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# EFFICACY OF THE SILENTAIRE PLASMA 2X4 TROFFER AGAINST AEROSOLIZED SARS-COV-2

**PROJECT: SILENTAIRE - PLASMA PANEL LIGHT 2X4 TROFFER - SARS-COV-2**

PRODUCT: PLASMA PANEL LIGHT 2X4 TROFFER

CAP LIC NO: 8860298

CLIA LIC NO: 05D0955926

STATE ID: CDF 00324630

**CHALLENGE ORGANISM:**

SARS-COV-2 USA-CA1/2020

**STUDY COMPLETION DATE:**

05/15/2022

**Medical Director**

Dana Yee, M.D.

**Testing Facility**

Innovative Bioanalysis, Inc.

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**Laboratory Project Number**

1235-TR

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## Efficacy Study Summary:

| | |
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| **Study Title** | EFFICACY OF THE SILENTAIRE PLASMA 2X4 TROFFER AGAINST AEROSOLIZED SARS-COV-2 |
| **Laboratory Project #** | 1235-TR |
| **Guideline:** | Modified ISO standards as no international standards exist. |
| **Testing Facility** | Innovative Bioanalysis, Inc. |
| **GLP Compliance** | All internal SOPs and processes follow GCLP guidelines and recommendations. |
| **Test Substance** | SARS-CoV-2 USA-CA1/2020 |
| **Description** | The SilentAire Plasma 2x4 Troffer provided by ETI Solid State Lighting (Zhuhai) Ltd was designed as a hybrid lighting solution that combines LED lighting with an internal UV-C disinfection system. Per the manufacturer, the built-in UVC disinfection system prevents direct exposure while continuously funneling air through the disinfection chamber to reduce pathogens. This study sought to determine the device's efficacy in lowering active aerosolized SARS-CoV-2 in a controlled environment. |
| **Test Conditions** | Testing was conducted in a 10'x8'x8' chamber following BSL-3 standards. The temperature during testing ranged between 71-74°F, with a relative humidity of 38-41%. An 8.49 x $10^6$ TCID50/mL of SARS-CoV-2 in suspension media was nebulized into the room with mixing fans before collection. Air sample collections occurred at 0, 60, and 120 minutes of device operation. |
| **Test Results** | The test results displayed more rapid reductions in viral concentration than natural viability loss observed in the controls. The SilentAire Plasma 2x4 Troffer reduced active SARS-CoV-2 to approximately 1.45 x $10^5$ TCID50/mL after 60 minutes. After 120 minutes, an average of 1.69 x $10^2$ TCID50/mL of active SARS-CoV-2 was recovered. |
| **Control Results** | Control testing was conducted in duplicate without the device and samples were taken at the corresponding time points used for the challenge. The results displayed a natural viability loss over time in the chamber and were used as a comparative baseline to calculate viral reduction. |
| **Conclusion** | The SilentAire Plasma 2x4 Troffer demonstrated the ability to reduce active SARS-CoV-2 in the air, as shown by the 98.30% gross reduction after 60 minutes. After 120 minutes, a 99.998% gross reduction was observed. |

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## Study Report:

Study Title: EFFICACY OF THE SILENTAIRE PLASMA 2X4 TROFFER AGAINST AEROSOLIZED SARS-COV-2

Sponsor: ETI Solid State Lighting, Inc.

Test Facility: Innovative Bioanalysis, Inc. 3188 Airway Ave Suite D, Costa Mesa, CA 92626

Device Testing: Plasma Panel Light 2x4 Troffer (Model: 559041###) *
(Note: The first ## maybe 00-99 represents different LED color temperature and the last # maybe 0-9 or blank for internal use.)

### Study Dates:

Study Report Date: 05/22/2022

Experimental Start Date: 04/07/2022

Experimental End Date: 04/09/2022

Study Completion Date: 05/15/2022

### Study Objective:

ETI Solid State Lighting (Zhuhai) Ltd supplied the SilentAire Plasma 2x4 Troffer for testing to determine efficacy against viral pathogens. The study evaluated the effectiveness of the SilentAire Plasma 2x4 Panel in its ability to reduce the viral strain referred to as SARS-CoV-2 USA-CA1/2020 within the air.

### Test Method:

Bioaerosol Generation:

Nebulization occurred using a Blaustein Atomizing Module (BLAM), as shown in Figure 1, with a pre-set PSI and computer-controlled liquid delivery system. Before testing, the nebulizer was checked for proper functionality by nebulizing the solution without the test virus present to confirm the average particle size distribution. The nebulizer was filled with 8.49 x $10^6$ TCID50/mL of SARS-CoV-2 in suspension media and nebulized at a flow rate of 1mL/min with untreated local atmospheric air. After nebulization, the nebulizer's remaining viral stock volume was weighed to confirm roughly the same amount was nebulized during each run. Bioaerosol procedures for the controls and viral challenges were performed in the same manner with corresponding time points and collection rates.

*Figure 1: BLAM Nebulizer*

** Note: The Plasma Panel Light 2x4 Troffer tested did not include a model number. The model # listed was provided by ETi Solid State Lighting, Inc. with supporting UL report documentation referenced in Appendix A.*

Bioaerosol Sampling:

This study used two probes for air sampling, each connected to a calibrated Gilian 10i vacuum device and set at a standard flow of 5.02L/min with a 0.20% tolerance. Before use, the devices were inspected for functionality, and the vacuum system calibration was confirmed using a Gilian Gilibrator-2 NIOSH Primary Standard Air Flow Calibrator. Sample collection volumes were set to 10-minute draws per time point, which allowed for approximately 50 liters of air collection per collection port. The air sampler operated with a removable sealed cassette and was manually removed after each sampling time point. Cassettes had a delicate internal filtration disc (Fig. 2) to collect virus samples, which was moistened with a virus suspension media to aid in the collection. Filtration discs from Zefon International, Lot# 28875, were used for testing. At each time point, all the sample discs were pooled into one collection tube to provide an average across the two sampling locations.

*Figure 2: Sensidyne 37mm directionnel air flow sample cassette.*

Test System Strains: SARS-CoV-2 USA-CA1/2020

The following reagent was deposited by the Centers for Disease Control and Prevention and obtained through BEI Resources, NIAID, NIH: SARS-Related Coronavirus 2, Isolate USA-CA1/2020, NR-52382.

TCID50 Procedure:

Materials and Equipment:

- Certified Biological Safety Cabinet
- Micropipette and sterile disposable aerosol resistant tips—20uL, 200uL, 1000uL
- Inverted Microscope
- Tubes for dilution
- Hemocytometer with coverslip
- Cell media for infection
- Growth media appropriate for the cell line
- 0.4% Trypan Blue Solution
- Lint-free wipes saturated with 70% isopropyl alcohol
- $CO_2$ Incubator set at 37°C or 34°C, or other temperature as indicated

Procedure:

1. One day before infection, prepare 96 well dishes by seeding each well with Vero E6 cells in DMEM plus fetal bovine serum, 4mM Glutamine, and antibiotics.
2. On the day of infection, make dilutions of virus samples in PBS.
3. Make a series of dilutions at 1:10 of the original virus sample. Fill the first tube with 2.0mL PBS and the subsequent tubes with 1.8mL.
4. Vortex the viral samples, then transfer 20uL of the virus to the first tube, vortex, and discard tip.
5. With a new tip, serial dilute subsequent tips transferring 200uL.

Additions of virus dilutions to cells:

1. Label the lid of a 96-well dish by drawing grid lines to delineate quadruplicates, number each grid to correspond to the virus sample, and label the rows of the plate for the dilution, which will be plated.
2. Include four (4) negative wells on each plate which will not be infected.
3. Remove all but 0.1mL of media from each well by vacuum aspiration.
4. Starting from the most dilute sample, add 0.1mL of virus dilution to each of the quadruplicate wells for that dilution.
5. Infect four wells per dilution, working backward.
6. Allow the virus to absorb into the cells at 37°C for 2 hours.
7. After absorption, remove the virus inoculum. Start with the most dilute and work backward.
8. Add 0.5mL infection medium to each well, being careful not to touch the wells with the pipette.
9. Place plates at 37°C and monitor CPE using the inverted microscope over a period of 1 to 4 weeks.
10. Record the number of positive and negative wells.

## Study Materials and Equipment:

**Equipment Overview:** The equipment (Fig. 3) arrived at the laboratory pre-packaged by the manufacturer and was inspected for damage upon arrival. Due to the closed design, no assessment was conducted on the inner components of the device. The device was powered on to confirm functionality before testing. No product label indicating the name, model or serial number was found on the device.

MANUFACTURER: ETI Solid State Lighting (Zhuhai) Ltd.

MAKE: SilentAire Plasma 2x4 Troffer

SIZE: 603mm x 1213mm x 84mm

SERIAL #: N/A

*Figure 3. SilentAire Plasma 2x4 Troffer as tested.*

**Testing Layout:**

Testing was conducted in a sealed 10'x8'x8' chamber per Biosafety Level 3 (BSL3) standards, as shown in Figure 4. The overall dimensions of the test chamber provided a displacement volume of 640 $ft^3$ (approximately 18,122.78 liters) of air. The chamber remained closed during testing, with no air entering or leaving the room. A nebulizing port connected to a programmable compressor system was in the center of the 10-ft wall protruding 24-inches from the wall. At each chamber corner, low-volume mixing fans (approx. 30 cfm each) were positioned at 45-degree angles to ensure homogenous mixing of bioaerosol concentrations when nebulized into the chamber. The room was equipped with two probes for air sampling positioned along the room's centerline and located six feet off the chamber floor. The device was mounted as close to the ceiling as possible in the center of the chamber and ran on high fan speed. The chamber was visually inspected, and pressure tested, and all internal lab systems and equipment were reviewed before testing.

*Figure 4. An image of the SilentAire Plasma 2x4 Troffer mounted in the center of the chamber for testing.*

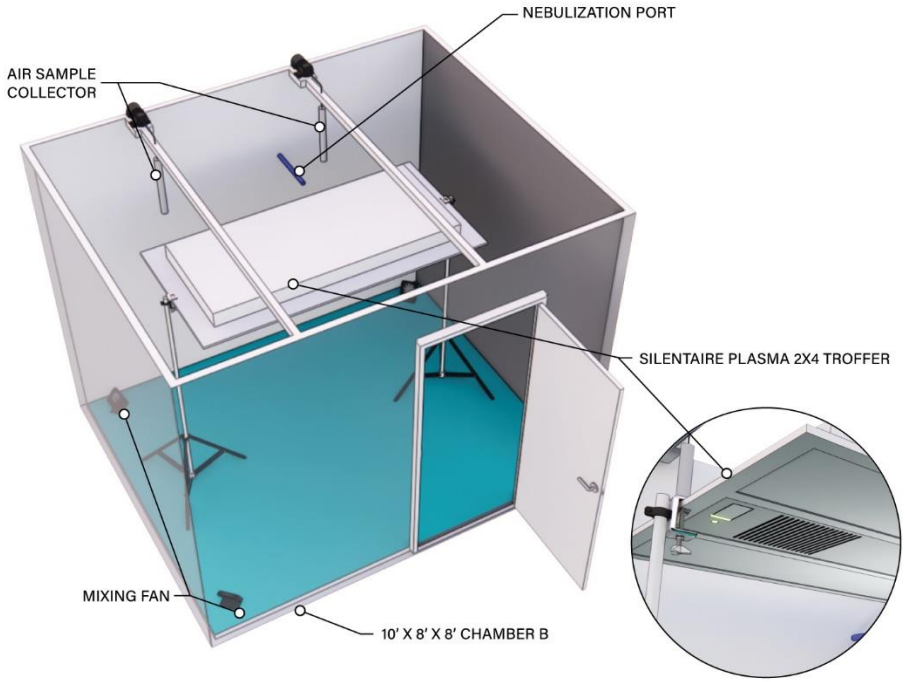



*Figure 5. 3D model of the testing layout for control and experimental trials.*

## Control Protocol:

Control testing was conducted in duplicate without the device operating in the testing chamber to assess the SilentAire Plasma 2x4 Troffer accurately. Control samples were taken in the same manner and at the corresponding time points used for the challenge trial to serve as a comparative baseline to assess the viral reduction when the device was operating.

## Test Procedures:

**Exposure Conditions:**

1. The temperature during all test runs ranged between 71-74°F, with a relative humidity of 38-41%.
2. The device fan speed was set at High (Setting 2) for all testing.
3. Testing time points were as follows, with T equal to minutes: T-0, T-60, and T-120.
4. Two controls and three viral challenges were conducted using the same methodology.

**Experimental Procedure:**

1. Before the initial control test and following each trial, the testing area was decontaminated and prepped per internal procedures.
2. 5mL of an 8.49 x $10^6$ TCID50/mL SARS-CoV-2 in suspension media was nebulized via a dissemination port into the room.
3. After nebulization (T-0), the SilentAire Plasma 2x4 Troffer was turned on via remote control.
4. At each predetermined time point, the device was turned off for sample collection.
5. Air sampling collections were set to 10-minute continuous draws at the point of sampling.
6. Sample cassettes were manually removed from the collection system and brought to an adjacent biosafety cabinet for extraction and placement into a viral suspension media.
7. All samples were sealed after collection and provided to lab staff for analysis after study completion.

**Post Decontamination:**

After each viral challenge test, the UV system inside the testing chamber was activated for 30 minutes. After 30 minutes of UV exposure, the air filtration system underwent a 30-minute air purge. All test equipment was cleaned with a 70% isopropyl alcohol solution at the end of each day. Collection lines were soaked in a bleach bath mixture for 30 minutes and then rinsed repeatedly with DI water. The nebulizer and vacuum collection pumps were decontaminated with hydrogen peroxide mixtures.

**Preparation of The Pathogen**

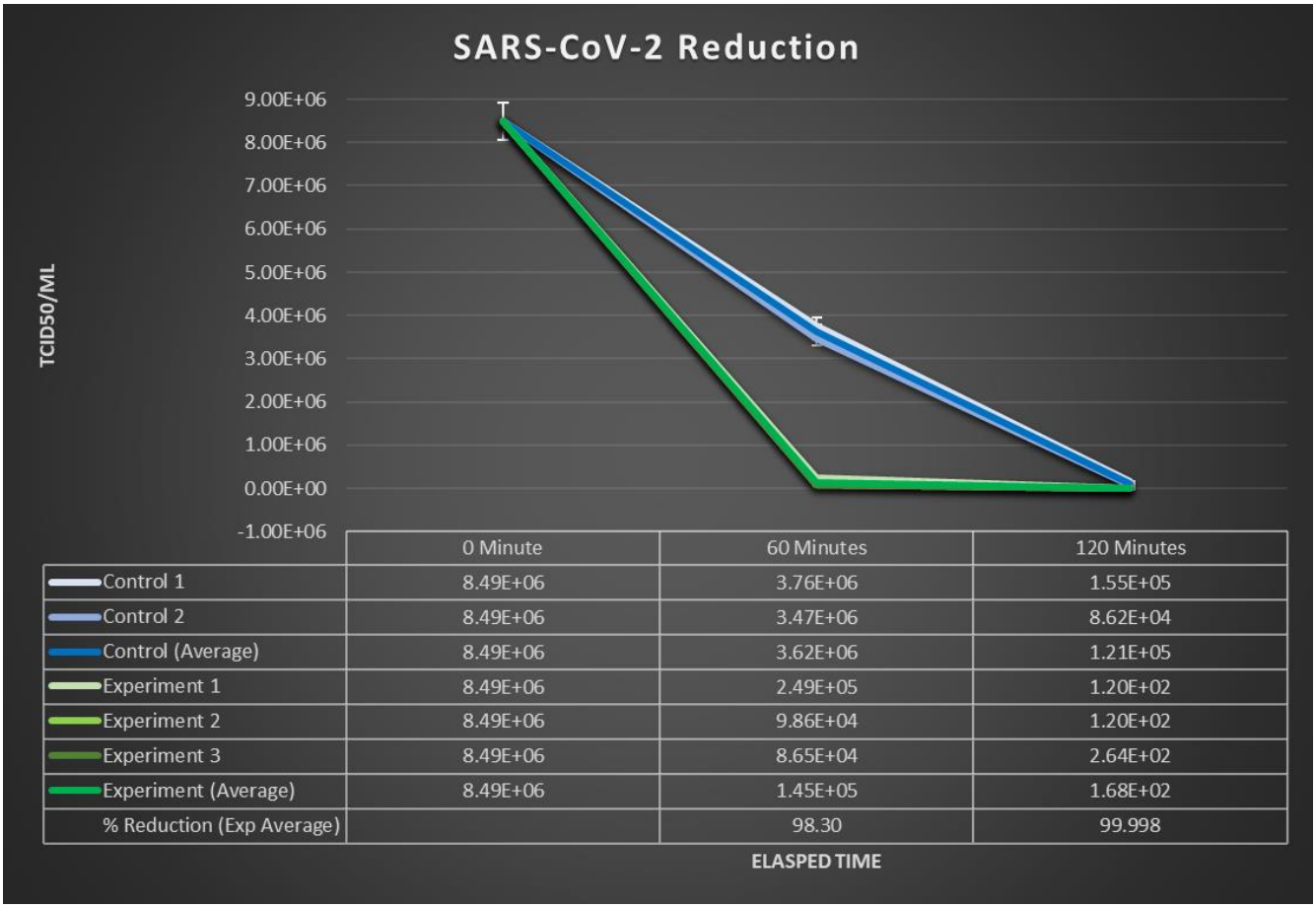
Viral Stock: SARS-CoV-2 USA-CA1/2020 (BEI NR-52382)

| TEST | SPECIFICATIONS | RESULTS |
|---|---|---|
| **Identification by Infectivity in Vero 6 Cells** | Cell Rounding and Detachment | Cell Rounding and Detachment |
| **Next-Generation Sequencing (NGS) of the complete genome using Illumina® iSeq™ 100 Platform** | ≥ 98% identity with SARS-CoV 2, isolate USA-CA1/2020 GenBank: MN994467.1 | 99.9% identity with SARS-CoV 2, isolate USA-CA1/2020 GenBank: MN994467.1 |
| Approx. 940 Nucleotides | ≥ 98% identity with SARS-CoV 2, strain FDAARGOS_983 isolate USA-CA1/2020 GenBank: MT246667.1 | 100% identity with SARS-CoV 2, strain FDAARGOS_983 isolate USA-CA1/2020 GenBank: MT246667.1 |
| **Titer by TCID50 in Vero E6 Cells by Cytopathic Effect** | Report Results | 2.8 X $10^5$ TCID50 per mL in 5 days at 37°C and 5% $CO_2$ |
| **Sterility (21-Day Incubation)** | | |
| Harpos HTYE Broth, aerobic | No Growth | No Growth |
| Trypticase Soy Broth, aerobic | No Growth | No Growth |
| Sabourad Broth, aerobic | No Growth | No Growth |
| Sheep Blood Agar, aerobic | No Growth | No Growth |
| Sheep Blood Agar, anaerobic | No Growth | No Growth |
| Thioglycollate Broth, anaerobic | No Growth | No Growth |
| DMEM with 10% FBS | No Growth | No Growth |
| **Mycoplasma Contamination** | | |
| Agar and Broth Culture | None Detected | None Detected |
| DNA Detection by PCR of extracted test article nucleic acid | None Detected | None Detected |

*The viral titer listed in the Certificate of Analysis is representative of the titer provided by BEI Resources. These viruses are grown on VeroE6 cells either in-house or at a partner lab to the concentrations listed within the experiment design.

## Study Results:

The graph below displayed recoverable active SARS-CoV-2 with and without the SilentAire Plasma 2x4 Troffer operating for 120 minutes. The controls showed a natural viability loss of aerosolized SARS-CoV-2 within the chamber, with an observed 98.579% of viability loss after 120 minutes in the chamber. Across three trials, the device reduced a starting concentration of 8.49 x $10^6$ TCID50/mL SARS-CoV-2 to 2.49 x $10^5$, 9.86 x $10^4$, and 8.65 x $10^4$ TCID50/mL, averaging to approximately 1.45 x $10^5$ TCID50/mL after 60 minutes. After 120 minutes, 1.20 x $10^2$, 1.20 x $10^2$, and 2.64 x $10^2$ TCID50/mL active SARS-CoV-2 was recovered, approximately 1.68 x $10^2$ TCID50/mL.




| | 0 Minute | 60 Minutes | 120 Minutes |
|---|---|---|---|
| Control 1 | 8.49E+06 | 3.76E+06 | 1.55E+05 |
| Control 2 | 8.49E+06 | 3.47E+06 | 8.62E+04 |
| Control (Average) | 8.49E+06 | 3.62E+06 | 1.21E+05 |
| Experiment 1 | 8.49E+06 | 2.49E+05 | 1.20E+02 |
| Experiment 2 | 8.49E+06 | 9.86E+04 | 1.20E+02 |
| Experiment 3 | 8.49E+06 | 8.65E+04 | 2.64E+02 |
| Experiment (Average) | 8.49E+06 | 1.45E+05 | 1.68E+02 |
| % Reduction (Exp Average) | | 98.30 | 99.998 |

** As it pertains to data represented herein, the value of 1.2E+02 indicates a titer that is lower than the specified limit of quantitation. The limit of quantitation for this assay is 1.2E+02.

***As it pertains to data represented herein; the percentage error equates to an average of ±5% of the final concentration.

## Conclusion:

The SilentAire Plasma 2x4 Troffer demonstrated the ability to reduce active, aerosolized SARS-CoV-2 more rapidly than the natural loss rate observed in the controlled environment after 60 minutes of device operation. The device achieved an average 98.30% gross reduction of active SARS-CoV-2 compared to the 57.38% viability loss in the controls after 60 minutes. After 120 minutes, the control and experimental trials observed low concentrations of recoverable active SARS-CoV-2 with a 98.579% loss in the controls and a 99.998% gross reduction with the device.

When aerosolizing pathogens and collecting said pathogens, some variables cannot be fully accounted for, namely, placement of pathogen, collection volume, collection points, drop rate, surface saturation, viral destruction upon collection, viral destruction on aerosolization, and possibly others. Every effort was made to address these constraints with the design and execution of the trials. And these efforts are reflected in the meaningful recovery of the virus in the control test.

Considering the variables, the SilentAire Plasma 2x4 Troffer achieved a measurable reduction after 60 minutes of operation. The results observed were consistent with the manufacturer's claim that the device can decrease concentrations of active pathogens. Overall, the device successfully reduced active SARS-CoV-2 in the air by 98.30% after 60 minutes under controlled conditions.

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Disclaimer

The Innovative Bioanalysis, Inc. ("Innovative Bioanalysis") laboratory is not certified or licensed by the United States Environmental Protection Agency and makes no equipment emissions claims pertaining to ozone or byproduct of any NVC International Holdings or ETI Solid State Lighting devices. Innovative Bioanalysis, Inc. makes no claims to the overall efficacy of any SilentAire Plasma 2x4 Troffer unit. The experiment results are solely applicable to the device used in the trial. The results are only representative of the experiment design described in this report. Innovative Bioanalysis, Inc. makes no claims as to the reproducibility of the experiment results given the possible variation of experiment results even with an identical test environment, viral strain, collection method, inoculation, nebulization, viral media, cell type, and culture procedure. Innovative Bioanalysis, Inc. makes no claims to third parties and takes no responsibility for any consequences arising out of the use of, or reliance on, the experiment results by third parties.

## Appendix A: Model Number Documentation (UL Report E524952)

File E524952
Project 4790328623 1.1

0000-00-00

REPORT

on

Ultraviolet Germicidal Irradiation Equipment And Similar Devices

ETI Solid State Lighting (Zhuhai) Ltd
Guangdong, China





DESCRIPTION

PRODUCT COVERED:

USL, CNL - Recess-Mounted type, Upper-room Germicidal Equipment, models 558101XXX and 559041XXX, where the first "XX" could be 00-99 represent color temperature, the last "X" may be 0~9 or blank for internal use).

NOTE: USL - United States Standard Listed
CNL - Canadian Standard Listed

ELECTRICAL RATINGS:

| Model No. | Input Ratings |
|---|---|
| 558101XXX | 120-277V, 50/60Hz, 101W |
| 559041XXX | 120-277V, 50/60Hz, 260W |

GENERAL CONSTRUCTION:

This product complies with the applicable Standards for USL and/or CNL germicidal equipment as noted under the "Technical Considerations" section noted below, the Section General, and the Description on the following pages.

TECHNICAL CONSIDERATIONS (NOT FOR FIELD REPRESENTATIVE'S USE):

USL - Products designated USL have been investigated using US requirements as noted in the Test Record.

CNL - Products designated CNL have been investigated using Canadian requirements as noted in the Test Record.

See full UL Report for more equipment specific details.