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BIO-OPTICAL REPORT

SPEEDYCARE 1500, 750 & SATELLITE

MOMPÍA HOSPITAL – IGUALATORIO CANTABRIA (AXA GROUP)

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1 Summary letter

FEBRUARY 12TH, 2021
Att. **SEWERTRONICSS™**
Avenida Monteclaro s/n
28223 Pozuelo de Alarcón - MADRID

SUBJECT: Bio-optical project for the evaluation of the germicidal efficacy of the surface disinfection equipment **SPEEDYCARE 1500, SPEEDYCARE 750, SPEEDYCARE SATELLITE** of the manufacturer SEWERTRONICS using germicidal ultraviolet radiation (UVC) and installed in the medical areas of CLINICA MOMPÍA, surgical hospital of the GRUPO IGUALATORIO of CANTABRIA. The project was carried out between 13 and 22 January 2021.

Dear all,

We have completed our bio-optical study on SPEEDYCARE equipment carried out in the **operating room, intervention room and dilation room** of CLÍNICA MOMPÍA. The biological material used as a model of microbiological contamination was **Escherichia coli, Staphylococcus epidermidis and SARS-CoV-2 RNA**.

Since the test site was a hospital setting, the two bacteria with the highest prevalence in healthcare settings according to the latest National Nosocomial Infection Surveillance Study in Intensive Care Medicine Services were selected:

- ✓ ***Escherichia coli***, responsible for urinary tract infections of varying severity.
- ✓ ***Staphylococcus epidermidis***, responsible for forming biofilms on plastic devices, which can lead to infections such as osteomyelitis or endocarditis.

Due to the current pandemic, **SARS-CoV-2 RNA** was also selected as a coronavirus model, as it was not possible to work with the whole virus, which requires handling in a biosafety laboratory 3-4.

In this project, a **MICROBIOLOGICAL ANALYSIS** has been carried out to determine the HOT SPOTS or points with the highest probability of contagion. A **RADIOMETRIC ANALYSIS** has also been carried out to model the radiation of each piece of equipment in the rooms and to determine the best positions for the equipment, as well as the irradiation times. A **SAFETY STUDY** has also been carried out to guarantee the protection of people when using these devices. Finally, a **BIODOSIMETRIC ANALYSIS** has been carried out to check the germicidal power of the equipment, in which biodosimeters have been used with

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the selected biological material, simulating microbiological contamination in each HOT SPOT, in a controlled and safe manner, to be subsequently irradiated by the SPEEDYCARE equipment for the established time in the determined positions. Chemical dosimeters have also been used as a test method.

After analysis of bacterial and viral biodosimeters and based on the results obtained in the project, the **SPEEDYCARE range successfully removes microbiological contamination from surfaces exposed to radiation**. Therefore, it is concluded that the biocidal effect is optimal.

On the following pages you will find the details of the project. If you have any questions, please do not hesitate to contact me.

Best regards,

VERÓNICA VIDAL
Biodosimetry and Innovation Responsible at FOTOGLASS

2 Introduction

2.1 Ultraviolet C Technology

Ultraviolet light C (UV-C) is a proven disinfectant against various micro-organisms (pathogenic and non-pathogenic) - viruses, bacteria, fungi, spores, etc. - and has been used for more than 100 years.

Ultraviolet C light is part of the electromagnetic spectrum, invisible to the human eye, which **has the power to damage the DNA/RNA of any cell**. In the case of micro-organisms, this damage translates into an inability to replicate, or in practical terms, the loss of the ability to divide cells. The inability of pathogenic micro-organisms to reproduce means that they are no longer contagious. All micro-organisms tested to date are sensitive to ultraviolet C light. **This makes it a broad-spectrum disinfection system.**

UV-C light can be used to **disinfect surfaces, air and water**. It is the best way to disinfect public places with many people, and where the probability of contagion is high, such as hospitals, food establishments, public administration buildings, transport, offices and schools, gyms, the food industry, doctors' surgeries and laboratories, etc.

As part of the disinfection strategy and combined with pre-cleaning, it is a **fast** system, as disinfection in closed rooms normally takes less than 20 minutes and does not require waiting times after application, and it is **economical**, both in terms of start-up and maintenance, but above all it is an **effective and safe technology**.

The global pandemic has clearly shown us the need for proven and effective systems to protect people from harmful micro-organisms, be it SARS-CoV-2, Ebola, tuberculosis or influenza. Moreover, we must be able to **prevent future pandemics.** And with this in mind, the COVID has put UV-C technology in the spotlight: **the best solution to combat pandemics and prevent them is to apply UV-C disinfection systems in our everyday spaces**.

2.2 Bio-Optic Projects

When a customer is interested in the use of ultraviolet C technology, he requires 2 elements that only work in coordination:

- **ULTRAVIOLETA C EQUIPMENTS**: UV-C equipment from a well-established manufacturer on the market and validated/verified by specialized companies. This validation is usually carried out in the laboratory.

- **BIO-OPTIC PROJECT**: A bio-optical project to adapt the installation of such equipment to a specific environment. This type of project must be carried out on site.

    - A bio-optical project combines the optical part - necessary for the **RADIOMETRIC ANALYSIS** of ultraviolet light luminaires - with the biomedical part - with which the **BIODOSIMETRIC ANALYSIS** is carried out to check the germicidal effect.

    - In the **RADIOMETRIC** part, the project gives visibility on the radiation pattern of the lamps used and their real behaviour in the equipment. Therefore, this project makes it possible to study which **EQUIPMENT is IDEAL** for different spaces and configurations.

    - In the **BIODOSIMETRIC** part, the germicidal effect is tested after establishing the exposure times necessary to reach a set dose to disinfect the room.

    - In UVC bio-optical projects, the **SAFETY REQUIREMENTS OF THE DEVICE** are also analysed.

    - In addition, it is also possible to establish with these projects the **REQUIREMENTS PRIOR** to disinfection for best results, as well as the maintenance conditions for routine germicidal performance checks.

    - In short, the bio-optical projects are **IN SITU IMPLEMENTATION PROJECTS** and respond to the assessment made by the Ministry of Science and Innovation and the CSIC in the REPORT ON THE USE OF ULTRAVIOLET RADIATION (UVC) FOR DISINFECTION - 29 May 2020, which states that *"laboratory tests are difficult to extrapolate to real situations because of the shadows that can be produced"*.

* RADIOMETRIC and SAFETY analyses will not be shown in this document due to the confidentiality of the data they provide.

2.3 Purpose of the report

The purpose of this report is **to evaluate the performance of SEWERTRONICS ultraviolet C disinfection equipment in order to ensure its correct operation in a real environment and to validate its germicidal effect.**

As a result of this evaluation, the following will be obtained:

- Radiometric verification and germicidal validation of SEWERTRONICS equipment.
- Bio-optical project for different scenarios

CLINICA MOMPÍA is the selected healthcare environment for the testing of UVC equipment.

CLÍNICA MOMPÍA is a Cantabrian hospital recently acquired by the AXA Insurance Group. It is the most important private healthcare company in Cantabria. The entity was created 65 years ago by a group of doctors.

The Clinic has 105 beds, and its surgical block is made up of 9 operating theatres, 3 of which were recently built. It is an eminently surgical hospital, performing 11,000 procedures a year, of which 6,000 are major surgeries.


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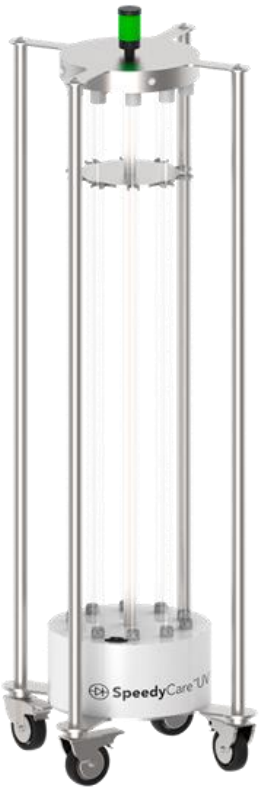
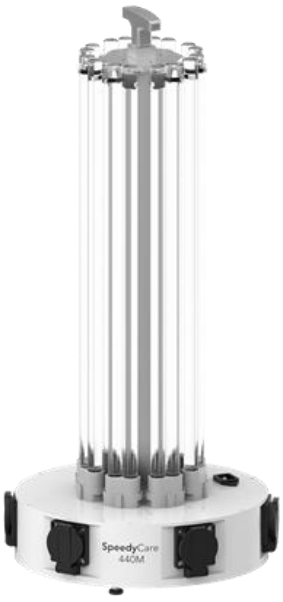
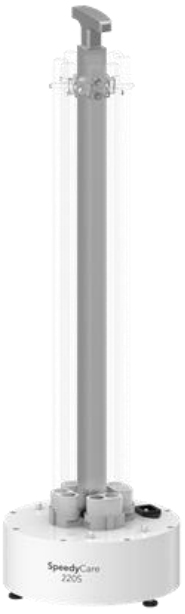
ZONA DE PRUEBAS
ULTRAVIOLETA C
NO PASAR
SpeedyCare™UV

3 Devices, Facilities and Equipment

3.1 Devices under study

The devices received are SPEEDYCARE devices from SEWERTRONICS manufacturer. Specifically, the models used for this project are as follows:

- ✓ SPEEDYCARE 1500
- ✓ SPEEDYCARE 750
- ✓ SPEEDYCARE SATELLITE

SPEEDYCARE 1500	SPEEDYCARE 750	SPEEDYCARE SATELLITE	
			
182 x 60 x 60 cm (59 Kg)	167 x 60 x 60 cm (39kg)	67 X 32 x 32 cm (8Kg)	67 X 20 x 20 cm (5Kg)

3.2 Selected test facilities

For the disinfection tests with SEWERTRONICS UV-C equipment, 3 sites were selected within the hospital:

- **OPERATING ROOM**

  The surgical block of the CLINICA MOMPÍA consists of 9 operating theatres. It is an eminently surgical hospital, performing 11,000 procedures a year, of which 6,000 are major surgeries. The operating theatre was the room selected for carrying out the **SPEEDYCARE 1500** tests, and specifically all the tests were carried out in operating theatre 4.

  Although initially it was also thought to be applied to Intensive Care Units (ICU), these facilities are now highly occupied, adding to the constant uncertainty of their availability. Considering the dimensions of each of the spaces, the SPEEDYCARE 1500 was chosen for the largest room (operating theatre) as it is the device with the largest number of lamps and, therefore, the highest power.

  The operating room measures approximately **50 m²** and is located at the end of the left aisle of the surgical area.

- **INTERVENTION ROOM**

  The intervention room is the room where therapeutic procedures are performed with minimally invasive techniques and guided by diagnostic imaging. Essentially, it is a small operating theatre where very extensive surgeries are avoided through rapid interventions that manage to reduce the patient's intervention time and postoperative period. Currently, this room is also used for teaching purposes. It is the space used for **SPEEDYCARE 750** tests.

  The **25 m²** intervention room is in the area before the entrance to the operating theatres.

- **DILATION ROOM**

  The dilation rooms are rooms set up for waiting before entering the delivery room. It is very similar to a hospital wardroom, both in size and layout.

  The dilation room has a bedroom and bathroom area, which is why it was chosen as the setting for the **SPEEDYCARE SATELLITE** tests.

  The dilation room measures **16 m²** and is in the delivery room area.

The plans of the spaces, their configuration and distribution are shown below:

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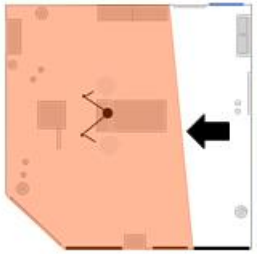
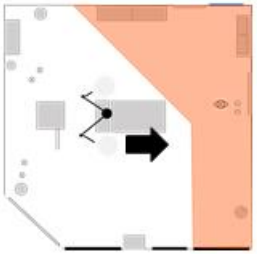
OPERATING ROOM
Photo report





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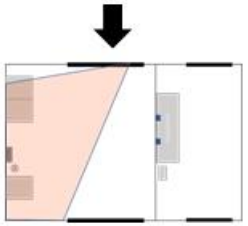
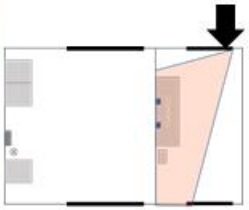
OPERATING ROOM ACCESSES

Photo report

MEDICAL ZONE



PATIENT ZONE



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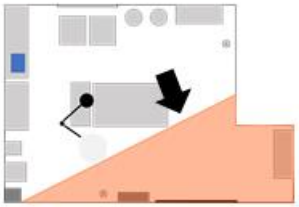
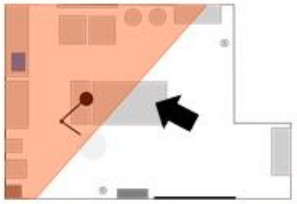
INTERVENTION ROOM
Photo report





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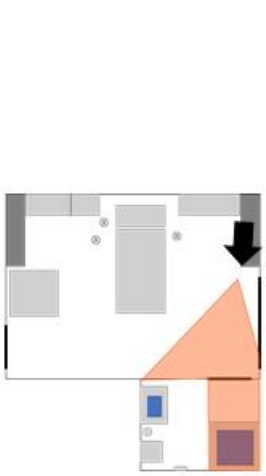
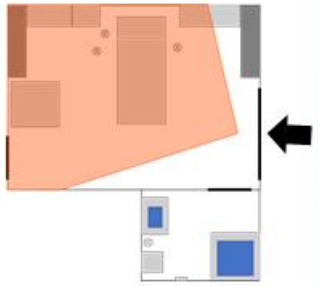
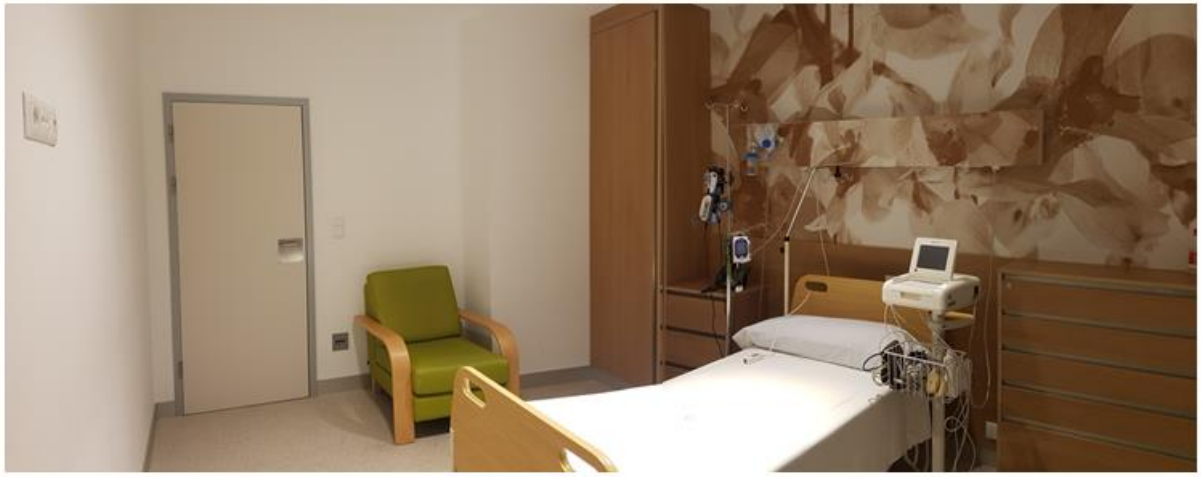
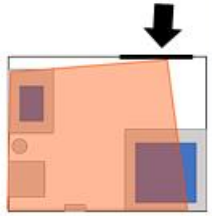
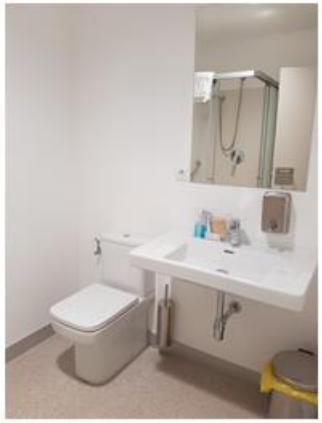
DILATION ROOM
Photo report











3.3 Advisory team

The advisory team for this project consisted of the following professionals:

Mr. JOSÉ LUIS FERNANDEZ LUNA

- Coordinator of Genetics Unit at the Marqués de Valdecilla University Hospital (HUMV).
- Head Researcher of the Cell Signalling and Therapeutic Targets in Cancer group at the Valdecilla Research Institute (IDIVAL).
- PhD in Biochemistry and Molecular Biology with specialization in molecular genetics from the Washington University School of Medicine (St. Louis, USA).
- Research Associate at the Washington University School of Medicine in St. Louis.
- Member of the Board of Directors of the Spanish Association for Cancer Research.
- More than 100 international publications and a high rating of scientific excellence, with more than 10,000 citations to his work and an h-index of 43.
- Regional Coordinator of new Genomic Medicine Programme in Cantabria, one of the 3 funded in the Infrastructure for Precision Medicine associated with Science and Technology (IMPaCT) of the Strategic Action in Health 2017-2020 of the ISCIII. Programme budget: 7.24 million euros.

Mr. FERNANDO MORENO GRACIA

- Director of the Optics Group of the University of Cantabria.
- PhD and Professor at the University of Cantabria.
- One of the 165 Senior Member of the Optical Society of America (OSA) in 2010, as recognition of his expertise and professional achievements in the field of optics and photonics.
- Visiting Research Professor at UC San Diego.
- Visiting Research Fellow at the Royal Signals and Radar Establishment in the UK.
- Co-authored four patents with members of the Army Research Laboratory in Maryland (Washington).
- Leader in several research projects, both public and private, with companies and technology centres.
- More than 35 years of experience, he has accumulated more than 100 international research publications.
- Part of the European PHEMTRONICS project for research and innovation on new future technologies.

Mr. FRANCISCO GONZÁLEZ FERNÁNDEZ

- Director of the Applied Physics Group of the University of Cantabria.
- Doctor and professor at the University of Cantabria.
- Research lines in fields such as Spectroscopy, Scattering of electromagnetic radiation by rough surfaces and microparticles, Physiological Optics, Colorimetry and for the last 15 years in Nanophotonic with applications in biomedicine, photocatalytic processes, control of the directionality of the "diffused" radiation, etc.
- Partner with researchers from international centres such as the Fresnel Institute in Marseille (France), CNR - NANOTEC, Bari (Italy), Duke University (USA) and the Army Research Laboratory (Maryland, USA).
- Principal investigator/collaborating researcher in more than 27 competitive projects (6 of international scope, funded by the Royal Society of London and the USA Army) and 20 projects with private companies.
- Co-author of more than 150 articles, 200 conference papers and 6 patents.

Mr. JESÚS MOZOTA ORTIZ

- Director of Preventive Medicine at the Mompía Clinic.
- Head of the Preventive Medicine and Public Health Service of the "Marqués de Valdecilla" University Hospital.
- Doctor of Medicine. Specialist in Preventive Medicine and Public Health, Specialist in Occupational Medicine, Specialist in Clinical Analysis and Specialist in Microbiology. Graduate in Anthropology.
- Head of the Microbiology Service of the Military Hospital of Barcelona, Head of the Preventive Medicine Service of the "Valle Hebrón" Hospital of Barcelona.
- Director of the "Virgen de la Cinta" Hospital in Tortosa and Director of the "Arnau de Vilanova" University Hospital in Lérida.
- Professor of Microbiology at the University School of Nursing of the Valle Hebrón Hospital in Barcelona, professor in charge of the subject of Preventive Medicine and Public Health at the Faculty of Medicine of the University of Cantabria and Director of the master's degree in Public Health of the Health Department of Cantabria. He has taught PhD courses at the Faculties of Medicine in Lérida and Cantabria. He has also been a teaching tutor for specialists in Preventive Medicine and Public Health and in Family and Community Medicine at the Valle Hebrón Hospital in Barcelona and the Marqués de Valdecilla Hospital in Santander.
- Supervisor with twelve doctoral theses and dissertations on Preventive Medicine, public health, quality of care and health management, and other research work.
- Author of 8 books and 90 publications on the speciality.
- President of the Northern Society of Preventive Medicine and Public Health, and member of the Spanish Society of Public Health and Health Administration, American Public Health Association.
- Numerary Member of the Royal Academy of Medicine of Cantabria and Corresponding Member of the Royal National Academy of Medicine.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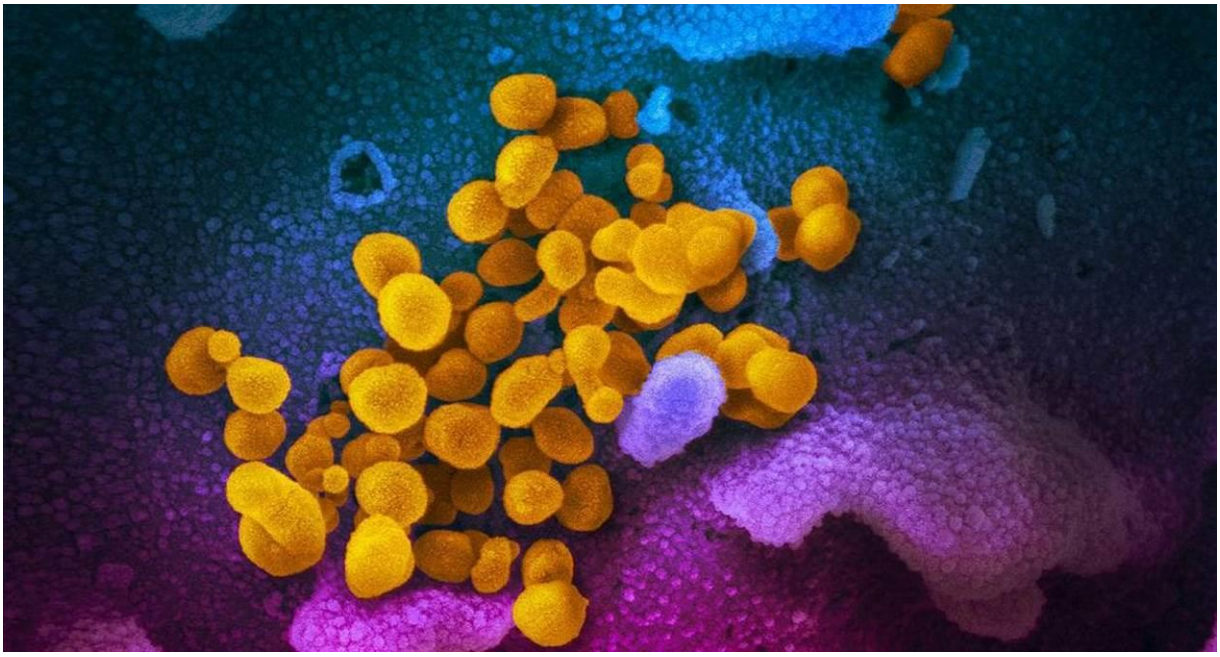
4 Microbiological study

4.1 Objective

Within a generic environment, not all surfaces have the same degree of microbiological contamination, nor do they have the same risk of being a point of contagion. **HOT SPOTS** are points with a high density of foot traffic where the risk of disease transmission increases at least temporarily due to conditions favourable to transmission or human behaviour.

It is therefore of great importance to determine which are these points to dedicate special attention to them when simulating ultraviolet C radiation and, ultimately, to carry out a disinfection protocol.



Any surface is susceptible to being colonised by micro-organisms (viruses, bacteria, fungi...) and these can be pathogens. The degree of contamination is in many cases associated with the number of interactions that people have with certain surfaces. The greater the interaction, the greater the degree of contamination and consequently the greater the probability of cross-transmission through hands to other surfaces or people, thus favouring the possibility of promoting infectious diseases in the presence of pathogens.

Therefore, the objective of the microbiological study focused on determining which of the various rooms to be disinfected using the SpeedycareUV equipment, the HOT SPOTS, were the most contaminated points.

4.2 Procedure

As described above, the areas with the highest microbiological load are the areas with the highest interaction, so this was the main criterion for selecting the analysis points.

Among the most obvious at a general level are:

- Door handles, doorknobs
- Furniture handles and knobs.
- Handrails
- Call buttons (telephones, entrances, lifts)
- Taps and cisterns.
- Controls
- Tables and worktops
- Touch devices, computers and telephones
- Household appliances for communal use

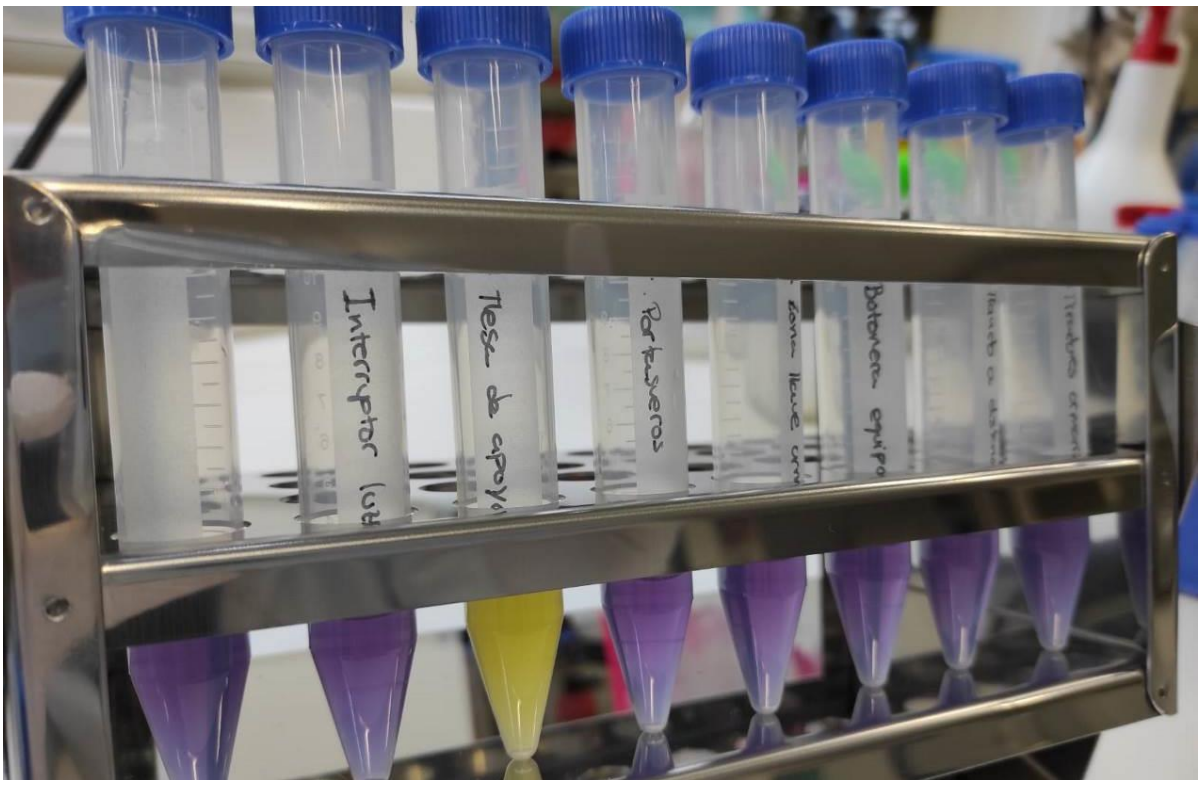
Within a specific space, such as a hospital, it is necessary to have certain procedural knowledge of the operations carried out in each room to correctly determine the HOT SPOTS, and for this reason, FOTOGLASS, throughout the project, has been in permanent contact with operating room managers, midwives, maintenance staff and cleaning staff at CLÍNICA MOMPÍA, to have all the necessary information in this line.

The procedure consisted of performing a Wipe test, BEFORE CLEANING the rooms, for each of the analysis points.

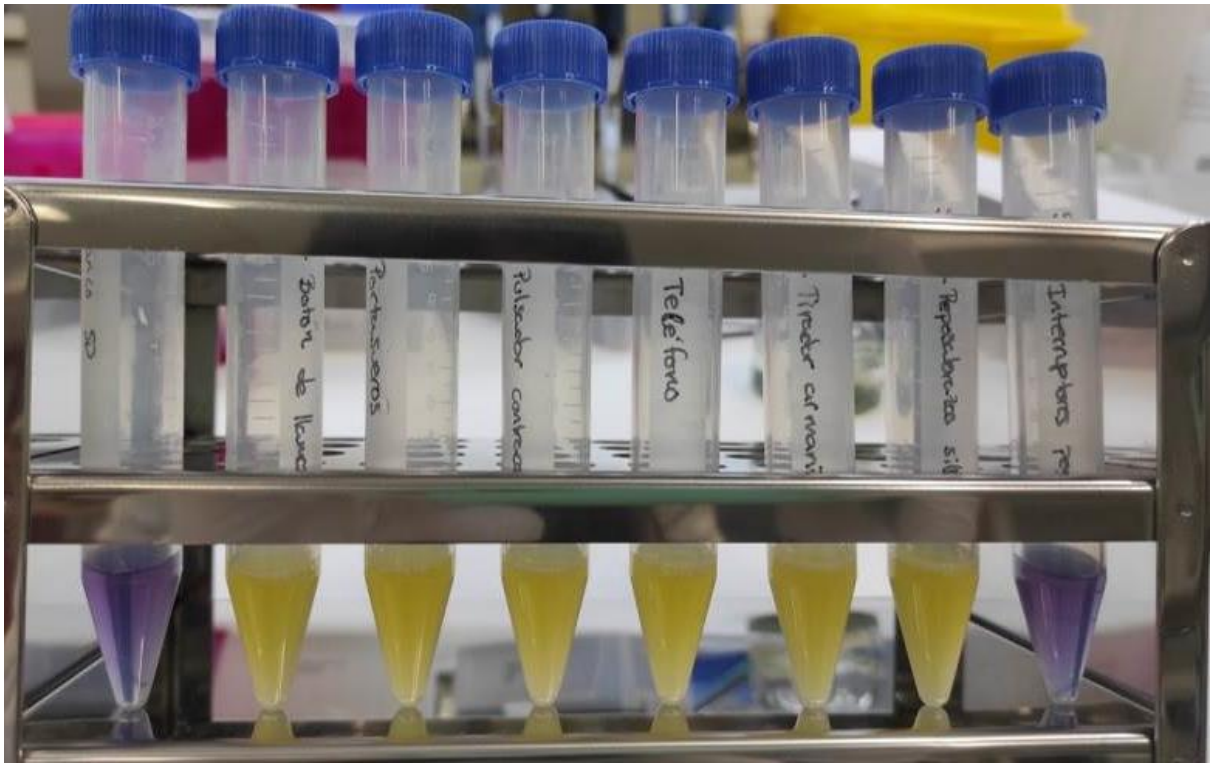
Once the sampling was completed, the tubes were transported to the laboratory.



The tubes were kept under optimal culture conditions. Subsequently, analysis was carried out to determine the growth of the microorganisms.



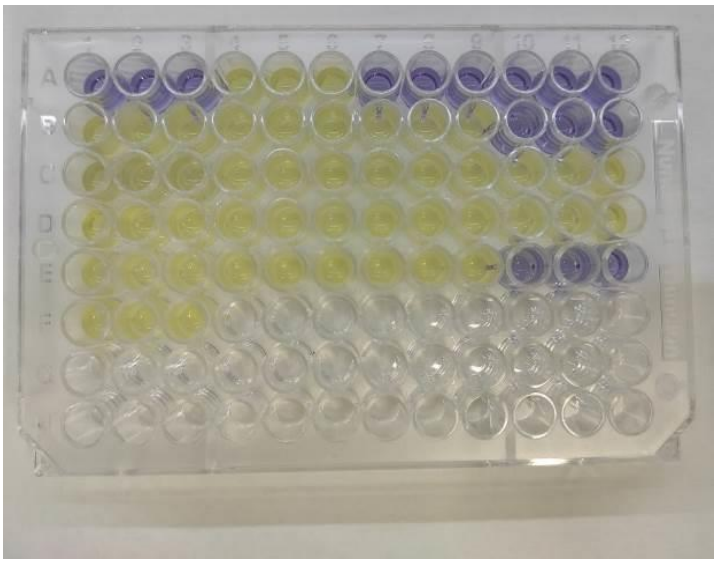
Sample collection tubes INTERVENTIONISM ROOM - 24 hours
Colour change is observed in 1 of them indicating microbiological growth.



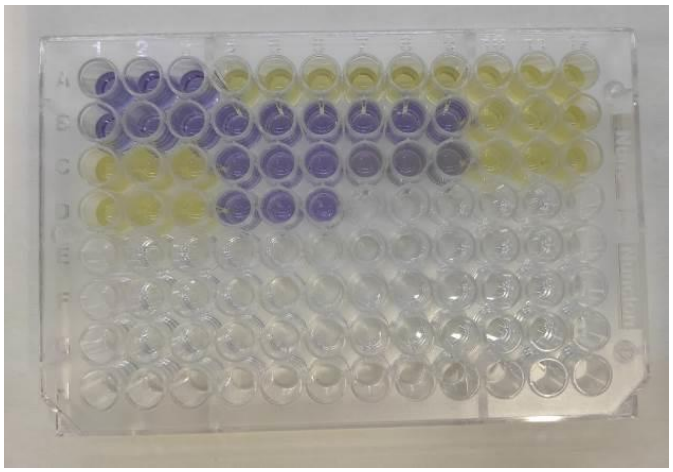
Sample collection tubes INTERVENTIONISM ROOM - 48 hours
Colour change is observed in 6 of them indicating microbiological growth.

Microbiological growth was determined by turbidimetry.

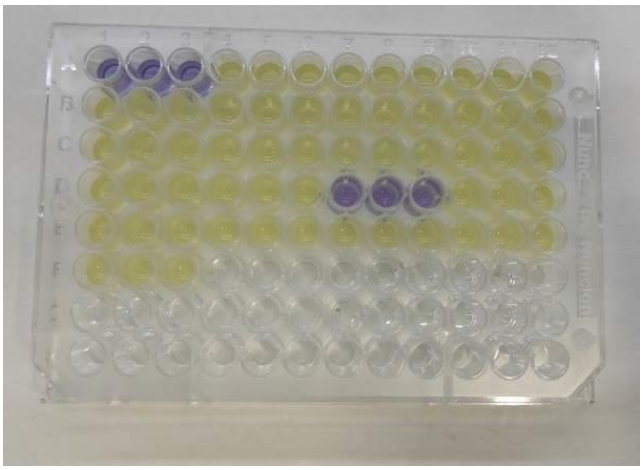
Preparation of microwell plate with samples after culture, for turbidimetric analysis.



Reading plate corresponding to the analysis points of the Operating Room and Access to the Operating Room.



Reading plate corresponding to the points of analysis of the Interventionist Room



Reading plate for the analysis points in the Dilation Room

The resulting HOT SPOTS are shown below for each of the selected rooms:

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OPERATING ROOM
HOT SPOTS

1. Medical access door switch
2. Auxiliary table
3. Patient access door switch
4. Technical panel remote control
5. Door holder
6. Anaesthesia equipment - Lateral button panel
7. Infusion pump - Button panel
8. Operating room trolley

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OPERATING ROOM
HOT SPOTS

9. Support table
10. Sash window handle for access to clean area
11. Laundry trolley cover
12. Light switch
13. Operating table button panel
14. Operating table
15. Lamp handle
16. Stool

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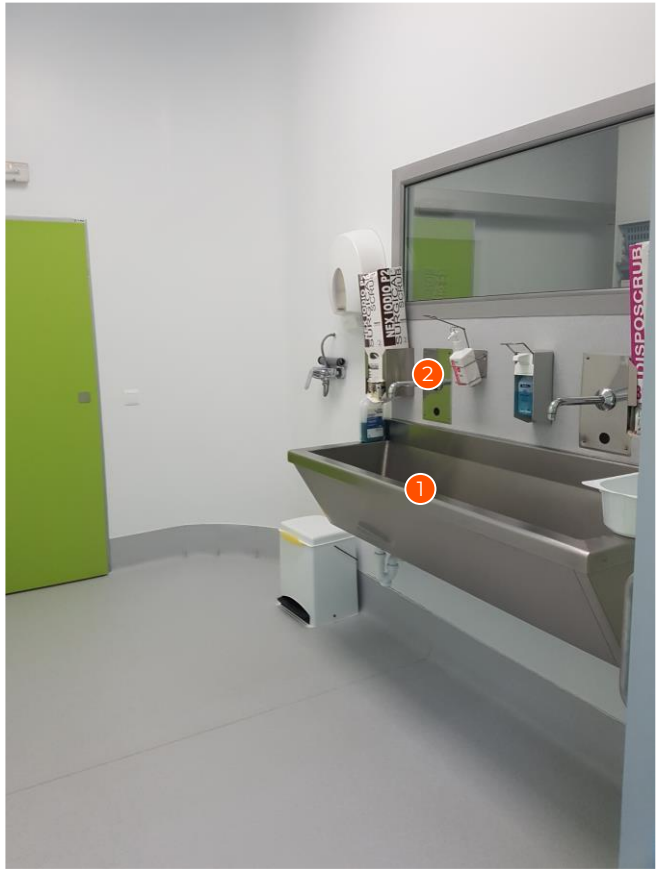
OPERATING ROOM ACCESSES

HOT SPOTS



MEDICAL AREA

1. Washbasin
2. Tap

PATIENT AREA

3. Operating room access door handle
4. Supply basket

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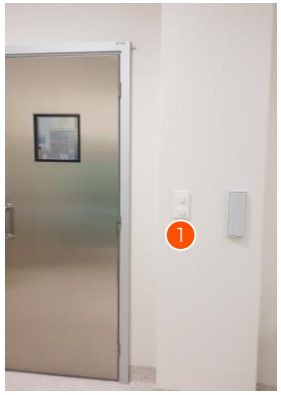
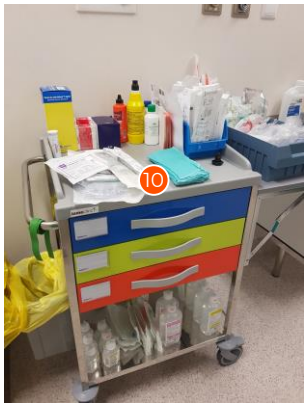
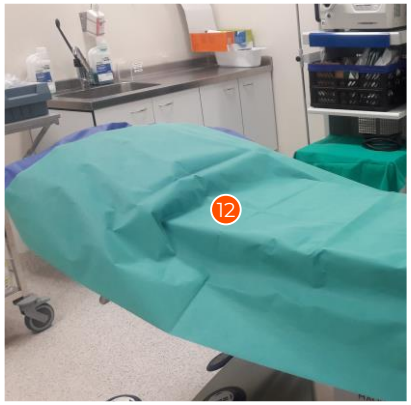
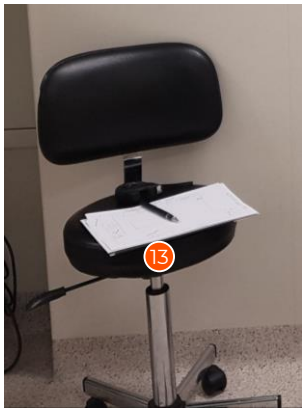
INTERVENTIONISM ROOM
HOT SPOTS









1. Light switch
2. Support table
3. Door holder
4. Supply cupboard lock
5. Endoscopy equipment button panel
6. Remote control technical panel
7. Washbasin countertop
8. Washbasin cupboard handles
9. Tap
10. Nursing table
11. Lamp handle
12. Operating table
13. Stool

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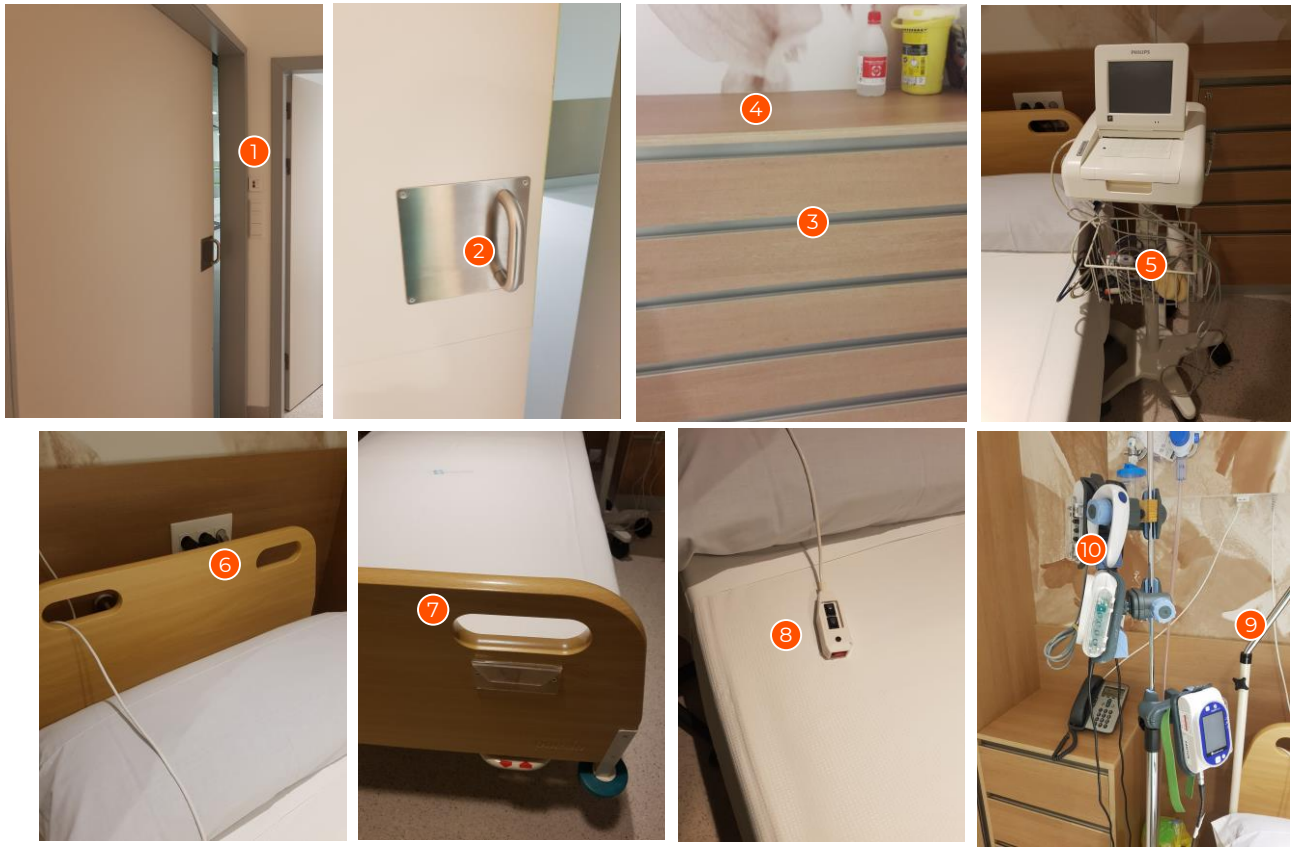
DILATION ROOM
HOT SPOTS



1. Large door switches
2. Large door handle
3. Supply module drawers
4. Supply module worktop
5. Fetal monitoring transducers
6. Bed front handle
7. Rear bed handle
8. Call button
9. Earbud holders
10. Anaesthesia button

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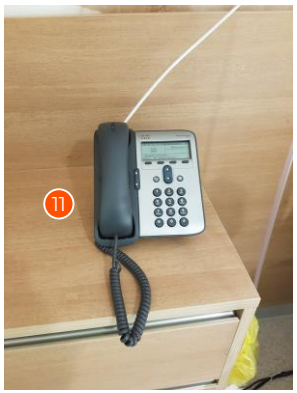
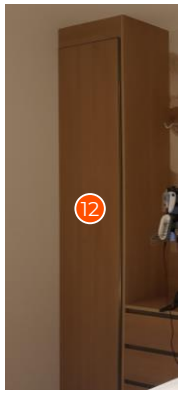
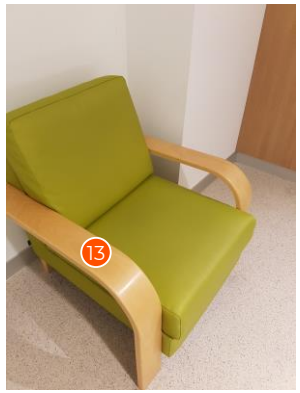
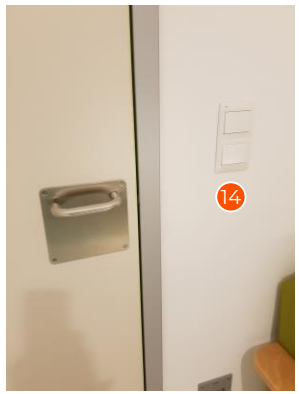
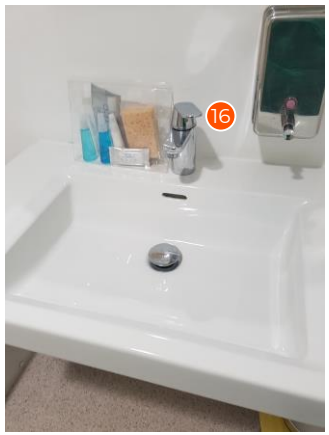
DILATION ROOM
HOT SPOTS

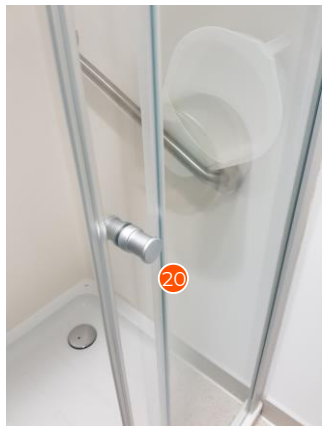












11. Telephone
12. Wardrobe handle
13. Family armrests
14. Small door switches
15. Toilet door handle
16. Washbasin tap
17. Toilet brush
18. WC cistern
19. Toilet lid
20. Shower door handle

4.3 Conclusions

In view of the results, it is concluded:

- Following the results obtained, **HOT SPOTS** (points with a high probability of contagion) are those in which the presence of micro-organisms was notable or slight, discarding those in which the presence was nil.
  - ✓ Operating Room: **16 Hot Spots**
  - ✓ Access to Operating Room: **4 Hot Spots**
  - ✓ Interventionism Room**: 13 Hot Spots**
  - ✓ Dilation Room**: 20 Hot Spots**

- These results were transferred to the physical-optical equipment to be considered as the points of maximum interest when carrying out the **RADIOMETRIC STUDY**. This means that in the radiometric simulation it must be guaranteed that these points have an excellent level of disinfection.

- Detecting the **presence of micro-organisms at the different points of analysis is a matter of course**: in areas with many people, different non-pathogenic micro-organisms are usually found in the environment and on our skin or mucosal surfaces which, after contact with objects, or through physiological processes such as coughing, talking, sneezing, etc., can end up being deposited on surfaces. As a result, we can determine which surfaces are touched more and which less.

- As mentioned above, the interest of the microbiological study of the bio-optical project is not based on differentiating which types of micro-organisms are found in the different points of analysis, but rather on determining **which points have the highest microbiological load and therefore the highest probability of contagion.**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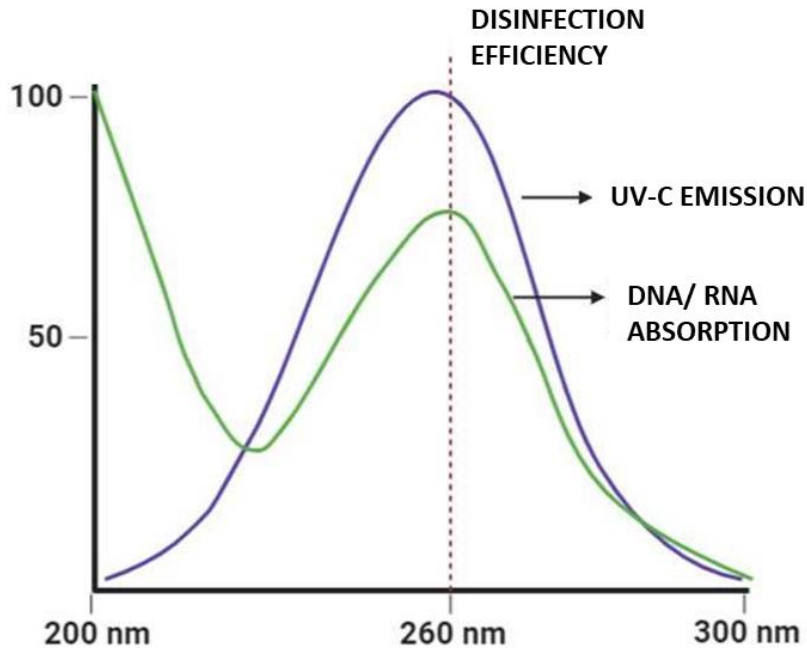
5 Biodosimetric Study

5.1 Objective

The intrinsic germicidal efficacy of UVC irradiation has been widely and scientifically proven for more than 100 years. The use of UV-C as a disinfection tool is based on its ability to cause damage to the genetic material (DNA and RNA) present in all living organisms.

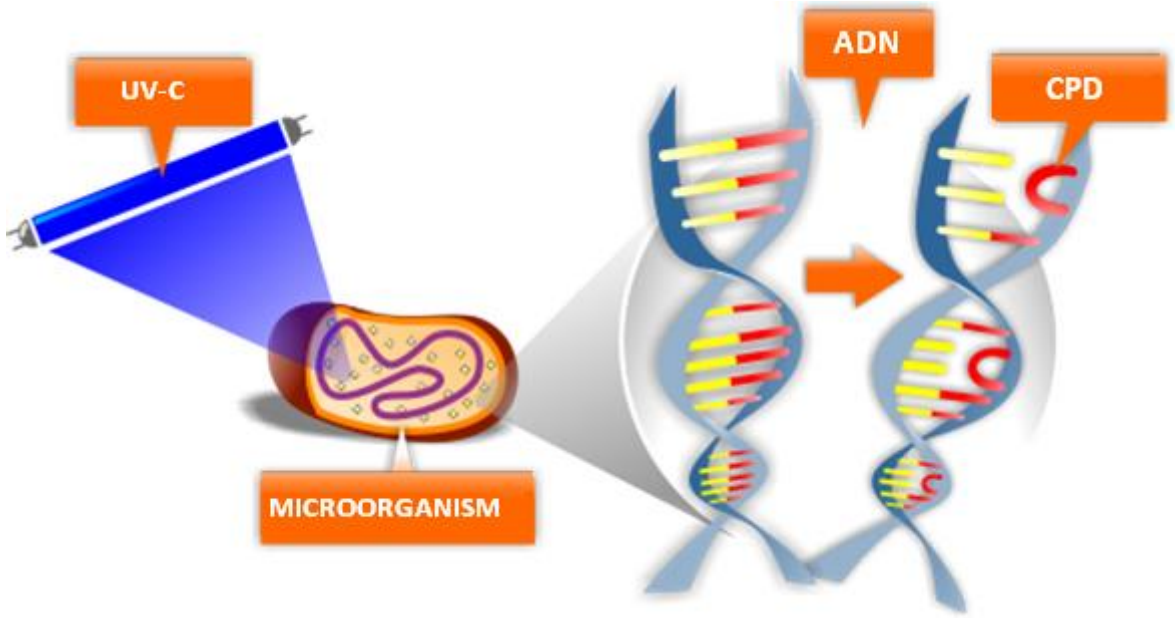
UV-C light emits at wavelengths between 100 and 280 nm and the absorption wavelength of nucleic acids (DNA and RNA) is 260 nm.



Graphical representation of the spectrum in which UV-C emits, which coincides with the absorption wavelength of the genetic material (DNA and RNA).

This causes a photochemical reaction that stably binds (covalent bonding) pyrimidine nucleotides (thymine, cytosine, uracil) forming cyclobutene pyrimidine dimers (CPD). This prevents the genetic material from replicating correctly, preventing the proliferation of the organism (viruses, bacteria, fungi) that has been irradiated and thus preventing the possibility of them causing infectious pathologies in humans.

However, not all microorganisms are equally sensitive to UVC light, as their genetic material is protected by biological structures that make them resistant to UVC to a greater or lesser extent.



UV-C irradiation causes covalent bonds in the genetic material of microorganisms, preventing them from replicating and thus causing infections.

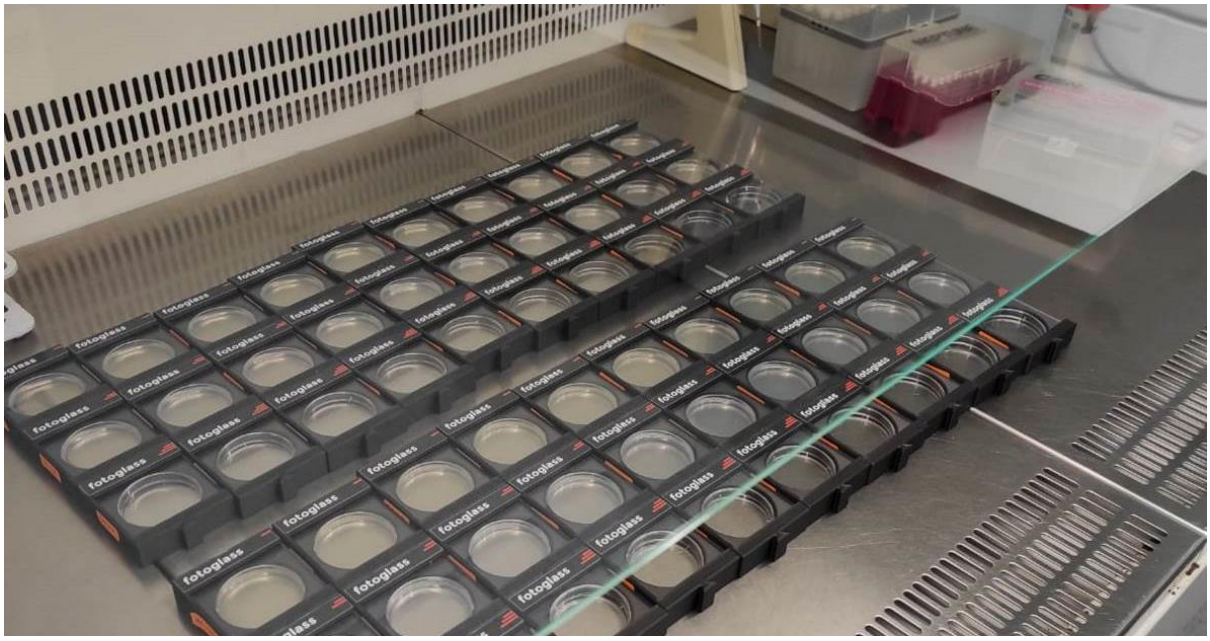
Nowadays, there are multiple studies that have determined the doses of UVC irradiation necessary to cause this damage in a wide range of microorganisms, since, as mentioned, each one of them has a different susceptibility to UVC irradiation. Basing the germicidal effectiveness of UVC disinfection equipment on such studies can be considered an approximation, **but not a reliable prediction of effectiveness**, since each of the studies presents different particularities, such as the environment in which the study was carried out (surface, air or water), types of luminaire (mercury vapour, LED), heating or stabilisation times of the luminaires, power, etc., which prevent exact extrapolation. In addition to a fundamental characteristic, the vast majority are carried out in the laboratory under controlled conditions that have nothing to do with a real environment.

Therefore, **when determining the germicidal power of a device**, an individualised Bio-optical Project must be carried out for each device. Its configuration must be considered, its disinfection capacity must be checked by means of **biodosimetry** using biological material and it must also be carried out in at least one of the real environments where it is going to perform its disinfection function.

5.2 Procedure

The use of biodosimeters allows us to carry out contamination in a **safe and controlled** situation in a real environment such as the sanitary environment, as the material inside is completely isolated from the outside environment. However, thanks to their design, they are susceptible to UVC irradiation, making them a suitable tool for testing the germicidal efficacy of the equipment.

The first step to be taken when preparing the **BIODOSIMETRIC STUDY** is to select the type of biological material to be deposited in the biodosimeters.



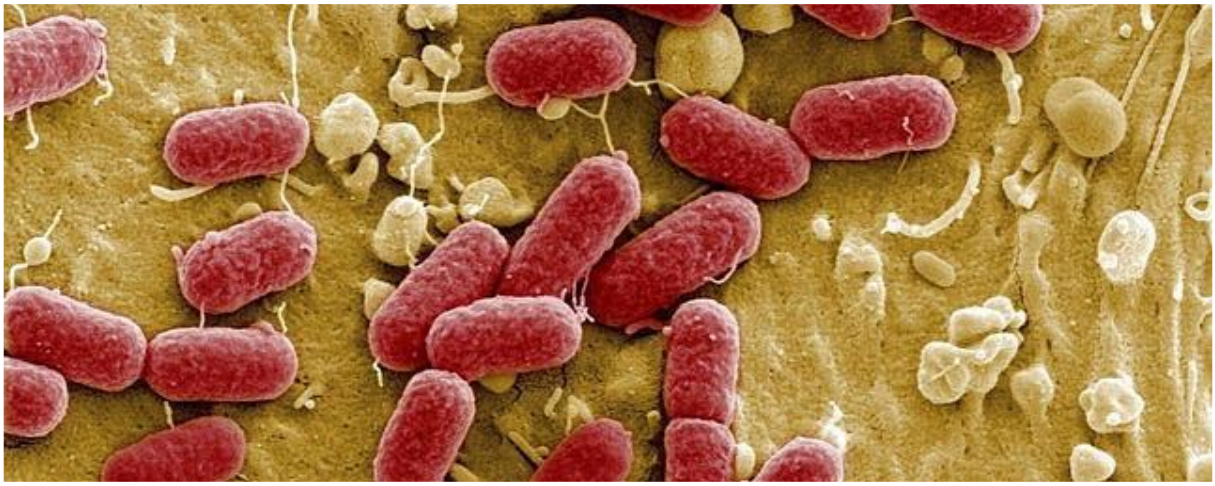
Biodosimeters specially designed for bio-optical projects.

When selecting the biological material for the project, the environment in which it is to be carried out (healthcare environment, food industry, means of transport, etc.) is considered, choosing as a contamination model those bacteria that are normally present in these environments.

For the selection of the **bacterial contamination models**, we based ourselves on the latest *National Surveillance Study of nosocomial infection in intensive care medicine services*.

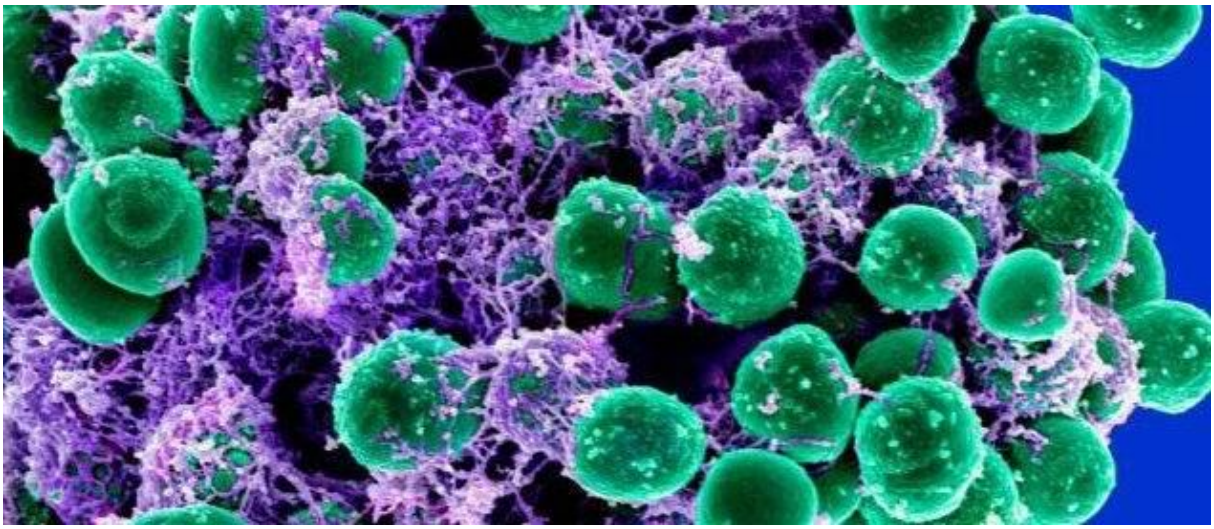
It specifies that in the ICU, the bacteria *Escherichia coli* as gram-negative bacteria and *Staphylococcus epidermidis* as gram-positive bacteria are the most abundant, which is why, together with their ease of handling, they were the two bacteria chosen. The distinction between gram-positive and gram-negative bacteria refers to the composition of their cell wall, which usually makes a difference in terms of their sensitivity to UVC.

> ***Escherichia coli*** is a highly negative bacterium that forms part of our intestinal flora. E. coli infection can be of varying degrees of severity, ranging from an annoying urinary tract infection to serious conditions such as the so-called Haemolytic Uremic Syndrome, which can lead to or prolong hospitalisation. This type of infection occurs mainly in patients with urinary catheters.



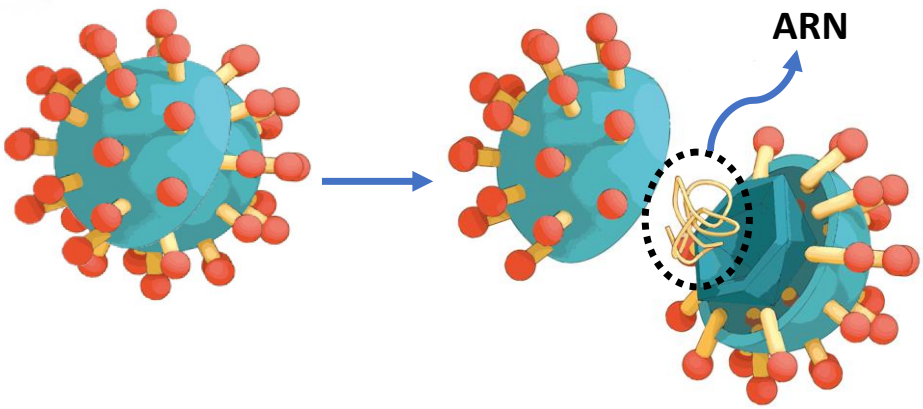
Escherichia coli

Staphylococcus epidermidis, is a gram-positive bacterium that is part of our normal body surface flora, however, its ability to attach and form biofilms on plastic components such as intravenous catheters, heart valves, joint replacements make it a very problematic bacterium in hospital environments.



Staphylococcus epidermidis

As a **model of viral contamination**, given the impossibility of working with viruses in vivo, as this requires high biosafety standards (type III laboratories) and therefore cannot be tested in real environments or in classical laboratories, an **RNA** fragment **of the SARS-CoV-2** coronavirus was selected. This material, individualised from the rest of the virus, becomes a non-infectious material that can be handled without any problems.



The SARS-CoV-2 coronavirus is a spherical particle composed of proteins and lipids that contains the genetic material (RNA) inside. As already mentioned, UVC irradiation damages this material and prevents the replication of the virus, therefore, the detection of this damage serves as a tool to determine the capacity of UVC equipment to damage this type of microorganism.

It is important to remember that, given the impossibility of working with the complete virus (only feasible in biosafety level 3 or 4 laboratories), it is not possible to give specific reduction results, but it does serve to link the equipment with tests on SARS-Cov-2.

After the selection of the biological material as models for bacterial and viral contamination, the biodosimeters were prepared.

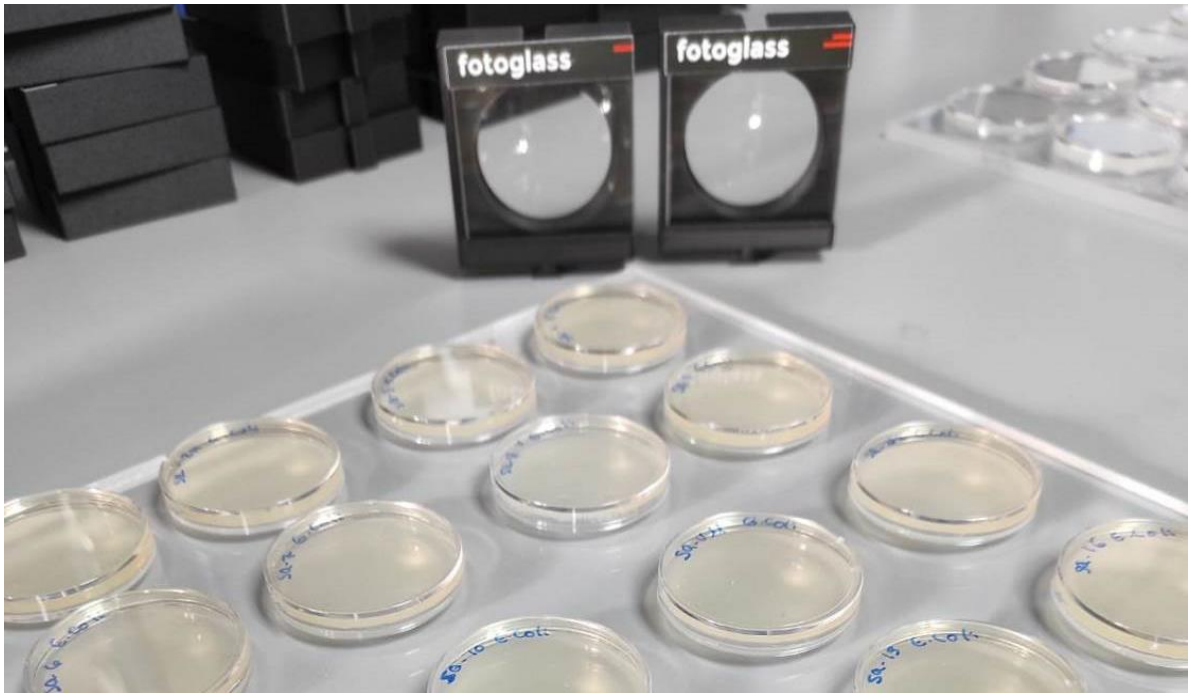
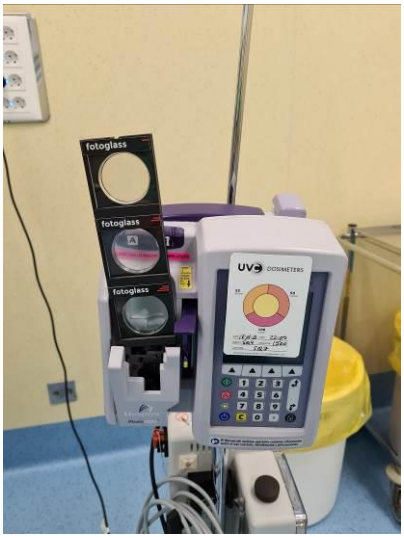


Plate preparation

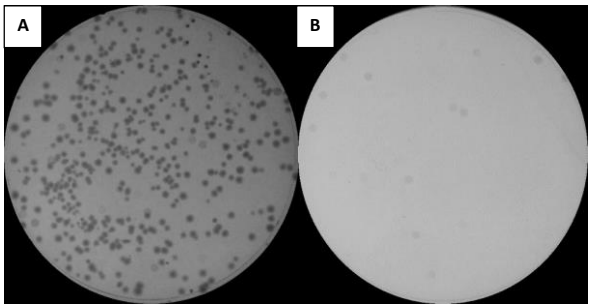


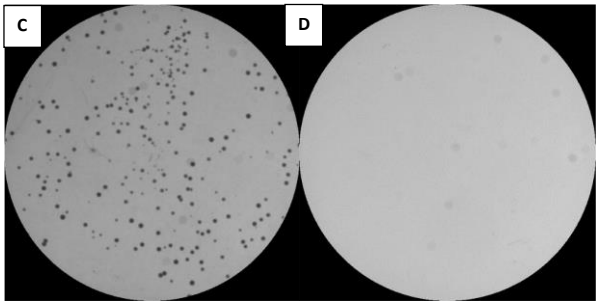
Installation of trio of biodosimeters and chemical dosimeters

After the placement of the biodosimeters, the disinfection cycle established for each of the rooms was carried out. Once completed, the biodosimeters were removed, stored and transported to the laboratory in an appropriate manner.

The chemical dosimeters were analysed in situ, as a verification of the dose received in each HOT SPOTS and archived.

Bacteriological Biodosimeters





Representative images of the results obtained after a disinfection cycle with SpeedyCare equipment.

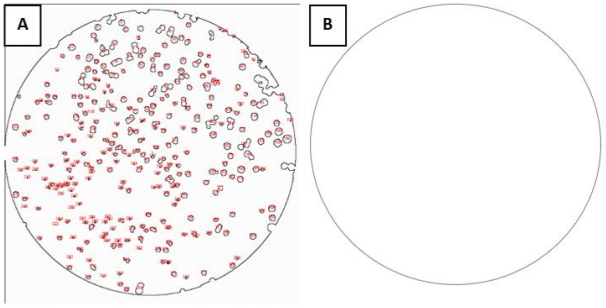
(A) E. coli bacterial growth without UVC irradiation, CFU observed.

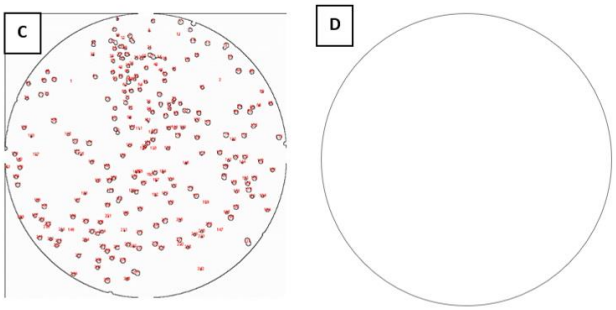
(B) E. coli after UVC irradiation, no growth.

(C) Bacterial growth of S. Epidermidis without irradiation, CFU observed.

(D) S. Epidermidis after irradiation, no growth.

Note: the shadows in images B and D correspond to marks of use of the transilluminator.





Software-assisted CFU counting.

(A) *E. Coli* without UVC radiation

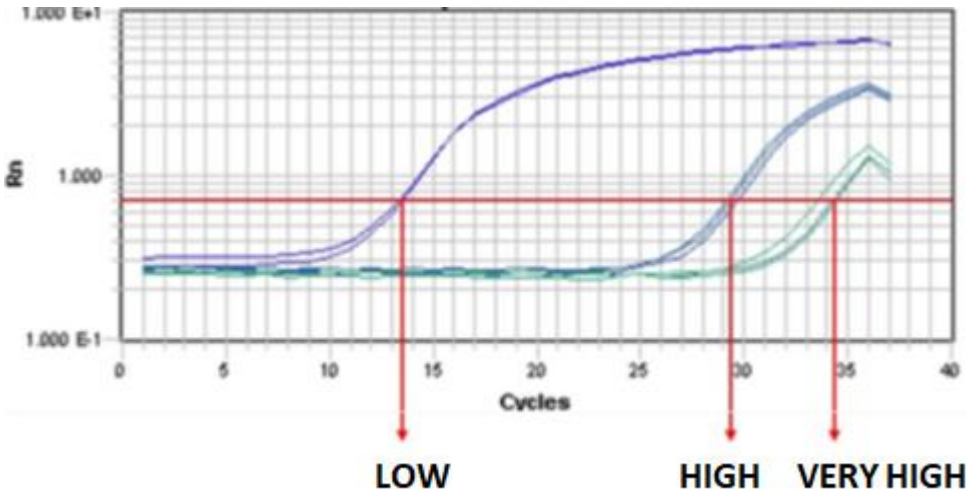
(B) *E. Coli* after UVC irradiation

(C) *S. Epidermidis* without UVC radiation

(D) *S. Epidermidis* after UVC irradiation

Viral Biodosimeters

We performed quantitative PCR (Real Time qPCR) to determine the degree of damage caused in each of the HOT SPOTS



DEGREE OF GENETIC DAMAGE

Representative image of the results obtained by Real Time Qpcr

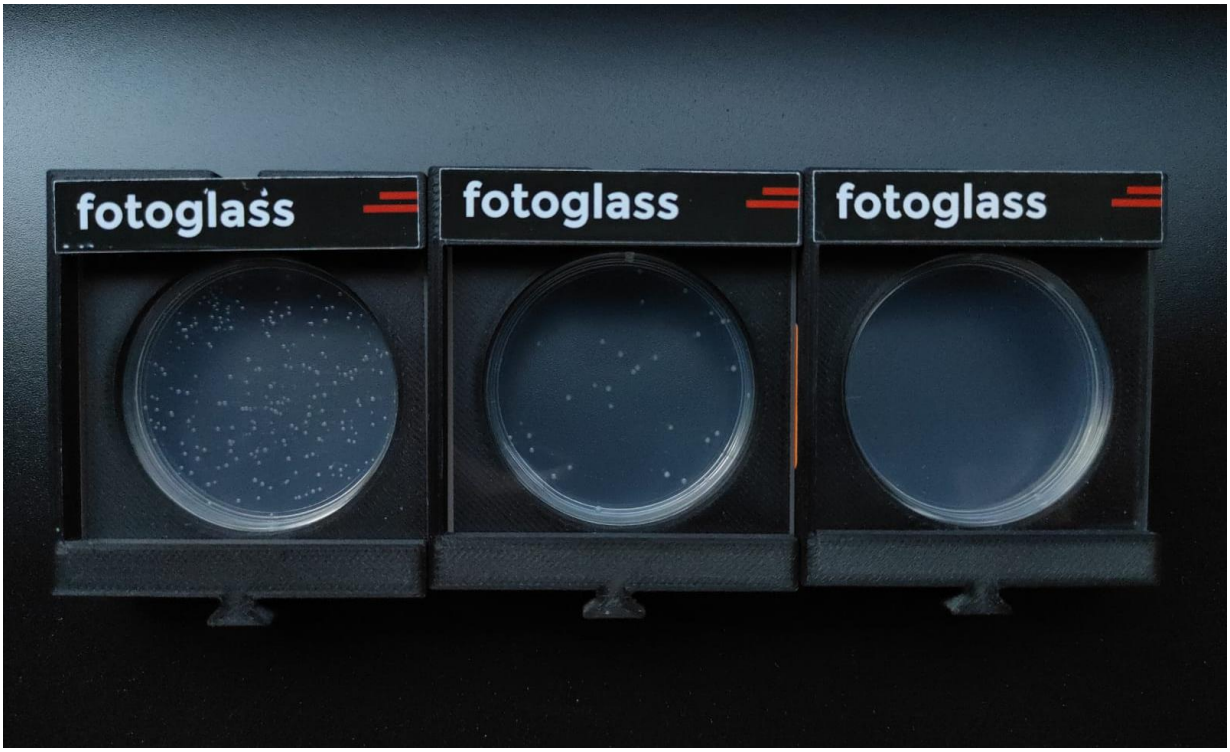
5.3 Results

SPEEDYCARE 1500	RESULTS
% Average Reduction (E. Coli)	99,80%
% Average Reduction (S. Epidermidis)	99,51%
% Average Reduction	**99,7%**
Average Log Reduction (E. Coli)	2,7
Average Log Reduction (S. Epidermidis)	2,3
Average Log reduction	**2,6**
Average Degree of damage SARS-COV2 RNA	**High**

SPEEDYCARE 750	RESULTS
% Average Reduction (E. Coli)	99,91%
% Average Reduction (S. Epidermidis)	99,23%
% Average Reduction	**99,6%**
Average Log Reduction (E. Coli)	3,1
Average Log Reduction (S. Epidermidis)	2,1
Average Log reduction	**2,5**
Average Degree of damage SARS-COV2 RNA	**High**

SPEEDYCARE SATELLITE	RESULTS
% Average Reduction (E. Coli)	99,94%
% Average Reduction (S. Epidermidis)	99,12%
% Average Reduction	**99,5%**
Average Log Reduction (E. Coli)	3,2
Average Log Reduction (S. Epidermidis)	2,0
Average Log reduction	**2,3**
Average Degree of damage SARS-COV2 RNA	**High**

Escherichia coli
Control (left), without biooptical project (centre) & with biooptical project (right)



Staphylococcus Epidermidis
Control (left), without biooptical project (centre) & with biooptical project (right)

Note: SARS-CoV-2 RNA is not visible to the naked eye.

5.4 Conclusions

Following the analysis and its interpretation it is concluded that:

- Under the specific conditions of time, distances and number of positions, the **SpeedyCare 1500, 750 and Satellite achieved bacterial reduction percentages equal to or greater than 99.5%** and a bacterial log reduction greater than 2.3.

- Within the scientific community, the **bacterial reduction ranges** most widely accepted as high levels of disinfection are between 99% and 99.9%. Achieving an increase in these values can involve great efforts in disinfection times, with very similar results in the face of a probability of contagion.

- Under the specific conditions of time, distances and number of positions, the **SpeedyCare 1500, 750 and Satellite achieved a HIGH degree of damage to SARS-CoV-2 RNA.**

- Since we work with SARS-CoV-2 coronavirus RNA, we cannot specify a percentage of virus reduction achieved, however, it is expected that the **greater the degree of damage caused to its genetic material, the greater the likelihood of eliminating the infective capacity of SARS-CoV-2.**

- Both two strains selected, besides being the most representative as contamination of hospital environments, present characteristics that make them good models of contamination, allowing us to have a **greater internal control of the results**:

  - ✓ *Escherichia Coli* is considered the model bacterium for any experiment involving the use of a micro-organism, so its use is widely accepted, and many studies exist, facilitating any necessary extrapolation.

  - ✓ On the other hand, given the high sensitivity of *Escherichia coli* to UVC irradiation, the use of *Staphylococcus epidermidis* is appropriate, as it requires a higher dose of irradiation providing a higher degree of difficulty as a model of bacterial contamination.

- During the disinfection protocol with UVC irradiation, it is necessary to define a **specific arrangement of the elements** present in a room, thus establishing a **pre-cleaning protocol.**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6 Concluding remarks

In view of the results, it is concluded that:

all the SPEEDYCARE range equipment tested has a germicidal effect of more than 99.5% under the conditions set out in this project.

The target rooms are disinfected in total times of less than 15 minutes, record times compared to other technologies:

- OPERATION ROOM & ACCESS:

  14 minutes with SPEEDYCARE 1500 - **5 positions**

- INTERVENTIONISM ROOM:

  12 minutes with SPEEDYCARE 750 – **3 positions**

- DILATION ROOM:

  15 minutes with SPEEDYCARE SATELLITE (room + bathroom with the height extension piece in place) – **3 positions**

7 Implementing regulations and directives

Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the placing on the market of electrical equipment designed for use within certain voltage limits.

Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility.

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE).

Directive 2006/25/EC of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation).

In addition to the above Directives, any other harmonised legislation that is applicable to the product according to its specific features.

UNE 0068:2020 - Safety requirements for UV-C equipment used for air disinfection of premises and surfaces.

UNE-EN ISO 15858:2017 - UV-C devices. Safety information. Admissible limits for human exposure).

UNE-EN 55011:2011/A1:2011 - Industrial, scientific and medical equipment. Radio disturbance characteristics. Limits and measurement methods)

UNE-EN 60598-2-1:1993 - Luminaires. Part 2: Particular Rules. Section one: Fixed luminaires for general use.

UNE-EN 61347-2-3:2012 - Lamp control gear. Part 2-3: Particular requirements for electronic control devices supplied with alternating current and/or direct current for fluorescent lamps.

UNE-EN 62471:2009 - Photobiological safety of lamps and equipment using lamps.

UNE-EN 61010-1:2011 - Safety requirements for electrical equipment for measurement, control and laboratory use. Part 1: General requirements.