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Wissenskunde: Anforderung an Wasser für die thermische Desinfektion im Reinigungs- und Desinfektionsgerät

Insight: Requirements for water used for thermal disinfection in a washer-disinfector

Report

Sleep disorders on the rise

More and more Germans are suffering from sleep disorders. The number of diagnoses of sleep disorders not caused organically increased nationwide by about 77 percent from 2011 to 2021. This is shown by data published by the Kaufmännische Krankenkasse KKH. According to the data, around 1.2 million Germans are affected by sleep disorders.

This is only the tip of the iceberg, since the evaluation is based exclusively on physician diagnoses, explained KKH physician Sonja Hermeneit. Non-organically caused sleep disorders include problems falling asleep and sleeping through the night, as well as nightmares and anxiety dream disorders, which can arise under high psychological stress.

The number of diagnoses increased by eight percent from the pre-Corona year 2019 to the second Corona year 2021, according to the KKH. A Forsa survey commissioned by the health insurer had previously revealed that it was primarily occupational stress (in 42 percent of respondents) and private worries (34 percent) that affected sleep.

Source: aerzteblatt.com

Contents

Editorial

Dear readers,

When writing an editorial, often major political topics or events are used. War, pandemic, energy supply would be particularly suitable for this in the present time. In this issue, however, we take a different approach and look around in a more manageable area. Internal views of a scientific advisory board. When we were suddenly allowed to participate in the editorial staff of aseptica in 2015 (Ulrike) and 2017 (Aaron), we got to know and appreciate our advisory board. From the outside, you might look at a "ragtag bunch", from our point of view an incredibly great heterogeneous and honest group that keeps us on the professional line and supports us humanly. As is often the case in other things, unfortunately far too self-evident. As in every group, a generational change is currently taking place here. It was with great regret that Prof. Pietsch passed away in September 2022.

The colleagues Dr. Holz, Dr. Wilbrand and Dr. Biering will soon devote themselves to private topics, which are without question no less exciting, and say goodbye to the advisory board. Thank you for everything! We have taken this as an opportunity to republish in this and the next issue "Best of Biering and Holz" with the articles "The Concept of Hygiene Consultations in the Catholic Hospital Main" and "100 Years of Peracetic Acid - An Old Active Ingredient with New Perspectives".

The "young savages" are certainly Dr. Brill, Dr. Kaufmann and I. Konschake, who challenge us with new liveliness and courageous changes of direction and sometimes generate critical letters to the editor. As new to this group, we can also welcome K. Mann and C. Diekmann – both full professionals in instrument reprocessing. Read more about this on page 46.

"To the guard of the wise" (and thus without belonging to the old iron) with a huge blow of decades of experience in the field of medical devices, we can count A. Hartwig, Dr. J. Steinmann, T. Miorini and Dr. Dr. F. v. Rheinbaben.

To our advisory board, wherever you are, a huge thank you. Like you all feel very well and a virtual La Ola wave.

To our honored readers, we wish you a lot of fun with the last issue for this year, a relaxed finish of 2022 and health and satisfaction for the new year.

Ulrike and Aaron

Insight: Requirements for water used for thermal disinfection in a washer-disinfector*

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Water plays a key role in thermal disinfection in washer-disinfectors in preserving the value of load items and reprocessing equipment. The key tasks performed by water are as follows:

- Stabilise circulation pump pressure
- Dissolve the ingredients of process chemicals
- Uniform distribution of rinse aid (if used)
- Transfer of heat, energy and mechanical action
- Final rinse

Contents of water relevant to thermal disinfection

Water and its ingredients used as an agent in reprocessing may cause surface changes to load items or the chambers of washer-disinfectors if the initial quality is insufficient. The AKI[1] considers the in Table 1 listed substances to be problematic.

Depending on the installation and machine specifications, softened water or demineralised water is used for thermal disinfection.

Water softening removes the calcium and magnesium cations responsible for water hardness from water and replaces them with sodium ions. This, however, does not reduce the total amount of dissolved ingredients (evaporation residue) nor chloride concentrations. In softened water and depending on the temperature, the time and the carbonate hardness of the water supply, alkalinity levels can rise significantly on account of the presence of sodium carbonate[1]. This is presented in Table 3. In thermal disinfection, this can affect materials which are sensitive to alkalis, e.g. anodised aluminium.

The AKI[1] recommends the following guidelines for softened water:

- Total hardness: < 3°dH (< 0.5 mmol CaO/l)
- Evaporation residues: < 500 mg/l
- Chlorides: < 100 mg/l
- pH value: 5-8

Water softeners can either be integrated into a washer-disinfector or installed externally in the upstream supply.

In the case of **full demineralisation**, all minerals are virtually completely removed from water. The systems available include reverse osmosis, cation and anion exchangers and electro-deionisation (EDI), also in combination, and even, in special cases, distillation.[1]

There is no definition for the composition of fully demineralised water. Consequently, criteria from the EN 285 and EN 13060 standards are often applied to instrument reprocessing.

For thermal disinfection, a conductivity of 15 µS/cm is deemed acceptable for feed water.

Devices to generate demineralised water are installed in the upstream supply line to washer-disinfectors.

The AKI[1] lists relevant substances in water in Table 3 and recommends the use of demineralised water for thermal disinfection for the following reasons:

- No staining
- No concentration of corrosive substances, e.g. chlorides
- No crystalline evaporation residues which could have a negative impact on the subsequent sterilisation stage
- Protection and stabilisation of anodised aluminium

*excl. thermal disinfection of containers for human excretions according to EN 15883-3

Tab. 1: Substances in water likely to cause problems.

Substances causing water hardness (calcium and magnesium salts)	Deposits and scaling caused by calcium and magnesium bicarbonate, risk of corrosion	Depending on the water hardness and temperature, these substances can result in difficult-to-remove deposits (calcareous deposits, scale and furring). In certain circumstances, this can even result in corrosion below the layer of scale.
Heavy and NF metals, e.g. iron, manganese, copper	Brownish-red scale, extraneous rust	Heavy and NF metals as well as their compounds in water, even in low concentrations, can result in discoloration. Iron dissolved in water in larger amounts can result in corrosion on surfaces (extraneous rust).
Silicates, silicon dioxide	Thin whitish-grey iridescent layer of deposits	Silicon dioxide and silicates, even at low concentrations, can cause whitish-grey, yellowish-brown or bluish-purple discolouration. When using ion exchangers to fully demineralise water, carryover of silicon dioxide may result in glaze-like deposits. In order to achieve reproducibly stain-free results on instruments, the silicate content should be permanently below 0.4 mg/l.
Chlorides	Pitting	Chlorides dissolved in water are particularly critical as they can result in higher concentrations in pitting, even on instruments made from higher-grade stainless steel. Generally speaking, the following factors increase the risk of chloride-induced pitting: • High chloride content • Higher temperatures • Lower pH values • Longer exposure times • Insufficient drying • Concentration through evaporation The relationship between chloride content in water and pitting is not always foreseeable. In laboratory experiments, signs of corrosion appeared on instruments exposed to a chloride content of 100 mg/l after only 2 hours at room temperature. The risk of pitting rises fast as the chloride content increases. At chloride levels above 50 mg/l combined with other inclement cleaning parameters (low pH value, elevated temperature or long exposure times), the risk of pitting on stainless chromium steel cannot be excluded.
Evaporation residues	Stains and deposits	As water evaporates, substances are left behind as mineral deposits. This can result in stains and/or corrosion. Given the ingredients of water, natural tap water is unsuitable in many stages of reprocessing.

Tab. 2: Max. levels according to EN 285[4] and EN 13060.[5]

	EN 285 Appendix B (feed water quality)	EN 13060 Appendix B (feed water quality)
Evaporation residues	≤ 10 mg/l	≤ 10 mg/l
Silicates	≤ 1 mg/l	≤ 1 mg/l
Cadmium	≤ 0,005 mg/ l	≤ 0,005 mg/l
Iron	/	≤ 0,2 mg/l
Lead	≤ 0,05 mg/l	≤ 0,05 mg/ l
Heavy metal residues except iron, cadmium, lead	≤ 0,1 mg/	≤ 0,1 mg/l
Chlorides	≤ 0,5 mg/l	≤ 2 mg/l
Phosphates	≤ 0,5 mg/l	≤ 0,5 mg/
Conductivity (at 20°C)	≤ 5 µS/cm	≤ 15 µS/cm
pH value (20°C)	5 bis 7,5	5 bis 7,5
Appearance	Colourless, clear, no deposits	Colourless, clear, no sediments
Hardness (∑ of alkaline earth ions)	≤ 0,02 mmol/l	≤ 0,02 mmol/l

> In view of this application, washer-disinfectors are often also referred to as thermal disinfectors.

Manufacturers of washer-disinfectors usually recommend the quality of water required in their operation and installation instructions.

'Swiss good practice guidelines on the reprocessing of medical products'[3] and the 'Health Technical Memorandum 01-01 (Management and decontamination of surgical instruments (medical devices) used in acute care Part D: Washer-disinfectors)'[10] recommend the use of demineralised water or RO water for thermal disinfection and in the final rinse.

Routine water inspections for thermal disinfection

The 'Guideline on the inspection, validation and monitoring of automated cleaning and disinfection processes for medical products' issued by the ÖGSV[2] recommends that the conductivity of demineralised water should be checked on a weekly basis.

Swiss good practice guidelines on the reprocessing of medical products state that water for the final rinse after the main wash should not impair the subsequent sterilisation process and should not cause damage to either washer-disinfectors or medical products. Reference is made to machine manufacturers regarding conductivity, pH values, hardness, ion concentrations and max. permissible concentrations. The water quality for the various stages of reprocessing must be defined and monitored[3].

Water and thermal disinfection

The disinfection of heat-resistant load items is preferably carried out using thermal disinfection. This phase in a washer-disinfector is also the last rinse cycle as there is no further intake of water after this step. The precondition for thermal disinfection is that load items are sufficiently cleaned and rinsed in preceding process stages. The A0 value concept was introduced as a parameter to describe disinfection performance[7]. The definition of the A0 value is as follows: A time equivalent for disinfection in seconds at 80°C with reference to a microorganism with a z value of 10 K[6]. Generally, a temperature of 90°C and an exposure time of approx. 5 minutes is used for the thermal disinfection of critical medical products, corresponding to an A0 value of at least 3000.[7]

	Tap water	Softened water	Fully demineralised water
Evaporation residues (mg/l)	500	530	5
Electrical conductivity (µS/cm)	650	700	3
Total hardness (°d)	14	< 0,1	< 0,1
Sodium salts (mg/l)	20	160	< 1
Chlorides	40	40	< 1
Silicates (ppm SiO_2)	12	12	< 0,1
pH value	6,7	8	5,5

Tab. 3: Comparison of water qualities.[1]

Selection of the A0 value is dependent on:
- The intended use of load items
- The material from which load items are manufactured
- The type and number of microorganisms on load items with respect to heat-resistant infectious organisms

During thermal disinfection, it is also necessary for a variety of process fluids to pass through each of the inner lumens on load items to be washed and disinfected.

Disinfection using heat is one of the oldest and safest disinfection processes. Heat is lethal to microorganisms, whereby each microorganism has its own intrinsic tolerance. Several common pathogens (such as Staphylococcus and Streptococcus) are deactivated at 55-60°C in combination with moist heat; other spore-forming bacteria require a temperature in excess of 100°C[9].

Against this backdrop, it is necessary to be aware of the use to which a medical product is put and the relevance of potential contamination (Spaulding Classification), and to take these factors into account in the selection of the appropriate disinfection parameters.

National criteria and recommendations from expert bodies apply to the microbiological composition of water, e.g. for the reprocessing of endoscopes.
The microbiological quality of water is guaranteed by the thermal disinfection phase as the last intake of water into a washer-disinfector[8].

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Costs for reprocessing medical devices in an outpatient surgery centre (Part 1)*

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Kathrin Mann

The article is divided into two parts: In Part 1 (present issue), the author devotes herself to the problem and the methodology and thus creates, among other things, an overview of the accruing processes in the reprocessing unit for medical devices of the aforementioned surgery center. In Part 2 (next issue 01/2023), the author addresses the reference variables and costs for the processes in the reprocessing unit for medical devicesof the surgery center.

The project sponsor is the operator of part of an outpatient surgery center in the Upper Palatinate. In the affiliated private clinic 7 beds are available for patients, per year about 2000 outpatient surgeries are performed, specialty vascular surgery. The operations are performed in 3 operating rooms, a reprocessing unit for medical device is attached to the facility.

Abstract

The costs incurred for the production of one sterilization unit (1 StU) can be calculated by accurately documenting the workflow practices. The costs for 1 StU in the project sponsor's outpatient surgery centre include the initial use of an instrument up to the final cleaning, packaging, sterilization and storage. Furthermore, the costs incurred for provision of equipment, for staff, electricity consumption, water and consumable materials can be calculated. Likewise, from this data an Excel-based calculation tool can then be developed, in which the analysed cost types are systematically broken down, assigned and brought to a single denominator. By dividing these costs by the (number of) sterilization units produced, a cost price can then be calculated. By calculating the costs for 1 StU, the project sponsor can quote an exact price for external medical device reprocessing, i.e., surgical instruments, when asked, since the costs for the reprocessing process are known. Furthermore, by developing an Excel-based calculation tool it is possible to provide corresponding calculations for other outpatient surgery centres and office-based medical practices. By calculating the costs of reprocessing medical devices in different outpatient surgery centres, a basis can be created for a broad cost analysis. This, in turn, is a prerequisite for negotiations with the paying authorities (medical insurance companies) on the reimbursement of the reprocessing costs. The reprocessing legal requirements have increased sharply over the last ten years but the reimbursement rates have failed to keep abreast of these.

The project sponsor is the economic operator of part of an outpatient surgery centre in the Upper Palatinate region of Germany. The affiliated private clinic has seven beds for patients and each year some 2000 outpatient vascular surgery operations are performed. The operations are carried out in three operating rooms (ORs); a CSSD is attached to the facility.

Background

The increasingly more stringent legal regulations, in particular in the hygiene domain (and the hygiene requirements to be met for medical device reprocessing) are a major challenge for many office-based medical practitioners, because the reimbursement structures in Germany have for many years now failed to keep pace with the rising demands. However, the same laws and resulting requirements that apply in hospitals also apply in office-based medical practices and outpatient surgery centres. Cost calculations are based on the relevant costs incurred for reprocessing medical devices for the vascular surgery section of an outpatient surgery centre and which can be directly assigned to the consumer.

*This article by Kathrin Mann was published for the first time in the journal ZENTRALSTERILISATION 03/2022 (pages 122-130) as a first publication.

Fig. 1: Operating room.

Tab. 1: Unclean area: processes and costs incurred.

Unclean area	Costs incurred	
Processes	Direct costs	Indirect costs
Manual cleaning: instrument basin, single-use cleaning brush, detergents	x	
Automated Processing: process chemicals for the washer disinfector	x	
Personnel costs (employer's gross payments)	x	
Washer disinfector repairs & maintenance	x	
Washer disinfector process validation	x	
Maintenance costs for demineralized water system		x
Maintenance costs for air conditioning system		x
Furniture, cabinets/ boxes, 10-year utilization period		x

Fig. 2: Unclean area of the CSSD.

Task definition

In Germany, a Medical Hygiene Regulation (MedHygV), based on the German Protection against Infection Act (IfSG), is required in each federal state. Each federal state is responsible for implementation of the hygiene requirements, such as e.g., the formulation of a hygiene/infection control policy, nomination of hygiene personnel and definition of their tasks, specific obligations of the institutions, etc. Other obligations relate to the demands addressed to the construction, equipment and operation of a facility. While the economic operator can avail of a plethora of recommendations/guidelines, their implementation calls for precise planning for which planning experts are well paid. The costs incurred for this are borne by the economic operator. Similarly, the economic operator is responsible for proper implementation of medical device reprocessing. Is it worthwhile having reprocessing done in-house or can the economic operator outsource these tasks or even switch to single-use devices? The reimbursement fees paid to the economic operator for their services do not reflect the medical device reprocessing costs incurred. The economic operator is hardly able to estimate the scale of the costs incurred for the hygiene measures. Can a physician doing surgical procedures still cover their costs these days? What does reprocessing 1 sterilization unit (1 StU) cost the economic operator?

Methods

First, a literature search was conducted to establish whether such cost analysis calculations for 1 StU had already been conducted in an outpatient surgery centre. The following databases were searched: Regensburg University Library and its database access to all relevant journals and textbooks as well as internet-based searches in the databases WiSo and the Bavarian Library Network (Gateway Bayern), using the German-language

search terms for "costs", "sterile supplies", "reprocessing", "unit costs", "production costs". Since in Germany medical device reprocessing is subject to the specific requirements of the individual federal state (Land), international comparability was not possible. Therefore, only German-language search terms were used. It was noted that there are no publications or scientific papers on this topic. Only lectures representing a basis for data collection of the costs to be considered were identified. Nor are there any German-language studies or publications for the hospital setting. Upon request, the device manufacturers make software available to the CSSD with which it can calculate the costs for partial areas or offer a calculation of the costs as a service for a fee. After extensive research it appears that no valid data are available either for the outpatient setting.

To clarify as far as possible the project sponsor's/customer's pertinent issues, activity-based costing is a suitable instrument for presenting the individual sub-processes for calculating 1 StU transparently and as accurately as possible.

Based on activity-based costing, the costs of the entire process (activities, material costs, etc.) are analysed and presented transparently. The costs of the process are recorded solely for the production of sterile supply, starting in the unclean area of the CSSD, followed by the clean area and sterile storage. Routes and transport costs are excluded. As a first step, the instrument reprocessing process was broken down into individual sub-processes by means of an activity analysis using document analysis and interviewing the employees in the project sponsor's CSSD. Attention must be paid to ensuring that only the most important reprocessing sub-processes are mapped. As the next step, the reference variables were defined. One example of a reference variable could be the personnel costs for reprocessing. Once the reference values had been defined, the corresponding process costs were calculated. This was done between 1 January 2019 and 31 December 2019. Cost rate formation was carried out as a last step cost rates for cost calculation.

Costs per process quantity = process costs: process quantity

Table 2 below (for reasons of space, list not complete) gives an example of the processes executed in the unclean area and the costs incurred. Here, as in the following cases, a distinction is made between, on the one hand, direct costs, e.g., material costs, personnel

Process	Sub-process	Materials required
Instrument inspection	Inspect instruments for cleanliness, apply care spray, sort out defective instruments	Care spray, cloths, compresses, swabs
Instrument packing	Place instruments in containers, wrap instruments in fleece, affix process indicator	Instrument containers, fleece, sterilization pouches, indicator tape
Sterilizer repairs & maintenance	Appointment scheduled by employee	Documentation, equipment log, invoices
Sterilizer validation	Appointment scheduled by employee	Documentation, equipment log, invoices
Personnel costs	Personal must be present throughout the entire reprocessing process	Omitted

Tab. 2: Clean area: processes and sub-processes.

costs, consumables, maintenance costs and procurement costs and, on the other hand, indirect costs such as rent, electricity consumption, water consumption. In the case of the present project sponsor, the costs for the water treatment system and air conditioning system are included in the rental price and are therefore not listed. In the following, all costs identified for the three areas are extrapolated separately in terms of indirect and direct costs for a production year. This is based on the information provided by the project sponsor's CSSD staff as well as on the author's own experience and observations during the time of data collection. These data are also taken into account in the cost analysis and cost calculation.

Data collection process

At the start of data collection a meeting was held with the project sponsor's infection control physician responsible for sterilization (medical device reprocessing) as well as with the surgical department management and a CSSD employee, who described the CSSD structures. The activities taking place in the three relevant areas of the CSSD were discussed. The presentation of the structures and the activities of CSSD are extremely relevant, because only in this way can proper cost analysis be conducted and the most important process variables identified beforehand. Furthermore, during the discussion future contact persons were nominated, from whom the required data and information for the preparation of the cost analysis were obtained.

First, the relevant data for calculating the costs for 1 StU were determined and defined. To get a picture of the instrument reprocessing processes, starting with the use of the instrument during the operation, through cleaning and sterilization to the storage of the sterile material, the second step was to accompany the project sponsor's employees over the course of three days. The observations took place during regular working hours. Hence, it was possible to closely observe and document through activity analysis the individual instrument reprocessing steps. Furthermore, a material analysis was carried out during the observation period to determine which materials were required for the various areas. These data were also recorded. Next, the costs were identified. To that effect, the CSSD employees and OR management of the project sponsor were available for personal discussions.

Tab. 3: Unclean area: reference variables and costs incurred.

Unclean area	Costs incurred	
Reference variables	Direct costs	Indirect costs
Cleaning: instrument basin, single-use cleaning brush, detergents	€0.30/tray	
Personnel costs (employer's gross payment, €16/hour)	€16 (60 minutes working time in unclean area for 6 trays)	
WD validation	€1,190 / year	
Furniture: cabinets / boxes, 10-year utilization period		€1,333.30 / year
Energy: electricity consumption for WD and ultrasonic bath (US)		WD: 3kW/batch = 0.90 €/batch US: 0.3kW = 0.09 €/batch

Activity analysis and file review

The first step in activity-based costing was to determine the individual processes. This was done through activity analysis and a review of the documents. The activity analysis was based on observations carried out in the project sponsor's CSSD and in one-to-one discussions with the responsible staff.

The materials required for instrument reprocessing were also analysed and evaluated through observation and questioning.

The cleaning and disinfection processes and their sub-processes in the unclean area of CSSD correspond to the activity descriptions defined in the project sponsor's internal quality management system. The personnel costs relate to the cleaning process and the sub-process of loading the washer/disinfector (WD) and to the manual pre-cleaning in the ultrasonic bath. Manual reprocessing of the instruments is not carried out in the project sponsor's CSSD. Furthermore, personnel costs are incurred for repair and maintenance of equipment, storage and generation of documentation, equipment log and invoices. The cleaning and disinfection processes have to be validated by external companies, for which staff must also be present. Staff members are required not to leave the room during reprocessing for hygienic reasons. This requirement is specified in the guideline of the Robert Koch Institute (RKI) and the Commission for Hospital Hygiene and Infection Prevention (KRINKO): "Hygiene requirements for reprocessing medical devices". Furthermore, working time is incurred for cleaning furniture and the utensils used to clean. Another important cost block is the purchase and maintenance of the washer/disinfectors (WDs). In the calculation carried out, a utilization period of ten years was assumed for the WD as well as for the ultrasonic bath. In addition, maintenance and repair services must be taken into account. In the CSSD air conditioning with sterile air is needed for both hygiene and room temperature reasons[1]. Since the purchase price of the air conditioning system is covered by the rental price in the case of the present project sponsor, only maintenance services and energy costs have to be taken into account, as is also the case with the demineralized water system.

In the table above, the processes and sub-processes executed in the clean area are now assessed by way of example (list not complete). The reprocessing staff member must now check for cleanliness the cleaned instruments passed through the hatch from the unclean area. Instruments with joints must be cared for with a spray (oil spray) and defective instruments must be sorted out for repair. To that effect, the employee will need to have to hand suitable implements such as oil spray, cloths, compresses and swabs. The instruments are then packed as per a standard operating procedure (SOP). To do this, the instruments are placed in an instrument basket/tray, which is wrapped with a fleece. The instrument tray wrapped with the fleece is then placed in an instrument container. Furthermore, the container must be appropriately labelled and a biological indicator must be inserted. In addition to the instrument containers, which are classified as costs assigned to the economic operator rather than sterilization costs, fleece, sterilization pouches and indicator tape are needed as consumables. The instruments packed in this way are placed in the sterilizer. The sterilizer is computer-controlled and monitors and sterilizes the instruments, which must then be removed again. Personnel costs are incurred in this process. Additional personnel costs are incurred for the repair and maintenance of the sterilizer because an employee must also be present to hand over documents such as the equipment logbook and validation results. The employee is also present at the time of process validation, which is carried out in the sterilizer. After completion of sterilization, the instruments must be removed. A cooling phase of around 30 minutes must be observed to avoid condensate formation within the packaging or container due to too rapid cooling. The sterile material must cool down to room temperature. However, the personnel costs are calculated only for the actual work activities, and not for the waiting times. For hygiene reasons the staff member is always present during activities in the clean area. Additional personnel and cleaning-utensil costs are incurred for cleaning cabinets, surfaces and the sterilizer. Equipment costs are also incurred in the clean area. A heat sealer whose service life has also been set at ten years is used in the CSSD to package single instruments; costs are also incurred for the steam sterilizer, which also has a useful life of ten years. The maintenance service and the energy consumption are calculated ad-

ditionally. The purchase of the air conditioning system, which must also contain clean air according to DIN EN 1946-4, is included in the rental price. The energy costs are included in the calculation, maintenance and servicing measures must also be taken into account, as is the case with the demineralized water system.

After the cooling phase, the instrument containers or individually wrapped sterile goods are transported to the sterile supply store. While in this room there is no absolute need for air conditioning or clean air as specified by DIN EN 1946-4, the sterile supplies should not be exposed to major temperature fluctuations and should be stored at room temperature[2]. Hence, an air conditioning unit is available in most sterile goods storage facilities. Here, too, personnel costs are incurred for cleaning cabinets and furniture as well as the cleaning-utensil costs. Personnel costs for transporting the sterile goods to and from the individual rooms were not taken into account because the rooms are in close proximity to the store.
In the next issue, you'll learn how the author determines the reference variables and costs for the processes in the surgery centre's CSSD and ultimately for 1 STE, and she discusses the results.

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The hygiene consultation concept at the Katholisches Klinikum Mainz

Hubert Holz, Heike Kiesel, Markus Kiesel

The kkm has had an admission screening programme in place for years. As a result, many pathogens carried by patients are identified as soon as the patients arrive at the hospital: of these, the most common are methicillin-resistant Staphylococcus aureus (MRSA)2 at 69 % and multi- resistant Gram-negative bacilli (MRGN) at 31 %. However, many other microbes are brought into the hospital in addition to these, with the result that more effort may be required to care for patients properly.

Development of hospital hygiene guidelines

The complexity of the hygiene rules is increasing continually: at one time, a recommendation from the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) would have been no more than a few pages long; nowadays, such recommendations take the form of extensive specialist publications with more than 100 literary sources. On the one hand, this is a welcome development because the more scientific approach makes for greater acceptance of the recommendations. On the other hand, it also means that the hygiene recommendations are more difficult for non-specialists to understand. At the same time, the Commission for Hospital Hygiene and Infection Prevention has stopped issuing dogmatic instructions. Instead, it is often the job of the facility or institution to define a procedure – as part of a risk analysis by the hospital hygienist – that is tailored to the individual circumstances of the hospital and wards, as well as the patient base and local hygiene concepts. A clear example of this can be found in the guideli- nes for dealing with MRGN. In this case, the hygiene measures do not depend solely on the type of pathogen and its resistance patterns, but also on the respective treatment unit and the specifics of the patient and any fellow patients.[3]

On top of this increasing complexity, you also have to consider the continually increasing workload, need for multidis- ciplinary ward staffing and role specialisation among the staff in situ, regardless of whether they are doctors or nurses. In light of all this, it quickly becomes apparent that these staff members do not have the time to master and apply all the algorithms and factors that need to be considered for each problem pathogen (see also Figure 2).

Launch of the project

For this reason, the kkm decided that the staff at the Hospital Hygiene Depart- ment would be required to hold a hygiene meeting/ consultation with the staff on the ground in relation to all patients that were (potentially) carrying a pathogen requiring their isolation and also in relation to all isolated patients. In the course of this discussion, they would decide whether isolation was necessary or avoidable, and if and when isolation would be allowed to end. This consultation decision would also have to be written up clearly and documented in the medical information system (MIS).

When setting up the new system, another aim was to avoid unnecessary isolation and to optimise bed utilisation at the kkm by cohorting patients where possible. At the same time, the intention was to cut material/ equipment costs and reduce any additional tying up of staff. An analysis at the kkm revealed that costs of up to €600 could be incurred per day of isolation, if the necessary beds could not be filled.[4] The consensus reached was that the existing procedure (no consultation unless requested by the wards, nothing documented in writing in the patient file) was neither adequate nor productive. Therefore, the first step was to build a feature into the MIS that would allow the ward to send an electronic consultation request to the Hospital Hygiene

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Patientenflyer Händehygiene Toilettenhygiene Basishygiene | Revision: 02 Dok.-Nr. : SOP-01282 Seite 1 von 1 | **Katholisches Klinikum Mainz** Hygiene

Patienten-Flyer zur Händehygiene und Toilettenhygiene für Patienten und Angehörige im kkm

Liebe Patienten, Liebe Angehörige und Besucher,

Ihre Mithilfe ist gefragt! Denn durch die Hände können Keime leicht übertragen werden. Dies geschieht meist unbemerkt durch direkten Kontakt von Hand zu Hand oder über Gegenstände und Flächen. Viele unserer Patienten sind abwehrgeschwächt und damit besonders infektionsanfällig. Die sicherste und einfachste Methode, um der Übertragung von Krankheiten im Krankenhaus vorzubeugen, ist die alkoholische Händedesinfektion. Worauf Sie dabei achten sollten, möchten wir Ihnen nachfolgend aufzeigen.
Als **Patient, Angehöriger oder Besucher** sollten Sie sich **beim Betreten und vor Verlassen** des Krankenhauses die Hände desinfizieren. Bereits in der Eingangshalle des kkm befindet sich hierfür ein Händedesinfektionsmittelspender. Sie müssen nichts anderes tun, als Ihre Hände unter die Düse zu halten und schon wird ein feiner Sprühnebel abgegeben. Bitte verreiben Sie diesen etwa 30 Sekunden in beiden Händen. Eine ausführliche Erläuterung finden Sie weiter unten.
Zudem besteht die Notwendigkeit, beim Betreten oder Verlassen der Patientenzimmern und der Intensivstation die Hände zu desinfizieren. Sie finden ausreichend Pumpspender in den Fluren bzw. in den Patientenzimmern. Bitte scheuen Sie sich nicht, diese zu benutzen.
Außerdem sollten Sie sich die Hände desinfizieren, bevor Sie die kostenlosen Trinkwasserspender verwenden, vor dem Essen oder Betreten der Cafeteria, nach der Benutzung der Sanitärbereiche und nach dem Naseputzen oder Husten in die Handfläche.
Bei Besuchen von Patienten mit resistenten Erregern/ isolierten Patienten können zusätzliche Vorgaben zu beachten sein. In diesem Fall werden Sie durch die Mitarbeiter des Bereiches eingewiesen. Sie erkennen dies an einem Schild an der Zimmertür.

Wie sollten Sie sich die Hände desinfizieren?

Eine Händedesinfektion muss für mindestens 30 Sekunden durchgeführt werden.
Dazu geben Sie 1-2 Hub Händedesinfektionsmittel in die hohle Hand und verreiben dieses gleichmäßig auf beiden Händen bis zu den Handgelenken.
Die Hände müssen während dieser Zeit feucht bleiben, gegebenenfalls entnehmen Sie erneut Desinfektionsmittel.

Copyright: Aktion Saubere Hände

Toilettenhygiene:
Auch über die Benutzung von Toiletten können Krankheitserreger übertragen werden, besonders wenn diese von mehreren Menschen genutzt werden. Desinfizieren Sie daher die Kontaktflächen der Toilette vor und nach jeder Nutzung wie folgt:

- Öffnen Sie die Toilette mit einem desinfektionsmittelgetränkten Tuch (Einmal-Tuch mit Händedesinfektionsmittel).
- Wischen Sie zunächst den Spülknopf und dann den Toilettensitz damit ab.
- Werfen Sie das Tuch anschließend **in den Mülleimer**, auf keinen Fall in die Toilette.
- Wischen Sie den Toilettensitz nach Benutzung erneut mit einem desinfektionsmittelgetränkten Tuch ab (s.o.).
- Schließen Sie damit den Toilettendeckel und drücken Sie den Spülknopf.
- Werfen Sie das Tuch unbedingt **nur in den Mülleimer**, nicht in das WC.
- Desinfizieren Sie sich abschließend die Hände, wie oben beschrieben.

Bei Fragen und Unsicherheiten wenden Sie sich bitte an das Behandlungsteam vor Ort.
Unsere Mitarbeiter erläutern Ihnen gerne die notwendige Vorgehensweise und unterstützen Sie bei der Umsetzung der erforderlichen Hygienemaßnahmen.

Erstellung:	Freigabe:
Markus Kiesel	Hr. Dr. Holz
Hygienemanager	Ltd. Krankenhaushygieniker

Ausgedruckte Dokumente unterliegen nicht dem Änderungsdienst

Fig. 1: kkm patient flyer on toilet hygiene.

Department. This marked the beginning of the hygiene consultations at the kkm.

How the consultations work

In addition to this request by the ward or area, the hospital hygiene staff also actively seek out cases that might require a consultation.

As a starting point for this, they refer to the in-depth findings from an external microbiological laboratory or from the kkm in-house laboratory (rapid influenza diagnostic test and MRSA screening[5]). In addition, the hospital has a special programme for detecting and analysing pathogens called the germ detective and mo- vement list. These electronic tools identify all recently confirmed cases of problem pathogens and send a notification to the Hospital Hygiene Department in the event of a known carrier being readmitted.In parallel with this, each member of staff carries out a check every working day to see if any special notes (called Cave notes) have been entered in the MIS for the areas falling under their responsibility. They then ask their colleagues on the ground whether a consultation is required for these.

At the kkm, the staff consultations are usually conducted by the hygiene specialists but are always coordinated with the hospital hygienist. If patients or relatives want to have a meeting with the Hospital Hygiene Department, this option is offered by the hospital hygienist. This means that the special doctor-patient relationship is properly respected within the context of infectious diseases or multi-resistant pathogens as well as everywhere else.

Hygiene guidelines

During the individual hygiene meeting, various aspects of hygiene management are checked as part of the consultation. (Incidental remark: The primary hygiene concept practised by the kkm is vertical hygiene, i.e. in the case of certain microbes, special barrier and/or isolation measures[6] must be implemented in addition to good basic hygiene.).

First and foremost, this means asking the fundamental question: Are these extra measures actually necessary on top of basic hygiene? If, for example, 3MRGN organisms (Gram-negative bacilli resistant to three antibiotic groups) were to be confirmed in a patient's urine on a normal ward that was observing the basic hygiene rules, the kkm would not consider this grounds for moving the patient to a single room. Instead, attention would simply be drawn to the importance of basic hygiene as part of the hygiene consultation and a flyer on sanitary hygiene would be handed out for the patient to read (see Figure 1).

If the patient were to undergo an operation and needed to be placed in the intensive care unit, a single room would be recommended (depending on the type of pathogen). Once the patient had been moved back to the normal ward, another consultation meeting would be held to decide whether to take them out of isolation. Given that this can be a very complex issue (as already described above), the hospital has developed a set of flow charts. By way of an example, Figure 2 contains the flow chart for deciding whether a patient should be isolated in the case of 3MRGN organisms.

Similarly, the hygiene consultation is used to discuss and determine the conditions under which an isolated patient will be allowed to leave their isolation room. Aside from the impact purely from a mental health perspective, this point is also particularly important for the acute geriatric unit at the kkm because the bulk of the treatment here consists of mobilisation, movement and integration into everyday ward life, as well as integrated therapeutic measures.

Strict isolation prevents this type of treatment from taking place and so is only used when absolutely necessary. It is also during the consultation that the specialist hygiene staff tailor the personal protective equipment (PPE) to the individual circumstances. If a patient were infected with the hepatitis B virus (HBV), the kkm would not normally suggest placing them in a single room (exception: delirium and/or aggression

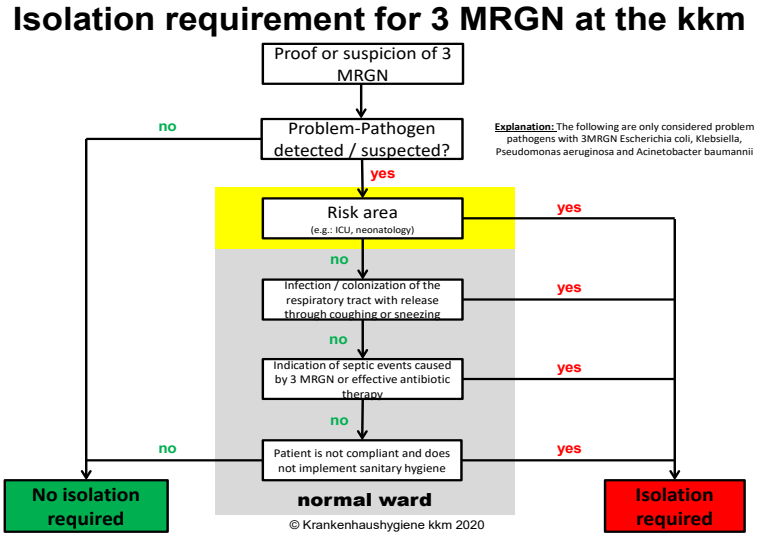


Abb. 2: Flow chart for making isolation decisions about 3MRGN at the kkm.

towards others, possible secretions). However, if there were a risk of staff coming into contact with secretions, they would not only be recommended to wear PPE in the form of disposable medical gloves[7] but also safety glasses and an impermeable gown (at the kkm: one with a safety class of at least 2B8). In addition, the hygiene specialists would insist that care only be delivered by effectively vaccinated staff.[9,10]

Hepatitis is also a good example of the hospital's approach to disinfectants. While fully virucidal disinfectants have to be used on hands and surfaces when treating patients with hepatitis A and E, products with limited virucidal activity are deemed sufficient for the bloodborne infections of hepatitis B, C and D.[11,12] Thus, a higher level of hygiene safety is achieved by holding the hygiene consultations.

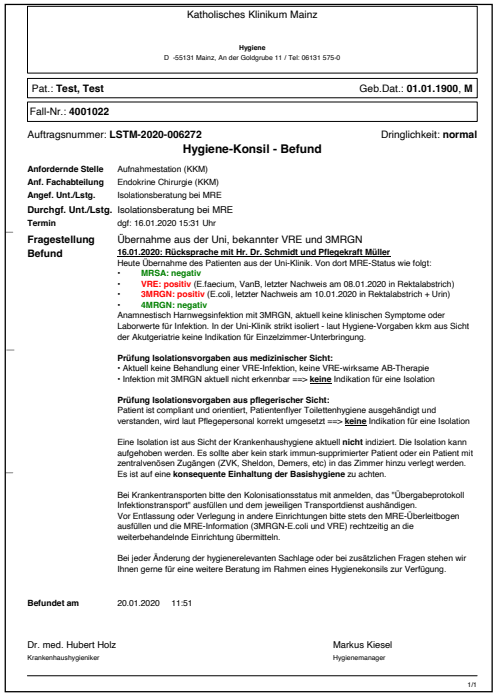
These meetings are also used to discuss another important point associated with this: terminal disinfection once patients have been removed from isolation or discharged. For this, the kkm has a three-level reprocessing concept that de- fines the extent of cleaning and disinfection required based on the degree to which the environment has been contaminated. The recommendation concerning the appropriate level is also incorporated into the consultation meeting. An example report from a hygiene consultation can be found in Figure 3.

To help them draft their hygiene consultation reports, new members of staff are provided with text templates, either in the form of a multiple-choice version with options for them to tick or in the form of ready-made text modules.

This ensures a standard format for the consultation reports. As they gain experience, individual members of staff can then start drafting consultation reports in their own words (e.g. in the case of special situations), which they can individually tailor to the specific scenario and the needs of the patient.

In addition, a reconsultation can also be agreed straight away if necessary. If, for example, the decolonisation of a patient with MRSA is discussed, a new consultation meeting is scheduled to take place once the control swabs have come back. At the kkm, this will usually be after a week (3 to 5 days of decolonisation, control swabs taken on days 4 to 6, result available on day 7).[5] Another example is a patient with gastroenteritis. In this case, a reconsultation would be arranged for when the symptoms subside in order to clarify whether the patient can be taken out of isolation.

There is a particularly high risk of confusion/mix-ups occurring when transferring patients between normal wards and intensive care units, e.g. if an isolated 3MRGN carrier is admitted to the intensive care unit but continues to be isolated once on the normal ward. Scheduled reconsultations with the hygiene specialists can help in this regard by promptly reducing the measures to the level actually required.



Katholisches Klinikum Mainz

Hygiene
D -55131 Mainz, An der Goldgrube 11 / Tel: 06131 575-0

Pat.: **Test, Test** Geb.Dat.: **01.01.1900, M**

Fall-Nr.: **4001022**

Auftragsnummer: **LSTM-2020-006272** Dringlichkeit: **normal**

Hygiene-Konsil - Befund

Anfordernde Stelle Aufnahmestation (KKM)
Anf. Fachabteilung Endokrine Chirurgie (KKM)
Angef. Unt./Lstg. Isolationsberatung bei MRE
Durchgf. Unt./Lstg. Isolationsberatung bei MRE
Termin dgf: 16.01.2020 15:31 Uhr

Fragestellung Übernahme aus der Uni, bekannter VRE und 3MRGN
Befund **16.01.2020: Rücksprache mit Hr. Dr. Schmidt und Pflegekraft Müller**
Heute Übernahme des Patienten aus der Uni-Klinik. Von dort MRE-Status wie folgt:
- **MRSA: negativ**
- **VRE: positiv** (E.faecium, VanB, letzter Nachweis am 08.01.2020 in Rektalabstrich)
- **3MRGN: positiv** (E.coli, letzter Nachweis am 10.01.2020 in Rektalabstrich + Urin)
- **4MRGN: negativ**

Anamnestisch Harnwegsinfektion mit 3MRGN, aktuell keine klinischen Symptome oder Laborwerte für Infektion. In der Uni-Klinik strikt isoliert - laut Hygiene-Vorgaben kkm aus Sicht der Akutgeriatrie keine Indikation für Einzelzimmer-Unterbringung.

Prüfung Isolationsvorgaben aus medizinischer Sicht:
- Aktuell keine Behandlung einer VRE-Infektion, keine VRE-wirksame AB-Therapie
- Infektion mit 3MRGN aktuell nicht erkennbar ==> **keine** Indikation für eine Isolation

Prüfung Isolationsvorgaben aus pflegerischer Sicht:
Patient ist compliant und orientiert, Patientenflyer Toilettenhygiene ausgehändigt und verstanden, wird laut Pflegepersonal korrekt umgesetzt ==> **keine** Indikation für eine Isolation

Eine Isolation ist aus Sicht der Krankenhaushygiene aktuell **nicht** indiziert. Die Isolation kann aufgehoben werden. Es sollte aber kein stark immun-supprimierter Patient oder ein Patient mit zentralvenösen Zugängen (ZVK, Sheldon, Demers, etc) in das Zimmer hinzu verlegt werden. Es ist auf eine **konsequente Einhaltung der Basishygiene** zu achten.

Bei Krankentransporten bitte den Kolonisationsstatus mit anmelden, das "Übergabeprotokoll Infektionstransport" ausfüllen und dem jeweiligen Transportdienst aushändigen.
Vor Entlassung oder Verlegung in andere Einrichtungen bitte stets den MRE-Überleitbogen ausfüllen und die MRE-Information (3MRGN-E.coli und VRE) rechtzeitig an die weiterbehandelnde Einrichtung übermitteln.

Bei jeder Änderung der hygienerelevanten Sachlage oder bei zusätzlichen Fragen stehen wir Ihnen gerne für eine weitere Beratung im Rahmen eines Hygienekonsils zur Verfügung.

Befundet am 20.01.2020 11:51

Dr. med. Hubert Holz
Krankenhaushygieniker

Markus Kiesel
Hygienemanager

1/1

Fig. 3: Example hygiene consultation report recom- mending that the patient be taken out of isolation.

Naturally, the hygiene consultations are subject to quality control: all the reports are read and double-checked by the hospital hygienist. Only on very rare occasions have any corrections been required. More complex circumstances are discussed with the hospital hygienist even before a consultation report is produced.

Results of the hygiene consultation project

The hygiene consultation project was launched at the beginning of 2019. The first project evaluation took place after a year as planned. This revealed that 2118 hygiene consultations had already been conducted in re- lation to 1269 patients over the 12-month period. That equates to approximately 180 consultations per month. Given that approximately 40 minutes are spent on each hygiene consultation on average, the annual workload amounts to around 1400 hours or a 0.8 full-time equi- valent. To allow for this additional work, we have signi- ficantly reduced routine ward checks in non-risk areas. No isolation or special hygiene measures were recom- mended in approximately 40 % of these consultations (relevant impact on occupancy management).

And simply by terminating the legitimate isolation of a patient at the right time and reversing any unjustified instances of isolation (see Figure 3), we have also been able to prevent significant material/equipment costs and the tying up of human resources. The number of unnecessary microbiological samples has also been dramatically reduced, such as the 20 % reduction we have achieved for CDI.

Another point that must not be neglected is the increased presence of the hospital hygiene team on the ward thanks to the daily face-to-face consultations with staff and the improved relationship that has built up as a result. The members of the hospital hygiene team are now seen more as partners who facilitate the care of potentially infectious patients than as remote "pen-pushers".

The automatic reconsultations that have been introduced as part of a patient's treatment have also proven worthwhile. Particularly when patients are infected with critical pathogens such as 4MRGN and LVRE and have to be isolated with no prospect of removal, barrier measure-related errors can sometimes creep in during longer treatment periods. By carrying out a regular and structured check as part of the hygiene consultations, any deviations from good practice can be promptly identified and corrected. In the majority of cases, the staff on the wards do not take this personally but regard it as a constructive contribution to local hygiene management.

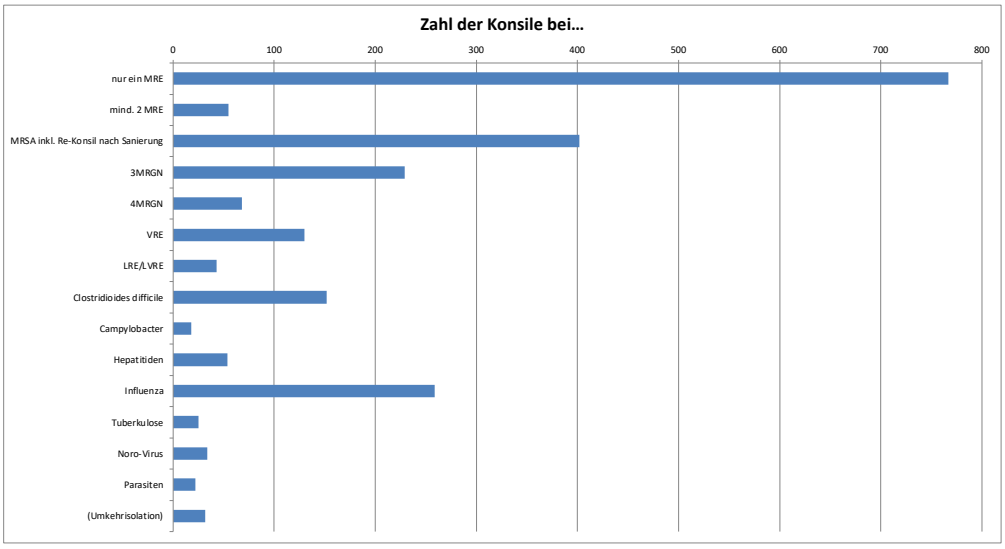


Fig. 4: Breakdown of hygiene consultations by pathogen group.

Even in the case of hygienically complex issues, such as the peripartum management of MRSA[13] or the need to keep immunosuppressed patients with infectious diseases in single rooms for prolonged periods (known as the Dresden model)[14], the hygiene consultations ensure practical advice and implementation. In addition, the fact that everything is documented electronically in the relevant patient file means that information remains available and can be accessed across multiple shifts.

Another positive aspect that cannot be underestimated is that it is now easier to account for isolation within the context of complex treatment (OPS 8-987 and 8-98g).[15] Firstly, the hygiene consultation automatically provides those funding the care with evidence of the individual advice and support provided by the hospital hygiene team; secondly, the hygiene specialists remind ward staff to complete the respective checklists that are required as evidence of the additional work necessitated by isolation.

One final point that nobody foresaw when planning the project was how difficult it would be to find rehabilitation spaces for patients carrying multiresistant pathogens or infectious diseases.[16] It was discovered that this lack of aftercare was leading to longer hospital stays and days of treatment at the kkm, particularly in acute geriatric care and thoracic surgery but also in abdominal and vascular surgery. Therefore, the hospital has started to produce additional consultation reports that provide recommendations for further care at external facilities. Of course, these are not binding and attention has always been drawn to the need for local hygiene plans and guidelines at the rehabilitation facilities. Nevertheless, patients have been immediately accepted as soon as the hygiene consultation report has been presented. And that goes for every single case. On many wards, the hygiene consultations are actively requested, and those responsible for coordinating beds are also eager for consultations so that planned patients can be optimally distributed at the kkm. And it is even quite common for the chief physician and other senior doctors to ring up and ask when they will be able to see the latest consulting report in the MIS.

That is why we are determined that the hygiene consultation service at the kkm should continue to provide all the parties involved – whether patients, visitors or staff – with additional peace of mind. Acting completely in the interest of the patients within our care, we intend to achieve a good balance so that we can put a stop to unnecessary and burdensome instances of patient isolation while at the same time ensuring that all necessary barrier measures are implemented.

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Miele takes over Tübingen hygiene specialist SMP

Gütersloh/Tübingen, November 10, 2022. – Miele's Professional business unit brings together the sale of machines and services in the field of laundry technology and commercial dishwashing as well as products and services for cleaning, disinfection and sterilisation in hospitals, medical practices and laboratories. With the acquisition of SMP GmbH, based in Tübingen, Germany, Miele is expanding its expertise and accelerating its growth. In addition to validation, the service portfolio will in future include the provision of test challenges and laboratory tests to Miele as well as to users and manufacturers of medical devices.

SMP GmbH was founded in 2000 and today, as an accredited test laboratory, offers a complete range of services supporting cleaning, disinfection and sterilisation processes. Background: The medical sector is subject to strict regulation with respect to hygiene and infection control. Processes for cleaning, disinfection and sterilisation, in which surgical instruments, for example, are reprocessed, must be validated regularly and must demonstrate the necessary process safety according to hygiene plans and country-specific requirements. For these tests, SMP produces standardised test devices, among other things. One example of this are intentionally contaminated crile clamps. After cleaning, the SMP laboratory inspects these items for residues of the contamination, thereby evaluating cleaning performance. SMP is one of the few suppliers providing and evaluating test devices on the German market.

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Fig. 1: SMP is now part of Miele. Dr Reinhard Zinkann, Co-proprietor, Olaf Bartsch, Executive Director Finance & Administration and Dr Christian Kluge, Senior Vice President Business Unit Professional (all Miele) met in Gütersloh with the previous owners Dr. Ludger Schnieder and Klaus Roth (from left) to sign the contract. (Photo: Miele)

Fig. 2: The Tübingen-based company SMP specialises in services relating to medical technology. (Photo: SMP)

SMP GmbH, with its current staff of 50, will remain an independent company in Tübingen as a 'Miele Group Member' and will continue to provide services for medical device manufacturers as an accredited test laboratory. The SMP team of engineers, physicists, biologists and chemists is also active in research, developing customer-specific test procedures, and has an established network of links to national and international players in the medical field. In addition, testing for technical homologation and the compilation of reprocessing instructions constitute part of their range of services. Due to additional order volumes from the Miele Group and the further internationalisation of its business, SMP will grow strongly in future and expand its capacities. Miele is therefore investing in the expansion of laboratory facilities in Tübingen.

The two SMP proprietors and Managing Directors Klaus Roth and Dr Ludger Schnieder are selling their business for age-related reasons but will continue to be available to the company in leading positions over the coming years. 'In Miele, we have found a strong, reliable and internationally positioned buyer with which SMP and our employees in Tübingen can look to the future with confidence', says company founder Klaus Roth. 'We will continue to provide services for our customers in the same proven quality. Trust and confidence have top priority here', adds Ludger Schnieder.

With this acquisition, Miele is further expanding in the medical technology sector. Regular validation, maintenance and service are essential for the long-term operation of equipment from Miele's Bielefeld plant and its

subsidiary Steelco. 'With SMP, we are taking another big step towards becoming a full-line system provider of hygiene solutions in the marketplace', explains Dr Christian Kluge, Senior Vice President of the Professional business unit. 'With Steelco, we significantly expanded our portfolio for hospitals and pharmaceutical companies in 2017. We also offer our own process chemicals and can now provide our customers with additional laboratory services', Kluge continues.

The Professional business unit of the Miele Group comprises five production sites. The plant in Bielefeld is responsible for washer-disinfectors for medical practices, dentists and laboratories. Steelco products (Riese Pio X and Cusano di Zoppola sites) are designed to cater for larger capacities in the hospital and pharmaceutical sectors. The Miele plant in Bürmoos, Austria, supplies stainless-steel baskets and inserts, conveyors and load carriers for Steelco and Miele machines, among other things, and oversees small sterilisers. Miele's commercial laundry technology is all located in Lehrte, Lower Saxony. Other professional products such as the Little Giants (semi-commercial washing machines and dryers) are supplied by other production plants.

Fig. 3: SMP's accredited test laboratory complements the service portfolio of Miele's Professional business unit. (Photo: SMP)

New in the scientific advisory board: Kathrin Mann and Carola Diekmann

Kathrin Mann

Kathrin Mann is a registered nurse and gained experience in the field of hygiene and business processes in hospitals and surgeries through her extra-occupational studies as a health economist leading to a B.A. in Business Administration (Steinbeis University Berlin) and a Master in Health Business Administration (MHBA) at the University of Erlangen-Nuremberg.

She acquired practical knowledge and experience as head of a large outpatient surgery, a position she held for several years. In 2013, Kathrin Mann founded the PRO.Q.MA health management company.

She works as author for medical publishing companies and is a scientific speaker at conventions and forums and contributes with her expertise on various hospital hygiene and health economics bodies, and is an advisor in the healthcare sector.

She shares her knowledge and long-term experience in the branch as part of her countrywide work as lecturer at universities and academies in the fields of hospital hygiene, quality management and the reprocessing of medical products. Since 2020, Kathrin Mann has been contract lecturer and project manager at the Steinbeis University in Berlin.

Carola Diekmann

Carola Diekmann is a specialist in hospital hygiene, a trained hygienist and an expert in the reprocessing of medical devices. After 18 years in a managerial position in an outpatient eye clinic in Detmold and several extra-occupational further education courses, she has worked since 2015 for a service provider in the field of hospital hygiene and as a self-employed specialist with a focus on providing advice to outpatient surgeries and ophthalmological clinics. She also lectures at various academies and provides training on current requirements in the field of infection control and medical device legislation. In providing advisory services, she combines her specialist knowledge in the field of ophthalmology and surgery with many years of experience working in hospitals and clinics. Relying on this wealth of experience, she provides support in planning new outpatient surgeries and advises existing surgeries, surgical centres and hospitals.

Ms. Diekmann is a long-standing member of the DGSV and DGKH associations and has been on the DGSV expert committee since 2011 and on the steering committee of the DGSV since 2019. She holds specialist talks at various congresses and events.

3 questions to...

Iven Kruse

Iven Kruse
General Sales Manager
Xylem Analytics Germany Sales GmbH & Co. KG

1. Why is the validation of reprocessing processes in CSSD an important part of the reprocessing of medical devices?

The German law §8 MPBetreibV requires "The reprocessing of medical devices used as intended to be low-germ or sterile must be carried out with suitable validated procedures in such a way that the success of these procedures is comprehensibly guaranteed and the safety and health of patients, users and third parties is not endangered". The validation of the processes is legally mandatory in Germany and Europe. With the validation of the reprocessing processes cleaning, disinfection and sterilization, the parameters are defined that are required for the reprocessing of sterile medical devices.

2. Who is allowed to perform the validations?

The validation must be carried out on behalf of the operator by qualified specialists. The qualification can be proven by presenting a certificate from a competent authority. A milestone for the requirement for the validation of cleaning and disinfection processes is the DIN 58341 standard. On the basis of the standard, the German organizations DGKH, DGSV and AKI are revising the guideline for the validation and routine control of machinel cleaning and thermal disinfection processes for medical devices. Appendix 2 of the revised guideline describes in detail the requirements for the qualification of validators in the future.

3. Why must the quality of machine cleaning and disinfection be ensured by routine control tests in addition to validation? What does this mean for operations in CSSD?

The KRINKO / BfArM recommendation "Requirements for hygiene in the reprocessing of medical devices" requires suitable routine controls in addition to validation to ensure the quality of the reprocessing used. These are periodic and batch-related routine checks based on risk analysis.

For the operator, this means that he defines suitable test methods and test specimens for batch or routine control within the scope of validation. CSSD staff must be trained so that you can perform and evaluate the routine checks. If measuring instruments are used, e.g. data loggers, the manufacturer's instructions regarding operation and calibration must be observed. Here I recommend training the software and the correct application of the data loggers.

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