Optimum-UV[®] Clinical & Laboratory Evidence

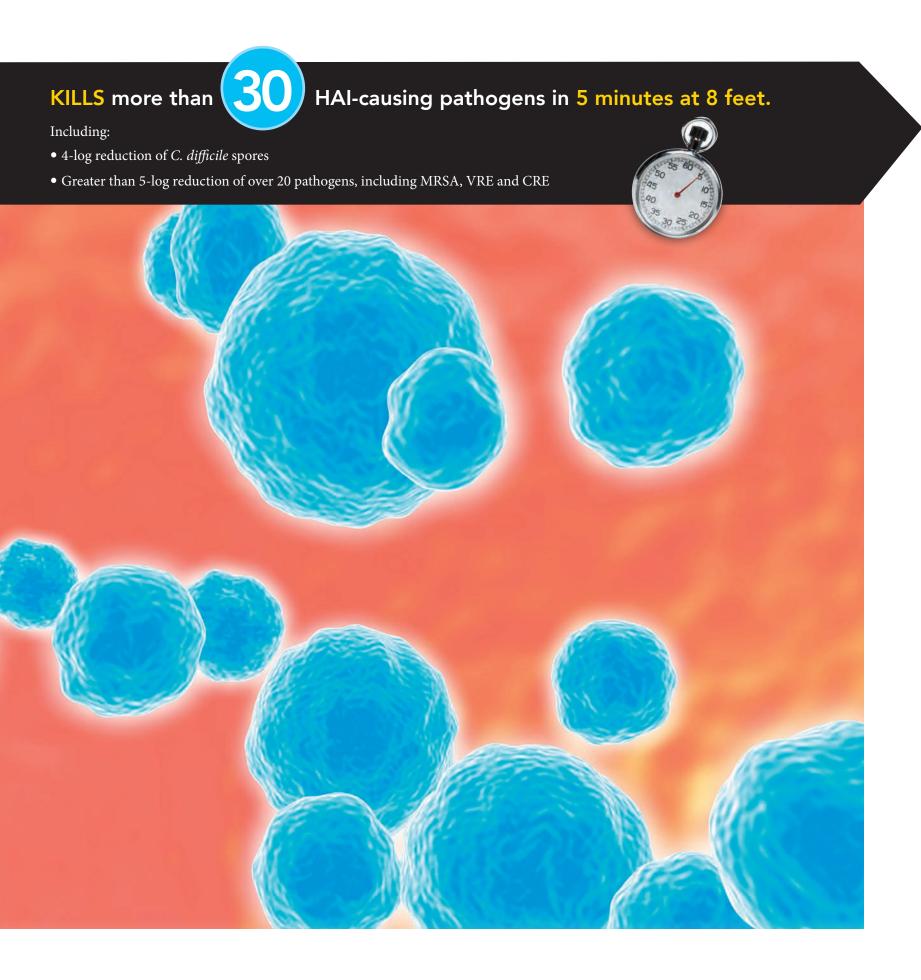




TABLE OF CONTENTS

Laboratory Micro-Efficacy Testing
Proven against more than 30 HAI-causing pathogens in 5 minutes at 8 feet 3
Clinical Evidence
University of Pennsylvania - David Pegues, MD5
The Optimum-UV® System reduced C . difficile infection (CDI) rates by 25% and averted \$134,568-\$191,604 annual direct medical costs in Hematology/Oncology units.
Johns Hopkins Hospital - Lisa Maragakis, MD, MPH 7
The Optimum-UV® System achieved a >5 log reduction against carbapenem-resistant <i>Enterobacteriaceae</i> (CRE; <i>K. pneumoniae, E. coli</i> and <i>E. cloacae</i>) in patient rooms.
Cleveland Clinic - Abhishek Deshpande, MD, PhD and Curtis Donskey, MD 9
Optimum-UV® System effectively reduced the presence of multidrug-resistant organisms (MDROs), including <i>C. difficile</i> and methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) in patient rooms.
Louis Stokes Cleveland VA Medical Center - Curtis Donskey, MD11
The Optimum-UV® System effectively kills <i>C. difficile</i> and methicillin-resistant <i>Staphylococcus aureus</i> (MRSA); standardized UV-C device efficacy testing is needed so that different devices can be compared.
UNC Health Care - William Rutala, MS, MPH, PhD13
The Optimum-UV® System is effective against carbapenem-resistant <i>Enterobacteriaceae</i> (CRE) and methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) plated on Formica® laminate in patient rooms.
UNC Health Care - William Rutala, MS, MPH, PhD15
The Optimum-UV® System is effective against methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) and <i>C. difficile</i> plated on Formica® laminate in patient rooms.
University of Arizona - Charles Gerba, PhD17
The Optimum-UV® System effectively inactivates <i>C. difficile</i> spores, MS-2 virus and MRSA on long-term care fomites when used in conjunction with with Clorox Healthcare® Hydrogen Peroxide.
OASIS Hospital - Maurice Croteau
A simple test demonstrates effective microbial load reduction by the Optimum-UV® System in an acute care setting when tested on vertical, horizontal and chemical sensitive surfaces.
Women's Hospital, Deaconess Health System - Sonya Mauzey, RN, BS, CIC21
The Optimum-UV® System reduces <i>Pseudomonas aeruginosa</i> infection incidence among patients in a neonatal intensive care unit.
Clinical studies and posters are also available digitally at https://www.cloroxprofessional.com/products/clorox-healthcare-optimum-uv-system/literature/

The studies enclosed are presented for informational purposes only. Please consult your Clorox Healthcare account representative for any questions.



Performance Validated by Third-Party Laboratory Micro-Efficacy Testing

	≥4.0 Log Reduction	≥5.0 Log Reduction	≥6.0 Log Reduction
Fungi		• Candida albicans	
Bacterial Spores	• Clostridium difficile		
Viruses	 Adenovirus Hepatitis A Virus Hepatitis C Virus† Herpes Simplex Virus 2 Human Coronavirus Respiratory Syncytial Virus Rhinovirus Rotavirus 	 Enterovirus 68 Herpes Simplex Virus 1 Influenza A Virus (H1N1) Norovirus[‡] Poliovirus 	
Bacteria		 Acinetobacter baumannii Bordetella pertussis Escherichia coli Escherichia coli (carbapenemresistant; CRE) Enterococcus faecium (vancomycinresistant; VRE) Listeria monocytogenes Methicillin-resistant Staphylococcus aureus (MRSA) Mycobacterium bovis (TB surrogate) Pseudomonas aeruginosa Salmonella enterica Staphylococcus aureus Staphylococcus epidermis (coagulasenegative; CoNS) 	 Enterobacter aerogenes Enterococcus faecalis Klebsiella pneumoniae Proteus mirabilis Serratia marcescens

[†] Via bovine viral diarrhea virus surrogate

 $\mathbf{3}$

[‡] Via feline calicivirus surrogate

The Optimum-UV® System reduced C. difficile infection (CDI) rates by 25% and averted \$134,568-\$191,604 annual direct medical costs in Hematology/Oncology units.

Principal Investigator:

David Pegues, MD, Professor of Medicine, Hospital of the University of Pennsylvania

Purpose:

To examine the impact of Optimum-UV® System deployment combined with manual surface disinfection with bleach on *C. difficile* infection rates in Hematology/Oncology units over a 12-month evaluation period.

Methods:

The Optimum-UV® System was deployed for a 12-month intervention period, in combination with standard manual surface disinfection with bleach. CDI rates were tracked pre- and post-intervention.

Results:

Deployment of the Optimum-UV® System resulted in a 25% decrease in CDI rates on the study units, as compared to the baseline period. An estimated \$134,568 to \$191,604 in annual direct medical costs were averted by preventing 21 cases of CDI on the study units.

	Baseline (Jan. 2013-Dec. 2013)	Intervention (Feb. 2014-Jan. 2015)
CDI Rate*	30.34	22.85

^{*}CDI rate is per 10,000 patient day

References:

Pegues, D.A.; Han, J.; Gilmar, C.; Mcdonnell, B.; Gaynes, S. Impact of Ultraviolet Germicidal Irradiation for No-Touch Terminal Room Disinfection on Clostridium Difficile Infection Incidence Among Hematology-Oncology Patients. Infect. Control Hosp. Epidemiol. 2016

Pegues, D.; Gilmar, C.; Denno, M.; Gaynes, S. Reducing *Clostridium difficile* Infection among Hematology-Oncology Patients Using Ultraviolet Germicidal Irradiation for Terminal Room Disinfection. In *IDWeek* (poster presentation); 2015.



The Optimum-UV® System achieved a >5 log reduction against carbapenem-resistant Enterobacteriaceae (CRE; K. pneumoniae, E. coli, and E. cloacae) in patient rooms.

Principal Investigator:

Lisa Maragakis, MD, MPH, Senior Director of Infection Prevention and Associate Professor of Medicine, The Johns Hopkins Health System

Purpose:

To examine Optimum-UV® System efficacy against carbapenem-resistant *Enterobacteriaceae* (CRE; *K. pneumoniae*, *E. coli* and *E. cloacae*) plated on Formica®. This study is part of a cluster, randomized, two-period crossover trial focused on evaluating MDRO transmission that includes daily patient room cleaning with UV-C in addition to terminal cleaning in Oncology and Solid Organ Transplant units.

Methods:

UV-C was applied to carbapenem-resistant *Enterobacteriaceae* plated on Formica® placed on more than 17 high-touch surfaces in a patient room and bathroom.

Results:

The Optimum-UV® System achieved a >5 log reduction against all three CRE microorganisms tested. No CRE microorganisms grew on 131 out of 133 plates tested following three 5-minute cycles of exposure to UV-C.

References:

Rock, C.; Curless, M.S.; Nowakowski, E.; Ross, T.; Carson, K.A.; Trexler, P.; Carroll, K.; Maragakis, L.L. UV-C Light Disinfection of Carbapenem-Resistant *Enterobacteriaceae* from High-Touch Surfaces in a Patient Room and Bathroom. *Infect. Control Hosp. Epidemiol.* 2016, 1–2.

Rock, C.; Curless, M.; Nowakowski, E.; Ross, T.; Carson, K.; Trexler, P.; Carroll, K.; Maragakis, L. UV Light Decontamination of Carbapenem-Resistant *Enterobacteriaceae* from High Touch Surfaces in a Patient Room and Bathroom. In SHEA (poster presentation); 2016.



Optimum-UV® System effectively reduced the presence of multidrugresistant organisms (MDROs), including C. difficile and methicillin-resistant Staphylococcus aureus (MRSA) in patient rooms.

Principal Investigators:

Abhishek Deshpande, MD, PhD, Assistant Professor of Medicine, Cleveland Clinic Lerner College of Medicine at Case Western Reserve University

Curtis Donskey, MD, Professor of Medicine, Case Western Reserve University and Staff Physician, Infectious Diseases Section, Louis Stokes Cleveland VA Medical Center

Purpose:

To examine Optimum-UV® System effectiveness against nosocomial pathogens in hospital rooms, including *C. difficile* and methicillin-resistant *Staphylococcus aureus* (MRSA). This study is part of a randomized ward-level crossover study on four medical surgical wards during an 8-month period, focused on evaluating *C. difficile* infection (CDI) rates. This study also included an evaluation of healthcare worker and environmental services staff perceptions.

Methods:

The Optimum-UV® System was run in isolation rooms on two units in an acute-tertiary care hospital for 6 months. Each patient room was treated for two 5-minute cycles, and the patient bathroom for one 5-minute cycle, for a total of 15 minutes per room. Cultures were collected before and after UV-C treatment to determine the levels of contamination of *C. difficile*, MRSA, vancomycin-resistant *Enterococcus* (VRE), and multidrug-resistant gram-negative organisms.

Results:

The Optimum-UV® System achieved significant reduction in recovery of MRSA and *C. difficile* during the intervention period, as compared to the preintervention period. MRSA and *C. difficile* recovery was reduced by 76% (p=0.03) during the intervention, as compared to the preintervention period.

References:

Deshpande, A.; Hartley, J.; Cadnum, J.; Jencson, A.; Sankar, T. Effectiveness of an Ultraviolet Light Decontamination Device in Reducing Hospital Room Contamination. In *SHEA* (poster presentation); 2016; p. 549.

Deshpande, A.; Hartley, J.; Einloth, C.; Fatica, C.; Donskey, C.; Fraser, T. Perceptions of Healthcare Workers and Environmental Services Staff Regarding Ultraviolet Room Decontamination Devices. In *APIC (poster presentation)*; 2016; p. 251.



The Optimum-UV® System effectively kills C. difficile and methicillinresistant Staphylococcus aureus (MRSA); standardized UV-C device efficacy testing is needed so that different devices can be compared.

Principal Investigator:

Curtis Donskey, MD, Professor of Medicine, Case Western Reserve University and Staff Physician, Infectious Diseases Section, Louis Stokes Cleveland VA Medical Center

Purpose:

To determine the impact of variation in UV-C efficacy test methods on log reduction results.

Methods

Two UV-C devices, including the Optimum-UV® System, were compared using a single test method for efficacy against MRSA and *C. difficile*. The Optimum-UV® System was then subjected to further testing whereby one variable at a time was altered to assess the impact on the results, including carrier distance from the lamps, height of the carriers relative to the floor, carrier type, inoculum spread, carrier angle relative to the device and organic load.

Results:

A >3 log reduction was achieved within 5 minutes for MRSA for both UV devices tested. As expected, log reductions for MRSA and *C. difficile* changed, depending on the variables tested, including inoculum dispersal, organic load, carrier orientation and carrier height. This study demonstrates the need for industrywide standards for evaluating UV-C device efficacy.

References:

Cadnum, J.L.; Tomas, M.E.; Sankar, T.; Jencson, A.; Mathew, J.I.; Kundrapu, S.; Donskey, C.J. Effect of Variation in Test Methods on Performance of Ultraviolet-C Radiation Room Decontamination. *Infect. Control Hosp. Epidemiol.* 2016, 1-6.

Cadnum, J.L.; Mana, T.S.C.; Jencson, A.L.; Deshpande, A.; Donskey, C.J. Not All Efficacy Testing Is Created Equal: Effect of Variation in Test Methods on Performance of an Ultraviolet Radiation Room Disinfection Device. In *SHEA* (poster presentation); 2015.



The Optimum-UV® System is effective against carbapenem-resistant Enterobacteriaceae (CRE) and methicillin-resistant Staphylococcus aureus (MRSA) plated on Formica® laminate in patient rooms.

Principal Investigator:

William Rutala, MS, MPH, PhD, Director of Hospital Epidemiology, UNC School of Medicine

Purpose:

To examine Optimum-UV® System efficacy against methicillin-resistant *Staphylococcus* aureus (MRSA) and carbapenem-resistant *Klebsiella pneumoniae* (CRKP) plated on Formica®, using two different device placement methods.

Methods:

UV-C was applied to clinical isolates of MRSA and carbapenem-resistant *Klebsiella pneumoniae* (CRKP) plated on Formica® laminate placed at various locations in a patient room. Two separate experiments were run using two different UV device placement setups to compare the log reductions obtained with each setup. In setup A, the device was placed in the center of the room and run for a single 5-minute cycle, and in setup B, the device was run for two 5-minute cycles with the device placed on either side of the patient bed.

Results:

The Optimum-UV® System achieved a >5 log reduction for directly exposed sites and a >4 log reduction for indirectly exposed sites against MRSA and CRKP in 10 minutes. Setup A was comparable to Setup B, with a statistically significant improvement in log reduction found for Setup B. This difference may not be clinically relevant, however, as a >2 log reduction is proposed to be clinically effective by the study authors.

Pathogen	MRSA		CRKP	
Device Setup	Setup A (one cycle)	Setup B (two cycles)	Setup A (one cycle)	Setup B (two cycles)
Surface Type	(Log ₁₀ Reduction)		(Log ₁₀ Reduction)	
Direct Surfaces	5.27	5.82	5.74	6.61
Indirect Surfaces	4.17	4.55	4.53	5.39
Overall	4.61	5.06	5.01	5.87

Reference:

Kanamori, H.; Rutala, W.A.; Gergen, M.F.; Weber, D.J. Patient Room Decontamination against Carbapenem-Resistant *Enterobacteriaceae* and Methicillin-Resistant *Staphylococcus aureus* Using a Fixed Cycle-Time Ultraviolet-C Device and Two Different Radiation Designs. Infect. Control Hosp. Epidemiol. 2016, 1-3.



The Optimum-UV® System is effective against methicillin-resistant Staphylococcus aureus (MRSA) and C. difficile plated on Formica® laminate in patient rooms.

Principal Investigator:

William Rutala, MS, MPH, PhD, Director of Hospital Epidemiology, UNC School of Medicine

Purpose:

To examine Optimum-UV® System efficacy against methicillin-resistant *Staphylococcus aureus* (MRSA) and *C. difficile* spores plated on Formica®.

Methods:

UV-C was applied to MRSA and *C. difficile* spores plated on Formica® laminate placed at various locations in two patient rooms. The UV device was run for either a single 5-minute cycle, or a 10-minute cycle to simulate the recommended two 5-minute cycle times to treat a patient room.

Results:

The Optimum-UV® System achieved a 3.56 log reduction against methicillin-resistant *Staphylococcus aureus* (MRSA) in 5 minutes, and a 2.78 log reduction against *C. difficile* spores in 10 minutes.

Pathogen	MRSA (5 minutes)	C. difficile spores (10 minutes)	
Surface Type	(Log ₁₀ Reduction)		
Direct Surfaces	4.1	3.35	
Indirect Surfaces	2.74	1.8	
Overall	3.56	2.78	

Reference:

Rutala, W.A.; Gergen, M.F.; Tande, B.M.; Weber, D.J. Room Decontamination Using an Ultraviolet-C Device with Short Ultraviolet Exposure Time. *Infect. Control Hosp. Epidemiol.* 2014, 35, 1070–1072.



The Optimum-UV® System effectively inactivates C. difficile spores, MS-2 virus and MRSA on long-term care fomites when used in conjunction with Clorox Healthcare® Hydrogen Peroxide.

Principal Investigator:

Charles Gerba, PhD, Professor, Microbiology & Environmental Sciences, University of Arizona

Purpose:

To examine the effectiveness of the Optimum-UV® System combined with Clorox Healthcare® Hydrogen Peroxide against *C. difficile* spores, MS-2 virus and MRSA.

Methods:

C. difficile spores, MS-2 virus and MRSA were plated on stainless steel, and MRSA was additionally plated on Formica® and 100% polyester. Then each plate was treated with Clorox Healthcare® Hydrogen Peroxide, followed by 10 minutes of exposure to the Optimum-UV® System.

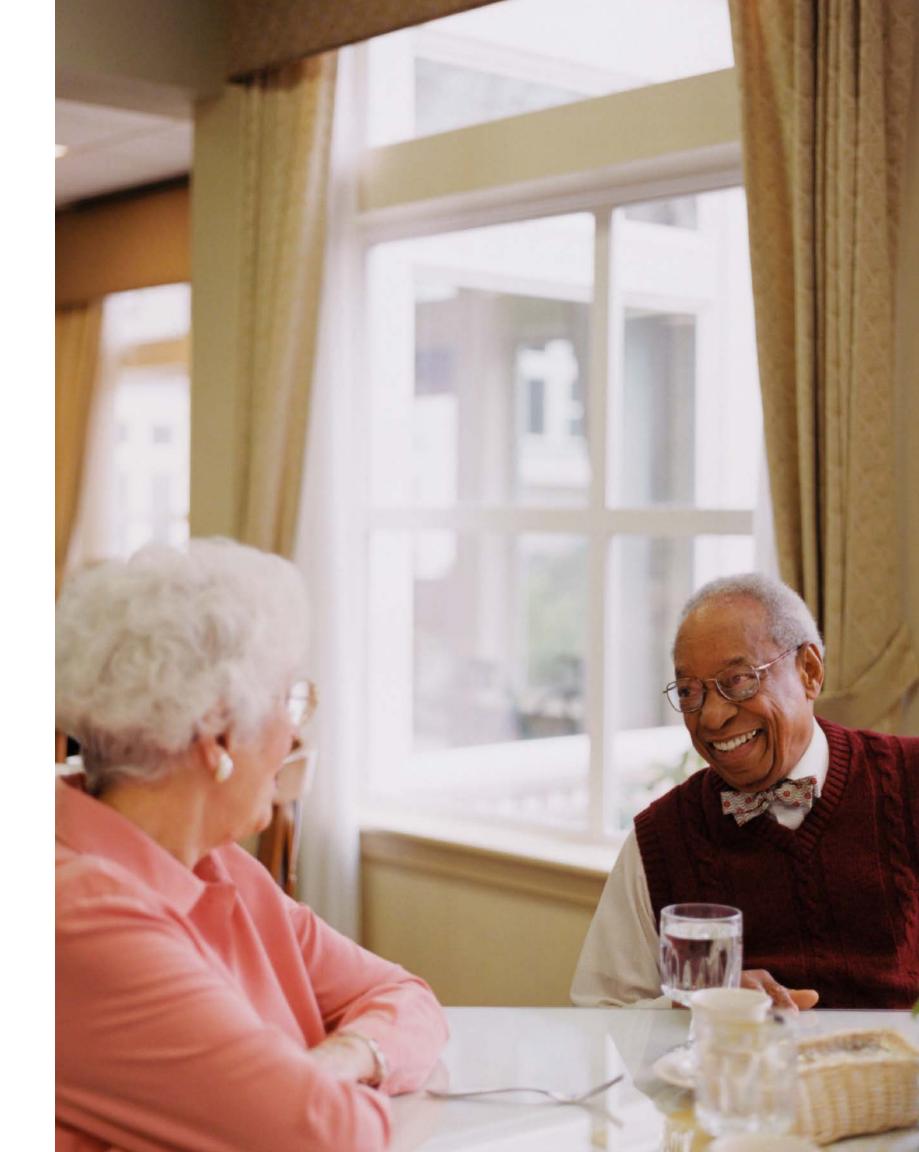
Results:

Hydrogen peroxide, when used in conjunction with UV, resulted in a \geq 4.0 log reduction against MRSA, *C. difficile* spores and MS-2 virus. This treatment effectively removed >6.0 logs of MRSA from the soft surface polyester.

Pathogen	MRSA (10 minutes)	C. difficile spores (10 minutes)	MS-2 virus (10 minutes)
Surface Type	(Log ₁₀ Reduction)		
Stainless Steel	4.14	>4	8.2
Formica®	>5.3		
Polyester	>6.0		

Reference:

Sifuentes, L.Y.; Peterson, A.; Pivo, T.; Gerba, C.P. Ultra Violet Light Efficacy in the Absence of Cleaning. In *APIC* (poster presentation); 2015.



A simple test demonstrates effective microbial load reduction by the Optimum-UV® System in an acute care setting when tested on vertical, horizontal and chemical-sensitive surfaces.

Principal Investigator:

Maurice Croteau, Director of Healthcare Services, Western Paper Distributors

Purpose:

To demonstrate the effectiveness of a simple test method to evaluate microbial load reduction in hospital rooms following treatment with UV-C.

Methods:

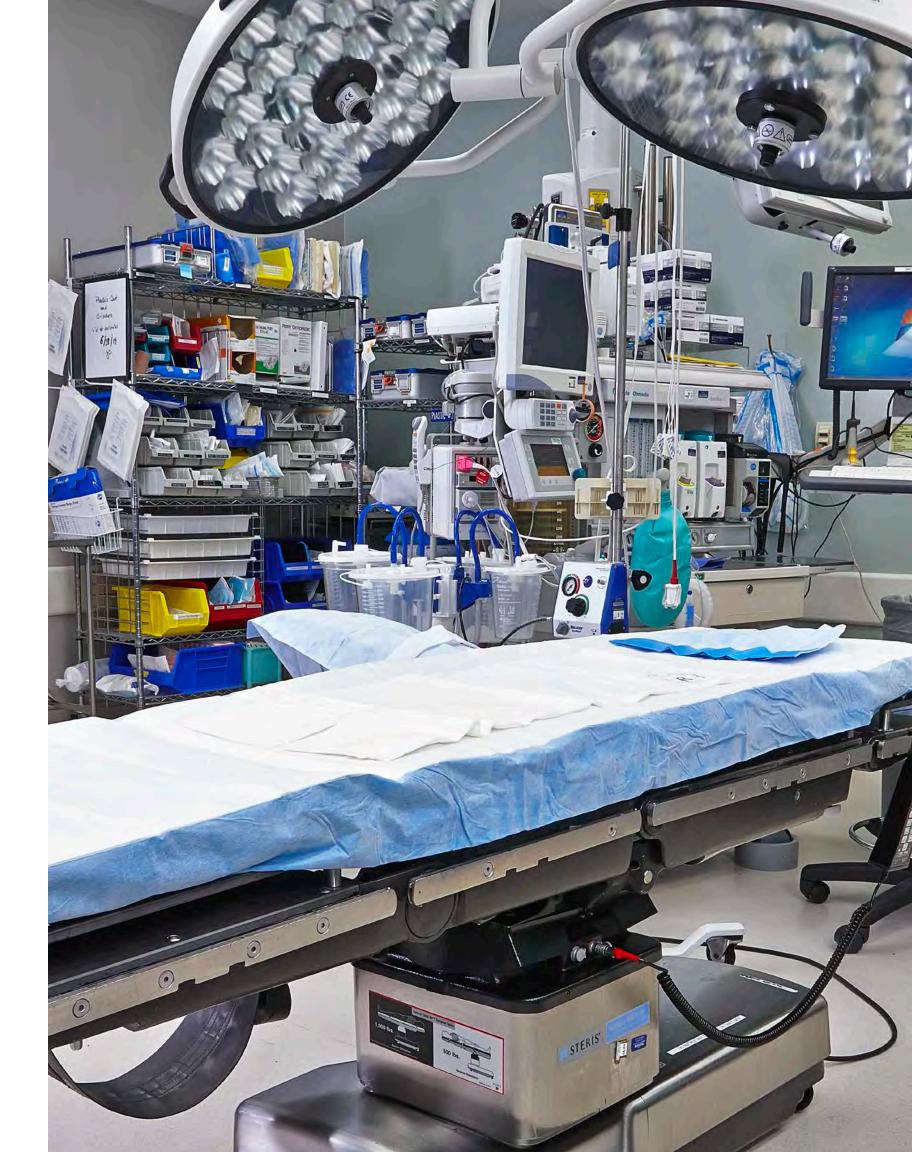
High-touch surfaces were sampled before and after UV-C treatment using RODAC™ contact plates. More than 30 surface types were tested in operating rooms, burn units, intensive care units and a special procedures unit in two hospitals.

Results:

A simple, easy-to-use microbial test showed that the Optimum-UV® System significantly reduced microbial presence on a variety of surfaces in two hospitals following standard manual surface disinfection. UV-C was effective on all surface types tested, including vertical, horizontal and sensitive electronic surfaces.

Reference:

Croteau, M.E.; Grover, T.M. Evaluating the Efficacy of UV-C Technology in Acute Care. In *APIC* (poster presentation); 2015.



The Optimum-UV® System reduces Pseudomonas aeruginosa infection incidence among patients in a neonatal intensive care unit.

Principal Investigator:

Sonya Mauzey, RN, BS, CIC, Infection Preventionist, The Women's Hospital – Deaconess Health System

Purpose:

To examine the impact of Optimum-UV® on *Pesudomonas aeruginosa* infection incidence in a neonatal intensive care unit.

Methods:

A retrospective review of positive *Pseudomonas aeruginosa* culture incidence was conducted on patients in a neonatal intensive care unit for a period of 3 years. Manual surface disinfection alone was used in the first half of the study (1.5 years), and the Optimum-UV® System was used as an adjunct to manual surface disinfection during the second half of the study.

Results:

Only one positive *Pseudomonas aeruginosa* culture was found among neonatal intensive care unit patients in the 1.5-year period when the Optimum-UV® System was used, as compared to 32 positive cultures found in the 1.5-year baseline period when manual surface disinfection alone was used.

Reference:

Mauzey, S. Impact of Ultraviolet Technology on Incidence of Pseudomonas in a Neonatal Intensive Care Unit. In *APIC (poster presentation)*; 2015.



