

Clinical and Laboratory Evidence



Designed and Manufactured
by UVDI in California, USA



ISO 9001:2015
ISO 14001:2015



UVDI EPA Establishment
Number 73542-CA-001



Table of Contents

Laboratory Micro-Efficacy Testing

Proven against more than 35 HAI-causing pathogens in 5 minutes at 2.44 meters	4
--	----------

Clinical Evidence

University of Pennsylvania – David Pegues, MD	6
--	----------

The UVDI-360 Room Sanitizer reduced *C. difficile* infection (CDI) rates by 25% and prevented \$134,568–\$191,604 annual direct medical costs in Hematology/Oncology units.

St. Mary’s Hospital for Children – Marianne Pavia, MS, BS, CIC, FAPIC	8
--	----------

The Effect of Ultraviolet-C Technology on Viral Infection Incidence in a Pediatric Long-term Care Facility.

UNC Health Care – William Rutala, MS, MPH, PhD	10
---	-----------

The UVDI-360 Room Sanitizer is effective against methicillin-resistant *Staphylococcus aureus* (MRSA) and *C. difficile* plated on Formica® laminate in patient rooms.

Johns Hopkins Hospital – Lisa Maragakis, MD, MPH	12
---	-----------

The UVDI-360 Room Sanitizer achieved a >5 log reduction against carbapenem-resistant *Enterobacteriaceae* (CRE; *K. pneumoniae*, *E. coli* and *E. cloacae*) in patient rooms.

Women’s Hospital, Deaconess Health System in Indiana – Sonya Mauzey, RN, BS, CIC	14
---	-----------

The UVDI-360 Room Sanitizer reduces *Pseudomonas aeruginosa* infection incidence among patients in a neonatal intensive care unit.

Cleveland Clinic – Abhishek Deshpande, MD, PhD and Curtis Donskey, MD	16
--	-----------

The UVDI-360 Room Sanitizer effectively reduced the presence of multidrug-resistant organisms (MDROs), including *C. difficile* and methicillin-resistant *Staphylococcus aureus* (MRSA) in patient rooms.

Cardiff University – Jean Yves Maillard, MD	18
--	-----------

Testing the microbial efficacy of the UVDI-360 Room Sanitizer.

UNC Health Care – William Rutala, MS, MPH, PhD	20
---	-----------

The UVDI-360 Room Sanitizer is effective against carbapenem-resistant *Enterobacteriaceae* (CRE) and methicillin-resistant *Staphylococcus aureus* (MRSA) plated on Formica® laminate in patient rooms.

Johns Hopkins Hospital – Lisa Maragakis, MD, MPH	22
---	-----------

Patient and health care worker perceptions of daily use of ultraviolet-C technology as an adjunct to daily cleaning in an academic hospital: Secondary study of Ultra Violet-C Light Evaluation as an Adjunct to Removing Multi-Drug Resistant Organisms.

The studies enclosed are presented for informational purposes only. Please contact your local distributor for any questions.



Performance validated by third-party laboratory micro-efficacy testing

The UVDI-360 Room Sanitizer is effective against more than 35 Hospital Acquired Infection-causing pathogens in 5 minutes at 2.44 meters, including 12 of the most prevalent Hospital Acquired Infection-causing pathogens and 4 of the most common outbreak and ward closure pathogens.*

Testing Distance and Time: 2.44 meters, 5 minutes			
	≥ 4.0 Log Reduction	≥ 5.0 Log Reduction	≥ 6.0 Log Reduction
Fungi		<ul style="list-style-type: none"> • <i>Candida albicans</i> 	
Bacterial Spores	<ul style="list-style-type: none"> • <i>Clostridium difficile</i> 		
Viruses	<ul style="list-style-type: none"> • Adenovirus • Hepatitis A Virus • Hepatitis C Virus† • Herpes Simplex Virus 2 • Human Coronavirus • Measles Virus • Respiratory Syncytial Virus • Rhinovirus • Rotavirus 	<ul style="list-style-type: none"> • Ebola • Enterovirus 68 • Herpes Simplex Virus 1 • Influenza A Virus (H1N1) • Middle East Respiratory Syndrome Coronavirus (MERS-CoV) • Norovirus†† • Poliovirus 	
Bacteria		<ul style="list-style-type: none"> • <i>Acinetobacter baumannii</i> • <i>Bordetella pertussis</i> • <i>Escherichia coli</i> • <i>Escherichia coli</i> (carbapenem-resistant; CRE) • <i>Enterococcus faecium</i> (vancomycin-resistant; VRE) • <i>Listeria monocytogenes</i> • Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) • <i>Mycobacterium bovis</i> (TB surrogate) • <i>Pseudomonas aeruginosa</i> • <i>Salmonella enterica</i> • <i>Staphylococcus aureus</i> • <i>Staphylococcus epidermis</i> (coagulase-negative; CoNS) 	<ul style="list-style-type: none"> • <i>Enterobacter aerogenes</i> • <i>Enterococcus aecalis</i> • <i>Klebsiella pneumoniae</i> • <i>Proteus mirabilis</i> • <i>Serratia marcescens</i>

*Based on third-party laboratory testing
 †Via bovine viral diarrhea virus surrogate
 ††Via feline calicivirus surrogate



Kills more than **35** HAI-causing
pathogens in **5** minutes at **2.44** meters

Including:

4-log reduction of *C. difficile* spores

Greater than 5-log reduction of over 20 pathogens, including MRSA, VRE and CRE

The UVDI-360 Room Sanitizer reduced *C. difficile* infection (CDI) rates by 25% and prevented \$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 (Leading teaching hospital in the U.S.A.)

Purpose:

To examine the impact of UVDI-360 Room Sanitizer 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 UVDI-360 Room Sanitizer 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 UVDI-360 Room Sanitizer 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 avoided 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 days

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.* 10, 2016

Update:

Subsequent to the study, Hospital of the University of Pennsylvania has deployed 9 UVDI devices.



The Effect of Ultraviolet-C Technology on Viral Infection Incidence in a Pediatric Long-term Care Facility

Principal Investigator:

Marianne Pavia MS, BS, CIC, FAPIC, Director of Infection Prevention – St. Mary's Hospital for Children (New York's largest and most experienced provider of long-term care to children with medically complex conditions. It's the only post-acute care facility for children.)

Purpose:

To examine the impact of the UVDI-360 Room Sanitizer on viral infection incidence rates in a pediatric long-term care facility.

Methods:

UV-C technology was deployed at St. Mary's during an approximately 12-month period. A single UV-C device was deployed in 5 of the 12 toddler unit rooms. The other 7 toddler rooms were cleaned using standard manual disinfection protocols only and were not treated with UV-C during the study period. Patient rooms were treated with UV-C on a rotating schedule to ensure even coverage of each room. Infection incidence data were collected in an electronic medical record, and infection rates were calculated monthly throughout the course of the study.

Results:

Ultraviolet-C (UV-C) technology implementation was associated with a 44% reduction in viral infection incidence among pediatric patients in a long-term care facility (incidence rate ratio, 0.56; 95% confidence interval, 0.37-0.84; P=.003).

Reference:

Marianne Pavia, MS, BS, CIC, FAPIC, Edwin Simpser, MD, Melissa Becker, MS, W. Keith Mainquist, PhD, Katherine A. Velez, PhD. The effect of ultraviolet-C technology on viral infection incidence in a pediatric long-term care facility. *American Journal of Infection Control* 46 (2018) 720-722.



The UVDI-360 Room Sanitizer 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 UVDI-360 Room Sanitizer 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 a single patient room. The UV device was run for a single 5-minute cycle for MRSA and a single 10-minute cycle for *C. difficile* spores.

Results:

The UVDI-360 Room Sanitizer 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)	<i>C. difficile</i> spores (10 minutes)
Surface Type	(Log ₁₀ Reduction)	
Direct Surfaces	4.10	3.35
Indirect Surfaces	2.74	1.80
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.

Update:

UNC currently has 4 successfully deployed UVDI devices.



The UVDI-360 Room Sanitizer 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 UVDI-360 Room Sanitizer 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 UVDI-360 Room Sanitizer 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.



The UVDI-360 Room Sanitizer 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 UVDI-360 Room Sanitizer on *Pseudomonas 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 UVDI-360 Room Sanitizer 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 UVDI-360 Room Sanitizer 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. *APIC [poster presentation]; 2015.*



The UVDI-360 Room Sanitizer effectively reduced the presence of multidrug-resistant 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 UVDI-360 Room Sanitizer 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 UVDI-360 Room Sanitizer 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 UVDI-360 Room Sanitizer 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. *SHEA (poster presentation); 2016.*



Testing the microbial efficacy of the UVDI-360 Room Sanitizer

Principal Investigator:

Jean Yves Maillard, MD, Professor of Pharmaceutical Microbiology, Cardiff School of Pharmacy and Pharmaceutical Sciences, Cardiff University, Cardiff, United Kingdom

Purpose:

Test the bactericidal and sporicidal efficacy of the UVDI-360 Room Sanitizer against a wide range of MDR isolates in both clean and dirty conditions.

Methods:

Ten different types of bacteria and spores were dried on a stainless steel coupon in both clean and dirty conditions. Coupons were placed in the room in horizontal and vertical orientation, direct and shadowed locations at three distances. The UV device was run for a 15 minute cycle and surviving organisms were recovered and enumerated according to standard operating procedures.

Results:

In all instances, the UVDI-360 Room Sanitizer produced $>4 \log_{10}$ reduction (in some instances $>5 \log_{10}$ reduction) in viable bacterial efficacy after 15 minutes of uninterrupted exposure. The bactericidal/sporicidal efficacy of the UVDI-360 Room Sanitizer was not affected by the clean vs dirty coupon conditions. There was no difference in efficacy when considering distance from the UVDI-360 Room Sanitizer. Placement of the coupon horizontally or vertically to the source did not affect microbicidal efficacy.

References:

Maillard, JY, Testing the Microbicidal Efficacy of the UVDI-360 Room Sanitizer, Cardiff School of Pharmacy and Pharmaceutical Sciences, Cardiff University; January 2017.



The UVDI-360 Room Sanitizer 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 UVDI-360 Room Sanitizer 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 UVDI-360 Room Sanitizer achieved a >5 log reduction for directly exposed sites and a >4 log reduction for indirectly exposed sites against MRSA and CRKP in 5-10 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	
	Setup A (one cycle)	Setup B (two cycles)	Setup A (one cycle)	Setup B (two cycles)
Device Setup				
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.



Patient and health care worker perceptions of daily use of ultraviolet-C technology as an adjunct to daily cleaning in an academic hospital: Secondary study of Ultra Violet-C Light Evaluation as an Adjunct to Removing Multi-Drug Resistant Organisms

Principal Investigator:

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

Purpose:

A cluster randomized crossover trial is in progress using several UVDI-360 devices is being conducted by Dr Lisa Maragakis clinical research group at John Hopkins School of Medicine, a premier academic school of health in Baltimore Maryland, to investigate the impact of daily ultraviolet (UV)-C light disinfection (in patient rooms and bathrooms) on the acquisition of vancomycin-resistant enterococci, *Clostridium difficile*, and other health care associated pathogens.

In conjunction with the trial, a first-of-its-kind patient and healthcare worker satisfaction survey has been conducted to assess the acceptance of UV technology for daily cleaning of the patient rooms.

Methods:

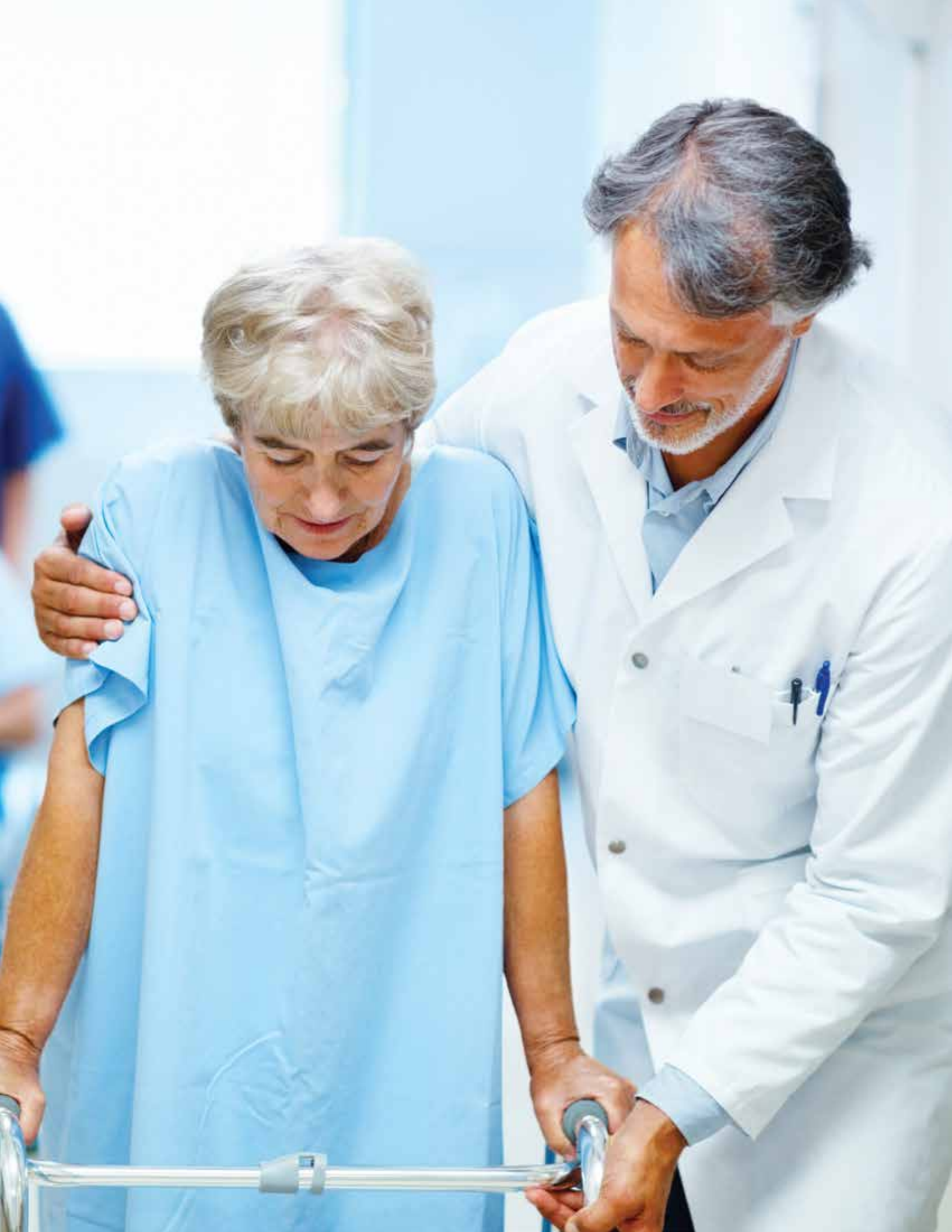
100 patients and 81 healthcare workers were randomly surveyed in hematological malignancy and bone marrow transplant units on their perceptions of daily use of the UVDI-360 devices for whole room disinfection. The surveys were conducted during August 2016, 8 months after initiation of the Ultra Violet-C Light Evaluation as an Adjunct to Removing Multi-Drug Resistant Organisms trial.

Results:

Most patients and healthcare workers perceived the UV-C light as an effort to protect them from infections. The results of this survey show that daily use of UV-C light is feasible and well accepted by patients and HCWs and may enhance the overall patient experience.

Reference:

Rock, C.; Curless, M.S.; Nowakowski, E.; Ross, T.; Carson, K.A.; Scheeler, V.; Maragakis, L.L. Patient and health care worker perceptions of daily use of ultraviolet-C technology as an adjunct to daily cleaning in an academic hospital: Secondary study of Ultra Violet-C Light Evaluation as an Adjunct to Removing Multi-Drug Resistant Organisms. *American Journal of Infection Control* 46 (2018) 348-9.





MKTFW 265 Rev F-012119 ENG



uvdi.com • sales@uvdi.com • Phone: +1.661.295.8140
26145 Technology Drive, Valencia, CA 91355



twitter.com/uvdi