

**Sterile Supply Specialist Training Course  
Level II**

**Fundamentals of Medical Device  
Reprocessing**

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# Fundamentals of Medical Device Reprocessing

## 1 Aims

Good cleaning and disinfection are essential prerequisites for effective decontamination of instruments and other medical devices in a Reprocessing Unit for Medical Devices (RUMED). The role of cleaning is to assure optimal conditions for effective sterilization and, in particular, protect patients against infection, whereas the purpose of disinfection as carried out during this process step is primarily to protect personnel.

This module is intended as a means of helping the student gain an understanding of the fundamentals of cleaning and disinfection, become acquainted with the merits, drawbacks and indications related to the various processes, get an idea of the types of process control and quality assurance measures needed, while becoming confident in the practical exercise of cleaning and disinfection duties. He/she should be able to recognize shortcomings and effectively overcome these.

## 2 Historical development of microbicidal processes

### (background)

Throughout the ages man has always more or less endeavoured to counter the spread of infectious (communicable) diseases. In the history of mankind the development of hygiene (infection control) was subjected to cultural trends. For example, while the Romans and Greeks, even from a present-day perspective, have impressive accomplishments to their name, in bathing hygiene, drinking water supplies and in disposal of effluent and waste, the Middle Ages are in general characterized by a marked decline in hygiene standards. Epidemic waves of plague, smallpox, cholera, the spread of tuberculosis and of malaria have had catastrophic effects. In many cases virtually entire regional populations were wiped out. This was accepted as fate, as punishment from God or was imputed to certain groups of people, to the power of demons or seen as a curse of the Devil. Man surrendered helplessly to this destiny.

In the absence of any knowledge of the microbiological processes at work here, infected and sick persons tended to be banished into isolation outside closed residential communities. This was more an instinctive than a deliberate measure. The spread of disease was also attributed to miasmas – that is to say to bad air. People used different devices, such as beak masks, to protect themselves against this “impure air” or they tried to improve the air by using various perfumes and essences, such as camphor, garlic, myrrh, pomander, sulphur, the shoots of coniferous trees, juniper berries, incense, onions, etc.

It was only in the mid 18th century that the first efforts were made to develop effective disinfectants. In 1774 chlorine was discovered. In the early 19th century the composition of hydrogen peroxide was identified and shortly afterwards hypochlorite began to be used as an antiseptic. Boiling water was recommended as a means of disinfecting it, and iodine and sodium hypochlorite (chlorine bleach liquor) were used to treat wounds. In 1834 phenol was produced from coal tar. In 1835 the very first disinfection regulation was decreed in Prussia. SEMMELWEISS recognized the need for hand disinfection with chlorinated lime in obstetrics. Quaternary ammonium bases and formaldehyde were discovered.

In 1867 LISTER began to test out carbolic acid (phenol), which at that time was being used to eliminate the odour emanating from wastewater drains. The antiseptic effects of carbolic acid were discovered in 1860 by LEMAIRE. He began preparing carbolic dressings and scored phenomenal successes in doing so: henceforth, there were markedly fewer cases of wound suppuration. Later, LISTER began washing hands and surgical instruments with carbolic acid. In his hospital in Glasgow the skin of patients was washed with carbolic acid and during surgery the patient was covered whenever possible with drapes impregnated with carbolic acid. LISTER finally developed a carbolic spray (can be viewed today in the Museum for the History of Man in Rome), which sprayed carbolic acid with steam into the operating room, resulting in, as reported by an eyewitness, the patient and surgeons being enshrouded in a carbolic mist. LISTER was thus the first person to have been able to successfully put into practice the new insights and observations.

As from 1877 L. PASTEUR set about studying anthrax in cattle and already back then drew attention to the importance of spores. Besides, he discovered that heating led to killing of many microorganisms (pasteurization).

In cholera wards dry heat was used for disinfection and PASTEUR generated overpressure (positive pressure) in an enclosed vessel through boiling. This was a method that was to become of decisive importance in physical disinfection, in particular in sterilization.

At around the same time, the bacteriostatic properties of silver were discovered, as were later the disinfectant properties of potassium permanganate in drinking water. In 1872 the disinfectant effects of ethyl alcohol were discovered. GAFKEY, KOCH and LÖFFLER in 1881 used flowing steam for disinfection, at somewhat the same time (saturated) steam under pressure was used for the first time for sterilization and at Wiesbaden Chemical Test Institute a carbolic soap solution was found to be suitable for disinfection. The bacteriologist ROBERT KOCH (1843 to 1910) discovered *Mycobacterium tuberculosis* and other bacteria. He defined standards (postulates) for microbiology.

In 1889 the disinfectant "Lysol" was introduced and first used in 1892 during a cholera epidemic in Hamburg. At around the same time M. TRAUBE recommended that drinking water be chlorinated. Peracetic acid was described in 1900 and chloramine in 1907. Already at that time FLÜGGE had made a distinction between surgical and hygienic hand disinfection.

From his studies on milk bacteria, FLÜGGE concluded that it was not possible to sterilize milk without considerably altering its taste and chemical properties. In practice boiling for 5 minutes is enough to render milk safe, even for infants, i.e. to kill any pathogens in the milk.

In 1898 FLÜGGE presented his method of room disinfection. A quantity of formaldehyde solution tailored to the specific room was introduced into the "Breslau apparatus" and brought to a vapour by adding a certain amount of methylated spirit. In this "FLÜGGE – apparatus" he had designed a method of room disinfection which to date has not been superseded.

In 1916 the bactericidal effects of quaternary ammonium bases were discovered and these were put to use by DOMAGK in 1935 as a disinfectant agent with good wetting and cleaning properties. It was only after 1945 that peracetic acid and glutardialdehyde (1963) were discovered as disinfectants.

Hence disinfectants and antiseptics were already in use for a long time before their method of action was at all understood.

### 3 Definition of terms and abbreviations

**Reprocessing:** reprocessing of medical devices, which as per their definition should only harbour a low microbial count or be sterile when put to use, means their cleaning, disinfection and sterilization after use for the purpose of reuse, including related procedures as well as verification and restoration of functional safety.

**Soils:** unwanted deposits found on surfaces.

**Cleaning:** removal and elimination of dirt. Aim: optically clean objects.

**Pretreatment:** elimination of course soils from MDs at the site of use.

**Precleaning:** cleaning that may be needed (manual or in ultrasonic basin) in the RUMED.

**Contamination:** a state where an object harbours pathogens.

**Disinfection:** killing or inactivation of pathogens and reduction of the microbial count with the aim of preventing the spread of infection via the disinfected object.

**Decontamination:** elimination of any microbial contamination present through disinfection to protect personnel.

**Sterilization:** killing or irreversible inactivation of all viable microorganisms (MOs); a process that means that there is a very high probability ( $10^{-6}$ ) that objects will be transformed to a sterile state.

**Microbial free state, sterility:** absence of microorganisms of any type (including, and in particular, of bacterial spores) with a probability of at least 1:1.000.000.

**Microbicidal:** endowed with the property of being able to kill microbes

**Microbiostatic:** able to stop the growth of microbes, but not to kill them

**Sporicidal:** able to kill spores (this refers to resistant bacterial spores and not to the more sensitive fungal spores)

**Antimicrobial:** used to counter microorganisms (viruses, bacteria, fungi, with no distinction made as to whether microbiostatic or microbicidal

**Toxic:** poisonous, harmful

**Teratogenic:** genotoxic

**Asepsis, aseptic:** states where microbes cannot be transmitted; no microbial transmission

**Antisepsis, antiseptic:** states where microbes on or in humans are controlled; harmful to microbes

#### Abbreviations:

**ppm:** parts per million or 1: 1.000.000 or  $10^{-6}$  (to the power of ten minus six)

**MD:** medical device

**RUMED:** *Reprocessing Unit for Medical Devices* (Category I-III)

**MPG:** Medical Devices Act

## 4 Introduction

### 4.1 *Microbiological risks*

The medical devices (MDs) to be reprocessed in a Reprocessing Unit for Medical Devices (RUMED) come into close contact with patients when used and can thus become contaminated with germs/pathogens (vehicles for spread of pathogens). Besides, since in busy medical departments the MDs are needed for different patients within a short period of time (outpatient departments, operating rooms, wards), germs could be easily spread if the MDs were not reprocessed after each patient. Hence MDs play a pivotal role in transmission of healthcare-associated infections and, as such, effective reprocessing of MDs is one of the prime aims of hospital hygiene.

While contaminated devices pose a risk primarily to patients, one must not forget that those persons entrusted with collection and delivery of MDs (i.e. RUMED staff) are also exposed to a major risk of infection (posed in particular by the causative organisms of hepatitis and of infections involving pus/suppuration).

MDs that permit microbial growth in the presence of moisture and nutrients (e.g. respiratory air humidifiers or moist cavities of MDs) can even be classified as infection sources and pose an additional risk to certain high-risk groups of patients.

Contaminated MDs represent a considerable potential risk:

- ◆ for healthcare workers (highest risk of infection emanating from cuts and puncture injuries)
- ◆ for patients for whom MDs subsequently used (hazard posed by inadequately reprocessed MDs)

### 4.2 *Strategies to prevent spread of infection via medical devices*

**Protection against contamination:** in principle this constitutes the most important strategy and plays a vital role in hand hygiene and in assuring hygienic surfaces. Since often this cannot be done in the case of MDs, the focus is on reprocessing!

Employment of **single-use devices** represents an effective and very attractive concept. But often this is expensive (procurement and disposal costs) and calls for large storage capacities and, in addition, in many cases employment of single-use devices means that hygiene problems are merely shifted to another area (e.g. problems related to large volumes of waste). Employment of single-use devices is indicated if the respective patient faces a high risk of contracting infection (urinary tract and vein catheterization, bronchial toilet, wound management; use of MDs in infectious patients or those especially at risk for infection) and if effective cleaning and disinfection cannot be guaranteed (e.g. hollow probes such as angiocatheters).

Devices designated for single-use only should not in principle be reprocessed since in general this entails a major risk of unsuccessful decontamination and, furthermore, such items might be damaged by the reprocessing methods normally used.

**Reprocessing of reusable devices** is in many cases the most advisable and economical strategy. Reprocessing is intended as a means of cleaning and disinfecting (or sterilising) medical devices and making them available for reuse in a functional state. This represents the most important function of the RUMED.

The entire reprocessing process and the reprocessed medical device must not pose a risk to the safety of patients, users or third parties.

## 5 Cleaning

Good cleaning is the most important **precondition** for effective **disinfection (and sterilization)**!

Under **normal conditions** (i.e. no epidemic microorganisms such as of plaque, cholera, etc.; disposal of washing residues via a closed drainage system, organized wastewater elimination), automated reprocessing processes are aimed at, first of all, removing soil as far as possible from objects before the disinfection step (cleaning before disinfection). This optimally combines mechanical removal and killing of microbes.

Only in **exceptional cases** (epidemic situation such as of plaque, cholera, haemorrhagic fever etc.) is there the requirement that the microorganisms removed from the materials being washed be killed before the cleaning solution enters the drainage system. These special cases also require that particularly intensive disinfection processes be used since despite the burden of soils they must assure effective disinfection (disinfection before cleaning).

If (in exceptional cases) (pre-) cleaning must be conducted manually, the exceptional regulations outlined below for epidemics apply: the materials must be disinfected before cleaning to protect the cleaning staff. In the last mentioned cases the disinfecting agent has to be extraordinary efficient to be able to kill microorganisms under “dirty conditions” but must not have a protein fixating effect. Therefore a combination of cleaner and disinfectant should be used.

### 5.1 *Fundamentals of the cleaning technology*

#### 5.1.1 Active components of a cleaning process using water

The four principal factors underlying cleaning are: mechanical action, time, temperature and chemical action.

The Sinner Circle describes the mutual dependence between these four factors and their reciprocal relationships. These are highlighted by the following two examples (see figure 1):

A single-tank washer-disinfector (WD used for instruments) with long cleaning times is capable of operating with comparatively smaller input of mechanical action, chemical action and temperature. A bedpan washer-disinfector, which is expected to operate quickly and can hardly utilise any chemicals (since recirculation of the cleaning solution is not possible) must as far as possible be endowed with a powerful cleaning mechanical action.

This means: if one reduces one of these factors, one has to increase one or several of the others to assure the same cleaning result. For example: the factor time is generally the chief determinant, but to reduce its impact either the chemical and mechanical action have to be reinforced or the temperature increased.

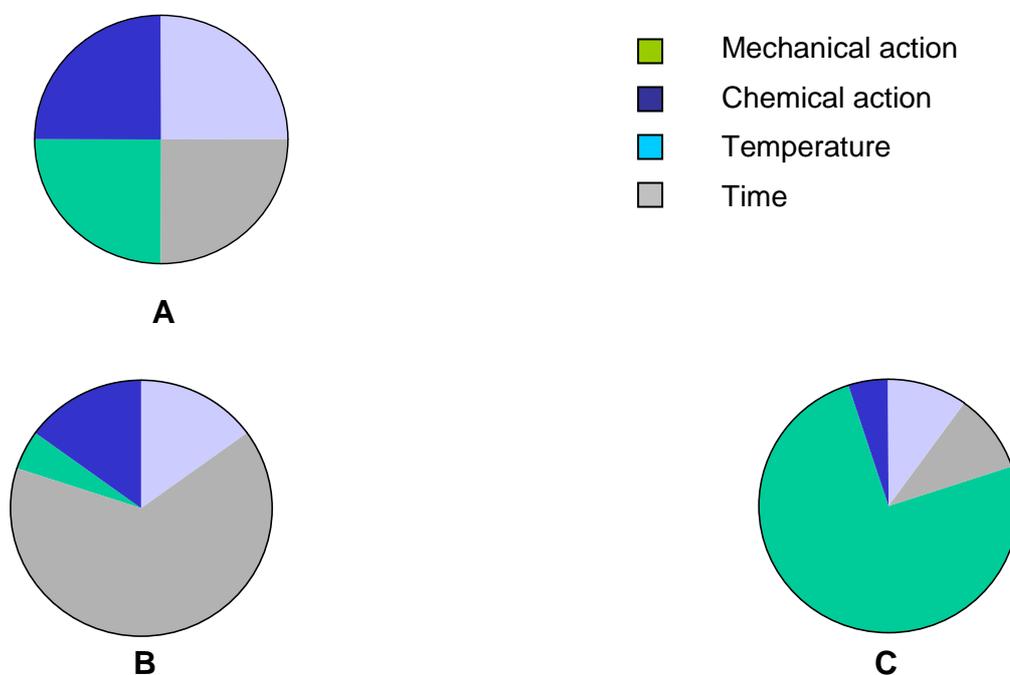


Fig. 1: Sinner cycle; A: Ideal case; B: Washer-disinfector for instruments; C: Bedpan washer

#### 5.1.1.1 Mechanical action factor

Mechanical energy is one of the most effective and least expensive resources in the cleaning process and has no negative impact on the environment. Nonetheless, many of the WDs used for medical devices do not operate with optimal cleaning action, thus resulting in increased use of chemical substances and prolonged processes. To prevent this, it is important that the cleaning efficacy of a WD is proved according to ISO 15883.

To clean with water, the water must be properly circulated:

- ◆ nozzle technology (permanently assembled or fitted to spray arms)
- ◆ washing machine drum principle etc.

**Nozzle systems** can produce good cleaning results, but often their limits are reached if

- ◆ the water quantity is too little,
- ◆ the water jets disintegrate (too fast a rotational speed, spray angle open too wide),
- ◆ if opposing influences begin to be exerted (colliding water jets, water build-up on surfaces),
- ◆ the pump pressure is not sufficient, e.g. because of foam formation.

Good nozzle systems are designed to ensure that, using a limited amount of water and within an acceptable period of time, an appropriate water jet, endowed with enough energy and set at an optimal angle, will reach all surfaces to be cleaned. This calls for – in addition to an appropriate water supply – suitable types of nozzles and nozzle arrangement:

#### 5.1.1.2 Temperature factor

An increase in temperature can improve the cleaning results (reducing viscosity of water and of fatty contaminants, and enhancing activity of detergents and chemical substances).

*But:* as from around 55 °C, proteins denature (i.e. their chemical nature is destroyed), causing “baking” of soils on the underlying surface.

Therefore effective cleaning is also needed, in particular, before thermal disinfection processes!

#### 5.1.1.3 Chemical action factor

Automated cleaning processes are underpinned by manifold chemical substances:

- ◆ surfactants (reducing surface tension of water and enabling it to penetrate cavities and gaps)
- ◆ complexing agents (helping to suspend soils in water)
- ◆ acids or alkaline solutions (acid dissolves lime, including inorganic soils, while alkaline solutions cause proteins to swell)
- ◆ emulsifiers (helping to suspend fats in water)
- ◆ solvents (helping to suspend fats, including organic substances in water)
- ◆ oxidizing agents (bleach soil pigments)
- ◆ etc.

#### 5.1.1.4 Time factor

Time underpins the effect of all other factors mentioned.

If time is in short supply, one has to either improve the mechanical action, use expensive, aggressive chemicals or be prepared to accept poor cleaning results. However, as pointed out above, the latter is unacceptable in MD reprocessing in order to protect patients and staff against infection. But time does not always solve all (cleaning) problems; in particular in the case of MDs there are soils (e.g. “gynaecological blood”) or MD designs (e.g. minimally

invasive surgical (MIS) instruments, non-dismantable instruments), where satisfactory results are not obtained despite enough time.

## **5.2 Cleaning processes**

The most important difference in cleaning processes is seen between manual and automated processes.

**Manual** processes are based on the use of muscle force and cleaning adjuncts (cloth, brush and water, and possibly with nozzles as well as chemical detergents). But the outcome is dependent on the care taken by the person discharging this task (and on training, motivation, time shortage) and is therefore very variable (i.e. very hard to standardise and almost impossible to reproduce). When handling medical devices that have been used and are thus possibly contaminated with pathogens such a staff member is also at risk (aerosols when using nozzles and brushes, risk of injury from pointed and sharp objects).

**Automated** processes try to deploy the aforementioned technical adjuncts in as optimal a manner as possible. Using a fully automated WD, the operator need only load the WD and start the cleaning process. All further steps will be executed by the programme control facility without any input from a human operator. Since the process unfolds within a closed chamber, any risk of infection of operating personnel is largely ruled out.

This topic will be elaborated on further in the following chapters.

## **6 Disinfection**

**Disinfection** means killing or inactivating germs and reducing the number of germs such that the disinfected objects can no longer transmit infection.

It is not aimed at complete elimination of all microorganisms (sterilization) since this is not needed in all cases. The discrepancy whereby among those spore-forming bacteria that are not killed by disinfection there are also disease-causing pathogens (e.g. bacteria causing gangrene, tetanus) can be explained by the fact that it is only under special circumstances that the latter will cause infection (penetration into sterile, poorly oxygenated tissue).

There are several ways of killing microbes. In principle, a distinction is made between chemical and physical methods. This division is further categorized by specification of the methodology used (see Fig. 2) and, on the other hand, by the spectrum of action (**see Specialist Course Level 1 Script**).

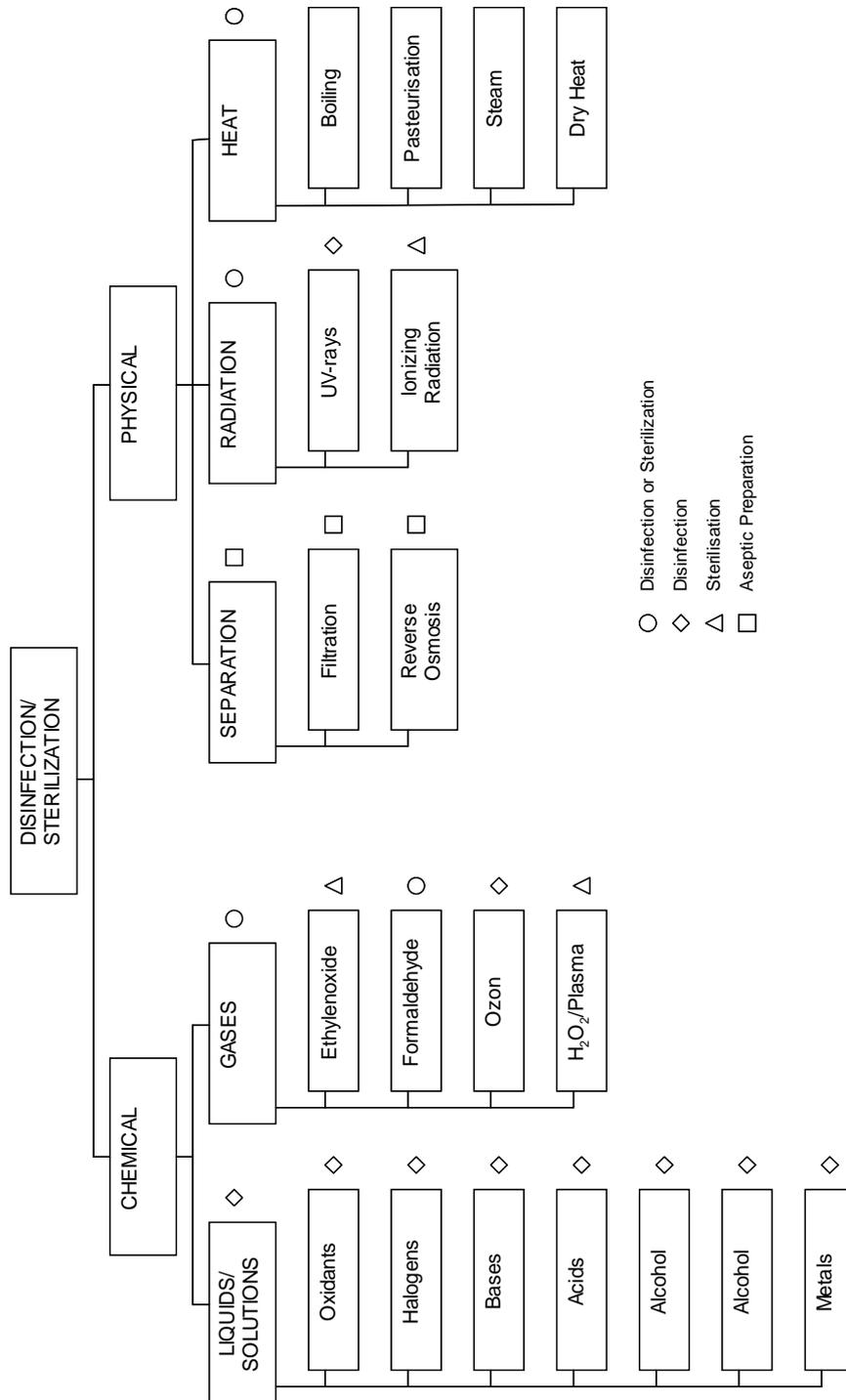


Fig.2: Agents and processes to reduce microbial count (as per Bodenschatz, 1993)

## 6.1 Thermal disinfection of MDs

During thermal disinfection enough heat energy must be transferred to the microorganisms so as to kill them. The thermal capacity (specific heat) of water (or steam) is much greater than that of hot air. This difference is due to **condensation** of steam. When steam at 100 °C condenses to water at 99 °C, 2,260 times more energy is released than when a similar amount of air at 100 °C cools down to 99 °C. *Moist heat is thus much more suitable than dry heat for disinfection. (see Specialist Course Level 1 Script)*

### 6.1.1 Thermal resistance of microorganisms

Bacteria can be classified according to different criteria. The features commonly used for classification are e.g. shape, staining properties, motility, spore formation or oxygen requirement (example: *Staphylococcus aureus* is a Gram-positive, aerobic, non-spore-forming, non-motile spherical bacterium).

However, these differentiation characteristics are not important in the context of thermal disinfection and sterilization. In this respect the only differentiation feature of relevance is the extent to which the various microorganisms can be inactivated at certain temperatures. This property known as **heat resistance** thus gives insights into which microorganisms will be able to survive under which temperature conditions and for how long.

To assure a uniform approach, heat resistance levels have been introduced since it has been demonstrated that different groups of microorganisms show considerable differences in their resistance to heat.

Resistance level	Microorganisms (test organisms)	Processes used in practice	Temperature and exposure time	Corresponds to spectrum of action
1	All vegetative forms of bacteria, fungi and fungal spores, viruses, parasites ( <i>Enterococcus faecium</i> )	Pasteurization, thermal disinfection of instruments, laundry, crockery	e.g. 62 °C/ 30 min e.g. hot water 85°C/ 10 min 90 °C/ 1-5 min	A, B  without HBV with HBV
2	Anthrax spores (spores of <i>Bacillus subtilis</i> )	Steam disinfection processes	e.g. flowing steam 100 °C/ 15 min	A, B, C
3	Gangrene and tetanus spores (spores of <i>Geobacillus stearothermophilus</i> )	Steam sterilization	e.g. (saturated) steam under pressure 121 °C/ 15 min or 134°C / 3 min	A, B, C, D (corresponds to sterilization in med. setting)
4	Highly thermoresistant thermophilic organisms, prions	Prolonged steam sterilization (of importance only for prions)	e.g. (saturated) steam under pressure 134 °C/ > 20 min	A, B, C, D + prions

Tab.1: Resistance levels of microorganisms and thermal processes used to kill them. Given in parentheses are the test organisms used to represent the respective resistance level (as per FLAMM, amended)

Designation of spectra of action of the various processes based on the List of Disinfectants tested and approved by the German Health Office:

A = killing of vegetative bacteria, including mycobacteria, fungal spores

B = inactivation of viruses

C = killing of anthrax spores (*Bacillus anthracis*)

D = killing of gangrene-, gas oedema- and tetanus-spores

### 6.1.2 Soils as an obstacle

When using heat for disinfection it must be ensured that the heat energy will be transferred to the microorganisms. The latter can be enclosed in various types of soil particles (e.g. blood, secretions) and thus protected in the short- or long-term against the effects of heat. This protective mechanism can be particularly reinforced by **denaturation**<sup>1</sup> of the protein substances enclosing the soil.

### 6.1.3 Thermal disinfection processes

The following thermal disinfection processes are important in practice:

- ◆ Pasteurization (e.g. milk)
- ◆ Hot water processes incl. Boiling (e.g. MDs, dishes, textiles)
- ◆
- ◆ Steam disinfection (e.g. mattresses, bedsteads)
- ◆ Incineration (e.g. waste)
- ◆ Annealing (e.g. for bacteriological loops)

**Pasteurization** means heating liquids to inactivate vegetative bacteria and fungi (fruit juices, milk, meat products).

**Hot water** at temperatures between 85 and 93 °C is used – in combination with effective cleaning processes – e.g. in instrument washer-disinfectors or dishwashers as well as thermal laundry disinfection.

**6.2** Steam disinfection *is based on the penetration of steam into the porous materials undergoing disinfection and on the high amount of heat released by the steam. Modern steam disinfectors operate at a slight overpressure and at temperatures of around 105 °C. When disinfecting delicate materials (furs, leather, books) lower disinfection*

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<sup>1</sup> Denaturation: chemical altering of the structure of proteins through chemical or physical influences

***temperatures are used, which means that, reflecting the lower steam pressure of the water in the disinfection chamber, subatmospheric pressure will prevail (approx 400 mbar abs. at 75 °C). Chemical disinfection***

In chemical disinfection microbes are killed by bringing the materials into contact with chemical disinfectants. This leads to denaturation of the protein of microorganisms, thus killing them.

### **6.2.1 Application methods**

Most disinfectants are used as a solution, but some are gases.

While immersion in a disinfectant solution is in principle an effective method which has been used for a long time for disinfection of MDs (and continues to be in some cases). But the disinfectant effect will not unfold in objects whose surface are not wetted by the solution (not fully immersed, air bubbles, high boundary surface tension, inadequate cleaning). Disinfection of narrow-lumened hollow objects is particularly challenging, e.g. the irrigation and manipulation channels of endoscopic instruments. These must be actively rinsed out with disinfectant solution. Since the disinfectant action will decline in tandem with increasing level of contamination, the immersion basins must be replenished at regular intervals (in general on a daily basis, except where there are expert opinions attesting to efficacy over a certain period of time even in the presence of a high protein load).

A wipe and scrub disinfection method is used for surfaces (and possibly for MDs with large surfaces, e.g. anaesthesia equipment). The mechanical effect plays a pivotal role in assuring successful disinfection since it may be necessary to break down protective envelopes enclosing the soils and the disinfectant must gain access to the microorganisms. This application method should therefore be given preference over spray disinfection. The latter also leads to higher build-up of disinfectants in the air and some substances (e.g. alcohols) can pose an explosion or fire hazard.

Gassing the materials to be disinfected with alcohol or peracetic acid vapours, formaldehyde or H<sub>2</sub>O<sub>2</sub> (hydrogen peroxide) cannot under any circumstances be viewed as constituting “reliable/safe” disinfection. A disinfectant or sterilization effect will unfold only subject to certain conditions that are difficult to control. These types of disinfection call for special equipment (e.g. ethylene oxide (EO) or formaldehyde (FO) sterilizers; **see chapter “Fundamentals of Sterilization”**) and may be carried out only by specially trained personnel.

The term chemothermal disinfection is used when chemical substances and heat are used together (e.g. for heat-sensitive objects such as flexible endoscopes in a WD)<sup>2</sup>.

## 7 Reprocessing of medical devices

**See also Guideline by the Robert Koch Institute (RKI): Hygiene requirements for reprocessing medical devices ([www.rki.de](http://www.rki.de))**

This chapter focuses on the main purposes for which cleaning and disinfection are used in the everyday RUMED activities. The following medical devices are the most commonly encountered in this setting:

- ◆ Normal surgical instruments
- ◆ Special surgical instruments (MIS, microsurgery)
- ◆ Rigid and flexible endoscopes
- ◆ Anaesthesia and respiratory accessories
- ◆ Possibly, collection vessels for secretions and drainage fluids

### Definition of "reprocessing":

Reprocessing of medical devices, which as per their definition should only harbour a low microbial count or be sterile when put to use, means their cleaning, disinfection and sterilization after use for the purpose of reuse, including related procedures as well as verification and restoration of functional safety.

### Reprocessing includes:

- ◆ Preparations (pretreatment, collection, if necessary precleaning, dismantling and transportation),
- ◆ Cleaning / disinfection, rinsing and drying,
- ◆ Testing for cleanliness and integrity, identification,
- ◆ Maintenance and repairs,
- ◆ Functional testing,
- ◆ Labelling,
- ◆ Packing,
- ◆ If necessary sterilization,
- ◆ Documented release of medical devices for use (QM).

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<sup>2</sup> The term "chemothermal" refers only to disinfection, but not to cleaning which is always carried out using chemical substances

### **Aim of reprocessing**

The entire reprocessing process and the reprocessed medical device must not pose any danger to the safety of patients, users or third parties.

Reprocessing must ensure that the reprocessed medical device will not pose any risk of damage to health when subsequently used, in particular such as:

- ◆ Infections
- ◆ Pyrogen-mediated reactions<sup>3</sup>
- ◆ Allergic reactions (due to chemical residuals)
- ◆ Toxic reactions (due to chemical residuals)
- ◆ or risks arising from changes in the functional safety of the medical device

<sup>3</sup> Pyrogens are fever-inducing substances, e.g. endotoxins (poisonous substances produced by bacteria when they are killed)

**To reach this aim the validation of all steps of reprocessing is essential!**

### **7.1 Responsibilities of manufacturer/ distributor**

In EU the manufacturers and distributors of medical devices are obliged to supply the user with appropriate reprocessing instructions that comply with the state of the art (i.e. with the pertinent standards). The minimum requirements governing such reprocessing instructions are set out in the international standard EN ISO 17664. Pursuant to the latter, a (validated) manual and automated process must be specified in each case. Users are called upon to demand these from the manufacturers/distributors. Reprocessing instructions such as those stating “Immerse in a lukewarm soapy solution” or “manual cleaning using a pipe cleaner” are unacceptable and must be rejected. In this respect it must be pointed out that in recent times a new term has appeared: “prevalidation”. This is understood to mean checking a medical device for amenability to cleaning/disinfection and sterilization under all circumstances of use. This means that a medical device is investigated under laboratory conditions, but using everyday reprocessing procedures to determine whether and under what conditions it can be reprocessed in compliance with the state of the art.

Remark: the term “validation” (unfortunately, despite harmonized legislation and standards, etc.) is not interpreted to mean the same thing throughout Europe (not to mention on a worldwide basis). For example, some European manufacturers are marketing their medical devices as “validated medical devices”, something that, of course, is not possible since it is the processes and not the devices that can be validated. This may – in the most positive sense – be intended to convey the prevalidation mentioned above, but in many cases it is merely a marketing ploy used in the hope that while the user is familiar with the word he will not exactly understand what it means.

## 7.2 **Classification into risk groups**

As per the RKI guideline “Hygiene requirements for reprocessing medical devices”, MDs are subdivided into three groups on the basis of the infection risk encountered at the time of use.

**See also RKI Guideline: Hygiene requirements for reprocessing medical devices ([www.rki.de](http://www.rki.de) )**

**Non-critical medical devices** are MDs that only come into contact with intact skin.

**Semi-critical medical devices** are MDs that come into contact with mucous membranes or with pathologically altered skin.

**Critical medical devices** are MDs that penetrate the skin or mucous membranes or come into contact with wounds or are used for blood, blood products and other sterile medicinal products

In addition, semi-critical and critical MDs are subdivided in accordance with their reprocessing requirements:

**Group A (simple design):** no special reprocessing requirements

**Group B (complex design, lumens/cavities):** more demanding reprocessing requirements

**Group C (only critical MDs):** ultra stringent reprocessing requirements

Based on the forthcoming regulation concerning Article 94 of the Medical Devices Act (MPG), assignment of the MDs to be reprocessed to the aforementioned groups will be legally binding. For guidance for doing so, please refer to the flow chart (Fig. 3 and 2b) as well as assignment table in the annex.

The following criteria must be borne in mind when classifying the MDs:

- ◆ how is the medical device constructed / designed?
- ◆ of what materials is it made?
- ◆ where is it used?
- ◆ what temperature may be used for disinfection and sterilization?
- ◆ what detergents and disinfectants may be used?

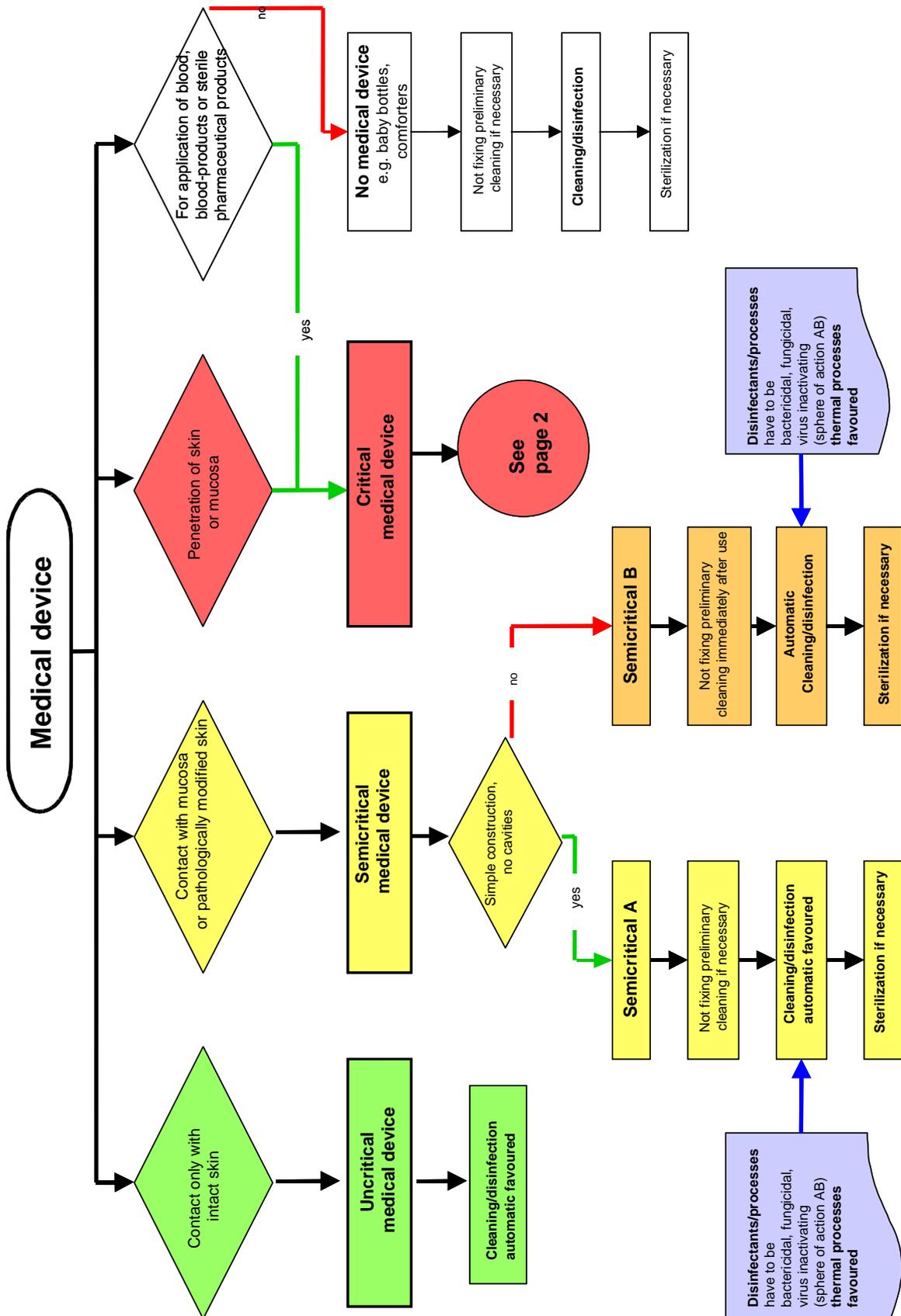


Fig 3.: Classification into risk groups as per RKI (non-critical, semi-critical)



Fig. 4: Classification into risk groups as per RKI (critical)

### 7.2.1 Non-critical MDs

Examples: bedpans, stethoscope, blood pressure cuffs, plaster cast scissors

Reprocessing: for cleaning and disinfection preferably automated reprocessing (i.e. manual reprocessing not ruled out).

Sterilization: generally not needed

### 7.2.2 Semi-critical MDs

#### **Semicritical A:**

Examples: forceps, dressings' scissors, laryngoscopy spatula, etc.

Pretreatment: use non-protein-fixing agents/processes if necessary

Reprocessing: for cleaning and disinfection preferably automated reprocessing (i.e. manual reprocessing is not ruled out)

Sterilization: if needed (preferably steam sterilization).

#### **Semicritical B:**

Examples: anaesthesia tubes, breathing masks, flexible endoscopes, etc.

Pretreatment: with non-protein-fixing agents/processes immediately after use

Reprocessing: for cleaning and disinfection only automated reprocessing (i.e. manual reprocessing is ruled out or permitted only for special items)

Sterilization: if needed (preferably steam sterilization).

### 7.2.3 Critical MDs

#### **Critical A (e.g. simple surgical instruments)**

Examples: forceps, clamps, scissors, bowls etc.

Pretreatment: if needed, with non-protein-fixing agents/processes immediately after use

Reprocessing: cleaning (preferably alkaline) and disinfection (preferably automated/thermal) as soon as possible after use to prevent drying of contaminants and corrosion damage (i.e. manual reprocessing is not ruled out),

Sterilization: preferably steam sterilization.

In principle, the following must be borne in mind:

- ◆ The MDs have shafts or ratchets – special attention must be paid to these when placing the device in the WD.
- ◆ Pay special attention to grooves and joints when inspecting cleaning.

**Critical B (e.g. special surgical instruments, MIS instruments)**

MDs belonging to Critical B risk group are MDs that need special treatment because of their particular features or susceptibility.

They make special demands on the WD and personnel. In general it is hard to determine whether the MD is clean (e.g. hollow instrument) and whether the functional capabilities are intact after reprocessing.

Examples: suction devices, dismantlable drivers, arthroscopy shafts, MIS instruments, etc.

Pretreatment: with non-protein-fixing agents/processes immediately after use

Reprocessing: only automated reprocessing; preferably alkaline cleaning, thermal disinfection

Sterilization: steam sterilization

The main focus here, too, is on automated cleaning and disinfection, without any manual substeps. To that effect, suitable loading trolleys are needed for the WD. Recesses and gaps in instruments must be cleaned directly. Instruments with cavities and channels must be connected to the nozzle system in a manner that assures good purging of cavities. For some instruments (e.g. those with a spiral guide wire) ultrasonic treatment in a cleaning and disinfectant solution can be highly effective. Also a combination of ultrasonic treatment and active purging are helpful (for long and narrow lumens).

The instruments for minimally invasive surgery (MIS) (“keyhole surgery”) pose a particular challenge: long, instruments with thin shafts and narrow lumens, moveable parts and cavities that are difficult to access must which work to a high degree of precision, transfer high forces without becoming deformed - and should be optimally cleaned and sterilized after use. It is precisely in this setting that one continues to encounter reprocessing methods that are not able to withstand the test of critical hygiene scrutiny. Effective cleaning and disinfection are virtually impossible without dismantling the device and thoroughly cleaning it. But dismantling a device often means that it will be less mechanically robust. Therefore one often faces the dilemma of having to choose between expensive single-use instruments, where complicated reprocessing can be dispensed with, and reprocessing, something that calls for very suitable washer-disinfectors (MDs).

In principle, single-use materials must be used instead of parts that are difficult to clean, are highly contaminated and cannot be reliably cleaned.

**Critical C (special surgical instruments that do not tolerate steam sterilization)**

These include MDs with e.g. critical B features but which do not tolerate steam sterilization. In principle, one must decide whether reprocessing can at all be carried out in a responsible

manner and non-single-use materials are available (e.g. angiography catheters). As per the forthcoming regulation, reprocessing must be conducted in a RUMED with a quality management system based on ISO 13485.

Examples: Choledochoscopy, angioscopy, epiduroscopy

Pretreatment: with non-protein-fixing agents/processes immediately after use

Reprocessing: preferably alkaline cleaning, disinfection (preferably automated/thermal)

Sterilization: suitable validated low-temperature sterilization process sterilization (e.g. formaldehyde sterilization).

### **7.3 Automated reprocessing**

Automated cleaning and disinfection in washer-disinfectors (WDs) should in principle be given preference over manual processes, for the following reasons:

- ◆ can be standardized (better reproducibility)
- ◆ less likelihood of application errors (see below)
- ◆ high degree of reprocessing reliability (thermal process)
- ◆ better control
- ◆ much less onerous
- ◆ much less demanding for staff
- ◆ fewer staff members needed
- ◆ less risk of damage to instruments
- ◆ less risk of contamination
- ◆ documentation of process parameters for each production batch
- ◆ documentation of responsibilities, process errors, repairs, etc.
- ◆ evaluation of process errors

Of paramount importance for an effective disinfectant action in such machines is, first, the quality of the cleaning system. This is particularly true if the soils to be eliminated have or may have a high microbial load (e.g. blood, pus, stools, infected urine or food residues harbouring microbes); in such cases even minute soil residues can lead to failure of the ensuing disinfection.

The cleaning results obtained in reality will depend not only on the constructional features of the machine but rather in particular on their correct positioning (placing supplies such that they can be cleaned properly, no overloading of machine, no impeding of moveable parts of cleaning systems) and proper maintenance (clean nozzles and filters, etc.).

The thermal disinfection processes integrated into the machine's programme generally involve the application of hot water (e.g. 90 °C/ 5 min) to the cleaned supplies, while during

the chemothermal processes chemical substances are added to the not so hot water (e.g. 60 °C).

The lower the temperature, the longer will be the exposure time needed and the more susceptible the disinfection process to interference factors, in particular to poor cleaning.

Chemothermal automated reprocessing is suitable for complex devices, such as flexible endoscopes, as well as for simple objects such as synthetic surgical shoes. **Note:** surgical shoes are not medical devices, therefore there is no need for validation of the method used to reprocess them.

The process generally comprises five steps:

1. **Prerinse** – cold water, without any additives, is used to remove coarse contaminants; in some WDs the use of a 2nd prerinse step, with addition of a small amount of detergent, has proved helpful.
2. **Cleaning** – cleaning is carried out at a temperature of 40 – 60 °C using a detergent (*Caution: in the case of certain detergents the dosage temperature is the chief determinant of foam formation, i.e. if the dosage temperature is too low, an enormous amount of foam can be produced*)
3. **Intermediate rinse** – the cleaning solution is removed with hot or cold water
4. **Disinfection** – thermal disinfection is performed using fresh demineralized water at a temperature between 80 and 93 °C. To inactivate hepatitis B viruses, which are particularly temperature resistant, as a rule a temperature of at least 90 °C is needed
5. **Drying**

### 7.3.1 Requirements for washer-disinfectors

The requirements to be met by WDs for reprocessing MDs are set out in the series of standards ISO 15883, Parts 1-4.

Part 1: General requirements, terms, definitions and tests

Part 2: Requirements and tests for washer-disinfectors (employing thermal disinfection) for surgical instruments, anaesthesia equipment, bowls, dishes, receivers, utensils, glassware, etc. (= instrument washer-disinfectors)

Part 3: Requirements and tests for washer-disinfectors (employing thermal disinfection) for human waste containers (= bedpan washer-disinfectors)

Part 4: Requirements and tests for washer-disinfectors (employing chemical disinfection) for thermolabile endoscopes (= endoscope washer-disinfectors)

Part 5 (ISO/TS 15883-5): Test soils and methods for demonstrating cleaning efficacy of washer-disinfectors.

This technical specification contains a number of (national) methods, which are used for type testing and (re)validation.

Routine monitoring of washer/disinfectors can be carried out as follows:

- Physical parameters (temperature and time) are monitored at each cycle (EN ISO 15883).
- Visual cleanliness of the devices are checked after each cycle
- Sensitive tests for detection of residual protein on cleaned instruments should be carried out e.g. weekly.
- Cleaning indicators can be used to demonstrate reproducibility of the washing process.

When issuing calls for tenders before purchasing new machines, compliance with these standards should be set out as a precondition. For machines already in operation, the following minimum requirements should be met to assure validation:

- ◆ automated programme cycles (if possible, providing for customized programming)
- ◆ (adjustable) temperature displays
- ◆ automated dosage of process chemicals (this should permit complete volumetric control)
- ◆ continuous error message generation in the event of programme malfunctioning (water shortage, temperature too low in disinfection phase, process chemicals' shortage)
- ◆ batch counter (or documented control system)
- ◆ process documentation (min. temperature/time variables as ACTUAL values, date, time)
- ◆ if necessary, suitable inserts for hollow instruments (MIS, AN)

**See also “ÖGSV Guideline for Testing, Validation and Monitoring of Automated Cleaning and Disinfection Processes for Medical Devices”**

**([www.oegsv.com](http://www.oegsv.com) > guidelines).**

### **7.3.2 $A_0$ values for thermal disinfection processes**

In the ISO 15883-1 the term  $A_0$  has been introduced as a measure for the killing of microorganisms in moist-heat processes (hot water). From such a disinfection process one can expect that a temperature over a certain period of time will kill a predictable number of microorganisms, which are endowed with a particular resistance. If particularly resistant microorganisms are selected and in a number that exceeds that found in everyday practice, the required temperatures and exposure times can be specified in a standardized manner. If these values are complied with, it is assumed that

the process will guarantee the requisite reduction. Being able to assume that the preceding cleaning step was impeccably executed is, of course, a precondition here.

What  $A_0$  value has to be reached will depend on the nature and number of microorganisms to be expected on the medical devices to be reprocessed as well as on the ensuing treatment steps (e.g. sterilization) or subsequent use.

The infection control (hygiene) team or the hospital's infection control officer is responsible for specification of the  $A_0$  values, bearing in mind the following recommendations.

The use of an  $A_0$  value of 60 for non-critical medical devices that only come into contact with healthy skin (as per RKI) is considered to be a minimum (e.g. bedpans).

An  $A_0$  value of 600 is viewed as adequate for semi-critical MDs if only a low microbial count can be assumed and no heat-resistant pathogens are likely to be present.

For all critical medical devices that could be contaminated with heat-resistant microorganisms, such as hepatitis B viruses, and are intended for use in physiologically sterile regions of the body or come into contact with blood, the RKI recommends thermal disinfection with an  $A_0$  value of at least 3000, corresponding to the AB spectra of action.

This can be achieved, for example, by exposure to hot water at 90 °C provided that the surface of the MD to be disinfected is able to reach, and withstand, this temperature, for at least 5 min.

Temp. of process (°C)	Exposure time for $A_0=3000$ (Ins. WD incl. hepatitis B)		Exposure time for $A_0=600$ (Ins. WD excl. hepatitis B)		Exposure time for $A_0=60$ (bedpan WD)	
	Sec	min	sec	min	Sec	min
65	94868	1581.1	18974	316.2	1897	31.6
70	30000	500.0	6000	100.0	600	10.0
75	9487	158.1	1897	31.6	190	3.2
80	3000	50.0	600	10.0	60	1.0
85	949	15.8	190	3.2	19	0.3
87	599	10.0	120	2.0	12	0.2
90	300	5.0	60	1.0	6	0.1
93	150	2.5	30	0.5	3	0.1
95	95	1.6	19	0.3	2	0.03

Ins. WD: Washer-disinfectors for instruments

Tab. 2:  $A_0$  values for various areas where medical devices used

The ÖGSV Specialist Committee for Testing takes a rather sceptical view of the Ao concept and rejects thermal disinfection below a start temperature of 80 °C (see Commentary on the ÖGSV homepage > “guidelines”).

### **7.3.3 Procedure for automated reprocessing**

- ◆ Remove course organic soils immediately after use (at site of use) with a cellulose cloth (e.g. tissue residues, pus, adherent substances such as bone cement)
- ◆ Contamination-proof transport to washer-disinfector
- ◆ Prepare devices/materials for disinfection: dismantle into individual parts, open jointed instruments
- ◆ Place sensitive instruments (e.g. probes) in trays or on special racks
- ◆ Do not overload trays
- ◆ Avoid spray shadowing caused by bigger objects, such as kidney bowls!
- ◆ Instruments with hollow spaces: use appropriate loading trolleys equipped with cleaning nozzles (internal cleaning)
- ◆ Check instruments for residues
- ◆ If there are any visible residues, clean and disinfect once again

## **7.4 *Manual reprocessing***

Formerly, manual reprocessing of medical devices was very common. Today, it should be limited to medical devices belonging to the risk group A and then only following pre-disinfection (decontamination) in order to protect personnel. Chemical decontamination in an immersion basin at ambient temperature is a process whose effectiveness is limited.

Gloves must be worn to minimise contact with disinfectants.

If pre-disinfection is not possible in exceptional cases, special protective measures must be taken when cleaning:

- ◆ Gloves and apron
- ◆ Orofacial mask and goggles
- ◆ Do not use brushes or cleaning nozzles because of the risk of spraying infectious materials or aerosols
- ◆ Dispose of protective clothing properly
- ◆ Disinfect hands and working surfaces on completion of cleaning tasks

In such a case disinfection is performed after cleaning, and chemical processes can also be used for certain MDs (risk group A and special materials that must not be subjected to automated thermal disinfection).

Disinfected items should in principle be dried as quickly as possible and stored in a dry place to avoid recontamination.

### **7.4.1 Procedure for manual disinfection**

- ◆ Products that are effective against HBV (HBV efficacy covers HCV and HIV) (called high level disinfectants, see Table 3)
- ◆ Replenish disinfectant solutions daily (except where there are expert opinions attesting to efficacy over a certain period of time even in the presence of a high protein load)
- ◆ Disinfection basin with filter and lid
- ◆ Immerse instruments fully in disinfectant solution, ensuring there are no air bubbles (use ultrasonic equipment if necessary)
- ◆ Wait until end of exposure time (set timer)
- ◆ Remove filter from basin and rinse instruments carefully under running water
- ◆ Rinse with demineralized or distilled water
- ◆ Check instruments for residues
- ◆ Dry carefully with disposable gloves, purge hollow instruments with compressed air

### **Potential errors made in manual disinfection**

- ◆ Incorrect dosage
- ◆ Exposure time too long or too short (the exposure time starts at the time the last instrument is placed in the solution)
- ◆ Inadequate wetting of instruments (instruments not fully immersed in the solution, hollow instruments)
- ◆ Solution not replenished as often as needed (protein error)
- ◆ Concentrate past its expiry date

<b>High-level disinfectants</b>	<b>Concentration</b>
Glutaraldehyde	> 2.0 %
Orto-phthalaldehyde (OPA)	0.55 %
Peracetic acide*	0.2 %
Hydrogen peroxide*	7.5 %
Hydrogen peroxide + peracetic acide*	1.0 / % 0.08 %
Hydrogen peroxide + peracetic acide *	7.5 / % 0.23 %
Glutaraldehyde + phenol/phenate	1.21 / % 1.93 %
* : May cause cosmetic and functional damage	

Tab. 3: High Level Disinfection of "Semicritical Objects"

### **7.4.2 Ultrasonic cleaning**

A high-frequency sound is introduced into the cleaning solution (water + detergent). This gives rise to alternating high and low pressure waves. They trigger a process known as "cavitation". Millions of microscopically small bubbles at negative pressure are formed and

these disintegrate immediately. The energy released is much greater than that generated by mechanical brushing. Cavitation in turn accelerates the breakdown of soil particles and brings the solution into active contact with the surfaces of the items being cleaned. Heat reinforces the chemical interactions of the detergent.

**General information on operation and functions of ultrasonic equipment:**

- ◆ Staff must be briefed by the manufacturer or distributor
- ◆ Compile standard operating procedure. This should be supplied with operating instructions.
- ◆ An ultrasonic machine must never be placed in operation without solution since this could cause damage to the oscillation system.
- ◆ Do not reach into the ultrasonic basin while it is in operation.
- ◆ Allow the machine to run for five minutes without any instruments, so as to degas the water.
- ◆ Place instruments in basin, for lumened instruments (if there are no cleaning connection facilities), use a syringe to collect solution and fit syringe.
- ◆ The machine should always be kept closed.
- ◆ Do not sonicate for more than the recommended time the manufacturer of the MD recommends as this could cause damage to materials
- ◆ Drain water after use and clean basin with ethanol or listed surface disinfectant.
- ◆ Regular functional checks are recommended, using e.g. aluminium foil or special test equipment

**7.5 *Maintenance and functional testing***

- ◆ Do not allow residues to dry (blood, saliva, tissue residues, working materials)
- ◆ Rinse off disinfectant and detergent residues thoroughly with demineralized or distilled water
- ◆ Reclean only with a soft cleaning brush
- ◆ Never allow instruments to stand in a moist or wet state for a long time
- ◆ Do not send corroded instruments for sterilization
- ◆ Using an instrument-care agent, manually lubricate instruments with threads or joints with a lubricant suitable for steam sterilization
- ◆ Functional test

**See also “Red Brochure of the Working Group Instrument Preparation”  
([www.a-k-i.org](http://www.a-k-i.org)).**

## 7.6 **Medical technical (MT) equipment**

MT instruments must be discussed separately because they cannot, as such, be classified into the aforementioned risk groups and, furthermore, they contain parts that involve direct or indirect patient contact as well as fine mechanical, optical and electronic elements that could be damaged by disinfection measures. In principle, medical technical equipment must be reprocessed as outlined above. However, often this is not possible because the materials or design of the equipment do not permit effective disinfection.

MT instruments must meet the following basic requirements to ensure that they will not pose any risk of infection to patients or personnel when used.

**Amenability to cleaning:** it must be easy to dismantle and, as far as possible, clean in a WD all parts of the instrument coming into contact with the patient or the patient's excretions.

**Amenability to disinfection:** it must be possible to disinfect, if possible with moist heat, instrument parts coming into contact with skin, mucous membranes, excretions or body fluids (e.g. for humidification of respiratory air or irrigation of hollow organs). This means that these instrument parts must be constructed such that they will not be damaged by temperatures of at least 80 °C or by transient exposure to moisture.

**Amenability to sterilization:** it must be possible to sterilise instrument parts coming into contact with wounds, tissue, sterile body cavities or the patient's bloodstream – if possible using saturated steam under pressure. They must therefore be able to withstand high temperatures (at least 121 °C), moisture and pressure fluctuations, if they are to avoid damage when exposed to (saturated) steam under pressure. Only for those instrument parts whose materials are not, as per present-day knowledge, sufficiently able to tolerate heat, water and pressure may disinfection and sterilization processes other than those mentioned be used. In this situation, instruments with a low microbial count or single-use instruments are a better alternative to a questionable reprocessing procedure!

**Good access to all critical instrument parts:** instrument parts involving direct or indirect patient contact should not contain any inaccessible moisture reservoirs, cavities or gaps (e.g. in gaskets). Liquid containers, cavities and gaskets must therefore be easily accessible, dismantable and amenable to cleaning. Instruments or parts of instruments that do not meet these requirements should be used only once and then disposed of.

**Hygienic safety of operating materials:** the operating materials used in medical technical equipment (gases, e.g. compressed air, liquids, lubricants) can contain and spread harmful microorganisms. Therefore they must not pose any hygienic risk. This means that they may contain at most only a low microbial count in situations necessitating disinfection or be sterile in situations requiring sterilization. Furthermore, microorganisms must not be able to reproduce in operating materials while they are being used or awaiting use.

Unfortunately, among the MT instruments are still equipment and reprocessing methods that do not meet the state of the art. The imperative here is to make users and reprocessors aware of this. And the latter, in turn, must let manufacturers and distributors know if they are being offered instruments that do not meet hygiene requirements. In this respect, it is the

purchasers and users who can exert greatest pressure on the manufacturers and not the infection control experts!

For MT instruments which cannot be safely cleaned, disinfected and sterilized but which, nonetheless, cannot be dispensed with, a concept for effective reprocessing must be formulated, in general, on the basis of close negotiations between infection control experts and microbiologists. The following are recurring aspects:

- ◆ critical instrument parts should be designed as single-use items (e.g. hollow probes and catheters intended for use in the urinary tract or blood vessels; human waste containers).
- ◆ if only chemical disinfection is possible, this should entail the use of a detergent component (wipe disinfection, use of a pump to clean instrument lumens with the disinfectant) used at an adequate concentration and exposure time.
- ◆ as far as possible, measures must be taken to protect against contamination those instrument parts coming into contact with the patient (example: respiratory filters to protect the tubular system and respirator against the patient's microbes).

## 8 Disinfectants

### 8.1 *Specifications of an ideal disinfectant*

- Broad spectrum: Should have a wide antimicrobial spectrum
- Fast acting: should produce a rapid kill
- Should not be affected by environmental factors; should be active in the presence of organic matter (e.g., blood, sputum, feces) and compatible with soaps, detergents, and other chemicals encountered in use
- Nontoxic: should not be harmful to the user or patient
- Surface compatibility: It should not corrode instruments and metallic surfaces and should not cause the deterioration of plastic, rubber and other materials
- Residual effect on treated surfaces: should leave an antimicrobial film on the treated surface
- Should be easy to use with clear label directions
- Odorless: should have a pleasant odor or no odor to facilitate its routine use
- Economical: should not be prohibitively high in cost
- Solubility: should be soluble in water
- Stability: should be stable in concentrated and diluted form
- Environmentally friendly: Its disposal should not damage the environment

As easily can be seen it is not possible to have an ideal disinfectant, one must always have in mind, which targets have to be met and which compromises have to be agreed.

## 8.2 **Glutaraldehyde**

- Glutaraldehyde is a saturated dialdehyde that has gained wide acceptance as a high-level disinfectant and chemical sterilant. Aqueous solutions of glutaraldehyde are acidic and in this state, are generally not sporicidal.
- Only when the solution is “activated” by use of alkalizing agents to pH 7.5-8.5 the solution becomes sporicidal.
- Once activated, these solutions have a shelf-life of a minimal of 14 days.
- Novel glutaraldehyde formulations (e.g., *glutaraldehyde-phenol-sodium phenate*, *potentiated acid glutaraldehyde*, *stabilized alkaline glutaraldehyde*, *glutaraldehyde-phenylphenol-amyphenol*) have extended the shelf life to 28-30 days.
- ≥2% glutaraldehyde solution is effective against *M. tuberculosis*, fungi, and viruses for a minimum of 20 minutes at room temperature, and spores of *Bacillus* and *Clostridium* species for three hours.
- It is non-corrosive to metal and does not damage lensed instruments, rubber, or plastics.
- Glutaraldehyde should not be used for cleaning noncritical surfaces because it is too toxic and expensive.
- Colitis caused by glutaraldehyde exposure from residual disinfecting solution in endoscope solution channels has been reported and is preventable by careful endoscope rinsing. Similarly, keratopathy and corneal decompensation have been caused by ophthalmic instruments that are inadequately rinsed after having been soaked in 2% glutaraldehyde.
- Healthcare personnel can be exposed to elevated levels of glutaraldehyde vapor when equipment is processed in poorly ventilated rooms, when spills occur, when glutaraldehyde solutions are activated or changed, or when open immersion baths are used. Acute or chronic exposure can result in skin irritation or dermatitis, mucous membrane irritation (eye, nose, mouth), or pulmonary symptoms.
- Glutaraldehyde should be used in air systems that provide 7-15 air exchanges per hour, tight-fitting lids on immersion baths, personal protection (e.g., gloves, mask).
- The glutaraldehyde exposure limit is 0.05 ppm; this level significantly irritates the eyes, throat, and nose.
- If glutaraldehyde disposal through the sanitary sewer system is restricted, sodium bisulfate can be used to neutralize the glutaraldehyde and make it safe for disposal.

## 8.3 **Ortho-phthalaldehyde**

- Ortho-phthalaldehyde (OPA) is a high-level disinfectant that has received FDA clearance.
- It contains 0.55% 1,2-benzenedicarboxaldehyde (OPA). OPA solution is a clear, pale-blue liquid with a pH of 7.5.
- OPA has excellent stability over a wide range (pH 3-9).
- It is not a known irritant to the eyes and the nasal passages, does not require exposure monitoring, has a barely perceptible odor, and requires no activation. A potential disadvantage of OPA is that it stains proteins gray. OPA residues remaining on inadequately water-rinsed instruments cause discoloration.

- Personal protective equipment should be worn during contact. In addition, equipment must be thoroughly rinsed to prevent discoloration of a patient's skin or mucous membrane.
- OPA is effective over a 14-day use cycle.
- If OPA disposal through the sanitary sewer system is restricted, glycine (25 grams/gallon) can be used to neutralize the OPA and make it safe for disposal.
- Exposure time for OPA differs from one country to other (e.g., 5 minutes in Europe, Asia, and Latin America; 10 minutes in Canada and Australia; and 12 minutes in the United States).

#### **8.4 Formaldehyde**

- Formaldehyde is used as a disinfectant and sterilant in both its liquid and gaseous states.
- Ingestion of formaldehyde can be fatal, and long-term exposure to low levels in the air or on the skin can cause asthma-like respiratory problems and skin irritation. These considerations and others, such as its role as a suspected human carcinogen, limit its role in sterilization and disinfection processes.
- OSHA has indicated that formaldehyde should be handled in the workplace as a potential carcinogen and that an employee exposure standard should be set for formaldehyde that limits an 8-hour time-weighted average exposure concentration of 0.75 ppm. For these reasons, employees should have limited direct contact with formaldehyde, and these considerations limit its role in sterilization and disinfection processes.

#### **8.5 Chlorine and Chlorine Compounds**

- Despite their different structures, chlorine and chlorine compounds are highly oxidizing agents and have similar chemical reactions.
- They provide high, intermediate or low level disinfection depending on the concentration and exposure time.
- The effective amount is >1000 ppm for prion decontamination. They could be used as an alternative to 1 N NaOH solution for this purpose.
- The most important sources of chlorine are chlorine gas and hypochlorite.
- Chlorine compounds include chloramines, sodium dichloroisocyanurate and chlorine dioxide. The main product of superoxidized water is chlorine.
- Chlorine has long been used as the disinfectant in water treatment. It is highly irritating and corrosive.
- The disinfecting efficacy of chlorine decreases with an increase in pH.
- Sodium hypochlorite at the concentration used in household bleach (5.25-6.15%) can produce ocular irritation or oropharyngeal, esophageal, and gastric irritation. It should have 50,000 ppm sodium hypochlorite (NaOCl).
- It should be free from metal acids such as ferrum and copper ions.
- They are considerably affected by organic substances and proteins.

- Hypochlorite is destroyed by light. Thus, they should be kept in non-light-absorbing plastic containers.
- Hypochlorite is widely used for surface disinfection, and disinfection of hydrotherapy tanks, haemodialysis machines, and water systems.
- The recommended time of contact is important, as it is for all disinfectants.
- A 1:10-1:100 dilution of 5.25% (50,000 ppm) sodium hypochlorite has been recommended for decontaminating blood spills. For small spills of blood (i.e., drops of blood) on non-critical surfaces, the area can be disinfected with a 1:100 dilution of 5.25%-6.15% sodium hypochlorite (500 ppm). Since hypochlorite and other germicides are substantially inactivated in the presence of blood, large spills of blood require that the surface be cleaned before a 1:10 (5000 ppm) (final concentration) solution of household bleach is applied.
- Hypochlorite solutions should be prepared with tap water daily. There will be loss of activity in kept solutions.
- New solutions should be prepared if contaminated.
- Bleach should never be used with acids such as hydrochloric acid and ammonia as they cause formation of toxic chemical compounds.
- One problem with chlorine-releasing granules is that they can generate chlorine fumes when applied to urine. The surfaces should be disinfected with bleach after cleaning and rinsing.
- Sodium dichloroisocyanurate (NaDCC) which is a chlorine compound is more effective and durable compared to hypochlorite.
- Sodium dichloroisocyanurate is presented as water-soluble powder, granule and tablet. The toxicity and irritation is less than those of hypochlorite.
- Chlorine dioxide (ClO<sub>2</sub>) is a water soluble gas.
- It has activity in a wide range of pH (pH 6-10).
- Like other chlorine compounds, it is affected by organic substances and light.
- They are corrosive and irritating. They are harmful for some metals (such as brass, copper) and plastics (such as polycarbonate, polyurethane).
- Liquid chlorine dioxide is high-level disinfection activity.
- It may cause corrosion in some metal and polymer parts of endoscopes. It may cause discoloration in external coating.
- The corrosive effect increases as the density and time of contact increase. Therefore, the least active concentration and the shortest time of contact are preferred for instrument disinfection.
- The gas form of chlorine dioxide is more effective than the liquid form.
- It may leave a white dust on the surfaces after application.

## **8.6 *Superoxide water***

- Superoxide (electrolyzed) water is used for disinfection of heat-sensitive instruments, endoscopes, hard surfaces and water systems.

- As it is an durable product, it is usually produced at the site of application and is used once.
- The activity should be monitored with pH (5-6.5) and oxide reduction potential (950 mvolt).
- Biocidal activity of this disinfectant decreased substantially in the presence of organic material.
- It is corrosive and may harm endoscope coating.
- The material compatibility may be increased by corrosion preventatives and pH adjustments.
- Electrolyzed water system is effective in prevention of biofilm formation and disintegration of the existing biofilm layer. Therefore, it is used in disinfection of water systems of dentistry units and filters.

### **8.7 Hydrogen peroxide**

- Published reports ascribe good germicidal activity to hydrogen peroxide and attest its bactericidal, virucidal, sporicidal, and fungicidal properties.
- Commercially available 3% hydrogen peroxide is a stable and effective disinfectant when used on inanimate surfaces.
- It has been used in concentrations ranging from 3% to 6% for disinfecting soft contact lenses, tonometer biprisms, ventilators, and endoscopes.
- Corneal damage due to hydrogen peroxide-soaked tonometer tip that was not properly rinsed has been reported.
- As with other chemical sterilants, dilution of the hydrogen peroxide must be monitored by regularly testing the minimum effective concentration.

### **8.8 Peracetic acid**

- Peracetic acid or peroxyacetic acid (PA) is characterized by rapid effect on all microorganisms.
- No harmful by-products are formed after use (acetic acid, water, oxygen, hydrogen peroxide) and there is no residue.
- It preserves activity in the presence of organic material and has sporicidal effect at low temperatures.
- It is corrosive on copper, brass, bronze, stainless steel and galvanized iron surfaces.
- Peracetic acid solution is harmful for metal parts of endoscopes and should be changed in 24 hours as it is not stable.

### **8.9 Peracetic acid and hydrogen peroxide**

- FDA has cleared a newer chemical sterilant with 0.23% peracetic acid and 7.35% hydrogen peroxide.
- The bactericidal properties of peracetic acid and hydrogen peroxide have been demonstrated.

- The combination of peracetic acid and hydrogen peroxide inactivated all microorganisms within 20 minutes, except for bacterial spores.
- The combination of peracetic acid and hydrogen peroxide has been used for disinfecting hemodialyzers.

### **8.10 Phenolics**

- Two phenol derivatives commonly found as constituents of hospital disinfectants are ortho-phenylphenol and ortho-benzyl-para-chlorophenol.
- Phenolics are absorbed by porous materials, and the residual disinfectant can irritate tissue.
- Phenolics should not be used to clean infant bassinets and incubators.

### **8.11 Quaternary Ammonium Compounds**

- Quaternary ammonium compounds are low level disinfectants.
- Quaternary ammonium compounds are widely used as low level disinfectants. They should not be used as antiseptics.
- The quaternaries are good cleaning agents, but high degree of water hardness and materials such as that in cotton and gauze pads can make them less microbicidal because the insoluble precipitates or cotton or gauze pads absorb the active ingredients.
- Some of the examples of quaternary ammonium compounds used in healthcare are alkyl dimethyl ammonium chloride, alkyl didecyl dimethyl ammonium chloride, and dialkyl dimethyl ammonium chloride.
- The newer quaternary ammonium compounds (i.e., fourth generation), referred to as twin-chain or dialkyl quaternaries (e.g. didecyl dimethyl ammonium bromide and dioctyl dimethyl ammonium bromide), purportedly remain active in hard water and are tolerant to anionic residues.
- The quaternaries are commonly used in ordinary environmental sanitation of non-critical surfaces, such as floors, furniture and walls.

### **8.12 Iodophors**

- Iodophors have been used both as antiseptics and disinfectants.
- Iodophors are intermediate-low level disinfectants depending on concentration and contact time.
- Dilutions of iodophor demonstrate more rapid bactericidal action than does a full-strength povidone-iodine solution. Therefore, iodophor must be diluted according to the manufacturers' directions to achieve antimicrobial activity.
- Iodophors formulated as antiseptics contain less free iodine than those formulated as disinfectants.
- Iodine or iodine-based antiseptics should not be used on silicone catheters because they can adversely affect the silicone tubing.
- Antiseptic iodophor is not suitable for use as hard-surface disinfectants.

### 8.13 Alcohol

- They are intermediate to low level disinfectants.
- They are rapidly bactericidal rather than bacteriostatic against vegetative forms of bacteria; they also are tuberculocidal, fungicidal, and virucidal, but do not destroy bacterial spores.
- Alcohols are colorless, volatile compounds and they leave neither stain nor residues on the surfaces, and they do not need rinsing.
- They are not toxic.
- Alcohols are flammable and must consequently be stored in a cool, well-ventilated area.
- In the healthcare setting, "alcohol" refers to water-soluble chemical compounds-ethyl alcohol (ethanol), isopropyl alcohol (isopropanol), and n-propyl alcohol (n-propanol).
- Alcohol concentration is important for its antimicrobial effect. Ethyl alcohol has an adequate effect with a concentration of over 60%, isopropyl alcohol with a concentration of 50%, and n-propyl alcohol with a concentration of 40%.
- Alcohols may cause skin dryness and irritation if used for long time. These effects can be prevented by skin protective additives.
- The optimum bactericidal concentration is 60%-95% solution in water (volume/volume). For skin antisepsis, a concentration of 70% (vol/vol) is optimal. However, it loses activity in concentrations of <50%.
- The most feasible explanation for the antimicrobial action of alcohol is denaturation of proteins and liquefying lipids. As protein denaturation requires some amount of water, absolute (96%) alcohol has a weak antimicrobial effect.
- Encapsulated viruses are rapidly inactivated, but higher concentrations and longer durations are required for non-encapsulated viruses.
- Adding iodine, povidone iodine, and chlorine hexidine to alcohol will provide stronger and longer efficacy.
- If used without proper cleaning, alcohols fix organic dirt as they have fixating properties.
- Alcohols have been used effectively to disinfect oral and rectal thermometers, hard and clean surfaces, tonometers, and fiberoptic endoscopes.
- Unless wide, hard and smooth surfaces may be disinfected by wiping with alcohol.
- As they are rapidly evaporated, medical instruments and materials can be disinfected effectively by soaking in alcohol for 10 minutes.
- They tend to swell and harden rubber and certain plastic tubings after prolonged and repeated use, and they bleach rubber and plastic tiles and damage the shellac mountings of lensed instruments.
- Passing alcohol through the channels of the endoscope is an effective method of drying after the procedure for endoscope preparation to ensure that there is no humidity inside.

### 8.14 Advantages and disadvantages of high and intermediate level disinfectants

Disinfectant	Advantages	Disadvantages
<b>Peracetic acid / Hydrogen peroxide</b>	<ul style="list-style-type: none"> <li>No activation required</li> <li>No significant odor or irritation</li> </ul>	<ul style="list-style-type: none"> <li>Material compatibility concerns (lead, brass, copper, zinc), both cosmetic and functional</li> <li>Limited clinical experience</li> <li>Potential for eye and skin damage</li> </ul>
<b>Glutaraldehyde</b>	<ul style="list-style-type: none"> <li>Excellent material compatibility</li> </ul>	<ul style="list-style-type: none"> <li>Respiratory irritation from glutaraldehyde vapor</li> <li>Pungent and irritating odor</li> <li>Relatively slow mycobactericidal activity</li> <li>Coagulates blood and fixes tissue to surfaces</li> </ul>
<b>Hydrogen peroxide</b>	<ul style="list-style-type: none"> <li>No activation required</li> <li>May enhance removal of organic matter and organisms</li> <li>No disposal issues</li> <li>No odor or irritation issues</li> <li>Good material compatibility</li> <li>Does not coagulate blood or fix tissues to surfaces</li> <li>Inhibits formation of biofilm</li> <li>Inactivates <i>Cryptosporidium</i></li> </ul>	<ul style="list-style-type: none"> <li>Material compatibility concerns (brass, zinc, copper, and nickel/silver plating), both cosmetic and functional</li> </ul>
<b>Ortho-phthalaldehyde</b>	<ul style="list-style-type: none"> <li>Fast acting high-level disinfectant</li> <li>No activation required</li> <li>No significant odor</li> <li>Excellent material compatibility claimed</li> </ul>	<ul style="list-style-type: none"> <li>Stains skin, clothing, and environmental surfaces</li> </ul>
<b>Peracetic acid</b>	<ul style="list-style-type: none"> <li>Rapid sterilization cycle time (30-45 minutes)</li> <li>Environmental friendly by-products</li> <li>Fully-automated</li> <li>Standardized cycle</li> <li>No adverse health effects to operators</li> <li>Compatible with many materials and instruments</li> <li>Does not coagulate blood or fix tissues to surfaces</li> <li>Rapidly sporicidal</li> </ul>	<ul style="list-style-type: none"> <li>Used for immersible instruments only.</li> <li>Potential material incompatibility (e.g., aluminum anodized coating becomes distorted)</li> <li>Biological indicator may not be suitable for routine monitoring</li> <li>One scope or a small number of instruments can be processed in a cycle</li> <li>Serious eye and skin damage</li> <li>Point-of-use system, no sterile storage</li> </ul>
<b>Hypochlorite</b>	<ul style="list-style-type: none"> <li>Wide spectrum Rapid effect</li> <li>Less toxicity</li> <li>Environment-friendly</li> <li>Effective on biofilm layer</li> <li>Is not affected by hardness of water</li> </ul>	<ul style="list-style-type: none"> <li>Affected by organic materials</li> <li>Causes corrosion</li> <li>Irritates skin</li> <li>Bleaches textile products</li> <li>Endurable, becomes distorted by light and heat</li> <li>Forms toxic chlorine gas with ammonium and acids</li> </ul>

<p><b>Chlorine dioxide (ClO<sub>2</sub>)</b></p>	<ul style="list-style-type: none"> <li>• Rapid and strong effect</li> <li>• Wide spectrum</li> <li>• Preferred more than chlorine in water disinfection as it has no bad taste and odor</li> <li>• Low toxicity</li> <li>• No carcinogenic or mutagenic effect</li> <li>• Harmful concentration can be measured in gas form (&gt;0.1 ppm)</li> <li>• Degraded into non-toxic compounds</li> </ul>	<ul style="list-style-type: none"> <li>• It is produced during use due to its indurability</li> <li>• Affected by organic materials and light</li> <li>• Corrosive, harmful for some metals (copper, brass) and Plastic</li> <li>• It can cause discoloration in some surface material</li> <li>• It causes respiratory, eye and mucous irritation over concentrations of safety (0,1 ppm)</li> <li>• Can explode in the air with 7-8% concentration</li> </ul>
<p><b>Alcohol</b></p>	<ul style="list-style-type: none"> <li>• Rapid effect, wide spectrum</li> <li>• Colorless, volatile, no residues</li> <li>• No bad odor or stain</li> <li>• Not toxic</li> <li>• No requirement for rinsing or drying</li> <li>• Good material compatibility</li> <li>• Durable</li> <li>• Synergetic effect with other antiseptics</li> </ul>	<ul style="list-style-type: none"> <li>• Not sporicidal</li> <li>• Flammable, explosive</li> <li>• May cause skin dryness and irritation</li> <li>• Fixative</li> <li>• Ineffective in dirty media</li> <li>• Hardens rubber and plastic materials</li> <li>• Harmful for assembled material of lenses</li> <li>• No clarification of the applied area as it is colorless</li> </ul>

Tab. 4: Advantages and disadvantages of high level disinfectants

### 8.15 *Disinfectant test strips*

- Used for assessment of minimal effective concentration (MEC) of disinfectant solution
- Should be specific for product. pH meters should not be used for this purpose.
- The frequency of this test is determined by the frequency of use for the solution.
- For example:
  - One test daily before using the solution
  - One test daily after each 10 applications
  - One test after each 10 applications for 30 daily applications
  - One test before use for weekly use
- Test strips cannot be used to extend the expiration date of the solution.
- Test strips should be assessed following the recommendations of the supplier. If the test result is negative, that solution should not be used or added, and a new solution should be prepared.
- As the chemical substance on the strip will be disrupted in time, the box should have an expiration date on it.
- When the box of test strips is opened, the date and the period for use should be written on the box (e.g., 120 days).
- Test results should be recorded.

## 8.16 Factors affecting the efficacy of disinfection

- Anaerobic microorganisms are more resistant to disinfectants compared to aerobes.
- Gas sterilants like EO cannot penetrate into crystal. In the presence of organic substance on the surface, as there will be crystallization, this surface will not be sterilized with ethylene oxide.
- The disinfectant should be used with the concentration recommended by the producing company.
- As the number of microorganisms increases, the effect of the disinfectant decreases.
- The effect of disinfectant increases as the temperature of the media increases. The recommendations of the producing company on temperature should be followed in disinfectants, the effects of which are heat-dependent.
- The disinfectant activity is affected by the pH of the media. Thus, pH values recommended by the producer should be preferred.
- Organic materials and lipid in the media have negative effect on disinfection.
- Surface active materials or metal ions may produce a positive or a negative effect depending on the type of the disinfectant.
- Microorganism type is important in the disinfection procedure. Enveloped viruses are the most sensitive and prions are the most resistant pathogens, and microorganisms in biofilm are more resistant to disinfection.

Microorganism	Procedure
Prions	Special prion procedure
Thermophilic bacterial spores and protozoa cysts	Sterilization
Mycobacteria and non-enveloped viruses	High-level disinfectants
Enveloped viruses, vegetative bacteria and fungi	Low to intermediate level disinfectants

Tab. 5: Susceptibilities of microorganisms to disinfectants

## 9 Cleaning and disinfection of surfaces

### 9.1 Role of surfaces in infection transmission

Microorganisms endowed with high tolerance to unfavourable environmental conditions (skin staphylococci, *Staphylococcus aureus*, enterococci, etc.) can easily survive on inanimate surfaces (some even for weeks!). A higher microbial load and organic substances (secretions, excretions) also enable Gram-negative bacteria that are sensitive to drying to survive for long periods on surfaces.

In most cases the microbes are transferred to surfaces through contact and then spread further, with the fingers being the chief vehicles implicated. The skin of the fingertips is constructed along the lines of a stamp cushion thanks to its relief structure and grooves in nail beds. Conversely, sedimentation of contaminated air particles on surfaces is of relevance only in special cases (e.g. sterile supplies' warehouse).

Only in the case of certain surfaces (e.g. directly used worktops, surfaces used to store instruments and clean supplies) can one be sure that disinfection will contribute to infection prevention. For other surfaces (floors, walls) the prevailing wisdom is that effective hygienic cleaning techniques are indispensable.

### **9.1.1 Non-contamination**

Examples: use of disposable covers on worktops, technical fittings such as remote control facilities or elbow leaver for washbasin taps; activation of door handles with elbow or forearm instead of fingers, automatic door openers, pedal to open disinfection equipment.

### **9.1.2 Cleaning measures**

In the medical setting only certain processes can be contemplated:

- ◆ **Dry cleaning** with specially adapted vacuum cleaners (exhaust air filters impervious to bacteria, exhaust air diffuser) or central suction device with "suction socket " fitted to wall; no brushes, dusters or domestic vacuum cleaners!
- ◆ **Moist cleaning** based on wiping with moist cloths
- ◆ **Wet cleaning** with cloths or a mop. Formerly, this was generally done using a "two-bucket method", but today preference is given to alternating mop systems where one mop is used only for a limited surface area (e.g. for one room) and immersed only once, i.e. in a clean condition, in the cleaning solution (see below).

For larger surfaces floor cleaning machines have proved popular. These use a fleece fabric or disc brushes and cleaning solution to clean the floor; the cleaning solution is suctioned off during the same working step by means of a powerful water suction device. This provides for a good cleaning effect and swift drying of surfaces after cleaning. Make sure brushes and discs are properly cleaned and disinfected! After use, the cleaning machine tanks must be emptied, cleaned and stored in a dry place.

### **9.1.3 Surface disinfection**

In principle, only approved disinfectants should be used. The Austrian Society of Hygiene, Microbiology and Preventive Medicine (ÖGHMP) is responsible for maintaining the "ÖGHMP Expertise List" listing approved products. Other lists of disinfectants can be consulted on the websites of the Association of Applied Hygiene (VAH) and the Robert Koch Institute (see links).

The method of choice is a wipe process together with or following wet or moist cleaning.

Spray processes are popular but their efficacy is not guaranteed: complete wetting of surfaces has to be assured, something that is particularly difficult in the case of oblique or vertical surfaces! This uncertainty factor and the adverse effect on respiratory air when using unsuitable substances are important arguments put forward against spray disinfection. Ready-to-use spray disinfectants are generally based on alcohol, thus posing a risk of fire when used on large surfaces.

For RUMEDs separate cleaning and disinfection policies must be compiled to, on the one hand, define routine measures and, on the other hand, give guidelines on the circumstances calling for well-targeted disinfection measures.

The efficacy of disinfectants should not be negated by substances present on the surfaces to be disinfected. The presence of protein-based substances (e.g. blood, pus, excretions) can detract from, or negate, the efficacy of disinfectants. Therefore disinfectants should only be used on precleaned surfaces.

The action of many disinfectants (especially those with cationic surfactants) is adversely affected by soaps ("*soap errors*"). Therefore no detergent may be added to a surface detergent.

Direct contact with disinfectant solution must be prevented by obliging cleaning personnel to wear gloves.

<i>Acinetobacter</i> spp.	3 days-5 months
<i>C. difficile</i> spores	5 months
<i>E. coli</i>	1,5 hour-16 months
Enterococci (including VRE)	5 days-4 months
<i>Klebsiella</i> spp.	2 hours-30 months
<i>M. tuberculosis</i>	1 day-4 months
<i>P. aeruginosa</i>	6 hours-16 months
Staphylococci (including MRSA)	7 days-7 months
<i>Candida albicans</i>	1-120 days
<i>C. parapsilosis</i>	14 days
<i>Torulopsus glabrata</i>	100-150 days
SARS associated virus	72-96 hours
CMV	8 hours
HAV, HBV	>1 week
HIV	>1 week

Tab. 6: Persistence of clinically relevant bacteria on inanimate surfaces (*BMC Infect Dis*, 2006; 6: 130)

### 9.1.3.1 Disinfection of walls, ceilings and furnishings

The walls and furnishings of the working areas of a RUMED should be washproof so that they can be cleaned and, if necessary, effectively disinfected. Walls should be cleaned to a working height on a routine basis. Disinfection is deemed necessary only after contamination (e.g. spraying of infectious secretions) (wipe disinfection).

Worktops on which clean medical devices and working materials, too, are stored should be subjected to routine wipe disinfection. However, such measures can only complement but not replace the much more important non-contamination (non-touch) techniques.

### 9.1.3.2 Maintenance of cleaning and disinfection implements

When used for cleaning and disinfection, cloths and mops collect considerable amounts of microorganisms. To prevent the spread of such microbes, these cleaning implements must only be used for a limited surface area and only within a demarcated space.

Microorganisms can quickly grow in undisinfected moist cloths, mops and on the brushes of cleaning machines, in particular pseudomonads and enterobacteria. Therefore when stored in a moist state, cleaning implements are an important microbial source. Hence cleaning implements must be disposed of after use or collected at the end of each day and, for example, cleaned and subjected to thermal disinfection. If thermal disinfection is not possible, e.g. in the case of the brushes of cleaning machines, cleaning implements must be

subjected to chemical disinfection. Make sure implements are thoroughly cleaned before chemical disinfection. Then immerse them overnight, or for at least six hours, in a container with a disinfectant. The disinfectant used can be a surface disinfectant, but a higher (double) concentration must be used than that specified for surface disinfection. The disinfectant solution must be replenished daily. If they are not to be reused immediately, the implements should be dried as quickly as possible and stored in a dry place.

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## 12 Learning objectives

Understand the fundamentals of cleaning and disinfection, so as to

- properly execute these processes
- identify mistakes
- be able to critically appraise and evaluate innovations and new developments, and, if deemed positive, integrate and use them.

Understand and be able to cite the requirements for reprocessing medical devices

Ability to orientate and understand the cleaning and disinfection processes used in the workplace (simple instruments, MIS and other special instruments, medical technical equipment, respiratory and anaesthesia equipment) as well as ancillary applications (hand hygiene, surface disinfection, laundry disinfection)

Organization and quality assurance of the entrusted cleaning and disinfection measures

Assuring a hygienic environment in the RUMED