

Compliance with Requirements
for the Weighing Chamber

White Paper

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Introduction

As early as 1870, the founder of what was then "Feinmechanischen Werkstatt F. Sartorius", Florenz Sartorius, started to produce short-beam analytical balances. In the following 140 years, the company grew and developed its leading role in the area of laboratory and process technologies. Today, the development and production of high-quality, process oriented balances for the pharmaceutical industry is one of the core competences of Sartorius Lab Instruments GmbH & Co. KG.

The balances in the Cubis® product range are designed for use in this very demanding environment based on the rules of "Good Manufacturing Practices" (GMP) and "Good Laboratory Practices" (GLP). Equipped with the "Advanced Pharma Compliance" (APC) design, function and service package, they use customer-friendly solutions to meet the process and quality requirements of the sector.

The right location of the balance is crucial for precise and repeatable weighing results. This relates not only to the direct footprint but also to the ambient conditions which make up the environment of the balance. The aspects explained below must therefore be considered when identifying the optimum location so that highly reliable results can be obtained in ideal conditions. The weighing technology of Sartorius Lab Instruments GmbH & Co. KG supports the adjustment of the balance to the ambient conditions in a number of ways.

The Weighing Chamber

Organizational, technical and regulatory requirements must be considered when designing a weighing chamber. According to the EU GMP guidelines, raw materials should preferably be weighed in a separate weighing chamber intended for this purpose.

The aim should be to achieve a spatial separation of the direct production or laboratory environment. The position of the weighing chamber plays a special role in this process. Consideration must be given to access control for personnel, an uninterrupted material flow, the cleaning of accessory materials which may be required before weighing and the controlled disposal of empty containers and other consumables. These measures are used, among other things, to avoid confusions, mix-ups and contaminations of the item being weighed.

In addition, the weighing chamber should be correctly sized, i.e. it must be sufficiently large and easy to clean. In addition, air conditioning of the weighing chamber must be provided as standard. Monitoring of the temperature and humidity is mandatory because both can have a significant

influence on the correctness of weighing. Ideally, there should also be suction or another system which reduces the release of dusts. This protects not only the product but also the employee carrying out the work, in particular when working with toxic or highly active substances. The weighing chamber should not be exposed to vibration and the balance should be located in a corner. This is because corners are generally the areas of a room with the lowest vibration levels. The chamber should also be free of drafts. In relation to this, consideration should also be given to the opening of doors. In this context, an ideal weighing chamber should be equipped with a sliding door because this reduces both vibrations and the air movement during opening to a minimum.

Physical Influences

External influence factors such as temperature, humidity and air flows play an important role in the repeatability of weighing results. As the weighing process is temperature-dependent, it is advisable to ensure that there is a constant room temperature.

Therefore, weighing in the direct proximity of heaters or windows should be avoided. In general, the balances of the Cubis® range are designed for a temperature range of +5°C to +40°C. With the isoCAL function, they offer regular and fully-automatic conduct of calibration and adjustment. The intervals for this can be specified or freely selected by the user. In addition, if a temperature range defined by the user is exceeded or not reached, the balance carries out calibration, and if necessary adjustment, independently. This function ensures that constant and repeatable weighing results are achieved at all times.

The relative humidity (% rH) depends on the temperature. The higher the temperature, the more water the air can absorb and therefore the higher the humidity. For balances of the Cubis® range, it is recommended that for temperatures up to 31°C, a relative humidity of 80% should not be exceeded (or 50% for temperatures up to 40°C). For microbalances and analytical balances, it is also recommended that humidity should be permanently monitored and corrected if possible because even the smallest fluctuations can influence the weighing result.

In general, positioning in the air flow of equipment with fans, such as computers or larger laboratory devices, or directly under an air conditioning or ventilation unit, should be avoided. In very sensitive balances, even the smallest puff of air can lead to a change in the weighing result. In order to keep this influence as low as possible, the analytical balances of Sartorius Lab Instruments GmbH & Co. KG are equipped with a wind shield as a matter of principle. This ensures they are optimally protected against air flows. Further factors which may disturb an optimum weighing result include the opening and closing of doors and the movement of employees in the room. Therefore, if possible, a balance should not be set up near a door or in very busy areas. The quieter the location of the balance, the more repeatable and constant the weighing result will be.

Aspects of the Room Setup

In addition to the external influence factors, the user can also make a positive contribution to the quality of their weighing results via lighting and a well-chosen base.

For good ease of use, the balance should be set up in a sufficiently bright location with an illumination of at least 500 Lux. However, in this case it must be ensured that the light source does not generate heat which could have an influence on the weighing result. In this area it is recommended that fluorescent tubes or modern LEDs should be used, which generate little heat but still offer sufficient working light for the users. In addition, the balance must be set up as far away as possible from windows in order to avoid the influence of solar radiation and the related generation of heat.

The base on which the balance is positioned also has a significant influence on the quality of the weighing results; a weighing table must be stable, must transmit as few vibrations as possible and under no circumstances must it bend when weight is applied. As corners are the parts of a room with the lowest vibration levels, as explained above, it is therefore recommended that a windowless corner of a room that is a sufficient distance from the door be used. In general, laboratory tables or stone tables can also be used as weighing tables, and in this case the balance should be positioned directly above the table legs in order to minimize vibrations. However, these do not guarantee optimum results because weighing tables should also be antistatic and antimagnetic, which rules out the materials plastic, glass and steel plate.

Sartorius Lab Instruments GmbH & Co. KG has developed special weighing tables and wall consoles for this purpose, which guarantee an optimum and repeatable weighing result. These usually have a weighing stone on which the balance is placed. The stone can be positioned to be precisely horizontal using socket screws and it excludes static and magnetic influences.

The precise horizontal position of the balance is indispensable for an optimum weighing result. In order to ensure this, Sartorius Lab Instruments GmbH & Co. KG has developed the Q-Level function for automatic leveling of Cubis® balances. It combines innovative sensors with state-of-the-art display technology, making it easy and quick to level the balance accurately. The Cubis® balance controls its precise leveling independently via this function. If the device identifies that it is no longer exactly level, a warning on the display asks the user to start the leveling process by pressing a button or, in the case of the active isoCAL function, the balance starts this completely automatically. Within seconds, internal motors bring the balance back into the perfect position and progress can be followed on the display. The automatic, motorized Q-Level leveling function means that an unintentional and unnoticed change in the balance position is immediately automatically recognized and remedied.

The isoCAL and Q-Level functions have been developed in a quality assured manner and classified in category 1 according to GAMP (Good Automated Manufacturing Practices).

Sartorius Lab Instruments GmbH & Co. KG supports the validation of the mentioned applications, if necessary, with comprehensive informative material, detailed document templates and accompanying services, and therefore ensures effortless integration of these products into ongoing pharmaceutical operations.

Synopsis

When selecting the room and position of a balance, it is necessary to consider the right aspects in order to achieve a consistent and repeatable weighing result.

In addition to recommendations for the optimum positioning of devices, Sartorius Lab Instruments GmbH & Co. KG GmbH offers numerous options for supporting accurate and correct weighing in the pharmaceutical industry, ranging from weighing tables, wall consoles and draft shields through to the development of specific applications. The isoCAL function installed as standard on balances in the Cubis® range permits independent and

automatic calibration of the balance and errors in leveling are immediately detected and remedied with the aid of automatic leveling via the Q-Level function. In addition to selecting suitable ambient conditions, these applications are additional innovative technical solutions from Sartorius Lab Instruments GmbH & Co. KG which ensure high measurement accuracy.

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