

Use of ISO or Manufacturers Specifications to Calibrate Pipettes

Anachem is a UK subsidiary of the world-wide METTLER TOLEDO Group. Our activities in the UK cover the supply and service of pipettes and laboratory consumables. The METTLER TOLEDO Group serves global customers on a worldwide base with the largest sales and service network in our industry. With METTLER TOLEDO the sales and service organizations around the globe ensure that we have factory-trained, experienced, and dedicated specialists serving our customers. Since its establishment in 1970, Anachem has consistently focused on bringing to market, products and services that help to improve scientists' overall laboratory productivity, assure the quality of their results and assist in meeting regulatory compliance. Anachem is ISO 9001:2008, ISO 14001-2004 certified, and its Pipette Service section operates under the prestigious UKAS 17025 accreditation requirements.

Each of our field based technicians is fully equipped with computers, labels, specialised testing equipment and immediate hard-copy reporting capabilities. This includes the latest pipette calibration specific 6 decimal place balances & MCP balances so that all single channel pipettes and all multichannel pipettes (with a maximum volume greater than 50ul) can be serviced & calibrated on-site significantly reducing down time in the laboratory and eliminating transportation costs.

All calibration equipment is traceable to ISO:17025 (UKAS) standards with copies of calibration certificates available on request; we have daily, weekly and monthly calibration routines for all of our balances. This is particularly important for any balance which is moved between locations to ensure the accuracy of the readings taken. Our technicians have daily targets for the number of pipettes which they can service and calibrate on site which changes depending on the calibration level selected. The technicians daily throughput is monitored to ensure that work is not rushed and the required amount of time is taken for all service and calibration work.

All pipettes are serviced following the manufacturer's instructions for the specific pipette model; calibration can be carried out to either manufacturer's specifications or to the ISO 8655 specifications. All service carried follows the process below:

- **Pipette inspection** - Thorough internal and external evaluation of functionality and parts
- **Sealing System Check** - Visual leak test
- **Service** - Internal cleaning, replacement of worn parts and adjustment
- **Documentation** - Dated service label affixed to pipette, detailed service and calibration report provided
- **Traceability** - UKAS accredited lab & operating procedure, full traceability of testing equipment & replacement parts

The choice of whether a pipette is calibrated to the manufacturer specification or the ISO 8655 specification is up to the customer as whichever specs are used they must be able to justify that they are suitable and appropriate for the work undertaken with the calibrated pipettes.

ISO specifications reflect how a pipette works in the real world. At nominal volume they are broadly similar; however they are typically wider near minimum volume than the manufacturer specifications. This is to reflect real life performance seen by end users. It is best practice to only use a pipette between 35% and 100% of nominal volume. A 20µL pipette used at 20µL will be more than twice as accurate as a 200µL pipette used at 20µL.

The Advantages of using the ISO 8655 specifications are:

One set of specifications for all pipettes regardless of make or model

- Brand to brand variation can be significant and can cause issues where many brands of pipettes are used on site or in a single lab.

Applicable regardless of which tips are used

- To comply with manufacturer specifications you must use the corresponding manufacturer pipette tip.

Negate the need to keep on top of any changes in manufacturers' specifications

- All manufacturers reserve the right to change specification without warning

Harmonisation with other countries and partners

- ISO 8655 specifications are widely used across Europe and the rest of the world
- Internationally recognised standards familiar to auditors and established in 2002.

Pipettes are designed to be used at nominal volume and performance below 35% becomes highly dependent on operator, environment and equipment used.

- User to User Variances at volumes below 35% are significant
- Poor environmental conditions amplify this

Variable volume pipettes must be checked at two test points (10% and 100%) to ensure the pipette is suitable for use across its range.

- Testing at 1 point (50%) is not suitable and does not test the pipettes Linearity or put the seal under maximum load.

Below is the statement from EN ISO 8655-2:2002 regarding maximum permissible errors, pipettes and tips.

7.6 Pipette Tips

The maximum permissible errors always apply to the total system of piston pipette and tip. When using pipette tips not delivered by the pipette supplier, the supplier's declaration or the certificate of conformity does not apply. In such cases, the evaluation of the maximum permissible errors shall be performed using the alternative tips with the method of test specified in ISO 8655-5.

Before the conformity evaluation of the piston pipette with the alternative tips, it shall be ascertained, that the piston pipette in combination with the original tips conforms to the metrological requirements specified in this part of ISO 8655.

Users may test the metrological performance for routine quality assurance procedures of the total system of:

- Piston pipette and tip (type A) and operator, or
- Tip and piston combination (type D) and operator

in accordance with ISO 8655-6 with alternative test methods (see note to clause 1).

Manufacturer specifications are far more reflective of an individual pipettes performance but there are issues with using them. Unfortunately it is not possible to use one manufactures specs for all pipettes as they vary in performance quite a lot. Each make, model and size will have a different specification leading to inconsistency of approach across any site that has a variety of pipettes. The manufacturer specification is set using the manufacturer pipette tips in an idealised environment. They are also quite tight which can lead to as-found failures due to natural drift or calibration variances. One solution some customers use is to standardize on the pipettes they buy/use to ensure consistency. As-found failure rates can be as high as 35%, but more reasonable would be about 3-5%, this will be dependent on use and care of the pipettes.