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**EVALUATION OF THE ANTIMICROBIAL EFFICACY
OF AN ENDOSCOPE WASHER-DISINFECTOR
" MEDITECNIC^{SWITZERLAND} ST 02 " (MEDITECNIC S.A.)
ASSOCIATED TO THE DETERGENT "SALVANIOS PH 10"
(LABORATOIRES ANIOS) AND A PERACETIC ACID BASED
DISINFECTANT "BIOXAL 2C" (SEPPIC)**

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I : DESCRIPTION OF THE STUDY :

- ✓ Title : Evaluation of the antimicrobial efficacy of an endoscope washer/disinfector "MEDITECNIC^{SWITZERLAND} ST 02" (MEDITECNIC SA) .
- ✓ Internal reference : Study N° : 0135.MED.02
- ✓ Sponsor : MEDITECNIC S.A.
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- ✓ Test period : From 11/03/02 to 16/07/02
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II : PURPOSE OF THE STUDY :

Evaluate, as it is required in the French circular letter DH/EM1 n° 987262 15/07/98 regarding the acquisition and the use of endoscope washer-disinfector, the antimicrobial efficacy against artificially contaminated digestive endoscopes of an endoscope washer-disinfector (WD) MEDITECNIC^{SWITZERLAND} ST 02 (MEDITECNIC S.A.) associated to the detergent "SALVANIOS pH 10" (laboratoires ANIOS) and a peracetic acid based disinfectant "BIOXAL 2C" (SEPPIC).

The tested cycle is the standard washing/disinfection cycle (generally used between 2 exams) using the detergent/disinfectant couple of products provided by the manufacturer.

Seeing that the tested cycle includes two washing stages and a disinfection phase, we have decided, according to our previous studies and published scientific data⁽¹⁾, to set the minimal required logarithmic reductions for a standard disinfection level (not sporicidal) of endoscopes to :

- ✓ 7 log for bacteria (*Pseudomonas aeruginosa*)
 - ✓ 6 log for fungi (*Aspergillus niger*)
 - ✓ 5 log for mycobacteria (*Mycobacterium terrae*) and
 - ✓ 4 log for bacterial spores (*Bacillus subtilis* and *Bacillus cereus*)
- and for a reinforced disinfection level (for which the sporicidal activity is required) to :
- ✓ 7 log for bacteria (*Pseudomonas aeruginosa*)
 - ✓ 6 log for fungi (*Aspergillus niger*)
 - ✓ 5 log for mycobacteria (*Mycobacterium terrae*) and
 - ✓ 6 log for bacterial spores (*Bacillus subtilis* and *Bacillus cereus*).

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The choice of the bacterial test strains is guided by the study of Spach⁽²⁾ which shows that *Pseudomonas aeruginosa* is the more frequently recovered bacteria in infections and colonisations associated to gastroscopy and coloscopy. *Aspergillus niger* and *Mycobacterium terrae* will allow us to widen the evaluation towards interesting microorganisms for bronchoscopy. Two bacterial spores (*B. subtilis* and *B. cereus*) are also used regarding their different sensibility to disinfectants.

III : PRINCIPLE :

All channels of a fiberscope (biopsy, suction, air/water) are artificially contaminated with a bacterial suspension containing interfering substances (10% foetal calf serum) and then submitted to the tested process. At the end of the standard washing-disinfection cycle, endoscopes are sampled using a validated recovering solution.

The efficiency of the automatic process is evaluated by comparing the contamination level of endoscopes before and after the washing-disinfection cycle.

Rq: All assays are performed without endoscope pre-treatment (wiping, suction, forced insufflation and swabbing) in order to perform the test in worst case conditions..

IV : MATERIAL :

a) Endoscopes :

Gastroscope Olympus GIF V
Gastroscope Olympus GIF V2
Duodenoscope Olympus JF 1T10

b) Microbial strains :

Pseudomonas aeruginosa CIP 103467
Aspergillus niger CIP 1431-83
Mycobacterium terrae CIP 104321
Bacillus subtilis globigii ATCC 9372 spores
Bacillus cereus CIP 78.3 spores

Those microbial strains correspond to the reference microbial strains of the CEN and AFNOR standards in force for the determination of the antimicrobial activities of disinfectants.

c) Interfering substances :

Foetal calf serumSigma N4637 batch n°: 10K8404

d) Recovering solution :

Tween 80.....3% (v/v) Sigma P17-54 batch n°: 121K0041
Lecithin.....0,3% (m/v) Sigma P53-94 batch n°: 128H8002
L-Histidin.....0,1% (m/v) Sigma H8000 batch n°: 11K0894
Sodium thiosulphate.....0,5%(m/v)Sigma S85-03 batch n°: 110K0284
Demineralized water.....qsp 100 ml

Steam sterilized 121°C for 20 min

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e) Endoscopes washer-disinfector :

- ✓ Name : MEDITECNIC^{SWITZERLAND} ST 02
- ✓ Description : Endoscope washer-disinfector, single chamber, 1 endoscope per chamber.
- ✓ Manufacturer: MEDITECNINC S.A.

PHASES	Nb. of phases	Time	Chemicals	Temperature
			Nature	
Cleaning	1	2 minutes	SALVANIOS pH 10 ^a - 0.5%	30°C
Rinsing	1	50 seconds	0.2µm filtered water	-
Cleaning	1	2 minutes	SALVANIOS pH ^a - 0.5%	30°C
Rinsing	1	50 seconds	0.2µm filtered water	30°C
Disinfection	1	10 minutes	Bioxal 2C ^b 3% (v/v) (1.5% (v/v) solution A + 1.5% (v/v) solution B) 750 ppm peracetic acid	30°C
Rinsing	1	1 minute	0.2µm filtered water	30°C

Table I : Characteristics of the tested cleaning/disinfection cycle :

- a) Detergent SALVANIOS pH 10 (laboratoires ANIOS) Batch n° : C16420
- b) Peracetic acid based disinfectant (BIOXAL EC) (SEPPIC, Activator batch n° : 262-81-2, base batch n° : 268-149-1)

f) Detergent :

Nature : Detergent pre-disinfectant for medical devices.

Manufacturer : Laboratoires ANIOS

Composition : Guanidinium acetate, quaternary ammonium propionate, non ionic detergent, Mg²⁺ and Ca²⁺ chelating agent

Batch n° : C16420

Tested concentration : 0.5%

g) Désinfectant :

Nature : Peracetic acid based disinfectant reconstituted from solution A (activator) and solution B (base).

Manufacturer : SEPPIC

Composition : Solution A : Peracetic acid 5%, hydrogen peroxide and acetic acid
Solution B : Potassium hydroxide 5-25%

Batch n° : Solution A : 268-149-1
Solution B : 262-81-2

Tested concentrations : 3% (v/v) (1.5% (v/v) solution A + 1.5% (v/v) solution B) that is to say 750 ppm

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V : METHOD :

The successive steps of the test method are :

- An experimental contamination of endoscope channels by injecting (using an all channels irrigator) 15 ml of a bacterial suspension containing 10% of calf foetal serum.
- After 30 minutes of incubation, the endoscope is submitted to the automatic washing-disinfection cycle without pre-treatment of the endoscope before.
- At the end of the automatic washing-disinfection cycle the endoscope is sampled by injecting 100 ml of the recovering solution in endoscope channels with an all channel irrigator and 50 ml via the biopsy channel port.
- Filtration of the samples through 0.45µm membrane filters and incubation on counting medium for specific incubation time and temperature.

For each tested microorganism, flushing solution, maintaining and counting medium and incubation conditions are those recommended by CEN and AFNOR standards in force.

<i>Microbial strains</i>	<i>Incubation temperature</i>	<i>Maintaining and counting medium</i>	<i>Incubation time</i>
<i>Pseudomonas aeruginosa</i> CIP 103467	37°C +/- 1°C	<i>trypcase soya agar</i>	48 hours
<i>Aspergillus niger</i> CIP 1431-83	30°C +/- 1°C	<i>Malt extract agar</i>	48-72 hours
<i>Bacillus subtilis globigii</i> ATCC 9 372	30°C +/- 1°C	<i>DBS agar</i>	72 hours
<i>Bacillus cereus</i> CIP 78.3	30°C +/- 1°C		72 hours
<i>Mycobacterium terrae</i> CIP 104321	30°C +/- 1°C	<i>7H11 agar</i>	7 days

Table II : Incubation conditions : Temperature and incubation times for each microbial strain.

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VI : RESULTS :

Results obtained for each bacterial strain, after treatment of endoscopes with the washing/disinfection cycle of MEDITECNIC^{SWITZERLAND} ST 02 including two cleaning stages of 2 minutes [SALVANIOS pH 10 (Laboratoires ANIOS)] and a 10 minutes disinfection stage [BIOXAL 2c (SEPPIC)], without pre-treatment, are presented in tables V to IX.

The mean, minimal and maximum values of the logarithmic reductions obtained for each test micro-organism are presented in table III.

Microorganisms	Short cycle 32 min		
	Mean	Min.	Max.
<i>Pseudomonas aeruginosa</i> CIP 103467	8,7±0,1	8,6	8,8
<i>Aspergillus niger</i> ATCC 16404	6,5±0,2	6,4	6,9
<i>Mycobacterium terrae</i> CIP 104321	7,1±0,2	6,8	7,3
<i>Bacillus subtilis</i> ATCC 9372	7,2±0,8	6,3	8,3
<i>Bacillus cereus</i> CIP 78.3	6,8±0,5	6,2	7,7

Table III : Results. Mean, minimal and maximum values of the logarithmic reductions obtained for each test micro-organism after treatment of endoscopes with the washing/disinfection cycle of MEDITECNIC^{SWITZERLAND} ST 02, without endoscope pre-treatment.

Mean logarithmic reductions obtained for each bacterial strain (see table III) after treatment of endoscopes with the washing/disinfection cycle of MEDITECNIC^{SWITZERLAND} ST 02 including two cleaning stages of 2 minutes [SALVANIOS pH 10 (Laboratoires ANIOS)] and a 10 minutes disinfection stage [BIOXAL 2c (SEPPIC)], are consistent with requirements whatever disinfection level is considered (standard or reinforced).

Independent analysis of each assay (see table IV) shows that even if endoscopes are not submitted to pre-treatment before being processed in the WD, all assays are consistent with minimal logarithmic reductions required, whatever disinfection level is considered (standard or reinforced) and whatever bacterial strain is used.

Microorganisms	NB. of consistent assays/Nb. of assays performed	
	Standard disinfection level	Reinforced disinfection level
<i>Pseudomonas aeruginosa</i> CIP 103467	6/6	6/6
<i>Aspergillus niger</i> CIP 1431-83	6/6	6/6
<i>Bacillus cereus</i> CIP 78.3	6/6	6/6
<i>Bacillus subtilis</i> ATCC 9372	6/6	6/6
<i>Mycobacterium terrae</i> CIP 104321	6/6	6/6

Table IV : Results. Distribution of the number of consistent assays compared to the number of assays performed for each tested microbial strain without pre-treatment, according to the disinfection level considered.

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VII : CONCLUSION :

SCORE
MEDITECNIC^{SWITZERLAND} ST 02 /SALVANIOS pH 10 / PAA BIOXAL 2C
(number of consistent assays / number of assays performed) X 5

	Double cleaning stage cycle, without pre-treatment	
Standard disinfection level	5/5	● ● ● ● ●
Reinforced disinfection level	5/5	● ● ● ● ●

Results obtained with the washing-disinfection cycle of the MEDITECNIC^{SWITZERLAND} ST 02 cycle (double cleaning stage with SALVANIOS pH 10 and one disinfection stage with BIOXAL 2C), without endoscope pre-treatment¹, are very satisfactory whatever disinfection level is considered : standard (score 5/5) or reinforced (score 5/5).

VIII : REFERENCES :

1. W. Rutala, D. Weber – FDA labeling Requirements for Disinfection of Endoscopes : A Counterpoint – Infect Control Hosp Epidemiol, 1995, 4, 231-35
2. D.H. Spach, F.E. Silverstein, W.E. Stamm – Transmission of infection by gastrointestinal endoscopy and bronchoscopy – Ann. Intern. Med., 1993, 2, 117-128.

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R E C H E R C H E & D E V E L O P P E M E N T**TABLE V**

Endoscope contamination levels after treatment with the washing-disinfection cycle of *MEDITECNIC*^{SWITZERLAND} *ST 02* associated to "Salvanios pH 10 – 0.5% (v/v)" (2 x 2 minutes) and "Bioxal 2C" (10 minutes)

Pseudomonas aeruginosa CIP 103467

<i>Endoscopes</i>	<i>Endoscope contamination levels Number of CFU / endoscope</i>		<i>Logarithmic reductions</i>
	<i>Before treatment</i>	<i>After treatment</i>	
Without endoscope pre-treatment			
Duodeno JF 1T10	3,8.10 ⁸	0	8,6
Gastro GIF V2	3,9.10 ⁸	0	8,6
Gastro GIF V2	6,6.10 ⁸	0	8,8
Gastro GIF V2	3,9.10 ⁸	1	8,6
Gastro GIF V2	6,2.10 ⁹	13	8,7
Gastro GIF V2	6,8.10 ⁸	0	8,8

¹ Without wiping of external parts, suction of biopsy channel, forced insufflation of air and water channels and swabbing of biopsy and suction channels.

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TABLE VI

Endoscope contamination levels after treatment with the washing-disinfection cycle of *MEDITECNIC*^{SWITZERLAND} *ST 02* associated to "Salvanios pH 10 – 0.5% (v/v)" (2 x 2 minutes) and "Bioxal 2C" (10 minutes)

Aspergillus niger ATCC 16404

<i>Endoscopes</i>	<i>Endoscope contamination levels Number of CFU / endoscope</i>		<i>Logarithmic reductions</i>
	<i>Before treatment</i>	<i>After treatment</i>	
Without endoscope pre-treatment			
Duodéno JF 1T10	2,7.10 ⁶	0	6,4
Duodéno JF 1T10	3,8.10 ⁶	0	6,6
Gastro GIF V2	7,7.10 ⁶	0	6,9
Gastro GIF V2	2,3.10 ⁶	0	6,4
Gastro GIF V2	2,4.10 ⁶	1	6,4
Gastro GIF V2	2,9.10 ⁶	0	6,5

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R E C H E R C H E & D E V E L O P P E M E N T****TABLE VII**

Endoscope contamination levels after treatment with the washing-disinfection cycle of *MEDITECNIC*^{SWITZERLAND} *ST 02* associated to "Salvanios pH 10 – 0.5% (v/v)" (2 x 2 minutes) and "Bioxal 2C" (10 minutes)

***Bacillus subtilis* ATCC 9372**

<i>Endoscopes</i>	<i>Endoscope contamination levels Number of CFU / endoscope</i>		<i>Logarithmic reductions</i>
	<i>Before treatment</i>	<i>After treatment</i>	

Without endoscope pre-treatment			
Duodéno JF1T10	2,9.10 ⁸	6	7,7
Gastro GIF V2	8,3.10 ⁸	4	8,3
Gastro GIF V	1,3.10 ⁸	4	7,5
Gastro GIF V2	1,0.10 ⁸	29	6,6
Gastro GIF V2	7,5.10 ⁷	39	6,3
Gastro GIF V2	7,5.10 ⁷	11	6,8

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R E C H E R C H E & D E V E L O P P E M E N T**TABLE VIII**

Endoscope contamination levels after treatment with the washing-disinfection cycle of *MEDITECNIC*^{SWITZERLAND} *ST 02* associated to "Salvanios pH 10 – 0.5% (v/v)" (2 x 2 minutes) and "Bioxal 2C" (10 minutes)

Bacillus cereus CIP 78.3

<i>Endoscopes</i>	<i>Endoscope contamination levels Number of CFU / endoscope</i>		<i>Logarithmic reductions</i>
	<i>Before treatment</i>	<i>After treatment</i>	
Without endoscope pre-treatment			
Gastro GIF V	4,4.10 ⁸	23	7,2
Gastro GIF V	2,9.10 ⁸	6	7,7
Gastro GIF V2	2,9.10 ⁸	83	6,5
Gastro GIF V2	6,3.10 ⁸	360	6,2
Gastro GIF V2	3,7.10 ⁸	135	6,4
Gastro GIF V2	3,0.10 ⁸	41	6,9

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TABLE IX

Endoscope contamination levels after treatment with the washing-disinfection cycle of *MEDITECNIC*^{SWITZERLAND} ST 02 associated to "Salvanios pH 10 – 0.5% (v/v)" (2 x 2 minutes) and "Bioxal 2C" (10 minutes)

Mycobacterium terrae CIP 104321

<i>Endoscopes</i>	<i>Endoscope contamination levels Number of CFU / endoscope</i>		<i>Logarithmic reductions</i>
	<i>Before treatment</i>	<i>After treatment</i>	
Without endoscope pre-treatment			
Gastro GIF V2	1,4.10 ⁹	85	7,2
Gastro GIF V2	7,4.10 ⁸	51	7,2
Gastro GIF V2	6,5.10 ⁸	31	7,3
Gastro GIF V2	6,9.10 ⁸	71	7,0
Gastro GIF V2	7,7.10 ⁸	103	6,9
Gastro GIF V2	8,6.10 ⁸	121	6,8

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