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FINAL REPORT

Study No. 0104-11

DEEAY TECHNOLOGIES
ULTRAWASH TABLE TOP WASHER
DETERGENT RESIDUAL AND CYTOTOXICITY EVALUATION

Prepared for:

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Date

Study No.	0104-11
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Study Personnel:	Roxanne Klein Joseph Klein
Test Objective:	To show that the detergent residuals and toxicity score will be within the acceptable range on the test devices cleaned with the UltraWash Table Top Washer.
Test Samples:	(1) Hatchet (3) Gracey curettes (1) Dental mirror #4 (1) Hemostat (2) Dental pliers (1) Forceps

References:

1) UltraWash Table Top Washer Owner's/Operator Manual.

2) AAMI RDS-TIR No. 12-1994. Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers. Association for Advancement of Medical Instrumentation, Arlington, VA.

3) Food and Drug Administration. 1996. Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance. April 1996. Office of Device Evaluation. FDA, Washington, D.C.

4) Food and Drug Administration. 1998. Guidance Document for Washers and Washer-Disinfectors Intended for Processing Reusable Medical Devices. U.S. Department of Health and Human Services, Infection Control Devices Branch. Food and Drug Administration, Division of Dental, Infection Control, and General Hospital Devices. Center for Devices and Radiological Health, Office of Device Evaluation, Washington, D.C.

5) Food and Drug Administration. 1998. Guidance on the Content and Format of Premarket Notification 510(k) Submissions of Washers and Washer-Disinfectors. U.S. Department of Health and Human Services, Infection Control Devices Branch. Food and Drug Administration, Division of Dental, Infection Control Devices Branch. Division of Dental, Infection Control, and General Hospital Devices. Center for Devices and Radiological Health, Office of Device Evaluation, Washington, D.C.

6) Ultraviolet/visible Spectroscopy (HP 8453). SOP/CHM/033. Revision C.1.

7) MEM Elution. SOP/CTX/003. Revision I.3.

INTRODUCTION:

This report details the methods used in evaluating the detergent residuals and cytotoxicty of the UltraWash Table Top Washer.

The worse case load was a fully loaded accessory tray containing a variety of previously processed reusable dental devices (See **ATTACHMENT A**, Figure 1). The majority of the test devices were stainless steel, and some of the devices possess non-metal components. The selected devices for detergent residual/cytotoxicty testing included those that are difficult to rinse and those with non-metal surfaces. (See **ATTACHMENT A**, Figure 2). Lumen instruments have been excluded from cleaning by the manufacturer of the UltraWash and therefore, were not included in this test.

Selected devices were analyzed for detergent residuals using ultraviolet/visible spectroscopy (UV/VIS). The Long (heavy) Cycle was used for detergent residuals testing. Refer to **ATTACHMENT B** for the Long Cycle parameters. This cycle represented the maximum concentration of solution. Refer to **ATTACHMENT C** for the formulation of the detergent solutions and their active components.

An MEM Elution test was performed on the selected devices used for the detergent residual analysis to demonstrate that the rinsing was effective in removing any detergent residues that may be present in cytotoxic concentrations. This test was performed to support the results of the detergent residual analysis, and prove that with no detectable residue, there was no cytotoxicity.

PROCEDURES:

WASHER PREPARATION:

A warm-up cycle was run on the washer to bring utilities up to functionality, no earlier than 45 minutes before each replicate. It was verified that the water supplies were operating at the proper parameters.

DETERGENT RESIDUAL ANALYSIS:

The detergent solutions were analyzed using UV/VIS to develop a standard curve for the test samples. Refer to **ATTACHMENT C** for the formulation of the detergent solutions and their active components.

The optical system of the UV/VIS instrument uses two light sources, a deuterium and a tungsten lamp. The 1024-element diode-array is a series of silicone photo diodes, which are sensitive to light. Each photo diode is connected to a capacitor, which is recharged at a constant interval by the control electronics. When light falls on a photo diode, its resistance changes proportional to the incident light and the capacitor is discharged. The amount of electricity required to recharge the capacitor at each recharge cycle is a measure of the light intensity. The measure of light intensity from the reference and sample spectra is used to calculate the absorbance spectra, which can be converted to transmittance spectra.

The spectrophotometer is equipped with General Purpose UV-Visible ChemStation software, which controls the equipment and performs data acquisition and evaluation. With this software it is possible to scan the ultraviolet wavelengths (190-340 nm) and the visible wavelengths (340-1100 nm). The software also allows users to measure absorbance at up to six wavelengths simultaneously, measure spectra and automatically find peaks and/or valleys, do single component quantification, and automate the measurement of standards, controls, and samples.

The selected devices were accurately weighted to the nearest 0.1 g. A known amount of USP purified water was added to the extraction vessel. The ratio of device weight to extraction fluid was sufficient to maximize extraction efficiency, and also allowed for adequate detection sensitivity. The sample/extraction fluid ratio used was 1:2.

A 1000 ppm stock solution standard was prepared for each detergent and serial dilutions were made from each of the stock solutions in ½ dilution increments. The stock solutions and their corresponding dilutions were measured in a quartz cuvette, and a characteristic wavelength was chosen to create a standard curve. The wavelength chosen for analysis was 194 nm, which gave the best resolution.

The absorbance of each test solution was measured and the results were entered into a validated computer spreadsheet. The total extracted ppm was calculated using the following equation:

$$\text{ppm residual} = \frac{\text{ppm of extract X extraction weight}}{\text{device unit weight}}$$

One peak was developed for each detergent and encompassed all of the ingredients listed in **ATTACHMENT C**. The absence of a peak for the selected devices indicated that there are no detectable residues present.

Devices were selected for their design that impedes rinsing (i.e., mated surfaces) and those with non-metal components. The devices were placed in the washer in the fully loaded configurations without bacterial contamination. The Long (heavy) Cycle was performed and the devices were extracted and analyzed for detergent residuals as outlined above. Refer to **ATTACHMENT B** for the long cycle parameters. A total of three replicates were performed for each selected device.

MEM ELUTION:

This test was designed to evaluate cytotoxicity of the extracts of materials. Samples were extracted using the USP weight recommendations. The extracts were placed in contact with cells, and the cells were examined for the presence or absence of cytotoxic effects.

SAMPLE PREPARATION:

The samples were prepared on the basis of weight. Weight was used because the samples did not have a uniform surface area. The following table was used to determine the extraction ratio for each sample. The extraction ratios in the table are ± 10%.

Thickness (mm)	Extraction Ratio	Example of Material
≤ 0.5	6 cm^2 / mL	Metal; synthetic polymer; ceramic; composite; film; sheet; tubing wall
> 0.5	3 cm^2 / mL	Metal; synthetic polymer; ceramic; composite; tubing wall; slab; molded items
≤ 1.0	3 cm^2 / mL	Natural elastomer
> 1.0	1.25 cm^2 / mL	Natural elastomer
Irregular	0.2 g/mL	Metal; synthetic polymer; ceramic; composite; pellets
Irregular	0.1 g/mL	Natural elastomer

Extraction ratio = amount of sample/mL of extract media

The exact ratio used for each sample was 0.2 g/mL. Samples were extracted in 1X MEM with 5% calf serum. Positive and negative control extracts were tested concurrently with the samples. The positive control was 4 grams of black rubber per 20 mL extraction media. The negative control was 4 grams of polypropylene pellets per 20 mL extraction media. Twenty mL of extraction media were added to an extraction container as a media control.

The samples and controls were extracted at 37 ± 1ºC for 24-25 hours in an incubator containing 5 ± 1% CO_2.

CELL EXPOSURE:

The media was carefully removed from the cell culture plates. The extracts were filtered through a 0.22 micron membrane filter prior to placing on cell monolayers. Two mL of test or control extract were added per well, using three wells (triplicate) per test. The cells were then incubated at 37 ± 1ºC with 5 ± 1% CO_2 for 48 ± 3 hours.

INTERPRETATION:

Each culture was examined after 48 ± 3 hours of incubation. The cytotoxicity was evaluated under a microscope using cytochemical stains where necessary. Each well was scored by morphologically discernable cytotoxicity on a relative scale of 0-4 as follows:

GRADE	REACTIVITY	DESCRIPTION OF REACTIVITY ZONE
0	None	Discrete intracytoplasmic granules, no cell lysis.
1	Slight	Not more than 20% of the cells are rounded, loosely attached, and without intracytoplasmic granules; occasional lysed cells are present.
2	Mild	Not more than 50% of the cells are rounded and devoid of intracytoplasmic granules; no extensive cell lysis and empty areas between cells.
3	Moderate	Not more than 70% of the cells are rounded and/or lysed.
4	Severe	Nearly complete destruction of the cells.

Each of the triplicate wells were scored and recorded, then the average for each was calculated and recorded. The test is acceptable if all three of the negative control test wells and media control test wells have a score of 0 and all three of the positive control test wells have a score of 3 or higher. Negative and positive control results are recorded in the quality control log. The sample meets USP requirements if none of the cell culture exposed to the sample shows greater than a mild reactivity (Grade 2).

ACCEPTANCE CRITERIA:

This study is considered acceptable because the following conditions or criteria were met: there was no detected detergent residuals on the test devices (the calculated residuals fall below the detectable limit), and the cytotoxicity score for the test devices was 2 or less.

RESULTS:

The detergent residual results are listed in Table 1. The limit of detection for the 1st detergent was calculated to be 20 ppm (µg/g). The limit of detection for the 2nd detergent was calculated to be 152 ppm (µg/g).

The MEM elution results are listed in Table 2.

ATTACHMENTS:

A – Photos: Figure 1, Fully loaded instrument tray; Figure 2, Test Samples.
B – Cycle Parameters
C – Detergent Composition

TABLE 1. Detergent Residuals Results

SAMPLE IDENTIFICATION	DETERGENT RESIDUAL	
	1st Detergent	2nd Detergent
Run 2 – Dental Mirror	<20 ppm (µg/g)	<152 ppm (µg/g)
Run 2 – Dental Pliers	<20 ppm (µg/g)	<152 ppm (µg/g)
Run 2 – Gracey Curette	<20 ppm (µg/g)	<152 ppm (µg/g)
Run 4 – Dental Mirror	<20 ppm (µg/g)	<152 ppm (µg/g)
Run 4 – Dental Pliers	<20 ppm (µg/g)	<152 ppm (µg/g)
Run 4 – Gracey Curette	<20 ppm (µg/g)	<152 ppm (µg/g)
Run 6 – Dental Mirror	<20 ppm (µg/g)	<152 ppm (µg/g)
Run 6 – Dental Pliers	<20 ppm (µg/g)	<152 ppm (µg/g)
Run 6 – Gracey Curette	<20 ppm (µg/g)	<152 ppm (µg/g)

TABLE 2. MEM Results

SAMPLE IDENTIFICATION	SCORE #1	SCORE #2	SCORE #3	AVERAGE
Run 1 – Dental Mirror	0	0	0	0
Run 1 – Dental Pliers	0	0	0	0
Run 1 – Gracey Curette	0	0	0	0
Run 3 – Dental Mirror	0	0	0	0
Run 3 – Dental Pliers	0	0	0	0
Run 3 – Gracey Curette	0	0	0	0
Run 5 – Dental Mirror	0	0	0	0
Run 5 – Dental Pliers	0	0	0	0
Run 5 – Gracey Curette	0	0	0	0
Negative Control	0	0	0	0
Media Control	0	0	0	0
Positive Control	4	4	4	4

ATTACHMENT A

FULLY LOADED INSTRUMENT TRAY

Figure 1

TEST SAMPLES

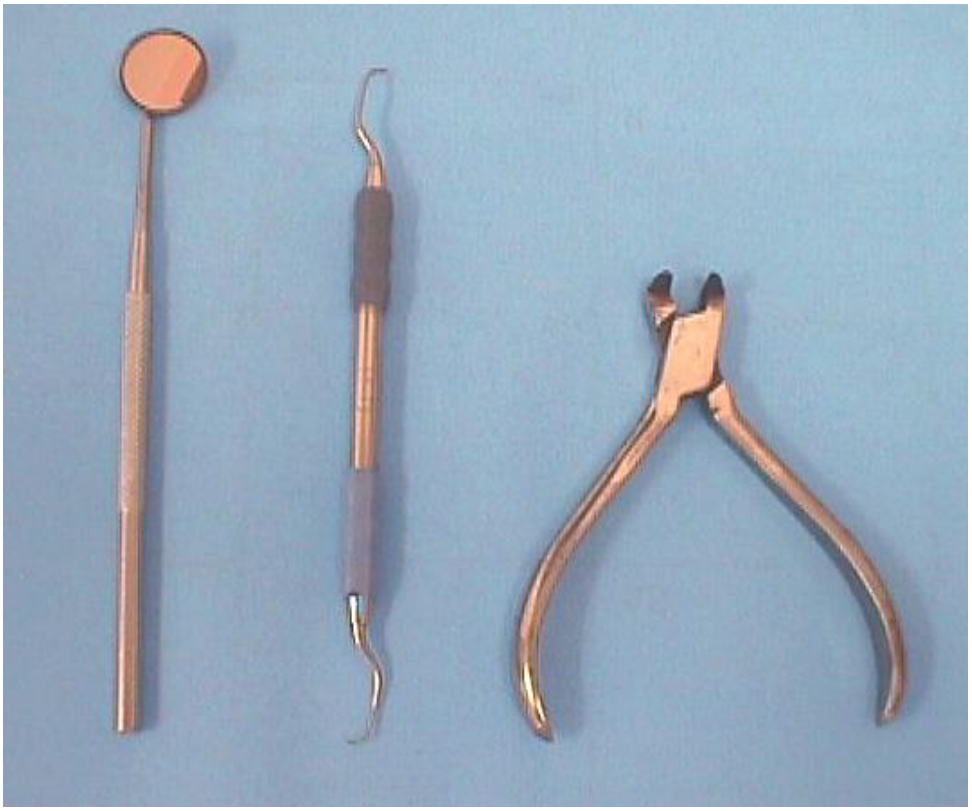

Figure 2

ATTACHMENT B

CYCLE PARAMETERS

Operation	Short (Normal) Cycle	Long (Heavy) Cycle
Cold Water Spray	15 rinses	30 rinses
1st Detergent Spray	1 rinse	2 rinses
Idle	15 seconds	30 seconds
Hot Water Spray	6 rinses	6 rinses
1st Detergent Spray	1 rinse	1 rinse
Idle	105 seconds	105 seconds
Cold Water Spray	4 rinses	6 rinses
2nd Detergent Spray	2 rinses	3 rinses
Idle	3 seconds	3 seconds
Hot Water Spray	10 rinses	12 rinses
Idle	3 seconds	3 seconds
Hot Water Spray	10 rinses	12 rinses

ATTACHMENT C

DETERGENT COMPOSITION

1. ULTRA WASH – First Detergent:

DESCRIPTION:	PERCENT	USE
Soft water -	81.70%	
Sodium meta silicate penta hydrate -	2.70%	Alkali agent
EDTA-4Na -	0.40%	Chelating agent
Triethanolamine -	4.00%	Neutralizer/solubizer
Dodecyl alkyl benzene sulphonic acid -	2.50%	Anionic surfactant
Propylene glycol mono methyl ether -	5.00%	Solvent
Nonylphenol ethoxylate -	3.00%	Nonionic surfactant
Alkylaminocarbonate -	0.50%	Ampholytic biocide/detergent
Formaldehyde -	0.20%	Preservative
Color, blue #1 -	0.0015%	Color

DETERGENT ANALYSIS: Active matter, free caustic, and pH

2. ULTRA WASH – Second Detergent:

DESCRIPTION:		
Soft water -	92.00%	
Citric acid -	2.00%	Acidic agent
Polyoxyethylene alkyl phosphate ester acid form -	5.00%	Wetting/dispersing/anti-corrosive agent
Nonylphenol ethoxylate -	1.00%	Nonionic surfactant
Color, yellow #5 -	0.0013%	Color
Color, blue #1 -	0.00029%	Color

DETERGENT ANALYSIS: Acid value and pH

SHELF-LIFE: At least 12 months