Flowstar V and Flowstar V LGR filter integrity test instruments

Operating Instructions

Original instructions

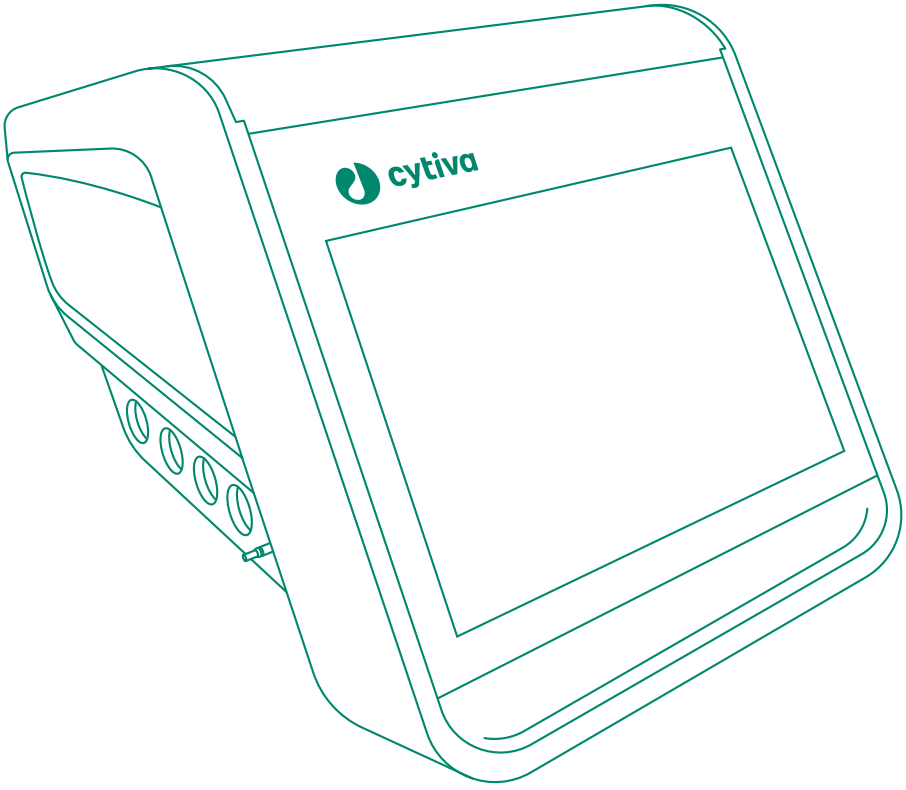

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Table of Contents

1 Introduction

About this chapter

This chapter contains information about this manual and associated user documentation, important user information, and intended use of the product.

In this chapter

1.1 Important user information

Introduction

This section contains important user information about the product and this manual.

Read this before operating the product

All users must read the entire *Operating Instructions* before installation, operation, or maintenance.

Always keep the *Operating Instructions* at hand when operating the product.

Do not install, operate, or perform maintenance in any other way than described in the user documentation. Improper use can result in exposure to hazards that can lead to personal injury and can cause damage to the equipment.

Intended use of the product

The Flowstar V instrument is a filter integrity test instrument designed for testing the filter integrity of hydrophobic sterilizing-grade filters and hydrophilic membrane filters.

The Flowstar V LGR instrument is designed for testing the integrity of flexible single-use systems (SUS), such as 2D- and 3D-bags or biocontainers, flowkits, manifolds. The Flowstar V LGR instrument can also perform the filter integrity tests described above for the Flowstar V instrument.

The Flowstar V instrument and the Flowstar V LGR instrument must not be used in a potentially explosive atmosphere.

Prerequisites

In order to operate the Flowstar V instrument and the Flowstar V LGR instrument in the way it is intended:

- The user must be acquainted with the use of bioprocessing equipment and with the handling of biological materials.
- The user must read and understand the Safety Instructions chapter in this manual.
- The user must be trained to use the instrument in accordance with the instructions in this manual.

- The instrument must be installed in accordance with the site requirements and instructions in this manual.

1.2 About this manual

Introduction

This section contains information about the purpose and scope of this manual, notes and tips, and typographical conventions.

Purpose of this manual

This manual provides information needed to install, operate, and perform maintenance in a safe way.

Scope of this manual

This manual is valid for the Flowstar V instrument and the Flowstar V LGR instrument. This manual covers the hardware and the software operations of the instrument. The software operations are performed on the touch screen of the instrument, as shown in the illustration below.

System definition

In this manual, the Flowstar V instrument and the Flowstar V LGR instrument are referred to as "the Flowstar V instrument" or as "the instrument". When there is a difference in installation, operation, or functionality, the full product name is used.

In this manual, the tested component (e.g., filter, vessel, biocontainer) together with the connected flow kit or piping are referred to as "the tested assembly".

Notes and tips

Note: *A note is used to indicate information that is important for trouble-free and optimal use of the product.*

Tip: *A tip contains useful information that can improve or optimize your procedures.*

Typographical conventions

The text on a graphical user interface is identified in this manual by ***bold italic*** text.

The text on the label of a hardware item is identified in this manual by **bold** text.

Text that the user must either type exactly as shown in the manual, or that the software displays as a response (not a regular part of the graphic user interface), is shown by a monospaced typeface (for example, `Recipe Information`).

Tip: *The text can include clickable hyperlinks to reference information.*

1.3 Associated documentation

Introduction

This section describes the user documentation that is delivered with the product, and how to find related literature that can be downloaded or ordered from Cytiva.

User documentation

The user documentation for the instrument is listed in the table below. Translations of the *Operating Instructions* can be downloaded from *cytiva.com*.

Documentation	Main contents
Flowstar V and Flowstar V LGR integrity test instruments Operating Instructions (USD3519) (this document)	Instructions needed to prepare and operate the Flowstar V instrument in a correct and safe way. Instrument overview, site requirements, and instructions for moving the instrument within the same building. Instructions for basic maintenance and troubleshooting.
Flowstar V and Flowstar V LGR integrity test instruments Privacy and Security Manual (29939219)	Describes the privacy and security considerations of the use of the instrument. The manual describes the expected intended use of the instrument, the privacy and security capabilities included, and how these capabilities are configured.

Additional user documentation

Additional documentation is listed in the table below. Translations of the *Palltronic Flowstar V MUX Instructions for Use* can be downloaded from *cytiva.com*.

Documentation	Main contents
Flowstar V Printer Instructions for Use (29750853)	Instructions needed to prepare and operate the Flowstar V printer in a correct and safe way.

Documentation	Main contents
Palltronic Flowstar V MUX Instructions for Use (USD3953)	Instructions needed to prepare and operate the Flowstar V MUX extension with the Flowstar V instrument in a correct and safe way. Instructions for basic maintenance and troubleshooting.
Palltronic Flow Check II Unit Instructions for Use (USD2642)	Instructions needed to prepare and operate the Flow Check II unit with the Flowstar V instrument in a correct and safe way. Instructions for basic maintenance and troubleshooting.
AquaWIT V filter integrity test system Operating Instructions (29748887)	Instructions needed to prepare and operate the Flowstar V system in a correct and safe way. System overview, site requirements, and instructions for moving the system within the same building. Instructions for basic maintenance and troubleshooting.
Palltronic Flowstar V Instrument Data Management System (DMS) Pro User Manual (USD3925)	Instructions needed to set up data synchronization, date and time synchronization, and domain authentication with the Data Management System (DMS) Pro software.
mPath Operational Insights Software User Manual (USD3867)	Instructions needed to set up a centralized data analysis and access management with the mPath™ Operational Insights software.
Domain authentication using Lightweight Directory Access Protocol (LDAP) Instructions for Use (USD3922)	Instructions needed to set up domain authentication with LDAP.
Remote control of filter integrity test instruments using the OPC UA server Instructions for Use (USD3923)	Instructions needed to set up remote control and data logging with Open Platform Communications Unified Architecture (OPC UA).
PAS-X for Flowstar V User Manual (29741432)	Instructions needed to set up remote control and data logging with the PAS-X manufacturing execution system.
Remote control of Flowstar V integrity test instrument using the PROFIBUS protocol Instructions for Use (USD3924)	Instructions needed to set up remote control and data logging with the PROFIBUS protocol.

Documentation	Main contents
Remote control of Flowstar V integrity test instrument using the PROFINET protocol Instructions for Use (USD3934)	Instructions needed to set up remote control and data logging with the PROFINET protocol.
Remote control of Flowstar V integrity test instrument using the serial automation protocol Instructions for Use (29875356)	Instructions needed to set up remote control and data logging with the serial automation protocol.

Access user documentation online

Scan the QR code or visit *cytiva.com/instructions*. Enter the title or the document number to access the file.

Regulatory support

To subscribe to regulatory support documentation, visit *http://www.cytiva.com/rsf* to register at the Cytiva regulatory support portal.

The regulatory support portal provides access to, for example, the following documents:

- Change control notifications
- Regulatory support files
- Validation guides
- Validation support files
- Extractables information

Other literature on the web

User documentation and other literature related to the system can be downloaded from the web. Follow the steps below to access the documentation.

Step	Action
1	Go to *cytiva.com* and search for Flowstar V.

Step	Action
2	Navigate to ***Documents***.
3	Select the type of document and download the chosen literature.

1.4 Abbreviations

Introduction

This section explains abbreviations that appear in the user documentation for the instrument.

Abbreviations

Abbreviation	Definition (English)	Translation (local language)
BP	bubble point	bubble point
CAN	controller area network	controller area network
DHCP	dynamic host configuration protocol	dynamic host configuration protocol
FF	forward flow	forward flow
HMI	human machine interface	human machine interface
ID	inner diameter	inner diameter
LAN	local area network	local area network
LT	leak test	leak test
OD	outer diameter	outer diameter
OPC UA	open platform communications unified architecture	open platform communications unified architecture
PD	pressure decay	pressure decay
PPE	personal protective equipment	personal protective equipment
SCADA	supervisory control and data acquisition	supervisory control and data acquisition
SSID	service set identifier	service set identifier
SUS	single-use equipment	single-use equipment
SUS LT	single-use equipment leak test	single-use equipment leak test
USB	universal serial bus	universal serial bus
VNC	virtual network computing	virtual network computing
WFI	water for injection	water for injection
WIT	water intrusion test	water intrusion test

2 Safety instructions

About this chapter

This chapter describes safety precautions, labels, and symbols. In addition, the chapter describes emergency and recovery procedures.

In this chapter

Important

WARNING

All users must read and understand the entire contents of this general safety chapter, and the specific safety precautions information in each subsequent chapter of this manual to become aware of the hazards involved.

2.1 Safety precautions

Introduction

This section describes the general hazards you must be aware of before performing installation, operation, or maintenance.

Definitions

This user documentation contains safety notices (WARNING, CAUTION, and NOTICE) concerning the safe use of the product. It also contains important notices for critical software or application information. See the definitions below.

WARNING

WARNING indicates a hazardous situation which, if not avoided, could result in death or serious injury. It is important not to proceed until all stated conditions are met and clearly understood.

CAUTION

CAUTION indicates a hazardous situation which, if not avoided, could result in minor or moderate injury. It is important not to proceed until all stated conditions are met and clearly understood.

NOTICE

NOTICE indicates instructions that must be followed to avoid damage to the product or other equipment.

IMPORTANT

IMPORTANT indicates instructions that are essential for the software or application to function.

General precautions

The following general precautions must be considered at all times. There are also context related precautions, which are written in their respective chapters.

WARNING

Risk assessment. Perform a risk assessment for the process or process environment. Evaluate the effects the use of the product and the operational processes can have on the classification of the hazardous area. The process can cause the hazardous area to increase or the zone classification to change. Implement the risk reduction measures needed, including use of personal protective equipment.

WARNING

Do not operate the product in any other way than as described in the user documentation.

WARNING

All installation, maintenance, operation, and inspection must be carried out according to local regulations by adequately trained personnel.

WARNING

Accessories. Use only accessories supplied or recommended by Cytiva.

WARNING

Do not use the product if it is not working correctly, or if it has suffered any damage, including:

- damage to the power cord or its plug,
- damage caused by dropping the product,
- damage caused by splashing liquid onto the product.
- damage caused by liquid flowing into the instrument after a test is completed.

WARNING

Access to power switch and power cord. The power switch must always be easy to access. The power cord must always be easy to disconnect.

WARNING

Pressurized flow path. During a power failure or a manual abort of a procedure, the flow path can remain pressurized. Make sure all lines and vessels are depressurized before opening a line or vessel.

WARNING

To extinguish fire on or around the system, use CO_2 fire extinguishers or class ABC powder-type extinguishers.

Personal protection

WARNING

Personal Protective Equipment (PPE). When packing, unpacking, transporting or moving the product, wear the following:

- Protective footwear, preferably with steel toe caps.
- Working gloves, protecting against sharp edges.

WARNING

Always use appropriate Personal Protective Equipment (PPE) during operation and maintenance of this product.

Flammable liquids and explosive environment

WARNING

Explosion hazard. The product is not approved for use in a potentially explosive atmosphere.

2.2 Labels and symbols

Introduction

This section describes the nameplate, labels, and other safety and regulatory labels and symbols.

Nameplate

The nameplate provides information about the model, manufacturer, and technical data.

Description of symbols and text

The following symbols and text can be present on the nameplate:

Symbol / text	Description
	Follow instructions for use in the *Operating Instructions*.
	**Warning!** Read the user documentation before using the instrument. Do not open any covers or replace parts unless specifically stated in the user documentation.
Part number	The product code number
Serial number	The unique identifying number for the individual product
Maximum operating pressure	The maximum pressure for operation
Power supply	Electrical rating: • Voltage (VAC ⁓) • Frequency (Hz) • Power (W)
Weight	Weight of the instrument
Year of manufacture	Year (YYYY) of manufacture

Labels concerning electrical components

The following symbols concern hazardous substances in electrical components:

Symbol	Description
	This symbol indicates that waste electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Contact an authorized representative of the manufacturer for information concerning the decommissioning of equipment.

2.3 Emergency procedures

Introduction

This section describes the shut down procedures in an unforeseen situation, and the actions required for restart.

The section also describes the result in the event of power failure.

Precautions

WARNING

Access to power switch and power cord. The power switch must always be easy to access. The power cord must always be easy to disconnect.

WARNING

Pressurized flow path. During a power failure or a manual abort of a procedure, the flow path can remain pressurized. Make sure all lines and vessels are depressurized before opening a line or vessel.

WARNING

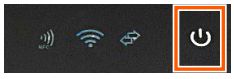
To extinguish fire on or around the system, use CO_2 fire extinguishers or class ABC powder-type extinguishers.

WARNING

Shock hazard. Do not use water to extinguish fire on or around the system. It can cause a fatal electrical shock.

Emergency shutdown

This section describes how to stop the run or switch off the instrument in case of an external unforeseen situation that is not caused by the instrument.

Intended action	Procedure	Result
Stop the run	Tap the  button on the touch screen.	• The run is aborted. • The instrument and the flow path are vented. • The air supply is not shut down.
Switch off the instrument	1. If possible, tap the power button on the right side of the touch screen.  2. If not possible: • Press the **O** position on the power switch on the instrument. Or • Disconnect the power cord from the wall socket. ***Note:*** *The data from the ongoing run is lost and the test result file shows that the test was aborted.*	• The touch screen is switched off. • The instrument is directly depressurized. • The air supply is not shut down.

Power switch

The power switch is located on the back of the instrument.

Power failure

The following table describes the consequences of a power failure.

Power failure to	Outcome
Flowstar V instrument	• The run is interrupted immediately. • The instrument reboots when the power is regained, and the main menu is displayed. • The data from the ongoing run is lost and the test result file shows that the test was aborted.
Air supply	• The run is aborted and the error message ***LINE PRESSURE OUTSIDE RANGE*** is displayed. • The instrument is directly depressurized.

Restart after emergency shutdown or power failure

Follow the instructions below to restart the instrument after an emergency shutdown or power failure.

Step	Action
1	Correct the condition that caused the emergency shutdown or power failure.
2	If power to the instrument has been lost, restart the instrument.

3 System description

About this chapter

This chapter gives an overview of the Flowstar V instrument, and a brief description of its function.

In this chapter

3.1 Instrument overview

Introduction

The Flowstar V instrument is a filter integrity test instrument designed for testing the filter integrity of hydrophobic sterilizing-grade filters and hydrophilic membrane filters.

The Flowstar V LGR instrument is designed for testing the integrity of flexible single-use equipment (SUS), such as 2D- and 3D-bags or biocontainers, flowkits, manifolds. The Flowstar V LGR instrument can also perform the filter integrity tests described above for the Flowstar V instrument.

The instrument is connected to the tested assembly. The tested assembly is the tested component (e.g., filter, vessel, biocontainer) together with the connected flow kit or piping. The instrument performs a self-test before starting a test. During a test, the instrument measures the flow and the pressure in real time. The instrument performs a direct flow measurement on the tested assembly.

Instrument components

The instrument consists of the following external components:

- touch screen
- inlet and outlet ports
- communication ports

See *Section 3.3 Illustrations, on page 30* for illustrations of the instrument.

See *Section 3.4 Accessories and related products, on page 36* for a brief description of the available accessories.

See *Chapter 4 Software description, on page 39* for more information about the software.

Test overview

The following tests can be run with the instrument:

- Water intrusion test (WIT)
- Forward flow test (FF)
- Bubble point test (BP)
- Combined forward flow and bubble point test (FF + BP)
- Leak test (LT)
- SUS leak test (SUS LT) (only for the Flowstar V LGR instrument)
- Pressure decay test (PD)
- Flow check test
- Self test (ST)

For more information, see *Section 3.2 Functional overview, on page 27*.

Other features

Other features of the instrument are:

- Printing using an external printer, a network printer, or a USB drive.
- Storing test results.
- Importing and exporting data using a USB drive or a network.

3.2 Functional overview

Introduction

This section gives an overview of the tests that can be run on the instrument.

Forward flow test

The forward flow (FF) test is designed to test the integrity of hydrophilic and hydrophobic membrane filters.

Before the FF test, the filter must be wetted with water or a solvent-water mixture. The FF test is based on measuring the flow rate of gas across a completely wetted membrane at a defined test pressure that is applied to the upstream side of the filter. The downstream side of the membrane is open to atmospheric pressure and the upstream side of the membrane is subjected to the test pressure. Therefore, the test gas diffuses across the membrane because of the pressure differential across the membrane. Larger pores and defects in the membrane result in flow rate that are much higher than the diffusional flow. The measured flow rate is compared to the threshold for the membrane type and filter area. If the filter exceeds the flow rate threshold, the filter is considered defective.

Note: *To test a hydrophobic filter with a FF test, it is necessary to first wet the membrane with a solvent water mixture, such as a 60% to 70% (v/v) isopropyl alcohol-water mixture.*

Bubble point test

The bubble point (BP) test is designed to detect the largest pores of hydrophilic and hydrophobic membrane filters.

Before the BP test, the filter must be wetted with water or a solvent-water mixture. The BP test is based on applying an incrementally increasing pressure to the upstream side of a wetted membrane, with the downstream side open to atmosphere. The pressure is increased until the wetting fluid is expelled from the largest pores or until a defect is detected. This pressure level results in a visible flow of bubbles from the outlet of the filter. The pressure at which bubbles are detected is compared to the minimum allowable bubble point for the tested filter. If the filter does not reach the minimum allowable bubble point, the filter is considered defect.

Note:

- *The BP test has a limitation in detecting single defects. It is recommended to combine the BP test with a FF test to determine the integrity of a filter membrane.*
- *In order to test a hydrophobic filter with a BP test, it is necessary to first wet the membrane with a solvent water mixture.*

FF + BP test

The combined FF + BP test performs a standard FF test followed by a BP test without the initial leak test (LT). The test is based on measurement of air flow through a wetted membrane and subsequently determining the bubble point.

Before the test, the filter must be wetted with water or a solvent-water mixture.

Water intrusion test

The water intrusion test (WIT) is designed to test the integrity of hydrophobic air and gas sterilization filters.

Before the WIT test, the filter housing from the upstream side must be filled with water or a solvent-water mixture. During the test, the flow rate of water across the membrane is measured. The WIT test is based on measuring the evaporative flow of water through the hydrophobic membrane which is completely submerged in water. A defined test pressure is then applied to the upstream side of the filter, with the downstream side open to atmospheric pressure. Intact hydrophobic filters have a very low evaporative flow whereas defect filters allow a higher flow rates. The measured flow rate is compared to the pass/fail threshold for the membrane type and the filter area. If the filter exceeds the maximum allowable flow, the filter is considered defective.

Leak test

The leak test (LT) is designed to test vessels or flow kits for leaks. The vessels and flow kits must be able to withstand a high pressure (50 to 6500 mbar). For flexible single use systems and flow kits, instead use the single-use equipment leak test (SUS LT).

The leak test is based on maintaining the defined pressure within the tested assembly. The instrument fills the tested assembly with the volume of gas that maintains the defined pressure. Any leaks within the tested assembly allow gas to flow out of the system, which results in a reduced pressure. The instrument refills the tested assembly with gas to maintain the test pressure. The instrument measures the amount of gas that dissipated through the leak.

Pressure decay test

The pressure decay (PD) test is designed to test rigid vessels for leaks. The vessels are recommended to have a volume above 50 L. This test is not recommended for use as a filter integrity test.

The instrument pressurizes the tested assembly to the test pressure. After the stabilization phase, the instrument records the test pressure, the test time, and the measured PD. If the PD curve greater than the defined maximum for the test assembly, it is considered to be defective.

SUS leak test

The SUS leak test (SUS LT) is designed to test flexible single-use equipment (SUS), such as 2D- and 3D-bags or biocontainers, flowkits, manifolds, or a combination of these. The volume of the tested assembly must be between 50 mL and 200 L. For rigid vessels and flowkits that withstand higher pressures, instead use the leak test. The SUS leak test can only be run with the Flowstar V LGR instrument.

The instrument pressurizes the tested assembly to a low pressure (20 to 50 mbar). If there are leaks within the tested assembly, gas flows out of it and thereby reduces the test pressure within the tested assembly. The instrument re-pressurizes the tested assembly to the defined test pressure and measures the gas volume needed to re fill the tested assembly. A tested assembly that shows a leak rate above the defined threshold is considered to be defective.

Flow check test

The flow check test is designed to test the flow measurement function of the instrument. The Flow Check II unit is required to perform a flow check test.

Before the flow check test, the Flow Check II unit must be connected to the instrument. The instrument pressurizes the Flow Check II unit to the test pressure. After the stabilization phase, the instrument measures the flow. If the test conditions are stable and the deviation in flow measurement is less than 5%, the instrument is considered to measure the flow correctly.

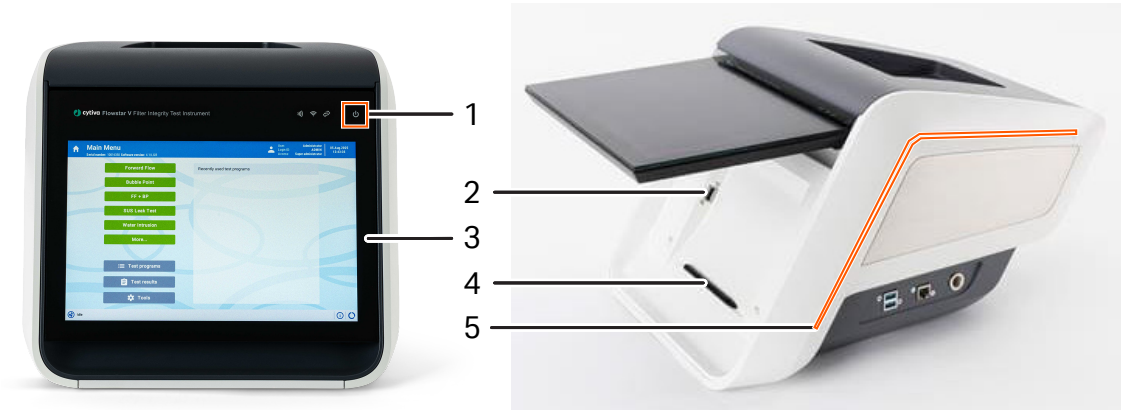
3.3 Illustrations

Introduction

This section provides illustrations of the instrument. The main features and components are indicated.

Front side

The illustration below shows the front side of the instrument.



Part	Description
1	Software power button
2	USB port
3	Touch screen
4	Touch screen pen
5	Indicator light

Indicator light

The indicator light on the side of the instrument shows the status of a run.

LED color	Description
Blue	• Indicates that a test is running. • Indicates that the instrument is idle.
Green[1]	Indicates that the last test ended with the ***Pass*** test result.
Red[1]	Indicates that the last test ended with an error or the ***Fail*** test result. Determine the root cause. See *Chapter 9 Troubleshooting, on page 286* for descriptions of error messages. The test can be restarted in the software, after the condition is corrected. ***Tip:*** *The header in the software becomes red if the last test ended with an error or the **Fail** test result.*

[1] The indicator turns off after the test results are viewed in the software.

Carrying handle

The illustration below shows the carrying handle of the instrument.

Right side

The illustration below shows where the connectors are located on the right side of the instrument.

Part	Description
1	Two USB ports[1]
2	Ethernet port (RJ45)
3	Port for connecting to the Flowstar V Printer[2]

[1] The USB ports can be used for remote control of the instrument by connecting the instrument with a PROFIBUS adapter or a PROFINET adapter.
[2] For instructions, refer to the Flowstar V Printer Instructions for Use (29750853).

Left side

The illustration below shows where the connectors are located on the left side of the instrument.

Part	Label	Description
1	**CAN**	CAN bus port[1]
2	**IN**	Air inlet port
3	**EXT VALVE**	Power outlet for the external vent valve[2]
4	**OUT**	Air outlet port
5	**BAG RETURN**	Bag return port[3]

[1] The controller area network (CAN) bus port is used by Cytiva service and to connect extensions.
[2] The external vent valve prevents test liquid from flowing in to the instrument after a test is completed.
[3] The bag return port is only used for the SUS LT test.

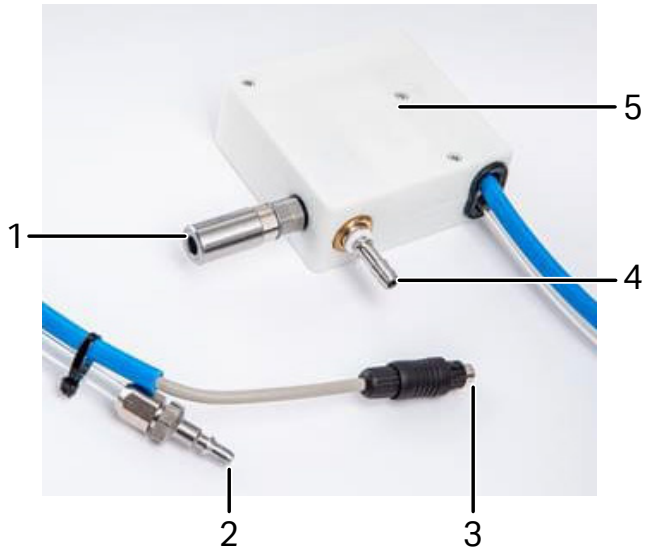
Back

The illustration below shows the back side of the instrument.

Part	Description
1	Power switch
2	Vent port
3	Power cord

External vent valve

The illustration below shows the external vent valve.



Part	Description
1	Stäubli connector for connection to the filter housing
2	Stäubli connector for connection to the Flowstar V instrument
3	24 VDC power cable
4	External vent port
5	External vent valve

3.4 Accessories and related products

Introduction

This section gives a brief description of the accessories that can be used with the Flowstar V instrument. This section also gives a brief description of the related product, the AquaWIT V system. Refer to the respective user documentation for more information, see *Additional user documentation, on page 10*.

Note: *Previous generation accessories can be connected to the Flowstar V instrument, but a software modification might be necessary. Contact your local Cytiva representative for support.*

Tip: *A test program can store the test parameters of an accessory. Connect the accessory and enable it in the software before creating the test program. For example, to include parameters for the Flowstar V MUX accessory, connect it to the instrument and enable the accessory in* ***Tools →General settings →Active extension****.*

AquaWIT V and extensions

The AquaWIT V system is a filter integrity test system designed for testing the filter integrity of hydrophobic sterilizing-grade filters and hydrophilic membrane filters. The system also prepares the filter before and after the filter integrity test. The Flowstar V instrument is integrated into the AquaWIT V system.

Barcode reader

The barcode reader (FFS-BARCODE) can be used to scan and decode a barcode into text. It allows the user to:

- Recall a test program.
- Enter data for a filter integrity test (e.g., the serial number of a filter).

External vent valve

The Flowstar V external vent valve (FFS-BHVALVE) prevents test liquid from flowing in to the instrument after a test is completed. The external vent valve is delivered with the instrument.

Flow check unit

The Flow Check II unit (FC02) allows the user to perform a flow check test on the Flowstar V instrument. The Flow Check II unit contains a capillary with a certified flow. The flow check test indicates if there is a deviation from the calibrated flow measurement on the instrument.

Flowstar V MUX

The four channel Flowstar V MUX extension (FFS05MUX) allows the user to prepare and test up to four filters in series.

Up to four Flowstar V MUX extensions can be connected to a Flowstar V instrument, to test up to 16 filters in series.

Flowstar V Printer

The Flowstar V Printer (FFS-PRNT) is a thermal printer that allows the user to print data and graphs from filter integrity tests performed on the Flowstar V instrument.

Remote control adapters

The Flowstar V instrument can be remotely controlled using three different adapters and automation protocols:

Automation protocol	Automation adapter
PROFIBUS protocol	FFS-AUTADAPTBUS adapter
PROFINET protocol	FFS-AUTADAPTPNET adapter
Serial automation protocol	FFS-AUTADAPTSBUS adapter

Through a remote connection, the ***Automation operator*** user can initiate the standard test functions of the instrument and specify the applicable parameters. It also receives the measured test result together with a pass or fail indication at the end of the test.

4 Software description

About this chapter

This chapter provides an overview of the software that is used on the Flowstar V instrument. It also gives a brief description of the settings, file names, user account management, and audit trails.

In this chapter

4.1 Control software

About this section

This section describes the most important menus and buttons that are used in the software. It also gives a brief overview of test programs and warnings.

In this section

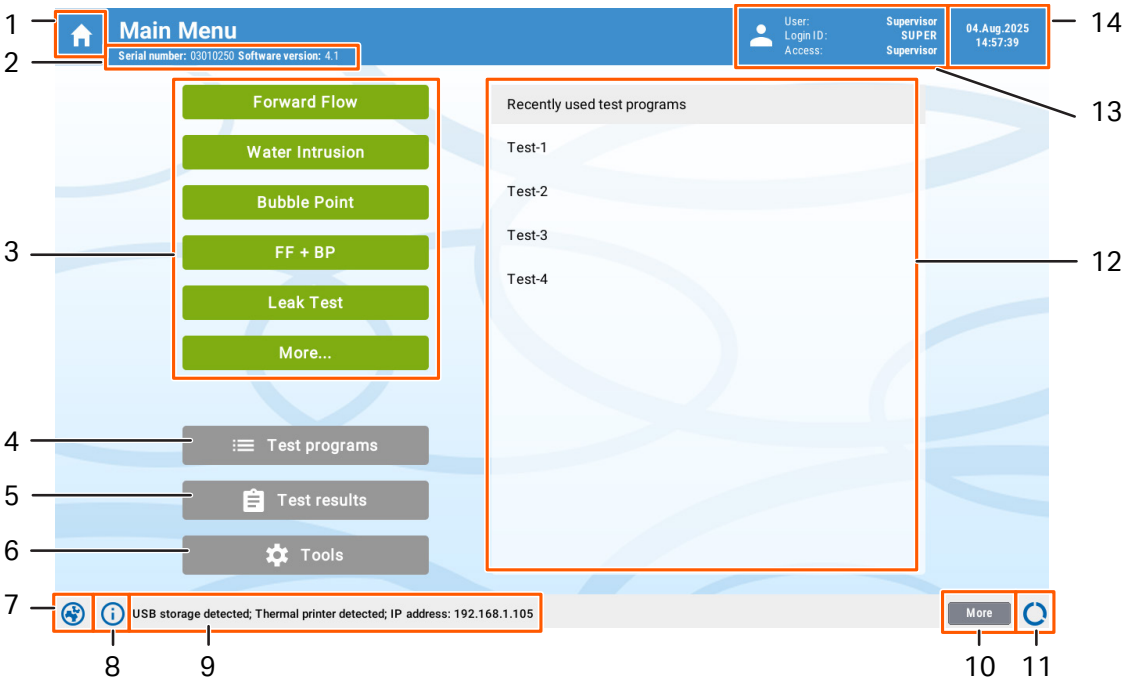
4.1.1 Main menu

The instrument is controlled by the software. The software is part of the configuration provided with the instrument. Use the touch screen pen to interact with the software.

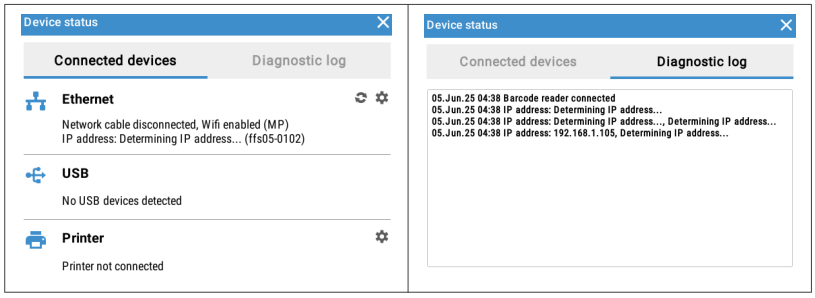
NOTICE

Do not operate the touch screen with sharp objects. Sharp objects can damage the touch screen.

The illustration below shows the ***Main Menu*** screen on the human machine interface (HMI).



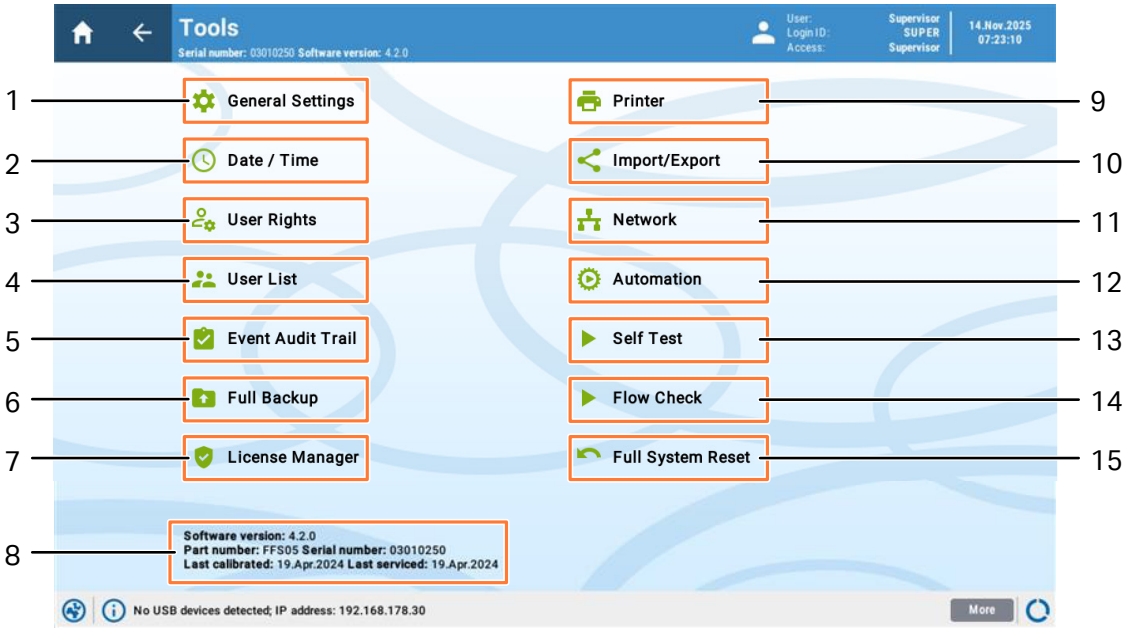
Part	Description
1	***Home*** button. Return to the main menu.
2	Instrument serial number and software version.
3	Buttons for the available tests. ***Tip:*** *The available tests that are displayed on the **Main Menu** can be configured in **Tools →General Settings →Main Menu Settings**.*
4	***Test programs*** button. Opens a display with the available test programs. Allows the user to edit test programs and create new test programs.
5	***Test results*** button. Opens a display with the test results.
6	***Tools*** button. Opens a display with the tools menu.

Part	Description
7	***Current test status*** button. Opens a display with status information about the current test.
8	***General information*** button. Opens a display with general information about connected USB drives.
9	Status bar displaying recent events regarding the connected accessories, the IP address of the connected network, and the error messages for the current run.
10	***More*** button. Opens the ***Device status*** window, which contains the ***Connected devices*** status tab and the ***Diagnostic log*** tab (see illustrations below). 
11	***Memory overview*** button. Opens a display with information about how many test results and test programs are stored on the instrument out of the respective number of available test results and test programs.
12	***Recently used test programs***. Displays a list of the recently used test programs.
13	If the instrument is set to high level access control (HLAC), the ***Main Menu*** displays user information, such as user name, login ID, and access level. Opens a display where the user can log in or log out.
14	The current date and time.

Tip: *The header in the software becomes red if the last test ended with an error or the **Fail** test result.*

4.1.2 Tools menu

The illustration below shows the ***Tools*** screen on the HMI.

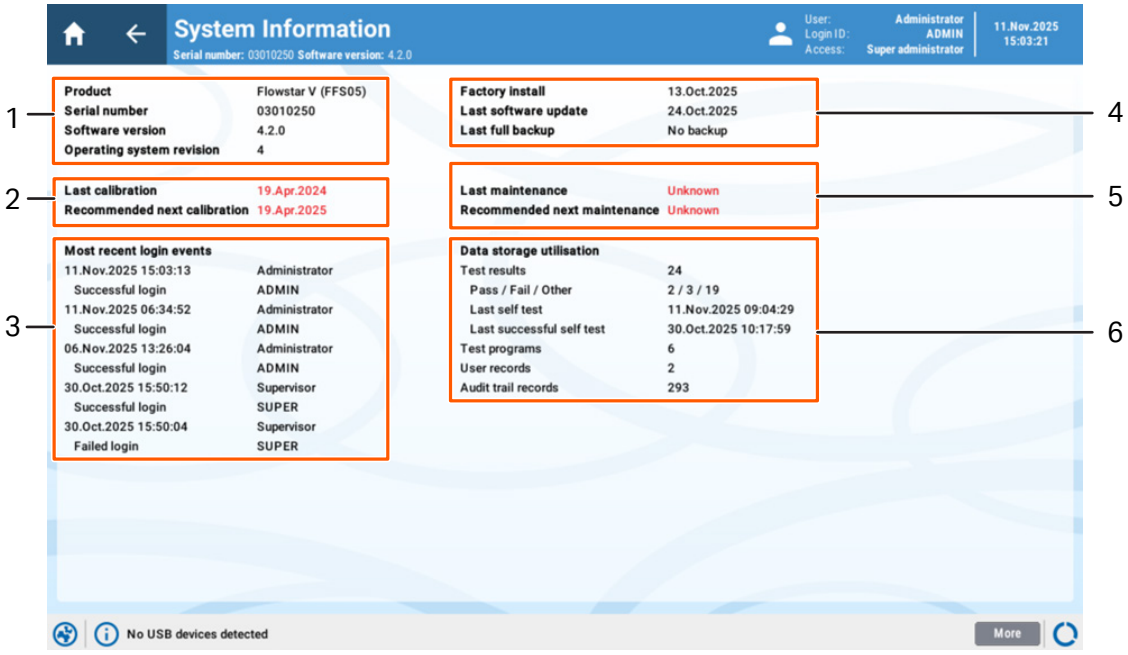


Part	Description
1	***General Settings*** button. Opens a display with the general software settings.
2	***Date/Time*** button. Opens a display with the software settings for date, time, and clock synchronization.
3	***User Rights*** button. Opens a display with the user rights software settings.
4	***User List*** button. Opens a display with the current user accounts. The user can edit user accounts and create new user accounts.
5	***Event Audit Trail*** button. Opens a display with the full event audit trail.
6	***Full Backup*** button. The instrument creates a full system backup in the location selected in the ***Import/Export*** software settings.
7	***License Manager*** button. Opens a display with the current software licenses. The user can add new software licenses.
8	***System information*** button. This area shows basic information about the instrument. The button opens a display with the detailed information about the instrument.
9	***Printer*** button. Opens a display with the software settings for printing.
10	***Import/Export*** button. Opens a display with the software settings for data import, data export, and the location for data transfer (e.g., a USB drive or a network location).

Part	Description
11	***Network*** button. Opens a display with the software settings for connecting to a network. The display includes the VNC viewer, if VNC is activated.
12	***Automation*** button. Opens a display with the software settings for automation.
13	***Self Test*** button. The instrument starts a self test.
14	***Flow Check*** button. The user can start a flow check test.
15	***Full System Reset*** button. Restores the software settings to the factory default settings. All data that is stored on the instrument is deleted. The ***Full System Reset*** button is only displayed when the ***Super-admin*** user is logged in.

4.1.3 System information screen

The illustration below shows the ***System information*** screen on the human machine interface (HMI).



Part	Description
1	Shows information about the instrument type (e.g. Flowstar V or Flowstar V LGR), the instrument serial number, the software version, and the operating system revision.
2	Shows information about the last calibration date, and the recommended next calibration date.
3	Shows a list of the most recent login events, including the date, the time, the login result (success or failure), and the user account.
4	Shows the factory installation date, the date of the last software backup, and the date of the last full backup.
5	Shows the last maintenance date, and the recommended next maintenance date.
6	Shows information about the number of test results, test result status, last self test, last successful self test, number of test programs, number of user records, and number of audit trail records stored on the instrument.

4.1.4 Software buttons

The table below shows the software buttons that are referred to in this manual.

Button	Function	Button	Function
	***Home***. Return to the main menu.		***Save***. Save the selected item.
	***Continue***. Continue to next page.		***Delete***. Delete the selected item.
	***Return***. Return to the previous page.		***Audit trail***. View and edit the audit trail for the selected item.
	***Export***. Export the selected item.		***New***. Create a new item in the selected menu.
	***Start***. Start the selected run.		***Print***. Print the selected item.
	***Abort***. Abort the selected run.		***Comment***. Type a comment to the selected item.
	***Deactivate***. Deactivate the selected item.		***Activate***. Activate the selected item.
	***Hide***. Hide the selected item.		***Show***. Show the selected item.
	***Network test***. Type the details of the network location.		***Edit***. Edit the selected item.
	***Bar code***.		***Search audit trail***. Search for items in the audit trail menu.
	***Graph***. Show the graph of the selected run.		***Reorder***. Reorder the listed items in the main menu settings.
	***Sign***. Sign the selected test result.		

4.1.5 Test programs

A test program stores the test parameters. When testing the same filter or tested assembly repeatedly, a test program can be used to make sure that the same test parameters are used, or to restrict the number of test parameters that can be edited by the operator.

Tip: *A test program can store the test parameters of an accessory. The accessory needs to be connected and enabled in the software before creating the test program. For example, to include parameters for the Flowstar V MUX accessory, connect it to the instrument and enable the accessory in* ***Tools →General settings →Active extension****.*

4.1.6 Warnings

Warnings are generated in the software to warn operating personnel that process parameters have exceeded preset high or low limits. The following can be selected if a warning pop-up message is displayed during a run:

- ***Confirm*** to continue the run.
- ***Abort*** to stop the run.

After a run, any warning is displayed at the bottom of the result file. When a test run encounters an error, the run is automatically aborted. After the run is aborted, the error is displayed at the bottom of the result file.

4.2 Software settings

About this section

This section describes the software settings of the instrument.

In this section

4.2.1 General settings

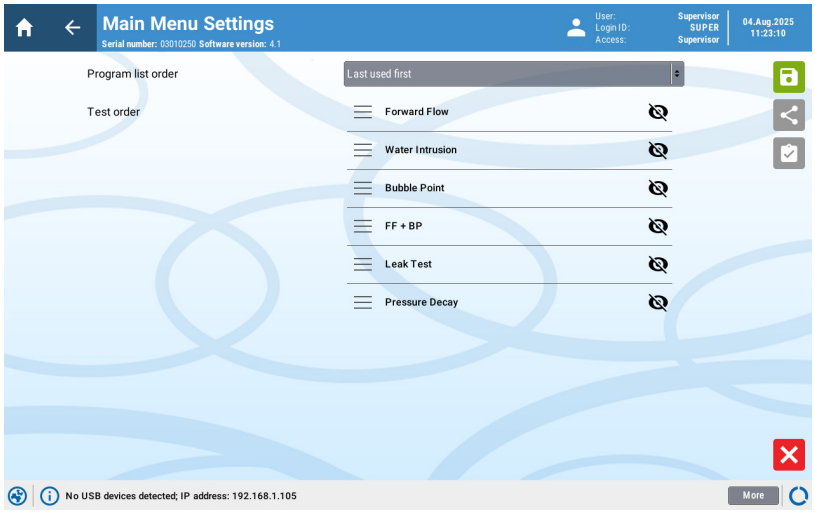
The ***General Settings*** menu is described in the table below.

Parameter	Description
Language	Select the language that is used in the software. The keyboard layout is automatically adjusted for the selected language. The options are: • Chinese • Dutch • English (UK) • English (US) • French • German • Italian • Japanese • Portuguese (Brazil) • Portuguese (Portugal) • Russian • Spanish ***Note:*** *For additional languages, contact your Cytiva representative.*
Active extension	Select the extension that is connected to the instrument. The options are: • ***None*** • ***Flowstar V MUX*** • ***AquaWIT V*** • ***AquaWIT V MUX*** • ***AquaWIT V Flush Set***

Parameter	Description
Pressure units	Select the unit that is used for the input pressure and output pressure. The options are: • ***mbar*** • ***psi*** • ***kp/cm²*** • ***kPa*** ***Note:*** *After changing the pressure unit in the settings, any previous test results or test programs retain the original pressure unit.*
Run self test	Select the interval for running a self test. The options are: • ***On manual request only*** • ***On power up*** • ***Daily*** • ***Weekly***
External vent valve	Select the default behavior for the external vent valve. The options are: • ***On***: The instrument verifies if an external vent valve is connected when starting a test. • ***On full power***: The instrument verifies if an external vent valve is connected when starting a test. The external vent valve is powered with 24 VDC during the entire test. • ***Off***: The external vent valve is not used.
Prestabilisation	Select to enable or disable the pre-stabilization time and the pre-stabilization pressure as obligatory parameters of a test. The options are: • ***Off*** • ***Manual prestabilisation***: The user can enter the pre-stabilization values before starting a test. • ***Auto-purge behaviour***: The instrument performs an automatic pre-stabilization phase. The pre-stabilization values are not entered when starting a test.

Parameter	Description
• ***FF option fields*** • ***WIT option fields*** • ***BP option fields*** • ***FF+BP option fields*** • ***LT option fields*** • ***PD option fields*** • ***SUS LT option fields*** (only for the Flowstar V LGR instrument)	Select up to two custom settings for each test type. Toggle between the two custom settings by tapping the ***1/1*** or ***2/2*** button. Type the field name and test parameter. The maximum length of the field name is 20 characters. The custom settings are added to the available settings of the respective test type and are recorded in the test results. ***Note:*** *The default field name of the custom fields is **{FilterLine}**. This field name can be adjusted.*
Minimum flow field	Select to enable or disable the minimum flow field for the forward flow (FF) test and the FF+BP test. The options are: • ***Off***: The instrument does not verify the minimum flow. • ***Manual entry***: The instrument verifies the minimum flow at the selected threshold. • ***5% of maximum flow limit***: The instrument verifies the minimum flow at 5% of maximum flow threshold. ***Note:*** *A **FLOW TOO LOW** warning is displayed when the instrument detects a flow below the minimum flow threshold. See Section 9.2 Instrument, on page 288 for troubleshooting error messages.*
Keyboard beep	Select to enable or disable the entry confirmation sound for the touchscreen keyboard. The options are: • ***Off*** • ***Quiet*** • ***Medium*** • ***Loud***

Parameter	Description
Keyboard layout	Select the keyboard layout. The options are: • ***Default for selected language***: The keyboard layout is adjusted for the selected language. There are no keyboards available for Chinese and Japanese. • ***US English*** • ***UK English*** • ***Danish*** • ***French*** • ***German*** • ***Hungarian*** • ***Italian*** • ***Japanese*** • ***Russian*** • ***Spanish*** • ***Swedish***
Power saving mode	Select to enable or disable the power saving mode for the instrument. The options are: • ***Off*** • ***Except when running tests*** • ***Always on***
Screen brightness	Select the screen brightness of the touch screen. The options are: • ***Low*** • ***Medium*** • ***High***

Parameter	Description
Main menu settings	Select the content and order of the ***Main Menu***. The options are: • ***Program list order*** • ***Test order*** • Reorder the listed items by selecting the ☰ button next to the item and dragging it to the selected location. • A test is hidden if the 👁 button is displayed. • A test is displayed if the 🚫 button is displayed. 

The settings related to preventing repeated tests are described in the table below.

Parameter	Description
Prevent repeat tests	Select to enable or disable if the instrument warns or blocks repeated tests. The test repeat counter is related to parameters of the tested assembly. The options are: • ***Yes***: Enable the test repeat counter. The instrument blocks a test when the counter threshold is reached. • ***Warn only***: Enable the test repeat counter. The instrument warns the user when the counter threshold is reached. • ***No***: Unrestricted repeats are allowed.
Number of repeats allowed	Select the number of times a test can be repeated before the instrument displays a warning or blocks the test. The counter is reset when a filter passes the test, or when another filter type, filter batch, and wetting fluid is selected for a test. The first test run is not counted.

Parameter	Description
Include in repeat counter	Select at which test phase the test repeat counter considers the current test a repeated test. The options are: • ***All tests***: A test is counted after tapping the ***Start*** button. • ***Test that reach pressure***[1]: A test is counted when it enters the stabilization phase. This excludes a test that aborts because of a setup failure, such as when the pressure supply is not connected. • ***Test that reach measurement***: A test is counted when it reaches the measurement phase. This excludes a test without a measured value.
Parameters determining repeated test	Select which parameters are monitored to consider a test a repeated. The options are: • ***Option 1***: Filter serial number and part number. • ***Option 2***: Filter serial number, part number, and wetting fluid.

[1] The recommended setting for ***Include in repeat counter*** is ***Test that reach pressure***.

4.2.2 Date and time settings

The ***Tools*** →***Date/Time*** settings for clock synchronization, and date and time adjustment are described in the table below.

Parameter	Description
Clock synchronisation	Select the source of the automatic time synchronization on the instrument. The options are: • ***Off***: The time synchronization is disabled. Enter the date and the time manually. Select the time zone, and if relevant, select the daylight-saving time for the selected time zone. Verify the date and time regularly. • ***DMS software***: The DMS Pro software is the source for time synchronization. For more information, refer to the *User Manual (USD3925)* of the DMS Pro software. • ***NPT server***: Select the IP address of the NTP server. Select time zone to activate regional daylight saving.
Date format	Select the date format, when ***Clock synchronisation*** is enabled. The options are: • ***DD.MMM.YYYY*** • ***DD/MMM/YYYY*** • ***DD-MMM-YYYY*** • ***MMM/DD/YYYY*** • ***YYYY-MMM-DD*** • ***YYYY/DD/MMM***
Time format	Select the time format, when ***Clock synchronisation*** is enabled. The options are: • ***24-hour*** • ***am/pm***
Current date	Displays the current date. Manually adjust to the correct date if ***Clock synchronisation*** is disabled.
Current time	Displays the current time. Manually adjust to the correct time if ***Clock synchronisation*** is disabled.

Parameter	Description
Include timezone	Select to include the timezone in the displayed time, when ***Clock synchronisation*** is enabled. The options are: • ***Off*** • ***Abbreviation***: The abbreviation of the time zone is displayed (e.g. CET/CEST). • ***Offset from UTC***: The time difference to the coordinated universal time (UTC) is displayed (e.g. ***+01:00***)
Timezone	Select the timezone, when ***Clock synchronisation*** is enabled. The options are: • ***UTC*** • ***US Pacific Time*** • ***US Mountain Time*** • ***US Central Time*** • ***Central America*** • ***United Kingdom*** • ***Central Europe*** • ***Eastern Europe*** • ***India*** • ***China*** • ***Japan*** • ***Central Australia*** • ***Eastern Australia***

4.2.3 User rights settings

The ***Tools*** →***User rights*** settings for user access rights are described in the table below.

Parameter	Description
Individual user login	Select to enable or disable the password requirement for login with for level 1 access authority (***Operator***). The options are: • ***Off***: Enables standard access control. • ***On***: Enables high level access control for compliance with 21 CFR Part 11. See *Section 4.4.2 User authority levels, on page 85* for more information about user authority levels and instrument access modes. • ***Domain-based login***: Enables high level access control using accounts set up at a network location. • ***Domain-based login (DMS)***: Enables high level access control using accounts set up using the DMS Pro software.
Administrator password	When ***Individual user login*** is switched off, type the ***Administrator*** password to log in.
Supervisor password	When ***Individual user login*** is switched off, type the ***Supervisor*** password to log in.
Signature type	Select how to sign test results. The options are: • ***Off*** (default) • ***Electronic (force)*** • ***Electronic*** • ***Manuscript***: The signature field is added to the printout. ***Note:*** *The electronic signature functionality requires a user list where the signature is linked to a specific user with a password.*
Password aging	Select the expiration time for passwords. The options are: • ***1 day (test OQ)***: Use this setting only for OQ testing purposes. • ***30 days*** • ***60 days*** • ***90 days*** • ***180 days*** • ***365 days*** • ***Off***

Parameter	Description
Password history	Select when a password can be reused. The options are: • ***Off*** • ***Remember the last 3 passwords*** • ***Remember the last 5 passwords*** • ***Remember all passwords***
Require complex password	Select if a password must include a character, a number, and a special character. The options are: • ***Off*** • ***On***
Minimum password length	Select the minimum number of characters in a password. The options are: • ***Off*** • ***4 characters*** (default) • ***6 characters*** • ***8 characters*** • ***10 characters*** • ***12 characters***
Password lock-out	Select the number of failed login attempts that are allowed before a user is locked out from the instrument. The options are: • ***3 attempts*** • ***5 attempts*** • ***10 attempts*** • ***Off***

Parameter	Description
Auto-deactivate inactive users after	Select the duration of inactivity before a user is deactivated on the instrument. An ***Administrator*** can reactivate the deactivated user account. The options are: • ***Off*** • ***30 days*** • ***60 days*** • ***90 days*** • ***180 days*** • ***365 days*** • ***1 day (test OQ)***: Use this setting only for OQ testing purposes.
Automatic logout period	Select the duration of inactivity before a user is logged out. The options are: • ***5 minutes*** • ***10 minutes*** • ***30 minutes*** • ***Off***: The user is not logged out on inactivity.
Lock-out duration	When ***Password lock-out*** is enabled, select the duration for which a user is locked out from the instrument. The options are: • ***5 minutes*** • ***10 minutes*** • ***30 minutes*** • ***Off***: The user is not locked out until the user account is reactivated.
Allow result export by operators	Select to enable or disable if users with level 1 (***Operator***) access authority can export single test results. The options are: • ***Off*** • ***On***
Allow deletion of test results by supervisor	Select to enable or disable if users with level 2 (***Supervisor***) access authority can delete test results. The options are: • ***Off*** • ***On***

Parameter	Description
Allow admins to run tests	Select to enable or disable if users with level 3 (***Administrator***) or level 4 (***Super-admin***) access authority can create and run tests. The options are: • ***No administrators***: Do not allow users with an ***Administrator*** or a ***Super-admin*** account to run a test. • ***All administrators***: Allow users with an ***Administrator*** and a ***Super-admin*** account to run a test. • ***Standard administrators only***: Only allow users with an ***Administrator*** account to run a test.
Allow admins to edit test programs	Select to enable or disable if users with level 3 (***Administrator***) or level 4 (***Super-admin***) access authority can create and edit test programs. The options are: • ***No administrators***: Do not allow users with an ***Administrator*** or a ***Super-admin*** account to edit a test program. • ***All administrators***: Allow users with an ***Administrator*** and a ***Super-admin*** account to edit a test program. • ***Standard administrators only***: Only allow users with an ***Administrator*** account to edit a test program.
Number of signatures	Select if a test result must be signed with one or two signatures, when ***Signature type*** is set to ***Electronic***. The second signature can be used to approve the test result. • ***1 signature*** • ***2 signatures***
Signature comment	Select if the user must type a comment when signing a test result. The options are: • ***Required*** • ***Optional***

4.2.4 User list settings

The ***Tools*** →***User list*** settings for creating and editing user accounts are described in the table below.

Parameter	Description
Full user name	Type the name of the user.
Access level	Select the access level of the user. The options are: • ***Operator*** • ***Automation operator*** • ***Supervisor*** • ***Administrator*** • ***(Super-admin)*** See *Section 4.4.2 User authority levels, on page 85* for a description of the level of user access authority.
Login ID	Type the login identifier of the user. The login identifier can contain letters and numbers, but cannot contain special characters.
Password	Type the password of the user. The restrictions for the password are selected in the ***Tools*** →***User rights*** settings.
Repeat password	Type the password of the user again.

4.2.5 Printer settings

The ***Tools*** →***Printer*** settings for the printer and data storage are described in the table below.

Parameter	Description
Enable printer	Select to enable or disable the print function. The options are: • ***Off***: No printer is connected to the instrument. • ***USB***: Printing using a USB-connected printer or to a USB drive. • ***Network***: Printing using a network printer or to a network location. • ***Thermal printer***: Printing using the Flowstar V Printer.
Enable auto-print for test results	Select to enable or disable automatic printing of the test results. The options are: • ***Off*** • ***On test completion only*** • ***Following last signature*** • ***On any update***
Printer 2	Select to enable or disable printing on a second printer in parallel to the first printer. The options are: • ***Off*** • ***USB*** • ***Network***
Include result graph on printouts	Select if the test result graph is included in the printout. The options are: • ***Off*** • ***On***

After setting ***Enable printer*** to ***Network***, the settings related to printing using a network printer are displayed. These settings are described in the table below.

Parameter	Description
Printer type	Select the data type that is used for storing or printing data. The options are: • ***PDF file*** • ***XML file***: Only for printing test results to an XML file. • ***Postscript compatible*** • ***PCL4 upwards***

Parameter	Description
Network path	Type the network path of the network used for data transfer. Format the network path according to the following examples: • `//IP address of the network host/name of the shared folder/…` • `//Domain name of the network host/name of the shared folder/…`
Username	Type the network user name of the network used for data transfer.
Password	Type the network password of the network used for data transfer.

4.2.6 Import and export settings

The ***Tools*** →***Import/Export*** settings for data import, data export, and printing are described in the table below.

Parameter	Description
USB port status	Select to enable or disable the USB ports. The options are: • ***Fully enabled***: Enable data import, data export, and printing using the USB ports. • ***Disable storage device only***: Disable data export using the USB ports. • ***Disable all USB devices***: Disable data import and export using the USB ports.
Enable import/ export	Select to enable or disable data import and export. The options are: • ***Off***: Disable data import and export. • ***USB***: Enable data import and export to a USB drive. • ***Network***: Enable data import and export using a LAN connection in a Windows network.
Enable barcode generator	Select to enable or disable the barcode generator. The options are: • ***Off*** • ***On***
FFS04 program transport	Select to enable or disable the import of test programs created on a Flowstar IV instrument. The options are: • ***Off*** • ***On***
PDF protection	Select to enable or disable the type of automatic encryption of ***PDF*** files. Options are: • ***Disabled*** • ***Prevent modification*** • ***Prevent modification and text copy*** • ***Prevent modification, text copy, and print***

Parameter	Description
Result filename ID1*/*Result filename ID2	Set up the naming convention for test result files. Options are: • ***None*** • ***Program name*** • ***Production area*** • ***Product batch number*** • ***Filter type***
DMS key	Type the DMS Pro key to connect the instrument to the DMS Pro software. Refer to the *User Manual (USD3925)* of the DMS Pro software.
Friendly name	If data import and export using the DMS Pro software is enabled, select the DMS Pro settings. Refer to the *User Manual (USD3925)* of the DMS Pro software.
Sync test program	If data import and export using the DMS Pro software is enabled, select the DMS Pro settings. Options are: • ***Off*** • ***Yes (prohibit local edits)*** • ***Yes (permit local edits)*** Refer to the *User Manual (USD3925)* of the DMS Pro software.

When ***Enable import/export*** is set to ***Network***, the settings related to data import, data export, and printing using a network are displayed. These settings are described in the table below.

Parameter	Description
Network path	Type the network path of the network used for data transfer. Format the network path according to the following examples: • `//IP address of the network host/name of the shared folder/…` • `//Domain name of the network host/name of the shared folder/…`
Username	Type the network user name of the network used for data transfer.
Password	Type the network password of the network used for data transfer.

Parameter	Description
Include result graph in export	Select to enable or disable if the test result graph is included in the printout. The options are: • ***Off*** • ***On***

4.2.7 Network settings

The ***Tools*** →***Network*** settings for connecting the instrument to a network are described in the table below.

Parameter	Description
Network	Select to enable or disable data import and export using a network. The options are: • ***Off*** • ***Use static address*** • ***Use dynamic address (DHCP)***
IP address	Type the network IP address.
Subnet mask	Type the network subnet mask.
Gateway	Type the network gateway.
MAC address	Type the MAC address of the network location.
Domain	Type the domain of the network.
Wifi	Select to enable or disable data import and export using a Wi-Fi network. The options are: • ***Off*** • ***Use static address*** • ***Use dynamic address (DHCP)***
VNC server	Select to enable or disable the virtual network computing (VNC) server on the instrument. The options are: • ***Off*** • ***On***
VNC password	Select the password for the VNC connection. The VNC password has restriction for password length or character combination.

When Wi-Fi data transfer is enabled, the settings related to data import and data export using a Wi-Fi connection are displayed. These settings are described in the table below.

Parameter	Description
SSID	Type the service set identifier (SSID) of the Wi-Fi network used for data transfer.

Parameter	Description
Hidden SSID	Select to enable or disable a hidden SSID for the Wi-Fi network. The options are: • ***Off*** • ***On***: Type the hidden SSID of the Wi-Fi network used for data transfer.
Wifi security type	Type the security type of the Wi-Fi network used for data transfer, such as ***PSK encryption*** or ***TLS encryption***.
Pre-shared key	Type the password of the Wi-Fi network used for data transfer.

4.2.8 Automation settings

The ***Tools*** →***Automation*** settings for remote control and automation are described in the table below.

Parameter	Description
Lock screen on startup	Select to enable or disable if the touch screen is locked when the instrument is switched on using remote control. The options are: • ***Off*** • ***On***
Lock screen default message	Type the message that is displayed on the locked screen when the instrument is run remotely.
OPC UA port	Select the port for connecting to the OPC UA Client. The recommended port is `4841`.
Allow anonymous OPC UA connection	Select to enable or disable to allow an anonymous OPC UA connection. The options are: • ***Off*** • ***On***
Enable admin password reset	Select to enable or disable to reset the password of the ***Administrator*** account to the initial password using the MPath Operational Insights software. The options are: • ***Off*** • ***On*** The administrator password is reset to the predefined password, see *Section 4.4.3 Predefined user accounts, on page 87*. For more information, refer to *mPath Operational Insights Software User Manual (USD3867)*.
Password reset authorization key	If ***Enable admin password reset*** is enabled, type the password reset authorization key.

4.2.9 Test program settings

The settings that relate to any test program or a run are described in the table below.

Parameter	Description
Test program	Select the name of the test program.
Operator (optional)	• If the instrument is in standard access control, type the name of the operator. • If the instrument is in HLAC mode, the software automatically fills in the name of the user that is currently logged in.
Production area	Type the location or room where the test is performed.
Filter line	Type the filter line.
Custom parameter (optional)	Type the value for the custom parameter. See *Set general settings, on page 111* for instructions to set up custom parameters.
Product name	Type the product name of the material that the tested assembly is used with.
Product batch	Type the product batch of the material that the tested assembly is used with.
Filter part number(s)	Type the filter part number.
Number of filters	Type the number of filters that are connected.
Filter serial number(s)	Type the filter serial number.
Filter housing	Type the filter housing type.

4.2.10 FF test settings

The settings that relate to a FF filter integrity test are described in the table below.

Parameter	Description	Range
Wetting liquid	Type the type of wetting liquid that is used in the test.	N/A
Test gas	Type the type of gas that is used in the test.	N/A
Pre-stabilization pressure (optional)	• Type the pre-stabilization pressure. • Leave the field empty to skip the pre-stabilization phase.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Pre-stabilization time (optional)	• Type the pre-stabilization time. • Leave the field empty to skip the pre-stabilization phase.	0 to 9999 s
Test pressure	Type the test pressure.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Max. test time	• Type the maximum operation time of the test. • Select ***AUTO*** to run the test until the flow rate is stable. The default maximum test time is 600 s.	• 100 to 9999 s • ***AUTO***
Minimum flow (optional)	• Type the expected minimum flow rate. • Leave the field empty to set the minimum flow to zero.	Max. 20% of the ***Maximum flow***
Maximum flow	Type the maximum FF value for the test.	0.1 to 1000 mL/min

4.2.11 BP test settings

The settings that relate to a bubble point (BP) filter integrity test are described in the table below.

Parameter	Description	Range
Wetting liquid	Type the type of wetting liquid that is used in the test.	N/A
Test gas	Type the type of gas that is used in the test.	N/A
Module factor / ***Membrane area***	For ***Module factor***: • Type the number that describes the size of the target filter. • Leave the field empty to select the default value (***1***).	• ***1*** for 254 mm (10 inch) filter cartridges • ***0.5*** for 128 mm (5 inch) filter cartridges (e.g., AB05 or SLK7002) • ***0.2*** for smaller filter cartridges (e.g., AB02 or SLK7001) • ***0.1*** for flat membranes (e.g., 142 mm discs) or mini capsules (e.g., Mini Kleenpak™) • ***0.01*** for small area filter capsules (e.g., Acro™ 25/50 or Mini Kleenpak 20)
	For ***Membrane area***, type the size of the membrane to adjust the sensitivity of the leak test phase.	6.25 to 625000 cm^2
Pre-stabilization pressure (optional)	• Type the pre-stabilization pressure. • Leave the field empty to skip the pre-stabilization phase.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Pre-stabilization time (optional)	• Type the pre-stabilization time. • Leave the field empty to skip the pre-stabilization phase.	0 to 9999 s
Start pressure	Type the starting pressure of the test.	• 250 to 2570 mbar • 3.63 to 5.40 psi
Minimum BP	Type the minimum pressure of the test.	• 400 to 6500 mbar • 5.80 to 94.24 psi

Parameter	Description	Range
Maximum pressure	• Type the maximum pressure of the test. • Leave the field empty to select the line pressure as maximum pressure of the test.	• Max. 7000 mbar • Max. 101.53 psi >250 mbar or 3.63 psi above the ***Minimum BP***[1]

[1] An error is displayed during the test, if the selected ***Maximum pressure*** is not 250 mbar or more above ***Minimum BP***.

4.2.12 FF + BP test settings

The settings that relate to a FF + BP filter integrity test are described in the table below.

Parameter	Description	Range
Wetting liquid	Type the type of wetting liquid that is used in the test.	N/A
Test gas	Type the type of gas that is used in the test.	N/A
Pre-stabilization pressure (optional)	• Type the pre-stabilization pressure. • Leave the field empty to skip the pre-stabilization phase.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Pre-stabilization time (optional)	• Type the pre-stabilization time. • Leave the field empty to skip the pre-stabilization phase.	0 to 9999 s
FF test pressure	Type the test pressure of the FF test.	• 50 to 6500 mbar • 0.73 to 94.27 psi
FF max. test time	• Type the maximum operation time of the test. • Select ***AUTO*** to run the FF test until the flow rate is stable. The default maximum FF test time is 600 s.	• 100 to 9999 s • ***AUTO***
FF maximum flow	Type the maximum flow rate of the test.	0.1 to 1000 mL/min
FF minimum flow (optional)	• Type the minimum flow rate. • Leave the field empty to set the minimum flow to zero.	Max. 20% of the ***FF maximum flow***
Minimum BP	Type the minimum pressure of the BP test.	• 400 to 6500 mbar • 5.80 to 94.27 psi >250 mbar or 3.63 psi above the ***FF test pressure***[1]

Parameter	Description	Range
Maximum BP pressure	• Type the maximum pressure of the BP test. • Leave the field empty to select the line pressure as maximum pressure of the BP test.	• Max. 7000 mbar • Max. 101.53 psi >250 mbar or 3.63 psi above ***Minimum BP***[2]

[1] An error is displayed during the test, if the selected ***Minimum BP*** is not 250 mbar or more above ***FF test pressure***.
[2] An error is displayed during the test, if the selected ***Maximum pressure*** is not 250 mbar or more above ***Minimum BP***.

4.2.13 WIT settings

The settings that relate to a water intrusion test (WIT) filter integrity test are described in the table below.

Parameter	Description	Range
Pre-stabilization pressure (optional)	• Type the pre-stabilization pressure. • Leave the field empty to skip the pre-stabilization phase.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Pre-stabilization time (optional)	• Type the pre-stabilization time. • Leave the field empty to skip the pre-stabilization phase.	0 to 9999 s
Test pressure	Type the test pressure.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Max. test time	• Type the maximum operation time of the test. • Select ***AUTO*** to run the test until the flow rate is stable. The default maximum test time is 900 s.	• 100 to 9999 s • ***AUTO***
Maximum flow	Type the maximum flow rate of the test.	0.03 to 50 mL/min

4.2.14 LT settings

The settings that relate to a leak test (LT) are described in the table below.

Parameter	Description	Range
System ID	Type the description of the tested assembly.	N/A
System batch	Type the batch of the tested assembly.	N/A
Pre-check phase	Select to enable or disable the pre-check phase. The pre-check phase verifies the function of the valves and the connectors.	• ***Enabled*** • ***Disabled***
Pre-stabilization pressure (optional)	• Type the pre-stabilization pressure. • Leave the field empty to skip the pre-stabilization phase.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Pre-stabilization time (optional)	• Type the pre-stabilization time. • Leave the field empty to skip the pre-stabilization phase.	0 to 9999 s
Test pressure	Type the test pressure.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Test time	Type the maximum operation time of the test.[1]	100 to 9999 s
Maximum flow	Type the maximum flow rate of the test. To calculate the ***Maximum flow*** from the pressure decay threshold, see *Calculate leak rate threshold, on page 214*.	0.1 to 1000 mL/min

[1] The automatic test time function is disabled for the LT test.

4.2.15 PD test settings

The settings that relate to a pressure decay (PD) test are described in the table below.

Parameter	Description	Range
Vessel ID	Type the description of the tested rigid vessel.	N/A
Pre-stabilization pressure (optional)	• Type the pre-stabilization pressure. • Leave the field empty to skip the pre-stabilization phase.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Pre-stabilization time (optional)	• Type the pre-stabilization time. • Leave the field empty to skip the pre-stabilization phase.	0 to 9999 s
Test pressure	Type the test pressure.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Stabilization time	Type the stabilization time. The recommended stabilization time is 600 s or higher.	100 to 9999 s
Test time	Type the maximum operation time of the test. The recommended test time is 600 s or higher.[1]	100 to 9999 s
Max. pressure decay	Type the maximum pressure decay for the test.	1 to 6500 mbar

[1] The automatic test time function is disabled for the PD test.

4.2.16 SUS LT settings

The settings that relate to a single-use equipment leak test (SUS LT) test are described in the table below.

Parameter	Description	Range
SUS part number	Type the part number of the tested assembly.	N/A
SUS batch number	Type the batch number of the tested assembly.	N/A
System volume	Type the approximate size of the tested assembly.	• ***Very small (> 50 mL)*** • ***Small (> 500 mL)*** • ***Medium (> 1 L)*** • ***Large (> 5 L)***
Actual volume	When ***System volume*** is set to ***Large (> 5 L)***, type the actual volume of the tested assembly.	5 to 200 L
Filling pressure	When ***System volume*** is set to ***Large (> 5 L)***, type the filling pressure of the test. The maximum value is 20% higher than the ***Test pressure***.	20 to 60 mbar
Fill hold time	When ***System volume*** is set to ***Large (> 5 L)***, type the maximum time to hold the filling pressure.	120 to 9999 s
Test pressure	Type the test pressure.	20 to 50 mbar
Pressure hold time	Type the maximum time to hold the filling pressure.	120 to 9999 s
Max. test time	Type the maximum operation time of the test.[1]	• 300 to 9999 s for volumes ≤ 50 L • 600 to 9999 s for volumes > 50 L
Maximum flow	Type the maximum flow rate of the test.	0.1 to 1000 mL/min

[1] The automatic test time function is disabled for the SUS LT test.

4.3 File naming conventions

Introduction

Data on the instrument can be transferred between Flowstar V instruments with a USB drive or using a network connection. By default, the instrument automatically generates the file names. The file naming convention of test result files can be customized, see *Set import and export settings, on page 112*.

Files and folder structure

The file naming, file format, and folder structure for each file type are described in the table below.

File type	File format options	Folder structure	File name
Test results	• PDF • XML • CSV	[FFS05 and instrument serial number]>[Date and time]>[Test Results].	The file name includes: • Serial number of the instrument • Test type • Test date, in the format YYYY-MM-DD • Test time, in the format HH.MM.SS • An indicator if the result is electronically signed: - ***[0]*** indicates that the test result file is not signed or that the electronic signature function is inactive - ***[1]*** indicates that the test result file is signed with one electronic signature - ***[2]*** indicates that the test result file is signed with two electronic signatures The complete file name is: [Serial number][Test type code][YYYYMMDD][HH.MM.SS][N]. An example of a file name: 12345678.12 FF 2025-05-15 10.02.45 0.pdf.
Test programs	• PDF • XML	[FFS05 and instrument serial number]>[Date and time]>[Test Programs].	The file name includes: • Test type • Test program name An example of the file name: FF Test88.pdf.
User list	• PDF • XML	[FFS05 and instrument serial number]>[Date and time][Users].	The file name includes: • User name An example of the file name: ADMIN.pdf.
User rights	• PDF • XML	[FFS05 and instrument serial number]>[Date and time][User Rights].	An example of the file name: UserSettings.pdf.

File type	File format options	Folder structure	File name
Audit trail	• PDF • XML • CSV	[FFS05 and instrument serial number]>[Date and time]>[Audit Trail].	The file name includes: • Storage date, in the format YYYY-MM-DD An example of the file name: 2025-06-25.pdf.
General settings	• PDF • XML	[FFS05 and instrument serial number]>[Date and time].	• AllSettings.pdf • AllSettings.xml

4.4 Access management

About this section

This section describes the access management on the instrument.

In this section

4.4.1 Access modes

The instrument can be operated in two access modes:

Access mode	Description
Standard access control	Includes three levels of user access authority: • Level 1: ***Operator*** • Level 2: ***Supervisor*** • Level 3: ***Administrator*** Standard access control does not require password for login with the level 1 access authority (***Operator***).
High level access control (HLAC)	Includes five levels of user access authority: • Level 0: ***Viewer*** • Level 1: ***Operator*** • Level 1: ***Automation operator*** • Level 2: ***Supervisor*** • Level 3: ***Administrator*** • Level 4: ***Super-admin*** HLAC requires password login for access authority levels 1 to 4. All activities are logged in the audit trail, see *Section 4.5 Audit trail, on page 88* for more information. ***Note:*** *HLAC is compliant with 21 CFR Part 11 for electronic records.*

4.4.2 User authority levels

The following table describes the user access authority for the specific functions for the instrument.

✓ Access allowed

(✗) Access not allowed by default. Can be switched on and off

✗ Access not allowed

Function	Level 0 *Viewer*	Level 1 *Operator*	Level 1 *Automation Operator*	Level 2 *Supervisor*	Level 3 *Administrator*	Level 4 *Super-admin*	Service
General system administration							
General settings	✗	✗	✗	✗	✓	✓	✗
Date and time settings	✗	✗	✗	✗	✓	✓	✗
User access rights	✗	✗	✗	✗	✓	✓[1]	✗
Access printer, network, automation	✗	✗	✗	✗	✓	✓	✗
Create and edit user accounts	✗	✗	✗	✗	✓	✓	✗
Import/export user rights	✗	✗	✗	✗	✓	✓	✗
Export general settings	✗	✗	✗	✗	✓	✓	✗
Import/export user list	✗	✗	✗	✗	✓	✓	✗
Export test results	✗	(✗)	✓[2]	✓	✓	✓	✗
Export audit trail	✗	✗	✓[2]	✓	✓	✓	✗
Delete data	✗	✗	✗	✗	✓	✓	✗
Delete users	✗	✗	✗	✗	✓	✓	✗
Delete test results	✗	✗	✗	(✗)	✓	✓	✗
Configure license keys	✗	✗	✗	✗	✗	✓	✗
Configure admins to run and edit programs	✗	✗	✗	✗	✗	✓	✗
Perform instrument backup	✗	✗	✗	✗	✓	✓	✗
Run a self test	✓	✓	✓	✓	✓	✓	✓
Full instrument reset	✗	✗	✗	✗	✗	✓	✗
Test program handling							
Create test program	✗	✗	✗	✓	(✗)	(✗)	✗
Generate test program barcodes	✗	✗	✗	✓	(✗)	(✗)	✗
Edit test program	✗	✗	✗	✓	(✗)	(✗)	✗
Export test programs	✗	✗	✗	✓	(✗)	(✗)	✗

Function	Level 0 *Viewer*	Level 1 *Operator*	Level 1 *Automation Operator*	Level 2 *Supervisor*	Level 3 *Administrator*	Level 4 *Super-admin*	Service
Import test programs	✗	✗	✗	✓	(✗)	(✗)	✗
Deactivate test programs	✗	✗	✗	✓	(✗)	(✗)	✗
Delete test programs	✗	✗	✗	✓	(✗)	(✗)	✗
Tests							
Define and start a test	✗	✓	✓[2]	✓	(✗)	(✗)	✗
Start a test from a test program	✗	✓	✓	✓	(✗)	(✗)	✗
View a running test	✓	✓	✓	✓	✓	✓	✗
Abort a test	✓	✓	✓[2]	✓	✓	✓	✗
View test results	✓	✓	✓	✓	✓	✓	✗
Sign and approve test results	✗	✓	✓[2]	✓	(✗)	(✗)	✗
View audit trail	✓	✓	✓[2]	✓	✓	✓	✗
Maintenance							
Access measurement module	✗	✗	✗	✗	✗	✗	✓

[1] Manage user access rights, including for ***Administrator*** authority access.
[2] A user with ***Automation Operator*** authority access can only use this functionality from a remote connection.

4.4.3 Predefined user accounts

IMPORTANT

Security risk. The default password must be changed immediately after the first login. The default password is intended to be temporary.

The Flowstar V instrument is delivered with the following predefined user accounts.

Access mode	Predefined user account	Account management
Standard access control	• User ***Supervisor*** • Default password ***super***	The ***Supervisor*** password can be changed. Change the default password immediately after the first login.
	• User ***Administrator*** • Default password ***pall***	The ***Administrator*** password can be changed. Change the default password immediately after the first login.
High level access control (HLAC)	• User name ***Super-admin*** • User name ***ADMIN*** • Default password ***pall***	The password of the ***Super-admin*** user account can be changed. Change the default password immediately after the first login. The ***Super-admin*** account cannot be deleted, because it is required for instrument recovery.

4.5 Audit trail

About this section

This section describes the following two audit trails that the instrument generates:

- Record-related audit trail
- Event audit trail

In this section

4.5.1 Record audit trail

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

- ***Automation***
- ***Date/Time***
- ***General Settings***
- ***Import/Export***
- ***Network***
- ***Test Programs***
- ***User List***
- ***User Rights***
- ***Printer***

The record audit trails can be printed, see *Section 7.8.4 Print record audit trails, on page 240*. The test results have no audit trail because they cannot be changed after storage, except by adding an electronic signature and a comment.

4.5.2 Event audit trail

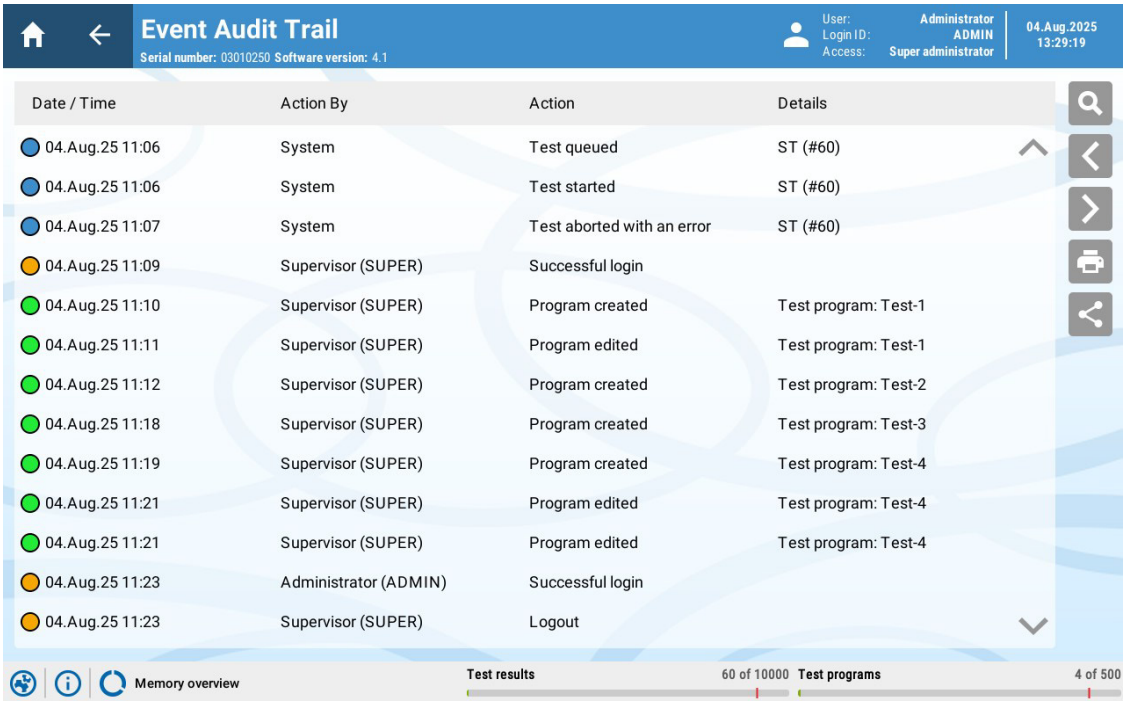
The event audit trail includes all activities that are not related to storing, editing, or deleting records. The event audit trail also includes which user performed the activity and the time stamp of the activity.

Examples of activities that are included in the event audit trail are:

- Test and test program related events
- Data deletion
- User login and logout events
- Backup
- Service records

The event audit trail runs continuously and requires no user activity to be started. The event audit trail cannot be modified or edited.

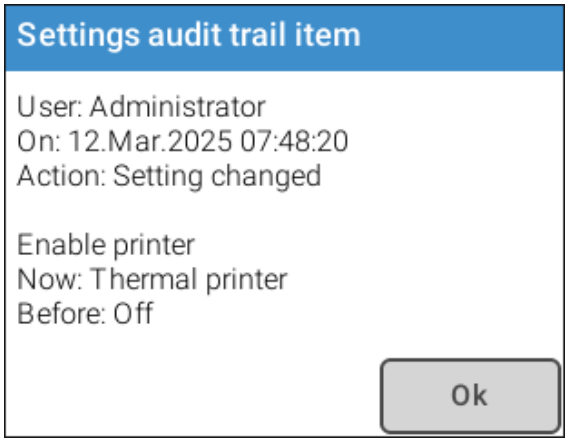
View the event audit trail in ***Tools*** →***Event audit trail***. The illustration below shows the ***Event Audit Trail*** screen.



The table below describes the details that are listed for each event audit trail entry.

Parameter	Definition
Color indicator	The color indicator shows the audit trail entry type. • Red: Indicates an audit trail entry related to the instrument setup, such as the general settings, the time settings, or the user rights. • Blue: Indicates an audit trail entry related to operation of a test, a test program, or a self test. • Green: Indicates an audit trail entry related to a test program. • Orange: Indicates an audit trail entry related to a user account. • Black: Indicates an audit trail entry related to any other recorded events.
Date/Time	The date and time of the audit trail entry.
Action By	The user account that made the change related to the audit trail entry.
Action	The change that resulted in the audit trail entry.
Details	The comment written to describe the change that resulted in the audit trail entry.

Tap the row to view the relevant audit trail. The illustration below shows an example of an audit trail pop-up window.



5 Installation

About this chapter

This chapter describes site requirements and necessary preparation to perform before installation.

In this chapter

5.1 Safety precautions

WARNING

Never exceed the operating limits stated in this document and on the nameplate. Operation outside these limits can damage equipment and cause personal injury or death.

WARNING

Overpressure. Make sure that the test pressure is less than the maximum operating pressure that is specified for the filter housing or the filter capsule. The filter can explode at overpressure and cause injury.

WARNING

All electrical installations must be performed by authorized personnel only.

WARNING

National Codes and standards (NEC, VDE, BSI, IEC, UL etc.) and local codes outline provisions for safely installing electrical equipment. Installation must comply with specifications regarding wire types, conductor sizes, plugs, branch circuit protection and disconnect devices. Non-compliance can result in personal injury and/or equipment damage.

CAUTION

Weight. The instrument weighs approximately 10 kg. Take suitable precautions when lifting and moving the instrument.

NOTICE

The Flowstar V instrument is a sensitive measurement instrument. Use suitable precautions when handling the instrument.

NOTICE

Stable room conditions. The operation temperature and pressure in the room must be stable and within the range described in the specifications. Fluctuations in temperature or pressure during a run can cause incorrect measurement values.

NOTICE

Liquid in the instrument. If required for the selected test, install the external vent valve between the instrument and the tested assembly. The external vent valve makes sure that the testing liquid does not enter the instrument. Liquid can cause damage to the instrument.

NOTICE

Contamination risk. Only use pneumatic tubing and connections that are clean, dry, and free from any fluids or contaminants. Valves can malfunction when contaminated with liquid or oil.

5.2 Site preparation

About this section

This section describes the site planning and preparation that must be performed before the product is installed.

In this section

5.2.1 Delivery, storage and unpacking

Introduction

This section outlines important information that must be considered when handling the transport crate, storing, and moving the delivery box.

When you receive the delivery

- Record on the receiving documents if there is any apparent damage on the delivery box. Inform your Cytiva representative of such damage.
- Move the delivery box to a protected location indoors.

Dimensions of the delivery box

The instrument is shipped in a delivery box with the following dimensions and weight:

Contents	Dimensions	Weight
Flowstar V instrument	583 × 520 × 570 mm (width × height × depth)	18.3 kg (including instrument and delivery box)

Storage requirements

The crate must be stored at a protected location indoors. The storage location for the unopened crate must meet the following requirements:

Parameter	Allowed range
Ambient temperature, storage	-20°C to 50°C (-4 to 122°F)
Relative humidity	80%, non-condensing, up to 31°C (87.8°F) 50%, non-condensing, at 40°C (104°F)

Unpacking the instrument

Save all the original packing material. If the instrument has to be repacked, for transportation or otherwise, it is important that the instrument can be safely packed using the original packing material. Two people are recommended to safely unpack the instrument, and no special equipment is needed.

Customer supplied equipment

The customer must supply the following:

- Personal protective equipment (PPE) as required.
- Electrical testing equipment as required.

5.2.2 Room requirements

Introduction

This section describes the requirements for the room where the instrument is placed.

Bench

The bench must be clean, flat and stable, and of sufficient size for the instrument and bench-top accessories. The illustration below shows a typical setup of the instrument.

Dimensions and weight

The following illustration shows the dimensions of the instrument.

Parameter	Description
H	263 mm (10.4 inch)
W	350 mm (13.8 inch)
D	450 mm (17.7 inch)
Weight	10.5 kg (24.3 lb) depending on installed accessories

5.2.3 Site environmental requirements

Safety precautions

This section describes the environmental requirements and conditions for installation of the instrument.

CAUTION

Do not use the product in a dusty atmosphere or close to spraying water.

CAUTION

The product is designed for indoor use only.

Environmental requirements

For details on environmental requirements for operation, storage and transport, see *Environmental requirements, on page 300*.

Environmental conditions

The following general requirements must be fulfilled:

- The temperature in the room must be kept stable.
- The pressure in the room must be kept stable.
- The instrument must not be exposed to sources of heat such as direct sunlight.
- Dust in the atmosphere must be kept to a minimum.

Instrument ventilation

There must be at least 10 cm clearance around the instrument to allow adequate air circulation.

NOTICE

Do not block the air vents on the equipment.

Heat output

The heat output data is listed in the table below.

Component	Heat output
Flowstar V instrument	Typically 75 W Maximum 150 W

5.2.4 Power requirements

Introduction

This section describes the electrical power requirements for the instrument.

WARNING

All electrical installations must be performed by authorized personnel only.

WARNING

Hazardous voltage. When energized, the product must always be connected to ground.

WARNING

National Codes and standards (NEC, VDE, BSI, IEC, UL etc.) and local codes outline provisions for safely installing electrical equipment. Installation must comply with specifications regarding wire types, conductor sizes, plugs, branch circuit protection and disconnect devices. Non-compliance can result in personal injury and/or equipment damage.

WARNING

The power plug must always be connected to a grounded power outlet.

Electrical power requirements

The following table specifies the power requirements for the instrument.

Parameter	Requirement
Supply voltage	100 to 240 VAC
Frequency	50/60 Hz
Power outlet type	Grounded mains outlets
Transient overvoltages	Overvoltage category II
Max. power consumption	150 W
Number of outlets	One outlet to power the instrument One 24 VDC outlet to power the external vent valve
Location of sockets	Maximum 2 m from the instrument (due to length of mains cable). Extension cables can be used if required.

Power quality

The power supply must be stable and conform to specifications at all times for reliable operation of the instrument. There must not be any transient or slow changes in average voltage outside the limits specified above.

5.2.5 Media supply

Media supply	Description
Compressed air	Oil and particle free, non-condensing air or nitrogen gas (according to ISO 8573-1:2010 Class 3.4.4 or better)

5.3 Hardware installation

About this section

This section describes the procedures performed by the user to install the instrument.

Note: *It is the responsibility of the customer to verify that the instrument is safely installed. After installation, verify that the instrument can be safely taken in operation.*

In this section

5.3.1 Connect power

Follow the instructions below to connect power to the instrument.

Step	Action
1	Locate the power cord and plug that are applicable for your region.

> **NOTICE**
> **Power cord**. Do not use the supplied power cords for any other equipment.

2	Push the power plug into the power supply socket on the instrument.

Result:
The power cord is correctly connected when the power plug snaps into place and makes an audible click sound.

3	Connect the power cord from the instrument to a grounded wall outlet with a voltage according to the site requirements in *Electrical power requirements, on page 102*.

> **WARNING**
> **Access to power switch and power cord.** The power switch must always be easy to access. The power cord must always be easy to disconnect.

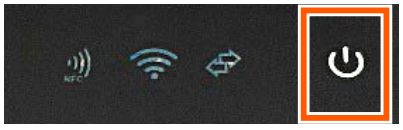
5.3.2 Start the instrument

Follow the instructions below to start the instrument.

Step	Action
1	On the back of the instrument, press the **I** position on the power switch.

NOTICE
Do not switch on the power switch before all connections are made.

2	If the instrument was restarted, also tap the power button on the right side of the touch screen.



3	If the instrument is in HLAC mode, log in with the relevant user account. **a.** Type your user name and password. **b.** Tap ***Ok***. *Result:* The user is logged in to the software.

See *Section 8.3.3 Self test, on page 251* for instructions on how to configure when a self test starts.

5.3.3 Connect compressed air supply

Follow the instructions below to connect the compressed air supply to the instrument.

Step	Action
1	Make sure that the pressure from the compressed air supply is within 3000 to 8000 mbar (43.5 to 116 psi). If necessary, adjust the pressure and the flow rate for the intended test. ***Note:*** *For air supply requirements, see Compressed air, on page 301.* **CAUTION** **Overpressure.** The pressure of the air supply must be locked using pressure regulator. Prevent unauthorized personnel from adjusting the pressure of the air supply. Hoses connected to the air inlet on the system can break due to overpressure and cause injury or damage to the system.
2	Connect the air supply to the **IN** port. Use the red air hose with a 6 mm ID (8 mm OD) and a Stäubli RBE03 male connector.  **NOTICE** **Contamination risk.** Only use pneumatic tubing and connections that are clean, dry, and free from any fluids or contaminants. Valves can malfunction when contaminated with liquid or oil.

5.4 Software configuration

About this section

This section describes the procedures performed by the administrator to set up the software configuration on the instrument.

In this section

5.4.1 Set up software configuration

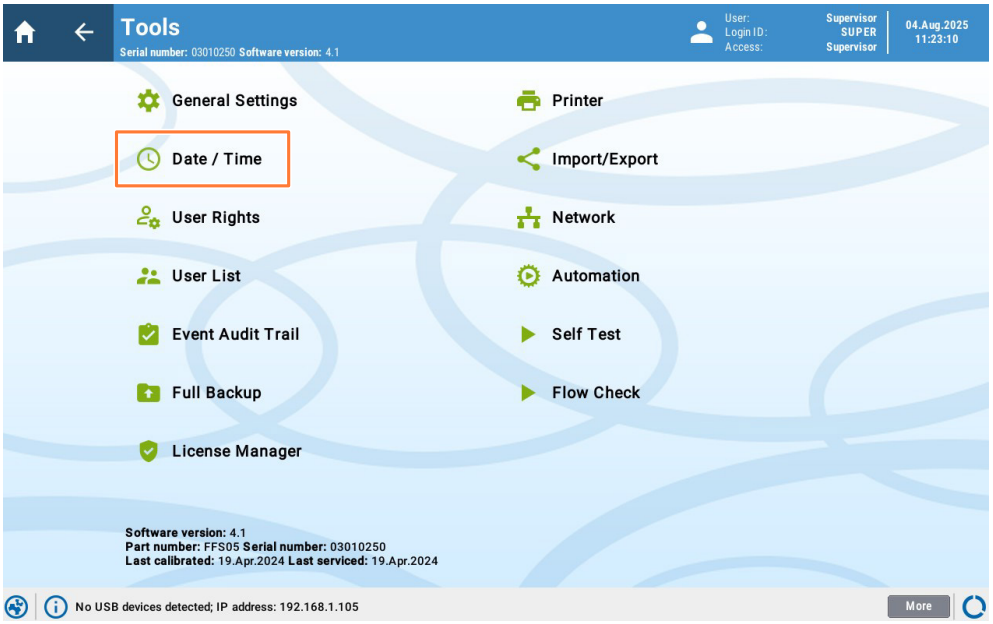
Before using the instrument for the first time, it is recommended to:

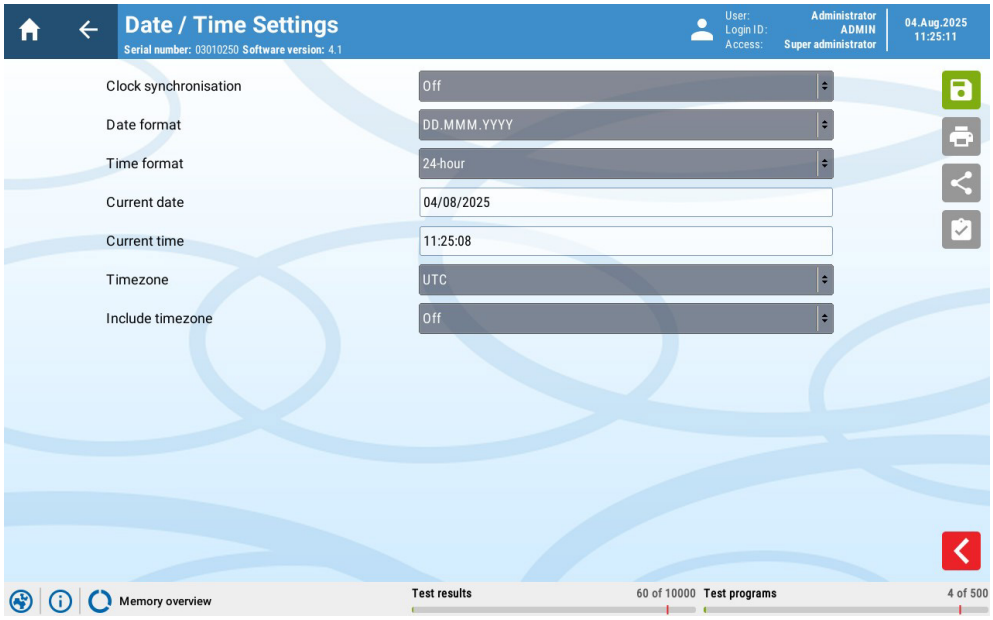
- Select the date and time settings.
- Select the general settings.
- Set up user accounts, see *Section 5.4.2 Set up access management, on page 115*.
- If required, connect to a printer and a network, see *Section 5.4.3 Connect to a network location or a printer, on page 121*.
- If required, set up remote control, see *Section 5.4.4 Remote control, on page 128*.

Set date and time

Follow the steps below to set up the date and time.

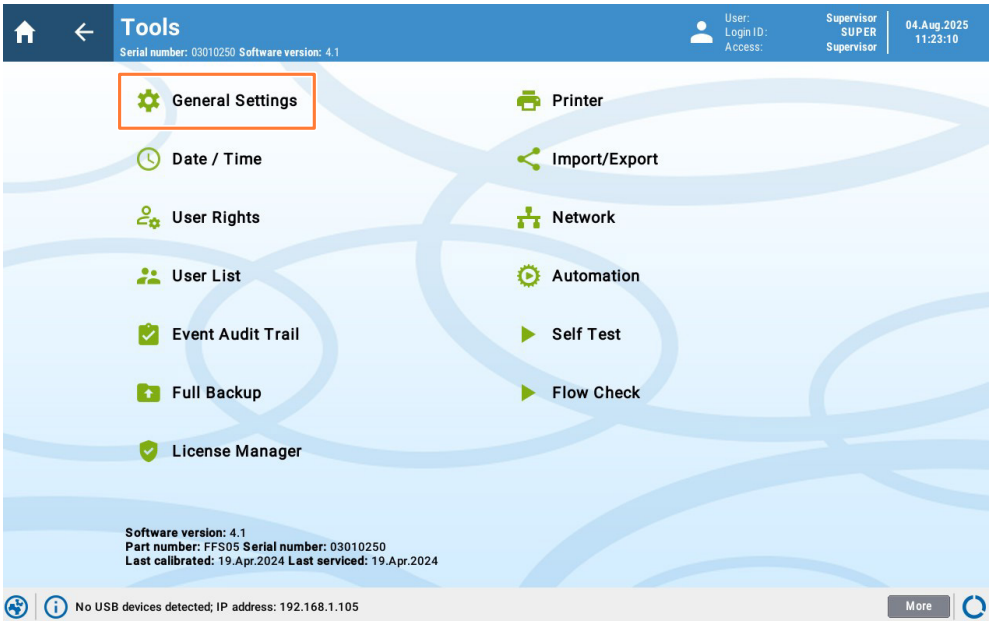
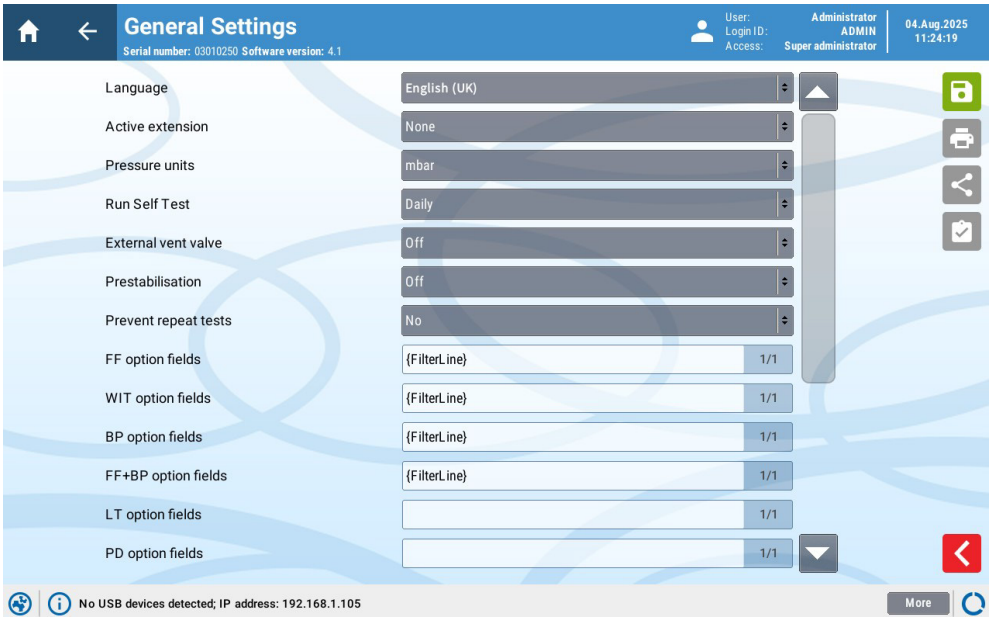
Step	Action
1	Log in with an ***Administrator*** or a ***Super-admin*** account.
2	Go to ***Tools*** →***Date/Time***.



Step	Action
3	Set the ***Date/Time*** parameters:  See *Section 4.2.2 Date and time settings, on page 56* for a description of the ***Date/Time*** parameters.

Set general settings

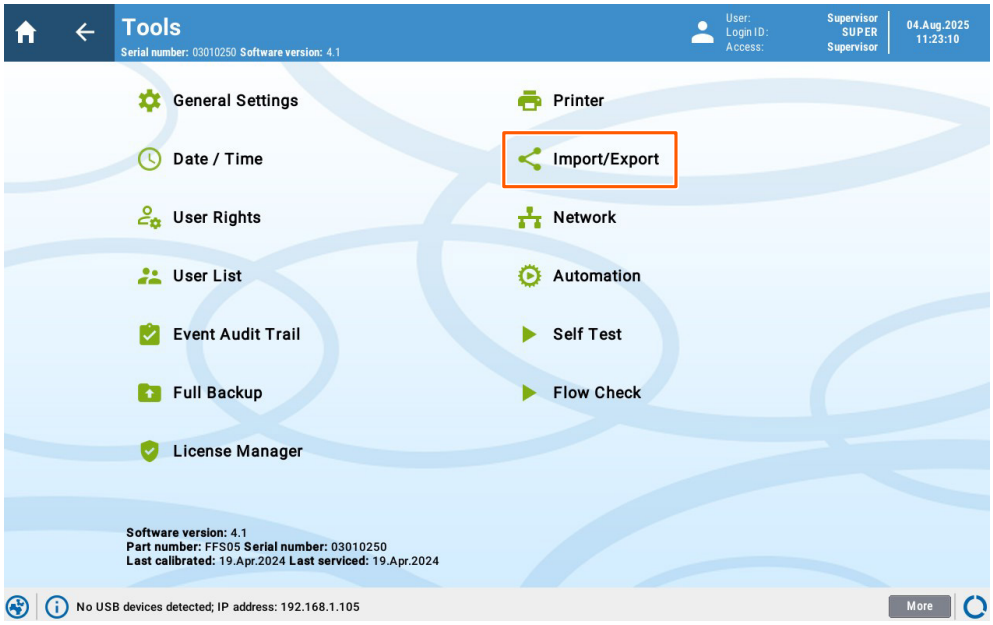
Follow the steps below to configure the general settings.

Step	Action
1	Log in with an ***Administrator*** or ***Super-admin*** account.
2	Go to ***Tools*** →***General Settings***. 
3	Set the ***General Settings*** parameters:  See *Section 4.2.1 General settings, on page 50* for a description of the ***General Settings*** parameters.

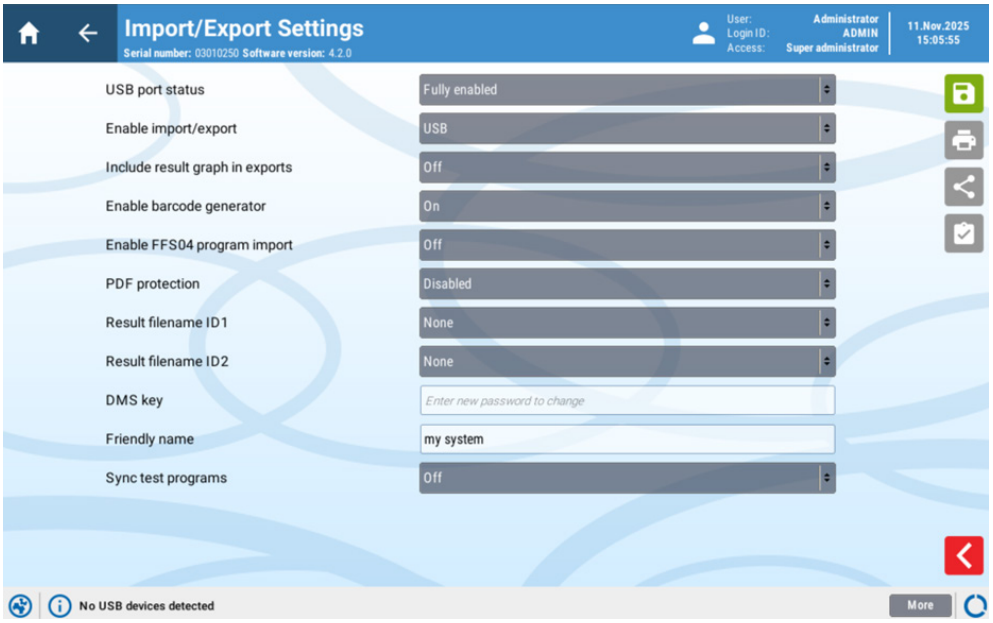
Set import and export settings

Before a data transfer, set the import and export settings.

Step	Action
1	Log in with an ***Administrator*** or ***Super-admin*** account.
2	Go to ***Tools*** →***Import/Export***.



Step	Action
3	Set the import and export parameters.



See *Section 4.2.6 Import and export settings, on page 65* for a description of the ***Import/Export*** parameters.

Note:

For information about settings for the optional DMS Pro software, refer to the User Manual (USD3925) of the DMS Pro software.

Tip:

To customize the file naming convention for test result files, set up the ***Result filename ID1*** *and* ***Result filename ID2*** *parameters.*

4 Optional: Set up data transfer using a network location.

a. Connect to a network. See *Connect to a network, on page 121*.

b. Go to ***Tools*** →***Import/Export***.

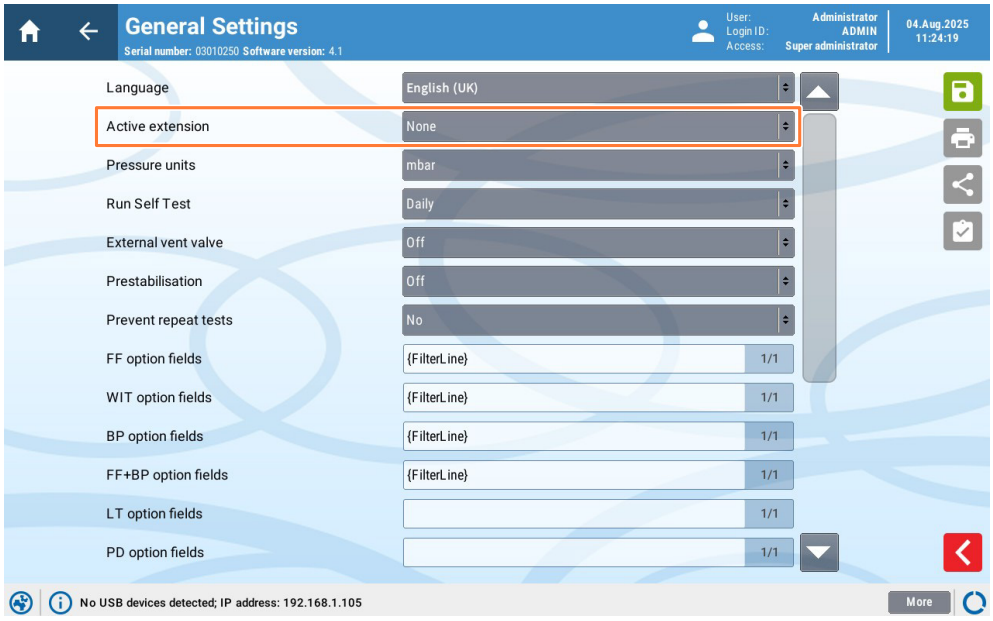
c. Set the parameters for data transfer using a network location.

See *Section 4.2.6 Import and export settings, on page 65* for a description of the parameters for data transfer using a network location.

Enable accessories in software

Follow the steps below to enable an accessory in the software.

Step	Action
1	Log in with an ***Administrator***, or a ***Super-admin*** account.
2	Verify that the accessory is connected to the instrument.
3	Go to ***Tools*** →***General Settings***.
4	Select the relevant accessory from the ***Active extension*** drop-down menu.



The options are:

- ***None***
- ***Flowstar V MUX***
- ***AquaWIT V***
- ***AquaWIT V MUX***
- ***AquaWIT V Flush Set***

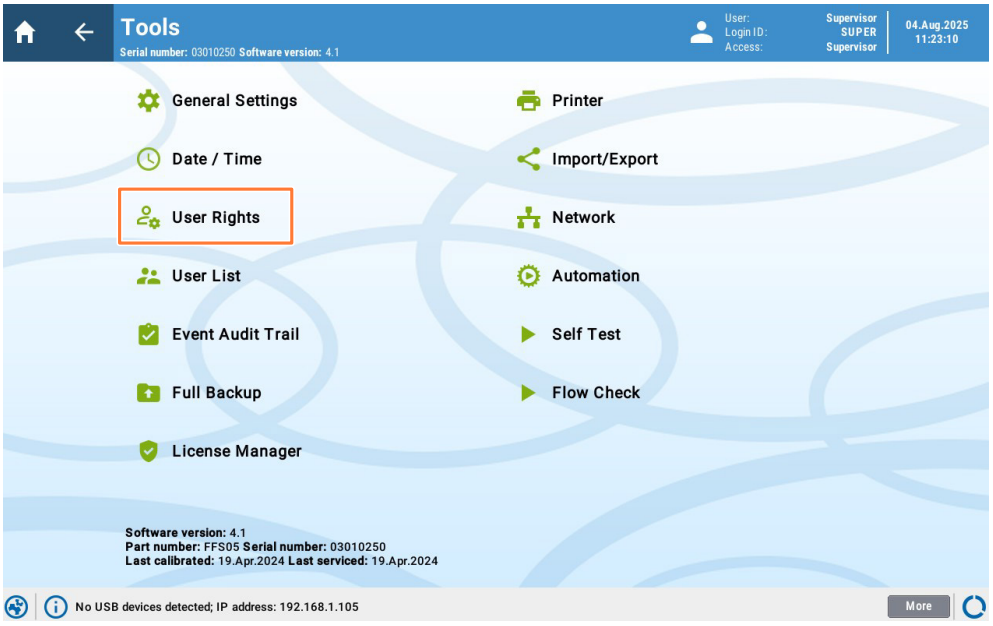
5.4.2 Set up access management

Access management is used to make sure that the instrument can only be operated by trained and authorized users.

Set up user rights

Follow the steps below to set up the user rights and user password requirements.

Step	Action
1	Log in with an ***Administrator*** or ***Super-admin*** account.
2	Go to ***Tools*** →***User Rights***.

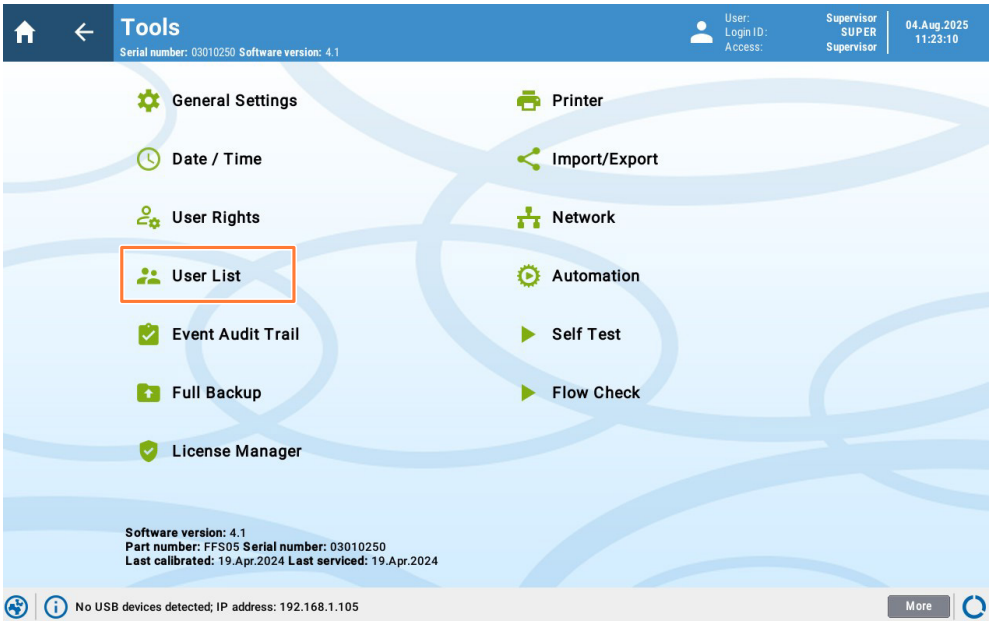
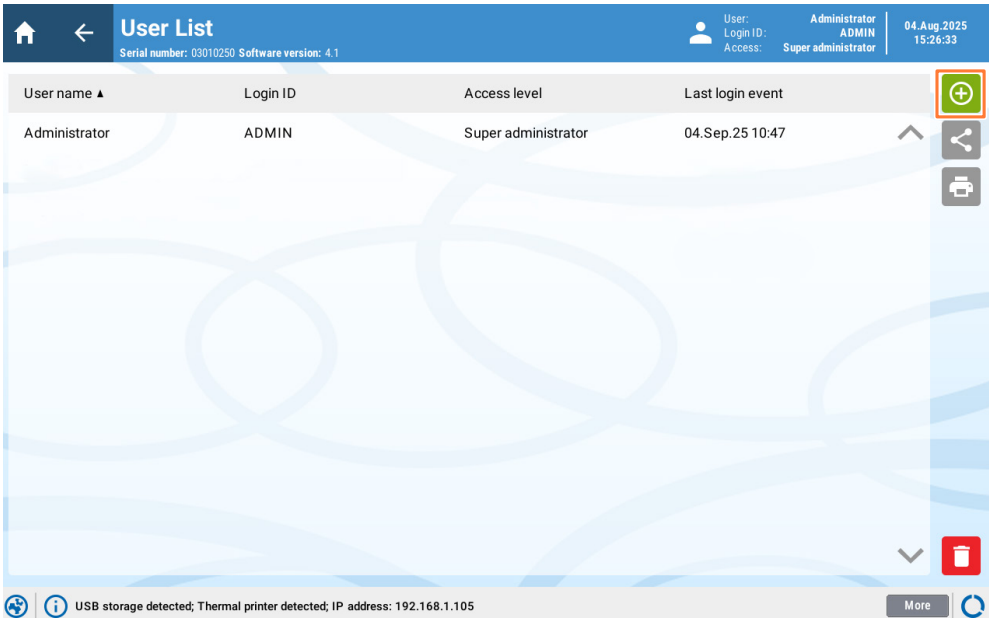


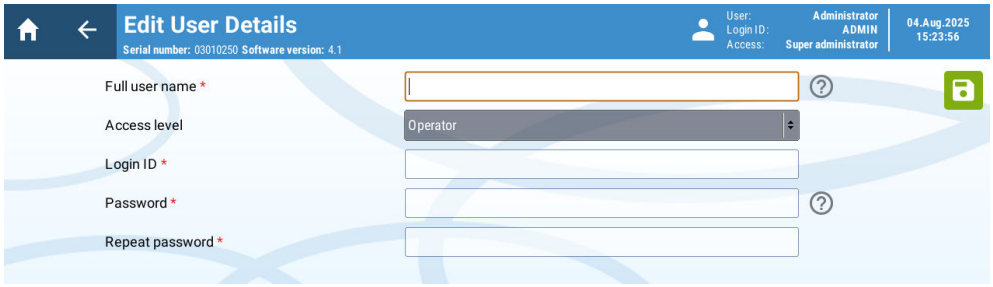
Step	Action
3	Set the ***User Rights*** parameters.  ***Tip:*** *To enable high level access control for compliance with 21 CFR Part 11, set the parameter* ***Individual user login*** *to* ***On****.* See *Section 4.2.3 User rights settings, on page 58* for a description of the ***User Rights*** parameters.

To create user accounts, see *Create a user, on page 117*.

Create a user

If high level access control is enabled, follow the steps below to create a user account.

Step	Action
1	Log in with an ***Administrator*** or ***Super-admin*** account.
2	Go to ***Tools*** →***User List***. 
3	Tap the  button. 

Step	Action
4	Set the user account parameters.  See *Section 4.2.4 User list settings, on page 62* for a description of the ***User List*** parameters. ***Note:*** *Make sure that the new user account has the correct authority level. If necessary, make sure that the new user account can electronically sign test records. See Section 4.4.2 User authority levels, on page 85 for a description of the available user authority levels.*
5	Tap the button.

IMPORTANT

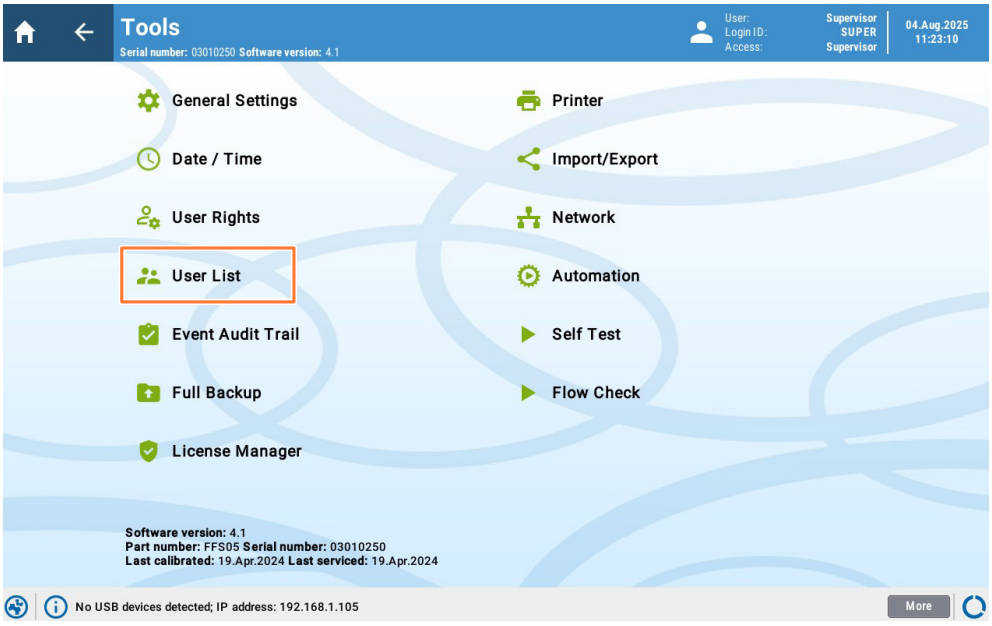
Security risk. The default password must be changed immediately after the first login. The default password is intended to be temporary.

Edit a user

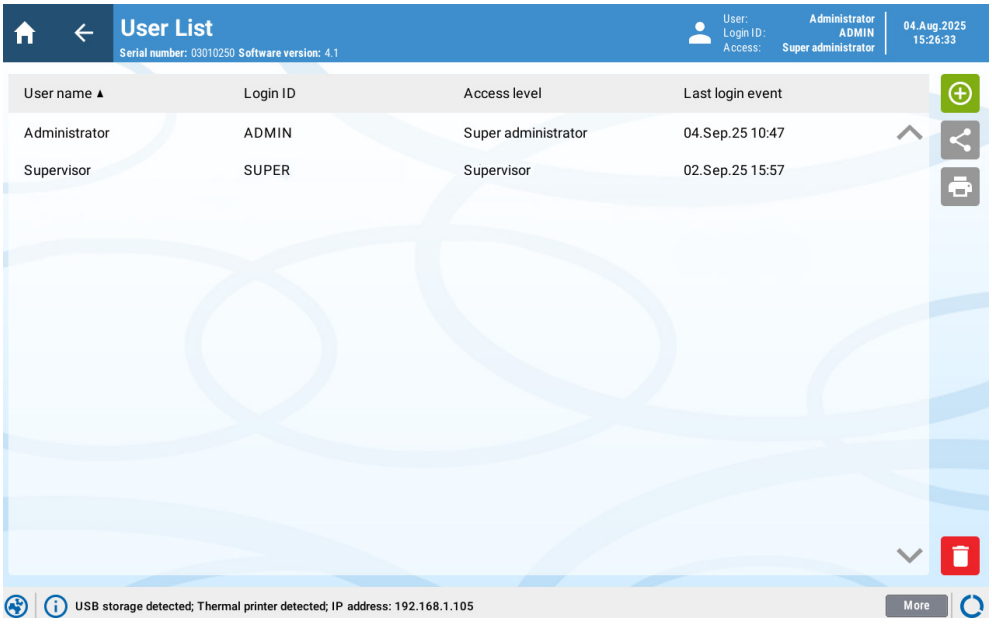
Follow the steps below to edit a user account.

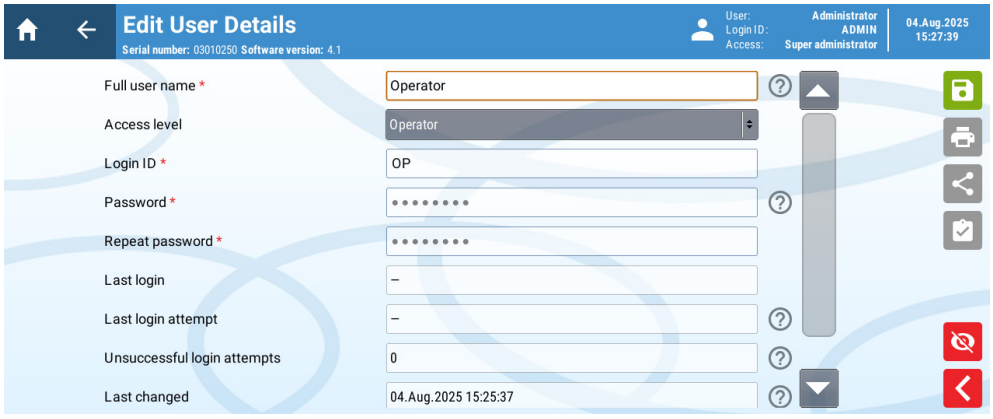
Step	Action
1	Log in with an ***Administrator*** or a ***Super-admin*** account.

Step	Action
2	Go to ***Tools*** →***User List***.



3	Tap the row with the relevant user account.

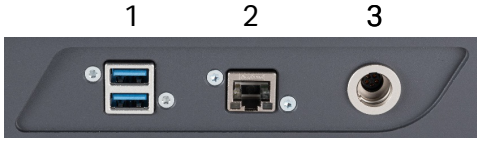
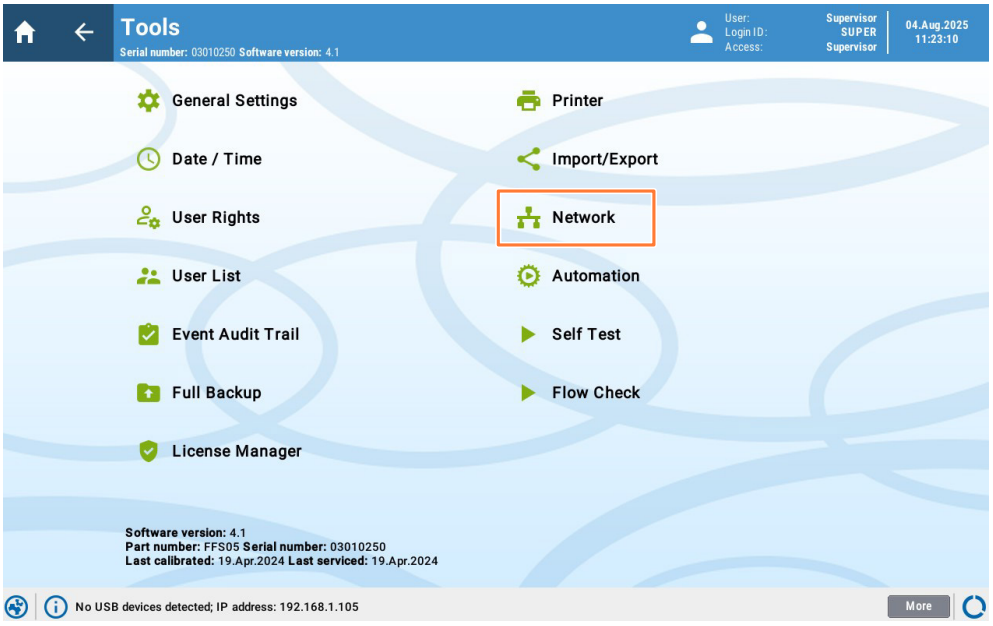


Step	Action
4	Adjust the user account parameters.  See *Section 4.2.4 User list settings, on page 62* for a description of the ***User List*** parameters. ***Note:*** *Make sure that the user account has the correct authority level. If necessary, make sure that the user account can electronically sign test records. See Section 4.4.2 User authority levels, on page 85 for a description of the available user authority levels.*
5	Tap the button.

5.4.3 Connect to a network location or a printer

Connect to a network

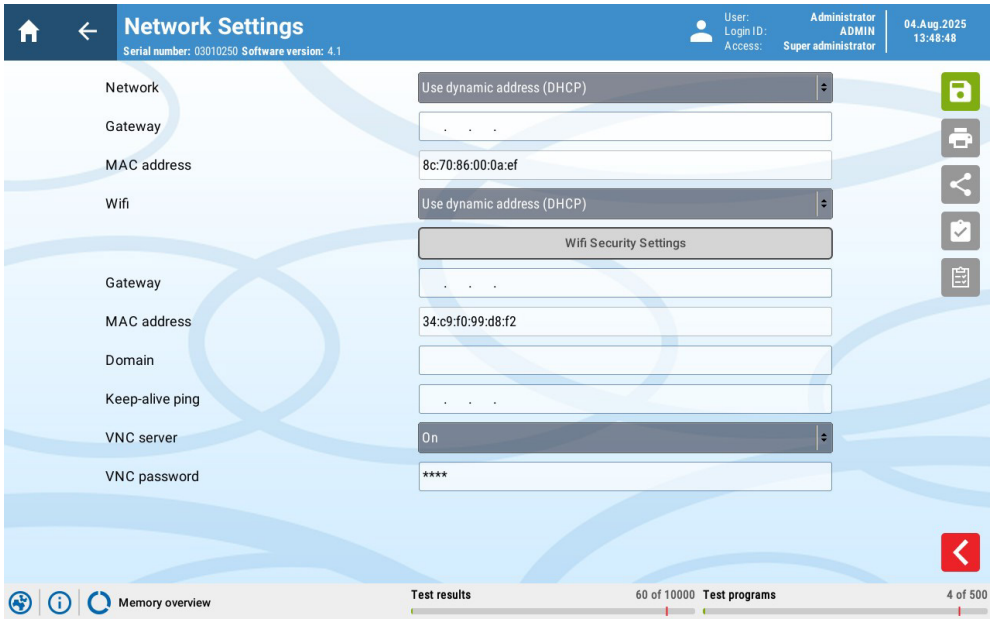
Follow the steps below to connect the instrument to a network.

Step	Action
1	Log in with an ***Administrator*** or a ***Super-admin*** account.
2	To connect to a wired network: **a.** Connect an Ethernet cable to the Ethernet port (2) on the right side of the instrument.  **b.** Make sure that the Ethernet cable is connected to the network.
3	Go to ***Tools*** →***Network***. 

Step	Action
4	Set ***Network*** to select the network type.

Network type	Action
Wired network	a. Set the ***Network*** setting to: • ***Use static address*** • ***Use dynamic address (DHCP)*** b. Set the ***Wifi*** setting to ***Off***.
Wireless network	a. Set the ***Network*** and the ***Wifi*** setting to: • ***Use static address*** • ***Use dynamic address (DHCP)*** b. Set the ***Wifi Security Settings***.

5 Set the other ***Network Settings*** parameters:

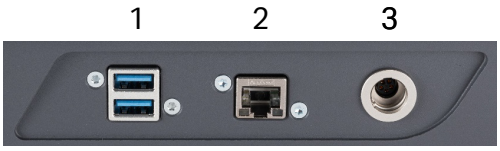


See *Section 4.2.7 Network settings, on page 68* for a description of the ***Network Settings*** parameters.

Connect printer

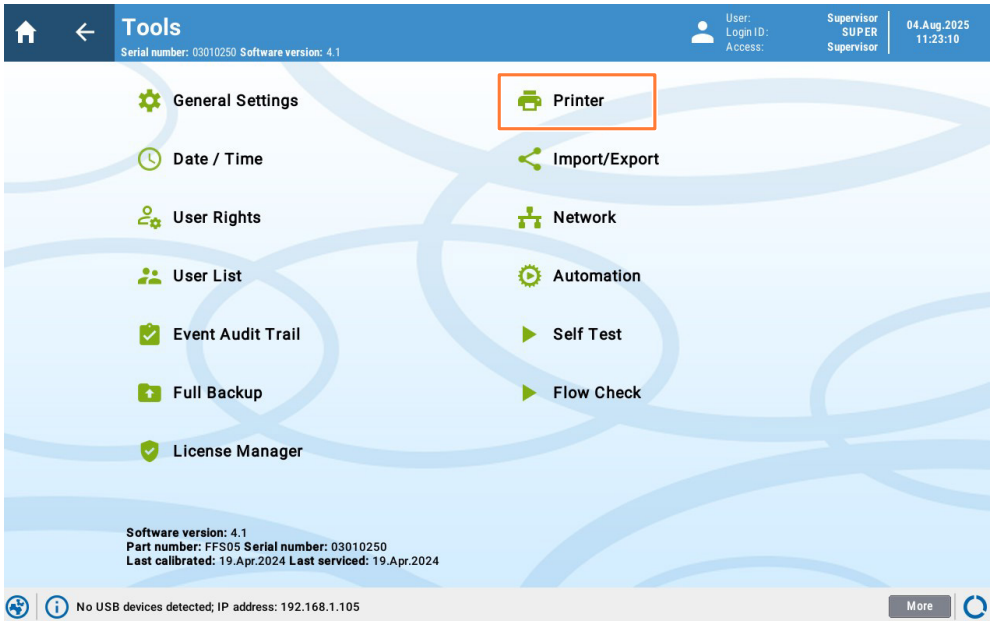
Follow the steps below to connect the instrument to the printer.

Step	Action
1	Log in with an ***Administrator*** or a ***Super-admin*** account.
2	Connect to a printer using one of the following options:



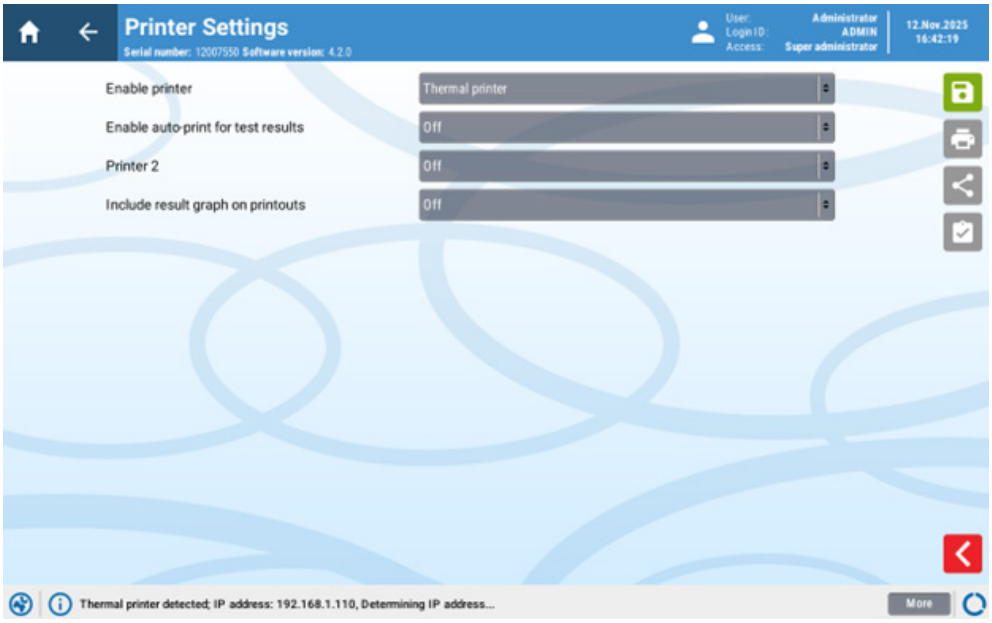
Printer type	Action
Flowstar V Printer	a. Connect the printer cable to the Flowstar V Printer. b. Connect the cable from the Flowstar V Printer to the printer port (3) on the right side of the instrument. ***Note:*** *For detailed instructions, refer to the Flowstar V Printer Instructions for Use (29750853).*
USB drive	Connect a USB drive to the USB port (1) on the right side of the instrument.
Network printer	a. Connect an Ethernet cable to the Ethernet port (2) on the right side of the instrument. b. Make sure that the Ethernet cable is connected to the network. c. Set up the network settings for the network printer in *step 5* . ***Note:*** *A network printer must be capable of handling one of the following printer languages:* • *PCL4 or higher* • *PostScript*

Step	Action
3	Go to ***Tools*** →***Printer***.



4	Set ***Enable printer*** to select the printer type.

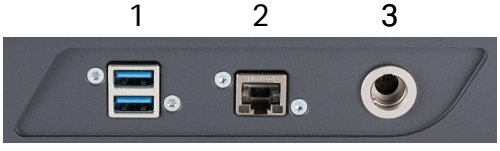
Printer type	Option
Flowstar V Printer	***Thermal printer***
USB printer	***USB***
Network printer	***Network***

Step	Action
5	Set the other ***Printer Settings*** parameters.  See *Section 4.2.5 Printer settings, on page 63* for a description of the ***Printer Settings*** parameters.

To create a printout, see *Section 7.8.3 Create a printout, on page 238*.

Connect a second printer

Files can be printed on two printers at the same time. Follow the steps below to connect the instrument to a second printer.

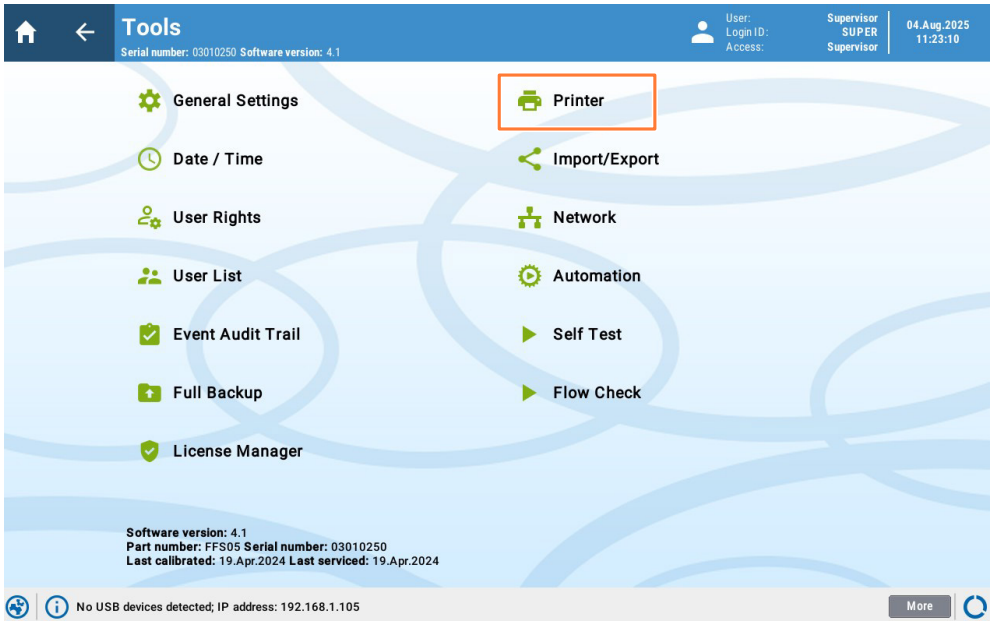
Step	Action
1	Log in with an ***Administrator*** or a ***Super-admin*** account.
2	Connect to a printer using one of the following options: 

Printer type	Action
USB drive	Connect a USB drive to the USB port (1) on the right side of the instrument.

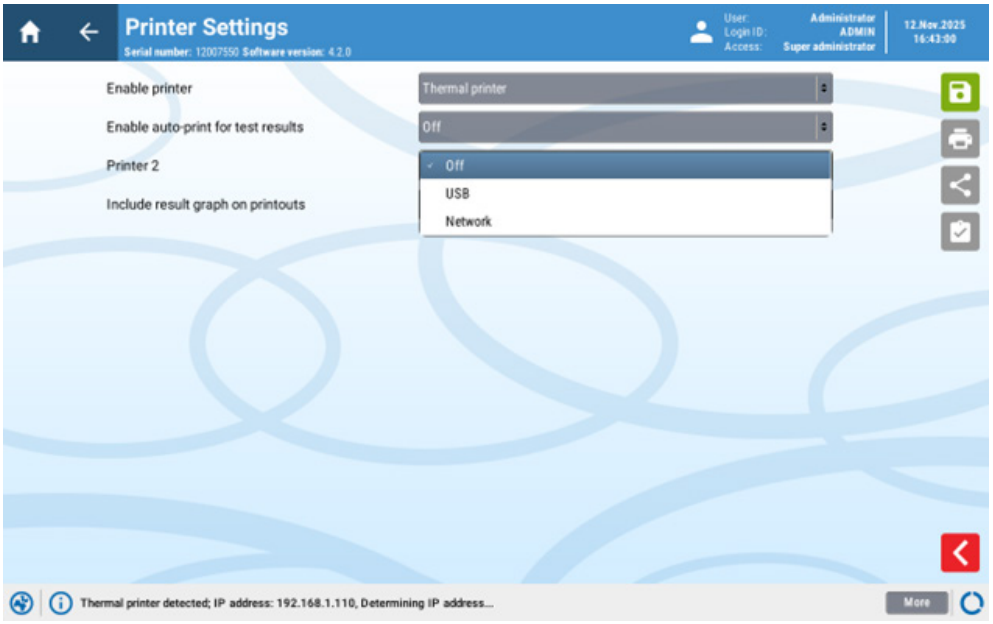
Step	Action

Printer type	Action
Network printer	a. Connect an Ethernet cable to the Ethernet port (2) on the right side of the instrument. b. Make sure that the Ethernet cable is connected to the network. c. Set up the network settings for the network printer in *step 5* . ***Note:*** *A network printer must be capable of handling one of the following printer languages:* • *PCL4 or higher* • *PostScript*

3 Go to ***Tools*** →***Printer***.

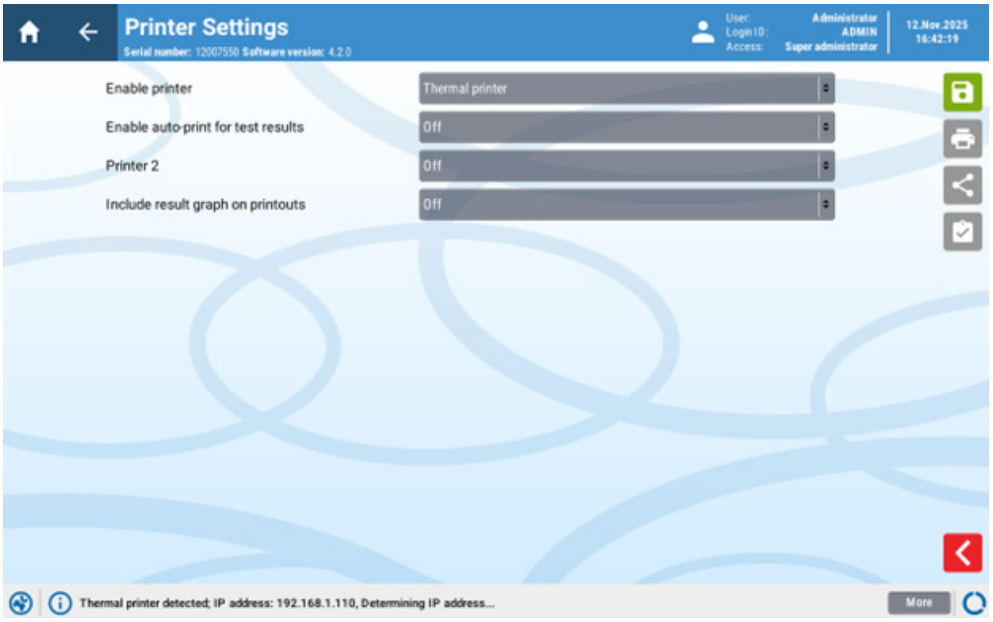


Step	Action
4	Set ***Printer 2*** to ***USB*** or ***Network***.



Result:
The second printer is enabled.

5	Set the other ***Printer Settings*** parameters.



See *Section 4.2.5 Printer settings, on page 63* for a description of the ***Printer Settings*** parameters.

To create a printout, see *Section 7.8.3 Create a printout, on page 238*.

5.4.4 Remote control

Introduction

This section gives a brief overview of the available remote control systems that can be used with the instrument. It also describes how to start setting up the software for remote control and set up of virtual network computing.

Remote control and data logging

The available remote control systems are briefly described in the table below.

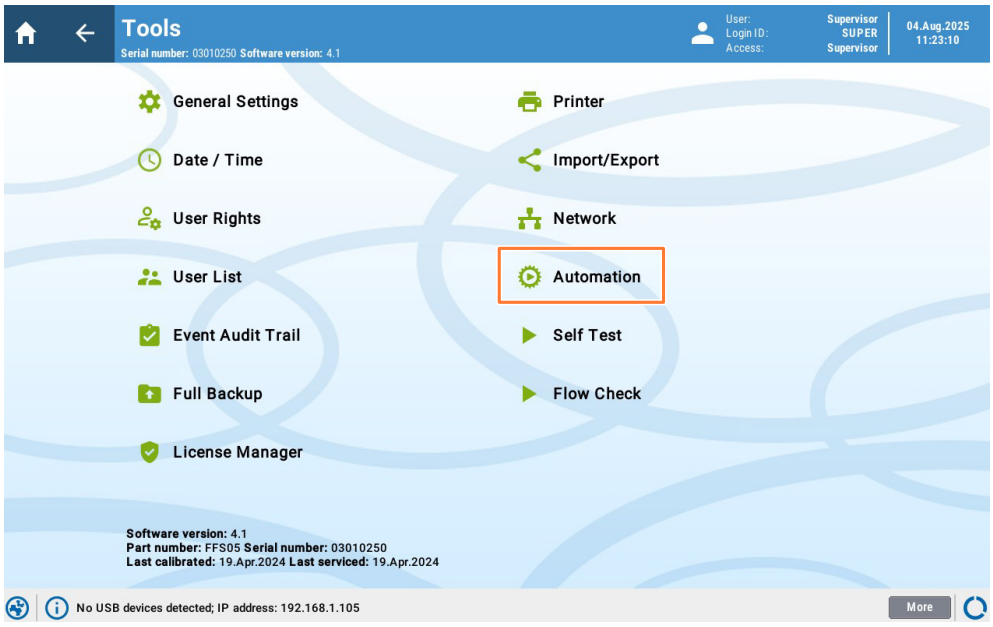
Remote control type	Description
DMS Pro	The Data Management System (DMS) Pro software can be used to set up test programs, data synchronization, data backup, date and time synchronization, and domain authentication. Requires a DMS Pro license. For more information, refer to *Pall-tronic Flowstar V Instrument Data Management System (DMS) Pro User Manual (USD3925)*.
LDAP	The Lightweight Directory Access Protocol (LDAP) can be used to set up domain authentication. For more information, refer to *Domain authentication using Lightweight Directory Access Protocol (LDAP) Instructions for Use (USD3922)*. ***Note:*** *It is not possible to create user accounts on the instrument, when the instrument is connected to Active Directory.*
OPC UA	The Open Platform Communications Unified Architecture (OPC UA) can be used to set up remote control for starting and monitoring tests, as well as data logging. For more information, refer to *Remote control of filter integrity test instruments using the OPC UA server Instructions for Use (USD3923)*.
PAS-X	The PAS-X manufacturing execution system can be used to set up remote control and data logging. Requires a PAS-X license. For more information, refer to *PAS-X for Flowstar V User Manual (29741432)*.

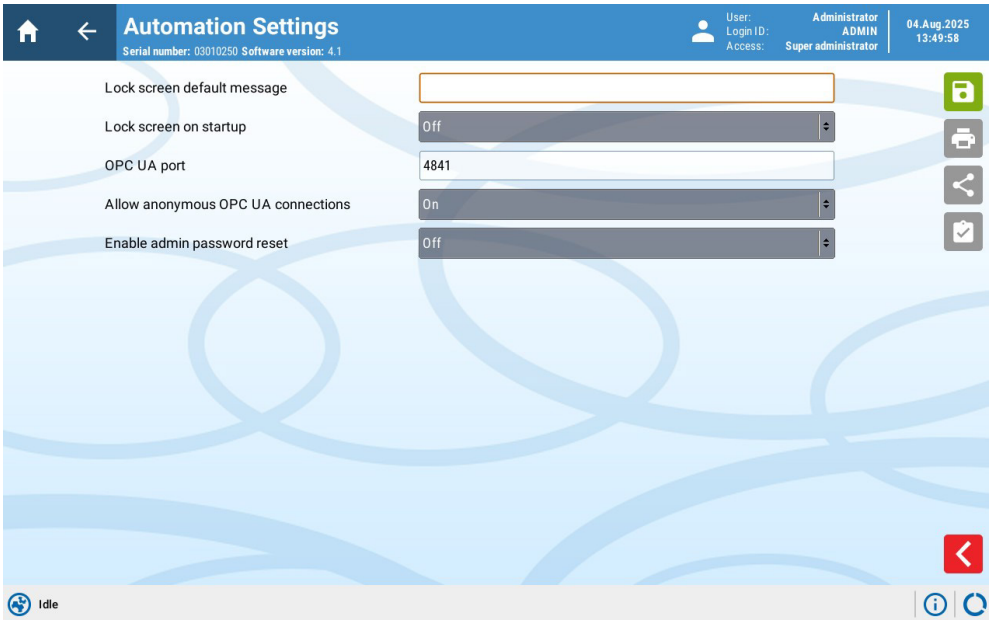
Remote control type	Description
PROFIBUS	The PROFIBUS protocol enables a standardized fieldbus for industrial communication between the instrument and a controller unit. It allows the user to set up remote control for starting tests, as well as data logging. Test results can be stored together with parameters of the tested assembly on a high-level Supervisory Control And Data Acquisition (SCADA) system to create an electronic batch record. Requires connecting the PROFIBUS adapter to a USB port on the right side of the instrument. For more information, refer to *Remote control of Flowstar V integrity test instrument using the PROFIBUS protocol Instructions for Use (USD3924)*.
PROFINET	The PROFINET protocol enables a standardized fieldbus for industrial communication between the instrument and a controller unit. It allows the user to set up remote control for starting tests, as well as data logging. Test results can be stored together with parameters of the tested assembly on a high-level SCADA system to create an electronic batch record. Requires connecting the PROFINET adapter to a USB port on the right side of the instrument. For more information, refer to *Remote control of Flowstar V integrity test instrument using the PROFINET protocol Instructions for Use (USD3934)*.
Serial automation	The serial automation protocol enables a standardized fieldbus for industrial communication between the instrument and a controller unit. It allows the user to set up remote control for starting tests, as well as data logging. Requires connecting the serial automation adapter to a USB port on the right side of the instrument. For more information, refer to *Remote control of Flowstar V integrity test instrument using the serial automation protocol Instructions for Use (29875356)*.
VNC	Virtual network computing (VNC) can be used to set up remote control and data logging via an external computer. Requires a VNC license. VNC must be installed by Cytiva Service.

Set automation settings

Before starting to set up any type of remote control, follow the steps below to select the automation settings.

Step	Action
1	Log in with an ***Administrator*** or a ***Super-admin*** account.
2	If relevant, connect the remote control adapter to a USB port on the right side of the instrument.
3	Go to ***Tools*** →***Automation***.



Step	Action
4	Set the automation parameters.  See *Section 4.2.8 Automation settings, on page 70* for a description of the ***Automation*** parameters.

Refer to the respective user documentation for detailed instructions, see *Section 1.3 Associated documentation, on page 10*.

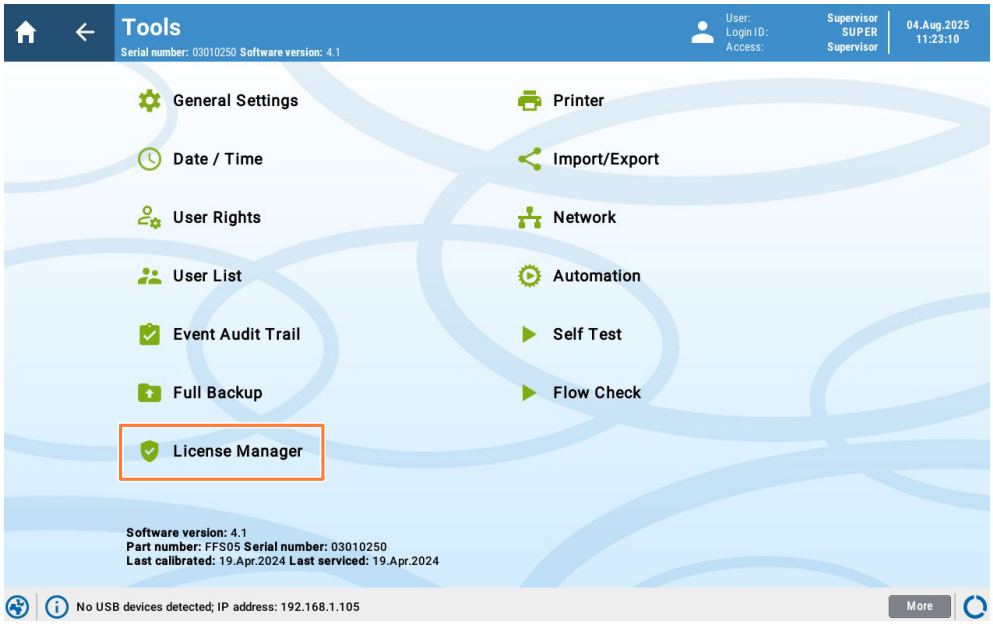
Set up licenses

Various software functionalities and external software that are used with the instrument requires a license. Examples are the DMS Pro software, the PAS-X software, and the Flowstar V LGR upgrade. Request a license key from Cytiva to enable the software on the instrument.

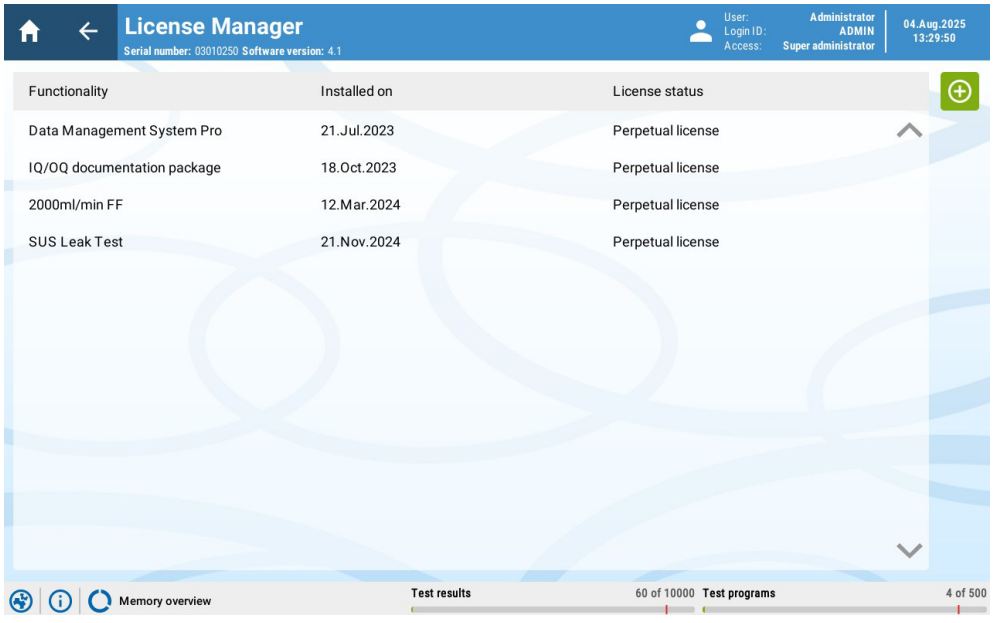
Follow the steps below to set up a software license.

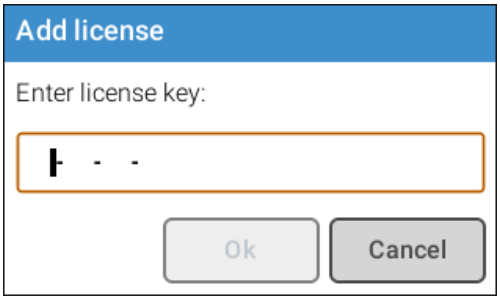
Step	Action
1	Log in with a ***Super-admin*** account.
2	Insert the USB drive with the license key into one of the USB ports of the instrument.

Step	Action
3	Go to ***Tools*** →***License Manager***.



Step	Action
4	Tap the ⊕ button.



Step	Action
5	Type the 20-digit alphanumeric license key. 
6	Tap ***OK***. *Result:* The instrument verifies the license key. The verified license is added to the ***License Manager*** screen.
7	Restart the instrument.

Follow the instructions described in the manual of the selected remote control type.

5.5 Software configuration of a second instrument

About this section

This section describes the procedures performed by the administrator to transfer software settings to a second instrument.

In this section

5.5.1 Transfer of general settings

Introduction

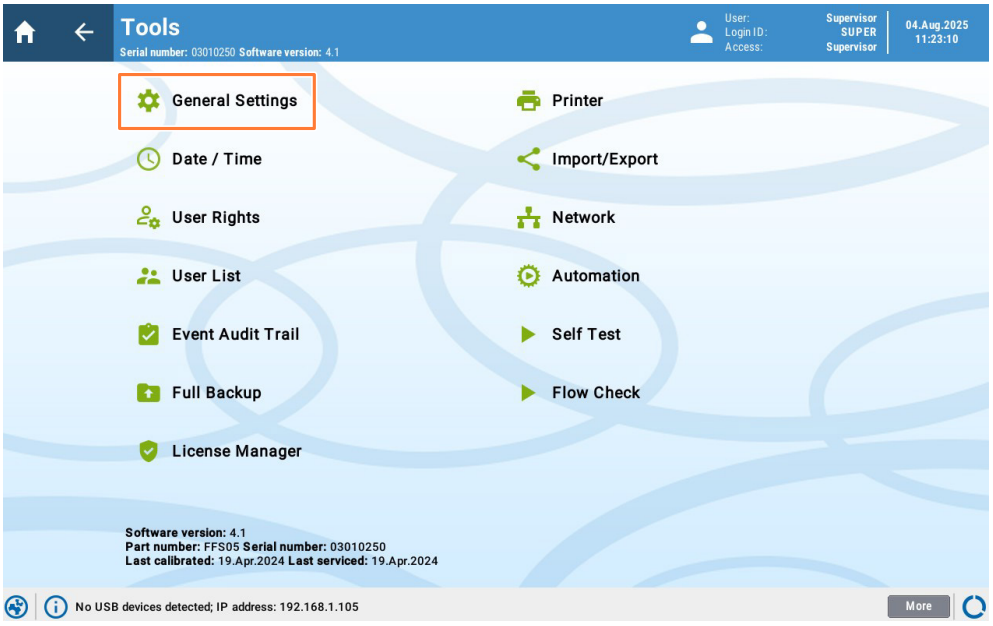
The software configuration can be transferred from one instrument to another instrument using a USB drive or using a network connection. This allows the user to configure instruments in the same way.

Export general settings

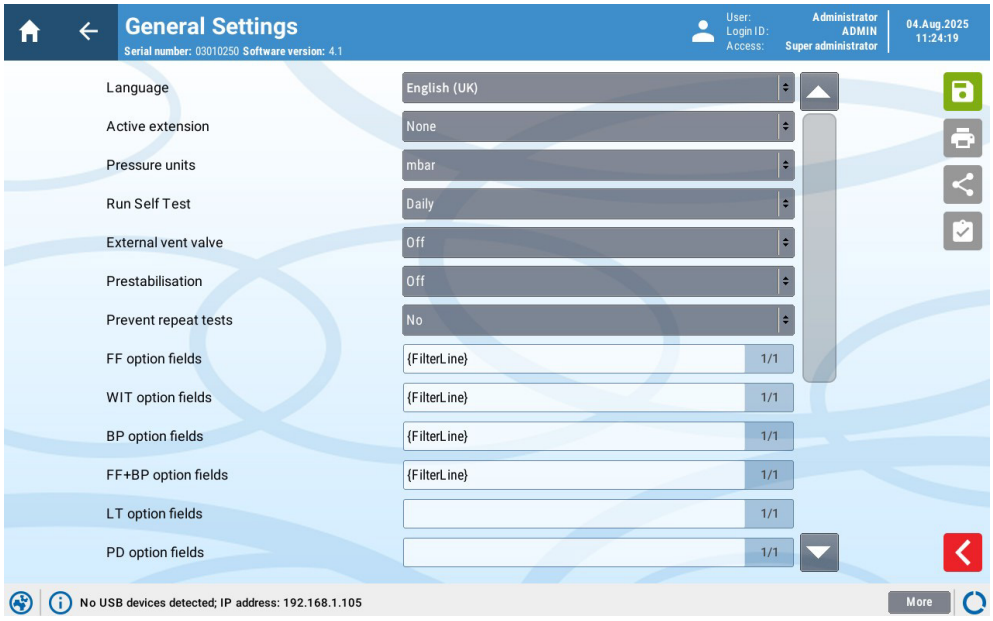
Note: *Make sure that the **Import/Export** settings are set up correctly. See Set import and export settings, on page 112.*

Follow the steps below to export the general settings .

Step	Action
1	Log in with an ***Administrator*** or ***Super-admin*** account.
2	• Connect a USB drive to one of the USB ports of the instrument. or • Make sure that the network is connected, as described in *Set import and export settings, on page 112*.
3	Go to ***Tools*** →***General Settings***.



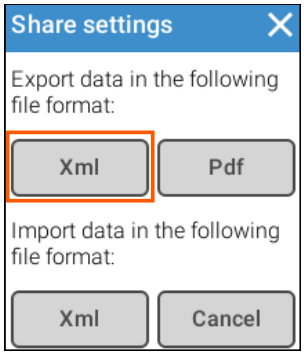
Step	Action
4	Tap the button.



Note:

Only the current version of the general settings are exported.

5 Select the ***XML*** file format for export.



Note:

*The general settings can be exported to **PDF** if they are not imported to another instrument.*

Result:

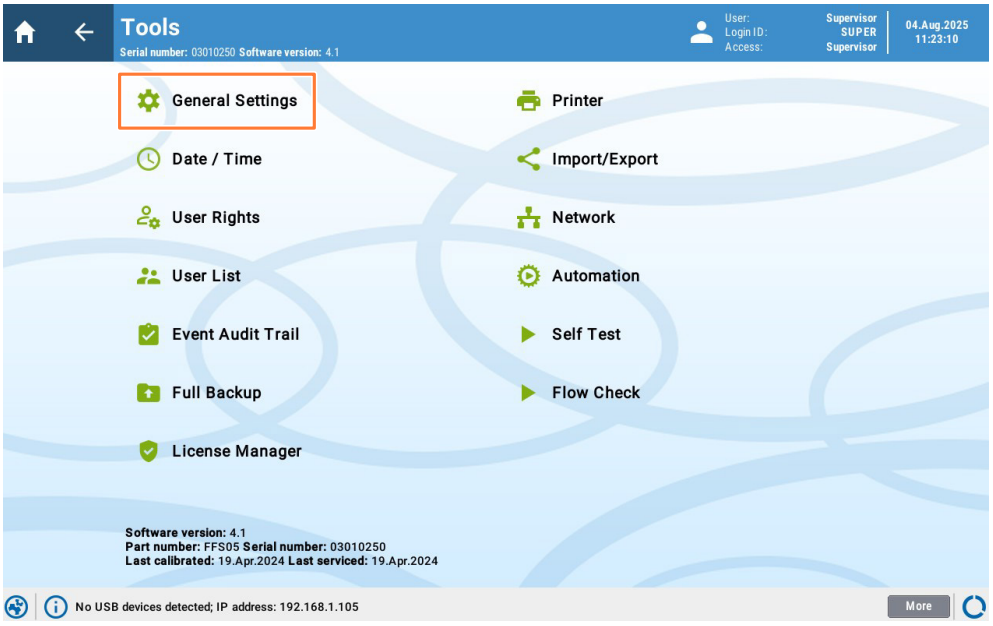
The general settings file is stored in a folder structure in the destination folder: `[FFS05 and instrument serial number]>[Date and time]`.

Import general settings

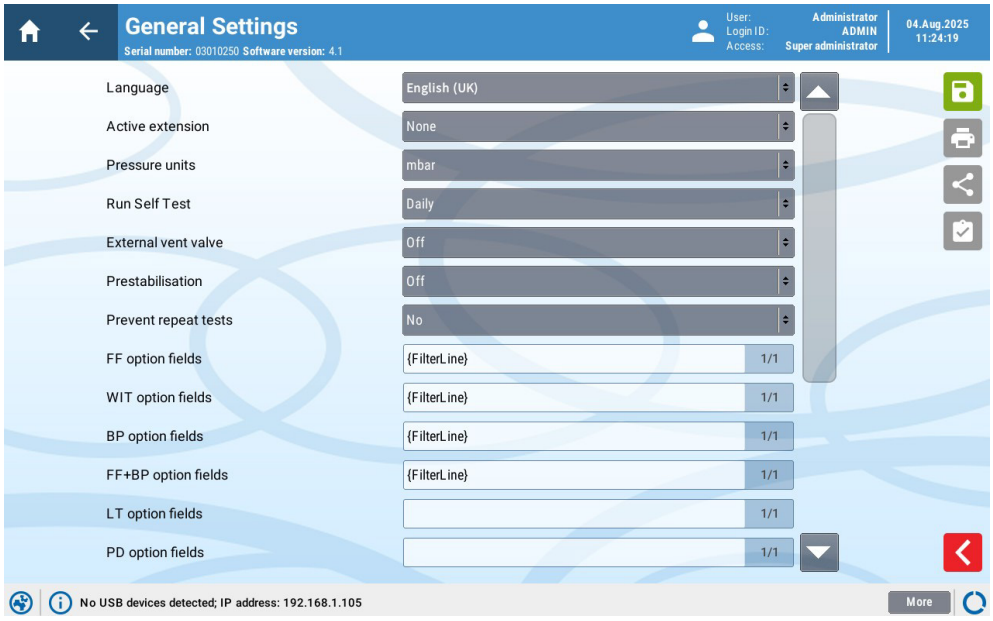
Note: *Make sure that the **Import/Export** settings are set up correctly. See Set import and export settings, on page 112.*

Follow the steps below to import the general settings from another instrument.

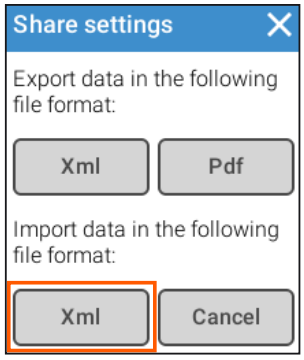
Step	Action
1	Log in with an ***Administrator*** or a ***Super-admin*** account.
2	• Connect a USB drive that contains a ***AllSettings.xxx*** file to one of the USB ports of the instrument. or • Make sure that the network is connected, as described in Set import and export settings, on page 112.
3	Go to ***Tools*** →***General Settings***.



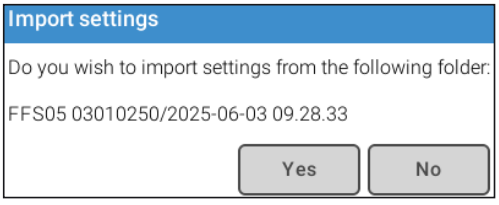
Step	Action
4	Tap the button.



5	Select ***XML*** as file format for import.



6	Tap ***Yes***.



Note:

The imported file overwrites a file with the same file name on the instrument.

5.5.2 Transfer of test programs

Introduction

The test programs can be transferred from one instrument to another instrument using a USB drive or with the DMS Pro software over a network connection. This allows the user to configure instruments in the same way.

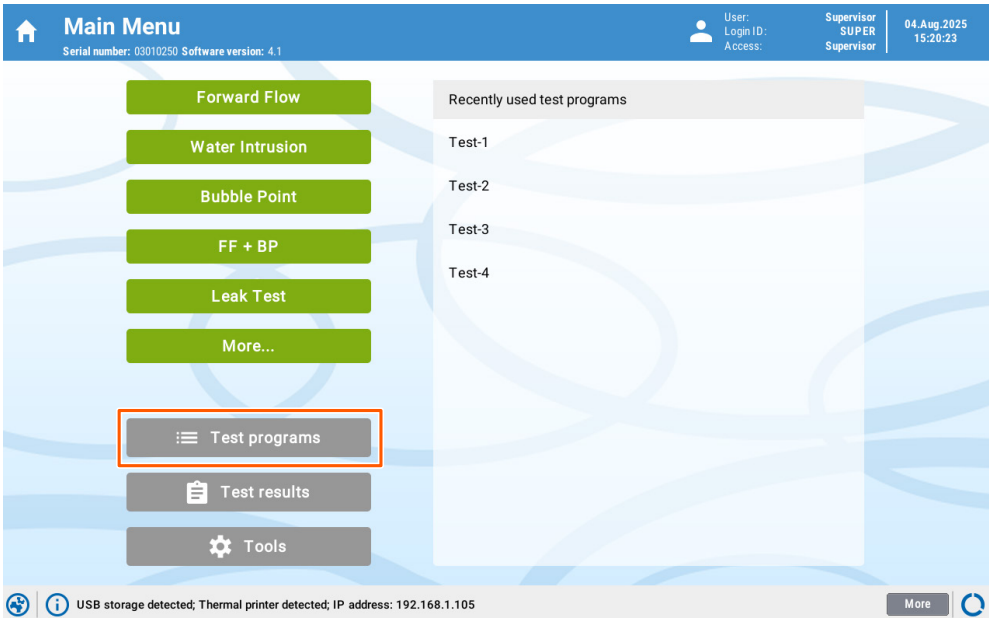
Transfer of test programs with the DMS Pro software is not described in this section. For more information, refer to the *User Manual (USD3925)* of the DMS Pro software.

Export a test program

Note: *Make sure that the **Import/Export** settings are set up correctly. See Set import and export settings, on page 112.*

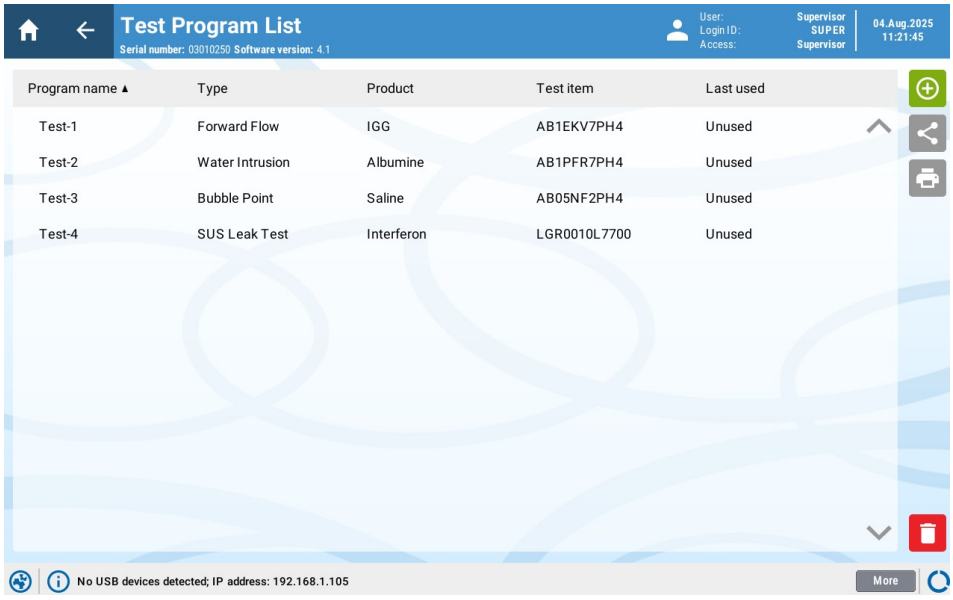
Follow the steps below to export a test program.

Step	Action
1	Log in with a ***Supervisor*** account, or if enabled, an ***Administrator***, or a ***Super-admin*** account.
2	• Connect a USB drive to one of the USB ports of the instrument. or • Make sure that the network is connected, as described in *Set import and export settings, on page 112*.
3	Tap ***Test Programs***.

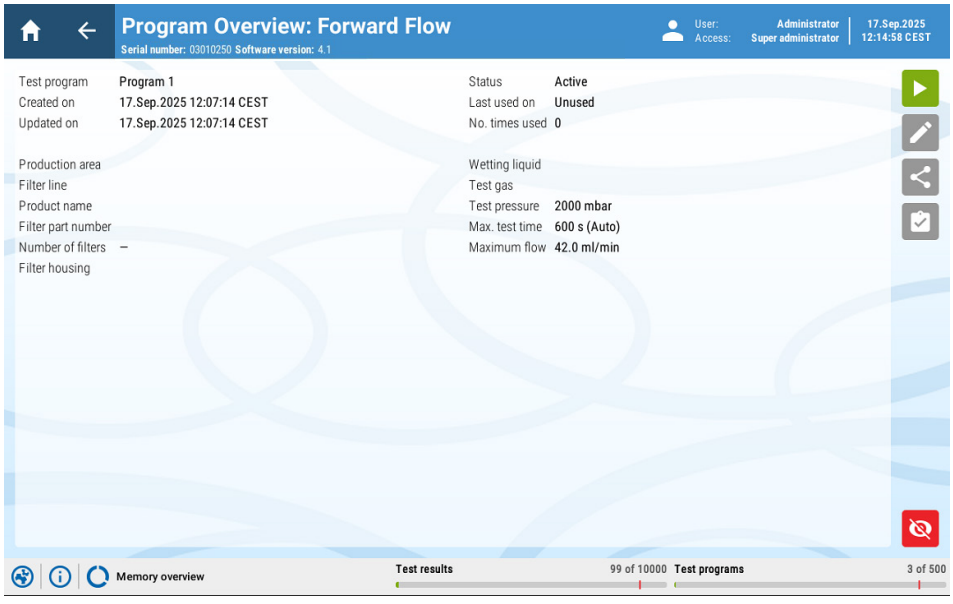


Step	Action
4	To export one test program:

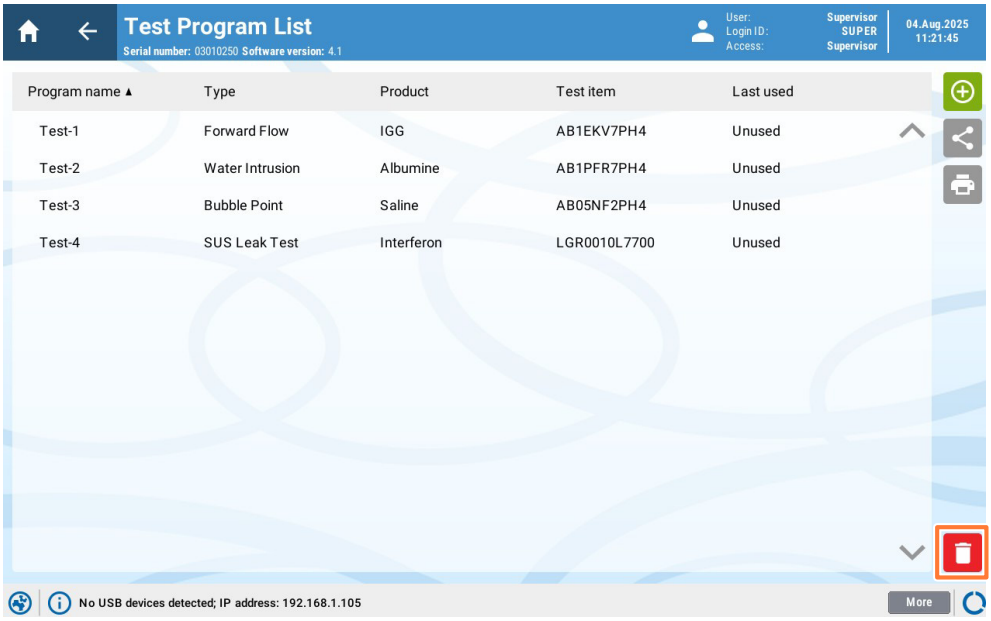
a. Tap the row with the relevant test program.



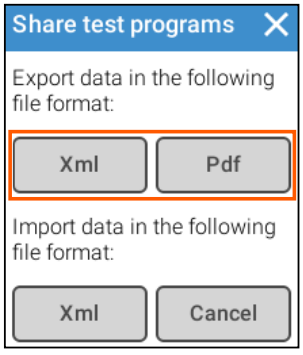
b. Tap the button.



Step	Action
5	To export all test programs: Tap the  button.



6	Select the file format for export (***PDF*** or ***XML***).



Note:

Only the current version of the test programs are exported.

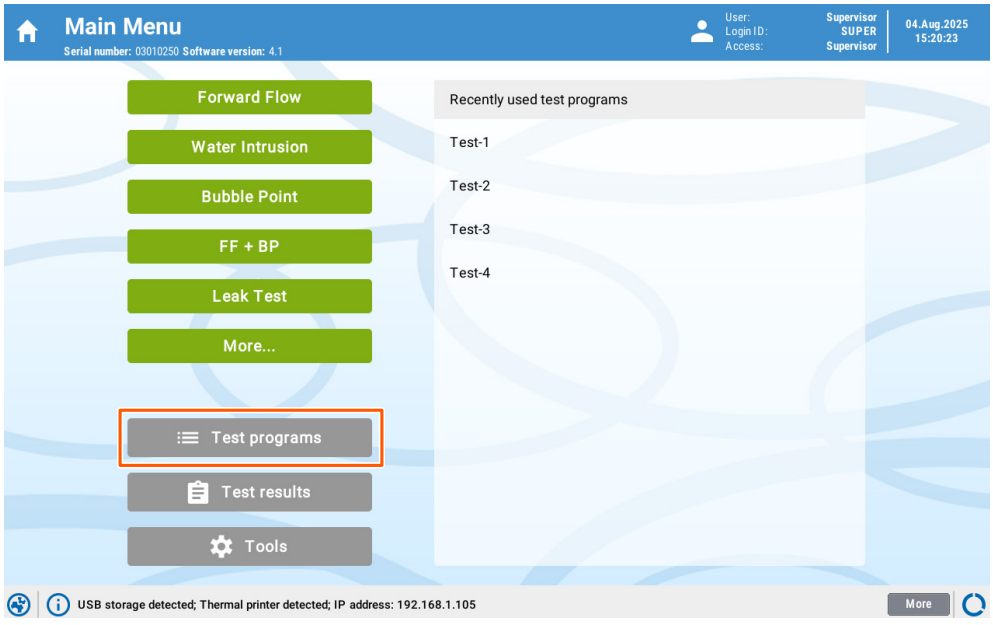
7	Select the target folder, and then tap ***Yes***. *Result:* The file is stored in a folder structure in the destination folder: `[FFS05 and instrument serial number]>[Date and time]>[Test Programs]`.

Import a test program

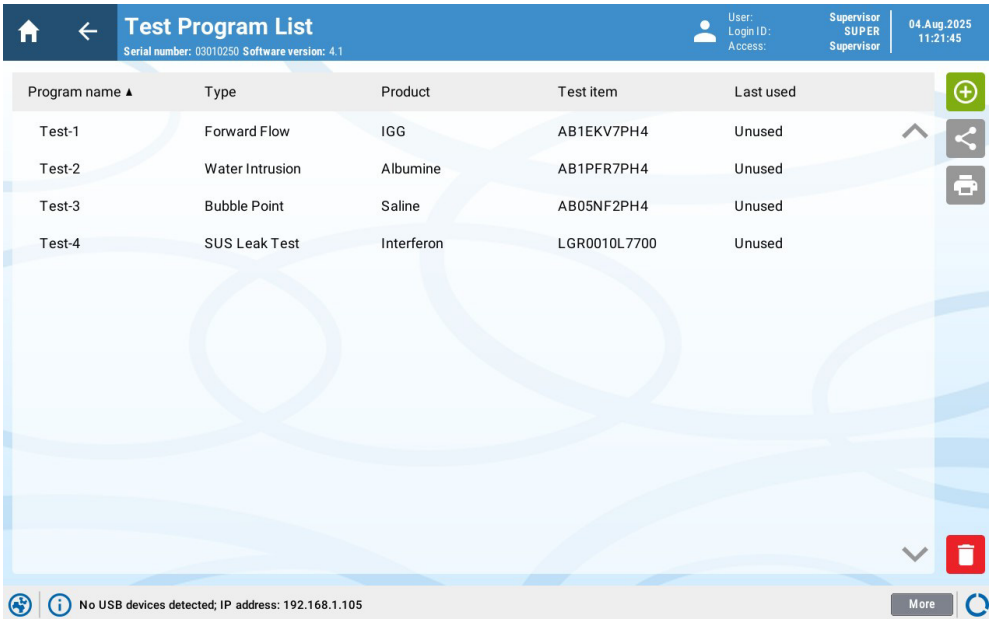
Note: *Make sure that the **Import/Export** settings are set up correctly. See Set import and export settings, on page 112.*

Follow the steps below to import a test program.

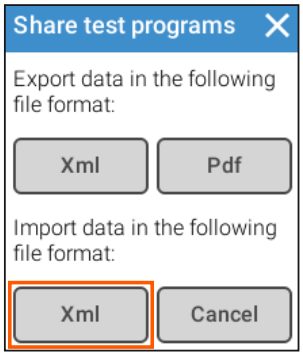
Step	Action
1	Log in with a ***Supervisor*** account, or if enabled, an ***Administrator***, or a ***Super-admin*** account.
2	• Connect a USB drive that contains a Flowstar V test program to one of the USB ports of the instrument. or • Make sure that the network is connected, as described in Set import and export settings, on page 112.
3	Tap ***Test Programs***.



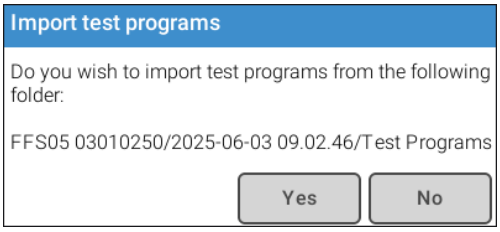
Step	Action
4	Tap the button.



5	Select ***XML*** as file format for import.



6	Tap ***Yes***.



Note:

The imported file overwrites a file with the same file name on the instrument.

Import a test program from Flowstar IV

The table below describes the compatibility of test programs from previous versions of Cytiva filter integrity products with the Flowstar V instrument. Compatible test programs can be imported and run on the Flowstar V instrument. Incompatible test programs cannot be imported to the Flowstar V instrument.

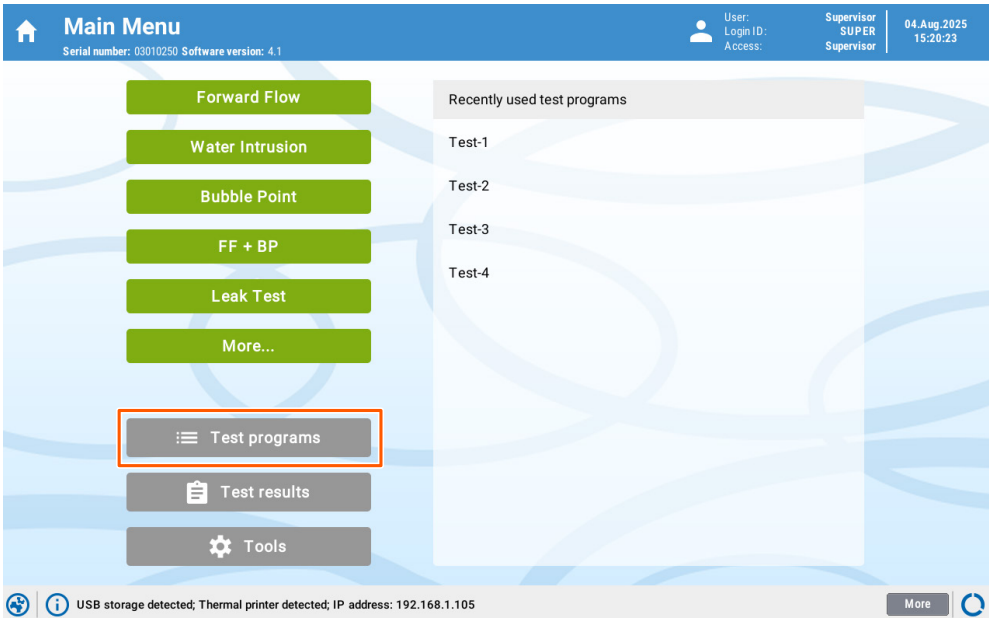
Instrument	Compatibility
AquaWIT IV	✗
Flowstar IV	✓
Flowstar IV LGR	✗

Note: *Make sure that the **Import/Export** settings are set up correctly. Set **FFS04 program transport** to **On**. See Set import and export settings, on page 112.*

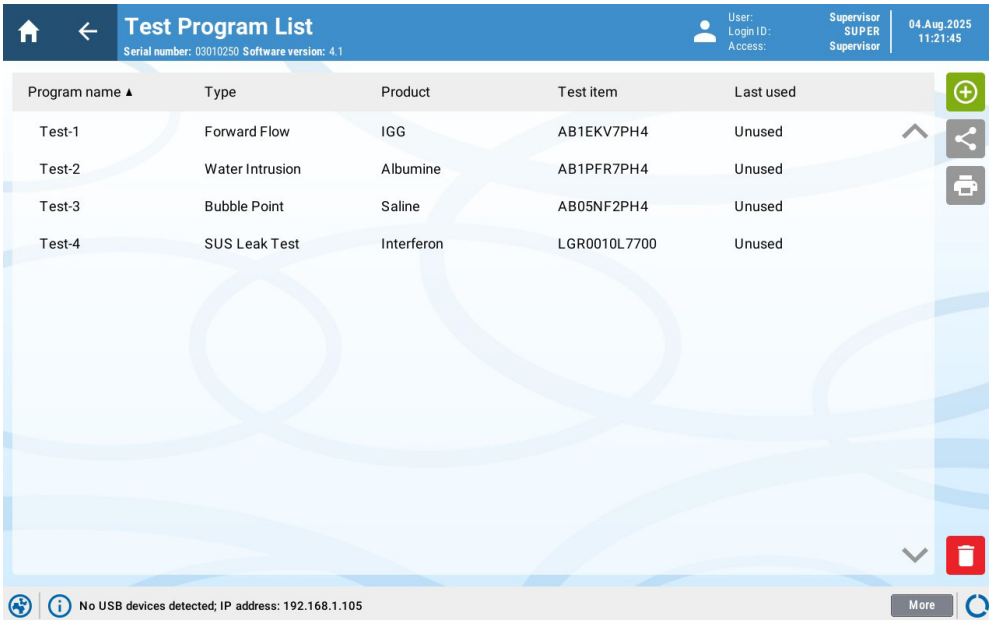
Follow the steps below to import a test program from the Flowstar IV instrument.

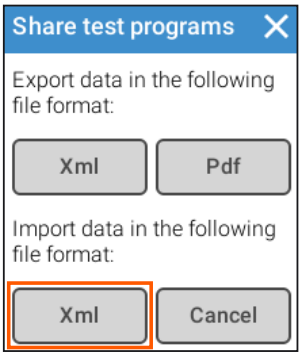
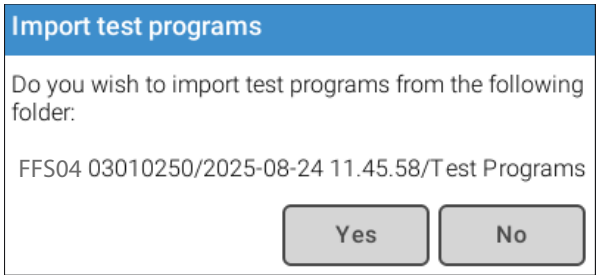
Step	Action
1	Log in with a ***Supervisor*** account, or if enabled, an ***Administrator***, or a ***Super-admin*** account.
2	Connect to the location of the Flowstar IV test program: • Connect the USB drive (containing a Flowstar IV test program) to one of the USB ports of the Flowstar V instrument. or • Connect to the network location with the Flowstar IV test program, as described in *Set import and export settings, on page 112*.

Step	Action
3	Tap ***Test Programs***.



4	Tap the  button.



Step	Action
5	Select ***XML*** as file format for import. 
6	Tap ***Yes***.  ***Note:*** *The imported file overwrites a file with the same file name on the instrument.*

5.5.3 Transfer of user list

Introduction

The complete user list can be transferred from one instrument to another instrument, using a USB drive or through a network connection. This allows the user to configure instruments in the same way.

Transferring the user list includes the following values for users of level 1 to 4 (e.g., ***Operator***, ***Automation operator***, ***Supervisor***, ***Administrator***, ***Super-administrator***):

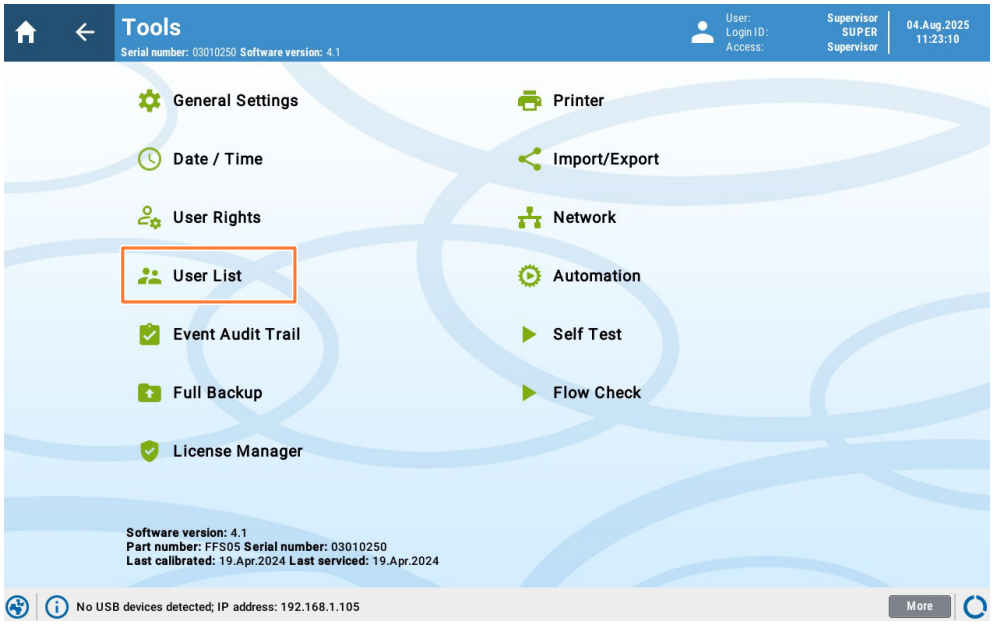
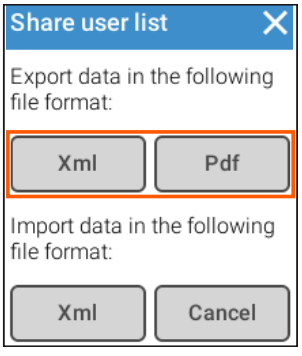
- ***Name***
- ***UserID***
- ***Password***
- ***Password expiration***

Export a user list

Note: *Make sure that the **Import/Export** settings are set up correctly. See Set import and export settings, on page 112.*

Follow the steps below to export a user list.

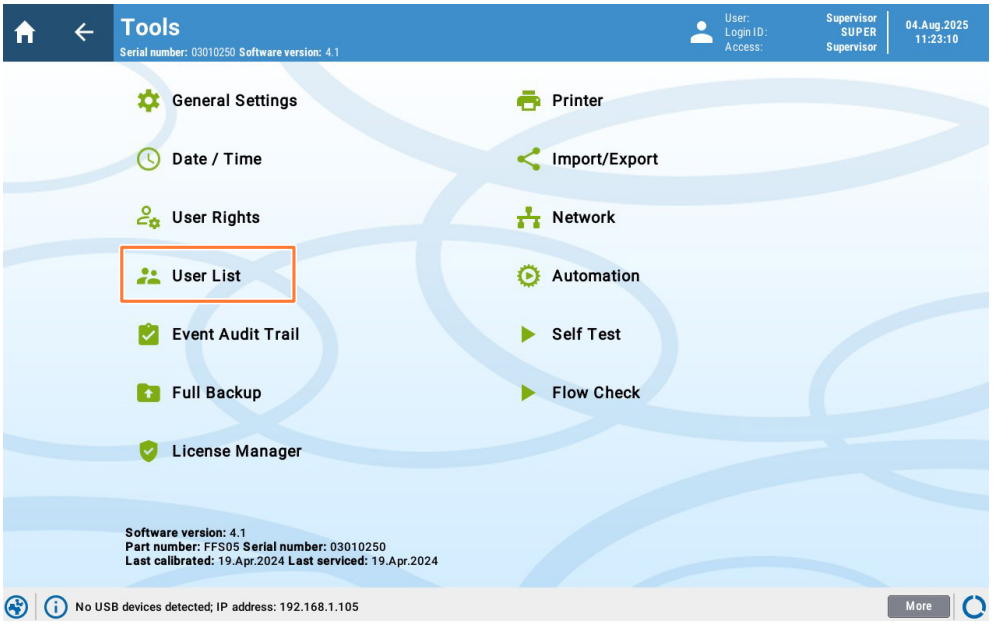
Step	Action
1	Log in with an ***Administrator*** or a ***Super-admin*** account.
2	• Connect a USB drive to one of the USB ports on the instrument. or • Make sure that the network is connected, as described in *Set import and export settings, on page 112*.

Step	Action
3	Go to ***Tools*** →***User List***. 
4	Tap the  button. ***Note:*** *Only the current version of the user list is exported.*
5	Select the file format for export (***PDF*** or ***XML***).  *Result:* The file is stored in a folder structure in the destination folder: `[FFS05 and instrument serial number]>[Date and time][Users]`.

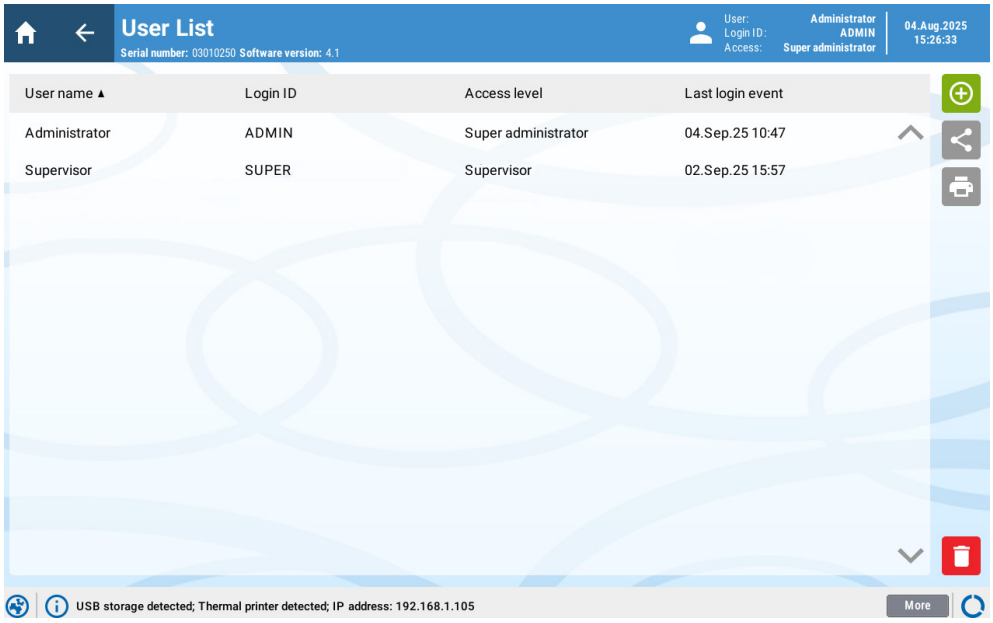
Import a user list

Note: *Make sure that the **Import/Export** settings are set up correctly. See Set import and export settings, on page 112.*

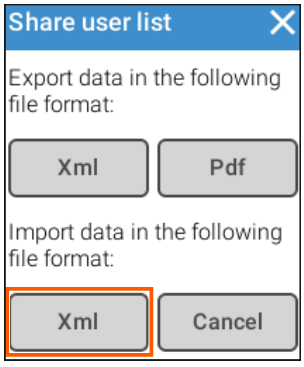
Follow the steps below to import a user list.

Step	Action
1	Log in with an ***Administrator*** or ***Super-admin*** account.
2	• Connect a USB drive that contains a user list file to one of the USB ports of the instrument. or • Make sure that the network is connected, as described in Set import and export settings, on page 112.
3	Go to ***Tools*** →***User List***. 

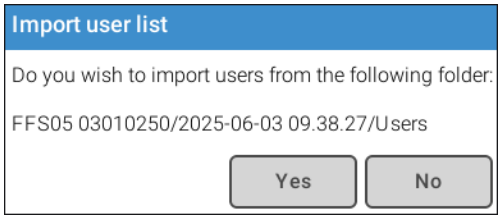
Step	Action
4	Tap the button.



5	Select ***XML*** as file format for import.



6	Tap ***Yes***.



Note:

The imported file overwrites a file with the same file name on the instrument.

5.5.4 Transfer of user rights

Introduction

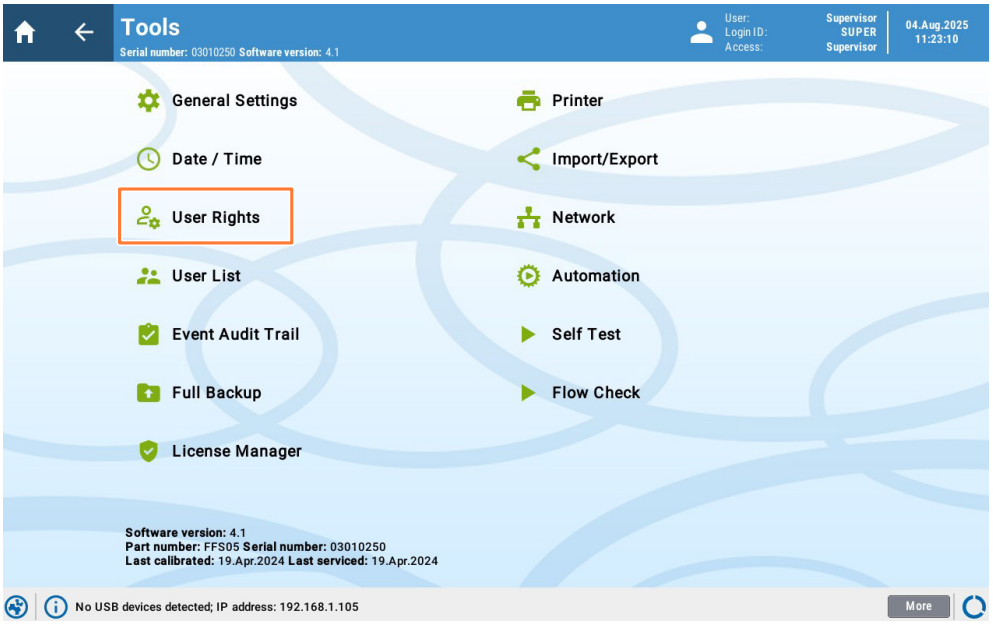
The user rights can be transferred from one instrument to another instrument using a USB drive, a network connection, or by using the DMS Pro software. This allows the user to configure instruments in the same way.

Export user rights

Note: *Make sure that the **Import/Export** settings are set up correctly. See Set import and export settings, on page 112.*

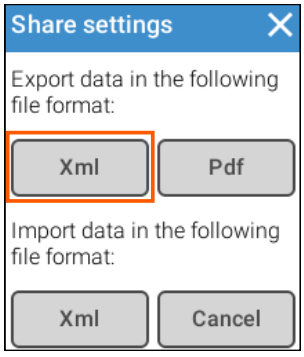
Follow the steps below to export the user rights.

Step	Action
1	Log in with an ***Administrator*** or a ***Super-admin*** account.
2	• Connect a USB drive to one of the USB ports of the instrument. or • Make sure that the network is connected, as described in Set import and export settings, on page 112.
3	Go to ***Tools*** →***User Rights***.



Step	Action
4	Tap the  button.

5	Select the file format for export (***PDF*** or ***XML***).



Note:

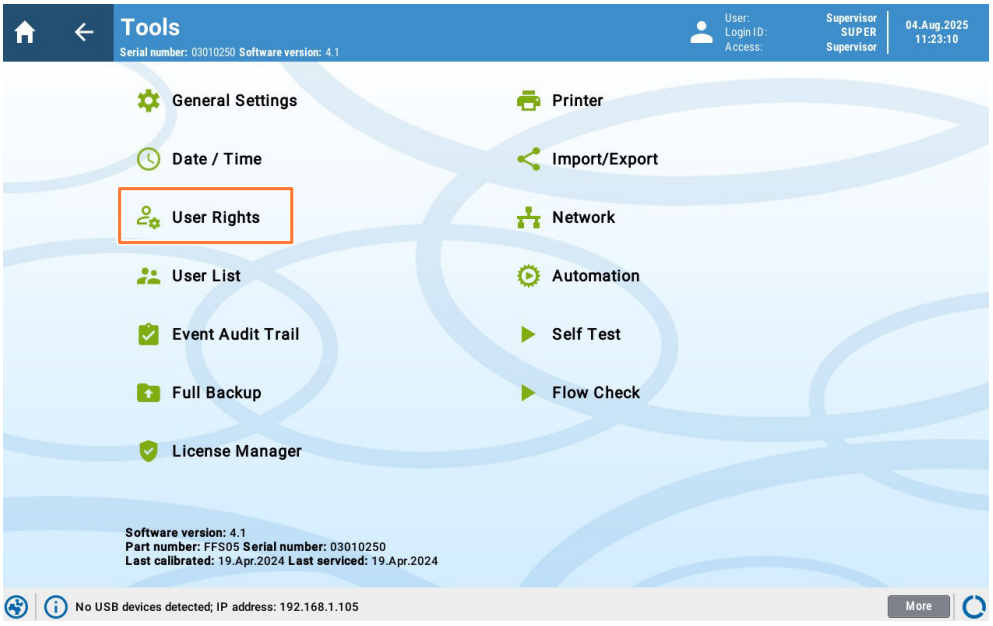
Only the current version of the user rights is exported.

Result:
The file is stored in a folder structure in the destination folder: `[FFS05 and instrument serial number]>[Date and time][User Rights].`

Import user rights

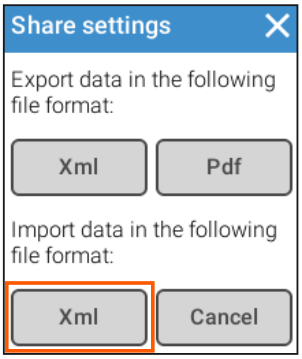
Note: *Make sure that the **Import/Export** settings are set up correctly. See Set import and export settings, on page 112.*

Follow the steps below to import the user rights.

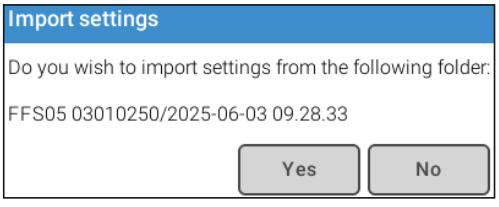
Step	Action
1	Log in with an ***Administrator*** or a ***Super-admin*** account.
2	• Connect a USB drive that contains a user rights file to one of the USB ports of the instrument. or • Make sure that the network is connected, as described in Set import and export settings, on page 112.
3	Go to ***Tools*** →***User Rights***. 

Step	Action
4	Tap the  button.

5	Select ***XML*** as file format for import.



6	Select the target folder to import from, then tap ***Yes***.



Note:

The imported file overwrites a file with the same file name on the instrument.

5.6 Moving the instrument

Introduction

This section provides instructions for moving the instrument within and between sites.

Safety precautions

WARNING

Transporting and moving the system must be performed by trained personnel, and must be performed in accordance with local regulations.

Before moving the instrument

Before moving the instrument, make sure that:

- All process wetted areas are clean and decontaminated.
- The power switch on the instrument is switched off.
- The power cord to the instrument is disconnected.
- All air supply lines to the instrument are disconnected.
- All communication cables to the instrument are disconnected.
- The new location fulfills the site requirements, see *Section 5.2 Site preparation, on page 95*.

Moving the instrument

NOTICE

Carefully transport the Flowstar V instrument. It is a sensitive measurement instrument.

The illustration below shows the recommended way to lift the instrument and to transport the instrument over a short distance.

It is recommended to use the Flowstar V transportation case when the instrument is transported between buildings or shipped for calibration or service.

Re-install the instrument at a new location

Follow the instructions below to re-install the instrument at the new location.

Step	Action
1	Place the instrument at its intended location.
2	Connect the mains power cable to a suitable power outlet, see *Section 5.3.1 Connect power, on page 105*.
3	Connect the instrument to the air supply, see *Section 5.3.3 Connect compressed air supply, on page 107*.
4	If applicable, connect the instrument to the tested assembly.
5	If applicable, connect the instrument to an accessory, a printer, or a network. See *Enable accessories in software, on page 114*, *Connect printer, on page 123*, *Connect to a network, on page 121*.
6	Recommended: Test the instrument performance by running a ***Self Test***, see *Section 8.3.3 Self test, on page 251*.

6 Preparation

About this chapter

This chapter gives the required information to prepare the Flowstar V instrument for operation.

In this chapter

6.1 Safety precautions

WARNING

Never exceed the operating limits stated in this document and on the nameplate. Operation outside these limits can damage equipment and cause personal injury or death.

WARNING

Always use appropriate Personal Protective Equipment (PPE) during operation and maintenance of this product.

NOTICE

Electrical damage. Do not connect or disconnect electrical or network connections when the product is switched on. This can cause damage to the electronic components in the product.

6.2 Handling test programs

About this section

This section describes how to create and edit a test program.

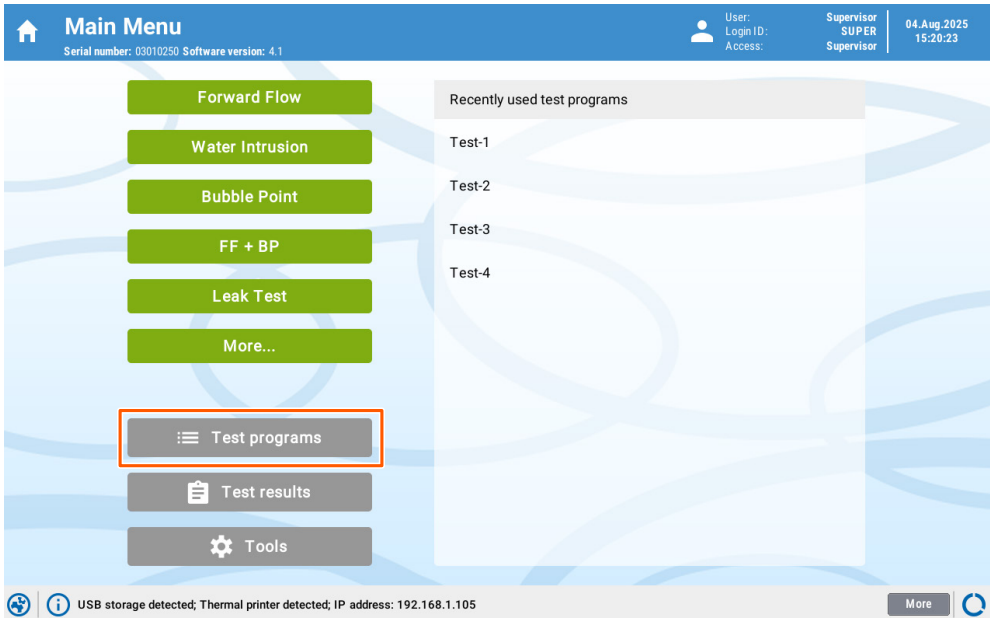
In this section

6.2.1 Create a test program

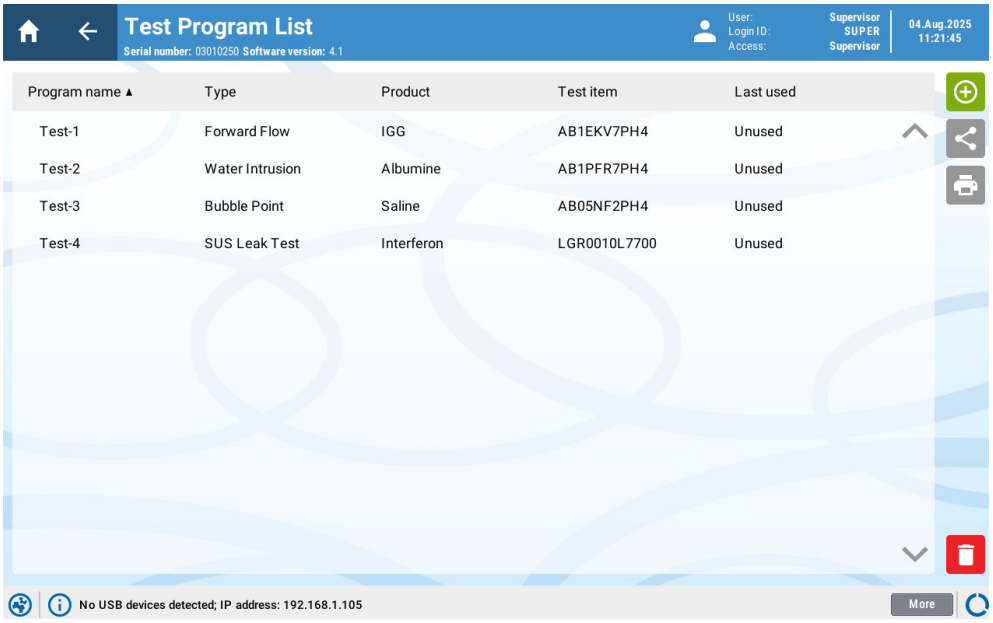
Tip: *A test program can store the test parameters of an accessory. Connect the accessory and enable it in the software before creating the test program. For example, to include parameters for the Flowstar V MUX accessory, connect it to the instrument and enable the accessory in* ***Tools →General settings →Active extension****.*

Follow the steps below to create a test program.

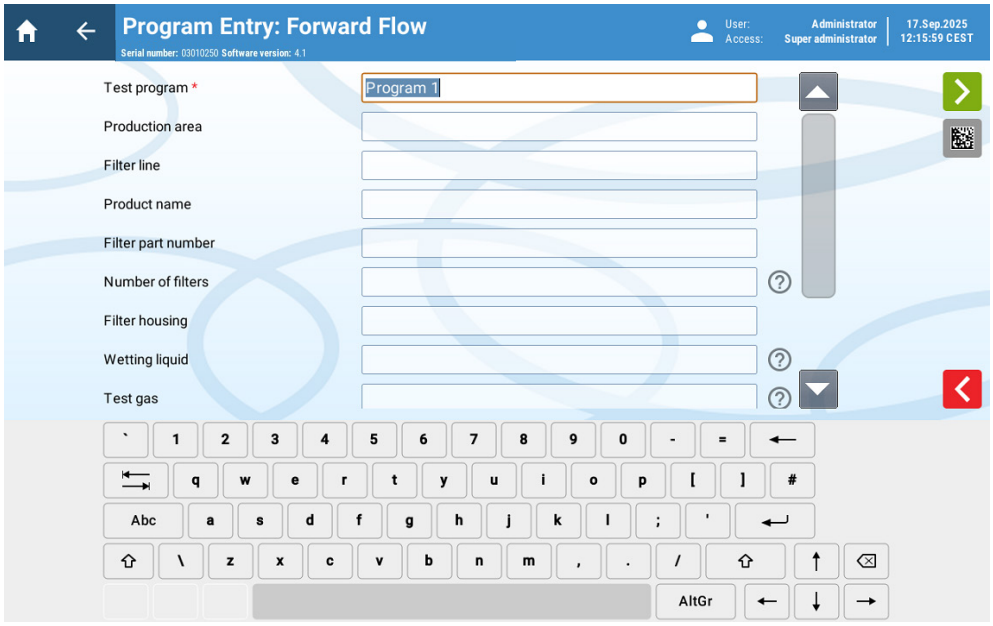
Step	Action
1	Log in with a ***Supervisor*** account, or if enabled, an ***Administrator***, or a ***Super-admin*** account.
2	Go to ***Test Programs***.



Step	Action
3	Tap the button.

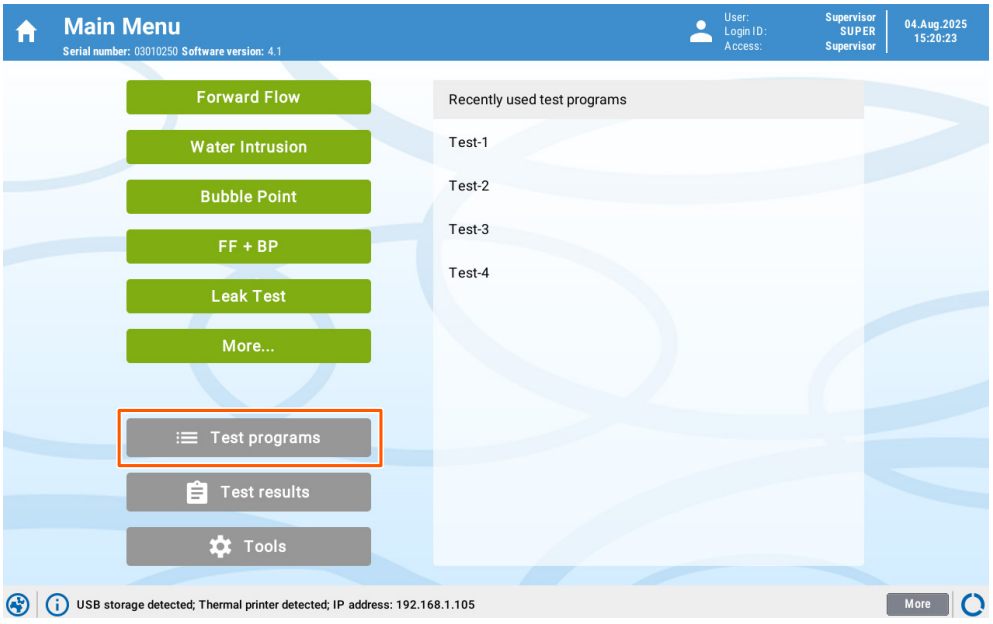
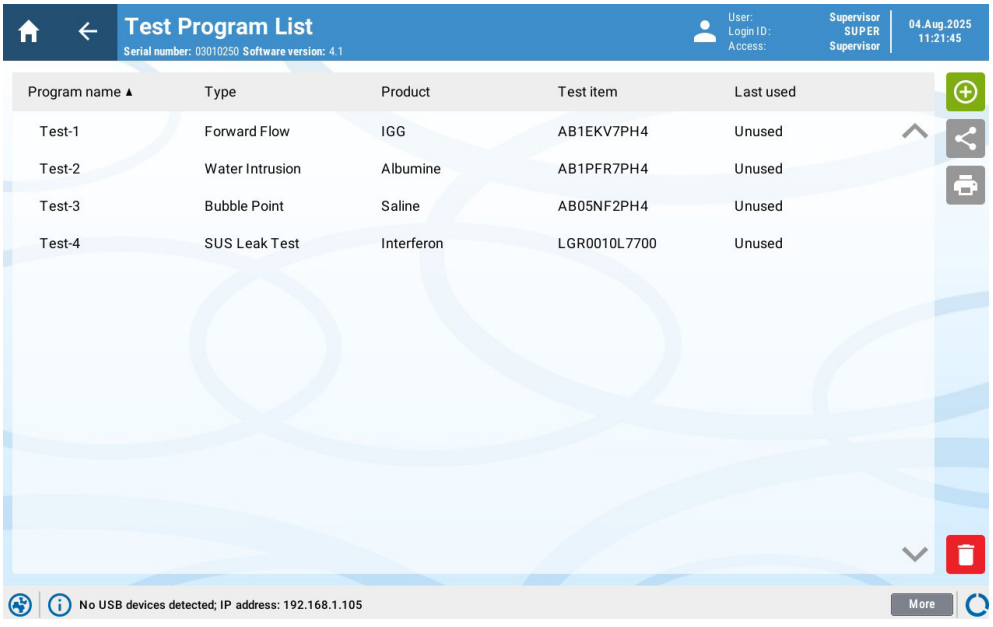


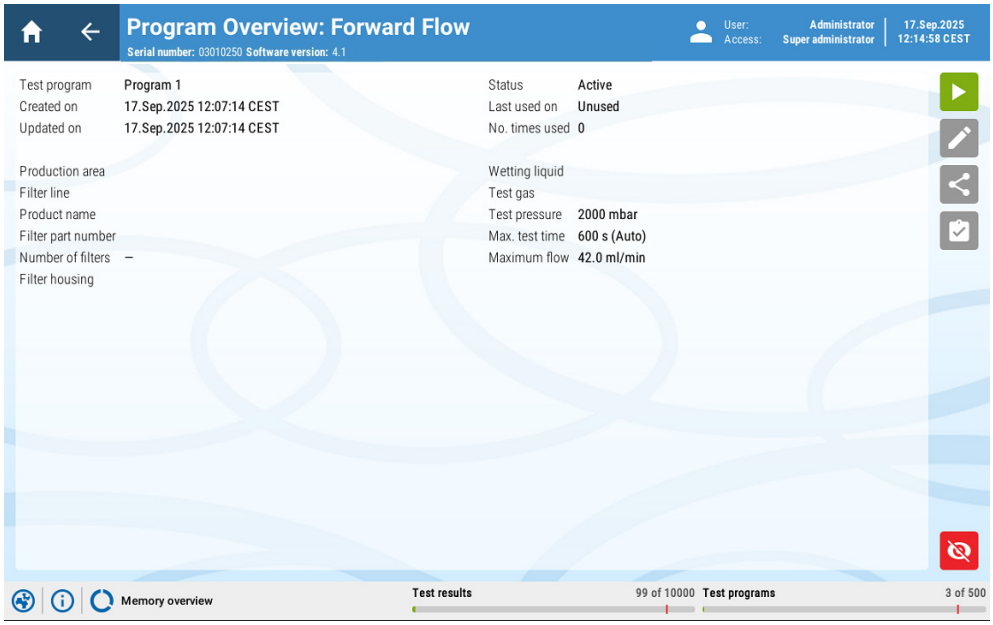
4	Select the type of test. The options are: • ***Forward Flow (FF)*** • ***Bubble Point (BP)*** • ***Combined Forward Flow and Bubble Point (FF/BP)*** • ***Water Intrusion (WIT)*** • ***Leak Test (LT)*** • ***SUS Leak Test (SUS LT)*** • ***Pressure Decay Test (PD)***

Step	Action
5	Type the parameters for the test program.  For more information about the test parameters, see: • *Section 4.2.13 WIT settings, on page 77* • *Section 4.2.10 FF test settings, on page 72* • *Section 4.2.11 BP test settings, on page 73* • *Section 4.2.12 FF + BP test settings, on page 75* • *Section 4.2.14 LT settings, on page 78* • *Section 4.2.15 PD test settings, on page 79* • *Section 4.2.16 SUS LT settings, on page 80*
6	Type a unique name for the test program.
7	Tap the button. *Result:* An overview of the test parameters is shown.
8	Tap the button. *Result:* The instrument saves the test program.

6.2.2 Edit a test program

Follow the steps below to edit a test program.

Step	Action
1	Log in with a ***Supervisor*** account, or if enabled, an ***Administrator***, or a ***Super-admin*** account.
2	Tap ***Test Programs***. 
3	Tap the row with the relevant test program. 

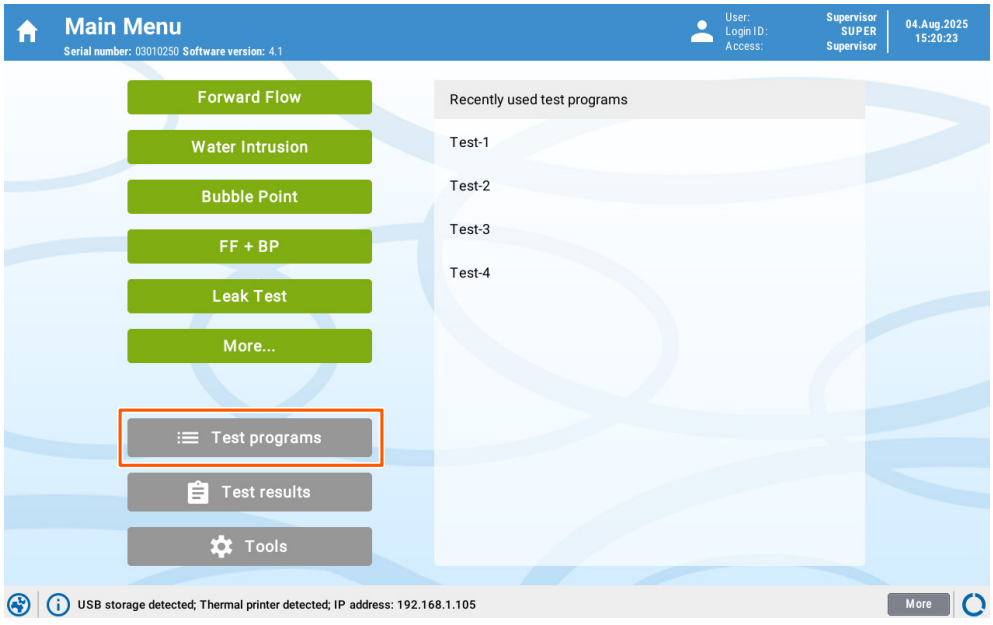
Step	Action
	Tip: *Sort the program list by tapping the column header (e.g., **Program**, **Type**, **Product**).* ***Tip:*** *Use the arrow buttons to scroll through the available test programs. The arrow button moves the selection to the next test program.*
4	Tap the button. 
5	Edit the parameters for the test program. For more information about the test parameters, see: • *Section 4.2.13 WIT settings, on page 77* • *Section 4.2.10 FF test settings, on page 72* • *Section 4.2.11 BP test settings, on page 73* • *Section 4.2.12 FF + BP test settings, on page 75* • *Section 4.2.14 LT settings, on page 78* • *Section 4.2.15 PD test settings, on page 79* • *Section 4.2.16 SUS LT settings, on page 80*
6	Tap the button. *Result:* An overview of the test parameters is shown.

Step	Action
7	Tap the  button. *Result:* The instrument saves the test program.

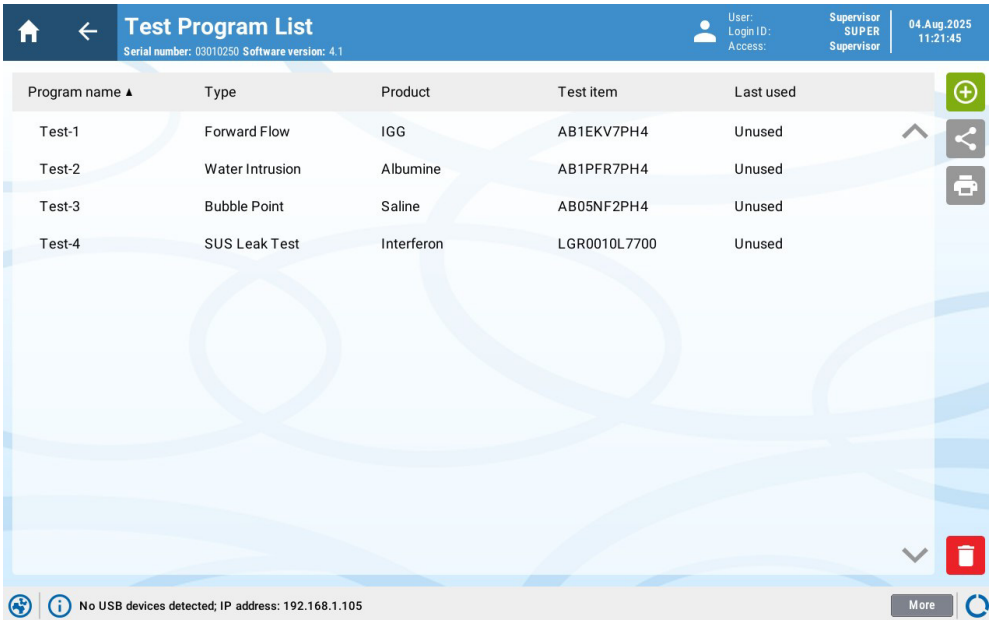
6.3 Generate a test program barcode

The instrument can generate a barcode for a test program. The barcode contains the selected parameters of the test program. A saved barcode can be scanned to load a saved test program.

Follow the steps below to generate a barcode.

Step	Action
1	Log in with a ***Supervisor*** account, or if enabled, an ***Administrator***, or a ***Super-admin*** account.
2	**a.** Connect the barcode reader to a USB port on the instrument.  **b.** Go to ***Tools*** →***Import/Export***. **c.** Set ***Enable barcode generator*** to ***On***.
3	Tap ***Test Programs***. 

Step	Action
4	Tap the row with the relevant test program.



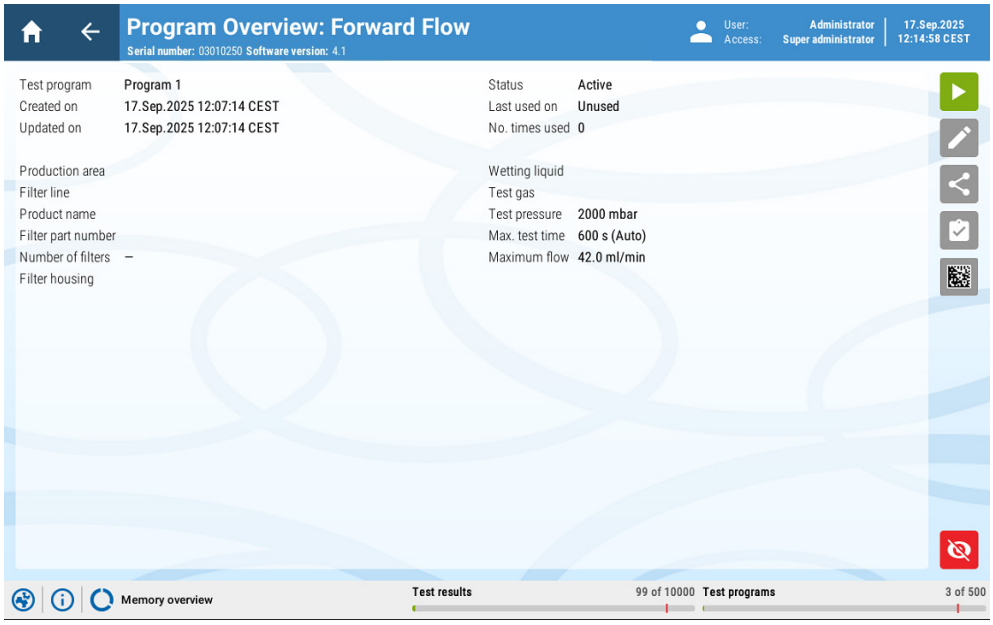
Tip:

*Sort the program list by tapping the column header (e.g., **Program**, **Type**, **Product**).*

Tip:

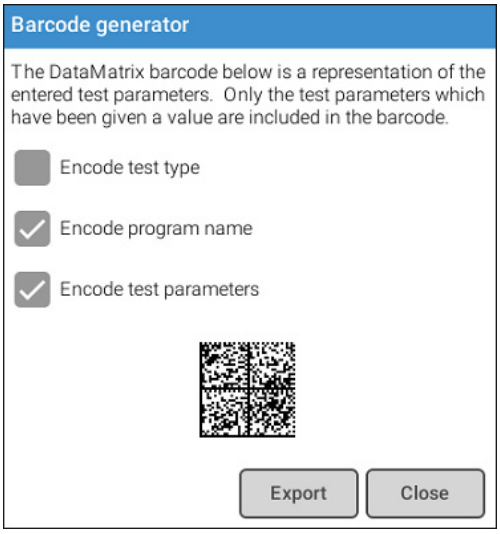
Use the arrow buttons to scroll through the available test programs. The arrow button moves the selection to the next test program.

Step	Action
5	Tap the button.



6	Optional: Adjust the test parameters.
7	Tap the button.
8	Tap the checkboxes to select what to include in the barcode. The options are: • ***Encode program name*** • ***Encode test type*** • ***Encode test parameters***

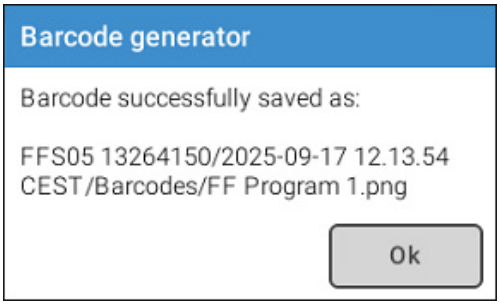
Step	Action



Note:
The user name cannot be included in the barcode.

9 Click ***Export***.

Result:
The barcode is stored in the destination folder as a PNG file.



6.4 Connect a tested assembly

About this section

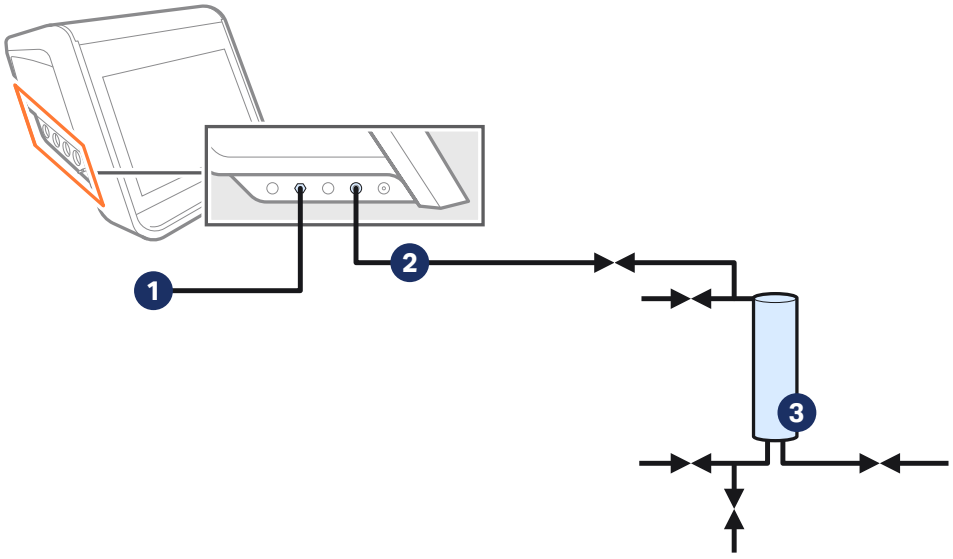
This section describes how to connect a tested assembly, such as a filter housing, a vessel, a single use bag or a biocontainer, before running a test.

In this section

6.4.1 Connect a filter housing for a default test

Required material: Use the supplied air hoses with a 6 mm ID (8 mm OD), with Stäubli RBE03 connectors to connect the filter housing. If other air hoses are used, make sure that they are rated to withstand a pressure of up to 8 bar (116 psi).

The illustration below shows the setup for a FF, a BP, or a FF+BP test.



Part	Description
1	Compressed air supply
2	Pressure line to the filter housing
3	Filter housing

Follow the steps below to connect a filter housing to the instrument for a FF, a BP, or a FF+BP test.

Step	Action
1	If necessary, adjust the pressure and the flow rate of the compressed air supply. ***Note:*** *For air supply requirements, see Compressed air, on page 301.*
2	Install the wetted filter in the filter housing.
3	Connect the air hose with a 6 mm ID (8 mm OD) and a Stäubli RBE03 female connector to the **OUT** port on the instrument.
4	If necessary, connect an adapter between the air hose and the filter.
5	Connect the air hose to the vent port (top) of the filter housing or to the adapter.
6	Open the downstream side of the filter housing to the atmosphere.

Step	Action
7	Verify that the instrument and the tested assembly are at ambient temperature.

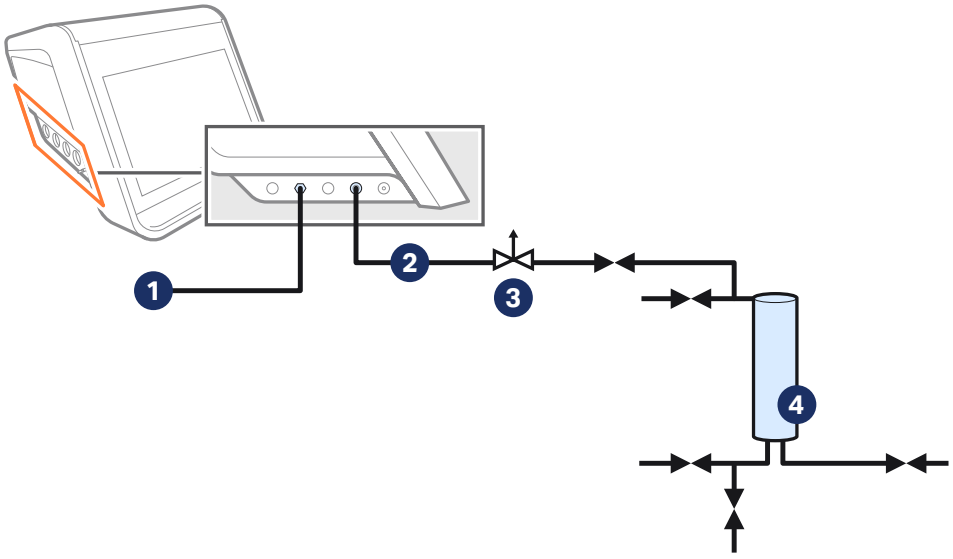
NOTICE

Stable room conditions. The operation temperature and pressure in the room must be stable and within the range described in the specifications. Fluctuations in temperature or pressure during a run can cause incorrect measurement values.

6.4.2 Connect a filter housing for a WIT test

Required material: Use the supplied air hoses with a 6 mm ID (8 mm OD), with Stäubli RBE03 connectors to connect the filter housing. If other air hoses are used, make sure that they are rated to withstand a pressure of up to 8 bar (116 psi).

The illustration below shows the setup for a water intrusion test (WIT).



Part	Description
1	Compressed air supply
2	Pressure line to the external vent valve
3	External vent valve
4	Filter housing

Follow the steps below to connect a hydrophobic filter to the instrument for a WIT test.

Step	Action
1	If necessary, adjust the pressure and the flow rate of the compressed air supply. ***Note:*** *For air supply requirements, see Compressed air, on page 301.*
2	**a.** Install the filter in the filter housing. **b.** Connect the filter housing to a facility supply line with water (e.g., water for injection (WFI)). **c.** Fill the filter housing with water.
3	**a.** Locate the external vent valve with the hose and the electrical cable.

Step	Action
	b. Connect the air hose with a 6 mm ID (8 mm OD) and a Stäubli RBE03 female connector to the **OUT** port on the instrument.

	c. Connect the 24 VDC power cable to the **EXT VALVE** port on the instrument.
4	**a.** Connect the external vent valve to the top of the filter housing.

	b. If necessary, connect an adapter between the external vent valve and the filter housing.
5	Open the downstream side of the filter housing to the atmosphere.

Step	Action
6	Verify that the instrument and the tested assembly are at ambient temperature.

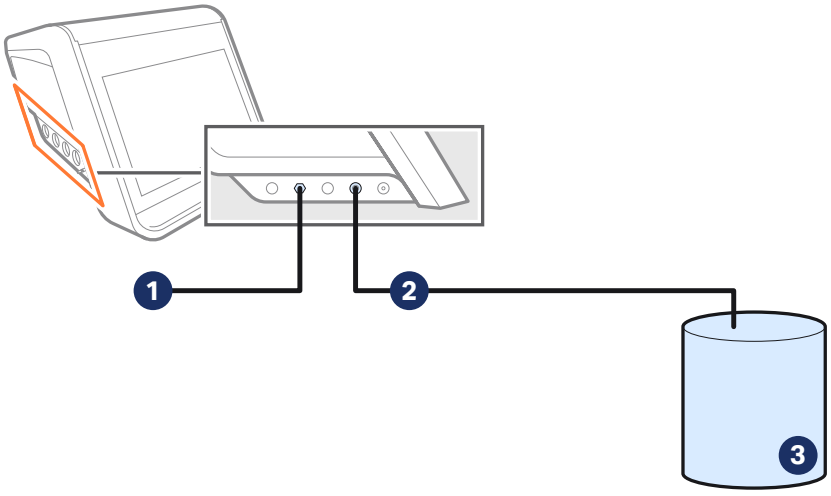
NOTICE

Stable room conditions. The operation temperature and pressure in the room must be stable and within the range described in the specifications. Fluctuations in temperature or pressure during a run can cause incorrect measurement values.

6.4.3 Connect a tested assembly for a LT/PD test

Required material: Use the supplied air hoses with a 6 mm ID (8 mm OD), with Stäubli RBE03 connectors to connect the tested assembly. If other air hoses are used, make sure that they are rated to withstand a pressure of up to 8 bar (116 psi).

The illustration below shows the setup for a LT or a PD test.



Part	Description
1	Compressed air supply
2	Pressure line to the tested assembly
3	Tested assembly

Follow the steps below to connect the tested assembly to the instrument for a LT or a PD test.

Step	Action
1	If necessary, adjust the pressure and the flow rate of the compressed air supply. ***Note:*** *For air supply requirements, see Compressed air, on page 301.*
2	Connect the air hose with a 6 mm ID (8 mm OD) and a Stäubli RBE03 female connector to the **OUT** port on the instrument.
3	If necessary, connect an adapter between the air hose and the tested assembly.
4	Connect the air hose to the tested assembly or to the adapter.

Step	Action
5	Verify that the instrument and the tested assembly are at ambient temperature.

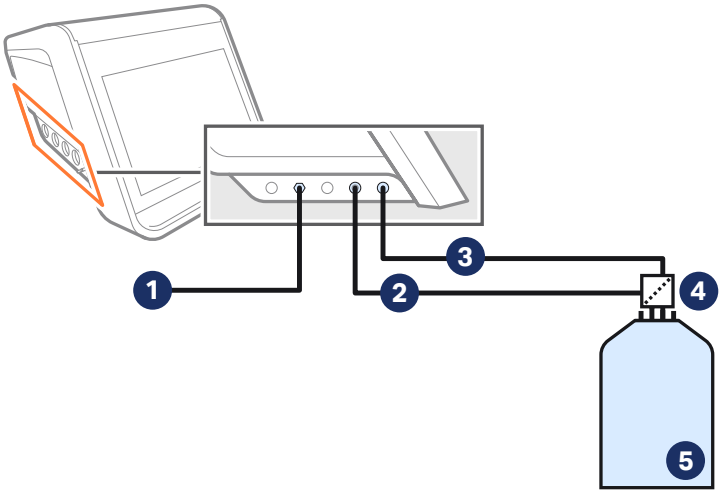
NOTICE

Stable room conditions. The operation temperature and pressure in the room must be stable and within the range described in the specifications. Fluctuations in temperature or pressure during a run can cause incorrect measurement values.

6.4.4 Connect a tested assembly for a SUS LT test

Required material: Use the supplied double air hose (FFS-LGRHOSE1) with the 6 mm ID (8 mm OD), with Stäubli RBE03 connectors to connect the tested assembly.

The illustration below shows the setup for a single-use equipment leak test (SUS LT).



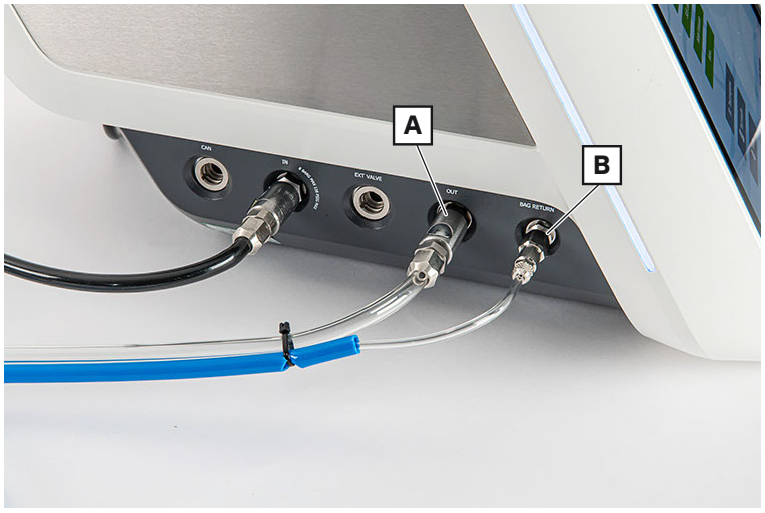
Part	Description
1	Compressed air supply
2	Pressure line to the tested assembly
3	Pressure measurement line to the instrument
4	Sterile air filter (optional)
5	Tested assembly

Follow the steps below to connect the tested assembly to the instrument to prepare the instrument for a SUS LT test.

Step	Action
1	If necessary, adjust the pressure and the flow rate of the compressed air supply. ***Note:*** *For air supply requirements, see Compressed air, on page 301.*
2	Connect the double air hose to the instrument. **a.** Locate the supplied double air hose.

Step	Action

b. Connect the female Stäubli RBE03 connector on the double air hose to the **OUT** port on the instrument (A).



c. Connect the male Stäubli MCR connector on the double air hose to the **BAG RETURN** port on the instrument (B).

3 Prepare the tested assembly:

a. Disconnect or isolate any components of the tested assembly that are not resistant to the test pressure, such as certain connectors or sensors.

b. Optional: Connect a sterile air filter to the tested assembly.

Note:

Make sure that compressed air used in the SUS LT test does not contaminate the sterile or aseptic assembly.

4 **a.** Connect the double air hose to:

- the tested assembly

  or

- the sterile air filter that is connected to the tested assembly

b. If necessary, connect an adapter between the air hose and the tested assembly.

For example:

- Stäubli RBE03 adapter
- CPC MPx adapter
- CPC MPc adapter
- ¾ inch TC adapter (purchased separately)

Step	Action
5	Verify that the instrument and the tested assembly are at ambient temperature.

NOTICE

Stable room conditions. The operation temperature and pressure in the room must be stable and within the range described in the specifications. Fluctuations in temperature or pressure during a run can cause incorrect measurement values.

7 Operation

About this chapter

This chapter gives instructions on how to operate the Flowstar V instrument in a safe way.

In this chapter

7.1 Safety precautions

WARNING

Never exceed the operating limits stated in this document and on the nameplate. Operation outside these limits can damage equipment and cause personal injury or death.

WARNING

Always use appropriate Personal Protective Equipment (PPE) during operation and maintenance of this product.

WARNING

Protective earth. The product must be connected to protective earth when energized.

WARNING

Overpressure. Make sure that filter housing is vented and is at atmospheric pressure before dismantling of the filter assembly. Overpressure can result in injury.

WARNING

Overpressure. Make sure that the test pressure is less than the maximum operating pressure that is specified for the filter housing or the filter capsule. The filter can explode at overpressure and cause injury.

CAUTION

Aerosols. During the venting phase, aerosolized liquid from the tested assembly is released from the external vent valve or the **VENT** port on the instrument. Take precautions suitable to the nature of the liquids in the tested assembly.

NOTICE

Filter and test method incompatibility. A mismatch between the filter and the test method can result in a failed process, wrong data, or a damaged filter.

NOTICE

The wetted parts of the product may be damaged by certain chemicals. Contact your Cytiva representative before using chemicals that are not listed in the chemical resistance information.

NOTICE

Electrical damage. Do not connect or disconnect electrical or network connections when the product is switched on. This can cause damage to the electronic components in the product.

NOTICE

Stable room conditions. The operation temperature and pressure in the room must be stable and within the range described in the specifications. Fluctuations in temperature or pressure during a run can cause incorrect measurement values.

NOTICE

Contamination risk. Only use pneumatic tubing and connections that are clean, dry, and free from any fluids or contaminants. Valves can malfunction when contaminated with liquid or oil.

NOTICE

Liquid in the instrument. If required for the selected test, install the external vent valve between the instrument and the tested assembly. The external vent valve makes sure that the testing liquid does not enter the instrument. Liquid can cause damage to the instrument.

7.2 Before starting a run

Introduction

Before starting a test, it is necessary to read and understand the information in this section and to perform the checks listed below.

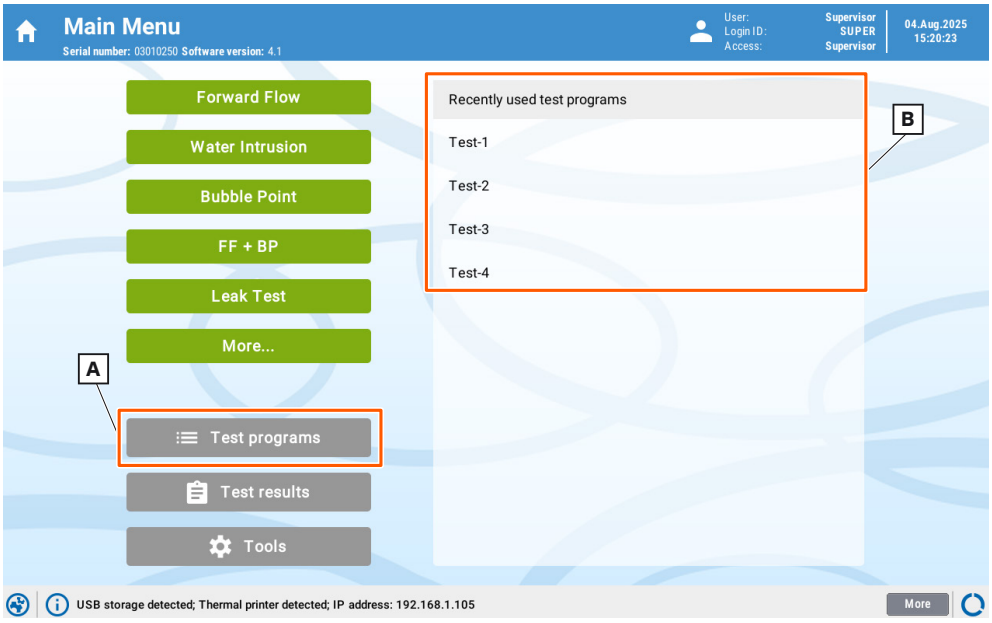
Checklist

Make sure that the instrument is correctly prepared.

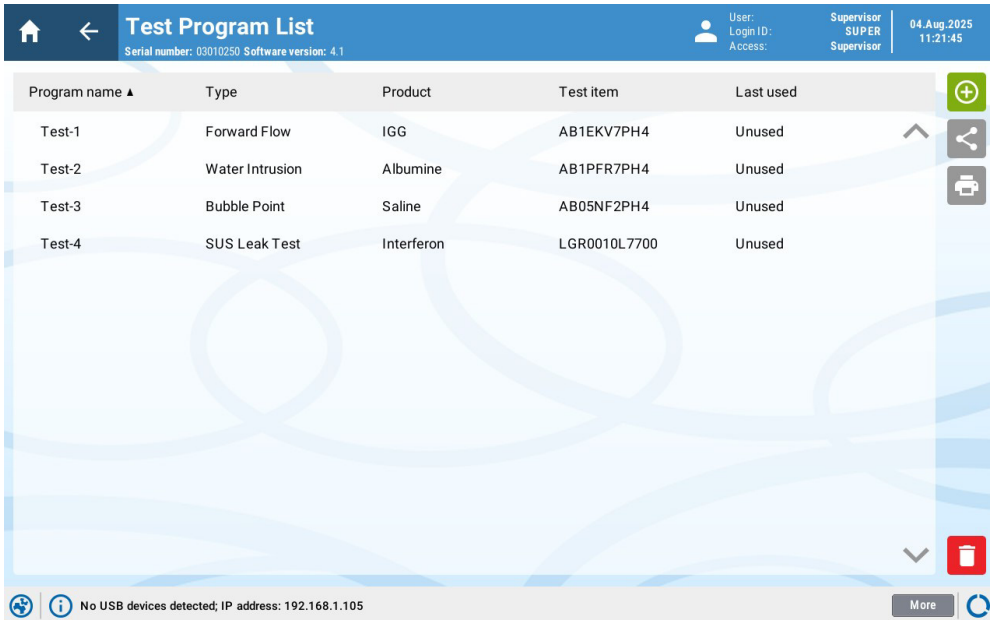
1. Connect the air supply, see *Section 5.3.3 Connect compressed air supply, on page 107*.
2. Start the instrument, see *Section 5.3.2 Start the instrument, on page 106*.
3. Connect the tested assembly, see *Section 6.4 Connect a tested assembly, on page 170*.
4. Select the correct test for the tested assembly.
5. Make sure that the flow path is free from any obvious leaks.
6. Make sure that the instrument and the tested assembly are at ambient temperature.

7.3 Start a test program

Follow the steps below to start a test program.

Step	Action
1	Log in with an ***Operator***, an ***Automation operator***, a ***Supervisor***, or if enabled, an ***Administrator***, or a ***Super-admin*** account.
2	Go to ***Test programs*** (A) or select a test program from ***Recently used test programs*** (B). 

Step	Action
3	In ***Test programs***, tap the row with the relevant test program.



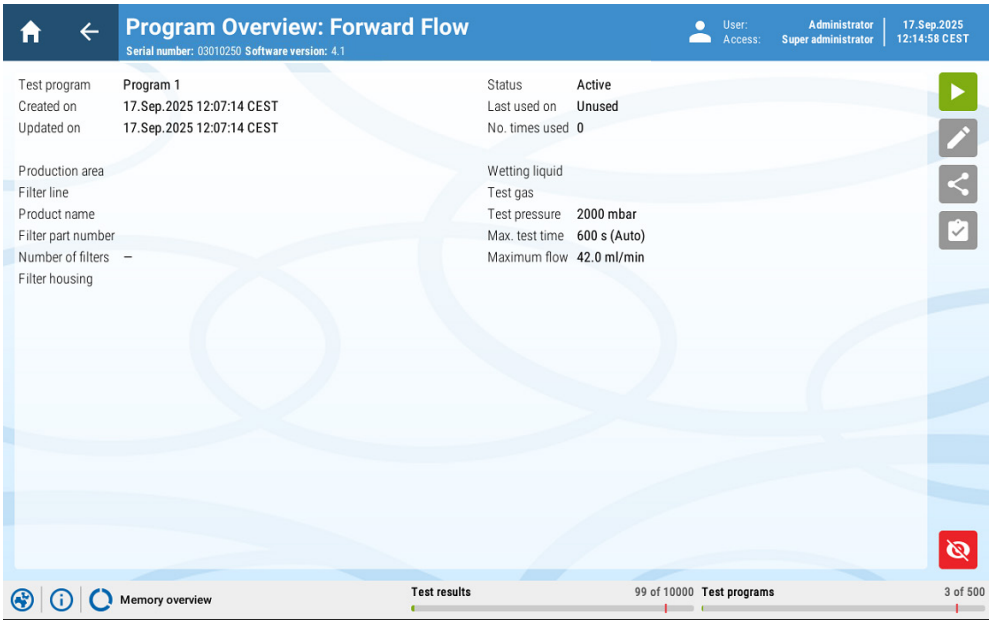
Tip:

*Sort the program list by tapping the column header (e.g., **Program**, **Type**, **Product**).*

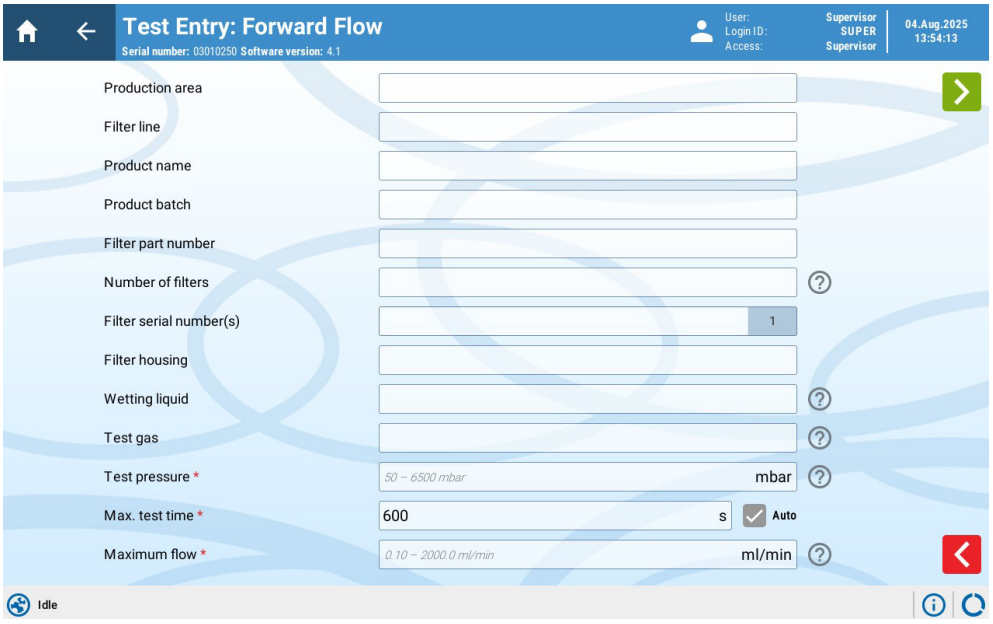
Tip:

Use the arrow buttons to scroll through the available test programs. The arrow button moves the selection to the next test program.

Step	Action
4	Tap the button.



Step	Action
5	Set the general run parameters.



Parameter	Description
Production area	Type the location or room where the test is performed.
Filter line	Type the filter line.

Step	Action

Parameter	Description
Product name	Type the product name of the material that the tested assembly is used with.
Product batch	Type the product batch of the material that the tested assembly is used with.
Filter serial number(s)	Type the filter serial number.
Filter part number(s)	Type the filter part number.
Number of filters	Type the number of filters that are connected.
Filter housing	Type the filter housing type.
Custom parameter (optional)	Type the value for the custom parameter. See *Set general settings, on page 111* for instructions to set up custom parameters.

Note:

The obligatory fields are marked with a red asterisk. The non-obligatory fields are for record keeping purposes, and are not essential to run a test.

6 Tap the button.

Result:
An overview of the test parameters is shown.

7 Tap the button.

Result:
The test starts. If you start a test during an ongoing run, the new run is placed in a queue. The queue is listed in the ***Test result*** screen.

Note: *The run can be aborted at any time. Tap the button, and then tap **Ok**. **Test result: MANUAL ABORT** is added to the test result file.*

7.4 Run a default test

About this section

This section describes how to run a forward flow test (FF), a bubble point test (BP), and a combined FF and BP (FF+BP) test. The tests are described in *Section 3.2 Functional overview, on page 27*.

In this section

7.4.1 Run a FF test

Introduction

This section describes how to run a FF test on the instrument.

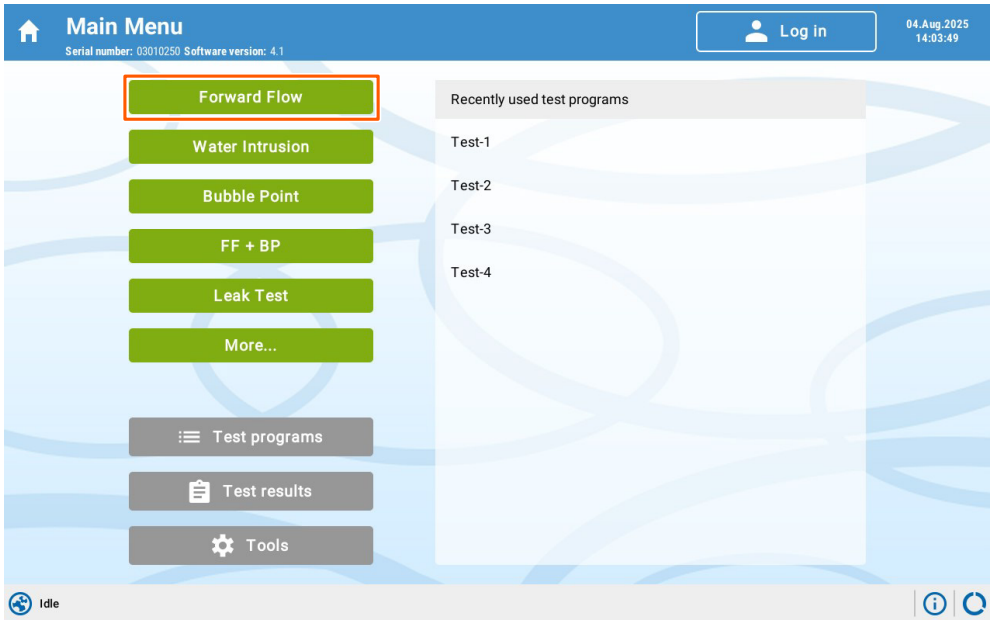
Start a FF test

A FF test can be started:

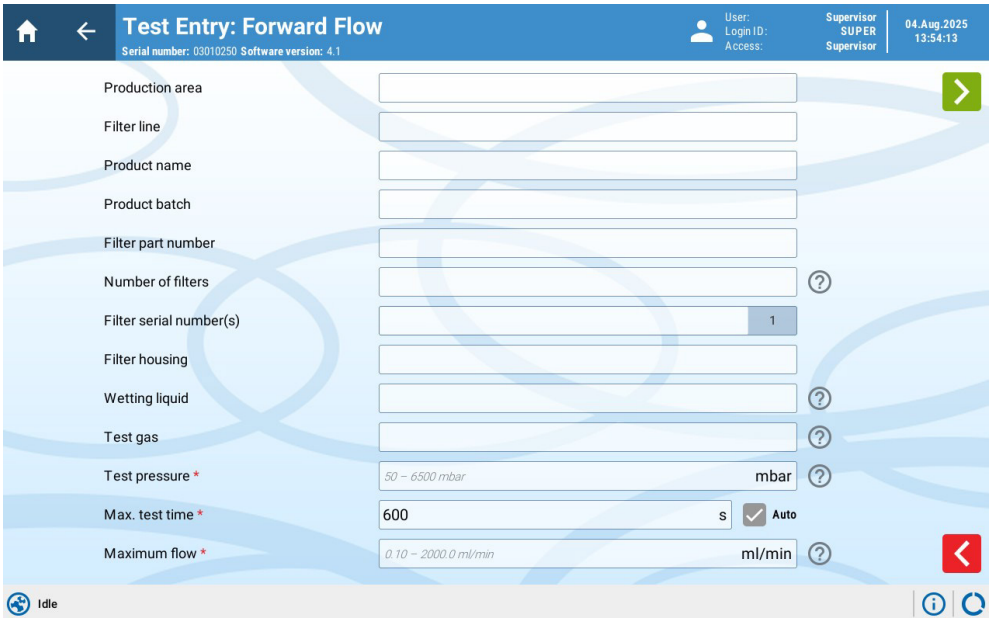
- from a saved test program, see *Section 7.3 Start a test program, on page 185*.
- after setting the parameters manually, as described below.

Follow the steps below to start a FF test after setting the parameters manually.

Step	Action
1	Log in with an ***Operator***, an ***Automation operator***, a ***Supervisor***, or if enabled, an ***Administrator***, or a ***Super-admin*** account.
2	Tap ***Forward flow***.



Step	Action
3	Set the general test parameters.



Parameter	Description
Operator (optional)	• If the instrument is in standard access control, type the name of the operator. • If the instrument is in HLAC mode, the software automatically fills in the name of the user that is currently logged in.
Production area	Type the location or room where the test is performed.
Filter line	Type the filter line.
Custom parameter (optional)	Type the value for the custom parameter. See *Set general settings, on page 111* for instructions to set up custom parameters.
Product name	Type the product name of the material that the tested assembly is used with.
Product batch	Type the product batch of the material that the tested assembly is used with.
Filter part number(s)	Type the filter part number.
Number of filters	Type the number of filters that are connected.
Filter serial number(s)	Type the filter serial number.

Step **Action**

Parameter	Description
Filter housing	Type the filter housing type.

Note:

The obligatory fields are marked with a red asterisk. The non-obligatory fields are for record keeping purposes, and are not essential to run a test.

4 Set the test parameters.

Parameter	Description	Range
Wetting liquid	Type the type of wetting liquid that is used in the test.	N/A
Test gas	Type the type of gas that is used in the test.	N/A
Pre-stabilization pressure (optional)	• Type the pre-stabilization pressure. • Leave the field empty to skip the pre-stabilization phase.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Pre-stabilization time (optional)	• Type the pre-stabilization time. • Leave the field empty to skip the pre-stabilization phase.	0 to 9999 s
Test pressure	Type the test pressure.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Max. test time	• Type the maximum operation time of the test. • Select ***AUTO*** to run the test until the flow rate is stable. The default maximum test time is 600 s.	• 100 to 9999 s • ***AUTO***
Minimum flow (optional)	• Type the expected minimum flow rate. • Leave the field empty to set the minimum flow to zero.	Max. 20% of the ***Maximum flow***

Step	Action

Parameter	Description	Range
Maximum flow	Type the maximum FF value for the test.	0.1 to 1000 mL/min

Tip:

When using standard wetting liquids, the test parameters are usually available from the manufacturer of filter.

Tip:

Increase the pre-stabilization time:

- *When testing large filter assemblies (over 20 L).*
- *When the filter requires a pre-pressurization phase at a different pressure than the test pressure.*

Note:

If you tap the  *button to return to the* ***Main menu****, the selected parameters are not saved.*

5 Tap the  button.

Result:
An overview of the test parameters is shown.

6 Tap the  button.

Result:
The test starts. If you start a test during an ongoing run, the new run is placed in a queue. The queue is listed in the ***Test result*** screen.

Note: *The run can be aborted at any time. Tap the*  *button, and then tap* ***Ok****.* ***Test result: MANUAL ABORT*** *is added to the test result file.*

During a FF test

The phases of a FF test are described in the table below.

Phase	Description
Pressurization	1. The instrument pressurizes the filter housing to the selected test pressure. 2. The stage of the measurement is displayed in a percentage bar on the HMI. A second bar shows the actual pressure. 3. When the test pressure reaches 100% of the selected test pressure, the instrument continues with the next phase.
Automatic pre-stabilization	1. If enabled, the instrument applies the pre-stabilization pressure to the filter for the pre-stabilization time. 2. If the pre-stabilization pressure is not reached or is not stable, the test is aborted.
Filter testing	• The percentage bar charts on the screen shows the time and the flow rate. • The measurement values on the screen shows the current flow rate. • Tap the  button to display a graph of the measured flow rate. Tap the ***Status*** button to return to the ***Test data*** screen. • A filter is considered intact, if the measured flow rate is below the threshold by the end of the test.
Test result	The test results are shown on the HMI and automatically saved to the internal memory. • ***PASS*** and ***Flow within limits*** indicate that the tested filter is functional. • ***FAIL*** and ***FLOW TOO HIGH*** might indicate a defective filter, a leak in the tested assembly, insufficient wetting of the filter before testing, or contamination of the filter membrane. ***Note:*** *If the HMI displays an error message, see Chapter 9 Troubleshooting, on page 286 for a description of possible causes and corrective actions.*

7.4.2 Run a BP test

Introduction

This section describes how to run a BP test on the system.

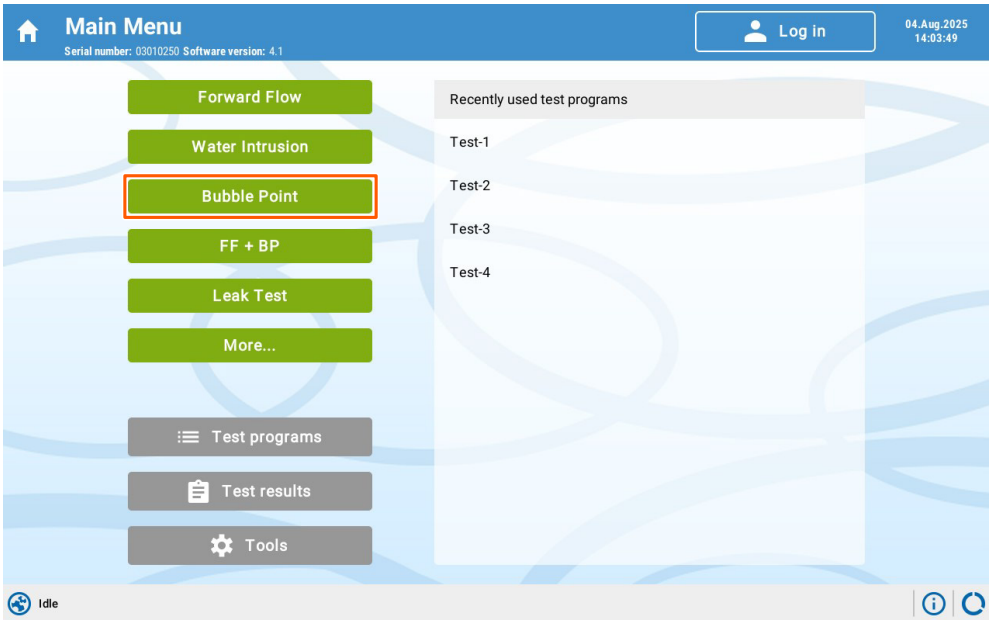
Start a BP test

A BP test can be started:

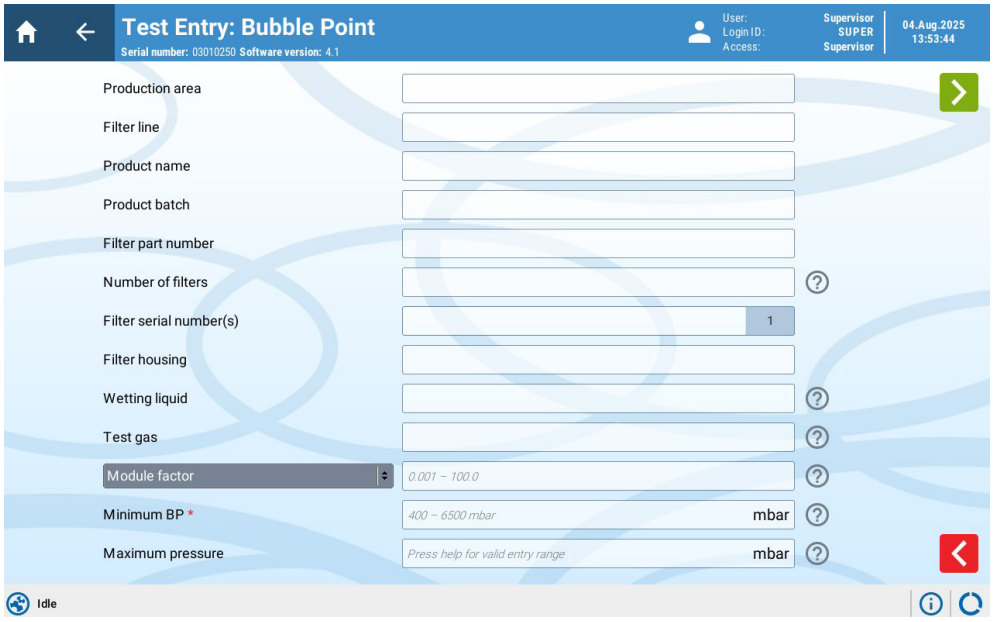
- from a saved test program, see *Section 7.3 Start a test program, on page 185*.
- after setting the parameters manually, as described below.

Follow the steps below to start a BP test after setting the parameters manually.

Step	Action
1	Log in with an ***Operator***, an ***Automation operator***, a ***Supervisor***, or if enabled, an ***Administrator***, or a ***Super-admin*** account.
2	Tap ***Bubble Point***.



Step	Action
3	Set the general test parameters.



Parameter	Description
Operator (optional)	• If the instrument is in standard access control, type the name of the operator. • If the instrument is in HLAC mode, the software automatically fills in the name of the user that is currently logged in.
Production area	Type the location or room where the test is performed.
Filter line	Type the filter line.
Custom parameter (optional)	Type the value for the custom parameter. See *Set general settings, on page 111* for instructions to set up custom parameters.
Product name	Type the product name of the material that the tested assembly is used with.
Product batch	Type the product batch of the material that the tested assembly is used with.
Filter part number(s)	Type the filter part number.
Number of filters	Type the number of filters that are connected.
Filter serial number(s)	Type the filter serial number.

Step **Action**

Parameter	Description
Filter housing	Type the filter housing type.

Note:

The obligatory fields are marked with a red asterisk. The non-obligatory fields are for record keeping purposes, and are not essential to run a test.

4 Set the test parameters.

Parameter	Description	Range
Wetting liquid	Type the type of wetting liquid that is used in the test.	N/A
Test gas	Type the type of gas that is used in the test.	N/A
Pre-stabilization pressure (optional)	• Type the pre-stabilization pressure. • Leave the field empty to skip the pre-stabilization phase.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Pre-stabilization time (optional)	• Type the pre-stabilization time. • Leave the field empty to skip the pre-stabilization phase.	0 to 9999 s

Step **Action**

Parameter	Description	Range
Module factor*/ *Membrane area	For ***Module factor***: • Type the number that describes the size of the target filter. • Leave the field empty to select the default value (***1***).	0.001 to 100.0 Use for example: • ***0.01*** for small area filter capsules (e.g., Acro 25/50 or Mini Kleenpak 20) • ***0.1*** for flat membranes (e.g., 142 mm discs) or mini capsules (e.g., Mini Kleenpak) • ***0.2*** for smaller filter cartridges (e.g., AB02 or SLK7001) • ***0.5*** for 128 mm (5 inch) filter cartridges (e.g., AB05 or SLK7002) • ***1*** for 254 mm (10 inch) filter cartridges
	For ***Membrane area***, type the size of the membrane to adjust the sensitivity of the leak test phase.	6.25 to 625000 cm²
Start pressure	Type the starting pressure of the test.	• 250 to 2570 mbar • 3.63 to 5.40 psi
Minimum BP	Type the minimum pressure of the test.	• 400 to 6500 mbar • 5.80 to 94.24 psi
Maximum pressure	• Type the maximum pressure of the test. • Leave the field empty to select the line pressure as maximum pressure of the test.	• Max. 7000 mbar • Max. 101.53 psi >250 mbar or 3.63 psi above the ***Minimum BP***[1]

[1] An error is displayed during the test, if the selected ***Maximum pressure*** is not 250 mbar or more above ***Minimum BP***.

Tip:

When using standard wetting liquids, the test parameters are usually available from the manufacturer of filter.

Step	Action
	Note: *Increase the pre-stabilization time when testing large filter assemblies (over 20 L).* ***Note:*** *If you tap the*  *button to return to the* ***Main menu****, the selected parameters are not saved.*
5	Tap the  button. *Result:* An overview of the test parameters is shown.
6	Tap the  button. *Result:* The test starts. If you start a test during an ongoing run, the new run is placed in a queue. The queue is listed in the ***Test result*** screen.

Note: *The run can be aborted at any time. Tap the*  *button, and then tap* ***Ok****.* ***Test result: MANUAL ABORT*** *is added to the test result file.*

During a BP test

The phases of a BP test are described in the table below.

Phase	Description
Leak test	1. The instrument pressurizes the upstream side of the tested assembly to 80% of the selected minimum pressure. 2. The instrument measures the gas flow rate. 3. The instrument compares the measured flow rate with the ***Module Factor*** or the ***Membrane area***. 4. The tested assembly is considered without leaks or defects, if the measured flow rate is below the threshold. 5. The test starts.
Automatic pre-stabilization	1. If enabled, the instrument applies 80% of the selected minimum pressure to the upstream side of the tested assembly for the pre-stabilization time. 2. If the pre-stabilization pressure is not reached or is not stable, the test is aborted.
Stabilization	The instrument applies the test pressure to the tested assembly for the selected stabilization time.

Phase	Description
Filter testing	• The instrument pressurizes the upstream side of the tested assembly incrementally until it reaches 80% of the selected test pressure. The instrument pressure starts from ***Start pressure*** and increases by 50 mbar with each step. • Between each pressure step, the instrument closes the inlet supply pressure and measures the pressure decay over a short time interval. The bubble point of the filter is identified when the measurement values shows a significant difference compared to the preceding value. • The percentage bar chart on the screen show the measured pressure. • Tap the  button to display a graph of the measured bulk flow (y-axis, mbar/min) and the measured pressure (x-axis, mbar). Tap the ***Status*** button to return to the ***Test data*** screen. • A filter is considered intact, if the measured bubble point is below the bubble point threshold.
Test result	The test results are shown on the HMI and automatically saved to the internal memory. • ***PASS*** and ***Bubble point within limits*** indicate that the tested filter is functional. • ***FAIL*** and ***BUBBLE POINT NOT OBTAINABLE*** might indicate a defective filter or a leak in the tested assembly. ***Note:*** *If the HMI displays an error message, see Chapter 9 Troubleshooting, on page 286 for a description of possible causes and corrective actions.*

7.4.3 Run a FF + BP test

Introduction

This section describes how to run a FF + BP test on the system.

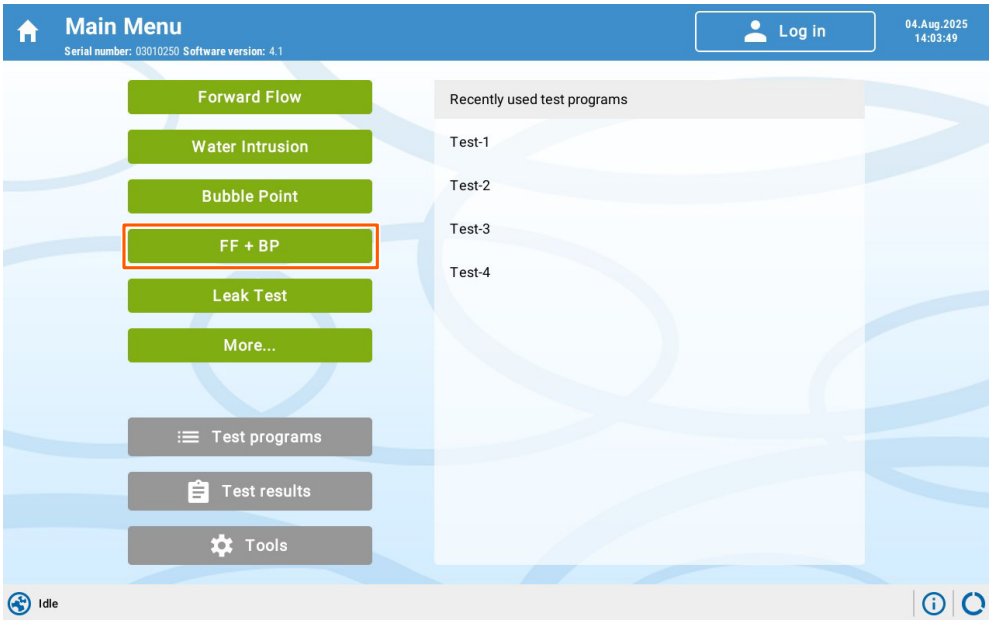
Start a FF + BP test

A FF + BP test can be started:

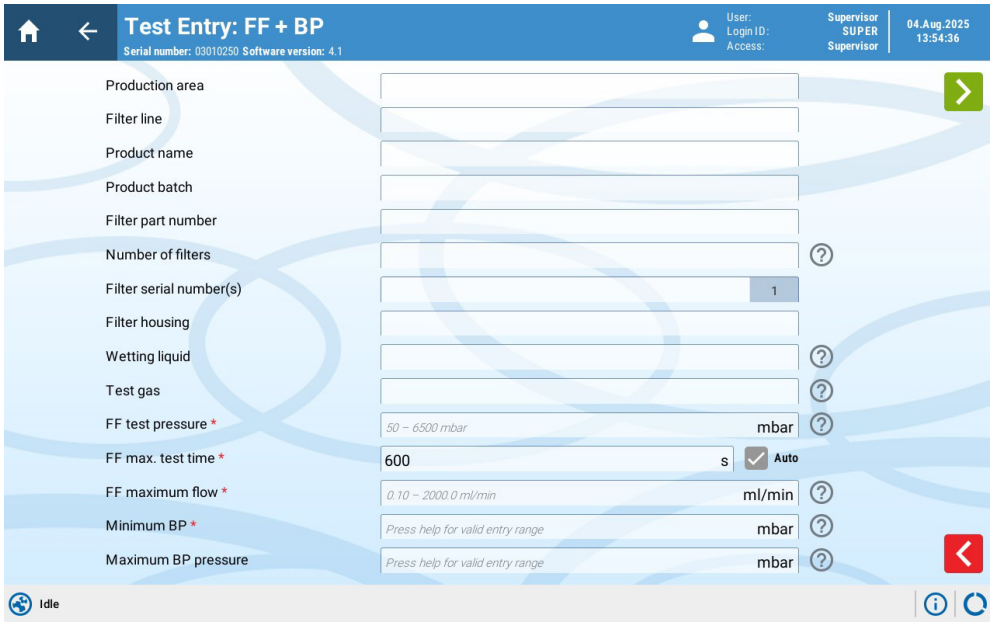
- from a saved test program, see *Section 7.3 Start a test program, on page 185*.
- after setting the parameters manually, as described below.

Follow the steps below to start a FF + BP test after setting the parameters manually.

Step	Action
1	Log in with an ***Operator***, an ***Automation operator***, a ***Supervisor***, or if enabled, an ***Administrator***, or a ***Super-admin*** account.
2	Tap ***FF + BP***.



Step	Action
3	Set the general test parameters.



Parameter	Description
Operator (optional)	• If the instrument is in standard access control, type the name of the operator. • If the instrument is in HLAC mode, the software automatically fills in the name of the user that is currently logged in.
Production area	Type the location or room where the test is performed.
Filter line	Type the filter line.
Custom parameter (optional)	Type the value for the custom parameter. See *Set general settings, on page 111* for instructions to set up custom parameters.
Product name	Type the product name of the material that the tested assembly is used with.
Product batch	Type the product batch of the material that the tested assembly is used with.
Filter part number(s)	Type the filter part number.
Number of filters	Type the number of filters that are connected.
Filter serial number(s)	Type the filter serial number.

Step **Action**

Parameter	Description
Filter housing	Type the filter housing type.

Note:

The obligatory fields are marked with a red asterisk. The non-obligatory fields are for record keeping purposes, and are not essential to run a test.

4 Type the test parameters.

Parameter	Description	Range
Wetting liquid	Type the type of wetting liquid that is used in the test.	N/A
Test gas	Type the type of gas that is used in the test.	N/A
Pre-stabilization pressure (optional)	• Type the pre-stabilization pressure. • Leave the field empty to skip the pre-stabilization phase.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Pre-stabilization time (optional)	• Type the pre-stabilization time. • Leave the field empty to skip the pre-stabilization phase.	0 to 9999 s
FF test pressure	Type the test pressure of the FF test.	• 50 to 6500 mbar • 0.73 to 94.27 psi
FF max. test time	• Type the maximum operation time of the test. • Select ***AUTO*** to run the FF test until the flow rate is stable. The default maximum FF test time is 600 s.	• 100 to 9999 s • ***AUTO***
FF maximum flow	Type the maximum flow rate of the test.	0.1 to 1000 mL/min
FF minimum flow (optional)	• Type the minimum flow rate. • Leave the field empty to set the minimum flow to zero.	Max. 20% of the ***FF maximum flow***

Step **Action**

Parameter	Description	Range
Minimum BP	Type the minimum pressure of the BP test.	• 400 to 6500 mbar • 5.80 to 94.27 psi >250 mbar or 3.63 psi above the ***FF test pressure***[1]
Maximum BP pressure	• Type the maximum pressure of the BP test. • Leave the field empty to select the line pressure as maximum pressure of the BP test.	• Max. 7000 mbar • Max. 101.53 psi >250 mbar or 3.63 psi above ***Minimum BP***[2]

[1] An error is displayed during the test, if the selected ***Minimum BP*** is not 250 mbar or more above ***FF test pressure***.
[2] An error is displayed during the test, if the selected ***Maximum pressure*** is not 250 mbar or more above ***Minimum BP***.

Tip:

When using standard wetting liquids, the test parameters are usually available from the manufacturer of filter.

Tip:

Increase the pre-stabilization time:

- *When testing large filter assemblies (over 20 L).*
- *When the filter requires a pre-pressurization phase at a different pressure than the test pressure.*

Note:

*If you tap the button to return to the **Main menu**, the selected parameters are not saved.*

5 Tap the button.

Result:
An overview of the test parameters is shown.

6 Tap the button.

Result:
The test starts. If you start a test during an ongoing run, the new run is placed in a queue. The queue is listed in the ***Test result*** screen.

Note: *The run can be aborted at any time. Tap the*  *button, and then tap* ***Ok****.* ***Test result: MANUAL ABORT*** *is added to the test result file.*

During a FF + BP test

The phases of a FF + BP test are described in the table below.

Phase	Description
FF	The instrument performs the FF test up to the filter testing phase. See *During a FF test, on page 194* for a detailed description of the phases. If the FF test fails, the BP test does not start.
BP	The instrument performs a BP test. The leak test phase is excluded during the FF + BP test. See *During a BP test, on page 199* for a detailed description of the phases.
Test result	The test results are shown on the HMI and automatically saved to the internal memory. • ***PASS***, ***Flow within limits***, and ***Bubble point within limits*** indicate that the tested filter is functional. • ***FAIL*** and ***FLOW TOO HIGH*** abort the FF+BP test. This result might indicate a defective filter or a leak in the tested assembly. • In the unlikely case of a failed BP test after passing the FF test, ***BUBBLE POINT NOT OBTAINABLE*** might indicate a defective filter or a leak in the tested assembly. ***Note:*** *If the HMI displays an error message, see Chapter 9 Troubleshooting, on page 286 for a description of possible causes and corrective actions.*

7.5 Run a WIT test

About this section

This section describes how to run a water intrusion test (WIT) on hydrophobic filters. The test is described in *Water intrusion test, on page 28*.

In this section

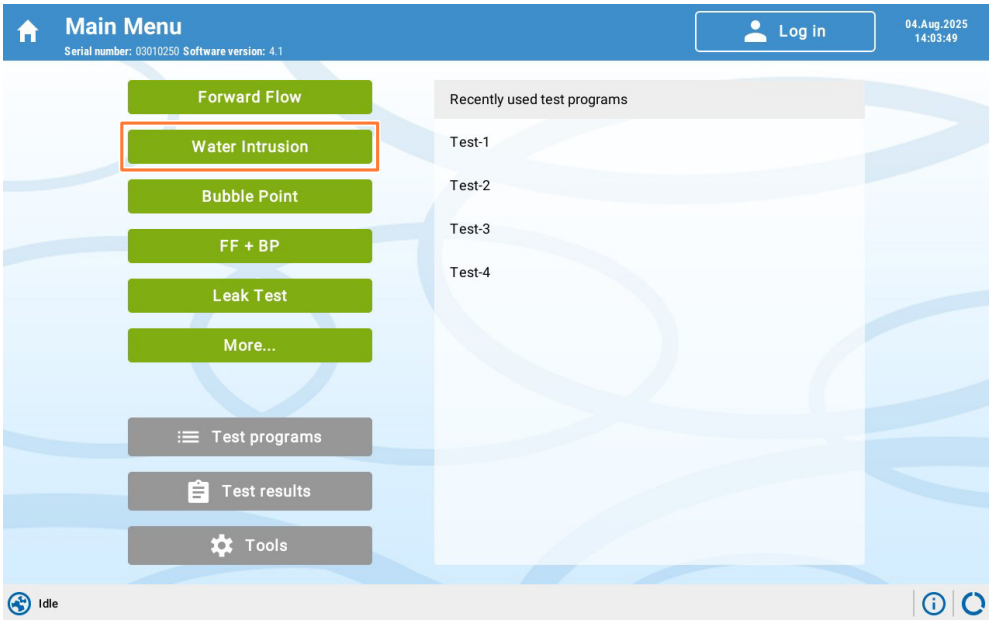
7.5.1 Start a WIT test

A WIT test can be started:

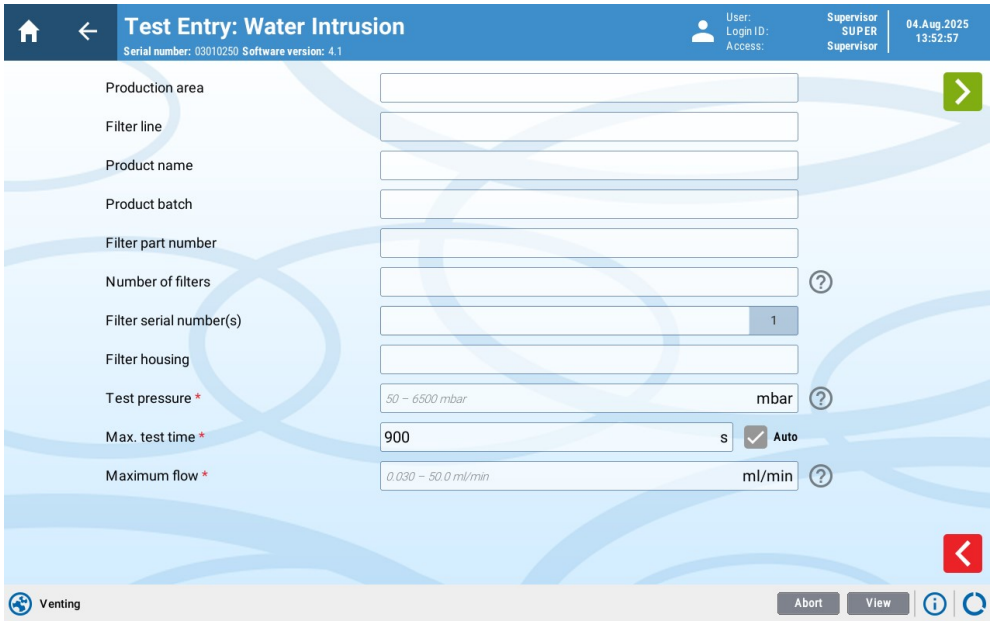
- from a saved test program, see *Section 7.3 Start a test program, on page 185*.
- after setting the parameters manually, as described below.

Follow the steps below to start a WIT test after setting the parameters manually.

Step	Action
1	Log in with an ***Operator***, an ***Automation operator***, a ***Supervisor***, or if enabled, an ***Administrator***, or a ***Super-admin*** account.
2	Tap ***Water Intrusion***.



Step	Action
3	Set the general run parameters.



Parameter	Description
Operator (optional)	• If the instrument is in standard access control, type the name of the operator. • If the instrument is in HLAC mode, the software automatically fills in the name of the user that is currently logged in.
Production area	Type the location or room where the test is performed.
Filter line	Type the filter line.
Custom parameter (optional)	Type the value for the custom parameter. See *Set general settings, on page 111* for instructions to set up custom parameters.
Product name	Type the product name of the material that the tested assembly is used with.
Product batch	Type the product batch of the material that the tested assembly is used with.
Filter part number(s)	Type the filter part number.
Number of filters	Type the number of filters that are connected.
Filter serial number(s)	Type the filter serial number.

Step **Action**

Parameter	Description
Filter housing	Type the filter housing type.

Note:

The obligatory fields are marked with a red asterisk. The non-obligatory fields are for record keeping purposes, and are not essential to run a test.

4 Set the test parameters.

Parameter	Description	Range
Pre-stabilization pressure (optional)	• Type the pre-stabilization pressure. • Leave the field empty to skip the pre-stabilization phase.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Pre-stabilization time (optional)	• Type the pre-stabilization time. • Leave the field empty to skip the pre-stabilization phase.	0 to 9999 s
Test pressure	Type the test pressure.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Max. test time	• Type the maximum operation time of the test. • Select ***AUTO*** to run the test until the flow rate is stable. The default maximum test time is 900 s.	• 100 to 9999 s • ***AUTO***
Maximum flow	Type the maximum flow rate of the test.	0.03 to 50 mL/min

Tip:

When using standard wetting liquids, the test parameters are usually available from the manufacturer of filter.

Tip:

Increase the pre-stabilization time:

- *When testing large filter assemblies (over 20 L).*

Step	Action
	• *When the filter requires a pre-pressurization phase at a different pressure than the test pressure.* ***Note:*** *If you tap the*  *button to return to the* ***Main menu****, the selected parameters are not saved.*
5	Tap the  button. *Result:* An overview of the test parameters is shown.
6	Tap the  button. *Result:* The test starts. If you start a test during an ongoing run, the new run is placed in a queue. The queue is listed in the ***Test result*** screen.

Note: *The run can be aborted at any time. Tap the*  *button, and then tap* ***Ok****.* ***Test result: MANUAL ABORT*** *is added to the test result file.*

7.5.2 During a WIT test

The phases of a WIT test are described in the table below.

Phase	Description
Pressurization	1. The instrument pressurizes the filter housing to the selected test pressure. 2. The stage of the measurement is displayed in a percentage bar on the HMI. A second bar shows the actual pressure. 3. When the test pressure reaches 100% of the selected test pressure, the instrument continues with the next phase.
Pre-stabilization	1. If enabled, the instrument applies the pre-stabilization pressure to the filter for the pre-stabilization time. 2. If the pre-stabilization pressure is not reached or is not stable, the test is aborted.
Filter testing	• The instrument pressurizes the filter housing filled with water to the selected test pressure. • The percentage bar charts on the screen show the time and the flow rate. • The measurement values on the screen show the current flow rate. • Tap the  button to display a graph of the measured flow rate. Tap the ***Status*** button to return to the ***Test data*** screen. • A filter is considered intact, if the measured flow rate is below the threshold by the end of the test.
Filter house venting	• The instrument uses the external vent valve to vent the filter housing. Venting the filter prevents the test liquid from entering the instrument. Test liquid could contaminate the instrument and damage the components. • Large filter housings can contain a residual pressure.

Phase	Description
Test result	The test results are shown on the HMI and automatically saved to the internal memory. • ***PASS*** and ***Flow within limits*** indicate that the measured flow rate is below the threshold by the end of the test. • ***FAIL*** indicates that the measured flow rate is above the threshold by the end of the test. ***Note:*** *If the HMI displays an error message, see Chapter 9 Troubleshooting, on page 286 for a description of possible causes and corrective actions.*

7.6 Run a LT/PD test

About this section

This section describes how to run a leak test (LT) and a pressure decay (PD) test. The tests are described in *Section 3.2 Functional overview, on page 27*.

In this section

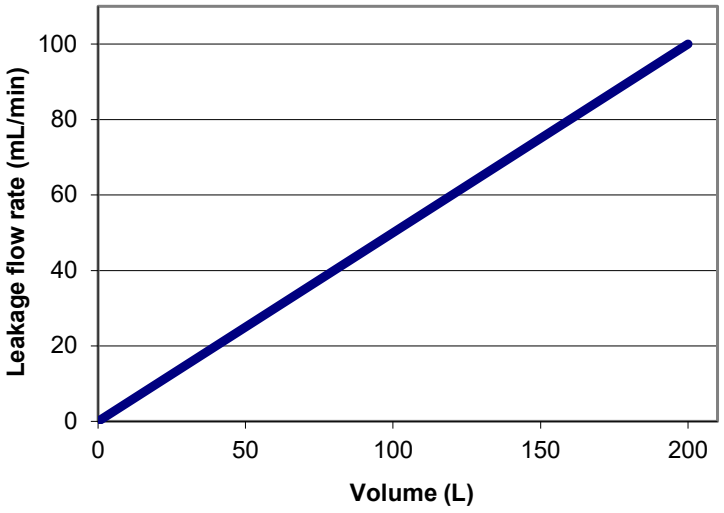
7.6.1 Run a LT test

Introduction

This section describes how to run a LT using the instrument.

Detection limit

The sensitivity of the LT test depends on the pressure change caused by the leak and on the volume of the tested assembly. The detection limit for the LT test is a volume deviation greater than 0.05% of the assembly volume. The graph below describes the relationship between the detection limit (i.e., the leakage flow rate) and the volume of the assembly.



Tip: *When testing an assembly with a volume over 50 L:*

- *A LT test has decreased sensitivity and increased pressurization time at high volumes.*
- *A PD test with a long test time may be more suitable at high volumes.*

Calculate leak rate threshold

The leak rate threshold for the ***Pass*** and ***Fail*** test result can be calculated from the maximum pressure decay.

The equation for the leak rate threshold in mbar:

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

A conversion factor of 1000 is used to convert to 1000 mbar absolute pressure.

The equation for the leak rate threshold in psi:

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

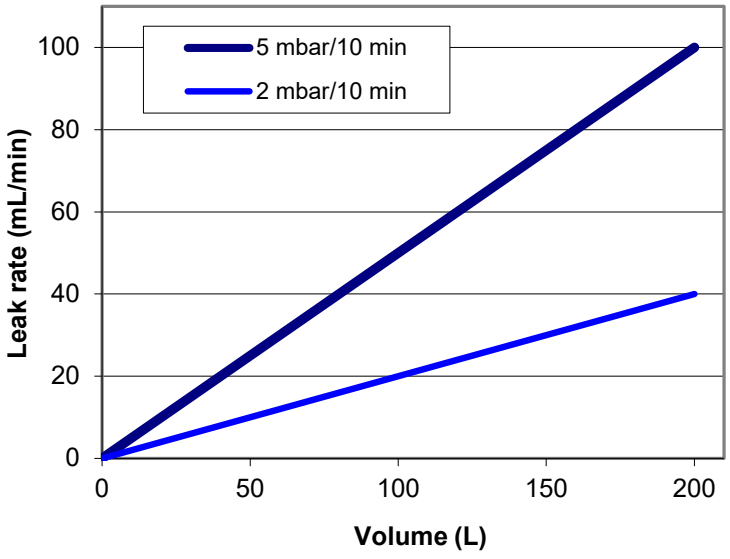
A conversion factor of 14.5 is used to convert to 14.5 psi absolute pressure.

The table below describes the equation parameters and units.

Equation parameters	Units
Leak rate	mL/min
Maximum pressure decay	mbar or psi
Volume	mL
Test time	min
Conversion factor to absolute pressure	N/A

The graph below shows the leak rate threshold for 0 to 200 liter at:

- a maximum pressure decay of 2 mbar (0.029 psi)/10 min
- a maximum pressure decay of 5 mbar (0.0715 psi)/10 min



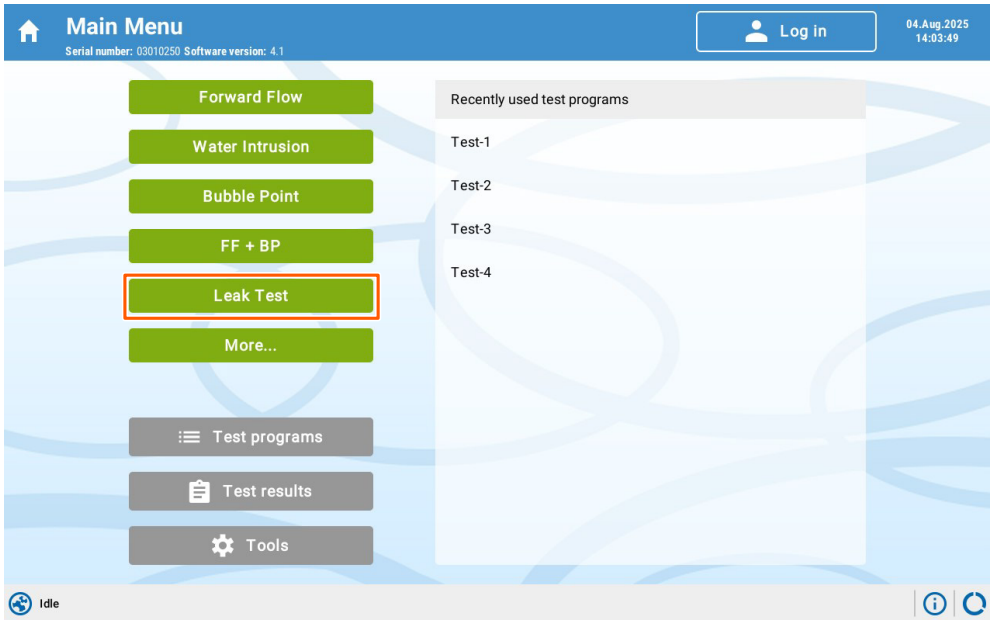
Start a LT test

A LT test can be started:

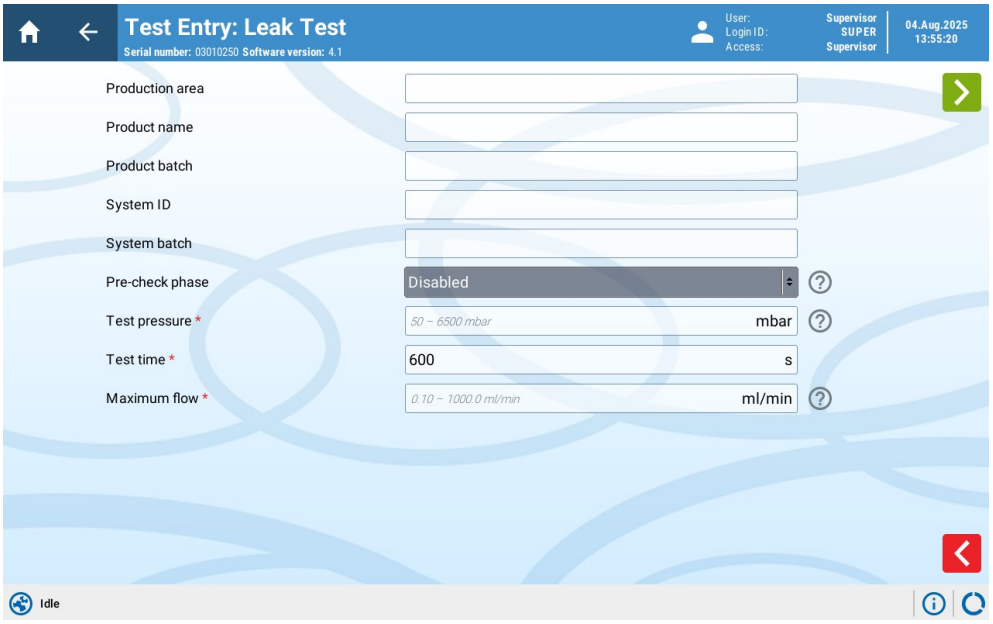
- from a saved test program, see *Section 7.3 Start a test program, on page 185*.
- after setting the parameters manually, as described below.

Follow the steps below to start a LT test after setting the parameters manually.

Step	Action
1	Log in with an ***Operator***, an ***Automation operator***, a ***Supervisor***, or if enabled, an ***Administrator***, or a ***Super-admin*** account.
2	Tap ***Leak Test***.



Step	Action
3	Set the general run parameters.



Parameter	Description
Operator (optional)	• If the instrument is in standard access control, type the name of the operator. • If the instrument is in HLAC mode, the software automatically fills in the name of the user that is currently logged in.
Production area	Type the location or room where the test is performed.
Custom parameter (optional)	Type the value for the custom parameter. See *Set general settings, on page 111* for instructions to set up custom parameters.
Product name	Type the product name of the material that the tested assembly is used with.
Product batch	Type the product batch of the material that the tested assembly is used with.

Note:

The obligatory fields are marked with a red asterisk. The non-obligatory fields are for record keeping purposes, and are not essential to run a test.

Step	Action
4	Set the test parameters.

Parameter	Description	Range
System ID	Type the description of the tested assembly.	N/A
System batch	Type the batch of the tested assembly.	N/A
Pre-check phase	Select to enable or disable the pre-check phase. The pre-check phase verifies the function of the valves and the connectors.	• ***Enabled*** • ***Disabled***
Pre-stabilization pressure (optional)	• Type the pre-stabilization pressure. • Leave the field empty to skip the pre-stabilization phase.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Pre-stabilization time (optional)	• Type the pre-stabilization time. • Leave the field empty to skip the pre-stabilization phase.	0 to 9999 s
Test pressure	Type the test pressure.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Test time	Type the maximum operation time of the test.[1]	100 to 9999 s
Maximum flow	Type the maximum flow rate of the test. To calculate the ***Maximum flow*** from the pressure decay threshold, see *Calculate leak rate threshold, on page 214*.	0.1 to 1000 mL/min

[1] The automatic test time function is disabled for the LT test.

Tip:

Increase the pre-stabilization time when testing large assemblies (over 20 L).

Note:

If you tap the  *button to return to the* ***Main menu****, the selected parameters are not saved.*

Step	Action
5	Tap the  button. *Result:* An overview of the test parameters is shown.
6	Tap the  button. *Result:* The test starts. If you start a test during an ongoing run, the new run is placed in a queue. The queue is listed in the ***Test result*** screen.

Note: *The run can be aborted at any time. Tap the*  *button, and then tap* ***Ok****.* ***Test result: MANUAL ABORT*** *is added to the test result file.*

During a LT test

The phases of a LT test are described in the table below.

Phase	Description
Pre-check	If enabled, the instrument applies pressure on the tested assembly and performs a short pressure hold test. The instrument verifies that all valves and connectors are properly closed. This phase protects the connectors from being exposed to a high pressure.
Pressurization	1. The instrument pressurizes the tested assembly to the selected test pressure. 2. The stage of the measurement is displayed in a percentage bar on the HMI. A second bar shows the actual pressure. 3. When the test pressure reaches 100% of the selected test pressure, the instrument continues with the next phase.
Pre-stabilization	1. If enabled, the instrument applies the pre-stabilization pressure to the tested assembly for the pre-stabilization time. 2. If the pre-stabilization pressure is not reached or is not stable, the test is aborted.

Phase	Description
Testing	• The instrument pressurizes the tested assembly to the selected test pressure. • The percentage bar charts on the screen shows the flow rate. • The measurement values on the screen show the current time and flow rate. • Tap the  button to display a graph of the measured flow rate. Tap the ***Status*** button to return to the ***Test data*** screen. • A tested assembly is considered intact, if the measured flow rate is below the selected threshold by the end of the test.
Test result	The test results are shown on the HMI and automatically saved to the internal memory. • ***PASS*** and ***NO LEAK DETECTABLE*** indicates that the flow rate is below the leak rate threshold. • ***FAIL*** indicates that the flow rate is above the leak rate threshold. ***Note:*** *If the HMI displays an error message, see Chapter 9 Troubleshooting, on page 286 for a description of possible causes and corrective actions.*

7.6.2 Run a PD test

Introduction

This section describes how to run a PD test.

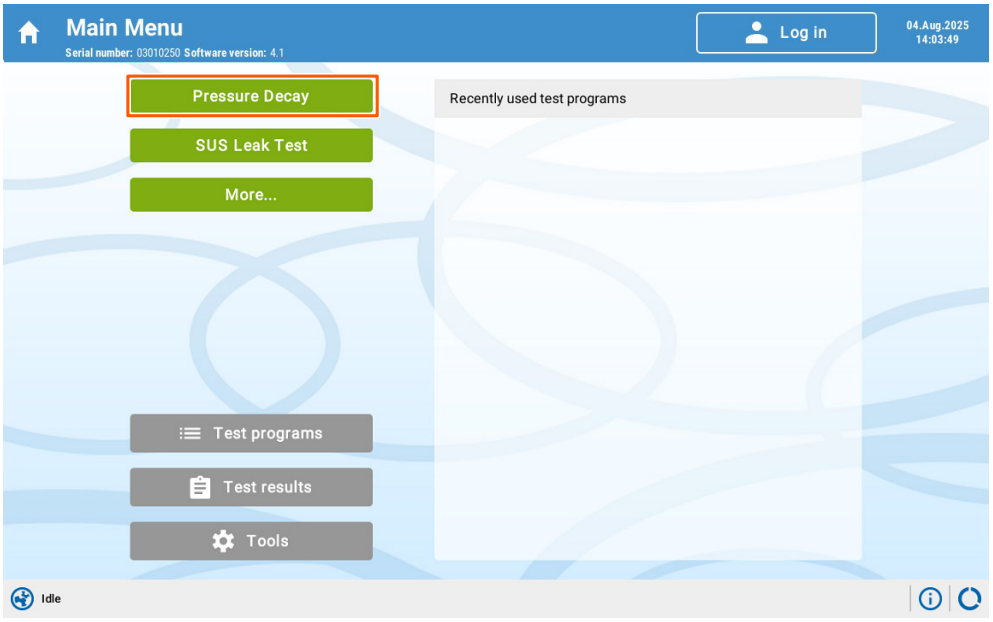
Start a PD test

A PD test can be started:

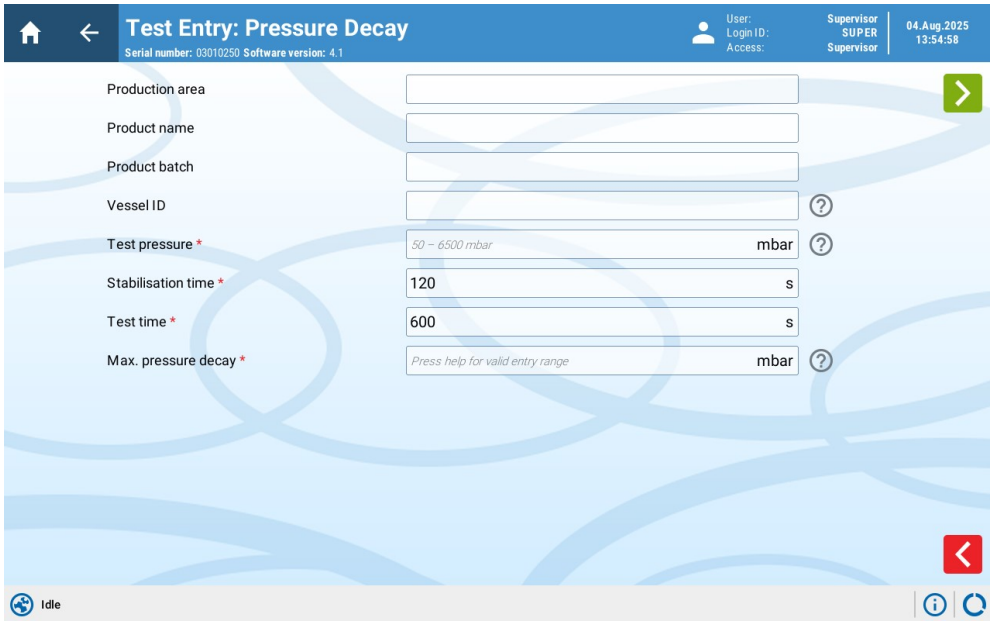
- from a saved test program, see *Section 7.3 Start a test program, on page 185*.
- after setting the parameters manually, as described below.

Follow the steps below to start a PD test after setting the parameters manually.

Step	Action
1	Log in with an ***Operator***, an ***Automation operator***, a ***Supervisor***, or if enabled, an ***Administrator***, or a ***Super-admin*** account.
2	Tap ***Pressure Decay***.



Step	Action
3	Set the general run parameters.



Parameter	Description
Operator (optional)	• If the instrument is in standard access control, type the name of the operator. • If the instrument is in HLAC mode, the software automatically fills in the name of the user that is currently logged in.
Production area	Type the location or room where the test is performed.
Custom parameter (optional)	Type the value for the custom parameter. See *Set general settings, on page 111* for instructions to set up custom parameters.
Product name	Type the product name of the material that the tested assembly is used with.
Product batch	Type the product batch of the material that the tested assembly is used with.

Note:

The obligatory fields are marked with a red asterisk. The non-obligatory fields are for record keeping purposes, and are not essential to run a test.

Step	Action

4 Set the test parameters.

Parameter	Description	Range
Vessel ID	Type the description of the tested rigid vessel.	N/A
Pre-stabilization pressure (optional)	• Type the pre-stabilization pressure. • Leave the field empty to skip the pre-stabilization phase.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Pre-stabilization time (optional)	• Type the pre-stabilization time. • Leave the field empty to skip the pre-stabilization phase.	0 to 9999 s
Test pressure	Type the test pressure.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Stabilization time	Type the stabilization time. The recommended stabilization time is 600 s or higher.	100 to 9999 s
Test time	Type the maximum operation time of the test. The recommended test time is 600 s or higher.[1]	100 to 9999 s
Max. pressure decay	Type the maximum pressure decay for the test.	1 to 6500 mbar

[1] The automatic test time function is disabled for the PD test.

Note:

If you tap the  *button to return to the* ***Main menu****, the selected parameters are not saved.*

5 Tap the  button.

Result:
An overview of the test parameters is shown.

6 Tap the  button.

Step	Action
	Result: The test starts. If you start a test during an ongoing run, the new run is placed in a queue. The queue is listed in the ***Test result*** screen.

Note: *The run can be aborted at any time. Tap the*  *button, and then tap* ***Ok****.* ***Test result: MANUAL ABORT*** *is added to the test result file.*

During a PD test

The phases of a PD test are described in the table below.

Phase	Description
Pressurization	1. The instrument pressurizes the vessel to the selected test pressure. 2. The stage of the measurement is displayed in a percentage bar on the HMI. A second bar shows the actual pressure. 3. When the test pressure reaches 100%, the instrument continues with the next phase.
Stabilization	The instrument applies the test pressure to the vessel for the selected stabilization time.
Testing	• The percentage bar charts on the screen shows the time and the flow rate. • The measurement values on the screen show the current pressure. • Tap the  button to display a graph of the measured pressure decay. Tap the ***Status*** button to return to the ***Test data*** screen. • The vessel is considered intact, if the measured pressure decay is below the threshold by the end of the test.
Test result	The test results are shown on the HMI and automatically saved to the internal memory. • ***PASS*** and ***Pressure decay within limits*** indicate that the pressure decay is below the pressure decay threshold. • ***FAIL*** and ***PRESSURE DECAY TOO HIGH*** indicate that the pressure decay is above the pressure decay threshold. ***Note:*** *If the HMI displays an error message, see Chapter 9 Troubleshooting, on page 286 for a description of possible causes and corrective actions.*

7.7 Run a SUS LT test

About this section

This section describes how to run a single-use equipment leak test (SUS LT). The test is described in *SUS leak test, on page 29*.

In this section

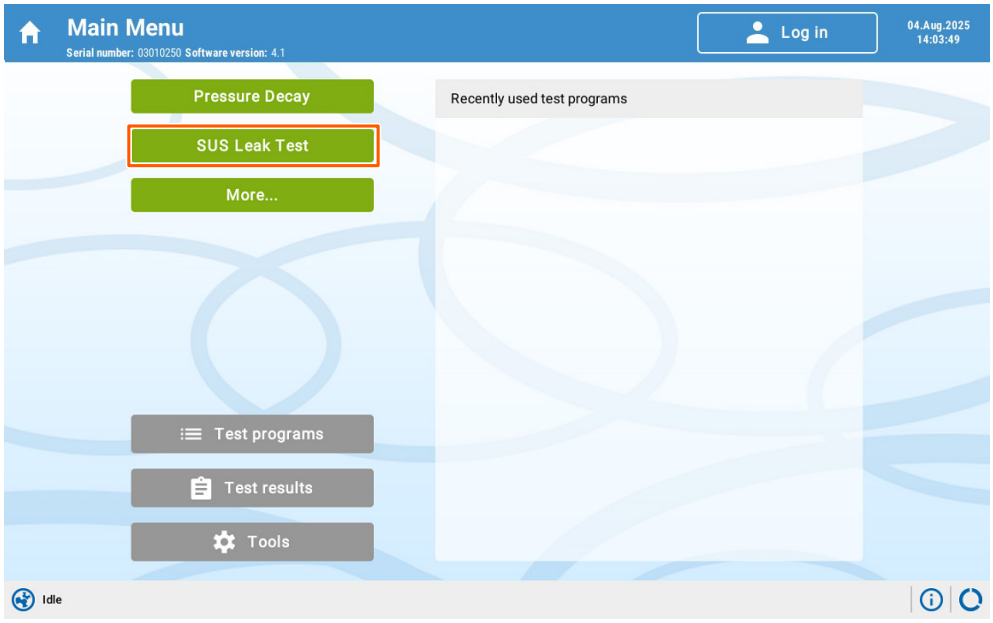
7.7.1 Start a SUS LT test

A SUS LT test can be started:

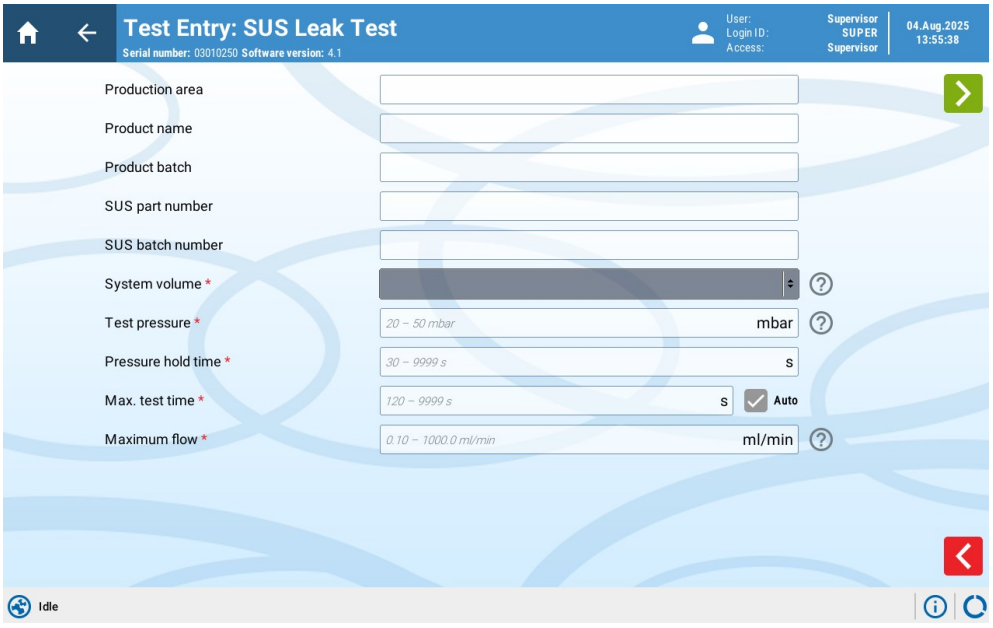
- from a saved test program, see *Section 7.3 Start a test program, on page 185*.
- after setting the parameters manually, as described below.

Follow the steps below to start a SUS LT test after setting the parameters manually.

Step	Action
1	Log in with an ***Operator***, an ***Automation operator***, a ***Supervisor***, or if enabled, an ***Administrator***, or a ***Super-admin*** account.
2	Tap ***SUS Leak Test***.



Step	Action
3	Set the general run parameters.



Parameter	Description
Operator (optional)	• If the instrument is in standard access control, type the name of the operator. • If the instrument is in HLAC mode, the software automatically fills in the name of the user that is currently logged in.
Production area	Type the location or room where the test is performed.
Custom parameter (optional)	Type the value for the custom parameter. See *Set general settings, on page 111* for instructions to set up custom parameters.
Product name	Type the product name of the material that the tested assembly is used with.
Product batch	Type the product batch of the material that the tested assembly is used with.

Note:

The obligatory fields are marked with a red asterisk. The non-obligatory fields are for record keeping purposes, and are not essential to run a test.

Step	Action
4	Set the test parameters.

Parameter	Description	Range
SUS part number	Type the part number of the tested assembly.	N/A
SUS batch number	Type the batch number of the tested assembly.	N/A
System volume	Type the approximate size of the tested assembly.	• ***Very small (> 50 mL)*** • ***Small (> 500 mL)*** • ***Medium (> 1 L)*** • ***Large (> 5 L)***
Actual volume	When ***System volume*** is set to ***Large (> 5 L)***, type the actual volume of the tested assembly.	5 to 200 L
Filling pressure	When ***System volume*** is set to ***Large (> 5 L)***, type the filling pressure of the test. The maximum value is 20% higher than the ***Test pressure***.	20 to 60 mbar
Fill hold time	When ***System volume*** is set to ***Large (> 5 L)***, type the maximum time to hold the filling pressure.	120 to 9999 s
Test pressure	Type the test pressure.	20 to 50 mbar
Pressure hold time	Type the maximum time to hold the filling pressure.	120 to 9999 s
Max. test time	Type the maximum operation time of the test.[1]	• 300 to 9999 s for volumes ≤ 50 L • 600 to 9999 s for volumes > 50 L
Maximum flow	Type the maximum flow rate of the test.	0.1 to 1000 mL/min

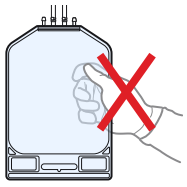
[1] The automatic test time function is disabled for the SUS LT test.

Step	Action
	Tip: • *Refer to the Technical Report (USTR3147) for recommended test parameters for running a SUS LT test.* • *The SUS LT test slowly pressurizes the tested assembly until it reaches the test pressure. Make sure that the* ***Pressure hold time*** *and the* ***Max. test time*** *are sufficient for size of the tested assembly.* ***Note:*** *If you tap the*  *button to return to the* ***Main menu****, the selected parameters are not saved.*
5	Tap the  button. *Result:* An overview of the test parameters is shown.
6	Tap the  button. *Result:* The test starts. If you start a test during an ongoing run, the new run is placed in a queue. The queue is listed in the ***Test result*** screen.
Note:	*The run can be aborted at any time. Tap the*  *button, and then tap* ***Ok****.* ***Test result: MANUAL ABORT*** *is added to the test result file.*

7.7.2 During a SUS LT test

The phases of a SUS LT test are described in the table below.

Phase	Description
Filling	1. The instrument fills the tested assembly to allow the bag to unfold. 2. The instrument fills the tested assembly at the selected filling pressure. 3. The instrument stops the filling phase if the tested assembly is not filled in the expected time for the selected volume.
Filling hold	For volumes above 50 L, holds the instrument the selected filling pressure for the selected ***Fill hold time***.
Stabilization	1. The instrument applies the test pressure to the tested assembly. The stabilization phase ends when the flow rate is within the defined limits. 2. If the pre-stabilization pressure is not reached within 15 minutes, the test is aborted. 3. If the instrument does not detect any flow rate, the test ends directly after the stabilization phase.
Pressure hold	The instrument holds the selected test pressure for the selected ***Pressure hold time***.
Testing	• The percentage bar charts on the screen shows the time and the flow rate. • The measurement values on the screen show the current flow rate. • Tap the  button to display a graph of the measured flow rate. Tap the ***Status*** button to return to the ***Test data*** screen.

Phase	Description
Venting	The instrument vents the tested assembly. The venting time depends on the volume of the tested assembly. **NOTICE** Disconnect the connection to the Flowstar V LGR instrument to allow air venting during bag deflation. Do not manually press on the SUS bag to speed up the venting process. 
Test result	The test results are shown on the HMI and automatically saved to the internal memory. • ***PASS*** and ***Flow within limits*** indicate that the flow rate is below the leak rate threshold, that no pressure loss could be detected in the tested assembly, or that the leak rate is below the detection threshold. • ***FAIL*** indicates that the flow rate is above the leak rate threshold. ***Note:*** *If the HMI displays an error message, see Chapter 9 Troubleshooting, on page 286 for a description of possible causes and corrective actions.*

7.8 After run procedures

About this section

This section describes how to access or sign result files, and how to shut down the instrument after a run.

WARNING

Overpressure. Make sure that filter housing is vented and is at atmospheric pressure before dismantling of the filter assembly. Overpressure can result in injury.

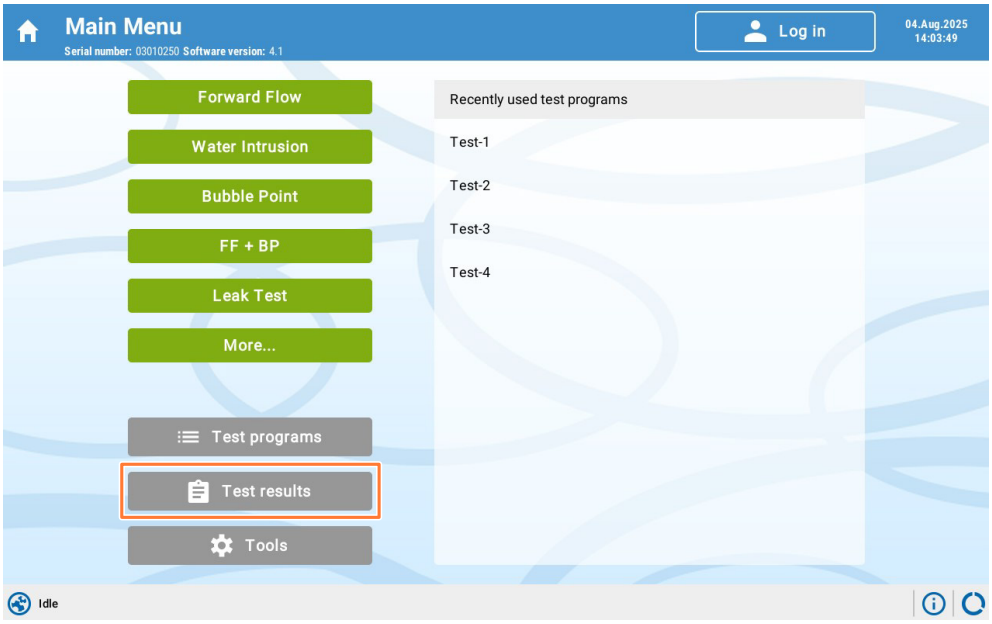
In this section

7.8.1 Access a test result

The instrument automatically stores all generated test results.

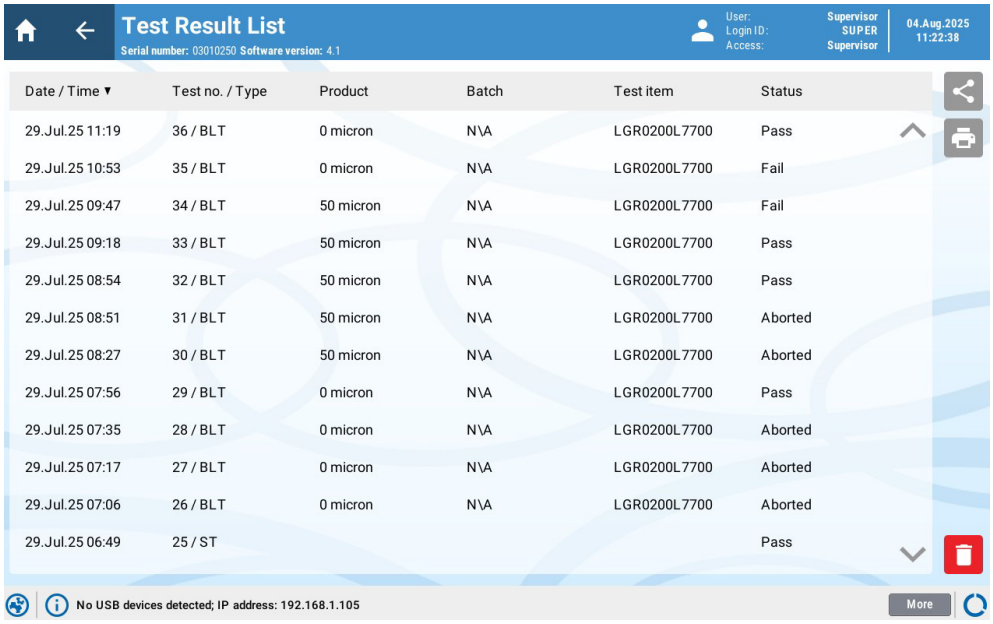
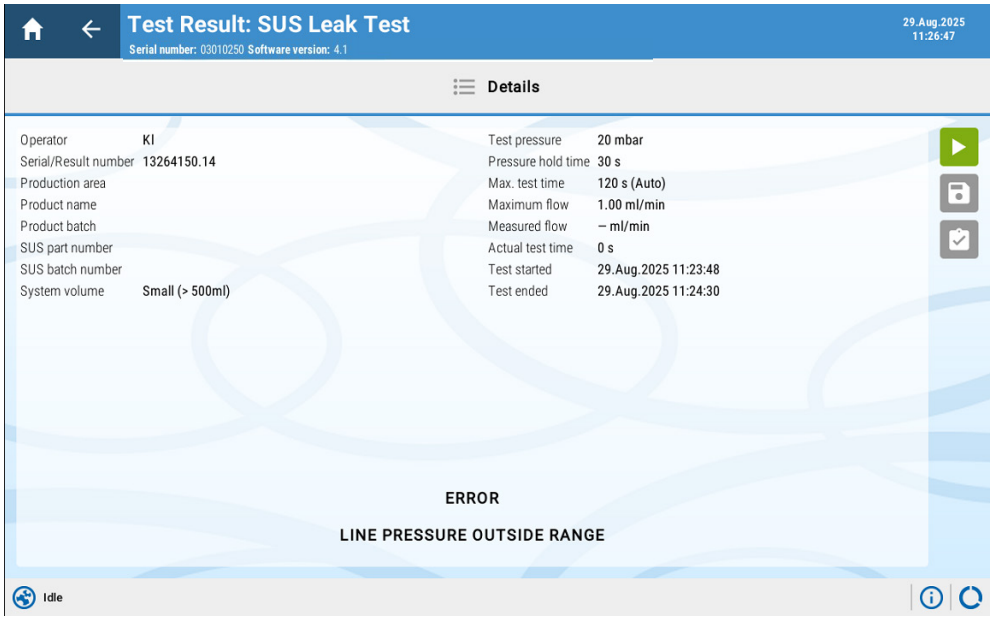
Follow the steps below to access and handle the test result files in the software.

Step	Action
1	Log in with an ***Operator***, an ***Automation operator***, a ***Supervisor***, or if enabled, an ***Administrator***, or a ***Super-admin*** account.
2	Go to ***Test Results***.



Result:

The test results are shown. The test results are initially ordered by the date and time of the run.

Step	Action
3	Tap the header of a column to order the test results according to that respective field. ***Note:*** *The test results are initially ordered by the **Date/Time** column. The most recent test result is displayed at the top of the test result list.* 
4	Tap a test result to display the details of that test. 

- To print the test result, see *Section 7.8.3 Create a printout, on page 238*.
- To transfer the test result, see *Section 8.4.1 Transfer of test results, on page 260*.

- To add an electronic signature, see *Section 7.8.2 Electronically sign a test result, on page 236*.

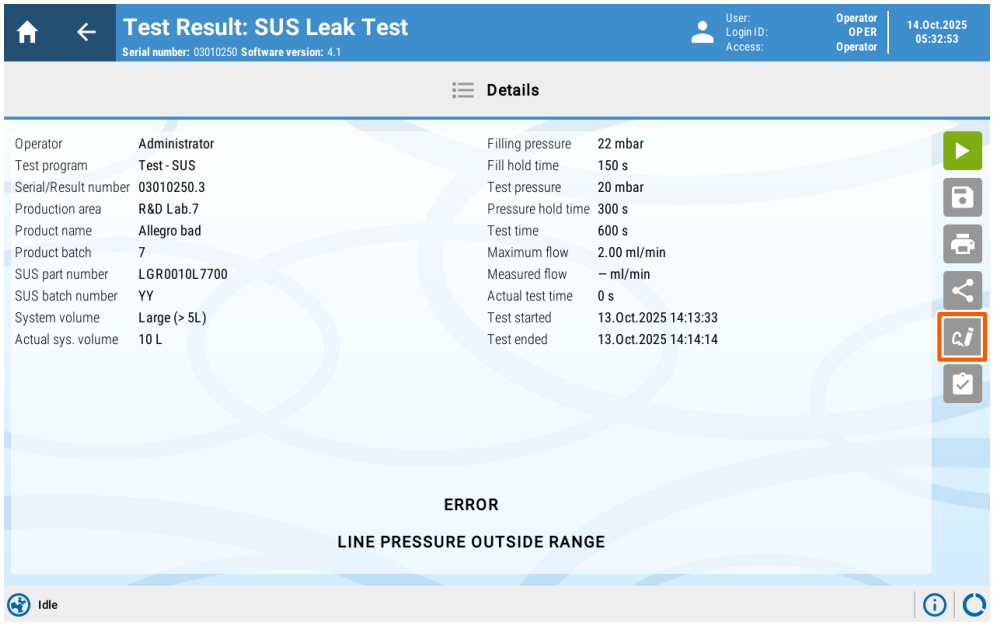
7.8.2 Electronically sign a test result

Select the settings for electronic signatures in the ***User Rights*** menu, see *Set up user rights, on page 115*. In high level access control (HLAC) all test results must be signed by at least one user. In standard access control, signatures can be added manually to test results.

Tip: *The test results can be signed on the printout, if* ***Signature type*** *is set to* ***Manuscript*** *in the* ***User Rights*** *settings.*

Follow the steps below to sign the test result files in the software.

Step	Action
1	Log in with an ***Operator***, an ***Automation operator***, a ***Supervisor***, or if enabled, an ***Administrator***, or a ***Super-admin*** account.
2	Go to ***Test Results***. Then, select the relevant test result.
3	Tap the button.



Step	Action
4	Sign the test result. 
5	If required, type a signature comment.
6	If required, add a second signature with another user account.  ***Note:*** *In HLAC mode a second signature may be required, as defined in the **User Rights** settings.*

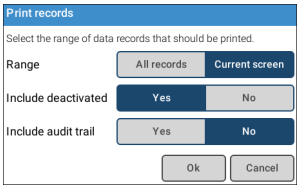
7.8.3 Create a printout

Follow the steps below to create a printout.

Step	Action
1	Connect the instrument to a printer or a USB drive, see *Connect printer, on page 123*.
2	Navigate to the target folder. Possible locations are: • ***Automation*** • ***Date/Time*** • ***Event Audit Trail*** • ***General Settings*** • ***Import/Export*** • ***Network*** • ***Test Programs*** • ***Test Results*** • ***User List*** • ***User Rights*** • ***Printer***
3	Print a file.

File type	Action
Test result	a. Tap the row with the relevant test result. b. Tap the  button. **Result:** The selected test result is printed using the connected printer.

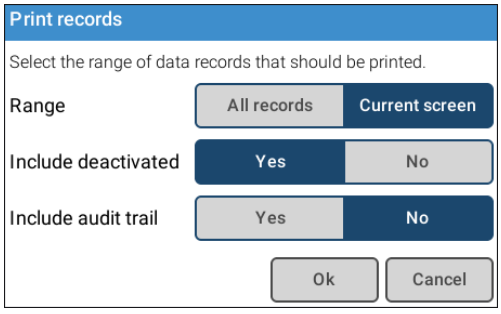
Step **Action**

File type	Action
Test program User list	a. Tap the row with the relevant test result. b. Tap the button. c. Select what to include in the printout.  The table below describes what can be included in the printout: **Parameter** / **Options** ***Range*** — All records; Current screen ***Include deactivated*** — Yes; No ***Include audit trail*** — Yes; No **Result:** The selected file is printed using the connected printer.

Tip: *Files can be printed on two printers at the same time. See Connect a second printer, on page 125 for instructions on how to connect a second printer.*

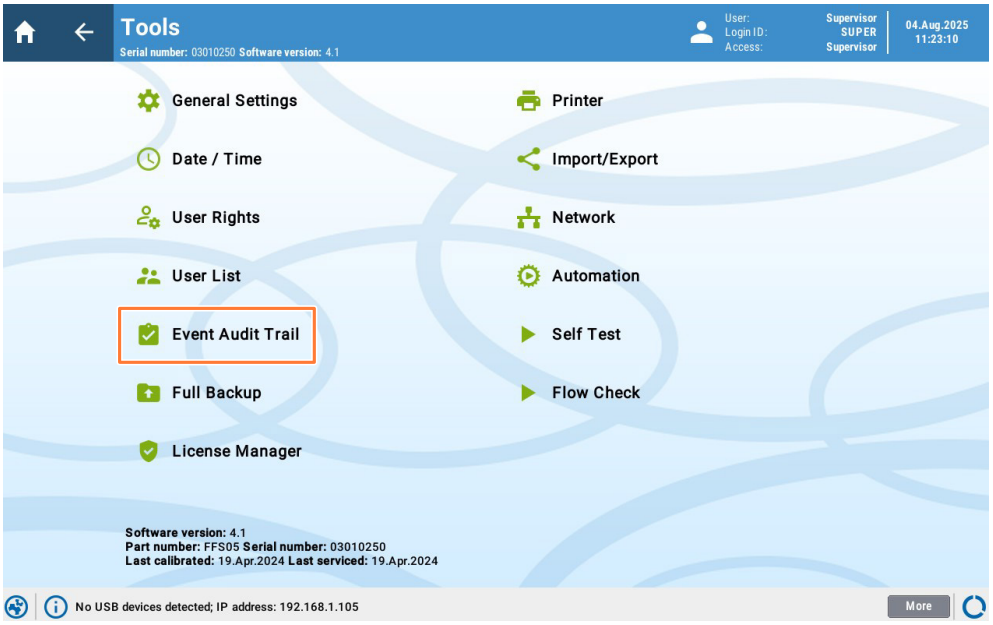
7.8.4 Print record audit trails

Follow the steps below to print a record audit trail.

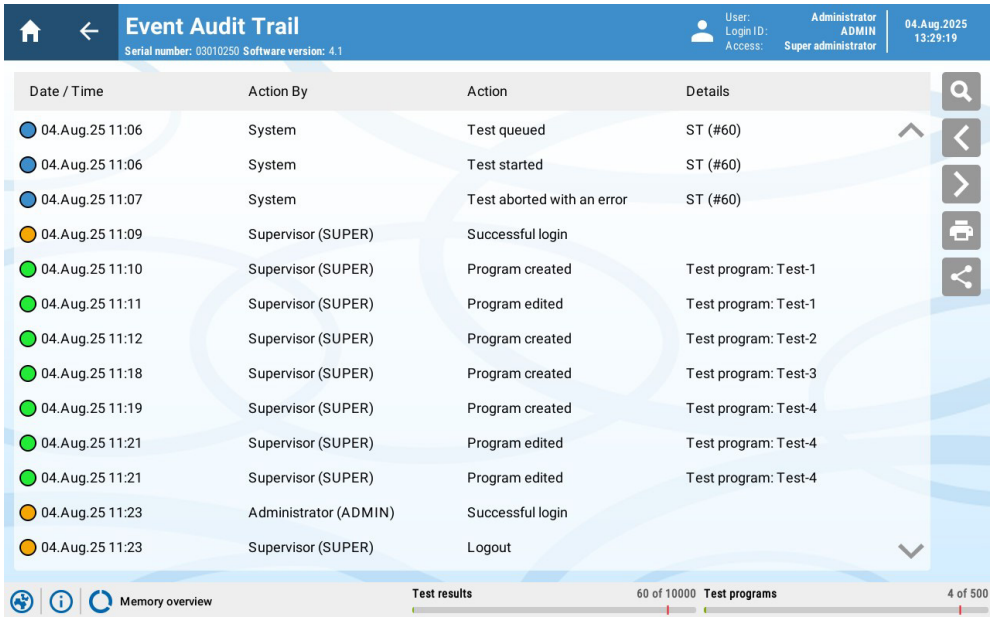
Step	Action
1	Connect the instrument to a printer, a USB drive, or a network location, see *Connect printer, on page 123*.
2	Navigate to the target location. Possible locations are: • ***Automation*** • ***Date/Time*** • ***General Settings*** • ***Import/Export*** • ***Network*** • ***Test Programs*** • ***User List*** • ***User Rights*** • ***Printer***
3	Optional: Tap the row to select the relevant item.
4	Tap the  button.
5	To include the audit trail, tap ***Yes*** in the ***Include audit trail*** row. 
6	Tap ***Ok***.

7.8.5 Print or view event audit trails

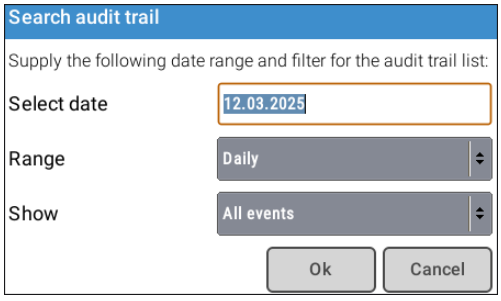
Follow the steps below to print or view an event audit trail.

Step	Action
1	Connect the instrument to a printer, a USB drive, or a network location, see *Connect printer, on page 123*.
2	Go to ***Tools*** →***Event Audit Trail***. 

Step	Action
3	Tap the button at the upper right corner.



Step	Action
4	Select the search parameters.



Parameter	Definition
Select date	Select the audit files created on this date.
Range	Select the audit files created during this range of dates. The options are: • ***Daily*** • ***Monthly***

Step	Action

Parameter	Definition
Show	Select the audit files that are related to a specific type of data. The options are: • ***All events*** • ***Settings only*** • ***Test programs only*** • ***Test results only*** • ***Service*** • ***All other events***

5 Tap ***Ok***, then tap the button.

Result:
The selected files are printed using the connected printer. The printout includes the current software version, the instrument serial number, the date, and the time.

7.8.6 Shut down the instrument

Follow the steps below to shut down the instrument.

Step	Action
1	On the right side of the HMI, press the power button. 
2	On the back of the instrument, press the **O** position on the power switch. **NOTICE** Do not switch on the power switch before all connections are made. 

8 Maintenance

About this chapter

This chapter provides information about maintenance and recommended frequency of actions that can be performed by users.

In this chapter

8.1 Safety precautions

WARNING

Only personnel authorized by Cytiva may perform service and maintenance of the product.

WARNING

Fuse replacement must only be performed by personnel authorized by Cytiva.

WARNING

Use only approved parts. Only spare parts and accessories that are approved or supplied by Cytiva can be used for maintaining or servicing the product.

WARNING

Always use appropriate Personal Protective Equipment (PPE) during operation and maintenance of this product.

8.2 Service and preventive maintenance

Introduction

Regular service and maintenance is necessary to maintain optimal condition and to extend the operational lifetime of the components.

Service and preventive maintenance work must be performed according to Cytiva recommendations, and according to the maintenance instructions of the component manufacturers.

Service frequency

The requirements for frequency of service and preventive maintenance depend on the frequency of use and the specific applications performed. A general recommendation is one service and preventive maintenance visit, including instrument calibration, every year. Perform a full instrument service every three years. Adhere to the maintenance intervals. Service can be performed locally or at an approved Cytiva service center. Contact your Cytiva representative for instrument repairs.

Service agreements

Contact your Cytiva representative for information about frequency of service requirements to suit individual process needs and for details of the Cytiva service agreement options available.

For mutual protection and safety of Cytiva service personnel and our customers, equipment and work areas must be clean and free of any hazardous contaminants before a Service Engineer starts working. To avoid delays in the servicing of your equipment, complete the Cytiva service checklist and present it to the Service Engineer upon arrival. Equipment and/or work areas not sufficiently cleaned, accessible and safe for an engineer might lead to delays in servicing the equipment and could be subject to additional charges. Knowledge of any additional hazards present at your site during Cytiva service is critical.

Qualification after software update

An Operational Qualification is performed on a generic instrument for each major software version (e.g., v2.0 to v4.0) that is taken into production. An Operational Qualification is not performed for each minor software versions (e.g., v4.0 to v4.1) because of the minor nature of the changes. Software functionality and qualification status are not affected for each software patch or bug fix (e.g., 4.2.0 to 4.2.1).

When an instrument is upgraded with a new software version, consider the following recommendations regarding re-qualification. Cytiva recommends to do a full re-qualification when a major software update is done. The user can request a re-qualification when a minor software update is done, but Cytiva does not consider the changes in minor software upgrade to affect the validated status of the instrument.

For further question on software updates, contact your local Cytiva service representative.

8.3 Hardware maintenance

About this section

This section describes the maintenance procedures that the user can perform on the instrument.

In this section

8.3.1 User maintenance schedule

Introduction

The maintenance recommendations vary depending on how frequently you use your system. Note that the recommendation might not apply to your specific use of the system. The system owner is solely responsible for establishing applicable routines for periodic maintenance. For maintenance work not described in this manual, contact your Cytiva representative.

Note: *The most recent calibration date and servicing date are stored on the instrument.*

Maintenance actions

The table below lists the maintenance actions.

Component	Action
Connections	Test the performance of the connections regularly. See *Section 8.3.3 Self test, on page 251*.
Exterior of the instrument	Clean the exterior of the instrument. See *Section 8.3.2 General cleaning, on page 250*.

8.3.2 General cleaning

Safety precautions

NOTICE
Do not use strong solvents or concentrated solutions of cleaning agents when cleaning the external surfaces of the product.

Cleaning the instrument

For the instrument to function properly, make sure that the instrument is kept clean and dry.

- Switch off the instrument before cleaning.
- Clean the touch screen with a soft cloth and 70% ethanol.
- Clean the exterior of the instrument with a soft cloth wetted with water (e.g., WFI) and 3% hydrogen peroxide or 70% ethanol.
- Cleaning agents must be disposed of according to national and local environmental regulations.

8.3.3 Self test

The ***Self Test*** is used to check the accurate function of the instrument before a run. The ***Self Test*** can also be used at any time to check the condition of the instrument, for example, after a prolonged stop.

Step	Action
1	Adjust the pressure of the compressed air supply to between 3000 to 8000 mbar (43.5 to 116 psi). ***Note:*** *For air supply requirements, see* *Compressed air, on page 301**.*

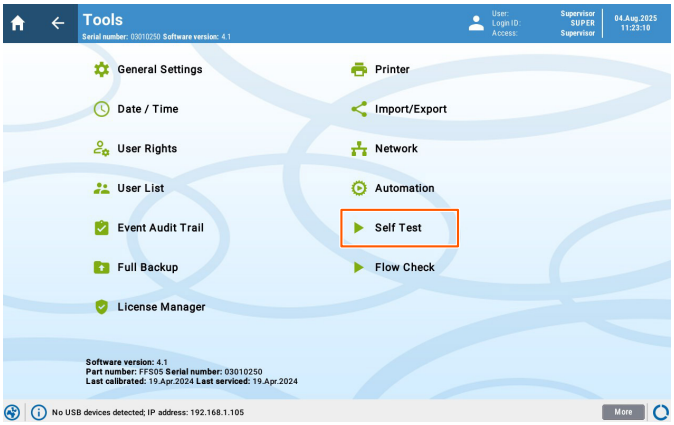
CAUTION

Overpressure. The pressure of the air supply must be locked using pressure regulator. Prevent unauthorized personnel from adjusting the pressure of the air supply. Hoses connected to the air inlet on the system can break due to overpressure and cause injury or damage to the system.

2 Select when to start the ***Self test***.

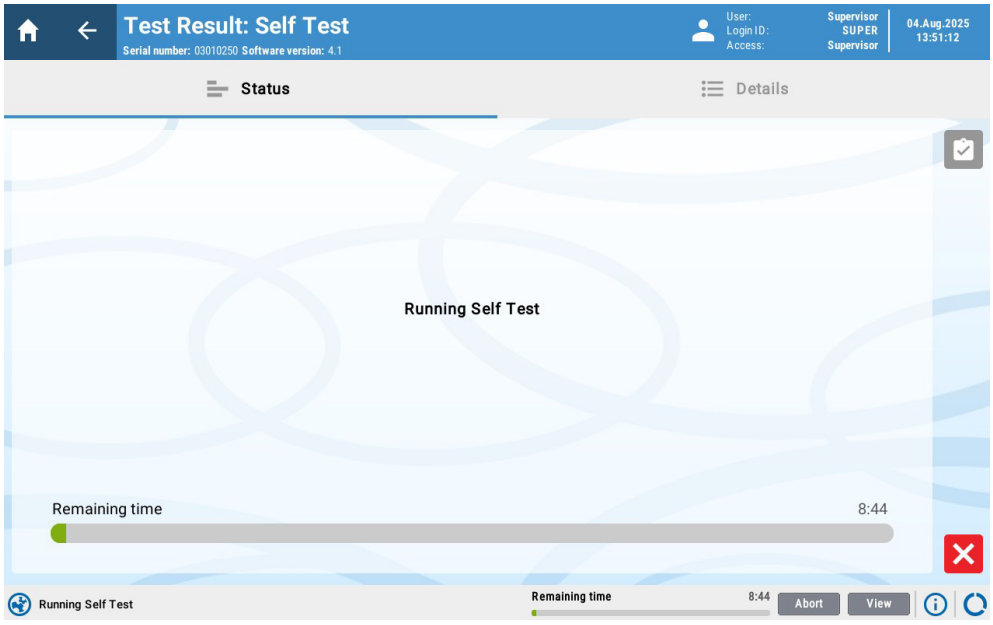
When a *Self test* starts	Action
Automatic run	a. Go to ***Tools*** →***General settings***. b. Select the relevant frequency from the ***Run Self-Test*** drop-down menu. The options are: • ***On manual request only*** • ***On power up*** • ***Daily*** • ***Weekly***

Step	Action

When a *Self test* starts	Action
Manual run	a. Go to ***Tools*** →***Self test***.  b. Tap the  button.

Result:

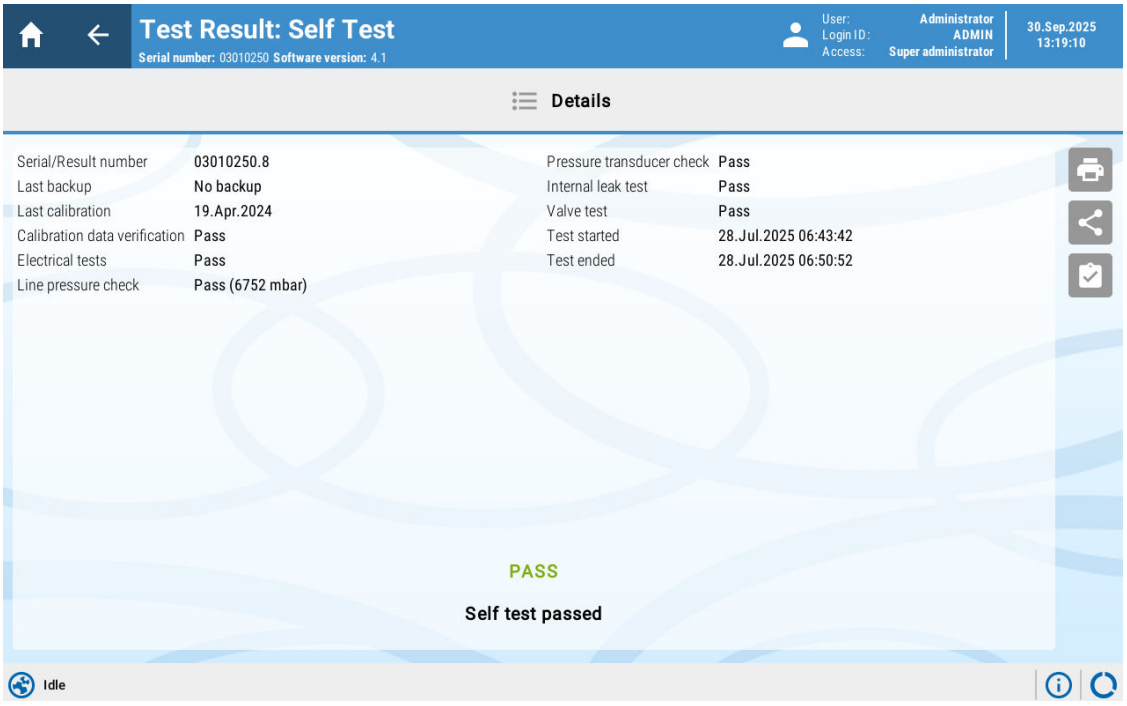
The self test runs at the selected time.



Note: *The run can be aborted at any time. Tap the*  *button, and then tap* ***Ok***. ***Test result: MANUAL ABORT*** *is added to the test result file. Selecting* ***No*** *continues the run.*

Self test result

The image below shows an example of a passed self test.



The phases of a self test are described in the table below.

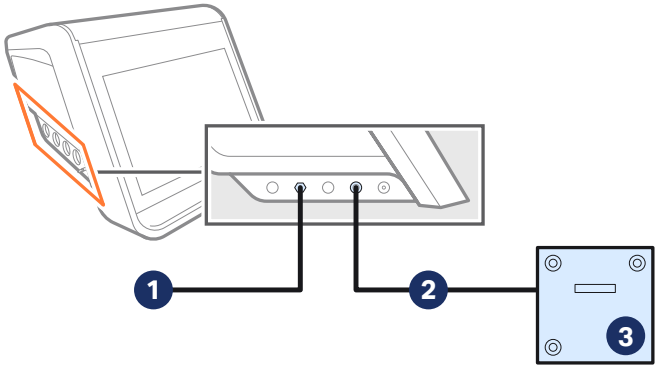
Phase	Description
Measurement	The ***Details*** tab shows the test information: • ***Serial number***: The serial number of the instrument. • ***Last backup***: The date of the most recent instrument backup. • ***Last calibration***: The date of the most recent instrument calibration. • ***Calibration data verification***: Displays if the calibration passed or failed the test. • ***Electrical test***: Displays if the test on the electrical components passed or failed the test. • ***Line pressure check***: Displays if the installed compressed air supply is sufficient. • ***Pressure transducer check***: Displays if the installed pressure sensors passed or failed the test. • ***Internal leak test***: Displays if the flow measurement block in the instrument is tight. • ***Valve test***: Displays if the valves on the flow measurement block are correctly installed and are functional. • ***Test started***: The date and time when the self test started. • ***Test ended***: The date and time when the self test finished.
Test result	The test results are shown on the HMI and automatically saved to the internal memory. • ***PASS*** indicates that the instrument is functional. • ***FAIL*** indicates that an instrument component is not functional. The HMI displays an error message. The *Chapter 9 Troubleshooting, on page 286* describes possible causes of a failed test. When the possible sources of the error have been checked and corrected, repeat the test. After three failed tests, request service for the instrument.

8.3.4 Flow check test

The ***Flow check test*** is used to verify the flow measurement of the instrument. The Flow Check II unit is required to perform the ***Flow check test*** and must be purchased separately.

See *Flow check unit, on page 37* for a brief description of the Flow Check II unit.

The illustration below shows the setup for a flow check test.



Part	Description
1	Compressed air supply
2	Pressure measurement line to the Flow Check II unit
3	Flow Check II unit

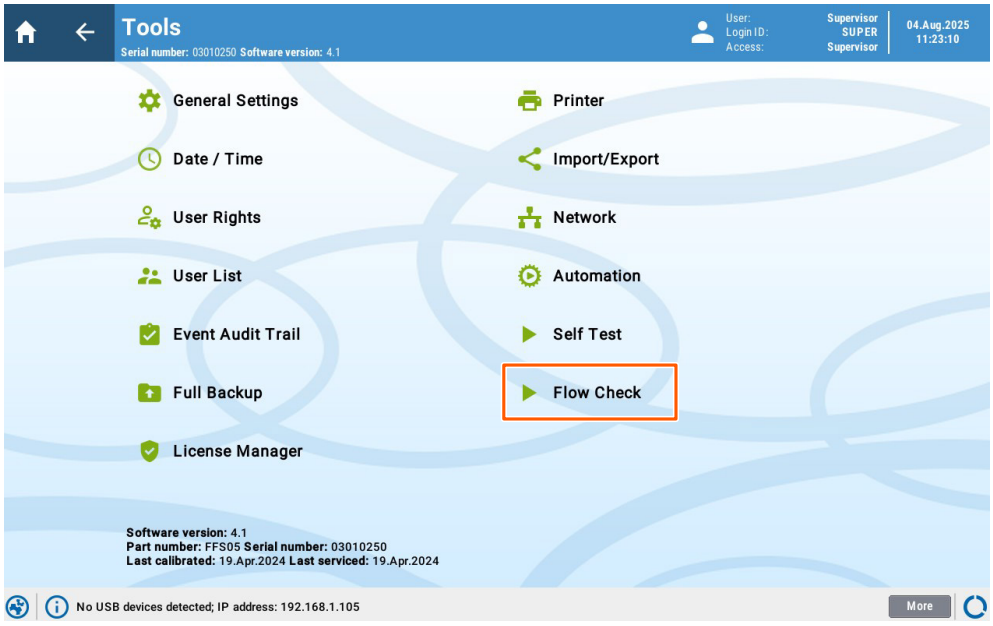
Follow the steps below to start a flow check test.

Step	Action
1	Adjust the pressure and the flow rate of the compressed air supply. ***Note:*** *For air supply requirements, see Compressed air, on page 301.* **CAUTION** **Overpressure.** The pressure of the air supply must be locked using pressure regulator. Prevent unauthorized personnel from adjusting the pressure of the air supply. Hoses connected to the air inlet on the system can break due to overpressure and cause injury or damage to the system.
2	Make sure that the instrument, the Flow Check II unit, and the components are at room temperature.
3	Connect the Flow Check II unit to the instrument. **a.** Connect the air hose with a 6 mm ID (8 mm OD) and a Stäubli RBE03 male connector to the **OUT** port on the instrument.

Step	Action

b. Connect the other end of the air hose with a 6 mm ID (8 mm OD) and a Stäubli RBE03 female connector to the Flow Check II unit.

4 Go to ***Tools*** →***Flow Check***.



5 Type the run parameters.

Parameter	Description	Range
Reference serial number	Type the serial number of the Flow Check II unit.	N/A
Test pressure	Type the test pressure of the test. The recommended test pressure for the ***Flow check test*** is 2000 mbar or 29.0 psi.	• 50 to 6500 mbar • 0.73 to 94.27 psi
Test time	Type the operation time of the test. The recommended test time is 600 s.	100 to 9999 s
Expected flow	Type the expected flow rate. The recommended flow rate is shown on the screen of the Flow Check II unit.	0.1 to 1000 mL/min

6 Tap the button.

Step	Action
	Result: An overview of the test parameters is shown.
7	Tap the  button. *Result:* The ***Flow check test*** starts.

Note: *The run can be aborted at any time. Tap the*  *button, and then tap* ***Ok****.* ***Test result: MANUAL ABORT*** *is added to the test result file. Selecting* ***No*** *continues the run.*

During a flow check test

The phases of a flow check test are described in the table below.

Phase	Description
Pressurization	The instrument pressurizes the Flow Check II unit to the selected test pressure. A message is displayed on screen of the instrument.
Stabilization	1. After reaching the selected test pressure (i.e., at 100%), the pressure stabilization phase starts. 2. The stabilization time is automatically controlled by the instrument. The stabilization phase ends as soon as the flow is stable (within the selected thresholds). 3. If the stabilization pressure is not reached or is not stable, the test is aborted. ***Note:*** *A prolonged stabilization time can be caused by various parameters, for instance if the temperature is not stable.*
Measurement	1. After the stabilization phase, the test phase starts. 2. The flow measurement is shown in the ***Graph*** tab. 3. At the end of the test, the Flow Check II unit is vented.

Phase	Description
Test result	The test results are shown on the HMI and automatically saved to the internal memory. • A percentage deviation of ± 5% of the certified flow value indicates that the instrument is functional. • A percentage deviation higher than ± 5% of the certified flow value indicates a deviation in the flow measurement of the instrument. Repeat the flow check test. If the problem persists, contact your Cytiva representative.

8.4 Software maintenance

About this section

This section describes the data management procedures performed by the administrator.

In this section

8.4.1 Transfer of test results

Introduction

The test results can be exported to a USB drive or a network location.

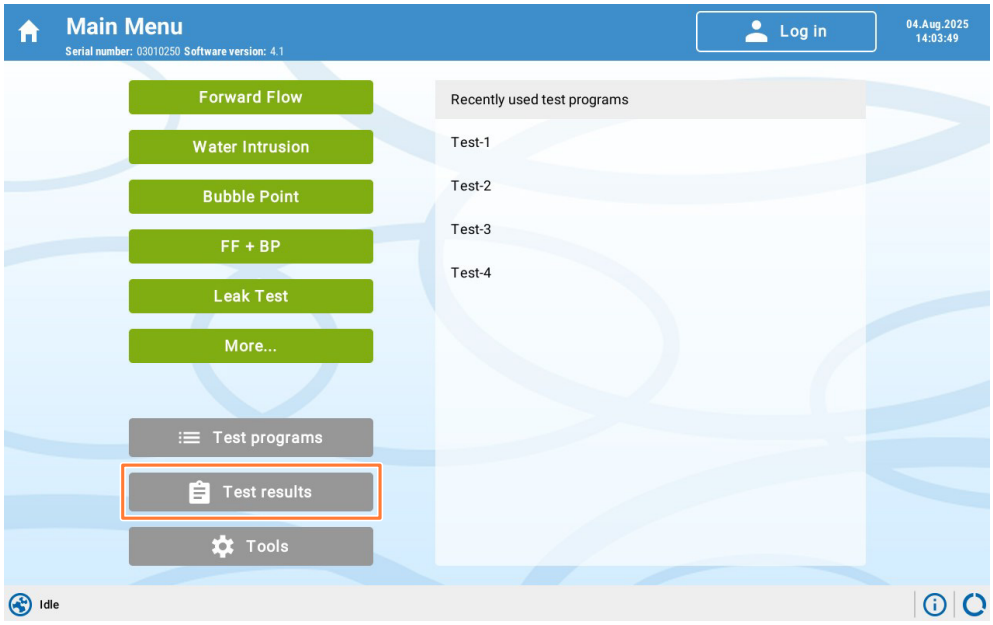
Transfer of test results with the DMS Pro software is not described in this section. For more information, refer to the *User Manual (USD3925)* of the DMS Pro software.

Export a test results

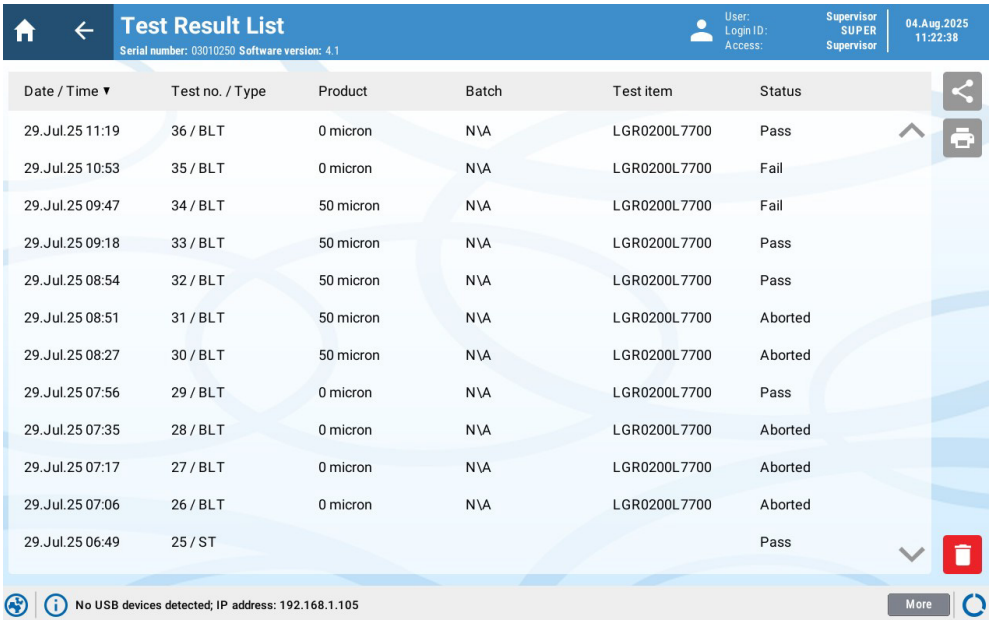
Note: *Make sure that the **Import/Export** settings are set up correctly. See Set import and export settings, on page 112.*

Follow the steps below to export a test results.

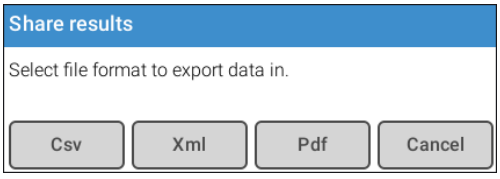
Step	Action
1	Log in with a ***Supervisor***, an ***Automation operator***, an ***Administrator***, or a ***Super-admin*** account, or if enabled, an ***Operator*** account.
2	• Connect a USB drive to one of the USB ports of the instrument. or • Make sure that the network is connected, as described in Set import and export settings, on page 112.
3	Tap ***Test results***.



Step	Action
4	Tap the  button.



5	Select the file format for export (***PDF***, ***XML***, or ***CSV***).



Result:
The file is stored in a folder structure in the destination folder: `[FFS05 and instrument serial number]>[Date and time]>[Test Results]`.

8.4.2 Transfer of audit trails

Introduction

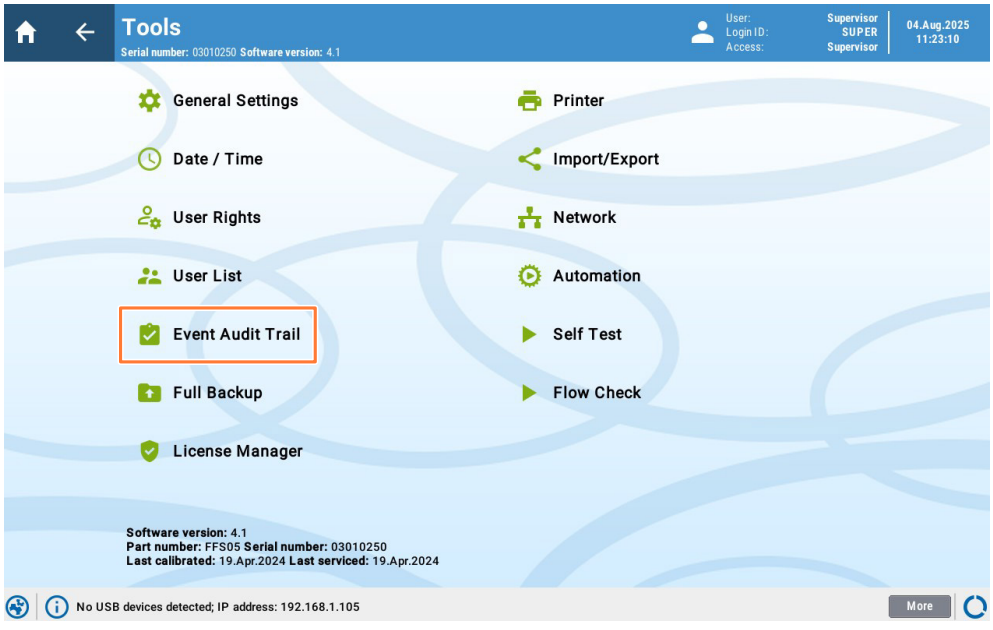
The audit trails can be exported to a USB drive or a network location.

Export an audit trail

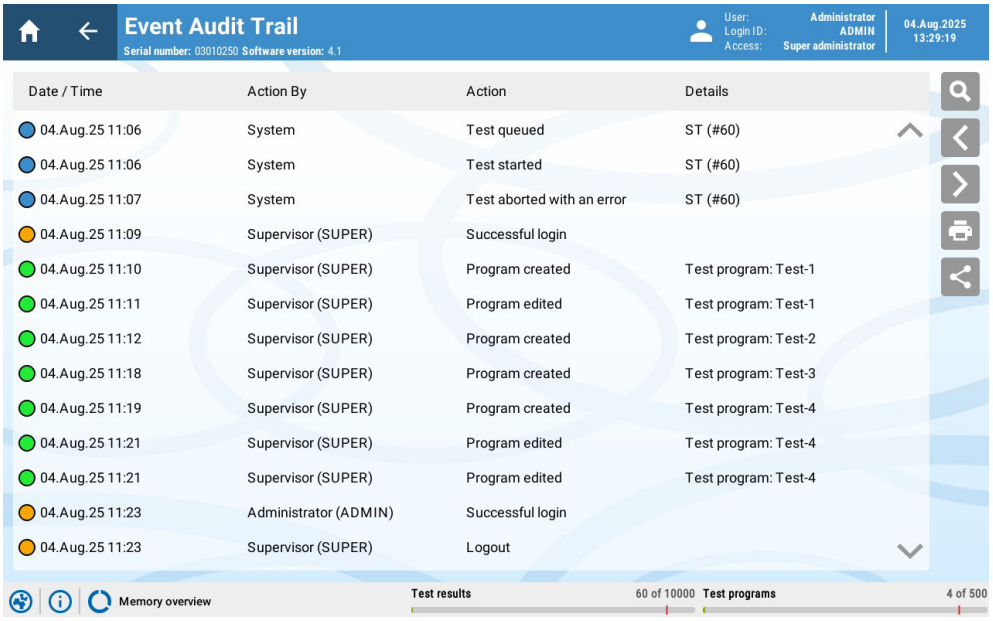
Note: *Make sure that the **Import/Export** settings are set up correctly. See Set import and export settings, on page 112.*

Follow the steps below to export an audit trail.

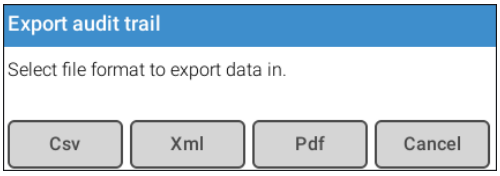
Step	Action
1	Log in with a ***Supervisor***, an ***Automation operator***, an ***Administrator***, or a ***Super-admin*** account.
2	• Connect a USB drive to one of the USB ports of the instrument. or • Make sure that the network is connected, as described in Set import and export settings, on page 112.
3	Go to ***Tools*** →***Event Audit Trail***.



Step	Action
4	Tap the  button.



5	Select the file format for export (***PDF***, ***XML***, or ***CSV***).



Result:
The file is stored in a folder structure in the destination folder: `[FFS05 and instrument serial number]>[Date and time]>[Audit Trail].`

8.4.3 Data backup

Introduction

Data can be backed up to a USB drive, a network location, or with the DMS Pro software.

Creating a backup with the DMS Pro software is not described in this section. For more information, refer to the *User Manual (USD3925)* of the DMS Pro software.

Note: *Although a software update does not affect the data stored on the instrument, Cytiva recommends backing up all programs and test results before starting a software update. The calibration status of the instrument is not affected by the software update.*

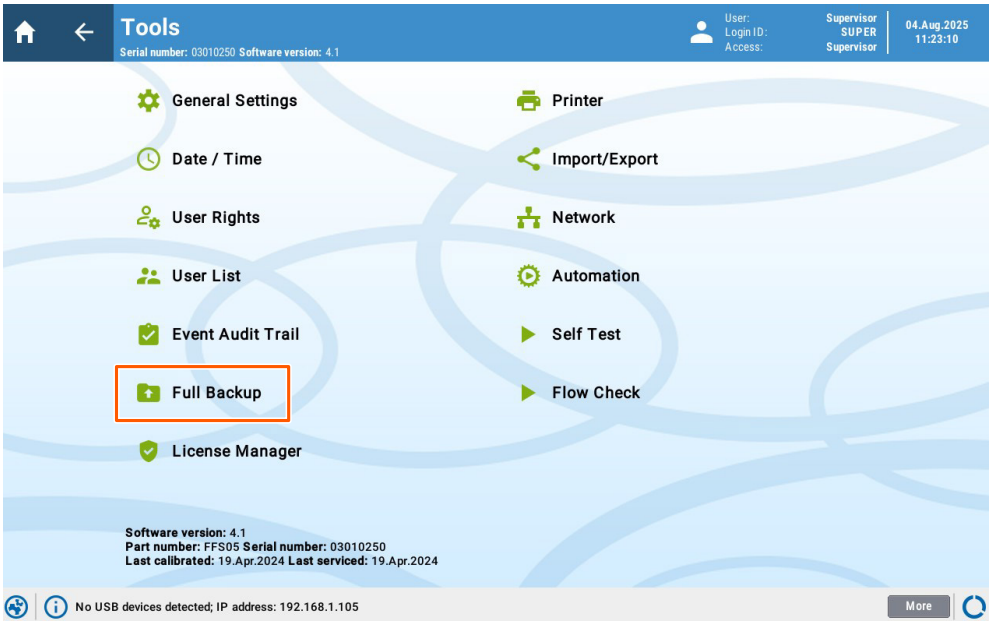
Create a backup

Note: *Make sure that the **Import/Export** settings are set up correctly. See Set import and export settings, on page 112.*

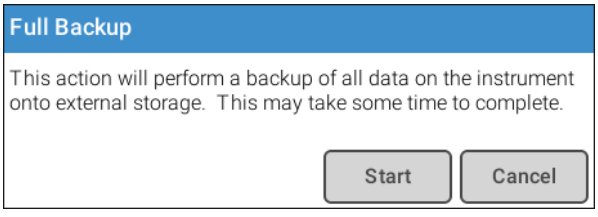
Follow the steps below to create a full backup.

Step	Action
1	Log in with an ***Administrator*** or a ***Super-admin*** account.
2	• Connect a USB drive to one of the USB ports of the instrument. or • Make sure that the network is connected, as described in Set import and export settings, on page 112.

Step	Action
3	Go to ***Tools*** →***Full Backup***.



4	Select the destination folder for the backup.
5	Tap ***Start***.



Tip:

To create a backup of a result file on a USB drive, see Section 7.8.3 Create a printout, on page 238.

8.4.4 Deactivate and delete files

Introduction

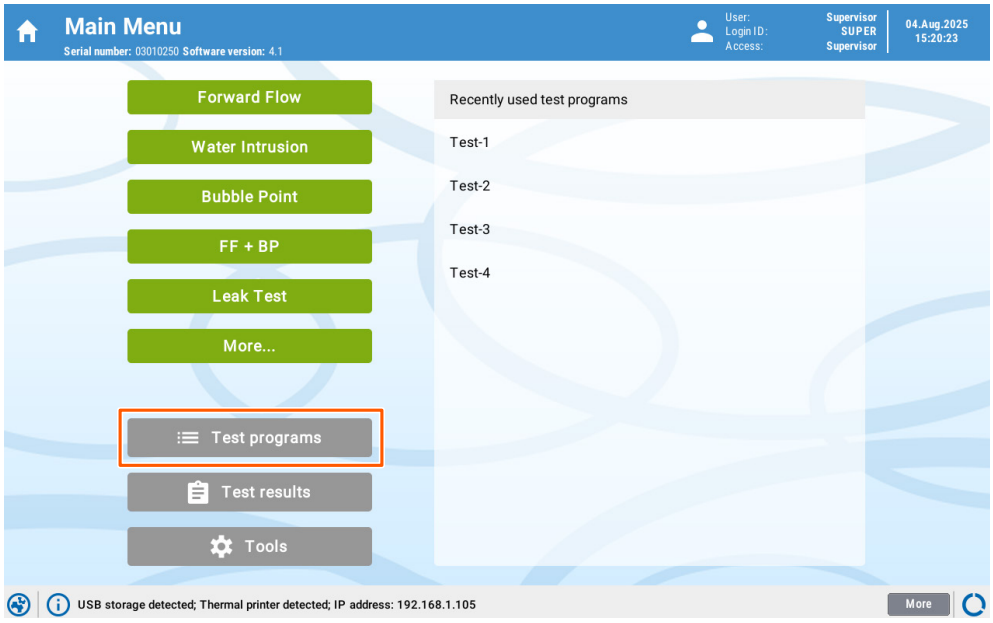
Test programs can be deleted or deactivated. Test results can be deleted. Before deleting a file, it is recommended to perform a backup, see *Section 8.4.3 Data backup, on page 264*.

Deactivate a test program

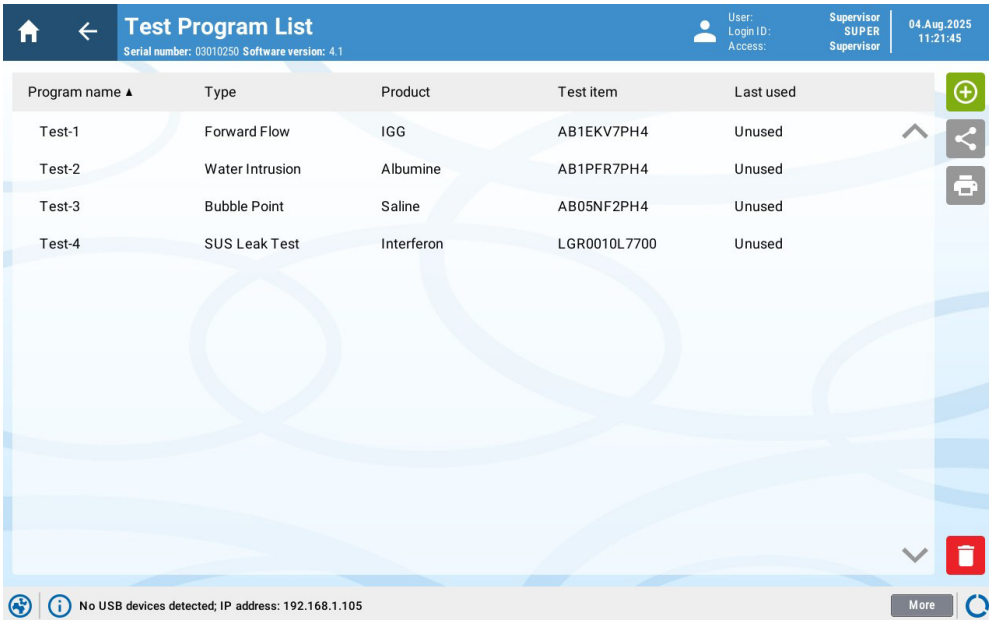
Deactivate a test program if it must no longer be used. A deactivated test program is greyed out on the ***Test Programs*** screen and cannot be selected when a user starts a test. Deactivated test programs are stored in the software as part of the audit trail.

Follow the steps below to deactivate a test program.

Step	Action
1	Log in with a ***Supervisor*** account, or if enabled, an ***Administrator*** or a ***Super-admin*** account.
2	Go to ***Test Programs***.



Step	Action
3	Tap the row with the relevant test program.



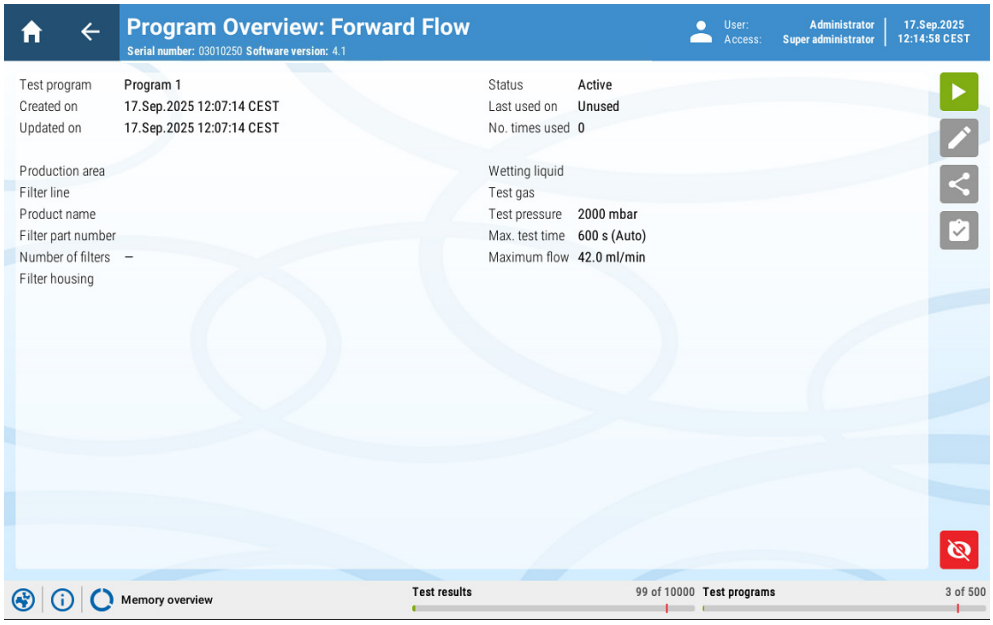
Tip:

*Sort the program list by tapping the column header (e.g., **Program**, **Type**, **Product**).*

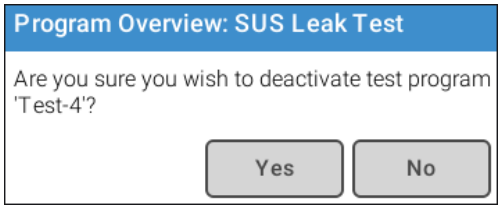
Tip:

Use the arrow buttons to scroll through the available test programs. The arrow button moves the selection to the next test program.

Step	Action
4	Tap the button in the lower right corner.



5	Tap ***Yes***.



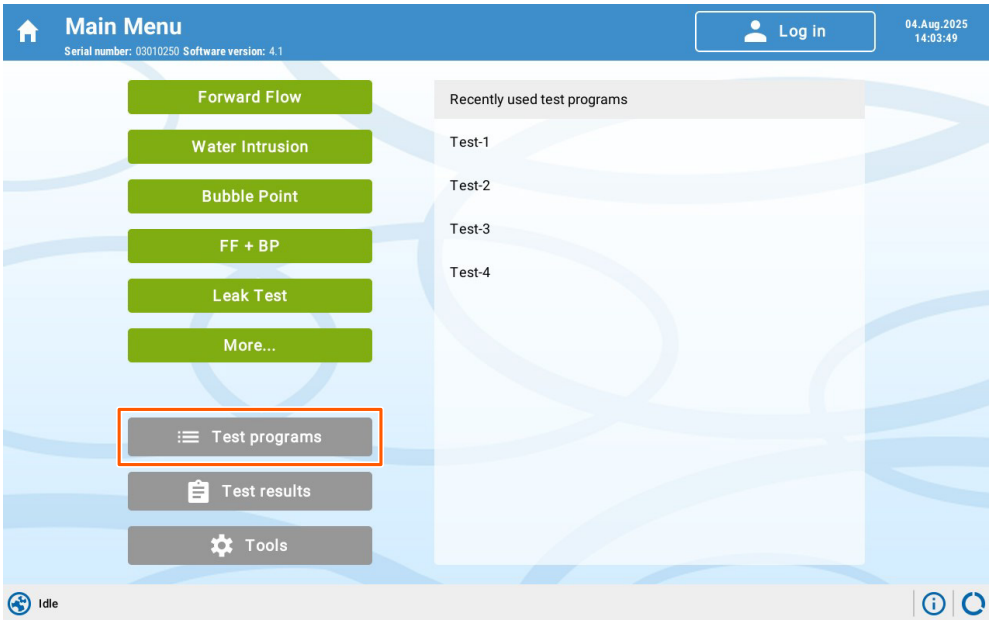
Result:
The test program is deactivated. The test program is no longer shown in the ***Test Programs*** screen.

Delete one test program

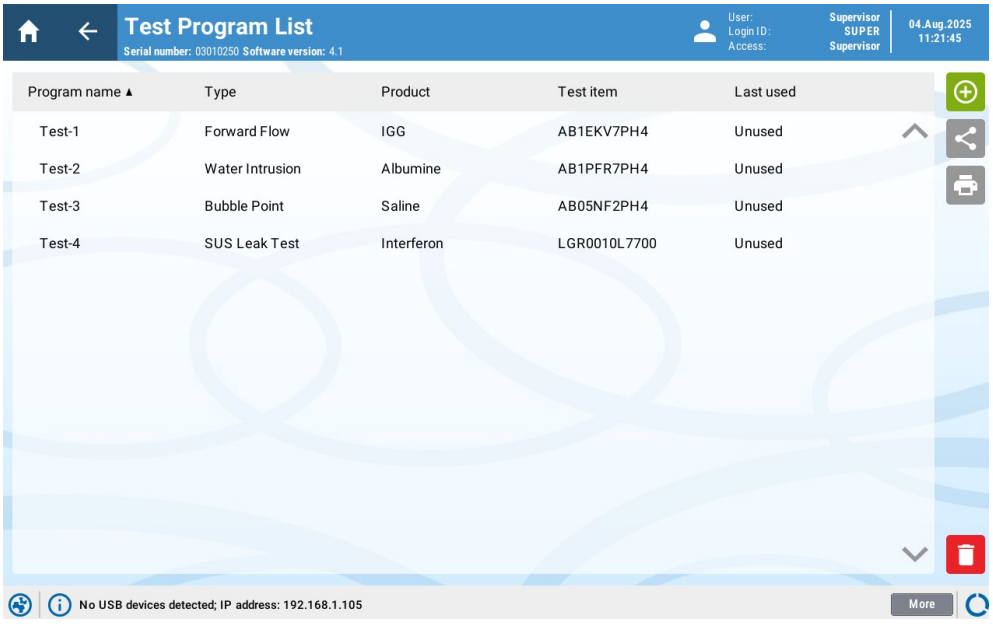
Follow the steps below to delete one test program from the instrument.

Step	Action
1	Log in with a ***Supervisor*** account.

Step	Action
2	Go to ***Home*** →***Test Programs***.

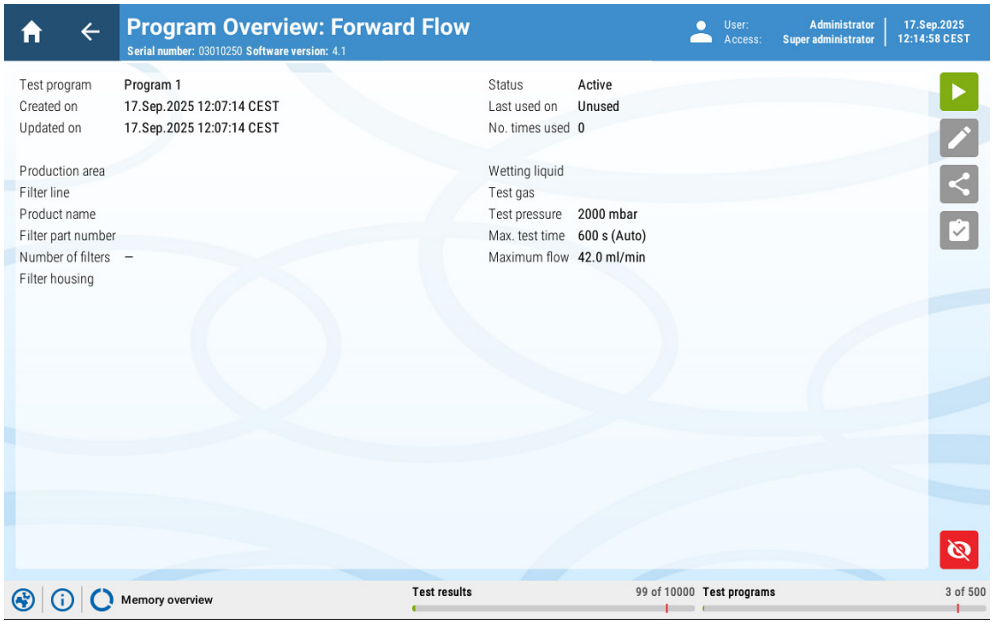


3	Tap the row with the relevant test program.

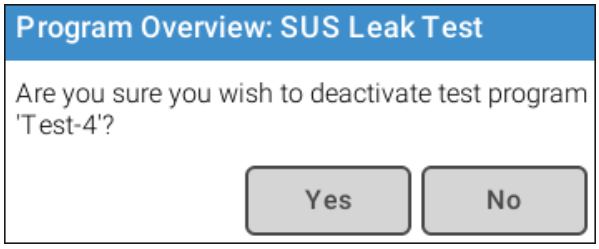


4	Tap the row with the relevant test program.

Step	Action
5	Tap the button in the lower right corner.



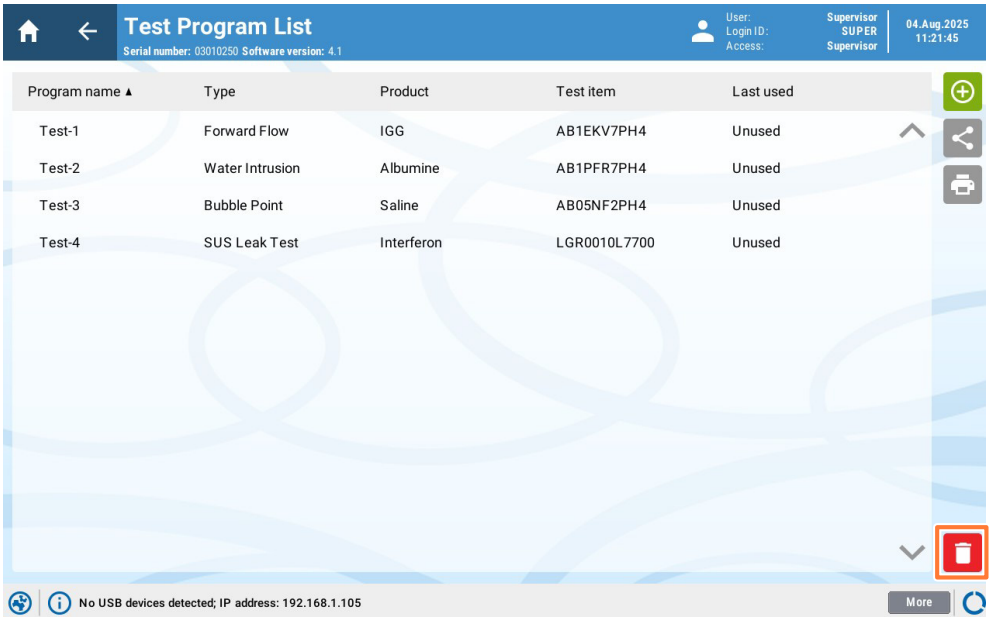
6	Tap ***Yes***.



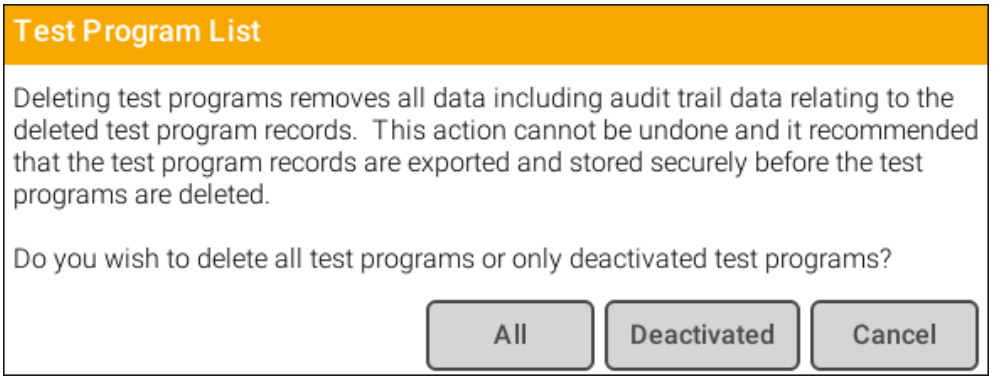
Result:
The test program is deactivated. The test program is greyed out on the ***Test Programs*** screen.

7	Tap to go back to the ***Test Program List***.

Step	Action
8	Tap the button in the lower right corner.



9	Tap the ***Deactivated*** button in the pop-up window.



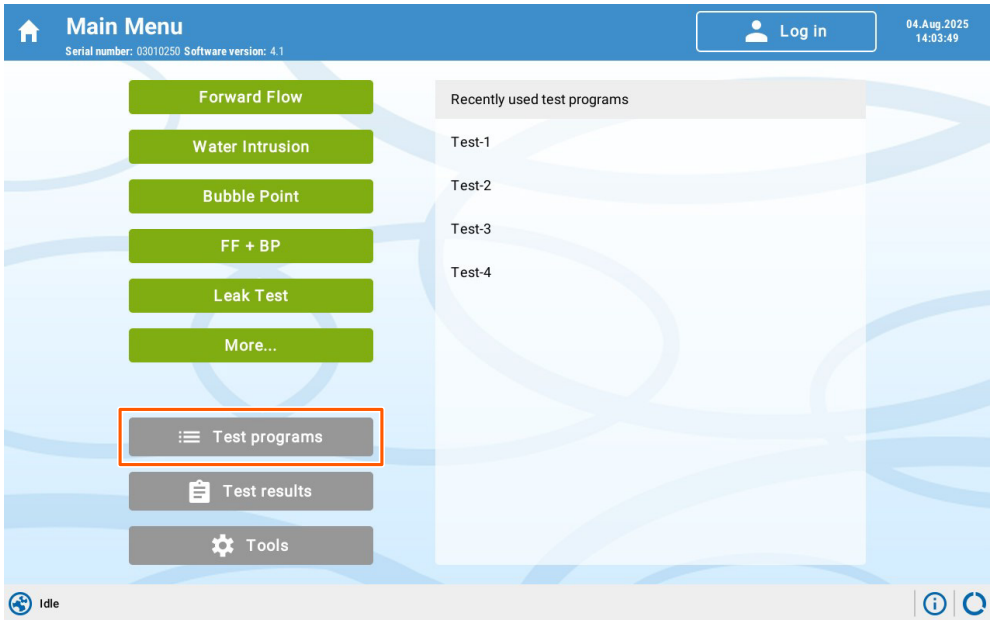
Result:
The deactivated test program is deleted.

Delete all test programs

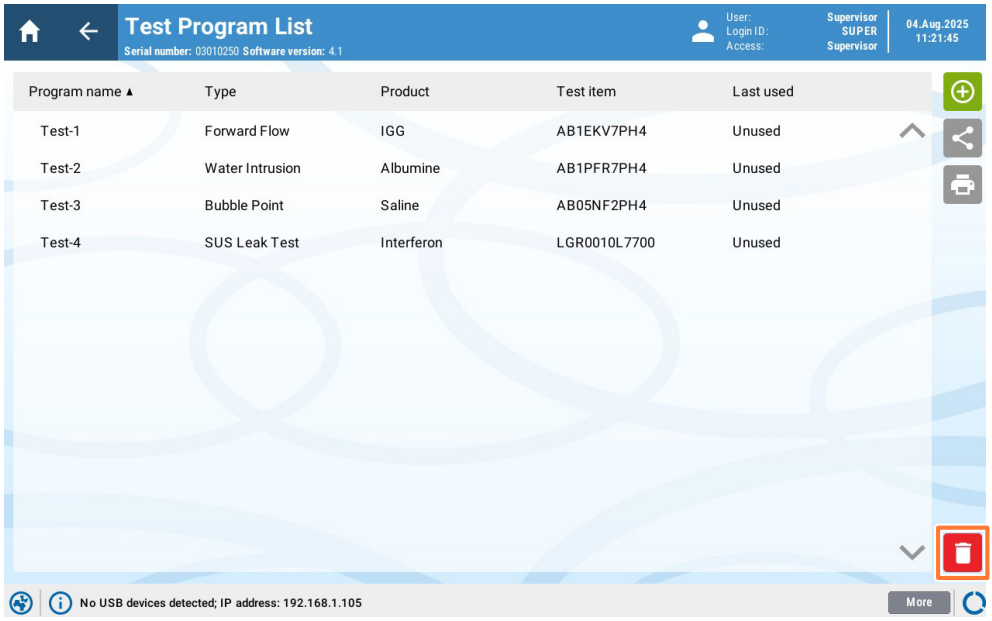
Follow the steps below to delete all test programs from the instrument.

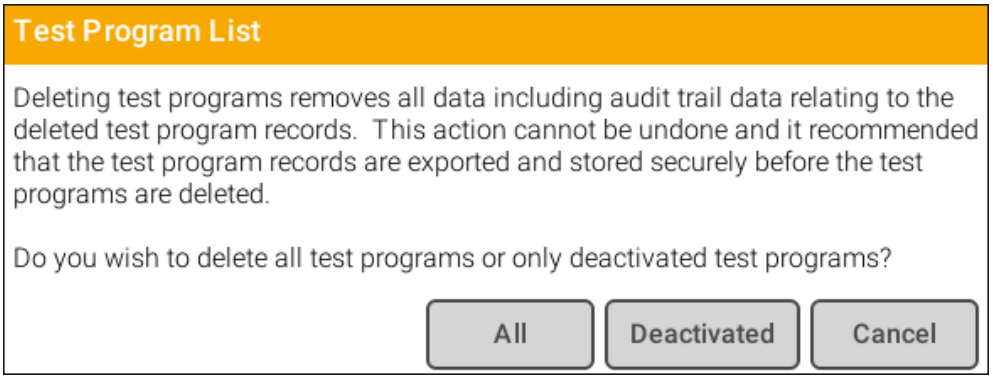
Step	Action
1	Log in with a ***Supervisor*** account.

Step	Action
2	Go to ***Home*** →***Test Programs***.



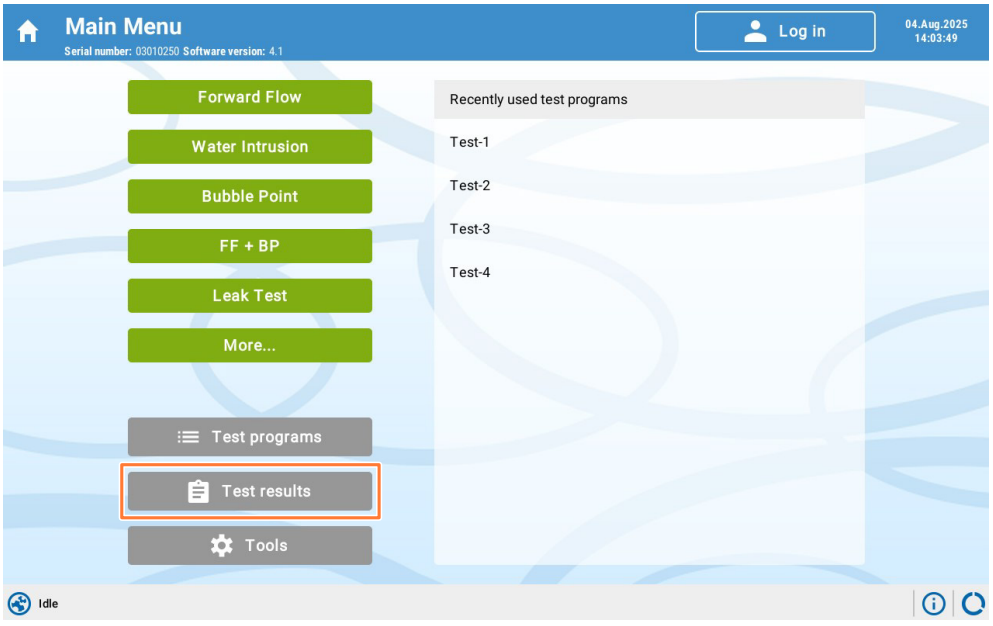
3	Tap the button in the lower right corner.



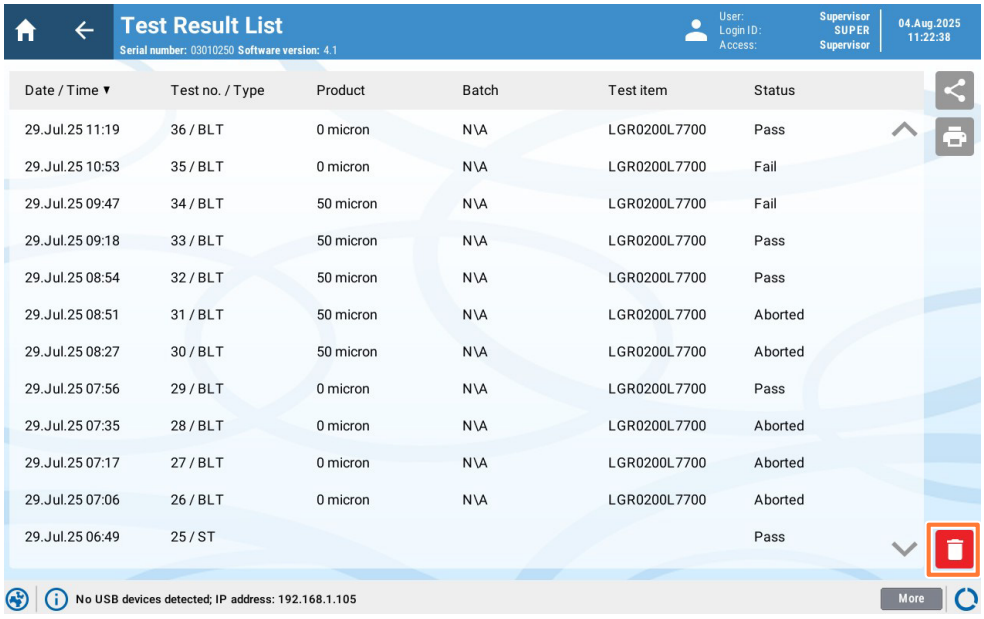
Step	Action
4	Tap the ***All*** button in the pop-up window.  *Result:* All test programs are deleted.

Delete test results

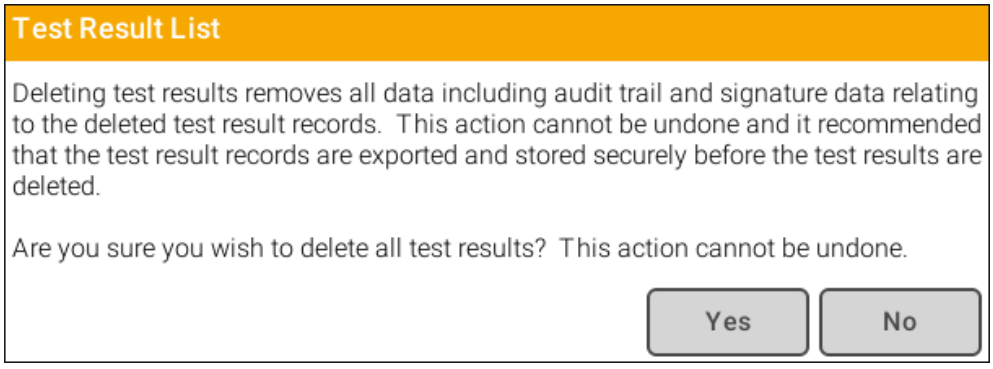
Follow the steps below to delete all the test results from the instrument.

Step	Action
1	Log in with an ***Administrator*** or a ***Super-admin*** account, or if enabled, a ***Supervisor*** account.
2	Go to ***Home*** →***Test Results***. 

Step	Action
3	Tap the button.



4	Tap ***Yes*** in the pop-up window.



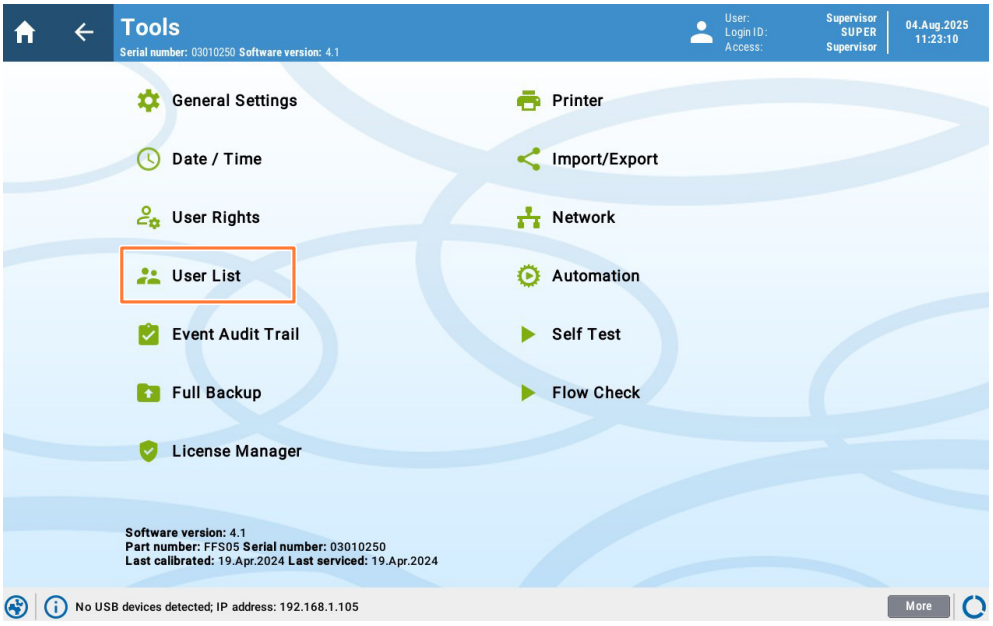
Result:
The test results are deleted.

Delete one user

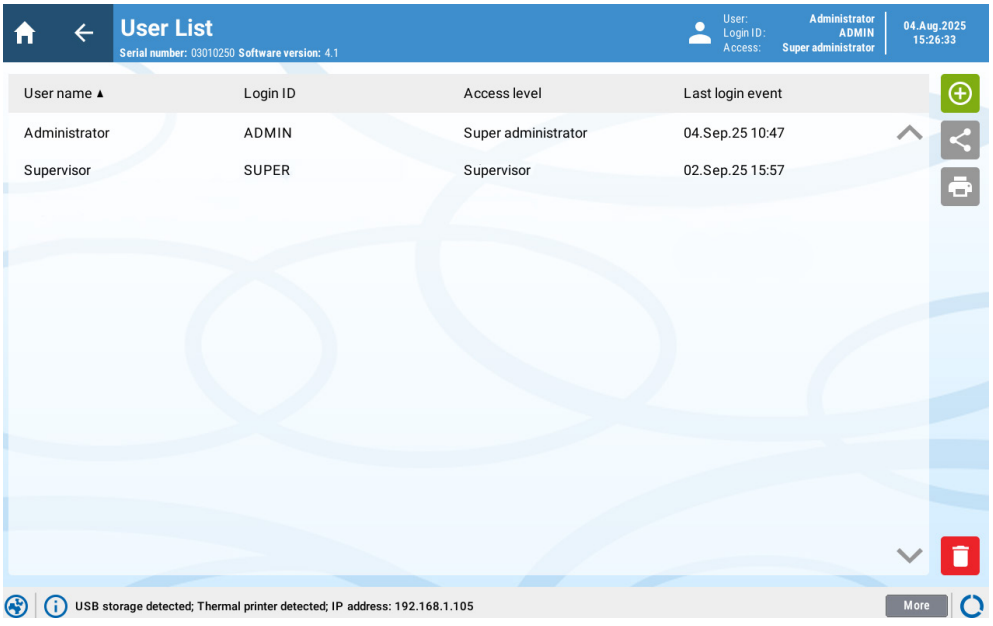
Follow the steps below to delete one user account.

Step	Action
1	Log in with an ***Administrator*** or ***Super-admin*** account.

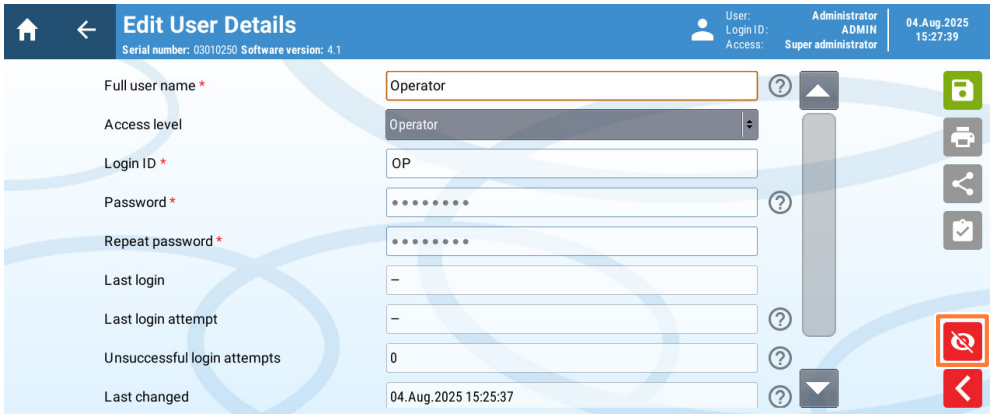
Step	Action
2	Go to ***Tools*** →***User List***.



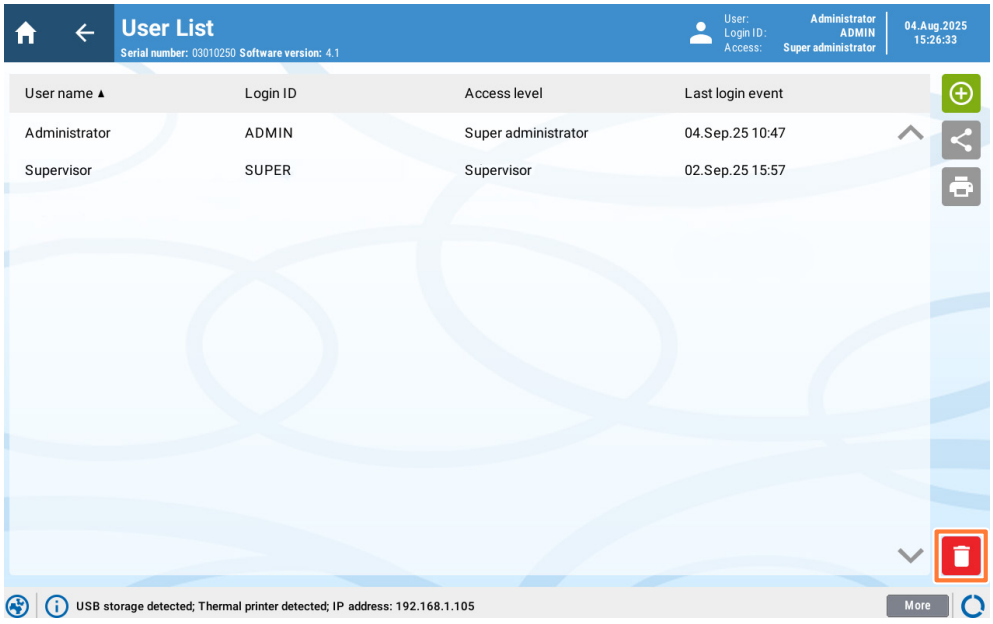
3	Tap the row with the relevant user account.

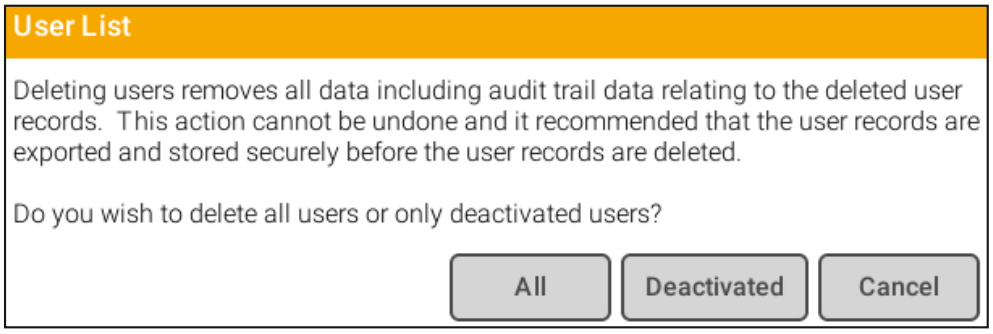


Step	Action
4	Tap the button in the lower right corner.



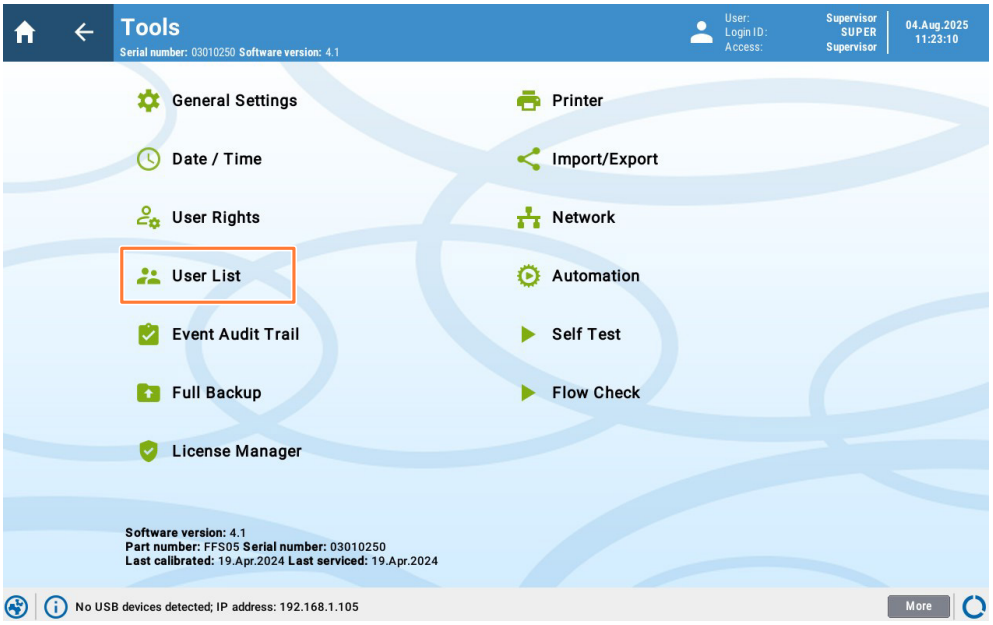
5	Tap ***Yes***. *Result:* The user account is deactivated.
6	Tap to go back to the ***User List***.
7	Tap the button.



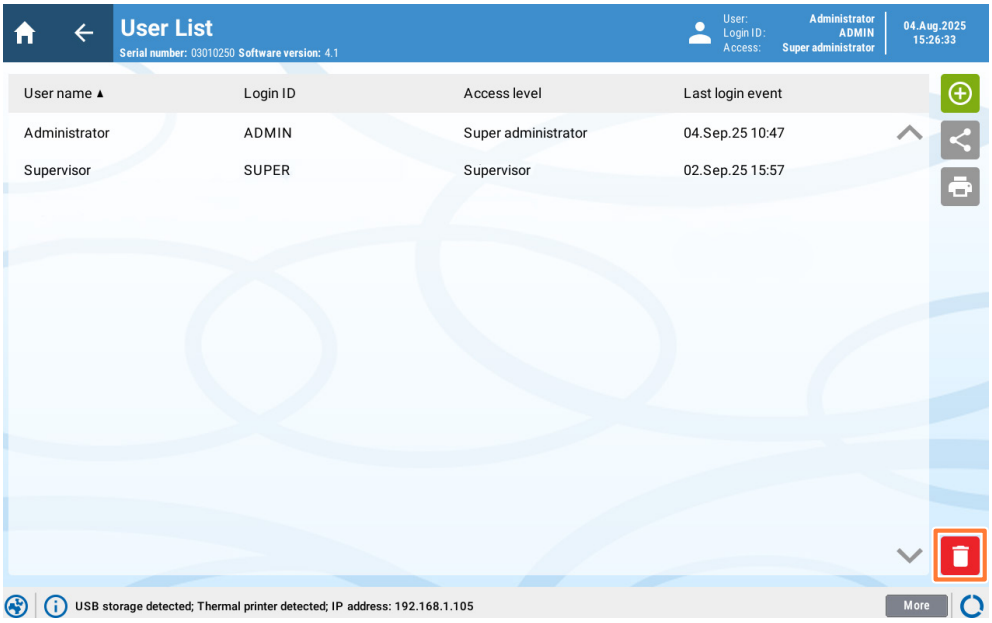
Step	Action
8	Tap the ***Deactivated*** button in the pop-up window.  *Result:* The deactivated user account is deleted.

Delete all users

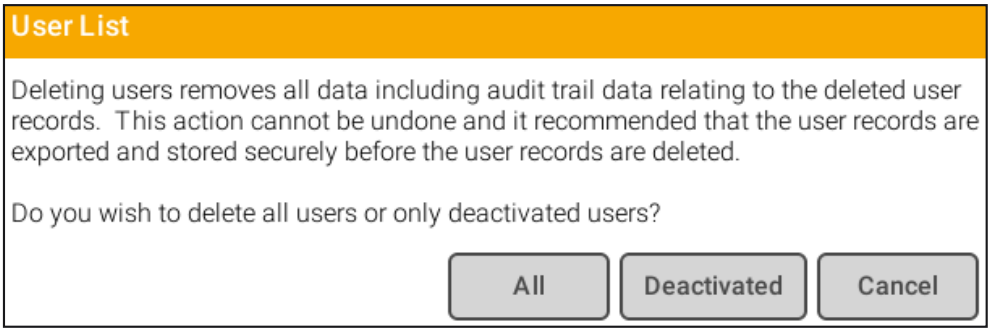
Follow the steps below to delete all user accounts.

Step	Action
1	Log in with an ***Administrator*** or ***Super-admin*** account.
2	Go to ***Tools*** →***User List***. 

Step	Action
3	Tap the button.



4	Tap the button.
5	Tap the ***All*** button in the pop-up window.



Result:
All user accounts are deleted, except for the predefined ***Super-Admin*** user account.

8.4.5 Reactivate test programs and users

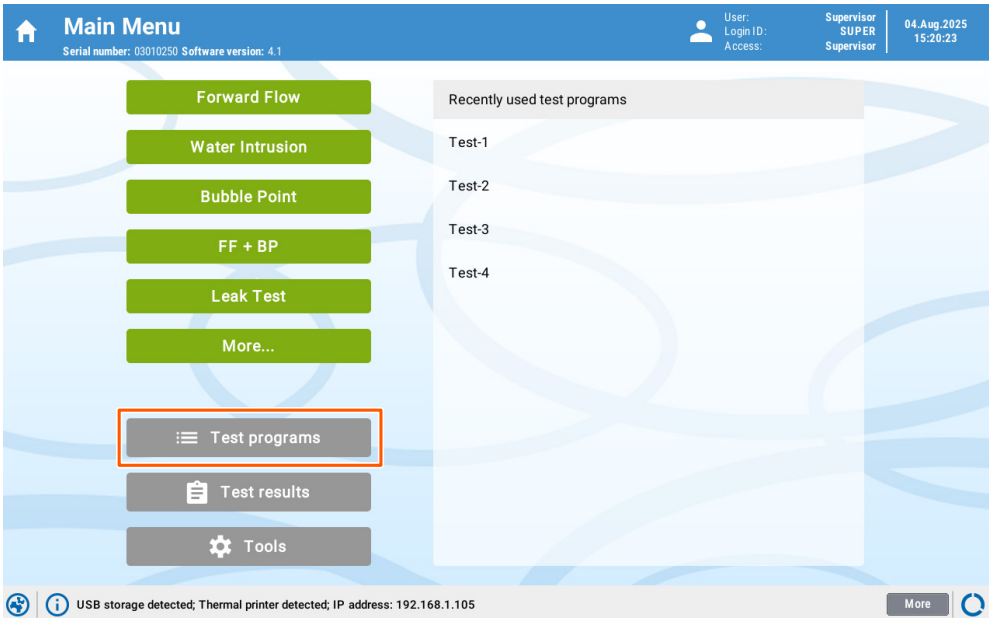
Introduction

Test programs and user accounts that are deactivated can be reactivated.

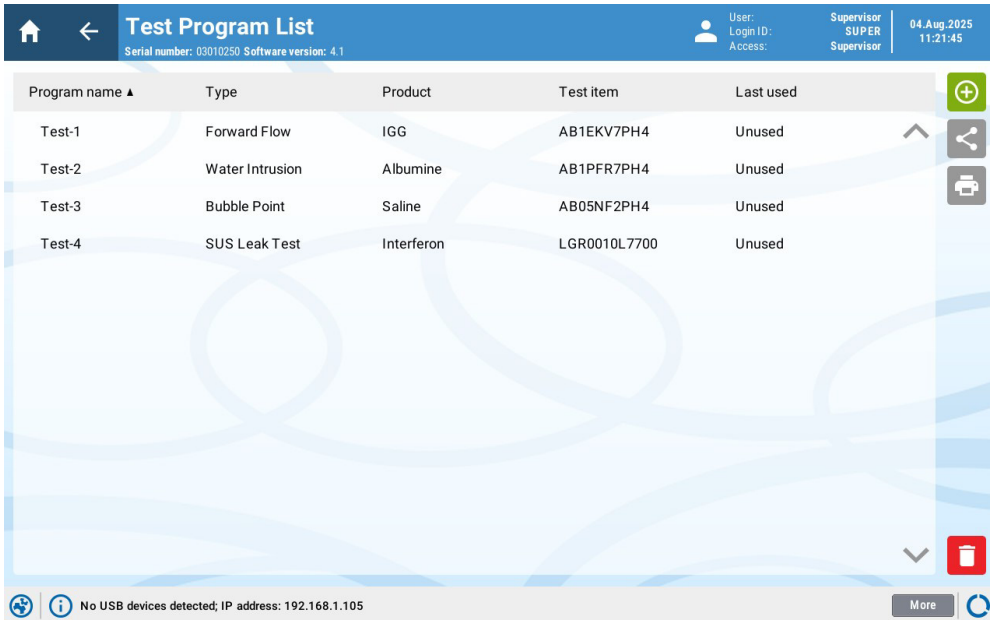
Reactivate a test program

Follow the steps below to reactivate a deactivated test program.

Step	Action
1	Log in to the instrument with a ***Supervisor*** account, or if enabled, an ***Administrator*** or a ***Super-admin*** account.
2	Go to ***Test Programs***.



Step	Action
3	Tap the row with the deactivated test program.

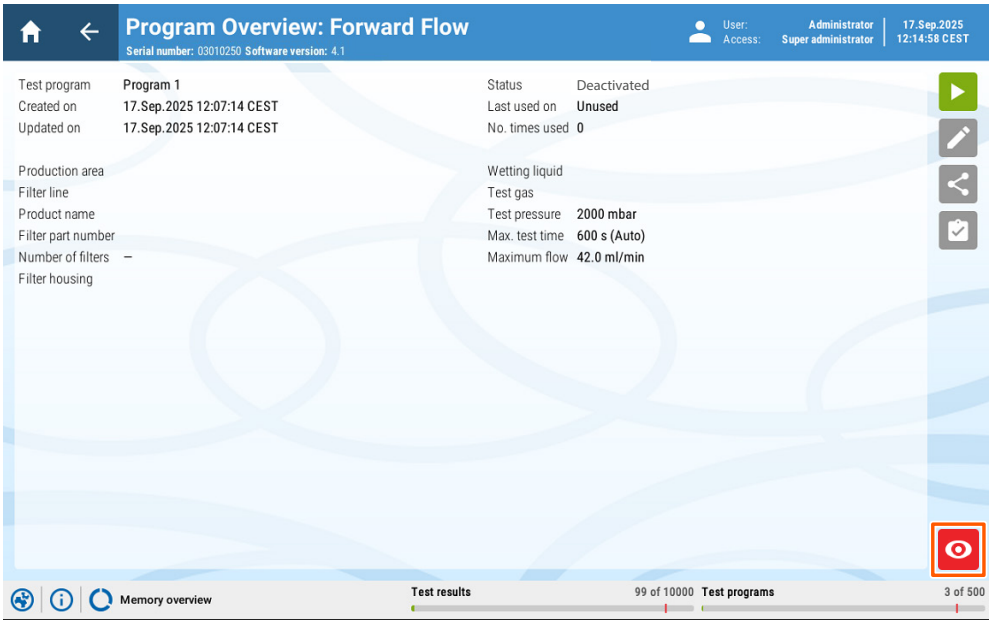


Tip:

*Sort the program list by tapping the column header (e.g., **Program**, **Type**, **Product**).*

Tip:

Use the arrow buttons to scroll through the available test programs. The arrow button moves the selection to the next test program.

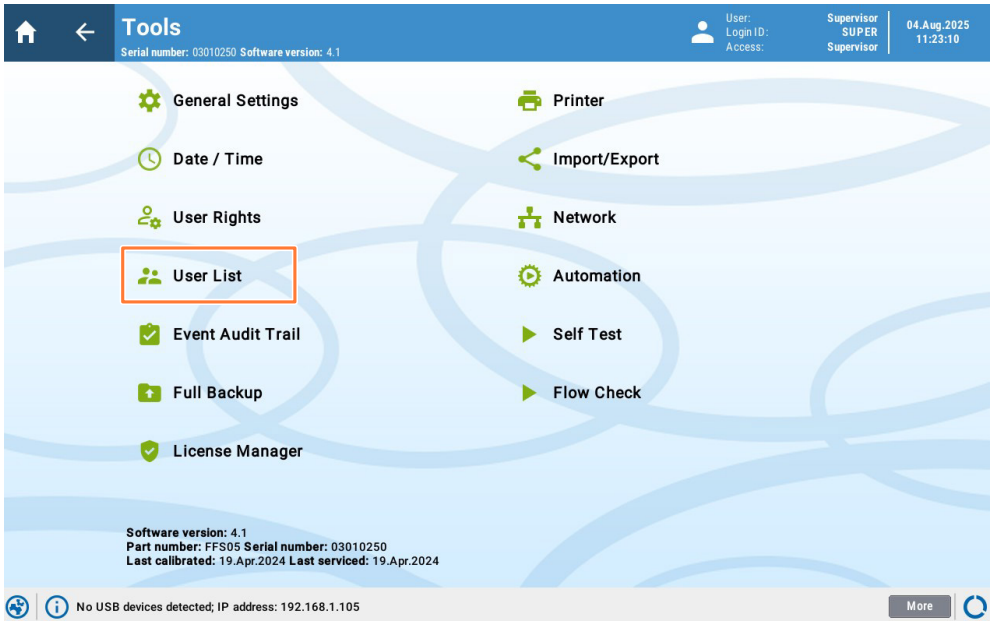
Step	Action
4	Tap the button in the lower right corner. 
5	Tap ***Yes***. *Result:* The test program is reactivated.

Reactivate a user

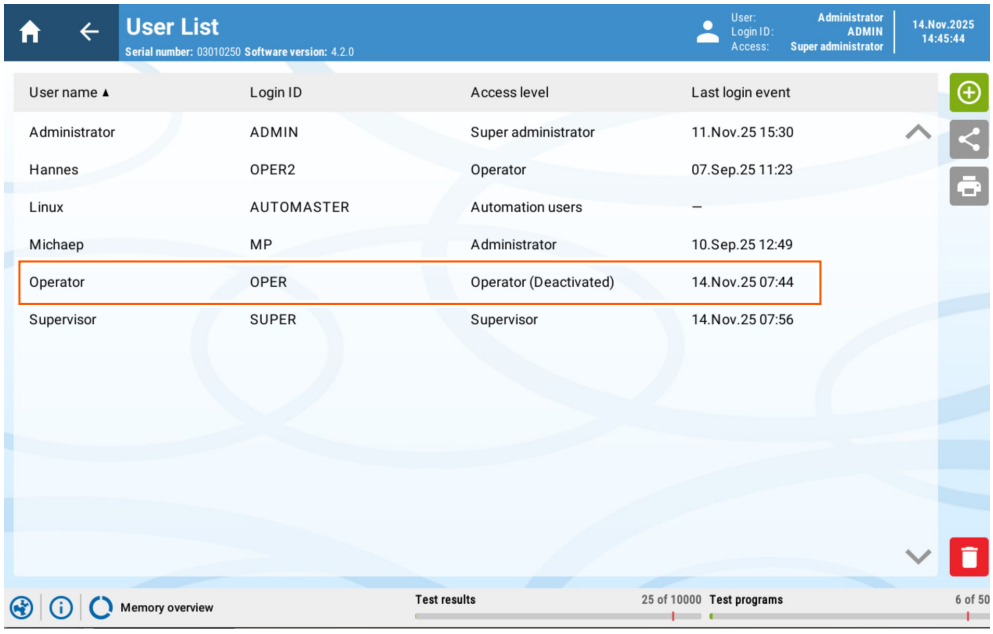
Follow the steps below to reactivate a deactivated user account.

Step	Action
1	Log in with an ***Administrator*** or a ***Super-admin*** account.

Step	Action
2	Go to ***Tools*** →***User List***.

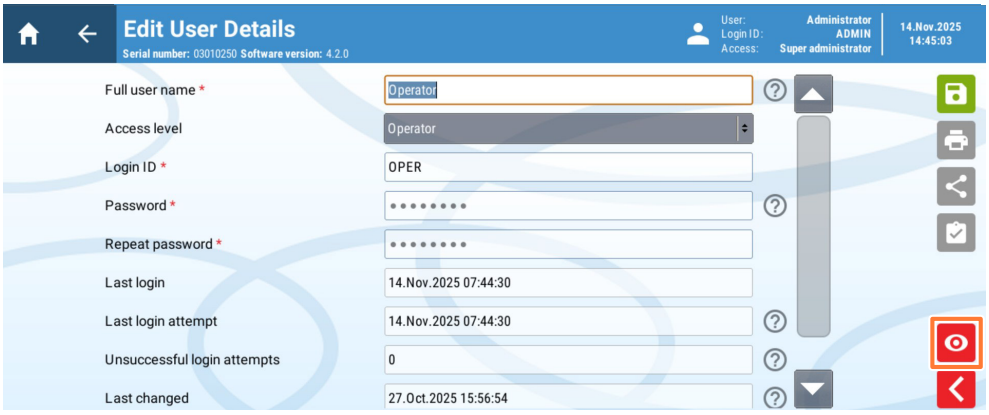
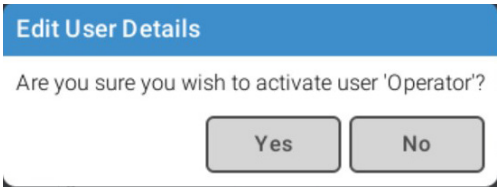


Step	Action
3	Tap the row with the deactivated user account.



Tip:

A deactivated user account is greyed out on the ***User List*** *screen.*

Step	Action
4	Tap the button in the lower right corner. 
5	Tap ***Yes***.  *Result:* The user account is reactivated.

8.4.6 Reset the instrument

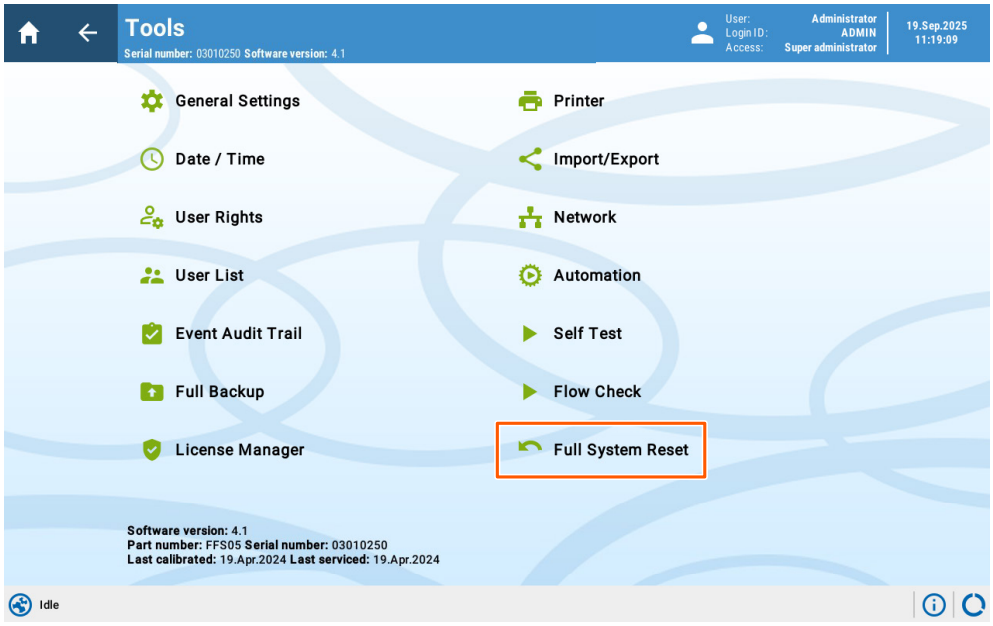
Introduction

The software configuration can be reset to factory settings. Before performing a factory reset, it is recommended to perform a backup, see *Section 8.4.3 Data backup, on page 264*.

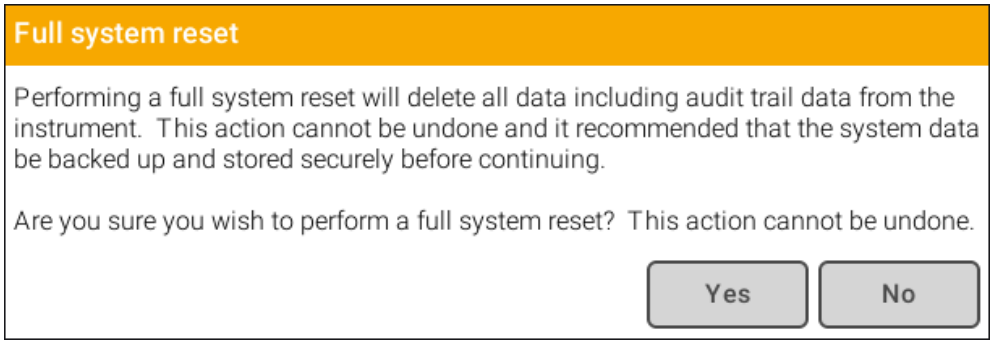
Factory reset

Follow the steps below to reset the instrument to the factory settings.

Step	Action
1	Log in with a ***Super-admin*** account.
2	Go to ***Tools*** →***Full System Reset***.



3	Tap ***Yes***.



Step	Action
	Result: The following files are reset to their respective factory setting: • General settings • Access management • User list • Audit trail The factory reset is recorded in the audit trail.

9 Troubleshooting

About this chapter

This chapter provides information to assist users and service personnel to identify and correct problems if they occur.

If the suggested actions in this guide do not solve the problem, or if the problem is not covered by this guide, contact your Cytiva representative for advice.

In this chapter

9.1 Error code occurrences

The table below shows the occurrences of the error codes for each test type.

Error code	ST	WIT	FF	BP	FF+BP	LT	PD	SUS LT
BUBBLE POINT NOT OBTAINABLE				X	X			
CALIBRATION FAILURE	X	X	X	X	X	X	X	X
Downstream pressure too high for vent valve check		X		X				
EXT VALVE ERROR		X						
FLOW TOO HIGH		X	X		X	X		
FLOW UNSTABLE		X	X		X	X		
GROSS LEAK DETECTED								X
INACCURATE MEASUREMENT								X
INSTRUMENT TOO COLD		X	X		X	X		
INSTRUMENT TOO HOT		X	X		X	X		
INTERNAL ERROR	X	X	X	X	X	X	X	X
INTERNAL ERROR [error code]	X	X	X	X	X	X	X	X
INTERNAL HARDWARE ERROR [error code]	X	X	X	X	X	X	X	X
INVALID FIRMWARE VERSION	X	X	X	X	X	X	X	X
INVALID TEST PARAMETERS	X	X	X	X	X	X	X	X
KLEENPAK CONNECTOR FAILURE								X
LEAK DETECTED						X		
LEAK TEST FAILURE				X				
LINE PRESSURE OUTSIDE RANGE	X	X	X	X	X	X	X	X
LINE PRESSURE TOO HIGH	X	X	X	X	X	X	X	X
LINE PRESSURE TOO LOW	X	X	X	X	X	X	X	X
LINE PRESSURE UNSTABLE		X	X	X	X	X	X	X
LOW FLOW		X	X		X			
MAXIMUM NUMBER OF REPEATS REACHED	X	X	X	X	X	X	X	X
MAXIMUM PRESSURE REACHED				X	X			
PRESSURE DECAY TOO HIGH							X	
PRESSURE EXCEEDED								
PRESSURE INCREASE DETECTED							X	
PRESSURE NOT OBTAINABLE		X	X	X	X	X	X	
SETUP ERROR		X	X	X	X	X	X	X
TEST FAILED WITH AN UNKNOWN	X	X	X	X	X	X	X	X
VOLUME TOO LARGE								X

9.2 Instrument

The following table lists error messages that can occur during normal operation of the instrument.

Error message	Possible cause	Corrective action
CALIBRATION FAILURE	The instrument detects data corruption.	Contact Cytiva service.
INSTRUMENT TOO COLD	The environmental conditions are outside the specified range.	Move the instrument to a warmer environment, and allow the instrument to reach ambient temperature. See *Environmental conditions, on page 99*.
INSTRUMENT TOO HOT	The environmental conditions are outside the specified range.	Move the instrument to a colder environment, and allow the instrument to reach ambient temperature. See *Environmental conditions, on page 99*.
INTERNAL ERROR	The internal hardware, the software, or the communication of the instrument do not function properly.	1. Restart the instrument. 2. If the problem persists, contact Cytiva service.
INTERNAL ERROR [xxxxxx] six digit number	The internal communication of the instrument does not function properly.	Contact Cytiva service.
INTERNAL HARDWARE ERROR [xxxxxx] six digit number	• A hardware component might be defective. • A connection error has occurred.	Contact Cytiva service.
INVALID FIRMWARE VERSION	The software is outdated.	Contact Cytiva service to update the software.
LINE PRESSURE OUTSIDE RANGE	• The pressure of the compressed air supply is too low. • There are fluctuations in the compressed air supply.	• Verify the pressure of the compressed air supply, see *Compressed air, on page 301*. • Increase the pressure of the compressed air supply, if needed.

Error message	Possible cause	Corrective action
LINE PRESSURE TOO HIGH	• The pressure of the compressed air supply is too high. • There are fluctuations in the compressed air supply.	• Verify the pressure of the compressed air supply, see *Compressed air, on page 301*. • Increase the pressure of the compressed air supply, if needed.
LINE PRESSURE TOO LOW	• The pressure of the compressed air supply is too low. • There are fluctuations in the compressed air supply.	• Verify the pressure of the compressed air supply, see *Compressed air, on page 301*. • Increase the pressure of the compressed air supply, if needed.
LINE PRESSURE UNSTABLE	The pressure of the compressed air supply is not stable enough.	Verify the pressure of the compressed air supply, see *Compressed air, on page 301*.
MAXIMUM NUMBER OF REPEATS REACHED	The maximum number of repeats for a tested assembly is reached.	The tested assembly is considered defect and cannot be used.
PRESSURE EXCEEDED	• The pressure of the compressed air supply is too high. • An air hose might be constricted. • The instrument and tested assembly was not set up correctly.	• Verify the pressure of the compressed air supply, see *Compressed air, on page 301*. • Verify that the instrument is set up correctly. • Repeat the test.

9.3 Self test

The following table lists error and warning messages that can appear during a self test, as well as possible outcomes, and suggested corrective actions.

Error message	Possible cause	Corrective action
INTERNAL (HARDWARE) ERROR [xxxxxx] six digit number	The internal communication of the instrument does not function properly.	1. Repeat the self test. 2. If the self test fails again, contact Cytiva service.
LINE PRESSURE OUTSIDE RANGE	• The pressure of the compressed air supply is too low. • There are fluctuations in the compressed air supply.	• Verify the pressure of the compressed air supply, see *Compressed air, on page 301*. • Increase the pressure of the compressed air supply, if needed.

9.4 Test programs

The following table lists error and warning messages that can appear during a test, as well as possible outcomes, and suggested corrective actions.

Error message	Possible causes	Action
Downstream pressure too high for vent valve check	• The filter is not installed. • The filter has a major defect.	• Install the filter. • Replace the filter, if needed.
EXT.VALVE ERROR	• The external valve is not connected. • The external valve does not open.	Verify that the external valve opens and closes correctly.
FLOW TOO HIGH	The flow rate is below the selected threshold for ***Minimum flow*** or ***FF minimum flow***.	The filter is considered defect.
FLOW TOO LOW	• The flow rate is above 0.1 mL/min (FF test) or below 0.03 mL/min (water intrusion test (WIT)). • The connection between the filter and instrument is interrupted or closed off. • The flow rate value for the filter is too low to be measured (relevant for small filters only).	• Verify the test setup (such as the flow path, the filter connection, and the pressure on the down stream side of the filter). • Replace the filter, if needed. • For a FF test, re-wet the filter and repeat the test.
FLOW UNSTABLE	• The flow rate increases and decreases quickly during measurement, due to a leakage in the filter housing during the measurement phase of a test. • The pressure is fluctuating. • The temperature is fluctuating.	• Verify the setup (such as the flow path, the connection to the tested assembly, the pressure on the down stream side of the filter) • Verify that the room temperature is constant.

Error message	Possible causes	Action
INVALID TEST PARAMETERS	• The test values contain invalid characters. • The test values are outside the specified range.	Verify that the correct values are selected for each test parameter.
LOW FLOW	• The flow rate is above 0.1 mL/min (FF test) or below 0.03 mL/min (WIT) test. • The connection between the filter and instrument is interrupted or closed off. • The flow rate value for the filter is too low to be measured (relevant for small filters only).	• Verify that the minimum flow setting is enabled. • Verify the test setup (such as the flow path, the filter connection, and the pressure on the down stream side of the filter).
PRESSURE NOT OBTAINABLE	• A major leakage occurred in the filter housing during the run. • The filter membrane is not wetted completely. • The filter has a major defect. • The pressure of the compressed air supply is too low. • There are fluctuations in the compressed air supply.	• Verify that the flow path is free of leaks. • For a FF test, re-wet the filter and repeat the test. • Replace the filter, if needed. • Verify the pressure of the compressed air supply.
SETUP ERROR	The pressurization phase did not start.	• Verify that the filter is connected. • Verify that the external vent valve opens and closes correctly.
TEST FAILED WITH AN UNKNOWN	A software error occurred.	Contact Cytiva service to update the software.
TEST FAILED WITH DEVIATION	The test parameters might have been changed during an ongoing test.	Verify the test setup and repeat the test.

9.5 BP test

The following table lists error and warning messages that can appear during a bubble point (BP) test, as well as possible outcomes, and suggested corrective actions.

Error message	Possible cause	Corrective action
BUBBLE POINT NOT OBTAINABLE	• The final pressure during the BP test is equal to the pressure of the compressed air supply (i.e., 0.25 barg (7.3 psig)). The pressure of the compressed air supply is too low. • An unusual BP curve that does not allow detection of the bubble point.	• Verify the pressure of the compressed air supply, see *Compressed air, on page 301*. • Re-wet the filter and repeat the test. • Replace the filter, if needed.
Downstream pressure too high for vent valve check	• The filter is not installed. • The filter has a major defect.	• Install the filter. • Replace the filter, if needed.
LEAK TEST FAILURE	• A major leakage occurred in the tested assembly during the run. • The filter membrane is not wetted completely. • The filter has a major defect.	• Verify the pressure of the compressed air supply. • Verify that the instrument is correctly connected to the filter. • Re-wet and re-test the filter. • Replace the filter, if needed.
LINE PRESSURE OUTSIDE RANGE	• The pressure of the compressed air supply is too low. • There are fluctuations in the compressed air supply.	• Verify that the pressure of the compressed air supply is above 0.5 barg (7.25 psig) above the minimum bubble point. *Compressed air, on page 301* • Increase the pressure of the compressed air supply, if needed.

Error message	Possible cause	Corrective action
MAXIMUM PRESSURE REACHED	The maximum pressure that is defined in the test parameters is reached but the bubble point is not detected.	• Verify that the system is correctly connected to the filter. • Re-test the filter in a system that has a higher pressure tolerance. • Replace the filter, if needed.

9.6 LT

The following table lists error and warning messages that can appear during a leak test (LT), as well as possible outcomes, and suggested corrective actions.

Error message	Possible cause	Corrective action
LEAK DETECTED	A leakage detected in the tested assembly during the run.	Verify that the flow path is free of leaks.

9.7 PD test

The following table lists error and warning messages that can appear during a pressure decay (PD) test, as well as possible outcomes, and suggested corrective actions.

Error message	Possible cause	Corrective action
PRESSURE DECAY TOO HIGH	A major leakage occurred in the tested assembly during the run.	Verify that the flow path is free of leaks.
PRESSURE INCREASE DETECTED	The pressure increased during the test.	Verify that the temperature of the instrument and the tested assembly are stable during the test.

9.8 SUS LT

The following table lists error and warning messages that can appear during a single-use equipment leak test (SUS LT), as well as possible outcomes, and suggested corrective actions.

Error message	Possible causes	Action
GROSS LEAK DETECTED	A leakage occurred in the tested assembly during the stabilization phase.	Verify the setup, such as: • the flow path • the connection to the tested assembly
INACCURATE MEASUREMENT	The instrument detects a stability drift.	1. Check the hoses and the tested assembly for damage or bent hoses. 2. Run the test again in a more stable environment
KLEENPAK CONNECTOR FAILURE	The instrument detects an problem with the Kleenpak connection.	Check the Kleenpak connection.
PRESSURE EXCEEDED	The tested assembly cannot be inflated correctly due to external pressure or mechanical pressure.	Move any objects that put pressure on the tested assembly. Repeat the test.
SETUP ERROR	• Back-pressure from the instrument. • Back-pressure from the tested assembly . • The double air hose is not connected to the **BAG RETURN** port on the instrument.	Verify that the double air hose is connected to the **BAG RETURN** port on the instrument and the tested assembly.
VOLUME TOO LARGE	The volume of the tested assembly is smaller than the selected ***System volume*** or ***Actual volume***.	1. Verify the volume of the entire tested assembly. 2. Re-start the test with the correct settings for the tested assembly volume.

10 Reference information

About this chapter

This chapter lists technical specifications of the Flowstar V instrument. The chapter also includes recycling information and regulatory information.

In this chapter

10.1 Specifications

Introduction

This section describes the specifications for the product.

Technical specification

Parameter	Specification
Supply voltage	100 to 240 VAC
Frequency	50/60 Hz
Power consumption, operation	75 W
Power consumption, peak	150 W
Dimensions (W × D × H)	350 × 450 × 263 mm (13.8 × 17.7 × 10.4 inch)
Weight	10.5 kg (23.3 lb) depending on installed accessories
Acoustic noise level	< 90 dB(A)
Wi-Fi frequency range	2412.0 to 2462.0 MHz
Wi-Fi power output	0.0219 W
Operating system	Built-in computer running the Linux operating system[1]
Vent	Hose connection 8 mm outer diameter
External vent valve	24 VDC
External pressure transducer	Relative (relative to gauge) pressure measurement, 4 to 20 mA signal
Compressed air outlet connection	Stäubli coupling RBE03.2904
Enclosure protective class	IP54

[1] The GNU General Public License (GPL) of the operating system is stored on the USB drive that is supplied with the instrument.

Connections

Parameter	Specification
Air inlet port	Stäubli RBE03 male connector, RBE03.6150
Air outlet port	Stäubli RBE03 female connector, RBE03.2904
Vent port	Air hose connection, 8 mm outer diameter

Software specifications

Parameter	Specification
Test program storage	Max. 500 programs
Test result storage	Max. 10 000 tests
Active user accounts	Max. 250 users

Environmental requirements

Parameter	Requirement
Allowed location	Indoor use only
Ambient temperature, operating[1]	5°C to 40°C (41 to 104°F)
Ambient temperature, storage	-20°C to 50°C (-4 to 122°F)
Relative humidity	80%, non-condensing, at temperatures up to 31°C 50%, non-condensing, at 40°C
Altitude, operating	Up to 2000 m above sea level
Pollution degree of the intended environment	Pollution degree 3

[1] Make sure that the operation temperature is in the same range as the temperature of the instrument at the time of calibration.

Process operating limits

Parameter	Specification
Measuring range	• Forward flow (FF) test: 0.1 to 1000 mL/min • Water intrusion test (WIT): 0.03 to 50 mL/min water • Bubble point (BP) test: 400 to 6500 mbar • Single-use equipment leak test (SUS LT): 20 to 50 mbar

Parameter	Specification
Test pressure range	20 to 6500 mbar (0.7 to 94.2 psi)
Accuracy[1]	• FF test: ± 3% of measurement or ± 0.05 mL/min, whichever is greater • WIT test: ± 3% of measurement or ± 0.02 mL/min, whichever is greater • SUS LT test: ± 3% of measurement or ± 0.05 mL/min, whichever is greater
Resolution	• FF test: 0.1 mL/min or 0.01 mL/min for a flow < 10 mL/min • WIT test: 0.01 mL/min • BP test: 50 mbar (0.7 psi)
Calibration limits	• Flow measurement: ± 3% of measurement or ± 0.05 mL/min, whichever is greater • Pressure measurement: ± 30 mbar (calibrated up to 7 bar) • Pressure measurement for ***SUS Leak Test*** operation: ± 1 mbar (calibrated up to 290 mbar)

[1] Refer to the *Validation Guide USTR3520* for details. The validation guide can downloaded from the regulatory support portal, see *Regulatory support, on page 12*.

Ingress protection

Parameter	Specification	Description
Field mounted instruments, control box, and power box	IP 54	Protected against access to hazardous parts with a wire and dust-protected. Protected against splashing water.

Compressed air

Note: *All pressure values are reported as pressure relative to ambient atmospheric pressure, i.e., gauge pressure, unless stated otherwise.*

Parameter	Specification
Maximum air pressure	8000 mbar (116 psi)
Minimum air pressure, self test	3000 mbar (43.5 psi)

Parameter	Specification
Minimum air pressure, operation at 0.01 to 149 mL/min	1000 mbar (14.5 psi) above the test pressure
Minimum air pressure, operation at 150 to 1000 mL/min	2000 mbar (29.0 psi) above the test pressure
Instrument air and process air quality	Oil and particle free, non-condensing air or nitrogen gas (according to ISO 8573-1:2010 Class 3.4.4 or better)

10.2 Recycling information

Introduction

This section contains information about the decommissioning of the product.

CAUTION

Always use appropriate personal protective equipment when decommissioning the equipment.

Decontamination

The product must be decontaminated before decommissioning. All local regulations must be followed with regard to scrapping of the equipment.

Disposal of the product

When taking the product out of service, the different materials must be separated and recycled according to national and local environmental regulations.

Recycling of hazardous substances

The product contains hazardous substances. Detailed information is available from your Cytiva representative.

Disposal of electrical components

Waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Contact an authorized representative of the manufacturer for information concerning the decommissioning of the equipment.

10.3 Regulatory information

Introduction

This section lists the regulations and standards that apply to the product. Your product is marked or listed according to the applicable regulatory requirements for your region. Local language translations are only provided according to regulatory requirements.

In this section

10.3.1 Contact information

Introduction

This section shows the contact information for support and to the legal manufacturer.

Contact information for support

To find local contact information for support and sending troubleshooting reports, visit *cytiva.com/contact*.

Manufacturing information

The table below summarizes the required manufacturing information.

Requirement	Information
Name and address of manufacturer	Pall International Sàrl Avenue de Tivoli 3 1700 Fribourg Switzerland

10.3.2 European Union and European Economic Area

Introduction

This section describes the information that applies to the product in the European Union and European Economic Area.

Conformity with EU Directives

Refer to the EU Declaration of Conformity for the directives and regulations that apply for the CE marking.

If not included with the product, a copy of the EU Declaration of Conformity is available on request.

CE marking

The CE marking and the corresponding EU Declaration of Conformity is valid for the product when it is:

- used according to the *Operating Instructions* or user manuals, and
- used in the same state as it was delivered, except for alterations described in the *Operating Instructions* or user manuals.

10.3.3 North America

Introduction

This section describes the information that applies to the product in the United States of America and Canada.

FCC compliance

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: *The user is cautioned that any changes or modifications not expressly approved by Cytiva could void the user's authority to operate the equipment.*

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

10.3.4 China

Introduction

This section describes the information that applies to the product in the People's Republic of China.

有害物质声明 (DoHS)
Declaration of Hazardous Substances (DoHS)

根据 SJ/T11364-2024《电子电气产品有害物质限制使用标识要求》特提供如下 有关污染控制方面的信息。

The following product pollution control information is provided according to SJ/ T11364-2024 Marking for Restriction of Hazardous Substances caused by electrical and electronic products.

电子信息产品污染控制标志说明
Explanation of Pollution Control Label

该标志表明本产品不含有超过中国标准 GB/T 26572 《电子信息产品中有毒有害物质的限量要求》中限量的有毒有害物质,报废后可以进行回收处理,不能随意丢弃。

This symbol indicates that this electrical and electronic product does not contain any hazardous substances above the maximum concentration value established by the Chinese standard GB/T 26572 , and can be recycled after being discarded, and should not be casually discarded.

有害物质的名称及含量
Name and Concentration of Hazardous Substances

产品中有害物质的名称及含量

Table of Hazardous Substances' Name and Concentration

部件名称 Component name	有害物质 Hazardous substance									
	铅 (Pb)	汞 (Hg)	镉 (Cd)	六价铬 (Cr(VI)或 Cr6+)	多溴联苯 (PBB)	多溴二苯醚 (PBDEs)	邻苯二甲酸二正丁酯 (DBP)	邻苯二甲酸二异丁酯 (DIBP)	邻苯二甲酸丁苄酯 (BBP)	邻苯二甲酸二（2-乙基）己酯 (DEHP)
FFS05	0	0	0	0	0	0	0	0	0	0
FFS05-LGR	0	0	0	0	0	0	0	0	0	0

0: 表示该有害物质在该部件所有均质材料中的含量均在 GB/T 26572 规定的 限量要求以下。

X: 表示该有害物质至少在该部件的某一均质材料中的含量超出 GB/T 26572 规定的限量要求。

- 此表所列数据为发布时所能获得的最佳信息.

0: Indicates that this hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in GB/T 26572.

X: Indicates that this hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirement in GB/T 26572.

- Data listed in the table represents best information available at the time of publication.

10.3.5 Japan

Introduction

This section describes the information that applies to the product in Japan.

Included power cord

NOTICE

Do not use the included power cord set with other products.

注記

同梱された電源コードセットは、他の製品に使用しないこと。

10.3.6 South Korea

Introduction

This section describes the information that applies to the product in the Republic of Korea.

Compliance statement

NOTICE

Class A equipment (equipment for business use).

This equipment has been evaluated for its suitability for use in a business environment.

When used in a residential environment, there is a concern of radio interference.

유의사항

A급 기기 (업무용 방송통신 기자재)

이 기기는 업무용환경에서 사용할 목적으로 적합성평가를 받은 기기로서 가정용 환경에서 사용하는 경우 전파간섭의 우려가 있습니다.

10.3.7 General regulatory statements

EMC emission, CISPR 11: Group 1, Class A statement

NOTICE

This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

Intended use for supplied power cord

NOTICE

Power cord. Do not use the supplied power cords for any other equipment.

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