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Bilingual

## The clean and well-groomed hand as an effective preventive measure in the healthcare sector

## The clean and well-groomed hand as an effective preventive measure in healthcare settings

# Editorial

Dear readers,

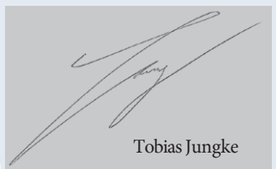
Reliable hygiene, standard-compliant preparation and ensuring sterile environments are a complex challenge even in normal times. It is hard to imagine the services that need to be provided in crisis areas such as Turkey and, of course, Ukraine in order to maintain reliable care and safe protection for patients on site. Also with a view to a stable energy and water supply, these are undoubtedly particularly extreme situations. We would therefore like to thank all the people who are currently making a special effort or even organizing relief supplies and donations.

In this first issue of 2023, we have once again selected a wide range of articles for you that are well worth reading. Dr. Sabine Kaufmann, Kathrin Mann and Stella Nehr- Werner deal with sterile barrier systems and also look at the question of how sterile packaging can be correctly protected during transport. With the right packaging and the right processes, it is ultimately possible to work much more economically. The second part of the article "Costs of preparing medical devices in outpatient ORs" also deals with cost-effectiveness. This time, Kathrin Mann takes a clear look at the exact parameters for the processes in the AEMP.

I'm finally doing it more and more often and perhaps you are too: shaking hands and meeting people in real life. To coincide with International Hand Hygiene Day on May 5, Ines Konschake and Aaron Papadopoulos take a closer look at the value of infection prevention through clean and well-groomed hands. Many hands can also be shaken again at the Freiburg Infectiology and Hygiene Congress from October 11-13.

From a technical perspective, I recommend the text by Iven Kruse and Stella Nehr-Werner on the initial validation of brand-new devices. And finally, in our application example from the St. Bernward Hospital in Hildesheim, I will discuss safe water purification for the CSSD/EMP with reverse osmosis without EDI.

I hope you enjoy reading the new aseptica



Tobias Jungke



# Cont ents



# Message

**OECD: EU citizens do not do enough sport**

More and more people in Europe are getting too little exercise. This is a trend that has been exacerbated by the coronavirus pandemic, according to a study by the Organization for Economic Cooperation and Development (OECD) and the World Health Organization (WHO).

The WHO recommends at least 150 minutes of moderate exercise per week. In 2016, only 35.4% of adults in the 27 EU member states did this. According to the study, more than half of Europeans exercised even less during the corona years. 34% said they did less sport and 18% stopped doing it altogether. Only 7% said they wanted to exercise more again after the pandemic.

According to the study, 45% of adults who do too little exercise do not do any sport at all. The situation is no better for young people: only 17.6% of boys and 9.6% of girls achieved the WHO recommendation of 60 minutes of moderate to intensive exercise every day. However, the situation does not improve with increasing age: only a quarter of adults over the age of 55 exercise at least once a week. According to the study, women exercise less than men.

According to the study, if everyone in the EU followed the WHO recommendations, more than
10,000 premature deaths among people aged between 30 and 70 could be prevented. People who currently do too little exercise could extend their average life expectancy by 7.5 months by being more physically active.

Source: aerzteblatt.com



# Knowledge base: Sterile barrier systems - Part 1

*Sabine Kaufmann, Kathrin Mann, Stella Nehr-Werner*

Sterile packaging is used to protect sterile goods during transport and storage. The goods to be sterilized are already packed in it before sterilization, sterilized in the packaging and can then be removed for transport and stored in a contamination-proof manner after sterilization - so much for the theory. But how do you actually find the right packaging? It should not only match the practice procedure, but also the type of sterilization process, the medical devices and, in addition to these practical aspects, not be too expensive. And how do you protect the sterile packaging during transportation, for example? How do you find the right packaging system?

## Legal and normative classification

In Germany, proper preparation is assumed if the recommendation of the Robert Koch Institute and the Federal Institute for Drugs and Medical Devices "Hygiene requirements for the preparation of medical devices" from 2012 is observed (MPBetreibV, §8 (2)). Part of the preparation is also the packaging. It is therefore worth taking a look at the RKI/KRINKO recommendation for legal and normative classification. Here the topic is explained in chapter 2.2.4 "Packaging". [2]

Firstly, a distinction must be made between the actual sterile barrier system and the protective outer packaging. It is important that the entire packaging is adapted to the sterilization process, i.e. steam or other sterilization agents, the properties of the medical device and stresses during transport and storage (e.g. mechanical impact during long transport routes).[2] This is the only way to enable sterilization and maintain sterility until reuse.

As chapter 2.2.5 of the RKI recommendation describes the steam sterilization process as the standard process, this article only deals with sterile supply packaging systems for steam sterilization. [2] DIN EN ISO 11607 Parts 1 and 2 regulate which requirements the packaging for medical devices to be sterilized in the final packaging must meet, describing general requirements as well as individual requirements for validation requirements.[1] The individual packaging materials and types as well as test methods for tightness are described in more detail in DIN 58953
Parts 6-9 are described. [6,7,8,9] The validation of packaging processes is described in the DGSV guideline for the validation of packaging processes in accordance with DIN EN ISO 11607-2:2020. [3] There is also specialist information on the selection of packaging, the correct packaging itself and the validation of the packaging process in various publications from professional associations, such as the DAHZ Hygiene Guide, Chapter 5. [4]

## Definitions of packaging systems

**Sterile barrier system**
"Minimum packaging that prevents the entry of microorganisms and enables aseptic preparation of the product at the point of use." [1] Examples include a sealed bag or tube, sheet goods or a sealed container.

**Prefabricated sterile barrier system**
"Partially assembled sterile barrier system for the filling and final closure or the

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final sealing." [1] Examples are a bag, bags or open, reusable containers.

**Protective packaging**
"Material configuration designed to prevent damage to the sterile barrier system and its contents from the time of assembly to the time of use." [1] One example is a suitable additional packaging sleeve in which the sterilized goods are placed, in the sense of dust protection packaging. It is often also used as a collection container for several individual sterile barrier systems.

**Packaging system**
"Combination of sterile barrier system and protective packaging." [1] This is a maximum packaging form. Based on the manufacturer's specifications, the maximum storage period is up to 5 years.

## Differentiation of packaging types

The packaging system must be adapted to the medical device to be packaged in accordance with the manufacturer's specifications (DIN EN ISO 17664-1). Weight and geometry play a decisive role here, as do the transportation requirements (mechanical protection) and the storage conditions (mechanical load) as well as the sterile goods storage period. Sterile presentation must be ensured for each type of packaging. Preparation and sterilization must be tested and validated for feasibility and effectiveness.
In terms of packaging types, a basic distinction is made between so-called hard packaging and soft packaging.

**Hard packaging refers** to prefabricated, rigid sterile barrier systems, i.e. containers that can be used multiple times. They usually consist of a tray, a lid, passages for the sterilization medium in the form of disposable or permanent filters, a closure and carrying handles. [5] These can be used to remove contaminated instruments from the operating theater and are available again as sterile goods containers after preparation and functional checks.

**Soft packaging** refers to prefabricated sterile pouches that are made of a transparent/paper composite and must be sealed after packaging. These are available both as tubular goods in various widths and as prefabricated pouches. There are also classic non-woven and paper packaging in which the sterilized items can be wrapped. [5]

## Requirements for packaging materials and packaging technology

A suitable material is selected on the basis of the manufacturer's product information and product specifications with information on the permissible sterilization processes, the quality of the material (e.g. $g/m^2$) and information on further processing. The packaging material must allow sufficient access for the sterilization medium. The packaging must not be impaired by the sterilization process and the barrier properties must be retained. The packaging must not be damaged by temperature or pressure. Furthermore, the packaging must

| Material | Standard |
|---|---|
| Transparent bags and tubes | DIN EN 868-5:2018 |
| Paper, fleece (steam sterilization) | DIN EN 868-2:2018<br>DIN EN 868-9:2018<br>DIN EN 868-10:2018 |
| Reusable sterilization containers (containers) | DIN EN 868-8:2018 |

**Table 1:** Requirements for the packaging materials.



| Material | Standard |
|---|---|
| Transparent bags and tubes | DIN 58953-7:2020<br>DIN EN ISO 11607-2 |
| Paper, fleece (steam sterilization) | DIN 58953-7:2020 |
| Reusable sterilization containers (containers) | DIN 58953-9:2020<br>DIN EN ISO 11607-2 |

**Table 2:** Requirements for packaging technology.

not be influenced by the medical device (e.g. by pointed, sharp or heavy medical products). DIN 58953:2020 describes the requirements for packaging technology, which differ for the various materials.
A validation with the corresponding sterilization procedure must be carried out for each type of packaging. If the type of packaging is changed (e.g. new manufacturer of fleece or container), the packaging must be revalidated in the device. The results of the validation must be evaluated and documented (DIN 58953-8).

## Requirements of the different types of packaging

**Fleece and paper**
DIN 58953-7 describes two different packing techniques: diagonal packing and parallel packing. Which type of packing technique is used depends on the AEMP or must be discussed and determined in the team with the management. However, it makes sense for every employee to use the same technique. The packing technique must be integrated into a work or procedural instruction and made accessible to everyone. The creation of a double pack is to be achieved by a double packing process. Single packaging with a double layer of fleece or paper does not result in double packaging. A short strip of adhesive tape with or without an indicator near the opening flap can be used to close the packaging. An indicator strip clearly shows whether the sterilization process has been completed. The packaging should then be provided with a self-adhesive label for identification, which usually also has an indicator. The size of the material must be optimally adapted to the size of the products to be packaged.

medical products. Various sizes of fleece are available. The paper or fleece must not be packed too loosely or too tightly. The screens must not be pushed onto the sheets, but must be positioned correctly to avoid perforations. The sheets should not be larger than necessary due to steam penetration, drying and not least for cost reasons. The paper and fleece must be laid evenly over the sterilized items, as smoothly as possible and without the use of force.
The packaging must not be stretched over the corners of the sterilizer, but must also not be too loose to allow movement of the packaging during the pressure changes during sterilization.

Labeling directly on the soft packaging is not permitted in order to prevent contamination of the sterile goods inside with solvent-based inks. Self-adhesive labels should be used for labeling. Non-woven and paper packaging are disposable items. If the sterilization process is interrupted, the medical device must be repackaged.

**Transparent bags and tubes Transparent** packaging is also disposable and therefore not reusable. The filling limit for transparent packaging must be strictly observed. The distance between the medical device and the sealed seam must be at least 3 cm. A sufficient overhang of material for aseptic removal is essential. The packaging weight in transparent packaging must not exceed 3 kg and is therefore a limiting factor in the selection (see manufacturer's instructions). The side seams must not be damaged during filling. Sharp objects and materials must be protected, and the

Steam permeability must be ensured. In the case of double packaging, the paper side must always face the paper side in order to allow air exchange and steam to pass through during sterilization. The inner packaging of a double pack
must not be kinked (> select sufficiently large packaging). The transparent packaging must always be labeled outside the product compartment, on the film side, to prevent contamination.

by paints containing solvents. Do not use sharp, hard pens for labeling. Soft, sterilization-resistant fibre-tip pens are suitable. Medical devices with a cavity must be packed in such a way that the opening to the

paper side.

*The article is divided into two parts. You will find part 2 in the next issue.*


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# Costs of reprocessing medical devices in outpatient surgery (Part 2)*


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


## Determination of reference values

In a further step, the reference values were then determined. In activity-based costing, the reference values served as the basis for calculating the indirect costs of a process. In the case of a main process, these reference variables were referred to as "cost drivers". By determining the measures, areas that are considered to be very cost-intensive, such as personnel costs or occupancy costs, can be identified.
Table 3 below shows an example of the costs for the unclean area for 2019, broken down into direct and indirect costs (list not exhaustive). The costs were calculated analogously for the clean area and sterile goods storage

calculated and charged. As can be seen from the cost overview table, the cost structures of the individual areas vary greatly in terms of number, time period and consumption. It is therefore clear that all costs, to put it in a nutshell must first be converted before they can be calculated. It is possible to calculate the costs for a year and divide them by the number of batches produced or to break down the individual costs directly to a batch.

## Determination of costs and cost rate formation

The costs of the individual sub-processes were then determined, the corresponding cost rates were calculated and extrapolated to 2019. These serve as the basis for calculating the costs for 1 STE. The extrapolation of the individual cost rates to 2019 was carried out separately for the individual premises: unclean area, clean area and sterile goods storage area. The following are examples of cost rates from the unclean and clean areas.

| 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: 3 kW/batch = 0.90 €/batch<br>US: 0.3 kW = 0.09 €/batch |

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

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

**Total costs for 1 STE**

Now that the large number of different costs have been compiled and calculated, they can be summarized. The data collected from the unclean and clean areas of the AEMP and the sterile goods warehouse is assigned to the cost drivers. They are divided into consumables, personnel costs and costs of the premises due to rent, depreciation of equipment and depreciation of furniture. The high number of cost items reflects the complex process of manufacturing a medical device.

By summarizing the costs for the three rooms (unclean room, clean room, sterile goods storage) for 2019, the sterile goods units produced can then be determined for this period. Based on the calculation shown in Table 7, this results in total costs for 1 sterile unit of € 117.92.

**Calculation tool**

Now that all individual processes have been analyzed and formulas have been developed for the cost calculation in order to reduce them to the same denominator, namely "one year", it is obvious to implement this knowledge in a table calculation in order to be able to calculate the costs for 1 STE in other units as well.

A calculation tool in the form of a spreadsheet was created based on the cost structures of the project sponsor's outpatient surgery center and its AEMP identified and analyzed in the thesis.

**Fig. 1:** Varicose vein set.

Here, a distinction is again made between the three rooms of the sterilization process (unclean room, clean room, sterile goods storage) and their cost drivers (e.g. personnel, consumables, equipment). The costs that have the greatest influence on the overall result are always at the beginning. The other factors are added as their importance for the overall costs decreases.

In the following development step, the tables for unclean room, clean room and sterile goods storage were summarized for the overall calculation and displayed in a spreadsheet, in this case Apple Numbers. As already mentioned in the design, the significance of the costs for the overall result follows in the corresponding order of importance. In a further step, the individual costing items were then added to the spreadsheet as a formula. Costs that appeared irrelevant in the total and could not be clearly assigned to the area, such as light in the sterile goods warehouse, were not included in the calculation.

Furthermore, summation functions for calculating the total costs in horizontal and vertical direction were stored and percentage calculations of the costs for premises and cost types were added. The costs per year are then calculated using a simple rule of three with the product "total sterile supply costs per year" and the denominator "number of sterile supplies per year". As large sterilizers that produce a maximum of 1 sterile unit are generally used in outpatient operating theatres, the number of sterilizer batches corresponds to the number of sterile units.

The costing table stored with the project owner's data can now be viewed below. In addition to the decisive total costs and the costs per STE, the individual total costs for the individual rooms and for the individual cost drivers or cost types can also be calculated and displayed. In addition, the percentage shares of the cost types and rooms in the total costs can be read off.



**Repair & maintenance RDG:**

*Repair* € 357 per year + *maintenance* € 952 per year = € 1309 per year

**Energy costs RDG:**

3 kW/h x 0.30 € = 0.90 €/h, RDG runtime 60 minutes per batch = 0.90 € per batch 0.90 € per batch x 300 batches = 198 € per year

**Table 4:** Impure area total costs for 2019.

**Follow-up/testing of the instruments:**

*Oil spray* at € 6.37 gross per unit, consumption 5 units per year = € 31.85 per year
*Cloths* etc. € 0.30 per sieve x 1800 sieves per year = € 540 per year
**Total costs:** € 31.85 + € 540 = **€ 571.85 per year**

**Energy costs heat sealer:**

*During operation:* 0.75 kW x 0.30 €/h = 0.23 € kW/h, ½ h operation per day = 0.11 € per day
*Stand-by:* 0.13 kW x 0.30 €/h = 0.039 €; 5 h per day = 0.20 € per day
**Total costs:** € 0.11 + € 0.20 = € 0.31 per day
365 days - 104 days (weekends) - 14 days (public holidays) - 14 days (vacation) = 233 days per year
**233 days per year x € 0.31 per day = € 72.23 per year**

**Tab. 5 & 6:** Pure area total costs for 2019.

## Results

In this specific example of an outpatient surgery center, an amount of approx. 118 € could be calculated for 1 STE. As 6 varicose vein sets can be sterilized in this 1 STE, the preparation of a varicose vein set costs approx. 20 €. The operator can thus easily assess whether in-house preparation still makes economic sense or whether outsourcing preparation or using disposable products is an alternative. With the help of the calculation tool, an operator can estimate his approximate costs for 1 STE.

**Table 7:** Total costs for 1 STE in 2019.

| Total costs | |
|---|---|
| unclean area | 15.061,65 € |
| clean area | 18.698,09 € |
| Sterile goods storage | 2.795,08 € |
| **Total** | **36.554,82 €** |
| **Number of batches carried out in 2019** | **310** |
| **Costs for 1 STE** | **117,92 €** |

## Discussion of the results

A literature search at the 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" revealed that there are no scientific works on this topic relating to the German healthcare system. Only calculations of individual areas by manufacturers and rough analyses of the costs. For example
B. Thiede in the Hessisches Ärzteblatt estimated the unit costs per instrument at € 1.00 - 1.80. [3] The Darmstadt - Giessen - Kassel regional councils arrive at a somewhat higher estimate of the costs per instrument, putting them at € 1.20 - € 2.20. [4]

The two publications mentioned obviously refer to an ear, nose and throat practice in the federal state of Hesse. The publication emphasizes that doctors with few small procedures, such as general practitioners and dermatologists, should make use of disposable instruments, while ophthalmologists, ear, nose and throat specialists, gynaecologists, orthopaedists and surgeons could possibly have their special instruments prepared externally. Preparation costs of €1.20 - €2.20 per instrument are stated here, whereby no distinction is made as to which type of instruments are to be prepared here (classification of medical devices into risk classes). As already mentioned, the preparation of critical instruments, especially group B, is associated with significantly higher costs than semi-critical or non-critical instruments, which are used by gynecologists, for example. Ophthalmologists have very special requirements for the preparation of their instruments (very fine and small instruments), as these must not only be clean and sterile after preparation, but must not contain any residues of acids or alkalis, as they would otherwise damage the inside of the eye. Cleaning and disinfection devices that meet these requirements are generally rare in Germany.

available for less than € 25,000 plus VAT. The calculated cost-intensive one-off purchases for the literature used, including furniture, validation and instruments, were estimated at € 16,000.
€ are given. It is therefore not really possible to assess the validity of the literature data in these two publications.

The costs were also not differentiated according to the period in which they were incurred; instead, costs per year were estimated but not visibly calculated. The maintenance services were estimated at € 400 for the sterilizer and € 300 for the washer-disinfector maintenance.
and do not necessarily correspond to the data provided, even after inquiries with the relevant companies. The process validation of washer-disinfectors and sterilizers was quoted at € 1000. It should be noted here that the validation relates to a process, i.e. the costs are incurred per process and device and not for an individual device. There is also talk of regular revalidation (renewed performance qualification).

Another publication from "Zentralsterilisa- tion" estimates the costs of a large sterilization unit for the sterilization process alone at € 21.30 for 1 STE.[5] In this work, the costs are broken down in great detail and the work processes are very well calculated and described. However, 8,847 sterilization cycles per year are carried out in this unit with six large sterilizers. The costs also relate only to the costs of the sterilization process. The preparation and storage of the sterile goods were not taken into account here.

It is difficult to transfer or compare the costs of a mass-produced system on an industrial scale to an AEMP in an outpatient setting. At best, this data provides an indication of the possible level of costs incurred. It is also clear that the costs of preparing sterile goods are likely to vary greatly in different preparation centers.

The preparation times described in the literature are calculated to be significantly higher than those in the AEMP

| | unclean area | clean area | Warehouse | Total costs in € | Share In % |
|---|---|---|---|---|---|
| Personnel costs | 4.800 | 3.999 | | 8.799 | 24,08 |
| Rental costs | 2.135,64 | 2.464,2 | 2.628,48 | 7.228,32 | 19,77 |
| Devices/Maintenance | 3.516,45 | 6.574,19 | | 10.090,64 | 27,6 |
| Amortization | 3.061,10 | 3.810,65 | 166,60 | 7.038,35 | 19,25 |
| Appliances/furniture | | | | | |
| Water & electricity | 471,46 | 538,56 | | 1.010,02 | 2,76 |
| Costs for consumables | 1.077,00 | 1.311,49 | | 2.388,49 | 6,53 |
| Total costs/year in € | 15.061,65 | 18.698,09 | 2.795,08 | 36.554,82 | |
| Share in % | 41,2 | 51,2 | 7,6 | | |
| Number of STE/year | | | | 310 | |
| **Costs 1 STE/year in €** | | | | **117,92** | |

**Tab. 8:** Calculation tool to calculate the costs for 1 STE.

of the project sponsor, which explains the different amounts. The costs for energy in the above illustration in relation to 1 STE must also be questioned, as the air conditioning system does not only run during the sterilization process, but permanently and is only in stand-by mode at night.

However, as can now be shown, the production of sterile supplies is very cost-intensive and represents an important cost factor in OR operations. It is also worth noting that personnel costs, usually the largest item in the healthcare sector, are only the second largest cost driver here.

The example of the project sponsor's AEMP now shows a cost block of € 117.92 for the preparation of 1 STE. The project sponsor calculates with six sets of varicose veins per STE, resulting in sterile goods costs of € 19.65 per varicose vein operation. Since a process accuracy of > 90 % is assumed for this project, the price for 1 STE is likely to be between € 110 and € 125. If the data used in the literature for the preparation of a Varizen sets from the project sponsor, the costs for 23 instruments per sieve would be between €23 and €51. This would mean costs of € 138 to € 303 for 1 STE.

The preparation costs of the project sponsor's AEMP therefore appear to be in a favorable range. If we now break down the costs of the project sponsor's AEMP into unclean, clean room and sterile goods storage and compare the individual cost items, we see that 41.2 % of the costs are incurred in the unclean room, 51.2 % in the clean room and 7.6 % in the storage. The cost drivers here are equipment/maintenance costs at 27.61%, followed by personnel costs at 24.08%, rental space at 19.77% and equipment provision and furniture depreciation at 19.25%. Water and electricity costs account for 2.76% and consumables for 6.53%. This shows that the hardware (total equipment costs, furniture) causes costs of 46.85 % in total. If the costs of the sterile goods are now set in relation to the revenue for a varicose vein operation (stripping

Vena saphena magna) in the outpatient sector, which is remunerated at € 308.26 per procedure according to the standardized assessment scale (EBM) under code 31204 (as of 2019), it turns out that the cost share for the instruments is 6.4 %. The costs of preparing medical devices, which are subjectively perceived as high, are apparently not as high as expected. However, this is only the case at first glance. If the calculated medical remuneration of 35% is calculated from the revenue, the sterile supply costs are estimated at a good 10%.

Overall, the costs of outpatient surgery have risen enormously over the last 20 years due to legal requirements, so that remuneration no longer appears to be sufficient and the number of outpatient procedures performed in Germany is far below average in an international comparison. According to a study by the Organization for Economic Cooperation and Development (OECD), only 50 % of outpatient operations were performed in Germany, compared to 80 to 93 % in other industrialized nations. [6]

The legal requirements, particularly those relating to the preparation of medical devices under the Medical Devices Act, the requirements of the KRINKO at the RKI (former Federal Health Office), the Medical Devices Operator Ordinance and the Infection Protection Act have become much stricter in recent decades. Due to the cost structures, many doctors who perform outpatient procedures such as material removal, minor surgery such as wound care etc. are no longer in a position to do so, as the costs of the instruments versus the costs of the revenue are no longer in an economically favorable ratio. The extreme increase in society's demands with regard to safety and quality in the healthcare sector is in stark contrast to the fact that revenues have been stagnating for years or even decades.
For example, the "EBM 2008" was adopted in 2008, which was based on EBM 2 from 1996 and EBM 2000 plus from 2000, in which technical and medical services were re-evaluated. Whether an evaluation of the

It is not possible to ascertain how costs were calculated and on what basis this may have been done. No further relevant adjustments have been made since then.

To date, there are also no validated cost analyses of varicose vein surgery or other services in the current scale of fees for physicians (GOÄ) of 12.11.1982, revised as of 1.1.1996. However, consultations are currently being held on this. In addition, new minimally invasive procedures (gentle surgical methods with minimal injury to the skin and soft tissue) have increased the technical requirements, which are also associated with the increased use of medical devices in varicose vein surgery and also require the provision of intraoperative (during an operation), diagnostic and imaging procedures (in this example ultrasound), which also require additional sterile material as disposable material during use.

Another problem is the completely different cost structures of outpatient surgical units, while remuneration is largely regulated uniformly in the Federal Republic of Germany and there are only small specific differences between the individual Associations of Statutory Health Insurance Physicians (KV). It should be clear to everyone, for example, that rental costs and personnel costs are significantly higher in Munich than in the Bavarian forest. Nevertheless, both surgeons receive the same remuneration for varicose vein surgery.

A number of health insurance companies have recognized the dilemma that operations that can still be performed on an outpatient basis are still being performed on an inpatient basis, and have introduced a
§ 140a SGB V, special care contracts have been concluded. [7] In these contracts, the remuneration is generally somewhat higher than in the EBM. These contracts make a decisive contribution to keeping outpatient surgical structures alive. This is also economical for the payers because these procedures, when performed as inpatient care, generate approximately four to six times the costs for the payers (in the case of varicose vein surgery, the revenue in the hospital is approximately €2,310; DRG = Diagnosis related group: F39a, corresponds to approx. 2310 €, however, all hospital services are included here and must still be adjusted for hotel and anesthesia services compared to the EBM calculation.



be adjusted. However, the building costs must be added back due to state funding in order to be able to make a direct comparison; as at 2019).

The costs of sterile processing must therefore be calculated individually for each unit and the conclusions to be drawn from this as to whether the preparation and/or provision of services for procedures is worthwhile also depend on many factors. The calculation of the preparation of medical devices can be realized easily and relatively quickly with the developed calculation tool and can therefore be very important for decision-making.

What the calculation tool does not include, however, are additional costs for ongoing training and further education for the personnel responsible for sterile supply. It should be mentioned here that a medical assistant or nurse requires additional further training, a so-called certificate of competence, in order to be allowed to work in this area. A standard certificate course currently costs around €500 plus VAT, depending on the provider. If the employee is not a specialist and has not learned a medical profession, it is necessary to complete a so-called specialist course. This is a three-week course that currently costs around €1,300 plus VAT. Only then is the employee sufficiently qualified to work in this area. [8] Ongoing training is required, however. The tool also does not cover costs that are required for internal and external consultation, such as quality assurance, certification of the quality management system if necessary, as well as the legally prescribed consultation by hospital hygienists, hygiene specialists, hygiene officers in nursing and doctors with responsibility for hygiene, who form a hygiene commission that must monitor the work in an AEMP. [9] As this commission is not only responsible for monitoring and advising the sterile area, no exact costs can be determined here. Furthermore, the calculated annual salary of the staff is higher than the costs for sterile supplies in the tool, as the staff member is not only 100% available for the processing of sterile supplies, but is also involved in

The calculation tool therefore converts the costs of actual working hours by specifying the time spent on individual preparation activities. As this cannot be calculated, the costs of the actual working time were therefore converted directly to 1 STE in the calculation tool by specifying the time of the individual preparation activities. For the calculation in a practice, a buffer should therefore be included in the calculation.

## Conclusion

The calculation tool presented in this article for calculating the most important costs for 1 STE in an outpatient surgery center can be used as a database and basis for calculations in reference centers. This could also enable specialist companies to calculate the actual costs of this area and include them in their contract negotiations with health insurance companies. For the project provider itself, the result is an important calculation parameter for analyzing the costs of its own AEMP and serves as a basis for calculations if the preparation of sterile goods is offered to customers as an external service.

Interest in the preparation of sterile goods will increase significantly over the next few years, as the demands on the process flow have increased to such an extent that small surgical or GP practices are unlikely to be able to afford these investment costs. Because this is the case, several manufacturers already offer disposable instruments. For example, the manufacturer Paul Hartmann charges €4.47 plus VAT for a pair of tweezers and scissors needed to pull sutures after an operation.[10] With a fee for a post-operative wound check of €17.91, according to EBM code 31600, it is clear that a large part of the revenue for post-operative wound checks is likely to be borne by the sterile goods. The question then arises as to who wants to take on this defi cient work at all.

One can only hope that contributions such as these will lead to data being collected on a factual basis and foundation, which will then lead to further discussion about costs and their reimbursement in the healthcare system.

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# The clean and well-groomed hand as an effective preventive measure in the healthcare sector

*Aaron Papadopoulos, Ines Konschake*

Hand hygiene consists of three essential elements: Disinfection, washing and care. Hand disinfection is one of the most effective infection prevention measures. From a holistic perspective, however, it is also important to remove dirt from hands and maintain the health of the skin. This article is intended to shed light on the topic of hand hygiene in healthcare, look at the beginnings and developments and provide practical experience for practical use.

## The birth of hand disinfection

Puerperal fever (childbed fever) is a febrile infectious disease that has been known since ancient times. At that time, women died en masse when they gave birth to their children in hospitals. With "pathological anatomy", the dissection of corpses, mortality continues to increase. Among other things, atmospheric and cosmic influences are suspected, but the true cause is a mystery to mankind and the pathogen remains unknown for the time being. "Only the large number of deaths remains an undoubted reality," writes Semmelweis.

It was only when a forensic doctor he knew died as a result of a cut after a dissection that Semmelweis recognized a connection between the injury and the sudden death of the doctor and introduced the first hygiene regulations for doctors, midwives and hospital staff. He demands the washing of hands at the bedside with chlorinated lime. The year was 1847 and although Semmelweis did not yet know what bacteria were at this time, he was credited with developing a simple but effective prevention against puerperal fever.

Within just 60 days, the mortality rate drops significantly from 17 to 1.2 percent. The discovery and historically decisive contribution to hand hygiene in medicine was thus made by Ignaz Philipp Semmelweis (1818-1865), a Hungarian-Austrian physician who was also known as the became known as the "Father of hand hygie

**Fig. 1:** Semmelweis painting in the maternity w of the General Hospital in Vienna, oil painting Robert
A. Thom - Watchtower Online Library.

## Application of historical findings - contemporary hand hygiene in medical facilities

The hands of staff are potentially contaminated with pathogenic agents during patient care and contact with the immediate patient environment and are carriers of these pathogens. With the establishment of hand disinfection in the healthcare sector, the most important measure for avoiding nosocomial infections (hospital infections) was introduced in healthcare facilities worldwide as a preventive measure for the benefit of patients. In addition, hygienic hand disinfection provides self-protection for medical staff.

Many studies have demonstrated the infection-preventive influence of increased hand hygiene compliance with alcohol-based disinfectants and the associated reduction in MRE (multi-resistant pathogens). An additional preventive potential for the reduction of nosocomial infections (NI) or the transmission of pathogens is the involvement of patient groups.

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**Fig. 2**: Hand hygiene display at Johanniter Hospital Stendal.


and visitors to hand disinfection. To promote awareness of hand disinfection, displays, signs or information flyers can be well established in the facilities (Fig. 2 and Fig. 3).

May 5 has been designated by the World Health Organization (WHO) as the annual
International Hand Hygiene Day. The date was chosen deliberately, as the day and month (05.05.) are representative of the five fingers of the left and right hand.

## The goal of hand hygiene

Hand hygiene has a major influence on protecting and preventing the spread of skin contamination. Hand disinfection eliminates transient pathogens. Transient skin flora, which is also known as temporary skin flora (approach flora), means that the skin is temporarily colonized or contaminated with bacteria, fungi and viruses, e.g. through direct contact from skin to skin or indirectly via objects on the hands.

Surgical hand disinfection, on the other hand, also leads to the extensive elimination of resident germs that live on the horny layer. Resident skin flora is the physiological skin flora, which consists of various germs and microorganisms, such as Staphylococcus epidermi- dis, propioni- and corynebacteria, which also fulfill important protective functions.

The distinction and separation between hygienic and surgical hand disinfection was introduced by the hygienist Carl Flügge in 1905.

**Fig. 3:** Sign before entering the infirmary / area at Johanniter Hospital Stendal.

Some pathogens cannot be deactivated by surgical or hygienic hand disinfection, such as Clostridioides difficile, a bacterium that occurs worldwide. Its habitat is the intestines of healthy humans and animals. If antibiotics are taken for a long period of time, the usual intestinal flora is altered or even destroyed. The bacteria are then transferred to objects (e.g. toilets, door handles) and other people via stool residues from sick people.
carry. The hands of staff are also known to be a possible source of transmission of Clostridioides difficile. To eliminate the bacteria, hands must be washed with soap after hygienic hand disinfection.

## Basic hygiene rules for staff on hand hygiene

In order to carry out sufficient hygienic hand disinfection, the entire skin of the hands must be considered, including fingertips, thumbs, spaces between the fingers and folds of the palms. For this purpose, the hand disinfectant (HDM) is rubbed into all areas of the hand for the entire exposure time recommended by the manufacturer in accordance with the self-administered application method.

Contaminated hands are first washed (caution: do not splash the surrounding area and clothing!), followed by hygienic hand disinfection (Fig. 4). If the forearms are contaminated, they should be included in the hygienic hand disinfection. During activities that require hygienic hand disinfection, jewelry such as rings (including wedding rings), bracelets, watches and friendship bracelets must be removed (in accordance with TRBA 250), and care must be taken to ensure that fingernails are well-groomed, short and untreated.

The wearing of artificial fingernails, nail extensions and gel nails is prohibited, as the bacterial density on artificial nails is higher than on natural nails. Only a medical indication may be an exception.




**Fig. 4:** Hand swab. The hands of healthcare staff are exposed to high levels of stress due to frequent hand disinfection and hand washing and need protection and care at the same time.

Skin cleansers are used to remove unwanted dirt from the skin. Hand washing should be kept to a minimum in everyday care routines as it reduces the skin's defenses. As a rule, hands should be washed when starting work or when visibly soiled. Too frequent washing causes the horny layer to swell, which removes skin oils and moisturizing factors. The skin dries out and there is an increased risk of irritant dermatoses [6]. This effect is so pronounced in the winter months that it is often referred to as "winter skin".

It is essential to wash hands before procedures, when in contact with food and after using the toilet.

To protect the skin, pH-neutral washing lotions or washing foams are recommended. If the hands are then disinfected, it is important to ensure that the hands and in particular the spaces between the fingers are dried carefully with a disposable towel.

The third component of hand hygiene is skin care. The KRINKO recommendation on hand hygiene in healthcare facilities states: "due to the increased strain on the skin it is recommended that all medical and nursing staff regularly care for their hands by using skin protection and skin care products suitable for their skin type". Skin care is just as important as hand disinfection, as germs and harmful substances have difficulty penetrating healthy skin.

A distinction is made here between skin protection (cream) and skin

skin care (lotion). It is recommended to apply skin protection before certain activities such as wet work, but also after every break or at regular intervals. Skin care, on the other hand, is used after work or before longer breaks. With both types of skin protection, it is important to ensure that they are applied to clean and dry hands.

Care products must not be used instead of protective agents. The skin care ingredients can increase the irritation and undesirable effects of the work equipment. The skin care products contribute to the regeneration of the skin barrier and are applied after skin-stressing activities. The nourishing ingredients maintain the skin's moisture, making it smooth and supple.

In general, a distinction is made between lotions and creams. Lotions are usually oil-in-water emulsions and contain more water and less oil, making them easier to spread. A cream, on the other hand, is a water-in-oil emulsion with a higher proportion of oil and a firmer consistency.

Skin care and protective measures for healthcare facilities are regulated by the TRGS
555. The operating instructions defined there are laid down by the employer's company doctor or by the employer itself in accordance w i t h TRGS 555 and can be found on the facility's hand and skin protection plan. It is binding for the employees concerned.

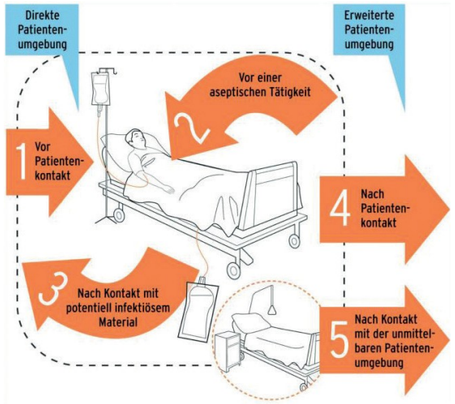



**Fig. 5:** WHO guidelines on hand disinfection in the healthcare sector.

## Hygiene and patient safety - The 5 moments of hand disinfection

**The 5 indications for hand hygiene are**

**Fig. 6:** Nurse disinfecting her hands in the Patient room.

- before patient contact,
- before aseptic activities (drawing up medication, manipulation of devices (e.g. CVC, drains), changing dressings, etc.).
- after contact with potentially infectious materials (blood, body fluids, secretions, excretions or contaminated objects)
- after patient contact,
- after contact with the (immediate) patient environment

After removing the gloves, hygienic hand disinfection is also mandatory. In order to achieve a high level of compliance with hand disinfection, hand sanitizers must be used wherever hand disinfection is required.

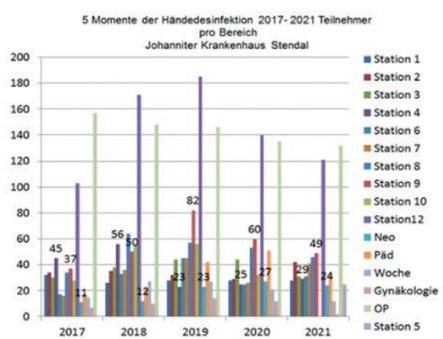



**Fig. 7:** Statistical survey / participants in the Hands workshop.

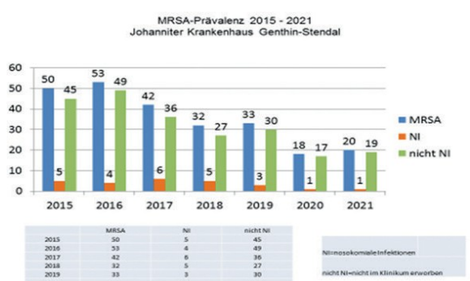
disinfectant dispensers should be made available. The dispensers should be easily accessible and located near the patient's bed. The Commission for Hospital Hygiene and Infection Prevention (KRINKO) recommends one dispenser for two patients in hospital wards and one dispenser per patient bed in intensive care and dialysis units.

Virucidal HDMs, which can be used for both surgical and hygienic hand disinfection, are recommended. Some products contain caring ingredients to improve skin compatibility.

The service life of the HDM must be observed in accordance with the manufacturer's instructions and must be noted with the date of use. Please note that the service life varies depending on the dosing device (wall dispenser, disposable pumps, etc.). Hand disinfectants that are already approved as medicinal products are subject to the German law on medicinal products. Please note that medicinal products may only be used in the original container. HDMs with biocidal approval in accordance with EU Regulation No. 528/2012 are now also used in healthcare facilities. These are declared as biocides accordingly.

Alcohol-based HDMs are well tolerated by the skin, effective and established, but measures to increase user compliance in healthcare facilities are still an important goal in the fight against multi-resistant pathogens (MRE) and nosocomial infections (NI).

**Fig. 8:** MRSA prevalence.




## Increase in compliance

Despite knowledge of the risk of transmission of germs from unclean hands, implementation - non-compliance with hand disinfection - remains a major challenge in the healthcare sector. In order to achieve an increase in hand disinfection, it is necessary to determine the current state of the NI situation, the consumption of HDM per patient day and the reasons for the failure to disinfect hands per area/ward. The infrastructure of the hand disinfectant dispensers placed in the areas should also be carefully examined. HDM dispensers should be easily accessible at the patient station, as an HDM dispenser that is far away from the patient station is more likely not to be used and is inconvenient. After evaluating these results, it is essential to regularly inform the relevant departments about their successes or necessary measures and to provide practical training.

The KRINKO specifies at least one training session. However, more frequent training should be aimed for in practice, as learning successes diminish after a short time.

The hygiene commission and the meetings of the hygiene group continuously monitor and discuss infection prevention measures and strategies. The quality of results must be made transparent to employees in a timely manner. The platform can be the in-house intranet, for example. By increasing hygienic hand disinfection in the healthcare sector, NI because clean hands contribute significantly to patient safety (Fig. 7: Statistical survey of hand disinfection in comparison Fig. 8: Reduction of NI at Johanniter Hospital Stendal).

## Practical tip: Designing a workshop on the clean hand

The fluorescent test with the box shows how well staff disinfect their hands. Hands that are not sufficiently disinfected are exposed by UV light, making it clear to training participants what is otherwise invisible.

## Outlook

The best basis for increasing compliance with hand disinfection is to regularly inform users about the successes they have achieved. Regular hand hygiene training offers opportunities to discuss and optimize work processes, consolidate specialist knowledge and avoid unnecessary hand disinfection. Good skin compatibility of a hand disinfectant and skin protection are important prerequisites for implementing hand hygiene compliance in accordance with the WHO criteria.

**Fig. 9:** Public Day / Patient Safety Day 17.09.2022.

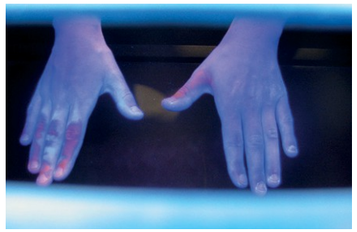


**Fig. 10:** Hand disinfection training using fluorescent HDM and UV box.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# Knowledge base: Initial validation of brand-new devices and validation intervals

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A brand-new preparation device is delivered, set up and installed by an expert technician and is now to be inspected again by an independent validator after commissioning. Especially in the field of dentistry, where devices are delivered in one piece and the installation is reduced to "plug and play", many questions always arise around the initial validation: why is the initial validation of new devices necessary at all, what are the benefits for the practice, why are there additional costs? Costs and what are the benefits in terms of patient protection?

## Where is it?

First of all, the requirement for validated preparation processes is clearly enshrined in law in Germany. §Section 8 MPBetreibV (1): "The preparation of medical devices intended for use as low-germ or sterile must be carried out using suitable validated procedures, taking into account the manufacturer's specifications, in such a way that the success of these procedures can be reproducibly guaranteed and the safety and health of patients, users or third parties is not endangered." Furthermore, proper preparation is assumed if the recommendation of the Robert Koch Institute and the Federal Institute for Drugs and Medical Devices "Hygiene requirements for the preparation of medical devices" from 2012 is observed (MPBetreibV, §8 (2)).

## What does this mean in practice?

All preparation steps must be considered during validation. The brand-new preparation is not

The requirement for validation applies not only to the preparation device, but also to all processes that take place in a preparation device, as well as all processes involved in the preparation of medical devices. This includes, for example, all packaging steps.[1, 2]

In practice, this means that the validator not only looks at the preparation device itself and, if necessary, takes measurements of the processes, but will also consider the environment. Manufacturer information, handling, interactions with other processes, installation conditions, effects of transportation... these are all components that can influence the preparation process and are therefore used to assess the processes.

## Where can I find specific instructions for carrying out a validation?

The requirements for validating the cleaning and disinfection processes in a washer-disinfector can be found in the relevant standard for washer-disinfectors - DIN EN ISO 15883 with the relevant part. For a dental practice, this would be parts -1, -2 and -5. The 2017 guideline from the DGKH, DGSV and AKI for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices provides practical information and a much more comprehensible approach to validation. [4] In addition, some professional associations have also addressed the topic of validation and prepared the topic specifically for their target group. [3]

DIN EN ISO 17665-1 provides important information on the validation of sterilization processes in a small steam sterilizer, as does DIN SPEC 58929. There is also a guideline from the DGKH from 2009. The information from the professional associations can also be found in the respective hygiene guidelines. [3]

## Who is allowed to validate?

Here, too, it is worth taking a look at MPBetreibV §8 (7)
"...The validation and performance assessment of the preparation process must be carried out on behalf of the operator by qualified specialists who meet the requirements of § 5 with regard to the validation and performance assessment of such processes."

The reference to MPBetreibV § 5 (2) results in the following requirements for the validator: "Compliance with these special requirements may be demonstrated by the presentation of a certificate from a body recognized by the authority responsible for notified bodies within the scope of this Regulation in accordance with Article 35 (1) of Regulation (EU) 2017/745 or Article 31 (1) of Regulation (EU) 2017/746. Compliance with the special requirements may also be demonstrated by certificates issued by the competent body in another Member State of the European Union or a contracting state of the European Economic Area and which correspond in content to the certificates pursuant to sentence 1."

But what does the term "qualified specialist" mean for the in
§5 described special requirements? A look at DIN 58341, which describes the requirements for validation in more detail, can help here. The requirements for validators, their qualifications and expertise can be derived very well from this.

## What is the difference between "Validation" and "requalification":

Validation consists of installation qualification, functional qualification and performance qualification. Section 6 of DIN 58341 explains the scope of validation of the cleaning and disinfection processes in accordance with DIN EN ISO 15883-1,-2 and -4. The scope of testing is defined in the validation plan and includes:

- Product groups and families
- Which procedures are used
- Validation period
- Which process chemicals are used
- Load carrier
- Medical devices to be reprocessed with cleaning instructions in accordance with DIN EN ISO 17664.

The scope of validation for sterilization processes also consists of installation qualification, functional qualification and performance qualification and is defined in the standards DIN EN ISO 17665-1, DIN SPEC 58929 and DIN 58946-7. Re-qualification is the "repetition of part or all of the validation to confirm the continued acceptability of a specified process."

The DGKH, DGSV and AKI guideline for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices from 2017 defines renewed performance qualification in Appendix 7 without special cause typically after 12 months and renewed performance qualification for special cause in Appendices 8 and 9.
The requalification of the sterilization processes is defined in DIN 58946-7 under point 9.3.2 with an annual interval or, if the influencing factors and evaluation criteria in Table 7 are met, an extension of the interval to a maximum of 2 years is possible.

## What does this mean for the user?

The operator is legally obliged to use validated procedures to reprocess medical devices that are intended to be used in a sterile or low-germ environment. [1]
New preparation appliances are type-tested by the manufacturer and quality-tested after production. However, the manufacturer's tests are no substitute for validating the preparation processes on site in practice.

## What is the importance of routine checks?

Routine tests must be defined depending on the technical equipment of the device (washer-disinfector or steam sterilizer). The DGKH, DGSV and AKI guideline for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices from 2017 describes the routine checks under 6.3 as well as in checklist 9 "Daily inspection of the WD" and checklist 10 "Matrix for creating a checklist for routine checks of the technical function". [4]

Routine controls ensure that users can monitor the processes in daily operation and quickly identify inadequacies. Information on routine checks for sterilization processes can be found in DIN EN ISO 17665-1.

## Conclusion

Validation is the documented procedure for obtaining, recording and interpreting the results required to prove that a process consistently delivers products, that the success of these processes is traceable and that the safety and health of patients, users or third parties is not endangered.


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# Reliable alternative for water quality: two-stage treatment with reverse osmosis without EDI

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In the end, the former managing director of the hospital was given two years' probation and a fine of 75,000 euros. The April 2021 verdict in the hygiene scandal at a German university hospital also revealed inadequate sterilization of surgical instruments. The court also cited outdated equipment for preparing and carrying out sterilization as well as the failure to regularly inspect the devices. Although it could not be proven whether patients were actually harmed by the defects, the scandal was doubly expensive for the clinic: not only did it lose its good reputation, but it also lost out on millions of euros in revenue due to canceled operations by worried patients. The hospital is currently claiming 15 million euros in damages from the former employee.

This example shows very drastically how hygiene deficiencies in the medical sector can have far-reaching consequences, and not just for patients. This is why water preparation systems must not only meet current requirements in the short term, but must also be permanently maintained and serviced.

Continuous monitoring and documentation of the legally prescribed parameters for the production of pure and ultrapure water are therefore non-negotiable.

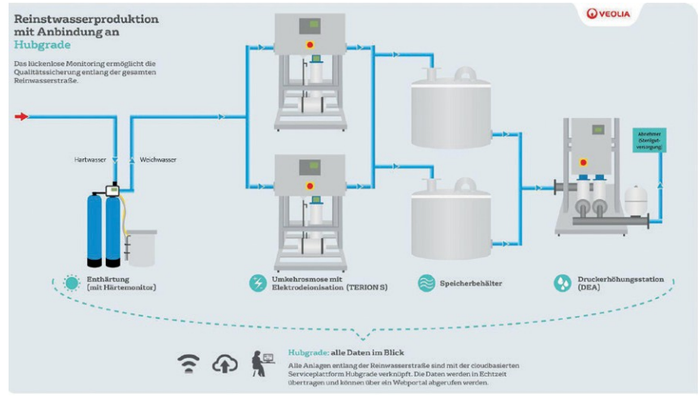
## General requirements for reliable process engineering

For the central sterile supply unit (CSSD) or the preparation unit for medical devices (AEMP), water of the quality specified in DIN EN 285 is generally used for large steam sterilizers. The Instrument Preparation Working Group (AKI) also recommends its own requirements for water quality. In order to reliably meet these requirements, various process steps are necessary for water preparation and storage.

(see example in Figure 1). Different methods can lead to the same result. The use of the appropriate solution depends above all on the local conditions, such as the quality of the outgoing water, the quantities and operating peaks, but also on the skills of the maintenance and servicing staff and the spatial situation.

Water preparation with reverse osmosis (RO) does not always have to be followed by electrodeionization (EDI) as a process step. Depending on the quality of the feed water, high-performance RO systems can be sufficient in a two-stage variant. This can significantly reduce investment and operating costs. Systems with a vertical extension and front access to the filter modules not only save additional space, but also make maintenance work more efficient. This makes it easy to upgrade and integrate on site.

**Fig. 1:** Ultrapure water production with connection to Hubgrade.



### Two-stage reprocessing for CSSD/ AEMP with RO/RO in practice

A good example of a two-stage RO system without EDI can be found at St. Bernward Hospital in Hildesheim:

The St. Bernward Hospital in Hildesheim was founded in 1852 and is now a modern specialist hospital with over 500 beds that has grown over the years. A good 1,600 employees treat 27,000 inpatients and 60,000 outpatients every year. In addition, there are another 37,000 emergency admissions per year, of which 16,000 patients receive further inpatient treatment. The hospital is therefore an indispensable part of the medical infrastructure for the city and region of Hildesheim. Since 2022, the hospital has been using a total of four reverse osmosis systems from the SIRION series by Veolia Water Technologies with a total capacity of 2,300 l/h - two large systems, each with 750 l/h, provide the basic supply primarily for the ventilation and air conditioning systems. The systems are connected in series and thus designed redundantly. This means that they can back each other up in the event that one system fails or requires maintenance. The two smaller systems produce the higher quality ultrapure water for sterile supplies. They also have a redundant design.

In order to be able to continuously ensure the quality of the systems and the water produced the RO systems can also be connected to a digital service platform. Process data, completed service measures and water analysis results are stored centrally. Digital monitoring thus replaces the principle of the classic analog operating diary. In addition, alarm functions warn of critical operating states and unsatisfactory water quality directly by email or on a cell phone.

### RO/RO or RO/EDI?

The use of RO systems without EDI is comparatively easy for staff. Performance parameters of the entire preparation process and the individual system components as well as the water quality can be called up live at any time thanks to special sensors. Computer models and AI can also analyze the data using appropriate online tools. All process steps can be logged and thus traced exactly. This makes modern systems less susceptible to misjudgements or maintenance faults.

Modern reverse osmosis systems without EDI are - Depending on the location, RO/EDI systems are an inexpensive but reliable alternative, can also relieve the burden on staff through digital support and, with manageable operating costs, are a safe solution for water preparation in medical facilities. Whether the RO/RO combination is sufficient for sterile goods preparation or an RO/EDI is necessary must always be decided on a case-by-case basis with experts.


## Imprint

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## Editorial

Dear readers,

Reliable hygiene, standard-compliant preparation and ensuring sterile environments are a complex challenge even in normal times. It is hard to imagine what challenges people are facing in crisis areas such as Turkey and, of course, Ukraine, in order to be able to maintain reliable care and secure protection for patients on site. Moreover, with lack of stable energy and water supply, these are undoubtedly extreme situations. We therefore like to thank everyone who is currently particularly committed or organizing relief supplies and donations for these regions.

In this first issue of 2023, we have again selected a wide range of texts worth reading for you. Dr. Sabine Kaufmann, Kathrin Mann and Stella Nehr-Werner take a look at sterile barrier systems and also look at the question of how sterile goods packaging can be properly protec- ted during transport. With the right packaging and the right processes, you can ultimately work much more economically. The second part of the article "Costs for reprocessing medical devices in an outpatient surgery center" is also about cost-effectiveness. This time, Kathrin Mann takes a vivid look at the precise parameters for the processes in the reprocessing unit for medical devices.

I'm finally doing it more and more often and maybe you too: shaking hands, having en- counters in real life. In keeping with the International Hand Hygiene Day on May 5th, Ines Konschake and Aaron Papadopoulos are going into more detail about the value of infection prevention through clean and well-groomed hands. By the way, many hands can also be shaken again from October 11th to 13th. at the Freiburg Infectiology and Hygiene Congress.

From a technical point of view, I recommend the text by Iven Kruse and Stella Nehr-Werner on the initial validation of brand-new devices. And finally, the customer example from the St. Bernward Hospital in Hildesheim, I will go into the safe water treatment for the reprocessing unit for medical devices with reverse osmosis without EDI.

I wish you an exciting read of the new aseptica

Tobias Jungke

## Report

**OECD: EU citizens do not do enough sport**

More and more people in Europe are taking too little exercise. This is a trend that has been exacerbated by the coronary heart disease, according to a study by the Organization for Economic Co-operation and Development (OECD) and the World Health Organization (WHO).

The WHO recommends at least 150 minutes of moderate exercise per week. In 2016, only 35.4 percent of adults in the 27 EU member states managed to do so. In the Corona years, more than half of Europeans exercised even less, according to the study. Thirty-four percent said they exercised less often and 18 percent stopped altogether. Only seven percent said they planned to exercise more after the pandemic.

According to the study, 45 percent of adults who exer- cise too little do not exercise at all. The situation is no better among young people: only 17.6 percent of boys and 9.6 percent of girls achieved the WHO recommen- dation of 60 minutes of moderate to intensive exercise every day. However, the situation does not improve with age: only a quarter of adults over 55 exercise at least once a week. According to the study, women exer- cise less than men.

If everyone in the EU followed the WHO recommen- dations, more than 10,000 premature deaths could be prevented each year among people aged 30 to 70, according to the study. People who have taken too little exercise so far could extend their average life expec- tancy by 7.5 months by being more physically active.

Source: aerzteblatt.com



## Contents

# Insight: Sterile barrier systems

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Sterile packaging is used to protect sterile goods during transport and storage. The goods to be sterilized are packaged in it before sterilization, sterilized in the packaging, and can then be removed for transport in a contamination-proof manner after sterilization and sent for storage - so much for the theory. But how do you actually find the right packaging? After all, it should not only fit the practi- ce procedure, but also the type of sterilization process, the medical devices and, in addition to these practical aspects, not weigh too heavily in terms of price. And how do you protect the sterile packaging during transport, for example? How do you find the right packaging system here?

## Legal and normative classification

In Germany, proper reprocessing is presumed, provided that the recommendation of the Robert Koch Institute and the Federal Institute for Drugs and Medical Devices "Requirements for hygiene in the reprocessing of medi- cal devices" from 2012 is observed (MPBetreibV, §8 (2)). Part of the reprocessing is also the packaging. For this reason, it is worth taking a look at the RKI recommen- dations for the legal and normative classification. He- re, the topic is explained in chapter 2.2.4 "Packaging". [2] First of all, a distinction must be made between the actu- al sterile barrier system and protective outer packaging. It is important that the entire packaging is adapted to the sterilization process, i.e. steam or other sterilization agents, the properties of the medical device and stres- ses during transport and storage (e.g. mechanical im- pact during long transport routes).[2] This is the only way to enable sterilization and maintenance of sterility until reuse. Since chapter 2.2.5 of the RKI recommen- dation describes the steam sterilization process as the standard procedure, this article deals exclusively with sterile packaging systems for steam sterilization.[2] DIN EN ISO 11607 Parts 1 and 2 define the requirements that must be met by the packaging for medical devices to be sterilized in the final packaging; general requirements and individual validation requirements are described.[1] The individual packaging materials and types as well as test procedures with regard to tightness are described in greater detail in DIN 58953 Parts 6-9. [6, 7, 8, 9] The implementation of the validation of packaging pro- cesses is described in the guideline for the validation of packaging processes according to DIN EN ISO 11607- 2:2020 of the DGSV.[3] Likewise, there is specialist advice on the selection of packaging, correct packaging per se, and validation of the packaging process in various pub- lications of specialist societies, such as the DAHZ Hygiene Guide, Chapter 5.[4]

## Definitions of packaging systems

**Sterile Barrier System**
"Minimum packaging that prevents the entry of micro- organisms and allows aseptic delivery of the product at the point of use. "[1] Examples may include a sealed pouch or tube, sheet stock, or a sealed container.

**Preassembled sterile barrier system.**
"Partially assembled sterile barrier system for filling and final closure or sealing. "[1] Examples include a pouch, bags, or open reusable containers.

**Protective Packaging**
"Material configuration designed to prevent damage to the sterile barrier system and its contents from the time of assembly to the time of use. "[1] An example is a sui- table further packaging envelope into which the steri- lized goods are placed, in the sense of dust protection packaging. It is also often used as a collection container for several individual sterile barrier systems.

**Packaging system**
"Combination of sterile barrier system and protecti- ve packaging. "[1] This is a maximum form of packaging. Based on manufacturer's data, the maximum storage period is up to 5 years.

## Differentiation of packaging types

The packaging system must be adapted to the medical device to be packaged in accordance with the manufacturer's specifications (DIN EN ISO 17664). Weight and geometry play a decisive role, but also the transport requirements (mechanical protection) and the storage conditions (mechanical load) as well as the sterile storage period. Sterile presentation must be ensured for each type of packaging. The reprocessing as well as the sterilization must be tested and validated for feasibility and effectiveness.

The types of packaging are basically divided into hard packaging and soft packaging.

**Rigid packaging** refers to prefabricated, rigid steriliza- tion containers, i.e., containers that can be used several times. They usually consist of a tray, a lid, passages for the sterilizing medium in the form of disposable or per- manent filters, a closure and carrying handles.[5] These can also be used for the removal of soiled instruments from the operating room and are available again as rigid containers after reprocessing and function control.

**Soft packaging** refers on the one hand to prefabricated sterile pouches, which are made of clear/paper composite and must be sealed after packaging. These are available both as tubular goods in various widths and as prefabricated pouches. In addition, there is also the classic nonwoven and paper, in which the sterilized goods can be wrapped.[5]

## Requirements for packaging materials and packaging technology

| Material | Standard |
|---|---|
| Sterile pouches and tubes | DIN EN 868-5:2018 |
| Paper, non-woven (steam sterilizing) | DIN EN 868-2:2018<br>DIN EN 868-9:2018<br>DIN EN 868-10:2018 |
| Reusable sterile container | DIN EN 868-8:2018 |

**Tab. 1:** Requirements for the packaging materials.

The selection of a suitable material is based on the manufacturer's product information and product specifications with information on the permissible sterilization processes, the quality of the material (e.g. $^{g/m2}$) and the information on further processing. The packaging material must allow sufficient access to the sterilization medium. The packaging must not be affected by the sterilization process and the barrier pro- perties must be maintained. The packaging must not be damaged by either the temperature or the pressure. In addition, the packaging must not be affected by the medical device (e.g. by pointed, sharp or heavy medical devices).

DIN 58953-:2020 describes the requirements for pack- aging technology, which differ for the various materials. For each type of packaging, validation must be perfor- med with the corresponding sterilization procedure. If the type of packaging is changed (e.g. new manufactu- rer of fleece or container), the packaging must be revali- dated in the device. The results of the validation must be evaluated and documented (DIN 58953-8).

**Tab. 2:** Packaging technology requirements.

| Material | Standard |
|---|---|
| Sterile pouches and tubes | DIN 58953-7:2020<br>DIN EN ISO 11607-2 |
| Paper, non-woven (steam sterilizing) | DIN 58953-7:2020 |
| Reusable sterile container | DIN 58953-9:2020<br>DIN EN ISO 11607-2 |

## Requirements of the different types of packaging

**Non-woven and paper**

DIN 58953-7 describes two different packing techniques: diagonal packing and parallel packing. Which type of packing technique is used depends on the CSSD or must be discussed and determined in the team with the management. However, it is then advisable that each employee uses the same technique. The packing tech- nique must be integrated into a work or process inst- ruction and made accessible to everyone. The creation of a double packing is to be achieved by packing twice. Single packing with a double layer of fleece or paper does not result in double packing. A short strip of tape with or without an indicator near the opening flap can be used to close the packaging. With an indicator strip, it is clearly visible whether the process of sterilization has been passed. The packaging must then be provi- ded with a self-adhesive label for identification, which usually also bears an indicator.

The size of the material must be optimally adap- ted to the size of the medical devices to be packaged. Various sizes of nonwoven are available. The paper or fleece must not be packed too loosely or too tightly. The screens must not be pushed onto the sheets, but must be correctly positioned directly to avoid perforations. The sheets should not be larger than necessary because of steam penetration, drying and not least for cost reasons. Paper and nonwoven must be placed evenly, without the use of force, as smoothly as possible over the items to be sterilized. The wrapping must not be taut over the corners of the items to be sterilized, but also not too loose, so that movements of the wrapping during pressure changes during sterilization are possible. Labeling directly on the soft packaging must not be done in order to prevent contamination of the sterilized items inside by solvent-based inks. Self-adhesive labels must be used for marking.

Non-woven and paper packaging are disposable items. If the sterilization process is interrupted, the medical device must be repackaged.

**Sterile pouches and tubes**

Clear packaging is also disposable and therefore not reusable. For clear packaging, the filling limit must be observed as a matter of urgency. The distance between the medical device and the sealed seam must be at least 3 cm. Sufficient excess material for aseptic removal is essential. The packaging weight in clear packaging must not exceed 3 kg and is therefore a limiting factor in the selection (see manufacturer's instructions). When fil- ling, the side seams must not be damaged. Pointed objects and materials must be protected, while ensu- ring vapor permeability. In double packaging, the paper side must always face the paper side to allow air exchange and steam passage during sterilization. The inner packaging of a double packaging must not be bent (> select sufficiently large packaging).

Labeling of the transparent packaging must always be done outside the product chamber, on the film side, to prevent contamination by solvent-based inks. Do not use sharp, hard pens for labeling. Soft, sterilization-resistant fiber pens are suitable. Medical devices with a cavity must be packed so that the opening faces the paper side.

*The article is divided into two parts. You will find part 2 in the next issue.*


Literature

1. Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019); German version EN ISO 11607-2:2020.
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10. DIN EN 868-5: Packaging for medical devices to be sterilized in the final packaging - Part 5: Sealable transparent pouches and -Hoses made of porous materials and composite plastic sheeting - Requirements and test methods; (German version EN 868-5:2018).

# Costs for reprocessing medical devices in an outpatient surgery center (part 2)*

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

## Determination of the reference variables

The next step was to define the reference variables. In activity-based costing the reference variables served as the basis for assignment of the indirect costs of a process. In the case of a main process, these reference variables were designated as "cost drivers". By determining the measured variables it is therefore possible to identify areas that are deemed very cost-intensive such as e.g., personnel costs or room costs. Table 3 below shows an example of the costs incurred for the unclean RUMED area for 2019, broken down into direct and indirect costs (list not complete). The costs were calculated similarly for the clean RUMED area and sterile supply store. As can be seen from the overview costs' table, the cost structures differ greatly between the various areas in terms of number, time period and con- sumption. Hence, it becomes clear that all costs must first be converted in order to bring them to a single denominator. Here, it is possible to calculate the costs on a yearly basis and to divide them by the number of batches produced or to break down the individual costs directly to one batch.

## Determination of costs and cost rate formation

Next, the costs were determined for the individual sub- processes; the corresponding cost rates were calculated and extrapolated for 2019. These serve as a basis for cal- culation of the costs of 1 StU. The individual cost rates were extrapolated separately for the different areas for 2019: unclean area, clean area and sterile supply store. The following are examples of the cost rates for the unclean and clean areas.

**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<br>US: 0.3kW = 0.09 €/batch |

**Total costs for 1 StU**

Having identified and calculated the large number of different costs, they can now be summarized. The data collected for the unclean and clean RUMED areas as well as for the sterile supply store are assigned to the cost drivers. These are broken down into consumables, personnel costs and costs incurred for the premises in terms of rent, depreciation of equipment and furniture. The large number of cost items reflects the complex process of producing a sterile medical device.

By adding together the costs for the three areas (unclean area, clean area, sterile supply store) for 2019, the sterile supply units produced for this period can be de- termined. Based on the calculation shown in Table 7, the total costs for 1 StU thus amount to €117.92.

**Calculation tool**

Now that all the individual processes have been analysed and cost calculation formulas developed to bring them to the same denominator, i.e. "one year", the next obvious step is to transfer this knowledge to a spread- sheet in order to be able to calculate the costs for 1 StU in other centers/units as well.

Based on the cost structures identified and analysed for the project sponsor's outpatient surgery centre and RUMED, a calculation tool was developed in the form of a spreadsheet. Here, too a distinction was made between the three areas underpinning the sterilization process (unclean area, clean area sterile supply store) as well as their cost drivers (e.g., personnel, consumables, equipment). Here, the costs with greatest impact on the overall outcome are always listed first. With decrea- sing importance for the total costs, the other factors are added.

In the following development step, the tables for the unclean area, clean area and sterile supply store were summarized for the total calculation and presented in a spreadsheet, here Apple Numbers. As already mentioned in the conceptual design phase, the significance of the costs for the overall result follows in the corresponding order of importance. In a further step, the individual costing items were then incorporated into the spreadsheet as a formula.

Costs that appeared irrelevant in the total and could not be clearly assigned to the area, such as the lighting costs in the sterile supply store, were not taken into account in the calculation.

Furthermore, summation functions were incorporated for calculation of the total costs in horizontal and verti- cal direction and percentage calculations of the costs for premises and cost types were added.

Next, the costs per year were calculated in a simple rule of three with the product "total sterile supply costs per year" and the denominator "number of sterilization units (StU) per year". Since large sterilizers producing the maximum 1 StUs are usually used in outpatient surgery centres, the number of sterilizer batches then also corresponds to the number of StUs.

The spreadsheet showing the project sponsor's data is presented below. In addition to the decisive total costs and the costs per StU, the individual total costs for the various areas as well as for the individual cost drivers or cost types can be calculated and displayed. Furthermore, the percentage contributions made by cost types and premises to the total costs can be seen.

**Fig. 1:** Varicose vein set.

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

**Tab. 4:** Unclean area: total costs for 2019.

| WD repairs & maintenance: |
|---|
| *Repairs* €357 per year + *maintenance* €952 per year = €1,309 per year |
| **WD energy costs:** |
| 3kW/h x €0.30 = €0.90/h, WD running time 60 minutes per batch = €0.90 per batch<br>€0.90 per batch x 300 batches = €198 per year |

**Tab. 5 & 6:** Clean area: total costs for 2019.

| Repeat reprocessing/inspection of instruments: |
|---|
| *Oil spray* with gross unit price of €6.37, consumption: 5 units per year = €31.85 per year<br>*Cloths, etc.* €0.30 per tray x 1,800 trays per year = €540 per year<br>**Total costs:** €31.85 + €540 = **€571.85 per year** |
| **Heat sealer energy costs:** |
| *In operation:* €0.75 kW x 0.30/h = €0.23 kW/h; ½ h operation daily = €0.11 per day<br>*Standby:* 0.13 kW x €0.30/h = €0.039; 5 h daily = €0.20 per day<br>**Total costs:** €0.11 + €0.20 = €0.31 per day<br>365 days - 104 days (weekends) - 14 days (public holidays) - 14 days (vacation) = 233 days per year<br>**233 days per year €0.31 per day = €72.23 per year** |

**Tab. 7:** Total cost for 1 StU in 2019.

| Total costs | |
|---|---|
| Unclean area | €15,061.65 |
| Clean area | €18,698.09 |
| Sterile supply store | €2,795.08 |
| **Total** | **€36,554.82** |
| **Number of batches reprocessed in 2019** | **310** |
| **Costs for 1 StU** | **€117.92** |

## Results

In this specific example of an outpatient surgery centre the amount calculated for 1 StU was around €118. Since six varicose vein sets can be sterilized in this 1 StU, the reprocessing costs incurred for one varicose vein set is around €20. The economic operator can therefore good estimate whether reprocessing in-house is still econo- mically viable or whether outsourcing reprocessing or using single-use devices could be an alternative. With the help of the calculation tool, an economic operator can estimate their approximate costs for 1 StU.



## Discussion of the results

A literature search was carried out in the Regensburg University Library and its database access to all relevant journals and textbooks as well as Internet-based searches in the WiSo databases and the Bavarian Libra- ry Network (Gateway Bayern) using the German-lan- guage search terms for "costs", "sterile supplies", "repro- cessing", "unit costs", "production costs" revealed that there are no scientific papers available on this topic rela- ting to the German healthcare system. The only calcula- tions available are those determined for individual areas by manufacturers and rough cost analyses. For example,
B. Thiede in the Hessian Medical Journal estimated the unit costs per instrument to be between €1.00 and €1.80.[3] The regional councils of Darmstadt - Gießen - Kassel come to a somewhat higher estimate of the costs per instrument, putting the costs per instrument at between €1.20 and €2.20.[4]

Both publications mentioned appear to refer to an ear, nose and throat practice in the federal state of Hesse. One publication points out that physicians carrying out only a limited number of minor surgical procedures, such as general practitioners and dermatologists, should use disposable instruments, while ophthalmologists, otolaryngologists, gynaecologists, orthopaedists and surgeons could perhaps outsource reprocessing of their special instruments. Here, reprocessing costs of between €1.20 and €2.20 per instrument are reported, with no distinction made with regard to the type of inst- ruments to be reprocessed (classification of medical de- vices into risk classes). As already stated, reprocessing of critical instruments, especially of group B instruments, is associated with significantly higher costs than semi-critical or non-critical instruments, which are certainly used by gynecologists for example. Ophthalmologists are subject to ultra-stringent reprocessing requirements for their instruments (very fine and small instruments), because they must not only be clean and sterile after re- processing, but must not contain any residues of acids or alkalis, otherwise they could damage the interior of the eye. Washer-disinfectors (WDs) that meet these re- quirements are generally not available in Germany for less than €25,000 plus value added tax (VAT).

The calculated cost-intensive one-time purchases, including furniture, validation and instrumentation, were reported in the literature consulted to be €16,000. It is therefore not possible to determine the validity of the figures cited in these two publications.

Besides, the costs were not differentiated in terms of the period in which they were incurred, with only the costs per year estimated and not calculated in detail. The maintenance services for the sterilizer were given as €400 and for the WD as €300 and do not necessarily correspond to the data cited, even after making inqui- ries to the companies concerned. Process validation of the WD and sterilizer was quoted as costing €1,000. It should be noted that validation relates to a process, i.e. the costs are incurred per process and device, and not for an individual device. Furthermore, there are reports of regular revalidations (performance requalification).

In another publication in Central Service the costs of a large sterilization system for the sterilization pro- cess alone were estimated to be €21.30 for 1 StU. [5] That publication gave a detailed breakdown of the costs and the workflow practices are very well calculated and described. However, in that unit 8,847 sterilization cycles were carried out per year with six large sterilizers. The costs also referred only to those costs incurred for the sterilization process. The reprocessing and storage costs of the sterilized items were not taken into account here. It is difficult to extrapolate or compare the costs of a large-scale industrial sterilizer to an outpatient set- ting RUMED. These data provide at most an indication of the possible level of costs incurred. It also becomes clear here that the sterile supply reprocessing costs are likely to vary greatly between the different reprocessing centers.

The reprocessing times described in the literature were calculated on a much higher scale than those in the project sponsor's RUMED, which explains the different cost items. Likewise, the energy costs for 1 StU are ques- tionable in the above calculation because the air con- ditioning system is in operation not only during the sterilization process but continuously, and is in stand- by mode only at night.

**Tab. 8:** Calculation tool for determining the costs of 1 StUE.

| | Unclean area | Clean area | Store | Total costs in € | Proportion as % |
|---|---|---|---|---|---|
| Personnel costs | 4,800 | 3,999 | | 8,799 | 24.08 |
| Rental costs | 2,135.64 | 2,464.2 | 2,628.48 | 7,228.32 | 19.77 |
| Equipment/maintenance | 3,516.45 | 6,574.19 | | 10,090.64 | 27.6 |
| Depreciation | 3,061.1 | 3,810.65 | 166.6 | 7,038.35 | 19.25 |
| Equipment/furiture | | | | | |
| Water & electricity | 471.46 | 538.56 | | 1,010.02 | 2.76 |
| Costs for consumables | 1,077.00 | 1,311.49 | | 2,388.49 | 6.53 |
| Total costs/year in € | 15,061.65 | 18,698.09 | 2,795.08 | 36,554.82 | |
| Proportion as % | 41.2 | 51.2 | 7.6 | | |
| Number of StUs/year | | | | 310 | |
| **Costs for 1 StU/year in €** | | | | **117.92** | |

However, as can now be demonstrated the production of sterile supplies is very cost-intensive and constitutes an important cost factor in surgery. Noteworthy is al- so the fact that the personnel costs, usually the largest item in healthcare setting, are only the second largest cost driver here.

Citing by way of example the project sponsor's RUMED, a cost block of €117.92 was identified for reprocessing 1 StU. The project sponsor calculates six varicose vein sets per StU, thus giving rise to sterile supply costs of €19.65 per varicose vein operation. Since a process accuracy of
> 90 % is assumed for this project, the price for 1 StU is likely to between €110 and €125.
If the data reported in the literature are used as a basis to calculate the costs for reprocessing a varicose vein set belonging to the project sponsor, the costs for 23 inst- ruments per tray would be between €23 and €51. This would mean costs in the range of €138 to €303 for 1 StU.

As such, the reprocessing costs incurred by the project sponsor's RUMED seem to be on a very reasonable scale.

If one now assigns the costs arising in the project sponsor's RUMED to the unclean area, clean area and sterile supply store and puts the individual cost items in relation to each other, one notes that 41.2 % of the costs arise in the unclean area, 51.2 % in the clean area and 7.6 % in the sterile supply store. The cost drivers are equipment maintenance costs at 27.61%, followed by personnel costs at 24.08%, rental space at 19.77% and equipment provision and furniture depreciation at 19.25%. Water and electricity costs account for only 2.76%, and consumables for 6.53%. This shows that the hardware (total equipment costs, furniture) accounts for a total of 46.85% of the costs.

If the costs of the sterile equipment are now set in re- lation to the reimbursement fee received for a varicose vein operation (stripping of the great saphenous vein) in the outpatient area, which is reimbursed at €308.26 per procedure as per code 31204 in accordance with the uniform assessment standard (EBM) (as of 2019), it be- comes apparent that the share of costs for the instru- ments amounts to 6.4 %.

The costs for reprocessing medical devices, which are subjectively perceived as high, do not appear to be as high as expected. However, this is only the case at first glance. If the remuneration fee of 35% paid to the physi- cian is deducted from the reimbursement fee, the sterile supply costs should be set as high as 10%.

Overall, the costs of outpatient operations have risen sharply over the last 20 years because of the legal regula- tions, hence the reimbursement scale no longer appears sufficient and the number of potentially possible outpatient operations performed in Germany is well below average compared with other countries.

According to a study by the Organization for Economic Cooperation and Development (OECD), only 50% of the potentially possible outpatient operations were per- formed in Germany, compared to 80 to 93% in other industrialized countries.[6]

The legal requirements, in particular for reprocessing medical devices pursuant to the Medical Devices Act, the requirements of the KRINKO at the RKI (former Federal Health Office), Medical Devices Operator Re- gulation and the Protection against Infection Act, have been greatly tightened over the past decades. Due to the cost structures, many physicians who perform out- patient surgical procedures, e.g., even small procedures such as suture removal, microsurgery like wound care, etc., no longer see themselves in a position to perform these procedures because the instrument reprocessing costs are no longer economically in line with the reim- bursement fee. The much more stringent demands made by society on safety and quality in the health care system are in stark contrast to the, over the past years and decades, stagnating reimbursement rates.

Accordingly, the uniform assessment standard, EBM 2008, was adopted in 2008, and based on EBM 2 from 1996 and EBM 2000 plus from 2000, in which technical and medical services were re-evaluated. It is not possib- le to ascertain whether costs were evaluated by calcula- tion and on what basis this may have been done. Since then, no relevant adjustments have been made.

Nor, so far, has there been any no validated cost analysis of varicose vein surgery or other services in the current

German Physicians Fee Guide (GOÄ) of 12 November 1982, r

January 1996. However, this matter is currently under debate.

Furthermore, the advent of new minimally invasive procedures has led to more stringent technical requi- rements, which are also associated with greater use of medical devices in varicose vein surgery and additio- nally require the use of intraoperative, diagnostic and imaging procedures (in this example ultrasound), also necessitating extra single-use sterile supplies.

Another problem is the completely different cost struc- tures in outpatient surgery centers, with the remune- ration rates largely uniformly regulated in the Federal Republic of Germany and with only small specific dif- ferences between the various associations of statutory health insurance physicians (KV). It should be clear to everyone that e.g., rental costs and personnel costs are significantly higher in Munich than in the Bavarian Forest. Nevertheless, surgeons in both regions both re- ceive the same reimbursement fee for a varicose vein operation.

A number of health insurance funds have recognized the dilemma that operations that could be performed in the outpatient setting are still carried out on an in- patient basis and have concluded special care contracts within the framework of Section 140a of Book V of the German Code of Social Law.[7] Based on these contracts, the reimbursement scale is generally somewhat higher than that offered as per the uniform assessment stan- dard (EBM). These contracts make a decisive contribu- tion to upholding outpatient surgical structures. For the paying authorities this is also economical because these surgical interventions provided on an inpatient basis account for around four to six times the costs for the paying authorities (in the case of the varicose operation the reimbursement fee in the hospital amounts to around €2,310; Diagnosis Related Group (DRG): F39a, corresponds to around €2,310. However, here all the hospital services are included and must still be adjusted for the hotel and anaesthesia services compared to the uniform assessment standard (EBM) calculation. The building costs, however, must be added back because of state funding in order to be able to make a direct com- parison; status 2019).

Therefore, the sterile supply reprocessing costs must be calculated individually in each center and the conclusi- ons to be drawn as to whether reprocessing and/or the provision of surgical services are worthwhile also de- pend on many factors.

Using the calculation tool presented here, it is easy to relatively quickly calculate the medical device reprocessing costs and this can therefore be very important in decision-making.

What the calculation tool does not include, however, are additional costs for continuing education and training (CET) of the staff entrusted with the production of sterile supplies. This means that the reprocessing or nursing personnel need additional specialist training to work in this area. A standard certification course cur- rently costs around €500 plus VAT, depending on the provider. If the employee is a non-specialist and does not belong to a medical profession, they must under- go specialist training. This is a three-week course that currently costs around €1,300 plus VAT. Only then is the employee properly qualified to work in this area.[8] However, continuing professional development is re- quired. What the tool also does not cover are the costs incurred for internal and external consulting services, such as quality assurance, certification of the quality management system, if necessary, as well as the legally mandated consultancy services provided by hospital infection control/hygiene specialists and other members of the infection control team who must monitor the working activities of the RUMED.[9] Since the infection control team is not only responsible for monitoring and advising the RUMED personnel, it is not possible to determine precisely the costs arising here. Besides, the calculated annual salary for staff is higher than the sterile supply costs calculated in the tool. This is because staff members do not invest 100% of their time in the re- processing of sterile supplies but also usually perform other tasks, and employees must also be kept availa- ble to deputize for colleagues in cases of illness and vacation. Since this cannot be calculated, the costs of the actual working time were therefore converted directly to 1 StU in the calculation tool by specifying the time of the individual reprocessing activities. To take account of such calculations in an office-based medical practice, funds must be earmarked to that effect.

## Conclusion

The calculation tool presented in this article for calculating the most important costs incurred in the produc- tion of one sterilization unit (1 StU) in an outpatient surgery centre can be used as a data basis for similar calculations in reference centres. This could also ena- ble professional societies to calculate the actual costs arising in this area and to take account of them when negotiating contracts with the health insurance com- panies. For the project sponsor these findings serve as an important calculation parameter for cost analysis in their own RUMED and can be used as a basis for calcu- lations in the event of providing medical device repro- cessing services to external parties.

Interest in sterile supply reprocessing is projected to rise in the coming years because the demands made on the process flow have become so stringent that small surgi- cal or general practices are unlikely to be in a position to meet these investment costs. Because of this, several manufacturers are already offering single-use devices (disposable instruments). For a pair of tweezers and a pair of scissors, needed to pull the thread after an operation, the manufacturer Paul Hartmann, for examp- le, calculates a price of €4.47 plus VAT.[10] With a reim- bursement fee of €17.91, as per the uniform assessment standard (EBM) number 31600, for a postoperati- ve wound check one can see that a large part of the reimbursement fee for the postoperative wound check is likely to be spent on the sterile supplies That raises the question as to who would want to take on this loss- making work at all.

One can only hope that publications such as this present contribution will result in data being collected on a factual basis, which will then lead to further discussion of costs and their reimbursement in the healthcare system.


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# The clean and well-groomed hand as an effective preventive measure in healthcare settings

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Hand hygiene consists of three essential elements: disinfection, washing and caring. Hand disinfection is one of the most effective measures of infection preven- tion. From a holistic point of view, how- ever, it is also important to remove con- tamination from hands and maintain the health of the skin. This article is intended to shed light on the topic of hand hygiene in healthcare, to view the beginnings and developments and to give practical expe- rience for healthcare worker.

## The beginning of Hand Disinfection

Puerperal fever (childbed fever) is a febrile infectious di- sease known since ancient times. At that time, many wo- men died when they gave birth to their children in hospitals. With the "pathological anatomy", the dissection of corpses, mortality continued to increase. Among other things, atmospheric and cosmic influences were suspec- ted, but the true cause was a mystery to humans and the pathogen remained unknown for the time being. "Only the large number of deaths remains unquestionably reality," writes Semmelweis.

Only when a forensic scientist known to him died resul- ting from a cut injury after a dissection does Semmelweis recognize a connection between the injury and the southern death of the physician and introduce the first hygiene regulations for doctors, midwives, and hospital staff. He demands the washing of hands at the bedside with chlorinated lime. The year is 1847 and although Semmel- weis does not yet know what bacteria are at this time, his merit is to have developed a simple but effective preven- tion against puerperal fever.

In just 60 days, mortality drops significantly from 17 to
1.2 percent. The discovery and the historically decisive contribution to hand hygiene in medicine was thus made by Ignaz Philipp Semmelweis (1818-1865), a Hungarian-Austrian physician who also became known as the "Father of hand hygiene".

**Fig. 1:** Semmelweis painting in the maternity ward of the Vienna General Hospital, oil painting by Robert A. Thom - Watchtower Online Library

## Application of historical findings - Modern hand hygiene in medical facilities

The hands of the staff are potentially contaminated with pathogenic pathogens during measures on the patient as well as in contact with the immediate patient envi- ronment and are carriers of these pathogens. With the establishment of hand disinfection in the healthcare sector, the most important measure for the preventi- on of nosocomial infections or HAI (hospital-acquired infections) was introduced worldwide in healthcare facilities as a preventive measure for the benefit of the patient. In addition, hygienic hand disinfection provi- des self-protection for medical staff.

Many studies can prove the infection-preventive influ- ence of increased hand hygiene compliance with alco- hol-based disinfectants and the associated reduction of multidrug-resistant pathogens.



An additional prevention potential to HAI or in the transmission of pathogens, the integration of patient and visitor into hand disinfection. To promote awareness in hand disinfection, displays, information signs or information flyers can be well established in the facilities (Fig. 2 and Fig. 3).

May 5th has been declared the annual International Hand Hygiene Day by the World Health Organization (WHO). The date was chosen deliberately, because day and month (5.5.) are representative of the five fingers of the left and right hand.

## The goal of hand hygiene

Hand hygiene has a great impact on protecting and spreading contamination of the skin. Proper hand disinfection eliminates the transient pathogens. In addition to the transient skin flora, which is also referred to as temporary skin flora (approach flora), the skin is temporarily colonized or contaminated with bacteria, fungi and viruses that reach the hands, e.g., through direct contact from skin to skin or indirectly via objects.

Surgical hand disinfection, on the other hand, also leads to the extensive elimination of the resident germs that live on the layer. Resident skin flora refers to the physio- logical skin flora, which consists of various germs and microorganisms, such as Staphylococcus epidermidis, propioni and coryne bacteria, which at the same time also fulfill important protective functions.

The distinction and separation between hygienic and surgical hand disinfection was introduced by the hygienist Carl Flügge in 1905. Some pathogens cannot be deactivated by surgical or hygienic hand disinfection, such as Clostridioides difficile, a bacterium that occurs worldwide. The habitat is the intestine of healthy peop- le and animals. With a prolonged intake of antibiotics, the usual intestinal flora is changed or even destroyed. The bacteria are then transferred to objects (e.g. toilets, doorknobs) and to other people. The hands of the staff are also known as a possible source of transmission of Clostridioides difficile. To eliminate the bacteria, the hands must then be washed with soap after hygienic hand disinfection.

## Basic rules for staff on hand hygiene

To carry out sufficient hygienic hand dis- infection, the entire skin of the hands must be considered, including fingertips, thumbs, spaces between the fingers and
folds of the palms. The disinfectant is rubbed into all areas of the hand according to the self-responsible rubbing method over the entire exposure time recommended by the manufacturer.

Dirty hands are washed first (cave: do not splash environmental contamination and clothing!) This is followed by hygienic hand disinfection (Fig. 4). In case of contamination of the forearms, they should be included in the hygienic hand disinfection.

For activities that require hygienic hand disinfection, jewelry such as rings (also wedding rings), bracelets, watches and friendship bands must beremoved (accor- ding to TRBA 250), care must be taken of well-groomed, short, and untreated fingernails.

The wearing of artificial fingernails, nail extensions and gel nails is prohibited, as the bacterial density on artificial nails is higher than on the natural nail. An exception may only be a medical indication.


**Fig. 2:** Displays for hand hygiene at the Johanniter Hospital Stendal.


**Fig. 3:** Sign before entering the infirmary / area in the Johanniter Hospital Stendall.

Contact plate unwashed hand

Contact plate disinfected hand

**Fig. 4:** Imitation of the hand. The hands of healthcare workers are heavily stressed by frequent hand disinfection and hand washing and need protection and care at the same time.

Soaps are used to remove unwanted dirt on the skin. Washing hands should be reduced to a minimum in everyday care, as it reduces the skin's defenses. As a rule, hands should be washed at the start of service or in case of visible soiling.

Too frequent washing causes the layer to swell, which removes skin oils and moisturizing factors. The skin dries out and there is an increased risk of irritation dermatoses.[6] This effect intensifies in the winter months to such an extent that it is often referred to as "winter skin".

It is essential to wash hands before surgery, in contact with the processing and distribution of food and after using the toilet.

To protect the skin pH-neutral washing lotions or washing foam are recommended. In the case of subsequent disinfection of the hands, it is important and should be noted that the hands and especially the spaces between the fingers must be carefully dried with a disposable towel.

The third component of hand hygiene is skin care. According to KRINKO's recommendation on hand hygiene in healthcare facilities, it says: "Due to the increased stress on the skin, regular care of the hands by using skin protection and skin care products suitable for the skin type is recommended for all employees working in medical and nursing care". Skin care is just as important as hand disinfection, as germs and pollu- tants are difficult to penetrate healthy skin.

A distinction is made between skin protection (cream) and skin care (lotion). It is recommended to apply skin protection before certain activities such as moistening, but also after each break or at regular intervals. Skin care, on the other hand, is used after work or before longer breaks. For both variants, it should be noted that they are applied to clean and dried hands.
Caring products must not be used instead of protecti- ve products. The nourishing ingredients can increase the irritation and undesirable effects of the work equip- ment.

The skin care products contribute to the regeneration of the skin barrier and are applied after skin-stressed activities. The nourishing ingredients maintain the moisture of the skin, making it smooth and supple.

In general, a distinction is made between lotions and creams. Lotions are usually oil-in-water emulsions and contain more water and less oil and are therefore easier to spread. The cream, on the other hand, is a water-in-oil emulsion with more oil proportions and rather firmer in consistency.

Skin care and protection measures for healthcare facilities are regulated by TRGS 555. The operating instructions defined there are defined according to TRGS 555 by the company doctor of the employer or by the employer himself and can be found on the hand and skin protection plan of the facility. It is binding for the employees concerned.

## Hygiene and patient safety - The 5 moments of hand disinfection

**The 5 indications of hand hygiene are:**

- before patient contact,
- before aseptic activities (withdrawal of medication, manipulation of devices (e.g., CVC, drainage), dressing changes, etc.).
- after contact with potentially infectious materials (blood, body fluids, secretions, excretions or contaminated objects)
- after patient contact,
- after contact with the (immediate) patient environment



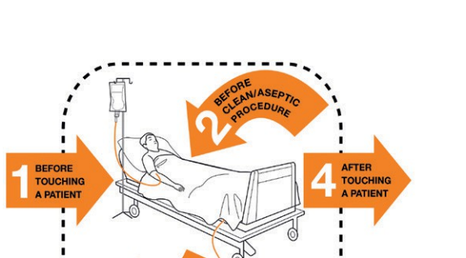



**Fig. 5:** WHO guidelines for hand disinfection in health care.

After taking off the gloves, hygienic hand disinfection is also mandatory. To achieve a high level of compliance of hand disinfection, disinfection dispensers must be provided wherever hand disinfection is to be carried out. Dispensers should be easily accessible and placed near the patient's bed. The Commission for Hospital Hygiene and Infection Prevention (KRINKO) recom- mends one dispenser for two patients in hospital wards and one dispenser per patient bed in intensive care and dialysis wards.

Virucidal hand disinfectants are recommended, which can be used for both surgical hand disinfection and hygienic disinfection. In some products, nourishing ingredients are incorporated for better skin compatibility.

The shelf life of the hand disinfectant must be observed according to the manufacturer's instructions and must be noted with the date of opening. Please pay atten- tion to the different shelf life depending on the product dosing used (Wall dispenser, single use pump, etc.) In some countries hand disinfectants are registered as medicinal products and need to comply with the Drug Law. Medicinal Products should only be used in original packaging. Very common in Europe are Hand Disin- fectants under the biocidal EU legislation Nr. 528/2012 being used in healthcare facilities.

The alcoholic rubbing preparations are well tolerated by the skin, effective and established worldwide, but measures to increase the compliance of users in pathogens (MDR) and nosocomial infections (NI) - are still an important goal.

## Increased compliance!

Despite knowledge of the risk of transmitting germs from not sufficiently disinfected hands, the implementa- tion - the non-compliance of hand disinfection - is still a major challenge in the healthcare sector.

health- care facilities - in the fight against multidrug-resistant

To achieve the increase in hand disinfection, an actu- al state of the current situation of NI, the consumption of HD per patient day and the reasons for the omission of hand disinfection per area/station must be determi- ned. The infrastructure of the placed hand disinfection dispensers in the areas must also be checked carefully. HD dispensers should be easily accessible at the patient place, because an HD dispenser that is far away from the patient place is rather not used and is un- economical. In evaluating these results, it is a must to regularly inform the departments concerned about their successes or necessary measuresand to provide practical training.

KRINKO specifies at least one one-time training course. However, more frequent training in practice should be sought, because learning success decreases after a short time with the user.

In the Hygiene Commission and in the meetings of the hygiene group, the event-related measures and strate- gies for infection prevention are continuou tored and discussed. The quality of the results must

**Fig. 6:** Nurse disinfecting her hands in patient room.



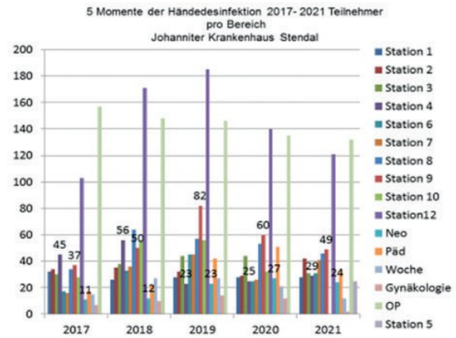



**Fig. 7:** Statistical survey / participants in the hand workshop.

be always made transparent to employees. The platform can be, for example, the in-house intranet. By increasing hygienic hand disinfection in the healthcare sector, NI can be reduced, because the clean hand contributes significantly to patient safety (Fig. 7: statistical survey of handdisinfection in comparison Fig. 8: Reduction of NI at the Johanniter Hospital Stendal).

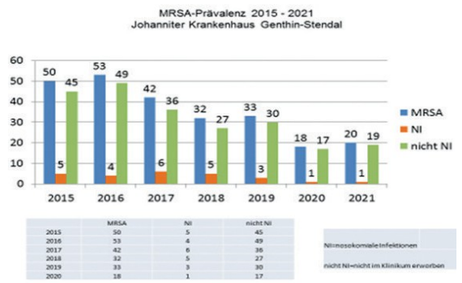
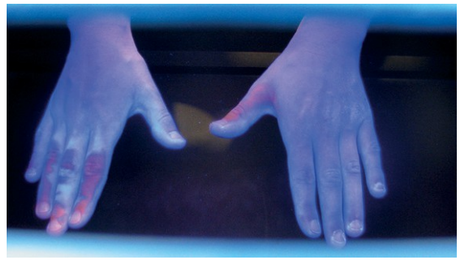



**Fig. 8:** MRSA prevalence.

**Fig. 9:** Public Day / Patient Safety Day 17.09.2022.

**Fig. 10:** Training of hand disinfection with a flourescent product and a UV box.



## Best Practice: Implementation of a workstore on clean hands

A workshop focusing hand hygiene has proven to be very successful in our institution. This can take place in May around the Day of Hands on 5 May. In addition to hand hygiene, the focus is on hand disinfection.

Regular training with a UV box takes place for all staff members. The fluorescent test with the box shows how well the staff disinfects their hands. Insufficiently disinfected hands are exposed by UV light, so the participants of the training visibly understand what you would not see otherwise.

## Outlook

The best basis for increasing the compliance of hand infection is the regular information of the users about their achieved successes. Regular training on hand hygiene offers opportunities to discuss and optimize workflows, consolidate expertise, and avoid unnecessary hand disinfection. To implement hand hygiene compliance according to the WHO criteria, the good skin compatibility of a hand disinfectant and skin protection are important prerequisites.

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# Insight: Initial validation of brand-new devices and validation intervals

*Iven Kruse, Stella Nehr-Werner*

A brand-new reprocessing device is delivered, set up and installed by an expert technician and is now to be inspected again by an independent validator after com- missioning. Especially in the field of dentistry, where equipment is delivered in one piece and installation is reduced to "plug and play", many questions arise around the initial validation: why is the initial valida- tion necessary at all for new equipment, what is the be- nefit for the practice, why are costs incurred here again and what is the benefit in terms of patient protection?

## Where to find?

First of all, the requirement for validated reprocessing processes is clearly anchored in law in Germany. §8 MPBetreibV (1): "The reprocessing of medical devices intended for use in a low-germ or sterile state must be carried out, taking into account the manufacturer's specifications, using suitable validated processes in such a way that the success of these processes can be verifiably guaranteed and the safety and health of patients, users or third parties is not endangered." Furthermore, pro- per reprocessing is presumed if the recommendation of the Robert Koch Institute and the Federal Institute for Drugs and Medical Devices "Requirements for hygiene in the reprocessing of medical devices" from 2012 is observed (MPBetreibV, §8 (2)).

## What does this mean for practice?

All reprocessing steps must be considered during validation. It is not the brand-new reprocessing device that is validated, but all processes that happen in a reproces- sing device are affected by the requirement for valida- tion, as are all processes that deal with the reprocessing of medical devices. Thus, for example, also all steps of packaging.[1, 2]

In practice, this means that the validator will not only look at the reprocessing device itself and, if necessary, take measurements of the processes, but will also look at the environment. Manufacturer specifications, handling, interactions with other processes, installation conditions, effects of transport... all these are components that can influence the reprocessing process and are there- fore used to assess the processes.

## Where can one find specific instructions for performing a validation?

For validation of the cleaning and disinfection processes in a washer-disinfector (WD), the requirements can be found in the relevant standard for WDs - this is DIN EN ISO 15883 with the relevant part. For a dental practice, this would be parts -1, -2 and -5. Practical advice and a much more comprehensible approach to validation is provided by the guideline from DGKH, DGSV and AKI for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices from 2017.[4] Furthermore, some professional societies have also dealt with the topic of validation and have again specifically prepared the topic for their target group.[3]

For the validation of sterilization processes in a small steam sterilizer, DIN EN ISO 17665-1 provides impor- tant information, as does DIN SPEC 58929. Here, too, there is a guideline from the DGKH from 2009. The information from the professional societies can also be found in the respective hygiene manuals.[3]

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## Who is allowed to validate?

Here, too, it is worth taking a look at MPBetreibV §8 (7) "...The validation and performance assessment of the re- processing process must be carried out on behalf of the operator by qualified specialists who meet the require- ments according to § 5 with regard to the validation and performance assessment of such processes."

The reference to MPBetreibV § 5 (2) results in the following requirements for the validator: "The fulfillment of these special requirements can be demonstrated by the presentation of a certificate from a body that has been recognized by the authority responsible for Notified Bodies in the area of application of this legal regulation in accordance with Article 35 (1) of Regulation (EU) 2017/745 or Article 31 (1) of Regulation (EU) 2017/746. Compliance with the special requirements may also be demonstrated by certificates issued by the competent body in another Member State of the European Union or a contracting state of the European Economic Area, the content of which corresponds to the certificates pursuant to sentence 1."

But what does "qualified specialist" mean for the special requirements described in §5? A look at DIN 58341 helps here, which describes the subject of requirements for validation in more detail. From this, the require- ments for the validator, his qualification and expertise can be derived very well.

## What is the difference between "validation" and "requalification":

Validation consists of installation qualification, operational qualification and performance qualification. Section 6 of DIN 58341 explains the scope of validation of cleaning and disinfection processes according to DIN EN ISO 15883-1,-2 and -4 The scope of testing is defi- ned in the validation plan and includes:

- Product groups and families
- Which processes are used
- Period of the validation
- Which process chemicals are used
- Load carriers
- Medical devices to be reprocessed with reprocessing instructions according to DIN EN ISO 17664.

The validation scope for sterilization processes also consists of installation qualification, operational qualification and performance qualification and is defined in the standards DIN EN ISO 17665-1, DIN SPEC 58929 and DIN 58946-7.

Requalification is the "repetition of part or all of a vali- dation to confirm the continuing acceptability of a specified process."

The 2017 DGKH, DGSV and AKI guideline for validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices defines requalification of performance in Appendix 7 without special cause typically after 12 months and requalification of performance for special cause in Appendix 8 and 9.

The requalification of the sterilization processes is defined in DIN 58946-7 under point 9.3.2 with an annual deadline or, if the influencing factors and evaluation criteria of table 7 are complied with, an interval of max. 2 years is possible.



## What does this mean for the user?

The operator is legally obligated to reprocess the inten- ded low-germ or sterile medical devices using validated procedures.[1]

New reprocessing devices are type-tested by the manufacturer and quality-tested after production. However, the tests at the manufacturer's premises do not replace validation of the reprocessing processes on site in practice.

## What is the significance of routine checks?

Depending on the technical equipment of the device (washer-disinfector or steam sterilizer), routine checks must be defined. The guideline of DGKH, DGSV and AKI for the validation and routine monitoring of au- tomated cleaning and thermal disinfection processes for medical devices from 2017 describes the routine checks under 6.3 as well as in checklist 9 "Operational daily check of the washer-disinfector" and checklist 10 " Matrix for the creation of a checklist for routine checks of the technical function. "[4]

Routine checks ensure that users can monitor their processes in daily operation and quickly identify inadequacies. For the sterilizing processes information for routine control can be found in the DIN EN ISO 17665-1.

## Conclusion

Validation is the documented process of obtaining, recording, and interpreting the results needed to demonstrate that a process consistently delivers products. that the success of these processes is traceably assured, and that the safety and health of patients, users, or third parties is not compromised.

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# Reliable alternative for water quality: two-stage treatment with reverse osmosis without EDI

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A former manager of the hospital was sentenced to two years of probation and a fine of 75,000 euros. The judgment of April 2021 about the hygiene scandal at a German university clinic also revealed insufficient sterilization of the surgical instruments. The court also listed obsolete devices for preparing and performing sterilization and the omission of regular inspection of the devices.

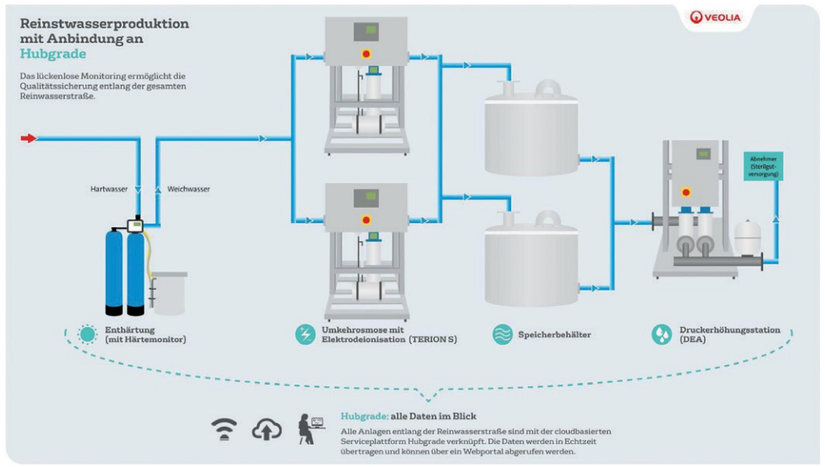
Although it could not be proven whether patients were actually harmed by the shortcomings, the scandal became doubly expensive for the clinic: on the one hand, not only the good reputation suffered, but the canceled operations of worried patients also meant millions in income. The clinic is currently demanding 15 million euros in damages from the ex-employee.

The example shows very drastically how lack of hygiene in the medical field can have far-reaching consequences not only for patients. Therefore, the water treatment systems not only have to meet the current requirements in the short term, but also have to be serviced and maintained on an ongoing basis. The continuous monitoring and documentation of the legally prescribed parameters for the production of pure and ultrapure water are therefore non-negotiable.

## General requirements for reliable process engineering

As a rule, water of the quality according to EN 285 is used for the Central Sterile Services Department (CSSD) and the processing unit for medical products. The German working group for the preparation of instruments (AKI) also recommends special requirements for water quality. In order to achieve this quality, various process steps of water treatment and storage are necessary (see example graphic 1). Different methods can lead to the same result. The use of the right soluti- on depends above all on the local conditions such as the quality of the feedwater, consumption quantities and peak times, but also on the skills of the maintenance and repair staff and on the spatial situation.

**Fig. 1:**
Typical ultrapure water production with integration into Veolia's Digital Services




Electrodeionization (EDI) does not always have to be a downstream process step for water treatment with reverse osmosis (RO). Depending on the quality of the feed water, high-performance RO systems can be sufficient in a two-stage variant. This significantly reduces investment and ope- rating costs. Systems with a vertical structure and front access to the filter modules not only save additional space, but also make maintenance work more efficient. This makes it easy to upgrade and integrate on site.

## Two-stage processing for CSSD with RO/RO in practice

A good example of a two-stage RO system without EDI is at St. Bernward Hospital in Hildesheim:

The St. Bernward Hospital in Hildesheim was founded in 1852 and is now a modern hospital with more than 500 beds that has grown over time. A good 1,600 em- ployees treat 27,000 inpatients and 60,000 outpatients every year. In addition, there are another 37,000 emer- gency admissions per year, of which 16,000 patients re- ceive further inpatient treatment. The hospital is an in- dispensable part of the medical infrastructure for the city and region in Hildesheim.

Since 2022, the hospital has been using a total of four reverse osmosis systems of the SIRION series from Veo- lia Water Technologies with a total capacity of 2,300 l/h

- two large systems, each with 750 l/h, provide the basic supply primarily for ventilation and air conditioning. The systems are connected in series and are therefore designed redundantly. This allows them to protect each other in the event that a system fails or needs mainte- nance. The two smaller systems produce the qualita- tively more demanding ultrapure water for the supply of sterile goods. They are also designed redundantly. In order to be able to continuously ensure the quality of the systems and the water produced, the RO systems can also be connected to a digital service platform. Pro- cess data, service measures and the results of water analyzes are stored centrally. The digital monitoring replaces the principle of the classic analogue operations log. In addition, alarm functions warn directly by email or mobile phone in the event of critical operating condi
tions and insufficient water quality.

## RO/RO or RO/EDI?

Using RO systems without EDI is comparatively easy for the staff. Performance parameters of the entire treat- ment process and the individual system parts as well as the water quality can be called up live at any time thanks to special sensors. With appropriate online tools, computer models and AI can also analyze the data. All pro- cess steps can be logged and thus exactly traced. This makes modern systems less susceptible to misjudge- ments or lack of maintenance.

Depending on the location, modern reverse osmosis systems without EDI are an economic but reliable alternative. They can also relieve staff through digital support and are a safe solution for water treatment in medi- cal facilities with manageable operating costs. Whether the combination RO/RO is sufficient for the proces- sing of sterile goods or whether an RO/EDI is necessary must always be decided on a case-by-case basis together with water experts.

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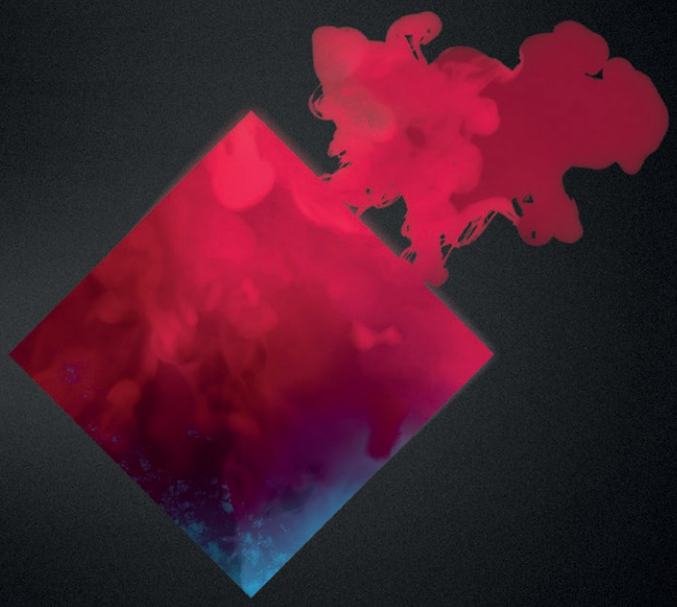

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