Heike Martiny, Univ. Prof. Dr. rer. nat.
Institute for Hygiene, Environmental and Occupational Medicine
Function area Hygiene and Environmental Medicine
of the Free University of Berlin.

OLYMPUS OPTICAL CO. (Europa) GmbH
Herrn Reinhard Blum
FM Sales & Marketing
Wendenstr. 14 - 16

D-20097 Hamburg

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Washing and Disinfectant Apparatus mini ETD
For the Fully Automatic Chemical-Thermal Treatment of Flexible Endoscopes

Assessment

In line with the enclosed investigation report dated 8.10.1998, the disinfecting effectiveness of the mini ETD washing and disinfection apparatus (Endo-Thermo-Disinfector) in the fully automatic, thermo-chemical treatment of flexible endoscopes was assessed.

The testing was carried out in the washing and disinfection apparatus mini ETD for endoscopes using the STANDARDplus program and the ECOplus program for the treatment of flexible endoscopes.

Results and Evaluation

Test substances:
The use of the cleaner and disinfectant in the two test runs is shown in Table 1.

Table 1: Cleaner and disinfectant consumption in the test run 1 and 2

Test Run (Program)	Cleaner Consumption [ml]	Disinfectant Consumption [ml]
1 (STANDARDplus)	20	50
2 (EC0plus)	20	50

The cleaner consumption for both programs was 20 ml. The disinfectant used in both programs was 50 ml.

The water consumption for the individual program phases was also measured for each test run and is shown in Tables 2 a and 2 b.

Table 2 a: Water consumption in the test run 1 (STANDARDplus program)

Program Phase	Water Consumption [m^3]
Pre-cleaning	0.0054
Cleaning	0.0057
Disinfection	0.0161
Rinsing	0.0098
	total: 0.0370

Table 2 b: Water consumption in the test run 2 (STANDARDplus program)

Program Phase	Water Consumption [m^3]
Pre-cleaning	0.0054
Cleaning	0.0052
Disinfection	0.0047
Rinsing	0.0048
	total: 0.0201

Checking the heat resistance of the test organism:
Reproductive test organisms were detected in 100% of the test specimens.

Colony count of the bacterial suspension:
The total colony count of the *Enterococcus faecium* bacterial suspension *(E. Faecium*: DSM 2146 and ATCC 6057 respectively) was 2.5 x 10^{10} CFU/ml[1].

Colony count of the blood-bacteria mixture:
The mean colony count of the blood bacterial mixture, consisting of 9.5 ml heparinised sheep blood, 0.35 ml bacterial suspension and 0.15 ml Protamin 1000 "Roche"®, was 4.0 x 10^{8} CFU/ml.

Treatment:
During the exposure of the test specimens in the washing and disinfection apparatus, the program phases indicated in the following tables (Table 3 a and Table 3 b) were running:

Table 3 a: Duration of the program phases and temperatures progress in test run 1 (STANDARDplus program)

Program Phase	Duration [minutes]	Maximum Temperature [°C]	Holding Period of the Maximum Temperature [minutes]
Precleaning	3	34	1
Cleaning	6	40	4
Disinfection	11	59	6
Rinsing	14	59	3

Table 3 b: Duration of the program phases and temperatures progress in test run 2 (STANDARDplus program)

Program Phase	Duration [minutes]	Maximum Temperature [°C]	Holding Period of the Maximum Temperature [minutes]
Precleaning	3	34	1
Cleaning	6	40	4
Disinfection	9	59	6
Rinsing	10	59	4

The holding periods of the maximum temperatures (40°C) achieved during the cleaning phases were 4 minutes.

[1] CFU = Colony-Forming Unit

The maximum temperature achieved in the chemical-thermal disinfection phase in both test runs was 59°C with a holding period of 6 minutes.
The treatment process in the STANDARDplus program was 34 minutes and in the ECOplus program 28 minutes.

The results of the macroscopic evaluation of the treated flexible tubing for cleanliness is shown in Table 4:

Table 4: Checking the treated test specimens for visual cleanliness for the various test runs and programs.

Test Run	Program	Test Specimen	Visual Cleanliness
	STANDARDplus	Tubing 1	(+)
	STANDARDplus	Tubing 2	(+)
	EC0plus	Tubing 4	(+)
	EC0plus	Tubing 5	(+)

All treated test specimens were judged to be macroscopically almost clean (slight residual contamination).

Determination of the recoverable bacteria:
The mean values of the colony count of the rinsing liquids of the treated and non-treated flexible tubing (= controls) are shown in Table 5:

Table 5: Recoverable colony count of the rinsing liquids of the treated and non-treated test specimens.

Test Specimen	Treatment (Program)	Colony Count [CFU/ml]
Tubing 1	yes (STANDARDplus)	0
Tubing 2	yes (STANDARDplus)	0
Tubing 3	no	3.0×10^5
Tubing 4	yes (EC0plus)	0
Tubing 5	yes (EC0plus)	0
Tubing 6	no	3.0×10^5

The mean maximum recoverable colony count of the non-treated test specimens (controls) was 3.0×10^5 CFU/ml.

Detection of the test bacterium and the bacteria remaining in the test specimen:

The results of the enriched cultures from the rinsing liquids of the treated and non-treated flexible tubing for the detection of the test bacterium and the results of the inoculated cultures for Kanamycin-Esculin-Acid-Agar are shown in Table 6.

For the quantitative detection of the remaining bacteria in the test specimens, the test specimens filled with Kanamycin-Esculin-Acid-Agar were assessed for growth of *E. faecium*. The results are shown in Table 6.

Table 6: Detection of the test bacterium in enriched cultures for Kanamcyin-Esculin-Acid-Agar in repeat determination and detection of remaining bacteria in the test specimens.

Test Specimen	Program	Growth in CSB	Growth for Kanamcyin-Esculin-Acid-Agar after incubation of	Growth in the test specimens*
		3 days	2 days	1 day
Flexible tubing 1	(STANDARDplus)	-	-/-	+
Flexible tubing 2	(STANDARDplus)	-	-/-	++
Flexible tubing 3	no treatment	+	+/+	+++
Flexible tubing 4	(ECOplus)	-	-/-	+
Flexible tubing 5	(ECOplus)	-	-/-	++
Flexible tubing 6	no treatment	+_	+/+	+++

* +: ≤ 5 CFU
++ : >5 < 25 CFU
+++: not countable

The test organism could not be detected in the enriched cultures of the rinsing liquids (CSB) of the flexible tubing 1, 2, 4 and 5.
After inoculation for the Kanamycin-Esculin-Acid-Agar, no growth of *E. faecium* was found in any of the samples of all treated test specimens (flexible tubing 1, 2, 4 an 5). In the test specimens filled with Kanamycin-Esculin-Acid-Agar only a very negligible bacterium growth of < 25 CFU per test specimen was found in all treated flexible tubing.

The results of the calculation of the reduction factors (log_{10}) for the treated test specimens are shown in Table 7:

Table 7: Calculation of the reduction factors:

Test Specimen	Program	CFU Control	CFU[2]	Reduction Factor
Tubing 1	STANDARDplus	3.0 x 105	< 1	≤ 5.5
Tubing 2	STANDARDplus	3.0 x 10'	< 1	≤ 5.5
Tubing 4	ECOplus	3.0 x 105	< 1	≤ 5.5
Tubing 5	ECOolus	3.0 x 101	< 1	≤ 5.5

The reduction factors for all treated test specimens are above 5 $\log_{10}$-steps.

In the controls, there is a differential of approximately 10^3 CFU between the incorporated bacterial count (4.0 x 10^8 CFU/ml) and recoverable bacterial count (3.0 x 10^5 CFU/ml). Therefore, a reduction of ≥ 7 $\log_{10}$-steps can even be assumed.

[2] Bitte prüfen; d. Ü.

Assessment

Adequate effectiveness is ensured in the disinfection if an infection can no longer originate from the disinfected object. This is assumed to be the case at a bacterial count reduction of > 5 $\log_{10}$-steps.

If the maximum recoverable colony count of 3.0×10^5 CFU/ml determined in the controls is used as a basis, no more bacteria should be detectable after treatment. This condition is met in all test specimens. The reduction factors (log) are clearly above the value 5. Reduction factors (log) of ≥ 5.5 have been determined.

On the basis of the present investigation result, it has been ascertained that the mini ETD washing and disinfection apparatus with the STANDARDplus and the ECOplus program in connection with the Olympus ETD-Cleaner and the Olympus ETD disinfectant is effective in the fully automatic thermo-chemical treatment of flexible endoscopes without qualification.

Summary

Under the conditions described, the use of the Olympus mini ETD washing and disinfection apparatus in connection with the Olympus ETD cleaner and the Olympus ETD disinfectant in the fully automatic thermo-chemical treatment of flexible endoscopes achieves the required disinfection results and is therefore recommended without qualification.

(Heike Martiny, Prof. Dr. rer. nat) (Beate Dietze, Physician)