

UV Disinfection in the Healthcare Environment:

Key Criteria for Performance, Operation and Safety



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Introduction

UV technology has been widely established as an effective disinfection technology to help prevent Healthcare-associated Infections. This has led to a proliferation of UV devices offered in the market today to prevent the spread of the SARS-CoV-2 virus. Various portable UV-C devices are available for hospitals, which can be easily moved into patient rooms, surgical suites, ICUs, and other critical areas that need surface and air disinfection during a terminal cleaning process or when a patient is diagnosed with pathogen-borne infection. Some of the pathogens of interest and their reduction in healthcare settings are multidrug-resistant, such as methicillin-resistant *Staphylococcus aureus* (MRSA), *Clostridium difficile*, *Acinetobacter baumannii*, and vancomycin-resistant *Enterococci* (VRE). These pathogens can be inactivated by proper application of UV-C energy.

UV devices for whole room disinfection vary greatly in both operational and safety features and product effectiveness claims — all of which can make it challenging to evaluate and select a device. The primary objective of this article is to inform the selection of proven, effective, and safe UV devices.

To do so, the content of this article covers the following criteria:

- 1) important parameters determining the efficacy of a UV device
- 2) the different types of evidence UV device manufacturers provide to support effectiveness claims
- 3) key operational and safety features to be considered for device selection and deployment

Mechanism of UV-C Inactivation

The ultraviolet spectrum is a band of electromagnetic radiation at higher energies than visible light, split into four major categories: UV-A (315 - 400 nm), UV-B (280 - 315 nm), UV-C (200 - 280 nm), and vacuum UV (VUV, 100 - 200 nm). UV-C light in the 200 - 280 nm range has been proven to be germicidal in nature and has been used for pathogen disinfection for over a century, with applications in water, air, and surface treatment.

Microorganisms are particularly susceptible to UV light at wavelengths close to 265 nm (Fig 1), since this represents the maximum absorption wavelength of the DNA or RNA molecules (ASHRAE, 2019). Where UV-C photons are absorbed by DNA/RNA, the resulting damage can inhibit the microorganism’s ability to replicate, rendering it no longer infectious. Low pressure mercury lamps emit greater than 90% of their output at 254 nm and are therefore ideally suited for germicidal applications.

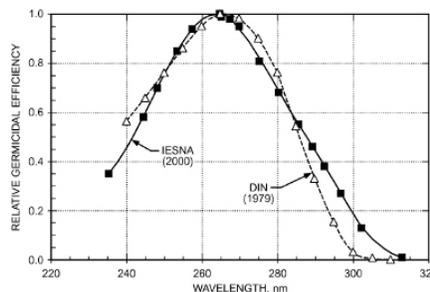


Figure 1. Germicidal Efficacy as a Function of Wavelength



UV Susceptibility of Microorganisms

It is well known that different pathogens exhibit varying susceptibility to UV-C light, with vegetative bacteria and viruses typically easier to inactivate than spores or fungi (Kowalski, 2009). Ultraviolet germicidal irradiation for surface disinfection has been demonstrated to be highly effective at eliminating vegetative pathogens, including MRSA, VRE, carbapenem-resistant Enterobacteriaceae, *Acinetobacter baumannii*, spores, such as *C. difficile* and *fungi* such as *Candida auris* (Rutala 2014, Rutala 2016, Maragakis, 2016, Donskey 2018).

Application of UV-C to any surface is based on the UV dose delivered to the surface. The UV dose delivered at a target surface is the product of UV irradiance at that target and exposure time, implying that a higher UV dose could be delivered by increasing the intensity of UV light and/or the exposure time.

The intensity of UV irradiance is inversely proportional to the square of the distance between the UV lamp and the exposed surface, based on the “inverse square law.” Therefore, a surface at twice the distance from the UV device will receive only one-fourth of the intensity. The applied dose can be increased by bringing the device closer and/or by increasing the exposure time.

It is important to note that UV-C operates by line-of-sight; it kills only what it can see. Surfaces which are “shadowed” from the UV-C light or receive indirect UV-C light from reflected walls and other objects in the room would require longer times to attain the target dose from the UV device. Device design, lamp power, lamp height, lamp configuration and reflective components are important design factors which affect the total UV-C intensity of the device.

Performance Evaluation

One of common misapplications of UV devices is the estimation of UV dose required to achieve a certain log reduction for a target pathogen. Due to limited data on the UV dose requirements for different microorganisms and lack of industry standards, any performance claims of the efficacy of UV devices from manufacturers should be scrutinized carefully. It is important to assess the specific evidence provided by device manufacturers to support the performance claims of their devices, such as the microbiological efficacy testing, the scope and type of studies performed in a laboratory or clinical setting.

With regards to testing protocols for UV devices, as EPA-designated pesticidal devices, there are no uniform testing standards similar to the Good Laboratory Practice Standards (GLPS), which ensure the quality and integrity of test data submitted to the Agency in support of a pesticide product registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

It is in this context that many manufacturers make pathogen inactivation claims supported by independent, accredited laboratory testing results and/or (2) internal testing, often cited as ‘data on file’. A common, yet less rigorous third practice is when manufacturers cite other companies’ results or results from the literature in support of their own device. UV devices make a broad array of efficacy claims, which can include:

- 99.99% inactivation of SARS-CoV-2 in 5 minutes at 12 feet distance
- 99.99% inactivation of SARS-CoV-2 at a distance of 14 feet
- 99.99% inactivation of SARS-CoV-2 in 2 minutes
- Disinfects SARS-CoV-2

A valid inactivation claim should include details of the protocol used for the testing, including the exposure time used, distance of the device from the test pathogen and orientation of the UV-C device from the test pathogen.

Accredited Laboratory Testing

Accreditation recognizes the technical competence of laboratories to perform specific types of testing, measurement, and calibration. To maintain this recognition, laboratories are re-evaluated periodically by the appropriate accreditation body to ensure their continued compliance with requirements.



Testing design is set by the manufacturer in collaboration with the laboratory where the testing will be completed. Testing at an accredited laboratory ensures results reflect independent evaluation, analysis, and verification.

Internal Testing

Some UV device manufacturers cite internal testing as support for pathogen inactivation. Internal testing is least expensive and fastest – and should be viewed with healthy skepticism. It is first important to seek basic information about the testing, including the testing site, the type of UV device or instrument used, and the source and quantity of pathogens or organism cultures used. In addition, key testing details – such as the specific protocols, exposure time and the distance of the tested pathogen from the device - should be investigated.

Clinical Study Types and Review Process

While it is well understood that UV-C is effective against microorganisms, it needs to be correctly applied to achieve the desired log reduction. Some device manufacturers utilize publicly available literature on UV-C efficacy as indirect proof of the effectiveness of their systems, which can be misleading about the actual effectiveness of their specific device.

To further validate device effectiveness against microorganisms, it is extremely important for hospital decision-makers to check for and review the relevant peer reviewed clinical studies that prove the efficacy of the device they are evaluating. There are multiple types of peer-reviewed clinical studies; prior to reviewing the most common types, it is important to understand the peer-review process.

Peer-Reviewed Published Clinical Studies

The peer-review process for publication of clinical studies recognizes scientific rigor and merit. The process entails a detailed assessment of manuscripts submitted to journals by an independent panel of experts. The core purpose of the peer-review is to identify and select the highest quality articles for publication. Selection is typically based upon multiple criteria:

- The scientific merit and validity of the article and its methodology
- The relevance of the article to the specific clinical practice – select work of the greatest interest to the readership
- The interest of the topic to the clinical reader
- The presentation and understandability of the article itself
- To improve the manuscript whenever possible
- To check against malfeasance within the scientific and clinical community.
- Provide editors with evidence to make judgments as to whether articles meet the selection criteria for their publication

Three types of clinical studies that can provide evidence of UV device effectiveness are: (1) HAI-reduction studies (2) efficacy in a clinical setting and (3) environmental bioburden reduction study.

HAI Reduction Studies

HAI-reduction studies represent the most significant impact on patient outcomes that a UV device – or any intervention for that matter – can make and, accordingly, feature the most rigorous and lengthy study design. While UV devices are being used in hospitals to improve the level of environmental disinfection beyond levels achieved from manual cleaning, the real value to the hospitals is a demonstrated reduction of the hospital acquired infections (HAI) rates. It is incumbent on the infection preventionists to perform their due diligence by reviewing the strength of HAI studies conducted for the devices they are evaluating. An exhaustive review and ranking of published UV-C related HAI studies has been conducted by employing a quality assessment criterion which included representativeness such as study population, inclusion and exclusion criteria, potential for bias, description of intervention, continuous monitoring, outcome assessment and rigor of statistical analysis (Marra 2017).

While there has been only one randomized, controlled study, most of the published studies have been before-after studies in which



HAI rates after implementation of UV-C were compared with those prior to UV-C use. Two luminary HAI reduction studies involving UV-C devices are Dr. David Pegues' study at the Hospital of the University of Pennsylvania and the multi-state BETR study, conducted by DICON and led by Dr. Deverick Anderson.

In Dr. Pegues' study, the objective was to evaluate the impact of no-touch terminal room disinfection using a 254 nm UV-C whole room disinfecting device on *C. difficile* infection (CDI) rates in three hematology-oncology units. The study design was an interrupted time series with a comparison arm involving a 12-month baseline period followed by a 12-month UV intervention period. The UV intervention involved deployment of a 254 nm UV-C whole room disinfecting device for a 12-month intervention period, in combination with standard manual surface disinfection with bleach. CDI rates were tracked pre- and post-intervention. The study results showed a decline of the CDI rate by 25% on study units but an increase of 16% on non-study units as a positive result of the UV intervention. The impact of UVGI use on average room cleaning time and turnaround time was negligible compared to the baseline period.

The *Benefits of Enhanced Terminal-Room Disinfection* study, or BETR-D study, examined UV-C disinfection and its effect on epidemiologically important pathogens. The \$2 million study, which was funded by the Centers for Disease Control and Prevention, was conducted throughout nine hospitals of varying size and census in the Duke Infection Control Outreach Network from 2012-2014. Researchers compared four different cleaning and disinfection scenarios: standard cleaning with quaternary ammonia; enhanced cleaning with quaternary ammonia and 254 nm UV-C disinfection; enhanced cleaning with bleach; and enhanced cleaning with bleach and 254 nm UV-C disinfection. Each hospital randomly rotated through the four cleaning protocols in each of the four, seven-month phases. In this study, the use of 254 nm UV-C was able to reduce the relative risk of colonization and infection caused by epidemiologically important pathogens among patients admitted to the same room by a cumulative 30% in hospital settings.

Efficacy in a Clinical Setting

A second type of study is to measure UV device efficacy, typically against one more pathogen, in a clinical setting like a hospital room. This is typically a controlled study wherein, before-and-after pathogen reductions are measured using carriers placed at various sites in the room. This type of study can be completed in as little as 48-72 hours.

A comprehensive review of such studies summarizing the multidrug-resistant organisms targeted and the log reduction achieved by various UV devices has been published (Weber, 2016).

Environmental Bioburden Study

A third type of study is a before-and-after environmental bioburden study. This type of study can be an indicator of efficacy of a UV device against a wide range of pathogen isolates in both clean and dirty conditions. The environmental bioburden study provides a measurement of bioburden reduction on a defined set of sites, individually and aggregated, over a defined time. Selected surfaces are sampled using TSA contact plates or swabs prior to cleaning protocol, typically with and without UV. This type of study can also be completed in as little as 48-72 hours.

Operational Features

After the efficacy of the UV device has been carefully vetted, the selection criteria should focus on the operational and usability differences between the UV devices in the health care setting.

A key operational feature to review is the device or manufacturer's ability to confirm that a specific germicidal dose has reached any targeted surface. The germicidal light emitted by UV devices inactivates pathogens when a specific dose reaches surfaces in both direct and indirect line of sight. UV devices use different technologies to estimate the time required to achieve a specific dose or to measure the actual dose delivered to a target surface.



Onboard Sensors – Radiometer-based

On-device radiometer sensors measure the UV light reflected to the device from all areas in the room. This data helps the device determine the cycle time required to deliver a predetermined dose to disinfect the whole room.

Onboard Sensors - Room Mapping

Automated laser room-mapping technology is deployed to determine the cycle time required to deliver a predetermined dose in the room.

Wireless Radiometers

A third technology, often deployed, are remote radiometer sensors, which are wirelessly connected to the device. The dose received by these sensors dictates the cycle time of the device to deliver a pre-determined dose to various parts of the room.

Dose Confirmation Technology

Another proven technology to confirm whether a germicidal dose has reached a targeted surface during the device cycle time is by using a colorimetric paper indicator (coupon) which changes color based on applied dose. The coupon can verify germicidal dose alone or doses calibrated to inactivate specific pathogens. It validates that an ample dose has been delivered to a specific surface. The color change response of these coupons may vary with different wavelengths, therefore it is important to verify whether the colorimetric indicator coupon has been calibrated to the output of the specific device. While the dose verification features available for the device are an important criterion for device selection, buyers should be aware that device manufacturers may use different values of dose as their criteria for determining the cycle time of the device. It is therefore important to verify that the supporting evidence for device performance has been obtained as per the manufacturer's protocol for the actual use of the device in a typical hospital setting.

Safety Features

All UV-C devices should be certified to meet the appropriate UL and NIOSH electrical and human safety standards. UV-C light can be harmful to human skin and eyes depending on the extent of exposure. Therefore, whole room disinfection UV-C devices can only be used when rooms are unoccupied.

Devices should have proven safety features such as: appropriate built-in UV safety sensors for automatic shutoff when they detect human presence, door warning signs, remote operation, easy device maneuverability and lamps that are set in protective sleeves.

Motion Sensors

These are sensors that shut off devices when motion is detected. It is important to assess the number and location of sensors used, as well as the detection range at which sensors can work.

Door Warning Signs

Door warning signs are placed outside of the room of use during operation. They provide a visible means to prevent people from entering a space where UV device is being used. It is important to assess basic features such as the size, legibility, and messaging of the signage, as well as the number of warning signs for multiple points of entry, as many operating rooms have.

Remote Operation

Remote operation refers to the ability to start and stop the UV device from outside the room. This is typically done via remote control or mobile tablet. It is key to assess the range of the remote device, its ease of use and mode of connectivity (e.g., Wi-Fi, BLE) with the device.

Device Maneuverability

Any workplace equipment or medical device that is heavy and hard-to-move can create potential for physical strain and injury. With



this is mind, to help prevent injuries related to device use, it is important to review device weight, height, ease-of-mobility, including the ability to fit in restrooms and doorways.

Protected Lamps

To ensure uninterrupted and safe device operation, it is key to ensure device lamps are protected. This can include protection via device hardware – such as a bar or barrier surrounding lamps. Lamps encapsulated in protective polymer sleeves provide protection against direct contact with lamps as well as protection against broken glass.

Ease of Operation

Multiple factors can make a device easier to use. These include simplicity of operation, remote operation capability via a mobile app or remote control, the ease and time of device setup and size and weight.

Product Selection Criteria

After an investigation into the above areas, the highest markers for performance and safety criteria should be prioritized in selecting a device:

User Safety Prioritized

Proven features to make the device easy and safe to operate, such as protected UV-C lamps, high-quality motion sensors and ease of mobility.

Independently Proven Effectiveness

Accredited independent laboratory-verified efficacy against high-risk pathogens at times and distances representative of whole room disinfection. Peer reviewed published clinical studies proving device effectiveness in real world healthcare settings.

UV Dose Confirmation

Proven technology confirming a sufficient germicidal UV dose has reached any targeted surface.

Proven to Help Reduce Healthcare-associated Infections

Demonstrated performance recognized in peer-reviewed publications.

In addition to these key performance, operational and safety criteria, the following device characteristics should be taken into consideration as well:

- Data capture and analytics
- Workflow integration
- Manufacturer’s recommended use protocols
- Warranty and service contracts
- Device reliability and quality assurance
- Total cost of ownership
- Manufacturer’s reliability and certifications

UV disinfection is part of a multimodal process and requires a cross-functional team of infection preventionists, environmental services and nursing staff that collaborate to achieve a high level of disinfection in hospital rooms. Like most tools when used properly and with limitations understood, a UV device which has been acquired through the proper vetting criteria discussed in this paper for performance, functionality, and safety, will go a long way in bringing down the facility’s infection rates and enhancing the safety of patients and hospital workers.



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