Air Guardian® and Air Guardian Plus™ White Paper

July 27, 2021

Breathe pure, safe air. Continuously.
Disinfect surfaces. Continuously.

This document is a high-level description of the novel air purification and surface disinfection devices of Air Guardian® and Air Guardian Plus™

This document has been prepared for **prospective clients** for review
Air Guardian® and Air Guardian Plus™ devices, Including CleanWhite™ technology

illumiPure's Mission and Vision

illumiPure's mission is to design solutions that offer the highest level of air purification, ventilation, and surface disinfection. To blend proven science with creative innovation and engineering. To constantly seek new scientific discoveries and technical breakthroughs that might become part of our future solutions.

To constantly enhance, improve, and expand our products - to help everyone, in every setting, breathe the cleanest, purest, and safest air possible.

We believe in the importance of setting new standards for indoor air quality.

We believe in educating the public; about how the air we breathe affects our health, cognition, well-being, and even lifespan. We believe that everyone has an absolute right to breathe clean, safe air.

We are committed to environmental and social responsibility - to be globally aware, and within that context, remain conscious of our commitments - from the materials and suppliers used to produce our products to the relationships we have with our employees, partners, and customers.

The illumiPure® approach

Air Guardian® and illumiPure® protect occupants within individual spaces - regardless of the built environment, design, ventilation challenges, or other variables that may affect air quality. Air Guardian® watches over - and guards - occupants within those spaces from infectious disease, pollutant health hazards, and dangerous gaseous compounds.

IllumiPure advocates, with our targeted innovations and products, for clean air spaces in every building. We believe there should be no exceptions or exemptions, no excuses, for occupants that are exposed to hazardous pollutants, volatile chemicals, ultrafine particles, or airborne pathogens in buildings where they live, work, regardless of construction design or local air pollution conditions.

If buildings are "too old" to be modernized with better air circulation, disinfection, ventilation, or built environment solutions, illumiPure ensures that each individual room is protected with Air Guardian's ability to ventilate, purify, and disinfect air and surfaces within each room.

We believe

We believe that no one should be exposed to pathogens, microbes, or contaminants that can impair cognitive function, transmit infections, or cause chronic or permanent diseases - such as obesity, cancer, heart disease, neurological degeneration, and many others.

Indoor Air Quality - Guidelines and Regulatory Statutes

Guidelines and regulations for indoor air quality, including pollution, pathogens, specific molecular compounds found in ambient room air, and particle counts, will vary and may include stand and/or federal regulations. Recommendations have also been established for certain buildings and use cases[1]. The CDC, for example, has different recommendations for room air changes, HVAC controls, and surface disinfection in certain types of businesses, buildings, rooms, and intended occupants.

Regulations and requirements may be established by the Centers for Disease Control[2] (and Opening up America Again in conjunction with the US Government)[3], IAQ oversight groups, ASHRAE[4], REHVA, EPA, FDA, FIFRA, and APIC.

For information about Air Guardian's alignment and compliance with regulatory agencies, see https://www.immaculight.com/technical and EPA, FDA, and other information here:

Certifications

CE, ETL. RoHS, IUVA
Patent-pending Immaculight

[1] Additional regulations, policies, procedures, and guidelines are often seen in specific use-case settings - such as classrooms, air travel, oncology, pediatric, dental, dialysis, intensive care, operating rooms, clean rooms, and other areas.
[2] https://www.cdc.gov
[3] https://www.whitehouse.gov/openingamerica/
[4] https://www.achrnews.com/articles/143009-discussing-the-cdc-and-ashrae-recommendations-for-hvac-systems

FDA Facility #10077990
EPA Establishment# 98105-TX-1
FDA Medica Device Classification: Device Class II - Listing #D420497

IllumiPure - The Device

The Air Guardian - the UVGI-based, multi-technology air disinfection and purification solution

Air Guardian® Science, Efficacy, and Design Summary

A statement on efficacy and the unique properties that make Air Guardian® an unmatched solution:

The Air Guardian® biophysical mechanisms and design elements have been proven to kill, inactivate, and destroy microbial pathogens within seconds or sub-seconds (depending on the device) while air moves through the multi-focal reaction chambers. Within these patented, sealed, and safe chambers, intense primary UV irradiation is emitted - along with multi-bounce secondary energies, which fill every cubic inch of space within the reaction chambers. Chemical clouds of oxidation are generated from up to 9,000 square inches of space within the chambers - intense clouds of reactive, destructive oxygen species.

Time and exposure within the Air Guardian® device

Throughout the nano-reaction chambers, patented internal structures and elements within the device facilitate residency times that hold air for us to 22 seconds, increasing dose-times and oxidative exposure times.

These elements include fluid-dynamic-designed structures that influence air movement and collectively induce longer air residency within the device. The CFD elements slow airspeed, create turbulence and produce vortices.

The collective power of Air Guardian® technologies

All surfaces within the nano-reaction chambers are powder-coated with highly reflective nanoparticle crystals. A multi-focal mirroring effect is created, which induces random "bounce" and "spread" of LED photon energies. For example, all sides of the chamber are like mirrors, which reflect UV photons back and forth against the chamber walls. As photons bounce in a spreading pattern against the chamber walls, they retain a portion of their initial energy, up to 40% of the initial energy in the first photon bounce.

One might imagine a chamber, then, where continuous LED-emitted energies (as both photons and wavelengths) are crisscrossing the chamber in a seemingly endless number of bounces. Although the secondary bounces lose energy, the chamber is always filled with primary photon wavelengths as well, creating a chamber that is always filled with heterogenous UV-C energy waves; some at full energy and many more at varying degrees of partial energies. It effectively creates a 28-foot gauntlet of destructive UV-C dose energy. And rather than speeding through the gauntlet, Air Guardian® air is captured and processed for between 8 and 22 seconds, depending on the device.

The high kill curve that results means single-pass Log reductions that far exceed the ability of other systems to purify the air and disinfect the air. For example, a 50 CFM fan with a UV-C lamp pushes air across the lamp at a speed of 14.4 miles per hour - with a single-energy exposure time of .2 seconds.

Air Guardian® Summary

1) Air Guardian® is the only commercially available, upper-room sealed UVGI device that will remove - not just filter - nearly all infectious pathogens in an ingested cubic volume of air.
2) Air Guardian® can be installed either in the ceiling plenum or mounted on the ceiling surface and is available in multiple form factors, including 2x2, 2x4, and portable form factors.
3) Air Guardian® devices are pre-configured to be controlled as either a single device or in tandem with up to four other devices from a single controller. Aspects of the Air Guardian® device can be controlled by the end-user via the controller itself or the Vertices™ integrated IAQ sensor system (described below). The controllable aspects are on/off, dose energy, and fan speed.
4) Third-party Computational Fluid Dynamic testing has certified Air Guardian® ambient air ingestion rates, air residency rates within the device, and the volume (in kg/second) and spread of downward airflow - all produced from patented design elements.
5) Air Guardian's innovative induction fan design, including angle, speed, and location, is uniquely effective at drawing-room air, which helps stimulate upward air movement around the downward columns of vented and dispersed air within the breathing zone.
6) Upward air movement is also generated by Air Guardian® through convection forces, which is created when cool air (approximately four degrees cooler than ambient room air) is vented from the multiple supply sources, which are positioned well away from air induction locations. This is a function of exposing resident air to a titanium dioxide surface area equal to twenty to sixty-three square feet.

7) The air temperature gradient between ingested and vented air is due to the known effects[56] of TiO2 surface reflection and thermal absorption. Thermal cooling is supplemented by fluid dynamic forces (airflow), near-zero surface friction, and the thermal shielding on the exterior of the Air Guardian® device shell, which enables the gradient between ambient room air and the interior of the device chambers.

8) The sum of Air Guardian's design elements enable more rapid ingestion of room air, enhanced air movement and convection upward, and thus more frequent - and complete - room air changes (ACH) while using fewer devices than any other solution.

9) Air Guardian's high kill-curve reduction rates and particle/chemical dissolution capability mean that each room air change (ACH) is of higher value than an equivalent ACH from any other sealed UVGI solution. Thus, room air change rates from other vendors may be a misleading measure of infection prevention and improved air quality and must be carefully considered.

10) With Air Guardian's innovative and patent-protected design, a cubic volume of ambient room air is forced through a residency period within the device, for a period of 8 to 22 seconds (depending on the device model). During residency, the ingested air volume is exposed to powerful ultraviolet energies generated by proprietary UV-A and UV-C LED diodes.

11) Air Guardian® Ultraviolet LED energy is continually directed at microbial, particulate, and chemical air elements. All captured air volume is exposed to UV energies.

12) Because of Air Guardian's proprietary diode and circuit design, the UV-C dose wavelength is a precise, unchanging, exact 265nm, which has been proven in multiple studies to be the optimal wavelength for microbial destruction and fastest kill-curve Log reductions.[7]

13) Warranties - Air Guardian® uses long-lasting proprietary LED diodes; the warranty for the diodes is 30,000 hours or more than three years of constant use. It is guaranteed never to shift off the 265nm wavelength during that time. The device itself, excluding LEDs and fans, is warranted for 25 years. The fans have a 50,000-hour warranty. These warranties reflect the superior grade of materials, manufacturing techniques, quality control, assembly, and design.

14) Maintenance - Air Guardian® has recommended periods for filter replacement, which depend on the use case. The filter replacement process is simple and device-accessible and is described in the installation and maintenance guideline document, which can be found at https://www.immaculight.com/installation-guide.

15) It has been proven that the sum of the Air Guardian's applied science mechanisms and design elements kill, inactivate, or destroy microbial pathogens within seconds or sub-seconds while resident within the cubic volume of air that passes through the proprietary internal structures of the device. These elements include intense UV energy and continuous photo-catalyzed oxidation.

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[55] B. Givoni, M.E. Hoffiman, Effect of building materials on internal temperatures, Research Report, Building Research Station, Technion Haifa, (1968).
(i) H. Taha, D. Sailor, H. Akbari, High albedo materials for reducing cooling energy use, Lawrence Berkeley Laboratory Report 31721, UC-530, Berkley CA, (1992). DOI: 10.2172/7000986
(ii) A. Seneca, A. Santamouris, W. Miller, A. Livada, A comparative study of the thermal performance of reflective coatings for the urban environment, in Proceedings of the International Conference Passive and Low Energy Cooling for the Built Environment, Santorini, Greece, (2005).

[6] https://www.scientific.net/KEM.545.95

[7] https://www.cdc.gov/niosh/nioshtic-2/20034387.html

16) The high UV kill curve in single-pass Log reductions is a result of dose energy over time rather than distance traveled within the chambers. The proprietary CFD design elements within the chamber increase the time under dose where the dose is between 55-210 Watts of precision UV wavelength irradiation.

17) Photo-catalyzed oxidation is also highly destructive to microbial pathogens. The number of surface areas upon which the oxidative reactions occur is directly related to efficacy. On every square inch of surface, chemical "clouds" of highly Reactive Oxygen Species continuously form. As ingested air passes through the device, it is constantly exposed to these oxidatively destructive forces that form on all surface areas. The Air Guardian® devices have between 2,750 and 9,000 square inches of the oxidative surface.

18) Air Guardian's unique and proprietary design enables a level of continuous and extensive oxidation not found in any other solution. There are a few devices that add photo-catalysis in the form of filters embedded with nanoparticles, but they can only expose air to oxidation processes for sub-second periods - and they require frequent, often expensive filter replacement.

19) The Air Guardian® oxidation process uses rutile TiO^2 nanoparticles embedded in a permanent powder coating, which covers every square inch inside the fixture. Importantly it also accounts for the device's ability to destroy harmful chemical compounds and particles that are often found in ambient air. These include PM1.0, PM2.5, PM10, volatile organic compounds, ozone, and pollutant chemicals and gases. It also destroys UFP (ultrafine particles) like PM 0.1 and nanoparticles like PM 0.3 (often called the most penetrating particle (MPP).

    That Air Guardian® can reduce and eliminate these compounds has been tested and certified by independent third-party laboratories.

20) Air Guardian® is available with a proprietary indoor air quality measurement system, Vertices™, which is a patented multi-sensor circuit-board for monitoring real-time and periodic measurement values. LED lights of the device offer visual cues on air quality for each room so that any material change in air quality can be immediately recognized.

21) The air quality measures include CO2, CO, TVOC, VOC, RH, PM1.0, PM2.5, PM10, smoke, temperature, and an aggregate AIQ measure. The user can monitor and control using a desktop application or an app that is approved for release in the Apple or Android app stores.

22) Air Guardian® includes multiple final stages, vent, and exhaust filters that may be customized by use case and can include HEPA, Micron, MERV-6, and, usually, Charcoal. In some models, an additional charcoal absorber material may be used in pre-filtration.

23) Air is vented from multiple ceiling locations to create downward air displacement and to provide **protective zones of air** within the breathing strata - this also **dilutes all room air and ventilates** even in unventilated rooms.

Air Guardian Plus

CleanWhite 405+470 antimicrobial white-illuminating LEDs Technology and Mechanism

illumiPure's CleanWhite™ technology is available as a separate luminaire or as an integrated component of the Air Guardian fixture.

The Immaculite fixture includes a patented form of visible light disinfection and illumination, called CleanWhite™.

CleanWhite 405/470 antimicrobial white-illuminating blue-light LEDs

Despite SARS-CoV-2 and Covid-19, resistant pathogens remain a worldwide threat. Vaccination development continues to focus on SARS-CoV-2 and emerging variants. Other treatments have shown promise but remain in early development.

One approach that has been proven effective against resistant pathogens is continuous photocatalyzed visible light disinfection.
Using precision photo-energy spikes, illumiPure's 405+470 LEDs can kill most studied pathogens, include ESKAPE pathogens and resistant ARG forms. Importantly, it accomplishes this while illuminating in visible white light.

Other 405 nm solutions **cannot reach adequate dose energy to effectively kill pathogens[8] without emitting in the blue-violet light spectrum**.

illumiPure's solution excludes all other blue wavelengths, including those in the harmful 435-455 nm spectrum, wavelengths known to be damaging to retinal cells. illumiPure uses a patented impurity-free polymer for fixture lenses, which enable over 90% of emitted wavelength energy to pass through the lens. The ability to surface-dose with >90% of the emitted energy is exclusive to illumiPure.

Why Air Guardian aBL is unique, powerful, and unmatched

The inability[9] of other fixtures to adequately dose surfaces with LED energy as promised in specification documents is rarely acknowledged and, in general, poorly understood.

When modeling the efficacy of dose energy (as expressed in specification documents as Watts or Joules/cm^2), one must consider the reflection of the photons against the inner surface of the lens. Most fixtures have lenses that cover the LED chips as part of the fixture. Lenses used by other fixture companies, with few exceptions (we have seen no exceptions to date), are not impurity-free.

[8] Most studies indicate that ~ 20-30 joules/cm^2 is require to effectively lower colony counts and offer Log reduction levels that provide acceptable, material levels of disinfection over time

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Unless the product literature explicitly states that their fixture lenses enable unimpeded passage of full-energy 405 wavelengths, with no reflection back into the fixture, buyers may assume impedance and bounce-back. In general, most lenses used in LED 405 fixtures bounce 40-50% of the energy back into the fixture, which throttles the dose energy emitted from the fixture and its ability to reach surfaces at needed energy levels.[10] And, when energetic wavelengths reflect back into the fixture and the energy dose lands on the chips or circuits, faster chip degradation, and wavelength variance may be expected.

Thus, an important part of product comparisons should be whether wavelength energies from LED chips can pass through their fixture lens with full dose energies.

Dose energies and important details

The importance of delivering dose to surfaces at high levels (Joules/cm^2) cannot be understated, especially with dangerous ESKAPE pathogens:

> *Maclean et al. (2009) investigated 405 nm irradiation at ten mW/cm^2 (.01 Joules) against a broad range of microorganisms, including all ESKAPE-pathogens. Their findings concerning the sensitivity of different genera are comparable to the results obtained here. A. baumannii, S. aureus, and P. aeruginosa are more susceptible to visible light, while for E. coli, enterococci, and K. pneumoniae, higher doses are necessary for 1 log reduction.*

A critical observation of this study shows that while 405 nm light does demonstrate an inactivation mechanism on bacterial species at (using the MacLean et al. study dose of .01 J/cm^2), the "inactivation dose" needed for a "noticeable" colony reduction is actually 300 J/cm^2.

Since MacLean's 405 delivery dose (from the study) is .01 Joules/cm2, the delivery rate is.01 joules/cm^2 per second. Therefore to reach 300 Joules/cm^2,

It is for this reason that many fixtures cannot deliver enough dose for reasonable disinfection over time. Because a) the Watts/cm2 energy is diminished by the lens and b) the energy needed for a reasonable kill time can only be delivered in purple-violet visible light.

Consider the experimental results referenced above and a modeled extrapolation for using 405 nm light for killing ESKAPE pathogens on surfaces:

> *". . . compared to Maclean et al. (2009)… the tendencies are similar, including the necessity of exposure of about 300 J/cm2 for enterococci until inactivation progress is noticeable.*
>
> *[compared to the MacLean et al. (2009) study] ... the inactivation dose of 42.9 J/cm2 for 1 log reduction of P. aeruginosa is comparable to the 57.1 J/cm2 results achieved here.*
>
> *Concluding, **the results for the necessary dose at 405 nm irradiation in this study are relatively high, especially concerning the inactivation of Enterobacteriaceae - including Klebsiella and Escherichia – and enterococci.** For S. aureus, there are several studies coming to similar conclusions with doses between 50.2 and 61.6 for a 1 log reduction (Enwemeka et al., 2008; Guffey et al., 2013;*

[10] Minimum surface dose energies for effective disinfection = 20 J/cm^2

McKenzie et al., 2016). Furthermore, our data is in agreement with the literature that Acinetobacter baumannii, declared as one of the most problematic species in the WHO priority list (World Health Organization, 2017), is the most susceptible ESKAPE pathogen at 405 nm irradiation.

"Inactivation doses" to achieve a 1 Log reduction (90%) or a 5 Log reduction (99.999%) may be delivered in an additive fashion, either in short periods of time at high dose or longer periods at a lower dose – but they must add to the required observed dose for inactivation using the 405 nm wavelength.

Deeper details: antimicrobial action and substrate saturation in a spatial environment

Experimental processes often measure required energy doses for Log reductions through a process of short-distance illumination of 405 nm wavelengths on surfaces, including agar plates, which is quite different from what happens in the process of disinfection within a whole room.

For example, if 400 joules of energy is needed to reduce colonies of a bacterial species at a 1 Log, and the LED light energy emission is 40 Joules/cm^2/sec, then the following would be expected:

1. The energy, in Joules, would need to be measured **at the substrate surface** of the bacteria
2. In a fixture rated at 40 Joules/cm^2/sec, we must assume that there would be a**) no impedance from the lens and b) no energy reduction in the distance between the fixture and the surface substrate (fixture-to-surface distance)**
3. Assuming 40 Joules/cm^2/sec is delivered to the bacteria, we proceed to #4
4. The process of photo-catalyzation would then begin when the 405 nm wavelength photons reach the bacterial, eukaryotic cell. Then, photo-excitation (catalysis) may begin, initiating an oxidation process, shown below, beginning at the cell wall and continuing in the DNA-containing organelles
5. In this example, 40 Joules/cm^2/sec would then need x amount of time to "saturate" the bacterial substrate, whether the bacteria is contained within an ORM (organic-rich media), in surface colonies, or in biofilms
6. The saturation process varies by substrate, and thus one must add significant saturation time to allow for the full process to occur at dose
7. For example, if 400 Joules is needed to achieve a 1 Log reduction of the specific bacterial species, one must account for the bacteria's presence in colony form on surfaces, within ORM, or within the biofilm.
8. Thus, one cannot assume that within 10 seconds, whole room disinfection will occur (40 Joules/cm^2/sec x 10 seconds = 400 Joules = I Log reduction). Rather, that should be considered **the point at which effective bactericidal saturation begins**, when a noticeable kill process begins.
9. Time must be allowed for saturation/oxidation to reduce the bacteria located on surfaces, in ORM, or in biofilms.
10. In this example, at 10 seconds, assuming #3 above, kill dose saturation begins.
11. The time to achieve a 6 Log reduction depends upon bacterial concentration and substrate location.
12. 405 nm is effective at completely reducing bacteria in ORM or biofilms, but additional time for saturation is required, which increases Log reductions, depending on the biofilm community or ORM solution.

13. For bacteria that are susceptible to a 400 Joules/cm2 dose of 405 nm energy, the time to achieve 4-6 Log reductions will vary, depending on initial concentration, bacterial environment, and substrate.
14. To estimate the time needed for a 4-6 Log reduction on all surfaces and media, a conservative approach should be used. illumiPure would calculate that projection using the following variable algorithm

    - 10 seconds to achieve an effective kill-dose of 400 Joules/cm^2
    - Within 60 seconds of 405 nm saturation, the 405 nm energy begins to photo-catalyze porphyrins to produce reactive oxygen species, beginning at the cell wall
    - Further saturation migrates the oxidation processes to cell organelles
    - Based on studies that extrapolate on the MacLean et al. original experiments, 95 minute saturation periods are used to measure log reduction amounts. In this case, a 4 Log reduction could be projected at the 95-minute mark, which would provide adequate time to saturate bacteria present, in all forms, at the effective kill-dose energy levels

15. Thus, for a bacterial strain that has a 400 Joule energy dose, illumiPure could expect a 4-6 Log reduction within 95 minutes.

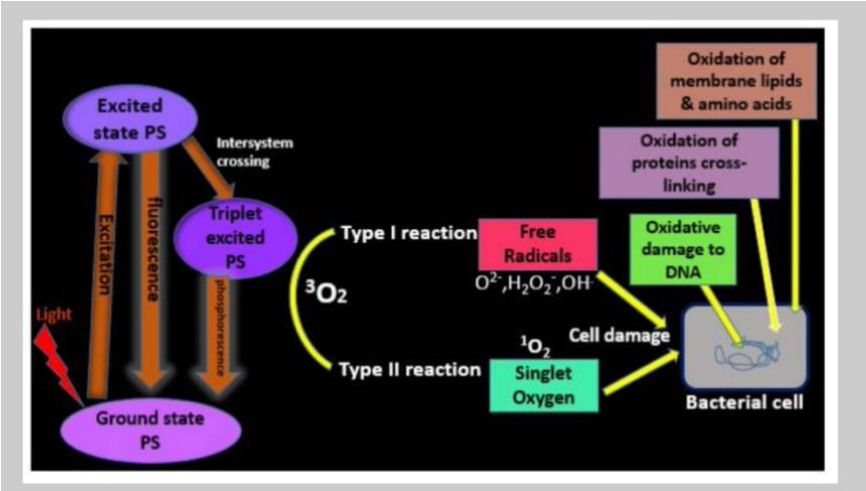
The above process is described, in detail, to illustrate the difference between experimental measurements and real-world whole-room reductions. This is an important understanding when evaluating different solutions.

For example, if full dose energy can only be achieved in a purple-violet light, then the illumination of that light, with at least 40 Joules of energy, must be continuously used for that period. When the light is turned off (dose energy is below 40 Joules), bacterial re-growth can be expected from aerosolized sources or incomplete colony/biofilm reductions. That's why illumiPure's always-on capability is so important. The always-on mode suppresses the formation of biofilms, CFUs on surfaces and in ORM. With little existing presence, any new introduction of bacteria is saturated and killed much more efficiently than it would have if dose-energy had not been consistently present.

Other considerations when evaluating illumiPure CleanWhite 405/470 antimicrobial white-illuminating blue-light LEDs versus other aBL (antimicrobial blue light) fixtures:

1. Almost all competing fixtures use lenses in which 405 wavelengths bounce back into the fixture and reduce the actual emitted energy dose by up to 50%.
2. All competing fixtures will require illumination in shades of violet-purple to achieve effective energy doses
3. If dose-energy is reduced because of lens impedance or the ability of the LED chip to deliver actual dose versus rated Watts (25 Joules, for example), the time to kill-dose saturation is extended, AND the incremental progression of saturation is slowed at the lower dose
4. With reduced or lower energy doses, an extended period of purple-violet illumination will be needed to achieve proper levels of disinfection in all substrates. Based on the resiliency or

susceptibility of the bacteria (e. coli, for example), purple-violet illumination could theoretically be required for several hours.



In other words, a fixture that cannot provide adequate dose levels without illumination in purple-violet light and which does not have an impedance-free lens is probably not going to be an effective solution, whether occupants are present or not. To overcome lens impedance and expected real energies emitted from the purple-violet LED chip, an extremely high level of Joule energy would be needed. Increased watts increase lumens, such that in a real-world room, purple-violet lights would be correspondingly bright, as high as 100-120 Watts.

Operating continuously, in surface dose energies between 30 joules/cm^2 and 80 joules/cm^2, illumiPure's single-chip technology 405+470 LEDs and patented lens material can deliver dose energies that can rapidly kill or inactivate bacteria, yeast, mold, and some viral species – even in biofilm form.

With illumiPure 405+470 LEDs, the time needed for high Log-reduction is four to twenty-four hours, depending on the initial colony counts within a given space. Many species of bacteria and microbes are reduced in high Log levels within 3-4 hours.

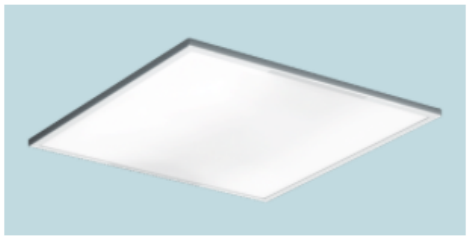
CleanWhite® 405+470

Air Guardian® Plus includes an integrated, fully controllable component of the Air Guardian® Plus device, which disinfects surfaces, called CleanWhite.

CleanWhite® is a patented surface disinfection technology that is not harmful to humans.

CleanWhite emits antimicrobial blue light (visible spectrum, near UV) in a white light illumination, which can constantly provide saturation at dose energies required to kill a vast species of microbes (containing cellular porphyrin) on any surface, substrate, ORM, or biofilm.

The mechanism proven in clinical studies is a 405+470-nanometer light-induced photodynamic process in which the wavelengths trigger a reaction within the cells and cell walls of the microbes – causing cellular destruction and preventing repopulation.



CleanWhite™

Continuous Surface Disinfection

CleanWhite provides continuous surface disinfection using patented, antimicrobial white-illuminating LEDs which destroy over 99% of surface microbes, including bacteria, spore forms, fungi, mold, and other harmful pathogens.

Air Guardian Plus™

Dual-Modality Air + Surface Disinfection Technology

Combines Air Guardian and CleanWhite in a single fixture to provide both surface and air disinfection. Both Air Guardian and Air Guardian Plus offer integrated, real-time monitoring of indoor air quality with mobile app and dashboard.

PART II
EVIDENCE AND DETAIL

Application of Science, Technology, and Research: Evidence

This section summarizes the research and literature that have led to the development and design of the novel Air Guardian fixture and its functional components, such as Air Guardian™ and CleanWhite™.

The evidence upon which Air Guardian has been designed, developed, patented, and registered, encompasses several different disciplines.

To form a complete picture of optimal safety and prevention, one must consider the peer-reviewed discoveries and knowledge found within each area. Contributions have been made by experts in Biotechnology, Cell Biology, Genomics, Ophthalmology, Dermatology, Oncology, Chemistry, Computational Biophysics, Photophysics, Environmental Biology, Microbiology, Airflow Dynamics, Engineering, Immunology, Virology, Infectious Disease, and regulatory agencies.

The variables that affect disease transmission, infection prevention, air quality, biosafety, and safety are found within the realms of these disciplines.

This is important because each physical space needs to be protected - and each space is different. Most spaces have a different use case or purpose. With that purpose, each space is its unique environment. And each room will have a myriad of possible variations, from airflow dynamics, ventilation, age, furnishings, occupants, previous occupants, building materials, proximity to other rooms, occupancy numbers, plumbing, adjoining rooms, etc.

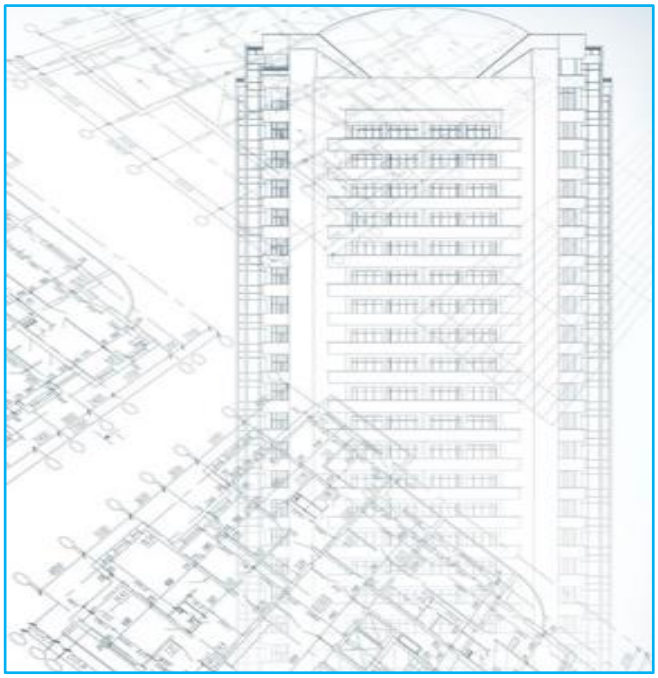
Each of these differences is a variable. Infection prevention specialists, indoor air quality experts, architects, plumbers, builders, microbiologists, chemists, engineers, and epidemiologists all recognize individual hazards and threats. Some hazards can be significant, perhaps unknown to tenants, occupants

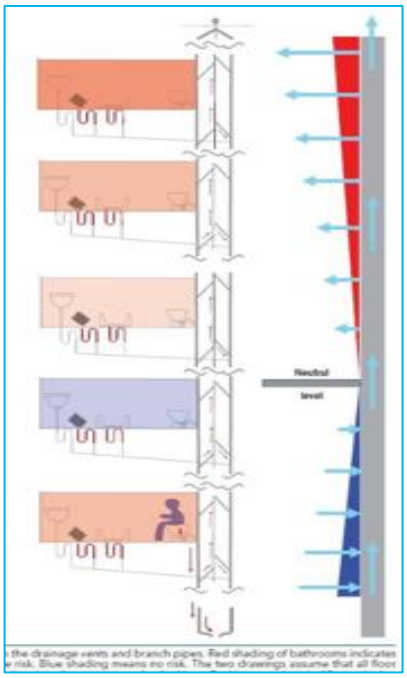
The goal is to solve for the variables.

In February 2020, in Guangzhou, China, researchers discovered that several people who had been socially isolating in their apartments were infected through fecal aerosols even though they were up to 12 floors apart in distance11. And, in 2003, in much the same fashion, fecal aerosols containing the SARS-Cov-1 virus were found to have infected more than 300 people in an apartment in Amoy Gardens[12].

[11] Probable Evidence of Fecal Aerosol Transmission of SARS-CoV-2 in a High-Rise Building
Min Kang, Jianjian Wei, Jun Yuan, Juxuan Guo, Yingtao Zhang, Jian Hang, Yabin Qu, Hua Qian, Yali Zhuang, Xuguang Chen, Xin Peng, Tongxing Shi, Jun Wang, Ji e Wu, Tie Song, Jianfeng He, Yuguo Li, and Nanshan Zhong Annals of Internal Medicine 0 0:0

[12] 17. Yu IT, Li Y, Wong TW, et al. Evidence of airborne transmission of the severe acute respiratory syndrome virus. N Engl J Med. 2004;350:1731-9. [PMID: 15102999]





Higher floors were shown to be more prone to infectious fecal aerosols

Solving for the variable that caused the infection required significant re-engineering and modification of plumbing, draining, venting, and HVAC systems. Only aggressive, fast room air changes to remove all contaminated air from the space would provide a modicum of safety before the construction and engineering work was to be completed.

Airflow Dynamics

A major variable is airflow dynamics. This is possibly the most important, but the least publicly understood variable. The dynamics are complex and include temperature convections, positive and negative pressures, HVAC venting location and pressure, door and window locations and use, object displacement, and other factors.

Complex airflow designs are often used in operating rooms, including positive pressure rooms, laminar airflows, separate air treatment systems with high MERV and HEPA filtered air, and even downward, highly treated airflow across the surgical space.

For example, in another well-known 2020 study, again in Guangzhou, China, it was demonstrated how airflow caused droplets and fine particles of shed virus to infect other customers at distances well beyond social distance recommendations. The figure below illustrates how HVAC airflow spread viral particles from two infected persons to tables on the other side of the room, infecting eight other people.

To solve this variable, it was proposed that increased distance was needed - as well as "improved

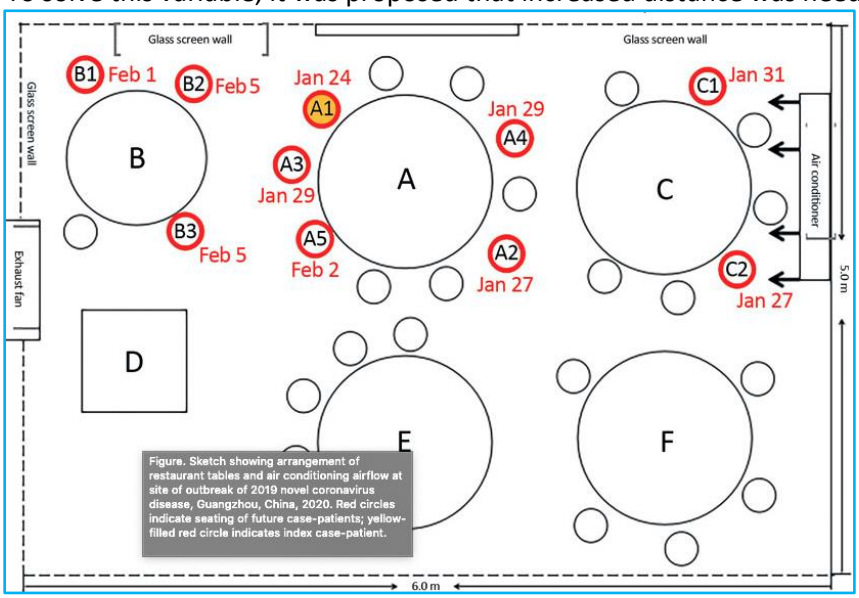


Figure. Sketch showing arrangement of restaurant tables and air conditioning airflow at site of outbreak of 2019 novel coronavirus disease, Guangzhou, China, 2020. Red circles indicate seating of future case-patients; yellow-filled red circle indicates index case-patient.

ventilation."

To learn more about this case, as well as the study that followed, link to:

https://bit.ly/3uPUZ0q

In a related study, it was proposed that there are three key elements of ventilation related to the transmission mechanism and the risk estimation of airborne infection. It postulated that **ventilation rate, flow direction, and airflow pattern most strongly influence the risk of airborne infection**.[13]

This study is vital to better understand the airflow features of the Immaculight solution.

The ability to create safe, clean air was shown to be essential (similar to what was described in an operating theater), along with the aggressive ingestion of droplet nuclei and airborne particles in upper room air.

Hua Qiet al.t al, described the mechanism of airborne transmission relative to risk:

[13] Qian H, Zheng X. Ventilation control for airborne transmission of human exhaled bio-aerosols in buildings. *J Thorac Dis*. 2018;10(Suppl 19): S2295-S2304. doi:10.21037/jtd.2018.01.24

"Transmission of infectious diseases occurs when the pathogen or agent leaves the source and spreads by one or more routes of transmission to the susceptible. Droplet spread and airborne transmission are two main routes to transmit respiratory diseases.

Droplet spread refers to the passage of pathogens from a source to a susceptible [host] through large droplets. It was calculated that droplets of greater than 100 m in diameter released from a height of 2 m deposited on the floor within 3–6 s with less than 1.5 m in the horizontal distance at room air temperature and relative humidity of less than 60%, while droplets of less than 100 m evaporated within 3–6 s. [Therefore] droplet-borne transmission is a short-range process, with a distance less than 2 m due to the evaporation and high settling velocity of large droplets."

Airborne transmission refers to the passage of pathogens from a source to a susceptible host through airborne aerosols, resulting in infections. The vehicle of airborne transmission is droplet nuclei, the residues of dried-out droplets, which can suspend in the air for a long time and transmit over a long distance.

Liu et al. investigated the interpersonal exposure of exhaled droplets and droplet nuclei between two standing thermal manikins affected by different factors, i.e., distance, temperature, and humidity.

Results showed that the mechanisms of transmission for droplet-based, short-range infections and longer-range airborne infections are both possible, although short-range transmission probabilities were higher.

Thus, as is well understood by most researchers today (March 2021), while short-range transmission had a much higher risk than long-range transmission does, both must be mitigated as changing variables based, not only on airflow and ejection mode (breathing, shouting, sneezing, coughing, physical exertion, etc.) but also, in the case of SARS-CoV-2, on the type of viral variant. For example, the variant B.1.1.7 variant has been proven significantly more contagious and transmissible than wild-type SARS-CoV-2[14], in part because of the higher rate and volume of viral shedding.

Thus, social distancing alone cannot be relied upon as an effective mitigation strategy for these many transmission variables, such as airflow, ejection pressure, viral variant, and volume of viral shedding. The determination of droplet-borne or airborne infection should not be according to the transmitted range, i.e., 2 m.

The main variable is the optimal application of airflow dynamics. The secondary variables are the risk of infection, particle size, the viral load (contagion), inhalation, and time. From the Qian et al. study - results:

"The results indicated that the performance of downward ventilation to remove exhaled pollutants was close to that of mixing ventilation. However, when the infector faced horizontally, the exhaled jet [breath, cough, particle shed] could penetrate [travel] for a long distance and [could carry] a high concentration layer of exhaled pollutants … due to the thermal stratification lock-up" phenomena, which certainly added the risk of short-range airborne infection transmission.

[14] Galloway SE, Paul P, MacCannell DR, et al. Emergence of SARS-CoV-2 B.1.1.7 Lineage — United States, December 29, 2020–January 12, 2021. MMWR Morb Mortal Wkly Rep 2021;70:95–99. DOI: http://dx.doi.org/10.15585/mmwr.mm7003e2external icon.

And if the height of the lock-up layer was in the breathing zone, the risk of long-range airborne transmission would also be high. The length of [the] exhaled jet [breath, cough, sneeze, shed] and height of the lock-up layer can be predicted, which is associated with a temperature gradient, exhaled momentum, and exhaled temperature difference with ambient air.

Preventing Airborne Transmission with Air Guardian®

While no one system will make for a "safe" space, Air Guardian® adds effective pathogen removal to any area, any room, in any environment - to help remove and eliminate harmful airborne microbes before they can be transmitted within a space.

Regardless of the quality, purity, or disinfection level of air vented into a space from the HVAC system - or in spaces with little or no ventilation - Air Guardian® produces purified, disinfected air (between 2 Log and 6 Log reductions) in a protective displacement fashion (at pressure), and rapidly replaces all room air.

Air Guardian® provides the highest level of occupant safety, infection protection, and air quality within a given space.

More on this topic can be found later in this document.

Optimal Room Ventilation Methods while reducing cross-contamination airflow

Qian and Li[15] developed an improved downward ventilation system to show a better performance to remove fine droplet nuclei. They compared the ventilation performances when exhausts were at different levels using full-scale experiments and CFD simulations. Results suggested that upper-level exhausts were more efficient than floor-level and near-head exhausts in removing gaseous contaminants due to upward body plumes.

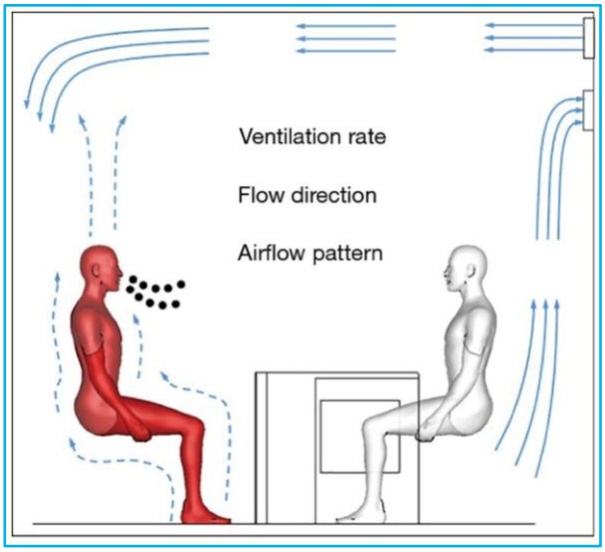
[15] doi:10.21037/jtd.2018.01.24

The low-temperature air was supplied vertically from the top and accelerated by gravity to deliver fresh air to HCWs directly, while the exhaust grill was also arranged at the top of the ward to remove the up-flowing exhaled fine droplet nuclei. The mechanism of removing large particles is due to deposition instead of ventilation. The significance of surface cleaning is then approved. The Immaculight Air Guardian® Solution is designed to do just that.

Photo catalyzed oxidation, ROS, and Advanced Oxidative Properties

Since intense photo catalyzed TiO^2 oxidation is one of two forms of continuous microbiological, chemical, and particulate destruction (the other being direct UVA and UVC irradiation), it is important to describe the process and the efficacy of photocatalyzed oxidation.

From a 2015 study[16] on the viability of photocatalysis for air purification:



"The components of indoor air that affect the human condition are myriad and both particulate and gaseous. Within the set of all particles, ultra-fine particles have been directly linked to heart health. Bioaerosols can be allergens, asthmatic triggers, or mold spores [and some particles are benign. Within the set of gaseous products, some are carcinogens; some cause respiratory distress; some are toxic; some are odiferous, and some are benign. If we wish to treat indoor air to make it "healthy," one technology alone will not suffice to treat the wide range of particulates that may be encountered, as well as the wide range of gaseous components.[17]""

The Titanium Dioxide Nanoparticle

[16] Hay SO, Obee T, Luo Z, et al. The viability of photocatalysis for air purification. *Molecules*. 2015;20(1):1319-1356. Published 2015 Jan 14. doi:10.3390/molecules20011319

[17] Hay SO, Obee T, Luo Z, et al. The viability of photocatalysis for air purification. *Molecules*. 2015;20(1):1319-1356. Published 2015 Jan 14. doi:10.3390/molecules20011319

The use of Titanium Dioxide to facilitate photocatalytic ROS generation, and thus oxidation, has been known - and used - for decades. In a 2003 study, TiO2 was described as an emerging technique to add to traditional UVC light and filtration to treat air for reducing particulate materials, chemicals, and pathogens.

From Hay, SO, et al.*: "Recently, there have been increasing numbers of people suffering from allergies, asthma, and bronchitis in Taiwan. Bioaerosols play an important role in these observed symptoms. Regarding the reduction in bioaerosol concentration, the commonly used methods include filtration, ultraviolet germicidal irradiation, and electrostatic precipitation. Currently, there is a new trend for pollutant control by photocatalytic oxidation (PCO) using TiO2. This process is referred to as heterogeneous photocatalysis or, more specifically, photocatalytic oxidation.*

The advantages of PCO are generally recognized as safe, less expensive with low power consumption, no consumption of oxidizing chemicals, and potentially long service life."

Regarding PCO, TiO2 is a semiconductor photocatalyst with a bandgap energy of 3.2 eV. When this material is irradiated with photons of <385 nm, the bandgap energy is exceeded, and an electron is promoted from the valence band to the conduction band. The resultant electron-hole pair has a lifetime in the space-charge region that enables its participation in chemical reactions. Hydroxyl radicals and superoxide ions are highly reactive species that could oxidize air pollutants adsorbed on the catalyst surface (Jacoby et al. 1996).

Particularly, the pollutants, volatile organic compounds (VOCs), are preferentially adsorbed on the surface and oxidized to carbon dioxide. Therefore, rather than simply changing the phase and concentrating the contaminant, the absolute toxicity of the treated airstream is reduced, allowing the photocatalytic reactor to operate as a self-cleaning filter relative to organic material on the catalyst surface."[18]

These early observations about adding the photo-catalyzed oxidation process to existing methods of air disinfection were important in that the oxidation process could be leveraged in a multi-system environment designed to destroying particulate matter, pathogens and reducing aerosolized chemicals to safe compounds - without the need for traditional filtration and by using three separate systems for particle, pathogen and chemical destruction.

Indoor Air Quality and Oxidation

Improving Indoor Air Quality includes more than just the destruction of infectious viral, bacterial, and vegetative pathogens. For example, from this same study[19], one finds:

"In normal indoor air, there are ca. 200 individual gaseous components, most in the 10-ppb range or lower, and most are volatile organic compounds (VOCs). The average tolerance index of the air found in office buildings by the BASE study is 0.884. In problem indoor air, the air that has generated complaints and or

[18] Chia-Yu Lin & Chih-Shan Li (2003) Effectiveness of Titanium Dioxide Photocatalyst Filters for Controlling Bioaerosols, Aerosol Science and Technology, 37:2, 162-170, DOI: 10.1080/02786820300951

[19] Hay SO, Obee T, Luo Z, et al. The viability of photocatalysis for air purification. *Molecules*. 2015;20(1):1319-1356. Published 2015 Jan 14. doi:10.3390/molecules20011319

illness, there may be a considerably higher total or higher concentrations of individual components, resulting in a significantly higher tolerance index

If our goal is to change air quality, we can simply rate an air purifier's effect based on its efficiency. However, in treating indoor air, our goal is to create cleaner or healthier air. This goal is somewhat nebulous as other VOCs can exhibit different effects. Some VOCs such as formaldehyde and benzene are carcinogens, some are toxic, some are odorous, and some are benign."

Oxidation Treatment Applications

Within the past two decades, the use of advanced oxidation processes (AOPs) has been extensively studied. In nearly every medium imaginable, there have been applications that have proven effective.

The studies have led to use-case applications in many areas, including water and effluent treatment, PCO and PECO air filtration, food storage, and protection. It has also been used in medical applications, including treatments that utilize photosensitizers absorbed by human tissue—new research into antibiotic-like drug development.

Advanced Oxidative Processes are now generally regarding as "the most encouraging method for the removal of pollutants, including organic, inorganic, and microbial contaminants, compared with traditional purification procedures[20].

TiO^2 photocatalyzed oxidation has the unique ability to remediate levels of CO^2 in spaces, which has been proven in numerous studies. While Air Guardian® is not a CO^2 absorbing system, the TiO^2 without its outer shell electron (TiO-) will provide a ready electron to which CO^2 is adsorbed. Gain, limited adsorption is possible, but over 9,000 square inches of surface area can remediate slightly high levels of CO^2 (again, proven in studies).

An Immediate Oxidative Cloud with UVA irradiance

Within Air Guardian®, air first passes through a ceramic mesh of titanium dioxide (see figure 2), embedded with TiO2 nanoparticles, which are rutile-state reflective crystals. They are highly reactive to ultraviolet light. The ceramic mesh used is irradiated by powerful UVA 365 light, thereby forming a cloud of highly reactive electrons and subsequent ROS. The UVA light irradiance itself is also destructive, so dual toxicity begins immediately within Air Guardian®.

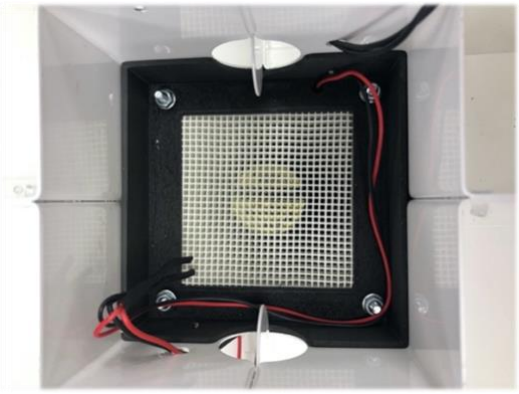
The UV-A light, by itself, also *destroys mycobacterium* without needing oxidative reactions.

Air Guardian® Advanced Oxidizing Process:

- UVA 365nm light catalyzes nanoparticles (within Air Guardian® Titanium dioxide is used)
- Extreme levels of ROS are created as air enters the device, as UVA 365 is directed against a concentrated nanoparticle matrix of titanium dioxide
- Energy directed against Titanium dioxide causes outer valence electrons to shed as highly reactive oxygen species (ROS) like -OH, -O, and H2O2, which are produced in abundance within the enclosed chamber
- The ROS wash over the incoming air from the Air Guardian® intake
- The ROS species aggressively oxidize organic contaminants to CO2 and inorganic ions

[20] Review on heterogeneous photocatalytic disinfection of waterborne, airborne, and foodborne viruses: Can we win against pathogenic viruses? DOI link: https://doi.org/10.1016/J.JCIS.2020.07.047

- The ROS reduce (disassemble) inorganic contaminants and volatile chemicals to nontoxic ions throughout the pathway corridors - using UVC-photocatalysis of coated nanoparticle surfaces
- The ROS inactivate microorganisms, including viral pathogens
- The ROS oxidation process produces no noxious compounds



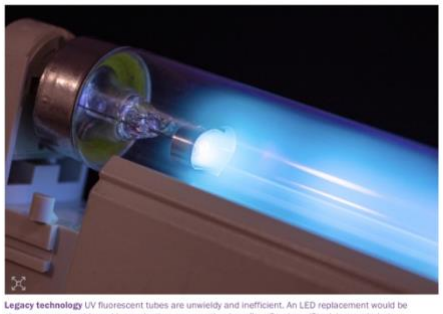
TiO2 ceramic mesh, which is composed of a TiO2-bound ceramic material, rather than just coated with nano crystals

After air passes through the TiO2 mesh and is irradiated with UVA energy, it enters the "nano-reaction chambers" described above.

Comparing LED UV energies with Lamps

The highest level of UV-C energy found in any other sealed, upper-room UVGI device today is 80,000 millijoules, with most systems ranging between 12,000 - 30,000 millijoules. With few exceptions, most UVGI fixtures use UV-C lamps (not LEDs), over which ingested air is passed within seconds or sub-seconds before being vented from the same fixture into the room. UV-C fluorescent-like tube lamps emit energy in a diffused fashion, as is illustrated below:

In addition to the fragile nature of the UV lamps, expected lifespans are low, and wave-shifting can occur in as little as 400 hours. Typical UV lamp lifespans are less than a year, depending on several factors.



Legacy technology UV fluorescent tubes are unwieldy and inefficient. An LED replacement would be cheaper, more tunable and longer-lasting, among other benefits. (Courtesy: iStock/proxyminder)

By comparison, LED lamps that emit in the UV-C spectrum have several appealing commercial properties. They can be tuned to exact wavelengths and have a much longer lifespan (Air Guardian® VioLED chips have a 30,000-hour warranty).

VioLED High-quality chips are engineered with circuit boards such that even slight color shifting can be prevented. Multiple LED chips can be used within a single board and multiple boards within a single device, far exceeding the UV energy which can be emitted from a single UV lamp.

Further, LEDs can be engineered to emit light in certain irradiance angles, which can focus and direct wavelength beam, rather than only diffusing light like that within a UV florescent-like tube lamp.

This has significant meaning for the Air Guardian® device, which uses VioLED chipsets manufactured by Seoul SETI.

The following test result illustrates the efficacy of the SETI VioLEDs used to irradiate the Air Guardian® channels. The results show that VioLED (Air Guardian) UV-C chips, which total 100 millijoules/cm2, kill SARS-CoV-2 human coronavirus in 1 second or less:

KR Biotech Co., Ltd.
Institute of Infectious Disease Control
Neungdong-ro 120, Konkuk university
Bld#12, Rm 406, Kwangjin-gu, Seoul

Test Report

Client	Personnel	Jae Hak Jeong	Tel. No.	82-70-4391-8629
	Affiliation	SEOUL VIOSYS Co., Ltd.	E-mail	Jaehak.jeong@seoulviosys.com
	Address	65-16, Sandan-ro, 163beon-gil, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea		
Request	Virucidal Activity Test by UV Irradiation			
Product	UVC module (100mW)			
Purpose of Use on the Product	Sterilization			
Test Virus	COVID-19 (SARS-CoV-2)		Cell Line	Vero E6
Test No.	KR-2011-065-SVS-01		Test Period	2020.11.20-12.01
Treatment time	1, 3, 5 sec		Titration	CPE
Test Temperature	Room Temperature (Approx. 20℃)		Tester	Hansam Cho

Test Result

Product Name	Virus Titer $TCID_{50}$	Treatment time	Distance	Virus Reduction Rate	
				(log)	(%)
UVC module (100mW)	$2.15x10^7$	1 sec	2 cm	2.250	99.437 %
		3 sec		2.583	99.739 %
		5 sec		2.751	99.823 %

Result: As a result of the sterilization test for COVID-19 (SARS-CoV-2) by UV generated in the UVC module (100mW) of SEOULVIOSYS Co., Ltd., it showed 99.437%, 99.739% , and 99.823% virucidal effect in 1, 3, and 5 seconds, respectively treatment at a distance of 2 cm.

December 04, 2020

Test Manager: Young Bong Kim (Seal)

KR BIOTECH Co., Ltd.

* This test report is a result limited to the sample and sample name provided by the client and does not guarantee the quality on the overall product.
* This report cannot be used for PR, advertising and litigation purposes, and use of this report other for its original purpose is prohibited.

Test results have proven that VioLED chips at this dose kill the actual SARS-CoV-2 virus, with the studies performed within Biohazard Labs.

The Air Guardian® ability to process air over time within a "single-pass."

No other device that works within a single room or space can ingest air and "hold" a volume of ingested air inside the device.

In devices that most other sealed UVGI devices use 50 - 100 CFM fans to ingest room air and blow that air across a UV-C lamp, consider the following:

- 100 cubic feet per minute = 14.1 miles per hour airspeed
- 14.1 mph = 2481.6 inches per second
- Bulb length of UV-C lamp = 18 inches
- Time in seconds that 1 cm^3 of air travels over UV bulb emission = .0007 seconds

By comparison, Air Guardian® is able to maintain 1 cm^3 of air within a device for a period of eight to twenty-two seconds, depending on the device design.

Note that particles floating within that 1 cm^3 do not always remain suspended in the same space and travel at equal speed.

Engineering studies of air movement within the Air Guardian® device shows the smallest particles do not uniformly travel with airflow in a linear fashion; rather, they move within vortices and turbulence, in Brownian-like actions, and are thus subjected to irradiance and oxidative effects for longer periods of time than what might be considered using a straight-line projection based on linear airspeed through the device.

As a sealed fixture, Air Guardian® can safely irradiate at these extreme UV-C energy levels because it does not expose humans to UV light. All UV light is sealed within the Air Guardian™ fixture. Kill-switch safeguards are built into the Air Guardian® device should the sealed fixture be breached in any way.

Regarding the UV disinfection mechanism

As previously stated, this UVC irradiation provides the following utility, as described in "The Study of an Ultraviolet Radiation Technique for Removal of the Indoor Air Volatile Organic Compounds and Bioaerosol":[21]

[UVC irradiation] is generally applicable in three areas, as follows: Inside the ducts used for mechanical ventilation, return air units, and any indoor area. The DNA of contagious airborne pathogens is damaged by the energy of UVGI (UVC) light, which interferes with its duplication, rendering the organisms noncontagious.

[21] http://dx.doi.org/10.3390/ijerph16142557

From "The Study of an Ultraviolet Radiation Technique for Removal of the Indoor Air Volatile Organic Compounds and Bioaerosols":

- The mechanism by which UV light removes air pollutants is photochemical dissociation.
- This process involves the absorption of photons by molecules, resulting in the excitation of their electrons, enabling them to jump from low- to high-energy states.
- Excited electrons can break the chemical bonds, thereby altering the physical and chemical properties of the molecule.
- The elimination of air pollutants by UVC at wavelengths less than 290-nm involves direct photolysis, in which molecules that absorb light energy enter a chemically active state that breaks their chemical bonds,
- In Shie et al., it was indicated that UV light of shorter wavelengths is more efficient for the removal of formaldehyde (HCHO). Air Guardian® uses 265-nm UVC wavelength
- The efficacy of photolysis is dependent upon the energy, distance, temperature, and relative humidity

Filtration and precision venting

As a final step, Air Guardian® uses both charcoal and HEPA (99.97% of 0.3-micron particles, 85% of 0.1-micron particles) filtration, which is used as a safety step to eliminate any unwanted molecular or volatile organic byproducts, should they remain after passing through the active pathway corridors.

After the air is processed, it is vented from the Air Guardian® fixture by two separate exits, which are then exhausted through at least six feet from the fixture such that air can be dispersed into the lower third of the room. This process provides for the constant distribution of clean, disinfected, and filtered air at average human height without creating aggressive biofilm aerosolization on floors or surfaces.

Generic fixtures that intake and exhaust within the same fixture cannot ensure reliable room air changes. Some UVGI systems recommend ceiling fans to circulate room air, which exposes the possibility of biofilm aerosolization. Air Guardian® vents in such a way that room air changes are more efficient and aerosolization is less likely. (see above section on Airflow Dynamics)
Air ingestion and venting to safe, clean zones.

Indoor Air Quality (IAQ) and disease

The air itself carries particles, pollutants, pathogens, and chemicals, all mixed within ambient chemicals we know as "air" - that is, H_2O CO_2, O_2, N, etc.

Indoor air quality is one of the major health challenges facing the world's population today. It is estimated that over 4 million people die each year from fine particle (PM 2.5) inhalation. Mortality is caused by cardiovascular disease, respiratory failure, pneumonia, and cancer.

Further, it is well-known that in environments where pollution (particulates) and contaminants are high, infectious disease is also found to be in greater incidence.

Recent studies[22] also link PM 2.5 particles to a greater incidence of Alzheimer's disease when children are exposed at a younger age.

Airborne chemical carcinogens, such as benzene, toluene, acetaldehyde, formaldehyde, and other compounds are known to be highly associated with many cancers, including lung cancer, lymphoma, and leukemia.

For example, ambient airborne Benzene has been definitively associated with cancer and can be emitted from certain household products made of plastics, resins, nylon, and synthetic fibers. Benzene is also used to make some types of lubricants, rubbers, dyes, detergents, drugs, and pesticides.[23]

Air Guardian's air purification process, consisting of oxidation and UVC irradiation, removes ambient airborne benzene.

The importance of this purification process can be emphasized by a review of this study:

Residential ambient benzene exposure in the United States and subsequent risk of hematologic malignancies[24]

For additional information on Air Guardian® science and research sources:
https://www.immaculight.com/science

[22] Li RL, Ho YC, Luo CW, Lee SS, Kuan YH. Influence of $PM_{2.5}$ Exposure Level on the Association between Alzheimer's Disease and Allergic Rhinitis: A National Population-Based Cohort Study. Int J Environ Res Public Health. 2019 Sep 11;16(18):3357. doi: 10.3390/ijerph16183357. PMID: 31514400; PMCID: PMC6765937.
[23] https://emergency.cdc.gov/agent/benzene/basics/facts.asp
[24] Lauren R. Teras W. Ryan Diver Emily L. Deubler Daniel Krewski 09 February 2019 https://doi.org/10.1002/ijc.32202

CleanWhite™ Antimicrobial Visible Light Solution

A detailed description of antimicrobial blue light technology

The utility, function, mechanism of action of antimicrobial blue light

Technology, and use Case examples

Validation of visible blue light efficacy

Extensive independent and laboratory testing has been conducted for more than a decade on the effects of 405 and 470 nm wavelengths on microbial disinfection. Research and literature on the subject have been exhaustive and have included studies on microbial species, dose, periodicity, and wavelength requirements to inactivate or reduce bacteria, mold, fungus, and yeast.

The results of these numerous studies have enabled and promoted the use of 405nm and 470nm disinfecting light into mainstream healthcare and commercial use in both in vitro and in vivo disinfection.

An extensive listing of the literature is referenced within and at the end of this document.

Note that many studies derived results using lower doses of 405 nm and 470 nm energies, guided by standard scientific laboratory processes. The doses used, often in mJ/cm^2, were often significantly lower than those used by the current dose emitted by the illumiPure® CleanWhite™ chipset, which is usually controlled to 44-60 Watts, or an equivalent of 44-60 J/cm^2. However, it can be precisely controlled to higher doses up to 120 J/cm^2.

illumiPure® used an independent lab to test generation 1 chipsets on specific species that represented known resistant pathogens, including:

Aspergillus brasiliensis BCRC 30506; ATCC 16404
Staphylococcus aureus subsp. Aureus (drug-resistant) BCRC 15211; ATCC 33591
Salmonella enterica subsp. Enteric (drug-resistant) BCRC 12947; ATCC 13311
The illumiPure® chipset used in the study was dosed at .6 J/cm^2. This independent, certified test validated the results expected with illumiPure® generation 1 chipset, based on the decades of study and testing mentioned above.

Over 97% colony reduction rates were observed for both Staphylococcus aureus subsp. Aureus (drug-resistant) and Salmonella enterica subsp. Enteric (drug-resistant) over 24 hours.

The testing also validated the expected result for Aspergillus brasiliensis, a spore-forming species known to be very resistant - except at higher 405-470 energy doses.

When the results are extrapolated to higher-energy illumiPure® ® 4th generation energy doses of 50-120 J/cm2 (between 83 and 200 times the dose used in the generation 1 chipset test), Aspergillus brasiliensis is shown to be highly susceptible to 405/470. However, the exact time to reach 2 Log reduction depends on colony size and dose.

Of further note, each species was tested in conditions of unusually high CFU counts, up to 9.0 x 10^4 (90,000 CFU's per square centimeter).

Thus, the existing literature and specific testing of the illumiPure® chipset confirm the utility and performance of the technology, even at low doses. Today's illumiPure® 4th generation chipsets are between 83 and 200 times more energy-dose efficient than those used in initial tests.

405 / 470 Technology and Mechanism

illumiPure's CleanWhite™ technology is available as a separate luminaire or as an integrated component of the Air Guardian® fixture.

The Air Guardian® Plus fixture includes a patented form of visible light disinfection and illumination called CleanWhite™.

In its utility, it emits sharp spikes of 405-nm and 470-nm wavelengths, which represent two specific, safe wavelengths known to energize an oxidative process, which is described in a study by Ramakrishnan et al. in 2016[25]:

"The mechanism of the bactericidal action, and the occurrence of mammalian cell toxicity beyond a threshold exposure level (Ramakrishnan et al., 2014), has not been fully elucidated, but it is thought to involve the photo-excitation of endogenous porphyrin molecules, a process which generates reactive oxygen species (ROS). ROS, including singlet oxygen (1O2), superoxide anion (O2•−), hydrogen peroxide (H2O2) and hydroxyl groups (•OH), are chemically reactive free radicals that play a crucial role in cell signaling and homeostasis, but overproduction becomes toxic to cells and alters redox balance causing significant damage to cell structures via oxidation of cellular macromolecules such as proteins, lipids, nucleic acids, NADH/NADPH and soluble thiols (Devasagayam et al., 2004). Since mammalian and bacterial cells contain intracellular porphyrins, during violet-blue light exposure, these porphyrins may become photosensitized, leading to an overproduction of ROS (Kotelevets et al., 1988; Lavi et al., 2004; Lubart et al., 2011).

As with traditional photodynamic inactivation reactions, which involve the use of exogenous photosensitive dyes or porphyrins (Gayl, 2001), photosensitization using violet-blue light is thought to cause cellular damage via two different pathways: Type I and Type II. With the Type I mechanism, the electronically excited sensitizer (e.g., endogenous porphyrin) reacts directly with the cellular component resulting in free radical formation (e.g., O2•− and •OH). These free radicals propagate further free radical chain reactions. In the Type II process, the excited photosensitizer reacts directly with molecular oxygen resulting in the formation of 1O2 (Pattison and Davies, 2006). Both pathways culminate in significant oxidative damage to exposed cells."

This mechanism is facilitated by Air Guardian's integrated (Clean-White™) patented, single circuit light-emitting diodes (LEDs) that spike, as described in precision 405-nm and 470-nm wavelengths.

[25] Cytotoxic responses to 405nm light exposure in mammalian and bacterial cells: Involvement of reactive oxygen species
DOI link: https://doi.org/10.1016/J.TIV.2016.02.011 Published: 2016-06

The wavelength energy has been tested to caused significant damage to bacterial and vegetative pathogens, as well as some known viral strains[26], such as norovirus, although few viral strains have been found susceptible to 405/470 damage, except when suspended within a bacterial biofilm or organic matter, upon which their damage is thought to be attributable to ROS-driven oxidative actions occurring within bacteria in biofilm or organic matter.

Fungal Light Sensitivity

Biologists have been aware since at least 1887 of visible blue light's capacity to stimulate phototropism—the ability plants possess to orientate themselves toward a light source (Sachs 1887). Visible blue light, it has also been noted, performs as a cue for fungi to perform important developmental tasks, such as metabolism, growth, pigment development, spore production, and tropism (Siegel et al. 1968; Casas Flores et al. 2006; Purschwitz et al. 2006). A particular type of red bread mold called Neurospora crassa has been shown to contain blue light receptors that respond significantly to changes in light intensity. Of its receptors, one type controls recognition of transitions between light and dark, while a protein it contains (VVD) aids in regulating its light controlling system.

Blue light, whose position in the spectrum exists in a range between 400 and 500nm, provides a cue for fungi to perform their asexual development and reproduction. However, when combined with photosensitive dyes, the light has a fungicidal effect. Candida is particularly susceptible to the combination of light and such dyes as phenothiazinium, dimethyl methylene blue, and toluidine blue.

[26] See R.M. Tomb et al., "New Proof-of-Concept in Viral Inactivation: Virucidal Efficacy of 405 nm Light Against Feline Calicivirus as a Model for Norovirus Decontamination," Food & Environmental Virology, Vol. 9(2), pp. 159-67 (2017).

Bacterial Light Sensitivity

Under controlled laboratory circumstances, bacteria have also shown sensitivity to blue light. Building on the knowledge that light at higher frequencies can destroy microbes, researchers have recently been interested in the effects of the higher frequency bands of visible light on the integrity of bacterial cells as well as on other microorganisms. The reports on these studies claim that light inhabiting the blue area of the spectrum (with wavelength ranging from 400 to 500 nanometers) retains some of the ability to harm these microbes while relinquishing the harmful effects of its higher frequency (ultraviolet) counterparts (<400nm in wavelength).

Some have shown, for example, that blue light acts as a phototoxic to the P. gingivalis and F. nucleatum groups (Feursteinet et al. 2004). Similarly, light from argon lasers emitted at low fluencies and existing within a band of 488 – 514nm have a phototoxic effect on the Gram-negative anaerobic and porphyrin-producing bacteria Porphyromonas and Prevotella spp. Bacteria that thrive in the oral cavity and which, exhibiting black pigmentation, is derived from dental plaque, have been destroyed by blue light emitted at an intensity level of 4.2 J $cm^{-2,}$ and P. melanogenic, despite requiring the higher intensity of 21 J cm^{-2}, was nevertheless also destroyed by the blue light.

Also inactivated by blue light emission were Propionibacterium acnes, and this occurred without any added exposure to photosensitizing substances that would induce increased light sensitivity. That is, the blue light by itself was enough to eliminate the viability of P. acnes. Salmonella aureus, too, which has no pigment, is sensitive to visible light, and the optimal wavelength for eliminating its viability has been pinpointed within a bandwidth of 10 nanometers. The lower part of the visible light spectrum—400 to 420nm—has been identified as that having the greatest bactericidal effect, with its peak effect occurring within the smaller 400 – 410 band (i.e., 405nm ± 5nm).

Many other studies have shown the effective parts of the spectrum to reside around the 405nm mark, with little effectiveness occurring at bands higher than 430nm.

However, other more recent studies have identified sanguine effects on the inactivation of bacteria and other microbes (Maclean et al., 2008). Guffey and Wilborn, for instance, show that S. aureus is inactivated using visible light of wavelength 470nm. Certain bacteria that inhabit the digestive system, such as the Helicobacter pylori, were also sensitive to visible light of a similar wavelength.

Of particular interest are those especially infective types Escherichia coli, Staphylococcus aureus (anaerobic bacillus that shown significant resistance to methicillin, an antibiotic), and Pseudomonas aeruginosa (PA). In vitro experiments have shown significant reductions in their viability as a result of blue light exposure (Guffy and Wilborn 2006). The light excites photosensitive porphyrins inside the bacteria, which causes them to exhibit the bactericidal effect upon exposure. However, it was also found that those bacteria without such light-sensitive compounds can also be killed by combining the exposure to blue light with the use of non-toxic dyes that themselves activate upon exposure to light. Examples of such dyes are the cationic phenothiazinium types. Together, the photo-activable dye and the blue light cause the production of reactive oxygen species (ROS).

Reactive Oxygen Species

Reactive oxygen species (ROS) have also been induced by bacteria's exposure to light. Included in these species are oxygen radicals, peroxides, and singlet oxygen—usually tiny molecules whose high reactiveness comes from the fact that they contain shell electrons of unpaired valence. Biological cells have negative responses to high quantities of ROS, and this property has been useful in such photodynamic treatments used in cancer and antibacterial therapies (Lubart et al., 2011).

Photodynamic therapy (PDT) usually uses exogenous photosensitizers added to the cells, to which the light source (set to an appropriate wavelength) is subsequently applied. The molecules used as photosensitizers give off energy to the surrounding molecules of oxygen, and this leads to ROS formation.

Visible light also can stimulate ROS in vivo once the light has been absorbed by the cell's endogenous sensitizers (e.g., porphyrins, flavins, cytochromes). These endogenous sensitizers can absorb light from a wide spectrum of its visible range, with maximum absorption occurring from the blue band. Bacteria, too, have endogenous photosensitizers, and Lubart et al. (2011) explores the possibility that blue light of high intensity could cause significant ROS in bacteria and thereby lead to their destruction. Bacteria such as Propionibacterium acnes, which do contain significant amounts of endogenous photosensitizers, readily die as a result of light exposure. Strains of the same bacteria whose difference manifested in their porphyrin content were shown to react differently under exposure to visible light (Lipovsky et al., 2009).

Light Wavelengths

Varying the wavelength of the light while it is being used in conjunction with the chemicals has also been shown to improve the effectiveness of the bactericidal and fungicidal treatments. Even polychromatic white light, when used in conjunction with the bisamino phthalocyanine BAM-SiPc (unsymmetrical), has been demonstrated to lower the viability of Candida albicans (So et al. 2010). The effectiveness is made more apparent when white light is coupled with cationic fullerenes: this combination renders Candida albicans ineffective with just 10 minutes of exposure (Tegos et al., 2005).

Methylene blue, BAM-SiPc, and BCA all act as an adjuvant to the effects of red light against C. Albicans. The combination of red light with methylene blue inhibits the growth of C. Albicans as well as the formation of its germ tube, and this occurs as a result of an increased permeability granted to the organism by the effects of both actants together. The food dye erythrosine (Red no. 3) is among the chemicals with photosensitizing properties that enable them to combine with light to increase fungicidal effects.

Contemporary research into 470nm blue light

De Lucca et al. 2012 research into the effects of blue light at a specific wavelength of 470nm uses:

- Two LEDs with the blue light that peaks at 470nm
- An incubation mechanism to test the effects of ambient temperatures on fungi or bacteria after exposure to LED

Two separate methods of using electromagnetic radiation via light-emitting diodes (LED) have been generally in use. Photodynamic therapy (PDT) uses the light of a particular wavelength (here 470nm) to stimulate a photosensitizer supplied by the researcher as a third ingredient. PDT shows great therapeutic

promise and is used to generate reactive oxygen species (ROS), which eliminate the microorganism to which it has been applied whenever the ROS reaches toxic levels. The second approach allows the light to locate, directly within the microbe, photosensitizers intrinsic to its cells. These will react with the light without intermediation by a third compound and provides a simpler and, therefore, more transparent process of bactericide and fungicide that supports examination and research.

The research done by De Lucca et al. (2012) closes gaps in the scientific community's knowledge about the effects of filamentous fungi on monochromatic light used in conjunction with photosensitizing chemicals. It also contributes to an understanding of blue light's effects on filamentous conidia of the non-germinated and germinating types, with distinctions made between blue light's use both in and out of the presence of erythrosine. The fungi used in the study are Penicillium digitatum (PD) and Fusarium Graminearum (FG). Citrus exposed to PD evince rot, and FD, which naturally occurs in environments where wheat is stored, renders grain unsafe for consumption after harvesting whenever storage conditions allow for the growth of the fungi.

Leuconostoc mesenteroides is a soil-borne bacterium that contributes to the deterioration of beet and cane sugars in U.S. agriculture, and Bacillus atrophaeus is used as a proxy for the more aggressive Bacillus anthracis. Pseudomonas aeruginosa (PA) causes serious infections to burn wounds, contaminates medical equipment, and leads in many cases to dermatitis upon contact with skin.

Effects of 470nm blue light on bacteria

2006 in vitro study, which determined that **470nm light kills S. aureus and P. aeruginosa**, was designed based on the apparent variability of the bacteria's behavior and dose (intensity) and wavelength of the light used. The S. aureus and P. aeruginosa were treated using lights that peak at 405 and 470nm. For the 470, energy levels ranging from 3 to 15 J cm^{-2} were used. The bacterial colonies were counted in preparation for comparison to control populations, which were not treated with light. The 470nm blue light rendered P. aeruginosa invalid (96.5% reduction) for every dose given. For S. aureus, however, the effective doses were limited to 10 and 15 J cm^{2}, with the highest reduction in colony count being 62%. The indication by these results is that blue light is indeed effective in killing bacteria, but the effect is dependent on the dosage for most (Guffey & Wilborn 2006).

In De Lucca et al. 2012 study, AR1 (the first light array, which was of an impure blue constitution) had the effect of significantly reducing the growth of Leuconostoc mesenteroides (LM). Their colony-forming units (CFU) began exhibiting reduction at an intensity of 150 J cm^{-2}, and when intensities grew to 180 J cm^{-2}, the CFU reduction and loss of viability reached 80%. Treatment with AR2 (the second light array which resided in the pure blue range) resulted in no reduction in the levels of LM. After treatment, LM levels increased only in an incubation environment of 25°C and remained dormant at other temperatures.

AR2's lack of bactericidal effect on LM was atypical of the experiment's general results. Both AR1 and AR2 reduced the levels of CFU in Bacillus atrophaeus (BA), with AR1 reducing the colonies significantly at light intensity levels of 40 J cm^{-2} and killing all colonies and bacilli at 80 J cm^{-2} in conjunction with incubation at 25°C and 30°C. AR2 did achieve viability reduction beginning at 100 J cm^{-2} but required a much higher

intensity of 300 J cm^{-2} and incubation temperatures of 37ºC and to achieve results comparable to those of AR1. AR2 achieved approximately 100% reduction and zero growth only at 300 J cm^{-2}. This is a much higher light intensity level than required by AR1 at 100 J cm^{-2}. The indication from these results is that blue light requires traces from other wavelengths to produce its more effective anti-bacillus effects.

Post-AR1 exposure to 60 J cm^{-2} of impure blue light intensity, BA cells were incubated at 25ºC, 30ºC, and 37C. Those that were incubated at the higher the highest temperature (37ºC) showed lower viability loss than those exposed to the lower temperatures of 25ºC and 30ºC. However, the differences were not statistically significant. Unlike those cells treated by AR1, AR2 cells did not exhibit a difference in viability loss between those exposed to 25ºC, 20ºC, or 37ºC temperatures.

The most sensitive of the various bacteria to blue light was the Pseudomonas aeruginosa

(PA), which responded to both AR1 and AR2 with significant reductions to viability. At just 8 J cm^{2}, PA showed the highest reduction of CFU, which amounted to 84% at incubation temperatures of 25ºC. When the energy levels were increased to 10 J $cm^{-2,}$ and PA's optimal incubation levels of 30ºC and 37ºC were used, the respective reduction rates were 58% and 54%. Interestingly, AR2 had a better effect on viability loss for PA at an intensity of 8 J cm^{-2}. The CFU reduction at these levels was 96% at a post-light treatment incubation temperature of 37ºC —which is the optimal growth level for this particular bacterium. Exposure to the lower temperatures of 25ºC and 30ºC resulted in viability reductions of 62% and 57%, respectively. The lethal effects of the blue light were increased for PA in direct relation with the increase of light intensity. Its behavior suggests that pure blue light is more effective at reducing its viability than impure blue alloyed with other wavelengths.

Effects of 470nm blue light on fungi

<u>Penicillium digitatum</u>

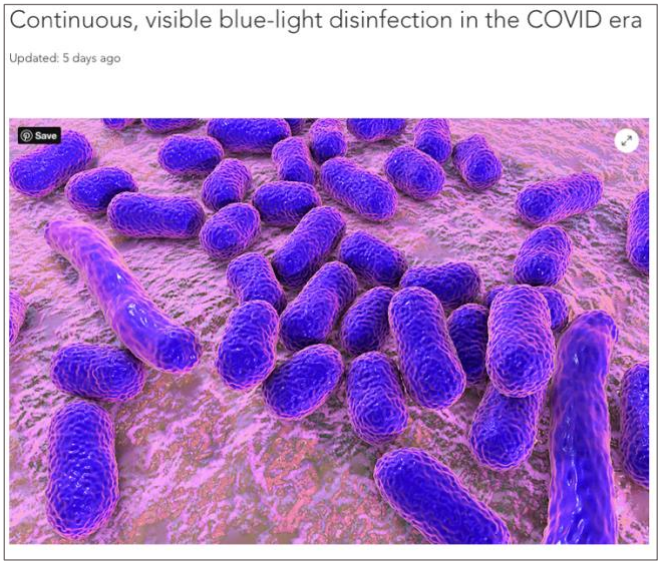
For Penicillium digitatum's germinating conidia, the study showed no significant reduction in CFU when exposed to ERY and blue light when compared with the control group, exposed neither to light nor ERY. Yet, the germinating conidia showed significantly higher susceptibility to the combination of blue light and ERY than their non-germinated counterpart. The decreases in viability were about 80% to 98% when blue light of intensity levels 40-100 J cm^{-2} was combined with 11.4 µmol l^{-1} of ERY, which represented a greater reduction than that shown by the control exposed to no ERY or light. When the ERY levels were doubled to 22.8 µmol $l^{-1,}$ and blue light levels lay at 40 and 100 J cm^{-2}, the reduction in CFU rose to 95% and 98%, respectively. When the light was combined with ERY in this way, it also caused a significant reduction in CFU as compared with the results from control groups exposed to blue light alone or ERY alone.

<u>Fusarium graminearum</u>

Blue light alone was enough to significantly reduce the levels of CFU for germinating conidia. This occurred at energy levels 40, 80, and 100 J cm^{-2} and respectively granted 36, 42, and 47% reductions in CFU levels. The viability losses increased to approximately 90% and 100% when these conidia were exposed to blue light of respective intensities of 40 and 80 J cm^{-2} in combination with 11.4 µmol l^{-1} of ERY. The blue light of intensities 20 and 40 J cm^{-2}, when combined with ERY of twice the concentration (22.8 µmol l^{-1}), led to a larger viability reduction of 80% and 100%. (Note the much lower intensities for blue light.)

The blue band of the light spectrum, 405–470 nm, has a bactericidal effect on Pseudomonas aeruginosa (PA) and on S. aureus, which has shown resistance to methicillin (Guffy and Wilborn 2006). The results of this research by De Lucca et al. show that a similar reduction in viability occurs for LM and BA in the presence of blue light. AR2 peaked at 470nm, and the blue light it emitted was purer than that emitted by AR1, which showed traces of light lying within three ranges of the spectrum: 420–450 nm (indigo), 500–510 nm (cyan), and 520–535 nm. Thus, the study shows in general that blue light produced with no adulteration of light from outside the 405–470 nm band was less effective at reducing the viability of bacteria than that which did contain traces of other types of light particularly indigo, cyan, and green.

For more information on CleanWhite™ technology and its important role in the Covid era, see our blog, "Continuous, visible blue-light disinfection in the COVID era." Which can be found at https://www.immaculight.com/post/continuous-visible-blue-light-disinfection-in-the-covid-era



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