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28. Jahrgang 2022 | Heft 2

Bilingual

DIN EN ISO 15883-5:2021 – Ein neuer Maßstab für die Reinheit von Medizinprodukten

DIN EN ISO 15883-5:2021 – a new standard for the cleanliness of medical devices

Editorial

Dear readers,

as experts get up to date with the latest developments in hygiene and reprocessing and learn all you need to know about these and other topics in our current issue.

Under Technology and Hygiene, Dr. Kohnen highlights various methods of indoor air hygiene as part of pandemic control. In particular, he discusses the different types of ventilation measures and their possibilities and limitations.

Mr. Papadopoulos provides information in his article "Correctly assessing and analyzing surface changes: Residues due to process chemicals" about the origin and causes of surface changes, as well as how to avoid and eliminate them.

In the Clinic and Hygiene section, learn more about the effectiveness and benefits of UV disinfection processes in hospitals. Learn about the possibilities offered by UV disinfection and where these devices can be used effectively.

I hope you enjoy reading and reading this issue of aseptica.
Stay healthy!

Stella Nehr-Werner

Report

Number of patent applications in Europe at a record high

Following a decline caused by the pandemic, the number of patent applications in Europe rose again last year. This was announced by the European Patent Office (EPO) in Munich. According to the EPO's patent index, 188,600 patent applications were filed last year, an increase of 4.5 % compared to the previous year. This was a new record for the EPO. According to the EPO's patent index, the main driving factors were digital and medical innovations, as well as Chinese companies. 15,400 applications were filed in the field of digital communication – 9.4 % more than in 2020. The field of medical technology was close behind with 15,231 applications, an increase of 8.8 %, ahead of computer technology with 14,671 applications, an increase of 9.7 %. The figures for 2021 indicate a "return to normality", said the EPO's Chief Economist Yann Ménière. Most patent applications came from the USA and Germany, followed by Japan and China. The USA filed 46,533 applications, around 5 % more than in the previous year, and China filed 16,665 applications, almost a quarter more than in the previous year. There were 25,969 applications from Germany, an increase of 0.3 %.

Source: aertzeblatt.de

Contents

aseptica's editorial team attends this year's DGKH Congress in Berlin

Fig. 1: left to right: Iven Kruse, Aaron Papadopoulos, Stella Nehr-Werner, Dr. Ulrike Weber

Some members of aseptica's current editorial team were among the attendees at this year's DGKH Congress in Berlin, held from 01.–04.05.2022. In addition to various fascinating lectures and workshops about hygiene and reprocessing, this year's Congress also provided an opportunity to finally share ideas in person again, at the specialist exhibition just next door. Our editorial team seized this opportunity to find out about new developments and trends. The topical issues discussed in talks and lectures are actively used to make the content of aseptica even more exciting. We very much look forward to discussing exciting topics and sharing ideas in person again at the DGSV Congress in Fulda and the WFHSS Congress in Barcelona in autumn.

Efficacy and benefits of UV disinfection methods in hospitals – implications for hospital hygiene

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Nosocomial infections have been linked to increased morbidity and mortality in hospitalised patients. According to estimates, 400,000 to 600,000 nosocomial infections occur in Germany every year.[1]
These figures make it clear that the prevention of nosocomial infections is enormously important when it comes to patient care in hospitals. The transmission of and infection with bacteria, fungi, viruses and parasites can occur in various ways. In addition to hand and skin contact, contaminated surfaces or medical devices are also possible causes of transmission, as are contaminated drinking water and pathogens in the air. Efficient and reliably effective disinfection methods are a key factor for successfully preventing hospital-acquired infections. In hospital hygiene, the various sources of contamination and routes of transmission mentioned above must be taken into account when it comes to selecting suitable disinfection procedures and agents.
One well-known method for damaging microorganisms is irradiation with ultraviolet light. The effectiveness of UV-C radiation in preventing microbial growth, in addition to eradicating and reducing the persistence of microorganisms – both bacteria and viruses, as well as other pathogens – was first discovered in 1877 and has been described and proven many times since.[2]

How UV-C disinfection works

Ultraviolet radiation (UV radiation for short) is a part of the optical radiation spectrum. It covers the wavelength range from 100 to 400 nm. UV rays are divided into the following three groups based on their physical and biological properties: UV-A (400–315 nm), UV-B (315–280 nm) and UV-C (280–100 nm) radiation. The UV-C radiation produced by the sun is absorbed by the upper layers of the atmosphere, meaning that it doesn't reach the earth. In order for UV-C radiation to be used, it must be generated artificially.[3]

UV-C disinfection works by damaging the genetic material of microorganisms using high-energy and short-wavelength radiation. UV light is generated with a wavelength of 254 nm using, for example, a low-pressure mercury lamp. Light of this wavelength is adsorbed by the DNA or RNA of the microorganisms, which is subsequently damaged.[4]

The further away the irradiated surface is from the light source, the less effective the disinfection and therefore the damage to the potentially pathogenic agents. The intensity decreases with the square of the distance from the radiation source; in practice, efficacy is limited to a distance of 2.4 m.[5] Essentially, the irradiation time and intensity must be great enough to achieve a desired result. The reduction of various microorganisms, including nosocomial infectious agents, at different UV doses has been summarised by Mahsa Masjoudi and colleagues[6]. The table on the following page provides examples of the radiation doses required at a wavelength of 254 nm for a 4-log reduction of some relevant human pathogens. This shows that microorganisms react to UV-C radiation with varying degrees of sensitivity.

The next section should provide an insight into the effectiveness and benefits of disinfection using UV rays and possible uses in hospitals.

Use of UV disinfection in hospitals

UV disinfection can be used in hospitals to disinfect surfaces and indoor air, but also in the treatment of drinking water and wastewater systems.

UV-C disinfection has become established as a proven method for the treatment and disinfection of drinking water.[13] UV-C irradiation is also used as a disinfection method in dialysis, to reduce the number of germs in dialysis water or in the wetted parts of dialysis machines.

UV disinfection is also an established method in the treatment of drinking water, used primarily by drinking water providers to ensure that, for example, the water kept in storage tanks remains free of germs. One Austrian study monitored a UV disinfection plant for drinking water over ten years, with UV irradiance at 254 nm. This study found that the ageing of the lamps, the UV transmittance of the water and the water temperature all affect the operation and effectiveness of the plant.[14] One advantage of UV disinfection of drinking water compared to chemical disinfection is that it does not alter the taste or odour of the water. The microorganisms in the water do not build up any resistance to UV radiation.

The coronavirus pandemic has brought more public attention to the quality of indoor air. In research and development, it has also given rise to new methods and options for air purification. The installation of UV-C disinfection units in mobile air purifiers or in the central air handling units gives the impression that low-germ indoor air is being produced. However, the air often remains in the effective range of the UV-C rays for such a short time, especially in central air handling units, that the dose is not high enough to successfully eliminate germs, or only eliminates them in small numbers. It would only be practical for the air handling unit to reduce germs when it is in recirculation mode, since otherwise it would only be disinfecting outdoor air, which already has a low level of pathogen contamination. When it comes to deciding whether or not to use UV disinfection within central air handling units or via mobile air purifiers, there are certain factors that must be carefully considered in relation to the desired disinfection performance: the specific parameters of the room size, irradiation intensity, flow velocity and, above all, the dwell time of the air. UV disinfection of air has not yet become established in the hospital sector, compared to filtration via HEPA filters.

The use of UV-C rays to disinfect surfaces has become more important due to the coronavirus pandemic, among other things. Pathogenic germs can remain on different surfaces for different lengths of time and therefore represent a source of transmission and infection. High-energy UV-C radiation not only damages potentially pathogenic germs; exposure to UV-C radiation can also be harmful to humans, causing considerable damage to the eyes and skin. All UV rays have been classified as carcinogenic by the International Agency for Research on Cancer.[15] For this reason, UV disinfection processes may only be carried out if they are guaranteed not to pose a risk to humans.

One study showed a significant reduction in the number of germs on computer keyboards in patient rooms following irradiation with UV-C.[16] Other studies report positive effects associated with disinfectants and UV use, showing a reduction in the incidences of Clostridioides difficile and vancomycin-resistant enterococci.[17, 18]

In some German hospitals, autonomous UV disinfection robots are used to disinfect surfaces. These robots usually consist of tubular light sources and can trav-

Microorganism	Required dose in mJ/cm² for a 4-log reduction	Reference
Acinetobacter baumannii	4.8	7
Klebsiella pneumoniae	12	8
Pseudomonas aeruginosa	6.3	9
VRE	13	9
MRSA	10	9
Adenovirus Type 4	116	10
Hepatitis A	16	11
Candida auris (AR Bank 0384)	100	12

Tab. 1: Reduction of hospital-typical pathogens depending on the UV dose

el through rooms to reach every surface. Some very important factors for ensuring successful disinfection are different exposure times, to account for the different microorganisms, and correct radiation intensity, in addition to the deep cleaning process required beforehand. Troublesome "shadow-forming" objects may prevent the disinfection of surfaces behind them. The varying exposure times for different microorganisms, mentioned above, mean that it is difficult to make any general statement about duration and intensity. Manufacturers specify periods of between 10–20 minutes per room for complete disinfection. Controlled studies on the prevention of nosocomial infections are not yet available. A UV-C system used in Switzerland as one of the measures for containing an outbreak of vancomycin-resistant enterococci (VRE) was shown to have probably helped to end the outbreak[5]. It is not possible to evaluate the individual impact of UV irradiation when it is one of many hygiene measures.

UV disinfection robots are always an extra measure, carried out in addition to standard room reprocessing, and they require a small number of personnel to carry out the disinfection procedure. In addition, the lay-out of rooms must be recorded, or "learned", prior to commissioning, and this process must be carried out again after repositioning furniture, etc. The robot can only operate fully autonomously if the paths to the sites of operation are completely barrier-free. There must be safety features in place when using the robot to prevent human exposure[19]. UV disinfection robots are particularly useful in sensitive areas such as intensive care units, surgeries and canteens/kitchens. Similarly, spaces that may not be used for a longer period of time but are nevertheless highly frequented, with surfaces contaminated with pathogenic microorganisms, such as unclean work rooms, might also be considered for UV-C disinfection.

Depending on the type of UV-C disinfection used, whether autonomous UV-C robots or freestanding appliances, lamps permanently installed in rooms or air ducts, or smaller hand-held devices, there are some criteria that must be considered when selecting a suitable location and the desired effect. These criteria include accessibility to the location, time windows during

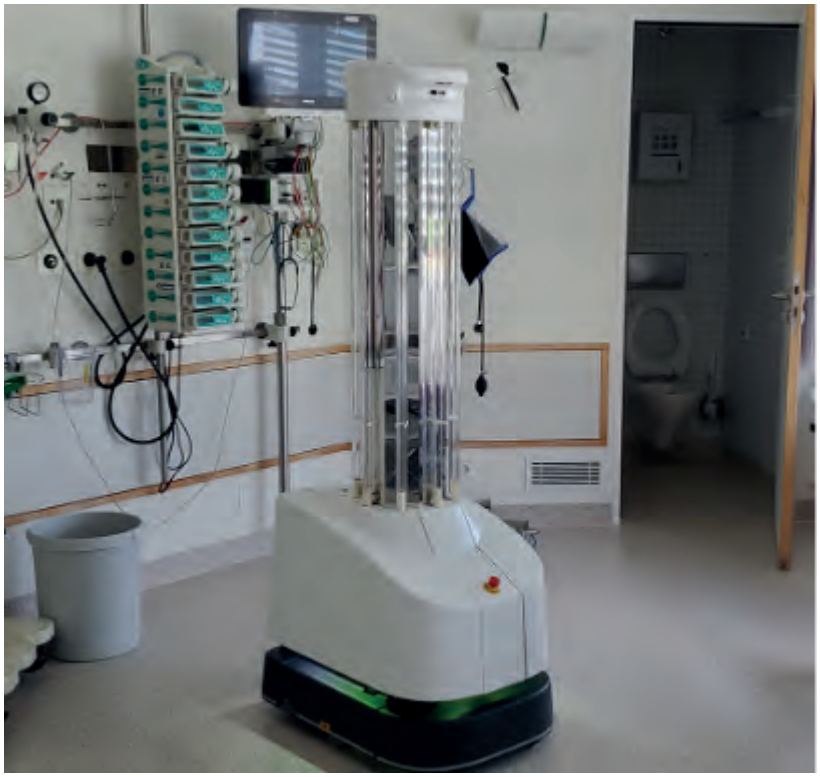

Fig. 1: UV disinfection robots in a patient's room. Source: authors

which the room will be unoccupied, the provision of additional safety measures if someone enters the room, positioning in the room or in the ventilation system and an indication of the rooms in which UV-C disinfection would be most effective.

Before disinfecting with UV-C radiation, physical cleaning measures must be carried out to remove any dirt and debris, so that the microorganisms are exposed and can be reached by the UV rays. As an additional safety measure for surfaces in highly sensitive areas, such as intensive care units and surgeries where it is particularly important to keep the number of germs to a minimum, or when disinfecting water or air, UV disinfection can help to reduce germs and therefore prevent infection.

As yet, there is little research on the effects of radiation on materials that are exposed to UV-C radiation during the disinfection of surfaces. It is therefore not yet possible to say whether frequent treatment with UV radiation causes faster wear and tear in surfaces.

Summary

In conclusion, it can be said that in some areas, such as dialysis, UV disinfection methods have already been in use for years. There are not yet any recommendations or guidelines from national or international agencies or medical associations regarding the use of UV disinfection as the sole method for preventing the transmission of infectious diseases. Although the efficacy of the method in damaging microorganisms is undisputed, there are still few findings or studies providing evidence that the method reduces hospital-acquired infections, especially compared with other established methods of cleaning and disinfection. It should also be noted that the durability of the UV lamps and the relevant maintenance and servicing cycles would need to be taken into account.

Before a decision is made to invest in a UV-C system, it is important to define the exact purpose and desired benefit, which relates to the other infection prevention measures in place. Ask yourself the following questions:

- Where and when would the machine be used? Which rooms would be available for the disinfection process and when? Isolation rooms? Intensive care units? Surgeries?
- What other benefits am I expecting from this system with regard to improving infection prevention? Will this system help me conserve resources and therefore possibly relieve the pressure on some departments? How will the introduction of a new form of technology affect the motivation of the staff who will be responsible for operating it?
- What documents/validation data am I expecting from the manufacturer? Proof of efficacy, for example, pursuant to DIN EN 17272? Field studies from other hospitals/departments? What does the manufacturer recommend for validation in the field? Is there support or training available for validation?
- Who will be responsible for the machine when it comes to validating its efficacy, maintenance and servicing, storage and updating the programmed rooms and spaces? What costs will be incurred in the operation of the machine and who will bear them? Who will be responsible for using the machine? It is important to clarify whether the use of the machine will be organised by staff from the cleaning team, the hygiene department or the ward, and which of these departments will be responsible for operating it. Sufficient resources must then be made available in these departments and the staff must be trained accordingly.

Outlook

New research methods, such as the use of UV LEDs, pulsed xenon ultraviolet, experiments with other wavelengths that may not have harmful effects on humans or research into disinfection with visible light, show that disinfection with UV radiation has a great deal of potential and may become an established method for reducing germs and therefore containing infectious diseases in the future, and not just in the field of hospital hygiene.

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COVID-19: assessing ventilation methods, taking into account mobile air purifiers

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Indoor air hygiene has been the subject of intensive discussion since the start of the COVID-19 pandemic, due to the airborne transmission of SARS-CoV-2. The debate has focussed primarily on the situation in school classrooms. But in hospitals, too, there are discussions as to how indoor spaces can be used in ways that also take air hygiene into account. This article will discuss some fundamental aspects and present a ventilation model that is suitable for conference rooms.

Effective air hygiene practices

When it comes to indoor air hygiene, one key factor is the regular exchange of air. This not only reduces the number of pathogens, but also minimises the amount of chemical pollutants, odour-active substances and CO2, while also removing humidity.

Generally speaking, there are three methods available for carrying out this exchange of air; they are listed below in order of effectiveness:

- Ventilation by means of air handling units (AHU) requires systems built in accordance with existing standards. These machines are usually equipped with heat exchangers so that the incoming air from outside is heated. Filters are built in to ensure the removal of corpuscular pollutants. Units that are not freely accessible and are regularly inspected in accordance with existing standards are safe from a hygienic point of view.
- Ventilation via windows and doors is easy to implement. It is important to ensure that the ventilation concept selected is suitable for the purpose of the room. The cooling of the indoor air that occurs during the colder months is reversible. By implementing suitable ventilation intervals and ventilation times, it is possible to achieve a sufficient improvement in air quality.
- The installation of fan-assisted supply and return air systems (e.g. in window openings) can support the principle of outdoor air supply. For this method, it is important to ensure a sufficient air supply. If necessary, these systems can be used to support simple window ventilation.

In principle, all three procedures have been tested and are now established. They can also be used to minimise aerosol transmission of SARS-CoV-2. However, in the case of air handling units, the percentage of recirculated air should be reduced to 0 % (i.e. fresh-air mode only) or additional, high-performance material filters should be installed.[1]

Decentralised air purifiers

In addition to the ventilation options listed above, there have also been discussions about the possibility of installing decentralised air purifiers in used indoor spaces to reduce the amount of aerosols occurring there and therefore reduce exposure to SARS-CoV-2. From a hygienic point of view, these machines do offer some benefits – though these may still need to be proven – but they also pose some risks:

- The lack of air supply means that there is no minimisation of other pollutants.
- A cross-flow of pathogens is created, which runs through the room towards the air purifiers. This pos-

Fig. 1: Materials for a ventilation system for conference rooms.

es an increased risk to people in the flow field between the infected person and the machine. This applies in particular to those in the vicinity of the machine.

- The machine itself is located in the sink of a contaminated flow field, which means that a high level of surface contamination is to be expected. The free accessibility of the machines can therefore pose an additional safety hazard.
- The effectiveness of the machines depends heavily on the room geometry and the lay-out of the machines. This can result in limitations with different levels of effectiveness in the room.
- Depending on the cleaning method used (e.g. ozone), secondary pollutants may be produced.

Studies on decentralised air purifiers focus primarily on the reduction of aerosols.[2] This means there is insufficient data on germ loads (effectiveness) or on germ problems in cross-flows or on the machines, especially when it comes to viral loads. Concepts designed to prevent cross-flows by means of additional protective walls[2] incur subsequent costs, but do not change the fundamental problem. Air purifiers are therefore not a substitute for compliance with direct preventive measures. They cannot replace ventilation and ventilation systems with the option of fresh-air supply. One also cannot rule out the possibility that the machines themselves may cause risks, up to and including infection of a person. It is therefore important to follow the recommendations of the German Environment Agency, i.e. to use rooms with ventilation options instead of air purifiers.[3,4]

Ventilation model

Soon after the realisation that the essential transmission medium for SARS-CoV-2 is air, staff at the Max Planck Institute for Chemistry in Mainz developed a ventilation model for school classrooms, which they then presented to the public.5 The model is constructed using materials from the hardware store, which can be assembled by users themselves using a template available on the Internet. This model was adapted for the conference room of the Department of Hygiene and Infection Prevention at the University Medical Center Mainz. However, significantly more prefabricated parts were used for this model, especially for the assembly of the ventilation pipes (Fig. 1). All materials were purchased

Fig. 2: Installed ventilation system with extractor hoods.

at the hardware store. The cost of the finished system (Fig. 2), including the fan, was about €200 euros. The extraction power of the fan is 170 m3 per hour. Given the size of the room, which is about 75 m3, the air in the room will be completely extracted around once every 25 minutes. Ideally, the fan should be installed in rooms with a sliding window, through which a stable shelf with the fan can be inserted. Installation is slightly more complicated with hinged windows. The advantage of both systems is the fact that extractor hoods are installed above the seats. After a short time, these create a continuous upward movement of air, so that exhaled particles, including microorganisms, are sucked in, transferred into the pipe system and taken outside by the fan. This model is suitable for rooms in which air movement is restricted and whose doors can be kept closed to avoid interrupting the upward air flow.

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Effectiveness of air purifiers in reducing particles

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Since the pandemic of 2020/2021, various measures have been implemented in many places, some of which have not yet been proven to be effective. Especially in enclosed spaces, there is a high risk of COVID-19 transmission. Among other things, air purifiers are used to reduce the virus concentration and thus the risk of infection. The efficacy of HEPA-filtering air purifiers should be verified using the following experimental set-up. In this case, the machine used was the Miele AirControl PAC 1080 air purifier.

To prove the efficacy of this machine, aerosol concentrations were continuously measured at fixed points around the room. To ensure the conditions in the room were as realistic as possible, six people were represented by heated dummies (Fig. 1).

An aerosol outlet was installed on each of these dummies, simulating human aerosol emission. When the air purifier was used, it was set to an air change rate of >/= 6 air changes per hour.

The following scenarios were simulated with the 0.5 µm aerosols:

Aerosol concentration with windows closed, with and without air purifier

The graphs show aerosol concentrations during constant aerosol discharge, measured at four points in the room. Data was recorded over a period of 45 minutes. Fig. 2 shows the aerosol concentration with the windows closed and without the air purifier. The measurements showed that the aerosol concentration increased by a factor of 2.5 within 45 minutes.
Fig. 3 shows the measurements at the same locations with the air purifier running. The orange horizontal line indicates the maximum values (across all test points) without the air purifier (measured after 45 minutes of aerosol discharge). In the scenarios with the air purifier running, an approximate mean increase of just 120,000 particles was measured across all test points over 45 minutes. Using an air purifier with the windows closed therefore reduces the aerosol load by a factor of approx. 3.6.

Aerosol concentration with windows open for ventilation, with and without air purifier

Fig. 4 and Fig. 5 show aerosol concentrations during constant aerosol discharge, measured at four points in the room. Data was recorded over a period of 100 minutes. Fig. 4 shows the aerosol concentration without the air purifier. Every 20 minutes, the windows were opened for 5 minutes (green arrow: window opened, red arrow: window closed), resulting in the jagged pattern on the graph.

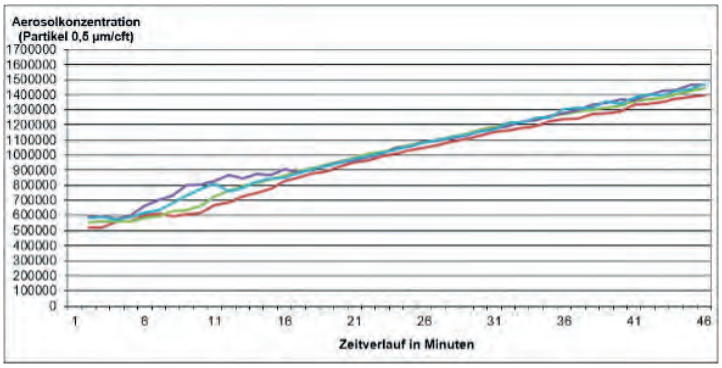

Fig. 2: Aerosol concentration without air purifier

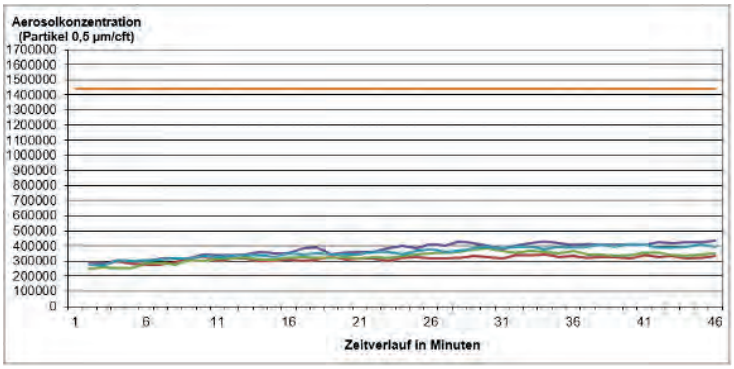

Fig. 3: Aerosol concentration with air purifier

Fig. 5 shows the aerosol concentration after opening the window twice, after 45 and 95 minutes, with the air purifier running. This results in a considerably smaller increase in the aerosolconcentration.

Conclusion

In both scenarios, the air purifier reduces the aerosol concentration. The recorded data shows that, both after ventilation and, most importantly, when ventilation is not possible, the air purifier reduces the concentration of potentially infectious aerosols in the room. This means that, during the colder winter months, the intervals between ventilation phases could be extended without increasing the concentration of aerosols. Dispensing with ventilation completely is not possible or recommended. Air purifiers should be viewed primarily as an accompaniment to ventilation, since it was the combination of room ventilation and an air purifier that achieved the lowest aerosol concentrations in the experiment.

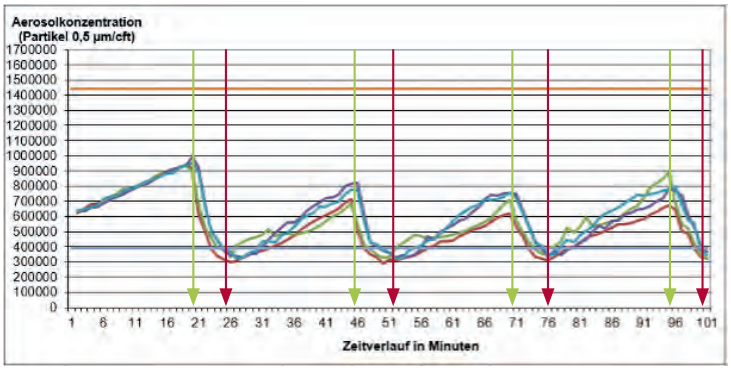

Fig. 4: Aerosol concentration without air purifier

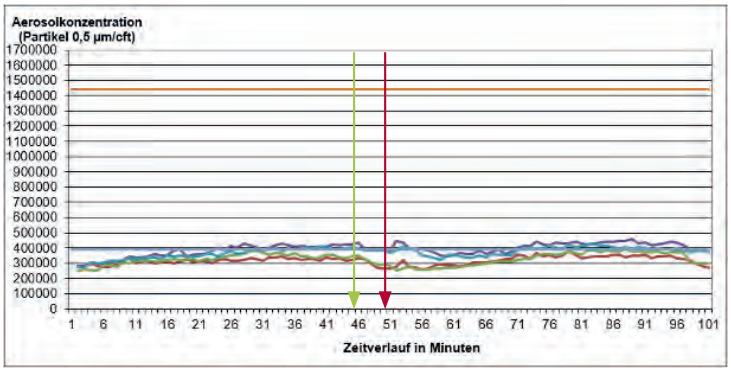

Fig. 5: Aerosol concentration with air purifier

DIN EN ISO 15883-5:2021 – a new standard for the cleanliness of medical devices after the cleaning stage of reprocessing procedures

Author |

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In the series of standards DIN EN ISO 15883 "Washer-disinfectors", the German version of the new Part 5 "Performance requirements and test method criteria for demonstrating cleaning efficacy" was published in November 2021.[1] The previous version of Part 5 of this series was a "Technical Specification", which comprised a compilation of various national test soils and methods for demonstrating cleaning efficacy.[2] The more recently published Part 5, on the other hand, is a standard that replaces the previous "Technical Specification". This new Part 5 not only details test soils and methods, but also

- performance criteria to demonstrate cleaning effectiveness,
- acceptance criteria for analytes, such as protein or haemoglobin, and
- alert and action levels for the respective analytes.

Analytes are components of test and/or clinical soils that can be quantified using primarily chemical analytical methods. Descriptions of test soils and methods are provided in the annexes of the standard or listed in tables with corresponding literature references.

This standard is used for

- type testing of washer-disinfectors under simulated use conditions, with defined test soils, and for
- performance qualification testing under clinical use conditions, with medical devices contaminated from use during a procedure on a patient, as part of the validation and requalification of washer-disinfectors.

The evaluation of cleaning efficacy is initially carried out by means of a visual inspection, as well as by measuring of the residual amount of protein. For invasive medical devices, the residual amount of at least one other analyte should be measured. The analytes listed in the standard and their respective alert and action levels are summarised in Table 1.

The standard specifies the following acceptance criteria for the performance qualification testing of cleaning efficacy with medical devices contaminated from clinical use, conducted as part of the validation or requalification of washer-disinfectors: the medical device must demonstrate an absence of visible soil and it must fall below the action level for protein and, if applicable, other analytes. The values specified for the residual amount of protein are in line with the acceptance criteria detailed in Annex 5 of the "Guidelines published by DGKH, DGSV and AKI on the validation and routine monitoring of machine-based cleaning and thermal disinfection processes for medical products".[3]

When it comes to operational qualification testing as part of validation and requalification, the standard does not directly specify any acceptance criteria for test models contaminated with test soil (for example, Crile forceps or test tubes). In this case, the author would recommend applying the acceptance criteria specified for type testing of washer-disinfectors with contaminated medical devices, i.e. the medical device should be visibly clean and should not exceed the alert level for the respective analyte. If measured values fall between the alert and action levels, steps must be taken to review the cleaning process. The values must not be allowed to exceed the action level.

These acceptance criteria correspond to the specifications in the German "Guidelines for the validation of automated cleaning and disinfection processes for the reprocessing of thermolabile endoscopes" as per Annex 8 for test hoses, with a guide value of ≤ 100 µg of protein/test objects.[3,4]

Testing the efficacy of subsequent process stages

After determining the criteria for the cleanliness of medical devices after the cleaning stage, it is logical to take these amounts of potential residual soiling into account when testing the efficacy of the subsequent reprocessing steps, such as terminal disinfection or sterilization. The author will now outline the current status of, as well as unresolved questions and problems for, the following process steps: terminal disinfection, steam sterilization and low-temperature sterilization with hydrogen peroxide.

Terminal disinfection

If the specifications of the standard DIN EN 14885 are applied when testing the efficacy of disinfectants for terminal disinfection under "clean conditions", the test organisms are mixed with 0.03 % bovine serum albumin (protein) in a carrier test. Then, 50 µl of this mixture is applied to a 1x1 cm area of the test surface[5]. This results in a protein load of 15 µg/cm^2.

This value is significantly higher than the alert and action level for the analyte "protein", providing a corresponding safety margin (see Table 1).

Steam sterilization

The efficacy of steam sterilization processes is tested either by means of thermometric tests, in accordance with the test method stipulated in DIN EN 285 for large sterilizers, or by means of thermometric and microbiological tests (which use biological indicators), in accordance with the test method stipulated in DIN EN 13060 for small sterilizers.[6,7] The standard DIN EN ISO 17665-1 also describes the possibility of conducting microbiological tests in addition to thermometric tests for the validation of steam sterilization processes.[8]

The biological indicators are produced in accordance with the standards DIN EN ISO 11138 Part 1 and Part 3, which do not stipulate the presence of protein or other analytes.[9,10]

In the author's opinion, the efficacy of these procedures should be tested in the presence of residual amounts of corresponding analytes, in compliance with the relevant alert and action levels, and the results should be considered in new versions of the standards, if necessary.

Low-temperature sterilization with hydrogen peroxide

An international ISO-level working group is currently devising a standard for testing the efficacy of low-temperature sterilization processes using hydrogen peroxide, which has already been published as a discussion draft.[11] However, the agent used in these processes (hydrogen peroxide) can be inactivated by protein, for example, which may result in an intolerance to residual amounts of this analyte.[12]

For this reason, the author believes that the new standard should describe methods for testing the efficacy of these procedures that take into account residual amounts of analytes in accordance with the relevant alert and action levels (see Table 1).

Analyte	Alert level	Action level
Protein	≥ 3 µg/cm^2	≥ 6.4 µg/cm^2
Total organic carbon (TOC)	≥ 6 µg/cm^2	≥ 12 µg/cm^2
Carbohydrates	≥ 0.9 µg/cm^2	≥ 1.8 µg/cm^2
Haemoglobin	≥ 1.0 µg/cm^2	≥ 2.2 µg/cm^2
Adenosine triphosphate (ATP)	≥ 10 femtomole ATP/cm^2	≥ 22 femtomole ATP/cm^2
Endotoxin	≥ 2.2 EU/device	≥ 20 EU/device

Tab. 1: Alert and action levels for analytes according to DIN EN ISO 15883-5:2021

Conclusion

The standard DIN EN ISO 15883-5:2021 defines tolerable amounts of residual soiling on cleaned medical devices for the first time. These residual amounts must not be exceeded, either during type testing of washer-disinfectors for thermostable and thermolabile medical devices using artificial soil or during performance qualification testing (as part of the validation and requalification of these devices) using clinically contaminated medical devices. The agents and procedures for the subsequent process stages, such as disinfectants for terminal disinfection or sterilization processes, should be tested for their efficacy, if they haven't been already, taking these residual amounts into account.

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Accurately assessing and analysing surface changes: changes caused by oxidation

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In practice, a wide array of medical devices undergo changes over time, starting from the surface, due to chemical, thermal and/or physical influences. The causes of these surface changes can normally be traced back to the treatment process, provided they were not caused during use. If surface changes occur, there is a systematic sequence of steps that must be followed to rectify and prevent them.

- Locate the type, origin and cause
- Assess the risks
- If necessary, follow the manufacturer's recommendations for repair
- Determine preventive measures and conduct a new performance qualification if necessary

This article will outline the surface changes that most commonly affect metal instruments made from stainless steel and/or devices made from plastic or rubber, based on the system described above.

Type of surface changes

Fig. 1: Retractor with black discoloured shank made from hardened Cr steel, as well as bare handle and blade made from non-hardenable CrNi steel.

Fig. 2: Detail of forceps: lock and ring area.

Fig. 3: Detail – titanium blades:
Left blade – brand new.
Right blade – cleaned by machine.

Fig. 4: The colour change usually
occurs evenly.
However, it may also appear patchy/multi-coloured.

Colour changes in metals due to oxidation

A shiny, grey-black passive layer of chromium oxide will only form on hardenable stainless steels; it is often first apparent on cutting instruments (e.g. scissors), but also on non-cutting instruments (e.g. forceps, tweezers).

On titanium materials (pure titanium or alloys), either an even, varying colour (e.g. grey, blue, violet, red, golden yellow, green) or a patchy, multi-coloured surface discolouration may form.

Origin and causes

In the case of the above-mentioned stainless steels, the passive layer is formed during machine-based cleaning by the neutraliser carried over in the last rinse cycle and/or by other passive layer-forming factors not yet identified in the cleaning process. Depending on the composition, density and thickness of the stainless steels, passive layers can range from transparent (which is common) to black. In addition to the influences mentioned above, the tendency to form grey-black passive layers of chromium oxide depends on the material composition, in particular on the ratio of chromium to carbon. In practice, this means that the higher the carbon content, the faster a grey-black colouration may become visible.
In the case of titanium materials, moist heat and/or the cleaning chemicals used during the various reprocessing steps can cause oxidation of the surface and therefore discolouration.
Titanium oxide layers may appear transparent or colourful depending on composition, density and thickness.

Recommendations for repair

It is not recommended that users repair this damage themselves due to the surface properties. If necessary, repairs should only be carried out in either case using a suitable surface treatment (mechanical for steel, chemical for titanium) by the manufacturer or a qualified repair service. In the case of stainless steels, the layer remains in place. Attempts to remove it with a basic cleaner would be ineffective due to the significant increase in corrosion resistance.

Preventive measures

For stainless steels, it is important to ensure precise dispensing of the neutraliser. Prevent the neutraliser from being carried over by ensuring a sufficient final rinse.
This is difficult or impossible to avoid with titanium materials, as they always react more or less visibly with the surface due to the prevailing environmental conditions during reprocessing (temperature, process chemicals, humidity).

Assessing potential risks

No corrosion – cosmetic effect
In the case of titanium materials, provided that a colour change would not pose a safety risk through the loss of any labelling/coding function, for example colour coding to indicate blade width (see picture), the colour changes caused by the formation of oxide layers with varying properties are completely harmless, i.e. they do not impact biocompatibility, hygiene, functionality or service life.

Discolouration may make it more difficult to conduct visual inspections (e.g. when detecting residual contamination).

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New DGSV e.V training curriculum for validators

Performance qualification of procedures in the reprocessing of medical devices for validators in accordance with the German Medical Device Ordinance (MPBetreibV)

Marion Stegner
Iven Kruse

Under §8 of the German Medical Device Ordinance (MPBetreibV), medical devices may only be used if they have been reprocessed using a suitable validated procedure. The validation of all reprocessing procedures must be conducted on the instruction of the operator by qualified specialists/validators certified in accordance with §5.

Compliance with the requirements set out in §5, para. 1 can be confirmed by the issuance of a certificate by the responsible authority or another recognised body, such as ZLG, TÜV, or by the responsible authority in another EU country.

The operator can or should request the relevant proof of knowledge from the validator before awarding the validation contract.

One useful resource about the requirements for validation is the standard DIN 58341[2], published in July 2020. DIN 58341[2] outlines, in detail, the conditions required to carry out validations and the knowledge required to carry out a validation of cleaning and disinfection processes.

The DIN 58341[2] standard and the revision of the DIN EN ISO 15883[3] standards were the starting point for the revision of the training curriculum for validators and the 5th edition of the "Guidelines published by DGKH, DGSV and AKI on the validation and routine monitoring of machine-based cleaning and thermal disinfection processes for medical devices"[4].

New training curriculum[11]

During 2022, the education committee of DGSV e.V. has developed and adopted a new training curriculum for the performance qualification (PQ) of reprocessing procedures for medical devices pursuant to MPBetreibV[1]. The training programme consists of several different modules and serves as a curriculum for validators of reprocessing procedures in healthcare facilities.

There are currently six modules in the training curriculum; four modules (Vali A, Vali B, Vali C and Vali E) were created and adopted in Revision 02 and two more modules (Vali D and Vali F) will be added to the curriculum at a later stage.

The training content of each module is as follows:
Vali A:
In the Vali A module, trainees are taught the basic principles of reprocessing procedures for medical devices in the course of 24 teaching units (TU). To participate in the Vali A module, trainees are required to have suitable professional training pursuant to MPBetreibV[1], for example technical training, and provide proof of at least 16 hours of observation in a CSSD.

Fig. 1: Validator training programme at the Xylem/ebro competence centre in Ingolstadt.

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Fig. 2: Practical training on process validation for washer-disinfector procedures.

Fig. 3: Practical training on process validation for steam sterilization procedures.

This module covers the basic principles of medical device reprocessing:
- Hygiene
- Medical device reprocessing
- Quality management and validation
- Testing

Vali B:
The Vali B module covers the basic regulatory principles of performance qualification of reprocessing procedures in 24 TUs. To participate in this module, trainees must present confirmation of participation in the German professional qualification course "Fachkunde 1" or the German proficiency training course for medical and dental practices ("Sachkunde für Arzt- und Zahnarztpraxen"), or have successfully completed the Vali A module.

This module covers the basic principles of performance qualification of processes:
- Basic principles
- Planning and organisation
- Tasks and documentation
- Testing

Vali C (C1, C2, C3):
The Vali C module covers the performance qualification of cleaning and disinfection processes and consists of C1: performance qualification of machine-based cleaning and thermal disinfection processes (washer-disinfector processes), 24 TUs, C2: performance qualification of machine-based cleaning and chemothermal disinfection processes (washer-disinfectors for endoscopes), 24 TUs, and C3: performance qualification of manual cleaning and disinfection processes, 24 TUs. To participate in this module, trainees are required to have suitable professional training pursuant to MPBetreibV[1], for example technical training, and provide proof of at least 16 hours of observation in a CSSD. Trainees must also have successfully completed modules Vali A and Vali B and demonstrate knowledge of washer-disinfectors in the healthcare sector.
This module covers the performance qualification of cleaning and disinfection processes (C1, C2):
- Risk management
- Part of validation
- Conducting the PQ
- Tasks following the PQ
- Testing

Vali D:
The Vali D module covers the performance qualification of packaging processes and consists of 24 TUs.
To participate in this module, trainees are required to have suitable professional training pursuant to MPBetreibV[1], for example technical training, and provide proof of at least 16 hours of observation in a CSSD. Trainees must also have successfully completed modules Vali A, Vali B and demonstrate knowledge of sealing devices in the healthcare sector.

This module covers the performance qualification of packaging processes:
- Risk management
- Part of validation
- Conducting the PQ
- Tasks following the PQ
- Testing

Vali E:
The Vali E module covers the performance qualification of steam sterilization processes and consists of 24 TUs.
To participate in this module, trainees are required to have suitable professional training pursuant to MPBetreibV[1], for example technical training, and provide proof of at least 16 hours of observation in a CSSD.

Trainees must also have successfully completed modules Vali A and Vali B and demonstrate knowledge of steam sterilizers in the healthcare sector.

This module covers the performance qualification of steam sterilization processes:
- Risk management
- Part of validation
- Conducting the PQ
- Tasks following the PQ
- Testing

Vali C3:
Performance qualification of manual processes
There is not yet a curriculum for the performance qualification of manual processes; this will be added to the training curriculum soon.

Entry requirements apply for all modules, meaning that trainees may only participate in one module at a time.
Validators who have completed the previous validation modules Vali A and Vali B meet the entry requirements for the new modules Vali C and Vali D, if they can also demonstrate knowledge of washer-disinfectors or sealing devices in the healthcare sector. The new modules are a prerequisite for understanding the performance qualification of machine-based cleaning and disinfection processes, packaging processes and manual reprocessing procedures.

After passing the examination, validators will receive a certificate of participation and a certificate from the training centre (Vali A and B) and a certificate from the DGSV confirming their successful completion of the module (Vali C, D, E)

Outlook

In the new 6th edition of the "Guidelines published by DGKH, DGSV and AKI on the validation and routine monitoring of machine-based cleaning and thermal disinfection processes for medical devices"[5], the contents of the training courses for the qualification of validators are revised and divided into basic requirements nd device-specific requirements.

A publication date has not yet been confirmed.

Conclusion

The training curriculum devised by the education committee of DGSV e.V. (comprising modules Vali A-E) and the standard DIN 58341[2] are important prerequisites for acquiring the required knowledge pursuant to MPBetreibV[1] §5 and represent key stepping stones to certification.

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Marketing Manager
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Healthcare

"3 questions for ..."

Aaron Papadopoulos

1. What key factors need to be considered when selecting process chemicals for a washer-disinfector?

In addition to the expected and necessary requirements, such as those relating to cleaning, neutralisation, disinfection and rinsing, there are other requirements that process chemicals should meet. For example, the process chemicals should demonstrate good material compatibility with the material being reprocessed, as well as with the washer-disinfector itself. It is particularly important to ensure that the process chemicals are compatible to prevent any cross reactions from occurring if the chemicals are carried over. The process chemicals must be specifically labelled for the purpose of machine-based reprocessing, because this means they will also have been thoroughly tested with regard to stability in washer-disinfector processes. Furthermore, the process chemicals must fulfil the requirements for biocompatibility, among others, and there must be a detection method available.

2. What is it that makes the reprocessing of flexible thermolabile endoscopes so difficult?

Due to the typical endoscope design and the combination of many different sensitive materials (including light metals, plastics, adhesive joints, glass), the reprocessing of flexible endoscopes is particularly challenging.

In order to achieve the required reprocessing result, various comprehensive process steps must be carried out – starting with a pre-treatment directly at the examination site, followed by a manual brush cleaning and then by the terminal disinfection of the flexible endoscope. There's a reason specially trained personnel are employed for the task of reprocessing flexible endoscopes. The process chemicals used must be approved for use in the field of endoscope reprocessing with regard to material compatibility, as well as cleaning and disinfection performance. This interaction and the process efficacy is verified by manufacturers/distributors of washer-disinfectors for endoscopes as part of the type testing required by DIN EN ISO 15883. This is also one reason why manufacturers of washer-disinfectors for endoscopes prescribe the use of certain process chemicals.

For more information and a detailed overview, I recommend reading the brochure: "Instrumenten Aufbereitung: Werterhaltende Aufbereitung Flexibler Endoskope" (English: "Instrument reprocessing: reprocessing of flexible endoscopes to retain value"), available at www.a-k-i.org.

3. What future trends have been identified in the reprocessing of medical devices?

In my opinion, there are three key factors here: automation, digitalisation and sustainability.

We are seeing a trend towards automating process steps wherever possible in order to ensure consistent process quality and minimise any sources of error. In the reprocessing of medical devices, all processes – both manual and automatic – are validated and constantly checked for deviations. The second trend, that is, the digitalisation of process steps, process parameters and checklists, is sure to be of benefit here. Digitalisation opens up a new dimension of data collection and processing and can help optimise quality management. Thanks to new possibilities for analysis, from short- to medium- to long-term analyses, deviations can be detected quickly and remedied promptly. The third trend we're seeing is sustainability. This includes, for example, the conservation of resources and the prevention of waste. The use of innovative process chemicals, such as high concentrates, can be helpful in this regard. These not only save packaging waste, but also storage and transport capacity, while also reducing consumption and therefore saving valuable resources.

WFHSS announcement

This year's WFHSS congress will take place from November 16-19 in Barcelona. Planned as a face-to-face event, the congress offers the possibility to attend scientific lectures around the topics of reprocessing and hygiene as well as information on the latest trends and technologies in the hygiene world shown in the connected industrial exhibition. Current developments such as the digitalization of CSSD, but also the topic of sustainability, form the core of the topics at this year's congress. The individual program items, organizational details, and the opportunity to register can be found here: https://www.wfhss-congress.com/

Freiburg Infectiology and Hygiene Congress, October 19-21, 2022 under the auspices of Health Minister Lauterbach

The Freiburg Infectiology and Hygiene Congress is set to take place from Wednesday, October 19 until Friday, October 21, 2022. A broad and diverse collection of topics awaits around 1500 hospital hygienists, hygiene specialists and infectiologists from the entire German-speaking world in the appealing setting of the centrally located Freiburg Concert Hall.

Corona continues to be a controversial subject

Reflecting the current situation, delegates will be presented with a highly nuanced reflection on the SARS-CoV-2 pandemic which has lasted almost 3 years from the viewpoint of hygiene, infectiology and administration. One key added-value benefit for participants will be the animated and dispassionate discussions which follow the presentation of papers as well as an exchange of views with colleagues.

Congress registration: https://www.bzh-freiburg.de/Hygienekongress/Kontakt/Kongressanmeldung.
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Title image: Miele
Circulation: 5.200
Publication schedule: three times a year
Printed on chlorine-free bleached paper

ISSN 1439-9016

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