Update on "No Touch" Room Disinfection Systems

Dr. Dick Zoutman, Queen's University, Kingston, Canada

A Webber Training Teleclass

Update on "no touch" room disinfection systems- uv lights, hydrogen peroxide and ozone

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Hosted by Martin Kiernan
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Conflict Of Interest Disclosure

- An inventor of AsepticSure®
- Chief Medical Officer of Medizone International Inc.
- Shareholder of Medizone International Inc
- Rapidly evolving field
  - Data can be hard to come by
  - Not possible to include ALL technologies out there

Objectives

- At the end of this presentation I hope you:
  - Will be able to describe the two types of UV lamp technologies, their characteristics and efficacy
  - Will be able to describe the basis for the hydrogen peroxide vapor and mist technologies and their efficacy
  - Will be able to describe how effective ozone based methods are as a space disinfection technology
  - Understand the synergy of combining ozone and hydrogen peroxide as a novel high level disinfection technology for health care spaces and other applications
  - Will know what to look for in *in vitro, in vivo* and clinical studies of the new technologies for room decontamination and disinfection

The Problem

- Too many healthcare infections
- Needless suffering and mortality
- Despite innovations and best efforts
- Environment a major source and reservoir
- We need to find a transformational technology!
- Just cleaning where the "dots are" is not good enough!

Characteristics of the Ideal Room Disinfection System

- ✓ Highest possible kill of all relevant organisms especially *C. difficile* spores
- ✓ Fast
- ✓ Simple to perform
- ✓ Cost effective
- ✓ Can be safely deployed
- ✓ No environmental residues
- ✓ Reduces incidence of healthcare infections
- ✓ High quality supportive scientific evidence

Quality of Evidence Concerning H_2O_2, UV, O_3

- Can be very mixed so read it critically
- Peer reviewed literature best
- *in vitro* studies
  - Using test chambers etc
  - Bacteria or other organisms on various materials
    - Steel discs/coupons
    - Fabric, carpet, plastics, various building finishes
  - Good controls with many replicates
  - Quantitative Carrier Tests (QCT) Protocol by Springthorpe and Sattar et al
  - Use of a soil load
  - Each organism brings unique challenges

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in vivo Testing

- In hospital rooms, laboratories, various field locations
  - Random assignment of rooms/spaces
  - No over lap of methods, "wash out times"
  - Detailed surface culture protocol with large number of samples
    - Highly standardized, with different methods
  - Supplemented with microbe loaded coupons in standard locations in the room
  - Always use spores of spore forming pathogens
    - eg *C. difficile, Bacillus spp, Geobacillus spp*. etc.

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Interpreting Results

- Want to see expression of data as $\log_{10}$ kill (or $\log_{10}$ survivor)
  - Kill =starting inoculum-survivors
    - Expressed as $\log_{10}$ kill
  - Use geometric means for large number of samples
  - Need dozens of replicates under any one set of conditions especially for *in vitro* testing
- Surface swabs
  - Typically expressed as cfu/cm^2
    - Typically see 10's to 100's cfu/cm^2
    - Count specific pathogens
    - Or count all heterotrophic bacteria on the surface

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Clinical Studies

- Before and after studies citing reductions in infections
  - Rates of HAI vary significantly over time
  - Be cautious in the interpretation of these results
- Prefer randomized and multicenter design ideally
  - Difficult to do and costly
  - Combined with surface cultures and loaded coupons and clinical outcomes to make a comprehensive evaluation

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A Bit of Physics About UV Light

- Ultraviolet germicidal irradiation (UVGI)
- Wavelength shorter than that of visible light
  - UVA 400 nm to 315 nm
  - UVB 315 nm to 280 nm
  - UVC 280 nm to 200 nm
- The entire UV spectrum can kill or inactivate many different microorganisms
- UVC energy provides the most germicidal
- 265 nm optimum wavelength

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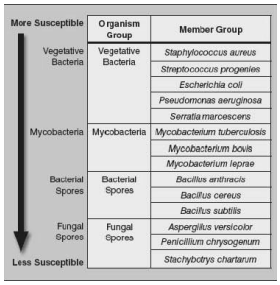
Susceptibility of Organisms to UVC



Organism Group	Member Group
Vegetative Bacteria	*Staphylococcus aureus*
	Streptococcus progenies
	Escherichia coli
	Pseudomonas aeruginosa
	Serratia marcescens
Mycobacteria	*Mycobacterium tuberculosis*
	Mycobacterium bovis
	Mycobacterium leprae
Bacterial Spores	*Bacillus anthracis*
	Bacillus cereus
	Bacillus subtilis
Fungal Spores	*Aspergillus versicolor*
	Penicillium chrysogenum
	Stachybotrys chartarum

From Martin SB et al . ASHRE Journal. August 2008

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Mercury Vapor Lamps

- In mercury vapor lamps, the mercury vapor is excited to create UV-C
- Create UV at 253.7 nm.
- This is close to the average peak DNA absorbed at 260-265 nm.
- Mercury lamps produce continuous UV light

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Xenon Vapor Lamps

- Pulsing a xenon UV lamp PX-UV
- Results in a flash of light with a broad spectrum from 200 nm to 320 nm
- Millisecond pulses
- More UV-C wavelengths are produced
- High intensity of the fast pulses may give PX-UV better disinfection efficacy?

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Tru-D Unit by Lumalier

From ECRI Health Devices May 2011

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Mercury UV System Tru-D

- An automated mobile UV-C unit
- Tru-D; by Lumalier
- Shown to produce a 3 log10 kill of vegetative bacteria
  - MRSA, VRE, and *A. baumannii*
- 2.4-log10 kill of *C. difficile* seeded onto Formica surfaces in experimentally contaminated patient room

Rutala WA, Gergen MF, Weber DJ. Room decontamination with UV radiation. *Infect Control Hosp Epidemiol* 2010;31:1025–1029.

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Tru-D

- Tru-D, Lumalier studied in reducing environmental contamination with vegetative bacteria
- Measured using aerobic colony counts and *C. difficile* inoculated onto stainless steel carrier disks
  - Boyce JM et al. *Infect Control Hosp Epidemiol* 2011;32:737–742

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Tru-D

- Room decontamination with the Tru-D UV system
- Reductions in aerobic bacteria on 5 high-touch surfaces.
- Mean *C. difficile* log10 reductions ranged from 1.8 to 2.9 when cycle times of 34.2–100.1 minutes were used.
- Surfaces in direct line of sight were significantly more likely to yield negative culture results after UV decontamination than before decontamination
  - Boyce JM et al. *Infect Control Hosp Epidemiol* 2011;32:737–742

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Tru-D

- On inoculated surfaces
- Reflected dose of 22,000 µWs/cm2 for 45 minutes
- Kill of *C. difficile* spores and MRSA by >2-3 log10 colony forming units (CFU)/cm2
- Kill of VRE by >3-4 log10 CFU/cm2

- Same level of kill of MRSA and VRE was achieved in 20 minutes at a reflected dose of 12,000 µWs/cm2,
- But killing of *C. difficile* spores was reduced significantly.
  - Nerandzic MM. *BMC Infect Dis* 2010;10:197.

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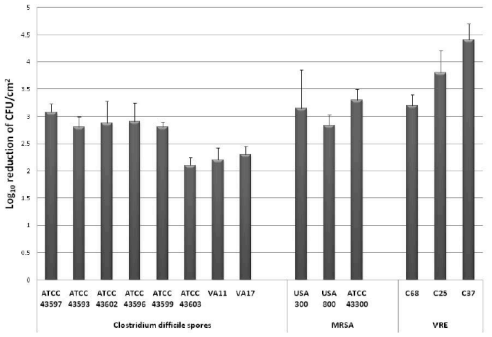
Tru-D Log10 Bacterial Kill



From Nerandzic MM et al. *BMC Infect Dis* 2010;10:197

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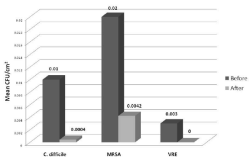
Tru-D Surface Swabs



- High touch surfaces of a bathroom
  - 60,000 cm²
  - *C. difficile* spores
    - Before: 600 spores
    - After: 24 spores
  - MRSA bacteria
    - Before: 1,200
    - After: 240
  - VRE bacteria
    - Before: 180
    - After: 0

From Nerandzic MM et al. *BMC Infect Dis* 2010;10:197

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Xenex

Pulsed xenon UV light

From: www.xenex.com

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XENEX *in vitro* Lab Study

Organism	Control (cfu)	Log10 Kill	
		480 sec (8 min)	720 sec (12 min)
MRSA	1.23×10^5	5.01	n/a
VRE	2.75×10^4	4.44	n/a
C. difficile	3.33×10^5	4.52	5.52

- ***C. difficile* was 1 meter from lamp, MRSA and VRE 2 meters from lamp.**
- ***C. difficile* 9 samples, MRSA & VRE 4 samples.**
- **"The experiment was conducted at an independent microbial testing laboratory"**
- **Modified from: Stibich M. *Abstract presented at SHEA/Fifth Decennial Meeting 2010***

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Xenex Study at MD Anderson

- January to March 2010 at MD Anderson Cancer Center, Houston Tx
- 12 rooms extensively surface cultured at discharge for VRE isolation
- Isolation clean with germicide x 30 mins.
- 3 x 4 min exposures to Xenex lamp
- Cultures taken before cleaning, after cleaning and using the Xenex lamp

Stibich et al. Infect Control Hosp Epidemiol 2011;32(3)

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XENEX

TABLE 2. Impact of Standard Cleaning and Pulsed-Xenon Ultraviolet (PX-UV) Disinfection on Room Bacterial Heterotrophic Plate Count (HPC)

Room status	No. of samples	HPC mean, CFU/cm²	*z*	*P*
Comparison 1			2.638	.0083
Before cleaning	73	33.0		
After standard terminal cleaning	91	27.4		
Comparison 2			6.430	<.0001
Before cleaning	73	33.0		
After PX-UV treatment	75	1.2		
Comparison 3			4.309	<.0001
After standard terminal cleaning	91	27.4		
After PX-UV treatment	75	1.2		

Stibich et al. Infect Control Hosp Epidemiol 2011;32(3)

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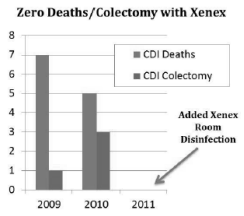
Xenex Cooley Dickinson Hospital Study



- 140 bed acute hospital, Northampton MA
- January-September 2011 Xenex used
- Uncontrolled observational study
  - 2x7 min in room
  - 1x7 min in bathroom
- Pre-cleaned with chlorine bleach (SOP throughout)
- CDI Rates
  - 2009: not stated
  - 2010: 0.95/1000 PtDay
  - 2008-2010 Q1-3: 0.98/1000 PtDay
  - 2011 (Q1-3): 0.32/1000 PtDay

Levin J et al. IDSA 2011 Abstract

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UV Light Summary

Property	UV-C Light	Xenon Pulse Light
Source	Mercury bulb	Xenon bulb
Exposure time	20-100 min	8-12 mins over 2-3 doses
Vegetative bacterial kill	3-4 log	4-5 log
C. difficile spore kill	2-3 log	4-5 log (limited data)
Risks	UV exposure	UV exposure
Toxicities/By Products	Mercury vapor	None
Controlled Clinical Trials	Yes	None yet
Costs	$124,500 capital $1,600 for lamps (9000 h)	?? Lamps x 3-4 months
Other	Line of sight effect	Scant data, line of sight effect

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H_2O_2 Technologies

- Bioquell
  - 30% H_2O_2 solution
  - H_2O_2 vapor
- Glosair (ASP)
  - 5-6% H_2O_2 solution
  - ASP (J&J) acquired Sterinis in 2009
  - H_2O_2 mist/aerosol
- VHP (Steris)
  - 35% H_2O_2 solution
  - H_2O_2 vapor

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Steris VHP 1000 ED System

From: www.steris.com

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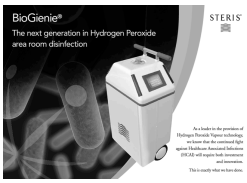
BioGienie



- Hyproxil®
  - 6% H_2O_2 with silver ions
  - Hyproxil as a liquid as 4-6 $\log_{10}$ kill of MRSA, E coli, P. aeruginosa
  - No published data on efficacy as HP vapour system
  - ≥3 hour cycle time

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BioQuell Q-10

www.bioquell.com

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Glosair (ASP)

Glosair 600

Glosair 400

www.aspjj.com

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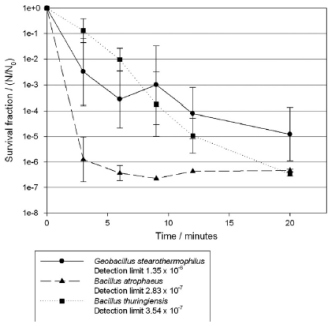
VHP (Steris) Against Aerobic Spores



Pottage T. Appl. Environ. Microbiol. 2012, 78(12):4169.

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Sealing Ducts in a Room

Jim Doyle in www.stltoday.com/business/article published August 15, 2010

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Bioquell Efficacy for CDI

- HPV decontamination of 5 high-incidence CDI wards followed by hospital-wide decontamination of rooms vacated by patients with *C. difficile* infection (CDI)
- 25.6% of cultures from surfaces before HPV decontamination yielded *C. difficile*
- compared with 0 cultures of samples obtained after HPV decontamination (*P* <.001)

Boyce et al. Infect Control Hosp Epidemiol 2008; 29:723–729

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Bioquell and CDI Cont'd

- During 9 month intervention period
- On the 5 high incidence wards rates of CDI dropped from 2.28 vs 1.28 cases per 1,000 patient-days (*P*<.047)
- Hospital wide incidence fell from 1.89 vs 0.88 cases per 1,000 patient-days (*P* <.047) during the high incidence months pre and post intervention.

Boyce et al. Infect Control Hosp Epidemiol 2008; 29:723–729

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Bioquell and MRSA

- 74% of 359 swabs taken before cleaning yielded MRSA
- After cleaning, all areas remained contaminated, with 66% of 124 swabs yielding MRSA.
- After treatment of 6 rooms with HPV (Bioquell) only 1 of 85 (1.2%) swabs showed MRSA
  - note smaller sample size after exposure however
- 5 hour cycle time
- 500 ppm H2O2 (high)
  - French GL et al. Journal of Hospital Infection (2004) 57, 31–37

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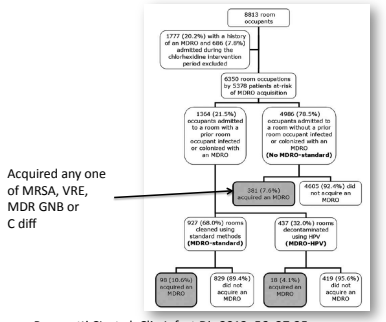
Bioquell Clinical Study



Passaretti CL et al. Clin Infect Dis 2013; 56: 27-35

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Bioquell Clinical Study

- HPV process took 1.5-3.0 hours
- The only reduction in MDRO was the reduced incidence seen for VRE acquisitions
  - 5 times less likely in the HPV treated rooms
  - adjusted IRR, 0.20
  - 95% CI, .08–.52
- No statistically significant reduction in acquisitions of MRSA, C. difficile or MDR gram negative bacilli

Passaretti CL et al. Clin Infect Dis 2013; 56: 27-35

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Bioquell Clinical Study

- 218 (21.0%) of the 1039 patient rooms sampled were contaminated with ≥1 MDRO
- HPV demonstrated reduced bacterial contamination in:
  - rooms contaminated with multiple MDROs (RR, 0.16; P < .01),
  - MDROs cultured from a room that differed from the room occupant's known MDRO (RR, 0.37; P = .01)
  - and MDROs cultured from empty rooms (RR, 0.31; P = .05)
- But not individually for MRSA, VRE, C difficile or MDR Gram Negative Bacilli containing rooms, but frequency of these was low
- Mostly VRE 35/55=64% of rooms during the HPV intervention
- One brand of paint used on the walls of one of the HPV
- units showed some incompatibility with the process

Passaretti CL et al. Clin Infect Dis 2013; 56: 27-35

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Sterinis Trial (becomes Glosair)

- Teaching hospital in Zonguldak, Turkey
- Steel discs inoculated and placed in many locations in patient rooms 53m3
- MRSA and *A. baumannii*
- Applied Sterinis HP Mist
- 2.5 hr cycles
  - Piskin N et al. Am J Infect Control. 2011 Nov;39(9): 757-62

Table 4. Comparison of the activity of the DMHP system according to presence or absence of a barrier

	Reduction in initial contamination, Mean (±SD), $\log_{10}$ cfu		
	In absence of a barrier	In presence of a barrier	*P* value
Pure MRSA suspension carrying disks	4.70 ± 0.0	3.52 ± 1.82	.059
Pure Acinetobacter suspension carrying disks	4.67 ± 0.0	3.79 ± 1.35	.059
Serum containing MRSA suspension carrying disks	4.45 ± 0.63	1.49 ± 1.86	.003
Serum containing Acinetobacter suspension carrying disks	4.44 ± 0.0	2.92 ± 1.75	.01

SD, standard deviation.

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Tru-D vs Bioquell "Head to Head"

- 500 bed hospital
  - 15 patient rooms at random from 8 wards
- 5 high touch surfaces cultured for ACC
- Steel discs loaded with 10^6 *C. difficile* spores placed in 5 areas close to high touch surfaces
- BI's with 10^4 and 10^6 *G. stearothermophilus*
- Results
- HPV (Bioquell)
  - 93% ACC negative
  - 6 log10 *C. difficile* kill
  - 99-100% BI's killed
  - 2.5-3 hr cycles
- UV-C (TRU-D)
  - 52% ACC negative
  - <2 log10 *C. difficile* kill
  - 0-22% % BI's killed
  - 0.6-1.7 hr cycles

Havell et al. Infect Control Hosp Epidemiol May 2012;33(5):507-512

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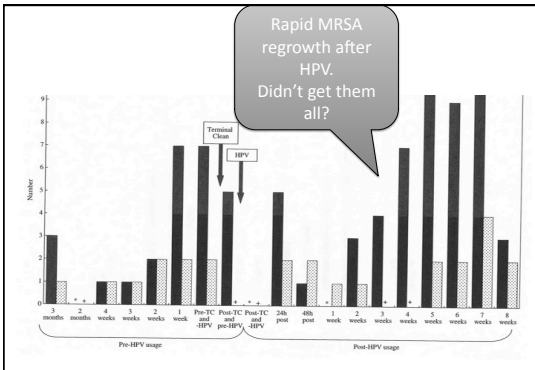

Hardy K et al. J Hosp Infect 2007;66:360-368

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Comparison of H_2O_2 Systems

Parameter	Glosair (ASP)	VHP (Steris)	BioGienie	BioQuell
H2O2 %	5-6%	35%	6%	35%
Dispersion	Dry Mist/ Aerosol	Vapor	Dry Mist/ Aerosol	Vapor
Final Conc H2O2	50-80 ppm	~500 ppm		~500 ppm
Cycle Time	~2-3 hr	2-8 hrs	≥3 hr	≥2 hr, up to 5 hr
C. difficile log10 kill	2-3 log	No data for *C. difficile*. 5-6 log for Bacillus	No data for *C. difficile*. 5-6 log for Bacillus	*6 log for C. difficile*. 6 log for Bacillus
Controlled Clinical Trials	Some small	?	?	Yes
Cost	$65,000? $50 per room	?	?	$44,000 capital Cost per room?

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Pure O_3 as Antibacterial

Table 1. Bacterial susceptibility to ozone gas

	ATCC #	Log 10 reduction in cfu's Wet sample	Dry sample
Gram-positive bacteria			
Bacillus cereus	11778	> 3.1	> 3.1
Bacillus spizizenii	6633	> 3.2	> 3.2
Clostridium difficile	43593	> 4.0	> 4.0
MRSA	Clinical isolates	> 3.0	> 3.0
Methicillin-sensitive	Clinical isolates	> 2.5	> 2.5
Staphylococcus aureus			
Propionibacterium acnes	11827	≥ 4	≥ 4
Streptococcus pyogenes	12384	≥ 4	≥ 4
Gram-negative bacteria			
Acinetobacter baumannii	19606	≥ 4	≥ 4
Enterococcus faecalis	51299	> 3	> 3
Escherichia coli	25922	> 3.1	> 3.1
Haemophilus influenzae	19418	≥ 4	≥ 4
Klebsiella pneumoniae	10031	≥ 4	≥ 4
Legionella pneumophila	33152	≥ 4	≥ 4
Pseudomonas aeruginosa	27853	≥ 4	≥ 4
Acid-fast bacteria			
Mycobacterium smegmatis	14468	> 2.7	> 2.7

Sharma & Hudson. Am J Infect Control 2008;36:559-63.

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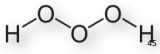
Ozone & Hydrogen Peroxide in Biological Systems

- Antibodies have been shown to have catalytic activity that produces **BOTH H_2O_2 AND O_3**
  - BUT the amount produced of each is so low that neither could kill any microorganism
- Trioxidane (H_2O_3) has been detected as the extremely reactive intermediary molecule of this reaction
- Trioxidane is lethal to organisms in minute amounts!

Nyffeler, Wentworth & Lerner et al. Angewandte Chemie 2004, from Scripps Research Institute and Oxford University



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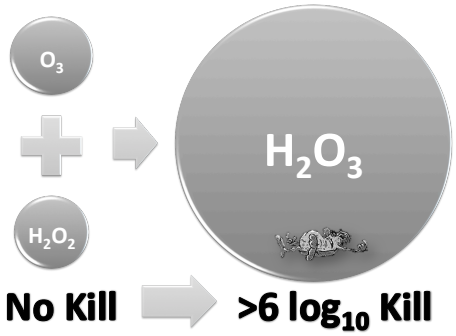
The Science of AsepticSure's Synergy



No Kill → **>6 log_{10} Kill**

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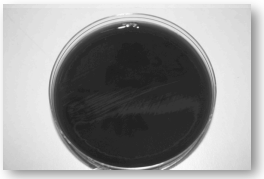
AsepticSure® Microbiology Techniques

1 cm stainless steel disks as the bacteria & spore carriers



The quantitative carrier test (QCT-2) standard used or modified

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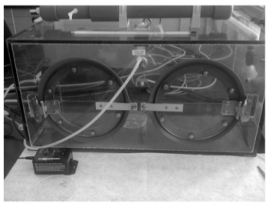
In vitro Testing System for AsepticSure

- Polycarbonate chamber
- Fully instrumented to measure conditions
- Computer controlled and recorded results
- Used MRSA as test organism initially to define optimal conditions



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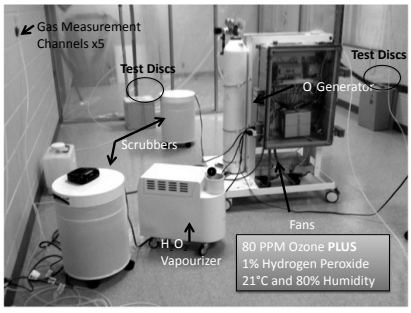
In vivo Testing System AsepticSure



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AsepticSure Results

Organism	Ozone (PPM)	H2O2 (%)	Exposure (min)	Microbial Kill (Log_{10})
MRSA	80	1	15	6.3
VRE	80	1	15	6.2
E. coli	80	1	15	6.5
S. typhimurium	80	1	15	6.1
P. aeruginosa	80	1	15	6.0
L. monocytogenes	80	1	15	6.3
C. difficile spores	80	1	15-30	6.1
B. subtilis spores	80	1	30	6.1
Mycobacterium terrae	80	1	30	6.2

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Testing Materials

- AsepticSure system also effective on:
  - Stainless steel
  - Plastic from toilet seats
  - Laminate
  - Carpeting
  - Cotton or synthetic cloth
  - With and without organic soil load

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Summary of AsepticSure

- **First ever** use of **ozone and hydrogen** peroxide for high level disinfection of clinical spaces and surfaces
- Capitalizes upon **HUGE synergy** between ozone and hydrogen peroxide producing **trioxidane**
- Very **fast**
- **Broad** spectrum
- Consistent **high level** disinfection (6 log_{10}=sterilization)
- **Penetrating** gas goes everywhere
- **Low doses** of ozone and hydrogen peroxide reduces costs, risks and damage to infrastructure
- Technology proven to be very **robust** and **reliable**
- Capital Cost~ $95,000 + ~$10-20 per room

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Am J Inf Control 2011;39:873-9

Effectiveness of a novel ozone-based system for the rapid high-level disinfection of health care spaces and surfaces

Dick Zoutman, MD, FRCPC,[a] Michael Shannon, MD, MSc,[b,c] and Arkady Mandel, MD, PhD, DSc[c]
Kingston and Ottawa, Ontario, Canada

Background: Vapor-based fumigant systems for disinfection of health care surfaces and spaces is an evolving technology. A new system (AsepticSure) uses an ozone-based process to create a highly reactive oxidative vapor with broad and high-level antimicrobial properties.
Methods: Ozone gas at 50-500 ppm was combined with 3% hydrogen peroxide vapor in a test chamber and upscaled in rooms measuring 82 m^3 and 90 m^3 in area. Test organisms included methicillin-resistant *Staphylococcus aureus*, vancomycin-resistant enterococcus, *Escherichia coli*, *Pseudomonas aeruginosa*, *Clostridium difficile*, and *Bacillus subtilis* spores dried onto steel discs or cotton gauze pads.
Results: The combination of 80-ppm ozone with 1% hydrogen peroxide vapor achieved a very high level of disinfection, with a ≥6 log_{10} reduction in the bacteria and spores tested on steel discs and MRSA tested on cotton gauze during a 30- to 90-minute exposure. The entire system was scalable such that it achieved the same high level of disinfection in both the 81-m^3 and 90-m^3 rooms in 60-90 minutes.
Conclusion: The ozone hydrogen peroxide vapor system provides a very high level of disinfection of steel and gauze surfaces against health care-associated bacterial pathogens. The system is an advanced oxidative process providing a rapid and effective means of disinfecting health care surfaces and spaces.
Key Words: Ozonation; hydrogen peroxide; fumigation.

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AsepticSure

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Update on "No Touch" Room Disinfection Systems

Dr. Dick Zoutman, Queen's University, Kingston, Canada

A Webber Training Teleclass

Characteristics of the Ideal Room Disinfection System

- ✓ Highest possible kill of all relevant organisms especially *C. difficile* spores
- ✓ Fast
- ✓ Simple to perform
- ✓ Cost effective
- ✓ Can be safely deployed
- ✓ No environmental residues
- ✓ Reduces incidence of healthcare infections
- ✓ High quality supportive scientific evidence

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The Final Result

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Coming Soon

21 March TB INFECTION CONTROL IN HIGH HIV BURDENED COUNTRIES
Speaker: Virinia Lipke, Centers for Disease Control, Atlanta

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Speaker: Dr. Shams B. Syed, World Health Organisation, Geneva

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Speaker: Jane Aston, NHS

17 April *(WHO Teleclass)* CLOSTRIDIUM DIFFICILE IN THE COMMUNITY: FOOD FOR THOUGHT
Speaker: Prof. Tomas Riley, University of Western Australia

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