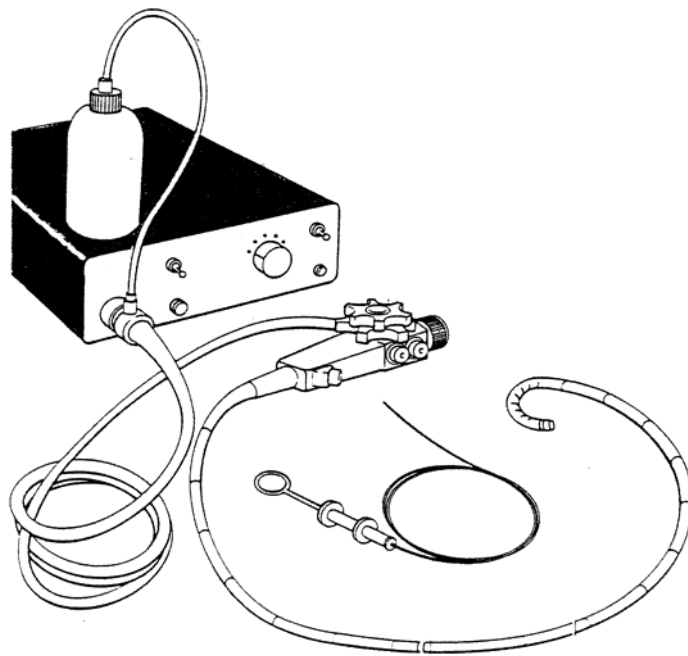


In use test of a Washer-disinfector reprocessing of flexible endoscopes

BHT INNOVA E4



Clean Endoscope
Copenhagen Hospital Corporation
Denmark

In use test of INNOVA E4 Washer Disinfector from BHT, Germany.

An aldehyde free thermo-chemical reprocessing of flexible endoscopes

Cleaner and disinfectant from Schülke & Mayr, Germany.

By Dr. T. Slotsbjerg (Hygiene Dr. from Denmark)

6 flexible endoscopes were tested immediately before 402 endoscopies in 17 weeks.

Introduction

In a quality control program for cleaning and disinfection of flexible gastrointestinal endoscopes (FE) at hospitals in Copenhagen and Copenhagen County 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* are worked out. Outliers from defect endoscopes and washer-disinfectors (WD) are excluded and the percentage of clean endoscopes is determined for every year. A database contains results from more than 10.000 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

BHT Hygienetechnik
D-86368 Gersthofen
Germany

KEN A/S
DK-5672 Broby
Denmark

Washer disinfectors

BHT INNOVA E4 washer disinfector (WD)

The FEs are placed in two separate patent pressure chambers and a pressure gradient forces fluids through the FE channels.

- Intake of detergent: 150 ml per 30 litres (0.5%)
- Intake of disinfectant: 300 ml per 30 litres (1.0 %)

Chemical products

- For manual cleaning: Ultrasan[®] (enzymatic detergent from Brenntag Nordic).
- Cleaner in WD: Thermosept ER[®] (Schülke & Mayr).
- Disinfectant in WD: Thermosept AF[®] (Schülke & Mayr).
- Soft water supply is necessary.

Endoscopy unit

The test is carried out at Surgical Outpatient Department 435, Hvidovre Hospital, Denmark.

Flexible endoscopes included

- 6 Sigmoidoscopes (Olympus)

Test laboratory

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

Definitions

A clean endoscope

- 0–4 CFU per 0.2 ml flush water corresponding to 0-20 CFU per ml (acceptable drink water).

A critical endoscope

- 5-49 CFU per 0.2 ml flush water. A number of critical endoscopes are accepted (see below)

A high-risk endoscope

- Equal or more than 50 CFU per 0.2 ml flush water.

The percentage of clean endoscope from the previous year (see above)

- 98% of the endoscopes were clean and 0.1% High-risk in 2003 (products from Olympus)

An accepted test result (a stable procedure)

- Least 98% – (3 X STD) of the endoscopes should be clean (STD = standard deviation)
- Highest 0.1% + (3 x STD) of High-risk endoscopes.

An unstable procedure

- Less than 98% – 3 x STD of the endoscopes are clean and/or more than 0.1% + 3 x STD are High-risk endoscopes. (Statistical out of control in a *g-control chart* with clusters of critical and high-risk FE)

Question before the in use test.

Using the INNOVA E4 and products from Schülke & Mayr

- Is the cleaning and disinfection procedure a stable procedure?
- Is the circulation through the FE water channel stable?
- Can residuals of organic material be detected in FE water channels after reprocessing?
- Are the process temperature and time constantly

Condition for the investigation

- The endoscopy unit follows the Danish recommendations for cleaning and disinfection of flexible endoscopes.
 - The moment the endoscope is removed from the patient, the channels were flushed with water.
 - Manual cleaning of channels and the outer of the endoscope was carried out with a detergent solution including brushing.
 - Before storage, the channels of the endoscopes were flushed with 70% alcohol, and the endoscopes have to be used within 3 days.

Sampling from the endoscopes

Samples were carried out immediately before an endoscopy. The endoscopes were connected with a sterile water bottle, filled with sterile water. Depressing the air/water feed button, the water channels were sampled by and irrigating the channel with water from the water bottle. Approximately 5 ml was collected into a sterile test tube at the distal end.

At the end of the day control samples were obtained from the water bottles.

The test tubes were stored in a cold store.

Laboratory procedure

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

Identification of bacteria and fungi

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

Micro organisms isolated from FE were split up in environmental/staff-related or patient-related micro organisms.

Sample size

400 – 410 samples from endoscopes were obtained immediately before an endoscopy.

Excluded samples

Samples from the endoscopes were excluded if

- A contaminated FE had a defect demonstrable on service.
- A contaminated FE was decontaminated in a WD with a defect demonstrable on service.
- The endoscopes were contaminated during alcohol flushing of FE channels.
- Critical or High-risk endoscopes were doing to insufficient compliance of the Danish recommendations for cleaning and disinfection of flexible endoscopes.

Time/temperature curves

Time/temperature curves of the reprocessing programs in INNOVA E4 are recorded before and after the in use test on a EBI-125A temperature logger (± 0.03 °C) from *-ebro-* Germany.

Cleaning test

Residuals of ATP were used as cleanness indicator for FE water channels. An UNI-LITE Xcel[®] portable luminometer and total ATP Aqua-Trace[®] test kits were used. The relation between RLU values from UNI-LITE Xcel[®] and ATP is easily detected. ATP was measured in random samples from the water channel of FE.

Data analyses

The numbers of clean and not clean (critical and high-risk) endoscopes follow a binominal distribution. Outliers from defect endoscopes and WD were excluded (see above).

The acceptable lower limit of clean endoscopes is 98% - 3 X STD (Joint Commission International). For 400 samples the critical number of clean endoscopes is 383 (95.8%).

A Cleaning control chart with a centre line CL (the central tendency of ATP residuals) and an upper control limit $UCL = CL + 3*STD$ is constructed.

The total cleaning process is reported as *in or out* of statistical control

Results

402 samples were obtained

Table 1 and **figure 1** show that 401 of 402 the endoscopes (99.8%) were clean immediately before an endoscopy (0-4 CFU per 0.2 ml). 1 of 402 (0.2%) endoscopes was a “critical FE” with 5 CFU per 0.2 ml. The isolates were coagulase-negative staphylococci (CNS) and were environment/staff-related. Bacteria’s from the intestinal channel was not detected.

As standard of reference table 1 shows results of quality control samples from the six sigmoideoscopes reprocessing in an old run-down Olympus ETD WD before the in use test, and results after reprocessing WDs using 2% glutaraldehyde at room temperature.

Figure 2 shows a control chard with ATP determinations of 33 of the 402 samples from the water channel of the sigmoideoscopes.

The control chard shows a total cleaning process in statically control. The cart indicates, that the water channel on the sigmoideoscopes was without significant quantises of organic material after reprocessing.

Figure 3 and 4 and the table below show that process temperature process time in INNOVA E4 had decreased during the in use test (See remarks from BHT).

	Process temperatures and time <i>before the in use test</i>	Process temperature and time <i>after the in use test</i>
Washing	8:30 minutes above 58.0 °C Maximum : 58.7 °C	5:16 minutes above 57.5 °C Maximum : 58.1 °C
Disinfection	8:25 minutes above 58.0 °C Maximum : 59.0 °C	6:30 minutes above 57.5 °C Maximum : 58.2 °C

Remarks

The practical course of the test

Precipitation of a calcareous greasy substance on the endoscope and in the inner of the WD occurred if the power supply of the soft water system was switched off.

Remarks from the staff

The staff from the endoscopy unit accepted the use of Thermosept ER[®] and AF[®]. No complaints of obnoxious smells during the test.

Process temperature

Unlike other products for thermo-chemical reprocessing of FE we use, Thermosept ER[®] and AF[®] in combination didn't fail against our thermal tolerant staphylococci at a process temperature below 59 °C.

Conclusion

- The thermo-chemical reprocessing of flexible endoscopes using INNOVA E4 with aldehyde free products from Schülke & Mayr was a stable procedure with 99.8% clean endoscopes (0-4 CFU per 0.2 ml). One sample presented 5 CFU per 0.2 ml.
- The circulation through the narrow water channels didn't fail.
- After reprocessing no significant residuals of organic material were identified in the water channel of FEs.
- The process temperature and time in INNOVA E4 were different before and after the in use test. Using other products than Thermosept ER[®] and AF[®] at 57.5 °C a disinfection failure of thermal tolerant bacteria is expected.

INNOVA E4 can consequently be recommended for thermo-chemical reprocessing of flexible endoscopes on the following conditions

- The WD should be connected to a soft water system.
- Endoscope reprocessing in glutaraldehyde should be reprocessing at least two times with the S&M products before the first endoscopy to prevent transfer of glutaraldehyde fixed materials from the endoscope to patients.
- Only Thermosept ER[®] and AF[®] should be used as cleaner and disinfectant at 57.5 °C.

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Table 1: 402 samples from the water channel of 6 flexible sigmoideoscopes obtained immediately before an endoscopy. Thermosept ER® 0.5% and Thermosept AF® 1.0 % are used in a BHT INNOVA E4 WD. Results of quality control samples form the sigmoideoscopes before the in use test are showed together with the golden standard (reprocessing with 2% glutaraldehyde)

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
	Number of FE		
INNOVA E4 with S&M products	401 (99.8%) (Mean: 0,1 CFU per 0.2 ml)	1 (0.2%) (5 CFU per 0.2 ml)	0
Critical limit*		17	
Environment/staff-related micro organisms.	CNS	CNS	
Micro organisms from the intestinal channel.	ND	ND	
Sampling from the sigmoideoscopes before the in use test. Old Olympus ETD WD Process temp.: 58.5 °C (Unstable procedure)	94,1%	5,3%	0,6%
Golden standard: Modern WDs with 2% glutaraldehyde at rum temperature (Unstable procedure)	91,0%	7,0%	2 %

CNS: Coagulase Negative Staphylococci, ND: Not detected

BHT INNOVA E4 Washer Disinfector Reprocessing of the endoscopes

402 samples from the water chanal of the endoscopes
immediately before an endoscopy

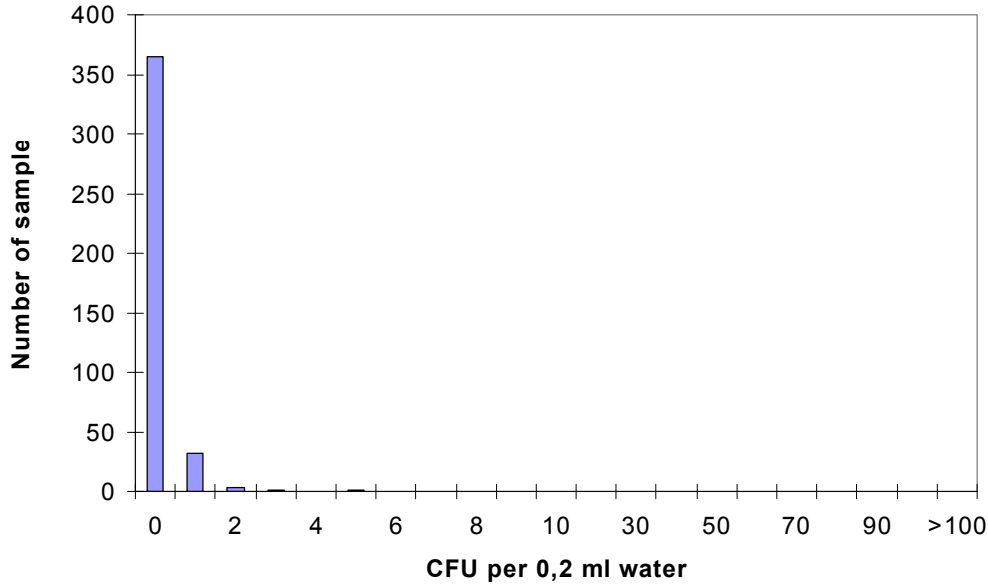


Figure 1: Results of 402 samples from the water channel of the endoscopes obtained immediately before an endoscopy. Cleaner: Thermocept ER[®] 0.5%. Disinfectant: Thermocept AF[®] 1.0%.

Residuals of organic material in the water channel of flexible endoscope after reprocessing BHT INNOVA E4 Washer Disinfector - Process temperature 59 °C Thermocept ER og AF cleaner and disinfectant

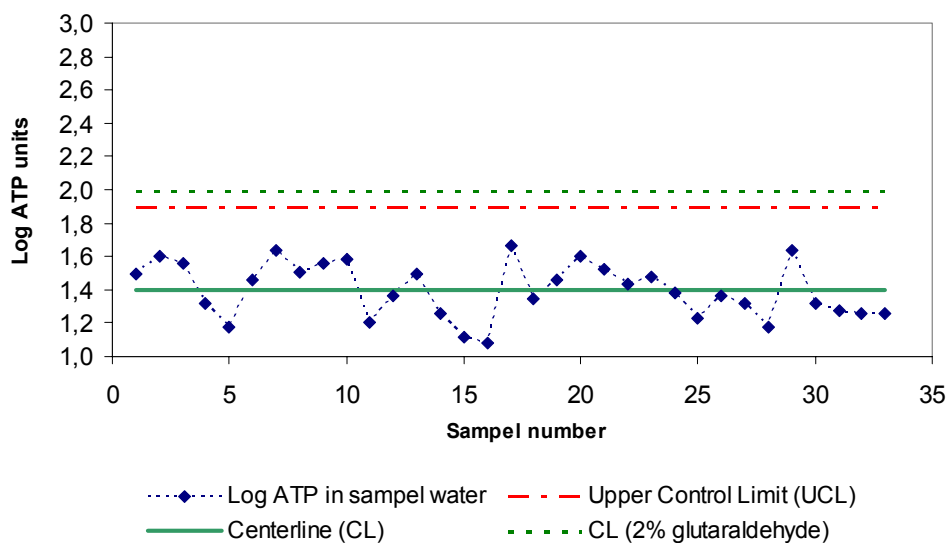


Figure 2: Residuals of organic material in the water channel of flexible endoscope after reprocessing In a BHT INNOVA E4 WD. Cleaner and disinfectant: Thermocept ER og AF

Remarks from BHT

Figure 3 and 4 and the table above show that process temperature process time in INNOVA E4 had decreased during the in use test. This is caused by a process program optimize done on the INNOVA E4.

Figure 3: Time/temperature curve for washing, disinfection and rinsing process in INNOVA E4 before the in use test.

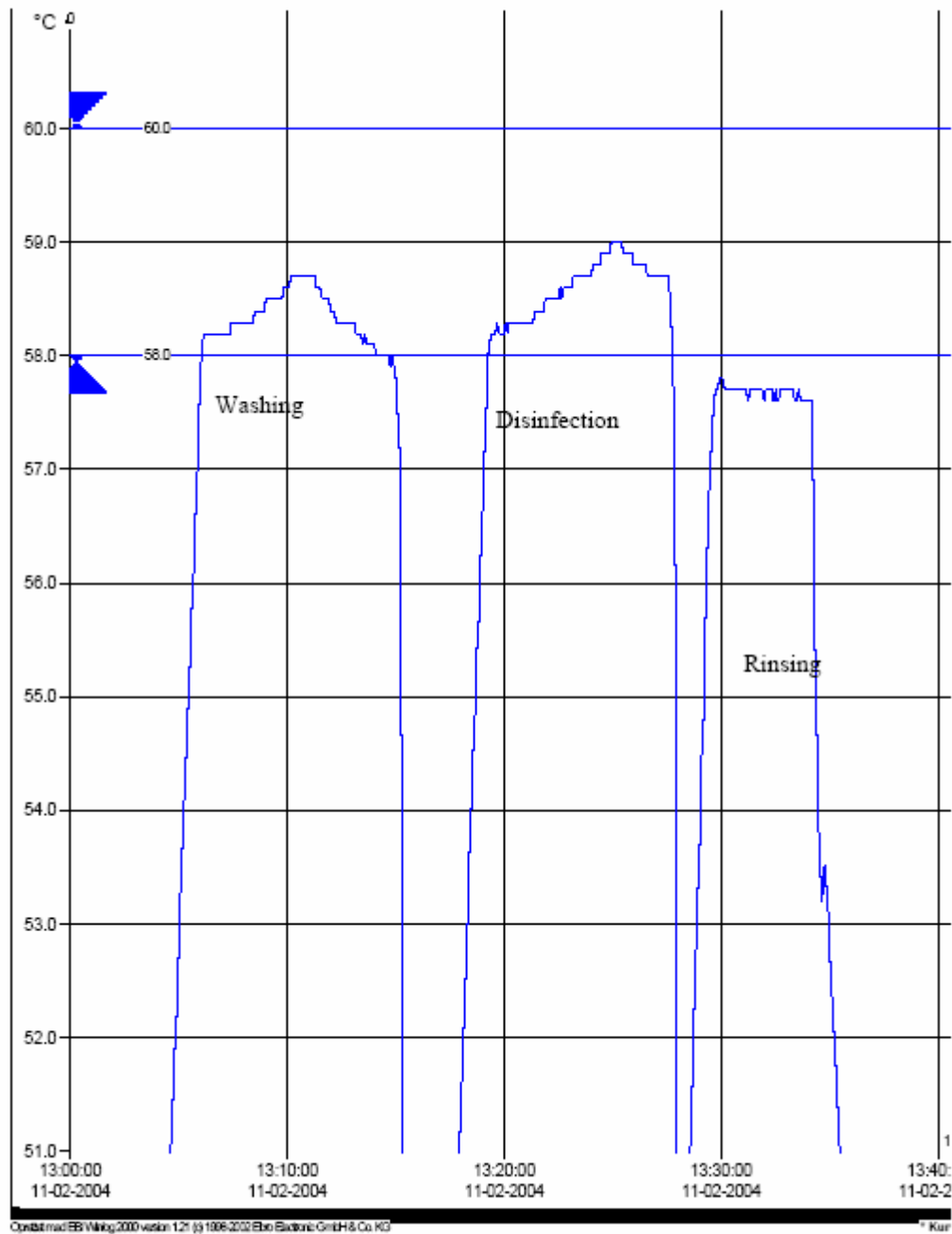


Figure 4: Time/temperature curve for washing, disinfection and rinsing process in INNOVA E4 after the in use test.

