

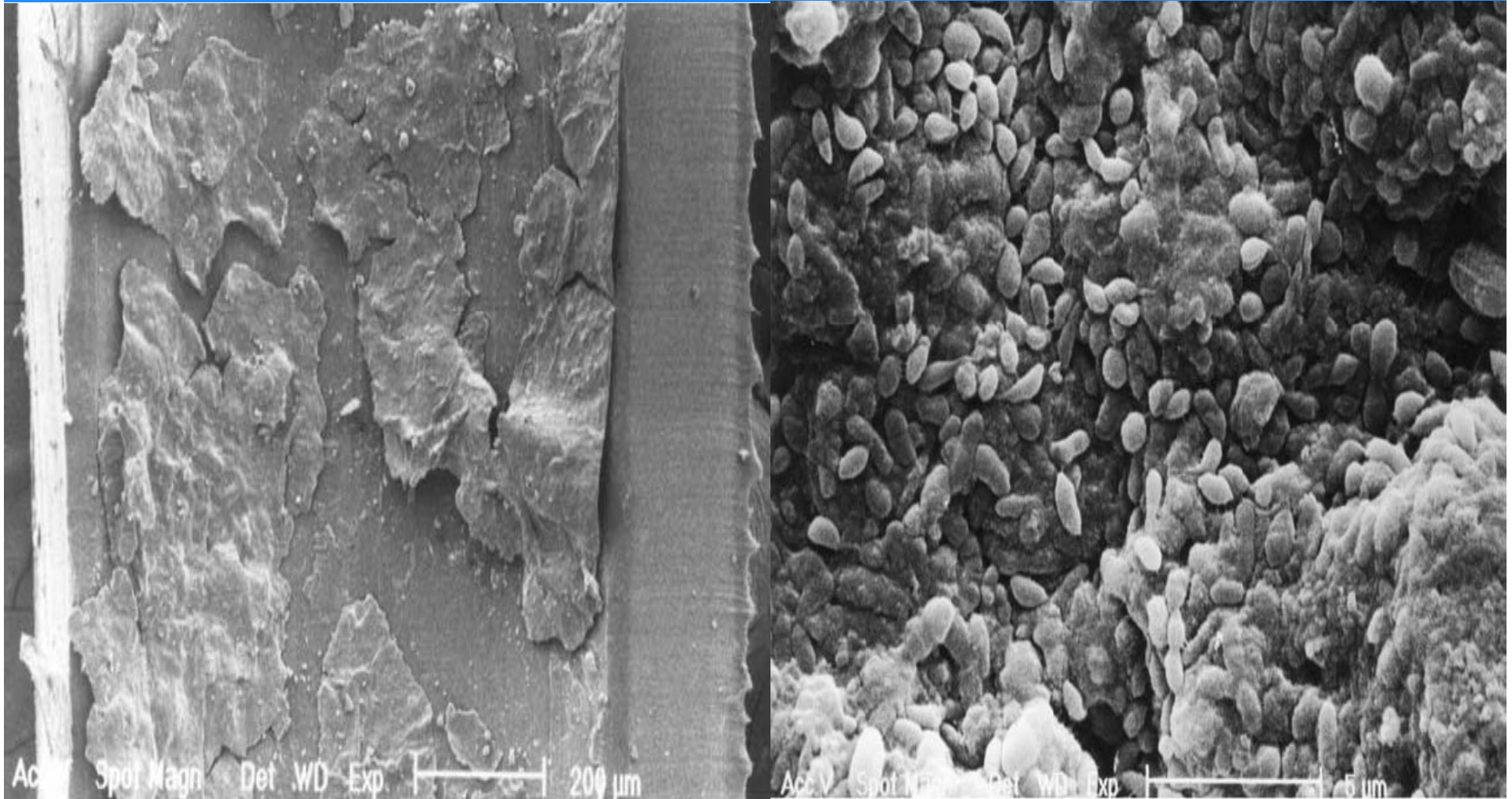
# Parameters exerting Influence on Cleaning of flexible Endoscopes

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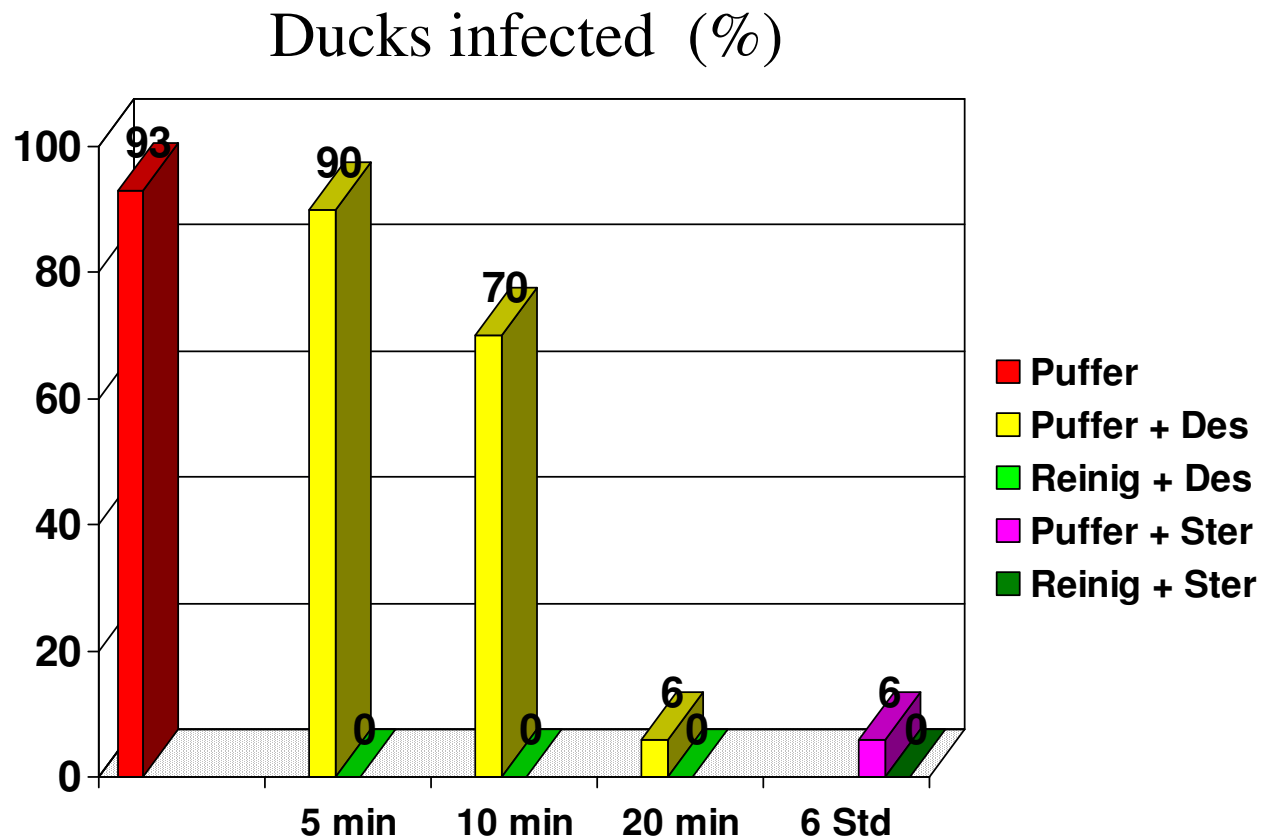
# Is biofilm accumulation on endoscope tubing a contributor to the failure of cleaning and decontamination?

Pajkos, Vickery, Cossart; J Hosp Infect (2004)



# Reprocessing of angioscopes after contamination with duck- HBV

Chaufour et al , J Vasc Surg (1999)



**Cleaning:**  
Detergent + Brush  
**Disinfection:**  
GDA, 2%ig  
**Sterilisation:**  
Ethylenoxid, 6h

# prEN ISO 15883-4

As at: 2007-04-16

- 3 Definitionen

- 3.5

- Microbial inactivation factor**

- measured change in microbial population,  
expressed as  $\log_{10}$ , caused by the lethal effect  
of the germicide

# prEN ISO 15883-4

## As at: 2007-04-16

### Efficacy of the disinfectant

- $\geq \log_{10} 6$  inactivation of vegetative bacteria including yeasts and yeast-like fungi
- $\geq \log_{10} 5$  inactivation of mycobacteria
- $\geq \log_{10} 4$  inactivation of fungal spores and viruses
- $\geq \log_{10} 6$  reduction of bacterial spores within 5 h exposure

# Max. bioburden after patient use

Type	cfu/ endoscope	air	water	instrum.	suction
		-channel			
Gastroscope		5.2	3.5	7.3	
Coloscope	9.5	7.8	7.0	9.0	10.2
Bronchoscope	7.3				
Duodenoscope	7.5				

Chu et al, AJIC (1997)

Vesley et al, Gastroenterology Nursing (1999)

Alfa et al, Am J Infect Control 1999

# prEN ISO 15883-4

As at: 2007-04-16

- 3 Definitionen

- 3.6

**Microbial reduction factor**  
**measured change in microbial population,**  
**expressed as  $\log_{10}$ , caused by the**  
**combination microbial inactivation factor**  
**and the physical removal of**  
**microorganisms**

# Alfa, Degagne, Olson

Am J Infect Control 1999

Flexible endoscopes after use ( $\log_{10}$  cfu)

<u>Manual cleaning</u>	<u>before</u>	<u>after</u>
• Bronchoscopes	4.0 - 7.3	3.8 - 5.7
• Duodenoscopes	0 - 7.5	3.7 - 5.3
• Colonoscopes	5.7 - 9.5	3.2 - 4.6



# Nelson et al

## Gastrointest Endosc 2003





### Consensus Paper

- 11 societies (u. a. SHEA, APIC)

**Change of the enzymatic cleaner  
after each Endoscope**

# Surface fixation of dried blood by glutaraldehyde and peracetic acid

Kampf, Bloß, Martiny, J Hosp Infect (2004)

Type of active agent	Photograph	Stage of process
Peracetic acid I		After disinfection
		After cleaning
Glutaraldehyde I		After disinfection
		After cleaning
QAC		After disinfection
		After cleaning
QAC + Amines		After disinfection
		After cleaning

# Surface fixation of dried blood by glutaraldehyde and peracetic acid

Kampf, Bloß, Martiny, J Hosp Infect (2004)

Active agent	No.	Rate of blood removal by exposure to disinfectant
Peracetic acid	1	8.1%
Peracetic acid	2	39.0%
Peracetic acid	3	59.0%
Peracetic acid	4	56.6%
Glutaraldehyde	5	21.7%
Glutaraldehyde	6	23.6%
Glutaraldehyde	7	8.1%
QAC	8	88.5%
QAC	9	88.2%
QAC + Amine	10	35.5%
Phenole	11	90.3%
Tenside	12	89.0%

Mean weight of blood soil on metal carriers after exposure to one of 12 disinfectants ('soiled and disinfected'); means of eight parallel experiments

# DIN ISO/TS 15883-5

## Test soils for flexible endoscopes

- AT Annex Nigrosin, wheat flour, hens egg, *E. faecium*
- DE Annex I Blood, *E. faecium*
- DE Annex J Tetramethylbenzidine, hydrogenperoxide solution, bovine haemoglobin
- FR Annex F Biofilm formed by *Pseudomonas aeruginosa*
- NL Annex L Bovine serum albumin, porcine mucin, bovin thrombin, bovin fibrinogen
- UK Annex R Glycerol, dehydrated hog mucin, horse serum, unbleached plain flour, aqueous safranin solution, water
- US Annex S Protein/organic soil (user preference), *B. atrophaeus* endospores

# DIN ISO/TS 15883-5

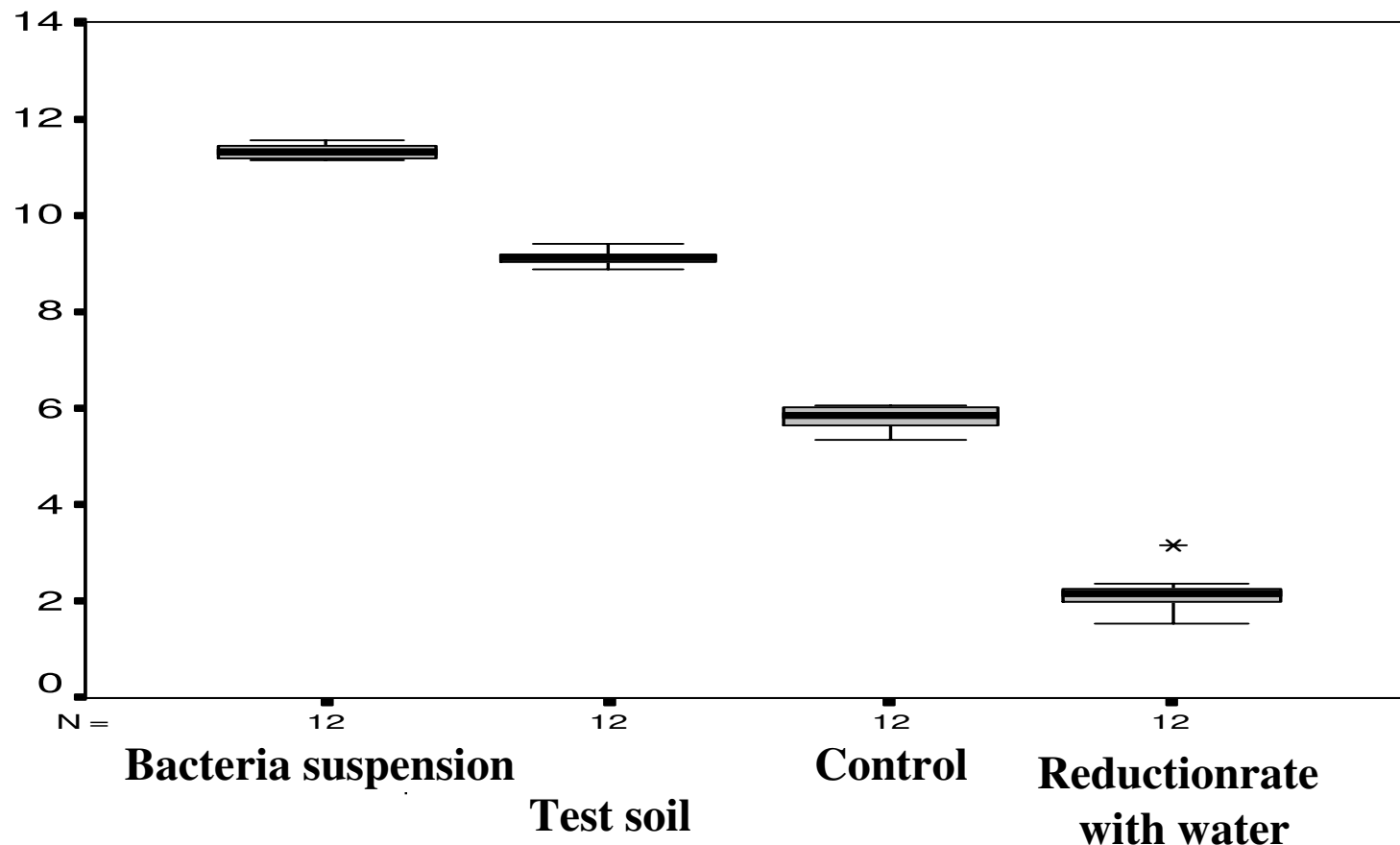
## Washer-Disinfectors

### Annex I

- *E. faecium*  $\geq 1 \times 10^{11}$  cfu/ml
- PTFE tubes 2 m, Ø 2 mm (transparent)
- Test soil
  - Sheeps blood, 0.2 % Heparin      9.50 ml
  - Susp. of test organism      0.35 ml
  - Protamin 1000      0.15 ml
- LAM
  - Liquefied-(Kanamycin Äsculin Azid) -**A**gar-**M**ethod

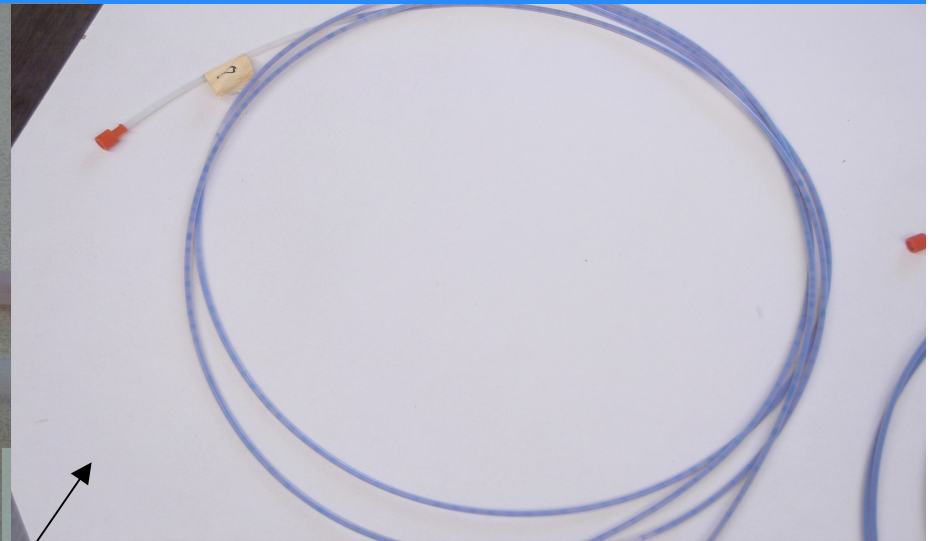
# Intra-laboratory reproducibility of the German test method

Zühlsdorf, Floss, Martiny, J Hosp Infect (2005)

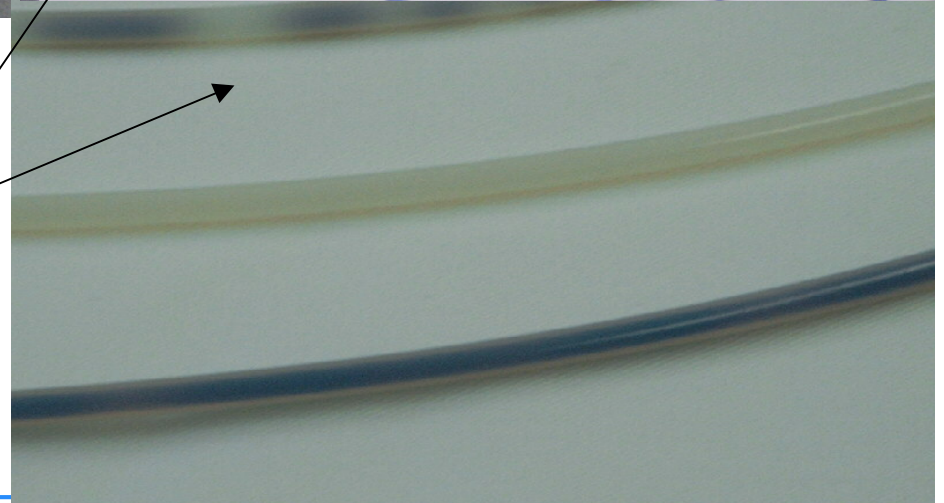


# German test method Test pieces

Test pieces cleaned



Liquid-Agar-Method  
LAM



# The importance of cleaning for the overall results of processing endoscopes

Martiny et al, J Hosp Infect (2004)

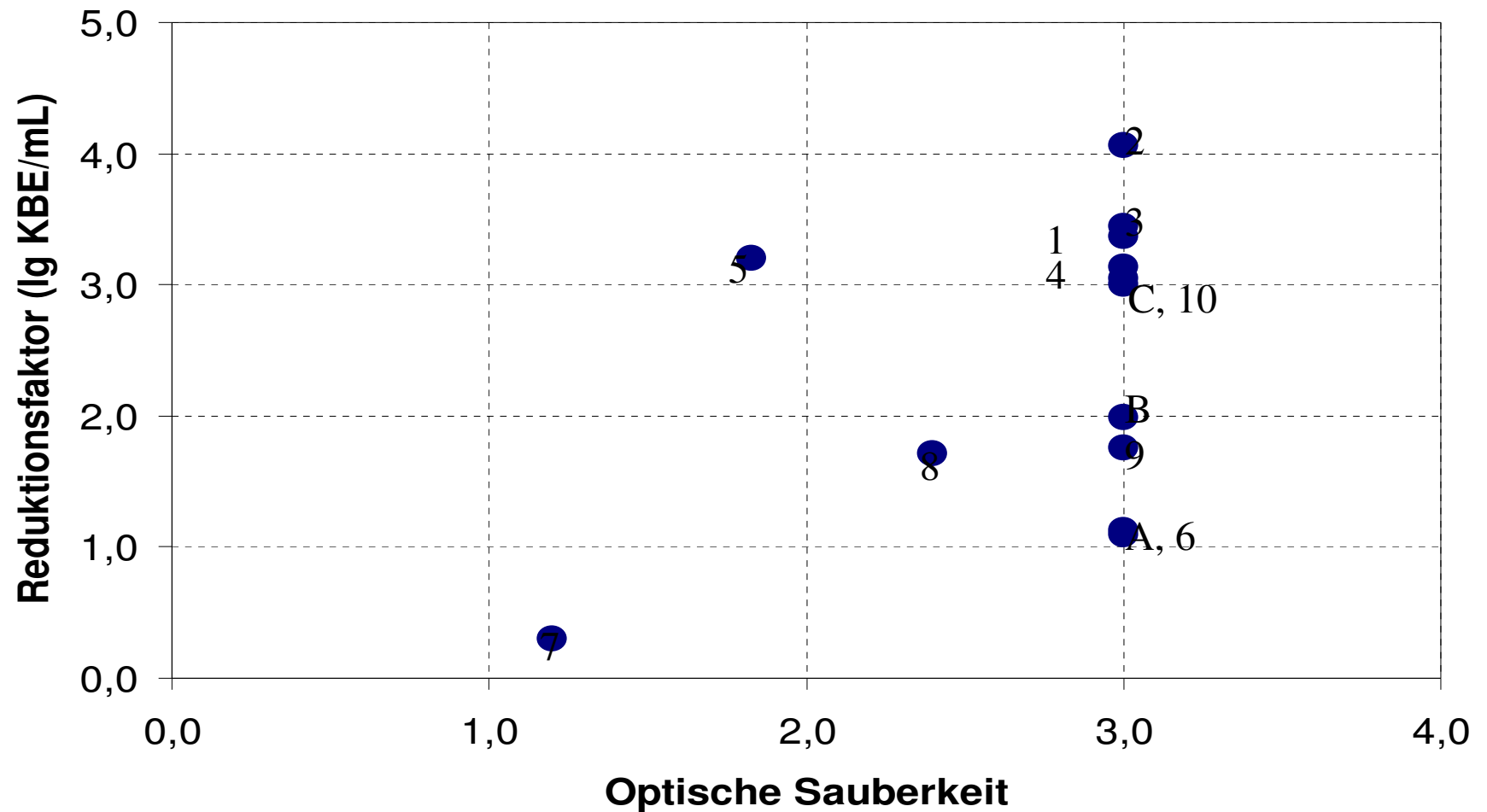
Log<sub>10</sub> Reduction (mean) ( n = 28)

- |   |     |
|---|-----|
| • A: Cleaning with water                                  | 1.1 |
| • B: Pre-rinsing and cleaning with water                  | 2.0 |
| • C: Pre-rinsing, cleaning with water and interim rinsing | 3.0 |



# Efficacy of ten different cleaning processes in a WD for flexible endoscopes

Zühlsdorf, Floss, Martiny, J Hosp Infect 56:305-311 (2004)



# Comparison of the cleaning efficacy and the cleaning and disinfecting efficacy of four washer-disinfectors for flexible endoscopes

Kircheis and Martiny, J Hosp Infect (accepted)

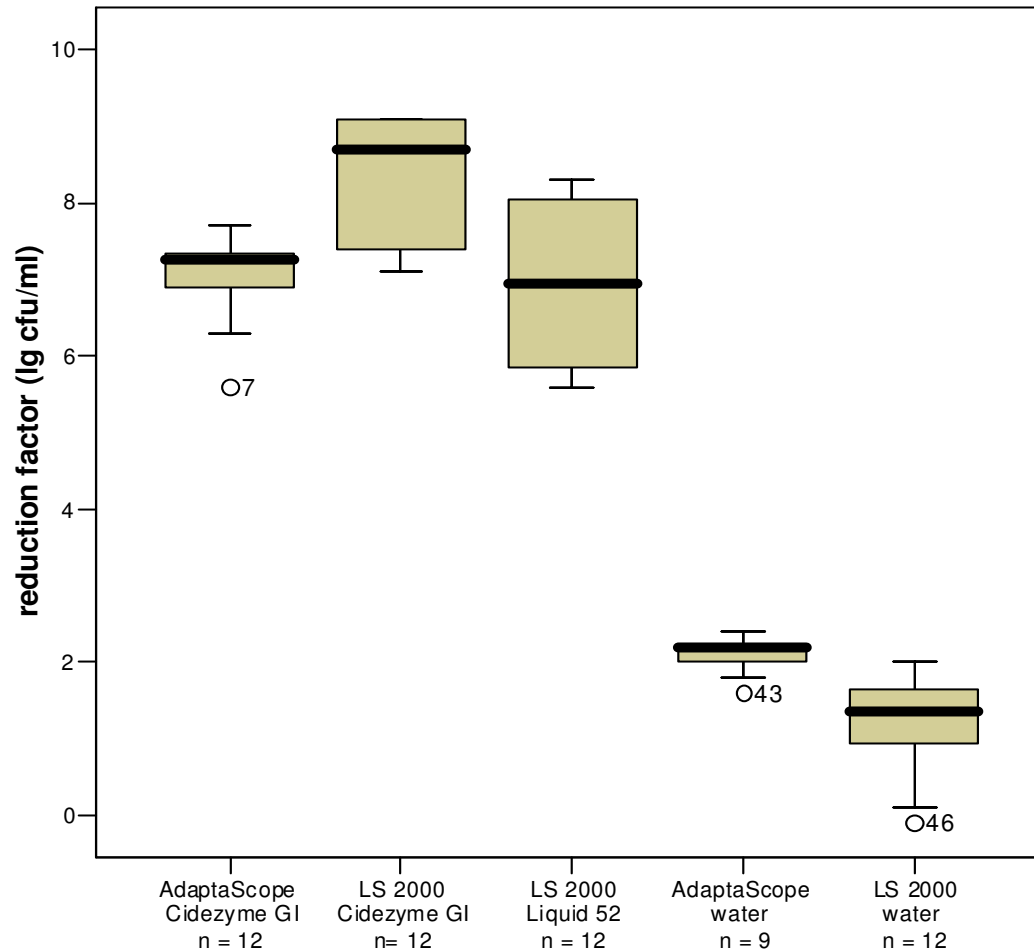


Figure 1: Medians of reduction factors (lg cfu) of the cleaning processes in the AdaptaScope (Cidezyme GI and water ) and in the LS 2000 (Cidezyme GI , Liquid 52, and water ) (n = 57)

# Cheetham, Berentsveig

## Australien Infection control 7 (2002)

- Cleaning efficacy and enzyme activity of 18 cleaner
  - *P. aeruginosa* - Biofilm
  - Edinburgh soil
  - Protease - activity
  - Amylase - activity

# Cheetham, Berentsveig

## Australien Infection Control 7 (2002)

### Enzyme activity

Cleaner	Manufact.	Protease		Amylase	
		fresh	old 14 d, 40°C	fresh	old 14 d, 40°C
3M Rapid Auto	3M	0.38	0.38	13,625	13,145
Arbest BF	Arbos	0.21	0.19	131	0
Sterizime	Maruishi	0.20	0.19	825	0
Endofresh S	Olympus	0.35	0.16	193	0
Endokleen	Kendall	0.10	0.07	2,843	2,725
Endozyme AW plus	Ruhof	0.00	0.00	14	0

# The importance of cleaning for the overall results of processing endoscopes

Martiny et al, J Hosp Infect (2004)

Log<sub>10</sub> Reduction (mean)  
(n = 36)

- Cleaning only
  - **Cleaner A** > 5.0
  - **Cleaner B** > 5.8
- Disinfecting only
  - **Disinfectant A** > 8.7
  - **Disinfectant B** > 9.6
- Cleaning and Disinfecting
  - **Cleaner A + Disinfectant A** > 8.7
  - **Cleaner B + Disinfectant B** > 4.8 - < 5.8

# Summary

- Important parameter affecting cleaning
  - Level of burden
  - Cleaning
    - Efficacy of cleaning
      - Manually
      - Automatically
    - Efficacy of the cleaner

# What we still need

“Cleaning assurance level”

“Disinfection assurance level”  
respec.

“Process assurance level”