FINAL STUDY REPORT

Protocol No: OZONE/01-2007/120207/Hospital Laundry Study, Version 6

A COMPARATIVE STUDY ON THE DISINFECTION OF HOSPITAL LAUNDRY USING OZONE: A 2-PART SINGLE BLIND STUDY USING STANDARD HOSPITAL LAUNDRY CLEANING TECHNIQUES VERSUS THE OTEX VALIDATED OZONE DISINFECTION SYSTEM

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Report prepared by REDSOX Research Ltd
22 June 2007

STATEMENT OF AUTHORITY

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Report prepared by REDSOX Research Ltd in association with authors:

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We hereby declare that the above mentioned Report is a true and full account of the study covered by Protocol No. OZONE/01-2007/120207/Hospital Laundry Study, Version 6 and titled appropriately in each and every detailed way as recorded.

The final Study Report is the property of JLA Ltd., Meadowcroft Lane, Ripponden, W.Yorks HX6 4AJ.

Copies of this report and all data accumulated in the report are held in the Department of Microbiology for a period of 15 years or more unless otherwise directed by JLA Ltd., Ripponden, W.Yorks.

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Signed: ..... **Date:** 22/6/07

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Signed: ..... **Date:** 22nd June 2007.

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1. INTRODUCTION

Concern has been expressed over the last 5 – 10 years in the UK and elsewhere about the efficacy and safety of laundry processes in hospital laundry establishments. The reason for this relates to the increasing number of significant and lethal hospital acquired infections (HAIs) which affect patients admitted to hospital, often in a weakened or immunologically compromised state.

Among recent infections with a significant and consistent mortality have been deaths attributed to Staphylococcus aureus and in particular, MRSA (Methicillin Resistant Staphylococcus Aureus) and Clostridium difficile (C.difficile). In addition, however, death certificates have also included notably E.coli and Coliform organisms amongst those which contribute to the potential lethality of hospital stays.

Although it is widely recognised that many patients subject to hospital acquired infections are either in a grossly weakened or immuno-compromised state, nonetheless, the frequency by which cross contamination in hospital wards and indeed, throughout hospitals, has occurred is giving increasing concern, not only to hospital based authorities but to the Government as a whole.

This appears to be particularly prevalent in the western world (possibly as a consequence of improved reporting methods and improved culture and sensitivity activities within a microbiological setting), but wherever illness, close confinement or inadequate cleaning techniques are applied, such phenomena may well occur.

On the basis of this, JLA Ltd, a company based in West Yorkshire, developed a methodology for generating ozone, a known powerful oxidising agent as a chemical disinfectant for water treatment, applied to laundry in the current setting.

The use of ozone in this respect has increased in medicine recently due to the large number of micro-organisms resistant to standard disinfection techniques including chlorine. The process used for washing highly contaminated hospital linen (a common occurrence) and in the volumes in which such laundry processes are carried out, can be summarised as follows:

1. The execution of one washing cycle with conventional chemical products (humidification and pre-wash).
2. One washing cycle with ozone (up to 4 g per hour)

Development of the technique, and in particular, the machinery and equipment required for generating ozone, was then accelerated by JLA in response to early bacteriological studies which showed its efficacy in eliminating a large number of micro-organisms present in hospital laundry.

Where hospital laundry has been cleaned appropriately, and without significant fabric damage, leaving a residual fresh odour in the laundry, then development of the industrial processes related to laundry cleaning using ozone generation took place.

Hospital laundry cleaning processes have been largely conventionally managed in the past and indeed currently adhere to HSG(95)18 guideline, using two broadly based standard hospital protocols, namely,

- A low temperature chemical disinfection technique involving sluicing, pre-washing, a main wash and subsequent multiple rinses with a spin at the end in which an alkaline detergent or mixture of detergents is added at the pre wash and main wash phases. Sodium hypochlorite (150 parts per million) is added to the second but last rinse and this has the effect of reducing the bacterial load in the laundry thus provided. Such a low temperature disinfection technique is suitable for heat labile fabrics.

- The alternative to this relates to a high temperature uniform wash in which a sluicing arrangement, pre-wash and main wash are followed by a cool down and three separate rinses as part of the standard uniform wash procedures. Again, in this circumstance, larger volumes of alkaline detergent and latterly alkaline detergent mixed with Hydrogen Peroxide are used to clean the hospital uniforms.

These techniques have been widely used in the UK and indeed in other areas globally as effective mechanisms both to decontaminate and to clean a variety of hospital acquired laundry materials including personal laundry, requiring high temperature cleaning and the other materials commonly used in a hospital setting such as sheets, duvets, pillowcases and the like.

Nonetheless, the costs of such washing processes which did require attention to detail were expensive both in terms of time and materials and a simpler, more straightforward low temperature wash arrangement has been sought. It was thought that the OTEX system, using a validated ozone disinfection system, whereby ozone generation was maintained within a closed circuit process could be used with advantage and had a number of benefits.

2. BACKGROUND AND RATIONALE

Increasing concern has been expressed at Aberdeen Royal Infirmary Hospital Laundries (servicing the whole of the North East Grampian Region of Scotland) as to the effectiveness, safety, tolerability and indeed suitability of current laundry washing processes.

An initial study of the OTEX validated ozone disinfection system was carried out at Woodend Hospital in the autumn of 2006 (September/October 2006). The initial results of that pilot study related to a reduction in total viable counts only (TVCs) and indicated that there may be value in a further a more formal pilot study whereby the referenced laundry cleaning system could be directly compared to the OTEX validated ozone disinfection system as recommended by JLA Ltd.

On that basis, therefore, a phase 1, single blind, randomised, controlled series group study of standard laundry disinfection techniques using the referenced VIKING machine versus the OTEX validated ozone disinfection system, was set up at the laundry at Woodend Hospital, Aberdeen.

The objectives for this study were to assess the safety, tolerability and efficacy of ozone applied in the OTEX validated ozone disinfection system versus standard laundry cleaning procedures (VIKING machine).

In addition, it was thought important to assess the reproducibility of the OTEX validated ozone disinfection system on a standardised series of heavily fouled laundry loads contaminated with hospital acquired bacteria, fungi and/or viruses in comparison to a matched series of heavily fouled laundry loads using the Standard VIKING laundry machine.

The loads were therefore divided into two groups:

a. Heavily soiled personal laundry (hereafter referred to as personal laundry) in which the standard low temperature disinfection laundry routine (VIKING, chemical process *) was compared to the OTEX machine process **.

b. Standardised loads of nurses uniforms in which the standard high temperature uniform wash (VIKING machine process) versus the OTEX machine process was compared.

* VIKING machine process refers to the current hospital standard processing operations, i.e. low temperature chemical or high temperature thermal processing. This can be carried out by a number of different laundry machines, in this instance the VIKING machine was used as the standard.

** Similarly, the OTEX machine process refers to any hospital laundry processing machine to which an OTEX processing unit has been fixed or attached. The study therefore compared current standard hospital laundry processing activity versus the OTEX machine laundry process incorporating the generation of ozone.

3. INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria

1. 40 heavily fouled standardised laundry loads.

2. Loads divided into two groups undergoing disinfection, cleaning and preparation.

3. All loads will be treated and laundered at Woodend Hospital, Aberdeen.

4. Two types of fouled hospital laundry loads would be considered.

    a. A series of 2 x 10 randomised, personal laundry loads (part of the usual laundry cleaning processes at Woodend Hospital, Aberdeen, selected for investigation using a chemical standard low temperature wash (VIKING machine process versus OTEX laundry process).

        No special contamination factors are noted and the materials used cover personal laundry items usually accommodated within routine Woodend Hospital laundry processes.

    b. A series of 2 x 10 randomised, fouled nurses uniforms loads (part of the usual laundry cleaning processes at Woodend Hospital, Aberdeen) were selected for investigation using a thermal standard high temperature uniform wash (VIKING machine process versus OTEX laundry process)

No special contamination factors were noted and the materials used covered standard nurses uniforms as routine laundry items common at Woodend Hospital, Aberdeen.

Exclusion Criteria

1. Any samples of laundry which, for whatever reason, do not fall within these two selected groups will be excluded from the study.

2. All microfibre cloths and mops (commonly serviced and laundered at Woodend Hospital Laundry, Aberdeen) will be excluded from the study.

4. STUDY DESIGN

4.1 Study Design and Method

A variety of study designs have been used in the past to investigate hospital laundry systems using ozone gas as a disinfection agent.

Ozone is a known powerful oxidising agent which has been used as a chemical disinfectant for water treatment in Europe for more than 100 years.

The use of ozone has increased in medicine recently due to the number of micro-organisms resistant to chlorine. The process used for washing highly contaminated hospital linen can be summarised as follows:

a. The execution of one washing cycle with conventional chemical products (humidification and pre-wash).
b. One washing cycle with ozone (up to 4 g per hour)

The details of the laundry cycles for each of the 2 machines to be used in the trial, the VIKING laundry process machine (Appendix 7) and the OTEX laundry process machine (Appendix 8), are noted.

Water samples will be collected using standard sterile 1 litre collection bottles (each containing a measured volume of sodium biosulphate solution) from access ports on each washing machine at the relevant phases of each laundry wash on each machine.

Pre-wash samples will be taken after 3 minutes of agitation without any additives. Post-wash samples (sterile 1 litre collection bottles) will be collected similarly from each machine following the final cycle of the laundry load.

All collection bottles will be stored (no more than 4 hours) in a receiving fridge at 4°C to 8°C before collection.

The bottles containing contaminated fluid (1 litre) will then be transported directly to the Public Health Laboratory within the Department of Microbiology, Aberdeen Royal Infirmary, by arrangement.

The 1 litre samples of laundry liquor will be plated in the usual way using routine standardised laboratory procedures. The plates will be read in the usual way for the standard contaminants of hospital laundry using Total Viable Count (TVC) as an index of contamination of each laundry wash.

In addition, important contaminants of this type of hospital laundry will be sent to the Microbiology Lab at Aberdeen Royal Infirmary for routine culture and sensitivity. These will include:

E.coli and Coliforms
Clostridium Difficile (C.Difficile)
S.Aureus (including MRSA)

Included in the usual laundry wash programmes at Woodend Hospital is the cleaning of microfibre cloths and mops using a standard thermal laundry system. For this pilot project, such laundry items were not included in the wash routine.

Some studies relating to an ozone disinfection system have shown that many species of bacteria, including E.coli, Streptococcus and Bacillus, can be inactivated by 30 seconds of exposure to a solution of ozone (equal to 0.2 mg per litre). In the proposed study, the key issues are to demonstrate not only the safety and tolerability to personnel and laundry of the ozone disinfection system, but also, and more particularly, the efficacy of the OTEX Validated Ozone Disinfection System in the removal of bacterial, fungal or viral contaminants in any one of a series of heavily fouled hospital laundry wash loads.

Assessment of efficacy will be determined by the total viable count of organisms cultured in the lab (TVC) together with the culture and sensitivity of selected organisms (common to soiled hospital laundry) with the objective of demonstrating a laundry processing system using ozone whereby contaminants can be reduced by a minimum factor (possibly x5 log) following the application of such a system.

The OTEX laundry process system utilising ozone complies with the Commission for Social Care Inspection (CSCI) national minimum standard regarding disinfection of laundry. The OTEX system does not rely on current thermal disinfection temperatures of 65°C for 10 minutes or 71°C for 3 minutes, to clean or disinfect laundry but nonetheless, such a system does produce satisfactory cleaning and antibacterial results through appropriate application of Ozone.

In addition, this protocol will confirm the initial clinical trial undertaken at Woodend Hospital on behalf of the Grampian NHS Trust over a 4-week period from September to October 2006. In this trial, the OTEX Validated Ozone Disinfection System was compared with standard laundry cleaning techniques using a total viable count (TVC) log evaluation system only.

This preliminary work confirmed a x5 log reduction of contaminants estimated by TVC in the Microbiology Lab at Aberdeen Royal Infirmary. A note of the advantages and the mechanisms by which ozone is generated is contained in Appendix 5.

4.2 Statistical Analysis

The following analyses will be carried out separately for (i) personal laundry and (ii) nurses uniform only.

TVC levels, E-coli, Coliforms, C.difficile and Staph aureus counts from the VIKING conventional wash process and the OTEX wash process will be compared using an independent two sample t-test or a Mann-Whitney test if the data is not normally distributed.

In addition, qualitative outcomes will be assessed by a Health and Safety questionnaire, completed by hospital laundry personnel. Percentages in the various response categories will be presented and tested for any significant majority selection using a Sign Test (2 categories) or Chi-squared Test (3 or more categories).

40 loads will be tested for each of the two washing methods with 20 loads over 3 days consisting of personal laundry and 20 loads over a further 3 days consisting of nurses' uniforms only. The same operative will be in charge over the whole trial. This design will ensure that each method is treated equitably in all other respects.

The alternating allocation will operate as follows:

(i) The first 7 loads of laundry ('personal laundry' for days 1 to 3 and 'nurses' uniforms' for days 4 to 6) used each day will be numbered 1 to 7 (numbered up to 6 on days 3 and 6) according to the alternating allocation schedule, and availability of appropriate laundry loads.

(ii) The loads will then be allocated to methods and washed according to the following bar chart, with **load numbers given in RED**:

Personal laundry: VIKING Standard Chemical vs OTEX

Date	VIKING Standard chemical				OTEX			
1	1	3	5	7	2	4	6	
2	2	4	6		1	3	5	7
3	1	3	5		2	4	6	

Nurses' Uniforms: VIKING Standard Thermal vs OTEX

Date	VIKING Standard thermal				OTEX			
4	2	4	6		1	3	5	7
5	1	3	5	7	2	4	6	
6	1	3	5		2	4	6	

NOTE: The above date schedules can be done in a convenient order, depending on availability of laundry type.

5. OBJECTIVES

The objectives for this study are 2-fold.

1. To assess the safety, tolerability and efficacy of ozone applied in the OTEX Validated Ozone Disinfection System versus standard laundry cleaning procedures.

2. To assess the reproducibility of the OTEX Validated Ozone Disinfection System on a standardised series of heavily fouled laundry loads contaminated with hospital acquired bacteria, fungi and/or viruses.

   The loads were divided into 2 groups.

   a. Personal laundry in which the standard low temperature disinfection laundry routine (VIKING, chemical) is compared to the OTEX process using TVC, and cultures and sensitivities of 4 species of common hospital acquired infections, namely E.coli, Coliforms, C.difficile and Staph Aureus (including MRSA).

   b. Standardised loads of nurses uniforms in which the standard high temperature uniform wash (VIKING machine) versus OTEX process will be compared using the same count and culture parameters.

6. RESULTS

The methods OTEX and VIKING conventional processes are compared with respect to the reduction of contamination in soiled laundry. For each wash load the contamination level is measured pre-wash and post-wash for 5 categories: TVC, E-coli, Coliforms, C.difficile and MRSA. 10 loads of nurses' uniforms and 10 loads of personal laundry are used for each method in a systematically designed experiment.

SPSS output follows the comment and is referred to within the comment in ***bold italics***.

Within this output, annotation in blue indicates the purpose of the statistical tests. Annotation in red gives statistical comment and the rationale associated with any decision based on key printed measures.

Statistical decisions are based on the likelihood of no difference existing between OTEX and VIKING conventional processes. **If this likelihood is less than 1 chance in 20 then we decide that a statistically significant difference exists at a significance level of 0.05.** This being the case we can then make statements about the nature of the difference e.g. OTEX displays significantly greater reduction in TVC than VIKING. This likelihood is denoted by 'Sig.' in SPSS.

6.1 Results

Because of the large contamination counts involved, the measures are converted to a log scale and the reduction caused by the washing method evaluated as the difference between the pre-wash and post-wash counts on this log scale. Detailed analysis is given in the following pages with the principal conclusions given below. The results used are listed in Appendix 1.

6.1.1 Data Collected

(i) **Nurses Uniforms:**

None of the loads washed using VIKING had E-coli contamination at the pre-wash stage, eliminating any comparison with OTEX.

None of the loads washed using OTEX had C.Difficile contamination at the pre-wash stage, and only 1 of the VIKING loads showed any incidence, eliminating any comparison for this category.

Only 3 of the 5 categories can be compared: TVC, coliforms and MRSA, although MRSA was present in only 3 OTEX loads,

Pre-wash levels of TVC and coliform counts turned out to be significantly higher for OTEX in the loads used, giving a **confounding effect in the analysis of reduction levels and post-wash levels** as opposed to having the desired similar distributions at the start of the washing process. This is clear in the table of means and the boxplot.(See ***1.1***). Boxplots are described in APPENDIX 2.

(ii) **Personal Laundry**:

All loads showed contamination with respect to TVC, E-coli and coliforms. C.difficile was not present in 2 OTEX loads and 3 VIKING loads. MRSA was not present in 4 OTEX loads and 6 VIKING loads.

Pre-wash levels were not significantly different between OTEX and VIKING loads for all categories of contamination, giving the desired similarity between methods at the start of the washing process. (See ***1.2***)

6.1.2 Significance Tests - Reductions

(i) **Nurses Uniforms:**

The mean reductions in log levels achieved by the two different methods are compared by t-tests, since the reductions are normally distributed ***(2.1)***.

No statistically significant differences in reduction levels by OTEX and VIKING are evidenced in any of the three categories available for comparison, viz TVC, coliforms and MRSA. The table of means shows OTEX having a higher mean reduction in coliforms and VIKING a higher mean reduction in the other two categories. The boxplots illustrate these differences graphically ***(2.2)***

The confounding effect caused by unequal contaminations at the outset across methods makes conclusions about differences difficult for Nurses Uniforms, although the higher mean reduction in TVC for STANDARD is interesting in the presence of lower initial levels of TVC.

(ii) **Personal Laundry**:

The mean reductions in log levels achieved by the two different methods are compared by t-tests, since the reductions are normally distributed ***(2.3).***

No statistically significant differences in reduction levels by OTEX and VIKING conventional processes are evidenced in any of the five categories compared. Mean levels are presented and the complete datasets are compared graphically in a boxplot. Mean reductions do fluctuate for the two methods over the five categories, but not in a significant way ***(2.4)***.

6.1.3 Significance Tests – Post-Wash Levels

(i) **Nurses Uniforms:**

The mean post-wash levels on the log scale achieved by the two different methods are compared by t-tests. VIKING gives significantly lower mean levels for TVC and Coliforms. **However, as stated in 6.1.1 (i), OTEX is starting with much higher levels of these contaminants.** The table of means shows OTEX having higher means in TVC and coliforms and complete elimination of coliforms by VIKING and complete elimination of MRSA by both The TVC differences are visually clear in the boxplot. ***(3.1)***

(ii) **Personal Laundry**:

The mean post-wash levels on the log scale achieved by the two different methods are compared by t-tests. OTEX gives significantly lower mean levels for C.difficile, eliminating this completely. OTEX also delivers significantly less variable results for 3 of the categories. The table of means shows OTEX having a zero mean for C.difficile and much lower standard deviations than the VIKING conventional process. MRSA has a zero mean for both methods. The C.difficile difference and the difference in variations are visually clear in the boxplot. ***(3.2)***

6.3 Conclusions

The experiment is too small to come to many statistically valid conclusions. (An Appendix is attached giving a discussion of sample size to statistically detect differences of certain magnitudes, APPENDIX 3)

Analysis seems to indicate that the two methods deliver similar reductions in the **Personal Laundry** washes, where the data collected is well balanced. OTEX shows a significantly better end wash for C.difficile with complete elimination, and OTEX residual contaminants exhibit significantly lower variation. Both methods successfully eliminate MRSA.

The **Nurses Uniforms** data has too much contamination free laundry for three of the contaminant categories and an imbalance in contamination at pre-wash level for the other two categories to arrive at any meaningful conclusions.

SPSS OUTPUT

1.1 t-Tests (Nurses Uniforms:Pre-Wash Levels)

Group Statistics

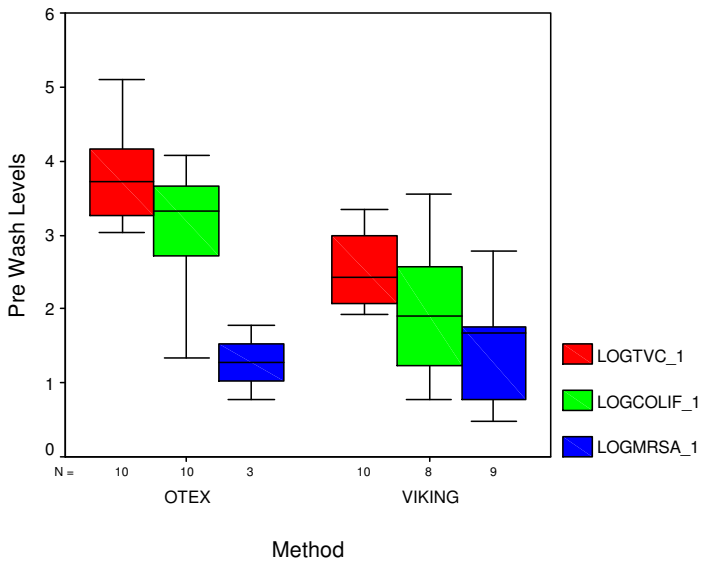
	Method	N	Mean	Std. Deviation	Std. Error Mean
LOGTVC_1	OTEX	10	3.7993	.61714	.19516
	VIKING	10	2.5497	.50272	.15898
LOGCOLIF_1	OTEX	10	3.0858	.86762	.27437
	VIKING	8	1.9676	.96594	.34151
LOGMRSA_1	OTEX	3	1.2814	.50266	.29021
	VIKING	9	1.4718	.76892	.25631

Means for OTEX considerably higher in pre-wash for log(TVC) and log (coliforms). 'Sig.' very much less than 0.05 below. .

Tests for equal pre-wash means

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means		
		F	Sig.	t	df	Sig. (2-tailed)
LOGTVC_1	Equal variances assumed	.087	.771	4.965	18	.000
	Equal variances not assumed			4.965	17.293	.000
LOGCOLIF_1	Equal variances assumed	.018	.894	2.585	16	.020
	Equal variances not assumed			2.553	14.314	.023
LOGMRSA_1	Equal variances assumed	1.532	.244	-.395	10	.701
	Equal variances not assumed			-.492	5.500	.642



OTEX has higher Pre-Wash levels of log(TVC) and log (coliforms)

1.2 t-Tests (Personal Laundry: Pre-Wash Levels)

Group Statistics

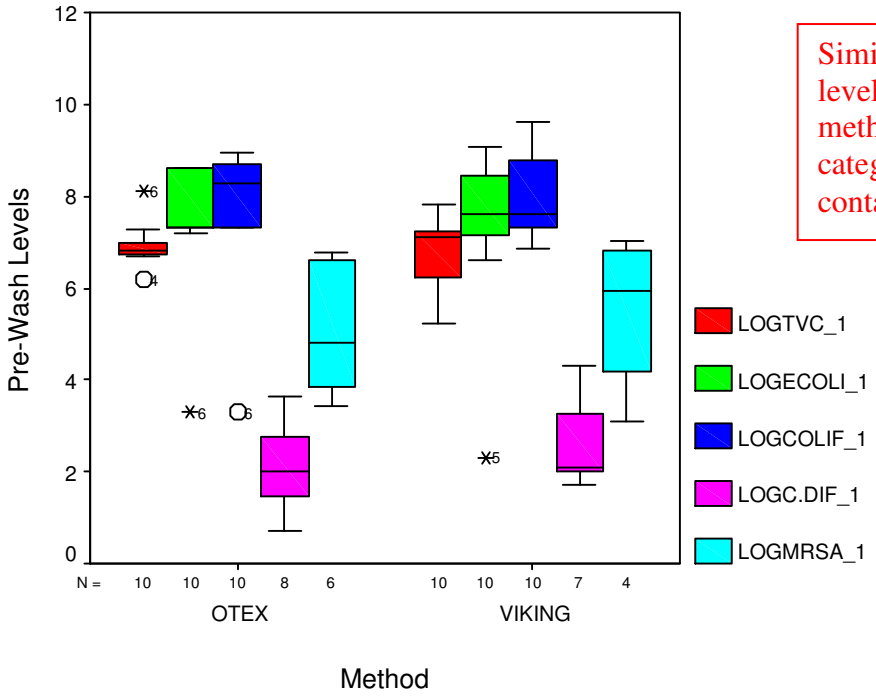
	Method	N	Mean	Std. Deviation	Std. Error Mean
LOGTVC_1	OTEX	10	6.9363	.49912	.15784
	VIKING	10	6.8596	.80462	.25444
LOGECOLI_1	OTEX	10	7.3527	1.55129	.49056
	VIKING	10	7.2705	1.89451	.59910
LOGCOLIF_1	OTEX	10	7.6944	1.67852	.53079
	VIKING	10	7.9912	.92852	.29362
LOGC.DIF_1	OTEX	8	2.0983	.94886	.33547
	VIKING	7	2.6726	.99822	.37729
LOGMRSA_1	OTEX	6	5.0462	1.45344	.59336
	VIKING	4	5.5063	1.76918	.88459

No evidence of any differences in Pre-wash means. All 'Sig.' levels greater than 0.05.

Tests for equal pre-wash means

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means			
		F	Sig.	t	df		Sig. (2-tailed)
LOGTVC_1	Equal variances assumed	2.267	.149	.256	18		.801
	Equal variances not assumed			.256	15.033		.801
LOGECOLI_1	Equal variances assumed	.181	.675	.106	18		.917
	Equal variances not assumed			.106	17.326		.917
LOGCOLIF_1	Equal variances assumed	.638	.435	-.489	18		.631
	Equal variances not assumed			-.489	14.036		.632
LOGC.DIF_1	Equal variances assumed	.106	.750	-1.142	13		.274
	Equal variances not assumed			-1.138	12.526		.277
LOGMRSA_1	Equal variances assumed	.033	.860	-.451	8		.664
	Equal variances not assumed			-.432	5.624		.682



Similar pre-wash levels for both methods over all categories of contamination.

2.1 Normality Test (Nurses Uniforms Reductions)

Tests reductions for normality

Data normal (All 'Sig.' > 0.05)

Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Log(TVC) Reduction	.090	20	.200*	.974	20	.843
Log(Coliforms) Reduction	.149	18	.200*	.951	18	.438
Log(MRSA) Reduction	.156	12	.200*	.936	12	.447

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

Note a number of loads have been omitted from the planned 10 because of zero contamination.

2.2 t-Tests (Nurses Uniforms)

Group Statistics

	Method	N	Mean	Std. Deviation	Std. Error Mean
Log(TVC) Reduction	OTEX	10	1.4705	.57231	.18098
	VIKING	10	2.0356	.78955	.24968
Log(E-coli) Reduction	OTEX	8	1.8420	.56896	.20116
	VIKING	0[a]	.	.	.
Log(Coliforms) Reduction	OTEX	10	2.7263	.87517	.27675
	VIKING	8	1.9676	.96594	.34151
Log(C.difficile) Reduction	OTEX	0[a]	.	.	.
	VIKING	1	.3010	.	
Log(MRSA) Reduction	OTEX	3	1.2814	.50266	
	VIKING	9	1.4718	.76892	

a. t cannot be computed because at least one of the groups is empty.

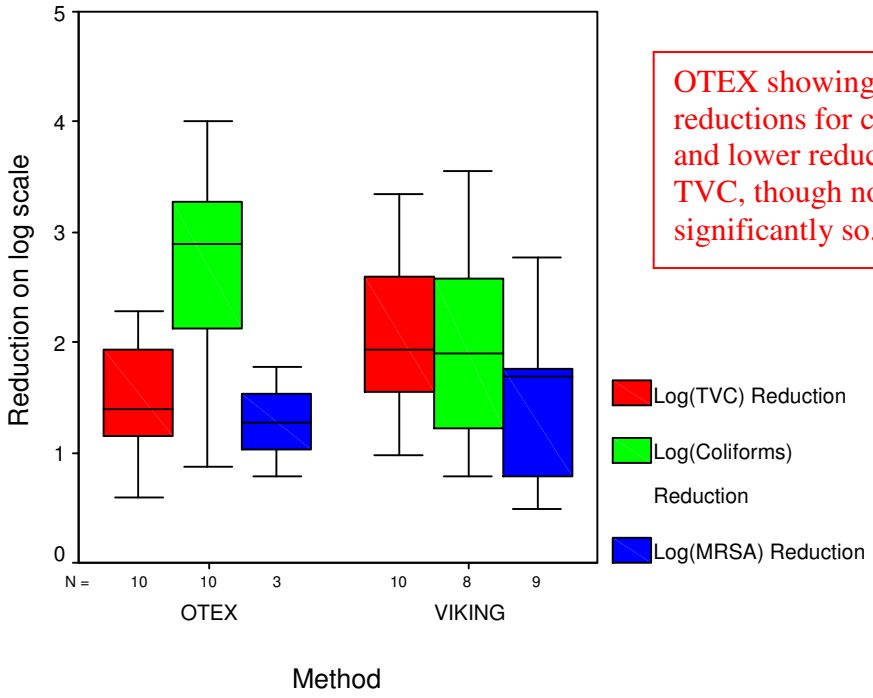
No evidence of any differences in reduction means. All 'Sig.' levels greater than 0.05.

Tests for equal reduction means

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means		
		F	Sig.	t	df	Sig. (2-tailed)
Log(TVC) Reduction	Equal variances assumed	.864	.365	-1.832	18	.083
	Equal variances not assumed			-1.832	16.411	.085
Log(Coliforms) Reduction	Equal variances assumed	.055	.817	1.746	16	.100
	Equal variances not assumed			1.726	14.387	.106
Log(MRSA) Reduction	Equal variances assumed	1.532	.244	-.395	10	.701
	Equal variances not assumed			-.492	5.500	.642

Boxplot of Reductions by Method of Wash (Nurses Uniforms)



OTEX showing higher reductions for coliforms and lower reductions for TVC, though not significantly so.

2.3 Normality Test (Personal Laundry Reductions)

Tests reductions for normality

Data normal (All 'Sig.' > 0.05)

Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Log(TVC) Reduction	.157	20	.200*	.908	20	.059
Log(E-coli) Reduction	.138	20	.200*	.961	20	.556
Log(Coliforms) Reduction	.161	20	.187	.923	20	.115
Log(C.difficile) Reduction	.139	15	.200*	.965	15	.783
Log(MRSA) Reduction	.222	10	.179	.889	10	.163

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

2.4 t-Tests (Reductions: Personal Laundry)

Mean levels fluctuate in magnitude between methods but not significantly

Group Statistics

	Method	N	Mean	Std. Deviation	Std. Error Mean
Log(TVC) Reduction	OTEX	10	3.6918	.58390	.18465
	VIKING	10	3.2461	.89437	.28283
Log(E-coli) Reduction	OTEX	10	4.6794	1.21975	.38572
	VIKING	10	5.5792	2.19467	.69401
Log(Coliforms) Reduction	OTEX	10	4.2498	1.68815	.53384
	VIKING	10	5.5582	1.81545	.57410
Log(C.difficile) Reduction	OTEX	8	2.0983	.94886	.33
	VIKING	7	1.8231	1.15881	.43
Log(MRSA) Reduction	OTEX	6	5.0462	1.45344	.59
	VIKING	4	5.5063	1.76918	.88

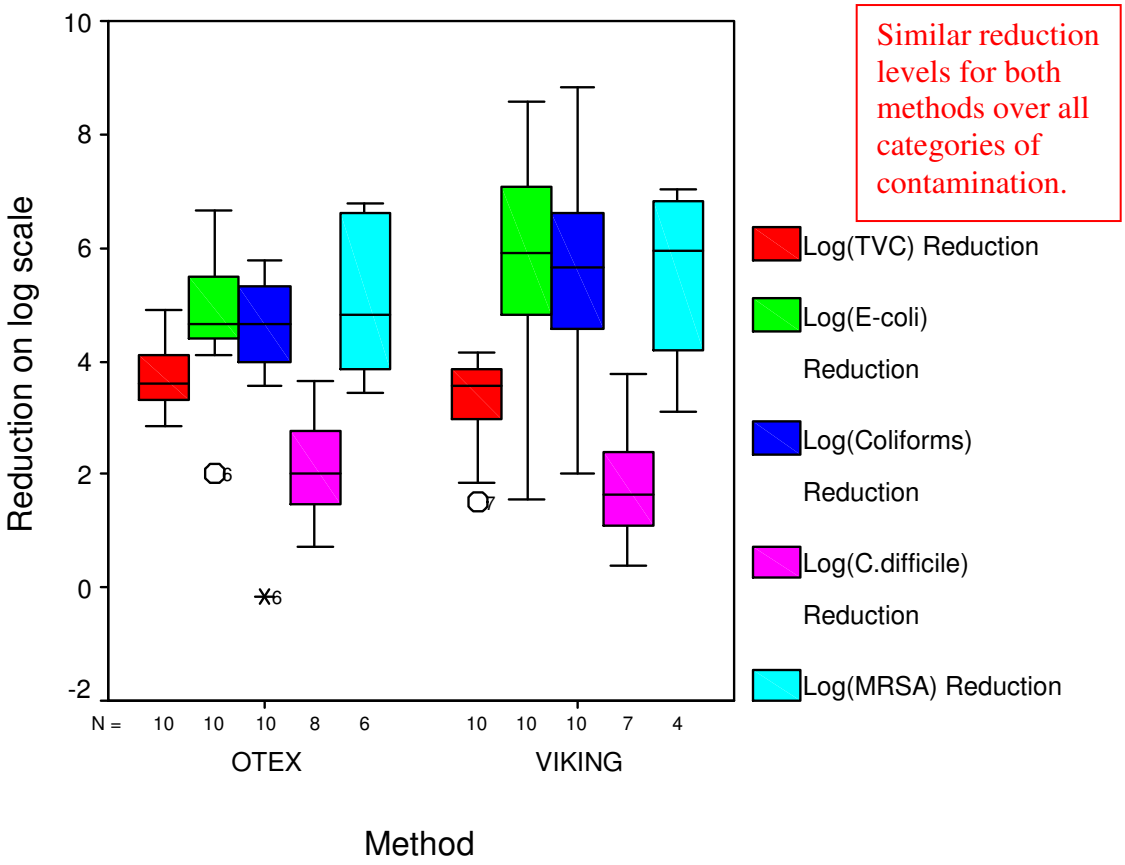
No evidence of any differences in reduction means. All 'Sig.' levels greater than 0.05.

Tests for equal reduction means

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means		
		F	Sig.	t	df	Sig. (2-tailed)
Log(TVC) Reduction	Equal variances assumed	1.464	.242	1.320	18	.203
	Equal variances not assumed			1.320	15.493	.206
Log(E-coli) Reduction	Equal variances assumed	2.534	.129	-1.133	18	.272
	Equal variances not assumed			-1.133	14.076	.276
Log(Coliforms) Reduction	Equal variances assumed	.226	.640	-1.669	18	.112
	Equal variances not assumed			-1.669	17.906	.112
Log(C.difficile) Reduction	Equal variances assumed	.305	.590	.506	13	.621
	Equal variances not assumed			.499	11.664	.627
Log(MRSA) Reduction	Equal variances assumed	.033	.860	-.451	8	.664
	Equal variances not assumed			-.432	5.624	.682

Boxplot of Reductions by Method of Wash (Personal Laundry)



Similar reduction levels for both methods over all categories of contamination.

3.1 t-Tests (Nurses Uniforms: Post-Wash Levels)

Group Statistics

	Method	N	Mean	Std. Deviation	Std. Error Mean
LOGTVC_2	OTEX	10	2.3288	.71429	.22588
	VIKING	10	.5141	.50302	.15907
LOGCOLIF_2	OTEX	10	.3595	.42485	.13435
	VIKING	8	.0000	.00000	.00000
LOGMRSA_2	OTEX	3	.0000	.00000[a]	.00000
	VIKING	9	.0000	.00000[a]	.00000

a. t cannot be computed because the standard deviations of both groups are 0.

Means lower for VIKING . Complete elimination of Coliforms by VIKING. Complete elimination of MRSA by both.

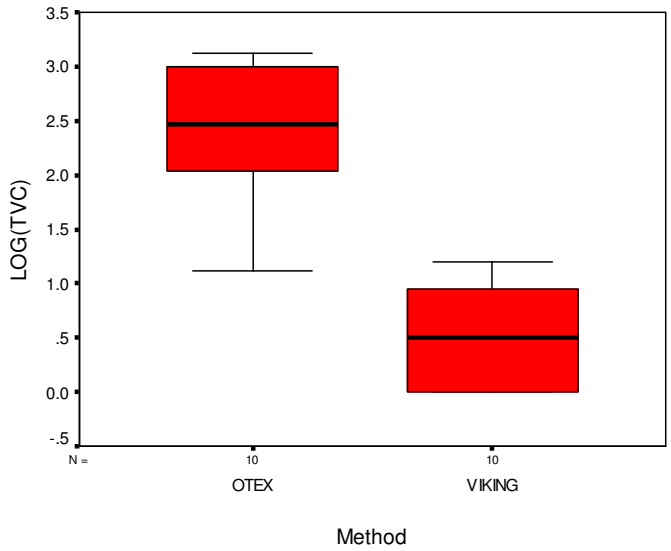
Tests for equal Post-Wash means

VIKING giving significantly lower means ('Sig.' < 0.05)

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means		
		F	Sig.	t	df	Sig. (2-tailed)
LOGTVC_2	Equal variances assumed	.691	.417	6.569	18	.000
	Equal variances not assumed			6.569	16.165	.000
LOGCOLIF_2	Equal variances assumed	27.677	.000	2.379	16	.030
	Equal variances not assumed			2.676	9.000	.025

Boxplot of Post-Wash Levels of TVC by Method of Wash (Nurses Uniforms)



Post-wash levels of TVC generally lower using VIKING

3.2 t-Tests (Personal Laundry: Post-Wash Levels)

OTEX eliminates C.difficile. Both eliminate MRSA. OTEX levels less variable (Std. Deviation Measure)

OTEX levels significantly less variable in 3 categories. Mean level of C.difficile significantly lower (zero) for OTEX ('Sig.' < 0.05)

Group Statistics

	Method	N	Mean	Std. Deviation	Std. Error Mean
LOGTVC_2	OTEX	10	3.2446	.32062	.10139
	VIKING	10	3.6135	.90162	.28512
LOGECOLI_2	OTEX	10	2.6732	.90525	.28626
	VIKING	10	1.6912	1.68678	.53341
LOGCOLIF_2	OTEX	10	3.4446	.65652	.20761
	VIKING	10	2.4330	1.79228	.56677
LOGC.DIF_2	OTEX	8	.0000	.00000	.00000
	VIKING	7	.8496	1.02195	.38626
LOGMRSA_2	OTEX	6	.0000	.00000[a]	.00000
	VIKING	4	.0000	.00000[a]	.00000

a. t cannot be computed because the standard deviations of both groups are 0.

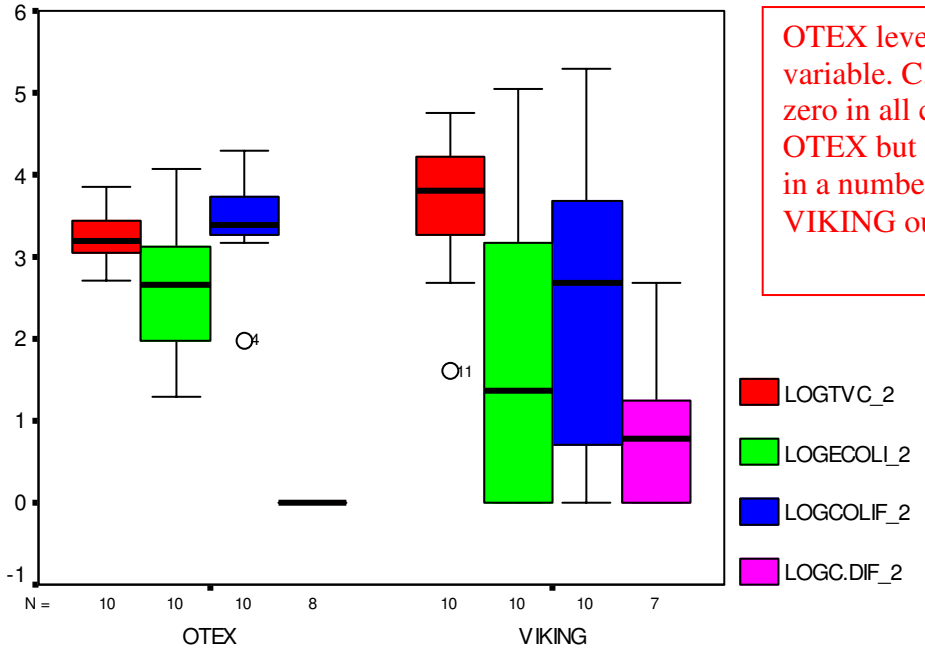
t: Tests for equal Post-Wash means

F: Tests for equal variation

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means		
		F	Sig.	t	df	Sig. (2-tailed)
LOGTVC_2	Equal variances assumed	4.491	.048	-1.219	18	.238
	Equal variances not assumed			-1.219	11.240	.248
LOGECOLI_2	Equal variances assumed	3.504	.078	1.622	18	.122
	Equal variances not assumed			1.622	13.787	.127
LOGCOLIF_2	Equal variances assumed	8.185	.010	1.676	18	.111
	Equal variances not assumed			1.676	11.373	.121
LOGC.DIF_2	Equal variances assumed	13.441	.003	-2.364	13	.034
	Equal variances not assumed			-2.199	6.000	.070

Boxplot of Post-Wash Levels by Method of Wash (Personal Laundry)



OTEX levels less variable. C.difficile zero in all cases for OTEX but still present in a number of VIKING outcomes.

7. DISCUSSION

This is the first in-house hospital comparative study in which the validated ozone disinfection system produced by JLA Ltd is compared directly using identical loads against a standard laundry cleaning procedure in this instance using a VIKING machine.

Both machines were modified slightly in that sample procedures using pre-wash and post-wash aspirations of identical materials and identical volumes into identical bottles were carried out for all loads throughout the entire clinical study.

In all, 20 loads of personal laundry were divided on an alternating basis between the OTEX machine and the VIKING machine. A further 20 loads of nurses personal laundry in the form of uniforms were similarly divided into 2 batches alternating between the OTEX machine and the VIKING machine.

The operating procedures for each machine were standardised throughout the study and the OTEX machine was operated as defined in Appendix 8 and the VIKING machine operated according to Appendix 7 for both chemical and high temperature wash loads.

It was recognised at the outset that 40 loads of laundry was a very small sample. This can therefore be described as a pilot study. The setting in which the study was placed accounted for 35,000-40,000 items of personal laundry serviced per week by the standard VIKING machine. Nonetheless, it was felt useful that in this instance, a formal comparison between standard operating Standard based laundry procedures would be useful when compared with the ozone generating OTEX machine in exactly the same circumstances.

One additional factor in the study, was that the same staff were used throughout and in particular, the Senior Supervisor in the Woodend Hospital Laundry together with an assistant to ensure QA control of the process from JLA, were present and responsible throughout the weeks of study procedures.

In addition, the laboratory personnel who undertook the analysis both of TVC and each of the 4 organisms (E.coli, Coliforms, C.difficile and Staph Aureus, including MRSA) were also constant throughout. All of the methods adopted in the Public Health Laboratory as the responsible laboratory for analysis, remained the same.

Standard laboratory procedures (SOPs) were adopted throughout in accordance with the Certificate of Compliance for all Public Health Laboratories. The study was overseen by Dr Tom Reid, Consultant Microbiologist at Aberdeen Royal Infirmary and Head of Service, and Dr DB Galloway of Redsox Research Ltd.

The allocation of loads between personal laundry and nurses uniforms were arranged in an alternating fashion between the 2 machines. All loads were delivered during the course of any 1 morning and each machine (of similar size) was filled to approximately 15-17 kilos of laundry on each occasion.

For the personal laundry, the VIKING machine was programmed to run on a chemical disinfection programme whilst for the nurses uniforms, a high temperature thermal programme was used as normal for the VIKING machine. The OTEX machine used the same programme throughout on a 40° C (low temperature) for each of the 2 types of laundry wash.

It was also notable that by virtue of the deliveries to Woodend Hospital Laundry, most nurses uniforms were delivered on Mondays and Tuesdays and hence, the nurses uniforms washes were done on those days. Personal laundry occurred every day and by and large was done on Wednesdays, Thursdays or Fridays of the weeks in question.

The time of start for any particular laundry day, and there were 6 in all, was determined by the arrival of the QA person from JLA and this could be as early as 0600 hours completing around 1330-1400 hours, or somewhere between 0830-0930 hours completing around 1430-1500 hours. These data have not been specifically recorded.

The statistical analysis of results are documented in section 6 of this report.

The outline rationale between any statistical decision in analyzing the data collected for both the nurses uniforms and personal laundry are highlighted and documented in the text.

The methods for OTEX and VIKING are compared with respect to the reduction of contamination in soiled laundry and also for pre-wash and post-wash levels. For each wash load the contamination level is measured pre-wash and post-wash for each of the 5 categories agreed – TVC, E.Coli, Coliforms, C.Difficile and MRSA.

A standard SPSS output is used throughout and recognized for its good presentation of results and similarly for detecting statistical differences and presenting these graphically.

In the personal laundry washes where the data collected is well balanced, it is clear that OTEX shows a significantly better end wash for C.difficile with complete elimination and OTEX residual contaminants exhibit significantly lower variation. Both of these factors are attributes of OTEX only and both methods, i.e. OTEX and VIKING successfully eliminate MRSA.

The box plots within the statistics section show clearly the difference and/or similarities between the 2 machines and it is recognized that the numbers of loads used in this exercise are insufficient to detect real differences other than those mentioned between the 2 machines.

Otherwise similar reductions in contamination in personal laundry were achieved by both OTEX and VIKING systems.

A number of differences were noted in the data collected and a comparison of the nurses uniforms is not considered valid for the following reasons:

i) None of the loads washed using the VIKING conventional process had E.coli contamination at the pre-wash stage and hence, no comparison with OTEX was possible.

ii) None of the loads washed using OTEX had C.difficile contamination at the pre-wash stage and only 1 of the VIKING loads showed any such contamination eliminating any comparison for this category.

iii) OTEX loads had significantly increased pre-wash levels of TVC and Coliforms indicating a lack of balance in the sampling procedure which had occurred by chance. Such an occurrence is unlikely in a larger study.

An indication of the power and sample size required to produce statistical tests which are meaningful based on rejection of or failure to reject the null hypothesis are outlined in Appendix 3. Both significance levels and the power of the t-test are illustrated for the variation detected in the study. This could be considered useful for designing any larger, future studies.

It is also recognized that there are some real constraints in increasing the number of loads under these strict circumstances in a normal working hospital laundry. The contribution of the hospital laundry supervisor, however, in comparing the 2 machines throughout the whole of the study period is of importance. She confirmed that the laundry is responsible for 35,000-40,000 articles per week and these articles are of varying texture and uses, for example jumpers, mops and microfibre cloths.

It is noted by the operatives involved here that the laundering processes can vary substantially in temperature, drum rotation and speed as well as the extraction efficiency, detergent and chemical usage for the various components which are routinely used in normal hospital laundry practices.

At the present time, the use of the VIKING machine involved approximately 20 different programmes and 6 different chemicals whereas the OTEX system, on day to day work quality issues has substantial benefits for all the operatives involved in the study. In particular, the benefits both at present and in future, as defined by the laundry operatives, have indicated that OTEX does disinfect articles which are difficult to do so in a VIKING machine (Appendix 4). The staff training is straightforward and there are substantially fewer damaged items because of human error in the programming of the OTEX machine as opposed to the Standard and similar hospital laundry equipment.

Further, all of the personnel indicated that the quality of the finished personal article, particularly jumpers, was both softer and had a pleasant, fresh odour as opposed to a number of items of personal clothing delivered by conventional cycles in the VIKING laundry processing machine.

It is clear, however, from the comments of the operatives at Woodend Hospital Laundry, that further work that they would like to do includes some experimental activity on stain removal (from a variety of fabrics), activities relating to kitchen materials and the cloths and clothing associated with kitchen work, mops of a variety of different kinds including microfibre mops and cloths, and a uniform programme with a shorter and slower final extraction process.

There is little doubt that the overall view of the laundry staff is that OTEX as a laundry system is both simpler and more straightforward to use, has fewer complications and produces a better end product than does the equivalent VIKING machine.

8. SUMMARY

This was a valuable exercise for JLA and Woodend Hospital Laundry in that the formal comparison between the OTEX validated ozone disinfection system and the routine VIKING laundry machine has been carried out under controlled circumstances with fixed and defined loads of laundry.

There are a number of points of advantage in favour of OTEX as a laundry process both in terms of cleanliness, disinfection and end product production. The use of the OTEX laundry system is not only more straightforward with a better outcome in the view of the laundry staff but is simpler and more straightforward to use for all staff involved.

9. CONCLUSIONS

This study has shown the current valid differences between the OTEX Validated Ozone Disinfection System and the standard laundry processing programmes in the VIKING machine.

Overall, the OTEX system produced a significantly better end wash in heavily fouled personal laundry for C.difficile with complete elimination. In addition, the residual contaminants following OTEX laundry processing were significantly more consistent than the VIKING conventional laundry system.

OTEX, like the VIKING laundry processing system, also completely eliminated MRSA from the personal laundry washes.

In all other respects the 2 laundry systems appear to be similar for personal laundry.

This is certainly worthy of further evaluation in a larger number of hospital laundry loads of similar type i.e. heavily fouled loads.

The conclusion in relation to the nurses uniforms data showed that there was too much contamination-free laundry for any meaningful conclusion to be drawn

It is argued, however, that a larger number of hospital loads involving nurses laundry in which the standard OTEX process at 40° C is compared with the high temperature thermal load of the VIKING machine, may be useful in the future in that the use of high temperature loads for this type of laundry does produce more rapid wear and tear of the uniforms provided.

Overall, this study provided good evidence both from the point of view of comparative laundry processes and the views of the personnel involved (see Appendix 4) that the OTEX Validated Ozone Disinfection System was the preferred and safer based laundry processing system to those, and in particular VIKING, currently in use.

A further, longer term and larger study with more frequent exposure to laundry loads is recommended to detect any further differences of significance beyond this small pilot study .

10. REFERENCES

1. Cardoso, C. et al, Letter to the Editor, Infection Control & Hospital Epidemiology, April 2000
2. Block SS. Disinfection of drinking water, swimming pool water and treated sewage effluents. *Disinfection, Sterilization and Preservation* 4th ed. London, UK: Lea & Fabiger, 1991: 713-729.
3. Kawamura K, Kaneko M, Tsuyoshi H, Tagushi K Microbial indicators for the efficiency of disinfection processes. *Water Sci Tech* 1986, 10: 175-184.
4. Nebel C. Ozone, the process water sterilant. *Pharmaceutical Industry* 1984, 2: 16.
5. Gurley B. Ozone: pharmaceutical sterilizant of the future? *Journal of Parenteral Science and Technology* 1985, 39: 256-261.

APPENDIX 1

DATA USED IN STUDY (Converted to log scale)

Results for: Nurses Uniforms

Data Display

Row	LABREF	Pre/Post	METHOD	LOGTVC	LOGECOLI	LOGCOLIF	LOGC.DIF	LOGMRSA
1	W07040282	1	OTEX	4.31806	2.62325	3.65610	0.000	0.00000
2	W07040283	2	OTEX	3.00000	0.00000	0.60206	0.000	0.00000
3	W07040284	1	STANDARD	1.92942	0.00000	1.27875	0.000	2.77815
4	W07040285	2	STANDARD	0.95424	0.00000	0.00000	0.000	0.00000
5	W07040286	1	OTEX	3.96848	2.07188	4.00432	0.000	1.27875
6	W07040287	2	OTEX	2.03743	0.00000	0.00000	0.000	0.00000
7	W07040288	1	STANDARD	2.45637	0.00000	0.00000	0.000	1.75587
8	W07040289	2	STANDARD	0.90309	0.00000	0.00000	0.000	0.00000
9	W07040290	1	OTEX	3.25527	0.00000	1.34242	0.000	0.00000
10	W07040291	2	OTEX	2.10721	0.00000	0.47712	0.000	0.00000
11	W07040292	1	STANDARD	2.06819	0.00000	0.00000	0.000	2.30103
12	W07040293	2	STANDARD	1.07918	0.00000	0.00000	0.000	0.00000
13	W07040294	1	OTEX	3.20412	1.00000	2.72428	0.000	0.00000
14	W07040295	2	OTEX	2.48714	0.00000	0.60206	0.000	0.00000
15	W07040338	1	STANDARD	2.90310	0.00000	3.56110	0.000	0.78000
16	W07040339	2	STANDARD	0.30100	0.00000	0.00000	0.000	0.00000
17	W07040340	1	OTEX	5.09690	2.30100	4.07190	0.000	0.78000
18	W07040341	2	OTEX	3.04140	0.00000	1.21480	0.000	0.00000
19	W07040342	1	STANDARD	3.09690	0.00000	3.17610	0.000	0.48000
20	W07040343	2	STANDARD	1.20410	0.00000	0.00000	0.000	0.00000
21	W07040344	1	OTEX	3.71600	2.21750	3.45940	0.000	0.00000
22	W07040345	2	OTEX	3.13030	0.00000	0.69900	0.000	0.00000
23	W07040346	1	STANDARD	1.99120	0.00000	0.77820	0.000	0.78000
24	W07040347	2	STANDARD	0.00000	0.00000	0.00000	0.000	0.00000
25	W07040348	1	OTEX	3.71600	1.86920	3.37660	0.000	0.00000
26	W07040349	2	OTEX	2.44090	0.00000	0.00000	0.000	0.00000
27	W07040350	1	STANDARD	2.40820	0.00000	1.84320	0.000	0.00000
28	W07040351	2	STANDARD	0.69900	0.00000	0.00000	0.000	0.00000
29	W07050371	1	STANDARD	3.34240	0.00000	1.97770	0.301	1.68120
30	W07050377	2	STANDARD	0.00000	0.00000	0.00000	0.000	0.00000
31	W07050372	1	OTEX	4.15840	1.25530	2.93950	0.000	1.78530
32	W07050378	2	OTEX	2.69900	0.00000	0.00000	0.000	0.00000
33	W07050373	1	STANDARD	3.00000	0.00000	1.17610	0.000	1.69020
34	W07050379	2	STANDARD	0.00000	0.00000	0.00000	0.000	0.00000
35	W07050374	1	OTEX	3.51850	0.00000	3.28330	0.000	0.00000
36	W07050380	2	OTEX	1.23040	0.00000	0.00000	0.000	0.00000
37	W07050375	1	STANDARD	2.30100	0.00000	1.94940	0.000	1.00000
38	W07050381	2	STANDARD	0.00000	0.00000	0.00000	0.000	0.00000
39	W07050376	1	OTEX	3.04140	1.39790	2.00000	0.000	0.00000
40	W07050382	2	OTEX	1.11390	0.00000	0.00000	0.000	0.00000

Results for: Personal Laundry

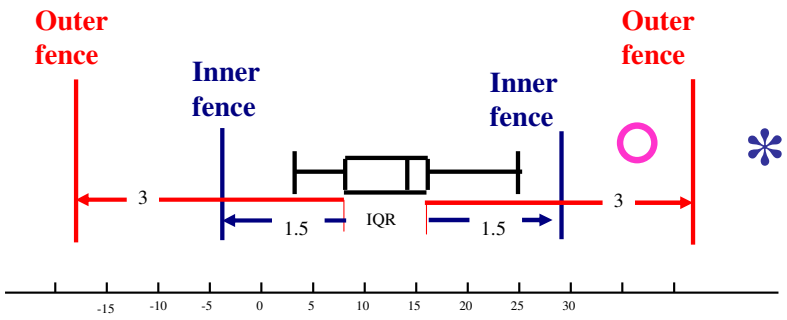
Data Display

Row	LABREF	Pre/Post	METHOD	LOGTVC	LOGECOLI	LOGCOLIF	LOGC.DIF	LOGMRSA
1	W07040209	1	STANDARD	7.22272	7.30000	7.30000	2.78000	7.0400
2	W07040210	2	STANDARD	3.74036	5.03743	5.30000	0.00000	0.0000
3	W07040211	1	OTEX	7.27184	7.30000	7.30000	2.60000	4.1100
4	W07040212	2	OTEX	3.14922	2.91960	3.72428	0.00000	0.0000
5	W07040213	1	STANDARD	7.80140	7.30000	7.30000	3.77815	0.0000
6	W07040214	2	STANDARD	3.84510	0.00000	0.69897	0.00000	0.0000
7	W07040215	1	OTEX	6.17609	7.30000	7.30000	0.00000	0.0000
8	W07040216	2	OTEX	3.06070	1.57978	1.97772	0.00000	0.0000
9	W07040217	1	STANDARD	7.21748	2.31597	7.30000	0.00000	0.0000
10	W07040218	2	STANDARD	4.23045	0.77815	2.72509	0.00000	0.0000
11	W07040219	1	OTEX	8.11059	3.30103	3.30103	1.70000	0.0000
12	W07040220	2	OTEX	3.22272	1.30103	3.47712	0.00000	0.0000
13	W07040221	1	STANDARD	6.24304	7.16137	7.30320	1.73000	0.0000
14	W07040222	2	STANDARD	4.74429	1.34242	3.07188	0.78000	0.0000
15	W07040252	1	OTEX	6.68570	7.30100	8.28330	2.95000	0.0000
16	W07040245	2	OTEX	3.84510	2.56110	3.62320	0.00000	0.0000
17	W07040253	1	STANDARD	7.13350	8.45940	8.79520	2.04000	0.0000
18	W07040246	2	STANDARD	3.26950	1.38020	2.63250	0.00000	0.0000
19	W07040254	1	OTEX	6.82610	8.63250	8.94690	1.99000	6.6200
20	W07040247	2	OTEX	2.69900	1.97770	3.15990	0.00000	0.0000
21	W07040255	1	STANDARD	5.21750	6.60850	6.84320	0.00000	0.0000
22	W07040248	2	STANDARD	1.60210	0.00000	0.00000	0.00000	0.0000
23	W07040256	1	OTEX	6.77450	7.30100	7.30100	2.00000	0.0000
24	W07040249	2	OTEX	3.09340	2.51050	3.30210	0.00000	0.0000
25	W07040257	1	STANDARD	6.82610	8.56110	8.81890	2.07920	0.0000
26	W07040250	2	STANDARD	2.69020	0.00000	0.00000	1.70760	0.0000
27	W07040258	1	OTEX	6.74040	8.60850	8.60850	0.00000	5.4800
28	W07040251	2	OTEX	3.42320	3.11330	3.30100	0.00000	0.0000
29	W07050397	1	STANDARD	6.08640	7.91910	7.91910	0.00000	3.1139
30	W07050403	2	STANDARD	4.22790	1.91910	1.91910	0.00000	0.0000
31	W07050398	1	OTEX	7.00000	8.60210	8.69900	3.64350	3.4314
32	W07050404	2	OTEX	3.50510	4.07190	4.30100	0.00000	0.0000
33	W07050399	1	STANDARD	7.04140	8.00000	8.69900	2.00000	5.2480
34	W07050405	2	STANDARD	3.75590	3.17610	3.68120	0.77820	0.0000
35	W07050400	1	OTEX	7.00000	8.00430	8.90310	0.69900	6.7782
36	W07050406	2	OTEX	3.44720	3.91910	4.30100	0.00000	0.0000
37	W07050401	1	STANDARD	7.80620	9.07920	9.63350	4.30100	6.6232
38	W07050407	2	STANDARD	4.02940	3.27880	4.30100	2.68120	0.0000
39	W07050402	1	OTEX	6.77820	7.17610	8.30100	1.20410	3.8573
40	W07050408	2	OTEX	3.00000	2.77820	3.27880	0.00000	0.0000

APPENDIX 2

BOXPLOT DESCRIPTION

(Box runs from lower quartile to upper quartile, width being the interquartile range, IQR. Line within box indicates the median value)



FENCES and OUTLIER INFORMATION

A mild outlier lies beyond the inner fence

An extreme outlier lies beyond the outer fence

NOTE: The longer the box (which represents the Interquartile Range, IQR) the larger the variation in the data.

APPENDIX 3

Power and Sample Size

The estimate of sample size depends upon the following:

- the difference in true response to be detected
- the inherent variation among experimental units
- the magnitude of risks to be tolerated (i.e. significance level and power of test to be used in the analysis)

Significance levels and power in the context of statistical tests are explained below.

Statistical Tests are based on 'rejection of' or 'failure to reject' a null hypothesis. A typical null hypothesis example is 'The mean scores for the two sampled populations are equal'
Significance levels, usually denoted by α, used for rejection are typically 0.05, 0.01 or 0.001 i.e. if the probability of being wrong in rejecting the null hypothesis, based on collected data, is smaller than α, we decide to reject the null hypothesis.
Power of a test is the probability of correctly rejecting the null hypothesis when it is false. In other words, power is the likelihood of identifying a significant difference when one exists. 0.8 is normally a minimal level of power before proceeding with the survey or experiment of a certain size. Mathematical formulae enable the computation of power levels for specific tests such as the two-sample t-test, using as input n = sample size, α = the significance level, inherent variation (represented by σ, the standard deviation) and the desired difference in means between the two samples, d. These same formulae can also be used to estimate minimal sample size for a stated power, the other inputs remaining the same.

In other words a study with sample size 64 (study size 128) will be capable of detecting a difference in means of magnitude 5 with 80% (0.801460) power at the significance level 0.05, a difference of 7.5 with 95% power at the 0.01 level, and a difference of 10 with 99% power at the 0.001 level.

Sample Size Estimation/

Sample Size Estimation

Using data from this study it is known that the maximum standard deviation in log scale reduction is 2.19 [log(coliforms) in ***2.4***]. Sample size estimations for a 2-sample t-test are given in the table below, for α = 0.05, σ = 2.19, d = 0.5, 1.0, 1.5, 2, 2.5, 3, 3.5, 4, Power = 0.8, 0.85, 0.9.

Power and Sample Size

```
2-Sample t Test

Testing mean 1 = mean 2
(versus not =)
Calculating power for
mean 1 = mean 2 +
difference
Alpha = 0.05  Assumed
standard deviation =
2.19
```

For example, a study with sample size 35 (study size 70) will be capable of detecting a difference in means on the log scale of magnitude 1.5 with 80% (0.806379) power at the significance level 0.05.

APPENDIX 4

OTEX USER SURVEY: Health & Safety Questionnaire

9 returns were received. Results were as follows, numbers relating to the questionnaire question numbers:

1 All had used OTEX before.

2 None needed training

3 All 9 indicated that they did not need much training.

4 a 7 found it **easy** to use. Remaining 2 did not respond.

b 7 indicated that it was **better** to use. 2 rated it the **same.**
One of these commented that 'A gentler final extraction would improve finish'.

c 7 found smell/freshness **pleasant**. Remaining 2 did not respond.

5 7 found that OTEX could be used for delicates **with no adjustment.** 2 felt OTEX needed **some adjustment.** Of these two, one commented that 'a programme with less agitation would improve the finish'. The other commented that it 'needs slight adjustment on final extraction'.

6 7 found the 40^0 feature in OTEX **good**. Remaining 2 did not respond.

7 7 responded **YES** that it would be beneficial/better value to switch to OTEX. Remaining 2 did not respond.

Comment: Responses were generally positive with 7 or more answering favourably throughout and none answering negatively. Comments of interest were mentioned in 4b and 5.

APPENDIX 5

OTEX VALIDATED OZONE DISINFECTION

Guaranteed substantial savings

OTEX saves time and money. The system takes 30 minutes less to disinfect than conventional thermal disinfection cycles and therefore reduces labour costs.

By using mostly cold water, it also slashes utility bills. And because of the way it actually processes laundry, it cuts detergent usage and increases linen life.

These are typical average savings:

Based on using correct wash programmes and detergent dosage

For more information about how OTEX can help your business, call

0800 591903

JLA Limited Meadowcroft Lane, Ripponden, West Yorkshire, HX6 4AJ
T 01422 822222 F 01422 824300 email otex@jla.com www.jla.com/otex

OTEX - What our customers say

The OTEX system is the perfect laundry solution for a wide range of markets.

For care homes, hospitals, the food industry, vets and stables, the system's ability to kill bacteria, viruses and superbugs on all wash cycles guarantees total peace of mind.

The way OTEX actually washes is particularly beneficial to the hospitality sector. Fibres in items such as towels and linen are lifted, giving them a softer feel and prolonging their life. They also smell much fresher.

For all markets, one of the system's biggest benefits is, of course, the substantial savings it achieves.

This is what a small selection of satisfied OTEX customers say:

'I cannot believe what a weight off my mind it is that the OTEX system is foolproof ... I would recommend it to anyone.'
David White, Sydenhurst residential home, Surrey

'Washing the drying times have been significantly reduced and the laundry room environment has really improved.'
Lynne Hughes, Harewood College, Coventry

'The fact OTEX kills all bugs is an added benefit to the home and one less thing for me and Matron to worry about.'
JW Day, Riverside Healthcare Centre, Solihull

'It has enabled us to bring the laundry system back in-house and a £10,000 budget can be used for other things.'
Keith Pocock, Peashouse, East Sussex

'Whites appear whiter ... the OTEX system provides a pleasant aroma with a hint of outdoor freshness.'
S Marsh, Well Springs Nursing Home, Bradford

JLA
Your In-house Laundry Partner

Kills bacteria, viruses and superbugs on all wash cycles

Cuts all laundry running costs

World leaders in ozone laundry technology

The OTEX laundry system is the result of more than 10 years of development and was launched amid mounting concern about cross contamination in laundries.

Data obtained by JLA showed that high temperature thermal disinfection wash programmes used for processing infected and foul laundry were often not used when they should have been. A foolproof system able to kill bacteria, viruses and superbugs on all cycles was clearly needed.

JLA joined forces with internationally respected technical experts and scientists and embarked on an intensive programme of research, testing and development to perfect a system which would give businesses complete peace of mind – and at the same time save them substantial amounts of money.

The result is OTEX, a system so effective that it has earned JLA global recognition as the leaders in ozone laundry technology.

Validated ozone disinfection

OTEX can not only kill bugs on all wash cycles, but can actually prove that it has done so.

The system is available with a sophisticated validation unit which monitors the amount of ozone being injected into the wash process and provides a printed 'receipt' confirming that the cycle has achieved disinfection.

This guarantees complete peace of mind in all environments where infection control is critical.

Kills bacteria, viruses and superbugs on all cycles

The OTEX laundry system kills bacteria, viruses and superbugs – including MRSA and Clostridium difficile – on all wash cycles.

To prove the system's effectiveness, exhaustive tests were carried out in laboratory-controlled conditions by microbiologists from widely respected and accredited Microsearch Laboratories.

Comparative tests were carried out on laundry contaminated with a strain of MRSA. One test was with a commonly used 40°C wash programme and the other was with an OTEX cycle. MRSA was still very much in evidence after the 40°C cycle – but after the OTEX cycle, there was no visible trace of the bug.

Other comparative tests centred on Clostridium difficile, which has been reported to be killing twice as many people as MRSA.

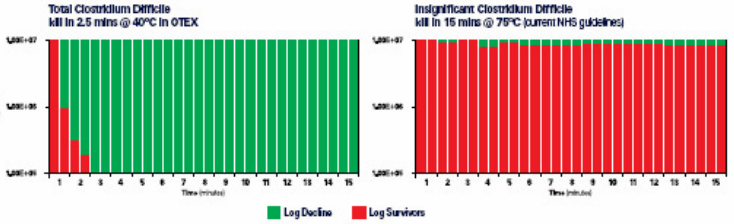
When water containing Clostridium difficile and processed by the OTEX system underwent an EU Suspension test, it was found to have no visible trace of spores after only two-and-a-half minutes.

Water containing Clostridium difficile which had not been processed by OTEX was then held at a temperature of 75°C for 15 minutes. Even though this was far hotter and longer than thermal disinfection cycles recommended by the NHS, Microsearch found innumerable Clostridium difficile spores remained – they said the reduction of spores was 'insignificant'.

Microsearch also carried out tests on microfibre mop heads used on a hospital ward. After a mop head was processed with OTEX it was found to be bug-free. But after a thermal disinfection cycle, another mop head remained rife with Clostridium difficile.

Based on one cubic centimetre of the mop head analysed, the entire mop head was still teeming with bugs - it was estimated to have had 150,000 Clostridium difficile CFUs (Colony Forming Units).

After studying scientific evidence, the Commission for Social Care Inspection (CSCI), stated that laundry systems using the 'specific technology' of OTEX comply with the National Minimum Care Standards.



HOW OTEX WORKS

APPENDIX 6

OTEX VALIDATED OZONE DISINFECTION

HEALTH & SAFETY QUESTIONNAIRE

Explanation of the Survey

We are interested in looking at the laundry procedure in NHS Grampian laundries. This is principally for health and safety reasons. We would like you to answer the questions honestly and openly as to whether you have experienced any differences between the routine processing of heavily fouled laundry in the normal Standard machine versus that which is currently being undertaken in the new OTEX machine.

Your help and cooperation in this survey, which will only take a few minutes, is much appreciated.

1. Have you used the OTEX/OZONE Laundry Systems before? **YES/NO**

2. If not, would you be prepared to be trained on the system? **YES/NO**

3. If you have used the OTEX System before, did you find you needed much training? **YES/NO**

   If so, how long?

   5 minutes 10 minutes 15 minutes 30 minutes 1 hour
   (please circle as appropriate)

4. How does the OTEX System compare with other machines in the laundry?

   a. For ease of use:

      Easy Not so easy Difficult
      (please circle as appropriate)

      If you chose Difficult, please explain why:

      ……..

      ……..

   b. For quality of finish of laundry

      Better Same Worse
      (please circle as appropriate)

      If you chose Worse, please explain why:

      ……..

      ……..

   c. For smell/freshness on completion of laundry service:

Pleasant Same Worse
(please circle as appropriate)

If you chose Worse, please explain why:

……

……

5. Overall, in using the OTEX System, could it be used for delicates as well as heavily soiled laundry?

With no adjustment With some adjustment Lot of adjustment
(please circle as appropriate)

If OTEX needed a Lot of Adjustment, please explain why:

……..

……..

6. How do you rate or value the 40 ° temperature feature in OTEX **GOOD/BAD**

If you chose Bad, please explain why:

……

……

7. Given your experience of the laundry and the machines in current use, would you think it beneficial/better value to switch the laundry to an overall OTEX System? **YES/NO**

If you chose No, please explain why:

……

……

Thank you for taking part in this survey.

Dr Tom Reid
Consultant Microbiologist
NHS Grampian

APPENDIX 7

STANDARD LAUNDRY MACHINE
(Model No. HS4022) SOP

Woodend Laundry, Aberdeen.

Standard Low Temperature Disinfection.

Section	Description	Time	Temperature	Dip Levels	Detergent Input	
1	Sluice	5 min	Cold	Med/High	None	No drain between Section 1 & 2. At 3 min mark flush tube for 20 seconds with Wash liquor then take sample.
2	Sluice	3 min	Cold	Med/High	Biosolve	
3	Sluice	3 min	Cold	Medium	0.4g/l alkaline detergent	
3	Pre Wash	10 min	40^{o}C	Medium	0.4g/l alkaline detergent	
4	Main Wash	10 min	40^{o}C	Medium	0.5g/l alkaline detergent	Flush sample tube for 20 secs at end of each cycle.
5	Rinse 1	3 min	Cold	Med/High	None	
6	Rinse 2	6 min	Cold	Med/High	Sodium Hypochlorite @ 150 ppm	
7	Rinse 3	3 min	Cold	Med/High	None	At end of section 7 at 2 min mark flush for 20 secs then take sample
8	Spin – 1000rpm	5 min	----	-----	----	

Woodend Laundry, Aberdeen.

Standard High Temperature Uniform Wash

Section	Description	Time	Temperature	Dip Levels	Detergent Input	
1	Sluice	5 min	Cold	Med/High	None	No drain between Section 1 & 2. At 3 min mark flush tube for 20 seconds with Wash liquor then take sample. Flush sample tube for 20 secs at end of each cycle. At end of section 7 at 1 min mark flush for 20 secs then take sample
2	Pre Wash	8 min	80°C	Medium	0.6g/l alkaline detergent	
3	Main Wash	10 min	80°C	Medium	0.8g/l alkaline detergent + Hydrogen Peroxide	
4	Cool Down	Temperature dependent	-4°C per minute by addition of cold water	Extra High where required		
5	Rinse 1	2 min	Cold	Med/High	None	
6	Rinse 2	2 min	Cold	Med/High	None	
7	Rinse 3	2 min	Cold	Med/High	None	
8	Spin – 1000rpm	5 min	----	-----	----	

Safe System of Work

Section 2

Washing Machines

Work Delivery –

Work is wheeled from sort area to washing machine area in blue or small tin barrows after being weighed.

Loading –

Work is then loaded into appropriate machine by weight (the maximum weight each machine may be loaded to is displayed on the front of each machine). Weight and program is punched into Henkel programmer, wash program is punched into machine keypad and start button is then pressed.
Wheel empty barrows back to sort area, if not in use stack three high with the help from another member of staff.

Unloading –

Work is unloaded from washing machines into white barrows, where it is then wheeled to either the tumble drier or calendar areas, whichever is appropriate.

Red Bags (fouled or infected linen)

When filling machines with fouled linen, contained in red alginate strip bags. Put the bag unopened into machine, the contents of any other type of red bag (fully alginate or non alginate) should be emptied into the machine and the bag disposed of in a clinical waste bag.
When emptying machines of foul or infected work, decant into a blue barrow and wheel to the sort area, to be sorted and re-washed.

Barrel Changeover –

Barrels of laundry chemicals are to be changed when green light indicates barrel is empty. (See appendix 1 – Detergent & Laundry Chemicals Storage).
Barrels should to be moved using designated handling equipment and protective equipment i.e. barrel lifter, gloves and goggles supplied, wheel to appropriate area, all paths must be cleared before embarking on this task always double check product and chemical name before inserting lance, when in doubt ask supervisor in charge **do not insert lance until supervisor has confirmed.**
Empty barrels are then placed in appropriate place for collection. (See appendix 1).
For any accidental spillage or splashing see appendix 2 for information.

Soap Powder Desimix –

Protective equipment (long gloves and face shield) must be worn while dealing with this product.
Slide 25kg bag onto table of lifting equipment, pumping it to height of Desimix. The bag is then opened and slowly pushed along the table emptying contents into Desimix. Empty bag is then disposed of into a black refuse bag. (See appendix 2 – Splash & Spillage Information). On the first day of every month and when the Desimix is at its lowest level, it should be inspected for hardened detergent. Any hardened detergent must be scraped free in accordance with Appendix 3

Clearing of the Filter basket
The drain cover allocated at the back of washing machine number 7 must be lifted daily, the filter basket removed, cleaned and replaced.

House keeping –

When time allows sweep floor of debris, wipe down glass doors and seals of washing machines with a damp cloth. Wipe down soap hoppers including under hopper lid.
All chemical drums and containers should be placed neatly and in order, with no protrusions such as lance. Nothing should be placed on top of drum or container.
All spills must be cleared immediately.
Soap store must be kept tidy with all containers placed in allocated space.

Stock take -

Stock take must be done weekly, recording and highlighting stock needs. When stock needs to be ordered place stock sheet on Donna's desk.

Washing machine area

Safety Advice –

The following advise is given to reduce risk of injury from manual handling, lifting and straining also substance handling.

1. **Protective clothing i.e. gloves & uniform are to be worn at all times. These should be removed at breaktimes and not taken into clean areas. For hygiene reasons and prevention of cross-infection it is essential hands should be washed each time a member of staff leaves the Sort Area.**

2. **IT IS ESSENTIAL THAT ANY MACHINE MALFUNCTION OR LEAK IS REPORTED IMMEDIATELY.**

3. **Face shield and long gloves are provided and must be worn when dealing with solvents, detergents and drains. (shields, masks and gloves are kept in secure cupboard on window-sill at the back of washing machine 6)**

4. **Barrows should be placed under window of washing machine while loading or unloading.**

5. **While loading and unloading machines each individual should do so in a manner that is safe and comfortable for them.**

6. **While loading and unloading machines do not use twisting action as this puts unnecessary strain on your back and arms, use your feet to turn.**

7. **When finding difficulty unloading bedscreens, staff must seek assistance.**

8. **Any trolley not running freely should be reported to the Estates Helpdesk and taken to designated area for repair.**

9. **When stacking blue barrows there should be one person at either end to lift, stacking them no more than 3 high. Do not lift on your own.**

10. **All water spills to be mopped up immediately.**

11. **Any solvent or detergent spills to be dealt with as in appendix 2**

12. **All walkways, designated by yellow lines, are to be kept clear at all times.**

13. **Any sharps or needles found must be reported and disposed of immediately into the nearest cinbin.**

14. **Ten minutes before stopping time each day do a general tidy and sweep up.**

APPENDIX 8

OTEX LAUNDRY SYSTEM MACHINE SOP

OTEX Foul & Infected Wash Process.

Woodend Laundry, Aberdeen.

Section	Description	Time	Temperature	Dip Levels	Detergent Input	Ozone	Actions
1	Sluice (Low Level)	5 min	Cold	28cm	Non	Ozone is injected throughout the whole wash process.	Sample taken after 3 mins (after level stop) with 20 sec drain to clear.
2	Pre Wash	6 min	40°C	20cm	60mls		20 sec drain to clear.
3	Main Wash	8 min	40°C	20cm	114mls		20 sec drain to clear.
4	Rinse 1	5 min	Cold	24cm	Non		20 sec drain to clear.
5	Rinse 2	10 min	Cold	24 cm	Non		20 sec drain to clear.
6	Rinse 3	5 min	Cold	24 cm	Non		Sample taken after 4 mins with 20 sec drain to clear.
7	Spin – 1000rpm	4 min	----	-----	----		

Machine type: JLA HF234 – 23 Kilo
Single OTEX Unit delivering max 4g/hr ozone
Woodend Laundry OTEX system set up – 9-10 leds, 5psi and 4SCFH.

NOTE: It is proposed to include a pre sluice section (5 min) to accommodate sampling of the wash liquor prior to ozone injection. This is to provide a pre process bacteriological count.

Samples of the wash liquor from the drum will be taken from a sampling point after allowing 20 secs of flow to flush the sampling tubing prior to collection. The sampling nozzle will be disinfected prior to sampling. Sampling will be conducted in an aseptic manner. Samples to be refrigerated prior to transferring to the microbiological laboratory for analysis.

APPENDIX 9

Study Protocol No. OZONE/01-2007/120207/Hospital Laundry Study, Version 6