

FINAL REPORT

Study No. 0102-06-1

DEEAY TECHNOLOGIES ULTRAWASH TABLE TOP WASHER PHYSICAL PERFORMANCE STUDY

Prepared for:

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Date

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Test Objective: To show that the UltraWash Table Top Washer will reach and maintain the specified process parameters throughout the short and long cycles for each of the preprogrammed steps.

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 physical performance of the UltraWash Table Top Washer in empty and full load cycles. The Short (Normal) Cycle and the Long (Heavy) Cycle were evaluated during this study. Both the process time and temperature were monitored for conformance. 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. Lumen instruments have been excluded from cleaning by the manufacturer of the UltraWash and therefore, were not included in this test.

LOAD CONFIGURATION

Devices chosen for this study are typical of a dental office where 4 to 5 dental instruments are used per patient. 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 to 8 dental instruments. The maximum number of instruments typically used would be 8.

DETERMINATION OF WORST CASE LOADS

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 the 10 devices be 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.

THERMOCOUPLE PLACEMENT

The accessory tray is quite small, so five (5) thermocouples were deemed appropriate to be placed within the tray. Because there is only one level within the UltraWash tray, the placement of the thermocouples were made at the right and left front, right and left rear, and center of the accessory tray. This placement was chosen to assure that the table top washer was capable of providing steady thermal conditions throughout the accessory tray. A sixth thermocouple was placed at the water spray nozzle to record the temperature of the water entering the unit. See thermocouple placement in the accessory tray, **Attachment C**.

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.

PHYSICAL PERFORMANCE – Normal Cycle – 2.5 minutes

Three (3) empty and three (3) full cycles were run and the results were recorded. For each replicate of the empty chamber cycle, thermocouples were placed in the left front, left rear, center, right rear and right front of the accessory tray. A sixth thermocouple was located at the sprayer nozzle. The data gathered can be found in **Attachments D – F**. For each replicate of the full load cycle, the test devices were placed at random within the accessory tray. Thermocouple locations remained the same as in the previous loads. The data gathered can be found in **Attachments G – I**. The process time was monitored in three consecutive cycles by timing with a calibrated stopwatch, with the following results:

Short (Normal) Cycle - 2.5 minutes		
	Calibrated Stop Watch	
	Minutes	Seconds
Cycle #1	2	43.41
Cycle #2	2	41.24
Cycle #3	2	41.45

PHYSICAL PERFORMANCE – Heavy Cycle – 3.0 minutes

Three (3) empty and three (3) full cycles were run and the results were recorded. For each replicate of the empty chamber cycle, thermocouples were placed in the left front, left rear, center, right rear and right front of the accessory tray. A sixth thermocouple was located at the sprayer nozzle. The data gathered can be found in **Attachments J – L**. For each replicate of the full load cycle, the test devices were placed at random within the accessory tray. Thermocouple locations remained the same as in the previous loads. The data gathered can be found in **Attachments M – O**. The process time was monitored in three consecutive cycles by timing with a calibrated stop watch, with the following results:

Long (Heavy) Cycle – 3.0 minutes		
	Calibrated Stop Watch	
	Minutes	Seconds
Cycle #1	3	13.99
Cycle #2	3	12.95
Cycle #3	3	11.14

RESULTS

All of the thermocouples used for monitoring during testing had temperature readings of greater than 60°C during the Hot water phase of the individual cycle regardless of if the tray was empty or full or if the Normal or Heavy cycle was selected. The typical average temperature of all thermocouples during the 1st Hot water spray was 76°C, the 2nd Hot water spray was 86.5°C and the 3rd Hot water spray was 84°C. The cycle times recorded for the 2.5-minute Normal cycles were greater than 2.5 minutes and the 3-minute Heavy cycles were recorded at greater than 3 minutes. The highest temperature recorded during testing was almost 105°C measured at the output nozzle by thermocouple number 6.

CONCLUSION

Results **validate** the Deeay Technologies UltraWash Table Top Washer's ability to achieve and maintain the specified process parameters throughout the long and short cycles as described below.

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

ATTACHMENTS:

A – Normal and Heavy Cycle Parameters

B – Photo of Test Devices

C – Photo of Devices in a Random Placement in Accessory Tray and Thermocouple Placement

D – I Short (Normal) Cycle Thermal Profiles, Empty and Full Loads

J – O Long (Heavy) Cycle Thermal Profiles, Empty and Full Loads

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 TEST DEVICES FOR WORST CASE LOAD



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

RANDOM POSITION OF INSTRUMENTS IN ACCESSORY TRAY
THERMOCOUPLE PLACEMENT

