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Part A Medical Technology Basics

1. Technology in Medicine: Its Role and Significance in Terms of Health Policy

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New avenues in diagnosis and therapy are today increasingly being opened up as a result of sophisticated and advanced technology, and at the forefront of this are evolutionary developments in existing technology. Many medical devices and pieces of equipment are developing at lightning speed as a result of digital technologies, which enable new medical concepts, strategies, and visions to be implemented faster than ever before. This means that developments which previously took a decade to implement are now being introduced at a rate of one a year. Technology thus not only has a dynamic interrelationship with medicine; it influences and shapes modern medical science on the basis of new technical possibilities. First-class health care would be inconceivable without progress and innovation in the field of medical technology.

1.1 A Short History

Medicine (from the Latin *ars medicīna*, *the art of healing*) and technology (from the Greek, meaning *skill, craft*) have inspired and fascinated mankind since its early beginnings. Technical instruments and devices have always had their place in medicine. Acupuncture needles are known to have been used in Far Eastern medicine since approximately 2500 BC. Hippocrates (460–370 BC), the founder of scientific medicine in the Western world and a prominent doctor of his time, was already using a proctoscope to inspect his patients' intestines. He also gave descriptions of a variety of instruments and apparatuses for the treatment of wounds. These included, for example, apparatuses with weights and straps which, in the case of an arm fracture, positioned the broken bones in relation to one another, straightened them, and simultaneously immobilized them. As striking evidence from archeological digs in the buried town of Pompeii has shown, sophisticated instruments and devices for surgical interventions were already being used in the Roman Empire (from 63 BC onwards). The vision aids known as glasses, on which many of us rely, are not an achievement of the 20th century but had already been invented by a craftsman at the end of the 13th century.

1.2 Early Breakthroughs of Medical Technology

The first major breakthrough in medical technology and boom in modern medicine took place around the turn of the 20th century with Röntgen's discovery of x-rays in 1895. Although the nomenclature of the electrocardiograph (ECG) – which is still in use today – had already been decided by Einthoven in 1895, use

of the first clinically viable ECG was not possible until 1903. In 1896, Riva-Rocci introduced the method of noninvasive palpatory measurement for determining blood pressure. The electroencephalogram (EEG) was first recorded in 1924 by Berger using a string galvanometer. Other milestones in medical technology were the invention and introduction of the artificial kidney (1942), the heart–lung machine (1953), hip-joint prostheses (1960), artificial cardiac valves (1961), and the first clinical patient monitoring devices (around 1965). Criteria which had already been used for classification in the USA were developed for measurement and standardization of the ECG according to the Minnesota Code around 1960. In the early 1940s, the construction of the first electronic computer ushered in a new era, and a new technology was born which was to revolutionize medical technology once more: data processing and information technology. This new technology overshadowed all the technological developments which went before it. If a modern calculator were equipped with electronic components (e.g., transistors) from 40 years ago, that calculator would require a power of 6000 W, provided by an electricity supply and emitted to the surroundings as heat. A weight of 50 kg and cube edges approximately 1 m in length would more likely suggest an oven than a calculator.

1.3 Analog to Digital

The radical change in technology from analogue to digital opened up new dimensions in medical technology: the computer tomograph (CT), which generates cross-sectional images of the body, was developed by Hounsfield and Cormack, and a prototype was installed and tested in a hospital in 1971. In 1977, Mansfield found success with a breakthrough for medical applications of magnetic resonance tomography using the magnetic resonance method, and the human thorax was imaged for the first time without the use of x-rays. Unique and sophisticated possibilities in diagnosis were introduced by a large-scale medical technology system which is used in nuclear medicine: the positron emission tomograph (PET). As an imaging system, the PET enhances the diagnostic range because it enables representations of physiological and metabolic processes in the human body to be determined both quantitatively and on a location-dependent basis. Molecular imaging with hybrid PET/CT scanners offers a view of things which had previously not been visible. However, other hybrids such as ultrasound and magnetic resonance imaging also not only have the advantage that they offer an image quality which is much more precise and accurate in every detail when compared with other imaging methods, but they can also be used without any exposure to radiation. It has so far been possible to reduce the radiation dose for a full body scan to as little as 40% compared with older systems.

As a result of the increasing integration of computer-based systems in x-ray technology, imaging methods are being redeveloped in ever shorter time cycles. The rapid growth of the spectrum of clinical applications and the continuous further development and implementation of new technologies have not only led to an altered and extended range of indications for these methods. Furthermore, imaging technologies are increasingly being developed as a complete solution, such as hybrid systems for interventional radiology or integrated IT solutions (picture archiving and communication system (PACS), radiology information system (RIS), etc.) which aim to optimize processes and thus increase efficiency in hospitals. The increasing interconnectedness of technology will change the health system.

To outline the progress and development of all the devices and achievements in medical technology would be to go beyond the scope of this book. Although medical technology is in most cases not original but rather adopts technological developments from fields such as electronics, optics, precision engineering, and plastics technology among others, and these developments are only thought of as being part of medical technology when applied to living creatures, medical technology has nevertheless established itself as a field, and medical care today would be unthinkable without it. This fact reveals the real significance of medical technology:

Medical technology devices and equipment (including in the laboratory and research field) are individual or interlinked instruments, apparatuses, machines, appliances, and auxiliary devices, and any necessary equipment which is used because of its function for the identification (diagnosis), treatment (therapy), observation (monitoring), and prevention (prophylaxis) of illness in humans.

1.4 Health Policy

The aim of health policy must be to provide human, modern, high-performance, efficient, and people-orientated medical care both in hospitals and on an ambulatory basis, with the focus on the patient. In the future, diagnosis and therapy will be adjusted according to the genetics of the patient, and technical solutions will be orientated towards the interaction between diagnosis and therapy. Another trend is that of orientation towards disease patterns. This aspect is even more important, because the risks of acute illnesses will increase as a result of ageing society. Investment in health care should provide benefits, not only in terms of administration at the level of individual hospitals and clinics but also in terms of national economics.

The development of medical technology as an essential part of health care is in permanent interaction with the changes in social lifestyles. The significance of medical technology in terms of health policy is therefore essentially based on the following points.

- The quality and security of medical care as a result of continuous modifications and improvements to diagnostic and therapeutic options and promotion of medical and technological research, and furthermore with broad application and extension to large population and patient groups using equipment-based mass screening (e.g., within the scope of illness prevention).
- Shortening the duration of illness or the length of hospital stay, which will reduce costs and therefore bring about associated benefits in terms of national economics.
- Relieving staff from time-consuming routine jobs.
- Meeting the expectations and demand level of the population in terms of the quality of the processes and of the results in health care.

Future developments in technical medicine must be geared towards the additional demands of health care as a result of limited resources.

- Medical technological diagnosis and therapy with high cost-savings potential, using environmentally friendly equipment and systems.
- Further development of minimally invasive procedures with the aim of reducing morbidity rates and convalescence times.
- Miniaturized compact systems, which are less time and cost intensive in terms of installation and servicing.
- User-friendly and operationally reliable design, which substantially avoids faulty operation. Invasive techniques will increasingly be replaced by less invasive and/or noninvasive techniques, such as disintegration of kidney and gall stones using a lithotripter instead of surgical intervention, endoscopic minimally invasive interventions instead of conventional surgery, three-dimensional (3-D) echocardiography to show complex malformations of the heart, pathomorphological changes in the mitral or tricuspid valve, and atrial or ventricular septal defects instead of the complex and high-risk procedure of cardiac catheterization, and imaging the coronary vessels using magnetic resonance imaging instead of contrast angiography or diagnosis by cardiac catheterization.

It is becoming apparent that the boundaries between diagnosis and therapy are becoming increasingly blurred by the use of current technological solutions such as interventional radiological or endoscopic procedures, for example.

Where operative interventions in traditional surgery were performed using a scalpel and surgical instruments, in the foreseeable future these will to a large extent be replaced by the *light and sound* of noninvasive surgery. Successful high-energy ultrasound operations on the brain have already been achieved in the field of neurosurgery, meaning not only that there are new methods of treatment opening up but that there is even talk of a paradigm shift in neurosurgical therapy. Neurosurgical treatment by means of ultrasound in the case of psychiatric disorders, such as affective psychoses, for example, should also be possible in the future.

1.5 New Key Areas

A key area of technology in health care of the 21st century is telematics, which has the potential to bring enormous advantages to all those involved in health care but will also mean that health care organizations

are faced with many new organizational, technological, and legal requirements. In the future, hospitals will be centers of telemedicine applications. Telemedical communication and systems – that is to say all IT applications in the health care system which are provided via public or long-distance communications networks – enable large amounts of data to be transferred quickly, meaning that physical distance is no longer an obstacle. This is also a reason for the fact that increasingly great importance is placed on telemedicine internationally. These endeavors are aimed at developing a uniform platform for telematics, so that use of modern telecommunications and information technology will improve the quality of care and economic efficiency in the future.

1.6 Innovation Versus Financial Resources

Today, limited financial resources in hospitals mean that it is only rarely possible to introduce and exploit every technical innovation and possibility. It is therefore imperative for the user to evaluate any investment decisions on a commercial and performance-related basis (e.g., by process-orientated technology assessment, which takes account primarily of criteria such as performance, effectiveness, and efficiency). Particularly with respect to the advantages of a real investment, it is important that it is not emotional but rather rational criteria which are at the fore in the decision-making process. One of the key questions is whether there are limits to technical progress, and where these limits might lie. Assessment of technological possibilities with respect to their benefits for patients requires an understanding of modern technology and its limits. Frequently, the aim of medical technological manufacturers and suppliers is to provide medical technological products and medical data-processing systems which are better and more technically perfect every time. The result is that, these days, the functions of many medical technological products go far beyond the needs and possible uses for them. Users – who are usually not technophiles – will pay for something extra that they cannot use. Numerous sophisticated products are perhaps technically perfect but are rarely tailored to suit a need. There is a lot which is feasible technologically, but equally it is obvious that humans can barely control this technology, as in the case of the complexity of various software interfaces, which are no longer completely understood even by highly qualified technicians. This means that the technical possibilities are frequently beyond the ability of many users to use them. Uncritical enthusiasm for technology can therefore very quickly turn into technophobia.

However, to do nothing or to make do without innovations and to cling to outdated technical products is not a solution either. In the future, the service provided to customers in hospitals or in a doctor's practice will itself become a product with greater potential for differentiation than the quality and technical performance of medical technological products. The innovations in medical technology which will also be indispensable in the future must have a *human dimension* and be tailored to suit a need. This will inevitably be embedded in the area of tension between technical and scientific knowhow, market orientation, and orientation towards individual customers. From the point of view of the user, virtually all products are becoming increasingly similar. Good customer service will be another factor in the success of medical products: the focus must increasingly be on the demand for products and not just supplying them *on offer*.

2. Medicine Is More Than Applied Technology for Human Beings

Giovanni Maio

Medicine owes many of its undeniable achievements to technological developments; without the elaboration of technologies, medicine would have been unable to devise or apply many methods of treatment which are, indisputably, a blessing for mankind. And yet, curative science has sometimes been dazzled by the alliance between medicine and technology. Medicine has been taken in by technology to such an extent that it has lost sight of what characterizes it as curative science and what constitutes its actual essence. Technology is not just a method to be chosen, but also a programme. Ethical reflections on the relationship between medicine and technology are presented in this chapter.

From the very moment when medicine presents a purely technical solution to the crisis of falling ill, medicine has not only chosen a method, but has devoted itself to a certain view of the world and humankind. If the relationship between medicine and technology is to be understood adequately, these basic preconceptions about humanity must be contemplated.

2.1 Technology Suggests Feasibility and Controllability

Despite the uncertainty that still remains, a system that backs technology alone assumes a high degree of controllability of the system. In this case, that which is incalculable merely represents a challenge to the developer to perfect technology to make it controllable. If technology is now used to heal the ill, and as a central instrument at that, this engineer's way of thinking also infiltrates how physicians think. In other words, physicians who rely fully on technology are under the tacit assumption that the problems faced by medicine are generally problems that can be solved using technology. If a problem remains, however, technology is to blame for not being sophisticated enough, according to this credo. This way, it is assumed that basically everything is feasible and that all problems faced by mankind can be solved using technology. The reproductive-medicine complex is one example of coupling treatment with technology. Reproductive medicine, in particular, which increasingly regards itself as a market-oriented service industry, equates remedy with the application of technical instruments; it responds to many persons' crisis of meaning by offering technical solutions. What is more, reproductive medicine implicitly declares the technical solution to be the only possible response to the challenge arising from involuntary childlessness. Medicine that regards itself in this way does not only create an offer, but also establishes standards that those who are confronted with involuntary childlessness are virtually unable to avoid [2.1]. In particular, however, reproductive medicine comprehended in this way fails to make use of the opportunity of making couples aware of the potential of alternative life

concepts at a sufficiently early stage. Such an absolutization of the technical solution leads to a continuation of infertile couples being dependent on the technical solutions offered by medicine, rather than making them aware that a crisis of meaning can also be overcome by giving life a new meaning, a meaning that may arise by opening up new prospects of life [2.2]. It is the example of reproductive medicine, in particular, that highlights the fact that humane medicine is more than about just being technically adept. It is equally important to invest in good consultation, in a good conversation which should, in particular cases, also include touching upon the potential failure of technology. Technology suggests feasibility – as can be clearly seen using reproductive medicine as an example – and puts the *victims* of technology in a situation where they are unable to escape from the resulting technical imperative. Thanks to technology, every woman has the opportunity to fall pregnant, and if they still remain infertile, they just have not invested enough or have not had a sufficient number of attempts. It hardly occurs to the majority of physicians, nor, secondarily, to many couples, that the technical solution may not be the adequate one. Thus, technology creates a maelstrom, a feasibility maelstrom, which can only be resisted with difficulty. This aspect must always be taken into consideration with every new technology.

2.2 Technology Knows No Bounds

Technology has no boundaries; it progresses into unchartered territory, it never shies away from the new, nor does it spare the essence of being; technology is always oriented towards change and dynamism. With such a basic concept, however, technology ensures that there is no longer such a thing as a reasonable boundary within medicine, and that there is no state that might not undergo technical optimization or change. Research on embryos is one example of this. Here, in particular, it can be seen that technical methods are considered almost blindly without thinking about morally tenable boundaries. There are grounds here for criticizing the basic approach of using an inherently problematic technical means for an undeniably good cause. The fact that the destruction of embryos was at all taken into account as an option is the actual core of the ethical problem, which is that, in their basic approach, the natural sciences and technology grasp blindly at methods simply because they are technically feasible or simply because they are required to make promises come true. Offering such options alone creates a problematic denial of any boundaries whatsoever. It is like asking a counterpart a certain question that simply should not be asked, no matter what the situation is, because it is, for example, an unreasonable demand. In the same way, there should be certain methods in technical research and development that one simply does not select, because they are bound to offend the feelings of far too many people, and should therefore be regarded as unacceptable. Consequently, the basic problem that research on embryos has to face only arose because research methods were chosen blindly from the start, and, from the very beginning, no respect was shown for the fact that merely the request of sacrificing embryos is an unreasonable demand for many people – and this is just one example representing many more. We need only think of cloning techniques, the creation of chimera, and so on. In this case, technicians cannot retract and deny any responsibility. Moreover, simply by selecting their methods, technicians assume responsibility, and this responsibility must become apparent prior to the development so that no *blind* mechanization occurs, but a mechanization on a humane scale. And this humane scale must also take boundaries into consideration, and must bear in mind that certain processes are inherently problematic. If they are still selected, despite being aware of these problems, presenting the whole of society with a fait accompli, this could signify a heavy burden in certain constellations.

And yet, it is not only the moral boundary that developers of technology defy without further reflection – the denial of the boundary itself is the basic problem of technical development. Technology knows no point at which it could be said that it is perfect now as it is; technology, i. e., those who work on technical products, are always anxious to surpass existing technology with one that is even faster, even more sophisticated, even smaller or even more comprehensive. This attitude towards endless development is based on the lack of a notion about the ideal state and on a glorification of efficiency. The credo is: the faster, the better; the more, the better, and so on. Admittedly, this credo may be useful when dealing with certain utensils. In the context of medicine, however, the credo cannot be generalized in all cases.

What about the discussion on enhancement? This is precisely where the esteem for *more and more* reaches its limits and where *less is more* makes sense [2.3]. The human being is not a machine that operates better the faster it runs; humans need efficiency as much as they crave leisure, they need to achieve their goals quickly, but also need changes in their lives, and resistance to be able to mature at all. Accelerating everything – human beings included – does not automatically mean that human beings are doing themselves a favor. With regard to humanity, offering less, decelerating or back-pedalling is often more conducive to reaching the goal, provided, of course, that humanity finds fulfilment is the desirable goal rather than rapid production.

2.3 Technology Is Unable to Answer the Question of Meaning

Technology knows only purpose-rational thinking, and if technology is proclaimed as the solution for mankind, the human being will primarily be regarded as a body machine within such thought. Technology does not ask about meaning, about the superior sense; indeed, it cannot ask what is meaningful, because it lacks the tools to assess the answer to this question – since the question of meaning cannot be expressed in figures and values. With regard to technology in the context of medicine, this aspect is particularly precarious. As a result of technology's triumph, medicine has sometimes fallen victim to an absolutization of the natural sciences and technology, with the grave consequence that medicine is time and again inclined to define not only what is proper but also what is good via the natural sciences. That which takes place as an applied natural science and technology in the course of the self-image of medicine is equating functionality with the good, equating natural scientific properness with what is good for mankind. In this context, organic functionality is occasionally seen as a value in itself; in other words, functionality should always be restored. Secondly, the loss of functionality is per se interpreted as something negative or even as a failure on the part of medicine under this natural scientific dictum. Both conclusions, however, are inherently problematic. First of all, trying to restore functionality by all means may be problematic if sight of the whole picture is lost. Concerning the superior sense, restoring functionality cannot be equated with the creation of meaningfulness; for example, organs can be restored but the treatment may be senseless regardless. The more medicine becomes specialized and regards itself as a natural science, the more it sometimes treats organs and x-ray photographs, blood gases, and laboratory values, but by doing this does not automatically treat the human being. Precisely this, then, becomes a serious problem if medicine sees itself only as a technically oriented specialist medicine.

2.4 Technology Alone Does Not Make Medicine Humane

Bearing all this in mind, it should become apparent that it is not a matter of demonizing technology. Technology per se is not the problem of modern medicine. The problem starts when the importance of technology is overestimated, i. e., when it is assumed that existential questions arising from a patient falling ill can only be solved by technological means. The central criticism is therefore not directed at technology itself, but at the thought that technology is the one and only solution. Medicine that categorically rejects technology is doomed to failure, because in this case, it often fails to exploit the potential of being able to assist. Medicine, however, that relies solely on technology and ignores everything else will equally fail. For this reason, humane medicine has to focus on implementing technology, whilst always bearing in mind that human beings need more than effective technology to recover. The art of healing is to precisely recognize where technology would be a good solution for human beings and where it is merely an apparent solution. This art of healing requires a pronounced practical power of judgement in a more comprehensive sense, and not only technical expertise.

The technical credo in modern medicine overlooks the fact that physicians often successfully bring about a cure by a good relationship in which technology has to be embedded. Technology without a relationship will generally achieve little. Great importance is attached to the technical aspect, whereas the human relationship is often completely ignored. This change in priorities represents the greatest challenge mechanized medicine has

to face. The more technology is used as a substitute for a relationship, the more this will lead to the loss of a curative culture. Consequently, as long as we do not expect more from technology than it is actually able to solve, and avoid using it as a substitute for everything, the sick will rightly hope that they will regain their health if possible or find comfort and meaning when there is no further chance of a cure. As long as medicine wishes to see itself as a curative science and not as a repair service, it will have to invest the same amount of energy in comforting the suffering and giving their life new meaning as in technical development.

Further Reading

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3. Hygiene in Medical Technology

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The application of new technologies in medicine leads to therapeutic and diagnostic advancements, yet also causes risks for patients to aquire health-care associated infections. In this chapter precautions to prevent the transmission of infectious agents from inanimate medicotechnical sources are shown.

Disinfection and sterilization processes are described in detail aside with requirements for cleaning equipement used for noninvasisve and invasive technology on the patient (Sects. 3.4–3.7). Targeted measures with focus on technical means for preventing the four most important device-related infections are pointed out in practical examples (Sect. 3.8). Furthermore special attention is given to dialysis departments because of high risk of infection both for patients and staff and to the special processing of medical devices that have been used on patients with proven or strongly suspected Creutzfeld–Jacob disease (CJD) respectively its new variant (vCJD).

Finally technical regulations and standards focused on german and european circumstances give an overview of what must be observed by manufacturers and users of medical devices (Sect. 3.9).

Technology is increasingly finding its way into medicine. Many diagnostic and therapeutic advancements have only become possible as a result of corresponding technical processes and further developments.

3.1 Background

The significance of hygiene becomes clear when we realize that even many years ago almost half of all infections contracted by patients in hospital were associated with medicotechnical measures or were (partly) caused by them [3.1]. Medical progress uses increasingly complicated and sophisticated technical facilities and equipment, the use and preparation of which also endangers employees.

It is difficult to obtain reliable data which is more or less representative from Germany, because to date there is no central collection point for this purpose. An indication can be gained by drawing on observations which are based on data from the Trade Association for Health and Welfare in Hamburg [3.2]. According to these observations, infectious diseases represent the second largest group after dermatosis with a frequency of 7.3%, but their numbers increase to one-third in the case of those occupational diseases for which compensation is awarded for the first time. The data do not show what percentage of the cases of dermatosis can also be attributed to technical use in the widest sense, such as handling of detergents and disinfectants.

Hygiene measures in the context of medical technology devices must therefore pursue the goals of

1. Protection of employees during handling,
2. Protection of patients during use of these devices *against the transmission of germs*, which can lead to
   a) Contamination,
   b) Colonization, or
   c) Infection.

The measures that are necessary in individual cases to achieve these goals depend on several factors.

3.1.1 Employee Protection

When using these devices on patients, the rule is to act such that the risk of coming into contact with the patient's germs is kept to a minimum. This is achieved by providing appropriate briefing regarding correct handling before a medical technology device is used for the first time. Hygiene guidelines govern which protective measures are necessary and when, but these protective measures are also dependent on the illness of the patient, the suspected bacterial colonization, and the possible transmission path. When dealing with medical technology devices in the course of reprocessing, maintenance, and repair, the employee can himself monitor whether the equipment is already visibly contaminated on the outside or components are dirty, for example. He/she must in particular have been instructed by the operator regarding whether the device has been used immediately beforehand for a patient with a contagious disease or with certain germs.

In such cases, disinfectant preliminary cleaning must be carried out before maintenance or repair is begun. Disinfection as a first step is also always necessary when handling of the device is linked with an increased risk of injury. Where reprocessing work is concerned, processes should be used in which the devices are cleaned and disinfected by machine, and this should be done with the application of heat and in one process. Under some circumstances, certain protective clothing (e.g., gloves) is sensible or even compulsory.

3.1.2 Patient Protection

How the medical technology device is used on the patient is crucial to the necessary measures. A pacemaker implanted in the patient must be and remain sterile and pyrogen-free during insertion. Disinfectant pretreatment is sufficient for medical equipment with only external (skin) contact, and in the case of equipment which stands at the bedside next to the patient, cleaning is generally sufficient. However, if parts of a piece of equipment which is situated remotely from the patient come into contact with sterile areas of the patient (e.g., tube systems which convey blood in a dialysis machine or in cardiac surgery equipment), then this system component must of course satisfy the same criteria as an implanted device. The same also applies when equipment is used to introduce fluids or medication into sensitive (e.g., lungs in the case of machine-assisted artificial respiration) or sterile regions of the body (e.g., infusion apparatus) [3.3–5].

The text which follows explains the principles of targeted hygiene measures and demonstrates, with reference to examples, how the risks can be recognized and which risk-based measures are necessary. Reference is made to sets of regulations which must be observed, although it is the duty of the person responsible for the area in question to adapt the catalog of measures to new scientific findings and recommendations in the course of regular training. General guidelines which are not

orientated towards practical use, the specific risk of infection, and the path of infection are often expensive, as they require a lot of personnel and time, but are rarely effective.

3.2 Causes of Infection

Requirements for an infection to develop are an infectious agent, a person susceptible to infection, and contact which enables the germs to colonize the individual such that an infection can develop. This multitude of requirements makes it clear that there is no reason to live in general fear of microorganisms, be they bacteria, viruses or fungi. Bacteria colonize our skin and mucous membranes and are an important part of our body's defenses. Over 40 different species can be isolated from our nasopharyngeal cavity, and there are up to 10^{12} germs living in every gram of feces.

The natural bacterial colonization present in the skin of every human being can be divided into *permanent* and *temporary*. Permanent germs are always present, whereas temporary germs are acquired and therefore change according to what the person has been handling or what work he/she has been carrying out. Washing the hands eliminates the majority (> 90%) of this acquired *contamination* but leaves the permanent bacterial colonization undisturbed. Disinfecting the hands or skin should completely eliminate acquired germs, but it also has an adverse effect on the permanent skin colony.

The skin and mucous membranes are mechanical barriers which, when they are not damaged, prevent microorganisms from penetrating into our bodies. This explains why damage to the skin and mucous membranes is always accompanied by an increased risk of infection, whether that be in the form of a local, superficial infection (pustule, abscess) or whether it be in the form of a widespread infection – usually occurring in immunocompromised patients – of the soft tissue (ulceration, gangrene), which can also result in sepsis with high fever.

In many fields, our body has also developed further defense mechanisms, such as the acid mantle of the skin, microorganism-killing enzymes in secretions and excretions (e.g., tear fluid), and special structures in our blood whose primary role is to eliminate intruders. These include the white blood cells which *eat up* and digest bacteria (phagocytose), and so-called antibodies which help blood cells identify structures in the body which they should destroy. These specific antibodies are formed in the lymphatic tissue of our body following such *stimulation*. Stimulation of this kind may be due to contact with the infectious agent itself (*natural immunization*) or may be as a result of vaccination (*artificial immunization*, see later).

If a germ nonetheless manages to attach to skin or mucous membranes, then the first important step has been successful. If this *colonization* persists, although it does not result in illness, the patient or member of staff would become an (undetected) source of further transmission, in case the germ in question is a problematic germ (infectious agent, multiresistant bacterium). However, if in the second step the germ is able to deploy its pathogenic properties and the person affected is not immune, then this would lead to an *infection* which, depending on the state of health of the affected individual, can result in an illness which varies in its severity.

3.3 Vaccinations

One of the most important measures for protecting against infections is vaccination. The vaccinations which are recommended and constantly updated by the Standing Committee on Vaccination (Ständige Impfkommission – STIKO) at the Robert Koch Institute (RKI) [3.6] are of particular importance for employees in the health care system. The vaccinations in category S (standard vaccinations with general application = standard vaccinations) are the vaccinations for infants and children and should be given to all employees in the health care system and, if necessary, should be regularly boosted. These include important vaccinations against such as tetanus, poliomyelitis, and diphtheria. Depending on the field of activity, so-called *indicated vaccinations* (category I) may also be added, such as vaccinations against hep-

atitis A and B, influenza, and varicella. The point of contact for questions regarding personal vaccine protection and work-related requirements is generally the occupational health officer.

3.4 Disinfection Methods

3.4.1 Basics of Disinfection

Like sterilization (Sect. 3.5), disinfection also has the aim of preventing transmission of pathogens. Complete freedom from germs (sterility) is not guaranteed, however. Disinfection of equipment and materials is always sufficient if, although the aim is to prevent transmission of microorganisms which are capable of multiplying, the body physiologically speaking has a certain level of self-protection in these areas as well as in other areas of the human body which have colonies of germs (e.g., the gastrointestinal tract). Obligate pathogens (those which always cause illness) must not be present on disinfected items, however.

When using disinfectants and disinfection processes, both the respective microbiological spectrum of activity and the field of use must be taken into consideration. Thermal disinfection processes, where they can be used, must always be given precedence over chemical disinfectants and disinfection processes. Provided they do not contain any other special directions, chemical disinfectants are usually only suitable for killing vegetative bacteria and fungi.

Before they come onto the market, disinfectants are tested for their antimicrobial action by means of microbiological analysis. There are standardized methods for this, whose results also determine whether a substance will be included in the list of substances permitted by the Robert Koch Institute in accordance with the German Infection Protection Act [3.7].

3.4.2 Disinfection Processes

Thermal processes are only suitable for thermostable objects, while *chemical* processes are also suitable for thermolabile objects and surfaces.

A distinction is made between the fields of use for chemical disinfection, as follows:

- Disinfection of hands, skin, and mucous membranes
- Disinfection of surfaces
- Disinfection of instruments.

Disinfection of Hands, Skin, and Mucous Membranes and Disinfection of Surfaces

Disinfection of hands, skin, and mucous membranes and disinfection of surfaces can only be carried out in the form of chemical disinfection, with various germicidal substance groups being used (Table 3.1). When selecting a substance, the purpose for which it will be used and the required strength of its effect as well as the required scope of its effect are crucial in this selection. Appropriate definitions should be regulated in area-specific or process-specific *hygiene plans* based on the corresponding KRINKO (Kommission für Krankenhaushygiene und Infektionsprävention) recommendation [3.8].

Table 3.1 Advantages and disadvantages and fields of use of the most common active substances in disinfectants

Active substance	Advantages	Disadvantages	Field of use
Alcohols	Fast-acting, no residues, low toxicity, pleasant odor	Not sporocidal, combustible/explosive, expensive	Hand disinfection, skin disinfection, small surfaces
Iodine/iodophosphorus compounds	Does not irritate mucous membranes, fast-acting	Allergies possible, naturally colored, (side-effects on thyroid?)	Skin disinfection, mucous membrane disinfection, hand disinfection
Formaldehyde/aldehyde	Broad spectrum of activity, biodegradable	Irritant, allergenic, moderately toxic, (carcinogenic?)	Surfaces, instruments, disinfection of rooms
Quaternary ammonium compounds	Good detergent action, low odor, low toxicity	Gaps in effectiveness, inactivated by soap and protein	Disinfection of surfaces in special areas (kitchen)
Peracids/peroxides	Broad spectrum of activity, fast-acting	Inactivated by protein, corrosive, irritant, unstable	Surfaces, instruments
Phenols	Low impact because of environment	Gaps in effectiveness, barely biodegradable	Disinfection of excretions, otherwise obsolete

Disinfection of Instruments

Instruments and equipment can be disinfected thermally, thermochemically, or else purely chemically. The choice of the process is dependent on the suitability of the material for certain types of disinfection, on the local conditions (infrastructure), and if applicable, on certain requirements. The most reliable option is mechanical thermal disinfection in special washer-disinfectors, because it is only when exposed to appropriate temperatures that the desired reduction in germs is guaranteed with sufficient certainty. The machines report faults in the program sequence, which means that it is not possible to remove items inadvertently before the disinfection process is complete, and errors are for the most part ruled out. Purely chemical processes, such as immersion in solutions, etc., are in contrast susceptible to errors in processing and require a high degree of reliability on the part of the staff performing the process.

3.4.3 Chemical Disinfecting Agents

The most common active substances in disinfectants, their advantages and disadvantages, and their fields of use are reproduced in Table 3.1. In the rarest cases, commercial disinfectants contain only one active substance, but they frequently consist of mixtures of active substances in order to achieve the most optimum antimicrobial action possible.

3.4.4 Carrying out Manual Disinfection

Selection of Disinfectants

Disinfectants are usually selected on the basis of the Network for Applied Hygiene (Verbund für angewandte Hygiene, VAH) list. However, in so doing it is necessary to bear in mind that, in addition to the field of use, the concentration, and the application time (which are dependent on one another), the necessary scope of activity is also ensured. Where there is any doubt, reference must be made to appropriate expert advice. A further important source of information, in particular from the point of view of occupational health, is the material safety data sheets according to 91/155/EEC – amended by 2001/58/EEC – for the disinfectants in question. With regard to material compatibility and effectiveness, particular care must be taken with materials which contain rubber and plastic.

Exposure Time

The maximum period during which the substance has its intended effect can be gathered from the relevant data sheets. If the solution becomes visibly dirty, however, then it should be replaced immediately. If a combination of detergents and disinfectants is used, the exposure time is generally only 24 h.

Sequence: Disinfection and Cleaning

In the case of instruments where there is a risk of injury, disinfection must be carried out *prior* to cleaning. In other cases, disinfection is performed *with or after* cleaning.

Procedures

Disinfectants for treating surfaces and instruments are provided by manufacturers in the form of a concentrate in various packaging sizes, from sachets to large packs, and must be made up to the appropriate usage concentration by the user by adding water. To avoid foam formation when preparing a disinfectant solution, water is added first and then the disinfectant. The solution is prepared by hand by means of dosing aids or using mixing equipment. The advantage of using mixing equipment is the automatic dosing of the disinfectant.

Disinfectants must only be used for the stated purpose and must not be mixed with detergents without prior testing, because this can result in a loss of effectiveness of the disinfectant (follow the information from the manufacturer). It becomes necessary to change the disinfectant solution when the exposure time stated by the manufacturer has been reached or when the solution becomes visibly dirty.

Effectiveness may be impaired in tubes and pipes with narrow lumen, e.g., as a result of air bubbles or impurities. It is therefore necessary to ensure that the item to be disinfected is completely submerged, that there are no bubbles, and that all surfaces are completely and thoroughly wetted.

All items should be disassembled as far as possible. Instruments should be immersed in the solution with care to prevent damage.

Cost-Saving Hints

The following options can be used for cost savings:

- It is often sufficient to carry out cleaning instead of disinfection prior to subsequent sterilization. Exceptions: Only pointed, sharp items must be disinfected prior to cleaning.
- Where feasible from a time perspective, low concentrations should be selected with a longer application time.

- If possible, make do without additional detergents, because a disinfectant solution with added detergent must be changed daily.
- Contaminate the solution as little as possible with organic materials, so that it is not necessary to change the solution before the end of the exposure time.
- Wipe down items instead of immersing them.

Pouring Away

To protect drainage systems against corrosion, care must be taken to ensure that the solution is diluted sufficiently before it is poured away. Disinfectants for treating instruments are generally provided with corrosion inhibitors. High concentrations can nevertheless be problematic for drains. The municipal wastewater bylaws must also be taken into account. Disinfectant concentrates are considered hazardous substances, and their disposal requires special supervision.

Personal Protection

When preparing the solution, immersing/removing items, and emptying and cleaning the bowl, gloves (disposable or household gloves) and protective clothing (waterproof apron) must be worn. If there is a danger of splashing, protective goggles and a face mask must be worn. Bowls filled with disinfectant must be covered to minimize evaporation into the surrounding air. Disinfectant solutions must always be made up with cold water (no warmer than lukewarm) for the same reason. Disinfectant concentrates must not be stored above eye level. The workplace-specific regulations to protect staff should take into account the relevant technical regulations (the German Technical Regulations for Biological Agents, TRBA, and the Technical Regulations for Hazardous Substances, TRGS) (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, BAuA).

Special Circumstances

There may be undesired effects on materials if unsuitable disinfectants are used. The chemical resistance of the items must therefore always be taken into account. Where there is any doubt, enquiries should be made to the instrument manufacturer.

3.4.5 Physical Disinfection Processes

With physical disinfection processes, a distinction is made between thermal and thermochemical disinfection processes.

Thermal Disinfection Processes

In thermal disinfection processes, pathogens are rendered harmless as a result of the influence of heat. The higher the temperature and the longer the application time, the more effective the process is. In practical applications, a distinction is made between *dry heat* and *damp heat*, depending on the presence or absence of free water. Only *damp heat* is of significance for combating hospital infections. When using a treatment with *damp heat*, a distinction is made between two processes:

1. Rinsing with hot water (washer-disinfectors) and
2. Treating with steam (steam disinfection process).

Washer-disinfectors

Washer-disinfectors are devices in which instruments, anesthesia accessories, laboratory materials (glassware and the like), and other thermostable items are processed by machine.

The series of standards DIN EN ISO 15883 specifies the performance and device requirements for washer-disinfectors.

Depending on the design, a distinction is made between washer-disinfectors with one processing chamber and devices with multiple processing chambers, so-called batch washer systems.

Washer-disinfectors are available in a front-loading design (loaded and unloaded in the same area) or in a through-loading design with two doors (separated into a *clean* and *dirty* side).

Batch washer systems (multichamber systems) consist of multiple washing chambers and drying chambers through which the items to be treated are passed on loading trolleys. The loading trolleys differ according to the items to be treated. Sensors on the loading trolleys allow the control unit in the system to identify what items are on the trolley and to automatically select the correct processing program, which means that operating errors as a result of incorrectly selected programs, temperatures, and times are ruled out.

The disinfection process which runs in each case is usually thermochemical or thermal. An ultrasonic cleaning tank can be added to the system as an additional feature for precleaning of heavily soiled items.

Different processing steps are performed in each chamber. Special tanks with the appropriate detergents are assigned to each chamber. The detergent solution is collected in the tanks and reused for the next processing batch. Because not all of the detergent solution is recaptured, some of the solution must be supplemented.

The exact dosing of the detergent is done using dosing pumps which are controlled via contact water meters. The contents of the processing tank must be emptied and refilled every working day.

Owing to their relatively high throughput rate, batch washer systems are predominantly used in central sterile supply departments.

Carrying out Machine Cleaning and Disinfection

To achieve a good cleaning and disinfection result, the way in which the machine is loaded is of crucial importance. It is important to ensure that all items are disassembled as far as is possible and that hollow parts are inserted with the opening pointing downwards. Fluid must also flow through the interior of instruments with long or narrow cavities, such as metal catheters, metal suction apparatus, special needles, etc. Special loading trolleys must be used for this.

In the case of use of detergents or combined disinfectants and detergents, the information provided by the manufacturer (application time, concentration, and temperature) must be followed precisely.

Only the correct dosage will ensure a perfect disinfection and cleaning result while providing the greatest possible protection of the material. Underdosing of alkaline detergents involves the risk that pitting may occur, as this is avoided at pH values of above 10.5. When using acidic detergents, corrosion may occur as a result of chlorides in the water, and this can only be precluded by using demineralized water.

In the case of machine cleaning, all residues from the cleaning phase must be reliably removed in the rinsing phase, as otherwise stains and discolorations may appear on the surgical instruments. Additional use of a suitable neutralizing agent can support this process and improve the result of rinsing.

Documentation

In the course of quality assurance, when processing medical equipment it is necessary for the process-relevant processing steps of the individual batches to be documented with direct assignment to the relevant items to be treated.

Inspections and Maintenance

Disinfection measures in cleaning equipment are only effective if maintenance and inspection of these machines are not neglected. The necessary inspection and maintenance are specified in the operating instruction, which should be issued by the manufacturer. Maintenance should be carried out at least once a year by trained specialists.

Tests

The ordinance regarding the installation, operation, and use of medical devices (German Medical Devices Operator Ordinance – Medizinprodukte-Betreiberverordnung, MPBetreibV) states the requirement that medical devices must be processed using suitable, validated processes such that reproducible success is ensured and the safety and health of patients, users, and third parties are not endangered. The KRINKO recommendation [3.9] likewise requires validated processing of medical devices.

Specific information about carrying out the validation and the subsequent periodic tests is set out in DIN EN ISO 15883-1 – Washer-disinfectors – General Requirements, Definitions, and Tests, and in the guideline from the German Society for Hospital Hygiene, the German Society for Sterile Supply, and the Working Group Instrument Preparation for routine monitoring of machine washer-disinfectors for thermolabile medical devices.

Validation is a documented process for providing, recording, and interpreting the results necessary to show that a process constantly produces the desired quality which conforms with the given specifications. For washer-disinfectors (WD), the validation consists of installation qualification, operating qualification, and performance qualification, performed for devices which have documented proof from the manufacturer of compliance with the requirements of DIN EN ISO 15883.

The installation qualification is performed to ensure that the WD and accessories have been properly supplied and installed and that the supply of operating media satisfies the special requirements. The tests and inspections which are to be carried out for the installation qualification must be defined and performed, and the results documented.

Tests and inspections which must be carried out are:

- Testing the scope of supply and delivery (in the case of existing installations, testing the stock)
- Loading trolleys/baskets, cartridges, and also plugs/adapters
- Installation plan, instructions for use
- Testing the connections and supply of media, and comparing them with the installation plan
- Electricity
- Water (cold/warm/demineralized)
- Steam

- Wastewater
- Exhaust air/ventilation.

The operating qualification is carried out to ensure that the WD and the supply of media comply with the manufacturer's specifications and the requirements set out in DIN EN ISO 15883. The tests and inspections which are to be carried out for the operating qualification must be defined and performed, and the results documented. In the performance testing, the specified washer-disinfector programs are tested for reference loading, and the results are documented. When observing the regulations, it should be ensured that results are obtained which can be reproduced at any time. Any reference loading must cover instruments with contamination which is typical of operation as well as critical design features. Reference loading is always operator specific and must be documented. A requirement for the performance qualification is specification and documentation of the necessary programs with the corresponding process flows. The description of the process must also include the preconditions for cleaning. The process description must be documented in detail, including precise information about the chemicals. The following tests are performed as part of the performance qualification.

Testing the Cleaning. The cleaning is tested using two different methods. Test instruments (hemostats after Crile) with defined test soiling in accordance with DIN EN ISO 15883 and instruments which are actually soiled following use are used. Every program used must be tested. The test instruments are removed from the WD using gloves following the cleaning phase and prior to the disinfection phase.

The results of the cleaning process are first evaluated visually, and these findings are documented. The test instruments must be visibly clean. The test instruments must then be tested for protein residues using a protein detection method which is at least semiquantitative. In practice, detection of protein residues using the Biuret method has proven successful. Testing of the instruments which are actually soiled is carried out in the same way.

Assessment. The limit value is that all test instruments must neither reach nor exceed the protein content of 100 µg protein per ml eluate. If this limit is exceeded, then the WD is immediately shut down. The guide value is a maximum of 50 µg protein per ml eluate for a test instrument, at which no measures are necessary.

Testing the Disinfection. The disinfection is tested using thermoelements which are distributed in the disinfection chamber at critical locations and which record the temperature profile during processing. The resulting temperature graphs show whether the temperature necessary for killing microorganisms was present at all locations in the chamber. The A_0 value can be calculated from the temperature graph in accordance with DIN EN ISO 15883. The A_0 value of a disinfection process with damp heat is a measure of the rate at which microorganisms are killed, given as a time in seconds at a temperature of 80 °C applied to the medical item by the process.

The A_0 value which must be achieved depends on the nature and quantity of the microorganisms on the contaminated medical device and on the subsequent use. In the case of crucial medical devices and medical devices which are or may be contaminated with heat-resistant viruses such as hepatitis B, the A_0 value must reach 3000. This corresponds to an application time of 5 min at a temperature of 90 °C or an application time of 50 min at a temperature of 80 °C.

An A_0 value of 600 is used in the case of noncritical medical devices which can only come into contact with undamaged skin. This corresponds to an application time of 1 min at a temperature of 90 °C or an application time of 10 min at a temperature of 80 °C.

In addition to the thermoelectric measurements (A_0 concept), biological indicators can also be used to make statements about the killing of microorganisms. Biological indicators are germ carriers which are contaminated with a blood/germ mixture which has a defined resistance to the disinfection process in question. The Robert Koch Institute stipulates the use of contaminated screws and tubes for testing thermal disinfection processes in washer-disinfector machines. Meanwhile, equally good biological indicators are available which allow testing which is easier for the user.

The performance qualification must be repeated annually. When the programs or process chemicals are changed or new medical devices are introduced which have to be processed differently, the performance qualification must be carried out once more.

Decontamination Systems

Decontamination systems have in the past been used first and foremost for cleaning and disinfection (decontamination) of bed frames and accessories. Requirements regarding hygiene, economic considerations, and occupational safety requirements (TRBA 401 hazard due to skin contact) have led to decontamination sys-

tems increasingly being used for other articles in the field of medicine as well, such as transport trolleys, containers (e.g., for medications, medical devices, sterile articles, and meals), operating theater shoes, transporting containers for small conveyor systems, and similar items.

A decontamination system consists of a decontamination chamber, which receives the items to be treated, and an apparatus compartment, which contains the units and components necessary for operation. The systems are generally constructed with a two-door design.

The items to be treated are pushed into the decontamination chamber on the *dirty side* (in some cases using special loading trolleys). Combined cleaning and disinfection of the items to be treated is carried out in the first phase using a separate nozzle system by means of a recirculation pump. The temperature of the decontamination agent solution and the decontamination period can be set and changed on the control panel, making it possible to optimally adapt the process quickly and simply to the items being treated. The decontamination agent solution is supplied from a heated storage tank.

Following the decontamination process, the items being treated are sprayed with a rinsing agent solution to remove residues of the decontamination agent solution and ensure fast and spotless drying. During the drying time, a ventilator extracts the damp warm air from the interior of the compartment, while at the same time sucking in fresh air from the clean side. The decontamination agent solution is pumped back into the storage tank via a recirculation pump, so that only about 20 l of water is required for each batch.

With regard to the requirements, operation, and testing of the effectiveness of decontamination systems, reference should also be made to DIN standards 58955 section 1–7.

Steam Disinfection Processes

Steam disinfection processes are preferably used to disinfect bedding (mattresses, laundry, and textiles) but also for waste which needs to be disinfected. Simultaneous use of these systems for disinfecting waste as well can be considered to be problematic because of the offensive smell and risk of contamination of the apparatus. With appropriate separation, however, joint use of the apparatus to disinfect both bedding and waste is also perfectly feasible.

The items to be disinfected are subjected to the effect of saturated steam in the steam disinfection apparatus. To ensure that all surfaces to be disinfected are exposed to unobstructed steam, the air must be removed from the disinfection chamber and from the items.

A distinction of steam disinfection processes can be made depending on the procedure:

1. Steam flow process, and
2. Fractionated vacuum process (vacuum–steam–vacuum (VSV) process).

Steam Flow Process (Range of Action, ABC: Sect. 3.4.6). In the steam flow process the air is forced out of the chamber and the items to be disinfected using saturated steam. The disinfection temperature is 100–105 °C, with an application time of at least 15 min. For porous items, the application time may be more than 1 h. The steam flow process is suitable for disinfecting waste which contains sufficient water, e.g., microbiological cultures.

Fractionated Vacuum Process. The process (Fig. 3.1) is characterized by:

1. Removal of the air from the chamber and the items to be disinfected by repeated evacuation alternated with influx of saturated steam
2. Disinfection with saturated steam
3. Drying of the disinfected items by evacuation.

To perform this process, steam which is largely free of air and foreign gases is necessary (cf. DIN EN 285). The disinfection chamber must be vacuumtight. The fractionated vacuum process is mainly used to disinfect porous items such as mattresses, blankets, and waste.

3.4.6 Application Times and Ranges of Action

The application times and ranges of action are presented in Table 3.2. In the list of disinfectants and disinfection processes tested and approved by the Robert Koch Institute [3.7], the ranges of action are identified by letters; these are:

- A – suitable for killing vegetative bacteria, including mycobacteria, as well as fungi, including fungal spores
- B – suitable for inactivating viruses
- C – suitable for killing spores of the anthrax pathogen.

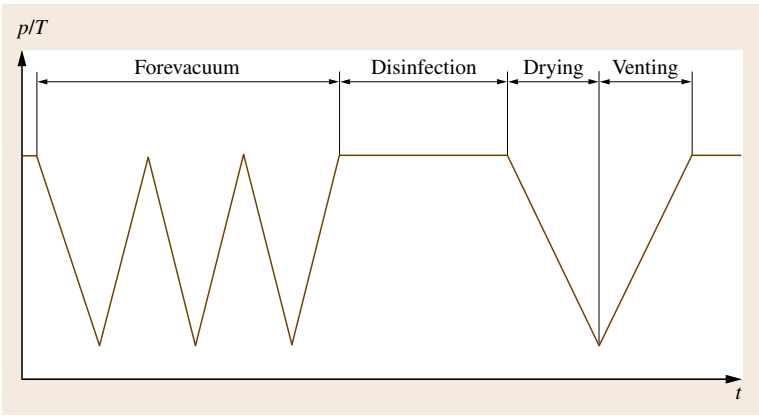

Fig. 3.1 Diagram of the fractionated vacuum process

Table 3.2 Application times and ranges of action of disinfection processes

Temperature (°C)	Duration (min)	Range of action
75	20	A, B (except viral hepatitis)
105	1	A, B
105	5	A, B, C

Higher temperatures and longer application times are sometimes used for disinfecting waste. Approved processes can be found in the RKI list. The requirements, operation, and testing of the effectiveness of steam disinfection apparatus are laid down in the DIN standards 58949 section 1–7.

3.4.7 Comparison of Chemical and Physical Disinfection Processes

Disadvantages of Chemical Disinfection

- Gaps in effectiveness, contamination
- (Primary) bacterial resistance
- Adaptation (biofilm formation)
- Possible distribution of germs in the hospital (central units)
- Dependence on concentration, temperature, and pH
- Decomposability, loss of effectiveness
- Inactivation by soap and protein
- Limited ability to penetrate organic material
- Risk of decontamination
- Disinfectant residues in the material (e.g., rubber)
- Material corrosion
- Health effects for staff and patients
- Pollution of the workplace and environmental damage
- High costs
- Increase in the volume of refuse.

Advantages of Physical Disinfection Processes

- Lower costs
- Lower impact on the environment
- Higher degree of reliability
- Automated operation possible
- Cleaning, disinfection, and drying in one process
- No toxicity and no allergization
- Testing for effectiveness.

3.5 Sterilization Methods

3.5.1 Sterilization Processes

- Physical processes
- Steam sterilization
- Hot air sterilization
- Physicochemical processes
- Ethylene oxide gas sterilization
- Formaldehyde gas sterilization
- H_2O_2 low-temperature plasma sterilization.

Physical Processes

Steam Sterilization. Sterilization with the aid of saturated and compressed steam, also sometimes referred to as damp heat, is the most reliable sterilization process and, because of its simple handling, is the most important process for sterilizing medical devices.

The principle of steam sterilization is based on the transfer of thermal energy to the contaminated surfaces as a result of condensation of compressed steam. Energy is released through condensation of the steam on the items to be sterilized, which causes irreversible damage to microorganisms.

The pressure and temperature of steam are dependent on one another; for example, compressed, saturated steam at a temperature of 121 °C has a pressure of 2 bar (1 bar = 105 Pa), while at a temperature of 134 °C it has a pressure of 3.2 bar. In practice, two standard conditions are used:

- 121 °C with application time of 15 min
- 134 °C with application time of 3 min (only for correspondingly heat-resistant items).

Pathogen Resistance to Damp Heat. The resistance of germs to damp heat is classified into four levels (Table 3.3).

A complete effect of the steam on the items to be sterilized is only possible if the air has been removed from the chamber and from the items which are to be sterilized. Processes for removing the air from the items to be sterilized include:

1. Fore-vacuum process. In the fore-vacuum process (Fig. 3.2), the air is removed from the sterilizer chamber using a vacuum pump. The process features the following operating phases:
   - Single evacuation of the sterilizer chamber to pressure of 20–70 mbar
   - Admission of steam until the operating pressure has been reached.

   The fore-vacuum process is not suitable for sterilizing porous items (e.g., laundry) in sterilization containers with a filter or valve in the lid of the sterilization container.
2. Fractionated vacuum process. The fractionated vacuum process (Fig. 3.3) features operating phases such as:
   - Evacuation to pressure < 130 mbar (1 mbar = 100 Pa), repeated several times
   - Alternated with influx of steam to a pressure which is below or above atmospheric pressure
   - Admission of steam until the operating pressure has been reached.

The fractionated vacuum process is suitable for all sterilization items in packaging approved for steam sterilization.

According to the German Medical Devices Operator Ordinance § 4, medical devices must be sterilized us-

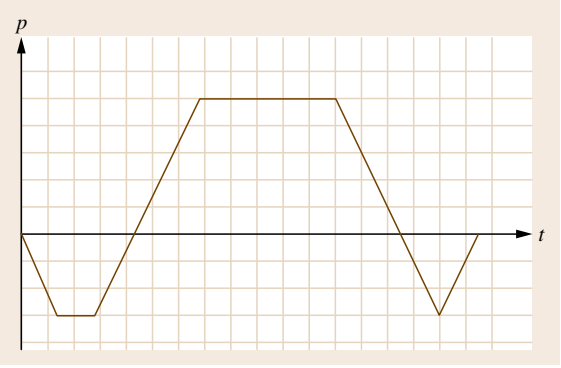

Fig. 3.2 Fore-vacuum process

Table 3.3 The four levels of resistance of germs to damp heat

Level of resistance	Temperature (°C)	Application time	Pathogens recorded
I	100	Seconds to minutes	Vegetative bacteria, fungi including fungal spores, viruses, protozoa
II	105	5 min	Bacterial spores with a lower level of resistance, e.g., anthrax spores
III	121 or 134	15 min or 3 min	Bacterial spores with a higher level of resistance
IV	134	Up to 6 h	Bacterial spores with a high level of resistance

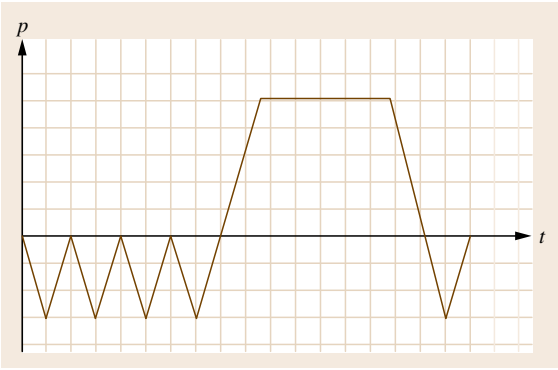

Fig. 3.3 Fractionated vacuum process

ing suitable, validated processes, such that reproducible success of these processes is ensured and the safety and health of patients, users, and third parties are not endangered. Validation serves to prove the effectiveness of the sterilization process under the operating conditions present in the location where the equipment is installed, with the items which are to be sterilized in routine operation, in the appropriate packaging, and with the loading model used. Validation consists of commissioning and performance qualification. DIN EN 554 and DIN 58946-6 have been replaced by DIN EN ISO 17665-1. Validation according to DIN EN ISO 17665-1 consists of installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ).

In the installation qualification, evidence must be found that the device equipment, documentation, operating media, and installation comply with the standard. It must also be demonstrated that the device is in good working order, and that there is no leakage of the operating media or in the equipment.

In the operational qualification, evidence must be provided that the sterilizer is able to perform the specified sterilization programs.

In the performance qualification, all sterilization items and the types of packaging used must be recorded and commissioned. The sterilization parameters of the resulting commissioned items are then measured and assessed in the sterilizer using physical test methods.

In addition to the physical test methods, DIN EN ISO 17665 also approves microbiological testing. Thermoelectric tests cannot be performed on medical devices (e.g., instruments for minimally invasive surgery). In this case, there is the option of contaminating the instrument directly with test germs or using suitable medical device simulators as per DIN 58921. The results must be documented in the validation report.

Documentation. As part of the quality assurance in the central sterilization supply department (CSSD), the sterilization batches must be documented. This is done firstly by recording the process-relevant sterilization parameters (pressure, temperature, and time) and secondly by testing each batch using a suitable chemical indicator in a special test specimen. Using a label with the batch number on ensures that the item to be sterilized is assigned to the batch. Once sterilization has taken place, the parameters are checked, and the batch is released and documented.

Hot Air Sterilization. Hot air sterilization is sterilization by dry heat. Because dry air is a poor thermal conductor, relatively high temperatures and long application times (e.g., 180 °C for 30 min sterilization time) are necessary to ensure reliable sterilization. Table 3.4 presents the sterilization times for hot air sterilization.

Germs, spores, and viruses are killed as a result of protein coagulation. The sterilization effect is strongly dependent on the preparation of the items to be sterilized. The items to be sterilized must be clean and dry (evaporatively cooled).

The following must be taken into consideration when loading the sterilizer.

- It must be possible for air to flow unhindered around all of the items.
- The direction of the air flow must be taken into account.
- Larger items can create a slipstream.
- The items to be sterilized must not be stacked in blocks.

Larger sterilizers must be equipped with forced air circulation equipment (ventilator). Because of their unreliable operation, hot air sterilizers should only be used to a very limited degree. Their fields of use are:

- Glass (laboratory)
- Metal
- Porcelain.

Suitable packaging materials are:

- Metal cases
- Glass bowls
- Aluminium foil.

Note that textile and paper packaging are not suitable.

Physicochemical Processes

Ethylene Oxide Sterilization. Sterilization with ethylene oxide must only be used if the item to be sterilized cannot be sterilized using any other process [3.10].

Table 3.4 Sterilization times for hot air sterilization

Sterilization temperature (°C)	Sterilization time (min)
160	120
170	60
180	30

According to the German Ordinance on Hazardous Substances and the TRGS 513, since 1 January 1995, ethylene oxide (EO) may only be used in validated, fully automatic sterilizers, in which an automated degassing program follows the sterilization program, with the sterilizer remaining locked until the program is finished.

Substance Properties. Ethylene oxide is a colorless, sweet-smelling, highly flammable gas, which can form explosive mixtures with air. It is toxic and can cause cancer and inheritable damage. A maximum allowable concentration (MAC value), in the sense of harmless concentration, can therefore not be given. The technical reference concentration (TRC value) for the breathing air in the workplace is 1 ppm-vol. EO irritates the eyes, the respiratory organs, and the skin. It is classified as hazardous to water (water hazard class WHC 2).

How It Works. Its good ability to penetrate cells makes it possible for various vital biochemical components in the metabolism of microorganisms, such as DNA, proteins, vitamins, and enzymes, to be exposed to EO. The alkylation reaction of proteins with EO kills the microorganisms.

The effectiveness of EO is influenced by various parameters. The relative humidity of the gas mixture is optimally 33% at a temperature of $55 \pm 3\,^{\circ}C$. Because the materials to be sterilized and their packaging absorb water to different degrees depending on how the sterilization chamber is loaded, relative humidity of 100% is in practice aimed for at the beginning of the sterilization process. Water loss due to vacuum and absorption then results in a reduction in the relative humidity. This initially high humidification should in practice prevent the relative humidity from dropping below the limit value of 33% which is necessary for reliable EO sterilization.

Adsorption and Desorption. Ethylene oxide binds to surfaces of solids (is adsorbed) depending on the material. With regard to EO sterilization this means that residues adhere to the materials following EO exposure. A relatively long degassing or desorption time is therefore necessary for the treated items following sterilization. These may contain a maximum residual concentration of 1 ppm EO before use on patients [3.11]. As already mentioned above, in accordance with TRGS 513, the desorption process must be performed in the sterilization chamber, which is automatically locked, after sterilization has ended. Reloading of the sterile items directly after sterilization into so-called ventilation cabinets is not permitted.

Exhaust Air from EO Sterilization Systems. A mass flow of 2.5 ppm EO (according to the German Technical Instructions on Air Quality Control, TALuft) must not be exceeded in the exhaust air from the system. Methods used for reducing the EO concentration are listed here.

- Combustion. This must be supported using auxiliary gas firing. The consumption of fuel gas is $\approx 0.5\,m^3/h$. In the process, EO is fully converted into carbon dioxide and water.
- Catalytic reaction. The necessary temperature of the catalyst is reached by supplying energy in the form of steam or electrical energy. It is virtually impossible to achieve complete decomposition of the EO.
- Gas wet scrubbing process (only for pure EO). The firm VIG provides a process in which the EO is bonded with a washing agent. Using diluted sulfuric acid in water, the EO is converted to ethylene glycol. The EO is disposed of completely, and there is no need to supply exhaust air.

Sterilization Processes

Vacuum Process. This process involves working with 100% EO in the vacuum range. After evacuation to below absolute pressure of 55 hPa and humidification of the sterilization chamber, the EO flows into the chamber, and the items to be sterilized are treated at an operating temperature of 50–60 °C for between 1 h and 6 h. The application time is essentially determined by the process parameters of EO concentration, pressure, humidity, and temperature. The pressure range is kept below the lower explosive limit of EO. The sterilization chamber is then purged and ventilated multiple times.

Overpressure Process. Following a pre-vacuum and humidification, sterilization is performed in the overpressure range using a gas mixture of 6% EO and 94% CO_2. As in the vacuum pressure process, the application time is essentially determined by the process parameters of EO concentration, pressure, humidity, and temperature. The inert gas (mostly carbon dioxide) helps to avoid explosion. After the sterilization phase, multiple vacuum and ventilation phases take place alternately to

achieve desorption of the EO from the sterile items. The desorption time is generally 8–10 h.

Requirements for Sterilizers. The requirements for reliable sterilization are described in detail in DIN 58948 and DIN EN 1422. According to the German ordinance for minimizing hazardous substances, care should be taken to ensure that sterilizers work with gas mixtures of 6% EO and 94% CO_2 and that the risks for staff, patients, and the environment are therefore reduced.

Requirements for Operating Staff. According to TRGS 513, operating staff must demonstrate knowledge of the subject through an approved course.

Formaldehyde Gas Sterilization

Substance Properties. Formaldehyde (FO) is a colorless, pungent-smelling gas with a broad spectrum of biocidal activity. It is toxic, allergenic, suspected to cause cancer, combustible, and can form explosive mixtures with air. With the exception of its allergenicity, the potential for danger in the areas just mentioned is lower than in the case of ethylene oxide, but it is also less effective. The maximum allowable concentration (MAC value) is 0.5 ppm. Formaldehyde is commercially available as a 30–50 weight percent solution (formalin).

Adsorption and Desorption. Formaldehyde is adsorbed by the surfaces of solids. With regard to FO sterilization, this means that residues remain on materials following FO exposure. After the sterilization phase, the FO residues adsorbed on the sterile items are removed by purging with air and steam (desorption). The extent of adsorption and desorption is dependent, among other things, on the type of material of the solids. Experiments looking at its desorption behavior have shown that the residues on sterilized products can often be removed relatively easily, but that the residues in the sterilization packaging are many times higher in comparison. FO-sterilized items stored in poorly ventilated spaces can lead to the MAC value for formaldehyde being reached in the air of the room. Storage locations in which sufficient dilution and aeration are guaranteed must accordingly be selected.

Process Sequence

1. Ventilation and humidification, often using a fractionated vacuum process. The FO sterilization process is not able to penetrate to the same extent as the EO sterilization process. To achieve sufficient penetration in the process, the FO sterilization process may only be performed using the fractionated vacuum process.
2. Sterilization, at a constant, low vacuum and high atmospheric humidity (at least 60%); i. e., formaldehyde and steam are used for sterilization in combination at temperature of 60–75 °C.
3. Desorption: purging and ventilation using steam/air scrubbing; i. e., the chamber and the items being sterilized are purged in 15–20 changes in pressure with air or steam.

Requirements for Sterilizers. Sterilizers must comply with the requirements of DIN 58948.

Requirements for Operating Staff. According to TRGS 513, operating staff must demonstrate knowledge of the subject through an approved course.

H_2O_2 Low-Temperature Plasma Sterilization (LTP)

Field of Use. Because of their well-known problems in respect of residues, there are considerable restrictions on operation of conventional gas sterilizers (ethylene oxide/formaldehyde) (German Ordinance on Hazardous Substances, TRGS 525). No harmful residues of the active substance are to be expected in the case of H_2O_2 LTP sterilization, which is based on the active substance H_2O_2, i. e., hydrogen peroxide plasma, and whose chamber temperature is 45 °C.

Active Principle. The active substance used is hydrogen peroxide (H_2O_2). In a vacuum it is evaporated, diffused through the sterilization packaging, and then excited by radiofrequency to form hydrogen peroxide plasma. Hydroxyl and hydroperoxy radicals form in the plasma, which inactivate the microorganisms. After the radiofrequency field is switched off, the radicals lose their high levels of energy and recombine to form water and oxygen [3.12, 13].

Process Sequence

First Phase: Vacuum. The sterilization chamber is evacuated to residual pressure of ≈ 1 mbar (1 mbar = 100 Pa). The radiofrequency generator is then switched on, and an air plasma is generated. The chamber is then ventilated and evacuated once more to prepare for the injection. The air plasma allows any residual moisture to be dried for better preparation for loading.

Second Phase: Injection. At room temperature, 1.8 ml H_2O_2 is injected into the chamber and evaporated at

pressure of ≈ 11 mbar. A short period of ventilation then follows. This ensures that the active substance penetrates quickly into the lumina.

Third Phase: Diffusion. The H_2O_2 diffuses into the items being sterilized. A vacuum is generated once again before the plasma phase.

Fourth Phase: Plasma. The pressure in the chamber is reduced to 0.7 mbar, and the plasma phase is begun by means of radiofrequency in the MHz range. The hydrogen peroxide vapor is thereby ionized, i. e., converted into gas plasma. This consists, among other things, of highly reactive hydroxy and hydroxyl radicals, which bond with functional building blocks of microorganisms, thus causing them irreversible damage. Phases 2–4 are carried out twice, the so-called first and second halves of the cycle.

Fifth Phase: Ventilation/Pressure Equalizing. Following completion of the 10 min plasma phase, the gas residues in the chamber and in the sterile items are removed harmlessly by fractionated air purging and active carbon filtering. The vacuum is equalized. When atmospheric pressure is reached, the cycle is ended and the door can be opened.

Process Duration. When fully loaded, the process lasts for 75 min. Smaller loads sometimes mean shorter process times.

Information for Use. Because of the way in which it works, this process can be used for sterilization of thermolabile items, but with certain restrictions [3.14]. Users of this process should draw up a list of all the thermolabile items which must be sterilized and then decide which items this process can be used for. A so-called positive list of articles which are approved for sterilization is issued by the manufacturer.

Based on comprehensive tests, open plastic tubes with internal lumen > 3 mm and up to 200 mm in length can currently be sterilized. Tubes with internal lumen < 3 mm must be provided with a diffusion amplifier before sterilization. Catheters which are closed at one end cannot be reliably sterilized.

The disadvantages of this process should be discussed very specifically: hydrogen peroxide vapor is strongly adsorbed by materials containing cellulose. Plasma sterilization therefore cannot be used for items to be sterilized which contain cellulose or for instruments in packaging containing cellulose. All packaging materials must be free from cellulose and are currently only available from the operating company. Packaging bags, for example, are also on average three times more expensive than similar products for steam sterilization. Containers for instruments, such as those which are available for steam sterilization, are only in the development stages. The instruments must be completely dry before loading the plasma sterilizer. In the case of organic contamination of the surface, the effect of plasma sterilization is restricted considerably, but this is also the case with all surface sterilization processes.

Inspection and Testing for Effectiveness. Test systems with biological indicators in accordance with ISO 14937 must be used to test effectiveness.

3.6 Hygiene of Noninvasive Technology Equipment

This category includes all equipment and technical measures which are used for diagnosis and therapy but which are not inserted into the patient. These may be electrocardiogram (ECG) electrodes, ultrasonic transducers or monitors by the patient's bed or in function-testing departments, and they may equally be small conveyor systems, ventilation technology or processing machines.

3.6.1 Equipment Used on the Patient

These must be included in regular cleaning. If the equipment does *not* come into contact with the patient, then cleaning – often only of the accessible surfaces – is usually sufficient. Environmentally friendly detergents should be given preference for this, and it is also important to bear in mind material compatibility and area-specific regulations (e.g., explosion protection).

Where such equipment is in areas with increased requirements in terms of sterility (e.g., operating theaters) or in isolation rooms (infectious patients, patients with multiresistant colonized bacteria, immunosuppressed patients), disinfectant cleaning must be stipulated. The disinfectant used must be suitable for the field of use (disinfectants for treating surfaces or instruments) and

must comply with requirements in the scope of its effect. When used in areas with increased requirements in terms of sterility, *all* potential pathogens should be covered, and when used in isolation areas, substances are preferred which act very quickly *against the known pathogens* with a long-lasting effect.

Equipment or equipment parts which come *into contact with the patient* must be cleaned carefully prior to use in accordance with the guidelines and must always be disinfected if there are corresponding regulations (e.g., after use on patients with multiresistant germs) or if, despite proper cleaning, there is still a risk of infection, e.g., in the case of severely immunocompromised patients for whom even harmless environmental germs can become a threat.

3.6.2 Equipment Not Used on the Patient

Initially, the same requirements apply for this equipment as for use outside a hospital. It must be maintained according to its intended purpose and regularly cleaned. Different requirements may be necessary when the equipment is used in *areas with increased requirements in terms of sterility*, and, when necessary, these increased requirements should be governed by in-house guidelines. If, as a result of use, the equipment/unit is contaminated with material from the patient, then disinfectant cleaning is recommended, and if the material is from an infectious patient then disinfectant cleaning is a requirement. For certain equipment (e.g., air-conditioning units, cleanroom benches), special regulations may need to be taken into account (see below).

3.6.3 Repair and Maintenance

Equipment which is handed in for repair and maintenance to relevant departments should have been given at least basic cleaning beforehand. Equipment parts which have been in contact with patients/patient material must only be disinfected before being worked on if they are visibly dirty, or if it can be assumed that it is contaminated with germs which should be prevented from spreading in the hospital (multiresistant germs), which can lead to infections in the maintenance staff, or which are subject to special regulations by law (German Infection Protection Act). These also include germs such as hepatitis and tuberculosis pathogens, and other similar pathogens.

Whether this pretreatment is carried out by the user, somebody in another position (processing unit) or the maintenance department itself may depend on the structure of the organization and also on the size of the hospital. It is therefore recommended that the procedure and the respective responsibility are set down in writing and that *hygiene plans* are used to regulate who has to do what, when, and in particular precisely how, and in what sequence. This should in any case be agreed upon together with the person responsible for hygiene (hygiene officer/infection control nurse) and possibly also with the member of staff responsible for occupational health and safety.

3.7 Hygiene of Invasive Technology Equipment

This includes all equipment, equipment parts, and technical measures which are used for diagnosis or therapy and which in the process are inserted *into* the patient. These may either be instruments or equipment which are used in the patient *without* penetrating the skin or mucosa (e.g., bronchoscope, oesophageal arteriography, suction aspirator), in which case there may be intentional (biopsy) or unintentional damage to the mucosa, or they may be instruments or equipment which are designed for use *with* or *after* penetration of the barrier of the skin/mucosa (e.g., biopsy forceps, arthroscope, and vascular catheter).

Disinfectant measures are usually sufficient for the first group, whereas a sterilization process is obligatory for the second group (see above).

Here, too, the following general *rule* applies: Primarily use thermal disinfection (washing) processes, and only consider thermochemical or even purely chemical processes when the materials are not compatible with thermal disinfection processes.

3.8 Practical Examples

Targeted measures to prevent transmission of germs and infections must be adapted to the pathogen, the group of people, and the hazard potential. Vaccination alone may be sufficient, or specific disinfection or steriliza-

tion measures or even isolation of the patient may be necessary. The route of transmission plays a crucial role in this (Table 3.5).

The German Infection Protection Act, which has been in force since 1 January 2001 and has replaced the old Federal Contagious Diseases Act, takes into consideration these findings but also takes into account the effects of technology in the changing world of medicine by stipulating in § 23 that infections acquired in hospitals must be continuously recorded, even those which

Table 3.5 Types of infection transmission and their features and protective measures (after [3.15])

Type of transmission	Features	Examples	Protective measures
Airborne transmission	Microorganisms attached to particles in the air with size of <5 µm, movement over a relatively long period of time therefore possible	1. Reasonable suspicion of or confirmed tuberculosis 2. Measles 3. Varicella/disseminated herpes zoster 4. HIV patients with cough, fever, and opaque pulmonary infiltrates, provided TB cannot be ruled out	1. Isolation in a single room (door and windows closed), cohort isolation potentially possible 2. Respiratory protection when entering the room if open-lung TB is identified or there is strong clinical suspicion 3. In the case of certain diseases (measles, varicella) nonimmune people should not enter the room; if unavoidable, only with respiratory protection
Droplet transmission	Microorganisms attached to particles >5 µm (these droplets are created when speaking, coughing, and sneezing)	1. Bacterial diseases: *H. influenzae* (type B) infections, meningococcal infections, multiresistant pneumococcal infections, diphtheria, pertussis, mycoplasma pneumonia infections 2. Viral diseases: influenza, mumps, rubella, parvovirus infections	1. Single room, cohort isolation if necessary; if not possible a distance of at least 1 m should be kept between the infectious patient and other patients or visitors 2. Mouth and nose protection required when working close to the patient (<1 m distance)
Contact transmission	Direct contact (touching) or indirect contact (secondary, e.g., via contaminated surfaces) with epidemiologically important pathogens in the case of infected or colonized patients	1. Infectious diarrheal diseases 2. *C. difficile* enteritis 3. Respiratory infections in children (bronchiolitis, croup) 4. Multiresistant pathogens such as Methicillin-resistant *Staphylococcus aureus* (MRSA), Vancomycin-resistant *Enterococcus faecium* (VRE) (except multiresistant TB) 5. Abscess or secreting wounds which cannot be covered	1. If possible single room; cohort isolation if necessary 2. Gloves and gowns depending on the pathogen and site of the infection (follow infection control recommendations) 3. Disinfect hands on leaving the room

are particularly influenced by technical factors (*device related*):

- *Postoperative* wound infections
- *Ventilator associated* pneumonias
- *Catheter-related* septicemias
- *Catheter-related* urinary tract infections.

Because these are also the four most common health-care acquired infections in hospitals and the measures required by law make an important contribution to sensible quality management, the following practical examples are limited to these infections and demonstrate the vital contribution that technology can make here.

3.8.1 Postoperative Wound Infections

The pathogens for postoperative wound infections either originate from the patient himself (germs in the skin or mucous membranes) or are introduced into the patient from outside during surgery as a result of a lack of hygiene. Before many surgical procedures, hair removal up to now is still carried out using a razor (medicotechnical measure). If this is done on the evening before the procedure, then the bacteria from skin flora have time overnight to migrate deep into the skin via the microscopic cuts in the skin which are unavoidably caused during shaving to cause inflammation there. The result is a significantly higher risk of developing surgical site infection. It is therefore recommended either not to shave at all and to simply cut the hair short using hair trimmers, or to shave immediately before the surgery and thus immediately before the skin is disinfected (see also KRINKO recommendation for the prevention of postoperative infections in the operating field [3.9]).

Further important measures for the avoidance of postoperative wound infections which are proven in their effectiveness and which relate to technical means are: sterile instruments, sterile implants, reliably sterilized equipment parts which are required for surgery (suction apparatus, counter with connection cable, etc.), correctly functioning air-conditioning units, sufficient vacuum in the case of reprocessed reusable drainage equipment, etc. [3.16].

3.8.2 Ventilator-Associated Pneumonias (VAP)

Pneumonia is the second most common overall infection in hospitals and is the most important in the case of intensive care patients. It is seen as the primary or secondary cause in 30–50% of deaths. With respect to diagnosis related groups (DRGs), it is also significant that health-care associated pneumonia increases the length of hospital stay by an average of 11.5 days. The main risk factor for developing health-care associated pneumonia is mechanical ventilation.

According to the KRINKO evidence criteria, orientated towards the criteria of the Centers for Disease Control and Prevention (CDC) [3.17], the following technically relevant points are important for targeted prevention [3.17–20].

1. Oral intubation is better than nasal (development of maxillary sinusitis); in the case of long-term artificial respiration prefer tracheotomy.
2. Use sterile or disinfected tracheal tubes.
3. Clean all equipment and tools thoroughly before disinfection and sterilization.
4. Do not carry out routine sterilization or disinfection of the circulation system of ventilators and anesthetic apparatus.
5. Do not change ventilator breathing circuits more frequently than every 48 h, including tubes and expiratory valves and also nebulizers and steam humidifiers, provided the equipment is only used for one patient (according to recent studies an interval of 7 days between changing is even possible).
6. Do not use atmospheric humidifiers, which form aerosols (= atomizer), if sterilization/disinfection and sterile water are not used on at least a daily basis.
7. Use sterile (not distilled or nonsterile) water for rinsing the processed equipment and tools which are used on the respiratory tract after they have been chemically disinfected.
8. Do not reprocess equipment and tools which have been manufactured for single use, unless there is data to show that reprocessing does not pose any threat to the patient and is cost-effective and that the functionality of the equipment and tools is not altered.
9. Sterilize or disinfect ventilation breathing circuits and humidifiers between use on different patients.
10. Do not use bacterial filters between the humidifier reservoir and the inspiratory tube.
11. Do not change the respiratory tube routinely if the system is connected to an heat and moisture exchange (HME) or heat and moisture exchange filter (HMEF), provided it is only used on one patient.
12. Change tubes between patients, including nose clamps or masks, which are used to supply oxygen from a wall outlet.
13. Sterilize atmospheric humidifiers which are used in inhalation therapy, e.g., for tracheostomy patients,

or disinfect between patients and every 24 h when used on the same patient.
14. Sterilize or disinfect portable spirometers, oxygen probes, and other respiratory tools which are used on various patients between uses.
15. Anesthetic equipment: clean and then sterilize or thermally/chemically disinfect the reprocessable parts of the respiratory circuit (such as the endotracheal tube or mask, inspiratory and expiratory tube, Y-piece, bag valve mask, humidifier, and tube) between use on different patients and observe the relevant manufacturer's instructions.
16. Pulmonary function testing: sterilize or disinfect reusable mouthpieces and tubes between different patients or in accordance with the manufacturer's instructions.

3.8.3 Catheter-Related Septicemia

Most cases of septicemia acquired in hospitals are the result of using a vascular catheter. The most important points to avoid resulting infections are checking of the indication for access, selection of the correct catheter and the correct access site, aseptic placement of the catheter, and aseptic dressing change. The technical component is comparatively low here and covers the following points [3.21]:

1. Change IV tubes including the three-way valves only every 72 h (every 24 h when blood/blood products or lipid solutions are administered), except where there are signs of infection.
2. When choosing transducers (pressure sensors), preference should if possible be given to disposable items (as opposed to reusable equipment).
3. The transducer, the tube system, and the rinse solution must be changed at least every 96 h.
4. All components of the blood pressure monitoring system must be sterile (including the calibration apparatus and the rinsing fluid). The entire pressure system (tube lines, transducers, and rinse solution) must be handled aseptically.
5. Reusable pressure systems must be processed and sterilized taking into account the manufacturer's instructions.
6. If preparation of mixed infusions in areas close to patients is unavoidable, then it must be done under controlled aseptic conditions.

In past years it has been increasingly common to reprocess certain expensive intravascular catheters within the hospital or to have them reprocessed by external providers (see later). This practice is currently the subject of controversial debate for very many different reasons (German Medical Devices Act, costs, borine spongiform enphalopaty (BSE)). In this context, reference should in particular be made to the recommendations of the German Commission for Hospital Hygiene and Infection Prevention at the RKI [3.21] and [3.9] with the explanations from the RKI and the final report of the vCJD taskforce: variant Creutzfeldt–Jakob disease (vCJD), epidemiology, identification, diagnosis, and prevention, with particular consideration of minimizing the risk of iatrogenic transmission via medical devices, particularly surgical instruments [3.22]. Reference is further made to specific literature [3.23–26].

3.8.4 Catheter-Related Urinary Tract Infection

Urinary tract infections make up more than 40% of all infections acquired in hospital and, as the starting point for urosepsis, are responsible for up to 15% of cases of septicemia. Up to 80% of these urinary tract infections are found in patients with urinary catheters, which emphasizes their significance. Technically relevant aspects of targeted prevention are as follows:

- Urinary catheters should only be placed if medically necessary and only for as long as is absolutely necessary; an indication as part of nursing care must be rejected.
- Only sterile, permanently sealed urine drainage systems with an antireflux valve should be used (i. e., without disconnection to empty the bag) [3.27, 28].

3.8.5 Dialysis

Because of the high risk of infection both for patients and also for staff, dialysis departments deserve special attention. The risks of infection are:

1. For the patient:
   a) Infections via the vascular access
   b) Bloodborne infections
   c) Contamination of the dialysate and dialyzer.
2. For the staff:
   a) Through infected dialysis systems
   b) Infections via blood and dialysate.

In comparison with peritoneal dialysis, hemodialysis is more significant from a technical viewpoint

and is the basis for the following explanations. However, some of the requirements also apply to peritoneal dialysis.

If drinking water is used for dialysis, it must undergo additional processing because it contains bacteria and pyrogens, even if chlorinated. The processes used for this are ion exchange (water softening), active carbon filtering, distillation, and reverse osmosis. However, it must be borne in mind that particularly the first process mentioned can provide waterborne bacteria (mainly *Pseudomonas* spp. and other Gram-negative bacteria such as acinetobacter and enterobacter) but also mycobacteria, which are present in water and are described as *atypical*, with good opportunities to multiply. Subsequent ultrafiltration to remove bacteria and bacterial toxins is therefore considered essential [3.29].

Although reverse osmosis is currently the most optimum processing method, it is still necessary to take into account that, even with this method, there may be microbial contamination of the membrane, and germs may find their way in if there are leaks. Once the dialysate is added, this forms a mixture which, because of its composition, is a good culture medium for waterborne bacteria. Various countries have therefore suggested guidelines for the assessment of dialysis water (Table 3.6).

To prevent contamination of hemodialysis equipment and supply apparatus, the following technical requirements are deemed necessary [3.30]:

- No open reservoirs for water and processed dialysis fluid
- No open reservoirs for concentrates
- Small line cross-sections in supply lines
- Route lines as a closed circular pipeline; avoid dead spaces (only for clean water)
- Complete disinfectability of the line system
- Pipe disconnection when disposing of the dialysis fluid to prevent retrograde microbial contamination.

In accordance with the hygiene guideline which is an appendix to the 2006 Dialysis Standard [3.31], dialysis equipment (hemo- and peritoneal dialysis) used must comply with the regulations of the German Medical Devices Act and must be maintained, operated, cleaned, and disinfected in accordance with the manufacturer's instructions (instructions for use, technical manual) [3.30]. Due to this required disinfection after each patient, the formerly required separation into a so-called *yellow* (for infectious patients) and *white* (for noninfectious patients) region is now obsolete. The operator is responsible for ensuring that all parts which come into contact with the used dialysate or even with the patient's blood are treated as potentially infectious and that the equipment is disinfected after each dialysis treatment.

This can be done by [3.29]:

- Sterilization with steam at a temperature of 121 °C, provided this is technically possible from a materials point of view (equipment with stainless-steel tanks)
- Disinfection using hot water (90–95 °C for 20 min); citric acid is automatically added during the process to prevent deposits in the equipment
- Thermochemical disinfection (for ecological reasons, preferably with peracetic acid, possibly also with formaldehyde or glutaraldehyde or with sodium hypochlorite).

Dialyzers have been regularly reprocessed in the past. Figures for the USA show that the proportion of dialysis centers reprocessing their equipment rose from 18% in 1976 to 82% in 1997 [3.32], and corresponding processing guidelines issued by the Association for the Advancement of Medical Instrumentation (AAMI) were adopted by official authorities [3.33]. The percentage then dropped to 62% by 2002. The literature describes infectious complications through to outbreaks in the course of reprocessing dialyzers, without being able to prove causality beyond doubt [3.34]. For quality assurance purposes it is therefore necessary to ensure that effective processes are used, which are currently based on thermochemical disinfection. The hygiene guideline which is an appendix to the 2006 Dialysis Standard – written by the German Commit-

Table 3.6 Guidelines for assessment of dialysis water in various countries

	Dialysis water (generally permeate)		Dialysis fluid	
	(CFU/ml)	Endotoxin	(CFU/ml)	Endotoxin
AAMI (USA 2004)	≤ 200	2 EU/ml	≤ 2000	2 EU/ml
European Pharmacopoeia (2008)	≤ 100	≤ 0.25 IU/ml	No information	No information
Swedish Pharmacopoeia (1997)	< 100	< 0.25 IU/ml	< 100	
Japanese Society for Dialysis Therapy (2008)	< 100	< 0.05 EU/ml	< 100	0.05 EU/ml

tee for Clinical Nephrology in collaboration with the Association of German Nephrology Centers run by the German Society of Nephrologists in Private Practice and also with the German Society of Pediatric Nephrology, in agreement with the German Commission for Hospital Hygiene and Infection Prevention – likewise points to the requirements for a processing method with appropriate validation and stresses that the German Committee for Nephrology currently does not favor reuse of dialyzers and tube systems, despite the financial ramifications [3.30]. Tests to monitor clean water and dialysis fluid must be performed and documented at least twice a year [3.30, 35]. The relevant water-conducting systems (e.g., closed circular pipelines) must be fitted with suitable sampling points.

The following procedure is considered necessary to test the microbiological quality of the water [3.35]:

- Disinfect hands before each sample is taken
- Use sterile glass bottles with a screw closure for collecting the sample; to test for endotoxins use pyrogen-free containers made from polystyrene
- Draw off ≈ 100 ml in each case
- *Demineralized water*
  - From the closed circular pipeline at the bedside
  - Aseptic sampling (disinfected adapter, at least twice a year)
- *Basic bicarbonate*
  - Only if it is taken as a concentrate from a closed circular pipeline at the bedside (not from canisters or cartridges)
  - Aseptic sampling (disinfected adapter)
  - Once a month
- *Dialysis fluid*
  - Sample taken from the dialyzer
  - Before the start and after the end of dialysis
  - Every 6 months
- *The assessment is performed according to the following guidelines*
  - In the processed water and in the dialysis fluid before the beginning of dialysis: 100 CFU/ml.

In an ISO standard [3.36] which appeared in 2009 and in which the quality of fluids for hemodialysis is formulated as an international standard, requirements, and limit values for the chemical constituents and impurities in water, concentrate, and dialysis fluid are listed in addition to microbiological quality standards. The operator of specialist dialysis departments is responsible for monitoring of microbiological water quality and also for chemical monitoring.

3.8.6 Creutzfeldt–Jakob Disease

After medical devices have been used on patients with a proven or strongly suspected case of Creutzfeldt–Jakob disease (CJD) or its new variant (vCJD), special processing procedures are necessary [3.22, 25]. According to the currently favored prion theory, particular significance is attributed to the cleaning which takes place during processing, because proteins must primarily be removed. For disinfectant processing, 1–2 M sodium hydroxide (NaOH), 2.5–5% sodium hypochlorite (NaOCl), or 4 M guanidinium thiocyanate (GdnSCN) is currently recommended [3.22].

Instruments which cannot be steam-sterilized are then subsequently processed with aldehyde disinfectant and finally rinsed with 70% alcohol (e.g., endoscope) and gas-sterilized.

Instruments which can be steam-sterilized undergo chemical decontamination before then being subjected to machine processing at 93 °C, and are finally autoclaved at 134 °C for 1 h.

The relevant appendices to the RKI guideline must be observed [3.22].

3.9 Regulations

3.9.1 Technical Regulations for Hazardous Substances

- TRGS 513. Fumigations with ethylene oxide and formaldehyde in sterilization and disinfection systems (edition June 2008).
- TRGS 525. Handling of hazardous substances in facilities for human medical care (as of May 1998 BArbBl. no. 5/1998, p. 58, currently undergoing revision).
- TRGS 401. Hazards due to skin contact (as of June 2008).
- TRBA/TRGS 406. Sensitizing substances for the airways (as of June 2008).
- TRBA 250. Technical regulations for biological agents (as of February 2008).

3.9.2 Standards

The importance of standards has been re-evaluated as a result of Directive 93/42/EEC about medical devices and the correspondingly harmonized German Medical

Table 3.7 Standards for the (minimum) standard for medical devices ▶

Type of standard	Source
DIN	German standard
E DIN	Published German draft standard
EN	European standard
DIN EN	Harmonized (European) standard
prEN, E	Published European draft standard
DIN EN/ISO	International standard

Table 3.8 Overview of major standards in the field of sterilization technology for the health care system

Standard	Steam sterilization	As of
DIN EN 285	Sterilization – steam sterilizers – large sterilizers	8/2009
DIN EN/ISO 17665-1	Requirements for the development, validation, and routine control of a sterilization process for medical devices	11/2006
DIN 58948	Sterilization – low-temperature steam formaldehyde sterilizers	
Section 17	Requirements for the installation and operation of low-temperature steam formaldehyde and formaldehyde sterilizers and their supply sources	3/2009
DIN EN 14180	Sterilizers for medical purposes Low-temperature steam and formaldehyde sterilizers – requirements and testing	1/2010
Standard	**Ethylene oxide sterilization**	**As of**
DIN EN 1422	Sterilizers for medical purposes – ethylene oxide sterilizers – requirements and test methods	8/2009
DIN 58948-7	Requirements on the installation and requirements on the service supply for ethylene oxide sterilizers	1/2010
DIN 58949	**Steam disinfection apparatus**	**As of**
Section 1	Terminology	1/2001
Section 2	Requirements	1/2001
Section 3	Efficiency testing	2/2004
Section 4	Biological indicators for efficacy tests	10/2006
Section 6	Operating of steam disinfection apparatus	2/2004
Section 7	Structural requirements and requirements on service supply	1/2001
DIN 58955	**Decontamination equipment for medical use**	**As of**
Section 1	Terminology	1/2003
Section 2	Requirements	7/2005
Section 3	Efficiency testing	9/1998
Section 4	Biological indicators for efficacy tests	3/2006
Section 6	Operation	3/2001
Section 7	Structural requirements and requirements on service supply	3/2001
DIN EN/ISO 11138	Sterilization of health care products – biological indicators	
Section 1	Requirements	8/2008
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