Technical report on environmental tests in elevators

Preface

The sanitization of environments has the purpose of containing and reducing the quantity of microorganisms present in them.

The role of environments in the contamination process of living beings, with particular attention to surfaces and furnishing accessories is a crucial topic. Both the surfaces and the furnishing accessories act as reservoirs for potentially pathogenic microorganisms, increasing the risk of cross-contamination through both direct and indirect contact and for this reason they are the main object of sanitation routines. Common sanitation routines are based exclusively on the use of chemical disinfectants.

The use of **chemical disinfectants has a very consistent environmental impact as well as presenting several disadvantages that are often little known**.

The effectiveness of a chemical biocide is linked to several factors: the type of microorganism, the concentration, the contact time, the pH, the temperature, the presence of organic material.

The first consideration to be made is **the limited effectiveness over time**: the disinfection in fact covers a maximum time span of containment of the microbial load which rarely reaches 30 minutes. At the end of this short period, the microbial load begins to grow uncontrollably. The different efficacy of the disinfectant in relation to the material of which the treated support is made must also be considered.

Another important chapter is the **ability of microorganisms to develop specific resistance to different disinfectants**, this type of evidence is widely described in the scientific literature. Ultimately, the impact on the environment of these chemical biocides is very heavy and difficult to control, with the only result of obtaining a diffusion of these chemicals in the air, water, and soil.

Considering the continuous increase in bacterial species resistant to both disinfectants and antibiotics and with the acceleration imposed by the ongoing SARS CoV-2 pandemic, **a paradigm shift in the sanitation of confined spaces was required using modern technologies, safe for living beings, ecological that can limit as much as possible the problems induced by chemical biocides, guaranteeing the correct safety of the environments.**

The use of visible light radiation in the space between 400 and 450 nanometers has been the subject of numerous efficacy tests with respect to different microbial species, amply demonstrating their effectiveness in countless scientific studies conducted by a multitude of universities and research centers.

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The possibility of using a common element in confined environments such as visible light realizes the new paradigm of sanitation, continuous sanitation.

A continuous action in the presence of living beings, safe, with little or no environmental impact, which does not generate resistance from microorganisms and which above all keeps the environmental microbial load under control without ever reaching complete sterility with the aim of maintaining reactive the immune system thanks to the continuous interaction with sub infectious doses of microorganisms, represents a Copernican revolution in the field of microbiological safety.

The great evolutionary success obtained by microorganisms suggests that theirs has been and is a fundamental role in the evolution of life and thinking about eliminating them recklessly appears to be an imprudent choice.

When we use disinfectants recklessly, we destroy the part of microorganisms that represent the natural environmental microbiota, helping to establish an "environmental dysbiosis", a condition which, although it does not present immediately diagnosable symptoms, as in the case of humans, leaves open a space for colonization to pathogenic microorganisms.

Context of action

A lift is an essential means in daily life, and it is therefore a perfect subject to any analysis trying to assess its microbiological safety in everyday use. In some cases, a lift is also the only way to access the highest floors in a building, especially in the case of elderly or very young people.

Due to its construction and use characteristics, an elevator represents a hygienically sensitive environment that is easy to transmit microorganisms.

In fact, elevators are characterized by narrow spaces, to which people have easy access, and where very often there are close contacts between users, albeit for short periods, as well as with surfaces, in particular the push-button panels, with which passengers have continuous interactions.

Thus, in office buildings, large condominiums, and commercial establishments open to the public, it is always necessary to ensure that lifts are always as safe as possible, not only by carrying out the maintenance, but guaranteeing their microbiological safety by proper cleaning routines and sanitation practices, even better through systems capable of guaranteeing a microbiological safety that is continuous and passive (i.e., unattended).

And, therefore, the implementation of correct systems to guarantee adequate sanitary conditions is fundamental both to prevent and to control the onset of any infectious risks.

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Project Segments

The project was divided into three different phases:

a) Supply by the Nextsense team of the necessary scientific documentation to support the microbicidal efficacy of the visible light wavelengths emitted by devices with Biovitae® technology and their safety for continuous use in the presence of living beings.

b) Design, manufacturing, and allocation by the Nextsense / Aurora team of the lighting devices to be installed in the elevators and that can guarantee the required lighting levels while ensuring continuous sanitization.

c) Microbiological verification in real environment of devices made with Biovitae® technology.

Analysis of the technical-scientific documentation

The analysis of the documentation provided by Nextsense had two purposes: the first was to provide evidence, from third parties, to support the technology microbicidal efficacy and its scientific background; the second was to provide the technical basis to demonstrate the absolute safety of the devices while continuously operated. The documentation provided was found to be robust enough to proceed with the next phase of the project.

Design, manufacturing, and allocation of the lighting devices

The Company requested that the lighting devices with Biovitae® technology supplied by the Nextsense/Aurora team were in the form of a GU10 lighting device that could be installed without making any changes to the original lighting system of the elevators of their production.
The lighting devices had to ensure the continuous sanitization of the lift to be used as the test site in addition to the correct lighting requirement for this type of lift.

The devices were made and sent to The Company which was able to verify the consistency of the required lighting characteristics and was therefore able to proceed to the final phase of the project.

Effectiveness test in a real environment

This phase involved the verification of microbiological efficacy in the cabin of an elevator of 1200mm x 1200 mm x 2200 mm size.

The following microorganisms were chosen for the microbiological tests, with sampling involving both swab of the internal surfaces and air collection:

- *Saccharomyces cerevisiae* (fungi)
- *Escherichia coli* (bacteria)

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Results and comments on bacteria and fungi testing

As can be seen from the final report provided by the Company, in a real environment the **Biovitae® technology is able to keep what it promises, i.e., an effective control of the microbial load on both surfaces and in the air, regardless of the distance from the light source.**

Results and comments on the virus testing

A deeper analysis is required on the laboratory tests carried out on the human coronavirus 229E/GFP.

Although there are no doubts about the perfect conduct of the test in the laboratory from a microbiological point of view, the problem to be highlighted is that the alleged unsatisfactory virucidal efficacy derives from the wrong experimental setting with respect to the choice of the device and to the viral population density. This is explained in the following lines.

Device used for laboratory tests on the virus in vitro.

From the beginning of the project, the Company asked the Nextsense / Aurora team to design and build a plug and play product, capable of replacing the lighting already present in the elevators without any structural change, which would adapt to replace the lighting of the elevators. already operational and could become the basis of those newly installed.

The device had to guarantee both the lighting requirements for a lift and guarantee microbicidal efficacy through the principle of continuous sanitation.

Obviously, the devices have been designed and then manufactured to guarantee protection from microbiological risks in consideration of the average quantity of microorganisms present on the surfaces and in the air in an elevator, as well as considering that in a real environment the microbial load is not concentrated in a unique space but is ubiquitously widespread on all exposed surfaces. Furthermore, GU10 devices with Biovitae® technology are designed considering the synergistic action they have when, installed within a real environment, they work together.

Let's start with a brief consideration: according to the ISO guidelines, testing a chemical disinfectant in vitro requires pouring a given quantity of that disinfectant inside a Petri dish, so that all microbial populations enter in contact with the whole quantity of disinfectant. But this has not happened during the in vitro test with the Biovitae® GU10 device, where only a fraction of the irradiated energy has reached the contaminated surface.

That said, we know that, according to Kurgat et al. (2019), in a real work environment, after 6 hours of workday activity, it is possible to measure an average virus concentration of 1,32 log10 PFU/cm2 (roughly, 20 PFU/cm^2).

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But during the test in vitro, experiments were conducted with an average load of 70000 PFU/ml (considering the 1E+05 factor, and where 1 $TCID_{50}$/ml = 0.7 PFU/ml). And it already means that the virus concentration of the test was 3500 times larger than the average virus concentration of a real environment.

We can see in fig. 1 a graphic representation of the scenario of the experiment as it was conducted, where it is evident that the flat area covered by the light radiation emitted by one single GU10 device installed at 50 cm distance was 23559 cm^2 (2,3559 m^2) which is much larger than the flat area of the 79 cm^2 of a Petri dish (assuming a 100mm diameter) in which the virus populations were concentrated. To perfectly cover the flat area of a Petri dish, the GU10 device had to be installed at 2,90 cm from the surface.

The difference is that while at 50 cm distance, starting from 0.44 mW nm-1 in the Soret-Band region, the irradiated energy was 0.0185 $mWcm^2$, at 2.90 cm distance the irradiated energy would have been 5.5283 $mWcm^2$, or a 298-fold factor.

Therefore, the energy that reaches the Petri dish is only $1/298^{th}$ of the total energy that would have been irradiated with the correct experimental setup. And with that in mind, the result takes on a completely different weight, as it can be assumed that with only a fraction of the total energy irradiated by a single GU10 device over a population of about 70000 PFU (1 $TCID_{50}$ = 0.7 PFU) in 60 minutes has however achieved, as we see from the table in paragraph 3.3.2 of the test report, a reduction of about 30% on Sample 1 and of about 78% on Sample 2 of the total viral load (and the relevant differences at the 30 and 90 minutes time points might indicate that while the Petri dishes removed at 60 minutes were placed at the center of the GU10 device, the other two series might have been placed at the edge of the light cone where, according to the cosine law, considering the distribution on a flat surface, the irradiance power counts for 1/4 of the central spot).

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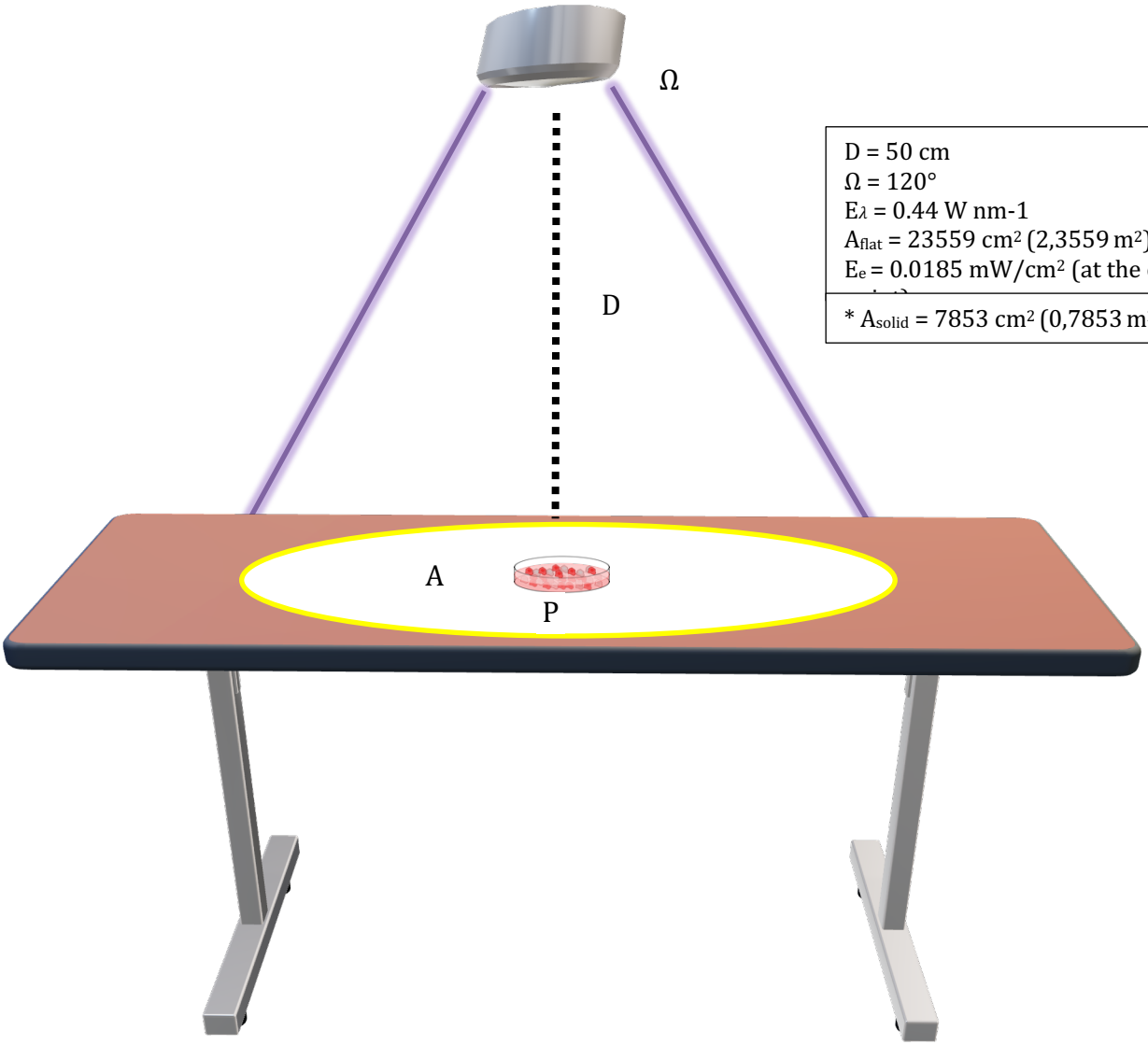

D = 50 cm Ω = 120° Eλ = 0.44 W nm-1 A_{flat} = 23559 cm² (2,3559 m²) * E_e = 0.0185 mW/cm² (at the center
* A_{solid} = 7853 cm² (0,7853 m²)

Ω = GU10 *beam angle*
D = *distance from the irradiating source*
E_e = irradiance *flux density*

A = *covered area*
P = *Petri dish*

Fig.1. In this figure you can see the area covered by the light when the lighting device with Biovitae® technology (GU10) is positioned 50 cm away from the surface. The radiant energy is equally spread throughout the area, while the microbial population is grouped inside the Petri dish. The area covered by the light could host 298 Petri dishes at the same time.

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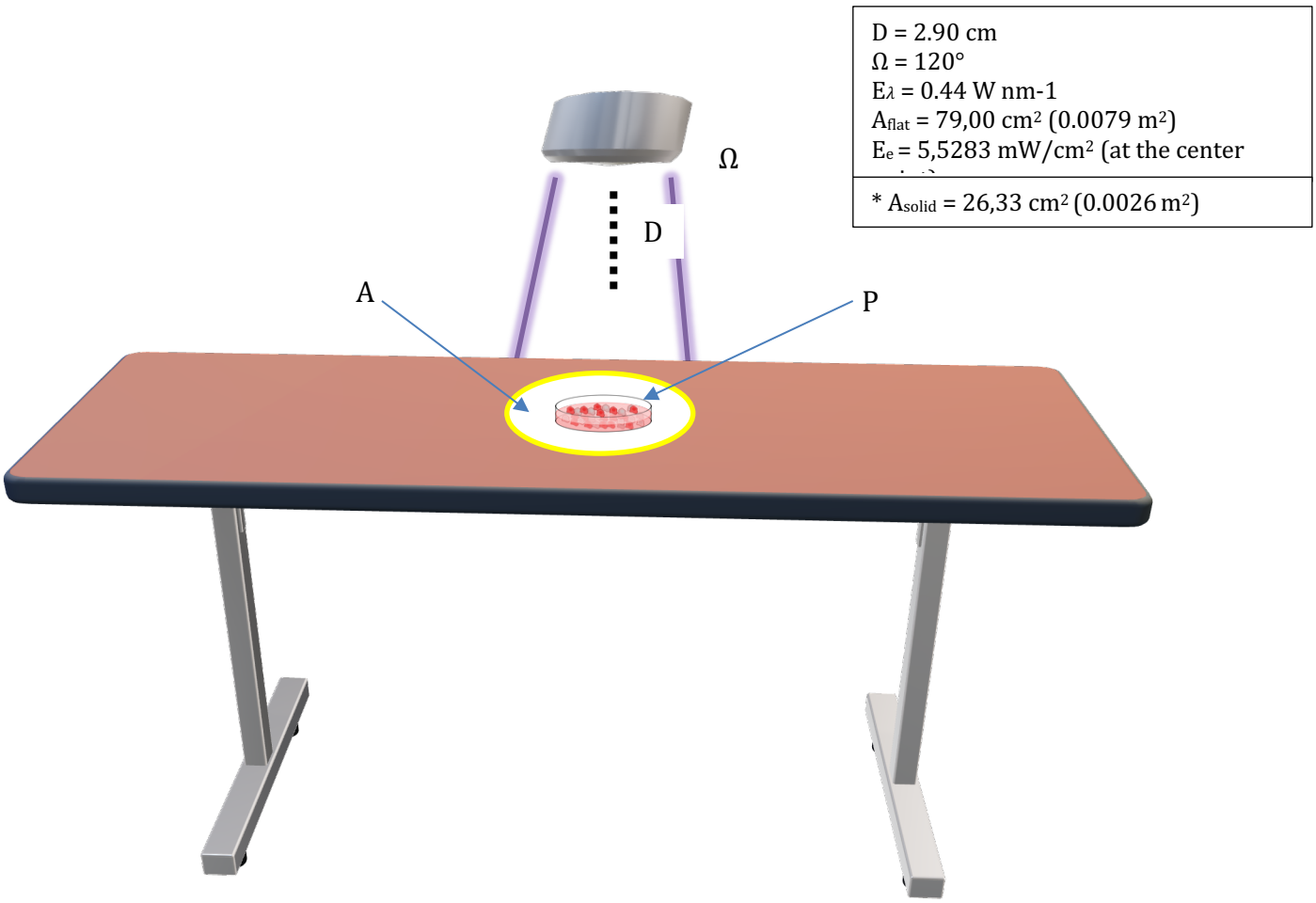
NEXTSENSE S.r.l.
P. IVA 05403770653

Sede legale
Via Trento 143/a
84129 Salerno

Amministrazione e Uffici
Via della Rotonda, 36
00186 – Roma
+39 (0)6 6932 2721 (tel.)
+39 (0)6 8395 5458 (fax)
info@nextsense.it

Sede operativa
P.zza Umberto I, 1
Palazzo Sorgenti degli Uberti
84121 – Salerno
+39 (0)89 2145 223 (tel. e fax)
info@nextsense.it

www.nextsense.it



Ω = GU10 *beam angle*
D = *distance from the irradiating source*
E_e = irradiance *flux density*
A = *covered area*
P = *Petri dish*

Fig. 2. In this slide you can see the area covered by the light when the lighting device with Biovitae® technology (GU10) is positioned 2.90 cm away from the surface. In this case, the irradiated energy is about 300 times higher than that shown in Fig.1 when the energy irradiated by the device covers only the area of the Petri dish.

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Experimental scenario for testing the virus in vitro

To perform a laboratory test with a single GU10, one could consider two approaches:

1) Increasing the exposure time to ensure that the correct dose of energy is reached in relation to the density of the populations (biomass) of microorganisms.
2) Bring the light source closer to the Petri dish so that the area covered by the radiation overlaps the area occupied by the Petri dish (at approximately 2.9 cm).

In the first case, it means an equivalent exposure time of 298 times for each time point considered in the main tests (30 mins = 149 hours, 60 mins = 298 hours, 90 mins = 447 hours). Whish is, clearly, possible but practically unfeasible.

The second case is more practical, but any prolonged exposure with a too close light source could alter the experimental conditions due to the emitted heat and, possibly, accelerate the mortality of the viral population.

For such reasons, for conducting proper in vitro tests, Nextsense has created a strip called Biovitae® Masterlight which is used in laboratory settings.

This kind of strip, which can be easily placed in a BSC, is provided with a heat dissipation system that guarantees that the temperature is always kept within limits; moreover, and more importantly, it also allows for a uniform distribution of the irradiated energy, so that the plates exposed at different spots, for the different time points to be considered, all receive equivalent irradiation levels.

Conclusions

The microbiological tests, as they were conducted, have shown not only excellent results for the part relating to bacteria (in simulation of a real contamination in the environment) but, in our professional opinion, also for the part relating to the virus, considering that the experimental implant was not the optimal one as highlighted in the relevant part of this document.

However, should the Company wish to conduct further human coronavirus testing, we will be more than happy to provide you with a Biovitae® Masterlight, to ensure that the test is performed correctly in vitro as well.

Kind regards

NEXTSENSE S.r.l.
Carmelo R. Cartiere, MSc (Oxon), MBCS
COO, Director of Research & development

NEXTSENSE S.r.l.
Rosario Valles, MD
COO, Director of Scientific Research