Customer information:

Change of measurement values according to ISO8655:2022

Dear customers,

We are preparing to update our processes and systems to the new ISO 8655:2022, and as a result, we will effectively carry out the evaluation of the measurement results according to the limit values of ISO 8655:2022 as of **July 1st** 2023. In an effort to ensure that your results are within the limits of the current version of the standard, we will adapt the changes for the method according to ISO 8655-6:2022, e.g. the exchange of the pipette tips, until **December 31, 2023.**

Who is affected?

Many of our customers take the manufacturer's limits as the basis for evaluating the measurement results. Therefore, only customers who need an evaluation according to ISO error limits are affected by the changeover.

During a calibration, the metrological uncertainties of a calibration are compared with a theoretical error limit. The three limit options commonly used are: 1. The ISO 8655 limits, 2. The limits defined by the manufacturer of the instrument (technical data of the device), 3. The error limits set by the user. Please note that the manufacturer limits are usually stricter than the ISO error limits, therefore if the new ISO standard is followed, it is still possible to check the pipette against manufacturer and customer limits.

How do the limit values of ISO 8655:2022 change compared to the version ISO 8655:2002?

The requirements for volumetric accuracy of piston-stroke pipettes, burettes and dispensers have been updated in the ISO 8655:2022 series. Some limits for the maximum deviation of the dispensed volume have been lowered.

To make it easier for the user, there are now limits specified in the standard for 10%, 50%, and 100% of the nominal volume. This eliminates the need to calculate the maximum permissible error limits for 50% and 10% of the nominal volume. For multichannel pipettes there is also a new, separate table with limits.

Will the new limits now cause more devices to fail the calibration if I want the evaluation according to ISO 8655:2022?

No, Eppendorf has statistically tested for the effect of the changes in the limit values. The result is that the version of the standard has no effect on the distribution of the limit values.

Therefore, the hypothesis is accepted that the version of the standard and consequently the change has no effect on the conformity statement in an assessment according to the ISO limits.

To check whether the changed theoretical error limits have an influence on the result of the conformity statement of your measurement, an internal comparative analysis of the theoretical error limits were carried out for the instruments calibrated by us (ISO 8655-2, -3, -5). In this analysis, the relative error limits of the two ISO standard versions were used and their distribution was investigated.

What do I have to do?

The new limits will be used for the evaluation and used for the conformity statements of July 1st, 2023. If you wish to continue using the ISO 8655:2002 series error limits for evaluation, please state this explicitly in your order.

Additional information:

Comparison of the maximum permissible errors (MPEs) of ISO 8655-2, -3, -5:2002 & ISO 8655-2, -3, -5:2022

To make it easier for you to compare the MPEs, the following table compares the MPEs of the two standard versions and, if differences occur, the effect of the change is analyzed statistically.

It should be noted that a statistical effect depends not only on the limits, but also on other factors such as sample size, measurement uncertainty, and analysis procedure.

Table 1: Comparison of the maximum permissible errors of ISO 8655-2,-3,-5:2002 & ISO 8655-2,-3,-5:2022. The differences are marked in blue. In addition, the effect of the change was calculated. The impact of the effect was used as an evaluation for the impact of the change. The value 0 would therefore mean that the change has no effect or a negligible effect. The value 1 describes that there is a maximum effect. A description of the analysis can be provided on request.

Nominal volume in µl	**Error limits for systematic measurement error (2002) in %.**	**Error limits for systematic measurement error (2022) in %.**	**Effect of the change (Cramer's effect size)**	**Error limits for random measurement error (2002) in %.**	**Error limits for random measurement error (2022) in %.**	**Effect of the change (Cramer's effect size)**
ISO 8655-2, types A and D1 (single-channel pipettes)						
1	**5,0**	**2,5**	0,004	**5,0**	**2,0**	0,0004
2	**4,0**	**2,5**	0,004	2,0	2,0	0
> 2 to 3	2,5	2,5	0	**1,5**	**2,0**	0,0004
> 3 to 5	2,5	2,5	0	1,5	1,5	0
Nominal volume in µl	**Error limits for systematic measurement error (2002) in %.**	**Error limits for systematic measurement error (2022) in %.**	**Effect of the change (Cramer's effect size)**	**Error limits for random measurement error (2002) in %.**	**Error limits for random measurement error (2022) in %.**	**Effect of the change (Cramer's effect size)**
> 5 to 10	1,2	**1,2**	0	**0,8**	**0,8**	0
> 10 to 20	1,0	1,0	0	**0,8**	**0,5**	0,0004
> 20 to 50	1,0	1,0	0	0,5	0,5	0
> 50 to 100	0,8	0,8	0	**0,3**	**0,3**	0
> 100 to 5 000	0,8	0,8	0	0,3	0,3	0
> 5 000 to 20 000	0,6	0,6	0	0,3	0,3	0
ISO 8655-2, types A and D1 (multichannel pipettes)						
1	**10,0**	**8,0**	0,016	**10,0**	**8,0**	0,016
2	8,0	8,0	0	**4,0**	**8,0**	0,016
> 2 to 3	5,0	5,0	0	3,0	3,0	0
> 3 to 5	5,0	5,0	0	3,0	3,0	0
> 5 to 10	2,4	2,4	0	**1,6**	**1,6**	0
> 10 to 20	2,0	2,0	0	**1,0**	**1,0**	0
> 20 to 50	2,0	2,0	0	**0,8**	**0,8**	0
> 50-100	1,6	1,6	0	0,6	0,6	0
> 100-5000	1,6	1,6	0	0,6	0,6	0

ISO 8655-2, type D2						
5	2,5	2,5	0	1,5	1,5	0
>5-10	2,0	2,0	0	1,0	1,0	0
>10-20	2,0	2,0	0	0,8	0,8	0
>20-100	**1,5**	**1,4**	0,004	0,6	0,6	0
>100-1000	1,2	1,2	0	0,4	0,4	0
ISO 8655-3, motor-driven piston burettes						
≤ 1	0,6	0,6	0	0,1	0,1	0
> 1-2	0,5	0,5	0	0,1	0,1	0
Nominal volume in µl	**Error limits for systematic measurement error (2002) in %.**	**Error limits for systematic measurement error (2022) in %.**	**Effect of change (Cramer's effect size)**	**Error limits for random measurement error (2002) in %.**	**Error limits for random measurement error (2022) in %.**	**Effect of the change (Cramer's effect size)**
> 2-5	0,3	0,3	0	0,1	0,1	0
> 5-25	0,2	0,2	0	0,07	0,07	0
> 25-50	0,2	0,2	0	0,05	0,05	0
> 50-100	0,2	0,2	0	0,03	0,03	0
ISO 8655-3, hand-driven piston burettes						
≤ 1	0,6	0,6	0	0,1	0,1	0
> 1-2	0,5	0,5	0	0,1	0,1	0
> 2-10	0,3	0,3	0	0,1	0,1	0
> 10-20	0,2	0,2	0	0,1	0,1	0
> 10-100	0,2	0,2	0	0,1	0,1	0
ISO 8655-5, single-stroke dispensers						
≤ 0,01	2,0	2,0	0	1,0	1,0	0
> 0,01-0,02	2,0	2,0	0	0,5	0,5	0
> 0,02-0,05	1,5	1,5	0	0,4	0,4	0
> 0,05-0,1	1,5	1,5	0	0,3	0,3	0
> 0,1-0,2	1,0	1,0	0	0,3	0,3	0
> 0,2-0,5	1,0	1,0	0	0,2	0,2	0
0,5-200	0,6	0,6	0	0,2	0,2	0

ISO 8655-5, multiple-delivery dispensers

0,001-0,002	5,0	5,0	0	5,0	5,0	0
> 0,002-0,003	2,5	2,5	0	3,5	3,5	0
> 0,003-0,01	2,0	2,0	0	2,5	2,5	0
> 0,01-0,02	1,5	1,5	0	2,0	2,0	0
> 0,02-0,05	1,0	1,0	0	1,5	1,5	0
> 0,05-0,2	1,0	1,0	0	1,0	1,0	0
Nominal volume in µl	**Error limits for systematic measurement error (2002) in %.**	**Error limits for systematic measurement error (2022) in %.**	**Effect of change (Cramer's effect size)**	**Error limits for random measurement error (2002) in %.**	**Error limits for random measurement error (2022) in %.**	**Effect of the change (Cramer's effect size)**
> 0,2-0,5	1,0	1,0	0	0,6	0,6	0
> 0,5-1	1,0	1,0	0	0,4	0,4	0
> 1-2	0,8	0,8	0	0,4	0,4	0
> 2-5	0,6	0,6	0	0,3	0,3	0
> 5-25	0,5	0,5	0	0,3	0,3	0
> 25-200	0,5	0,5	0	0,25	0,25	0