

**THE MICROBIOLOGICAL
EFFICACY OF
STERILOX**

THE TOTAL SOLUTION

STERILOX

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.

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 penicillinders.

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)

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 NCTC 12900*</i> (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

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

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

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
<i>Poliovirus Type 2*</i>	Suspension	300 - 400AFC	>4.5 log - 2 mins
<i>Duck Hepatitis B</i>	Suspension	300 - 400AFC	6 log - 2 mins
<i>HIV 1*</i>	Suspension	300 - 400AFC	>4.5 log - 2 mins

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

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:

1. All internal channels of the endoscopes were contaminated according to the ASTM protocol E 1837-96.
2. The external body was contaminated by swabbing twice.
3. The endoscopes were air dried at room temperature for 60 minutes.
4. The endoscopes were NOT cleaned or reprocessed prior to subsequent test cycles.

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

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:

1. 20 ml 0.9% saline samples were taken immediately from the suction channels following patient use.
2. After clinical procedures, all endoscopes were manually pre-cleaned following endoscope manufacturers' and the Society of Gastroenterology, Nurses, and Associates guidelines.
3. 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.
4. 20 ml 0.9% saline samples were taken immediately from the suction channels following endoscope reprocessing.
5. 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	3.09 x 10 ⁴	0
Colonoscope	15	2.41 x 10 ⁵	0
Gastroscopes	9	6.2 x 10 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.

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