The application of new technologies in medicine leads to therapeutic and diagnostic advancements, yet also causes risks for patients to acquire 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 equipment used for noninvasive 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–Jakob 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).

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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 endanger 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