



WHITE PAPER
EFFICACY OF ICX RENEW™ DENTAL UNIT WATERLINE
SHOCK TREATMENT

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BACKGROUND

The inner lumen of dental unit waterline (DUWL) tubing provides an ideal environment for bacteria* and other microorganisms to develop and flourish; due to the narrow diameter, extensive length of the tubing, and long periods without flow. Research has demonstrated that bacterial counts can exceed 2×10^5 CFU/mL within 5 days [1]. To combat this issue A-dec, Inc. has developed ICX Renew™, a specially formulated DUWL shock treatment. ICX Renew is intended to lower and remove build-up of bacterial contamination from the waterlines. ICX Renew consists of a simple two-part liquid solution, which is mixed at the point of use. The study below was conducted to evaluate the effectiveness of ICX Renew at penetrating and removing of bacterial contamination in dental unit waterlines in comparison to a leading competitor's product.

TEST METHOD

Summary

This study was designed and conducted to closely match the conditions of the dental operator, and followed the test method specified in ISO 16954 [2]. DUWL systems were inoculated with specified concentrations of two bacterial* species to generate bacterial contamination. Once the bacterial contamination had been sufficiently established, the systems were treated with ICX Renew and the competitor's product in accordance with their respective instructions for use (IFU).

Test Systems

The systems used for this study were directly modeled after and built with components of the A-dec 532 self-contained water system. The systems included all water bearing components of this representative A-dec self-contained water system. A programmable logic controller was integrated to control water flow in the systems to simulate daily use of dental units according to the ISO 16954 standard.

BACTERIAL CONTAMINATION GENERATION

To generate an appropriate level of bacterial* contamination for testing, test water was inoculated with specified concentrations (1.0×10^2 – 1.0×10^3 CFU/mL) of the two bacterial species and run through each of the units Monday through Friday. The water flowed through each line at 30 second intervals followed by a pause of 9 minutes; this cycle was repeated 30 times per day. Overnight and on the weekends the lines remained full of inoculated water.

This process was repeated until the planktonic, or free floating, bacterial concentration in each unit reached 1×10^4 CFU/mL or greater.

Upon generation of sufficient planktonic bacterial concentration, each unit's waterlines were cross sectioned, then critical point dried to preserve the structure of the bacterial contamination, and reviewed in the Scanning Electron Microscope (SEM) to confirm at least semi-confluent coverage (Figures 1(A) and 2(A)).

* non-public health bacteria

Bacterial Contamination Removal

Following the generation period, each of the units was treated with either ICX Renew, or the competitor's product once a day for three days, following the corresponding IFU. After each treatment was completed, planktonic bacterial counts were taken, and samples of each waterline were cross sectioned and analyzed by SEM.

TEST RESULTS

Planktonic Bacterial Populations

Prior to treatment, each of the surrogate systems had planktonic bacterial* counts measuring $>7.5 \times 10^5$ CFU/mL. Similar bacterial concentrations in DUWL have been reported in clinical settings, especially when no measures to control against bacteria growth are practiced.

Bacterial Contamination Removal

DUWL systems treated with ICX Renew demonstrated a consistent pattern of diminishing bacterial contamination coverage following the first, second and third treatments (refer to Figure 1 below). After two treatments, all of the test units had planktonic bacterial counts measuring at <1.0 CFU/mL, meaning a $>99.999\%$ reduction of planktonic bacteria was achieved after just the second administration of ICX Renew. Tubing subjected to three treatments with ICX Renew exhibited little to no observable coverage, as shown in Figure 1(D).

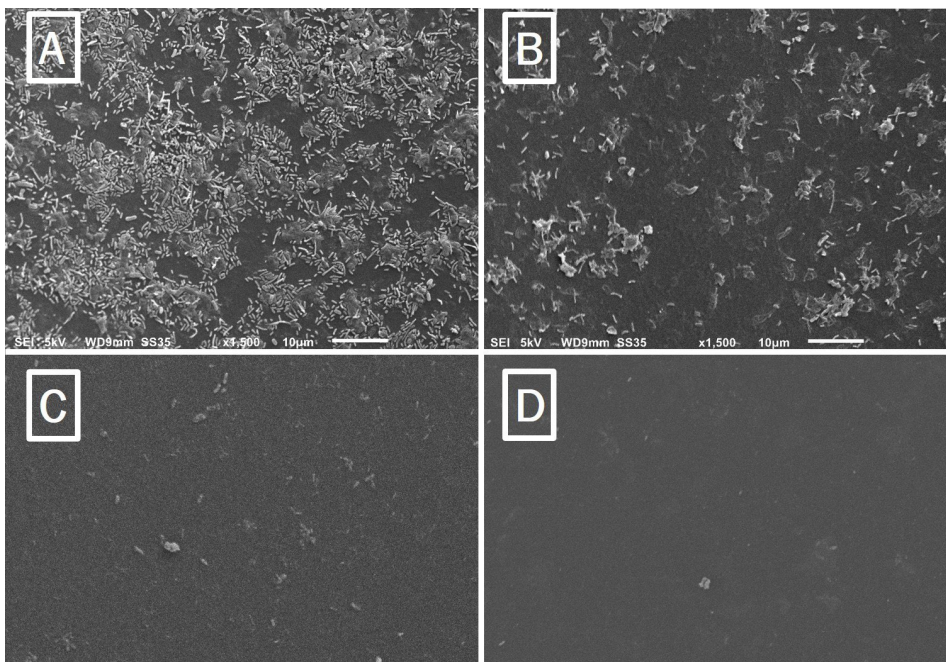


Figure 1. SEM Images (1500x) of surrogate DUWL tubing treated with ICX Renew: Before treatment (A), after one treatment (B), after two treatments (C) and after three treatments (D).

* non-public health bacteria

While DUWL systems treated with the competitor's product also exhibited <1.0 CFU/mL, the waterlines showed little observable removal of bacterial contamination after three treatments as shown in Figure 2. DUWL tubing maintained semi-confluent coverage after three treatments.

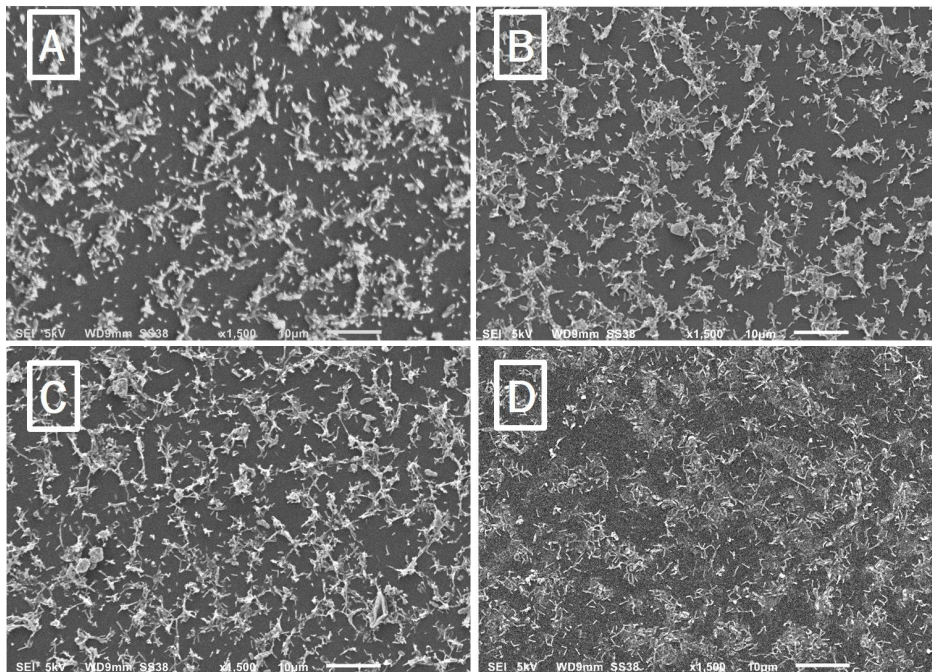


Figure 2. SEM Images (1500x) of surrogate DUWL tubing treated with the competitor's product: Before treatment (A), after one treatment (B), After two treatments (C) and after three treatments (D).

CONCLUSIONS

While both ICX Renew and the competitor's product showed a reduction of planktonic bacterial counts to <1.0 CFU/mL, only the waterline tubing treated with ICX Renew showed effective removal of bacterial* contamination from the DUWLs.

In comparison to treatment with the competitor's product, ICX Renew effectively penetrated and removed bacterial contamination in the dental unit waterlines, resulting in little to no observable bacterial contamination. The removal of residual contamination is important for controlling against recontamination in DUWLs.

REFERENCES

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* non-public health bacteria

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