AN ADVANCED VAPOR TECHNOLOGIES (AVT) WHITE PAPER

Sustainable Healthcare Cleaning and Disinfection

in an Era of Widespread Infectious Diseases

ADVANCED VAPOR TECHNOLOGIES

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1. INTRODUCTION:

In a time of rising global contagious illness coupled with a need for sustainable healthcare operations while decreasing reliance on user-variable, inconsistent and toxic methods, this paper explores problems, solutions and supporting research with the goal of achieving greener, effective healthcare cleaning and disinfection to prevent infectious illness.

2. TRENDS IN CONTAGIOUS ILLNESS

According to a formerly "Classified" US Federal document - *Global Infectious Disease Threat and Its Implications for the United States* – **http://www.fas.org/irp/threat/nie99-17d.htm**

- The dramatic increase in drug-resistant microbes, combined with the lag in development of new antibiotics, the rise of megacities with severe health care deficiencies, environmental degradation, and the growing ease and frequency of cross-border movements of people and produce, have greatly facilitated the spread of infectious diseases that pose a rising global health threat.
- Many infectious diseases originate outside US borders and are introduced by international travelers, immigrants, returning military personnel, or imported animals and foodstuffs.
- According to the US Institute of Medicine, the next major infectious disease threat to the United States may be a previously *unrecognized* pathogen.
- The most dangerous known infectious diseases likely to threaten the United States over the next two decades will be new, more lethal variants of influenza among other illnesses.
- Hospital-acquired infections pose a major threat. Highly virulent and increasingly antimicrobial resistant pathogens are major sources of hospital-acquired infections that kill some 14,000 patients annually.
- Influenza now kills some 30,000 Americans annually, and epidemiologists generally agree that it is not a question of whether, but *when*, the next killer pandemic will occur.
- Infectious diseases will increase pressure on national health bills that already consume some *7 to 14 percent* of GDP in developed countries.

"...it is not a question of whether, but *when*, the next killer pandemic will occur"

The problem has become acute in healthcare facilities.

According to Benjamin D. Tanner, Ph.D., President, Antimicrobial Test Laboratories:

We live in an era of increasing antibiotic resistance. Bacterial infections once easily cured by penicillin now resist whole *classes* of antibiotics. Terms like "multi-drug resistant" and "extremely drug resistant" are fairly new, but have quickly become common in hospitals.

The proximate causes of most antibiotic-resistant infections are invasive medical devices and compromised immunity, but how do the bacteria spread from one person to the next?

Environmental surfaces play a key role. Infected patients and colonized staff interact with the hospital environment in hundreds of ways every day: An infected patient contaminates his bedding, which in turn contaminates his bedrail. A colonized nurse removes a difficult bandage, stopping to adjust the room lighting. A rushed doctor grabs a doorknob, then remembers she forgot to wash her hands after checking a problematic catheter.

Patients and hospitals can no longer depend on new antibiotics to solve infection problems. Large pharmaceutical companies, the traditional pipeline, simply aren't investing in antibiotic discovery as in years past. The research commitment necessary to identify and exploit uniquely bacterial cellular targets is costly and increasingly fruitless. A quick assessment of drug company ads will confirm – pharmaceutical research dollars go to long-term, chronic conditions amenable to daily medication.

Since breakthrough cures for antibiotic-resistant infections aren't likely to come any time soon, it is necessary to take a fresh look at surface disinfection.

3. CHALLENGES OF HIGH-TOUCH OBJECT (HTO) DISINFECTION

The fewer pathogens on a high-touch surface the better. But it is impractical to disinfect a surface every time it is touched. In "real life" most high touch surfaces are disinfected once a day, at best. Disease transmission by high-touch surfaces could be better controlled by increasing the frequency with which these surfaces are disinfected.

However, increasing the frequency of disinfection amplifies the negative attributes of chemical disinfection (e.g., toxicity, corrosiveness, etc.).

Most disinfectant chemicals are respiratory and eye irritants. For the average person, this represents only a minor health risk. For the average hospital patient, however, increasing disinfection cycles could dramatically increase toxic exposure, the chance of chemical irritation or other complications.

Chemicals (especially oxidants like bleach) may degrade surfaces over time. Shortening the disinfection interval could increase the rate of surface degradation (yellowing, cracking, etc.).

Another problem with increasing the frequency of chemical surface disinfection is that during the contact time required for efficacy, the surface becomes unusable. Certainly no one would be happy to touch a doorknob or desktop covered in a soapy quaternary product or caustic bleach.

Moreover, it is common for environmental services workers to improperly dilute, apply, and short-cut the required dwell time of disinfectant chemicals, reducing their effectiveness.

-Benjamin D. Tanner, Ph.D., President, Antimicrobial Test Laboratories

4. DISINFECTION OPTIONS

According to Carl Solomon Sr. - Director of Hospitality Services, UC San Francisco (UCSF) Medical Centers:

> Healthcare facilities across the nation strive to strike a balance between environmental disinfectants that are effective in reducing or destroying undesirable microbes, while ensuring patient and employee safety, and protecting furnishings and surfaces. This section takes a look at options in chemical and non-chemical disinfecting systems, their "greenness", benefits, risk factors, and safety considerations.

Characteristics of the Ideal Room Disinfection System

- Highest possible kill of all relevant organisms, especially C. Difficile spores
- Fast
- Simple to perform

- Cost effective
- Non-consumptive, sustainable
- Can be safely deployed
- No environmental residue
- Reduces incidence of healthcare infections
- High quality supportive scientific evidence.

Approaches to Greener Disinfecting

Today, the most common products or equipment types used to reduce the presence of pathogens in the healthcare environment include:

A. Chemical Disinfectants
B. Ultraviolet Room Disinfecting Systems
C. Steam Vapor Sanitation Systems
D. Disinfecting Foggers

Below is a description of each, and advantages and disadvantages one should consider:

A. ***Chemical Disinfectants*** typically include ingredients such as Volatile Organic Compounds, Glycol Ethers, Quaternary Ammoniums, Phenols, Ethanolamine, Chlorine Compounds, Ammonia, and Sodium Chlorides (e.g., bleach). All of these are considered hazardous; some are registered as pesticides. They usually require storage in locked rooms or cabinets, and caution must be taken not to allow these chemicals to come into contact with other chemicals that are not compatible. These chemicals each come with a Safety Data Sheet (SDS), and may require specific actions be taken for spill clean-up and product disposal.

Advantages

- Easy to obtain
- Easy to initially train staff in the use of these products
- Relatively inexpensive upfront compared to other products or systems
- Most chemicals can be purchased in concentrated form, and dispensed through closed dilution systems
- Some products are pH-neutral and, in proper use-dilution do not leave a film on the floor
- A few of the products (Chlorine Compounds and Sodium Chlorides) are effective in killing all microorganisms when used as directed.

Disadvantages

- Chemical disinfectants are generally not good cleaners, and gross matter must be removed first before the disinfectant can effectively kill germs
- All EPA-registered products are labeled as pesticides and require special handling, storage, use, and clean-up
- Some products are not effective against blood serum, hepatitis, tuberculosis, and other hard to kill bacteria [C-diff, MRSA, prion disease (mad cow), etc.]
- Inhalation or exposure may cause respiratory distress, chemical sensitivity, skin dermatitis on certain individuals, other issues
- Ensuring proper use, such as proper dilution and dwell time is challenging.

B. ***Ultraviolet Room Disinfecting Systems*** use ultraviolet light (UVC) to provide broad coverage in a closed environment, such as a patient room or an operating room.

Advantages

- Reliable biocide activity against a wide range of pathogens
- Surfaces and equipment decontaminated
- The system is quiet in use
- Low energy consumption
- Room decontamination is rapid (~15 min) for vegetative bacteria
- HVAC system does not need to be disabled and room does not need to be sealed
- UVC is residue-free; does not give rise to common environmental health and safety concerns
- No consumable products so operating costs are low (key cost = acquisition).

Disadvantages

- UVC emitters contain glass and mercury
- No studies evaluating whether use reduces HAIs
- Can only be done for terminal disinfection (i.e., not daily cleaning)
- All patients and staff must be absent from the room
- Substantial capital equipment costs
- Does not remove dirt, dust, blood or body fluids, which would require manual removal
- Sensitive use parameters (e.g., UV dose delivered)
- Does not work in shadows.

C. ***Steam Vapor Sanitation Systems*** use tap water and a cleaning cloth to capture dirt and other matter during the cleaning and sanitizing process. Units equipped with water treatment modules and low-moisture (6%) saturated steam (hotter than other types) often make disinfecting claims **(see Addendum: "Guide to EPA Regulated Disinfection Devices")**

Advantages

- Low contact time of saturated steam required to kill most pathogens (MRSA, VRE in 2-3 seconds with units making disinfecting claims)
- Thoroughly tested by some manufacturers, peer-reviewed data available
- Moist heat as the functional agent outperforms most traditional chemical cleaning methods
- Non-toxic: only needs tap water, and a microfiber or cotton cleaning cloth
- Non-consumptive, petroleum- and chemical-free
- Inexpensive to operate (uses only electricity and tap water)
- Quiet, no internal moving parts, except directed steam
- Training on the use of the equipment is fairly simple
- Does not add a training compliance burden under the UN's Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

because it is non-toxic and no SDS is needed

- Mobile - wheeled carts - requiring no lifting
- Dry (6%) saturated steam provides rapid kill, and penetrates vertical and horizontal surface pores that a cleaning cloth or wipe cannot
- Potential effectiveness on textiles (i.e., privacy curtains) due to penetration
- Reduces cross-contamination because saturated steam kills applicator germs
- Can replace chemical modalities many hospitals have in place.

Disadvantages

- The system uses a microfiber cloth that must come into contact with surfaces
- Steam can damage some surfaces and cause operator scalding if equipment is not used per instructions
- Multiple units and storage are needed to outfit each employee
- Proper use and training is important for efficacy.

D. DISINFECTING FOGGERS DISPENSE A MIST OF DISINFECTANT THROUGHOUT THE ROOM.

Advantages

- The fog mist covers and penetrates all items within the patient room
- Complete room coverage can be achieved in a relatively short period of time
- A variety of germicidal solutions can be dispensed through the system.

Disadvantages

- Requires Personal Protective Equipment
- Fogging does not remove soiling, blood, or body fluids. Cleaning is still required.
- Moisture may leave condensate on windows in a patient room.
- According to the CDC's 2008 *Guideline for Disinfection and Sterilization in Healthcare Facilities*, this technique of spraying of disinfectants is an unsatisfactory method of decontaminating air and surfaces and is not recommended for general infection control in routine patient-care areas.
- According to the CDC, disinfectant fogging is rarely, if ever, used in US healthcare facilities for air and surface disinfection in patient-care areas.

OPTIMUM QUALITIES OF SURFACE DISINFECTING SYSTEMS

- Easy to use
- Disinfect quickly (3 to 5 seconds)
- Kill a broad range of pathogens, without "gaps" in the efficacy spectrum
- Reduce potential for cross-contamination of adjacent surfaces
- Non-toxic; non-chemical; sustainable
- Psychologically acceptable to use around patients
- No health risk to sensitive populations (asthmatics, patients with chemical sensitivities, etc.)
- Frequent use will not damage surfaces
- Effective on three-dimensional, vertical and porous surfaces

- Safe for cleaning staff, even for long-term use
- Peer-reviewed efficacy.

REFERENCES

- Rutala WA (editor). *Disinfection, Sterilization, and Antisepsis: Principles, Practices, Current Issues, New Research, and New Technology*. Association for Professionals in Infection Control and Epidemiology, Washington, DC. 2010
- Rutala WA, Weber DJ, HICPAC. 2008. *CDC guideline for disinfection and sterilization in healthcare facilities*. www.cdc.gov
- Dr. Benjamin Tanner- Principal of Antimicrobial Test Laboratories
- *American Journal of Infection Control*
- *Cleaning & Maintenance Management Magazine*
- Dick Zoutman, MD, FRCPC, Emeritus Professor- Medical Microbiology & Infectious Diseases- Queen's University
- CDC's 2008 *Guideline for Disinfection and Sterilization in Healthcare Facilities*

Carl Solomon Sr. - Director of Hospitality Services, UC San Francisco (UCSF) Medical Centers.

5. CASE STUDY - SEATTLE CHILDREN'S HOSPITAL

Environmental Services Strives to Protect Health at One of the Nation's Best Children's Hospitals

Seattle Children's Hospital - the main clinical, teaching and research site for the Department of Pediatrics at the University of Washington School of Medicine - is a 250-bed facility specializing in meeting the physical, emotional and developmental needs of children. The Seattle campus and seven regional facilities serve more than 300,000 patients each year - from infants to young adults - in Washington, Alaska, Montana and Idaho; the largest region of any children's hospital in the US.

Mitch Birchfield, former Director of Environmental Services, believes the hospital's 100-year tradition of excellence – now with nearly 60 pediatric subspecialties, and ranking among the best children's hospitals in America – should extend to the way the environment is cleaned and maintained.

"The quintessential issue is the patients: Children. Their tolerance is very low," said Birchfield. Since asthma and chemotherapy patients constitute the two largest groups receiving inpatient care, the ambient environment during and after cleaning is vitally important.

During his tenure, Birchfield had selected less-chemically-intensive ways of cleaning and disinfecting while ensuring that hospital-acquired infections were kept in check.

Pictured: AVT's MondoVap with TANCS® disinfection

Steam vapor sanitation devices (Advanced Vapor Technologies, Everett WA) equipped with a Thermal Accelerated Nano Crystal Sanitation (TANCS) water treatment module, were chosen because they clean and disinfect rapidly using only tap water - and without chemicals. The TANCS module converts minerals in tap water to nano crystals

energized by heat and delivered by the low-moisture, low-pressure steam to disinfect within seconds of contact time. Seattle Children's purchased several units used regularly in patient rooms, restrooms and in foodservice areas, but it all started in kitchens.

"We were looking at alternatives for replacing solvent type cleaners, degreasers and caustic products for ovens and deep fryers in our kitchens. Traditional products were hard on surfaces, the odors were problematic, and there were safety issues, especially with trainees," said Birchfield.

"Steam vapor cleaning is incredibly effective for greasy areas, grills and ovens; it's better than chemicals, it melts away the grease. You are not dealing with odors and VOCs or exposing people to harmful substances," said Birchfield.

The steam vapor units are self-contained on a compact rolling cart with tools, enable continuous re-filling, and, importantly, work quickly. "The continuous fill aspect is very helpful since you can keep refilling as needed without waiting for cool-down unlike other steam vapor equipment we had used. You can finish without stopping and re-starting," he said.

"Traditional products were hard on surfaces, the odors were problematic, and there were safety issues, especially with trainees"

Birchfield and his staff used steam vapor for deep cleaning patient rooms and public restrooms.

"One of our central themes was to use products or tools with a safer process. For patient discharge room cleaning, we don't want to bring in intermediate-level disinfectants because, while they destroy pathogens, they impair indoor air quality, and you need to allow time for proper air exchange before the rooms can be used again. With steam vapor you can turn the room 25-30% faster with similar hygienic outcomes based on ATP and other testing."

In restrooms, Birchfield says that labor times were comparable to older methods, but that deep cleaning using steam facilitated restorative and preventive maintenance.

The environmental services staff used the steam vapor combined with blue color-coded microfiber cloths for patient rooms and general cleaning, and orange microfiber cloths for restrooms. While the steam rapidly killed pathogens within the microfiber or other applicator, color-coding provided an extra degree of insurance against cross-contamination while signaling the need for different processes in different areas.

Given the versatility of the equipment, Birchfield said that training of internal staff was key, and vendor training support was critical. "Our vendor provided very thorough initial and follow-up training, spending perhaps an hour per session getting our technicians up to speed, and providing documentation that the training occurred and was effective."

"It's important to mention, though, that the machine is relatively easy to use. Instead of using chemicals that you mix or add into a machine, it's a compact self-contained system that just needs water. Staff does not need to go back to the supply closet for more chemicals, saving time and labor. Using steam is often much easier than teaching people the dilution ratios and pH levels of chemicals, plus it eliminates the problem of chemical disposal. With help from our vendor, we developed a regular, standardized procedure, and the staff became confident in their ability and the machine's ability to get the job done well."

Disinfecting chemicals - though necessary for compliance in some cases - when used unnecessarily are *expensive* in more ways than one, he observes. "It just did not make sense to be using unhealthy products in a healthcare environment when there were safer processes available."

6. PATENT PROOF

According to Walter J. Bauer, President, Bauer Energy Design Inc., the **TANCS** patent holder (**US Patent No. 7,547,413**): "The patent includes broad claims to novel methods and systems and their use in disinfecting or sterilizing a surface, an object or an environment with a special treated water steam."

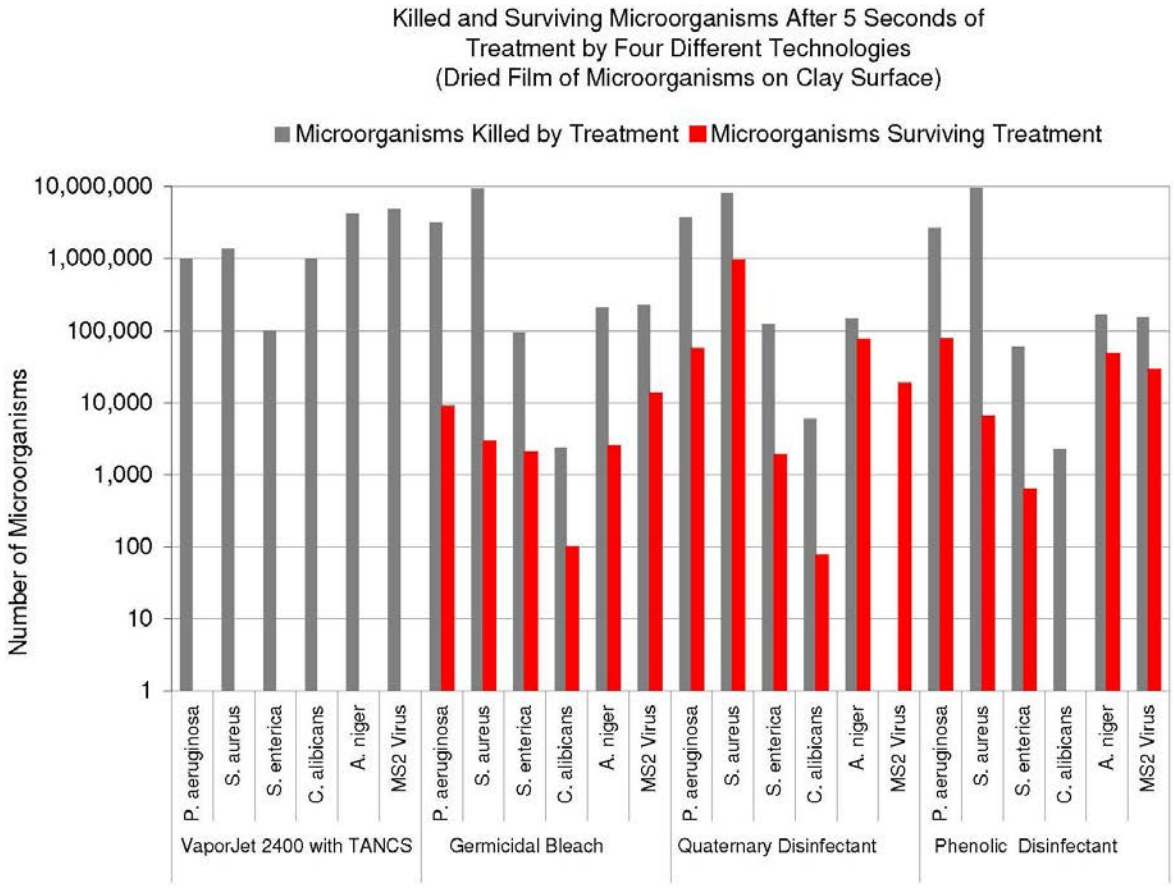
Bauer continues: "Surface-mediated infectious disease transmission is a major concern in a variety of settings... Chemical disinfectants frequently used to reduce contamination pose significant risks to humans and the environment. Some microorganisms have natural resistance to chemical disinfectants which operate over a narrow range of pathogens. Additionally, the chemical formulations require long dwell or exposure times which are often overlooked during application."

The patented technology now featured in all AVT steam vapor sanitation devices equipped with **TANCS® disinfection** includes claims to an enhanced type of steam vapor that can effectively kill a broad range of microorganisms within 3 - 5 seconds, reduce surface-mediated infection risks, and serve as a green, more effective alternative to chemical disinfectants.

"Advanced Vapor Technologies LLC (AVT) of Everett, WA pioneered the use of this patented steam as a hard surface disinfection protocol (**TANCS® disinfection**), and is the [sole] licensee for this application. The protocol is suitable for a wide range of cleaning and disinfection issues not readily addressed by traditional chemical disinfectants," concluded Bauer.

Results achieved in disinfecting contaminated hard surfaces with this novel steam vapor system with **TANCS® disinfection**, and protected by the U.S. patent, were peer reviewed and published in the scientific *American Journal of Infection Control* (AJIC, 2009 Feb;37(1):20-7).

The chart below – from Antimicrobial Test Laboratories Study Report, "Quantitative Technology Comparison for Traditional Liquid Chemical Disinfectants," Completed September 1, 2007, Issued September 4, 2007 - shows typical comparative results between **TANCS disinfection**-equipped steam vapor and other common chemical disinfection methods (brand names are available upon request).



7. SCIENTIFIC PROOF

Download Study Reports: **http://www.advap.com/reports/**

N1: *Testing Antimicrobial Action on Hard Surfaces*: describes the procedures for determining the efficacy of a steam vapor device tested against 10 representative challenge organisms. The procedure was designed to test the kill rate when applied to contaminated hard porous surfaces and is based on the AOAC Official Method 961.02 *Germicidal Spray Products*...18 pages. Nelson Labs, No 274841, Nov 2004

N1A: Condensed Summary showing results for Steam Vapor Device used on inoculated hard porous surfaces, at three different exposures times: 7 sec, 10 sec and 30 sec for each organism tested. *Nelson Lab Report* No. 274841, Nov 2004

N2: *Testing Steam Vapor Device w/TANCS for Virucidal Effectiveness against Norwalk and Norwalk like viruses* on unglazed clay test coupons; two time points of 7 and 10 seconds. MICROBIOTEST Proj # 567-102, June 2006

N3: *Testing Steam Vapor Device w/TANCS for Virucidal Effectiveness against Canine parvovirus* on unglazed clay test coupons at a single time point of 7 seconds. MICROBIOTEST Proj # 567-105, Dec 2006

N4: *Testing Steam Vapor Device w/TANCS for Virucidal Effectiveness against Avian influenza* on unglazed clay test coupons at a single time point of 7 seconds. MICROBIOTEST Proj # 567-106, Dec 2006

N5: *Testing Steam Vapor Device w/TANCS for Efficacy at Ultra-Low Contact Times* of 0.5, 1.0, 2.0 and 5 seconds, using 6 challenge organisms plus virus surrogate MS2. ATL, PT 513, July 2007

N6: *Testing Steam Vapor Device w/TANCS for Efficacy at Ultra-Low Contact Times* of 0.5, 1.0, 2.0 and 5 seconds using MRSA and VRE contaminated coupons, data and kill time chart. ATL PT507, Aug 2007

N7: *Testing Steam Vapor Device w/TANCS for Efficacy against C. difficile* endospore on unglazed clay coupons at time points of 5, 10 and 30 seconds. ATL PT506, Sep 2007

N8: *Qualitative Comparison Study of 4 Disinfection Technologies, including Steam Vapor Device w/TANCS* and common hospital grade disinfectants, 5 pages. ATL PT508, Sep 2007

N9: *Testing Steam Vapor Device w/TANCS for Efficacy at Ultra-Low Contact Times* of 0.5, 1.0, 2.0 and 5 seconds for 8 organisms including MRSA and VRE, with time kill-curve generation, 3 pages. ATL PT505, Oct 2007

N10: *Testing Steam Vapor Device w/TANCS for Efficacy at Ultra-Low Contact Times* of 0.5, 1.0, 2.0 and 5 seconds against Shigella and E. coli. ATL PT504, Oct 2007

N11: *Quantitative Comparison Study of 4 Disinfection Technologies* including Steam Vapor Device w/TANCS, 5 second dwell time, 4 pages. ATL PT509, Sep 2007

N12: *Results for Efficacy using Steam Vapor Device w/TANCS* applying 5 intermittent contacts of 1 second each to inoculated test surface to replicate ordinary 'cleaning motion', 3 organisms. ATL PT502, Nov 2007

N13: *Testing Steam Vapor Device w/TANCS for Efficacy at Ultra-Low Contact Times* of 0.5, 1.0, 2.0 and 5 seconds against A. baumannii on hard, porous, unglazed clay coupons, with data and time kill-curve. ATL SOP C-005, July 2008

N14: *Testing Steam Vapor Device w/TANCS for Efficacy at Ultra-Low Contact Times* of 0.5, 1.0, 2.0, and 5.0 seconds against K. pneumoniae NDM-1 (aka CRKP) on hard, porous, unglazed clay coupons, with Data table and Quantitative graph, 5 pages. ATL NG2478-A3, Feb 2011

N15: Peer reviewed scientific paper, "Reduction in infection risk through treatment of microbially contaminated surfaces with a novel, portable, saturated steam vapor disinfection system", published online in the July, 2008 *American Journal of Infection Control*. See **http://www.ajicjournal.org/article/S0196-6553(08)00557-9/abstract**

N16: Peer reviewed scientific paper, "Reduction in the microbial load on high-touch surfaces in hospital rooms by treatment with a portable saturated steam vapor disinfection system." See **http://digitalreprints.elsevier.com/issue/40750**

N17: Peer reviewed scientific paper “Biofilms on environmental surgaces: Evaluation of the disinfection efficacy of a novel steam vapor system.” See **http://www.ajicjournal.org/article/S0196-6553(11)01317-4/abstract**

ADVANCED VAPOR TECHNOLOGIES

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GLOSSARY

INFECTIOUS DISEASE

An illness due to a specific infectious agent that is spread from an infected person, animal, or inanimate reservoir to a susceptible host, either directly or indirectly, through an intermediate plant or animal host, vector, or the inanimate environment.

EPIDEMIC

The occurrence in an area of a disease or illness in excess of what may be expected on the basis of past experience for a given population (in the case of a new disease, such as AIDS, any occurrence may be considered "epidemic").

PANDEMIC

A worldwide epidemic affecting an exceptionally high proportion of the global population.

Q: **How do pesticide devices differ from registered pesticide products?**

According to the EPA, a pesticide device is “an instrument or contrivance (other than a firearm) that is used to destroy, repel, trap or mitigate (lessen the severity of) any pest such as insects, weeds, rodents, certain other animals, birds, mold/mildew, bacteria and viruses.”

By contrast, a pesticide product “contains a substance or mixture of substances that is intended to destroy, repel, prevent or mitigate (lessen the severity of) a pest.”

EPA: “Pesticides are commonly thought of as chemicals.” A pesticide product “must be registered unless it qualifies for an exemption.”

Q: **How can you recognize a regulated device versus a registered product?**

Recognizing a Device by Reading the Label.

Per EPA: “A pesticide device that is EPA regulated will include an EPA Establishment Number on the label. It will not include an EPA Registration Number, which would only be found on chemical pesticide products.

Q: **What does the device claim mean?**

A pesticide device “works by physical means (such as electricity, light or mechanics), and does not contain a substance or mixture of substances to perform its intended pesticidal purpose.”

Q: **How are pesticide devices EPA Regulated?**

EPA: “We do not require registration for these. However, these devices are regulated in that ‘false or misleading claims’ cannot be made about the effectiveness of devices. If a manufacturer is making claims about a device, they should have *scientific data* to back up the claims.