Report to Rhima Australia Pty. Ltd.

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Microbiological Evaluation of DEKO-190 Washer Disinfector

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A report on a microbiological study undertaken by the Centre for Infectious Diseases & Microbiology Laboratory Services, Institute of Clinical Pathology & Medical Research, Western Sydney Area Health Services, Westmead

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DEKO-190 Washer Disinfector
A Microbiological Evaluation

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1. INTRODUCTION

In June 1997, Westmead Hospital purchased a new washer disinfector, manufactured in Finland, called the Deko-190 and distributed by Rhima Australia Pty. Ltd. The machine was installed and commissioned by the Maintenance and Facilities Development Department (MFDD) of Westmead Hospital to requirements as specified by the manufacturer. The machine has since been in continuous use in the Emergency Department.

A microbiological evaluation was requested by Mr. Ian Brown, Acting Manager, Area Consulting Service, Western Sydney Area Health Service (in a memorandum dated 22 July 1997) to produce Australian data applicable to the Deko-190 Washer Disinfector.

The temperature profile of the machine under operating conditions was tested by MFDD using a protocol similar to that of the Institute for Planning and Rationalisation of the Medical and Social Welfare, Sweden[1]. The results of MFDD's testing are not contained in this report. During the course of our microbiological testing of the Deko-190, we measured the come-up time and duration of the pasteurising temperatures of the machine, in effect extending the temperature studies performed by MFDD. This and the microbiological evaluation of the machine and associated studies are detailed in this report.

2. AIMS

(a) To verify that the Deko-190 meets a number of established performance criteria. The criteria include efficacy of disinfection (inactivation of selected microorganisms) and visualisation of washing cleanliness.

(b) To determine the temperature profile of the machine in the washing/disinfecting chamber.

3. METHODS

3.1 CHOICE OF CHALLENGED ORGANISMS

Except for the choice of organisms and specification of the plastic tubing used, this study is similar to that of the Helsinski study[2] (Department of Public Health, Helsinski, Finland, 1993). Three microbial preparations, namely pure cultures of *Enterococcus faecalis* NCTC 775 and *Poliovirus type 1*, and a 1% faecal suspension containing spores of *Clostridium perfringens* were used as the challenged organisms for the evaluation of the machine.

Enterococcus faecalis is faecal indicator of pollution; it is relatively more heat resistant than other non-spore-forming enteric pathogens, such as salmonellae including typhoid bacilli, shigellae, pathogenic *E. coli*, vibrios and yersiniae. *Clostridium perfringens* is an anaerobic bacteria commonly present in stool specimens. The organism sporulates actively in the intestinal tract of cases of *Clostridium perfringens* food poisoning. The challenged material in our experiment was taken from the stool specimen of a patient who was confirmed to have *Clostridium perfringens* food poisoning. *Poliovirus* type 1 is generally more heat resistant than other clinically significant viruses and has been selected for this reason. The test organism, *Bacteriophage Felix 01*, used in the Helsinski study was not used in our trial, as it was not readily available at short notice.

3.2 CULTURE OF ORGANISMS AND PREPARATION OF CULTURE TUBINGS

The organisms (bacterial and viral) described below were grown and dispersed homogeneously in a suspending fluid. Sealed tubings of the organisms were then prepared by aliquoting approx. 0.3 mL into one of several thin-walled plastic tubings and sealed by heat. The prepared culture tubings were used for both the *in-vitro* laboratory heat resistance tests and the Deko-190 tests.

Description of plastic tubings: heat-resistant polypropylene, 4mm external diameter, 0.10mm wall thickness, length 120mm, capacity is approx. 1 mL (cat. no. 4972-905; Benton Dickinson).

3.2.1 BACTERIAL

Enterococcus faecalis NTCC 775 was sub-cultured onto horse blood agar (HBA) and McConkey agar plates, incubated overnight at 37°C and inspected the next day for growth and purity of culture. Growth from HBA was harvested in a bottle containing 20 mL physiological saline. The suspension was vortexed for 1 minute until uniformly distributed. The turbidity was measured and adjusted to 0.5 McFarland (approx. 10^7 organisms per mL). A volume of approximately 0.3 mL culture suspension was aseptically dispensed in a sterile tubing and sealed. Seven culture tubings were made for the *in-vitro* heat resistance tests and eleven made for the Deko-190 tests.

Faecal suspension. A stool specimen from a patient who had laboratory-diagnosed *Clostridium perfringens* food poisoning was selected for this test. A 1% (w/v) suspension of the specimen was prepared in physiological saline. The same number of tubings of this suspension was similarly prepared.

3.2.2 VIRAL

The standard *Poliovirus* type 1 strain was previously prepared in the laboratory by growth in human embryonic fibroblasts (HEF) MRC5 strain in 1% fetal calf serum. The virus was harvested when 100% cytopathogenic effect (CPE) was observed. The cells were disrupted by rapid freeze-thaw (3x) and the suspension centrifuged in a bench-centrifuge at 2000 rpm for 10 minutes. The supernatant was collected and 0.5 mL aliquotes were stored at -70°C. The concentration of virus was tested by serial dilution, inoculating in HEF cells and incubating for 7 days at 37°C (titre ~ 10^7 per mL). The serotype was confirmed by dilution of the virus

and tested by neutralisation against the three standard *Poliovirus* serotypes and observing growth in HEF cells for 7 days at 37°C. For this experiment sufficient virus was thawed and combined to prepare the plastic tubings.

0.3 mL aliquote of *Poliovirus* type 1 was pippetted into each sterile plastic tubings and heat sealed. Six viral culture tubings were made for the *in-vitro* heat resistance tests and eleven made for the Deko-190 tests.

3.3 HEAT RESISTANCE STUDIES (*IN-VITRO* TESTS)

The purpose of the tests is to determine the heat resistance of the organisms at various temperatures for an exposure period of one minute, which is the approximate time of exposure in the Deko-190 during the pasteurising cycle.

3.3.1 HEAT TREATMENT

Heat treatment of cultures of *Enterococcus faecalis,* faecal suspension containing *Clostridium perfringens* and *Poliovirus* type 1 in the laboratory was performed as follows:

A beaker of water (1-litre) was heated gently over a bunsen burner. The water was mixed with a stirring rod and temperature measured using a calibrated mercury thermometer. When the desired temperature was reached, the beaker was then placed in a lagging material, and the sealed bacterial and viral organisms were immersed for exactly 1 minute. Following the heat treatment, the sealed culture tubings were removed from the heating medium and allowed to cool on the bench before further testing.

The temperatures selected for each of the challenged organisms were as follows:
Enterococcus faecalis: 40, 50, 60, 70, 80 and 90°C
Poliovirus type 1: 40, 50, 60, 70, and 80°C
Faecal suspension containing *C. perfringens* spores: 70, 80, 90 and 100°C. For the latter temperature, culture tubings were immersed in boiling water for 1 minute, 10 minutes and 30 minutes respectively.

3.3.2 CONTROLS

The concentration of the challenged organisms prior to heat treatment was determined by testing untreated controls along with the heat-treated organisms. The procedures for performing test controls associated with the *in-vitro* laboratory and Deko-190 studies were the same (see Section 4) but the concentration was not necessarily identical.

Enterococcus faecalis
The control was a non-heat treated culture tubing from the same batch as the treated tubings kept at room temperature (22°C).

Faecal Suspension
The control was also a non-heat treated culture tubing from the same batch as the treated tubings kept at room temperature (22°C). Quantitative enumeration of this control as described in 3.3.3 gives the total anaerobic count.

Poliovirus

Two controls were setup for *Poliovirus* type 1 and were titrated with the heated cultures. These were (a) a pooled viral stock kept refrigerated after thawing and (b) a viral culture tubing incubated at 37°C for 1minute.

3.3.3 BACTERIAL TESTS

Following heat treatment, the top end of each culture tubing was cut aseptically. Serial dilutions were performed by removing 0.1mL using a pipettor into a test tube containing 0.9 mL saline. The serial dilutions tested varied with the organism and heat treatment. For *Enterococcus faecalis*, dilutions to 10^{-6} were made for 60°C and below, and dilutions to 10^{-3} for the higher temperatures. For faecal suspension containing spores of *Clostridium perfringens* all culture tubings were serially diluted to 10^{-6} . An inoculum size of 0.1 mL from each neat and serial dilutions was plated onto plates. Plate Count Agar (PCA) plate was used for *Enterococcus faecalis* and Horse Blood Agar (HBA) for *Clostridium perfringens* and total anaerobes. Plates were allowed to dry on the bench following spreading the inoculum with a hocky stick and incubated at 37°C, aerobically for *Enterococcus faecalis* and anaerobically (in anaerobic chamber) for *Clostridium perfringens* and total anaerobes. Plates were counted after 48 hour incubation and the count of each organism type was calculated. *Clostridium perfringens* appeared as large (3-4 mm) colonies with a unique curtain-like morphology spreading outwards in most colonies. Haemolysis was not observed in the predominanting *Clostridium perfringens* population. The organism was also biochemically confirmed using standard laboratory tests (Anaerobe Lab, ICPMR).

3.3.4 VIRAL TESTS

Viral tests were performed using detection methods routinely used in the Viral Isolation Lab, ICPMR. The specific procedures followed are given here.

Following heat treatment each of the *Poliovirus* culture tubing including the control tubing was wiped with 70% alcohol and the top end of the tubing cut with sterile scissors and the poliovirus pipetted into a bijou bottle. A 0.1 mL aliquote was added directly to the first well in a cell culture plate (Falcon 48-well sterile cell culture plate). The two remaining 0.1 mL aliquotes were separately serially diluted with Hank's balanced salt solution (0.9 mL) to give dilutions of 10^{-1} to 10^{-7}. This was followed by dispensing 0.1 mL of each dilution to the cell culture plate in an orderly manner. An 80 mL suspension of Human embryonic fibroblasts cells (HEF) was then prepared in growth medium using 1% trypsin versene solution. The HEF cells had been grown in a cell culture flask containing minimum essential medium with 9% foetal calf serum. A volume of 0.3 mL of the cell suspension was added to each well. The plate was covered and placed in a 37°C CO_2 incubator. The cultures were observed each day and any changes noted. At the end of seven days the final results were recorded and the cultures discarded.

4. EFFICACY TESTING OF DEKO-190'S PROCESS OF DISINFECTION

The Deko-190 has been designed for use as a washer/sanitiser. During the disinfection cycle of the machine when hot water and steam are introduced to the chamber (temperature should record 92°C for just over a minute) the machine is expected to achieve a high degree of disinfection (but not sterilisation). The process is expected to consistently inactivate non-

spore forming bacteria and all viruses but not heat resistant spore-forming bacteria. The three test materials were selected for the purpose of verifying these microbiological outcomes.

Deko-190 has a choice of five standard programs. Programs 2-4 include a disinfection cycle which is of the same duration. *Program 3* was used in our experiment and is a short wash including a detergent wash and disinfection.

The machine was loaded at maximum capacity with two bedpans and two urine bottles. The prepared culture tubings were frmly secured using adhesive tapes in 5 positions and were labelled as shown in the table below (*Run1*). A second run was performed immediately after the first run, with an additional set of cultures taped on the inside of a urine bottle.

Table 1

Position of Vials	**Enterococcus faecalis**	**Faecal suspension**	**Poliovirus**
Run 1			
1. BedPan1, right	S1	F1	P1
2. Bedpan2, left	S2	F2	P2
3. Back of machine	S3	F3	P3
4. Urine bottle1 (outside)	S4	F4	P4
5. Right wall of machine	S5	F5	P5
Run 2			
6. BedPan1, right	S6	F6	P6
7. BedPan2, left	S7	F7	P7
8. Back of machine	S8	F8	P8
9. Urine bottle (outside)	S9	F9	P9
10. Urine bottle1 (Inside)	S10	F10	P10
11. Right wall of machine	S11	F11	P11

4.1 MICROBIOLOGICAL TESTS

The general procedures for testing bacterial and viral cultures are as described previously (section 3.3). Any departures from those described are indicated below.

Enterococcus faecalis cultures were tested neat (undiluted) with PCA and McConkey agar plates, each with 0.1 mL of suspension.

Faecal suspension (1%w/v). Faecal suspensions were plated onto Horse Blood Agar (anaerobic count) and McConkey and Horse Blood Agar plates (aerobic count) with 0.1 mL and 0.01 mL in each set of plates.

Viral cultures

Cultures were titrated at 10^{0} and 10^{-1} dilution (0.1 mL in each) i.e four titrations were made

for each test position in the chamber.

Controls
A separate set of controls (not machine disinfected) was performed for bacterial and viral tests as this study was not undertaken on the same day as the laboratory heat resistance tests. The concentrations of the organisms in the culture tubings were quantitatively determined as described previously (section 3.3.2). A "standard" spore count was determined on the *faecal suspension* control tubing by heating at 80°C for 10 minutes.

5. WASHING CLEANLINESS

Cleaning efficiency

The cleaning efficiency of the Deko-190 Washer Disinfector was studied after being used under normal clinical conditions. Bedpans and urinals were placed in the machine after being used in the clinical environment and therefore contained either urine or faecal matter. The items were placed in the machine (2 bedpans and four urinary bottles each made of plastic) immediately after use and flushed while awaiting a full load. When a load was achieved the machine was commenced on program 3, and the process repeated for each item and load. After washing, the degree of cleanliness was estimated visually.

Wash bowls containing water and neutral soap were used to wash patients following a trauma accident. Blood stained solution was emptied out of the bowl and the bowl was then placed into the machine.

Following a trauma accident, a major procedural pack, kidney dish and 2 gallipots stained with blood and betadine, left standing after the trauma for 30 minutes, were placed into the machine, flushed on program 1, then program 3. Another instrument also used in the trauma was put through the same process. This was studied to measure the possibility of eliminating the manual handling of staff cleaning instruments prior to being sent to the sterilising department and not as a substitute for sterilisation.

A cleaners bucket used for mopping up the two accident and emergency trauma bays following a trauma where large blood spraying had occurred was emptied and processed through the machine on program 3.

Results

On visual inspection the Washer Disinfector proved cleaning to be efficient as items processed were observed clean. Due to age of some equipment the wear and tear of items was still evident, ie they were not returned to an 'as new' state but were in fact clean.

Utilisation of the machine for cleaning instruments prior to sterilisation and minimising the need for staff to manually handle instruments proved successful as instruments were carefully observed and shown to be free from visual contamination.

The results of the test washings are shown in Table 2.

Table 2

Results on the cleaning efficiency of the ward disinfector

ITEM	CLEAN	ALMOST CLEAN	DIRTY
Bedpans	10/10	-	-
Urinary Bottles	20/20	-	-
Cleaners Bucket	1/1	-	-
Wash Bowls	10/10	-	-
Instruments	44/46	2	-
Kidney Dish	1/1	-	-
Gallipots	2/2	-	-

The instruments that were almost clean were two pairs of clamps that had not been opened when placed into the tray and a minute amount of material only was seen.The overall cleanliness of the instruments had, however, surpassed the usual manual cleaning method.

6. MICROBIOLOGICAL RESULTS

6. 1 HEAT RESISTANCE STUDIES *(IN-VITRO TESTS)*

6.1.1 HEAT RESISTANCE OF *ENTEROCOCCUS FAECALIS*

TABLE 3 shows the PCA count of *Enterococcus faecalis* after exposure for one minute at varying temperatures and the microbial reduction achieved compared to the count of the unheated control

Temperature	**Count per mL**	**Microbial Reduction**
Control (room temp)	3.0×10^7	Initial count
40°C	2.9×10^7	None
50°C	3.3×10^7	None
60°C	2.3×10^7	Insignificant reduction
70°C	3.4×10^2	5 logs
80°C	$<10^1$	> 7 logs
90°C	$<10^1$	> 7 logs

Comments on Results

The tests confirm that *Enterococcus faecalis* is a relatively heat resistant non-sporing bacteria. As the DEKO-190's disinfection cycle is just over 1 minute, the heat susceptibility tests was performed in this experiment for exactly 1 minute. Our laboratory data, under the conditions of the tests, show that the organism was:

- ❒ not significantly reduced at 40-60°C
- ❒ reduced by about 5 logs at 70°C (to 0.0001% of initial numbers)
- ❒ totally inactivated at 80-90°C with logarithmic reduction of greater than 7

6.1.2 HEAT RESISTANCE OF *CL. PERFRINGENS* SPORES

The viability of spores of *Clostridium perfringens* in a stool sample was determined at varying temperatures.

Test Specimen: The specimen tested was collected from a patient confirmed as having *Clostridium perfringens* food poisoning and is known to have large numbers of spores. Spores of this organism are known to be resistant to at least 80°C

Plating media: Horse Blood Agar (incubated anerobically)

Table 4 shows the HBA anaerobic count after a faecal suspension was exposure for one minute at varying temperatures

Temperature	Count per mL	Comments
Control (room temp)	9.0×10^5	Represents intial total anaerobic count[a]
70°C/1 min[b]	1.7×10^5	Vegetative bacteria inactivated, spores[c] remain viable
80°C/1 min[b]	1.6×10^5	spores remain viable[c]
90°C/1 min[b]	3.7×10^4	spores reduced 0.7 log
100°C/1 min[b]	1.0×10^1	spores reduced 4-5 logs
100°C/ 10 min	<10	spores totally inactivated, >5 logs
100°C/30 min	<10	spores totally inactivated, >5 logs

Notations

a Total counts including vegetative bacterial forms. These represent total strict and facultative anaerobes and includes non-*Clostridium perfringens* as well.

b Represents mainly spore counts, as vegetative bacteria are inactivated at these temperature.

c Spores were predominantly *Clostridium perfringens*. Two strains were present - haemolytic and non-haemolytic, the latter in greater proportion, approximately 10 times as many.

Comments on Results

The test result shows the test specimen to be a good specimen to use in the Deko-190 as the spores of *Clostridium perfringens* were moderately heat resistant. The laboratory data, under the conditions of the tests, show that the spores of the organism were:

- ❒ not affected at 70°C and 80°C for 1 minute exposure
- ❒ reduced by 0.7 log at 90°C for 1 minute exposure
- ❒ reduced by 4-5 logs at 100°C for 1 minute exposure
- ❒ totally inactivated (>5 logs) at 100°C for 10-30 minutes

6.1.3 HEAT RESISTANCE OF *POLIOVIRUS TYPE 1*

Table 5 shows the concentration of viral particles of *Poliovirus* type 1 after exposure for one minute at varying temperatures and the viral reduction achieved compared to the count of the unheated controls

	Virus Titre[a]		Viral Particles per mL	Viral Reduction
	Replicate #1	Replicate #2		
Control 1 (Viral stock/4°C)	10^4	10^5	10^5- 10^6	Initial Count
Control 2 (37°C)	10^6	10^6	~ 10^7	Initial Count
40°C	10^5	10^4	10^5 - 10^6	no significant reduction
50°C	10^4	10^5	10^5 - 10^6	no significant reduction
60°C	$<10^0$	$<10^0$	$<10^1$	>5 logs
70°C	$<10^0$	$<10^0$	$<10^1$	>5 logs
80°C	$<10^0$	$<10^0$	$<10^1$	>5 logs

Notations

a "Titre" refers to the reciprocal of the dilution factor at which a positive result is obtained.

b "Viral particles per mL" refers to the detectable number of poliovirus (10 x titer) and is a semi-quantitative estimation. Where replication differs by a ten-fold titre which is acceptable "viral particles per mL" is given as a range.

Comments on Results

The test result shows that *Poliovirus* type 1 is a relatively heat susceptible organism compared to the bacterial organisms. Our laboratory data, under the conditions of the tests, show that

- ❒ the virus was not significantly reduced at all at 40-50°C
- ❒ No viable virus was detected after 1 minute exposure to 60°C and above. (Reduction >5 logs of initial viral load)

7. MICROBIOLOGICAL EVALUATION OF DEKO-190

7.1 VIABILITY OF *ENTEROCOCCUS FAECALIS*

Plating media: Plate count agar (PCA) & McConkey agar
Inoculum size: 0.1 mL
Initial Count: 3.6×10^6 per mL

Table 6 shows the PCA and McConkey agar count of *Enterococcus faecalis* after processing the culture tubings in various positions in Deko-190 using program 3 in two separate runs.

Location of Vials	**Count of *Enterococcus faecalis* On media (cfu/mL)**	
	PCA	**McConkey**
Run1 bedpan1 (S1)	<10	<10
Run1 bedpan2 (S2)	<10	<10
Run1 Back of Machine (S3)	<10	<10
Run1 Urine bottle (S4)	<10	<10
Run1 Right wall (S5)	<10	<10
Run2 bedpan1 (S6)	<10	<10
Run2 bedpan2 (S7)	<10	<10
Run2 Back of machine (S8)	<10	<10
Run2 Urine bottle (S9)	<10	<10
Run2 Urine bottle, inside (S10)	<10	<10
Run2 Right wall (S11)	<10	<10

Summary of Result: No *Enterococcus faecalis* colonies were seen in any of the treated culture tubings. This indicates that a microbial inactivation of greater than 6 logs of the organism was achieved at every point in the chamber tested.

7.2 VIABILITY OF FAECAL ORGANISMS: ANAEROBIC AND AEROBIC

7.2.1 ANAEROBIC COUNTS

Inoculum size on plating media:	0.1 mL and 0.01 mL
Plating media:	Horse Blood Agar
Spore Count:	2.0×10^5 per mL
Total Anaerobic Count:	9.0×10^5 per mL

Table 7 shows Anaerobic count after processing the culture tubings of 1% faeces suspension in various positions in Deko-190 using *program 3* in two separate runs.

Position of vials	**Anaerobic Count per mL**
Run1 bedpan1 (F1)	1.8×10^5
Run1 bedpan2 (F2)	1.9×10^5
Run1 Back of machine (F3)	2.0×10^5
Run1 Urine bottle (F4)	1.8×10^5
Run1 Right wall (F5)	2.2×10^5
Run2 bedpan1 (F6)	2.0×10^5
Run2 bedpan2 (F7)	2.0×10^5
Run2 Back of machine (F8)	1.9×10^5
Run2 Urine bottle (F9)	1.9×10^5
Run2 Urine bottle, inside (F10)	2.0×10^5
Run2 Right wall (F11)	1.7×10^5

Suumary of results: The initial count of all anaerobes were reduced from 9.0×10^5 per mL to ~ 2.0×10^5 per mL. The spore count of *Clostridium perfringens* in the faeces suspension was present in the same order of magnitude in the vials before and after processing in the machine.

7.2.2 AEROBIC COUNT

Plating media: McConkey Agar and Horse Blood Agar
Initial Aerobic Counts: On McConkey Agar Plate: 1.7×10^6 per mL
On Horse Blood Agar: 7.0×10^6 per mL

Table 8 shows aerobic count in McConkey and Horse Blood Agar after processing the culture tubings of 1% faeces suspension in various positions in Deko-190 using *program 3* in two separate runs.

	Aerobic Count (per mL)	
	McConkey Agar	**Horse Blood Agar**
Run1 bedpan1 (F1)	30	80
Run1 bedpan2 (F2)	20	70
Run1 Back of machine (F3)	<10	<10
Run1 Urine bottle (F4)	30	90
Run1 Ride wall (F5)	30	50
Run2 bedpan1 (F6)	80	40
Run2 bedpan2 (F7)	10	50
Run2 Back of machine (F8)	20	70
Run2 Urine bottle (F9)	50	40
Run2 Urine bottle, inside (F10)	40	50
Run2 Right wall (F11)	20	50

Summary of Result: The aerobic counts (predominantly lactose-fermenting organisms) of the test specimen on McConkey agar and Horse Blood Agar before processing in the Deko-190 were in the order of 10^6 organisms per mL. All the eleven processed vials had low count, all less than 100 cfu per mL. The microbial reduction achieved by the heat process at every point in the chamber was greater than 4 logs. Survivors were predominantly *Bacillus* spp. (aerobic spore formers)

7.3 VIABILITY OF *POLIOVIRUS TYPE 1*

Table 9 shows viral concentration of *Poliovirus* type 1 (virus titre & viral particles per mL) after processing the culture tubings in various positions in Deko-190 using *program 3* in two separate runs.

	Virus Titre[a]		**Viral Particles per mL**	**Viral Reduction**
	Replicate No.			
	#1	**#2**		
Control 1 (Viral stock/4°C)	10^7	10^7	~ 10^7	Initial Count
Control 2 (37°C)	10^6	10^5	10^6 - 10^7	Initial Count
Run1 bedpan (P1)	$<10^0$	$<10^0$	$<10^1$	$>10^5$
Run2 bedpan (P2)	$<10^0$	$<10^0$	$<10^1$	$>10^5$
Run1 Back of machine (P3)	$<10^0$	$<10^0$	$<10^1$	$>10^5$
Run1 Urine Bottle (P4)	$<10^0$	$<10^0$	$<10^1$	$>10^5$
Run1 Right wall (P5)	$<10^0$	$<10^0$	$<10^1$	$>10^5$
Run2 bedpan (P6)	$<10^0$	$<10^0$	$<10^1$	$>10^5$
Run2 bedpan (P7)	$<10^0$	$<10^0$	$<10^1$	$>10^5$
Run2 Back of machine (P8)	$<10^0$	$<10^0$	$<10^1$	$>10^5$
Run2 Urine bottle (P9)	$<10^0$	$<10^0$	$<10^1$	$>10^5$
Run2 Urine bottle, inside (P10)	$<10^0$	$<10^0$	$<10^1$	$>10^5$
Run2 Right wall (P11)	$<10^0$	$<10^0$	$<10^1$	$>10^5$

Summary of result: *Poliovirus* type 1 was not detectable in any of the processed vials. This indicates that a viral inactivation of greater than 5 logs of this organism was achieved at every point in the chamber tested.

8. DISCUSSION

The microbiological performance of the Deko-190 was found to be excellent during the period of the trial. This was demonstrated by efficacy tests using selected microorganisms of varying thermal susceptibilities. *Enterococcus faecalis*, a non-spore forming bacterium which is relatively more heat resistant than common enteropathogens such as salmonellae and shigellae, was completely inactivated during the disinfection cycle, . Similarly, *Poliovirus type 1* did not survive the heating process. Hardier organisms containing spores, as exemplified by *Clostridium perfringens* were not affected to any observable degree by the process. In our trial, it was necessary to contain the challenged organisms within sealed plastic tubings. This in effect protected the organisms from direct exposure to steam and reduced marginally the degree of inactivation of the microorganisms. Under actual operating conditions the pasteurising effect of steam on microorganisms will no doubt be enhanced. The final outcome of the process is one whereby all heat susceptible and marginally heat resistant microorganisms are inactivated or reduced to negligible numbers. Health workers should realise of course that this process which is included in Deko-190's programmed heating cycles is one of disinfection, not sterilisation.

The above outcomes assume that all utensils including bedpans and urinal bottles are adequately cleaned, allowing direct exposure of steam to inactivate the microorganisms. Our evaluation has shown that the cleaning efficacy of the machine was extremely good. In our study, we used contaminated utensils in a clinical setting, not artificially contaminated materials, even though the latter approach may have been advantageous in some respects.

An additional factor which is vitally important in a disinfection process is the ability of the machine to maintain proper temperatures over the duration of its disinfection cycle. The machine was able to do this very well when in use, as judged by the temperature gauge in the machine. However, when we measured the temperatures at various points in the chamber during operation, the peak temperatures of several points were lower than expected (range 87-90.5°C) and were maintained between 40-60 seconds. A more complete study was performed by our Maintenance and Facilities Development Department and reference to the engineering performance of the machine including temperature profiling should be made to their report. As the microbiological performance of the machine is intricately linked to the engineering aspects of the machine e.g. delivery of adequate water for flushing, water heating and steam generation, evaluating these important engineering aspects over the life of the machine is important.

The Deko-190 Washer Disinfector has proved to be a successful innovation. It provides two machines in one and saves precious space within the institution.With the continuing emergence of multi-resistant organisms within our hospitals it is important that equipment can be cleaned adequately whilst reducing the risk of exposure to the health care worker. It was evident that education of staff prior to operating the instrument is important to ensure that the machine can be cost effective and used to its full potential. With the advances in medical technology and cleaning technology health care workers should no longer be unnecessarily placed at risk of exposure to blood or body fluids by way of manually cleaning equipment such as wash bowls, kidney dishes or any other instrument prior to sending to the sterilising department for decontamination or sterilisation. The full potential of this machine

is still being realised because of historical attitudes and the current Australian Standard for Flusher/Sanitizer for Bed Pans and Urine Botttles[3].

ISSUES Arising from Use

- As with any machinary it is important to implement an ongoing preventative maintenance program with either the company or institutions own maintenance and facilities department. This will facilitate in the cost effective running of the machine and enhance its efficiency

ISSUE / LIMITATION	SOLUTION / ACTION	DISCUSSION
Detergent bottle open at top and not enclosed in machine	Door flap available to close detergent holding area with a window to enable visual observation of detergent level	This currently comes as a optional extra but may be able to become standard for machines purchased in Australia
Detergent bottle itself opaque and restricts visually seeing level of detergent	Bottles will be changed to either clear or to have a window to see level of detergent	
No automatic switch off if detergent is empty	Close monitoring of detergent by staff, allocating person to be responsible for	Automatic switch off would be ideal however it is evident that detergent is empty if machine noise level rises. Staff education encompasses this. Preventative maintenance also assists on monitoring this. Temperatures are however still reached

The above issues were easily discussed with the company and the overall efficiency and capabilities of the machine were not compromised.

9. REFERENCES

1. Institute for Planning and Rationalisation of the Medical and Social Welfare. *Washer and Flusher Disinfector: testing of disinfection efficiency (heat disinfection).* SPRI specification 742-03.

2. Juhani Ojajarvi (1993). *Study of the Cleaning and Disinfection Efficiency of the Ward Disinfector Deko 190.* Department of Public Health, University of Healsinski, Finland.

3. Standards Association of Australia. *Australian Standard for Flusher/Sanitizers for Bed Pans and Urine Bottles.* AS 2437-1987.

10. APPENDICES (*TEMPERATURE PROFILES*)

Appended in this report are temperature profiles obtained at various points in Deko-190 during operation. These data were intended to help us better interpret the microbiological results as well as to complement the findings obtained by our Maintenance and Facilities Development Department (enquiries on MFDD's results should be made to Mr. Nigel Mullenger).

Methodology

The temperature readings were measured using an instrument produced by Kane-May, model KM1242 which uses thermocouples. The instrument has five channels, thus five points could be measured simultaneously. The temperature profiles were performed using exposed "bare wire" thermocouples in the chamber or with the thermocouples inserted within plastic tubings. In the first approach, the ends of thermocouple wires were positioned and secured down with adhesive tape at various nominated points in the disinfection chamber, similar to those described in section 4 (Efficacy Testing of Deko-190's Process of Disinfection, Table 1). In the second approach , each thermocouple was inserted into a plastic tubings containing 0.3 mL water and the opening sealed with blue tack (Bostik). The tubings were then fastened on the surface of utensils or wall of the chamber in like manner as before with adhesive tape. The door of the chamber was closed, and program 3 was run either from cold ("cold start" in appendix 1 and 3) or after being warmed up (appendix 2). In each of the three runs shown in the appendices, the temperature of the probes was measured every 20 seconds, and recorded in a printout automatically. The readings so obtained were then entered in *Microsoft Excel 5* spreadsheets, charted as graphs, and printed in colour, with each colour representing a location in the chamber (or machine temperature gauge).

Appendices

Appendix 1

Deko-190: Temperature Profiles at Various Points in the machine (thermocouple probes exposed). Run #1 - cold start.

Appendix 2

Deko-190: Temperature Profiles at Various Points in the machine (thermocouple probes exposed). Run #2 - machine warmed up

Appendix 3

Deko-190: Temperature Profiles at Various Points in the machine (within small tubings)

Note: in appendix 1, the temperature profile for channel 3 (Pan/left) is not shown as the test was invalid - probe was inadvertantly covered by tape.

Comments

Examining the temperature profiles in appendix 1 and 2 (including the raw data which is not presented here), the peak temperatures of the probes positioned on utensils or the side of the chamber in no instance reached 92°C, with the exception of the probe sited at the back of the chamber. These peak temperatures range from 87-90.5°C and were maintained over 40-60

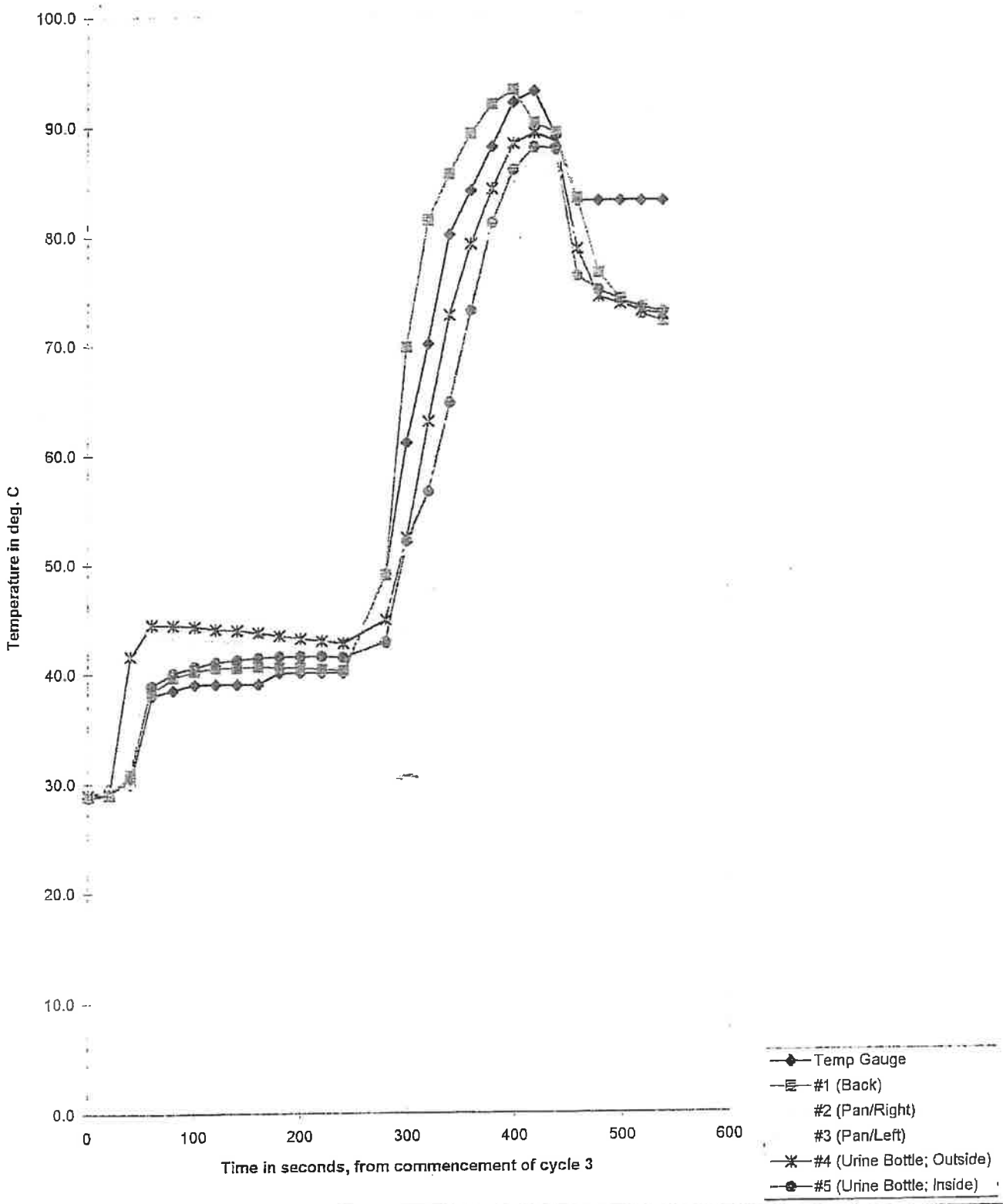
seconds. The gauge temperature peaked at around 93-94°C. The reason for this is unclear. We checked the instrument in the laboratory against a calibrated mercury thermometer and found it to be accurate. As the instrument gave only readings in 20 second intervals, tighter readings were not possible when five channels were used simultaneously.

There was a slight upward shift in temperature after the machine has been warmed up, resulting in slightly higher temperature peaks.

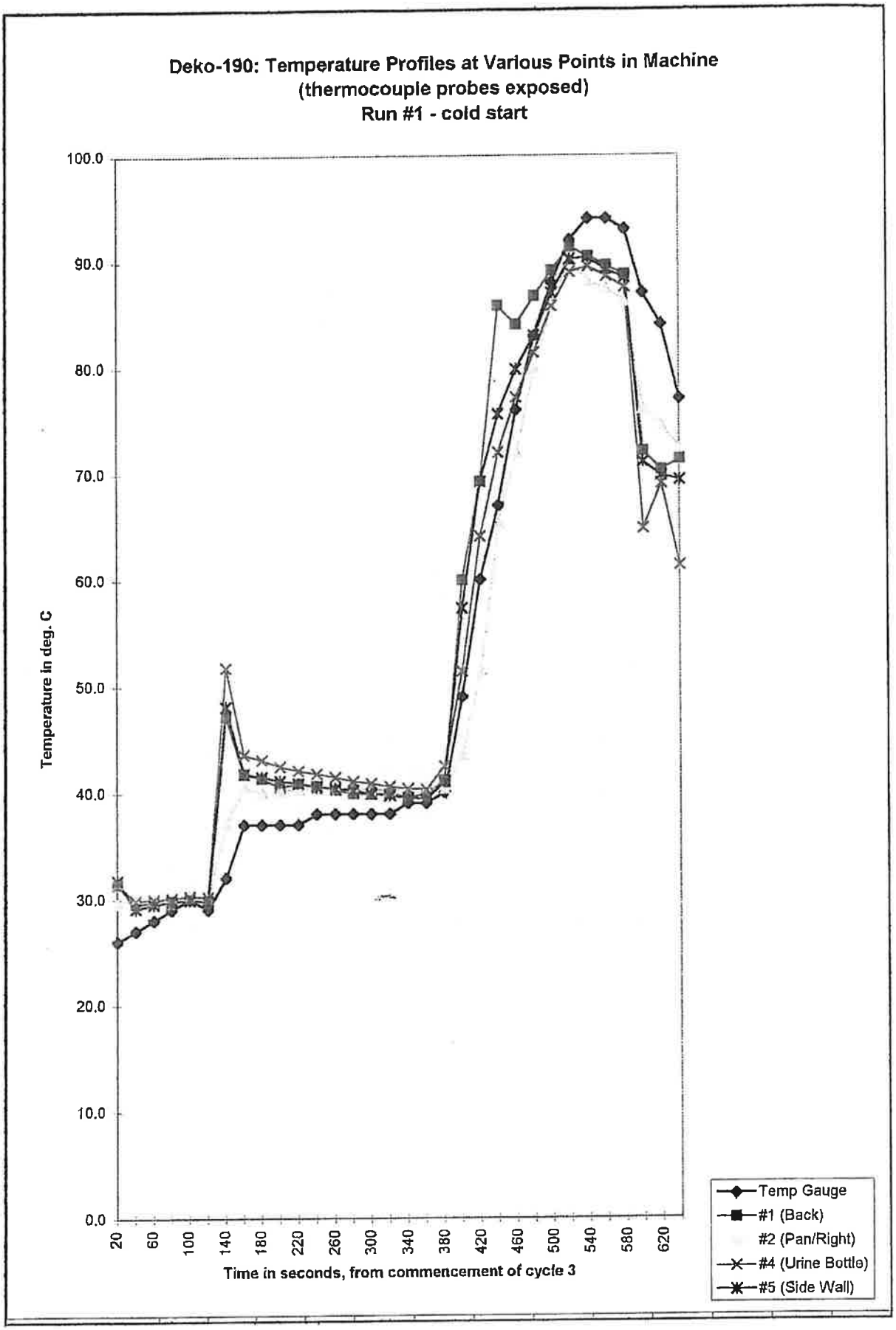
Appendix 3 shows the temperature profiles taken at various points with the thermocouple placed inside the plastic tubings. The peak temperatures were generally 1-2 degrees lower than those observed when the probes were exposed (see appendix 1& 2). This was not unexpected, as this was caused by heat transference factors in the tubing and the short duration of the heating cycle.

Appendix 3

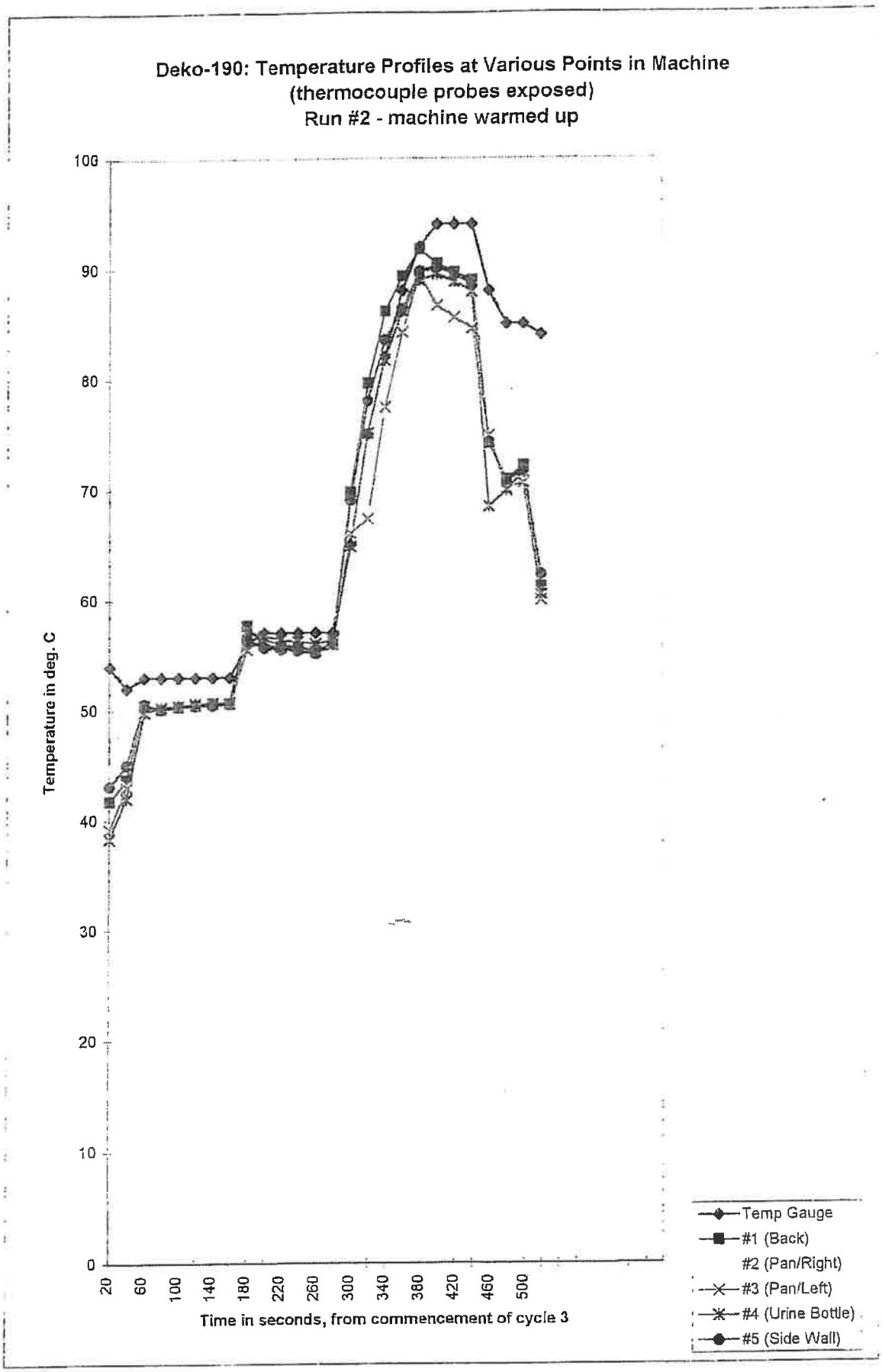
Deko-190: Temperature Profiles at Various Points in the Machine (within small tubings)



Appendix 1


Deko-190: Temperature Profiles at Various Points in Machine
(thermocouple probes exposed)
Run #1 - cold start
Temperature in deg. C
100.0
90.0
80.0
70.0
60.0
50.0
40.0
30.0
20.0
10.0
0.0
20
60
100
140
180
220
260
300
340
380
420
460
500
540
580
620
Time in seconds, from commencement of cycle 3
Temp Gauge
#1 (Back)
#2 (Pan/Right)
#4 (Urine Bottle)
#5 (Side Wall)

Appendix E


Deko-190: Temperature Profiles at Various Points in Machine
(thermocouple probes exposed)
Run #2 - machine warmed up
Temperature in deg. C
100
90
80
70
60
50
40
30
20
10
0
20
60
100
140
180
220
260
300
340
380
420
460
500
Time in seconds, from commencement of cycle 3
Temp Gauge
#1 (Back)
#2 (Pan/Right)
#3 (Pan/Left)
#4 (Urine Bottle)
#5 (Side Wall)