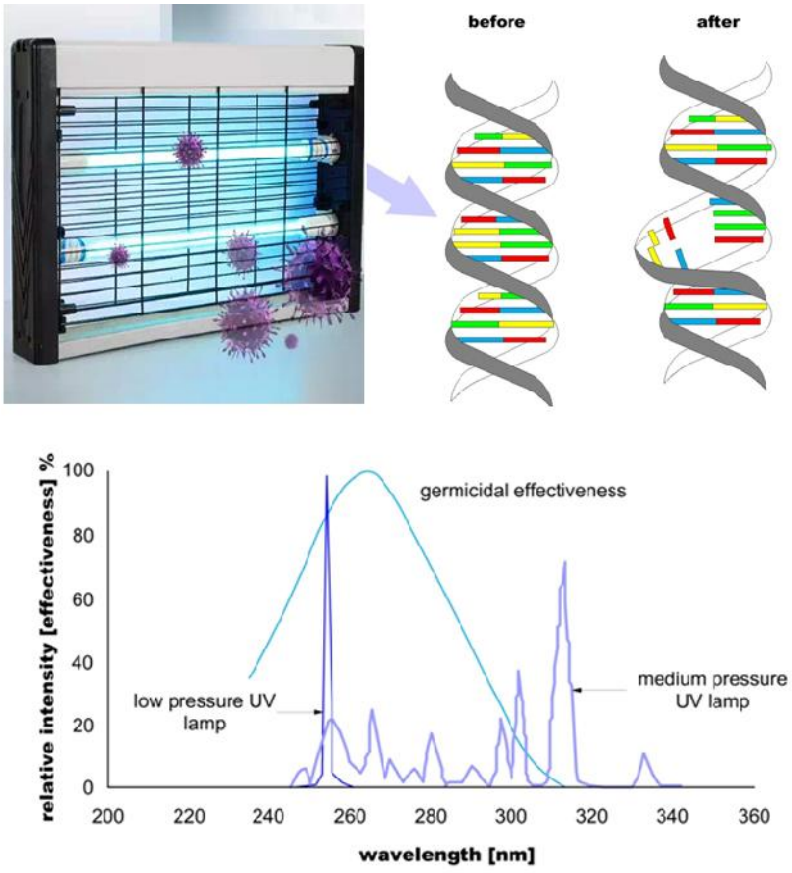
Open Product Describtion

Scientific Foundations, Applications, and Regulatory Framework of Germicidal UV-Lights



prepared by

北京华德海扬科技有限公司

(Beijing Huade Haiyang Science & Technology Co., Ltd.)

Beijing, March 2021

IMPORTANT:

The following material is non-confidential and free to use for decision making and discussion.

Important:

(a) The following data and analysis were compiled in the most accurate way according to common good practice, the latest scientific studies, use experience, as well as the current regulatory environment. No warranty either expressed or implied is given. Reliance on the deliverables as presented in this report by any party shall be at such parties' sole risk.

(b) Forward-looking statements
This report contains forward-looking statements. These statements are based on current expectations, estimates and projections, analysis, and forecasts of Beijing Huade Haiyang Science & Technology Co., Ltd. (北京华德海扬科技有限公司) as well as information currently available to this company. The statements involve certain risks and uncertainties that are difficult to predict and therefore Beijing Huade Haiyang Science & Technology Co., Ltd. (北京华德海扬科技有限公司) does not guarantee that its expectations will be realized. Furthermore, Beijing Huade Haiyang Science & Technology Co., Ltd. (北京华德海扬科技有限公司) has no obligation to update the statements contained in this report.

I. Objectives:

The objective of this open paper is to

- Introduce the scientific basis for the efficacy of germicidal UV lights,
- Describe the application of germicidal UV lights as well as
- Introducing the current international framework surrounding use.

II. In Summary:

- UVC radiation (as in UVC/germicidal lamps) are a highly effective and inexpensive way to inactivate airborne and surface-bound microbes such as the 2019 (COVID-19) corona virus, chickenpox, measles, mumps, and tuberculosis (TB), and cold viruses.

- Manufacturers' recommendations and guidelines how to use UVC/germicidal lamps have to be observed.

- Research is ongoing and in favor of the use of germicidal lamps.

- For the Cameroonian market, we have chosen to introduce a highly effective UVC/germicidal lamp, which is inexpensive, and certified according to the European CE standards. The lamp we introduce is certified to be introduced into the European Union and allowed to be operated in this highly restrictive legal environment.

III. What is UV light and how does it work?

Light is electromagnetic radiation. Ultraviolet (UV) light is electromagnetic radiation adjacent to the visible spectrum of visible light towards shorter wavelength. UV lights have more energy than radio waves or visible light but less energy than X-rays, see Fig. 1.

One can be exposed to UV light through natural sunlight or man-made sources like tanning beds. UV lights are divided into three classifications:

- UVA (320-400 nm),
- UVB (280-320 nm), and
- UVC (200-280 nm).

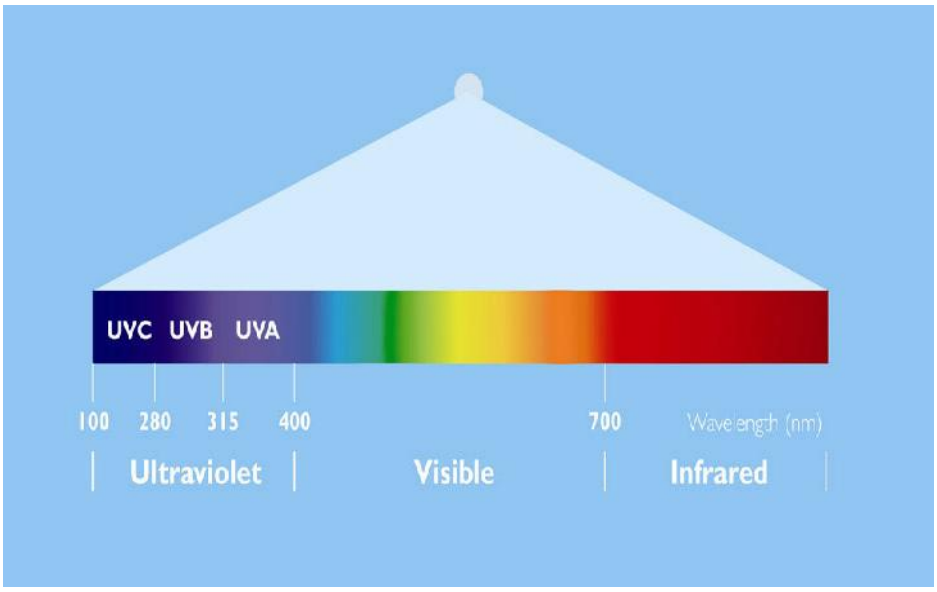


Fig. 1: The visible spectrum of light with adjacent wavelength of UV (ultraviolet) and IR (infrared)

UVC is absorbed by RNA and DNA bases and can cause the photochemical fusion of two adjacent pyrimidines into covalently linked dimes, which then become non-paring bases. In essence, the photochemical process of inactivating RNA and DNA bases can be visualized like in the following Fig. 2.

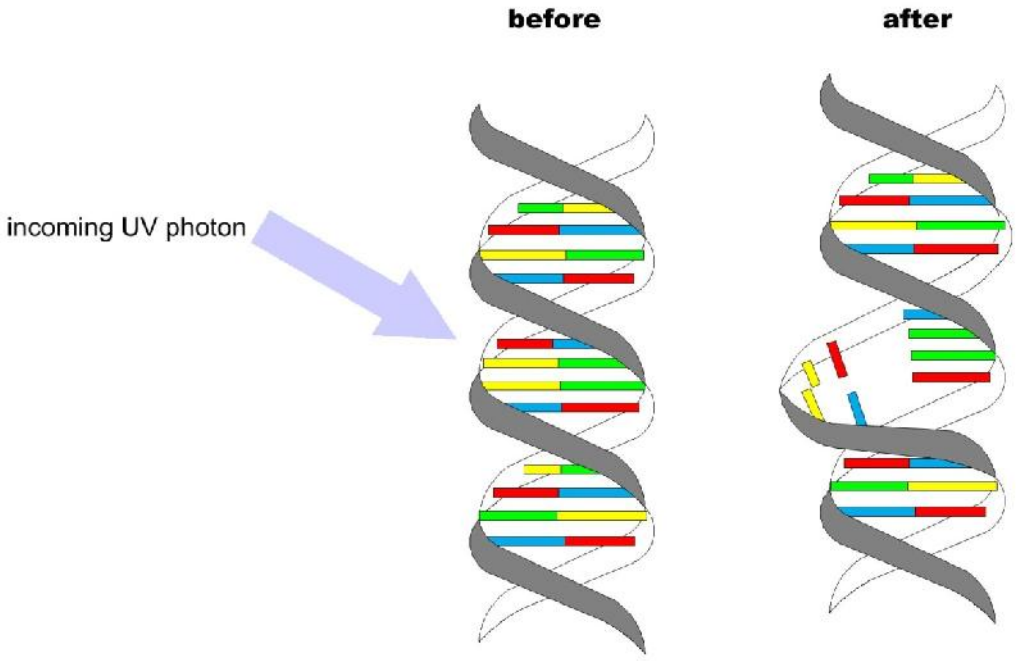


Fig. 2: Inactivation of RNA and DNA via UVC radiation.

UVA rays have the longest wavelengths, followed by UVB, and UVC rays, which have the shortest wavelengths. While UVA and UVB rays are transmitted through the atmosphere, all UVC and some UVB rays are absorbed by the ozone layer. Therefore, most of the UV rays humans come into contact with are UVA with a small amount of UVB.

Like all forms of light in the electromagnetic (EM) spectrum, UV radiation is classified by wavelength. Wavelength describes the distance between the peaks in a series of waves.

- UVA rays have a longer wavelength that can penetrate the middle layer of the skin (the dermis).
- UVB rays have a shorter wavelength that reaches the outer layer of the skin (the epidermis).
- UVC radiation has the highest energy portion of the UV radiation spectrum. UVC radiation from the sun does not reach the earth surface because it is blocked by the ozone layer in the atmosphere. Thus, the only way that humans can be exposed to UVC radiation is from an artificial source like a lamp or laser (U.S. Food and Drug Association, FDA).

The following figure (Fig. 3) shows the UV emission spectrum of low pressure (darker blue, UVC emission peak at 253.7 nm, the tubes on offer for the Cameroonian market) and medium-pressure UV light tubes (a spectrum of emissions from 245 nm to 340 nm).

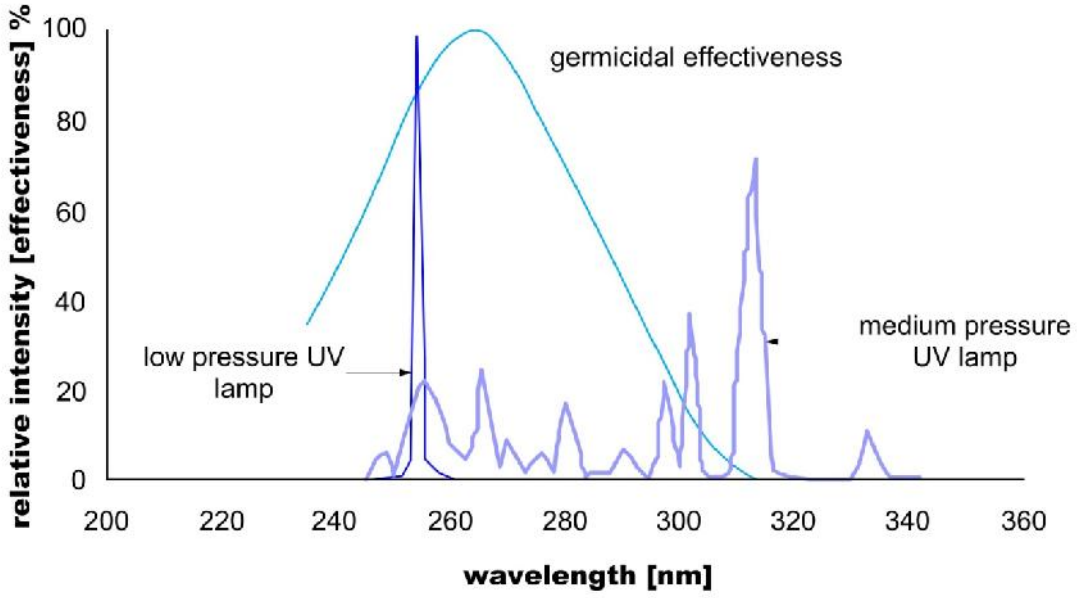


Fig. 3: UV radiation versus germicidal effectiveness. The tubes on offer peak at 253.7 nm, which is the highest germicidal effectiveness currently physically possible

Our tubes are industry standard low pressure UVC emitting tubes with a single peak at 253.7 nm. The light blue bell curve marks the relative germicidal effectiveness over the emitted wavelength in nm.

By comparison, we see clearly that the UVC emissions peak of our low pressure UVC tubes emit light with a sharp peak close to the photochemical optimum with regard to germicidal effectiveness. This is industry standard and the best that can currently be done with respect to aligning the physical emission spectrum with photochemical effectiveness against airborne and surface-bound viruses and bacteria.

UVC lamps can either be non-ozone generating or ozone generating. With one sharp UVC emission peak at 253.7 nm, our UVC tubes are non-ozone generating.

Ozone-generating low pressure UVC tubes do have one more emissions peak at 185 nm. This 185 nm wave leads to ozone generating photochemical reaction with the oxygen in the air as follows:

$$O_2 \xrightarrow{185\ nm\ UVC} O\cdot + O\cdot$$
$$O_2 + O\cdot \rightarrow O_3$$

Ozone, chemically O_3, is a highly reactive gas with a characteristic smell that will, like UVC, inactivates DNA and RNA of viruses and bacteria. In addition, the ozone would reach places (like under tables, chairs etc.) that lights may not reach. The use of ozone, however, requires ventilating a room or a venue after use of such ozone-generating lights in order to avoid negative side-effects to humans.

To make UVC tube ozone generating, an additive in sub milligram quantities is added in the production process of the tube. Thus, for us as distributors and for the customer, there is no cost advantage or disadvantage of using either tube.

We did, however, purposefully introduce non-ozone generating UVC tubes only into the Cameroonian market at first. The reason is that we want to make the application of our germicidal lamps as easy and safe as possible for not yet fully experienced customers. We do this by omitting the need to learn about ozone and the need to appropriately handle ozone in human habitats.

IV. Summary of scientific research of germicidal UV light efficacy and comparison with heat treatment methods to inactivate viruses and bacteria.

The ultraviolet (UV) treatment process is an invisible photochemical process. Ultraviolet lights mutate and/or degrade DNA. DNA (or deoxyribonucleic acid) is the part of the cell that gives an organism its instructions on how to function and reproduce.

When the DNA is damaged, the organism is unable to function because its instructions are garbled or missing. An organism that has no instructions cannot function and reproduce, hence cannot cause infection. It is rendered harmless and eventually dies1. (International Commission on Illumination: CIE 155:2003)

For example, in the UV disinfection process of air, the UVC lamp hit micro-organisms and pathogens, and this destroys their DNA and RNA structure. After the sterilization process, the organisms cannot cause any infection.

IV.a. UVC for disinfecting air:

The American Journal of Scientific Reports (AJSR) explored using non-ozone generating UVC lights to inactivate two types of human corona viruses in air. These two corona viruses 229E and OC43 cause the common cold in humans. Based on their results with these viruses, researchers (Grieb et. al., 2002) concluded that, when applied to current regulatory standards, UVC light will inactivate 99.9 % of airborne corona viruses in about 25 minutes. Due to the similar surface structure, it was concluded that these findings will extend to SARS-CoV-2 (Covid-19) as well.

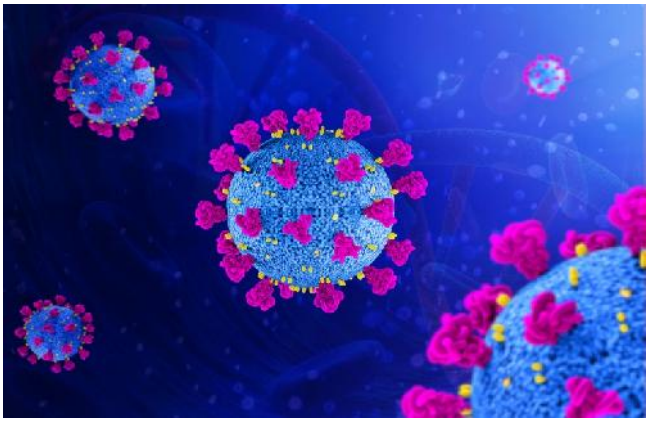


Fig. 4: Corona virus 229E as studied by Grieb et al.

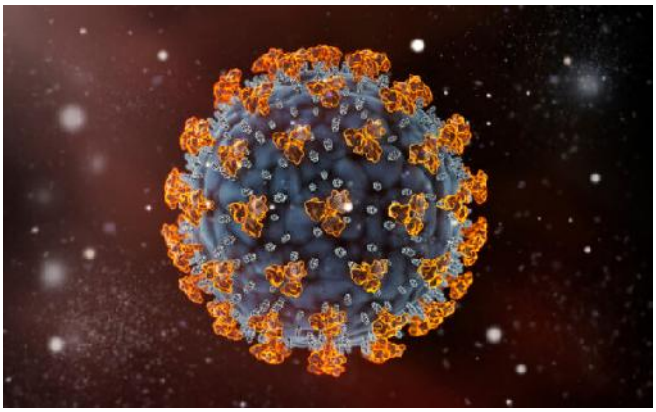


Fig. 5: Corona virus OC43 as studied by Grieb et al.

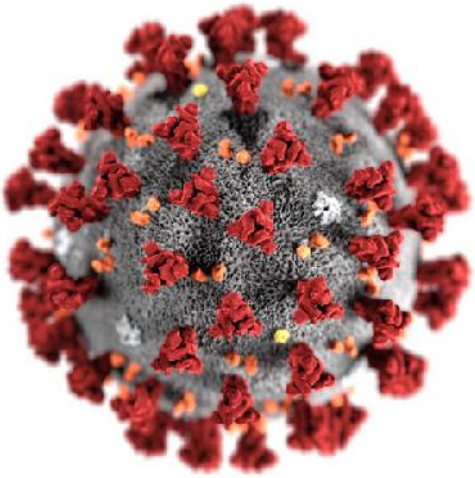


Fig. 6: Non mutated Sars-CoV 2 (Covid 19), the virus that causes the current pandemic

Please compare figures 4, 5, and 6 to see the similarity of corona virus 229E, OC43, and Sars CoV-2, hence the classification as 'corona viruses'. It has been concluded that our germicidal UVC lights are effective against Sars-CoV 2 (Covid 19). And as the photochemical mechanism of inactivation though our UVC lights remains unchanged, these lamps will also be effective against mutated virus.

IV.b. UVC for disinfecting surfaces:

The American Journal of Infectious control (AJIC) looked at using UVC light (non-ozone generating) to inactivate SARS – CoV-2 (Covid-19) on laboratory surfaces. The study found that the UVC light reduced the live corona virus by 99.7% in 30 seconds when the surfaces were free from dust or other materials that might have prevented the rays from reaching its targeted areas. The photochemical process is as described earlier.

IV.c. UVC for disinfecting liquids:

The UVC lamps now available in Cameroon are for air and surface disinfection. We find it necessary to talk about UVC water purification as well, because it might be of future importance and to further broaden the understanding of our audience. We are able to supply UVC lamp systems for the purpose of water purification when customers demand it.

A recent study in the American Journal of Infectious Control (AJIC) investigated the use of UVC to inactivate large amounts of the new corona virus in liquid cultures. The study found that UVC light exposure completely inactivated the virus in 9 minutes.

IV.d. Alternative heat treatment to inactivate viruses and bacteria:

In addition, in order to further complete our short discourse of UVC lights for germicidal purposes, we briefly discuss using heat treatment to achieve comparable disinfecting results.

UVC lamps are not the only means of inactivating viruses and bacteria. Other means include the use of heat. Heat can inactivate viruses by denaturing the secondary protein structure. This changes the spatial structure of the virus, changing its shape, and thus making it biochemically inactive by inhibiting the virus' ability to attach to a host cell and replicate within a host cell (Lelie et. al. (1987), and Schlegel et. al. (2001)).

In order to test the feasibility of heat treatment to inactivate SARS-CoV-2 virus, these were incubated in 1.5 ml polypropylene cryo-tubes at three different temperatures (56˚C, 65˚C, and 75˚C) for increasing periods of time, see Fig. 7.

It was found that at 56˚C most of the viruses were inactivated after 20 min. However, remaining virus remained active at a level close to the limit of detection for the assay for at least 60 minutes suggesting that some virus particles were stable at 56˚C. At 65℃, most of the

virus was inactivated if incubated for longer than 4 minutes. Again, some active virus could still be detected close to the limit of detection for the assay, after 20 min at 65°C.

While virus was incompletely inactivated at 56°C and 65°C even at 60 minutes, complete inactivation was found at 75°C in 45 minutes. Surprisingly, at both 56°C and 65°C the virus was inactivated at early time points but at 60 minutes, a small amount of active virus could still be detected (M.E.R Darnell et al., Journal of Virologial Methods 121 (2004)). One possible explanation for this result might the presence and subsequent dissociation of virus aggregates. As a conclusion, the experimental results of applying heat treatment to active virus suggest that viral inactivation by pasteurization may be very effective.

For the purpose of inactivating virus and bacteria either via heat treatment or via germicidal UVC radiation, we find that germicidal UVC lamps are more cost effective, convenient, quick, and with far better results compared with heat treatment. In addition, heat treatment guarantees complete virus inactivation at or above 75°C , which is impossible to achieve in a meeting room, a customer service hall, a waiting room, and other localities where humans interact.

Another means of air cleaning is the use to bio-filters in specialized air purification devices. Thos devices function by sucking in room air and pressing it through a bio-filter, which holds pathogens back. Such devices have moving parts, which makes them less reliable by principle, and more expensive. Additionally, bio-filter needs to be regularly changed for the device to remain effective, which adds costs to the user. In addition, such air purification devices, by design, cannot inactivate pathogens on surfaces.

Air purifiers are efficient in an environment, where PM 2.5 and PM 10 from polluted rooms need to be filtered. An additional bio-filter component may be helpful. Such devices, by means of design are not the optimum choice for the use case of primarily inactivating pathogens in room air and on room surfaces. In addition, UVC lamps are far cheaper to purchase and operate.

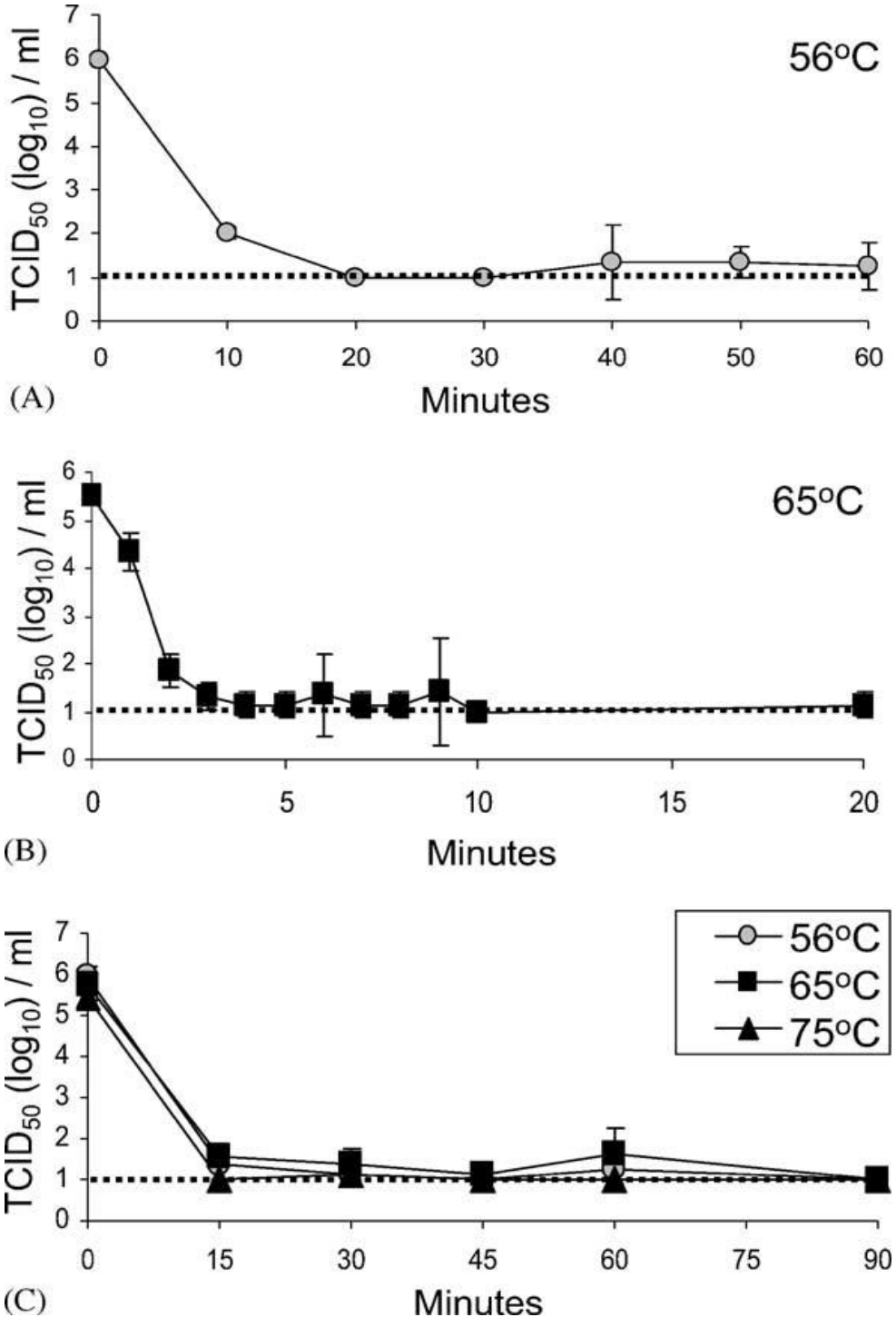


Fig. 6: Sars-CoV 2 (Covid 19) inactivation as a function of temperature and time

V. Necessary UVC dose to ensure proper pathogen inactivation/manufacturer's recommendation

We need to make a statement about for how big rooms we can recommend to use our lamps with and how long these rooms should be radiated in order to reach the desired germicidal effect. This brings us directly to a brief discussion about UV doses and afterwards to our recommendation how to use our UVC lamps.

The UV dose is a measurement on how much UVC light energy is absorbed by a specified amount of area. We express the UV dose mWs/cm^2 (Milliwatt seconds/cm^2). In physics, the power applied for a certain amount of time can be expressed in watt seconds. Watt seconds equals Joule, which is the unit to measure energy. Therefore, our UV dose in mWs/cm^2 (Milliwatt seconds/cm^2) equals mJ/cm^2 (Millijoules/ cm^2). Most UV manufacturers have a variety of systems suitable for different dose requirements.[1]

Intensity is the quantity of UV light per unit area, and time is the amount of "contact time" the UV lamp spends in a particular area during sterilization. So the dose of UV light is determined by calculating two amounts: UV light intensity and time. To simplify the discussion at this point, over a wide range, customers can choose to use stronger UVC tubes over a shorter time or vice versa to achieve the required dose for sterilization. This range is up to the maximum area recommended by the manufacturer of the lamp. In our case, 30W (2x15W) 253.7 nm UVC tubes are recommended for a maximum room size of 40m^2 (minimum 5m^2) and a radiation time of 25 minutes with no person inside during that time. If rooms are larger than 40m^2, then additional lamps have to be added[2]. The accepted standard UVC dose for most applications and for corona virus is 12 -18 mJ/cm^2. The manufacturers' recommendation is set towards achieving this dose.

There are different factors that influence the sterilization process. When disinfecting air, a factor like wind will play a great role in the disinfection process. If it is windy while sterilizing, it will take a longer time for the area to be completely disinfected unlike disinfecting a non windy environment. Similar applies when surface or water purification, just different factors like water current and dust influence duration of sterilization.

---

[1] To calculate the UV dose, one will determine the power density at the targeted surface in Milliwatts/ cm^2 and then multiply it by the number of seconds of exposure. This enables us to conduct quantitative efficacy experiments, but also allows to quantify manufacturers' recommendations.

[2] There are larger and smaller UVC germicidal lamps available. We choose the sweet spot applicable for most, which leads to our volume discounts and to cheaper prices for replacement tubes once this becomes relevant after 3 years or more (8.000 hours) of use.

Translating this framework to the application of our 30W (2x15W) 253.7 nm UVC tubes and the geometry of a variety of rooms and locations, then we arrive at the manufacturers' recommendation for a maximum room size of 40m^2 (minimum 5m^2) and a radiation time of 25 minutes with no person inside during that time.

For practical applications at home, that may mean, for instance, to disinfect a sleeping room half an hour before sleep, or disinfecting a living room before house cleaning. In a professional setup, may it be in a bank, a bar, a shop, at a point of sales, an office, or other places: Before and after use, daily, radiate the room with our UVC lights then proceed with daily cleaning operations as anyway scheduled. This way, regardless whether at home or in a professional setup, the use of our UVC lights can be seamlessly integrated into the daily cleaning routine.

VI. The stance of the American Food and Drug Administration (FDA) and other trusted sources on the use of UVC lamps to inactivate bacteria and virus

The U.S Food and Drug Administration (FDA) is responsible for regulating firms who manufacture, reliable, and or import medical devices sold in the United States of America. We lay emphasis on the American Food and Drug Administration (FDA) because it is often referred to in the absence of national or international standards. At the very minimum, our UVC lamps, which we offer in Cameroon, are all CE certified, which means that those comply with European laws and regulations and are legal to use in any country of the European Union.

The FDA has currently no applicable performance standards, which a UVC lamp, which is regulated as an electronic product, has to adhere to. In May 2020, the American Centre for Disease Control and Prevention (CDC) recommended to businesses preparing to reopen following the pandemic the use of germicidal UV lamps to reduce the likelihood of disease transmission.

UVC radiation can cause burns (of the skin) and eye injuries (photokeratitis). Avoid direct skin exposure to UVC radiation and never look directly into a UVC light source. For nearly a century, short-wave ultraviolet (UV) C energy similar to sun rays has been used to inactivate airborne and surface-bound microbes, including chickenpox, measles, mumps, and tuberculosis (TB), and cold viruses. The corona virus disease 2019 (COVID-19) pandemic, however, is highlighting UVCs potential as an effective air and surface disinfectant.

Consumers should follow the product label directions for use. Consumers should contact manufacturer or seller of the germicidal device directly if they have any questions about how to use products or about its safety or efficacy.

VII. How to use our germicidal UVC lamp

Our 30W UVC lamps are very easy and efficient to use. Fig. 7 illustrates the two ways how to correctly place or hang a UVC sterilization lamp before use. Those can either be hung on the wall with an already made hanging chain, or placed to stand on any surface of choice and then plugged into current.

Then the user steps out of the room and uses a remote control to turn on the lamp. Sterilization for the first time should be done for 30 minutes, after which 25 minutes sterilization will then be done onwards. How often to sterilize depends on the premises. For banks, offices, restaurants, bars, and supermarkets, sterilization should be done twice a day (morning and evening).

Fig. 7: Hang or put our UVC lights at a place of choice

The wave length of the lamp as seen above is 253.7nm. Both tubes are each rates 15W for a combined power consumption of 30W. One 30W lamp can cover a surface area of up to 40m^2. Lamps have to be added to cover a room size of more than 40 m^2. Therefore, it is advisable to know the size of the room the sterilizer is intended to be used in. See Fig. 8 for a summary of the specifications for the lamp on offer.

NON-OZONE UVC
STERILIZATION LAMP.

SPECIFICATIONS:
Model No: 1k281-2x15W.
Watt: 30W+-20%
Input: 220V-240V 50Hz/60Hz.
Size: 49*26*5.5cm
Coverage area: 5-40 m^2
Weight: 1.2 kg
Wave length peak: 253.7nm
Disinfection time: 25 minutes

Fig. 8: Specifications

VIII. Why are UVC lamps very necessary in Africa?

Given that Africa is still far behind when it comes to sanitation and sterilization of homes and public places, it is very necessary to have UVC lamps. They are cost effective in purchase and during use, have a long life span of about 3 years (8.000 hours) and are environmentally friendly. The continent of Africa has currently no effective means of mass-treating Covid-19 and

other air born diseases for a population on the continent of 1.2 billion people. It is therefore preferable to prevent diseases in the first place over waiting for a cure given the effectiveness of these lamps. While respecting social distancing and the use of face masks, it is wise and far preferable to invest in UVC lamps at the same time. Main reason is that Africa still has crowded places like restaurants, bars, banks, markets, churches etc. And last, but by no means least: Preventive measures are always cheaper than curative measures, so they say.

IX. Conclusion

UVC lamps have been used in the past and are currently being used as germicide to reduce the spread of airborne and surface transmissible diseases. These include diseases like measles, mumps, tuberculosis, including the current corona virus. UVC lamps cause no harm, however, have to be used appropriately. UVC lamps are of great health benefits through disease prevention. The most important aspect of UVC lamps is its effects to human skin. As stated by the American Food and Drug Association, the penetration depth of UVC radiation is very low; the risk of skin cancer, cataracts or permanent vision loss is also thought to be very low. This being the case, UVC light should be used in homes, offices, hospitals, restaurants, bars, banks and similar settings to prevent airborne transmission of pathogens such as corona viruses.

References:

1) Scientific report on a "UVC light (222 nm) efficiently and safely inactivates airborne human corona viruses" by Manuela Buonanno, David Welch, Igor Shuryak & David J. Brenner

2) Bai, Y. *et al*. Presumed asymptomatic carrier transmission of covid-19. *JAMA*, (2020)

3) Van Doremalen, N. *et al*. Aerosol and surface stability of sars-cov-2 as compared with sars-cov-1. *N. Engl. J. Med*, (2020)

4) The American Food and Drug Administration (FDA)

5) World Health Organization. *Coronavirus disease (COVID-2019) situation reports*. Available on: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports (2020).

6) van Doremalen, N. *et al*. Aerosol and surface stability of sars-cov-2 as compared with sars-cov-1. *N. Engl. J. Med*, (2020).