

Sartorius Lab Instruments GmbH & Co. KG, 37070 Göttingen

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June 4, 2024

Expected implementation date	Customer action required by Sartorius	Type of action
August 01, 2024	No	N/A

Information Letter

ECR 45782-45035-43078: Adjustment of Sartorius Pipette Portfolio to Revised Standards

Dear Valued Customer,

This information letter is to inform you of changes to our pipette portfolio. In order to meet the compliance needs of our customers we are pleased to inform that at the Sartorius manufacturing sites we will transition to the latest revision (2022) of the ISO 8655 standard series. Simultaneously, we will adopt the most recent version (2023) of ISO/TR 20461 which relates to the determination of uncertainty for volume measurements of piston-operated volumetric apparatus.

Change Description

To ensure compliance with the ISO 8655:2022, we are implementing the following changes to our products:

1. The minimum usable volume of Tacta, Proline Plus, Mline, and Proline pipettes will be harmonized to 10% of the nominal volume. The minimum usable volume for Picus 10µL variants will be adjusted from 0.2µL to 0.5µL. For further details, please refer to Appendix 1.
2. Certain maximum permissible systematic or random errors will be updated to align with revised testing procedure in ISO 8655-6. Please see Appendix 2 for details. Changes are highlighted in teal.
3. The Quality Control certificate template for Tacta, Proline Plus, Mline, and Proline will be updated. An example is provided below. Picus 2 pipettes are already utilizing a similar template. For a comprehensive list of changes, please see Appendix 3.

Impacted Products

The list of impacted products can be found in the Appendix 4.

Sartorius Lab Instruments GmbH & Co. KG

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Registered Office:
Göttingen
Local Court of Registration:
Amtsgericht Göttingen
HRA 201253

The company is a limited
commercial partnership

Individually liable shareholder

Sartorius Weighing Technology
GmbH
Registered Office:
Göttingen
Local Court of Registration:
Amtsgericht Göttingen
HRB 201458
Managing Directors:
Mario Hespe,
Carsten Wolter

Change Implementation

This change is controlled internally in accordance with Sartorius change management procedures.

This change will be implemented starting August 1, 2024. The first deliveries are planned for August 2024. As we introduce these changes, please note that it may take some time for them to become fully available across all our distribution channels. Due to stock levels and our product portfolio mix, it is possible that products produced according to the new and old revision of the ISO 8655 standard are delivered at the same time.

We continuously strive to implement solutions to our products and services to enable you to get your treatments to patients faster. We thank you for your trust and continued use of Sartorius products, and we look forward to assisting you in managing this change.

Sincerely,

DocuSigned by:
Kimberly Wicklund
 Signer Name: Kimberly Wicklund
Signing Reason: I approve this document
Signing Time: 2024-06-10 | 14:28:20 CEST
14C0B46C51644C94AF1CC4102DD09B5B

DocuSigned by:
Susanne Gerighausen
 Name des Unterzeichners: Susanne Gerighausen
Signiergrund: Ich genehmige dieses Dokument
Signierzeit: 2024-06-04 | 13:09:36 MESZ
165B30A4A29E4CD99853CE51CFCFDDBF

Kimberly Wicklund
Head of Product Management LPS
Sartorius Corporation

Susanne Gerighausen
Head of Quality Assurance and Control LPS
Sartorius Lab Instruments GmbH & Co. KG

Note: List of affected manufacturing site(s) / manufacturing site(s) of impacted products
-Sartorius Biohit Liquid Handling Oy, Helsinki and Kajaani, Finland

Appendix 1: New Minimum Usable Volumes.

Before the change: Material number and description	After the change: Material number and description
LH-747021 Picus 2 1-ch 0.2-10µL	LH-747021 Picus 2 1-ch 0.5-10µL
LH-747321 Picus 2 8-ch 0.2-10µL	LH-747321 Picus 2 8-ch 0.5-10µL
LH-747421 Picus 2 12-ch 0.2-10µL	LH-747421 Picus 2 12-ch 0.5-10µL
LH-729010 Tacta 1-ch 0.1-3µL	LH-729010 Tacta 1-ch 0.3-3µL
LH-729020 Tacta 1-ch 0.5-10µL	LH-729020 Tacta 1-ch 1-10µL
LH-729120 Tacta 8-ch 0.5-10µL	LH-729120 Tacta 8-ch 1-10µL
LH-729220 Tacta 12-ch 0.5-10µL	LH-729220 Tacta 12-ch 1-10µL
LH-729130 Tacta 8-ch 5-100µL	LH-729130 Tacta 8-ch 10-100µL
LH-729230 Tacta 12-ch 5-100µL	LH-729230 Tacta 12-ch 10-100µL
725010 Mline 1-ch 0.1-3µL	725010 Mline 1-ch 0.3-3µL
725020 Mline 1-ch 0.5-10µL	725020 Mline 1-ch 1-10µL
725120 Mline 8-ch 0.5-10µL	725120 Mline 8-ch 1-10µL
725220 Mline 12-ch 0.5-10µL	725220 Mline 12-ch 1-10µL
725130 Mline 8-ch 5-100µL	725130 Mline 8-ch 10-100µL
725230 Mline 12-ch 5-100µL	725230 Mline 12-ch 10-100µL
728010 Proline Plus 1-ch 0.1-3µL	728010 Proline Plus 1-ch 0.3-3µL
728020 Proline Plus 1-ch 0.5-10µL	728020 Proline Plus 1-ch 1-10µL
728120 Proline Plus 8-ch 0.5-10µL	728120 Proline Plus 8-ch 1-10µL
728220 Proline Plus 12-ch 0.5-10µL	728220 Proline Plus 12-ch 1-10µL
720010 Proline 1-ch 0.1-2.5µL	720010 Proline 1-ch 0.25-2.5µL
720015 Proline 1-ch 0.5-10µL	720015 Proline 1-ch 1-10µL
720210 Proline 8-ch 0.5-10µL	720210 Proline 8-ch 1-10µL
720310 Proline 12-ch 0.5-10µL	720310 Proline 12-ch 1-10µL

Appendix 2: Tables of Maximum Permissible Systematic and Random Errors.

Picus 2:

Picus 2 maximum permissible error limits (8655:2022)						
Model	Mode ²	Systematic ¹		Random ¹		
	Volume	%	µL	%	µL	
LH-747021 1-ch 0.5-10µL	P	10	1.0	0.1	0.4	0.04
	P	5	1.2	0.06	0.7	0.035
	P	1	3.0	0.03	2.0	0.02
	P	0.5	8.0	0.04	4.0	0.02
	D	1	6.0	0.06	7.0	0.07
LH-747041 1-ch 5-120µL	P	120	0.5	0.6	0.15	0.18
	P	60	0.7	0.42	0.23	0.14
	P	12	2.0	0.24	1.0	0.12
	P	5	5.5	0.275	2.5	0.125
	D	12	4.0	0.48	4.0	0.48
LH-747061 1-ch 10-300µL	P	300	0.6	1.8	0.15	0.45
	P	150	0.6	0.9	0.2	0.3
	P	30	2.0	0.6	0.8	0.24
	P	10	6.0	0.6	2.4	0.24
	D	30	3.0	0.9	3.0	0.9
LH-747081 1-ch 50-1,000µL	P	1000	0.45	4.5	0.15	1.5
	P	500	0.6	3	0.2	1
	P	100	2.0	2	0.5	0.5
	P	50	4.0	2	1.0	0.5
	D	100	2.5	2.5	2.0	2
LH-747101 1-ch 100-5,000µL	P	5000	0.5	25	0.15	7.5
	P	2500	0.7	17.5	0.2	5
	P	500	1.6	8	0.4	2
	P	100	8.0	8	2.0	2
	D	500	2.4	12	2.4	12
	P	10000	0.6	60	0.2	20

LH-747111 1-ch 500- 10,000µL	P	5000	0.9	45	0.3	15
	P	1000	3.0	30	0.6	6
	P	500	7.0	35	1.2	6
	D	1000	4.0	40	2.4	24
LH-747321 8-ch & LH-747421 12-ch 0.5-10µL	P	10	1.2	0.12	0.5	0.05
	P	5	1.5	0.075	0.8	0.04
	P	1	4.0	0.04	3.0	0.03
	P	0,5	10.0	0.05	6.0	0.03
	D	1	12.0	0.12	15.0	0.15
LH-747341 8-ch & LH-747441 12-ch 5-120µL	P	120	0.6	0.72	0.3	0.36
	P	60	0.8	0.48	0.4	0.24
	P	12	2.5	0.3	1.67	0.2
	P	5	6.0	0.3	4.0	0.2
	D	12	4.5	0.54	8.0	0.96
LH-747361 8-ch & LH-747461 12-ch 10-300µL	P	300	0.6	1.8	0.2	0.6
	P	150	0.8	1.2	0.3	0.45
	P	30	2.33	0.7	1.0	0.3
	P	10	8.0	0.8	3.0	0.3
	D	30	3.33	1	6.0	1.8
LH-747391 8-ch & LH-747491 12-ch 50-1,200µL	P	1200	0.6	7.2	0.2	2.4
	P	600	1.0	6	0.3	1.8
	P	120	2.5	3	1.0	1.2
	P	50	8.0	4	2.0	1
	D	120	3.33	4	3.33	4

¹ The values provided for systematic and random errors apply specifically to the pipettes mentioned, when used in conjunction with compatible Sartorius Optifit non-sterile tips. These values can be attained only under strictly controlled conditions, such as during type examinations conducted in accordance with ISO 8655 standards. When the mentioned pipettes are used with other Sartorius tips, they meet the specifications outlined in ISO 8655.

² P= Pipetting mode, D=multi-dispensing mode

Tacta and Mline:

Tacta and Mline maximum permissible error limits (8655:2022)					
Model	Volume	Systematic ¹		Random ¹	
	μL	%	μL	%	μL
LH-729010 1-ch 0.3-3μL	3	1.6	0.048	0.8	0.024
	1.5	3.0	0.045	1.6	0.024
	0.3	12.0	0.036	6.0	0.018
LH-729020 1-ch 1-10μL	10	1.0	0.1	0.6	0.06
	5	1.5	0.075	1.0	0.05
	1	3.0	0.03	2.0	0.02
LH-729030 1-ch 2-20μL	20	1.0	0.2	0.4	0.08
	10	1.5	0.15	0.7	0.07
	2	6.0	0.12	3.0	0.06
LH-729050 1-ch 10-100μL	100	0.8	0.8	0.2	0.2
	50	1.0	0.5	0.3	0.15
	10	3.0	0.3	1.0	0.1
LH-729060 1-ch 20-200μL	200	0.6	1.2	0.2	0.4
	100	1.0	1	0.3	0.3
	20	2.5	0.5	0.9	0.18
LH-729070 1-ch 100-1000μL	1000	0.7	7	0.2	2
	500	0.9	4.5	0.2	1
	100	3.0	3	0.6	0.6
LH-729080 1-ch 500-5000μL	5000	0.6	30	0.2	10
	2500	0.7	17.5	0.25	6.25
	500	2.4	12	0.6	3
LH-729090 1-ch 1000-10000μL	10000	0.6	60	0.2	20
	5000	1.2	60	0.3	15
	1000	3.0	30	0.6	6
LH-729120 8-ch 1-10	10	1.5	0.15	1.0	0.1
	5	2.5	0.125	2.0	0.1
	1	5.5	0.055	4.0	0.04
LH-729130	100	0.9	0.9	0.4	0.4

8-ch 10-100	50	1.2	0.6	0.6	0.3
	10	4.0	0.4	2.0	0.2
LH-729140 8-ch 30-300	300	0.6	1.8	0.25	0.75
	150	1.0	1.5	0.4	0.6
	30	3.0	0.9	1.0	0.3
LH-729220 12-ch 1-10	10	1.5	0.15	1.0	0.1
	5	2.5	0.125	2.0	0.1
	1	5.5	0.055	4.0	0.04
LH-729230 12-ch 10-100	100	0.9	0.9	0.4	0.4
	50	1.2	0.6	0.6	0.3
	10	4.0	0.4	2.0	0.2
LH-729240 12-ch 30-300	300	0.6	1.8	0.25	0.75
	150	1.0	1.5	0.4	0.6
	30	3.0	0.9	1.0	0.3

¹ The values provided for systematic and random errors apply specifically to the pipettes mentioned, when used in conjunction with compatible Sartorius Optifit non-sterile tips. These values can be attained only under strictly controlled conditions, such as during type examinations conducted in accordance with ISO 8655 standards. When the mentioned pipettes are used with other Sartorius tips, they meet the specifications outlined in ISO 8655.

Proline Plus:

Proline Plus maximum permissible error limits (8655:2022)					
Model	Volume	Systematic ¹		Random ¹	
	μL	%	μL	%	μL
728010 1-ch 0.3-3μL	3	1.6	0.048	0.8	0.024
	1.5	3.0	0.045	1.6	0.024
	0.3	12.0	0.036	6.0	0.018
728020 1-ch 1-10μL	10	1.0	0.1	0.6	0.06
	5	1.5	0.075	1.0	0.05
	1	3.0	0.03	2.0	0.02
728030 1-ch 2-20μL	20	1.0	0.2	0.4	0.08
	10	1.5	0.15	0.7	0.07
	2	6.0	0.12	3.0	0.06
728040 1-ch 5-50μL	50	1.0	0.5	0.3	0.15
	25	1.6	0.4	0.5	0.125
	5	5.0	0.25	1.5	0.075
728050 1-ch 10-100μL	100	0.8	0.8	0.2	0.2
	50	1.0	0.5	0.3	0.15
	10	3.0	0.3	1.0	0.1
728060 1-ch 20-200μL	200	0.6	1.2	0.2	0.4
	100	1.0	1	0.3	0.3
	20	2.5	0.5	0.9	0.18
728070 1-ch 100-1000μL	1000	0.7	7	0.2	2
	500	0.9	4.5	0.2	1
	100	3.0	3	0.6	0.6
728080 1-ch 500-5000μL	5000	0.6	30	0.2	10
	2500	0.7	17.5	0.25	6.25
	500	2.4	12	0.6	3
728090 1-ch 1000-10000μL	10000	0.6	60	0.2	20
	5000	1.2	60	0.3	15
	1000	3.0	30	0.6	6

728120	10	1.5	0.15	1.0	0.1
8-ch	5	2.5	0.125	2.0	0.1
1-10	1	5.5	0.055	4.0	0.04
728130	100	0.9	0.9	0.4	0.4
8-ch	50	1.2	0.6	0.6	0.3
10-100	10	4.0	0.4	2.0	0.2
728140	300	0.6	1.8	0.25	0.75
8-ch	150	1.0	1.5	0.4	0.6
30-300	30	3.0	0.9	1.0	0.3
728220	10	1.5	0.15	1.0	0.1
12-ch	5	2.5	0.125	2.0	0.1
1-10	1	5.5	0.055	4.0	0.04
728230	100	0.9	0.9	0.4	0.4
12-ch	50	1.2	0.6	0.6	0.3
10-100	10	4.0	0.4	2.0	0.2
728240	300	0.6	1.8	0.25	0.75
12-ch	150	1.0	1.5	0.4	0.6
30-300	30	3.0	0.9	1.0	0.3

¹ The values listed for the systematic and random errors are valid for listed pipettes used in combination with suitable Sartorius Optifit non-sterile tips and can only be achieved under strictly controlled conditions during type examinations in accordance with ISO 8655. The listed pipettes with other Sartorius tips fulfill specifications listed in ISO 8655

Proline:

Proline maximum permissible error limits (8655:2022)					
Model	Volume	Systematic ¹		Random ¹	
	μL	%	μL	%	μL
720010 1-ch 0.25-2.5μL	2.5	3.0	0,075	2.4	0.06
	1.25	5.0	0.0625	4.0	0.05
	0.25	18.0	0.045	14.0	0.035
720015 1-ch 1-10μL	10	1.2	0.12	0.8	0.08
	5	2.0	0.1	1.5	0.075
	1	6.0	0.06	5.0	0.05
720080 1-ch 2-20μL	20	1.0	0.2	0.5	0.1
	10	1.7	0.17	0.9	0.09
	2	7.5	0.15	4.0	0.08
720025 1-ch 5-50μL	50	1.0	0.5	0.4	0.2
	25	1.8	0.45	0.7	0.175
	5	8.0	0.4	3.0	0.15
720050 1-ch 10-100μL	100	0.8	0.8	0.3	0.3
	50	1.2	0.6	0.5	0.25
	10	4.5	0.45	2.0	0.2
720070 1-ch 20-200μL	200	0.8	1.6	0.3	0.6
	100	1.2	1.2	0.4	0.4
	20	4.0	0.8	1.3	0.26
720060 1-ch 100-1000μL	1000	0.8	8	0.3	3
	500	1.2	6	0.4	2
	100	4.0	4	1.2	1.2
720110 1-ch 1000-5000μL	5000	0.8	40	0.3	15
	2500	1.0	25	0.4	10
	1000	2.0	20	0.7	7
720210 8-ch 1-10μL	10	2.4	0.24	1.6	0.16
	5	4.0	0.2	2.8	0.14
	1	12.0	0.12	8.0	0.08

720220 8-ch 5-50µL	50	1.5	0.75	0.7	0.35
	25	2.5	0.625	1.2	0.3
	5	10.0	0.5	5.0	0.25
720240 8-ch 50-300µL	300	0.9	2.7	0.35	1.05
	150	1.3	1.95	0.6	0.9
	50	2.8	1.4	1.4	0.7
720310 12-ch 1-10µL	10	2.4	0.24	1.6	0.16
	5	4.0	0.2	2.8	0.14
	1	12.0	0.12	8.0	0.08
720320 12-ch 5-50µL	50	1.5	0.75	0.7	0.35
	25	2.5	0.625	1.2	0.3
	5	10.0	0.5	5.0	0.25
720340 12-ch 50-300µL	300	0.9	2.7	0.35	1.05
	150	1.3	1.95	0.6	0.9
	50	2.8	1.4	1.4	0.7

¹ The values listed for the systematic and random errors are valid for listed pipettes used in combination with suitable Sartorius Optifit non-sterile tips and can only be achieved under strictly controlled conditions during type examinations in accordance with ISO 8655. The listed pipettes with other Sartorius tips fulfill specifications listed in ISO 8655

Appendix 3: Tacta, Proline Plus, Mline, and Proline Quality Control Certificates

Quality Control certificate for mechanical pipettes before the change:

SARTORIUS

Quality Control Certificate

000200122895

**Tacta® Mechanical 1- channel
Pipette 100-1,000 µl**

Serial Number: 43787039

Mode: P	Volume: 100,0 µl
Mean:	100,0 µl
Inaccuracy:	0,05 %
Imprecision:	0,34 %

Date:	9-February-2023 11:23:09
According to:	ISO 8655; 20 °C
Tested by:	TaH

This is an electronic document and valid without signature

Sartorius Biohit Liquid Handling Oy
Laippatie 1, FI-00880 Helsinki, Finland

1000086591

Quality Control certificate for mechanical pipettes after the change:

SARTORIUS

Quality Control Certificate

Certificate number:
123456789012

Tacta Mech. Pipette, 1-ch, 100-1000 µl

Serial number:
1234567890

Volume µl	Mode	Channel	Mean µl	Systematic error µl	Systematic error %	Random error µl	Random error %
100	P	1	100,1	+0,1	+0,1	0,21	0,2

Date:

11-May-2024 13:23:45

Tested by:

JKy

Test method:

ISO 8655-7:2022, A.2

Ex (20°C)

Number of measurements:

5 / Volume without tip change

Tips used:

Sartorius

791000

Test conditions:

20,1 °C

1013 hPa

55,1 %-RH

This is an electronic document and valid without signature

WARRANTY

Sartorius products are meant to be used as described in the user manual. Sartorius Mechanical pipettes are covered by a two-year warranty against defects in workmanship and materials.

ANY WARRANTY WILL, HOWEVER, BE DEEMED AS VOID IF THE FAULT IS FOUND TO HAVE BEEN CAUSED BY MISTREATMENT, MISUSE, UNAUTHORIZED MAINTENANCE OR SERVICE, NEGLIGENCE OF REGULAR MAINTENANCE AND SERVICE, ACCIDENTAL DAMAGE, INCORRECT STORAGE, OR USE OF THE PRODUCT FOR OPERATIONS OUTSIDE THEIR SPECIFIED LIMITATIONS, OUTSIDE THEIR SPECIFICATIONS, CONTRARY TO THE INSTRUCTIONS GIVEN IN THE USER MANUAL, OR WITH TIPS OTHER THAN THE MANUFACTURER'S ORIGINAL ONES.

User manual is available at the following internet address:
<https://www.sartorius.com/en/pr/certificates-and-technical-documents>

Sartorius Biohit Liquid Handling Oy
Läppatie 1, FI-00880 Helsinki, Finland
www.sartorius.com

Appendix 4: Please refer to the attached document.