Das Fachmagazin für Krankenhaus- und Praxishygiene

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30. Jahrgang 2023 | Heft 2

Bilingual

Wissenskunde: Wasserführende Systeme in zahnärztlichen Behandlungseinheiten.

Insight: water leading systems in dental chairs

Editorial

Dear readers,

How does hygiene actually feel on the other side - as a patient? What does the patient see and does he feel more unsettled by the measures or is it reassuring when they are made transparent. I recently had to switch sides myself and was able to experience first-hand what it's like to be on the other side as a patient. As hygiene and reprocessing professionals, we know what is done in detail and how the measures should look and be carried out correctly. The "normal" patient, however, can easily become confused because measures look different than in the well-known doctor's series or because, due to the much helps much mentality during Corona in everyday life, the measures are supposedly too lax. Our task as professionals is also to pick up the patient for hygiene, to present all measures taken transparently and thus to take away some of the fear. Knowledge is extremely helpful in this regard, so that we can also appear confident to the patient and answer questions in a patient-friendly manner.

Refresh your knowledge and read about current trends in hygiene and reprocessing in the latest issue of aseptica.

I hope you enjoy reading and reading this issue of aseptica.

Stay healthy,

Stella Nehr-Werner

Report

New hygiene quick check app

As the world's first clinic, Asklepios Klinik Nord at the Heidberg site has presented an innovative hygiene quick check developed by Hamburg-based startup Darvis Healthcare. The principle: A "virtual airlock" consisting of optical sensors and artificial intelligence (AI) checks the correct donning of personal protective clothing such as mouth-nose protection, gloves, safety goggles, protective gowns or headgear among staff. The doctors, nurses and functional service staff use the new technology only on a voluntary basis and they are digitally anonymized in the process; all images and objects are "translated" by the software into 3D schematics. The correct or incorrect donning of protective clothing is displayed on monitors with corresponding indications (green/red light).

"The digital hygiene quick check using optical sensors replaces the need to look in the mirror or the time-consuming check by a colleague when putting on personal protective clothing - and can thus increase safety for our employees and the patients," says Prof. Dr. Klaus Herrlinger, Medical Director of the Asklepios Clinic North - Heidberg and Head Physician of the Department of Internal Medicine. The digital quick check verifies in seconds whether everything has been thought of when putting on the personal protective clothing, for example whether the mouth-nose protection fits correctly and whether both gloves have been put on. The system then immediately provides visual feedback as to whether everything is correct.

Source: kma-online.de

Contents

Insight: Sterile barrier systems - part 2

Authors

Dr. Sabine Kaufmann
Diplom-Biologin
Klinikum Winterberg gGmbH
Winterberg 1
66119 Saarbrücken, Germany
skaufmann@klinikum-saarbruecken.de

Kathrin Mann, MHBA
PRO.Q.MA Gesundheitsmanagement
Wilhelmstraße 14
93049 Regensburg
info@kathrin-mann.de

Stella Nehr-Werner
Global Infection Control
and Prevention Consultant
Sirona Dental Systems GmbH
Fabrikstr. 31
64625 Bensheim, Germany
stella.nehr-werner@dentsplysirona.com
www.dentsplysirona.com

Sabine Kaufmann, Kathrin Mann, Stella Nehr-Werner

The article is divided into two parts – this is the 2nd part. Part 1 can be found in the previous issue.

The process of sealing

A heat seal seam is intended to protect the sterile goods in the packaging from germs until they are used. The surfaces of two materials are joined together irreversibly by the action of heat, pressure and time (process parameters). The process parameters must be monitored regularly and should be laid down in the QMS by means of instructions and checklists. According to DIN 58953-7, the process of heat sealing must be carried out according to a validated procedure.

A validatable heat sealing device must be used for this purpose. Depending on the application, different sealing seams can be produced. The requirements for the heat sealing device can be found in DIN 58953-7 and in the RKI/KRINKO recommendation, Annex 4 (monitoring of process parameters, alarm in case of deviation, process interruption).[2]

Reusable containers

Containers are prefabricated rigid sterile barrier systems (DIN EN ISO 11607). Containers are classified as non-critical medical devices, but should preferably be reprocessed by machine (disinfection A0 600). The manufacturer's instructions (DIN EN ISO 17664) must always be observed during reprocessing.

The containers must be checked for quality after each reprocessing and before the contents are used. Only a fully intact container is a recontamination-safe package and can preserve the sterility of the medical devices inside. The container tray and container lid must match and be from the same manufacturer.

Container packaging exists in various sizes, which are selected depending on the contents to be packaged. The medical devices can be packed in the container with or without fleece. Inner packaging is not necessary and is not required by any standard, law or guideline, but it can facilitate the removal of the trays and aseptic presentation. The loading weight must be observed (recommendation max. 10 kg), because containers are only approved for a certain weight. The maximum stacking pressure according to EN 868 Part 8 is approx. 70 kg (0.5 N/cm2, minimum 100N).

Different loadings must be taken into account during validation (worst case loading; maximum loading; minimum loading, etc.). In case of overloading, successful sterilization is not guaranteed. In addition, containers should not be too heavy for reasons of occupational safety.

Sterilization containers must be checked before each reuse. Without effective control, there is a real risk that the sterile barrier effect and thus the sterility of the medical device are not guaranteed. Defective containers or container lids must be replaced. However, most containers are maintenance-free (observe manufacturer's instructions).

Sterilization containers can be stacked in the sterilizer and during transport and storage, which is a clear advantage over soft packaging in general.

Marking of the sterile barrier systems

The following information must be indicated on the packaging in accordance with DIN 58953-7:

- Responsible employee who packaged the medical device
- Designation of the medical device
- Marking of the batch/number
- Shelf life of the sterile product (expiry date)
- Possibly information about storage
- Process indicator
- Marking "sterile"
- Date of sterilization.

Type of packaging	Storage unprotected	Storage protected
Sterile barrier system	To be made available for consumption within 48 h	6 month, but not longer than expiring date
Packaging system Sterile barrier system + protective packaging	5 years, unless a different expiry date is specified by the manufacturer.	

Tab. 3: Storage times.

Storage and storage duration

The acceptable storage period for sterile medical devices depends largely on external influences and impacts during storage, transport and handling. The loss of integrity of the sterile packaging (EN 868-1) or the loss of sterility (DIN 58953-9) are usually considered to be event-related and not time-related, i.e. they depend less on the storage period and more on the circumstances of storage.

Released medical devices must be stored in closed containers. This can be done in closed transport trolleys (temporary), cabinets, shelves and drawers. Open storage must be avoided at all costs, as it is imperative that sterile goods are protected from dust (particle-bound contamination) and UV light.

The maximum storage period in a sterile barrier system is 6 months. The responsibility for the storage period and the storage conditions lies with the operator of the facility.

Quality assurance

Routine inspections must be an integral part of functional qualification according to DIN EN ISO 11607-2. The quality properties of a particular packaging material must be checked and documented by visual inspection. Visual inspection for integrity must be performed routinely during each packaging process (e.g. container check) and before each batch release after sterilization. For the combinations specified in the validation plan, a defined number of sterile barrier systems of the same material must be packaged (samples) and checked for the predefined quality properties.[3] This ensures that changes are detected in good time before a sterile barrier system no longer meets the requirements.

For further routine checks, the intervals (daily, weekly, monthly) must be defined, including the procedure to be followed if a check is not passed. The results of routine checks must be documented.[3]

Documented orientation of new staff and documented training are also components of quality assurance. Staff must be trained in such a way that any visible impairments to the sterile barrier system during daily handling are identified before use.[3] All aspects to be checked and special features of the sterile barrier systems to be used must be formulated in a procedural instruction and must already be communicated as part of the initial training.

The sterile barrier system also has a significant influence on the drying success in the steam sterilization process. Even before a decision is made in favor of a particular sterile barrier system, it should be tested and ensured that the packaging system and medical devices are compatible and that drying is successful. If drying does not succeed, the process, packaging and/or loading must be optimized and confirmed as part of the process validation of steam sterilization. Insufficient drying results can, not least, be an exclusion criterion for a particular sterile barrier system.

Example: Routine checks on heat sealers

Integrity of the sealing seam

The tightness of the sealing seam on the heat-sealing device must be checked regularly. The RKI/KRINKO recommendation suggests the seal check or ink test for this purpose.[2] The ink test can be used especially for packaging with side gussets. The seal seams should have the following quality characteristics:

- intact sealing at a specified sealing width
- no channel formation or open sealing seams
- no punctures or tears
- no delamination or detachment of materials.

With the seal check, an indicator strip can be used to show whether the quality characteristics are met. If a process parameter deviates, this can be made visible on the indicator strip.

Fig. 2 : Ink test.

In the ink test, approx. 2 ml of suitable test ink is poured into the bag just above the seal seam using a pipette. After a short time, you can see whether the sealed seam is tight. If the sealing seam is defective, the test ink penetrates the bag. These tests should be performed and documented every working day.

Peelability

When opening a sterile package, care must be taken to ensure that the paper can be easily opened from the film and vice versa and does not "peel off". There is a standardized test for this peel procedure in accordance with DIN EN 868-5 ("Method for determining the peel characteristics of paper/plastic composite materials"). The peel test can be performed as follows: [10]

- Seal a section of the sterilization tubing on the peel side and add it to a sterilization process
- after removal from the sterilizer, carefully and slowly pull apart the sealed seams with both hands along the peel direction
- a visual check is made to see whether the seal seam is continuous and whether the paper can be separated from the film without fraying.

The results of the peel test must be documented.

Fig. 3: peel test.

Example:
Routine checks on containers

- Visual inspection of the container for damage
- Residues of process chemicals?
- Filter and filter holder (rubber lip intact?)
- Filter gasket (porous? cracked? contaminated?)
- Lid (fit warped? contaminated? manufacturer?)
- Lid gasket (porous? cracked? contaminated? rusty?)
- Tub rim (fit warped? contaminated? rusty? manufacturer?)
- Paper filter intact? (pay attention to container manufacturer!)
- Paper filter inserted? (pay attention to container manufacturer!)
- Round filter holder engaged? (audible "click")
- Closure functional and undamaged? (Oil closure hinges occasionally, e.g. with Sterilit)
- Closure flaps engaged? ("click")
- Seal in place? (pay attention to container manufacturer!)
- Carrying handles intact and undamaged?

Risk assessment

The use of any packaging material involves individual risks. The advantages and disadvantages of the different sterile barrier systems must be weighed up against each other, taking into account the in-house situation, before a decision is made.[3] Maintaining sterility until use or until the expiration date is reached is an absolute priority. In addition to costs, the nature of the medical devices to be packaged, user requirements, user-friendliness, safety aspects and transport logistics play a decisive role in selecting the right packaging.

There are also risks involved in changing a sterile barrier system for the user or handling. There will inevitably be effects on the working methods of the OR nurses or assistants. For this reason, all users must be involved in the decision-making process. User safety is achieved through sound familiarization, continuous training and ultimately only through a routine.

Costs

With the current continuous increase in consumption and energy costs, a business assessment of the sterile barrier systems, the associated consumables and investment costs is essential. After all, most CSSD affiliated with a hospital are exclusively cost centers that do not generate a profit. But even in the private practice sector, hygiene costs account for a not inconsiderable share and must therefore be kept in mind.

In principle, standardization should always take place and as few different sterile barrier systems as possible should be used. In this way, warehousing and ordering costs can also be minimized.

There are some cost factors which must be taken into account. Investment costs for containers and the associated consumption costs (filters, labels, etc.) must be compared with the consumption costs for soft packaging (nonwoven, paper-foil packaging, adhesive tape, labels, protective packaging, etc.). The time required for the actual packaging process and handling must also be critically examined. The type of packaging significantly determines the requirements for storage and transport. Thus, it must be checked whether the existing cabinet systems, storage systems as well as transport systems are suitable. Maintenance and repair costs, especially for containers (filter holder, tub, lid, closure), must also be considered. The reprocessing costs for the containers must also be considered. In contrast, when soft packaging is used, the disposal effort and the resulting costs must be calculated.

Environmental aspects

The fact that more waste is generated when using nonwovens than when using container systems does not require further explanation. Nevertheless, even when using containers, there are consumables such as filters and seals or even an inner and/or drying fleece. An additional fleece in the container should always be critically questioned if it is not absolutely obligatory for user safety or the steam sterilization process. Not only is there more waste, but an additional fleece also means additional costs and additional work. The rule here is that less is more.

When processing containers, it must again be considered that there is a higher consumption of media, of course, water and chemicals are used. In the newer generations of equipment, however, there is the possibility of deionized water recycling. This means that the deionized water from the last rinsing step of the disinfection in the WD can be used for the first rinsing step in the container and trolley washer. This means that no fresh water is required for this first step and the water does not have to be heated.

Conclusion

Selecting the appropriate sterile barrier system is not an easy decision. It depends on various factors and is ideally decided by a team. If it fits the workflows in the OR, in the CSSD or in the practice, it helps to optimize the processes and is an essential part of the reprocessing process. Clear, familiar procedures, uniform packaging systems and adherence to the minimum principle not only help to prevent errors, they also speed up the overall process and thus save money.

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Processing of cleaning textiles - DIN 13063 Hospital cleaning

André Funke,
Antoinette Stritzke

Authors

Dipl.-Ing. André Funke
Senior Program Leader
Corporate Accounts Technical Service
Institutional Europe
Ecolab Deutschland Gmbh
Ecolab-Allee 1
D-40789 Monheim am Rhein
T +49-2173-599-0
andre.funke@ecolab.com

Dipl. Kffr., Dipl.-Ing. (FH) Antoinette Stritzke
Laundry Applications & Sales Support
Customer Segments & Solutions
Miele & Cie. KG
Business Unit Miele Professional
Carl-Miele-Str. 29
33332 Gütersloh
Phone: +49 5241 89-1478
antoinette.stritzke@miele.com

DIN 13063 (2021) Hospital cleaning at a glance

DIN 13063 specifies the requirements for the cleaning of hospitals and other medical facilities (facilities for outpatient surgery, preventive or rehabilitation facilities, dialysis facilities and day clinics).

More than 50 experts from science and research, hygiene institutes, service societies and industry as well as the supplier industry participated. In addition, the expertise of the Robert Koch Institute, the German Hospital Association, the German Society for Hygiene and Microbiology, the German Society for Hospital Hygiene and the Federal Environment Agency as well as the DIN Consumer Council were available.

The purpose of this standard is to ensure consistent quality and effectiveness of cleaning services to ensure a hygienic environment for patients, visitors, and medical staff. Another important concern is to describe the permissibility of cleaning processes, especially if further standards are binding. For this reason, the chapter "Scope of application" deals with the inventory and equipment in the patient's room. These can be disinfectant cleaned according to the standard, even if they are classified as a medical device.

The structure of the standard is based on the three dimensions of quality management in the healthcare sector: structural quality – process quality – quality of results. In particular, in the chapter on structural quality, requirements for both the client and the contractor are described. Thus, this standard is aimed at all parties involved in the cleaning process.

Requirements for cleaning textiles for disinfectant cleaning

Cleaning textiles are all textiles that are used for the (disinfecting) cleaning of surfaces and objects. The essential functions of the cleaning textile are the delivery and distribution of detergent/disinfectant solution, transfer of sufficient mechanics to achieve wipe disinfection, mobilization of dirt, absorption of dirt and excess detergent/disinfectant solution. The characteristics of the cleaning textiles are, on the one hand, the structure of the textile, the durability and the compatibility in use with disinfectants. Nowadays, cleaning textiles are therefore technical products that have to withstand a high load in the application and in the washing processes (including drying). Unsuitable materials have too high a depletion of active ingredients and falsify the result.

Here are some important aspects to consider:

- **Cleanliness:** Cleaning textiles should be clean before they are used. They should be washed regularly, disinfected and, if necessary, sterilized to prevent the transmission of germs.
- **Material:** The cleaning textiles used should be made of materials that are suitable for their intended purpose. They should be durable, tear-resistant, and chemical-resistant to meet hospital cleaning needs.
- **Color coding:** It is recommended to use different color codes for cleaning textiles in different areas of the hospital to avoid cross-contamination. For example, specific colors can be set for cleaning patient rooms, bathrooms, operating rooms, etc.

Fig. 1: Example of a cleaning textile with color coding (Ecolab).

- **Intended use:** Cleaning textiles should be used according to their intended use. It is important to use separate textiles for cleaning floors, surfaces, toilets, etc., to minimize the transmission of germs.

In addition to economic factors, the properties and quality of the cleaning textiles should be at the forefront of procurement. Once used, cleaning textiles, such as disposable wipes, must be disposed of properly after use. Recyclable textiles must be subjected to a proper and professional reprocessing process before reuse.

Components of the reprocessing process of reusable cleaning textiles

When preparing the cleaning textiles, the complete process must be considered from a hygienic point of view. The process begins with the intermediate storage of the cleaning textiles after their application, followed by the washing and disinfection process, the downstream process steps, such as mechanical drying or pre-impregnation, as well as the storage and transport of the textiles to the place of use. This process and the resulting requirements for processing apply both to internal processing, i.e. in the object itself, as well as to processing outside the object as well as to the outsourcing of processing to third parties. For internal processing, the necessary structural requirements for the client are named, this is the only way to ensure proper processing.

Regardless of the place of reprocessing, the organization of the logistical processes must be evaluated from a hygiene point of view. Here, particular attention must be paid to the separation of soiled cleaning textiles and textiles that have already been processed. This separation is important to avoid unwanted recontamination. In addition to the textiles, however, the containers for transporting the textiles must also be separated into unclean and clean containers and, if necessary, disinfected.

Preparation methods

For the first time, three different treatment methods are described in detail

1. Disinfectant wash cycle with subsequent drying of the cleaning textiles
2. Disinfectant wash cycle with machine pre-soaking
3. Disinfectant wash cycle with manual pre-soaking

Common to all reprocessing methods is the disinfectant washing process. This is derived from the fact that a separation of the cleaning textiles before reprocessing according to

- Only used for cleaning
- Used for disinfectant cleaning

is not safe to comply with in practice.

In the case of disinfectant washing processes, a distinction is made between thermal, chemo-thermal and chemical disinfection washing processes. In order to ensure the disinfecting effect of this process, compliance with the parameters of disinfection temperature, temperature holding time and liquor ratio must be reliably maintained. For all chemo-thermal and chemical disinfection washing processes, compliance with the dosing quantities and the dosing time are an important part of this process.

Tested chemo-thermal disinfection processes are listed, for example, in the list of the "Verbund für Angewandte Hygiene e.V." (VAH - Association for Applied Hygiene). Specifications for a thermal disinfection washing process, on the other hand, are listed in the disinfectant list of the Robert Koch Institute (RKI).

Certain commercial washer have such disinfectant washing procedures. Proof is provided by validation. This is also accompanied by the equipment of safety functions, such as the fact that these procedures cannot be aborted. Various processes can be added downstream of the disinfecting washing process. From a hygienic point of view, drying the cleaning textiles is a safe method that does not include any restrictions on storage. However, this requires complete drying. This standard describes for the first time how proper drying can be demonstrated, namely by measuring the so-called a_w value.

Another method described is mechanical pre-soaking. In this process, the cleaning agents or surface disinfectants are added in the last treatment step of the disinfecting washing process. To ensure this procedure, the manufacturer's instructions must be observed. In the absence of manufacturer's information, the test intervals with regard to the effectiveness of this method must be determined as part of a risk analysis.

The third variant is wet storage with subsequent manual pre-impregnation. In the case of pre-impregnation, the maximum service life must be determined. At the end of the maximum service life, the cleaning textiles must meet the specified microbiological guideline values. The most important criterion for quality assessment is effectiveness on the surface.

Quality tests for the functionality of the cleaning textile

In general, functional tests of cleaning textiles are an important part of quality management in hospital cleaning. Specific testing procedures and criteria may vary from facility to facility, depending on internal policies and requirements. Here are some typical aspects that are considered when functional testing of cleaning textiles in hospital cleaning:

Cleanliness: The cleaning textiles should be clean and have no visible dirt or contamination.

Integrity: The cleaning textiles should be in good condition, with no tears, holes or other damage that could affect the cleaning performance.

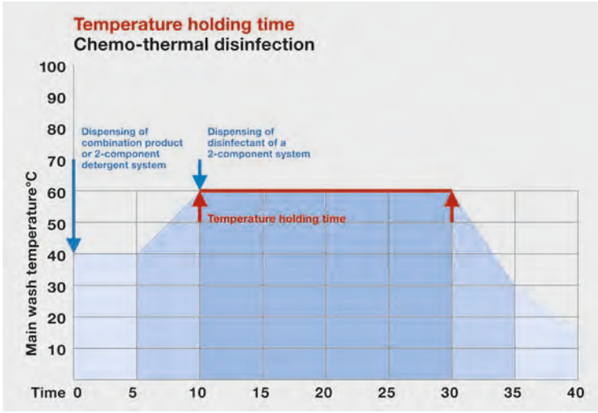

Fig. 2: Schematic representation of the disinfection phase in a chemothermal disinfection washing process. Source: Miele

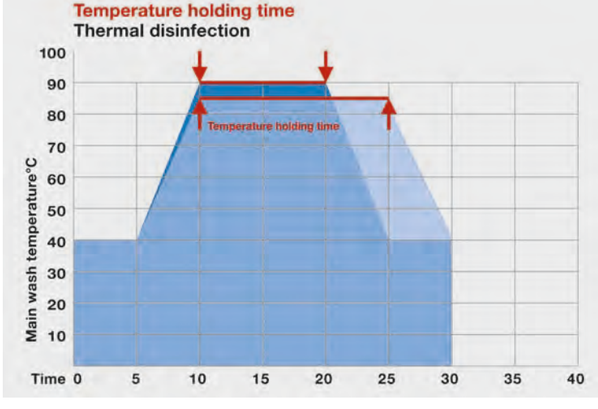

Fig. 3: Schematic representation of the disinfection phase in a thermal disinfection process. Source: Miele

Washability: The cleaning textiles should be washable and able to retain their shape and properties after washing.

Disinfectant suitability: The cleaning textiles should be suitable for disinfection and should not contain any materials that could impair the effectiveness of disinfectants.

Low residues: The cleaning textiles should be low in residues and leave no fibers or residues on the cleaned surfaces.

A first indication that the functionality is no longer given is the increase or decrease in weight of the cleaning textile.

Summary

DIN 13063 is a comprehensive document that describes the requirements for cleaning and disinfectant cleaning in hospitals and other medical facilities. With the clearly structured structure in terms of structure, process and result quality, the requirements for preparation, implementation and quality controls are also listed.

Cleaning textiles must meet many requirements for hygienic cleaning performance. Only reusable cleaning textiles advertised by the manufacturer can be properly reprocessed. The organizational and logistical procedures for reprocessing are dealt with in this standard from a hygienic point of view.

To ensure that the cleaning textiles fulfil their functionality on the surface after processing, the disinfecting washing process, processes downstream of the washing process and their inspection are described in detail in DIN 13063 Hospital cleaning.

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Specific inspection of lumened instruments in CSSD at MKM

Authors

Dr. med. Hubert Holz
Medical specialist for hygiene & environmental medicine/anaesthesia
Chief Hospital Hygienist
at Marienhaus Kliniken GmbH
Katholisches Klinikum Mainz
An der Goldgrube 11
55131 Mainz
Hubert.Holz1@marienhaus.de
www.kkm-mainz.de

Udo Dettmann
registered hygiene specialist
Hospital hygiene department
Marienhaus Klinikum Mainz
An der Goldgrube 11
55131 Mainz
udo.dettmann@marienhaus.de

Hubert Holz, Udo Dettmann

The reprocessing of lumened instruments places great demands on washer-disinfectors and on CSSD personnel. A visual inspection of lumens is not possible or only to a limited extent. In the face of this, the MKM introduced a quarterly and additional inspection of lumened instruments several years ago. To this end, reprocessing is interrupted in the washer-disinfector to allow lumened instruments to be inspected by a hygiene specialist.

Method

1)
A swab soaked in isotonic sodium chloride solution is introduced to the lumens, cones and valves and the inner surfaces swabbed intensively. This is followed by wiping the swab on a casein soya peptone agar plate (25 cm^2). The plates are then incubated for 3 days at 36°C. A first inspection of the plates takes place after 24, 48 and finally after 72 h.

2)
Irrigation of lumened instruments using a sterile syringe, filled with sterile isotonic sodium chloride solution. Complete wetting of a sterile swab with the fluid (in the event of conspicuous findings, also examination of eluate), followed by wiping out the swab on a casein soya peptone agar plate (25 cm^2). The plates are then incubated for 3 days at 36°C. A first inspection of the plates takes place after 24, 48 and finally after 72 h.

Conclusion

As part of validated processes in a CSSD, it makes sound sense to carry out random internal quality control inspections. High product quality can be assured at an early stage in the interests of quality management through process monitoring, in this case on a complex medical product.

Fig. 1: Swabbing of laparoscopic cannula.

Fig. 2: Swabbing of bi-polar sleeve.

This affords an additional level of security before instruments are used again on patients. To secure this standard of quality, a quarterly microbiological inspection was introduced alongside the routine validation of processes. These inspections have so far produced favourable results throughout.

Our evaluations have so far not produced any negative results and no additional measures were ever necessary. It can be confirmed that the CSSD team performs highly diligent reprocessing work, even on complex medical products.

Fig. 3: Irrigation of trocar.

No.	Sampling point	Agar	Testresult	Target	Evaluation
1.	Sleeve Bipolar 8384.974 Hose connection	Bacteria	0 CFU/24 cm^2	0 CFU/24 cm^2	inconspicuous
		Fungi	0 CFU/24 cm^2		
2.	Trocar EK 5248 Gas connection	Bacteria	0 CFU/24 cm^2	0 CFU/24 cm^2	inconspicuous
		Fungi	0 CFU/24 cm^2		
3.	Trocar sleeve EK 090R Inner lumen	Bacteria	0 CFU/24 cm^2	0 CFU/24 cm^2	inconspicuous
		Fungi	0 CFU/24 cm^2		
4.	Sleeve Grasping forceps distal end	Bacteria	0 CFU/24 cm^2	0 CFU/24 cm^2	inconspicuous
		Fungi	0 CFU/24 cm^2		
5.	LSK Suction cup 8383.71 Connection hose	Bacteria	0 CFU/24 cm^2	0 CFU/24 cm^2	inconspicuous
		Fungi	0 CFU/24 cm^2		

Fig. 4: Assessment of findings.

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Insight: water leading systems in dental chairs

Authors

Gloria Jöst
Global Product Manager
Sirona Dental Systems GmbH
Fabrikstr. 31
64625 Bensheim, Germany
gloria.joest@dentsplysirona.com
www.dentsplysirona.com

Stella Nehr-Werner
Global Infection Control
and Prevention Consultant
Sirona Dental Systems GmbH
Fabrikstr. 31
64625 Bensheim, Germany
stella.nehr-werner@dentsplysirona.com
www.dentsplysirona.com

Michael Sift
Product Owner Hygiene
Sirona Dental Systems GmbH
Fabrikstr. 31
64625 Bensheim, Germany
michael.sift@dentsplysirona.com
www.dentsplysirona.com

Gloria Jöst, Stella Nehr-Werner, Michael Sift

Water plays an important role in dental treatment. The dental chair is connected to the drinking water and supplies both the motors and the multifunction syringe with water for safe and pleasant treatment. Likewise, the patient is supplied with fresh water via the tumbler filler for rinsing during and after treatment. But who ensures that the water in the dental chairs is always fresh and reaches the patient hygienically uncontaminated? Are there design and construction measures that influence water hygiene? And how do I, as the operator, notice that something in my dental chair is no longer in order?

What role does water play in dental treatment?

Water in the dental treatment unit is used at various points during patient treatment. Classically, a mixture of air and water is used to cool the rotating instrument during tooth preparation. In this case, the dentist and assistant as well as the patient come into contact with the water from the unit. Furthermore, dental chairs have a multifunctional syringe which enables the dentist to use air and/or water to rinse the area to be prepared, for example. Some units also have ultrasonic or sonic instruments, which offer water cooling to minimize heat build-up on the tooth and to directly rinse off any concrements that may accumulate. Not to forget the tumbler filler, through which the patient receives water to rinse the oral cavity during or after the treatment. The use of water from the dental chair is therefore manifold and indispensable during treatment.

Fig. 1: spray of a turbine.

Legal classification of water

In Germany, drinking water is subject to the Drinking Water Ordinance (TrinkwV), which regulates how drinking water must be treated, especially regarding its microbiological composition. It also specifies how drinking water must be protected from contaminated water being fed into the system, e.g. with a so-called free fall section that prevents contaminated water from flowing back into the drinking water circuit. What this mechanical protection looks like is declared in EN 1717. Depending on the type of potential contamination, it must meet certain requirements. Therefore, it is specified exactly how the dental chair must be structurally separated from the pipe network.

The dental chair itself is a medical device, which means that it needs to be approved and CE declared while fulfilling the requirements of medical device law (now MDR or MDD). It must meet all the necessities of these legal conditions and the manufacturer must provide information regarding care, maintenance, and hygiene measures. Evidence must be provided for these details, i.e. the manufacturer must prove that these measures actually work. A medical device as well as the water used must not pose any risk to the patient or user.

Since the RKI guidelines for dentistry ("Requirements for hygiene in dentistry" 2006) are no longer being revised, reference is made to the recommendations of professional societies for special areas. Thus, information about water in dental chairs can be found in the current DAHZ Hygiene Guide.[1]

What does this mean for the practice?

Although the water in the dental chair is not considered drinking water according to the German Drinking Water Ordinance (TrinkwV), the water quality must of course be equivalent to drinking water. The practice team must therefore ensure that the water quality is always consistently good so as not to endanger either patients or its own team. Initially, it must be ensured that the piping network and the domestic installation in the practice are in order and thus do not supply contaminated water. The challenge here is that many factors affecting water quality are building-related. For example, inadequate house inlet filters, dead sections in the piping system or old pipes can reduce the quality of the water and cause permanent difficulties. But poor home insulation or underfloor heating next to the supply line to the units can also promote fouling in the lines. Therefore, even before installation, the water lines should be sampled to ensure that good water quality prevails before connecting a new treatment unit to the mains.

If everything is in order at the time of installation, hygiene measures taken by the practice team and regular routine checks ensure that the quality of the service water remains consistent. It is important that the measures recommended by the manufacturer are carried out meticulously. It is also worthwhile to have the house installation regularly inspected by experts and to monitor the quality with routine water samples.

What is biofilm?

In general, biofilms are communities of microorganisms. Optimally adapted to their environment and living conditions, their survival probabilities are higher in a group than alone and thus it is advantageous for these living organisms to form colonies. To the human eye, this colonization only becomes visible when a large biofilm has already formed and thus an exorbitant colonization has already taken place. Drinking water, which also feeds the waterways of dental chairs, also contains microorganisms that can potentially build up biofilms on the surfaces of water-bearing systems. Drinking water is never free of microorganisms, but certain limits must be observed with regard to microbiological quality. Once microorganisms have attached themselves to the surfaces, they form a slime layer that not only serves to absorb nutrients and thus feed this colony, but also to protect it from chemical and physical environmental influences. Particularly good biofilm formers are microorganisms such as P. aeruginosa, which are especially critical because of their hygienic relevance.

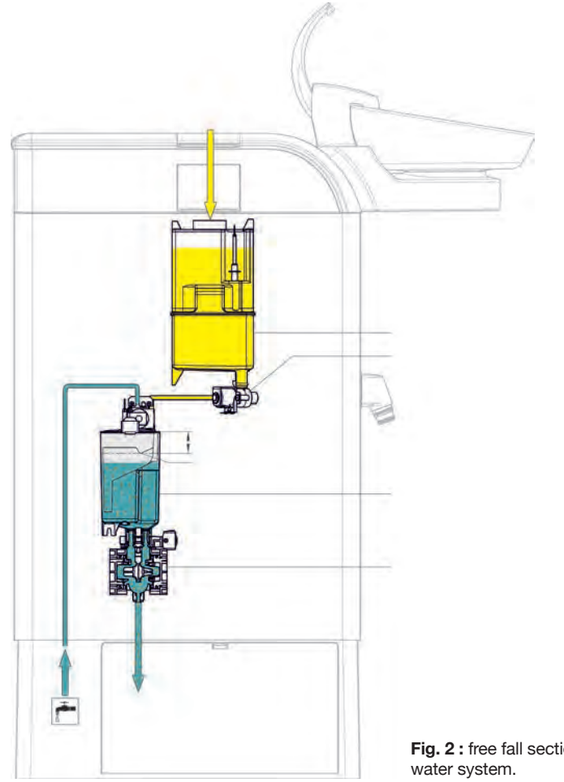

Fig. 2 : free fall section in the water system.

Conversely, this means that preventing biofilm is much more effective than combating it. This is because an already formed and firmly anchored slime layer (microorganisms protected by the so-called extracellular matrix) can hardly be removed with simple measures such as vigorous rinsing or disinfectants. Already existing biofilms, which have negative hygienic effects, must be eliminated with elaborate measures such as a so-called biofilm removing. This usually involves dissolving the biofilm from the surface by treating it with special pro-

ducts. This results in downtime and additional costs. The selection of materials as well as the nature of the water (nutrient supply, temperature, and flow behavior) also influence the formation of biofilms.[2]

How good should the water in the dental chairs be?

The water quality must always meet the national requirements for drinking water. In Germany, the Drinking Water Ordinance (TrinkwV) applies, according to which a maximum of 100 CFU (colony-forming units) per milliliter of water may be measured, of which a maximum of one CFU of Legionella per milliliter is allowed.[3]

Fig. 3: dental chair from Dentsply Sirona – Axano.

What are the options for biofilm prevention and what is a bottle system?

Manufacturer offer various systems and processes to ensure the water quality in the unit and to prevent the formation of biofilm. A common variant is a hygiene system installed in the unit, where chemicals are permanently added to the water in the dental chair to prevent the formation of biofilm and thus achieve consistent water quality. The practice staff has to regularly maintain these systems with chemicals. Modern dental chairs monitor the measures and report inadequacies directly to the user. In some units, it is also possible to view the condition of the units centrally in the practice via a monitoring system. It shows which measures have been carried out on which unit and indicates the current level of chemicals. With these hygiene systems, it is important that the practice team adheres precisely to the manufacturer's instructions, especially when selecting the chemicals and adhering to the routine measures. This is the only way to ensure that the units survive the process and that the material is not damaged.

Another measure usually offered by manufacturers to ensure water quality is the so-called bottle system. Here, the operator has the possibility to use the unit independently of the normal pipeline network. This measure becomes particularly necessary if the supplied drinking water (city water) is contaminated. Then the responsible health office publishes a notice stating that the water must be boiled before consumption. Again, for legal reasons, only the solutions offered by the manufacturer should be used.

Fig. 4: Bottle-System.

Another necessity for the use of external cooling water is the treatment of immunosuppressed patients or extensive surgical procedures. Here, one should use the sterile saline solution and an external pump installed on the unit.

How important are routine checks and maintenance?

Routine checks ensure that the user can monitor his processes in daily operation and quickly detect inadequacies. This applies on the one hand to water quality, but also on the other hand, for example, when using chemicals for correct dosing. Regular water sampling can certainly help to monitor water quality optimally. Inadequacies can also be detected and remedied immediately during daily, weekly, or monthly care and maintenance work specified by the manufacturer for the dental chair. Maintenance and replacement of filters and strainers, as well as many other measures, belong to these care intervals.

How can the manufacturer support?

Construction and design
Manufacturers support hygiene processes in the dental chair with an appropriate design of the waterways. Few stagnation elements, waterways aligned to flow velocities and the avoidance of dead stretches are just a few selected design measures. Furthermore, hygiene already plays a significant role in the planning of new treatment units and is reflected seamlessly in all elements of the unit from the very first design.

Materials
Hygiene is also considered in the selection of materials for the waterways. In addition to the general suitability of the materials for water-bearing systems intended for human use, the materials should at least make colonization by biofilm difficult. Thus, the right material in combination with routine hygiene measures is a critical component in maintaining water quality.

Manufacturer information
Manufacturers evaluate all hygiene measures of their medical devices for effectiveness and material compatibility. The used agents (cleaners, auxiliaries, disinfectants, etc.) are validated in connection with the method described in the instructions for use. This gives the user the assurance that the agents described are effective and harmless to the materials.

Conclusion

The water paths in the dental chairs are complex. Keeping them hygienically stable is no easy task, as various influencing factors can affect the quality of the water. In addition to regular monitoring of the on-site water installations, the water in the units must also be monitored. It is worthwhile to carry out the measures specified by the manufacturer in order to take preventive action and not to react only when the values deteriorate. This not only serves to protect patients and staff, but also helps to avoid expensive remediation measures such as biofilm removing.

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Validation of automated cleaning and disinfection processes for the reprocessing of thermolabile endoscopes according to the DGSV framework curriculum

Authors

Johnny Wenzel
Aera Representative North / East, ebro
Xylem Analytics Germany Sales
GmbH & Co. KG
Peringerstrasse 10
D-85055 Ingolstadt
johnny.wenzel@xylem.com

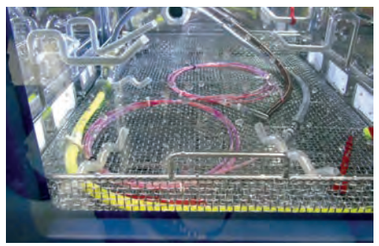
Robert Streller
R&D, Lab, CompetenceCenter, ebro
Xylem Analytics Germany GmbH
Peringerstrasse 10
D-85055 Ingolstadt
robert.streller@xylem.com

Johnny Wenzel, Robert Streller

In recent years, the validation of automated cleaning and disinfection processes for reprocessing thermolabile endoscopes has gained significantly in importance.
German hospitals are for the most part equipped with modern washer-disinfectors for thermolabile endoscopes (WD-E), whose reprocessing processes have been validated for many years.

In private practice, there is a constant change from manual to mechanical reprocessing. However, gastroenterologists, who generally work with mechanical reprocessing processes, do not make up the majority of those who switch from manual to mechanical reprocessing. Rather, there are other medical specialties that work with thermolabile endoscopes, such as urologists in private practice, regardless of whether they are larger group practices or smaller individual practices. The demand for machine reprocessing of thermolabile endoscopes has steadily increased in these areas.

Fig. 1: Test tube for testing the cleaning performance.



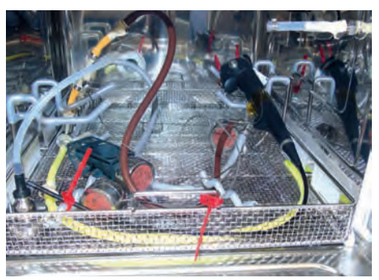


Fig. 2: Real endoscope in process. Measurement of temperature and conductivity of the rinsing liquor and the rinsing pressure.

One reason for the increasing number of validated processes as well as the steadily increasing demand for certified training courses are the relevant paragraphs of the MPBetreibV [1] = Medical Devices Operator Regulations, such as §8 (1) "The reprocessing of medical devices intended for use aseptic or sterile must be carried out with suitable validated procedures, taking into account the manufacturer's specifications, in such a way that the success of these procedures is traceably guaranteed and the safety and health of patients, users or third parties is not endangered." and § 5 (2) Requirements for the validator: "Compliance with these specific requirements may be demonstrated by the presentation of a certificate issued by a body recognized by the authority responsible for notified bodies in the scope of this legal regulation (Article 35 (1) (EU) 2017/745) [2] or (Article 31 (1) (EU) 2017/746) [3] ".

In this context, there was an increase in demand from validation companies for specific training courses especially in the area of performance qualification of automated cleaning and chemo-thermal disinfection processes.

Since 2022, the DGSV[4] has therefore been offering a new uniform framework curriculum and a separate module on the topic of "Validation of automated cleaning and disinfection processes for the reprocessing of thermolabile endoscopes". This helps to further improve and optimize validations in this segment.

The framework curriculum designed by DGSV[4] comprises 4 modules:

Framework curriculum - parts

Vali A Basics of medical device reprocessing (24TU)

Vali B Basics of performance qualification of reprocessing processes (24TU)

Vali C Performance qualification of cleaning and disinfection processes (24TU)

Vali E Performance qualification of steam sterilization processes (16TU)

The Vali-C module includes two courses, C1 and C2. Each part has 24 teaching units (1TU = 45min).

Fig. 3: Spypach „Classic" endoscope dummy with EBI12 data logger for measuring pressures and temperatures in the simulated endoscope.

The module Vali-C2 is specially designed for the needs of performance qualification of automated cleaning and chemo-thermal disinfection processes and consists of the following components:

- Welcome/Introduction 1 TU
- Risk management in the performance qualification of automated cleaning and chemo-thermal disinfection processes 2 TU
- Sequence plans 1 TU
- Validation of cleaning and disinfection processes 16 TU
- Tasks after performed process validation 4 TU
- Knowledge review

The course begins with a round of introductions of the participants and speakers, after which the contents, objectives and focal points of the validation course are explained by the course leader.

In the following part "Risk management" the connection of the risk management with the performance qualification according to the standard DIN EN ISO 14971[5] and the guideline VDI 5700-1[6] is taught.

The topic "Sequence plans" deals with the general process of a performance qualification. Points such as important contact persons during performance and possible incidents that could prevent performance qualification are also discussed.

The part "Validation of cleaning and disinfection processes" refers mainly to the performance qualification and requalification. It also briefly discusses the other components of validation, installation and operational qualification. The topic of routine inspections is also a brief part of the module. Reference is made to the most important standards and laws. The performance qualification is covered on the basis of the current WD-E guideline 7 and the most important standards for this area, DIN EN ISO 15883-1[8], DIN EN ISO 15883-4[9], DIN EN ISO 15883-5[10] and DIN 58341[11].

For this module, we recommend conducting the performance qualification in a practical part on the WD-E.


MUSTERBERICHT VALIDIERUNG

-ebro-

Validierungsbericht

Reinigungs-Desinfektionsprozess

Fig. 4: A report summarizing the results is required.

Overview of the most important components

Decision making of the processes to be validated, breakdown of the thermolabile endoscopes to be reprocessed into endoscope families as well as the configuration/ equipment in the individual reprocessing programs.

- Prerequisites / preparations of the process validation
- Significance of different influences on the respective result of process validation
- Components of the process validation (IQ/OQ/PQ)
- Sequence of the different reprocessing processes and their characteristics

- Determination of the components of performance qualification to be carried out and the number of test runs
- Components of requalification without special cause as well as for special cause
- Theoretical and practical performance qualification based on the following steps:
  - Testing of the cleaning performance on the basis of test specimens and indicators
  - Testing of the overall process on the basis of test specimens and really soiled endoscopes
  - Testing of process-relevant parameters (temperature, rinsing pressure, dosing quantity, etc.)
  - Testing of the rinse water for process chemical residues
  - Microbiological condition of the rinse water
  - Testing of the drying process
- Handling of test specimens as well as requirements for test specimens and test laboratories
- Handling of measuring equipment and evaluation software
- Determination of routine checks

After the practical part, the exercises will be taught after the process validation has been performed.

This includes:

- Content and form of the validation report
- Contents of the follow-up discussion
- Release of the validation report
- Dealing with defects reporting.

A written examination follows after all components of the Vali-C2 module have been completed. Participants who pass the exam receive a DGSV[4] certificate.

More information can be found at:
www.fht-dsm.com/kurse/sterilisation-validierungs-lehrgang-für-validierer

Conclusion

The DGSV course Vali C2 is an important prerequisite for being able to perform validations of machine-based WD-E processes. This certificate enables the validator to meet the qualification requirements of [Medical Devices Operator Regulations 1, §5 (2)]. This ensures legal and process safety for the user as well as for the patients' protection.

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Reprocessing of single-use products in endoscopy

Birgit Kampf, Annette Rittich, Helmi Henn

The increasing use of disposable products is a current trend in endoscopy. This not only applies to endoscopic accessories and components, but also increasingly to the endoscopes themselves. By definition (according to Commission Implementing Regulation (EU) 2017/745, also known as Medical Device Regulation, MDR, article 2, point 8), single-use products should only be used once on a single patient.[1] Therefore, the instructions for use for single-use products do not contain any information on safe reprocessing practices or functional checks after reprocessing. To ensure these devices are utilized only once, some manufacturers have designed their single-use products in such a way that reprocessing is not possible after use ("single-use by design" principle).

Surprisingly, reprocessing of single-use products is generally not prohibited even if it contradicts the intended use as defined by the manufacturer. §17 MDR regulates the reprocessing of single-use products, but national regulations must be used as a prerequisite for the permissibility of this practice. In these cases, the reprocessing entity becomes the "new manufacturer" and must assume the responsibility of the original manufacturer according to §17 MDR. This includes preparation of the technical documentation. For example, required risk management practices must include an evaluation of the following product characteristics:

- materials
- design
- properties and
- intended us

In this context, the reprocessability must also be considered. This should include assessments of:

- the microbiological contamination to be expected during normal use of the product,
- how reprocessing may affect the material changing of the product, in particular regarding the soluble or chemically reactive components of these materials, and
- remnants of reprocessing, that may cause pyrogenic, allergic, or toxic reactions.

The Commission Implementing Regulation (EU) 2020-1207[2] further explains that single-use products must not be reprocessed where severe incidents have occurred, such as patient infections related to improper reprocessing. If successful reprocessing of a single-use device seems possible through risk management, then all steps of the reprocessing process, including initial treatment at the point of use, must be validated. This also includes a determination of the maximum possible reprocessing cycles. Furthermore, procedures for performance testing and product lot releases must be defined and included in a quality management system. The manufacturer's responsibility does not end with the product release but extends to the obligation to report incidents and to ensure the traceability of all disposable products that have been reprocessed and brought into use.

In summary, from the point of view of the Instrument Reprocessing Working Group (AKI), the only endoscopes, accessories and components that should be reprocessed are those intended to be reprocessed by the respective manufacturer and for which there are corresponding instructions for use.

Authors

Dr. Birgit Kampf
Infection Prevention Consultant
Medical Scientific Affairs
birgit.kampf@olympus.com
OLYMPUS EUROPA SE & CO. KG
Wendenstraße 20
20097 Hamburg
Germany

Annette Rittich
Global Lead Infection Prevention & Control
Medical Scientific Affairs
annette.rittich@olympus.com
OLYMPUS EUROPA SE & CO. KG
Wendenstraße 20
20097 Hamburg
Germany

Helmi W. Henn
Abteilungsleiterin Global Hygienemanagement, RBSMP
Director of Global Hygiene Management, RBSMP
Richard Wolf GmbH
Pforzheimer Strasse 32
75438 Knittlingen
helmi.henn@richard-wolf.com

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Dr. Sabine Kaufmann
Graduate Biologist
Klinikum Winterberg gGmbH

3 questions for...

Dr. Sabine Kaufmann

1. What makes the job in the CSSD so exciting?

Working in an CSSD is very varied and demanding. No two days are the same. I like the close cooperation and communication with the OR and the surgeons, but also with the many other interface departments such as hygiene, quality management, human resources, the business department or the technical department. CSSD is a small company within a company. Therefore, business management thinking and meeting qualitative specifications and requirements are also absolutely necessary.

Especially the instrument management is very exciting. As a result, the CSSD has a direct influence on the design and quality of medical devices and sets, which has a direct added value for the users and ultimately a positive impact on the care of our patients.

2 What do you despair of from time to time, even in your job?

Sentences like "It's always been like this" make me despair. There is always a possibility to become better and to optimize processes. You shouldn't lose sight of this, even in your stressful day-to-day business. It is exhausting, but essential. The ever-increasing demands on CSSD, but also the current problems, such as the shortage of skilled workers, the omnipresent supply bottlenecks and the energy crisis, even make it inevitable to question and optimize processes. Only through continuous further development can an CSSD exist and work both qualitatively and economically.

The shortage of personnel is actually also something that gives me many sleepless nights. Unfortunately, even as a manager, you have only limited influence and possibilities to find and keep employees. There is nothing worse than a high turnover in an existing and actually functioning team.

3. The shortage of skilled workers is felt in many professions, including CSSD. How can the profession of medical device reprocessing specialist be brought to the attention of young people?

The shortage of skilled workers is indeed a cause for concern. Of course, the work in CSSD must be adequately remunerated, especially because the demands on employees are constantly increasing, but that is certainly not the only adjustment screw that can be turned to make the job more attractive overall. It is important to provide detailed information about the content and challenges of the job.

That's why our Corporate Communications department uses social media such as Facebook and Instagram to appeal to the younger generation in particular and to make the job more popular and raise awareness. Our work takes place "behind the scenes," but it is still a pivotal point. I think it is important to reflect this to the existing team, but also to potential new colleagues. Because new blood is often in short supply in CSSD, but it's really good for an existing team because it opens up new perspectives and gets us away from "we've always done it that way".

Our job advertisements are also publicized in various ways in order to reach as many people and professional groups as possible. After all, career changers are always welcome. Thanks to the support provided by a special IT system/batch documentation system or digitalization, even employees with no previous knowledge can quickly find their way around the job.

Another cornerstone is the sound training of employees in the CSSD. We attach great importance to induction training at our CSSD and have a comprehensive induction concept. Only those who are well trained can take on responsibility and develop further.

In order to give new colleagues a perspective, opportunities for further development in the CSSD are essential. Since last year, we have been working with the provider of an e-learning portal to offer the opportunity for continuous internal online training and to complete the Specialty Course I online with only one week of classroom instruction at our facility. This format is particularly attractive for people who are unable to be away for three weeks or who are not mobile.

The term appreciation sounds trite, but it is a recurring theme among my employees. Often located in the low-wage sector, the importance of the CSSD in a hospital is not infrequently misjudged and not sufficiently appreciated, especially in terms of external perception. However, the "steri" of 20 years ago has nothing to do with the CSSD of today. The work is not only physically demanding, but also requires a high level of concentration, initiative and commitment from the employees.

For young people today, the work-life balance is playing an increasingly important role. We therefore offer, among other things, a wide variety of shift models tailored to life situations and reliable duty rosters and working hours. These times call for a rethink and new ways of doing things.

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Office, das Büro der aseptica
Bernd Vieregge
Frieda-Nadig-Straße 53
33332 Gütersloh
E-Mail: info@aseptica.com

Responsible for content:
Dr. Ulrike Weber
Business Unit Miele Professional
Miele & Cie. KG
Carl-Miele-Straße 29
33332 Gütersloh
Telefon: 05241 89-1494
E-Mail:
ulrike.weber@miele.com

Overall production:
COLLET Concepts Communication
Ziethenstraße 10
33330 Gütersloh
Telefon: 05241 50 56 664
E-Mail: info@aseptica.com
Internet: www.aseptica.com
Stefan Collet, Anne Majcen

In co-operation with:
Ecolab Deutschland GmbH
Ecolab-Allee 1 | 40789 Monheim am Rhein;
Miele & Cie. KG
Postfach | 33325 Gütersloh;
Dentsply Sirona Deutschland GmbH
Fabrikstraße 31 | 64625 Bensheim;
Xylem Analytics Germany Sales GmbH & Co. KG
Ebro
Peringerstraße 10 | 85055 Ingolstadt;
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Deutschland GmbH
Lückenweg 5 | 29227 Celle

Editorial team:
Aaron Papadopoulos, Ecolab
Ulrike Weber, Miele
Stella Nehr-Werner, Dentsply Sirona
Iven Kruse, ebro
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Title image: Dentsply Sirona Deutschland GmbH
Circulation: 5.200
Publication schedule: three times a year
Printed on chlorine-free bleached paper

ISSN 1439-9016

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* Comparison of the microbiological kinetics of action of the disinfectants Dentosept S and Dentosept Clean, HygCen Germany GmbH, 2021.
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