

Decontamination and Disinfection of Medical Instruments

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Manual cleaning and chemical disinfection are not standard procedures and their efficiency cannot be verified in everyday practice



REGULATIONS FOR CLEANING AND DISINFECTION OF MEDICAL DEVICES

- 1. Medical Devices Directive (93/42/EEC)**
- 2. German Medical Devices Operator Ordinance**
- 3. Recommendation of the Robert Koch-Institute
“Hygiene requirements for processing medical devices”**
- 4. prEN 15883-1 and 155883-2**

Cleaning of reusable medical devices is a basic requirement for the subsequent disinfection and sterilisation steps and thus makes an indispensable contribution to patient safety

Cleaning is understood as the removal of undesirable substances from the surface to a defined degree (optical cleanliness is the criterion used to judge this).

The most problems during cleaning causes fibrin load deposited on rough surfaces and on the jaw parts of instruments

Verifying the Cleaning Efficacy of Washer-Disinfectors

- **Measurement of the residual protein content**
- **Soil test**
- **Monitoring the washer-disinfector**

Disinfection in Washer-Disinfectors

- **Thermal disinfection for heat-resistant medical devices**
- **Chemical and combined (thermal and chemical) disinfection for heat-sensitive medical devices**

Conditions for Thermal Disinfection in Washer- Disinfectors

Instead of 93 °C/10 min

A. concept for thermal disinfection

The A₀ concept

”A” = the time equivalent in seconds at 80 °C which generates a certain disinfection action against microorganisms with a defined z value

z value = measurement (in °C) of the temperature relationship to the killing process which corresponds with D value

D value = the time required at a particular temperature to kill 90% microbial population

The A_o concept (PrEN ISO 15883-1)

A_o 60 = 80 °C/60 sec
90 °C/ 6 sec
70 °C/10 min

A_o 600 = 80 °C/10 min
90 °C/ 1 min
93 °C/30 sec

The A₀ concept

(PrEN ISO 15883-1)

A₀ 3000 = 80 °C/50 min
90 °C/ 5 min
93 °C/2,5 min

The A₀ value of 3000 is recommended for programmes used to process surgical instruments

Verifying the Disinfection Efficacy of Washer-Disinfectors

- **Chemical indicators**
- **Monitoring the washer-disinfector**

Lot # 1001



DES-CHECK

BGA - 10min 93°C

FOR THERMAL CHARACTERIZATION
AND THERMAL STABILITY

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**BLAU
BLUE**

Lot # 1002



DES-CHECK

BGA - 10min 93°C

FOR THERMAL CHARACTERIZATION
AND THERMAL STABILITY

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Monitoring the Washer-Disinfectors

- * **Cleaning**
- * **Disinfection**
- * **Drying**

Cleaning

Critical parameters to be monitoring

- Detergent quality
- Water quality
- Water pressure
- Water flowrate
- Water temperature
- Additives flowrate

Disinfection

Critical parameters to be monitoring

- **Water quality**
- **Water temperature**
- **Time for disinfection**

Drying

Critical parameters to be monitoring

- Air temperature
- Air flowrate