Evaluating Disinfection Technologies for Improved Healthcare Outcomes

Critical environmental & functional considerations

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The healthcare industry has grappled with the issue of healthcare associated infections (HAIs) for years, which has been a catalyst for [healthcare] facilities exploring and adopting the safest, most effective technologies to kill pathogens. Statistics reveal the magnitude of this issue: 1 in 31 hospitalized patients have at least one HAI at any given time, with more than 680,000 infections resulting in billions of dollars in related costs across the U.S. annually [1,2]. Reducing HAIs improves patient safety, combats antimicrobial resistance and its complications, and reduces healthcare costs.

Whole Room Disinfection

Achieving whole room disinfection poses a universal challenge across various settings. The necessity for this disinfection varies significantly from one environment to another, as do the obstacles encountered in its execution. Each context presents unique disinfection considerations. Addressing these diverse challenges is paramount to ensuring the safety and well-being of patients, caregivers, and visitors alike.

The environment plays a critical role in the transmission of disease, with contaminated surfaces and air serving as potential reservoirs for pathogens. Inadequate room disinfection can exacerbate the problem by allowing pathogens to spread, leading to increased rates of HAIs[3]. Therefore, implementing rigorous disinfection protocols is essential to mitigate the risk of transmission.

While all forms of disinfection are nominally beneficial, whole room disinfection systems are engineered and optimized for specific applications. Combined efficacy, safety, and lifecycle costs make them inherently better for some applications than others. Areas within the hospital where infection control is of utmost concern include Operating Rooms (ORs), Emergency Departments (EDs), Patient Rooms, Sterile Processing Departments (SPDs), Pharmacies, Dialysis Units, and other high-traffic areas. Examining each of these settings—and their challenges—will help determine the most effective cleaning protocol for whole room disinfection.

Operating Room (OR)Challenges

1. *Complex Surfaces:* ORs typically contain a variety of complex surfaces with crevices that make thorough cleaning and disinfection difficult.
2. *Accessibility:* Areas within the OR may be difficult to access, making comprehensive disinfection of all areas challenging.
3. *Time Constraints:* ORs often have limited time between surgeries, reducing the thoroughness of disinfection and increasing the risk of inadequate cleaning.
4. *Compatibility of Disinfectants:* Certain medical equipment and surfaces may be sensitive to chemical disinfectants, which limits the disinfection methods used or requires additional steps be taken to ensure effectiveness.
5. *Microbial Resistance:* Some pathogens, such as MRSA and VRE, are highly resistant to standard disinfection methods. Specialized approaches may be necessary to effectively eliminate these resistant organisms.
6. *Human Factors:* Effective disinfection relies on adherence to proper cleaning protocols, making training, supervision, and compliance monitoring essential.
7. *Validation of Disinfection Efficacy:* Verifying the effectiveness of disinfection involves monitoring programs, such as surface sampling and microbial testing to assess its adequacy.
8. *Size:* ORs are typically 400-600 sq ft, with some rooms exceeding 800 sq ft. This requires solutions to be deployed at multiple points throughout the room to ensure full coverage.

1. Centers for Disease Control and Prevention. (2020). Healthcare-Associated Infections Data Portal. Retrieved from https://www.cdc.gov/hai/data/portal/index.htmlThis link is external to health.gov.
2. Magill, S.S. et al. (2018). Changes in Prevalence of Health Care-Associated Infections in U.S. Hospitals. New England Journal of Medicine, 379, 1732-1744. DOI: 10.1056/NEJMoa1801550.
3. Dancer SJ. Controlling hospital-acquired infection: focus on the role of the environment and new technologies for decontamination. Clin Microbiol Rev. 2014 Oct;27(4):665-90.

Emergency Department (ED) Challenges

1. *High Patient Volume:* The ED typically sees a high volume of contagious or infectious patients. The rapid turnover makes it challenging to thoroughly clean and disinfect treatment areas between visits.
2. *Irregular Operating Hours:* The ED operates 24/7, experiencing daily fluctuations in patient volume and staffing levels. This poses challenges for maintaining consistent disinfection practices, increasing the risk of environmental contamination and transmission of infections. Developing flexible cleaning schedules to accommodate fluctuations in patient flow and staffing levels is crucial to ensuring effective disinfection in the ED.
3. *Urgent Care Requirement:* Patients in the ED often require immediate medical attention, leaving little time for thorough disinfection between patients. Healthcare workers must balance the need for prompt treatment with the necessity of maintaining a safe environment.
4. *Varity of Patient Conditions:* The ED treats patients with a variety of medical conditions. Each patient may present unique disinfection requirements based on their condition, increasing the complexity of cleaning protocols.
5. *Movement of Patients and Staff:* Patients and staff frequently move throughout the ED, increasing the likelihood of spreading pathogens. Effective disinfection strategies must support this dynamic movement.
6. *Limited Space and Resources:* In many EDs, treatment areas are shared among multiple patients simultaneously, increasing the risk of cross-contamination. Many EDs are also in tight spaces with limited resources and storage space for cleaning supplies and equipment, which hinders effective cleaning practices. Moreover, some disinfecting technologies require trained personnel and the space be cleared for a specified period, which presents logistical challenges.

Patient Room Challenges

1. *Occupancy:* Patient rooms are typically occupied, making it challenging to perform thorough disinfection without disruption. Healthcare workers must balance the need for cleanliness with patient comfort, privacy, and safety.
2. *Time constraints and Patient Turnover:* Patient rooms require thorough disinfection within limited timeframes due to patient turnover. Extended stays increase the risk of environmental contamination and pathogen transmission. Additionally, some disinfecting techniques necessitate clearing the room, rendering it temporarily unavailable for use. Balancing the need for effective disinfection with timely room turnover presents a significant challenge, requiring careful coordination and efficient cleaning protocols.
3. *High Touch Surfaces*: Patient rooms contain numerous high-touch surfaces frequently contaminated with pathogens, therefore requiring thorough disinfection to prevent the spread of infection.
4. *Complex Layouts:* Patient rooms often have complex layouts, making it difficult to access and disinfect all areas effectively, increasing the likelihood of missed spots during routine cleaning.
5. *Sensitive Equipment:* Patient rooms often contain sensitive medical equipment, which requires special care during disinfection to avoid damage or malfunction.
6. *Variety of Materials:* Patient rooms contain a variety of materials that require specific cleaning and disinfection methods to avoid causing damage.

Sterile Processing Department (SPD) Challenges

1. *Complex Instrumentation:* SPDs process a wide variety of intricate and specialized medical instruments, requiring meticulous attention to detail and knowledge of manufacturer guidelines to prevent damage or contamination during cleaning.
2. *Biofilm Formation:* Medical instruments used in surgical procedures are susceptible to biofilm formation, which can be resistant to conventional disinfection methods, necessitating specialized cleaning techniques to remove them effectively.
3. *High Volume of Instruments:* SPDs handle a high volume of instruments daily. Processing them within limited timeframes can strain resources and increase the risk of errors or oversights during disinfection procedures.
4. *Variety of Contaminants:* Medical instruments may be contaminated with a wide range of biological and chemical substances. Effective disinfection protocols must address these diverse contaminants while ensuring the instruments' integrity.
5. *Compatibility with Sterilization Methods:* Disinfection processes in SPDs must be compatible with the sterilization methods used to ensure the efficacy of the overall sterilization cycle, without damage to instruments.
6. *Regulatory Compliance:* SPDs must adhere to stringent regulatory standards governing the sterilization and disinfection of medical instruments. This requires ongoing training, documentation, and quality assurance measures to ensure disinfection safety and effectiveness.
7. *Preventing Cross-Contamination:* Proper segregation and handling of contaminated and clean instruments is essential to prevent cross-contamination in SPDs. Effective disinfection protocols must minimize the risk of transferring pathogens between instruments and ensure the maintenance of sterile conditions throughout the processing workflow.

Hospital Pharmacy Challenges

1. *Sterile Compounding Areas and Equipment:* Hospital pharmacies have specialized areas for sterile compounding where medications are prepared under strict aseptic conditions. This compounding equipment must be thoroughly disinfected between use to prevent cross-contamination and ensure the safety of compounded medications. Any lapse in disinfection protocols in these critical areas can lead to serious patient harm.
2. *High-Touch Surfaces:* Like other areas of the hospital, pharmacies have numerous high-touch surfaces that serve as reservoirs for pathogens and require frequent disinfection to prevent the spread of infection. Proper disinfection of compounding equipment is essential for maintaining sterility and preventing microbial contamination of compounded medications.
3. *Regulatory Compliance:* Pharmacies are subject to strict regulatory standards governing medication storage, handling, and dispensing. Compliance with these regulations requires robust disinfection protocols and detailed documentation of cleaning activities to demonstrate adherence.
4. *Emergency Preparedness:* Pharmacies must be prepared to respond quickly and effectively to public health emergencies; therefore, disinfection protocols must be adaptable to rapidly changing circumstances, prioritizing the safety of pharmacy staff and patients in emergent situations.
5. *High-Traffic Area:* The pharmacy can be a high-traffic area. Contamination can be brought into these areas from other, less sterile areas and subsequently transferred to the sterile core where compounding is performed.

Infusion Center Challenges

1. *High Infection Risk:* Dialysis and chemotherapy patients often have compromised immune systems, making them more susceptible to infection. The proximity of patients during treatment sessions increases the risk of cross-contamination and transmission of pathogens within the facility.

2. *Complex Equipment and Settings:* These centers are equipped with specialized medical devices that require thorough disinfection between patient use. The complexity of equipment and settings poses challenges for effective disinfection; improper cleaning can lead to the accumulation of biofilm and microbial contamination.

3. *Chemical Hazards:* In chemotherapy infusion centers, handling hazardous drugs presents an additional challenge. Chemotherapy drugs are toxic substances requiring special handling and disposal procedures to minimize exposure and contamination risks for both patients and healthcare workers.

4. *Patient Isolation and Precautions:* Some chemotherapy patients require isolation precautions due to their immunocompromised status or treatment regimen. Dialysis patients may also require isolation if they are infected with bloodborne pathogens. Disinfection protocols must address the unique challenges of maintaining isolation and preventing cross-contamination between patients receiving treatment.

5. *Regulatory Compliance:* Dialysis and chemotherapy infusion centers are subject to strict regulatory standards governing infection control and patient safety. Compliance requires adherence to established disinfection protocols, documentation of cleaning activities, and regular inspections to ensure the facility meets regulatory requirements. Patients in these locations will have a port (dialysis) or fistula (hemodialysis) that penetrates the skin barrier and acts as a potential port of entry. The consequences of an infection can be severe, particularly in the case of hemodialysis where the fistula has direct, central-line access. Equally important, these treatments often take hours to perform, leaving the patient in a potentially compromised environment during that time.

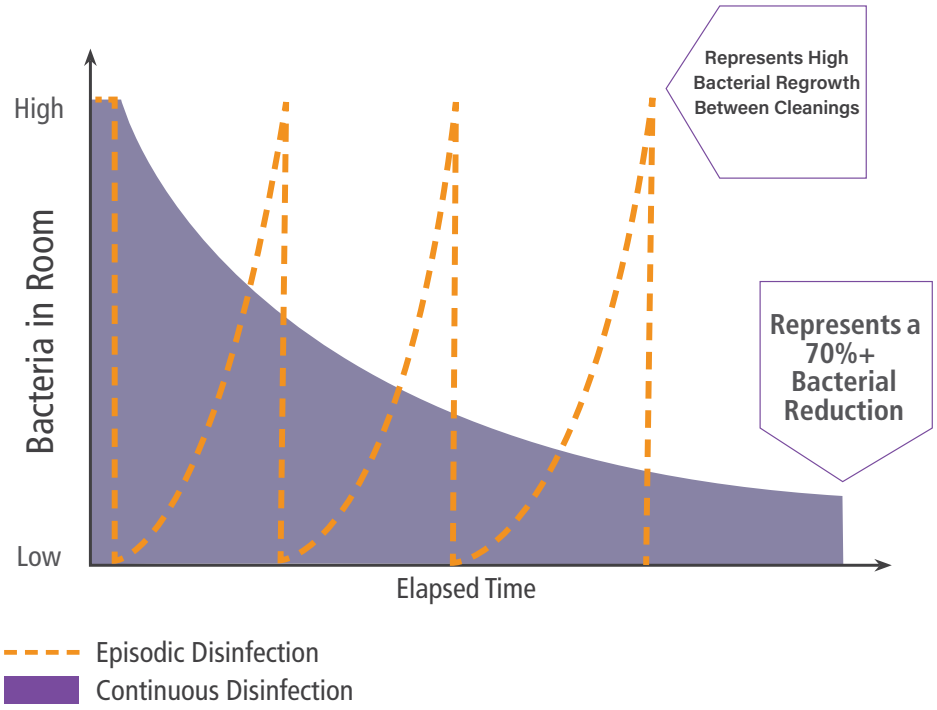
Healthcare facilities must adhere to strict infection control protocols to prevent the spread of HAIs, including specific and consistent disinfection requirements and procedures. Ensuring healthcare staff are properly trained in disinfection protocols and consistently adhere to them is crucial for effective room disinfection. Staff turnover and varying levels of compliance impact overall cleanliness throughout the facility.

Addressing these challenges requires a comprehensive approach that combines appropriate disinfection methods, effective training and education for staff, careful planning and scheduling, and ongoing quality assurance to ensure the highest standards of infection control in healthcare environments.

Therefore, a complementary approach using a whole room disinfection system to remove contamination missed during routine cleaning represents an improved protocol. Simultaneously, these systems have inherent tradeoffs that may not be immediately apparent to decision makers and hospital staff. These tradeoffs typically involve efficacy, safety, room usage, operational costs, and compliance training. Given the range of potential uses, no single choice is the best for each user and/or application. Disinfection options are often delineated by their intervals of delivery: continuous versus episodic.

Disinfection Technology Options: Continuous versus Episodic Disinfection

Continuous and episodic disinfection are two approaches to controlling the spread of pathogens in various healthcare environments.



Continuous disinfection involves the ongoing application of disinfectants to prevent the growth and spread of pathogens. This approach aims to maintain a consistently low level of microbial contamination, reducing the risk of infection. Continuous disinfection methods include:

- **Air filters** providing continuous disinfection by neutralizing airborne pathogens, helping to maintain a cleaner and safer indoor environment.
- **Chlorine-based disinfectants** are commonly used in water treatment to kill or inactivate pathogens.
- **Ozone treatment** uses a powerful oxidizing agent to disinfect water and air by destroying microorganisms and organic contaminants.
- **Antimicrobial agents** inhibit microbial growth on some surfaces.
- **Antimicrobial aerosols,** such as hydrogen peroxide, play a crucial role in continuous disinfection strategies, effectively targeting a wide range of pathogens to maintain a hygienic environment. These can be unsafe for room occupants depending upon the concentration used.
- **405 nm visible light disinfection** is clinically shown to continuously reduce microbial load in various room settings, while being safe for room occupants.

Episodic disinfection involves the intermittent application of disinfectants to reduce microbial contamination. This approach is typically used to augment routine cleaning, or in response to specific events, such as contamination or outbreaks of infectious diseases. Episodic disinfection methods include:

- **Fumigation or fogging** of disinfectant sprays, dispersed as mists or aerosols, to disinfect large or hard-to-reach spaces.
- **Surface disinfection** involves manually cleaning using disinfectant wipes, sprays, or solutions.
- **Thermal disinfection** uses heat treatment, such as steam cleaning or hot water washing, to disinfect surfaces.
- **UV-C (ultraviolet) light disinfection,** while effective at inactivating bacteria, viruses, and other microorganisms by damaging their DNA or RNA, thereby preventing replication, poses risks to human health.

Both continuous and episodic disinfection play important roles in preventing the spread of infectious disease. The choice of method depends on factors such as the specific environment, pathogens present, regulatory requirements, and resource availability.

Fixed UV-C Versus 405 nm Visible Light

This table presents a comparison of UV-C and 405 nm visible light disinfection based on disinfection mechanism, safety, and operational considerations:

Aspect	405nm Visible Light Disinfection	UV-C Disinfection
Safety	Safe for room occupants under continuous use with no known adverse effects to human health.	Poses risks to human skin and eyes if not properly shielded.
Operations	Room can be in use during disinfection.	Room is typically vacated during disinfection.
	Ceiling mounted & disinfects automatically, no need for trained personnel. Eliminates compliance issues.	Trained personnel required for operation. Potential compliance issues.
	Safe, seamless & automatic integration of continuous disinfection into daily operations.	Requires scheduled downtime for intermittent disinfection.
	Useful in areas that must remain operational 24/7.	Useful in outbreak or terminal cleaning applications.
Disinfection Mechanism	Generates Reactive Oxygen Species (ROS) by targeting pathogenic Porphyrin to neutralize pathogens. Reaches high percentage of disinfection in a few hours.	Damages pathogen DNA, preventing replication. Reaches high percentage of disinfection in minutes.
Pathogens Targeted	Specific bacteria and viruses, including ESKAPE organisms*.	Effective against a wide range of pathogens.
	Sporicidal claim: 70%+ under specified conditions.	Sporicidal claim: 99%+ under specified conditions.
	Kills organisms in the air & on surfaces throughout the room, kills in shadowed areas via emitted light scattering in all directions.	Requires line of sight to disinfect – effective only where the UV light hits directly.
Contact Time	Results achieved in hours to days.	Results achieved in minutes to hours.

**ESKAPE pathogens are responsible for ~90% of HAIs. This group includes Enterobacter aerogenes, Staphylococcus aureus, Klebsiella pneumonia, Acinetobacter baumannii, Pseudomonas aeruginosa, and Enterococcus faecalis.*

Although both approaches show different degrees of effectiveness, both face challenges in clinical validation and infection prevention outcome data collection given the generally low rates of infection, which are statistically challenging to validate. Further complicating this assessment is the complexity of healthcare environments and the multitude of variables involved in patient outcomes. As such, it is important for potential users of these systems to examine evidence from contamination reduction in occupied room settings, demonstrating the potential benefit of each.

While all forms of whole room disinfection have their advantages, the room's application will often determine the best technology choice. For example, 405 nm visible light disinfection is ideal for highly occupied rooms where an increased risk of infection exists, such as the operating room. By comparison, in a room-turn over or outbreak scenario, UV-C is typically a better option due to its lower contact time.

Key Considerations When Selecting a Whole Room Disinfection System

When choosing a whole room disinfection system for healthcare facilities, several considerations are key to optimizing efficacy, safety, automation, and lifecycle costs, while minimizing room downtime.

Efficacy: Continuous disinfection methods, such as 405 nm visible light, provide ongoing protection measured over a 24-hour cycle. Episodic methods, like UV-C, offer high efficacy in the short term but regrowth occurs between applications, complicating a direct comparison between the two technologies.

Safety: The safety of patients and staff is paramount. Continuous systems, like 405 nm visible light, pose no known risks to human health and thus are safe for continuous use in occupied rooms. By contrast, UV-C systems pose documented risks to human skin and eyes if not properly shielded, therefore the room must be unoccupied or removed from service to prevent harmful exposure during UV-C use.

Automation: Automated systems minimize human involvement, thereby improving safety and efficacy. For instance, 405 nm visible light systems can be seamlessly mounted into the ceiling, operating automatically without the need for trained personnel, thereby eliminating compliance concerns. In contrast, episodic systems necessitate training and require the space be cleared, rendering the room unusable during disinfection. Additionally, due to labor shortages, trained staff may be unavailable. In these instances, the significant capital investment in a portable device is wasted due to the absence of labor to operate it.

Lifecycle Costs: Consideration of lifecycle costs is crucial: labor, consumables, software, and maintenance expenses. The labor required to operate and maintain a system is important to identify, as this "soft" cost can easily exceed the cost of the hardware over its lifecycle. UV consumables, such as bulbs or light sources, including labor for their replacement, possibly rolled into a maintenance contract, represent a significant cost. By comparison, 405 nm visible light disinfection can last 10 years without the need for a maintenance agreement.

Room Downtime: Integration with room operations is vital to minimize downtime and disruption to facility workflow, particularly in an operating room, which provides most of a hospital's revenue via elective surgeries. Continuous systems, such as 405 nm visible light, seamlessly integrated into daily operations for use in occupied rooms, eliminates the need for room downtime. In some cases, UV-C can be deployed at day's end in a terminal cleaning application, or between patient room admissions, to minimize disruption. However, this creates the potential for re-contamination prior to next use.

Selecting the right whole room disinfection system requires careful consideration of efficacy, safety, automation, lifecycle and operational costs relative to specific application requirements. Light-based disinfection technologies, such as 405 nm visible light, are increasingly recognized as effective tools for reducing pathogen transmission and are complementary to traditional environmental cleaning protocols.

While there are numerous manufacturers of UV-C technology with varying degrees of clinical evidence and certification, only one manufacturer has successfully commercialized 405 nm technology, providing clinical evidence to demonstrate its effectiveness in pathogen and SSI reduction: Indigo-Clean by Kenall Manufacturing.

Indigo-Clean®

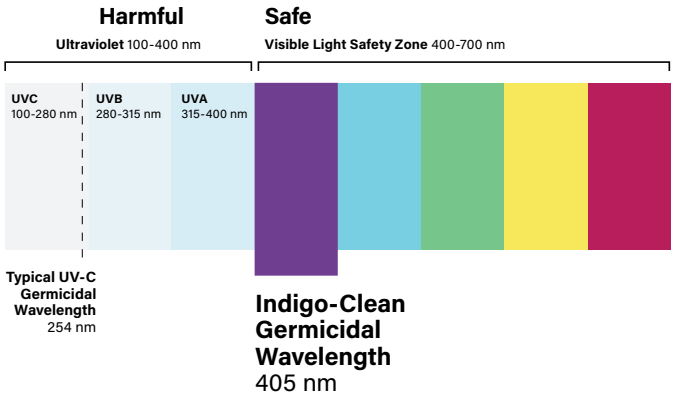
Indigo-Clean A Revolutionary 405 nm Visible Light Disinfection System

Indigo-Clean represents a breakthrough in continuous disinfection, harnessing the power of 405 nm visible light to combat harmful viruses and bacteria. Seamlessly integrated into ceiling mounted luminaires, this patented solution operates around the clock, safely and automatically, eliminating pathogens in the air and on surfaces. Unlike traditional disinfection methods, Indigo-Clean requires no special training, additional staff, or consumables to operate efficiently.

By emitting 405 nm light, Indigo-Clean reflects off walls and surfaces to target and neutralize pathogens, reaching the many shadowed areas routine cleaning often misses. The 405 nm light targets and excites naturally occurring molecules within the pathogens called porphyrins, producing intra-cellular Reactive Oxygen Species (ROS). Similar to bleach, these ROS create an oxidative environment within the organism, inactivating it and preventing it from re-populating the space.

The key to successfully deploying this technology involves three key factors:

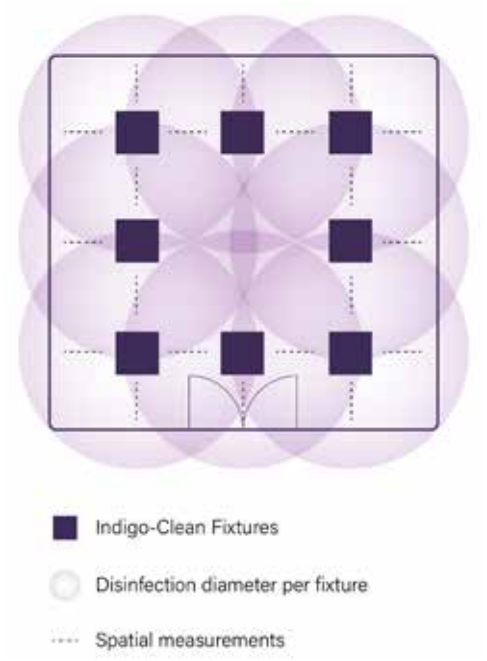
- Optimal disinfecting wavelength
- Irradiance
- Room Dosing



Optimal Disinfecting Wavelength – The biological process initiated by the absorption of "405 nm" light can be improved by more closely matching the center wavelength of the LEDs to the length of the chemical bond in the target porphyrin molecules. Kenall identified this early in the technology's research and development and has optimized its LED spectrum to a similar, but different wavelength "near" 405 nm. This makes Indigo-Clean different from other manufacturer's 405 nm products and is a key reason why implementation of this technology has superior clinical results. This approach maximizes the per-photon efficacy and is vital to disinfecting challenging organisms such as *C.diff*

By comparison, although many UV-C manufacturers utilize custom spectra, they still refer to their product as "UV-C." Each category of UV products asserts their own claims and usage guidelines.

Irradiance – The second factor essential to effective clinical use of the technology is the concentration—or irradiance—of light. This parameter, measured in mW/cm2, is critical to achieving a given level of disinfection over a set period. For challenging organisms like *C. diff*, this is the basis for a sporicidal claim, much like UV-C manufacturers use in similar applications. Initial testing done on a non-sporicidal product by Rutala, et. al[4] showed the ability to reduce *C. diff* using extended contact times. Subsequent 405 nm testing has shown that a product designed for sporicidal applications can continuously reduce *C. diff* by 70% in areas such as patient bathrooms, a common location for this pathogen. Indigo-Clean is the only commercially available product with a meaningful sporicidal claim backed by actual third-party test data.



Room Dosing – The final consideration crucial to effective clinical use is understanding the dose required over a given period to achieve a clinically observable result. The result is typically bacterial reduction, however, under specially controlled conditions, a difference in SSIs may also be observed. Indigo-Clean is the only product supported by multiple studies performed in occupied ORs demonstrating a reduction in contamination. It's also the only product that has shown a reduction in SSIs over a 1-year period. This result was achieved by quantifying the amount of indigo light in the room over a 24-hour period, and indexing it to laboratory and observed bacterial reduction. This patented algorithm has been used in numerous subsequent studies pending publication.

While less relevant than the significant reduction in HAIs, Indigo-Clean is the only product shown to be effective against enveloped viruses, such as SARS-CoV-2 and Influenza A, in a manner equivalent to actual clinical use. This deep technical understanding of the technology is fundamental to its successful clinical deployment, highlighting why all 405 nm, as well as UV-C products, are not created equal.

4. Gould CV, File TM Jr, McDonald LC. Causes, Burden, and Prevention of Clostridium difficile Infection. Infect Dis Clin Pract (Baltim Md). 2015

Key Benefits of Indigo-Clean

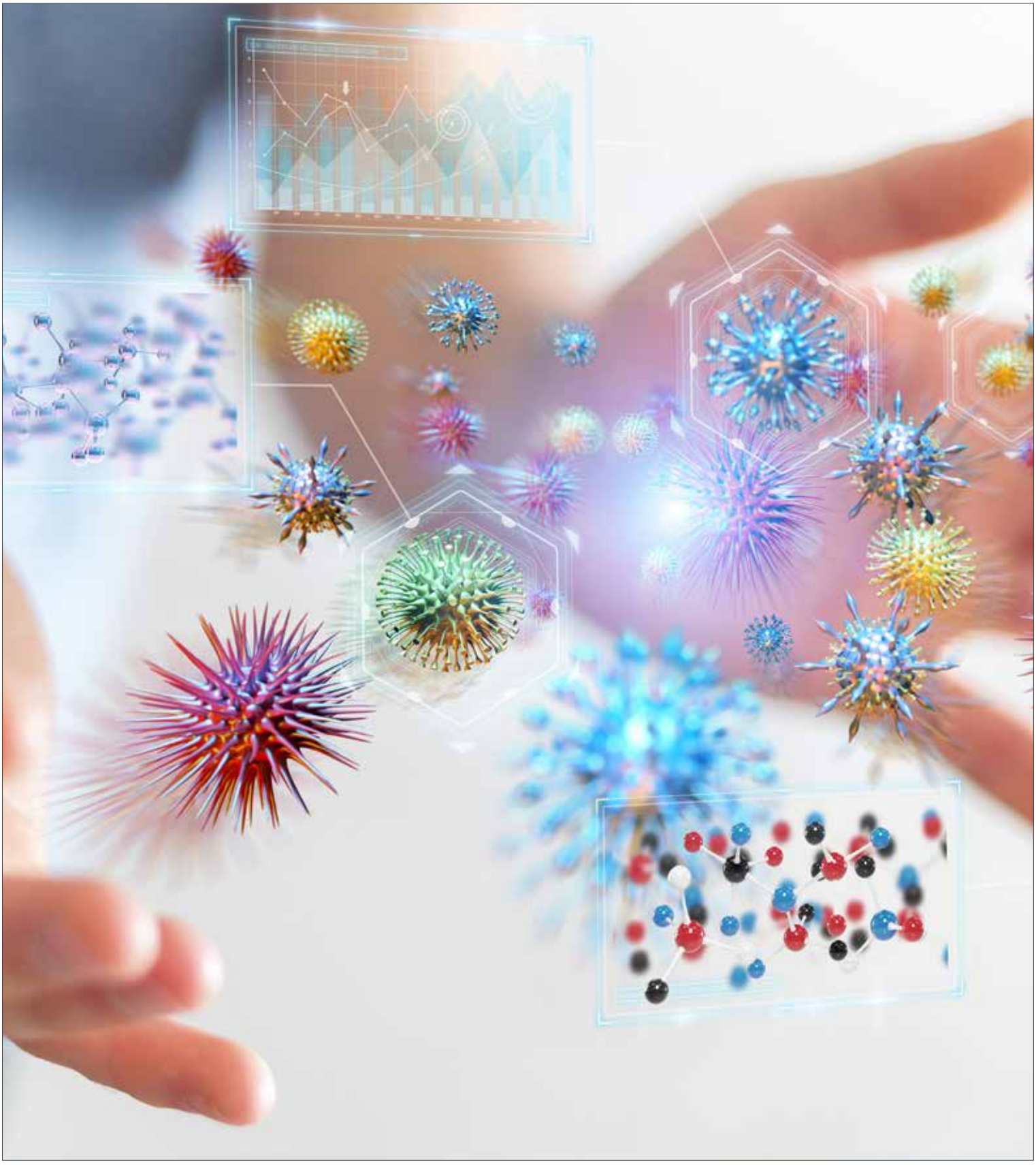
Eliminates room turnover costs
Indigo-Clean not only reduces the transmission of organisms within patient rooms during procedures but it also eliminates room turnover costs. With a one-time installation cost comparable to that of a single SSI, the system's LED-based lighting ensures maintenance-free operation for approximately 10 years.

Safe, automatic, continuous
Indigo-Clean prioritizes safety and convenience, featuring automatic operation and dual-mode functionality. While the high-intensity mode delivers enhanced disinfection capabilities, the system seamlessly switches to dual mode upon detection of human occupancy, ensuring continuous disinfection without compromising comfort.

Ideal for environments with extended periods of vacancy daily, such as operating rooms, patient room bathrooms, pharmacies, waiting rooms, infusion centers, and burn units, Indigo-Clean offers a safe, efficient, and unobtrusive solution to maintaining hygiene by reducing the risk of infection.

Healthcare facilities are carefully evaluating various light disinfection approaches, including Indigo-Clean: a pioneering solution offering safe, automated, and continuous disinfection. By prioritizing these key considerations and adopting innovative solutions like Indigo-Clean, healthcare facilities can create safer environments for patients, staff, and visitors alike, ultimately improving overall healthcare outcomes while reducing costs.

Considering the time, resources, costs, and challenges related to terminal cleaning, Indigo-Clean offers a powerful solution enabling facilities to maintain the bioburden reduction between terminal cleanings. It's seamlessly integrated into overhead lighting to disinfect whenever the light is on. When paired with controls, facilities can 'set it and forget it', ensuring safe, automatic, and continuous whole room disinfection. Given a return on investment (ROI) of less than three months, the cost of the system is quickly recovered. The cost of reducing SSIs and saving lives…priceless.



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