



CLEANING AND WIPEDOWN

Lighthouse Worldwide Solutions



Overview

Controlling Cleanroom Contamination

Controlling cleanroom contamination is mission critical for sterile manufacturing processes. It is vital the equipment taken into the cleanroom and used in the cleanroom are easy to wipe down and keep free from particle contamination or even prevent them from being particle traps where contamination can build up on the equipment due to a poor design which is a little ironic that the equipment used to monitor for contamination could actually be a contributor to the contamination. Therefore understanding what to look for in your monitoring equipment will help you get on the right path quickly. An inadequate microbial control program can cause significant risk to patient safety, at the very least product recall, and financial loss to the company. Control of microbiological contamination and root-cause investigation are among the top ten most observed deficiencies by the US agency FDA since 2012. A similar situation is observable in Europe, based on MHRA deficiencies reported.



Equipment Used

Monitoring equipment used in cleanrooms to measure viable and non-viable particle contamination consists of Particle Counters and Air Samplers. Particle Counters measure all particles and provide reports based on sample volume and particle sizes and counts in the air and Air Samplers capture an air sample on a media dish such as a TSA agar plate typically 90mm in diameter and the sample is then incubated and if viable particles are present in the sample then colony forming units will be observed.

Wipedown Process

The best way to perform a wipe down of your particle counter or air sampler equipment is to use a damp cloth with the validated cleaning solution sprayed onto the cloth. Turn the instrument off and cap the sample inlet of the particle counter and wipe down the whole exterior. Air sampler exteriors can also be wiped down in a similar manner and the sample head and base should also be autoclavable.

Monitoring Equipment

What to Look Out for in Your Monitoring Equipment

When looking to purchase cleanroom monitoring equipment the exterior of the instrument should be closely observed. One of the main issues with badly designed cleanroom monitoring instruments is the exterior of the unit. The exterior should be free from particle traps and have a good sealed exterior. Let's look at a particle counter in this example where we can point out good qualities in the design to look out for. Below are the top 4 features on the front of **the ApexZ Portable particle counter** which eliminate particle and contamination propagation.



- Sealed sample inlet base avoids buildup of wipe down excess and potential particle trap and difficult area to keep free from ingress debris and potential home for bacteria.
- 2 Sealed housing seam. Waterproof sealed housing seam without any cervices where cleaning solution can build up and moisture accumulate.
- 3 Sealed glass touchscreen eliminates problematic push buttons and promotes easy operator interface.

Sealed printer cover with easy access for paper replacement and alignment.

What to Look Out for in Your Monitoring Equipment

ApexR Remote Particle Counter with Smart Bracket



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- 2 Sealed housing seam. Waterproof sealed housing seam without any cervices where cleaning solution can build up and moisture accumulate.
- 3 Sealed smart bracket that can actually withstand low pressure water shower
- Concealed tubing and cables that normally hang out at the bottom of the unit and crate particle traps and are difficult to clean.

What to Look Out for in Your Monitoring Equipment

Active Count 100H Portable Air Sampler



- 1 Autoclavabe sample head and magnetic base for easy removal. It is important to autoclave the sample base as well as the sample head.
- 2 Sealed housing seam. Waterproof sealed housing seam without any cervices where cleaning solution can build up and moisture accumulate.
- 3 Sealed touchscreen eliminates problematic push buttons and promotes easy operator interface.
 - Concealed inlet and outlet ports at the back of the unit to eliminate particle traps.