intensive cleaning of the entire machine weekly.

4.2.2.2 Options for emptying drinking bottles – advantages / disadvantages

Below you will find options for manual, semi-automatic, and fully automatic emptying of drinking bottles:

Table 4-3

	Option	Advantages	Disadvantages
Manual systems	Decapping of bottles with a special cap lifter; immediate emptying of liquids into a suitable sink	Cost-effective; can be realized within an existing system; flexible	Low capacity; ergonomically difficult, bottle drinking nipple / seal heavily stressed
Semi-automatic systems	Automatic decapping of bottles (pneumatically or mechanically); immediate manual emptying of liquids into a suitable sink	Gentle decapping, can be realized within an existing system	Although ergonomically recommended, sometimes higher acquisition costs
Fully automatic systems	Fully automatic decapping of bottles and emptying of liquids with help of robots or machines	Timesaving; ergonomically beneficial; high capacity; running with reduced staff possible	Although ergonomically recommended, significantly higher acquisition costs; possible restrictions due to necessary standardization; high maintenance: deployment of more highly qualified personnel required

Note: In the case of mechanical decapping (partially and / or fully automatic systems), care should be taken when selecting the system and function to avoid mechanical stress on the bottles and drinking caps and on the nipples during the decapping process and to ensure a gentle process.

Fully automatic solutions for supplying animals with drinking water, so-called automatic drinking systems, can significantly reduce the number of employees needed. For the necessary and possible mechanical processing of system components such as drinking valves and distribution pipes on the IVC frame, the necessary equipment of the cleaning systems must be considered. Appropriate connection devices (e.g. in a cage and frame cleaning system for the internal cleaning of the drinking water pipes on the IVC frame) and cleaning baskets for the positioning and targeted cleaning of the drinking valves must be considered.

4.3 Washing / Rinsing / Drying

4.3.1 Requirements for cleaning machines

The function of a washer in the wash-up area of an animal facility is to clean and, where necessary, decontaminate items (please refer to chapter 3) pursuant to operator-specific standards and conditions. The cleaning is done with suitable process chemicals, following an effective and standardized washing procedure. Usually the process begins with washing, using a recirculating water and detergent system, followed by subsequent freshwater rinsing, possibly with added rinse aid.

The proper selection of the necessary equipment technology is crucial for sustainable operation.

Depending on the required throughput, it must be considered whether one system can be used for different types of processing goods. This saves not only investment but also operating costs and allows the existing space to be used more effectively. To avoid particle carryover, the operating processes must be adapted accordingly.

With regards to the necessary equipment redundancy in daily operation or for bridging peak loads, an additional compact and powerful system can be provided (e.g. a cage cabinet cleaning system -*cabinet washer*- in addition to a cleaning system for cages, racks and transport systems).

In addition, highly efficient systems should be used in which the duration and design of the cleaning process can be individually adapted to the actual load and contamination and the loading capacity can be increased to a maximum.

The use of heat recovery systems, such as air-water heat exchangers for e.g. cage cabinet cleaning systems, or high-efficiency heat pumps for e.g. cleaning systems for cages, racks and transport systems, should be considered in planning in the interest of sustainable operation.

Below you will find a description of the most important machine types, process steps, and technical components:

4.3.1.1 Machine types and their common design

The process cycle (chapter 2) shows the different types of machines that are generally suitable for cleaning the material to be processed.

Table 4-4

	Typical processing goods	For small rodent facilities up to 2000 cages type 2L[4] per week	For large rodent facilities from 2000 cages type 2L[4] per week	Common usable dimensions of cleaning chamber (H x W x D in mm)	usual external dimensions device (H x W x D in mm)	Number of doors
Cabinet cage cleaning system (as front loader or hood system)	Cages, tops, wire lids, accessories (if necessary, drinking bottles[5])	YES	NO	600–800 x approx. 1300 x 600–800	1700–2000[1] x 1400–1900 x approx. 1000	1-D / 2-D
Belt cleaning system for cages	Cages, tops, wire lids, accessories	NO	YES	300–700 x 600–1000[2]	2100–2800 x 900–1400 x Length[3]	-
Cleaning system for cages, racs and transport systems	Racks, cages tops, wire lids, accessories (if necessary, drinking bottles[5])	YES	YES	approx. 2100 x 900–1200 x 1800–3000	2500–3100 x 2200–3500 x 2300–3500	1-D / 2-D
Bottle cleaning system without automatic decapping	Drinking bottles	YES	NO	300–800 x 500–1300 x 500–800	1400–2000 x 600–1900 x 600–1000	2-D or passthrough
Bottle cleaning systems with automatic decapping and buffer zone	Drinking bottles	YES	YES	300–800 x 500–1300 x 500–800	1400–2100 x 2600–3500 x 600–1000	2-D or passthrough

[1] Height when closed. Machines with vertically opened hood / door can measure up to 3000 mm.

[2] These dimensions describe the height and width of the pass-through section

[3] The length of the system depends on the required throughput capacity and usually ranges from 7 m to 15 m.

[4] Cage type 2L: Common cage size for housing mice, dimensions approx. 365 x 207 x 140 mm (L x W x H).

[5] A general recommendation is to separate the cleaning of cage parts from the cleaning of drinking bottles in such systems and to use separate drinking bottle cleaning systems for this purpose. However, due to cost and capacity reasons it might be necessary that cages AND bottles need to be cleaned within the same system. To avoid any particle carryover during the switching between cage bases and drinking bottles, a thorough cleaning of the cleaning chamber and the nozzles as well as the replacement of the cleaning solution is necessary.

4.3.1.1.1 Cabinet cleaning systems for cages

Below you will find common designs for cabinet cage cleaning systems:

- Systems with front doors (sliding or hinged doors)
- System with hoods that open upwards, for a three-sided opening

Fig. 4-9: Cabinet cleaning system for cages with hinged or sliding door

Fig. 4-10: Cabinet cleaning system for cages with hood (if applicable, extention of loading and unloading tables will be required)

The machines operate discontinuously, i.e. in batch operation. They can be run with one or two doors (for example systems with pass-through sections where dirty and clean sides are physically separated). The hoods or doors can be opened manually or automatically.

4.3.1.1.2 Belt cleaning systems for cages

Other than cabinet cleaning systems, belt cleaning systems operate in line. The items are washed in separate series of washing zones (for the respective process steps see chapter 4.3.1.2), thereby being conveyed on a belt from loading side to unloading side. Separation zones and splash guards amongst the washing zones are used to minimize the carryover of dirt and cleaning detergents in between the zones. The throughput as well as the cleaning and drying result is determined by the length of the zones and conveying velocity.

Fig. 4-11: Belt cleaning system for cages with different zones

4.3.1.1.3 Cleaning systems for cages, racks and transport systems

This machine type is the only one to combine cage cleaning with automatic cleaning of racks and other large-sized or bulky items. Therefore, these systems offer floor-level access (designed in a pit or with ramps).

The machines work discontinuously, i.e. in batch operation. They can be run with one or two doors (for example with a pass-through section where dirty and clean sides are physically separated). The machine is available with wing hinged or sliding doors, which can be opened manually or automatically.

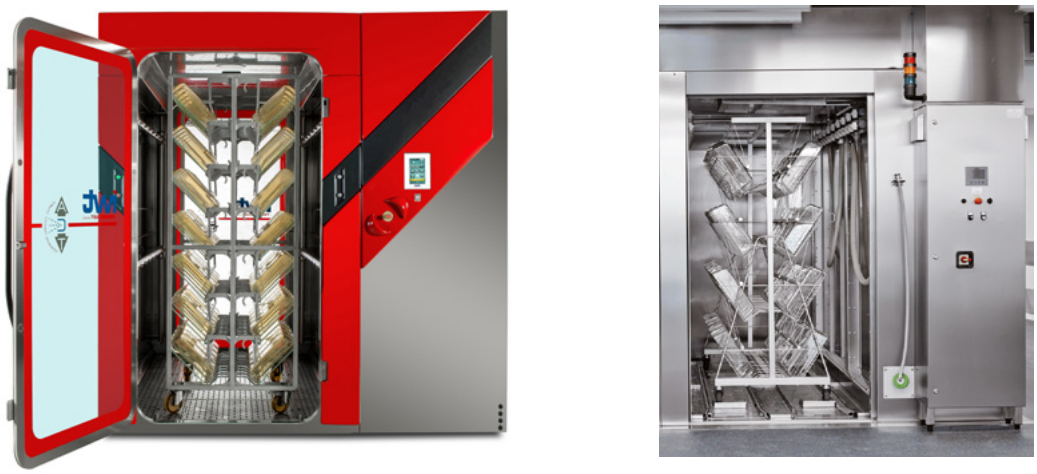


Fig. 4-12: Cleaning system for racks, cages and transport systems

4.3.1.1.4 Cleaning systems for bottles

Cleaning systems for bottles have been developed for cleaning drinking bottles and bottle caps. As the refilling of the drinking bottles usually follows immediately after the cleaning process, drying is not necessary. To prevent litter particles from being carried over into the bottle caps, it is recommended that bottles and caps are not cleaned in the same machine as the cages (risk of dying of thirst for the animals due to clogged bottle

caps). Should it be necessary to deviate from this in justified exceptional cases, this may only be done after thorough cleaning of the nozzles, the cleaning chamber and emptying of the wash tank contents.

Thanks to new technologies, the cleaning of the drinking bottles can be carried out by direct and targeted application of the cleaning solution, e.g. by means of a single nozzle arrangement.

Particular attention should be paid to the way in which the bottle caps are cleaned, as the inside of the bottle cap nipples cannot be sufficiently covered and rinsed by the water jet when the baskets are loaded in bulk by dumping the nipples into the basket. This type of loading can also result in scooping cavities and thus carry over water and cleaning agent residues. This can be remedied by using special bottle cap baskets (see chapter 4.3.1.3 Feeding systems) or the automatic individual positioning of the bottle caps after decapping for a targeted alignment to the spray nozzles.

Bottle washers are commonly available in the following designs:

- Cleaning systems with hoods opening upwards for three-sided opening
- Cleaning systems with front doors (sliding or hinged doors)
- Cleaning systems with hoods / or front doors with combined / or without automatic capping of drinking bottles and / or capping of drinking bottles

The machines work discontinuously, i.e. in batch operation, and they can be designed with one or two doors (e.g. as a pass-through cleaning system, with spatial separation between the dirty and clean sides). The hood or door can be opened manually or automatically. These machines are usually preceded by a bottle emptying section with drinking bottle capping (manual, semi-automatic or fully automatic) and followed by a filling section with drinking bottle capping (manual, semi-automatic or fully automatic) (see chapters 4.2.2 and 4.4.2).

Fig. 4-13: Bottle cleaning system as pass-through system or with hood and tables without automatic decapping

Figure 4-14: Bottle cleaning system with automatic decapping, conveying, cleaning, filling and capping

Figure 4-15: Bottle cleaning system with automatic loading of the bottle cages from a transport trolley, decapping, conveying, cleaning, filling, capping and automatic unloading of the bottle cages back into a transport trolley

4.3.1.2 Process steps of typical cleaning procedure

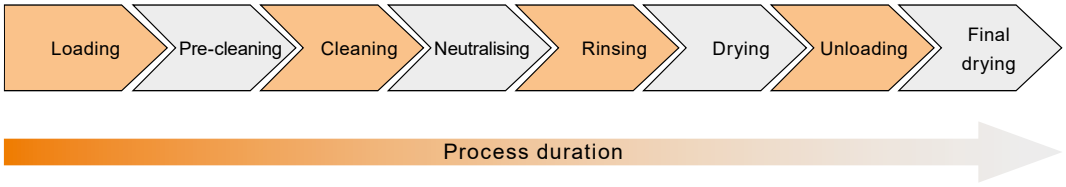


Fig. 4-16: Necessary (orange) and possibly required (grey) process steps of mechanical cleaning processes

Loading
Loading means placing the items to be cleaned on the loading trolley (for cabinet, rack and bottle cleaning systems) or on the conveyor belt (for belt cleaning systems). This can also be done by using partially or fully automated systems such as automatically driven infeed conveyors or robot systems. Loading also includes bringing the loading trolleys or racks into the cleaning chamber, which is usually done manually. To make the process more ergonomic, this can also be done using driverless transport systems (e.g. AGV - Automated Guided Vehicle). In bottle cleaning systems - depending on the design - the bottles can be loaded into a bottle basket, then into the decapping machine and into the cleaning chamber using a conveyor belt or in combination with a robot (see belt cleaning system). To achieve the desired cleaning and drying of the items, the manufacturer's loading instructions must be observed if necessary.

Pre-cleaning
So-called pre-cleaning zones are possible in belt cleaning systems. In cabinet cleaning systems and cleaning systems for cages, racks and transport systems, this can be achieved with a special pre-cleaning phase.

For heavily soiled cage bases (e.g. autoclaved), mechanical pre-cleaning (e.g. by manual scraping with a soft plastic spatula) may be necessary.

Cleaning
The warm water mixed with cleaning agent (alkaline, pH-neutral or acidic) in a tank is sprayed onto the items to be processed via the nozzle system. In cleaning systems for cages, racks and transport systems, the detergent solution (also called cleaning solution) collects in a collecting tray located below the cleaning chamber. From there, it is pumped back into the cleaning tank. In cabinet and belt cleaning systems, the water collects in the cleaning tank below. By circulating the detergent solution, it is possible to spray a large volume flow onto the items to be cleaned without a fresh water supply.

The cleaning process step may be performed several times in succession, e.g. alkaline and acidic cleaning. For this purpose, the cleaning system may need to be equipped with several cleaning tanks.

To minimize water consumption, it is common practice to largely reuse the detergent solution for subsequent batches and only renew a portion (approx. 4-7%) for each batch.

To reduce the amount of rinse water required for rinsing off the cleaning agents, the dripping process step is helpful in cabinet cleaning systems and cleaning systems for cages, racks and transport systems. This is a waiting time that is sufficient for the detergent to drip off the surface on its own.

Neutralizing
To ensure that alkaline cleaners are rinsed off with as little residue as possible, the surface should be neutralized after alkaline cleaning. This is done either by a neutralization step immediately following the rinsing or with an acidic rinse aid during rinsing. Neutralization is particularly important for the cage material polycarbonate (PC) in order to avoid damage to the material caused by remaining alkaline residues during sterilization.

Rinsing
To remove all cleaning agents' residues, plain hot water is sprayed onto the items to be cleaned through the rinse nozzles. Rinse aid (or acidic rinse aid for neutralization if necessary) can be added. To avoid limescale or salt stains on the items to be cleaned, the use of demineralized water is recommended. Only suitable rinse aids should be used for polysulfone (PSU).

Carryover of cleaning solution into the rinse water should be avoided.

Drying
The aim of the drying process is to dry the items to be processed until the residual moisture reaches a tolerable level.

By adding suitable rinse aids during the rinsing phase, the drying of the items to be cleaned after unloading from the cleaning chamber can be supported.

In belt cleaning systems, it is common for the items to be processed to be dried continuously in a drying zone with ambient and / or hot air.

The moist air (vapor) that is produced in a belt cleaning system should be fed into a central extraction system, which can be equipped with heat recovery (if necessary, in combination with a heat pump), via integrated vapor extractors at the entrance and exit of the tunnel and in the rinsing zone.

In cleaning systems for cages, racks and transport systems, drying can be further supported by hot air within the cleaning chamber. In this case, the chamber is ventilated before and during drying and steam or moist air is removed from it. The drying of the processed goods can also be supported by introducing (clean) steam into the cleaning chambers of discontinuously operating systems. Here, too, appropriate systems such as heat exchangers and / or heat pumps can be connected downstream for heat recovery.

For sustainable and resource-saving processing, it should be checked whether energy-intensive and time-consuming drying processes can be dispensed with.

In bottle cleaning systems, the addition of rinse aid during the rinsing process and subsequent hot air drying are not necessary, since the drinking bottles are usually refilled with drinking water after cleaning.

Unloading
In cabinet, rack and bottle cleaning systems, unloading means moving the loading trolleys or racks out of the cleaning chamber and removing the items to be cleaned from the loading trolley or conveyor belt (in the case of belt cleaning systems). This can also be done using partially or fully automated systems such as automatically driven discharge conveyors, automated guided vehicles (AGV) or robot systems. During unloading, post-drying outside the machine already begins.

Post-drying outside the machine
The heat stored in the items to be processed causes any residual moisture to evaporate (drying through its own heat). The prerequisite is that the items to be processed are sufficiently heated during the post-rinsing or drying in the machine. If necessary, precautionary measures must be taken to prevent the operating personnel from being burned by the material's own heat (e.g. setting up a post-drying zone with warning signs; determining a minimum cooling time after which safe handling is possible).

4.3.1.3 Technical components

Cleaning chamber

All surfaces of the cleaning chamber that come into contact with the media should be smooth and the corners should be rounded; dead spaces and gaps should be avoided. Sufficient gradient should be considered to ensure that the process fluids drain completely and thus prevent the formation of deposits in the cleaning chamber and in the cleaning and rinsing tanks.

In addition, care should be taken to ensure that there are no other unnecessary fittings, such as internal water pipes and pumps, in addition to the guide rails, nozzle arms and splash water plates. These should be located outside the cleaning chamber for hygienic reasons and ease of maintenance.

To protect the circulation system from dirt particles, especially to prevent the nozzles from becoming clogged, fine mesh collecting sieves should be provided in the drainage area of the cleaning chamber. To clean these sieves, easy access should be possible, ideally outside the cleaning chamber. Modern systems also have self-cleaning filters available to continuously and automatically filter out dirt particles from the cleaning system.

All connection points, seals or passages in the watertight cleaning chamber must be matched to the process chemicals used in terms of chemical resistance. In addition, the components used must preferably be made of stainless steel (material 1.4301 / AISI 304 or higher) or suitable plastics due to the temperatures and mechanical stress that occur.

The walls of the cleaning chamber and the cleaning and rinsing tanks should - where applicable - comply with the requirements of DIN 4140.

Further technical features of the cleaning chambers are listed in the following table.

Table 4-5

Cabinet cleaning system for cages Bottle cleaning systems	• One or two loading levels • Various pick-up devices can be used (e.g. insert crates, wash item carriers, etc.) • Conveyor belt for bottle washers for automatic crates transport
Belt cleaning system for cages	• Conveyor belt, conveyor belt carrier and belt guide rails made of stainless steel or plastic for transporting the material to be processed • Device for targeted return of the spray water to the tank of the respective cleaning zone and to prevent carry-over
Cleaning system for cages, racks and transport systems	• Design of the chamber floor for flexible use of charging trolleys with different track widths • Interior lighting • Emergency stop device with door release function in the cleaning chamber

Cleaning and rinsing tanks

The same requirements that apply to the cleaning chambers in terms of shape, design and choice of material apply to the cleaning and rinsing tanks as well. Depending on the type of machine, the tanks can be located below / above the cleaning chamber, to the side of it or can be a part of the cleaning chamber. Depending on the design of the cleaning process and the machine type, several tanks may be required. To reduce media consumption, the cleaning and rinsing tanks should be designed to have a minimum volume for the process. Heat loss can be minimized through appropriate design measures (large-area insulation, arrangement of tanks next to each other, etc.).

Nozzle systems

The nozzle system used is also essential for the cleaning success. It must ensure that the cleaning agent hits the items being processed completely and in sufficient quantity. For cabinet cleaning systems for racks and cages it is recommended to use oscillating nozzle technologies and, where technically possible, with vertical, linear movement to avoid spray shadows. For drinking bottle cleaning, it is recommended to use systems with an individual nozzle arrangement for precise and faster cleaning success, i.e. each bottle is cleaned with an individual nozzle during cleaning. The nozzles are usually made of stainless steel or plastic. They can be fed by either one- or two-pipe systems.

The following has a major influence on the cleaning and rinsing success:

- Number, arrangement and design of the nozzles
- Spray pressure on the item being processed
- Volume flow (e.g. liters per minute) of the cleaning solution
- Spray and inclination angle of the nozzles
- Nozzle movement, e.g. oscillating, rotating, linear movement or fixed
- Ease of cleaning of the nozzle systems, e.g. screwed-in nozzles, possibility of removing the nozzle carrier
- Structural design of the spray system with the lowest possible pump output but with high-volume flow, to achieve a high TTI value (TTI value is the impulse of the water that occurs on the surface of the material to be treated, definition and calculation see chapter 11).

For an optimal cleaning process, the spray nozzle system must be matched to the water pressure, volume flow of the pumps, the design capacity and size of the heat exchangers, tanks and dosing devices. A cleaning process can only be used effectively, safely and reproducibly if it is carefully designed.

Loading systems
Loading levels are used in cage cabinet cleaning systems to load the chamber with the goods to be processed. To ensure that the surface drains better, it is generally beneficial to arrange the animal cages at a slight angle. Due to the different goods to be processed, holding devices specially tailored to the goods are usually required.

The chamber of a cleaning system for cages, racks and transport systems is loaded with the goods to be processed using special loading trolleys that are driven into the cleaning chamber at floor level. To avoid spray shadows and to guarantee effective cleaning, the goods to be processed should be able to be fixed to the trolley in a suitable position and adapted to the nozzle arrangement. Due to the different items to be processed, racks specially tailored to the goods are usually required.

To maximize the capacity of the goods to be processed per cycle and at the same time reduce the energy and media consumption per part to be cleaned to a minimum, specially designed nozzle arrangements and functions with suitable loading trolleys can be used, especially for cleaning systems for cages, racks and transport systems.

Holders and loading trolleys must be made of stainless steel (e.g. material 1.4301 / AISI 304) or suitable plastics. The rollers must be resistant to process chemicals and operating temperatures. For hygienic reasons, hollow spaces and dead spaces should be avoided by suitable design features.

The processing of drinking caps should take place in special holding frames in which a defined individual arrangement of 18 or 36 drinking caps is possible. The previously common use of baskets with caps in bulk should be avoided to minimize the risk of animals dying of thirst due to clogged drinking caps (see Chapter 4.3.1.1.4 and 9.6). If this is not possible, at least the number of loose caps in bulks per basket should be greatly reduced and the functionality of the drinking nipples should be checked before the bottles are inserted into the cage (see Chapter 9.6).

For filter hoods for IVC cages with recesses for external drinking bottles, special loading systems are required so that liquids can drain off completely, e.g.:

- Crates or special loading levels to achieve tilted positioning of items in cabinet and belt cage cleaning systems
- Special belt design for the correct placement of filter hoods and for placing other processing goods in belt cages cleaning systems
- Loading racks for tilted positioning in cage and rack cleaning systems

System cladding
The cladding of the cleaning systems is preferably made of stainless steel with standard surface treatment (e.g. polished). Access to the unit area for maintenance purposes should be sufficiently large. The cladding parts should be designed as doors or be easy to open or dismantle using other systems.

Service and maintenance area
The necessary pumps, pipes, valves, tanks, dosing devices, etc. are in the unit area of the system, which can be arranged differently depending on the machine type.

Particular attention must be paid to ensure that the installed components are arranged in a clear and maintenance-friendly manner.

Measurement, control and regulation technology (MCR)

Machine control
The entire program sequence should be automatic. The required program is selected from an operating panel (located on the loading side or on the control cabinet, e.g. membrane keyboard, touchscreen). It is recommended to install programmable logic controllers (PLCs) or microprocessor controllers, which allow process parameters to be changed (password-protected if necessary) if required.

Displays and monitoring
The cleaning systems should have appropriate control and display instruments (e.g. display / touchscreen) for the following parameters:

- the program selected by the operator
- the set parameters
- the respective process step during the operating sequence
- the remaining processing time
- the temperatures of the cleaning solution and the rinsing water
- the temperature in the cleaning chamber
- the end of the program in batch operation
- the empty notification of the process chemicals containers (canisters or barrels)
- error messages

Remote access and diagnosis
To be able to carry out a quick diagnosis by the manufacturer in the event of faults or malfunctions of the system, even without the presence of a qualified service technician on site, modern control systems with the option of external remote access via the Internet should be used. To implement this, the necessary hardware and software preparations as well as the network and firewall settings must be coordinated early on with the in-house IT department with the involvement of the manufacturer. When planning new buildings, it is advisable to specify this in the planning phase.

Safety components
The systems must comply with the professional association regulations where applicable and be equipped with VDE-certified (or according to local regulation) safety devices. The systems must also have a CE certificate of conformity (see also risk assessment by the operator in Chapter 6).

The safety devices include, for example, a locking mechanism for chamber doors to prevent them from being opened during operation to protect people so that no harmful substances can escape into the work areas, an emergency release inside walk-in cleaning chambers, a program interruption when the chamber is opened, and an easily accessible emergency stop device.

For cage belt cleaning systems, additional emergency stop buttons must be provided on the loading and unloading side and a monitoring sensor at the belt outlet, which stops the belt movement if the operator removes the material to be processed too late.

Control cabinet
All electronic and control components as well as push buttons, indicator lights etc. must be housed in a splash-proof control cabinet with protection class IP 54 or higher. All electrical equipment installed in the unit area must be designed in accordance with protection class IP 54 or higher.

4.3.1.4 Documentation

The accompanying documents for cleaning systems should be supplied in the local language upon acceptance and should consist of the following documents:

- Instruction manual with maintenance instructions and troubleshooting
- Electric diagram
- Piping and instrumentation drawing (P&ID)
- Spare parts list

The supply and disposal lines, utilities and other construction measures required for the machines are described in chapter 5.

4.3.2 Requirements for process chemicals

The process chemicals used in the cleaning machines must have specific properties that are tailored to the intended use. To avoid damage to the processing goods listed in this brochure and to the cleaning machines, only process chemicals that have been specially developed for use in cleaning machines and whose suitability has been proven may be used.

Liquid process chemicals that are automatically dosed are used. It is recommended that the process chemicals be dosed directly from the delivery container, e.g. canisters, barrel or storage containers (see Chapter 5.5).

In detail, the following requirements for process chemicals must be observed:

4.3.2.1 Process chemicals

The selected chemicals must fit the described technical conditions of the washer; they must not cause any excessive foam or deposits (please refer to chapter 4.3.1). The manufacturer‘s recommendations on the safety data sheet about the use of chemicals must be considered, in order to avoid health hazards.

4.3.2.1.1 Cleaning agents

It is generally possible to use acidic, pH neutral, and alkaline detergents as well as combinations of acidic and alkaline detergents in suitable cleaning systems. For water bottles, acidic detergents are recommended. Goods and detergents must always be compatible.

4.3.2.1.2 Neutralizing agents

Acidic neutralizers can be used to remove alkaline detergents. Depending on the application, those chemicals can help avoid water salt deposits.

4.3.2.1.3 Rinse aids

Rinse aids should achieve an even and sufficient wetting of the different materials of a wash load. They can thus contribute to the drying process and help avoid spots and drops. Acidic rinse aids are preferred because of the following reasons:

- De-activation of water hardness
- Neutralization of the alkalinity of the softened water
- Neutralization of possible alkaline residues of the detergent

Plastics susceptible to stress cracking, especially polysulfone and occasionally polycarbonate, require suitable rinsing agents.

4.3.2.2 Characteristics and physical parameters

4.3.2.2.1 Material compatibility

When used correctly, chemicals should not cause corrosion or other material damages within the manufacturer-stated life expectancy of the items that are processed (please refer to chapter 3).

4.3.2.2.2 Dispensing and determination of concentration

Process chemicals can be dispensed centrally or locally (please refer to chapter 5.5). Information on dosage is provided by the manufacturers on the trading unit labels. For detailed information, please refer to the corresponding data sheets.

Chemical manufacturers can further list methods for determining the correct concentration (+/- 10 % of the set point, e.g. titration or conductivity measurement).

4.3.2.2.3 Temperature

Chemicals must be adequate for the temperature range of a specific washing procedure, as recommended by the manufacturers of the items to be washed and machines to be used.

4.3.2.2.4 Replacing the cleaning agent

The cleaning agent is to be regenerated or replaced as required. Depending on the items to be washed, the tanks, mesh filters, and nozzles must be checked regularly and cleaned daily if required (please refer to chapter 6) to ensure a satisfactory cleaning result.

4.3.2.3 Documentation and safety

For each process chemical manufacturers must provide a technical data sheet and material safety data sheet. The operator must then compile operating instructions. For the rinse aid, manufacturers must provide a toxicological risk assessment, if applicable.

4.4 Filling components

After cleaning, the cage bases are usually refilled with bedding as the drinking bottles are with water. They are then returned into the animal facility. However, the filling process can also take place within the animal housing facility. This may require the bedding and water to be hygienically processed separately.

4.4.1 Cage filling

4.4.1.1 Health aspects

When the cage is filled, only fine dust from the clean bedding is released. Certain types of wood can cause allergies, some are classified as carcinogenic. In addition, fine dust, even if not classified as hazardous, must be minimized at a permanent workplace in accordance with the Occupational Safety and Health Act and extracted where necessary.

Another important aspect is the strain on the human musculoskeletal system. Continuous one-sided work, such as manual filling cage bases, often leads to tension and chronic pain in the back, neck and shoulder area (see publications in chapter 10).

4.4.1.2 Handling of clean bedding

When handling clean bedding (usually at the bedding storage place or wash-up area), the following aspects should be considered:

- When handling cages, gloves, suitable respiratory masks as well as suitable work clothing should always be worn.
- Open storage of bedding over long periods of time should be avoided
- Dust should be avoided. A procedure-specific suction device is recommended
- Ergonomic working heights of approx. 800 to 900 mm are recommended
- When handling bedding manually, light, small bags are to be preferred
- When using large bedding bags, suitable technical applications such as a crane track with lifting gear and trolleys must be provided
- Bedding bags should only be moved with suitable transport systems and over the shortest possible distance

4.4.1.3 Design of bedding dispensers

For a convenient, staff-friendly workflow, unnecessary stacking and moving of items should be avoided. Hence, a bedding dispensing machine should be located in a way that the cage bases can be refilled immediately after they have been removed from the cleaning system. This requires largely dried cages. For the best possible workflow, the transport systems described in chapter 4.1 should be moved adjacent to the dispensing machine and locked there. Generally, avoiding major torso twists and long transport distances is not only ergonomically reasonable, but also timesaving.

Size: When designing filling systems, current and future capacities and requirements should be considered.

Material: Stainless steel (material 1.4301 / AISI 304 or higher) offers the greatest advantages in terms of durability and cleaning.

Cleaning: The filling station should be easy to clean and be designed accordingly. Conventional cleaning should be done every day, an intensive cleaning of the entire machine every week.

4.4.1.4 Bedding dispensing systems - advantages / disadvantages

Table 4-6

	Variant	Advantages	Disadvantages
Manual filling	Filling from bags or containers	Cost-effective; it can be realized within an existing facility; flexible	Time-consuming; high dust exposure; ergonomic burden; low capacity; requires manual transport of bedding from the bedding storage place
Semi-automatic filling*	Filling via bedding belt or mobile dosing tank	Can be realized within an existing facility; high capacity	High dust exposure; although ergonomically recommended, higher investment cost; requires manual transport from the bedding storage; partially high pollution of the working environment due to bedding losses
	Mobile dispensing station with suitable dust suction device	Can be realized within an existing system, medium high capacity. Nearly no dust exposure; flexible	Although ergonomically recommended, higher acquisition cost; requires manual transport of the bedding from the bedding storage;
	Filling systems with pneumatic conveying, with suitable dust suction device	Does not require manual transport of bedding from the bedding storage (timesaving); low fine dust exposure; can be realized within an existing facility; high capacity; reproducible bedding quantities	Higher acquisition cost
Fully automatic filling*	Filling systems with pneumatic conveying and fully automatic handling via robots or automatic machines, with or without turning technology for cage bases	Does not require manual transport from the bedding storage; time and ergonomic relief; hardly any fine dust pollution; high capacity; running with reduced staff possible; reproducible bedding quantities	Although ergonomically recommended, it may only be profitable from larger quantities of reprocessed goods; space requirements; possible restrictions due to necessary standardization; maintenance intensive

*In semi- and / or fully automated systems, the process capability of the bedding used plays a key role. Hence, it is important to use fiber-reduced bedding (avoiding lightweight / fluffy materials) or to take technical measures inside the dispensing station to prevent the material from being bridged. If no suitable technical measures can be taken, free flowing bedding types are to be preferred to reduce interruptions in the system and achieve a repeatable process.

Fig. 4-17: Example of a semi-automatic system: Mobile dispensing station with suitable dust suction device

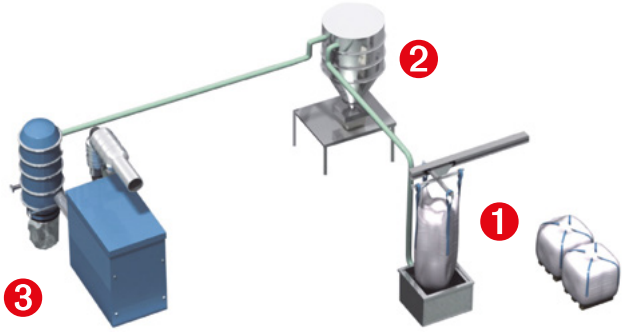


Fig. 4-18: Example of a semi-automatic system: Filling funnel e.g. for BIG-Bag and crane track (1), dosing funnel with dust extraction device (2) and vacuum generator and dust filter (3) for pneumatic conveying

Fig. 4-19: Example of a fully automatic system: Bedding filling of automatically turned cage bases after cleaning in a cage belt cleaning system

Fig. 4-20: Example of a fully automatic system: Filling the cages with robots or automatic machines (1), filling funnel for clean bedding, e.g. with BIG-Bag (2), optional storage silo (3), dosing funnel with dust extraction device (4) and vacuum generator and dust filter (4) for pneumatic conveying.

4.4.1.5 Health risks of different types of bedding

The choice of bedding in research facilities depends on various aspects such as compatibility with the experiments, absorption capacity, availability and cost. The impact on health and the environment are also important factors in selection.

Wood-based bedding is predominantly used. In addition to the type of wood, the assessment of the risk potential also depends on the particle size and geometry as well as the total dust content of the respective bedding. This should be very low, ideally < 0.2 % of the particle size spectrum < 200 µm. Reference is made to the relevant literature (e.g. EC Directive 2004/37/EC, Annex 1/5 and TRGS 906). This applies in principle to all bedding raw materials.

Other raw materials such as corn or hemp can also be suitable. Highly processed products, such as paper-based bedding, have a higher CO_2 footprint.

4.4.1.6 Bedding trading units

Bedding can generally be supplied in three different types of containers:

In bags (e.g. 10 to 15 kg), in big bags and in tank trucks. Due to the high strain on the musculoskeletal system and the high expenditure of time required for handling, the bags are only recommended for use in small facilities. Big bags are handled using lifting trolleys and crane tracks. They combine ergonomics with time savings and high capacity at a reasonable cost. Silo solutions that are filled using trucks can be useful when there is a very high material turnover. However, they are very expensive and must be considered when planning the building, and it must also be clarified whether the bedding supplier can operate this solution with tank trucks.

4.4.2 Filling drinking bottles

4.4.2.1 Processing drinking water

Water can be treated with additives such as chlorine or acid to slow down bacterial growth. Please refer to the GV-SOLAS information brochure „Trinkwasser für Versuchstierhaltungen“, “Gelbes Heft“ “Drinking water for laboratory animal facilities”, (“yellow booklet”).

4.4.2.2 Design of the filling station

To avoid unnecessary stacking, transporting and unstacking and thus reducing the workload of the staff, the filling station should be set up in such a way that the drinking bottles can be filled immediately after the cleaning system has been unloaded. An ergonomic working height must be ensured (approx. 800–900 mm). As a rule, filling stations can therefore be designed and arranged “in a line” as part of the entire bottle processing system.

To optimize the workflow, the transport systems described in chapter 4.1 should be driven and secured directly next to the filling station. As a rule, large torso turns and carrying distances should be avoided, which not only has ergonomic advantages but also saves time.

Size: When designing filling systems, current and future capacities and requirements as well as the bottle crates grid (e.g. 18-bottle grid) should be considered.

Material: Stainless steel (material 1.4301 / AISI 304 or higher) offers the greatest advantages in terms of durability and cleaning. When using chlorinated drinking water or drinking water acidified with hydrochloric acid, special care must be taken (see chapter 9.5)!

Cleaning: The filling station must be designed so that it is easy to clean. Cleaning should be carried out daily, and the entire station should be thoroughly cleaned weekly.

4.4.2.3 Bottle filling systems - advantages / disadvantages

In the following, a distinction is made below between manual, semi-automatic and fully automatic variants:

Table 4-7

	Variant	Advantages	Disadvantages
Manual systems	Single filling with hose and / or use of a manual hand-fill rake	Cost-effective; can be realized in existing system; flexible	Time-consuming; low capacity; ergonomically very unfavorable
Semi-automatic systems	Multiple fillings with stationary filling rake, automatic detection and filling	Relatively inexpensive; can be realized in an existing system; time savings	Medium capacity; ergonomically unfavorable
Fully automatic systems	Fully automatic filling and capping using robots or machines	Time and ergonomic relief; high capacity; running with reduced staff possible	Although ergonomically recommended, sometimes high acquisition costs; possible limitations due to necessary standardization; maintenance-intensive; large space requirement

4.5 Steam sterilization

Steam sterilization has proven its reliability as a universal sterilization procedure in animal facilities.

4.5.1 Requirements for steam sterilizers

Sterilizers in animal facilities can be necessary for the following purposes (as described in chapter 2):

- to provide sterilized items for specific operational areas (“sterilize in”)
- to dispose of potentially infectious or genetically modified material from specific operational areas to the outside (“sterilize out”).

Please find below a description of different machine groups, processes, dimensions and technical components.

4.5.1.1 Goods and materials

When selecting and operating animal facility sterilizers, it is necessary to make the following distinction:

- Thermostable / thermolabile
- Solids / liquids
- for solids: porous / non-porous

In this application, thermostable goods are understood as being material that can be sterilized at a sterilization temperature of 121 °C for at least 20 minutes with the corresponding saturated steam pressure. Thermolabile goods cannot tolerate this thermal load (e.g. computers, microscopes, power tools).

For safety reasons, different processes are used for solid and liquid materials (e.g. boiling delay for filled drinking bottles). Porous goods (e.g. feed bags, cages with bedding, textiles) require special procedures for air removal and vapor penetration due to their surface structure. Non-porous goods have a smooth, closed surface structure (e.g. cages, racks, empty drinking bottles).

In addition to the physical properties of the goods, in the case of potentially infectious goods, their classification into risk groups also requires special attention. Biological agents are divided into four risk groups according to the risk of infection they pose in accordance with Directive 2000/54/EG or 2020/739/EU. Due to its pandemic nature, the virus SARS-CoV-2 (Covid), for example, was temporarily assigned to risk group R3. When planning animal facilities, special requirements for risk groups R1 to R4 must therefore also be considered in individual cases. In the following, increased requirements are therefore discussed at relevant points.

4.5.1.2 Devices and procedures

The sterilizers used should comply with DIN 58951-2 “Steam sterilizers for laboratory sterilization goods”. This standard describes various device groups. Sterilizer for animal facilities can be found in group D.

Depending on the type of goods to be sterilized, the sterilizers should permit combinations of process steps as described in the table below:

Table 4-8

Goods	Pretreatment	Sterilisation phase	Aftercare
non-porous	VOVV / FRVV	Suitable temperature / time combinations, e.g. 121 °C with 20 min exposure time	VMT
porous	FRVV		VMT
liquid	VOVV		DLK / SAK
Waste / GMO	FRVV		VOT / VMT
Animal carcass	FRVV		DEA / VOT

VOVV: Pre-vacuum process
FRVV: fractionated vacuum process
VMT: Vacuum with drying time
VOT: Vacuum without drying time
DLK Vapor-air mixture cooling (indirect cooling with support pressure, active cooling)
SAK Self-cooling, in which the sterilization material is cooled exclusively by heat dissipation to the environment (with or without support pressure, passive cooling process)
DEA: (slow) depressurization to atmospheric pressure

Please note the following:

- When sterilizing polycarbonate material, ensure that there are no alkaline residues on the goods (otherwise the material will be destroyed by hydrolysis, see chapter 9.1)
- When sterilizing feed or bedding in bags: Use needled plastic bags or vapor-permeable bag material.
- When autoclaving food, it should be noted that the heat exposure should be reduced to the minimum required for sterility to avoid unnecessarily damaging thermolabile food components (vitamins, etc.). Otherwise, problems may arise with the breeding and keeping of the animals.
- For liquid goods: Temperature measurement in the reference vessel (otherwise danger to life due to boiling delay; withdrawal temperature < 80 °C) necessary. If the shortest possible batch times are required, active cooling with support pressure is preferable.
- When sterilizing filled polycarbonate drinking bottles: To protect the material, use a lower sterilization temperature, e.g. 118 °C, if necessary, with a longer exposure time, e.g. 40 min.
  If a microbiological test is desired, significantly longer exposure times are required to inactivate the germs.
- When sterilizing drinking bottles with attached drinking caps: Bottles with silicone sealing rings are essential here, as otherwise leaks will occur (different expansion coefficients of metal and plastic).
- For solids (especially cage bases) and porous loads (e.g. cage bases with litter): Place in the sterilizer as dry as possible (evaporative cooling, drying time).
- For waste treatment (potentially infectious goods): Chamber exhaust air and condensate must be treated (e.g. exhaust air filtration and condensate sterilization). It is essential to use packaging material that ensures safe vapor access to the waste.
- When sterilizing animal carcasses, special programs must be used in consultation with the appliance manufacturer, depending on the size of the animal.
- In the case of porous loads (e.g. bedding, feed), localized overheating may occur as a result of hygroscopic condensation.

4.5.1.3 Dimensions and sizes

There are basically different types of sterilizers:

- Floor-level / non-floor-level accessible chamber
- 1-door and 2-door

The usable chamber dimensions are usually given in decimeters as height x width x depth, i.e. a sterilizer 18 x 12 x 15 has a cuboid loading chamber of at least 1800 mm (H) x 1200 mm (W) x 1500 mm (D). The clear chamber dimensions must be correspondingly larger in all dimensions and adapted to the loading system.

The usual preferred sizes for floor-level sterilizers in animal housing are:

18 x 10 x 15 (clear chamber dimensions: approx. 2000 x 1100 x 1600 mm)
18 x 12 x 15 (clear chamber dimensions: approx. 2000 x 1300 x 1600 mm)

Installations in the chamber can lead to restrictions in the usable space. All necessary information about the items to be sterilized (e.g. largest individual item, maximum load) must be considered. Ergonomic aspects must be considered when selecting the chamber size. Optimal chamber utilization should be sought for sustainability reasons.

In addition to the usual preferred sizes, floor-level sterilizers with a clear chamber height of up to 2200 mm and a correspondingly larger clear chamber depth are also required. This is due both to new IVC racks with larger dimensions (especially height and depth) and to the fact that, for ergonomic or hygienic reasons, existing IVC racks do not have ventilation pipes on the racks removed prior to sterilization.

Depending on the structural conditions, the external dimensions of certain system components must be coordinated with the installation options and the installation situation, see chapter 5.

4.5.1.4 Technical components

The general requirements for appliance and safety technology are described in detail in DIN 58951-2. Some examples are highlighted again below.

Airtight partitioning for barrier areas
The design of the partitioning is generally explained in DIN 58951-2, point 7.7. In practice, the penetration seal should have a mechanically strong connection to the sterilizer chamber and be tightly connected to the side walls, ceiling and floor. Particularly in the case of pit sterilizers, attention must be paid to good sealing in the floor area below the chamber during installation, as this area is practically inaccessible later. The requirements of the air conditioning system for maintaining defined pressure differences in the separate areas apply as the upper limit for maximum permissible leaks.

Authorizations
If operating personnel change frequently, it is advisable to protect the starting of programs with passwords (employee password). Additional passwords or key switches, which are only available to selected people, should be available for changes to the machine or for executing special functions (e.g. cancelling the barrier).

Vacuum pump
Vacuum pumps generate a relatively high noise level during operation, which may affect the animal rooms. As many animals are sensitive to this, it is recommended that the vacuum pumps are installed in more distant technical rooms. If an external installation of the vacuum pump is not possible for space reasons, sound insulation measures should always be taken inside the sterilizer.

Connection of the sterilizer to the on-site cooling circuit
By connecting the sterilizer to an on-site cooling circuit, the consumption of operating resources, especially cooling water, can be significantly reduced.

Centralized recording of fault messages
The sterilizer should be able to automatically forward process-relevant fault messages to a central control room.

Remote access and diagnosis
Modern control systems with the option of external remote access via the Internet should be used to enable rapid diagnosis by the manufacturer in the event of system faults or malfunctions, even without the presence of a qualified service technician on site. For this purpose, the necessary hardware and software preparations as well as the network and firewall settings should be coordinated at an early stage with the in-house IT department in consultation with the manufacturer. In the case of new building plans, it is recommended that this is already specified in the planning phase.

Vapor injection into the chamber
The sterilization of cages with bedding makes special demands on the flow of steam into the chamber. To prevent the bedding from being swirled up, the steam must not be channeled directly onto the cages. This requires special installations on the chamber wall to ensure gentle distribution of the vapor. As an accumulation of bedding on the chamber floor cannot be completely avoided, the chamber floor should be easy to clean (sweep). Therefore, installations on the floor should be avoided and existing dirt traps and sieves should be easily accessible and easy to clean. Evacuation openings must also be fitted with a sieve (no sucking in of nesting material etc.).

Floor-level sterilization chamber
The design of the chamber floor should allow flexible use of charging trolleys with different track widths (no protruding fixtures in the floor area).

Flexible reference probe for the sterilization of filled feeding bottles
The temperature sensor should be easily accessible from both sides. In programs without using the reference sensor, the sensor should be mechanically protected on the chamber wall, including its cable. For special protection, it may be necessary in some cases to protect the cable with an additional metal hose.

Liquid sterilization with natural cooling (post-treatment SAK)
The cooling of liquids in open containers (e.g. drinking bottles) can be carried out not only by active cooling but also by “natural” or “self-cooling”. The heat of the liquids is slowly released into the environment. For natural cooling, neither a high connection power of compressed air for a support pressure nor a media connection for softened water for active jacket cooling is required. Process monitoring with a flexible reference sensor is carried out in the same way as programs with active jacket cooling.

The correspondingly longer cooling or cycle times can be compensated, if necessary, by starting the sterilization process in the evening, for example, and running it overnight.

Mutual locking of the doors
With sealed appliances, the load can only be passed through the sterilizer in a defined direction by sterilization. In the opposite direction, air locking without sterilization is usually possible. The direction of sterilization must be clearly defined (SPF area, quarantine area). In special cases, it may also be necessary for sterilization to always be carried out in both directions. The exact design or the possibility of switching between these variants must be precisely specified when the order is placed.

Batch documentation
To document the sterilization process, the temperature and pressure profile should be continuously recorded during sterilization. In accordance with GLP-compliant work, documentation must be provided that enables the sterile goods to be assigned to a documented batch. In addition to temperature and pressure, a batch document should contain at least the date and time, sterilization program, batch number and release.

Exhaust air filter / filter in the vacuum line
Device for sterile filtration of the evacuated air from the sterilization chamber during the pre-treatment of a sterilization process with potentially infectious material.

Exhaust air filters are installed in the vacuum line between the chamber and the vacuum pump and should be sterilizable “in-line”. Sterilization of the filter is particularly necessary before disassembly and disposal.

In the statement of the “Laboratory Technology” project group of the Committee for Biological Agents (ABAS) on “Installation Recommendations for New Systems, Retrofitting or Additions, for the Selection of Exhaust Air Treatment of Autoclaves” dated 17 November 2021, installation recommendations for exhaust air filters in autoclaves for laboratory areas of protection levels S1 to S4 are provided (see Table 4-9).

Table 4-9

Protection level S1	One exhaust air filter
Protection level S2	One exhaust air filter
Protection level S3	Thermal exhaust air treatment Alternatively, two exhaust air filters connected in series (police filter)
Protection level S4	Thermal exhaust air treatment

Thermal exhaust air treatment
Device for thermal inactivation of the evacuated exhaust air from the sterilization chamber during the pretreatment of a sterilization process with potentially infectious goods.

Systems for thermal exhaust air treatment are installed in the vacuum line between the chamber and the vacuum pump and heat the air extracted from the chamber to temperatures of 400 to 600 °C. Detailed requirements for the technical design of systems for thermal exhaust air treatment are specified in the statement of the “Laboratory Technology” project group of the Committee for Biological Agents (ABAS) on “Installation Recommendations for New Systems, Retrofitting or Additions, for the Choice of Exhaust Air Treatment of Autoclaves” dated November 17, 2021.

The space required for two exhaust air filters connected in series or a thermal exhaust air treatment process must be considered accordingly when planning autoclaves.

Condensate stabilization
Device for safely retaining and inactivating the condensate produced during a sterilization process with infectious material.

Standby function / sleep mode
If the device is not used for a long period of time between two sterilization processes, it should switch to a standby or sleep mode after a set time or immediately after the end of the program. The heating of the jacket is stopped, and the device cools down. Steam consumption is thus minimized. If the sterilizer is not used for a longer period of time (e.g. overnight or on the weekend), it should be switched off.

4.5.2 Special requirements for process validation

4.5.2.1 Normative starting situation

Process validation is carried out in accordance with DIN EN ISO 17665. Ideally, the scope of process validation and acceptance criteria are defined in agreement with the operator.

Note: Acceptance criteria are defined in DIN EN 285 exclusively for medical devices and are therefore not relevant for applications in animal facilities.

4.5.2.2 Functional assessment (empty chamber profiles)

Checking the temperature distribution in the empty chamber.

Acceptance criteria:
The acceptance criteria should ideally be defined in consultation with the operator.

Suggestions / recommendations for implementation:
- 1 x empty chamber profile per sterilization program (e.g. 134 °C, 118 °C), thermometric measurement in each case
- Reproducibility of the measurement (3 x) without loading is generally not required in animal facilities.
- Thermocouples / thermologgers must be positioned on the empty loading trolley / loading carrier

4.5.2.3 Performance assessment (loading configurations)

Testing of temperature distribution within the loaded chamber. The loading configurations to be tested must be specified by the operator / client.

Acceptance criteria:
The acceptance criteria should be defined in consultation with the operator. Product-specific factors (e.g. avoidance of overheating of feed) must be considered when defining the criteria.

Suggestions / recommendations for implementation:
- Reproducibility of the measurement (3 x) with loading for either every or only defined sterilization programs, thermometric measurement and microbiological test if necessary
- Thermocouples / thermologgers must be positioned in the goods to be loaded, if this is not possible on the loading trolley / loading carrier

4.5.2.4 Items-to-be-sterilized which require special attention

Feed / bedding:
Special attention must be paid to feed and bedding (container size, abrasion, caking, overheating). In the case of feed, overheating can damage ingredients (e.g. vitamins). Such overheating should not be much higher than 3 K. If hygroscopic condensation occurs, the above-mentioned limit values for the temperature band can sometimes be significantly exceeded. This overheating as a result of hygroscopic condensation has nothing to do with a malfunction of the sterilizer, but is a physical consequence of porous goods. In such cases, further action must be coordinated with the operator.

Bedding in cages:
Moisture problem: Depending on the preparation / stacking, vapor can enter, but the resulting condensate cannot be removed. The moist bedding clumps together and may not be sterile.

4.5.2.5 Suggestions / recommendations for test cycles

- The AK KAB recommends a reassessment once a year, but no later than after 2 years.
- Recommendations for acceptance criteria can be requested from the manufacturer.

4.6 Germ reduction of thermolabile goods with hydrogen peroxide (H_2O_2) / peracetic acid (PAA)

In connection with cage processing, the in- / out-transfer of thermolabile goods that cannot be steam sterilized is of particular interest. In general, the in- / out-transfer of thermolabile goods using H_2O_2 / PAA is referred to as a germ reduction process. In this case, the aim is to inactivate pathogenic microorganisms. In contrast to thermal sterilization, the local effect can only be verified using indicators and cannot be measured directly using process parameters (e.g. temperature or pressure). Pure room fumigation is not covered in this context.

4.6.1 Material locks

The processes relevant for the in- / out-transfer of thermolabile goods can basically be divided into gaseous processes - such as fumigation with hydrogen peroxide (H_2O_2) - and wet spraying processes using peracetic acid (PAA). Special cases such as removal from S3 / S4 areas are not generally considered here, as these always require individual testing. Typical examples of thermolabile goods are shown below for each of the two germ reduction processes presented:

- Typical thermolabile goods for both processes: e.g. vacuum-packed, gamma-irradiated feed or bedding bags or sacks
- Typical thermolabile goods exclusively for H_2O_2 applications: e.g. power tools, computers, microscopes, measuring devices, blower units, cage changing stations, microbiological safety cabinets, ventilated animal housing cabinets, litter discharge stations
- Typical thermolabile goods for PAA applications: simple corrosion-resistant tools, other goods with a solid PAA-resistant surface
- Transport container for introducing animals into the barrier area

Note:
When fumigating plastic cages with H_2O_2, outgassing problems may occur because of previous strong absorption. GV-SOLAS therefore recommends that plastic cages should not be fumigated to avoid any risk of increased exposure of the test animals to H_2O_2.

4.6.2 Requirements for treatment processes with H_2O_2

Below you will find a description of the effect and suitability of vaporized H_2O_2 for reducing organisms in locks as well as its limitations of use that need to be examined more closely.

Germ reduction with H_2O_2
H_2O_2 is a strong oxidizing agent that is effective in inactivating microorganisms - such as spores, bacteria, viruses and fungi - particularly in the gaseous state. In the liquid or gaseous state, H_2O_2 is colorless and odorless. Information on the safe handling of H_2O_2 in both the liquid and gaseous state can be found in the data sheets for occupational safety (refer to the manufacturer's safety data sheets). With liquid H_2O_2 and especially with condensed and thus concentrated H_2O_2 (H_2O is more volatile than H_2O_2) there is a risk of chemical burns (skin contact) and material attack, e.g. corrosion. Materials such as cellulose, textiles or bedding (wood) heavily absorb H_2O_2. Chemical reactions lead to a reduction in the flash point of these goods. Therefore, these goods should not be treated with H_2O_2.

A major advantage of fumigation with H_2O_2 over chlorine dioxide or formaldehyde is that it leaves no visible or toxic residues. Due to its instability (thermally induced decomposition, decomposition through exposure to light, catalytic decomposition), it is split back into H_2O and O_2 after the fumigation process. In addition, the H_2O_2 fumigation process can be carried out at room temperature and atmospheric pressure, so that no pressurized container is required from a design point of view and there is no temperature or pressure load on the goods to be fumigated.

Until now, a maximum workplace concentration (MAK value) after fumigation of MAK H_2O_2 = 1.0 ppm has been common. A maximum permissible workplace limit value (AGW) in according to the Hazardous Substances Ordinance of July 21, 2021, is set at 0.5 ppm in TRGS 900.

Application limits that require special consideration
In addition to the already mentioned reduction in the flash point of the above-mentioned materials, time-dependent outgassing must be expected. In addition to absorption, certain materials - such as nylon, rubber or natural rubber (e.g. floor coverings) - can be attacked by H_2O_2 fumigation. In general, the question of material resistance to H_2O_2 must be clarified on a case-by-case basis. The surfaces of the goods must be clean, dry and have closed pores. Fumigation of heavily soiled and porous surfaces should be avoided.

4.6.2.1 Basic airlock types for H_2O_2 fumigation

A general distinction is made between the following basic variants of H_2O_2 fumigation:

- Large, walk-in airlocks (chamber in gas-tight design or stainless-steel chamber), standard usable chamber dimensions approx. 2000 mm x 1000 mm x 2000 mm (H x W x D)
  In addition to the usual preferred sizes, larger chamber dimensions of up to 2200 mm are sometimes required. This is due both to new IVC racks with larger dimensions (especially height) and to the fact that, for ergonomic or hygienic reasons, existing IVC racks do not have the ventilation pipes on the racks removed before H_2O_2 fumigation, for example.
- Small pass-through airlocks, standard usable space dimensions approx. 560 mm x 560 mm x 760 mm (H x W x D)
- Sterilizers or suitable rack cleaning systems that act as airlocks

If sterilizers and rack cleaning systems are used as gas locks, the additional process times required for this must be considered when calculating the capacity and designing the systems. For all three variants, the H_2O_2 generator can be permanently integrated or docked as an external, mobile unit.

4.6.2.2 Design requirements

The design requirements include the mechanical design, the process engineering components and the electrical design of the H_2O_2 fumigation locks.

4.6.2.2.1 Mechanical design

The mechanical structure of an H_2O_2 lock must meet the following requirements:

- Design of lock chambers in stainless steel
- For room airlocks, the material compatibility and surface quality of walls and floors must be checked (H_2O_2-resistant epoxy resin).
- Gas-tight doors with an appropriate sealing system can be made of safety glass or stainless steel with a viewing window.
- Air-tight connection of the airlock to the building.
- Measuring nozzle or measuring line for the leak test.
- A measuring nozzle for determining the H_2O_2 concentration must be provided in the chamber or in the gas extraction line.

4.6.2.2.2 Process engineering components

The following process engineering components must be provided for H_2O_2 fumigation locks:

- HEPA filter for supply and exhaust air (inside the airlock or on site).
- Air recirculation system for gas distribution (for smaller chambers this is provided by the generator itself, for larger chambers by a recirculation system or swiveling fans in the airlock).
- Automatic valves or butterfly valves with feedback.
- Discharge of exhaust air containing H_2O_2 is only permitted through a separate exhaust air duct via the roof.
- H_2O_2 can optionally be recirculated via a catalyzer before discharge to reduce the H_2O_2 concentration in the exhaust air pipe or, if necessary, to dispense with it.
- Gas-tight shut-off dampers (in supply and exhaust air ducts).
- Both the pipework for the airlock (internal) and for the generator connection must be made of stainless steel or plastic (e.g. PP, PVC-U). Camlock couplings on the generator side are recommended to facilitate

universal applications (the dimensions of the connections must be coordinated with the generator supplier).
- If galvanized sheet steel and copper pipes (catalytically active) are used at all, special precautions must be taken to protect against material damage and to ensure effectiveness.

4.6.2.2.3 Electrical installation

The electrical design of H_2O_2 fumigation locks must meet the following requirements:
- Control and communication (control via PLC or microprocessor control, release, signal exchange, start / stop and abort signal, end of gassing, time control via validation) to the H_2O_2 generator.
- Display and operating indicators on loading and unloading side (operating indicator process running, door release, warning light).
- Door control monitoring (seal monitoring via door seal pressure, closing contact) and locking during the fumigation cycle.
- The feedback signal of the valves must be monitored.
- Power connection for the generator and optional socket in the chamber.
- Emergency stop on each side and safety devices (emergency door release) inside walk-in chambers.

4.6.2.3 Process requirements

Regarding the process requirements, the following points are considered:

Leakage test
A leak test of the airlock is recommended before a gassing cycle. This can be carried out using the H2O2 generator, for example.

Safety / environment monitoring
H2O2 is a faint-smelling gas that is heavier than air. A monitoring sensor with automatic fault indication should ideally be installed at a height of 0.5 to 1.5 meters. The sensor should be protected against mechanical damage.

H_2O_2 fumigation cycle
Figure 4-21 shows a typical, idealized H_2O_2 gassing cycle. After an initial **dehumidification** and **temperature control** of the airlock, a gaseous H_2O_2 air mixture is introduced (**fumigation**) until a desired concentration is reached. This is followed by the **plateau phase**, in which the H_2O_2 concentration is kept constant. In the following step (**aeration**), the airlock is ventilated or the H_2O_2 is removed with the exhaust air, thus completing the fumigation cycle.

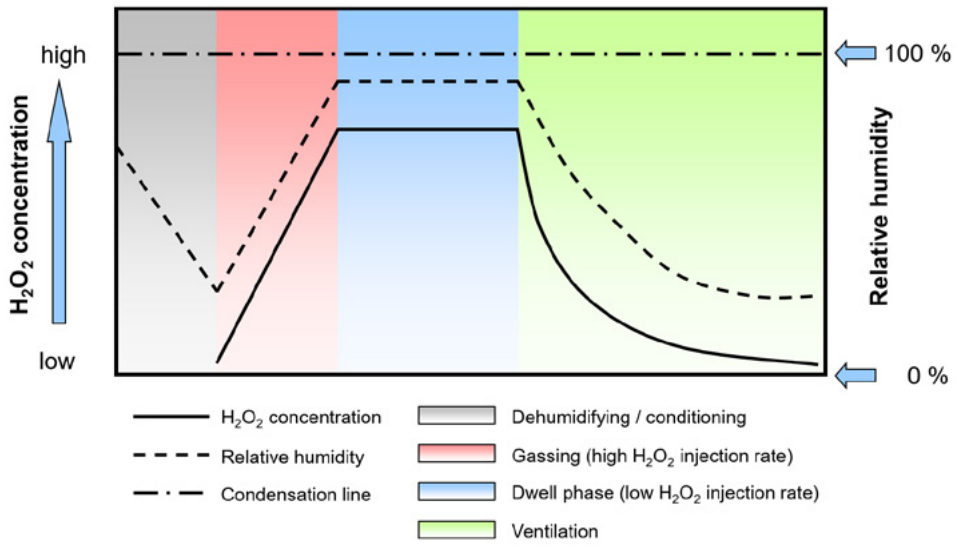


Fig. 4-21: Typical idealized process diagramm of a H_2O_2 fumigation cycle

However, it should be noted in Fig. 4-21 that the germ reduction effect is verified purely via bioindicators. At present, it is not possible for the user to measure the change in the H_2O_2 concentration over time (concentration curve) with sufficient accuracy.

A fixed H_2O_2 injection rate is specified within each of the individual cycle phases, gassing and plateau phase. Based on the selected injection rate, the effective H_2O_2 concentration in the airlock does not necessarily have to remain constant during the plateau phase, in contrast to the idealized process shown. Rather, the H_2O_2 concentration may increase or decrease. Simply extending the plateau time without re-validating the cycle can therefore lead to problems, as condensation of H_2O_2 can occur due to possible H_2O_2 supersaturation.

The volume and configuration of the load influence the required H_2O_2 injection rate, gas distribution and aeration. Materials that absorb H_2O_2, such as plastics, may require a longer aeration time in individual cases. Different loading configurations may therefore require their own program cycles. In principle, the effectiveness must be proven, whereby ideally the processes should be validated. This must be considered when planning the systems.

Cycle development
As part of the cycle development, the process parameters are adapted to the respective airlock and its load. The cycle development must be coordinated with the generator manufacturer. Clearly visible condensation must be prevented to avoid material damage. The following section contains information on the application (e.g. electronic devices) as well as the relevant parameters for cycle development:

- Avoid air humidity above the saturation state (verification e.g. via mirror / disc test). Room volume, initial temperature and initial humidity must be considered.
- Adjust the required H_2O_2 injection rate depending on the absorption behavior of the chamber surfaces or the load.
- The surface temperature and volume of the goods to be fumigated influence the maximum permissible H_2O_2 concentration without condensation (surfaces that are too cold increase the risk of condensation).
- Inflow of the warm H_2O_2 air mixture into the open space (e.g. from above) to prevent condensation on a colder wall, door or load that is too close.
- Computers or other electronic devices should be cleaned beforehand (remove dust) and switched-on during fumigation (PC fans, blower units etc. must be running).
- Heavy condensation leads to increased H_2O_2 consumption, differences in the concentration distribution, increased material attack and longer ventilation times.
- With long supply lines, heavy condensation can be prevented by preheating or heating.

Proof of efficacy / validation
The H_2O_2 concentration distribution is checked via color change of chemical indicators. Visual inspection is made possible via a viewing window in the airlock during the ongoing process.

Bioindicators are used to verify microbiological effectiveness. Usually, special spore strips suitable for H_2O_2 fumigation (*Geobacillus stearothermophilus*) with a population of 10^5 to 10^6 are used for this purpose. In consultation with the user, other bacteria (e.g. *Bacillus subtilis, Enterococcus faecium*) can also be used for this purpose. At least six of these bioindicators must be used at critical positions per cubic meter of H_2O_2 lock volume.

4.6.2.4 Batch documentation

The batch report must be created automatically by the H_2O_2 generator. In accordance with GLP-compliant work, documentation must be provided that allows the material to be processed to be assigned to a documented cycle. The log should contain information on temperature, relative humidity, air flow, operator, date, time, injection times and rates, aeration time, total H_2O_2 consumption per cycle phase, time sequence, selected fumigation program, error messages and release.

4.6.3 Requirements for treatment processes with peracetic acid

The importance of the peracetic acid process (PAA) has declined significantly as it has been replaced in many cases by H_2O_2 applications. In the following, the effect and suitability of PAA for germ reduction in PAA locks as well as application limits that require special consideration are explained.

Germ reduction with peracetic acid
In general, PAA is a wet process that is only suitable for treating goods with closed surfaces. PAA is a highly effective disinfectant that has a strong oxidizing effect. Information on the safe handling of PAA can be found in the data sheets for occupational safety (refer to the manufacturer's safety data sheets). PAA inactivates spores, bacteria, viruses and fungi even at low concentrations (0.5 - 1.5 %) and low temperatures of 4 to 20°C.

PAA is always in equilibrium with H_2O_2 and acetic acid in aqueous solution. Therefore, limit values for H_2O_2 (1 ppm) and acetic acid (10 ppm) must be observed. It can be assumed that the air limit values are complied with if no acetic acid odor is perceptible. However, visible residues may occur due to inadequate ventilation.

Safety instructions:

PAA is highly irritating to the skin and eyes of humans and animals. This must be considered during the introduction of animals (i.e. **no introduction without air-tight transport containers**).

Application limits that require special consideration

In general, the question of material resistance to PAA must be clarified in each individual case. Particular attention must be paid to the resistance of the sealing materials. For example, natural rubber, rubber, soft PVC, aluminum, iron / steel, brass and copper are not suitable.

4.6.3.1 Design requirements

The design requirements include the mechanical design, the process engineering components and the electrical design of the PAA spray gates. PAA spray airlocks are usually used in animal housing as pass-through airlocks with usable dimensions of approx. 560 mm x 560 mm x 760 mm (H x W x D).

4.6.3.1.1 Mechanical design

The mechanical design of PAA spray locks must meet the following requirements:
- Sluice and pipes made of stainless steel in hygienic design (avoidance of dead spaces and puddle formation).
- A large-mesh, removable drip grid must be provided in the airlock.
- Spray heads for fine atomization and homogeneous distribution of PAA.
- Two sealed safety glass doors locked against each other must be provided.
- Gas-tight floor drain.
- Airtight connection of the airlock to the building.
- Connection piece for feeding the PAA media line with shut-off valve.
- Storage rooms for storing PAA must be equipped with forced ventilation and a drip tray.

4.6.3.1.2 Process engineering components

The following process engineering components must be provided for PAA spray locks:
- PAA must not be enclosed in pipes between valves and must not be used in closed systems. Containers and pipes must have venting devices. The intrusion of impurities must be excluded.
- HEPA filter for supply and exhaust air (inside the airlock or on site)
- Gas-tight and PAA-resistant shut-off dampers (ventilation).
- Compressed air for atomizing the PAA must be available.
- PAA must not be fed into normal drains; suitable collection containers with separate ventilation must be available (drain must be gas-tight and can be shut off via a valve).
- Exhaust air must be discharged via a separate duct (50 to 100-fold air exchange for degassing or drying).

4.6.3.1.3 Electrical installation

The electrical design of PAA spray locks must meet the following requirements:
- Control and communication (control via PLC or microprocessor control, enable, start / stop and cancellation signal, end of cycle, time control via validation).

- Display and operating indicators on loading and unloading side (operating indicator process running, door release, warning light).
- Door control monitoring (seal monitoring via door seal pressure, closing contact) and locking during the process.
- Feedback from the valves must be monitored.
- Fill level monitoring of the storage / collecting container.
- Emergency stops on each side.

4.6.3.2 Process requirements

The following process requirements are placed on PAA spray locks:

- Visual assessment of the distribution of the spray mist.
- Cycle development: spraying time, PAA quantity, aeration time.
- Loading volume and configuration: Avoid puddles forming on the material to be treated.
- Proof of efficacy with bioindicators.

4.6.3.3 Batch documentation

The batch record must be created automatically by the control system. In accordance with GLP-compliant work, documentation must be provided that allows the material to be processed to be assigned to a documented cycle. The log should contain the temperature, operator, date, time, PAA consumption, aeration time, selected spray program, error messages and release.

5 Structural Requirements

The prerequisite for the proper functioning of all systems used in cage processing are professional planning (see also chapter 6.1), structural preparation and the correct coordination of the operating equipment supply and disposal systems.

Ideally, this is done for a new building, where a targeted coordination of all factors can take place before construction begins.

Since more building renovations are to be expected in the future due to the aspect of resource / climate protection, early coordination between all those involved is a high priority in this case. This lays the foundation for later sustainable operations. The use of renewables instead of fossil fuels is fundamentally important.

The energy source electricity is used, for example, in central steam generators and even for heating up cleaning systems.

At this point, reference is made to an early life cycle assessment with the evaluation parameters according to DIN EN 15978 or 15804 to take into account the entire life cycle of the building, including operation, maintenance and dismantling of all components, when considering the building holistically.

5.1 Distribution of responsibilities

When purchasing systems for cage processing, it should be noted that connecting the systems to the installations (supply air, exhaust air, steam, water, compressed air, electricity, etc.) is the responsibility of the respective construction trades. Shut-off valves are on-site services.

The client or operator must provide the manufacturer with the necessary documents for the preparation of the construction preparatory drawings.

5.2 Utility and supply requirements

The manufacturer must inform the client or operator in good time which equipment must be provided, of what quality and to what extent, and which on-site measures must be taken for the installation, connection and operation of the treatment systems.

The requirements specified by the manufacturer regarding the quality and scope of the operating equipment, including supply and disposal systems, must be complied with by the operator. Otherwise, inadequate functions must be expected, such as inadequate cleaning, rinsing and drying performance, insufficient sterilization, longer batch times, damage to the reprocessed items and damage to the equipment.

The following should be noted regarding the individual media and interfaces:

5.2.1 Water, softened water and demineralized / deionized (DI) water

Water first means drinking water. When used for cage processing, water must meet the following required limits. In some cases, it needs to be processed first, e.g. by softening, demineralization.

Softened water

Appearance	colorless, clear
Total hardness up to	3° d or 0.5 mmol/l
pH value	5–9
Vapor residue	< 500 mg/l
Chlorides	< 100 mg/l

To avoid stains on the items to be treated caused by dissolved salt from the softened water, AK KAB recommends using demineralized water at least for the final rinse.

Fully demineralized water (= DI water)

Demineralized water is understood to be water treated as follows, as it can also be used to feed pure steam generators (in accordance with EN 285):

Appearance	Colorless, clear without deposits
Electrical conductivity (at 25 °C)	≤ 5 µS/cm
Hardness (sum of alkaline earth ions)	≤ 0.1°d or ≤ 0.02 mmol/l
pH value	5–7.5
Vapor residue	≤ 10 mg/l
Chlorides	≤ 2 mg/l
Phosphates (P_2O_5)	≤ 0.5 mg/l
Silicates as SiO_2	≤ 1 mg/l
Iron	≤ 0.2 mg/l
Lead	≤ 0.05 mg/l
Cadmium	≤ 0.005 mg/l
Heavy metal residues (except iron, cadmium, lead)	≤ 0.1 mg/l

Note:
To optimize the entire mechanical treatment process, the use of demineralized water is recommended (to prevent corrosion and staining, see chapter 9). In contrary to above mentioned data, experience shows that demineralized water with an electric conductivity of approx. 15 µS/cm is tolerable.

The water connection must be made in compliance with the DVGW regulations (Technical Rules for Water Installations) or local equivalent. The material compatibility of the pipework must be considered.

For the water supply, the operator must be informed by the manufacturer of the construction preparation before delivery:

- Minimum overpressure or flow pressure at the transfer point to the system
- Connection dimensions
- Design capacity (peak value)
- Maximum consumption per hour
- Water quality / hardness
- Water temperature

5.2.2 Steam

The steam pipes must be fitted with a filter and drained directly before the system. Horizontal pipes must be laid with a gradient of 1:50 towards the point of use. The steam pipes must be insulated against heat loss in accordance with the German Thermal Insulation Regulation or local equivalent.

5.2.2.1 Heating vapor

Steam quality required for heating the cleaning systems:

Table 5-1

Parameters	Units	Max. values
Vapor dryness	kg steam/kg steam + water	> 0.95
Total hardness	mmol/l	≤ 0.02
pH value	pH	5–9
Conductivity (at 20 °C)	µS/cm	≤ 10
Appearance		colorless, clear
Chlorides (Cl-)	mg/l	-
Iron	mg/l	≤ 0.1
Cadmium	mg/l	-
Lead	mg/l	-
Heavy metal residues (except iron, cadmium and lead)	mg/l	-
Silicates as SiO_2	mg/l	≤ 15
Phosphates (P_2O_5)	mg/l	-
Dirt particles	Size in µm	≤ 300

5.2.2.2 Clean steam

Quality of the vapor that comes into direct contact with the goods (see also vapor specification according to EN 285). This applies especially to steam sterilization and steam drying in cleaning systems:

Table 5-2

Parameters	Units	Max. values
Pressure for steam sterilisation	cash	2.4–2.8
Vapor dryness	kg steam/kg steam + water	> 0.95
Total hardness	mmol/l	≤ 0.02
pH value	pH	5–7
Conductivity (at 20 °C)	µS/cm	≤ 3
Appearance		Colourless, clear without deposits
Chlorides	mg/l	≤ 0.1
Iron	mg/l	≤ 0.1
Cadmium	mg/l	≤ 0.005
Lead	mg/l	≤ 0.05
Heavy metal residues (except iron, cadmium and lead)	mg/l	≤ 0.1
Silicates as SiO_2	mg/l	≤ 0.1
Phosphates (P_2O_5)	mg/l	≤ 0.1
Non-condensable gases	ml/l	≤ 35

Note: Whether a steam quality can be achieved by filtering heating steam that does not fully correspond to pure steam quality, but is nevertheless sufficient for the application in question, must be checked on a case-by-case basis (see “AK-Steri-Dampf, Leitfaden für die Praxis”).

5.2.2.3 Requirements of heating steam and clean steam

The manufacturer must provide the customer with the following information:
- Minimum overpressure at the transfer point to the system
- Connection dimension (e.g. DN 20 PN 16)
- Design capacity (peak value)
- Maximum consumption per hour
- Vapor quality (see above)

Depending on the steam quality required as mentioned above, special materials (preferably stainless steel) should be used for steam pipework on site. The system manufacturer must be informed of the material quality of the pipework used.

Very fast pressure control stations must be used to maintain the required steam pressure during sterilization, as very rapid changes between maximum and minimum steam requirements occur in the sterilizer. It has also been shown that the use of high-speed steam generators is not recommended.

5.2.3 Condensate

When operating a system with steam, condensates are produced which can be returned if necessary. The amount of condensate produced, and the pipe dimensions must be communicated to the operator.

5.2.4 Compressed air

The compressed air (industrial quality - filtered and oil-free) is used for pneumatic work and control processes as well as for building up the support pressure during the sterilization of filled drinking bottles. The compressed air must be available at an overpressure of 6–8 bar at the transfer point.

Quality of compressed air for pneumatic control processes:

Max. size of dirt particles	40 µm, according to ISO 8573-1 class 5
Dewpoint	+3 °C, according to ISO 8573-1 class 4
Max. oil content	0.1 mg/m³, according to ISO 8573-1 class 2

Quality of compressed air for pneumatic decapping processes of drinking bottles (process air):

Max. size of the dirt particles	1 µm, according to ISO 8573-1 class 2
Dewpoint	+3 °C, according to ISO 8573-1 class 4
Max. oil content	0.01 mg/m³, according to ISO 8573-1 class 1

The operator must be informed by the manufacturer:
- Connection dimension
- Design capacity (peak value)
- Maximum consumption per hour

5.2.5 Electricity

The connection conditions in accordance with **DIN EN VDE 0100** must be observed. The following mains connection must be provided on site.

Nominal voltage	3 x 400 V	(3/N/PE)
Rated frequency	50 Hz	

(any deviations must be reported to the manufacturer)

A lockable main switch must always be provided on site in the electrical supply line of each system.

The operator must be informed by the manufacturer:
- Connected load (max. power consumption)
- Protection
- Consumption per hour (maximum consumption)

5.2.6 Network connection for remote access and diagnosis

To set up remote access and diagnosis, a network connection must be provided within the range of the systems for connecting the device control.

5.2.7 Wastewater

DIN 1986 (drainage systems for buildings and properties) basically applies here. If special local wastewater regulations are to be considered, the customer must notify the manufacturer. The manufacturer on his / her part must inform the customer about the required connection dimensions and amount of wastewater to be expected. The drainpipes must be acid-resistant.

In addition to central wastewater neutralization on site, control and regulation of the wastewater temperature and pH value can also be provided on the device side.

5.2.8 Process exhaust air

The cleaning chambers / cleaning tunnels must be vented to the outside via an internal fan or an on-site exhaust fan using a separate on-site pipe. The extracted air contains water vapor / fumes and possibly also cleaning agent residues. The ducts must therefore be watertight and temperature and acid resistant. A suitable discharge of condensate must also be ensured.

In the interests of sustainable operation, the heat from the resulting process exhaust air should be recovered using appropriate heat exchangers, which can be installed on the device or on site.

The exhaust air from the sterilization process (exhaust air from the vacuum pumps) should be led outside in a second separate line to prevent odor nuisance. The same applies to the exhaust air from H_2O_2 / PAA material airlocks. The type of exhaust air opening and its location in relation to surrounding buildings should be selected so that even in unfavorable weather conditions, there is no return via the air intake nozzles for air conditioning systems or open windows.

The manufacturer must provide the customer with information on:

- Volume flow in m3/h
- Exhaust air temperature
- Exhaust air humidity
- Connection dimension

For pipes with higher pressure losses, an additional fan may have to be installed on site at the end of the pipe.

To maintain the desired relative room air pressure, the various exhaust air volumes (general exhaust air from the supply center, exhaust air from machines, exhaust air from handling bedding) must be considered.

Note: Special care is required when selecting the material of the pipes or ducts which have contact with H_2O_2.

5.2.9 Heat dissipation

Heat emitted by the systems into the room must be dissipated. If the heat is dissipated by extraction of air, fresh air must be supplied to prevent overheating (> 50 °C) in the unit room. When designing the ventilation systems, not only the heat of the machines is to be considered, but also the heat coming from the goods being processed.

The manufacturer must provide the operator with information on:

- Heat loads emitted by the systems (e.g. in kW)

5.3 Construction dimensions, ceiling load-bearing capacity and pit

The manufacturer must provide information on the installation dimensions, weight and operational weight of each processing machine so that room dimensions, structural load of the slab and ceiling can be calculated accordingly. This also applies to the minimum dimensions and loads of the transport route (façade openings, corridors etc. to the installation site). A potential replacement of the machines at a later time, after the building is finished, must also be taken into account.

For systems that can be driven over at ground level, a waterproof pit must be provided on site. The edges of the pit must be protected with stainless steel reinforcements and the pit must be designed with pit drainage and odor trap according to manufacturer's instructions. A common pit depth ranges up to 250 mm.

The manufacturer must provide the customer with information on:

- Required pit dimensions with position of the drain

5.4 Maintenance access and service room

For maintenance work within the system, no on-site installations (e.g. ventilation ducts, pipework, cable trays) may obstruct maintenance work, particularly at the technical and maintenance access points specified by the manufacturer. For accessible unit rooms, lighting and a socket outlet with IP54 must be provided on site.

5.5 Dosing system for process chemicals

The dosing of process chemicals can be decentralized or centralized. In case of decentralized dosing, the containers are usually placed next to the cleaning systems or, if necessary, in the unit room. For the delivery of process chemicals in large containers, the access doors must be sufficiently large (observe barrel and pallet dimensions).

Centralized dosing systems offer the advantage of supplying various cleaning systems with process chemicals from large containers. The dosing centers are usually housed in separate rooms. These should be easily accessible for the delivery of large containers. The decision on the type of dosing system must be considered at the planning stage, as this has an influence on the structural requirements. The supplier of process chemicals should be involved in the planning early on.

Dosing by means of centralized dosing systems can be conducted either by direct connection with the cleaning systems (Fig. 5-1) or by using storage tanks (Fig. 5-2).

When storing process chemicals, the relevant legal requirements according to the Water Resources Act must be considered. The provisions of the safety data sheets and, if applicable, the Hazardous Substances Ordinance must also be observed. The use of drip trays, eye showers, etc. must be decided on accordingly.

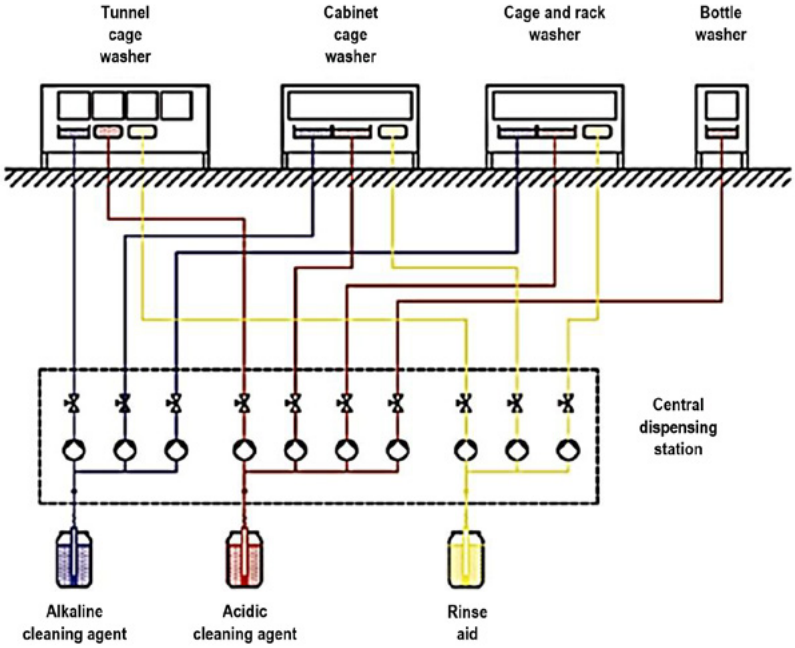


Fig.5-1: Example of a dosing center without storage container

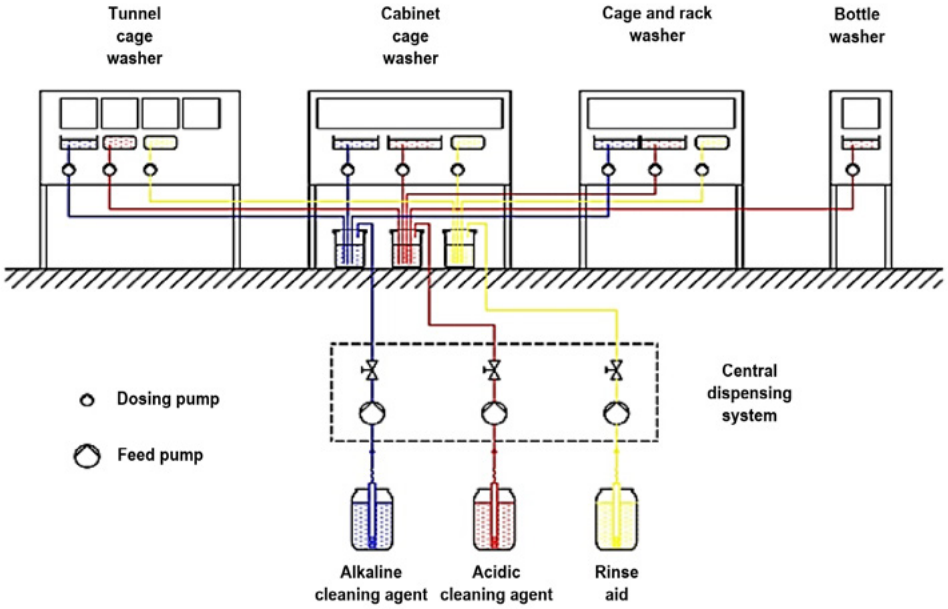


Fig. 5-2: Example of a dosing system with storage containers

5.6 Connection and consumption values

In order to prepare for construction, it is necessary to know about installation and consumption data of the processing machines. This information must be provided by the machine manufacturer. The following table might be a helpful guide:

Table 5-3

Shortname	Naming	Nominal diameter	Pressure	Temperature	Connection[1]	Consumption
FD 1	Heating vapor	DN	bar	---	kg/h	kg/h
FD 2	Clean steam	DN	bar	---	kg/h	kg/h
KO	Condensate	DN	bar	°C	kg/h	---
KW	Cold water	DN	bar	---	m³/h	m³/h
HW	Hot water	DN	bar	°C	m³/h	m³/h
VE	Demineralized water	DN	bar	---	m³/h	m³/h
DL	Compressed air, oil-free	DN	bar	---	Nm³/h	Nm³/h
A	Wastewater	DN	---	°C	l/min	---
BA	Floor drain	DN	---	---	---	---
ALK	Exhaust air chamber / tunnel	DN	Pa	°C	m³/h	---
WA	Heat dissipation	---	---	---	kW	kWh
EL	Electrical connection 3 / N / PE 400 V AC 50 Hz	---	---	---	kW	
		Protection			A	

[1] Connection could also stand for design output or peak load.

6 Operation and Operate

After describing the technical relationships and requirements in the previous chapters, the following section will explain which aspects need to be considered when operating the machines to achieve the desired result. The aspects of sustainability (see Chapter 8) and the client's specifications (e.g. DGNB and / or EGNATON certification) must also be considered at an early stage in the planning process.

6.1 Influence of planning on operation

At the latest when an animal facility is commissioned, it will become clear how mature the planning of the machines and the operating concept is. The planning itself is very complex and highly dependent on the individual circumstances of each case. Even if not all aspects of complete planning can be considered in this brochure, some important aspects are presented below.

Cleaning systems for animal facilities are usually installed in a supply center. To ensure efficient operation, the systems must be well arranged in relation to each other and according to the room dimensions, that corresponds with the flow of material (please refer to chapter 2). For this reason, the following points must be included in an iterative planning process already in the early planning phase.

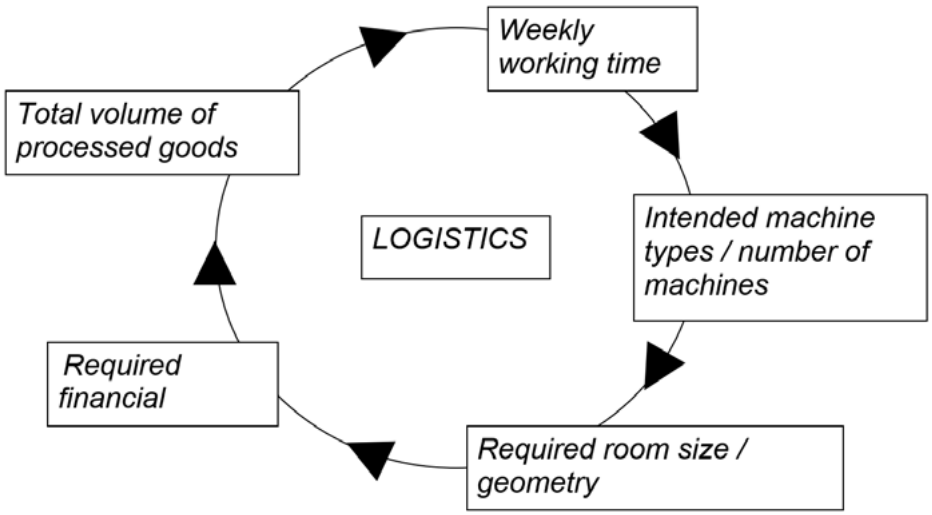


Fig. 6-1: Iterative planning process

It is first essential for dimensioning the machines to determine the definite capacity of the different goods to be processed (please refer to chapter 3) in the animal facility. For this purpose, it is necessary to know not only the number of goods (e.g. cage bases, wire lids, water bottles, trolleys, etc.), but also the cleaning interval (calculation of capacity!). This data as well as the weekly working hours will define potential machine concepts (type and number of machines) and with that the deployment of personnel (not further discussed here) as well as spatial and financial requirements. Ergonomic aspects (conveying velocity, working heights, "arm length", weights, etc.) and well approved loading models must also be considered.

When planning in detail, the following aspects must also be considered:

- Downtime and response times
- Redundancies
- Areas as storage space / buffer / short-term storage within the supply center
- Areas for process chemicals and dosing systems
- Accessibility for service
- Replacement option / façade opening for large, non-dismountable system components
- Occupational safety regulations / health and safety measures
- Cleaning and, if necessary, disinfection of the wash-up area and the equipment placed therein

On the one hand, the supply centers are generally highly technical areas, but on the other hand, they involve rather stressful activities (cleaning work, handling materials contaminated by feces and urine, odor and noise

pollution, etc.). The quality of the work carried out is of great importance for the operation of the animal facility. The operation of the systems must therefore be designed to be simple in order to prevent incorrect operation as much as possible through technical precautions.

Operator safety is also an important aspect to be considered:

- Body parts getting caught in moving machine parts
- Temperatures of the goods being processed
- Temperatures of the external surfaces of the cleaning systems
- Chemical vapors
- Temperature at the workplace
- Relative humidity at the workplace
- Sound pressure level at the workplace
- Working heights of the various machines (800 and 900 mm)
- Dust and allergen exposure

6.2 Commissioning

Initial commissioning must be carried out by the manufacturer or an expert appointed by the manufacturer. All regulations, control and safety devices must be checked for proper function and correct adjustment.

6.3 Handover

The manufacturer must provide the operator of the system with the accompanying documents, including the declaration of conformity, operating instructions and maintenance documents and, if agreed on, a performance certificate (see chapter 7) for the machine.

Remark:
For large systems, a trial run is recommended before handover. If this is desired, this should be specified when requesting a quote. A factory acceptance test at the manufacturer's site may be useful.

6.4 Operating staff

The personnel responsible for operating the system must be instructed in this task by the manufacturer when the system is handed over and made familiar with the operating instructions. The operator is responsible for providing adequate training in how to operate the system (operating instructions). The operator also prepares a risk assessment of the workplace (according to Section 5 of the Occupational Safety Act, Section 3 of the Industrial Safety Ordinance, Section 7 of the Biological Agents Ordinance and Section 7 of the Hazardous Substances Ordinance).

In this context, it is worth considering at an early stage whether and which work steps can be partially or fully automated.

6.5 Device log

A device log must be kept in which unusual occurrences (e.g. malfunctions) and regularly occurring work (e.g. maintenance and repairs) as well as any changes to the set parameters are recorded.

6.6 Operating instructions

The operating instructions must be available in the relevant national language and must be stored as part of the system in the installation room in an easily accessible place so all operating staff can consult the guide as needed. A short version of the operating instructions must be displayed in a clearly visible location in the immediate operating area of the system.

6.7 Standard Operating Procedure (SOP)

The standard operating procedure for a system contains all important information for proper operation in a generally understandable form. It is usually created by the operator based on the manufacturer's user information. Appropriate templates from the manufacturer, which can be adapted to a specific on-site situation, are helpful for the operator.

6.8 Setting values of the process parameters

When operating the machines, it is recommended to keep the parameters specified in the operator guide and selected during the test phase. These parameters are, for example temperature, dwell time, conveying velocity, concentration of process chemicals, and drying time. If, due to local conditions, it proves necessary to adjust those parameters, it must be recorded in the machine log and, where required, verified with another test phase.

Examples of program sequences and parameters of the most common programs for cleaning systems and steam sterilizers are shown in the following tables:

Discontinuous cleaning systems

Table 6-1

Device	Cage cabinet cleaning system	Cleaning system for cages, racks and transport systems	Bottle washer
Cleaning temperature	approx. 55–65 °C	approx. 55–65 °C	approx. 55–65 °C
Cleaning time	approx. 120–180 sec.	approx. 120 sec.	approx. 60–120 sec.
Rinse temperature	approx. 80–90 °C	approx. 80–90 °C	approx. 80–90 °C
Rinsing time	approx. 30 sec.	approx. 30 sec.	approx. 20–30 sec.
Drying time	-	approx. 60–210 sec.	-
Ventilation	approx. 120 sec.	approx. 180 sec.	-
Cleaner concentration	2–5 ml/l	2–5 ml/l	2–5 ml/l

Continuously operating cleaning systems

Table 6-2

Device	Cage belt cleaning system
Cleaning temperature pre-cleaning zone	approx. 40–50 °C
Pre-cleaning time	approx. 60 sec.
Cleaning temperature Cleaning zone	approx. 55–60 °C
Cleaning time	approx. 120 sec.
Rinse temperature	approx. 80–90 °C
Rinsing time	approx. 50–90 sec.
Drying temperature	approx. 40–100 °C
Drying time	approx. 120–240 sec.[1]
Cleaner concentration	2–5 ml/l
Rinse aid concentration	0.5–2 ml/l

[1] The drying time depends largely on the desired drying result.

Steam sterilizers

Table 6-3

Programs	Procedure	Fractiona-tions	Sterilisation temperature [°C]	Contact time [min][2]	Drying time [min]	Batch time
[min]						
Airlocks with steri-lization	VOVV / VOT	1	134	3	1	approx. 20
Solid goods, racks	VOVV / VMT	1	134	5	2–5	approx. 30
Cages, feed and bedding	FRVV / VMT	2–4	121	20	10	approx. 65
Polycarbonate cages	FRVV / VMT	2–4	118	40	10	approx. 85
Filled polycarbona-te drinking bottles	VOVV / DLK	1	118	40	Cooling < 80 °C	approx. 180–220
Filled drinking bottles made of high-temperature-resistant plastics [3]	VOVV / DLK	1	121	20	Cooling < 80 °C	approx. 165–205
Empty drinking bottles made of high-temperature resistant plastics[3]	VOVV / VMT	1	121	20	2–5	approx. 50
Animal carcass	FRVV / DEA -VOT	2–4	121–134	20–60	---	approx. 60–120
Thermolabile goods	FRVV / VMT	4	75[1]	20	10	approx. 60

[1] At 75 °C there is no sterilization, only germ reduction.
[2] Time during which the sterilization temperature takes effect.
[3] e.g. polysulfone, polyetherimide and polyphenylsulfone

6.9 Testing and inspection

The routine measures prescribed in the operating instructions and in the standard operating procedure (SOP) should be executed at the indicated intervals. The measures include, for example:

- Check concentration, temperature and, if necessary, the pH value or conductivity of the cleaning solution
- Replacement of the detergent solution by emptying the cleaning tank (see chapter 4.3.2.2.4)
- Regular cleaning of the sieves and containers
- Check the nozzles for free passage and correct spray position (see also notes on maintenance and perio-dic inspection in chapter 6.11)

6.10 Check of cleaning, drying and steam sterilization results

Effectiveness tests are of great importance for operation. For the performance assessment of cleaning sys-tems, these must be carried out in accordance with Chapter 7. For germ reduction processes with H_2O_2 / PAA, information on performance assessment is contained in Chapter 4.6.

6.11 Maintenance measures

To ensure the safe and reproducible operation of the systems, maintenance measures must be carried out regularly as prescribed by the manufacturer. This includes all necessary inspection, maintenance and repair work (see definition according to DIN 31051). These may only be carried out by qualified and trained personnel. The following points must be considered when carrying out the work:

- Compliance with safety regulations
- Checking the process parameters
- Checking whether the appropriate process chemicals are used in the correct concentration.
- Using the spare parts recommended by the manufacturer

If components are replaced that could cause a change in the process parameters of the cleaning process, an extraordinary inspection must be arranged.

It is strongly recommended that you negotiate a maintenance contract with the manufacturer, as maintenance work requires special expertise and tools. This can also be a prerequisite for enforcing warranty claims. A correct evaluation of the different maintenance contract offers, for example in connection with service specifications, is only possible if the maintenance services to be offered are sufficiently specified in terms of type and scope and are therefore comparable.

Note: In addition to the maintenance measures in the form of a maintenance contract by the manufacturer, the periodic inspection of the cleaning, decontamination, rinsing and drying results is also recommended, particularly for type-tested cleaning systems in accordance with AK KAB. The criteria for periodic on-site inspections are described in detail in chapter 7.6.3.

6.12 Emergency plans

Geopolitical events and crises can lead to unexpected bottlenecks at short notice, meaning that the processing of animal facility systems and thus the care of the animals is very limited or no longer possible. Examples of this can include a limited supply of fossil fuels for steam generation, problems in the supply chains and limited staff availability, which can arise, for example, due to pandemic events.

For these emergencies, it is therefore advisable to establish emergency plans early on together with the relevant departments and authorities and to define temporary solutions.

Examples that can be considered for emergency plans:

Limited supply of fossil fuels for steam generation

- Reduction (where possible) and centralization of housing capacities
- Extension of cage change intervals
- Assess the need for backup systems for steam generation or equipment heating with electrical energy
- Review the use of irradiated feed and / or bedding
- Review the temporary use of disposable material

Problems with the supply chains

- Increase stocks of consumables (e.g. bedding, feed and process chemicals, etc.)
- Ensuring supply chains through several suppliers

Note: The above examples are not intended to be exhaustive. All specifications that are applied in an emergency must be agreed on in advance with the relevant specialist departments (e.g. in relation to animal welfare and hygiene), the authorities and representatives of the scientific community.

7 Performance Evaluation Checks for Cleaning Systems

To secure a flawless operation once the system is installed, it is necessary to check the washing, decontamination, rinsing, and drying performance during the acquisition phase of the project. Please find below principal requirements and methods for performance evaluation:

7.1 Requirements

7.1.1 Cleaning

Washing generally means the process of removing soiling off objects to a degree required for further processing or intended item use.

7.1.2 Decontamination

The decontamination process consists of cleaning and process-related germ reduction. This is important for the further use of the processed goods - even with subsequent sterilization - as this requires a defined hygienic status. This is achieved by reducing the microorganisms by at least 5 powers of ten (5 lg levels) by definition.

7.1.3 Rinsing

The rinsing must ensure that the residues of process chemicals on the processed goods are sufficiently removed. When using alkaline or acidic cleaners, no residual alkalinity or acid must be detectable on the surface of the processed goods using pH indicators. In individual cases, such as in toxicological studies, it may be necessary for the user to check whether special requirements must be placed on the tolerable residues.

7.1.4 Drying

Drying of the goods to be processed is understood to mean the removal of water from all surfaces inside and outside the cleaning system that is necessary for further processing or the intended use (tolerable residual moisture). The user must determine which of the above-mentioned degrees of drying are required, or whether drying is required at all, depending on his or her individual circumstances before obtaining a quote.

7.2 Test procedures for cleaning and decontamination of cages, racks and wire lids

Test specimens are used in a specific arrangement for both cleaning and decontamination. Although soiling mainly occurs on plastic surfaces, stainless steel test specimens are used instead of plastic test specimens for reasons of low adhesion and a potentially disruptive interaction between test soiling and test specimen material. Stainless steel test specimens have already proven their worth in tests on commercial dishwashers (DIN 10510, DIN 10512, EN 17735) and large-scale decontamination systems (AK-BWA brochure, 9th edition 2022; DIN 58955 series of standards) in the field of medicine.

Please find below a description of the setup of test specimens, followed by a description of test methodology.

7.2.1 Setup of test specimen and test parameters

The test specimens must be attached at a distance (approx. 5 mm) from the surface of the material being processed. This ensures that the test specimens are completely washed, including on their non-contaminated back, and is intended to prevent evaluation errors caused by gaps forming between the test specimen and the surface. The use of stainless steel screws and spacer nuts is recommended for this purpose. The contaminated side of the test specimen must face in the same direction as the surface of the material being processed that is to be cleaned.

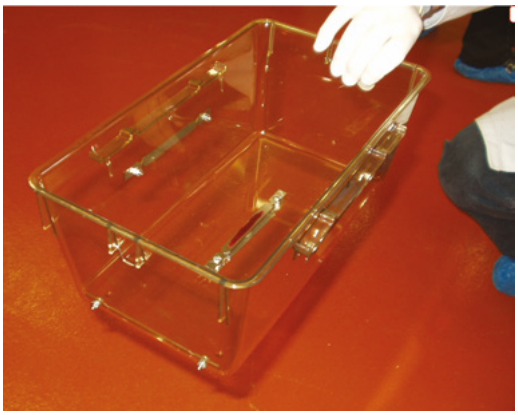


Fig. 7-1: Example test cage

7.2.1.1 Cage bases

7.2.1.1.1 Number of test specimens per cage base

Five test specimens per cage base

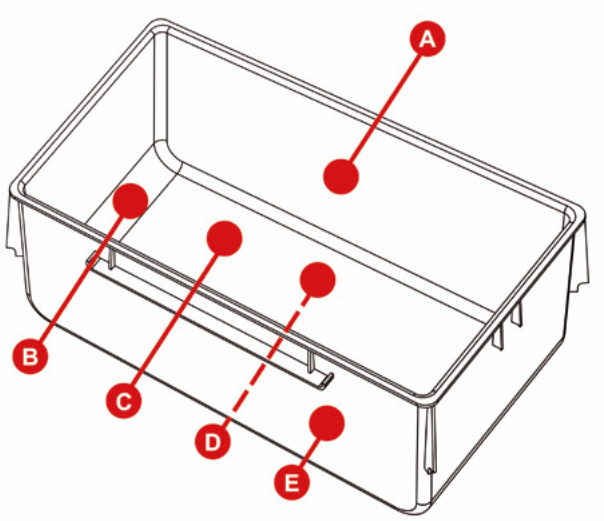


Fig: 7-2: Position of the test specimen on cage base

7.2.1.1.2 Test setup

1 inside on the long side wall, horizontal (A)

1 inside in a corner (B)

1 inside center of the floor (C), 1 outside center of the floor (D)

1 outside on the long side wall, horizontal (E)

7.2.1.2 Wire lid

7.2.1.2.1 Number of test specimens per wire lid

Two test specimens per wire lid

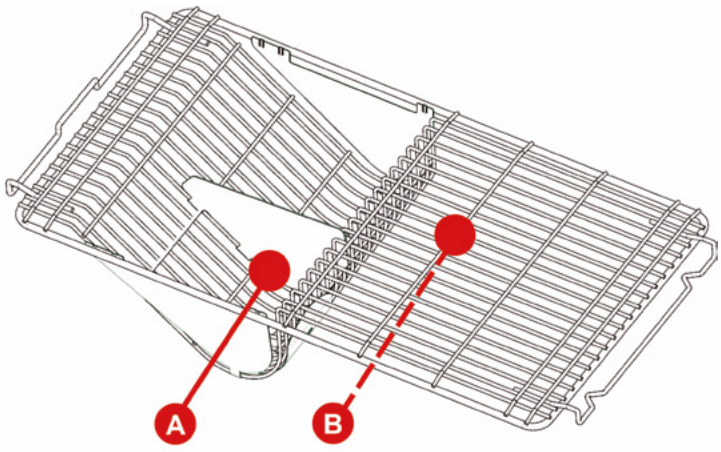


Fig: 7-3: Position of the test specimen on wire lid

7.2.1.2.2 Test setup

1 at the feed hooper (at the lowest point) (A)
1 on flat wire lid surface (inside) (B)

7.2.1.3 Racks (cage racks as well as storage and transport racks)

7.2.1.3.1 Number of test specimens per rack

6 test specimens per IVC rack
8 test specimens per storage and transport rack

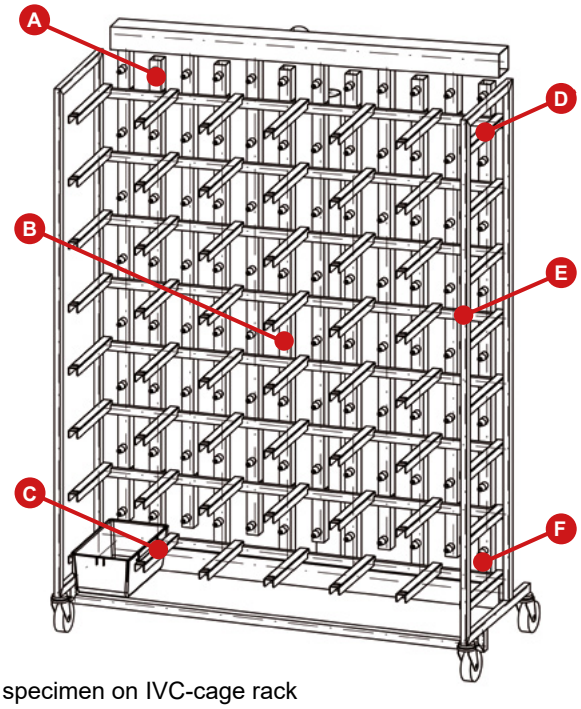


Fig: 7-4: Position of test specimen on IVC-cage rack

7.2.1.3.2 Test setup for IVC racks

2 on the guide rails (C, D)
3 in the exhaust air opening area (A, B, F)
1 at the front on the outside of the rack (E)

Cable ties in conjunction with suitable spacers may be suitable for fastening the test specimens. The contaminated side of the test specimen must face in the same direction as the surface of the material to be cleaned.

Remark:
The use of the test specimens to assess the cleaning or decontamination performance in the air plenums of IVC racks does not appear to be meaningful for two reasons:

- Soiling in the plenums depends on many complex influencing factors (feed used, bedding, air exchange rates, positive / negative pressure operation, etc.), which cannot be standardized with reasonable effort for the test methodology described.
- The geometry of IVC racks varies greatly depending on the manufacturer, which makes standardized testing methods difficult.

For these reasons, the evaluation of the cleaning performance in IVC air plenums should be assessed purely optically without test specimens.

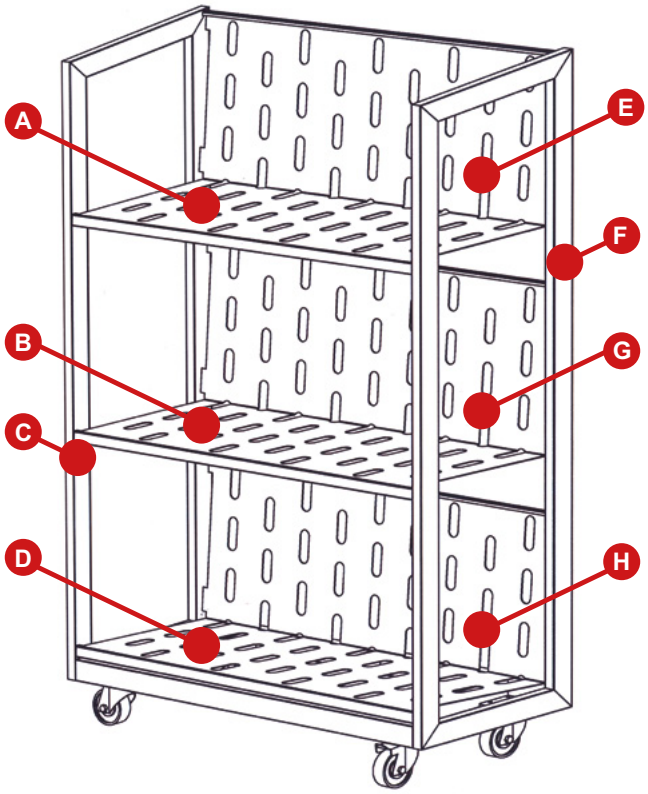


Fig: 7-5: Position of the test specimen on storage and transport rack

7.2.1.3.3 Test setup for storage and transport racks

6 on the 3 mounting levels (approx. 2 test specimens per level on the mounting level and rear wall, preferably in the sheet metal edges / corners in the case of inclined levels) (A, B, D, E, G, H)

2 on the rack frame, inside and outside (C, F)

7.2.1.4 IVC filter hoods

Due to their different designs, IVC Filter hoods are special cases that must be examined individually and therefore cannot be considered here.

Nevertheless, testing is strongly recommended. The number and arrangement of the test specimens is a case-by-case decision.

7.2.2 Test procedures for evaluating the cleaning of cage bases, wire lids and racks

Test specimens contaminated with test soiling are used to evaluate the cleaning. The number of processed items and test specimens required for the test and the number of consecutive batches are specified in section 7.6. The evaluation is carried out visually.

The cleaning result is evaluated in the following stages:

Clean, i.e. there is no recognizable test soiling on the surface of the test specimen.

Slightly soiled, i.e. slight residues of the test soiling are present on the surface of the test specimen

Dirty, i.e. 1/3 of the originally contaminated surface of the test specimen is still covered with the test soiling

Very dirty, i.e. at least 2/3 of the originally contaminated surface of the test specimen is still covered with the test soiling

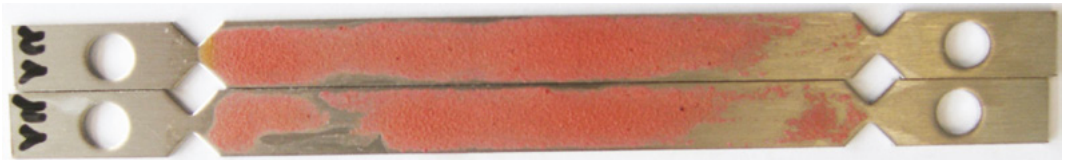


Fig. 7-6: Illustration of test specimens with different cleaning results

Note:
Due to the methyl red dye in the test soiling, any residues of this soiling do not have a reddish but a yellowish appearance when alkaline cleaning agents are used.

Against this background, the following acceptance criteria are defined:

Table 7-1

Material to be processed	**The cleaning process is rated as sufficient if**
Cage base	No more than **10 %** of the test specimens used are **slightly soiled**.
Wire lid	
Racks (storage and transport racks)	
IVC racks (exterior)	No more than **20 %** of the test specimens used are **slightly soiled**.
IVC filter hoods	

These acceptance criteria are general recommendations. It cannot be ruled out that higher requirements may be necessary in individual cases due to special hygiene requirements.

7.2.2.1 Producing the test soiling

The test soiling is prepared according to the following procedure:

Weigh 10 g urea, 5 g Serva 11930 and 10 g Sigma M-2378 and mix all with 3 g vegetable oil in a 250 ml beaker. Then add 13 g of cellulose and 1 g of calcium carbonate, followed by 0.3–0.4 g of methyl red for coloring.

These ingredients are then mixed with 100 ml distilled water. Subsequently heat the entire mixture up while stirring to approximately 50 °C in order to avoid clumping. Furthermore, the test soiling is kept at a constant temperature and stirred during the whole process to prevent segregation. By using a pipette 0.1 ml of the mixture is applied to each test strip and dried for 24 hours at room temperature, before being put in a drying cabinet at 80 °C for another two hours.

Table 7-2

Chemical	Source of supply
Urea Methyl red Serva 11930 (Albumin bovine fraction V pH 7.0) Sigma M-2378 (Mucin Type II Porcine Stomach) Cellulose microcrystalline for thin layer chromatography	FLUKA chemicals catalogue, CH-Buchs
Calcium carbonate precipitated	Carl Roth GmbH and Co., Karlsruhe
Mazola 100 % germ oil (cholesterol-free) or any other 100 % germ oil	Grocery store

7.2.2.2 Test specimen for cleaning evaluation

The test specimens used are plates made of stainless steel X5 CrNi 18-10 in accordance with DIN 10088-1, cut 80 grain, size 10 mm x 130 mm (e.g. Simicon, Munich). The area intended for soiling is 10 mm x 100 mm. Before application, the test specimen is visually inspected for any soiling. When applying the test soiling, it must be ensured that it does not get onto the side surface. To ensure even distribution over the surface, the test specimens must be thoroughly degreased. Repeated use is only possible after proper preparation. After contamination, they are stored in a dry place. The storage time of the contaminated test specimens before use in the cleaning system must be limited to a maximum of 1 week.

7.2.3 Test procedures for evaluating the decontamination of cage bases, wire lids and racks

This is a test procedure for evaluating chemical-thermal decontamination processes for processing goods mentioned in chapter 3.1. The number of processing items and test specimens to be used for the test as well as the number of consecutive batches are specified in section 7.6. The process test consists of a test with germ carriers.

7.2.3.1 Test organism

Enterococcus faecium ATCC 8459 (e.g. Oxoid GmbH, Wesel) is used as the test organism. The bacterial count of the bacterial suspension for the preparation of the test soiling must be at least 1x 10^8 CFU/ml. The test organism is cultivated in accordance with DIN EN 12353.

7.2.3.2 Germ carriers

Stainless steel plates X5 CrNi 18-10 in accordance with DIN 10088-1, ground 80 grit, size 10 mm x 130 mm, are used (e.g. Simicon, Munich). The area intended for contamination is 10 mm x 100 mm.

7.2.3.3 Contamination

9 ml defibrinated sheep blood (e.g. Acila AG, Mörfelden-Walldorf) is mixed with 1 ml germ suspension. The prepared test soiling is applied to the germ carrier. It must be ensured that it does not get onto the side surfaces. To ensure even distribution over the surface, the germ carriers must be thoroughly decreased (alcohol is not sufficient! Grease solvents, laboratory cleaners or processing in an automatic cleaning machine at approx. 60 °C are recommended). Apply 0.1 ml of the test soiling evenly to each contaminated surface and dry for 24 hours at 22 °C ± 1 °C and a humidity of 50 % ± 10 % (humidity and temperature must be specified in the test report). The test must be carried out within 10 days after production of the test specimens. Storage should be at room temperature and protected from contamination (e.g. in aluminum foil or glass tubes). The bacterial count per contaminated test specimen must be so high that the required reduction factor can be achieved considering the detection limit (at least 1x 10^7 CFU/test specimen).

Contaminated test specimens can be obtained from Simicon, Munich, for example.

7.2.3.4 Evaluation of test specimen

After passing through the cleaning system, the test specimens are removed under aseptic conditions (e.g. one sterilized pair of tweezers per test specimen), visually inspected for residues of the test soiling and transferred into test tubes containing10 ml phosphate buffer solution (PBS), if necessary, with inactivation substances.

Composition of the phosphate buffer solution (PBS)

Solution A:	16 g NaCl, 0.4 g KCl, 0.4 g KH2PO4 To dissolve in 1600 ml distilled water.
Solution B:	0.2 g CaCl2 To dissolve in 200 ml distilled water.
Solution C:	0.2 g MgSO4 To dissolve in 200 ml distilled water.

Solutions A to C must be sterilized separately and, after complete cooling, mixed under sterile conditions, adding the inactivation substance (see above) if necessary.

The recovery of the test bacteria is carried out by shaking out the test specimens transferred to test tubes. Shaking is carried out in test tube racks on shaking devices at a frequency of approx. 500 rpm for at least 20 min. The bacterial count is then determined from the shaking liquid. The method used must be specified.

The transport controls are transferred in parallel- but without treatment in the cleaning system- in the same way in 10 ml PBS and evaluated.

The following methods are permitted for determining the bacterial count:

- Dilution series and surface culture
- Spiral device

A suitable selective culture medium (e.g. kanamycin-aesculin-acid agar) can be used to suppress the growth of other microorganisms. The inoculated culture media are incubated at 36 ± 1 °C for 48 hours. The method used to determine the bacterial count and the nutrient solutions and culture media used must be specified in the expert report.

The germ reduction results from the difference between the number of CFU detected in the test germs on the treated test specimens and the mean value of the three untreated test specimens (transport controls). Against this background, the following acceptance criterion is defined: The reduction factor must be at least 5 lg levels for 90% of the test specimens used.

7.3 Test procedures for cleaning and decontamination of drinking bottles

The cleaning of drinking bottles is tested using test soiling by means of direct contamination.

7.3.1 Cleaning:

The cleaning test is carried out in accordance with DIN 10511. The drinking bottles are directly contaminated with the test soiling; no separate test specimens are used. The number of processing goods to be used for the test and the number of consecutive batches are specified in Table 7-2. A visual evaluation is carried out.

7.3.1.1 Producing the test soiling

The contamination occurs from reconstituted skimmed milk. To prepare 100 ml of reconstituted skimmed milk, 10 g of skimmed milk powder are added to 100 ml of distilled water, stirred vigorously and steam sterilized at 121 °C for 5 minutes. For particularly good adhesion of the soiling, 13 g of cellulose must be added before sterilization.

Table 7-3

Chemical	Source of supply
Spray-dried skimmed milk powder	Pharmacy
Cellulose (microcrystalline for thin-layer chromatography)	FLUKA chemicals catalogue, CH-Buchs

7.3.1.2 Application of the test soiling

A drinking bottle is filled approximately halfway with the test soiling and emptied again with a rotating movement while tilting it in a way that after emptying, the entire inner surface is wetted with the test soiling. To wet the edge of the bottle, the edge is dipped into the test soiling to a depth of approx. 1 cm. The drying takes place for a total of 2 hours, with the bottles initially placed upside down in a bottle basket and turned over after 1 hour.

The evaluation is carried out visually and differentiates between clean and dirty bottles (see illustrations). Acceptance criterion: All test bottles must be visually clean.

Fig. 7-7: Drinking bottle with contamination

Fig. 7-8: Drinking bottle with insufficient result

Fig. 7-9: Drinking bottle with sufficient result

7.3.2 Decontamination

Since drinking bottles are not subjected to the same level of contamination and germs as cages and other processed goods (e.g. feces, urine, etc.), decontamination of drinking bottles is not as important as for these other processed goods. Checking the decontamination of drinking bottles is possible in principle, but it involves a great deal of effort. The reason is that there is no standardized test specimen for this and a separate process would have to be developed for each individual bottle type. The working group therefore recommends that in cases where the processing of drinking bottles needs to be hygienically standardized, the drinking bottles should be autoclaved. This is also common practice.

7.4 Test procedure for confirming the rinsing of cage bases, wire lids, racks, drinking bottles and bottle caps

The effectiveness of the rinsing can be tested using pH indicators when alkaline and acidic cleaning agents are used. The test is carried out on the items being processed after the rinsing.

A rough determination of the effectiveness of the rinsing can be achieved with the following indicators:

Table 7-4

Cleaner	pH indicator	pH turnover range	Realisation	Colour reaction
alkaline	Phenolphthalein solution*	9.4–10.6	Record the residual moisture with a cloth. This cloth is moistened with a few drops of indicator to detect the pH value.	reddish-purple indicates alkalinity
alkaline	Phenolphtalein paper	9.4–10.6	Immerse / wet the paper in any residual moisture according to the manufacturer and read off the color value.	reddish-purple Indicates alkalinity
acidic	Methyl orange**	3.0–4.4	Record the residual moisture with a cloth. This cloth is moistened with a few drops of indicator to detect the pH value.	Red indicates acidity, otherwise the indicator solution is yellow-orange
Alkaline and acidic	Litmus paper	All pH ranges	Immerse / wet the paper in any residual moisture according to the manufacturer and read off the color value.	According to manufacturer

*1% in ethanol / **strongly diluted solution (0.04 g methyl orange in 100 ml 20% ethanol)

Note: Softened rinse water can simulate the presence of alkaline detergent residues due to its alkalinity; fully demineralized water, which is often used for rinsing, can have an “acidic” pH value and simulate acidic detergent residues.

A more precise way of testing rinsing effectiveness can be carried out using pH indicator sticks.

For this purpose, it is recommended to take the following samples beforehand and carry out the described measurements, which should also be documented.

- Sampling of the rinse water entering the cleaning system (on-site supply line), subsequent measurement of the pH value (e.g. with pH indicator sticks, see Fig. 7-8).
- Sampling of the rinse water prepared in the cleaning system (from the rinse tank), the pH value (e.g. with pH indicator sticks, see Fig. 7-8).
- Documentation of the process chemicals used for cleaning and rinsing and their dosing concentration.
- In addition, it is recommended to document the amount of water used for rinsing in a cycle or at a specific time (e.g. per hour).

The cleaning chamber is now loaded with the maximum possible number of cage bases, for example, and a cleaning and rinsing process is started. At the end of the cycle, the pH value of the remaining water on the surface (on all surfaces, inside, outside, sides) of 10 % of the loaded cage parts is checked using pH indicator strips. To do this, residual drops are picked up with the pH indicator strips and the color change and the displayed pH value are documented. This process is repeated for a total of 3 cycles with a new cage load.

The acceptance criterion for effective rinsing is that 90% of all cage parts tested preferably have a neutral pH value (7.0 with a tolerance of +/- 1.0) of the holding water on the surfaces. If the pH value measured in the incoming rinsing water in the cleaning system deviates significantly from a neutral pH value (see comments above), this must be considered when evaluating the results.

Fig. 7-10: Example pH indicator strips

7.5 Test procedures for drying of cage bases

The drying result is evaluated visually in the following stages:

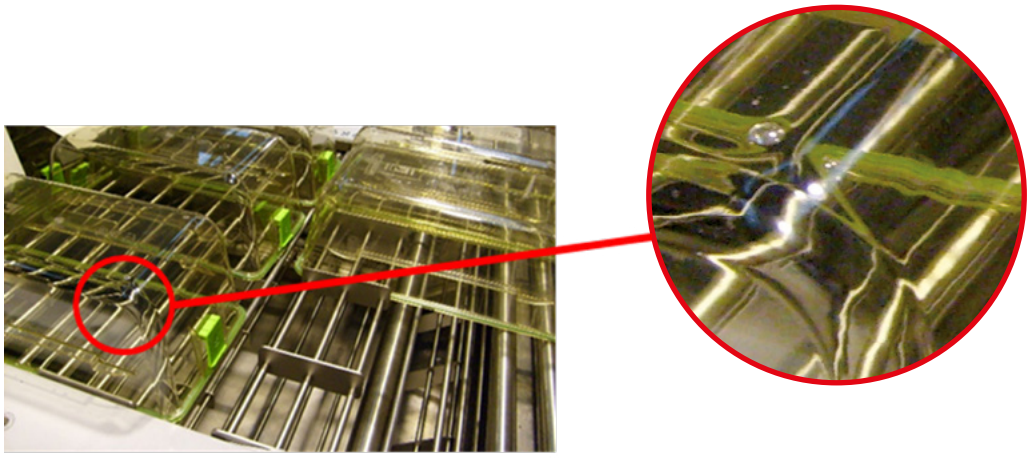


Fig. 7-11: Illustration of cage, no recognizable water residue, also no drops - stage 1

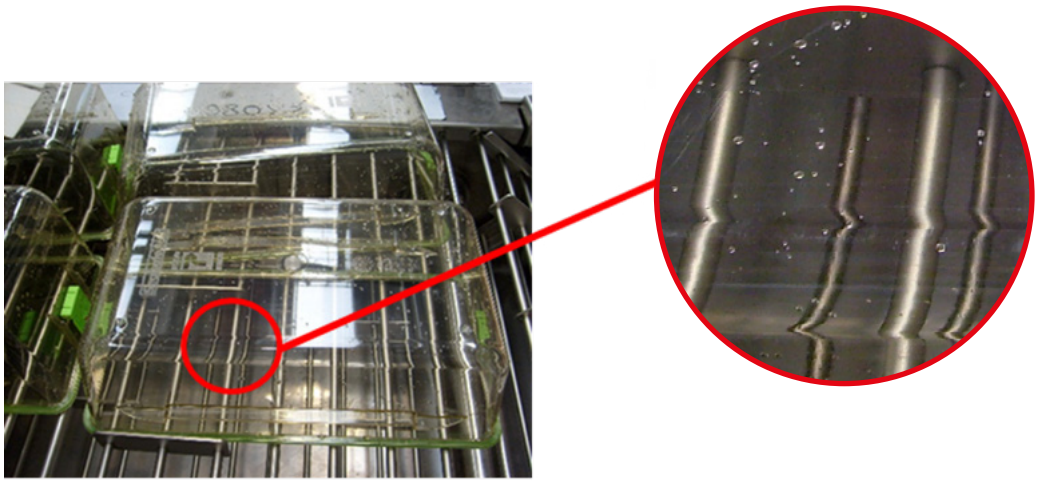


Fig. 7-12: Illustration of cage, isolated drops can be recognized - stage 2

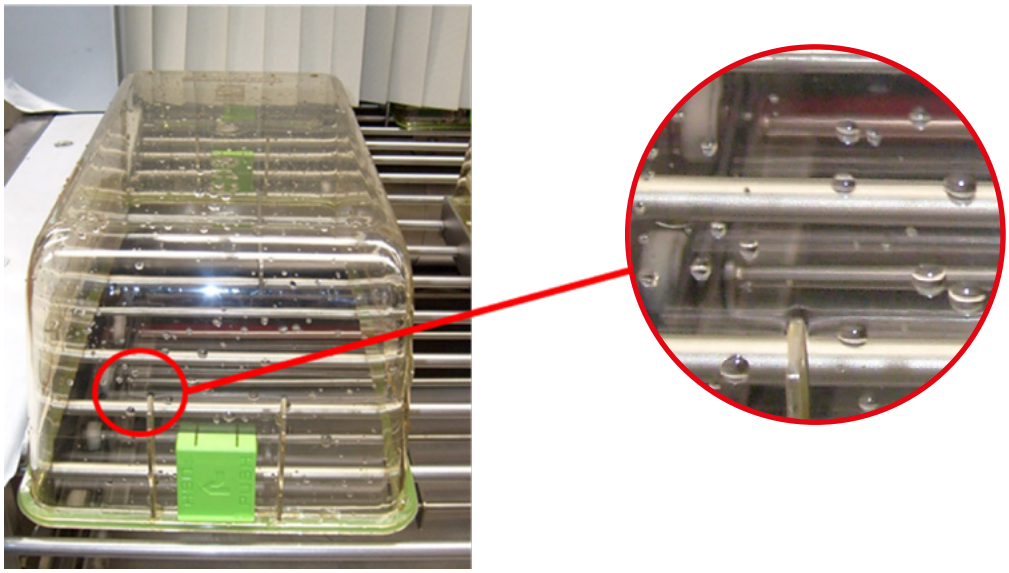


Fig. 7-13: Illustration of cage, many drops are present - stage 3

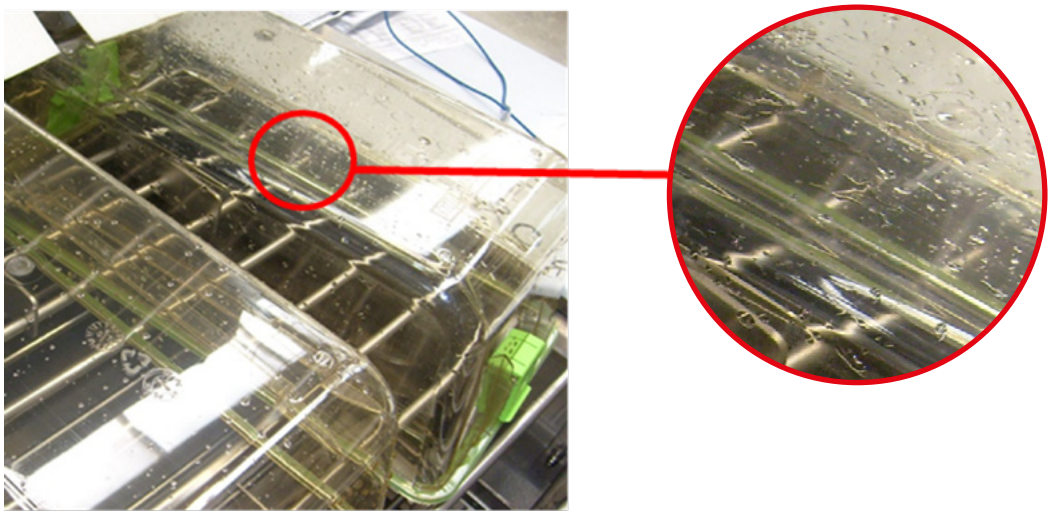


Fig. 7-14: Illustration of cage, large parts of the surface wetted with water - stage 4

7.6 Types of examination

A distinction must be made between the types of examination:
Type testing, testing after installation, periodic testing and extraordinary testing, see Table 7-5.

Table 7-5

Type testing at the manufacturer (Chapter 7.6.1)	Procedure developed by the KAB working group for the performance assessment of machine type. The type test is carried out at the factory. The manufacturer must specify which types (or series, if applicable) the tests carried out apply to. See Table 7-6
Inspection after installation (chapter 7.6.2)	The method is the same as for type testing at the manufacturer, but with the resources available on site. Which tests (e.g. cleaning, decontamination, rinsing and / or drying) are carried out and to what extent is the responsibility of the operator. If a system has been type tested by the manufacturer (7.6.1), the scope of testing on site can be reduced if necessary.

Periodic on-site inspections (Chapter 7.6.3)	Recurring inspection, recommended annually (see Table 7-7)
Extraordinary audits (Chapter 7.6.4)	On-site inspection after process-related repairs, program changes, changes to process chemicals or changes to the material being processed.

To avoid purchasing cleaning systems that are unsuitable for cage preparation, the AK KAB recommends purchasing only type-tested cleaning systems. The model of self-declaration, with which the manufacturer unambiguously confirms the results of such a type test, is shown in Appendix 12. It is also expressly pointed out that for safe operation, a test after installation and regular periodic tests on site are essential, as well as extraordinary tests if necessary.

7.6.1 Tests at the manufacturer's site (type testing)

The tests at the manufacturer's premises should include the cleaning test (see 7.2.1 and 7.2.2), the decontamination test (see 7.2.1 and 7.2.3), the rinsing test (see 7.4) and the drying test (see 7.5).

Table 7-6

	Preparation material			
Cleaning system	**Cage base**	**Grid lid**	**IVC rack**	**Storage and transport rack**
Cage cabinet cleaning system (3 batches each)	10%*	1 stack with 3 grid lids on top of each other, test specimen only on the center grid lid, 10 % of the stacks*	-	-
Cage belt cleaning system (in 15 min.)	10%*	1 stack with 3 grid lids on top of each other, test specimen only on the center grid lid, 10 % of the stacks*	-	-
Cleaning system for cages, racks and transport systems (3 batches each)	10%*	1 stack with 3 grid lids on top of each other, test specimen only on the center grid lid, 10 % of the stacks*	1	1

* the loading capacity

When checking the cleaning of bottles at the manufacturer, the following procedure should be followed: Bottles are usually cleaned in machines in which two 18-bottle baskets are placed next to each other in parallel. For this configuration, the following bottles marked with X should be checked for 3 batches:

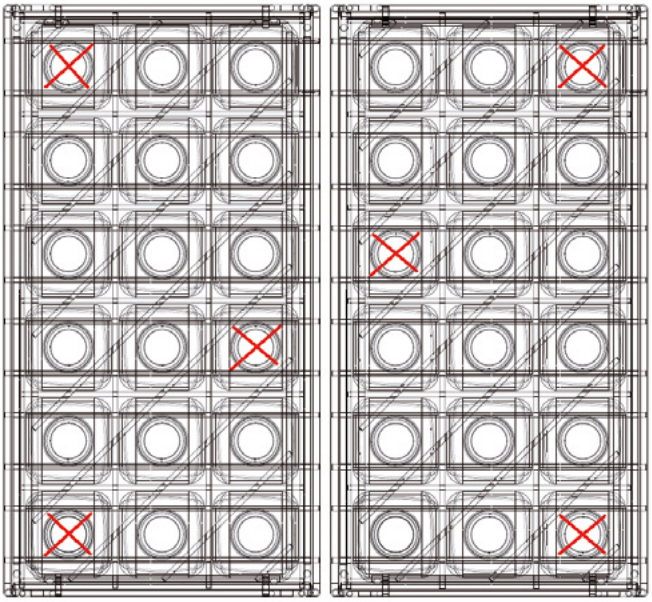


Fig. 7-15 View of two 18-bottle baskets

For other constellations, a test arrangement must be used in which at least 20% of the bottles are tested. Test bottles must be placed at the points that are considered critical under the respective conditions, considering the machine type, spray geometry, loading configuration, etc.

7.6.2 Tests at the installation site (after installation)

Testing at the installation site is at the discretion of the operator. In principle, the same testing procedures should be used as for the manufacturer (see 7.6.1), but with equipment available on site. If the operator wishes to have such tests at the installation site, as recommended by AK KAB, this must be ordered separately.

7.6.3 Periodic on-site inspections

Periodic testing is at the discretion of the operator. It is recommended to carry out testing at least once a year to demonstrate that the cleaning system continues to meet the requirements placed on it. A recurring test using the processing materials specified in Table 7-7 is sufficient for this purpose.

Table 7-7

	Material to be processed			
Cleaning system	**Cage base**	**Wire lid**	**IVC rack**	**Storage and transport rack**
Cage cabinet cleaning system (one batch)	2	1	-	-
Cage belt cleaning system	2	1	-	-
Cleaning system for cages, racks and transport systems (one batch)	2	1	1	1

The periodic check of the cleaning performance of bottles should be carried out as described for the type test, but the test can be limited to one batch if necessary.

Note:
The adenosine triphosphate (ATP) bioluminescence measurement method is used in the food industry to test the cleanliness of surfaces. This method can be used to test organic residues that contain ATP. Although this ATP method provides an indication of whether the surfaces tested are free of organic residues (“clean”) after cleaning, it does not allow any statement to be made about the performance of the cleaning process carried

out, because initial contamination is not known. For this reason, the ATP method is not suitable as a replacement for the use of bioindicators that have a defined initial bacterial load. This also applies to checking the cleaning performance, which should be carried out in a standardized manner. It should also be noted that the result of the ATP measurement depends to a very large extent on external factors, such as particles on the surface, residues of process chemicals or the condition of the surface to be tested. For this reason, the AK KAB recommends testing with bio / cleaning indicators for all types of testing. If necessary, the ATP measurement method can also be used for periodic testing. Swabs are taken from ten items to be treated at critical points that are difficult to rinse, using a template if necessary. ATP is detected in a luminometer using the light emitted by the luciferin/luciferase reaction.

7.6.4 Extraordinary inspections

After repairs that affect the process, program changes, changes to the process chemicals or changes to the material being processed, an extraordinary test is recommended. The decision to carry out an inspection rests with the operator. It is carried out in accordance with the operator's requirements and depends on the extent of the intervention. Depending on the type of process intervention, the scope of the extraordinary inspection can be between that of the inspection after installation and that of the periodic inspection.

7.7 Drinking caps

The following recommendations can be given to check the processing of drinking caps.

After cleaning, a visual inspection should be carried out. Before inserting the bottles into the cage, the functionality of the drinking nipple should be checked (see chapter 9.6).

7.8 Examination of sustainability

The tests for the performance assessment of cleaning systems, described in great detail in this chapter, consider the cleaning, decontamination, rinsing and drying results to be achieved, as are generally required in animal facilities. In addition to performance, media consumption and thus the economic operation of the systems and their sustainability are also assessed today. The European Society for Sustainable Laboratory Technologies e.V. (EGNATON) has defined criteria for cleaning systems, considering the recommendations of the German Sustainable Building Council (DGNB), with which the sustainable operation of systems can be checked. The performance defined in Chapter 7 is used to test sustainability and is related to media consumption. Further information on this can be viewed and downloaded at www.egnaton.com.

8 Sustainability

8.1 Definition of the term "sustainability"

When planning, constructing and operating modern research and laboratory buildings, the ecological footprint and thus sustainability should be given high priority. While externally the ecological aspects are often in the foreground with buzzwords such as "zero emissions", a well-founded analysis must take all factors of sustainability into account.

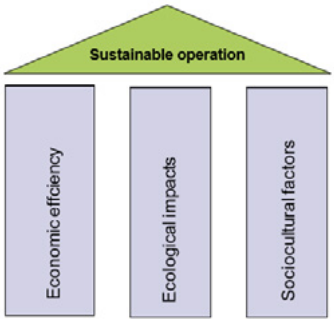


Fig.: 8-1 Three-pillar model

The three pillars of sustainability, economic efficiency (reduction in operating costs), ecological impact and socio-cultural factors are to be implemented equally as recommendations for planners, suppliers, operators and users.

In addition to the basic standard DIN EN ISO 14001 for the introduction of an environmental management system, there are other relevant DIN EN ISO standards that affect, for example, environmental labels and declarations in many areas.

The Federal Ministry for Housing, Urban Development and Building has initiated a Sustainable Building Assessment System (Bewertungssystem Nachhaltiges Bauen: BNB), which also enables the certification of research and laboratory buildings (BNB_L) using defined “profiles” from accredited certification bodies. The German Sustainable Building Council – DGNB e.V. also focuses on sustainability in the construction and real estate industry.

In addition to the planning and design of a laboratory and research building, the equipment used in it has a significant impact on the overall sustainability assessment.

Based on the principles of the BNB and the DGNB, expert committees (e.g. EGNATON e.V.) have set themselves the goal of evaluating and certifying sustainable laboratory technologies. This can also be used to define clear minimum requirements for cage preparation in animal facilities in the planning and procurement phases to be able to make subsequent sustainable operation measurable.

8.2 Economic efficiency

Recognized calculation aids, such as those from the Federal Environment Agency, can be used as a basis for life cycle costing (pillar “economic efficiency”).

All factors that are reflected in costs regarding the use and service life of the system must be considered.

Just considering the acquisition costs alone ignores a significant, if not the largest, block of costs that arises from operation. This includes all the necessary maintenance measures and, finally, the costs for proper disposal of the system after the end of use. Only a holistic view enables a well-founded statement.

According to information from the Federal Environment Agency, taking life cycle costs into account in the procurement process is permissible under procurement law and in some cases even mandatory.

8.3 Ecological requirements

The processing systems for animal cages, drinking bottles, racks and other goods must ensure a perfect result over the entire service life with the lowest possible use of energy, water and process chemicals. From an ecological point of view, the following requirements must be met:

Water
In terms of water consumption, processing methods that allow partial reuse within the machine cleaning process are preferable. For example, the rinse water used after alkaline or acidic cleaning and the rinse water mixed with rinse aid can be reused for rinsing cycles without impairing the cleaning result. However, a final rinse should always be carried out with fresh, demineralized water with added rinse aid if necessary (see chapter 5.2.1).

Energy
A certain amount of energy is required to ensure trouble-free operation. To keep this as low as possible, all available and economically viable options must be exploited in line with the current state of the art.

Process chemicals
The application concentration of the process chemicals must be set constant over the entire operating time to ensure a reproducible cleaning result. Manufacturers of cleaning systems and process chemicals produce dosing devices and central dosing systems to ensure precise dosing. Overdosing would result in unnecessary environmental pollution, while underdosing would result in poor cleaning or rinsing results. Process chemicals must be developed and produced using raw materials with the lowest possible environmental impact. Due to the properties of the dirt to be removed, the application solutions of the cleaning agents are usually in the acidic or alkaline pH range. Rinse aids are usually in the slightly acidic pH range (see Chapter 4.3.2).

The most important ingredients of the process of chemicals are:

Alkalis
Alkalis support the cleaning process by swelling and removing organic dirt residues such as starch, protein and fat, and lead to a high (alkaline) pH value of the cleaning solution. The dilution that occurs in the company's internal wastewater system with other, sometimes acidic wastewater reduces the pH value of the wastewater from a cleaning plant to the limit values set out in the wastewater legislation. Where this is not the case, a neutralization system can be installed.

Phosphates
Phosphates bind the hardness-forming substances present in the water and support the cleaning process through their emulsifying and dispersing effect. Along with inorganic nitrogen compounds, phosphates are one of the most important nutrients in water and lead to an intensification of bioproduction (overfertilization) if excessive amounts are added. In sewage treatment plants with a precipitation stage (3rd stage), phosphates are largely eliminated.

Phosphate substitutes
Phosphate substitutes can currently only replace phosphates in certain areas. Like phosphates, they are used to bind water hardness. The critical ecological assessment of possible substitutes for binding water hardness, e.g. the partial lack of biodegradability, prevents their widespread use.

Active chlorine carrier
Active chlorine is used to reduce germs and for the oxidative decomposition of organic residues. Since active chlorine is harmful to the environment due to AOX formation, attempts are increasingly being made to do without this ingredient.

Surfactants
Surfactants reduce the interfacial tension of the cleaning solution or the rinsing water and must be biodegradable, i.e. they are broken down by microorganisms in the sewage treatment plant.

Acids
Inorganic or organic acids in acidic cleaners are used to remove mineral residues. Rinse aids bind the residual hardness in the rinse water and thus counteract calcification. Acids give the application solution a low (acidic) pH value. The pH value of the wastewater from a cleaning plant is neutralized to the limit values set out in the wastewater laws by diluting it with other wastewater within the machine or in the company's internal wastewater system. Where this is not the case, a neutralization system can be installed.

Delivery containers
The delivery containers for process chemicals should, if possible, be made of plastics (such as PE or PP) that have as little impact on the environment as possible. The prerequisite for the orderly disposal of empty containers is that they are completely emptied. In general, the disposal of empty plastic containers can be limited by increasingly using large containers as refillable reusable containers. This means that the process chemicals can be delivered in refillable containers instead of canisters.

Hydrogen peroxide and peracetic acid
Hydrogen peroxide (H_2O_2) or peracetic acid (PES) are often used in airlocks to reduce germs in thermolabile goods. Since these substances can pose a risk to the environment, especially in concentrated form, special care must be taken when using them. In particular, the safety data sheets and the disposal instructions contained therein must be observed. Further information on H_2O_2 and PES can be found in Chapter 4.6.

Wastewater
Operators of cleaning systems in laboratory animal facilities are usually so-called indirect dischargers of wastewater. The indirect discharge of wastewater into the sewer system is regulated by regulations for which the local authorities of the cities and municipalities are responsible. This means that the respective local regulations may vary. Indirect dischargers pay a wastewater fee, which covers the costs of the wastewater charge, the sewer system, the operation of the sewage treatment plant and wastewater monitoring. To motivate indirect dischargers to reduce the pollutants discharged into their companies, many cities and municipalities have therefore introduced so-called wastewater coefficients, which use analysis data to assess how high the pollution of wastewater from individual indirect dischargers actually is. A fee is then calculated from this, adjusted to the pollution (polluter pays principle). Regardless of this fee issue, there are also binding wastewater limit values for indirect dischargers in the indirect discharge regulations of the federal states, which must not be exceeded. Due to the high dilution, the biocidal active substances and other ingredients of the process

chemicals that may be contained in wastewater do not influence the performance of the biological treatment stage of a wastewater treatment plant. If there are limit values that affect the wastewater temperature, it is also possible to cool the wastewater by adding cold water to cleaning machines.

Exhaust air

Essentially, three types of exhaust air must be taken into account:

- The general exhaust air from the treatment center (is discharged via the on-site room exhaust air duct).
- The exhaust air from mechanical cleaning technology and steam sterilizers.
- The exhaust air from the bedding system.

Exhaust air from machine cleaning technology and steam sterilizers is usually very humid and warm. During and after the cleaning process, it is discharged from the system to the on-site exhaust air systems in the form of a fixed connection or via an exhaust air hood. Heat recovery may therefore be useful. The on-site exhaust air ducts must be temperature-resistant, waterproof and, above all, corrosion-resistant due to the process temperatures and the process chemicals used. The materials used are plastic (e.g. PP - polypropylene, PVC - polyvinyl chloride) or stainless steel.

The exhaust air from bedding handling systems must be viewed in different ways:

Mobile discharge stations usually work in recirculation mode, i.e. they return the extracted air to a cleaned state. Here, it is important to ensure that the filter quality for the solid particles is high (at least H13). Sustainable neutralization of the gaseous substances (odors) is very difficult, which is why an impairment is to be expected here. In stationary systems with pneumatic transport, fine dust and odors are also extracted. Here, it is important to ensure that the exhaust air from these systems is not recirculated but rather blown out over the roof or fed into the animal house exhaust air (TA-Luft must be observed). If this is not possible for technical reasons, recirculation via activated carbon filters can be considered. However, the regular filter changes required have an impact on operating costs. Bedding filling systems also require high-quality fine dust filters. However, the odor problem does not occur, which is why these systems can also be used in recirculation mode.

The exhaust air from material locks in which processing goods are treated with hydrogen peroxide is contaminated with a high concentration of hydrogen peroxide, depending on the process step. After the sterilization process, it is released from the system to the building's exhaust air systems in the form of a fixed connection. Due to the toxic, oxidative and condensing properties of hydrogen peroxide, the building's exhaust air ducts must be airtight and watertight and, above all, corrosion resistant. The ideal materials to use are plastic (e.g. PP - polypropylene, PVC - polyvinyl chloride) or stainless steel.

Heat dissipation

Manufacturers of cleaning and sterilization systems must minimize heat radiation as far as economically and technically feasible. On-site, steam pipes must be insulated against heat loss in accordance with the Thermal Insulation Ordinance and the Heating Systems Ordinance (HeizAnlV).

8.4 Sociocultural factors

The range of factors extends from regulatory requirements (regulations, laws) to "political" goals (minimizing CO_2 emissions) to factors based on a social consensus.

Scientific research institutions in particular are focused on the transparent presentation of benefits, their external impact and social recognition. This pillar is therefore of equal importance to the others, which are traditionally always considered first, but its importance increases in a changing social environment.

Another example of this is the so-called 3R principle, which reduces the number of animal experiments, improves animal welfare and has also become legally binding through its inclusion in the European Directive 2010/63/EU.

8.5 Implementing the concept of sustainability for cleaning systems

Analogous to Chapter 7, the focus was placed on the cleaning systems below. Of course, all systems listed in Chapter 4 that are used in further process steps in cage processing can also be subjected to an assessment of sustainable operation.

To define, evaluate and apply the influencing factors in practice, the specialist knowledge of all those involved must be bundled into so-called "profiles", analogous to the procedure in the Sustainable Construction Assessment System (BNB).

All criteria should be defined in a practical and device-specific manner as the basis for certification of the sustainability of processing systems to transparently show which data must be provided for certification and which procedures must be used to determine them.

Analogous to the type test in Chapter 7, certification of the sustainability of the cleaning systems listed in Chapter 4.3 should be sought.

In principle, the focus in cage processing is on mechanical processing, which offers decisive advantages over manual options. As a rule, it is clearly standardized, easier to control and significantly more efficient in the handling of media and energy consumption. In a modern animal facility in particular, many components such as cage bases, cage covers, grids, IVC racks, bottles, transport baskets / trolleys and other equipment are used every day, which must be efficiently reprocessed in a targeted manner with reproducible results.

The basis and therefore prerequisite is proof of the effectiveness of the cleaning for the typical processing items that arise in laboratory animal facilities. The certificate and the test report of the type test in accordance with AK KAB (Cage Processing Working Group, see Chapter 7.6.1) are an objective and reliable basis for this. This is the only way to ensure that the systems to be certified are at a comparable level.

8.6 Implementing the concept of sustainability in sterilizers

For reasons of sustainability, the following points should be considered during steam sterilization (see chapter 4.5):

- Optimal chamber utilization through loading
- Connection of the sterilizer to the on-site cooling circuit to reduce cooling water consumption
- Liquid sterilization with natural cooling to reduce cooling water consumption and compressed air consumption (no support pressure required)
- Standby-function / sleep-mode to reduce steam consumption during downtimes

In addition, it should be checked whether the use of decentralized electric steam generators could have energy advantages in addition to central pure steam generators.

8.7 Inspection and certification of the systems

To inspect and certify the system according to the sustainability criteria (e.g. according to Egnaton-CERT), the consumption values must be determined under real operating conditions in the AK KAB type test phase. The ecological requirements listed in Chapter 8 must also be observed to ensure a perfect cleaning result and sustainable operation over the entire use and service life of the cleaning system with the lowest possible use of energy, water and process chemicals. Together with other criteria, these measured values are included in a life cycle cost calculation of the systems.

When testing the systems, it should be taken into account that media consumption can be reduced through special device configurations (e.g. energy recovery from the process of exhaust air or wastewater).

The system control system must enable individual configuration of all program parameters. This ensures that the programs can be adapted to the specific requirements for the processing of the goods, which can have a positive effect on operating consumption and therefore costs.

In addition to the ecological aspects, local regulations for discharged wastewater should also be considered. The aim should be to meet the requirements for wastewater temperature and pH value by equipping the systems accordingly, without having to consider the use of on-site post-treatment systems.

9 Potential Root-Causes for Quality Issues

In animal facilities, it is not uncommon that items for processing (please refer to chapter 3) soon suffer surface changes, in form of deposits, corrosion and stress / micro cracks, which might make it necessary to replace them. Usually, these damages do not result from natural, unavoidable wear, but from physical and chemical influences due to improper treatment. Depicted below are the most important causes of defects and damage in items being processed as well as suitable preventative measures.

9.1 Material haze (when using polycarbonate)

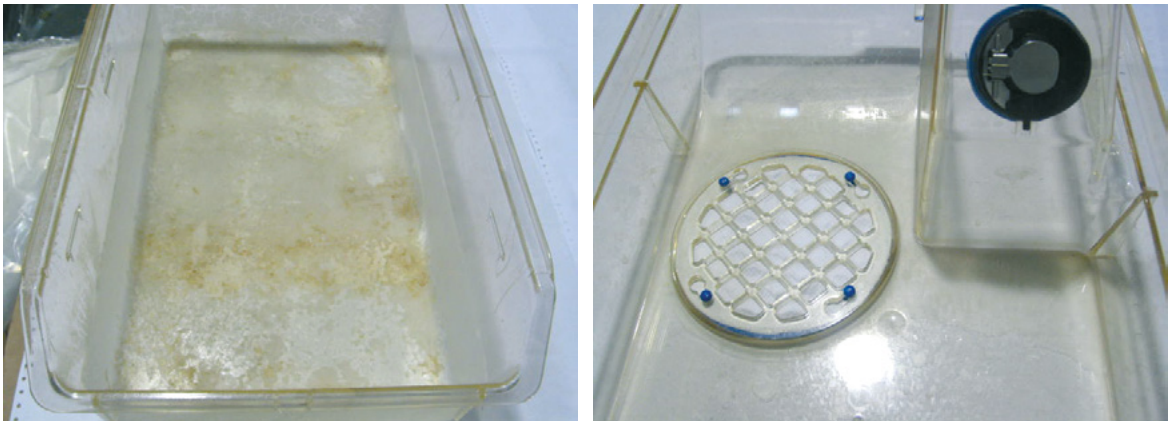


Fig. 9-1: Left cage with material clouding, right cage top with material clouding

Table 9-1

Origin and causes	Measures for prevention
If alkaline cleaning agent residues are not rinsed off, they will lead to material decomposition of polycarbonate during subsequent sterilization.	Ensure sufficient rinsing to remove the alkaline cleaning agent from the surfaces of the items to be reprocessed.
Softened water reacts alkaline, especially after heating. This is caused by the cation exchange of the calcium and magnesium hardeners contained in the raw water for sodium salts during the softening process and the associated formation of alkaline sodium carbonate. Adhering softened rinse water can lead to material decomposition of polycarbonate during sterilization.	Use deionized water and / or an acidic rinse aid for the final rinse.
Alkaline corrective chemicals during vapor generation also lead to material degradation in polycarbonate.	The specifications of EN 285 should be observed when generating steam.
Material decomposition can also occur when using highly resinous bedding (coniferous wood) if cages are sterilized together with this bedding.	The use of low-resin bedding (hardwoods e.g. aspen, birch, poplar) should be considered.
If processed goods, and in particular cage bases from infectious animal facilities, have to be sterilized, this leads to material clouding in polycarbonate in a very short time.	When sterilizing out of a barrier, the cage material polysulfone, polyetherimide or higher should be used.

9.2 Material haze (when using polysulfone and polyphenylsulfone)

Fig. 9-2: left Cage top and drinking bottle made of polysulfone with milky white looking material clouding, right detailed view of cage bonnet

Table 9-2

Origin and causes	Measures for prevention
This damage pattern is a swelling of the surface material, which is characterized by a milky white clouding of the material. According to the current state of knowledge, studies show that this clouding can occur if these surfaces are frequently exposed to natural and / or artificial daylight and sunlight (UV), e.g. in the scullery, in animal husbandry and / or storage and these plastic parts are then autoclaved regularly. If one of these two factors (UV exposure or autoclaving) is omitted, experience has shown that there is no comparable change in the material. The investigations also show that these material clouding effects are due to the chemical-physical properties of these plastics and are therefore manufacturer-independent. Based on the findings to date, there is no evidence of any loss of quality in terms of stability and mechanical durability.	Use suitable UV filters for the UV spectrum with artificial daylight in the illuminant. If possible, avoid autoclaving.

9.3 Deposits

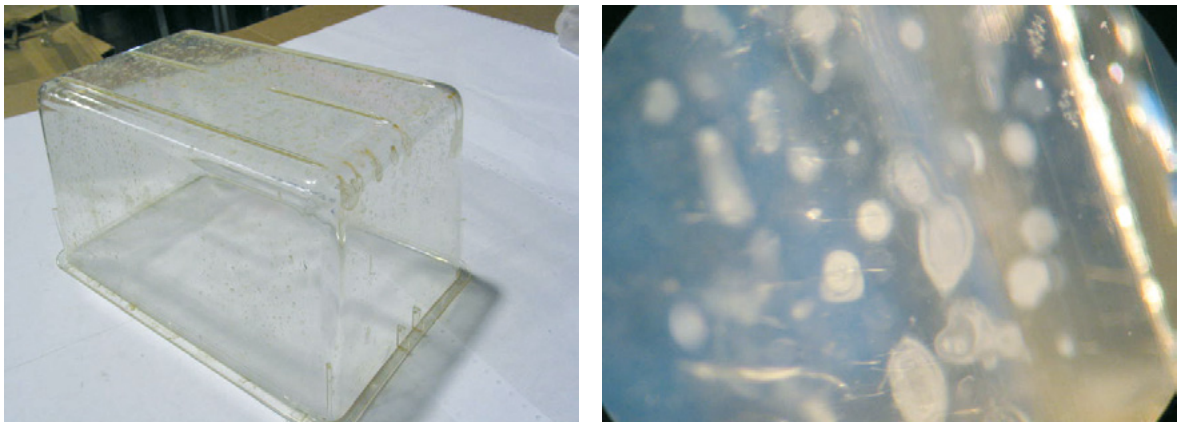


Fig. 9.3: Left view of cage base with deposit formation, right detailed view of a cage base

Table 9-3

Origin and causes	Measures for prevention
The formation of urine scale and / or limescale can cause deposits on the surfaces of the wash ware.	Cleaning the goods to be processed with an acidic cleaning agent.
Coagulation of blood residues during cleaning with hot water can cause these residues to deposit on the surfaces of the items being processed.	Manual pre-cleaning and / or soaking of the items to be processed in cold water or, if necessary, using an alkaline cleaning agent.
Residues from the cleaning process lead to deposits on the surfaces of the items to be processed	Ensuring sufficient rinsing to remove the cleaning agent from the surfaces.
The use of inadequate water qualities can lead to residues or deposits, especially on items with gaps and troughs where liquid can collect.	Use softened water or preferably demineralized water for rinsing.
Poor steam quality or ingredients can also cause deposits during the sterilizations process.	When generating steam, the specifications of EN 285 should be observed

9.4 Stress / micro cracks

Fig. 9-4: Left view of cage base with stress cracks, right detailed view of cage base

Table 9-4

Origin and causes	Measures for prevention
The use of unsuitable rinse aids in conjunction with subsequent sterilization can lead to stress cracks in the material of plastics that are sensitive to stress cracking, such as polysulfone or polyphenylene oxide (Noryl®)	Use special rinse aids that are customized to the material. Recommendation: Consult the cage manufacturer beforehand!
Excessive mechanical impact, e.g. incorrect emptying of the cage base and scratching out the bedding as well as pushing the material on rough and angular surfaces, can cause hairline cracks and scratches, which can then lead to larger cracks and other damage during sterilization.	Use suitable utensils, e.g. plastic spatula or hand brush. In general, care must be taken when handling, transporting and storing the processing materials.

9.5 Deformations

Fig. 9-5: View of drinking bottles with deformations

Table 9-5

Origin and causes	Measures for prevention
Depending on the plastic material, incorrect process temperatures during cleaning and sterilization can lead to deformation of the goods being processed.	Observe the maximum permissible temperatures and times for the respective plastics in the cleaning and sterilization process (see chapter 3). Recommendation: Follow the manufacturer's instructions!
Deformations caused by cage bases being stacked too high can occur during transport and sterilization.	The stack height during these processes should be limited to a maximum of 20 cage bases, depending on the cage size and cage material. Recommendation: Observe manufacturer's instructions!
If cage bases are sterilized with the top on and closed at the same time, deformations may occur in the closing mechanisms (e.g. clamps) and these may partially lose their function.	Cage bases and tops should be sterilized separately or, if the top is in place, the locking mechanisms (e.g. clamp) should be open.
Overheating during the sterilization process leads to material softening, which can result in deformation and / or leaks in drinking bottles. Reason: to be able to heat liquids in drinking bottles to 121 °C within reasonable batch times, it is necessary to heat at higher steam temperatures, such as 124 °C (in sterilization technology this is referred to as "temperature advance"). However, polycarbonate reaches its material limits at approx. 123 °C.	Two possibilities: A. Use a lower sterilization temperature (e.g. 118 °C). B. Use drinking bottles made of polysulfone, as this material can withstand sterilization temperatures of 134 °C without any problems. Note: Bottles with a conical neck (without silicone sealing ring) must always be sterilized without the drinking caps fitted.

9.6 Damage to plastic goods due to the use of unsuitable autoclave bags

Fig. 9-6: Deformation of cage bases on the left, cracks in cage shells on the right

Table 9-6

Origin and causes	Measures for prevention
If unsuitable sterilization autoclave bags are used, the following damage may occur to the plastic processing items: - Cracking - Irreversible, plastic deformations (e.g. at the stacking corners)	Use of suitable, vapor-permeable autoclave bags or closed, vapor-permeable sterilization containers.

9.7 Corrosion / pitting / external rust in stainless steel

In general stainless steel 1.4301 / AISI 304, 1.4571 / AISI 316 TI is used.

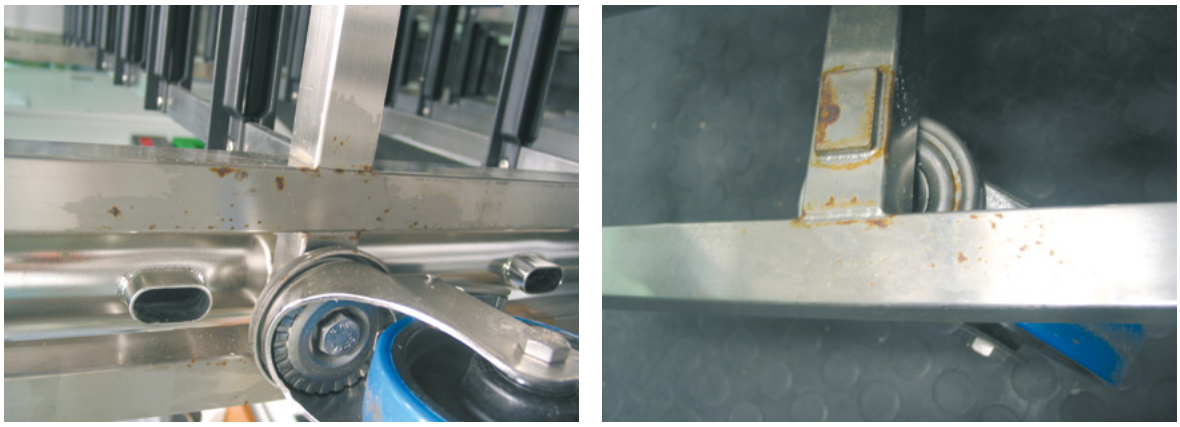


Fig. 9-7: View of stainless steel racks with corrosion

Table 9-7

Origin and causes	Measures for prevention
The drying of disinfectants containing chloride or the evaporation of floor cleaners containing hydrochloric acid or similar can lead to chloride-induced pitting on the stainless steel surface.	Such disinfectants should be rinsed off sufficiently after the prescribed contact time. Alternatively, chloride-free disinfectants can be used. Cleaners containing hydrochloric acid should be avoided.
Improper use (e.g. inadequate rinsing) of cleaning agents containing active chlorine leads to pitting.	Ensure sufficient rinsing to remove the cleaning agent from the surfaces of the items to be processed.
If drinking water is acidified with hydrochloric acid (HCl), residues of acidified water can cause chloride-induced pitting on stainless steel parts.	Use of alternative acids, such as sulphuric acid or phosphoric acid.
Rust deposits can form on the surface due to external rust ingress via water and / or steam pipes.	Use of suitable media supply lines (e.g. plastic or stainless steel) or appropriate water treatment (limit values see 5.2.1 and 5.2.2).

9.8 Problems with the processing of drinking nipples

(Drinking nipples release too little or no water)

Table 9-8

Origin and causes	Measures for prevention
In some cases, drinking caps are cleaned in cleaning systems designed for cages. This can lead to bedding particles being carried into the nipple, causing it to clog. Sometimes unsuitable cleaning agents or none are used.	Reprocess the drinking caps in special cleaning systems (e.g. bottle and drinking cap cleaning systems with individual nozzle arrangement); Use suitable cleaning agents (e.g. acidic cleaner). Do not clean caps in a cleaning system in which cages with bedding were previously processed. Or: Mechanical cleaning of the caps only after the cleaning system has been thoroughly cleaned to avoid particle carry-over.

The baskets (in which the drinking caps are placed during cleaning) are often overloaded. Containers are often used when cleaning the drinking caps (e.g. plastic baskets with only very small “openings”) that offer little or no opportunity for the water to reach the material being treated.	When cleaning the drinking caps in universal baskets as bulk goods, the number of caps should be limited so that all caps, and particularly the inside of the capillaries, can be sufficiently exposed to water. For more suitable and safe processing of the drinking caps, wire baskets should be used so that the spray shadow is as small as possible. For special requirements, special cap baskets are available in which the drinking caps are arranged in a defined manner and cleaned specifically by the water jet.
Residues of oily or fatty substances - even if only present in minimal quantities - can also lead to drinking caps releasing too little or no water at all (see Fig. 9.6 on the left).	Checking and maintaining the **compressed air quality** required by the customer (see chapter 5.2.4) to exclude oily residues in the compressed air for decapping the drinking bottles and during sterilization (support pressure). Checking and maintaining the **steam quality** required on site (clean steam in accordance with EN 285, see also section 5.2.2.2) to avoid substances such as corrosion inhibitors in the steam, which can create an oil film in the drinking nipples. Checking and maintaining the **water quality** required on site (see chapter 5.2.1) to avoid oily residues in the water supply for bottle filling. If necessary, check the suitability of the grease used in the sterilizer to lubricate the door seals.

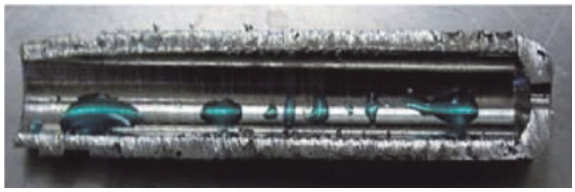


Fig. 9-8 Left: Cut-open drinking nipple with insufficient water flow. The poor wetting with water on the inside of the capillary is clearly recognizable.

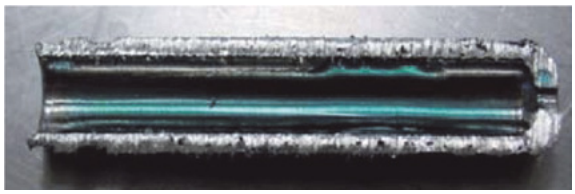


Fig. 9-8 Right: Cut-open drinking nipple in which the water can flow correctly

If there are already problems with unsuitably reprocessed drinking caps, an extended special cleaning process with alkaline cleaner often helps. If oil or grease residues are present or suspected, a 20-minute pretreatment in an ultrasonic bath with a 5 % alkaline cleaner solution should be carried out first, followed by the normal cap cleaning process and finally a long rinse with fresh deionized water.

There is also a simple test option with which the functionality of the drinking nipples (or the flowability of the water in them) can be checked regularly or occasionally:

- Fill a drinking bottle with water.
- Put on the drinking cap.
- Place the bottle in the bottle well of a cage / IVC top.
- Wait for about 20 seconds until the water and air are in equilibrium.
- If you now touch the tip of the nipple with a wet finger, you should be able to “pull off” a drop (see Fig. 9-9) - if this is not possible, you must check the possible causes or measures mentioned above.

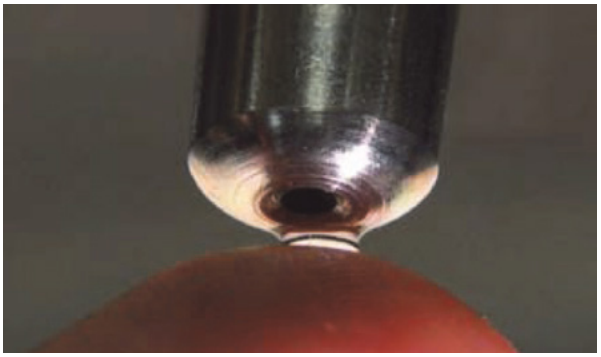


Fig. 9-9: Illustration of drinking nipple with water drop (finger test to remove a drop)

Drinking caps and their correct functionality are vital for the animals, which is why everyone involved in animal facilities is obliged to exercise the greatest care here.

Conclusion on 9.1 - 9.8:

Most of the time, the problems are not due to the inadequate product quality of the processed goods. Careful selection of the influencing factors (processed goods, cleaning system, process chemicals, sterilizer, SOPs, etc.) and coordination of these with one another is important.

9.9 Criteria for rejecting damaged material

In addition to the material changes mentioned above, normal cleaning and sterilization processes cause material-related aging, which can lead to the processed goods being discarded. These goods should therefore be checked regularly for their suitability.

Note: Processed goods do not have to be disposed of in the normal way and may need to be burned. This is a form of disposal that is harmful to the environment. Goods made of plastic can be recycled and the material obtained can be used in other industrial sectors as raw material for the manufacture of other plastic parts. Various cage manufacturers offer take-back and recycling programs.

10 Literature, standards, publications

Normative references

DIN 31051: Basics of maintenance

DIN 4140: Insulation work on technical installations in industry and in technical building equipment - Execution of thermal and cold insulation

EN 285: Sterilization; steam sterilizers; large sterilizers

DIN 58951-2: Steam sterilizers for laboratory sterilization goods

DIN EN ISO 17665-1: Sterilization of health care products - Moist heat

ISO 8573-1: Compressed air -- Part 1: Contaminants and purity classes

DIN EN VDE 0100: Regulations for the installation of power installations with rated voltages up to 1000 V

DIN 1986: Technical rules for drinking water installations (TRW). Drainage systems for buildings and properties

Fact sheet B 012 Laboratory animal facility: DGUV Information 213-108 – as of 03/2022 - ISBN 978-3-86825-013-8

DIN 10510: Food hygiene - Commercial dishwashing with multi-tank transport dishwashers - Hygienic requirements, process testing

DIN 10511: Food hygiene - Commercial glass washing with glass washing machines - Hygienic requirements, testing

DIN 10512: Food hygiene - Commercial dishwashing with single-tank dishwashers - Hygienic requirements, type testing

Note: DIN 10510, 10511 and 10512 have been replaced by EN 17735 - Commercial dishwashers - Hygienic requirements and testing; German version and DIN 10544 - Food hygiene - Commercial dishwashers - Additional hygiene requirements and testing

DIN 58955: Decontamination systems in the medical field

DIN EN 12353: Chemical disinfectants and antiseptics - Storage of test organisms for testing bactericidal, mycobactericidal, sporicidal and fungicidal activity

DIN 10088-1: Stainless steels - Part 1: List of stainless steels

DIN 15978 and DIN EN 15804 specific basic rules for the preparation of life cycle assessments of buildings and construction products (life cycle assessment)

Guidelines / Regulations

GV-SOLAS:
Planning and organization of experimental animal facilities and laboratories, as of July 1, 2021 (Rev. 2):
https://www.gv-solas.de/wp-content/uploads/2022/03/2022_07_01_Planung-Organisation.pdf

DIN EN ISO 11139 Sterilization of healthcare products

DVGW guidelines: Technical rules for water installations

Appendix A of the Council of Europe, ETS 123 (Official Journal of the European Union of July 30, 2007 (2007/526/EC) See link at www.gv-solas.de

Directive 2010/63/EU of the European Parliament and of the Council of September 22, 2010 on the protection of animals used for scientific purposes
See link at www.gv-solas.de

TRGS 900 - Technical rules for hazardous substances, workplace exposure limits

TRGS 906 - Technical rules for hazardous substances, list of carcinogenic activities or processes according to Section 3 Paragraph 2 No. 3 GefStoffV

TRGS 540 - Technical rules for hazardous substances, sensitizing substances

TRGS 553 - Technical rules for hazardous substances, wood dust

TRBA 120 - Technical rules for biological agents - laboratory animal facilities

Directive 2004/37/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of workers from risks related to exposure to carcinogens or mutagens at work, Annex I, No. 5

Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work

Commission Directive (EU) 2020/739 of 3 June 2020 amending Annex III to Directive 2000/54/EC of the European Parliament and of the Council as regards the inclusion of SARS-CoV-2 in the list of biological agents known to cause infectious diseases in humans and amending Commission Directive (EU) 2019/1833
Regulation (EU) 2023/1230 on machinery (formerly Machinery Directive 2006/42/EC)

Regulations on the point “Risk assessment” and occupational safety:

Occupational Safety and Health Act (ArbSchG)

Chemicals Act (ChemG)

Workplace Ordinance (ArbStättV)

Occupational Safety and Health Ordinance (BetrSichV)

Professional Association Regulations BGV A1 - Principles of Prevention

Hazardous Substances Ordinance (GefStoffV)

Statement of the Committee for Biological Agents (ABAS)

“Installation recommendations for new systems, retrofitting or additions, on the choice of exhaust air treatment for autoclaves”

Resolution 3/2009 of the ABAS dated April 21, 2009 www.baua.de/abas
ABAS Resolution 15/2017 dated December 7, 2017
ABAS Resolution 11/2021 dated November 17, 2021

List of homepage addresses for occupational safety:
www.bgrci.de
www.hvbg.de
www.gefahrstoff-info.de (GDL)
www.lgl.bayern.de

Publications

„Leitfaden für die Praxis: Dampfversorgung zur Sterilisation von Medizinprodukten“; überarbeitete Neuauflage 2005; Herausgeber: AK-Steri-Dampf
“Guide for practice: Steam supply for the sterilization of medical products”; revised new edition 2005; Publisher: AK-Steri-Dampf

Instrumentenaufbereitung im Veterinärbereich richtig gemacht (grüne Broschüre), 1. Ausgabe 2005, herausgegeben vom Arbeitskreis Instrumentenaufbereitung
Instrument preparation in the veterinary sector properly done (green brochure), 1st edition 2005, published by the Instrument Preparation Working Group

AK BWA brochure, 9th edition 2022 German, 7th edition English, 2006

„Aktueller Stand zur Raumdekontamination mit gasförmigem Wasserstoffperoxid“, Hygiene & Medizin; 35 [6]; 204 - 208
“Current status of room decontamination with gaseous hydrogen peroxide”, Hygiene & Medicine; 35 [6]; 204 – 208

“Musculoskeletal Load in and Highly Repetitive Actions of Animal Facility Washroom Employees” 2011, Journal of the American Association for Laboratory Animal Science (AALAS) from the Helmholtz Center for Health and Environment Neuherberg and the Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA) - formerly BGIA

2003 ILAR Magazine entitled “Engineering Controls and Facility Design” - An Ergonomic Process for the Care and Use of Research Animals”.

Europäische Gesellschaft für Nachhaltige Labortechnologien e.V. (EGNATON)
Steckbriefe für die Nachhaltigkeitszertifizierung von Käfig-Reinigungsanlagen (EGNATON CERT)
http://www.egnaton.com
European Society for Sustainable Laboratory Technologies e.V. (EGNATON)
Profiles for the sustainability certification of cage cleaning systems (EGNATON CERT)
http://www.egnaton.com

11 Terms / Definitions

AGV
Automated Guided Vehicle (driverless transport vehicle)

Animal husbandry
This refers to the rooms in which the animals are kept.

Animal husbandry facility
In this context, this includes all rooms that are required for the operation and supply and disposal of animal husbandry, e.g. animal rooms, scullery / processing center, corridors, storage, technical rooms, locks and, if applicable, laboratories.

AOX compounds
Adsorbable organic halogen compounds are formed by excess active chlorine when reacting with organic dirt components. These resulting halogenated hydrocarbons have unfavorable ecological properties.

Biological protection level / Biosafety Level (BSL)
The biological protection level is a hazard classification of biological agents, in particular microorganisms (see Directive 2000/54/EC - Protection of workers against risks related to exposure to biological agents at work; cf. Centers for Disease Control and Prevention (CDC) in the USA).

Bisphenol-A
Is one of the monomers (reactive molecules) used in the manufacture of polycarbonate.

Boiling delay
See: Danger to life due to delayed boiling

Carryover
In the case of carryover, dirt residues or residues of the cleaning agent solution from an upstream cleaning step are transferred to the material to be processed that has already been cleaned due to deficiencies in the process control or in the system design.

CFU
Colony forming units

Chloride-induced pitting
Pit corrosion caused by chlorides on metal surfaces covered with passive layers.

Circulation cleaning process
In the circulation cleaning process, the spray water mixed with cleaning agents is circulated in the cleaning system and thus applied to the material to be processed several times.

Cleaning
Removal of dirt from an object to the extent necessary for further processing or the intended use.

Cleaning liquor / detergent solution
Referring to the amount of water in the tank mixed with cleaning agents that is circulated in the cleaning system during the circulation cleaning process.

Collecting containers
This is where the discarded bedding is collected or temporarily stored. These can be simple plastic bags as well as large containers or suction containers.

Corrective chemicals
Additives in the steam, for example to prevent corrosion within the steam pipes.

Danger to life due to delayed boiling
After liquids have been sterilized, they are cooled using a “support pressure” that is significantly higher than the boiling pressure. At the end of the cooling process, the support pressure is reduced to atmospheric pressure. Insufficiently cooled liquids can then have a temperature above the boiling temperature without boiling themselves. A trigger is needed for boiling (boiling). This can be a shock when the load is moved out of the chamber. This is followed by a sudden boiling and a spontaneous release of steam, which can lead to containers overflowing and possibly bursting. This release of steam also leads to the entrainment of hot liquid, which is also sprayed. Due to the large mass of a sterilizer load, there is a danger to life from scalding if the liquids are not cooled sufficiently.

Decontamination
Removal of contamination (cleaning) from an object and reduction of the number of viable microorganisms to the level necessary for further processing or use.

Discharge funnel
Fixed or movable station for emptying the dirty bedding from the cage base. Both passive (by gravity) and active (with suction) funnels can be meant.

Electrical conductivity measurement
The electrical conductivity of aqueous solutions is a total parameter for dissolved, dissociated substances (ions). The magnitude of the conductivity depends on the concentration and degree of dissociation of the ions as well as on the temperature and the substance-specific migration speed. By measuring conductivity, the concentration of dissolved process chemicals can be determined.

Enrichment articles
Articles added to the cages to enrich the animals' living space. In principle, this includes all articles that can be put into a cage for this purpose. In the present context, this primarily refers to cellulose products, wood wool, plastic and wooden houses as well as biting sticks, etc.

Ergonomics
Science of the performance capabilities and limits of working people, here in particular the interaction between man and machine. The interface is usually considered from the perspective of the physical strain on the operator.

Evaporative cooling
The condensate that arises during steam sterilization is evaporated again by evacuation after sterilization. During this process ("evaporation"), the condensate cools down. For complete drying, heat must be supplied from the environment, e.g. from the item being sterilized itself. The success of the drying depends heavily on the amount of heat available, which can be too low in the case of large amounts of condensate, e.g. in cages.

Fine dust
Dust with particle sizes between 0.3 and 10 µm. This spectrum is respirable and can hardly be held back by the nasal mucous membranes. Even substances that are not dangerous in themselves can have a negative impact on health.

GLP
Good Laboratory Practice

GMO
Genetically Modified Organism

Hygroscopic condensation / overheating
Overheating is often observed with hygroscopic materials (e.g. bedding, feed, etc.) that are introduced into the sterilizer chamber when very dry. This results in what is known as hygroscopic condensation: the hygroscopic material has already assumed the temperature of the surrounding steam but is still trying to increase its relative humidity. This happens through condensing steam. The condensation heat released in the process is noticeable in local overheating. The overheating effect caused by hygroscopic condensation is greater the drier the initial state of the material.

IVC systems
Individually Ventilated Cage. This refers to cage systems that offer hygiene / allergy protection for animals and humans / environment at cage level. This is achieved by closing the cage with a so-called cage hood. To ensure that the animals are still supplied with air, appropriate ventilation and / or exhaust fans are required to ensure that air flows through the cages.

LAF
Laminar air flow

Loading trolley
The loading trolley is a mobile rack that is used to hold and transport different items to be processed into the cleaning system or sterilizer. Different loading trolleys are required depending on the item to be processed and the system.

MAK value
The maximum workplace concentration (MAK value) indicates the highest permissible concentration of a hazardous substance such as gas, vapor or suspended matter in the air at the workplace, which, according to current knowledge, does not generally affect the health of the employee or cause unreasonable discomfort, even with long-term exposure, i.e. eight hours of work per day.

Media contact
All components of systems that come into contact with operating materials (usually steam, water) and the process chemicals are referred to as media contact.

Occupational exposure limit (OEL)
The occupational exposure limit (OEL) is the limit value for the time-weighted average concentration of a substance in the air at the workplace in relation to a given reference period. It indicates at which concentration of a substance acute or chronic harmful effects on health are generally not to be expected (Ordinance on the Protection against Hazardous Substances, Hazardous Substances Ordinance - GefStoffV of July 21, 2021). The determination is based on exposure of generally eight hours on five days a week during the working life. The occupational exposure limit is given in mg/m³ and ml/m³ (ppm).

PAA lock
Lock for the introduction or removal of thermolabile goods into or from a barrier area. Peracetic acid is used as a disinfectant.

pH value
Aqueous solutions are divided into the ranges “strongly acidic, weakly acidic, neutral, weakly alkaline, strongly alkaline”. The unit of measurement for this is the pH value. The numerical scale for the pH values ranges from 0 - 14, with values < 7 indicating the acidic range and values > 7 indicating the alkaline range.
Aqueous solutions with a pH value of 7 are classified as neutral.

Process capability of the bedding
Every process is tailored to specific products, including partially or fully automatic cage filling. Certain, very fibrous types of bedding tend to form bridges in containers, which means they cannot be reliably removed, which poses the risk of fluctuating filling levels in cages.

Process chemicals
Generic term for cleaning, neutralizing and rinse aids in mechanical processing that are mixed into the water.

Processed goods
All goods that are processed within an animal husbandry facility (see table in Chapter 2)

Processing
Processing means the cleaning, if necessary, disinfection and sterilization, of all goods that are supplied to the animal facility area from the processing center, including all associated emptying, filling and transport activities.

Processing center
See wash-up area

Risk assessment of the workplace
Risks for employees should be kept as low as possible. For this reason, the employer must carry out a risk assessment for each workplace. The risk assessment is regulated by various legal provisions: Section 5 of the Occupational Safety Act, Section 3 of the Industrial Safety Ordinance and Section 7 of the Hazardous Substances Ordinance. The following points must be considered in detail:

- Hazards from activities at the workplace, including the design of work processes (assessment of the complete work process “overall view”: selection / combination / interaction of various devices, hazardous substances, positioning in the room, qualifications of the staff, etc.)
- Hazards from activities with hazardous substances, such as cleaning and disinfection agents (protection level concept)
- Hazards from the use of work equipment, such as machines and interaction with hazardous substances, etc.
- Determination of the inspection intervals for system components, systems and the entire system
- Details on the risk assessment can be found not only in the relevant legal provisions but also in the guidelines of the professional associations and the various state offices responsible for occupational safety

Scooping cavities
Depressions and areas on the material being processed in which (residual) liquid and dirt can collect.

SOP

Standard Operating Procedures

SPF area
Area for keeping / breeding specified pathogen-free animals.

Spray water
Spray water is the water applied to the material being processed under pressure via nozzles in cleaning systems, which can contain process chemicals.

Steam
Humid, warm air that is generated during operation in a cleaning system or in a steam sterilizer.

Sterilization
Validatable process that is used to make a product free of viable microorganisms.

Surface disinfection
Surface disinfection is a targeted, chemical killing or inactivation of certain undesirable microorganisms in defined quantities on surfaces. This is done by irreversibly interfering with the structure or metabolism of the microorganisms with the aim of preventing their further spread so that they no longer pose a risk of infection. Surface disinfection can be carried out in the form of wipe disinfection or, on visually clean surfaces, in the form of spray disinfection.

Thermolabile and thermostable goods
See chapter 4.5.1.1

Titration
Measurement analysis method for determining the amount of substance in a liquid (concentration determination). A reagent of known concentration (standard solution) is added dropwise to a substance using a burette until the concentrations are balanced and the indicator contained in the standard solution shows a color change.

Tolerable residual moisture
Tolerable residual moisture is considered to be individual drops of water (not puddles of water) that still adhere to the goods being processed in unfavorable places after removal from the cleaning system, without hindering the immediately following processing steps of the goods.

TTI value (as a measurement value alongside other factors)
TTI value is the impulse of the water that acts on the surface of the material to be treated.
The formula for TTI is: TTI = 0.024 * Q * √ P
Q = volume flow / liter per minute
P = spray pressure in kgf/cm2
1 Newton = 9.80665 kgf
The higher the value of the TTI, the higher the impulse of the water that acts on the surface of the material to be treated and thus achieves the cleaning performance.
As can be seen from the formula, the volume flow of the water has the greatest influence on the TTI. Information that only defines the value of the water pressure or a high number of nozzles does not accurately reflect the facts.
With the above calculation, the manufacturer of a system can design the overall effect (TTI) of the nozzle system that applies to the respective cleaning system and disclose it as a quality criterion.
This provides an objective value to compare the quality of the high-pressure nozzle system of different systems and thus enable the future operator to make the right choice.

Wash-up area
In the wash-up area (or processing center), all the necessary mechanical systems that are required for cleaning, disinfecting and, if necessary, sterilizing the goods are arranged in a spatially connected manner.

12 Appendix

OWN DECLARATION on the verifable properties of cleaning systems

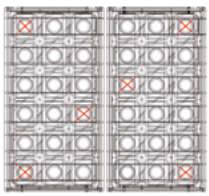
This declaration refers to the following cleaning systems
(lines that do not apply must be crossed out):

Cage cabinet cleaning system
Cage belt cleaning system
Cleaning systems for cages, racks and transport systems
Bottle cleaning system

Manufacturer: ……Type/Series ……

We carried out the corresponding type test for the above-mentioned cleaning system in accordance with the AK KAB test guidelines and used the number of test specimens entered in the right-hand columns (in the table below). The test results were determined in ..... batches.

	Number of reprocessed goods prescribed by AK KAB during the test					BIDDER'S INPUT FIELDS **A total of y test specimens were used on z processing goods:**	
Cleaning system	**Batches / Duration**	**Cage Base**	**Wire Lid**	**IVC rack**	**Storage and transport rack**	**during CLEANING**	**at DEKONTAMINATION**
Cage cabinet cleaning system	3	10 %*	1 stack with 3 grid lids on top of each other, test specimen only on the center grid lid, 10 % of the stacks*	N/A	N/A	y = ... z (cages) = ...	y = ... z (cages) = ...
						y = ... z (grid) = ...	y = ... z (grid) = ...
Cage belt cleaning system	In 15 min.	10 %*	1 stack with 3 grid lids on top of each other, test specimen only on the center grid lid, 10 % of the stacks*	N/A	N/A	y = ... z (cages) = ...	y = ... z (cages) = ...
						y = ... z (grid) = ...	y = ... z (grid) = ...
Cleaning system for cages, racks and transport systems	3	10 %*	1 stack with 3 grid lids on top of each other, test specimen only on the center grid lid, 10 % of the stacks*	1	1	y = ... z (cages) = ...	y = ... z (cages) = ...
						y = ... z (grid) = ...	y = ... z (grid) = ...
						y = ... z (IVC racks) = ...	y = ... z (IVC racks) = ...
						y = ... z (racks) = ...	y = ... z (racks) = ...

		Bottles					
Bottle washer Bottles are usually cleaned in machines in which two 18-bottle baskets are placed parallel next to each other.	3	6 per batch, at these points: 		N/A	N/A	z (bottles) = ……	z (bottles) = ……

* the loading capacity

With this declaration, we confirm that the audit methodology of AK KAB was applied in all aspects of the audit, in particular regarding

- Type and number of test specimens / germ carriers
- Test soiling for test specimens for testing cleaning performance
- Test organism for testing decontamination performance
- Contamination for testing decontamination performance
- Evaluation for decontamination
- Position of the test specimens

and that our entries on the two tables (A and B) correspond to the test report mentioned below:

A: Cleaning:

	Acceptance criteria according to **AK KAB**		**BIDDER'S INPUT FIELDS**		
Test results according to AK KAB chapter 7.2.2	No more than **10**% of the test specimens used are **slightly soiled**	No more than **20**% of the test specimens used are **slightly soiled**	**n**% of the test specimens used are **slightly soiled**	**n**% of the test specimens used are **soiled**	**n**% of the test specimens used are **heavily soiled**
Cage base	X		n = ……	n = ……	n = ……
Grid lid	X		n = ……	n = ……	n = ……
Racks (storage and transport racks)		X	n = ……	n = ……	n = ……
IVC racks (exterior)		X	n = ……	n = ……	n = ……
IVC filter hoods		X	n = ……	n = ……	n = ……
	Acceptance criteria n. AK KAB		INPUT FIELD OF THE BIDDER		
Drinking bottles	All bottles are visually clean		….% of the bottles are ……		

B : Decontamination:

	Acceptance criteria according to **AK KAB**	**BIDDER'S INPUT FIELDS**	
Test results according to AK KAB chapter 7.2.2	A reduction of > 5lg levels must be achieved in 90% of the test specimens used.	A reduction of z lg levels was measured for Y% of the test specimens used.	
Cage base	X	y = ……	z = ……
Grid lid	X	y = ……	z = ……
Racks (storage and transport racks)	X	y = ……	z = ……
IVC racks (exterior)	X	y = ……	z = ……
IVC filter hoods	X	y = ……	z = ……

We hereby declare that the cleaning system offered by us fully fulfils the test specifications of the AK KAB in accordance with the above information.

This (self-) declaration is based on the audit report dated .....(date), which was prepared

by ..... (audit institution).

Should my offer be shortlisted, we are able and agree to submit this test report within 6 working days.

.....	.....	.....
Place	**Date**	**Signature and name in block letters**

Company stamp:

Final provisions:

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