

Calibration of the Sartorius ME215S

2.7.1 Measurement Uncertainty and Minimum Weight

1. The measurement uncertainty of a balance, used for "accurately weighing", must be determined. In the case of a new balance, this shall be done at the OQ stage. For all balances, the measurement uncertainty and minimum weight shall be determined at the 6 monthly planned maintenance and at anytime the balance is relocated. If it is necessary to determine minimum weight between PM visits, the following procedure should be followed.
2. Use a 100mg weight for replicate weighings. Perform 10 replicate weighings.
3. Calculate standard deviation (sd) of the 10 replicate weighings, using the following formula:

$$sd = \sqrt{\frac{\sum (x - \bar{x})^2}{n - 1}}$$

4. Measurement Uncertainty is calculated as being three times the standard deviation of ten replicate weighings divided by the mean of the ten readings for that weight ($\sqrt{10}$).

The minimum uncertainty (MU) is calculated as follows:

$$MU = (3 \times sd) / \text{Mean weight}$$

Hence the minimum weight can be calculated as follows:

$$\text{Minimum weight} = \text{Calculated MU} \times \text{Mean weight} \times 1000$$

Record results in Appendix V. Results must be second person reviewed for errors, and signed.

2.7.2 Weekly Full Calibration of 5 Place Analytical Balances

1. Check the balance is level, then zero the balance by suitable means and perform an internal calibration, adjustment. To do the Internal Adjustment process, press the 'CAL' softkey, then press the 'Start' softkey.
2. Using mass pieces of nominal weight values 100mg, 1g, 10g and 200g, perform the following procedure:
3. Place the weight on the pan, allow to stabilise and record the value on the balance weight record sheet (Appendix II). The weight should be within the following ranges :-

Weight	Tolerance from Certified Value
100mg	± 0.1%
1g	± 0.05%
10g	± 0.01%
200g	± 0.0005%

TABLE 1

USP<1241> states that minimum uncertainty should be no more than 0.1% of the mass weighed. Since the ME215S balance specification fits well within this range for mass pieces over 1g, the limits have been tightened to check functional operation of the balance.

4. If any of the calibration data falls outside these limits, a repeat determination should be performed. Failure should be reported to the QC manager, calibration co-ordinator or raw material team leader.

2.7.3 Daily Drift Check

1. Measure the drift on a daily basis (except weekends and laboratory shutdowns) using a single, individual check-weight which will be used on the same balance. The mass of the check-weight is determined by the mean of 10 replicate weighings of the 20g nominal weight $\pm 0.2\text{mg}$ which is performed every six months. Tare the balance before each of the 10 readings, which must be within 0.2mg of the final mean. This tolerance needs to be established anytime the check weight is changed or the balance undergoes maintenance, repair or is moved. Use Appendix IV to record check weight determination. A second person must review for errors and sign each time a determination is done.
2. The observed variation in the weight must not exceed $\pm 0.2\text{mg}$ of the check weight, above. Record daily check weight in relevant Appendices (5 place balance, Appendix III)
3. If a balance fails the daily drift check an 'out of use' label must be filled in and attached to the instrument and arrangements should be made to have the balance checked by an engineer.