The Validation of the Sterinis Machine

At Adelaide Meath Hospital, Tallaght, Dublin.

BA (Mod) Thesis 2005

Damien Joseph Tackney

Declaration

I, Damien Tackney, certify that the experimentation recorded herein represents my own work.

I further certify that I have read the University regulations concerning plagiarism contained within The University of Dublin Calendar 2004-05 Part 1, G13-G14 and that this thesis write-up represents my own unaided work.

Signature of Student:

Date:

ABSTRACT

Research has shown increasing evidence that the hospital environment has a heavy impact on hospital acquired infection rates. Nosocomial infections (i.e. those that originate or occur in hospitals) are recognized as a critical world wide problem. [1]Methods of disinfection currently available commercially (for example direct spraying, nebulisation and wet spraying) are not effective enough and cannot be used to diffuse and apply disinfectant products in all areas and on all surfaces, including medical devices and equipment.[3] As a result infectious agents can quickly re-contaminate the area that is affected. The situation seems to be getting worse as infections previously encounter in hospital environments essentially are now starting to affect all places frequented by the public.

A French company Gloster Sante Europe has developed the Sterinis machine which is a new technology to eradicate nosocomial pathogens in healthcare facilities. The Sterinis machine operates by generating a dry mist of high kinetic energy hydrogen peroxide (Fig. 1). The aim of this research was to evaluate the effectiveness of the Sterinis process in Tallaght Hospital in real conditions of use. It is based on a series of 10 to 12 samples of surfaces distributed in the environment of the patient making it possible to measure the effectiveness of the Sterinis process by comparison "before/after" the process.The complete process of decontamination took an average of an hour and as will be seen from the results proves more effective than the routine decontamination process that is in place at the moment.

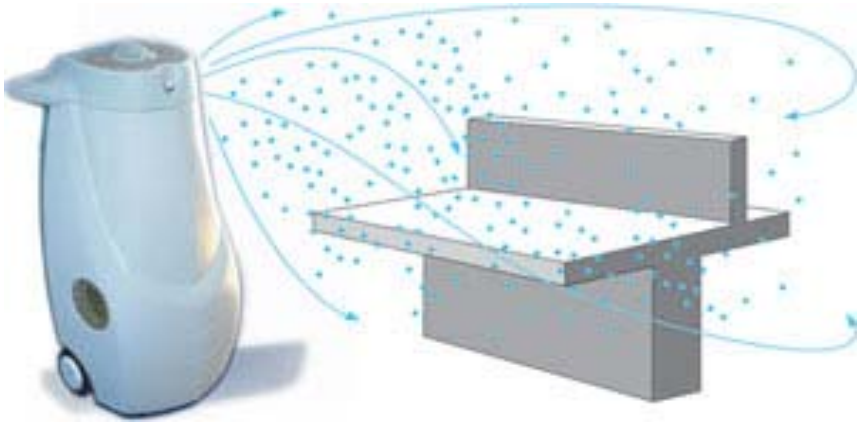

FIG. 1: Sterinis Dry Mist Dispenser

INTRODUCTION

Nosocomial infections and antimicrobial resistance are topics that have been intensely studied in medicine because of their significant impact on health. Nosocomial infections increase in prevalence with the increase in intensive care practices of many hospitals. Prolonged hospitalization and the use of invasive devices and procedures increase the risk of nosocomial disease. Organisms isolated as nosocomial infections have an increasingly broad spectrum of antimicrobial resistance.[6] Nosocomial infections and antimicrobial resistance may have a serious impact on the future because the cost and ability to treat patients may be affected by the loss of access to or effectiveness of antimicrobial drugs.[5] An important factor in preventing nosocomial infections is improving the environmental cleaning of a room after the discharge of an infectious patient.[2]There is an exact protocol set in place by Tallaght Hospital for the cleaning of rooms but it is not ideal and could be improved with the implementation of hydrogen peroxide decontamination.

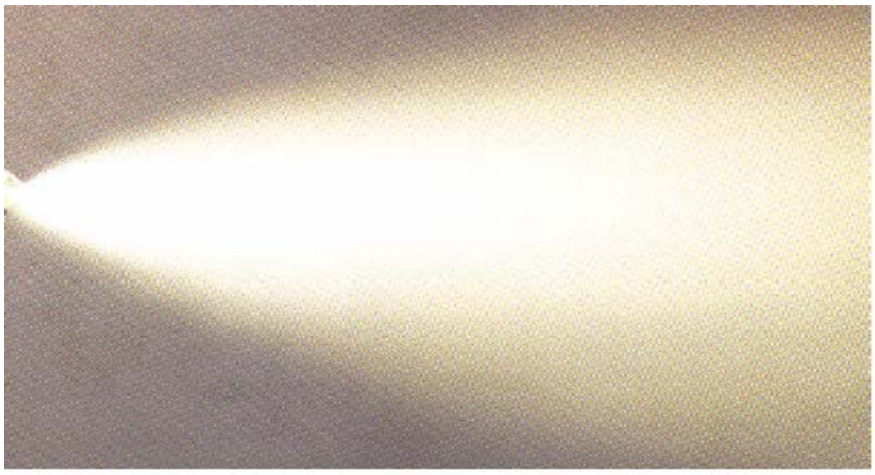

FIG. 2: Dry Mist of ionized hydrogen peroxide

Gloster Sante Europe has developed a disinfection concept, utilizing a spraying technique which generates very thin drops of a product. This phenomenon is called the dry mist, that is, drops of a diameter ranging between 8 to 12 µm in Gauss average (Fig. 2). The nozzle head specifically designed to produce these drops allow perfect diffusion of the solution into the whole volume as well as a homogeneous distribution on the surfaces. The combination of the drop size and nozzle is the basis of the device's high capacity to generate an optimal disinfection level. The smaller the drops, the lighter they are and their suspension time is longer, producing a better impregnation of the surfaces and a homogeneous distribution of the disinfectant. The diffusion of the dry mist occurs thanks to the different gradients of the various constituents of the disinfectant volume (Diffusionphoresis). This principle allows the disinfectant to be in contact with all the surfaces in the room, including those which seem unreachable. The apparatus capable of this is Sterinis (Fig. 3).

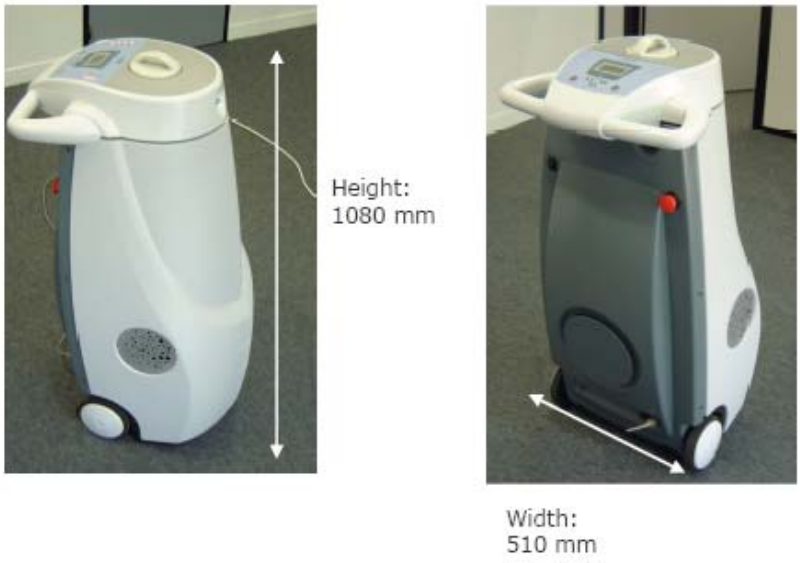

FIG. 3: Sterinis Measurements

There are two principles of the dry mist concept which explain the mechanism of the high disinfectant power of this machine. The first principle is the ionization phenomena, which occurs when an aerosol quality dry mist is achieved by putting an electrical charge on the drops which in turn increase the nucleation phenomena. This second principle, the nucleation phenomena is where the very small size drops adhere to particles present in the atmosphere and on the surfaces. This adherence, favoured by the ionization phenomena, requires even lower energy consumption when the support particle is “wet able”. Therefore on highly "wet able" particles, the disinfectant micro - drops have a high reserve of energy to concentrate and form a liquid film on the support particles (Fig. 4). Since most micro-organisms are hygroscopic (attract humidity), they naturally become excellent nucleation targets for the disinfectant product, Sterusil.

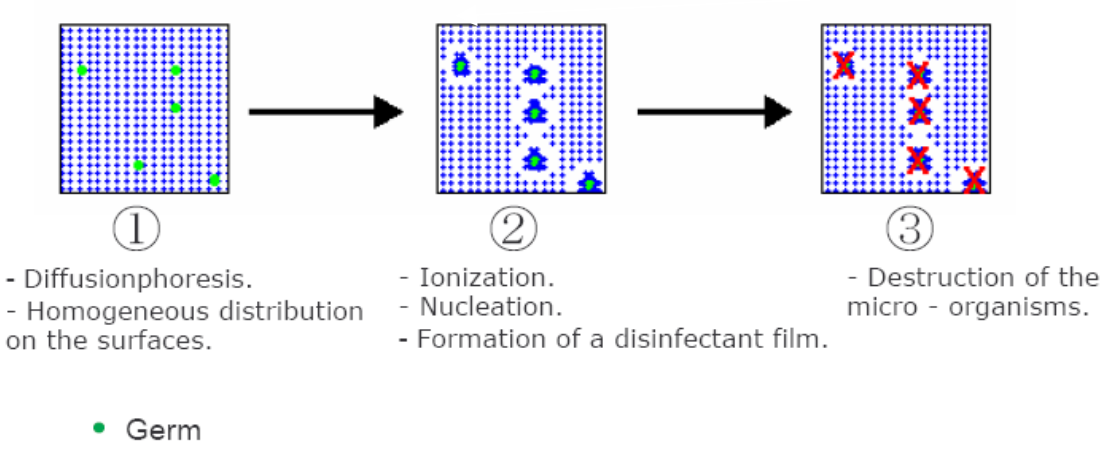

FIG. 4: Ionization and Nucleation phenomena

Sterusil is put forward as the ideal companion to the Sterinis dry mist dispenser. Sterusil is a disinfecting solution containing 5% hydrogen peroxide, **s**tabilized orthophosphoric acid at less than 50 ppm, silver cations at less than 50 ppm, gum Arabic at 1 ppm and is 95% osmosed water. It comes in 2litre cartridges (Fig. 5). Sterusil is non-corrosive and biodegradable breaking up into water and oxygen without toxic residues.

FIG. 5: Sterusil cartridges with barcode

Functions and characteristics of Sterinis

The Sterinis dry mist dispenser is an entirely programmable apparatus. The appliance is fitted with an electronic control system, the functions include inviolable disinfectant cartridges, controls the volume used, a data traceability system and an automatic operating mode. The user has either the possibility of

programming the apparatus within a framework or through an automatic mode following a weekly plan for disinfection. The parameters to register for each room to disinfect are disinfection level, room volume and the weekly plan. It has secured functions with traceability which is achieved through having these single use disinfectant cartridges. The principle for the use of single and specific cartridge makes it possible to ensure that the apparatus diffuses the validated product, prevents, thanks to a barcode scanner and an electronic management system the risk linked to a worn and re-filled cartridge being used, and finally the recording of cartridge data in the management system of the apparatus, thus ensuring a traceability of the product used.

Control of the Outflow:

A set of sensors, connected to the pump and the control system, enables the user to measure and adapt the outflow of the dry mist and compare it thanks to an integrated calculation program to pre established fixed parameters that have been set. This system enables the device to automatically activate an alarm in case of malfunction and, to control the quantity of product consumed in relation to the numbers of operations run. This information is registered in the memory of the device over a period of 6 months. A USB connection is available to collect the data to a P.C

METHODS AND MATERIALS

Cotton tipped sterile swabs were moistened in sterile saline and used to sample surface areas of approximately 15 cm^3 by standardized swabbing in two directions at right angles. Between 10 and 12 different sites, chosen to include surfaces likely to be touched by patients or staff hands were sampled in each room. Swabs were used to inoculate Blood Agar, and also MacConkey agar. Blood agar was chosen because it is a non-selective general purpose medium. It can grow pathogenic and non-pathogenic bacteria. Macconkey agar were chosen as a differential media. It has the ability to support the growth of pathogenic Gram-positive cocci and was particularly useful in cultivating pathogens from a variety of surfaces. It is selective yet does not suppress a mixed bacterial flora to the same extent as other inhibitory media. The Blood and MacConkey agar was incubated at 35°C for 24 hours. Growth was recorded quantitatively through colony forming unit (cfu) counts.

The Sterinis dry mist apparatus and Sterusil hydrogen peroxide disinfectant were used to sterilize the rooms. The time the Sterinis takes to generating the dry mist depends on the size of the room. Each room received a preventive level 1 disinfection, 3ml/m^3 with a mist output of 20ml/minute (Fig. 6). The contact time is an hour after diffusion of the disinfectant.

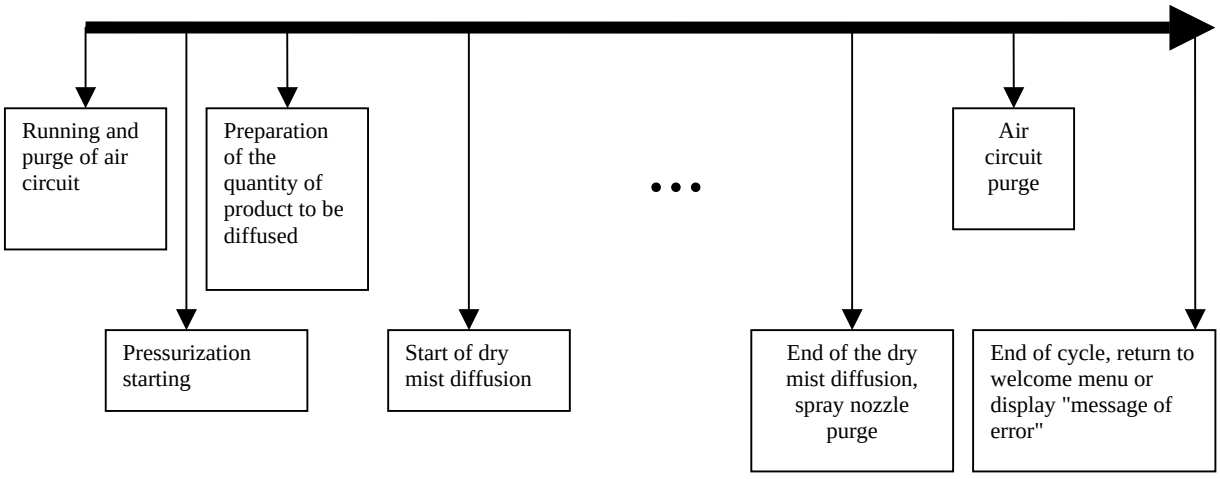

FIG. 6: Phases of disinfection

To establish the optimal results of Sterinis the positioning of the machine in the room had to be considered. The dry mist is generated about 2m from the apparatus and 1.8m in height from the floor. Therefore no obstacles could to be in this zone.

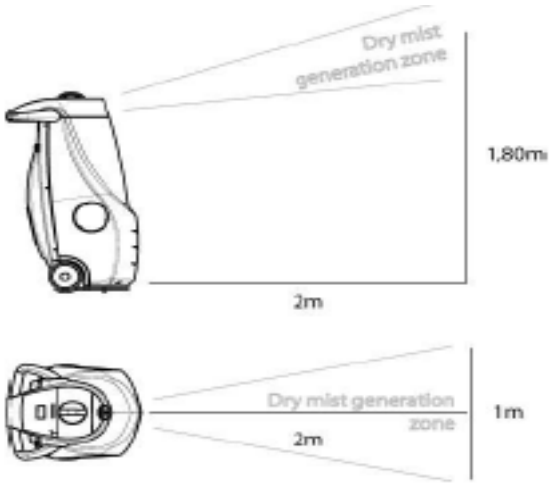

FIG. 7: Sterinis generation of the dry mist zone

RESULTS

Laboratory Medicine Department

The first room is a laboratory where molecular identification of cystic fibrosis pathogens specifically *Burkholderia ceperia compler* takes place. The Laboratory was 80m^3 (Fig. 8,9,10) . The laboratory work surfaces were not swabbed after the mornings work to increase the number of bacteria present and further test the capabilities of the Sterinis apparatus. Colonies found were identified as co-agulase negative *Staphylococcus aureus. Burkholderia ceperia compler.*was identified by the laboratory technician on the before plates.

FIG. 8: Corner of the Laboratory

FIG. 9: Central view of the laboratory

FIG. 9: Left corner of Laboratory

FIG. 10: *Burkholderia ceperia compler* work bench

Location	Angle	Material	Before	After
Cold Room Door Handle	Vertical	Plastic	3cfu	0
Centrifuge Surface	Horizontal	Plastic	13cfu	1cfu
Steel work table	Horizontal	Metal	5cfu	3cfu
Laboratory Sink	Vertical	Enamel	2cfu	0
Hand Sink	Horizontal	Enamel	448cfu	131cfu
Lab Coats	Vertical	Polyester	39cfu	12cfu
Bench 1	Horizontal	Wood	4cfu	0
Bench 2	Horizontal	Wood	1cfu	0
Tray	Horizontal	Plastic	3cfu	1cfu
Ledge	Horizontal	Metal	2cfu	0

TABLE 1: *Burkholderia ceperia compler* Laboratory

The Day Care Centre

This sterilization was carried out in the Day Care Centre on two rooms where minor surgical practices are carried out, such as the removal of boils or ingrown toenails. Both rooms are of equal size and are very similar in lay out (Fig. 11,12,13,14). Sterilization was carried out at the end of the day after all the minor surgeries were completed no cleaning was undertaken before the initial swabs were taken. A ceiling tile was lifted in the suspended ceiling, in both rooms to expose the attic space to disinfection.

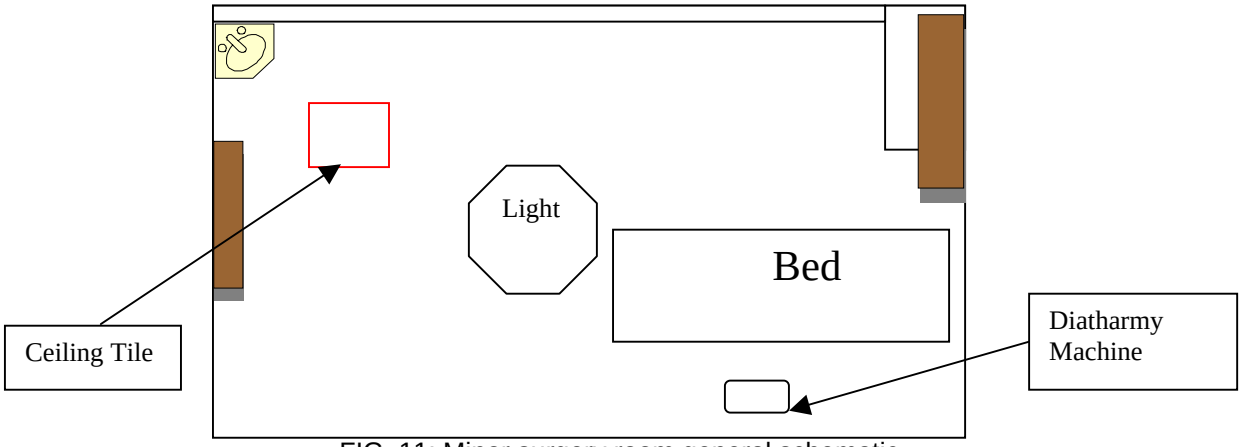

FIG. 11: Minor surgery room general schematic

FIG. 12: Minor Surgery Room 1

FIG. 13: Alternative angle of minor surgery

FIG. 14: Minor Surgery reversed angle.
Diatharmy machine can be seen. It is used to heat coagulate blood vessels

Location	Angle	Material	Before	After
Bench Ledge	Horizontal	Wood	12cfu	5cfu
Storage Unit	Vertical	Wood	21cfu	12cfu
Bed	45°	Leather	13cfu	0cfu
Sink	Horizontal	Enamel	0cfu	0cfu
Suspended Lighting	Horizontal	Metal	27cfu	0cfu
Shelving	Horizontal	Wood	14cfu	0cfu
Ceiling Tiles	Horizontal		0cfu	0cfu
Ceiling	Horizontal	Metal	0cfu	0cfu
Storage	Horizontal	Wood	22cfu	0cfu
Window Sill	Horizontal	Metal	0cfu	0cfu

TABLE 2: Minor Surgery 1

Location	Angle	Material	Before	After
Bench ledge	Horizontal	Wood	4cfu	0cfu
Storage Unit	Vertical	Wood	26cfu	6cfu
Bed	45°	Leather	1cfu	0cfu
Sink	Horizontal	Enamel	0cfu	0cfu
Suspended Lighting	Horizontal	Metal	92cfu	2cfu
Shelving	Horizontal	Wood	6cfu	0cfu
Ceiling Tiles	Horizontal	Wood	0cfu	0cfu
Ceiling	Horizontal	Metal	336cfu	0cfu
Storage	Horizontal	Wood	13cfu	2cfu
Window Sill	Horizontal	Plastic	2cfu	0cfu

TABLE 3: Minor Surgery 2

The Lane Ward

At departure of the patient and before cleaning, 11 surface samples were taken in the room. The same samples were taken after a standard cleaning and a Sterinis disinfection. This room was on the Lane Ward, the patient was discharged after recovering from a *Clostridium difficile* infection. The ward is dedicated to Urology patients. The cleaning of the room is not completely effective yet the number of bacteria is relatively low and the Sterinis totally removed the remaining quantity of bacteria.

Sample Location	Angle	Material	Before	Cleaning	After
Bathroom Window Sill	Horizontal	Plastic	11cfu	0	0
Bathroom Light	Horizontal	Metal	0cfu	0	0
Hand Sink	Horizontal	Enamel	1cfu	0	0
Bedside Locker	Horizontal	Wood	736cfu	0	0
Locker Drawer	Horizontal	Wood	47cfu	0	0
Ledge	Horizontal	Metal	12cfu	50cfu	0
Bed Frame	45°	Metal	11cfu	3cfu	0
Food Table	Horizontal	Wood	5cfu	4cfu	0
Corner Table	Horizontal	Wood	19cfu	9cfu	0
Armchair	Horizontal	Leather	1cfu	2cfu	0
Curtains	Vertical	Cotton	0cfu	2cfu	0
Window Sill	Horizontal	Plastic	0cfu	9cfu	0

TABLE 4: Lane Ward

Children's Outpatient Ward

Treatment Room

Treatment Room was 30 m^3 and used for consultations and surgical dressing (Fig. 15,16,17). A ceiling tile was lifted in order to further test the capabilities of Sterinis. Although the attic space was very dusty only a small quantity of microorganisms were found. The prominent organisms were identified as a species of *Bacillus*.

FIG. 15: Press, hand sink and open drawer (bottom left) in treatment room

FIG. 16: Computer desk and table

FIG. 17: Left corner of treatment room

Location	Angle	Material	Before	After
Window sill	Horizontal	Plastic	0cfu	0cfu
Table	Horizontal	Metal	50cfu	9cfu
PC desk	Horizontal	Wood	7cfu	0cfu
Blood Pressure Machine	Vertical	Plastic	16cfu	0cfu
Ceiling	Horizontal	Metal	27cfu	0cfu
Ceiling Tiles	Horizontal	Wood	0cfu	0cfu
Drawer	Horizontal	Wood	5cfu	0cfu
Top Of Storage Press	Horizontal	Plastic	88cfu	18cfu
Sink	Vertical	Metal	0cfu	0cfu

TABLE 5: Treatment Room

Plaster Room

This room was used for adding and removing plaster of paris it was 30 m^3 (Fig. 18,19,20,21). The nurses considered it a dirty room but were surprised with the results. It would be expected that a cast worn for months would harbor large amounts of microbial flora from the human body and that when removed they would spread around the room. A drawer was opened on the press to further test the Sterinis. All microorganisms present were kill by the Sterinis dry mist.

FIG. 18: Plaster room

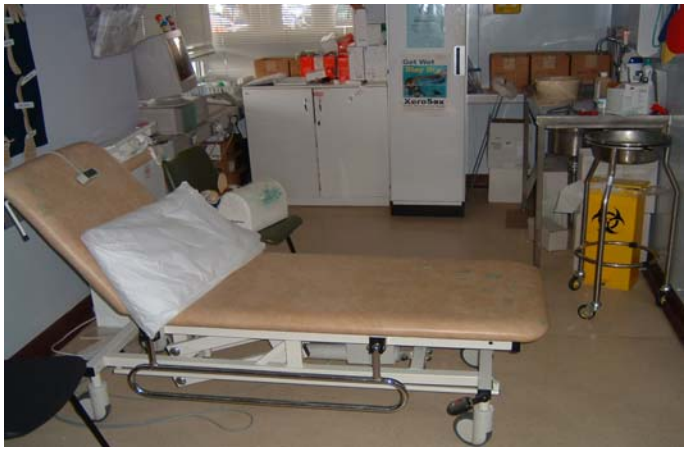

FIG.19 Bed in plaster room

FIG. 20: Reverse angle of plaster room

FIG. 21: Plaster removal device

Sample location	Angle	Material	Before	After
Window Sill	Horizontal	Plastic	1cfu	0
Suspended light	Horizontal	Metal	3cfu	0
Sink	Vertical	Metal	6cfu	0
Sink Counter	Horizontal	Metal	2cfu	0
Hand Sink	Vertical	Enamel	1cfu	0
Plaster removal Saw	Vertical	Metal	3cfu	0
Desk	Horizontal	Wood	6cfu	0
Open Drawer	Vertical	Wood	9cfu	0
Press Top	Horizontal	Wood	10cfu	0
Bed	45°	Leather	2cfu	0

TABLE 6: Plaster Room

Examination Room

This room was an examination room for children suffering from cystic fibrosis (Fig. 22,23,24). The most frequently isolated microorganisms form cystic fibrosis patients are *Staphylococcus aureus* (59.89%), *Pseudomonas aeruginosa* (49.45%), *Stenotrophomonas maltophilia* (4.9%) and *Haemophilus influenzae* (3.8%).[4] Swabs were taken of wet areas and air sampling was carried out using the Shaw Scientific 180 static air sampler because the bacteria were most likely to be airborne from the children coughing. Swabs were taken wet surfaces because that is where *Pseudomonas aeruginosa* is most likely to be found.
The tests were carried out at the end of the day after the outpatients clinic had finished for the day. Blood agar and Macconkey agar were used. The bacteria identified were of the *klebseilla* and *Staphylococcal*.The *klebseilla* colonies appeared pink and muciodal on the Macconkey plates and the *Staphylococcal* colonies appeared pale pink and opaque.

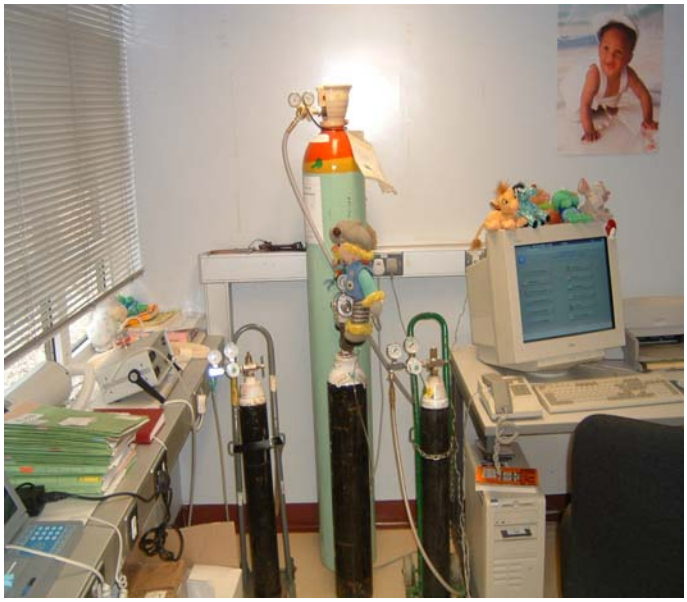

FIG. 22: Examination room

FIG. 23: Sink and V-max MFS machine

FIG. 24: Computer Desk

Agar	Before	Average	After	Average	Average % Reduction in cfu
Blood	77cfu	72cfu	13cfu	19cfu	73.6%
Blood	66cfu		25cfu		
MacConkey	86cfu	101cfu	26cfu	37cfu	63.4%
MacConkey	116cfu		48cfu		

TABLE 7: Static Air Samples

Location	Angle	Material	Blood Before	Blood After	MacConkey Before	MacConkey After
Sink	Horizontal	Metal	1cfu	0	0	0
Sink Basin	Horizontal	Metal	0	0	0	0
Mass Flow	Vertical	Plastic	1	0	0	0
Desk	Horizontal	Wood	0	0	51cfu	0
PC Ledge	Horizontal	Metal	26cfu	4cfu	13cfu	0
PC Desk	Horizontal	Wood	0	0	0	0
Window Sill	Horizontal	Plastic	2cfu	0	0	0

TABLE 8: Examination Room

Ruttle Ward

This room was in the Ruttle Respiratory and Neurology Ward. The room was 35 m^3 with a 5 m^3 ensuite and had been occupied by a patient suffering from the norovirus (Fig. 25,26, 27). The room was cleaned with soap, water and a disinfectant Actichlor. Actichlor contains 250g of sodium dichloroisocyanurate. It claims to be effective against viruses, bacteria and bacterial spores including HIV and Hepititis B. The cleaning was not effective in sterilizing the room as the cfu counts were high on the majority of surfaces sampled before decontamination by the Sterinis. Filamentous bacteria and hemolytic grey circular colonies were found on the plates.

FIG. 25: Norovirus room

FIG. 26: Bathroom

FIG. 27: Actichlor

Location	Angle	Material	Before	After
Window Sill	Horizontal	Plastic	14cfu	0cfu
Locker	Horizontal	Wood	68cfu	0
Bed Frame	45°	Metal	0cfu	0cfu
Ledge	Horizontal	Metal	78cfu	8cfu
Food Table	Horizontal	Wood	0cfu	0cfu
Door Handle	Vertical	Metal	122cfu	9cfu
Soap Dispenser	Vertical	Plastic	6cfu	0cfu
Bathroom Window Sill	Horizontal	Plastic	38cfu	2cfu
Corner of Shower	Vertical	Plastic	4cfu	0cfu
Corner of Room	Vertical	Paint	0cfu	0cfu

Table 9: Norovirus Room

Discussion

As can been seen from the above results the Sterinis dry mist dispenser has proved very effective in the elimination of bacteria in all rooms of the hospital. The dry mist method is particularly useful for decontaminating equipment and furniture that is difficult to clean manually. The ability of Sterinis to decontaminate those areas which are normally inaccessible such as the cavity between the roof and the suspended ceiling is of great benefit because by lifting a ceiling tile and calculating the attic space this area can be sterilized with minimum effort. As well as this Sterinis is capable of decontaminating rooms up to $200m^3$ which means virtually no room in a hospital is impossible to sterilize.

Further investigation could concentrate on the curative level of disinfection as all disinfections were carried out at preventive level, $3ml/m^3$ so the results are only for preventative disinfection as time was a factor as rooms were always in big demand. The option of carrying out a curative disinfection would give an even higher level of decontamination. The level 2 disinfection has a contact time of 2 hours with a disinfectant quantity of $6ml/m^3$. The unavailability of a room of methicillin-resistant *Staphylococcus aureus* patient or a *Clostridium tuberculosis* patient is also worth noting as the Sterinis has been proven effective against both these pathogens. Unfortunately no such rooms were available during my time in Tallaght.

In total 96 swabs were taken, 64 yielded a positive result (a positive result being the growth of at least one cfu). Only 17 swabs had a positive result after sterilization of the area with Sterinis. This gives a 73.5% success rate with the entire microbal population killed and this is at the low disinfection level of $3ml/m^3$. This percentage does not even take into account that the positive results before sterilization have higher cfu counts and that many of the positive results after sterilization are counting colonies of less than 5. The fact that ionized hydrogen peroxide is ideal for decontamination and the opportunity to work in volumes of up to $200m^3$ presents Sterinis as the way forward in the fight against nosocomial infections. With standard cleaning procedures falling short of the required level of hygiene the inclusion of the Sterinis into the current procedures for decontaminating rooms would certainly improve the cleaning process and single handily reduce the dilemma surrounding nosocomial infections. The finding of this report concurs with previous tests carried out in France in the Rangueil regional hospital, in the Netherlands in Gooi-Noord, Blaricum's regional hospital and in Ireland in St. Josephs Hospital, Cork which all yielded positive results

Acknowledgements

I would like to acknowledge the cooperation of the staff and laboratory technicians of Tallaght Hospital for there help and guidance. In particular I would like to thank the infection control nurses and Jonathan Collins for all thier assistance. Finally I would like to thank Tom Mc Phillips for all the information and his technical support

References

1. **Chen YY, Chou YC, Chou P.** 2005. Impact of nosocomial infection on cost of illness and length of stay in intensive care units. Infect Control Hosp Epidemiology. 26(3):281-7.

2. **Dharana, S., P. Mourougaa, P. Copina, G. Bessmerb, B. Tschanzb and D. Pitteta,** 2002. Routine disinfection of patients' environmental surfaces. Myth or reality? Infection Control Programme, University Hospitals of Geneva, Geneva, Switzerland

3. **French G.L ,Otter J.A, Shannon K.P, Adams N.M.T, Watling D, Parks M.J.** 2004. Tackling contamination of the hospital environment by methicillin-resistant *Staphylococcus aureus* (MRSA): a comparison between conventional terminal cleaning and hydrogen peroxide vapour decontamination. J Hosp Infect. 57(1):31-7.

4. **Garcia AD, Ibarra A, Rodriguez FC, Casal M.** 2004 Antimicrobial susceptibility of bacterial isolates from patients with cystic fibrosis**.** Rev Esp Quimioter. 17(4):332.

5. **Johnson JA.** 2002. Nosocomial infections.Vet Clin North Am Small Anim Pract; 32(5):1101-26.

6. **Warren DK, Fraser VJ.** 2001. Infection control measures to limit antimicrobial resistance. Crit Care Med. N128-34. Division of Infectious Diseases, Washington University School of Medicine, Saint Louis, MO, USA.