



# Testing and Validation – Cr<sup>a</sup>sh, Br\*ea#k<sub>down</sub> and B@d Luck

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T. Miorini  
Institute for Applied Hygiene, Graz

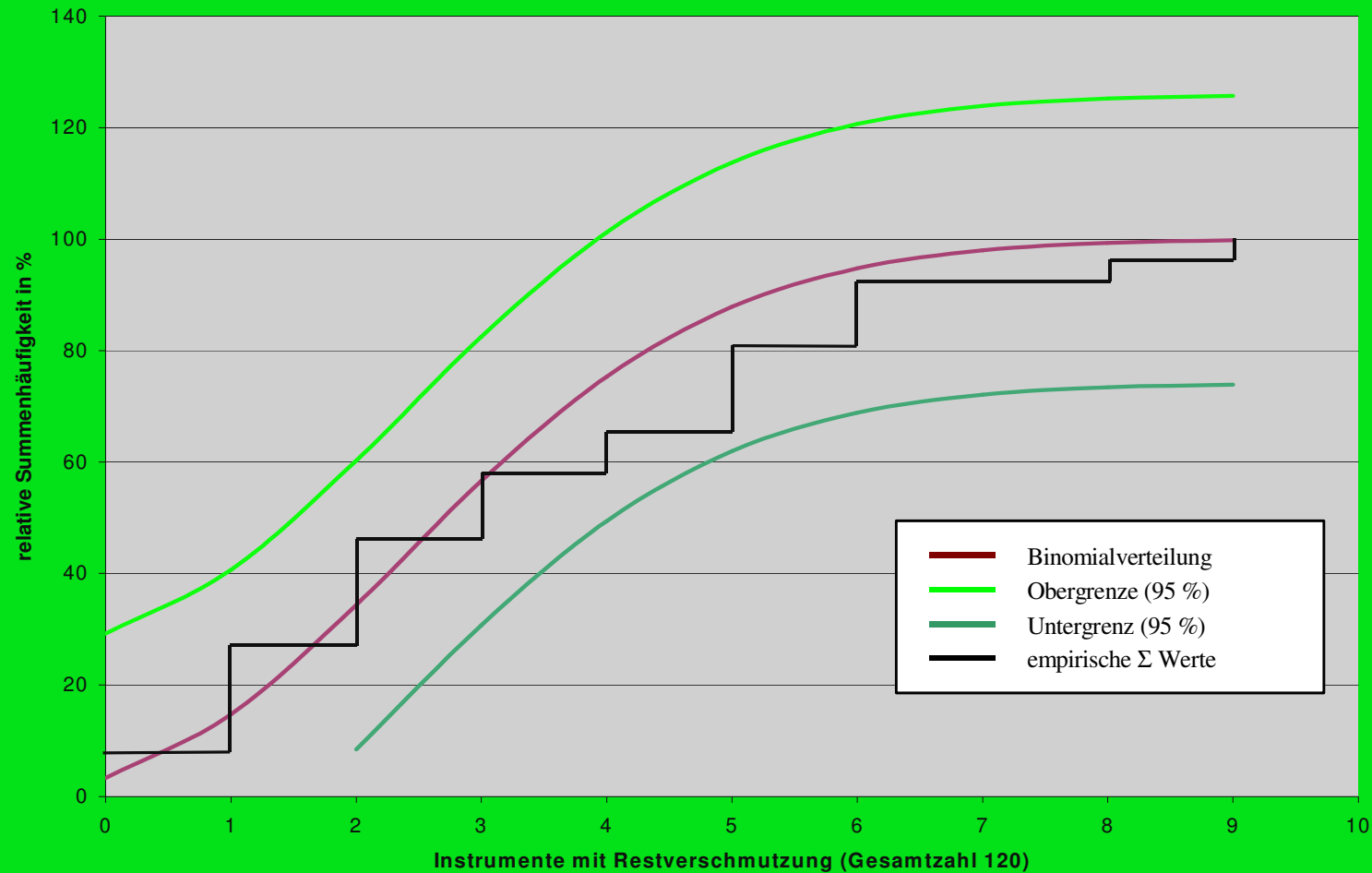


# Testing and Validation – Cr<sup>a</sup>sh, Br\*ea#k<sub>down</sub> and B@d Luck



- Institute for Applied Hygiene, Graz
- >10 Years of Experience with Testing of WDs for Medical Products
- New Austrian Test Methods (ISO/TS 15883-5) and ÖGSV-Guideline for Validation of Cleaning-Disinfection processes (2005)
- About 450 WDs for surgical instruments and about 100 WDs for flexible Endoscopes were tested in the last 5 years with the new method

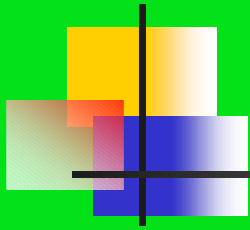
# Reproducibility of the Test Method



# Testing and Validation – Cr<sup>a</sup>sh, Br\*ea#k<sub>down</sub> and B@d Luck



- Type tests, Operational-, Process-  
Qualification
- Process testing
  - Testing of Cleaners in Combination with  
established WDs and Programmes
- Partly severe faults were detected
  - Technical faults
  - Operating errors
  - Problems with Cleaners
- Whatever can happen, happens  
(Shit happens)



# Planning?

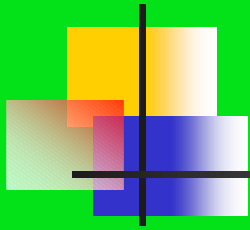


# WDs for Surgical Instruments

## EN ISO 15883-2



- Different Cleaning efficacy with WDs of the same type, the same chemistry and the same programmes
  - Load carriers? „Monday device“? Amount of water?
- Weak point „Water“
  - Water level not reproducible (up to 15 l of difference due to varying water pressure)
  - Diameter of water tubing too small
  - Cold- and Hot water tubes interchanged
  - Deionised water mixed with cold water (Capacity problems)



# Technical Faults



- Water pump running backwards
  - Interchanged poles
- Water connection of load carrier
  - Positioning of coupling (interlocks)
  - Difference up to 1 cm with same types
  - After routine use up to 2 cm distance
- Connectors for anesthetic equipment and MIS-instruments
  - Poor definitions, what to connect where
  - No (poor) fixation
  - No (poor) cleaning at contact spots



# Water connection





# Position fixing

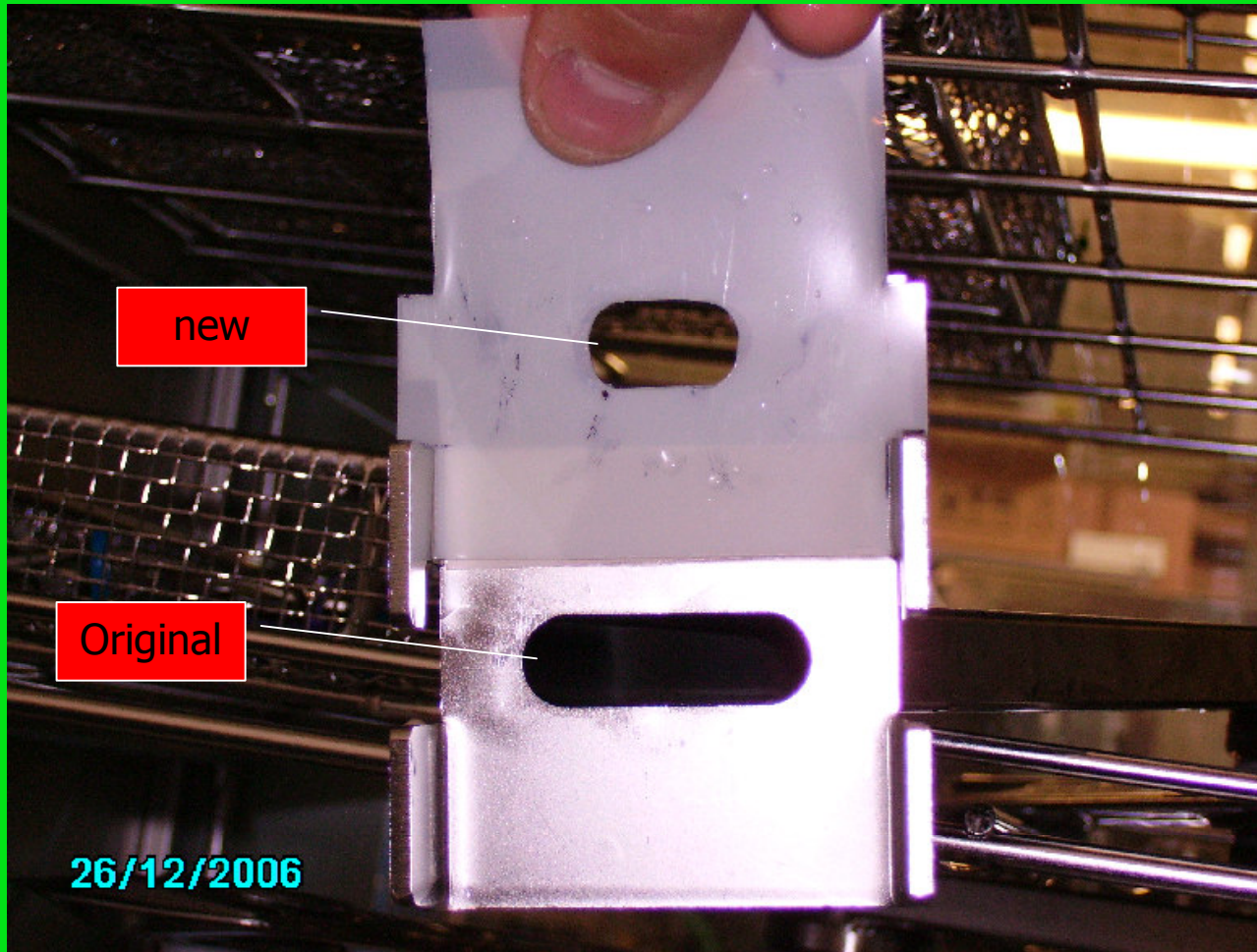


# Load Carriers



- Washing arms
  - Speed
    - too fast: Washing of chamber walls
      - maybe at one level only
      - better efficacy with mild alkaline cleaner!? (foam)
    - too slow: too less mechanical energy
  - Wrong washing arms (changing between load carriers)
  - Drilling or closing of holes on site

# Reduction of Diameter



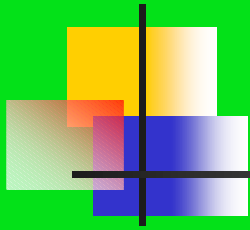


# „Amputated Wings”



# Sealed Nozzles





# Dosing System



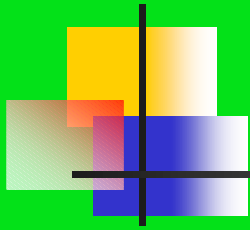
- Wrong dosing pumps activated
  - e.g. Neutralizer instead of cleaner
- Dosing pump adjusted wrong
  - e.g. Rinse agent 1,0 instead of 0,1 %
- Negative dosing (!?)
  - Dosing pump turning backwards
- Dosing temperature too low:
  - Neutral cleaners - foam



# „Foam beaker“







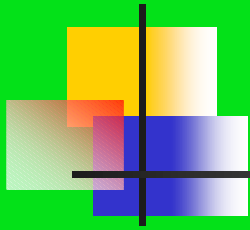
# Operating Errors



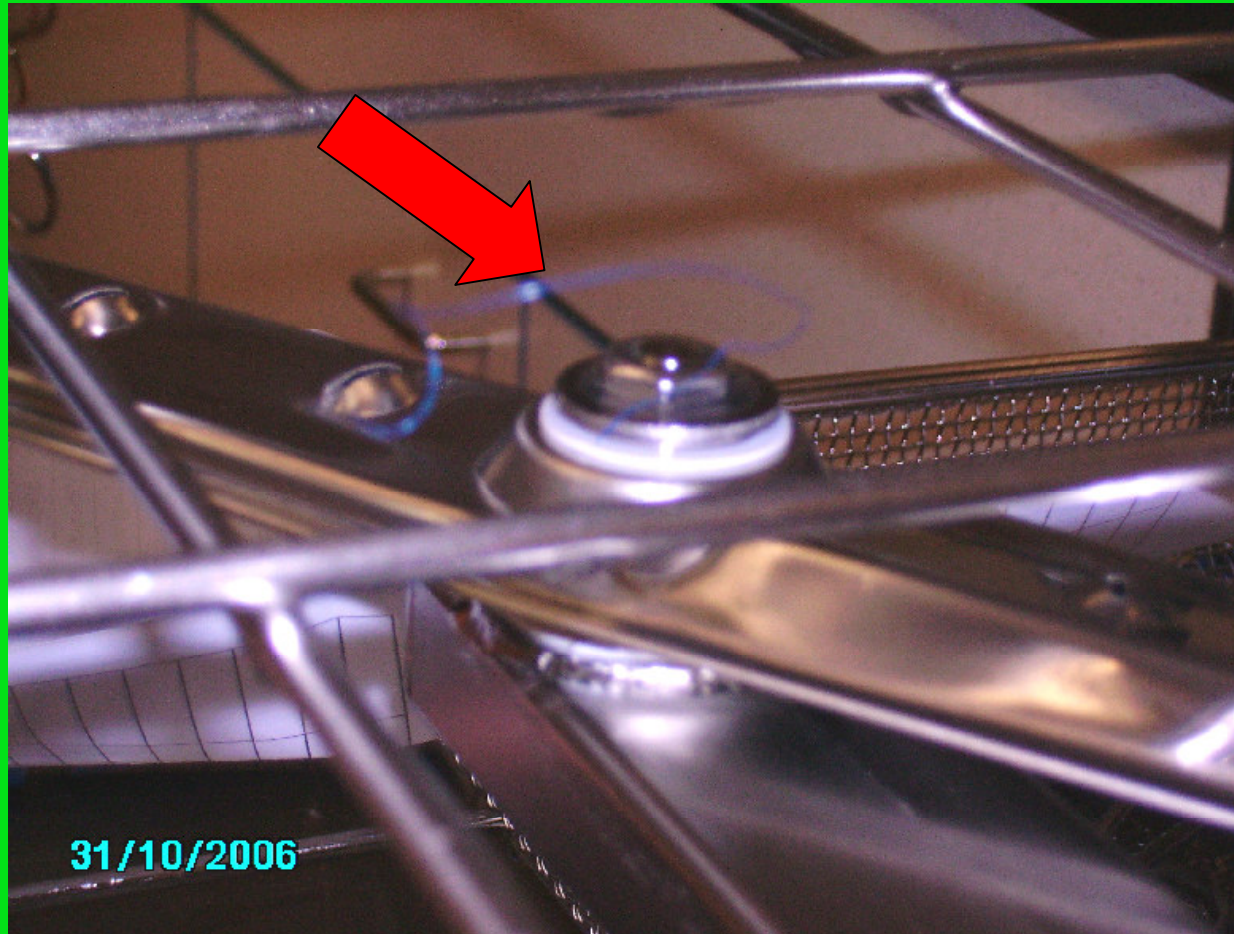
- Obstructed nozzles or sieves
  - Washing arms with needles, threads, chemical indicators, pieces of glass etc.
  - Linting of OT shoes
    - Recommendation: specific machines
- Inadequate loading of MIS-load carriers
- Unused connectors on MIS-load carriers
- Poor maintenance and care

# Sieves



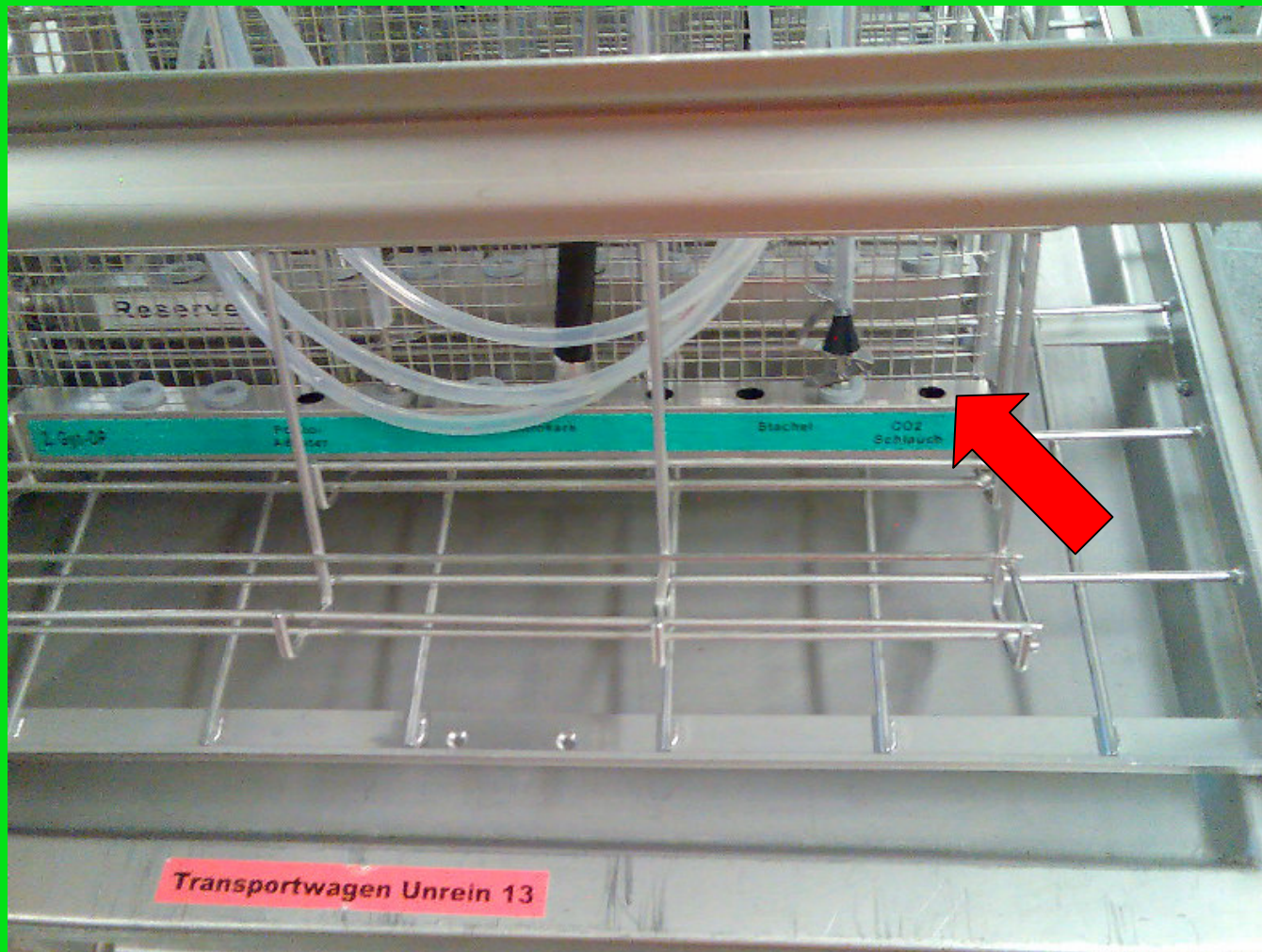


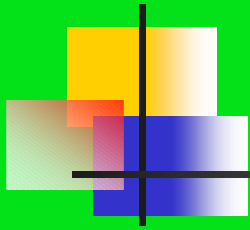
# Washing Arms





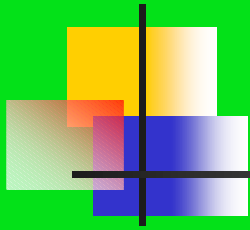
# Unused Connectors





# Maintenance, Care?





# Process Qualification



- MIS-Instruments
  - Severe cleaning faults  
( $> 100 \mu\text{g}/\text{Instrument}$ )
    - Old residual soiling?
      - basic cleaning!
    - Routine controls!



# WDs for human waste containers (EN ISO 15883-3)



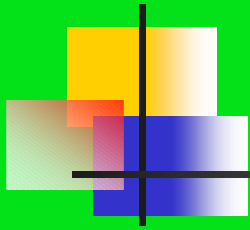
- Poor cleaning and disinfection of urine bottles
- Incompatible racks for human waste containers
- Recontamination with water borne germs
  - first of all *Pseudomonas aeruginosa* due to back rinsing with cold water



# WDs for Endoscopes (prEN ISO 15883-4)



- Cleaning problems: Channel, Chamber, Outer surfaces
- „Short programmes“ without intermediate rinsing between cleaning and disinfection
  - Residual soiling in dummies during testing according to ISO/TS 15883-5
  - Federal secretary for Safety in health care: each programme in WDs for flexible Endoscopes must have an intermediate rinsing between cleaning and disinfection stage

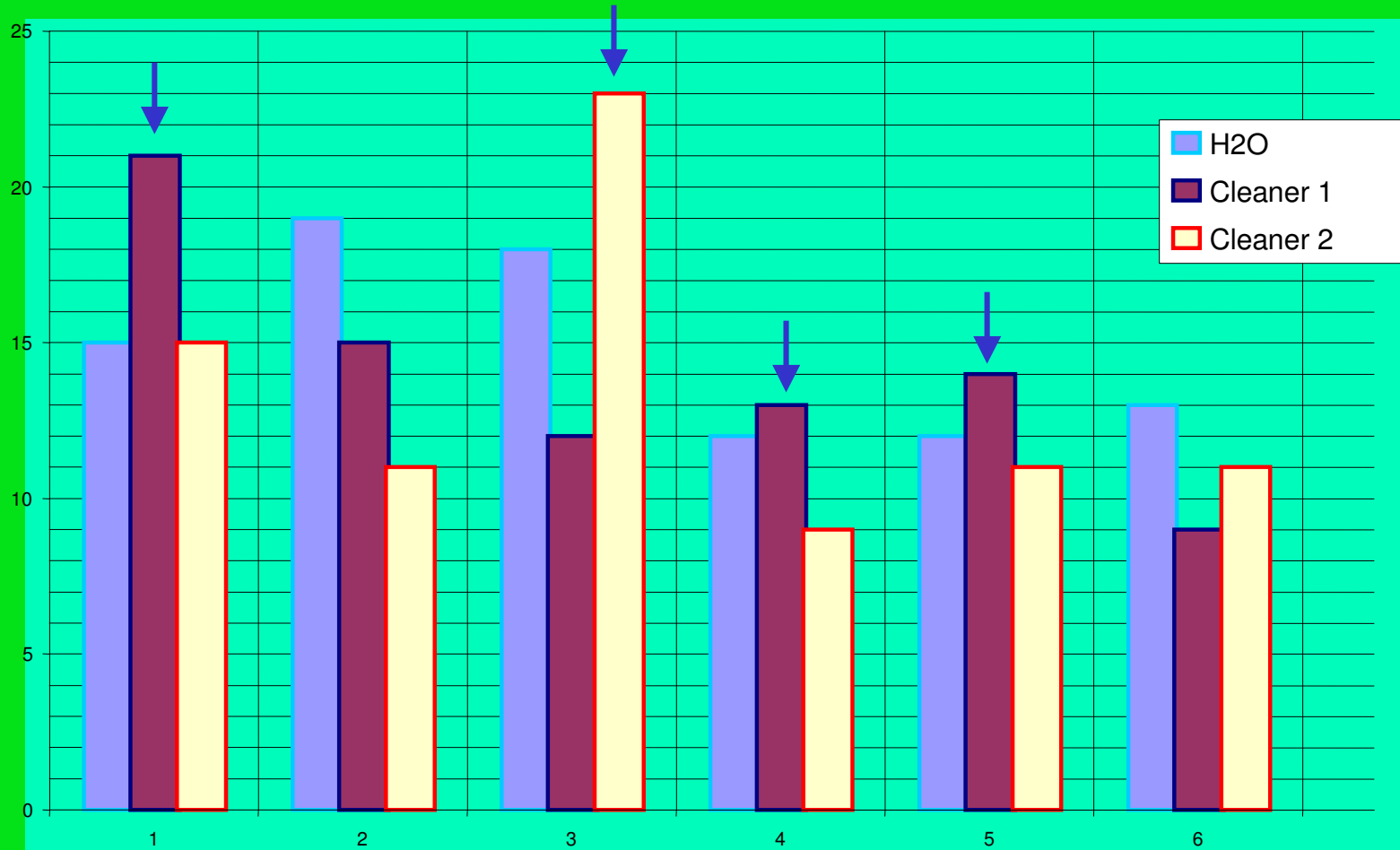


# Problems with Cleaners



- Poor cleaning efficacy
  - Cleaners, which do not clean better than pure water
- Foam formation
  - Difference between single batches
- pH-Value (Specification at 20 °C/ deionised water)
  - higher temperature: pH ↓
  - Softened water: pH ↓

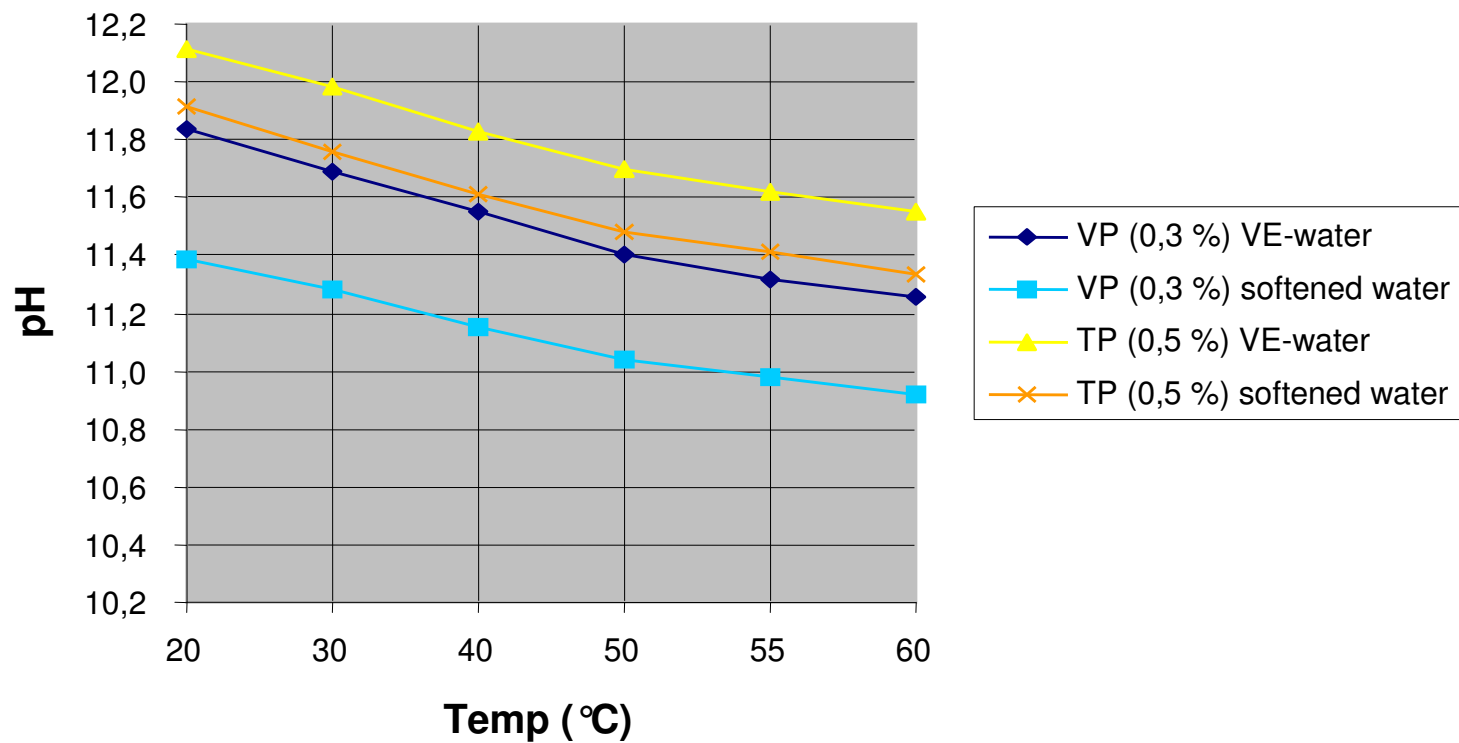
# Water or Cleaner?



# pH-Value



pH Comparison

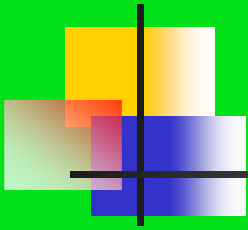




# Summary



- Type tests, Operational Qualifications, Process Qualifications and Validations are reasonable!
- Due to the new testing method technical faults and operating errors could be detected, which were not obvious during routine use.
- By means of adequate optimising measurements nearly all respective problems could be solved.



**Thank you for  
your Attention!!!**

