

STERILOX

THE MICROBIOLOGICAL EFFICACY OF STERILOX

SPORICIDAL TEST RESULTS

Using the AOAC carrier test (966.04) Sterilox was tested against *B. subtilis* and *C. sporogenes* spores on Dacron loops and porcelain penicylinders.

Organism	Test	Sterilox Concentration	Result
<i>B. subtilis</i>	AOAC (966.04)	650 at 25°C	Pass - 24 hrs
<i>C. sporogenes</i>	AOAC (966.04)	650 at 25°C	Pass - 24 hrs

Sterilox has also shown to be rapidly sporicidal against the following bacteria:

Organism	Test	Sterilox Concentration	Result
<i>B. subtilis var niger</i>	Suspension + 1% serum	300 - 400AFC	7 log-5 mins
<i>C. difficile**</i>	Suspension + 1% serum	300 - 400AFC	>5 log-5 mins

* J.B. Selkon, J.R. Babb and R. Morris. Journal of Hospital Infection (1999) 41: 59-70 (tests done at 300-400AFC)

** N. Shetty, S. Srinivasan, J. Holton and G.L. Ridgway. Journal of Hospital Infection (1999) 41: 101-105. (tests done at 300-400AFC)

MYCOBACTERIUM / TUBERCULOCIDAL TEST RESULTS

The AOAC Quantified Tuberculocidal suspension test (965.12) was carried out using Sterilox at 20°C against *Mycobacterium bovis* (BCG). Sterilox is tuberculocidal at less than MRC in 10 minutes.

Organism	Test	Sterilox Concentration	Result
<i>Mycobacterium bovis</i> (BCG)	AOAC 965.12	600AFC	Pass - 10 mins

Sterilox has also shown to be rapidly efficacious against a range of medically important mycobacteria:

Organism	Test	Sterilox Concentration	Result
<i>M. tuberculosis*</i>	Suspension + 1% serum	300 - 400AFC	>5.3 log-4 mins
<i>M. avium intracellulare*</i>	Suspension + 5% serum	300 - 400AFC	>6 log-2 mins
<i>M. smegmatis**</i>	Suspension + 5% serum	300 - 400AFC	>8 log-2 mins
<i>M. xenopi**</i>	Suspension + 5% serum	300 - 400AFC	>5 log-2 mins
<i>M. chelonae**</i>	Suspension + 5% serum	300 - 400AFC	>5 log-2 mins

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BACTERICIDAL TEST RESULTS

The AOAC Use Dilution Test (955.14) was used to test the bactericidal activity of Sterilox at 20°C. The results show that Sterilox is bactericidal in a maximum time of 5 minutes.

Organism	Test	Sterilox Concentration	Result
<i>S. choleraesuis</i>	AOAC 955.14	400AFC	Pass - 5 mins
<i>S. aureus</i>	AOAC 955.14	400AFC	Pass - 5 mins
<i>P. aeruginosa</i>	AOAC 955.14	600AFC	Pass - 5 mins

Sterilox has also shown to be efficacious against the following pathogenic bacteria:

Organism	Test	Sterilox Concentration	Result
<i>E. coli</i> NCTC 12900* (O157 type strain)	Suspension + 5% serum	300 - 400AFC	>7 log-5 mins
VRE**	Suspension + 5% serum	300 - 400AFC	>7 log-2 mins
<i>Helicobacter pylori**</i>	Suspension + 5% serum	300 - 400AFC	>7 log-2 mins

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FUNGICIDAL TEST RESULTS

T. mentagrophytes was exposed to Sterilox according to the methods of the AOAC Fungicidal Activity of Disinfectants Test (955.17). No growth was observed within a 2.5 minute contact time. These results indicated there is a margin-of-safety in the high-level disinfection label claim of 10 minutes.

Organism	Test	Sterilox Concentration	Result
<i>T. mentagrophytes</i>	AOAC 955.17	300AFC	Pass - 2.5 mins

Sterilox has also shown to be efficacious against the following organisms:

Organism	Test	Sterilox Concentration	Result
<i>Aspergillus niger</i>	EN 1275 suspension	300 - 400AFC	4 log-5 mins
<i>Candida albicans*</i>	Suspension + 5% serum	300 - 400AFC	>5.2 log-2 mins

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VIRUCIDAL TEST RESULTS

Sterilox was tested at 20°C against *Herpes simplex* using EPA virucidal methods test method (DIS/TSS-7). Sterilox effectively neutralized *Herpes simplex* virus within 5 minutes of exposure. These results indicate there is a margin-of-safety in the high-level disinfection label claim of 10 minutes.

Organism	Test	Sterilox Concentration	Result
<i>Herpes simplex</i>	EPA (DIS/TSS-7)	600AFC	Pass - 5 mins

Sterilox has also shown to be efficacious against the following organisms:

Organism	Test	Sterilox Concentration	Result
Poliovirus Type 2*	Suspension	300 - 400AFC	>4.5 log - 2 mins
Duck Hepatitis B	Suspension	300 - 400AFC	6 log - 2 mins
HIV 1*	Suspension	300 - 400AFC	>4.5 log - 2 mins

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STERILOX HAS BEEN EXTENSIVELY

TESTED TO DEMONSTRATE OUTSTANDING

GERMICIDAL EFFICACY.

WITH A CONTACT TIME OF 10 MINUTES

FOR HIGH-LEVEL DISINFECTION,

STERILOX IS EFFECTIVE IN KILLING

BACTERIAL ENDOSPORES, BACTERIA

(INCLUDING RESISTANT MYCOBACTERIA),

VIRUSES AND FUNGI.

CLINICAL IN-USE STUDIES

STUDY LOCATION

Clinical in-use studies were performed at two UK hospitals, with Sterilox below its US MRC. A total of 12 Olympus bronchoscopes, 15 Olympus colonoscopes and 9 Olympus gastroscopes were sampled at random using the following protocol:

- 20 ml 0.9% saline samples were taken immediately from the suction channels following patient use.
- After clinical procedures, all endoscopes were manually pre-cleaned following endoscope manufacturers' and the Society of Gastroenterology, Nurses, and Associates guidelines.
- Endoscopes were reprocessed in a QED automatic endoscope reprocessor following the manufacturer's instructions. The Sterilox disinfection cycle was of 5-minute duration. Sterilox at 180-220AFC was used.
- 20 ml 0.9% saline samples were taken immediately from the suction channels following endoscope reprocessing.
- All samples were incubated on selective media at 37°C either aerobically or anaerobically for 3 to 5 days.

RESULTS

Endoscope Type	Number of Endoscopes Tested	Total CFU/ml	
		Pre-Treatment	Post Treatment
Bronchoscope	12	3.09x10 ⁴	0
Colonoscope	15	2.41x10 ⁵	0
Gastroscopes	9	6.2x10 ⁴	0

Results show Sterilox germicide at well below its MRC to be completely effective in high-level disinfecting endoscopes in 5 minutes during routine clinical instrument reprocessing.

SIMULATED USE STUDIES

Simulated use tests were performed below MRC against the following organisms dried onto the surface and internal channels of flexible endoscopes:

- *Bacillus subtilis* spores with 3% v/v heat activated calf serum (HACS)
- *Clostridium sporogenes* spores with 10% HACS
- *Mycobacterium terrae* with 5% HACS

Three flexible endoscopes models representing examples of the most complex and difficult devices to reprocess were studied:

Endoscope	Model	Design Feature
Olympus Duodenofiberscope	TJF-140F	Elevator guide wire channel: extremely small diameter and because of the high pressures required for flow
Pentax Colonoscope	EC 3840TL	Dual biopsy channel
Olympus Bronchoscope	BF-IT30	Small diameter working channel

THE FOLLOWING PROTOCOL WAS USED:

- All internal channels of the endoscopes were contaminated according to the ASTM protocol E 1837-96.
- The external body was contaminated by swabbing twice.
- The endoscopes were air dried at room temperature for 60 minutes.
- The endoscopes were NOT cleaned or reprocessed prior to subsequent test cycles.
- The endoscope was disinfected with Sterilox below MRC according to the Sterilox user manual, for 10 minutes (*Mycobacterium terrae*) or 30 minutes (*B. subtilis* and *C. sporogenes* spores).
- A sterile brush was used to sample the biopsy channel; the brush tip was aseptically removed after it exited the distal end of the endoscope and cultured for growth.
- Each internal channel was then flushed 3 times with 10 ml of sterile saline. All rinsates were filtered through a 0.45 mm filter, placed on trypticase Soy Agar plates and incubated at 37°C for 24 to 48 hours.
- Inoculated external surfaces of each instrument were rubbed with two cotton swabs moistened with sterile saline solution. Both swabs were placed in the same recovery tube, exposed to ultrasound for 5 minutes and the fluid expressed from the swabs used for culturing. The fluid was filtered through a 0.45 mm filter, placed on trypticase Soy Agar plates and incubated at 37°C for 24 to 48 hours.

RESULTS

Greater than six (6) log reduction of the challenge organism (*B. subtilis*, *C. sporogenes* or *M. terrae*) was observed in all channels on all scopes (Table).

Endoscope Model	Sterilox Contact Time & Temperature Load	% Calf Serum Organic CFU/ml	Test Organism	Average Site Inoculum	Endoscope Sites Tested	Result
Olympus Duodenofiberscope	30 min 20°C 600AFC	3	<i>Bacillus subtilis</i>	2.3x10 ⁶ 1.7x10 ⁷ 1.5x10 ⁷ 1.8x10 ⁷	Exterior Surface Biopsy Channel Elevator Guide Wire Air Water Channel Rinsate	>log 6 kill
Pentax Colonoscope	30 min 20°C 600AFC	3	<i>Bacillus subtilis</i>	1.1x10 ⁶ 6.1x10 ⁶ 4.0x10 ⁶ 1.3x10 ⁶	Exterior Surface Biopsy Channel Elevator Guide Wire Fwd Water Jet Channel Rinsate	>log 6 kill
Olympus Bronchoscope	30 min 20°C 600AFC	3	<i>Bacillus subtilis</i>	1.1x10 ⁶ 1.5x10 ⁶	Exterior Surface Working Channel Rinsate	>log 6 kill
Olympus Duodenofiberscope	30 min 25°C 600AFC	5	<i>Clostridium sporogenes</i>	1.2x10 ⁶ 4.0x10 ⁶ 3.4x10 ⁶ 1.7x10 ⁶	Exterior Surface Biopsy Channel Elevator Guide Wire Air Water Channel Rinsate	>log 6 kill
Pentax Colonoscope	30 min 25°C 600AFC	10	<i>Clostridium sporogenes</i>	1.1x10 ⁶ 5.9x10 ⁶ 8.1x10 ⁶ 9.0x10 ⁶	Exterior Surface Biopsy Channel Elevator Guide Wire Fwd Water Jet Channel Rinsate	>log 6 kill
Olympus Duodeno fiberscope	10 min 25°C 600AFC	5	<i>Mycobacterium terrae</i>	2.8x10 ⁴ 2.3x10 ⁷ 2.4x10 ⁷ 9.6x10 ⁶	Exterior Surface Biopsy Channel Elevator Guide Wire Air Water Channel Rinsate	>log 6 kill
Pentax Colonoscope	10 min 25°C 600AFC	5	<i>Mycobacterium terrae</i>	1.1x10 ⁶ 6.1x10 ⁶ 1.4x10 ⁶ 5.1x10 ⁶	Exterior Surface Biopsy Channel Air Water Channel Fwd Water Jet Channel Rinsate	>log 6 kill