STERIS®

PATHOGON™ UV DISINFECTION SYSTEM

APPLICATION

The PATHOGON UV Disinfection System is designed for use as part of a cleaning and disinfection program to kill pathogens on environmental surfaces. After completion of a manual cleaning process, the system is employed to automatically deliver a dose of germicidal Ultraviolet-C (UVC)* energy, which alters the DNA of aggressive pathogens, to kill them.

* *Ultraviolet-C (UVC) has a wavelength range of 100 to 280 nanometer (nm) and peak germicidal effectiveness at 253.7 nm.*

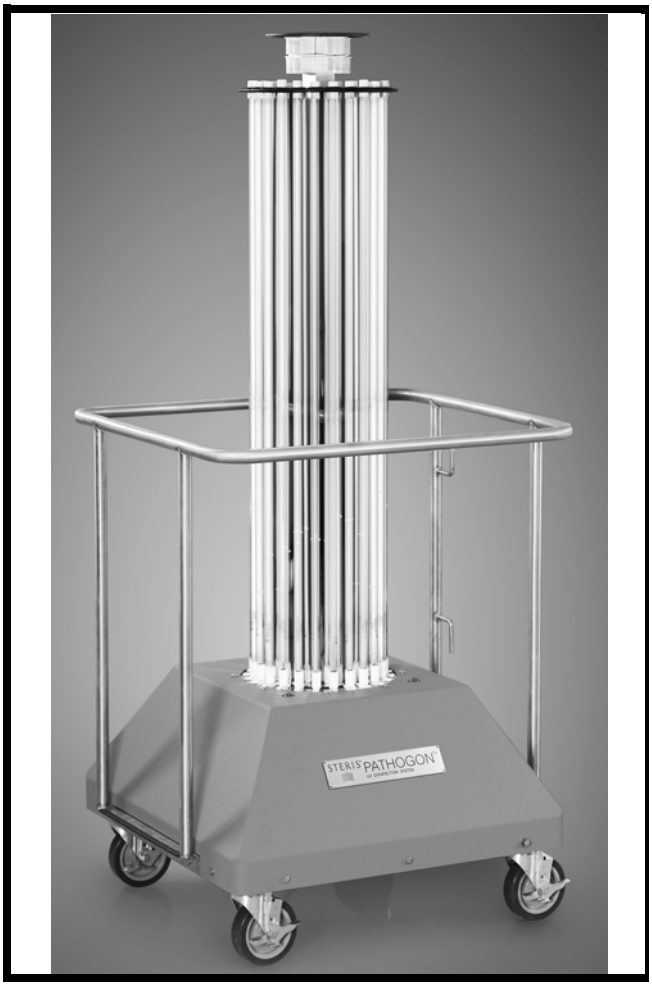
The process produces no ozone or secondary contaminants and rooms can be re-occupied immediately after treatment. The system is effective on the following healthcare-associated organisms.[1]

- *Clostridium difficile*
- *Staphylococcus aureus*
- *Pseudomonas aeruginosa*
- Methicillin Resistant *Staphylococcus aureus* (MRSA)
- Vancomycin Resistant *Entercoccus faecalis* (VRE)
- *Acinetobacter baumannii*
- *Klebsiella pneumoniae*
- Influenza A
- Feline Calicivirus (Surrogate for Human Norovirus)

1. Independent laboratory testing conducted December 2012. See Tables 1 to 3.

DESCRIPTION

The PATHOGON UV Disinfection System is a mobile electronic device consisting of vertical mast mounted on a UVC-resistant base with large diameter casters. The unit is rugged enough to handle daily use, yet easy to maneuver through a healthcare facility. The system is controlled wirelessly by a Windows-based tablet controller and an internal Programmable Logic Controller (PLC). The unit is equipped with a 360° motion and heat sensor not intended for use as a primary safety device to guard against accidental exposure to individuals who enter the room during the disinfection cycle. The unit has twenty-four, 45" (1143 mm) UVC lamps. Each lamp has a 12,000-hour rated life.



(Typical only - some details may vary.)

STANDARDS

This PATHOGON UV Disinfection System meets the applicable requirements of the following standards:

- **Underwriters Laboratories (UL): UL 61010-1 Second Edition** as certified by ETL Testing Laboratories, Inc.
- **Canadian Standards Association (CSA) Standard C22.2 No. 61010-1 Second Edition.**

Item _____

Location(s)_____

_____

SIZE (W X L X H)

Overall Dimensions: Width x Length x Height:

28 x 31 x 67" (711 x 787 x 1702 mm)

FEATURES

Motion Sensors - A bank of eight motion and heat sensors is mounted to the top of the PATHOGON UV Disinfection System in a square formation. There are two sensors mounted on each side of the square to provide redundant protection if the motion and heat sensor fails. Each sensor has a detection range of 180°. The sensors are placed in a square formation to provide overlapping coverage and prevent blind spots. Sensors are connected to a safety rated relay, wired as a Control Category 3 stop, to protect against UVC exposure to any persons who may enter the room during a disinfection cycle. When the sensors detect motion and heat, the UV lights are turned off and the cycle is stopped.

Wireless Controller – The wireless controller allows the operator to exit the room before initiating the countdown to start the disinfection cycle, reducing the chance of accidental exposure to UVC energy. The wireless remote also allows the operator to monitor unit status without entering the room.

Password Protection – The controller is password protected. A valid login name and password must be entered into controller before initiating a disinfection cycle.

Protective Lamp Cover/Door Barriers – The protective lamp cover doubles as a door barrier to be placed at the entrance and exit of the room. The barriers are clearly marked that a UV hazard is present and precaution must be taken.

Data Logging – The controller aids in documentation by keeping records for room number, cycle selected and operator. This data is downloadable to a PC.

Redundant Power Circuit Design – A redundant relay circuit is used in the lamp circuit so if in the event of a relay failure, a second relay is recruited to turn off lamps.

CYCLE DESCRIPTION

The PATHOGON UV Disinfection System performs four pre-programmed UVC cycles:

Target Organism	Application Diameter	Cycle Time
Bacteria/Virus	≤ 10 ft. (3 m)	4 minutes
Bacteria/Virus	≤ 18 ft. (5.4 m)	9 minutes
Bacterial Spore *C. difficile*	≤ 10 ft. (3 m)	11 minutes
Bacterial Spore *C. difficile*	≤ 18 ft. (5.4 m)	25 minutes

PREVENTIVE MAINTENANCE

Customers are encouraged to contact STERIS concerning annual maintenance programs. Preventive maintenance, adjustments and replacement of worn parts are provided on a scheduled basis to help ensure optimal equipment performance and help minimize untimely and costly interruptions. STERIS maintains a worldwide staff of well-equipped, factory-trained technicians to provide these services, as well as on-site installation, training and expert repair services. Contact STERIS for details.

NOTES

1. Internal fuse rating: 15 Amp
2. Power cable length: 15’ (4.6 m)
3. Unit weighs approximately 145 lb (66 kg)
4. Lamp type: GML 515
5. Lamp quantity: 24
6. Individual UVC lamp life: 12,000 hours
7. Controller battery life: ~8 hours (rechargeable)
8. Consult manufacturer’s manual for proper charging procedures for the tablet controller.
9. U.S. Environmental Protection Agency (EPA) Establishment Number: 89568-IN-001/89568-IL-001

ENGINEERING DATA

Electricity

- 120 Vac, 60 Hz, 20 Amp receptacle required

CUSTOMER IS RESPONSIBLE FOR COMPLIANCE WITH APPLICABLE LOCAL AND NATIONAL CODES AND REGULATIONS.

The base language of this document is ENGLISH. Any translations must be made from the base language.

PATHOGON UV DISINFECTION SYSTEM PRODUCT EFFICACY DATA SUMMARY

The following summary provides a description of the efficacy studies conducted to substantiate the effectiveness of the PATHOGON UV Disinfection System against six bacterial strains, two viruses and *C. difficile* spores. The studies were conducted at an independent laboratory, ATS Labs (Eagan, MN), under EPA Good Laboratory Practice (GLP) (40 CFR Part 160). GLP compliance includes independent in-process and final report audits by the ATS Quality Assurance Unit which provides a report that is incorporated into each efficacy report.

The study design utilized by ATS followed a simulated in-use design based on EPA Product Performance Test Guidelines, Series 810 for hard surface, hospital disinfectants (http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series810.htm). For all studies a standard 18'8.5" x 16'8" x 11'9" test room (3663.7 $feet^3$/104 m^3) was used for testing. The room included a shelf and table to support the test carriers and simulate typical room furnishings. To aid in blinding the study, a sponsor/registrant representative was responsible for operation of the PATHOGON UV device. The device was placed in the room and operated in accordance with the use directions and labeling.

Following AOAC and ASTM standard test methods, glass test carriers contaminated with dried test organisms were placed in the room by ATS staff at a height of 5 feet from the floor and located 5 or 9 feet from the device. Where applicable, the test strains utilized were those required by EPA to support bactericidal, virucidal and *C. difficile* sporicidal disinfection claims as required by EPA. At each distance, three test carriers per organism were exposed to the UV output of the device. The carriers were exposed at ambient temperature and humidity. Following exposure, bacterial test carriers were individually placed in neutralization/growth media and the survivors were quantitatively recovered by plating in duplicate and/or filtration. For virucidal efficacy studies, following exposure, the test carriers were neutralized and assayed for infectivity and/or cytotoxicity. Untreated population control carriers were prepared in triplicate alongside the test to determine a $\log_{10}$ reduction. Sterility, purity and verification of antibiotic resistance controls were also conducted with each study as applicable.

The PATHOGON system demonstrated a >5 log reduction for all bacterial and viral strains tested after four minutes exposure at 5 feet and 9 minute exposure at 9 feet from the device. The system achieved 2.90 log reduction against *C. difficile* spores after 11 minute exposure at 5 feet and 3.97 log reduction after 25 minute exposure at 9 feet from the device. The system achieved >4 log reduction against *C. difficile* spores after 15 minute exposure at 5 feet and 30 minute exposure at 9 feet from the device.

Evaluation of Antimicrobial Effectiveness of a UVC Generating Device on Hard Nonporous Surfaces

Table 1. Bacterial Efficacy

Strain	Untreated Control (Mean Log CFU/in^2)	PATHOGON UV Disinfection System Mean Log Reduction at 5' Height	
		4 min. @ 5 feet	9 min. @ 9 feet
Staphylococcus aureus	7.32	>7.32	>6.64
Pseudomonas aeruginosa	7.23	5.94	6.28
Acinetobacter baumannii	6.56	>5.97	>5.93
Vancomycin Resistant *Entercoccus faecalis* (VRE)	5.71	>5.51	>5.71
Klebsiella pneumoniae	7.49	>7.39	>7.23
Methicillin Resistant *Staphylococcus aureus* (MRSA)	7.42	>7.42	>7.16

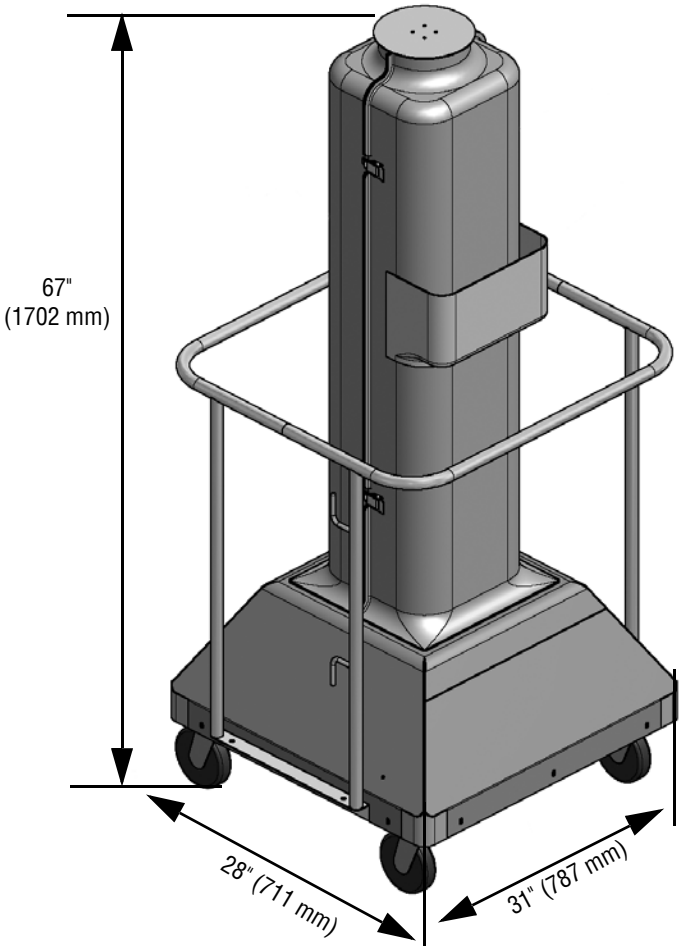
Table 2. Virucidal Efficacy

Strain	Dried Virus Control (Avg. $TCID_{50}$/100µl)	PATHOGON UV Disinfection System Average Log Reduction at 5' Height	
		4 min. @ 5 feet	**9 min. @ 9 feet**
Influenza A	5.95	≥5.45	
	5.80		≥5.12
Feline Calicivirus (Surrogate for Human Norovirus)	7.05	5.45	
	6.93		5.01

Table 3. Bacterial Spore Efficacy

Strain	Untreated Control (Mean Log CFU/in^2)	PATHOGON UV Disinfection System Mean Log Reduction at 5' Height	
		11 min. @ 5 feet	**25 min. @ 9 feet**
Clostridium difficile spore	5.86	2.90	3.97
		15 min. @ 5 feet	**30 min. @ 9 feet**
	7.30	4.83	4.16

Drawing is not to scale.
Dimensions are typical.



For Further Information, contact:

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