

FINAL REPORT

Study No. 0102-06

DEEAY TECHNOLOGIES ULTRAWASH TABLE TOP WASHER CLEANING EVALUATION STUDY

Prepared for:

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Date

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Test Objective: To validate the UltraWash Table Top Washer for use in the cleaning of soiled non-lumen dental instruments in a short (normal cycle) of 2.5 minutes and long (heavy cycle) of 3.0 minutes.

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.

INTRODUCTION

This report details the methods used in evaluating the cleaning efficacy of the UltraWash Table Top Washer. The Short (Normal Cycle) represents the minimum performance specifications for the washer as the cycle times are longer in the Long (Heavy Cycle). The Deeay Technologies UltraWash Operational Manual states “Instruments with stubborn dirt can be cleaned manually using the special brushes” located on the UltraWash. Because this study represents worst case conditions, no pre-cleaning of the instruments was performed with the special brushes before placing the instruments in the tray for a cleaning cycle. The long cycle was also evaluated during this study for additional information. Please refer to **Attachment A** for the cycle parameters. The worst case load chosen for this study was a fully loaded accessory tray. The tray contained a full set of dental instruments representative of those used in a dental office or clinic. Testing did not include any devices with lumens. Lumen instruments have been excluded from cleaning by the manufacturer of the UltraWash and therefore, were not included in this test.

DETERMINATION OF WORST CASE LOADS

Devices chosen for this study are typical of a dental office where 4-5 dental instruments are used per patient. These are typically an exploratory instrument or two, a mirror, forceps and pliers. Some dentists also include 2-3 extra instruments that perform various functions (i.e. explorer, carver, hatchet, curette, excavator). Therefore, an average dental office or clinic would have available for use with each patient 4-8 dental instruments. The maximum amount of instruments typically used would be 8. As an additional safety factor, a 9th instrument was added to achieve a “worst case” load of dental instruments for this study. The limited space within the accessory tray also dictated that no more than 10 devices are run per cleaning cycle. Please refer to **Attachment B** for a picture of the test devices and **Attachment C** for their position in the accessory tray.

DEVICE SOILING

The blood soil used in this study was comprised of 80% defibrinated sheep blood and 20% physiological saline. This concentration is much greater than would ordinarily be found on dental instruments. Each instrument was totally submerged in the blood/saline mixture, allowed to drain for ten seconds, then dried for 30-40 minutes before cleaning. The condition and appearance of representative test devices were photo-documented. A picture of the soiled instruments can be found in **Attachment C** along with one taken after completion of a cleaning cycle.

WASHER PREPARATION

A warm-up cycle was run with the washer to bring utilities up to functionality, no earlier than 45 minutes before each replicate. Water supplies were verified to be operating at the proper values.

CLEANING EFFICACY – Normal Cycle

For each replicate of the test devices, a random placement in the accessory tray was established for analysis. After soiling all the devices as outlined above, the devices were loaded in the accessory tray of the UltraWash Table Top Washer. The Short (Normal) Cycle was then selected and a cleaning cycle run. Using tweezers, the devices were removed from the UltraWash Table Top Washer at the completion of the cleaning cycle. Devices were placed on a field of CSR wrap and allowed to dry for a minimum of 60 minutes. Each device was evaluated for the presence of any visible soil remaining on the test device. Evaluations were performed visually by eye and under 2X and 15X magnification. Results were recorded per device, using the rating system identified on the following page. Each device was evaluated using this inspection technique by two separate laboratory technicians and individual results were compared.

Visible soil was rated for each device on a relative scale of 0-4.

Rating	Criteria
0	No visible soil
1	Spot of soil ≤ 2 mm in size
2	Spot of soil > 2 mm - ≤ 5 mm
3	Spot of soil > 5 mm - ≤ 10 mm
4	Spot of soil > 10 mm

After inspection, test devices were soaked in a 1.0 % solution of Liqui-Nox[®] for 20 minutes. Devices were then washed and rinsed thoroughly with running tap water and then an additional three rinses were performed with distilled water. Devices were drained and appropriately dried before use in additional replicate cycles. The cleaning efficacy test was then repeated for two additional cycles for a total of three replicates.

CLEANING EFFICACY – Heavy Cycle

For each replicate of the test devices, a random placement in the accessory tray was established for analysis. After soiling all the devices as outlined above, the devices were loaded in the accessory tray of the UltraWash Table Top Washer. The Long (Heavy) Cycle was then selected and a cleaning cycle run. Using tweezers, the devices were removed from the UltraWash Table Top Washer at the completion of the cleaning cycle. Devices were placed on a field of CSR wrap and allowed to dry for a minimum of 60 minutes. Each device was evaluated for the presence of any visible soil remaining on the test device. Evaluations were performed visually by eye and under 2X and 15X magnification. Results were recorded per device, using the rating system identified below. Each device was evaluated using this inspection technique by two separate laboratory technicians and individual results were compared.

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STUDY RESULTS

All test devices evaluated in this study were found to be within acceptable cleaning conditions. No visible soil was detected on any of the cleaned devices at 0X, 2X and 15X magnification. All devices were given a visual soil rating of 0 as described in the above rating criteria scale.

CONCLUSION

Results validate the Deeay Technologies UltraWash Table Top Washer's ability to achieve a cleaning rating of 0 or No Visible Soil retained on any of the dental instruments processed in the cleaning cycles identified below. Therefore, based on the results of this study the Deeay Technologies UltraWash can be used successfully as a cleaner in dental facilities.

Min. Hot Water Temp:	60°C
Exposure Time:	2.5 minutes
Cycle configuration:	Normal
Tray configuration:	Full
Min. Hot Water Temp:	60°C
Exposure Time:	3.0 minutes
Cycle configuration:	Heavy
Tray configuration:	Full

ATTACHMENTS:

A – Normal and Heavy Cycle Parameters

B – Photo of Test Devices

C – (Top) Photo of Soiled Devices in a Random Placement in Accessory Tray

C – (Bottom) Photo of Devices after Cleaning

NOTICE: All reports are submitted to clients on a confidential basis. Test results are applicable only to the Test Samples that were tested within the limits of the testing procedures identified and are not necessarily indicative of the characteristics of any other samples from the same or other lots. SPSmedical Supply Corp. shall not be liable under any circumstances for any amount in excess of the cost of the test(s) performed.

ATTACHMENT A

TYPICAL CYCLE PARAMETERS

Operation	Short (Normal) Cycle	Average Temperature	Long (Heavy) Cycle	Average Temperature
Cold Water Spray	15 rinses	21°C	30 rinses	21°C
1 st Detergent Spray	1 rinse		2 rinses	
Idle	15 seconds		30 seconds	
Hot Water Spray	6 rinses	77.6°C	6 rinses	80.3°C
1 st Detergent Spray	1 rinse		1 rinse	
Idle	105 seconds		105 seconds	
Cold Water Spray	4 rinses	21°C	6 rinses	21°C
2 nd Detergent Spray	2 rinses		3 rinses	
Idle	3 seconds		3 seconds	
Hot Water Spray	10 rinses	95°C	12 rinses	92°C
Idle	3 seconds		3 seconds	
Hot Water Spray	10 rinses	78°C	12 rinses	72°C

Average hot water temperature – 60 to 95 °C

Minimum water pressure - 10.00 psi

Detergent per normal wash cycle – 11.11 cc

Detergent per heavy wash cycle – 15.00 cc

ATTACHMENT B

DENTAL DEVICES FOR CLEANING



- 1 – Hatchet
- 2 through 4 – Gracey Curette
- 5 – Dental Mirror #4
- 6 – Hemostat
- 7 and 8 – Dental Pliers
- 9 – Forceps

ATTACHMENT C

SOILED INSTRUMENTS PRIOR TO CLEANING



INSTRUMENTS AFTER 2.5 MINUTE CYCLE

