

# **Expert Opinion**

on the efficacy of

**EndoDet and EndoDis + EndoAct**

for cleaning and disinfection of

**Olympus Gastroscope Type GIF-2T200**

with the

**Endo Thermo Disinfector ETD3**

tested according to the recommendations for

**“Testing and Evaluating the Cleaning and  
Disinfection Efficacy of Endoscope  
Washer/Disinfectors and Disinfection Automates”**

with

***Enterococcus faecium***

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## **Summary of the results:**

The products **EndoDet** and **EndoDis + EndoAct** were tested according to the “*Recommendations for Testing and Evaluating the Cleaning and Disinfection Efficacy of Endoscope Washers / Disinfectors and Disinfection Automates* (Hyg. Med 1995: 20, 40-47)”. This method consists of a suspension test according to the DGHM-guideline, a near practice test with tube models of endoscope channels and a near practice test with original endoscopes in the washer disinfectant. The present investigation focused on the testing of tube models of endoscope channels and the reprocessing of original endoscopes in the Olympus Endo Thermo Disinfector ETD3 under use-related conditions.

In the contrary to the guideline mentioned above, samples of the rinsing fluids were not available in our test design and could not be tested for the presence of germs. Instead of this control Rodac plates were taken from the chamber of the machine.

Our tests with channel models as well as original endoscopes confirmed the safety of the reprocessing procedure with **EndoDet (0.6 %)**, **EndoDis (1.2 %)** and **EndoAct (1.2 %)** in the Endo Thermo Disinfector ETD3 for Olympus GIF-2T200 gastroscopes.

A reprocessing program with **EndoDet (0.6 %)** in the cleaning step and **EndoDis (1.2%) + EndoAct (1.2%)** in the disinfection step showed a good efficacy against *Enterococcus faecium* on artificially contaminated original gastroscopes when reprocessed in the ETD3.

The experiments are documented under B02.00219 in VTB-Hygiene & Microbiology, Henkel KGaA.

## **Introduction**

The product-combination of **EndoDet (0.6 % as cleaner)** and **EndoDis (1.2 %) + EndoAct (1.2 % as disinfectants)** was tested according to the guideline published in 'Hyg. Med. 20, 1995, p. 40 - 47 (*Testing and Evaluating the Cleaning and Disinfection Efficacy of Endoscope Washer/Disinfectors and Disinfection Automats - Testing the processing procedure under use-related conditions*) in a near practice test with an endoscope against *Enterococcus faecium*. This test procedure consists of a suspension test according to the DGHM-guideline, a near practice test with tube models of the original endoscope channels and a near practice test with artificially contaminated original endoscopes in the Olympus ETD3 washer disinfectant. The present 'Expert Judgement' focused on the testing of the processing procedure under use-related conditions with model tubes and original endoscopes.

In contrast to the guideline samples of the final rinsing fluids of the reprocessing program were not available in this test design and could not be tested for the presence of germs. Instead of this control Rodac plates were taken from the chamber of the machine.

## **Material:**

### **1. Test products**

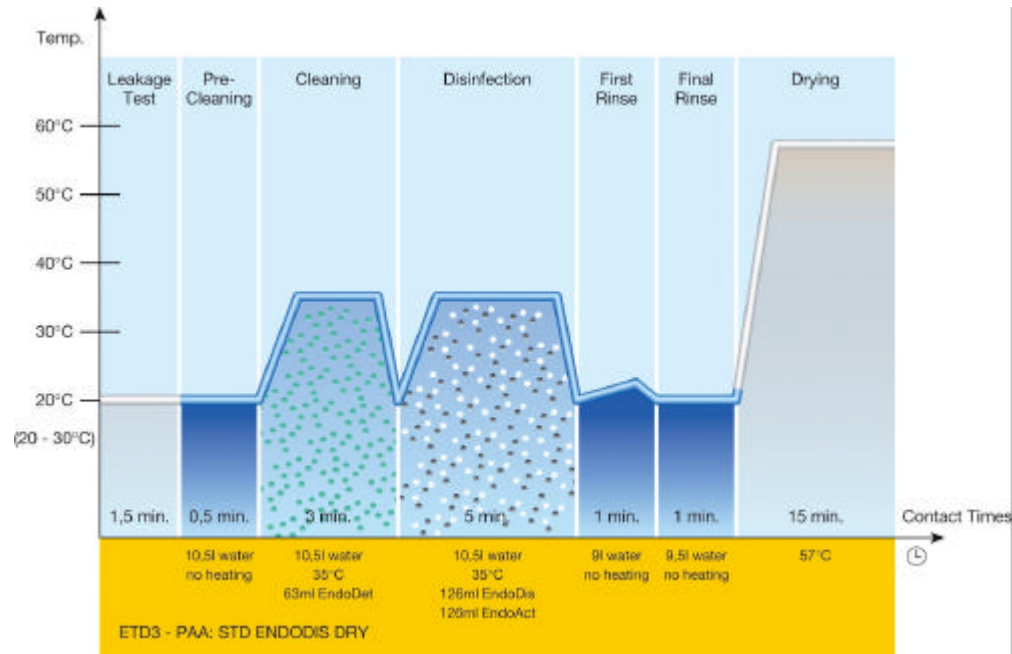
- **Cleaner: EndoDet, SN 6394-064-004T; application concentration: 0.6 %**
- **Disinfectant: EndoDis, SO 7238-185-01; application concentration: 1.2 %**
- **Aktivator: EndoAct, SO 7238-180-043; application concentration: 1.2 %**

### **2. Machine for cleaning and disinfection of endoscopes**

Olympus ETD 3

### 3. Machine program

Peracetic acid (PAA) process; program STD-EndoDIS (+DRY); total duration ca. 28,5 min.



	Leakage Test	Pre-Cleaning	Cleaning	Disinfection	1. Rinse	Final Rinse	Drying
Contact time	1,5 min	0,5 min	3 min	5 min	1 min	1 min	3 – 15 min
Water quantity		10,5 l water	10,5 l water	10,5 l water	10 l water	10 l water	
Temperature		Cold water	35 °C	35°C	Cold water	cold water	57 °C
Chemical quantity			63 ml EndoDet	126 ml EndoDis 126 ml EndoAct			

**Note:**

- Inlet water is additionally treated with 10 ppm EndoDis and UV-light in every process phase to kill microbes from fresh water.
- DRYING is an optional process

#### 4. Test Specimen

- 1 mm test tube with connective pieces (as a model for an endoscope channel)
- 2 mm test tube with connective pieces (as a model for an endoscope channel)
- Olympus Gastroscope, type GIF-2T200

#### 5. Test germs / protein load

- *Enterococcus faecium* (DSM 2146)
- Contamination of an endoscope channel, diameter 1 mm:  
Test tubes were contaminated with a mixture of 7.65 ml Caso-Bouillon + 2 ml heparinised sheep blood + 0.35 ml germ suspension and dried for 60 min at room temperature
- Contamination of an endoscope channel, diameter 2 mm:  
Test tubes were contaminated with a mixture of 9.5 heparinised sheep blood + 0.35 ml germ suspension + 0.15 ml Protamin 1000 and dried for 60 min at room temperature
- Contamination of an original endoscope:  
0.35 ml bacterial suspension was added to 9.5 ml heparinised sheep blood and mixed with 0.15 ml Protamin 1000.  
Endoscope working channel was contaminated with the blood/bacteria mixture using a sterile injection syringe and dried at room temperature for 60 minutes. After the first 30 minutes the instruments were turned to achieve an even distribution of the soil.  
Before starting the processing procedure, the channels were pre treated with the biopsy forceps to remove blood plugs inside the channel.

For contamination cell suspension with about  $2.0 \times 10^8$  cfu / ml of *Enterococcus faecium* was used in this experiment.

Control experiments showed that germ concentrations of 1.0 to 1.5 log steps below the initial count of the test organism suspension can easily be reisolated from an endoscope channel. For example starting with an inoculum of  $2.32 \times 10^8$  cfu / ml *E. faecium* about  $9.46 \times 10^7$  cfu / 20 ml rinsing fluid ( $4.73 \times 10^6$  cfu / ml) could be measured.

## 6. Neutralization solution

- 3 % Tween 80 + 0.3 % lecithin + 0.1 % thiosulphate + 0.5 % histidine.

### Method:

#### 1. Carrier test with cannal tubes (1 mm and 2 mm diameter)

Test tubes were contaminated (see point 5) and treated in the ETD3 using the cycle described above. The tubes were then rinsed with 50 ml neutralization solution which was titrated for the presence of test germs. Moreover the tube was cut into 1 cm pieces and 10 of them were incubated in neutralization broth (CaSo broth with neutralization substances, see point 6) to estimate residual germs on the surface.

#### 2. Near practice test with original gastroscopes

The working channel of the above mentioned endoscopes were contaminated with the blood-bacteria mixture indicated in section 5 using a sterile injection syringe and stored at room temperature. The endoscope was then placed in the machine described under section 2 and treated according to the program sequence indicated in section 3. For the test strain (*Enterococcus faecium*) a cleaning and disinfection cycle using **EndoDet** (0.6 %) and **EndoDis** (1.2 %) + **EndoAct** (1.2 %) on the original gastroscope Olympus GIF 2T 200 was carried out.

After having undergone the processing procedure the working channels of the endoscopes were examined by rinsing with 50 ml TLH-CaSo-solution and the germ content of this solution was determined by plate counting on CaSo agar.

In addition, Rodac-samples were taken after each test cycle of the internal machine space.

### Results:

In our investigation according to: 'Hyg. Med. 20, 1995, p. 40 - 47' (*Testing and Evaluating the Cleaning and Disinfection Efficacy of Endoscope Washer/Disinfectors and Disinfection Automats -Testing the processing procedure under use-related*

conditions), the cleaning and disinfecting process in the Olympus ETD 3 tested by using the product-combination of the cleaner **EndoDet** (0.6 %) and **EndoDis** (1.2 %) in combination with **EndoAct** (1.2 %) has shown a **good efficacy against *Enterococcus faecium*** by testing an original gastroscope Olympus type GIF-2T200.

The results are shown in the following tables. After carrying out the STD-ENDODIS-disinfection program with the product-combination of **EndoDet** (0.6 %) and **EndoDis** (1.2 %) + **EndoAct** (1.2 %) in the ETD3 *Enterococcus faecium* test germs could not be found in any model channels (see Table 1).

This was also true for the rinsing fluids received from the original endoscope (see Table 2) or rodac plate samples taken from several different points of the inner machine chamber (see Table 3).

## Conclusion

**EndoDet (0.6 %)** and **EndoDis(1.2 %)** in combination with **EndoAct (1.2 %)** proved to be highly effective in the PAA-process in the Olympus ETD3. A germ reduction of more than  $10^6$  cfu / ml for *E. faecium* could be observed for artificially contaminated original gastroscopes type Olympus GIF-2T200.

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**Table 1: Efficacy of the STD-ENDODIS program with EndoDet (0.6 %) and EndoDis (1.2 %) + EndoAct (1.2 %) in the Endo Thermo Disinfector ETD3 against E. faecium. Germ concentration found in 50 ml rinsing fluid taken from model tubes of endoscope channels after the processing procedure in the ETD 3.**

<i>Germ carrier /</i>	<i>Inoculum*</i>	<i>Germ content in 50 ml rinsing fluid</i>	
		<i>Processed tube</i>	<i>Control tube</i>
Endoscope tube 1mm diameter	Enterococcus faecium 2.76 x 10 <sup>8</sup> cfu / ml	< 1 cfu / ml	10 <sup>5.69</sup> / ml
Endoscope tube 2mm diameter	Enterococcus faecium 1.97 x 10 <sup>8</sup> cfu / ml	< 1 cfu / ml	10 <sup>6.80</sup> / ml
<b><i>Determination of residual test germs in 1 cm tube pieces</i></b>			
Tube pieces (2mm diameter tube)	Enterococcus faecium 1.97 x 10 <sup>8</sup> cfu / ml	0 from 10 positive	

\* germ count of the blood/bacteria mixture for the contamination of the endoscope

**Table 2: Efficacy of the STD-ENDODIS program with EndoDet (0.6 %) and EndoDis (1.2 %) + EndoAct (1.2 %) in the Endo Thermo Disinfector ETD3 against E. faecium. Germ concentration found in 50 ml rinsing fluid taken from the channels of an original gastroscope type GIF-2T200 after the processing procedure.**

<i>Germ carrier</i>	<i>Inoculum*</i>	<i>Germ content in 50 ml rinsing fluid</i>	
Original Gastroscope type Olympus GIF-2T200	Enterococcus faecium 1.84 x 10 <sup>8</sup> / ml	Working channel	< 1 cfu / ml
		Suction channel	< 1 cfu / ml
		Air-water-channel	< 1 cfu / ml
		Albarran-channel	< 1 cfu / ml

\* germ count of the blood/bacteria mixture for the contamination of the endoscope

**Table 3: Efficacy of the PAA program with EndoDet (0.6 %) and EndoDis (1.2 %) + EndoAct (1.2 %) in the Endo Thermo Disinfector ETD3. Results of Rodac samples taken from the machine chamber after processing an *E. faecium* contaminated gastroscopie GIF-2T200.**

<b>No.</b>	<b>Sampling location inside ETD3</b>	<b>Results on Caso-Agar</b>
1	Right wall	No germs detected
2	Left wall	No germs detected
3	Wall, above	No germs detected
4	Door	No germs detected
5	Sump, smooth place	2 cfu (but not the test germ)
6	Sump, filter	No germs detected