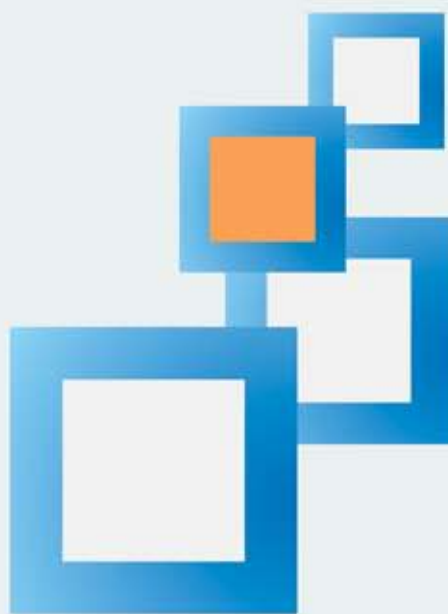




Communication for medical scientific staff

Biotechnology Systems  [®]
MEDIBIOS
by NOCOSYSTEM



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The company which was founded in 2008 to provide experience and knowledge in the field of hospital infections to be put to use by healthcare professionals, to protect health and ensure safety of the community in general, NOCOSYSTEM is considered, to this day, one of the leading companies in the sector of the environmental BIO-decontamination and aerial disinfection of surfaces.

We create innovative solutions for the prevention and the control of nosocomial infections. The MEDIBIOS SYSTEM is mostly used in several critical areas such as operating theatres, intensive care units, sterilization units, laboratories, emergency areas and in ventilation systems of the treated areas.

The proper maintenance of the ventilation system is fundamental for the hygiene and upkeep of equipment and preservation of the environmental conditions which are most favourable to minimize the possibility of microbial contamination of surfaces and air inside the different rooms.

Its development has permitted the use of the MEDIBIOS SYSTEM also in pharmaceutical, food, zootechnic field, as well as in public entities and institutions, where the environmental quality result is a very important factor for healthcare.







REDUCE THE RISK OF INFECTIONS FOR THE HEALTHCARE

Nosocomial infections are a big challenge for health systems, they have a high impact on health costs and are indicators of the quality of service provided to patients.

Our objective is to create better and optimal living conditions providing our products and services with high technological content, eco-sustainable, biodegradable, in accordance with the regulations in force and that don't represent any danger to human health.

We're constantly working to provide effective solutions to dramatically reduce the human and financial costs (cost-benefit) that all facilities tackle daily in the fight against nosocomial infections.





According to the World Health Organization the nosocomial infections are one of the leading causes of death¹. Over 1.4 million people worldwide are suffering from infections acquired in hospital. Between 5% and 10% of patients taken in for care in modern hospitals in the developed world acquire one or more infections. The risk of health care-associated infections in developing countries is from 2 to 20 times higher than in developed countries. In some developing countries, the proportion of patients affected by a health care-acquired infection can exceed 25%².

According to a study lead by the European Centre for Disease Prevention and Control approximately 4,1 million patients are estimated to acquire a healthcare-associated infection in the European Union every year. The number of deaths occurring as a direct consequence of these infections is estimated to be at least 37.000³.

The studies carried out indicate that 30% of hospital infections are avoidable. In Italy it would mean saving from 1.350 to 2.100 lives each year⁴.

Disinfection procedures have a very important role in the matter of the protection and the collective prevention.



¹ World Health Organization. Prevention of Hospital-Acquired Infections: A Practical Guide. 2d ed. Geneva: World Health Organization, 2002.

² World Alliance for Patient Safety. Global Patient Safety Challenge 2005-2006. Geneva: World Health Organization, 2007.

³ European Centre for Disease Prevention and Control. Healthcare-Associated Infections (HAI)

⁴ Inf Nos 2 2002- 2004. Carried out with the scientific advice of Istituto Lazzaro Spallanzani in Rome and funded by the pharmaceutical multinational GlaxoSmithKline

THE OPERATING ROOM



HIGH RISK ENVIRONMENT

The operating theatre represents a complicated environment, historically considered as "high risk" because the surgery that takes place, necessarily exposes the patient to a high risk of infection. The special attention given is planned so as to ensure the safety of patients and of professionals. The classification of the operating areas as departments with high risk of infection is such that in them and it is really shown an elevated value of incidence of nosocomial infection.

Bacterial contamination in the operating room is mainly due to airborne microorganisms, whose source of primary carriers is represented by the operating team and by patients. Other secondary sources are represented by defective introduction of air from the ventilation and air-conditioning system with contamination control or from contamination of the introduced instruments⁵.

When we speak about disinfection in the operating room it is important to pay attention to the type of disinfectant that is used to prevent damage to the equipment inside, but at the same time it is also necessary that an effective disinfection system is used and that it maintains a suitable environmental quality level for the safety of patients and staff.



⁵ASO S. Croce e Carle di Cuneo. Descriptive document. Hospital Infections Committee. Microbiological Environmental Control in the Operating Room. 20 April 2004



THE RISK OF INFECTION

For over a century it is well known that the hospital can represent a place of high for the acquisition of infections from other patients, staff, equipment/devices contaminated or from the same environment (Moro et al., 1986; Moro, 1993). In particular, the Intensive Care Units are the departments at highest risk of hospital infections for the concurrence of multiple factors (Curti et al., 1999):

- the often critical conditions of the patients;
- the frequent use of invasive diagnostic and therapeutic procedures;
- the simultaneous presence in a limited area of patients highly susceptible to infections and of infected patients;
- the use of immunosuppressive drugs
- the antibiotic pressure, with the consequent selection of resistant microorganisms difficult to eradicate.

The opportunity to initiate programs to prevent and control infections in the Intensive Care Unit is supported both by the frequency of preventable infections, both by the significant impact on clinical and economic terms of the onset of a infection in these departments (Alberti et al., 2002; Chaix et al., 1999; DiGiovine et al., 1999; Fagon et al., 1994; Girou et al., 1998; Moine et al., 2002)⁶.

⁶ Servizio Sanitario Regionale Emilia-Romagna. Regione Emilia-Romagna. Dossier 104-2005. Surveillance and Control of Infection in Intensive Care Unit. Survey in Emilia-Romagna



THE NEED FOR HIGH STANDARDS

The sterilization unit is a key area in the activity of the operating theatre.

In this area the risk of infection for the professional is very high due to the frequent exposure to biological agents from infected materials.

Disinfection of the sterilization unit is the most effective way to prevent from exposure and/or potential exposure to biological agents that lay the health of the professionals on the line, it is then a collective measure of security.

The staff most exposed to risk of infection and that are the cause of contamination of air and surfaces are those whom transport and wash the organic compounds.

Moreover, the presence of specific medical and surgical instruments requires a special attention for the use of disinfectant in order to avoid damage to equipment.





ELIMINATE THE BIOLOGICAL RISK

The biological risk in the laboratory is very high because the activity takes place in it is based on the manipulation of biological materials, sometimes highly infected.

This risk can be greatly reduced by implementing appropriate preventive measures⁷.

People exposed to biological risk can contract an infectious disease, that is a morbid form, determined by a biological agent that is able to penetrate, multiply and produce harmful effects in a living organism. The same biological agent may then be able to get away from it and to penetrate into other organisms⁸.

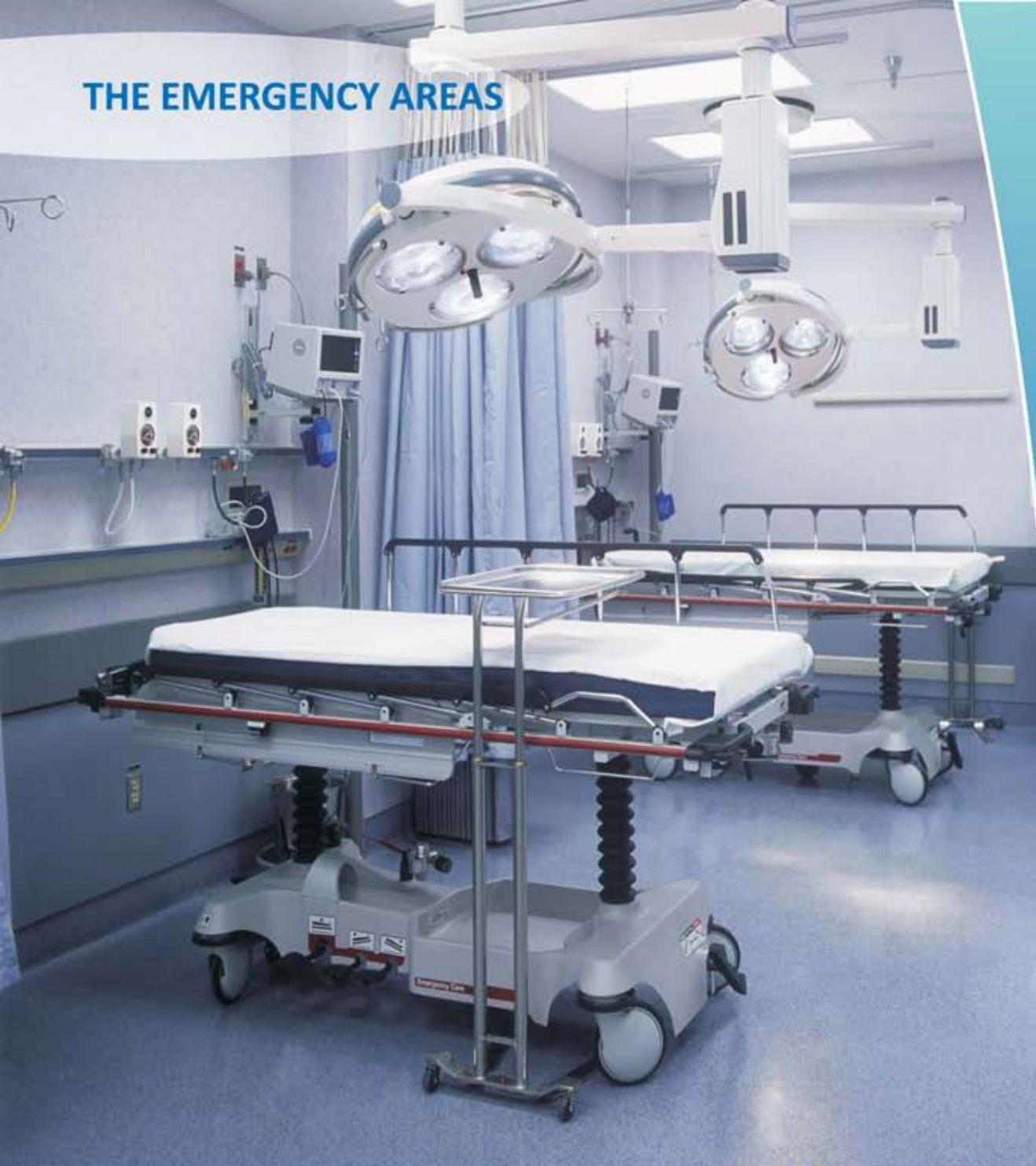
The particular critical conditions due to constant exposure to the microbial agents in the laminar flow cabins and the maintenance of the clean rooms in the laboratories, creating the need for disinfection of the air and surfaces to protect the health of operators and to ensure the accuracy of reports.



⁷ U.O.A. Prevention of Infectious Risk. Azienda Sanitaria Locale 3 di Torino. The Biological Risk

⁸ Università degli Studi di Trieste. Dipartimento di Biochimica Biofisica e Chimica delle Macromolecole. Informative Document for the Security in the Laboratories. Biological Risk. By the Health Commission and Department Safety

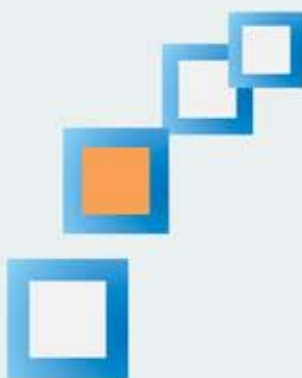
THE EMERGENCY AREAS



THE IMPORTANCE OF THE QUICKLY REUSABLE PREMISES

The emergency rooms, the ambulances and other emergency areas, are visited daily by a large numbers of people who are potentially contaminated and the risk that we encounter without an adequate disinfection is that these critical and sensitive areas may represent a high source of infection.

A fundamental feature of these areas is the need to re-use as soon as possible the structures and the equipments inside to cope with emergencies.





The disinfection of the air and surfaces in the environments at risk, along with a proper hand washing hygiene, are the most important prophylactic tools for the prevention of infectious pathologies that find their way into the environment and their natural habitat.

The degree of contamination present in an indoor environment may represent a potential factor for health risk.

The infections may arise from:

- bacterial flora already present in the patient (primary endogenous infection, for example that given by *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Escherichia coli*)
- a microorganism that comes from another area of the body of the patient (secondary endogenous infection such as that caused by *Acinetobacter* spp, *Serratia* spp, *Klebsiella*)
- microorganisms coming from the environment: exogenous infection (*Staphylococcus*)⁹

The limit of traditional disinfection protocols highlight the impossibility of eliminating the risk of infection and of contamination derived from the continuous exchange between air and surfaces.



Currently the prevention for the health of the patients and/or of the nursing staff in hospitals, in particular, and more generally of the persons in the public sphere, is managed through unsatisfactory technical means, using primarily toxic products.

A thorough and systematic disinfection of the facilities and the premises is one of the main actions of preventive nature aimed at reducing the health risks associated with microbiological contamination of indoor environments.

To ensure an effective solution to the risk of infection, we have produced studies and researches of new disinfection systems able to minimize the infectious risk and eliminate microbial agents.

THE SYSTEM EVOLUTION

EVOLYSE

After several years of study and research, in collaboration with some Italian universities, arises EVOLYSE. Its main purpose is to ensure a safe and aseptic environment in the hospital field.

The selected active principle is the hydrogen peroxide, whose disinfectant properties and its effectiveness against bacteria, viruses, spores and fungi have long been known.

The main reason of the success of EVOLYSE is the safety for the users and the environment (eco-compatible, biodegradable product to 99.9%, non-toxic and non-corrosive) and appears then to be a possible alternative to the harmful substances for the health of the operator (formaldehyde, glutaraldehyde, phenols, active chlorine, etc.).

Registered as Class IIa Medical Device, according to the EC Directives on Medical Devices (Directive 2007/47/EC amending the Directive 93/42/EC) and with EC Certification 0546, EVOLYSE prevent and control the infections without creating resistant strains and without releasing any type of residue in the environment (It doesn't wet and doesn't settle).

Its rapid action and the easy use allow a wide range of applications with excellent results.

The range EVOLYSE has been designed to meet the different customers needs and market demands with products based on hydrogen peroxide, silver salts and distilled water.

- EVOLYSE BASIC is composed of 6% hydrogen peroxide and 10 ppm of silver salts. This product is considered the basic version from which have developed three other disinfectants
- EVOLYSE FAST that with the 10% of hydrogen peroxide allows to disinfect the environment more quickly
- EVOLYSE STRONG that with the 12% of hydrogen peroxide eliminates the most resistant microorganisms
- EVOLYSE DENTAL is a specific product for the dental sector
- STEREXP is a sanitizing product for air, environment and surfaces.

Presentation of Evolyse at ICAR 2010 Valladolid "International Conference of Antimicrobial Research"

EVALUATION OF BIOCIDAL ACTIVITY OF EVOLYSE, A DISINFECTANT BASED ON HYDROGEN PEROXIDE AND SILVER NITRATE



M. Barbara Pisano¹, V. Altana², M. Elisabetta Fadda¹, L. Mura²,

M. Deplano¹ and S. Cosentino¹

¹Department of Experimental Biology, Section of Hygiene, University of Cagliari, Cittadella
Universitaria, 09042 Monserrato, Cagliari, Italy

²All Side, Adde sa Tanca, 4, 07040 Tissi, Sassari, Italy



Introduction

Indoor pollution by microbial contaminants is increasingly receiving attention as a public health problem (1). Bioaerosols could be responsible for allergic responses, infectious disease and respiratory problems. Indoor air and surfaces disinfection is considered the most important measure to prevent the spread of infectious disease, especially in the hospital environment.

Evolyse is a new peroxygen based disinfectant containing hydrogen peroxide (5.9 %) and silver nitrate (10 ppm).

The aim of this study was to test the *in vitro* biocidal activity against a wide spectrum of microorganisms, including bacteria, spores and fungi and evaluate the antimicrobial efficacy under practical conditions in different hospital environments.

Materials and Methods

In vitro activity against the test strains was determined using the quantitative suspension tests described by the European Committee for Standardization (Table 1) (2, 3, 4). Reduction of 5 log₁₀, 4 log₁₀ and 3 log₁₀ were regarded as denoting bactericidal, fungicidal and sporicidal activity, respectively.

The antimicrobial activity of Evolyse was also analysed under practical conditions, in the following hospital environments: operating room, sterilization room, dental office. The rooms disinfection was performed nebulising the product at the concentration of 1 mL/m³. The efficacy of this disinfection system was evaluated by microbiological monitoring of air and surfaces, before and after disinfection treatment. Microbial air contamination was assessed by active sampling using the Surface Air System (SAS) to determine the number of CFU/m³. Contact plates containing different agar media were used for enumeration of microorganisms on surfaces. The following microbiological parameters were determined: Total Bacteria Count in Plate Count Agar (PCA, Microbiol, Cagliari, Italy), Staphylococci in Mannitol Salt Agar (MSA, Microbiol) *Enterobacteriaceae* in Violet Red Bile Glucose Agar (VRBG, Microbiol), yeasts and moulds in Potato Dextrose Agar (PDA, Microbiol).

Results

Table 1 - Bactericidal, sporicidal and fungicidal activity of Evolyse in suspension tests

| Test microorganisms | European Standard Test | Time (min) | Log ₁₀ -reduction ¹ factor |
|--|------------------------|------------|--|
| <i>Staphylococcus aureus</i> ATCC 25923 | EN 1276 | 5 | >5 |
| <i>Staphylococcus aureus</i> DBS collection* | EN 1276 | 5 | >5 |
| <i>Listeria monocytogenes</i> ATCC 7644 | EN 1276 | 5 | >5 |
| <i>Pseudomonas aeruginosa</i> ATCC 27853 | EN 1276 | 5 | >5 |
| <i>Escherichia coli</i> ATCC 25922 | EN 1276 | 5 | >5 |
| <i>E. coli</i> ATCC 35150** | EN 1276 | 5 | >5 |
| <i>Salmonella enteritidis</i> ATCC 13076 | EN 1276 | 5 | >5 |
| <i>Legionella pneumophila</i> ATCC 33152 | EN 1276 | 5 | >5 |
| <i>Bacillus cereus</i> ATCC 11178 | EN 13704 | 45 | >3 |
| <i>Candida albicans</i> ATCC 10231 | EN 1650 | 30 | >4 |
| <i>Saccharomyces cerevisiae</i> ATCC 2601 | EN 1650 | 30 | >4 |
| <i>Aspergillus flavus</i> ATCC46283 | EN 1650 | 15 | >4 |
| <i>A. niger</i> DBS collection | EN 1650 | 15 | >4 |
| <i>Penicillium chrysogenum</i> ATCC 9179 | EN 1650 | 30 | >4 |

*DBS: decontaminated strains

**ATCC: American Type Culture Collection

¹ For testing systems under the Council of Directive 76/308/EEC, the usual procedure for the calculation of the reduction

References

1. E. E. Bled, Disinfection, Sterilization and Preservation, Lea and Febiger, Philadelphia, 1981.
2. European Standard EN 1276: Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas. Test method and requirements (Johns J, 1992). Brussels: European Committee for Standardization, 1992.
3. European Standard EN 13704: Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas. Test method and requirements (Johns J, 1992). Brussels: European Committee for Standardization, 1992.
4. European Standard EN 1650: Chemical disinfectants. Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas. Test method and requirements (Johns J, 1992). Brussels: European Committee for Standardization, 1992.

In experiments simulating dirty conditions (3 mg/ml bovine albumin) the disinfectant exhibited bactericidal activity against *S. aureus* ATCC 25923, methicillin-resistant *S. aureus* strain, *L. monocytogenes* ATCC 7644, *Escherichia coli* ATCC 25922, *Salmonella* Enteritidis ATCC 13076, *P. aeruginosa* ATCC 27853 and *L. pneumophila* ATCC 33152 after 5 min contact at room temperature. Sporicidal activity against *B. cereus* ATCC 11178 spores was obtained after 45 min contact at room temperature. The disinfectant also showed fungicidal activity against *A. flavus* ATCC 46283 and an *A. niger* wild strain after 15 min contact at room temperature and against *C. albicans* ATCC 10231, *S. cerevisiae* ATCC 2601 and *P. chrysogenum* ATCC 9179 after 30 min contact time.

Figure 1 - Microbial air contamination of hospital environments. Percent reduction of microorganisms (%) after disinfection treatment.

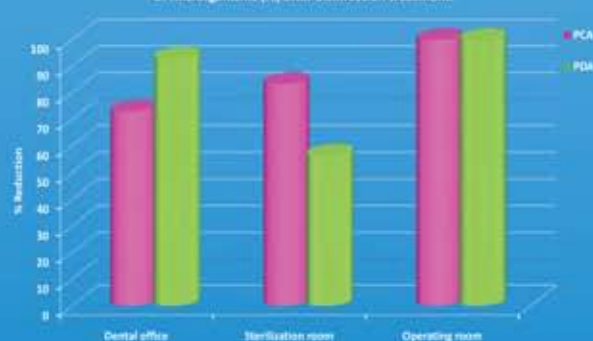
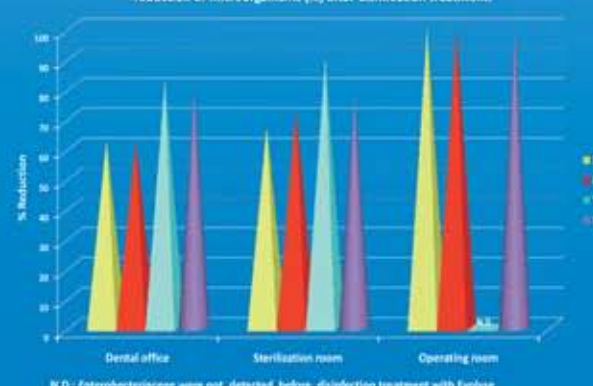


Figure 2 - Microbial contamination of surfaces in the hospital environments: percent reduction of microorganisms (%) after disinfection treatment.



Microbiological monitoring of the air, before and after disinfection treatment, showed a percent reduction of bacteria and fungi higher than 70% in the majority of microbial samples carried out in the different hospital environments analysed.

Disinfection treatment with Evolyse resulted in 60-100 % reduction of microbial growth on surfaces .

Conclusions

The results of this study showed the good biocidal activity of Evolyse and offer promising perspective for the use of this product in hospital environments.

MEDIBIOS was made with high strength materials and is managed by a software that has the following features:

- Setting of the date and hour of the start
- Setting of m³
- Setting of the protocols
- Control of the disinfection cycle progress
- Detector of the temperature
- Management of product/program
- Identification of the operation through cold led light
- Setting of the password for each professional
- USB for data transmission and software update
- Washing cycle



MONITORING AND CONTROL SYSTEM

The monitoring and control system is easy to use, allows the verification of the successful atomization of hydrogen peroxide and protects the operator from biological risk indicating the amount of ppm present in the environment and therefore the possibility of re-use of the premises having the full safety for the health of operators and patients as described by the Legislative Decree dated 9 April 2008, No. 81 Implementation of Article 1 of the law dated 3 August 2007, No. 123, in matter of protection of health and safety in workplaces and Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work. A remote display applied out of the room will inform in real time on the values of hydrogen peroxide in the environment.

All this information is transmitted via cable to a server for the tracking.

PROTOCOLS

The protocols represent a part of our intellectual property, have been developed with Universities, Hospitals and Experimental Zooprophyllactic Institutes to guarantee a safe and appropriate environment and to ensure a treatment that it meets the needs of users reaching the result that we wish to obtain: the elimination of a particular microorganism in a specific area without causing damage to people and equipment.

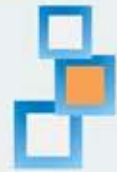
The protocols of sterilization are measured and certified using biological indicators with high resistance such as the *Geobacillus Stearothermophilus* spores.



THE FOUR POINTS OF STRENGTH

THE MEDIBIOS SYSTEM IS ABLE TO OFFER HIGH STANDARDS OF DISINFECTION IN ALL CRITICAL AREAS ENSURING THE MINIMUM INFECTIOUS RISK THROUGH ITS FOUR POINTS OF STRENGTHS:

- 1- HIGH LEVEL DISINFECTANT SOLUTIONS OF NEW GENERATION
- 2- ATOMIZER EQUIPMENT WITH HIGH TECHNOLOGICAL CONTENT, WITH SAFE RELIABILITY AND IN KEEPING WITH THE MOST IMPORTANT EUROPEAN STANDARDS
- 3- MONITORING AND CONTROL SYSTEM OF THE CONCENTRATIONS OF HYDROGEN PEROXIDE IN PPM
- 4- PROTOCOLS DEVELOPED WITH IMPORTANT RESEARCH INSTITUTE.





- Evaluation of effectiveness in the meat industry - Cosmolab Laboratori and Università degli Studi di Pavia
- Evaluation of effectiveness in the aerial disinfection of surfaces (effectiveness against *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Enterococcus faecalis*, *Escherichia coli*, *Serratia marcescens*, *Klebsiella pneumoniae* ESBL +, *Acinetobacter baumannii* complex multiresistente) - Laboratorio di Microbiologia e Virologia, Ospedale "A. Manzoni" - Lecco
- Evaluation of effectiveness in the following confined environment: quarantine local small pets in the pound, room of bottling and lyophilization of the Pharmaceutical Office and biosafety cabinet of the Maximum Security Unit against *Staphylococcus xylosus*, *Bacillus* spp., *Mucoraceae*, Yeast, *Geobacillus stearothermophilus*, *Bacillus atrophaeus*, *Streptococcus uberis*, *Salmonella abortusovis*, *Escherichia coli* and infectious bovine rhinotracheitis (IBR) virus - Istituto Zooprofilattico Sperimentale dell'Umbria e delle Marche - Perugia
- Dental Setting: Pilot study to evaluate the effectiveness in a dental practice - Ospedale S. Paolo e Università degli Studi di Milano
- Bacteriological study of laboratory against *Bacillus Subtilis*, *Staphylococcus aureus*, *Staphylococcus epidermidis* - Laboratorio de Análisis Clínicos del Estado de Veracruz
- Sanification protocols in removing the microbiological charge in environmental surfaces and air inside the operating rooms - Dr.ssa Frabetti
- Determination of antiviral activity on A-H1N1 virus - Università di Sassari Dipartimento di Scienze Biomediche Sezione di Microbiologia Sperimentale e Clinica
- Bactericidal activity in accordance with standard EN 1276 against *Staphylococcus aureus*, *Listeria monocytogenes*, *Staphylococcus aureus* meticillinoresistente, *Pseudomonas aeruginosa*, *Escherichia coli*, *Salmonella enteritidis*, *Legionella pneumophila* - Università di Cagliari Dipartimento di Biologia Sperimentale "B. Loddo"
- Fungicidal activity in accordance with standard EN 1650 against *Candida albicans*, *Saccharomyces cerevisiae*, *Aspergillus flavus*, *Aspergillus niger* ceppo DBS, *Penicillium chrysogenum* - Università di Cagliari Dipartimento di Biologia Sperimentale "B. Loddo"
- Sporocidal activity against *Bacillus cereus* strain in accordance with standard EN 13704 - Università di Cagliari Dipartimento di Biologia Sperimentale "B. Loddo"
- Sporocidal activity against *Bacillus cereus* strain in accordance with standard EN 13704 (after 45 minutes of contact) - Università di Cagliari Dipartimento di Biologia Sperimentale "B. Loddo"
- Microbiological sampling of air and surfaces in area of pound - Università di Cagliari Dipartimento di Biologia Sperimentale "B. Loddo"
- Microbiological sampling of air and surfaces in the following confined environment: food microbiology laboratory, dental practice, bus, hospital (sterilization unit and operating room) before and after the disinfection treatment - Università di Cagliari Dipartimento di Biologia Sperimentale "B. Loddo"

This brochure has been prepared using scientific information taken from:

- World Health Organization. Prevention of Hospital-Acquired Infections: A Practical Guide. 2d ed. Geneva: World Health Organization, 2002.
- World Alliance for Patient Safety. Global Patient Safety Challenge 2005-2006. Geneva: World Health Organization, 2007.
- European Centre for Disease Prevention and Control. Healthcare-Associated Infections (HAI)
- Inf Nos 2 2002- 2004. Carried out with the scientific advice of Istituto Lazzaro Spallanzani in Rome and funded by the pharmaceutical multinational GlaxoSmithKline
- ASO S. Croce e Carle di Cuneo. Descriptive document. Hospital Infections Committee. Microbiological Environmental Control in the Operating Room. 20 April 2004
- Servizio Sanitario Regionale Emilia-Romagna. Regione Emilia-Romagna. Dossier 104-2005. Surveillance and Control of Infection in Intensive Care Unit. Survey in Emilia-Romagna
- U.O.A. Prevention of Infectious Risk. Azienda Sanitaria Locale 3 di Torino. The Biological Risk
- Università degli Studi di Trieste. Dipartimento di Biochimica Biofisica e Chimica delle Macromolecole. Informative Document for the Security in the Laboratories. Biological Risk. By the Health Commission and Department Safety
- Università degli Studi di Roma Tor Vergata. Facoltà di Medicina e Chirurgia. Cattedre di Microbiologia, Virologia e Microbiologia Clinica. The Hospital Infection

Main Legislative Decrees and Guidelines:

- Legislative Decree dated 9 April 2008, No. 81 Implementation of Article 1 of the law dated 3 August 2007, No. 123, in matter of protection of health and safety in workplaces
- Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16, paragraph 1, of Directive 89/391/EEC)
- Directive 2007/47/EC of the European Parliament and of the Council amending Directive 93/42/EC concerning Medical Device
- Guidelines for the health protection and promotion in confined environment. Ministry of Health Director General of Prevention
- Guidelines for Prevention and Control of Legionellosis
- Guidelines for the definition of technical protocols for predictive maintenance on air conditioning systems
- Guidelines on standards of occupational safety and hygiene in the operating department. National Institute for Occupational Safety and Prevention. Department of Occupational Hygiene

All information is available on www.nocosystem.com



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www.medibios.com
medibios@medibios.com