Beghelli S.p.A.

Via Mozzeghine 13/15 – loc. Monteveglio
40053 Valsamoggia, Bologna (IT)
P.IVA 00666341201

ENVIRONMENTAL SANITIZATION: UV-C TECHNOLOGY TO REDUCE THE RISK OF CONTAGION IN LIVING AND WORKING ENVIRONMENTS

BEGHELLI PRODUCTS designed for AIR SANITIZATION

The new Beghelli sanitization systems called SanificaAria, use an axial fan system to treat the air using an ultraviolet lamp (cartridge) in C band (UV-C).

The air present in the environment is forced into a chamber in which the UV-C source is active. This is where the sanitization process is carried out. After completion, the air is expelled and returned to the environment.

Characteristics and effectiveness of air treatment using ultraviolet technology are highlighted in the attached bibliography.

AIR SANITIZATION using UV-C TECHNOLOGY

UV-C technology has been used for years in the treatment of fluids sanitization, as the efficacy of UV-C to act on DNA of viruses has been proven to inactivate cell replication.

In support of this, two important documents update the considerations already present in extensive scientific literature, especially related to what happened in the year 2020 regarding COVID-19:

- CIE Position Statement on Ultraviolet (UV) Radiation to Manage the Risk of COVID-19 Transmission - May 12,2020 (Annex 1),
- ISS COVID-19 Report no. 25/2020 of 15/05/2020 (ISS – Italian Istituto Superiore di Sanità):

"*UV-C radiation has the ability to modify the DNA or RNA of microorganisms, preventing them from reproducing and therefore being harmful. For this reason, it is used in various applications, such as the disinfection of food, water, and air.*

In vitro, studies have clearly shown that UV-C light can inactivate 99.99% of the flu virus in aerosols. The virucidal and bactericidal action of UV-C has been demonstrated in studies on the MHV-A59 virus, a murine analogue of MERS-CoV and SARS-CoV-1.

Application to droplets containing MERS-CoV resulted in undetectable levels of the MERS-CoV virus after only 5 minutes of exposure to the UV-C emitter (a reduction greater than 99.99%) and has also been found to be effective in sterilizing blood samples.

In particular, the inactiviation of over 95% of the H1N1 influenza virus aerosolized by a nebulizer capable of producing aerosol droplets of similar size to those generated by the human cough and respiration has been demonstrated".

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CHARACTERIZATION OF BEGHELLI TECHNOLOGICAL SOLUTIONS

Beghelli considered it essential to carry out characterization tests of the technological solutions adopted in the realization of its products and in particular with, the SanificaAria 30 product, under various points of view:

- Effectiveness: assessment of the capacity to inactivate bacteria and viruses according to the applicable technical regulations.
- Safety: evaluation of the safety of use of the product with particular reference to the elimination of intrinsic risks related to the danger of UV-C radiation and the generation of ozone, to allow the use of products even in the presence of people.
- Efficiency: evaluation of the effective sanitization efficiency of the environments, where "infectious" and "infectable" subjects are hypothetically present.

Concerning the **efficacy and safety assessments**, the design approach adopted in the development of the current devices for air sanitization was preceded by the analysis of the regulatory context, to identify the most appropriate available normative references, **in consideration of the use of UV-C sanitizing devices in the presence of people:**

- **Efficacy** -> evaluation of antibacterial activity:

  The product has been subjected to tests to verify the germicidal activity against microorganisms that are different from each other in terms of resistance to UV-C light.

  The analyses were carried out at the Tecnal srl laboratory, a laboratory recognized as competent to operate according to the UNI CEI EN ISO / IEC 17025: 2005 standard, in collaboration with Gelt International srl, between 06/12/2020 and 07/13/2020.

  The test is conducted according to the requirements of the technical standard ISO 15714: 2019: "*Method of evaluating the UV dose to airborne microorganisms transiting in-duct ultraviolet germicidal irradiation devices*". The standard describes test methods for analytical laboratories to verify the performance of germicidal devices with UV-C irradiation placed in heating, ventilation, and air conditioning ducts.

  The results obtained, confirm that the Beghelli SanificaAria device has an effective UV-C dose between 25 and 120 J / m2, deactivating up to 90% of the Gram-positive microorganisms and up to 99% of the Gram negative ones. The test fungus, Cladosporium sphaerospermum, is inactivated no more than 33% as it would require higher UV doses.
  (Report n.20TR0026 / 01 or 07/14/2020)

- **Efficacy** -> antiviral activity evaluation:

  The anti-viral efficacy tests of the Beghelli SanificaAria 30 system were performed at the Laboratory of Microbiology and Virology of UNIMORE - University of Modena and Reggio Emilia.

  The tests involved the use of 2 types of viruses: Adenovirus and OC43 Coronavirus HCov-OC43 (the latter completely similar to the HCoV-SARS-2 responsible for CoViD-19).

  The virus used in this study is the human coronavirus HCov-OC43 which has an extremely high homology of structure with the virus responsible for CoViD-19, HCoV-SARS-2, from both a phylogenetic and molecular point of view.

The results of the tests have shown that the virucidal action of SanificaAria 30 is as follows:

CORONAVIRUS HCoV-OC43:

99.7% inactiviation percentage (**2.5 log reduction**)

ADENOVIRUS AdV-5:

94.4% inactiviation percentage (**1.25 log reduction**)

(Report n. MS2_2020_R42 of 28/07/2020)

- **Safe use in the presence of people** -> dangerous radiation emission:

  Standard IEC 60335-2-65: 2002 + AMD1: 2008 + AMD2: 2015 (subclause 32.102).

  "*Household and similar electrical appliances - Safety - Part 2-65: Particular requirements for air-cleaning appliances*"

  "**32.102** Appliances shall not emit radiation in hazardous amount.
  Compliance is checked by the following test.
  The appliance is supplied at rated voltage and operated under normal operation. The irradiance is measured at a distance of 300 mm, the measuring instrument being positioned so that the highest radiation is recorded. If the appliance has an inspection window, the device was subjected to the analysis of the emission of spurious UV-C radiation in order to verify its safety in daily use."

- **<u>Safe use in the presence of people</u>** -> <u>ozone emission</u>:

  Standard IEC 60335-2-65: 2002 + AMD1: 2008 + AMD2: 2015 (subclause 32.101)

  "*Household and similar electrical appliances - Safety - Part 2-65: Particular requirements for air-cleaning appliances*"

  32.101 The ozone concentration produced by air-cleaning appliances shall not be excessive. *"Compliance is checked by the following test, which is carried out in a room without openings having dimensions of 2.5 m x 3.5 m x 3.0 m, the walls being covered with polyethylene sheet."*

  The device was subjected to an analysis of the ozone emission in order to check for any emissions, despite the use of lamps with intrinsic safety features (declarable "ozone free" with an emission lower than 0.01g / KWh).

  The tests have shown that the ozone concentration in 24 hours (Standard IEC 60335-2-65: 2002 + A1: 2008 + A2: 2015 § 32.101 + UNI EN 14625: 2012) is equal to 8.6 µg / m3 compared to of an allowed limit of 100.
  (Report No. 20COA01109 of 11/11/2020)

  With regard to evaluations on the effectiveness of use, it was necessary to combine skills in the fields of virology and risk assessment in workplaces.
  Beghelli identified these skills within the University of Padua, and in particular at the Department of Molecular Medicine and the Department of Industrial Engineering - Civil and Industrial Safety Engineering.
  The study commissioned the researchers to have as its object "Reduction of microbiological risk in confined environments through the use of" SanificaAria 30 ".

  This result of the studies (Scientific Report of 10/09/2020) can be summarized as follows:

  "In conclusion," SanificaAria 30 "guarantees the inactivation of Gram-positive and Gram-negative bacteria and fungi in 1 hour, also reducing the risk of respiratory infection caused by these microorganisms. Non-enveloped viruses such as Adenoviruses are particularly difficult to control due to their innate resistance to UV-C radiation. In fact, in the worst case, "SanificaAria 30" can reduce the risk of Adenovirus infection after 5 hours of activation. On the other hand, enveloped viruses such as the Coronavirus SARS-CoV-2 which causes COVID-19 are more sensitive to UV-C radiation and the risk of infection by these pathogens is reduced to approximately zero after two hours of activating the device."

  It should be noted that the aforementioned assessments were carried out with specific reference to the flow rate of the product in cubic meters / hour, assuming the coexistence of infectious and healthy people in view of a precise definition of the actual quantity of "infectious droplets" issued by a sick subject who breathes 0.45m3 / hour and can potentially breathe, sneeze and cough.

CONCLUSIONS

Performance and safety of the Beghelli SanficaAria products have been tested on the basis of known legislation and using third-party testing bodies of recognized competence. Information is available to customers on the packaging and also on the dedicated company website.

With regard to use in the field, illustrative information and criteria have been provided that can allow the user to identify the best positioning according to the various environmental situations.

The technical file containing the entire set of reports mentioned in this document is available upon agreement with the Company and is subject to confidentiality agreements.

BEGHELLI SPA
Ing. Fabio Pedrazzi
Valsamoggia, 02/03/2021

International Commission on Illumination
Commission Internationale de l'Eclairage
Internationale Beleuchtungskommission

CIE Position Statement on Ultraviolet (UV) Radiation to Manage the Risk of COVID-19 Transmission

May 12, 2020

Introduction

The coronavirus disease (COVID-19) pandemic has accelerated the search for environmental controls to contain or mitigate the spread of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) responsible for the disease. SARS-CoV-2 is usually transmitted from person to person by contact with large respiratory droplets, either directly or by touching virus-contaminated surfaces (also denoted as fomites) and subsequently touching the eyes, nose or mouth. Importantly, there is growing evidence of virus transmission via the airborne route as the large respiratory droplets dry out and form droplet nuclei which can remain airborne for several hours. Depending on the nature of the surface and environmental factors, fomites can remain infectious for several days (van Doremalen, 2020).

The use of germicidal UV radiation (GUV) is an important environmental intervention which can reduce both contact spread and airborne transmission of infectious agents (like bacteria and viruses). GUV within the UV-C range (200 nm–280 nm), primarily 254 nm, has been used successfully and safely for over 70 years. However, GUV must be knowledgably applied with appropriate attention to dose and safety. Inappropriate GUV application can present human health and safety issues and produce insufficient deactivation of infectious agents. Application in the home is not advisable and GUV should never be used to disinfect the skin, except when clinically justified.

What is GUV?

Ultraviolet radiation is that part of the optical radiation spectrum that has more energy (shorter wavelengths) than visible radiation, which we experience as light. GUV is ultraviolet radiation that is used for germicidal purposes.

Based on the biological impact of ultraviolet radiation on biological materials, the ultraviolet spectrum is divided into regions: UV-A is defined by CIE as radiation in the wavelength range between 315 nm and 400 nm; UV-B is radiation in the wavelength range between 280 nm and 315 nm; and the UV-C wavelength range is between 100 nm and 280 nm. The UV-C part of the UV spectrum has the highest energy. Whilst it is possible to damage some microorganisms and viruses with most of the ultraviolet radiation spectrum, UV-C is the most effective and hence UV-C is most commonly used as GUV.

The radiant exposure required for the deactivation of an infectious agent by 90 % (in air or on a surface) depends on the environmental conditions (such as relative humidity) and the kind of infectious agent. It typically ranges between 20 J/m^2 and 200 J/m^2 for mercury lamps predominantly emitting radiation at 254 nm (CIE, 2003). Previously, GUV of 254 nm has been shown to be effective in disinfecting surfaces contaminated with the Ebola virus (Sagripanti and Lytle, 2011; Jinadatha et al., 2015; Tomas et al., 2015). Other studies have demonstrated