Demo Laboratory (sample) Quality Control - balance room 2

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User: Demo Admin

Validation pack

SAMPLE - demo laboratory, made with demo values · The UP^SCALE system: weighing data, users, audit trail, signatures, records · Pipette check and pipette calibration · Compounding assistant and solution mode · Routine check before use, minimum weight and air buoyancy correction · Fill weighing and the check of prepackages (e, NIST HB 133) · Density mode (Archimedes) · LIMS / ELN forwarding

System	SAMPLE - demo laboratory, made with demo values
UP^SCALE	UP^SCALE (DIY) #76439 (DIY) · E83DC1241BB0
Versions	App 1.01312 · Firmware 1.01312
Document	UPSCALE-VALPACK-1 · 11/9/2026, 4:57:17 AM · Demo Admin
Status	draft until it is signed (chapter 14)

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1 Purpose, scope and intended use

This pack documents the validation of the UP^SCALE system in your laboratory: the UP^SCALE (scale or RS-232 adapter with your balance), its firmware and the UP^SCALE app on the devices you use. It shows that the system is installed as described (IQ), works as specified (OQ) and gives correct results under your conditions (PQ).

Fill in the blank fields, attach the records named in the tests, assess every deviation and sign chapter 14. The release for use follows with the Validation Summary Report (VSR) of the app.

Chapters in this pack: The UP^SCALE system: weighing data, users, audit trail, signatures, records · Pipette check and pipette calibration · Compounding assistant and solution mode · Routine check before use, minimum weight and air buoyancy correction · Fill weighing and the check of prepackages (e, NIST HB 133) · Density mode (Archimedes) · LIMS / ELN forwarding

Intended use

* Weighing with records: every value comes from the balance, is recorded with its user, time and reason and cannot be changed unnoticed.

* Records and reports for work under ISO/IEC 17025, GLP / GMP and 21 CFR Part 11: audit trail, users with roles, electronic signatures, sealed reports.

* Pipette check: an intermediate check of piston pipettes between their calibrations (ISO/IEC 17025, 6.4.10) - systematic and random error against the limits, PASS or FAIL.

* Pipette calibration: the gravimetric calibration of piston pipettes along ISO 8655-6:2022 with the uncertainty of every volume along ISO/TR 20461:2023, the CMC of the lab and a decision rule; the pipette register with its records.

* Dispensers and piston burettes: the same check and calibration for bottle-top and repeating dispensers (ISO 8655-5) and piston burettes (ISO 8655-3), with the limits of their standards.

* Compounding assistant: batches of a master formula guided step by step by the UP^SCALE - lots, use-by dates and identity check of the raw materials, weighing to the goal, checks, in-process controls, filling with the uniformity of mass (Ph. Eur. 2.9.5) - into a sealed batch record that two people sign, and the label.

* Solution mode: standard and stock solutions in fixed proportions, with the recalculation of the other goals and a signed report.

* Routine check before use with known weights along a profile you choose (Lab: USP <41>, Lab: Ph. Eur. 2.1.7, trade, industry QA, quick check, own SOP): PASS or FAIL, a reminder when it is due and a warning on every device after a failure.

* The minimum weight warning (USP <41>) and, where you use it, the air buoyancy correction: the true mass next to the reading.

* Fill weighing against a nominal quantity with the e rules (76/211/EEC, German FPackV), NIST Handbook 133 or an own tolerance, with live statistics and a report of every fill; the lot check of the closed packs with its sample plan.

* Density of solids by weighing in air and in a liquid (Archimedes), water by its temperature, with the air term when the air buoyancy correction is on; the uncertainty from the resolution of the balance.

* The app sends the events you choose (activity log, weighings, sealed files, batches, the status for use, validation runs, live weight) as JSON to a server of your laboratory, and sends them again later when it was not reachable.

Not covered by this pack

* The metrology of the balance itself: its calibration certificate and the test suite of the app (PQ, chapter 10).

* Your procedures: SOPs, training, the identity check of the users, the storage, backups and time servers of your IT.

* The pipetting technique of the operators and the environment control of the room.

* Functions you do not use: leave their tests out and say so in chapter 14.

2 System description

App version	1.01312
App code fingerprint (SHA-256)	9b73d70ee8af5815f1de2a5163f19e94b5590e1d73f34a0dea7d39a8342c9228
UP^SCALE	UP^SCALE (DIY) #76439 (DIY)
Device ID	E83DC1241BB0
Edition	ENTERPRISE & COMPLIANCE
Firmware	1.01312
Firmware fingerprint (SHA-256 of the build)	fe7d35bb22604a7ac91aa65859a2d87ddad155a00d3fc2073b044b15f5525cb0
Weighing range (scale data)	Max 120 g · d 10 µg

Instrument, counters, certificate data	Firmware 1.01312 configuration counter 40
Equipment register entry	-
Users and audit	users with roles
Qualified devices (phones / PCs)	0 of 0 devices qualified
Browser of this device	Mozilla/5.0 (X11; Linux x86_64) AppleWebKit/537.36 (KHTML, like Gecko) Chrome/157.0.0.0 Safari/537.36
Validation of the calculations	Validation of the calculations on this device, 11/9/2026, 4:57:09 AM: 304 cases passed, 0 failed.

Pipette check and pipette calibration

Balance (lab settings)	Semi-micro balance 120 g / d 0.01 mg (demo, inv. no. DEMO-B01) · Calibration certificate DEMO-2026-0412 of 2026-03-02
Instruments (lab settings)	Water thermometer: Water thermometer, resolution 0.1 °C (demo, DEMO-T01) · Calibration certificate DEMO-2026-0388 of 2026-02-17 Barometer: Barometer, resolution 1 hPa (demo, DEMO-P01) · Calibration certificate DEMO-2026-0389 of 2026-02-17 Hygrometer: Hygrometer, resolution 1 %RH (demo, DEMO-H01) · Calibration certificate DEMO-2026-0390 of 2026-02-17
Standard uncertainties of the instruments (k = 1)	u(water) 0.1 °C · u(air) 0.15 °C · u(p) 5 hPa · u(RH) 2.5 %
The runs	check 4 / calibration 10 deliveries per volume · evaporation 60 s · room reference 20 °C · water air-saturated
Decision rule	simple acceptance (|e| <= limit) · k = 2
Limits of ISO 8655-2	ISO 8655-2 - app table (secondary sources) SHA-256 3cba194d8834724b2324b9b78b70347c88e74148c12e8bbadcf7ee6ab608c849
CMC table (version in use)	-
Pipette register	5 pipettes in the register (without the retired ones)

3 Validation approach and acceptance criteria

Risk-based, along GAMP 5 (second edition) and ISO/IEC 17025:2017, 7.11.2: the effort follows the risk of each function for your results and your data (chapter 6). Your laboratory decides the GAMP category of the system; for a configured product with its own calculations, category 4 is a common choice.

The supplier gives the structure, the reference cases and the test scripts; your laboratory executes the tests, records what it observed, assesses deviations and approves the result.

Acceptance criteria

* IQ: every check met, or the deviation is assessed and accepted.

* OQ part A: every reference case of chapter 8 passed on this device.

* OQ part B: every test of chapter 9 shows the expected result; a different result is a deviation (chapter 14).

* PQ: the results of chapter 10 within your acceptance limits (pipettes: En <= 1).

* Every deviation documented, assessed and closed before the release.

4 References

* ISO/IEC 17025:2017 - General requirements for the competence of testing and calibration laboratories (6.4 equipment, 6.4.10 intermediate checks, 7.11 control of data and information management)

* US FDA 21 CFR Part 11 - Electronic records; electronic signatures

* EudraLex Volume 4, Annex 11 - Computerised systems (2011)

* ISPE GAMP 5: A risk-based approach to compliant GxP computerized systems, second edition (2022)

* OECD Series on Principles of Good Laboratory Practice No. 17 - Application of GLP principles to computerised systems (2016)

* PIC/S PI 041-1 - Good practices for data management and integrity in regulated GMP/GDP environments (2021)

* OIML R 76-1:2006 - Non-automatic weighing instruments (the test suite of the app)

* USP <41> Balances and USP <1251> Weighing on an analytical balance (the routine check of the app)

* EURAMET Calibration Guide No. 18, version 4.0 (2015) - Calibration of non-automatic weighing instruments

* In the US: 21 CFR 211.68 and 211.160 (GMP), 21 CFR Part 58 (GLP), 42 CFR Part 493 (CLIA)

* ISO 8655-1:2022 - Piston-operated volumetric apparatus - Part 1: Terminology, general requirements and user recommendations

* ISO 8655-2:2022 - Part 2: Pipettes (the maximum permissible errors)

* ISO 8655-6:2022 (corrected version 2022-06) - Part 6: Gravimetric reference measurement procedure for the determination of volume

* ISO/TR 20461:2023 - Determination of uncertainty for volume measurements made using the gravimetric method

* JCGM 100:2008 (GUM) - Evaluation of measurement data, guide to the expression of uncertainty in measurement; JCGM 200:2012 (VIM)

* ILAC P14:09/2020 - ILAC policy for measurement uncertainty in calibration

* ILAC G8:09/2019 - Guidelines on decision rules and statements of conformity

* EURAMET Calibration Guide No. 19, version 4.1 (12/2025) - Guidelines on the determination of uncertainty in gravimetric volume calibration

* NIST IR 7383 (2019), SOP 14 - Gravimetric calibration of volumetric standards using an electronic balance

* M. Tanaka, G. Girard, R. Davis, A. Peuto, N. Bignell: Recommended table for the density of water between 0 °C and 40 °C based on recent experimental reports, Metrologia 38 (2001) 301-309

* OIML R 111-1:2004 - Weights of classes E1 ... M3, annex E (air density)

* ISO 3696:1987 - Water for analytical laboratory use

* European Pharmacopoeia (Ph. Eur.) 2.9.5 - Uniformity of mass of single-dose preparations (the edition your laboratory follows)

* EudraLex Volume 4, Part I, Chapter 4 - Documentation (2011)

* PIC/S PE 010-4 (1 March 2014) - Guide to good practices for the preparation of medicinal products in healthcare establishments

* USP <795> Pharmaceutical compounding - nonsterile preparations (official 1 November 2023)

* In the US: 21 CFR 211.101 (charge-in of components) and 211.188 (batch production and control records)

* In Germany: Apothekenbetriebsordnung (ApBetrO), § 7 Rezepturarzneimittel and § 8 Defekturarzneimittel

* European Pharmacopoeia (Ph. Eur.) 2.1.7 - Balances for analytical purposes (the edition your laboratory follows)

* OIML D 28:2004 - Conventional value of the result of weighing in air (the air buoyancy correction)

* Council Directive 76/211/EEC of 20 January 1976 on the making-up by weight or by volume of certain prepackaged products

* Germany: Fertigpackungsverordnung (FPackV) of 18 November 2020

* NIST Handbook 133-2026 - Checking the net contents of packaged goods (Category A)

* OIML R 87:2016 - Quantity of product in prepackages

* IETF RFC 8259 (2017) - The JavaScript Object Notation (JSON) data interchange format

* IETF RFC 9110 (2022) - HTTP semantics

* NIST FIPS 180-4 (2015) - Secure Hash Standard (SHA-256)

* EudraLex Volume 4, Annex 11 (2011), clause 5 - Data exchanged with other systems

* MHRA GXP Data Integrity Guidance and Definitions, revision 1 (March 2018)

Editions as used for this version of the app. The limits of ISO 8655-2 in the app come from public secondary sources unless your laboratory typed its own table (chapter 2). UP^SCALE is not affiliated with ISO, OIML, EURAMET, NIST, ILAC, ISPE or any authority.

5 Requirements and their tests

The requirements of the intended use and the tests that show them. Add your own requirements at the end and give each one a test.

ID	Requirement	Shown by
URS-01	The recorded weight is the weight the balance shows (same digits, unit, stable mark).	IQ-04, OQ-F01
URS-02	The calculations of the app and the firmware are correct.	OQ part A
URS-03	Only users with a login work; a role limits what each one may do.	IQ-06, IQ-07, OQ-F03, OQ-F04
URS-04	Every change of a setting or a record is in the audit trail: who, when, what (old and new value) and why.	OQ-F02
URS-05	Electronic signatures carry the name, date, time and meaning and stay linked to their record.	OQ-F05
URS-06	A saved record or report cannot be changed unnoticed.	OQ-F06
URS-07	Records can be exported and archived in a readable form.	OQ-F07, IQ-10
URS-08	Time stamps are right.	IQ-08, OQ-F08
URS-09	A power cut loses no record and does not break the audit trail.	OQ-F09
URS-10	The software in use is the validated version.	IQ-01, IQ-02, chapter 13
URS-P1	Volumes by the gravimetric procedure of ISO 8655-6:2022: Z factor, evaporation, the conditions at the start and the end.	OQ part A (PIP), OQ-P02, OQ-P05
URS-P2	Systematic and random error against the limits, PASS / FAIL by the decision rule of the lab.	OQ part A (PIP, MPE, LIM), OQ-P03
URS-P3	The uncertainty of every volume along ISO/TR 20461:2023; the reported U never below the CMC.	OQ part A (PIP, CMC), OQ-P07
URS-P4	The balance and the instruments are suitable (ISO 8655-6:2022 tables 1 and 2); a deviation from the standard is shown on the report.	IQ-P1 ... IQ-P3, OQ part A (BAL, DEV), OQ-P06
URS-P5	Every delivery is taken from the balance; an implausible value is kept or redone with a reason.	OQ-P01, OQ-P04
URS-P6	Each run is kept in the register with all values; the due dates follow; old data can be imported with an import record.	OQ-P08, OQ-P09
URS-P7	Multichannel pipettes: every channel tested and named on the report.	OQ-P10
URS-P8	The results agree with an external calibration under the conditions of the lab.	PQ-P1
URS-C1	Only the approved version of a master formula (rows, SOP, process plan) runs; a change needs a new approval.	IQ-C2, OQ-C01
URS-C2	An expired or locked lot blocks the start; a weigh step opens only for a container with an approved code and the lot of the batch, or a confirmed label.	IQ-C1, OQ-C02
URS-C3	Every ingredient is weighed to its goal within its tolerance; only a stable value is taken, with user and time.	OQ part A (SOL), OQ-C03, OQ-C08
URS-C4	A value over its goal needs a QM release (another user, password, reason) or a recalculation of the other goals; both are in the batch record.	OQ-C04, OQ-C08
URS-C5	A NO to a check or an in-process value out of its tolerance needs a reason and is a deviation in the batch record.	OQ-C05
URS-C6	The uniformity of mass along Ph. Eur. 2.9.5 is right.	OQ part A (UM), OQ-C06
URS-C7	The batch record is complete, sealed and signed by the operator and by a QM who did not make it; the label shows the batch number and the use-by date.	IQ-C3, OQ-C07, PQ-C1
URS-C8	A tolerance the balance cannot resolve (narrower than d at the batch size) is flagged by the UP^SCALE before the start, and the batch record names the band that was accepted.	OQ part A (SOL), OQ-C09
URS-R1	Repeatability and accuracy (or sensitivity) are judged by the limits of the profile: PASS or FAIL.	OQ part A (RT), OQ-R01, OQ-R02
URS-R2	Every value comes from the balance when it is stable, minus the empty plate before it.	OQ-R01
URS-R3	After a failed check every device shows NOT RELEASED FOR USE until a check passes or an ADMIN removes the warning with a reason; a due check is shown too.	OQ-R03, OQ-R04

ID	Requirement	Shown by
URS-R4	A weight below the minimum weight is recorded only after a warning, and then logged.	IQ-R2, OQ-R05
URS-R5	Checks, removed warnings and changes of these settings are recorded (activity log, sealed PDF).	OQ-R06
URS-R6	The true mass is worked out from the density of the THING and the air density; the reading stays unchanged.	IQ-R3, OQ part A (AB), OQ-R07
URS-W1	The limits of the rule are right: TNE, T1, T2; MAV and moisture allowance; own - / +.	OQ part A (FE, FM, HB), OQ-W01
URS-W2	Every fill is judged and shown: orange under, yellow between T1 and the nominal, green in the tolerance, red over.	OQ part A (FS), OQ-W02
URS-W3	Only a stable fill is taken; one outside the limits only after a confirmation.	OQ-W03
URS-W4	Statistics and verdict of the run are right; the run goes on after a reload, on another device and after a restart.	OQ-W04, OQ-W05
URS-W5	The report names the rule and its limits and lists every bag with time, weight and deviation.	OQ-W06
URS-W6	A lot of closed packs is checked with the sample plan of the rule.	IQ-W1, OQ-W07, PQ-W1
URS-D1	Both weights come from the balance, taken when stable and after a zero.	OQ-D01
URS-D2	The liquid density is right: water from the table of the firmware (0 ... 40 °C), the listed liquids, an own value.	OQ part A (DEN), OQ-D02
URS-D3	Density, volume, uncertainty and the air term are right; an implausible measurement is shown.	OQ part A (DEN, AB), OQ-D03, OQ-D04
URS-D4	The result agrees with a body of known density.	OQ-D05, PQ-D1
URS-D5	Results can be copied into your records and saved as a THING.	IQ-D2, OQ-D06
URS-L1	Only the chosen events go to your https address, with your token.	IQ-L1, OQ-L01
URS-L2	Every event has a fixed id, device, UP^SCALE, user and time, so a double can be dropped.	OQ-L01, OQ-L05
URS-L3	The values equal the records: weight, unit, user, time, below the minimum weight.	OQ-L03
URS-L4	Lines of the activity log come with sequence number and chain hash; missed lines follow.	IQ-L3, OQ-L02
URS-L5	Sealed files come with their SHA-256 and the seal.	OQ-L04
URS-L6	When the server is not reachable, events wait and go again in order; a warning shows.	OQ-L05
URS-L7	Batches, solutions, routine checks and validation runs arrive as structured records.	OQ-L06, OQ-L07

6 Risk assessment

Pre-filled by UP^SCALE as a starting point: confirm or change the ratings for your use (H high, M medium, L low) and write your own rating in the last column.

Function	Possible failure	Effect	Severity	Likelihood	Control in the system	Tested by	Your rating
Reading the balance	a wrong or rounded value is recorded	wrong result	H	L	the value of the balance line with its digits; stable mark	OQ-F01	
Calculations	a wrong formula or limit	wrong result	H	L	reference cases worked out by hand	OQ part A	
Audit trail	a change is not recorded	data integrity	H	L	hash-chained activity log in the scale	OQ-F02	
Access control	an unauthorised person changes data	data integrity	H	M	users, roles, lockout	OQ-F03, OQ-F04	
Electronic signatures	a signature is not linked to its record	data integrity	H	L	signed with the number and code of the report	OQ-F05	
Records and reports	a record is changed after saving	data integrity	H	L	seal and integrity code	OQ-F06	

Function	Possible failure	Effect	Severity	Likelihood	Control in the system	Tested by	Your rating
Power cut	a record is lost or the log is broken	data loss	M	M	repair of the log at the start	OQ-F09	
Time stamps	a wrong time in the records	data integrity	M	M	clock of the scale, device qualification	OQ-F08	
Taking a delivery	an unstable or wrong value is taken	wrong volume	H	L	stable hold, plausibility check, KEEP / REDO	OQ-P01, OQ-P04	
Conditions (Z factor)	wrong temperatures or pressure	small volume error	M	M	asked at the start and the end; deviations listed	OQ-P02, OQ-P06	
Limits	a wrong limits table	wrong verdict	H	M	the source of the limits on every report	OQ-P03, IQ-P4	
Uncertainty and CMC	U smaller than the CMC	wrong statement	M	L	reported U = max(U, CMC)	OQ-P07	
Balance suitability	d too coarse for the volume	wrong volume	H	L	a calibration does not start	OQ-P06, IQ-P3	
Due dates	an overdue pipette is used	wrong results in the lab	M	M	due list, stickers, status	OQ-P08	
Data migration	an import changes data	wrong register	M	M	preview and import record with SHA-256	OQ-P09	
Identity of the raw materials	a wrong container or lot is used	wrong product	H	M	identity check of the code, its lot and use-by date; wrong scans recorded	OQ-C02	
Lots and use-by dates	an expired or locked lot is used	wrong product	H	L	start blocked; the UP^SCALE checks the dates with its own clock	OQ-C02	
Weighing	a wrong amount is taken	wrong product	H	L	tolerance per ingredient, stable value only	OQ-C03	
Value over its goal	it is accepted without review	wrong product	H	M	QM release with a reason, or recalculation; both in the batch record	OQ-C04	
Master formula	a changed formula runs	wrong product	H	L	a change needs a new approval	OQ-C01	
Batch record	it is incomplete or changed	data integrity	H	L	made by the UP^SCALE, seal, four eyes	OQ-C07	
Tolerance narrower than d	a row is accepted outside its tolerance	wrong product	H	L	the UP^SCALE flags the row, the app warns and asks at the start, the batch record names the accepted band	OQ-C09	
Verdict of the check	a wrong formula or limit	a faulty balance is used	H	L	reference cases; every value, mean and s shown	OQ part A (RT), OQ-R01	
Test weights	a wrong value typed or a weight out of tolerance	wrong verdict	M	M	a note when the weight tolerance is over a third of a limit	IQ-R1, OQ-R02	
Failed or due check	it is ignored	results from an unchecked balance	H	M	bars on every device; only an ADMIN removes a warning, with a reason, logged	OQ-R03, OQ-R04	
Minimum weight	a weighing below it is recorded	relative error too big	H	M	warning first, entry in the activity log	OQ-R05	
Air buoyancy	a wrong density or air density	small mass error	M	L	no correction without a density; the reading is kept; changes logged	OQ-R07	
Limits of the rule	a wrong TNE or MAV	packs short or overfilled	H	L	reference cases; the limits on the report	OQ part A, OQ-W01	
Taking a fill	an unstable or wrong value	wrong statistics	M	L	stable value only; confirmation outside the limits; UNDO	OQ-W03	
Verdict	a wrong verdict for the run	packs short	H	L	reference cases; every bag on the report	OQ-W04	

Function	Possible failure	Effect	Severity	Likelihood	Control in the system	Tested by	Your rating
Open bags	content is lost before the bag is closed	packs short	M	M	a note that this is not the e control; the lot check of the closed packs	OQ-W07	
Balance	not verified, used for packs sold by quantity	legal risk	H	M	your procedure (the 420 and 710 are not verified)	IQ-W1	
Readings	an unstable value or a wrong zero	wrong density	H	L	taken when stable; waits for the zero	OQ-D01	
Liquid	a wrong water temperature or liquid	small density error	M	M	the liquid density is in the saved result	IQ-D1, OQ-D02	
Handling	bubbles; the item touches the container	wrong density	H	M	warnings; MEASURE AGAIN	OQ-D04, PQ-D1	
Record	kept only in the browser, without user or seal	data integrity	M	M	COPY TABLE into your record	IQ-D2, OQ-D06	
App not open	closed, or the device sleeps	weighings missing on the server	M	M	activity log and sales catch up; one fixed lab computer	IQ-L2, OQ-L02	
Server not reachable	queue full, the oldest events dropped	records missing	M	L	1000 events wait, sent in order, red bar; the records stay in the UP^SCALE	OQ-L05	
Transfer	a value differs, or an event comes twice	wrong data in the LIMS	H	L	values of the record as JSON; fixed id	OQ-L03, OQ-L05	
Files	changed on the way	data integrity	M	L	SHA-256 and the seal of the UP^SCALE	OQ-L04	
Settings	switched off or queue emptied unnoticed	records missing	M	M	a gap in the sequence numbers of the activity log	IQ-L3, OQ-L02	

7 Installation qualification (IQ)

The app fills in what it knows from this device and marks it; "by the tester" means: check it and write down what you found.

ID	Check	Expected	Found	Result	Initials / date
IQ-01	App version and code fingerprint	recorded; the same as in the validation run of chapter 8	1.01312 · 9b73d70ee8af5815f1de2a5163f19e94b5590e1d73f34a0dea7d39a8342c9228	met	
IQ-02	Firmware and its fingerprint	recorded; the version you planned to validate	1.01312 · fe7d35bb22604a7ac91aa65859a2d87ddad155a00d3fc2073b044b15f5525cb0	met	
IQ-03	Edition and Device ID of the UP^SCALE	ENTERPRISE & COMPLIANCE on the UP^SCALE of this pack	ENTERPRISE & COMPLIANCE · E83DC1241BB0	met	
IQ-04	Balance connected, weighing range and d	the range and d of the balance (its display or data sheet)	Max 120 g · d 10 µg	met	
IQ-05	Identity and calibration certificate of the balance	entered in the certificate data; the certificate is valid	Firmware 1.01312 configuration counter 40	by the tester	
IQ-06	Users and audit	users with roles; strict audit if your procedure asks for reasons	users with roles	met	
IQ-07	Every person has a user of their own; the user access register is up to date and reviewed	yes (user access register, signed)		by the tester	
IQ-08	Devices (phones / PCs) that keep records are qualified (clock, storage)	every device in use is qualified	0 of 0 devices qualified	by the tester	
IQ-09	The seal of the UP^SCALE checks on the public check page	a sealed report of this UP^SCALE checks as valid		by the tester	
IQ-10	Backup: archive of the activity log and the record files on your storage	saved where your procedure says		by the tester	
IQ-P1	Balance, thermometers, barometer and hygrometer entered with their certificates (lab settings)	all entered	all entered with a certificate	met	
IQ-P2	The uncertainties of the instruments	within ISO 8655-6:2022 table 2	within ISO 8655-6:2022 table 2	met	

ID	Check	Expected	Found	Result	Initials / date
IQ-P3	The d of the balance for the instruments in the register (pipettes, dispensers, burettes)	fine enough (ISO 8655-6:2022 table 1)	d 0.0100 mg - fine enough for all 5 instruments (pipettes, dispensers, burettes)	**met**	
IQ-P4	Lab settings reviewed: limits table, decision rule, k, reference temperature, water	as your procedure says	ISO 8655-2 - app table (secondary sources) · simple acceptance (|e| <= limit)	by the tester	
IQ-P5	CMC table in use (accredited laboratories)	the version of your scope	-	by the tester	
IQ-C1	THINGS of the ingredients with approved codes and label names; lots with use-by dates in the lot store	entered and checked against the containers		by the tester	
IQ-C2	Formulas approved by a QM; the protection "only approved recipes can run"	as your procedure says		by the tester	
IQ-C3	At least one QM besides the operators; label printer; storage of the sealed batch records outside the browser	as your procedure says		by the tester	
IQ-R1	Profile, test weights with certificates, weight tolerance (self-check data), smallest net weight, minimum interval	as your procedure says		by the tester	
IQ-R2	Minimum weight of the balance (SCALE DATA block)	the value of its certificate or qualification		by the tester	
IQ-R3	Air buoyancy correction, if used: the air density at the balance and the densities of the THINGS	set; the block shows when and by whom		by the tester	
IQ-W1	Balance for packs sold by quantity: verified (legal for trade) where your national rules ask for it	balance and its verification recorded		by the tester	

ID	Check	Expected	Found	Result	Initials / date
IQ-W2	Rules, nominal quantities, tolerances, label unit and moisture allowance (HB 133)	as your procedure says		by the tester	
IQ-W3	The d of the balance (HB 133: at most MAV / 6); bag THINGS and the label setup	checked on a test label		by the tester	
IQ-D1	Calibrated thermometer; water quality; density of an own liquid; string, container and stand	as your procedure says		by the tester	
IQ-D2	Where the results are recorded (the browser keeps the last 30, without user)	written in your procedure		by the tester	
IQ-L1	Receiver: https, token, CORS headers, a 2xx answer, POST size for files; a store where entries are only added	TEST answers OK		by the tester	
IQ-L2	One forwarding app only, on a qualified device next to the UP^SCALE that stays open and connected	named in your procedure		by the tester	
IQ-L3	Events ticked; the receiver drops doubles and checks the sequence and the chain of the activity log	as your procedure says		by the tester	

8 Operational qualification (OQ), part A: the calculations

The reference cases are worked out by hand from the standards named in each case and computed on this device by the code that judges the results: the cases of the tests and of the pipettes by the firmware of the connected UP^SCALE, the others by this app. The working of every case is public on up-scales.com/check.

A different app or firmware gives a different fingerprint (chapter 2): run the validation again after every update (chapter 13).

Validation of the calculations on this device, 11/9/2026, 4:57:09 AM: 304 cases passed, 0 failed.

Area	Cases	Passed	Failed
Scale test suite (OIML R 76-1)	98	98	0
Routine check (USP <41>)	7	7	0
Air buoyancy (OIML D 28 / R 111)	8	8	0
Uniformity of mass (Ph. Eur. 2.9.5)	7	7	0
Rounding of money (DIN 1333)	7	7	0
Package checks (NIST HB 133)	29	29	0
Density mode	8	8	0
Fill weighing (e, HB 133)	32	32	0
Pipettes: density, Z, volumes, uncertainty, decision rule	30	30	0
Recipes, solutions, compounding: goals, recalculation, state of a row	16	16	0
Units (the legal definitions of oz, lb, ozt, gr, tola, dwt, ct)	11	11	0
Pipettes: limits (ISO 8655-2) and the lab table	21	21	0
Statistics page (also NIST StRD)	6	6	0
Pipettes: balance requirements (ISO 8655-6 table 1)	7	7	0
Pipettes: deviations from ISO 8655-6	6	6	0
Pipettes: CMC and the reported U	11	11	0

Every case with its expected and calculated value: annex A.

9 Operational qualification (OQ), part B: test scripts

Run each test with the equipment of your laboratory, write down what you observed, mark pass or fail and sign it. Attach the records the test names (printouts, PDFs, screenshots).

Use a test user or a test pipette where a test changes data, and note them in chapter 14.

The UP^SCALE system: weighing data, users, audit trail, signatures, records

ID	Test and steps	Expected result	Observed	Pass / fail	Initials / date
OQ-F01	Weighing data path Put three test weights one after the other on the balance (small, middle, near Max), wait for the stable value and save a record each; then press on the pan (unstable) and save.	Each saved value equals the display of the balance (digits and unit); an unstable reading is not saved as stable.			
OQ-F02	Audit trail Change a setting that changes the weight or the records (e.g. the minimum weight) and give a reason; open the activity log.	One entry with user, date, time, old and new value and the reason; the chain check of the log shows no gap.			
OQ-F03	Roles Log in as an OPERATOR and try to change the users, the calibration or a protected setting.	Refused; the refusal is in the activity log.			
OQ-F04	Lockout Enter a wrong password five times for a test user.	The user is locked; the wrong passwords and the lock are in the log; an ADMIN can unlock.			
OQ-F05	Electronic signature Sign a saved report with the meaning "reviewed"; try once with a wrong password.	The wrong password is refused; the signature shows name, date, time and meaning, is linked to the report number and is in the activity log.			
OQ-F06	Seal and integrity Save a report as PDF and check it on the public check page; change one character in the HTML report attached to it and check that copy.	The original checks as valid (seal and integrity code); the changed copy is shown as changed.			
OQ-F07	Export and archive Export a record file (CSV / JSON) and the archive of the activity log; open them on another device.	Complete and readable; sealed files check as valid.			
OQ-F08	Time Compare the time of a new log entry with a reference clock; open the device qualification of this device.	Within the tolerance of your procedure; this device is shown as qualified.			
OQ-F09	Power cut While a record is saved (or a run is going on), cut the power of the UP^SCALE for 10 s, switch it on and connect again.	No record lost or changed; an interrupted log entry is finished or marked; the chain check passes.			

Pipette check and pipette calibration

ID	Test and steps	Expected result	Observed	Pass / fail	Initials / date
OQ-P01	Delivery mass with a calibrated weight Start a pipette check (100 µL, 4 deliveries). As each delivery put a calibrated weight of about 100 mg (class E2 or F1) into the vessel; take it out again in between (the UP^SCALE takes a new vessel reading by itself).	Each single value (mg) on the record equals the conventional mass of the weight within its maximum permissible error plus d.			
OQ-P02	Z factor Enter water 20.0 °C, air 20.0 °C, 1013 hPa, 50 %RH and run a check.	Z on the record 1.00285 µL/mg (1.0029 in the published tables); the record names the water density used.			
OQ-P03	Limits and verdict Run a check whose deliveries are inside the limits, then one outside (calibrated weights as in OQ-P01, or a pipette set off by 1 %).	PASS inside, FAIL outside; the record shows the limits and their source.			
OQ-P04	Implausible value In a run, deliver about half the volume once (or a much smaller weight); choose REDO with a reason.	The UP^SCALE stops at the value; the discarded value and the reason are on the report and in the activity log.			

ID	Test and steps	Expected result	Observed	Pass / fail	Initials / date
OQ-P05	Evaporation and conditions at the end Run a calibration with the evaporation measurement; enter the conditions at the end.	The evaporation rate is on the report and corrects each delivery; the conditions at the start and the end are on the report.			
OQ-P06	Balance and deviations Start a calibration of a pipette that needs a finer balance (e.g. 10 µL on a 0.01 mg balance); then one with a room of 25 °C and 4 deliveries.	The first does not start (the app shows the d and the d needed); the second lists the deviations before the start and its report says "based on ISO 8655-6:2022 with deviations".			
OQ-P07	Uncertainty and CMC Upload a CMC table with a row for 20 - 200 µL; calibrate a 100 µL pipette at 100 µL and at a volume outside the table.	U is never below the CMC (marked "CMC" when raised); the volume outside the table is marked and the accreditation text is left off for it.			
OQ-P08	Records and due dates Finish a run; open the pipette card, the sealed PDF and the activity log.	The run with all single values is in the register; the next due date moved; the PDF checks as valid; the activity log has the entry.			
OQ-P09	Import of old data Import a CSV of pipettes from your old system (semicolon, decimal comma); keep the import record.	Every row new, updated, skipped or refused as shown in the preview; the import record names the file and its SHA-256.			
OQ-P10	Multichannel pipette Run a check of a multichannel pipette with every channel (or a rotating group).	Each channel is a block of its own; the next channel starts by itself (or asks for an OK, lab setting); the report names the channels.			
OQ-P11	App lost during a run Close the app during a run; open it and connect again.	The run goes on in the UP^SCALE; the app shows it again; no value is lost.			

Compounding assistant and solution mode

ID	Test and steps	Expected result	Observed	Pass / fail	Initials / date
OQ-C01	Master formula and approval Save a test formula with NEW FORMULA (3 ingredients, a check, an in-process control, a filling step). Try to start a batch; let a QM approve it; change one share and save again.	The batch starts only after the approval, and not after the change (waiting); the approval is in the activity log.			
OQ-C02	Lots and identity check Identity check scan to unlock. Type an expired lot, then a locked one, then valid lots, and START BATCH. At a weigh step scan a code that is not approved, a GS1 code with another lot, then the right code.	The expired and the locked lot block the start; the wrong codes give wrong container and the step stays locked; the right code opens it; every scan is in the batch record.			
OQ-C03	Weighing to the goal Batch size 100 g. Press OVERTAKE with an ingredient under its goal, weigh another one, come back; press OVERTAKE while the weight moves, then stable on the goal. Open the formula on a second device.	The part under the goal is kept and counts; a moving weight is not taken; the value is taken with user and time; the second device shows the same step and values.			
OQ-C04	QM release and recalculation Weigh an ingredient 5 % over its goal. QM RELEASE: try the logged-in user, a QM with a wrong password, then a QM with password and reason. In another test batch use RECALCULATE.	The first two are refused; the release is in the activity log and the batch record with name and reason; the other goals follow its proportion, noted in the batch record.			
OQ-C05	Checks and in-process controls Answer a check with NO; type pH 6.2 for a control of 5.5 ± 0.3; give the reasons. Then X ABORT BATCH with a reason.	Both are deviations with their reason in the batch record; the check stays open; the aborted record is closed as ABORTED.			
OQ-C06	Uniformity of mass A filling step of 20 units with fills of known mass: one batch with 2 units outside the limit of the dosage form, a second batch with 3.	Average, units outside the limit and twice the limit agree with a hand calculation (e.g. capsules under 300 mg: 10 %); 2 outside: met; 3 outside: NOT met, and a reason is asked.			

ID	Test and steps	Expected result	Observed	Pass / fail	Initials / date
OQ-C07	Batch record and label OK FINISH; make the PDF (SEALED) and SIGN it as the operator; the same user tries to sign as QM, then another QM signs; print the LABEL; check the PDF on the public check page.	Lots, use-by dates, values, users, releases and deviations are listed; the maker is refused as QM; the PDF checks as valid; the label shows the batch and use by = end + shelf life.			
OQ-C08	Solution mode SOLUTION MODE with 2 rows as parts 1 and 4, total 50 g. WEIGH NOW the first row 4 % over its goal and press ; weigh the second; OK FINISH; make the PDF.	New goals in the same proportion; a row is green within its ± % or within one d, whichever is wider; FINISH only when every row is green; one line per ingredient in the weighing log; the report lists goal, weight, user and time.			
OQ-C09	Tolerance narrower than d A test formula with an ingredient of 10 % and a tolerance of 0.2 % on a balance with d 0.1 g. Set the batch size to 1000 g, then to 100 g; at 100 g press START BATCH, weigh that row 0.08 g over its goal and OK FINISH.	At 1000 g (tolerance ± 0.2 g) no warning; at 100 g (± 0.02 g) the warning box names the row with accepted ± 0.1 g and START asks once more; the row is green at +0.08 g; the batch record marks it with a warning line and the accepted band ± 0.1 g.			

Routine check before use, minimum weight and air buoyancy correction

ID	Test and steps	Expected result	Observed	Pass / fail	Initials / date
OQ-R01	Repeatability (USP <41>) On the [x] TEST page choose Lab: USP <41>, a test weight of e.g. 100 g and your smallest net weight; START ROUTINE CHECK and load the weight 10 times.	Each value equals the display minus the empty plate; mean, s (at least 0.41 d), 2 s / smallest net weight and 2000 x s agree with a hand calculation; PASS at 0.10 % or less.			
OQ-R02	Accuracy and a failed check Run Lab: Ph. Eur. 2.1.7 with a second weight of at least 5 % of Max; run it again with the value of that weight typed 0.2 % too high.	First run: the error is judged against 0.05 % (USP: 0.10 %). Second run: FAIL with an error of about -0.2 %.			
OQ-R03	Failed check on every device After the FAIL open the app on a second device; press REMOVE WARNING as an OPERATOR; then RE-TEST.	The red bar NOT RELEASED FOR USE shows on both devices; the OPERATOR is refused; the bar goes after the pass; fail and pass are in the activity log.			
OQ-R04	Check due Try to set the minimum interval as an OPERATOR; set every 4 hours as an ADMIN; wait 4 hours.	The OPERATOR is refused; a yellow bar with START shows on every device until a check passes; the change is logged.			
OQ-R05	Minimum weight As an ADMIN type 20 g (a test value) in the SCALE DATA block and SUBMIT; save 10 g with SUM and record it anyway; try a change as an OPERATOR; type the value of the certificate again.	BELOW THE MINIMUM WEIGHT with both values; the record and every change are in the activity log; the OPERATOR is refused.			
OQ-R06	Records of the checks Make PDF OF THIS CHECK, PDF REPORT and EXPORT LOG; check the PDFs on the public check page.	Every value, limit, user and verdict; failures with their re-test or removed warning; missed intervals; both PDFs check as valid.			
OQ-R07	Air buoyancy correction As an ADMIN switch it on with PRESET 0.00120 and SUBMIT; load a THING of density 1.0 g/ml and put 100 g on; then air density from 20 °C, 1013.25 hPa, 50 %.	The reading stays 100 g; true mass 100.105 g, factor 1.001051 (shown to one digit more than the balance); air density 0.00120 g/cm³; each change logged with old and new value.			

Fill weighing and the check of prepackages (e, NIST HB 133)

ID	Test and steps	Expected result	Observed	Pass / fail	Initials / date
OQ-W01	Limits of the rules Open FILL WEIGHING (ROASTERY or CCLUB MODE). e rules EU with 250 g, 150 g and 40 g; then NIST HB 133 with 454 g (label unit g).	250 g: TNE 9 g, T1 241 g, T2 232 g; 150 g: TNE 6.8 g, T1 143.2 g, T2 136.4 g; 40 g: TNE 3.6 g, T1 36.4 g, T2 32.8 g; 454 g: MAV 19.9 g, MAV line 434.1 g.			
OQ-W02	Fill state START FILLING with e 250 g, the green range one TNE, AUTO TARE off; load a tared container to 240, 241, 250, 259 and 260 g.	Orange at 240 g, yellow at 241 g, green at 250 and 259 g, red at 260 g.			

ID	Test and steps	Expected result	Observed	Pass / fail	Initials / date
OQ-W03	Taking a bag Press OK TAKE BAG while the weight moves; take a bag of 238 g; press UNDO.	A moving weight is not taken; the 238 g bag asks first; UNDO removes it from the run and the statistics.			
OQ-W04	Statistics and verdict A new run (e, 250 g): 8 bags of 252 g, 1 of 255 g, 1 of 238 g.	Mean 250.9 g, s 4.63 g, total 2509 g, overfill 9 g; 1 bag below T1 = 10 %: too many; none below T2; verdict X.			
OQ-W05	A run that goes on During a run reload the app, take a bag on a second device, cut the power of the UP^SCALE for 10 s.	Every bag is kept on both devices, none is counted twice.			
OQ-W06	Report and stock OK FINISH; make the print, PDF and CSV; check the PDF on the check page (sealed with ENTERPRISE).	Rule, limits, user, batch, verdict and every bag; the CSV has the same rows; the PDF checks as valid; the stock moved once, no sale booked.			
OQ-W07	Lot check of closed packs In STATISTICS & e choose EU e packs, 250 g, lot size 300; weigh 50 closed packs (or HB 133, lot size 200: 12 packs).	Sample plan 50 / 3 / 4 (HB 133: 12, none over the MAV); the verdict follows the three rules; the lot report lists every pack.			

Density mode (Archimedes)

ID	Test and steps	Expected result	Observed	Pass / fail	Initials / date
OQ-D01	Readings Start DENSITY MODE with something on the plate; empty it; weigh a 50 g steel weight dry, then hanging in water.	Nothing is taken before the zero; both values are taken when stable and equal the display.			
OQ-D02	Density of the water Water at 20, 23, 27 and 45 °C: measure and SAVE each; COPY TABLE.	Liquid 0.9982, 0.9975, 0.9965 (interpolated) and 0.9922 (the 40 °C value).			
OQ-D03	Calculation From A (in air), W (displaced) and the liquid density rho(liq) work out density = A / W x rho(liq), volume = W / rho(liq) and u = density x sqrt((d / A)² + (d / W)²); with the air correction on: A / W x (rho(liq) - rho(air)) + rho(air).	The app shows the same to the last digit; with the correction the note with the air density.			
OQ-D04	Warnings Let the item rest on the bottom; then measure an item under 5 g on a 0.1 g balance.	A warning that both weights are almost the same; for the small item the ± % it is good to.			
OQ-D05	Body of known density Measure a body with a density certificate three times with MEASURE AGAIN.	Within the shown uncertainty plus that of the certificate, or within your limit.			
OQ-D06	Keeping the result SAVE, COPY TABLE; SAVE AS THING with SAVE ON THE SCALE; weigh the body with this THING.	The table has name, date, both weights, liquid, density, uncertainty; the volume shown = weight / density.			

LIMS / ELN forwarding

ID	Test and steps	Expected result	Observed	Pass / fail	Initials / date
OQ-L01	Connection In Settings > LIMS / ELN FORWARDING type address and token, press TEST; again with a wrong token.	The ping arrives with id, device and time, and the app shows OK; with the wrong token the server refuses and the app shows the error.			
OQ-L02	Activity log Change a setting; close the forwarding app; make two changes on another device; open it again and wait a minute.	Every line arrives once with sequence number, user, text and chain hash; no gap; the chain checks.			
OQ-L03	Weighings Save three weighings with SUM, one below the minimum weight.	grams, unit, user and time as in the weighing log; below_min_weight: true on that one.			
OQ-L04	Sealed file Tick the sealed reports with the file itself; make a sealed PDF.	A sealed and a sealed_file event with the same log_seq; the decoded file has the SHA-256 of sha256_file and checks as valid.			

ID	Test and steps	Expected result	Observed	Pass / fail	Initials / date
OQ-L05	Server not reachable Stop the receiver for 10 minutes, make some records, start it again.	The waiting events and the error are shown; then all arrive in their order, every id once.			
OQ-L06	Finished programs Tick the finished programs with the report as a file; finish a test batch.	A programs event of the kind batch (UPSCALE-BATCH-1) and the report file with its SHA-256, valid on the check page.			
OQ-L07	Status and validation Run a passed, a failed and a passed routine check; run the validation of the calculations.	routine_check and release events (released, not_released, released); a validation event with every case.			

10 Performance qualification (PQ)

The performance under your conditions, with your balance, your operators and your room. Attach the records.

PQ-1 Balance

The final report of the test suite of this balance (repeatability, accuracy, eccentricity and what your procedure asks for) with traceable test weights - the PQ baseline the VSR asks for.

Report no.	Date	Result	Initials

PQ-P1 Pipettes: comparison with an external calibration

Calibrate a reference pipette that has a recent calibration certificate of an accredited laboratory with this system under your routine conditions, at the volumes of the certificate. En = |V(this system) - V(certificate)| / sqrt(U(this system)² + U(certificate)²); pass: En <= 1.

The rows below are pre-filled with the last calibrations in the register (mean and reported U of this system); fill in the certificate values.

Pipette	Volume µL	Certificate no.	Certificate mean µL	Certificate U µL	This system mean µL	This system U µL	En	En <= 1
PIP-0114	200				200.195	0.403		
PIP-0114	100				100.057	0.204		
PIP-0114	20				19.995	0.051		

PQ-C1 Compounding: routine batches

Make three batches of a formula in routine use with your operators, raw materials and room. Pass: every batch record is complete and reviewed by a QM, and the results meet your specification (uniformity of mass, in-process values and, where your procedure asks, the assay).

Test	Result	Acceptance limit	Pass / fail	Initials / date

PQ-R1 Routine check in daily use

Run the routine check with your profile and weights at the planned interval for a set period (e.g. one month). Pass: the PDF REPORT shows no missed interval, and every failure is followed by a passed re-test or a removed warning with its reason.

Test	Result	Acceptance limit	Pass / fail	Initials / date

Test	Result	Acceptance limit	Pass / fail	Initials / date

PQ-W1 Fill weighing of a production lot

Fill one lot under routine conditions, then check the closed packs with the lot check on your verified balance. Pass: the lot is accepted, and the mean and the overfill of the run are within your targets.

Test	Result	Acceptance limit	Pass / fail	Initials / date

PQ-D1 Density under the conditions of the lab

Measure a body of known density and a typical sample five times each, by your operators at your water temperature. Pass: the mean for the body agrees with its certificate, and the spread of both is within your limits.

Test	Result	Acceptance limit	Pass / fail	Initials / date

PQ-L1 Forwarding in routine use

After a set period of routine use (e.g. two weeks), compare your server with the UP^SCALE and the app: the activity log by sequence number, sealed files by SHA-256, batch records and routine checks by number. Pass: no gap, no double, the same values.

Test	Result	Acceptance limit	Pass / fail	Initials / date

11 21 CFR Part 11 / EU GMP Annex 11 checklist

What the system brings for each point, and what stays with your procedures. A function of the product is no compliance by itself: compliance comes from the validated system together with your procedures.

Clause	Requirement	UP^SCALE	Your procedure
§11.10(a)	Validation	this pack, reference cases, fingerprints	execute, assess, approve
§11.10(b)	Accurate and complete copies	PDF and HTML reports, CSV / JSON exports - sealed	-
§11.10(c)	Protection and retention of records	records in the UP^SCALE, sealed files, archive of the activity log	storage and retention period
§11.10(d)	Access limited to authorised people	users, roles, passwords	who gets a user
§11.10(e)	Audit trail	hash-chained activity log: who, when, what (old / new), why	audit trail review (record in the app)
§11.10(f)	Operational checks (sequence)	guided steps, e.g. the pipette sequence and the routine check	-
§11.10(g)	Authority checks	roles QM, ADMIN, OPERATOR	assignment of the roles
§11.10(h)	Device checks	Device ID of the UP^SCALE, qualification of each phone / PC	qualify the devices
§11.10(i)	Training	training dates in the user access register	training
§11.10(j)	Accountability policy	-	written policy
§11.10(k)	Control of the system documentation	manual, changelog, this pack	document control
§11.50 / §11.70	Signature manifestation and linking	name, date, time, meaning; linked to the number and code of the report	-
§11.100	Uniqueness of signatures	permanent user numbers, never given twice	identity check of the people
§11.200 / §11.300	Signature components, password controls	user and password; lockout after 5 wrong passwords; password age; a password set by an ADMIN is changed at the first login	password policy
Annex 11 §4	Validation	this pack	your validation
Annex 11 §7 / §17	Data storage, archiving	records in the UP^SCALE, exports, archive of the log	backups and archive
Annex 11 §10	Change management	a firmware change is in the activity log; the VSR asks to confirm the release	change control (chapter 13)
Annex 11 §11	Periodic evaluation	-	periodic review (chapter 13)
Annex 11 §12	Security	users, roles, lockout	IT security
Annex 11 §16	Business continuity	-	plan for a failure of the system

12 Supplier information

Product: the UP^SCALE app (a web app, also as a single file for offline use) and the firmware of the UP^SCALE, up-scales.com.

Versions: every app and firmware release has a version number. The app computes a code fingerprint (SHA-256) of its calculation code and of the reference cases; the firmware reports the SHA-256 of its build. The same build gives the same fingerprints on every device.

Changes: the changes of each version are in the changelog on up-scales.com; a new firmware build is written into the activity log of the UP^SCALE ("Firmware changed").

Reference cases: worked out by hand from the named standards; the working of each case is public on up-scales.com/check, so your laboratory can check every expected value.

Known limits: the limits of ISO 8655-2 come from public secondary sources unless your laboratory types its own table; UP^SCALE makes no claim of certification or compliance and is not affiliated with any standards body or authority.

13 Change control and periodic review

When to repeat which part of the validation. Record every change in your change control.

Change	What to do
New firmware of the UP^SCALE (activity log "Firmware changed"; the VSR asks to confirm the release)	IQ-02, OQ part A, the OQ tests touched by the change (changelog) or all, new VSR
New app version (a new code fingerprint)	IQ-01, OQ part A, the touched OQ tests, new VSR

Change	What to do
Balance replaced, repaired, calibrated or adjusted (start the change control yourself - only the UP^SCALE 420, 710 and HDS count their own calibrations)	IQ-04, IQ-05, PQ-1; pipettes: PQ-P1; new VSR
Lab settings of the pipettes changed (limits table, CMC, decision rule, instruments)	IQ-P1 ... IQ-P5, OQ-P03, OQ-P07 as touched
New phone or PC	device qualification, IQ-08
Periodic review (e.g. yearly)	audit trail review, user access review, open deviations, the release status in the VSR

14 Deviations, conclusion and approval

Deviations

No.	Test	Deviation	Assessment and action	Closed (date, initials)
1				
2				
3				
4				

Conclusion

* [ ] The system is suitable for the intended use (chapter 1).

* [ ] Suitable with restrictions (see the deviations).

* [ ] Not suitable.

Remarks	

Approval

Role	Name	Date	Signature
Performed by			
Reviewed by			
Approved by (QA)			

The release for use of the UP^SCALE follows with the Validation Summary Report (VSR) on the TEST page of the app, which takes this pack as its IQ/OQ document.

Annex A - the reference cases of this device

Case	Clause	Result	Expected	Calculated
T3-01	R 76-1 Table 3	OK	[II]	[II]
T3-02	R 76-1 Table 3	OK	[II]	[II]
T3-03	R 76-1 Table 3	OK	[III]	[III]
T3-04	R 76-1 Table 3	OK	[III, IIII]	[III, IIII]
T3-05	R 76-1 Table 3	OK	IIII	IIII
T3-06	R 76-1 Table 3	OK	[IIII]	[IIII]
T3-07	R 76-1 Table 3	OK	[I, II]	[I, II]
T3-08	R 76-1 Table 3	OK	[III]	[III]
T3-09	R 76-1 Table 3	OK	[II, III]	[II, III]
T3-16	R 76-1 Table 3	OK	[I, II]	[I, II]
T3-10	R 76-1 Table 3, 3.4.3	OK	0.1	0.1
T3-11	R 76-1 Table 3, 3.4.3	OK	0.2	0.2
T3-12	R 76-1 Table 3, 3.4.3	OK	5	5
T3-13	R 76-1 Table 3, 3.4.3	OK	20	20
T3-14	R 76-1 Table 3, 3.4.3	OK	50	50
T3-15	R 76-1 Table 3, 3.4.3	OK	2	2
T6-01	R 76-1 Table 6	OK	0.5	0.5
T6-02	R 76-1 Table 6	OK	1	1
T6-03	R 76-1 Table 6	OK	1	1
T6-04	R 76-1 Table 6	OK	1.5	1.5
T6-05	R 76-1 Table 6	OK	1	1
T6-06	R 76-1 Table 6	OK	0.5	0.5
T6-07	R 76-1 Table 6	OK	1	1
T6-08	R 76-1 Table 6	OK	1.5	1.5
T6-09	R 76-1 Table 6	OK	0.5	0.5
T6-10	R 76-1 Table 6	OK	1.5	1.5
T6-11	R 76-1 Table 6	OK	1	1
T6-12	R 76-1 Table 6	OK	1.5	1.5
T6-13	R 76-1 Table 6	OK	10	10
LV-01	R 76-1 3.5.1, 3.5.2	OK	ok	ok
LV-02	R 76-1 3.5.1, 3.5.2	OK	ok	ok
LV-03	R 76-1 3.5.1, 3.5.2	OK	maybe	maybe
LV-04	R 76-1 3.5.1, 3.5.2	OK	warn	warn
LV-05	R 76-1 3.5.1, 3.5.2	OK	bad	bad
LV-06	R 76-1 3.5.1	OK	ok	ok
A44-01	R 76-1 A.4.4.1, Table 3	OK	[5, 300, 500, 2000, 3000]	[5, 300, 500, 2000, 3000]
A44-02	R 76-1 A.4.4.1, Table 3	OK	[5, 300, 500, 600, 750, 1050, 1500, 2000, 2250, 3000]	[5, 300, 500, 600, 750, 1050, 1500, 2000, 2250, 3000]
A44-03	R 76-1 A.4.4.1, Table 3	OK	[20, 300, 500, 2000, 3000]	[20, 300, 500, 2000, 3000]
A410-01	R 76-1 A.4.10	OK	6	6
A410-02	R 76-1 A.4.10	OK	3	3
A410-03	R 76-1 A.4.10	OK	10	10
A410-04	R 76-1 A.4.10	OK	[2400]	[2400]
A410-05	R 76-1 A.4.10	OK	[1500, 3000]	[1500, 3000]
A443-01	R 76-1 A.4.4.3	OK	{err: 1, errD: 0.2, u: 0}	{err: 1, errD: 0.2, u: 0}
A443-05	R 76-1 A.4.4.3	OK	{err: 0.5, errD: 0.1, u: 0}	{err: 0.5, errD: 0.1, u: 0}
A443-06	R 76-1 A.4.4.3, 3.5.3.2	OK	{err: 1, errD: 0.2, u: 0.5}	{err: 1, errD: 0.2, u: 0.5}
A443-02	R 76-1 3.5.3.2	OK	{err: 0.1, errD: 1, u: 0.5}	{err: 0.1, errD: 1, u: 0.5}
A443-03	R 76-1 A.4.1.6	OK	{err: 0.03, errD: 0.3, u: 0.1}	{err: 0.03, errD: 0.3, u: 0.1}
A443-04	R 76-1 3.7.1	OK	{err: 0.1, errD: 1, u: 1.5}	{err: 0.1, errD: 1, u: 1.5}

Case	Clause	Result	Expected	Calculated
W-01	R 76-1 A.4.4.1, 3.5.1	OK	{checks: [[0.2, 0.1], [0.6, 0.1], [1.2, 0.1], [0.9, 0.1], [0.3, 0.1], [0.3, 0.2], [0.1, 0.2]], status: meets}	{checks: [[0.2, 0.1], [0.6, 0.1], [1.2, 0.1], [0.9, 0.1], [0.3, 0.1], [0.3, 0.2], [0.1, 0.2]], status: meets}
R-01	R 76-1 3.6.1, A.4.10	OK	{checks: [[1, 0.5], [2, 1]], status: maybe}	{checks: [[1, 0.5], [2, 1]], status: maybe}
R-02	R 76-1 3.6.1, A.4.10	OK	{checks: [[0.5, 0.1], [0.7, 0.2]], status: meets}	{checks: [[0.5, 0.1], [0.7, 0.2]], status: meets}
R-03	R 76-1 3.6.1, 3.5.2	OK	{checks: [[2, 0.1], [3, 0.2]], status: fails}	{checks: [[2, 0.1], [3, 0.2]], status: fails}
C-01	R 76-1 3.9.4.1, 3.9.4.2, A.4.11	OK	{checks: [[0.4, 0.5], [0.1, 0.2], [0.2, 0.5]], status: meets}	{checks: [[0.4, 0.5], [0.1, 0.2], [0.2, 0.5]], status: meets}
C-02	R 76-1 3.9.4.1	OK	{checks: [[0.4, 0.5], [0.3, 0.2], [0.1, 0.5]], status: fails}	{checks: [[0.4, 0.5], [0.3, 0.2], [0.1, 0.5]], status: fails}
Z-01	R 76-1 4.5.2, A.4.2.3.1	OK	{checks: [[0.1, 0.25]], status: meets}	{checks: [[0.1, 0.25]], status: meets}
Z-02	R 76-1 4.5.2	OK	{checks: [[0.3, 0.25]], status: maybe}	{checks: [[0.3, 0.25]], status: maybe}
Z-03	R 76-1 4.5.2	OK	{checks: [[0.5, 0.25]], status: fails}	{checks: [[0.5, 0.25]], status: fails}
S-01	R 76-1 4.4.2, A.4.12	OK	{checks: [[1, 1], [2, 1]], status: fails}	{checks: [[1, 1], [2, 1]], status: fails}
D-01	R 76-1 3.8.2.2, A.4.8.2	OK	{checks: [[0, 0.5], [1, 0.5]], status: fails}	{checks: [[0, 0.5], [1, 0.5]], status: fails}
LIN-01	least squares (EURAMET cg-18 style, R 76 has no linearity limit)	OK	{a: 1.0001, maxDev: 0}	{a: 1.0001, maxDev: 0}
LIN-02	least squares	OK	{a: 1.5, maxDev: 0.333333}	{a: 1.5, maxDev: 0.333333}
ECC-01	R 76-1 3.6.2, Table 6 (difference to the middle, EURAMET cg-18)	OK	{maxD: 0.7, mpe: 1, u: 0.2, level: ok}	{maxD: 0.7, mpe: 1, u: 0.2, level: ok, absD: null, absU: null, absMpe: null, absLevel: null}
ECC-02	R 76-1 3.6.2, Table 6	OK	{maxD: 1, mpe: 1, u: 1, level: maybe}	{maxD: 1, mpe: 1, u: 1, level: maybe, absD: null, absU: null, absMpe: null, absLevel: null}
ECC-03	R 76-1 3.6.2, 3.5.2	OK	{maxD: 2.5, mpe: 1, u: 0.2, level: bad}	{maxD: 2.5, mpe: 1, u: 0.2, level: bad, absD: null, absU: null, absMpe: null, absLevel: null}
ECC-04	R 76-1 3.6.2, A.4.7 (against the true mass)	OK	{absD: 0.5, absU: 0.1, absMpe: 1, absLevel: ok}	{maxD: 0.5, mpe: 1, u: 0.2, level: ok, absD: 0.5, absU: 0.1, absMpe: 1, absLevel: ok}
ECC-05	R 76-1 3.6.2, A.4.7, 3.7.1	OK	{absD: 1, absU: 1, absMpe: 1, absLevel: maybe}	{maxD: 1, mpe: 1, u: 1, level: maybe, absD: 1, absU: 1, absMpe: 1, absLevel: maybe}
ECC-06	R 76-1 3.6.2, 3.5.2	OK	{absD: 1.2, absU: 0.1, absMpe: 1, absLevel: warn}	{maxD: 1.2, mpe: 1, u: 0.2, level: maybe, absD: 1.2, absU: 0.1, absMpe: 1, absLevel: warn}
ECC-07	R 76-1 A.4.7	OK	{absD: 0, absLevel: ok}	{maxD: 3, mpe: 1, u: 0.2, level: bad, absD: 0, absU: 0.1, absMpe: 1, absLevel: ok}
W111-01	R 76-1 3.7.1	OK	false	false
W111-02	R 76-1 3.7.1	OK	true	true
W111-03	R 76-1 3.7.1	OK	false	false
RT-01	USP <41> repeatability + accuracy	OK	{mean: 100.03, s: 0.048305, minW: 96.609178, checks: [[0.966092, 1], [0, 1]], pass: true}	{mean: 100.03, s: 0.048305, sEff: 0.048305, minW: 96.609178, checks: [[0.966092, 1], [0, 1]], pass: true}
RT-02	USP <41> repeatability (s replaced by 0.41 d)	OK	{s: 0, sEff: 0.041, minW: 82, checks: [[0.82, 0.5], [0, 0.5]], pass: false}	{mean: 50, s: 0, sEff: 0.041, minW: 82, checks: [[0.82, 0.5], [0, 0.5]], pass: false}
RT-03	Ph. Eur. 2.1.7 sensitivity	OK	{checks: [[0.82, 2], [6, 5]], pass: false}	{mean: 100, s: 0, sEff: 0.041, minW: 82, checks: [[0.82, 2], [6, 5]], pass: false}
RT-04	Routine check, own tolerance (quick profile)	OK	{mean: 1005, checks: [[5, 10]], pass: true}	{mean: 1005, s: 1, sEff: 1, minW: 2000, checks: [[5, 10]], pass: true}
RT-05	Routine check, own tolerance (minimum 2 d)	OK	{mean: 102.666667, checks: [[2.666667, 2]], pass: false}	{mean: 102.666667, s: 0.57735, sEff: 0.57735, minW: 1154.700538, checks: [[2.666667, 2]], pass: false}
RT-06	R 76-1 3.5.2 (in use = 2 x mpe of Table 6)	OK	{checks: [[2, 2], [3, 3]], pass: true}	{mean: 1001, s: 1, sEff: 1, minW: 2000, checks: [[2, 2], [3, 3]], pass: true}
DS-01	R 76-1 Table 3; NIST HB 44 S.1.2.1 (d = 1, 2 or 5 x 10^n)	OK	[II, III]	[II, III]

Case	Clause	Result	Expected	Calculated
DS-02	R 76-1 Table 3, 3.4.3	OK	10	10
DS-03	R 76-1 Table 3	OK	[III]	[III]
DS-04	R 76-1 Table 3	OK	[]	[]
DS-05	R 76-1 Table 3	OK	[]	[]
MI-01	R 76-1 3.3 / Table 3 for each partial range (multi-interval; our reading: a class fits when it fits every range)	OK	[III]	[III]
MI-02	R 76-1 Table 6 (mpe in e of the partial range of the load)	OK	2.5	2.5
MI-03	R 76-1 Table 6 (mpe in e of the partial range of the load)	OK	1.5	1.5
MI-04	R 76-1 Table 6, the boundary of a partial range	OK	2.5	2.5
MI-05	R 76-1 A.4.4 (error of a reading, rounding d / 2 of the range of the load)	OK	{err: 5, errD: 2.5, u: 1.25}	{err: 5, errD: 2.5, u: 1.25}
AB-01	OIML D 28 (conventional mass, reference 8000 kg/m3, air 1.2 kg/m3) - air buoyancy correction	OK	1.001053	1.001053
AB-02	OIML D 28 - air buoyancy correction	OK	1.001372	1.001372
AB-03	OIML D 28 - air buoyancy correction	OK	1	1
AB-04	OIML D 28 - air buoyancy correction	OK	0.999912	0.999912
AB-05	OIML R 111-1:2004 E.3-1 (air density, approximation)	OK	0.001199	0.001199
AB-06	OIML R 111-1:2004 E.3-1 (air density, approximation)	OK	0.001117	0.001117
AB-07	Archimedes with the air term (density mode, readings are conventional masses)	OK	{density: 2.695498, volume: 10.008529}	{density: 2.695498, volume: 10.008529}
AB-08	OIML D 28 - true mass of a reading	OK	50.042543	50.042543
UM-01	Ph. Eur. 2.9.5 - capsules, average mass < 300 mg	OK	{n: 20, mean: 0.25, limitPct: 10, out1: 2, out2: 0, pass: true}	{n: 20, mean: 0.25, limitPct: 10, out1: 2, out2: 0, pass: true}
UM-02	Ph. Eur. 2.9.5 - more than 2 units outside the limit	OK	{n: 20, mean: 0.25, limitPct: 10, out1: 4, out2: 0, pass: false}	{n: 20, mean: 0.25, limitPct: 10, out1: 4, out2: 0, pass: false}
UM-03	Ph. Eur. 2.9.5 - a unit outside twice the limit	OK	{n: 20, mean: 0.25, limitPct: 10, out1: 2, out2: 2, pass: false}	{n: 20, mean: 0.25, limitPct: 10, out1: 2, out2: 2, pass: false}
UM-04	Ph. Eur. 2.9.5 - tablets, average mass 250 mg or more	OK	{n: 20, mean: 0.3, limitPct: 5, out1: 2, out2: 0, pass: true}	{n: 20, mean: 0.3, limitPct: 5, out1: 2, out2: 0, pass: true}
UM-05	own limit around the target fill (not Ph. Eur.)	OK	{n: 4, mean: 10.125, limitPct: 5, out1: 1, out2: 0, pass: false}	{n: 4, mean: 10.125, limitPct: 5, out1: 1, out2: 0, pass: false}
UM-06	Ph. Eur. 2.9.5 - 20 units are needed	OK	{n: 10, mean: 0.25, limitPct: 10, out1: 0, out2: 0, pass: false}	{n: 10, mean: 0.25, limitPct: 10, out1: 0, out2: 0, pass: false}
UM-07	Ph. Eur. 2.9.5 - the limits of the table	OK	[10, 5, 7.5, null, 5]	[10, 5, 7.5, null, 5]
PR-01	DIN 1333 - commercial rounding to the cent	OK	1.01	1.01
PR-02	DIN 1333 - price x weight	OK	4.52	4.52
PR-03	DIN 1333 - price x weight	OK	1.5	1.5
PR-04	DIN 1333 - price x weight	OK	9.98	9.98
PR-05	DIN 1333 - price x weight	OK	4.52	4.52
PR-06	DIN 1333 - a minus amount	OK	-2.68	-2.68
PR-07	DIN 1333 - six decimals (Bitcoin)	OK	0.000013	0.000013
HB-01	NIST HB 133-2026 Table 2-5 (g)	OK	12.7	12.7
HB-02	NIST HB 133-2026 Table 2-5 (g)	OK	3.6	3.6
HB-03	NIST HB 133-2026 Table 2-5 (g)	OK	3.59	3.59
HB-04	NIST HB 133-2026 Table 2-5 (g)	OK	3.6	3.6
HB-05	NIST HB 133-2026 Table 2-5 (g)	OK	5.4	5.4
HB-06	NIST HB 133-2026 Table 2-5 (g)	OK	35.3	35.3
HB-07	NIST HB 133-2026 Table 2-5 (g)	OK	600	600
HB-08	NIST HB 133-2026 Table 2-5 (oz)	OK	19.490297	19.490297

Case	Clause	Result	Expected	Calculated
HB-09	NIST HB 133-2026 Table 2-5 (lb)	OK	19.958064	19.958064
HB-10	NIST HB 133-2026 Table 2-1	OK	[[1, null, 0], [5, 1.242, 0], [12, 0.635, 0], [24, 0.422, 0], [48, 0.29, 1]]	[[1, null, 0], [5, 1.242, 0], [12, 0.635, 0], [24, 0.422, 0], [48, 0.29, 1]]
HB-11	NIST HB 133-2026 2.3.7 - average within the SEL	OK	{n: 12, ume: 0, avgError: -0.5, sel: 0.74152, pass: true}	{n: 12, ume: 0, avgError: -0.5, sel: 0.74152, pass: true}
HB-12	NIST HB 133-2026 2.3.7 - average outside the SEL	OK	{n: 12, ume: 0, avgError: -1.333333, sel: 0.988694, pass: false}	{n: 12, ume: 0, avgError: -1.333333, sel: 0.988694, pass: false}
HB-13	NIST HB 133-2026 2.3.7 - unreasonable minus error	OK	{n: 12, ume: 1, avgError: 1.666667, pass: false}	{n: 12, ume: 1, avgError: 1.666667, sel: 2.932939, pass: false}
HB-14	NIST HB 133-2026 Table 2-1 - one pack over the MAV allowed (n = 48)	OK	{n: 48, ume: 1, avgError: 0.708333, pass: true}	{n: 48, ume: 1, avgError: 0.708333, sel: 0.586011, pass: true}
HB-15	NIST HB 133-2026 2.3.7 - cannabis without the moisture allowance	OK	{n: 12, ume: 0, avgError: -0.583333, sel: 0.123587, pass: false}	{n: 12, ume: 0, avgError: -0.583333, sel: 0.123587, pass: false}
HB-16	NIST HB 133-2026 2.3.8.1, Table 2-3 - cannabis, moisture allowance 3 %	OK	{n: 12, ume: 0, avgError: 0.256667, pass: true}	{n: 12, ume: 0, avgError: 0.256667, sel: 0.123587, pass: true}
HB-17	NIST HB 133-2026 2.3.8.1 - example flour	OK	27.21	27.21
HB-18	NIST HB 133-2026 Table 2-7 - MAV by count	OK	[0, 1, 1, 2, 7, 20, 20, 30]	[0, 1, 1, 2, 7, 20, 20, 30]
HB-19	NIST HB 133-2026 Table 2-11 - low count (50 or fewer)	OK	[[5, 1], [12, 1], [24, 2], [48, 3]]	[[5, 1], [12, 1], [24, 2], [48, 3]]
HB-20	NIST HB 133-2026 4.2.1 - example pencils	OK	{n: 12, short: 1, defective: 1, pass: true}	{n: 12, short: 1, defective: 1, pass: true}
HB-21	NIST HB 133-2026 4.2.1 - too many short packs	OK	{n: 12, short: 2, defective: 0, pass: false}	{n: 12, short: 2, defective: 0, pass: false}
HB-22	NIST HB 133-2026 4.2.2 / 2.3.7 - more than 50 items	OK	{n: 12, ume: 0, avgError: -0.166667, sel: 0.247173, pass: true}	{n: 12, ume: 0, avgError: -0.166667, sel: 0.247173, pass: true}
HB-23	NIST HB 133-2026 Table 2-6 - MAV by volume	OK	[0.5, 14.7, 29, 300, 14.786765]	[0.5, 14.7, 29, 300, 14.786765]
HB-24	NIST HB 133-2026 3.2 - density of 2 packs	OK	{density: 0.944, diff: 2}	{density: 0.944, diff: 2}
HB-25	NIST HB 133-2026 3.2 / 2.3.7 - a lot labeled by volume	OK	{n: 12, ume: 0, avgError: -0.833333, sel: 1.235867, pass: true}	{n: 12, ume: 0, avgError: -0.833333, sel: 1.235867, pass: true}
HB-26	NIST HB 133-2026 Table 2-3 - packs to open for the tare	OK	[12, 17, 8, 2, 24, 2, 2]	[12, 17, 8, 2, 24, 2, 2]
HB-27	NIST HB 133-2026 2.3.5 - tare sample, few packs	OK	{init: 2, total: 2, ratio: 11.5, avg: 12.2, done: true}	{init: 2, total: 2, rc: 4.6, rt: 0.4, ratio: 11.5, avg: 12.2, done: true, need: 0}
HB-28	NIST HB 133-2026 2.3.5 - tare sample, open more	OK	{init: 2, total: 12, need: 10, done: false}	{init: 2, total: 12, rc: 0.5, rt: 0.5, ratio: 1, avg: null, done: false, need: 10}
HB-29	NIST HB 133-2026 Table 2-1 col. 5 / 6 - initial tare sample	OK	[2, 3, 2, 2, 1]	[2, 3, 2, 2, 1]
CAL-01	R 76-1 A.4.4.3 (rounding of a digital reading), 3.7.1, Table 6 - calibration check	OK	{mean: 1000.016667, errD: 0.166667, u: 0.55, mpe: 1, level: ok, verdict: ok}	{mean: 1000.016667, errD: 0.166667, u: 0.55, mpe: 1, level: ok, verdict: ok}
CAL-02	R 76-1 A.4.4.3, Table 6 - calibration check (the rounding does not average out)	OK	{mean: 1000.05, errD: 0.5, u: 0.55, mpe: 1, level: maybe, verdict: ok}	{mean: 1000.05, errD: 0.5, u: 0.55, mpe: 1, level: maybe, verdict: ok}
CAL-03	R 76-1 3.7.1 (test weights), A.4.4.3 - calibration check	OK	{mean: 1000.016667, errD: 0.166667, u: 1, mpe: 1, level: maybe, verdict: ok}	{mean: 1000.016667, errD: 0.166667, u: 1, mpe: 1, level: maybe, verdict: ok}
CAL-04	R 76-1 A.4.4.3 (readings before rounding), Table 6 - calibration check	OK	{mean: 1000.13, errD: 1.3, u: 0.15, mpe: 1, level: warn, verdict: ok}	{mean: 1000.13, errD: 1.3, u: 0.15, mpe: 1, level: warn, verdict: ok}
CAL-05	R 76-1 A.4.4.3, Table 6 - calibration check, own limits	OK	{mean: 1003.333333, errD: 3.333333, u: 0.55, mpe: 1, level: bad, verdict: acceptable}	{mean: 1003.333333, errD: 3.333333, u: 0.55, mpe: 1, level: bad, verdict: acceptable}
CAL-06	R 76-1 Table 6 - calibration check, own limits	OK	{mean: 1006.333333, errD: 6.333333, u: 0.55, mpe: 1, level: bad, verdict: recalibrate}	{mean: 1006.333333, errD: 6.333333, u: 0.55, mpe: 1, level: bad, verdict: recalibrate}
CAL-07	R 76-1 A.4.4.3, Table 6 (multi-interval: rounding and mpe in the partial range of the load) - calibration check	OK	{mean: 10006.666667, errD: 3.333333, u: 1.5, mpe: 2.5, level: maybe, verdict: acceptable}	{mean: 10006.666667, errD: 3.333333, u: 1.5, mpe: 2.5, level: maybe, verdict: acceptable}
A443-07	R 76-1 A.4.4.3 note (multi-interval: ½ e of the range of the load, ½ e1 at the zero)	OK	{err: 0.6, errD: 0.3, u: 0}	{err: 0.6, errD: 0.3, u: 0}

Case	Clause	Result	Expected	Calculated
MI-06	R 76-1 A.4.4.1, 3.3 (the example of the standard: Max = 2 / 5 / 15 kg, e = 1 / 2 / 10 g)	OK	[20, 500, 2000, 4000, 5000, 15000]	[20, 500, 2000, 4000, 5000, 15000]
R-04	R 76-1 3.6.1, 3.7.1 (the same weight: its tolerance is not in the difference)	OK	{checks: [[1, 0.62], [2, 1]], status: maybe}	{checks: [[1, 0.62], [2, 1]], status: maybe}
W-02	R 76-1 3.5.1 (up and down each within the mpe; no limit for their difference)	OK	{checks: [[0.1, 0.1025], [0.8, 0.11], [0.5, 0.115], [0.8, 0.11], [0.2, 0.1025], [1.6, 0.2], [0.1, 0.2]], status: meets}	{checks: [[0.1, 0.1025], [0.8, 0.11], [0.5, 0.115], [0.8, 0.11], [0.2, 0.1025], [1.6, 0.2], [0.1, 0.2]], status: meets}
ECC-08	R 76-1 3.6, A.4.7 (the error at each measurement, not the mean of the rounds)	OK	{maxD: 0.75, u: 0.2, level: ok, absD: 1.2, absU: 0.1, absMpe: 1, absLevel: warn}	{maxD: 0.75, mpe: 1, u: 0.2, level: ok, absD: 1.2, absU: 0.1, absMpe: 1, absLevel: warn}
ECC-09	EURAMET cg-18, R 76-1 3.3 (multi-interval: the rounding in the range of the load)	OK	{maxD: 5, mpe: 2.5, u: 2.5, level: maybe}	{maxD: 5, mpe: 2.5, u: 2.5, level: maybe, absD: null, absU: null, absMpe: null, absLevel: null}
C-03	R 76-1 3.9.4.1, 3.9.4.2, 3.3 (multi-interval: e of the load, zero return 0.5 e1)	OK	{checks: [[2.5, 1.25], [2.5, 0.5], [0, 0.5]], status: maybe}	{checks: [[2.5, 1.25], [2.5, 0.5], [0, 0.5]], status: maybe}
S-02	R 76-1 4.4.2, A.4.12, 3.3 (multi-interval: e of the load)	OK	{checks: [[2.5, 2.5]], status: meets}	{checks: [[2.5, 2.5]], status: meets}
D-02	R 76-1 3.8.2.2, A.4.8.2 (the actual scale interval at the load)	OK	{checks: [[0, 1.25]], status: meets}	{checks: [[0, 1.25]], status: meets}
RT-07	USP <41> repeatability (0.41 d with the d at the test weight)	OK	{mean: 10000, s: 0, sEff: 2.05, minW: 4100, checks: [[2.05, 2.5], [0, 5]], pass: true}	{mean: 10000, s: 0, sEff: 2.05, minW: 4100, checks: [[2.05, 2.5], [0, 5]], pass: true}
DEN-01	Density mode - water at 20 °C, no air term	OK	{liquid: 0.9982, density: 2.69754, volume: 9.997996, u: 0.002882}	{liquid: 0.9982, density: 2.69754, volume: 9.997996, u: 0.002882}
DEN-02	Density mode - water at 23 °C (a row of the table)	OK	{liquid: 0.99754, density: 18.855939, volume: 0.822022, u: 0.023027}	{liquid: 0.99754, density: 18.855939, volume: 0.822022, u: 0.023027}
DEN-03	Density mode - water at 27 °C (interpolated between 25 and 30 °C) with the air term	OK	{liquid: 0.996484, density: 7.824717, volume: 13.330878, u: 0.005944}	{liquid: 0.996484, density: 7.824717, volume: 13.330878, u: 0.005944}
DEN-04	Density mode - isopropanol (0.786 g/cm³ at 20 °C) with the air term	OK	{liquid: 0.786, density: 2.117711, volume: 3.837345, u: 0.00075}	{liquid: 0.786, density: 2.117711, volume: 3.837345, u: 0.00075}
DEN-05	Density mode - own liquid 1.2 g/cm³	OK	{liquid: 1.2, density: 2.678571, volume: 18.666667, u: 0.013103}	{liquid: 1.2, density: 2.678571, volume: 18.666667, u: 0.013103}
DEN-06	Density mode - salt water, temperature unknown	OK	{liquid: 1.025, density: 7.1684, volume: 1.083941, u: 0.065236}	{liquid: 1.025, density: 7.1684, volume: 1.083941, u: 0.065236}
DEN-07	Density mode - water above 40 °C: the 40 °C value	OK	{liquid: 0.99222, density: 1.98444, volume: 5.039205, u: 0.004437}	{liquid: 0.99222, density: 1.98444, volume: 5.039205, u: 0.004437}
DEN-08	Density mode - own liquid outside 0.5 - 3 g/cm³: not known	OK	{liquid: 0, density: null, volume: null, u: null}	{liquid: 0, density: null, volume: null, u: null}
FE-01	76/211/EEC annex I - 250 g: TNE 9 g, T1 241 g, T2 232 g, max. 2.5 % below T1	OK	{tne: 9, t1: 241, t2: 232, pct: 2.5, nominal: 250}	{tne: 9, t1: 241, t2: 232, pct: 2.5, nominal: 250}
FE-02	76/211/EEC annex I - 40 g: 9 % = 3.6 g	OK	{tne: 3.6, t1: 36.4, t2: 32.8, pct: 2.5, nominal: 40}	{tne: 3.6, t1: 36.4, t2: 32.8, pct: 2.5, nominal: 40}
FE-03	76/211/EEC annex I - 150 g: 4.5 % = 6.75 g, rounded up to 0.1 g	OK	{tne: 6.8, t1: 143.2, t2: 136.4, pct: 2.5, nominal: 150}	{tne: 6.8, t1: 143.2, t2: 136.4, pct: 2.5, nominal: 150}
FE-04	76/211/EEC annex I - below 5 g: no TNE	OK	{tne: null, t1: null, t2: null, pct: 2.5, nominal: null}	{tne: null, t1: null, t2: null, pct: 2.5, nominal: null}
FE-05	76/211/EEC annex I - 2 kg: 1.5 % = 30 g	OK	{tne: 30, t1: 1970, t2: 1940, pct: 2.5, nominal: 2000}	{tne: 30, t1: 1970, t2: 1940, pct: 2.5, nominal: 2000}
FE-06	FPackV § 22 - above 10 kg: no TNE in the German table	OK	{tne: null, t1: null, t2: null, pct: 2, nominal: null}	{tne: null, t1: null, t2: null, pct: 2, nominal: null}
FE-07	FPackV § 9 / § 10 (3) - drained weight 500 g: T2 = Qn - 3 TNE, max. 2 % below T1	OK	{tne: 15, t1: 485, t2: 455, pct: 2, nominal: 500}	{tne: 15, t1: 485, t2: 455, pct: 2, nominal: 500}
FE-08	NIST HB 133-2026 Table 2-5 - 454 g labeled in g: MAV 19.9 g	OK	{tne: 19.9, t1: 434.1, t2: null, pct: null, nominal: 454}	{tne: 19.9, t1: 434.1, t2: null, pct: null, nominal: 454}
FE-09	NIST HB 133-2026 2.3.8.1 - 907 g flour (3 % moisture), labeled in oz	OK	{tne: 31.751466, t1: 848.038534, t2: null, pct: null, nominal: 879.79}	{tne: 31.751466, t1: 848.038534, t2: null, pct: null, nominal: 879.79}
FE-10	NIST HB 133-2026 - own moisture allowance 5 %, labeled in lb	OK	{tne: 63.502932, t1: 2091.059068, t2: null, pct: null, nominal: 2154.562}	{tne: 63.502932, t1: 2091.059068, t2: null, pct: null, nominal: 2154.562}

Case	Clause	Result	Expected	Calculated
FE-11	76/211/EEC - 40 fills of 250 g, 1 below T1 (2.5 % of 40 = 1 allowed)	OK	{mean: 250.725, belowT1: 1, belowT2: 0, ok: true}	{mean: 250.725, belowT1: 1, belowT2: 0, ok: true}
FE-12	76/211/EEC - 40 fills, 2 below T1: more than 2.5 %	OK	{mean: 251.375, belowT1: 2, belowT2: 0, ok: false}	{mean: 251.375, belowT1: 2, belowT2: 0, ok: false}
FE-13	76/211/EEC - one fill below T2	OK	{mean: 253.75, belowT1: 1, belowT2: 1, ok: false}	{mean: 253.75, belowT1: 1, belowT2: 1, ok: false}
FE-14	76/211/EEC - the mean below Qn	OK	{mean: 249.5, belowT1: 0, belowT2: 0, ok: false}	{mean: 249.5, belowT1: 0, belowT2: 0, ok: false}
FE-15	FPackV - 50 fills, 1 below T1 = 2 %: allowed	OK	{mean: 501.64, belowT1: 1, belowT2: 0, ok: true}	{mean: 501.64, belowT1: 1, belowT2: 0, ok: true}
FE-16	NIST HB 133 - mean below the nominal (no lot: every pack against the MAV)	OK	{mean: 453.5, belowT1: 0, belowT2: 0, ok: false}	{mean: 453.5, belowT1: 0, belowT2: 0, ok: false}
FE-17	NIST HB 133 - one pack below Qn - MAV (unreasonable minus error)	OK	{mean: 454.166667, belowT1: 1, belowT2: 0, ok: false}	{mean: 454.166667, belowT1: 1, belowT2: 0, ok: false}
FS-01	fill weighing e 250 g, green up to Qn + 9 g: under T1 / low / ok / over	OK	[0, 3, 3, 1, 1, 2]	[0, 3, 3, 1, 1, 2]
FS-02	fill weighing e 250 g without an upper limit (over 0)	OK	[3, 1, 1]	[3, 1, 1]
FS-03	fill weighing own tolerance 100 g - 2 / + 5 g	OK	[0, 1, 1, 2]	[0, 1, 1, 2]
FS-04	filling step Ph. Eur. 2.9.5 capsules 250 mg: ± 10 % around the target	OK	[0, 1, 1, 2]	[0, 1, 1, 2]
FS-05	filling step own limit ± 5 % around 10 g	OK	[0, 1, 1, 2]	[0, 1, 1, 2]
FS-06	fill weighing US 454 g (MAV 19.9 g): below Qn - MAV is under	OK	[0, 3, 3, 1]	[0, 3, 3, 1]
FM-01	NIST HB 133-2026 Table 2-5 (g) - the fill weighing of the UP^SCALE	OK	12.7	12.7
FM-02	NIST HB 133-2026 Table 2-5 (g) - the fill weighing of the UP^SCALE	OK	3.6	3.6
FM-03	NIST HB 133-2026 Table 2-5 (g) - the fill weighing of the UP^SCALE	OK	3.59	3.59
FM-04	NIST HB 133-2026 Table 2-5 (g) - the fill weighing of the UP^SCALE	OK	3.6	3.6
FM-05	NIST HB 133-2026 Table 2-5 (g) - the fill weighing of the UP^SCALE	OK	5.4	5.4
FM-06	NIST HB 133-2026 Table 2-5 (g) - the fill weighing of the UP^SCALE	OK	35.3	35.3
FM-07	NIST HB 133-2026 Table 2-5 (g) - the fill weighing of the UP^SCALE	OK	600	600
FM-08	NIST HB 133-2026 Table 2-5 (oz) - the fill weighing of the UP^SCALE	OK	19.490297	19.490297
FM-09	NIST HB 133-2026 Table 2-5 (lb) - the fill weighing of the UP^SCALE	OK	19.958064	19.958064
PIP-01	Water density - Tanaka 2001, 15 °C, 1013.25 hPa	OK	0.999103	0.999103
PIP-02	Water density - 20 °C, 1013.25 hPa (table 998.2067 kg/m3)	OK	0.998207	0.998207
PIP-03	Water density - 25 °C, 1013.25 hPa	OK	0.997047	0.997047
PIP-04	Water density - 20 °C, 950 hPa (compressibility)	OK	0.998204	0.998204
PIP-05	Air density - OIML R 111-1 E.3-1 (= the simplified CIPM formula, EURAMET cg-19 eq. 4), 20 °C, 1013.25 hPa, 50 %RH	OK	0.001199	0.001199
PIP-06	Air density - 23 °C, 980 hPa, 40 %RH	OK	0.001148	0.001148
PIP-07	Z factor at 20 °C, 1013.25 hPa (published tables: 1.0029 µL/mg)	OK	1.002851	1.002851
PIP-08	Z factor at 15 °C (published table: 1.0020)	OK	1.00197	1.00197
PIP-09	Z factor at 25 °C (published table: 1.0040)	OK	1.004	1.004

Case	Clause	Result	Expected	Calculated
PIP-10	Z factor at 30 °C (published table: 1.0054)	OK	1.005392	1.005392
PIP-11	Volumes of 10 deliveries of a 100 µL pipette, no evaporation	OK	{mean: 100.036037, es: 0.036037, esp: 0.036037, sr: 0.016071, cv: 0.016066, volumes: [100.027009, 100.050082, 100.012965, 100.056101, 100.037041, 100.024, 100.045066, 100.031022, 100.05911, 100.017981]}	{mean: 100.036037, es: 0.036037, esp: 0.036037, sr: 0.016071, cv: 0.016066, volumes: [100.027009, 100.050082, 100.012965, 100.056101, 100.037041, 100.024, 100.045066, 100.031022, 100.05911, 100.017981]}
PIP-12	The same with an evaporation rate of 0.0005 mg/s (corrected per cycle time)	OK	{mean: 100.045422, es: 0.045422, esp: 0.045422, sr: 0.016171, cv: 0.016163, volumes: [100.036238, 100.059662, 100.021943, 100.06553, 100.046821, 100.033128, 100.054445, 100.040552, 100.06844, 100.02746]}	{mean: 100.045422, es: 0.045422, esp: 0.045422, sr: 0.016171, cv: 0.016163, volumes: [100.036238, 100.059662, 100.021943, 100.06553, 100.046821, 100.033128, 100.054445, 100.040552, 100.06844, 100.02746]}
PIP-13	The same with gamma 2.4e-4 /°C at a water temperature of 21.5 °C (volume referred to 20 °C)	OK	{mean: 99.999645, es: -0.000355, esp: -0.000355, sr: 0.016066, cv: 0.016066, volumes: [99.99062, 100.013684, 99.976581, 100.019701, 100.000648, 99.987612, 100.00867, 99.994631, 100.022709, 99.981595]}	{mean: 99.999645, es: -0.000355, esp: -0.000355, sr: 0.016066, cv: 0.016066, volumes: [99.99062, 100.013684, 99.976581, 100.019701, 100.000648, 99.987612, 100.00867, 99.994631, 100.022709, 99.981595]}
PIP-14	Quick check: 4 deliveries of 100 µL	OK	{mean: 99.99429, es: -0.00571, esp: -0.00571, sr: 0.021664, cv: 0.021665, volumes: [99.99429, 99.974233, 100.024376, 99.984262]}	{mean: 99.99429, es: -0.00571, esp: -0.00571, sr: 0.021664, cv: 0.021665, volumes: [99.99429, 99.974233, 100.024376, 99.984262]}
PIP-15	Uncertainty of the mean volume - 100 µL, d 0.01 mg (ISO/TR 20461 model as rebuilt)	OK	{uc: 0.016264, U: 0.032528, uuse: 0.224856, Uuse: 0.449713, contrib: [0.005114, 0.010032, 0.001, 0.010032, 0.001295, 0.005418, 0.002229, 0.00019, 0.000099, 0.000051, 0.000065, 0.000201, 0.000025, 0, 0.016171, 0.200091, 0.100045, 0, 0]}	{uc: 0.016264, U: 0.032528, uuse: 0.224856, Uuse: 0.449713, contrib: [0.005114, 0.010032, 0.001, 0.010032, 0.001295, 0.005418, 0.002229, 0.00019, 0.000099, 0.000051, 0.000065, 0.000201, 0.000025, 0, 0.016171, 0.200091, 0.100045, 0, 0]}
PIP-16	Uncertainty - 10 µL on a micro balance (d 0.001 mg)	OK	{uc: 0.004793, U: 0.009586, uuse: 0.023692, Uuse: 0.047385, contrib: [0.00207, 0.002006, 0.0001, 0.002006, 0.000129, 0.00325, 0.000215, 0.000019, 0.00001, 0.000005, 0.000007, 0.00002, 0.000003, 0, 0.006544, 0.019993, 0.009997, 0, 0]}	{uc: 0.004793, U: 0.009586, uuse: 0.023692, Uuse: 0.047385, contrib: [0.00207, 0.002006, 0.0001, 0.002006, 0.000129, 0.00325, 0.000215, 0.000019, 0.00001, 0.000005, 0.000007, 0.00002, 0.000003, 0, 0.006544, 0.019993, 0.009997, 0, 0]}
PIP-17	Uncertainty - 1000 µL on an analytical balance (d 0.1 mg), no evaporation measured	OK	{uc: 0.157907, U: 0.315813, uuse: 2.251289, Uuse: 4.502578, contrib: [0.063298, 0.100326, 0.010006, 0.100326, 0.012952, 0, 0.022803, 0.001895, 0.000991, 0.000525, 0.000641, 0.002008, 0.000247, 0, 0.200164, 2.001159, 1.00058, 0, 0]}	{uc: 0.157907, U: 0.315813, uuse: 2.251289, Uuse: 4.502578, contrib: [0.063298, 0.100326, 0.010006, 0.100326, 0.012952, 0, 0.022803, 0.001895, 0.000991, 0.000525, 0.000641, 0.002008, 0.000247, 0, 0.200164, 2.001159, 1.00058, 0, 0]}
PIP-18	Decision rule - simple acceptance, pass	OK	{verdict: 1, sys: true, rand: true}	{verdict: 1, sys: true, rand: true}
PIP-19	Decision rule - simple acceptance, random error too big	OK	{verdict: 2, sys: true, rand: false}	{verdict: 2, sys: true, rand: false}
PIP-20	Decision rule - guard band, pass	OK	{verdict: 1, sys: true, rand: true}	{verdict: 1, sys: true, rand: true}
PIP-21	Decision rule - guard band, inconclusive	OK	{verdict: 3, sys: true, rand: true}	{verdict: 3, sys: true, rand: true}
PIP-22	Decision rule - guard band, fail	OK	{verdict: 2, sys: false, rand: true}	{verdict: 2, sys: false, rand: true}
PIP-23	Decision rule - one delivery: no random error	OK	{verdict: 1, sys: true, rand: true}	{verdict: 1, sys: true, rand: true}
PIP-24	EURAMET cg-19 v4.1 (2025), example 2: 100 mL pycnometer, m 99.7500 g, 18.94 °C, air density 0.0012 g/mL, 1e-5 /°C (published V20 = 100.014 mL)	OK	{mean: 100014.182682}	{mean: 100014.182682, es: 14.182682, esp: 0.014183, sr: null, cv: null, volumes: [100014.182682]}
PIP-25	EURAMET cg-19 v4.1 (2025), example 1: 1000 mL flask, m 996.9505 g, 19.11 °C, air density 0.0012 g/mL, 1e-5 /°C (published V20 = 999.628 mL)	OK	{mean: 999622.565086}	{mean: 999622.565086, es: -377.434914, esp: -0.037743, sr: null, cv: null, volumes: [999622.565086]}
PIP-26	Water density of air-saturated water - 20 °C, 1013.25 hPa (Tanaka 2001; EURAMET cg-19 eq. 3)	OK	0.998204	0.998204

Case	Clause	Result	Expected	Calculated
PIP-27	Z factor with air-saturated water - 20 °C, 1013.25 hPa, 50 %RH	OK	1.002854	1.002854
PIP-28	EURAMET cg-19 v4.1 example 2 (100 mL pycnometer) with air-saturated water	OK	{mean: 100014.443882}	{mean: 100014.443882, es: 14.443882, esp: 0.014444, sr: null, cv: null, volumes: [100014.443882]}
PIP-29	A lab with the reference temperature 27 °C: gamma 2.4e-4 /°C, water 26.5 °C - the volume referred to 27 °C	OK	{mean: 100.16993, es: 0.16993, esp: 0.16993, sr: 0.016093, cv: 0.016066, volumes: [100.160889, 100.183993, 100.146826, 100.19002, 100.170934, 100.157876, 100.17897, 100.164907, 100.193033, 100.151849]}	{mean: 100.16993, es: 0.16993, esp: 0.16993, sr: 0.016093, cv: 0.016066, volumes: [100.160889, 100.183993, 100.146826, 100.19002, 100.170934, 100.157876, 100.17897, 100.164907, 100.193033, 100.151849]}
PIP-30	Handling of the instrument 0.1 % of the volume in U of the mean volume (EURAMET cg-19 v4.1 6.3.7.2) - otherwise as PIP-15	OK	{uc: 0.101359, U: 0.202718, uuse: 0.246109, Uuse: 0.492217, contrib: [0.005114, 0.010032, 0.001, 0.010032, 0.001295, 0.005418, 0.002229, 0.00019, 0.000099, 0.000051, 0.000065, 0.000201, 0.000025, 0, 0.016171, 0.200091, 0.100045, 0, 0.100045]}	{uc: 0.101359, U: 0.202718, uuse: 0.246109, Uuse: 0.492217, contrib: [0.005114, 0.010032, 0.001, 0.010032, 0.001295, 0.005418, 0.002229, 0.00019, 0.000099, 0.000051, 0.000065, 0.000201, 0.000025, 0, 0.016171, 0.200091, 0.100045, 0, 0.100045]}
SOL-01	Recipe / solution: the goals of the rows from their shares - 200 g, shares 50 / 30 / 20 %	OK	{goals: [100, 60, 40], sum: 100}	{goals: [100, 60, 40], sum: 100}
SOL-02	The shares as the app sends them (goal / biggest x 100): 90 g, shares 50 / 100	OK	{goals: [30, 60], sum: 150}	{goals: [30, 60], sum: 150}
SOL-03	A share of exactly 100 % counts in the sum (above 100: a fixed weight, not counted) - 300 g, shares 100 / 50	OK	{goals: [200, 100], sum: 150}	{goals: [200, 100], sum: 150}
SOL-04	Recalculation: the base row (goal 100 g) was taken with 105 g - every goal in the same proportion	OK	{goals: [105, 63, 42], total: 210}	{goals: [105, 63, 42], total: 210}
SOL-05	Recalculation from the second row: goal 60 g taken with 57 g	OK	{goals: [95, 57, 38], total: 190}	{goals: [95, 57, 38], total: 190}
SOL-06	No recalculation when the base row has nothing weighed	OK	{goals: [100, 60, 40], total: 200}	{goals: [100, 60, 40], total: 200}
SOL-07	State of a row - goal 100 g, tolerance 0.5 %, d 0.1 g: 100.4 g	OK	{state: ok, w: 100.4}	{state: ok, w: 100.4, tolg: 0.5, band: 0.5, below: false}
SOL-08	The same row with 100.6 g	OK	{state: over, w: 100.6}	{state: over, w: 100.6, tolg: 0.5, band: 0.5, below: false}
SOL-09	The same row with 99.4 g	OK	{state: under, w: 99.4}	{state: under, w: 99.4, tolg: 0.5, band: 0.5, below: false}
SOL-10	Tolerance 0: a value within 1 d of the goal is ok (100.1 g, d 0.1 g)	OK	{state: ok, w: 100.1}	{state: ok, w: 100.1, tolg: 0, band: 0.1, below: false}
SOL-11	Already in the vessel: base 40 g + reading 60.3 g, tolerance 0	OK	{state: over, w: 100.3}	{state: over, w: 100.3, tolg: 0, band: 0.1, below: false}
SOL-12	Air buoyancy correction of the row +1000 ppm: reading 99.95 g, tolerance 0.1 %	OK	{state: ok, w: 100.04995}	{state: ok, w: 100.04995, tolg: 0.1, band: 0.1, below: false}
SOL-13	Tolerance narrower than d - goal 10 g, tolerance 0.2 %, d 0.1 g: flagged, accepted within 1 d (10.08 g)	OK	{state: ok, w: 10.08, tolg: 0.02, band: 0.1, below: true}	{state: ok, w: 10.08, tolg: 0.02, band: 0.1, below: true}
SOL-14	Tolerance equal to d - goal 10 g, tolerance 1 %, d 0.1 g: not flagged (10.1 g)	OK	{state: ok, w: 10.1, tolg: 0.1, band: 0.1, below: false}	{state: ok, w: 10.1, tolg: 0.1, band: 0.1, below: false}
SOL-15	Tolerance wider than d - goal 100 g, tolerance 0.5 %, d 0.1 g: the band is the tolerance (100.4 g)	OK	{state: ok, tolg: 0.5, band: 0.5, below: false}	{state: ok, w: 100.4, tolg: 0.5, band: 0.5, below: false}
SOL-16	No tolerance - goal 100 g, d 0.1 g: the band is 1 d, not flagged (100.1 g)	OK	{state: ok, tolg: 0, band: 0.1, below: false}	{state: ok, w: 100.1, tolg: 0, band: 0.1, below: false}
UNIT-01	Unit - 100 g in avoirdupois ounces (1 oz = 28.349523125 g)	OK	3.527396	3.527396
UNIT-02	Unit - 1000 g in pounds (1 lb = 453.59237 g, international pound 1959)	OK	2.204623	2.204623
UNIT-03	Unit - 1 troy ounce (31.1034768 g)	OK	1	1

Case	Clause	Result	Expected	Calculated
UNIT-04	Unit - 10 kg in grains (1 gr = 64.79891 mg)	OK	154323.583529	154323.583529
UNIT-05	Unit - 10 kg in tola (1 tola = 180 gr = 11.6638038 g)	OK	857.353242	857.353242
UNIT-06	Unit - 1 pennyweight (24 gr = 1.55517384 g)	OK	1	1
UNIT-07	Unit - 1 g in metric carats (1 ct = 0.2 g)	OK	5	5
UNIT-08	Unit - 3.5 g in eighths (the eighth of the shops: 3.5 g - not 1/8 oz)	OK	1	1
UNIT-09	Unit - 2500 g in kg	OK	2.5	2.5
UNIT-10	Unit - 12.5 mg as mg	OK	12.5	12.5
MPE-01	ISO 8655-2:2022 (secondary sources) - 100 µL single-channel at the nominal volume	OK	{sys: 0.8, rand: 0.3}	{sys: 0.8, rand: 0.3}
MPE-02	Multichannel 1000 µL x 8: the default of the app, two times the single-channel limits (the rule of ISO 8655-2:2002)	OK	{sys: 16, rand: 6}	{sys: 16, rand: 6}
MPE-03	A nominal volume between the rows (300 µL): the % of the next bigger row (500 µL)	OK	{sys: 2.4, rand: 0.9}	{sys: 2.4, rand: 0.9}
MPE-04	10 µL single-channel	OK	{sys: 0.12, rand: 0.08}	{sys: 0.12, rand: 0.08}
MPE-05	Test volumes of a calibration: nominal, 50 %, max(10 %, lower limit) - 100-1000 µL	OK	[1000, 500, 100]	[1000, 500, 100]
MPE-06	Test volumes - 0.5-10 µL (10 % above the lower limit)	OK	[10, 5, 1]	[10, 5, 1]
MPE-07	Test volumes - a fixed-volume pipette	OK	[200]	[200]
MPE-08	Lab table with multichannel columns - 100 µL x 8	OK	{sys: 1.5, rand: 0.6}	{sys: 1.5, rand: 0.6}
MPE-09	The same table - a single-channel 100 µL pipette	OK	{sys: 0.8, rand: 0.3}	{sys: 0.8, rand: 0.3}
MPE-10	Lab table - 150 µL x 8 between the rows 100 and 200 µL	OK	{sys: 2.25, rand: 0.9}	{sys: 2.25, rand: 0.9}
MPE-11	Lab limits at one test volume - 100 µL pipette at 10 µL	OK	{sys: 0.25, rand: 0.15}	{sys: 0.25, rand: 0.15}
MPE-12	The same line for 100 µL x 8 without multichannel columns	OK	{sys: 0.5, rand: 0.3}	{sys: 0.5, rand: 0.3}
MPE-13	A test volume without its own line - the line of the nominal volume	OK	{sys: 0.8, rand: 0.3}	{sys: 0.8, rand: 0.3}
MPE-14	Piston burette, motor-driven, 25 mL at the nominal volume (ISO 8655-3:2022 table 1: 0.20 % / 0.070 %)	OK	{sys: 50, rand: 17.5}	{sys: 50, rand: 17.5}
MPE-15	The same burette at 10 % (2.5 mL): the 10 % column of table 1 (2.0 % / 0.70 %)	OK	{sys: 50, rand: 17.5}	{sys: 50, rand: 17.5}
MPE-16	Motor-driven burette 50 mL at 50 % (25 mL): the 50 % column (0.40 % / 0.10 %)	OK	{sys: 100, rand: 25}	{sys: 100, rand: 25}
MPE-17	Motor-driven burette 1 mL at 10 % (0.1 mL): the row up to 1 mL (6.0 % / 1.0 % at 10 %)	OK	{sys: 6, rand: 1}	{sys: 6, rand: 1}
MPE-18	Piston burette, manual, 25 mL (maker procedure: 0.2 % / 0.1 %)	OK	{sys: 50, rand: 25}	{sys: 50, rand: 25}
MPE-19	Bottle-top dispenser 10 mL at 10 % (1 mL): 6.0 % / 2.0 % (maker procedure, ISO 8655-5:2022)	OK	{sys: 60, rand: 20}	{sys: 60, rand: 20}
MPE-20	Repeating dispenser: no default limits (maker or own limits needed)	OK	{sys: null, rand: null}	{sys: null, rand: null}
LIM-01	The limits table as typed in the lab settings (decimal comma, a line for a test volume, two bad lines)	OK	{rows: [[100, 0.8, 0.3, 1.5, 0.6]], vrows: [[100, 10, 0.25, 0.15]], bad: [3, 4]}	{rows: [[100, 0.8, 0.3, 1.5, 0.6]], vrows: [[100, 10, 0.25, 0.15]], bad: [3, 4]}

Case	Clause	Result	Expected	Calculated
WU-01	The unit table of the app: g per unit = the legal definitions, gram -> unit = 1 / (g per unit)	OK	[[1, 1], [28.349523, 0.035274], [3.5, 0.285714], [453.59237, 0.002205], [31.103477, 0.032151], [0.2, 5], [0.064799, 15.432358], [11.663804, 0.085735], [1.555174, 0.643015], [420, 0.002381], [1000, 0.001], [0.001, 1000], [0.000001, 1000000], [1000000, 0.000001]]	[[1, 1], [28.349523, 0.035274], [3.5, 0.285714], [453.59237, 0.002205], [31.103477, 0.032151], [0.2, 5], [0.064799, 15.432358], [11.663804, 0.085735], [1.555174, 0.643015], [420, 0.002381], [1000, 0.001], [0.001, 1000], [0.000001, 1000000], [1000000, 0.000001]]
ST-01	Statistics page - 10, 12, 14 g	OK	{n: 3, mean: 12, min: 10, max: 14, range: 4, sd: 2, cv: 16.666667}	{n: 3, mean: 12, min: 10, max: 14, range: 4, sd: 2, cv: 16.666667}
ST-02	Statistics page with limits: setpoint 10 g, perfect +/- 1 %, ok +/- 5 % - 9.8, 10.0, 10.2, 10.4 g	OK	{mean: 10.1, range: 0.6, sd: 0.258199, cv: 2.556425, perfect: 25, ok: 75, out: 0, cp: 0.645497, cpk: 0.516398}	{n: 4, mean: 10.1, min: 9.8, max: 10.4, range: 0.6, sd: 0.258199, cv: 2.556425, perfect: 25, ok: 75, out: 0, cp: 0.645497, cpk: 0.516398}
ST-03	NIST StRD univariate data set NumAcc1 (10000001, 10000003, 10000002): certified mean 10000002, standard deviation 1	OK	{n: 3, mean: 10000002, sd: 1}	{n: 3, mean: 10000002, min: 10000001, max: 10000003, range: 2, sd: 1, cv: 0.00001}
ST-04	A large offset after the design of NIST StRD NumAcc3: 1000000.2 and 50 pairs 1000000.1 / 1000000.3 (101 values)	OK	{n: 101, mean: 1000000.2, sd: 0.1, min: 1000000.1, max: 1000000.3}	{n: 101, mean: 1000000.2, min: 1000000.1, max: 1000000.3, range: 0.2, sd: 0.1, cv: 0.00001}
ST-05	One value: no standard deviation	OK	{n: 1, mean: 5, sd: 0, cv: 0, range: 0}	{n: 1, mean: 5, min: 5, max: 5, range: 0, sd: 0, cv: 0}
ST-06	The limits of the statistics from % of a setpoint: 200 g, perfect -1 % / +2 %, ok +/- 5 %	OK	{perfect: [198, 204], ok: [190, 210]}	{perfect: [198, 204], ok: [190, 210]}
BAL-01	ISO 8655-6:2022 balance - 10 µL: d 0.001 mg, s 0.006 mg, U in use 0.012 mg	OK	{d: 0.001, s: 0.006, u: 0.012}	{d: 0.001, s: 0.006, u: 0.012}
BAL-02	ISO 8655-6:2022 table 1 - 100 µL: d 0.01 mg, s 0.025 mg, U in use 0.05 mg	OK	{d: 0.01, s: 0.025, u: 0.05}	{d: 0.01, s: 0.025, u: 0.05}
BAL-03	1000 µL x 8 on a single-channel balance: repeatability and uncertainty x 2 (table 1, footnote a)	OK	{d: 0.1, s: 0.4, u: 0.8}	{d: 0.1, s: 0.4, u: 0.8}
BAL-04	20 µL: the second row starts at 20 µL	OK	{d: 0.01, s: 0.025, u: 0.05}	{d: 0.01, s: 0.025, u: 0.05}
BAL-05	0.5 µL single-channel: below 2 µL the U in use must stay below 1/4 of the max. systematic error (table 1, footnote e)	OK	{d: 0.001, s: 0.006, u: 0.00625}	{d: 0.001, s: 0.006, u: 0.00625}
BAL-06	10 mL: the row 200 µL - 10 mL includes 10 mL	OK	{d: 0.1, s: 0.2, u: 0.4}	{d: 0.1, s: 0.2, u: 0.4}
BAL-07	1 µL x 8 on a single-channel balance: footnote e is for single-channel pipettes, footnote a doubles	OK	{d: 0.001, s: 0.012, u: 0.024}	{d: 0.001, s: 0.012, u: 0.024}
DEV-01	ISO 8655-6:2022 clause 4 - a calibration with no deviation the app can see (100 µL, 10-100 µL)	OK	[]	[]
DEV-02	8.1.1 / 8.1.2 - only the nominal volume of an adjustable pipette and 4 deliveries	OK	[volumes, n]	[volumes, n]
DEV-03	6 / 7.2 - room 24.0 °C, 40 %RH, water 23.0 °C (start)	OK	[room_t, room_rh, water_air]	[room_t, room_rh, water_air]
DEV-04	7.2 - reference temperature 27 °C, humidity not entered, the room 26.0 -> 26.8 °C	OK	[rh_none, room_change]	[rh_none, room_change]
DEV-05	5.5 table 2 - air thermometer u 0.5 °C, hygrometer u 5 %RH (k = 1)	OK	[inst_ta, inst_rh]	[inst_ta, inst_rh]
DEV-06	Air temperature left empty, a fixed 200 µL pipette, stopped early	OK	[ta_none, stopped]	[ta_none, stopped]
CMC-01	CMC lookup - an absolute row (10-100 µL: 0.1 µL)	OK	0.1	0.1
CMC-02	CMC lookup - a relative row (100-1000 µL: 0.2 %)	OK	1	1
CMC-03	CMC lookup - a + b x V (1-10 µL: 0.05 + 0.001 V)	OK	0.055	0.055

Case	Clause	Result	Expected	Calculated
CMC-04	CMC lookup - two rows meet at 100 µL: the bigger CMC	OK	0.2	0.2
CMC-05	CMC lookup - outside the scope (no row for 20 mL air displacement)	OK	-	-
CMC-06	CMC lookup - a row for positive displacement only does not cover an air displacement pipette	OK	-	-
CMC-07	ILAC P14 - the reported U is never smaller than the CMC (raised)	OK	{U: 0.1, raised: true, outside: false}	{U: 0.1, raised: true, outside: false}
CMC-08	ILAC P14 - U bigger than the CMC stays	OK	{U: 0.2, raised: false, outside: false}	{U: 0.2, raised: false, outside: false}
CMC-09	ILAC P14 - no CMC: outside the scope, U as calculated	OK	{U: 0.2, raised: false, outside: true}	{U: 0.2, raised: false, outside: true}
CMC-10	CMC of a burette: only the burette row (5 mL: 0.1 % = 5 µL; the pipette row is not used)	OK	5	5
CMC-11	CMC of a pipette (air displacement): only the pipette row, never a burette row	OK	15	15

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Firmware 1.01312 · configuration counter 40 · Code: 4c036345ba8263a2

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