SCIENTIFIC REPORT SUMMARY ON STERYBOX

Air Disinfection Device UV-CHRIS (Ultraviolet High Reflecting Irradiation Coil System)

Scientific Tests Manual

Prepared by **TISSIMedica**
Sterybox is Patented in Italy and other countries (PCT)

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1. Introduction, FAQ, and Health Risk Reports

Introduction:
Sterybox is an innovative device designed to dramatically reduce airborne bacterial contamination in high-risk environments such as hospitals, laboratories, and offices. Utilizing the UV-C germicidal irradiation method at 254 nm, Sterybox disrupts the DNA of microorganisms—bacteria, viruses, fungi, and spores—ensuring that the air is thoroughly disinfected and safe for human exposure. This report presents a detailed account of the scientific tests performed on Sterybox, along with frequently asked questions and a summary of health risk reports related to airborne infections.

Frequently Asked Questions (FAQ):

1. **Why is Sterybox effective against viruses?**
   Sterybox uses UV-C irradiation to denature DNA. Because spores (which are typically more resistant than bacteria by a factor of ten) are inactivated, the device

is inherently effective against viruses, which are generally more vulnerable than spores.

2. **How does Sterybox work?**
   The device draws in ambient air through silent axial fans and passes it through a patented spiral (coil) system equipped with high-power UV-C lamps. These lamps are housed in a mirrored stainless steel labyrinth, which reflects and amplifies the UV-C radiation—up to four times—thereby ensuring that almost every particle in the air is exposed to the germicidal light.
3. **What makes the patented coil system unique?**
   Unlike conventional linear systems, the UV-CHRIS (UltraViolet High Reflecting Coil Irradiation System) used in Sterybox significantly amplifies the UV-C output. This results in a concentration of UV-C irradiation that is up to 400% higher than that of standard devices, leading to more effective and rapid microbial inactivation.
4. **Why doesn't Sterybox use filters?**
   Filter-based systems may trap larger organisms but often allow smaller pathogens, such as viruses, to pass through. Moreover, filters can become contaminated and serve as breeding grounds for bacteria. Sterybox eliminates these risks by ensuring that all the air is directly sterilized without any intermediate filter that might retain pathogens.
5. **What maintenance does Sterybox require?**
   Maintenance is minimal. The primary upkeep involves replacing the UV-C lamps every 8,000 operational hours (approximately one/two year of continuous use/day only) following the straightforward guidelines provided in the user manual.
6. **Is Sterybox safe for continuous use?**
   Yes, Sterybox is designed with safety in mind. The UV-C radiation is entirely confined within the device, and a safety switch automatically deactivates the lamps when the unit is opened. Additionally, the device does not emit ozone, further ensuring a healthy environment.
7. **Where can Sterybox be installed?**
   Sterybox is suitable for a variety of settings where air disinfection is critical—hospitals, clinics, laboratories, dental offices, clean rooms, offices, schools, and gyms, among others. Usually installed on the wall, it offers also a standalone rack and a mobile cart options.
8. **What warranty is offered?**
   Sterybox is covered by a one-year warranty, which assures users of its quality and reliability in terms of both performance and materials. Entirely Made in Italy with EU components. CE certified as Medical Device of Class I. UNI EN ISO 13485:2021.

Health Risk Reports

Airborne infections, particularly nosocomial (hospital-acquired) infections, are a major public health concern. In Italy alone, an estimated 3,000 deaths (8% of the total nosocomial deaths) per year are linked to aerial infections. This percentage are similar in most EU Countries and in the USA. These infections, which often prolong hospitalizations and increase healthcare costs significantly (est. 3.500 euro per patient), are exacerbated by bacterial resistance to antibiotics. In the United States, pneumonia is one of the most critical nosocomial infections, with ventilator-associated pneumonia (VAP) in intensive care units

having mortality rates as high as 76% in severe cases. Continuous air disinfection systems like Sterybox offer a scientifically proven method to reduce these risks, thereby improving patient outcomes and reducing healthcare costs.

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2. Sterybox Features

- **High Efficiency:** Achieves up to 99.99% reduction in airborne contamination within 30 minutes.
- **Continuous Operation:** Safe to use even when people are present, as the UV-C radiation is fully contained.
- **No Ozone Release:** The specialized UV-C lamps without mercury, prevent the formation of ozone, ensuring safe and odorless air quality.
- **Automatic Cycles:** Features programmable on/off cycles for effortless operation, air is released purified, without odor, by very noiseless vents.
- **Certified Effectiveness:** Its performance has been validated through extensive independent scientific testing and thousands of units installed worldwide.

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3. Biolab Tests: Bacteria and Spore Reduction

Objective:
To determine the efficacy of Sterybox in reducing airborne bacteria and spores under controlled laboratory conditions.

Methodology:

- Bacterial and spore samples were aerosolized within a sealed chamber.
- The Sterybox unit was activated, and air samples were collected at pre-determined intervals.
- Microbiological plating techniques were used to quantify the reduction in the concentration of pathogens.

Results:

Time (minutes)	Bacterial Reduction (%)
10	80%
20	95%
30	99.99%

Conclusion:
The tests confirmed that Sterybox exhibits a high capacity for reducing both bacteria and spores in the air, thereby ensuring a safe and disinfected environment.

4. Biolab Functional Tests with Bacteria and Spores

Objective:
To evaluate the performance of Sterybox when challenged with high concentrations of specific pathogens in a controlled setting.

Methodology:
The following microorganisms were tested:

- *Staphylococcus aureus* ATCC 6538
- *Pseudomonas aeruginosa* ATCC 9027
- *Salmonella bony* CIP 83/37
- *Listeria innocua* CIP 80.11
- *Aspergillus niger* ATCC 15404
- *Candida albicans* ATCC 10231

Results:

Time (minutes)	Germicidal Reduction (%)
1	100%
3	100%
6	100%
12	100%

Conclusion:
The Sterybox device successfully eliminated all tested strains within 12 minutes, highlighting its robust germicidal efficiency even in challenging conditions.

5. Sigla Laboratory Tests: E. Coli Reduction

Objective:
To assess the effectiveness of Sterybox in reducing *Escherichia coli* populations in a controlled environment.

Results:

Time (minutes)	Bacterial Reduction (%)
10	85%
20	98%
30	99.99%

These results further confirm the rapid and effective disinfection capabilities of Sterybox.

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6. Sanipan Tests: Hospital and Dental Office Evaluations

Hospital Environment Test:

- **Location:** Clinical Diagnosis and Operational (CDO) Hospital
- **Outcome:** Achieved a 99.9% reduction in airborne bacteria within 30 minutes, thereby ensuring a safer clinical environment.

Dental Office Test:

- **Location:** Sanipan Dental Clinic
- **Outcome:** Recorded a 98% reduction in airborne bacteria within 20 minutes, significantly improving the air quality during dental procedures.

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7. TEI.SI Tests: Ozone Emission and Noise Level Analysis

Ozone Emission Test:
Measurements were taken at two positions to ensure that no harmful ozone was generated during operation.

Test Position	Ozone Concentration (µg/m³)
Air Outlet	< 100
5m Distance	< 100

Noise Level Analysis:
Noise measurements were recorded to verify that the device operates quietly, which is critical in environments such as hospitals and offices.

Distance	Noise Level (dB)
1m	52.4
5m	47.7

Both tests confirm that Sterybox meets stringent safety and operational standards.

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8. Al-Mafraq Hospital Tests

Objective:
To evaluate the real-world performance of Sterybox in a clinical setting.

Methodology & Results:

- Tests conducted in various departments of the hospital consistently demonstrated a bacterial reduction of over 95%.
- These results validate the practical efficiency of Sterybox in reducing airborne pathogens in busy hospital environments.

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9. Airborne Pathogen Database

This section provides an extensive documentation of the pathogens against which Sterybox has been tested. The database includes laboratory results, resistance profiles, and comparative analyses, offering comprehensive evidence of the device's effectiveness across a broad spectrum of microbial challenges.

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10. Final Notes

Final Conclusions:

- **Certified by Independent Laboratories:** All tests have been verified by reputable external agencies.
- **Compliance with International Safety Standards:** Sterybox meets or exceeds regulatory requirements for air disinfection medical devices.
- **Patented Technology:** The UV-CHRIS system ensures superior performance and operational safety.

Contact Information

Profile
Since 2001, TISSIMedica has been producing and exporting advanced air sterilization solutions for hospitals and medical facilities across 20+ countries worldwide. The Sterybox Line, a globally patented product (PCT), is designed to ensure superior air and instrument sterilization, with independent testing reports confirming its effectiveness and reliability.

Production & Quality
Manufactured in Milan, Italy, the Sterybox Line includes various air sterilization devices specifically developed for hospitals, medical clinics, and dental facilities. Each unit undergoes a rigorous assembly, testing, packaging, and shipping process within our facility, ensuring

complete quality control. Key components are sourced from Italy, Germany, and Switzerland, ensuring compliance with international medical and healthcare standards, including CE certification.

Global Distribution & Customer Support
TISSIMedica products are distributed through long-term partnerships with established distributors worldwide, some of whom have collaborated with the company for over 20 years. A comprehensive after-sales service ensures that customers receive prompt technical assistance and readily available spare parts, reinforcing our commitment to customer satisfaction and seamless product operation.

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