Das Fachmagazin für Krankenhaus- und Praxishygiene

Schutzgebühr 6,– €

aseptica

Besuchen Sie www.aseptica.com und nutzen Sie das umfangreiche Archiv!

29. Jahrgang 2023 | Heft 1

Bilingual

Die saubere und gepflegte Hand als effektive Präventionsmaßnahme im Gesundheitswesen

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 what challenges people are faced 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 protected 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 encounters 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 Organisation 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 exercise 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 recommendation 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 exercise less than men.

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

Source: aerzteblatt.com

Contents

Insight: Sterile barrier systems

Authors

Sabine Kaufmann, Kathrin Mann, Stella Nehr-Werner

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

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

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

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 practice 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 medical 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 recommendations for the legal and normative classification. Here, the topic is explained in chapter 2.2.4 "Packaging". [2] First of all, a distinction must be made between the actual 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 stresses during transport and storage (e.g. mechanical impact 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 recommendation 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 processes 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 publications 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 microorganisms 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 suitable further packaging envelope into which the sterilized 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 protective 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 sterilization 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 permanent 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 sterile 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	Norm
Sterile pouches and -tubes	DIN EN 868-5:2018
Paper, non-woven (steam sterilizing)	DIN EN 868-2:2018 DIN EN 868-9:2018 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 properties 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 packaging technology, which differ for the various materials. For each type of packaging, validation must be performed with the corresponding sterilization procedure. 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).

Tab. 2: Packaging technology requirements.

Material	Norm
Sterile pouches and -tubes	DIN 58953-7:2020 DIN EN ISO 11607-2
Paper, non-woven (steam sterilizing)	DIN 58953-7:2020
Reusable sterile container	DIN 58953-9:2020 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 technique must be integrated into a work or process instruction 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 provided with a self-adhesive label for identification, which usually also bears an indicator.

The size of the material must be optimally adapted 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 filling, the side seams must not be damaged. Pointed objects and materials must be protected, while ensuring 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.
2. Recommendation from the Commission on Hospital Hygiene and Infection Protection at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene requirements for the reprocessing of medical devices".
3. DGSV e.V.: Leitlinie für die Validierung der Verpackungsprozesse nach DIN EN ISO 11607-2:2020. Zentralsterilization 4; Volume 28; Suppl 2020.
4. Deutscher Arbeitskreis für Hygiene in der Zahnmedizin (Hrsg.): Hygieneleitfaden, 14. Ausgabe 2021.
5. Enko, Maria Theresia: Verpackung von Sterilgut; 2009; WFHSS Basisskriptum; https://wfhss.com/wp-content/uploads/wfhss-training-1-06_de.pdf (28.01.2022).
6. DIN 58953-6: Sterilisation - Sterilgutversorgung - Teil 6: Prüfung der Keimdichtigkeit von Verpackungsmaterialien für zu sterilisierende Medizinprodukte (2016).
7. DIN 58953-7: Sterilisation - Sterilgutversorgung - Teil 7: Anwendungstechnik von Sterilisationspapier, Vliesstoffen, Papierbeuteln und siegelfähigen Klarsichtbeuteln und -schläuchen (2020)
8. DIN 58953-8: Sterilisation - Sterilgutversorgung - Teil 8: Logistik von sterilen Medizinprodukten (2019).
9. DIN 58953-9: Sterilisation - Sterilgutversorgung - Teil 9: Anwendungstechnik von Sterilisierbehältern (2010).
10. DIN EN 868-5: Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 5: Siegelfähige Klarsichtbeutel und -schläuche aus porösen Materialien und Kunststoff-Verbundfolie - Anforderungen und Prüfverfahren; (Deutsche Fassung EN 868-5:2018).

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

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

Kathrin Mann

The article is divided into two parts: In Part 1 (last issue), the author devotes herself to the problem and the methodology and thus creates, among other things, an overview of the accruing processes in the reprocessing unit for medical devices of the aforementioned surgery center. In Part 2 (present issue 01/2023), the author addresses the reference variables 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 consumption. 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 subprocesses; the corresponding cost rates were calculated and extrapolated for 2019. These serve as a basis for calculation 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 US: 0.3kW = 0.09 €/batch

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

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 determined. 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 spreadsheet in order to be able to calculate the costs for 1 StU in other centres/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 decreasing 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 vertical 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.

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 €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 *Cloths, etc.* €0.30 per tray x 1,800 trays per year = €540 per year **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 *Standby:* 0.13 kW x €0.30/h = €0.039; 5 h daily = €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 €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 economically 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 Library Network (Gateway Bayern) using the German-language search terms for "costs", "sterile supplies", "reprocessing", "unit costs", "production costs" revealed that there are no scientific papers available on this topic relating to the German healthcare system. The only calculations available are those determined for individual areas by manufacturers and rough cost analyses. For example, B. Thiede in the Hessischen Ärzteblatt (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 instruments to be reprocessed (classification of medical devices 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 gynaecologists 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 reprocessing, 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 requirements 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 inquiries 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 process 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 setting 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 centres.

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 questionable in the above calculation because the air conditioning system is in operation not only during the sterilization process but continuously, and is in standby 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 also 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 instruments 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 relation 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 becomes apparent that the share of costs for the instruments 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 physician 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 regulations, 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 performed 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 Regulation and the Protection against Infection Act, have been greatly tightened over the past decades. Due to the cost structures, many physicians who perform outpatient 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 reimbursement 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 possible to ascertain whether costs were evaluated by calculation 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, revised as of 1 January 1996. However, this matter is currently under debate.

Furthermore, the advent of new minimally invasive procedures has led to more stringent technical requirements, which are also associated with greater use of medical devices in varicose vein surgery and additionally 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 structures in outpatient surgery centres, with the remuneration rates largely uniformly regulated in the Federal Republic of Germany and with only small specific differences 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 receive 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 inpatient 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 standard (EBM). These contracts make a decisive contribution 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 comparison; status 2019).

Therefore, the sterile supply reprocessing costs must be calculated individually in each centre and the conclusions to be drawn as to whether reprocessing and/or the provision of surgical services are worthwhile also depend 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 currently 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 undergo 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 required. 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 reprocessing of sterile supplies but also usually perform other tasks, and employees must also be kept available to deputise 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 production 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 enable professional societies to calculate the actual costs arising in this area and to take account of them when negotiating contracts with the health insurance companies. 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 calculations in the event of providing medical device reprocessing 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 surgical 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 example, calculates a price of €4.47 plus VAT.[10] With a reimbursement fee of €17.91, as per the uniform assessment standard (EBM) number 31600, for a postoperative 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.

Literature

1. DIN 1946, Teil 4: Raumlufttechnik – Raumlufttechnische Anlagen in Gebäuden und Räumen des Gesundheitswesens.
2. Bundesgesundheitsblatt 2012, Ausgabe 55: Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten, S. 1258.
3. Thiede, B.: Die Aufbereitung von Instrumenten beim niedergelassenen Arzt – Mögliche Alternativen zur eigenen Aufbereitung, in: Hessisches Ärzteblatt 2911; 12:743–744.
4. Regierungspräsidien Darmstadt – Gießen – Kassel: Hinweise und Kostenschätzung für den niedergelassenen Arzt, Darmstadt 2011.
5. Caquas, S.; Chapirot, C.; Coquard, A.; Dieu, B: Nutzung der Softwareanwendung T-Doc® zur Berechnung der Sterilisationskosten, in: Zentr Steril 2010; 18 (2): 75–85.
6. Brökelmann, J.: Chirurgische Versorgungsforschung braucht eine verwertbare OP-Statistik, in: Chirurgenmagazin, Jersbek 2015; 75/76 (3/4): 20–24.
7. Bundesministerium der Justiz und für Verbraucherschutz, § 140a SGB V; Verträge zu besonderen Versorgungsformen.
8. Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten, Bundesgesundheitsblatt 2012; 55: 1276.
9. Bayerisches Staatsministerium für Umwelt und Gesundheit; MedHygV: Verordnung zur Hygiene und Infektionsprävention in medizinischen Einrichtungen.
10. www.praxisdienst.de/Instrumente/Instrumentarium/Einweginstrumente. [Zugriff: 28.02.2022]

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

Aaron Papadopoulos, Ines Konschake

Authors |

Aaron Papadopoulos
Marketing Manager Healthcare
ECOLAB DEUTSCHLAND GMBH
Ecolab-Allee 1
40789 Monheim am Rhein
aaron.papadopoulos@ecolab.com
www.ecolab.com

Ines Konschake
Hygienemanagement
Johanniter GmbH
Johanniter Krankenhaus Stendal
Wendstraße 31, 39576 Stendal
ines.konschake@sdl.johanniter-kliniken.de
www.johanniter.de/johanniter-kliniken/stendal/

Hand hygiene consists of three essential elements: disinfection, washing and caring. Hand disinfection is one of the most effective measures of infection prevention. From a holistic point of view, however, it is also important to remove contamination 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 experience for healthcare worker.

The beginning of Hand Disinfection

Puerperal fever (childbed fever) is a febrile infectious disease known since ancient times. At that time, many women 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 suspected, 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 resulting from a cut injury after a dissection does Semmelweis recognize a connection between the injury and the sudden 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 Semmelweis does not yet know what bacteria are at this time, his merit is to have developed a simple but effective prevention 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 environment and are carriers of these pathogens. With the establishment of hand disinfection in the healthcare sector, the most important measure for the prevention 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 provides self-protection for medical staff.

Many studies can prove the infection-preventive influence of increased hand hygiene compliance with alcohol-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 physiological 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 people 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 disinfection, 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 first washed (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 (according 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 pollutants 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 protective products. The nourishing 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-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

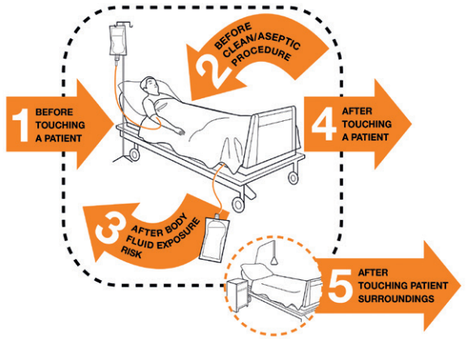


Fig. 5: WHO guidelines for hand disinfection in health care.

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) recommends 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 attention 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 Disinfectants 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 healthcare facilities - in the fight against multidrug-resistant pathogens (MDR) and nosocomial infections (NI) - are still an important goal.

Increased compliance!

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

To achieve the increase in hand disinfection, an actual 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 determined. 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 uneconomical. 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 strategies for infection prevention are continuously monitored and discussed. The quality of the results must

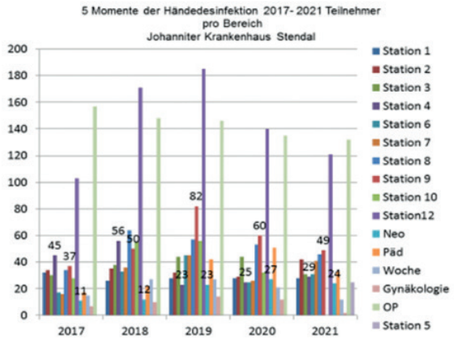


Fig. 7: Statistical survey / participants in the hand workshop.

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

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).

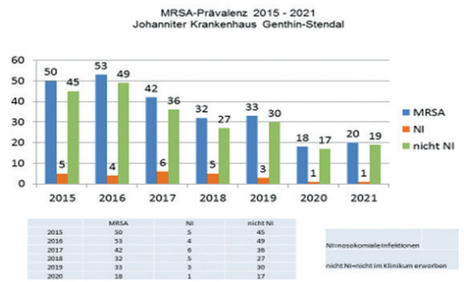
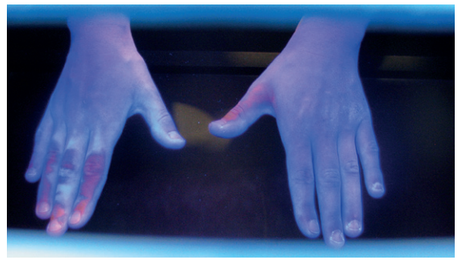


Fig. 8: MRSA prevalence.

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

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



Best Practice: Implementation of a workshop 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.

Literature

1. Kampf G, Hrsg. (2002): Hände-Hygiene im Gesundheitswesen. Springer Verlag Berlin Heidelberg New York 2002.
2. Gastmeier P. (2010): Association of parameters on structure and process quality with result-quality parameters of the KISS databases (SPE-KISS), Final Report 2010. National Reference Center for Surveillance of Nosocomial Infections at the Institute of Hygiene and Environmental Medicine Charité – Universitätsmedizin Berlin.
3. Kampf G, Reichel M, Feil Y, Eggerstedt S, Kaulfers PM (2008): Influence of the rub-in-technique on required time and hand cover-age in hygienic hand disinfection. BMC Infect Dis. 2008; 8: 14.
4. Source: Deutsches Ärzteblatt Studieren.de, 2/2011: 22.
5. Bundesgesundheitsblatt 2016-59;1189-1220DOI 10.1007/s00103-016-2416-6.
6. Epidemiologisches Bulletin 15/22.
7. KRINKO recommendation "Hand hygiene in health care facilities" Federal Health Gazette 2016 DGUV
8. Information 212-017 "Selection, provision and use of occupational skin products".

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 commissioning. 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 validation necessary at all for new equipment, what is the benefit 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, proper 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 reprocessing device are affected by the requirement for validation, 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 therefore 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 important 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]

Authors

Iven Kruse
General Sales Manager
Xylem Analytics
Germany Sales GmbH & Co. KG
Peringerstraße 10
85055 Ingolstadt
Iven.Kruse@xylem.com
www.ebro.com

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

Who is allowed to validate?

Here, too, it is worth taking a look at MPBetreibV §8 (7) "...The validation and performance assessment of the reprocessing process must be carried out on behalf of the operator by qualified specialists who meet the requirements 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 requirements 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 defined 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 validation 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 intended 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 automated 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.

Literature

1. Verordnung über das Errichten, Betreiben und Anwenden von Medizinprodukten (Medizinprodukte-Betreiberverordnung - MPBetreibV); Neugefasst durch Bek. v. 21.8.2002 I 3396; zuletzt geändert durch Art. 7 V v. 21.4.2021 I 833.
2. Kommission für Krankenhaushygiene und Infektionsprävention (KRINKO) beim Robert Koch-Institut (RKI) und des Bundesinstitutes für Arzneimittel und Medizinprodukte (BfArM): Anforderung an die Hygiene bei der Aufbereitung von Medizinprodukten. Bundesgesundheitsblatt, Gesundheitsforschung, Gesundheitsschutz, 2012; 55:1244-1310.
3. Deutscher Arbeitskreis für Hygiene in der Zahnmedizin (Hrsg.): Hygieneleitfaden, 14. Ausgabe 2021.
4. Leitlinie von DGKH, DGSV und AKI für die Validierung und Routineüberwachung maschineller Reinigungs- und thermischer Desinfektionsprozesse für Medizinprodukte, 2017.
5. DGKH: Empfehlung für die Validierung und Routineüberwachung von Sterilisationsprozessen mit Sattdampf für Medizinprodukte vom 01.07.2009.

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

Tobias Jungke

Author |

Tobias Jungke
PR- und Content Manager
WATER TECHNOLOGIES

Veolia Water Technologies Deutschland GmbH
Lückenweg 5
29227 Celle
www.veoliawatertechnologies.de
tobias.jungke@veolia.com

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 solution 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.

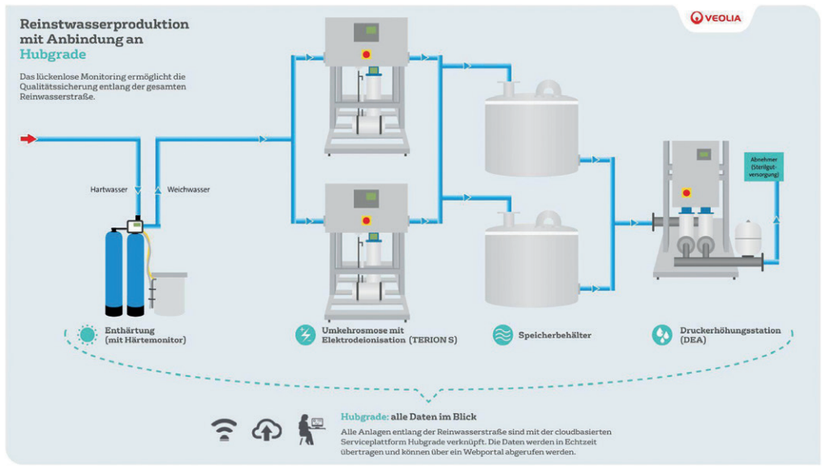


Fig. 1: Typical ultrapure water production with integration into Veolias Digital Services

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 operating 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 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 an indispensable 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 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 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 maintenance. The two smaller systems produce the qualitatively 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. Process 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 conditions 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 treatment 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 process steps can be logged and thus exactly traced. This makes modern systems less susceptible to misjudgements 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 medical facilities with manageable operating costs. Whether the combination RO/RO is sufficient for the processing of sterile goods or whether an RO/EDI is necessary must always be decided on a case-by-case basis together with water experts.

Legal notice

Scientific advisory council:
F. Brill, Hamburg
C. Diekmann, Detmold
S. Kaufmann, Saarbrücken
I. Konschake, Stendal
K. Mann, Regensburg
T. Miorini, Graz
F. v. Rheinbaben, Schwerin
J. Steinmann, Bremen

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

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

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

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

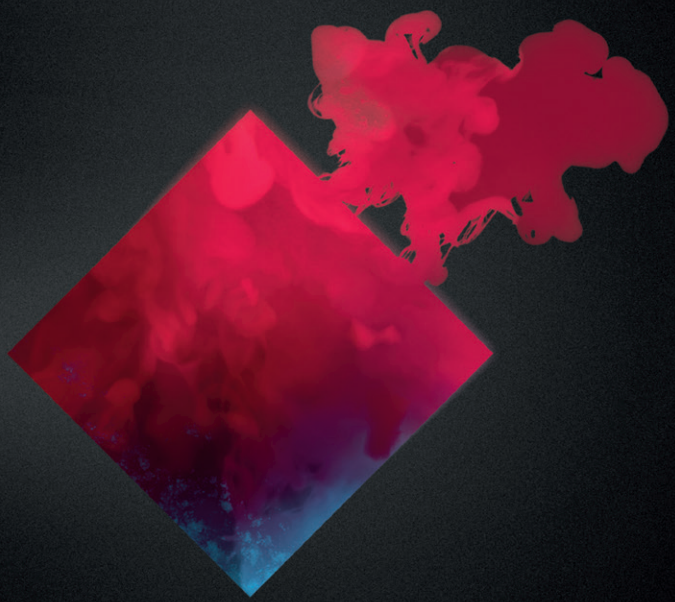
Editorial team:
Aaron Papadopoulos, Ecolab
Ulrike Weber, Miele
Stella Nehr-Werner, Dentsply Sirona
Iven Kruse, ebro
Tobias Junke, Veolia

Title image: Adobe Stock
Circulation: 5.200
Publication schedule: three times a year
Printed on chlorine-free bleached paper

ISSN 1439-9016

Miele

Move your **Practice.**



Miele
MOVE

Intuitiv, transparent, effizient:
Miele MOVE vernetzt Reinigungs- und Desinfektionsgeräte sowie Sterilisatoren, um die Aufbereitungsprozesse in Ihrer Praxis stetig weiter zu verbessern.

Die digitale Lösung verbindet komfortable Nutzeroberflächen mit hilfreichen Funktionen wie Prozessdokumentation und einer direkten Serviceunterstützung für ein effizientes Geräte-, Daten und Prozessmanagement.

Gewinnen Sie mehr Zeit für Ihre Patientinnen und Patienten: miele-move.com

Manage **O**ptimize **V**isualize **E**mpower

Miele Professional. Immer Besser.