

Prevention of infection in dental medicine – Demands on hygiene

Information from the Commission for Hospital Hygiene and Infectious Disease Prevention at the Robert Koch Institute



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A publication
of the Robert
Koch Institute

Infection control is an ongoing task for any surgery team

Effective prevention of infection is indispensable. Because viruses, bacteria and fungi pose a constant threat to the health of patients and dental staff in a surgery. A consistent hygienic regime requires therefore a careful assessment of the risks of infection and incessant action against permanent contamination. The Robert Koch Institute (RKI) has published a comprehensive guide to hygiene in dental medicine, which we are able to present to interested users of the Dürr System Hygiene courtesy of the RKI.

We print the text without additional comments; however, some parts have been highlighted to facilitate orientation. Also, illustrated examples of applications of the Dürr System Hygiene are to help gain an understanding of the practice without problems. We would be pleased to respond to any questions you may have on hygiene in the surgery.

Dürr Dental, November 2007



Foreword

After two years of intensive consultation and formulation, the Commission for Clinical Hygiene and Infection Prevention of the Robert-Koch Institute has now presented their recommendation for „Infection Prevention in Dental Medicine – Demands on Hygiene“. It is clearly more expansive than the formerly applicable guideline „Recommendations on Hygiene in Dentistry“, as published by the Commission back in 1998, and which it now replaces. Individual recommendations were revised to reflect today’s state-of-the-art knowledge and requirements on scientific recommendations relating to evidence and transparency. They were categorized step by step, and verified by quoting relevant literature.

The central focus of this publication is on the topic of preparing medical devices. In future we will no longer talk about non-invasive or invasive instruments, but we’ll have to adopt a new vocabulary using terms such as „non-critical, semi-critical, or critical medical devices“, also „risk-evaluation and classification of medical devices“ or “release authorization“. Preparing medical devices requires special expertise which needs updating whenever new processes or new medical devices are introduced.

Of all medical disciplines, it was the field of dental medicine that was first to convert the „Demands on hygiene in preparing medical devices“ specifically designed for the clinical application into a field-specific guideline, to strip it of unnecessary over-regulation and breaking a way for systematic quality assurance.

Since the year 2001 the mutual recommendation of the Robert-Koch Institute and the Federal Institute for Pharmaceuticals and

Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte) regarding „Demands on Hygiene in Preparing Medical Devices“ applies to dental medicine as well. The very strict demands quoted there for validation were adapted to the needs of dental medicine, with the consequence that an on-site validation at the dental practice was no longer mandatory.

“Infection Prevention in Dental Medicine – Demands on Hygiene” is obligatory reading, both for dentists and dental assistants. This concerns primarily the field of preparation, since here legislation makes adherence to the recommendations of the RKI an absolute must.

We owe our thanks to Dürr Dental for spreading the information on the RKI’s recommendations with their brochure. The Federal Association of Dentists (Bundeszahnärztekammer) and the German Committee for Hygiene in the Dental Practice (Deutscher Arbeitskreis für Hygiene in der Zahnarztpraxis [DAHZ]) have used their scope for action to prepare a framework hygiene-plan to be available contemporaneously with the publication of the RKI recommendations. Now it lies in the hands of the dentists to make their practice fit for the new regulations.

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Introduction

In dental medicine, various infectious risks apply for patients and employees in this sector, due to certain particularities involved with dental treatments. These risks can be reduced significantly through

- the determination of the anamnesis,
- effective hygienic measures,
- a system of work methods (such as the basic rule of non-contamination),
- as well as through accepted technologies.

These recommendations include prerequisites and trusted steps for the prevention of infections in dentistry, stomatology and orthodontics.

As guidelines for other fields, in particular from the German Biological Agents Regulations (BioStoffV), already exist, health and safety aspects will not be explained in detail in this document. However, as the aim of many health and safety measures is also to protect the patient, these recommendations have the purpose, wherever possible, to describe

uniform operational procedures for the prevention of infection of patients and staff, thus preventing duplication of work as well as conflicting statements [1].

The Commission for Hospital Hygiene and Infectious Disease Prevention and the Robert Koch Institute have already commented in former publications on some of the central and generally applicable measures for the prevention of infection. For the sake of clarity and comprehensibility, only the most important statements of these publications shall be repeated here. In case of need for more in-depth information, the readers of these recommendations are required to refer to the individual source of information for details (all documents can also be read on the web pages of the RKI under www.rki.de, section “Prevention of Infection”, keyword “Hospital Hygiene”, sub-item “Guidelines/recommendations by the Commission for Hospital Hygiene”).



Example for infectious disease prevention in case of the formation of spray mist: aerosol suction

1 Assessment of risks

The following paths of infection are relevant for the field of dentistry:

- direct contact with blood, saliva or other potentially infectious secretions including,
- splashes of blood, saliva, nasopharyngeal secretions onto healthy or injured skin or mucosa,
- indirect transmission, e.g. via contaminated instruments, dental materials, workpieces or hands,
- aerosol formation with contaminated water from treatment units or the patient's oral cavity [2, 3].

Some of the infectious germs that are potentially hazardous to patients as well as to the staff are:

Pathogens transmitted by blood, such as

- Hepatitis B viruses (HBV),
- Hepatitis C viruses (HCV),
- HIV.

Pathogens transmitted mostly by direct or indirect contact, such as

- Herpes simplex viruses,
- staphylococci.

Pathogens transmitted mostly through droplets or droplet cores, such as

- bacteria and viruses leading to infections of the respiratory tract or which are excreted via this tract, or also such pathogens as can lead to systemic infections (e.g. streptococci, influenza viruses etc.),
- mycobacterium tuberculosis.

So far, it cannot be said for certain whether there is an infectious risk with regard to the use of water from dental units through legionella, pseudomonads (above all, *P. aeruginosa*) and ubiquitous (non-tubercular)

mycobacteria for patients with a weakened immune system [4, 5, 6, 7, 8, 9] (with regard to details, we refer to number 5 “Water-carrying systems”).

Next to these exogenous risks, there is also an endogenous infectious risk stemming from the patient's own oral microflora [10, 11], which shall be described here only to the extent as it is connected with interventions by the dentist and can be influenced by direct measures of infection control.

On account of the infectious risks mentioned above, it is necessary with regard to dental treatment to define requirements as to hygiene based on the potential transmission paths (see also [12]).

“Special hygienic requirements are (...) to be observed in general for all surgical dental/stomatological interventions on patients bearing an increased risk of infection.”

Special hygienic requirements must be met in case of any surgical dental/stomatological procedures with subsequent saliva-proof wound closure (such as implantations, transplantations of autogenic bone or connective tissue, sinus-lift procedures, root apex excisions) and generally also in case of all dental/stomatological surgical procedures on patients with an increased risk of infection [12, 13, 14, 15, 16, 17].

2 Measures of infection control on the patient

2.1 Anamnesis

The determination of the anamnesis allows to detect potential infectious risks determined by the patient. It is to be updated at regular intervals (Cat. IB) [18].

2.2 Oral antiseptics

The cleaning of teeth and mucosa antiseptics lead to a considerable reduction of the microflora in the saliva and on the mucosa. This also reduces the concentration of pathogens in the aerosol. Therefore the antiseptic treatment of the mucosa (for example using chlorhexidin gluconate, polyvidone iodine or essential oils) is required before the surgical dental/stomatological treatment of patients with an increased risk of infection as well as before all dental operations with subsequent saliva-proof wound closure (Cat. II) [19, 20, 21].

2.3 Antibiotic prophylaxis

Antiseptic mucosa treatment is not a substitute for a antibiotic prophylaxis which may be indicated. Reference is made in particular to the scientific statements in this regard of the „Deutsche Gesellschaft für Zahn-, Mund- und Kieferheilkunde“ (see www.dgzmk.de) and the publications of the Paul Ehrlich Society (PEG) (see www.p-e-g.org) [22].

3 Infection prevention measures of the medical staff

3.1 Hygiene of the hands

(The following statements have been reconciled with the recommendation of the Commission for Hospital Hygiene and Infectious Disease Prevention on “Hygiene of the hands” [23]. For more detailed information, please refer to this source.)

“The hands of the staff are the most prominent transmission vehicle of pathogens.”

The hands of the staff are the most prominent transmission vehicle of pathogens. Therefore

the hygiene of the hands is among the most important measures of infectious disease prevention. It protects the patient as well as the medical staff (Cat. IA) [23].

Rings, watches and other jewellery on hands and forearms may not be worn during the examination and treatment (Cat. IV) [24]. Furthermore, it is recommended that fingernails may not project above the fingertips on account of a possible damage to the protective gloves (Cat. IB) [12, 23].

3.1.1 Washing hands

It is one of the general rules of the hygiene of the hands to wash hands with water and soap before starting work and after ending work. Washing hands is also a matter of course, for example, in case of visible soiling, after blowing the nose, before meals as well as after visiting the bathroom (Cat. IB) [23].

3.1.2 Hygienic disinfection of hands

Hygienic disinfection is required before every treatment, in breaks between the treatment, when the gloves are changed and after the treatment is completed, even if gloves are or were worn (Cat. I A) [23].

The disinfectant is dispersed from an appropriate dispenser onto the clean and dry hands (palms and back of hands, including wrist, surfaces between the fingers and thumbs) and thoroughly rubbed in. Particular care must be paid to the disinfection of the fingertips and the nail fold.

A prerequisite for an effective disinfection of the hands is that the hands are kept moist during the prescribed residence time with the disinfectant. For a hygienic disinfection of the hands alcoholic preparations should be pre-

ferred if possible (Cat. IB) [23]. Suitable agents are listed in official guidelines [25].

3.1.3 Surgical disinfection of the hands

A surgical disinfection of hands before putting on sterile gloves is required in case of complex surgical dental/stomatological operations and for all surgical dental/stomatological operations on patients with an increased risk of infection (Cat. II) [23].

It involves 2 procedural steps:

- First all soiling that may occur on the surface needs to be removed from the hands with a washing lotion. After drying, the disinfectant, taken from an appropriate dispenser, is rubbed onto the hands and forearms. Hands and fore arms are then kept moist for the prescribed residence time (mostly 3 min.). The gloves are put on when the hands are dry (Cat. IB) [23].
- If short surgical operations (lasting up to 60 min.) with low contamination occur in close succession, washing hands before next surgical disinfection can be neglected. Following operations that lasted more one hour, hands should be washed again (Cat. II) [23, 24, 25, 26, 27, 28, 29, 30, 31].

3.2 Protection from contamination

Protection from contamination comprises various barrier measures, which include, for instance:

- personal protective equipment (Cat. IV) [24, 32, 33],
- intraoral barriers (cofferdam application) (Cat. IB) [34, 35, 36],
- covering the direct environment of the patient,
- operational-functional measures to prevent contamination (touch discipline, rational use of instruments),
- suitable suction technology [36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49],
- accident-safe disposal (Cat. IV) [24, 50].

3.2.1 Protective gloves

Protective gloves are to be worn in case of infectious risks and also if areas or surfaces contaminated with body fluids or secretions are touched (Cat. IB, IV). Even with the gloves on, wounds at the hands pose an increased risk of infection [24, 32, 33, 51, 52, 53, 54].



Example: How to perform a hygienic disinfection of the hands - standard rub-in method according to CEN/EN 1500

The gloves are to be changed in between the treatments of different patients (Cat. IB) [55, 56, 57, 58, 59]. In case of contact with saliva only, undamaged gloves with a proven durability towards the disinfectant used can be continued to be worn after a hygienic disinfection of the hands (Cat. IB) [24, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80].

“Protective gloves are to be worn in case of infectious risks and also if areas or surfaces contaminated with body fluids or secretions are touched.”

Particular care has to be paid to allergy prophylaxis (including choice of the gloves, measures of skin protection, non-powdered, low-protein gloves) (Cat. IV) [24, 35]. Currently, there may be no proof that the question of the treating person wearing unsterilised or sterile gloves makes a difference with regard to infections after tooth extraction [81]. However, as the requirements for the material of sterile gloves (quality) are higher (e.g. lower perforation rate), the use of such gloves can minimise the transmission of microorganisms from the hands of the treating persons to the area of the wound and also the risk of a contamination of the skin with blood or body fluids of the patient [54]. This means they are likely to offer an increased degree of protection (Cat. III) if a contact with blood is to be expected. Sterile gloves should therefore be used in particular in cases of surgical dental/stomatological operations with subsequent saliva-proof wound closure and for all surgical dental/stomatological operations on patients with an increased risk of infection (Cat. IB) [12].

Disposal and cleaning procedures require gloves that are resistant against cleaning agents as well as pierce-proof (Cat. IV) [24, 55].



Example: Dürr Dental washing lotion with skincare and oil-restoring substances prevents from skin irritation.

3.2.2 Face mask, eye protection

To reduce the infectious risk through aerosols containing microorganisms as well as splashes of blood and saliva, a suitable and snug-fitting face mask as well as protective glasses also shielding the eyes also at the outer corners should be worn (Cat. IV) [24, 32]. The face mask is to be changed when soiled and penetration of moisture occurred. After contamination, the glasses are to be wiped-clean (for instance with a disinfectant wipe) (Cat. IB) [37, 82].

3.2.3 Protective clothing

Protective clothing (coat, apron, possible hair net) is to be worn if the professional clothing could be contaminated with pathogens during the treatment (Cat. IV) [24, 33, 51].

3.2.4 Covering surfaces and objects

Surfaces/ Objects that are difficult to clean or to disinfect as well as all surfaces/objects that could be contaminated with blood, saliva or pus should be protected from contamination by being covered. For this purpose, one may

use materials that don't have to be sterile, but should be of low microbiological contamination (Cat. II) [12].

The materials used as cover are to be treated hygienically or disposed of after the treatment (Cat. IV) [12, 24].

3.3 Prophylaxis by vaccination

To minimise a specific risk of infection, protective vaccinations are the most effective preventive measure. They are of particular importance in dental medicine to protect staff and prevent infecting patients (Cat. IB) [12, 24, 51].

Before any staff can take up work the employer is to ensure a preventive occupational medical examination for hepatitis B and C virus, offering at the same time vaccination against hepatitis, unless the staff already has protecting immunity (Cat. IV) [51]. Furthermore, all employees should be inoculated against diphtheria and tetanus.

If children are treated regularly in the surgery, preventive examinations for bordetella pertussis, measles virus, mumps virus, rubella virus and varicella zoster virus are to be carried out as well. If the existing protection through vaccination is not sufficient, vaccinations are to be offered. These abovementioned examinations are a prerequisite for the activity for any dental professional (Cat. IV) [51].

A vaccination, preceded by additional preventive examinations, is also advised in case of other risks of infection connected with the activity, such as influenza.

The recommendations of the German Standing Vaccination Committee (STIKO) are published regularly (mid-year) in the “Epidemi-

miologisches Bulletin” [83]. They include all relevant information on the procedure of protective vaccinations. The complete text is available on the Internet on www.rki.de in the section “Prevention of infection” under the keyword “Vaccination”.

Further advice primarily counselling for individual cases are offered by company doctors, public health administration agencies and the offices of labour, for health and safety administration.

Measures for HIV post-exposition prophylaxis in their latest version are available on the web pages of the RKI (www.rki.de).

3.4 Employment restrictions

Risks of infections for patient can also be posed by the dental staff. The transmission of pathogens can take place via blood contact, aerogenously (droplet cores), through droplets and by way of smear infection.

“Risks of infection for the patient can also be posed by the dental staff.”

Wearing face mask as well as gloves is generally sufficiently safe to prevent a transmission of pathogens from the staff to the patient. Also, vaccinations carried out in line with the STIKO recommendations contribute to minimizing risk.

Literature has laid particular emphasis on the transmission of HBV and HIV from dentists to patients [84]. The German Association for the Control of Virus Diseases and the Robert Koch Institute have given some advice in the evaluation whether carriers of HBV, HCV and HIV should be able to continue activities involving a risk of transmission [85, 86, 87, 88, 89, 90].

The following aspects may help assess the risk of a transmission from the staff to the patient:

- Dentists and employees with an acute infection should not be involved in the treatment of patients. Exceptions may be, after careful consideration of the individual case, “banal infections” where the respective person is able to work and a risk of transmission can be minimised through protective measures (see above).
- Information on the most important infectious diseases can also be found in the pamphlets of the Robert Koch Institute (www.rki.de, section „Infektionskrankheiten A–Z” [in German]). Offices for health and safety can also be contacted in the individual case.
- The evaluation whether present occupational tasks may still be performed in the presence of illness, or if restrictions need to be enforced, is the responsibility of the treating doctor or company doctor. It should also be taken into account here in how far the respective person carries out activities susceptible to injuries. If a risk for third persons cannot be precluded, a relocation to a different workplace, employment restrictions or even complete barring from the present professional occupation may have to be ordered by the competent authority may have to be considered (Cat. IV) [91]. Before a decision as to whether a carrier of HBV or HCV has to accept restrictions with regard to his or her professional activity, an expert committee hearing should be held (Cat. IB) [85, 90].

The protection of the patients and their environment may possibly involve examinations to trace back such patients as were treated by the carrier of the infection [88, 92].

4 Preparation of medical products

Demands on preparation of medical products are based on the German Medical Devices Act (MPG), the Medical Devices Operator Ordinance (see in particular Sec. 4 MPBetreibV) as well as the recommendations “Demands on hygiene when preparing medical devices” (German) [93, 94, 95]. Requirements of a more general nature as to dentistry shall be specified in the following.

Only persons that have gained the required specialised knowledge by way of their professional education and practical activity may be trusted with the servicing, (maintenance, inspection, repair and preparation) of medical devices (such as dental instruments) (Cat. IV) [24, 32, 93]. Modified work conditions or the introduction of new procedures or new medical devices require an adaptation of the knowledge by way of appropriate instruction. A correct preparation can be assumed if the joint recommendation of the „Robert Koch Institute” and the Federal Institute for Drugs and Medical Devices, “Demands on hygiene when preparing medical devices” is adhered to, while also taking into account specialised knowledge of dentistry (Cat. IV) [93, 94, 95].

“Only persons (...) with the required specialised knowledge may be commissioned with the maintenance (...) of medical devices (...).”

The marketability of re-usable medical devices includes that the manufacturer is to provide information on the preparation [94]. According to DIN EN ISO 17664, the manufacturers are obliged to give information on the validated preparation procedures. Declarations

of conformity by the manufacturer of single-use instruments cover the single use only (Cat. IV) [94, 95].

“For this purpose, a risk assessment and evaluation of the medical products has to take place before the preparation”

The type and scope of preparation depend on the medical devices to be prepared, its intended use as well as on the information given by the manufacturer. For this purpose, a risk assessment and evaluation of the medical products have to take place before the preparation, which clearly states how often and with which procedures the individual medical devices or product groups are to be prepared. For product groups frequently used in dentistry evaluation advice can be found in **Table 1 as well as in the annexes**. If the manufacturer defines the maximum number of possible preparations of a medical device, the dental instrument must be labelled accordingly, so as to report the number of preparations carried out previously when a decision on a new preparation is to be taken (Cat. IB) [94].

Under consideration of the manufacturer’s instructions, appropriate and validated procedures are to be used for the preparation of medical devices whose intended application involves low-germ or sterile conditions (Kat. IV) [93]. The validation is to be in line with the medical device and its risk assessment and evaluation and to take place in accordance with the generally accepted principles of technology under consideration of the state of science and technology. This means that for the preparation of medical devices with low-germ or sterile application documented and verifiable procedures are to be adopted, which make sure that the targets set will be reached with the executed preparation process before a new application of the medical device.



Example for the manual disinfection of rotating instruments

“The disinfection procedures used are to be proven to be bactericidal, fungicidal and virucidal.”

Manual cleaning and disinfection procedures must be carried out on the basis of documented standardised procedural instructions as well as with means and procedures that have been tested for effectiveness and adapted to the medical device [94]. The disinfection procedures used are to be proven to be bacteriocidal, fungicidal and virucidal [94].



Example: Dürr Dental disinfectants VAH/DGHM certification; the safety data sheets are available on the Internet

4.1 Notes on handpieces, angle pieces and turbines (transmission instruments)

The preparation of transmission instruments requires particular care due to the complex structure of these medical devices. Furthermore, depending on the individual device, there may be internal contamination due to return suction of the spray and cooling water. In addition to this contamination, a microbiological contamination of the spray water channels through cooling water must also be expected [96, 97, 98, 99, 100, 101].

Only careful cleaning and disinfection of the external and internal surfaces following the treatment of each patient can make sufficiently sure that the microorganisms that have accessed the internal parts of the transmission instruments can be ruled out as a potential source of infections (Cat. IB) [94, 97, 98].

Transmission instruments should allow automatic preparation and be thermostable (Cat. IB) [94, 102, 103, 104]. In case of surgical dental/stomatological operations with subsequent saliva-proof wound closure, the instruments need to be packaged and sterilised and used in sterile condition (Cat. IB) [104].

4.2 Notes on the accessory devices

Accessory devices with or without the discharge of air, liquids or particles (such as intraoral cameras, devices for caries diagnosis, air abrasion units, polymerisation lamps, odontexesis devices) are to be prepared in accordance with the manufacturers' instructions (Cat. IV) [93]. A thermal disinfection or sterilisation of removable device parts is recommended, provided this is authorised by the manufacturer.



Example for accessory devices: Adhere to Manufacturers' information on the preparation

Accessory devices with the discharge of air/water should be rinsed with air/water for at least 20 seconds after the treatment of the patient (Cat. IB) [12].

4.3 Notes on rotating and pulsating instruments

Due to the complex surface of rotating and pulsating instruments as well as endodontic instruments, special requirements apply to cleaning and disinfection (see definition of semi-critical B in Table 1). They are preferentially carried out automatically with final thermal disinfection [107, 108, 109, 110]. In case of manual preparation, the treatment in an ultrasonic bath is recommended, using special cleaning agents and disinfectants (adhere to manufacturer's instructions) or in a drill bath. Manual preparation is completed with a thermal disinfection in the steam steriliser (Cat. IB) [94].

“Due to the complex surface of rotating and pulsating as well as endodontic instruments, special requirements apply to cleaning and disinfection.”

Due to a possible contamination with blood as well as the particular difficulties with regard

to cleaning, polishing brushes and cups pose particular problems as they are usually covered in a mix of blood, saliva and polishing paste. If all this cannot be removed through manual or automatic preparation, such parts may not be reused (Cat. IB) [94, 107, 108, 109, 110].

4.4 Cleaning and disinfection

When cleaning and disinfecting medical devices, a distinction must be made between manual and automatic preparation, with the latter usually being preferred. Thermal procedures in cleaning and disinfection devices (RDG) are to be preferred over chemical products, as far as this is feasible for the individual medical device (Cat. IB) [94]. This means that such instruments as can be cleaned and disinfected with thermal procedures are to be preferred when instruments are procured. It should be pointed out that for some medical devices there is currently no appropriate automatic procedure for cleaning and disinfection (see also DIN EN ISO 17664).

4.4.1 Automatic cleaning and disinfection

The procedural steps of automatic cleaning and disinfection generally comprise:

- appropriate prearrangements for the preparation, contamination-safe transport from the treatment unit to the preparation area,
- disassembly of separable instruments in accordance with staff protection measures,
- cleaning/disinfection, rinsing and drying in the cleaning and disinfection device in accordance with the manufacturer's instructions (loading pattern/prevention of unrinsed areas, temperature and time, cleaning agent, disinfectant if required),
- check for cleanliness and integrity, care, maintenance, functional test (technical and

functional safety),

- labelling of the number of preparations, if required,
- then, if required (see Table 1 and annex): documented authorisation for use or for storage protected from dust (low-germ medical devices) or
- packaging and sterilisation, authorisation for use or for storage protected from dust of the packaged medical devices (sterile medical devices) (Cat. IB) [94].

“For the disinfection of instruments, use substances with proven bacteriocidal, fungicidal and virucidal effect.”



Example: Automatic disinfection of the instruments in the ultrasonic bath

4.4.2 Manual cleaning and disinfection

The procedural steps of manual cleaning and disinfection according to standardised work instructions generally comprise:

- appropriate prearrangements for preparation, contamination-safe transport from the treatment unit to the preparation area,
- disassembly of separable instruments in accordance with the staff protection measures,
- immediate bubble-free laying in an appropriate cleaning solution or cleaning (non fixating) disinfectant, which has to moisten and cover the instrument completely on

the inside and outside (adhere to manufacturer's instructions on the compatibility of materials),

- mechanical cleaning (sometimes an ultrasonic cleaning can also take place),
- chemical disinfection (bacteriocidal, fungicidal and virucidal).
- After completion of the residence time: rinsing of the instruments, tools or materials with appropriate water to remove residues of cleaning agent and disinfectant,
- drying,
- check for cleanliness and integrity, care, maintenance, functional test (technical and functional safety),
- labelling of the number of preparations, if required,
- then, if required (see **Table 1 and annex**): possible final thermal disinfection in the steam steriliser and documented authorisation for use or for storage protected from dust (low-germ medical devices) or
- packaging, labelling and sterilisation, authorisation for use or for storage protected from dust of the packaged medical devices (sterile medical devices) (Cat. IB) [94].

For the disinfection of instruments, use substances with proven bacteriocidal, fungicidal and virucidal effect. Corresponding lists are available to help with the selection of the appropriate substances [25]. Thermal disinfection (in the steam steriliser if required) should always be preferred as far as possible.

Cleaning/disinfectant solutions have to be renewed at least on a daily basis, unless the manufacturer can prove with expert opinions that the effectiveness is ensured also over a longer period of time (Cat. IB) [111]. In case of visible soiling, the solutions are to be renewed immediately.

If no appropriate water is used to rinse the medical devices, one of the consequences may be salt/lime deposits on the surfaces of the medical devices, which affect the subsequent sterilisation process and also the functionality of metal instruments. Careful drying of the instruments after the manual preparation helps reduce deposits on the surface of the medical devices to non-critical values (see also 10.2) [112].

“The packaging is to protect the sterilised good from microbiological recontamination.”



Example: Manual disinfection and cleaning in the Hygobox, use of the instrument gripping pliers

4.5 Packaging of the sterile goods and sterilisation

All medical products that interfere with the integrity of the body and are used in surgical dental/stomatological operations (critical medical devices see **Table 1**), are to be sterilised after cleaning and disinfection and have to be applied on the patient in sterile condition. They are therefore to be sterilised in sterile good packaging and to be stored in a sterile condition or to be used immediately. A contamination-safe transport within the surgery has to be ensured. The packaging is to protect the sterilised good from microbiological recontamination. The packaging units are to be kept small to fit and to be labelled with information that is relevant for the intended use, disclosing the content and, if applicable, sterilisation procedure (if several procedures/devices are available) as well as sterilisation date or storage life (Cat. IB) [94].

Steam sterilisation procedures are to be preferred (Cat. IB) [94, 112, 113, 114]. This

should be considered when procuring medical devices (instruments and other working materials). When using containers/trays, make sure that the steam can reach the device to be sterilised via a suitable filter, and that no condensate can settle at the bottom of the container.

When acquiring new sterilisation devices, steam sterilisers should be preferred, which also ensure a safe sterilisation of the inner sides of hollow articles and enable automatic control or documentation. Steam sterilisers with sterilisation cycle B (for packaged massive as well as hollow or porous sterilised material) meet this requirement profile. Small-scale steam sterilisers with sterilisation cycle S should be accompanied by a written declaration of the manufacturer on the individual performance range required. Steam sterilisers with sterilisation cycle N are designed only for completing the preparation of solid, massive medical products in unpackaged condition (steam disinfection; see also 10.3) [115, 116].



Example: Preparation of the disinfectant solution

4.6 Authorisation for use or storage of medical devices prepared

The preparation ends with the authorisation of the medical device for storage or reuse, either after disinfection or – if required – after sterilisation. If deviations from the correct procedure were detected during preparation, the medical device must once again be subjected to the procedure, following the correction of the fault (Cat. IV) [94].

“The preparation ends with the authorisation of the medical device.”

4.7 Storage of medical devices

Instruments, working tools and materials should be stored, packaged or unpacked (sterile or non-sterile – according to the requirements) but in any case in a clean and dry place.

The storage life of sterilised devices depends on the type of packaging and storage.

There are no objections against storage lives for medical products (in drawers or closed



Example: Sterile good packaging with Hygopac Plus

cabinets) of up to 6 months in container packaging or in simple sterile transparent packs or up to 5 years in double sterile packaging (DIN 58953 – 9).

4.8 Notes on infection control concerning Creutzfeldt-Jakob disease (CJD) and related disease patterns

Concerning the issue of transmissible spongiforme encephalopathies (TSE) we refer to the related publications of the Robert Koch Institute as well as to publications of Smith (2003) (www.rki.de) [117, 118, 119, 120]. Procedures going beyond the usual careful preventive measures (see these present recommendations) is indicated only in case of patients with corresponding symptoms or overtly expressed suspicion for a TSE according to the publications mentioned above.

Patients suspected of a transmissible spongiforme encephalopathy (CJD, vCJD etc.), or for whom such a disease is clinically indicated, should be treated within institutions that have sufficient experience and the appropriate means of infection control (Cat. IB) [119, 120]. For

the treatment of such patients, single use materials are to be used whenever possible, which will then have to be disposed of safely.

5 Water-carrying systems

Pursuant Sec. 3 TrinkwV (German Drinking Water Ordinance) only water meeting these requirements may be used in dental units [121]. Even if this standard is met, the water-carrying systems, such as for transmission instruments, multifunctional syringes, ultrasonic for tooth cleaning, mouth rinsing are frequently populated by various microorganisms [16, 122, 123, 124, 125, 126, 127, 128]. These form colonies and multiply at the internal walls of the water-carrying systems [4, 16, 129]. These biofilms can lead to a massive contamination of the cooling water in periods of stagnation.

“Water-carrying systems are to be rinsed at the beginning of each working day (without the transmission instruments fitted) at all tapping points as well as at the water glass tap at spittoon, for approx. 2 min.”

When looking at the contamination of water-carrying systems, there is a distinction to be made between

- contamination through stagnation of the water fed in (creation of biofilm) and
- contamination through blood/secretions of the patient.

The contamination through blood/secretions of the patients is subdivided further into

- contamination of the suction units, occurring regularly in operation, and
- retrograde contamination of the rinsing water channels of the transmission instruments.

The measures detailed in the following represent means that are effective against microbiological contamination in water-carrying systems in dental units if used individually, but in particular if combined with each other:

- The information of the device manufacturers need to be adhered to and the relevant operational parameters are to be controlled (Cat. IV) [93, 95].
- Disinfection units for the water-carrying systems of the treatment units whose effectiveness in the practical field has been proven can help reach a reduction of the microbiological contamination of the cooling water [130, 131, 132].
- If disinfection units are retrofitted, any existing biofilm colonisation is to be removed in order to achieve an appropriate initial status as precondition for a long-term low-germ condition [133, 134].
- Water-carrying systems are to be rinsed at the beginning of each working day (without the transmission instruments fitted) at all tapping points as well as at the water glass tap at spittoon, for approx. 2 min. (Cat. IB) [16]. This helps considerably to reduce the micro-biological accumulation created during the stagnation [12, 16, 135].



Example: Suction unit disinfection from the OroCup

Table 1

Risk assessment and evaluation of medical devices used in dentistry before their preparation

Medical devices	Contact with mucosa or pathologically affected skin	Penetration of skin or mucosa
Merely contact with intact skin		
Non-critical medical devices ^a	Semi-critical medical devices ^a	Critical medical devices ^a
Non-critical	Semi-critical A Without special requirements on the preparation	Critical A Without special requirements on the preparation
e.g. extraoral parts of the face-bow calliper	hand instruments for general, preventive, restorative or orthodontical (non-invasive) measures	Instruments and tools for surgical, parodontic or endodontic (invasive) measures
	Rotating or pulsating instruments for general preventive, restorative or orthodontic treatment Transmission instruments general, restorative or orthodontic treatment	Rotating or pulsating instruments for surgical, parodontic or endodontic measures Transmission instruments for surgical, parodontic or endodontic treatment
	Accessory devices without the discharge of liquids and/or air or particles	
	Medical devices which merely come into contact with skin. Semi-critical medical devices: Medical devices that come into contact with mucosa or pathological skin. Critical medical devices: Medical devices for the application of blood, blood products and other sterile medicaments and medical devices permeating the skin or mucosa and coming into contact with blood, internal tissue or organs, including wounds. Constructive details as well as details of the product design with regard to material technology can mean higher requirements as to the preparation. It is therefore necessary to further subdivide this classification (Cat. IB). Semi-critical and critical medical devices can be subdivided further into such devices where the preparation does not involve special requirements (group A) and such devices involving increased requirements (group B).	
	Medical products posing increased requirements as to the preparation are those devices where - the effectiveness of the cleaning procedures cannot be proven immediately through visual inspection (e.g. due to long, narrow, in particular terminal lumina, hollow cavities with only one opening [no rinsing, only dilution possible], complex surfaces difficult to access and therefore difficult to rinse), - effects affecting the application and functional safety of the preparation, including transport, on the medical device and its material qualities cannot be precluded (e.g. medical devices easy to bend, sensitive surfaces) and which therefore mean increased effort in the technical-functional inspection - the number of applications or of the preparation cycles has been restricted by the manufacturer to a specific value.	

- Water-carrying systems may potentially be contaminated also retrogradely from the patient's oral microflora [98]. The cooling systems therefore need to prevent all return flow of liquids. The microbiological contamination of the water-carrying system through the treatment of the previous patient is reduced by rinsing the systems that were in use in the mouth of this patient (including those with an integrated return flow block) for about 20 seconds (Cat. II) [12, 132, 135, 136, 137, 138, 139]. At the end of the treatment day, the water-carrying systems should be also be rinsed after the treatment of the last patient in order to eliminate any possible microorganisms that may have occurred (Cat. II) [4].
- When procuring new treatment units, the manufacturers should be asked as to how far the materials used in the devices and coming into contact with water inhibit the growth of the microorganisms. The materials and devices used should have passed the test according to DVGW Worksheet W 270 "Multiplication of microorganisms on materials for the drinking water range – Test and evaluation".

Although the risk of infection for healthy patients or treating persons from the contamination of the cooling and rinsing water resulting from biofilm formation is said to be low [140, 141] and a connection with dental treatments has been established only in the form of individual case reports [122, 142], the generally accepted principles of infection control stipulate that the risk of damages to health is to be reduced through the use of water that is free from microbiological loads [7, 121, 143].

Based on the abovementioned evaluation of the current state of technology as well as on the discussion conducted on this issue, the inspection of the following parameters is deemed appropriate to evaluate the proper

operation of a dental unit regarding the microbiological quality of the water: The microbiological test (one tapping point per treatment unit is deemed sufficient) comprises the determination of the colony number in 36 °C (according to Annex 1 No. 5 TrinkwV current version) as well as the determination of legionella by a laboratory with sufficient know-how. The sample to be tested is taken by qualified staff after water has been running for 20 seconds (Cat. III).

In well-maintained treatment units, a number of colonies of 100/ml is not exceeded; therefore this value can be taken as the guiding value here; higher numbers of colonies indicate an extended biofilm colonisation and require more intensive rinsing before the treatment of the patient and, if required, a disinfection in coordination with the manufacturer (Cat. III) [143, 144].

Currently the risk of a legionella infection in connection with a dental treatment cannot be defined accurately for reasons of insufficient epidemiologic studies [4, 140, 141, 144, 145]. For reasons of a preventive health protection, the internationally accepted guiding value of less than 1 CFU legionella/1 ml should not be exceeded (Cat. III).

The intervals between the tests should be defined according to pragmatic aspects. If there are no indications pointing to a fault, 12 monthly intervals appear appropriate. Any suspicion of a water-related infection due to dental treatment has to elicit a cause-related follow-up examination (Cat. IV) [91].

5.1 Special requirements for patients with immunosuppression

The *Pseudomonas* spp., found in the rinsing water of the dental unit, will find better conditions for long-term colonisation and subsequent infection of the mucosa and respiratory tracts of patients with immunosuppression than on those of healthy persons [146, 147, 148]. Nosocomial outbreaks due to mouth rinsing solutions contaminated with ram-negative bacteria have been described [149, 150, 151]. Water from dental installations used for the treatment of patients with a high-degree immunosuppression therefore has to be free of pseudomonads, cryptosporidiosis [152] and legionella (Cat. IB) [153, 154, 155, 156, 157].

If a dental intervention on patients with a high degree of immunosuppression cannot be delayed until the immune system of the patient has recovered, the intervention should be carried out in close coordination with the doctors responsible for the treatment of the underlying disease (Cat. II). If an antibacterial chemoprophylaxis is required, this should be adapted to the colonisation of the patient with resistant isolates, if such a colonisation is known (Cat. II). Examples for patients with a high degree of immunosuppression in this sense are patients with connatal immune deficiencies such as those in conjunction with a high-degree neutropenia ($< 0.5 \times 10^9/L$), patients during an intensive antineoplastic chemotherapy (inductive treatment of leukemia, of a lymphoma or intensive chemotherapy of a solid tumour), patients directly before or in the first 100 days after a stem cell transplantation, patients treated with a high dose of steroids or other immunosuppressives following an organ transplantation or for other reasons (cyclophosphamide-based protocols such as the Fauci scheme; steroids with a prednisone equivalent of more than

0.5 mg/kg per day over 4 weeks or 5 mg/kg over more than 5 days), HIV infected patients in the AIDS state. Naturally, this list is non-exhaustive. The responsible doctors should evaluate the risk involved with the infection in the individual case and decide for or against the use of sterile rinsing solution to cool the rotating instruments, as they see fit (Cat. IB). Treatment centres caring regularly for patients with a high degree of immunosuppression should hold special dental treatment units with sterile cooling water for the transmission instruments.

“In case of complex surgical dental/stomatological operations and all dental treatments of patients with an increased risk of infection, sterile solutions are to be used for cooling, for the abovementioned reasons.”

As the multifunctional syringes of the treatments cannot usually be connected to sterile rinsing solutions, treatment units where patients with a high degree of immunosuppression are treated regularly must be equipped with disinfection units for the water-carrying systems.

In case of complex surgical dental/stomatological operations and all dental treatments of patients with an increased risk of infection, sterile solutions are to be used for cooling, for the abovementioned reasons (Cat. IB) [16, 158, 159, 160].

As with patients carrying mucoviscidosis the point of time of the colonisation with *P. aeruginosa* or *B. cepacia* is of paramount importance for long-term analysis, an infection or colonisation of the patient with *Pseudomonas* spp. in the course of a medical intervention must be prevented by all means [161, 162, 163]. This also applies to patients that are already colo-

nised with *Pseudomonas* spp., as a superinfection by other serotypes is possible, which may lead to an exacerbation of the disease [164, 165]. For this reason, sterile cooling water for the rotating instruments is to be used for patients carrying mucoviscidosis as well (Cat. IB). For the use of a water/air mix from multifunctional syringes a cofferdam isolation should be carried out, if possible.

5.2 Suction units

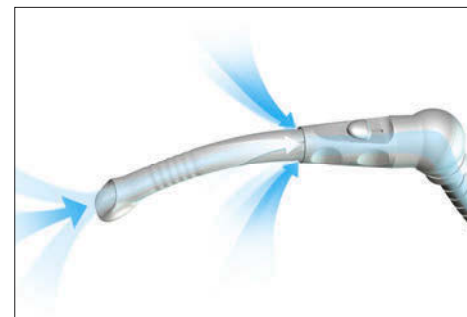
The literature states that some circumstances may lead to a return flow of aspirated cooling water, blood and saliva into the oral cavity of a patient if a suction cannula (especially the suctor) is closed off by soft tissue that is sucked in (such as cheek or tongue mucosa), which could mean that as a consequence contaminated liquids reach the oral cavity of a patient

from the suction hose, thus creating a risk of infection [12, 166, 167, 168].

Studies have shown that gravity may lead to a return flow of contaminated liquids from the suction hose if the suction hose is led above the patient (and the suction power is low) [12, 166, 167, 168, 168a]. It is therefore important for all treatments to ensure that the position of the suctor and the suction hose prevent a return flow of aspirated liquids into the mouth of the patient due to gravity (Cat. II). Technical modifications of the suction cannulas (through additional ventilation) may help reduce the risk of underpressure in case of suction devices adhering to tongue or cheek, without affecting the suction performance.

6 Cleaning and disinfection of impressions and dental workpieces

For dental workpieces, impressions, odontoscopies etc. exchanged between dental surgery and dental laboratory, special arrangements have to be imposed with regard to cleaning and disinfection. Dental workpieces, impressions, odontoscopies etc. must be seen as microbiologically contaminated and have to be handled in such a way as to preclude the infection of patients and staff in the dental laboratory or of third persons during transport (Cat. IV) [12, 169, 170, 171, 172, 173]. It is recommended to hand over all materials and dental workpieces that must be seen as contaminated from the dental area only after cleaning and disinfection (Cat. II) [12, 169, 170, 171, 172, 173]. With regard to material compatibility, adhere to the information of the manufacturers.



Example: Secondary air nozzle prevents backflow



Example: Disinfection of impressions in the Hygojet

Drinking water, which is used for example in water baths to bring wax boards or impression materials to the right temperature, has to be renewed after each patient if it was contaminated with saliva or other body liquids. The water tank is to be disinfected before the refill (Cat. IB) [94].

7 Surface disinfection and Cleaning

For a detailed description of the “Requirements as to hygiene concerning the cleaning and disinfection of surfaces”, we refer to the information of the Commission for Hospital Hygiene and Infectious Disease Prevention at the Robert Koch Institute [174].

7.1 Furniture in the treatment area



Example: Quick disinfection of surfaces in the proximity of the patient

The efficiency of cleaning and disinfection also depends on the nature of the surfaces.

The surfaces of furniture and medical devices in areas for the treatment of patients therefore need to be smooth, wipeable and easy to clean and disinfect, especially at the points of contact (Cat. IB) [174]. It is therefore recommended, in particular with regard to new procurement, to make sure that the surfaces are washable and resistant to disinfectants (such as membrane keyboards, functional control via foot pedal, detachable couplings of the suction hoses or detachable suction hoses or similar).

Following the treatment of each patient, the surfaces in proximity of the patient that have been contaminated through contact or aerosol (dentist element, assistant element, medical devices and furniture in the treatment areas for patients) are to be disinfected. The accessible areas of hoses, couplings and tubulars of the suction units are to be disinfected on the outside after each patient (Cat. IB) [12, 174, 175]. Targeted measures of disinfection are necessary if surfaces not in proximity of the patient (including the floor) have also been visibly contaminated with blood, saliva or other potentially infectious secretions or if a situation of increased risk applies (Cat. IB) [174]. A surface disinfection of all work surfaces is to be carried out on a daily basis at the end of the treatment day. All measures of disinfection are to be carried out as a wiping disinfection (Cat. IB) [174].

7.2 X-ray areas

Contaminated parts of X-ray equipment are to be disinfected after each patient. Intraoral X-ray films are to be packaged in such a way that they can be disinfected once they have been extracted from the oral cavity (Cat. IB) [174].

Other targeted measures of disinfection may be necessary if surfaces not in proximity of the patient (including the floor) have also been

visibly contaminated with blood, saliva or other potentially infectious secretions or if a situation of increased risk applies (Cat. IB) [174].



Example: Disinfection of intraoral filters

7.3 Floors

For the floors of the treatment rooms, wet cleaning without added disinfectants at the end of each day is sufficient. Targeted measures of disinfection become necessary if there is a visible contamination of the floor with blood, saliva or other potentially infectious secretions (Cat. IB) [174].



Example: Preparation of the disinfection solution for the wet cleaning of floors

8 Washing work clothes and protective clothing

Work clothes are clothing for work specific to an activity, but without specific protective function against harmful influences. Protective clothing protects the wearer or the work clothes from contamination. If it has to be assumed that the work clothes have been contaminated with pathogens it is to be changed and handled as if it were protective clothing (Cat. IV) [24]. Work clothes can be washed in the surgery or by laundry services. From a hygienic point of view there are no objections against washing work clothes at home.

Used protective clothing is to be collected in containers or bags that are sufficiently tear-resistant and dense, separated according to the type of washing procedure (thermal or chemothermal) (Cat. IV) [24, 176].

9 Disposal

The keeper of the surgery is to define the measures of waste disposal in a hygiene plan. Correct disposal requires practicable, comprehensible and transparent handling of the waste (separate collection at the location of accumulation, possibly pre-treatment, collection transport and appropriation for disposal).

The basis of correct disposal are the provisions of the waste, infection control, health and safety, chemicals and hazardous substances laws (Cat. IV). Furthermore, regional regulations on tendering as well as surrender obligations must be adhered to. The details are governed by the directive on the regular disposal of wastes from health care institutions, published by the Länderarbeitsgemeinschaft Abfall (Regional Workgroup on Waste-LAGA) [50].

There are no hygienic objections against the material recycling of glass, paper, metal, plastic or other materials (such as film or photographic paper), as long as these are collected separately and do not contain and are not contaminated with blood or hazardous soiling.

Waste from treatment and examination rooms is to be collected in sufficiently tear-resistant, dense and moisture-resistant (if required) single-use containers, which are to be closed before transport. If correct handling is ensured, they do not pose a more significant risk than household waste that was disposed of correctly. The disposal of contaminated single-use instruments and materials is to take place in such a way that the injury and health risks for the surgery team or other persons is reduced to a minimum. This can be ensured, for example, for pointed, sharp or fragile objects in sealable pierce-proof and break-proof containers or through embedding in a rigid mass.



Example: Disposal of the amalgam collection tank

If this waste, for which no particularly strict control is indicated, is surrendered to public disposers for disposal, a special and individual allocation to a waste code of the European List of Waste is not required if the waste volume accumulated is low (as is the case for dental surgeries).

Waste contaminated with particularly infectious or dangerous pathogens (such as pathogens of the haemorrhagic fever, the open pulmonary tuberculosis or anthrax), do not usually occur in a dental surgery. However, if these are found waste code (AS) 18 01 03* applies to them, which is to say there are special requirements applying to their disposal from the perspective of infection control. They must either be disinfected (procedures with the effective range ABC) or collected in appropriate, tight, safely sealed containers (labelled with the “Biohazard” icon) before disposal and then be combusted in an accredited plant. Contaminated dry waste stemming from individual cases of infected patients (AIDS, virus hepatitis), such as contaminated swab, OP covers, cotton wool rolls, are not included in this and are not subjected to the requirements of AS 18 01 03*.

Body parts and organic waste is to be disposed of separately without prior mixing with household waste (AS 18 01 02). Extracted teeth do not belong to such body parts in the sense of the waste code.

10 Quality assurance

Pursuant to Sec. 36 Par. 2 Infection Protection Act, dental surgeries, doctor’s surgeries and surgeries of other medical professions where in-vasive operations are performed can be observed by the public health office with regard to infection control and hygiene [91].

“Pursuant to Sec. 36 Par. 2 Infection Protection Act, dental surgeries where invasive operations are performed can be observed by the public health office with regard to infection control and hygiene.”

10.1 Hygiene plan

The measures to be defined in the hygiene plan are generally aimed at protecting the patient, the staff and third persons alike from risks of infection (Cat. IV) [51]. Dental medicine (dental practice of laboratory) generally does not involve activities that would have to be allocated to protection class 2 in the sense of the BioStoffV (Biological Agents Regulations) [24, 51]. Based on the required risk assessment, operational instructions and a hygiene plan are to be installed, defining rules of conduct and measures of cleaning, disinfection and sterilisation, supply and disposal, use of protective clothing as well as instructions for emergencies and health and safety precautions. The observation of the rules of conduct and measures defined is to be inspected. It is possible to combine the hygiene plan and the operational instructions (procedural instructions, work instructions) (Cat. IV) [24, 51].



Example: Disinfection and cleaning plan

Merely adopting a pre-defined framework of hygiene plans is not enough. Rather, such rules and instructions have to be adapted to the individual field of activities, checked regularly for their topicality and modified as required. Employees need to be instructed through the appropriate presentation of the hygiene plan upon the start of their employment, in case of changes in their field of activity and when new work materials or procedures are introduced. These instructions must be repeated regularly and documented (Cat. IV) [24, 32, 51]. The hygiene plan is to be available for consultation or be distributed to the staff (Cat. IV) [51].

“Merely adopting a pre-defined framework of hygiene plans is not enough.”

10.2 Control of cleaning and disinfection procedures for medical devices

Cleaning and disinfection should take place thermally and automatically by preference (in particular, in view of the elimination of HBV and the residence times needed in practice, at no less than 90 °C).

The quality of automatic cleaning and disinfection is ensured through:

- the acceptance inspection of cleaning and disinfection devices,
- batch-related routine checks (for instance, the simplest yet indispensable check is the visual inspection of the medical devices prepared, unless these have hollow cavities),
- inspection of the prerequisites for every procedure (such as cleaning chemicals) and the correct procedures for conformity with the standard work instructions, for example by recording relevant process parameters (batch-related documentation),

Important requirements as to the operation of small-scale steam sterilisers

(see also installation/operational qualification [commissioning])

- evidence on the suitability of the steriliser for the medical devices intended for sterilisation (see information of the manufacturer of the steriliser (CE mark; DIN EN 13060¹⁾ and of the medical devices [DIN EN ISO 17664] as well as risk assessment for the medical products²⁾),
- evidence on the suitability of the operating resources at the operator's (such as supply water of the defined quality; compliance of the installation conditions; provision of the required safety installations) (empty tank inspection/ inspection with test load),
- provision of the operating instructions/instructions of use,
- information of the manufacturer concerning required checks/suitable test tools,
- evidence on the instruction/information of the staff entrusted with the operation,
- evidence of the regular maintenance according to the information of the manufacturer (such as seals, control and measuring parts).

(see also performance assessment)

- appropriate presentation of the medical devices used/configurations³⁾,
- disclosure/documentation of the most difficult/representative load (e.g. photo; critical parameters are, for instance lumina, porosity/textiles, large mass, complex packaging. The maximum load is not necessarily the most difficult load),
- evidence on the suitability of the sterilisation parameters; if required, also substantiation of the equivalence of the individual load with tested reference loads on sterilisers of the same type while stating appropriate chemical indicators and test pieces.

Routine checks according to the manufacturer's information every working day

- (such as visual inspection of chamber and seal for correct condition; inspection of the supply water and the tank [e.g. for volume and suitability]), (if required, vacuum test, empty run, steam permeation test according to manufacturer's information).

Batch-related routine check and batch documentation

(controlling and documenting the complete and correct process; correct choice of the sterilisation programme [cycle] depending on the goods to be sterilised/the load),

- use of treatment indicators (class 1; DIN EN ISO 11140-1),
- documentation of the critical/relevant process parameters (control of the process parameters with measuring technology: temperature and pressure variation/plateau duration (process evaluation system if required [DIN EN 13060, Annex B]),
- batch control (process indicator); evidence of the air removal/steam permeation for medical devices where air removal is required (at least chemical indicator class 5 (DIN EN ISO 11140-1); for critical A devices: without PCD (process challenge device), for critical B devices with PCD, such as Helixtest (DIN EN 867-5),
- visual inspection: inspection of the packaging for dryness and integrity (such as tightness and sealing),
- inspection of labelling
- documentation of the authorisation decision through authorised (designated, experienced and instructed staff),
- representation of the procedure in case of deviations from the correct processes/SOP

Periodic inspections

carried out in appropriate intervals (e.g. according to information from the manufacturer of the device) are to certify that no unintended process-relevant changes have occurred. If required, the times of their application can be coordinated with maintenance.

¹⁾ Sterilisers that technically do not meet the requirements of the current standard (DIN EN 13060) require a higher effort for the performance assessment and possibly also retrofitting.

²⁾ see "Requirements as to hygiene in the preparation of medical devices" [94].

³⁾ Configuration= good to be sterilised in sterile good packaging with defined load pattern (here, information of the steriliser's manufacturer on appropriate configurations would be very helpful; standardisation of loads as far as possible)

- periodic checks/maintenance according to the manufacturers' instructions in case of automatic cleaning and disinfection (Cat. IB) [94].

Manual cleaning and disinfection are carried out in accordance with standard work instructions while including the information of the manufacturers of cleaning chemicals and disinfectants (see also above and [94]).

10.3 Supervision of sterilisation procedures

Sterilisation is a so-called special procedure, whose effectiveness cannot be proven by direct control and inspection of the product before the latter is used. To prove the effect of such procedures, a steriliser that is suitable for the medical devices to be sterilised is to be used and the accompanying parameters for the procedure are to be observed.

Summary 1 comprises the main prerequisites for the correct operation of small-scale steam sterilisers in tabular form.

11 Constructional requirements

In addition to the legal provisions of the Workplaces Ordinance and the workplace directives, there are certain constructional requirements to be observed, so that dental treatments can be carried out under immaculate hygienic conditions. We recommend to consult a specialised doctor for hygiene and environmental medicine, factory doctors and/or health and safety experts as advisors when planning dental surgeries (Cat. III). Deviations from the requirements may be admissible if the keeper of the surgery takes other measures with an equivalent effectiveness. In case of constructional conversions in existing surgeries, the constructional conditions should meet these requirements as far as possible. For the purposes of effective infection control, a spatial separation between the treatment areas and other areas is helpful [12].

"Appropriate dispensers for hand cleaning lotions and hand disinfectants as well as single-use towels need to be available"

11.1 Treatment room(s)

Treatment rooms have to be equipped with easily accessible washing facilities with hot and cold water in close proximity to the treatment unit. Appropriate dispensers for hand cleaning lotions and hand disinfectants as well as single-use towels need to be available. It must be possible to operate the water fittings as well as the dispensers for liquid material without hand contact (Cat. IV) [24]. If several treatment units are installed in one and the same treatment area – such as in clinics or orthodontical surgeries – every treatment unit, including those for the assistant staff, have to be equipped with easily accessible disinfectant dispensers (Cat. IV) [24]. If several

treatment units exist in one and the same treatment area, separating walls are recommended for psychological reasons alone. Air-conditioning is not required in dental medicine. However, an air conditioning system may be installed to reduce the room temperature.

Each recovery room (if required or existing) needs to be equipped with at least one dispenser for hand disinfectant (Cat. II) [24]. The floors need to be suitable for wet cleaning, disinfection and sealed against liquids. This also applies to the external surfaces of installed fittings and furniture. Patient's couches need to have surfaces that are easy to clean and disinfect (Cat. IB) [174].

11.2 X-ray room/ area

At least one dispenser for hand disinfectant is to be fitted in this area (Cat. II) [174]. For intraoral X-ray film and tools for recording technology (cotton wool rolls, film holders, chin rests) depositing surfaces have to be provided, to be disinfected after each treatment. Surface contamination can be prevented through the use of trays [174].



Example: Dispenser for hand disinfectant

11.3 Preparation room/ area; Waste disposal

A dedicated room for the preparation of medical devices (cleaning, disinfection and sterilisation) and waste disposal must be defined. Work procedures are to be divided into “impure” and “pure” procedures (Cat. IV) [50, 94].

11.4 Waiting room/ area

The furniture should be easy to clean. Providing magazines and arranging plants in the room is unobjectionable.

11.5 Staff rooms

The staff is to be provided with a break/dressing room which, if required, also offers facilities to store meals and beverages. Consuming meals and beverages as well as smoking in treatment and preparation areas are forbidden for hygienic reasons (Cat. IV) [51]. Dressing between the personal clothes and work clothes takes place in the break room or in a separate dressing room, if such a room exists. In this regard it must be possible to separate the personal clothes from clean and used work clothes. Break rooms may not be entered with protective clothing (Cat. IV) [51].

11.6 Toilet facilities

The staff must have separate toilets with washing basin, soap dispenser and single-use towels, which are not available for the patients (Cat. IV) [51], (right of continuance regulations see workplace law) [178].

12 Legal framework conditions

The legal framework conditions are stipulated by laws and ordinances of the national government and the federal state governments as well as by self-governed law of the statutory accident insurance carriers. The laws of the federal states concerning the medical profession and public health bodies contain provisions engaging doctors and dentists to perform their profession carefully and keep themselves informed on the regulations applying to their professions.

The control of the manufacturers, operators and users of medical devices is regulated in Sec. 26 MPG. According to the latter, organisations and institutions where medical devices are manufactured, clinically tested, subjected to a performance evaluation test, packaged, presented, marketed, erected, operated/ used, or where medical devices intended for low-germ or sterile use are prepared for others, are subject to supervision through the competent authorities. The competent authority takes the measures required for the elimination of infringements determined or for the prevention of future infringements. It inspects to the appropriate scope under special consideration of possible risks of the medical devices whether the prerequisites for bringing the devices into circulation and for commissioning them are met [95].

Pursuant to the Workplace Ordinance [178], the generally accepted safety-relevant, medical and hygienic rules must be met. The Work Conditions Act (ArbSchG) engages all employers to take the required measures for the health and safety of the employees and to take into account the current state of technology, occupational medicine, hygiene as well as other proven knowledge in the field of health and safety. The most important provisions

for medical health and safety routine are found in the Biological Agents Regulations (Bio-StoffV) [51], which engages employers to prepare a risk assessment for every workplace before taking the required protective measures. According to the Young Persons Employment Act (JArbSchG) and the Maternity Protection Act (MuSchG), employment restrictions or prohibitions may apply. According to the Ordinance on Hazardous Substances (GefStoffV) the work procedures are to be designed preferably in such a way that no hazardous gases, fumes or suspended substances are released and that contact of the skin with hazardous substances is prevented.

Work accidents and occupational diseases as well as work-related health hazards are to be prevented by all appropriate means pursuant to the Seventh Code of Social Law – Statutory Accident Insurance (SGB VII). Accident prevention regulations of the competent accident insurance carriers (Sec. 15 SGB VII) have to be available for consultation to the employees in every surgery. They represent directly applicable laws for such employees. The experts for health and safety, occupational doctors as well as the health and safety offices and offices of the factory inspection are competent for medical health and safety issues (<http://www.baua.bund.de>).

The Recycling Management and Waste Law (KrW-/AbfG) defines special requirements for waste that contains, or could be the source of, pathogens of infectious diseases. The execution regulation for this is the so-called LAGA directive, which is also part of the directive for hospital hygiene and infection control (<http://www.rki.de>).

Pursuant to Sec. 36 Par. 2 IfSG, “dental surgeries, doctor’s surgeries and surgeries of other medical professions where invasive operations are performed, as well as other institutions and organisations where pathogens can be transmitted by blood through the activities performed on the human body ... can be observed by the public health office with regard to infection control and hygiene.” Further regulations concerning infection control can be found in some federal state laws on the public health services.

In the frame of its official functions (Sec. 4 IfSG), the Robert Koch Institute publishes “directives” and “recommendations”, such as the “Directive for hospital hygiene and infectious disease prevention” (Sec. 23 Par. 2 IfSG). They are directed towards public as well as private institutions or persons. They are not of a direct legally binding character. However, it should be noted that these recommendations generally represent the medical standard and reflect the state of science and technology. Therefore deviating from the recommendations is appropriate only for very good reasons [1].

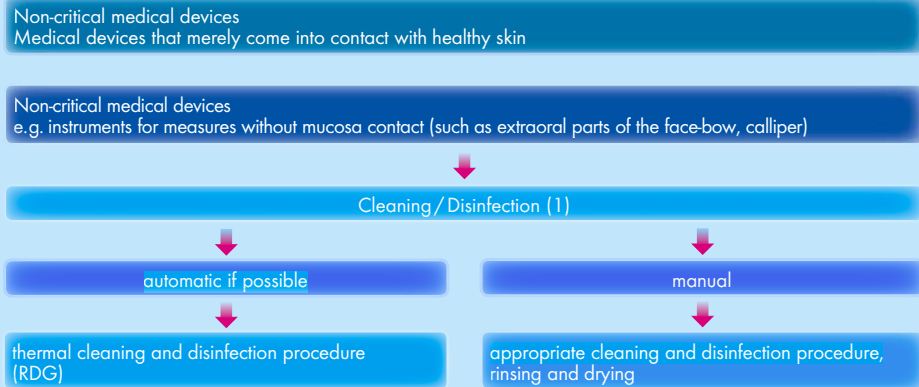
The recommendations were prepared on an honorary basis and without the influence of commercial interest groups by order of the Commission for Hospital Hygiene and Infectious Disease Prevention by J. Becker (Head of the workgroup), Düsseldorf, D. Buhtz, Berlin, M. Exner, Bonn, R. Hilger, Düsseldorf, H. Martiny, Berlin, M. Mielke, A. Nassauer, G. Unger (for the RKI)

Literature

- Nassauer A, Mielke M (2000) Rechtsgrundlagen zum Infektionsschutz im Krankenhaus – Anmerkungen für die Arbeitsmedizin. Bundesgesundheitsbl 43: 459-465
- Bolyard EA, Tablan OC, Williams WW, et al. (1998) Guideline for infection control in health care personnel. Hospital Infection Control Practices Advisory Committee. Infect Control Hosp Epidemiol 19: 407-463
- Szymanska J (2005) Exposure to bacterial endotoxin during conservative dental treatment. Ann Agric Environ Med 12: 137-139
- Pankhurst CL, Johnson NW, Woods RG (1998) Microbial contamination of dental unit waterlines: the scientific argument. Int Dent J 48: 359-368
- Pankhurst CL (2003) Risk assessment of dental waterline contamination. Prim Dent Care 10: 5-10
- Pankhurst CL, Coulter W, Philpott-Howard JJ, et al. (2003) Prevalence of legionella waterline contamination and Legionella pneumophila antibodies in general dental practitioners in London and rural Northern Ireland. Br Dent J. 195: 591-594
- Pederson ED, Stone ME, Ragain JC Jr, Simecek JW (2002) Waterline biofilm and the dental treatment facility: a review. Gen Dent 50: 190-195
- Szymanska J (2004) Risk of exposure to legionella in dental practice. Ann Agric Environ Med 11: 9-12
- Walker JT, Bradshaw DJ, Finney M, et al. (2004) Microbiological evaluation of dental unit water systems in general dental practice in Europe. Eur J Oral Sci 112: 412-418
- Hollbrook WP (2001) Bacterial infections of oral soft tissues. Curr Opin Dent 1: 404-410
- Quirryn M, De Soete M, Dierickx K, van Steenberghe D (2001) The intra-oral translocation of periodontopathogens jeopardises the outcome of periodontal therapy. A review of the literature. J Clin Periodontol 28: 499-507
- Centers for Disease Control and Prevention (2003) Guidelines for Infection Control in Dental Health-Care Settings. MMWR: 52 (No. RR-17)
- Kommission für Krankenhaushygiene und Infektionsprävention (1998) Anforderungen an die Hygiene in der Zahnmedizin. Bundesgesundheitsbl 41: 363-369
- Chiarello LA, Bartley J (2001) Prevention of blood exposure in health care personnel. Seminars in Infection Control 1: 30-43
- Wahl G (2003) Grundprinzipien enoraler Operationen. In: Zahnärztliche Chirurgie, Urban & Fischer, München; 4. Auflage: 68-88
- Barbeau J, Tanguay R, Faucher E, et al. (1996) Multiparametric analysis of waterline contamination in dental units. Applied and Environmental Microbiology 62: 3954-3959
- Rolston KV (2005) Challenges in the treatment of infections caused by gram-positive and gram-negative bacteria in patients with cancer and neutropenia. J Clin Oncol 23: 1125-1135
- Becker J, Pawelzik J (2002) Anamnese, Befunderhebung, Dokumentation. In: Curriculum Zahn-, Mund- und Kieferkrankheiten. Quintessenz Verlag Berlin 2: 25-33
- Sekino S, Ramberg P, Uzel NG, et al. (2003) Effect of various chlorhexidine regimens on salivary bacteria and de novo plaque formation. J Clin Periodontol 30: 919-925
- Herrera D, Roldan S, Santacruz I, et al. (2003) Differences in antimicrobial activity of four commercial 0,12% chlorhexidine mouthrinse formulations: an in vitro contact test and salivary bacterial counts study. J Clin Periodontol 30: 307-314
- Fine DH, Furgang D, Korik I, et al. (1993) Reduction of viable bacteria in dental aerosols by preprocedural rinsing with an antiseptic mouthrinse. Am J Dent 6: 219-221
- Vogel F, Bodmann KF (2004) Empfehlungen zur kalkulierten parenteralen Initialtherapie bakterieller Erkrankungen bei Erwachsenen. Chemotherapie Journal 13: 46-105
- Kommission für Krankenhaushygiene und Infektionsprävention (2000) Händehygiene. Bundesgesundheitsbl 43: 230-233
- Technische Regel Biologische Arbeitsstoffe, TRBA 250 (2003) Biologische Arbeitsstoffe im Gesundheitsdienst und in der Wohlfahrtspflege. Bundesarbeitsblatt 11; siehe auch www.baua.de
- Liste der nach den Richtlinien für die Prüfung chemischer Desinfektionsmittel geprüften und von der Deutschen Gesellschaft für Hygiene und Mikrobiologie als wirksam befundenen Desinfektionsverfahren. Stand: 31. Dezember 2003
- Benzer H, Brühl P, Dietzel W, et al. (1996) Meine Hände sind sauber. Warum soll ich sie desinfizieren? Leitfaden zur hygienischen Händedesinfektion. Wiesbaden mhp-Verlag
- Larson E (1988) A causal link between handwashing and risk of infection? Examination of the evidence. Infect Control 9: 28-36
- Bauer TM, Ofner E, Just HM, et al. (1990) An epidemiological study assessing the relative importance of airborne and direct contact transmission of microorganisms in a medical intensive care unit. J Hosp Infect 15: 301-309
- Pittet D, Dharan S, Touveneau S, et al. (1999) Bacterial contamination of the hands of hospital staff during routine patient care. Arch Intern Med 159: 821-826
- Centers for Disease Control and Prevention (1993) Recommended infection-control practices for dentistry. MMWR: 42
- Casewell M, Phillips I (1977) Hands as route of transmission for Klebsiella species. Br Med J 2: 1315-1357
- Verordnung über Sicherheit und Gesundheitsschutz bei der Benutzung persönlicher Schutzausrüstung bei der Arbeit (PSA-Benutzungsverordnung-PSA-BV). BGBl 1996 I: 1841
- Hauptverband der gewerblichen Berufsgenossenschaften (HVBG) (2004) Berufsgenossenschaftliche Vorschrift (alt: Unfallverhütungsvorschrift) „Grundsätze der Prävention BGV A1, hier: Vierter Abschnitt „Persönliche Schutzausrüstung“. Siehe: www.hvbg.de Rubrik Datenbanken
- Cochran MA, Miller CH, Sheldrake MA (1989) The efficacy of the rubber dam as a barrier to the spread of microorganisms during dental treatment. J Am Dent Assoc 119: 141-144
- Kamann WK (1999) So legen Sie effizient einen Kofferdam. ZM 89 (15): 1786
- Winkler L (1991) Kofferdam in Theorie und Praxis. Quintessenz Verlag Berlin
- Seifert ST (2000) Untersuchung des bakteriellen Infektionspotenzials dentaler Aerosole. Diss. Marburg
- Böhme W, Goldmann L, Regensburger K, Reitemeier B (1990) Untersuchungen zur Ausbreitung des Sprayrückpralls bei unterschiedlichen Arbeitsbedingungen. Zahn-Mund-Kieferheilkd 78: 621-627
- Kilpatrick HC (1974) Works implication in dental practice. Saunders, Philadelphia
- Micik RE, Miller RL, Mazzarella MA, Ryge G (1969) Studies on dental aerobiology. Bacterial aerosols generated during dental procedures. J Dent Res 48: 49-56
- Bauer E, Langer H, Portele K (1967) Turbine und Keimstreuung. Dtsch Zahnärztl Z 22: 1183
- Bauer E, Portele K (1966) Infektionsgefahr und Schutzmaßnahmen bei der Präparation mit Turbinengeräten. Zahnärztl Praxis 17: 91
- Borneff M (1986) Hygiene-Probleme in der zahnärztlichen Praxis unter besonderer Berücksichtigung der Dentaleinheiten. Zbl Hyg Bakt (Serie B) 138: 130
- Grün L, Crott K (1969) Über den Keimgehalt des Turbinensprays. Dtsch Zahnärztl Z 24: 189 und 870
- Lenk V, Eichner K (1963) Experimentelle Untersuchungen beim hoch- und höchsttourigen Bohren und Schleifen. Dtsch Zahnärztl Z 18: 118
- Meyer H (1959) Turbine und Hygiene. 49: 593
- Riethel P (1960) Über die Infektionsmöglichkeit bei der Anwendung von luftgetriebenen Schnellstaugeräten. Dtsch Zahnärztl Z 15: 353
- Tonne E, Zschunke E (1977) Untersuchungen zur räumlichen Aerosolausbreitung bei der Turbinenanwendung. Stomat DDR 27: 440
- Tschamer H (1961) Überblick über die Gefahren einer gesundheitlichen Schädigung des Zahnarztes durch seinen Beruf, unter besonderer Berücksichtigung der Infektionsgefährdung bei der Verwendung der hoch- und höchsttourigen Bohrmaschinen. Dtsch Zahnärztl Z 16: 1233
- Länderarbeitsgemeinschaft Abfall (LAGA) (2002) Richtlinie über die ordnungsgemäße Entsorgung von Abfällen aus Einrichtungen des Gesundheitsdienstes (LAGA-Merkblatt). Siehe: www.rki.de
- Biotoffverordnung (BioStoffV). BGBl 1999 I: 50-60; zuletzt geändert durch Art. 8 der Verordnung zur Anpassung der Gefahrstoffverordnung vom 29.12.2004, BGBl. I: 3807
- Deutsche Gesellschaft für Krankenhaushygiene (Hrsg.) (1998) Anforderungen an Handschuhe zur Infektionsprophylaxe im Gesundheitswesen. Krankenhaushygiene/Hospital Hygiene (2). mhp-Verlag, Wiesbaden 75-78
- Olsen RJ, Lynch P, Coyle MB, et al. (1993) Examination gloves as barriers to hand contamination in clinical practice. JAMA 270: 350-353
- DIN EN 455-1: 2001-01 und 455-2: 2001-01 Medizinische Handschuhe zum einmaligen Gebrauch
- Centers for Disease Control and Prevention (CDC) (1988) Perspectives in disease prevention and health promotion update: universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. MMWR 38: 377-382, 387-388
- Martin MV, Dunn HM, Field EA (1988) A physical and microbiological evaluation of the re-use of non-sterile gloves. Br Dent J 165: 321-324
- Adam D, Bagg J, Limaye M, et al. (1992) A clinical evaluation of glove washing and re-use in dental practice. J Hosp Infect 20: 153-162
- DeGroot-Kosocharen J, Jones JM (1989) Permeability of latex and vinyl gloves to water and blood. Am J Infect Control 17: 196-201
- Korniewicz DM, Laughon BE, Butz A, Larson E (1989) Integrity of vinyl and latex procedure gloves. Nurs Res 38: 144-146
- Bagg J, Jenkins S, Barker GR (1990) A laboratory assessment of the antimicrobial effectiveness of glove washing and re-use in dental practice. J Hosp Inf 15: 73-82
- Burke FJ, Baggott FJ, Lomax AM (1996) Assessment of the risk of glove puncture during oral surgery procedures. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 82: 18-21
- Burke FJ, Wilson NH (1990) The incidence of undiagnosed punctures in non-sterile gloves. Br Dent J 168: 67-714 | Bundesgesundheitsbl – Gesundheitsforsch – Gesundheitsschutz 4 - 2006 Empfehlung
- Avery CM, Hjort A, Walsh S, Johnson PA (1998) Glove perforation during surgical extraction of wisdom teeth. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 86: 23-25
- Otis LL, Cottone J (1989) Prevalence of perforations in disposable latex gloves during routine dental treatment. J Am Dent Assoc 118: 321-324
- Kotilainen HR, Brinker JP, Avato JL, Gantz NM (1989) Latex and vinyl examination gloves. Quality control procedures and implications for health care workers. Arch Intern Med 149: 2749-2753
- Morgan DJ, Adams D (1989) Permeability studies on protective gloves used in dental practice. Br Dent J 166: 11-13
- Merchant VA, Molinari JA, Pickett T (1992) Microbial penetration of gloves following usage in routine dental procedures. Am J Dent 5: 95-96
- Pitten FA, Herdemann G, Kramer A (2000) The integrity of latex gloves in clinical dental practice. Infection 28: 388-392
- Jamal A, Wilkinson S (2003) The mechanical and microbiological integrity of surgical gloves. ANZ J Surg 73: 140-143
- Schwimmer A, Massoumi M, Barr CE (1994) Efficacy of double gloving to prevent inner glove perforation during outpatient oral surgical procedures. J Am Dent Assoc 125: 196-198
- Patton LL, Campbell TL, Evers SP (1995) Prevalence of glove perforations during double-gloving for dental procedures. Gen Dent 43: 22-26
- Mellstrom GA, Lindberg M, Boman A (1992) Permeation and destructive effects of disinfectants on protective gloves. Contact Dermatitis 26: 163-170
- Jordan SL, Stowers MF, Trawick EG, Theis AB (1996) Glutaraldehyde permeation: choosing the proper glove. Am J Infect Control 24: 67-69
- Baumann MA, Rath B, Fischer JH, Iffland R (2000) The permeability of dental procedure and examination gloves by an alcohol based disinfectant. Dent Mater 16: 139-144
- Richards JM, Sydkis RJ, Davidson WM, et al. (1993) Permeability of latex gloves after contact with dental materials. Am J Orthod Dentofacial Orthop 104: 224-229
- Pitten FA, Müller P, Heeg P, Kramer A (1998/99) Untersuchungen zur wiederholten Desinfizierbarkeit von Einweghandschuhen während des Tragens. Zentbl Hyg Umweltmed 201: 555-562
- Schiffner U (1998) Defekthäufigkeit an Einmalhandschuhen nach längerer Behandlungsdauer. Dtsch Zahnärztl Z 44: 661-663
- Murray CA, Burke FJ, McHugh S (2001) An assessment of the incidence of punctures in latex and non-latex dental examination gloves in routine clinical practice. Br Dent J 190: 377-380
- Checchi L, Conti S, D'Achille C (1991) Evaluation of the permeability of latex gloves for use in dental practice. Quintessenz Int 22: 949-959
- Douglas CWI, Millward TA, Clark A (1989) The use of various handwashing agents to decontaminate gloved hands. Br Dent J 167: 62-65
- Cheung LK, Chow LK, Tsang MH, Tung LK (2001) An evaluation of complications following dental extractions using either sterile or clean gloves. Int J Oral Maxillofac Surg 30: 550-554
- Pippin DJ, Verderame RA, Weber KK (1987) Efficacy of face masks in preventing inhalation of airborne contaminants. J Oral Maxillofac Surg 45: 319-323
- Ständige Impfkommision (STIKO) (2005) Empfehlungen der ständigen Impfkommision am Robert Koch-Institut. EpidBull 30
- Hofmann F (2001) Zur HBV-, HCV- und HIV-Infektion von Patienten durch medizinisches Personal. ErgoMed 3: 70-74
- Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten (DVV) (1999) Zur Verhütung von Hepatitis-B-Virusinfektionen im Gesundheitsdienst. EpidBull 30: 221-223
- Maass G (1998) Zur Beschäftigung von infizierten Mitarbeitern im Gesundheitsdienst. In Hofmann, Reschauer, Stöbel (Hrsg.) Arbeitsmedizin im Gesundheitsdienst Band 11: 201-209
- Jacobs M (2002) Der kranke Arzt: Virale Hepatitiden im Gesundheitswesen – Möglichkeiten und Pflichten zur Vermeidung der Übertragung von Personal auf Patient aus arbeitsrechtlicher Sicht. MedR Nr 3: 140-145
- Gerlich HW (2004) Hepatitis B und C. Übertragungsgefahr auf Patienten durch infiziertes Personal. Bundesgesundheitsbl 47: 369-378
- Nassauer A, Pauli G, Schreier E (1999) Zur Problematik der nosokomialen Übertragung von HIV. Regelungen und Empfehlungen zur Infektionsprävention. EpidBull 34: 251-253
- Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten (DVV) (2001) Empfehlungen zur Verhütung der Übertragung von Hepatitis-C-Virus infiziertes Personal im Gesundheitsdienst. EpidBull 3: 15-16
- Infektionsschutzgesetz (2000) BGBl I: 1045-1077
- Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten (DVV) Empfehlungen zur Prävention der nosokomialen Übertragung von Hepatitis B Virus (HBV) und Hepatitis C Virus (HCV) durch im Gesundheitswesen Tätige. www.dvv-ev.de

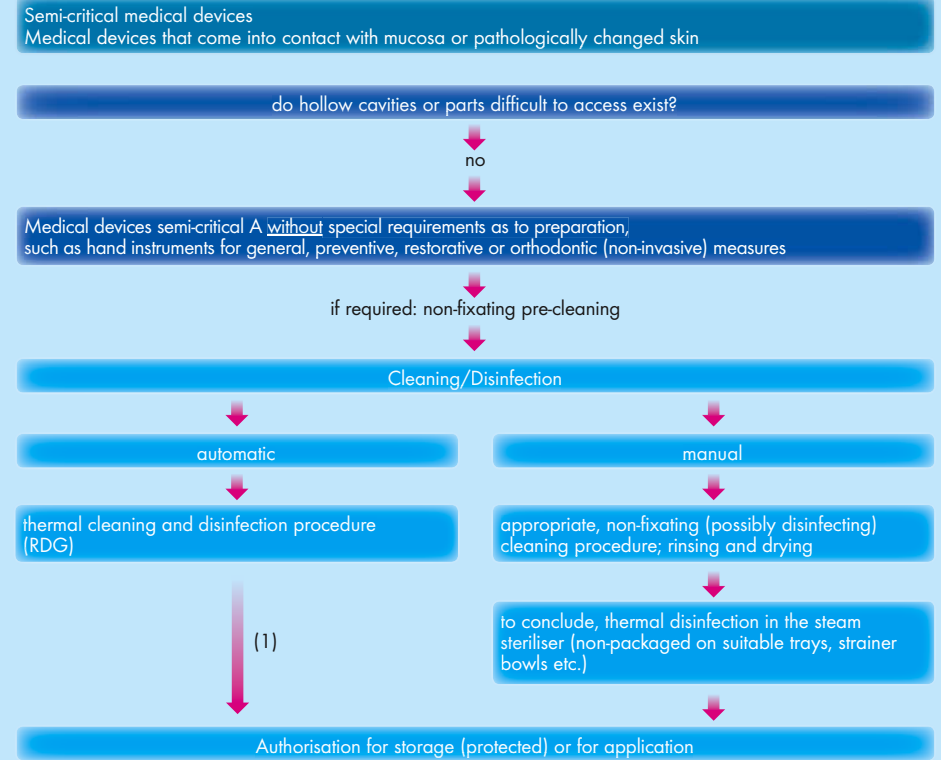
93. Medizinprodukte-Betreiberverordnung (MPBetreibV) BGBl I 2002: 3397-3404
94. Kommission für Krankenhaushygiene und Infektionsprävention (2001) Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten. Bundesgesundheitsbl 44: 1115-1126
95. Gesetz über Medizinprodukte (MPG) vom 2. August 1994, BGBl. I: 1963; zuletzt geändert durch Art. 109 V vom 25. November 2003, BGBl. I: 2304
96. Gooch B, Marianos D, Ciesielski C, et al. (1993) Lack of evidence for patient-to-patient transmission of HIV in a dental practice. *J Am Dent Assoc* 124: 38-44
97. Checchi L, Montebugnoli L, Samaritani S (1998) Contamination of the turbine air chamber: a risk of cross infection. *J Clin Periodontol* 25: 607-611
98. Lewis DL, Arens M, Appleton SS, et al. (1992) Cross-contamination potential with dental equipment. *Lancet* 340: 1252-1254
99. Lewis DL, Boe RK (1992) Cross-infection risks associated with current procedures for using high-speed dental handpieces. *J Clin Microbiol* 30: 401-406
100. Mills SE, Kuehne JC, Bradley DV Jr. (1993) Bacteriological analysis of high-speed handpiece turbines. *J Am Dent Assoc* 124: 59-62
101. Crawford JJ, Broderius C (1988) Control of cross-infection risks in the dental operatory: prevention of water retraction by bur cooling spray systems. *J Am Dent Assoc* 116: 685-687
102. Kuehne JS, Cohen ME, Monroe SB (1992) Performance and durability of autoclavable dental highspeed handpieces. NDRI-PR 92-03. Bethesda, MD: Naval Dental Research Institute
103. Andersen HK, Fiehn NE, Larsen T (1999) Effect of steam sterilization inside the turbine chambers of dental turbines. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 87: 184-188
104. Leonard DL, Charlton DG (1999) Performance of high-speed dental handpieces subjected to simulated clinical use and sterilization. *J Am Dent Assoc* 130: 1301-1311
105. Hokett SD, Honey JR, Ruiz F, et al. (2000) Assessing the effectiveness of direct digital radiography barrier sheaths and finger cots. *J Am Dent Assoc* 131: 463-467
106. Hodson NA, Dunne SM, Pankhurst CL (2005) The effect of infection-control barriers on the light intensity of light-cure units and depth of cure of composite. *Prim Dent Care* 12: 61-67
107. Rapisarda E, Bonaccorso A, Tripi TR, Guido G (1999) Effect of sterilization on the cutting efficiency of rotary nickel-titanium endodontic files. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 88: 343-347
108. Filho IB, Esberard RM, Leonardo R, del Rio CE (1998) Microscopic evaluation of three endodontic files preand postinstrumentation. *J Endodontics* 24: 461-464
109. Silvaggio J, Hicks ML (1997) Effect of heat sterilization on the torsional properties of rotary nickel-titanium endodontic files. *J Endodontics* 23: 731-734
110. Kazemi RB, Stenman E, Spangberg LS (1995) The endodontic file is a disposable instrument. *J Endodontics* 21: 451-455
111. Miller CH, Riggen SD, Sheldrake MA, Neeb JM (1993) Presence of microorganisms in used ultrasonic cleaning solutions. *Am J Dent* 6: 27-31
112. Miller CH, Palenik CJ (2001) Sterilization, disinfection, and asepsis in dentistry [Chapter 53]. *Block SS ed. 5th ed. Disinfection, sterilization and preservation*, Philadelphia, PA Lippincott Williams & Wilkins: 1049-1068
113. Rutala WA (1998) Disinfection, sterilization and antisepsis in health care. Association for Professionals in Infection Control and Epidemiology, Inc. Washington, D.C. USA and Polyscience Publications, Inc. Champaign, N.Y. USA
114. Wallhäuser KH (1995) Praxis der Sterilisation, Desinfektion – Konservierung. 5. Aufl. Georg Thieme, Stuttgart New York
115. Scheel KT, Bössmann K (1999) Auswirkungen Europäischer Normen auf Dampf-Klein-Sterilisatoren für die Zahnmedizin. *Quintessenz* 50: 631-635
116. Guggenheim B, Bombelli A, Wiehl P (1999) Sterilisation in der zahnärztlichen Praxis: Definitionen, Verfahren, Euro-Normen und Empfehlungen (III). *Schweiz Monatsschr Zahnmed* 109: 1061-1072
117. Smith A (2003) CJD and the dentist. *Dent Update* 5: 180-186
118. Hamilton K, Brewer A, Smith A (2004) Dental treatment of a patient in the new 'at-risk' category for CJD. *J Hosp Infect* 57: 184-185
119. Simon D, Pauli G (1998) Krankenversorgung und Instrumentensterilisation bei CJK-Patienten und CJK-Verdachtsfällen. *Bundesgesundheitsbl* 41: 279-285
120. Task Force vCJK am Robert Koch-Institut (2002) Die Variante der Creutzfeldt-Jakob-Krankheit (vCJK). Epidemiologie, Erkennung, Diagnostik und Prävention unter besonderer Berücksichtigung der Risikominimierung einer iatrogenen Übertragung durch Medizinprodukte, insbesondere chirurgische Instrumente. *Bundesgesundheitsbl* 45: 376-394
121. Trinkwasserverordnung (TrinkwV) BGBl I 2001: 959
122. Martin MV (1987) The significance of the bacterial contamination of dental unit water systems. *Br Dent J* 163: 152-154
123. Walker JT, Bradshaw DJ, Bennett AM, et al. (2000) Microbial biofilm formation and contamination of dental-unit water systems in general dental practice. *Appl Environ Microbiol* 66: 3363-3367
124. Schulze-Röbbcke R, Feldmann C, Fischeder R, et al. (1995) Dental units: an environmental study of sources of potentially pathogenic mycobacteria. *Tuber Lung Dis* 76: 318-323 *Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz* 4 - 2006 | Guidetti L, Galiano A, D'Angelo M (2004) Contamination by Legionella spp of dental unit water systems: preliminary results from a survey in al Local Health Authority in Northern Italy. EWGLI Meeting, Chamonix
126. Fitzgibbon EJ, Bartzokas CA, Martin MV, et al. (1984) The source, frequency and extent of bacterial contamination of dental unit water systems. *Br Dent J* 157: 98-101
127. Fayle SA, Pollard MA (1996) Decontamination of dental unit water systems: a review of current recommendations. *Br Dent J* 181: 369-372
128. Exner M, Haun F, Kocikowski R (1981) Zahnärztliche Einheiten als Kontaminationsquellen für *Pseudomonas aeruginosa*. *Dtsch Zahnärztl Z* 36: 819-824
129. Williams HN, Johnson A, Kelley JI, et al. (1995) Bacterial contamination of the water supply in newly installed dental units. *Quintessenz Int* 26: 331-337
130. Walker JT, Bradshaw DJ, Fulford MR, Marsh PD (2003) Microbiological evaluation of a range of disinfectant products to control mixed-species biofilm contamination in a laboratory model of a dental unit water system. *Appl Environ Microbiol* 69: 3327-3332
131. Lee TK, Waked EJ, Wolinsky LE, et al. (2001) Controlling biofilm and microbial contamination in dental unit waterlines. *J Calif Dent Assoc* 29: 679-684
132. Montebugnoli L, Chersoni S, Prati C, Dolci G (2004) A between-patient disinfection method to control water line contamination and biofilm inside dental units. *J Hosp Infect* 56: 297-304
133. Bierhenke R, Schmage P (2002) Zur Verbesserung der mikrobiologischen Wasserqualität in zahnärztlichen Behandlungseinheiten. *ZMK* 80: 550-560
134. Bierhenke R, Schmage P, Nergiz I, et al. (2001) Verhinderung der Keimbesiedelung des Kühlwassersystems in zahnärztlichen Behandlungseinheiten. *Dtsch Zahnärztl Zeitschr* 56: 118-121
135. Santiago JI, Huntington MK, Johnston MA (1994) Microbial contamination of dental units water lines. Short and long-term effects of flushing. *Gen Dent* 45: 528-535
136. Singh R, Bagga BS, Murphy RA, et al. (1984) Contamination of dental unit cooling water with oral microorganism and its prevention. *JADA* 109: 712-716
137. Bagga BS, Murphy RA, Anderson AW, Pupwani J (1984) Contamination of dental cooling water with oral microorganisms and its prevention. *J Am Dent Assoc* 109: 712-716
138. Scheid RC, Rosen S, Beck FM (1990) Reduction of CFUs in high-speed handpiece water lines over time. *Clin Prev Dent* 12: 9-12
139. Miller C (1996) Back flow in low-volume suction lines may lead to potential cross-contamination. *RDH* 16: 30
140. Reinhaller F, Mascher F, Stütznier D (1987) *Legionella pneumophila*: Seroepidemiologische Untersuchung bei Zahnärzten und zahnärztlichem Personal in Österreich. *Zbl Hyg Bakt (Serie B)* 185: 164-170
141. Oppenheim BA, Sefton AM, Gill OM, et al. (1987) Widespread *Legionella pneumophila* contamination of dental stations in a dental school without apparent human infection. *Epidemiol Infect* 99: 159-166
142. Pankhurst CL, Coulter W, Philpott-Howard JN, et al. (2005) Evaluation of the potential risk of occupational asthma in dentists exposed to contaminated dental unit waterlines. *Prim Dent Care* 12: 53-59
143. Exner M (2003) Hygiene und Mikrobiologie – unter besonderer Berücksichtigung der Wasserversorgung. *Hyg Med* 28: 483-494
144. Jorgensen MG, Detsch SG, Wolinsky LE (1999) Disinfection and monitoring of dental water lines. *Gen Dent* 47: 152-156
145. Luck PC, Lau B, Seidel S, Postl U (1992) Legionellen in Dentaleinheiten – ein hygienisches Risiko? *Dtsch Zahn Mund Kieferheilkd Zentralbl.* 80: 341-346
146. Waltimo T, Christen S, Meurman JH, Filippi A (2005) [Dental care of patients with leukemia]. *Schweiz Monatsschr Zahnmed* 115(4): 308-315
147. Ohmagari N, Hanna H, Graviss L, et al (2005) Risk factors for infections with multidrug-resistant *Pseudomonas aeruginosa* in patients with cancer. *Cancer* 104(11): 205-12
148. Barasch A, Gordon S, Geist RY, Geist JR (2003) Necrotizing stomatitis: report of 3 *Pseudomonas aeruginosa*-positive patients. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 96(2): 136-140
149. Stephenson JR, Heard SR, Richards MA, Tabaqchali S (1985) Gastrointestinal colonization and septicaemia with *Pseudomonas aeruginosa* due to contaminated thymol mouthwash in immunocompromised patients. *J Hosp Infect* 6(4): 369-378
150. Levy-Polack MP, Sebelle P, Polack NL (1998) Incidence of oral complications and application of a preventive protocol in children with acute leukemia. *Spec Car Dentist* 18(5): 189-193
151. Wohlschlaeger A (2004) Prevention and treatment of mucositis: a guide for nurses. *J Pediatr Oncol Nurs* 21(5): 281-287
152. Exner M, Gornik V (2004) Parasitic zoonoses transmitted by drinking water. *Giardiasis and cryptosporidiosis*. *Bundesgesundheitsbl* 47: 698-704
153. Centers for Disease Control and Prevention (2000) Guidelines for preventing opportunistic infections among hematopoietic stem cell transplant recipients. *MMWR Recomm Rep* 49(RR-10)
154. Exner M, Kramer A, Lajoie L, et al. (2005) Prevention and control of health care-associated waterborne infections in health care facilities. *Am J Infect Control* 33(5 Suppl 1): 26-40
155. Leclerc H, Schwartzbrod L, Dei-Cas E (2002) Microbial agents associated with waterborne diseases. *Crit Rev Microbiol* 28(4): 371-409
156. Singh N (2004) Chapter 59, Nosocomial Infections in Solid Organ Transplant Recipients. In: Mayhall C (ed.) *Hospital Epidemiology and Infection Control*. 3rd Edition ed. Philadelphia Baltimore New York: Lippincott Williams & Wilkins: 985-1009
157. Cosgrove S, Perl TM (2004) Chapter 60; Infection Control and Prevention in Hematopoietic Stem Cell Transplant Patients. In: Mayhall C (ed.) *Hospital Epidemiology and Infection Control*. 3rd Edition ed. Philadelphia Baltimore New York: Lippincott Williams & Wilkins: 1011-1070
158. Singh R, Colin SO, Smith DL, et al. (2003) Microbial diversity of biofilms in dental unit water systems. *Appl Environ Microbiol* 69: 3412-3420
159. Szymanska J (2003) Biofilm and dental unit waterlines. *Ann Agric Environ Med* 10: 151-157
160. Clarkson JE, Worthington HV, Eden OB (2003) Interventions for preventing oral mucositis for patients with cancer receiving treatment. *Cochrane Database Syst Rev* 3: CD000978
161. Doring G, Conway SP, Heijerman HG, et al. (2000) Antibiotic therapy against *Pseudomonas aeruginosa* in cystic fibrosis: a European consensus. *Eur Respir J* 16(4): 749-767
162. Jensen ET, Giwercman B, Ojienyi B, et al. (1997) Epidemiology of *Pseudomonas aeruginosa* in cystic fibrosis and the possible role of contamination by dental equipment. *J Hosp Infect* 36(2): 117-122
163. Rajan S, Saiman L (2002) Pulmonary infections in patients with cystic fibrosis. *Semin Respir Infect* 17(1): 47-56
164. Saiman L, Siegel J (2003) Infection control recommendations for patients with cystic fibrosis: microbiology, important pathogens, and infection control practices to prevent patient-to-patient transmission. *Infect Control Hosp Epidemiol* 24(5 Suppl): 6-52
165. Saiman L, Siegel J (2004) Infection control in cystic fibrosis. *Clin Microbiol Rev* 17(1): 57-71
166. Barbeau J, ten Bokum L, Gauthier C, Prevost AP (1998) Cross-contamination potential of saliva ejectors used in dentistry. *J Hosp Infect* 40: 303-311
167. Mann GL, Campbell TL, Crawford JJ (1996) Backflow in low-volume suction lines: the impact of pressure changes. *J Am Dent Assoc* 127: 611-615
168. Watson CM, Whitehouse RL (1993) Possibility of cross-contamination between dental patients by means of the saliva ejectors. *J Am Dent Assoc* 124: 611-615
- 168a. Mielke M, Reitemeier B, Neumann K, Jatzmank L (2005) Zahnärztliche Absauganlagen – ein potenzieller Übertragungsweg für Hepatitisviren. *Hyg. Med.* 30: 453-458
169. Muller-Bolla M, Lupi-Pegurier L, Vally AM, Bolla M (2004) A survey of disinfection of irreversible hydrocolloid and silicone impressions in European Union dental schools: epidemiologic study. *Int J Prosthodont* 17: 165-171
170. Sofou A, Larsen T, Fiehn NE, Owall B (2002) Contamination level of alginate impressions arriving at a dental laboratory. *Clin Oral Invest* 6: 161-165
171. Sofou A, Larsen T, Owall B, Fiehn NE (2002) In vitro study of transmission of bacteria from contaminated metal models to stone models via impressions. *Clin Oral Invest* 6: 166-170
172. Jagger DC, Huggett R, Harrison A (1995) Cross-infection control in dental laboratories. *Br Dent J* 179: 93-96
173. Merchant VA (1992) Update on disinfection of impressions, prostheses, and casts, ADA 1991 guidelines. *J Calif Dent Assoc* 20: 31-35
174. Kommission für Krankenhaushygiene und Infektionsprävention (2004) Anforderungen an die Hygiene bei der Reinigung und Desinfektion von Flächen. *Bundesgesundheitsbl* 47: 51-61
175. O'Donnell MJ, Tuttlebee CM, Falkner FR, Coleman DC (2005) Bacterial contamination of dental chair units in a modern dental hospital caused by leakage from suction system hoses containing extensive biofilm. *J Hosp Infect* 59: 348-360
176. Kommission für Krankenhaushygiene und Infektionsprävention (1995) Anforderungen der Hygiene an die Wäsche aus Einrichtungen des Gesundheitsdienstes, die Wäscherei und den Waschvorgang und Bedingungen für die Vergabe von Wäsche an gewerbliche Wäschereien – Anlage zu den Ziffern 4.4.3 und 6.4 der Richtlinie Krankenhaushygiene und Infektionsprävention. *Bundesgesundheitsbl* 38: 280-283
177. Glass BJ, Terezhalmay GT (1996) Infection control in dental radiology [Chapter 15]. In: Cottone JA, Terezhalmay GT, Molinari JA, eds. *Practical infection control in dentistry*. 2nd ed Baltimore. MD: Williams & Wilkins: 229-238
178. Arbeitsstättenverordnung (ArbstättV) mit zugehörigen Arbeitsstättenrichtlinien (ASR); vom 12.8.2004. BGBl. I: 2179, siehe auch www.baua.de, Rubrik Praxis/Arbeitsstätten

Annex 1



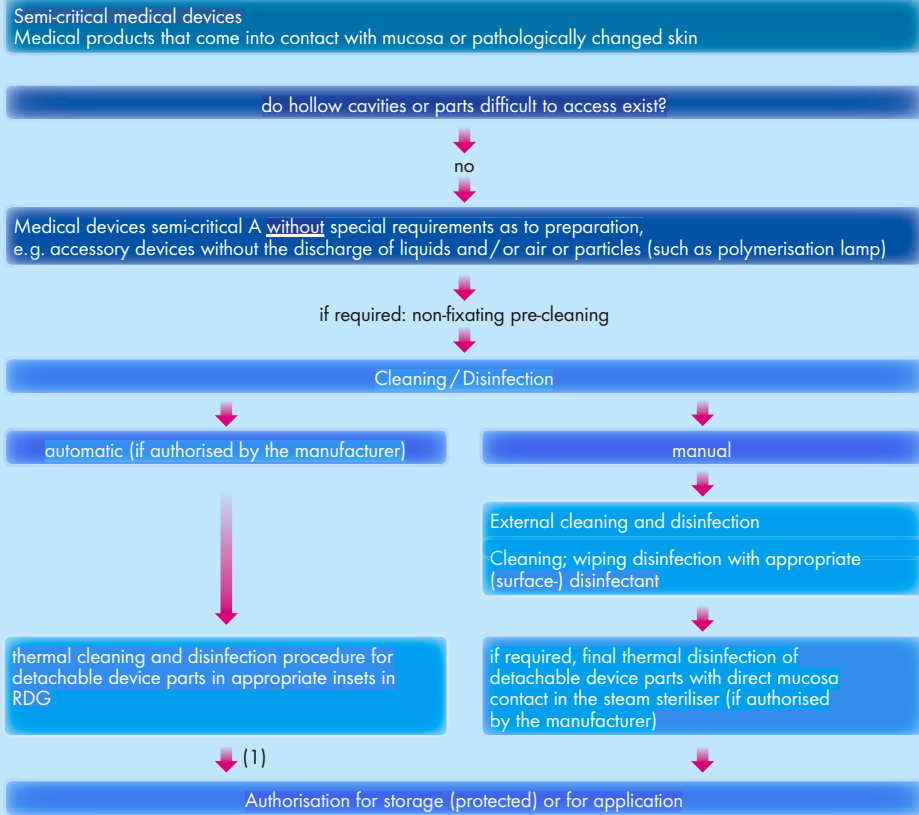
1) General disinfection for practical reasons and because of the general proximity of the mucosa.

Annex 2



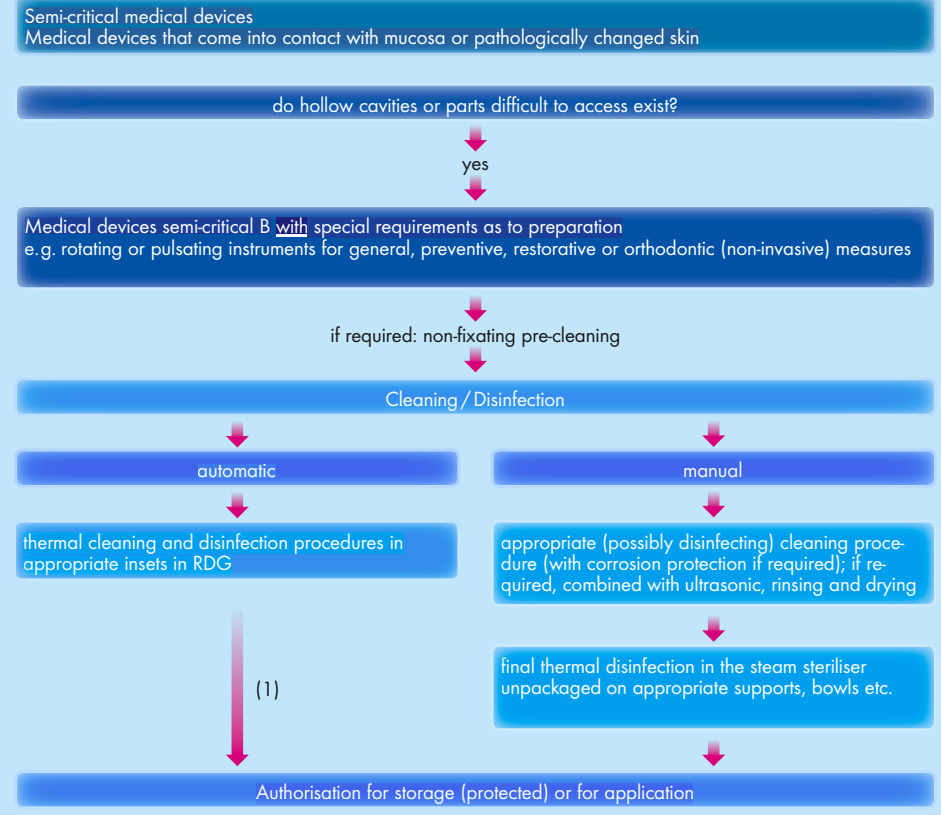
1) If only automatic cleaning is carried out (without evidenced disinfection) a final thermal disinfection in the steam steriliser is required.

Annex 3



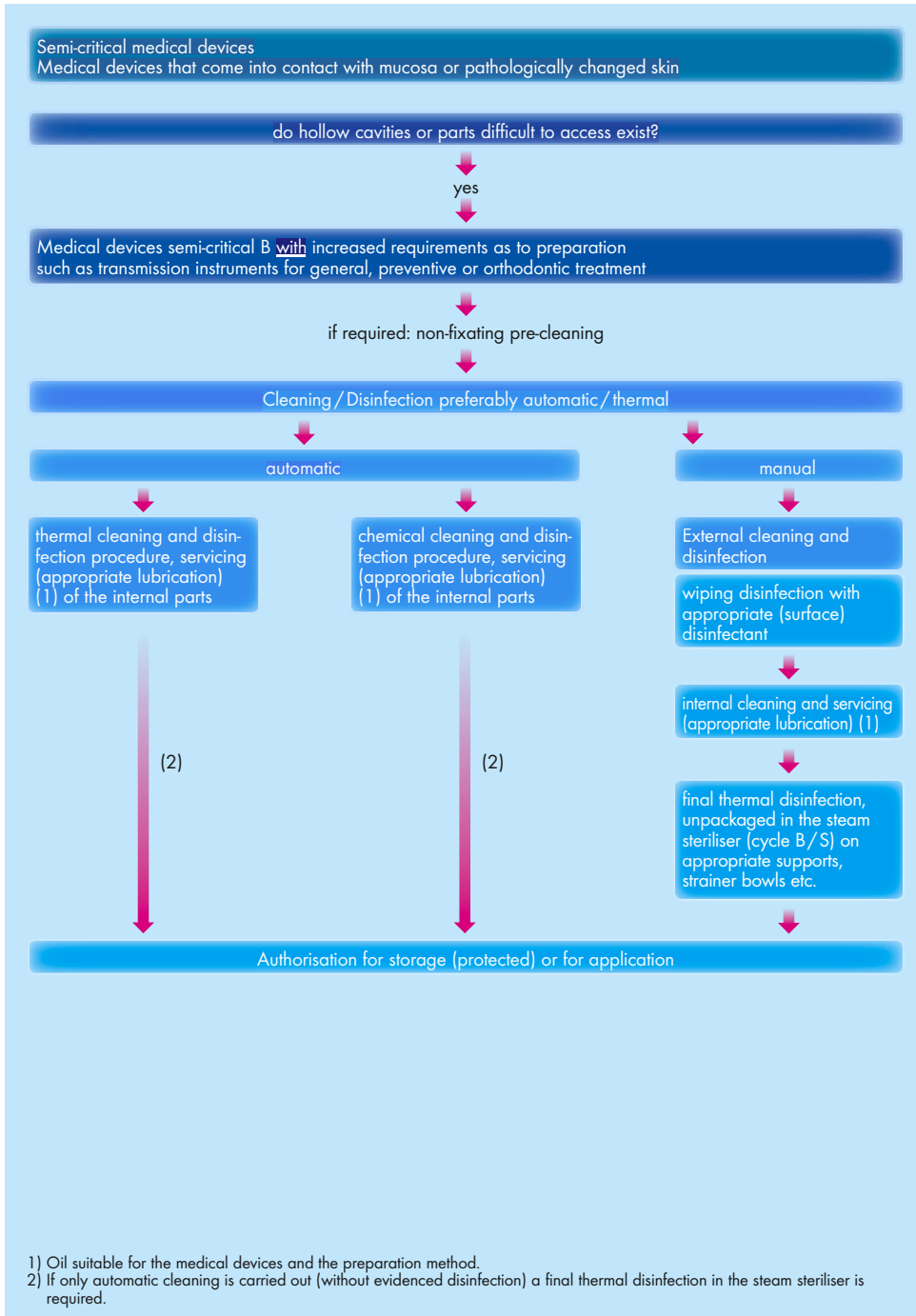
1) If only automatic cleaning is carried out (without evidenced disinfection) a final thermal disinfection in the steam steriliser is required.

Annex 4

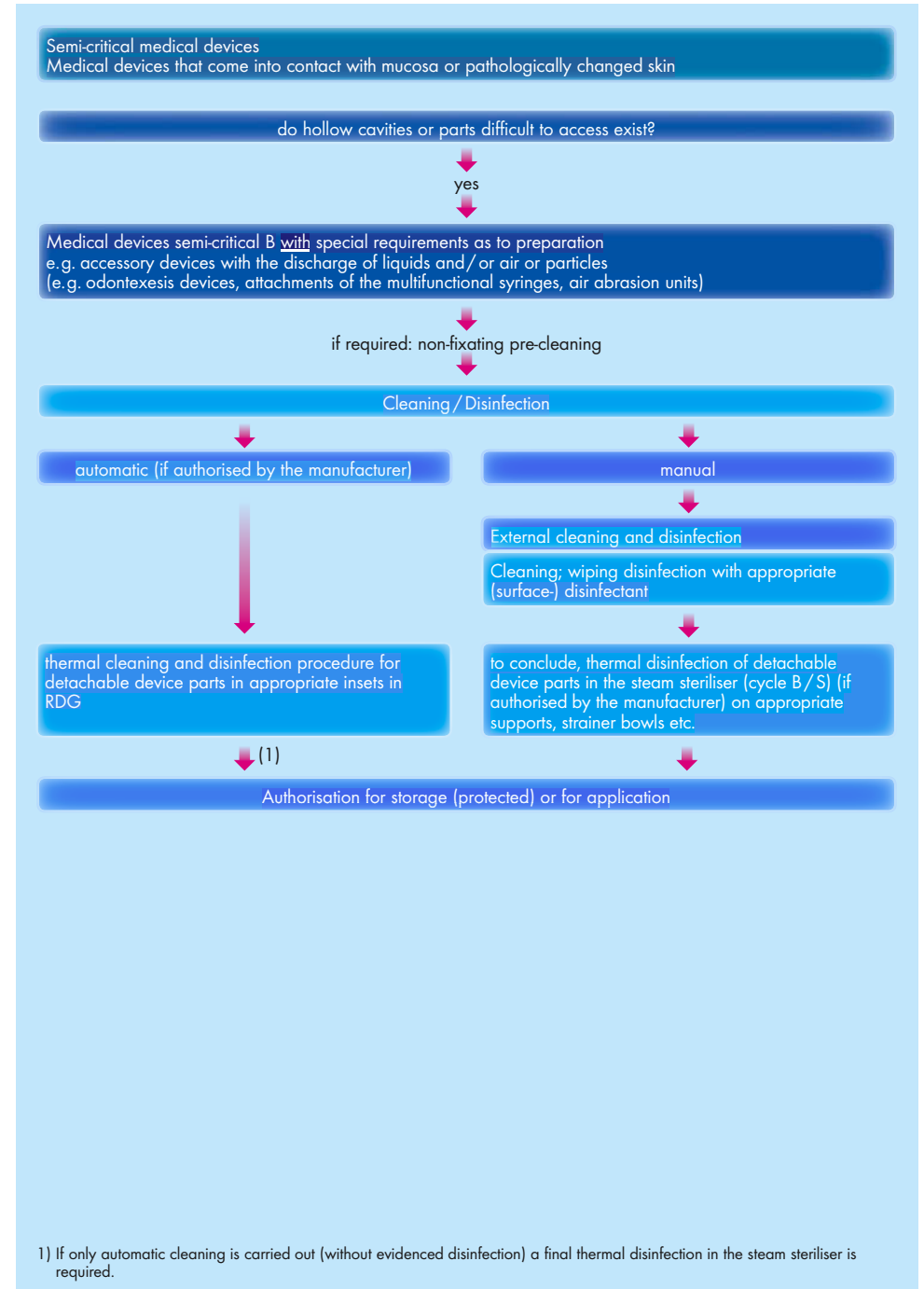


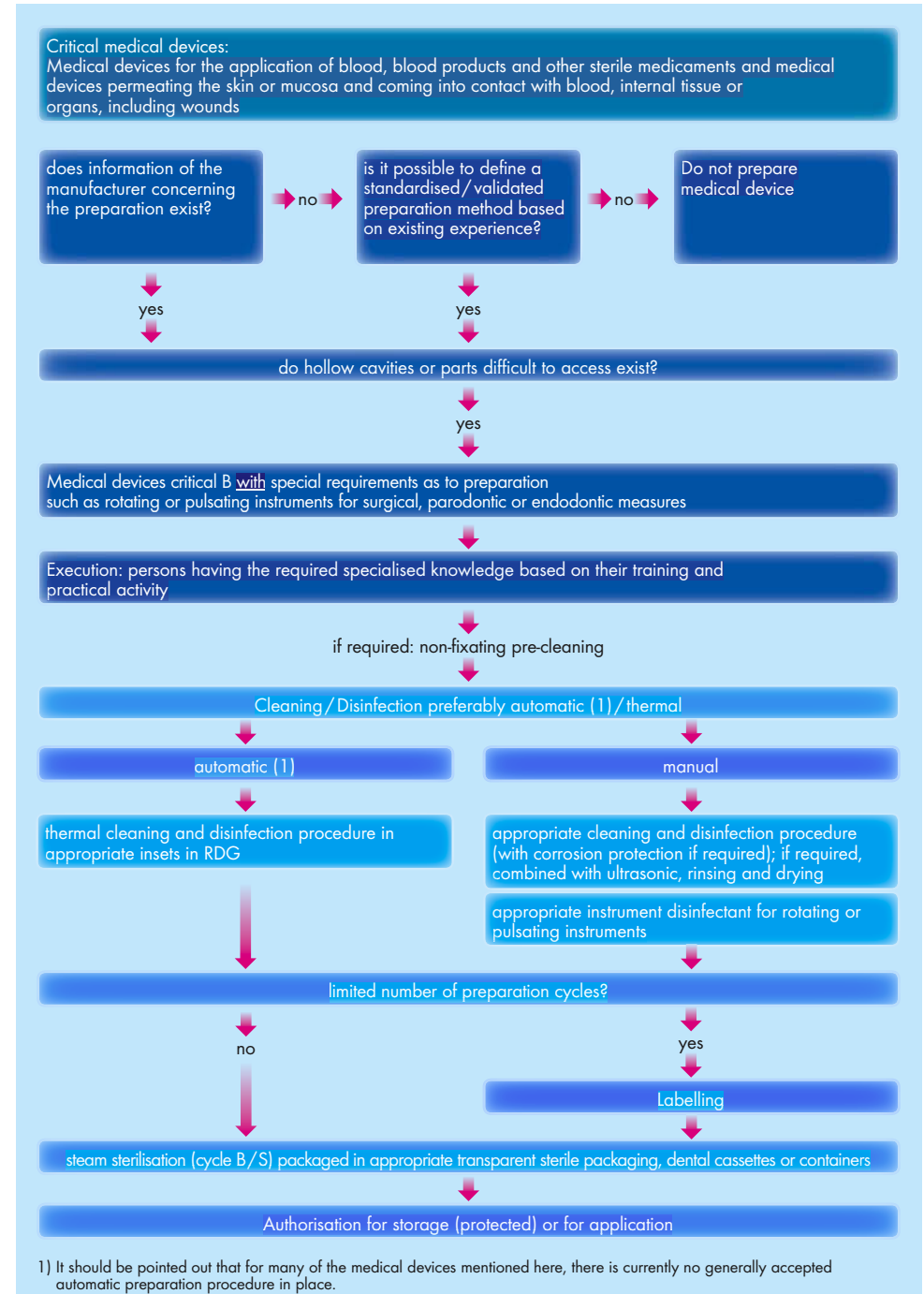
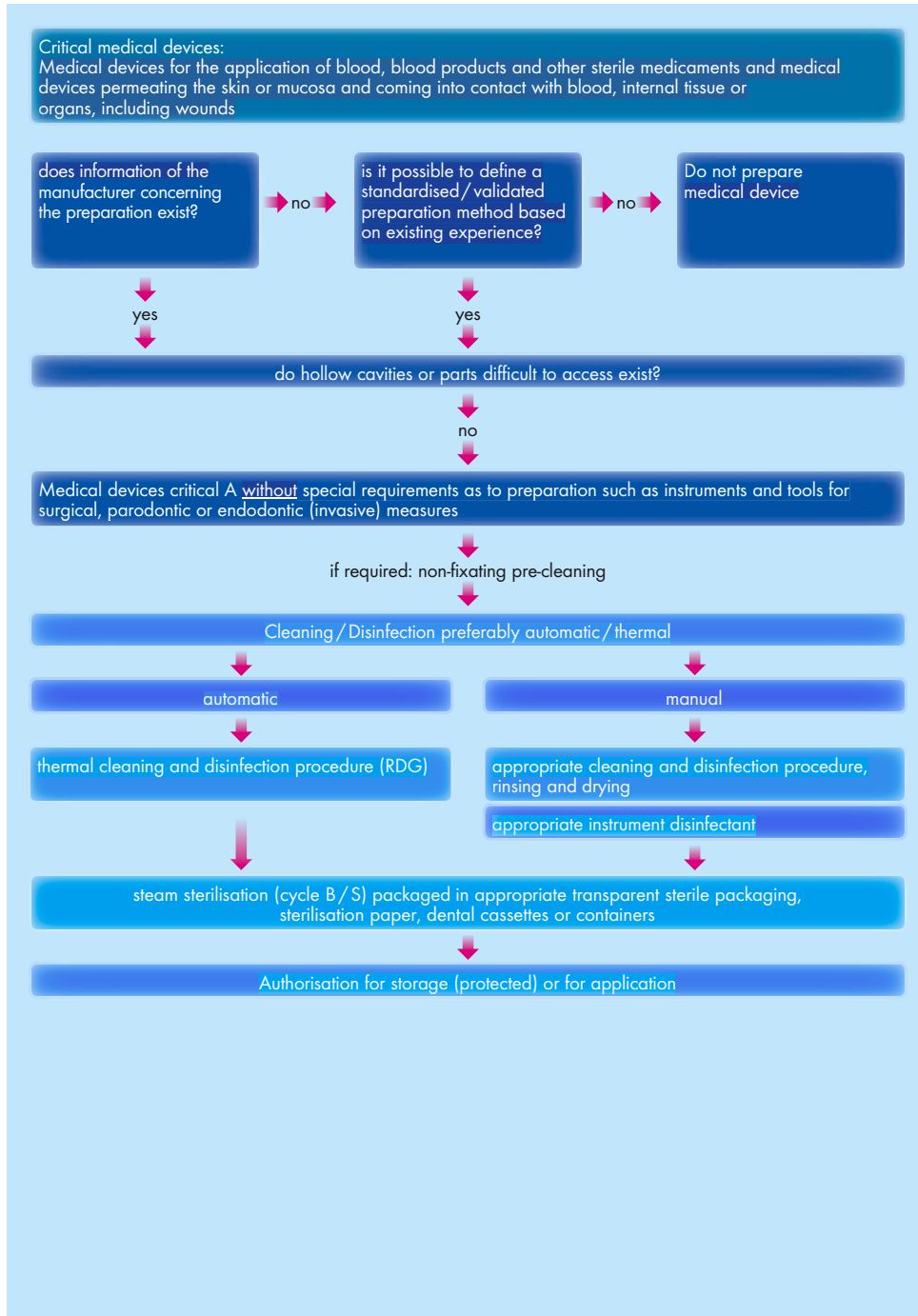
1) If only automatic cleaning is carried out (without evidenced disinfection) a final thermal disinfection in the steam steriliser is required.

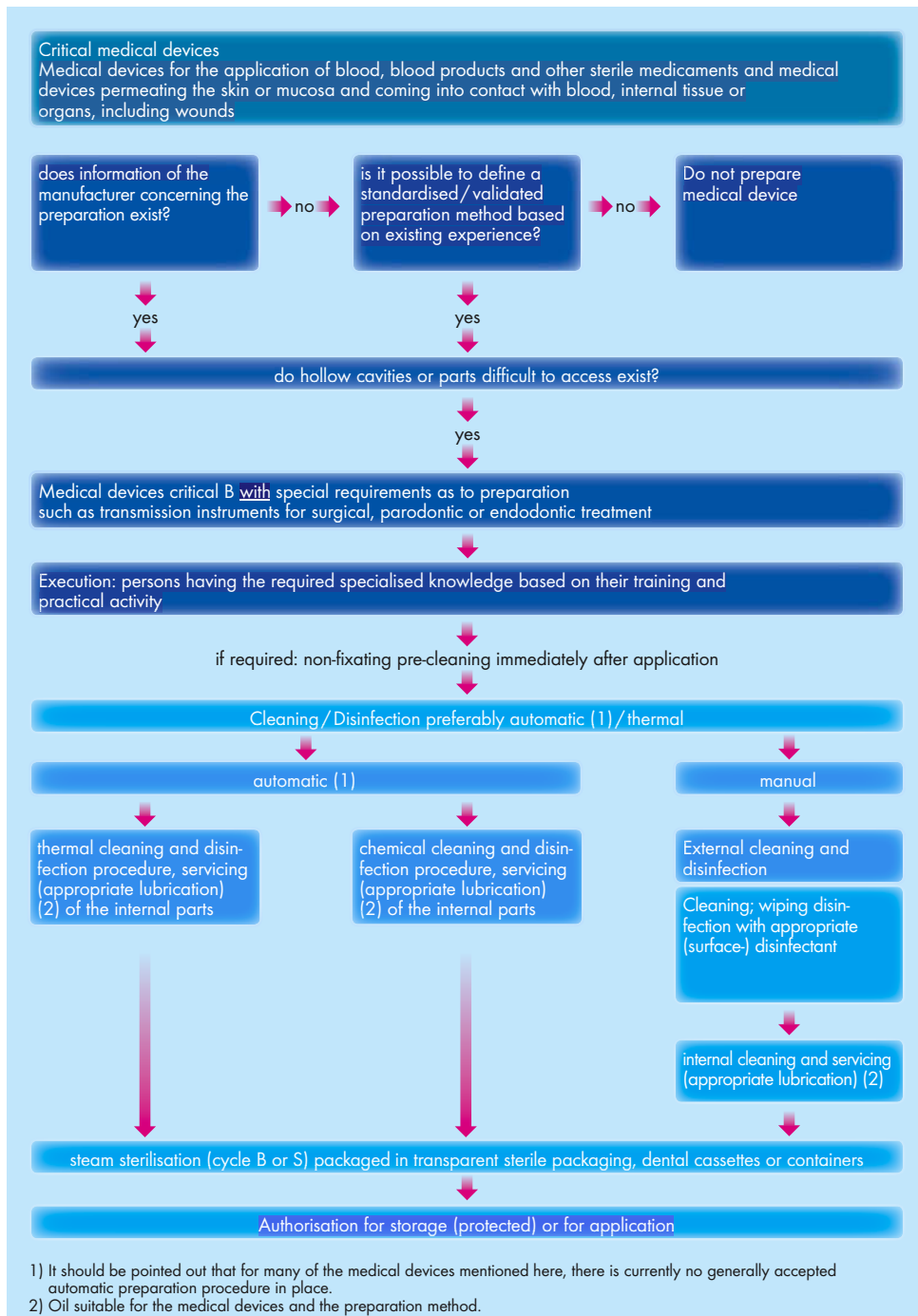
Annex 5



Annex 6







In 1997, the members of the Commission for Hospital Hygiene and Infectious Disease Prevention at the Robert Koch Institute agreed to revise the individual recommendations of the Guideline for Hospital Hygiene and Infectious Disease Prevention according to today's state of science and in line with the requirements for scientific recommendations (evidence and transparency). This challenge is met by a graded classification, evidenced by the relevant literature mentioned.

- **Category I:**
Strong recommendation
Category IA:
The recommendations are based on thoroughly planned experimental or epidemiologic studies.
Category IB:
The recommendations are considered to be effective by experts according to a consensual decision of the Commission for hospital hygiene and Infectious Disease Prevention at the Robert Koch Institute; they are based on well-founded indications as to their effectiveness. An allocation of the respective recommendation to category IB may also be possible if scientific studies on this have not been conducted yet.
- **Category II:**
Conditional recommendation
The recommendations are based on indicating clinical or epidemiological studies, partially on comprehensible theoretic reasons or studies to be implemented in some, but not all, hospitals/situations.
- **Category III:**
No recommendation/Unsolved question
Measures whose effectiveness is only insufficiently backed by indications or about which there is no consensual agreement.
- **Category IV:**
Legal provisions
Requirements, measures and procedures in hospitals and other medical institutions to be met due to legal provisions self-dependent laws or administrative provisions.

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