

# **In use test (phase 3 test) of Cleantop-21<sup>®</sup>**

**An enzyme free detergent applied for manual cleaning of flexible endoscopes  
Enclosure to a phase 3 test of Channel Cleaner<sup>®</sup> Ball Brushes**

---

**Endoscopy Unit  
Surgical Gastrointestinal Department K  
Bispebjerg Hospital  
Copenhagen University Hospital**

**Clean-endoscope  
Hvidovre Hospital  
Copenhagen University Hospital  
Denmark**

# In use test of Cleantop-21<sup>®</sup> applied for manual cleaning of flexible endoscopes

---

## Introduction

Manual cleaning is the most important procedure in reprocessing of flexible endoscopes and in some investigations 95% or more of flexible endoscopes (FE) are microbiologic clean after the manual cleaning.

**Microbiologic control samples** have some pitfalls because some bacteria and Hepatitis B and C are unculturable at the applied methods and the length of time needed for results are at least 24 hours.

**ATP bioluminescence** is used for measuring levels of organic soil on surfaces. Opposed to a Microbiologic control samples an ATP cleaning test can be performed in less than 2 minutes

Residual soil is an indicator that the surfaces may be unclean and could provide a potential reservoir and harbour for bacteria, fungi and virus increasing the risk of cross infection between patients. <sup>1</sup>

**ATP bioluminescence** was applied to detect the effect of **Cleantop-21<sup>®</sup>** - a detergent without enzymes for manual cleaning of FE. The water channel of FE was used as checkpoints.

## Product:

### Product:

Cleantop-21<sup>®</sup> – a detergent with out enzymes for manual cleaning of flexible endoscopes.

- RETOX (Febr09): No local irritation and no allergy (in use solution)<sup>4</sup>

### Order from

Braun Scandinavia A/S

Lervej 25

DK-3500 Værløse

### Washer disinfectors

Olympus ETD2+ and ETD 3 with per acetic acid (PAA)

## Chemical products

- For manual cleaning: Cleantop-21<sup>®</sup>
- Cleaner in WD: EndoDet<sup>®</sup> 0.6%, Ecolab
- Disinfectant in WD: EndoDis<sup>®</sup> 1.2% + EndoAct<sup>®</sup> 1.2%, Ecolab

## Endoscopy department

The Endoscopy Unit

Surgical Gastrointestinal Department K

Bispebjerg Hospital

Copenhagen University Hospital

## Flexible endoscopes included

Routine gastroscopes and colonoscopes

## Test laboratory

Clinical Microbiology Department, Hvidovre Hospital, Copenhagen University Hospital, has training the endoscopy staff at ATP measuring.

## Condition for the investigation

- The endoscopy unit follows the Danish recommendations for cleaning and disinfection of flexible endoscopes.<sup>2</sup>
  - In the reprocessing area manual cleaning is performed of all channels and the outer of the endoscope in a detergent solution. Suction- and biopsy channels are brushed. The detergent solution is discarded after each use.
  - Before storage we flush the channels with 70% alcohol, and the endoscopes can be used within 3 days.

## 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 channels<sup>1</sup>. Low-level ATP residuals indicate that patient related secretes are removed (no hepatitis B + C risk), and that the subsequent disinfection will be successfully. Log CFU (CFU = colony forming units) and Log ATP are not correlated on surfaces contaminated with human secretes.

An UNI-LITE NGI<sup>®</sup> portable luminometer and total ATP Aqua-Trace<sup>®</sup> test kits were used (3M). The relation between Relative Light Units (RLU) values from UNI-LITE NGI<sup>®</sup> ATP are earlier computed as  $\log \text{RLU} = \text{Log ATP} + 1$  (femtomol),  $R^2 = 0.99$ .

$\text{Log RLU} = \text{Log ATP-units}$  ( $10^{-14}$  mol).  $3 \log \text{ATP-units} \approx 10^{-3} \mu\text{l blood}$ .

## ATP Sampling

### Water channel

The endoscopes were connected with a sterile water bottle with sterile water. The water channels were sampled by depressing the air/water feed button. This procedure is irrigating the channel with water from the water bottle. Approximately 5 ml was collected into a sterile test tube at the distal end. ATP residuals were detected in the sampling water according to the manufacturer's instruction.

## Data presentation

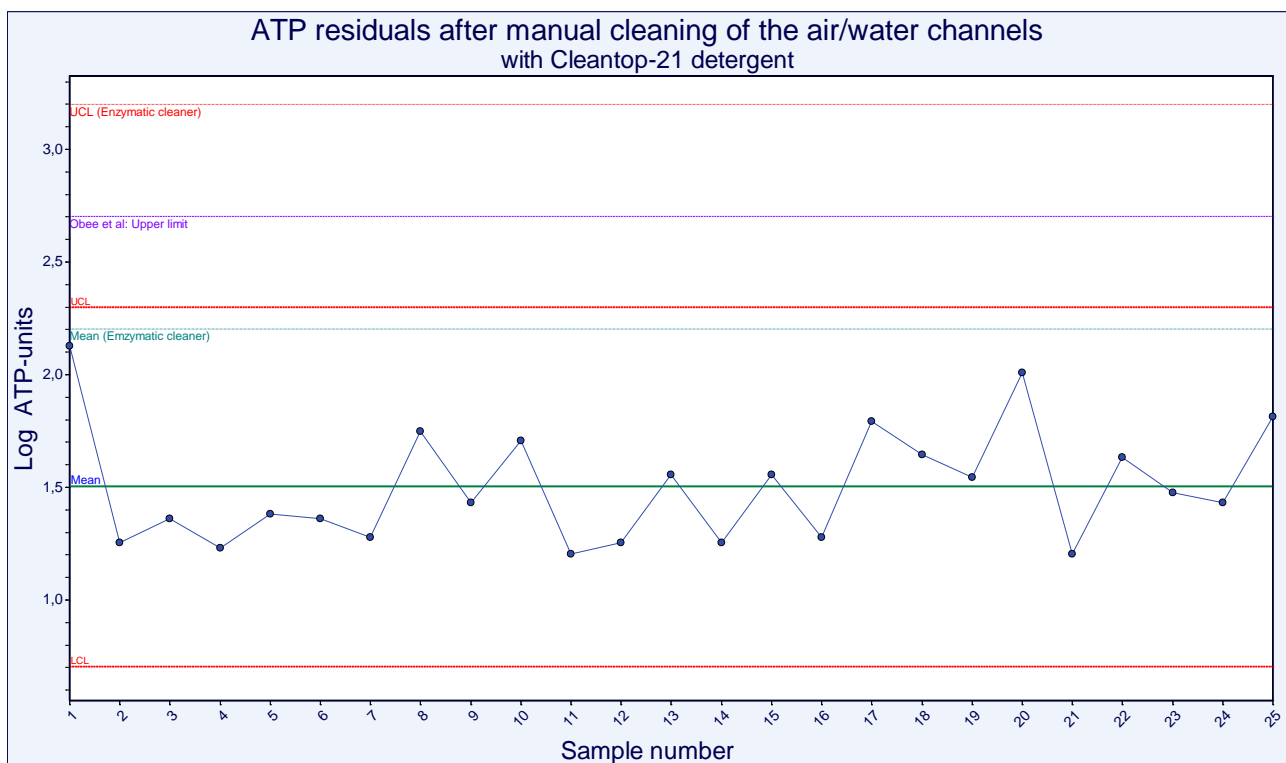
- Results were entered in a **Six Sigma Control chart** with determination of centreline (CL or mean), upper control limit (UCL) =  $\text{CL} + 3\Sigma$  and lower control limit (LCL) =  $\text{CL} - 3\Sigma$ . CL (mean) represents the central tendency of the cleaning effect.<sup>3</sup>
  - **Limits:** All results should be inside the control limits.
    - The upper limit suggested of Obee et al is  $2.7 \log \text{ATP-units}^1$

# Results

## ATP residuals after manual cleaning

### Water channel

The mean of log ATP-units was 1.5 after 25 manual cleaning procedures of the water channels of FEs with Cleantop-21<sup>®</sup>.



**Figure 1:** ATP residuals after manual cleaning of the water channel of flexible endoscopes with Cleantop-21<sup>®</sup>. Mean: Centreline, UCL: Upper control limit and LCL: Lower control limit. Centreline and upper control limit for a traditional enzymatic cleaner for FE are showed.

Figure 1 shows an effective cleaning process in statistical control (No control point outside the control limits). 100% of the endoscopes passed the upper limit suggested of Obee et al (2.7 log ATP-units)<sup>1</sup>. All results are below the centreline obtained from a traditional enzymatic cleaner for manual cleaning of FEs.

## Conclusion

1. Manual cleaning of the water channel of flexible endoscopes with Cleantop-21<sup>®</sup> is a statistical stable process. Mean log ATP-units = 1.5 (1.2-2.1).
2. Cleantop-21<sup>®</sup> can on the above and the results from the phase 3 test of the cleaning procedure of the biopsy/suction channel be recommended for manual cleaning of flexible endoscopes. The results indicate that Cleantop-21<sup>®</sup> removes blood and other human secretions from the endoscopes and by this the Hepatitis B and C risk.

04-06-2010

*Torsten Slotsbjerg*

(Torsten Slotsbjerg)

Consultant  
Clean-endoscope  
Clinical microbiologic department  
Hvidovre Hospital  
Denmark

## Dansk resume

Resterne af Adenosintrifosfat (ATP) er bestemt i vandkanalen efter 25 manuelle rengøringsprocedurer af fleksible gastro- og koloskoper. ATP findes i store mængder i blod og andre humane sekreter.

### Resultater

1. ATP-bestemmelserne viser lave resultater med relativt små variationer.
2. De målte værdier er alle under den øvre grænse, som Obee og medarbejdere har foreslået<sup>1</sup>.
3. Alle resultater ligger under den middelværdi, der tidligere er fundet efter manuel rengøring med et enzymholdigt detergent specielt til endoskoper.

### Samlet konklusion

Sammenholdes de ovenstående resultater med en fase 3 test, hvor Cleantop-21<sup>®</sup> blev anvendt ved manuel rengøring af biopsi/sugekanalen på gastro- og koloskoper<sup>5</sup>, kan produktet anbefales til manuel rengøring af fleksible endoskoper.

04-06-2010

*Torsten Slotsbjerg*

(Torsten Slotsbjerg)

Consultant  
Clean-endoscope  
Clinical microbiologic department  
Hvidovre Hospital  
Denmark

## Reference List

- (1) Obee PC, Griffith CJ, Cooper RA, Cooke RP, Bennion NE, Lewis M. Real-time monitoring in managing the decontamination of flexible gastrointestinal endoscopes. *Am J Infect Control*. 2005;33:202-206.
- (2) [Råd og anvisninger om rengøring og desinfektion af fleksible endoskoper]. *Råd og Anvisninger, Statens Seruminstitut*. 2001;4 edition, 2001.
- (3) Benneyan JC, Lloyd RC, Plsek PE. Statistical process control as a tool for research and healthcare improvement. *Qual Saf Health Care*. 2003;12:458-464.
- (4) <http://www.pinfo.rn.dk/NR/rdonlyres/0A1FA0BA-84BC-40EB-B085-3262B095ED60/0/APBlistefebbruar2009.pdf>
- (5) Clean-endoscope: In use test (phase 3 test) of Channel Cleaner<sup>®</sup> Ball Brushes applied for manual cleaning of flexible endoscopes. 2010