使用Odorox®技術將肺結核病傳播風險降至最低

介紹

結核病（TB）是一種由結核分枝桿菌（M. tuberculosis）引起的空氣傳播疾病。結核分枝桿菌和七個密切相關的分枝桿菌種（牛分枝桿菌、非洲分枝桿菌、小分枝桿菌、卡普拉分枝桿菌、皮尼佩迪分枝桿菌，卡內蒂分枝桿菌和芒吉分枝桿菌）一起構成了結核分枝桿菌。已經發現這些物種中的大多數（但不是全部）會導致人類疾病。在美國，大多數結核病例是由結核分枝桿菌引起的。結核分枝桿菌生物也稱為結核桿菌。

結核分枝桿菌附著在直徑為1至5微米的顆粒（稱為飛沫）在空氣中傳播。這些在空氣中傳播的顆粒也稱為氣溶膠。當患有肺結核或喉結核病的人咳嗽、打噴嚏、喊叫或唱歌時，就會產生傳染性飛沫。根據環境的不同，這些微小的顆粒可能會在空氣中懸浮數個小時。結核分枝桿菌通過空氣傳播，而不是通過表面接觸傳播。當人吸入含有結核分枝桿菌的飛沫，並且飛沫通過口腔或鼻腔、上呼吸道和支氣管到達肺泡時，就會引發傳染。

當肺泡攝入細菌時會發生感染。 這些攝入的細菌大多數被破壞或抑制。少數細菌可能在細胞內繁殖並在細胞死亡時擴散。如果細菌繼續存活，這些細菌可能通過淋巴道或通過血液傳播到其他的組織和器官（包括最有可能發展為結核病的區域：區域淋巴結、肺、腎、腦和骨骼）。這種傳播過程會使免疫系統產生全身系統性反應。

有四個因素決定了結核分枝桿菌傳播的可能性，總結如下。

因子	描述
易感性	接觸者的易感性（免疫狀態）
傳染性	結核病患者的傳染性與他或她排入空氣中的結核桿菌數量非常相關。許多有結核桿菌的患者更具傳染性
環境	影響結核分枝桿菌生物體濃度的環境因素
曝光	接觸程度、頻率和持續的時間

有多種環境因素會提高結核分枝桿菌的傳播機率，總結如下：

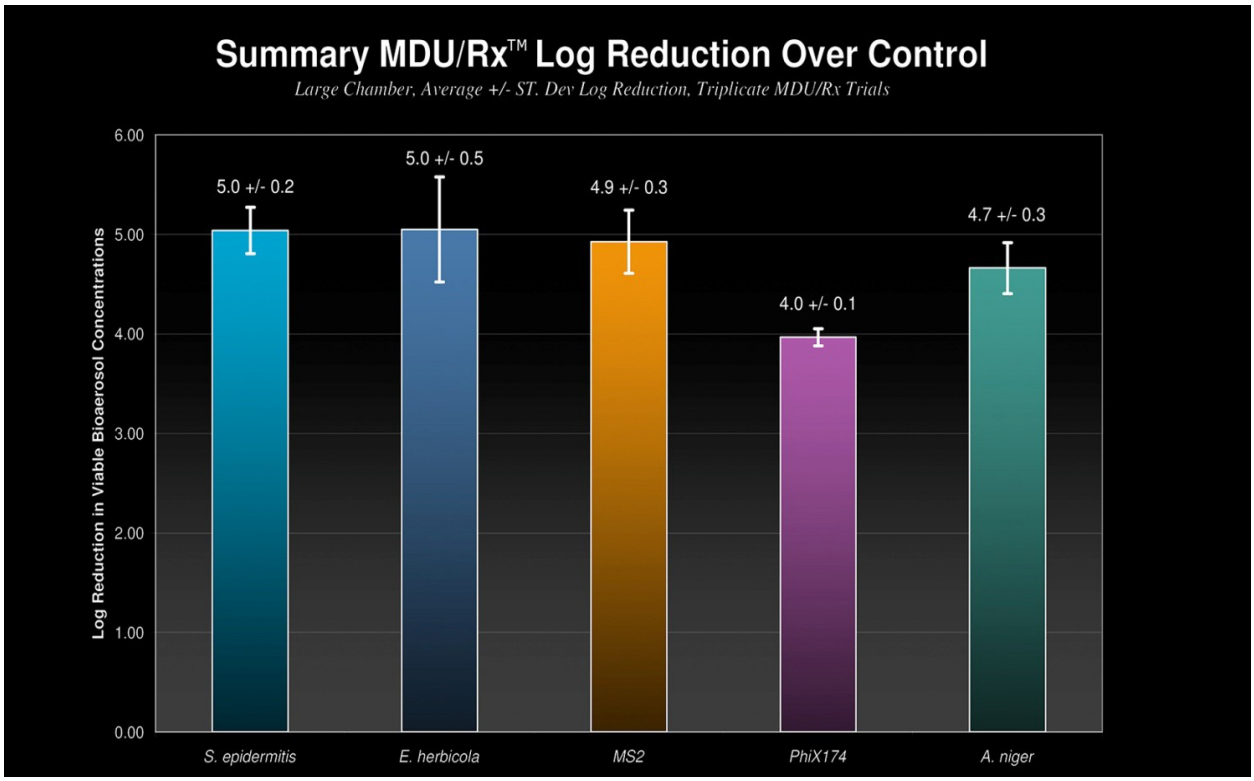
因子	描述
傳染性飛沫濃度	空氣中的飛沫越多，結核分枝桿菌傳播的可能性就越大
空間	狹小且封閉的空間
通風	整體通風不足，導致飛沫稀釋或去除感染性能力不足
空氣流通	空氣中含有感染性飛沫不斷循環
標本處理	不當的處理程序，產生感染性的飛沫
空氣壓力	感染患者房間內的正氣壓會導致結核分枝桿菌生物體流向其他區域

結核病在醫院、急救中心、醫生候診室、學校、療養院和辦公場所等傳播，潛在感染者密集地聚集在這些空氣不斷循環的空間是一個特別嚴重的問題。

增強處理結核病傳播的環境因素

減少結核病傳播的最有效方法是持續消除飛沫化結核菌。FDA已批准HGI Odorox® MDU/Rx™羥基消毒系統，作為一種安全且有效的空氣消毒系統，可用於醫療機構的空間（FDA 510（k）＃133800）。FDA的批准氣溶膠研究與工程實驗室進行的氣溶膠化研究，使用FDA批准的方法，在室內大小的不銹鋼試驗室中，在受控條件下評估MDU/Rx™系統對氣溶膠細菌、病毒和黴菌物種的殺菌率。在二到三個小時內達到 4 到 5 個對數還原離子有非常高的殺菌率（>99.999%），結果如下圖圖表中。在相對較短的時間內實現極高的殺菌效率。通常FDA接受3-4個重複實驗，在8小時期間作為療效的證明。FDA接受這些結果作為所有細菌的代表，因此，Odorox® MDU/Rx™系統應同樣有效殺死氣溶膠結核桿菌。

實現和改善這些衛生水平的最佳方法是持續使用Odorox®系統。對於大量空間，HGI提供各種型號，如 IDU™和 MVP™系統，已集成到供暖、通風和空調（HVAC）系統中，以處理數百萬立方英尺的空間，包括 HVAC 系統中很難消毒的管道中，並且可能帶有微生物菌落。這些系統使用與 MDU / Rx™設備相同的Odorox®技術，以處理更大的空間。特別的是，由於FDA將這些類型的系統與HVAC系統集成在一起，因此不需要FDA批准，在醫療機構中即可使用這些系統。



關於羥基

太陽輻射能量對大氣中水蒸氣的作用會不斷產生羥基自由基，被稱為大氣羥基。在白天，平均每立方厘米的室外空氣中有200萬個大氣羥基。它們在白天時是對流層中與碳氫化合物進行反應的主要元素，能夠中和大多數天然和人造污染物，包括甲烷、硫化氫和臭氧等溫室氣體。

大氣羥基也被證明可以殺死細菌，病毒和黴菌，因為它們能夠與脂質、蛋白質、碳水化合物和其他有機化合物組成的細胞膜結構作出反應和破壞。但是人類、動物和植物與大氣羥基共生，不影響外表皮和粘膜。大氣羥基是大自然提供無害化學物質，和病原體環境組成。大氣羥基在室內的存在量不足，無法對對室內空氣進行消毒。在戶外產生的羥基在不到一秒鐘的時間內發生反應，因此在室內的任何地方都不存在。

羥基基消毒過程

HGI Odorox®系統使用高能紫外光源生成羥基來消毒室內環境。 HGI Odorox®原理非常簡單。紫外線（UV）輻照與氧氣發生反應，生成各種活性氧，這些活性氧從水蒸氣中除去氫原子，從而生成大氣羥基自由基（HO·）。 HGI Odorox®定制光學元件（光源能量），專利的反應室設計和有效的過程控制可產生與自然界中相同濃度的安全有效的大氣羥基。

HGI Odorox®羥基自由基是高反應性和出色的自由基轉移劑。它們與微生物和幾乎所有的有機化學物質迅速反應。它們除去氫原子並形成一連串的有機基團，這些基團被進一步氧化形成過氧（R-C-O-O·）和氧（R-C-O·）自由基，它們也是很好的氧化劑和消毒劑。這些副產品足夠穩定，可以在高速風扇的影響下進行循環，以徹底消毒大面積空間中的空氣、表面和多孔織物。

大氣羥基及其副產物是不穩定的物質，不會在空氣中或表面停留。只要Odorox®系統運行，連鎖反應就會持續。關閉系統後，羥基自由基和其他自由基會在幾秒鐘內消散。

有效性與安全性

FDA不對用於商業或消費類應用的UV輻射空氣清潔設備（例如HGI）進行監管或要求獲得510（k）的售前批准，因為它們類似於在自然界中所發現的輻射方式進行清潔環境空氣。在醫療機構中，未經FDA批准，也可以使用與暖氣、通風和空調系統集成的Odorox®系統。但是，在醫療機構中佔用空間內使用的紫外線空氣消毒系統需要獲得FDA的批准。FDA評估功效和安全性後以便作為醫療器具使用標準。基於對微生物、化學、機械、電和輻射數據的廣泛評估，HGI在醫療設施的空間（＃133800）中使用Odorox®MDU / Rx™系統獲得了FDA 510（k）批准。系統既有效又安全。根據針對被測細菌種類測得的高殺菌率，FDA批准該設備可用於所有細菌。根據FDA的經驗和指南，這些細菌一起被視為所有細菌的代表。

根據HGI的要求，美國國家環境衛生科學研究所搜索了NIH，CDC和OSHA的資料庫、PubMed和美國國家醫學圖書館，“找不到任何科學或研究表明羥基自由基的產生對人體健康有害。這適用於大氣和人造類型”（美國國家環境局通信和公共聯絡辦公室Colleen Chandler，8-5-10）。

Odorox®羥基系統已經使用了十多年，並且沒有不良反應的報導。作為評估安全性的進一步措施，HGI委託比較生物科學公司（Sunnyvale, CA）使用FDA嚴格測試協議，稱為“優良實驗室規範”（GLP）來進行毒理學研究。該研究使用20隻大鼠為對照組和40隻大鼠為治療組，它們連續暴露於正常濃度2-3倍的羥基環境，持續13週。研究結果表明，試驗動物對暴露量的耐受性良好，在整體或細胞水平上均無異常臨床觀察。

引用

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2. D. E. 赫德，《大氣測量分析技術》，布萊克韋爾出版社，2006年——英國里茲大學教授。

Using Odorox® Technology to Minimize the Risk of Tuberculosis Transmission

Introduction

Tuberculosis (TB) is an airborne disease caused by the bacterium *Mycobacterium tuberculosis* (*M. tuberculosis*). *M. tuberculosis* and seven very closely related mycobacterial species (*M. bovis, M. africanum, M. microti, M. caprae, M. pinnipedii, M. canetti* and *M. mungi*) together comprise what is known as the *M. tuberculosis* complex. Most, but not all, of these species have been found to cause disease in humans. In the United States, the majority of TB cases are caused by *M. tuberculosis*. *M. tuberculosis* organisms are also called tubercle bacilli.[1]

M. tuberculosis is carried in airborne particles, called droplet nuclei, of 1 to 5 microns in diameter. These airborne particles are also commonly referred to as aerosols. Infectious droplet nuclei are generated when persons who have pulmonary or laryngeal TB disease cough, sneeze, shout, or sing. Depending on the environment, these tiny particles can remain suspended in the air for several hours. *M. tuberculosis* is transmitted through the air, not by surface contact. Transmission occurs when a person inhales droplet nuclei containing *M. tuberculosis*, and the droplet nuclei traverse the mouth or nasal passages, upper respiratory tract, and bronchi to reach the alveoli of the lungs.

Infection occurs when the bacilli are ingested by alveolar macrophages. The majority of these bacilli that are ingested are destroyed or inhibited. A small number may multiply intracellularly and are released when the macrophages die. If alive, these bacilli may spread by way of lymphatic channels or through the bloodstream to more distant tissues and organs (including areas of the body in which TB disease is most likely to develop: regional lymph nodes, apex of the lung, kidneys, brain, and bone). This process of dissemination primes the immune system for a systemic response.

There are four factors that determine the probability of transmission of *M. tuberculosis* and they are summarized below.

Factor	Description
Susceptibility	Susceptibility (immune status) of the exposed individual
Infectiousness	Infectiousness of the person with TB disease is directly related to the number of tubercle bacilli that he or she expels into the air. Persons who expel many tubercle bacilli are more infectious than patients who expel few or no bacilli
Environment	Environmental factors that affect the concentration of *M. tuberculosis* organisms
Exposure	Proximity, frequency, and duration of exposure

There are a variety of environmental factors that enhance the probability that *M. tuberculosis* will be transmitted, they are summarized below:

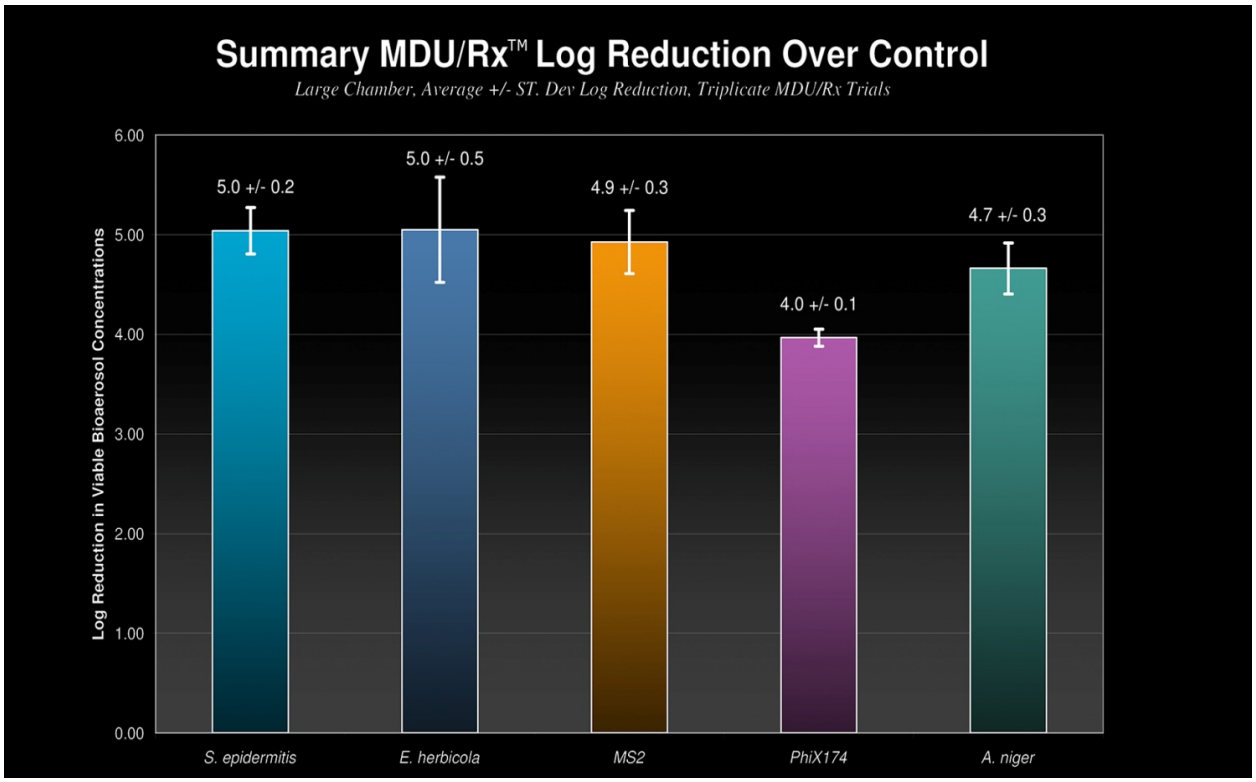
Factor	Description
Concentration of infectious droplet nuclei	The more droplet nuclei in the air, the more probable that *M. tuberculosis* will be transmitted
Space	Exposure in small, enclosed spaces
Ventilation	Inadequate local or general ventilation that results in insufficient dilution or removal of infectious droplet nuclei
Air circulation	Recirculation of air containing infectious droplet nuclei
Specimen handling	Improper specimen handling procedures that generate infectious droplet nuclei
Air Pressure	Positive air pressure in infectious patient's room that causes *M. tuberculosis* organisms to flow to other areas

TB transmission in hospitals, emergency treatment centers, physician waiting rooms, schools, nursing homes, and office spaces etc. where potentially infected people are gathered together densely in spaces with recirculated air is a particular problem.

Treatment of Environmental Factors that Enhance Transmission of TB

The most effective means of minimizing TB transmission would be to continuously eliminate as much aerosolized TB bacteria as possible. The FDA has approved the HGI Odorox® MDU/Rx™ hydroxyl sanitizing system as a safe and effective air sanitizing system for use in occupied spaces in medical facilities (FDA 510(k) #133800) based on extensive studies of the very high kill rates of aerosolized microorganisms. The FDA based their approval on aerosolization studies done by Aerosol Research and Engineering Laboratories to evaluate the kill rates of aerosolized bacteria, virus and mold species by the MDU/Rx™ system under controlled conditions in a room-sized stainless steel test chamber using a methodology approved by the FDA. Very high kill rates of 4 to 5 log reductions (>99.999% reduction) were achieved within two to three hours, as summarized in the following chart below. These are exceedingly high values, achieved in a relatively short period of time. Typically the FDA would accept 3-4 log reductions over as much as an eight hour period as evidence of efficacy. The FDA accepts these results as representative of all bacteria and, as such, the Odorox® MDU/Rx™ system should be equally as effective killing aerosolized TB bacilli.

The optimum method for achieving and maintaining these levels of sanitation is to use the Odorox® systems continuously. For large volumes of space, HGI offers various models such as the IDU™ and MVP™ systems that are integrated into heating, ventilation and air conditioning (HVAC) systems to treat millions of cubic feet of space, including the duct work of the HVAC system which is normally very difficult to sanitize and can harbor colonies of microorganisms. These systems use the same Odorox® technology as the MDU/Rx™ device and scale to treat larger spaces. Note that the FDA does not require approval for the use of these types of systems in medical facilities as they are integrated with the HVAC system.



About Hydroxyls

Hydroxyl radicals are continuously produced by the action of the sun's radiated energy on water vapor in our atmosphere and are called atmospheric hydroxyls. There are, on average, two (2) million atmospheric hydroxyls in each cubic centimeter of ambient outdoor air during daylight hours. They are the main driving force behind the daytime reactions with hydrocarbons in the troposphere and neutralize most natural and man-made pollutants including greenhouse gases like methane, hydrogen sulfide and ozone.

Atmospheric hydroxyls are also proven to kill bacteria, virus and mold because they are able to react with the lipids, proteins, carbohydrates and other organic compounds that make up the cell membrane and disrupt their structure. The interior contents of the cells leak and the organism is destroyed. Conversely, humans, animals and plants have evolved symbiotically with atmospheric hydroxyls and developed outer surfaces and mucosa that are essentially impervious to their effect. Atmospheric hydroxyls are a critical component of nature's dynamic ability to provide environments that are free of harmful chemicals and pathogens.[2] Atmospheric hydroxyls do not exist indoors in sufficient amounts to sanitize indoor air. Hydroxyls generated outdoors react in less than a second and are thus consumed very near any point of entry indoors.

Hydroxyl Radical Sanitization Process

HGI Odorox® systems sanitize indoor environments by generating hydroxyls using high energy UV sources. The HGI Odorox® irradiation process is fundamentally very simple. Ultraviolet (UV) radiation reacts with the oxygen to generate a variety of reactive oxygen species, which remove a hydrogen atom from water vapor to generate atmospheric hydroxyl radicals (HO·). HGI's Odorox® custom optics (energy sources), patented reaction chamber design and active process controls result in the generation of safe and effective concentrations of airborne hydroxyls within the same concentrations as those found in nature.

The HGI Odorox® hydroxyl radicals are highly reactive and excellent radical transfer agents. They rapidly react with microorganisms and with nearly every organic chemical available. They remove a hydrogen atom and form a cascade of organic radicals that is further oxidized to form peroxy (R-C-O-O·) and oxy (R-C-O·) free radicals, which are also good oxidizing and sanitizing agents. These by-products are stable enough to circulate under the influence of high velocity fans to completely sanitize air, surfaces and porous fabrics in even exceptionally large spaces.

Atmospheric hydroxyl radicals and their by-products are unstable species which do not linger in the air or on surfaces. As long as the Odorox® system is running, the chain reactions persist. When the system is shut off, the hydroxyl radicals and other free radicals dissipate within seconds.

Efficacy and Safety

As a category, the FDA does not regulate or require premarket 510(k) approval for UV irradiation air cleaning devices – such as HGI's – that are used for commercial or consumer applications since they irradiate ambient air and cleanse in a manner similar to that found in nature. In medical facilities, Odorox® systems integrated with heating, ventilation and air conditioning systems may also be used without FDA approval. FDA approval, however, is required for ultraviolet air sanitizing systems used within occupied spaces in medical facilities. The FDA evaluates both efficacy and safety in order to provide approval for medical devices. HGI received FDA 510(k) approval for the use of the Odorox® MDU/Rx™ system in occupied spaces in medical facilities (#133800) based on an extensive evaluation of microbiological, chemical, mechanical, and electrical and radiation data that proved the system was both effective and safe. The device is approved for use against all bacteria by the FDA based on the high kill rates measured against the bacteria species tested. Together these bacteria are considered representative of all bacteria based on the FDA's experience and guidelines.

At HGI's request the National Institute of Environmental Health Sciences searched the NIH, CDC, and OSHA databases, PubMed and the National Library of Medicine and "cannot find any hard science or research indicating that hydroxyl radical generation is harmful to human health. That applies to both atmospheric and man-made generation" (Colleen Chandler, NIEHS Office of Communications and Public Liaison, 8-5-10).

Odorox® hydroxyl systems have been in use for over ten years and no adverse effects have been reported. As a further measure to evaluate safety, HGI commissioned Comparative Biosciences (Sunnyvale, CA) to conduct toxicology studies using the FDA's rigorous testing protocol called Good Laboratory Practices (GLP). The studies involved a control group of 20 rats and a treated group of 40 rats that were exposed continuously to 2 to 3 times the normal concentrations of hydroxyls for a period of 13 weeks. The study results indicated that the test animals tolerated the exposure well with no abnormal clinical observations either at the gross or cellular level.

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