GE Healthcare
Life Sciences

UniFlux™ System

Operating Instructions

Original instructions

10

30

120

400

Table of Contents

1 Introduction

Scope of this document

This manual is valid for all variants of standard UniFlux systems. Your system is CE-classified and the system configuration for your system is described in the General Specification and on the system label.

Prerequisites

In order to operate UniFlux System safely and according to the intended use the following prerequisites must be met:

- You should be acquainted with the use of general bioprocessing equipment and with handling of biological materials.
- UniFlux System must be installed according to the instructions in the Installation chapter of this manual.

About this chapter

This chapter contains important user information, description of safety notices, regulatory information, a general description of UniFlux System and its intended use, and a list of associated documentation.

In this chapter

This chapter contains the following sections:

1.1 Important user information

Read this before using UniFlux System

All users must read the Safety chapter of the *Operating Instructions* before installing, using or maintaining UniFlux System.

Do not operate UniFlux System 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 System

UniFlux systems are intended for pilot through 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 is not suitable for operation in a potentially explosive atmosphere or for handling flammable liquids.

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

WARNING

Do not operate UniFlux System in any other way than described in the *Operating Instructions*.

Safety notices

This user documentation contains WARNINGS, CAUTIONS and NOTICES concerning the safe use of the product. See definitions below.

Warnings

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.

Cautions

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.

Notices

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.*

Typographical conventions

Software items are identified in the text by ***bold italic*** text. A colon separates menu levels, thus ***File:Open*** refers to the ***Open*** command in the ***File*** menu.

Hardware items are identified in the text by **bold** text (e.g., **Power** switch).

1.2 Regulatory information

This section lists the directives and standards that are fulfilled by UniFlux System.

Manufacturing information

Requirement	Content
Name and address of manufacturer	GE Healthcare Bio-Sciences AB, Björkgatan 30, SE 751 84 Uppsala Sweden
Place and date of declaration	See EC Declaration of Conformity
Identity of person authorized to sign DoC	See EC Declaration of Conformity

International standards

The following standards have been applied:

Standard	Description	Notes
IEC/EN 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use	
EN 61326-1	EMC emissions and immunity requirements for electrical equipment for measurement, control and laboratory use. Emission according to CISPR 11, Group 1, class A	Harmonized with 2004/108/EC
EN-ISO 12100	Safety of machinery - General principles for design - Risk assessment and risk reduction	Harmonized with 2006/42/EC

Additional regulatory compliance

In addition, this product fulfils the following requirements:

Standard	Description	Notes
ASME-BPE	All steel piping welds, including contact welds	

Standard	Description	Notes
USP class VI, EN 10204 2.1	Traceability for process wetted and pressure retaining polymers and elastomers	
EN 287:1, 1418, EN ISO 15607, 15609-1, 15614-1, 5817, 6520, 3834-2	Welding	

CE Conformity

This product complies with the European directives listed in the table, by fulfilling the corresponding harmonized standards.

A copy of the Declaration of Conformity is available on request.

Directive	Title
2006/42/EC	Machinery Directive (MD)
2004/108/EC	Electromagnetic Compatibility (EMC) Directive

CE Marking

CE

The CE marking and the corresponding Declaration of conformity is valid for the instrument when it is:

- used as a stand-alone unit, or
- connected to other CE marked instruments, or
- connected to other products recommended or described in the user documentation, and
- used in the same state as it was delivered from GE Healthcare, except for alterations described in the user documentation.

Regulatory compliance of connected equipment

Any equipment connected to the UniFlux System should meet the safety requirements of EN 61010-1/IEC 61010-1, or relevant harmonized standards. Within EU, connected equipment must be CE marked.

1.3 Associated documentation

System specific documentation

The most important documents in the document package with regard to technical aspects of UniFlux System are:

Document	Abbreviation	Purpose/Contents
Piping and Instrument Diagram	P&ID	Schematic overview of the entire process flow, all components and instruments and the control system.
General Specification	GS	Technical data for UniFlux System.
Assembly Drawing	AD	Physical layout. Provides all dimensional data.
Bill of Material	BOM	Detailed specifications for process related components.

Software documentation

Together with each system, the following software documentation is supplied providing additional information that applies to UniFlux 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.

Third-party component documentation

Documentation for components produced by a third-party are, if existent, also included in the document package.

2 Safety instructions

About this chapter

This chapter describes safety precautions and emergency shutdown procedures for UniFlux. The labels on the system and information regarding recycling are also described.

Important

WARNING

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

Failure to do this may cause human injury or death, or damage to the equipment.

In this chapter

This chapter contains the following sections:

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 product documents.*

General precautions

WARNING

Perform a risk assessment for any risks due to the process or process environment. Evaluate the effects the use of UniFlux System 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 protection equipment.

WARNING

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 UniFlux System and the entire process.

WARNING

Do not operate UniFlux System in any other way than described in the *Operating Instructions*.

WARNING

Protective earth. UniFlux System must always be connected to protective earth when energized.

WARNING

Do not use UniFlux 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 personnel authorized by GE Healthcare may open the cabinet doors. There is high voltage inside the cabinet that can cause human injury or death.

WARNING

The electric cabinet doors may only be opened when UniFlux System is taken out of operation and subject to **LOCK OUT / TAG OUT**.

Flammable liquids and explosive environment

WARNING

Flammable liquids. UniFlux System is **not approved** to handle flammable liquids.

WARNING

Explosive environment. UniFlux System is **not approved** for work in a potentially explosive atmosphere, in areas classified as Zone 0 to Zone 2 according to IEC 60079-10 2002. UniFlux System does not fulfill the requirements of the ATEX Directive.

Personal protection

WARNING

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

WARNING

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

WARNING

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

CAUTION

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

CAUTION

Do not touch the system while 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

Use ear protection whenever working close to the system in operation.

Installing and moving

WARNING

UniFlux must be installed and prepared by GE Healthcare personnel or third party authorized by GE Healthcare.

WARNING

To prevent bacterial growth, UniFlux System may be partly filled with denatured Ethanol (18% C_2H_5OH (Ethanol), 2% C_3H_7OH (Isopropanol) and 80% H_2O (water)) or 0.1 M NaOH (Sodium Hydroxide) at delivery.

Flush out the denatured Ethanol or Sodium Hydroxide before assembling, testing or integrating UniFlux into the intended process context.

WARNING

Move transport crates. Make sure that the forklift has 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

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

WARNING

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

WARNING

The UniFlux shall only be lifted using the lower part of the skid. The UniFlux is not fitted with lifting eye bolts or other devices for hoist lift.

CAUTION

The wheels of UniFlux should be locked during normal use. The wheels should be unlocked only when moving the unit.

CAUTION

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

CAUTION

UniFlux System is designed for indoor use only.

CAUTION

Do not use UniFlux System 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 System the following must be done:

1 Empty the UniFlux.

2 Shut down the UniFlux and disconnect the power cord.

3 Disconnect the air supply lines.

4 Disconnect all process lines.

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 UniFlux System without pooling.

CAUTION

Make sure that the console arm is firmly positioned with the top part of the handle fully inserted, so that the bushing is able to absorb the weight of the console when the console arm is fully extended. The console may fall and cause damage and/or injury if the console arm is not properly positioned.

CAUTION

When handling the operator console, make sure that no body parts are caught between the sections of the console arm.

NOTICE

Any computer used with the equipment shall comply with IEC 60950 and be installed and used according to the manufacturer's instructions.

Power supply

WARNING

Protective ground. UniFlux System 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, plug, branch circuit protection and disconnect devices. Failure to do so may result in personal injury and/or equipment damage.

WARNING

All electrical installations must be performed by authorized personnel only.

System operation

WARNING

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

WARNING

During operation, all doors must always 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

Operating limits. Never exceed the operating limits stated in this document and on the system label. Operation of UniFlux outside these limits may damage equipment and bodily harm or death may occur.

WARNING

Power failure. During a power failure, or if the **EMERGENCY STOP** button is pressed, UniFlux 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 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 the piping system to leak or break.

WARNING

Alarms signals. Make sure to change back to the original alarm level after UNICORN alarm buzzer test.

CAUTION

If an external Uninterruptible Power Supply (UPS) is used, this unit must be powered before any other equipment.

CAUTION

To safely operate UniFlux System, knowledge of how to use UNICORN is required. Refer to UNICORN user documentation as required.

CAUTION

When handling the operator console, make sure that no body parts are caught between the sections of the console arm.

CAUTION

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

Maintenance

WARNING

LOCK OUT / TAG OUT! Before any maintenance or decommissioning work is performed on UniFlux System, make sure that:

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

WARNING

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

WARNING

Only spare parts and accessories that are approved or supplied by GE Healthcare may be used for maintaining or servicing UniFlux.

WARNING

For continued protection against injury risks due to fluid jets, burst pipes or potentially explosive atmosphere, the piping system must be tested for leakage at maximum pressure:

- After assembly or maintenance
- Before operation or CIP

CAUTION

Do not climb on any parts of UniFlux except where clearly allowed. Follow local regulations and make sure that equipment is properly secured when inspecting UniFlux at high level.

2.2 Labels

Introduction

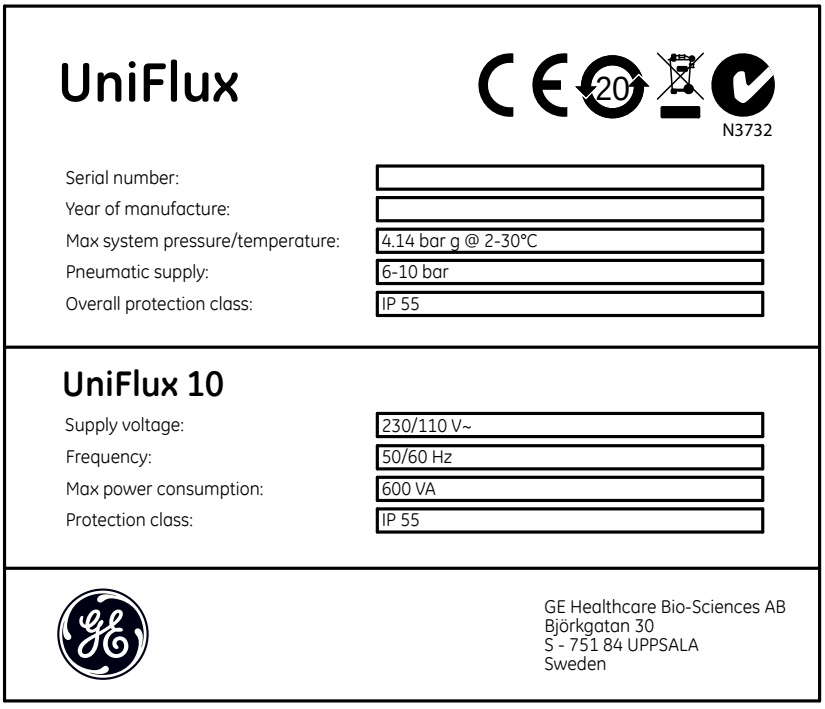
This section describes the various labels on UniFlux and their meaning.

System labels

The illustrations below show examples of system labels for the UniFlux System.

Note: *The specific data shown on the system labels below are only examples. Actual data is specific for each individual system and may vary from system to system.*

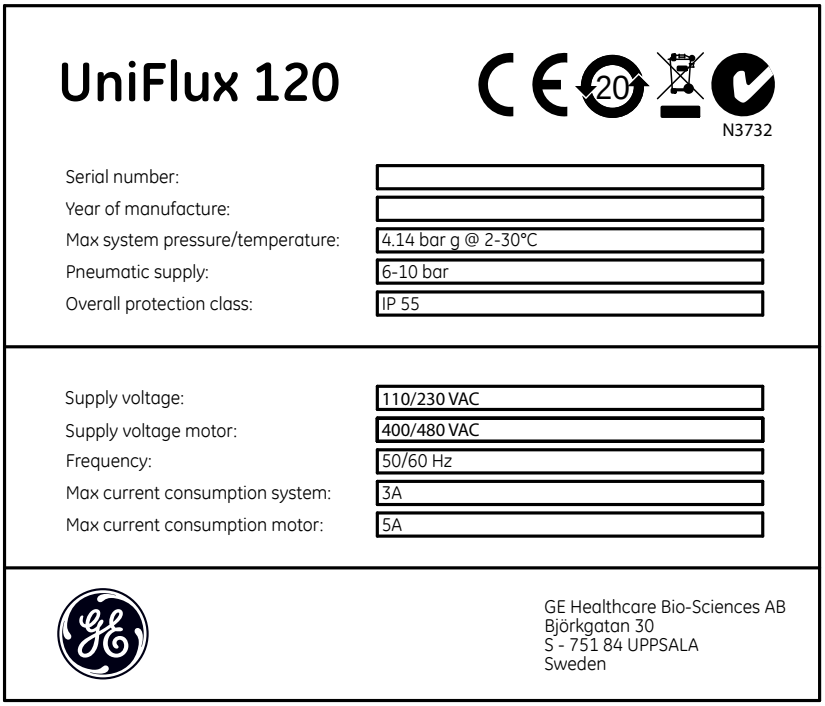
UniFlux 10 system label illustration



UniFlux 10 system label description

Label text	Description
	The system complies with applicable European directives.
	This symbol indicates that the product contains hazardous materials in excess of the limits established by the Chinese standard SJ/T11363-2006 Requirements for Concentration Limits for Certain Hazardous Substances in Electronics.
	This symbol indicates that the waste of 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.
	The system complies with the requirements for electromagnetic compliance (EMC) in Australia and New Zealand.
Serial number	System serial number.
Year of manufacture	Manufacturing year.
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 except the electric cabinet.
Supply voltage	Supply voltage.
Frequency	Supply voltage frequency.
Max power consumption	Max power consumption.
Protection class	Protection class, ingress protection according to IEC 60529. This covers the electric cabinet only.

UniFlux 30 and 120 system label illustration



UniFlux 30 and 120 system label description

Label text	Description
CE	The system complies with applicable European directives.
20	This symbol indicates that the product contains hazardous materials in excess of the limits established by the Chinese standard SJ/T11363-2006 Requirements for Concentration Limits for Certain Hazardous Substances in Electronics.

Label text	Description
	This symbol indicates that the waste of 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.
	The system complies with the requirements for electromagnetic compliance (EMC) in Australia and New Zealand.
Serial number	System serial number.
Year of manufacture	Manufacturing year.
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 except the electric cabinet.
Supply voltage	Supply voltage.
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.

UniFlux 400 system label illustration

UniFlux™ System		
GE Healthcare Code no.	28982307	
GE Healthcare Serial no.	2777	
GE Healthcare Model no.	UniFlux 400	
Year of manufacture	2011	
Power supply system	1ph110/230VAC	
Power supply pump	3ph400/480VAC	
Frequency	50/60 Hz	
Max current consumption system	5 A	
Max current consumption pump	18 A	
Min fuse rating system	10 A SB	
Min fuse rating pump	30 A SB	
Protection class	IP 55	
Ambient temperature range	2 - 30°C	
Process temperature range	2 - 60°C	
Max process pressure	4.15 bar g	
Pneumatic supply min-max	6 - 10 bar g	
GE Healthcare		**GE Healthcare** **Björkgatan 30** **751 84 UPPSALA** **Sweden**

UniFlux 400 system label description

Label text	Description
	The system complies with applicable European directives.
	This symbol indicates that the waste of 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.
GE Healthcare Code no.	GE Healthcare Code no.
GE Healthcare Serial no.	GE Healthcare Serial no.
GE Healthcare Model no.	GE Healthcare Model no.
Year of manufacture	Year of manufacture.
Power supply system	Power supply system.
Power supply pump	Power supply pump.
Frequency	Supply voltage frequency.
Max current consumption system	Max current consumption system.
Max current consumption pump	Max current consumption pump.
Min fuse rating system	Min fuse rating system.
Min fuse rating pump	Min fuse rating pump.
Protection class	Protection class, ingress protection according to IEC 60529. This covers the electric cabinet only.
Ambient temperature range	Ambient temperature range.
Process temperature range	Process temperature range.
Max process pressure	Max process pressure.

Label text	Description
Pneumatic supply min-max	Pneumatic supply min-max.

Safety labels

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

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!** Max operating pressure as stated on the label.
	**EMERGENCY STOP** label, yellow with black text. (emergency stop button is red). Refer to *Section 2.3 Emergency procedures, on page 32* for further information regarding the emergency stop.
	**WARNING! High voltage inside cabinet!** Authorized personnel only! For continued protection against fire, only replace fuses with the same type and rating.
	**IMPORTANT!** Before service/maintenance or return to GE Healthcare, 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.

<table>
<tr><th>Symbol/text</th><th>Description</th></tr>
<tr><td>CAUTION!
Pressure control valve shall be set to 5.5 – 7 bar g for instrument air supply</td><td>CAUTION! Pressure control valve shall be set to 5.5 – 7 bar g for instrument air supply.</td></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</td></tr></table></td></tr>
<tr><td>  </td><td>Use ear protection whenever working close to the system in operation.</td></tr>
<tr><td>  </td><td>Hot surface. Risk of burning injuries.</td></tr>
</table>

2.3 Emergency procedures

Introduction

This section describes how to do an emergency shutdown of UniFlux System, and the result in the event of power failure.

Precautions

WARNING

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

WARNING

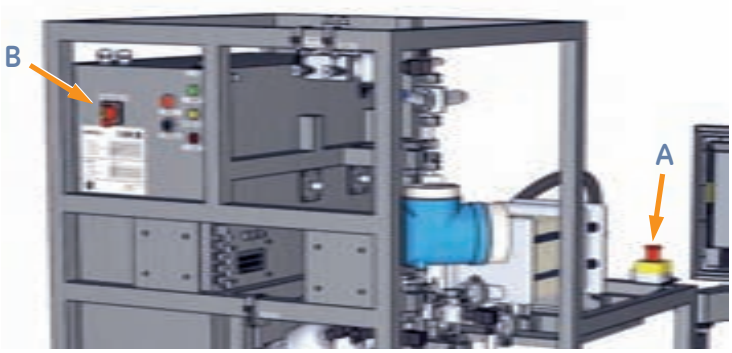
Power failure. During a power failure, or if the **EMERGENCY STOP** button is pressed, UniFlux may remain pressurized. Opening a line or vessel at this point could result in the release of potentially hazardous process or cleaning fluid, and cause bodily harm.

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

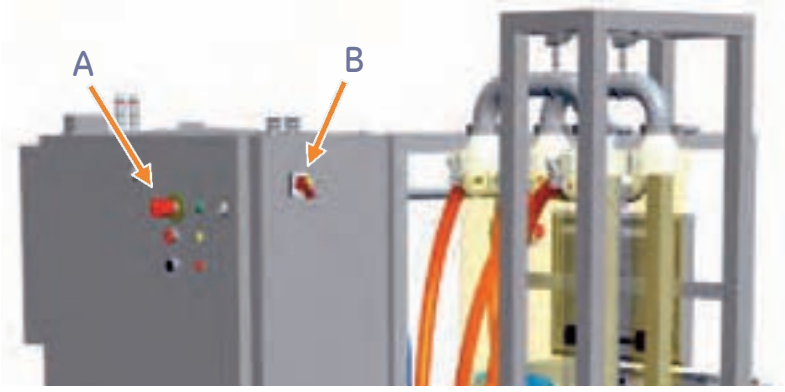
Emergency stop button and main power switch

UniFlux 10

UniFlux 30 and 120



UniFlux 400



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

Emergency shutdown

Step	Action	Result
1	Press the **EMERGENCY STOP** button (A).	• All motors and externally moving components stop immediately. • The built-in computer and other components remain powered. • No data is lost.
2	If required, also switch off the mains power supply (B), disconnect the power cord or switch off the fixed power supply circuit breaker.	• The entire system, including the computer becomes powerless. • Data and run status may become lost.

Power failure

The system power is lost if the **MAIN SWITCH** on the cabinet is turned off, the mains cable disconnected or the power supply is lost.

All pumps stop if the electrical power to the system is lost. All valves will immediately revert to default positions. Any data that has not been saved at that time may be lost.

If only the system is affected by the power failure and not the computer, UNICORN will display text saying that communication has been broken and that no data are recovered. 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 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.

Step	Action
2	
	Reset the **EMERGENCY STOP** button by twisting it clock-wise.
3	Press the ***CONTINUE*** button in UNICORN.

2.4 Recycling information

Introduction

This section contains information about the decommissioning of UniFlux System.

Decontamination

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

Recycling of hazardous substances

UniFlux System contains hazardous substances. Detailed information is available from your GE Healthcare 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.

2.5 Declaration of Hazardous Substances (DoHS)

Introduction

The following product pollution control information is provided according to SJ/T11364-2006 Marking for Control of Pollution caused by Electronic Information Products.

根据SJ/T11364-2006《电子信息产品污染控制标识要求》特提供如下有关污染 控制方面的信息

Symbols used in pollution control label

电子信息产品污染控制标志说明

Label	Meaning
	This symbol indicates the product contains hazardous materials in excess of the limits established by the Chinese standard SJ/T11363-2006 Requirements for Concentration Limits for Certain Hazardous Substances in Electronic Information Products. The number in the symbol is the Environment-friendly Use Period (EFUP), which indicates the period during which the toxic or hazardous substances or elements contained in electronic information products will not leak or mutate under normal operating conditions so that the use of such electronic information 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.

Label	Meaning
	该标志表明本产品含有超过SJ/T11363-2006《电子信息产品中有毒有害物质的限量要求》中限量的有毒有害物质。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

List of hazardous substances and their concentrations

产品中有毒有害物质或元素的名称及含量

Indication for each major part if substance exceeds limit

Value	Meaning
O	Indicates that this toxic or hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in SJ/T11363-2006. 表示该有毒有害物质在该部件所有均质材料中的含量均在SJ/T11363-2006 标准规定的限量要 求以下
X	Indicates that this toxic or hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirement in SJ/T11363-2006. • Data listed in the table represents best information available at the time of publication 表示该有毒有害物质至少在该部件的某一均质材料中的含量超出SJ/T11363-2006 标准规定的 限量要求 • 此表所列数据为发布时所能获得的最佳信息

List of hazardous substances

Component name 部件名称	Hazardous substance 有毒有害物质或元素					
	Pb 铅	Hg 汞	Cd 镉	Cr6+ 六价铬	PBB 多溴联苯	PBDE 多溴二苯醚
UniFlux 10 [1]	X	O	O	O	O	O
UniFlux 30 [1]	X	O	O	O	O	O
UniFlux 120 [1]	X	O	O	O	O	O
UniFlux 400 [1]	X	O	O	O	O	O

1 The product has not been tested as per the Chinese standard *SJ/T11363-2006 Requirements for Concentration Limits for Certain Hazardous Substances in Electronic Information Product.*

3 System description

About this chapter

This chapter provides an overview of the technical properties of UniFlux.

In this chapter

This chapter contains the following sections:

3.1 Overview

General

These Operating Instructions cover the UniFlux 10, 30, 120 and 400 systems.

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

UniFlux systems are intended for pilot through 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.

Material compliance

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

Used materials are traceable back to their production batches.

You can find information about the design and materials used in your system in the System Documentation.

Chemical resistance is described in *Section 9.3 Chemical resistance, on page 157*

A list of process wetted materials can be found in *Section 9.2 Process wetted materials, on page 156*.

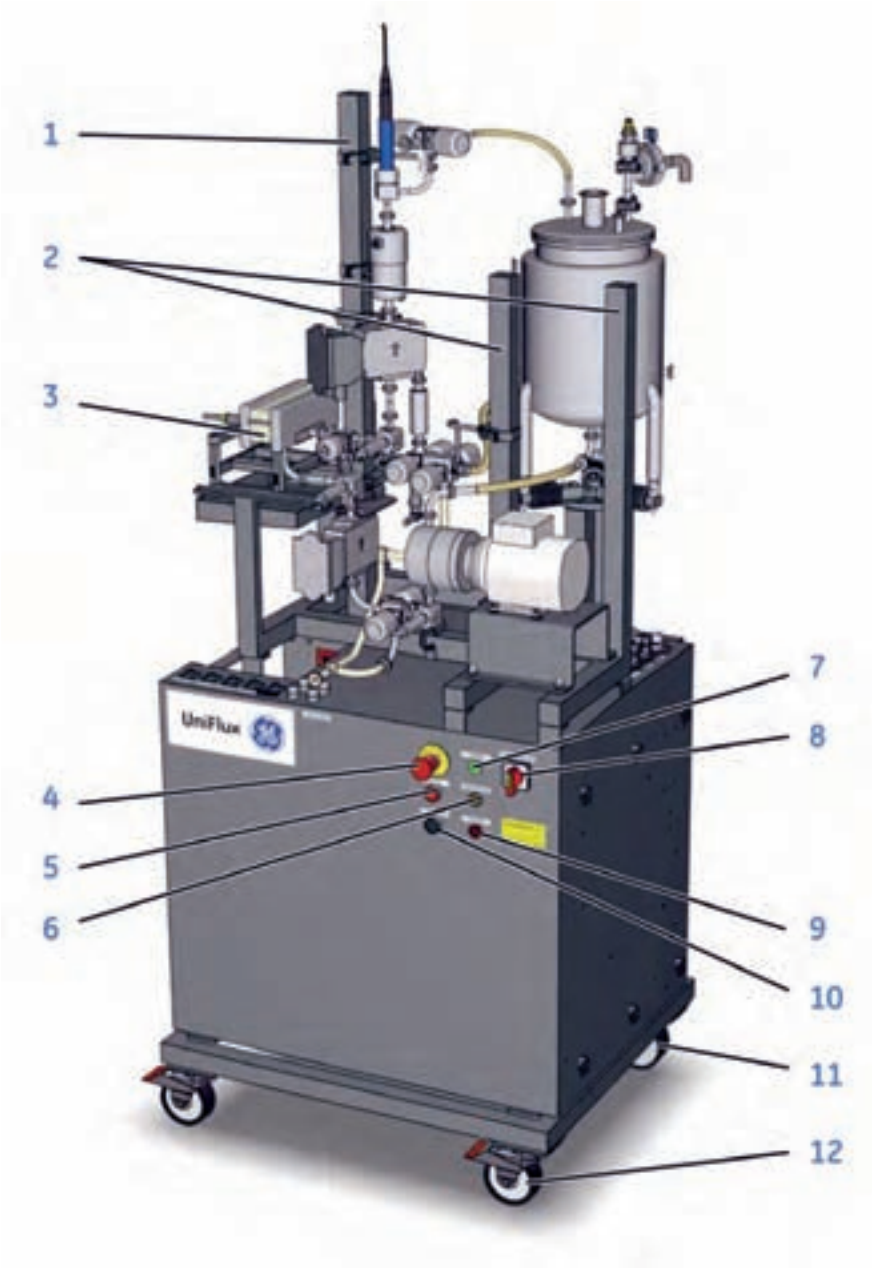
3.2 UniFlux systems layout

In this section

This section contains the following subsections:

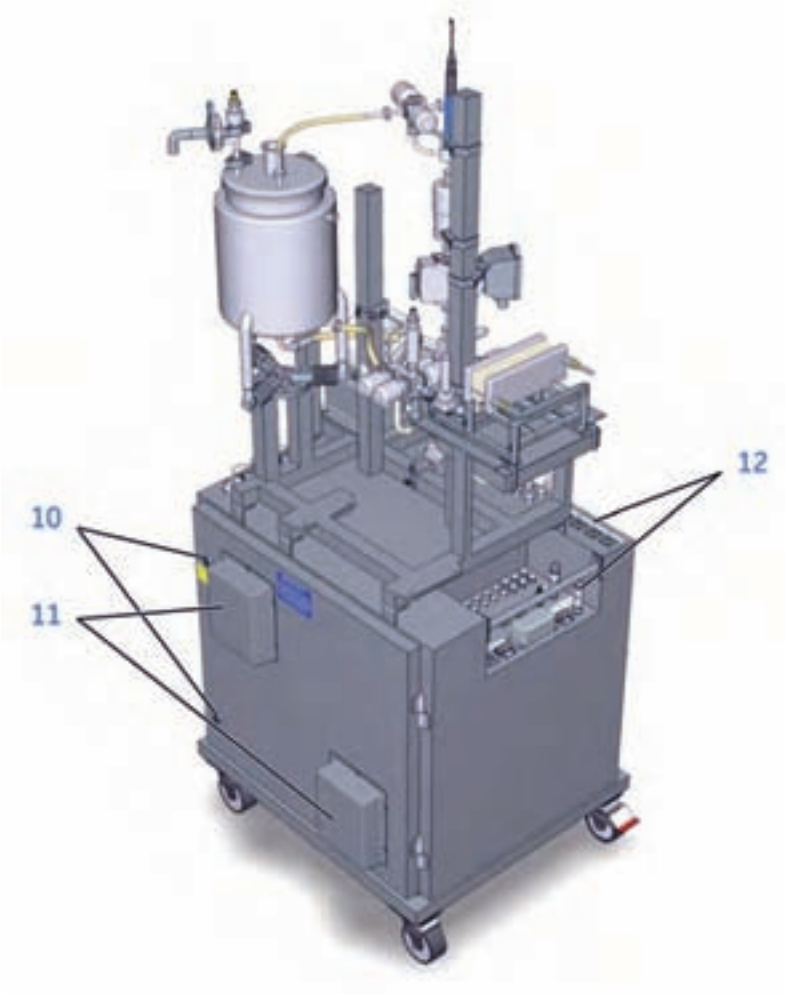
3.2.1 Illustrations of UniFlux 10 system

UniFlux 10: Front view



Part	Function
1	Permeate line equipment mounting beam
2	Tank and peristaltic pumps mounting beam
3	Filter cassette, cassette configuration shown
4	**EMERGENCY STOP** button
5	**PAUSE** button
6	**RUN/PAUSE** indicator light
7	**POWER** indicator light
8	**MAIN SWITCH**, power
9	**ALARM** indictaor light
10	UNICORN **CONTINUE** button
11	Caster without brake (2 pcs)
12	Caster with brake (2 pcs)

UniFlux 10: Rear view



Part	Function
10	Electric cabinet door locks (2)
11	Filter and fan for cabinet cooling
12	External device connectors

UniFlux 10: External connectors

Connectors in front recess

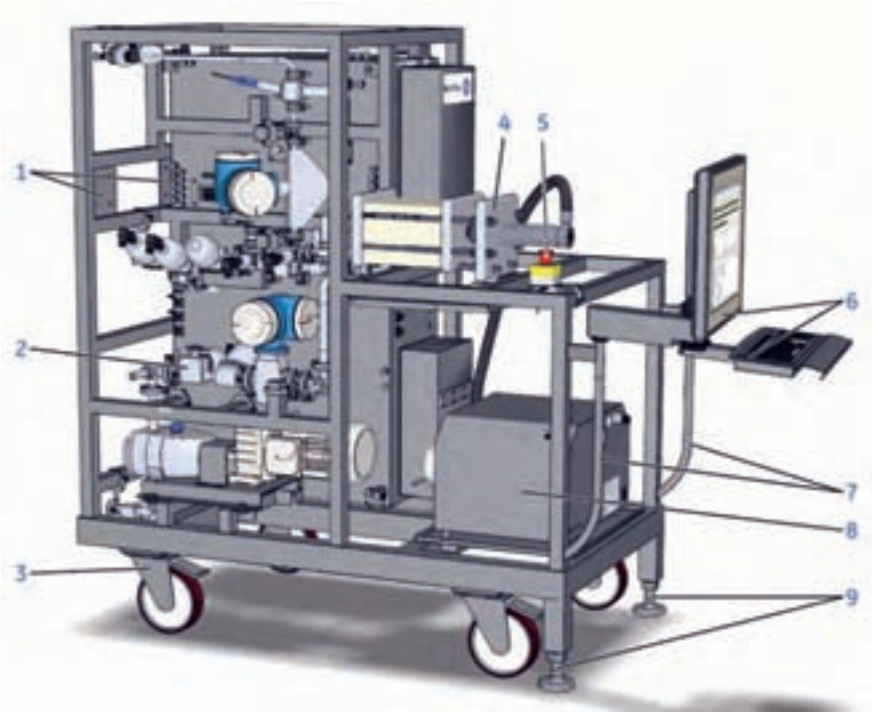
Part	Function
M-241	Mixer motor control
AIT-131	UV-connector
EXTERNAL SIGNALS	Connector for user process site signal communications
PROFIBUS	Profibus connector
AIR INLET	System air inlet
UNICORN ETHERNET	UNICORN Ethernet connector
AIR EXHAUST	System air exhaust
ZSO-064	Hollow fiber drain valve control 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 on rear side

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

3.2.2 Illustrations of UniFlux 30 and 120 systems

UniFlux 30: Front view



The illustration shows UniFlux 30, but also applies to UniFlux 120.

Part	Function
1	Mounting plates for peristaltic pumps
2	CIP-media outlet
3	Swivelling caster with brake (4 pcs)
4	Filter cassette holder
5	Emergency stop button
6	User interface console
7	Skid maneouvering handles
8	Hydraulic manouvering unit for filter cassette holder
9	Adjustable floor supports

UniFlux 30: Rear view

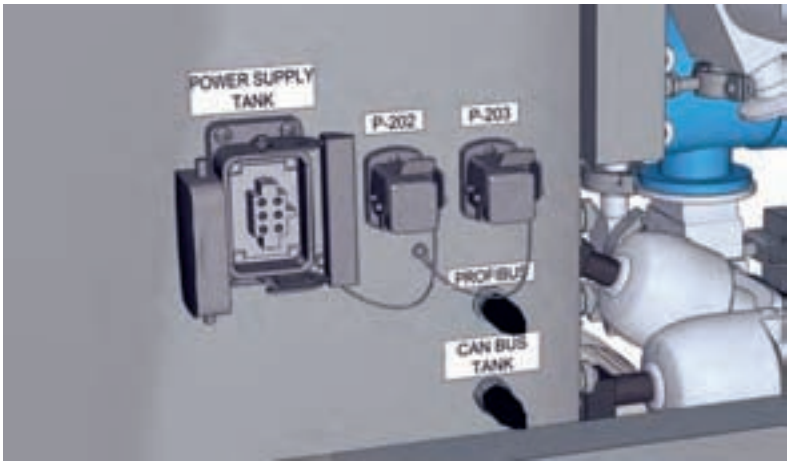
The illustration shows UniFlux 30, but also applies to UniFlux 120.

Part	Function
10	Connectors on top
11	Electric cabinet
12	Permeate outlet connection
13	Permeate recycle connection
14	UNICORN status lights
15	Main power switch
16	System label
17	Retentate outlet (cassette configuration)
18	Electrical connectors

Part	Function
19	Feed inlet connection
20	Feed drain outlet connection

UniFlux 30 and 120: External connectors

Rear wall connectors



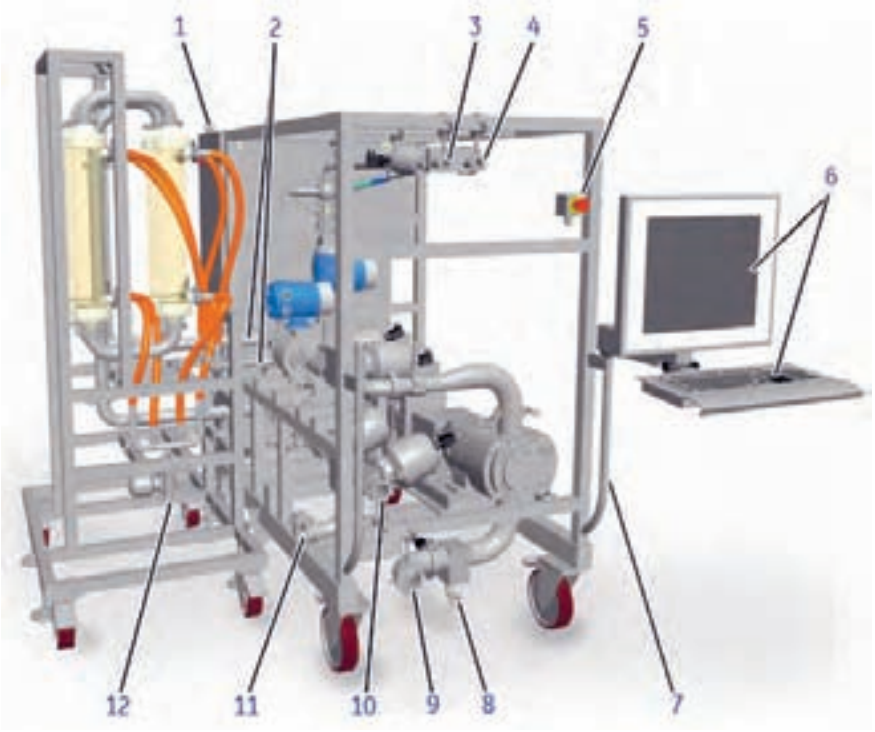
Connector	Function
POWER SUPPLY TANK	Connection to UniFlux tank if provided
P-202	Connection to transfer pump option
P-203	Connection to permeate pump option
PROFIBUS	Connection to UniFlux tank Profibus control (or other controlled external equipment)
CAN BUS TANK	Connection to UniFlux tank CAN-bus control

Top connectors

Connector	Function
UNICORN ETHERNET	Unicorn Ethernet connection
LTS-166	Connection to external tank digital level sensors
AIR EXHAUST	System air exhaust
AIR INLET	System air inlet
EXTERNAL SIGNALS	Connection to process site signals

3.2.3 Illustrations of UniFlux 400 system

UniFlux 400: Front view



Part	Function
1	Connectors on top
2	Filter skid connector pipes
3	Permeate outlet connection
4	Permeate recycle connection
5	Emergency stop button
6	User interface console
7	Skid maneouvering handle
8	Feed drain outlet connection
9	Feed inlet connection

Part	Function
10	Retentate outlet connection
11	Retentate drain outlet connection
12	Filter drain

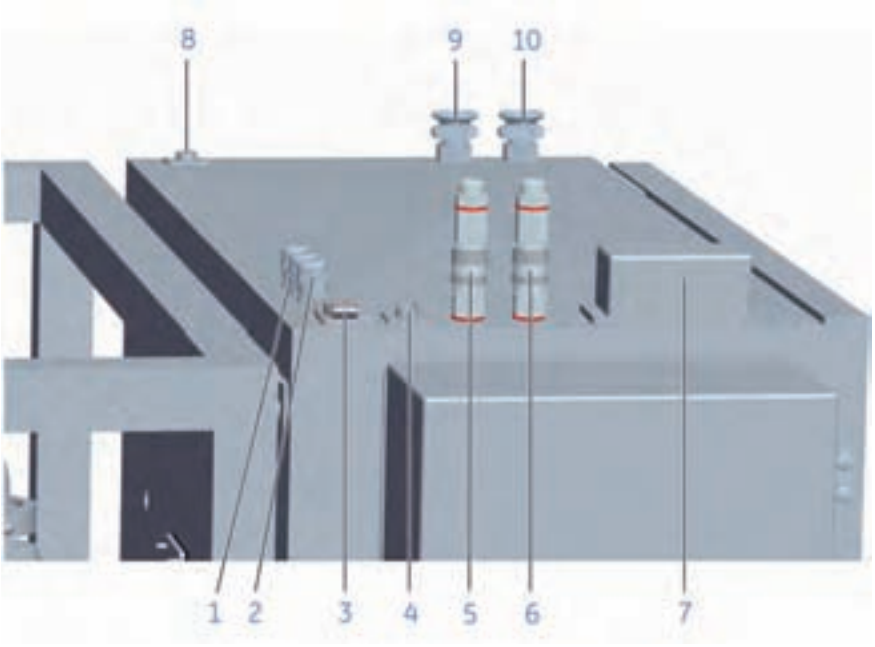
UniFlux 400: Rear view

Part	Function
13	Emergency stop button
14	UNICORN status lights
15	Connectors on top

Part	Function
16	Main power switch
17	Skid maneouvering handle
18	CIP-media outlet
19	Swivelling caster with brake
20	Adjustable floor supports

UniFlux 400: External connectors

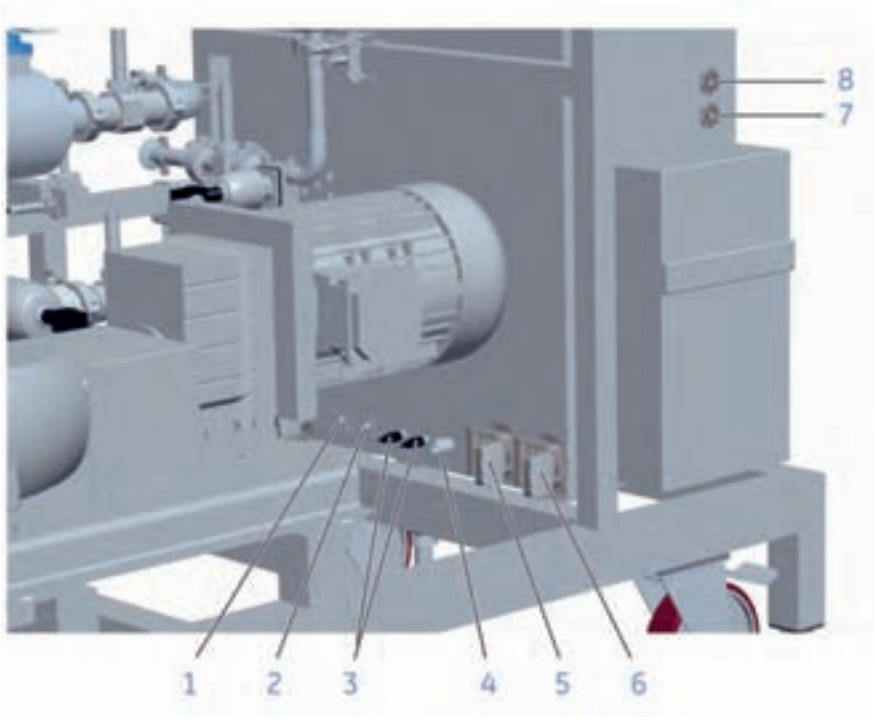
Top connectors



Part	Function
1	UPS power failure alarm input
2	Remote alarm output
3	UNICORN Ethernet port
4	Digital level sensor input

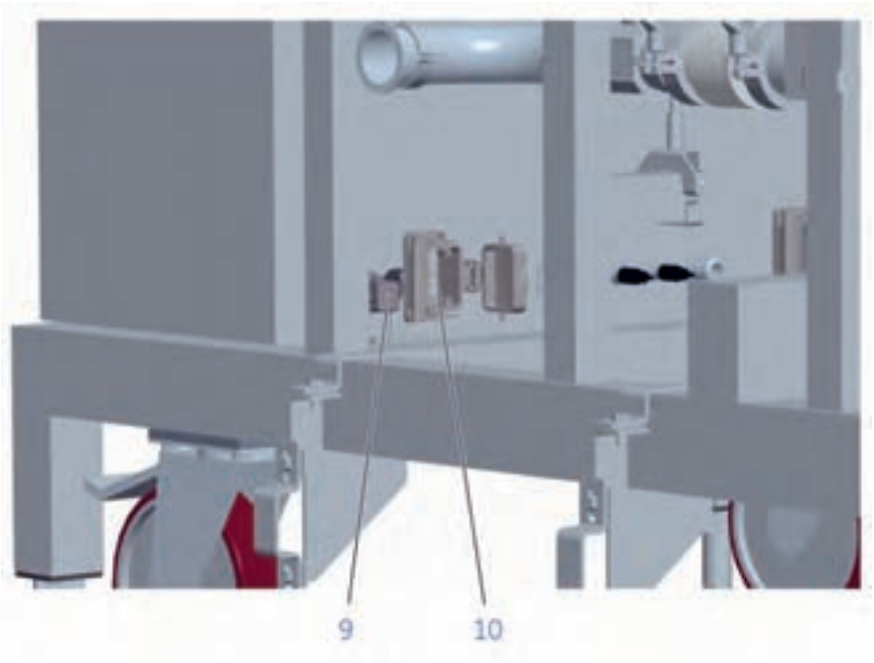
Part	Function
5	Air exhaust
6	Air inlet
7	Optional I/O interface
8	Analog level sensor input
9	Main power supply
10	Power supply P-201

Inner wall connectors



Part	Function
1	Control signal ZSO-065
2	Pressure signal hydraulic unit system side
3	Pluto safe bus
4	Control signal P-202/P-203/tank

Part	Function
5	Power supply transfer pump P-202
6	Power supply permeate pump P-203
7	Control signal operator console
8	Power supply operator console



Part	Function
9	Power supply hydraulic unit HC-291
10	Power supply tank

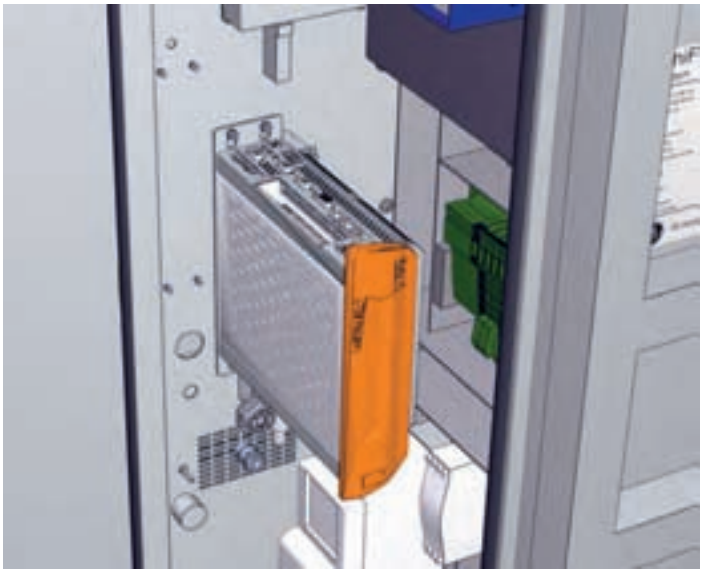
3.3 Automation

Control system

The UniFlux 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 3.7 UNICORN control system, on page 80* for information on the UNICORN control system.

Computer for UniFlux 30, 120 and 400



The optional computer is built into the cabinet and fully protected from the outside environment. If the computer option is not ordered, stand-alone computers are used instead.

The computer automatically starts when the system power is turned on, no specific starting procedure is required for the computer.

For computer specifications, refer to the system documentation kit.

User console for UniFlux 30, 120 and 400

The display and input devices are ergonomically designed for use in a clean production environment.

Communications

All communication with controlled components mounted outside the cabinet uses the Profibus™ industry standard communication protocol and hardware.

3.4 Cassette holders

Description

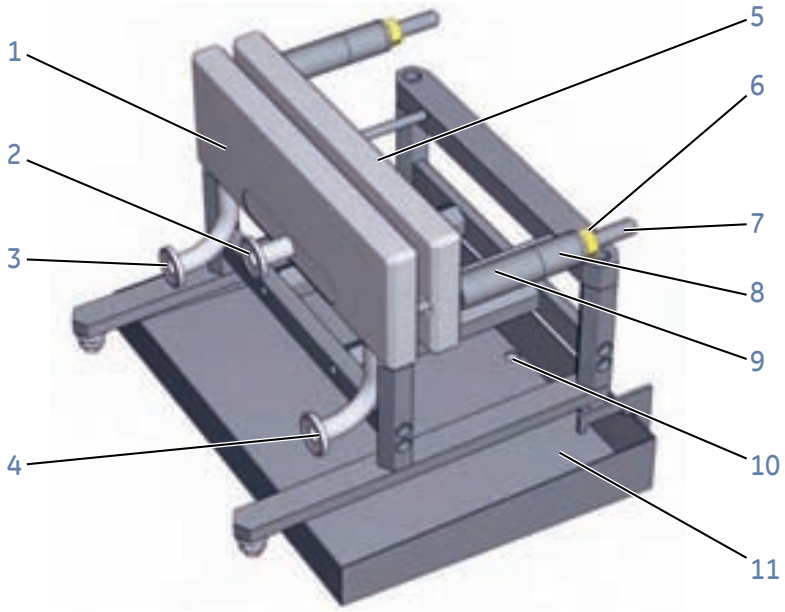
The cassette holder provides a convenient way to install and use the filter cassettes for a filtering run.

The cassette holder follow 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.

More information regarding the cassette holders are available in the Data File with article no 18-1171-61.

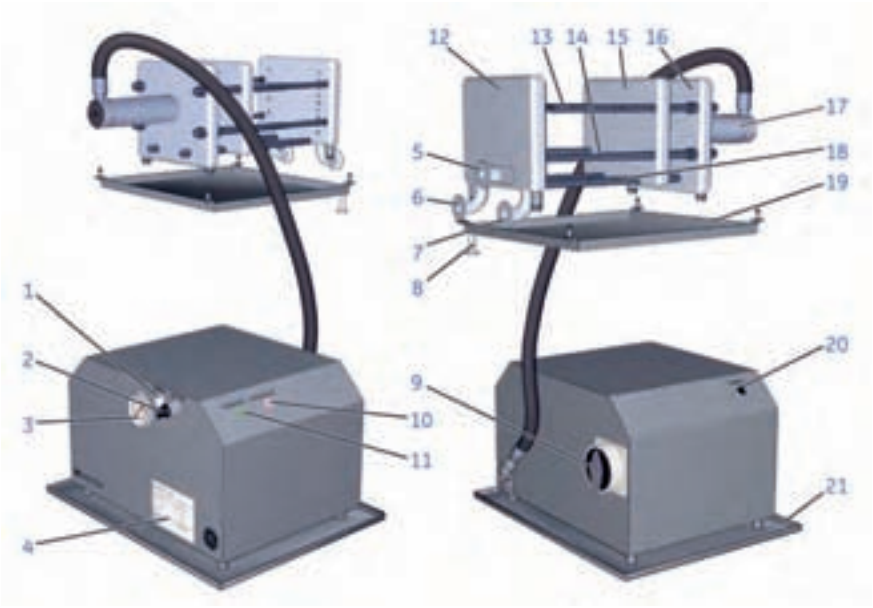
Cassette holder for UniFlux 10



Part	Function
1	Stationary filter distributor plate
2	Permeate outlet
3	Feed inlet

Part	Function
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

Cassette holder for UniFlux30, 120 and 400



Part	Function
1	Power on indicator light
2	Power on lock with key
3	Hydraulic unit pressure indicator

Part	Function
4	Hydraulic unit system label
5	Filter cassette holder permeate outlet
6	Filter cassette holder retentate outlet
7	Filter cassette holder feed inlet
8	Filter cassette spillage waste outlet
9	Hydraulic unit main power switch
10	Depressurize button
11	Pressurize button
12	Cassette holder distributor plate
13	Cassette holder upper guide pin (2 versions supplied for different types of filter)
14	Cassette holder lower guide pin
15	Cassette holder movable pressurization plate
16	Cassette holder fixed pressurization plate
17	Hydraulic cylinder
18	Cassette holder bottom filter support
19	Filter cassette spillage collection plate
20	Hydraulic unit operation enabling button
21	Hydraulic unit spillage collection plate

3.5 Hollow fiber (HF) configuration

Overview

When the UniFlux systems are operated with hollow fiber cartridges, required components of the piping system must be installed.

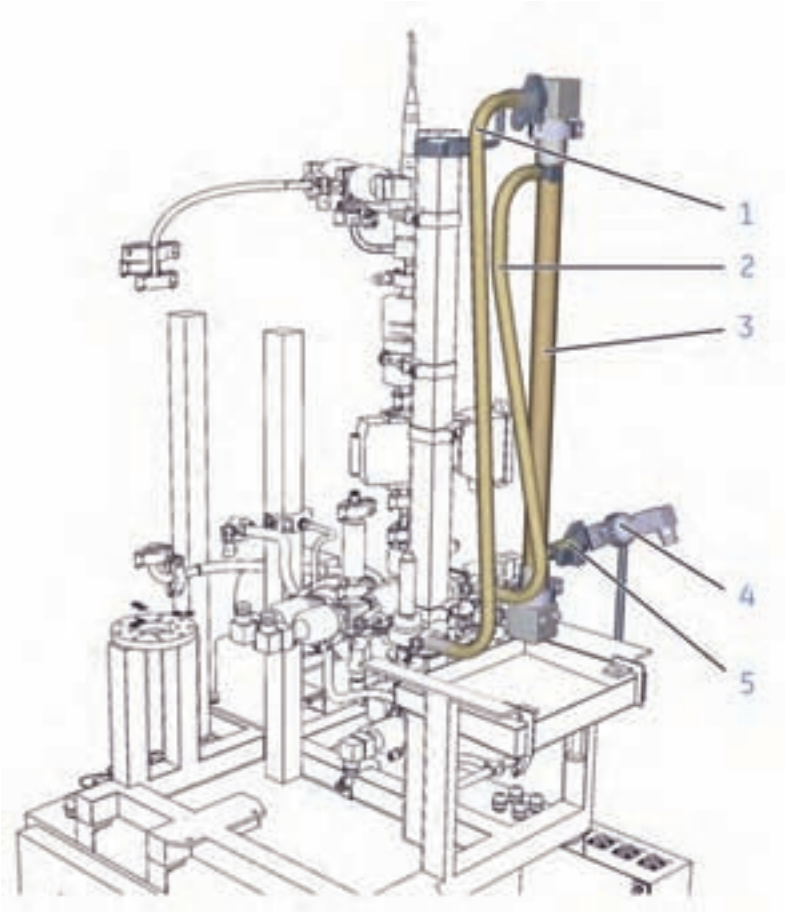
The retentate line must be located in the upper position.

In this section

This section contains the following subsections:

3.5.1 UniFlux 10 HF configuration

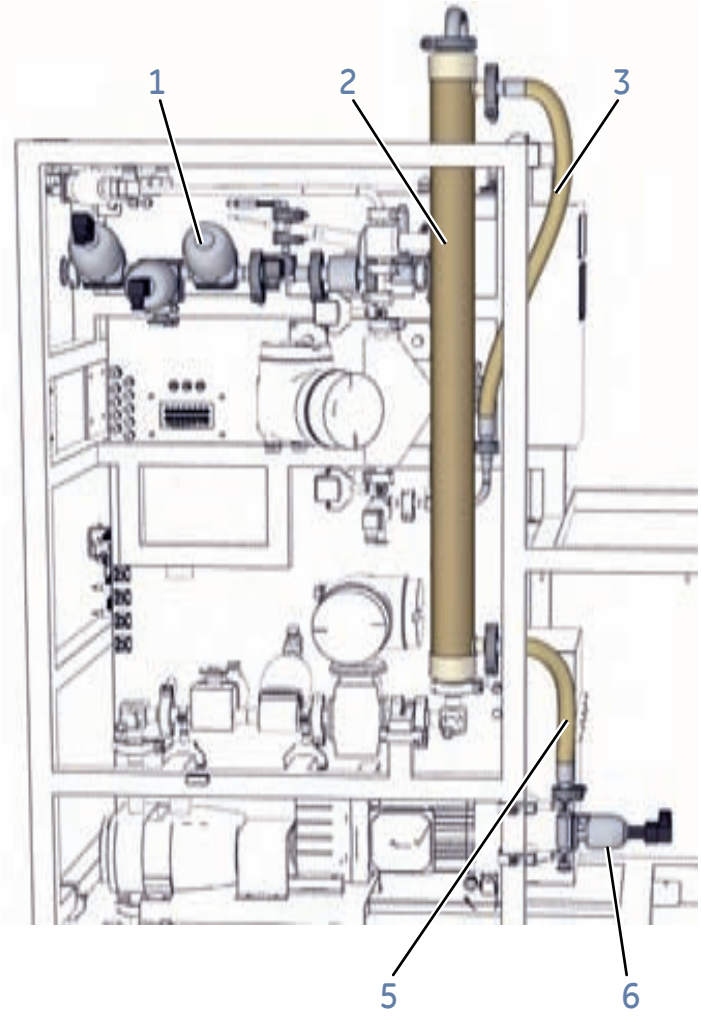
Illustration



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

3.5.2 UniFlux 30 HF configuration

Illustration: Hollow fiber size 75



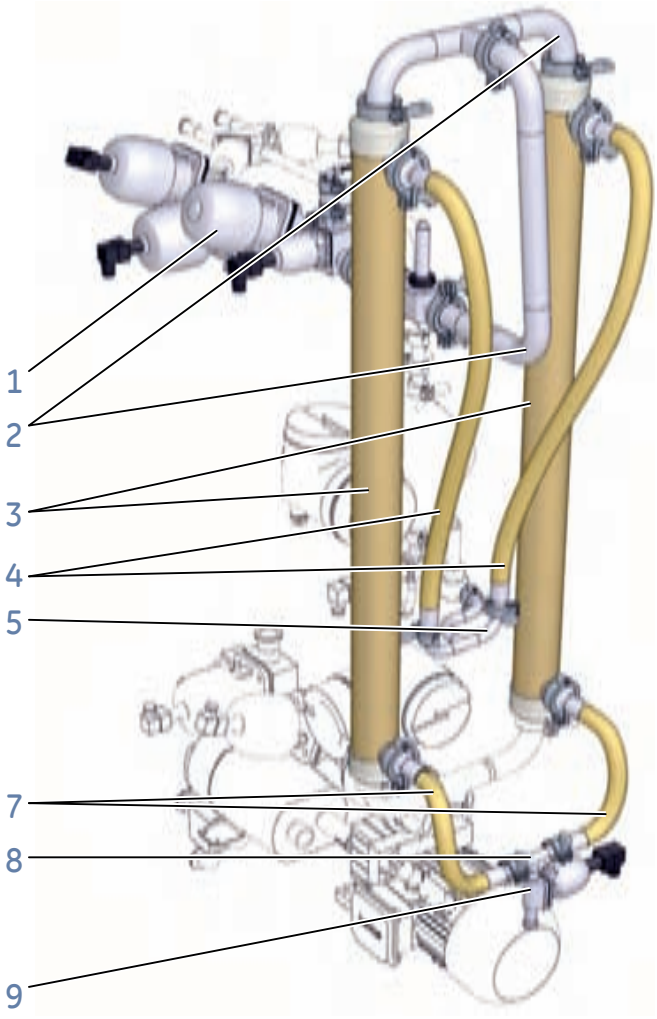
An optional spool piece kit is needed to mount size 75 hollow fibers on the system.

Description of HF components

Part	Function
1	Retentate line, re-arranged to upper position for HF configuration
2	Hollow fiber cartridge
3	Permeate outlet hose
4	Feed line extension pipe
5	HF cartridge drain hose
6	HF cartridge drain valve (**XV-065**)

3.5.3 UniFlux 120 HF configuration

Illustration: Hollow fiber size 75



An optional spool piece kit is needed to mount size 75 hollow fibers on the system.

Description of HF components

Part	Function
1	Retentate line mounted in upper position
2	Retentate collector manifold
3	Hollow fiber cartridges (2)
4	Permeate hoses (2)
5	Permeate collector manifold
6	Feed extension pipes (2)
7	Permeate drain hoses (2)
8	Permeate drain collector manifold (2)
9	Permeate drain valve (**XV-065**)

3.6 Flow charts

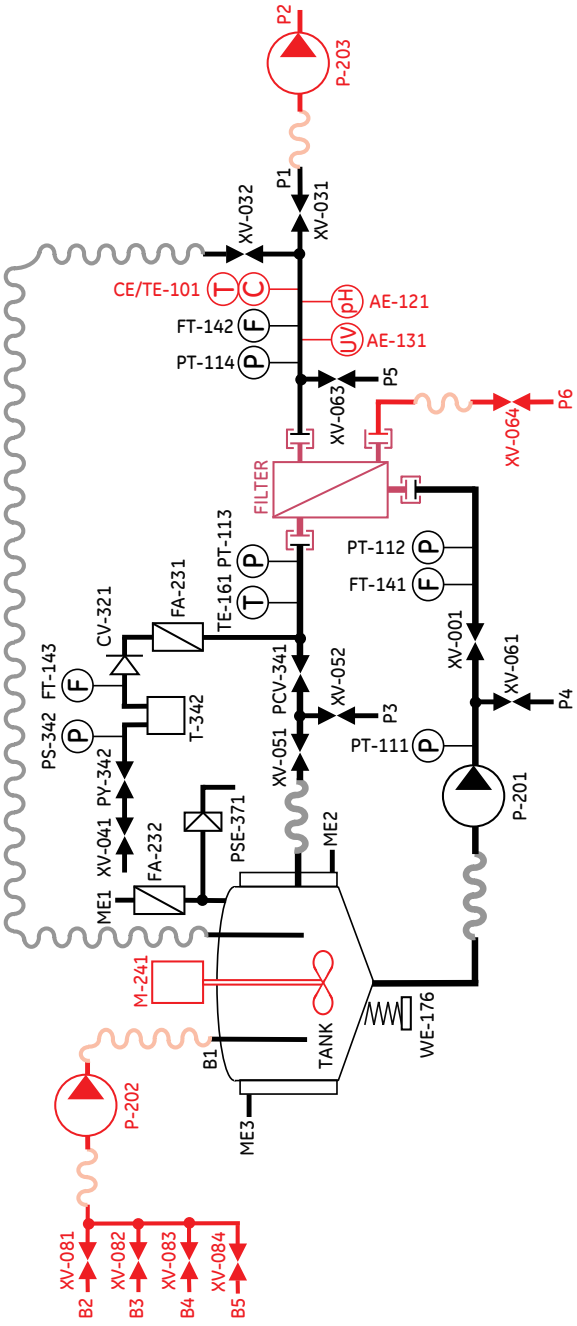
Overview

This section contains flow diagrams and component descriptions for the UniFlux System.

In this section

This section contains the following subsections:

3.6.1 UniFlux 10

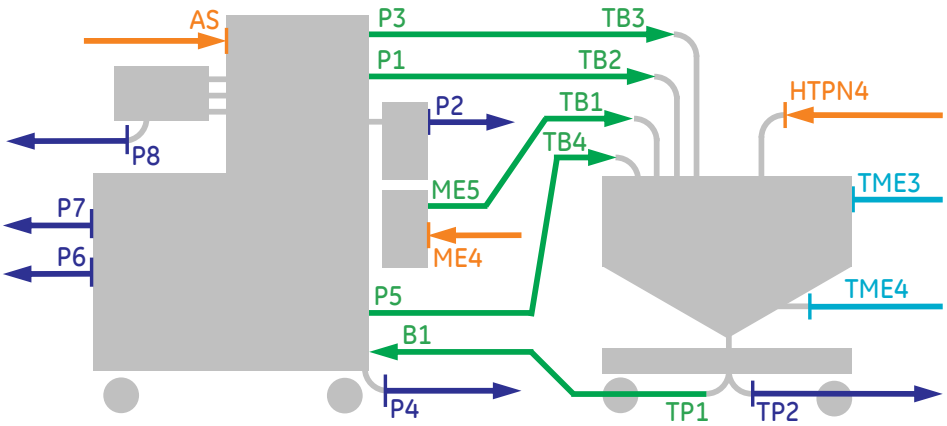


Tag / System	Function	Note
AE-121	Permeate pH-meter	Option
AE-131	Permeate UV-meter	Option
B1	Tank feed inlet	
B2, B3, B4	Quadruple inlets 1, 2 and 3	Part of quadruple inlet option
B5	Quadruple inlet 4	
CE-101	Permeate conductivity meter with an integrated temperature meter (**TE-101**)	Option
CV-321	Filter integrity test check valve	
FA-231	Filter integrity test sanitary filter	
FA-232	Tank vent sanitary filter	
FILTER	Cross flow filter. Can be either hollow fibre (HF) cartridge or filter cassette.	Not included in system, provided by customer or sold separately.
FT-141	Feed flow meter	
FT-142	Permeate flow meter	
FT-143	Filter integrity test flow meter	
M-241	Feed tank agitator motor	Option
ME1	Tank vent	
ME2	Tank jacket connection	
ME3	Tank jacket connection	
P1	Permeate outlet	
P2	Permeate pump outlet	Part of permeate pump option
P3	Retentate drain	
P4	Feed drain / CIP outlet	
P5	Permeate drain	
P6	HF filter cartridge drain	HF configuration only
P-201	Feed pump	

Tag / System	Function	Note
P-202	Feed transfer pump	Option
P-203	Transfer and permeate pump	Option
PCV-341	Retentate pressure control	
PS-342	Filter integrity test pressure sensor	
PY-342	Filter integrity test pressure regulator	
PSE-371	Feed tank pressure relief safety valve	
PT-111	Feed pump outlet pressure meter	
PT-112	Feed pump outlet pressure meter	
PT-113	Retentate pressure meter	
PT-114	Permeate pressure meter	
TANK	Feed tank	
T-342	Pressure regulator pulse damper	
TE-101	Permeate temperature meter	Option. Included in cond CE-101.
WE-176	Tank load cell	
XV-001	Pump feed valve	
XV-031	Permeate outlet valve	
XV-032	Permeate recycle valve	
XV-051	Retentate outlet valve	
XV-052	Retentate drain valve	
XV-061	Feed drain	
XV-062	Filter integrity test valve	
XV-063	Permeate drain valve	
XV-064	HF filter cartridge drain valve	HF configuration only
XV-081, 082, 083, 084	Quadruple inlet 1, 2, 3 and 4 valves	Part of quadruple inlet option
XY-342	Filter integrity test valve	

3.6.2 UniFlux 30, 120 and 400

External connections



Symbol	Color	Description
	Blue	Outlets
	Orange	Inlets
	Cyan	Non-directional
	Green	Interface points

Battery limits

"Battery limits" represents all interface points between the UniFlux and the customer process plant.

System battery limits require hose connections not provided by GE Healthcare.

Normally, the user provides hoses for these connections.

Tag	Location	Function	Direction
AS	System	Air / nitrogen supply for integrity test	Inlet
HTPN4	Tank	Air / nitrogen supply for pressurization (optional)	Inlet
ME4	System	Feed supply to transfer pump (optional)	Inlet
P2	System	Permeate	Outlet
P4	System	Feed drain	Outlet
P6	System	Retentate drain	Outlet
P7	System	Permeate drain	Outlet
P8	System	Filter drain (Only mounted/used in Hollow fiber systems.)	Outlet
TME3, TME4	Tank	Tank jacket media supply and return (Only mounted/used in Hollow fiber systems.)	N/A
TP2	Tank	Feed drain	Outlet

Interface points

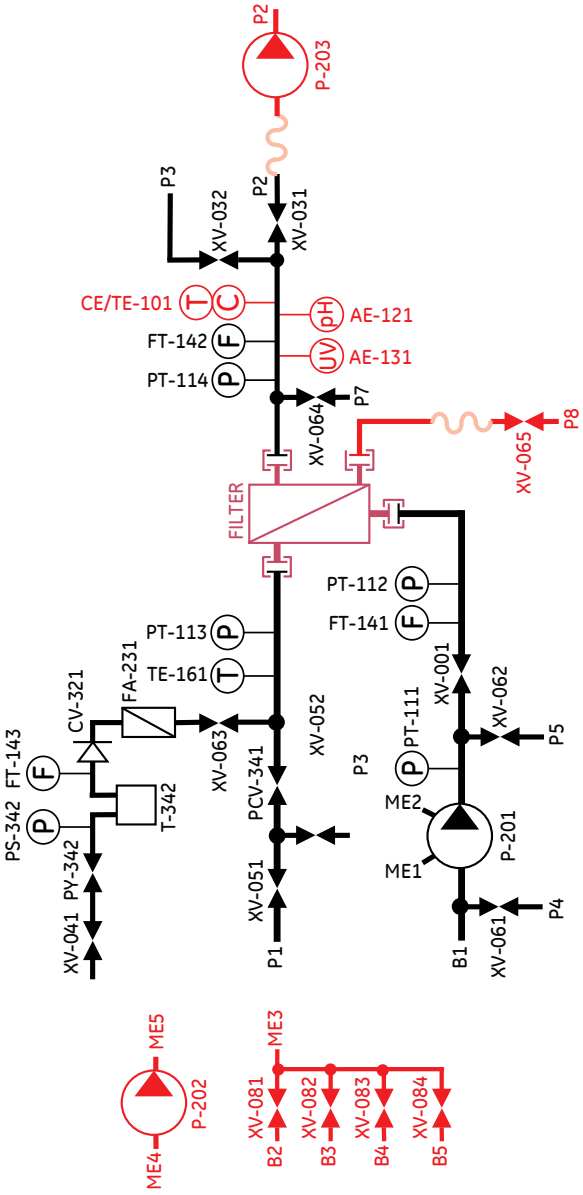
Diagram color: Green

Interface points provide process connections between the UniFlux system and the optional UniFlux tank. Hoses for these connections are normally delivered by GE Healthcare as option to the tank delivery.

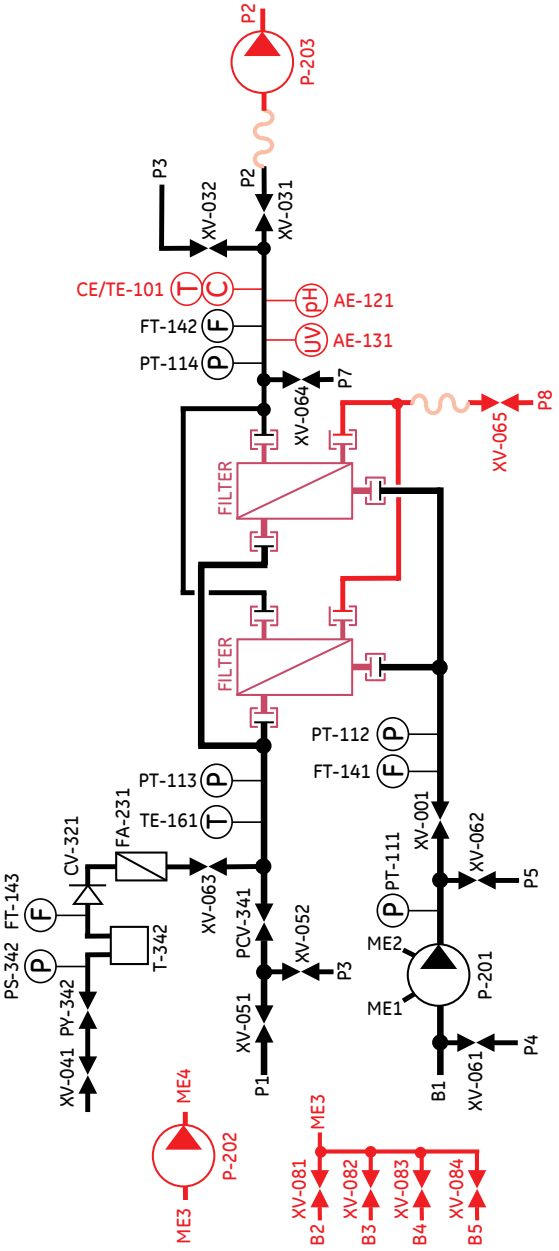
Tag	Function	Direction
ME5 - TB1	Feed from optional transfer pump to tank	System -> Tank
P1 - TB2	Retentate recycle	System -> Tank
P3 - TB3	Permeate recycle	System -> Tank
P5 - TB4	CIP media supply to tank	System -> Tank
TP1 - B1	Feed supply to system	Tank -> System

Flowcharts

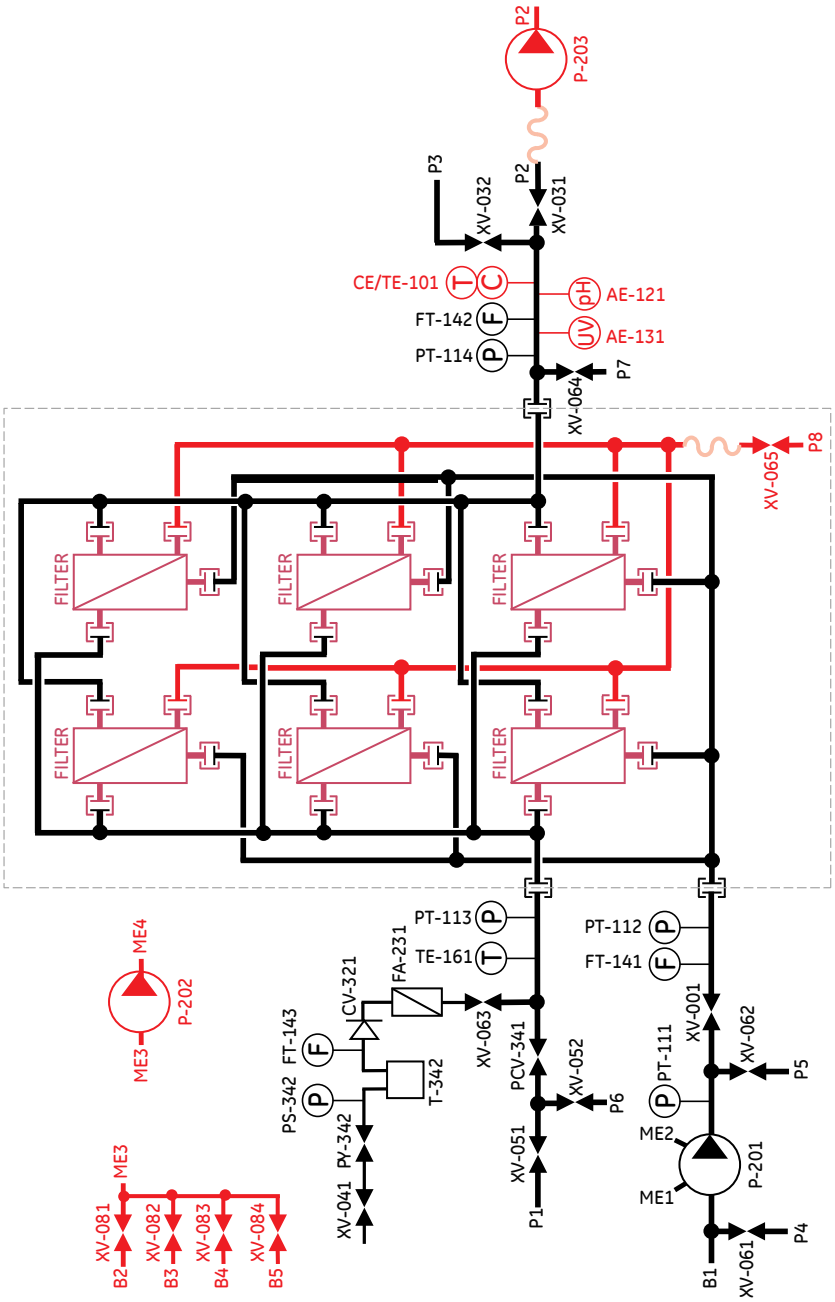
UniFlux 30



UniFlux 120


P2
P-203
P3
XV-032
P2
XV-031
CE/TE-101
T
C
AE-121
pH
FT-142
F
AE-131
UV
PT-114
P
P7
XV-064
P8
XV-065
FILTER
FILTER
PT-112
P
FT-141
F
PT-113
P
TE-161
T
FA-231
CV-321
XV-001
XV-062
P5
PT-111
P
FT-143
F
XV-063
PCV-341
XV-052
P3
ME2
PS-342
P
T-342
P-201
ME1
XV-051
PY-342
P1
P4
XV-041
B1
XV-061
ME4
ME3
P-202
ME3
XV-081
XV-082
XV-083
XV-084
B2
B3
B4
B5

UniFlux 400


P2
P-203
P3
XV-032
P2
XV-031
CE/TE-101
AE-121
FT-142
AE-131
PT-114
P7
XV-064
XV-065
P8
FILTER
FILTER
FILTER
FILTER
FILTER
FILTER
PT-113
TE-161
FA-231
CV-321
FT-143
PS-342
T-342
PY-342
XV-063
PCV-341
XV-052
P6
XV-051
P1
XV-041
PT-112
FT-141
XV-001
XV-062
P5
PT-111
ME2
ME1
P-201
P4
B1
XV-061
ME4
P-202
ME3
ME3
XV-081
XV-082
XV-083
XV-084
B2
B3
B4
B5

Tag / System	Function	Note
AE-121	Permeate pH-meter	Option
AE-131	Permeate UV-meter	Option
B1	Feed pump inlet	
B2, B3, B4	Quadruple inlets 1, 2 and 3	Part of quadruple inlet option
B5	Quadruple inlet 4	
CE-101	Permeate conductivity meter with an integrated temperature meter (**TE-101**)	Option
CV-321	Filter integrity test check valve	
FA-231	Filter integrity test sanitary filter	
FILTER	Cross flow filter. Can be either hollow fibre (HF) cartridge or filter cassette.	Not included in system, provided by customer or sold separately.
FT-141	Feed flow meter	
FT-142	Permeate flow meter	
FT-143	Filter integrity test flow meter	
ME1	Feed pump coolant connection	
ME2	Feed pump coolant connection	
ME3	Quadruple inlet option outlet	Part of quadruple inlet option
ME4	Transfer pump inlet (from buffer)	Part of transfer pump option
ME5	Transfer pump outlet (to tank)	
P1	Retentate outlet	
P2	Permeate outlet, direct or by pump	
P3	Permeate recycle	
P4	Feed drain	
P5	CIP valve	
P6	Retentate drain	
P7	Permeate drain	

Tag / System	Function	Note
P8	HF filter cartridge drain	HF configuration only
P-201	Feed pump	
P-202	Feed transfer pump	Option
P-203	Transfer and permeate pump	Option
PCV-341	Retentate pressure control	
PS-342	Filter integrity test pressure sensor	
PY-342	Filter integrity test pressure regulator	
PT-111	Feed pump outlet pressure meter	
PT-112	Feed pump outlet pressure meter	
PT-113	Retentate pressure meter	
PT-114	Permeate pressure meter	
TANK	Not included in system	Feed tank available as option
T-342	Pressure regulator pulse damper	
TE-101	Permeate temperature meter	Option. Included in cond CE-101.
XV-001	Pump feed valve	
XV-031	Permeate outlet valve	
XV-032	Permeate recycle valve	
XV-051	Retentate outlet valve	
XV-052	Retentate drain valve	
XV-061	Feed drain	
XV-062	Feed pressure outlet (CIP) valve	
XV-063	Filter integrity test valve	
XV-064	Permeate drain valve	
XV-065	HF filter cartridge drain valve	HF configuration only

Tag / System	Function	Note
XV-081, 082, 083, 084	Quadruple inlet 1, 2, 3 and 4 valves	Part of quadruple inlet option
XY-342	Filter integrity test valve	

In the flow diagram for UniFlux 400, the gray box represents the filter skid.

3.7 UNICORN control system

Overview

UniFlux System is controlled by UNICORN process control software.

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

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

The UNICORN *manual package* provides 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 compliant with FDA 21 CFR Part 11.

Knowledge prerequisite

At least basic knowledge of UNICORN is expected to operate UniFlux 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 GE Healthcare representative for advice if required.

System networks

UNICORN can be installed on a stand-alone computer to control one to four locally attached 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	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 System.
System Control	Process online control and monitoring using pre-defined methods or manual control.
Evaluation	Evaluation and presentation of stored results.

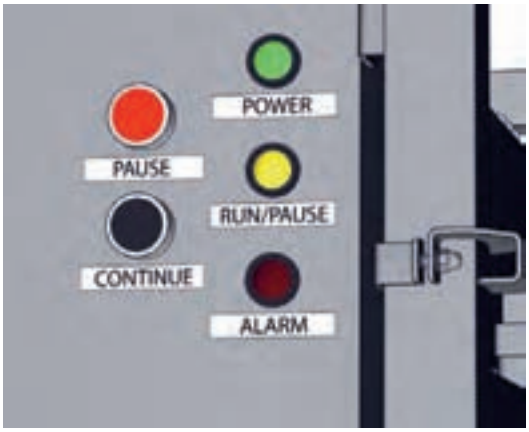
Note: *The modules are active when the program is operating and are not closed when minimized. A minimized System Control unit may control a process.*

Workflow

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

Step	Action
1	Program an UniFlux 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 open 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



Typical image showing cabinet controls and indicators, for UniFlux 30 and 120 systems.

Label	Type	Color	Function
PAUSE	Button	Red	Sets UNICORN in ***PAUSE*** mode (equal the PAUSE button in the UNICORN computer user interface)
CONTINUE	Button	Black	Sets UNICORN in ***RUN*** mode (equal 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.

Alarms

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.

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.

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.

4 Installation

About this chapter

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

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 *Chapter 2 Safety instructions, on page 12* as listed below:

- *General precautions, on page 13*
- *Personal protection, on page 15*
- *Installing and moving, on page 16*
- *Power supply, on page 19*

In this chapter

This chapter contains the following sections:

4.1 Site requirements

Space and floor load

For space and floor requirement, see external dimensions and weights in *Section 9.1 Specifications, on page 150*.

- Make sure that the floor can handle the UniFlux 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 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 kit.

Avoid:

- Direct sunlight.
- Strong magnetic or electric fields.
- Vibrations.
- Corrosive gas.
- Dust.

Allowed ranges for environmental parameters are presented in *Section 9.1 Specifications, on page 150*.

Electrical power

Refer to *Section 4.4 Power supply, on page 90* and *Section 9.1 Specifications, on page 150* for power, voltage and phase requirements.

Compressed air

- Dry and particle free air for system supply.
- Refer to *Section 9.1 Specifications, on page 150* regarding capacity requirements.

Media supply

Refer to *Section 9.1 Specifications, on page 150* regarding requirements on media supply and delivery.

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

Battery limits

"Battery limits" represents all interface points between the UniFlux and the customer process plant.

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

Computer

An industrial built-in computer can be ordered as an option for UniFlux 30 and 120, otherwise a stand-alone computer shall be used. 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.

NOTICE

Any computer used with the equipment shall comply with IEC 60950 and be installed and used according to the manufacturer's instructions.

4.2 Transport

In the transport crate

- Use a pallet jack or fork lift with a minimum capacity to match the empty weight of the system plus the transport box. Refer to *Section 9.1 Specifications, on page 150* regarding system weight.
- Make sure that intended openings and apertures are large enough to allow passage of the box when lifted from the floor for transport.

  For UniFlux 10: For minimum door aperture size, refer to *Section 9.1 Specifications, on page 150*.

Unpacked

WARNING

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

- UniFlux can be rolled by hand on hard and level surface with wheel brakes released.
- If the floor quality does no allow rolling the UniFlux on its own wheels, it can be moved with a pallet jack or fork lift.
- For minimum door aperture size, refer to *Section 9.1 Specifications, on page 150*.

4.3 Unpacking

Tools required

- Suitable lifting device, fork lift or similar. Refer to *Section 9.1 Specifications, on page 150* for dimensions and weight to be handled.
- 13 mm wrench (or ratchet with 13 mm socket).
- Electrical screwdriver with Phillips no. 2 bit.
- Knife.
- Lever (enclosed in crate).

Visual inspection

Check:

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

If any equipment is missing or damages are found, contact your GE Healthcare representative immediately.

Precautions

WARNING

To prevent bacterial growth, UniFlux System may be partly filled with denatured Ethanol (18% C_2H_5OH (Ethanol), 2% C_3H_7OH (Isopropanol) and 80% H_2O (water)) or 0.1 M NaOH (Sodium Hydroxide) at delivery.

Flush out the denatured Ethanol or Sodium Hydroxide before assembling, testing or integrating UniFlux into the intended process context.

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, user console 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.

4.4 Power supply

Power requirements

The power supply requirements are specified in *Section 9.1 Specifications, on page 150*.

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

Electrical power. All electrical installations must be performed by authorized personnel only.

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.
- The integrity of all ground connections must be periodically checked.

Circuit breaker

A circuit breaker must be present in the fixed power supply.

Breaking the power supply to the UniFlux System by using this breaker must be eqvivalent 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 GE Healthcare may perform service, installation, and maintenance of components inside the UniFlux cabinet.

Wire colors and tags

All instrument power cord wires must be connected to the fixed power supply wires with corresponding colors and tags.

Function	USA	EU	Marking
Neutral	White	Blue	N
Live	Black	Black or brown	L
Protective ground (earth)	Green	Green/yellow	PE = GND 

Live and neutral wire cross section area

All live- and neutral wiring must have a cross section area equal to or more than the specification in this table:

Mains current up to	Mains and neutral conductor minimum area
10 A	1 mm^2
16 A	1.5 mm^2
25 A	2.5 mm^2

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 System is not equipped with a general Ground Fault Circuit Breaker and it is not an option that is available from GE Healthcare.

However, if ground fault protection for the system is desired,

- a Ground Fault Circuit Interruptor may be installed, or
- 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 system and the pumps are equipped with circuit breakers inside the cabinet. Refer to the System Documentation for the specific types used in your system.

More information

Voltage, power, fuse requirements and the tripping current for the fixed power supply ground fault protector can be found in the General Specification, provided with the system document package.

4.5 Setup

Precautions

WARNING

To prevent bacterial growth, UniFlux System may be partly filled with denatured Ethanol (18% C_2H_5OH (Ethanol), 2% C_3H_7OH (Isopropanol) and 80% H_2O (water)) or 0.1 M NaOH (Sodium Hydroxide) at delivery.

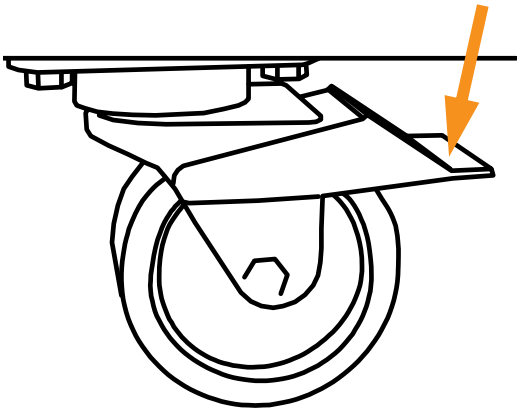
Flush out the denatured Ethanol or Sodium Hydroxide before assembling, testing or integrating UniFlux into the intended process context.

In this section

This section contains the following subsections:

4.5.1 Lock wheels

After positioning the system at its designated location, lock the wheels (figure).



4.5.2 Operator console for UniFlux 30, 120 and 400

Introduction

The operator console is packed separately in a cardboard box which is enclosed in the system crate for UniFlux 30 and 120.

All connections to and from the monitor and the keyboard (DVI signal, USB connection and power) are included in one multi-conductor cable (ODU minisnap 24-pin connector). One ODU minisnap 3-pin connector is used for the power supply.

These two cables are attached to the system located underneath the cabinet.

Precautions

CAUTION

Make sure that the console arm is firmly positioned with the top part of the handle fully inserted, so that the bushing is able to absorb the weight of the console when the console arm is fully extended. The console may fall and cause damage and/or injury if the console arm is not properly positioned.

NOTICE

Operator console

- Do not use the operator console to push or drag the system
- Do not lean on the console

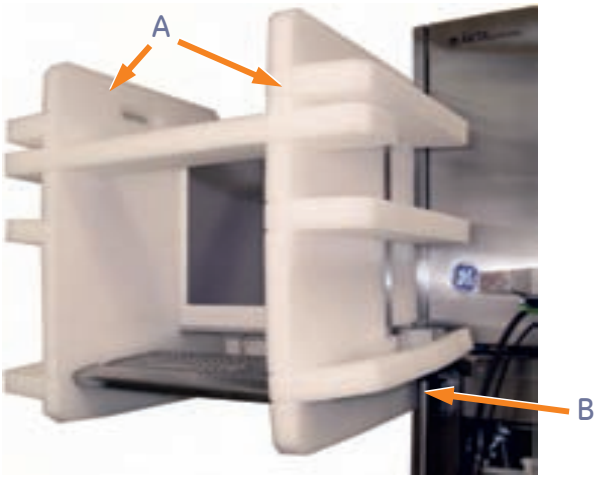
The console arm is only designed to support the weight of the operator console.

Mount the console to the system

At arrival to the production site, the user console is packed separately and needs to be assembled to the system skid. Refer to *Section 4.5.2 Operator console for UniFlux 30, 120 and 400, on page 95*. Except for the console, the UniFlux System is delivered fully assembled at production site arrival. No further specific assembly procedures are required.

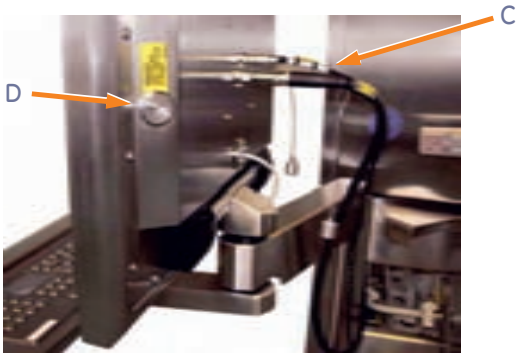
Follow this sequence when mounting the operator console to the UniFlux 30 and 120 systems:

Step	Action
1	Open the box and remove the assembled console. Do not remove the styrofoam protection, this can be used for lifting.
2	Carefully slide the console arm over the system handle (B) until it is firmly attached. Keep the styrofoam protection (A) in place when attaching the console arm.



3	Remove the styrofoam protection.

Step	Action
4	Attach the two ODU minisnap connectors (C) to the console as shown in the picture.



NOTICE

The protective screw cap (D) should always be in place when the USB connector is not in use.

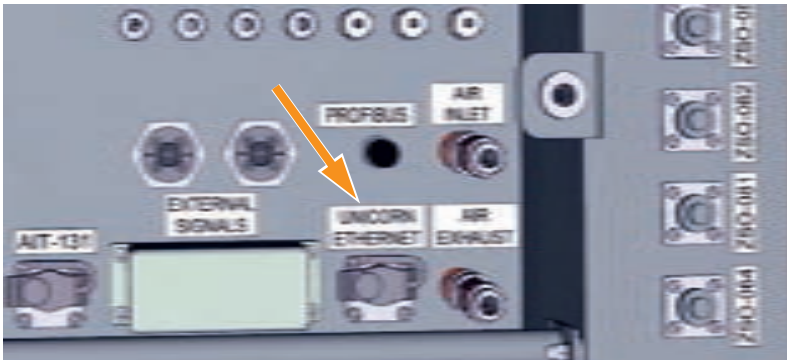
5	

Press the Rotation Stop on to the console arm as shown in the picture and push it into place around the rotation center.

4.5.3 Stand-alone computer for UniFlux 10

Connect a stand-alone computer to UniFlux 10

Connect a stand-alone computer with UNICORN to UniFlux 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.*

4.5.4 Connect compressed air supply

Locate your air inlet and air exhaust and connect to the compressed air supply.

For requirements on air supply, refer to *Section 4.1 Site requirements, on page 85*.

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

Install Controller Unit 960 (CU-960)

The CU-960 is part of the UniFlux system at the delivery. It is an external 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.

4.5.6 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.

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.

NOTICE

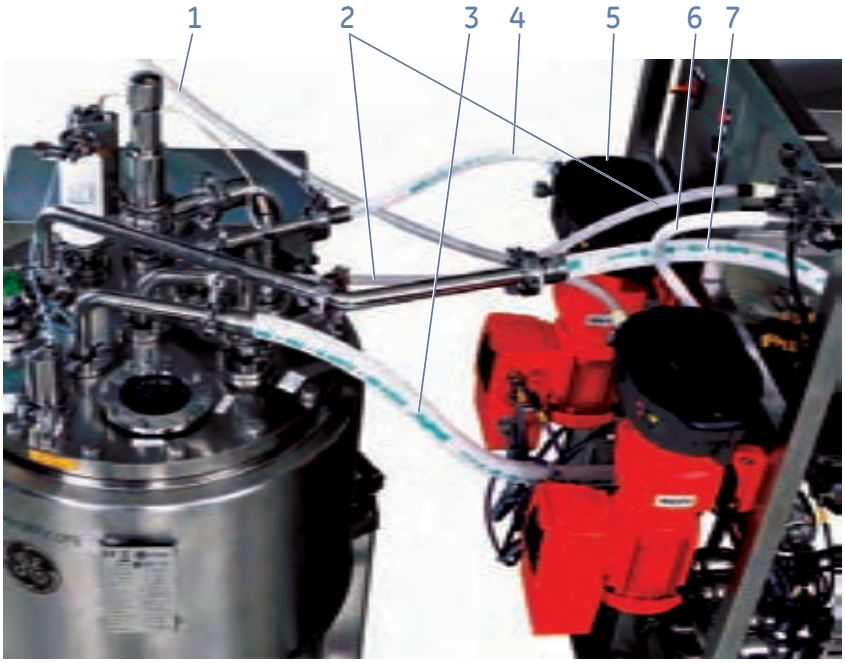
Do not use an in-line filter screen on the piping between the recirculation tank and the feed pump. If such a filter screen becomes clogged, the flow to the feed pump will be restricted and the pump may be damaged because of cavitation.

4.5.7 Process component connections for UniFlux 30, 120 and 400

Introduction

This section provides guidelines for the connection of process components to UniFlux 30, 120 and 400 systems.

Typical hook up, all options included



The image shows the typical hook up for the UniFlux 30 and 120 systems.

Part	Function	From	To
1	Permeate output	UniFlux system permeate pump	Plant downstream process or waste
2	Permeate recycle	UniFlux system	UniFlux tank

Part	Function	From	To
3	Retentate recycle	UniFlux system	UniFlux tank
4	Transfer of media	UniFlux system transfer pump	UniFlux tank
5	Transfer of media (not visible)	Plant upstream process	UniFlux system transfer pump
6	Permeate output	UniFlux system	UniFlux system permeate pump
7	CIP media	UniFlux system	UniFlux tank

5 Run preparations

About this chapter

This chapter provides the information required to safely prepare the UniFlux System for operation.

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

- *Chapter 4 Installation, on page 84* and
- actions before operation in *Section 7.1 User maintenance schedule, on page 131*.

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 *Chapter 2 Safety instructions, on page 12* as listed below:

- *General precautions, on page 13*
- *Personal protection, on page 15*
- *System operation, on page 20*

NOTICE

Only use chemicals that have been proven not to be harmful to the wetted parts of the unit.

Refer to *Section 9.3 Chemical resistance, on page 157* for more information.

In this chapter

This chapter contains the following sections:

5.1 Starting UniFlux

Starting UniFlux

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 cabinet doors are closed and locked.
4	Switch on power to UniFlux by turning the **Mains power** switch to the "**I**" position. See *Section 3.2 UniFlux systems layout, on page 42* for location.
5	Make sure that UNICORN is started according to the instruction in *Starting UNICORN, on page 106*. Wait for connection.

After this sequence is completed, the following occurs:

- The computer is turned on.
- The **POWER** indicator lamp flashes.
- When communication with UNICORN software is established, the **POWER** indicator lamp shows a steady green light.

Starting UNICORN

Refer to *Section 3.7 UNICORN control system, on page 80* 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 ***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***.
5	Click ***OK***.
6	In the ***System Control*** module, select ***System:Connect***.

Step	Action
7	In the dialog shown, select the appropriate system name and click ***OK***. The system name is specified during installation configuration.
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.

5.2 Filter installation

In this section

This section contains the following subsections:

5.2.1 Installing hollow fiber (HF) 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.
2	Prepare the HF cartridge(s) according to the manufacturer's instructions.
3	Install the cartridge into the system, refer to illustrations in *Section 3.5 Hollow fiber (HF) configuration, on page 62*.

5.2.2 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 120* for instructions.
2	Prepare and check the cassettes according to the manufacturer's instructions.

5.2.3 Cassettes for UniFlux 10

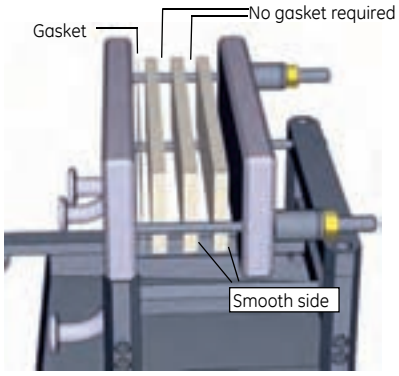
Preparations

Loosen the retaining nuts and slide the back plate far enough away from the forward fixed distribution plate to accomodate the total amount of Kvick Lab cassettes to be used for the filtration run.

Installation

Note: *This assembly instruction applies to GE Healthcare cassettes only. For information on installing other cassettes, please contact your local GE Healthcare representative.*

Step	Action
1	To install one cassette, clean and wet a silicone gasket by rinsing it with deionized (DI) water or water-for-injection (WFI).
2	Place the gasket against the flow distribution manifold, aligning the holes in the gasket with the holes in the manifold. The gasket will stick to the manifold.
3	From the top, place the cassette into the holder with the gasket-side of the cassette facing the backing plate, and slide the cassette against the gasket.
4	Place the second cassette into the holder between the first cassette and the backing plate. Ensure the gasket-side of the second cassette faces the backing plate. Place subsequent cassettes in the holder in similar fashion.



Tighten the cassette assembly

Step	Action
1	Slide the back plate towards the cassettes until they make contact.
2	Screw the 2 retaining nuts by hand until the backplate is pressing against the cassettes. Make sure that the back plate is sliding orthogonally.
3	Tighten the 2 retaining nuts in small increments in a cross-wise pattern until the torque 20 Nm is reached. Make sure that the nuts are tightened equally to prevent uneven pressure over the cassettes.

5.2.4 Cassettes for UniFlux 30, 120 and 400

Hydraulic pressure

Make sure that the hydraulic pressure required to prevent filter leakage with sufficient margin is known.

NOTICE

Too high hydraulic pressure will have a negative effect on the pressure drop caused by the cassette and can cause damages on the cassettes.

The hydraulic pressure shall be restricted to 140 bar (2000 psi) to avoid overload of cassette holder.

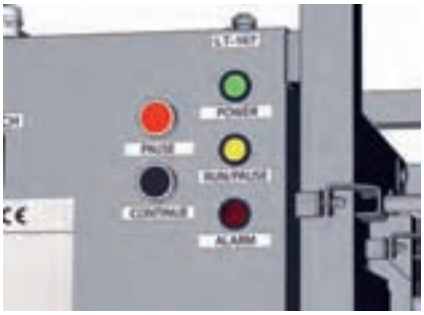
For all filter cassettes, empirical testing is needed to decide what hydraulic pressure to use. Contact your GE Healthcare representative for advice.

Preparations

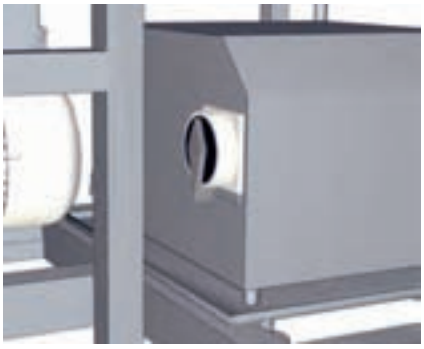
Step	Action
1	Prepare and check the cassettes according to the manufacturer's instructions.

Step	Action
2	Make sure that:

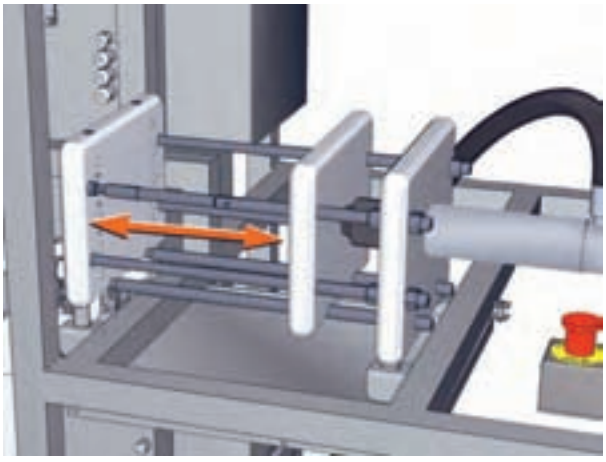
UNICORN is started and the Yellow system status light **RUN/PAUSE** is on and steady.

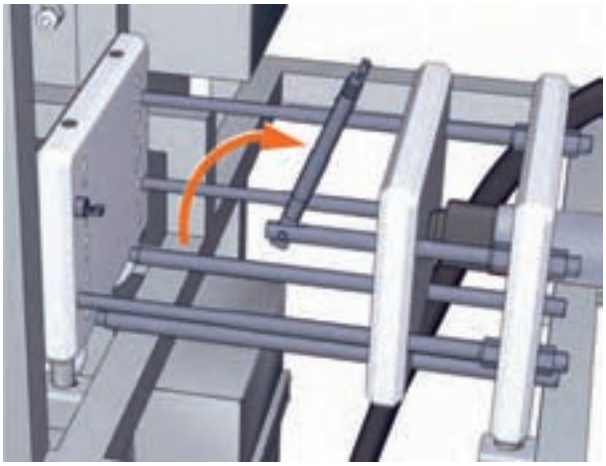


The hydraulic unit is switched on.



The key on the hydraulic unit front side is switched to **ON** and the white **POWER** light is on.

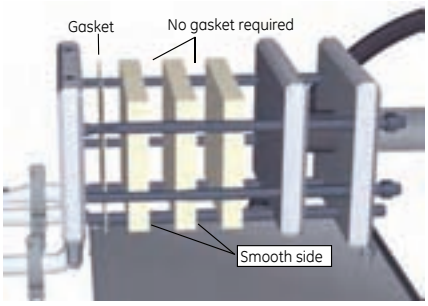
Step	Action
3	
	Move the filter pressurization cylinder backwards by simultaneously pressing the **ENABLE** and **DEPRESSURIZE** buttons on the hydraulic unit.
4	Remove any hydraulic piston extensions attached to the hydraulic piston by unscrewing the extensions.
5	
	Slide the cassette holder pressurization back plate backwards by hand until it meets the hydraulic cylinder piston.

Step	Action
6	 Slide back the sleeve on the movable guide rod and lift the guide rod up.
7	Install one or both hydraulic piston extensions by screwing them into the end of the hydraulic piston using this schedule as a guide: • 1 to 4 cassettes, use the 2-inch and 4-inch extensions. • 5 to 10 cassettes, or 1 to 2 block cassettes (block cassettes are the 2.33 m^2 {25 ft^2}, use the 4-inch extension. • 10 to 15 cassettes, or three block cassettes, do not use an extension. • Other combinations of cassettes, choose a combination of extenders that will enable the backing plate to slide up to the cassettes, while still providing about three inches of piston travel when the hydraulic cylinder is pressurized.

Installation

Note: *This assembly instruction applies to GE Healthcare cassettes only. For information on installing other cassettes, please contact your local GE Healthcare representative.*

Step	Action
1	To install one cassette, clean and wet a silicone gasket by rinsing it with DI water or water-for-injection (WFI).
2	Place the gasket against the flow distribution manifold, aligning the holes in the gasket with the holes in the manifold. The gasket will stick to the manifold.

Step	Action
3	From the top, place the cassette into the holder with the gasket-side of the cassette facing the backing plate (hydraulic cylinder), and slide the cassette against the gasket.
4	Place the second cassette into the holder between the first cassette and the backing plate. Ensure the gasket-side of the second cassette faces the backing plate. Place subsequent cassettes in the holder in similar fashion.
	
5	After you insert all the cassettes into the holder, lower and lock the guide rod into its original position.
6	Slide the backing plate and cassettes towards the flow manifold, ensuring the holes in the cassettes and gasket are aligned with the holes in the flow distribution manifold.

Pressurization

WARNING

To avoid the possibility of crushing, notify all assistants to clear the holder area and visually ensure no assistant is working on the holder before energizing the hydraulic pump.

Using the hydraulic pump, pressurize the hydraulic cylinder according to the previously performed calculation.

5.3 Priming and testing

Introduction

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

1 For UniFlux 30, 120 and 400: Prime the lobe rotor pump.

2 Perform a leakage test.

3 Perform an air integrity test.

Priming the lobe rotor pump

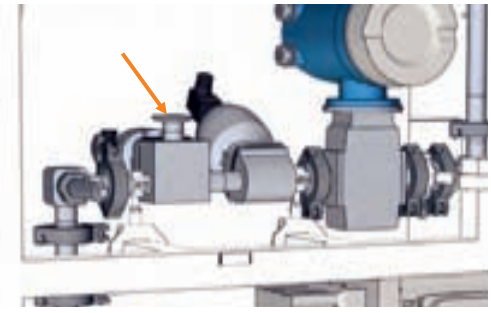
Priming is done for UniFlux 30, 120 and 400.

NOTICE

Do not start the lobe rotor pump before it is primed with the intended media.

The CIP valve (XV-062) is used in order to prime the lobe rotor pump.

Step	Action
1	Connect the suction side of the pump to the intended feed supply.
2	Make sure that waste ejected from the CIP valve outlet is collected.
3	Open the CIP valve.



4	Run the pump while watching the flow through the transparent waste hose from the CIP valve.
5	When liquid only and no air exits the CIP valve, stop the pump and close the CIP valve.

Leakage test

Step	Action
1	Pressurize the system up to the maximum intended process pressure. For GE Healthcare Kvick Flow and Kvick Lab cassettes, maximum system pressure is 4.15 bar g (60 psi g).
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: 1 Flush the system and filter with water or buffer. 2 Drain the system from all fluid. 3 Make sure that process grade air supply to the integrity test is connected and turned on, refer to *Section 4.5.4 Connect compressed air supply, on page 99*.
2	Isolate the upstream process by closing the following valves: • Feed valve **XV-001**. • Retentate pressure control valve **PCV-341**. • Retentate valve **XV-051**.
3	Open the Permeate valve **XV-031** to Permeate.

Step	Action
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: 1 Set the ***Integrity_Test_Pressure*** to the pressure specified by the filter manufacturer. 2 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: 1 Wait for a stable air flow reading from the flow meter **FT-143**. 2 Compare this value to the integrity air flow value specified by the filter manufacturer.
6	Terminate the air integrity test: 1 Set ***Integrity_Test_Pressure*** to zero. 2 Close the integrity test valve **XV-063**. 3 Open the retentate valve **XV-051**. 4 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.

Unexpected flowrate

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.

6 Operation

About this chapter

This chapter provides the information required to safely operate the UniFlux System.

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 *Chapter 2 Safety instructions, on page 12* as listed below:

- *General precautions, on page 13*
- *Personal protection, on page 15*
- *System operation, on page 20*

NOTICE

Only use chemicals that have been proven not to be harmful to the wetted parts of the system.

Refer to *Section 9.3 Chemical resistance, on page 157* for more information.

In this chapter

This chapter contains the following sections:

6.1 Perform the run

Precautions

WARNING

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

CAUTION

Use ear protection whenever working close to the system in operation.

NOTICE

Operator console

- Do not use the operator console to push or drag the system
- Do not lean on the console

The console arm is only designed to support the weight of the operator console.

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 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 *Test, on page 83*.

Starting

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

Monitoring

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 possibilites that the UNICORN user interface offers is available in the UNICORN *manual package*.

Ending

Normal completion

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

End before 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.)

6.2 Procedures after usage

Cleaning the filters

The filters can be cleaned in place if the method is set within the specifie ranges for solutions, temperature and pressure. The filters should be cleaned as described in *Filters , on page 134*.

UNICORN shut-down

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	Exit Windows.
4	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 7.3 Storage, on page 136* as required.

7 Maintenance

About this chapter

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

In this chapter

This chapter contains the following sections:

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 *Chapter 2 Safety instructions, on page 12* as listed below:

- *General precautions, on page 13*
- *Personal protection, on page 15*
- *Power supply, on page 19*
- *Maintenance, on page 22*

7.1 User maintenance schedule

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, refer to *Section 7.5 pH calibration, on page 140*.
Alarm buzzer	Check the function ***Alarms:BuzzerTest***.
Complete system	Clean/sanitize the system according to the procedure described in *Cleaning-in-place (CIP), on page 133*.
Protective earth	Make sure that the protective earth wiring is not disconnected or damaged.

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 GE Healthcare 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/Cond monitor	Replace the pH electrode if difficulties are experienced during calibration.

Component	Action
Cond monitor	Clean and calibrate the cond monitor.

7.2 Cleaning

General

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 UniFlux (and connected equipment) from growth or contamination.

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.

Refer to *Section 9.3 Chemical resistance, on page 157*.

NOTICE

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

Cleaning before maintenance/service

Before maintenance/service is performed, the system owner must first clean the system and complete a Health & Safety Declaration Form. Contact GE Healthcare for further information.

Cleaning-in-place (CIP)

CIP hookup

Applies to UniFlux 30, 120 and 400.

The UniFlux system and Tank combination is preferably cleaned together as one unit.

The UniFlux system feed outlet **P5 / CIP** shall be connected to the tank CIP-ball inlet **TB4 / CIP INLET** using the provided hose. Ensure proper position of the ball using the positioning marks.

Refer to *UniFlux Feed Tank Operating Instructions* for information on how to clean the Tank.

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 System has been heavily contaminated and the normal CIP-procedure is not sufficient, cleaning performance can be improved by:

- Extending the total CIP time period.
- Changing to an alternative CIP-agent.
- Filling the UniFlux 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 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.

Filters

- GE Healthcare Kvick Lab cassettes cleaning procedures are provided in the *Kvick Lab and Kvick Flow Cassettes User Manual*, GE Healthcare article no 18-1171-69.

  GE Healthcare Kvick Lab and Kvick Flow cassettes cleaning procedures are provided in the *Kvick Lab and Kvick Flow Cassettes User Manual*, GE Healthcare article no 18-1171-69.
- GE Healthcare Hollow fiber cartridges cleaning procedures are provided in the *Hollow fiber cartridges for membrane separations Operating Handbook*, GE Healthcare article no 18-1165-30.
- Filter units provided by other manufacturers shall be cleaned according to the instructions from the respective manufacturer.

External surfaces

The UniFlux 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 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 electric cabinet.

7.3 Storage

NOTICE

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

NOTICE

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

Short term storage

This procedure works for storage duration up to one month.

Step	Action
1	Perform cleaning as described in *Section 7.2 Cleaning, on page 133*.
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 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 System to prevent contamination caused by the surrounding environment.

Long term storage

This procedure is applicable for storage duration 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 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 connector rubber gaskets in good condition suitable for processing and place them in dark and cold storage while UniFlux 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 is stored for long periods of time.

Filters

- GE Healthcare Kvick Lab and Kvick Flow cassettes storage procedures are provided in the *Kvick Lab and Kvick Flow Cassettes User Manual*, GE Healthcare article no 18-1171-69.
- GE Healthcare Hollow fiber cartridges storage procedures are provided in the *Hollow fiber cartridges for membrane separations Operating Handbook*, GE Healthcare article no 18-1165-30.
- Filter units provided by other manufacturers shall be stored according to the instructions from the respective manufacturer.

7.4 Disassembly and assembly

User-allowed actions

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

WARNING

Only personnel authorized by GE Healthcare may open the cabinet doors. There is high voltage inside the cabinet that can cause human injury or death.

WARNING

The electric cabinet doors may only be opened when UniFlux System is taken out of operation and subject to **LOCK OUT / TAG OUT**.

WARNING

LOCK OUT / TAG OUT! Before any maintenance or decommissioning work is performed on UniFlux System, make sure that:

- it is empty and depressurized.
- it is disconnected from process feed, electrical power and pneumatic supply.
- it is prevented from accidentally becoming re-energized during maintenance.
- it 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 piping system must be tested for leakage at maximum pressure:

- After assembly or maintenance
- Before operation or CIP

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.

While these operations can be performed by a properly skilled user Technician, GE Healthcare recommends that a GE Healthcare service engineer is assigned for this work.

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

Other components

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

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

7.5 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

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***.
5	Remove the pH-probe from the holder and rinse it with distilled water.

Step	Action
6	Remove the cup with the first buffer from the holder and replace it with the cup with the second buffer.
7	Re-locate 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.

8 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 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 GE Healthcare 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 *Chapter 2 Safety instructions, on page 12* as listed below:

- *General precautions, on page 13*
- *Personal protection, on page 15*
- *Power supply, on page 19*
- *Maintenance, on page 22*

System

Component	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 **PAUSE/-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).

Component	Possible cause	Corrective action
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 GE Healthcare service personnel.
	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 as described in *Section 7.2 Cleaning, on page 133*.

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

Refer to *Air integrity test, on page 120*.

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, or 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 the oil level and add oil if the level is too low.

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 electric cabinet. 2 Run instruction: ***P202_clear faults*** or ***P203_clear faults***. 3 Contact your local GE Healthcare representative.
	Little or no flow.	Broken or damaged hose.	1 Check the pump hose. 2 Contact your local GE Healthcare 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 separate manual.
	Dirty conductivity cell.	Clean the conductivity cell, refer to *Section 7.2 Cleaning, on page 133*
Absolute conductivity value is wrong.	Bad calibration.	Calibrate the conductivity cell, see separate manual.
	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 separate manual.

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 manual.
pH reading appears to be incorrect.	pH-sensor not properly calibrated.	Calibrate the pH-sensor as described in *Section 7.5 pH calibration, on page 140*.

9 Reference information

About this chapter

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

The UniFlux System is a modular built instrument that can be configured in many different ways.

To understand the specific configuration that applies to your UniFlux System, please refer to the system documentation supplied with the instrument.

In this chapter

This chapter contains the following sections:

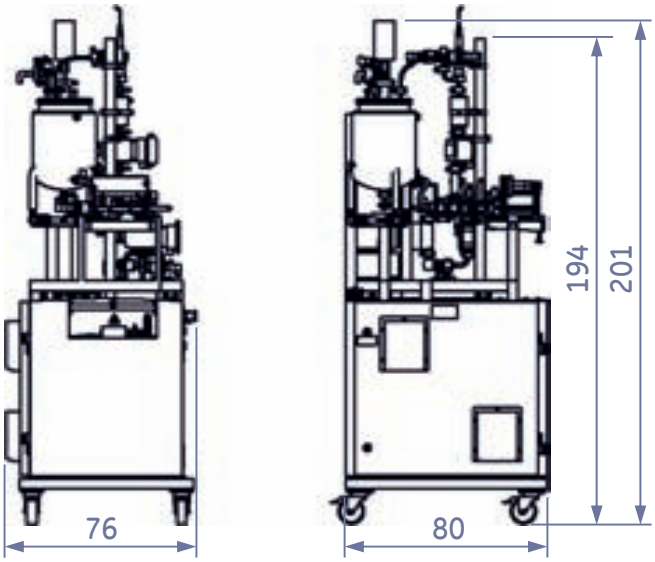
9.1 Specifications

Dimensions

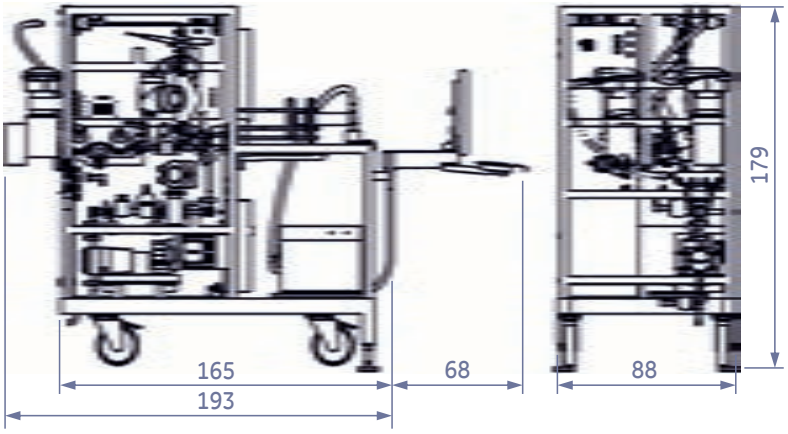
Note:

- *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



UniFlux 30



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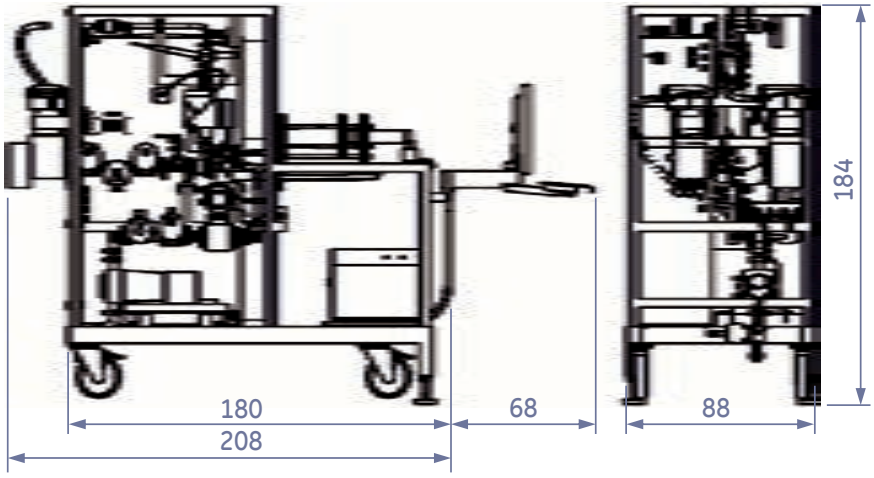
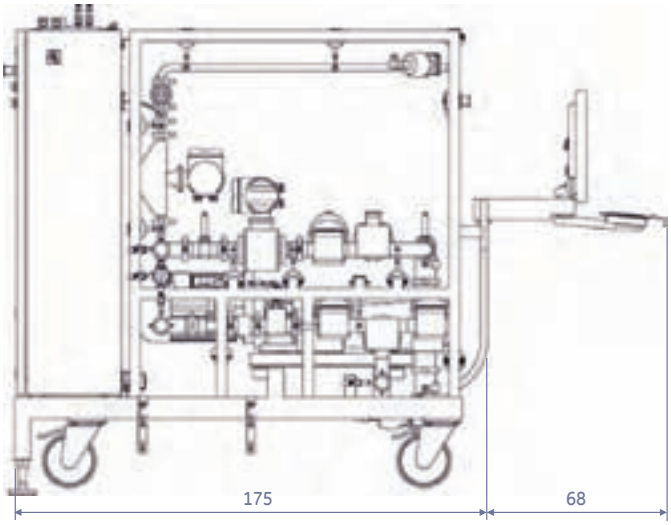
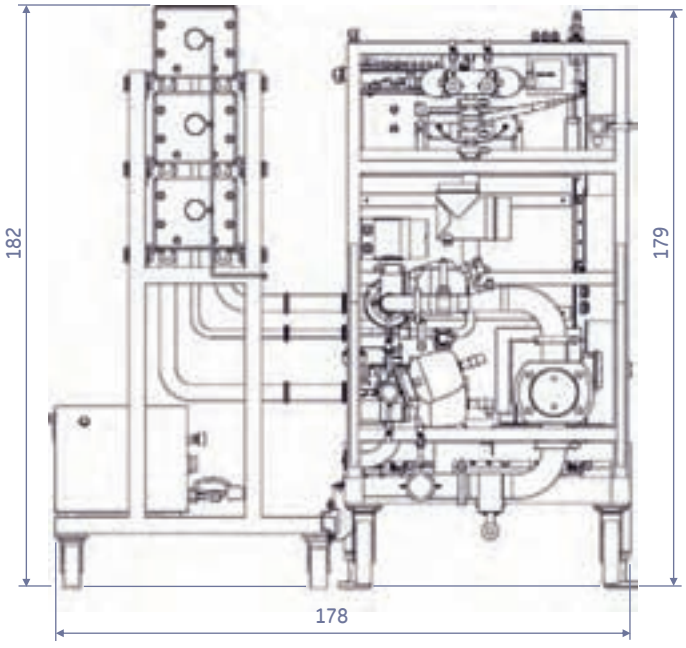


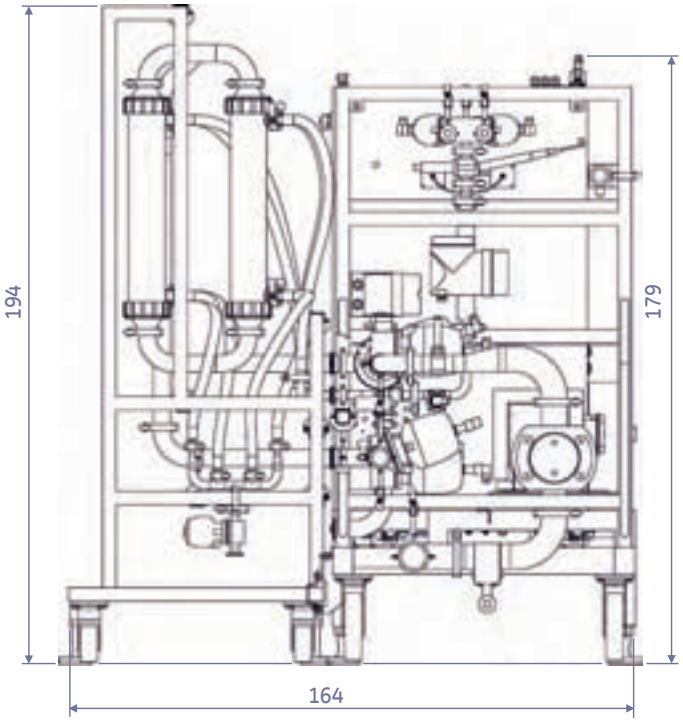
UniFlux 400



UniFlux 400 Cassette configuration



UniFlux 400 HF configuration



Technical specifications

Parameter for UniFlux System		10	30	120	400 System skid	400 Filter skid
Main power supply	Voltage, frequency	L-N-PE 110/230 VAC, 50/60 Hz				N/A
	Min fuse rating	16 A (110 VAC) 10 A (230 VAC)	16 A SB (110 VAC) 10 A SB (230 VAC)			
System pump power supply	Voltage, frequency	N/A	L1-L2-L3-PE, 400/480 VAC, 50/60 Hz			
	Min fuse rating		16 A SB (230 VAC)		30 A SB (230 VAC)	
Electrical inputs, all		Fixed installation, Shielded cable 2.5 mm^2/14 AWG, UL/CE approved				
Overvoltage category		II				
Pollution degree		2				
Weight, empty without filters	AC	300 kg	440 kg	540 kg	600 kg	400 kg
	HF		410 kg	500 kg		200 kg
	All options additional weight	38 kg	54 kg		400 kg	N/A

Operating limits

Property			Value
Feed pump pressure at 20°C, 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
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

Power consumption

UniFlux	1-phase 110/230 VAC	3-phase 200 VAC	3-phase 400/480 VAC
10	3 A	-	-
30/120	3 A	7.5 A	5 A
400	3 A	-	18 A

9.2 Process wetted materials

For a complete list of wetted materials, refer to the Bill of Material in the product documentation kit.

9.3 Chemical resistance

Introduction

The table below gives allowed exposure concentrations and times for various chemicals that may be used in GE Healthcare BioProcess instruments in general.

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

WARNING

Flammable liquids. UniFlux System is **not approved** to handle flammable liquids.

WARNING

Some of the chemicals used with UniFlux System may be flammable under certain conditions. Make sure to use chemicals only under conditions where they are not flammable. Refer to local and/or national classifications of flammable liquids.

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 passiva-tion

Chemical	Concentration	Max time / cycle	Max acc. expos.	Usage
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
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

9.4 More information

Spare parts and accessories

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

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

Remaining aspects

Regarding

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

Please contact your local GE Healthcare representative for advice.

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

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For local office contact information, visit
www.gelifesciences.com/contact

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