



The Importance of Biocompatibility Testing of Breathing Gas Pathways in Medical Devices



Overview

Many medical devices used to assist in monitoring and treating respiratory issues or delivering anesthesia and other gas-borne treatments can pose a unique set of risks to patients. Chemicals used to manufacture or maintain the devices can be emitted into the breathing gas pathways resulting in exposure risk for the patient using the device. This exposure can result in health and safety consequences for patients who are receiving medical interventions that require direct access to the breathing pathway. The U.S. Food and Drug Administration (FDA) requires that manufacturers of medical devices in contact with a patients' airways or breathing gas pathways validate the biocompatibility of any airway contacting material via their 510(k) Premarket Notification process. Yet, despite these requirements, the FDA reports that nearly one-third of 510(k) submissions provide inadequate information regarding device biocompatibility or worse, fail to provide any biocompatibility data at all.¹ The failure to conduct adequate biocompatibility testing or to submit sufficient documentation validating biocompatibility typically results in the rejection of the 510(k) submission or an extended delay in its review by the FDA. Notably, the clearance time was even longer for manufacturers of anesthesiology devices averaging 245 days from submission to clearance.³ The specific standard that governs devices for breathing gas pathways is ISO 18562 (Parts 1-4) Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications. Published in March 2017, the ISO 18562 standard outlines the risk assessment criteria for the evaluation of the biological characteristics of the medical devices' components used in all types of respiratory care.

This UL Solutions white paper discusses the importance of biocompatibility testing of breathing gas pathways in medical devices and how testing in accordance with the technical requirements of the ISO 18562 series of standards can strengthen claims of biocompatibility in support of FDA 510(k) submissions. Beginning with a brief review of the FDA's clearance process for medical devices and the timelines for the agency's review of 510(k) submissions, the paper then discusses the specific biocompatibility challenges associated with medical devices that include breathing gas pathways. The white paper includes insights on the benefits of a preventive and proactive approach to assessing and testing the biocompatibility of gas pathways in medical devices. UL Solutions provides a scientific approach to testing throughout the product lifecycle. While testing device components at the beginning of their lifespan is important, it is also important to consider testing at other points in the lifecycle such as after sterilization, cleaning and disinfection, service maintenance, or end of life. Testing at different stages of the expected service life provides assurance that the emissions do not increase or significantly change during the product's useful life.



The FDA's Clearance process for medical devices

Virtually all medical devices sold or marketed in the U.S. must meet mandatory regulations administered by the FDA to protect the health and safety of patients and healthcare providers alike. It is imperative that device manufacturers understand and fulfill these requirements as they are developing their products to prevent costly delays to market and to protect vulnerable patients' safety. If the data from testing is erroneous, this bad data can result in a faulty understanding of the product's safety risks. When the product's materials are not safe, patients' health can be seriously affected.

Biocompatibility challenges in medical devices with breathing gas pathways

Modern medical devices with breathing gas pathways are composed of a diverse range of materials and components, each with unique physical and chemical characteristics that break down. These failures can include the decomposition of device materials attributable to heat or wear during normal or extended device operation or the migration of chemicals and/or particles from internal device components into the patient's breathing air path. For devices that are used for a long period of time, assessing the impact of that aging on the device and its components is important. For medical device components that must be evaluated because they have direct contact to the patient, such as cannulas, breathing masks or intubation mechanisms, exposures to volatile organic compounds (VOCs), particles, extractables and leachables must be tested with care. Biocompatibility risks can also be introduced through manufacturing and post-production processes that can

have an adverse effect on components and materials. For example, contact with lubricants or other chemicals during production or maintenance can compromise the chemical integrity of a device. Similarly, extended use can degrade some components, and certain unapproved sterilization and disinfection techniques may also adversely affect device emissions.

UL Solutions approach to the testing of medical devices with breathing gas pathways

UL Solutions testing and exposure assessment services offer manufacturers a comprehensive approach to assessing the compliance of medical devices with breathing gas pathways with the requirements of the ISO 18562 series of standards. A comprehensive biocompatibility assessment includes testing for particles, VOCs and leachables in condensate within the context of a comprehensive risk assessment process, as defined by ISO 18562. Developing a test program that adequately addresses worst-case conditions for researching potential pollutants requires extensive knowledge of the device design, use indications, and operating modes. UL Solutions experts work directly with product manufacturers to explain how key parameters, such as air flow rate and temperature, may affect the level of airborne particles and VOCs in the breathing gas stream. The normal wear and tear that occurs when using a product over several years can cause product components to degrade and release compounds into the patients' airway, increasing risk to the patient. To address these risks, UL Solutions' testing methodology can be employed at different points in the product lifecycle. Using multiple laboratories with capabilities for aging, testing, analysis, and reporting, UL Solutions is uniquely situated to partner with medical device manufacturers to develop and execute customized test plans.



Summary

Assessing the biocompatibility of medical devices with breathing gas pathways is a complex process that must evaluate many potential health and safety risks to patients. The failure to provide a complete and thorough assessment consistent with applicable standards can result in requests from regulators for additional information on biocompatibility metrics. Such requests typically result in delays in the FDA's decision regarding the approval of a given medical device, resulting in significant revenue loss. Recent product recalls demonstrate that inadequate testing can compromise patients' health, damage companies' reputations and reduce revenues. Our medical device team is an industry leader in biocompatibility assessment, providing testing and toxicology services for manufacturers to fulfill the requirements of the standard for respiratory and ventilation devices and accessories.

UL's medical device testing helps ensure a comprehensive assessment of biocompatibility risks. With its global reach, UL Solutions has an extensive knowledge of local and international safety requirements for medical devices that interact with human airways. The thoroughness of UL Solutions' testing throughout the product lifecycle, and its comprehensive evaluation of emitted chemicals and particles helps to predict the vulnerability of the components over time, not just when the product has been first introduced, and helps manufacturers comply with the requirements of the current standard, launch products without extensive delays, and most importantly, protect the safety of patients.



We can help you understand the necessary testing and compliance requirements for your respiratory and ventilation devices and accessories, so you can gather the information required for FDA 510(k) clearance and notified body review to facilitate quicker review and time to market.

To learn more about the advantages of a preventive and proactive approach to FDA 501(k); contact us at: <https://www.ul.com/ul-solutions-testing-services-respiratoryventilation-device-manufacturers>.

Endnotes

1. “Analysis of Pre-Market Review Times Under the 510(k) Program,” U.S. Food and Drug Administration, Center for Devices and Radiological Health, November 9, 2011. Web. 4 October 2017. <https://www.fda.gov/downloads/aboutfda/centersoffices/cdrh/cdrhreports/ucm263386.pdf>.
2. “MDUFA Performance Goals and Procedures, Fiscal Years 2018 through 2022,” U.S. Food and Drug Administration, December 2, 2016. Web. 4 October 2017. <https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf>.
3. “How long it takes the US FDA to clear medical devices via the 510(k) process: An examination of 15,000 medical device applications cleared by the US Food and Drug Administration between 2012 and 2016,” a report by The Emergo Group, March 2017. Web. 15 November 2017. <https://www.emergogroup.com/sites/default/files/emergo-fda-510k-data-analysis-2017.pdf>.



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