Information sheet 3 (ENG)

SPECIFICATIONS, pipettes, dispensers etc.

This information sheet describes which specifications can be selected when filling out Form 11 *DANAK accredited calibration* or Form 12 *Standard calibration*. Pipettes are usually specified based on how they perform in terms of accuracy (systematic error) and precision (random error in CV%) and often the pipette manufacturer has specified these as performance specifications.

Definitions:

- Systematic error (accuracy) in % – The difference between the measured (mean) volume and the set volume.
- Random error (precision) - CV% spread, or the coefficient of variation – the relative standard deviationspread in a set of measurements in relation to the mean volume.
- Measured (mean) volume - the average value in of a set of measurements. Each measurement is the volume determined gravimetrically according to ISO 8655:2022
- Set volume – The desired test volume set on the pipette.
- Nominal volume – The pipette's max. volume ~ the manufacturer's defined volume size for the pipette.

To choose the most suitable specifications, it is important to consider the following:

- High/strict criteria for specifications (low %) makes high demands for pipetting technique, procedure, equipment, and environment.
- It is recommended to use original tips, as the pipette and tip are considered as one unit.

EN ISO/IEC 8655:2022 Max. permissible errors (the most common used tolerance limits)

The ISO 8655 max. errors specifications are valid to all pipette brands (manufacturers) and are commonly used when choosing acceptance tolerances. The ISO 8655 specifications are often slightly wider – especially in the low volume range compared to the manufacturer's own specifications and can be selected in connection with calibration in the Dandiag Calibration Laboratory or at customers location (in situ).

Please note that it is not recommended to use a pipette in the volume range <10% of max volume, according to ISO 8655:2022

The max. permissible errors specifications are specified in:
ISO 8655-**2**:2022 is applicable for Pipettes (piston operated).
ISO 8655-**3**:2022 is applicable for Burettes (piston operated).
ISO 8655-**4**:2022 is applicable for Diluters (piston operated).
ISO 8655-**5**:2022 is applicable for Dispensers and Bottle-top-dispensers (piston operated).

Manufacturer's (performance) specifications

Performance specifications are defined by the individual pipette manufacturer and are specific to every pipette size and type.
The manufacturer specifications are often stated only valid for P-mode and are obtained under strict standardized calibration conditions - according to requirements in ISO 8655-6:2022. Manufacturer´s specifications are the most "narrow/strict" tolerance limits, that can be select. Pipettes of older date might need replacement of spare parts to meet the performance specifications and often it will be beyond economic repair.

Note: If calibration according to the performance specifications is desired, pipettes must be sent to Dandiag Calibration Laboratory, as it is often not possible to meet these specifications at In situ calibration on customers location.

Manufacturer's specifications x 1,5

Manufacturer's specifications multiplied by 1,5 - often referred to as User specifications – can be used for calibration of pipettes in use.
The accepted tolerance limits are often between ISO 8655 max. permissible errors and Manufacturer's performance specifications.
The manufacturer's specifications multiplied by 1,5 can be selected if in situ calibration is desired.

Costumer defined specifications

Costumer defined specifications are based on the data and needs from the pipette users. It is not recommended to define "stricter" acceptance criteria than the manufactures specifications. Manufacturer's specifications multiplied by 1,5 specifications can be used as a starting point when tolerance limits are to be defined for own specifications.

It is recommended to consult with Dandiag QA-support@dandiag.dk whether own specifications can be met, especially if Dandiag performs the calibration.

Customer defined specifications are available at In situ calibration – but only by agreement with Dandiag.

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