English

SOP
0624

Titrette®

Standard Operating Procedure

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1. Introduction

The test instruction transfers standards relevant to the test into a practical form. It can therefore be used as a basis for test equipment monitoring according to DIN EN ISO 9001, DIN EN ISO 10012, and DIN EN ISO/IEC 17 025.

Basically, we recommend an inspection every 3…12 months. However, the testing interval may be adjusted to your individual requirements. In the case of high frequency of use or the use of aggressive media, it is advisable to check more frequently.

The following instruments can be checked using these test instructions:

Instrument

Titrette®

For the regular checks according to DIN EN ISO 9001, DIN EN ISO 10 012, and DIN EN ISO/IEC 17 025 as well as the GLP Guidelines, we offer a calibration service (see BRAND Calibration Service). This calibration service saves you time and internal effort, especially if you still have to perform calibrations in addition to ongoing operation.

Legend

In order to simplify the collection of the relevant data, the SOP refers to the respective items in the test report. The following graphics indicate to these positions:

Example:

Position in the test report:

Instrument

In the appendix, you will also find the health clearance form required to send in equipment as well as information about our accredited calibration laboratory and EASYCAL™ 5 calibration software.

2. Preparation

2.1. Instrument type and serial number

1. Determine instrument type and nominal volume. Enter the result in the test report: 1
2. Read off the serial number. The serial number is located on the Housing . Enter the result in the test report: 1
3. Read customers identification, if available. Enter the result in the test report: 1

2.2. Minimum required equipment

You need at least the following minimum equipment of this laboratory instrument to test the Titrette®:

+ Titrette®
+ Titrating tubes
+ Filling tube
+ Installation tool

In addition, a balance and other test equipment is required. These are specified under test instruments and accessories. Use only original parts

2.3. Cleaning

1. Rinse the laboratory instrument with cleaning solution. Then rinse several times with distilled water. Select cleaning solution according to the previously dispensed medium.
2. Titrette® wipe outside.

2.4. Visual inspection for damage and leaks

+ Housing
+ Titrating tubes
+ Filling tube
+ Recirculation tube
+ Display
+ Controls
+ Leakage

Enter the result in the test report 2.

Possible errors and the actions that can be taken as a result:

Error	Measures
Bent, defective titrating tube or aspiration tube	A bent, defective titrating tube or aspiration tube may pose a safety risk. The part should therefore be replaced (see instructions for use under Accessories/spare parts)
Leakage	Leaks may pose a safety risk; parts must therefore be replaced or the instrument returned for repair.
Defective controls	Send instrument for repair.

2.5. Functional test

1. Screw Titrette® onto a bottle filled with distilled or deionized water (in accordance with ISO 3696, at least quality 3).
2. Vent (see instructions for use).
   → A few air bubbles of up to 1 mm in the glass cylinder are permissible.
3. Check controls.
   → Hand wheels running smoothly.
   → Function of the On/Off, Pause, and CLEAR keys.
4. Enter the result in the test report 3.

If the instrument does not function properly (e.g., sluggish piston, stuck valves, or leaks), consult chapter Troubleshooting in the instructions for use.

3. Test instruments and accessories

+ Titrette®
+ Bottle (at least 500 ml) filled with distilled or deionized water (in accordance with ISO 3696, at least quality 3, ambient temperature). Adjustment of water and ambient temperature
+ Fill the collecting vessel (e.g., Erlenmeyer flask, narrow-necked) with a small amount of water
+ Thermometer with a max. measuring deviation: ± 0.2°C
+ Place the instrument in the test chamber for at least 1 h (not packed). Allow instrument to adjust to ambient temperature.
+ Balance, recommended specifications:

Nominal volume of the instrument to be tested	Resolution of the display	Repeatability	Expanded measurement uncertainty in use
V	mg	mg	mg
10 ml	0.1	0.2	0.2
25 ml < V ≤ 50 ml	1	2	2

Traceability of test results to the national standard

By using calibrated test equipment (balance and thermometers), the requirement of DIN EN ISO 9001, DIN EN ISO 10 012, and DIN EN ISO/IEC 17 025 for traceability of the test to the national standard is fulfilled. The calibration of the balance can be done by DAkkS calibration, a direct official calibration of the balance, or by calibrating the balance with correspondingly traced weights (corresponding precision). The thermometer can also be calibrated by means of a DAkkS calibration, an official calibration, or by comparison with corresponding traceable thermometers (under defined conditions).

4. Gravimetric testing

1. Determine the temperature of the test water.
   → Enter the result in the test report 4.
2. Fill the instrument to the upper stop.
3. Dispense five drops in a separate vessel and wipe off the titrating tube.
4. Set display to zero (“Clear”).
5. Place the collecting vessel on the balance and tare.
6. Place the collecting vessel under the titrating tube, and dispense the entire nominal volume without stopping. Make sure that the cannula does not touch the vessel wall.
   → Dispense with both hands in order to enable rapid dispensing
7. Wipe the titrating tube on the collecting vessel.
8. Place the collecting vessel on the balance, and note the weight value.
   → Enter the result in the test report 5.
9. Re-tare the balance.
10. Repeat steps 2 through 9 ten times.
11. Then dispense 50 or 10% of the nominal volume 10 times in the same way .
12. Partial volumes do not require refilling before each dispensing.

5. Evaluation of gravimetric test results

The weight values obtained during the gravimetric test are only the mass values of the dispensed volume. In order to obtain the actual volume, an adjustment calculation must be carried out. The following calculations must be carried out:

Step	Calculation	Remark
1.	**Mean weight**: (Example for 10 weight values) $\bar{x} = \frac{x_1 + x_2 + x_3 + x_4 + x_5 + x_6 + x_7 + x_8 + x_9 + x_{10}}{10}$	
2.	**Mean volume**: $\overline{V} = \bar{x} * Z$	Factor Z (see Table 1). Enter the result in the test report 6a.
3.	**Standard deviation**: $s = Z * \sqrt{\frac{\sum(x_i - \bar{x})^2}{n-1}}$	Factor Z (see Table 1). Enter the result in the test report 6b.
4.	**Accuracy**: $A\% = \frac{\overline{V} - V_0}{V_0} * 100$	Enter the result in the test report 6c.
5.	**Coefficient of variation**: $CV\% = \frac{100\ s}{\overline{V}}$	Enter the result in the test report 6d.
	Actual/nominal value comparison: For error limits, see and and the following accuracy tables for the respective instrument, or define your own error limits.	Enter the result in the test report 6e.
	Result:	Enter the result in the test report 6g.

If the calculated values (A% and CV%) are less than or equal to the error limits, the instrument is in good working order.

If the calculated values are greater than the error limits:

+ Check that all instructions have been carried out correctly.
+ Follow the instructions in the “Troubleshooting” section in the instructions for use.
+ Adjust Titrette® according to the instructions for use.

If these measures do not lead to success, we recommend that you use the BRAND calibration service (see *'BRAND Calibration Service, p. 14'*).

We recommend using software to help perform the calculation and evaluation. For this purpose, BRAND offers the EASY-CAL™ calibration software (see here). This convenient software runs on Windows and speeds up the calculation considerably.

5.1. Possible volume error

Possible volume errors and the actions that can be taken:

Error	Possible causes	Measures
Volume too large	Drop hangs on the titrating tubes.	+ Before weighing, wipe off any drops on the collecting vessel. + Tare the balance.
	Dispensed too quickly or unevenly.	Repeat test, and vary speed.
Volume too small	Instrument used with media that form deposits in the cylinder.	Clean according to the medium used.
	Filling valve or titrating tubes leaking.	Tighten or clean the filling valve or titrating tube in accordance with the instructions for use, and replace if necessary.
Other influencing variables	Instrument incorrectly calibrated (<CAL> appears in the display).	Establish basic setting; see instructions for use.
	Irregular dispensing	Turn the hand wheels evenly and without pressure.
	Temperature calibration of instrument, ambient, and water temperature not completed.	Perform temperature adjustment.

5.2. Temperature and factor Z

Extract from DIN EN ISO 8655

Table refers to 1,013 hPa.

In the validity range from 950 hPa to 1040 hPa.

Temperature: ° C	Factor Z ml/g		Temperature: ° C	Factor Z ml/g
15	1.0020		23	1.0035
15.5	1.0020		23.5	1.0036
16	1.0021		24	1.0038
16.5	1.0022		24.5	1.0039
17	1.0023		25	1.0040
17.5	1.0024		25.5	1.0041
18	1.0025		26	1.0043
18.5	1.0026		26.5	1.0044
19	1.0027		27	1.0045
19.5	1.0028		27.5	1.0047
20	1.0029		28	1.0048
20.5	1.0030		28.5	1.0050
21	1.0031		29	1.0051
21.5	1.0032		29.5	1.0052
22	1.0033		30	1.0054
22.5	1.0034			

5.3. Manufacturer error limits for Titrette®

Volume ml	Partial volume ml	A ≤ ± %	CV ≤ %
10	10	0.10	0.05
	5	0.20	0.10

Volume ml	Partial volume ml	A ≤ ± %	CV ≤ %
	1	1.00	0.50
25	25	0.07	0.025
	12.5	0.14	0.05
	2.5	0.70	0.25
50	50	0.06	0.02
	25	0.12	0.04
	5	0.60	0.20

5.4. ISO error limits for burettes

Nominal volume	Error limits for the systematic measurement deviation	Error limits for the random measurement deviation
ml	± % [A]	% [CV]
10	0.3	0.1
25	0.2	0.1
50	0.2	0.1

5.5. Error limits to be defined by the user

For calibration, the applicable error limits must be defined by the user. Different methods can be applied to accomplish this:

If the application requires it and the optimized test conditions exist for measurement, the error limits specified in the can also be expected in the case of used, intact volumetric instruments.

In accordance with the German Calibration Law, however, it is also admissible to apply operational limits. The operational limits equate to double the calibration error limits. This means that the values of the manufacturer's error limits must be doubled. Users may also define their own individual error limits related to their particular application, which their calibrated (adjusted) measuring instrument should adhere to.

This procedure meets the requirements of DIN EN ISO 9001, DIN EN ISO 10 012, and DIN EN ISO/IEC 17 025.

6. Test report for volumetric instruments

1 Instrument

- ☐ Titrette®
- ☐ Burette Digital
- ☐ Dispensette®
- ☐ Transferpette®
- ☐ Transferpette® S
- ☐ Transferpette® electronic
- ☐ Transferpettor

Type

- ☐ fixed
- ☐ variable

- ☐ analog
- ☐ digital

Nominal volume:

Serial number:

Customer's marking:

2 Damage

Nominal volume:

Serial number:

Customer's marking:

3 Operating defects

- ☐ Type of damage
- ☐ Damage remedied
- ☐ none
- ☐ Type of functional defect
- ☐ Functional defect eliminated

4 Environment

Water temperature:

Balance:

Thermometer:

Continued on next page

Relative humidity: (at least 45%):

Correction factor Z:

5 Weight values of the gravimetric test

Weight value No.	At 10% in mg	At 50% in mg	For nominal volume in mg
x_1:			
x_2:			
x_3:			
x_4:			
x_5:			
x_6:			
x_7:			
x_8:			
x_9:			
x_{10}:			

6 Evaluation of the gravimetric test

Calculated value		At 10%	At 50%	For nominal volume
6a	$\overline{V}$			
6b	s			
6c	A [%] actual			
6d	CV [%] actual			
6e	A [%] target			
6e	CV [%] target			
6g	Result			

The test was carried out according to DIN EN ISO 8655 and DIN EN ISO 4787.

Date: Signature:

7. Appendix

7.1. Abbreviations, units, and notations

The following abbreviations are used in this or other test instructions:

Symbol	A < B: A is less than B A ≤ B: A is less than or equal to B
Ranges	Example: 980…1000 hPa Avoids sign confusion: Hyphen as a minus sign
	Example: 20 µl < V < 100 µl The volume V is between 20 µl and 100 µl (V is larger than 20 µl and smaller than 100 µl).
Materials	PFP: Perfluorinated pentacene
	PMP Polymethylpentene
	PFA Perfluoroalkoxy polymer
	Boro 3.3 Borosilicate glass
	AR-GLAS®: A soda-lime glass from SCHOTT AG, 55122 Mainz, Germany
	PUR: Polyurethane
W_1	Tare weight of the weighing vessel
W_2	Weight of the weighing vessel filled with the medium to be weighed.
A	Accuracy
CV	Coefficient of variation:
V	Volume
s	Second
l	Liter
ml	Milliliter(s)
µl	Microliters
g	Gram(s)
mg	Milligrams(s)

7.2. Declaration on the Absence of Health Hazards

Please enclose with the instrument or send as an e-mail to service@brand.de.

BRAND GMBH + CO KG

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service@brand.de
F +49 9342 808 91290

We are required by law to protect our employees against hazards caused by contaminated instruments. Therefore, we thank you for understanding that we can only perform calibrations| repairs when this declaration is completed, signed and provided to us.

CAUTION! If you are a customer outside of Germany, please contact our local service partner in your country. Please send in instruments from outside Germany only after being requested to do so. Unsolicited instruments cannot be processed.

To the equipment shipment from | To the delivery note number

Instrument | Serial Number

The undersigned hereby declares:

+ That the instruments have been carefully cleaned and decontaminated before shipment.
+ That the instruments pose no danger through bacteriological, viral, chemical, and/or radioactive contamination.

Applications

Media used:

- ☐ Acids
- ☐ Bases
- ☐ Solvents
- ☐ Serum, blood
- ☐ Cell culture media, buffers
- ☐ Other:

Measures for decontamination:

Company / laboratory (official stamp)

Name:

Pos.

Date / legally binding signature:

Tel. / fax / e-mail

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7.3. BRAND Calibration Service

BRAND offers a complete service that includes calibration and adjustment of BRAND and third-party instruments as well as any necessary maintenance and repair of BRAND instruments. This saves time and money, with the added benefit of testing by an independent laboratory. Find more information and the order form for the repair and calibration service on brand.de.

7.3.1. Range of instruments

1. Piston-operated pipettes (single- and multi-channel)
2. Bottle-top dispensers
3. Bottle-top burettes
4. Repetitive pipettes

7.3.2. Testing in accordance with DIN EN ISO 8655

A team of qualified staff, working in temperature and humidity controlled rooms and using state-of-the-art balances and calibration software, calibrates Liquid Handling instruments, regardless of their make, in accordance with DIN EN ISO 8655.

Variable volume instruments such as the HandyStep®Touch, HandyStep®Touch S, HandyStep® electronic, Transferpette®, Transferpette®S, Transferpette®electronic, Transferpette®-8/-12, Transferpette®-8/-12 electronic, Transferpette®S -8/-12, Transferpettor, Dispensette®, digital burettes, or Titrette® are checked at nominal volume, 50% of the nominal volume, and at 10% or 20% of the nominal volume.

To document the results, a detailed test report that fully complies with all relevant regulations is compiled.

The BRAND Calibration Service provides:

1. Calibration of Liquid Handling instruments, regardless of their make
2. Detailed calibration certificate
3. Return of instrument within a few working days
4. Cost-efficient implementation

7.4. EASYCAL™ Calibration software – test equipment monitoring made easy

The EASYCAL™ 5 calibration software facilitates the monitoring of liquid handling instruments (piston-stroke instruments such as pipettes, dispensers, burettes, and manual dispensers) as well as volumetric instruments made of glass or plastic according to GLP/GMP and DIN EN ISO 9001. EASYCAL™ 5 can be used not only for BRAND instruments but also for the instruments of all manufacturers.

EASYCAL™ 5 performs all calculations automatically and compares them with the tolerances from the current standards or their individually defined limits. The tolerances of numerous instruments and the interface settings of over 100 test instruments (e.g., balances) are already stored for you.

Choose between a stand-alone version for working on one workstation (recommended for small laboratories where calibration is done by a single person) or a client/server version for parallel, distributed work on multiple workstations (floating licenses are installed on the server).

Functions:

+ Testing of liquid handling instruments and volumetric instruments made of glass and plastic in accordance with ISO 8655, ISO 4787, and others.
+ Open software, suitable for all volumetric instruments – regardless of manufacturer.
+ Extensive library with instrument specifications from well-known manufacturers can be expanded and modified by the user.
+ Scope of testing can be individually defined by the user via test plans. An extensive library of test plans is included to help you get started with EASYCAL™ 5 and minimize data entry time.
+ Instrument management – quickly and easily search and find the owner, test history, and next test date.
+ Continuous control of the current actual state during the test by graphical representations and ad hoc calculation of statistical values.
  Reminder function for upcoming tests with automatic notification of the instrument owner via e-mail.
+ Integration of the address data of your customers and suppliers in a business partner database User administration with user roles (e.g., auditor, supervisor, system administrator) and access restriction to EASYCAL functions.
  Dual-control principle for the release of critical data such as test plans, calibration orders before certificate printing, and instrument specification.

+ Interface connection via RS232 of measuring instruments such as balances, thermometers, barometers, and hygrometers with automatic transmission of the measured values.
+ In the integrated certificate editor, you can customize the certificates, and test reports supplied to your needs and create the design.

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We want to inform and advise our customers through our technical writings. However, the transferability of general empirical values and results under test conditions to the specific application depends on a variety of factors beyond our control. We therefore ask for your understanding that no claims can be derived from our advice. The transferability must therefore be checked very carefully by the user himself in each individual case.

Technical changes, errors and misprints excepted.

At store.brand.de you will find accessories and spare parts, user manuals, test instructions (SOP) and videos for the product.

For more information on products and applications, please visit our Youtube channel mylabBRAND.

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