cytiva

UniFlux10

Operating Instructions

Original instructions

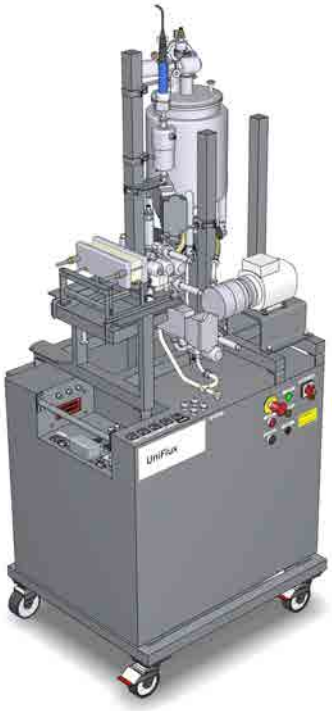

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Table of Contents

1 Introduction

About this chapter

This chapter contains important user information, descriptions of safety notices, intended use of the UniFlux™ 10 system and a list of associated documentation.

In this chapter

1.1 About this manual

Purpose of this manual

The *Operating Instructions* provide you with the information needed to install, operate, and maintain the product in a safe way.

Scope of this manual

This Operating Instructions covers all variants of UniFlux 10 system.

The components included in the configuration are described in the General Specification (GS). Classification information for your system is described on the system label.

Typographical conventions

Software items are identified in the text by ***bold italic*** text.

Hardware items are identified in the text by **bold** text.

In electronic format, references in *italics* are clickable hyperlinks.

1.2 Important user information

Read this before operating the product

All users must read the entire *Operating Instructions* before installing, operating or maintaining the product.

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

Do not operate the product in any other way than described in the user documentation. If you do, you may be exposed to hazards that can lead to personal injury and you may cause damage to the equipment.

Intended use of UniFlux 10 system

UniFlux 10 system is intended for pilot to production scale biological separations.

The systems are configured to operate hollow fiber cartridges suited for microfiltration applications such as cell clarification/harvesting, or cassettes/hollow fibers for ultrafiltration applications, such as protein concentration and diafiltration in downstream unit operations.

UniFlux 10 system shall not be used in any clinical procedures, or for diagnostic purposes.

UniFlux 10 system shall not be used for operation in a potentially explosive atmosphere or for handling flammable liquids.

WARNING

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

Prerequisites

In order to operate UniFlux 10 system in a safe way, and according to the intended purpose, the following prerequisites must be met:

- You should be acquainted with the use of bioprocessing equipment and with the handling of biological materials.
- You must have read and understood the Safety chapter of these *Operating Instructions*.
- The system must be installed according to the instructions in *Chapter 4 Installation, on page 78*.
- You must have a working knowledge of the UNICORN™ software. Refer to the UNICORN manuals for instructions on the software structure and the work flow.

Safety notices

This user documentation contains safety notices (WARNING, CAUTION, and NOTICE) concerning the safe use of the product. See 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.

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.*

1.3 Associated documentation

System-specific documentation

In addition to the *Operating Instructions*, the documentation package supplied with the UniFlux 10 system also includes product documentation binders containing detailed specifications and traceability documents. The most important documents in the document package with regard to technical aspects of the UniFlux 10 system are:

Document	Abbreviation	Purpose/Contents
Piping and Instrumentation Diagram	P&ID	Schematic overview of the entire process flow, all components and instruments and the control system.
General Specification	GS	Technical data for the system.
Assembly Drawing	AD	Physical layout. Provides all dimensional data.
Bill of Material	BOM	Detailed specifications for process related components.
Declaration of Conformity	DoC	EU declaration of conformity.
Spare Part List	SPL	List of spare parts available from Cytiva.

Software documentation

Together with each system, the following software documentation is supplied providing additional information that applies to UniFlux 10 system, independent of the specific configuration:

Document	Purpose/Contents
UNICORN™ manual package	• The manuals contain detailed instructions on how to administer UNICORN, work with methods, perform runs and evaluate results. • The Online help contains dialog descriptions for UNICORN. The Online help is accessed from the ***Help*** menu.

Component documentation

Documentation for components produced both by Cytiva and by a third-party are, if existent, also included in the product documentation package.

1.4 Abbreviations

Introduction

This section explains abbreviations that appear in the user documentation for UniFlux 10.

Abbreviations

Abbreviation	Definition (English)	Translation
EPDM	Ethylene Propylene Diene Monomer	Ethylene Propylene Diene Monomer
HEPA	High Efficiency Particulate Air	High Efficiency Particulate Air
PID	Proportional Integral Derivative A PID controller calculates an error value as the difference between a measured process variable (PV) and a desired setpoint (SP). The PID controller attempts to minimize the error by adjusting the process control inputs (CV).	Proportional Integral Derivative A PID controller calculates an error value as the difference between a measured process variable (PV) and a desired setpoint (SP). The PID controller attempts to minimize the error by adjusting the process control inputs (CV).
PLC	Programmable logic controller	Programmable logic controller
PV	Process variable, measured	Process variable, measured
SP	Setpoint The target value that an automatic control system, for example PID controller, will attempt to reach by adjusting the process control inputs.	Setpoint The target value that an automatic control system, for example PID controller, will attempt to reach by adjusting the process control inputs.
TC-clamp	Hygienic tubing connection clamp	Hygienic tubing connection clamp
UPS	Uninterruptible power supply	Uninterruptible power supply

2 Safety instructions

About this chapter

This chapter describes safety precautions, emergency shutdown procedures and labels information for UniFlux 10

In this chapter

Important

WARNING

Before installing, operating or maintaining the product, all users must read and understand the entire contents of this chapter to become aware of the hazards involved.

2.1 Safety precautions

Introduction

The safety precautions in this section are grouped in the following categories:

Note: *Some of the safety precautions in this chapter may concern components or situations described in other UniFlux 10 product documents.*

General precautions

WARNING

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

WARNING

The customer must make sure that all installation, maintenance, operation and inspection is carried out by qualified personnel who are adequately trained, understand and adhere to local regulations and the operating instructions, and have a thorough knowledge of the product and the entire process.

WARNING

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

WARNING

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

WARNING

Do not use UniFlux 10 system if it is not working properly, or if it has suffered any damage, for example:

- damage to the power cord or its plug
- damage caused by dropping the equipment
- damage caused by splashing liquid onto it

WARNING

Only authorized personnel may open the electrical cabinet doors. There is hazardous voltage inside the electrical cabinet that can cause human injury or death.

WARNING

The electrical cabinet doors may only be opened when the product is taken out of operation and subject to **LOCK OUT / TAG OUT (LOTO)** (lockout-tagout).

CAUTION

Hot surface. When pumping fluid through the system that has a temperature above the normal working temperature, do not touch the system until you are sure that this can be done without risk and when all components in the system have reached the normal working temperature range.

CAUTION

Do not insert your fingers or other objects into fans or other moving parts.

Flammable liquids and explosive environment

WARNING

Flammable liquids. This product is **not approved** to handle flammable liquids.

WARNING

Explosive environment. The product is **not approved** for work in a potentially explosive atmosphere. The product does not fulfill the requirements of the ATEX Directive.

Personal protection

WARNING

Hazardous substances and biological agents. When using hazardous chemical and biological agents, take all suitable protective measures, such as wearing protective clothing, glasses and gloves resistant to the substances used. Follow local and/or national regulations for safe operation and maintenance of UniFlux 10 system.

WARNING

Personal Protective Equipment (PPE). Whenever packing, unpacking, transporting or moving the system, wear protective footwear, preferably with steel toe caps.

WARNING

High pressure. The product operates under high pressure. Wear protective glasses and other required Personal Protective Equipment (PPE) at all times.

Installing and moving

WARNING

The product must be installed and prepared by Cytiva personnel or a third party authorized by Cytiva.

WARNING

Move transport crates. Make sure that the lifting equipment has the capacity to safely lift the crate weight. Make sure that the crate is properly balanced so that it will not accidentally tip when moved.

WARNING

The system is not fitted with lifting eye bolts or other equipment for lifting with telphers or similar equipment. The system should only be lifted using the lower part of the frame.

WARNING

Heavy object. Because of the significant weight of the product, great care must be taken not to cause squeezing or crushing injuries during movement. At least two, but preferably three or more, people are recommended when moving the unit.

WARNING

Heavy object. The ramp is not reinforced in the center. Do not use a pallet lifter or forklift on the ramp.

WARNING

Heavy object. When rolling the system down the ramp take great care to avoid the wheels slipping off the edge of the ramp.

WARNING

Access to power switch and power cord with plug. Do not block access to the power switch and power cord. The power switch must always be easy to access. The power cord with plug must always be easy to disconnect.

WARNING

Fixed power supply: Access to power switch and isolation switch. The power switch and the isolation switch must always be easy to access.

WARNING

When the system is operated from a remote controlling computer, the operator must always make sure that no one is present and exposed when the system is started and that no one enters the risk area around the system during operation.

CAUTION

The wheels of the product must be locked during normal use. The wheels must be unlocked only when moving the unit.

CAUTION

Make sure that all tubing, hoses and cables are placed so that the risk of tripping accidents is minimized.

CAUTION

The product is designed for indoor use only.

CAUTION

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

CAUTION

Make sure that correct air pressure is always maintained. Too high or too low air pressure may be hazardous and may cause erroneous results and leakage.

CAUTION

Before moving the UniFlux 10 system, make sure that:

1. The power supply to the system is switched off.
2. All power cords to the systems are disconnected.
3. All air supply lines to the systems are disconnected.
4. All process lines to the systems are disconnected.
5. All communication cables to the systems are disconnected.

CAUTION

Make sure that the common waste outlet is:

- Never exposed to back-pressure.
- Connected to piping with at least the same diameter as the common waste outlet piping.
- Connected to piping that allows maximum waste flow to be transported away from the product without pooling.

CAUTION

Use the supplied network cable with encased RJ45 connectors to protect from liquids. Do not replace this cable with an unprotected cable.

CAUTION

To prevent bacterial growth, the product may be partly filled with denatured alcohol (18% C_2H_5OH (ethanol), 2% C_3H_7OH (isopropanol) and 80% H_2O (water)) at delivery.

The denatured alcohol mixture can be hazardous to humans if consumed.

Flush out the denatured alcohol before assembling, testing or integrating the product into the intended process context.

NOTICE

Any computer used with the equipment must comply with EN/IEC 60950-1, and be installed and used according to the manufacturer's instructions.

Power supply

WARNING

Protective ground. The product must always be connected to a grounded power outlet.

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 may result in personal injury and/or equipment damage.

WARNING

All electrical installations must be performed by authorized personnel only.

CAUTION

Connection of an external Uninterruptible Power Supply (UPS) (uninterrupted power supply) for system operation shall only be performed by authorized personnel to avoid mismatching or connection errors. Contact your local Cytiva representative for more information.

System operation

WARNING

Safe distance. Always maintain a safe distance from UniFlux 10 system during drainage or other activities that may involve splashing.

WARNING

During operation, all cabinet doors must be closed and locked.

WARNING

Before operation, all process connections and the piping system must be tested for leakage at maximum pressure for continued protection against injury risks due to fluid jets, burst pipes or potentially explosive atmosphere.

WARNING

Use a harmless fluid in the beginning of the process. This will make it possible to detect leakage with minimized consequences and the risk for potential leakage of hazardous fluids is avoided.

WARNING

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

WARNING

Power failure - equipment may remain pressurized. During a power failure, or if the **EMERGENCY STOP** button is pressed, the equipment may remain pressurized. Opening a line or vessel at this point could result in the release of potentially hazardous process or cleaning fluid, and cause bodily harm.

When recovering from a power failure or emergency shutdown, make sure all lines and vessels are depressurized before opening.

WARNING

Shutdown does not automatically result in depressurizing of the piping system.

WARNING

Emergency stop. Pressing the **EMERGENCY STOP** will not shut off mains power to the electrical cabinet.

WARNING

Alarm signals. All alarm signals must be set within the limits specified in the system documentation. Pressure and temperature control must be activated while the system is in use to prevent leakage or damage to the piping system.

WARNING

Alarm signals. Make sure to change back to the original alarm level after UNICORN for BioProcess alarm buzzer test.

CAUTION

Make sure that the pH probe is mounted correctly after reassembly.

CAUTION

The operator must always make sure that no one is present and exposed before energizing the hydraulic pump.

Maintenance

WARNING

Decontaminate before service. Before performing any service work on the system, make sure that the system has been properly decontaminated.

WARNING

LOCK OUT / TAG OUT (LOTO)! Before any maintenance or decommissioning work is performed on the system, make sure that:

- the system is empty and depressurized.
- the system is disconnected from process feed, electrical power and pneumatic supply.
- the system is prevented from accidentally becoming re-energized during maintenance.
- the system is clearly tagged as taken out of operation.
- all process wetted areas are clean and decontaminated.

WARNING

Only personnel authorized by Cytiva may perform service, installation, and maintenance of components inside the electrical cabinet of the system.

WARNING

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

WARNING

For continued protection against injury risks due to fluid jets, burst pipes or potentially explosive atmosphere, the user must test the piping system for leakage at maximum operating pressure.

- Always perform a leakage test after assembly or maintenance.
- Always perform a leakage test before operation or CIP.

2.2 Labels

Introduction

This section describes the various labels on the UniFlux 10 system and their meaning.

System label

The system label is located on the back of the equipment. The system label identifies the equipment and shows electrical data, regulatory compliance, and warning symbols.

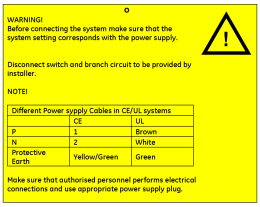
Description of symbols on the system label

Label	Meaning
Serial number	System serial number
Manufac-turing Year/ Month	Year (YYYY) and month (MM) of manufacture
Max system pressure/ temperature	Max system pressure at temperature
Pneumatic supply	Pneumatic supply pressure requirement
Overall protection class	Overall protection class, ingress protection according to IEC 60529. This cover all components of the system including the electric cabinet
Supply voltage	Supply voltage system
Supply voltage motor	Supply voltage motor
Frequency	Supply voltage frequency
Max current consumption system	Max current consumption system
Max current consumption motor	Max current consumption motor

Safety labels

The table below describes the various safety labels that may be found on UniFlux 10.

Symbol/text	Description
	**Warning!** Read the user documentation before using the system. Do not open any covers or replace parts unless specifically stated in the user documentation.
	**Warning! High Voltage** Always make sure that the system is disconnected from electric power before opening the cabinet doors or disconnecting any electric device.
	**Warning! Hot surface** Risk of burning injuries.
	**Warning! Crush injury risk area** Keep fingers and other body parts away from moving components.
	**Warning!** Risk of spraying fluid jets.
	**WARNING!** Max operating pressure as stated on the label.
	**WARNING! High voltage inside cabinet!** Authorized personnel only! For continued protection against fire, only replace fuses with the same type and rating.

<table>
<tr><th>Symbol/text</th><th>Description</th></tr>
<tr><td> 
</td><td>Warning! Before connecting the system, make sure that the system setting corresponds with the power supply.
Disconnect switch and branch circuit to be provided by installer.
NOTE!
<table><tr><td colspan="3">Different power supply cables in CE/UL systems</td></tr><tr><td></td><td>CE</td><td>UL</td></tr><tr><td>P</td><td>1</td><td>Brown</td></tr><tr><td>N</td><td>2</td><td>White</td></tr><tr><td>Protective earth</td><td>Yellow/green</td><td>Green or Yellow/green</td></tr></table>
Make sure that authorized personnel perform electrical connections and use appropriate power supply plug.</td></tr>
<tr><td> 
</td><td>EMERGENCY STOP label, yellow with black text. (emergency stop button is red).
Refer to Section 2.3 Emergency procedures, on page 25 for further information regarding the emergency stop.</td></tr>
<tr><td> 
</td><td>IMPORTANT! Before service/maintenance or return to Cytiva, clean the equipment and accompany it with a decontamination statement, specifying substances with which it has been in contact during use and the method of cleaning.</td></tr>
<tr><td> 
</td><td>CAUTION! Pressure control valve shall be set to 6 bar g for instrument air supply.</td></tr>
<tr><td>  </td><td>Use ear protection whenever working close to the system in operation.</td></tr>
</table>

2.3 Emergency procedures

Introduction

Under normal circumstances, the UniFlux 10 system should always be shut down as described in *Section 5.4 Procedures after usage, on page 114*.

Shutting down the UniFlux 10 system by pressing the **EMERGENCY STOP** button should only be performed if an emergency situation prevents normal shutdown.

This section describes how to perform an emergency shutdown of the UniFlux 10 system, the result in the event of power failure, and the procedure for restarting the UniFlux 10 system after a power failure.

Precautions

WARNING

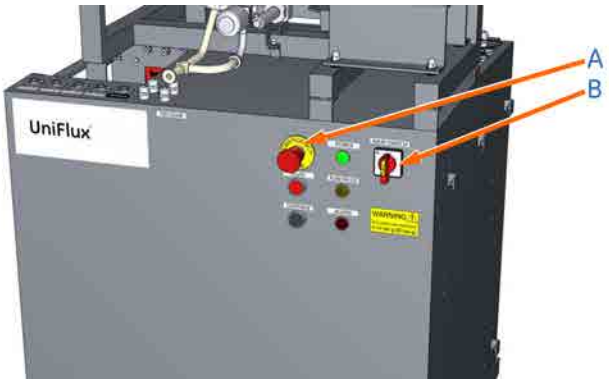
Emergency stop. Pressing the **EMERGENCY STOP** will not shut off mains power to the electrical cabinet.

WARNING

Power failure - equipment may remain pressurized. During a power failure, or if the **EMERGENCY STOP** button is pressed, the equipment may remain pressurized. Opening a line or vessel at this point could result in the release of potentially hazardous process or cleaning fluid, and cause bodily harm.

When recovering from a power failure or emergency shutdown, make sure all lines and vessels are depressurized before opening.

Emergency stop button and main power switch



Part	Function
A	**EMERGENCY STOP** button
B	**MAIN SWITCH**, power

Emergency shutdown

Step	Action
1	Press the **EMERGENCY STOP** button (A). *Result:* • All motors and externally moving components stop immediately. • No data is lost.
2	If required, also switch off the **MAIN SWITCH** (B), disconnect the power cord or switch off the fixed power supply circuit breaker. *Result:* • Power will be lost to the entire system. • All valves will shut immediately and not in sequence.

NOTICE

To power down the system, always follow the controlled shutdown procedure described in *Section 5.4 Procedures after usage, on page 114*.

Power failure

The system power is lost if any of the following applies:

- The **MAIN SWITCH** on the electrical cabinet is turned off.
- The mains cable disconnected.
- The power supply is lost.

If the electrical power to the system is lost, the following happens:

- All pumps stop.
- All valves will immediately revert to default positions.

When power returns to normal, the system will be in ***End*** state (i.e., it will not resume the run).

Restart after emergency shut down or power failure

Follow the instruction below to restart UniFlux 10 system after emergency shut down or power failure.

Step	Action
1	Make sure that the condition that caused the power failure or emergency stop is corrected.
2	 Reset the **EMERGENCY STOP** button by twisting it clockwise.
3	Press the ***Continue*** button in UNICORN.

Note: *Forcing UNICORN or the Microsoft® Windows® operating system to close during upload of data from the* **CU-960** *will cause the unsaved data to be lost.*

NOTICE

If UniFlux 10 system fails to restart correctly following an emergency shutdown or power failure, contact Cytiva for further advice and assistance.

Data recovery upon restart

The UNICORN interface control unit, **CU-960** (located inside the electrical cabinet), has capabilities to store real time data during short disconnection from the computer. Data stored on the **CU-960** can be uploaded to the computer once communication to the computer is re-established. Upload of data from the **CU-960** to the computer will be indicated on the monitor. The system can be controlled again once the upload of data from the **CU-960** is completed. Data upload can take several minutes to complete. For more information about uploading data from the **CU-960**, refer to the UNICORN manual package.

3 System description

About this chapter

This chapter provides descriptions of UniFlux 10 system and an overview of all components, including the UNICORN control system.

In this chapter

3.1 Configurations

Introduction

The UniFlux 10 series is a product range of cross flow filtration (CFF) systems that utilizes UNICORN software for full automation with data logging capabilities over the entire cross flow process.

The systems are configured to operate hollow fiber cartridges suited for microfiltration applications such as cell clarification/harvesting, or cassettes/hollow fibers for ultrafiltration applications, such as protein concentration and diafiltration in downstream unit operations.

UniFlux 10 system can be individually configured according to the specific process requirements. This section summarizes the standard and optional components of UniFlux 10, and indicates where further information on these components is to be found.

Components

Standard UniFlux 10 components are described in *Section 3.3 Standard components, on page 35*.

Optional UniFlux 10 components are described in *Section 3.4 Optional components, on page 47*.

The UNICORN control system is described in *Section 3.9 UNICORN control system, on page 74*. The product documentation package includes the Software Configuration Description, which describes all functions of the control software in detail.

Material compliance

All plastic and polymer materials that come in contact with buffers and samples are compliant with USP Class VI.

All materials used are traceable back to their production batches.

You can find information about the design and materials used in your system in the the documentation package supplied with the system.

Chemical resistance is described in *Section 8.4 Chemical resistance, on page 153*.

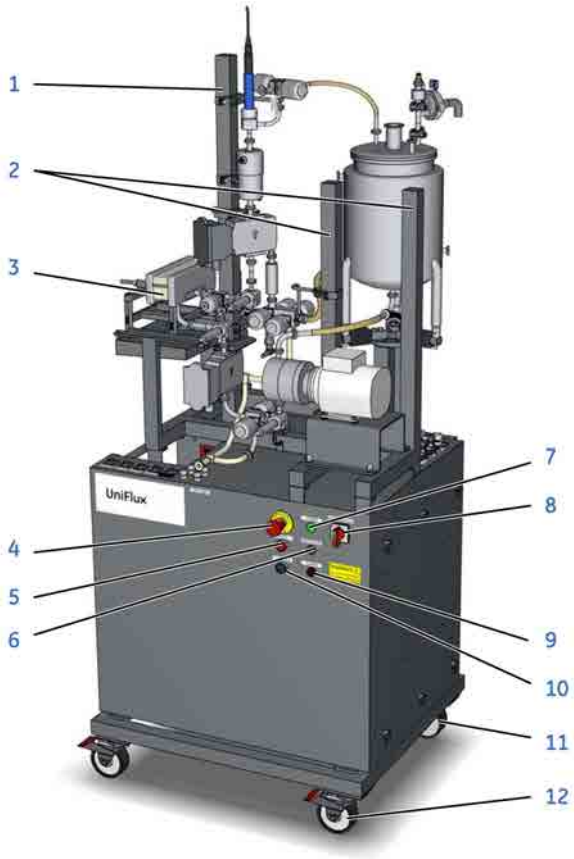
Information about process wetted materials can be found in *Process wetted materials, on page 166*.

3.2 Illustrations

Introduction

This section provides illustrations of the UniFlux 10 system. The main features and components are indicated.

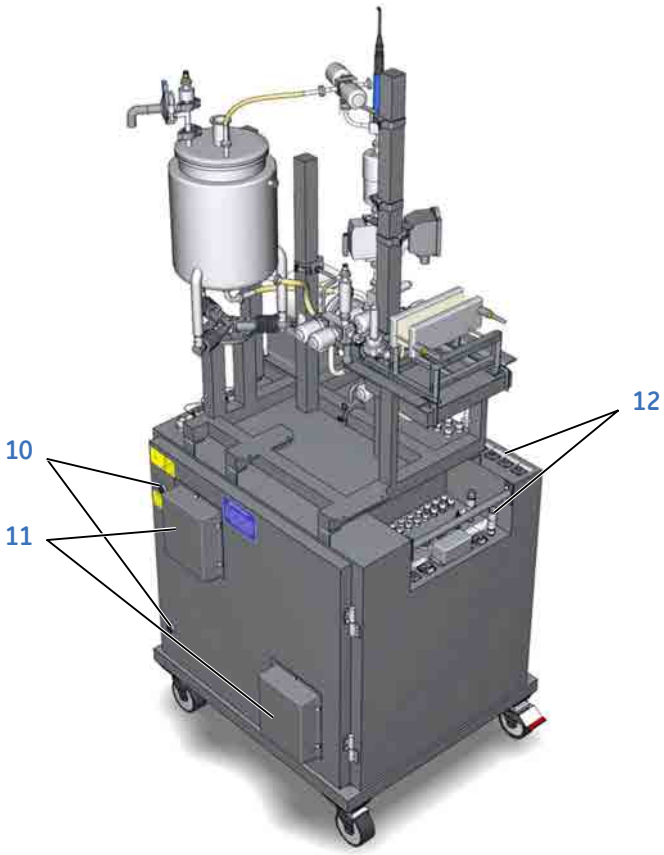
Front view



Part	Function
1	Permeate line equipment mounting beam
2	Tank and peristaltic pumps mounting beam
3	Filter cassette, cassette configuration shown

Part	Function
4	**EMERGENCY STOP** button
5	**PAUSE** button
6	**RUN/PAUSE** indicator light
7	**POWER** indicator light
8	**MAIN SWITCH**, power
9	**ALARM** indicator light
10	**CONTINUE** button
11	Caster without brake (2 pcs)
12	Caster with brake (2 pcs)

Rear view



Part	Function
10	Electrical cabinet door locks (2 pcs)
11	Filter and fan for cabinet cooling
12	External device connectors, refer to *External connectors, on page 33*

External connectors

The illustrations below show the external connectors on the UniFlux 10 system.

Part	Function
M-241	Mixer motor control
AIT-131	UV-connector
EXTERNAL SIGNALS	Connector for user process site signal communications
PROFIBUS	PROFIBUS™ connector
AIR INLET	System air inlet
UNICORN ETHERNET	UNICORN Ethernet connector
AIR EXHAUST	System air exhaust
ZSO-064	Hollow fiber drain valve control signal connector
ZSO-081	Quadruple valve option control signal connector
ZSO-082	Quadruple valve option control signal connector
ZSO-083	Quadruple valve option control signal connector
ZSO-084	Quadruple valve option control signal connector

Connectors in front recess

Part	Function
P-202	Transfer pump control
P-203	Permeate pump control
AIT-131	UV-signal

Connectors on rear side

3.3 Standard components

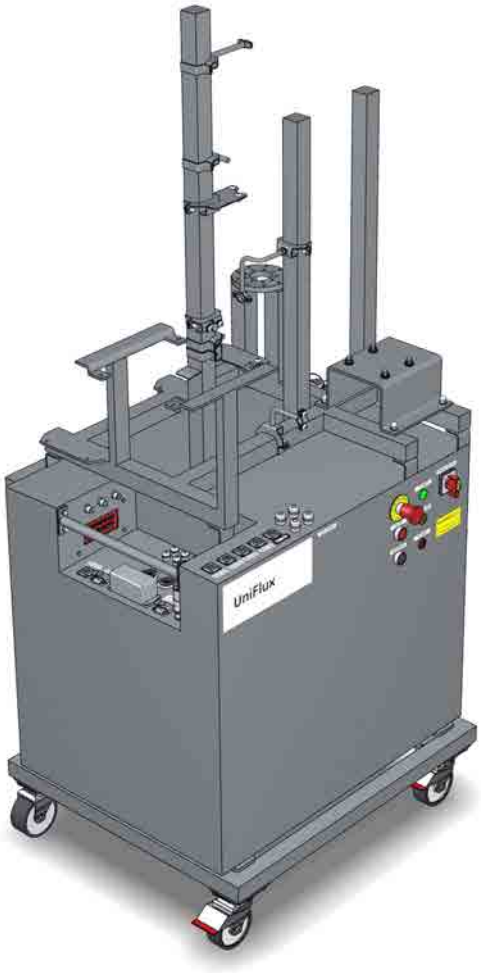
About this section

This section provides an overview of the standard components of UniFlux 10 system.

In this section

3.3.1 Structural components

Skid



The rigid stainless steel structure supports and protects all process components and the electrical cabinet. The structure is designed for handling in a production environment and is easy to move and keep clean.

The structure occupies a small box-shaped space that makes it easy to fit into any location in the production facility.

Electrical cabinet

The electrical cabinet contains all electrical and pneumatic equipment. When the door is closed, the entire cabinet is ingress protected according to IP55.

3.3.2 Control system components

Introduction

This section describes the components that allow automation of the UniFlux 10 system by the UNICORN control system.

Control system

The UniFlux 10 system is fully automated by means of the UNICORN control system. Once the required methods are created and approved, a non-expert user can safely operate the system.

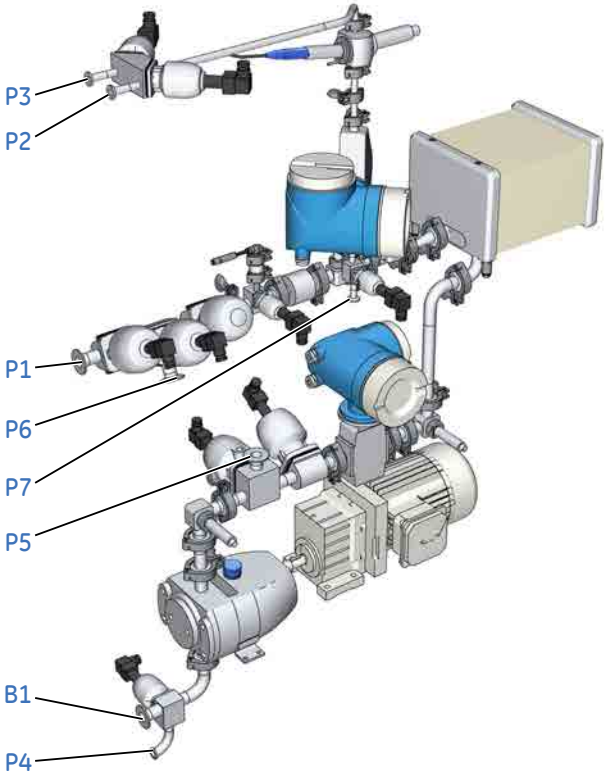
Refer to *Section 3.9 UNICORN control system, on page 74* for information on the UNICORN control system.

Communications

Communication with most controlled components mounted outside the electrical cabinet uses the PROFIBUS industry standard communication protocol and hardware.

3.3.3 Connections and drains

Illustration



Part	Label on system	Function
B1	**FEED**	Feed inlet to system
P1	**RETENTATE**	Retentate outlet
P2	**PERMEATE**	Permeate outlet
P3	**PERMEATE RECYCLE**	Permeate recycle to feed tank
P4	**FEED DRAIN**	Feed drain point and product outlet
P5	**CIP**	Clean-In-Place agent outlet
P6	**RETENTATE DRAIN**	Retentate line drain point
P7	**PERMEATE DRAIN**	Permeate line drain point

Description

The basic configuration of the UniFlux 10 system is provided with the following process connections:

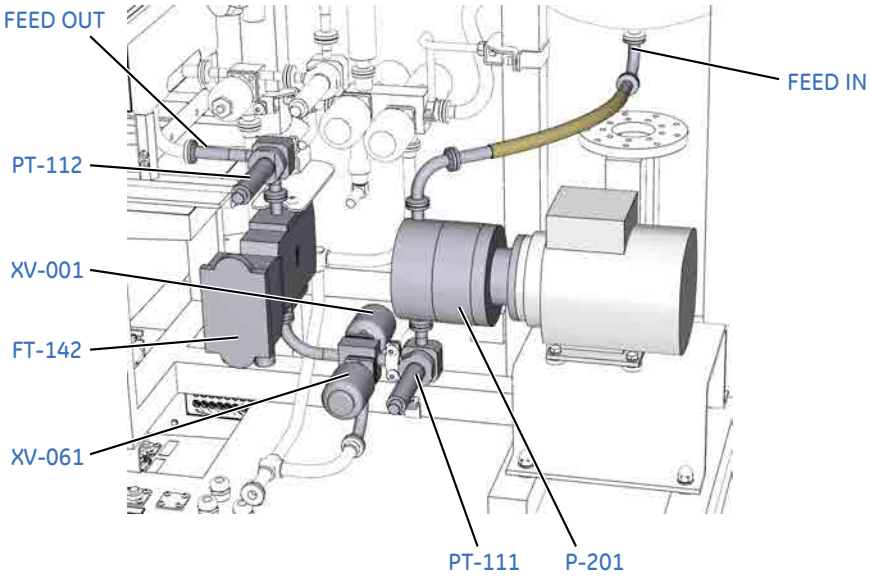
- Feed inlet
- Filter inlet, filter outlet and drain connections
- Retentate outlet
- Permeate outlet
- Permeate recycle outlet
- Pump outlet located before filters and meters. Can be used to supply feed tank CIP.

On the UniFlux 10 system, the feed inlet, retentate outlet and permeate recycle outlets are connected to the integrated feed tank.

For a detailed description of interface points between the UniFlux System and the customer plant process equipment, refer to *Section 3.8 Flowchart, on page 70* and *Section 8.3 Battery limits, on page 151*.

3.3.4 Feed pump and feed line

Illustration



Description

The main purposes of the feed line are to transfer product (or feed) from the recirculation tank, to the filter (FILTER) and to raise the pressure of the feed so that correct trans membrane pressure (TMP), filter pressure and feed flow is achieved. This is done by the feed pump, **P-201**.

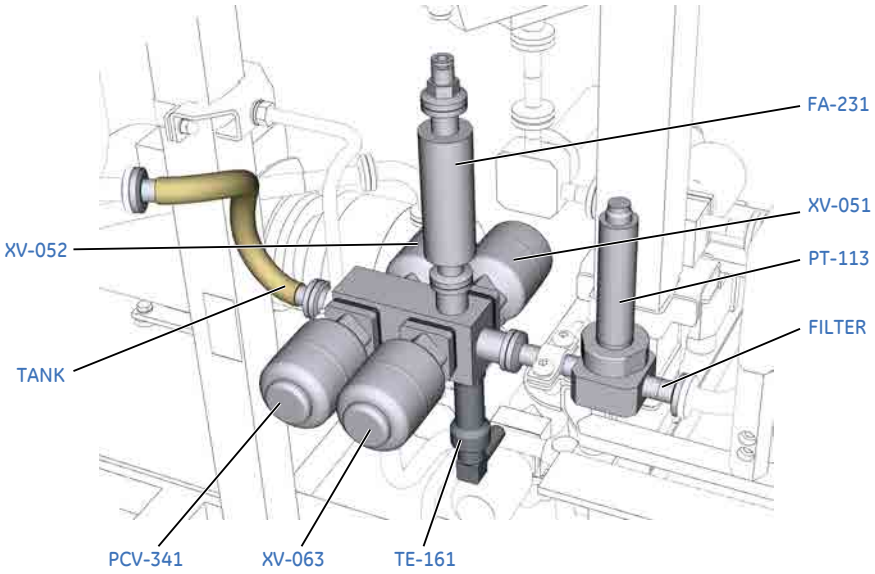
To protect the system against over pressure, two pressure sensors, **PT-111** and **PT-112** are provided for redundancy. If one should fail, an alarm will be triggered in UNICORN but the remaining functional pressure sensor will still make sure that the system is not subject to over pressure.

The feed line can be shut off with the **XV-001** valve and drained through the **XV-061** valve.

The internal diameter of the feed line is selected to keep the flow velocity of the product within a favourable range with regard to the flow range for the each system.

3.3.5 Retentate line

Illustration



Description

Particles / molecules that are too large to pass through the filter pores are retained through the filter as retentate.

Retentate is exhausted from the filter (FILTER) through the retentate connection and then guided to the retentate outlet.

Sensors for pressure, **PT-113,** and temperature, **TE-161** are located on the retentate outlet line.

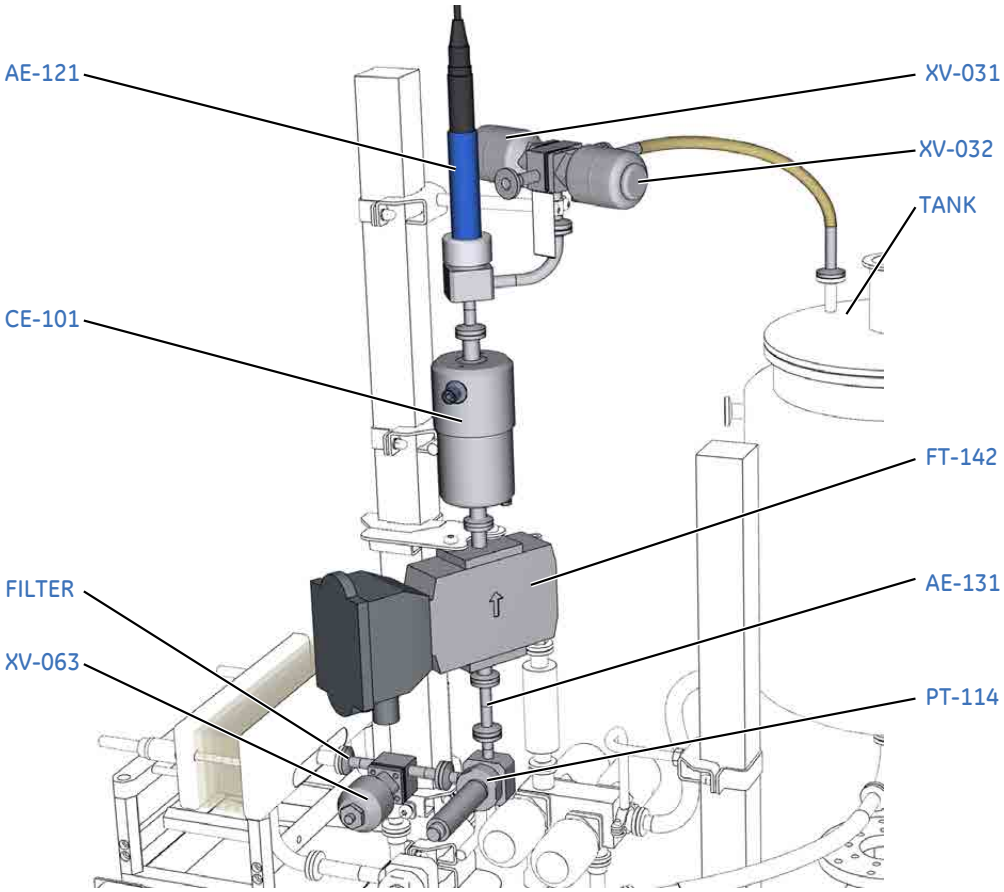
TMP is controlled by the pressure control valve **PCV-341** regulated by UNICORN.

The entire retentate line can be shut off by closing the retentate valve **XV-051**.

The retentate line is drained through the drain valve **XV-052**.

3.3.6 Permeate line

Illustration



Description

Particles / molecules that are small enough to pass through the filter pores are collected as permeate.

Permeate is exhausted from the filter through the permeate connection (FILTER) and guided to the permeate outlet through **XV-031** or back to the recirculation tank (TANK) through **XV-032**.

Sensors for pressure (**PT-114**) and flow (**FT-142**) are located on the permeate outlet line. Optionally, sensors for UV (**AE-131**), conductivity (**CE-101**) and pH (**AE-121**) can also be installed on the permeate line.

TMP is controlled by means of the pressure control valve **PCV-341** on the retentate line and the permeate pump **P-203** if installed (option).

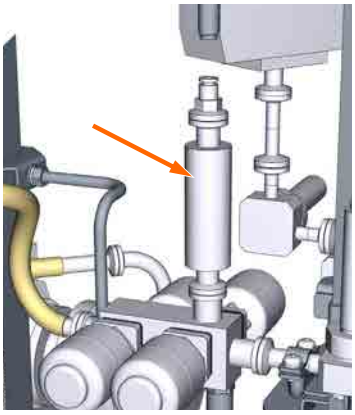
Flow control

Permeate flow can be controlled by the optional permeate pump, see *Permeate control pump P-203, on page 48*.

Recycling

The permeate recycle line allows permeate to be routed back to the feed tank, for instance when the process is set up and calibrated or during CIP.

3.3.7 Air integrity test device



Description

UniFlux 10 is provided with an air integrity test device.

The principle is to apply pressurized air or nitrogen to the filter feed inlet with the retentate outlet closed. The air or nitrogen will then escape through the wetted filter to the permeate outlet with a certain flowrate depending on the characteristics of the installed filter.

Components

The air integrity test device includes the components **XV-063**, **FA-231**, **CV-321**, **FT-143**, **PS-342**, **PY-342** and **XY-041**.

See *Section 3.8 Flowchart, on page 70* for more information regarding these components.

Testing and evaluating the results

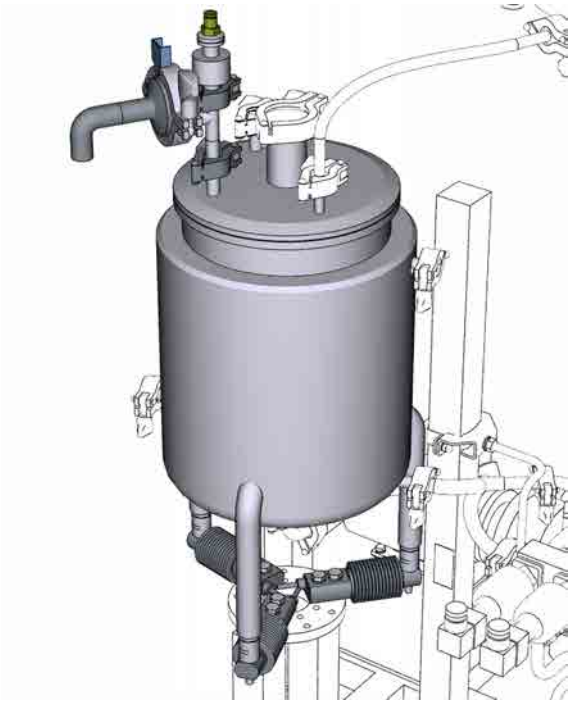
For detailed information about the air integrity test see *Air integrity test, on page 105*.

Characteristic flowrate

It is recommended to perform an air integrity test on each new filter to establish its characteristic air or nitrogen flow.

3.3.8 Feed tank

Illustration



Description

The UniFlux 10 system is provided with a built-in feed tank with 5 or 10 liter volume.

The feed tank is connected to the pump feed inlet, the retentate outlet and the permeate recycle outlet by means of flexible hoses routed so that mass measuring during processing is not affected.

The weight of the tank contents is measured with a built in balance (load cell).

The tank is provided with a jacket with connections that can be used for either cooling or heating as required.

As an option, a motor driven mixer can be provided.

3.4 Optional components

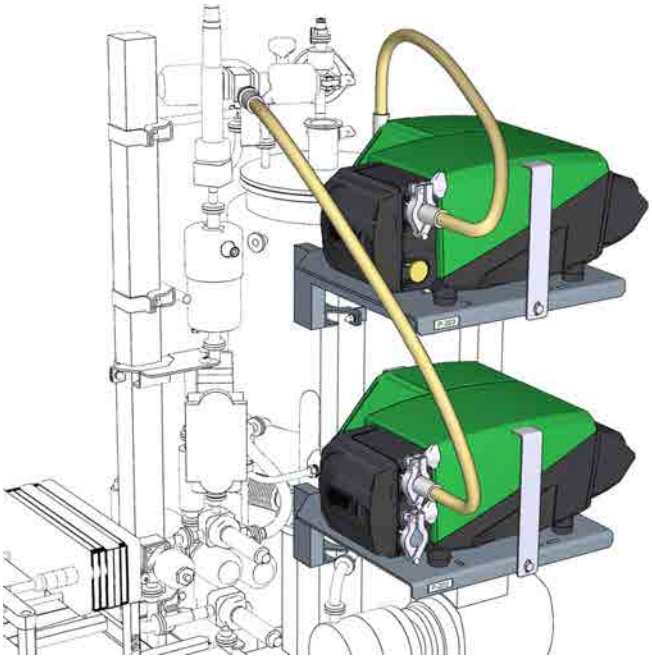
About this section

UniFlux 10 system can be ordered or upgraded with a range of optional components. This section briefly describes the optional components.

In this section

3.4.1 Peristaltic pumps

Illustration



Transfer pump P-202

The transfer pump **P-202** (option) supplies material to the feed tank for a hooked up UniFlux 10 system.

As material is separated out from the feed as permeate, the transfer pump can keep the feed tank level within set limits.

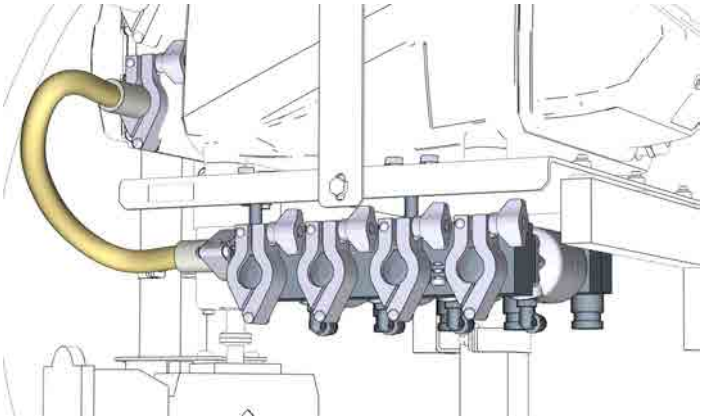
If a feed tank is not provided by Cytiva, a signal from the customer plant installations can be used to control the transfer pump through UNICORN. Refer to the SW-documentation provided with the system or contact your Cytiva representative for more information.

Permeate control pump P-203

The permeate pump **P-203** (option) controls the permeate flow rate.

3.4.2 Multiple inlets

Illustration



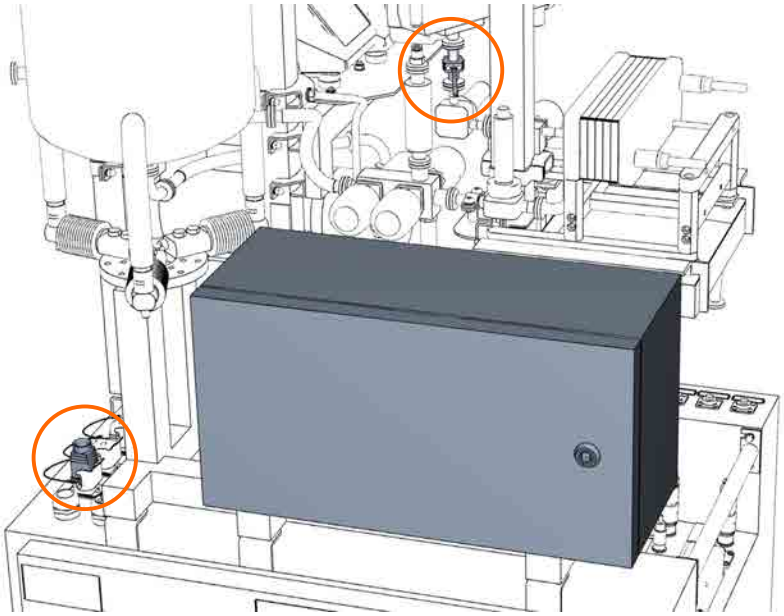
Description

The feed inlet (option) is an upgrade to a multiple inlets blocks with four valves.

Typically, the inlets can be connected to product, buffer, water and CIP.

3.4.3 UV monitor

Illustration



Description

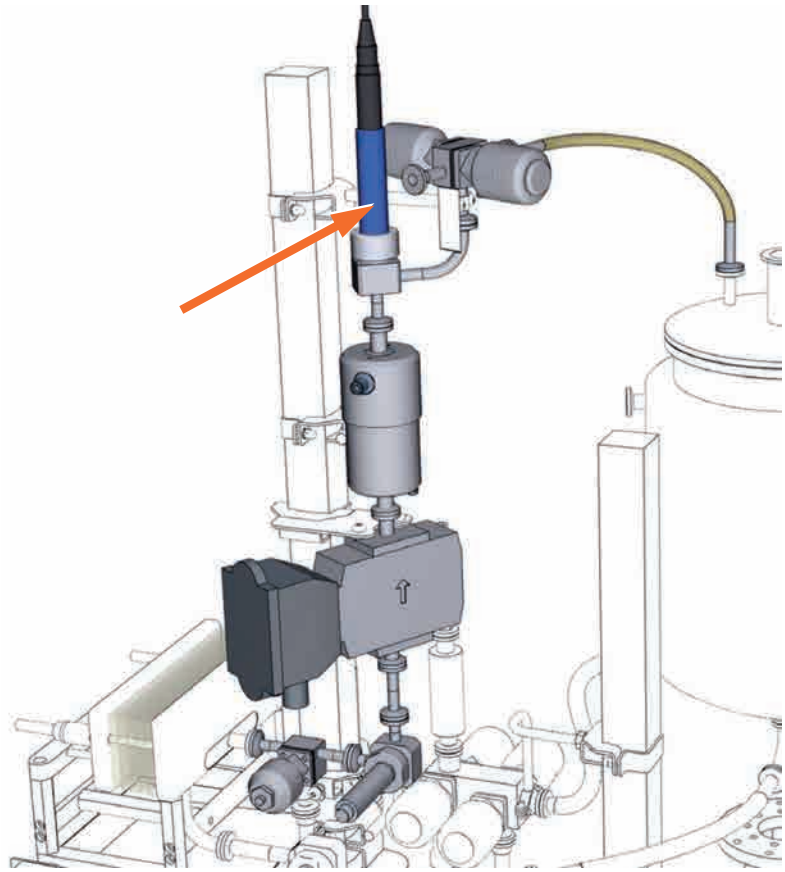
The UV monitor (optional) is installed on the permeate line and is used to detect protein leakage through the filter.

The UV light and detector operates at 280 nm.

Since UV measuring employs optics, it must be understood that the optical system must be kept clean and undamaged to provide reliable readings.

3.4.4 pH sensor

Illustration

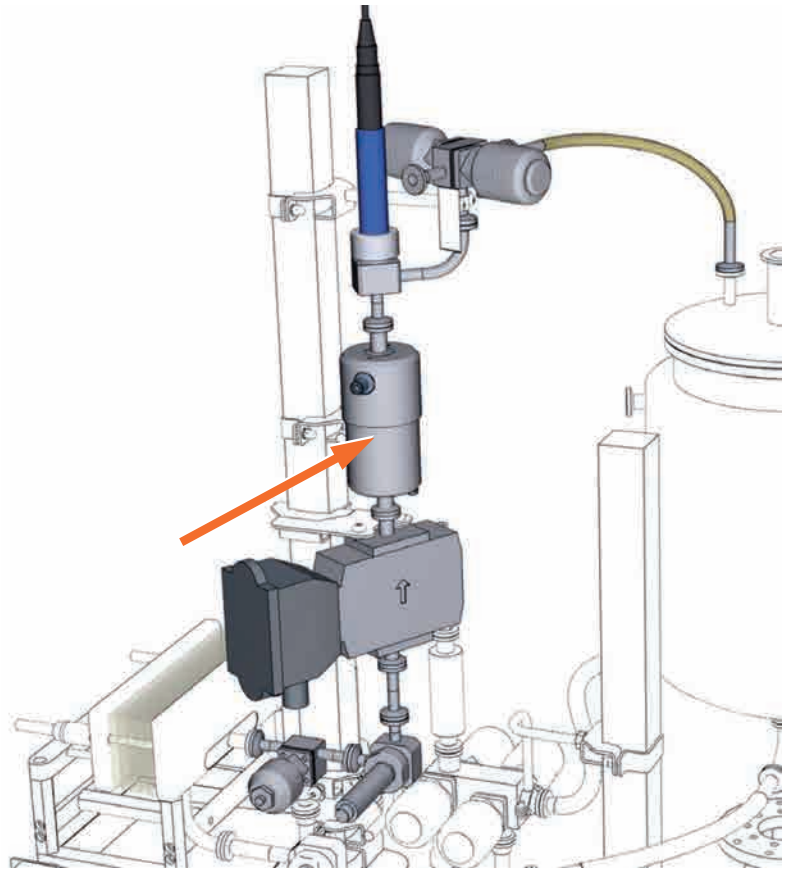


Description

The pH sensor **AE-121** (option) is installed on the permeate line and is used to measure the pH of the permeate.

3.4.5 Conductivity sensor

Illustration

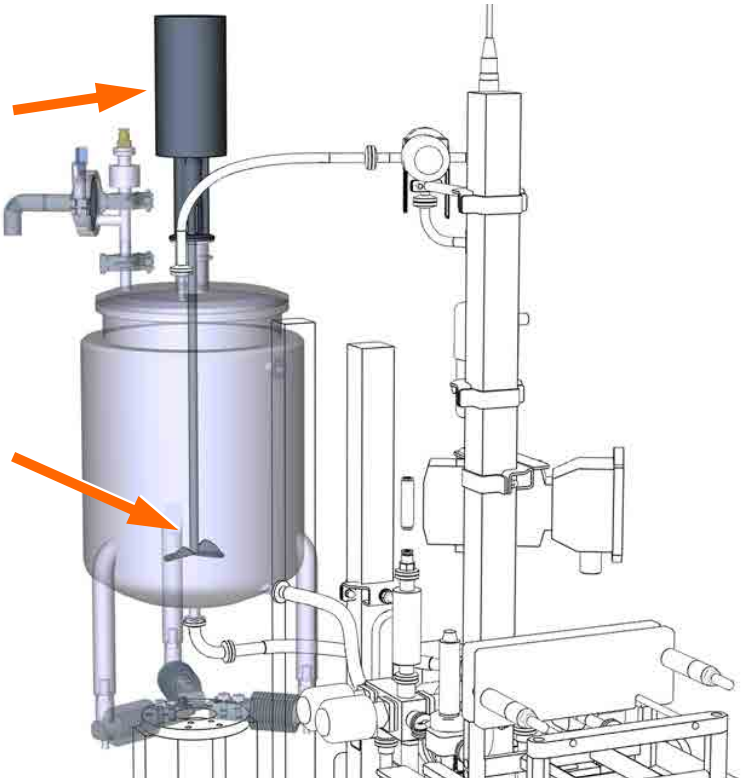


Description

The conductivity sensor **CE-101** (option) is installed on the permeate line and is used to measure the conductivity of the permeate.

3.4.6 Feed tank mixer

Illustration



Description

The mixer option allows the feed to be stirred during processing. The mixer motor is completely controlled by UNICORN.

3.5 Filter cassette configuration

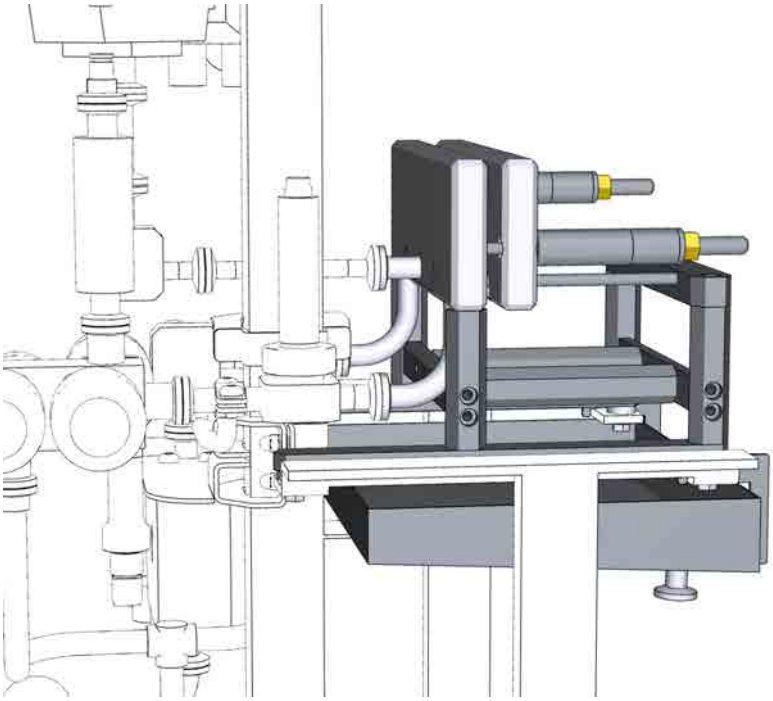
Overview

When the UniFlux 10 system is operated with filter cassettes, the cassette holder and required components of the piping system must be installed. The retentate line must be located in the lower position.

In this section

3.5.1 Filter cassette components

Illustration



3.5.2 Cassette holder

Description

The cassette holder provides a convenient way to install and use the filter cassettes for a filtering run.

The cassette holder follows industry standard cassette dimensions and accepts other cassettes of standard layout.

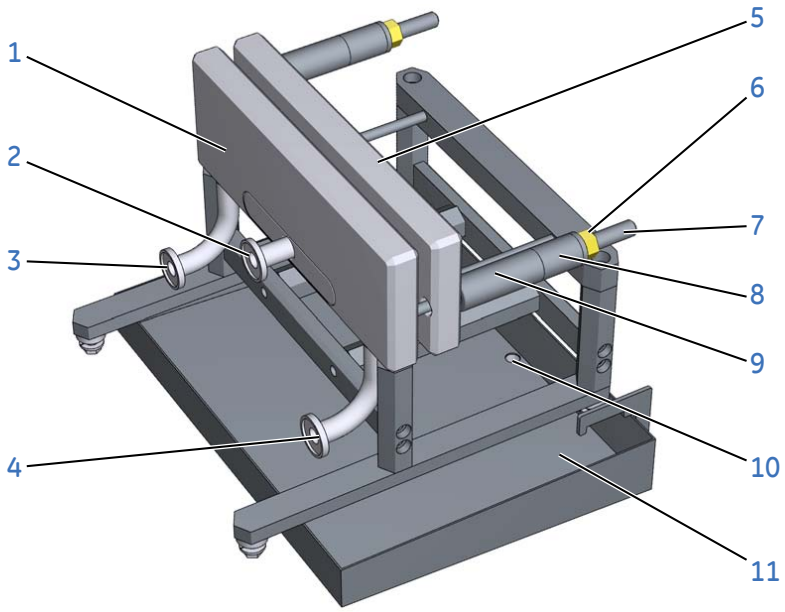
When pressure is applied, the package of installed cassettes forms a single filtering block.

From 1 to 5 filter cassettes can be installed in the cassette holder. The cassette holder is manually adjusted.

See *Section 5.1.4 Install filter cassettes, on page 104* for more information on how to set up the cassette holders for a filter run.

More information regarding the cassette holders is also available in the UniFlux 10 system Data File with article no 18117765.

Illustration



Part	Function
1	Stationary filter distributor plate
2	Permeate outlet

Part	Function
3	Feed inlet
4	Retentate outlet
5	Movable back plate
6	Filter retaining nut (2)
7	Filter retaining threaded rod (2)
8, 9	Filter retaining spacers (4)
10	Spillage plate drain outlet
11	Spillage plate

3.5.3 Filter cassettes

Illustration of membrane filter cassettes

Description

Membrane filter cassettes consist of many layers of membranes, separated with a mesh. The size of the pores determines the filtering characteristics of the cassette, that is, the cut-off size for particles that either will be retained or filtered out with the permeate.

Every second membrane gap houses either the feed-retentate flow or the permeate that passes through the membrane.

The substances in the gaps between the membranes are collected through the holes in the edge of each cassette. The large holes are connected to the feed and retentate compartments and the small holes will collect the permeate.

When more than one cassette is used for a filtering run, the holes of the cassettes align with each other to form common sealed channels.

Available types of cassettes

Refer to your Cytiva representative for information regarding different cassettes that can be used with the UniFlux 10 filtration system.

3.6 Hollow fiber (HF) configuration

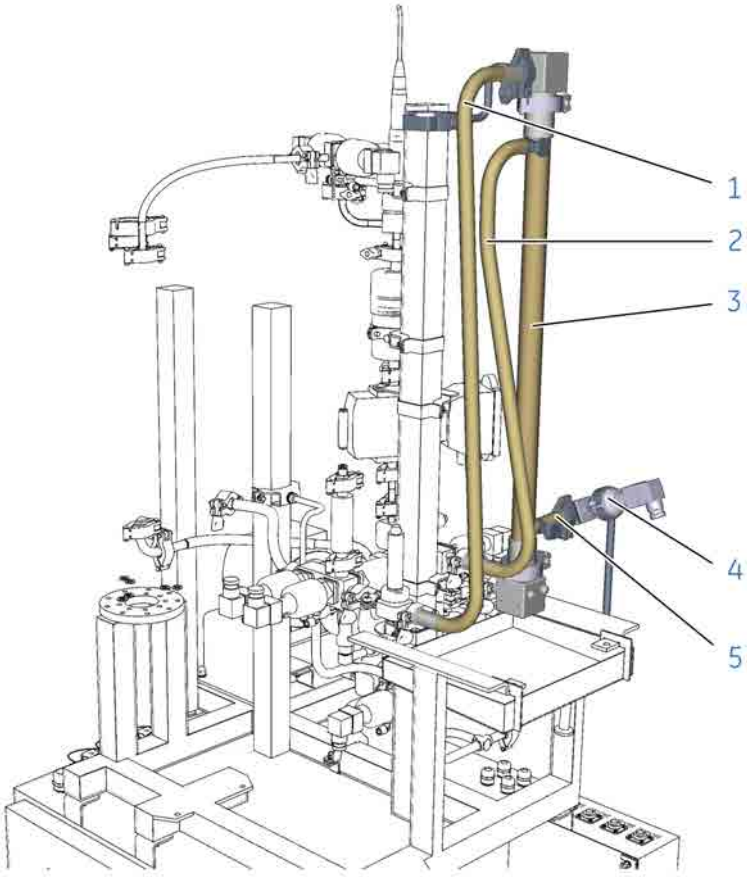
Overview

When a UniFlux 10 system is operated with hollow fiber cartridges, required components of the piping system must be installed.

In this section

3.6.1 UniFlux 10 HF configuration

Illustration



Part	Function
1	Retentate hose
2	Permeate hose
3	Hollow fiber cartridge, size 5 or 6 is accepted.
4	HF cartridge drain valve (**XV-064**)
5	HF cartridge drain hose

3.6.2 HF cartridges

Illustration of HF cartridge

Description of HF cartridges

Hollow fiber (HF) cartridges contain numerous very thin hollow fibers glued together in the ends. Each fiber is open in the ends and the feed flows inside the fibers and out the other end.

The size of the pores determines the filtering characteristics of the cartridge, that is, the cut-off size for particles that either will be retained or filtered out with the permeate.

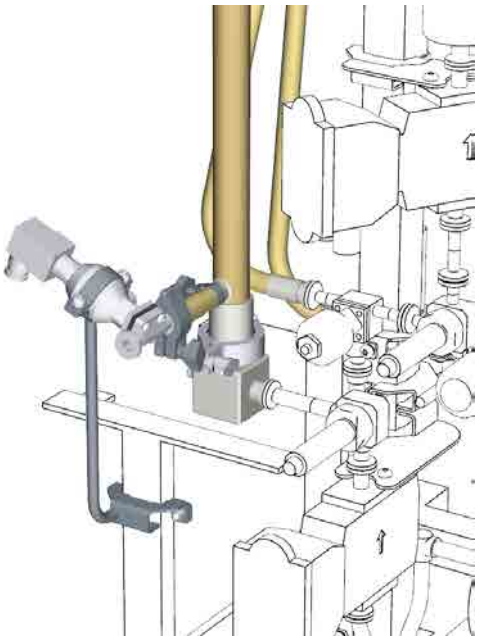
The permeate flows outside the fibers and is collected through one of the side connectors.

Available types of HF cartridges

UniFlux 10 system is designed to accept Hollow fiber cartridges of different sizes. These cartridges are described in the Hollow fiber cartridges for membrane separations Operating Handbook, Cytiva article no 18116530. and in the Hollow fiber cartridges and systems for membrane separations Selection Handbook, Cytiva article no. 18116529.

For available hollow fiber cartridge models and sizes, see *Section 8.1 Specifications, on page 146*.

HF cartridge draining



Hollow fibre cartridges are provided with two connections to the permeate compartment, one in each end.

When mounted vertically, which is the case for all UniFlux 10 systems, the bottom connection serves as drain for the permeate. This allows for more complete recovery of the permeate.

3.7 Meters and sensors

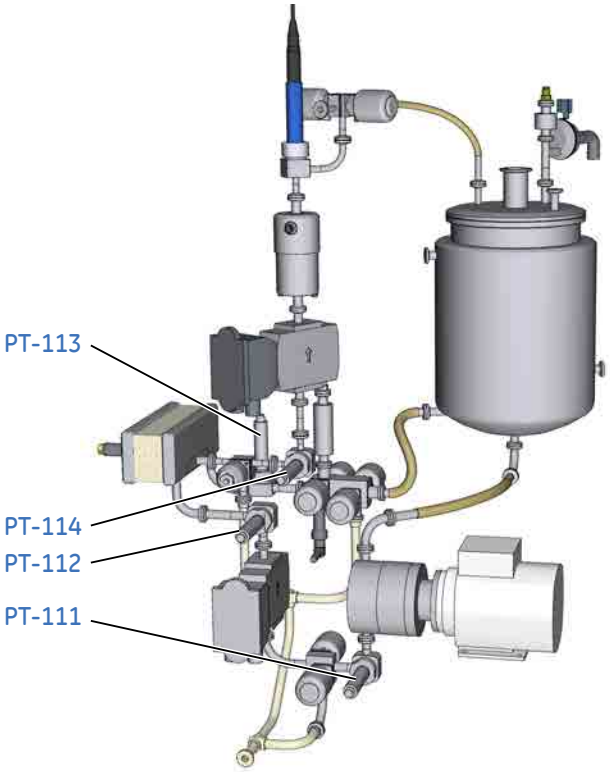
About this section

This section describes the meters and sensors that are available as basic configuration and optional components for UniFlux 10 system.

In this section

3.7.1 Pressure

Pressure sensors



Description

Four pressure sensors are provided. The pressure sensors **PT-111** and **PT-112** provide pressure data for the feed pump outlet and filter feed inlet pressure, **PT-113** measures retentate pressure and **PT-114** measures permeate pressure.

The pressure drop (delta P) is calculated in UNICORN by subtracting the retentate pressure from the feed pressure.

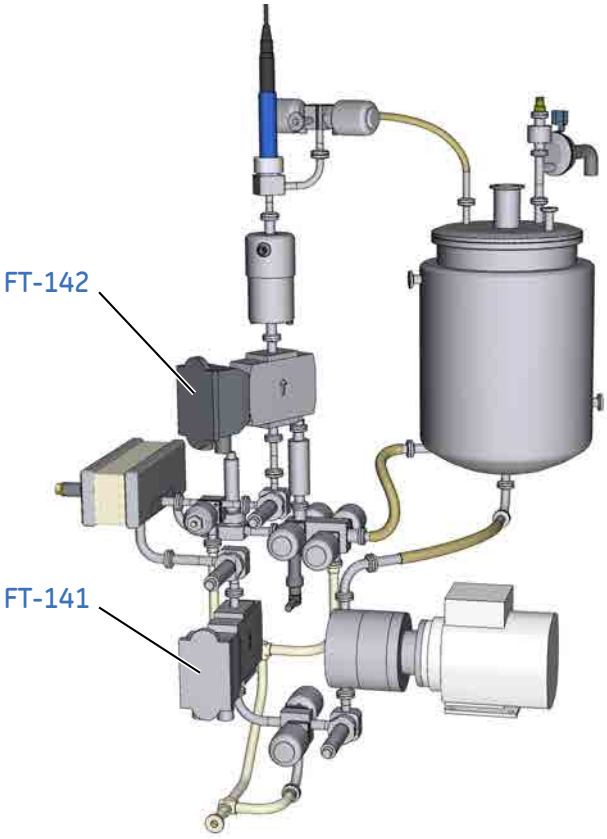
The transmembrane pressure (TMP) is calculated in UNICORN by subtracting the permeate pressure from the average of the feed and retentate pressure.

The pump outlet pressure sensors also provide feed pump and system over pressure protection.

More information on the pressure sensors is provided in the system documentation package.

3.7.2 Flow

Flow sensors



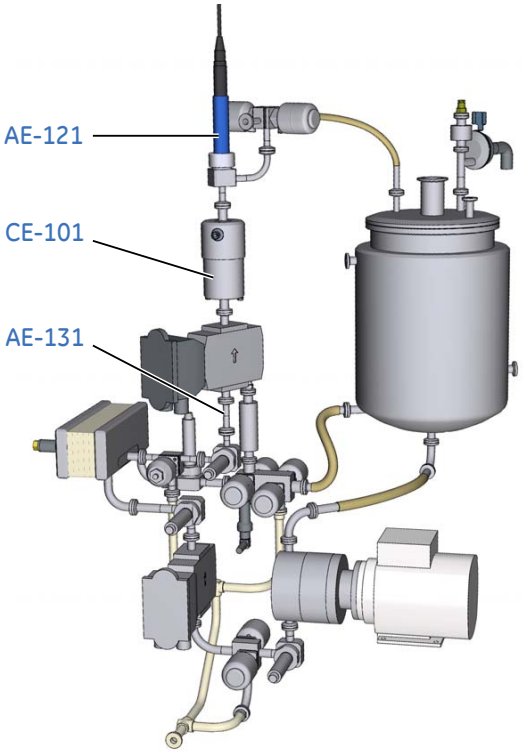
Description

FT-141 measures the feed flow and **FT-142** measures the permeate flow.

The retentate flow is calculated by UNICORN by subtracting the permeate flow from the feed flow.

3.7.3 pH, conductivity and UV

pH, Cond and UV



Description

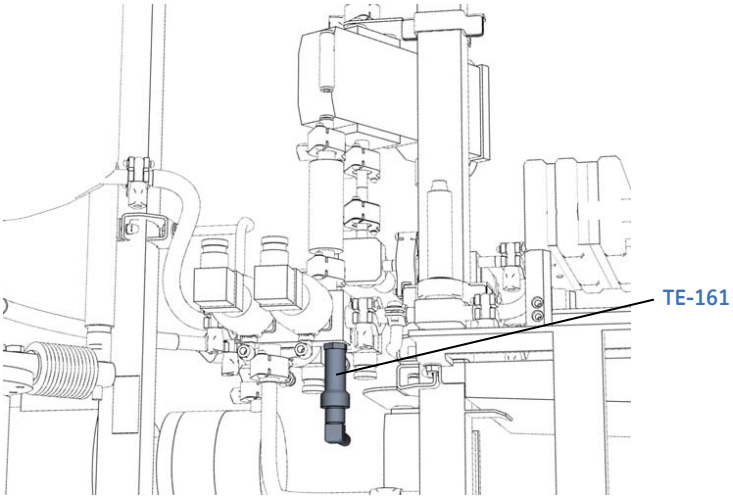
The optional pH sensor **AE-121** measures permeate pH. Calibration prior to each filtration run is recommended. pH calibration is described in *Section 6.5 pH calibration, on page 129*.

The optional conductivity sensor **CE-101** measures permeate conductivity. Calibration at regular intervals is recommended.

The optional UV sensor **AE-131** measures the UV absorption in the permeate line.

3.7.4 Temperature

Temperature

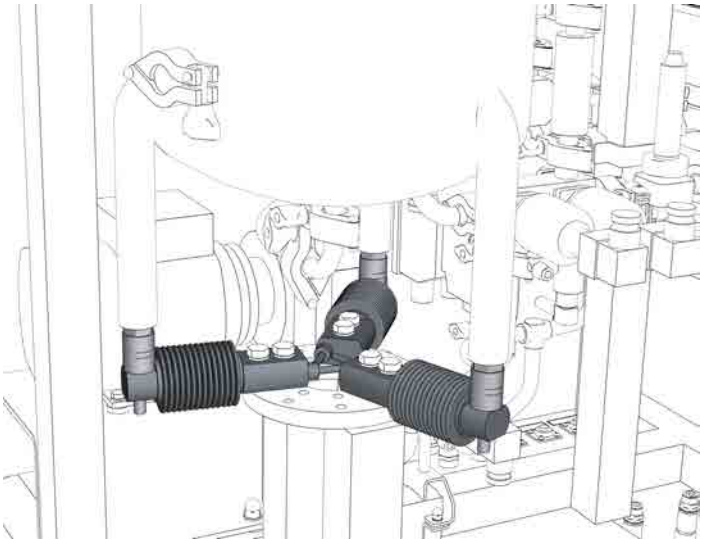


Description

Temperature is measured in the retentate line with the sensor **TE-161**.

3.7.5 Tank mass balance

Illustration



Description

The UniFlux 10 system has a built-in feed tank that is provided with a balance for mass measuring.

Prior to each filter run the balance should reset to zero to ensure reliable output. The balance should be calibrated each time the system is moved or its balance is disturbed. Calibration of the balance is described in *Section 5.2.1 Preparing mass measuring, on page 109*.

Note: *It is important that the balance is not loaded with any objects or disturbed in any similar way during the calibration procedure and filter run.*

NOTICE

If the UniFlux 10 system is moved with load cells unlocked, the tank must be empty and only small gentle movements are allowed.

If the tank shall be transported or put into storage, the load cells should always be locked.

3.7.6 More information

Sensor signals

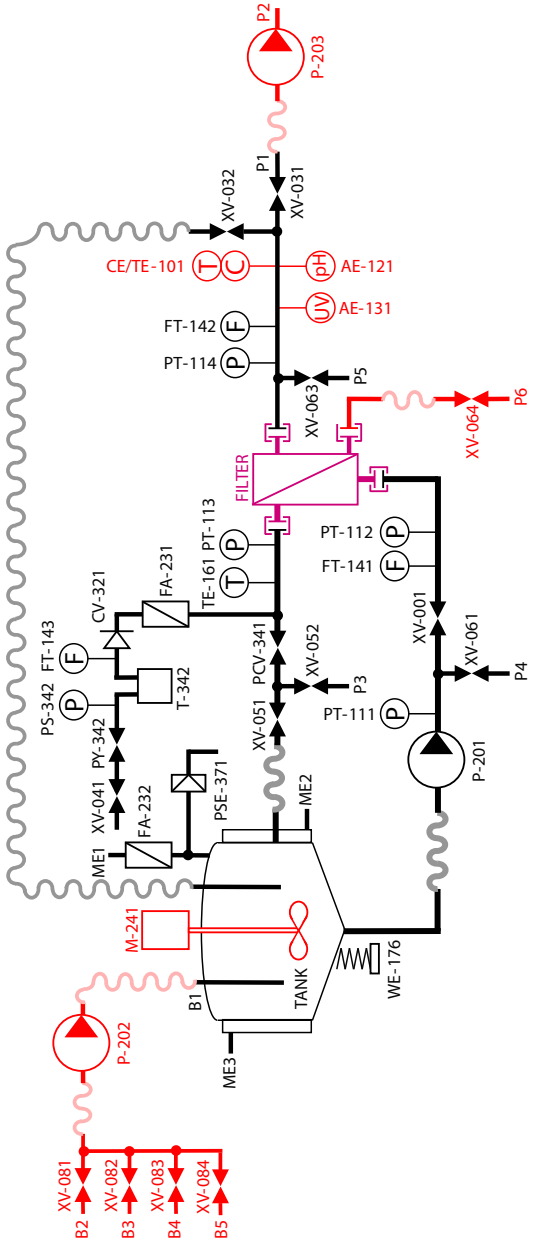
Sensor signals are described in detail in *Section 8.2 Signals, on page 150*.

Location and tagging of sensors

Location and tagging of each sensor is described in *Section 3.8 Flowchart, on page 70*.

3.8 Flowchart

UniFlux 10: Flow diagram



Component description

Tag / System	Function	Note	More information
AE-121	Permeate pH sensor	Option	*Section 3.7.3 pH, conductivity and UV, on page 66*
AE-131	Permeate UV monitor	Option	
B1	Tank feed inlet		*Section 3.3.8 Feed tank, on page 46*
B2, B3, B4	Quadruple inlets 1, 2 and 3	Part of quadruple inlet option	*Section 3.4.2 Multiple inlets, on page 49*
B5	Quadruple inlet 4		
CE-101	Permeate conductivity sensor with an integrated temperature sensor (**TE-101**)	Option	*Section 3.7.3 pH, conductivity and UV, on page 66*
CV-321	Filter integrity test check valve		*Section 3.3.7 Air integrity test device, on page 45*
FA-231	Filter integrity test sanitary filter		
FA-232	Tank vent sanitary filter		*Section 3.3.8 Feed tank, on page 46*
FILTER	Cross flow filter. Can be either hollow fibre (HF) cartridge or filter cassette.	Not included in system, provided by customer or sold separately.	*Section 3.5 Filter cassette configuration, on page 54*
FT-141	Feed flow meter		*Section 3.7.2 Flow, on page 65*
FT-142	Permeate flow meter		*Section 3.7.2 Flow, on page 65*
FT-143	Filter integrity test flow meter		*Section 3.3.7 Air integrity test device, on page 45*
M-241	Feed tank agitator motor	Option	*Section 3.3.8 Feed tank, on page 46*
ME1	Tank vent		
ME2	Tank jacket connection		*Section 3.3.8 Feed tank, on page 46*
ME3	Tank jacket connection		*Section 3.3.8 Feed tank, on page 46*
P1	Permeate outlet		*Section 3.3.6 Permeate line, on page 43*

Tag / System	Function	Note	More information
P2	Permeate pump outlet	Part of permeate pump option	*Permeate control pump P-203, on page 48*
P3	Retentate drain		*Section 3.3.3 Connections and drains, on page 39*
P4	Feed drain / CIP outlet		*Section 3.3.3 Connections and drains, on page 39*
P5	Permeate drain		
P6	HF filter cartridge drain	HF configuration only	*Section 3.6 Hollow fiber (HF) configuration, on page 59* and *Section 3.3.3 Connections and drains, on page 39*
P-201	Feed pump		*Section 3.3.4 Feed pump and feed line, on page 41*
P-202	Feed transfer pump	Option	*Section 3.3.4 Feed pump and feed line, on page 41*
P-203	Transfer and permeate pump	Option	*Permeate control pump P-203, on page 48*
PCV-341	Retentate pressure control		*Section 3.3.5 Retentate line, on page 42*
PS-342	Filter integrity test pressure sensor		*Section 3.3.7 Air integrity test device, on page 45*
PY-342	Filter integrity test pressure regulator		
PSE-371	Feed tank pressure relief safety valve		*Section 3.3.8 Feed tank, on page 46*
PT-111	Feed pump outlet pressure meter		*Section 3.7.1 Pressure, on page 64*
PT-112	Feed pump outlet pressure meter		
PT-113	Retentate pressure meter		
PT-114	Permeate pressure meter		
TANK	Feed tank		*Section 3.3.8 Feed tank, on page 46*
T-342	Pressure regulator pulse damper		*Section 3.3.7 Air integrity test device, on page 45*

Tag / System	Function	Note	More information
TE-101	Permeate temperature meter	Option. Included in cond CE-101.	*Section 3.7.4 Temperature, on page 67*
WE-176	Tank load cell		*Section 3.3.8 Feed tank, on page 46*
XV-001	Pump feed valve		*Section 3.3.4 Feed pump and feed line, on page 41*
XV-031	Permeate outlet valve		*Section 3.3.6 Permeate line, on page 43*
XV-032	Permeate recycle valve		
XV-051	Retentate outlet valve		*Section 3.3.5 Retentate line, on page 42*
XV-052	Retentate drain valve		
XV-061	Feed drain		*Section 3.3.3 Connections and drains, on page 39*
XV-062	Filter integrity test valve		*Section 3.3.7 Air integrity test device, on page 45*
XV-063	Permeate drain valve		*Section 3.3.3 Connections and drains, on page 39*
XV-064	HF filter cartridge drain valve	HF configuration only	*Section 3.3.3 Connections and drains, on page 39*
XV-081, 082, 083, 084	Quadruple inlet 1, 2, 3 and 4 valves	Part of quadruple inlet option	*Section 3.4.2 Multiple inlets, on page 49*
XY-342	Filter integrity test valve		*Section 3.3.7 Air integrity test device, on page 45*

3.9 UNICORN control system

Introduction

The UniFlux 10 system is controlled by UNICORN software.

UNICORN can save established processes as methods. Methods include the instructions necessary for process operation and documentation.

UNICORN includes a comprehensive system of user access levels to be set, limiting the operations a given user may perform on UniFlux 10 system. To operate the system in a safe way, you should limit access to the system to those qualified and trained in its operation.

The UNICORN software wizards and the UNICORN *manual package* provide complete instructions for programming and for using the software for process control.

System operators are responsible for designing methods which conform to standard operating procedures and Good Manufacturing Practice procedures.

UNICORN is technically compatible with all relevant sections of FDA 21 CFR Part 11.

A part 11-system assessment checklist is available on request through the local Cytiva representative.

Prerequisite knowledge

A working knowledge of UNICORN is required to operate the UniFlux 10 system safely.

Information on how to use UNICORN can be obtained from the UNICORN User Manuals and available tutorials. This manual does not cover how to use UNICORN.

Contact your local Cytiva representative for advice if required.

System networks

UNICORN can be installed on a stand-alone computer to control one to four locally connected systems. However, the computer can only show one system at a time. Multiple computers can view the output data from one system. UNICORN can also be installed on a network.

Software modules

The UNICORN control software consists of four modules:

Module	Function
UNICORN Manager/ Administration (UNICORN version dependent)	File handling and administration tasks; for example, definition of systems and managing user profiles.
Method Editor	Method creation and editing for preprogrammed control of UniFlux 10 system.
System Control	Process online control and monitoring using pre-defined methods or manual control.
Evaluation	Evaluation and presentation of stored results.

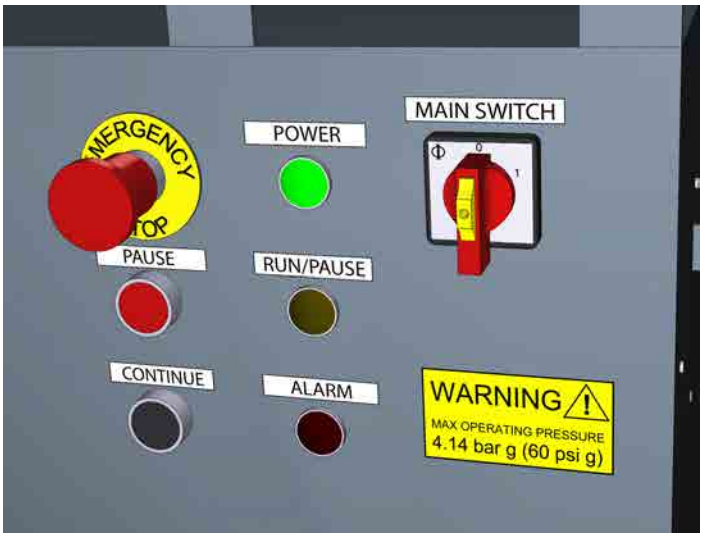
Note: *The modules are active when the program is operating and are not closed when minimized. A minimized System Control unit may control a process.*

Workflow

The workflow for using UNICORN for automatic system control includes these general steps:

Step	Action
1	Program a UniFlux 10 system method run using the UNICORN software. It is possible to use an existing method or modify an existing method to meet your run objectives.
2	Start the run using the method you created.
3	Monitor the run's progress using the ***System Control*** module. All the data about your run is displayed in the ***System Control*** module. You have a choice of four different panes that can be opened one at a time or all at once, in separate parts of the window.
4	After completing the run, you can display the data in a detailed report using extensive tools provided by the UNICORN ***Evaluation*** module.

Cabinet controls and indicators



Note: *The* **EMERGENCY STOP** *and* **MAIN SWITCH** *controls are not part of UNICORN and are described in* *Section 2.3 Emergency procedures, on page 25**.*

Label	Type	Color	Function
PAUSE	Button	Red	Sets UNICORN in ***PAUSE*** mode (is equal to the ***PAUSE*** button in the UNICORN computer user interface)
CONTINUE	Button	Black	Sets UNICORN in ***RUN*** mode (is equal to the ***CONTINUE*** button in the UNICORN computer user interface)
POWER	Indicator	Green	**Power is on**: *Flashing*: UNICORN starting up. *Steady*: UNICORN ready.
RUN/PAUSE	Indicator	Yellow	**UNICORN method is active**: *Flashing*: UNICORN in state pause. *Steady*: UNICORN in state run.
ALARM	Indicator	Red	**System alarm**: Check UNICORN for detailed information.

Warnings

Warnings are generated to warn operating personnel that process parameters have exceeded preset high and/or low limits, and that the process method continues.

Alarm signals

If equipment is connected that has lower limits than the system, the alarm levels must be set accordingly.

If an analog or digital signal passes the predetermined alarm level, several things happen at once:

- An audible alarm is sounded (according to user preference settings).
- The system is set to ***Pause*** mode.
- The valves and other components on the system are set to their default positions.

Note: *If an alarm is displayed that is not explained in the Software documentation, please contact your local Cytiva representative.*

Alarm test

The alarm buzzer can be tested from the control system using the buzzer test function ***Alarms*** →***BuzzerTest***.

To test a specific instrument alarm it is possible to lower the alarm limit for the instrument below the current process value.

Alarm reset

The alarm is reset through the control system by acknowledging the alarm message. The process can be started again using the ***Continue*** function in UNICORN, if the situation has been rectified.

More information

All required manuals are available from the UNICORN user interface. Select ***Help*** →***Manuals*** from the UNICORN top menu. The UNICORN user reference manual for BioProcess™ is especially suited for usage with BioProcess systems.

Information about how to create a method for the UniFlux 10 in the UNICORN ***Method Editor*** is presented in the end of this Operating Instructions.

4 Installation

About this chapter

This chapter provides required information to enable users and service personnel to unpack, install, move and transport UniFlux 10 system.

In this chapter

Precautions

WARNING

Before attempting to perform any of the procedures described in this chapter, you must read and understand all contents of the corresponding section(s) in the Safety instructions chapter as listed below:

- *General precautions on page 12*
- *Personal protection on page 14*
- *Installing and moving on page 15*
- *Power supply, on page 18*

4.1 Site requirements

Space and floor load

For space and floor requirement, see external dimensions and weights in *Section 8.1 Specifications, on page 146*.

- Make sure that the floor can handle the UniFlux 10 system weight at fully loaded conditions. Please observe that for the weight to be equally distributed over all wheels, the floor must be level and without irregularities.
- In order to allow convenient working conditions for the operator, sufficient space should be provided at all sides of the combined UniFlux System and UniFlux Tank when installed at the intended production location.

Environmental requirements

- The UniFlux 10 system is intended for indoor use only.
- The room must have forced ventilation.
- Requirement regarding ambient air temperature is specified in the General Specification included in the system documentation package.

The following conditions should be avoided.

- Sources of heat, such as direct sunlight
- Strong magnetic or electric fields
- Vibrations
- Corrosive gas
- Dust
- Temperatures outside recommended operating ranges. For ambient environment temperature range, see *Section 8.1 Specifications, on page 146*.

Electrical power

See *Section 4.5 Power supply, on page 91* and *Section 8.1 Specifications, on page 146* for power, voltage and phase requirements.

Compressed air

- Dry and particle free air for system supply.
- See *Section 8.1 Specifications, on page 146* regarding capacity requirements.
- See *Section 4.4.4 Connect compressed air supply, on page 88* regarding connections to the instrument.

Media supply

Supply must be arranged so that piping dimensions, piping lengths, valves and height differences do not obstruct processing.

See *Section 8.1 Specifications, on page 146* regarding requirements on media supply and delivery.

Battery limits

The term "battery limits" represents all interface points between the UniFlux 10 and the customer process plant.

System battery limits require connections, not included in the Cytiva delivery.

See *Section 3.8 Flowchart, on page 70* and *Section 8.3 Battery limits, on page 151* for description of required connections.

4.2 Transport

Introduction

This section outlines important information that must be considered when transporting UniFlux 10 system.

Transport in crate

Use a pallet jack or forklift with a minimum capacity to match the empty weight of the system plus the transport crate. See *Section 8.1 Specifications, on page 146* regarding system weight.

Note: *Make sure that intended openings and apertures are large enough to allow passage of the box when lifted from the floor for transport.*

For minimum door aperture size, refer to *Section 8.1 Specifications, on page 146*.

Moving when unpacked

WARNING

Heavy object. Because of the significant weight of the product, great care must be taken not to cause squeezing or crushing injuries during movement. At least two, but preferably three or more, people are recommended when moving the unit.

UniFlux 10 system can be rolled by hand on hard and level surfaces with wheel brakes released.

If the floor quality does no allow rolling the system on its own wheels, it can be moved with a pallet jack or forklift.

For minimum door aperture size, see *Section 8.1 Specifications, on page 146*.

4.3 Unpacking

Precautions

WARNING

Heavy object. Because of the significant weight of the product, great care must be taken not to cause squeezing or crushing injuries during movement. At least two, but preferably three or more, people are recommended when moving the unit.

WARNING

Move transport crates. Make sure that the lifting equipment has the capacity to safely lift the crate weight. Make sure that the crate is properly balanced so that it will not accidentally tip when moved.

CAUTION

To prevent bacterial growth, the product may be partly filled with denatured alcohol (18% C_2H_5OH (ethanol), 2% C_3H_7OH (isopropanol) and 80% H_2O (water)) at delivery.

The denatured alcohol mixture can be hazardous to humans if consumed.

Flush out the denatured alcohol before assembling, testing or integrating the product into the intended process context.

Tools required

- Suitable lifting device, fork lift or similar. See *Section 8.1 Specifications, on page 146* for dimensions and weight to be handled.
- 13 mm wrench (or ratchet with 13 mm socket).
- Electrical screwdriver with no. 2 bit.
- Knife.
- Lever (enclosed in crate).

Note: *Refer to the unpacking instructions for UniFlux Systems (art. no 29065657) for detailed unpacking instructions.*

Visual inspection

Check the following:

- Check that all equipment is enclosed in the crate according to the packing list.
- Check that the equipment for any apparent damage and document carefully if found.

If any equipment is missing or damage is found, contact your Cytiva representative immediately.

General unpacking instructions

Note: *Refer to the unpacking instructions attached to the outside of the crate when unpacking the crate. In absence of the unpacking instructions, follow the general unpacking instructions below.*

Step	Action
1	Remove the front, side and back panels by loosening the bolts.
2	Remove the ramp, accessories and documentation package.
3	Attach the ramp on the cabinet side of the crate.
4	Remove the brackets on the cabinet side.
5	Carefully roll the system out of the crate.

WARNING

Heavy object. The ramp included in the transport crate is not reinforced in the center. Do not use a pallet lifter or forklift on the ramp.

WARNING

Heavy object. When rolling the system down the ramp take great care to avoid the wheels slipping off the edge of the ramp.

4.4 UniFlux 10 Setup

Precautions

CAUTION

To prevent bacterial growth, the product may be partly filled with denatured alcohol (18% C_2H_5OH (ethanol), 2% C_3H_7OH (isopropanol) and 80% H_2O (water)) at delivery.

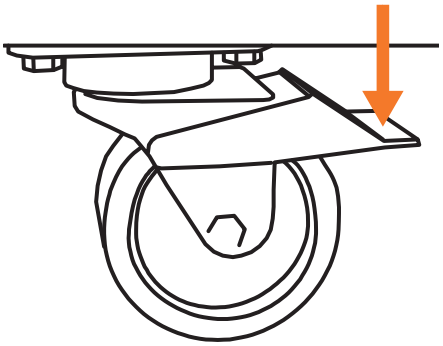
The denatured alcohol mixture can be hazardous to humans if consumed.

Flush out the denatured alcohol before assembling, testing or integrating the product into the intended process context.

In this section

4.4.1 Lock the wheels

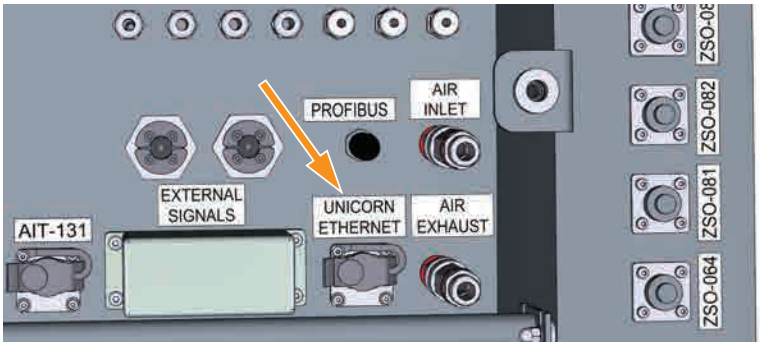
After positioning the system at its designated location, lock the wheels as illustrated below.



4.4.2 Stand-alone computer

Connect a stand-alone computer to the UniFlux 10 system

Connect a stand-alone computer with UNICORN to UniFlux 10 by plugging in an Ethernet cable to the **UNICORN ETHERNET** connector illustrated below.



Note: *When installing a stand-alone computer ensure that it is installed with appropriate precautions for the intended environment that might expose the computer to liquids and moisture.*

4.4.3 Setup of control system and network

Introduction

This section describes the steps that need to be performed to set up the UNICORN control system and network connections.

Install UNICORN

Make sure that the UniFlux 10 control software UNICORN is installed on your computer. A system must be defined, and the UniFlux 10 configuration or strategy must be installed. Refer to *UNICORN Administration and Technical manual* for more information.

Set up Controller Unit 960 (CU-960)

The **CU-960** is part of the UniFlux 10 system at the delivery. It is a control unit that communicates with UNICORN via Ethernet connection.

To use the Ethernet connection, the **CU-960** must be set up like a network device with IP address, default gateway and subnet mask address.

Refer to the control unit manual for more information.

4.4.4 Connect compressed air supply

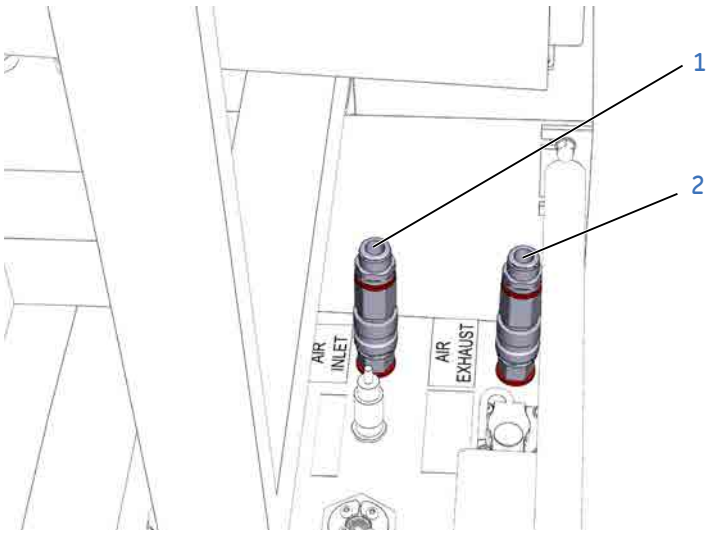
Introduction

This section describes how to connect the compressed air supply.

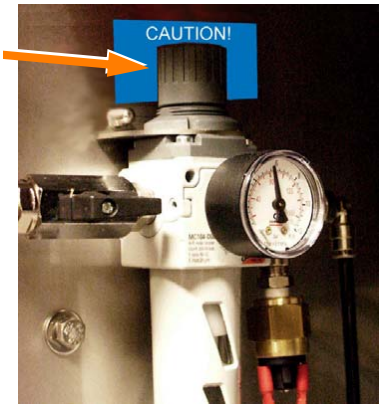
For requirements on air supply, see *Section 4.1 Site requirements, on page 79*.

Connect compressed air supply to UniFlux 10 10

Step	Action
1	Connect compressed air to the **AIR INLET** on the electrical cabinet.



Part	Function
1	Air exhaust
2	Air inlet

Step	Action
2	Make sure that the supply pressure to the cabinet is between 5.5 and 7 bar g. The manometer is set to 6 bar g at the factory and shall not be changed. 

4.4.5 Filter setup, feed pump and CFF filter protection

Filter setup

If the system is configured for the intended filter type (HF or cassette), no need for further installations are required at arrival to the process site or between processing.

If the system needs to be reconfigured from HF- to cassette setup or the other way round, see *Section 6.7 Change filter type, on page 133*.

Feed pump and CFF filter protection

To protect the system from feed containing particles that may clogg the CFF-filter or damage the pump, use upstream normal flow filtering as described in *Section 5.1.1 Sample handling, on page 98*.

NOTICE

Do not use an inline filter screen on the piping between the recirculation tank and the feed pump. If such a filter screen becomes clogged, the flow to the feed pump will be restricted and the pump may be damaged because of cavitation.

4.5 Power supply

Introduction

This section gives an overview of the power requirements for UniFlux 10 system. This includes a description of the various circuit breakers.

Power requirements

The power supply requirements are specified in *Section 8.1 Specifications, on page 146*.

WARNING

Protective ground. The product must always be connected to a grounded power outlet.

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 may result in personal injury and/or equipment damage.

Installation

Connect the system power cord to a fixed power supply by means of a permanent connection which can be detached only by the use of a tool.

WARNING

All electrical installations must be performed by authorized personnel only.

UPS power supply

Cytiva does not offer a UPS (Uninterrupted Power Supply) as an accessory. However, the system is prepared for UPS operation.

For UPS operation, a UPS should be connected to the main power supply of UniFlux 10.

CAUTION

Connection of an external Uninterruptible Power Supply (UPS) (uninterrupted power supply) for system operation shall only be performed by authorized personnel to avoid mismatching or connection errors. Contact your local Cytiva representative for more information.

Grounding and protective earth

- The protective earth wire must be connected to system ground.
- Ground impedance must conform to the requirements of national and local industrial safety regulations and/or electrical codes.
- If the leak current exceeds 10 mA, a high leakage current earth connection must be provided and confirmed before connecting power supply.

  See *Electric power, on page 149* or the system documentation package for information regarding the leakage current for your system.
- The integrity of all ground connections must be periodically checked.

Isolation switch

An isolation switch must be present in the fixed power supply.

Breaking the power supply to the UniFlux 10 system by using this isolation switch must be equivalent to disconnecting the power cord for a non-fixed connected instrument.

Power supply cable

The mains power supply cable is shielded ÖLFLEX™ of type: 150CY Quattro (3G x 2.5 mm^2, G = with PE conductor, X = without PE conductor)

If the cable needs to be replaced due to damage, the same type of cable or equivalent must be used.

WARNING

Only personnel authorized by Cytiva may perform service, installation, and maintenance of components inside the cabinet.

Main power supply wire colors and tags

The power cord wires are color coded as shown in the table below. They must be connected to the corresponding terminals in the fixed power supply or to a connector compatible with IEC 60309-2.

Function	EU (CE marking)	Terminal label
Live (Phase)	1 (Black or brown)	L
Neutral	2 (Black or blue)	N
Protective ground (earth)	Yellow/green	PE = GND 

Protective earth wire cross section area

All protective earth wiring must have a cross section area equal to or more than the specification in this table:

Leak current	PE conductor minimum area
> 10 mA	10 mm^2 copper or 16 mm^2 aluminium
≤ 10 mA	Equal to or larger than the L and N-wire

Ground fault breaker

UniFlux 10 system is not equipped with a general Ground Fault Circuit Breaker and it is not an option that is available from Cytiva.

However, if ground fault protection for the system is desired, check the following:

- A Ground Fault Circuit Interrupter may be installed.
- The system may be connected to an outlet that is protected by a permanently installed Ground Fault Circuit Breaker.

The tripping current for such an interrupter must be higher than the leak current as found in the *test protocol* in the *system documentation kit*.

Built-in circuit breakers

The mains power supply to the UniFlux 10 system and the pumps are equipped with circuit breakers inside the electrical cabinet. Refer to the System Documentation for the specific types used in your system.

More information

Wiring diagrams for the system, voltage, power, fuse requirements and the tripping current for the fixed power supply ground fault protector can be found in the system documentation package.

5 Operation

About this chapter

This chapter provides the information required to operate the UniFlux 10 system in a safe way.

In this chapter

Precautions

WARNING

Before attempting to perform any of the procedures described in this chapter, you must read and understand all contents of the corresponding section(s) in the Safety instructions chapter as listed below:

- *General precautions on page 12*
- *Personal protection on page 14*
- *System operation on page 18*

WARNING

Before operation, all process connections and the piping system must be tested for leakage at maximum pressure for continued protection against injury risks due to fluid jets, burst pipes or potentially explosive atmosphere.

NOTICE

Only use chemicals listed in the Chemical Resistance information.

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

See *Section 8.4 Chemical resistance, on page 153* for more information.

5.1 Prepare the system

About this section

This section describes the steps that should be performed to prepare UniFlux 10 system for a run.

In this section

Prerequisites

Before the UniFlux 10 system is taken into operation, make sure that all procedures in the following chapter and section have been performed:

- Actions described in *Chapter 4 Installation, on page 78*
- Actions before operation as described in *Section 6.1 User maintenance schedule, on page 117*.

5.1.1 Sample handling

Reasons for Normal flow filtration (NFF)

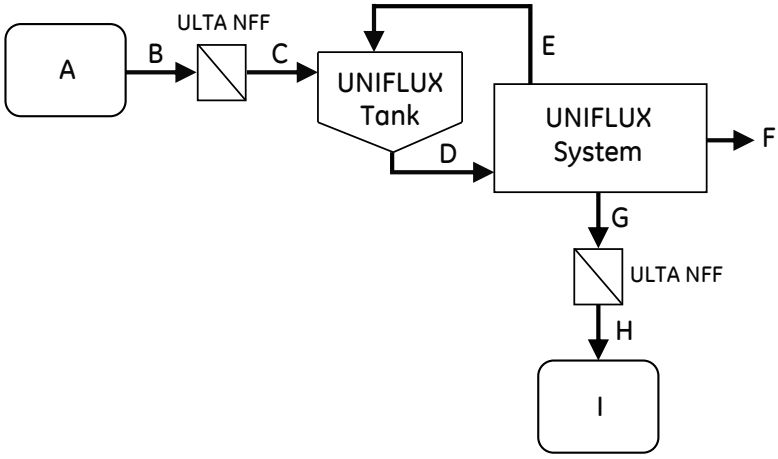
Action	Description
NFF before CFF	If it can be suspected that large particles may be present in the sample, for instance because of settling during sample hold, a Normal Flow Filter (NFF) can be used to prevent these particles from entering the UniFlux 10 during operation. **NOTICE** Make sure that large particles are prevented from entering the UniFlux 10 system during operation, otherwise, the filters may become clogged and the feed pump may malfunction.
NFF after CFF	If there is a need to prevent residual particles, larger than the CFF cutoff size, to be recovered from the completed run, a NFF can be used when recovering the processed product from the system.

Recommendations

The table below describes the situations where the Cytiva range of ULTA™ NFF capsules can be used.

If...	Then use the following NFF...	Placement...
If large particles are present in the sample container	• ULTA Prime CG capsule	Between the sample container and the system feed inlet
If large particles are present in the product	• ULTA Prime CG 0.2 µm • ULTA Pure HC 0.2 µm sterile grade • ULTA Pure SG 0.2 µm sterile grade	Between the recovery outlet and the product container

Illustration of sample handling



Part	Function
A	Container for starting material
B	Starting material feed to ULTA NFF filter
C	Filtered material to UniFlux 10 feed inlet
D	Feed from tank to system
E	Retentate from system to tank
F	Permeate out
G	Recovered material from UniFlux 10 after completed CFF run
H	ULTA NFF filtered recovered material

Part	Function
I	Container for recovered material, preferably a ReadyCircuit™ bag (part of the ReadyToProcess™ portfolio) or equal

5.1.2 Start the system and software

Start UniFlux 10

Step	Action
1	Make sure that the air supply to the system is turned on.
2	Turn on the UPS if used.
3	Make sure that the electrical cabinet doors are closed and locked.
4	Switch on power to UniFlux 10 system by turning the **MAINS POWER** switch to the "**I**" position. See *Section 3.2 Illustrations, on page 30* for location.
5	Make sure that UNICORN is started according to the instruction in *Start UNICORN, on page 101*. Wait for connection.

Start UNICORN

See *Section 3.9 UNICORN control system, on page 74* for more information regarding the UNICORN control system, warnings and alarms.

Step	Action
1	Switch on the computer.
2	Log on to Microsoft Windows.
3	Start UNICORN by double-clicking on the UNICORN icon on the Windows desktop.
4	When the UNICORN ***Logon*** dialog appears, select a user from the ***Users list*** and enter the password. If you log on for the very first time, select ***default*** and enter the password ***default***. ***Note:*** *For some UNICORN versions it is also possible to select the* ***Use Windows Authentication*** *checkbox and enter a network ID in the user name field.*
5	Click ***OK***.
6	In the ***System Control*** module, select ***System*** →***Connect***.
7	In the dialog shown, select the appropriate system name and click ***OK***. The system name is specified during installation configuration.

Step	Action
8	When UNICORN is connected to the system, the ***Run*** button in the status bar is enabled. The button initially has a green color indicating the system is ready to run.

5.1.3 Install hollow fiber cartridges

Follow the instruction below to install the HF cartridges.

Step	Action
1	Make sure that the system is configured for using HF cartridges and of the intended size, see *Section 6.7 Change filter type, on page 133* if required.
2	Prepare the HF cartridge(s) according to the manufacturer's instructions.
3	Install the cartridge into the system, refer to illustrations in *Section 3.6 Hollow fiber (HF) configuration, on page 59*.

5.1.4 Install filter cassettes

General preparation of the cassettes

The table below describes general preparations before installing the cassettes.

Step	Action
1	If the filter cassettes to be used are new, it is strongly recommended to perform an air integrity test to establish its characteristic air or nitrogen flow. See *Air integrity test, on page 105* for instructions.
2	Prepare and check the cassettes according to the manufacturer's instructions.

5.1.5 Testing

Introduction

Before using your UniFlux 10 system and cassette to process product, do the following:

1. Perform a leakage test.
2. Perform an air integrity test.

Leakage test

Note: *For allowed deviations from reference values during leakage testing, refer to Section 8.2 Signals, on page 150 or Functional Test Records, in the documentation package.*

Step	Action
1	Pressurize the system up to the maximum intended process pressure.
2	Watch the system for leaks while maintaining this pressure. Pay special attention to the filter installation. If a leak-free seal is not achieved at this pressure, there may be a cassette, gasket, or surface finish irregularity. Proceed as follows:
3	Remove the filters and inspect the sealing surfaces.
4	Correct any found problem, reinstall the filters and perform the test again.

Air integrity test

It is recommended to perform an air integrity test on each filter before usage.

All instructions below are performed in UNICORN.

Step	Action
1	Prepare the system for the test: **a.** Flush the system and filter with water or buffer. **b.** Drain the system from all fluid. **c.** Make sure that process grade air supply to the integrity test is connected and turned on, refer to *Section 4.4.4 Connect compressed air supply, on page 88*.
2	Isolate the upstream process by closing the following valves: • Feed valve **XV-001**. • Retentate pressure control valve **PCV-341**. • Retentate valve **XV-051**.

Step	Action
3	Open the Permeate valve **XV-031** to Permeate.
4	**NOTICE** Never let the test pressure exceed the maximum filter pressure as stated by the filter manufacturer. If the filter is subjected to pressures exceeding this value, unrecoverable damage may occur. Apply air pressure to the filter: **a.** Set the ***Integrity_Test_Pressure*** to the pressure specified by the filter manufacturer. **b.** Open the Integrity test valve **XV-063**. ***Note:*** *If the pressure as indicated by* **PT-113** *takes more than 15 minutes to build up and stabilize, this indicates that there is a leak somewhere in the system.* *Identify and seal all leakages before proceeding with the test.*
5	When the specified test pressure has been reached: **a.** Wait for a stable air flow reading from the flow meter **FT-143**. **b.** Compare this value to the integrity air flow value specified by the filter manufacturer.
6	Terminate the air integrity test: **a.** Set ***Integrity_Test_Pressure*** to zero. **b.** Close the integrity test valve **XV-063**. **c.** Open the retentate valve **XV-051**. **d.** Open the Retentate drain valve **XV-052**.
7	Open the retentate pressure valve **PCV-341** in small increments to protect the filter. When the **PT-113** pressure indicator reads zero, the system is depressurized and the test procedure completed.

If the flow deviates from the characteristic flow during an air integrity test, the following conclusions can be drawn:

If...	Then...
The air/nitrogen flow is significantly **lower** than the characteristic flow.	The filter is clogged and needs to be cleaned.
The air/nitrogen flow is significantly **higher** than the characteristic flow.	The are pores in the membranes or fibers that have become larger than the nominal pore size. or The fibers or membranes are broken. The filter will allow larger particles than the nominal cut-off size to pass to the permeate and must hence not be used for processing any more.

Unexpected flowrate

5.2 Calibrations

About this section

This section describes how to establish and enter hold-up volume, prepare mass measuring, control meter range and calibration.

In this section

5.2.1 Preparing mass measuring

Introduction

Before the mass measuring system can be used to reliably measure and indicate the contents of the tank, make sure that all load cell locking screws are fully released.

The measuring scale must then be set with regard to zero point and slurry density if the density differs significantly from 1.0.

See *Calibration: Mass measuring, on page 131* for the calibration procedure.

5.2.2 Establishing and entering holdup volume

Introduction

The holdup volume is necessary for correct ***VolTank*** data. This is critical for the concentration factor and diafiltration factor calculations as these instructions latch onto the ***VolTank*** value.

Working principle

This method empirically determines the total retentate recirculation hold-up volume including retentate piping and filter.

When to use this procedure

If the holdup volume is not known since previous filtration runs with the same setup, this procedure should be performed to establish the correct holdup volume before the filtration run is started.

Instruction

Step	Action
1	Remove all liquid from the recirculation loop.
2	Transfer a set volume into the tank with the ***TransferFeedPump*** set to 50%.
3	Recirculate the liquid for one minute.
4	Calculate the difference between the ***Tank Fill Volume*** and the ***VolTank*** reading. The resulting difference is the holdup volume.
5	Enter the calculated holdup volume by performing the following steps: **a.** In UNICORN ***System Control*** module, select ***System*** →***Settings***. **b.** In the UniFlux 10 Instructions dialog, select ***Specials*** and ***System_Volume***. **c.** In the ***Skid*** field, enter the correct holdup volume. Click ***OK***.

5.2.3 Meter range and calibration

Conductivity range

Make sure that the conductivity meter is set to the correct range. See *Conductivity range, on page 131*.

Conductivity calibration

If necessary, calibrate the conductivity meter. See *Conductivity test, on page 132*.

pH-calibration

Calibrate the pH sensor. See *Section 6.5 pH calibration, on page 129*.

5.3 Perform a run

Precautions

WARNING

During operation, all cabinet doors must be closed and locked.

NOTICE

Excessive temperatures may damage the equipment. Do not run the system at higher temperatures than the specified maximum operation temperature as stated on the system label.

Final checks before start

NOTICE

Make sure that the actions listed below are completed before UniFlux 10 is started.

- Check that the pump is filled with correct lubricant oil before start, refer to the pump supplier documentation found in the document package for details.
- Check that all inlets and outlets to the system are connected, closed or in the state that they are supposed to be before the system is started.
  - Inlets that are not in use shall be closed.
  - Outlets that are not in use shall be fitted with tubing and directed to waste.
- Check the condition of all connections and gaskets.
- Check that no chemicals that may be harmful to the system will be used.
- Perform an alarm test according to *Alarm test, on page 77*.

Start a run

Step	Action
1	In the UNICORN ***System Control*** module, select ***Run*** in the ***File*** menu.

Step	Action
2	Select the method to start. Click ***OK.*** A Start Protocol is displayed, consisting of a number of dialog boxes. On the ***Variables*** page, it is possible to fine-tune the method before proceeding. Checking the ***Show details*** box will display more detailed information.
3	Check that the sample volume is correct.
4	Click ***Next*** or ***Back*** to navigate through the dialog panels, adding the information required as well as your own comments.
5	Click the ***START*** button in the ***Result Name*** dialog box. This will initiate the method run.

Note: *The pump needs a completely open flow path to enable start.*

Monitor the run

The progress of the run can be viewed in detail in the UNICORN ***System Control*** module.

Up to four different panels can simultaneously display different aspects of the run. To customize content and layout of a panel, right-click in it and select ***Properties...*** from the menu displayed. By selecting ***Documentation*** →***Run notes***, it is possible to add notes during a run. Entered notes will be included in the results.

More information regarding the monitoring possibilities that the UNICORN user interface offers is available in the UNICORN *manual package*.

End the run, normal completion

If no unexpected events occur during the run, UNICORN enters ***END*** state at method completion without need for user interaction.

Ending the run before the method has finished

To end the run before the method has finished, click on the ***End*** button at the top of the ***Control module*** window.

This will produce a confirmation dialog. Click ***OK*** in the dialog to end the run, or click ***Cancel*** to keep running.

In the dialog, you can choose to save the (partial) results from the run so far. If the run is part of a scouting run, you are also given the choice of ending this. (If you do not, the next run will start automatically.)

5.4 Procedures after usage

Clean the filters

The filters can be cleaned in place if the method is set within the specific ranges for solutions, temperature and pressure. The filters should be cleaned as described in *Clean the filters, on page 121*.

UNICORN shutdown

Step	Action
1	In UNICORN, select ***File*** →***Quit*** or click the ***Close*** icon in the ***Manager/ Administration*** module.
2	Confirm that you want to quit and select to leave system locked or unlocked.
3	Shut down the computer from the Windows ***Start*** menu.
4	When the computer screen has switched off, turn off the system power switch. ***Note:*** *Since the system power will be shut down, the system cannot be operated from another workstation before the system is powered up again, regardless if it is locked or unlocked at shut down.*

Preparing for storage

Prepare the system for storage as described in *Section 6.3 Storage, on page 124* as required.

6 Maintenance

About this chapter

This chapter provides required information to enable users and service personnel to clean, maintain, calibrate and store the UniFlux 10 system.

In this chapter

Precautions

WARNING

Before attempting to perform any of the procedures described in this chapter, you must read and understand all contents of the corresponding section(s) in the Safety instructions chapter as listed below:

- *General precautions on page 12*
- *Personal protection on page 14*
- *Power supply, on page 18*
- *Maintenance on page 20*

WARNING

For continued protection against injury risks due to fluid jets, burst pipes or potentially explosive atmosphere, the user must test the piping system for leakage at maximum operating pressure.

- Always perform a leakage test after assembly or maintenance.
- Always perform a leakage test before operation or CIP.

WARNING

Decontaminate before service. Before performing any service work on the system, make sure that the system has been properly decontaminated.

6.1 User maintenance schedule

Introduction

The maintenance recommendations are different depending on how frequently you use your system. Note that the recommendation may not apply to your specific use of the system. The system owner is solely responsible for establishing applicable routines for periodic maintenance.

Before each run or weekly

This section covers maintenance actions required for each run or weekly (depending on which happens first).

Component	Action
UV monitor	Set auto-zero by using the function in UNICORN.
pH monitor	Clean, calibrate and store the pH electrode adequately, see *Section 6.5 pH calibration, on page 129*.
Alarm buzzer	Check the function ***Alarms*** →***BuzzerTest***.
Complete system	Clean/sanitize the system according to the procedure described in *Section 6.2.2 Cleaning-in-place (CIP), on page 123*.
Protective earth	Make sure that the protective earth wiring is not disconnected or damaged.

Monthly maintenance

The table below lists maintenance actions that are required monthly.

Component	Action
Pump	Check for oil leakage. (If the pump leaks, contact your local Cytiva representative).
Connections and seals	Check for leakage. Replace seals if needed. Perform a leakage test at maximum operating pressure.

Annually or as needed

This section covers maintenance actions required annually or as needed.

Component	Action
Complete system	A preventive maintenance test procedure on all instruments, sensors, pumps and valves should be performed annually by trained and certified personnel. Contact your local Cytiva representative. Replace all gaskets, o-rings and valve diaphragms.
Complete stainless steel system	Inspect stainless steel systems for rust. If needed, passivate the steel by recirculating a solution of 5% phosphoric acid in the system overnight at room temperature and then rinse with purified water until the pH of the outlet liquid is neutral.
Pump	Replace all wear and tear parts. Replace drive element lubricant. Refer to the System Documentation for details.
UV monitor	Replace the UV lamp when the intensity is low or when a lamp failure is indicated in UNICORN.
pH sensor	Replace the pH electrode if difficulties are experienced during calibration.
Conductivity monitor	Clean and calibrate the conductivity monitor.

6.2 Cleaning

About this section

This section describes procedures and recommendations for cleaning UniFlux 10 system. Procedures for cleaning both the exterior, and CIP (cleaning-in-place) protocols for cleaning the flow path are described.

In this section

Precautions

WARNING

Flammable liquids. This product is **not approved** to handle flammable liquids.

WARNING

Hazardous substances and biological agents. When using hazardous chemical and biological agents, take all suitable protective measures, such as wearing protective clothing, glasses and gloves resistant to the substances used. Follow local and/or national regulations for safe operation and maintenance of UniFlux 10 system.

WARNING

For continued protection against injury risks due to fluid jets, burst pipes or potentially explosive atmosphere, the user must test the piping system for leakage at maximum operating pressure.

- Always perform a leakage test after assembly or maintenance.
- Always perform a leakage test before operation or CIP.

NOTICE

Replace the pH electrode with the pH-probe dummy before performing CIP with strong acids or alkali.

NOTICE

The filter may not be compatible with the CIP solutions. If so, remove the filter and store or dispose of it in accordance with the recommendations of the manufacturer.

6.2.1 Important considerations for cleaning

Cleaning frequency

A suitable frequency of routine cleaning is determined by the nature of the starting material and the type of process. However, routine cleaning shall be performed at intervals aimed at prevention rather than cleaning the system from growth or contamination.

Cleaning before planned maintenance/service

To ensure the protection and safety of service personnel, all equipment and work areas must be clean and free of any hazardous contaminants before a Service Engineer starts maintenance work.

Please complete the checklist in the *On Site Service Health and Safety Declaration Form* or the *Health and Safety Declaration Form for Product Return or Servicing*, depending on whether the instrument is going to be serviced on site or returned for service, respectively.

Health and safety declaration forms

Health and safety declaration forms are available for copying or printing in the *Reference information* chapter of this manual, or on digital media supplied with the user documentation.

Recommended cleaning agents

All components can be cleaned with the most commonly used agents, such as detergents, Ethanol, weak acids, Sodium Hydroxide and salt solutions.

See *Section 8.4 Chemical resistance, on page 153*.

NOTICE

Avoid Sodium Chloride solutions below pH 4.0. Rinse UniFlux 10 thoroughly with water immediately after contact with salt solutions, to lessen the risk of corrosion.

Clean the UV and conductivity cell

The UV cell and conductivity cells are cleaned by flushing the cells with 1 M sodium hydroxide or 20% ethanol.

Clean the filters

- Cytiva Hollow fiber cartridges cleaning procedures are provided in the *Hollow fiber cartridges for membrane separations Operating Handbook, Cytiva article no 18116530.*.

- Filter units shall be cleaned according to the instructions from the respective manufacturer.

Clean external surfaces

The UniFlux 10 system is designed to be operated in a clean environment and the external surfaces should not normally accumulate any substantial amount of dust or dirt.

Regularly, wipe the outside of the UniFlux 10 system with a clean cloth. Use a mild cleaning agent such as water, followed by 70% Ethanol. Regular wiping and care of the equipment will help keep the surfaces uncorroded.

It is not recommended to spray or splash liquids towards external surfaces.

Do not spray or splash liquids towards filters or the fan on the electrical cabinet.

6.2.2 Cleaning-in-place (CIP)

CIP methods in UNICORN

It is recommended that specific CIP protocols are developed to standardize the CIP procedure in a repeatable and reliable manner depending on the applied user application.

A routine cleaning method can be set up in UNICORN for regular cleaning and sanitizing of the system and connected components.

Refer to UNICORN *manual package* for comprehensive instructions on how to create a sanitizing / CIP method in UNICORN.

Extended cleaning performance

If the UniFlux 10 system has been heavily contaminated and the normal CIP procedure is not sufficient, cleaning performance can be improved by the following actions:

- Extending the total CIP time period.
- Changing to an alternative CIPagent.
- Filling the UniFlux 10 system and attached components with cleaning agent to redissolve contaminants for an extended time period before applying CIP.

Rinsing

After completed CIP, rinse the UniFlux 10 system interior and all cleaned components thoroughly with water of desired quality, for example Water For Injection (WFI), to remove all traces of the cleaning agent.

6.3 Storage

Introduction

This section provides instructions for short-term and long-term storage of UniFlux 10 system.

Precautions

WARNING

Hazardous substances and biological agents. When using hazardous chemical and biological agents, take all suitable protective measures, such as wearing protective clothing, glasses and gloves resistant to the substances used. Follow local and/or national regulations for safe operation and maintenance of UniFlux 10 system.

NOTICE

It is recommended to prepare UniFlux 10 system for storage by filling with 0.01 M sodium hydroxide or denatured alcohol (18% C_2H_5OH (ethanol), 2% C_3H_7OH (isopropanol) and 80% H_2O (water)). Drying the system using sterile nitrogen or air flow may cause static discharge that can damage valve control mechanisms, especially on systems with polypropylene tubing.

If the system is dried, the valve bodies should be grounded before nitrogen or air flow is applied. Contact your Cytiva representative regarding purchase and installation of grounding kits.

NOTICE

Fit protective caps on all electrical and optical connectors when not in use.

NOTICE

When the product is filled with a storage solution, the temperature must be high enough to prevent freezing, and low enough to prevent evaporation.

Short-term storage

The table below describes the procedure for short-term storage. This procedure is applicable for storage durations of up to one month.

Step	Action
1	Perform cleaning as described in *Section 6.2 Cleaning, on page 119*.
2	If the system is configured for filter cassettes, release the pressure of the hydraulic unit to approximately 50 bar.
3	Replace the pH electrode with the pH plug. The electrode should be stored in a 1:1 mixture on 4.0 pH buffer and 1 M KNO_3. Place the pH electrode in the pH electrode holder with the end submerged in storage solution. ***Note:*** *Do not store the pH electrode in water only.*
4	Fill the UniFlux 10 system with 20% Ethanol up to approximately one quarter of maximum operating volume to prevent microbial growth. Make sure that the filter cassettes are at least partially wetted during the storage.
5	Seal off the UniFlux 10 system to prevent contamination caused by the surrounding environment.

Long-term storage

The table below describes the procedure for long term storage. This procedure is applicable for storage durations of longer than one month.

Step	Action
1	Perform the actions described for short-term storage above, with the difference that the filter cassettes first shall be replaced with filter cassette dummies.
2	Place the UniFlux 10 system in a dust free environment with well-controlled climate. The temperature should be in the range 4°C to 25°C and stable. The air humidity and air temperature differences should be kept as low as possible to prevent condensation and corrosion.
3	Remove TC connection rubber gaskets in good condition suitable for processing and place them in dark and cold storage while UniFlux 10 is out of operation. This prevents them from aging and drying out. Use other sealings, not in processing condition, as replacement during the storage period.

To prevent microbial growth, the storage solution shall be replaced regularly if the UniFlux 10 is stored for long periods of time.

Filter storage

The reference below provides storage procedures for Hollow fiber filters.

- Cassettes storage instructions are provided by the filter cassette manufacturer.
- Cytiva Hollow fiber cartridges storage procedures are provided in the *Hollow fiber cartridges for membrane separations Operating Handbook, Cytiva article no 18116530.*.

6.4 Disassembly and assembly

Introduction

This section covers all disassembly and assembly procedures that the end user is allowed to perform without support from Cytiva.

Precautions

WARNING

Only authorized personnel may open the electrical cabinet doors. There is hazardous voltage inside the electrical cabinet that can cause human injury or death.

WARNING

The electrical cabinet doors may only be opened when the product is taken out of operation and subject to **LOCK OUT / TAG OUT (LOTO)** (lockout-tagout).

WARNING

LOCK OUT / TAG OUT (LOTO)! Before any maintenance or decommissioning work is performed on the system, make sure that:

- the system is empty and depressurized.
- the system is disconnected from process feed, electrical power and pneumatic supply.
- the system is prevented from accidentally becoming re-energized during maintenance.
- the system is clearly tagged as taken out of operation.
- all process wetted areas are clean and decontaminated.

WARNING

For continued protection against injury risks due to fluid jets, burst pipes or potentially explosive atmosphere, the user must test the piping system for leakage at maximum operating pressure.

- Always perform a leakage test after assembly or maintenance.
- Always perform a leakage test before operation or CIP.

User-allowed actions

The following components may be disassembled or assembled by the user:

- **Components for filter configurations**

> **NOTICE**
>
> In order to reconfigure the system from cassette usage from hollow fiber (HF) to cassette usage, or the other way round, a number of components must be removed and installed.
>
> The procedures for doing this is described in *Section 6.7 Change filter type, on page 133*.
>
> While these operations can be performed by a properly skilled user technician, Cytiva recommends that a Cytiva service engineer is assigned for this work.
>
> Contact your Cytiva representative for more information on changing filter configurations if required.

- **The pH probe**, see *Section 6.5 pH calibration, on page 129*.

Other components

Other than described in this chapter, the UniFlux 10 is not designed to be disassembled or assembled by the user.

If the need for further disassembly should arise, always contact your Cytiva representative for advice before attempting any actions not described by this document.

6.5 pH calibration

Required equipment

- pH reference solution for low pH-measuring point, preferably pH 4.00.
- pH reference solution for high pH-measuring point, preferably pH 7.00.
- Clean cloth.
- Clean water in spray bottle.

Calibration procedure

The table below describes how to calibrate the pH probe.

Note: *Always have one end of the grounding strip submerged in the buffer during calibration.*

Step	Action
1	Prepare two cups with the buffers representing the actual required pH range.
2	Place one of the cups in the cup holder. Locate the pH-probe in the holder with the end submerged in the buffer. ***Note:*** *Attach the cap to the pH flow cell when to prevent foreign objects to enter the flow path.*
3	Select ***System*** →***Calibrate*** in UNICORN ***System Control*** module.
4	Enter the pH value for the first buffer in the ***Reference value 1*** field, wait for the value to stabilize, and click ***Read value 1***.

Step	Action
5	Remove the pH-probe from the holder and rinse it with distilled water.
6	Remove the cup with the first buffer from the holder and replace it with the cup with the second buffer.
7	Relocate the pH probe in the holder with the end submerged in the buffer.
8	Enter the pH value for the buffer in the ***Reference value 2*** field, wait for the value to stabilize, and click ***Read value 2***.
9	Wait for response and, if the electrode passed, click ***Close***. Otherwise, click ***Close***, refresh/change the pH electrode, and repeat the calibration procedure.
10	Remove the cup from the holder.
11	Relocate the pH probe in the flow cell as shown in the right image above.

6.6 Repair and calibration

Introduction

This section describes component checks, repair and calibration of other components (beside the pH probe) that the user can perform without Cytiva support.

Procedures can also be found in the respective product manuals found in the product documentation package.

Components not covered in this manual may not be calibrated or repaired by the user. If any such components of UniFlux 10 system do not operate according to specifications, contact your Cytiva representative.

WARNING

Do not attempt to perform any actions not described in these documents.

Always contact your Cytiva representative for advice if such a need should arise.

Calibration: Mass measuring

If the process run involves using the tank with liquids with a density that differs significantly from water (1 kg/l), the scale weight measuring must be adjusted so that the scale will report correct volume data.

The density can be set in UNICORN, in the ***Recirc Instructions***.

Air integrity test

This method can be used to check that the filter is not damaged and that it has been fitted correctly.

See *Air integrity test, on page 105*.

Conductivity range

The table below describes the two different conductivity ranges and when they can be used.

Range	Usage
High	Normal operation
High and Low	CIP

Conductivity test

For instructions on how to calibrate the conductivity probe, refer to the system documentation.

Remaining components

For instructions on how to calibrate other components and sensors, refer to the respective manufacturer's manual in the system documentation package.

Components not covered by any of the above described procedures may not be calibrated by the user.

If any non user-calibratable components on the UniFlux 10 system appear to operate off specifications, contact your Cytiva representative for advice.

6.7 Change filter type

Introduction

The UniFlux 10 filtration systems can be operated either with filter cassettes or with HF cartridges. While systems in general, including the entire automation SW, supports both configurations, some components must be exchanged to allow running the systems with each filter type.

This chapter describes the procedures and components required to switch between cassette and HF operation.

NOTICE

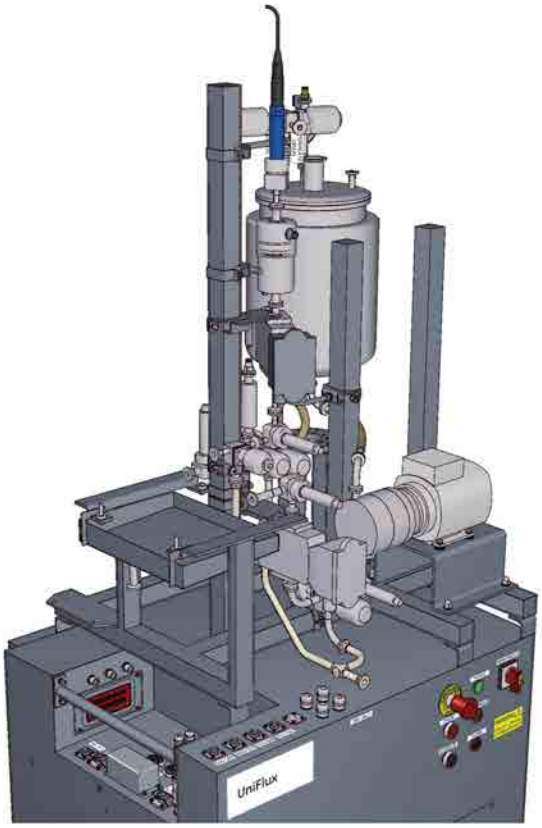
While system filter type reconfiguration can be performed by a properly skilled user technician, Cytiva recommends that a Cytiva service engineer is assigned for this work.

Contact your Cytiva representative for more information on changing filter configurations if required.

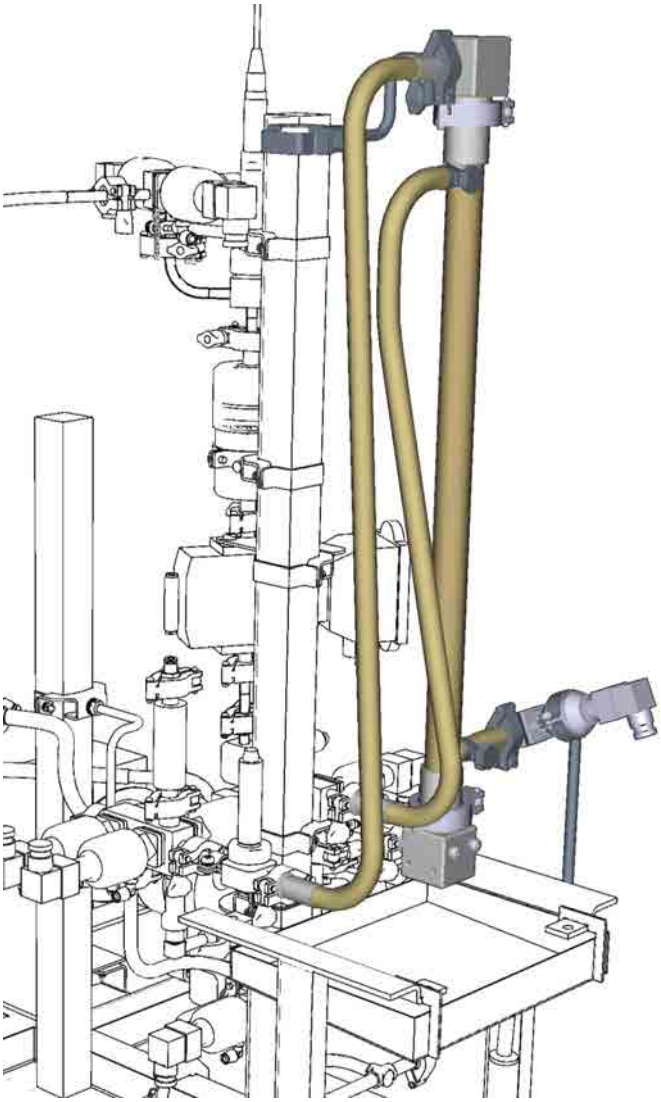
Change from filter cassette to HF cartridge

Step	Action
1	Make sure that all components required for the HF setup as shown on the illustration above are available, refer to *Section 3.6.1 UniFlux 10 HF configuration, on page 60*.

Step	Action
2	Remove the following components: • The cassette holder. • All cassette holder fittings. The system should look like this when all components are removed:



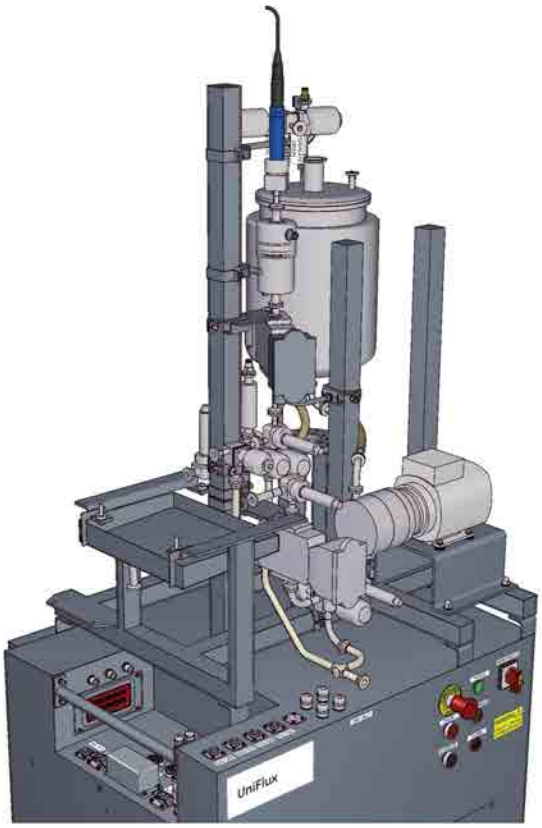
Step	Action
3	Install the HF-specific components as shown in the illustration:

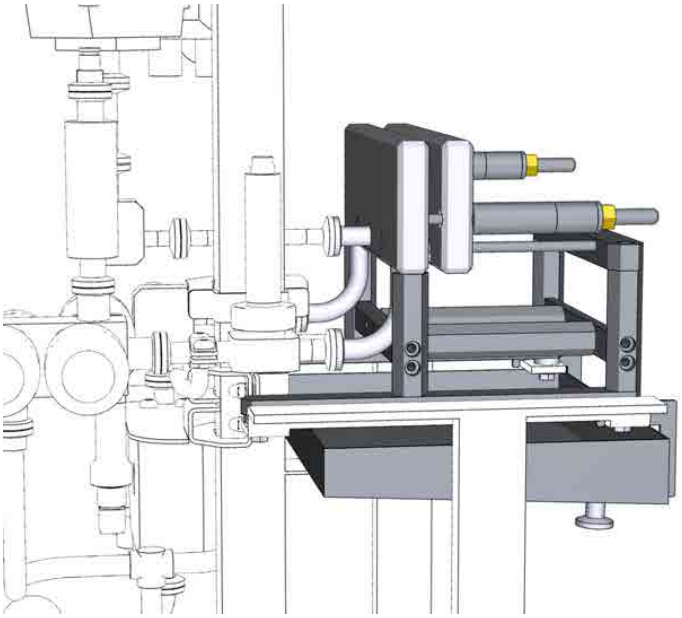


4	Install a decommisioned or dummy HF cartridge and test the system for operation and leakages.

Change from HF cartridge to filter cassette

Step	Action
1	Make sure that all components required for the cassette setup are available, refer to *Illustration, on page 55*.
2	Remove the following components: • The HF cartridge. • All connecting hoses with fittings. • The XV-064 permeate drain valve. The system shall look like this when all components are removed:



Step	Action
3	Install the cassette specific components as shown in the illustration: 
4	Install a dummy or decommisioned filter cassette and test the system for operation and leakages.

7 Troubleshooting

About this chapter

This chapter provides required information to enable users and service personnel to identify and correct problems that may occur when operating UniFlux 10 system.

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.

Precautions

WARNING

Before attempting to perform any of the procedures described in this chapter, you must read and understand all contents of the corresponding section(s) in the Safety instructions chapter as listed below:

- *General precautions on page 12*
- *Personal protection on page 14*
- *Power supply, on page 18*
- *Maintenance on page 20*

System

Compo-nent	Possible cause	Corrective action
Computer	No system found when starting up UNICORN.	• Make sure the system is switched on. • Check communication cable and connectors. • Reboot PC: shut down Windows, switch off the system power switch, wait at least 5 sec, restart system.

Component	Possible cause	Corrective action
Computer	No connection between the system and UNICORN.	1. Open a ***System Control*** module. 2. • Select the ***System*** →***Connect*** menu command. or • Click the ***Connect to system*** toolbar icon. *Result:* The System Connect dialog box opens. 3. Select the system you want to connect. 4. Click ***OK***.
Power	Power failure during a run.	Check circuit breaker, both in system and for external supply, as applicable.
Compressed air	Compressed air failure during a run. The alarm "No air supply to the system" is displayed and the system enters ***Pause*** mode.	Insufficient air pressure caused by, for instance, malfunctioning air supply equipment or a leaking air hose. a) Rectify the air supply problem. b) Restart the run by pressing the ***Continue*** button.
Valves	Alarm ***"Valve error"*** is displayed.	If the ***"Valve error"*** alarm is accompanied by ***"No air supply to the system"***, the alarm is caused by a compressed air failure (see above).
Pump	Pump not working.	• Emergency button has been pressed. • No inlet or outlet valve open. Check method and valves. • Incorrect method. Check by entering ***Pump*** →***ManFlow*** > 1%. • If none of the above, contact Cytiva service personnel.

Compo-nent	Possible cause	Corrective action
	Little or no flow.	• Check that connected inlet is actually used. • Inlet containers are placed too low relative to the pump. Check inlet containers. • No liquid is supplied to the pump. Check inlet containers. • Tubing from inlet container causes pressure or flow loss. Reasons may be too long tubing, too small internal diameter, tube may have a narrow section or is partly plugged. • Malfunctioning valve at container battery limit.
	Too high outlet pressure.	• Check that connected outlet is actually used. • Outlet containers are placed too high relative to the pump. • Tubing to outlet container causes pressure or flow loss. Reasons may be too long tubing, to small internal diameter, tube may have a narrow section or is partly plugged. Check also for non-functioning valve(s). • Malfunctioning valve at container battery limit.

UV curve

Error symptom	Possible cause	Corrective action
Ghost peak.	Dirt or residues in the flow path from previous runs.	Clean the system.
Noisy UV signal, signal drift or instability.	Bad UV fiber connections.	Check the connections of the UV cell optical fiber. Replace if necessary.
	Dirty UV cell.	Clean the UV cell, see *Section 6.2 Cleaning, on page 119*.

Pressure curve

Error symptom	Possible cause	Corrective action
Erratic flow, noisy baseline signal, irregular pressure trace.	Gas bubbles passing through or trapped in the pump.	Check that there is sufficient supply of liquid.
		Check all connections for leaks.
	Blockage or partial blockage of flow path.	Flush through to clear blockage.

Cross flow filtration

See *Air integrity test, on page 105*.

Component	Problem	Possible cause	Corrective action
Filter problems	The flow is too high in the air integrity test.	Clogged filter.	Clean the filter.
	The flow is too low in the air integrity test.	The pores in the membrane or fibers have become larger than the nominal size	Change the filter.
		The fibers or membranes are broken.	Change the filter.
Hydraulic unit	The pump does not operate.	The unit is not connected to electrical power.	Plug the unit into the power supply.
		The power switch is in the **OFF** position.	Turn the power switch to the **ON** position.
	The pump does not reach the desired pressure.	The regulator is set below the desired pressure.	Adjust the regulator so that the desired pressure can be reached.
		Low oil level in the reservoir.	Check visually the oil level and add oil if the level is too low. The oil level should be approximately 60% of the reservoir's volume (3 L), then the hydraulic cylinder and the tubes and hoses should be filled with oil.

Peristaltic pump

Component	Problem	Possible cause	Corrective action
Peristaltic pump	Displayed error message: "***P202 not healthy***" or "***P203 not healthy***".	The affected peristaltic pump is either disconnected, faulty set up or not working.	1. Check all cables and connectors from the pump to the electrical cabinet. 2. Run instruction: ***P202_clear faults*** or ***P203_clear faults***. 3. Contact your local Cytiva representative.
	Little or no flow.	Broken or damaged hose.	1. Check the pump hose. 2. Contact your local Cytiva representative.

Conductivity

Error symptom	Possible cause	Corrective action
Baseline drift or noisy signal.	Leaking tube connections.	Tighten the clamps. If necessary, replace the clamps.
	Bad pump.	See manufacturer's user documentation.
	Dirty conductivity cell.	Clean the conductivity cell, see *Section 6.2 Cleaning, on page 119*.
Absolute conductivity value is wrong.	Bad calibration.	Calibrate the conductivity cell, see manufacturer's user documentation.
	Calibration solution not correctly prepared.	Recalibrate using a new calibration solution.
Incorrect or unstable reading.	Bad pump or valve action.	Check the pump and the valves.
	Temperature compensation not properly set.	Check the temperature compensation, see manufacturer's user documentation.

pH curve

Error symptom	Possible cause	Corrective action
No response to pH changes.	The cable to the electrode not properly connected.	Check the cable connection.
	The electrode membrane might be cracked.	Replace the electrode.
Small or slow response to pH changes.	The electrode membrane might be contaminated.	Clean the electrode, refer to the manufacturer's user documentation.
pH reading appears to be incorrect.	pH-sensor not properly calibrated.	Calibrate the pH-sensor as described in *Section 6.5 pH calibration, on page 129*.

8 Reference information

About this chapter

This chapter provides reference information that may become useful when installing, operating, maintaining and troubleshooting UniFlux 10 system. It also contains ordering information.

The UniFlux 10 system is a modular built instrument that can be configured in many different ways. To understand the specific configuration that applies to your UniFlux 10 system, please refer to the system documentation supplied with the instrument.

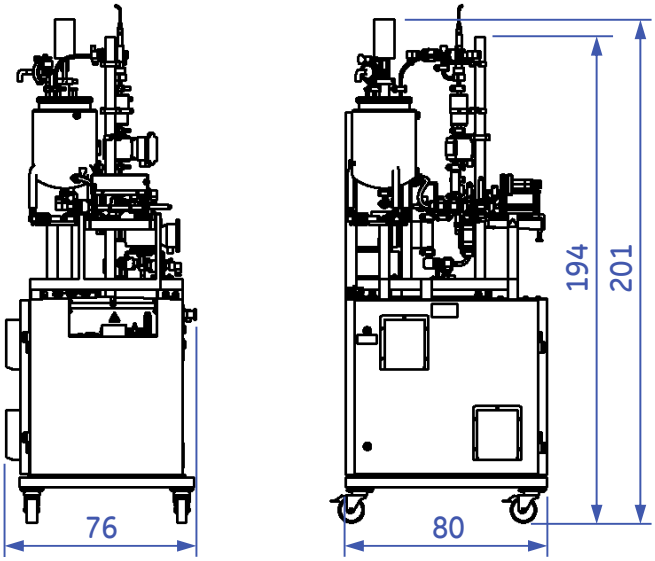
In this chapter

8.1 Specifications

Dimensions

Note:

- *All dimensions are presented in cm where nothing else is noted.*
- *Dimensions and weights are valid for standard systems.*
- *Dimensions may vary for individual units by +/- 1 cm.*
- *Weights may vary for individual units by +/- 10 kg.*



UniFlux 10

Cable lengths

Cable	Length
Communication	10 m (max 80 m)
Power supply, system and pump	5 m
External I/O	5 m

Weights

Configuration	Weight
Complete configuration	300 kg
Complete configuration including crate, accessories and documentation kit	440 kg

Capacity

Property		Value
Operating flow, feed pump / recirculation flowrate	Min	1 L/min at 4 bar
	Max	10 l/min
Feed transfer- and permeate control pump option, flow at 2 bar outlet back-pressure	Min	20 ml/min
	Max	2300 ml/min
Feed tank		5 or 10 liter

Operating limits

Property			Value
Feed pump pressure at 20%, max			4.14 bar g (60 psi g)
Transfer and permeate pumps	Feed temperature	Min	5°C
		Max	40°C
	Outlet back pressure, max		2 bar
Battery limits back pressure		Min	0
		Max	0.2 bar (3 psi)
Process temperature		Min	2°C (36°F)
		Max	60°C (140°F)

Environmental limits

Parameter	Value
Altitude	Max 2000 m

Parameter	Value
Relative Humidity	Max 80% for temperatures up to 31°C, decreasing linearly to 50% relative humidity at 40°C.
Ambient temperature	Requirement regarding ambient temperature is specified in the General Specification included in the system documentation kit
Ingress protection	IP 55

Compressed air

Property	Value
Pressure	6 to 10 bar (87 to 145 psi)
Consumption	50 Nl/min
Type	Particle-free and non-condensing

Hollow fiber specifications

Property		Value
No of filter cartridges, type		1, Hollow fiber
Cartridge	Size	5 or 6
Total filter area	Min	1.3 ft^2 / 0.12 m^2
	Max	5.2 ft^2 / 0.48 m^2

Membrane cassette specifications

Property		Value
No of cassette holders, type		1, Kvick Lab
No of cassettes	Min	1
	Max	5
Total filter area	Min	1.2 ft^2 / 0.11 m^2
	Max	6 ft^2 / 0.55 m^2

Sound levels

Property		Value
Feed pump	Max	<80 dB
	Typical value under normal running conditions[1]	59 dB

[1] Measured at the feed flow rate 5 l/min and feed pressure 2 bar

Electric power

Property			Value
Power supply	System	Type	L-N-PE
		Voltage	110/230 V AC ±10%
		Frequency	50 to 60 Hz
	Pump	Type	N/A
		Voltage	400/480 V AC ±10%
		Frequency	50 to 60 Hz
Fuse rating	System	110 V AC	16 A SB
		230 V AC	10 A SB
	Pump		N/A
Ground fault interrupter, minimum break current			300 mA
Leak current			3.5 mA
Transient overvoltages			Overvoltage category II
Pollution degree			2

System hold-up volume

System hold-up volume is the volume in the feed and retentate piping from the system feed inlet (B1) to the system retentate outlet (P1).

The approximate hold-up volume for indicated sections of the system is 0.2 liter. Values may vary between individual systems.

8.2 Signals

Signal		Signal / Tag name	Measuring unit	Set range	Acceptance range
Feed	Weight	WIT-176	g	0 to 30 000	0 to 25 000
	Pressure	PT-111, PT-112	bar g	0 to 6	0.1 to 6
	Flow	FT-141	l/min	0 to 15	0.5 to 10
Retentate	Pressure	PT-113	bar g	0 to 6	0.1 to 6
	Temperature	TE-161	°C	0 to 100	2 to 60
Permeate	Pressure	PT-114	bar g	-1 to 5	0.1 to 5
	UV	AIT-131	AU	-1 to 4	0 to 1
	Flow	FT-142	l/min	0 to 0.3	0.02 to 2.5
	Conductivity	UUC-382	mS/cm	0.005 to 300	Low scale: 0.01 to 100
					High scale: 100 - 300
	pH	AT-121	pH	0 to 14	4 to 7 / 7 to 10
Air integrity	Flow	FT-143	ml/min	0 to 100	10 to 70

8.3 Battery limits

About battery limits

Battery limits represent interface points between the UniFlux 10 system and the customer plant process equipment.

Battery limits can be thought as the points where functional responsibility is handed over from the plant to the UniFlux 10 system or *vice versa*.

Process

The indicated dimensions represent the tubing connection (TC) flange size and the minimum inner diameter for used hoses required to match battery limit connections.

Battery limit	Label	Tag	Dimension
Feed inlet	**FEED**	**B1**	1/2" TC25
Retentate outlet	**RETENTATE**	**P1**	N/A
Permeate outlet	**PERMEATE**	**P2**	3/8" TC25
Retentate drain	**RETENTATE DRAIN**	**P3**	1/2" TC25
Feed drain	**FEED DRAIN**	**P4**	1/2" TC25
Permeate drain	**PERMEATE DRAIN**	**P5**	9.5 mm TC25
HF cartridge drain	**CARTRIDGE DRAIN**	**P6**	1/2" TC25

Pneumatic

Battery limit	Label	Tag	Size and connector type
Air inlet	**AIR INLET**	**PN1**	Quickfit, female, hose 10 x 1 mm
Air outlet	**AIR OUTLET**	**PN2**	Quickfit, female, hose 10 x 1 mm

Electrical

Battery limit	Tag	Size and connector type
Main power supply	**ELI**	Shielded cable 5 m 2.5 mm2 I 14 AWG ULI CE approved
Remote alarm output	**EL2**	Terminal connection (switchinq dry contact)

Battery limit	Tag	Size and connector type
UPS power failure alarm input	**EL3**	Terminal connection, normally low
Optional I/O interface	**EL4**	16-pole connector
Unicorn Ethernet port on system	**EL5**	4-pole connector

8.4 Chemical resistance

Introduction

The table below gives allowed exposure concentrations and times for various chemicals that may be used in Cytiva BioProcess™ instruments in general. For information regarding hollow fiber chemical resistance, please refer to *Hollow fiber cartridges for membrane separations Operating Handbook, Cytiva article no 18116530*.

Some of the chemicals listed may not be applicable for your instrument.

List of chemicals allowed

Chemical	Concentration	Max. time / cycle	Max. acc. expos.	Usage
Acetic acid	25%	3 h	3000 h	CIP
Acetone	10%	1 h	Unlimited	UV cell test
Citric acid	pH 2 to 2.5	1 h at temp ≤ 60°C	1000 h	CIP
Ethanol	20%	12 months	Unlimited	Storage
Ethanol / Acetic acid	20%	3 h	3000 h	CIP
Guanidine hydrochloride	6 M	5 h	5000 h	CIP
Hydrochloric acid	0.1 M at pH=1	1 h	1000 h	CIP
Phosphoric acid	5%	Overnight	Unlimited	For SS passivation
2-propanol	30%	1 h	1000 h	CIP
Sodium chloride	0 to 3 M	3 h	3000 h	Purification, CIP
Sodium hydroxide	1 M at pH=14 0.5 M 0.01 M at pH=12	24 h at temp ≤ 40°C 3 h at temp ≤ 60°C 12 months	1000 days 3000 h Unlimited	CIP CIP Storage
Sodium hypochlorite	300 ppm	3 h at temp ≤ 60°C	3000 h	CIP
Sodium hydroxide /Ethanol	1 M / 20%	3 h	3000 h	CIP

Chemical	Concentration	Max. time / cycle	Max. acc. expos.	Usage
Urea	8 M	5 h	5000 h	Purification, CIP
Cleaning solutions	1% to 6% STERIS™ CIP 100™, 0.5% Henkel P3™-11, 0.2% Micro, 0.2% Terg-a-zyme™, 0.1% Tween™ 80	3 h at temp ≤ 60°C	3000 h	CIP

8.5 Recycling information

Introduction

This section contains information about the decommissioning of the UniFlux 10 system.

Decontamination

UniFlux 10 system shall be decontaminated before decommissioning and all local regulations shall be followed with regard to scrapping of the equipment.

Disposal, general instructions

When taking the UniFlux 10 system out of service, the different materials must be separated and recycled according to national and local environmental regulations.

Recycling of hazardous substances

UniFlux 10 system contains hazardous substances. Detailed information is available from your Cytiva representative.

Disposal of electrical components

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

8.6 Regulatory information

Introduction

This section lists the regulations and standards that apply to the product.

In this section

8.6.1 Contact information

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	Cytiva Sweden AB Björkgatan 30 SE 751 84 Uppsala Sweden
Telephone number of manufacturer	+ 46 771 400 600

8.6.2 European Union and European Economic Area

Introduction

This section describes regulatory information for the European Union and European Economic Area that applies to the equipment.

Conformity with EU Directives

See 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 instrument 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.

8.6.3 Eurasian Economic Union Евразийский экономический союз

This section describes the information that applies to the product in the Eurasian Economic Union (the Russian Federation, the Republic of Armenia, the Republic of Belarus, the Republic of Kazakhstan, and the Kyrgyz Republic).

Introduction

This section provides information in accordance with the requirements of the Technical Regulations of the Customs Union and (or) the Eurasian Economic Union.

Введение

В данном разделе приведена информация согласно требованиям Технических регламентов Таможенного союза и (или) Евразийского экономического союза.

Manufacturer and importer information

The following table provides summary information about the manufacturer and importer, in accordance with the requirements of the Technical Regulations of the Customs Union and (or) the Eurasian Economic Union.

Requirement	Information
Name, address and telephone number of manufacturer	See *Manufacturing information*
Importer and/or company for obtaining information about importer	LLC Global Life Sciences Solutions Rus Russian Federation, 123112 Presnenskaya nab., 10, fl. 12, pr. III, room 6 Telephone: + 7 495 739 6931 Fax nr: + 7 495 739 6932 E-mail: *rucis@cytiva.com*

Информация о производителе и импортере

В следующей таблице приводится сводная информация о производителе и импортере, согласно требованиям Технических регламентов Таможенного союза и (или) Евразийского экономического союза.

Требование	Информация
Наименование, адрес и номер телефона производителя	См. *Информацию об изготовлении*

Требование	Информация
Импортер и/или лицо для получения информации об импортере	ООО "Глобал Лайф Сайэнсиз Солюшнз Рус" Российская Федерация, 123112 Пресненская наб., д. 10, эт. 12, пом. III, ком. 6 Телефон: + 7 495 739 6931 Факс: + 7 495 739 6932 Адрес электронной почты: *rucis@cytiva.com*

Description of symbol on the system label
Описание обозначения на этикетке системы

This Eurasian compliance mark indicates that the product is approved for use on the markets of the Member States of the Customs Union of the Eurasian Economic Union

Данный знак о Евразийском соответствии указывает, что изделие одобрено для использования на рынках государств-членов Таможенного союза Евразийского экономического союза

8.6.4 Regulations for North America

Introduction

This section describes the information that applies to the product in the USA 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.

8.6.5 Regulatory statements

Introduction

This section shows regulatory statements that apply to regional requirements.

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.

South Korea

Regulatory information to comply with the Korean technical regulations.

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.

주의사항

A급 기기 (업무용 방송통신 기자재)

이 기기는 업무용환경에서 사용할 목적으로 적합성평가를 받은 기기

로서 가정용 환경에서 사용하는 경우 전파간섭의 우려가 있습니다.

8.6.6 Declaration of Hazardous Substances (DoHS)

根据 SJ/T11364-2014《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/T11364-2014 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

该标志表明本产品含有超过中国标准 GB/T 26572《电子电气产品中限用物质的限量要求》中限量的有害物质。标志中的数字为本产品的环保使用期，表明本产品在正常使用的条件下，有毒有害物质不会发生外泄或突变，用户使用本产品不会对环境造成严重污染或对其人身、财产造成严重损害的期限。单位为年。

为保证所申明的环保使用期限，应按产品手册中所规定的环境条件和方法进行正常使用，并严格遵守产品维修手册中规定的定期维修和保养要求。

产品中的消耗件和某些零部件可能有其单独的环保使用期限标志，并且其环保使用期限有可能比整个产品本身的环保使用期限短。应到期按产品维修程序更换那些消耗件和零部件，以保证所申明的整个产品的环保使用期限。

本产品在使用寿命结束时不可作为普通生活垃圾处理，应被单独收集妥善处理。

This symbol indicates the product contains hazardous materials in excess of the limits established by the Chinese standard GB/T 26572 Requirements of concentration limits for certain restricted substances in electrical and electronic products. The number in the symbol is the Environment-friendly Use Period (EFUP), which indicates the period during which the hazardous substances contained in electrical and electronic products will not leak or mutate under normal operating conditions so that the use of such electrical and electronic products will not result in any severe environmental pollution, any bodily injury or damage to any assets. The unit of the period is "Year".

In order to maintain the declared EFUP, the product shall be operated normally according to the instructions and environmental conditions as defined in the product manual, and periodic maintenance schedules specified in Product Maintenance Procedures shall be followed strictly.

Consumables or certain parts may have their own label with an EFUP value less than the product. Periodic replacement of those consumables or parts to maintain the declared EFUP shall be done in accordance with the Product Maintenance Procedures.

This product must not be disposed of as unsorted municipal waste, and must be collected separately and handled properly after decommissioning.

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 Compo-nent name	有害物质 Hazardous substance					
	铅 (Pb)	汞 (Hg)	镉 (Cd)	六价铬 (Cr(VI))	多溴联苯 (PBB)	多溴二苯醚 (PBDE)
28993587	X	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.

8.6.7 Other regulations and standards

Introduction

This section describes the standards that apply to the product.

Additional design considerations

For additional design considerations, such as ASME-BPE, GMP and cGMPs information refer to the product-specific specification information provided in the documentation package delivered with each equipment.

8.7 Further information

Process wetted materials

For a complete list of wetted materials, refer to the Equipment List and the General Specification in the product documentation package.

Spare parts and accessories

Additional information regarding spare parts and acccessories can be found in the system documentation.

Your local Cytiva representative will also be able to suggest recommended spare parts and accessories.

Remaining aspects

Regarding any of the below topics, please contact your local Cytiva representative for advice.

- Training
- Service
- Method optimization
- Ordering information
- Other issues not covered by this manual

Contact information is found on the back cover of this manual.

8.8 Health and Safety Declaration Form

On site service

cytiva

On Site Service Health & Safety Declaration Form

Service Ticket #:	

To make the mutual protection and safety of Cytiva service personnel and our customers, all equipment and work areas must be clean and free of any hazardous contaminants before a Service Engineer starts a repair. To avoid delays in the servicing of your equipment, complete this checklist and present it to the Service Engineer upon arrival. Equipment and/or work areas not sufficiently cleaned, accessible and safe for an engineer may lead to delays in servicing the equipment and could be subject to additional charges.

Yes	No	Review the actions below and answer "Yes" or "No". Provide explanation for any "No" answers in box below.
○	○	**Instrument has been cleaned of hazardous substances**. Rinse tubing or piping, wipe down scanner surfaces, or otherwise make sure removal of any dangerous residue. Make sure the area around the instrument is clean. If radioactivity has been used, perform a wipe test or other suitable survey.
○	○	**Adequate space and clearance is provided to allow safe access** for instrument service, repair or installation. In some cases this may require customer to move equipment from normal operating location prior to Cytiva arrival.
○	○	**Consumables, such as columns or gels, have been removed or isolated from the instrument and from any area that may impede access to the instrument.**
○	○	**All buffer / waste vessels are labeled. Excess containers have been removed from the area to provide access.**
Provide explanation for any "No" answers here:		

Equipment type / Product No:		Serial No:	

I hereby confirm that the equipment specified above has been cleaned to remove any hazardous substances and that the area has been made safe and accessible.

Name:		Company or institution:	
Position or job title:		Date (YYYY/MM/DD):	
Signed:			

Product return or servicing

Health & Safety Declaration Form for Product Return or Servicing

Return authorization number:		*and/or* **Service Ticket/Request:**	

To make sure the mutual protection and safety of Cytiva personnel, our customers, transportation personnel and our environment, all equipment must be clean and free of any hazardous contaminants before shipping to Cytiva. To avoid delays in the processing of your equipment, complete this checklist and include it with your return.

1. Note that items will NOT be accepted for servicing or return without this form
2. Equipment which is not sufficiently cleaned prior to return to Cytiva may lead to delays in servicing the equipment and could be subject to additional charges
3. Visible contamination will be assumed hazardous and additional cleaning and decontamination charges will be applied

Yes	No	Specify if the equipment has been in contact with any of the following:	
◯	◯	Radioactivity (specify)	
◯	◯	Infectious or hazardous biological substances (specify)	
◯	◯	Other Hazardous Chemicals (specify)	

Equipment must be decontaminated prior to service / return. Provide a telephone number where Cytiva can contact you for additional information concerning the system / equipment.

Telephone No:		
Liquid and/or gas in equipment is:	☐	**Water**
	☐	**Ethanol**
	☐	**None, empty**
	☐	**Argon, Helium, Nitrogen**
	☐	**Liquid Nitrogen**
	Other, specify	

Equipment type / Product No:		**Serial No:**	

I hereby confirm that the equipment specified above has been cleaned to remove any hazardous substances and that the area has been made safe and accessible.

Name:		**Company or institution:**	
Position or job title:		**Date (YYYY/MM/DD)**	
Signed:			

To receive a return authorization number or service number, call local technical support or customer service.

Appendix A
Create a method with UNICORN 5

About this chapter

This chapter describes how to create a method for UniFlux 10 system in the UNICORN ***Method Editor***.

In a basic example, the general structure of a method is shown, along with the different steps required to create it.

For information about methods in general, and for detailed information about the ***Method Editor***, refer to the UNICORN manuals.

In this chapter

A.1 The ***Method Editor***

In this section

A.1.1 Introduction to the *Method Editor*

Description

The ***Method Editor*** is used to build new methods in a step-by-step manner using blocks and instructions as building elements. The ***Method Editor*** can also be used to edit already existing methods.

Blocks

Blocks are used to organize instructions into functional units. A block may, for instance, contain instructions for washing a filter/cartridge. Blocks can be nested (i.e., a block can contain other blocks).

Blocks are useful for organizing instructions and structuring methods, and also allow for reuse of existing sets of instructions. Individual blocks can be moved and used in any method (within the same strategy) as required.

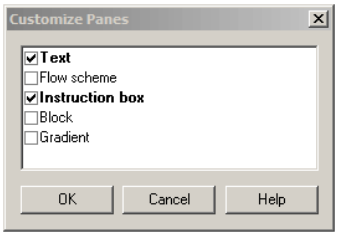
Create a block

The general procedure to create a block in the ***Method Editor*** is:

Step	Action
1	Select ***Block*** →***New...*** from the menu.
2	In the dialog shown, give the block a name and select the type of ***Base*** (***Time*** or ***Volume***) for the block. The choice of base depends on the function of the block.

Open the *Method Editor*

Open the ***Method Editor*** window from the UNICORN ***Manager*** module by selecting it in the task bar at the bottom of the screen.

Step	Action
1	Click on the ***Customize Panes*** icon in the ***Method Editor*** toolbar. 
2	Select ***Text*** and ***Instruction box*** in the ***Customize Panes*** dialog shown. 
3	Click ***OK***. The upper part of the ***Method Editor*** window now shows the ***Text*** pane and the lower part the ***Instruction box***. It is also possible to show an optional flow diagram, or a block diagram in the ***Method Editor***, by selecting the appropriate items in the ***Customize Panes*** dialog. These diagrams can help when programming advanced methods, but are not required for building or editing a method. They are therefore not included in the following discussion.

A.1.2 *Method Editor* layout

Text pane

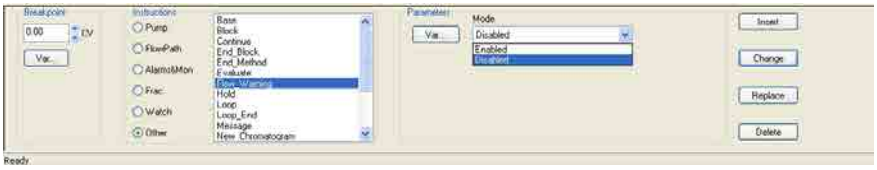
The ***Text*** pane contains an overview of the method in the form of an expandable list with all blocks and instructions in the method. Blocks are marked by blue square symbols. The figure to the right shows a method with several blocks and instructions. For a newly created method, only the ***Main*** block is shown, with a defined ***Base***.

The list in the ***Text*** pane has a tree structure and individual blocks can be expanded or contracted, as indicated by the **+** or **-** signs. When expanded, all the block instructions and nested blocks are displayed and available for editing.

Editing is done in the ***Instruction box*** in the lower part of the ***Method Editor*** window.

Instruction box

The parameters for the block or instruction that is currently selected in the ***Text*** pane are displayed and available for editing in the ***Instruction box*** in the lower part of the ***Method Editor*** window.



The ***Instruction box*** is divided into four areas. These are, from left to right:

- ***Breakpoint*** — Contains a field for setting the breakpoint for the instruction or block, in the unit currently selected as ***Base*** (***Time*** or ***Volume***).
- ***Instructions*** — Contains controls for selecting an instruction from a list. The instructions available are grouped according to function. Groups are selected using the radio buttons to the left of the list area.
- ***Parameters*** — Contains parameter fields for the chosen instruction. The parameters will vary between the different instructions.
- Buttons — There are four buttons: ***Insert***, ***Change***, ***Replace***, and ***Delete***. ***Change***, ***Replace*** and ***Delete*** affect the instruction or block currently selected in the ***Text*** pane. ***Insert*** adds a new instruction before, or after (if it has the same breakpoint as an old instruction), the current selection.

Note: *Changing the **Breakpoint** of an instruction using **Change** will move not only the instruction, but also all subsequent instructions in the block. Using **Replace** moves only the selected instruction.*

Instructions placed at the same breakpoint will execute simultaneously, while blocks will execute in the order they occur in the ***Text*** pane.

Changing valve positions, or changing the speed of the pump does not take place momentarily, but requires a small amount of time. A small time lag, such as 0.10 min, should therefore be introduced after time-based instructions affecting mechanical components.

Note: *There is no undo-function in UNICORN for BioProcess and you are therefore recommended to regularly save the method you are working with, preferably using different version numbers.*

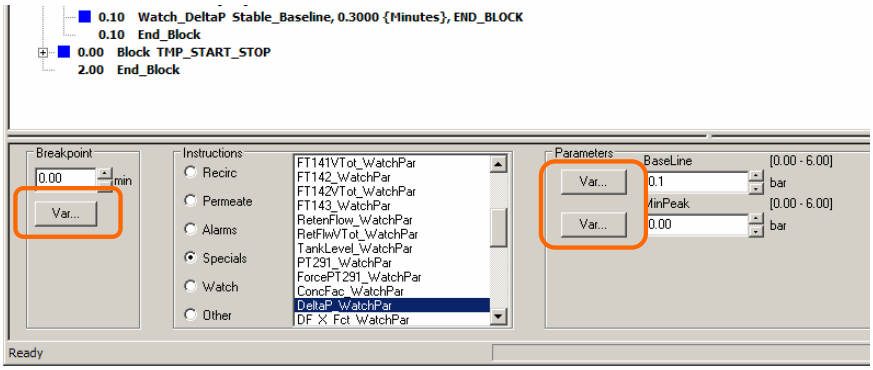
A.1.3 Other *Method Editor* features

Introduction

The method created in the following chapter covers the most basic aspects of how a method is built. Follow this example to learn the basics of designing a filtration method.

A few useful features demonstrated in this example are briefly described here.

Variables



There is one ***Var...*** button in the ***Breakpoint*** field and one ***Var...*** button for each parameter in the ***Parameters*** field.

These are used to create variables representing breakpoints or parameters. Variables enable reuse of defined breakpoints and instructions in other blocks.

Totalizers

A totalizer monitors the accumulated volumes passing through the flow meters. For each totalizer, there is a watch instruction allowing easy programming of desired actions triggered by specific events.

Follow the instruction below to define an action based on the totalizer, for instance for the permeate volume.

Step	Action
1	Reset the totalizer to 0 liters by inserting instruction ***FT142VTot_Reset*** (under ***Permeate***).
2	Insert watch instruction ***Watch_FT142VTot*** (under ***Watch***) and set values for ***Test*** (e.g., ***Greater_Than***), ***Value*** (volume in liters) and ***Action*** (e.g., ***END_BLOCK***).

The allowed noise, or error, for a totalizer can be defined using the appropriate ***FT14VTot_WatchPar*** instruction (under ***Specials***).

A.2 An example of using the ***Method Editor***

In this section

A.2.1 Introduction

About the example

Create a method involves:

1. Creating and naming the method.
2. Adding the blocks and instructions to it.

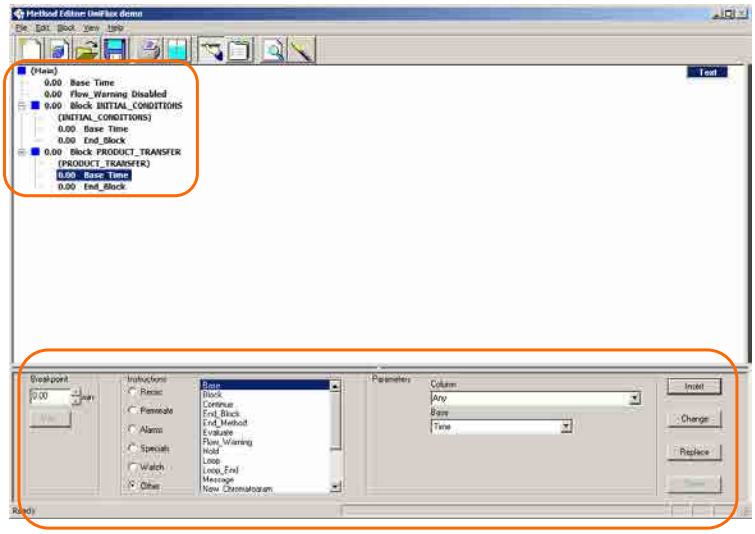
In this section, a basic example is used to illustrate the different steps required.

The steps are explained in detail at the beginning and more briefly in the later parts, as the user becomes familiar with the interaction.

NOTICE

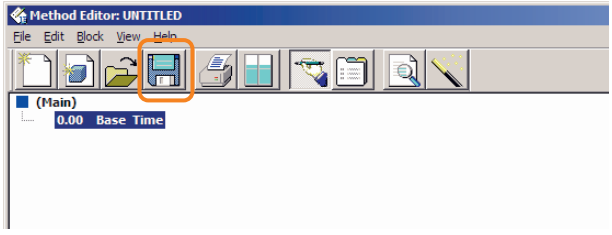
The method used in this example is for training purpose only. It is not intended as an example of a production method.

Tip:



*Modify an instruction by selecting it in the **Text** pane and make the changes in the **Instruction box**.*

Tip:



Save your method at regular intervals while developing it by pressing the disk-icon or select ***File*** *→****Save*** *in the menu.*

Preconditions

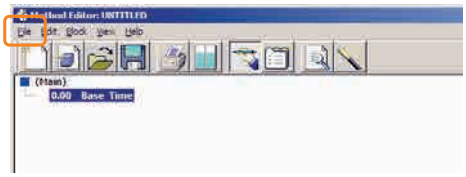
In order to create a method, the following preconditions must be fulfilled:

- A strategy, valid for the system must be installed.[1]
- UNICORN must be installed on a stand-alone computer connected to the UniFlux 10 system.[1]
- UNICORN must be running.
- The correct system must be selected in UNICORN.[1]
- The method developer must have a basic knowledge on how the UNICORN ***Method Editor*** is used.

[1] Installed on customer site.

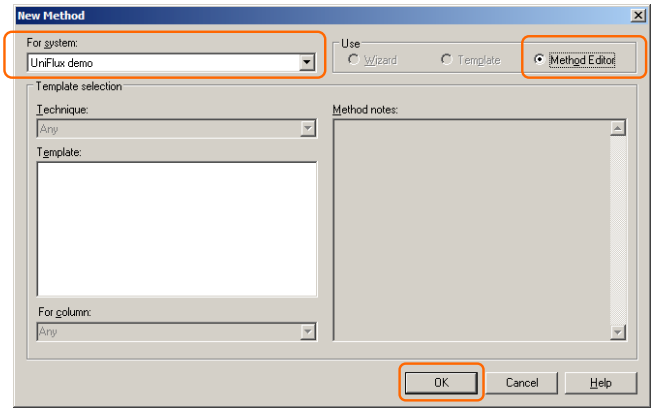
A.2.2 Create the method

This step creates the method and sets some initial conditions to it.

Step	Action
1	 Select ***File*** →***New*** in the ***Method Editor*** menu.

Step	Action

2

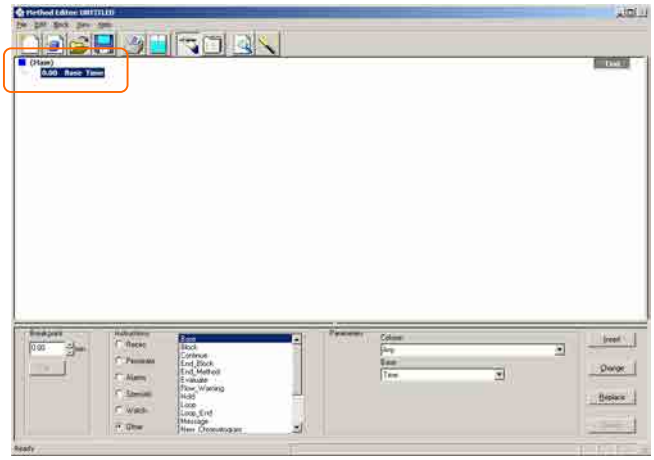


In the ***New Method*** dialog shown:

a. Select the desired system.

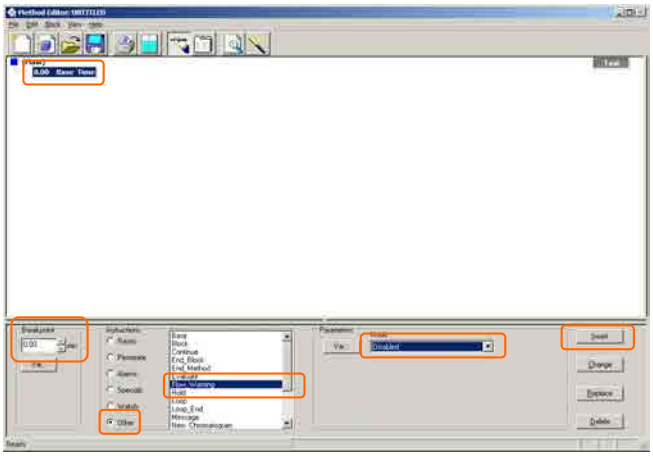
b. Select ***Method Editor*** (pre-selected).

c. Click ***OK***.



The new method will be displayed in the ***Text*** pane as the ***Main*** block with a single ***Base Time*** instruction.

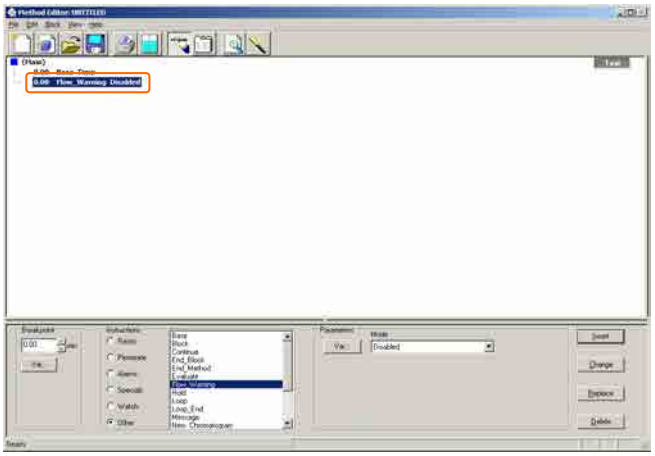
Step	Action
3	This instruction is required to avoid repeated display of the warning message "***No flow in beginning of method***".



a. In the ***Text*** pane, select the ***Base Time*** instruction.

b. In the ***Instruction box***, do the following settings:

- Set ***Breakpoint*** to ***0.00 min***.
- In the ***Instructions*** group box, select ***Other*** and ***Flow_Warning***.
- In the ***Parameters*** field, set ***Mode*** to ***Disabled***.
- Click the ***Insert*** button.



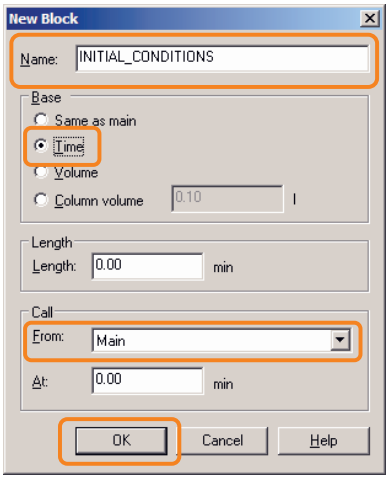
The new instruction will now show up in the ***Text*** pane below ***Base Time***.

A.2.3 Block 1: Initial conditions

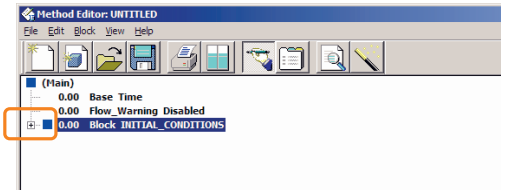
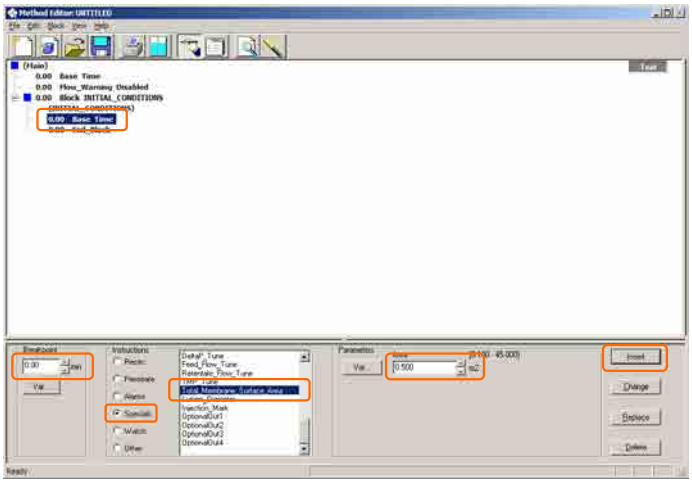
Purpose

The first block in the method will set the filter area and the pressure alarms.

Block: Initial conditions

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Main*** node.
2	 In the ***Method Editor*** menu, select ***Block*** →***New***.
3	 In the ***New Block*** dialog shown, do the following settings: • In the ***Name*** field, type an appropriate name, for instance ***INITAL_CONDITIONS*** (space is not allowed). • In the ***Base*** group box, select ***Time***. • In the ***Call*** group box, select ***Main***. • Click ***OK*** to insert the new block.

Instruction: Membrane area

Step	Action
1	 In the ***Text*** pane, expand the ***Block INITIAL_CONDITIONS*** block by clicking the ***+*** to the left of the block.
2	 In the ***Block INITIAL_CONDITIONS*** instructions list, select the ***Base Time*** instruction.
3	In the ***Instruction box***, do the following settings: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions*** group box, select ***Specials*** and ***Total_Membrane_Surface_Area***. • In the ***Parameters*** field, set ***Area*** to the correct value in ***m2***, depending on your filter setup. • Click the ***Insert*** button. The new instruction will now be displayed in the ***Text*** pane.

Instructions: Filter pressure alarm

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block INITIAL_CONDITIONS*** block.
2	In the ***Instruction box***, do the following settings: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions*** group box, select ***Alarms*** and ***DeltaP_Alarms***. • In the ***Parameters*** field, set ***High Alarm***, ***Low Alarm***, ***High Warn*** and ***Low Warn*** to appropriate values according to the specifications for the filter in use. • In the ***Parameters*** field, set ***Mode*** to ***Enabled***. • Click the ***Insert*** button.

Instructions: TMP alarm

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block INITIAL_CONDITIONS*** block.
2	In the ***Instruction box***, do the following settings: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions*** group box, select ***Alarms*** and ***TMP_Alarms***. • In the ***Parameters*** field, set ***High Alarm***, ***Low Alarm***, ***High Warn*** and ***Low Warn*** to appropriate values according to the specifications for the filter in use or requirements of the intended application (if lower than filter specifications). • In the ***Parameters*** field, set ***Mode*** to ***Enabled***. • Click the ***Insert*** button.

A.2.4 Block 2: Product transfer

Purpose and structure

The second block in the method will fill the tank with the solution to be processed.

This block will contain nested blocks.

Block: Product transfer

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Main*** node.
2	In the ***Method Editor*** menu, select ***Block*** →***New***.
3	In the ***New Block*** dialog: • In the ***Name*** field, type an appropriate name, for instance ***PRODUCT_TRANSFER***. • In the ***Base*** group box, select ***Time***. • In the ***Call*** group box, select ***Main***. • Click ***OK*** to insert the new block.

Nested block: Product transfer path

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block PRODUCT_TRANSFER*** block.
2	In the ***Method Editor*** menu, select ***Block*** →***New***.
3	In the ***New Block*** dialog: • In the ***Name*** field, type an appropriate name, for instance ***PRODUCT_TRANSFER_FLOWPATH***. • In the ***Base*** group box, select ***Time***. • In the ***Call*** group box, select ***Block PRODUCT_TRANSFER***. • Click ***OK*** to insert the new block. The new block will be placed inside the ***Block PRODUCT_TRANSFER*** block.

Instruction: Recirculation loop

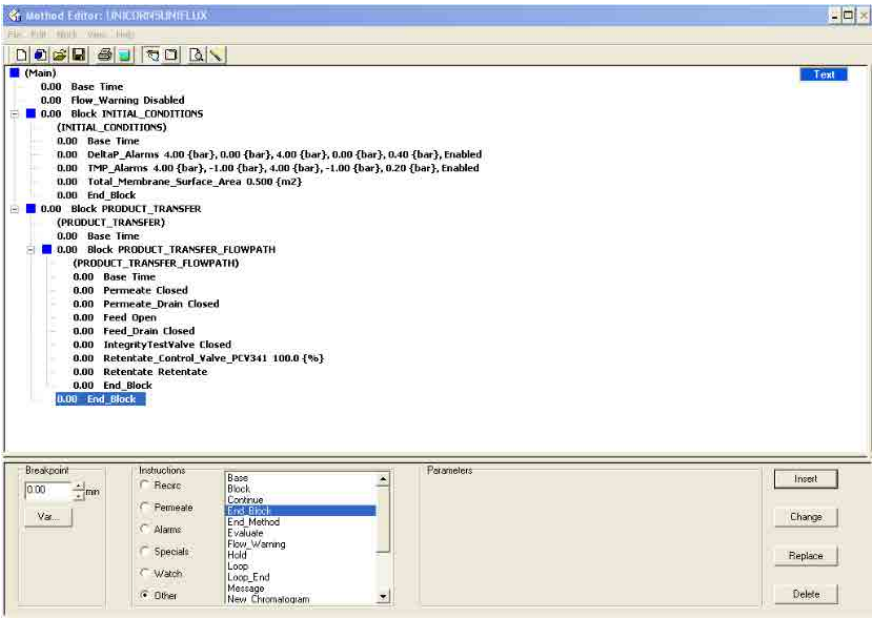
Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block PRODUCT_TRANSFER_FLOWPATH*** block.
2	In the ***Instruction box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions*** group box, select ***Recirc***.
3	Select ***Feed***, set to ***Open***, click ***Insert***.
4	Select ***Feed_Drain***, set to ***Closed***, click ***Insert***.
5	Select ***IntegrityTestValve***, set to ***Closed***, click ***Insert***.
6	Select ***Retentate_Control_Valve_PCV341***, set to ***100 %***, click ***Insert***.
7	Select ***Retentate***, set to ***Retentate***, click ***Insert***.

Instruction: Permeate outlets

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block PRODUCT_TRANSFER_FLOWPATH*** block.
2	In the ***Instruction box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions*** group box, select ***Permeate***.
3	Select ***Permeate***, set to ***Closed***, click ***Insert***.
4	Select ***Permeate_Drain***, set to ***Closed***, click ***Insert***.

Progress review

The ***Method Editor*** should now look something like this.



Nested block: Delay to allow the valves to react

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block PRODUCT_TRANSFER_FLOWPATH*** block
2	In the ***Method Editor*** menu, select ***Block*** →***New***.
3	In the ***New Block*** dialog: • In the ***Name*** field, type an appropriate name, for instance ***DELAY_3_SEC***. • In the ***Base*** group box, select ***Time***. • In the ***Call*** group box, select ***Block PRODUCT_TRANSFER_FLOWPATH***. • Click ***OK*** to insert the new block. The new block will be placed inside the ***Block PRODUCT_TRANSFER_FLOWPATH*** block.
4	In the ***Text*** pane, select the ***End_Block*** instruction of the ***Block DELAY_3_SEC*** block.
5	In the ***Instruction box***: • Set ***Breakpoint*** to ***0.05 min*** (equals 3 seconds). • Click the ***Change*** button.

Nested block: Start and stop the product transfer

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block PRODUCT_TRANSFER*** block.
2	In the ***Method Editor*** menu, select ***Block*** →***New***.
3	In the ***New Block*** dialog: • In the ***Name*** field, type an appropriate name, for instance ***PRODUCT_TRANSFER_VOLUME***. • In the ***Base*** group box, select ***Time***. • In the ***Call*** group box, select ***From*** →***Block PRODUCT_TRANSFER*** and ***At*** →***0.00 min***. • Click ***OK*** to insert the new block. The new block will be placed inside the ***Block PRODUCT_TRANSFER*** block.

Instruction: Transfer feed pump

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block PRODUCT_TRANSFER_VOLUME*** block.
2	In the ***Instruction box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions*** group box, select ***Recirc***. • Select ***TransferFeedPump***, set ***Flow*** to ***90%***, click ***Insert***.

Instruction: Tank level watch

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block PRODUCT_TRANSFER_VOLUME*** block.

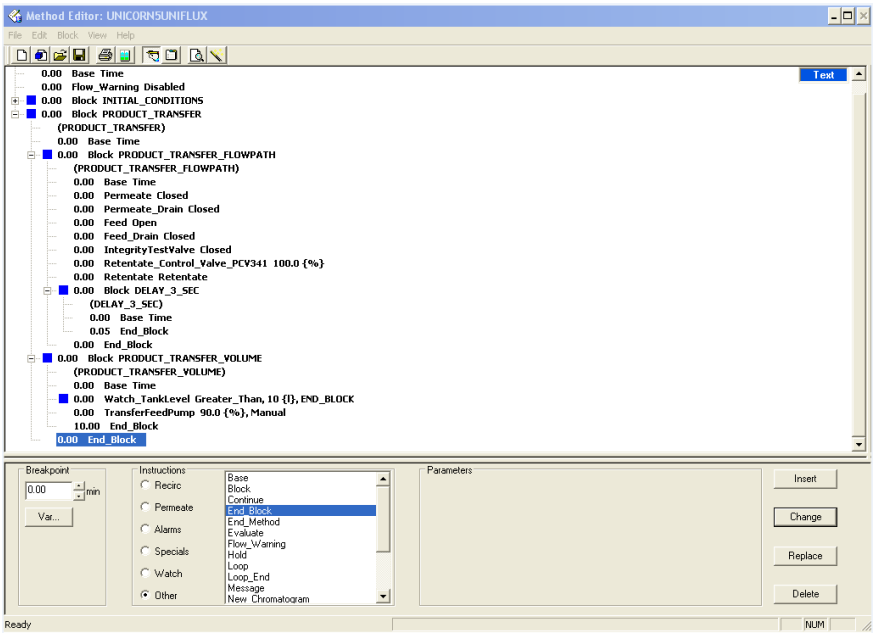
Step	Action
2	In the ***Instruction box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions*** group box, select ***Watch*** and ***WatchTankLevel***. • Set: a. ***Test*** to ***Greater_Than***. b. ***Value*** to a number in liters given by the tank specification or the application requirements. c. ***Action*** to ***END_BLOCK***. • Click the ***Insert*** button.

End block: Allow the tank to be filled

Step	Action
1	In the ***Text*** pane, select the ***End_Block*** instruction of the ***Block PRODUCT_TRANSFER_VOLUME*** block.
2	In the ***Instruction box***: • Set ***Breakpoint*** to a value high enough for the tank to reach the volume set for ***WatchTankLevel*** (in the previous step). • Click the ***Change*** button.

Progress review

The ***Method Editor*** window should now look something like this.


Method Editor: UNICORN5UNIFLUX
File Edit Block View Help
Text
0.00 Base Time
0.00 Flow_Warning Disabled
0.00 Block INITIAL_CONDITIONS
0.00 Block PRODUCT_TRANSFER
(PRODUCT_TRANSFER)
0.00 Base Time
0.00 Block PRODUCT_TRANSFER_FLOWPATH
(PRODUCT_TRANSFER_FLOWPATH)
0.00 Base Time
0.00 Permeate Closed
0.00 Permeate_Drain Closed
0.00 Feed Open
0.00 Feed_Drain Closed
0.00 IntegrityTestValve Closed
0.00 Retentate_Control_Valve_PCV341 100.0 {%}
0.00 Retentate Retentate
0.00 Block DELAY_3_SEC
(DELAY_3_SEC)
0.00 Base Time
0.05 End_Block
0.00 End_Block
0.00 Block PRODUCT_TRANSFER_VOLUME
(PRODUCT_TRANSFER_VOLUME)
0.00 Base Time
0.00 Watch_TankLevel Greater_Than, 10 {l}, END_BLOCK
0.00 TransferFeedPump 90.0 {%}, Manual
10.00 End_Block
0.00 End_Block
Breakpoint
0.00
min
Var...
Instructions
Recirc
Permeate
Alarms
Specials
Watch
Other
Base
Block
Continue
End_Block
End_Method
Evaluate
Flow_Warning
Hold
Loop
Loop_End
Message
New_Chromatogram
Parameters
Insert
Change
Replace
Delete
Ready
NUM

A.2.5 Block 3: Fed-batch concentration

Purpose and structure

This block will start the concentration of the feed.

Block: Fed-batch concentration

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Main*** node.
2	In the ***Method Editor*** menu, select ***Block*** →***New***.
3	In the ***New Block*** dialog: • In the ***Name*** field, type an appropriate name, for instance ***FED_BATCH_CONCENTRATION***. • In the ***Base*** group box, select ***Time***. • In the ***Call*** group box, select ***Main***. • Click ***OK*** to insert the new block.

Nested block: Feed concentration flow path

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block FED_BATCH_CONCENTRATION*** block.
2	In the ***Method Editor*** menu, select ***Block*** →***New***.
3	In the ***New Block*** dialog: • In the ***Name*** field, type an appropriate name, for instance ***FLOWPATH_CONCENTRATION***. • In the ***Base*** group box, select ***Time***. • In the ***Call*** group box, select ***From*** →***Block FED_BATCH_CONCENTRATION*** and ***At*** →***0.00 min***. • Click ***OK*** to insert the new block. The new block will be placed inside the ***Block FED_BATCH_CONCENTRATION*** block.

Instructions: Recirculation loop

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block FLOWPATH_CONCENTRATION*** block.
2	In the ***Instruction box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions*** group box, select ***Recirc***.
3	Set ***Feed*** to ***Open***, click ***Insert***.
4	Set ***Feed_Drain*** to ***Closed***, click ***Insert***.
5	Set ***IntegrityTestValve*** to ***Closed***, click ***Insert***.
6	Set ***Retentate_Control_Valve_PCV341*** to ***100%***, click ***Insert***.
7	Set ***Retentate*** to ***Retentate***, click ***Insert***.

Instructions: Permeate outlets

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block FLOWPATH_CONCENTRATION*** block.
2	In the ***Instruction box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions*** group box, select ***Permeate***.
3	Set ***Permeate_Drain*** to ***Closed***, click ***Insert***.
4	Set ***Permeate*** to ***Permeate***, click ***Insert***.

Nested block: Delay to allow the valves to react

Here, the 3 second delay block created earlier will be reused to allow all valves to react.

Step	Action
1	In the ***Text*** pane, select the last instruction before the ***End_Block*** instruction of the ***Block FLOWPATH_CONCENTRATION*** block.

Step	Action
2	In the ***Instruction box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions*** group box, select ***Other*** and ***Block***.
3	In the ***Parameters*** field, select the ***Block DELAY_3_SEC*** block.
4	Click ***Insert***.

Nested block: Fed-batch concentration parameters

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block FED_BATCH_CONCENTRATION*** block.
2	In the ***Method Editor*** menu, select ***Block*** →***New***.
3	In the ***New Block*** dialog: • In the ***Name*** field, type an appropriate name, for instance ***PARAMETERS_CONCENTRATION***. • In the ***Base*** group box, select ***Time***. • In the ***Call*** group box, select ***From*** →***Block FED_BATCH_CONCENTRATION*** and ***At*** →***0.00 min***. • Click ***OK*** to insert the new block. The new block will be placed inside the ***Block FED_BATCH_CONCENTRATION*** block.

Instruction: Tank level and hysteresis

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block PARAMETERS_CONCENTRATION*** block.
2	In the ***Instruction box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions*** group box, select ***Recirc*** and ***TankLevel***.

Step	Action
3	In the ***Parameters*** field: • Check ***Maintain*** or set ***Setpoint*** for the tank level to a desired value. • Set ***Hysteresis*** to an appropriate value, for instance ***0.5 l***. • Set ***Tank Fill*** to ***Enabled***.
4	Click ***Insert***.

Instruction: Transfer feed setup

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block PARAMETERS_CONCENTRATION*** block.
2	In the ***Instruction box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions*** group box, select ***Recirc*** and ***TransferFeedPump***.
3	In the ***Parameters*** field: • Set ***Setpoint*** (that is the pump flow) to ***50%***. • Set ***StartMode*** to ***TankFill***.
4	Click ***Insert***.

Instruction: Reset the flow meter totalizer

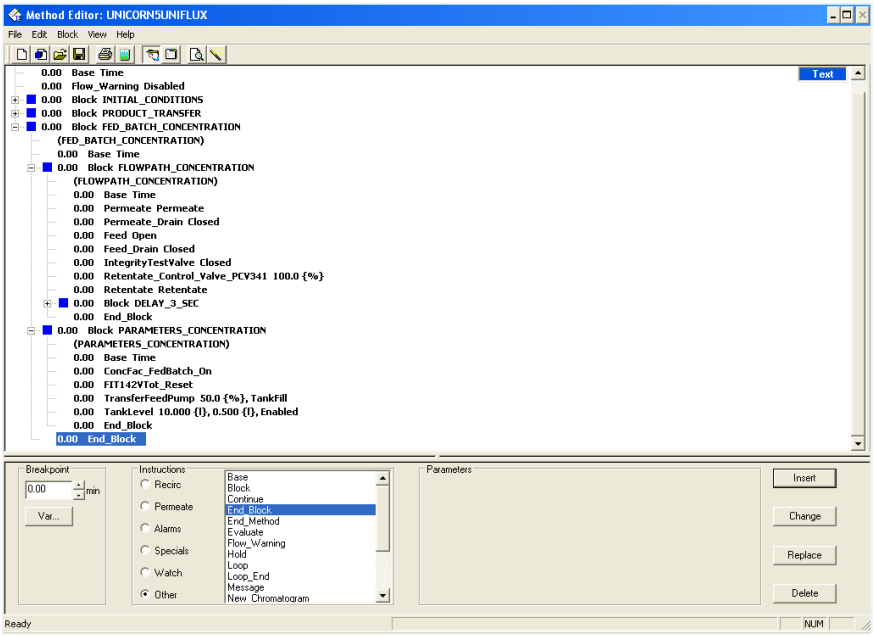
Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block PARAMETERS_CONCENTRATION*** block.
2	In the ***Instruction box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions*** group box, select ***Permeate*** and ***FIT142Tot_Reset***.
3	Click ***Insert***.

Instruction: Start concentration factor calculation

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block PARAMETERS_CONCENTRATION*** block.
2	In the ***Instruction box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions*** group box, select ***Recirc*** and ***ConcFac_FedBatch_On***.
3	Click ***Insert***.

Progress review

The ***Method Editor*** should now look something like this.



Nested block: Stable differential pressure (Delta P)

This block ensures that a stable Delta P value is reached.

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block FED_BATCH_CONCENTRATION*** block.
2	In the ***Method Editor*** menu, select ***Block*** →***New***.
3	In the ***New Block*** dialog: • In the ***Name*** field, type an appropriate name, for instance ***STABLE_DELTA_P***. • In the ***Base*** group box, select ***Time***. • In the ***Call*** group box, select ***From*** →***Block FED_BATCH_CONCENTRATION*** and ***At*** →***0.00 min***. • Click ***OK*** to insert the new block. The new block will be placed inside the ***Block FED_BATCH_CONCENTRATION*** block.

Instruction: Setting Delta P value

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block STABLE_DELTA_P*** block.
2	In the ***Instruction box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions*** group box, select ***Recirc*** and ***DeltaP***.
3	In the ***Parameters*** field, set ***Setpoint*** to an appropriate value, for instance ***1.5 bar***.
4	Click ***Insert***.

Instruction: Setting Delta P variations

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block STABLE_DELTA_P*** block.
2	In the ***Instruction box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions*** group box, select ***Specials*** and ***DeltaP_WatchPar***.

Step	Action
3	In the ***Parameters*** field: • Set ***BaseLine*** to for instance ***0.1 bar***. • Set ***MinPeak*** to ***0.00 bar***.
4	Click ***Insert***.

Instruction: Setting Delta P watch

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block STABLE_DELTA_P*** block.
2	In the ***Instruction box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions*** group box, select ***Watch*** and ***Watch_DeltaP***.
3	In the ***Parameters*** field: • Set ***Test*** to ***Stable_Baseline***. • Set ***Minutes*** to ***1.0***. • Set ***Action*** to ***END_BLOCK***.
4	Click ***Insert***.

Set block end time

Change the block end time to 10 minutes to give Delta P some time to stabilize.

Step	Action
1	In the ***Text*** pane, select the ***End_Block*** instruction of the ***Block STABLE_DELTA_P*** block.
2	In the ***Instruction box***, set ***Breakpoint*** to ***10.00 min***.
3	Click ***Change***.

Nested block: Trans membrane pressure (TMP) setup

This block sets the TMP value.

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block FED_BATCH_CONCENTRATION*** block.
2	In the ***Method Editor*** menu, select ***Block*** →***New***.
3	In the ***New Block*** dialog: • In the ***Name*** field, type an appropriate name, for instance ***TMP_START_STOP***. • In the ***Base*** group box, select ***Time***. • In the ***Call*** group box, select ***From*** →***Block FED_BATCH_CONCENTRATION*** and ***At*** →***0.00 min***. • Click ***OK*** to insert the new block. The new block will be placed inside the ***Block FED_BATCH_CONCENTRATION*** block.

Instruction: Setting the TMP value

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block TMP_START_STOP*** block.
2	In the ***Instruction box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions*** group box, select ***Recirc*** and ***TMP***.
3	In the ***Parameters*** field, set ***Setpoint*** to an appropriate value, for instance ***1.0 bar***.
4	Click ***Insert***.

Instruction: Set the tank level watch

Step	Action
1	In the ***Text*** pane, select the ***Base Time*** instruction of the ***Block TMP_START_STOP*** block.
2	In the ***Instruction box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions*** group box, select ***Watch*** and ***Watch_FIT142VTot***.

Step	Action
3	In the ***Parameters*** field: • Set ***Test*** to ***Greater_Than***. • Set ***Value*** to an appropriate permeate volume. • Set ***Action*** to ***END_BLOCK***.
4	Click ***Insert***.

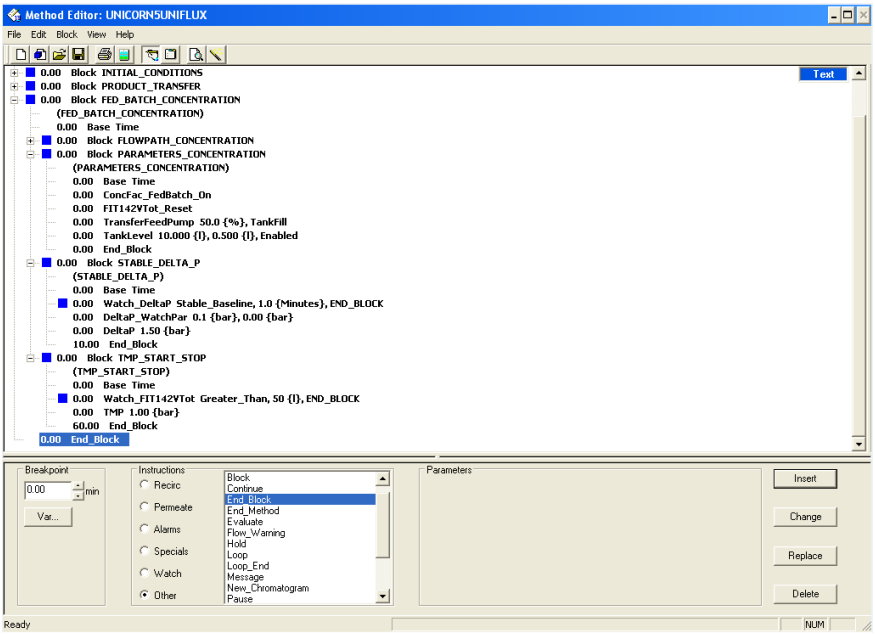
Set block end time

Change the block end time so that the tank level has time to reach the volume set in the tank level watch.

Step	Action
1	In the ***Text*** pane, select the ***End_Block*** instruction of the ***Block TMP_START_STOP*** block.
2	In the ***Instruction box***, set ***Breakpoint*** to a suitable time, for instance ***60.00 min***.
3	Click ***Change***.

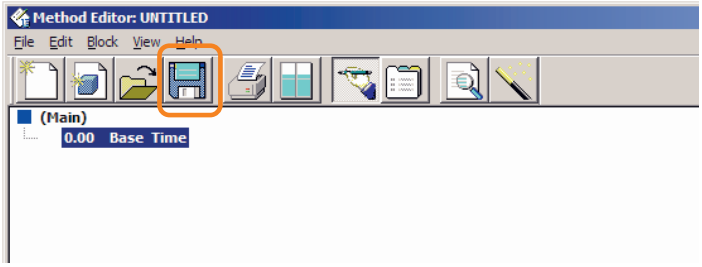
Progress review

If all the steps described above have been performed, the ***Method Editor*** window should now look something like this.



If any step appears to be missing, misplaced or carries incorrect values, use the various editing methods available in the ***Method Editor*** to correct the errors.

A.2.6 Saving the method



To save the method, click the discette icon or select ***File*** →***Save*** in the menu.

Appendix B

Create a method with UNICORN 6 and above

About this chapter

This chapter describes how to create a method for UniFlux 10 system in the UNICORN ***Method Editor***.

In a basic example, the general structure of a method is shown, along with the different steps required to create it.

For information about methods in general, and for detailed information about the ***Method Editor***, refer to the UNICORN manuals.

In this chapter

B.1 The ***Method Editor***

In this section

B.1.1 Introduction to the *Method Editor*

Description

The ***Method Editor*** is used to build new methods in a step-by-step manner using phases, blocks and instructions as building elements. The ***Method Editor*** can also be used to edit already existing methods.

Phases and blocks

Phases and blocks are used to organize instructions into functional units. A phase may, for instance, contain instructions for washing a filter/cartridge. Phases and blocks can be nested (i.e., a block can contain other blocks).

Phases and blocks are useful for organizing instructions and structuring methods, and also allow for reuse of existing sets of instructions. Individual phases and blocks can be moved and used in any method (within the same configuration) as required.

For detailed descriptions of phases and blocks, refer to the UNICORN manuals.

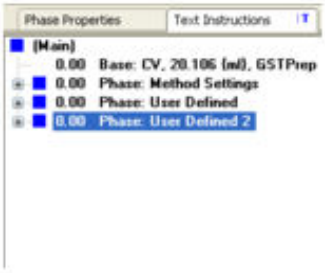
Note: *There are no predefined phases for the UniFlux 10 systems.*

Create a phase

A new empty method has the ***Method Settings*** phase in the ***Method Outline***.

The table below describes how to add a phase to the ***Method Outline*** using drag-and-drop.

Step	Action
1	Select the ***User Defined*** phase in the ***Phase Library*** pane and drag-and-drop the phase to the requested position in the ***Method Outline*** pane. *Result:* The phase is included in the method at the requested position.

Step	Action
2	When the ***User Defined*** phase has been added to the ***Method Outline***, the phase name is enabled for editing.  Type a name for the phase and press the ***Return*** keyboard key. ***Note:*** *The **User Defined** phase is marked with the letter **T**, meaning that it is text edited. This phase contains only **Base** and **End_Block** instructions, so any functional instruction must be added manually.*
3	To include instructions for the ***User Defined*** phase, select the ***Text Instructions*** tab and text edit the method.  ***Note:*** *The **Phase Properties** tab will show a list of variables used in the phase.*

Create a block

Follow this general procedure to create a block in the ***Method Editor***.

Step	Action
1	In the ***Instruction Box***: In the ***Instructions:*** list, select ***Other*** and ***Block***.
2	In the ***Parameters for*** field, type an appropriate name.
3	Click the ***Insert*** button.

B.1.2 *Method Editor* layout

Text Instructions tab

Click the ***Method Editor*** window from UNICORN by selecting it in the task bar at the bottom of the screen.

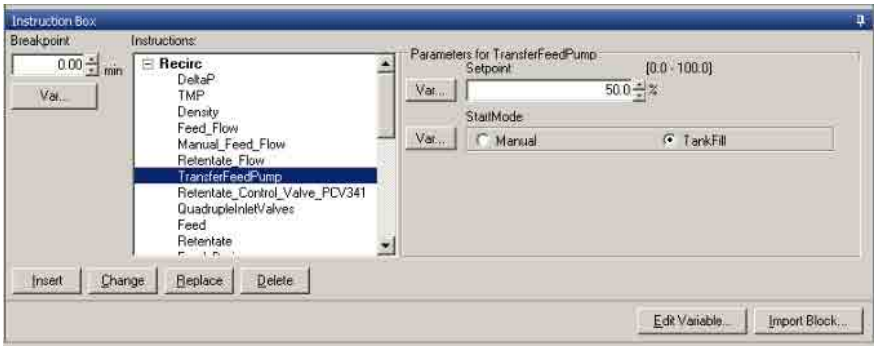
The ***Text Instructions*** tab contains an overview of the method in the form of an expandable list with all phases, blocks and instructions in the method. Phases and blocks are marked by blue square symbols. The figure to the right shows a method with several phases, blocks and instructions. For a newly created method, only the ***Method Settings*** phase is shown in the ***Method Outline***.

The list in the ***Text Instructions*** tab has a tree structure and individual blocks can be expanded or contracted, as indicated by the **+** or **-** signs. When expanded, all the block instructions and nested blocks are displayed and available for editing.

Editing is done in the ***Instruction Box*** below the ***Text Instructions*** tab.

Instruction Box

The parameters for the block or instruction that is currently selected in the ***Text Instructions*** tab are displayed and available for editing in the ***Instruction Box*** below the ***Text Instructions*** tab.



- ***Breakpoint*** — Contains a field for setting the breakpoint for the instruction or block, in the unit currently selected as ***Base*** (***Time*** or ***Volume***).

- ***Instructions:*** — Contains controls for selecting an instruction from a list. The instructions available are grouped according to function.
- ***Parameters for*** — Contains parameter fields for the chosen instruction. The parameters will vary between the different instructions.
- Buttons — There are four buttons: ***Insert***, ***Change***, ***Replace***, and ***Delete***. ***Change***, ***Replace*** and ***Delete*** affect the instruction or block currently selected in the ***Text Instructions*** tab. ***Insert*** adds a new instruction before, or after (if it has the same breakpoint as an old instruction), the current selection.

Note: *Changing the breakpoint of an instruction using* ***Change*** *will move not only the instruction, but also all subsequent instructions in the block. Using* ***Replace*** *moves only the selected instruction.*

Instructions placed at the same breakpoint will execute simultaneously, while blocks will execute in the order they occur in the ***Text Instructions*** tab.

Changing valve positions, or changing the speed of the pump does not take place momentarily, but requires a small amount of time. A small time lag, such as 0.10 min, should therefore be introduced after time-based instructions affecting mechanical components.

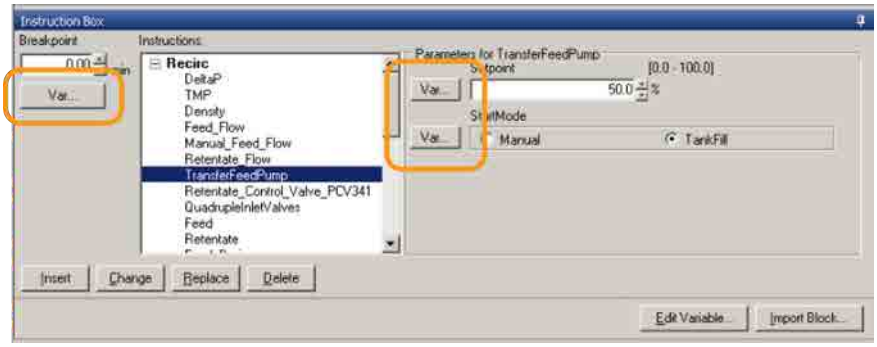
B.1.3 Other *Method Editor* features

Introduction

The method created in the following chapter covers the most basic aspects of how a method is built. Follow this example to learn the basics of designing a filtration method.

A few useful features demonstrated in this example are briefly described here.

Variables



There is one ***Var...*** button in the ***Breakpoint*** field and one ***Var...*** button for each parameter in the ***Parameters for*** field.

These are used to create variables representing breakpoints or parameters. Variables enables reuse of defined breakpoints and instructions in other blocks.

Totalizers

A totalizer monitors the accumulated volumes passing through the flow meters. For each totalizer there is a watch instruction allowing easy programming of desired actions triggered by specific events.

Follow the instruction below to define an action based on the totalizer, for instance for the permeate volume.

Step	Action
1	Reset the totalizer to 0 liters by inserting instruction ***FT142VTot_Reset*** (under ***Permeate***).
2	Insert watch instruction (under ***Watch***) and set values for ***Signal (FT142Vtot)***, ***Test*** (e.g., ***Greater_Than***), ***Value*** (volume in liters) and ***Action*** (e.g., ***End block***).

The allowed noise, or error, for a totalizer can be defined using the appropriate ***FT14VTot_WatchPar*** instruction (under ***Specials***).

B.2 An example of using the ***Method Editor***

In this section

B.2.1 Introduction

About the example

Create a method involves the following steps:

1. Creating and naming the method.
2. Adding the blocks and instructions to it.

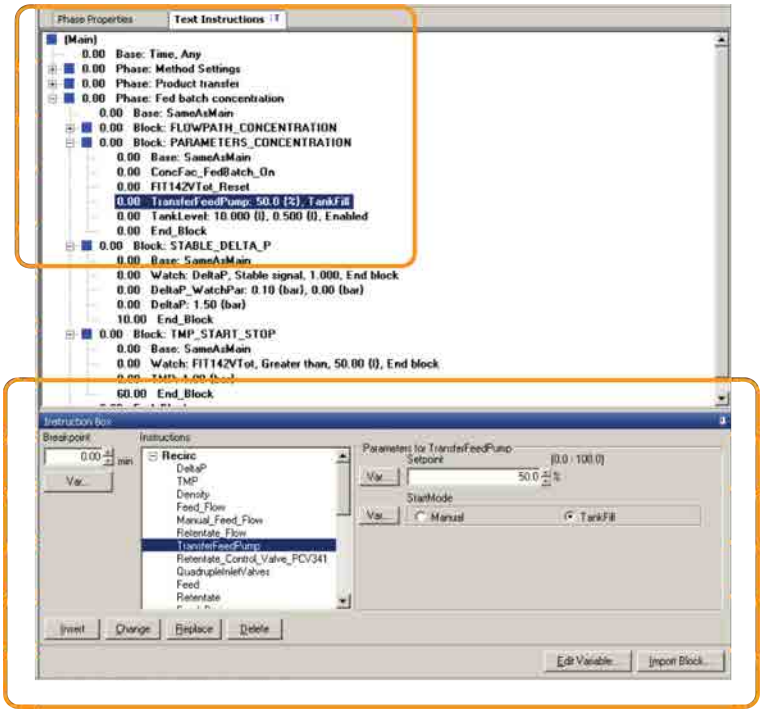
In this section, a basic example is used to illustrate the different steps in the procedure.

The steps are explained in detail at the beginning and more briefly in the later parts, as the user becomes familiar with the interaction.

NOTICE

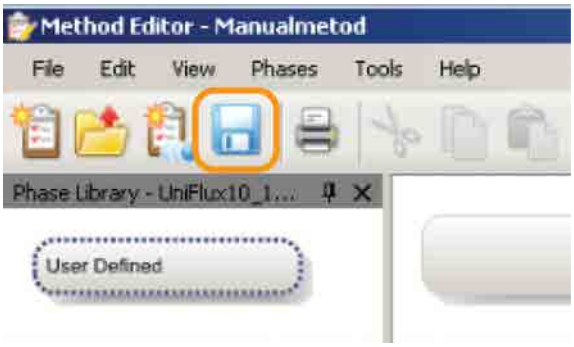
The method used in this example is for training purpose only. It is not intended as an example of a production method.

Tip:



*Modify an instruction by selecting it in the **Text Instructions** tab and make the changes in the **Instruction Box**.*

Tip:



Save your method at regular intervals while developing it by pressing the disk-icon or select ***File*** *→****Save*** *in the menu.*

Preconditions

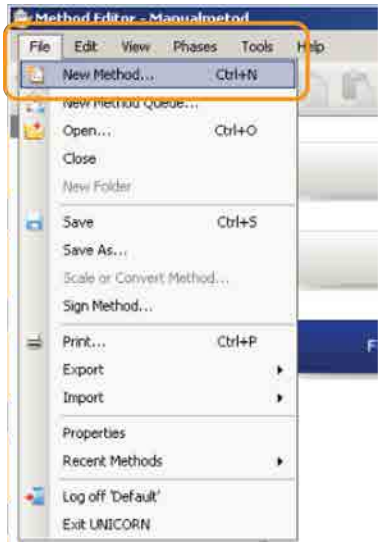
In order to create a method, the following preconditions must be fulfilled:

- A configuration, valid for the system must be installed.[1]
- UNICORN must be installed on a stand-alone computer connected to the UniFlux 10 system.[1]
- UNICORN must be running.
- The correct system must be selected in UNICORN.[1]
- The method developer must have a basic knowledge on how the UNICORN ***Method Editor*** is used.

[1] Installed on customer site.

B.2.2 Create the method

The following step creates the method and sets some initial conditions to it.

Step	Action
1	 Select ***File*** →***New Method*** in the ***Method Editor*** menu.

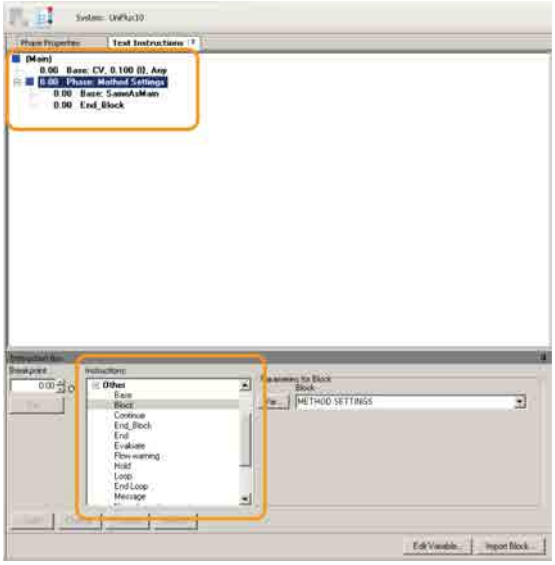
Step	Action
2	

In the ***New Method*** dialog shown:

a. Select the desired system.

b. Click ***OK***.

The new method will be displayed in the ***Text Instructions*** tab.



The new method starts with the ***Phase →Method Settings*** phase, for UniFlux 10 systems this contains a ***Base →SameAsMain*** instruction and an ***End_Block*** instruction.

c. Under the ***Main*** node, select the ***Base:*** instruction.

d. In the ***Instruction Box***, select ***Other*** and set the instruction ***Base*** parameter ***Column Type*** to ***Any***, and the ***Base*** parameter to ***Time***.

B.2.3 Phase 1: Method Settings

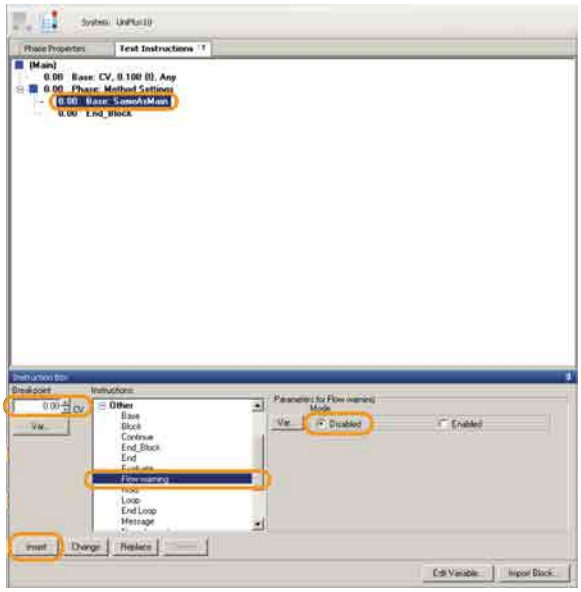
Purpose

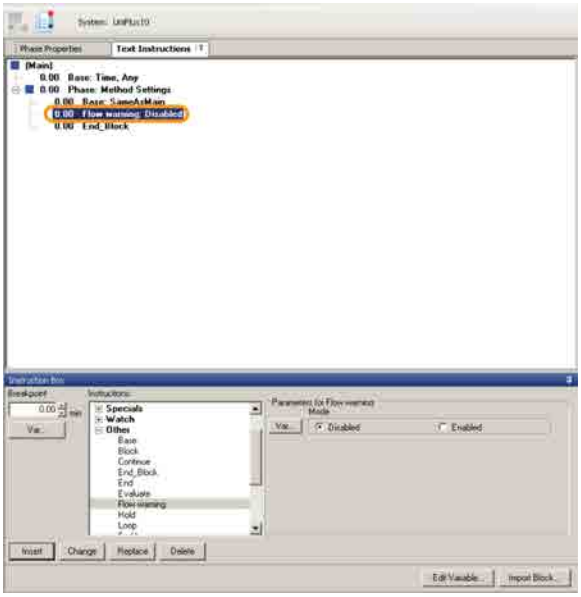
The first phase in the method will set the filter area and the pressure alarms.

Phase: Method Settings

This instruction is required to avoid repeated display of the warning message "***No flow in beginning of method***".

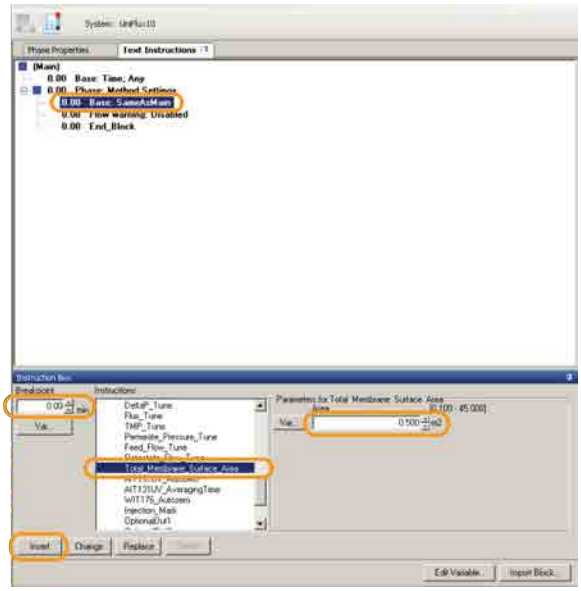
Step	Action
1	In the ***Text Instructions*** tab, expand the ***Phase*** →***Method Settings*** phase by pressing the ***+*** to the left of the phase.
2	Select the ***Base*** →***SameAsMain*** instruction of the ***Phase*** →***Method Settings*** phase.



Step	Action
3	In the ***Instruction Box***, do the following settings: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Other*** and ***Flow_Warning***. • In the ***Parameters for*** field, set ***Mode*** to ***Disabled***. • Click the ***Insert*** button. The new instruction will now show up in the ***Text Instructions*** tab below ***Base*** →***SameAsMain***. 

Instruction: Membrane area

Step	Action
1	In the ***Text Instructions*** tab, select the ***Base →SameAsMain*** instruction of the ***Phase →Method Settings*** phase.



2	In the ***Instruction Box***, do the following settings: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Specials*** and ***Total_Membrane_Surface_Area***. • In the ***Parameters for*** field, set ***Area*** to the correct value in ***m2*** depending on your filter setup. • Click the ***Insert*** button. The new instruction will now be displayed in the ***Text Instructions*** tab.

Instructions: Filter pressure alarm

Step	Action
1	In the ***Text Instructions*** tab, select the ***Base →SameAsMain*** instruction of the ***Phase →Method Settings*** phase.

Step	Action
2	In the ***Instruction Box***, do the following settings: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Alarms*** and ***DeltaP_Alarms***. • In the ***Parameters for*** field, set ***High Alarm***, ***Low Alarm***, ***High Warn*** and ***Low Warn*** to appropriate values according to the specifications for the filter in use. • In the ***Parameters for*** field, set ***Mode*** to ***Enabled***. • Click the ***Insert*** button.

Instructions: TMP alarm

Step	Action
1	In the ***Text Instructions*** tab, select the ***Base →SameAsMain*** instruction of the ***Phase →Method Settings*** phase.
2	In the ***Instruction Box***, do the following settings: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Alarms*** and ***TMP_Alarms***. • In the ***Parameters for*** field, set ***High Alarm***, ***Low Alarm***, ***High Warn*** and ***Low Warn*** to appropriate values according to the specifications for the filter in use or requirements of the intended application (if lower than filter specifications). • In the ***Parameters for*** field, set ***Mode*** to ***Enabled***. • Click the ***Insert*** button.

B.2.4 Phase 2: Product Transfer

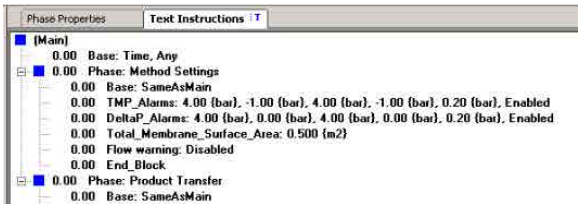
Purpose and structure

The second phase in the method will fill the tank with the solution to be processed.

This phase will contain nested blocks.

Creating a phase: Product Transfer

Follow the instructions below to create a new phase.

Step	Action
1	Select the phase in the ***Phase Library*** pane and drag-and-drop the phase to the requested position in the ***Method Outline*** pane. In the example, a ***User Defined*** phase is used. *Result:* The phase is included in the method at the requested position.
2	When the ***User Defined*** phase has been added to the ***Method Outline***, the phase name is enabled for editing. Type a name for the phase, for instance ***Product Transfer***, and press the ***Return*** keyboard key.  ***Note:*** *The **Product Transfer** phase is marked with the letter **T**, meaning that it is text edited. This phase contains only **Base** and **End_Block** instructions, so any functional instructions must be added manually.*
3	To include instructions for the ***Phase →Product Transfer*** phase, select the ***Text Instructions*** tab and text edit the method.  ***Note:*** *The **Phase Properties** tab will show a list of variables used in the phase.*

Nested block: Product Transfer path

Step	Action
1	In the ***Text Instructions*** tab, select the ***Base →SameAsMain*** instruction of the ***Phase →Product Transfer*** phase.
2	In the ***Instruction Box***, do the following settings: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Other*** and ***Block***. • In the ***Parameters for*** field, type an appropriate name, for instance ***PROD_TRANSFER_FLOWPATH***. • Click the ***Insert*** button. The new block will be placed inside the ***Phase →Product Transfer*** phase.

Instruction: Recirculation loop

Step	Action
1	In the ***Text Instructions*** tab, select the ***Base →SameAsMain*** instruction of the ***Block →PROD_TRANSFER_FLOWPATH*** block.
2	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Recirc***.
3	Select ***Feed***, set to ***Open***, click ***Insert***.
4	Select ***Feed_Drain***, set to ***Closed***, click ***Insert***.
5	Select ***IntegrityTestValve***, set to ***Closed***, click ***Insert***.
6	Select ***Retentate_Control_Valve_PCV341***, set to ***100%***, click ***Insert***.
7	Select ***Retentate***, set to ***Retentate***, click ***Insert***.

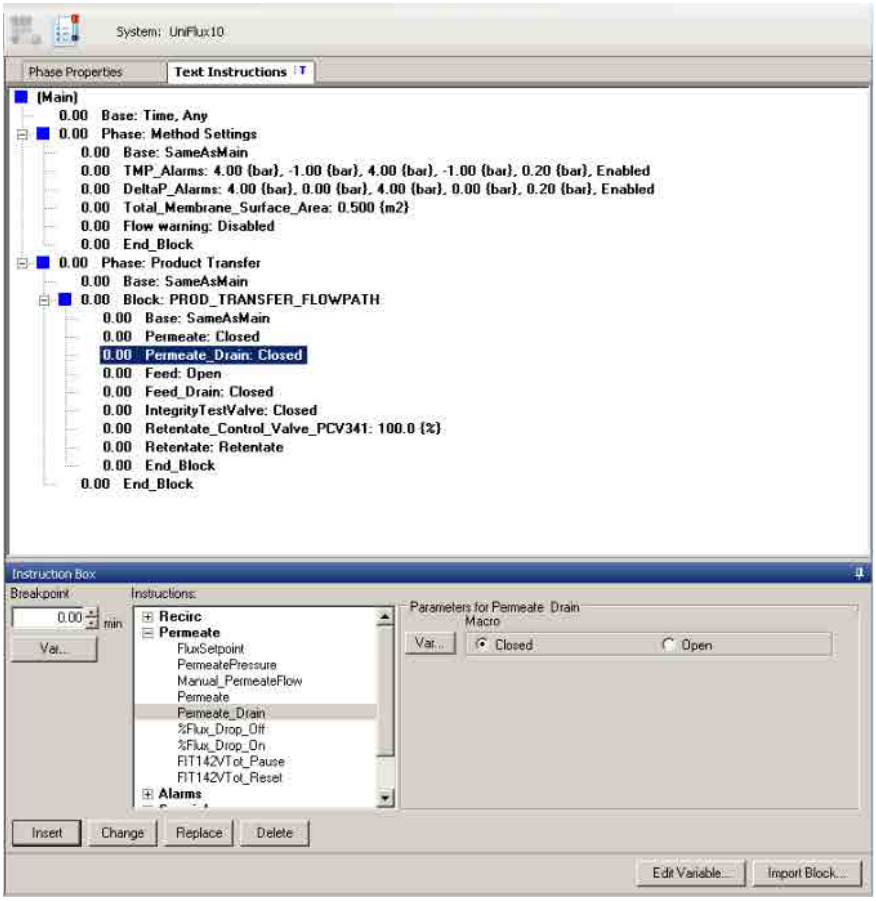
Instruction: Permeate outlets

Step	Action
1	In the ***Text Instructions*** tab, select the ***Base: SameAsMain*** instruction of the ***Block →PROD_TRANSFER_FLOWPATH*** block.

Step	Action
2	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Permeate***.
3	Select ***Permeate***, set to ***Closed***, click ***Insert***.
4	Select ***Permeate_Drain***, set to ***Closed***, click ***Insert***.

Progress review

The ***Method Editor*** should now look something like this.



Nested block: Delay to allow the valves to react

Step	Action
1	In the ***Text Instructions*** tab, select the last instruction before the ***End_Block*** instruction of the ***Block →PROD_TRANSFER_FLOWPATH*** block.
2	In the ***Instruction Box***, do the following settings: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Other*** and ***Block***. • In the ***Parameters for*** field, type an appropriate name, for instance ***DELAY_3_SEC***. • Click the ***Insert*** button. The new block will be placed inside the ***Block →PROD_TRANSFER_FLOW-PATH*** block.
3	In the ***Text Instructions*** tab, select the ***End_Block*** instruction of the ***Block →DELAY_3_SEC*** block.
4	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.05 min*** (equals 3 seconds). • Click the ***Change*** button.

Nested block: Start and stop the product transfer

Step	Action
1	In the ***Text Instructions*** tab, select the ***Block →PROD_TRANSFER_FLOW-PATH*** instruction of the ***Phase →Product transfer*** phase.
2	In the ***Instruction Box***, do the following settings: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Other*** and ***Block***. • In the ***Parameters for*** field, type an appropriate name, for instance ***PROD_TRANSFER_VOLUME***. • Click the ***Insert*** button.

Instruction: Transfer feed pump

Step	Action
1	In the ***Text Instructions*** tab, select the ***Base*** →***SameAsMain*** instruction of the ***Block*** →***PROD_TRANSFER_VOLUME*** block.
2	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Recirc***. • Select ***TransferFeedPump***, set ***Flow*** to ***90%***, click ***Insert***.

Instruction: Tank level watch

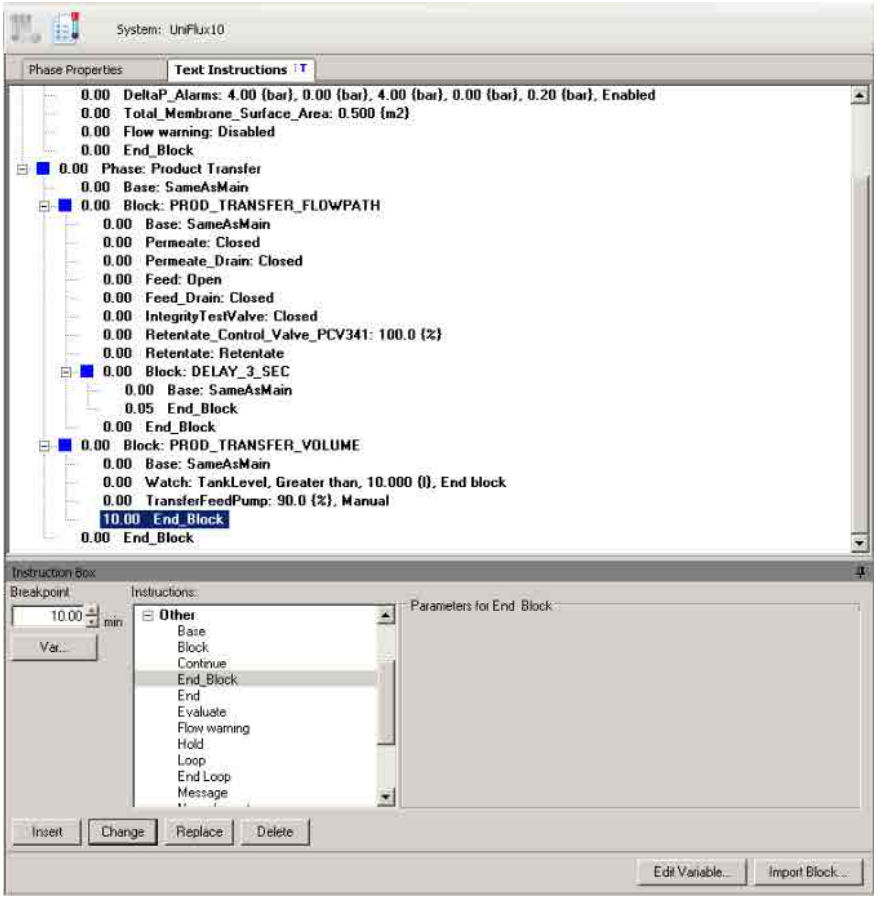
Step	Action
1	In the ***Text Instructions*** tab, select the ***Base*** →***SameAsMain*** instruction of the ***Block*** →***PROD_TRANSFER_VOLUME*** block.
2	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Watch*** and ***Watch***. • Set: a. ***Signal*** to ***Tank_Level***. b. ***Test*** to ***Greater_Than***. c. ***Value*** to a number in liters given by the tank specification or the application requirements. d. ***Action*** to ***End block***. • Click the ***Insert*** button.

End block: Allow the tank to be filled

Step	Action
1	In the ***Text Instructions*** tab, select the ***End_Block*** instruction of the ***Block*** →***PROD_TRANSFER_VOLUME*** block.
2	In the ***Instruction Box***: • Set ***Breakpoint*** to a value high enough for the tank to reach the volume set for ***Watch*** (in the previous step). • Click the ***Change*** button.

Progress review

The ***Method Editor*** window should now look something like this.



B.2.5 Phase 3: Fed Batch Concentration

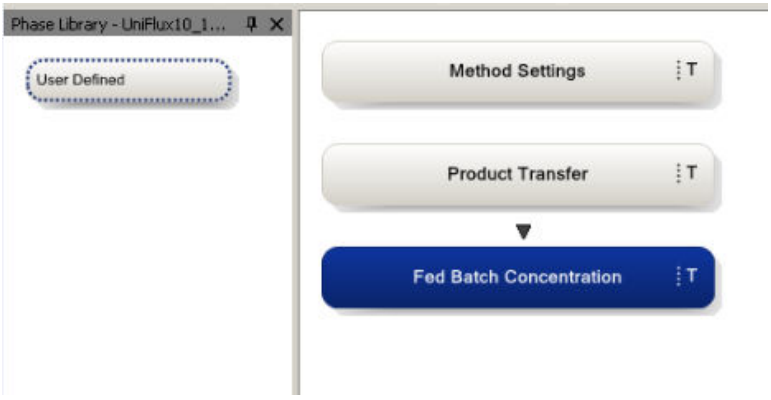
Purpose and structure

This phase will start the concentration of the feed.

Creating a phase: Fed Batch Concentration

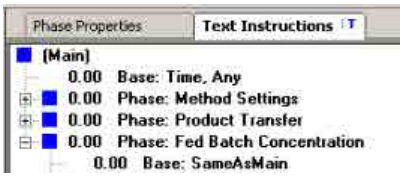
Follow the instructions below to create a new phase.

Step	Action
1	Select the phase in the ***Phase Library*** pane and drag-and-drop the phase to the requested position in the ***Method Outline*** pane. In the example, a ***User Defined*** phase is used. *Result:* The phase is included in the method at the requested position.
2	When the ***User Defined*** phase has been added to the ***Method Outline***, the phase name is enabled for editing. Type a name for the phase, for instance ***Fed Batch Concentration***, and press the ***Return*** keyboard key.



Note:

*The **Fed Batch Concentration** phase is marked with the letter **T**, meaning that it is text edited. This phase contains only **Base** and **End_Block** instructions, so any functional instructions must be added manually.*

Step	Action
3	To include instructions for the ***Phase →Fed Batch Concentration*** phase, select the ***Text Instructions*** tab and text edit the method.  ***Note:*** *The **Phase Properties** tab will show a list of variables used in the phase.*

Nested block: Feed concentration flow path

Step	Action
1	In the ***Text Instructions*** tab, select the ***Base →SameAsMain*** instruction of the ***Phase →Fed Batch Concentration*** phase.
2	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Other*** and ***Block***. • In the ***Parameters for*** field, type an appropriate name, for instance ***FLOWPATH_CONCENTRATION***. • Click the ***Insert*** button. The new block will be placed inside the ***Phase →Fed Batch Concentration*** phase.

Instructions: Recirculation loop

Step	Action
1	In the ***Text Instructions*** tab, select the ***Base →SameAsMain*** instruction of the ***Block →FLOWPATH_CONCENTRATION*** block.
2	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Recirc***.
3	Set ***Feed*** to ***Open***, click ***Insert***.
4	Set ***Feed_Drain*** to ***Closed***, click ***Insert***.

Step	Action
5	Set ***IntegrityTestValve*** to ***Closed***, click ***Insert***.
6	Set ***Retentate_Control_Valve_PCV341*** to ***100%***, click ***Insert***.
7	Set ***Retentate*** to ***Retentate***, click ***Insert***.

Instructions: Permeate outlets

Step	Action
1	In the ***Text Instructions*** tab, select the ***Base →SameAsMain*** instruction of the ***Block →FLOWPATH_CONCENTRATION*** block.
2	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Permeate***.
3	Set ***Permeate_Drain*** to ***Closed***, click ***Insert***.
4	Set ***Permeate*** to ***Permeate***, click ***Insert***.

Nested block: Delay to allow the valves to react

In this block, the 3 second delay block created earlier will be reused to allow all valves to react.

Step	Action
1	In the ***Text Instructions*** tab, select the last instruction before the ***End_Block*** instruction of the ***Block →FLOWPATH_CONCENTRATION*** block.
2	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Other*** and ***Block***.
3	In the ***Parameters for*** field, select the ***Block →DELAY_3_SEC*** block.
4	Click ***Insert***.

Nested block: Fed Batch Concentration parameters

Step	Action
1	In the ***Text Instructions*** tab, select the ***Block →FLOWPATH_ CONCEN-TRATION*** instruction of the ***Phase →Fed Batch Concentration*** phase.
2	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Other*** and ***Block***. • In the ***Parameters for*** field, type an appropriate name, for instance ***PARAMETERS_ CONCENTRATION***. • Click ***Insert***. The new block will be placed inside the ***Phase →Fed Batch Concentration*** phase.

Instruction: Tank level and hysteresis

Step	Action
1	In the ***Text Instructions*** tab, select the ***Base →SameAsMain*** instruction of the ***Block →PARAMETERS_ CONCENTRATION*** block.
2	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Recirc*** and ***TankLevel***.
3	In the ***Parameters for*** field: • Check ***Maintain*** or set ***Setpoint*** for the tank level to a desired value. • Set ***Hysteresis*** to an appropriate value, for instance ***0.5 l***. • Set ***Tank Fill*** to ***Enabled***.
4	Click ***Insert***.

Instruction: Transfer feed setup

Step	Action
1	In the ***Text Instructions*** tab, select the ***Base →SameAsMain*** instruction of the ***Block →PARAMETERS_ CONCENTRATION*** block.

Step	Action
2	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Recirc*** and ***TransferFeedPump***.
3	In the ***Parameters for*** field: • Set ***Setpoint*** (that is the pump flow) to ***50%***. • Set ***StartMode*** to ***TankFill***.
4	Click ***Insert***.

Instruction: Reset the flow meter totalizer

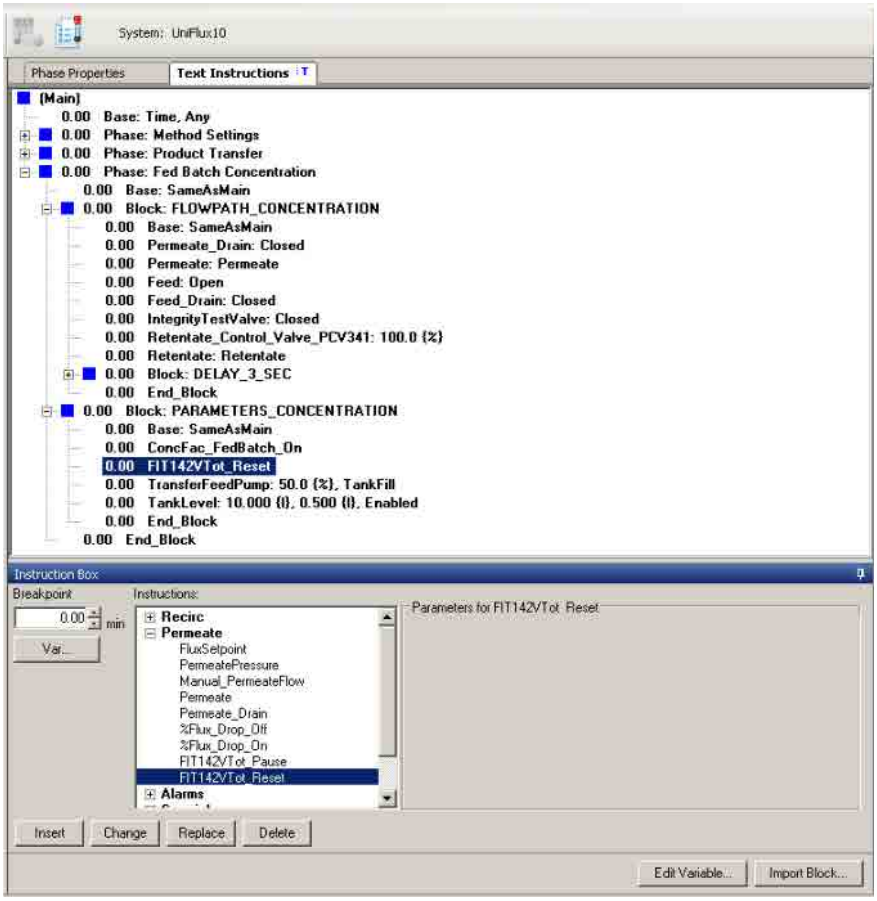
Step	Action
1	In the ***Text Instructions*** tab, select the ***Base →SameAsMain*** instruction of the ***Block →PARAMETERS_CONCENTRATION*** block.
2	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Permeate*** and ***FIT142Tot_Reset***.
3	Click ***Insert***.

Instruction: Start concentration factor calculation

Step	Action
1	In the ***Text Instructions*** tab, select the ***Base →SameAsMain*** instruction of the ***Block →PARAMETERS_CONCENTRATION*** block.
2	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Recirc*** and ***ConcFac_FedBatch_On***.
3	Click ***Insert***.

Progress review

The ***Method Editor*** should now look something like this.



Nested block: Stable differential pressure (Delta P)

This block ensures that a stable Delta P value is reached.

Step	Action
1	In the ***Text Instructions*** tab, select the ***Block*** →***PARAMETERS_CONCENTRATION*** instruction of the ***Phase*** →***Fed Batch Concentration*** phase.

Step	Action
2	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Other*** and ***Block***. • In the ***Parameters for*** field, type an appropriate name, for instance ***STABLE_DELTA_P***. • Click ***Insert***. The new block will be placed inside the ***Phase →Fed Batch Concentration*** phase.

Instruction: Setting Delta P value

Step	Action
1	In the ***Text Instructions*** tab, select the ***Base →SameAsMain*** instruction of the ***Block →STABLE_DELTA_P*** block.
2	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Recirc*** and ***DeltaP***.
3	In the ***Parameters for*** field, set ***Setpoint*** to an appropriate value, for instance ***1.5 bar***.
4	Click ***Insert***.

Instruction: Setting Delta P variations

Step	Action
1	In the ***Text Instructions*** tab, select the ***Base →SameAsMain*** instruction of the ***Block →STABLE_DELTA_P*** block.
2	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Specials*** and ***DeltaP_WatchPar***.
3	In the ***Parameters for*** field: • Set ***BaseLine*** to for instance ***0.1 bar***. • Set ***MinPeak*** to ***0.00 bar***.
4	Click ***Insert***.

Instruction: Setting Delta P watch

Step	Action
1	In the ***Text Instructions*** tab, select the ***Base →SameAsMain*** instruction of the ***Block →STABLE_DELTA_P*** block.
2	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Watch*** and ***Watch***.
3	In the ***Parameters for*** field: • Set ***Signal*** to ***DeltaP***. • Set ***Test*** to ***Stable signal***. • Set ***Minutes*** to ***1.0***. • Set ***Action*** to ***End block***.
4	Click ***Insert***.

Set block end time

Change the block end time to 10 minutes to give Delta P some time to stabilize.

Step	Action
1	In the ***Text Instructions*** tab, select the ***End_Block*** instruction of the ***Block →STABLE_DELTA_P*** block.
2	In the ***Instruction Box***, set ***Breakpoint*** to ***10.00 min***.
3	Click ***Change***.

Nested block: Trans membrane pressure (TMP) setup

This block sets the TMP value.

Step	Action
1	In the ***Text Instructions*** tab, select the ***Block →STABLE_DELTA_P*** instruction of the ***Phase →Fed Batch Concentration*** phase.

Step	Action
2	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Other*** and ***Block***. • In the ***Parameters for*** field, type an appropriate name, for instance ***TMP_START_STOP***. • Click ***Insert***. The new block will be placed inside the ***Phase →Fed Batch Concentration*** phase.

Instruction: Setting the TMP value

Step	Action
1	In the ***Text Instructions*** tab, select the ***Base →SameAsMain*** instruction of the ***Block →TMP_START_STOP*** block.
2	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Recirc*** and ***TMP***.
3	In the ***Parameters for*** field, set ***Setpoint*** to an appropriate value, for instance ***1.00 bar***.
4	Click ***Insert***.

Instruction: Set the permeate totalizer watch

Step	Action
1	In the ***Text Instructions*** tab, select the ***Base →SameAsMain*** instruction of the ***Block →TMP_START_STOP*** block.
2	In the ***Instruction Box***: • Set ***Breakpoint*** to ***0.00 min***. • In the ***Instructions:*** list, select ***Watch*** and ***Watch***.

Step	Action
3	In the ***Parameters for*** field: • Set ***Signal*** to ***FIT142VTot***. • Set ***Test*** to ***Greater_Than***. • Set ***Value*** to volume of permeate. • Set ***Action*** to ***End block***.
4	Click ***Insert***.

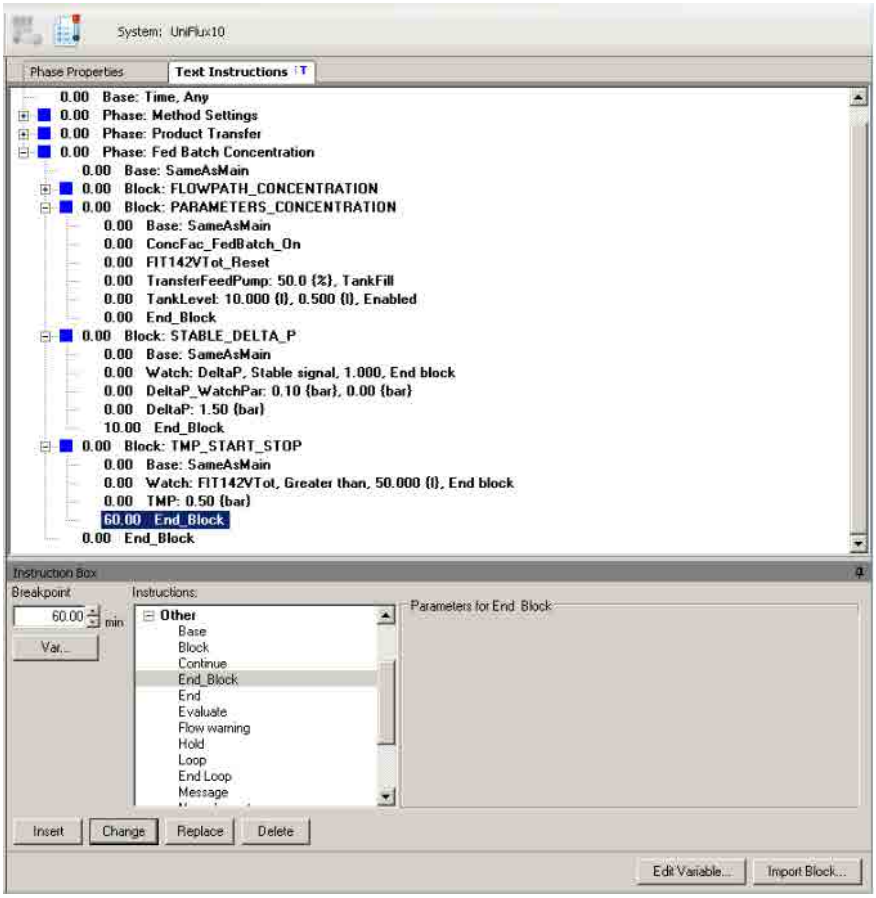
Set block end time

Change the block end time so that the tank level has time to reach the volume set in the tank level watch.

Step	Action
1	In the ***Text Instructions*** tab, select the ***End_Block*** instruction of the ***Block →TMP_START_STOP*** block.
2	In the ***Instruction Box***, set ***Breakpoint*** to a suitable time, for instance ***60.00 min***.
3	Click ***Change***.

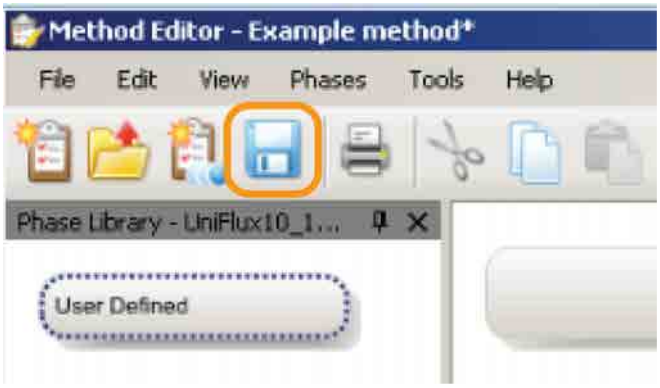
Progress review

If all the steps described above have been performed, the ***Method Editor*** window should now look something like this.



If any step appears to be missing, misplaced or carries incorrect values, use the various editing methods available in the ***Method Editor*** to correct the errors.

B.2.6 Saving the method



To save the method, click the discette icon or select ***File*** →***Save*** in the menu.

Appendix C
Evaluation for UNICORN 5

Associated documentation

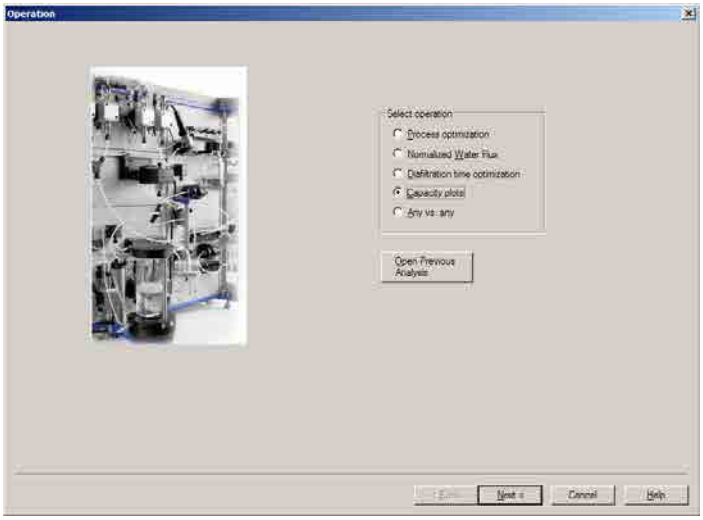
This section is only valid for UNICORN 5. There is no corresponding evaluation function for UNICORN 6.

The use of the ***Crossflow Evaluation*** module in UNICORN 5 is described in detail in the *User Reference Manual - UNICORN 5.1 - Evaluation for Cross Flow Filtration*.

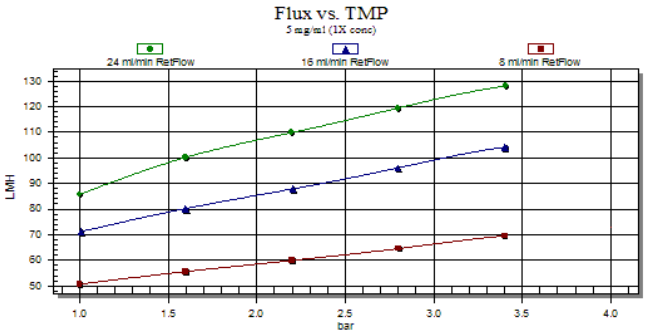
Opening the evaluation module

In UNICORN ***Evaluation*** click the ***Membrane System Evaluation*** icon.

The Operation dialog is displayed.



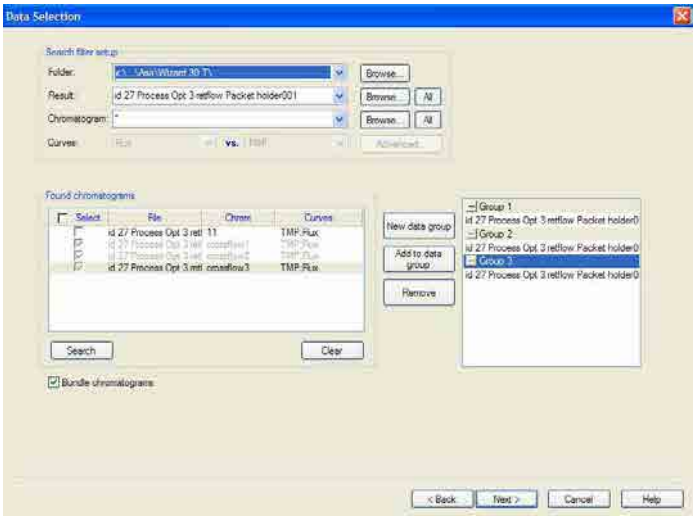
Main functions

Function	Usage
Any vs any	Generates a plot of any combination of process data collected during a run. The process data could be for example detector signals, flows, flux, and pressures.
Process optimization	Creates a graphical analysis of process optimization run(s). For example a process optimization to find an optimal flux as a function of TMP.  The image above shows an example of process optimization.

Evaluation example

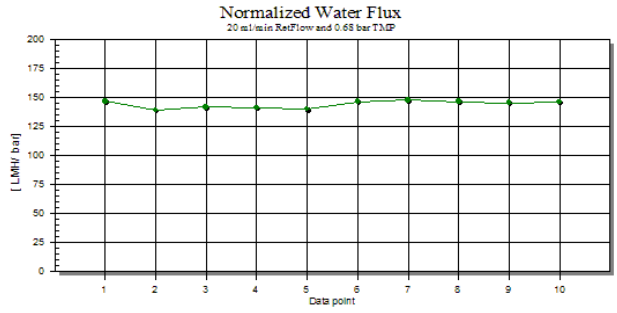
The example is a result from a run with up to three different cross flows in the same run.

Step	Action
1	Select a preferred process result, ***Found chromatograms*** are displayed.
2	Check the box ***Bundle chromatograms***, the Chromatogram groups will be displayed to the right.
3	Check the box for the first chromatogram, e.g. “crossflow 1” and click the ***New data group*** button.
4	Check the box for the second chromatogram, e.g. “crossflow 2” and click the ***New data group*** button.

Step	Action
5	Repeat the procedure until all chromatograms have been selected as groups. The displayed dialog should now look something like this: 
6	Click ***Next*** to continue the evaluation.

Normalized Water Flux

Use this function to get normalized Water Flux values calculated. The results can be used to maintain long term analysis of the filter recovery.



The image shows an example of plotted Normalized Water Flux.

Capacity plots

Use this function to create a graphical analysis of the filter capacity during a filtration.

Appendix D
PID control and feedback tuning

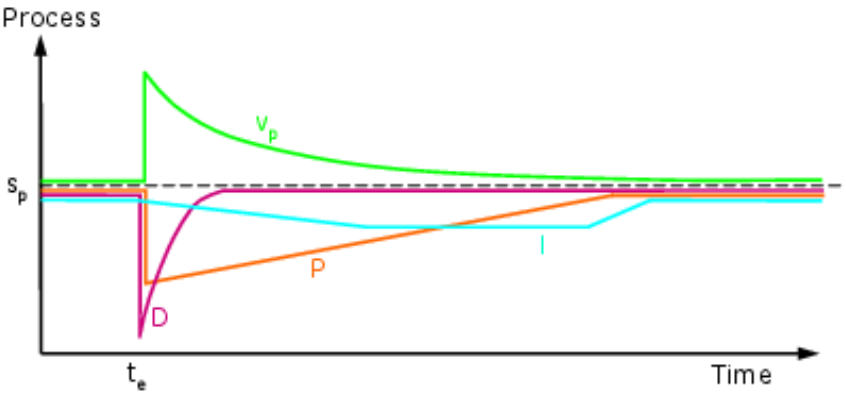
About this chapter

This chapter provides information to enable users to set up a satisfactory control behaviour of the UniFlux 10 by being able to understand and use the PID control functions provided by UNICORN.

In this chapter

D.1 Introduction

Illustration



This illustration shows the behaviour of the P, I and D components of a typical PID process control regulator.

- **Process** is the process to be controlled.
- **Time** is elapsed time.
- **s_p** is the "set point" where the process should operate.
- **t_e** is a point in time where the process is disturbed and the regulator will act.
- **v_p** is the process value.
- **P** (orange) is the proportional component of the regulator.
- **I** (cyan) is the integral component of the regulator.
- **D** (purple) is the derivate component of the regulator.

PID parameter description

Parameter	Meaning	Behaviour	Usage
P	Proportional	Guides the process to its setpoint with an input that varies proportinally to the error.	Reduces the effect of an error but does not completely eliminate it. A simple P-regulator results in a stable stationary error between actual and requested flow or pressure. • Too large P-component will make the system unstable. • Too small P-component will make the regulator slow and prevent it from eliminating the error entirely.

Parameter	Meaning	Behaviour	Usage
I	Integrating	Samples the error over time and reinforces the regulator output as long as the error is not eliminated.	The I parameter eliminates the stationary error, but results in a slight instability leading to oscillations in the actual flow or pressure. The I parameter can have values between 0 and infinity. • Too large I-component will cause the system to oscillate after the error has been eliminated. • Too small I-component will prevent the regulator from eliminating the entire error.
D	Derivating	Delivers an inital "kick" to the regulator with an amplitude that is proportional to the error change rate.	The D parameter can reduce the oscillations introduced by a PI-regulator. D can have values between 0 and infinity. • Too large D-component may cause the system to overshoot initally and make the system sensitive to noise. • Too small D-component may cause for the system to respond slowly to errors and possiblly oscillate.

D.2 Using PID control

Usage in UNICORN for UniFlux 10

Whenever an automated process step requires the control of pressure (feed, retentate and permeate pressure), the UNICORN control software of UniFlux 10 employs PID-type controllers to control the pressure to its setpoint.

The controllers for the feed pump and the trans membrane pressure (TMP) may require adjustment depending on the type and behaviour of the filter.

The I parameter can have values between 0 and infinity. Smaller values have a greater effect and a value of infinity has no effect. Note: The value infinity is set as ***9999*** in UNICORN.

Most often, a simple PI-regulator is preferable for control of pressure, and UniFlux 10 is therefore configured by default with the D parameter set to zero.

Setting up feedback tuning

UNICORN uses so-called PI feedback tuning, where P and I are parameters that determine the tuning characteristics.

There are two ways to apply the feedback tuning instructions:

- In the ***Method Editor*** module.
- In the ***System Control*** module, reached with the commands ***Manual*** or ***System Settings***.

D.3 More information

Introduction

This section describes tuning and adjustments and related troubleshooting.

Tuning the PID parameters

If tuning of the PID control is required, it is most likely that control settings for feed pump or permeate pump need to be adjusted.

Common methods for PID optimization (e.g. *Ziegler-Nichols method*) can be applied.

Faster and slower response

Condition	Then do the following...
If slower, more stable control is required	Increase I Decrease P
If faster (less stable) control is required	Decrease I Increase P
If the system tends to overshoot intially	Decrease D
If the system tends to keep on oscillating after the error has been eliminated	Decrease I Decrease P Increase D

Adjustment rate

No drastic changes should be applied.

An appropriate measure is to change the I parameter by a factor of 0.5 or 2, respectively, while initially keeping the P parameter constant.

Faster regulation required

When optimizing the parameters to obtain a faster regulation, a recommended start may be to do the following:

- Decrease I parameter by dividing with 2.
- Increase P parameter by multiplying with 1.2.

More stable regulation required

When the regulation is too fast, for example noisy curves, it may be necessary to optimize the parameters in the opposite way, i.e., increase I parameter and decrease P parameter.

Troubleshooting

If the parameter...	Is too...	Consequence
P	Large	The system will become unstable.
	Small	The system will respond slow to errors and possibly be unable to eliminate errors completely.
I	Large	The system will oscillate after the error has been eliminated.
	Small	The system will be unable to eliminate errors completely.
D	Large	The system will overshoot initally when regulating for errors.
	Small	The system will be prevented from increasing the P-component enough to achieve fast response without resulting oscillations.

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