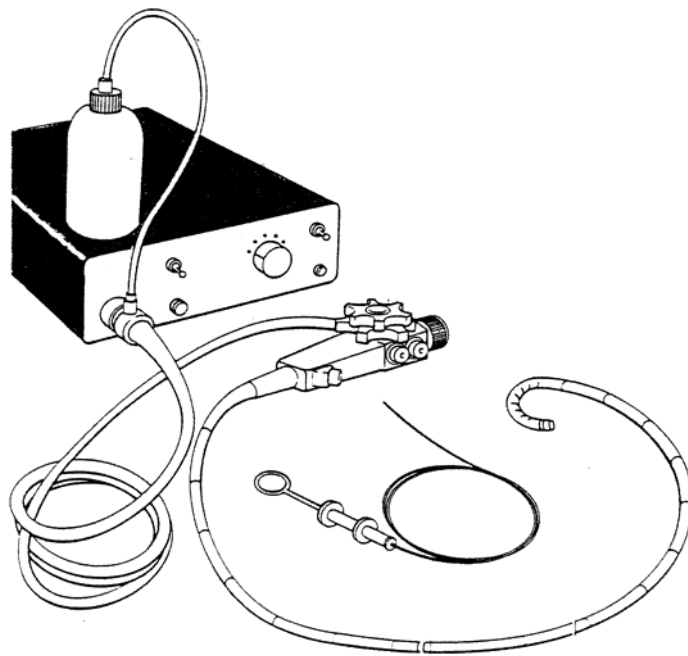


In use test of a Washer-disinfector
reprocessing of flexible
endoscopes

Olympus ETD 3 with PAA



Clean Endoscope
Copenhagen Hospitals
Denmark

In-use test of Olympus ETD 3 Washer-disinfector with PAA

Cleaner and disinfectant from Ecolab, Germany

By Dr. T. Slotsbjerg, Hvidovre Hospital, Denmark

31 flexible endoscopes were tested before 416 endoscopies in less than 8 weeks.

Introduction

In a quality control program for cleaning and disinfection of flexible gastrointestinal endoscopes (FE) at hospitals in Copenhagen flush water from the water channel is used to evaluate the whole procedure for reprocessing FE.

A continuous quality control is established with sampling one day a month before all endoscopies (before 5-6% of the endoscopies per year). The reprocessing of the biopsy channels of FE are controlled by audit.

A report forwards to the endoscopy units every month and *control charts*¹ are worked out. Outliers from defect endoscopes and washer-disinfectors (WD^s) are excluded and the percentage of clean endoscopes is determined for every year. A database contains results from more than 14.000 control samples.

The results and methods from the quality control are also used to evaluate new products for cleaning and disinfection of FE.

Order from

Olympus Medical Systems Europa GMBH
Wendenstrasse 14-18
20097 Hamburg
Germany

Washer disinfector(s)

Two Olympus ETD 3 with per acetic acid (PAA)

Both ETD3 PAA machines did have the following main features:

- Automatic Leak Test.
- Pre-Cleaning stage with water (no heating).
- Cleaning stage with 0,6% EndoDet at 35°C for 3 minutes.
- Disinfection stage with 1,2% EndoDis (PAA) and 1,2% EndoAct at 35°C for 5 minutes.
- Rinse 1 with water (no heating).
- Final Rinse with Water (no heating).
- Optional selectable Drying function (15 minutes) at 60°C.

Each stage of the process runs with fresh water (no reuse of water) and all chemical products are single use. All incoming fresh water is treated with UV-light radiation and with small amount of PAA (10-15ppm).

The ETD3-PAA is doing an automatic System Check every morning after first Switch-On. During the System Check all water feeding tubes and the integrated Water Softener are disinfected with 0.5% PAA (EndoDis) solution.

The machines at Bispebjerg hospital are serial products. They are equipped with Automatic Endoscope Identification (EndoID) and Flow Control.

Chemical products

- For manual cleaning: 3-enzyme, Olympus Denmark
- Cleaner in WD: EndoDet[®] 0.6%, Ecolab
- Disinfectant in WD: EndoDis[®] 1.2% + EndoAct[®] 1.2%, Ecolab

Endoscopy department

The Endoscopy Unit
Surgical Gastrointestinal Department K
Bispebjerg University Hospital
Copenhagen DK

Flexible endoscopes included

- Gastrosopes, sigmoidoscopes and colonoscopes (Olympus)

Test laboratory

Clinical Microbiology Department, Hvidovre Hospital, has carried out the laboratory work.

Definitions

A clean endoscope: CFU < 5 per 0.2 ml flush water corresponding to 0-20 CFU per ml (range for acceptable drink water).

A critical endoscope: CFU are between 5 and 50 CFU per 0.2 ml flush water.

Critical FE^s with 11-50 CFU per 0.2 ml flush water is correlated to fixation of organic materials to the inner surface of the water channel (Data from the quality control program)

A high-risk endoscope: CFU >50 per 0.2 ml flush water.

High-risk FE with more than 50 CFU per 0.2 ml flush water is correlated to proliferation of microorganisms during storage.

A stable procedure

- At least 95% of the endoscopes should be clean
- No occurrence of high-risk endoscopes.

An unstable procedure

- Less than 95% of the endoscopes are clean and/or occurrence of high-risk endoscopes. (The reprocessing is out of control in g-control chart with a centre line = 20 clean FE between a not clean FE^s)^{1,2}

The mean of the previous year

- 98.6 % of the endoscopes were clean in 2006.

Acceptable lower limit of clean endoscopes

- The acceptable lower limit of numbers of clean endoscope is 98.6 % - (3 X SD) (Joint Commission International). SD = Standard deviation

Questions before the in use test

1. Is the reprocessing of FE a stable procedure?
2. Is the percentage of clean FE > 98.6% - 3 X SD?
3. Are significant residuals of organic material demonstrable in FE water channels after reprocessing?
4. Prevents reprocessing in ETD 3 proliferation of micro organisms (and development of biofilm) in FE channels during storage? ⁴
5. Are significant residuals of organic material demonstrable in biopsy port valves after reprocessing? ³
6. Are the process temperatures and times constantly?

Condition for the investigation

- The endoscopy unit follows the Danish recommendations for cleaning and disinfection of flexible endoscopes.
 - When the endoscope is still connected to the power source we flush the channels of with water.
 - Manual cleaning in the reprocessing area of all channels and the outer of the endoscope in a detergent solution with brushing.
 - Before storage we flush the channels with 70% alcohol, and the endoscopes can be used within 3 days. Duodenoscopes are decontaminated and flushed with alcohol before use.

Sampling from the endoscopes

Samplings are carried out immediately before an endoscopy. The endoscopes are connected with a sterile water bottle with sterile water. The water channels are sampled by depressing the air/water feed button and irrigating the channel with water from the water bottle. Approximately 5 ml is collected into a sterile test tube at the distal end. These samples contain material from the water bottle and the water and the distal jointed air/water channel. At the end of the day control samples are obtained from the water bottles. The test tubes are stored in a cold store and forward to the Clinical Microbiologic Department the same day.

Laboratory procedure

In the laboratory ten droplets of 20 µl are put down a 5% blood agar the same day. After incubation for 48 hours at 35 °C in CO₂ the number of CFU was counted.

Identification of bacteria and fungi

Samples with <5 CFU per 0.2 ml are identified as species. Other samples are identified after the routine of the laboratory. Staphylococci are identified as coagulase positive (*S. aureus*) and coagulase negative (CNS)

Isolates from FE^s are split up in environmental/staff related or patient related microorganisms.

Sample size

400 – 420 samples from endoscopes are obtained immediately before an endoscopy.

Excluded samples

Samples from endoscopes are excluded if

- A contaminated endoscope has a defect demonstrable on service.
- A contaminated FE is decontaminated in a WD with a defect demonstrable on service.
- The endoscopes are contaminated during alcohol flushing of FE channels (*Bacillus spp.*)
- Samples with > 4 CFU per 0.2 ml related to inadequate compliance with the reprocessing protocol.

Time/temperature curves

Time/temperature curves of the reprocessing program in ETD 3 are recorded before and after the in use test on an EBI-125A temperature logger (± 0.1 °C) from *-ebro-* Germany.

Cleaning tests

ATP-test

Residual Adenosine Tri-Phosphate (ATP), which is found in large quantities in human blood and other tissue fluids, are used as cleanness indicator for FE water channels and biopsy port valves.

An UNI-LITE Xcel[®] portable luminometer and total ATP Aqua-Trace[®] and Clean-Trace[®] test kits are used (Biotrace International). The relation between Relative Light Units (RLU) values from UNI-LITE Xcel[®] and ATP in fento-mol (10^{-15} mol) is previous detected.

Log RLU = log ATP +1, log RLU = log ATP-unit, 3 log ATP-units corresponds to 10^{-3} µl blood.

Water channels

ATP measures (Aqua-Trace test kits) on more than 25 random samples from the water channels of FE.

Biopsy port valves³

ATP measures (Clean-Trace swab test kit) on 25 random biopsy port valves after manual cleaning and decontamination in ETD 3.

Data analyses

The number of clean and not clean endoscopes follows a binominal distribution.

Outliners from defects endoscopes are excluded and the percent of clean endoscopes are determined.

The acceptable lower limit of numbers of clean endoscope is 98.6% - (3 X SD) (Joint Commission International).

If an endoscope is not clean in more than one sampling the critical numbers of not clean results will be determinate.

If more than 8 endoscopes are not clean a Number-Between g-Type Statistical Quality Control Charts will be made-up^(1,2)

ATP residual values are imported in cleaning control chats

Water channels: Centre line (CL) and Upper Control Limit (UCL) are calculated. The total cleaning process is reported as in or out of statistical control. In samples from the water channels in new FE^s CL and UCL are 1,4 and 1,9 log ATP-units respectively.

Biopsy port valves: CL and UCL are calculated. The total cleaning process is reported as in or out of statistical control.

Results

416 samples were obtained and lower acceptable limit for clean FEs is (98.6% - 1.7%) = 96.9%

Table 1 and **figure 1** show that **413 of 416** endoscopes (99.3%) were clean before an endoscopy (0-4 CFU per 0.2 ml). Table 1 shows furthermore that 3 of 416 (0.2%) endoscopes were critical FE^s with 5, 7 and 8 CFU per 0.2 ml. water respectively. No endoscopes were excluded. The isolates were coagulase-negative staphylococci (CNS) and gram-negative coliform bacteria.

As standard of reference table 1 shows results of quality control samples from FE^s at the Endoscopy department after reprocessing in Olympus ETD2+ WD^s before the in use test. After reprocessing in ETD3 PAA and ETD 2+ the percent of critical FE with 10-50 CFU per 0.2 ml flush water was 0% and 1.4% respectively and the difference is significant (p=0.017).

Table 2 and **figure 2** show that 99.6% and 98.2% of the FE was clean after reprocessing the same day and 1-3 days before respectively. The difference is not significant.

Figure 3 shows a control chart with ATP determinations in 48 of samples from the water channel of the endoscopes. The control chart shows a total cleaning process in statically control. The centreline of the control cart (CL = 1.4 log ATP-units) indicates that PAA don't fix organic materials at the inner surfaces of the water channels, but a high upper control limit (2.9 log ATP-units) indicates that the manual cleaning can be improved.

Figure 4 shows a control chart with ATP residuals in 26 biopsy port valves after manual cleaning and reprocessing in ETD3 PAA. The reprocessing of the valves is out of statistical control (four outliners). ATP-residuals in the biopsy port valves outliner corresponds to $< 10^{-4}$ µl blood.

Table 3 and figure 5 and 6 show that process temperatures and times during the in use test were constantly in the ETD3 PAA WD^s.

Conclusion

- Chemical reprocessing at 35 °C of flexible endoscopes using ETD3 PAA is a stable procedure with 99.3% clean endoscopes (0-4 CFU per 0.2 ml flush water). Three samples (0.7%) presented 5 – 8 CFU per 0.2 ml and were all detected within 7 days.
- 99.3% clean FE^s are above the lower acceptable limit for clean FE^s at 96.9%.
- The reprocessing of 416 FE including the ETD3 PAA process, using cold-water final rinse during 8 weeks has prevented significant proliferation of microorganisms with biofilm formation and clusters of High risk FE during storage (0-3 days). Therefore the cold-water final rinse doesn't contaminate the endoscopes significantly.
- Removal of organic material from the water channel of FE^s was a statistical stable process, but the manual cleaning could be improved with use of an alternative detergent.
- The cleaning process of biopsy port valves was out of statistical control, but the ATP residuals in the biopsy port valves outliners were not critically. An alternative detergent for manual cleaning is under consideration⁴.
- The process temperatures and times were constantly during the in-use test in the two ETD3 PAA WD^s.

ETD3 PAA can consequently be recommended for chemical reprocessing of flexible endoscopes on the following conditions

- Detergents used for manual cleaning should be approved of Olympus
- FE channels should be flushed with 70% alcohol before storage in accordance with the Danish Guideline for Cleaning and Disinfecting of Flexible Endoscopes (CDC category 1A⁵).
- Flexible endoscopes (except duodenoscopes, bronchoscopes and cystoscopes) can be used within 72 hours after a reprocessing.

Torsten Slotsbjerg



MD, Consultant
Clean Endoscope
Hvidovre Hospital
Denmark

Table 1: 416 samples from the water channel of 31 flexible gastrointestinal endoscopes obtained before an endoscopy after manual cleaning with 3-enzyme and reprocessing in ETD3 PAA WD^s. To comparison are results of 433 quality control samples from the endoscopy department (manual cleaning with 3-enzyme and reprocessing in ETD2+ WD^s)

Table 1	Clean endoscopes 0-4 CFU per 0.2 ml	Critical endoscopes 5-49 CFU per 0.2 ml.		High-risk endoscopes ≥50 CFU per 0.2 ml
		5-10 CFU (low critical)	11-49 CFU	
Number of FE				
ETD3 PAA	413 (99.3%)	3 (0.7%)	0*	0
ETD 2+ (0.24% glutaraldehyde)	424 (97.9%)	3 (0.7%)	6 (1.4%)*	0

*) p=0.017

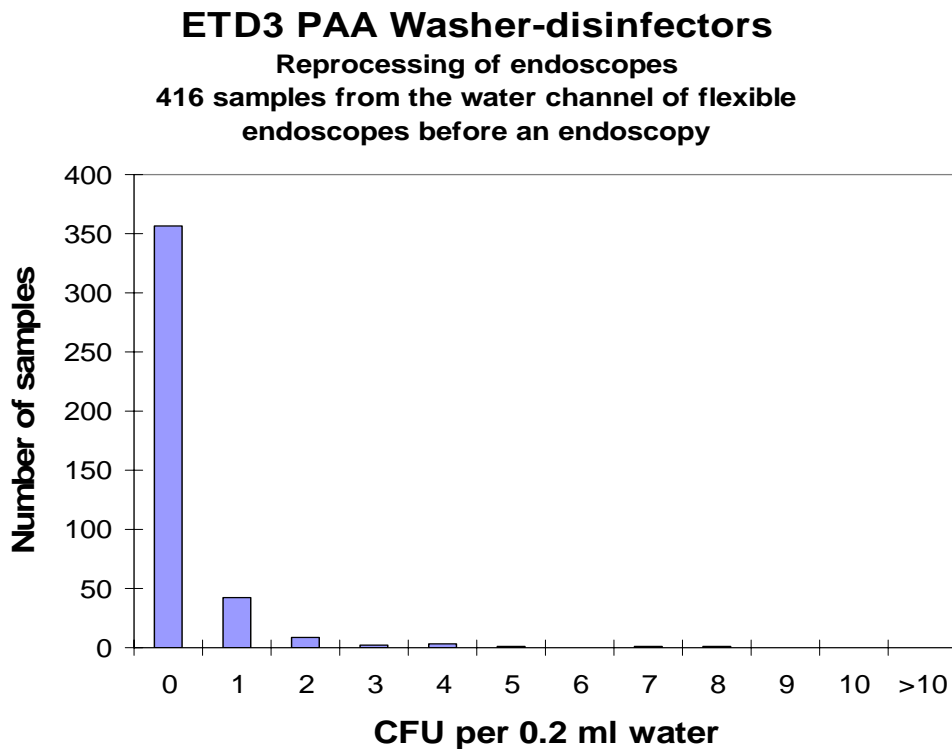


Figure 1: Results of 416 samples from the water channel of the 31 flexible GI endoscopes

obtained before an endoscopy after reprocessing of the endoscopes in ETD3 PAA

Table 2: Distribution of CFU per 0.2 ml flush water and isolates in samples from Flexible endoscopes reprocessed the same day and after 1-3 days respectively

ETD3 PAA	Sampling day after reprocessing				
	Same day	1	2	3	Total
Number (%) of samples	271 (65.1%)	110 (26.5%)	10 (2.4%)	25 (6.0%)	416
Number of clean FE	270 (99.6%)	108 (98.2%)	10	25	413 (99.3%)
Number of "low" critical FE	1 (0.4%)	2 (1.8%)			3 (0.7%)
Bacteria	Coliforms ⁺	CNS ⁺⁺			
Endoscopes	CF Q160 gastroscopes	Two CF Q160 gastroscopes			
Washer-disinfector	WD 1	WD1 + WD2			

⁺ Patient related, ⁺⁺ environmental/staff related

ETD3 PAA Washer-disinfectors Samples with growth

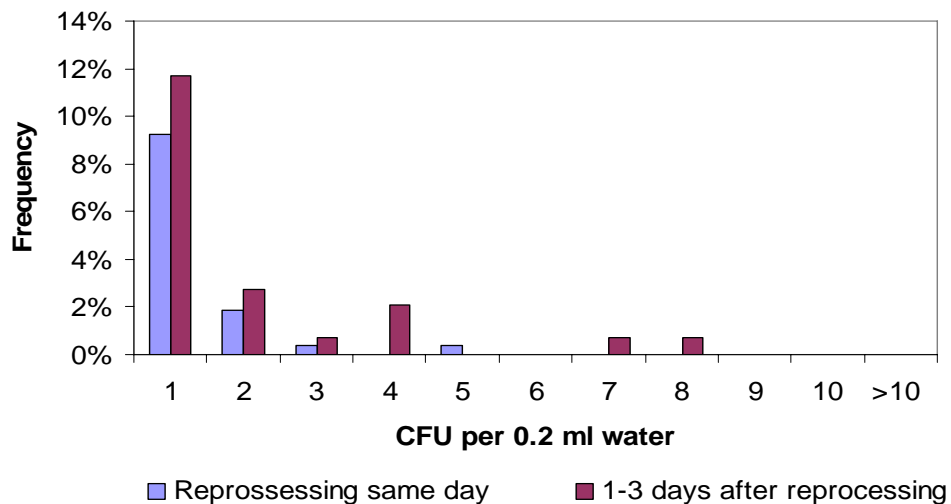


Figure 2: Distribution of CFU per 0.2 ml flush water in samples with growth reprocessed the same day and after 1-3 days respectively

Residuals of organic materials in the water channel of flexible endoscopes after reprocessing

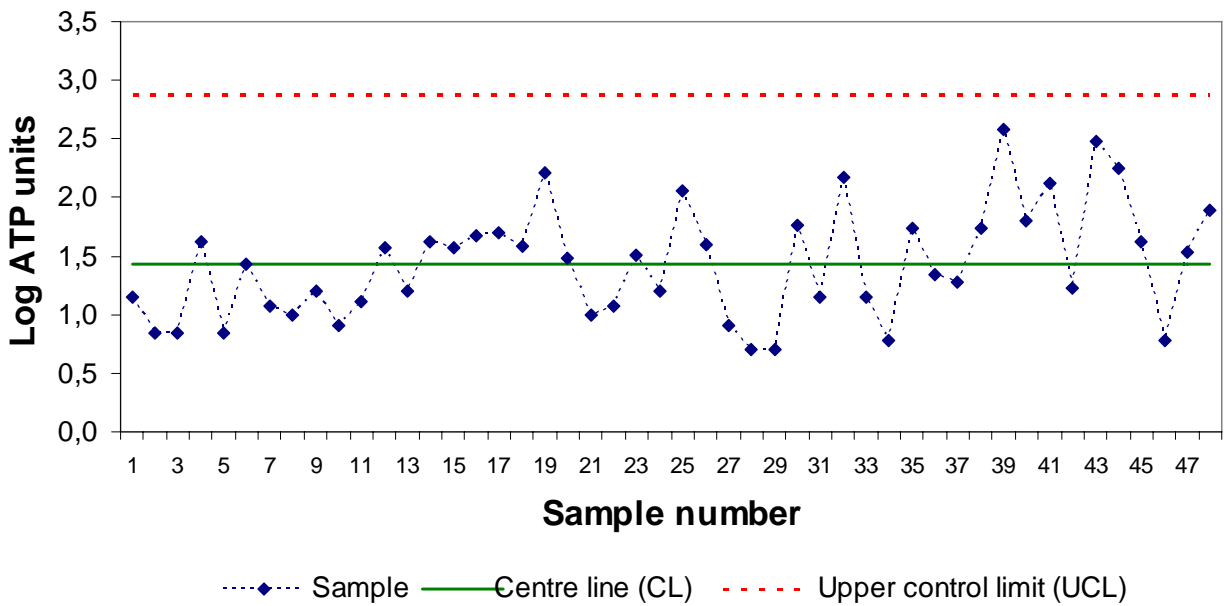


Figure 3: Residuals of organic material in the water channel of flexible endoscope after manual cleaning and reprocessing in an ETD3 PAA Washer-disinfector.

Biopsy Port Valves Residuals of organic materials

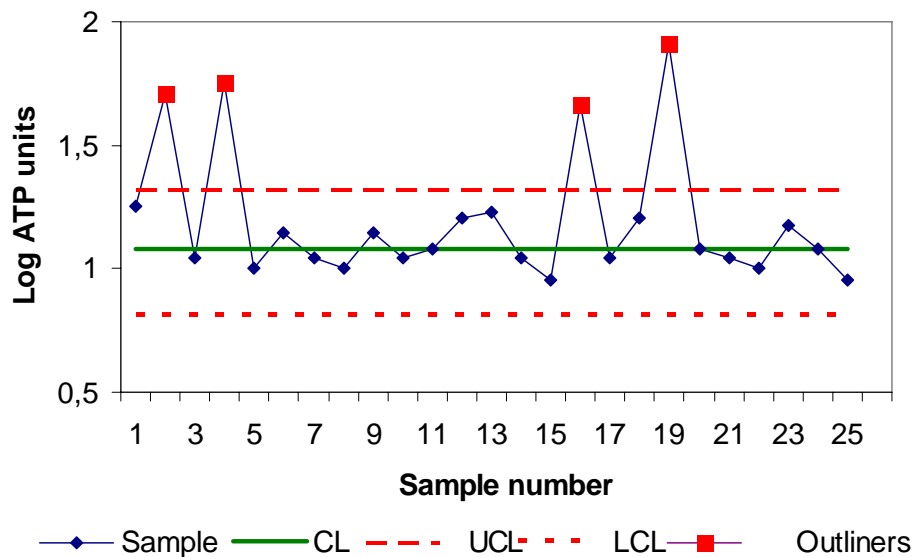
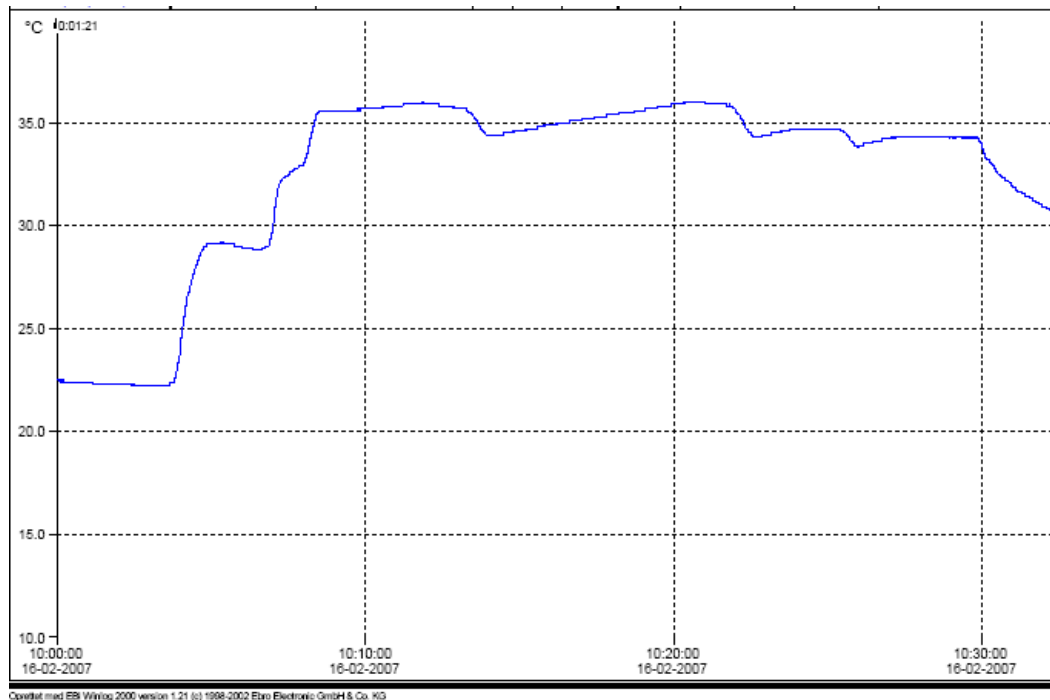


Figure 4: Residuals of organic material in biopsy port valves of flexible endoscope after manual cleaning and reprocessing in an ETD3 PAA Washer-disinfector (LCL = lower control limit)

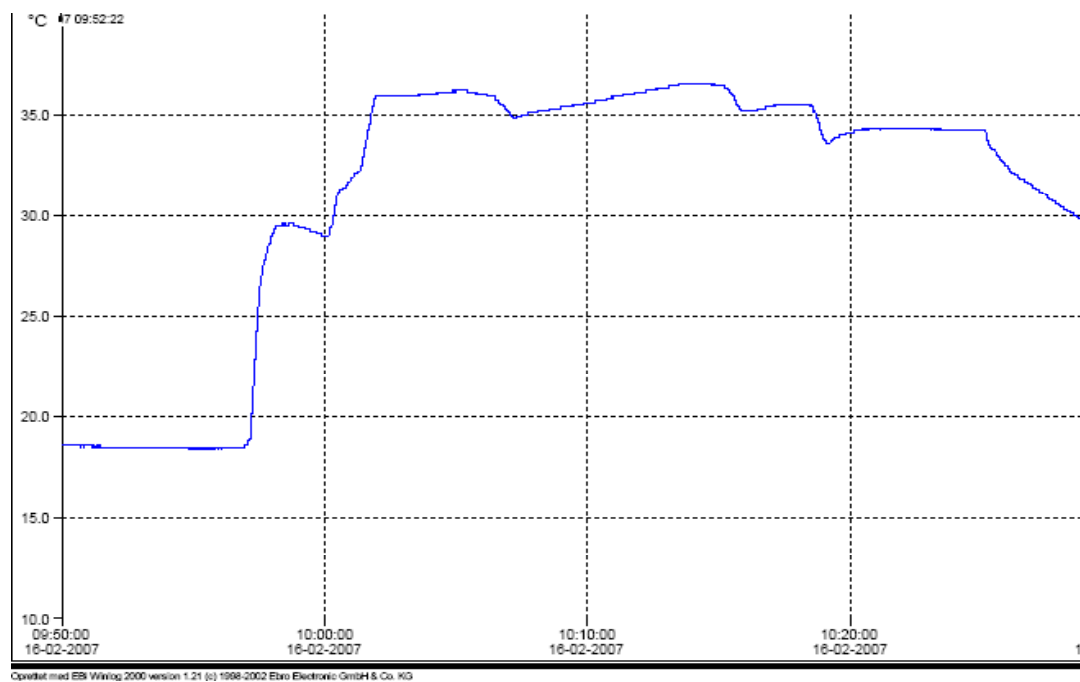
Table 3: Results of time/temperature measuring of during reprocessing of flexible endoscopes in the ETD3 PAA washer-disinfectors.

Part of the ETD3 PAA reprocessing	First part of the in-use test				Second part of the in-use test			
	WD 1		WD 2		WD 1		WD 2	
	Time	Temp.	Time	Temp.	Time	Temp.	Time	Temp.
Pre-rinsing	2:32	29.2	2:29	29.5	2:56	30.0	2:54	30.5
Washing	7:30	35.9	7:15	36.2	7:34	36.2	7:19	36.2
Disinfection	8:47	36.0	8:52	36.5	8:18	37.1	8:31	37.0
Rinsing 1	3:18	34.7	3:00	35.8	3:29	34.4	3:26	35.5
Rinsing 2	4:05 [*]	34.3	6:04	34.3	5:33	33.6	5:56	35.3

**^l Rinsing2 time was 6:00 minutes in the following reprocessing.*

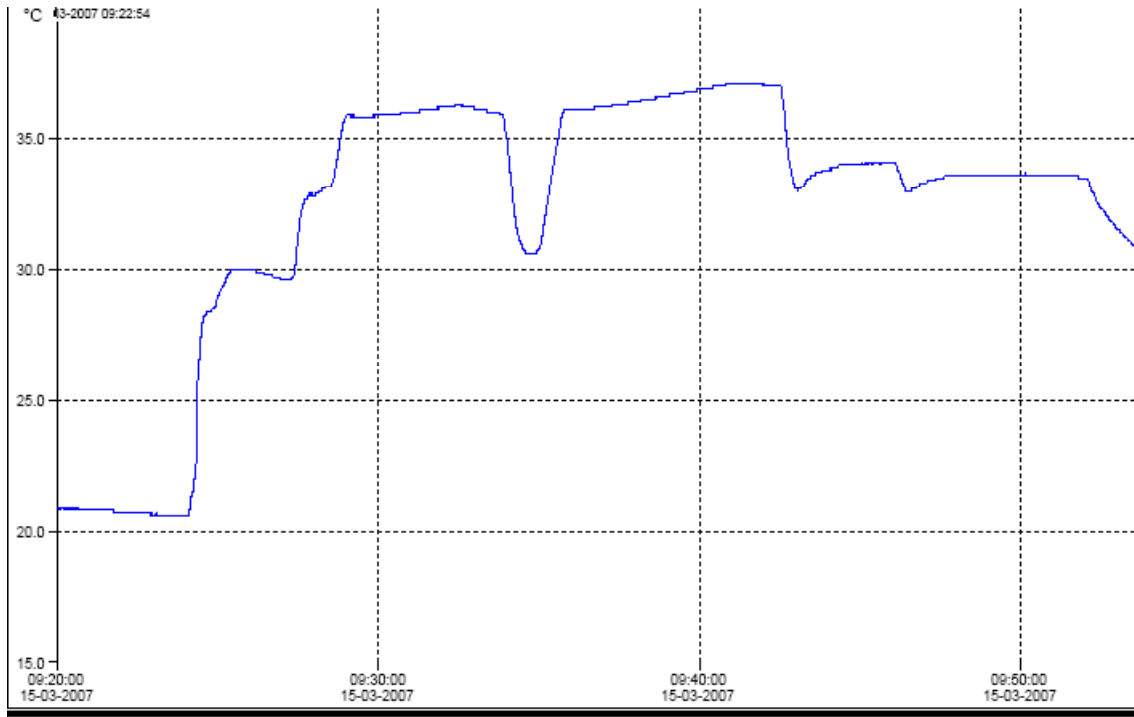


WD1

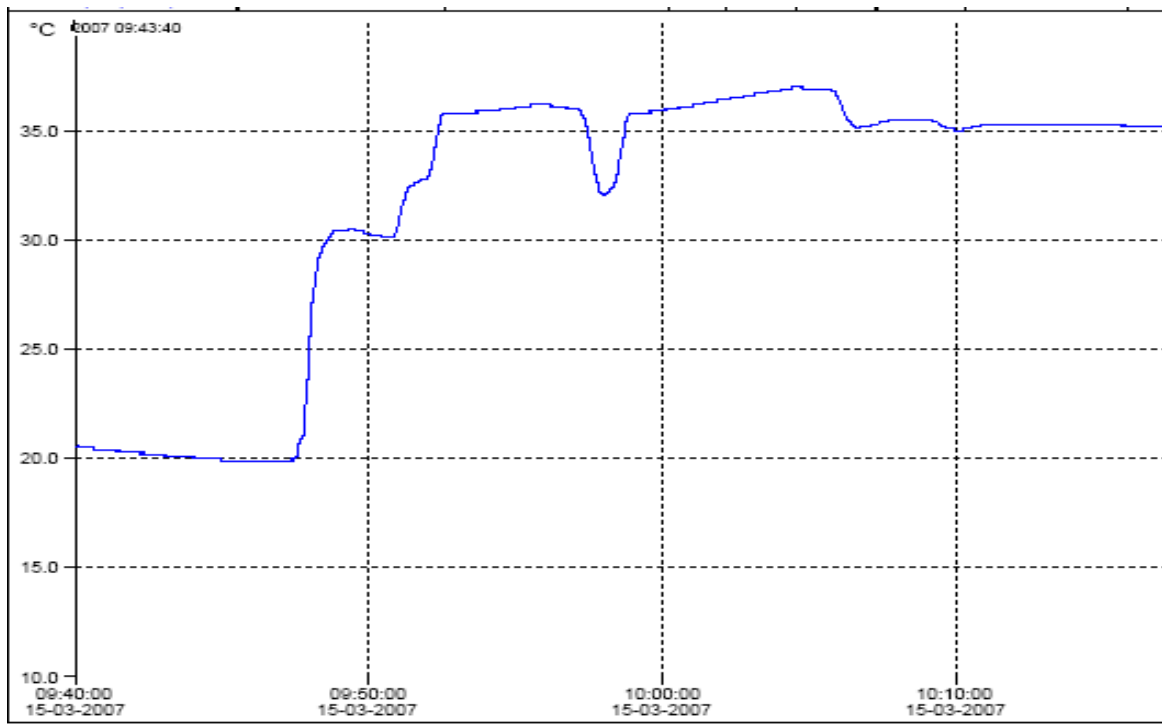


WD2

Figure 5: Temperature/time curves from ETD3 PAA Washer-disinfectors from first part of the in-use test.



WD1



WD 2

Figure 6: Temperature/time curves from ETD3 PAA Washer-disinfectors from second part of the in-use test.

References

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