



Life Sciences

Instruction For Use

USD2594^(8a)

Palltronic[®] Flowstar IV LGR Instrument

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Safety and Information Symbols

Safety and information is identified in this instruction manual with the following symbols:



Warning! Identifies a dangerous situation where there is a safety risk that may result in personal injury.



Important: Identifies a potentially dangerous situation risk to the equipment or other important information.



Please note: Identifies user guidelines and other useful information.

1. Safety Instructions



Warning! The user must read the complete Operating Instructions carefully and thoroughly before using the instrument.

1.1.. Installation

- The Palltronic Flowstar IV unit is a sensitive measuring instrument that must be handled with appropriate care.
- Good manual handling practice must be used lifting the instrument.
- The Instrument should be installed in a manner that prevents accidental draining of fluid back into the instrument.
- Compressed gas will exit from the external vent valve (when fitted) and the 'VENT' connection at the end of the test cycle. Exiting gas may contain aerosolized fluids from the assembly under test.

1.2.. Test Assembly

- The applied test pressure must be less than the claimed maximum operating pressure rating of the system under test.

1.3.. Personal Safety

- Appropriate protective clothing should be worn by the user (e.g. gloves and safety goggles) when working with chemicals and compressed air.
- On test completion check that the pressure has been vented and has reached atmospheric pressure before attempting to use or dismantle the assembly.
- Care should be taken when disconnecting pneumatic tubing from pressurized assemblies.

1.4.. Use of Compressed Gas

- The user must ensure that an oil-free regulated gas supply is used during operation of the instrument.
- The maximum inlet pressure of 8 bar (116 psi) must not be exceeded.
- All pneumatic tubing used for integrity testing must be rated to withstand the gas pressures used (up to 8 bar / 116 psi).
- The user must ensure that all tubing and connectors are integral and free from damage before each use.
- The user must ensure that all tubing and connections are clean, dry and free from any fluids or contaminants before each use.
- To prevent the danger of kinking tubing do not use a male-to-male pneumatic tube on the air outlet connection.

1.5.. Electrical

- Avoid contact with water and other solvents, particularly at the rear of the instrument.
- Instrument Repairs and Calibration can only be performed by Pall authorized service personnel. Repair and/or Calibration work by unauthorized personnel may cause accidents or injury to the end user.
- Do not open the instrument enclosure under any circumstance.
- Check the electrical cable for damage before powering up the Instrument. First connect the cable to the instrument before connection to an earthed power source.

Because of developments in technology, data or procedures may be subject to change. Consequently, we advise users to review their continuing validity annually.

2. Introduction

This document is valid for all Palltronic Flowstar test instruments with the following part numbers:

Part Number	Differences
FFS04R-LGR	Including the leak test option for single use systems
FFS04RS-LGR	Including serial (RS232) interface
FFS04RP-LGR	Including ProfiBUS interface
FFS04RD-LGR	Including DeviceNet interface

Part Number	Differences to standard version
FFS04B	No network functions (e.g. network storage, network printer, etc). No electronic signatures. No user lists and individual log-ins. No configuration of the Main Menu
FFS04S	None (Standard version)
FFS04R	As FFS04S plus wireless network option
FFS04SS FFS04RS	Including serial (RS232) interface
FFS04SP FFS04RP	Including ProfiBUS interface
FFS04SD FFS04RD	Including DeviceNet interface

2.1.. Integrity Test Protocols

The Palltronic Flowstar instrument provides the ability to perform a Forward Flow Bubble Point, combined Forward Flow and Bubble Point or a Water Intrusion Tests appropriate for filter integrity testing.

The filter can be tested in place or off-line and its performance capacity remains unaffected by the test when suitable protocols are followed.

The Instrument also has the ability to perform a Pressure Decay Test and a Leak Test.

The instrument provides direct flow measurement of the system under test. This measurement is independent of upstream volume over a wide range. Extensive internal Self Test features and use of high precision components virtually eliminate the possibility of significant measurement errors. The instrument is connected upstream of the system under test. The measurements are, therefore, non-invasive of the downstream side of the system and risk of contamination is eliminated.

2.2.. Basic Features

The test instrument is a small and lightweight portable unit, which has been specifically designed for ease of use and accuracy of measurement. Data input is carried out using a touch screen that also displays other essential information. The instrument measures flow and pressure in real time. An integral printer provides a permanent record of the test parameters and results. In addition, up to 10,000 test results can be stored electronically in the instrument's memory.

The test instrument is dust proof and splash proof to a rating of IP54, providing protection against severe laboratory and production conditions. The venting system includes an External vent valve to prevent test liquid from migrating into the Instrument on completion of the chosen test.

2.3.. Standard Functions

The instrument features the following standard functions:

- Forward Flow Test (FF)
- Bubble Point Test (BP)
- Combined Forward Flow and Bubble Point Test (FF/BP)
- Water Intrusion Test (WIT)
- Leak Test (LT)
- SUS Leak Test
- Pressure Decay Test (PD)
- Printout via internal printer
- Storage of test results
- Time and date display
- Automatic Self Test
- Automatic control of stabilization and test times
- Language options: English, English (US), German, French, Spanish, Italian, Portuguese, Japanese and Chinese
- Units of pressure in mbar, psi, kPa or kp/cm²
- External vent valve
- Password-protected storage of 500 test programs

3. Set-up Procedure

3.1.. Transport

The instrument is supplied in a robust wheeled carrying case. This should be retained by the user for transport to calibration and service facilities if required.

There is also a carry handle underneath the instrument which can be swung out for transporting short distances.



Figure 1: Carrying Handle extended



Warning! Please use the carry handle with care in order to avoid trapping fingers



Please note: The instrument is provided with a wheeled case for transportation. Avoid lifting or carry the instrument where possible.

3.2.. Connections

3.2.1.. Power Supply

The Instrument is designed for input voltages of 100-240 V AC and input frequencies of 50 or 60 Hz. Connect the electrical lead to the connector at the back of the Instrument.

3.2.2.. Pressure Supply

Connect the pressurized air supply to the male Stäubli* connector on the left side of the instrument. In order to avoid the risk of contamination of the internal components, it is recommended that the red pneumatic tubing should always be used to connect the Instrument to the compressed air line. The inlet pressure of the compressed air supply should be adjusted according to the following table:

Flow rate	Inlet pressure
Self Test	Minimum 3000 mbar (43.5 psi)
Flow limit < 150 mL/min	Minimum 1000 mbar (14.5 psi) above test pressure
Flow Limit > 150 mL/min	Minimum 2000 mbar (29 psi) above test pressure

It is recommended that the instrument is operated with an inlet pressure between 6000 – 8000 mbar (87 – 116 psi)



Please note: Throughout this document pressure values given in psi or mbar are relative to atmospheric pressure.



Warning! The operating pressure of the system under test must not be exceeded.

The maximum inlet pressure of the Instrument (8000 mbar/116 psi) must not be exceeded.

3.2.3.. Connection to the System Under Test

Connect the system under test to the female Stäubli connector on the left side of the instrument.

In all cases the blue pneumatic tubing should be used to connect the instrument to the system, filter housing or filter capsule.

The single use system must have been designed to allow the connection female Stäubli connector (OUT) on the left side of the instrument. In case of pre-use test on a sterile system the design of the single use system should ensure that there will be no impact on the sterility of the system. If a system under test contains Kleenpak™ sterile connectors, filling needles or similar components the fluid path lines need to be clamped before these devices prior the test.

3.2.4.. External Vent Valve

Insert the External vent valve plug into the socket at left the side of the instrument. The External vent valve connector should not be inserted or removed while the measurement instrument is switched on, in order to prevent the possibility of damaging the instrument due to electrical transient conditions. The External vent valve is connected in-line between the measurement instrument outlet hose and the System under test with Stäubli connectors. The female Stäubli connection of the vent valve is connected to the System under test.

3.2.5.. External Pressure Transducer/External Sensor

If the use of an external pressure transducer or external sensor (Temperatur or conductivity) is required, insert the plug from the transducer into the white socket at left the side of the instrument. The connector should not be inserted or removed while the instrument is switched on, in order to prevent damage to the instrument due to electrical transient conditions.

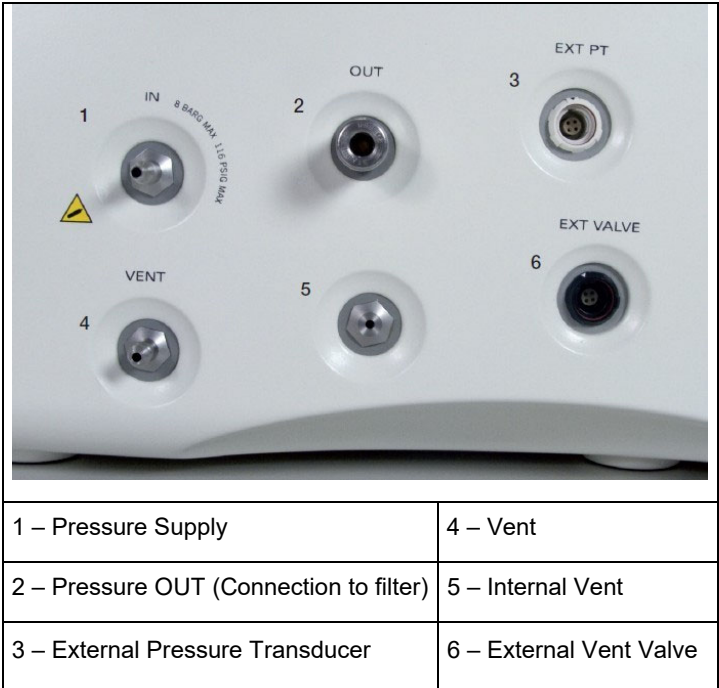


Figure 2: Pneumatic and electrical connections on the left side of the instrument:

3.2.6.. USB Connections

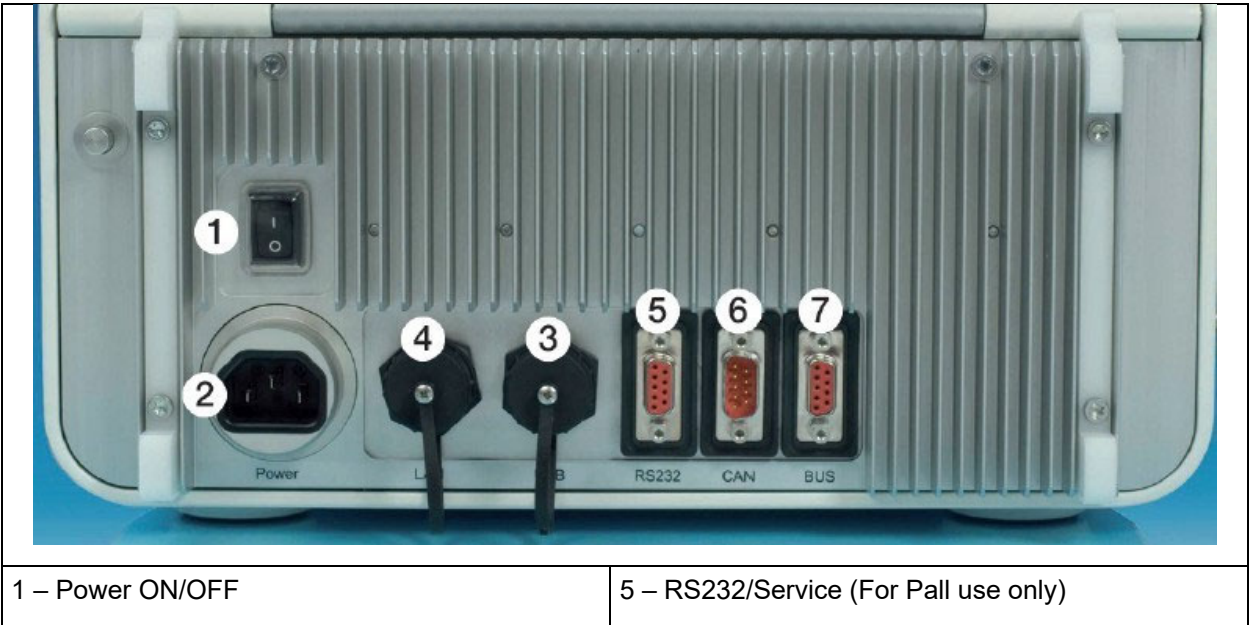
There is one USB (Universal Serial Bus) connection in front of the internal printer and one USB connection on the back of the instrument. The instrument is supplied with a USB flash drive installed in the connection in front of the printer.

3.2.7.. Network Connection

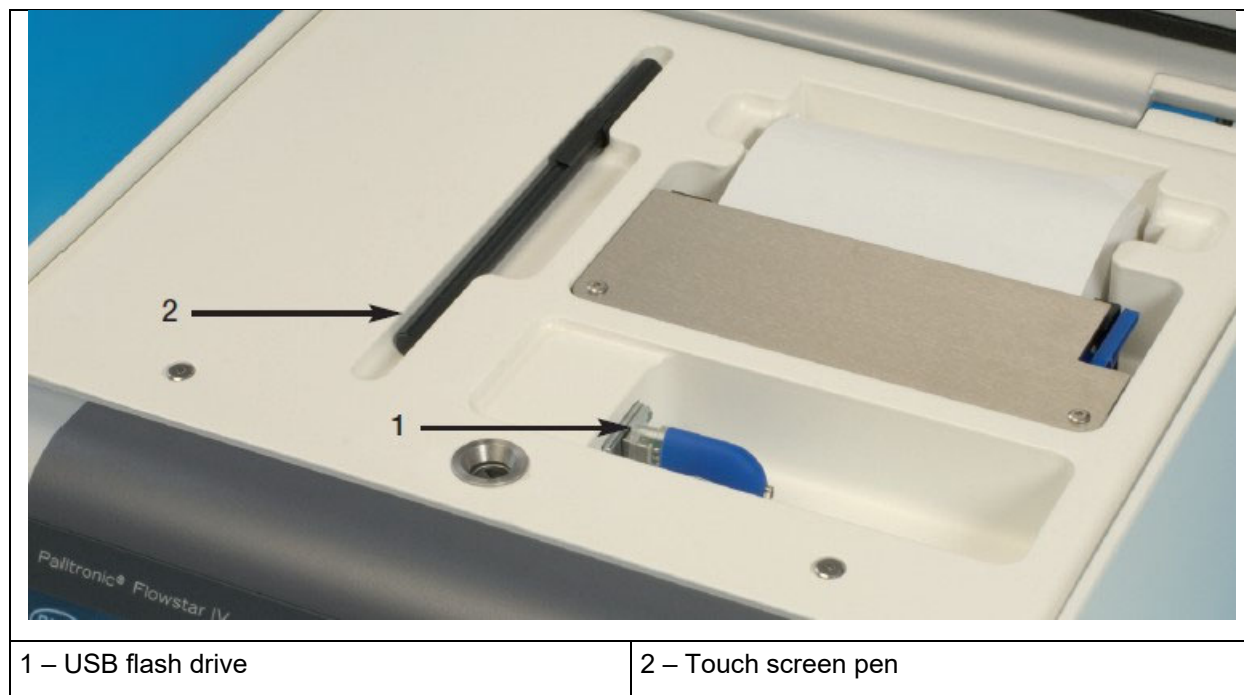
The network connection (RJ45) is located on the back of the instrument.

3.2.8.. BUS Connection

The BUS connection is located on the back of the instrument.



2 – Power connection	6 – CAN Bus (Controller Area Network Bus) (For Pall use only)
3 – USB	7 – PROFIBUS* or serial (RS232) port for automation
4 – Ethernet (RJ45)	

Figure 3: Connectors on the Back of the instrument**Figure 4:** USB flash drive and touch screen pen at the internal printer

4. Start Up Procedure

The instrument is turned on using the power switch on the back of the instrument.

4.1.. Self Test and Warm-up Period

When turned on the instrument automatically enters into the Self Test mode after a few seconds.



The Self Test will start automatically only once per day when first switched on.

On completion of the Self Test and the warm-up time the system displays the Main Menu.

During the Self Test following the primary electronic checks it is possible to navigate from the Self Test screen to the Main Menu and subsequent screens while the Self Test is running. It is not possible to start another test or to change the system configuration until either the Self Test is completed successfully or aborted.

The Self Test can be aborted, although this procedure is not recommended if the equipment has been switched off for a long period between operations. Abort the Self Test by touching 'Abort' on the screen.



In order to carry out the Self Test, the pressure of the compressed air supply must be between 3000 mbar (43.5 psi, 3.06 kp/cm²) and 8000 mbar (116 psi, 8.16 kp/cm²).

In the case that one of the test fails the test should be repeated, After the third unsuccessful test with the same failure a service for the instrument should be initiated. The instrument can be used further, in case of a fatal error the instrument is blocked. The flow measurement function could be tested using a Palltronic FlowCheck device and the FlowCheck function.

4.2.. Screen Navigation

After the Self Test has been completed the Main Menu screen is displayed.

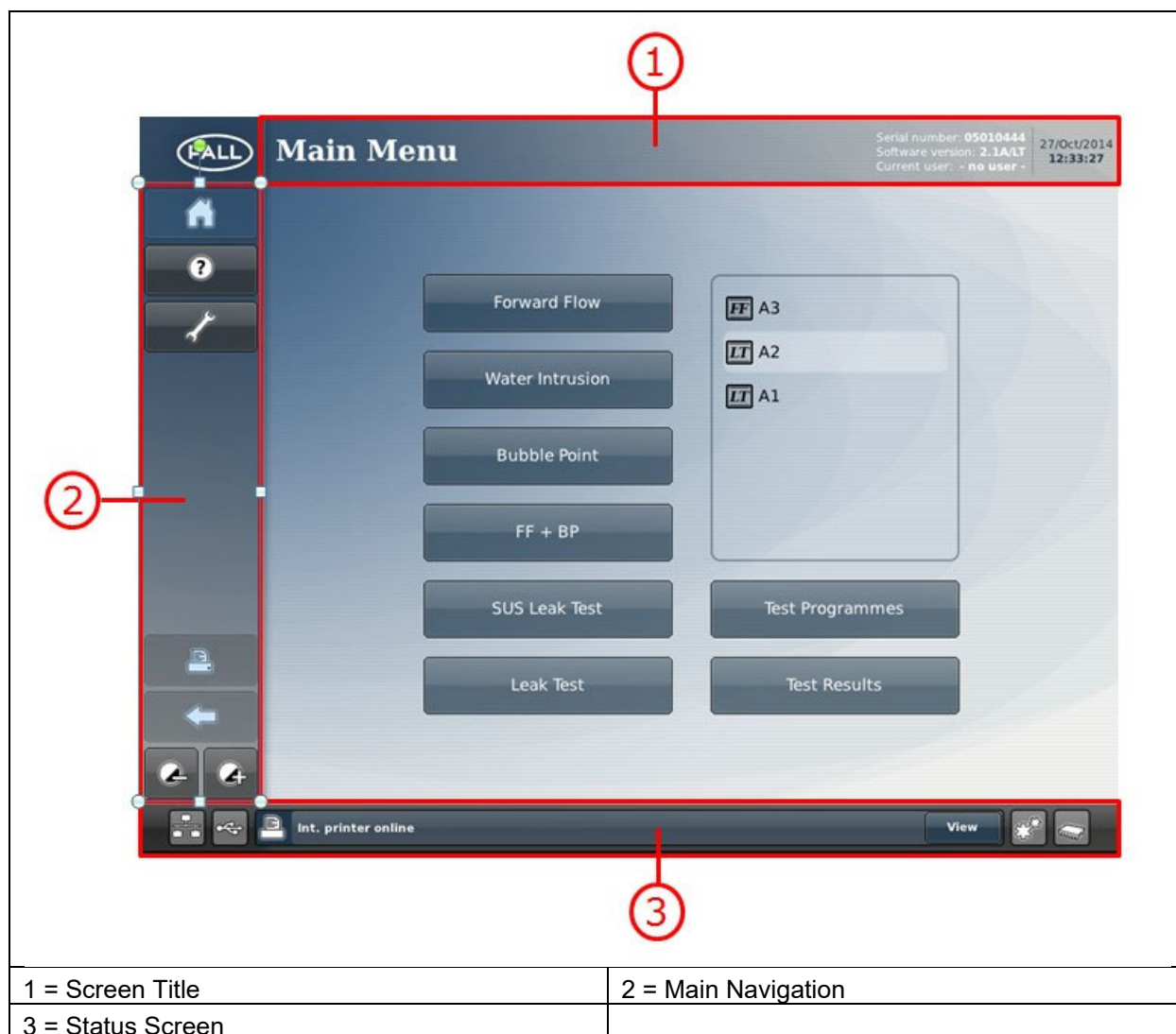


Figure 5: Main Menu screen

At the top of the screen, the screen title, the serial number and software version of the instrument are displayed.

If the LogIn function is active the name of the user logged in is displayed.

At the left side of the screen the main navigation buttons are displayed. Functions which are not active on the screen are grayed out.

At the bottom of the screen there is a status section which displays the number of stored test results, the number of test programs and the number of users. Other background activities, for example - a test in progress - are also displayed in the status section.

4.3 Use of the Touch Screen

The Palltronic Flowstar instrument has an easy-to-use touch screen and liquid crystal display for data input and display. Instrument functions can be selected via buttons on the touch screen, while the large screen allows to display real time graphs and other test data

Avoid touching the screen unless selecting a function, otherwise inadvertent selection of the wrong function may occur.

Do not use sharp tools when operating the touch screen.

The touchscreen should be used to operate the touch screen functions. The pen is located beside the internal printer. There are magnets in the face of the instrument on either side of the touch screen to hold the pen temporarily when not in use.

4.4.. Help Function

To access the help function touch the '?' button on the left side of the screen. During parameter entry the help function can be accessed using the '?' button beside the parameter field.

5. System Configuration

Prior to first use the following actions are recommended:

- Set the date and time, if required
- Set up the system configuration (language, pressure unit etc.)
- Configure the access management

To access these functions touch the TOOLS button on the left side.



Level 3 access is required for these activities. The initial password is <pall> For details see Section 6.

It is not possible to change the configuration of the system when a test is running.

5.1.. Basic Configuration

5.1.1 Date/Time

The date and time change function can be accessed from the TOOLS Screen.

The date and time format can be selected along with the method of time synchronization.

5.1.1.1 Manual Entry

If the instrument is not connected to a network the date and time must be set manually and should be checked regularly.

It is possible to define times zones, With the time zone setting you can activate the daylight saving time valid for the defined time zone.

5.1.1.2 Automatic Network Time Discovery

The instrument searches for the DHCP server on the network and requests address of the NTP server and the local time zone. The instrument then requests every day the time signal and synchronize with this time signal.

If the network does not provide the time zone the instrument will only update for daylight saving times if the time source on the network is updated.



Internal network settings may limit the access of the instrument. In this case contact the local IT administrator.

5.1.1.3 Use Windows Domain Server

If you enter the name of the Windows domain the instrument will synchronize the time with this domain server.

With the time zone setting you can activate the daylight saving time valid for your location.



Internal network settings might limit the access of the instrument. In this case contact the local IT administrator.

5.1.1.4 Use Specific NTP Server

The IP address of a specific NTP server can be entered here. The IP address of NTP servers can be found on the internet. Note that these servers may not recognize daylight saving times.

The time zone can be selected to activate daylight saving time changes.



Internal network settings may limit the access of the instrument. In this case contact the local IT administrator.

5.1.1.5 Use Flowstar Synchronization Software

With the Palltronic Flowstar synchronization software the time of all Palltronic Flowstar instruments connected to a network can be synchronized. The software Timesync.exe can be found on the USB flash drive supplied with the instrument or is available from Pall.

The software can be run from a PC and will synchronize the time of the PC with the Palltronic Flowstar instruments. The time zone of the PC is used as standard time. The software can be configured to set the synchronization intervals from every hour up to every forty eight hours.

To control the access for the instrument you can define a password for the instrument which also has to be entered into the PC software.



For the repeated synchronization the PC must be switched on and the synchronization software must be running at that time.



The following points can be defined under TOOLS and CONFIGURATION

5.1.2 Language

The following languages are available:

English
English (US)
German
French
Spanish
Italian
Portuguese
Japanese
Chinese



The full list of available languages installed on an individual instrument can be seen in the system configuration.

5.1.3 Pressure Units

This function determines the unit of input and output of pressure values. Pressure units may be shown in mbar, psi, kp/cm² or kPa.



If the pressure units are changed, Test results and Test programs generated prior to the change of unit will maintain the original pressure unit used for those results and programs.

5.1.4.. Keyboard Beep

This function enables the operator to switch off the keyboard entry confirmation sound. It can be switched off or on and the volume level can be defined.

5.1.5.. Flowstar IV extensions

This option enables the operator to activate or deactivate the Palltronic Flowstar IV extensions.

Options are:

- None
- AquaWIT IV
- AquaWIT/MUX IV
- AquaWIT/MUX IV (5 channels)
- Flowstar MUX IV

5.1.6.. Test Repeat Settings

These settings define the number of times a filter test is can be repeated until the instrument displays a warning or blocks the test.

The counting is linked to the same combination of filter type, filter batch and wetting fluid.

If a filter passes the test the counter is reset to allow the same number of test pre and after use.

The settings are:

Prevent repeat tests: Yes/No

This allows to activate or deactivate the function.

Number of repeats allowed

Defines the number of repeats allowed. The first test does not count as repeat so if only three tests should be allowed the number of repeats must be set to 2.

Include in repeat counter

This allows to define at what stage the following test is considered as repeat.

- All tests

Any tests will be counted at the moment the <Start> button is used.

- Test that reach pressure

All tests which enter the stabilization phase are counted. Test by simple setup failure, for example where the pressure supply is not connected are not included in counting,

- Test that reach measurement

Those tests which reach the measurement phase are counted. Test without a measured value are not considered as countable test.

It is recommended to use the 'Test that reach pressure' option.

Parameters determining repeated test

This defines which parameters entered are used to detect repeated test. Options are:

Option 1: Filter serial number, part number

Option 2: Filter serial number, part number wetting fluid

It is recommended to use option 2.



The following points can be defined under TOOLS and CONFIGURATION and 'Advanced Settings'

5.1.7.. Pre-stabilization

A pre-stabilization time can be activated in the system configuration.

When activated, time and pressure will be requested for all tests.

Specifying a longer pre-stabilization time is useful when testing large filter assemblies (> 20 L), when draining the wetting fluid from the filter housing before the test or if the filter requires a pre-pressurization step at a different pressure than the test pressure.

5.1.8.. Minimum Flow Field

This option introduces an additional entry field for the Forward Flow Test and the FF+BP Test. This enables a minimum flow limit to be entered. If the measured flow is below this limit a 'Low Flow' warning will be displayed and the system should be checked for any restriction to gas flow between the instrument and the filter under test.

5.1.9.. External Vent Valve

This option checks if an external vent valve is fitted. If the setting is ON, the instrument will check if an external vent valve is installed when a test is started. If no external vent valve is detected, or the external vent valve does not open, the test will be aborted.

If the setting is OFF, no checks are carried out and the test will run with or without an external vent valve.

5.1.10 External Pressure Transducer/External Sensor

For the configuration of the external pressure transducer/external sensor first the sensor type must be selected.

Options are:

- Pressure
- Temperature
- Conductivity

The instrument is designed to handle sensor with a 4-20 mA output. The sensor is not scope of the supply by PALL.

5.1.10.1 Pressure

Filter integrity tests are based on the differential pressure across the filter membrane. The membrane is either wetted with a wetting agent (FF + BP) or covered with water (WIT) and the flow caused by the differential pressure enables the integrity of the filter membrane to be confirmed. The test set up and parameters are based on atmospheric pressure on the downstream side. This means that the downstream side of the filter under test should be atmospheric pressure.

If the downstream side of the filter is closed during the test there is a risk that a higher flow across the membrane will cause the downstream side of the membrane to become pressurized thus reducing the differential pressure across the membrane under test. The reduced differential pressure will lower the measured flow, thus producing a risk that a filter with a major defect will not be detected due to the reduced differential pressure. To mitigate against this situation there is the option of installing a pressure transducer downstream of the filter, connected to the instrument. If the pressure downstream of the filter increases significantly during the test, the result will be reported as FAIL.

The downstream pressure transducer can be connected to the instrument (Ext. PT) on the left side of the instrument.

The pressure transducer should be a relative (relative to gauge) pressure sensor with a 4 – 20 mA signal.

Configuration

The pressure transducer can be set to OFF/ON or Mandatory.

If 'Mandatory' is selected the instrument will check if the pressure transducer is connected and active. If the transducer is not connected or the connection is interrupted the test will not be started, and a warning message displayed.

In the settings menu the maximum pressure signal of the external pressure transducer can be defined under "Ext. PT" span depending on the pressure transducer used. Options are: 1, 2, 3, 4 and 6 bar.

If a pressure transducer is installed, the test will be aborted if the downstream pressure increases to > 500 mbar for the Forward Flow and the Water Intrusion test and to >1000 mbar for the Bubble Point test as default value. These values are sufficient for most applications. If required these limits can be changed in the configuration menu under "Ext. PT" limit.

The 'Ext PT reading' displays the actual pressure reading of the pressure transducer (in mbar only)

The 'Ext. PT reading (raw)' displays the actual reading of the pressure transducer as an electrical value in mA.

If the pressure transducer is installed downstream of a filter, the filter can be removed, the Palltronic Flowstar instrument can pressurize the system and the target pressure can be compared to the reading

5.1.10.2 Temperature

The temperature of the wetting fluid has a significant impact on the filter test. The temperature should not be far beyond the temperature of the environment of the filter under test to avoid uncontrolled temperature impact on the test result.

A temperature sensor allows to define the limits within the temperature must be to start the test. In the case of a temperature outside this range the instrument will not start the test.

Configuration:

Start range minimum

This value defines the lower limit of the acceptable temperature range.

Start range maximum

This value defined the upper limit if the acceptable temperature range.

If the measured temperature is outside of these limits the filter test will not be started.

External sensor reading

This displays the actual value of the temperature measured. This value can be used for calibration.

External sensor reading (raw)

This displays the sensor signal as mA value.

Adjustment point 1/Adjustment point 2

This allows to adjust the sensor for the required range. It is recommended to use a reference below and above the temperature range intended to use.

Conductivity

The conductivity of the flushing fluid could be used as indicator of the cleanliness of a filter after flushing and before testing.

A conductivity sensor allows to define the limits within the conductivity must be to start the test. In the case of a value outside this range the instrument will not start the test.

Configuration:

Start range minimum

This value defines the lower limit of the acceptable conductivity range.

Start range maximum

This value defined the upper limit if the acceptable conductivity range.

If the measured conductivity is outside of these limits the filter test will not be started.

External sensor reading

This displays the actual value of the conductivity measured. This value can be used for calibration.

External sensor reading (raw)

This displays the sensor signal as mA value.

Adjustment point 1/Adjustment point 2

This allows to adjust the sensor for the required range. It is recommended to use a reference below and above the conductivity range intended to use.

5.1.11 Network Setting

The Ethernet port can be activated or deactivated by selecting ON or OFF.

The instrument can either read an IP address from the network if the prompt 'Use dynamic address' is set to 'Yes' or alternatively the IP address/Subnetmask/Gateway can be defined manually.

For the instrument part number FFS04R the WLAN network name (WLAN SSID) and password (WLAN WPA-PSK) can be defined.

5.1.12 Data Management Settings

The Palltronic Flowstar instrument with software version 2.1c or higher installed allows to

- Use the UserID/password from an Active Directory
- Synchronize test programs within a group of instruments
- Automatically store test results on a server
- Remove the cached password after 24h

Settings for these functions can be found under this option. For this the installation of the Data Management software (DMS) on the network is required. For details see the Instructions For Use for the Data Management software.

5.1.13 Automation settings

If the instrument is equipped with an active remote port (Serial, ProfiBus or DeviceNet) accessible through the BUS port at the back of the instrument this option allows the configuration of this port.

Device address: Defines the BUS address of the port

Compatibility mode: If the instrument replaces a previous version of the Palltronic Flowstar this allows to differentiate between FFSXC and FFS01. This is relevant for the serial communication only.

Pressure unit: The pressure unit should be set to the pressure unit of the remote system.

5.1.14 Main Menu Configuration

This option allows configuration of the Main Menu.

The test methods that are displayed on the Main Menu can be selected. Test methods with the option '0' are not displayed.

The options 1 – 6 define the order of the test method buttons.

If more than 6 options are activated the 6th button on the Main Menu will be labeled 'MORE' and the additional test option(s) will be displayed on a separate screen, accessed via the 'MORE' button.

In addition, the order of the test programs displayed in the box on the Main Menu screen can be defined.

Options are:

- Alphabetical
- Last used first
- Most used first

5.1.15 Customized test data fields

The user can define three additional fields and field names which are added to the test parameters for all available tests and for each test individually. This allows the user to add additional parameters to the test record.

The field name can be defined (Maximum length 20 characters).

For option 1 'Filter Line' is used as the default name.

5.1.16 Keyboard layout

The keyboard layout changes depending on the language setting. With this function another keyboard layout can be defined.

5.2..Printer setting

The Palltronic Flowstar IV instrument offers a number of different printing options.

5.2.1.. Internal printer

The internal printer can be switched ON, On + Graph and OFF.

When the internal printer is ON, the test record may be printed in full including the graph, or as an option without the graph.



The internal printer will start printing only when the cover is open.

5.2.2.. External printer

The external printing function enables the test record and other data to be printed via the network or as a file printout.

The external printer can be switched On, On + Graph or Off.

The test record may be printed in full including the graph, or as an option without the graph.

Advanced Printer Settings

USB printer

A USB printer can be connected to the USB port on the back of the instrument.



A printer type HP P1505N or compatible is recommended. The printer should be capable of handling the printer language PCL5e and above.

Network printer

A network printer can be connected to the instrument. When printing via a network the IP address of the networked printer must be known



A printer type HP P1505N or compatible is recommended. The printer should be capable of handling the printer language PCL5e and above..

The printer port (number) can also be defined, the paper size (A4 or American letter format)

There are three options for the printer language: Postscript, Laserjet4 and Colorlaserjet5C

File printer (PDF or XML File)

The data can be 'printed' in a file format either to a USB flash drive or a network location. For printing to a network a destination folder on the target network must be defined and selected. The instrument will create a folder with the serial number of the instrument.

The file format can be either Portable Document Format (PDF) or Extensible Markup Language (XML).



If XML is selected only test results will be printed into a file, all other printouts will not be printed into a file

Automatic printing

When set to 'On' test results will be printed automatically without action from the operator



This option is to be used only with an external printer (i.e. USB Flash drive, Network printer, USB printer).

It can be selected for printing as follows

- On test completion
- On last signature

Destination

When file printing is activated the destination can be either a USB flash drive or a network folder. If the network folder is selected the path and – if required – the user name/password for this folder can be defined.

Folder structure/File name

The subfolder structure generated is dependent of the type of record 'printed'. For test result printing the file name can be modified as described below.

- **Test results**

The file name is created by the instrument and includes the test type followed by the date when the test was performed in the format YYYYMMDD.

Two additional identifiers ID1 and ID2 can be selected from the test parameter entry:

Program name
Production area
Product name
Product batch No

Filter type (will be replaced by <Test item> for leak and pressure decay test)

At the end there is an indicator on the electronic signature status.

[0] No signature or electronic signature inactive
[1] The test result includes an electronic signature
[2] The test result includes two electronic signatures

The complete file name will be:

[Test type code [YYYYMMDD]][ID1][ID2][N]

The Self Test and Flow Check tests will be stored as [Test type] [YYYYMMDD][N].

- **Test Programs**

Test programs will be printed as PDF files into a folder named "Test programs".

The file name includes the test type and the program name and the storage date in the format YYYYMMDD.

- **Configuration**

Configurations will be stored as PDF files in the folder named "Configuration".

The file name includes storage date in the format YYYYMMDD.

- **Access Management**

Access management settings will be stored as PDF files in the folder "Access Management".

The file name includes storage date in the format YYYYMMDD.

- **User**

User details will be stored as PDF files in the folder "User".

The file name includes the storage date in the format YYYYMMDD.

- **Other Records**

Other data printed into a file will be stored as PDF files in the folder "Other records".

The file includes a data identifier and the storage date in the format YYYYMMDD.

The following data identifier is used:

DT = Date Time setting

6. Access Management

Access management is an important feature to assure that critical functions can only be used by trained and authorized users. The Instrument can be operated in two access modes:

- Standard Access Control
- High Level Access Control (HLAC) for operating electronic records in accordance with 21 CFR Part 11

In addition, the instrument under HLAC enables test results to be signed electronically.

The settings described below can be found under Access Management on the TOOLS screen.



User Level 3 required for this activity. The initial password is 'pall' For details see Section 6.



Note that passwords are case sensitive.

6.1.. Standard Access Control

The standard access control is a password controlled access to the definition of test programs and to the system configuration.

For this the 'Individual user login in the access management has to be set to 'Off'

There are three levels for the access management:

Level 1 (Operator)

Can run tests and review test results:

No password required

Level 2 (Supervisor)

Can perform data transfer and backup.

As level 1, plus definition of test programs:

Password 1 required

Level 3 (Administrator)

As level 2, plus access to system configuration

Password 2 required

Configuration; Date/Time setting and access management

The passwords can be changed under access management.



The default password 1 is <super> and password 2 is <pall>. It is recommended that these passwords are changed during the initial system configuration.

6.2.. High Level Access Control

This function can be activated in the Access Management.

For this the 'Individual user login in' the access management has to be set to 'On'

When this function is activated any activity requires a user to log in to the instrument.
An access level can be assigned to each individual user.

The access levels are:

Level 1 (Operator)

Restricted to running of tests and review of test results

Level 2 (Supervisor)

As level 1, plus definition and editing of test programs

Level 3 (Administrator)

Access to system configuration; Date/Time setting and access management and backup

In the standard configuration also Level 2 access, this can be deactivated in the access management settings.

Level 4 (User 1)

Access to system configuration; Date/Time setting and access management and backup.

No access to test related functions (Tests and test programs). User 1 is linked to the instrument and his access code is not transferred to other instruments when user lists are transferred.

To gain access to the instrument the operator must enter a UserID and a password which have previously been defined in the user list.



When this option is activated the user list contains one user level 4 with the default UserID ADMIN and the default password <pall>.

When a user is logged in all activities which produce an electronic record (Creating or changing a test program, changing the system configuration or creating or editing users, etc.) are linked to the user name identified by the login in the audit trail.

6.3.. Active Directory access control

With software 2.1c or higher the UserID/password and the access level can be linked to an Active Directory within the network. For this the instrument must be connected to a network and a copy of the Data Management Software (DMS provided by Pall must be installed within the network).

For further details, see the Instructions for Use for the Data Management Software.

6.4.. Signature/Electronic Signature

The instrument can be operated with manual signatures (default setting) or with electronic signatures.

It can also be configured so that a test result requires either one or two signatures.

The second signature can be used for approval of the test result.

When the electronic signatures function is deactivated, two signature fields will be on the printout.

The electronic signature function requires a user list where the name which appears as the signature is entered, and the User ID and password linked to this name have been defined.

Test results can be signed electronically immediately after the test or later by recalling the test result.

6.5.. Create/Edit user

When the High Level Access Control and/or the electronic signature are activated the users which are permitted access to the instrument or are permitted to electronically sign test results should be defined first, together with the access level for each user. This can be done in the user list.

If a user has been created the administrator must enter the User ID and the initial password.

The user should change this initial password at the first log in.

A user can change password at any log in.



If the link to the active directory is used the password cannot be changed on the instrument.

6.6.. Password management (Advanced settings)

To enhance the password security different controls can be defined for the password:

Password Aging

This option sets the expiration period of the current password in number of days, after which the user is forced to change the password.

Options:

1 (OQ Testing), 30, 60, 90, 180, 365 days or 'OFF' ('OFF' means that there is no password aging)

The option '1 day (test OQ)' is for test purpose only.

Exclude from password ageing (2.1c or higher only)

This option allows to exclude administrator which need access only at a low frequency.

Options:

None, Super Admin user only, All admin user

Minimum Password Length

This defines the minimum number of characters that must be used in a password.

Options:

4 (default value), 6 or 8 characters

Require complex password

Options:

ON/OFF

If set to on the password must include a character, a number and a special character.

Password History

This defines the number of different passwords which must be set before a previous password can be reused.

Options:

Remember the last 3, the last 5 or all passwords or OFF

Password Lockout

If an attempt is made to access the instrument using an incorrect password, no entry is permitted, and the password entry screen remains displayed. The number of failed access attempts is counted, and Password Lockout defines the number of failed attempts to access the system that is allowed before the user is locked out.

Options:

3, 5 or 10 attempts or OFF

Lockout Duration

This defines the lockout time after the number of failed attempts to enter a password for a UserID is exceeded.

Options:

5, 10, 30, 60 min, 24 h or 'until manually reset' or OFF.

If a lockout duration time is set, the user will be automatically unlocked after that time.

If the option 'until manually reset' has been selected, the user must be unlocked in the user list (Access Management). To unlock a user, the user must be selected and their password reset by the administrator (Level 3).

Automatic Logout period

If the instrument is left switched on, with a User logged in, then the instrument can be set so that the user is logged out after a given time with no touch screen operation. This parameter defines the time of inactivity before the user is logged out.

For the standard access mode, the instrument displays the password entry screen

Options:

5, 10, 20, 30, 60 (time in minutes) or 'OFF'.

If 'OFF' is selected, the option is disabled and users are not logged out.

6.7..Admin Restrictions

The administrators can be excluded different functions this includes all test related functions.

Exclude from user import (2.1c or higher only)

This allows to exclude administrator from being transferred within a user list.

Options:

Super Admin user only, All admin user

Exclude from running tests

This allows to exclude all administrators from running tests. User 1 (Super admin) is always excluded and this cannot be changed.

Exclude from program editing

This allows to exclude all administrators from creating and editing test programs. User 1 (Super admin) is always excluded and this cannot be changed.

‘Lock’ function

The settings on administrator restrictions can be locked by using the ‘Lock’ button.

For unlocking a master password is required from Pall. This password is only valid for one day and allow to redefine the restrictions.

7. Audit Trail

The instrument generates two type of audit trail, a record related audit trail and an event audit trail.

7.1..Record Audit Trail

An audit trail is generated for each of the following records:

- Test programs
- Configuration
- Date/Time Setting
- Access Management configuration
- Creating/editing users

The test results have no audit trail as they cannot be changed after storage except by adding an electronic signature and a comment.

The record audit trail can be reviewed by using the print function on the relevant screen.

Selecting a test program and touching the print button will create a printout including the original version of the test program, a list of changes and the current version.

The same applies to all other records that include an audit trail. Due to the complexity of the configuration the record audit trail for the configuration is dependent in the screen the printing is started.

The backup/export of these records always includes the record audit trail.

7.2..Event Audit Trail

Beside the audit trail for stored or edited records there is an event audit trail to trail activities not directly related to storing/editing/deleting records.

The audit trail logs for example events like login/logoff or false login attempts to login, the start and end of a test, changing in the system settings as well as the deletion of data, changes in the time setting and in the access management. It also records when the instrument is serviced.

This audit trail runs continuously and requires no user activity to be started. There is also no function to modify or edit this audit trail.

To view this audit trail, press the button 'View audit trail' on the 'Tools screen.

The contents of the audit trail can be selected by date or by month. The full audit trail uses colors to structure it:

- | | |
|-------|--|
| Red | – System related (Configuration/Time settings/asccess management etc.) |
| Blue | – Test program related |
| Green | – Test related |
| Black | – all other recorded events. |

It is also possible to reduce the audit trail to these four groups after selecting the date/month.

As additional function this audit trail can be exported as xml file which can be easily imported as MS Excel for further review and printing or as pdf file.

8. Instrument Operation

8.1.. The Forward Flow Test (FF)

8.1.1.. Introduction

The Forward Flow Test is designed to test the integrity of hydrophilic and hydrophobic membrane filters. The test is based on measuring the gas flow across a completely wetted membrane at a defined test pressure on the upstream side. When the downstream side of the membrane is at atmospheric pressure a diffusion flow of gas is established due to the pressure differential. Larger pores and defects will be de-wetted at the given test pressure causing a higher gas flow across the membrane. The measured flow is compared to the flow limit dependent on membrane type and filter area. If the filter exceeds the flow limits established by the membrane validation it is considered that the filter may be defective.

8.1.2.. Test Set-Up

A standard set up is shown in the following figure:

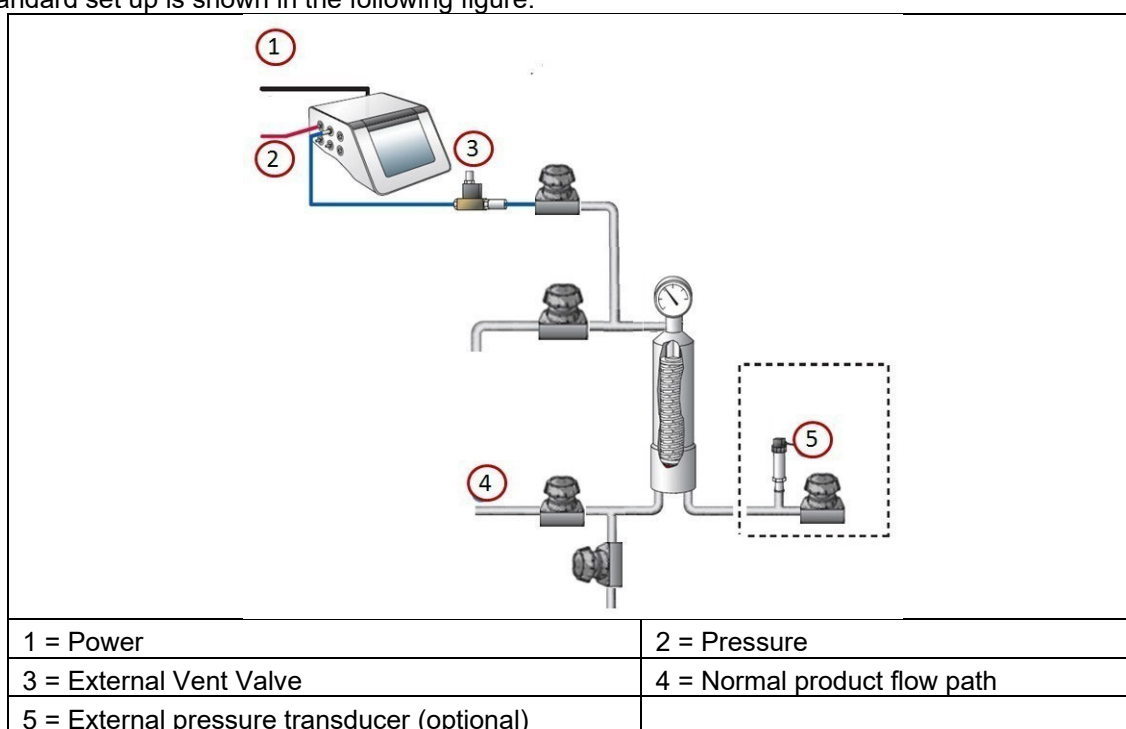


Figure 6: Standard Test Set-up



The instrument should be connected to the highest point (filter vent) of the housing to avoid fluid flowing back to the instrument.



In the standard configuration the downstream side of the filter should be at atmospheric to ensure a defined differential pressure across the filter under test. If the downstream side of the filter is closed due to the specific installation, it is recommended to measure the downstream pressure using an external pressure transducer connected to the instrument.

8.1.3.. Test Preparation

Prior to the test, the filter cartridge or capsule should be completely wetted with a suitable test fluid. Standard wetting fluids are water or solvents for hydrophilic filters and solvent water mixtures for hydrophobic filters. For standard wetting fluids the test parameters can be obtained from the filter supplier. For non-standard wetting fluids (e.g. product) the test pressure and flow limit must be established individually.

Wherever possible, the test assembly should be brought to the ambient temperature prior to testing. Temperature shifts must be avoided during the measurement.

8.1.4.. Input for the Forward Flow Test

There are two ways to conduct a Forward Flow Test. One way is to recall previously stored test programs (See Test Programs Section 9). In this case the main parameters for the filter test are completed from the test program and individual test details only need to be added. A list of available test programs are displayed on the Main Menu screen or can be selected by the 'Test program' button on the Data Input screen which is displayed after touching the Forward Flow Test button.

The second method is to manually input all parameters at the beginning of each test using the data input screen. Parameters input manually at the Forward Flow Test screen are not stored for use in future tests.

To input data, touch the required box. The box will then be highlighted and a cursor will appear in it. The keyboard on the touch screen can be used as a conventional keyboard to input data. To move onto the next input box, touch the required box.

Test Parameters for the Forward Flow Test:

Parameter	Contents/Range	Mandatory
Test program name	Test program name	N
Operator	Enter operator name The name of the user logged in will be filled in automatically	Y
Production area	Enter production area	N
<Option 1>	User-defined field	N
<Option 2>	User-defined field	N
<Option 3>	User-defined field	N
Product name	Enter product name	N
Product batch no.	Enter product batch number	N
Filter part number.	Enter filter part number	N
Number of filters	Enter number of filters in the housing under test	N
Filter serial number <1-12>	Enter filter serial number 1-12	N
Filter Housing	Enter housing name	N
Wetting liquid	Enter wetting liquid The flow limit must be issued for this wetting liquid!!	N
Test Gas	Enter test gas. The test limit must be issued for this gas!!	N
Pre-stabilization . pressure	Enter pre-stabilization pressure 50 – 6500 mbar (0.725 – 94.2 psi : 5 – 650 kPa : 0.05 – 6.629 kp/cm ²) If 0 is entered the step will be skipped	N
Pre-stabilization time	0 – 9999 sec If 0 is entered the step will be skipped	N
Test pressure	50 – 6500 mbar (0.725 – 94.2 psi : 5 – 650 kPa : 0.05 – 6.629 kp/cm ²)	Y
Test time	100 – 9999 sec or AUTO	Y
Maximum flow	0.1 – 1000 mL/min	Y
Minimum flow	0.1-100 mL/min	N
Comments	Optional Editable After Test	N

<Option#> means the field name can be defined by the user – see section 5.1.15.

Option 1 is 'Filter Line' as default.

Pre-stabilization pressure, Pre-stabilization time and Minimum Flow are only available when activated in the configuration.

Entry of test pressure, test time and maximum flow is sufficient for a Forward Flow Test. All other data are for record-keeping purposes and are not required for the instrument to begin the test. The 'Test Time' mode is selected by setting 'Auto' on or off. If 'Auto' is selected, the Palltronic Flowstar instrument will automatically run for the shortest possible test time.

The default maximum test time in Auto mode is 600 seconds.

The 'Minimum Flow' should be set between 5 and 10% of the Maximum Flow. If left blank the minimum flow will be set to zero.



When a test program is used it is not possible to change test parameters previously entered using the Test Programs screen except for the production area, product name, product batch, filter serial number, housing and user-defined fields (Option 1 – 3)

When data input is finished touch 'OK' and a screen with an overview of all test parameters will appear.

Touching the 'Home' button will return to the Main Menu but any data manually added in the data input screen will not be saved.

Touch the 'Queue' button to start the test later and store the test under 'Test results' for recall and start.

Touch the start button for immediate start.



*If a test is already running when pressing the 'Start' button, the new test will be automatically put in a queue.
The test can be observed in the list displayed in the Test Results screen and started by touching the 'Start' button.*

8.1.5.. Procedure for the Forward Flow Test

Manual Abort

The following automatic procedure can be aborted at any time by touching the 'Cancel' button on the touch screen. When the question 'Cancel test? Yes/No' is answered by touching 'Yes,' the screen displays "Test result: MANUAL ABORT" and the test result is printed out. If 'No' is touched, the test will continue to run.

Pressurization to Set Test Pressure

The instrument increases the test pressure in the filter housing. The build-up is displayed by a bar chart. The scale ranges from 0-200%, where 100% corresponds to the entered test pressure.

Stabilization of Test Pressure

When the preset test pressure is reached (100%), pressure stabilization commences. The stabilization time is automatically controlled by the equipment, and finishes as soon as the flow has stabilized within defined limits. This gives automatically reduced stabilization times that are often below five minutes. Prolonged stabilization times may be due to various factors including thermal fluctuation. If the system is not stable within 15 minutes an error message appears.

Test Phase

Once the stabilization phase is complete, the test phase commences. The test pressure, test time and measured flow are displayed as bar charts. The 100% marks correspond to the test pressure, maximum test time and maximum allowed flow.

The flow bar shows the average flow value for the previous 150 seconds. During the first 150 seconds the Instrument uses values measured during the stabilization time to calculate the average flow. The measured flow, test time and test pressure are also displayed numerically on the screen.

Touch the 'Graph' button to see a graphical display of the flow measurement. The flow displayed on the graph corresponds to the bar chart and is the average value for the previous 150 seconds. For an integral filter, the measured flow line will be below the pass limit line at the end of the test. A filter not meeting the test specifications will have the measured flow line above the pass limit line at the end of the test.

To return to the test data screen from the Forward Flow Test graphical display screen touch the 'Diagram' button.

Venting

Once the test is complete, the filter housing is vented. The timing of the venting sequence is designed to first vent the filter through the external vent valve, thereby eliminating the possibility of contamination, in the form of the test liquid entering the measurement instrument. If not prevented, the test liquid can enter the internal instrument valves and other sensitive components and cause malfunctions. The external vent valve connector should not be inserted or removed while the instrument is turned on, to prevent the possibility of damaging the instrument due to electrical transients.

Test Result

The test result is shown on the display.

"Flow within limits" indicates an integral filter.

"FLOW TOO HIGH" or "FLOW OUTSIDE LIMITS" indicates that the filter element may be defective, or that there is a leak in the system.

The test printout shows the test parameters, the date and time and the test result.



Test parameter fields which are empty except filter type, wetting fluid and test gas will not appear on the printout.

The test result is automatically saved and may be redisplayed or reprinted any time. See Section 10.

To return to the Main Menu touch the 'Main Menu' button.

To repeat or conduct another Forward Flow Test and return to the Forward Flow Test screen touch the 'BACK' button.

To print another copy of the test result, touch the 'Print' button.

8.2.. The Water Intrusion Test (WIT)

8.2.1.. Introduction

The Water Intrusion Test is designed to test the integrity of hydrophobic membrane filters. The test is based on measuring the water flow across a hydrophobic membrane completely covered with water at a defined test pressure on the upstream side. When the downstream side of the membrane is at atmospheric pressure a low evaporative water flow is established across the membrane due to the pressure differential. Larger pores and defects will allow bulk liquid water flow through the hydrophobic membrane at the given test pressure causing a higher water flow across the membrane. The measured flow is compared to the flow limit dependent on membrane type and filter area. If the filter exceeds the flow limits established by the membrane validation it is considered that the filter may be defective.

8.2.2.. Test Set-Up

A standard set up is shown in the following figure:

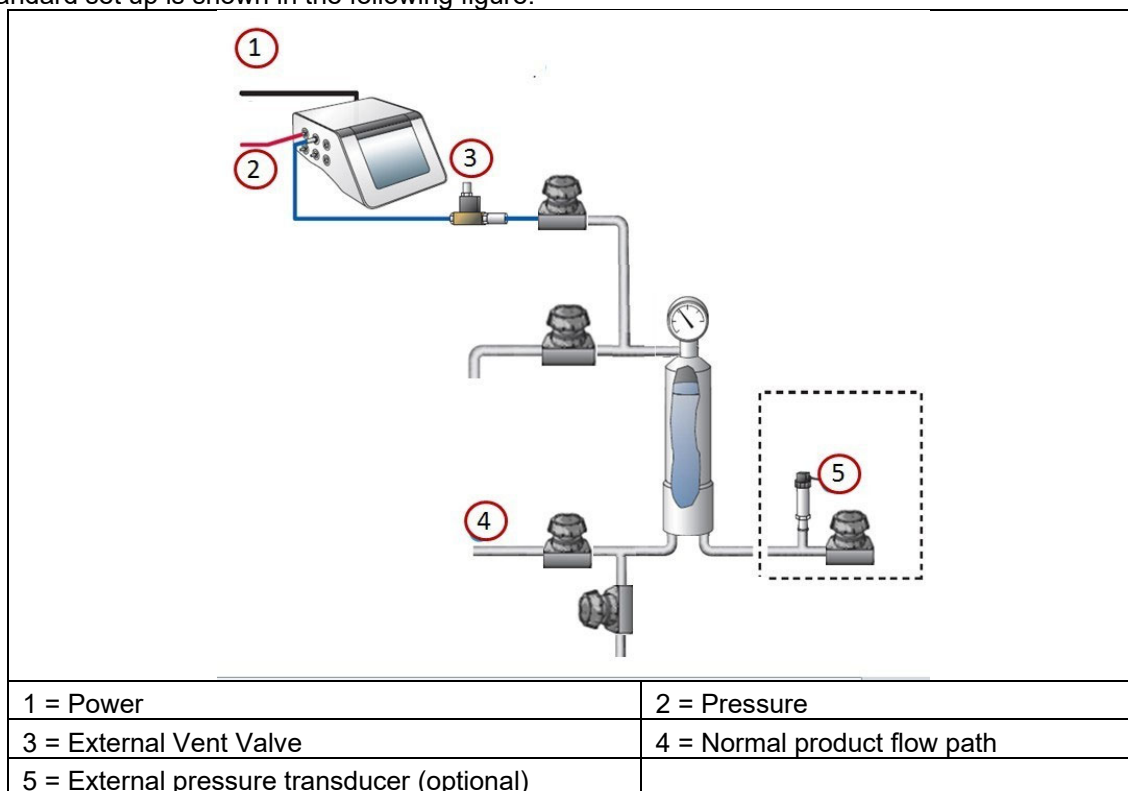


Figure 7: Water Intrusion Test Standard Test Set-up



The instrument should be connected to the highest point (filter vent) of the housing after the filling with water to avoid fluid flowing back to the instrument.



In the standard configuration the downstream side of the filter should be open to atmosphere to ensure a defined differential pressure across the filter under test. If the downstream side of the filter is closed due to the specific installation, it is recommended to measure the downstream pressure using an external pressure transducer connected to the instrument.

8.2.3.. Test Preparation

Prior to the test, the filter cartridge or capsule should be completely filled with water. Deionized water or water of a higher purity should be used.

Wherever possible, the test assembly should be brought to the ambient temperature prior to testing. Temperature shifts must be avoided during the measurement.

8.2.4.. Input for the Water Intrusion Test

There are two ways to conduct a Water Intrusion Test. One way is to recall previously stored test programs (See Test Programs Section 9). In this case the main parameters for the filter test are filled in from the test program and must only be completed. A list of available test programs is displayed on the Main Menu Screen or can be selected using the 'Test program' button on the Data Input screen which is displayed after touching the Water Intrusion Test button.

The second method is to manually input all parameters at the beginning of each test using the data input screen. Parameters input manually are not stored for use in future tests.

To input data touch the required box. The box will then be highlighted and a cursor will appear in it. The keyboard on the touch screen can be used like a conventional keyboard to input data. To move onto the next input box touch the required box.

Test Parameters for the Water Intrusion Test:

Parameter	Contents/Range	Mandatory
Test program name	Test program name	N
Operator	Enter operator name The name of the user logged in will be filled in automatically	Y
Production area	Enter production area	N
<Option 1>	User-defined field	N
<Option 2>	User-defined field	N
<Option 3>	User-defined field	N
Product name	Enter product name	N
Product batch No.	Enter product batch number	N
Filter part number	Enter filter part number	N
Number of filters	Enter number of filters in the housing under test The flow limit must be issued for the number of filters!!	N
Filter serial number. <1-12>	Enter filter serial number 1-12	N
Filter housing	Enter housing name	N
Pre-stabilization pressure	Enter pre stabilization pressure 50 – 6500 mbar (0.725 – 94.2 psi : 5 – 650 kPa : 0.05 – 6.629 kp/cm ²) If 0 is entered the step will be skipped	N
Pre-stabilization time	0 – 9999 sec If 0 is entered the step will be skipped	N
Test pressure	50 – 6500 mbar (0.725 – 94.2 psi : 5 – 650 kPa : 0.05 – 6.629 kp/cm ²)	Y
Test time	100 – 9999 sec or AUTO	Y
Maximum flow	0.05 – 50 mL/min	Y
Comments	Optional Editable After Test	N

<Option#> means the field name can be defined by the user – see section 5.1.15.

Option 1 is 'Filter Line' as default.

Pre-stabilization pressure and Pre-stabilization time are only available when activated in the configuration.

Entry of test pressure, test time and maximum flow is sufficient for a Water Intrusion Test. All other data are for record-keeping purposes and are not required for the instrument to begin the test. The 'Test Time' mode is selected by setting 'Auto' on or off. If 'Auto On' is selected, the Palltronic Flowstar system will automatically run for the shortest possible test time. The default maximum test time in Auto mode is 900 seconds.



When a test program is used it is not possible to change test parameters previously entered using the Test Programs screen except for the production area, product name, product batch, filter serial number and user-defined fields (Option 1 – 3)

When data input is finished touch 'OK' and a screen with an overview on all test parameters will appear. Touching the 'Home' button will return to the Main Menu but any data manually added in the data input screen will not be saved.

Touch the 'Queue' button to start the test later and store the test under 'Test results' for recall and start.

Touch the start button for immediate start.



*If a test is already running when pressing the 'Start' button, the new test will be automatically put in a queue.
The test can be observed in the list displayed in the Test Results screen and started by touching the 'Start' button.*

8.2.5.. Procedure of the Water Intrusion Test

Manual Abort

The following automatic procedure can be aborted at any time by touching the 'Cancel' button on the touch screen. When the question 'Cancel test? Yes/No' is answered by touching 'Yes,' the screen displays "Test result: MANUAL ABORT" and the test result is printed. If 'No' is touched the test will continue to run.

Pressurization to Set Test Pressure

The instrument builds up the test pressure in the filter housing. The build-up is displayed by a bar chart. The scale ranges from 0-200% where 100% corresponds to the entered test pressure.

Stabilization of Test Pressure

When the preset test pressure is reached (100%), pressure stabilization commences. The stabilization time is automatically controlled by the equipment.

Test Phase

Once the stabilization phase is complete, the test phase commences. The test pressure, test time and measured flow are displayed as bar charts. The 100% marks correspond to the test pressure, maximum test time and maximum allowed flow. The flow bar shows the average flow value for the previous 150 seconds.

During the first 150 seconds the instrument uses values measured during the stabilization time to calculate the average flow. The measured flow, test time and test pressure are also displayed numerically on the screen. Touch the 'Graph' button to see a graphical display of the flow measurement. The flow displayed on the graph corresponds to the bar chart and is the average value for the previous 150 seconds.

For an integral filter, the measured flow line will be below the pass limit line at the end of the test. A filter not meeting the test specifications will have the measured flow line above the pass limit line at the end of the test. To return to the test data screen from the Water Intrusion test graphical display screen touch the 'Diagram' button.

Venting

Once the test is complete, the filter housing is vented. The timing of the venting sequence is designed to first vent the filter through the External vent valve, thereby eliminating the possibility of contamination in the form of the test liquid entering the measurement instrument. If not prevented, the test liquid could enter the internal instrument valves and other sensitive components and cause malfunctions. The External vent valve electrical connector should not be inserted or removed while the measurement instrument is turned on, to prevent the possibility of damaging the instrument due to electrical transients.

Test Result

The test result is shown on the display. "Flow within limits" indicates an integral filter. "FLOW TOO HIGH" or "FLOW OUTSIDE LIMITS" may indicate either a defective filter element, a leak in the system, insufficient dryness of the filter before testing or hydrophilic contamination of the filter membrane.

To return to the Main Menu touch the 'Home' button. If you wish to conduct another Water Intrusion Test touch the 'BACK' button to return to the Water Intrusion Test screen.

The test printout shows the test parameters, the date and time and the test result.



Test parameter fields which are empty except filter type, wetting fluid and test gas will not appear on the printout.

The test result is automatically saved and may be redisplayed or reprinted any time. See Section 10.

8.3.. The Bubble Point Test (BP)

8.3.1.. Introduction

The Bubble Point Test is designed to detect the largest pores of hydrophilic and hydrophobic membrane filters. The test is based on measuring the gas flow across a completely wetted membrane at increasing gas pressure on the upstream side. With the downstream side of the membrane being at atmospheric pressure a diffusion flow is established due to the pressure differential. Larger pores and defects will be de-wetted at lower pressure causing a higher gas flow across the membrane. This flow increases significantly as larger pores are de-wetted. This increase is analyzed to determine the pressure at which a significant increase is observed. The estimated pressure is compared to the pressure limit depending on the membrane type and filter area. If the filter exceeds the membrane specific limit the test is a pass.



The Bubble Point Test can be subjective and loses accuracy, particularly with high area filters. It is recommended to combine the Bubble Point Test with a Forward Flow Test for determining the integrity of a filter membrane.

8.3.2.. Test Set-Up

A standard set up is shown in the following figure:

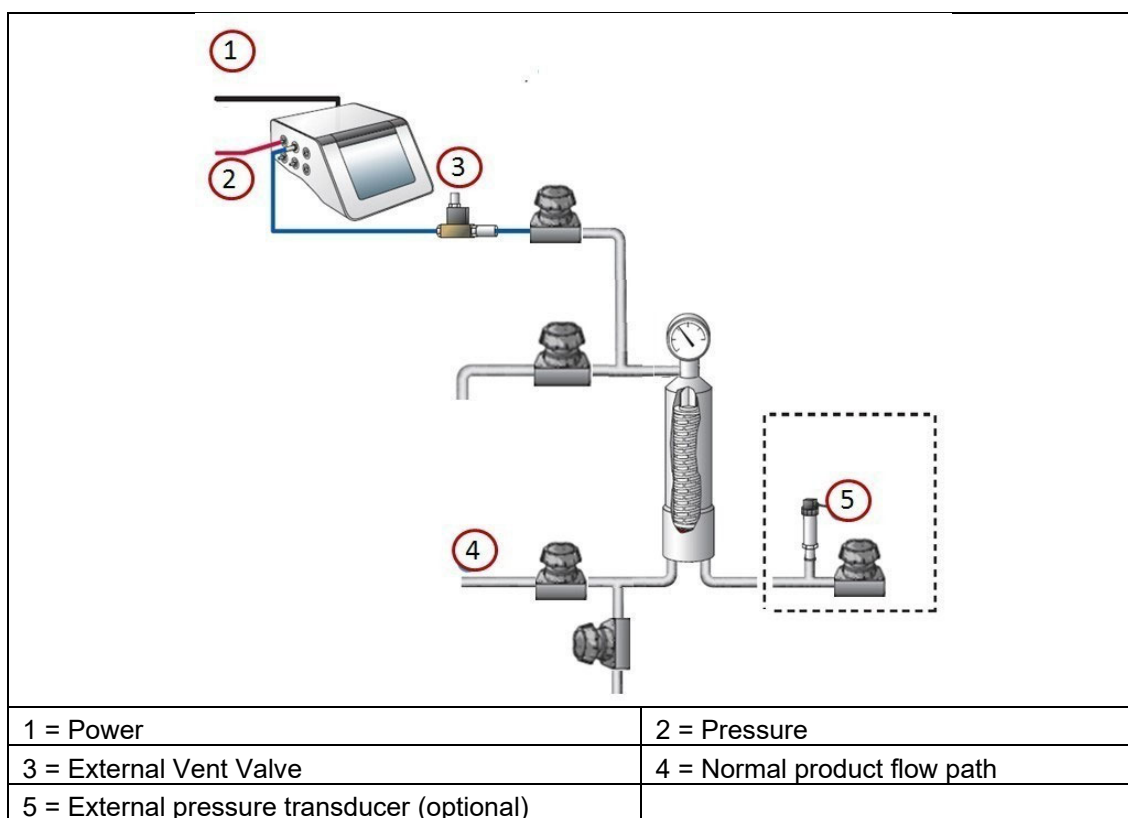


Figure 8: Bubble Point Test Standard Test Set-up



The instrument should be connected to the highest point (filter vent) of the housing to avoid fluid flowing back to the instrument.



In the standard configuration the downstream side of the filter should be open to atmosphere to assure a defined differential pressure across the filter under test. If the downstream side of the filter is closed due to the specific installation, it is recommended to measure the downstream pressure by an external pressure transducer connected to the instrument.

8.3.3.. Test Preparation

Prior to the test, the filter cartridge or capsule should be completely wetted with a suitable test fluid.

Standard wetting fluids are water or solvents for hydrophilic filters and solvent water mixtures for hydrophobic filters. For standard wetting fluids the test parameters can be obtained from the filter supplier. For non-standard wetting fluids (e.g. product) the test pressure and flow limit have to be established individually.

Wherever possible, the test assembly should be brought to ambient temperature prior to testing. Temperature shifts must be avoided during the measurement.

8.3.4.. Input for the Bubble Point Test

There are two ways to conduct a Bubble Point Test. One way is to recall previously stored test programs (See Test Programs Section 9). In this case the main parameters for the filter test are filled in from the test program and must only be completed. A list of available test programs is displayed on the Main Menu Screen and on the Data Input screen which is displayed after touching the Bubble Point Test button. Another method is to manually input all parameters at the beginning of each test using the data input screen. Parameters input manually at the Bubble Point Flow Test screen are not stored for future use.

To input data touch the required box. The box will then be highlighted and a cursor will appear in it. The keyboard on the touch screen can be used like a conventional keyboard to input data. To move onto the next input box touch the required box.

Test Parameters for the Bubble Point Test:

Parameter	Contents/Range	Mandatory
Test program name	Test program name	N
Operator	Enter operator name The name of the person logged in will be filled in automatically	Y
Production area	Enter production area	N
<Option 1>	User-defined field	N
<Option 2>	User-defined field	N
<Option 3>	User-defined field	N
Product name	Enter product name	N
Product batch No.	Enter product batch number	N
Filter part number	Enter filter part number	N
Filter serial number. <1-12>	Enter filter serial number 1-12	N
Filter housing	Enter housing name	N
Wetting liquid	Enter wetting liquid	N
Test gas	Enter test gas	N
Module factor	Defines the sensitivity for the Leak Test function The "Module Factor" should be set to the number of 10" modules. It should be set to 0.5 for 5" cartridges (e.g. AB05 or SLK7002), 0.2 for smaller (e.g. AB02 or SLK7001) filter and 0.1 for flat membranes (e.g. 142 mm discs) or mini capsules (KA02 or similar) For software versions > 2.0b, the user can set the Module Factor to as low as 0.01 for small area filters such as the Acro 25/50 and KM5 devices. Default value is 1 if nothing is entered	Y

Pre-stabilization pressure	Enter pre stabilization pressure 50 – 6500 mbar (0.725 – 94.2 psi : 5 – 650 kPa : 0.05 – 6.629 kp/cm ²) If 0 is entered the step will be skipped	N
Pre-stabilization time	0 – 9999 sec If 0 is entered the step will be skipped	N
Minimum BP	400 – 6500 mbar (5.8 – 94.2 psi : 40 – 650 kPa : 0.407 – 6.629 kp/cm ²)	Y
Maximum pressure	Enter max pressure for the system Is set to line pressure when nothing is entered	N
Comments	Optional Editable After Test	N

<Option#> means the field name can be defined by the user – see Section 5.1.15.

Option 1 is 'Filter Line' as default

Pre-stabilization pressure and Pre-stabilization time are only available when activated in the configuration.

The entry of minimal Bubble Point and the module factor are sufficient for a Bubble Point Test. All other data are for record-keeping purposes and are not required for the instrument to begin the test.



When a test program is used it is not possible to change test parameters previously entered using the Test Programs screen except for the production area, product name, product batch, filter serial number, housing and user-defined fields (Option 1 – 3)

When data input is finished touch 'OK' and a screen with an overview on all test parameters will appear. Touching 'ESC' or 'BACK' will return to the Main Menu but any data manually added in the data input screen will not be saved.

Touching 'Home' button will return to the Main Menu but any data manually added in the data input screen will not be saved.

Touch the 'Queue' button to start the test later and store the test under 'Test results' for recall and start.

Touch the start button for immediate start.



*If a test is already running when pressing the 'Start' button, the new test will be automatically put in a queue.
The test can be observed in the list displayed in the Test Results screen and started by touching the 'Start' button.*

8.3.5.. Procedure of the Bubble Point Test

Manual Abort

The following automatic procedure can be aborted at any time by touching the 'Cancel' button on the touch screen. When the question 'Cancel test? Yes/No' is answered by touching 'Yes', the screen displays "Test result: MANUAL ABORT" and the test result is printed. If 'No' is touched the test will continue to run.

Pressurization and Leak Test

The initial leak test seeks to establish that there are no gross leak/defect in the system under test. For this the upstream side of the filter is pressurized to 80% of the minimum BP value programmed and then 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'.

If the gas flow measured is below the limit value, the BP test proceeds.

Test Phase

During the measurement phase of the test the pressure in the upstream volume of the filter system is increased in increments of 50 mbar. Between each pressure increment the inlet supply pressure is closed and pressure decay is measured over a short interval. The bubble point is identified when two sequential pressure decay values are obtained that are significantly greater than the preceding values. During the test the pressure is represented as a bar chart on the display. Touch the 'Graph' button to see a graphical display of the Bubble Point Test measurement. The y-axis shows the pressure decay per minute and the x-axis shows the pressure. For an integral filter, the bubble point will be to the right of the minimum bubble point line. A filter not meeting the test specifications will have the bubble point to the left of minimum bubble point line. To return to the test data screen from the Bubble Point Test screen, touch the 'Diagram' button.

Venting

Upon completion of the test, the filter housing is vented. The timing of the venting sequence is designed to first vent the filter through the External vent valve, thereby eliminating the possibility of contamination, in the form of the test liquid entering the measurement instrument. If not prevented, test liquid could enter the internal instrument valves and other sensitive components and cause malfunctions.

Test Result

The test result is shown on the display. "BP within limits" indicates an integral filter. "BP OUTSIDE LIMITS" may indicate that the filter element is defective, or that there is a leak in the system.

To return to the Main Menu touch the 'Main Menu' button. To conduct another Bubble Point Test and return to the Bubble Point program selection screen, touch the 'BACK' button.

The test printout shows the test parameters, the date and time and the test result.



Test parameter fields which are empty except filter type and wetting fluid will not appear on the printout.

The test result is automatically saved and may be redisplayed or reprinted any time. See Section 10 for more details. To print another copy of the test result immediately, touch the 'Print' button.

8.4.. The Combined Forward Flow and Bubble Point Tests (FF/BP)

8.4.1.. Introduction

The combined Forward Flow and Bubble Point test performs a standard FF Test followed by a BP Test without the initial test for leaks.

8.4.2.. Test Set up

A standard set up is shown in the following figure:

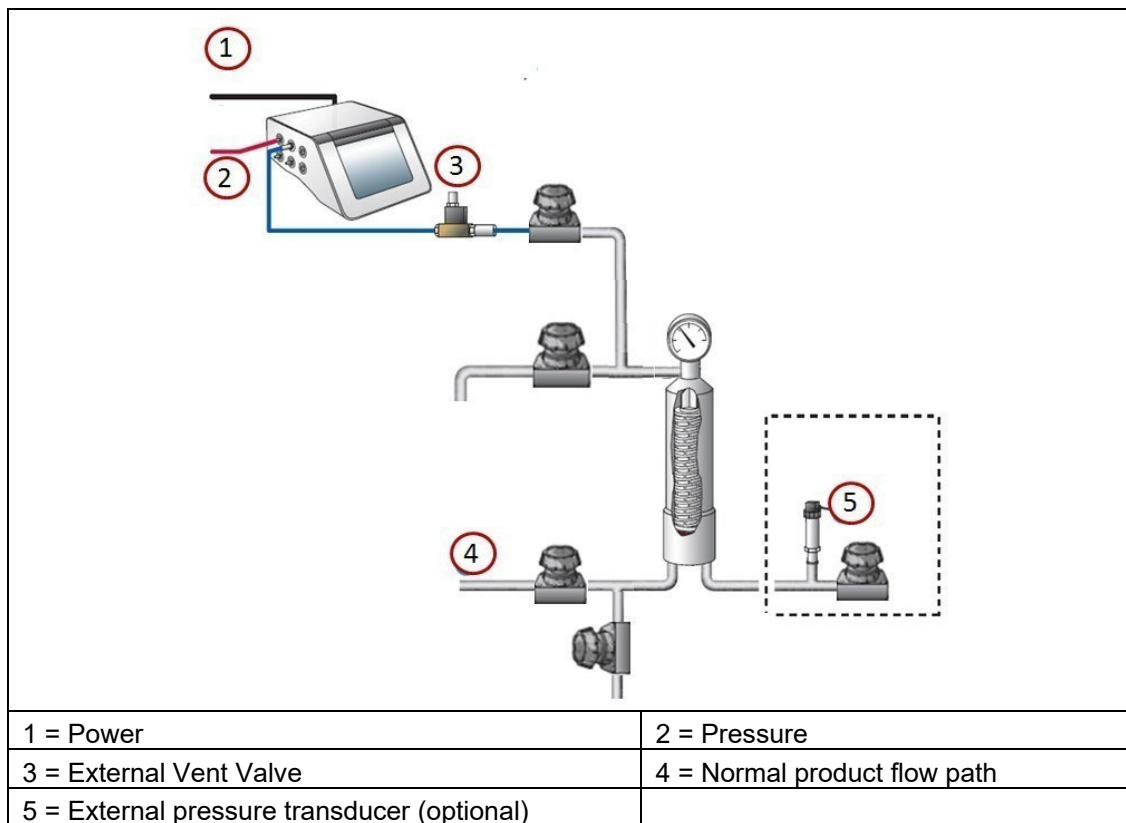


Figure 9: Combined Forward Flow and Bubble Point Test Standard Test Set-up



The instrument should be connected to the highest point (filter vent) of the housing to avoid fluid flowing back to the instrument.



In the standard configuration the downstream side of the filter should be open to atmosphere to assure a defined differential pressure across the filter under test. If the downstream side of the filter is closed due to the specific installation it is recommended to measure the downstream pressure by an external pressure transducer connected to the instrument.

8.4.3.. Test Preparation

Prior to the test, the filter cartridge or capsule should be completely wetted with a suitable test fluid. Standard wetting fluids are water or solvents for hydrophilic filters and solvent water mixtures for hydrophobic filters. For standard wetting fluids the test parameters can be obtained from the filter supplier. For non-standard wetting fluids (e.g. product) the test pressure and flow limit have to be established individually.

Wherever possible, the test assembly should be brought to ambient temperature prior to testing. Temperature shifts must be avoided during the measurement.

8.4.4.. Input for the Combined FF and BP Tests

There are two ways to conduct a FF+BP Test. One way is to recall previously stored test programs (see Test Programs, Section 9). In this case the main parameters for the filter test are filled in from the test program and must only be completed. A list of available test programs is displayed on the Main Menu screen or can be touched by the 'Test program' button on the Data Input screen which is displayed after touching the FF+BP Test button. Another method is to manually input all parameters at the beginning of each test using the data input screen. Parameters input manually at the combined Forward Flow and Bubble Point Test screen are not stored for future use.

To input data touch the required box. The box will then be highlighted and a cursor will appear in it. The keyboard on the touch screen can be used like a conventional keyboard to input data. To move onto the next input box touch the required box.

Test Parameters for the FF+BP Test:

Parameter	Contents/Range	Mandatory
Test program name	Test program name	N
Operator	Enter operator name The name of the user logged in will be filled in automatically	N
Production area	Enter production area	N
<Option 1>	User defined field	N
<Option 2>	User defined field	N
<Option 3>	User defined field	N
Product name	Enter product name	N
Product batch No.	Enter product batch number	N
Filter part number	Enter filter part number	N
Number of filters	Enter number of filters in the housing under test The flow limit must be issued for the number of filters!!	N
Filter serial number. <1-12>	Enter filter serial number 1-12	N
Filter housing	Enter housing name	N
Wetting liquid	Enter wetting liquid The flow limit must be issued for this wetting liquid!!	N
Test gas	Enter test gas	N
Pre-stabilization pressure	Enter pre stabilization pressure 50 – 6500 mbar (0.725 – 94.2 psi : 5 – 650 kPa : 0.05 – 6.629 kp/cm ²) Usually the test pressure if not specified different If 0 is entered the step will be skipped	N
Pre-stabilization time	0 – 9999 sec If 0 is entered the step will be skipped	N
FRF test pressure	50 – 6500 mbar (0.725 – 94.2 psi : 5 – 650 kPa : 0.05 – 6.629 kp/cm ²)	Y
FF test time	100 – 9999 sec or AUTO	Y
FF maximum flow	0.1 – 1000 mL/min	Y
FF minimum flow	0.1-100 mL/min	
Minimum BP	400 – 6500 mbar	Y
Maximum. pressure	Enter max pressure for the system Is set to line pressure when nothing is entered	N
Comments	Optional Editable After Test	N

<Option#> means the field name can be defined by the user – see Section 5.1.15.

Option 1 is 'Filter Line' as default.

Pre-stabilization pressure and Pre-stabilization time are only available when activated in the configuration.

The entry of the test pressure, the test time, the max flow, the minimal Bubble Point and the module factor are sufficient for a FF+BP Test. The 'Minimum Flow' should be set between 5 and 10% of the Maximum Flow. If left blank the minimum flow will be set to zero.

All other data are for record-keeping purposes and are not required for the instrument to begin the test.



When a test program is used it is not possible to change test parameters previously entered using the Test Programs screen except for the production area, product name, product batch, filter serial number, housing and user-defined fields (Option 1 – 3).

When data input is finished touch 'OK' and a screen with an overview on all test parameters will appear. Touching the 'Home' button will return to the Main Menu but any data manually added in the data input screen will not be saved.

Touch the 'Queue' button to start the test later and store the test under 'Test results' for recall and start.

Touch the start button for immediate start.



*If a test is already running when pressing the 'Start' button, the new test will be automatically put in a queue.
The test can be observed in the list displayed in the Test Results screen and started by touching the 'Start' button.*

8.4.5.. Procedure of the Combined FF and BP Test

Manual Abort

The following automatic procedure can be aborted at any time by touching the 'Cancel' button on the touch screen. When the question 'Cancel test? Yes/No' is answered by touching 'Yes', the screen displays "Test result: MANUAL ABORT" and the test result is printed out. If 'No' is touched the test will continue to run.

Test Phase

The instrument performs the Forward Flow Test and after the housing is vented, the Bubble Point Test then follows. See Sections 8.1 and 8.3 for further details of the procedures of these tests.

If the Forward Flow Test fails the Bubble Point Test is not performed.

Venting

Once the test is finished, the filter housing is vented. The timing of the venting sequence is designed to first vent the filter through the External vent valve, thereby eliminating the possibility of contamination in the form of the test liquid entering the measurement instrument. If not prevented, the test liquid could enter the internal instrument valves and other sensitive components and cause malfunctions.

Test Results

The Forward Flow Test results are displayed on the screen and printed out after the Forward Flow Test is complete. The screen then displays the progress of the Bubble Point Test. After completion of the Bubble Point Test, the test results are printed out.

When the Bubble Point Test is completed the Forward Flow Test results can be viewed by touching the 'Select FF' button. To return to the Bubble Point Test touch the 'Select BP' button. "Flow within limits" and "BP within limits" indicates an integral filter. "FLOW TOO HIGH" or "FLOW OUTSIDE LIMITS" and "BP OUTSIDE LIMITS" may indicate a defective filter. To return to the Main Menu touch the 'Main Menu' button. To run another combined Forward Flow and Bubble Point Test and to return to the program selection screen touch the 'BACK' button.

The test printout shows the test parameters, the date and time and the test result.



Test parameter fields which are empty except filter type, wetting fluid and test gas will not appear on the printout.

The test result is automatically saved and may be redisplayed or reprinted any time. See section 10. To reprint the test result, touch the 'Print' button.

8.5 Leak Test

8.5.1.. Introduction

The Leak Test function of the instrument allows an operator to test volumes such as tanks or tubing for leaks.

The algorithm is based on flow measurement using a similar method to the algorithm used for the Forward Flow test function. The Instrument pressurizes the volume to the test pressure and then records any pressure loss due to a leak. If it detects a pressure loss the system refills the volume with gas to maintain the test pressure and measures the amount of gas required to achieve this. The amount of gas required for refilling the volume is equivalent to the gas loss due to a leak.

8.5.2.. Limitations

The sensitivity of a leak test depends on a pressure change caused by a leak and is strictly dependent on the size of the volume which is under test.

As general rule a leak which is greater than 0.05% of the volume can be detected.

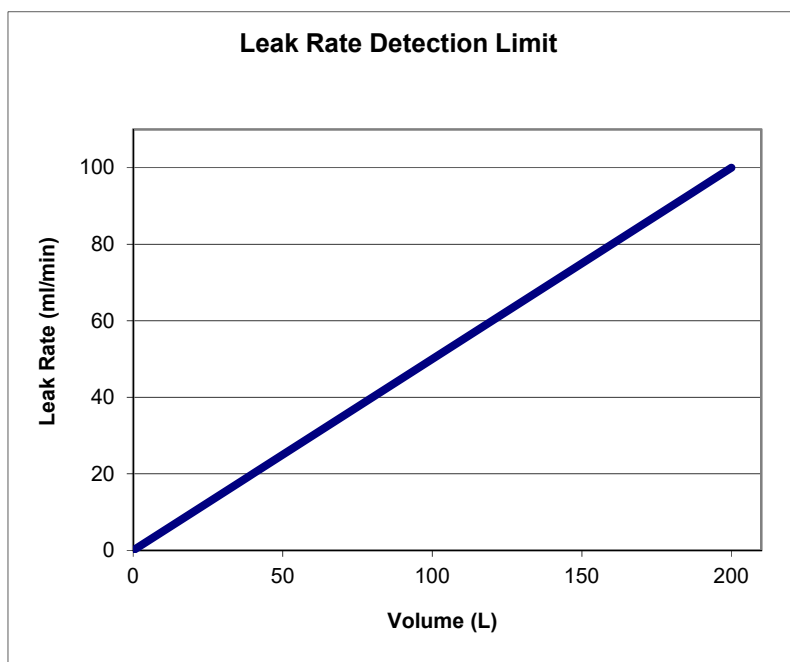


Figure 10: Detection limit vs. volume

As shown in the figure, the larger the volume, the less sensitive is the leak test. This is typical for any leak test based on the pressure change in a volume caused by a leak. Theoretically larger volumes can be tested but it should be regarded that with increasing volume the sensitivity of the test is decreasing and the pressurization time will increase significantly, depending on the test pressure and the line pressure. For larger volumes (> 50 liters) a long term pressure decay test might be more useful.

As with all pressure measurements the pressure can be influenced by temperature changes. To avoid false measurements the tests should be carried out under stable temperature conditions.

8.5.3.. Conversion of pressure decay limits to leak rates limit.

For leak tests pressure decay limits are often used to define the PASS/FAIL criteria. These limits can easily be converted into equivalent leak rates for flow measurement.

The basic equation for this is:

$$\text{Leak rate (ml/min)} = \frac{\text{Max pressure decay (mbar)} \times \text{Volume (ml)}}{\text{Test time (min)} \times 1000}$$

(1000 = 1000 mbar absolute pressure)

or if the pressure unit is psi;

$$\text{Leak rate (ml/min)} = \frac{\text{Max pressure decay (psi)} \times \text{Volume (ml)}}{\text{Test time (min)} \times 14.5}$$

(14.5 = 14.5 psi absolute pressure)

In the figure the leak rate limits for a max pressure decay of 2 mbar (0.029 psi)/10 min and 5 mbar (0.0715 psi)/10 min is shown for volumes from 0 to 200 liters.

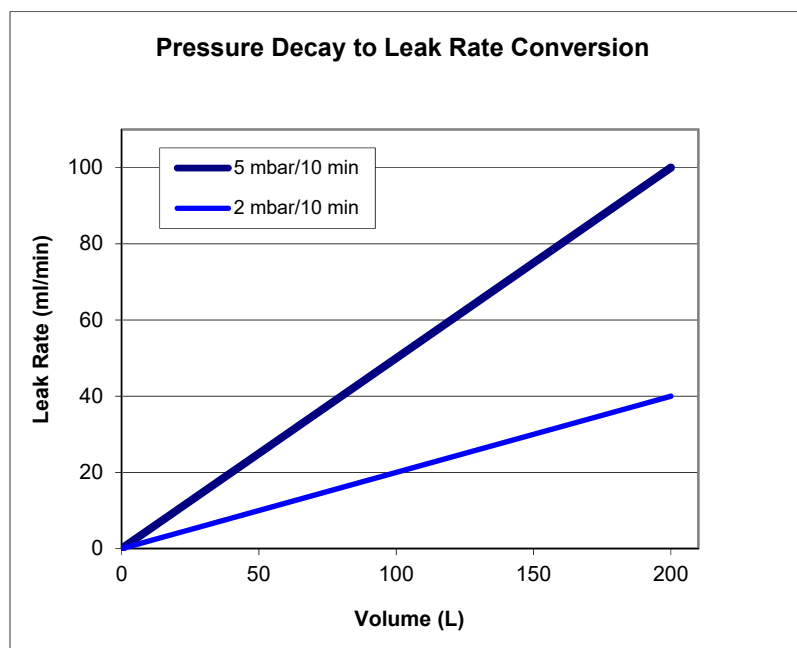


Figure 11: Leak rate limit for two different max pressure decay values vs. volume

8.5.4.. Leak test

The leak test is designed to test solid system like stainless steel tanks, piping and tubing in a single use system at pressures above 500 mbar for leaks.

8.5.4.1 Test set up

The test set up is shown in the following figure:

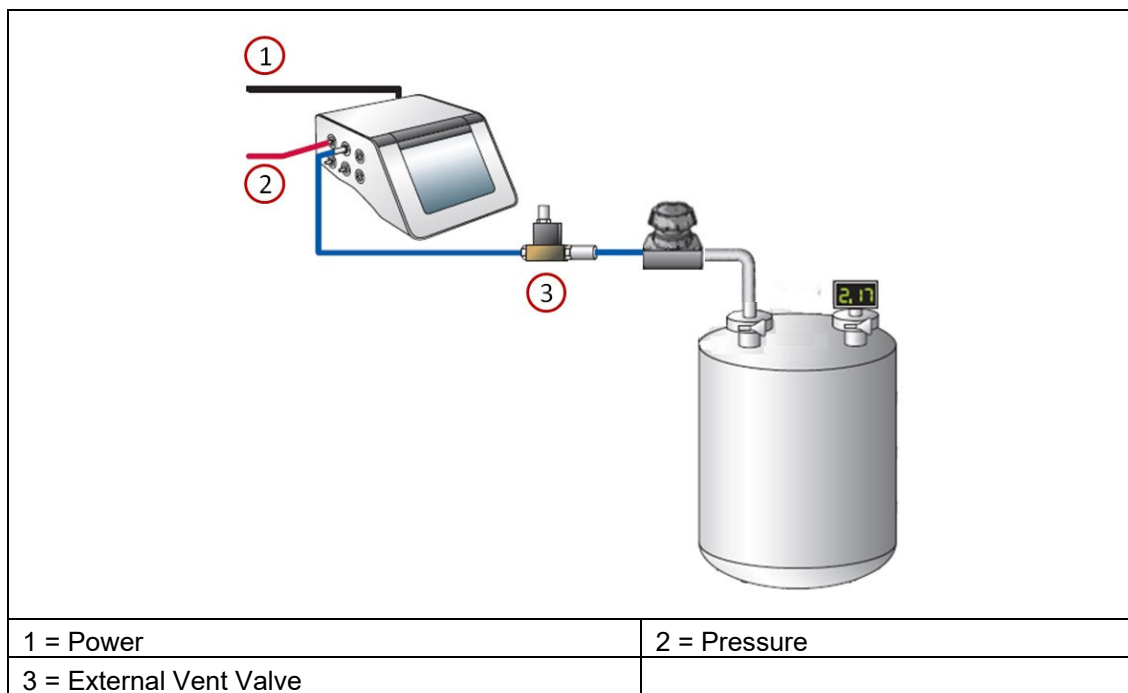


Figure 12: Leak Test Set-up

Prior to the test, the test assembly should be brought to the ambient temperature and temperature shifts should be avoided during the test.



Important: Check that the test pressure does not exceed the maximum pressure rating of the volume under test.

8.5.5.. Input for the Leak Test

There are two ways to conduct a Leak Test. One way is to recall previously stored test programs. (See Test Programs, section 9). In this case the main parameters for the test are filled in from the test program and must only be completed. A list of available test programs is displayed on the Main Menu Screen or can be selected by the 'Test program' button on the Data Input screen which is displayed after touching the Leak Test button. Another method is to manually input all parameters at the beginning of each test using the data input screen. Parameters input manually at the Leak Test screen are not stored for future use.

To input data touch the required box. The box will then be highlighted and a cursor will appear in it. The keyboard on the touch screen can be used like a conventional keyboard to input data. To move onto the next input box touch the required box

Test Parameters for the Leak Test:

Parameter	Contents/Range	Mandatory
Test program name	Test program name	N
Operator	Enter operator name The name of the user logged in will be filled in automatically	Y
Production area	Enter production area	N
<Option 1>	User-defined field	N
<Option 2>	User-defined field	N
<Option 3>	User-defined field	N
Product name	Enter product name	N
Product batch No.	Enter product batch number	N
Vessel ID	Enter description of volume under test	N
Pre-check phase	Enabled/Disabled	N
Pre-stabilization pressure	Enter pre-stabilization pressure 50 – 6500 mbar (0.725 – 94.2 psi : 5 – 650 kPa : 0.05 – 6.629 kp/cm ²) Usually the test pressure if not specified different If 0 is entered the step will be skipped	N
Pre-stabilization time	0 – 9999 sec If 0 is entered the step will be skipped	N
Test pressure	50 – 6500 mbar (0.725 – 94.2 psi : 5 – 650 kPa : 0.05 – 6.629 kp/cm ²) The pressure of the system under test must not be exceeded!!!	Y
Test time	100 – 9999 sec	Y
Maximum flow	0.1 – 1000 mL/min	Y
Comments	Optional Editable After Test	N

<Option#> means the field name can be defined by the user – see section 5.1.15.

Pre-stabilization pressure and Pre-stabilization time are only available when activated in the configuration.



When the pre-check phase is enabled the instrument will perform a short pressure hold test at the beginning to check for open valves or connectors not properly closed. This will also protect connectors against higher pressure.

The entry of the test pressure, the test time and the max flow is sufficient for a Leak Test. All other data are for record-keeping purposes and are not required for the instrument to begin the test.

A minimum test time of 600 seconds is recommended.



The Auto test time function available for FF tests and WIT tests is disabled as it can lead to false failures.



When a test program is used it is not possible to change test parameters previously entered using the Test Programs screen except for the production area, product name, product batch and user defined fields.

When data input is finished touch 'OK' and a screen with an overview on all test parameters will appear. Touching the 'Home' button will return to the Main Menu but any data manually added in the data input screen will not be saved.

Touch the 'Queue' button to start the test later and store the test under 'Test results' for recall and start.

Touch the start button for immediate start.



*If a test is already running when pressing the 'Start' button, the new test will be automatically put in a queue.
The test can be observed in the list displayed in the Test Results screen and started by touching the 'Start' button.*

8.5.6.. Procedure of the Leak Test

Manual Abort

The following automatic procedure can be aborted at any time by touching the 'Cancel' button on the touch screen. When the question 'Cancel test? Yes/No' is answered by touching 'Yes,' the screen displays 'Test result: MANUAL ABORT' and the test result is printed out. If 'No' is touched the test will continue to run.

Pressurization to set test pressure

The instrument increases the test pressure in the volume under test. The build-up is displayed by means of a bar chart. The scale ranges from 0-200% where 100% corresponds to the entered test pressure.

Stabilization of test pressure

When the preset test pressure is reached (100%), pressure stabilization commences. The stabilization time is automatically controlled by the equipment, and finishes as soon as the flow has stabilized within defined limits. This means automatically reduced stabilization times which are often below five minutes. Prolonged stabilization times depend on various parameters including thermal stabilization. If the system is not stable within 15 minutes an error message appears.

Test phase

Once the stabilization phase is complete, the test phase commences. The test pressure, test time and measured flow are displayed as bar charts. The 100% marks correspond to the test pressure, maximum test time and maximum allowed flow.

The flow bar shows the average flow value for the previous 150 seconds. During the first 150 seconds the instrument uses values measured during the stabilization time to calculate the average flow. The measured flow, test time and test pressure are also displayed numerically on the screen. Touch the 'GRAPH' button to see a graphical display of the flow measurement. The flow displayed on the graph corresponds to the bar chart and is the average value for the previous 150 seconds. To return to the test data screen from the Leak Test graphical display screen touch the 'DIAGRAM' button.

Venting

Once the test is complete, the volume is vented. The timing of the venting sequence is designed to first vent the volume through the external vent valve, thereby eliminating the possibility of contamination, in the form of the test liquid entering the measurement instrument.

If not prevented, the test liquid could enter the internal instrument valves and other sensitive components and cause malfunctions. The external vent valve connector should not be inserted or removed while the measurement instrument is turned on, to prevent the possibility of damaging the instrument due to electrical transients.

Test result

The test result is shown on the display.

If the instrument is not able to detect a pressure loss in the volume or the leak rate is too small to be detected by the instrument, it will report “NO LEAK DETECTABLE” or “FLOW WITHIN LIMITS” as the result.



The test (Measurement) phase may not start if during the stabilization time of the Leak Test the measurement algorithm determines that there is no flow detectable. The instrument will therefore not switch over to the measurement phase and report “NO LEAK DETECTABLE” evaluated as PASS. As the instrument has not started the test phase the reported test time may be 0 sec.

If the instrument can measure a flow rate but it is below the limit entered the result will be a “PASS”. If the leak rate is above the limit it will be a “FAIL”.

The test printout shows the test parameters, the date and time and the test result.



Test parameter fields which are empty except ‘Test Item’ will not appear on the printout.

The test result is automatically saved and may be redisplayed or reprinted any time. See Section 10.

To return to the Main Menu touch the ‘Main Menu’ button.

To repeat or conduct another Leak Test and return to the Leak Test program selection screen touch the ‘BACK’ button.

To print another copy of the test result, touch the ‘PRINT’ button.

8.6.. SUS Leak test

The SUS Leak test is designed to test flexible single use systems (SUS) such as those including biocontainer at pressures below 500 mbar for leaks. The algorithm includes a special sequence to unfold and pressurize a flexible system.

8.6.1.. Test set up

The test set up is shown in the following figure:

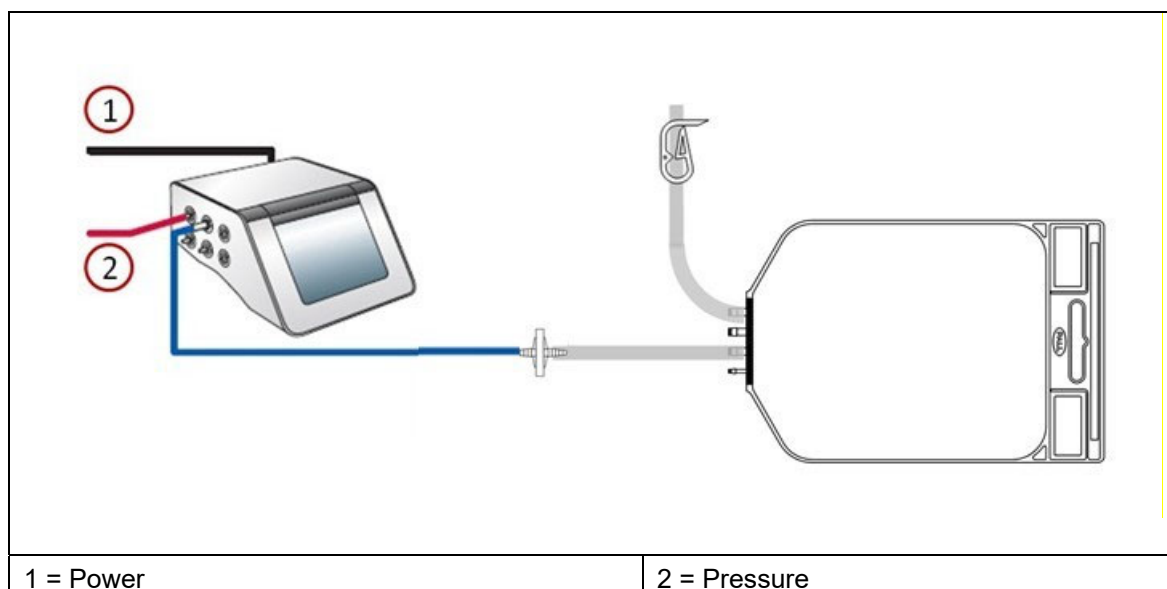


Figure 12: SUS Leak Test Set-up

Prior to the test, the test assembly should be brought to the ambient temperature and temperature shifts should be avoided during the test.



Warning Check that the test pressure does not exceed the maximum pressure rating of the volume under test.

Important: Check that the system under test is configured for leak testing.

The external vent valve should only be used for tests after use and if no filter is installed between biocontainer and instrument as shown in Figure 12

8.6.2.. Input for the SUS Leak Test

There are two ways to conduct a SUS Leak Test. One way is to recall previously stored test programs. (See Test Programs, section 9). In this case the main parameters for the test are filled in from the test program and must only be completed. A list of available test programs is displayed on the Main Menu Screen or can be selected by the 'Test program' button on the Data Input screen which is displayed after touching the SUS Leak Test button.

Another method is to manually input all parameters at the beginning of each test using the data input screen. Parameters input manually at the SUS Leak Test screen are not stored for future use.

To input data touch the required box. The box will then be highlighted and a cursor will appear in it. The keyboard on the touch screen can be used like a conventional keyboard to input data. To move onto the next input box touch the required box

Test Parameters for the SUS Leak Test:

Parameter	Contents/Range	Mandatory
Test program name	Test program name (if test program used)	N
Operator	Enter operator name The name of the user logged in will be filled in automatically	Y
Production area	Enter production area	N
<Option 1>	User-defined field	N
<Option 2>	User-defined field	N
<Option 3>	User-defined field	N
Product name	Enter product name	N
Product batch no.	Enter product batch number	N
System ID	Enter system identifier	N
System volume	Very small > 50 mL Small > 500 mL Medium > 1 L Large > 5 L	Y
Actual system volume	If > 5 L the actual system volume is requested: 5 -200 L These values must only be a rough estimate /	
Filling pressure	Enter pre-stabilization pressure 50 – 500 mbar (0.725 – 7.25 psi : 5 – 50 kPa : 0.05 – 0.5 kp/cm ²)	N
Test pressure	50 – 500 mbar (0.725 – 94.2 psi : 5 – 650 kPa : 0.05 – 6.629 kp/cm ²) The pressure of the system under test must not be exceeded!!!	Y
Pressure hold time	30 – 9999 sec	Y
Test time	100 – 9999 sec	Y
Maximum Flow	0.1 – 1000 mL/min	Y
Comments	Optional Editable After Test	N

<Option#> means the field name can be defined by the user – see section 5.1.15.

The entry of the system volume, the test pressure, the test time and the maximum flow is sufficient for a SUS Leak Test. All other data are for record-keeping purposes and are not required for the instrument to begin the test.

A test time of 600 seconds is recommended. If a biocontainer is under test, it may be necessary to extend the test time to 900 seconds because after pressurization the biocontainer can expand slowly to reach its final volume under pressure and the instrument can interpret this expansion as flow.



The Auto test time function available for FF tests and WIT tests is disabled as it can lead to false failures.



When a test program is used it is not possible to change test parameters previously entered using the Test Programs screen except for the production area, product name and product batch.

When data input is finished touch 'OK' and a screen with an overview on all test parameters will appear. Touching the 'Home' button will return to the Main Menu but any data manually added in the data input screen will not be saved.

Touch the 'Queue' button to start the test later and store the test under 'Test results' for recall and start.

Touch the 'Start' button for immediate start.



*If a test is already running when pressing the 'Start' button, the new test will be automatically put in a queue.
The test can be observed in the list displayed in the Test Results screen and started by touching the 'Start' button.*

8.6.3.. Procedure of the SUS Leak Test

Manual Abort

The following automatic procedure can be aborted at any time by touching the 'Cancel' button on the touch screen. When the question 'Cancel test? Yes/No' is answered by touching 'Yes,' the screen displays 'Test result: MANUAL ABORT' and the test result is printed out. If 'No' is touched the test will continue to run.

Filling (Unfolding)

The instrument fills the system at a pressure below test pressure to allow unfolding of the system or manifold. The instrument will time out if the system does not fill in a reasonable time.

Filling (Expanding)

The instrument fills the system slowly up to the filling pressure. The instrument will time out if the pressure cannot be achieved in a reasonable time.

Pressure hold

The instrument holds the preset filling pressure for the preset pressure hold time. The pressure hold time can reduce the impact of the initial slow creeping of a biocontainer and enhances the stability of the subsequent measurement.

Stabilization

After the pressure hold phase at the filling pressure, the instrument sets the defined test pressure. When the test pressure is reached the pressure stabilization commences. The stabilization time is automatically controlled by the instrument, and finishes as soon as the flow has stabilized within defined limits. This means automatically reduced stabilization times which are often below five minutes.

Prolonged stabilization times depend on various parameters including thermal stabilization. If the system is not stable within 15 minutes an error message appears.

Test phase

Once the stabilization phase is complete, the test phase commences. The test pressure, test time and measured flow are displayed as bar charts. The 100% marks correspond to the test pressure, maximum test time and maximum allowed flow.

The flow bar shows the average flow value for the previous 150 seconds. During the first 150 seconds the instrument uses values measured during the stabilization time to calculate the average flow. The measured flow, test time and test pressure are displayed numerically on the screen.

Venting

Once the test is complete, the volume is vented.

Test result

The test result is shown on the display.

If the instrument is not able to detect a volume change or the leak rate is too small to be detected by the instrument, it will report "PASS: No leak detectable" or "PASS: Flow within limits" as the result.



The test (Measurement) phase may not start if during the stabilization time of the Leak Test the measurement algorithm determines that there is no flow detectable. The instrument will therefore not switch over to the measurement phase and report "No leak detectable" evaluated as PASS. As the instrument has not started the test phase the reported test time may be 0 sec.

If the instrument can measure a flow rate but it is below the limit entered the result will be a "PASS". If the leak rate is above the limit it will be a "FAIL". "FAIL: FLOW OUTSIDE LIMITS"

The test printout shows the test parameters, the date and time and the test result.



Test parameter fields which are empty except 'Test Item' will not appear on the printout.

The test result is automatically saved and may be redisplayed or reprinted any time. See Section 10.

To return to the Main Menu touch the 'Main Menu' button.

To repeat or conduct another Leak Test and return to the Leak Test program selection screen touch the 'BACK' button.

To print another copy of the test result, touch the 'PRINT' button.

8.7.. Pressure Decay Test

8.7.1.. Introduction

The pressure decay test is designed as alternative method for leak testing more applicable for rigid vessels with volumes greater than 50 liters.

The test is not recommended for use as a filter integrity test since the size of the upstream volume is not measured and consequently the test result can be inaccurate.

8.7.2.. Test Set Up

The test set up is shown in the following figure:

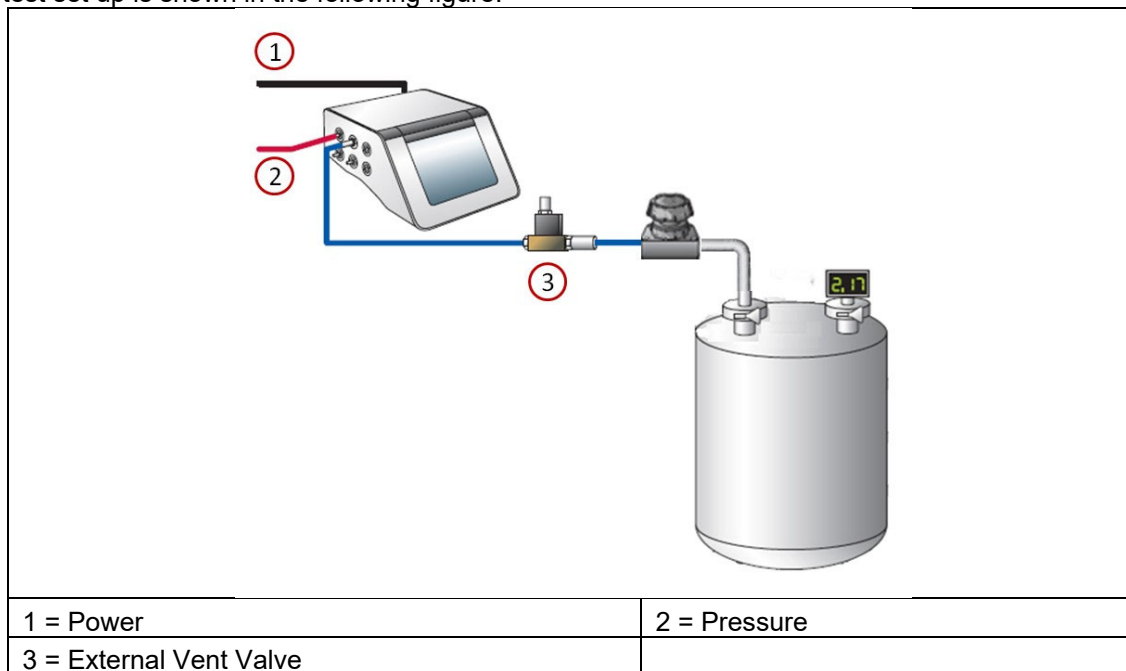


Figure 13: Pressure Decay Test Set-up

Prior to the test, the test assembly should be brought to the ambient temperature and temperature shifts should be avoided during the test.



Important: Check that the test pressure does not exceed the maximum pressure rating of the volume under test

8.7.3.. Input for the Pressure Decay Test

There are two ways to conduct a Pressure Decay Test. One way is to recall previously stored test programs. (See Test Programs, section 9). In this case the main parameters for the test are filled in from the test program and the rest of the data must only be completed. A list of available test programs is displayed on the Main Menu Screen or can be selected by the 'Test program' button on the Data Input screen which is displayed after touching the Pressure Decay Test button. Another method is to manually input all parameters at the beginning of each test using the data input screen. Parameters input manually at the Pressure Decay Test screen are not stored for future use.

To input data touch the required box. The box will then be highlighted and a cursor will appear in it. The keyboard on the touch screen can be used like a conventional keyboard to input data. To move onto the next input box touch the required box.

Test Parameters for the Pressure Decay Test:

Parameter	Contents/Range	Mandatory
Test program name	Test program name	N
Operator	Enter operator name The name of the user logged in will be filled in automatically	Y
Production area	Enter production area	N
<Option 1>	User defined field	N
<Option 2>	User defined field	N
<Option 3>	User defined field	N
Product name	Enter product name	N
Product batch no.	Enter product batch number	N
Vessel ID	Enter description of volume under test	N
Pre-stabilization pressure	Enter pre stabilization pressure 50 – 6500 mbar (0.725 – 94.2 psi : 5 – 650 kPa : 0.05 – 6.629 kp/cm ²) If 0 is entered the step will be skipped	N
Pre-stabilization time	0 – 9999 sec If 0 is entered the step will be skipped	N
Test pressure	50 – 6500 mbar (0.725 – 94.2 psi : 5 – 650 kPa : 0.05 – 6.629 kp/cm ²) The pressure of the system under test must not be exceeded!!!	Y
Stabilization time	100 – 9999 sec	Y
Test time	100 – 9999 sec	Y
Max. pressure decay	1-6500 mbar	Y
Comments	Optional Editable After Test	N

<Option#> means the field name can be defined by the user – see Section 5.1.15.

Pre-stabilization pressure and Pre-stabilization time are only available when activated in the configuration.

The entry of the test pressure, the stabilization time, the test time and the max pressure decay is sufficient for a pressure decay test. All other data are for record-keeping purposes and are not required for the instrument to begin the test.

A minimum stabilization and test time of 600 seconds is recommended.



The Auto test time function available for FF-tests and WIT tests is disabled as it might lead to false failures.



When a test program is used it is not possible to change test parameters previously entered using the Test Programs screen except for the production area, product name, product batch and user defined fields.

When data input is finished touch 'OK' and a screen with an overview on all test parameters will appear. Touching 'Home' button will return to the Main Menu but any data manually added in the data input screen will not be saved.

Touch the 'Queue' button to start the test later and store the test under 'Test results' for recall and start.

Touch the start button for immediate start.



*If a test is already running when pressing the 'Start' button, the new test will be automatically put in a queue.
The test can be observed in the list displayed in the Test Results screen and started by touching the 'Start' button.*

Touch the 'Start' button to start the Pressure Decay Test



*If a test is already running when pressing the 'Start' button, the new test will be automatically put in a queue.
The test can be observed in the list displayed in the Test Results screen and started by touching the 'Start' button.*

8.7.4.. Procedure of the Pressure Decay Test

Manual Abort

The following automatic procedure can be aborted at any time by touching the 'Cancel' button on the touch screen. When the question 'Cancel test? Yes/No' is answered by touching 'Yes,' the screen displays "Test result: MANUAL ABORT" and the test result is printed out. If 'No' is touched the test will continue to run.

Pressurization to set test pressure

The instrument builds up the test pressure in the volume under test. The buildup is displayed by a bar chart. The scale ranges from 0-200% where 100% corresponds to the entered test pressure.

Stabilization of test pressure

When the preset test pressure is reached (100%), pressure stabilization commences. The stabilization time is automatically controlled by the equipment,

Test phase

Once the stabilization phase is complete, the test phase commences. The test pressure, test time and measured pressure decay are displayed as bar charts. The 100% marks correspond to the test pressure, maximum test time and maximum allowed pressure decay.

The pressure decay bar shows the pressure decay measured since the start of the measuring phase. The measured pressure decay, test time and test pressure are also displayed numerically on the screen. Touch the 'GRAPH' button to see a graphical display of the pressure decay measurement. If the volume under test does not meet the test specifications, the measured pressure decay line will increase above the pass limit line before the end of the test. To return to the test data screen from the Leak Test graphical display screen touch the 'DIAGRAM' button.

Venting

Once the test is complete, the vessel is vented. The timing of the venting sequence is designed to first vent the vessel through the external vent valve, thereby eliminating the possibility of contamination, in the form of the test liquid entering the measurement instrument. If not prevented, the test liquid could enter the internal instrument valves and other sensitive components and cause malfunctions. The external vent valve connector should not be inserted or removed while the measurement instrument is turned on, to prevent the possibility of damaging the instrument due to electrical transients.

Test result

The test result is shown on the display.

If the instrument measures a pressure decay below the limit entered the result will be a "PASS". If the pressure decay is above the limit it will be a "FAIL".

The test printout shows the test parameters, the date and time and the test result.



Test parameter fields which are empty except 'Test Item' will not appear on the printout.

The test result is automatically saved and may be redisplayed or reprinted anytime. See Section 10.

To return to the Main Menu touch the 'Home' button. To repeat or conduct another Leak Test and return to the Leak Test program selection screen touch the 'BACK' button. To print another copy of the test result, touch the 'PRINT' button.

9. Test Programs

For filters or systems that are tested repeatedly using the same test parameters or where it is required to restrict the input of test parameters by the end users. The test parameters can be stored in a Test Program that can be recalled to start a test.

9.1.1.. Creating Test Programs

To create a new test program, touch 'Test Programs' from the Main Menu screen.



*Level 2 Access is required for this activity. The initial password is 'Pall'.
For details see Section 6*

Select the type of test for the test program.

Alternatively test programs can be created from the data entry screen of the required test, where a 'Test program' button is also available. In this case the test type is pre-selected from the data entry screen.

The single arrow key will refresh the screen to show the next test programs and the double arrow will move the selection up or down 25 test programs.

Touch the 'Edit' button to move into the Test Program Input screen.

In the Test Program Input screen touch a test data input box to highlight. A cursor will appear in the box and the keyboard on the touch screen can be used as a conventional keyboard to input data. To proceed to the next data input box touch the required box.

A unique name is mandatory for each test program.

9.1.2.. Editing Test Programs

To edit a test program touch 'Test Programs' from the Main Menu screen.



*Level 2 Access is required for this activity. The initial password is 'Pall'.
For details see Section 6*

The test programs are listed by test type. Select the test type and then the test program from the list displayed. Then touch 'OK'. The single arrow key will refresh the screen to show the next test programs and the double arrow will move the selection up or down 25 test programs. Touch the 'Edit' button to move into the Test Program Input screen.

In the Test Program Input screen edit the test parameters by touching the data input box to highlight it. A cursor will appear in the box and the keyboard on the touch screen can be used like a conventional keyboard to input data. To proceed to the next data input box simply touch it. If the data entry is completed, touch OK.

9.1.3.. Deactivating Test Programs

Deactivated Test Programs are no longer visible in the Test Programs menu or available to users when starting a test. However, deactivated Test Programs are stored in the instrument memory as part of the audit trail. To deactivate a test program touch 'Test Programs' from the Main Menu screen. The test programs are protected by password or Level 2 Access is required when logged in so that only authorized personnel can delete or deactivate test programs.

To delete or deactivate a test program, select the test program, press the "Edit" button, and then press the "Deactivate" to deactivate the test program and "Delete" to deactivate the test program.

9.1.4.. Printing Test Programs

To print test programs touch the 'Print all' button. The instrument will print all test programs of the selected test option. The printing can be aborted at any time.

If there is no test program stored for the selected test option the 'Print all' button is grayed out.

To print the current test program, select the program from the list and touch the "Print" button and select "Without Audit Trail"

If the user selects to print "With Audit Trail" the printout will first display the initial version, list and dates of changes followed by the current version

10. Recall of Stored Test Results

The instrument automatically stores all generated test results. To redisplay or reprint a test result that has been saved, touch the 'Test Results' button in the Main Menu screen.

Test results are initially displayed sorted by date/time when the test was performed.

10.1 Searching a test result

Selecting a test type displays only the test results of the selected test type.

10.2 Sorting test results

Touching the header of a column groups the test results according to the corresponding field content.

10.3 Reprint of a test result

A test result can be selected from the list and reprinted on an active printer

10.4 Electronic signature

Electronic signatures can be added to a test result. For an electronic signature this function must be activated in Access Management (see Section **Fehler! Verweisquelle konnte nicht gefunden werden.**) and a user list must exist.

11. Maintenance

Routine maintenance of the instrument is essential to ensure extended operation. This includes testing of the internal component and connections, changing the printer paper and cleaning the External vent valve. These operations can be carried out by the user and are described in the following section. When properly operated, the instrument is protected against contamination of the components by an internal filter and an External vent valve. Additional maintenance or repair work should not be undertaken by the user. For all repairs the equipment must be serviced by Pall approved service engineers. Pall recommend that the equipment undergoes a full service every three years by Pall, during which all components are cleaned and checked and a recalibration is carried out. A calibration is recommended at least every 12 months. This can be performed locally on site or at an approved Pall service center.

The maintenance functions are available from the Tools screen which can be recalled by touching the <Tools> button on the left side on every screen.

11.1 Self Test

This button starts a Self Test of the instrument which is usually performed when the instrument is switched on.

11.2 Flow Check

11.2.1 Introduction

This function allows checking the flow measurement function of the instrument.

A Palltronic Flow Check unit can be purchased separately as an optional accessory (Pall part number FC02, FC02M or FC02H). The Palltronic Flow Check unit is recommended for performing a fast and simple function test. This test can be performed regularly to show that the flow measurement function of an instrument is working correctly. The Palltronic Flow Check unit contains a capillary with a certified flow. The capillary is protected by a Pall Gaskleen® filter. The Palltronic Flow Check unit can be connected to an integrity test instrument and the flow through the capillary measured to show that there is no major deviation in the flow measurement capability of the instrument.

11.2.2 Test Preparation

Connect the Palltronic Flow Check unit to the OUT port of the instrument. The test assembly should be brought to room temperature before conducting a Flow Check test.

The test set up is shown in the following figure:

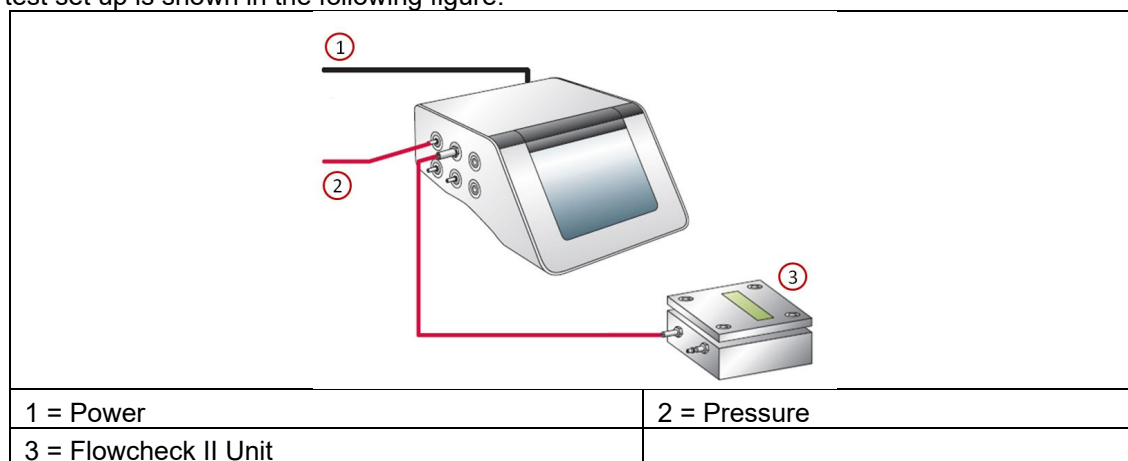


Figure 14: Flow Check Test

11.2.3 Input for the Flow Check Test

After selection of the Flow Check test from the Main Menu the Flow Check screen appears. Touch the data entry box required. A cursor will then appear and the keyboard on the screen can be used as a conventional keyboard to input data. To move onto the next input box touch the relevant box on the screen. The arrow and delete keys ('Del' and 'Del Line') can be used to edit text that has already been entered into a data input box. For a standard Palltronic Flow Check unit the parameters are:

Test Pressure: 2000 mbar (29.0 psi)

Test Time: 600 seconds

The certified forward flow rate for the Palltronic Flow Check unit is displayed on the FC02(M)(H) LCD screen.

A 'Start' button will appear on the screen automatically when the expected flow value has been entered. Touch the 'Start' button to start the Flow Check test.

11.2.4 Procedure of the Flow Check Test

Manual Abort

The following automatic procedure can be aborted at any time by touching the 'Cancel' button on the touch screen. When the question 'Cancel test? Yes/No' is answered by touching 'Yes' the screen displays "Test result: MANUAL ABORT" and the test result is printed out. If 'No' is touched the test will continue to run.

Pressurization to Set Test Pressure

The instrument pressurizes the Flow Check unit. The pressure build-up is displayed by a bar chart. The scale ranges from 0 – 200% where 100% corresponds to the entered test pressure.

Stabilization of Test Pressure

When the preset test pressure is reached (100%), pressure stabilization commences. The stabilization time is automatically controlled by the equipment, and finishes as soon as the flow has stabilized within defined limits. The automated control can provide reduced stabilization times, which are often below five minutes. Prolonged stabilization times depend on various parameters including thermal stabilization. If the system is not stable within 15 minutes an error message appears.

Measurement Phase

Once the stabilization phase is complete, the test phase commences. The test pressure, test time and measured flow are displayed as bar charts. The 100% marks correspond to the set test pressure, test time and expected flow. The flow bar shows the average flow value for the previous 150 seconds. During the first 150 seconds the instrument uses values measured during the stabilization time to calculate the average flow. The measured flow, test time and test pressure are also displayed numerically on the screen. Touch the 'Graph' button to see a graphical display of the flow measurement. The flow displayed on the graph corresponds to the bar chart and is the average value for the previous 150 seconds.

To return to the test data screen from the Graph screen touch the 'Diagram' button. Once the test is complete the Palltronic Flow Check unit is vented.

Test Result

The measured flow is displayed on the screen and on the test printout together with the percentage deviation. Under stable test conditions and using a Palltronic Flowstar instrument the reported flow value should be within $\pm 10\%$ of the certified flow value. In the event of results outside this limit the test should be repeated. If further results outside this limit are obtained, contact your local Pall office or Pall distributor.

11.3 Printer Test

This function generates a test printout on all activated printers.

11.4 Network Test

This function allows testing the network connection of the instrument. A 'Ping' is sent to a defined IP address and the instrument waits for a reply.

11.5 Cleaning

The correct set up and operation avoids the contamination of the instrument with wetting fluid or product. The final phase of a standard test sequence includes venting through the External vent valve and a venting algorithm to prevent reverse airflow. If such a contamination occurs despite these precautions there are two options to clean the parts potentially contaminated inside of the instrument.

Air Clean

The Air Clean function automatically cycles a flow of air through the Instrument to flush out any contaminants that may have inadvertently entered the instrument through the Air Out port.

In order to circulate the air completely through the test instrument, open the instrument 'OUT' port e.g. by using a male Stäubli* to Tri-clamp adapter. Touch 'Air Clean' from the Cleaning Menu followed by Start Phase 1. A countdown then appears on the screen. The Air Clean lasts a maximum of ten minutes, and can be stopped at any time by touching the 'Stop' button.

To flush the area between the OUT port and the Vent connect a clean empty volume to the OUT port and start 'Phase 2'.

Wet Clean



Important! Ensure that the instrument is connected to the power supply and the pneumatic supply before starting the wet clean function.

The Wet Clean function allows flushing the area between OUT port and the Vent by fluid. Touch 'Wet Clean' from the Cleaning Menu followed by Start. Connect the fluid supply to the 'Vent' and a male Stäubli fitting to the OUT port to collect the fluid coming out of the instrument.

The fluid can then be introduced to the instrument by a syringe, a pump or by gravity. Note that the fluid will come out of the OUT port.

- Neutral cleaning agents (e.g. neutral detergents) are recommended for this purpose.
- The cleaning agent should be removed by water and flushed out.
- At the end the fluid should be drained through the vent port. This can be enforced by connecting air pressure to the OUT.

The wet clean should be followed by a dry clean as described above.

11.6 Audit Trail

This function allows to view the event audit trail. The audit trail can be viewed for a day or a month. It can also be selected if the complete audit trail is displayed or only for settings, test results, test programs or others. It is also possible to export the selection from this screen.

11.7 Screen Adjustment

In the case of a screen misalignment this function enables the screen to be realigned. The screen displays four crosses in the four corners of the screen. Touch each corner with the pen followed by 'OK'.



Note: If the screen is fully misaligned the screen adjustment can also be reached by pressing the screen in the top left area for more than 20 sec

Press each of the highlighted calibration point once



Note: Avoid to touch the screen anywhere else or the area around the screen during this procedure

Once completed tap the screen to save the new setting or wait more than 20 sec to leave the screen without saving the settings.

11.8 Changing the Printer Paper

The printer paper should be changed as soon as a red edging appears. The integral thermal printer requires thermal paper rolls 112 mm (4.4 inch) wide with a maximum outer diameter of 50 mm (2.0 inch).

Note that the lifetime of the printout is dependent on the paper quality and the storage conditions before and after use. Printouts should be stored at ambient temperature and in the dark.

To change the printer roll lift the top cover of the instrument. Lift the small lever at the right side of the printer and remove the old paper roll, pulling any remaining paper out of the guide. Push the end of the paper as far as possible into the paper guide. If the paper is far enough into the paper guide, the printer will start feeding. Put the lever back into its position and insert the paper roll spindle into the paper roll and place the paper roll in the holder.



Warning! Take care when operating the printer during paper change to avoid trapping loose clothing.

The paper cutter is sharp, avoid touching the cutter.

11.9 Cleaning the External Vent Valve

After heavy usage the External vent valve may become contaminated. In this case, the following procedure should be followed in order to clean the valve.

1. Switch off and unplug the instrument.
2. Unplug the External vent valve from the instrument.
3. Remove the cap nut (11) using a 13 mm spanner (or wrench) and remove the coil and cable assembly (10) from the valve stem (8).
4. Remove the spring washer (9). Remove valve stem (8) from the valve block (3) using a 14 mm spanner (or wrench).
5. Remove the pallet (5) and springs (6) from the valve stem (8), taking care not to lose the o ring (7). Please note the correct orientation for the springs, and maintain this during reassembly.

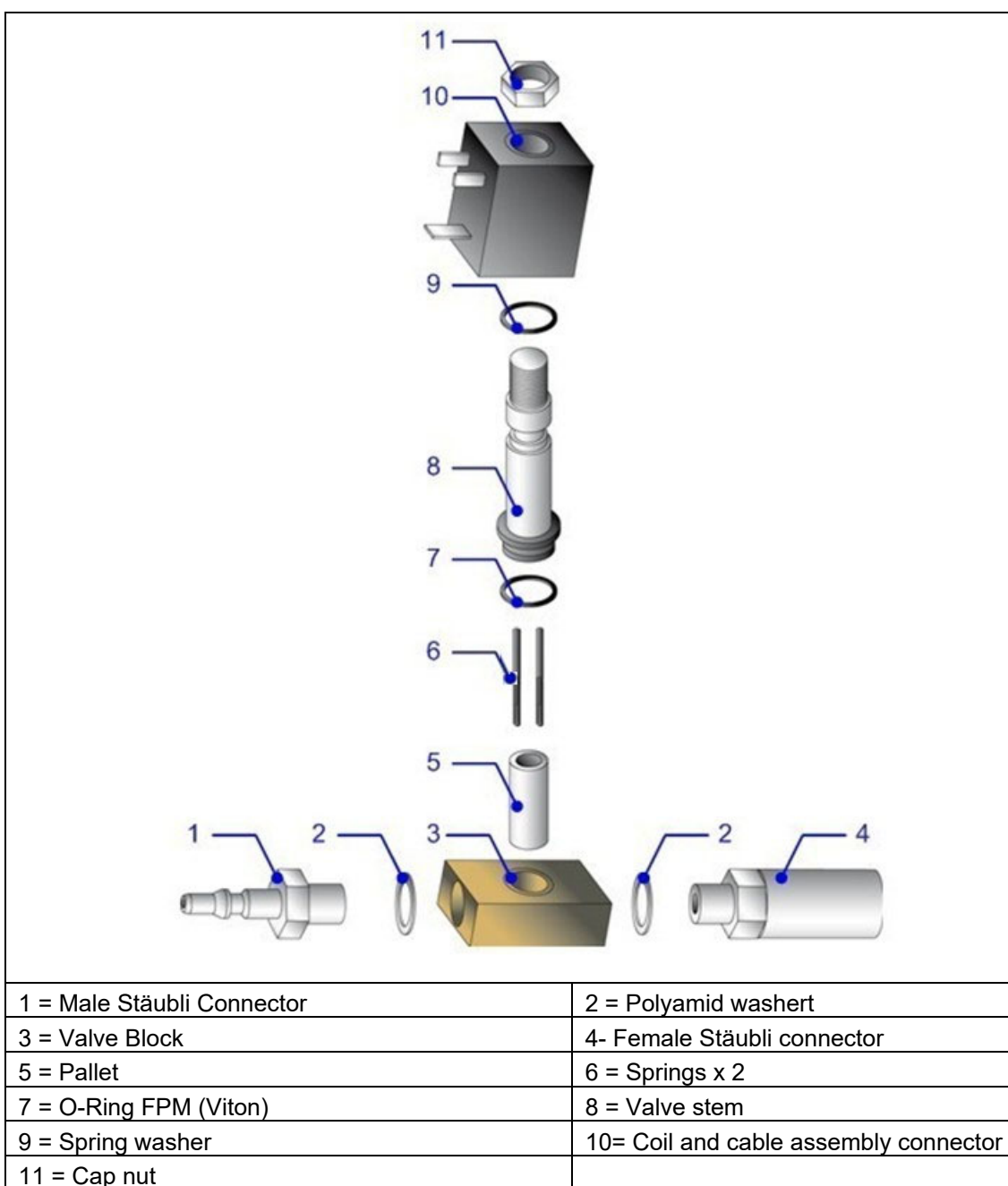


Figure 15: Components of the External vent valve

6. Clean the valve block (3) and all other contaminated parts using a clean lint free cloth slightly wetted with a dilute ammonia solution (5-10% by weight) or glass cleaner.

7. If possible, place the valve block in an ultrasonic bath with **Decon** 90 or other appropriate cleaning agent for five minutes, then rinse with clean tap water.
8. Ensure all parts of the valve are completely dry and then reassemble.
9. If the external vent valve requires further servicing or repair contact your local Pall sales office or distributor.

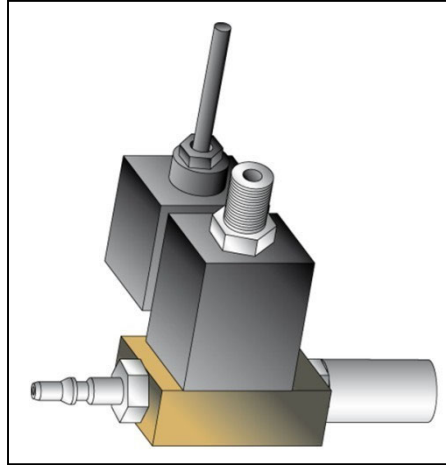


Figure 16: Assembled External Vent Valve

10. Please verify performance of the external vent valve by performing a FlowCheck test – see section 11.2.
11. Once this cleaning has been completed twice on an external vent valve, discard the valve and re-order a complete valve assembly using Pall part number S26.5.12.

11.10 Cleaning the Instrument

The touch screen should be cleaned using a soft cloth. A neutral detergent or alcohol may be used if necessary. The Touch Screen Protector that is included with the instrument is intended to prevent heavy objects from damaging the screen when not in use.

The instrument enclosure can also be cleaned using a soft cloth and a neutral detergent or diluted alcohol solution. Do not use abrasive cleaning agents.

12. Data Transfer

The instrument offers the option to transfer data between multiple instruments and to transfer data from the instrument to a network location. This section covers data transfer operations.



*Level 3 Access is required for this activity. The initial password is 'Pall'.
For details see Section 6.*

12.1 Backup

For backup, the data can be transferred from the instrument to a USB flash drive or to a network location. For a backup to a network a destination folder on the target network location has to be defined and selected.



Note: The network path should contain the target network location, for instance a shared folder in a PC, in which the data will be stored. The network path should be of the form:

///IP address of the network host/name of the shared folder/...

Or

//Domain name of the network host/name of the shared folder/...

If further details are needed data export over a network, please contact your Pall representative

If the network folder requires a user name and password this can be defined and stored for future use as option.

The data will be stored as Portable Document Format (PDF) and XML or XML only.



Important: If pdf is used as file format the backup will last a reasonable time (approximately 4 records/min) It is recommended to backup and delete the results frequently.

The file name is created by the instrument and includes the test type followed by the test date in the format YYYYMMDD.

For test results two additional identifiers ID1 and ID2 can be selected from the test parameter entry:

Program name

Production area

Product name

Product batch No

Filter type (will be replaced by <Test item> for leak and pressure decay test)

At the end there is an indicator if the result is electronically signed

[0] No signature or electronic signature inactive

[1] The test result includes an electronic signature

[2] The test result includes 2 electronic signatures

The complete file name would be:

[Test type code][YYYYMMDD][ID1][ID2][N]

The Self Test and Flow Check tests will be stored as [Test type][YYYYMMDD][N]

- **Test Programs**

Test programs will be printed as PDF files into a folder named Test programs.

The file name includes the test type, the program name and the storage date in the format YYYYMMDD.

- **Configuration**

Configurations will be stored as PDF files in the folder named Configuration.

The file name includes the storage date in the format YYYYMMDD.

- **Access Management**

Access management settings will be stored as PDF files in the folder Access Management.

The file name includes the storage date in the format YYYYMMDD.

- **User**

User details will be stored as PDF files in the folder User.

The file name includes the storage date in the format YYYYMMDD.

- **Other Records**

Other data printed to file will be stored as PDF files in the folder Other records.

The file includes a data identifier and the storage date in the format YYYYMMDD.

The following data identifier is used:

DT = Date Time setting

12.2 Export Test Results

The export of test results consists basically of printing all test records stored on the instrument in a file format.

The data will be stored as Portable Document Format (PDF) and XML or XML only.



Important: If pdf is used as file format the backup will last a reasonable time (approximately 4 results/min) It is recommended to backup and delete the results frequently.

The data can be either 'printed' to a USB flash drive or a network location.

For printing to a network a destination folder on the target network has to be defined and selected.

If the network folder requires a user name and password this can be defined and stored for future use as option.

The graph may be included in the 'printout' as an option.

The file name is created by the instrument and includes the test type followed by the date when the test was performed in the format YYYYMMDD.

Two additional identifiers ID1 and ID2 can be selected from the test parameter entry:

Program name

Production area

Product name

Product batch No

Filter type (will be replaced by <Test item> for leak and pressure decay test)

At the end there is an indicator if the result is electronically signed

[0] No signature or electronic signature inactive

[1] The test result includes an electronic signature

[2] The test result includes 2 electronic signatures

The complete file name would be:

[Test type code][YYYYMMDD][ID1][ID2][N]

The Self Test and Flow Check tests will be stored as [Test type][YYYYMMDD][N]

12.3 Export Configuration

This option allows transferring the actual instrument configuration to a USB flash drive and then to another instrument or via a network location.

This is designed to enable users of multiple instruments to ensure that instruments are configured in the same way.

Select the export destination. This may be either a USB flash drive or a network destination.

Start the transfer.

The data will be stored in a folder. The folder name will be the serial number of the instrument and a subfolder with the type of data and the transfer date.

Only the current version of the configuration will be exported excluding the audit trail.

12.4 Import Configuration

This option enables an instrument configuration to be loaded on an instrument from a USB flash drive or a network location.

Select the location of the data to be imported.

Select the set of data to be imported.

Start the transfer.



When importing data to the instrument all the current existing data of this type will be overwritten!

The new configuration will be active after a restart.

The configuration audit trail will be the initial version generated by the system with the time stamp of the transfer.

12.5 Export Access Management Configuration

This option allows transferring the actual instrument access management configuration to a USB flash drive and then to another instrument or via a network location.

This is designed to enable users of multiple instruments to ensure that instruments are configured in the same way.

Select the export destination. This may be either a USB flash drive or a network destination.

Start the transfer.

The data will be stored in a folder. The folder name will be the serial number of the instrument and a subfolder with the type of data and the transfer date.

Only the current version of the configuration will be exported excluding the audit trail.

12.6 Import Access Management Configuration

This option enables an instrument access management configuration to be loaded on an instrument from a USB flash drive or a network location.

Select the location of the data to be imported.

Select the set of data to be imported.

Start the transfer.



When importing data to the instrument all the current existing data of this type will be overwritten!

The new configuration will be active after a restart.

The configuration audit trail will be the initial version generated by the system with the time stamp of the transfer.

12.7 Export Test Programs

This option enables all of the test programs on the instrument to be transferred to a USB flash drive or a network location and then to another instrument.

This is designed to enable users of multiple instruments to ensure that instruments can operate with the same test programs.

Select the export destination. This may be either a USB flash drive or a network destination.

Start the transfer.

The data will be stored in a folder. The folder name will be the serial number of the instrument and a subfolder with the type of data and the transfer date.

Only the current version of the program will be exported excluding the audit trail.

12.8 Import Test Programs

This option enables a set of test programs to be loaded from a USB flash drive or a network location, and used to replace any existing test programs on the instrument.

Select the location of the data to be imported.

Select the set of data to be imported.

Start the transfer.



If an imported test program has the same name as an existing test program on the instrument, the existing test program will be overwritten. Otherwise the test programs will be added to the list.

The test program audit trail will be the initial versions generated by the system with the time stamp of the transfer.

12.9 Export User Lists

This option enables the complete user list to be transferred to a USB flash drive or a network location and then to another instrument.

This is designed to enable users of multiple instruments to ensure that a group of users have access to several instruments.

Select the export destination. This may be either a USB flash drive or a network destination.

Start the transfer.

The data will be stored in a folder. The folder name will be the serial number of the instrument and a subfolder with the type of data and the transfer date.



All users except the System Administrator (User 1/Level 4) will be transferred with their actual Name/UserID/password and password expiration.

Only the current version of the users will be exported excluding the audit trail.

12.10 Import User Lists

This option allows replacement of the current user list with a user list from another instrument via a USB flash drive or the network location onto the instrument.



This operation can only be carried out by the System Administrator (User 1/Level 4, see section 6) as this user will not be in the transferred user list

Select the location of the data to be transferred.

Select the set of data to be transferred.

Start the transfer



When importing data to the instrument all existing data of this type will be overwritten!

The user audit trail will be the initial version generated by the system with the time stamp of the transfer.

12.11 Export Audit Trail

This options allows to export the event audit trail on an USB flash drive or a network location

13. Deletion of Records

13.1 Delete Stored Data

It is possible to erase records from the instrument.



User Level 3 required for this activity. The initial password is <pall>. For details see Section 6.

For the deletion of records go to <Tools> followed by <Backup> and touch <Delete stored data>.

On this screen, it is possible to delete all test results and all test programs and all user except user1 and to reset the instrument to factory settings.



It is strongly recommended that a backup is carried out before deleting/resetting any records or configurations

13.2 Removal of deactivated records

You can remove deactivated test programs and user by exporting these data. When exporting the data you will be asked if you want to delete deactivated records on the instrument.

13.3 Export Debug Log

This option allows to export the internal status of the instrument on a USB drive which can be analyzed by Pall.

14. Remote Control and Data Logging

In this section the capabilities of remote control and data logging are briefly described.

For further details contact Pall.

14.1 OPC Server

This function is described in detail in the 'Instructions For Use: Remote Control of the Palltronic Flowstar IV Instrument Using OPC Communication', Pall reference USD 2755. Contact your local Pall representative for details.

14.2 Fieldbus

The Instrument includes a Fieldbus connection which allows the core test parameters to be sent to the instrument and a test to be started. It also enables test results to be logged.

The FieldBus option is only activated when the type of Bus is specified when ordered. Otherwise this function must be activated by the Palltronic service team. Contact your local Pall representative for details.

15. Error Messages

The table below enumerates most common error messages and their possible causes. The error messages are displayed on the screen and can be printed out. If errors are encountered that are not described here, please contact Pall.

Self Test		
Error Message	Possible Causes	Action
LINE PRESSURE TOO LOW	Line pressure below 3000 mbar (43.5 psi) Subsequent tests not completed	Increase line pressure
LINE PRESSURE UNSTABLE	Line pressure not stable enough	Check pressure supply
SELF TEST FAILED	Self Test failure	Check Self Test printout for additional information. Repeat Self Test.
INTERNAL ERROR	Internal communication of the instrument disturbed	Restart the Self Test. If not successful contact Pall instrument services
Filter Test (FF/WIT/LT/FC)		
Error Message	Possible Causes	Action
SETUP ERROR	Pressurization could not start	Check if filter is connect and remote vent valve is operating
LINE PRESSURE TOO LOW	Line pressure is too low or there are fluctuations in the compressed air supply	Check/increase line pressure.
LINE PRESSURE UNSTABLE	Line pressure not stable enough	Check pressure supply
PRESSURE NOT OBTAINABLE	<ul style="list-style-type: none"> Major leak in the filter system under test or Filter not wetted completely or Filter has a major defect or Line pressure too low or fluctuating 	Check system for leaks. Re-wet and re-test filter. Replace filter if needed. Check line pressure
FLOW OUTSIDE LIMITS	<ul style="list-style-type: none"> Leak in the filter system or Non-integral filter or Filter not completely wetted 	Check system for leaks. Replace filter if needed. Re-wet (FF-test) and re-test the filter
FLOW TOO HIGH	<ul style="list-style-type: none"> Flow >1000 mL/min (FF test) or >50 mL/min (WIT) or Leak in the filter system or Non-integral filter or filter not completely wetted 	Replace filter if needed. Check system for leaks. Re-wet (FF-Test) and re-test the filter

FLOW TOO LOW	<ul style="list-style-type: none"> Flow <0.1 mL/min (FF test) or <0.03 mL/min (WIT) or Connection between filter and instrument interrupted/closed or Flow value for the filter too low to be measured (small filters only) 	<p>Check test system. Re-wet (FF-Test) and re-test the filter. Replace filter if needed</p>
FLOW UNSTABLE	<p>Fast increase in flow during measurement due to a leak filter de-wetting during the test or</p> <ul style="list-style-type: none"> Fluctuating pressure or Fluctuating temperature 	<p>Check test system. Check for temperature conditions</p>
DOWNSTREAM PRESSURE TOO HIGH	Filter not installed or filter has a major defect	Check/Replace filter
EXT.VALVE ERROR	<ul style="list-style-type: none"> External Valve not connected External Valve not opening 	Check external valve
EXT PT ERROR	<ul style="list-style-type: none"> External pressure transducer not connected External pressure transducer defect 	<p>Check external pressure transducer Check configuration if external pressure transducer is not used</p>

Filter Test (BP)

Error Message	Possible Causes	Action
SETUP ERROR	Pressurization could not start	Check if filter is connect and remote vent valve is operating
LINE PRESSURE TOO LOW	<p>Line pressure too low or fluctuations in the compressed air supply</p> <p>Note: Line pressure must be > 500 mbar (7.25 psi) above the minimum BP</p>	Check/increase line pressure
PRESSURE NOT OBTAINABLE	<ul style="list-style-type: none"> Major leak in the filter system under test or Filter not wetted completely or Filter has a major defect or Line pressure too low or fluctuating 	<p>Check system for leaks. Re-wet and re-test filter. Replace filter if needed. Check line pressure</p>
LEAKTEST FAILURE	<ul style="list-style-type: none"> Major leak in the filter system under test or Filter not wetted completely or Filter has a major defect 	<p>Check system for leaks. Re-wet and re-test filter. Replace filter if needed.</p>

BP NOT OBTAINABLE	<ol style="list-style-type: none"> 1. Final pressure is line pressure – 250 mbar (7.3 psi): Insufficient line pressure: 2. Unusual BP curve does not allow detection of the bubble point 	Check line pressure. Check connection between instrument and filter Re-wet and re-test the filter. Replace filter if needed
MAXIMUM PRESSURE REACHED	Maximum pressure defined in test parameters reached but no BP detected	Check connection between instrument and filter Retest the filter in a system with higher pressure tolerance Replace filter
BP OUTSIDE LIMITS	<ul style="list-style-type: none"> • Non-integral filter or • Filter not completely wetted 	Re-wet and retest the filter. Replace filter if needed
DOWNSTREAM PRESSURE TOO HIGH	Filter not installed or filter has a major defect	Check/Replace filter
EXT.VALVE ERROR	<ul style="list-style-type: none"> • External Valve not connected • External Valve not opening 	Check external valve
EXT PT ERROR	<ul style="list-style-type: none"> • External pressure transducer not connected • External pressure transducer defect 	Check external pressure transducer
SUS Leak Test (BLT)		
Error Message	Possible Cause	Action
PRESSURE TOO HIGH	<ul style="list-style-type: none"> • System not connected • Specified volume not connected 	Check system Check volume entry
SETUP ERROR	<ul style="list-style-type: none"> • Pressurization could not start 	Check if the system is connect
LINE PRESSURE TOO LOW	<ul style="list-style-type: none"> • Line pressure is too low or there are fluctuations in the compressed air supply 	Check/increase line pressure
LINE PRESSURE UNSTABLE	<ul style="list-style-type: none"> • Line pressure not stable enough 	Check pressure supply
PRESSURE NOT OBTAINABLE	<ul style="list-style-type: none"> • Major leak in the system under test or • Line pressure too low or fluctuating 	Check system for leaks Check line pressure
FLOW OUTSIDE LIMITS	<ul style="list-style-type: none"> • Leak in the system 	Check system for leaks
FLOW TOO HIGH	<ul style="list-style-type: none"> • Flow >1000 mL/min 	Check system for leaks and open clamps/connectors

Pressure Decay Test (PD)		
Error Message	Possible Causes	Action
SETUP ERROR	Pressurization could not start	Check if filter is connect and remote vent valve is operating
LINE PRESSURE TOO LOW	Line pressure is too low or there are fluctuations in the compressed air supply	Check/increase line pressure.

PRESSURE NOT OBTAINABLE	<ul style="list-style-type: none"> Major leak in the filter system under test or Filter not wetted completely or Filter has a major defect or Line pressure too low or fluctuating 	Check system for leaks. Check line pressure
PRESSURE DECAY OUTSIDE LIMITS	Leak in the system under test	Check system for leaks
PRESSURE INCREASE DETECTED	Pressure increase during test time	Temperature increase in system under test
EXT: VALVE ERROR	<ul style="list-style-type: none"> External Valve not connected External Valve not opening 	Check external valve

16. Technical Data

Physical Dimensions

Weight: tbd.

Width, height, depth: 320 mm x 202 mm x 480 mm (12.6 in. x 8.0 in. x 18.9 in.)

Filter Tests

Forward Flow Test (FF)

Bubble Point Test (BP)

Combined Forward Flow / Bubble Point Test (FF/BP)

Water Intrusion Test (WIT)

Other Tests

Leak Test (LT)

Single Use System (SUS) Leak Test

Pressure Decay Test (PD)

Functional Tests

Self Test

Flow Check Test

Network Test

Printer Test

Operating System

Linux

(The source code which falls under the GNU General Public License (GPL) is stored on the USB flash drive supplied with the instrument)

Data Capacity

Test Program Storage: > 500 programs

Test Result Storage: > 10,000 tests

Active User Storage: > 250 users

Language Options

US English

English

French

German

Italian

Spanish

Portuguese

Japanese

Chinese

(Ask your Pall representative for other languages).

Communication Ports

USB ports
RS232/Service port (Pall use only)
Ethernet port (RJ45)
Wireless Ethernet (Optional)
Can Bus (Pall use only)
Bus port (ProfiBus, Device Net, on request)
Ethernet and Bus port not available for part number FFS04B

Measuring Range

Forward Flow Test: 0.1 – 1000 mL/min
Water Intrusion Test: 0.03 - 50 mL/min water
Bubble Point Test: 400 - 6500 mbar (0.725 – 94.2 psi)

Accuracy

Forward Flow Test: $\pm 3\%$ of measurement or ± 0.05 mL/min, whichever is greater
Water Intrusion test: $\pm 3\%$ of measurement or ± 0.02 mL/min, whichever is greater
See *Validation Guide USTR 2710* for details

Resolution

Forward Flow Test 0.1 mL/min (0.01 mL/min for a flow < 10 mL/min)
Water Intrusion Test 0.01 mL/min
Bubble Point Test 50 mbar (0.7 psi)

Calibration Limits

Flow Measurement: $\pm 3\%$ of measurement
Pressure Measurement: $\pm 0.33\%$ of full scale

Electrical Data

Voltage: automatically adjusted between 100 - 240 V AC
Input Frequency: 50 Hz / 60 Hz
Power: typically 75 W, peak 150 W
Fuse: 3.15 A, slow blow.
External Vent Valve: 24 V DC
External pressure transducer: relative (relative to gauge) pressure measurement, 4 – 20 mA signal

Touch Screen

Size: diagonal 26.4 cm (10.4 in.), 1024 x 768 pixels
Features: Color, illuminated background, adjustable contrast

Pneumatic Specifications

Maximum Gas Supply Pressure: 8000 mbar (116 psi)
Minimum Gas Supply
 Self Test: 3000 mbar (43.5 psi)
 Flow Range 0.01 - 149 mL/min 1000 mbar (14.5 psi) above test pressure
 Flow Range 150 - 1000 mL/min 2000 mbar (29.0 psi) above test pressure
Test Pressure Range: 50 to 6500 mbar (0.7 to 94.2 psi)

Pneumatic Connections

Compressed Air Inlet: Stäubli Nipple RBE03.6150
Compressed Air Outlet: Stäubli Coupling RBE03.2904
Vent: Hose Connection 8 mm Outer Diameter

Internal Printer

Thermal printer

Lifetime of the printout > 10 years depending on storage conditions

Paper Width: 112 mm (4.4 in.)

Paper Roll Diameter: 50 mm (1.9 in.)

Environmental Conditions

Splash Proof: IP54

To meet the full requirements of IP 54 splash proof electrical connections to the instrument are necessary.

These are available as accessories; please contact your local Pall representatives for details.

Operating Temperature: +5 °C to +50 °C (+41 °F to +122 °F)

Storage Temperature: -20 °C to +70 °C (-4 °F to +158 °F)

Humidity: 95% rh (no condensation)

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