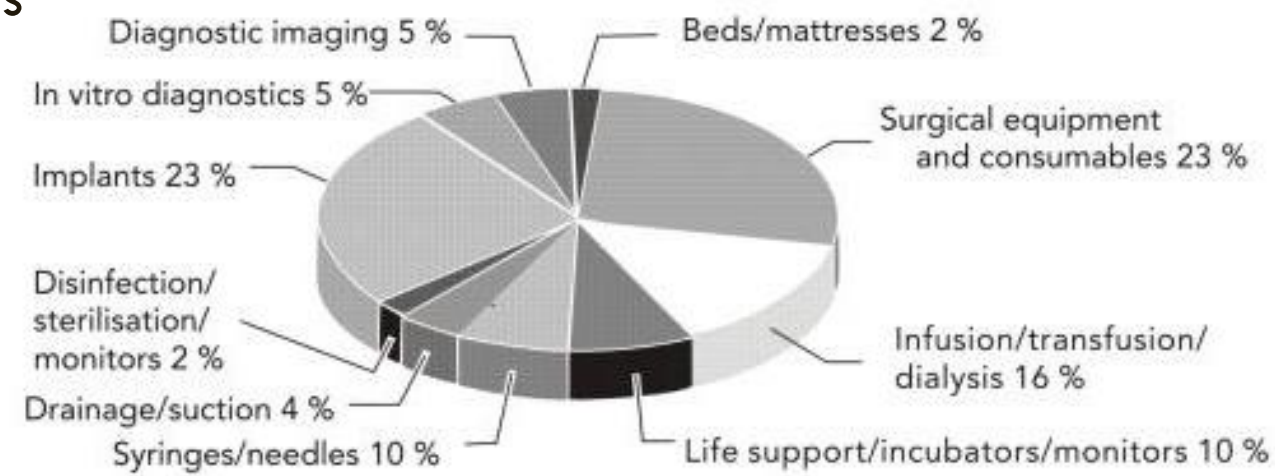
SAFETY IN MEDICAL DEVICES

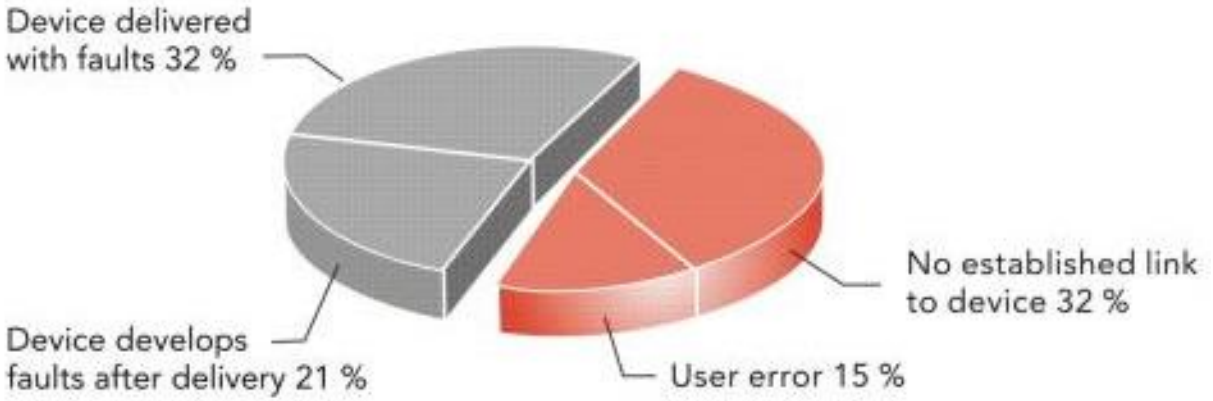
Recommended Reference

- Springer Handbook of Medical Technology,
  Rüdiger Kramme, Klaus-Peter Hoffmann, Robert S. Pozos (Eds),
  Springer-Verlag, Heidelberg, 2011.

Incidents in Medical Devices

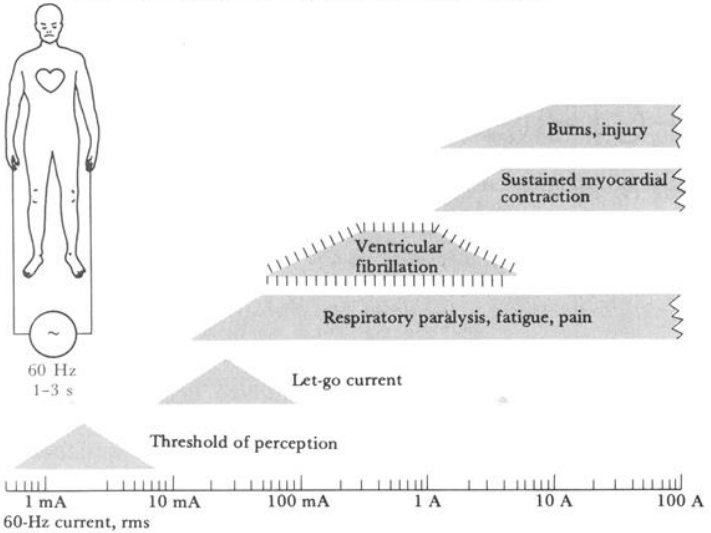
- Potential hazards
  - Electrical
  - Mechanical
  - Biological

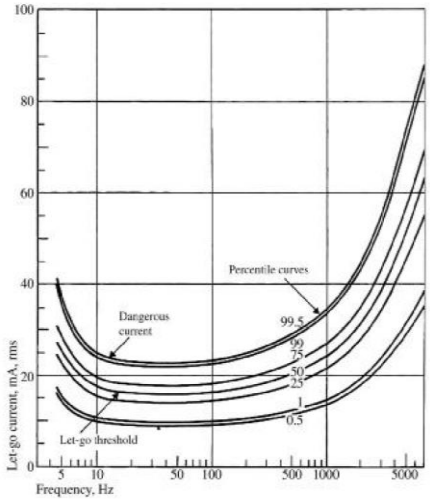


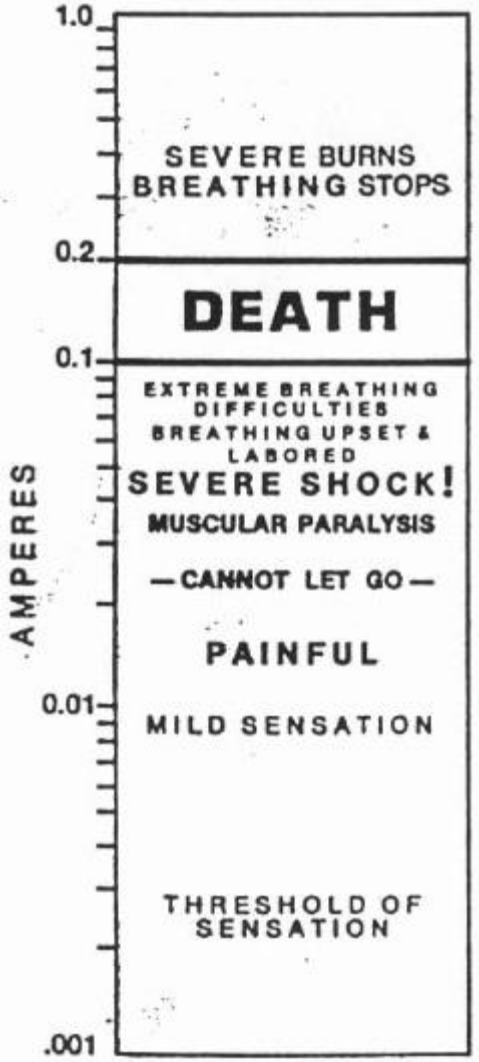


Physiologic Effects of Electricity

Current	Reaction
Below 1 mA	Generally not perceptible
1 mA	Faint tingle
5 mA	Slight shock felt, not painful but disturbing; average individual can let go; strong involuntary reactions can lead to other injuries
6 to 25 mA (women)	Painful shock, loss of muscular control
9 to 30 mA (men)	The freezing current or let-go range; individual cannot let go but can be thrown away from the circuit if extensor muscles are stimulated
50 to 150 mA	Extreme pain, respiratory arrest, severe muscular contractions; death possible
1,000 to 4,300 mA	Rhythmic pumping action of the heart ceases; muscular contraction and nerve damage occur; death likely
10,000 mA	Cardiac arrest, severe burns; death probable

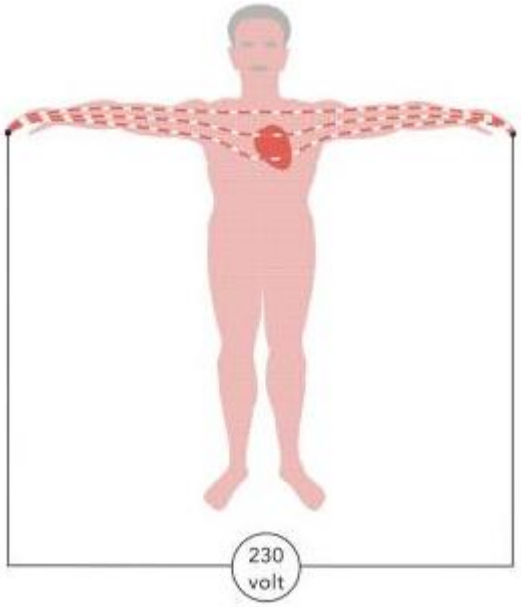


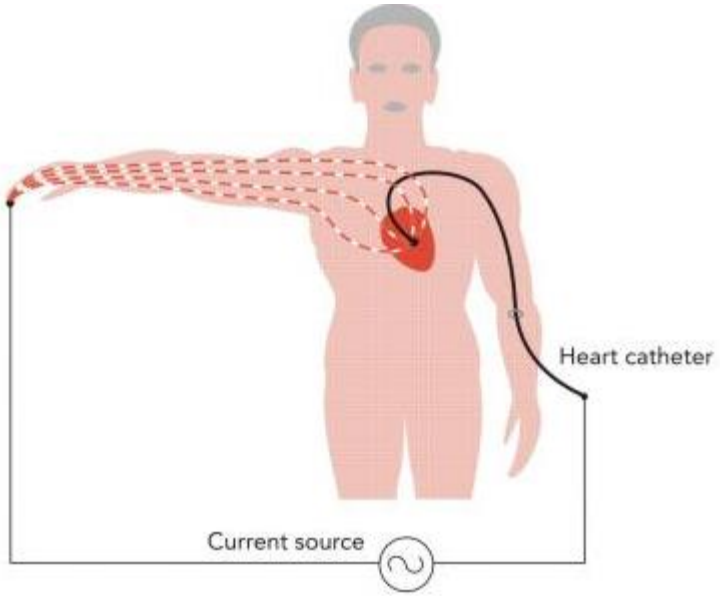




Macroshock and Microshock

- Macroshock
  - Externally applied current spreads throughout body with small part through the heart
- Microshock
  - Internally applied current resulting in all current passing through the heart

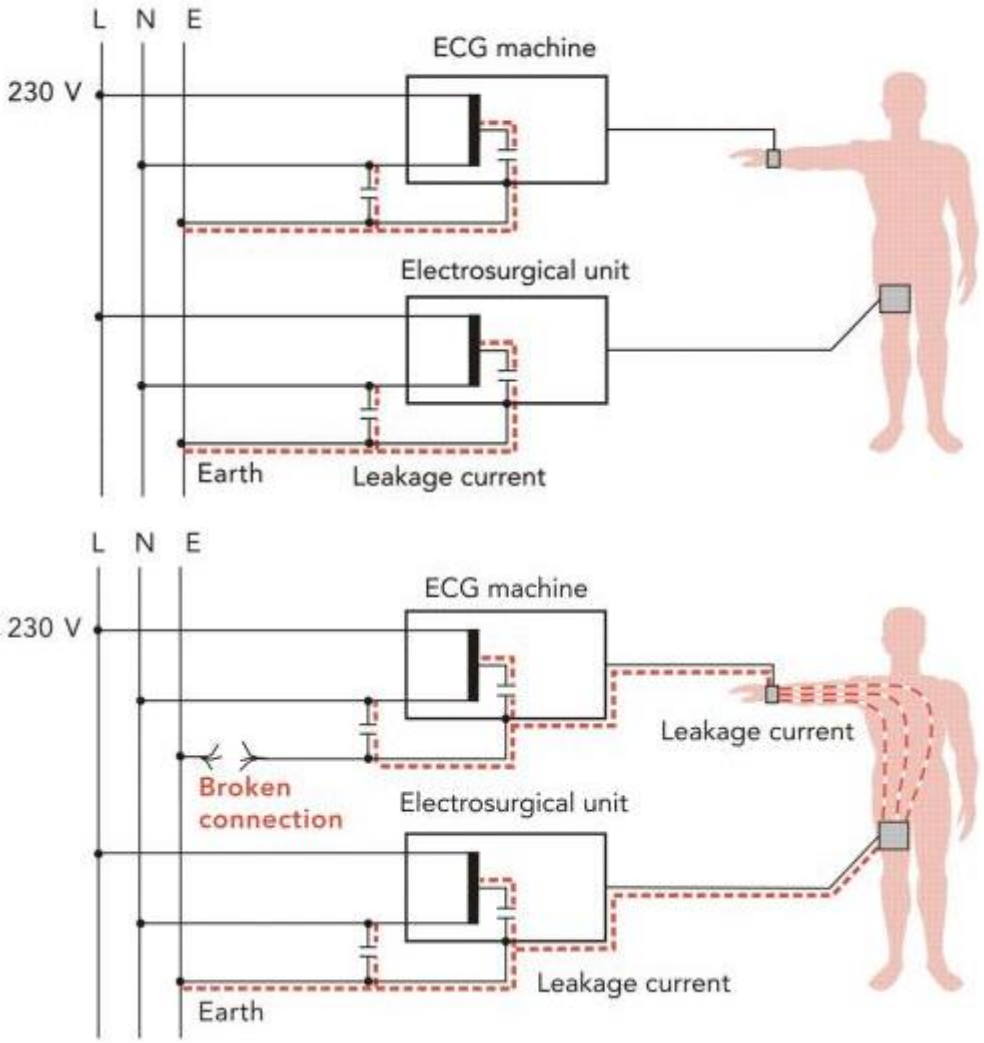




Skin and Body Resistance

- Resistance of skin limits currents that can flow into the body when person comes in contact with voltage source
  - For 1 cm^2 of contact with dry intact skin, resistance range: 15kΩ to 1MΩ
  - Depends on body part and amount of moisture or sweat present
  - For wet or broken skin, resistance drop as low as 1% that of dry skin
- Internal resistance is much lower
  - 200Ω for each limb and 100Ω for trunk, i.e., 500Ω between any two limbs
- Medical procedures that lower or eliminate skin resistance increase vulnerability to macroshock
  - Biopotential electrode gel reduces skin resistance
  - Electronic thermometers or implantable devices bypass skin

Importance of Earth Connection



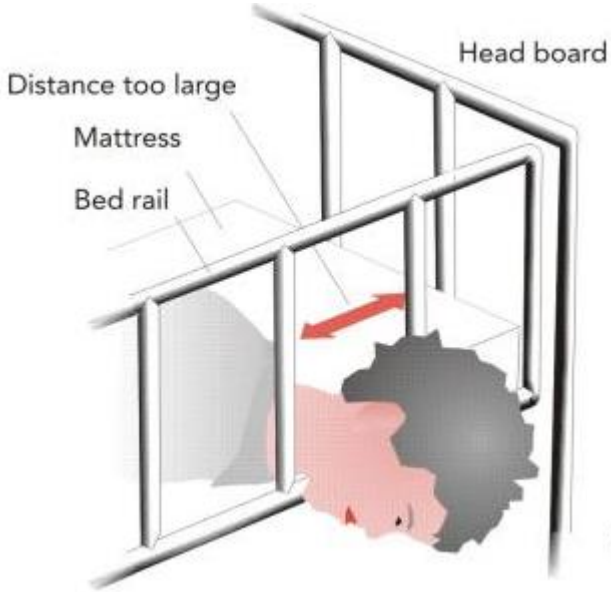
Mechanical Safety

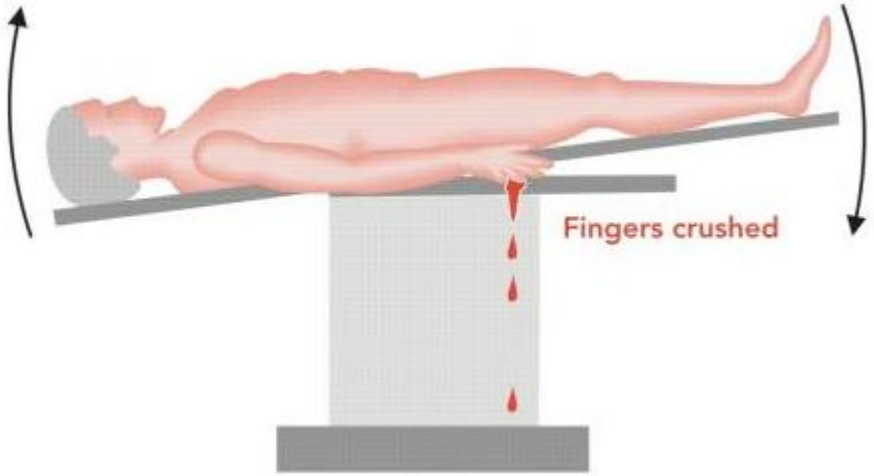
- Mechanical Strength
  - The enclosure of the device must be sufficiently strong to retain its integrity under conditions of normal wear and tear (inward force and impact)
  - Handles of portable equipment are tested with a force of four times the weight of the product
  - Parts which support patients, or patient limbs, e.g. foot rests are designed with safety factors (specific for each application) to ensure their durability
  - Hand held part are submitted to drop test from a height of 1m
  - Portable equipment drop test (e.g., 10kg is dropped from height of 5cm)
  - Mobile equipment is made to travel at 0.4m/s down a step of 2cm – This test is repeated 20 times (step test)
- After these tests equipment should not cause a safety hazard
  - that is it should comply with the requirements of the standard.

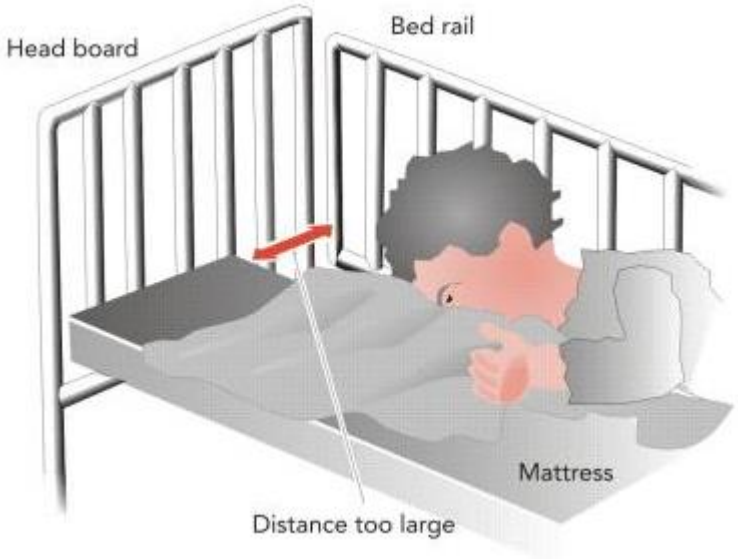
Mechanical Safety

- Moving Parts
  - Moving parts which could produce a safety hazard must be suitably guarded to prevent access, unless exposure is essential to the operation of the equipment
  - If movement of the equipment, or parts of the equipment can cause injury to the patient, this movement can only be achieved by continuous operation of the control by the operator
  - Any electrically controlled mechanical movement must have an emergency switch
- Sharp Edges
  - The device must not have sharp edges, corners, etc.
- Stability
  - Medical devices must not overbalance when tilted to an angle of 10°.

Mechanical Safety: Examples







Biological Safety

- Application of new technologies in medicine leads to therapeutic and diagnostic advancements, yet also causes risks for patients to acquire health-care associated infections
  - Almost half of all infections contracted by patients in hospital were fully or partly associated with *medicotechnical* measures
- It is important to know precautions to prevent the transmission of infectious agents from inanimate *medicotechnical* sources

Goals of Hygiene Measures

- Hygiene measures in the context of medical technology devices must pursue the following goals:
  - Protection of employees during handling
  - Protection of patients during use of medical devices against transmission of germs, which can lead to:
    - Contamination
    - Colonization
    - Infection
- Disinfection aims to prevent transmission of pathogens
  - Complete freedom from germs (sterility) is not guaranteed in disinfection
- Sterilization aims to guarantee complete killing of germs

Causes of Infection

- Natural bacterial colonization present in human skin 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
- Skin and mucous membranes are mechanical barriers which, when intact, prevent microorganisms from penetrating into our bodies
  - Damage to skin and mucous membranes is always accompanied by increased risk of infection

Causes of Infection

- First Step: germ manages to attach to skin or mucous membranes
  - 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
- Second Step: germ is able to deploy its pathogenic properties and this would lead to an infection
  - depending on state of health of affected individual, this can result in illness which varies in its severity
- Requirements for infection to develop are:
  - Infectious agent
  - Person susceptible to infection
  - Contact which enables the germs to colonize individual such that infection can develop

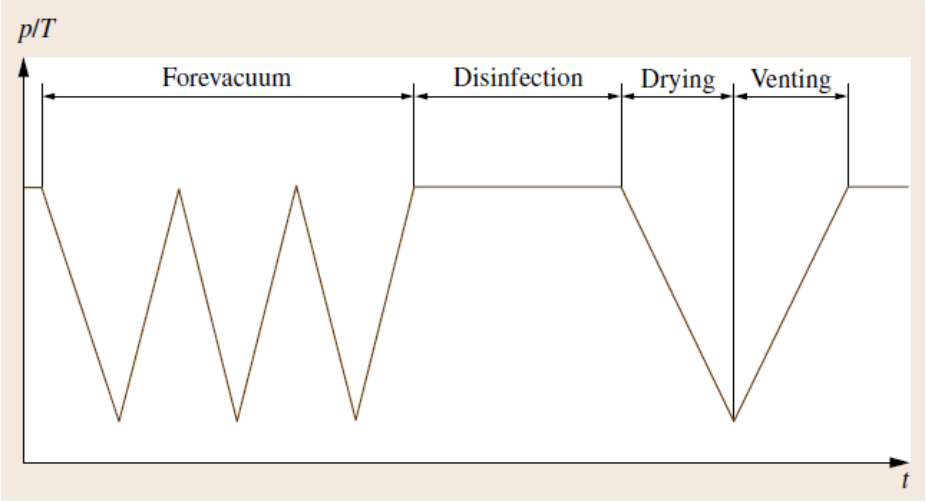
Chemical Disinfection

- Chemical disinfection
  - Disinfection of hands, skin, and mucous membranes
  - Disinfection of surfaces
  - Disinfection of instruments

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

Thermal Disinfection

- Items are subjected to effect of saturated steam
- Steam flow process
  - Air is forced out of chamber and items using saturated steam
  - Disinfection temperature is 100–105 °C, applied for at least 15 min
- Fractionated vacuum process (vacuum–steam–vacuum (VSV))
  - steam which is largely free of air and foreign gases is necessary
  - Disinfection chamber must be vacuum-tight



Application Times and Ranges of Action

- 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

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

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.

Sterilization

- Processes validated to perform required sterilization function
  - Physical processes
  - Steam sterilization
  - Hot air sterilization
  - Physicochemical processes
  - Ethylene oxide gas sterilization
  - Formaldehyde gas sterilization
  - H_2O_2 low-temperature plasma sterilization

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

Targeted Measures to Prevent Transmission of Germs and Infections

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

Targeted Measures to Prevent Transmission of Germs and Infections

Type of transmission	Features	Examples	Protective measures
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)

Targeted Measures to Prevent Transmission of Germs and Infections

Type of transmission	Features	Examples	Protective measures
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

Suggested Readings and Assignments

- Chapters 3 of Recommended Reference

- Problem set posted on web site