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Final Report

Disinfectant Validation Study for Bedpan/Flusher Sanitiser

Conducted for:

Malmet Australia Pty Ltd
9-11 McKay Avenue
Leeton NSW 2705
AUSTRALIA

Conducted by:

AMS Laboratories Pty Ltd
8 Rachael Close
Silverwater NSW 2128
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Authors:

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Teresa Susanto, B.Sc.

Report Ref. No. 1213067
28th Augusts 2012

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SUMMARY

This study was designed to evaluate the efficacy of Bedpan/Flusher Sanitiser manufactured by Malmet Australia. **ES Energy Saver Sanitiser 21Amp with Detergent** was evaluated for both disinfection and physical cleaning in this study. Disinfection studies against both *Clostridium difficile* as a culture suspension and faecal suspension showed that the normal disinfection cycle was able to reduce the number of viable cells of the organism by approximately 3 logs. The disinfection cycle also demonstrated efficacy of the machine to reduce the viable cells of *Enterococcus faecalis* in a culture suspension by greater than 5 logs. Physical cleaning test showed that the heavy soil applied on the surface of bedpan was effectively removed by about 96% leaving the bedpan visibly clean.

STUDY DIRECTOR STATEMENT

The study was conducted according to the procedures indicated by the sponsor.

To the best of my knowledge and belief, the study was conducted in compliance with the requirements set in the agreed protocol, and there were no circumstances that may have adversely affected the quality and integrity of the study.

Signed..... Date 03-09-2012
Imtiaz Ahmed, M.Phil. MASM
Sterile Products Testing Manager, AMS Laboratories
Study Director

ANALYSTS STATEMENT

The work reported herein is a true and accurate account of the results obtained in carrying out the stated procedures.

Signed..... Date 3/9/12
Teresa Susanto, BSc
Senior Microbiologist, AMS Laboratories

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1. INTRODUCTION

Malmet Australia Pty Ltd approached AMS Laboratories, Australia to perform validation studies to verify the effectiveness of their Bedpan/Flusher Sanitizers. **ES Energy Saver Sanitiser 21Amp with Detergent** was evaluated in this study. The studies were aimed at validating whether the equipment is effective in disinfecting and physically cleaning of reusable laboratory and clinical articles.

The experimental work was conducted at AMS Laboratories Pty Ltd, 8 Rachael Close, Silverwater, NSW 2128. AMS Laboratories are licensed by the Australian Therapeutic Goods Administration for analysis and testing (Licence No. 15112007-LI-002191-11 and GMP Certificate No MI-2010-LI-01063-3), Australian Pesticide and Veterinary Medicines Authority (Licence No 6139), certified by Office of Gene Technology Regulator as Physical Level 2 (PC2) Facility (Certificate No 2649) and registered with Federal Drug Administration USA (DUNS No 754742088 and Facility Establishment Identifier No 3006635869).

2. SCOPE

The study was undertaken to qualify the use of Bedpan/Flusher Sanitisers in disinfection and physical cleaning of reusable laboratory and clinical articles. Two organisms were nominated by Malmet for qualification studies with the inoculation of on the organisms in a faecal suspension. One of the organisms used is a sporeformer. An inorganic heavy soil was used for physical cleaning studies. The studies will thus validate the effectiveness of this machine in infection control mechanism.

3. REFERENCED DOCUMENTS

3.1 Disinfection Validation Protocol Ref. no 12008IA dated 16-07-2012.

3.2 AS 2437-1987. 'Flusher / sanitizers for bed pans and urine bottles'.

3.3 Journal of Hospital Infections September 2000: 46(1):50-4 "Evaluation of the Cleaning and Disinfection efficacy of the DEKO-190; award-based automated washer/disinfector."

3.4 IS0 15883-1: "Washer disinfectors Part 1: General requirements, terms and definitions, tests".

3.5 IS0 15883-2 "Washer disinfectors Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware etc".

3.6 IS0 15883-3 'Washer disinfectors Part 3: "Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers".

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MATERIALS:

4 Bedpan/Flusher Sanitiser:

ES Energy Saver Sanitiser 21Amp with Detergent.

4.2 Soil Used:

The heavy soil used for physical cleaning studies was prepared as described below:

Fresh Egg yolk (chicken)	100mL
Sheep blood	2mL
Hog mucin	2g
Mince Meat (beef)	5g

Mix hog mucin in a small quantity of blood to form a smooth paste and add the rest of the Ingredients to form a smooth paste. This can be stored up to 14 days at 4-8°C.

4.3 Microorganisms:

The 2 microorganisms used for this study are given in the table below

Type	Strain Number	Supplied by
Clostridium difficile	ATCC 700792	AMS
Enterococcus fecalis	ATCC 19433	AMS

4.4 Culture Suspension:

Culture suspensions of both the organisms were prepared as described below:

"Stock culture of both *Clostridium difficile* and *Enterococcus faecalis* were prepared with 10^6-10^7 CFU/mL using physiological saline after harvesting from overnight grown culture and dispensed in 10mL aliquots and stored in 4°C until use. 1.0 mL of each culture suspension in heat resistant polyethylene tubes and stored in freezer in sealed tubings was used in the test by placing in different locations of machine".

4.5 Faecal Suspension:

Faecal suspension with *Clostridium difficile* was prepared as described below:

"Faeces of a healthy baby aged between 1 and 2 years was collected in 50mL centrifuge tubes and sterilised by autoclaving at 121°C for 15 minutes. 10g of sterilised faeces was weighed in a beaker and 20mL of distilled water added to the beaker. The faeces were broken up with a glass rod. A further 80mL of distilled water was then added and transferred to a plastic bag and homogenised 2 minutes.

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Approximately 10^6-10^7 CFU/g of *Clostridium difficile* prepared as above were added with continuously agitation using a wide bore pipette. The faecal suspension thus prepared was dispensed to a bottle and refrigerated until required. On the day of testing 1 gram of this faecal suspension in sealed tubing was placed at different locations in the machines.

5 TEST PROCEDURE:

Testing methodology was based on Disinfection Validation Protocol for Washer Disinfectors and Bedpans Sanitisers Reference No 12008IA dated 16-07-2012 approved by Malmet Australia and is described below:

6.1 Disinfection Studies:

Disinfection studies were carried out using both bacterial pathogens and faecal suspension prepared as above. The machines were loaded to near maximum capacity as per manufacturer's instructions. All three suspensions were tested separately by placing the prepared suspension tubes at 5 different positions within the disinfection unit. The machine was then run as per manufacturer's instructions. At the end of the process, the tubings were recovered and a quantitative test performed. The testing was performed in duplicate.

6.2 Physical Cleaning Efficacy Studies:

Cleaning efficacy study of the machine was performed using a normal wash cycle with dirty bedpans simulating clinical conditions. Plastic bedpans were soiled with 0.5 $\pm$0.05 g of an artificial heavy soil produced as described above. Degree of cleanliness was examined visually. A square grid pattern with 100 squares was used for the evaluation of visual cleaning.

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7 RESULTS:

Study results are presented in the tables blow:

Table 1: Disinfection Efficacy Results for *Clostridium difficile*:

Disinfection Efficacy Results for *Clostridium difficile*				
Run	**Location**	**Count (CFU/mL)**	**Log**	**Log Reductions**
1	Front of Machine -Right	30	1.48	3.21
	Front of Machine-Left	<10	<1.00	>3.69
	Back of Machine-Right	40	1.60	3.09
	Back of Machine-Left	<10	<1.0	>3.69
	Middle of Machine	30	1.48	3.21
2	Front of Machine -Right	40	1.60	3.09
	Front of Machine-Left	30	1.48	3.21
	Back of Machine-Right	100	2.00	2.69
	Back of Machine-Left	45	1.65	3.04
	Middle of Machine	15	1.18	3.51
Inoculum Count: 4.9×10^4 CFU/mL (Log 4.69)				

Table 2: Disinfection Efficacy Results for *Enterococcus faecalis*:

Disinfection Efficacy Results for *Enterococcus faecalis*				
Run	**Location**	**Count (CFU/mL)**	**Log**	**Log Reductions**
1	Front of Machine -Right	<10	<1.00	>5.54
	Front of Machine-Left	<10	<1.00	>5.54
	Back of Machine-Right	<10	<1.00	>5.54
	Back of Machine-Left	<10	<1.00	>5.54
	Middle of Machine	<10	<1.00	>5.54
2	Front of Machine -Right	<10	<1.00	>5.54
	Front of Machine-Left	<10	<1.00	>5.54
	Back of Machine-Right	<10	<1.00	>5.54
	Back of Machine-Left	<10	<1.00	>5.54
	Middle of Machine	<10	<1.00	>5.54
Inoculum Count: 3.5×10^6 CFU/mL (Log 6.54)				

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Table 3: Disinfection Efficacy Results for Faecal Suspension:

Disinfection Efficacy Results for Faecal suspension with *Clostridium difficile*				
Run	**Location**	**Count (CFU/mL)**	**Log**	**Log Reductions**
1	Front of Machine -Right	<10	<1.00	>3.30
	Front of Machine-Left	40	1.60	2.70
	Back of Machine-Right	<10	<1.00	>3.30
	Back of Machine-Left	40	1.60	2.70
	Middle of Machine	20	1.30	3.00
2	Front of Machine -Right	10	1.00	3.30
	Front of Machine-Left	10	1.00	3.30
	Back of Machine-Right	<10	<1.00	>3.30
	Back of Machine-Left	<10	<1.00	>3.30
	Middle of Machine	15	1.18	3.12
Inoculum Count: 2.0 x 10^4 CFU/mL (Log 4.30)				

Table 4: Physical Cleaning Efficacy Results:

Bedpan-Run 1										**Bedpan-Run 2**									
x														x			x	x	x
																			x
x																			x
x: Soil present after washing																			
Soiling: 0.5±0.05g spread over 5 x 5 cm																			

Following method was used for evaluation:

- Evident removal of the stains in small square grid represents 1% clean; hence removal of stains on all 100 small squares represents 100% clean.
- Percent cleaning calculated on the basis of total no of grids with no stains minus no of grids with stains.

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Table 5: Summary of Results:

Summary of Results				
Test	**Location**	**Result Run 1**	**Result Run 2**	**Average Result***
Disinfection Test with *Clostridium difficile*	Front of Machine-Right	3.21	3.09	3.15
	Front of Machine-Left	3.69	3.21	3.45
	Back of Machine-Right	3.09	2.69	2.89
	Back of Machine-Left	3.69	3.04	3.37
	Middle of Machine	3.21	3.51	3.36
Disinfection Test with *Enterococcus faecalis*	Front of Machine-Right	5.54	5.54	5.54
	Front of Machine-Left	5.54	5.54	5.54
	Back of Machine-Right	5.54	5.54	5.54
	Back of Machine-Left	5.54	5.54	5.54
	Middle of Machine	5.54	5.54	5.54
Disinfection Test with Faecal suspension	Front of Machine-Right	3.30	3.30	3.30
	Front of Machine-Left	2.70	3.30	3.00
	Back of Machine-Right	3.30	3.30	3.30
	Back of Machine-Left	2.70	3.30	3.00
	Middle of Machine	3.00	3.12	3.06
Physical Cleaning Test	Bedpans	98	94	96
* Log reduction for disinfection and percent cleaning for physical cleaning.				

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8 DISCUSSION AND CONCLUSION:

Clostridium difficile is an anaerobic, gram positive spore forming bacteria. *C. difficile* is the most serious cause of antibiotic-associated diarrhea (AAD) and can lead to pseudomembranous colitis, a severe inflammation of the colon. Elderly, debilitated and immunocompromised patients are at highest risk. Being a sporeformer it is heat resistant and relatively difficult organism to kill.

Enterococcus faecalis is a gram positive, commensal bacterium inhabiting the gastrointestinal tract of humans and other mammals. Like other species in the genus *Enterococcus*, *E. faecalis* can cause life-threatening infections in humans, especially in the hospital environment, where the naturally high levels of antibiotic resistance found in *E. faecalis* contribute to its pathogenicity.

These two organisms were chosen for the study based on their prevalence in the hospital environment and relatively resistant nature. The Energy Saver Sanitiser 21Amp with detergent was evaluated with a normal disinfection cycle at 90ºC for 1 minute. Disinfection and Physical cleaning with this disinfection cycle was evaluated in duplicate with all the parameters as described above.

The results indicate that ES Energy Saver Sanitiser was effective in reducing the bacterial suspension and faecal suspension of *Clostridium difficile* by 3 logs which equates to 99.9% kill with the exception of one location, back right of machine where a log reduction of 2.89 was achieved with *Clostridium difficile* culture suspension. The culture suspension of *Enterococcus faecalis* was, however, completely killed and a greater than 5 log reduction was achieved in the same cycle. This equates to 99.999% kill.

The physical cleaning results for the same cycle showed that bedpans inoculated with a heavy soil were cleaned by approximately 96% evaluated on a scale as described above. As such it complies with the cleaning efficacy requirements as set in Section 8.2 (b) of AS 2437- Flusher Sanitisers for Bed Pans and Urine Bottles.

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