ANALYTICAL DIVISION

THE SCALE PEOPLE, INC.

SUBSIDIARY OF S.P.I. LTD. 9693-C Gerwig Lane, Columbia,MD 21046 | 410-309-5880

USP CHAPTER 41

Has your balance's accuracy and repeatability changed?

OUT-OF-LEVEL BALANCE

How inaccurate are your results?

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U.S. PHARMACOPEIA CHAPTER 41

Has your balance's accuracy and repeatability changed?

OVERVIEW

In 2013 U.S. Pharmacopeia chapter 41 for balances was revised, with the new requirements becoming mandatory December 1,2013. Since the revision, the formula for calculating the repeatability of a balance was further revised. The new revision in USP chapter 41 also included a slight change in the definition. Compliance with the new requirements have become mandatory as of July 1,2014

WHAT CHANGED IN USP CHAPTER 41? The formula for repeatability in a balance

	PURPOSE OF FORMULA	REPEATABILITY FORMULA
Previous USP Chapter 41 Requirements	Repeatability of a balance was calculated using the nominal value of the weight used	2 x standard deviation I nominal weight ≤ 0.10%
Requirements as of July 1, 2014	Repeatability of a balance was calculated using the desired smallest net weight	2 x standard deviation I desired smallest net weight ≤ 0.10%

Key benefits for the change

- The new formula for repeatability shows us whether a balance meets the requirements at the desired smallest net weight
- The new requirements also give the users a better approach to ensuring a balance is compliant.

Key reason for the change

The calculation change for repeatability occurred in USP chapter 41 to resolve a question regarding the use of a balance. It is believed that it is more important to know how a balance will perform at the point of its desired smallest net weight than at the nominal weight used for measurement.

NOTES

How will this affect your work?

- You now have a correct way to assess your balances accuracy and performance where it matters: at the smallest desired net weight.

- All calculation sheets and certificate templates must have the new formula as of July 1,2014

- All calibration certificates handed out prior to July 1,2014 will be valid until your next balance calibration is due

Key benefits of our Calibration Certificates

- Our certificates are accurate and reliable according to USP Chapter 41 requirements

- We will indicate to you, your balances desired smallest net weight and whether you have been operating within it.

USP Chapter 41 Certificates

from

THE SCALE PEOPLE, INC.

All calibration certificates from The Scale People are compliant with the latest revisions to U.S.Pharmacopeia Chapter 41

MAJOR PROBLEMS AN OUT-OF-LEVEL BALANCE CAN CAUSE

Before we continue, a basic discussion of the fundamentals of weighing is needed in order to understand how the effects of gravity on a balance can cause potentially large errors in overall accuracy. Weight, as we all know, is defined as follows:

The importance of proper leveling

If you own a balance, mass comparator, or high-resolution industrial scale, it is important that the device is not only calibrated in its final location but also leveled properly. With that said, any of us who are regularly involved in the use of a scale or balance know that the infamous level (spirit) is usually located on the rear of the balance in a difficult place to find and inconspicuously positioned as if it weren't really that important. In fact, it is critical in the overall accuracy of the balance. The more expensive your balance, the higher the resolution (analytical, semi-micro, micro, etc.), the more significant this paper is for you.

Example of leveling a balance utilizing an assisted leveling display

New technology now available to properly level balances utilizes an internal assisted leveling display. This display allows the user to level a balance quickly, accurately, and safely with minimum effort.

A comprehensive look at a balance not in level.

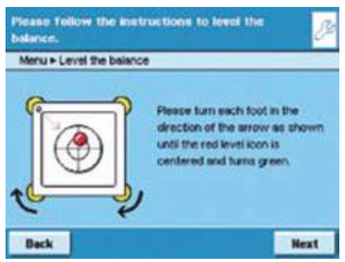


Figure 1 - Diagram showing the new-generation Sartorius Cubis balance with assisted leveling on the display.

There are few manufacturers that produce balances above the 1 microgram level due to the technology needed to accurately display a repeatable result. When these manufacturers calibrate a particular unit, they first ensure that the level vial is perfectly centered by a process of positioning the balance on a jig that is mounted to a calibrated table. This table is calibrated to be perfectly level (within an extremely tight tolerance, primarily checked with laser positioning systems), so that each balance is manufactured at exactly the same reference point

Therefore, when setting up a balance at your facility in its final position, it is critical that each balance be:

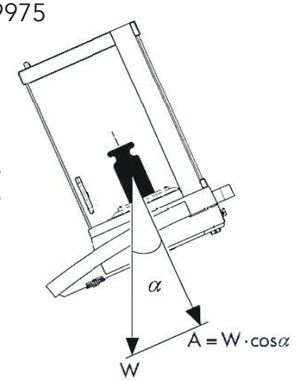
- Parallel to the direction of acceleration due to gravity
- Perpendicular to the weighing system

Example:

At an angle a=0.3°, the following applies:

A=W-cos*a* = W · 0.9999875
200 g x 0.9999875 = 199.9975

This means a 200g sample would weigh 0.0025 g less on a tilted balance. Always level the balance using the level indicator as a guide! Understanding the effects of gravity in weighing accuracy.



The weight force that we can actually sense can be represented in this simple equation:

Weight (w) = Mass (m) x Gravity (g) 9.80665 m/s2 or 32.174 ft/s2

The gravity listed in the above equation is an average for the planet Earth and shouldn't be assumed for any specific location where a balance is being used. Gravity can in effect be up to 0.5% different from location to location; even moving a balance from a basement to a third floor can cause enough moderation in the gravitational effect to result in an error on very accurate balances. Therefore, a balance needs to be located in its final position prior to an initial calibration, as the simple act of moving a balance after calibration will, in all probability, cause the balance to be out of tolerance.

Example:

Moving an analytical balance to a location that is only 4 m higher really makes a noticeable difference: Instead of 200.0000 g, only 199.9997 g is displayed, which means 0.0003 g lighter than the actual mass. Each time a balance is moved to another location, it must be calibrated (adjusted).

Not to digress, but it is critical to realize that not only the levelness but also the final location of a balance will have a direct impact on its performance. A balance is always calibrated in the factory where it's produced and may even come with a "certificate of calibration." However, this certificate simply reflects a manufacturer's overall quality system; therefore, a balance always needs to be recalibrated with certified weights at its final resting place.

Other factors that affect accuracy

- Temperature and humidity fluctuations
- Vibrations
- Static charges
- Magnetically charged samples
- Air buoyancy

Scale manufacturers have taken significant steps to help dampen and sometimes alleviate environmental factors; however, it is important to take special care in determining where a precision balance is located. Remember, balances don't like change, so always keep them in the same location and under the same ambient conditions, and especially keep them level.