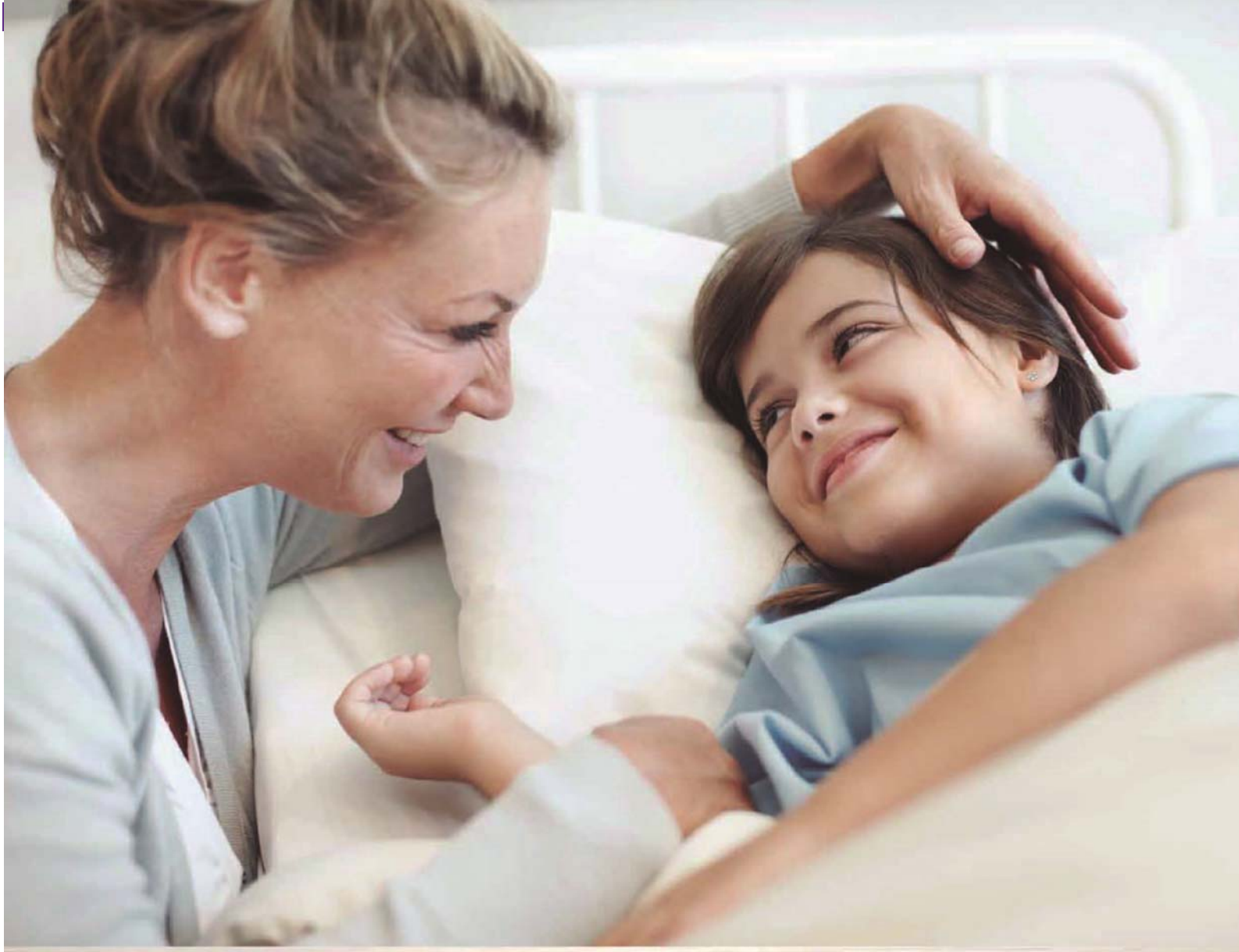
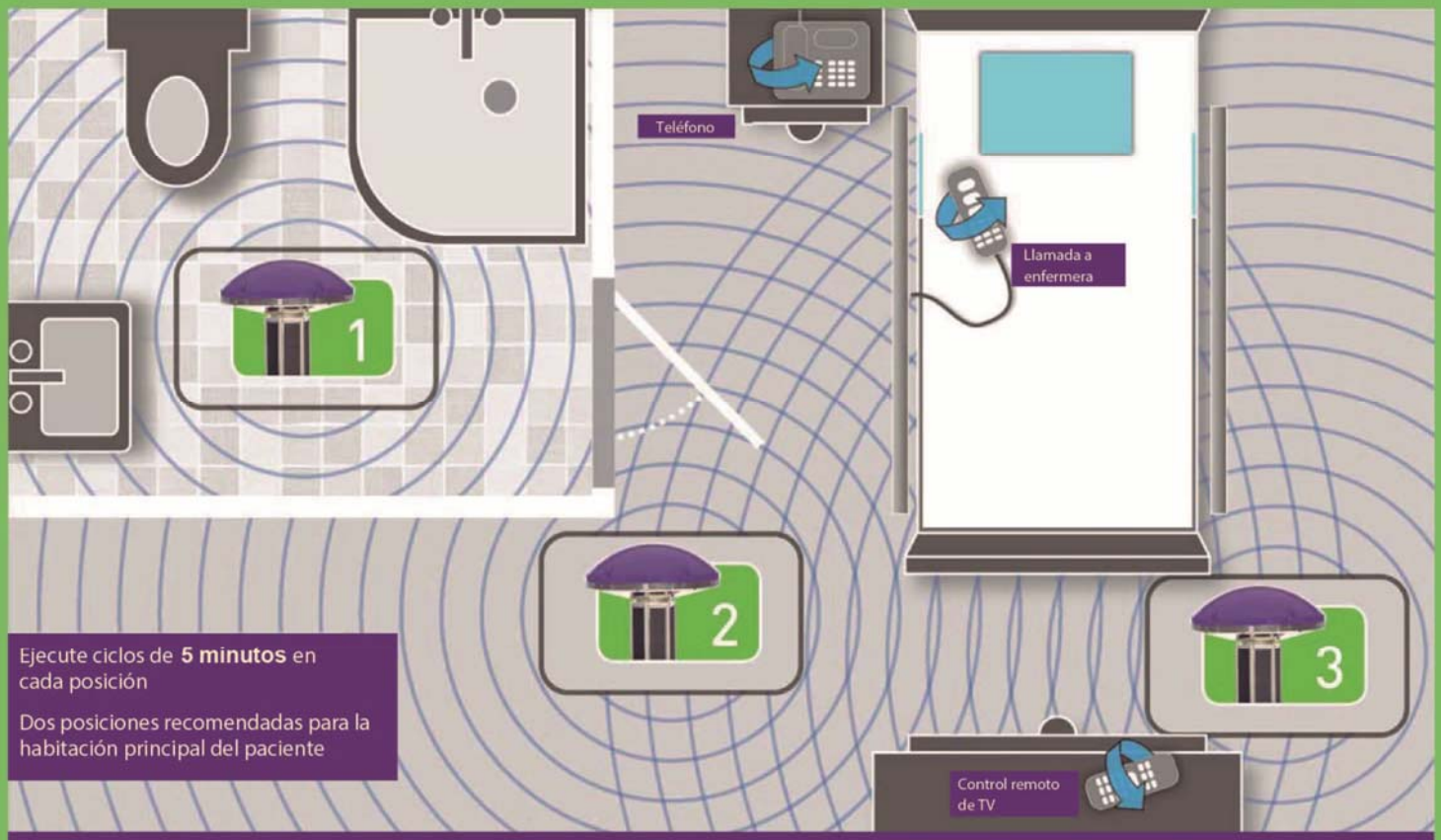


Xenex Robots Improve Patient Safety.™

La ÚNICA tecnología de desinfección con luz UV mostrada en estudios publicados revisados por pares para reducir HAI

XENEX®
GERM-ZAPPING ROBOTS™

XENEX@GRUPOCLECE.COM
Tel: 900 82 87 44



Cómo tratar una habitación utilizando un robot con luz ultravioleta mediante lámpara de xenón pulsado.

Resultados comprobados:

53% de reducción en las tasas de infección de *clostridium difficile*
Estudio de resultados revisado por pares realizado en Cooley Dickinson y publicado en AJIC

57% de reducción en las tasas de infección del MRSA en todo el hospital
Estudio de resultados revisado por pares realizado en Cone Health System y publicado en JIP

0 recuperación del VRE en habitaciones aisladas
Estudio de resultados revisado por pares realizado en M.D. Anderson Cancer Center y publicado en *ICHE*

25% más rápida que la limpieza química
Estudio en Temple VA presentado en el Simposio Nacional de VA

"Es la tecnología más rápida y poderosa disponible".

– Lynn Grudzielanek, Vicepresidente Senior de Operaciones,

Wheaton Franciscan Hospital

Nadie quiere estar enfermo dos veces

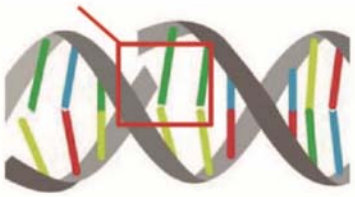
La ciencia de la desinfección mediante xenón pulsado:

Desarrollado por un equipo de epidemiólogos y científicos, los robots destruyen el ADN de los gérmenes en el ambiente hospitalario. La luz UV de xenón pulsado destruye los agentes patógenos a nivel del ADN submicroscópico de diversas maneras,

4 Mecanismos de destrucción:

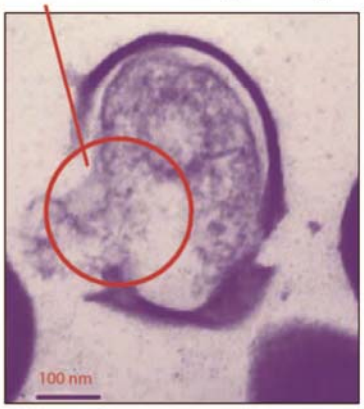
Fotodimerización: Daño en el lazo de ADN

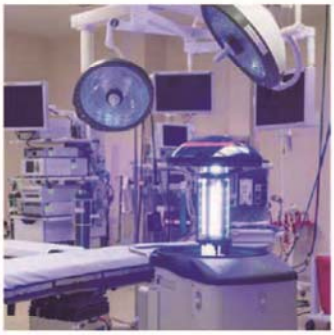
Fotodivisión: Rotura de la cadena de ADN



Fotohidratación: Inhibe las funciones del ADN

Fotocruzamiento: Daño y lisis de la pared celular





En los Estados Unidos todos los años, más personas mueren a causa de infecciones contraídas en la atención de su salud que de SIDA, cáncer de mama y accidentes de auto combinados, a un coste anual estimado de 40 mil millones de $.

La eliminación de los agentes patógenos de las habitaciones de pacientes es la **manera más rápida y fácil** de reducir el riesgo de infecciones adicionales. En dos estudios de resultados revisados por pares, los hospitales que utilizan los robots **redujeron** las tasas de *clostridium difficile* y MRSA en más del **50%**, disminuyendo significativamente re-admisiones costosas y estadías de pacientes.

CONOZCA EL X4 GERM-ZAPPING ROBOT

Diagnóstico interno
El robot informa automática e instantáneamente cualquier problema

Software de actualización automática
El software de usuario intuitivo se actualiza automáticamente en segundo plano, incorporando nuevas características.

Luz UV mediante xenón pulsado
La tecnología patentada proporciona intensidad de luz UV full spectrum™ para una desinfección rápida y eficaz.

Detección de movimiento del sensor
El cono de detección de movimiento del sensor triple puede sentir el movimiento en toda una habitación, reforzando el sistema de seguridad para habitaciones más grandes.

Hardware resistente a impactos
Hardware diseñado para durabilidad y confiabilidad extrema

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1 SCIENCE COMPENDIUM

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BURDEN OF HAIs

Each year over 722,000 patients become infected with a healthcare associated infection (HAI) and more than 75,000 of those die during their hospital stay. That amounts to 1 in 25 hospital patients becoming infected with an HAI. Of those, 1 in 9 will die, at an annualized cost of approximately $9.8 billion to the US healthcare system. As antimicrobial resistance increases, HAIs will become even more life-threatening and costly. Currently, the Centers for Medicare and Medicaid Services penalize hospitals based on their quality metrics, of which the HAI rates for *Clostridium difficile (C. difficile)* and methicillin resistant *Staphylococcus aureus* bacteremia make up a substantial part of both the value based purchasing (VBP) and the health care acquired conditions reduction (HAC-R) programs. [1, 2] Additionally, rankings of hospitals based on quality scores, largely driven by HAIs, are published routinely.

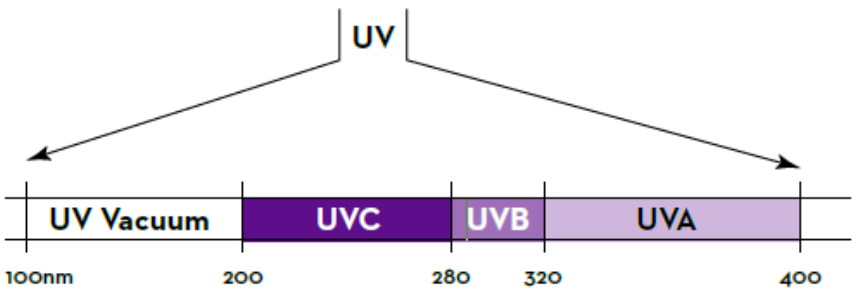
ROLE OF THE ENVIRONMENT IN HAIs

Contamination of the hospital environment can create the risk of HAI transmission to patients and therefore is a core component for any Infection Control program. Multiple studies have shown that the manual disinfection of high touch surfaces in the patient environment is only around 50% effective, with pathogens being detectable after rooms are terminally cleaned.[3, 4] Pathogens can survive for weeks to months in the hospital environment and have been found on equipment, healthcare workers' hands, high-touch surfaces, and even in the homes of nurses.[5, 6] Furthermore, there is an increase in HAI risk if the prior patient in a room has had an HAI [7-13] and studies have shown that enhanced environmental disinfection using UV light can reduce the rate of HAIs. [14-21]

WHAT IS GERMICIDAL ULTRAVIOLET LIGHT?

Not all light is effective in the eradication of pathogens. Germicidal UV (with a range between 200-315 nm) can penetrate the cell walls of microorganisms and cause irreparable damage. **Figure 1** to the right, depicts where germicidal UV falls within the light spectrum. Germicidal UV can further be broken down into UVB (280-315nm) and UVC (200-280nm). Germicidal ultraviolet light is different than the UV light with which we are familiar.

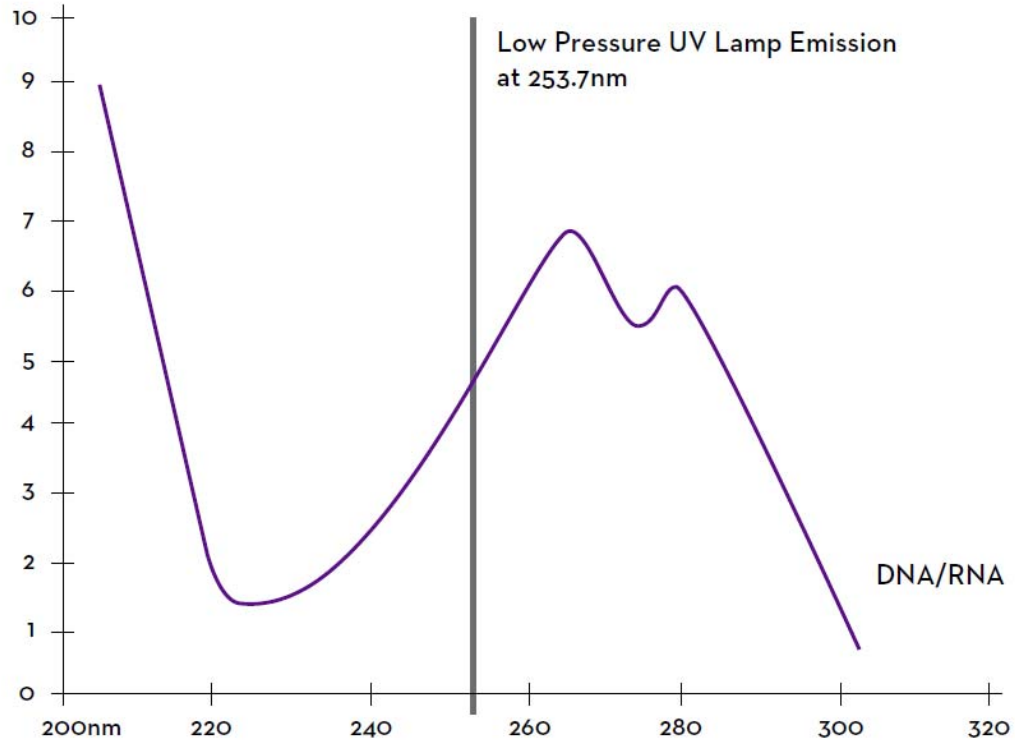
Figure 1. The Electromagnetic Spectrum from Ultraviolet to Infrared



Germicidal UV-C is blocked by the ozone layer in the atmosphere, and the light never makes it to Earth's surface. Because these UV wavelengths do not naturally occur on Earth, bacteria and viruses have not developed resistance to these wavelengths.[22] Germicidal UV is able to cause many different types of damage to cells, including the fusing of DNA or RNA molecules (photodimerization), the insertion of water molecules into the DNA/RNA (photohydration), the splitting of the DNA/RNA "chain" (photosplitting) and the binding of protein molecules together (photocrosslinking). After sufficient damage, the organism is considered "deactivated". A deactivated organism cannot reproduce or cause infection and eventually dies.

Science Compendium [continued]

Different organisms have different susceptibility to Germicidal UV. As a rule of thumb, bacterial spores such as *C. difficile* are the most UV resistant due to the thick outer "shell" that they form. Action spectrums are graphs that show the effectiveness of various Germicidal UV wavelengths in deactivating organisms. This is important because different wavelengths of light have different levels of effectiveness against organisms. If the correct wavelengths of light are not used, it can be difficult to efficiently deactivate an organism. The graph below illustrates which Germicidal UV wavelengths are most effective in deactivating organisms. (**See Figure 2**).



Nucleic Acid Absorption

Of the Germicidal UV wavelengths from 200 to 315nm, this graph demonstrates the regions of the spectrum which are most absorbed DNA and RNA. That nucleic acid absorption translates to damage to the genetic material and pathogen deactivation (death). as illustrated in Figure 2, the regions of highest absorption are 200 to ~205nm, and two other peaks are seen at 265nm and at 280nm.

There are two divergent technologies in the market capable of producing germicidal UV for room disinfection: low pressure mercury vapor systems and pulsed xenon systems. Mercury vapor systems only produce germicidal UV at

a wavelength of 253.7 nm with a low intensity continuous output lamp. As illustrated in Figure 2, this single wavelength is not the most effective wavelength for producing damage to the DNA orRNA of organisms. Pulsed

xenon systems produce germicidal UV at all wavelengths from 200-315 nm. The broad spectrum UV light produced by pulsed xenon systems includes, for each type of organism, the most effective wavelengths for producing damage. Additionally, Pulsed xenon systems create high intensity bursts of germicidal UV that rapidly destroy the DNA and RNA of organisms.

WHO IS XENEX?

Xenex Disinfection Services manufactures the LightStrike™ Disinfection Robot. LightStrike is a pulsed xenon ultraviolet disinfection robot that effectively destroys pathogens to reduce the risk of transmission and rate of infection caused by pathogens present in the environment. LightStrike was created to address a need in infection control to provide reliable and repeatable disinfection of the healthcare environment.

The robot can be operated by environmental services staff (EVS) after manual disinfection of a room has been completed. The robot is wheeled into a patient room, operating room or other area and positioned in order to maximize the surfaces directly exposed to the UV light. For example, in a patient room, the robot is positioned in the bathroom and run for 5 minutes (4 minutes with certain models). It is then placed on either side of the bed and run for an additional 5 minutes (4 minutes with certain models), see **Figure 3.** While the robot is running in the bathroom, the EVS staff can continue to clean in the main patient room in order to minimize the room turnover time. For terminal cleaning of operating rooms, the robot is placed on either side of the operating table, and run for a 10 minute cycle (8 minute cycle with certain models), see **Figure 4**. Prolonged UV-C light exposure can cause eye irritation, so in order to assure the safety of hospital staff, no one can be directly exposed to the germicidal light from the robot. Motion sensors will shut the robot down if someone enters the room while it is running. This protocol is based on multiple published studies which demonstrate reductions in environmental contamination.

Figure 3. Room Map Showing Robot Placement for Discharge Cleaning of an In-Patient Room

Figure 4. Room Map Showing Robot Placement for Terminal Cleaning of an Operating Room

Features of the LightStrike Robot:

1.) Size/Functionality: The LightStrike Robot has a footprint smaller than a wheelchair. While being transported, the bulb retracts into the robot allowing the operator to easily see over the top of the robot for navigation and eliminating the risk of damaging the bulb during transit. The robot has a 4 pound push weight, allowing for a wide variety of personnel to easily operate the robot. The design is robust and durable, meant for a busy hospital environment, and includes bumpers, an enclosed bulb, and shock absorbing wheels.

2.) Xenon: The LightStrike Robot uses xenon gas to create germicidal ultraviolet light. Xenon is an inert, noble gas found in trace amounts in the atmosphere. Xenon is safe and common in applications such as headlights. When electricity is applied to specially pressurized xenon gas, that energy is released as light. If this is done extremely fast (microseconds) then the light released is extremely high-energy germicidal ultraviolet. This produces the following characteristics:

a.) Spectrum: Pulsed xenon is able to produce full spectrum germicidal UV light from 200nm-315 nm. This spectrum includes higher energy photons that have an increased germicidal effect beyond mercury based germicidal light emissions at 253.7 nm (See **Figure 2**).

b.) Intensity: Because the stored energy transferred into the bulb is released in a microsecond burst, the pulse

Science Compendium [continued]

of the LightStrike Robot is very intense. In order to deactivate a pathogen, a minimum threshold of UV light dose must be reached. LightStrike Robots are able to rapidly meet this dose due to the high intensity of each burst of light, even on abraded or rough surfaces that might shelter microbes and are typically found in patient care environments.

c.) Duration: As mentioned before, a pulsed xenon "flash" is measured in microseconds (0.000001 seconds). In a 5 minute cycle time*, the total UV "on" time is less than 1 second.

3.) Quality/Service: Xenex offers a comprehensive customer service program to assist hospitals in developing a quality improvement program around enhanced environmental disinfection using the LightStrike Robot. This program includes development of customized utilization strategy, routine reporting on compliance with the utilization strategy, and retraining of EVS staff as needed. Robots are also equipped with a reporting system, allowing hospital leadership to track real-time usage of the robots throughout the hospital.

4.) Materials compatibility: UV light is known to cause damage and degradation of materials, including plastics, if there is prolonged exposure. Degradation of hospital equipment has been reported with the use of mercury- based UV devices.[23] However, this damage has not been reported with xenon-based UV systems because of the short "on time" of the light. (See above, 2c: Duration)

5.) Environmental Concerns: Because LightStrike Robots use inert xenon gas and not mercury vapor or chemicals, and due to Xenex's manufacturing methods and component selection, LightStrike Robots are an environmentally friendly method of disinfection.

6.) Made in the USA: Xenex produces its robots in its facility in San Antonio, Texas, and uses suppliers based in the North America.

7.) Run time: The LightStrike sporicidal run time of 5 minutes per position* has been validated in multiple studies. This run time and other features allow Xenex customers to disinfect dozens of rooms per day with each robot.

8.) Scale: Xenex currently has over 400 U.S. hospital customers and has disinfected over 5 million patient rooms and ORs in the U.S. Xenex is the largest and most used no touch room disinfection technology.

9.) Training: Xenex will conduct on-site trainings with environmental services staff and supervisors, infection control and hospital leadership. From our experience, we know that in order to achieve infection rate reductions with LightStrike Robots, they must integrate into existing operations and programs. We bring the best practices from our existing customer base to every new customer.

LIGHTSTRIKE ROBOT IMPACT ON HEALTHCARE ENVIRONMENT CONTAMINATION

There are two general methods for evaluating the effectiveness of ultraviolet disinfection systems; evaluations in an artificial laboratory setting and evaluations in a healthcare environment setting. Unlike EPA regulation of chemical disinfectants, there is no specific laboratory testing protocol that is used to determine the effectiveness of UV disinfection systems. This allows individual laboratories to develop different test protocols which can lead to vastly different results based on the techniques used.[24] Because of this variation, it is appropriate to test the effectiveness of UV systems in both the laboratory setting, and the actual hospital environment in which they will be deployed. This allows for factors such as natural soiling (dust, dirt, skin oils, etc.), shaded areas, and variations in distance from the UV system to be incorporated into the testing. Following is a summary of both the laboratory and real world environmental testing that has been published related to LightStrike Robots.

*4 minute cycle time in certain models.

Science Compendium [continued]

Does LightStrike work against a wide variety of pathogens including Ebola and Anthrax?

Design: LightStrike's efficacy was assessed in the laboratory setting against a variety of organisms with a significant public health impact. Organisms were inoculated onto carriers and exposed to the Pulsed Xenon lamp at 1 meter for various cycle times, dependent on the UV sensitivity of the organism of interest.

Results: LightStrike Robots were able to achieve complete elimination of Ebola virus (>4 log) in 1 minute and Anthrax (>3 log) in 15 minutes. Greater than 3 log reduction for spore-forming organisms and 6 log reduction of MRSA, CRE, MDR-*A. baumannii* and other common vegetative pathogens were achieved in 5 minutes.

Site: Texas Biomed BSL-4 lab, San Antonio, TX; and National Center for Biotechnology, Spain [25]

What is the impact of LightStrike on environmental contamination and does shading, soil loading, pathogen concentration and protein loading impact efficacy?

Design: Multi-phase design that included both laboratory testing on glass carriers, as well as environmental sampling in real-world patient rooms for the recovery of *C. difficile*, MRSA and VRE from surfaces.

Results: LightStrike is not affected by shading, soil loading, pathogen concentration, or protein loading. The authors reported a 99.6% reduction in real-world hospital bioburden in the absence of manual cleaning; and 75%, 78% and 100% reduction in *C. difficile,* MRSA and VRE positive high-touch surface swab cultures, respectively.

Site: Louis Stokes Cleveland VA Medical Center, Cleveland, OH [26]

Can LightStrike be used as a substitute for Sodium Hypochlorite (bleach) as the sporicidal agent for terminal cleaning of C. difficile rooms?

Design: Two arm pre-post disinfection study in 30 *C. difficile* isolation rooms. Recovery of *C. difficile* spores on high-touch surfaces was compared between 15 rooms disinfected with bleach and 15 rooms disinfected with quaternary ammonium (non-sporicidal) plus LightStrike.

Results: Disinfection with bleach removed 70% of *C. difficile* spores while quaternary ammonium clean plus LightStrike removed 95%. Based on the results of this study, MD Anderson eliminated the use of bleach for terminal cleaning of *C. difficile* isolation rooms.

Site: MD Anderson Cancer Center, Houston, TX [27]

Is LightStrike superior to chemical disinfection and is LightStrike reliant on chemical disinfection?

Design: 12 VRE isolation rooms were selected following patient discharge. Environmental samples from high touch surfaces were taken before cleaning, after standard chemical disinfection and again after LightStrike disinfection. A subset of samples were taken without manual cleaning to determine if LightStrike is dependent on chemical disinfection.

Results: Bacterial contamination was recovered on 78% of surfaces prior to cleaning, 63% of surfaces after chemical disinfection and 36% of surfaces following LightStrike disinfection. No VRE was recovered from surfaces following LightStrike disinfection. LightStrike was equally effective in disinfecting surface regardless of whether chemical disinfection had been performed.

Site: MD Anderson Cancer Center, Houston, TX [28]

Is LightStrike superior to chemical disinfection for removal of MRSA on surfaces?

Design: Compare the recovery of general bioburden and MRSA from samples taken on five high-touch surfaces in 20 rooms vacated by MRSA-positive patients. Rooms were disinfected using standard chemical cleaning and then subsequently disinfected with LightStrike.

Results: Disinfection with LightStrike was 7 times more effective than traditional manual cleaning for general bioburden,

Science Compendium [continued]

and 16 times more effective for MRSA.

Site: Central Texas VA Health Care System [29]

Is LightStrike effective in the absence of manual cleaning?

Design: 38 patient rooms were identified prior to standard manual cleaning practices. Five high touch surfaces were sampled for bacterial contamination before and after disinfection with LightStrike, with no manual disinfection being performed.

Results: Significant reduction were found on all high touch surfaces after disinfection with LightStrike in the absence of manual cleaning. Results show that LightStrike will still be effective even on surfaces that housekeepers may miss during routine manual cleaning.

Site: Central Texas VA Health Care System, Temple, TX [30]

What is the microbiological, environmental, operational, and user impact of LightStrike in an NHSHospital?

Design: Multi-phase design that included: (1) laboratory efficacy testing against MDROs, (2) environmental sampling of isolation rooms following discharge prior to terminal cleaning, following standard manual cleaning and following disinfection with LightStrike, (3) time studies and interviews for EVS staff and Nursing staff perception.

Results: (1) 5 log reduction of MRSA, VRE, *Acinetobacter* and CRE, (2) After disinfection with LightStrike, bacterial contamination decreased 78% as compared to standard manual cleaning, and 91% as compared to pre-cleaning bioburden levels, (3) Minimal impact of LightStrike disinfection cycle times on patient throughput, and high staff enthusiasm and willingness to adjust traditional routine to incorporate LightStrike.

Site: NHS Queen's Hospital - Romford, United Kingdom [31]

LIGHTSTRIKE IMPACT ON HAIs AND SSIs

The primary purpose for hospitals considering the implementation of UV disinfection systems is to decrease the rates of hospital associated infections. The studies presented below show that pulsed-xenon based disinfection systems are able to decrease infection rates across a variety of hospital settings and for many different infection types.

Infection Rate Reductions in the Acute Care Environment

What impact can LightStrike have on C. difficile infection rates in a controlled evaluation?

Design: To determine the effect of LightStrike on hospital-acquired *C. difficile* infection rates, LighStrike was implemented for 6 months on 3 medical units, while 3 medical units with similar baseline infection rates and patient populations served as real-time controls.

Results: The units using LightStrike for disinfection saw a 39% decrease (p=0.03) in *C. difficile* infection rates, with 85% of all discharges receiving disinfection with LightStrike. There was a non-significant increase in *C. difficile* infection rates on control units over same time period.

Site: Mayo Clinic, Rochester, MN [32]

Is LightStrike effective in reducing C. difficile incidence in smaller community hospitals?

Design: Examined the impact of LightStrike disinfection on facility wide *C. difficile* infection rates within a small community hospital for the first year of implementation compared with a one year baseline period.

Results: *C. difficile* infection rates remained stable for two years prior to use of LightStrike. A significant 53% reduction (p=0.01) was found for the first year following implementation of the LightStrike program.

Science Compendium [continued]

Site: Cooley Dickinson Hospital, Northampton, MA [14]

Can LightStrike be operationalized throughout a hospital system to achieve reductions in MRSA infections?

Design: Examined the facility wide impact of LightStrike on MRSA infection rates for the first 18 months after implementation compared with a 15 month baseline period. LightStrike was primarily used for terminal cleaning of rooms that housed a patient with a MRSA infection.

Results: The study found a statistically significant 57% reduction in hospital-acquired MRSA infection rates system wide (p=0.001). An estimated 51 cases were avoided when compared to the expected number of cases based on previous infection rates.

Site: Moses Cone Healthcare System, Greensboro, NC [15]

Is LightStrike effective in reducing rates of multiple MDRO infections in a large, acute care setting?

Design: Retrospective study comparing MDRO acquisition during a 30 month baseline period that consisted of standard terminal cleaning and disinfection of patient care areas, to a 22 month intervention period that utilized LightStrike following discharge cleaning of isolation rooms and other high-risk areas.

Results: The study found a statistically significant 20% decrease (p<0.001) in all hospital acquired MDROs facility wide following 22% compliance to Xenex discharge cleaning practices. 185 cases were avoided when comparing against the predicted number of infections based on previous rates.

Site: Westchester Medical Center, Valhalla, New York [17]

Is LightStrike effective in reducing C. difficile incidence in an acute care facility?

Design: Examined the impact of LightStrike on *C. difficile* infection rates facility wide and within the adult ICU. Infection rates were studied for the first year of LightStrike implementation compared with a one year period prior to LightStrike.

Results: Significant 70% reduction (p<0.001) in *C. difficile* infection rates was found within the adult ICU with an estimated 30 cases avoided year over year. A non-significant 22% reduction (p=0.06) was found facility wide. The compliance with Xenex discharge cleaning practices was significantly higher within the ICU than the rest of the hospital.

Site: Westchester Medical Center, Valhalla, New York [16]

Is it better to use LightStrike only on isolation rooms or to use it on every discharge on a targeted unit?

Design: Examined the impact of LightStrike on multiple MDROs (*C. difficile,* MRSA, VRE) during the first 22 months after Lightstrike implementation compared with a 22 month baseline period. The robot was used in a targeted implemented in the intensive care unit (ICU), with a goal of disinfecting all discharges and transfers after standard cleaning and prior to occupation of the room by the next patient. For all non-ICU discharges and transfers, LightStrike disinfection was only performed for *C. difficile* isolation room discharges.

Results: Combined MDRO infection rates reduced 29% facility wide and 61% in ICU. In the ICU specifically, VRE decreased 87%, *C. difficile* decreased 45%, and MRSA decreased 56%. 390 bed days were generated and approximately $730,000 was saved in excess medical costs throughout study period.

Site: South Seminole Hospital, Longwood, FL [18]

INFECTION RATE REDUCTIONS IN SURGICAL SERVICES

Is LightStrike effective in reducing rates ofsurgical site infections (SSIs)?

Design: A 15 month baseline period that involved standard nightly terminal cleaning and disinfection of 13 operating rooms was compared to a 21 month intervention period that added LightStrike disinfection. The influence of UV disinfection would be expected to affect clean incision sites, defined as Class I surgical wounds. UV would have less influence on more contaminated incisions (Class II-IV due to pre-existing wound contamination prior to surgery.)

Science Compendium [continued]

Results: Class I SSIs were significantly reduced by 46% (p=0.05) after LightStrike disinfection was added to terminal cleaning processes. 23 potential infections were avoided and $478,055 saved . While non-significant, Class II (clean- contaminated) procedures increased by 22.9%.

Site: Lowell General Hospital, Lowell, MA [21]

Is LightStrike effective in reducing rates ofsurgical site infections following total joint procedures?

Design: Examine the impact of a one year infection control bundle to reduce surgical site infections following total joint procedures. Bundle included using LightStrike following nightly terminal cleaning practices in OR suites, and a quality improvement initiative consisting of pre-operative screening for MRSA, bathing with CHG, standardizing perioperative order sets, and early ambulation on surgery day when possible.

Results: SSIs following total-hip and total-knee procedures were eliminated. Year over year incidence decreased from 7 in 544 procedures to 0 in 585 procedures; an estimated $290,990 saved during study period.

Site: Trinity Medical Center, Birmingham, AL [20]

INFECTION RATE REDUCTIONS IN THE LONG TERM CARE ENVIRONMENT

Is LightStrike effective in reducing C. difficile incidence in LTACs?

Design: Two hospital-associated *C. difficile* prevention methods were assessed over a 3 year period within a long-term acute care hospital. In the first 12 month period, a multidisciplinary team of healthcare workers was assembled to implement a variety of prevention measures. In the subsequent 15 month period, LightStrike was added to the manual cleaning process throughout the facility, in addition to the previous interventions implemented by themultidisciplinary team.

Results: A non-significant 17% reduction (p=0.91) in *C. difficile* transmission was found following the multidisciplinary team intervention. A significant and sustained 57% reduction (p=0.02) in facility-wide *C. difficile* transmission was found following the implementation of LightStrike disinfection.

Site: Southeastern GA facility [19]

Is LightStrike effective in a Nursing Home setting?

Design: This study examined the impact of LightStrike disinfection on nursing home infection rates within the first year of implementation compared with a 3 year baseline period.

Results: There were significant decreases in nursing home acquired relative to hospital-acquired infection rates for all infections tracked (p = .004), including urinary tract infection rates (p = .014), respiratory system infection rates (p = .017) and rates of infection of the skin and soft tissues (p = .014).

Site: Jewish Home and Care Center, Milwaukee, WI [33]

Is LightStrike effective in reducing C. difficile infection rates within a military burn ICU?

Design: LightStrike disinfection efficacy was examined in patient rooms, along with the impact on burn intensive care unit infection rates during a 3 month intervention compared to 3 month control periods before and after. Because the intervention period was short, demonstrating statistically significant reductions was not an intent of this study.

Results: Significant reductions in bacterial load were found in burn unit ORs and patient rooms. *C. difficile* cases were eliminated in the burn ICU, despite *C. difficile* rates remaining stable throughout the rest of the facility when compared to the control period. This was the longest duration with no cases of *C. difficile* infections in burn ICU in 2 years.

Site: San Antonio Military Medical Center, San Antonio, TX [34]

Science Compendium [continued]

ON CAUSALITY AND EVIDENCE

In epidemiology, one of the most important concepts is that of causality and how causality can be established. For example, if one wants to assert that smoking causes lung cancer, there are multiple conditions that must be met to "prove" that assertion. These are the same conditions that must be met to assert any relationship between an intervention and an outcome, either positive or negative. In the end, one must look at the totality of the evidence and make an inference as to whether a causal relationship exist. The following are 9 conditions enumerated by the U.S. Surgeon General as guidelines for judging whether an association is casual (in the following examples, we will be examining if "A" causes "B"):

1. **Temporal Relationship:** A must come before B.
2. **Strength of Relationship:** How much of B does A explain?
3. **Dose-response Relationship:** If you increase A, then B increases.
4. **Replication of Findings:** The association is reported in multiple populations.
5. **Biological Plausibility:** There is something about A that could cause B based on our understanding of biology.
6. **Consideration of Alternate Explanations:** Have C, D, and E been controlled for?
7. **Cessation of Exposure:** If A stops, then B stops.
8. **Consistency with Other Knowledge:** Do surrogates for A also show increases in B?
9. **Specificity of the Association:** Does only A explain B and only B? Note: not all relationships are required in order to assert causality

Table 1. Causality: Does Use of Pulsed Xenon Cause HAI Reductions?

Relationship	Pulsed Xenon Evidence	Reference
Temporal	After using pulsed xenon, hospitals report drops in HAI rate	[14-21]
Strength	HAI rate reductions of up to 70% have been reported	[16]
Dose-Response	Increased utilization of pulsed xenon led to greater HAI rate reductions	[16, 17]
Replication	Multiple studies have been published with consistent results	[14-21]
Biological Plausibility	Risk of environment transmission of infections is well established	[7-13]
Alternative Explanations	Some studies on the use of pulsed xenon disinfection have controlled for the effects of other confounding factors on the infection rates being measured	[14, 16, 17]
Cessation of Exposure	To date, no time-series study involving the cessation of pulsed xenon disinfection has been conducted.	n/a
Consistency with Other Knowledge	Other environmental interventions show HAI reductions	[35, 36]
Specificity of Association	When pulsed xenon disinfection is only implemented on certain units in a facility, only those units see decreases in infection rates.	[16, 18, 32]

Science Compendium [continued]

BETR-D Study on Mercury UV

A study by Duke examining a variety of methods of room disinfection was published in the Lancet.[37] In this study, the investigators examined standard cleaning, bleach, and mercury UV disinfection.

In short, these findings showed a reduction in VRE infections by 64% when mercury UV disinfection is used in conjunction with bleach, a non-statistically significant reduction in MRSA of 22% and no change in *C. difficile* infections.

While this is the most robust study to date on the use of mercury-based UV systems, it should not be used when considering pulsed xenon UV systems. It should be noted when discerning the impact of enhanced disinfection systems on nosocomial infection rates, there are three fundamental considerations: product, process, and frequency. In this study, UV disinfection device using mercury vapor lamps to generate germicidal light (product) were used in a single position in each room (process) on select rooms (frequency).

The authors voiced concerns that reductions in hospital acquired *C. difficile* infection rates reported in previous studies were not observed with enhanced disinfection with mercury-based UV light. We believe that product, process and frequency of use could explain the difference in the reductions reported in the previous literature and this study.

The studies cited by this article in which reductions in the hospital acquired *C. difficile* infection rate were observed differed in all three of these variables. In the cited studies, a pulsed xenon UV device (product) which produces more intense and broader germicidal light was used in three positions (process -- once in the bathroom and twice in the patient room) and used for every discharge on the targeted units (frequency).

Because of these differences in product, process and frequency; we strongly believe that the results reported in this study are not generalizable to all UV disinfection devices and instead we reiterate the 3 fundamental considerations to be taken into consideration when evaluating this means of enhanced room disinfection, product, process, and frequency.

Science Compendium [continued]

APPENDICES

APPENDIX A: Meta-Analysis of Environmental Studies on UV-C

There has been criticism of the use of laboratory studies as a sole means of evaluating products for infection control [24] There have been examples of non-replicable laboratory data that resulted in the EPA issuing a "stop sale" order as well as studies that examine product efficacy under hospital conditions revealing that humidity, process, skin oils and other factors can reduce the efficacy of products greatly. Additionally, decisions made in the laboratory study design, such as adding soil, initial inoculum concentration, as well as methods used for recovery and enumeration all can influence the conclusion of a laboratory study. Because of these variables, it is difficult to perform meaningful comparisons of the laboratory results reported for competing UV systems. It has also been noted in the literature that the results reported in the laboratory environment do not correlate with effectiveness of UV systems in hospital environment.[38]

A more robust mechanism for reporting the effectiveness of UV disinfection technology is to perform microbiologic sampling of a hospital room where a patient has previously been housed. Testing in this environment allows researchers to determine how the system will perform in a setting where patients have been shedding pathogens into the environment, and the pathogens have been spread throughout the environment on the hands of the patient and healthcare workers. There are several variables that differentiate this environment from the laboratory testing methods that were previously described:

- The first is that the baseline contamination levels are much lower. While the concentration in the laboratory testing is determined in advance by the researchers, the contamination in the hospital environment is dependent on the rate of bacterial shedding from the patient, the persistence of the organisms in the environment, and the thoroughness of the daily cleaning performed by the EVS staff. This means that the pathogen load in the hospital environment is much lower than the laboratory environment.
- The use of manual cleaning in the hospital environment results in variations in not only the amount of pathogens, but the amount of soil left behind on surfaces. The soil in the hospital environment can consist of oils and skin cells shed by the patient, dirt, food residue, and biofilms. The presence of soil decreases the efficacy of some UV disinfection systems.[26, 39]
- The location of the surfaces that require disinfection also varies in the hospital environment. In the laboratory setting, all of the samples are placed a consistent height and distance from the light emitting source. This is not the case in the hospital environment, where the distance of surfaces from the light emitting source varies dramatically. This directly impacts the dose of UV light that these surfaces will receive, and therefore the efficacy of the system on these surfaces.
- The final component that affects the differential efficacy of these systems in the laboratory and hospital environment is the use of reflected UV light for disinfection. Some UV disinfection systems run a single cycle in the room, and claim that reflected UV light will disinfect areas that are not in the direct line of sight. Other systems deploy in multiple positions throughout the room, and increase the number of surfaces exposed to direct light. The reflective qualities of surfaces in the hospital environment vary substantially, and this may reduce the effectiveness of systems that utilize a reflected light strategy.[22]

In order to evaluate the effectiveness of UV disinfection systems in the hospital environment, a review of the literature was conducted to identify studies that performed sampling before and after the use of UV disinfection systems in hospital rooms. To assure that the reductions would be applicable to the actual use of UV disinfection systems, only studies where manual disinfection was performed prior to the use of a UV disinfection system were reported in this analysis. A total of seven studies were identified; two for mercury-based disinfection systems, and five for xenon-based disinfection systems. The total number of colonies present after manual disinfection and then after UV disinfection was abstracted from the identified studies, or was calculated from the presented data. Total bacterial contamination before and after UV disinfection was summed across the studies, and log reductions were calculated, see **Table 2** and **Table 3**. These reductions were then compared for mercury-based and pulsed xenon-based UV systems, see **Table 4**. Pulsed xenon-based systems were found to outperform mercury-based systems in the hospital environment.

Science Compendium [continued]

Table 2. Results of Mercury-Based UV Systems

Study	Cycle Time (minutes)	Pathogen Count Before Disinfection	Pathogen Count After Disinfection	Log Reduction
Heterotrophic Plate Count				
Mahida 2013 [40]	30-40	150	0	2.18
Havill 2012 [41]	73	3,045	518	0.77
HPC Log Reduction		**3,195**	**518**	**0.79**

Table 3. Results of Xenon-Based UV Systems

Study	Cycle Time (minutes)	Pathogen Count Before Disinfection	Pathogen Count After Disinfection	Log Reduction
Heterotrophic Plate Count				
Stibich 2011 [28]	12	2,493	90	1.44
Nerandzic 2015 [26]	10	52,304	612	1.93
Jinadatha 2014 [29]	15	4,490	84	1.73
Hosein 2016 [31]	15	1,398	312.8	0.65
Hosein 2016 [31]	15	3,588	312.8	1.06
Green 2016 [34]	15	212	116	0.26
HPC Log Reduction		**64,485**	**1,527.6**	**1.63**

Table 4. Total Room Log Reduction Comparisons

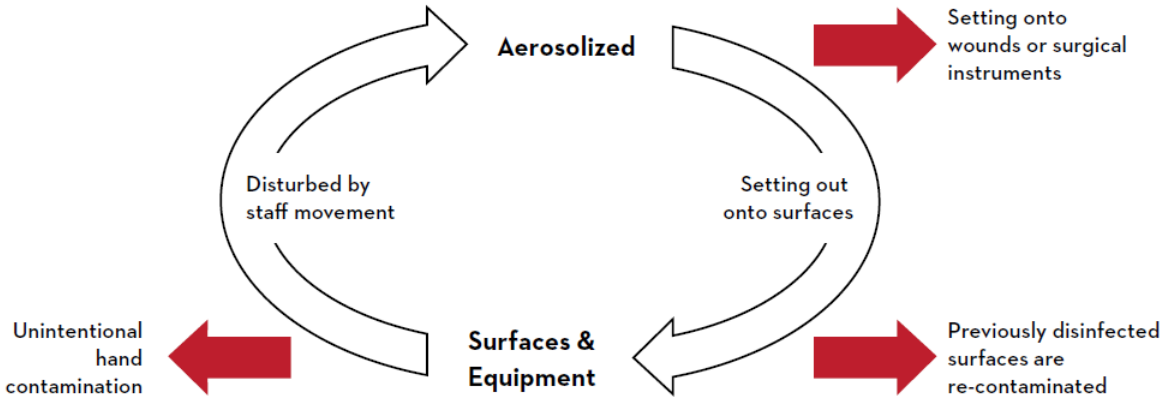
Organism	Time Range (minutes)	Log Reduction	Contamination Reduction Differential
Heterotrophic Plate Count			
Mercury	17-73	0.79	6.84
Xenon	10-15	1.63	

Science Compendium [continued]

APPENDIX B: Using Pulsed Xenon for Disinfection of Operating Rooms

Background: There is growing evidence that the environment plays a role in the transmission of surgical site infections.[42] **Figure 5** shows a proposed mechanism for how this contamination moves from the contaminated surfaces to the patient or the sterile field, leading to the development of an infection. In essence, residual contamination left on surfaces across the surgical suite after manual cleaning can be disturbed and aerosolized by movements of staff members or equipment prior to or during the surgical procedure.[43] These aerosolized particles then settle onto sterile instruments or the sterile field, onto high-touch surfaces leading to hand contamination, or into the surgical wound itself. Even small movements such as the surgeon bending at the waist have been shown to significantly increase the level of aerosolized particles contaminating the sterile surgical field.
[44] The presence of pathogens on surfaces has been shown to increase the contamination rates of hands of healthcare workers, both on bare hands and gloved hands.[45, 46] Edmiston et al. found that air in the operating room was frequently contaminated, and that half of air samples taken within 0.5 meters of the surgical wound showed growth of both pathogenic and opportunistic organisms.[47] In fact, Whyte and colleagues determined that 98% of cultures from incision sites during an orthopedic joint surgery came from airborne bacteria.[48] The relationship between air contamination and surgical site contamination has also been demonstrated in more recent research.[49].

Figure 5. Proposed Mechanisms for Dispersal of Environmental Contaminants Across the Surgical Field



Methods: This study took place across 144 different operating rooms in 23 separate facilities between 2013 and 2016. Surfaces sampled include the anesthesia area, back table, documentation station areas, OR table, OR light, supply cabinets, Pyxis, Bovie, and other miscellaneous items. Three different analyses were performed using the final Colony Forming Units (CFUs) count for each plate:

1. Examination of the difference in mean CFUs after standard terminal clean and after pulsed xenon UV disinfection. Comparison was made using Wilcoxon matched-pairs sign rank test. Comparisons were made for all surfaces combined, and individual surfaces with more than 30 samples collected in each arm. P values of less than 0.05 were considered statistically significant.

Examination of the number of samples with greater than 15 colonies that decrease below 15 colonies following pulsed xenon UV. To do this we counted the number of samples that had 15 colonies or greater growth following manual cleaning. From this sub-set of samples, we identified how many had fewer than 15 colonies following pulsed xenon UV. Comparison was made using a Chi square test. Comparisons were made for all surfaces combined, and individual surfaces with more than 30 samples collected in each arm. P values of less than 0.05 were considered statistically significant.

Science Compendium [continued]

2. Examination of the difference in detectable (positive/negative) CFUs after standard terminal clean and after pulsed xenon UV disinfection. Comparison was made using a Chi square test. Comparisons were made for all surfaces combined, and individual surfaces with more than 30 samples collected in each arm. P values of less than 0.05 were considered statistically significant.

Results: Statistically significant decreases ($p<0.05$) were identified for all three analyses. Results are summarized for each analysis in the tables below for all areas sampled, as well as a sub-analysis for surfaces where more than 30 samples were collected in each arm.

Table 5. Reduction of Total CFU for Surfaces in the Operating Room

Surfaces Sampled	Total CFU (Average CFU) After Manual Disinfection	Total CFU (Average CFU) After PX-UV Disinfection	% Reduction	P-value
Anesthesia Machine	1,802 (12.26)	231 (1.57)	87%	<0.0001
Nurses Documentation Station	2,531 (18.08)	900 (6.43)	64%	<0.0001
Back Table	2,190 (16.10)	195 (1.43)	91%	<0.0001
OR Table	1,987 (16.15)	85 (0.69)	96%	<0.0001
Supply cabinet doors	644 (5.80)	98 (0.88)	85%	<0.0001
Remaining Surfaces	2,578 (34.37)	179 (2.39)	93%	n/a
Grand Total	**11,732 (16.03)**	**1,688 (2.31)**	**86%**	**<0.0001**

Table 6. Percent of Surfaces with >15 CFU after Manual Disinfection and after PX-UV Disinfection

Surfaces Sampled	# (%) of surfaces with >15 After Manual Disinfection	# (%) of surfaces with >15 After PX-UV Disinfection	% Reduction	P-value
Anesthesia Machine	23 (16%)	2 (1%)	91%	0.001
Nurses Documentation Station	29 (21%)	10 (7%)	66%	<0.0001
Back Table	19 (14%)	2 (1%)	89%	<0.0001
OR Table	17 (14%)	0 (0%)	100%	<0.0001
Supply cabinet doors	9 (8%)	1 (1%)	89%	0.001
Remaining Surfaces	28 (37%)	3 (4%)	89%	n/a
Grand Total	**125 (17%)**	**18 (2%)**	**86%**	**<0.0001**

Science Compendium [continued]

Table 7. Percent of Surfaces with any CFU after Manual Disinfection and After PX-UV Disinfection

Surfaces Sampled	# (%) of surfaces with any CFU After Manual Disinfection	# (%) of surfaces with any CFU After PX-UV Disinfection	% Reduction	P-value
Anesthesia Machine	98 (67%)	61 (41%)	38%	<0.0001
Nurses Documentation Station	112 (80%)	63 (45%)	44%	<0.0001
Back Table	84 (62%)	46 (34%)	45%	0.005
OR Table	70 (57%)	34 (28%)	51%	0.007
Supply cabinet doors	77 (69%)	40 (36%)	48%	0.002
Remaining Surfaces	53 (71%)	33 (44%)	38%	n/a
Grand Total	**494 (67%)**	**277 (38%)**	**44%**	**<0.0001**

Conclusion: Using pulsed xenon UV as an adjunct to manual terminal cleaning practices in the OR settings can improve environmental cleanliness, and has the potential to positively impact patient safety. The percent reduction measures on each surface appears to be directly related to the distance of the surfaces from the UV disinfection system. The surface closest to the disinfection system for both disinfection cycles was the OR bed, which also had the greatest reduction in CFU. The back table, anesthesia machine, and supply cabinet doors were only in close proximity to the disinfection system for a single disinfection cycle, and received a second dose of UV light at a greater distance during the second disinfection cycle. This slightly decreased dose of UV light corresponds with the lower reduction in CFU, 91%, 87%, and 85% respectively. Finally the nurse's documentation station the greatest distance from the UV disinfection system for both cycles, and a CFU reduction of only 64% was detected. These results correspond with previously reports of how UV dose and distance between the UV lamp and surface affect the efficacy of UV disinfection systems.[39, 50] Despite the variation in the reported reductions across different surfaces, all the reductions were statistically significant. These results demonstrate that the addition of pulsed xenon disinfection to manual methods for terminal cleaning is a significant improvement over manual methods alone.

Science Compendium [continued]

APPENDIX C: XENEX RETURN ON INVESTMENT

The table below summarized the return on investment at facilities that have published reductions in HAIs after implementing LightStrike. These avoided infections have monetary value that offsets the capital purchase costs associated with pulsed xenon disinfection systems.

Table 8. Review of the Return on Investment for Published HAI Reductions

Study Site	Organism of Interest	Healthcare Setting	Incidence Reduction	Estimated Impact	Number of Robots	ROI
Lowell General Hospital [8]	Class I Surgical site infections (SSIs)	Operating Room	46%	23 fewer cases in 10,883 procedures ($478,055)	2	9 to 1
Trinity Medical Center [9]	Total Hip/Knee SSIs (Class I)	Operating Room	100%	7 fewer cases in 544 procedures ($145,495)	1	10 to 1
Westchester Medical Center [10]	Multiple MDROs	Acute Care	20%	185 fewer cases in 22 months ($3,026,415)	2	60 to 1
Cooley Dickinson Hospital [11]	*C. difficile*	Acute Care	53%	17 fewer cases in 12 months ($191,845)	2	6 to 1
LTAC Facility [12]	*C. difficile*	LTAC	57%	29 fewer cases in 15 months ($327,265)	1	18 to 1
Westchester Medical Center [13]	*C. difficile*	ICU	70%	30 fewer cases in 12 months ($338,550)	2	11 to 1
Cone Healthcare System [14]	MRSA	Healthcare System	56%	58 fewer cases in 18 months ($948,822)	4	13 to 1
Orlando Health South Seminole Hospital [15]	Multiple MDROs; *C. difficile*	Acute Care	61%	39 fewer cases in 22 months ($638,001)	2	12 to 1

Science Compendium [continued]

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2 DISINFECTING PERSONAL PROTECTIVE EQUIPMENT WITH PULSED XENON ULTRAVIOLET AS A RISK MITIGATION STRATEGY FOR HEALTH CARE WORKERS

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Brief report

Disinfecting personal protective equipment with pulsed xenon ultraviolet as a risk mitigation strategy for health care workers

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Key Words:
Environmental disinfection
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Personal protective equipment
Doffing process
Outbreak control
Ultraviolet

The doffing of personal protective equipment (PPE) after contamination with pathogens such as Ebola poses a risk to health care workers. Pulsed xenon ultraviolet (PX-UV) disinfection has been used to disinfect surfaces in hospital settings. This study examined the impact of PX-UV disinfection on an Ebola surrogate virus on glass carriers and PPE material to examine the potential benefits of using PX-UV to decontaminate PPE while worn, thereby reducing the pathogen load prior to doffing. Ultraviolet (UV) safety and coverage tests were also conducted. PX-UV exposure resulted in a significant reduction in viral load on glass carriers and PPE materials. Occupational Safety and Health Administration–defined UV exposure limits were not exceeded during PPE disinfection. Predoffing disinfection with PX-UV has potential as an additive measure to the doffing practice guidelines. The PX-UV disinfection should not be considered sterilization; all PPE should still be considered contaminated and doffed and disposed of according to established protocols.

Low levels of contamination with Ebola virus are sufficient to infect a human host.[1] Personal protective equipment (PPE) protects health care workers by providing a physical barrier when caring for infected patients. However, a risk is created during the doffing of PPE because any error in this detailed process could result in the contamination of the health care worker's hands or other part of their body.[2] Despite training and the use of an observer, 100% proficiency to successfully adhering to the Centers for Disease Control and Prevention's (CDC's) guidelines for PPE doffing cannot be expected at all times.[3,4] Fluorescent powder and other tracers are routinely used during training on the doffing process to demonstrate the presence of human error despite following these guidelines.[5] Furthermore, health care workers may be asked to don and doff PPE that they are unfamiliar with or have not received training on during emergency situations, increasing the likelihood of a doffing error.

This study examines the use of a pulsed xenon ultraviolet (PX-UV; Xenex Disinfection Services, San Antonio, TX) germicidal device as an additional process for disinfecting PPE prior to doffing as a risk mitigation strategy. The goal of this process is to reduce the probability of transmission in the event of a doffing error. PX-UV disinfection has been adopted by multiple hospitals for surface disinfection[6] and has demonstrated a reduction in the infection rates of *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus*, and other multidrug-resistant organisms.[7-9] Ebola virus has

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Conflicts of interest: Ms. Simmons, Mr. Dale, Dr. Stibich, and Dr. Stachowiak are employees and shareholders of Xenex Disinfection Services. All work on this project was governed by the Cooperative Research and Development Agreement between the Central Texas Veterans Health Care System (CTVHCS) and Xenex Healthcare Services. Dr Jinadatha has served as principal investigator on other research projects conducted at CTVHCS, which were funded by Xenex Healthcare Services and governed by the Cooperative Research and Development Agreement between the 2 entities. Dr. Ganachari-Mallappa, Mr. Villamaria, Ms. Goulding, and Dr. Tanner have nothing to disclose.

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Table 1
Effectiveness of PX-UV disinfection on different surfaces inoculated with canine parvovirus

Inoculated surface	Distance (m)	Control (average log per carrier)	Log reduction (relative to respective time zero control)
Glass slide	2	5.98	>4.00
Face shield (PPE)	1	5.98	>4.00
Surgical gown (PPE)	1	5.98	>4.00

PPE, personal protective equipment; *PX-UV*, pulsed xenon ultraviolet.

a known sensitivity to germicidal ultraviolet (UV) light and is much more susceptible than hardy spores, such as *C difficile*.[10,11]

To determine the feasibility of PPE disinfection using PX-UV, the authors examined the following in a laboratory setting: (1) the effectiveness of PX-UV disinfection against an Ebola surrogate virus on a dry inanimate surface; (2) the effectiveness of PX-UV disinfection against PPE material inoculated with an Ebola surrogate virus; (3) the level of UV exposure for a person wearing PPE; and (4) the distribution of germicidal light coverage on PPE.

MATERIALS AND METHODS

The CDC and Environmental Protection Agency (EPA) recommend the use of hospital disinfectants with label claims for a nonenveloped virus (eg, norovirus, rotavirus, adenovirus, poliovirus) to disinfect environmental surfaces in rooms of patients with suspected or confirmed Ebola virus infection.[12] Canine parvovirus (ATCC VR-2016), a nonenveloped virus not infective to humans, was selected as the surrogate organism for this research because it meets the CDC's and EPA's recommendations and was safe to the researchers involved in this study. The virus was diluted to obtain a target density of 5-6 $\log_{10}$ per 0.02 ml and was then supplemented with heat-inactivated fetal bovine serum to a concentration of 5.0% to simulate typical amounts of protein loading. Glass carriers were inoculated with 0.02 ml volume in triplicate with triplicate controls and exposed to PX-UV for 5 minutes at 2 m.

For PPE disinfection, a plastic face shield (T5 hood with face shield; Stryker, Kalamazoo, MI) and a fluid-resistant gown (MicroCool gown; Kimberly-Clark, Irving, TX) were used as hard and soft surface samples. Two and a half centimeters square segments were cut from the surgical gown and face shield and affixed onto glass carriers. As described previously, samples were inoculated in triplicate with triplicate controls with the same volume and concentration of viral solution. All samples were dried completely, allowing the solution to soak into the absorbent material of the gown. Exposure was for 5 minutes at a 1-m distance from the PX-UV system.

Samples were harvested into a neutralization medium (2% fetal bovine serum Eagle's minimal essential medium), serially diluted, and plated onto host cells (dog tumor cells, ATCC CRL-1542). Plates were incubated for 6 days, and a secondary hemagglutination assay was performed to confirm the presence or absence of virus.

To determine the potential UV exposure to a health care worker through PPE, a spectrometer (USB2000 + XR; OceanOptics, Dunedin, FL) was used to determine the amount of UV light that penetrates the PPE material when it is 1 m away from the UV source. PPE should be worn according to well-accepted published protocols, with full coverage of skin and eyes.[13] Final readings were compared with published standards of UV exposure limits recommended for safety purposes.[14]

UV photochromatic stickers were placed on specific areas of the PPE to assess light distribution: clavicle area, shoulders, arms, chest, back, hips, legs, and shoe covers. The stickers were qualitatively assessed for color change to indicate a sufficient dose of germicidal UV light. The photochromatic stickers were used to assess reflectors designed to shorten the exposure time by collecting and redirecting light being emitted from the opposite side of the disinfection system.

RESULTS

Glass carriers, face shield, and gown material at 5.98 log per carrier demonstrated a >4.00 log reduction relative to respective time zero controls. Negative cell culture controls demonstrated no cytopathic effects (Table 1).

The spectral readings for UV light passing though the face shield and gowns were less than established UV exposure limits. The addition of the reflector allowed for increased redirection of light toward the person and effectively reduced the exposure time for PPE disinfection by half.

DISCUSSION

These results indicate that UV disinfection can be used to reduce the contamination levels of nonenveloped viruses in a controlled experimental environment on PPE material. This preliminary safety and effectiveness data could lead to further research investigating applications that include real-world PPE contamination of nonenveloped viruses, especially Ebola. To our knowledge, this is the first study where PX-UV disinfection has been shown to be effective on nonenveloped virus-contaminated PPE material. The distribution of UV light throughout the PPE, especially when used in conjunction with the UV reflector, provided useful information and should be a consideration in future research. Photochromic stickers, if placed prior to UV exposure, may be a method of validation of UV dose for use in real-world settings.

Prior to conducting experiments where study personnel would be in the same room with a functioning device, UV exposure measurements were taken through the PPE material to assure that personnel were not at risk. The study personnel who wore the PPE and stood in front of the device reported no adverse symptoms related to noise of the device or the light from the PX-UV bulb. Heat stress could be a factor during this process; however, the individual exposed to the process did not report excessive discomfort. Additional studies should consider multiple raters of brightness, sound, and heat factors during the process of PX-UV disinfection.

Whether PX-UV is similarly effective in reducing Ebola virus load on PPE, the extent to which bodily fluids obstruct the PX-UV efficacy, and whether this process leads to a decrease in transmission are future areas of investigation. Of course, these questions may be unanswerable because of the extreme rarity of Ebola transmission in the health care setting in the United States and the justifiably limited access to the Ebola virus for research purposes. Because the CDC and EPA have recommend hospitals using nonenveloped virus claims to be adequate markers of effectiveness against Ebola, we believe this preliminary data could be used by facilities interested in exploring additional decontamination methods.

It is well-documented that doffing is a risky process with the potential for causing infection. Hence, adding UV disinfection to the doffing process has the potential to provide an additional layer of safety for health care workers based on the data provided here. However, proper PPE selection, donning practices prior to patient care, and proper doffing processes are paramount to patient safety and cannot be compromised. Training on and adherence to established practices is the first priority for safety.

The addition of PX-UV disinfection does not replace any of the existing steps associated with doffing PPE, and special care should be taken with degloving because fluids on gloves may inhibit PX-UV disinfection. After PX-UV exposure, all PPE should still be treated as though it is contaminated and doffed and disposed of

according to the most current CDC protocol. No disinfection system will be able to completely eliminate the risk associated with doffing contaminated PPE.

Furthermore, only PX-UV disinfection has been validated in this study. We did not test low-pressure mercury-based germicidal light disinfection technology. More research into the uses of the PX-UV addition into any Ebola containment protocol could provide additional insight into these preliminary findings.

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3

XENEXFULLSPECTRUM™PULSE DXENON–UV DISINFECTION FOR SURFACES POTENTIALLY EXPOSED TO HIGH-RISK PATHOGENS

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The Xenex Full Spectrum™ Pulsed Xenon UV Robot ("Xenex Robot") has been documented to be effective against non-enveloped viruses. The 2014 CDC Guidance cited a study suggesting that Ebola virus was found, relative to other enveloped viruses, to be quite sensitive to inactivation by ultraviolet light and drying, suggesting that Xenex can be an important supplement to traditional hospital disinfectant measures in situations where exposure to high-risk pathogens is possible.

To accomplish the above, Xenex has created this protocol, which will allow for the disinfection of multiple areas within a healthcare facility. This as an additive approach that provides an important extra layer of assurance to existing environmental hygiene protocols and other practices. In all cases, current disinfection standards should be met or exceeded.

Customization of the protocols to individual situations and facilities may be achieved through contacting Xenex.

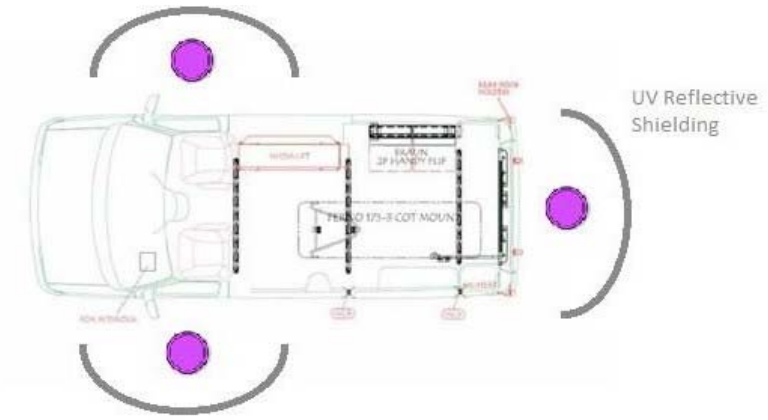
The protocols below cover ambulances, emergency department exam rooms and public areas, trauma rooms, patient rooms, and equipment. Unless specified otherwise, all cycle times are 10 minutes.

NOTE: The included protocol only applies to the Xenex Full Spectrum Pulsed-UV Robot. The Xenex team cannot recommend the use of this protocol for other UV systems.

PATIENT ARRIVAL

AMBULANCE:

• After gross decontamination of the transporting ambulance, expose all high-touch surfaces such as drawer and cabinet handles.



Place the Xenex Pulsed UV robot at the rear of the ambulance, with the doors open. A UV reflective shield (Xenex - patent pending) can be added to optimize the distribution of the UV and to keep UV light isolated from the surrounding area and people. If available, position the reflective shield to enclose the robot and direct the UV light into the back of the ambulance.

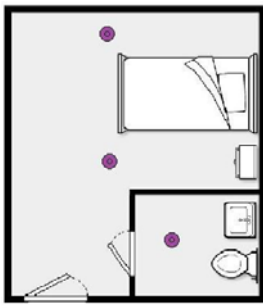
After the reflective shield is positioned, run one cycle. Place the robot on the driver's side with the door open for one cycle, and the passenger's side with the door open for one cycle, similarly positioning the reflective shield to contain the UV light and direct the maximum amount of light into the ambulance.

NOTE: If no reflective shield is available on-site, this procedure can still be performed following the same

protocol. Eye protection of any persons present in the disinfection area is required in the absence of a reflective shield. The typical PPE eye protection is adequate to block the UV light.

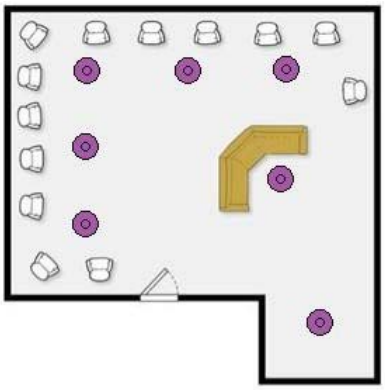
EMERGENCY ROOM ADMISSION AND CARE

Patient Care Room



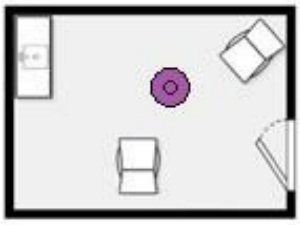
- When the patient has been transferred from the care area to an inpatient room, the care area should be manually disinfected per hospital protocol.
- After disinfection, the room should receive three ten-minute cycles of UV disinfection.

Considerations for PublicAreas

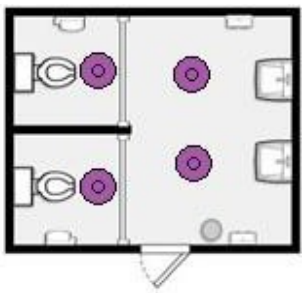


Not all patients will arrive via ambulance, or be immediately identified as a potential case. In these situations, common areas of the emergency room may become contaminated.

- **Waiting rooms** should be disinfected as soon as it becomes known that a potentially infectious patient was in the area. A full manual disinfection of the area should be performed, followed by multiple cycles of UV light. The number and placement of the cycles will be determined by the size and geometry of the area.



- **Triage areas** are typically used for initial screening, and have a high volume of patients entering and exiting throughout the day. Use of these areas by suspected patients should be avoided if possible. If an infectious patient is cared for in one of these rooms, it should be manually disinfected and treated with UV as soon as possible.

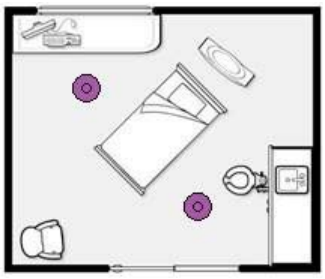


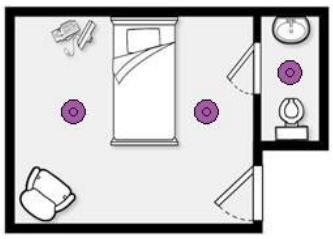
- **Public restrooms** should be disinfected if they were used by an infected patient. The number and location of the cycles will depend on the configuration of the restroom.

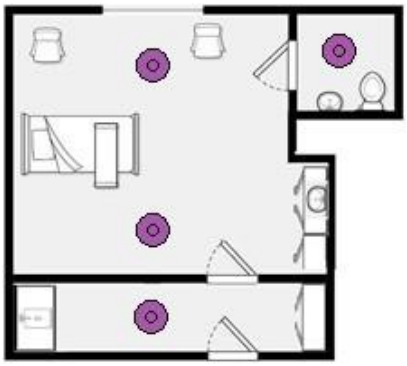
INPATIENT ADMISSION AND CARE

Patient Care Room

- When the patient has been transferred out of the inpatient room, the care area should be manually disinfected per hospital protocol. After disinfection, the room should receive two cycles of UV disinfection, and additional cycles in the separate bathroom, and anteroom, if one exists.







FINAL ROBOTDECONTAMINATION:

Once the decontamination room is no longer needed, the robot should be disinfected on all exterior surfaces using an EPA registered disinfectant with a non-enveloped virus claim. Special attention should be paid to the handle and touchscreen. The wheels should also be rolled through disinfectant solution. Once this has been completed, place the robot in a room and run a 10 minute cycle. The same process should be used after a robot has been used to disinfect patient care areas.

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