WHITE PAPER

EFFECTS OF ULTRA-D FOGGER FOR AIR, ROOM AND DEEP CLEANING DISINFECTION PURPOSES

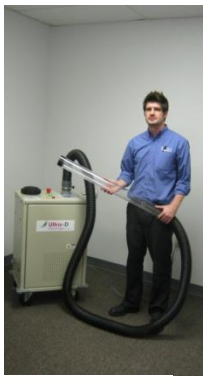
By TOMI Environmental Solutions, Inc.

Currently, 271 people a day, the equivalent of one airline crash, will die from healthcare-associated infections (HAI's) such as Methicillin-resistant Staphylococcus aureus (MRSA) infections. HAI's kill more people than AIDS, breast cancer and auto accidents combined (www.cdc.gov/ncidod/dhqp/healthDis.html). In many cases, these HAIs are a result of naturally-occurring bacteria on ones skin that enter the bloodstream of another person during a medical procedure and become a life-threatening infection (www.medicalnewstoday.com/articles/87452.php). The fourth-leading cause of death in the U.S. is often a result of bacteria on patients' skin stemming from failure to disinfect the surfaces, medical equipment and personnel in hospital operating rooms, ICU's and patient rooms effectively.(Center for Disease Control - http://www.cdc.gov/ncidod/dhqp/healthDis.html)

The Ultra-D Room Fogger from TOMI Environmental Solutions, Inc. ($TOMI_{ES}$) offers a product with "game changing" technology that will eliminate the chances of transference infections. The Ultra-D Room Fogger has received prominent attention in the Healthcare Industry and clinical field trials have proven this piece of equipment is a revolutionary step in disinfecting operating rooms, ICU's and patient rooms while saving labor costs.

The Ultra-D Fogger is the most practical room-disinfecting technique available today with a 15-minute dry-misting process that Ultra-Disinfects (killing >99.999% or 6 log of all harmful bacteria, viruses, and spores) all room surfaces and equipment while doing no damage to any surface, including circuit boards, touch screens and wiring. Conventional labor-intensive methods of room cleaning with chemical disinfectants, rags, wipes and cotton swabs have proven to be very ineffective while damaging equipment and takes costly manpower and time.

With the patent pending Magnetic Resolution Activation, the Ultra-D Fogger generates activated hydroxyls that kill surface microorganisms, killing them on contact and then transforming into H_2O and O_2 and evaporating. The Ultra-D leaves absolutely no residue on the disinfected surface and the room or equipment is quickly disinfected and available again for service within minutes.



Application:

1.) Hospitals/Clinics- For smaller sized rooms, approximately 18 ft x 18 ft. Anywhere Ultra-Disinfection of equipment, furniture or tools is needed. Ideal for isolation or any room after patient is discharged; any/all items in the room can be Ultra-Disinfected "in-place." Equipment that is difficult to take out of service for extended periods of time like mobile X-ray units, EKG units, Neonatal equipment, etc., are quickly disinfected and available again for service within minutes.

2.) Sports Facilities- Athletic equipment: shoulder pads, knee braces, helmets; physical therapy rooms; training rooms.

3.) Institutional Use- Nursing Homes, Schools, Mental Health Facilities, Correctional Facilities.

4.) Military/Government- Use in barracks, medical rooms, facilities, offices.

Product Features:

• Fast; Ultra-Disinfects most rooms in less than 15 minutes with occupancy in 45 minutes
• Effective; kills all known microorganisms including: **MRSA, VRE, Acinetobacter and C-Diff spores** to >6 log
• As easy to use as a microwave oven
• Safe on all materials, including sensitive electronics equipment – Non-allergenic, Non-corrosive
• Silent – Doesn't disturb other patient rooms
• Fluid cartridges store safely; easily replaced, long shelf-life
• No special electrical requirements - plugs into standard 110 outlet
• Low maintenance
• Very affordable cost per cycle

Critical Cleaning and Infectious Disease Control

Why Proper Surface Cleaning Methods Make a Difference

Disease causing organisms include bacteria, viruses and fungi. They are microscopic and thus may be invisible to the naked eye. Surfaces include walls, floors, ceilings, counter tops, furniture, fixtures and appliances. In areas where concerns about possible pathogen contamination are suspected or known then critical cleaning techniques are required. Traditional cleaning methods are usually unsuccessful in removing surface pathogens.

These are just some of the locations where bacteria and fungus may be found.

Door knobs, light switches, entry thresholds, counter tops, television remote control units, telephones, bed rails, bathroom fixtures, fans, window blinds, faucets, carpeting, air conditioning registers and returns, lamp shades, computer key boards, medical instruments, food trays and so on. Bacterial, fungal and viral cells and spores can travel great distances and will often attach to common dust.

Critical Cleaning Methods

In order to reduce the incidents of infectious organisms in health care facilities a different method of cleaning is required. All surfaces must be cleaned prior to being disinfected. Think of this analogy, if you decide to wax your car don't you wash it first? You do this to remove surface grime, dirt, bird droppings, road debris etc. You would never just wax over a dirty car. This procedure of clean first is essential. Remember that the cleaning step is utilized to remove surface particles and some pathogens.

Critical Cleaning

Cleaning alone is not sufficient but prepares the surface for disinfection. When cleaning a surface the individual shall work from the top down, side to side and from clean to less clean. Circular cleaning strokes will never be used as they only smear surface particles and pathogens and leave the surface no cleaner then when you began.

Surface Cleaning Methods

An approved cleaning agent shall be applied to the surface either by spray, mist or direct application. The individual shall wear powder free gloves and use lint free wipes. The wipe shall be folded in quarters with the folded edge facing the surface and the open edge towards the gloved hand. The surface will be wiped from top to bottom or side to side and only in a single direction. The wipe will be turned and opened to expose clean areas and moderate pressure will be applied.

Once surface cleaning is done to an area, the room is prepped and ready for the Ultra-D Process.

Lee Memorial Health System Field Trial Biological Results:

Overview

The Lee Memorial Hospital staff conducted surface sampling tests for resident microorganism utilizing Rodac touch plates (sterile petri dishes overfilled with a sticky growth medium) in February, 2009 and repeated the tests in April, 2009.

The rooms tested were typical hospital patient rooms ranging in size from 150 to 280 square feet. Various locations in the room were sampled before any cleaning, after the hospital cleaning process and after the Ultra-D process. The sampling technique involved removing the cover of the Rodac plate and gently touching the surface with the sticky plate medium then placing the plates in incubators for 48hrs. CFU's (colony forming units) of microorganisms were then identified and counted and those results are summarized in this document. This testing process is considered here as an Industry Standard test method for biological surface sampling.

Cleaning Method

The test results labeled Post-Clean were taken after the hospital completed their typical cleaning process. That process involves the hospital housekeeping employee first removing gross contaminates, trash, soiled linen and any medical equipment (ventilators, IV pumps etc.) that were used by the discharged patient. The housekeeper then utilized a spray bottle containing a hospital grade germicide and a cloth rag to wipe down target surfaces in the room.

Typically, a hospital room is completed in 20 minutes and around 5-8 minutes is taken to disinfect surfaces. This cleaning process was followed in the February, 2009 testing. The April, 2009 cleaning process time was 40 to 60 minutes and thus involved significantly more cleaning effort on the surface disinfection cleaning.

Virex, from Johnson Diversey, was used exclusively by the Hospital for cleaning and disinfection in both tests.

Ultra-D Process

After the cleaning process, the Ultra-D Room Fogger was used to Ultra-Disinfect the entire room and all of its contents: beds, chairs, walls, laptop computers, ventilators, IV pumps, Pulse OX monitors, and any other sensitive electronics equipment. The Room Fogger treatment cycles ranged from 8 to 15 minutes.

Findings

The data clearly shows that the hospital's current cleaning method utilizing a hospital grade germicide and a rag only reduced the microorganism count on the surfaces in the tested patient rooms by around 50%. Therefore, current hospital room cleaning methods leave high colony counts of potentially dangerous bacteria, viruses and spores to continue to reproduce.

Further, cleaning was done with only a germicide (Virex) and not a sporicide; therefore, no spores present would be likely killed.

	April, 2009 Tests	Kill %	February, 2009 Tests	Kill %
Pre Clean:	1,050 CFU's		861 CFU's	
Post Clean:	484 CFU's	53.9%	401 CFU's	53.4%
Post Ultra D:	5 CFU's	99.5%	5 CFU's	99.4%

The data clearly showed that the Ultra-D process was extremely effective at reducing resident microorganism on all surfaces tested to near zero levels. Generally, hospital cleaning kills or removes 50% of the microorganisms in a room and a single treatment from the Ultra-D Room Fogger killed almost all of the remaining microorganisms.

It is worthwhile to note that the expanded time and effort to disinfect similar hospital rooms was not effective. This suggests that current methods of hospital room cleaning and disinfection are not likely to improve killing efficacy with more time and effort.

THE PROBLEM

Today, studies show that hospitals are leaving between 30% and 60% of surface microorganisms on surfaces after they clean with "Hospital Grade" germicides….even after spending over 60 minutes "cleaning". Traditional "Spray Bottle and Rag" delivery method continues to be the method of choice and these traditional methods are logically not very efficient.

Testing confirms the ineffectiveness of traditional method -The "Lysol Effect." Virtually no surface testing is done in a hospital so the assumption is that if the label says it kills it, and I sprayed it in the room, it must be clean?

The problem is…..Microorganisms survive outside of the body for lengthy periods of time:

- **MRSA (Staph)- 9 months+**
- **Hepatitis C- 16 hrs to 4 days**
- **Clostridium Difficile (C-Diff)- 70 days+**
- **Acinetobacter baumannii- 20 days+**

The Ultra-D would provide Ultra (>6 log) germicidal and sporicidal disinfection services as needed with total surface contact to the following areas:

- **Surgical suites (terminal cleans)**
- **Cath Lab**
- **Emergency Room**
- **Physical Therapy**
- **ICU**
- **Neonatal ICU**
- **Any high risk discharge patient room**
- **Ambulances**
- **Medical equipment- Med. Pumps, ventilators, transport equipment, hand held monitors, BP cuffs.**

The Ultra-D was Field Tested in Baltimore, Maryland at Sinai Hospital to measure the disinfection rate of pathogens in a patient room and operating room.

FIELD TESTING ABSTRACT

OPERATING SUITE TEST

Sinai Hospital, Baltimore -September 2009

1 Overview

This preliminary study was performed on September 22, 2009 to evaluate the capability of the Ultra D™ Room Disinfection System to kill high levels of bioburden in a hospital patient room. Ultra D™ is manufactured by $TOMI_{ES}$. The test was conducted at Sinai Hospital, located in Baltimore, MD.

The Ultra D™ Room Disinfection System is a highly specialized bioburden reduction process for healthcare industries. Ultra D™ is a patented process that activates a proprietary mist that rapidly disinfects air and surfaces, while using only a small amount of Ultra D™ Disinfection Solution. Ultra D™ achieves inactivation of a wide range of microbiological contaminants, including vegetative bacteria, bacterial endospores, and fungi.

The specific goal of this study was to evaluate the effectiveness of the Ultra D™ Room Disinfection System in an actual hospital environment, and to determine product design and implementation requirements for the use of this technology in the hospital environment specifically in operating, regular patient rooms and ICU rooms.

On September 22, 2009 testing was conducted in an Operating Room at Sinai Hospital. Challenges were introduced to the environment via *geobacillus stearothermophilus* stainless steel coupons inoculated with *geobacillus stearothermophilus* spores and Klebsiella pneumoniae. These test articles were subsequently incubated to evaluate the effectiveness of the Ultra D™ Room Disinfection System.

The purpose of using this testing configuration was to provide:

a. The “best representation” of the hard/non porous surface types present in a hospital environment;

b. The “best representation” of the hardest to kill microorganism typically found in any environment; and,

c. The best indicator of killing efficacy against all of the more vulnerable microorganisms found in the hospital environment – including MRSA, C-Diff, VRE and *Acinetobacter baumannii*.

2 Testing Methodology

2.1 Sample Preparation

The first set of samples were inoculated spore coupon samples were provided by Raven Laboratory’s in the form of *geobacillus stearothermophilus* 10^6 stainless steel spore coupons. The second set of samples were provided by AssuredBio Laboratory in the form of Teflon discs inoculated with Klebsiella pneumoniae. Prior to testing, each coupon was aseptically removed from its pouch and placed in a sterile Petri dish. After the test, the coupons were removed and placed into Raven Laboratory’s Tryptic Soy Broth tubes (for the spores) with volumes of 5.5

ml and AssuredBio bacterial growth tubes. Dishes were placed on the OR table during the treatment process.

These coupon filled tubes were then labeled and incubated for 7 days. The spore tubes were incubated at 55c and the bacteria tubes were incubated at 37c. Tubes were then observed as noted in findings for color change in the broth which indicates any growth and therefore identifying coupons that had spores or bacteria that survived the Ultra D treatment.

2.2 Sample Locations

2.2.1 For this test, a sterile Petri dish containing 1ea 106 spores inoculated and 1ea bacteria inoculated coupon was placed in each of the following locations, as called for in the Test Plan. Room size in cubic feet is listed for each room.

OR 18 – Operating Suite (4,400 $ft^{3)}$

Sample locations:

- Positive Control
- On main OR table

2.3 Ultra D™ Disinfection Parameters

The treatment cycle consisted of a specific run time based on the size of the room. Air scrubbing took place immediately following fogging cycle to remove residual H_2O_2 vapors from the air in the room down to a level below 5 ppm per OSHA guidelines. Samples were removed at completion of the cycle (after air scrubbing).

2.4 Sample Analysis

Spore viability on the spore coupons was determined by aseptically inoculating Tryptic Soy broth with the individual coupons from the field tests and incubating at 55 to 60^{o}C. Bacteria viability on the coupons was determined by aseptically inoculating bacteria growth tubes from the field test and incubating at 37c for 7 days. Both sets of coupons were allowed to incubate for 7 days and the tubes were observed for any evidence of growth.

3 Results

3.1 Table 1, Microbiological Test Results (below) provides a summary of the test results including the sample ID number and any growth observed for each sample. The results for the spore coupons provide ultra disinfection testing results and are expressed in terms of “Growth” (growth occurred) or “No Growth” (no growth occurred).

Table 1 - Microbiological Test Results

Description	Sample Number	Results	Distance in Ft.
OR 18			
4,400 cubic feet			
Klebsiella pneumonia			
Positive Control	**SH922-2**	Growth	
OR Table	**SH-KP 3**	No Growth	10
geobacillus stearothermophilus			
Positive Control	**SH PC-1**	Growth	
OR Table	**SH GS-3**	No Growth	10

Additional Findings

In addition to evaluating the capability of the Ultra D™ system to inactivate the microbiological challenge, measurements were taken to determine the extent to which chemical vapors migrate into adjacent areas. The purpose of these measurements is to ensure that an area can be treated while an adjacent area is in use, without exceeding OSHA exposure limits for personnel in these adjacent areas. The short term exposure limit is <1ppm.

4 Conclusions

The efficacy of the Ultra-D process was shown to be extremely effective against one of the hardest spore challenges available, *geobacillus stearothermophilus* and an aggressive bio-film forming bacteria in Klebsiella pneumoniae. Since C-Diff is documented to be easier to kill than the chosen spore challenge, a conclusion can be made that Ultra-D would be very effective at killing C-Diff spores in the target environments without doing damage to any of the surfaces or equipment present. Furthermore, the Klebsiella pneumoniae is an industry standard surrogate for MRSA and other forms of Staph.

Again, the stainless-steel and Teflon coupons (with 10^6 of *geobacillus stearothermophilus* and Klebsiella pneumoniae*)* is the best representative of the types of surfaces that must be disinfected in the hospital environment as the vast majority of surfaces are hard and non-porous. This series of tests demonstrated that the process can indeed be executed within the time requirements for use in the OR, and extend to patient rooms and ICU suites

Measurements taken during the trial demonstrated that there are no significant risks associated with the migration of the H_2O_2 vapor into adjacent areas.