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**REPORT FOR**

**ASSESSMENT OF RAPID GERMICIDAL (TIME KILL)  
ACTIVITY FOR UltraBlu™ TOOTHBRUSH**

**HTR Study No.: 08-129295-106**

**November 26, 2008**

**FOR**

**TECHLIGHT SYSTEMS, INC.**

**P.O. Box 190**

**Dunnellon, FL 34430**

**BY**

**HILL TOP RESEARCH CORPORATION**

**6088 Main & Mill Streets**

**Miamiville, Ohio 45147**

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## 1.0 SUMMARY

- The test article identified as UltraBlu™ Toothbrush was received from TechLight Systems, Inc. for use in this test.
- The test article was tested in triplicate against the test organisms contained in whole saliva collected from healthy human volunteers (unrestricted), *Candida albicans*, ATCC 18804, *Fusobacterium nucleatum*, ATCC 10953 and *Porphyromonas gingivalis*, ATCC 33277 with a 2 minute exposure to the UltraBlu™ Toothbrush "blue light."
- After an exposure period of two minutes, no reduction in numbers of *F. nucleatum* or organisms contained in human saliva was seen. Under the same test conditions, The test organism *C. albicans* showed a 7% reduction in yeast organisms and the test organism *P. gingivalis* showed a 17% reduction in the number of bacteria.
- An additional test article, identified as UltraBlu™ Toothbrush (engineering prototype) was received from TechLight Systems, Inc. on October 29, 2008 for use in this test as directed in Protocol Amendment #1. This test exposed the test organism *P. gingivalis* to ten, 2 minute exposures over a 29 minute period (2 minutes on, 1 minute off, 10 times).
- When compared to an untreated control, the test article, UltraBlu™ Toothbrush (engineering prototype) showed a 99.39% reduction (2.22 log<sub>10</sub>) in numbers of the test organism *P. gingivalis* after 10 - 2 minute exposures over 29 minutes.

## **2.0 PURPOSE**

The purpose of this study was to evaluate the antibacterial effect of the UltraBlu™ Toothbrush “blue light” in reducing bacteria found in human saliva and other selected microorganisms known to be present in the mouth when artificially deposited on a glass surface and exposed to the “blue light” under simulated use conditions without brushing.

## **3.0 STUDY SPONSOR**

TechLight Systems, Inc.  
P.O. Box 190  
Dunnellon, FL 34430

**SPONSOR REPRESENTATIVE:** Michael Barnes

## **4.0 INVESTIGATIVE PERSONNEL**

Study Director: Kathleen A. Baxter, B.S.  
Study Manager: Jane M. Young, B.S.  
Study Coordinator: Margaret K. Haines, B.S.

## **5.0 RESEARCH STANDARDS**

This study was conducted according to standardized microbiological laboratory practices as outlined in the Standard Operating Procedures of Hill Top Research Corporation.

## **6.0 PROTOCOL**

The study protocol and Protocol Amendment #1 as described in Appendix III were followed.

## 7.0 STUDY SCHEDULE

Date Study Initiated: October 9, 2008  
Date Study Completed: November 26, 2008

## 8.0 TEST ARTICLES

The test article identified as UltraBlu™ Toothbrush was received from TechLight Systems, Inc. on September 23, 2008, for use in this test.

An additional test article, identified as UltraBlu™ Toothbrush (engineering prototype) was received from TechLight Systems, Inc. on October 29, 2008 for use in this test as directed in Protocol Amendment #1.

The test article received October 29, 2008 will be returned to the sponsor upon completion of testing.

## 9.0 PROTOCOL

The study protocol and Protocol Amendment #1 were followed.

## 10.0 RESULTS

The Summary Table and Tables of Results are presented in Appendix I for the 2 minute exposure period and the Summary Table and Table of Results-Protocol Amendment #1 (10, 2 minute exposure periods) is presented in Appendix II.

## 11.0 CONCLUSION

Conclusions, as a result of testing, are as follows:

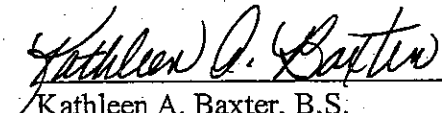
- The test article, identified as UltraBlu™ Toothbrush, was tested in triplicate against the test organisms contained in whole saliva collected from healthy human volunteers (unrestricted), *Candida albicans*, ATCC 18804, *Fusobacterium nucleatum*, ATCC 10953 and *Porphyromonas gingivalis*, ATCC 33277 with a 2 minute exposure to the UltraBlu™ Toothbrush "blue light."

## 11.0 CONCLUSION CON'T.

- After an exposure period of two minutes, no reduction in numbers of *F. nucleatum* or organisms contained in human saliva was seen. Under the same test conditions, the test organism *C. albicans* showed a 7% reduction in yeast organisms and the test organism *P. gingivalis* showed a 17% reduction in the number of bacteria.
- An additional test article, identified as UltraBlu™ Toothbrush (engineering prototype) was received from TechLight Systems, Inc. on October 29, 2008 for use in this test as directed in Protocol Amendment #1. This test exposed the test organism *P. gingivalis* to ten, 2 minute exposures over a 29 minute period (2 minutes on, 1 minute off; 10 times).
- When compared to an untreated control, the test article, UltraBlu™ Toothbrush (engineering prototype) showed a 99.39% reduction (2.22 log<sub>10</sub>) in numbers of the test organism *P. gingivalis* after 10 - 2 minute exposures over 29 minutes.

## 12.0 SIGNATURE

HILL TOP RESEARCH CORPORATION

  
Kathleen A. Baxter, B.S.                      11/26/08  
Study Director                                      Date  
Microbiology Business Unit

# APPENDIX I

HTR Study No. 08-129295-106  
TechLight Systems, Inc.

**HILL TOP RESEARCH CORPORATION**

**APPENDIX I**

**SUMMARY TABLE AND TABLES OF RESULTS**

**SUMMARY TABLE OF RESULTS**  
**LOG<sub>10</sub> REDUCTION with UltraBlu™ Toothbrush after Two Minutes Exposure**

| Test Organism                                   | Numbers Control at 2 minutes            | Average Count (CFU/surface) | Average Log <sub>10</sub> CFU/surface | Percent Reduction | Log <sub>10</sub> Reduction |
|---|---|-----------------------------|---------------------------------------|-------------------|-----------------------------|
| <i>Candida albicans</i> ,<br>ATCC 18804         | Numbers Control at 2 minutes            | 1.3 x 10 <sup>6</sup>       | 6.11                                  | NA                | NA                          |
|   | Treatment at Exposure Time of 2 minutes | 1.2 x 10 <sup>6</sup>       | 6.08                                  | 7.69              | 0.03                        |
| <i>Fusobacterium nucleatum</i> ,<br>ATCC 10953  | Numbers Control at 2 minutes            | 4.4 x 10 <sup>5</sup>       | 5.64                                  | NA                | NA                          |
|   | Treatment at Exposure Time of 2 minutes | 4.7 x 10 <sup>5</sup>       | 5.67                                  | NR                | NR                          |
| <i>Porphyromonas gingivalis</i> ,<br>ATCC 33277 | Numbers Control at 2 minutes            | 2.9 x 10 <sup>5</sup>       | 5.46                                  | NA                | NA                          |
|   | Treatment at Exposure Time of 2 minutes | 2.4 x 10 <sup>5</sup>       | 5.38                                  | 17.24             | 0.08                        |
| Saliva  | Numbers Control at 2 minutes            | 2.1 x 10 <sup>7</sup>       | 7.32                                  | NA                | NA                          |
|   | Treatment at Exposure Time of 2 minutes | 2.2 x 10 <sup>7</sup>       | 7.41                                  | NR                | NR                          |

NA = Not Applicable  
 NR = No Reduction

**TABLE I OF RESULTS**  
**REDUCTION IN NUMBERS OF *Candida albicans*, ATCC 18804**  
**With UltraBlu™ Toothbrush**

**Test Period:** October 13 – 15, 2008      **Incubation:** 48 ± 4 hours at 25 ± 2°C  
**Test Organism:** *C. albicans*, ATCC 18804      **Exposure Period:** 2 minutes at 37 ± 2°C

| Replicate                               | Bottle*           |      | 10 <sup>-1</sup> | 10 <sup>-2</sup> | 10 <sup>-3</sup>       | 10 <sup>-4</sup> | 10 <sup>-5</sup> | Count (CFU/mL)        | Count (CFU/surface)   | Average Count (CFU/surface) | Average Log <sub>10</sub> CFU/surface | Percent Reduction | Log <sub>10</sub> Reduction |
|---|-------------------|------|------------------|------------------|------------------------|------------------|------------------|-----------------------|-----------------------|-----------------------------|---------------------------------------|-------------------|-----------------------------|
|   | TNTC <sup>a</sup> | TNTC | TNTC             | TNTC             | TNTC                   | TNTC             | TNTC             |                       |                       |                             |                                       |                   |                             |
| Numbers Control at 2 minutes            | TNTC              | TNTC | TNTC             | TNTC             | <u>37</u> <sup>b</sup> | 8                | 0                | 3.1 x 10 <sup>4</sup> | 6.2 x 10 <sup>5</sup> | 1.3 x 10 <sup>6</sup>       | 6.11                                  | NA <sup>c</sup>   | NA                          |
|   | TNTC              | TNTC | TNTC             | TNTC             | 25                     | 4                | 0                | 7.4 x 10 <sup>4</sup> | 1.5 x 10 <sup>6</sup> |                             |                                       |                   |                             |
|   | TNTC              | TNTC | TNTC             | TNTC             | <u>52</u>              | 8                | 1                |                       |                       |                             |                                       |                   |                             |
| Treatment at Exposure Time of 2 minutes | TNTC              | TNTC | TNTC             | TNTC             | <u>95</u>              | 12               | 0                | 8.8 x 10 <sup>4</sup> | 1.8 x 10 <sup>6</sup> | 1.2 x 10 <sup>6</sup>       | 6.08                                  | 7.69              | 0.03                        |
|   | TNTC              | TNTC | TNTC             | TNTC             | <u>81</u>              | 8                | 0                | 7.0 x 10 <sup>4</sup> | 1.4 x 10 <sup>6</sup> |                             |                                       |                   |                             |
|   | TNTC              | TNTC | TNTC             | TNTC             | <u>94</u>              | 13               | 1                |                       |                       |                             |                                       |                   |                             |
| Treatment at Exposure Time of 2 minutes | TNTC              | TNTC | TNTC             | TNTC             | <u>59</u>              | 11               | 0                | 7.7 x 10 <sup>4</sup> | 1.5 x 10 <sup>6</sup> | 7.2 x 10 <sup>5</sup>       | 0.03                                  | 0.03              | 0.03                        |
|   | TNTC              | TNTC | TNTC             | TNTC             | <u>82</u>              | 7                | 0                | 3.6 x 10 <sup>4</sup> | 7.2 x 10 <sup>5</sup> |                             |                                       |                   |                             |
|   | TNTC              | TNTC | TNTC             | TNTC             | <u>64</u>              | 4                | 0                |                       |                       |                             |                                       |                   |                             |
| Treatment at Exposure Time of 2 minutes | TNTC              | TNTC | TNTC             | TNTC             | <u>90</u>              | 7                | 0                | 3.6 x 10 <sup>4</sup> | 7.2 x 10 <sup>5</sup> | 7.2 x 10 <sup>5</sup>       | 0.03                                  | 0.03              | 0.03                        |
|   | TNTC              | TNTC | TNTC             | TNTC             | <u>30</u>              | 3                | 0                | 3.6 x 10 <sup>4</sup> | 7.2 x 10 <sup>5</sup> |                             |                                       |                   |                             |
|   | TNTC              | TNTC | TNTC             | TNTC             | <u>41</u>              | 3                | 0                |                       |                       |                             |                                       |                   |                             |

**Inoculum Count**

| 10 <sup>-5</sup> | 10 <sup>-6</sup> |           | 10 <sup>-7</sup> |   | Count (CFU/mL)        | Theoretical CFU/surface (CFU/mL X 30 µl X 0.001) |
|------------------|------------------|-----------|------------------|---|-----------------------|--|
| TNTC             | <u>57</u>        | <u>54</u> | 4                | 1 | 5.6 x 10 <sup>7</sup> | 1.7 x 10 <sup>6</sup>                            |

\*1.0 mL plated across 3 plates in duplicate  
<sup>a</sup>TNTC = Too Numerous To Count

<sup>b</sup> Underlined values used in calculations  
<sup>c</sup> NA = Not Applicable

<sup>d</sup> LA = Lab Accident; gross plate contamination

**TABLE II OF RESULTS**  
**REDUCTION IN NUMBERS OF *Fusobacterium nucleatum*, ATCC 10953**  
**With UltraBlu™ Toothbrush**

**Test Period:** October 13 – 15, 2008  
**Test Organism:** *F. nucleatum*, ATCC 10953  
**Incubation:** 48 ± 4 hours at 25 ± 2°C  
**Exposure Period:** 2 minutes at 37 ± 2°C

| Replicate                               | Bottle*           |      |      | 10 <sup>-1</sup> | 10 <sup>-2</sup>      | 10 <sup>-3</sup>      | 10 <sup>-4</sup> | 10 <sup>-5</sup> | Count (CFU/mL)        | Count (CFU/surface)                              | Average Count (CFU/surface) | Average Log <sub>10</sub> CFU/surface | Percent Reduction | Log <sub>10</sub> Reduction |
|---|-------------------|------|------|------------------|-----------------------|-----------------------|------------------|------------------|-----------------------|--|-----------------------------|---------------------------------------|-------------------|-----------------------------|
|   | TNTC <sup>a</sup> | TNTC | TNTC | 202 <sup>b</sup> | 19                    | 0                     | 0                | 0                |                       |  |                             |                                       |                   |                             |
| Numbers Control at 2 minutes            | TNTC              | TNTC | TNTC | 151              | 19                    | 0                     | 0                | 0                | 1.8 x 10 <sup>3</sup> | 3.6 x 10 <sup>4</sup>                            |                             |                                       |                   |                             |
|   | TNTC              | TNTC | TNTC | TNTC             | TNTC                  | 49                    | 2                | 0                | 4.4 x 10 <sup>4</sup> | 8.8 x 10 <sup>5</sup>                            | 4.4 x 10 <sup>5</sup>       | 5.64                                  | NA <sup>c</sup>   | NA                          |
|   | TNTC              | TNTC | TNTC | TNTC             | TNTC                  | 38                    | 3                | 1                | 2.1 x 10 <sup>4</sup> | 4.2 x 10 <sup>5</sup>                            |                             |                                       |                   |                             |
| Treatment at Exposure Time of 2 minutes | TNTC              | TNTC | TNTC | TNTC             | 235                   | 22                    | 2                | 0                | 2.9 x 10 <sup>4</sup> | 5.8 x 10 <sup>5</sup>                            |                             |                                       |                   |                             |
|   | TNTC              | TNTC | TNTC | TNTC             | 194                   | 20                    | 0                | 1                | 3.0 x 10 <sup>4</sup> | 6.0 x 10 <sup>5</sup>                            | 4.7 x 10 <sup>5</sup>       | 5.67                                  | NR <sup>d</sup>   | NR                          |
|   | TNTC              | TNTC | TNTC | TNTC             | TNTC                  | 33                    | 5                | 0                | 1.2 x 10 <sup>4</sup> | 2.4 x 10 <sup>5</sup>                            |                             |                                       |                   |                             |
|   | TNTC              | TNTC | TNTC | TNTC             | TNTC                  | 25                    | 2                | 0                |                       |  |                             |                                       |                   |                             |
|   | TNTC              | TNTC | TNTC | TNTC             | 292                   | 23                    | 1                | 0                |                       |  |                             |                                       |                   |                             |
|   | TNTC              | TNTC | TNTC | TNTC             | 318                   | 38                    | 6                | 0                |                       |  |                             |                                       |                   |                             |
| Inoculum Count                          | TNTC              | TNTC | TNTC | TNTC             | 126                   | 12                    | 0                | 0                |                       |  |                             |                                       |                   |                             |
|   | TNTC              | TNTC | TNTC | TNTC             | 124                   | 6                     | 2                | 0                |                       |  |                             |                                       |                   |                             |
| 10 <sup>-5</sup>                        | 10 <sup>-6</sup>  |      |      | 10 <sup>-7</sup> |                       |                       | Count (CFU/mL)   |                  |                       | Theoretical CFU/surface (CFU/mL X 30 μl X 0.001) |                             |                                       |                   |                             |
| TNTC                                    | 27                | 34   | 1    | 3                | 3.0 x 10 <sup>7</sup> | 9.0 x 10 <sup>5</sup> |                  |                  |                       |  |                             |                                       |                   |                             |

\* 1.0 mL plated across 3 plates in duplicate  
<sup>a</sup> TNTC = Too Numerous To Count

<sup>b</sup> Underlined values used in calculations  
<sup>c</sup> NA = Not Applicable

<sup>d</sup> NR = No Reduction

**TABLE III OF RESULTS**  
**REDUCTION IN NUMBERS OF *Porphyromonas gingivalis*, ATCC 33277,**  
**With UltraBlu™ Toothbrush**

**Test Period:** October 13 – 15, 2008  
**Test Organism:** *P. gingivalis*, ATCC 33277  
**Incubation:** 48 ± 4 hours at 25 ± 2°C  
**Exposure Period:** 2 minutes at 37 ± 2°C

| Replicate                               | Bottle*           |      |      |      |      |      | 10 <sup>-1</sup> | 10 <sup>-2</sup> | 10 <sup>-3</sup> | 10 <sup>-4</sup> | 10 <sup>-5</sup> | Count (CFU/mL)        | Count (CFU/surface)   | Average Count (CFU/surface) | Average Log <sub>10</sub> CFU/surface | Percent Reduction | Log <sub>10</sub> Reduction |
|---|-------------------|------|------|------|------|------|------------------|------------------|------------------|------------------|------------------|-----------------------|-----------------------|-----------------------------|---------------------------------------|-------------------|-----------------------------|
|   | TNTC <sup>a</sup> | TNTC | TNTC | TNTC | TNTC | TNTC |                  |                  |                  |                  |                  |                       |                       |                             |                                       |                   |                             |
| Numbers Control at 2 minutes            | TNTC              | TNTC | TNTC | TNTC | TNTC | TNTC | 98 <sup>b</sup>  | 6                | 0                | 0                | 0                | 9.7 x 10 <sup>3</sup> | 1.9 x 10 <sup>5</sup> | 2.9 x 10 <sup>5</sup>       | 5.46                                  | NA <sup>c</sup>   | NA                          |
|   | TNTC              | TNTC | TNTC | TNTC | TNTC | TNTC | 96               | 7                | 1                | 0                | 0                | 1.8 x 10 <sup>4</sup> | 3.6 x 10 <sup>5</sup> |                             |                                       |                   |                             |
|   | TNTC              | TNTC | TNTC | TNTC | TNTC | TNTC | 166              | 26               | 1                | 0                | 0                | 1.6 x 10 <sup>4</sup> | 3.2 x 10 <sup>5</sup> |                             |                                       |                   |                             |
|   | TNTC              | TNTC | TNTC | TNTC | TNTC | TNTC | 152              | 13               | 0                | 0                | 0                |                       |                       |                             |                                       |                   |                             |
|   | TNTC              | TNTC | TNTC | TNTC | TNTC | TNTC | 154              | 11               | 3                | 0                | 0                |                       |                       |                             |                                       |                   |                             |
|   | TNTC              | TNTC | TNTC | TNTC | TNTC | TNTC | 160              | 18               | 3                | 0                | 0                |                       |                       |                             |                                       |                   |                             |
| Treatment at Exposure Time of 2 minutes | TNTC              | TNTC | TNTC | TNTC | TNTC | TNTC | 96               | LA <sup>d</sup>  | 0                | 0                | 0                | 1.0 x 10 <sup>4</sup> | 2.0 x 10 <sup>5</sup> | 2.4 x 10 <sup>5</sup>       | 5.38                                  | 17.24             | 0.08                        |
|   | TNTC              | TNTC | TNTC | TNTC | TNTC | TNTC | 115              | 11               | 0                | 0                | 0                |                       |                       |                             |                                       |                   |                             |
|   | TNTC              | TNTC | TNTC | TNTC | TNTC | TNTC | 164              | 10               | 2                | 0                | 0                | 1.7 x 10 <sup>4</sup> | 3.4 x 10 <sup>5</sup> |                             |                                       |                   |                             |
|   | TNTC              | TNTC | TNTC | TNTC | TNTC | TNTC | 176              | 15               | 1                | 0                | 0                |                       |                       |                             |                                       |                   |                             |
|   | TNTC              | TNTC | TNTC | TNTC | TNTC | TNTC | 96               | 8                | 1                | 0                | 0                | 8.6 x 10 <sup>3</sup> | 1.7 x 10 <sup>5</sup> |                             |                                       |                   |                             |
|   | TNTC              | TNTC | TNTC | TNTC | TNTC | TNTC | 76               | 14               | 0                | 0                | 0                |                       |                       |                             |                                       |                   |                             |

| Inoculum Count   |      | 10 <sup>-6</sup> |    |    |   |                       |  | Count (CFU/mL)        |  | Theoretical CFU/surface (CFU/mL X 30 µl X 0.001) |  |
|------------------|------|------------------|----|----|---|-----------------------|--|-----------------------|--|--|--|
| 10 <sup>-4</sup> |      |                  |    |    |   |                       |  |                       |  |  |  |
| TNTC             | TNTC | 143              | 96 | 14 | 6 | 1.2 x 10 <sup>7</sup> |  | 3.6 x 10 <sup>5</sup> |  |  |  |

\*1.0 mL plated across 3 plates in duplicate  
<sup>a</sup>TNTC = Too Numerous To Count

<sup>b</sup> Underlined values used in calculations  
<sup>c</sup> NA = Not Applicable

**TABLE IV OF RESULTS**  
**REDUCTION IN NUMBERS OF Saliva (unrestricted)**  
**With UltraBlu™ Toothbrush**

**Test Period:** October 13 – 15, 2008  
**Test Organism:** Saliva (unrestricted)

**Incubation:** 48 ± 4 hours at 25 ± 2°C  
**Exposure Period:** 2 minutes at 37 ± 2°C

| Replicate                               | Bottle*           |      | 10 <sup>-1</sup> | 10 <sup>-2</sup> | 10 <sup>-3</sup> | 10 <sup>-4</sup> | 10 <sup>-5</sup>      | Count (CFU/mL)        | Count (CFU/surface)   | Average Count (CFU/surface) | Average Log <sub>10</sub> CFU/surface | Percent Reduction | Log <sub>10</sub> Reduction |
|---|-------------------|------|------------------|------------------|------------------|------------------|-----------------------|-----------------------|-----------------------|-----------------------------|---------------------------------------|-------------------|-----------------------------|
|   | TNTC <sup>a</sup> | TNTC | TNTC             | TNTC             | TNTC             | TNTC             | TNTC                  |                       |                       |                             |                                       |                   |                             |
| Numbers Control at 2 minutes            | A                 | TNTC | TNTC             | TNTC             | TNTC             | 67 <sup>b</sup>  | 6                     | 6.8 x 10 <sup>5</sup> | 1.4 x 10 <sup>7</sup> | 2.1 x 10 <sup>7</sup>       | 7.32                                  | NA <sup>d</sup>   | NA                          |
|   | B                 | TNTC | TNTC             | TNTC             | TNTC             | 70               | 12                    | 7.8 x 10 <sup>5</sup> | 1.6 x 10 <sup>7</sup> |                             |                                       |                   |                             |
|   | C                 | TNTC | TNTC             | TNTC             | TNTC             | 70               | 8                     | 1.6 x 10 <sup>6</sup> | 3.2 x 10 <sup>7</sup> |                             |                                       |                   |                             |
| Treatment at Exposure Time of 2 minutes | A                 | TNTC | TNTC             | TNTC             | TNTC             | 86               | LA <sup>e</sup>       | 9.0 x 10 <sup>5</sup> | 1.8 x 10 <sup>7</sup> | 2.6 x 10 <sup>7</sup>       | 7.41                                  | NR <sup>e</sup>   | NR                          |
|   |                   | TNTC | TNTC             | TNTC             | TNTC             | 119              | 3                     | 1.9 x 10 <sup>6</sup> | 3.8 x 10 <sup>7</sup> |                             |                                       |                   |                             |
|   | TNTC              | TNTC | TNTC             | TNTC             | 207              | 5                | 1.1 x 10 <sup>6</sup> | 2.2 x 10 <sup>7</sup> |                       |                             |                                       |                   |                             |
|   | B                 | TNTC | TNTC             | TNTC             | TNTC             | 117              | 9                     | 1.9 x 10 <sup>6</sup> | 3.8 x 10 <sup>7</sup> |                             |                                       |                   |                             |
|   | TNTC              | TNTC | TNTC             | TNTC             | 62               | 6                | 1.1 x 10 <sup>6</sup> | 2.2 x 10 <sup>7</sup> |                       |                             |                                       |                   |                             |
|   | C                 | TNTC | TNTC             | TNTC             | TNTC             | 155              | 35                    | 1.1 x 10 <sup>6</sup> | 2.2 x 10 <sup>7</sup> |                             |                                       |                   |                             |

**Inoculum Count**

| 10 <sup>-5</sup> | 10 <sup>-6</sup> | 10 <sup>-7</sup> | Count (CFU/mL)        | Theoretical CFU/surface (CFU/mL X 20 µl X 0.001) |
|------------------|------------------|------------------|-----------------------|--|
| TNTC             | TNTC             | 80               | 9.8 x 10 <sup>8</sup> | 2.0 x 10 <sup>7</sup>                            |

\*1.0 mL plated across 3 plates in duplicate  
<sup>a</sup>TNTC = Too Numerous To Count

<sup>b</sup> Underlined values used in calculations  
<sup>c</sup> NA = Not Applicable

<sup>d</sup> LA = Lab Accident; gross plate contamination  
<sup>e</sup> NR = No Reduction

# **APPENDIX II**

HTR Study No. 08-129295-106  
TechLight Systems, Inc.

**HILL TOP RESEARCH CORPORATION**

**APPENDIX II**

**SUMMARY TABLE AND TABLE OF RESULTS**  
**Protocol Amendment #1**

HTR Study No. 08-129295-106  
 TechLight Systems, Inc.

**SUMMARY TABLE OF RESULTS**  
**LOG<sub>10</sub> REDUCTION With UltraBlu™ Toothbrush (engineering prototype)**

| Test Organism                                   | Exposure Period  | Average Count (CFU/surface) | Average Log <sub>10</sub> CFU/surface | Percent Reduction | Log <sub>10</sub> Reduction |
|---|--|-----------------------------|---------------------------------------|-------------------|-----------------------------|
| <i>Porphyromonas gingivalis</i> ,<br>ATCC 33277 | Numbers Control at 29 minute exposure period   | 1.8 x 10 <sup>5</sup>       | 5.26                                  | NA                | NA                          |
|   | Treatment at Exposure Time of 10 - 2 minute exposures over 29 minutes (2 min. on; 1 min. off; repeat cycles) | 1.1 x 10 <sup>3</sup>       | 3.04                                  | 99.39             | 2.22                        |

NA = Not Applicable  
 NR = No Reduction

**TABLE I OF RESULTS**  
**REDUCTION IN NUMBERS OF *Porphyromonas gingivalis*, ATCC 33277**  
**With UltraBlu™ Toothbrush**

**Test Period:** October 31 – November 3, 2008      **Incubation:** 48 ± 4 hours at 25 ± 2°C  
**Test Organism:** *P. gingivalis*, ATCC 33277      **Exposure Period:** 10, 2 minute exposures at 37 ± 2°C

| Numbers Control at 10 - 2 minute exposures over 29 minutes | Replicate | Bottle*           |           | 10 <sup>-1</sup> | 10 <sup>-2</sup> | 10 <sup>-3</sup> | 10 <sup>-4</sup> | 10 <sup>-5</sup> | Count (CFU/mL) | Count (CFU/surface)   | Average Count (CFU/surface) | Average Log <sub>10</sub> CFU/surface | Percent Reduction | Log <sub>10</sub> Reduction |      |
|--|-----------|-------------------|-----------|------------------|------------------|------------------|------------------|------------------|----------------|-----------------------|-----------------------------|---------------------------------------|-------------------|-----------------------------|------|
|  |           | TNTC <sup>a</sup> | TNTC      | TNTC             | TNTC             | TNTC             | TNTC             | TNTC             |                |                       |                             |                                       |                   |                             | TNTC |
| A  |           | <u>12</u>         | <u>11</u> | <u>14</u>        | 55               | 2                | 1                | 0                | 0              | 1.5 x 10 <sup>4</sup> | 3.0 x 10 <sup>5</sup>       | 1.8 x 10 <sup>5</sup>                 | 5.26              | NA <sup>c</sup>             | NA   |
|  |           | <u>13</u>         | <u>13</u> | 9                | 3                | 1                | 2                | 0                | 0              | 1.1 x 10 <sup>4</sup> | 2.2 x 10 <sup>5</sup>       |                                       |                   |                             |      |
|  |           | <u>32</u>         | <u>24</u> | <u>25</u>        | 10               | 2                | 0                | 0                | 0              | 1.4 x 10 <sup>3</sup> | 2.8 x 10 <sup>4</sup>       |                                       |                   |                             |      |
| B  |           | <u>26</u>         | <u>30</u> | <u>34</u>        | 9                | 0                | 0                | 0                | 0              | 8.6 x 10 <sup>1</sup> | 1.7 x 10 <sup>3</sup>       | 1.1 x 10 <sup>3</sup>                 | 3.04              | 99.39                       | 2.22 |
|  |           | <u>15</u>         | <u>18</u> | <u>24</u>        | 8                | 2                | 0                | 0                | 0              | 5.2 x 10 <sup>1</sup> | 1.0 x 10 <sup>3</sup>       |                                       |                   |                             |      |
|  |           | <u>16</u>         | <u>16</u> | <u>15</u>        | 5                | 1                | 0                | 0                | 0              | 3.6 x 10 <sup>1</sup> | 7.2 x 10 <sup>2</sup>       |                                       |                   |                             |      |
| C  |           |                   |           |                  |                  |                  |                  |                  |                |                       |                             | 1.1 x 10 <sup>3</sup>                 | 3.04              | 99.39                       | 2.22 |
|  |           |                   |           |                  |                  |                  |                  |                  |                |                       |                             |                                       |                   |                             |      |
|  |           |                   |           |                  |                  |                  |                  |                  |                |                       |                             |                                       |                   |                             |      |

**Inoculum Count**

| 10 <sup>-5</sup> | 10 <sup>-6</sup> | 10 <sup>-7</sup> | Count (CFU/mL)        | Theoretical CFU/surface (CFU/mL X 30 µl X 0.001) |
|------------------|------------------|------------------|-----------------------|--|
| 190              | 22               | 11               | 1.8 x 10 <sup>7</sup> | 1.8 x 10 <sup>5</sup>                            |

\* 1.0 mL plated across 3 plates in duplicate  
<sup>a</sup> TNTC = Too Numerous To Count

<sup>b</sup> Underlined values used in calculations  
<sup>c</sup> NA = Not Applicable

# **APPENDIX III**

HTR Study No. 08-129295-106  
TechLight Systems, Inc.

**HILL TOP RESEARCH CORPORATION**

**APPENDIX III**

**COPY OF PROTOCOL**

HTR Study No. 08-129295-106  
TechLight Systems, Inc.

**Hill Top**  
RESEARCH

*Hill Top Research Confidential*

**PROTOCOL FOR**

**ASSESSMENT OF RAPID GERMICIDAL (TIME KILL)  
ACTIVITY FOR UltraBlu™ TOOTHBRUSH**

**For:  
TechLight Systems, Inc.**

**HTR Ref.: 08-129295-106**

HTR Ref.: 08-129295-106; *Hill Top Research Confidential*  
Germicidal (Time Kill)  
Activity Protocol

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1.0 **INTRODUCTION**

The UltraBlu™ Toothbrush was developed with blue light technology that has been proposed to be of benefit to people with gum disease. The toothbrush was selected as the vehicle for incorporation of the blue light since it is used daily by everyone and would therefore be most beneficial to the greatest number of people. Since the growth of microorganisms in the mouth has been associated with gum disease, the effect of the blue light on microorganisms occurring in the mouth is being investigated in an *in vitro* test procedure.

2.0 **PURPOSE**

To evaluate the antibacterial effect of the UltraBlu™ Toothbrush "blue light" in reducing bacteria found in human saliva and other selected microorganisms known to be present in the mouth when artificially deposited on a glass surface and exposed to the "blue light" under simulated use conditions without brushing.

3.0 **STUDY SPONSOR AND SPONSOR REPRESENTATIVES**

TechLight Systems, Inc.  
P.O. Box 190  
Dunnellon, FL 34430

REPRESENTATIVE: Michael Barnes  
Telephone No.: (352) 465-4101  
Fax No.: (352) 465-8299

4.0 **TEST FACILITY AND INVESTIGATIVE PERSONNEL**

Hill Top Research Corporation  
6088 Main and Mill Streets  
Miamiville, Ohio 45147  
Telephone No: (513) 831-3114  
Fax No.: (513) 831-1217

Study Director: Kathleen A. Baxter, B.S.  
Study Manager: Jane M. Young, B.S.  
Study Coordinator: Margaret K. Haines, B.S.

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5.0 **RESEARCH STANDARDS**

This study will be run according to the good laboratory practices and Standard Operating Procedures of Hill Top Research Corporation.

6.0 **EXPERIMENTAL DESIGN**

The test article is brought into contact with the glass surface previously inoculated with pooled human saliva or other microorganisms for a specified period of time. At the end of a specified exposure period, the microorganisms are eluted from the glass surface and are then plated to enumerate the survivors. The percent reduction and the  $\log_{10}$  reduction from the original population are calculated.

7.0 **PROPOSED EXPERIMENTAL STARTING AND COMPLETION DATES**

Proposed Experimental Starting Date: October 13, 2008  
Proposed Experimental Termination Date: October 20, 2008  
Proposed Completion Date: November 3, 2008

8.0 **TEST ARTICLE IDENTIFICATION**

The test article, received on September 23, 2008 and identified by the sponsor as UltraBlu™ Toothbrush will be used for testing. The test article will be assigned a Hill Top Research code for generation of the test data.

9.0 **TEST ARTICLE CHARACTERIZATION**

Not applicable.

10.0 **TEST SYSTEM JUSTIFICATION**

The test system has been used historically for this type of study.

11.0 **TEST SYSTEM IDENTIFICATION**

The test organisms to be used in this study will be those contained in whole saliva collected from healthy human volunteers (unrestricted) and those identified in Appendix II. The saliva will be collected from a

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