



Henkel KGaA

VTB Hygiene & Microbiology

Managementsystem
VTB



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Expert Judgement

Report No. 0200153

on the virus-efficacy of
the processing procedure under near use-related
conditions of

**EndoDis,
EndoDet
and EndoAct**

tested adapted to the recommendations for

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

of the
ETD 2 Cleaning and Disinfection Process
against *Bovine Parvovirus (BPV)*

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Endo dis Endoskop Parvoviren V2 e.doc

The following assessment is based on the results of an investigation undertaken at VTB-Hygiene & Microbiology of Henkel KGaA and documented in the testing facility under the laboratory number B01.02178, B02.00194 / ASS 0103566-0, ASS 0200154-0.

Introduction

In endoscopic examinations there is always the risk of transfer of viral pathogens if the equipment is not properly prepared. A cleaning and disinfection process for endoscopes must therefore exclude any risk of infection, especially the risk of transfer of HIV, hepatitis B- and hepatitis C-virus.

In this present investigation we selected Bovine Parvovirus (BPV) for the test virus. BPV is one of the most stable hitherto known conventional viruses and has a high resistance to thermal and chemical influences. It is considerably more difficult to inactivate than HIV, HBV and HCV and may be considered as a model for all viruses relevant in endoscopy.

The product-combination of **EndoDet (~0.5 %)**, **EndoDis (~1.0 %)** and **EndoAct (~1.0 %)** was tested adapted to the publication: '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/* modified) in a near practice test with an endoscope against Bovine Parvovirus (BPV).

In contrast to the guideline we used Bovine Parvovirus (BPV), 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 swaps were taken from the endoscopes and from the chamber of the machine.

Material

1. Test products

- **EndoDet**, SN 6394-064-004T; **test concentration: ~ 0.5 %**
- **EndoDis**, SO 7238-185-01; **test concentration: ~ 1.0 %**
- **Aktivator**, SO 7238-180-043; **test concentration: ~ 1.0 %**

2. Machine for cleaning and disinfection of endoscopes

Olympus ETD2 with upgrade kit for use of EndoDis (capacity 2 endoscopes).

3. Machine program

Total duration 25 min.

Cleaning

- 60 sec cold water inlet (10 l),
- heating of the water to 30-35 °C (3 to 6 min, dependent on the water inlet temperature),
- cleaning cycle: adding 60 ml EndoDet (30 sec); 5 min 30-35 °C; 30 sec drainage with circulation; 30 sec just drainage.

Disinfection

- 60 sec cold water inlet (10 l),
- Disinfection cycle: adding EndoDis and EndoAct (60 sec); heating to 35°C; disinfection at 35°C for 7 min.; 30 sec drainage with circulation; 30 sec just drainage.

First rinse

- 60 sec cold water inlet (10 l) for the first rinsing,
- 60 sec rinsing,
- 30 sec drainage with circulation; 30 sec just drainage.

Final rinse

- 60 sec cold water inlet (10 l)
- 3 min rinsing; 60 sec just drainage

4. Test Specimen

- Gastroscope; Type: Olympus GIF P Q 20

5. Test virus / indicator cells / addition load

- Bovines Parvovirus St. Haden, cultivated and titrated on bovine embryonic lung and kidney cells (BEL)
- Defibrillated mutton blood, Messrs. Froschek

The following mixture was used to contaminate the two endoscopes:

9.5 ml mutton blood
+ 0.5 ml virus suspension
+ 150 µl protamine

Endoscopes were contaminated with the blood/virus mixture using a sterile injection syringe (blood / virus-mixture: $\sim 10^7$ virus particles / 50 µl) and dried at room temperature (maximum drying time 60 minutes). After 30 minutes the instruments were turned. Before starting the processing procedure, the channels were treated with biopsy forceps.

Method

The instrument channels of the above mentioned endoscopes were contaminated with the blood/virus mixture indicated in section 5 using a sterile injection syringe and stored for 60 minutes at room temperature. The endoscope was then placed into the machine listed under section 2 and prepared according to the programme sequence indicated in section 3.

A total of 2 independent tests were carried out for the investigation.

After completion of the relevant test cycles, samples were taken using 5 swabs from the outer surface of the endoscope. The biopsy channel was examined using a little foam sponge that was pulled through the biopsy channel using biopsy forceps. In addition, 5 swab samples were taken after each test and control cycle in the bottom area of the machine internal spaces (sump).

The following points were selected as sampling points for the swabs on the endoscope:

- suction valve
- inlet of the instrument channel after detaching the coupling connection
- outlet at the distal end
- two swabs of the outer surface in the area of the control part and of the insertion tube

The swabs or sponges were shaken for 30 seconds (Vortex, 2500 rpm) immediately after preparation of the sample in 1 ml DMEM (Dulbecco's Mod. of Eagles Medium) and the remainder inoculated in portions of 50 µl each on the cell cultures of a 96-well microtitre plate. The complete rinse-solution was added on the cell cultures of a bovine embryonic lung and kidney cells (BEL) (0.5 ml per 2 ml cells 12-well microtitre plate).

The final evaluation of the plates for occurrence of the typical cytopathic effects was made after 14 days.

Results

This test showed that no residual virus could be detected in the ETD2 with upgrade kit after carrying out the standard programme. They show negative findings for all samples taken without exception in two independent tests.

The results are shown in Table 1.

In our investigation, the cleaning and disinfecting process in the Olympus ETD2 with upgrade kit tested by us using the product-combination of **EndoDet (~0.5 %)**, **EndoDis (~1.0 %)** and **EndoAct (~1.0 %)** has shown a good efficacy in two independent tests against Bovines Parvovirus on original gastroscope.

Düsseldorf, the 18th of February 2002



Prof. M. Heinzl



Dr. M. Weide

Table 1: Efficacy of the cleaning and disinfection procedure of EndoDet (~0.5 %), EndoDis (~1.0 %) and EndoAct (~1.0 %) inside the Endo Thermo Disinfector ETD2 with upgrade kit against Bovines Parvovirus. Results found in 10 ml rinsing fluid taken from the channels of an original gastroscope GIF-PQ 10 after the processing procedure, on sponge and swabs as described.

Machine	Endo-scope	Sample	Sampling Location	Results	
				Test 1	Test 2
ETD2 with upgrade kit	GIF-PQ 20	Small sponge	Biopsy channel	-	-
		Rinsing fluid (10 ml)	Biopsy channel	-	-
		Rinsing fluid (10 ml)	Air channel	-	-
		Swab	Connection-junction	-	-
		Swab	Inlet	-	-
		Swab	Outlet	-	-
		Swab	Inner-surface	-	-
		Swab	Outer-surface	-	-
	GIF-PQ 20	Small sponge	Biopsy channel	-	-
		Rinsing fluid (10 ml)	Biopsy channel	-	-
		Rinsing fluid (10 ml)	Air channel	-	-
		Swab	Connection-junction	-	-
		Swab	Inlet	-	-
		Swab	Outlet	-	-
		Swab	Inner-surface	-	-
		Swab	Outer-surface	-	-

Legend + detectable residual virus
 - no residual virus detectable

Machine	Endo- scope	Sampl e	Sampling Location	Results	
				Test 1	Test 2
not on apply	not on apply	Swap	Blood/virus-mixture	+	+

Blood / virus-mixture: $\sim 10^7$ virus particles / 50 μ l

Legend + detectable residual virus
 - no residual virus detectable