TISSI®
Medical Dental Systems

Dasa-Rägister
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Scientific Summary
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Integrated Scientific Analysis of Airborne Infection Control Guidelines and the Efficacy of STERYBOX Systems in Hospital Settings

Airborne transmission of infectious agents poses a persistent challenge in healthcare environments. Recent global health events have underscored the urgent need for robust infection control strategies, particularly in hospitals where vulnerable populations reside. This summary integrates EU healthcare guidelines for airborne infection control with insights from the "Scientific Test Report on STERYBOX" to present a comprehensive overview of current strategies and technological innovations. In addition, it highlights the technical and operational characteristics of the Air Sterilization STERYBOX systems, produced by TISSIMedica in Italy, and emphasizes their role as a complementary tool in reducing nosocomial respiratory infections as outlined by WHO and European guidelines.

Airborne Infection Control: Guidelines and Rationale

Recent scholarly investigations have focused on establishing evidence-based guidelines to mitigate airborne pathogen transmission in clinical settings. The literature consistently underscores the importance of multi-layered strategies that include environmental controls, engineering interventions, and supplemental disinfection technologies. Several studies

point to the necessity of robust air filtration systems—such as HEPA filters—and the strategic use of ultraviolet-C (UV-C) irradiation as effective means to inactivate airborne microorganisms.

European guidelines emphasize that hospitals must adopt a systematic approach combining:

- **Engineering Controls:** Ensuring proper ventilation and air exchange rates.
- **Administrative Measures:** Regular monitoring and maintenance of air disinfection systems.
- **Supplementary Disinfection Technologies:** Utilizing devices that can inactivate pathogens effectively in areas where airborne transmission is a significant risk.

This comprehensive strategy is supported by further research that demonstrates the synergistic effect of combining UV-C irradiation with conventional methods. Such studies have documented significant reductions in the microbial load within clinical environments, thereby lowering the incidence of nosocomial infections.

Moreover, guidelines issued by European health authorities and the World Health Organization (WHO) advocate for regular updates and adherence to scientifically validated protocols. They stress that disinfection systems must not only reduce pathogen load but also be integrated into broader infection prevention frameworks that include both environmental and behavioral measures. Research indicates that when airborne disinfection systems are used alongside other measures, such as surface decontamination and

proper ventilation, the overall risk of airborne infection is substantially reduced.

Complementary Disinfection Systems and Their Role in Infection Prevention

In addition to established engineering and administrative controls, complementary disinfection systems play an essential role in hospital infection control. These systems are designed to provide an additional barrier against pathogens, particularly in high-risk areas like operating rooms, intensive care units, and emergency departments. Studies have shown that integrating advanced air disinfection devices with conventional cleaning protocols creates a multi-modal defense that is more effective in reducing the transmission of airborne pathogens.
A key innovation in this space is the STERYBOX system, which is designed to enhance existing disinfection practices and meet the rigorous standards set by international health bodies.

The STERYBOX System: Scientific Evaluation and Test Report Insights

The "Scientific Test Report on STERYBOX" provides detailed evidence regarding the efficacy of this disinfection system under conditions that closely simulate real hospital environments. The report outlines laboratory and field evaluations demonstrating that STERYBOX can achieve substantial reductions in airborne microbial loads. Key findings include:

- **Rapid Pathogen Inactivation:** Under controlled conditions, the system achieves reductions of several log units in the concentration of airborne bacteria and viruses. This rapid inactivation is critical for preventing the spread of infections in dynamic healthcare settings.
- **Uniform Disinfection:** The design ensures that a continue flow of sterilized air under disinfecting agents (notably UV-C light) are evenly distributed throughout the treatment zone. This uniformity is essential to eliminate microbial "hotspots" that can occur in areas with stagnant airflows.
- **Compliance with International Standards:** The performance metrics reported align with the recommendations provided by both WHO and European Centre for Disease Prevention and Control (ECDPC) guidelines, reinforcing the system's suitability for hospital use.

These findings confirm that STERYBOX not only meets but exceeds the disinfection efficacy required for high-risk environments, making it an effective adjunct to traditional infection control measures.

Technical Characteristics and Operational Features of STERYBOX

STERYBOX systems incorporate several advanced technical features that contribute to their effectiveness and ease of integration into existing hospital infrastructures:

1. **Advanced UV-C Irradiation:**

   The system employs high-intensity UV-C lamps, which are renowned for their germicidal properties, using a multi-stage patented flow

design which improve up to 400% the UV-C irradiation. UV-C light disrupts the nucleic acids of microorganisms, effectively preventing replication and infection. This mechanism is particularly effective against airborne pathogens, which can be rapidly inactivated upon exposure.

2. **Modular and Scalable Design:**
   Designed for versatility, the STERYBOX system can be easily installed in diverse healthcare settings. Its modular architecture allows hospitals to scale the system according to the size and specific needs of various clinical environments, from small clinics to large hospitals.
3. **Automated Operation and Monitoring:**
   The device features integrated a user-friendly control interface that facilitate programming and disinfection performance. This automation minimizes the need for manual intervention and ensures that the system operates optimally throughout its use.
4. **Safety Features:**
   Recognizing the potential hazards of UV radiation, STERYBOX do not release UV-C rays outside the device and incorporates multiple safety measures to prevent accidental exposure. These features include interlock switch systems that disable UV-C output when service or unauthorized opening of the unit is detected, ensuring that both patients and staff are protected.

Integration with WHO and European Guidelines

Both the WHO and European regulatory bodies have established comprehensive guidelines for airborne infection control in healthcare settings. These guidelines emphasize the importance of:

- **Effective Air Exchange:** Adequate ventilation and air sterilization to dilute and remove airborne pathogens.
- **Use of UV-C Disinfection:** Leveraging the proven germicidal effects of UV-C light in high-risk areas.
- **Continuous or programmable Operating:** Implementing system that allow for ongoing assessment of air quality to ensure that disinfection measures remain effective.

The system's design is not intended to replace traditional disinfection methods but to complement them. By providing an additional layer of protection, STERYBOX helps healthcare facilities achieve a higher standard of air quality and reduces the risk of nosocomial respiratory infections. This integrated approach is particularly valuable in settings where conventional measures alone may be insufficient to control the spread of highly infectious airborne pathogens.

Global Deployment and Proven Track Record

STERYBOX systems, manufactured by TISSIMedica in Italy, have been successfully installed in hospitals across numerous countries for many years. Their global deployment is a testament to their reliability and effectiveness. Hospitals utilizing STERYBOX have reported noticeable improvements in air quality and a reduction in the incidence of nosocomial

infections. This proven track record underlines the system's value as a critical adjunct to existing disinfection protocols worldwide.

The widespread acceptance of STERYBOX reinforces the importance of integrating advanced disinfection technologies with established infection control practices. As healthcare systems continue to face the challenges posed by airborne pathogens, the role of such complementary technologies becomes increasingly indispensable.

Conclusion

The scientific literature clearly supports a multi-modal approach to airborne infection control in healthcare settings. Guidelines from both European authorities and the WHO advocate for integrating engineering controls, routine monitoring, and advanced disinfection systems to reduce the risk of airborne pathogen transmission. The STERYBOX system exemplifies this approach by safely-confined, high-intensity UV-C irradiation, providing a robust, scalable, and effective solution for enhancing air quality in hospitals. Validated by the "Scientific Test Report on STERYBOX," the device consistently demonstrates significant reductions in airborne microbial loads, thereby supporting its role as a critical adjunct to traditional infection control methods. Moreover, its compliance with WHO and European guidelines ensures that it meets the stringent standards required for safe and effective operation in clinical environments.

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Produced by TISSIMedica in Italy under the UNI EN ISO 13485:2021 normative and installed in hospitals around the world, STERYBOX offers healthcare facilities an innovative tool to combat nosocomial respiratory infections and improve patient outcomes. As part of an integrated infection control strategy, STERYBOX not only enhances existing disinfection protocols but also contributes to a safer, healthier environment for both patients and healthcare professionals.

Sources

- ✓ WHO guidelines on airborne infection control in healthcare settings
- ✓ WHO Study on the efficacy of UV-C disinfection in clinical environments
- ✓ European guidelines for hospital infection prevention and control
- ✓ European Review of engineering controls for airborne pathogen mitigation
- ✓ European Evaluation of complementary disinfection systems in healthcare facilities
- ✓ Scientific Test Report on Sterybox 2025