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Knowledge base: Requirements for water for thermal disinfection in the washer-disinfector

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

Editorial

Dear readers,

When writing an editorial, people like to pick up on major political topics or events. War, the pandemic and energy supply would be particularly suitable in the current climate. In this issue, however, we are taking a different approach and looking at
in a more manageable area. Inside views of a scientific advisory board. When we were suddenly allowed to join the editorial team of aseptica in 2015 (Ulrike) and 2017 (Aaron), we got to know and appreciate our advisory board. From the outside, it may seem like a "motley crew", but from our point of view it is an incredibly diverse and honest group that keeps us on the same professional track and supports us on a personal level. As is often the case in other things, this is unfortunately taken far too much for granted. As in every group, we are currently experiencing a generational change. It is with great regret that Prof. Pietsch passed away in September 2022.

Our colleagues Dr. Holz, Dr. Wilbrand and Dr. Biering will soon be devoting themselves to private matters, which are no less exciting, and are leaving the Board. Thank you for everything! We have taken this as an opportunity to republish "Best of Biering / Holz" in this and the next issue with the articles "The concept of hygiene consultations at the Catholic Hospital on the 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 have given us
with new vitality and courageous changes of direction and also generate critical letters to the editor. New to the team are K. Mann and C. Diekmann - both full professionals in the preparation of instruments. Read more about this on page 22.

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

A huge thank you to our advisory board, wherever you are. May you all have a great time and a virtual La Ola wave.

We hope our readers enjoy the last issue of this year, wish you a relaxed final spurt in 2022 and health and happiness for the new year.

Ulrike and Aaron

Message

Sleep disorders are increasing significantly

More and more Germans are suffering from sleep disorders. The number of diagnoses of non-organic sleep disorders increased nationwide by around 77 percent from 2011 to 2021. This is shown by data published by the commercial health insurance company KKH. According to the data, around 1.2 million Germans are affected by sleep disorders.

This is only the tip of the iceberg, as the evaluation is based exclusively on doctors' diagnoses, explained KKH doctor Sonja Hermeneit. Non-organic sleep disorders include difficulty falling asleep and sleeping through the night as well as nightmares and anxiety dream disorders, which can occur under high levels of psychological stress.

According to the KKH, the number of diagnoses rose by eight percent from the pre-corona year 2019 to the second corona year 2021. A Forsa survey commissioned by the health insurer had previously shown that professional stress (42% of respondents) and private worries (34%) were the main factors affecting sleep.

Source: aerzteblatt.com

Contents

Knowledge base: Requirements for water for thermal disinfection in the washer-disinfector*

Ulrike Weber

During thermal disinfection in washer-disinfectors, water plays a decisive role in preserving the value of processing goods and equipment. The main tasks are described as follows:

- Influencing the pressure of the circulation pump
- Dissolving ingredients of the process chemicals
- Even distribution of rinse aid (if used)
- Transfer of heat, energy and mechanics
- Final rinse

Water constituents with relevance for thermal disinfection

As a medium and operating fluid, water and water-based substances can also be the cause of surface changes on processing goods or washer-disinfectors if the initial quality is inadequate. The AKI1 identifies the water ingredients described in Table 1 as problematic.

Depending on the installation and appliance equipment, softened water or demineralized water is used for thermal disinfection.

During **softening,** the calcium and magnesium cations (hardness formers) contained in the water are replaced by sodium ions. However, this does not reduce the total load of water constituents (waste water residue) (including the chloride content). In the case of softened water, the alkalinity can increase considerably due to the sodium carbonate formed depending on the temperature, time and carbonate hardness in the outlet water.1 This is shown in Table 3. In thermal disinfection, this can have an effect on alkali-sensitive materials (such as anodized aluminium surfaces).

The AKI1 recommends the following guide values for softened water:

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

Water softening systems are either integrated in the washer-disinfector or connected externally upstream.

In **demineralization,** all mineral substances are removed from the drinking water as far as possible. Reverse osmosis, cation and anion exchangers and electrodeionization (EDI) are used for this purpose, also in combination, as well as distillation in special cases.1

There is no definition for the composition of demineralized water. Therefore, the criteria of EN 285 and EN 13060 are often used in the field of instrument preparation.

For thermal disinfection, 15 µS/cm is an acceptable conductivity value for the feed water.

Systems for producing demineralized water are connected externally upstream of the WDs.

The AKI1 compares relevant water constituents in Table 3 and recommends the use of demineralized water for thermal disinfection for the following reasons:

- No staining
- No concentration of corrosive ingredients, e.g. chlorides
- No crystalline drying residues that could negatively affect the subsequent sterilization process
- Protection and stabilization of anodized aluminium surfaces

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*without thermal disinfection of containers for human excretion according to EN 15883-3

Table 1: Water constituents that can lead to problems.

Hardeners (calcium and magnesium salts)	Scale formation, limescale due to calcium and magnesium hydrogen carbonate, corrosion potential	Depending on the existing water hardness and temperature, hardness formers lead to the formation of deposits that are difficult to remove ("lime scale"). Under certain circumstances, this can even lead to corrosion under the scale formation.
Heavy and non-ferrous metals, e.g. iron, manganese, copper	Brownish-red coating formation, secondary rust	Heavy and non-ferrous metals and their compounds in water can lead to colored deposits even in low concentrations. Higher quantities of iron dissolved in water can lead to corrosion on surfaces (secondary rust).
Silicates, silicic acid	White-grey, thin deposits with a colored appearance	Silicic acid and silicates can cause white-grey, yellow-brown to blue-violet discoloration even in low concentrations. When using ion exchangers for complete demineralization, silica slippage may occur, resulting in the formation of glaze-like deposits. In order to obtain reproducible stain-free instruments, the silicate content should be permanently below 0.4 mg/l.
Chlorides	Pitting corrosion	Dissolved chlorides in water are particularly critical, as they can cause pitting corrosion in higher concentrations, for example, even on stainless steel instruments. In general, the risk of chloride-induced pitting corrosion increases with: • increasing chloride content, • increasing temperature, • decreasing pH value, • longer exposure time, • insufficient drying, • Concentration due to drying. The correlation between chloride content in water and pitting corrosion is unpredictable in some cases. In laboratory tests, instruments with a chloride content of 100 mg/l at room temperature show signs of corrosion after just two hours. The risk of pitting corrosion increases rapidly as the chloride content increases. With chloride contents above 50 mg/l and unfavorable cleaning parameters (low pH value, increased application temperature and exposure time), the risk of pitting corrosion cannot be ruled out with stainless chrome steel.
Evaporation residue	Stains and coatings	When water evaporates, water constituents can remain as visible mineral deposits. These can lead to staining and/or corrosion. Due to the substances contained in the water, natural drinking water cannot be recommended for all treatment steps.

	EN 285 Annex B (feed water quality)	EN 13060 Annex B (feed water quality)
Evaporation residue	≤ 10 mg/l	≤ 10 mg/l
Silicate	≤ 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
Chloride	≤ 0.5 mg/l	≤ 2 mg/l
Phosphate	≤ 0.5 mg/l	≤ 0.5 mg/
Conductivity (at 20 °C)	≤ 5 µS/cm	≤ 15 µS/cm
pH value (20 °C)	5 to 7.5	5 to 7.5
Appearance	colorless, clear, without deposits	colorless, clear, without sediment
Hardness (∑ of the alkaline earth ions)	≤ 0.02 mmol/l	≤ 0.02 mmol/l

Table 2: Normative maximum values according to EN [2854] and EN 13060.[5]

WD manufacturers usually recommend water qualities in the operating instructions and installation instructions.

The "Swiss Good Practice for the Preparation of Medical Devices "3 and the Health Technical Memorandum 01-01 (Management and decontamination of surgical instruments (medical devices) used in acute care Part D. Washer-disinfectors)1[0] recommend mineralized water or osmosis water for thermal disinfection and final rinsing in the washer-disinfector: Washer-disinfectors)1[0] recommend demineralized water or osmosis water for thermal disinfection and final rinsing in the washer-disinfector.

Routine checks of the water for thermal disinfection

The "Guideline for the testing, validation and monitoring of automated cleaning/disinfection processes for medical devices" of the ÖGSV2 recommends a weekly check of the conductivity of the deionized water.

The "Swiss Good Practice for the Preparation of Medical Devices" describes that water for the final rinse after cleaning must not impair the sterilization process and must not damage washer-disinfectors and medical devices. Recommendations regarding conductivity, pH value, degree of hardness,

The ion concentration and limit values for impurities must be specified by the device manufacturer. The water qualities in the various treatment steps must be defined and monitored.[3]

Water and thermal disinfection

Disinfection of thermostable items is preferably carried out using thermal disinfection. This step in the washer-disinfector is also the last rinsing step, as no further water is used afterwards. The prerequisite for thermal disinfection is that the items to be processed have been sufficiently cleaned and rinsed in the previous process steps. The A0 value concept was introduced as a parameter for describing the disinfection effect[7]. The definition of the A0 value is: The time equivalent in seconds at 80 °C given by the disinfection process in relation to a microorganism with a z-value of 10 [K6]. For the thermal disinfection of critical medical products, temperatures around 90 °C are mainly used over an exposure time of approx. five minutes, which achieves an A0 value of at least 3000.[7]

Table 3: Examples of water qualities in the Comparison.[1]

	Drinking water	Softened water	Fully demineralized water
Evaporation residue (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

> Due to this use, washer-disinfectors are also known as thermal disinfectors. labeled.

The selection of the A0 value depends on:

- The intended use of the loading items
- The materials from which the objects are made
- The type and level of microorganisms on the load items with special consideration of heat-resistant infectious organisms

During thermal disinfection, it is also necessary for the different process fluids to flow through each of the internal channels and/or cavities of the items to be cleaned and disinfected, which must be disinfected.

Disinfection using heat is one of the oldest and safest disinfection methods. Heat is lethal (deadly).

The temperature is the same for all microorganisms, with each microorganism having its own intrinsic tolerance. Some common pathogens (such as Staphylococcus and Streptococcus) are killed at 55-60°C and moist heat, while other spore-forming bacteria require more than 100°C.[9]

Against this background, it is necessary to know the use of the medical device and the relevance of the potential contamination (spaulding classification) and to take this into account when selecting the disinfection parameters.

National criteria and specialist recommendations (e.g. endoscope preparation) apply with regard to the microbiological composition of the water. The thermal disinfection phase as the last water-bearing phase in the washer-disinfector also ensures the microbiological quality of the [water8].

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Costs of reprocessing medical devices in outpatient surgery (Part 1)*

Kathrin Mann

The article is divided into two parts: In Part 1 (present issue), the author addresses the problem definition and methodology and thus provides an overview of the processes occurring in the AEMP of the surgical center mentioned. In part 2 (issue 01/2023), the author discusses the reference values and costs for the processes in the AEMP of the surgery center.

The project sponsor is the operator of part of an outpatient surgery center in the Upper Palatinate. The attached private clinic has 7 beds for patients and performs approx. 2000 outpatient operations per year, specializing in vascular surgery. The operations are performed in 3 operating theaters, an AEMP is attached to the facility.

The increasing legal requirements, particularly in the area of hygiene (and requirements for hygiene in the preparation of medical devices), pose major challenges for many practice operators and registered doctors, as the remuneration structures in Germany have not been adapted to the increased requirements for many years. Nevertheless, the same laws and resulting requirements apply in the practice and for outpatient surgery as in the hospital. The calculation is based on relevant costs that are incurred in the preparation of medical devices for the vascular surgery section in an outpatient surgery center and that can be directly allocated to the user.

Problem definition

In Germany, a medical hygiene regulation (MedHygV) is required in every federal state as a result of the Infection Protection Act (IfSG). The implementation of the required hygiene measures such as
e.g. maintenance of a hygiene plan, provision of specialist hygiene staff and their tasks, special obligations of the facilities, etc. are the responsibility of the individual federal states.

tions. This also includes the requirements for the construction, equipment and operation of a facility. Although many recommendations/guidelines are available to practice operators to help with this, implementation requires concrete planning, for which specialist planners are well paid. The costs incurred for this are borne by the practice operator. Also
The practice operator is responsible for the correct implementation of medical device reprocessing. Is it worthwhile preparing them yourself or can the operator outsource this service or even switch to disposable products? The preparation of the medical devices is not reflected in the remuneration of his services. The operator can hardly estimate how high the costs are in connection with the hygiene requirements. Can an operating doctor still cover his costs these days? What does it cost the operator to prepare a sterilization unit (1 STE)?

Methodology

First, a literature search was conducted to determine whether such calculations already exist for cost analysis 1 STE in an outpatient surgical center. The following databases were used for this purpose: Regensburg University Library and its database access to all relevant specialist journals and textbooks as well as Internet-based searches in the WiSo databases and the Bavarian Library Network (Gateway Bayern), with the keywords "costs, sterile goods, reprocessing, unit costs, production costs". International comparability is not possible due to the country-specific peculiarities in the preparation of medical products. For this reason, only German search terms were used. It was found that there are no publications or scientific papers on this topic. Only articles were found that provide a basis for collecting data on the costs to be considered.

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There are also no German-language studies or publications for the hospital sector. On request, the device manufacturers provide the AEMP with software with which it can calculate the costs for sub-areas or offer cost calculation as a service for a fee. After extensive research, there also appears to be no valid data for the outpatient sector. In order to be able to answer the project sponsor's/client's question as well as possible, process costing is a suitable instrument for presenting the individual sub-processes for calculating 1 STE transparently and as accurately as possible.

Activity-based costing is used to analyze and transparently present the costs of the entire process (activities, material inputs, etc.). The costs of the process are allocated solely to the Sterile supply area, starting in the non-sterile area of the AEMP, followed by the clean area and sterile storage area. Travel and transportation costs are excluded. In a first step, the process of instrument preparation was broken down into individual sub-processes by means of an activity analysis using document analysis and interviews with employees in the AEMP of the project sponsor. Care must be taken here to ensure that only the most important sub-processes of preparation are mapped. In the next step, the reference variables are determined. An example of a reference variable could be the personnel costs for preparation. Once the reference variables have been determined, the corresponding process costs are calculated. This was done for the period 01.01.-31.12.2019. In the last step, cost rates are formed to calculate the costs.

Costs per process quantity = process costs : process quantity

Fig. 1: Operating theater.

unclean area	Costs incurred	
Processes	Direct costs	Indirect costs
Manual cleaning: Instrument tray, cleaning brush for single use, cleaning agent	x	
Automated reprocessing: process chemicals for the washer-disinfector	x	
Personnel costs (employer gross)	x	
Repair & maintenance RDG	x	
Process validation RDG	x	
Maintenance costs VE system		x
Maintenance costs for air conditioning		x
Furniture: cupboards / boxes, useful life 10 years		x

Table 1: unclean area: processes and costs incurred.

Table 1 (not listed in full for reasons of space) provides an example of the processes and their costs incurred in the non-clean area. As in the following, a distinction is made between direct costs, e.g. material costs, personnel costs, consumables, maintenance costs and acquisition costs, and indirect costs such as rent, electricity consumption and water consumption. In the case of the project sponsor, the costs of the water purification system and the air conditioning system are included in the rental price and are therefore not listed.

In the following, all costs determined for the three premises are extrapolated to a production year, broken down into indirect and direct costs. This is based on the information provided by the project sponsor's AEMP employees as well as the author's own experience and observations during the data collection period. This data is also taken into account in the cost analysis and cost calculation.

Data collection procedure

At the beginning of the data collection, an interview was held with the project sponsor's doctor responsible for sterilization, the head of the operating theatre and a specialist from the AEMP, who explained the structures of the AEMP. The activities in the three relevant rooms of the AEMP were explained. The presentation of the structures and activities of the AEMP are extremely relevant, as this is the only way to carry out a correct cost analysis by determining the most important process variables in advance. Furthermore, future contact persons were determined during the discussion, from whom the data and information required for the cost analysis were obtained.

First, the relevant data for calculating the costs for 1 STE was determined and defined. In order to get a clear picture of the instrument reprocessing processes, starting with the

Fig. 2: Unclean area of the AEMP.

In a second step, the employees of the project sponsor were shadowed over a period of three days to gain an insight into the use of the instrument during surgery, cleaning and sterilization and the storage of sterile items. The work shadowing took place during regular working hours. This allowed the individual instrument reprocessing processes to be closely observed and documented by means of an activity analysis. Furthermore, a material analysis was carried out during the work shadowing to determine which materials were required for the individual rooms. This data was also noted down. The next step was to determine the costs. The staff of the AEMP and the OP management of the project sponsor were available for this in personal discussions.

Activity analysis and file review

The first step in activity-based costing was to determine the individual processes. This was done by analyzing the activities and reviewing the documents. The activity analysis was carried out by observing the project sponsor's AEMP and in personal discussions with the responsible employees. The materials required for preparing the instruments were also analyzed and evaluated through observation and interviews.

The cleaning and disinfection processes and their sub-processes in the unclean area of the AEMP 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 or manual pre-cleaning in the ultrasonic bath. Manual preparation of the instruments does not take place in the project sponsor's AEMP. Furthermore, personnel costs are incurred in the area of repair and maintenance of the devices, storage and provision of documents, device book and invoices. The cleaning and disinfection processes must be validated by external companies; the presence of the employee is also necessary here. Staff are required not to leave the room during preparation for hygiene reasons. This requirement is based on the guidelines of the Robert Koch Institute (RKI) and the Commission for Hospital Hygiene and Infection Prevention (KRINKO): "Hygiene requirements for the preparation of medical devices". Furthermore, working time is incurred for cleaning furniture and cleaning utensils. Another important cost item is the purchase and maintenance of the washer-disinfector. The calculation assumes a service life of ten years for the washer-disinfector and the ultrasonic bath. Furthermore, maintenance services must be

and maintenance services must also be taken into account. In the AEMP area, air conditioning with low-germ air is necessary for reasons of both hygiene and room temperature[1]. Since the purchase of the air conditioning system is covered by the rental price in the case of the project sponsor, only maintenance services and energy costs need to be taken into account, as is the case with the VE system.

Table 2 "clean area" now shows examples of the processes and sub-processes of the clean area (list not exhaustive). The employee must now check the clean instruments that she takes from the unclean area through the pass-through for cleanliness. Instruments with joints must be treated with a care spray (oil spray) and defective instruments must be sorted out so that they can be repaired. To do this, the employee needs appropriate utensils such as oil spray, cloths, compresses and swabs. The instruments are then packed in accordance with an existing work instruction by placing them in an instrument basket wrapped in fleece. The instrument tray wrapped with the fleece is then placed in an instrument container. It is also necessary to label the container accordingly and provide it with a bioindicator. In addition to the instrument containers, which are not part of the cost

Since the sterilization costs are not attributable to the sterilization process, but rather represent the surgeon's costs, fleece, sterilization bags and indicator tape are required as consumables. The instruments packaged in this way are transferred to the sterilizer. This is computer-controlled and monitors and sterilizes the instruments, which must then be removed again. This incurs personnel costs. Additional personnel costs are incurred for the repair and maintenance of the sterilizer, as the employee must also be present to present documents such as the equipment logbook and validation results. The employee is also present during the validation of processes carried out in the sterilizer. Once sterilization is complete, the instruments must be removed. A cooling phase of approx. 30 minutes must be observed in order to avoid the formation of condensate within the packaging or in the container due to too rapid cooling. The sterile goods must cool down to room temperature. However, the personnel costs are only calculated for the pure activities and not for the waiting times. For reasons of hygiene, the employee is always present during the activities in the clean area. Additional costs for staff and cleaning utensils are incurred when cleaning cabinets, surfaces and the sterilizer. Equipment costs are also incurred in the clean area. A heat-sealing device is used in the AEMP to pack individual instruments, the useful life of which is also limited.

Process	Sub-process	Materials required
Testing the instruments	Check instruments for cleanliness, maintain with oil spray, sort out defective instruments	Care spray, wipes, compresses, swabs
Packing the instruments	Place instruments in container, pack instruments with fleece, stick on process indicator	Instrument container, fleece, sterilization bags, indicator tape
Repair & maintenance sterilizer	Scheduling by employee	Documents, device book, invoices
Sterilizer validation	Scheduling by employee	Documents, device book, invoices
Personnel costs	Staff must be present during the entire reprocessing process	Not applicable

Table 2: Processes and sub-processes.

Table 3: Impure area: reference values and costs incurred.

unclean area	Costs incurred	
Reference values	Direct costs	Indirect costs
Cleaning: Instrument tray, cleaning brush for single use, cleaning agent	0,30 €/sieve	
Personnel costs (employer gross, €16/hour)	16 € (60 minutes working time in the unclean area for 6 sieves)	
Validation RDG	1190 €/ year	
Furniture: cupboards / boxes, useful life 10 years		1333.30 €/ year
Energy: Power consumption for washer-disinfector and ultrasonic bath (US)		RDG: 3kW/charge = 0.90 €/charge US: 0.3kW = 0.09 €/charge

The useful life of the steam sterilizer is also set at ten years, as are the costs for the steam sterilizer, which also has a useful life of ten years. The maintenance service and energy consumption are calculated additionally. The purchase of the air conditioning system, which must also contain clean air in accordance with DIN EN 1946-4, is included in the rental price. The energy costs are included in the calculation, and maintenance and servicing measures must also be taken into account, as is the case with the VE system.

After the cooling time, the instrument containers or individually packaged sterile goods are transported to the sterile goods storage area. This room does not require air conditioning and clean air in accordance with DIN EN 1946-4.

However, the sterile goods should not be exposed to large temperature fluctuations and should be stored at room [temperature2]. This means that most sterile goods stores have a climate control unit. Here too, personnel costs are incurred for cleaning cabinets and furniture as well as costs for cleaning utensils. Personnel costs for transporting the sterile goods to and from the individual rooms were not taken into account due to the close proximity of the rooms. In the next issue, you will find out how the author calculates the reference values and costs for the processes in the AEMP of the OR center and finally for 1 STE and presents the results for discussion.

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The hygiene consultations concept at Mainz Catholic Hospital

Hubert Holz, Heike Kiesel, Markus Kiesel

The Katholisches Klinikum Mainz (kkm) is a hospital providing specialized care with 602 beds and around 1,500 employees. Every year, 50,000 patients are treated as inpatients and outpatients in 19 clinics and ten centers.[1]

Thanks to the long-established admission screening process at kkm, many pathogens brought into the hospital are identified on arrival: Of these, we most frequently find methi- cillin-resistant Staphylococcus aureus (MRSA)[2] (69%) and multi-resistant Gram-negative pathogens (MRGN) (31%). In addition to these, however, there are a large number of other germs that are brought into the hospital and may mean increased effort for patient care.

Development of the requirements in hospital hygiene

The complexity of hygiene rules continues to increase: While a recommendation from the Committee for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) used to be just a few pages long, these recommendations now correspond to larger specialist publications and have well over 100 literature sources. On the one hand, this development is to be welcomed, as the increased scientificity ensures greater acceptance of the recommendations, but on the other hand it also makes the recommendations more difficult to understand for "non-hygiene experts". At the same time, the KRINKO no longer makes dogmatic determinations. Rather, for many topics, it is the responsibility of the facility - as part of a risk analysis by the hospital hygienist - to determine a procedure that is tailored to the individual circumstances of the clinic and wards as well as the patient clientele and the hygiene concepts on site. This is exemplified by the guidelines on MRGN, where, in addition to the pathogen and resistance pattern, the hygiene measures also depend on the respective treatment method.

The results of the treatment depend on the individual characteristics of the patient and his fellow patients.[3]

If you add to this increasing complexity the ever-increasing concentration of work, interdisciplinary ward occupancy and task specialization among the staff on site, regardless of whether nursing or medicine, it quickly becomes clear that they do not have the time to learn and apply the individual algorithms and considerations for each problem pathogen (see also Figure 2).

Start of the project

For this reason, the kkm has stipulated that all patients with a pathogen (potentially) requiring isolation and all isolated patients are to be given a hygiene consultation by the staff of the hospital hygiene department or a consultation with the staff on site, during which a decision is made in a dialog as to whether an isolation is necessary.
The advice is also clearly formulated and documented in the hospital information system (HIS). This advice is also clearly formulated and documented in the hospital information system (HIS).

The aim was also to avoid unnecessary isolation and to optimize bed occupancy in the kkm through possible cohorting. At the same time, the costs for materials were to be reduced as far as possible and the additional personnel commitment reduced. In an evaluation at kkm, costs of up to €600 per isolation day were calculated if the required beds could not be occupied.[4]
The consensus was that the previous procedure (consultation only at the request of the wards, no written do-

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Patient flyer Hand hygiene Toilet hygiene Basic hygiene	Revision: 02 Doc. no. : SOP-01282 Page 1 from 1	Catholic Hospital Mainz Hygiene

Patient flyer on hand hygiene and toilet hygiene for patients and relatives at kkm Dear patients, relatives and visitors,

Your help is needed! Because germs can easily be transmitted through the hands. This usually happens unnoticed through direct hand-to-hand contact or via objects and surfaces. Many of our patients have weakened immune systems and are therefore particularly susceptible to infection. The safest and simplest method to prevent the transmission of diseases in hospital is alcohol-based hand disinfection. We would like to show you below what you should pay attention to.
As a **patient, relative or visitor,** you should disinfect your hands **when entering and before leaving** the hospital. There is a hand disinfectant dispenser in the entrance hall of the kkm. All you have to do is hold your hands under the nozzle and a fine spray is dispensed. Please rub this in both hands for about 30 seconds. You will find a detailed explanation below.
It is also necessary to disinfect your hands when entering or leaving patient rooms and the intensive care unit. You will find sufficient pump dispensers in the corridors and patient rooms. Please do not hesitate to use them. You should also disinfect your hands before using the free drinking water dispensers, before eating or entering the cafeteria, after using the sanitary facilities and after blowing your nose or coughing into the palm of your hand.
Additional guidelines may need to be observed when visiting patients with resistant pathogens/isolated patients. In this case, you will be instructed by the staff of the department. You will recognize this by a sign on the room door.

How should you disinfect your hands?

Hand disinfection must be carried out for at least 30 seconds.
To do this, pour 1-2 pumps of hand sanitizer into the palm of your hand and rub it evenly into both hands up to the wrists.
The hands must remain moist during this time; if necessary, use disinfectant again.

Copyright: Clean Hands Campaign

Einreibemethode
für Ihre Händedesinfektion

Toilet hygiene:
Pathogens can also be transmitted through the use of toilets, especially if they are used by several people. Therefore, disinfect the contact surfaces of the toilet before and after each use as follows:

- Open the toilet with a disinfectant-soaked cloth (disposable cloth with hand disinfectant).
- First wipe the flush button and then the toilet seat with it.
- Then throw the cloth **in the waste garbage can**, never in the toilet.
- Wipe the toilet seat again with a disinfectant-soaked cloth after use (see above).
- Use it to close the toilet lid and press the flush button.
- **Only** throw the wipe **into the waste garbage can**, not into the toilet.
- Finally, disinfect your hands as described above.

If you have any questions or uncertainties, please contact the treatment team on site.
Our staff will be happy to explain the necessary procedure to you and support you in implementing the required hygiene measures.

Printed documents are not subject to the amendment service

Creation:	Release:
Markus Kiesel	Mr. Dr. Holz
Hygiene manager	Ltd. hospital hygienist

Fig. 1: Patient flyer toilet hygiene kkm.

documentation in the patient file) was not sufficient and effective. The first step was therefore to create the option in the HIS for the ward to submit an electronic consultation request to the hospital hygiene department, marking the birth of hygiene consultations at kkm.

Carrying out the consultations

In addition to this registration via the ward or functional areas, the hospital hygiene staff actively search for cases where advice may be required.
An indication of this are the incoming findings from the external microbiological laboratory and from the kkm's in-house laboratory (rapid influenza test and MRSA screening[5]). In addition, a special program for pathogen detection and evaluation, the so-called germ detective and the movement list, is used. These electronic tools show all newly detected problem pathogens and report any readmission of known carriers to the hospital hygiene department. In addition to this, each employee checks their assigned areas every working day for so-called cave notes in the HIS and asks their colleagues on site whether they need advice.

At kkm, staff consultations are generally carried out by the hygiene specialists, always in consultation with the hospital hygienist, carried out. If patients or relatives wish to speak to the hospital hygiene department, this is offered by the hospital hygienist. This also takes into account the special patient-doctor relationship in the case of questions about infectious diseases or multi-resistant pathogens.

Hygiene requirements

During the individual hygiene consultations, various aspects of hygiene management are examined as part of the consultations. (Side note: At kkm, the concept of vertical hygiene measures is primarily pursued, i.e. for certain germs, separate barrier and / or isolation measures must be implemented in addition to good basic hygiene[6]. must be implemented in addition to good basic hygiene).

First and foremost is the fundamental question of whether these measures, which go beyond basic hygiene, are really necessary. The proof of a

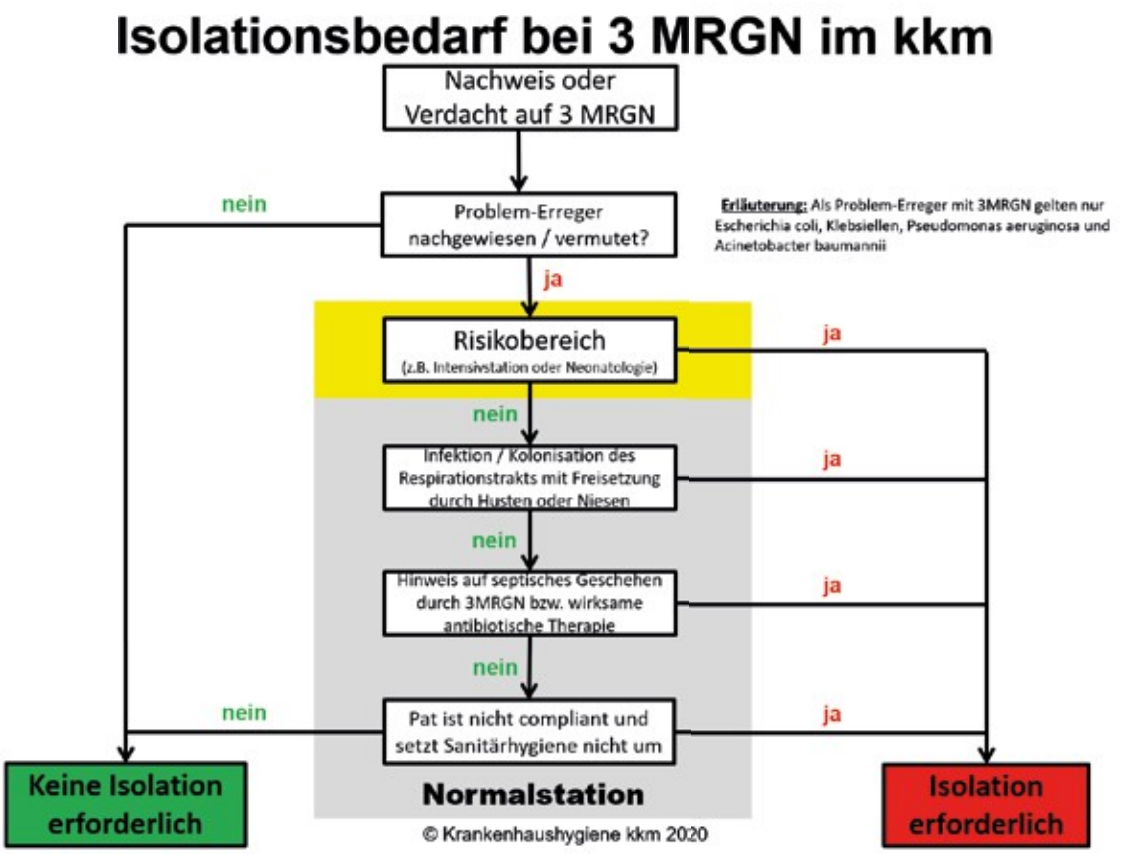


Fig. 2: Flow diagram of insulation requirements for 3MRGN in kkm.

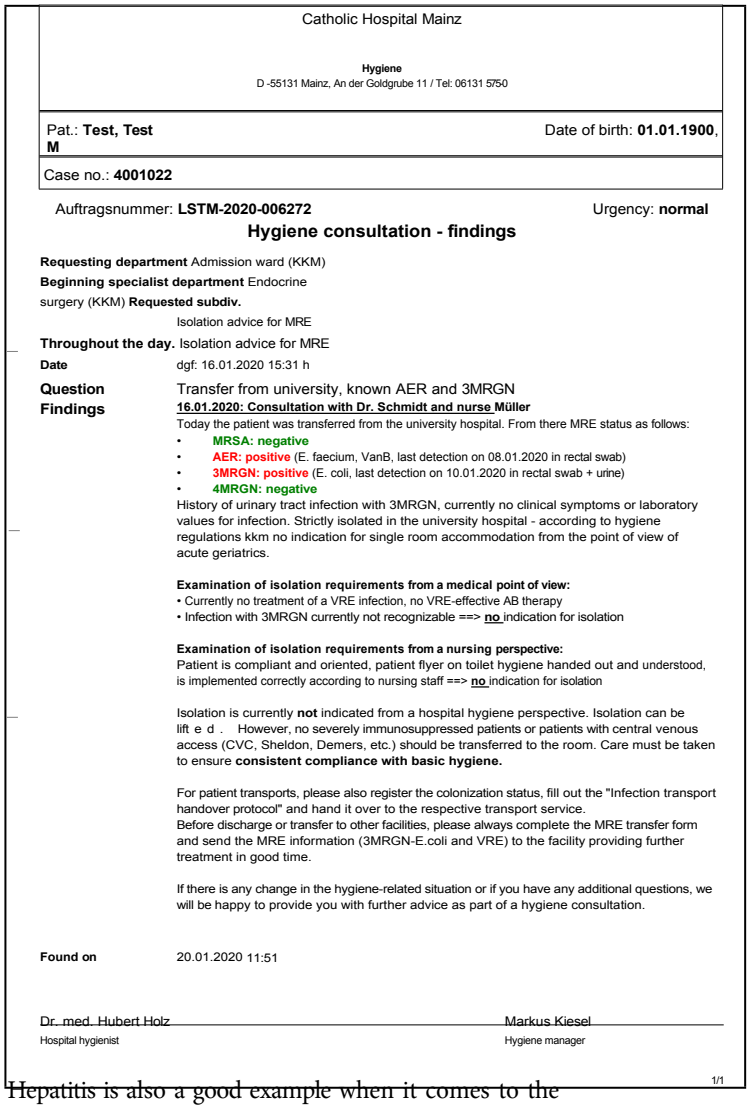
The presence of a 3MRGN in the urine of a patient on normal status who adheres to the basic hygiene rules is not a reason for single room accommodation in kkm, for example. In this case, only the importance of basic hygiene would be pointed out during the hygiene consultation and a sanitary hygiene flyer would be issued to the patient. (see Fig. 1)

If the patient is operated on and has to be treated on the intensive care unit, single room accommodation would be recommended (depending on the type of disease). After the patient has been transferred back to the normal ward, this isolation would be lifted again in a further consultation if necessary. As this question alone can be quite complex, as described above, flow charts have been developed. Figure 2 shows an example of the flow chart for the isolation decision in 3MRGN.

The hygiene consultation also discusses and determines the conditions under which the patient can leave the isolation room if necessary.

may be allowed. In addition to the purely psychological component, this point is particularly important for acute geriatrics at the kkm, as a large part of the treatment here consists of mobilization, movement and inclusion in everyday ward life as well as integrated therapeutic measures. Strict isolation prevents this therapy and is therefore only implemented for absolutely necessary cases.

Personal protective equipment (PPE) is also individually adapted by the hygiene staff during the consultation. For a patient with hepatitis B virus (HBV), single room accommodation in the kkm would generally not be specified (exception: delirium and / or external aggression, possible release of secretions). With regard to PPE, however, in addition to low-germ disposable gloves[7], protective goggles and liquid-proof protective gowns (in kkm at least protection level 2B[8]) would also be recommended if there is a risk of splashing secretions. In addition, care by effectively vaccinated staff would be specified here.[9,10]



Catholic Hospital Mainz

Hygiene
D -55131 Mainz, An der Goldgrube 11 / Tel: 06131 5750

Pat.: **Test, Test M** Date of birth: **01.01.1900**,

Case no.: **4001022**

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

Hygiene consultation - findings

Requesting department Admission ward (KKM)
Beginning specialist department Endocrine surgery (KKM) **Requested subdiv.**
Isolation advice for MRE
Throughout the day. Isolation advice for MRE
Date dgf: 16.01.2020 15:31 h

Question Transfer from university, known AER and 3MRGN
Findings
16.01.2020: Consultation with Dr. Schmidt and nurse Müller
Today the patient was transferred from the university hospital. From there MRE status as follows:
- **MRSA: negative**
- **AER: positive** (E. faecium, VanB, last detection on 08.01.2020 in rectal swab)
- **3MRGN: positive** (E. coli, last detection on 10.01.2020 in rectal swab + urine)
- **4MRGN: negative**

History of urinary tract infection with 3MRGN, currently no clinical symptoms or laboratory values for infection. Strictly isolated in the university hospital - according to hygiene regulations kkm no indication for single room accommodation from the point of view of acute geriatrics.

Examination of isolation requirements from a medical point of view:
• Currently no treatment of a VRE infection, no VRE-effective AB therapy
• Infection with 3MRGN currently not recognizable ==> **no** indication for isolation

Examination of isolation requirements from a nursing perspective:
Patient is compliant and oriented, patient flyer on toilet hygiene handed out and understood, is implemented correctly according to nursing staff ==> **no** indication for isolation

Isolation is currently **not** indicated from a hospital hygiene perspective. Isolation can be lift e d . However, no severely immunosuppressed patients or patients with central venous access (CVC, Sheldon, Demers, etc.) should be transferred to the room. Care must be taken to ensure **consistent compliance with basic hygiene.**

For patient transports, please also register the colonization status, fill out the "Infection transport handover protocol" and hand it over to the respective transport service.
Before discharge or transfer to other facilities, please always complete the MRE transfer form and send the MRE information (3MRGN-E.coli and VRE) to the facility providing further treatment in good time.

If there is any change in the hygiene-related situation or if you have any additional questions, we will be happy to provide you with further advice as part of a hygiene consultation.

Found on 20.01.2020 11:51

Dr. med. Hubert Holz
Hospital hygienist

Markus Kiesel
Hygiene manager

1/1

Fig. 3: Example of a hygiene consultation with recommendation to lift the Isolation.

An example of a hygiene consilium can be found in Figure 3.

There are text templates for new employees for the subsequent writing of hygiene consultations, either as a multiple-choice version to check off or as ready-made text modules. This ensures a standard for the consultation. With increasing experience, individual employees can then also write freely formulated consultations, e.g. for special situations, and adapt them individually to the respective situation and patient needs.

In addition, a so-called re-consultation is arranged immediately if required: If, for example, the decontamination of an MRSA patient is discussed, a new consultation is scheduled after receipt of the control swabs. In kkm, this is usually after 7 days (3 to 5 days of decontamination, control swabs on the 4th to 6th day, results on the 7th ^{day5}). Another example would be a patient with gastroenteritis: a new consultation would be arranged for the time when the symptoms stop in order to clarify the possibility of de-isolation.

Hepatitis is also a good example when it comes to the use of disinfectants: the use of fully virucidal disinfectants for surfaces and hands is required for the treatment of patients with hepatitis A and E, whereas limited virucidal products are sufficient for blood-borne hepatitis B, C and D.[11,12] The implementation of hygiene consults therefore results in greater hygiene safety.

Another important and subsequent point that is discussed in the hygiene consils is the final disinfection after isolation or discharge of patients. The kkm has a cleaning concept in three "levels" that determines the extent of cleaning and disinfection depending on the environmental contamination. The level recommendation is included in the consultation.

Transfers between normal and intensive care wards in particular can also lead to confusion if, for example, an isolated 3MRGN carrier is transferred from the intensive care ward and continues to be isolated on the normal ward. Here, planned re-consultations by hygiene specialists can ensure that measures are reduced to the necessary level in a timely manner.

Of course, there is also a quality control system for these hygiene consultations: all consultations are proofread and checked by the hospital hygienist. Corrections were only necessary in the rarest of cases. More complex issues are discussed with the hospital hygienist before a consultation is drawn up.

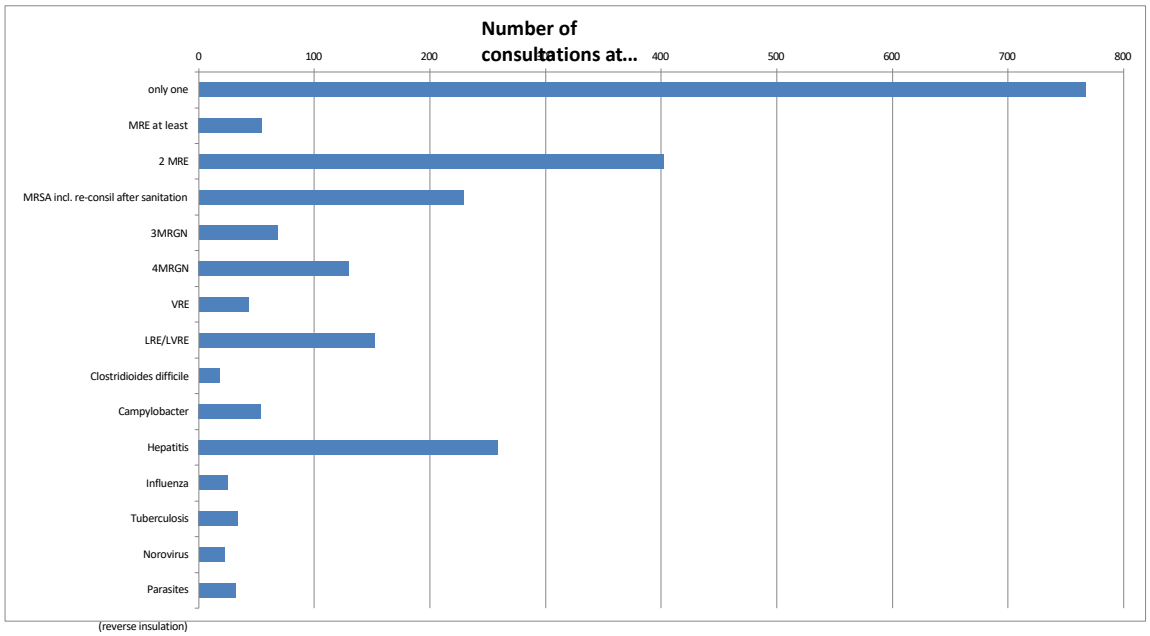


Fig. 4: Distribution of hygiene consultations by pathogen group.

Results of the hygiene consultations

The hygiene consultations project was launched at the beginning of 2019. After one year, the first project evaluation was carried out as planned: after 12 months, 2,118 hygiene consultations had already been carried out for 1,269 patients. This corresponds to approx. 180 consultations per month. With an average workload of approx. 40 minutes per hygiene consultation, this results in an annual workload of approx. 1,400 hours or a 0.8 full-time position. In order to be able to afford this additional workload, we have significantly reduced the number of routine inspections in non-risk areas. 40% of these consultations **did not** result in a recommendation for isolation or special hygiene measures (relevant impact on occupancy management).

The timely termination of an individual isolation and the discontinuation of unjustified isolations alone (see Figure 3) also prevented considerable material costs and personnel commitment. The number of unnecessary microbiological samples was also significantly reduced; for example, we achieved a 20% reduction in CDI.

Another point that should not be neglected is the increased presence of hospital hygiene on site through the daily, personal consultation with staff and the associated improved relationship. Hospital hygiene is perceived less as a remote "desk officer" and more as a partner and supporter in the care of potentially infectious patients.

The introduction of automatic re-consultations during the course of patient treatment has also proven its worth. Especially in the case of particularly critical pathogen isolations such as 4MRGN and LVRE, where isolation is not possible, errors in barrier measures can creep in during longer treatment times. Deviations can be detected and corrected promptly through regular, structured monitoring as part of the hygiene concepts. In most cases, staff on the wards do not see this as personal criticism, but as a constructive addition to on-site hygiene management.

Even with hygienically complex issues, such as the peripartal management of MRSA[13] or prolonged single-room accommodation for immunosuppressed patients, the

The hygiene consultations ensure practical explanation and implementation for patients with infectious diseases (the so-called Dresden model)[14]. In addition, electronic documentation in the respective patient file ensures that information remains available and retrievable over several shifts.

Another positive aspect that should not be underestimated is the improved billability of the so-called complex treatment isolation (OPS 8-987 and 8-98g)[15]. On the one hand, the hygiene consultation automatically proves to the cost bearers the individual advice and care provided by the hospital hygiene department, on the other hand, the hygiene specialists remind the staff on the wards to keep the necessary checklists to prove the additional workload caused by the isolation.

A final point that no one had anticipated when planning the project was the considerable problems in finding rehabilitation places for patients with multi-resistant pathogens or infectious diseases[16]. The lack of follow-up treatment at kkm, particularly in the area of acute geriatrics and thoracic surgery, but also in visceral and vascular surgery led to extended hospital stays and treatment days. Additional consultations with recommendations for further care in external facilities were therefore begun. Although these are of course not binding and the need for hygiene plans and guidelines from the local rehabilitation facilities was always pointed out, the immediate transfer was successful in every case after these hygiene consultations were submitted. On many wards, the hygiene consultations are very actively requested, and the bed coordination colleagues also request advice on the optimized distribution of planned patients in the kkm. And it is not uncommon for chief physicians and senior physicians to call to ask when the current consultation will be available in the HIS.

We have therefore decided that the kkm's hygiene configuration service will continue to ensure additional safety for all those involved - be it patients, visitors or staff. In the interests of the patients entrusted to us, we will ensure a balanced approach that puts an end to unnecessary, stressful isolation while still ensuring the necessary professional barrier measures.

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Miele takes over Tübingen-based hygiene specialist SMP

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Gütersloh/Tübingen, 10 November 2022 - In the Professional business unit, Miele bundles its business with appliances and services for laundry technology and commercial dishwashing as well as products and services for cleaning, disinfection and sterilization in clinics, medical practices and laboratories.

With the acquisition of SMP GmbH, based in Tübingen, Miele is expanding its expertise and accelerating its growth course. In addition to validations, the service portfolio will in future include the provision of test horns and laboratory tests for Miele as well as for users and manufacturers of medical products.

SMP GmbH was founded in 2000 and today, as an accredited testing laboratory, offers a complete range of services relating to cleaning, disinfection and sterilization processes. Background: The medical sector is subject to strict regulatory requirements for hygiene and infection prevention. Cleaning, disinfection and sterilization processes in which surgical instruments, for example, are cleaned

The test equipment used in the production process must be validated regularly and must demonstrate the necessary process reliability in accordance with hygiene plans and country-specific requirements. Among other things, SMP manufactures standardized test harnesses for these tests. One example of this is specifically contaminated surgical clamps. After cleaning, the SMP laboratory examines these clamps for residues of the test soiling and thus evaluates the cleaning performance. SMP is one of the few providers on the German market for the provision and evaluation of test hammers.

SMP GmbH, which currently has 50 employees, will remain an independent company in Tübingen as a "Miele Group Member" and will continue to offer services for medical device manufacturers as an accredited testing laboratory. The SMP team of engineers, physicists, biologists and chemists is also active in research, develops customer-specific test procedures and has an established network of national and international players in the medical field. In addition, technical device testing (type testing) and

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

Fig. 2: The Tübingen-based company SMP specializes in services for medical technology devices. (Photo: SMP)

The creation of preparation instructions is also part of the product range. Due to additional order volumes from the Miele Group and the further internationalization of the business, SMP will grow strongly in the future and expand its capacities. Miele is therefore investing in the expansion of the laboratory area in Tübingen.

The two SMP owners and managing directors Klaus Roth and Dr. Ludger Schnieder are selling for reasons of age, but will continue to be available to the company in leading positions in the coming years. "In Miele, we have found a strong, reliable and internationally positioned buyer with whom SMP and our employees in Tübingen can look to the future with confidence," says company founder Klaus Roth. "We will continue to provide our customers with the same proven quality of service. Confidentiality is our top priority here," adds Ludger Schnie- der.

With this acquisition, Miele is further expanding its growth in the medical technology sector. Regular validation, maintenance and services are essential for the long-term operation of the appliances from the Miele plant in Bielefeld and the subsidiary Steelco. "With SMP, we are taking another major step towards becoming a complete system provider for hygiene solutions on the market," 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 cha and can now provide our customers with additional laboratory services," Klu- ge 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. The Steelco products (Riese Pio X and Cusano di Zoppola sites) are designed for larger capacities in the hospital and pharmaceutical sectors. The Miele plant in Bürmoos, Austria, supplies stainless steel baskets, conveyor belts and load carriers for Steelco and Miele appliances and services the small sterilizers. Miele concentrates its commercial laundry care operations in Lehrte, Lower Saxony. Other professional products such as the "Little Giants" (semi-professional washing machines and dryers) are supplied from other production plants.

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

New members of the Scientific Advisory Board: Kathrin Mann and Carola Diekmann

Kathrin Mann

Kathrin Mann is a registered nurse and acquired her specialist knowledge of hygiene processes and business management procedures in clinics and practices through studies accompanying her career as a health economist (VWA), B.A. in Business Administration and B.A. in Business Administration. Administration (Steinbeis University Berlin) and a Master of Health Business Administration (MH-BA) at the University of Erlangen-Nuremberg.

She gained practical knowledge and experience over several years as head of a large outpatient clinic. operating center. In 2013, Kathrin Mann founded the company PRO.Q.MA Gesundheitsmanagement. She works as an author for specialist medical publishers and gives scientific presentations at specialist conferences and forums, contributes her expertise to various specialist societies in hospital hygiene and health economics and advises healthcare institutions.

She passes on her knowledge and many years of industry experience in her work as a lecturer at universities and specialist academies throughout Germany in the fields of hospital hygiene, quality management and medical device preparation. Kathrin Mann has been a lecturer and project supervisor at Steinbeis University Berlin since 2020.

Carola Diekmann

Carola Diekmann is a hospital hygiene specialist, hygiene specialist and medical device reprocessing specialist. After 18 years as a manager in an outpatient eye clinic in Detmold and several professional training courses She has been working for a service provider in hospital hygiene and as a freelance consultant in outpatient surgical and ophthalmic facilities since 2015. She is also a lecturer for

She is a member of various academies and a trainer in the implementation of current infection hygiene and medical device law requirements. She combines her specialist knowledge in ophthalmology and surgical areas with many years of professional experience in everyday clinical practice. As a result, she offers support during the planning of a new outpatient surgery or practice and in existing practices, outpatient surgery centers and hospitals.

Ms. Diekmann is a long-standing member of the DGSV and the DGKH and has been a member of the DGSV expert committee since 2011 and the DGSV advisory board since 2019. She gives specialist lectures at various congresses and events.

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

3 questions for...

Iven Kruse

1. Why is the validation of the preparation processes in the AEMP an important part of the preparation of medical devices?

Section 8 of the MPBetreibV requires "The preparation of medical devices intended for use in a low-germ or sterile condition must be carried out using suitable validated procedures in such a way that the success of these procedures is reproducibly guaranteed and the safety and health of patients, users and third parties is not jeopardized". The validation of processes is legally binding in Germany and Europe. Validation of the preparation processes of cleaning, disinfection and sterilization defines the parameters that are required for the reprocessing of sterile medical devices.

2. Who is authorized to carry out the validations?

Validation must be carried out by qualified specialists on behalf of the operator. Proof of qualification can be provided by submitting a certificate from a competent authority. The DIN 58341 standard is a milestone for the validation of cleaning and disinfection processes. Based on this standard, the DGKH, DGSV and AKI are revising the guideline for the validation and routine control of automated cleaning and disinfection processes.

thermal disinfection processes for medical devices. Annex 2 of the revised guideline describes the requirements for the qualification of validators in detail in future.

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

The KRINKO / BfArM recommendation "Hygiene requirements for the preparation of medicinal products" calls for suitable routine controls in addition to validation to ensure the quality of the preparation used. These are periodic and batch-related routine controls that are based on the risk analysis.

For the operator, this means defining suitable test methods and test horns for batch and routine checks as part of the validation process. The AEMP employees must be trained so that they can carry out and evaluate the routine tests. If measuring devices such as data loggers are used, the manufacturer's instructions regarding operation and calibration must be observed. Here I recommend training in the software and the correct use of the data loggers.

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DGSV validation courses conducted by Xylem Analytics Brand ebro / FHT / Brandenburgisches Bildungswerk

DGSV validation courses conducted by Xylem Analytics Brand ebro / FHT / Brandenburgisches Bildungswerk

In 2023, Xylem/ebro, in cooperation with FHT from Bad Kreuznach and the Brandenburgisches Bildungswerk in Potsdam, will again be running validation courses in accordance with the new DGSV framework course for validators.

The technical requirements for the validation of processes in the steam sterilizer, washer-disinfector, washer-disinfector-E, DAC Universal and Careclave are constantly increasing, and with them the demand for training courses and workshops.

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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 pri- marily 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 Hospi- tal 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 equip- ment. The key tasks performed by water are as follows:

- Stabilize circulation pump pressure
- Dissolve the ingredients of process chem- icals
- 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 AKI1 considers the substances listed in Table 1 to be problematic.

Depending on the installation and machine specifications, softened water or demineralized 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 carbonate1. This is presented in Table 3. In thermal disinfection, this can affect materials which are sensitive to alkalis, e.g. anodized aluminium.

The AKI1 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 demineralization**, all minerals are virtually completely removed from water. The systems available include reverse osmosis, cation and anion ex- changers and electro-deionization (EDI), also in com- bination, and even, in special cases, distillation.[1]

There is no definition for the composition of fully dem- ineralized water. Consequently, criteria from the EN 285 and EN 13060 standards are often applied to in- strument reprocessing.

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

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

The AKI1 lists relevant substances in water in Table 3 and recommends the use of demineralized 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 sterilization stage
- Protection and stabilization of anodized 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 discoloration. When using ion exchangers to fully demineralize 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 [2854] 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 to 7.5	5 to 7.5
Appearance	Colorless, clear, no deposits	Colorless, 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 op- eration and installation in- structions.

'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-disinfec- tors)'[10] recommend the use of demineralized 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 moni- toring of automated cleaning and disinfection process- es for medical products' issued by the ÖGSV[2] recom- mends that the conductivity of demineralized 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 sterilization process and should not cause damage to either washer-disinfectors or medical products. Reference is made to machine manufacturers regarding con- ductivity, 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 pro- cess 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 equiva- lent for disinfection in seconds at 80°C with reference to a microorganism with a z value of 10 [K6]. 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 demineralized 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 in- ner 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 microor- ganisms, 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°C9].

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 wa- ter, 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-disinfector8].

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

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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 sur- gery 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 affil- iated private clinic 7 beds are available for patients, per year about 2000 outpatient surgeries are performed, specialty vascular surgery. The operations are per- formed 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. Further- more, the costs incurred for provision of equipment, for staff, electricity consumption, water and consuma- ble materials can be calculated. Likewise, from this data an Excel-based calculation tool can then be developed, in which the analyzed cost types are systematically broken down, assigned and brought to a single denominator. By dividing these costs by the (number of) steriliza- tion 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 centers and office-based medical practices. By calculating the costs of repro- cessing medical devices in different outpatient surgery centers, 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 re- processing legal requirements have increased sharp- ly 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 center 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 oper- ations 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 ap- ply in office-based medical practices and outpatient surgery centers. Cost calculations are based on the rel- evant costs incurred for reprocessing medical devices for the vascular surgery section of an outpatient surgery center 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-

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 hygienic 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 eco- nomic operator can avail of a plethora of recommen- dations/guidelines, their implementation calls for pre- cise planning for which planning experts are well paid. The costs incurred for this are borne by the economic operator. Similarly, the economic operator is respon- sible for proper implementation of medical device re- processing. 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 reprocess- ing 1 sterilization unit (1 StU) cost the economic op- erator?

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 center. The following databases were searched: Regensburg University Library and its database access to all relevant journals and textbooks as well as internet-based search- es in the databases WiSo and the Bavarian Library Net- work (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), in- ternational 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 pub- lications 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 da- ta 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 analyzed 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 refer- ence variables were defined. One example of a refer- ence variable could be the personnel costs for repro- cessing. 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	Personnel 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 in- formation provided by the project sponsor's CSSD staff as well as on the author's own experience and obser- vations 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 in- strument reprocessing steps. Furthermore, a material analysis was carried out during the observation peri- od 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 employ- ees 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 ac- tivity analysis was based on observations carried out in the project sponsor's CSSD and in one-to-one discus- sions with the responsible staff.

The materials required for instrument reprocessing were also analyzed 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 person- nel costs relate to the cleaning process and the sub-pro- cess of loading the washer/disinfector (WD) and to the manual pre-cleaning in the ultrasonic bath. Manual re- processing 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 pro- cesses 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 repro- cessing 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 ultra- sonic bath. In addition, maintenance and repair servic- es must be taken into account. In the CSSD air condi- tioning with sterile air is needed for both hygiene and room temperature [reasons1]. Since the purchase price of the air conditioning system is covered by the rent- al price in the case of the present project sponsor, only maintenance services and energy costs have to be tak- en into account, as is also the case with the demineral- ized water system.

In the table above, the processes and sub-processes executed in the clean area are now assessed by way of ex- ample (list not complete). The reprocessing staff member must now check for cleanliness the cleaned instruments passed through the hatch from the unclean area. Instru- ments 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, com- presses 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 appro- priately labeled and a biological indicator must be in- serted. In addition to the instrument containers, which are classified as costs assigned to the economic operator rather than sterilization costs, fleece, sterilization pouch- es 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. Ad- ditional 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 employ- ee 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 person- nel costs are calculated only for the actual work activi- ties, 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-uten- sil 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 in- struments; 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 servic- ing 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 abso- lute 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 [temperature2]. Hence, an air conditioning unit is available in most sterile goods storage facilities. Here, too, personnel costs are incurred for cleaning cab- inets 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 center'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 program 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 methcillin-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 conti- nually: at one time, a recommendation from the Com- mission 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 spe- cialist publications with more than 100 literary sour- ces. On the one hand, this is a welcome development because the more scientific approach makes for grea- ter 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 dogma- tic 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 meas- ures do not depend solely on the type of pathogen and its resistance patterns, but also on the respective treat- ment unit and the specifics of the patient and any fel- low 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 specialization among the staff in situ, re- gardless of whether they are doctors or nurses. In light of all this, it quickly be- comes 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 path- ogen (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

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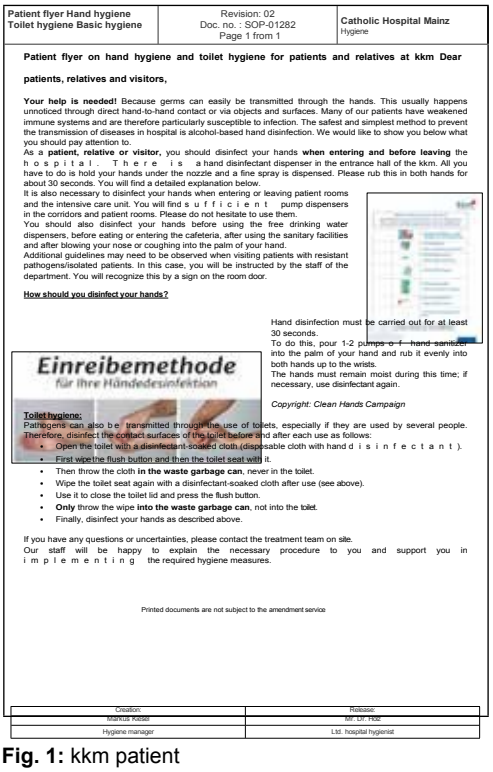
an electronic consultation request to the Hospital Hygiene



Patient flyer Hand hygiene
Toilet hygiene Basic hygiene

Revision: 02
Doc. no. : SOP-01282
Page 1 from 1

Catholic Hospital Mainz
Hygiene

Patient flyer on hand hygiene and toilet hygiene for patients and relatives at kkm Dear patients, relatives and visitors,

Your help is needed! Because germs can easily be transmitted through the hands. This usually happens unnoticed through direct hand-to-hand contact or via objects and surfaces. Many of our patients have weakened immune systems and are therefore particularly susceptible to infection. The safest and simplest method to prevent the transmission of diseases in hospital is alcohol-based hand disinfection. We would like to show you below what you should pay attention to.
As a **patient, relative or visitor,** you should disinfect your hands **when entering and before leaving** the hospital. There is a hand disinfectant dispenser in the entrance hall of the kkm. All you have to do is hold your hands under the nozzle and a fine spray is dispensed. Please rub this in both hands for about 30 seconds. You will find a detailed explanation below.
It is also necessary to disinfect your hands when entering or leaving patient rooms and the intensive care unit. You will find sufficient pump dispensers in the corridors and patient rooms. Please do not hesitate to use them.
You should also disinfect your hands before using the free drinking water dispensers, before eating or entering the cafeteria, after using the sanitary facilities and after blowing your nose or coughing into the palm of your hand.
Additional guidelines may need to be observed when visiting patients with resistant pathogens/isolated patients. In this case, you will be instructed by the staff of the department. You will recognize this by a sign on the room door.

How should you disinfect your hands?

Hand disinfection must be carried out for at least 30 seconds.
To do this, pour 1-2 pumps of hand sanitizer into the palm of your hand and rub it evenly into both hands up to the wrists.
The hands must remain moist during this time; if necessary, use disinfectant again.

Copyright: Clean Hands Campaign

Einreibemethode
für ihre Händedesinfektion

Toilet hygiene:
Pathogens can also be transmitted through the use of toilets, especially if they are used by several people. Therefore, disinfect the contact surfaces of the toilet before and after each use as follows:

- Open the toilet with a disinfectant-soaked cloth (disposable cloth with hand disinfectant).
- First wipe the flush button and then the toilet seat with it.
- Then throw the cloth **in the waste garbage can**, never in the toilet.
- Wipe the toilet seat again with a disinfectant-soaked cloth after use (see above).
- Use it to close the toilet lid and press the flush button.
- **Only** throw the wipe **into the waste garbage can**, not into the toilet.
- Finally, disinfect your hands as described above.

If you have any questions or uncertainties, please contact the treatment team on site.
Our staff will be happy to explain the necessary procedure to you and support you in implementing the required hygiene measures.

Printed documents are not subject to the amendment service

Creation:	Release:
Markus Keller	Mr. Dr. Hist
Hygiene manager	Ltd. hospital hygienist

Fig. 1: kkm patient flyer on toilet hygiene.

Department. This marked the be- ginning of the hygiene consulta- tions 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 screen- ing[5]). In addition, the hospital has a special program for de- tecting and analyzing pathogens called the germ detective and mo- vement list. These electronic tools identify all re- cently confirmed cases of problem pathogens and send a notification to the Hospital Hygiene Department in the event of a known carrier being readmitted.In par- allel 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 are- as falling under their responsibility. They then ask their colleagues on the ground whether a consultation is re- quired for these.

At the kkm, the staff consultations are usually conduct- ed 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 Depart- ment, 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 every- where else.

Hygiene guidelines

During the individual hygiene meeting, various as- pects 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 iso- lation 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 or- ganisms (Gram-negative bacilli resistant to three anti-biotic 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 these grounds for moving the patient to a single room. Instead, attention would simply be drawn to the importance of basic hy- giene 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 need- ed 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 isolat- ed 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 mobilization, movement and integration into everyday ward life, as well as inte- grated therapeutic measures.

Strict isolation prevents this type of treatment from taking place and so is only used when absolutely ne- cessary. It is also during the consultation that the spe- cialist 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

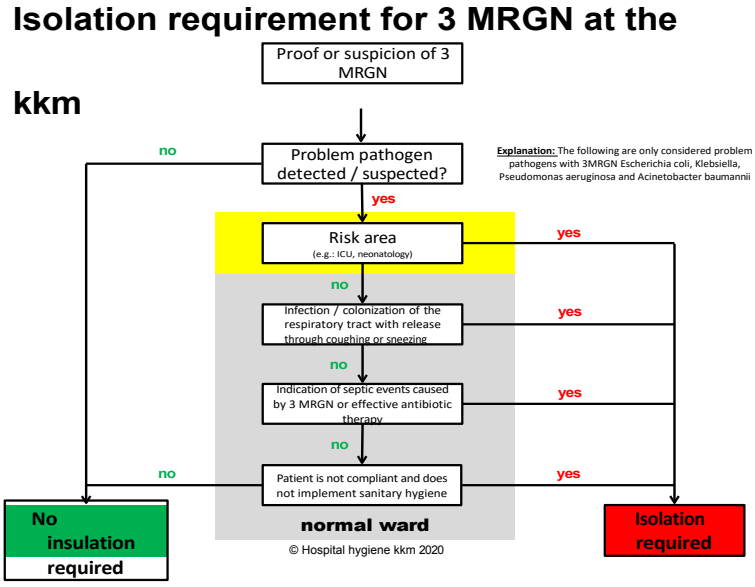


Fig. 2: Flow chart for making isolation decisions about 3MRGN at the kkm.

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 safe- ty 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 repro- cessing concept that de- fines the extent of cleaning and disinfection required based on the degree to which the environment has been contaminated. The recommen- dation concerning the appropriate level is also incorpo- rated into the consultation meeting. An example report from a hygiene consultation can be found in Figure 3.

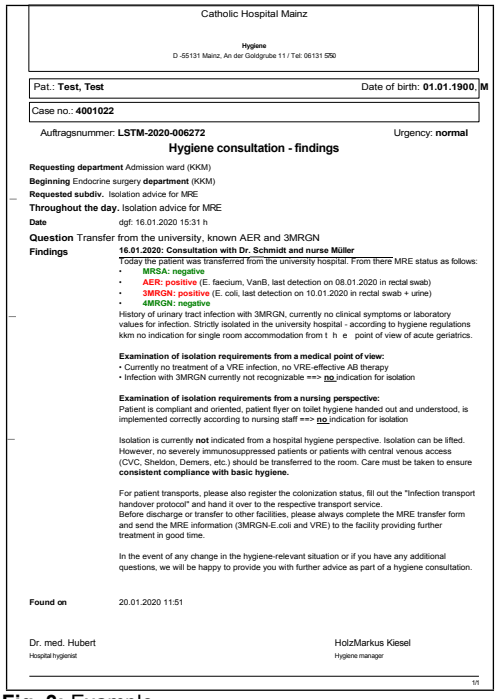
To help them draft their hygiene consultation reports, new members of staff are provided with text templates,

either in the form of a multiple-choice version with op- tions for them to tick or in the form of ready-made text modules.

This ensures a standard format for the consultation re- ports. 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 decolonization of a patient with MRSA is discussed, a new consulta- tion meeting is scheduled to take place once the control swabs have come back. At the kkm, this will usual- ly be after a week (3 to 5 days of decolonization, 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 asepticaVolume 28 | 2022 | Issue 3 when transferring patients between n o r m a l 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 meas- ures to the level actually required.



Catholic Hospital Mainz

Hygiene
D -55131 Mainz, An der Goldgrube 11 / Tel: 06131 550

Pat.: **Test, Test** Date of birth: **01.01.1900** M

Case no.: **4001022**

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

Hygiene consultation - findings

Requesting department Admission ward (KKM)
Beginning Endocrine surgery **department** (KKM)
Requested subdiv. Isolation advice for MRE
Throughout the day. Isolation advice for MRE
Date dgf: 16.01.2020 15:31 h

Question Transfer from the university, known AER and 3MRGN

Findings

16.01.2020: Consultation with Dr. Schmidt and nurse Müller
Today the patient was transferred from the university hospital. From there MRE status as follows:
- **MRSA: negative**
- **AER: positive** (E. faecium, VanB, last detection on 08.01.2020 in rectal swab)
- **3MRGN: positive** (E. coli, last detection on 10.01.2020 in rectal swab + urine)
- **4MRGN: negative**

History of urinary tract infection with 3MRGN, currently no clinical symptoms or laboratory values for infection. Strictly isolated in the university hospital - according to hygiene regulations kkm no indication for single room accommodation from t h e point of view of acute geriatrics.

Examination of isolation requirements from a medical point of view:
• Currently no treatment of a VRE infection, no VRE-effective AB therapy
• Infection with 3MRGN currently not recognizable ==> **no** indication for isolation

Examination of isolation requirements from a nursing perspective:
Patient is compliant and oriented, patient flyer on toilet hygiene handed out and understood, is implemented correctly according to nursing staff ==> **no** indication for isolation

Isolation is currently **not** indicated from a hospital hygiene perspective. Isolation can be lifted. However, no severely immunosuppressed patients or patients with central venous access (CVC, Sheldon, Demers, etc.) should be transferred to the room. Care must be taken to ensure **consistent compliance with basic hygiene.**

For patient transports, please also register the colonization status, fill out the "Infection transport handover protocol" and hand it over to the respective transport service.
Before discharge or transfer to other facilities, please always complete the MRE transfer form and send the MRE information (3MRGN-E.coli and VRE) to the facility providing further treatment in good time.

In the event of any change in the hygiene-relevant situation or if you have any additional questions, we will be happy to provide you with further advice as part of a hygiene consultation.

Found on 20.01.2020 11:51

Dr. med. Hubert
Hospital hygienist

HolzMarkus Kiesel
Hygiene manager

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 hospi- tal 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 av- erage, the annual workload amounts to around 1400 hours or a 0.8 full-time equi- valent. To allow for this additional work, we have significantly reduced routine ward checks in non-risk areas. No isolation or special hygiene measures were recom- mended in approx. 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 al- so 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 poten- tially 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 re- gard it as a constructive contribution to local hygiene management.

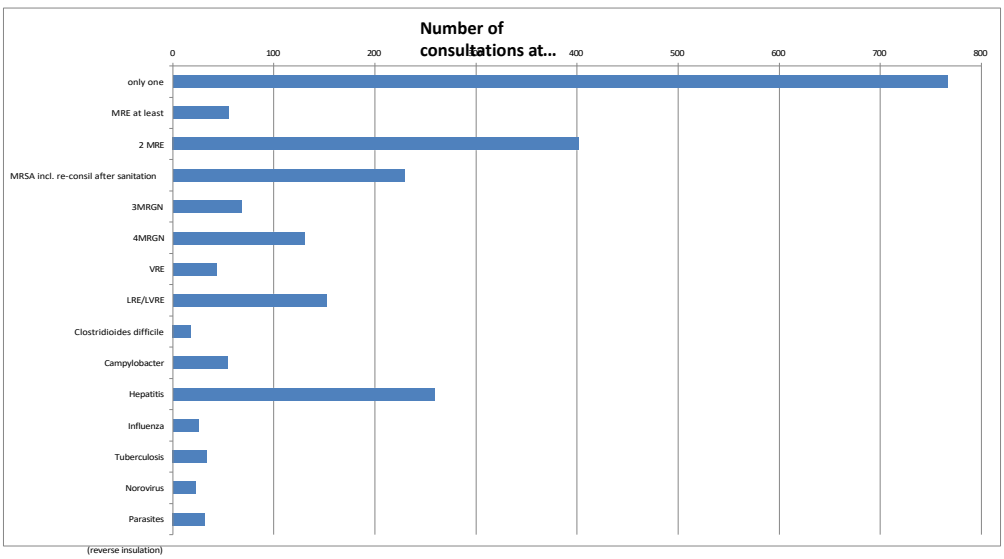


Fig. 4: Breakdown of hygiene consultations by pathogen group.

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 en- sure 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 necessitat- ed 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 facil- ities. Nevertheless, patients have been immediately ac- cepted 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 re- quested, 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 consul- tation 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 un- necessary and burdensome instances of patient isola- tion 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 sterilization 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 ser- vices supporting cleaning, disinfection and sterilization processes. Background: The medical sector is subject to strict regulation with respect to hygiene and infection control. Processes for cleaning, disinfection and sterilization, in which surgical instruments, for example, are re- processed, must be validated regularly and must demonstrate the necessary process safety according to hygiene plans and country-specific requirements. For these tests, SMP produces standardized test devices, among other things. One example of this are intentionally contaminated crile clamps. After clean- ing, the SMP laboratory inspects these items for resi- dues of the contamination, thereby evaluating cleaning performance. SMP is one of the few suppliers provid- ing 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 specializes 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 internationalization 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 Profes- sional business unit. 'With Steelco, we significantly ex- panded our portfolio for hospitals and pharmaceuti- cal companies in 2017. We also offer our own process chemicals and can now provide our customers with ad- ditional 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 prac- tices, 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 sterilizers. 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 lectur- er 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 clin- ic in Detmold and sever- al extra-occupational fur- ther education courses, she has worked since 2015 for a service provider in the field of hospital hygiene and as a self-employed special- ist with a focus on providing advice to outpatient sur- geries and ophthalmological clinics. She also lectures at various academies and provides training on current requirements in the field of infection control and med- ical device legislation. In providing advisory services, she combines her specialist knowledge in the field of ophthalmology and surgery with many years of expe- rience working in hospitals and clinics. Relying on this wealth of experience, she provides support in planning new outpatient surgeries and advises existing surgeries, surgical centers 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 compre- hensibly guaranteed and the safety and health of patients, users and third parties is not endangered". The validation of the processes is legally- ly mandatory in Germany and Europe. With the validation of the reprocessing processes clean- ing, disinfection and sterilization, the parame- ters are defined that are required for the repro- cessing 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 qualifi- cation 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 revis- ing the guideline for the validation and routine control of machinel cleaning and thermal disin- fection 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 qual- ity of the reprocessing used. These are periodic and batch-related routine checks based on risk analysis.

For the operator, this means that he defines suit- able test methods and test specimens for batch or routine control within the scope of validation. CSSD staff must be trained so that you can per- form and evaluate the routine checks. If measur- ing instruments are used, e.g. data loggers, the manufacturer's instructions regarding operation and calibration must be observed. Here I recom- mend training the software and the correct ap- plication of the data loggers.

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