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TECHPAPER

Best Practices and Bev-A Line XX® Tubing

Insights from ISO/TR 14644-21:2023

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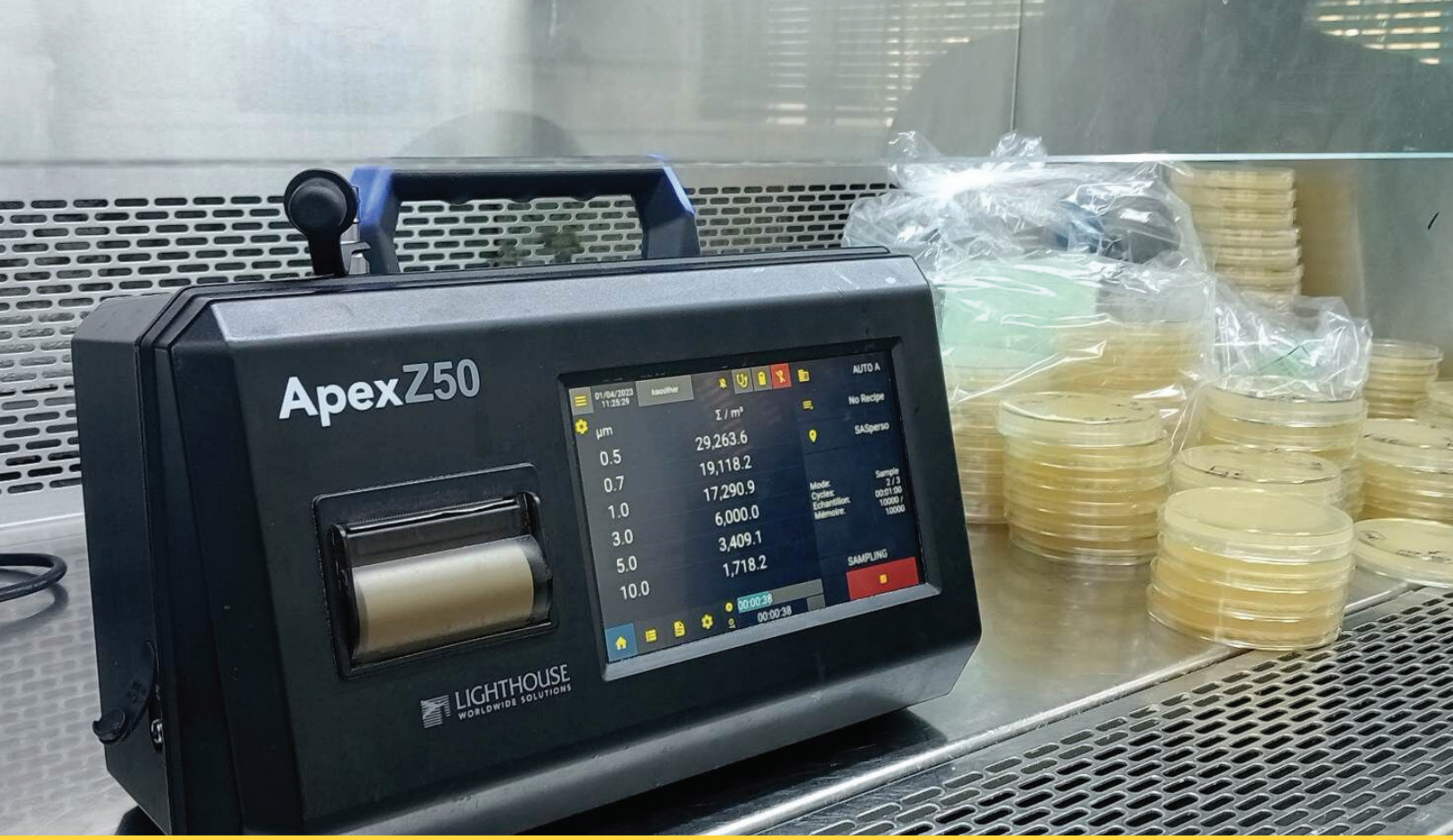


Overview

Particle counters play a crucial role in maintaining cleanroom integrity and ensuring product quality in critical manufacturing environments. The accuracy of these devices is paramount, especially in industries where contamination can have severe consequences, such as pharmaceutical production. While particle counters themselves are designed to meet stringent standards like ISO 21501-4:2018, the sampling systems that transport air to these devices are equally important yet often overlooked.

Bev-A-Line XX® tubing, with its Hytrel® inner lining, is a popular choice for particle sampling due to its low friction coefficient and smooth inner wall. However, the tubing's exposure to sterilization chemicals and processes like Vapor Hydrogen Peroxide can lead to degradation over time, potentially compromising sample integrity. Regular monitoring and replacement of this tubing is essential to maintain accurate particle counting.

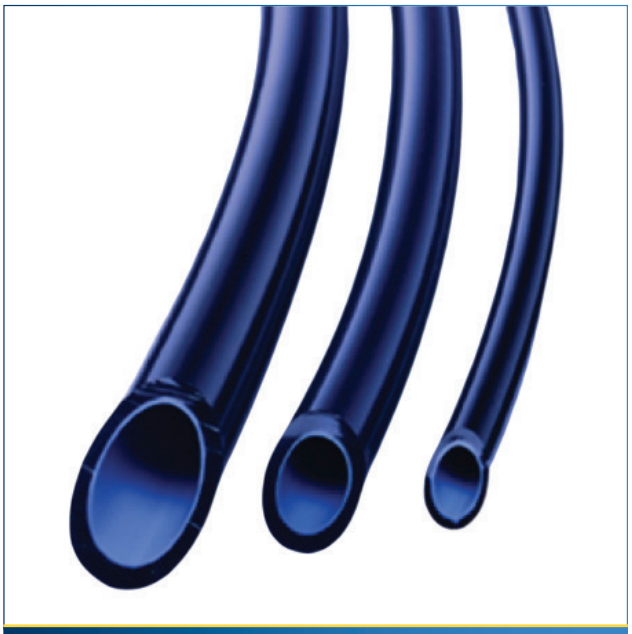
For environments with frequent VHP exposure, 316L Stainless Steel tubing presents a more durable alternative. Additionally, the application of ISO/TR 14644-21:2023 guidelines is crucial in designing effective sampling systems, considering factors such as tubing length and bends to minimize false positives and ensure representative sampling.

With Particle Counters widely used in cleanrooms the data produced by these devices is mission critical for many processes and operations from certifying cleanrooms to monitoring critical aseptic manufacturing environments ensuring that these manufacturing environments are maintaining the clean sterile air that passes over the critical zones where product integrity and product quality is vital.

Contamination in aseptic pharmaceutical products can have a detrimental effect on patients that rely on intravenous saline products or any other injectable products during operations or periods of extended healthcare when the immune system is weakened. Therefore, it is critical that the data gathered and recorded by particle counters has data integrity built into the sampling system and not just the particle counter. ISO 21501-4:2018 ensures particle counter accuracy in calibration. However, the sampling systems that transport air samples to the particle counter need as much understanding and attention.

Particle Counters rely on tubing sampling systems to transport sampled air from a specific environmental location (critical zones in monitoring systems based on EU GMP Annex1:2022 and ISO 14644-2:2015) or multiple locations (in cleanroom certification based on ISO 14644-1:2015) to reach the particle counter sensor where particles are sized and counted.

Ensuring these sampling systems do not contribute to misinterpretations of the actual



Bev-A-Line XX® particle sampling tubing

environmental conditions that are sampled or provide contamination themselves is of upmost importance. Therefore, it is prudent to routinely test these systems. One of the most common particle transport tubing systems used in cleanrooms is Bev-A-Line XX® tubing which has an inner lining of Hytrel® material with properties such as a low friction coefficient with its smooth inner wall making it a good transportation option for particles as they are pulled into the particle counter to be sampled. Most particle counter manufactures supply this tubing when you purchase a particle counter from them.

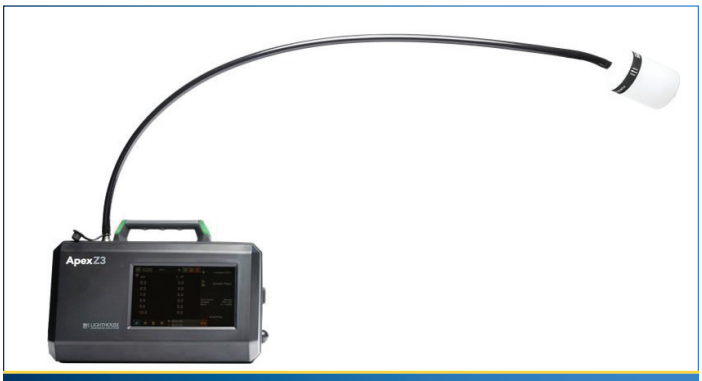
Hytrel is a thermoplastic polyester elastomer (TPC-ET) developed by DuPont®. It combines the flexibility of rubber with the strength and processability of thermoplastics. Hytrel is widely used in various industries, including tubing, hoses, seals, gaskets, and automotive components, due to its excellent mechanical and thermal properties.

According to information from manufacturers and online, Bev-A-Line XX is gas permeable and withstands repeated autoclaving without separation of its two layers. Available in non-conductive formulations Bev-A-Line XX is FDA sanctioned. However, what manufacturers fail to understand in the cleanroom industry where the tubing is sterilized by various chemicals designed to kill microorganisms these solutions along with autoclaving may have the capacity to break down the inner Hytrel tubing internally where particle shedding will occur.

One of the biggest issues with Hytrel degradation and oxidation is Vapor Hydrogen Peroxide (VHP) which is widely sprayed in cleanrooms frequently to sanitize rooms routinely and kill microorganisms. Some sterility and sanitization processes also require VHP to be run through Hytrel tubing where exposure causes oxidation and a breakdown of the tubing.

If you are using Bev-A-Line XX tubing in an environment where it will be exposed to VHP, it is important to monitor the tubing regularly for signs of wear or degradation. Lighthouse Worldwide Solutions recommends **replacing Bev-A-Line XX tubing every 3-6 months** if the tubing has been exposed to VHP or if monitoring indicates shedding is occurring internally.

Furthermore, in order to test Bev-A-Line XX tubing we recommend that a Zero Count filter be placed on one end of the tubing and the other end connected to a particle counter. If you find that there is a False Count Rate that exceeds the ISO 21501-4:2018 guideline based on a 95% confidence interval, then replace the tubing. If you do see small counts in the smallest channel of the particle counter, they are acceptable but if counts are found in the larger channels and the counts increment upwards steadily then then there is contamination inside the tubing potentially due to tubing corrosion after VHP exposure and the tubing should be replaced.



Particle Counter with Zero Count filter testing sample tubing

Alternatively, if the application uses VHP sanitation frequently and the tubing is exposed then considerations should be given to the use of 316L Stainless Steel for transportation of particles to the particle counter instead of Bev-A-Line XX.

316L Stainless Steel resists a broader range of chemicals, including strong acids and bases and has superior mechanical strength and longevity. For pharmaceutical applications, the inner surface roughness of 316L stainless steel tubing is generally recommended to be Ra ≤ 0.5 µm. This level of smoothness helps to minimize the risk of microbial growth and ensures that the tubing can be effectively cleaned and sterilized.

In terms of sampling systems, it is also important to consider the application of ISO/TR 14644-21:2023 to ensure that the length, number of bends conform to acceptable limits. False counts can occur in these systems if there are long tubing runs and numerous bends then particles sampled can become trapped on the bends and walls of the tubing and any vibration would release them and they would be counted as "False Positives". The decision tree in this technical report should be consulted. There is a link below to our website where you will find more information on this subject and information on how to validate the sampling system for particle losses. Auditors are starting to enforce the guidelines in this technical report that was released in November 2023.

ISO/TR 14644-21:2023 advocates for direct sampling methods as the gold standard for minimizing sample loss and contamination. This approach eliminates the need for lengthy tubing, which can compromise sample quality, especially when dealing with larger particles.

Our comprehensive overview provides insights into the advantages of direct sampling and offers practical advice on implementing these techniques to capture the most representative samples from critical locations within your cleanroom.

It addresses the importance of understanding that:

- for classification, the quality of the sample is the most important factor;
- for monitoring, the quality of the data is the most important factor;
- direct sampling without tubing is preferred. However, sample tubing is sometimes necessary to get a representative sample at a significant or critical location;
- to reduce sampling loss in tubing, this tubing is as short and straight as possible;
- a sampling system is evaluated to assess the impact of any compromises in its set up.

An evaluation of legacy systems can deem them suitable for continued use even if the installation is assessed as less than optimal. See link below for further information on how to get the most accurate sampling system to improve the quality, integrity and validity of your particle counter sampling data.

If you'd like to learn more about the intracasies of Accurate Sampling Techniques, or the ins and outs of ISO/TR 14644-21:2023, visit our **Applications page**.

Conclusion

The integrity of particle sampling systems in cleanrooms is paramount for ensuring product quality and patient safety. While Bev-A-Line XX tubing is commonly used, its vulnerability to degradation from VHP exposure necessitates regular monitoring and replacement. Alternatively, 316L Stainless Steel tubing offers superior chemical resistance and longevity. The recent ISO/TR 14644-21:2023 guidelines emphasize the importance of direct sampling and proper tubing configuration to minimize particle loss and contamination. As cleanroom technology evolves, it's crucial for manufacturers to stay informed about best practices in sampling techniques. By prioritizing the quality of samples for classification and data for monitoring, and by regularly evaluating sampling systems, cleanroom operators can significantly enhance the accuracy and reliability of their particle counting processes. This attention to detail in sampling systems is not just a regulatory requirement, but a critical step in maintaining the highest standards of cleanliness and product integrity in controlled environments.

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