



Cleaning Verification

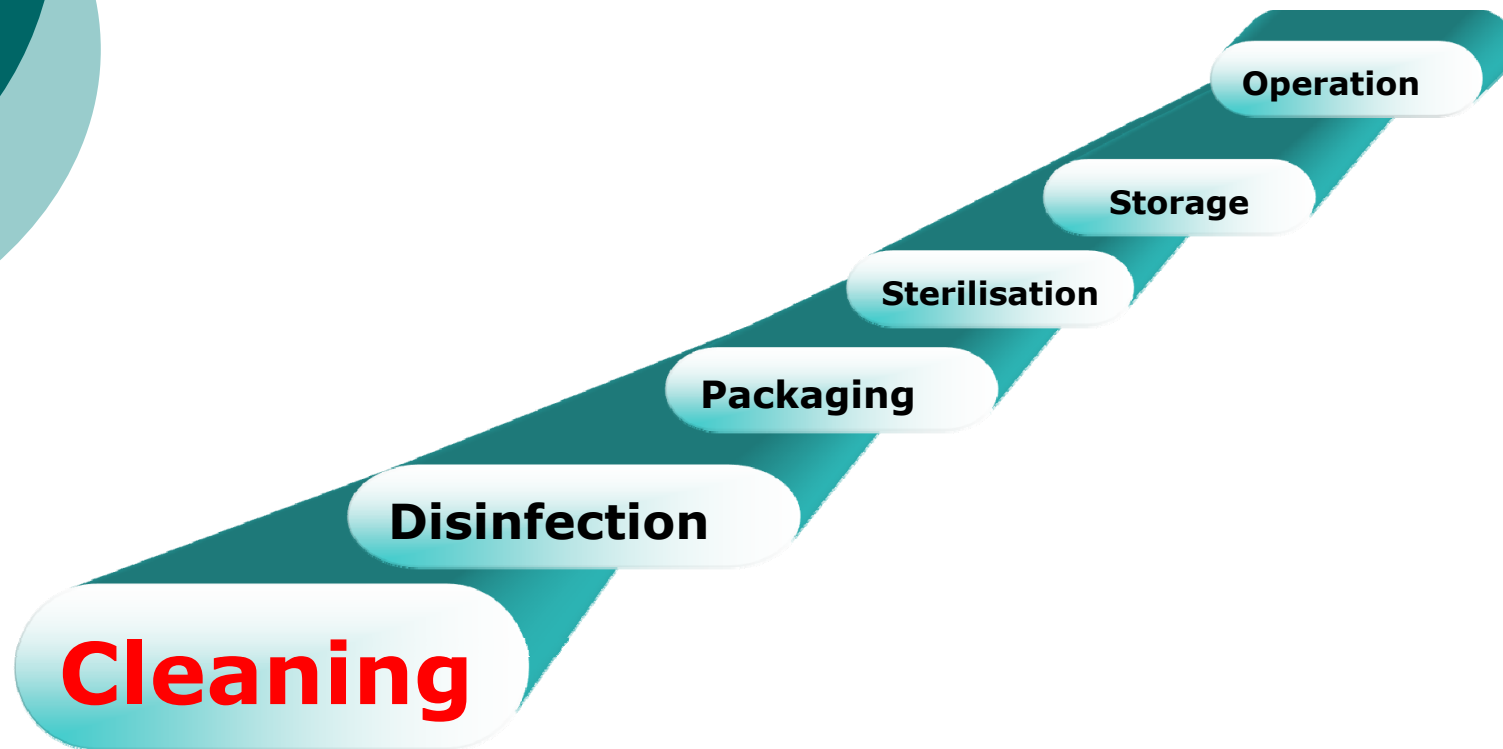
Importance of clean instruments and the requirements for residue testing methods



OVERVIEW

- **Importance of the Cleaning Process**
- **Cleaning Parameters**
- **Blood-Soil and Cleaning Problems**
- **EN ISO 15883**
- **Validation and Routine Monitoring**

Validation and Routine Monitoring of Washer Disinfectors





Cleaning Requirements

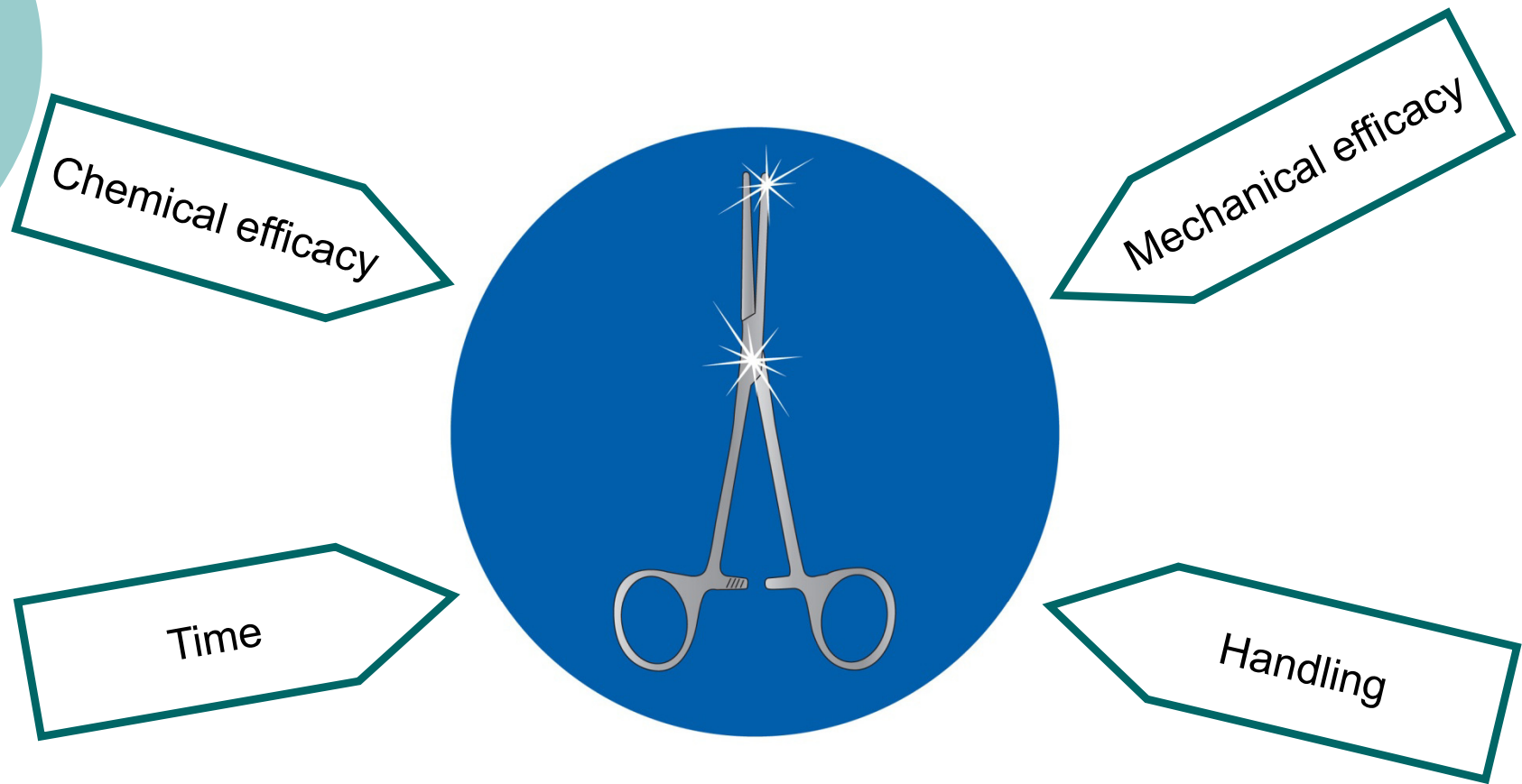
To protect the patient from:

- Infections
- Toxic reactions
- Allergic reactions
- Pyrogenic reactions

To protect the staff

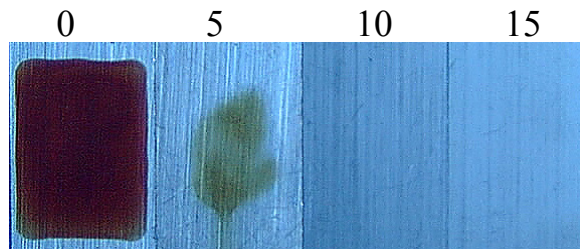
**INSTRUMENTS MUST NOT ONLY BE
STERILE BUT ALSO CLEAN!**

Critical Process Parameters

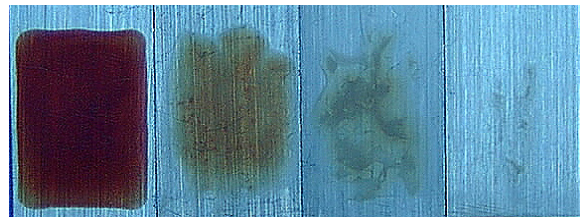
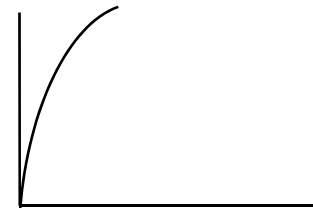


Chemical cleaning efficacy

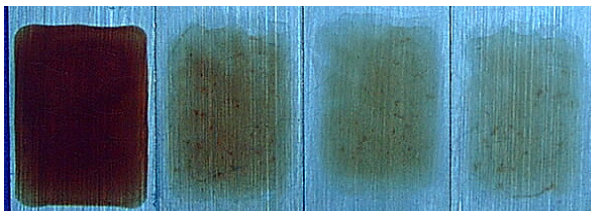
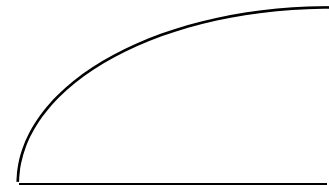
time in minutes



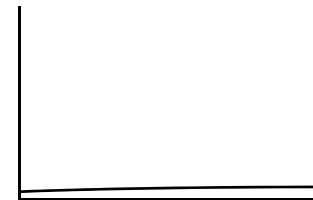
alkaline detergent
0,5% - 70°C



enzymatic detergent
1% - 45°C

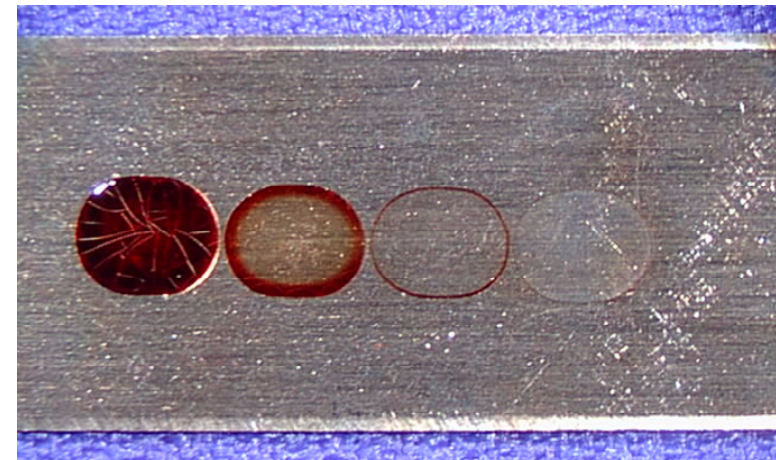
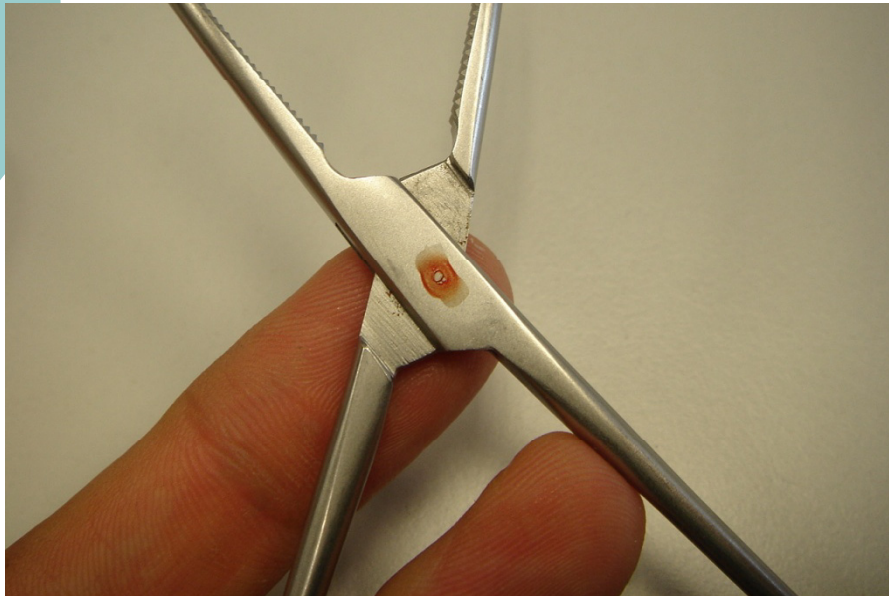


neutral detergent
1% - 45°C



Testing and validation of the cleaning process

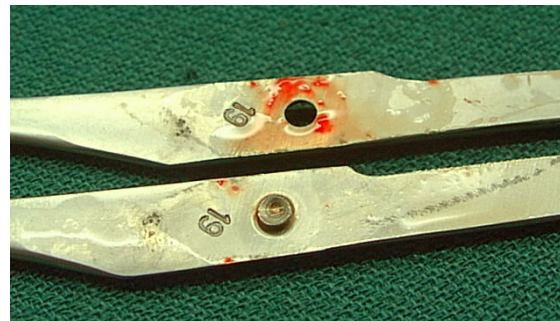
Visual Check



100 μ g 10 μ g 1 μ g 0.1 μ g

Validation and Routine Monitoring of Washer Disinfectors

Residue on instruments:
Characteristics of blood





Validation and Routine Monitoring of Washer Disinfectors

EN ISO 15883 for Washer Disinfectors

- Verification of cleaning efficacy is a key aspect of establishing satisfactory performance of a washer-disinfector



EN ISO15883-5

○ Test soils

- Austrian test-soil
- German test-soil
- Netherlands test-soil
- Swedish test-soil
- British test-soil
- American test-soil

○ Test methods

- OPA method
- Ninhydrin method
- BCA assay
- Peroxidase test
- Microbiological tests



○ Sensitivity

Detection of common and possible harmful residue
No interference with harmless substances

○ Detection limit

Safe detection of even small residue:
Surgical instruments must be completely clean!

○ Recovery

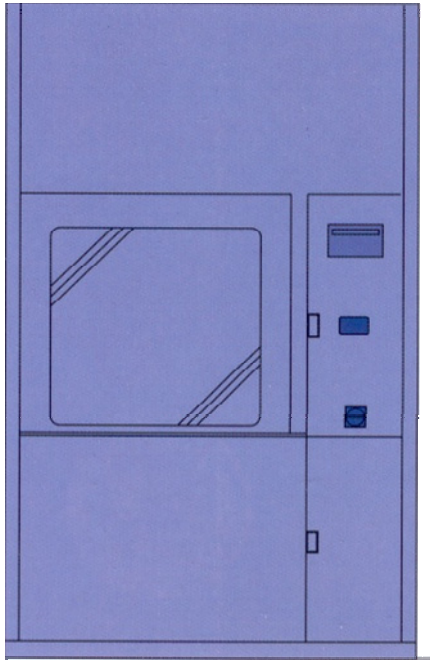
Detection of residue after a cleaning cycle
(denaturated and insoluble or chemically changed residue)

○ Handling

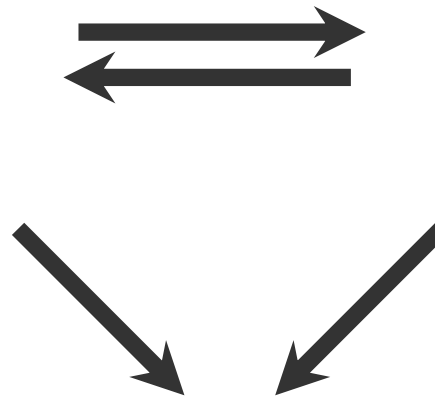
Easy and quick to use / non toxic

Interaction of practical use and testing

Cleaning process



Test method



Clean instruments



Thank you for the opportunity, it's
the first time I come to Brazil.
*It was a pleasure to speak at this
conference!*

Muito Obrigado!

Gracias!