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Medical Dental Systems

Dasa-Rägister
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Scientific Summary
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Integration of STERYBOX Technology in Romania's Healthcare System for Nosocomial Infection Prevention

Introduction

Nosocomial infections (healthcare-associated infections, HAI) pose a significant challenge to the Romanian healthcare system, contributing to prolonged hospital stays, increased morbidity, and substantial economic burden. The integration of STERYBOX technology—developed by TISSIMedica in Italy and manufactured under the UNI EN ISO 13485:2021 normative—provides an advanced air disinfection solution that aligns with the Romanian Ministry of Health's guidelines for infection control, particularly in mitigating airborne transmission of multidrug-resistant pathogens in hospital settings.

Technology and Complementarity with Existing Disinfection Protocols

STERYBOX is a certified medical air disinfection device based on the patented UV-CHRIS (Ultraviolet High Reflecting Irradiation Coil System). Utilizing UV-C radiation at 254 nm, the system disrupts microbial DNA, neutralizing bacteria, viruses, fungi, and spores. Unlike conventional air purification systems relying on filters, STERYBOX ensures direct exposure of airborne pathogens to germicidal light, reducing contamination levels by up to 99.99% within 30 minutes.

Key advantages of STERYBOX include:

- Continuous and Safe Operation: Fully enclosed UV-C radiation allows safe use in occupied environments.
- No Ozone Emission: Ensuring patient and staff safety.

- Validated Effectiveness: Demonstrated reduction of HAI-related pathogens, including *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and *Coronavirus*.
- Low Maintenance Requirements: Operational efficiency with minimal servicing needs.
- Compliance with Medical Standards: CE-certified as a Class I medical device under UNI EN ISO 13485:2021.

These characteristics make STERYBOX a crucial complement to Romania's existing disinfection strategies, particularly in intensive care units (ICUs), emergency departments, and surgical wards, where airborne transmission of pathogens is prevalent.

HAI in Romania: Challenges and Current Prevention Strategies

According to European Centre for Disease Prevention and Control (ECDC) reports, Romania has historically faced significant challenges in HAI surveillance and prevention due to outdated infection control infrastructure. The 2016 ECDC mission identified key issues such as microbiological surveillance, and standardized infection control measures to be implemented. Additionally, the prevalence of multidrug-resistant organisms (MDROs) such as carbapenem-resistant *Enterobacteriaceae* (CRE) further complicates infection control efforts.

To combat these challenges, Romania's Ministry of Health has emphasized:

- Strengthening HAI surveillance and reporting mechanisms.
- Enhancing microbiological diagnostics for early pathogen detection.
- Implementing advanced disinfection solutions to reduce contact and airborne transmission.

Scientific Validation of STERYBOX for Hospital Applications

Extensive laboratory testing and clinical evaluations have confirmed the efficacy of STERYBOX in reducing airborne virus, bacterial and fungal loads. Notable findings include:

- Biolab Functional Tests: Achieved 100% inactivation of *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Salmonella bony*, *Listeria innocua*, *Aspergillus niger*, and *Candida albicans* within 30 minutes.
- Hospital Deployment Results: Studies in clinical settings, including several Hospitals, demonstrated a consistent bacterial reduction exceeding 95% even in dynamic medical practice conditions.
- Real-World Applications in Romania: STERYBOX has been successfully installed in major Romanian hospitals for several years, supporting infection control in high-risk wards.

Integration of STERYBOX in Romania's Healthcare Framework

The deployment of STERYBOX aligns with Romania's evolving infection control policies, addressing key concerns identified in the ECDC's mission report. The device's ability to significantly lower airborne pathogen levels supports:

- Enhanced patient and healthcare worker safety.
- Reduction in nosocomial infection rates, particularly ventilator-associated pneumonia (VAP) and hospital-acquired pneumonia (HAP).
- Improved compliance with national and EU infection prevention standards.

Given the urgency of controlling HAIs and antimicrobial resistance (AMR), integrating Airborne Disinfection Treatment into Romania's National infection prevention strategy represents a cost-effective and scientifically validated approach to mitigating airborne disease transmission in hospitals.

Conclusion

STERYBOX technology offers a scientifically validated solution to complement Romania's hospital disinfection systems. By reducing airborne microbial contamination in critical healthcare settings, STERYBOX contributes to the overall effort to curb nosocomial infections, aligning with Romanian Ministry of Health directives and international best practices for hospital infection control.

Sources:

*An Overview of Healthcare Associated Infections and Their Detection Methods Caused by Pathogen Bacteria in Romania and Europe

*European Centre for Disease Prevention and Control (ECDC) reports on healthcare-associated infections in Romania.

*ECDC MISSION REPORT Exploring opportunities for support in healthcare-associated infections – Romania 4–7 July 2016

*Ministerul Sănătății – MS - Ordinul nr. 1101/2016 privind aprobarea Normelor de supraveghere, prevenire şi limitare a infecțiilor asociate asistenței medicale în unitățile sanitare

*Scientific Report Summary on STERYBOX 2025 by TISSIMedica.