CleanRooms®

Cleanroom weighing

Choosing the right scale in the most critical applications

by Ryan Titmas, Sartorius North America

When it comes down to choosing which scale is right for your cleanroom environment, you must define certain criteria and understand the area of installation. Equipment used within a cleanroom is required to emit only limited amounts of particulates into the air. This includes weighing equipment such as scales, balances and tank weighing systems. The fact is, however, that most scales are not designed specifically for cleanroom environments, rather they are adapted to "fit" the established guidelines. Yet today, scale manufacturers are now beginning to better engineer solutions specifically for the cleanroom environment from the start.

How are scales designed and constructed for cleanrooms?

Understanding the actual "accuracy" requirements for a specific scale located in a cleanroom is only one requirement. There are several major manufacturers that produce scales that can satisfy most high-accuracy requirements. The real problem arises when a scale not only needs to meet accuracy requests, but also must handle a strict cleaning regimen.

The EU GMP Guide states that weighing instruments are to be cleaned after each work-order-specific set of weighing tasks has been completed to avoid transfer of materials to subsequent orders. The underside of the scale and the bottom of the pit or floor under the scale must be cleaned because these areas are more prone to contamination.

Once the cleanroom classification is determined (ISO Class 5, for example), the type of weighing equipment can then be sourced to meet the needs of the environment. These requirements are primarily based on the equipment's material construction and whether it has moving parts (e.g., lift deck system, portable scale). Most weighing equipment will have no problem being outfitted in ISO Class 8 (Class 100,000) and ISO Class 7 (Class 10,000) cleanrooms. However higher-class areas require equipment with better-grade stainless (better finishes, lower surface roughness) and easy cleanability (see Fig. 1).

Very strict hygiene regulations are applied in the pharmaceutical and medical technology industries. More and more companies are putting their trust in electropolished stainless steel, with its smooth, easy-to-clean surface. Electropolishing meets the strictest hygiene requirements because its surfaces are smooth enough that neither microorganisms nor the residues upon which they would feed can take hold. Moreover, it is highly corrosion-resistant and can withstand even the most aggressive cleaning agents used in sterile environments.

The preferred material for surfaces that come into contact with products in pharmaceutical applications is austenitic stainless steel in the AISI 300 series (e.g., AISI 304, 316, 316L, or 316Ti).

Stainless steel grades and performance

Stainless steel is especially resistant to chemically aggressive, aqueous solutions. Most grades of stainlesssteelcontain12percent chrome and a maximum of 1.2 percent carbon by weight. The high corrosion resistance of stainless steel is due to a passive layer that forms on the surface of the metal. It's a layer of a metal oxide or hydroxide, rich in chrome and only a few Angstrom units thick, that separates the metal from the attacking medium. The passive layer on stainless steel is not constant; over time it tends toward a state of equilibrium, in composition and structure, with the ambient media. Thus, a passive layer once formed cannot be transferred to another medium. If the passive layer is damaged (e.g., mechanically), it generally reforms spontaneously. If a particular medium cannot form an adequate passive layer, or if the existing passive layer is penetrated or completely destroyed by a given chemical, corrosion damage may ensue.

Figure 1. Higher-class cleanrooms require equipment with better finishes, lower surface roughness, and easy cleanability.

Chrome is the decisive alloy in determining the ability of a stainless steel to form a passive layer. Chrome content above the level of 12 percent will suppress the formation of rust under normal atmospheric corrosive influences. A further increase of the chrome content or, under certain circumstances, the addition of molybdenum or other alloying elements, will extend the corrosion resistance of the stainless steel so that it can withstand far more aggressive conditions. Only the alloying additions dissolved in the metal are effective in achieving passivation. This is why the best corrosion resistance is provided by matrices that are free of segregation and are not depleted of chrome or molybdenum due to precipitations or formation of inter-metallic phases.

The correct heat treatment for achieving optimum material structure is described in data sheets on the particular materials. Stainless steels can suffer from wear corrosion on the surface and from various forms of local corrosion. Surface-wear corrosion can be expected primarily when working with acids and strong alkalis.[1]

The stainless weighing surface

It is essential that equipment surfaces be easy to clean. All surfaces that come into contact with the product must be completely resistant not only to the product itself, but also to the detergents and other agents used in cleaning, disinfecting and sterilizing the equipment. Furthermore, these surfaces must be made of a non-absorbent material and must conform to the specifications dictating the permitted surface roughness. The surface characteristics must conform to the defined mean roughness Ra, and must be free of defects such as holes, brush marks or grooves, and fissures. For large surfaces, Ra should be ≤ 0.8 µm. Surfaces that do not touch the product must be smooth enough to enable easy and thorough cleaning.

Ra refers to the average roughness of the steel across its surface and is also known as *Arithmetic Average* (AA) or *Center Line Average*. The average roughness is defined as the area between a roughness profile and the mean line (see Fig. 2). The following methods are used to ensure surfaces with low roughness characteristics:

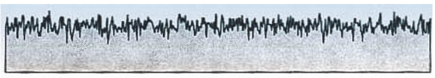

Figure 2. The average roughness is defined as the area between a roughness profile and the mean line.

Bead blasting: The abrasive polishing agents used on unalloyed metals cannot be used to polish stainless steel, as the iron particles rubbed off in polishing might lead to extraneous rust on stainless steel. To avoid corrosion and extraneous rust, it is important to ensure that polishing agents used on stainless steel are free of both iron and sulfur.

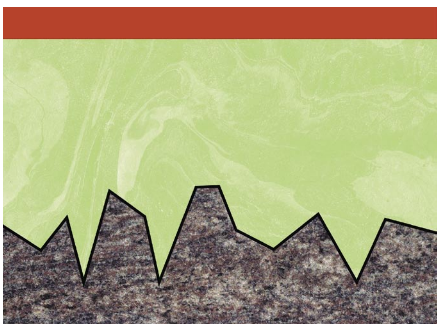

Figure 3. Stainless steel before electropolishing.

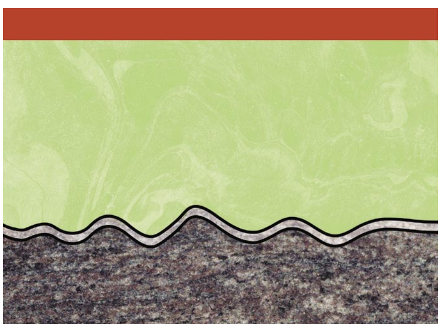

Figure 4. Stainless steel after electropolishing.

Electropolishing: Also called chemical polishing or finishing, electropolishing is ideal for polishing metal parts that cannot be mechanically polished (e.g., parts that have complex forms or thin walls, or that bend easily). In the electropolishing procedure, the part to be polished is immersed in a special bath and made anodic. The introduction of a cathodic metal to the bath causes the metal ions to be removed from the surface of the anodic test piece, which both decreases its surface roughness and significantly increases the proportion of chromium on the surface. This, in turn, improves corrosion resistance (see Figs. 3 and 4). The advantage of an ultrasmooth surface is clear: it prevents deposits that could otherwise lead to crevice corrosion. Only a perfectly smooth, bright surface is effectively resistant to the corrosion that can originate in crevices or holes. The surface roughness of electropolished stainless steel is as low as 0.2 to 0.3 µm.

Mechanical designs

Constructing weighing devices with stainless steel is only one part in developing a scale suitable for cleanroom environments. Typical bench and floor scales used in everyday weighing applications (e.g., shipping scales) are

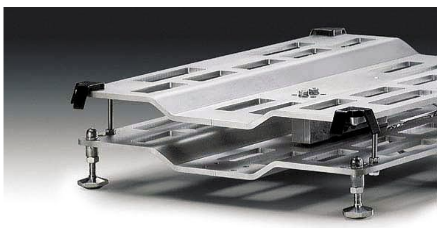

Figure 5. Combics bench scale with open-frame design.

constructed with one thing in mind: price. This is an excellent strategy when an application doesn't require accuracy or sanitary wash-down. However, a "typical" scale should never be used in a cleanroom or in any environment where sanitation is critical.

Scales designed for cleanroom environments will have an open-frame design for easy cleaning and disinfection (see Fig. 5), and limited corners and crevices to eliminate gathering points for bacteria. Also, large platforms must be equipped with some type of pressure-lifting device to allow cleaning underneath the platform (see Fig. 6).

Figure 6. Pharmaline platform scale opened to 90 degrees for easy cleaning below the scale. This low-profile platform scale is designed for cleanroom areas. Its AISI 304 electropolished construction, rounded corners, and integrated pressure-lift system satisfies basic cleanroom needs.

Conclusion

Finding the right scale for a cleanroom area is not as easy as it looks. There are many factors that must first be investigated to determine whether a piece of weighing equipment will not only satisfy your accuracy needs, but will also satisfy stringent cleaning regimens. Carefully inspect the scales in your cleanrooms and ask yourself the following questions:

What resolution to capacity ratio are the scales? Take the maximum capacity of the scale and divide it by the resolution (readability). If this number is less than 30,000, then you can probably find a higher-accuracy alternative with little price increase.

Does the scale look "easy to clean"? Every scale looks simple to clean on the surface, but what does it look like when you lift the weighing surface off? Does it have an open-frame design and are there many corners and crevices? Do you have a floor scale with no means of cleaning below the unit? If your scale is located in a sanitary area and it is not easy to clean, then scale replacement should be considered.

Notes

1. For more details on the corrosion resistance of stainless steel when exposed to various media, see *Corrosion of stainless steels*, available for download at: http://www.NIROSTA.de (click on "English" and navigate to "Products > Materials").

Ryan Titmas is the industrial product manager for Sartorius North America. Contact him at 800-635-2906, ext. 8307 or email **ryan.titmas@sartorius.com**.