

Disinfection and Sterilization: Newest Technologies

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DISCLOSURES

2022-2023

- **Consultations**
 - PDI (Professional Disposables International)
- **Honoraria**
 - PDI
- **Other**
 - Kinnos, Ideate Medical

Disinfection and Sterilization: Newest Technologies

- Overview DS
- Sterilization
 - HLD to Sterilization
 - New steril tech
 - Duodenoscopes-single use, endcaps
- HLD
 - No new FDA-cleared HLD
- LLD
 - Electrostatic sprayers-new tech
- LLD
 - New sporicide-HP-new tech
 - Colorized disinfectant-new tech
 - “No” touch room decontamination
 - Robotic
 - Continuous room decontamination technologies
 - ◆ Continuously active disinfectant-new technology
 - ◆ Far UV 220nm

Disinfection and Sterilization

EH Spaulding believed that how an object will be disinfected depended on the object's intended use.

CRITICAL - objects which enter **normally sterile tissue** or the vascular system or through which blood flows should be **sterile**.

SEMICRITICAL - objects that touch **mucous membranes** or skin that is not intact require a disinfection process (**high-level disinfection[HLD]**) that kills all microorganisms but high numbers of bacterial spores.

NONCRITICAL -objects that touch only **intact skin** require **low-level disinfection**.

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GI Endoscopes: Shift from Disinfection to Sterilization

Rutala, Weber. JAMA 2014. 312:1405-1406

EDITORIAL

Editorials represent the opinions of the authors and JAMA
and not those of the American Medical Association.

Gastrointestinal Endoscopes A Need to Shift From Disinfection to Sterilization?

William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

More than 10 million gastrointestinal endoscopic procedures are performed annually in the United States for diagnostic purposes, therapeutic interventions, or both.¹ Because gastrointestinal endoscopes contact mucosal surfaces, use of a contaminated endoscope may lead to patient-to-patient transmission of potential pathogens with a subsequent risk of infection.¹

In this issue of *JAMA*, Epstein and colleagues² report findings from their investigation of a cluster of New Delhi metallo- β -lactamase (NDM)-producing *Escherichia coli* associated with gastrointestinal endoscopy that occurred from March 2013 to July 2013 in a single hospital in northeastern Illinois. During the 5-month period, 9 pa-

First, endoscopes are semicritical devices, which contact mucous membranes or nonintact skin, and require at least high-level disinfection.^{3,4} High-level disinfection achieves complete elimination of all microorganisms, except for small numbers of bacterial spores. Because flexible gastrointestinal endoscopic instruments are heat labile, only high-level disinfection with chemical agents or low-temperature sterilization technologies are possible.³ However, no low-temperature sterilization technology is US Food and Drug Administration (FDA)-cleared for gastrointestinal endoscopes such as duodenoscopes.

Second, more health care-associated outbreaks and clusters of infection have been linked to contaminated endoscopes than to any other medical device.^{3,5} However, until now,



Related article page 1447

Infections/Outbreaks Associated with Semicritical Medical Devices

SES

Rutala, Weber. Am J Infect Control. Rutala WA, Weber DJ. Am J Infect Control. 2019 Jun;47S:A79-A89.

- HBV and HCV transmission during endoscopy and use of semicritical medical devices can occur, but it is rare (3)
- No articles related to possible transmission of HIV via medical device
- Greatest evidence of transmission associated with GI endoscopes/bronchoscopes (~130 outbreaks) likely due to microbial load and complexity.
- Several other semicritical medical devices are associated with infections related to inadequate reprocessing

Table 2

Infections and outbreaks associated with semicritical medical devices^a

Instruments	# Outbreaks/ Infections	# Outbreaks/ Infections with bloodborne pathogens
Vaginal probes	0 ^{**}	0
Nasal endoscopes	0	0
Hysteroscopes	0	0
Laryngoscopes	2 ⁴³⁻⁴⁵	0
Urologic instrumentation (eg, cystoscopes, ureteroscopes)	8 ⁴⁶⁻⁵³	0
Transrectal-ultrasound guided prostate probes	1 ⁴⁰	0
Transesophageal echocardiogram	5 ^{51,54-57}	0
Applanation tonometers	2 ^{41,42}	0
GI endoscopes/bronchoscopes	~130 ^{7,8}	3 HBV ³⁴ , HCV ^{35,36}

GI, gastrointestinal; HBV, hepatitis B virus; HCV, hepatitis C virus.

^aThese infections/outbreaks were found in the peer-review literature through PubMed and Google.

^{**}Does not include outbreaks associated with contaminated ultrasound gel used with vaginal probes or transmission via health care personnel.

Slide 7

SES3

please confirm correct cite- it was listed as "in press"

Shenoy, Erica Seiguer, M.D., Ph.D., 8/27/2021

Future Approaches to Endoscope Reprocessing to Improve Patient Safety

Rutala et al. AJIC 2019;47:A62; Chua et al. Techniq Innov Gastro Endo 2021;23:190

- Optimize current LTST (ETO, VHP, HP plus ozone) or new LTST proving SAL 10^{-6} achieved
- Disposable endoscopes (device innovations)
 - Partially-endcaps, decrease bacterial contamination after HLD
 - Fully-GI and bronchoscopes; cost, scope performance
- Steam sterilization for GI and other endoscopes
- Use of non-endoscopic methods to diagnose or treat disease
- Stop HLD for affected Storz urological endoscopes, transition to sterilization

NEW STERILIZATION TECHNOLOGY



- Hydrogen Peroxide Gas Plasma sterilizer designed specifically for the terminal sterilization of flexible endoscopes
- Incorporates a proprietary vapor diffusion technology to direct Vaporized Hydrogen Peroxide (VHP) into the internal lumen channels of an endoscope
 - Utilizes a pressure differential in each internal endoscope channel to rapidly diffuse VHP to sterilize all endoscope channels
 - Achieves the required VHP efficacy concentration in all internal endoscope channels (up to 4 meters) in < 20 secs
 - Uses lower overall concentration of H_2O_2 with shorter exposure times, thereby eliminating potential damage to the endoscope
- Incorporates a proprietary sterilization container that interfaces with the sterilizer during the sterilization process and facilitates sterile storage (6 months) of the endoscope after processing
- Incorporates a proprietary pre-sterile single-use channel connector that is pressure activated. It seals during VHP transfer and then releases to allow sterilization of the mated connector interface
- Based on initial testing, we were able to sterilize an Olympus duodenoscope (TJF-Q160F) 125 times with no damage to the device

Transition to Innovative Duodenoscope Designs-Disposable Endcaps or Fully Disposable Duodenoscopes

Duodenoscopes with disposable endcap



Sterile, single-use duodenoscope for ERCP



Effect of Disposable Elevator Cap Duodenoscopes on Microbial Contamination

Forber et al. JAMA IM 2023;183:191-200

Microbial contamination detected in 11.2% of standard duodenoscopes and 3.8% of disposable elevator cap duodenoscopes without affecting technical performance and safety of ERCP

Table 2. Primary and Secondary Study Outcomes

	Disposable elevator cap duodenoscope			Standard duodenoscope			
Outcome	No. (%)	Scope ID	Occurrences/ cases performed	No. (%)	Scope ID	Occurrences/ cases performed	P value
Microbiology outcomes							
No.	208	NA	NA	214	NA	NA	NA
Persistent microbial contamination ^a							
Yes	8 (3.8)	NA	NA	24 (11.2)	NA	NA	.004
No	200 (96.2)	NA	NA	190 (88.8)	NA	NA	

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High-Level Disinfection of “Semicritical Objects”

Exposure Time $\geq$ 8m-45m (US), 20°C

Germicide	Concentration
Glutaraldehyde	$\geq$ 2.0%
Ortho-phthalaldehyde	0.55%
Hydrogen peroxide*	7.5%
Hydrogen peroxide and peracetic acid*	1.0%/0.08%
Hydrogen peroxide and peracetic acid*	7.5%/0.23%
Hypochlorite (free chlorine)*	650-675 ppm
Accelerated hydrogen peroxide	2.0%
Peracetic acid	0.2%
Glut and isopropanol	3.4%/26%
Glut and phenol/phenate**	1.21%/1.93%

*May cause cosmetic and functional damage; **efficacy not verified

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Evaluation of an electrostatic spray disinfectant technology for rapid decontamination of portable equipment and large open areas in the era of SARS-CoV-2

[Jennifer L. Cadnum](#), BS,^a [Annette L. Jencson](#), CIC,^a [Scott H. Livingston](#), MD,^b [Daniel F. Li](#), BS,^a
[Sarah N. Redmond](#), BS,^b [Basya Pearlmuter](#), BS,^a [Brigid M. Wilson](#), PhD,^c and [Curtis J. Donskey](#), MD^{b,c,*}

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This article has been [cited by](#) other articles in PMC.

Abstract

[Go to:](#) 

In the setting of the coronavirus disease 2019 pandemic, efficient methods are needed to decontaminate shared portable devices and large open areas such as waiting rooms. We found that wheelchairs, portable equipment, and waiting room chairs were frequently contaminated with potential pathogens. After minimal manual precleaning of areas with visible soiling, application of a dilute sodium hypochlorite disinfectant using an electrostatic sprayer provided rapid and effective decontamination and eliminated the benign virus bacteriophage MS2 from inoculated surfaces.

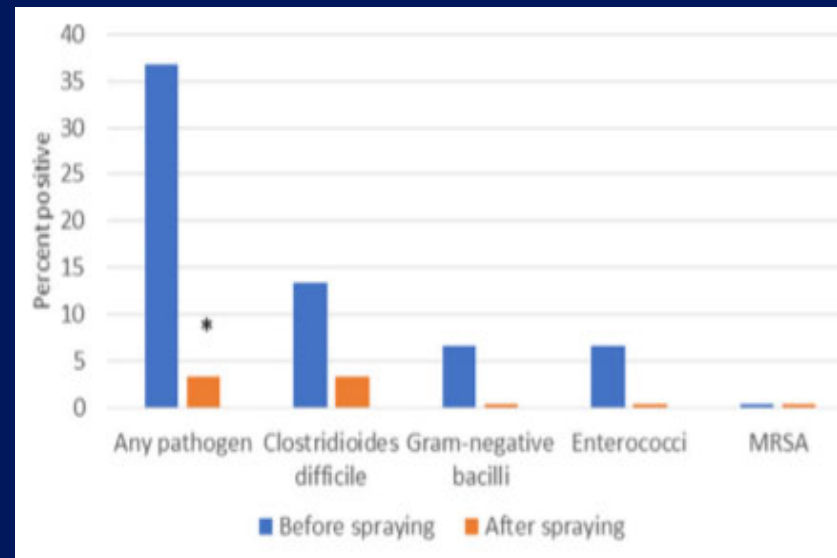
Efficacy of Disinfectant Electrostatic Spray (positive charged droplets attracted to negatively charged surfaces or microbes) in Reducing Pathogen Contamination

Cadnum et al. AJIC 2020

Picture of electrostatic sprayer
(0.25% sodium hypochlorite)



Efficacy of disinfectant spray
(waiting room chairs)



UVC vs Electrostatic Sprayer (0.25% NaOCl) for Adjunctive Room Decontamination

Carlisle MG, Rutala WA...Donskey CJ. ICHE. 2022. doi:10.1017/iche.2022.132

ES Sprayer and UVC similarly effective in reducing pathogen contamination on floors and high-tech surfaces

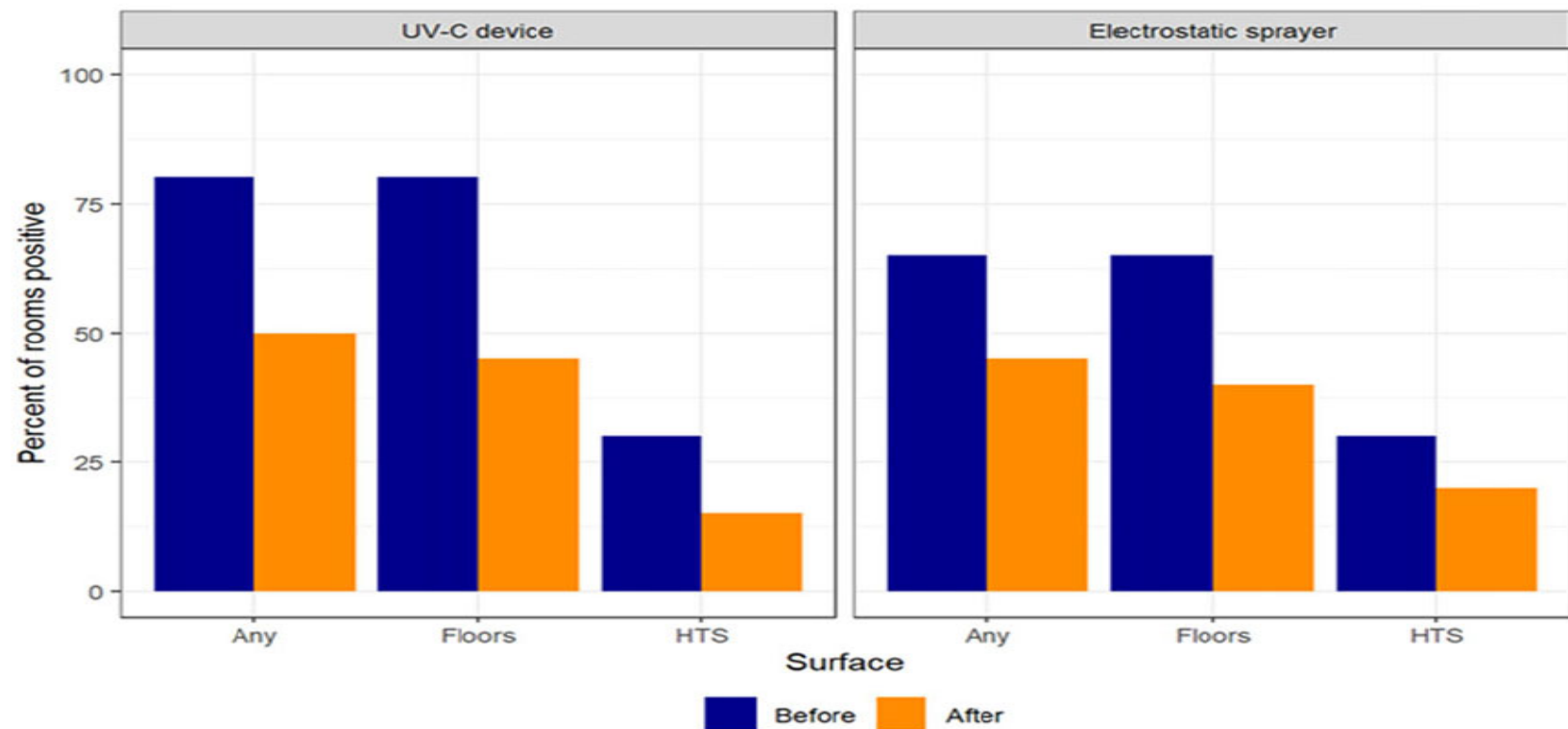


Fig. 1. Percentages of rooms with positive cultures for 1 or more healthcare-associated pathogens before versus after treatment with the ultraviolet-C (UV-C) light device or the electrostatic sprayer. Note. HTS, high-touch surface.

Summary of Electrostatic Sprayer Issues Include

- Optimal **droplet size** is between 40-70u; what is the droplet size of the proposed unit
- **Spray patterns vary tremendously** across vendors and even across products from a single vendor
- EPA demands that all surfaces being disinfected be thoroughly **wetted for the contact time** of the specific disinfectant
- Person applying the disinfectant **may need to wear full PPE** because of inhalation concerns
- Electrostatic sprayer **does not replace the initial cleaning and disinfecting** that EVS performs
- Cadnum/Donskey study used sporicidal disinfectant alone with no pre-cleaning or wiping
- Electrostatic sprayers might be most useful for items and areas that are not amenable to standard cleaning and disinfection (Cadnum/Donskey)
- Effectiveness on soft surfaces?
- **Considerations for purchase include: coverage requirements, weight of loaded device; ease of handling; effective distance; particulate size; and disinfectant safety**
- Electrostatic sprayers are promoted as a “get in” and “get out” time saving technology
- **How many seconds per square foot with a sprayer to properly treat the surface**
- Equipment can be easily misused (must prevent misuse and consider sprayer, time allotted to perform, disinfectant, surface [soft v hard], space/area to disinfect, level of cleaning prior to application, user training)

Novel Hydrogen Peroxide Sporicide

Cadnum et al. AJIC 2021

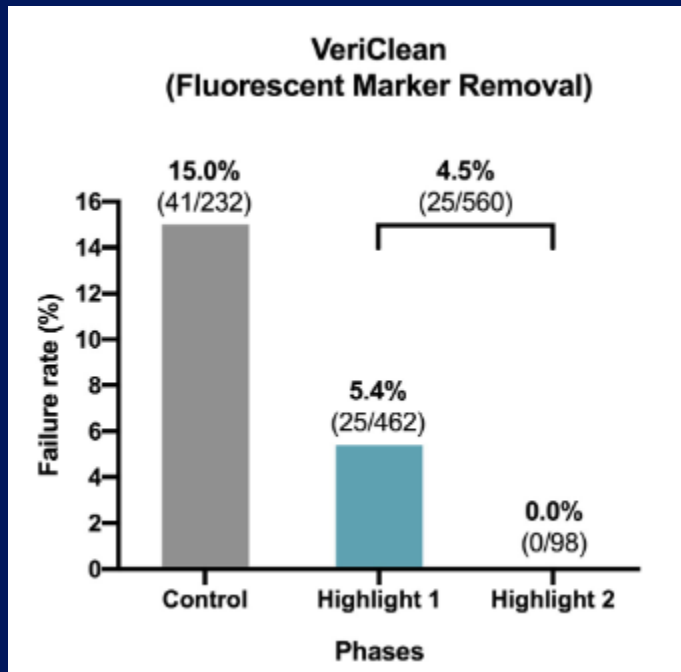
A novel 4% HP was effective against MRSA, CRE, *C. difficile* spores and *C. auris*. HP may be a useful addition to the sporicidal products available in healthcare.

Table. Mean (Standard error) log₁₀ reductions in healthcare-associated pathogens using a quantitative carrier test with a 1-minute exposure time

Disinfectant	<i>C. difficile</i>	MRSA	CRE (<i>E. coli</i>)	<i>Candida auris</i> (N=2)
Sani-HyPerCide	4.7 (0.08)	≥6.4 (0)	≥5.6 (0)	>5.1 (0)
Clorox germicidal bleach	≥6.7 (0)	≥6.4 (0)	≥5.6 (0)	≥6.1 (0)
OxyCide	≥5.0 (0)	≥5.48 (0)	≥5.6 (0)	≥5.1 (0)
Oxivir 1	2.6 (0.3)	≥6.5 (0)	6.2 (0.3)	≥5.1 (0)

Colorized Bleach Disinfectant Wipe Improves Thoroughness of Cleaning/Disinfection

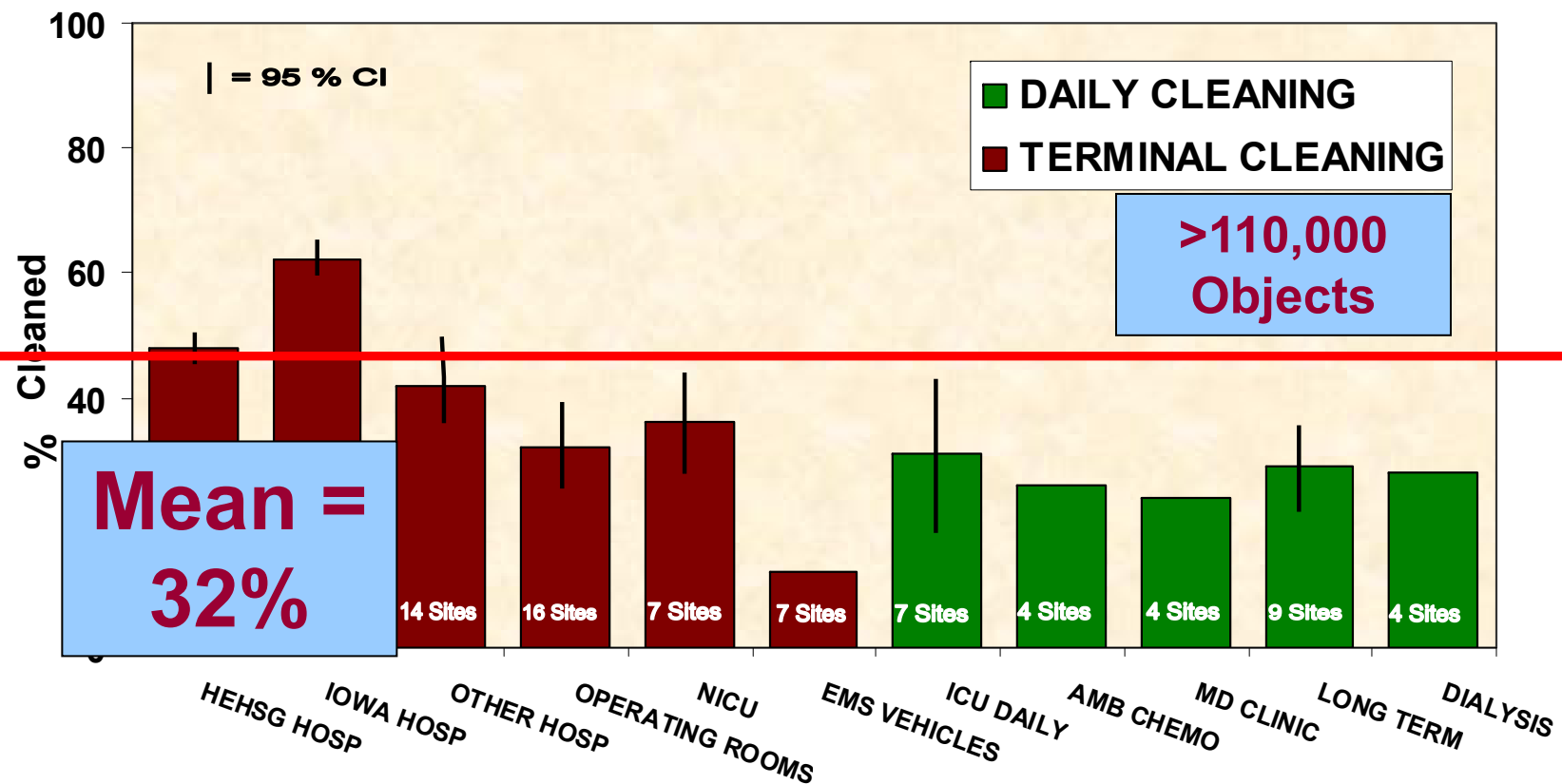
Tyan, et al. AJIC 2002;50:469-472



- Sustained high-quality CD technique is challenging without constant feedback and training of staff
- Colorized disinfectant indicates where surfaces have been wiped and fades to colorless to provide real-time visual feedback on CD
- Reduced failure rates of CD based on fluorescent marker removal (15%-4.5%)

Thoroughness of Environmental Cleaning

Carling et al. ECCMID, Milan, Italy, May 2011



Admission to Room Previously Occupied by Patient C/I with Epidemiologically Important Pathogen



- Results in the newly admitted patient having an increased risk of acquiring that pathogen by 39-353%
- For example, increased risk for *C. difficile* is 235% (11.0% vs 4.6%) (Shaughnessy et al ICHE)
- Exposure to contaminated rooms confers a 5-6 fold increase in odds of infection, hospitals must adopt proven methods for reducing environmental contamination (Cohen et al. ICHE. 2018;39:541-546)

Status Quo is an Invisible Process

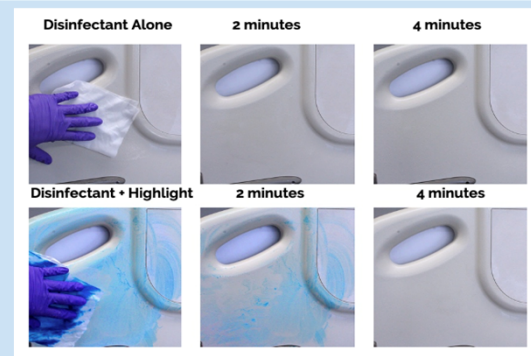
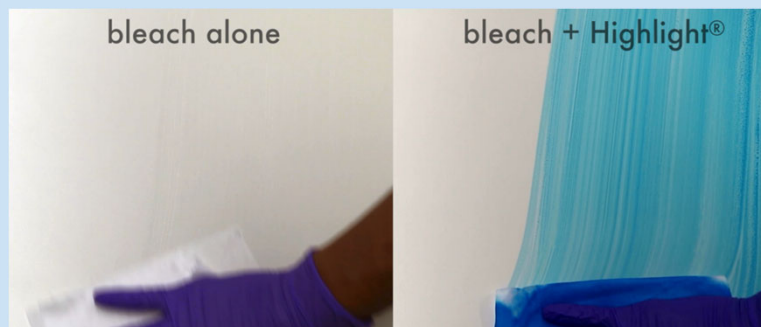
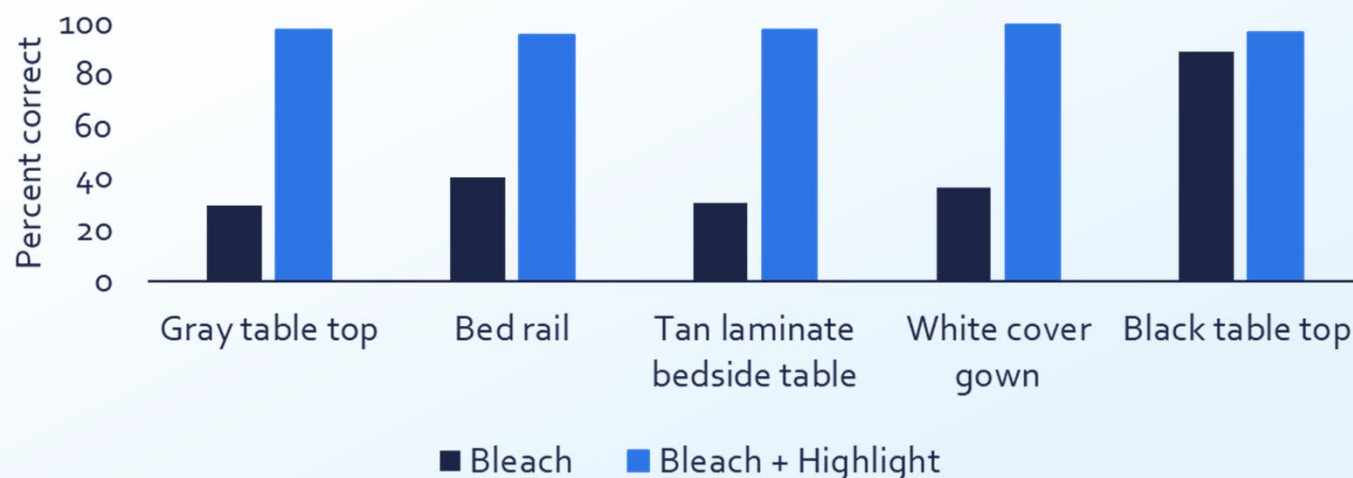
- Healthcare staff asked where disinfectant was applied 30 seconds after application
- Most staff **unable to correctly determine surface coverage** with disinfectant alone



Am J Infect Control. 2018. 46(1):119-121.

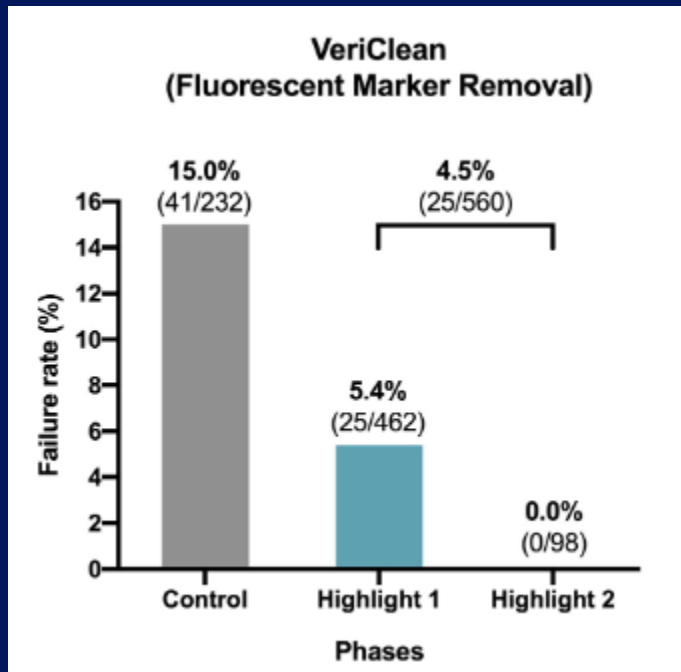
VAHealth

Disinfectant Coverage Accuracy Test



Colorized Bleach Disinfectant Wipe Improves Thoroughness of Cleaning/Disinfection

Tyan, et al. AJIC 2002;50:469-472



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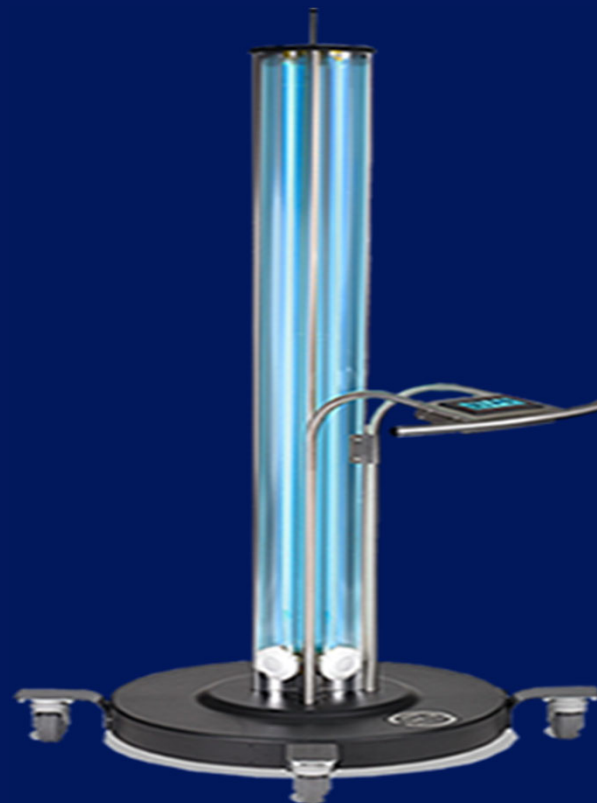
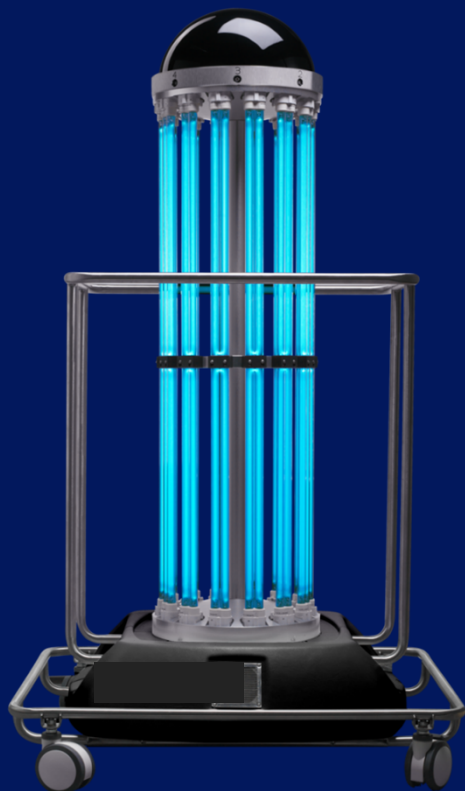
Environmental Contamination Leads to HAIs

- By contaminating hands/gloves via contact with the environment and transfer to patient or patient self inoculation
- Surfaces should be hygienically clean (not sterile)-free of pathogens in sufficient numbers to prevent human disease
- **Two environmental surface concerns**
 - **Discharge/terminal-prevent infection to new patient in room**
 - **Daily room decontamination, suboptimal CD and recontamination**

“NO TOUCH” APPROACHES TO ROOM DECONTAMINATION

(UV/VHP~20 microbicidal studies, 12 HAI reduction studies; will not discuss technology with limited data)

Weber, Kanamori, Rutala. Curr Op Infect Dis 2016;29:424-431; Weber, Rutala et al. AJIC; 2016:44: e77-e84; Anderson et al. Lancet 2017;389:805-14; Anderson et al. Lancet Infect Dis 2018;June 2018.



Enhanced Disinfection Leading to Reduction of Microbial Contamination and a Decrease in Patient Col/Infection

Anderson et al. Lancet 2017;289:805; Rutala et al. ICHE 2018;39:1118

	Standard Method		Enhanced method	
	Quat	Quat/UV	Bleach	Bleach/UV
EIP (mean CFU per room) ^a	60.8	3.4	11.7	6.3
Reduction (%)		94	81	90
Colonization/Infection (rate) ^a	2.3	1.5	1.9	2.2
Reduction (%)		35	17	4

All enhanced disinfection technologies were significantly superior to Quat alone in reducing EIPs. Comparing the best strategy with the worst strategy (i.e., Quat vs Quat/UV) revealed that a reduction of 94% in EIP (60.8 vs 3.4) led to a 35% decrease in colonization/infection (2.3% vs 1.5%). Our data demonstrated that a decrease in room contamination was associated with a decrease in patient colonization/infection. First study which quantitatively described the entire pathway whereby improved disinfection decreases microbial contamination which in-turn reduced patient colonization/infection.



ELSEVIER

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org



Major Article

Rapid disinfection of radiology treatment rooms using an autonomous ultraviolet germicidal irradiation robot

Conor McGinn BA, BAI, PhD^{a,b,*}, Robert Scott BA, BAI, MAI^a, Cornelia Ryan BA (Mod)^c,
Niamh Donnelly BEng, MSc^b, Michael F. Cullinan^{a,b}, Michael Beckett BA (Mod), PhD^c

^a School of Engineering, Trinity College Dublin, Dublin, Ireland

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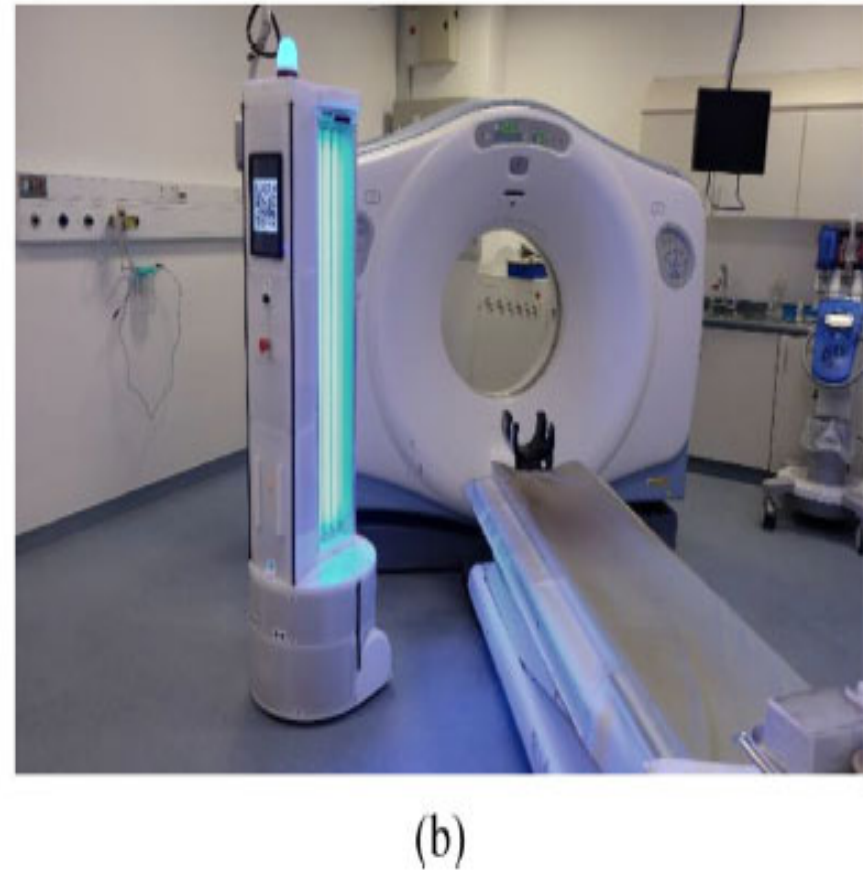
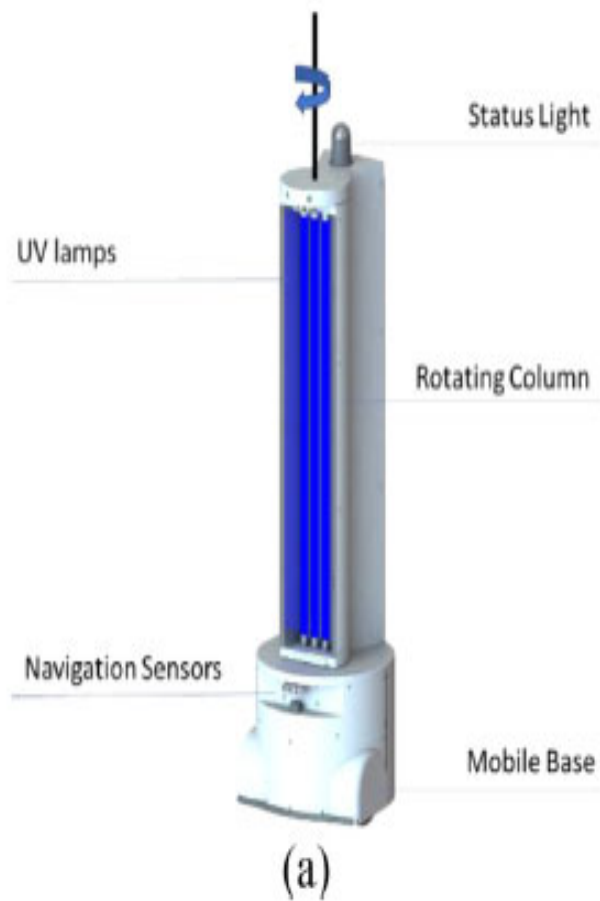
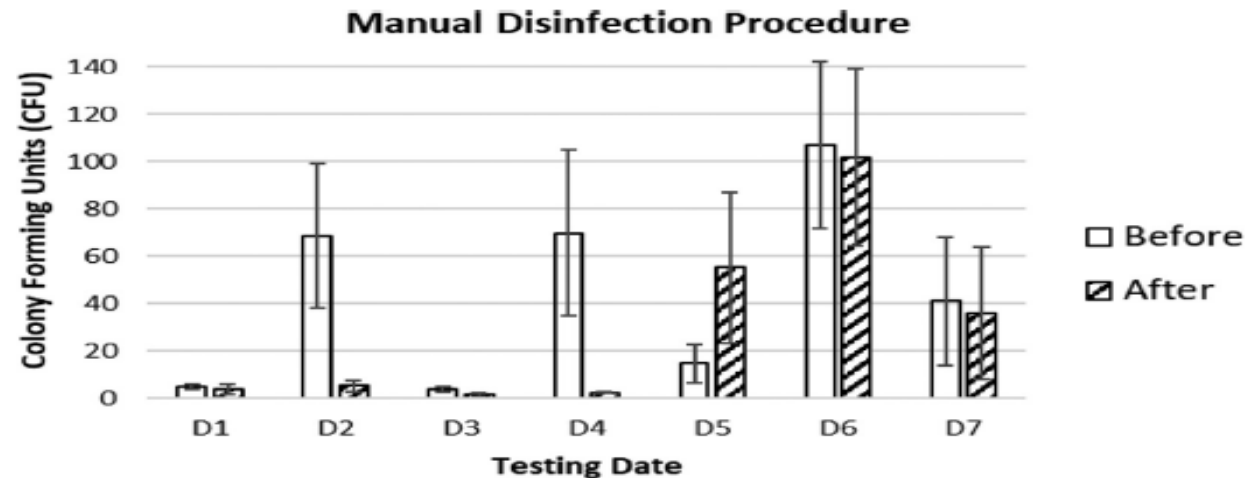
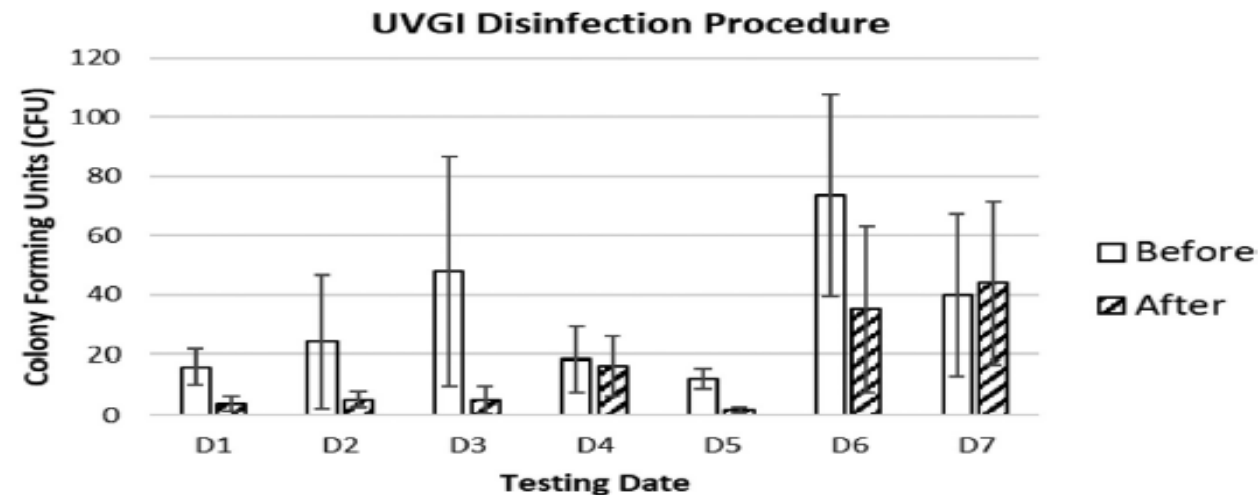


Fig. 1. The robotic UVGI platform used in this study, showing (a) labeled schematic of the robot, (b) photo of the robot in the CT scan room where the study took place.

Significant reduction in microbial load measured for both UVC and manual disinfection with UVC largest effect size. Manual disinfection time variable, 20-45m, robot 10m. Automated deployment of UVC can lead to germicidal performance comparable or better than manual CD



(a)



(b)

Environmental Contamination Leads to HAIs

- By contaminating hands/gloves via contact with the environment and transfer to patient or patient self inoculation
- Surfaces should be hygienically clean (not sterile)-free of pathogens in sufficient numbers to prevent human disease
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Continuous Room Decontamination Technologies for Disinfection of the Healthcare Environment

Weber, Rutala et al. AJIC. 2019;47:A72; Rutala et al. ICHE 2019; Weber D, Rutala W. AJIC 2013;41:S31

- Visible light disinfection through LEDs
- Dry/dilute hydrogen peroxide; hydroxyl radicals, free reactive oxygen
- Self-disinfecting surfaces (e.g., heavy metals-copper, silver)
- Far UV 222 nm
- Bipolar ionization
- Multijet cold air plasma
- Continuously active disinfectant (CAD) or persistent disinfectant that provides continuous disinfection action
 - Allows continued disinfection and may eliminate the problem of recontamination
 - Patients, staff and visitors can remain in the room

Far UV-C 222

Continuous decontamination of air and surfaces



- Filters block $>230\text{nm}$
- Safe for occupied areas
- Turn off on proximity to people to keep exposure over 8 h $<160\text{mJ}/\text{cm}^2$
- Placed on wall
- Kill microbes ($3\log_{10}$ reduction in 45m) in air and on surfaces when within 2-3m
- Long-term safety needs to be investigated

Continuous Room Decontamination Technologies for Disinfection of the Healthcare Environment

Weber, Rutala et al. AJIC. 2019;47:A72; Rutala et al. ICHE 2019; Weber D, Rutala W. AJIC 2013;41:S31

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Efficacy of a Continuously Active Disinfectant Against Healthcare Pathogens

Rutala WA et al. ICHE 2019;40:1284; Redmond et al. ICHE 2021, <https://doi.org/10.1017/ice.2021.66>

4-5 log₁₀ reduction in 5 min over 24hr for HA pathogens; ~99% reduction with *Klebsiella* and CRE *Enterobacter*. Redmond et al. found 5 log₁₀ reduction for CRE *Enterobacter*, *K. pneumoniae*, MRSA, VRE, and *C. auris*

Test Pathogen	Mean Log ₁₀ Reduction , 95% CI n=4
<i>S.aureus</i> *	4.4 (3.9, 5.0)
<i>S.aureus</i> (formica)	4.1 (3.8, 4.4)
<i>S.aureus</i> (stainless steel)	5.5 (5.2, 5.9)
VRE	≥4.5
<i>E.Coli</i>	4.8 (4.6, 5.0)
<i>Enterobacter sp.</i>	4.1 (3.5, 4.6)
<i>Candida auris</i>	≥5.0
<i>K pneumoniae</i>	1.5 (1.4, 1.6)
CRE <i>E.coli</i>	3.0 (2.6, 3.4)
CRE <i>Enterobacter</i>	2.0 (1.6, 2.4)
CRE <i>K pneumoniae</i>	2.1 (1.8, 2.4)

Comparison of CAD with Three Disinfectants Using EPA Method and *S. aureus*

Rutala WA, Gergen M, Sickbert-Bennett E, Anderson D, Weber D. ICHE 2019

Test Disinfectant	Mean Log ₁₀ Reduction
Continuously Active Disinfectant	4.4
Quat-Alcohol	0.9
Improved hydrogen peroxide	0.2
Chlorine	0.1

Efficacy of a Continuously Active Disinfectant Against SARS-CoV-2 and Human Coronavirus, 229E, Evaluated after 48 hours

Rutala WA et al. ICHE, 2021 doi:10.1017/ice.2021.481

A novel disinfectant studied using an EPA protocol (wears/re-inoculations) **demonstrated excellent continuous antiviral activity (i.e., >4-log₁₀ reduction) in 1 minute after 48 hours for SARS-CoV-2 and human coronavirus, 229E**

Table 1. Inactivation of SARS-CoV-2 and the Human Coronavirus 229E by a Continuously Active Disinfectant Following a 48-Hour Period of Wear and Abrasion Exposure

Carrier Treatment with Wears and Reinoculations	Contact Time	Mean Viral Recovery Titer per Carrier (Log ₁₀)	HCoV 229E Log ₁₀ Reduction	SARS-CoV-2 Log ₁₀ Reduction
Control (sterile NP water, n=3)	1 min	≥ 6.00 ± 0.00		NA
Continuously active disinfectant, n=3	1 min	≤ 1.50 ± 0.00	>4.50	>4.22

Note. NA, not available.

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Disinfection and Sterilization:

New Technologies

- Endoscope represent a nosocomial hazard. Urgent need to transition from HLD to sterilization. New technology (e.g., disposable endcaps, LT sterilization, disposable scopes) should reduce or eliminate infection risk.
- Implement evidence-based practices for surface disinfection (product, practice, train, improve compliance, “no touch”; emerging pathogens)
- Continuous room decontamination technology (e.g., continuously active disinfectants, $>4 \log_{10}$ reduction in 1-5 min) shows promise and could reduce the risk of infections associated with devices (portable equipment) and surfaces
- Innovation strategies (e.g., sporicides and sporicide use, “no touch”, shift from HLD to sterilization, colorized disinfectants) are likely to improve thoroughness of cleaning and disinfection, and reduce risk associated with surface and devices

THANK YOU!
www.disinfectionandsterilization.org

