

# **Sterilox Clinical In-Use Studies**

## **1. Objectives**

The objective of this study was to evaluate the efficacy of Sterilox in the decontamination of flexible endoscopes within a clinical environment. Two hospitals within the United Kingdom, which routinely use Sterilox as a liquid chemical germicide during the reprocessing of flexible endoscopes, were selected as clinical study sites. All samples were taken during the course of clinical endoscopy procedures and assessed by the hospital diagnostic microbiology laboratories for microbial contamination before and after disinfection with Sterilox.

## **2. Methods**

### **2.1. Location of Study**

A total of 25 Olympus endoscopes were sampled at random from The Royal Haslar Hospital (Gosport, Hants, UK).

A total of 7 Olympus colonoscopes and 12 Olympus bronchoscopes were sampled at random from Leeds General Infirmary (Great George St, Leeds, UK).

### **2.2. Sterilox Liquid Chemical Disinfectant**

The Sterilox 2501 generator was used according to the user manual (1) to produce Sterilox solution at concentrations of between 180-220 ppm Available Free Chlorine (AFC). The Sterilox generator was used in combination with either a QED Single automatic washer disinfectant (Leeds) or QED Double automatic washer disinfectant (Royal Haslar) according to the manufacturers instructions (2).

### **2.3. Endoscope Reprocessing**

After clinical procedures, all endoscopes were manually precleaned in warm water using a high alkaline ionic detergent following endoscope manufacturers' and the British Society of Gastroenterology (the British equivalent of The Society of Gastroenterology Nurses and Associates) guidelines. Then endoscopes were attached to a QED automatic endoscope reprocessor following the manufacturers instructions (2) and run through the routine Sterilox reprocessing cycle (180 second wash using recommended detergent, 90 second rinse, 5 minute Sterilox disinfection cycle and 90 second rinse cycle in bacteria-free water).

### **2.4. Sampling Technique**

A sample from the suction channel of each endoscope were taken immediately after patient use and following endoscope reprocessing. The suction channel of each endoscope was sampled by placing the distal end of the scope into 0.9% sterile saline. The end of one arm of the endoscope secretion trap was located firmly over the suction valve hole in the control head of the endoscope. The other arm of the

secretion trap was attached to a suction pump by means of sterile plastic tubing. Suction was applied until 20 ml of saline had been flushed through the channel of the endoscope and into the main vessel of the bronchial secretion trap for collection. All samples were processed for culture within 2 hours of collection. It was unnecessary to add a neutralizer to the saline solution collection medium as any Sterilox remaining within the endoscope following the disinfection cycle is diluted to an ineffective antibacterial concentration by the final rinse cycle of the washer disinfectant machine.

## 2.5. Microbiological Analysis

All samples from both sites were serially diluted in  $10^{-6}$  strength in Ringers solution (Oxoid Code BR52) and plated out in triplicate. All batches of growth media used in the studies were checked to ensure that they would support the growth of clinical specimens by the hospital media laboratory facility.

At Royal Haslar, 10  $\mu$ l loop of each dilution was spread onto one of the following media, (i) CLED agar, (ii) blood agar, (iii) blood agar plus a metronidazole antibiotic disc or (iv) chocolate agar. All samples were incubated at 37°C either aerobically (CLED agar), in a CO<sub>2</sub> incubator (blood and chocolate agar) or anaerobically (blood agar + Mz disc). Following incubations, colony-forming units (CFUs) were counted. The test method at Royal Haslar has a detection limit of 100 CFU per ml of sample recovered from the endoscope.

At Leeds Infirmary, 0.1 ml of each dilution was spread onto Columbia agar plates containing horse blood. All samples were either incubated aerobically 37°C for 3 days or anaerobically incubated at 37°C for 5 days. Following incubation colony forming units were counted. The test method at Leeds has a detection limit of 10 CFU per ml of sample recovered from the endoscope.

## 3. Results

### 3.1. Royal Hospital Haslar

Microbial levels after patient use and prior to reprocessing ranged from  $10^3$ - $10^5$  CFU/ml (Table 1). Average bioburden levels were  $1.15 \times 10^5$  CFU/ml in the colonoscopes and  $1.3 \times 10^5$  CFU/ml in the gastroscopes. Using an independent group t-test, no statistical difference was observed at the 5% level (p-value 0.4974) between the mean bioburden values in the suction channels of colonoscope and gastroscopes. Selective identification of the bioburden on the colonoscopes showed the main contaminants to be coliform bacilli. Bioburden levels on eight endoscopes were below the limit of assay detection.

Following reprocessing, no detectable surviving microorganisms were observed except in one sample isolated from a colonoscope (Table 1). This was subsequently identified as a coagulase negative *Staphylococcus* and verified by the hospital diagnostic laboratory to be a staff handling skin contaminant.

### 3.2. Leeds General Infirmary

Bioburden levels following patient treatment and prior to reprocessing ranged from

$2 \times 10^1$  to  $2.89 \times 10^5$  CFU/ml (mean  $3 \times 10^4$  CFU/ml) in the bronchoscopes and from  $1.92 \times 10^3$  to  $1.72 \times 10^6$  CFU/ml (mean  $4 \times 10^5$  CFU/ml) in the colonoscope (Table 2). Using an independent group t-test, no statistical difference was observed at the 5% level (p-value 0.075) between the mean bioburden values in the suction channels of colonoscopes and bronchoscopes. However, the low p-value (0.075) indicates that further data would likely show a statistical difference between the two data sets.

After Sterilox reprocessing, no surviving organisms were found in the Leeds study (Table 2).

#### **4. Discussion**

In-use studies were carried out to evaluate the capacity of Sterilox liquid chemical germicide to decontaminate endoscopes routinely during clinical procedures. Samples were taken prior to endoscope reprocessing to measure the bacterial contamination levels present in endoscope lumens following clinical procedures, and after reprocessing in Sterilox germicide.

Bioburden levels in both clinical studies were found to be as high as  $10^5$  CFU/ml after endoscope procedures (Table 3). This data agrees with previous studies (3,4), which reported endoscopes to harbour up to  $10^5$  CFU/ml of bacteria following clinical use.

Mean contamination levels following clinical use were  $2.41 \times 10^5$  CFU/ml in the colonoscopes,  $3.09 \times 10^4$  CFU/ml in the bronchoscopes and  $1.3 \times 10^5$  CFU/ml in the gastroscopes (Table 3). This data is in general agreement with a previous study by Alfa & Sitter (4), which reported mean bioburden levels prior to endoscope reprocessing of  $1 \times 10^4$  CFU/ml for bronchoscopes and  $5 \times 10^5$  CFU/ml for colonoscopes.

#### **5. Conclusion**

This study presents in-use data which demonstrates Sterilox liquid chemical disinfectant at 180-220ppm AFC to be highly effective in rapidly and completely disinfecting endoscopes in 5 minutes during routine clinical instrument reprocessing.

#### **References**

- 1 Sterilox 2501 User Manual (1999).
- 2 QED Washer Disinfector Instruction Manual (1998).
- 3 Chu NJ, McAlister D & Antonoplos A (1998),. *Gastrointest Endosc* Vol 48 No 2 pg 137-142.
- 4 Alfa MJ & Sitter FL (1994), In-hospital evaluation of ortho-phthalaldehyde as a high level disinfectant for flexible endoscopes, *J Hosp Infect* Vol 26 15-26.

**Table 1** Bacterial counts pre and post-Sterilox decontamination (Department of Pathology, Royal Hospital Haslar)

Date of Procedure	Endoscope Type	Total CFU/ml		Detectable Organism
		Pre Treatment	Post Treatment	
2 Nov 99	Colonoscope	1.1x10 <sup>5</sup>	0	ANO2 <sup>+</sup> Coliform
4 Nov 99	Colonoscope	1.1x10 <sup>5</sup>	0	Pyo <sup>++</sup> Coliform
8 Nov 99	Colonoscope	2x10 <sup>5</sup>	0	Strept <sup>b b</sup> Coliform
10 Nov 99	Colonoscope	1x10 <sup>5</sup>	10 <sup>3**</sup>	Group D <sup>±</sup> Coliform
30 Nov 99	Colonoscope	2x10 <sup>5</sup>	0	BHS <sup>b</sup> α-Strep*
6 Dec 99	Colonoscope	1x10 <sup>5</sup>	0	Not stated
14 Dec 99	Colonoscope	1x10 <sup>5</sup>	0	Coliforms
29 Dec 99	Colonoscope	1x10 <sup>3</sup>	0	Coliforms
1 Nov 99	Gastroscope	2x10 <sup>3</sup>	0	CNS** Coliform
5 Nov 99	Gastroscope	1.1x10 <sup>5</sup>	0	CNSα-Strept*
11 Nov 99	Gastroscope	2x10 <sup>5</sup>	0	Dip <sup>±±</sup> Strept <sup>b b</sup>
23 Nov 99	Gastroscope	2x10 <sup>5</sup>	0	α-Strept* Neisseria
25 Nov 99	Gastroscope	2x10 <sup>5</sup>	0	α-Strept* Neisseria
2 Dec 99	Gastroscope	2x10 <sup>5</sup>	0	CNS Coliform
31 Jan 00	Gastroscope	1x10 <sup>5</sup>	0	Coliforms
15 Feb 00	Gastroscope	1x10 <sup>5</sup>	0	Pyo
10 Dec 99	Unknown	2x10 <sup>5</sup>	0	α-Strept* Coliform

Colonoscope Mean Bioburden Levels: 1.15x10<sup>5</sup> CFU/ml

Gastrosopes Mean Bioburden Levels: 1.3x10<sup>5</sup> CFU/ml

- \* α-Streptococci
- \*\* Coagulase negative Staphylococcus
- + Anaerobic strain
- ++ Pseudomonas
- ± Group D Streptococci
- ±± Diphtheria
- b B-haemolytic Streptococcus
- bb Streptococci

**Table 2** Bacterial counts pre and post Sterilox decontamination (Infection Control Laboratory, Old Medical School, Leeds)

Date of Procedure	Endoscope Type and Serial Number	Aerobic count CFU/ml		Anaerobic count CFU/ml		Total CFU/ml	
		Pre Treatment	Post Treatment	Pre Treatment	Post Treatment	Post Treatment	Pre Treatment
14.10.99	Colonoscope Serial No 2400167	$6.8 \times 10^2$	0	$5 \times 10^3$	0	$5.68 \times 10^3$	0
14.10.99	Colonoscope Serial No 2910348	$6.2 \times 10^2$	0	$1.3 \times 10^3$	0	$1.92 \times 10^3$	0
19.10.99	Colonoscope Serial No 2300063	$4.7 \times 10^4$	0	$1.3 \times 10^5$	0	$1.77 \times 10^5$	0
19.10.99	Colonoscope Serial No 2300063	$1.6 \times 10^5$	0	$1.48 \times 10^5$	0	$3.08 \times 10^5$ 0	0
22.10.99	Colonoscope Serial No 2400167	$4.8 \times 10^5$	0	$1.28 \times 10^5$	0	$6.08 \times 10^5$	0
25.10.99	Colonoscope Serial No 2300063	$3.2 \times 10^5$	0	$1.4 \times 10^6$	0	$1.72 \times 10^6$	0
25.10.99	Colonoscope Serial No 2400167	$3.6 \times 10^3$ 0	0	$2.3 \times 10^4$	0	$2.66 \times 10^4$	0
14.10.99	Bronchoscope Serial No 2300200	$1 \times 10^1$	0	$1 \times 10^1$	0	$2 \times 10^1$	0
14.10.99	Bronchoscope Serial No 2511303	$5.1 \times 10^3$	0	$1.5 \times 10^3$	0	$6.6 \times 10^3$	0
26.10.99	Bronchoscope P200	$2.4 \times 10^3$	0	$1.2 \times 10^4$	0	$1.44 \times 10^4$	0
26.10.99	Bronchoscope P200	$1.48 \times 10^3$	0	$1.7 \times 10^3$	0	$3.18 \times 10^3$	0
28.10.99	Bronchoscope P200	$7.3 \times 10^2$	0	$9.1 \times 10^2$	0	$1.64 \times 10^3$	0
28.10.99	Bronchoscope P200	$1.3 \times 10^3$	0	$3.2 \times 10^3$	0	$4.5 \times 10^3$	0
06.03.00	Bronchoscope Serial No 2611682	$1.09 \times 10^5$	0	$1.81 \times 10^5$	0	$2.89 \times 10^5$	0
06.03.00	Bronchoscope Serial No 2611682	$1.2 \times 10^4$	0	$4.3 \times 10^4$	0	$5.5 \times 10^4$	0
07.03.00	Bronchoscope Serial No 2611682	$2.1 \times 10^2$	0	$1.2 \times 10^3$	0	$1.41 \times 10^3$	0
09.03.00	Bronchoscope Serial No 2611682	$4.4 \times 10^2$	0	$8.5 \times 10^2$	0	$1.29 \times 10^3$	0
14.03.00	Bronchoscope Serial No 2611682	$2.7 \times 10^2$	0	$1.6 \times 10^2$	0	$4.3 \times 10^2$	0
20.03.00	Bronchoscope Serial No 2611682	$1.2 \times 10^2$	0	$1.7 \times 10^2$	0	$2.9 \times 10^2$	0

Colonoscope Mean Bioburden levels:  $4 \times 10^5$  CFU/ml

Bronchoscope Mean Bioburden Levels:  $3 \times 10^4$  CFU/ml

**Table 3** Summary of total bioburden found in endoscopes following patient use

<b>Endoscope</b>	<b>Bioburden Range found in Channel CFU/ml</b>	<b>Total Mean Bioburden CFU/ml in channel</b>
Bronchoscope	$2 \times 10^1$ - $2.89 \times 10^5$	$3.09 \times 10^4$
Colonoscope	$1.92 \times 10^3$ - $1.72 \times 10^6$	$2.41 \times 10^5$
Gastrosopes	$2 \times 10^3$ - $2 \times 10^5$	$1.3 \times 10^5$