Cleaning Processes and Methods in CSSD

- Water qualities (Corrosion, Discolouration, Aging)
- Detergents
- Requirements of the European Medical Device Directive

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Effective factors of the cleaning and disinfection process

- Chemicals
- Temperature
- Water
- Mechanics
- Time
Effective Factors

• **Mechanics**
  - wash arms, spray nozzles have to work properly, even in narrow instruments, e.g. rigid endoscopes, the right quantity of cleaning solution has to reach every spot on the goods to be washed

• **Chemicals**
  - supports the cleaning process by dissolving, emulsifying and dispersing the dirt, material protection to the instruments

• **Temperature**
  - Parameters of disinfection
  - the best cleaning temperature, depending on the kind of dirt (denaturalisation of proteins)

• **Time**

• **Water quality**
  - depending on the cleaning result and quality of the material the proper water quality has to be chosen
Why automatic reprocessing?
Advantages of machine cleaning and disinfection

- Standardization
- High reliability of the reprocessing
- Makes the work much easier
- Lower risks for personal (vapors of disinfections, allergies, injuries)
- Lower risk of damaging instruments
- Lower risk of contamination
- Documentation of the process parameters
Cleaning process for all surgical instruments

- Pre-rinse with cold water
- Mildly alkaline cleaning 10 min
- Intermediate rinse
- Thermal disinfection and drying

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Alkaline cleaning process

Process with chemical disinfection

*In particular cases, the neutralization can be replaced by a second intermediate rinse.
Medical Device Directive 93/42/ECC

All cleaner and disinfectant used for the reprocessing of medical devices are accessories and medical devices on their own

Classification - Dr. Weigert

• Medical Devices **Class I**

⇒ **Detergents**

• Medical Devices **Class II a**

⇒ **Disinfectants**
Medical Device Directive 93/42/ECC

The European Member States shall take all necessary steps to ensure that devices may be placed on the market and put into service only if they do not compromise the safety and health of patients, users and, where applicable, other persons when properly installed, maintained and used in accordance with their intended purpose.
Essential Requirements

- The manufacturer has to supply data for each intended purpose on the labelling, in the instructions and/or in promotional materials.
- Technical file for every medical device
- Risk analysis
- Manufacturing: Special standards concerning cleanness and hygiene.
- QM-system according EN 13485 as well as additional requirements of the directive for the QM-system.
- Safety officer for medical devices
- System for information on incidents occurring following placing of devices on the market.
neodisher® MediClean forte

< D > Zur maschinellen Reinigung von thermostablen und thermolablen Instrumenten
- Flüssigkonzentrat - Nur für gewerbliche Anwendung! RKI-Richtlinie, MPBetreibV beachten! Inhaltsstoffe:
  < 5 % nichtionische Tenside, Polycarboxylate, 5 - 15 % NTA, außerdem: Enzyme, Konservierungsmittel
  (Phenoxyethanol, Methyl-, ethyl-, butyl-, propyl-, isopropylparaben)

< GB > For machine cleaning of thermostable and thermolabile instruments
- Liquid concentrate - For professional use only! Components: < 5 % non-ionic surfactants, polycarboxylates, 5 - 15 %
  NTA, also: enzymes, preservation agents (Phenoxyethanol, Methyl-, ethyl-, butyl-, propyl-, isopropylparaben)

< F > Pour le lavage mécanique d’instruments thermostabiles et thermolabiles
- concentré liquide - Uniquement pour un usage professionnel! Composants: < 5 % agents de surface non
  ioniques, polycarboxylates, 5 - 15 % NTA, en outre: enzymes, agents conservateurs (Phenoxyethanol, Methyl-,
  ethyl-, butyl-, propyl-, isopropylparaben)

< NL/B > Voor machinale reiniging van thermostabiele en thermolabiele instrumenten
- geconcentreerde vloeistof - Voor professioneel gebruik! Inhoudsstoffen: < 5 % niet-ionene oppervlakteac-
  tieve stoffen, polycarboxylaten, 5 - 15 % NTA, bovendien: enzymen, conservieringsmiddelen (Phenoxyethanol,
  Methyl-, ethyl-, butyl-, propyl-, isopropylparaben)

Dos.:
2 - 10 ml/L
Transport in 1000 km³ pro Jahr
Rot = Modellberechnung (MPI, ECHAM 3; 1992)
Blau = Beobachtung (Baumgartner & Reichel; 1975)
Water in Central Sterilisation

Washer/ Disinfectors

- Tap water
- Softened water
- Deionised water (DI water)
Constituents in tap water, which may cause problems in washer/disinfectors

**Water hardness** (Calcium, Magnesium):

Scaling and deposits in machine and on contents
Constituents in tap water, which may cause problems in washer/disinfectors

Heavy and non-ferrous metals
(Iron, Manganese, Copper):

Dark discolorations and deposits, inactivation of water softener
Constituents in tap water, which may cause problems in washer/ disinfectors

Silicic acid/ silicates:
Stubborn yellowish-brown or bluish-violet glaze-like deposits
Constituents in tap water, which may cause problems in washer/disinfectors

Chlorides:
Pinhole-like pitting corrosion on chrome steel
Chlorides: corrosion on chrome steel
Reason for pitting corrosion:
High content of chlorides in water or other liquids which come in contact with instruments:

Physiological saline solution

Blood stopping liquid based on Aluminium chloride solution
Constituents in tap water, which may cause problems in washer/disinfectors

Evaporation residues provoke:
Spotting, deposits
Water in Central Sterilisation

Steam Sterilisers

• Boiler feed water       EN 285
• Boiler water           DIN 58946
• Steam condensate       EN 285
Water in Central Sterilisation

- Test, if spots on the instruments derive from the washer/disinfector or from the steam steriliser

- Test, if spots derive from the packaging in the steam steriliser (residues from textiles, polysaccharides...)

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Thank you for your attention!