BIOTECH

Validation Guide

USTR 3520

Validation Guide for Palltronic® Flowstar V Integrity Test Instrument

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Contents

1 Introduction

The Palltronic Flowstar V filter integrity test instrument must be validated to ensure that the instrument satisfies both process and regulatory requirements.

This validation guide provides guidance to enable users to achieve and maintain a validated state for this instrument.

Section 2 of this document (Procedures and Documents to Achieve a Validated State) is designed to assist users of the instrument in meeting the validation requirements of the various regulatory authorities within the pharmaceutical industry.

Section 3 (Verification of Measurement Functions of the Palltronic Flowstar V Instrument) describes details of the measurement operation of the Palltronic Flowstar V instrument.

Section 4 (Verification of the Pressure Measurement and Pressure Control by the Palltronic Flowstar V Instrument) describes details of performed tests to verify the accuracy and reproducibility of the instrument, including an extended set of data.

2 Procedures and Documents to Achieve a Validated State

2.1 Introduction

This part of the document describes a method to validate a filter integrity test instrument such as the Palltronic Flowstar V integrity test instrument.

The current document for Good Automated Manufacturing Practice (GAMP® 5)[1] has been used as a guideline. It should be noted that procedures for individual users may vary depending on the user's quality management system.

GAMP defines a lifecycle approach, in which the project phase includes the following steps:

- Planning
- Specification, configuration and coding*
- Verification
- Reporting and release

(See GAMP 5, section 4, 'Life Cycle Phases', page 29)[1]

*Configuration and coding are not covered in this document.

2.2 Planning

The planning phase for the installation of a filter integrity test instrument should include a risk assessment (2.2.1), a definition of the system complexity (2.2.2) and a supplier assessment (2.2.3).

2.2.1 Risk Assessment

A risk assessment should evaluate the impact of filter integrity test instrument usage on patient safety, product quality and data integrity.

This risk assessment should focus on the instrument's performance and on the impact of the intended operating environment.

A functional risk assessment focusing on the instrument performance was carried out during development and is available from Pall on request (Document No: FFS05 RA/A). This risk assessment was used to determine the scope of qualification testing performed by Pall.

2.2.2 Definition of the System Complexity (Software and Hardware Category)

GAMP 5 provides a classification system for categories of software and hardware to assist with the assessment of the system complexity.

This classification has a significant impact on the required verification and documentation.

The Palltronic Flowstar V instrument as an 'off-the-shelf' instrument may be classified according to the GAMP 5 guideline as software category 3 (instrument) and hardware category 1 (standard hardware).

[1]GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems (ISPE 2008). GAMP is a trademark of International Society for Pharmaceutical Engineering, Inc. (ISPE)

2.2.3 Supplier Assessment

The user should assess the quality and reliability of the proposed supplier.

The instrument manufacturer should have the skill and expertise to develop and build a filter integrity test instrument.

Pall Corporation has been manufacturing filter integrity test instruments for the last 40 years. The Palltronic Flowstar V instrument is the latest generation of filter integrity test instruments. Pall has a quality management system accredited to ISO 9001:2008, under which development documentation for the Palltronic Flowstar V integrity test instrument has been generated.

(See also GAMP 5, section 2, 'Key Concepts', page 19 ff. and section 3, 'Life Cycle Approach', page 25)[2]

2.3 Specification

The user should specify the requirements in a User Requirements Specification (URS).

This will enable the URS to be compared to an off-the-shelf product to establish if the product meets the specification.

In order to draft a URS, the user should consider the following questions:

- Which type of tests will be carried out?
- Which filters will be tested? Does the filter integrity test instrument have the capability to test these filters?
- Does the test pressure range and the measuring range cover all the filter assemblies to be tested?
- Is the instrument capable of testing all filters on the market, or are its capabilities limited to filters only from certain suppliers?
- Are there any product or process demands that result in specific requirements for the instrument?
- Will the results be handled as electronic or paper records? If electronic records are used, does the instrument have the capability to generate electronic records as defined by regulatory authorities e.g. Food and Drug Administration (FDA), including Title 21 of the Code of Federal Regulations (CFR) Part 11[3,4,5] and Medicines & Healthcare products Regulatory Agency (MHRA)[6]?
- Is there an intent to use electronic signatures, and does the instrument have the required features?

A Design Review of a supplier technical specification against the URS can then be carried out.

Detailed specifications like software, hardware and functional specifications are not required by users for software category 3 products.

(See also GAMP 5, 'Management Appendices', 'Appendix M4 - Categories of Software and Hardware', page 127 ff.)[2]

However, documents like the software design specification (Document No: 00050/SDS), hardware design specification (Document No: 00050-MM/HDS) and functional specification (Document No: 00050/FS), which have been generated as part of the development of the Palltronic Flowstar V instrument, are available through an audit on request.

[2]GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems (ISPE 2008)
[3]21 CFR Part 11. Electronic Records; Electronic Signatures; Final Rule Electronic Submissions; Establishment of Public Docket; Notice (FDA 1997)
[4]Guidance for Industry Part 11, Electronic Records; Electronic Signatures – Scope and Application (FDA 2003)
[5]Data Integrity and Compliance with Drug CGMP, Questions and Answers, Guidance for Industry (FDA 2018)
[6]'GxP' Data Integrity Guidance and Definitions (MHRA 2018)

2.4 Verification

The user verification should confirm that the instrument complies with the specification as given in the URS. This verification includes design reviews and qualification testing.

For an 'off-the-shelf' instrument like a filter integrity test instrument, it is expected that extensive qualification by the supplier has been carried out prior to release.

GAMP 5 guidelines recommend taking advantage of the supplier documentation, where justified by a supplier assessment, to reduce the duplication of effort.

The testing for an individual instrument can then be reduced to tests that demonstrate the fitness for use. This, in combination with the supplier testing data, allows the acceptance of the instrument against specification.

(See also GAMP 5, 'Development Appendices', 'Appendix D5 - Testing of Computerized Systems', 'Test Strategy', '4.2.3 Using Results of Supplier Assessments', page 201)[7]

During the development of the Palltronic Flowstar V instrument, the software and hardware have been tested extensively. The final test program carried out with a generic instrument is summarized in the Operational Qualification part 1 (OQ1). It is not necessary to repeat the tests documented in this qualification for additional Palltronic Flowstar V instruments which utilize the same hardware and software.

In addition to these tests conducted with a generic instrument, the following qualifications should be carried out for the complete qualification of an individual instrument:

- Installation Qualification (IQ)

The IQ should check and confirm that the instrument is delivered as specified and can be installed correctly.

- Operational Qualification part 2 (OQ2)

This document includes a series of tests to demonstrate the correct operation of the individual instrument.

2.5 Reporting and Release

The user will need to generate a validation report using the documents listed in Table 1 and put the instrument into service according to internal release procedures.

2.6 Operation

Before putting the instrument into full operation, the procedures to maintain the validated state should be defined and the operator training should be completed.

The validity of a filter test result is dependent on the use of the correct test parameters. The test parameters may depend on the test type, the filter type, the wetting fluid, the test pressure and the test gas.

It is recommended that these parameters are issued by the filter supplier for each filter configuration.

2.7 Training

The generation of Standard Operating Procedures (SOPs) and intensive training for operators is essential for the correct usage of the instrument in a regulated environment.

The highest risk of a failure during use is still when an operator is using the wrong test parameters for a given filter system which can invalidate the filter test result.

[7] GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems (ISPE 2008)

If the test records will be handled as electronic records and/or if electronic signatures will be used in accordance to 21 CFR part 11[8,9,10], specific training for operators should be requested according to the regulation.

Pall Corporation can offer support for operator training for the Palltronic Flowstar V instrument.

2.8 Calibration

To maintain the validated state, a regular calibration is required. The calibration interval (usually 1 year) should be defined by the user.

Integrity test instruments measure both pressure and flow and therefore both measurements should be calibrated against references traceable to national standards.[11]

The calibration carried out by Pall covers calibration of the pressure transducers and the flow measurement against traceable references.

2.9 Maintenance and Service

A regular service for the Palltronic Flowstar V instrument is recommended.

Pall offers a comprehensive range of instrumentation services staffed by engineers and technical specialists certified in Palltronic Flowstar V instrument calibration, qualification and repair. Services encompass: Instrument Qualification, Calibration, Repair, Preventive Maintenance, Instrument Training, Instrument Upgrades, Service Contracts, Spare Parts and Documentation.

2.10 Overview of Documents for the Palltronic Flowstar V Instrument

Table 1 summarizes the documents recommended for the specification and verification of a filter integrity test instrument and also lists the supported documents and activities available for the Palltronic Flowstar V instrument.

Table 1

Validation documentation for the Palltronic Flowstar V instrument

Phase	Documents (User Responsibility)	Documents and Support Available from Pall
Planning	Risk assessment	Functional risk assessment
	Supplier assessment	ISO 9001 certificate Audit by request
	User requirement specification	Instrument specification Validation guide (this document)
Verification	Installation qualification (IQ)	IQ
	Operational qualification (OQ)	OQ1 (generic) OQ2 (instrument specific)
Operation	Standard operating procedure (SOP)	Recommendations for filter test procedures Issue of filter test parameters
Training	Operator training	Training support
Service/calibration	Service and calibration agreements	Maintenance, repair and calibration services Calibration procedure

[8] 21 CFR Part 11. Electronic Records; Electronic Signatures; Final Rule Electronic Submissions; Establishment of Public Docket; Notice (FDA 1997)
[9] Guidance for Industry Part 11, Electronic Records; Electronic Signatures – Scope and Application (FDA 2003)
[10] Data Integrity and Compliance with Drug CGMP, Questions and Answers, Guidance for Industry (FDA 2018)
[11] GAMP Good Practice Guide: Calibration Management (ISPE 2001)

3 Verification of Measurement Functions of the Palltronic Flowstar V Instrument

3.1 Introduction

As follows, the tests and test results verifying the accuracy and reproducibility of the test functions are documented.[12, 13]

3.2 Test Functions of the Palltronic Flowstar V Instrument

3.2.1 The Forward Flow Test (FF)

The Forward Flow test is carried out by measuring the gas flow across a liquid-wetted filter membrane (hydrophilic or hydrophobic) when gas pressure is applied to the upstream side of the filter assembly.

3.2.2 The Water Intrusion Test (WIT)

The water intrusion test is carried out by measuring the flow of water across a hydrophobic membrane covered with water when pressure is applied to the upstream side of the filter assembly.

3.2.3 The Bubble Point Test (BP)

The bubble point test is carried out by incrementally increasing the gas pressure on the upstream side of a filter assembly containing a liquid-wetted filter membrane (hydrophilic or hydrophobic). The bubble point value is the upstream pressure at which a significant increase in the gas flow across the filter assembly is detected. This is indicative of liquid having been expelled from the largest pores of the membrane.

3.2.4 The Leak Test (LT)

The leak test is carried out by pressurizing the volume under test to a pre-determined pressure and measuring the flow out of this system as the leak rate.

3.2.5 The Pressure Decay Test (PD)

The pressure decay test is carried out by pressurizing the volume under test with gas to a pre-determined pressure and measuring the pressure loss out of the system under test. The pressure decay is an indicator for a leak in the system.

3.3 Measurement Technique

3.3.1 Flow Measurement

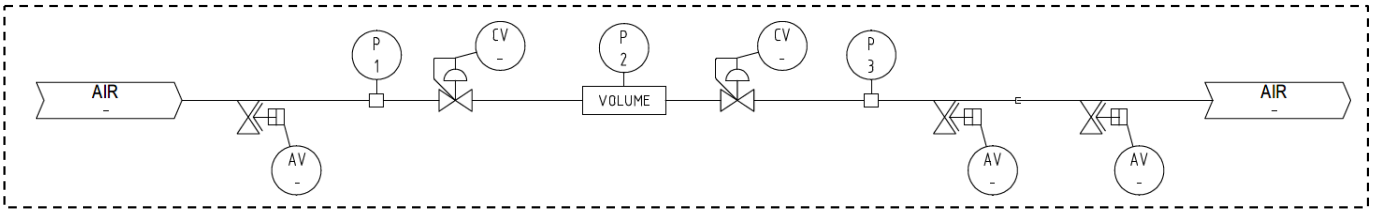
The core technology of the Palltronic Flowstar V integrity test instrument determines gas flow out of a pressurized volume by measuring the amount of gas required to maintain a constant test pressure in the pressurized volume. This unique technique is used for the Forward Flow test, the water intrusion test, the leak test and the flow check test.

The measurement principle is one of ‘volume dosing’. The measurement module consists of high-precision pressure transducers and internal chambers of precisely defined volume (Figure 1). The system is controlled by purpose-designed software.

[12] Palltronic Flowstar V Instrument Validation (Document No: FFS05/Validation)
[13] Palltronic Flowstar V Instrument Operational Qualification (Document No: FFS05/OQ1)

Figure 1

Illustration of the volume dosing measurement system inside the Palltronic Flowstar V instrument



Air or other suitable gases like e.g. nitrogen enters the system from the pressure supply, indicated on the left of the diagram, the pressure transducer (P1) measures the filling pressure for the volume chamber. The pressure transducer (P2) measures the pressure in the volume chamber and pressure transducer (P3) measures the filter test pressure as air is supplied to it, shown on the right of the diagram.

As gas is leaving the pressurized volume either through the control valves (CV), air vent valves (AV), a leak or as gas or liquid passes through the filter under test, constant pressure is maintained on the upstream side by discharging the pressurized gas held in the volume chamber. The volume chamber size used depends on the flow rate across the filter membrane. The precise quantity of gas discharged can be derived from the volume size, the pressure inside the chamber before and after discharge and by the number of discharges over time. With this, the precise flow rate is measured.

As the gas flow is measured in a pressurized system, the result is normalized to atmospheric pressure except for the water intrusion test. Since this test is based on the measurement of the flow of non-compressible water, the normalization to atmospheric pressure is not applicable.

Volume dosing has been shown to be a reliable, robust and stable flow measurement method that has been successfully used in Palltronic instruments for over 30 years.

3.3.2 Bubble Point Measurement

During the bubble point test, the Palltronic Flowstar V instrument pressurizes the upstream side of the liquid-wetted filter to the starting gas pressure, typically 80 or 90% of the pre-defined minimum bubble point pressure of the filter membrane under test. After the pressure is stabilized an initial leak test is performed within the stabilizing phase to establish that there are no gross leaks/defects in the system under test. Therefore, the instrument measures the gas flow occurring at this gas pressure and compares this against a limit value which is determined by setting a 'Module Factor' or by setting a 'Membrane area (cm^2)'. If the measured gas flow is below the limit value, the bubble point test proceeds.

During the measurement phase the pressure is then increased in 50 mbar (0.7 psi) increments. At each pressure step, a short pressure decay measurement is carried out to assess the gas flow across the membrane. When the bubble point is reached, the gas flow and resultant pressure decay increases significantly. This increase in pressure decay measurements is analysed by the instrument, and the pressure where this occurs is reported as bubble point.

3.3.3 Pressure Decay Measurement

When carrying out a pressure decay measurement, the Palltronic Flowstar V instrument pressurizes the system under test to the pre-defined test pressure. After stabilization of the pressure and isolation of the filter assembly, the pressure supply is disconnected, and the instrument reads the pressure in the upstream housing volume at the beginning and at the end of the test time. The difference between these two values is reported as pressure decay.

In order to analyze the result and to correlate it to a leakage rate, the exact size of the system being tested must be known or determined, as the pressure decay caused by a given flow is directly dependent on the upstream volume size.

4 Verification of the Pressure Measurement and Pressure Control by the Palltronic Flowstar V Instrument

For all integrity tests, it is essential to pressurize the system under test to the pre-defined test pressure. For the integrity test based on flow measurement, it is also important that the test pressure is maintained for the full test time. As follows, the tests to verify the pressure control of the Palltronic Flowstar V instrument are documented.

4.1 Verification of the Pressure Setting

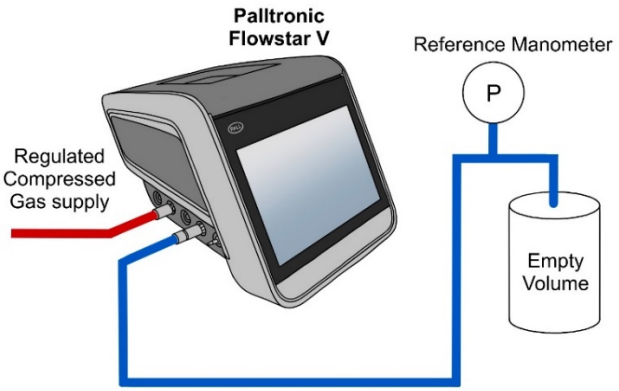
The goal of these tests was to verify that the Palltronic Flowstar V instrument pressurizes the upstream side of the filter correctly.

4.1.1 Test Method

The Palltronic Flowstar V instrument (S/N: 03010250) was connected to an empty volume and a reference manometer (Huber HM28, S/N: J110502) was connected between the instrument and the volume (Figure 2).

Figure 2

Setup for pressure settings test



Forward Flow tests were initiated with test pressures between 50 and 6500 mbar. The volume was varied between 60 mL and 17590 mL and the pressure on the reference manometer was approximately recorded 30 s after the stabilization phase has reached at least 33% (Table 2). The tests were repeated initiating a water intrusion test with a pressure of 2500 mbar and a volume of 60 mL and 460 mL (Table 3).

The tests were repeated initiating the pressure decay test function. The test pressure was varied between 50 and 6500 mbar. The volume was varied between 60 mL and 17590 mL (Table 4). Regarding the pressure decay test the pressure on the reference manometer was recorded 30 s after the stabilization phase had been started and ‘Remaining time’ was shown.

The pressure deviation was calculated (pressure value shown on Palltronic Flowstar V screen minus pressure reference).

4.1.2 Results

The test results are summarized in Table 2, Table 3, and Table 4.

Table 2

Accuracy of the pressure setting for the Forward Flow test function with variable target pressures and upstream volumes

Upstream Volume (mL)	Target Pressure (mbar)	Pressure Palltronic Flowstar V Instrument (mbar)	Reference Pressure (mbar)	Deviation (mbar)
60	50	51	51	0
	500	502	501	1
	1500	1505	1503	2
	2500	2506	2502	4
	3500	3505	3499	6
	4500	4501	4493	8
	5500	5501	5493	8
	6500	6502	6491	11
2060	50	50	51	-1
	500	500	500	0
	1500	1500	1499	1
	2500	2500	2499	1
	3500	3500	3499	1
	4500	4500	4499	1
	5500	5500	5499	1
	6500	6500	6501	-1
17590	50	50	50	0
	500	500	501	-1
	1500	1501	1502	-1
	2500	2500	2501	-1
	3500	3500	3502	-2
	4500	4500	4503	-3
	5500	5500	5504	-4
	6500	6499	6505	-6

Table 3

Accuracy of the pressure setting for the water intrusion test function with variable upstream volumes

Upstream Volume (mL)	Target Pressure (mbar)	Pressure Palltronic Flowstar V Instrument (mbar)	Reference Pressure (mbar)	Deviation (mbar)
60	2500	2505	2502	3
460	2500	2500	2502	-2

Table 4

Accuracy of the pressure setting for the pressure decay test function with variable target pressures and upstream volumes

Volume (mL)	Target Pressure (mbar)	Pressure Palltronic Flowstar V Instrument (mbar)	Reference Pressure (mbar)	Deviation (mbar)
60	50	41	41	0
60	500	499	500	-1
460	1500	1496	1497	-1
460	2500	2497	2498	-1
2060	3500	3499	3497	2
2060	4500	4499	4497	2
5060	5500	5499	5496	3
5060	6500	6499	6496	3
17590	50	50	50	0
17590	500	500	501	-1

For all test types as well as for different upstream volumes and pressures the test pressure was achieved well within the range of the accuracy of the pressure transducer (± 30 mbar).

4.1.3 Summary

The pressure setting is accurate over the full pressure range and for different upstream volumes.

4.2 Verification of the Pressure Stability (Flow Measurement)

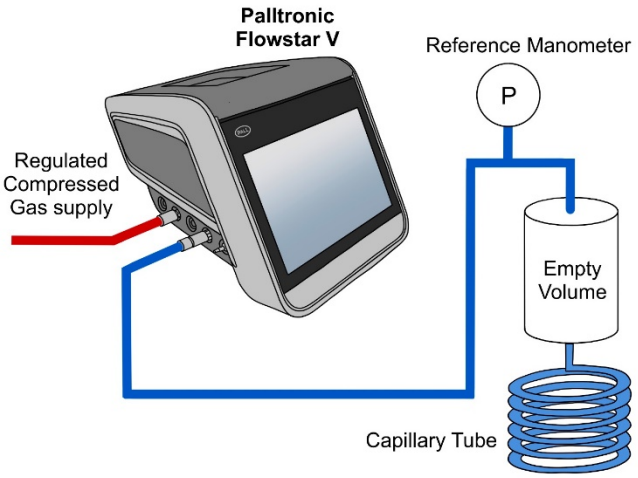
The goal of these tests was to verify that the Palltronic Flowstar V instrument maintains a stable test pressure during the test phase of an integrity test.

4.2.1 Test Method

The Palltronic Flowstar V instrument (S/N: 03010250) was connected to an empty volume and a reference manometer (Huber HM28, S/N: J110502) was connected between the instrument and the volume. The volume was also connected to a capillary instrument (Palltronic Flow Check II unit) to simulate gas flow out of this volume (Figure 3).

Figure 3

Setup for pressure stability testing



Forward Flow tests were carried out with upstream volumes of 60 mL, 460 mL and 5060 mL at a test pressure of 2000 mbar (29 psi). The expected flow of the Flow Check II unit (FC02, S/N: 14028417) was 9.07 mL/min. The ratio between the flow rate and the upstream volume might have an impact on the pressure stability. The higher the flow rate out of a small volume, the higher the challenge on the pressure stability. As an indicator the flow/volume ratio was calculated and given in %.

$$\text{Flow/Volume ratio (\%)} = \frac{\text{Flow}\left(\frac{\text{mL}}{\text{min}}\right) \text{x } 100}{\text{Volume (mL)}}$$

The tests cover flow/volume ratios between 0.2 and 15.1%. Typically, the flow/volume ratio for a filter system is between 1 – 10%.

The Forward Flow test time was set to 300 s and during the test the pressure on the reference manometer was recorded over the entire test time after 60, 120, 180, 240 and 300 s.

The pressure deviation was calculated (pressure value shown on Palltronic Flowstar V screen minus pressure reference).

4.2.2 Results

The results are summarized in Table 5, Table 6, and Table 7.

Table 5

Stability of the test pressure during the test phase for different upstream volumes (60 mL). Flow/volume ratio = 15.1%.

Test Time (s)	Pressure Palltronic Flowstar V Instrument (mbar)	Reference Pressure (mbar)	Deviation (mbar)
60	2000	1998	2
120	1997	1994	3
180	2001	1999	2
240	2004	2001	3
300	2001	1999	2

Table 6

Stability of the test pressure during the test phase for different upstream volumes (460 mL). Flow/volume ratio = 2.0%.

Test Time (s)	Pressure Palltronic Flowstar V Instrument (mbar)	Reference Pressure (mbar)	Deviation (mbar)
60	2000	1999	1
120	1999	2000	-1
180	2000	1999	1
240	1999	1998	1
300	2001	2000	1

Table 7

Stability of the test pressure during the test phase for different upstream volumes (5060 mL). Flow/volume ratio = 0.2%.

Test Time (s)	Pressure Palltronic Flowstar V Instrument (mbar)	Reference Pressure (mbar)	Deviation (mbar)
60	2000	1999	1
120	2000	1999	1
180	2000	1999	1
240	2000	1999	1
300	2000	1999	1

The test pressure was maintained during the entire test phase so that the defined test condition (test pressure) was stable during the complete filter test.

4.2.3 Summary

During the entire flow measurement, the test pressure did not deviate more than 3 mbar (0.04 psi).

4.3 Verification of the Pressure Unit Conversion

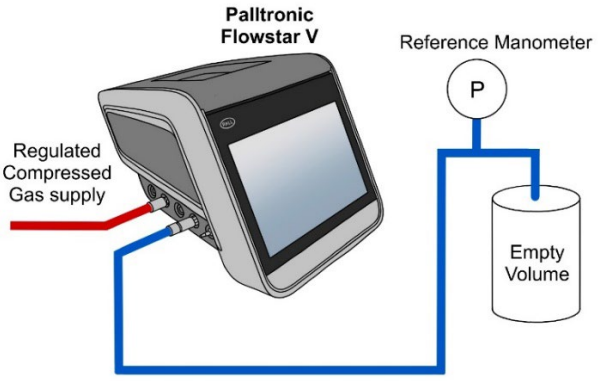
The goal of this test was to verify that the Palltronic Flowstar V instrument converts pressure units to psi, kp/cm² and kPa with accuracy and precision.

4.3.1 Test Method

The Palltronic Flowstar V instrument (S/N: 03010250) was connected to an empty volume and a reference manometer (Huber HM28, S/N: J110502) was connected between the instrument and the volume (Figure 4).

Figure 4

Setup for pressure unit conversion tests



Three Forward Flow tests were performed with a test pressure of 40 psi, 276 kPa and 3 kp/cm^2. In each test the pressure on the reference manometer was recorded 30 s after the target pressure was reached.

4.3.2 Results

The test results are summarized in Table 8.

Table 8

Accuracy of the pressure unit conversion (psi, kPa and kp/cm^2)

Programmed Test Pressure	Expected Value (mbar)	Reference Value (mbar)	Deviation (mbar)	Deviation (%)
40 psi	2758	2760	2	0.07
276 kPa	2760	2763	3	0.11
3 kp/cm^2	2942	2945	3	0.10

The operation of the instrument using a pressure unit other than mbar does not affect the correct pressure setting.

4.3.3 Summary

The pressure unit conversion allows a correct pressure setting using a pressure unit other than mbar.

4.4 Verification of the Accuracy of Forward Flow Measurement

The goal of these tests was to verify the accuracy and reproducibility of the flow measurement system of the Palltronic Flowstar V instrument using calibrated capillaries. This method was chosen because capillaries provide highly reproducible flow rates when a pre-determined gas pressure is applied. The ratio between the flow to be measured and the gas volume has magnitude of impact on the accuracy, which was determined by variation of the upstream gas volume.

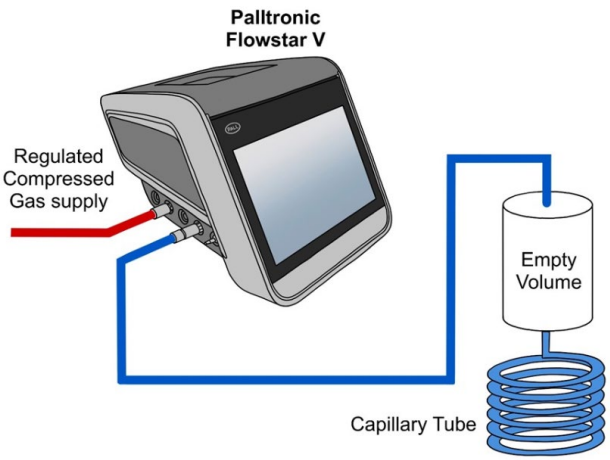
4.4.1 Test Method

Forward Flow tests were conducted using a Palltronic Flowstar V instrument (S/N: 03010250) and different capillary instruments (Palltronic Flow Check II units). The Palltronic Flowstar V instrument was connected to an empty volume and corresponding capillary was installed downstream of the empty volume (Figure 5). The capillary instruments were calibrated so they were known to provide an expected and reproducible flow rate when a pressure of 2000 mbar was applied.

The Palltronic Flowstar V instrument was programmed to carry out Forward Flow tests at 2000 mbar using air as test gas with a fixed test time of 600 s.

Figure 5

Setup for flow measurements



Forward Flow tests were carried out on seven capillary instruments which provided expected flows of 1.17 mL/min (FC02, S/N: 20128917), 2.60 mL/min (FC02, S/N: 13028317), 9.07 mL/min (FC02, S/N: 14028417), 50.0 mL/min (FC02M, S/N: 15028517), 96.3 mL/min (FC02M, S/N: 16028617), 193.6 mL/min (FC02M, S/N: 17028717) and 1055.8 mL/min (FC02H, S/N: 18028817) at 2000 mbar. As the calibrated flow of each capillary depends on atmospheric pressure the flow of the capillary can slightly vary. The respective flow of the capillary under the current atmospheric pressure during tests is indicated in the tables below.

Each capillary instrument was tested with different upstream volumes between the instrument and the capillary. Upstream volumes of 60 mL, 460 mL, 810 mL, 2060 mL, 5060 mL and 17590 mL were tested. Three measurements were carried out on each capillary/upstream volume combination. For each series of tests, the percentage deviation between the average of the measured flow values and the expected flow was calculated.

The coefficient of variation for repeated measurements was also calculated. The calculations were carried out using the following formula:

$$Deviation\ (\%) = \frac{(Average\ measured\ value\ -\ Expected\ value)\ x\ 100}{Expected\ value}$$

and

$$Coefficient\ of\ variation\ (\%) = \frac{Standard\ deviation\ (\sigma)\ x\ 100}{Average\ measured\ value}$$

The flow values measured through the capillary instruments using a Palltronic Flowstar V instrument are shown in Tables 9 - 14.

4.4.2 Results

The results are shown in Tables 9 - 14.

Table 9

Accuracy of the flow measurements for different flow rates and 60 mL upstream volume

Description	Results		
Flow/volume ratio (%)	1.95	4.37	15.12
Flow reference (mL/min)	1.17	2.62	9.07
Measured flow (mL/min)	1.18	2.60	8.91
	1.18	2.62	8.90
	1.17	2.59	8.90
Average measured flow (mL/min)	1.18	2.60	8.90
Deviation (%)	0.57	-0.64	-1.84
Coefficient of variation (%)	0.49	0.59	0.06

Table 10

Accuracy of the flow measurements for different flow rates and 460 mL upstream volume

Description	Results					
Flow/volume ratio (%)	0.26	0.57	1.98	10.9	21.0	42.3
Flow reference (mL/min)	1.18	2.62	9.13	50.3	96.7	194.5
Measured flow (mL/min)	1.22	2.60	9.17	48.8	95.9	193.2
	1.20	2.61	9.16	49.0	95.7	193.2
	1.20	2.60	9.17	48.8	95.7	193.1
Average measured flow (mL/min)	1.21	2.60	9.17	48.9	95.8	193.2
Deviation (%)	2.26	-0.64	0.40	-2.8	-1.0	-0.7
Coefficient of variation (%)	0.96	0.22	0.06	0.2	0.1	<0.1

Table 11

Accuracy of the flow measurements for different flow rates and 810 mL upstream volume

Description	Results						
Flow/volume ratio (%)	0.15	0.32	1.12	6.2	11.9	24.0	131.0
Flow reference (mL/min)	1.18	2.60	9.11	50.2	96.8	194.6	1061.0
Measured flow (mL/min)	1.25	2.60	9.08	48.9	95.0	192.8	1053.6
	1.26	2.61	9.05	48.8	95.0	192.7	1053.6
	1.26	2.61	9.04	49.0	94.9	192.6	1054.0
Average measured flow (mL/min)	1.26	2.61	9.06	48.9	95.0	192.7	1053.7
Deviation (%)	6.50	0.26	-0.59	-2.6	-1.9	-1.0	-0.7
Coefficient of variation (%)	0.46	0.22	0.23	0.2	<0.1	<0.1	<0.1

Table 12

Accuracy of the flow measurements for different flow rates and 2060 mL upstream volume

Description	Results						
Flow/Volume ratio (%)	0.06	0.13	0.44	2.4	4.7	9.4	51.5
Flow Reference (mL / min)	1.18	2.60	9.13	50.3	96.8	194.6	1061.0
Measured flow (mL / min)	1.36	2.67	9.30	48.7	95.1	193.2	1055.2
	1.37	2.67	9.31	48.6	95.1	192.7	1055.2
	1.42	2.69	9.18	49.3	95.2	192.7	1055.4
Average measured flow (mL / min)	1.38	2.68	9.26	48.9	95.1	192.9	1055.3
Deviation (%)	17.23	2.95	1.46	-2.8	-1.7	-0.9	-0.5
Coefficient of variation (%)	2.32	0.43	0.78	0.8	<0.1	0.1	<0.1

Table 13

Accuracy of the flow measurements for different flow rates and 5060 mL upstream volume

Description	Results						
Flow/volume ratio (%)	0.02	0.05	0.18	1.0	1.9	3.8	21.0
Flow reference (mL/min)	1.18	2.62	9.08	50.0	96.8	194.7	1061.0
Measured flow (mL/min)	1.58	3.11	9.32	49.1	95.5	193.4	1056.6
	1.60	2.98	9.32	49.2	95.4	193.3	1057.1
	1.53	3.07	9.38	49.0	95.6	193.4	1056.5
Average measured flow (mL/min)	1.57	3.05	9.34	49.1	95.5	193.4	1056.7
Deviation (%)	33.05	16.54	2.86	-1.8	-1.3	-0.7	-0.4
Coefficient of variation (%)	2.30	2.18	0.37	0.2	0.1	<0.1	<0.1

Table 14

Accuracy of the flow measurements for different flow rates and 17590 mL upstream volume

Description	Results						
Flow/volume ratio (%)	0.01	0.01	0.05	0.3	0.5	1.1	6.0
Flow reference (mL/min)	1.18	2.61	9.10	50.1	96.4	193.9	1057.0
Measured flow (mL/min)	2.28	2.15	9.96	52.0	96.0	192.5	1056.4
	2.58	2.77	9.83	48.8	95.1	192.6	1055.7
	2.44	3.40	9.86	49.2	94.6	192.4	1054.5
Average measured flow (mL/min)	2.43	2.77	9.88	50.0	95.2	192.5	1055.5
Deviation (%)	106.21	6.26	8.61	-0.2	-1.2	-0.7	-0.1
Coefficient of variation (%)	6.17	22.54	0.69	3.5	0.7	<0.1	<0.1

The data showed that the flow measurement is accurate over a wide range of flow/volume ratios and is over a wide range independent of the upstream volume. Only in those cases where the flow out of the pressurized volume becomes very small compared to the upstream volume the flow deviation exceeds > 3%.

This is the potential case when the ratio between the flow and the upstream volume is in the range of approximately 0.15% which means that the flow (in mL/min) out of the pressurized volume (in mL) is approximately 0.15%. The range for a flow/upstream volume of a typical filter system is usually 1 – 10% and the instrument showed a high accuracy in this range.

4.4.3 Summary

The results showed that the flow measurement is accurate over a wide range of flow/volume ratios. The design space regarding flow measurements, referring to the data shown in Tables 9 - 14 can be defined to > 0.18 % and up to a range of > 100 %.

4.5 Verification of the Reproducibility of Forward Flow Measurements

The goal of these tests was to verify that Forward Flow measurements of the Palltronic Flowstar V instrument show a high reproducibility.

4.5.1 Test Method

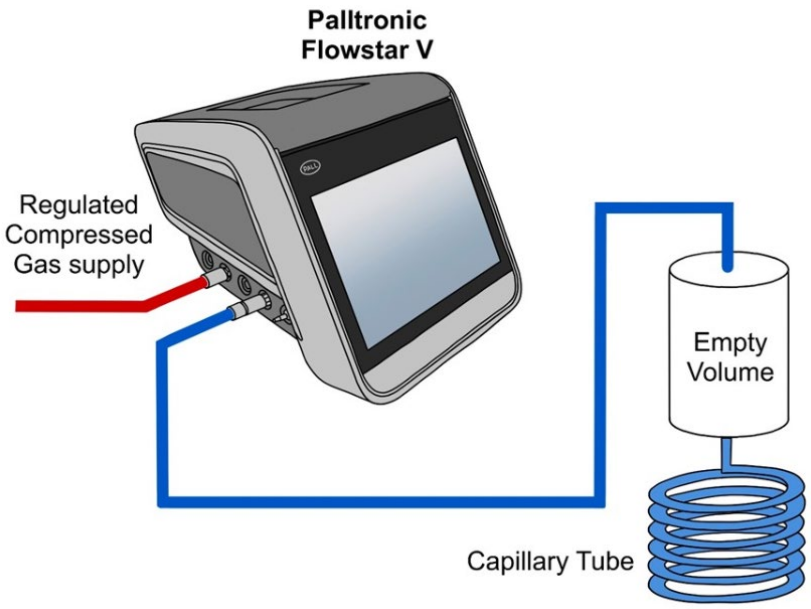
Forward Flow tests were conducted using a Palltronic Flowstar V instrument (S/N: 03010250) and different capillary instruments (Palltronic Flow Check II unit). The Palltronic Flowstar V instrument was connected to an empty volume and corresponding capillary was installed downstream of the empty volume (Figure 6). The capillary instruments were calibrated so they were known to provide an expected and reproducible flow rate when a pressure of 2000 mbar was applied. The Palltronic Flowstar V instrument was programmed to carry out Forward Flow tests at 2000 mbar using air as test gas with a fixed test time of 600 s.

Five consecutive Forward Flow tests were carried out on three combinations of empty volumes and capillary instruments. Used capillaries provided expected flows of 9.07 mL/min (FC02, S/N: 14028417), 96.3 mL/min (FC02M, S/N: 16028617) and 193.6 mL/min (FC02M, S/N: 17028717 at 2000 mbar. As the calibrated flow of each capillary depends on atmospheric pressure the flow of the capillary can slightly vary. The respective flow of the capillary under the current atmospheric pressure during tests is indicated in Table 15.

Upstream volumes of 2060 mL, 5060 mL and 17590 mL were tested. The flow/volume ratio (%), mean value, standard deviation (σ) and the coefficient of variation (%) were calculated.

Figure 6

Setup for forward flow reproducibility



4.5.2 Results

The results are summarized in Table 15.

Table 15

Reproducibility of the flow measurement

Description	Results		
Upstream volume (mL)	2060	5060	17590
Flow/volume ratio (%)	0.44	1.9	1.1
Flow reference (mL/min)	9.08	96.4	193.6
Test 1	9.41	96.2	194.9
Test 2	9.24	95.6	193.6
Test 3	9.21	95.4	193.0
Test 4	9.17	95.4	193.0
Test 5	9.13	95.3	192.4
Mean value	9.23	95.6	193.4
Standard deviation (σ)	0.11	0.4	0.9
Coefficient of variation (%)	1.17	0.4	0.5

The results show a high reproducibility with a standard deviation of ≤ 0.11 and a coefficient of variation of ≤ 1.17%.

4.5.3 Summary

The Forward Flow measurement results showed a high reproducibility for different flow/upstream volume combinations.

4.6 Verification of the Water Intrusion Measurement Function

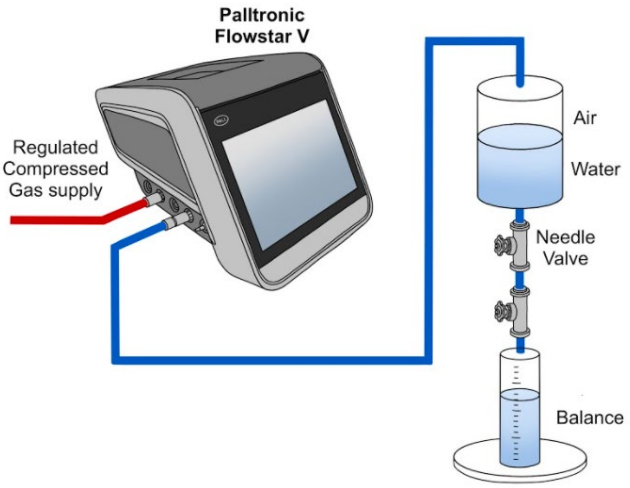
The goal of this series of tests was to verify the accuracy of Water Intrusion measurements using a test system that had been designed to produce small water flows typically of those measured during Water Intrusion tests through hydrophobic filter cartridges.

4.6.1 Test Method

The Palltronic Flowstar V instrument (S/N: 03010250) was connected to an empty volume of 100 mL, which was filled with water. On the downstream side of the water filled volume two needle valves were connected in series to control the water flow rate, which was measured gravimetrically using an analytical balance (Mettler Toledo, MS104TS/00, S/N: B942447189). The test assembly is shown in Figure 7.

Figure 7

Setup for water intrusion measurement



The Palltronic Flowstar V instrument was programmed to carry out Water Intrusion tests by using air as test gas, a pressure of 2500 mbar and a fixed test time of 900 s. Prior to the start of each test, needle valves were adjusted to provide a small and stable flow of water (0.15 – 1 mL/min).

During the water intrusion tests carried out by the Palltronic Flowstar V instrument, the flow of water was simultaneously measured gravimetrically by collecting the water issuing from the needle valve in a small beaker placed on a calibrated analytical balance. The weight of water, which was collected during the last 120 s of the Water Intrusion test (780 – 900 s) was used as a reference measurement of water flow and compared to the measured water flow given by the Palltronic Flowstar V instrument. The reference water flow (mL/min) was calculated based on the measured weight (g) within 120 s using a density of 1 g/cm^3 and rounded to two decimal places.

Two series of tests were carried out. In the first series of tests an upstream volume of 57 mL Table 16 and in the second series of tests an upstream volume of 157 mL Table 17 was used. For each series of tests five consecutive Water Intrusion tests were carried out.

4.6.2 Results

The results are shown in Table 16, Table 17.

Table 16

Accuracy of water intrusion measurement at an upstream gas volume of 57 mL

Test No.	Measured Weight Within 120 s (g)	Calculated Reference Water Flow (mL/min)	Measured Water Flow by Palltronic Flowstar V Instrument (mL/min)	Deviation (mL/min)
1	0.4902	0.25	0.25	0.00
2	0.2910	0.15	0.14	-0.01
3	0.5274	0.26	0.26	0.00
4	0.5954	0.30	0.29	-0.01
5	0.4158	0.21	0.21	0.00

Table 17

Accuracy of water intrusion measurement at an upstream gas volume of 157 mL

Test No.	Measured Weight Within 120 s (g)	Calculated Reference Water Flow (mL/min)	Measured Water Flow by Palltronic Flowstar V Instrument (mL/min)	Deviation (mL/min)
1	0.7544	0.38	0.37	-0.01
2	0.4740	0.24	0.24	0.00
3	0.6156	0.31	0.30	-0.01
4	0.4650	0.23	0.24	0.01
5	0.4383	0.22	0.23	0.01

The accuracy of the results obtained using the Palltronic Flowstar V instrument was determined by comparing the results with those obtained using the reference measurement of water flow. The maximum deviation between the results obtained with the Palltronic Flowstar V instrument and the reference measurement was less than or equal to ± 0.01 mL/min. The influence of the upstream volume was determined by carrying out two series of tests, one series where an upstream volume of 57 mL and the other series where an upstream volume of 157 mL was used. The accuracy of the results was not influenced by the change in upstream volume demonstrating that Water Intrusion tests carried out by the Palltronic Flowstar V instrument are independent regarding upstream volume variation (equals to approximately 6 m tubing with an inner diameter of 6 mm connected between Palltronic Flowstar V and filter system tested by water intrusion test).

4.6.3 Summary

The water intrusion measurements using a Palltronic Flowstar V instrument were verified to be accurate and to be within ± 0.01 mL/min compared to a reference water flow measurement. The water intrusion measurements determined by the Palltronic Flowstar V instrument were demonstrated to be independent regarding upstream volume variation.

4.7 Verification of the ‘Auto’ and ‘Fixed’ Test Time Mode

The Palltronic Flowstar V instrument has 'Auto' and 'Fixed' test time options for Forward Flow and water intrusion tests. In the 'Fixed' test time mode, the programmed test time (s) by the operator is completely carried out during the measurement phase. In the 'Auto' test time mode, the measurement phase automatically ends when the measured flow characteristics satisfy the internal algorithms for determining a stable flow.

The goal of this series of tests was to compare Forward Flow and water intrusion test times when 'Auto' and 'Fixed' test time modes were used and to verify that the 'Auto' test time feature does provide the same integrity test evaluation (e.g. ‘pass’) as a ‘Fixed’ test time measurement.

4.7.1 Test Method

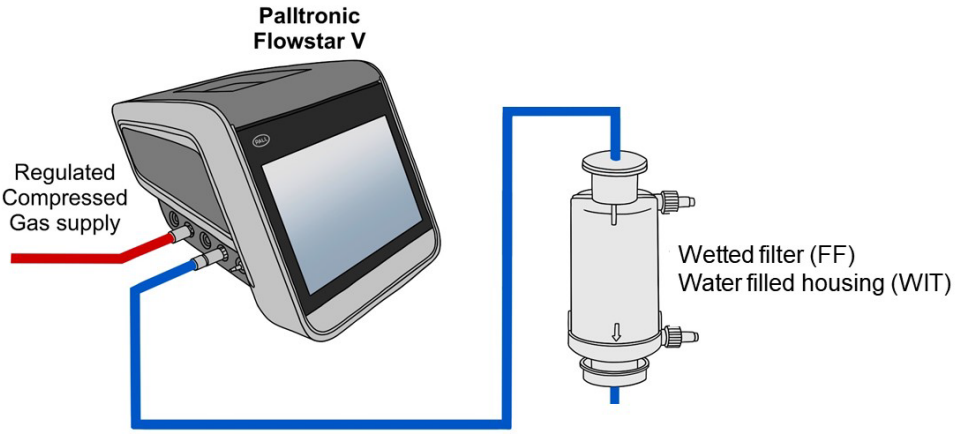
Appropriate filter assemblies and corresponding maximal acceptable flow (mL/min) values were selected for carrying out Forward Flow and water intrusion tests. The Forward Flow and water intrusion tests were carried out using a Palltronic Flowstar V instrument (S/N: 03010250) according to the normal recommended procedures.

Integrity tests were carried out repetitively (three times) using the 'Fixed' and 'Auto' test time modes. For the Forward Flow and water intrusion tests using the ‘Fixed’ test time mode, a test time of 600 s was set (Table 18, & Table 19 Test No. 1). Further tests were then carried out using the 'Auto' test time mode. In order to determine the safety of the 'Auto' test time mode two test sequences (Table 18 & Table 19, Test No. 2 – 3) were carried out to show that the ‘Auto’ test time algorithm does prolong the test time, when measured flows are close to the entered pass limit and does reduce the test time when measured flows have a higher safety margin compared to the entered pass limit.

The test assembly is shown in Figure 8.

Figure 8

Setup for forward flow and water intrusion measurements



4.7.2 Results

The results are shown in Table 18, and Table 19.

Table 18

Test results for 'Fixed' and 'Auto' test time (Forward Flow test). For the Forward Flow test a Supor® EKV filter (AB1EKV7PH4, 0.2 µm, 0.6 m^2) was used. The filter was wetted with water and tested at 2760 mbar using air as test gas.

Test No.	Forward Flow Test Limit (mL/min)	Test Time Mode	Measured Flow (mL / min)	Test Time (s)	Test Result
1	17.0	Fixed	13.4	600	Pass
			13.9	600	Pass
			13.6	600	Pass
2	16.0	Auto	14.0	227	Pass
			14.2	232	Pass
			14.3	235	Pass
3	21.0	Auto	14.6	124	Pass
			14.4	124	Pass
			14.4	121	Pass

Table 19

Test results for 'Fixed' and 'Auto' test time (Water Intrusion test). For the Water Intrusion test an Emflon® PFR filter (AB1PFR7PVH4, 0.2 µm, 0.8 m^2) was used. The filter housing was filled with water and the Water Intrusions test performed at 2500 mbar using air as test gas.

Test No.	Water Intrusion Test Limit (mL / min)	Test Time Mode	Measured Flow (mL / min)	Test Time (s)	Test Result
1	0.33	Fixed	0.16	600	Pass
			0.14	600	Pass
			0.13	600	Pass
2	0.17	Auto	0.15	324	Pass
			0.16	600	Pass
			0.15	268	Pass
3	0.22	Auto	0.17	244	Pass
			0.17	171	Pass
			0.16	159	Pass

Under the same test conditions and in comparison to the 'Fixed' test time, the 'Auto' test time mode significantly reduced the overall test time down to 121 s for the Forward Flow test (Table 18, Test No. 3) and down to 159 s for the Water Intrusion test (Table 19, Test No. 3). In all these tests a 'pass' result was obtained because the measured flow rates were well below the entered pass limit.

During the tests carried out with the 'Auto' test time mode the reported flow rates were slightly higher than the results obtained with the 'Fixed' test time mode because in these tests the flow had not completely stabilized to a constant value.

The ‘Auto’ test time function did prolong the test time for the Forward Flow tests (Table 18, Test No. 2, 227– 235 s) and Water intrusion tests (Table 19, Test No. 2, 268 – 600 s), when measured flows were close to the entered pass limit and did reduce the test time further for the Forward Flow tests (Table 18, Test No. 3, 121 - 124 s) and Water Intrusion tests (Table 19, Test No. 3, 159 – 244 s), when measured flows have a higher safety margin compared to the entered pass limit.

4.7.3 Summary

The use of the 'Auto' test time mode reduced overall Forward Flow and Water Intrusion test times by up to 20 % compared to standard test times using the 'Fixed' test time mode. During tests carried out where the measured flow value was close to the entered pass limit, the test time was automatically prolonged to ensure that safe results were estimated.

4.8 Verification of Bubble Point Measurements

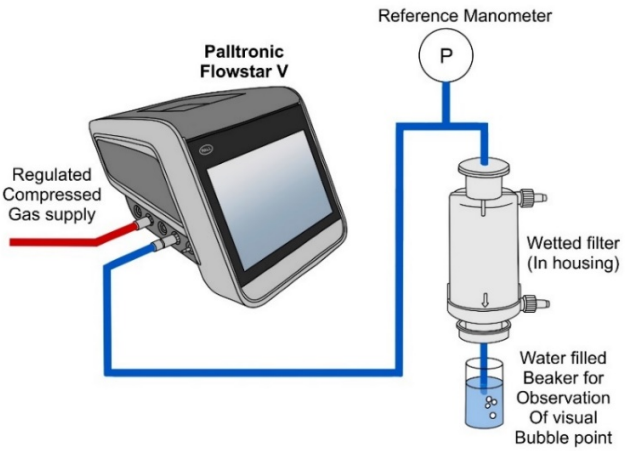
The goal of this series of tests was to verify that the bubble point values determined by the Palltronic Flowstar V instrument are comparable to the bubble point observed visually downstream of the filter at the same time as the automatic test is carried out.

4.8.1 Test Method

Bubble point measurements were carried out using a Palltronic Flowstar V instrument (S/N: 03010250) on four filter assemblies, including 142 mm membrane discs grade 0.2 µm (NRG14225, 150 cm^2) and 0.45 µm (NXG14225, 150 cm^2) and a 0.2 µm filter capsule/cartridge (KA3NFP1G, 2300 cm^2 and AB1NF7PH4, 7900 cm^2). A length of clear plastic tubing was connected to the downstream side of the filter assembly and inserted into a beaker containing water. A reference manometer (Huber HM28, S/N: J110502) was installed on the upstream side of the filter assembly, as shown in Figure 9.

Figure 9

Setup for bubble point measurements



As the automatic test was carried out, the pressure at which a steady stream of bubbles was observed coming out of the tubing was recorded using the external reference manometer. This pressure was compared to the bubble point value reported by the Palltronic Flowstar V instrument. For each filter assembly three bubble point tests were carried out. Filter wetting was repetitively performed.

4.8.2 Results

The results are shown in Table 20, Table 21, Table 22, and Table 23.

Table 20

Bubble point test results for a 142 mm membrane disc (NXG14225, 0.45 µm, 150 cm^2). Minimum bubble point for this filter = 2000 mbar. The filter was wetter with water prior bubble point tests were carried out. Air was used as test gas.

Measured Bubble Point by Palltronic Flowstar V Instrument (mbar)	Visual Bubble Point (mbar)	Deviation (mbar)
2150	2190	40
2150	2220	70
2150	2211	61

Table 21

Bubble point test results for a 142 mm membrane disc (NRG14225, 0.2 µm, 150 cm^2). Minimum bubble point for this filter = 3180 mbar. The filter was wetter with water prior bubble point tests were carried out. Air was used as test gas.

Measured Bubble Point by Palltronic Flowstar V Instrument (mbar)	Visual Bubble Point (mbar)	Deviation (mbar)
3200	3262	62
3200	3284	84
3200	3244	44

Table 22

Bubble point test results for a Kleenpak™ filter capsule (KA3NFP1G, 0.2 µm, 2300 cm^2). Minimum bubble point for this filter = 3180 mbar. The filter was wetter with water prior bubble point tests were carried out. Air was used as test gas.

Measured Bubble Point by Palltronic Flowstar V Instrument (mbar)	Visual Bubble Point (mbar)	Deviation (mbar)
3350	3370	20
3350	3390	40
3350	3387	37

Table 23

Bubble point test results for a filter cartridge (AB1NF7PH4, 0.2 µm, 7900 cm^2). Minimum bubble point for this filter = 3180 mbar. The filter was wetter with water prior bubble point tests were carried out. Air was used as test gas.

Measured Bubble Point by Palltronic Flowstar V Instrument (mbar)	Visual Bubble Point (mbar)	Deviation (mbar)
3350	3418	68
3400	3431	31
3400	3433	33

In comparison to the measured bubble point by the Palltronic Flowstar V instrument, the visual bubble point was always above as visual observations downstream to determine the bubble point is subjective. The overall deviation between the bubble point detected by the Palltronic Flowstar V instrument and visually was < 100 mbar. A claim on the accuracy of the bubble point test cannot be given as there are no references of a known accuracy available for this type of test. Moreover, as the Palltronic Flowstar V instrument performs during the bubble point measurement pressure increments in 50 mbar and rounds down the reported bubble point value to the previous performed 50 mbar increment, the visual bubble point can be expected to be above the bubble point value reported by the Palltronic Flowstar V instrument.

4.8.3 Summary

The Palltronic Flowstar V bubble point test results were comparable to visual observations of the bubble point.

4.9 Verification of Pressure Decay Measurements

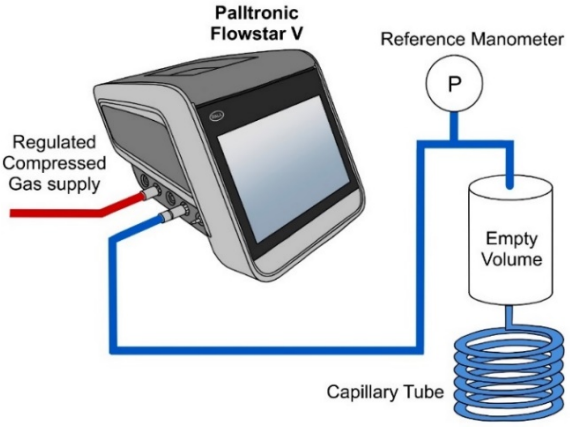
The goal of these tests was to verify that the pressure decay measurement of the Palltronic Flowstar V instrument is accurate.

4.9.1 Test Method

Pressure Decay tests were conducted using a Palltronic Flowstar V instrument (S/N: 03010250) using an empty volume of 5060 mL. Different capillary instruments (Palltronic Flow Check II units) were connected downstream to the empty volume to generate different pressure decays. The setup is shown in Figure 10.

Figure 10

Setup for pressure decay measurements



The Palltronic Flowstar V instrument was programmed to carry out a pressure decay test at 2000 mbar with a stabilization time and a test time of 300 s using air as test gas.

After completion of the stabilization phase the pressure on the reference manometer (Huber HM28, S/N: J110502) was recorded at the beginning and at the end of the test time of the pressure decay measurement phase. The pressure difference between these two values was compared to the pressure decay reported by the instrument. Six consecutive pressure decay tests were carried out using six different capillary instruments using the same empty volume of 5060 mL.

The six different capillaries provided expected flows of 2.65 mL/min (FC02, S/N: 13028317), 9.10 mL/min (FC02, S/N: 14028417), 50.4 mL/min (FC02M, S/N: 15028517), 96.3 mL/min (FC02M, S/N: 16028617), 193.9 mL/min (FC02M, S/N: 17028717) and 1059.2 mL/min (FC02H, S/N: 18028817) at 2000 mbar. As the calibrated flow of each capillary depends on atmospheric pressure the flow of the capillary can slightly vary. The respective flow of the capillary under the current atmospheric pressure during tests is indicated in Table 24.

To show the reproducibility, a pressure decay test using an empty volume of 5060 mL was used and connected to a capillary which provided a flow of 50.4 mL/min (FC02M, S/N: 15028517) at 2000 mbar. A stabilization time and a test time of 300 s were used for these tests. This test was repeated five times. The mean value, standard deviation (σ) and the coefficient of variation (%) were calculated Table 25.

4.9.2 Results

The results are shown in Table 24, and Table 25.

Table 24

Accuracy of the pressure decay measurement for different pressure decay values

Flow Reference (mL/min)	Reference Pressure Test Start (mbar)	Reference Pressure Test End (mbar)	Pressure Decay Calculated (mbar)	Pressure Decay Measured by Palltronic Flowstar V Instrument (mbar)	Deviation (mbar)
2.65	2001	1998	3	4	1
9.11	2001	1992	9	10	1
50.4	2000	1948	52	52	0
96.4	1999	1902	97	97	0
194.0	1997	1804	193	193	0
1060.0	1985	1147	838	841	3

The test results reported by the instrument and manually recorded values showed a deviation of 1 mbar at a low pressure decay (flow references 2.65 mL/min and 9.11 mL/min) and 3 mbar (<0.5 %) at a higher pressure decay (flow reference 1060.0 mL/min).

Table 25

Reproducibility of the pressure decay measurement

Description	Results
Test 1	52 mbar
Test 2	52 mbar
Test 3	52 mbar
Test 4	52 mbar
Test 5	52 mbar
Mean value	52 mbar
Standard deviation (σ)	N/A
Coefficient of variation (%)	N/A

N/A = Not applicable

The test on reproducibility of pressure decay measurements did not show a deviation in five repeated tests, which also correlates to the performed measurement shown in Table 24, where the pressure decay test using the flow reference of 50.4 mL/min (FC02M, S/N: 15028517) did not show a deviation as well.

4.9.3 Summary

The pressure decay reported by the instrument is relatively consistent with the pressure decay indicated by the reference manometer, and the reproducibility is high.

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