



Comparative Study upon Cleaning Indicators for Washer-Disinfectors for flexible Endoscopes

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Rationale for the study

- The harmonization of test methods for WDs for flexible endoscopes is „**hot item**“ in Austria
- A lot of **problems** with WD-Es arose in the past few years, some could have been **avoided**



Content of the study

- 3 cleaning Indicators
- 4 enzymatic cleaners
- 3 alkaline detergents
- 5 and 10 minutes cleaning time
- 45 (35) and 58 °C
- Reference: german test method given in part 5 of ISO/TS 15883



Indicators tested

–Tosi FlexiCheck (Pereg)



–Simicon RI (Simicon)



–WashCheck H (Dr. Früh)





Cleaners

Enzymatic

Cleaners (0,5%)

- Olympus **C**leaner
- Olympus **E**ndo **D**et
- Thermosept **ER**
(Schülke+)
- **P**rolystica **E**nzymatic
Cleaner (Steris)
(0,05%)

Alkaline

Detergents (0,5%)

- Neodisher
Medi**C**lean **F**orte
(Dr. Weigert)
- **A**lka**C**lean **F**orte
(Schülke+)
- **P**rolystica **A**lkaline
Detergent
(Steris) (0,05%)



Questions indicators

- Can cleaning indicators for WD-Es indicate **failures** in the cleaning phase?
- Are the results somehow **comparable**?
- Are they more or less challenging than the **german method** which uses blood?



Questions cleaners

- Which cleaners are most **effective**?
- Are enzymatic cleaners and alkaline detergents **comparable**?
- Influence of the cleaning **temperature** and **time**?

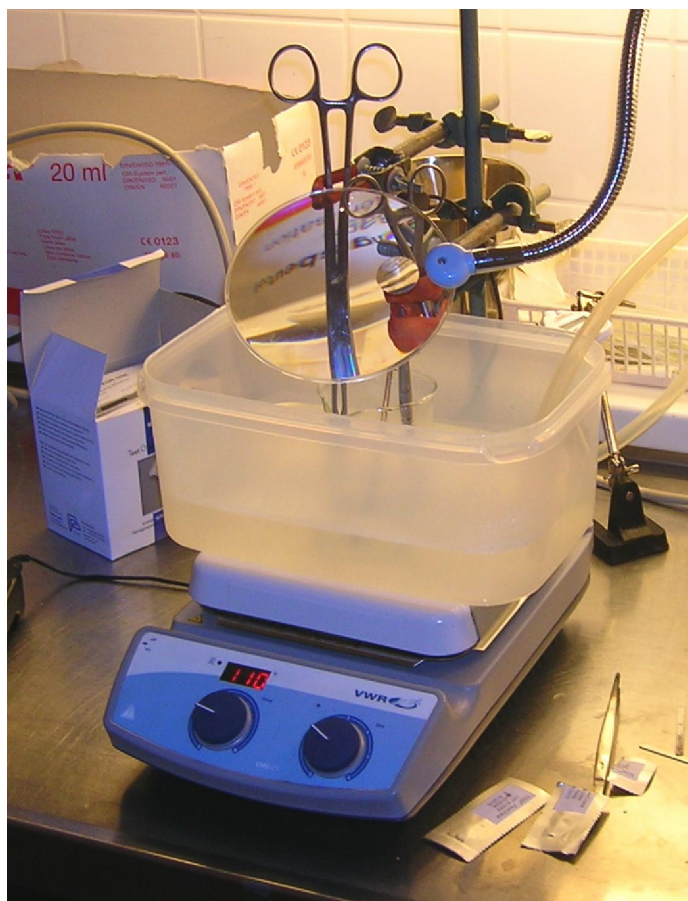


Test conditions

- The tests were carried out in two different test rigs
 - Immersion test rig
 - Flow test rig
- The results of the immersion test rig are not shown



Immersion-Test-Rig





Flow-Test-Rig



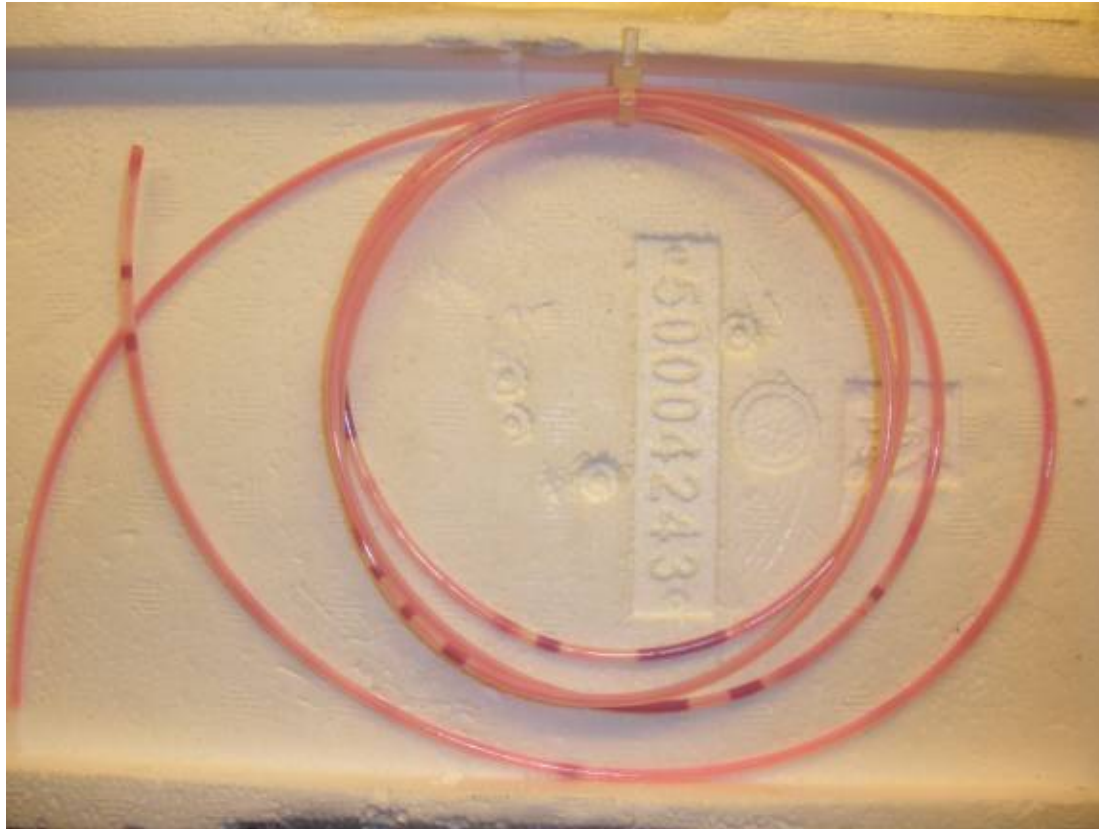


Testing chamber for indicators





Reference method



Teflon tube soiled with **reactivated blood**



Evaluation scheme

0	No visible residuals
1	Weak residuals visible
2	Heavy residuals visible
3	Test soil partly removed
4	Test soil completely preserved



Results Water 45 °C / 5 min

Cleaner	FlexiCheck	Simicon RI	WashCheck	Blood VR	Mean
HW	4	4	4	4	4,0
SW	2	4	4	4	3,5
AD	2	3	4	4	3,3
Mean	2,6	3,6	4,0	4,0	3,6

HW: Hard Water, SW: Softened Water, AD: Aqua deionisata

Conclusion: 5 minutes water shows very bad results



Results Enzymatic Cleaners 45 °C / 5 min

Cleaner	FlexiCheck	Simicon RI	WashCheck	Blood VR	Mean
OC	2	4	4	4	3,5
OED	2	4	4	4	3,5
ER	2	4	4	3	3,3
PEC	1	4	3	0	2,0
Mean	1,7	4,0	3,7	2,7	3,1

OC: Olympus Cleaner, OED: Olympus Endo Det, ER: Thermosept ER,
PEC: Prolystica Enzymatic Cleaner

Conclusion: 5 minutes of enzymatic cleaning is still not sufficient



Results Alkaline Detergents 45 °C / 5 min

Cleaner	FlexiCheck	Simicon RI	WashCheck	Blood VR	Mean
MCF	1	3	2	0	1,5
ACF	1	3	3	3	2,5
PAD	0	2	4	1	1,8
Mean	0,7	2,7	3,0	1,3	1,9

MCF: Neodisher Mediclean forte, ACF: Alkaclean forte, PAD: Prolystika Alkaline Detergent

Conclusion: 5 minutes „alkaline“ the results get better



Results Enzymatic Cleaners 45 °C / 10 min

Cleaner	FlexiCheck	Simicon RI	WashCheck	Blood VR	Mean
OC	2	3	4	0	2,3
OED	2	3	4	4	3,3
ER	2	3	4	1	2,5
PEC	0	3	1	0	1,0
Mean	1,5	3	3,2	1,2	2,3

OC: Olympus Cleaner, OED: Olympus Enzymatic Detergent, ER Thermosept ER,
PEC: Prolystica Enzymatic Cleaner

Conclusion: 10 min „enzymatic“ the results get better



Results Alkaline Detergents 45 °C / 10 min

Cleaner	FlexiCheck	Simicon RI	WashCheck	Blood VR	Mean
MCF	0	0	0	0	0,0
ACF	1	2	3	2	2,0
PAD	0	0	4	0	1,0
Mean	0,3	0,7	2,3	0,7	1,0

MCF: Neodisher Mediclean forte, ACF: Alkaclean forte, PAD: Prolystika Alkaline Detergent

Conclusion: 10 min. „alkaline“ show the best results



Results Alkaline Detergents 58 °C / 5 min

Cleaner	FlexiCheck	Simicon RI	WashCheck	Blood VR	Mean
MCF	2	3	1	0	1,5
ACF	2	3	2	4	2,8
PAD	2	4	4	3	3,3
Mean	2,0	3,3	2,3	2,3	2,5

MCF: Neodisher Mediclean forte, ACF: Alkaclean forte, PAD: Prolystika Alkaline Detergent

Conclusion: higher temperatures do not improve efficacy



Results Alkaline Detergents 58 °C / 10 min

Cleaner	FlexiCheck	Simicon RI	WashCheck	Blood VR	Mean
MCF	1	1	0	0	0,5
ACF	1	2	2	1	1,5
PAD	2	1	3	4	2,5
Mean	1,3	1,3	1,7	1,7	1,5

MCF: Neodisher Mediclean forte, ACF: Alkaclean forte, PAD: Prolystika Alkaline Detergent

Conclusion: the results get better but do not reach the ones at 45 °C



Summary indicators

- **Capability of indicating failure in the cleaning phase ?**
 - YES

- **Are the results somehow comparable?**
 - To a certain extent



Summary indicators

- Are they more or less challenging than the german blood method?
 - Flexicheck: less challenging
 - Simicon RI: more challenging
 - WashCheck H: more challenging



Summary Cleaners

– Effectiveness of the cleaners?

Enzymatic:

PEC

OC

OED

ER

Alkaline:

MCF

PAD (45 °C)

ACF (58°C)

– Comparability of enzymatic and alkaline cleaners?

- NO



Summary Cleaners

- **Influence of the cleaning temperature and time?**
 - **5 min** cleaning time are **too short**, especially for enzymatic cleaners
 - At **45°C** the results were **better than at 58°C**



What is the Problem ?

- Cycles in WD-Es are **too short** for effective cleaning
- Austrian Society proposes:

10 minutes for **alkaline** and
15 minutes for **enzymatic** cleaners



Thank you



For your attention !



Guideline of the Austrian Society for Sterile Supply (ÖGSV):

Checks / tests needed for WDs and Sterilizers after maintenance / repair works carried out by (service) engineers

T. Miorini

Austrian Society for Sterile Supply



ÖGSV guideline: Tests after maintenance/repairs

- Compiled by the Testing Committee of the Austrian Society for Sterile Supply (ÖGSV)
- Several (serious) defects were detected in the course of routine checks or revalidation of washer-disinfectors and sterilizers.
- WD-E:
 - Mixed up dosing pumps after repair works
 - Water softening unit not working – no fault indication
 - No water flowing through the channels - no fault indication
- WD:
 - No dosage after maintenance - no fault indication
 - Exchange of spray arms without check and information



ÖGSV guideline: Tests after maintenance/repairs

- The tables list the **checks / tests to be carried out**, following repairs and maintenance tasks.
- Indication, if the **infection control expert** has to be informed.
- Decision, whether an **operational requalification** is required
- In this case the responsible test body is to be informed as soon as possible.
- **Documentation** of maintenance tasks or repairs and tests must be forwarded to the management of the CSSD.



Checklist for WDs and WD-Es

Maintenance / repairs	Checks / tests by technician before release of the equipment	Expert to be informed
Routine maintenance	Thermoelectric measurement for at least one (blank) cycle	
Changes to program cycles, apart from drying	Thermoelectric measurement for at least one (blank) cycle using the modified program	x*
Interventions in the dosing system	Volumetric or gravimetric check of dosage	
Changes to the detergent or disinfectant and /or their set points	Volumetric or gravimetric check of dosage Check of fault signalling system	x
Replacement of circulation pumps	Technical functional test, check for correct direction of rotation	x



Checklist for WDs and WD-Es (2)

Maintenance / repairs	Checks / tests by technician before release of the equipment	Expert to be informed
Modification / adjustment / replacement of instrumentation	Thermoelectric measurement for at least one (blank) cycle, calibration protocol	
Modification / adjustment / replacement of load carriers	If applicable pressure measurement for at least one (blank) cycle	x
Replacement / repair of water-softening unit	Check of water hardness	
Software update	Thermoelectric measurement for at least one (blank) cycle, Program printout for all programs	
Only endoscope WDs for all tasks outlined above	<u>Additionally,</u> cycle with batch control system	



Checklist for Steam Sterilizers

Maintenance / repairs	Checks / tests by technician before release of the equipment	Expert to be informed
Routine maintenance	Vacuum test, B&D test	
Changes to program cycles (conditioning, sterilization phase)	Thermoelectric / pressure measurement for at least one (blank) cycle	x
Replacement of vacuum pump	Vacuum test, B&D test	x
Modification / adjustment / replacement of instrument parts (temperature and, if applicable, pressure sensors, etc.)	Thermoelectric / pressure measurement for at least one (blank) cycle, Calibration protocol	
Changes to feed water supply	Check of conductivity	
Modification / repair of steam supply system	B&D test	x
Replacement of door seals	Vacuum test, B&D test	



Summary

- Checks/tests after maintenance/repairs save time, money and loss of reputation!
- Advantage for hospitals and companies
 - Hospitals have the guarantee that their machines are OK
 - Companies can provide evidence that they have committed the machine in good order

The guideline will soon be published by the wfhss



Thank you



For your attention !