Analysis and validation of the germicidal system Air Blue 330 which uses the UV-C radiation technology to sanitize civil and hospital environments.

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INDEX

1. Introduction

Under the convention having as object "**Analysis and validation of products and equipment to sanitize civil and hospital environments based on the UV radiation technology**", agreed between the **Department of Medicine, Surgery and Dentistry of the University of Salerno** and **MediBlue Srl** with its legal offices in Via Tommaso Caruto n. 9 I.A., 84131 Salerno, the activity which has been carried out, is dedicated to the analysis of the procedures currently in use to sanitize civil and hospital fields and to the reference standards. The aim is to validate the new UV-C radiation technology to sanitize continuously the air that circulates in closed environments.

The project is set up in two phases:

- The first phase is related to the collection of the scientific documentation to realize the project and to the knowledge of the density parameters of the radiant energy (or *light dose*) necessary to the reduction and/or complete inactivation of microbial species, fungi, and viruses, considering both the scientific documentation and the patents present at international level;

- The second phase focuses on the development of a procedure for the correct use of the equipment in order to implement and to improve the disinfection levels in the civil and healthcare fields, while ensuring the health and safety protection of the operators at their workplace as well as the programming of the verification activities and checks of the correct performance of the procedure and adherence to the aims.

2. Specific aims of the activity

The general aim of the activity is to verify the capability of the system, called Air Blue 330, to reduce the microbial load in the air, and the subsequent comparison of the density parameters of the radiant energy which is necessary, as reported in the literature, to the reduction and/or complete inactivation of microbial species, fungi and viruses (included SARS-CoV-2).

Specifically, the activity is proposed to validate the Air Blue 330 system, a technology proposed by the company MediBlue in Salerno, with the aim to improve the air quality in civil and healthcare environments and to assure the levels of hygiene required by the current regulatory standards.

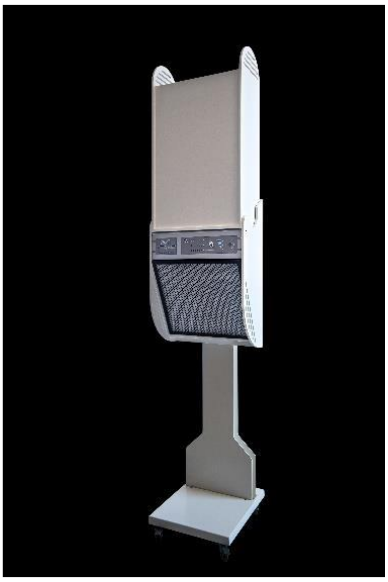

Figure 1 – Air Blue 330 system

In the period of observation the following steps have been performed:

- A deep bibliographic study addressed to the measures carried out to verify the efficacy of the air sanification systems;
- The choice of the analytic methods adapting them to the instruments of interest for the experiment;
- Measurements of the airflow rate, air speed, calculation of the density of radiant energy and the sound level of the device in decibel.

The details of the activities carried out are reported in the next paragraphs.

3. Methods and operating protocols

Bibliographic research has been conducted throughout the main scientific browsers (Web of Science, Scopus, Google Scholar).

National and International rules have been consulted, concerning the limits as to the current legislation.

The measurements have been carried out by means of a multifunctional datalogger Delta Ohm HD 31 with a combined sensor HP472AC R, irradiation is expressed in mW/cm^2, air speed is expressed in m/s or L/s; the sound level has been measured by the device Castel Group GA213.

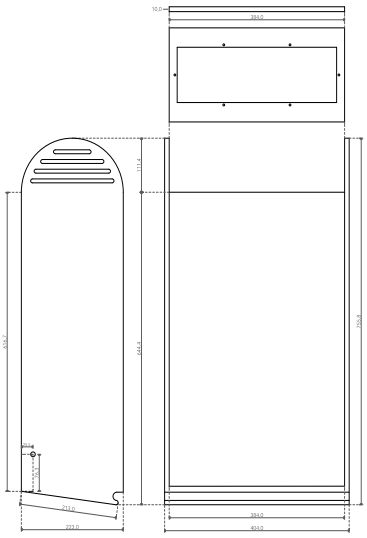

Figure 2 – dimension of the irradiation chamber

4. Results achieved

During this last year, due to the Covid-19 pandemic, people in the whole world become more sensible to assure the best conditions for general health and indoor hygiene. In particular numerous studies have been done on products and procedures that sanitize the environments before their use, to protect the health of each person in the sanitized areas. One of the disinfection methods used to prevent SARS-CoV-2 is the use of sanitizing devices that exploit ultraviolet radiations.

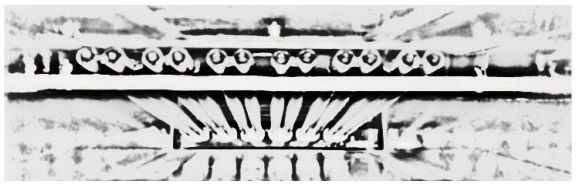

Figure 3 – Irradiation chamber with Philips TUV PL-L 55W lamps

MediBlue, a company in Salerno which is specialized in the supply of sanitizing devices in the healthcare field, has for this reason chosen to validate Air Blue 330, a patented system composed of two parts: *Active Pack AP4330N* which contains 6 UV-C lamps of 55W each, optic labyrinths, internal reflectors of optic aluminium and a microchip that communicates with the Fixed Unit; *Fixed Unit UF4000N* which contains fans, the electronic power supply at high frequency for the UV-C tubes, control panel and electronic system. The environmental air is being forced by 2 powerful fans and, passing through an antidust filter, it's being circulated in the big irradiation chamber where it touches the germicidal UV-C lamps and then reissued, sanitized for 99,99%, into the environment. The optic labyrinths situated at the entrance and exit of the irradiation chamber block the emission of harmful radiations to the outside, thus making the device secure to be used in presence of people without any risk.

Typically, the germicidal lamps used in sterilization systems have a dominant emission at a wavelength of 253nm and the components get filtered at a wavelength lower than 250nm to avoid the risk of ozone production. In these cases the lamp is defined *ozone free*. The Air Blue 330 device uses Philips lamps with a wavelength of 253,7nm and the special glass used for the tubes filters the radiations that produce ozone from 185nm (as stated by the producer). The UV-C radiation acts by modifying the DNA or RNA of the micro-organisms avoiding reproducing themselves and becoming harmful. In fact for many years it has been used in various applications to disinfect food, water and air. Studies in vitro have demonstrated that the UV-C is capable to inactivate 99,99% of the influenza virus in the aerosol[1,2]. The virucidal and bactericidal action of the UV-C rays has been evidenced also in studies concerning MHV-A59 virus, which is similar to MERS-CoV and SARS CoV-1, by means of droplets. The results show that after only 5 minutes of exposure to the UV-C lamp there is a reduction percentage exceeding 99,99%[3]. Other studies report also the efficacy concerning the sterilization of the blood samples[4]. In particular, there is evidence about the inactivation of more than 95% of the influenza H1N1 virus aerosolized by a nebulizer capable to produce a droplet aerosol of dimensions similar to those generated by cough and human breathing. The study of Bedell et al.[3] describes experiments concerning the analyses of the efficacy of a disinfection method of the surfaces rapidly, efficiently and automated, based on UV-C radiations, potentially capable to prevent the spreading of viruses in the healthcare facilities. However a fundamental aspect of these instruments is the need to use UV-C radiations with a constant intensity and stability in time. The power of UV-C lamps and the time must guarantee the correct disinfection, otherwise the surface which is exposed to not sufficiently intense radiation may result as inadequately disinfected with the subsequent problems of security and performances[1]. Therefore, in the experimental set-up used for the validation of the Air Blue 330 device, we considered various positions and various heights to evaluate the impact of these conditions on the efficacy of the system. The results have shown that the irradiation chamber of this device is adequate to obtain homogeneous radiation for the whole section where the air passes during the sanification process. The engineering of the device permits the air to pass through the chamber and along the lamps at a constant speed and induces an effective lowering of the microbic and viral species as indicated in the data of literature.

Figure 4 – Experimental Set

Traditional systems with germicidal lamps generated by UV-C lamps, without a user's protection to their exposure, represent a potential risk due to the wavelength, intensity and exposure duration[5-6-7]. The UV-C radiation can produce serious damage to the eyes and skin, in the range between 180-280 nm. Furthermore, UV-C radiation is a carcinogen for ocular and skin cancer (Group 1 A IARC)[5].

Due to the possible damage to health and safety on work, the use of such systems is governed by the law D.Lvo 81/2008 Title VII Chapter V, which describes the obligation to evaluate the risks of the artificial optic radiation sources and fixes specific values limits to the exposure to prevent side effects on eyes and skin resulting from UV exposure, as specifically indicated in the test of the law which transposes the European Directive 2006/25/EU Artificial Optic Radiations[8-9].

To overcome this problem the disinfection of objects with UV-C radiation, for example, has to be done in a closed environment in which the UV light can not escape to the outside, due to the presence of a plexiglass or glass box which can efficiently screen the radiation.

The Air Blue 330 system, though using UV-C radiation to disinfect the air, has an internal chamber (the irradiation chamber) which protects the operator from being exposed to the radiation emitted by the lamps; furthermore it has an alert system which indicates the replacement of the lamps after a continuous functioning of approx. 9000 hours, as declared by the producer. These characteristics permit the use of the device in absolute safety without any risk for people present in the environment, guaranteeing simultaneously an adequate and constant level of hygiene.

Another aspect to highlight is the relation between the efficacy of the germicidal action and the sanification capacity: it's fundamental to keep in mind that the presence of dust and dirt, both on the lamps and in the environment, reduces drastically the germicidal action. Therefore, in traditional systems the germicidal lamp may be switched on only after an accurate cleaning of the environment in absence of people, and regularly cleaned as to the indications given by the producer. The maintenance of such devices is extremely important for their efficacy and security.

The Air Blue system has an antidust filter at the air inlet which has the double advantage to preserve the germicidal lamps from dust and to guarantee at the same time the quality of the air at the exit of the device.

During the activity done for comparison and validation of the technical parameters of the Air Blue system, we considered the most recent scientific works relative to the disinfection with UV-C radiation against SARS-CoV-2. In particular, N. Storma et al. (2020) describe the inactivation of SARS-CoV-2 not only in wet but also in dry form using the UV-C radiation at 254nm and obtaining a complete inactivation of the contaminated surfaces in just a few seconds of exposure: the infectivity of the virus SARS-CoV-2 has been reduced to lower levels than those revealable in 9 seconds for the dry virus and in 4 seconds for the virus in water[10]. Dwedi et al. (2021) have demonstrated that the exposure of the virus to UV-C for one or two seconds has given a

reduction higher than 2,9 and 3,8 log_{10}, while for longer exposure times (from 4 to 120 seconds) a reduction higher than 4,7 log_{10}.

Until now, data reported in the literature show that UV-C radiation is effective against all coronaviruses, even if the absorption capacity of the devices may modify the result of the test. The higher limit calculated for the median dose of logarithmic reduction (in devices with low absorption) is 10,6 mJ/cm^2, but probably the most precise estimation is 3,7 mJ/cm^2[11-16].

These results have been obtained by investigating various coronaviruses, included SARS-CoV and MERS-CoV. Nevertheless, we may presume that they are applicable also on SARS-CoV-2 and all future mutations as the RNA mutations influence the pathogenicity of the virus but do not imply structural differences, especially as far as the UV absorption property of RNA is concerned, which is the main aspect of the antiviral effect of the ultraviolet radiation. The above indicated doses of log-reduction are in the same order or even lower than the log-reduction doses for other important pathogens like *Staphylococcus aureus, Escherichia coli, Klebsiella pneumonia* or *Candida albicans*[17].

And even more, a recent study done by the research center "Columbia University Center for Radiological Research" (CCR) emphasizes again the efficacy of the UV-C irradiation.

The reported values result even lower than, for example, the international standard for disinfection of the drinking water by UV which is 40 mJ/cm^2[17]. Therefore, we may conclude that the analyzed systems and the procedures of UV-C disinfection can inactivate all coronaviruses, included SARS-CoV-2. In table 1 we report the data obtained for the calculation of the UV-C dose for the three different flows of the Air Blue device (speed 1, 2 and 3) and the influence of the presence of the upper grid. As it can be seen from Table 1 and Figure 5, data are perfectly aligned with those present in the literature and with a possible reduction of the virus of approx. 99,99%.

Table 1. Results calculation light dose in speed 1,2 and 3.

UV Dose mJ/cm^2	Flow m/s	σ	
7,88	1,12	± 0,02	
6,71	1,32	± 0,03	with upper grid
5,08	1,74	± 0,02	
5,75	1,54	± 0,04	
5,02	1,76	± 0,02	without upper grid
3,80	2,33	± 0,03	

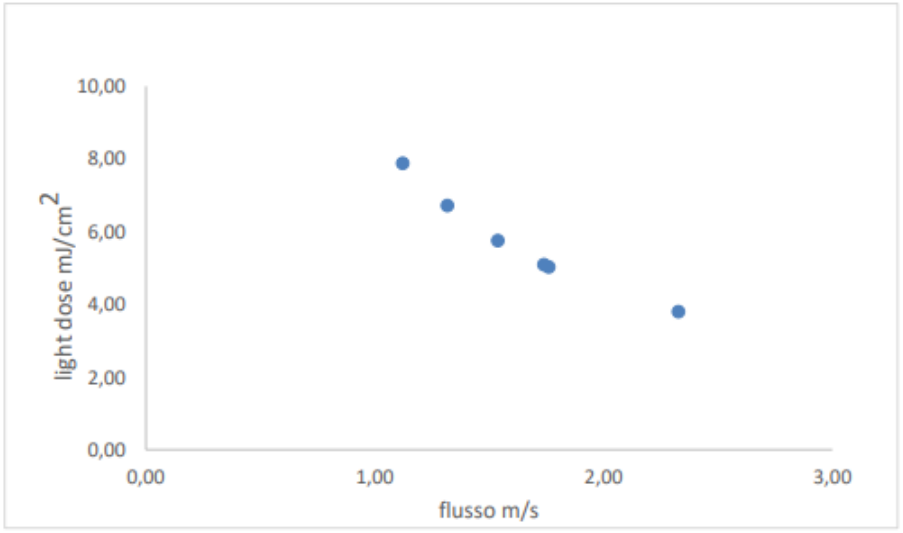

Figure 5. Trend of radiant energy density related to the speed of air inlet.

Another very important aspect that has to be considered is the noisiness of the device in various conditions. The noise exposure, in fact, may compromise people's health and have serious side effects on air pollution and toxic substances, as declared during the launching of the new guidelines about the noise of the WHO. The document is a result of a group of experts published on October 8th, 2009 and may be considered an implementation to the previous guidelines of 1999 concerning the noise in the community and stems from the need to satisfy the European Directive 2002/49/CE (otherwise known as Environmental Noise Directive) that is related to the verification and managing of environmental noise.

Table 2. Results of noise determination relative to speed 1, 2 and 3.

Noise (dBA)	Speed	σ	distance
47,3	1	± 0,6	close
54,1	2	± 0,4	close
57,0	3	± 0,5	close
45,4	1	± 0,4	1 m
49,0	2	± 0,8	1 m
54,8	3	± 0,5	1 m

The level which is considered critical to avoid hearing damage is 90 decibels, the one of pain is around 120 decibels. The WHO fixed average levels which must not be exceeded to avoid a series of related disorders: sleeping and concentration problems, the onset of stress, anxiety and irritability, cardiovascular system disorders and even digestive and respiratory disorders. The average level recommended by the WHO is 55dBA, or A-weighted decibel, which considers the different sensibility of the ear at different frequencies, during the day (from 6 till 22) and 45 dBA during the night (from 22 till 6).

In the working environment the daily exposure level to noise LEX, 8h dBA is the main descriptor of the risk to noise exposure defined by Legislative Decree 81/08. The decree fixes three levels of LEX,8h: the lowest level of action of 80 dBA, the higher level of action of 85 dBA and the limit value of 87 dBA, the precise value of 140 dBA.

The measurements done on Air Blue 330 by means of the Castel Group GA213 device have produced medium values congruent to those reported by WHO as recommended values and are not harmful to users and present people, as indicated in table 2.

5. Deviations, critical issues and corrective actions

In this first stage of the project there have not been deviations concerning the initial planning. The criticalities that emerged are related to the possible techniques to be used to improve the efficiency of the lamp in only one step or in particular contaminated environments.

Concerning the regulations regarding the definition of the biocidal and/or disinfecting product, since the sanitizing activity of the ultraviolet radiation is based on a physical principle, the disinfection systems based on UV-C radiation fall outside the application of Reg. (EU) n. 528/20212 which exclude expressly the definition of biocide for the products that act by means of physical and mechanical actions. Also on a national level the regulations as to DPR 392 dated October 9th, 1998 already excluded the products which have a disinfection activity by means of physical or mechanical actions, from the medical surgical device classification (PMC). Nevertheless, these systems have demonstrated a real biocidal capability, may be used in continuous, also in presence of people and do not harm individuals and objects inside the environment.

6. Conclusions

The activity carried out has shown that excellent air sanification can be achieved with the technology of the Air Blue 330 system. From the tests has arisen that the device has a density emission of radiant energy between 5,08 mJ/cm^2 (speed 3) and 7,88 J/cm^2 (speed 1), doses for which literature shows a 99,99% reduction and elimination of the viruses. In literature are shown in vitro tests on surfaces; in our case the tests have been carried out in real conditions of

use and it can be imagined that, in continuous aspiration cycle, the air makes more passages through the irradiation chamber and increases furthermore the sanification grade which is already estimated in 99,99% at a single passage.

Although further evidence will be needed to show the efficacy evaluated on the field, the methodology used by the Air Blue system may represent a standard for the disinfection of the hospital environments in order to reduce the infection rates caused by the presence of pathogens and viruses.

In conclusion, the system may be indicated for the disinfection of any kind of environment with a high probability of transmission of airborne pathogens.

Fisciano, May 27th 2021

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