

# **ÄKTA** readyflux Operating Instructions

Original instructions Translation disc included





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## 1 Introduction

#### **About this chapter**

This chapter contains important user information, descriptions of safety notices, regulatory information, intended use of ÄKTA<sup>™</sup> readyflux<sup>™</sup>, and lists of associated documentation.

#### In this chapter

Section		See page
1.1	About this manual	5
1.2	Important user information	6
1.3	Associated documentation	8
1.4	Abbreviations	10

### 1.1 About this manual

#### **Purpose of this manual**

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

#### Scope of this manual

The Operating Instructions cover the ÄKTA readyflux instrument including the optional 2D bag trolley Bagkart<sup>™</sup> and the optional flat sheet filter trolley Fluxkart<sup>™</sup>, and references to UNICORN 7. The illustration below shows the ÄKTA readyflux system.



#### **Typographical conventions**

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

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

## 1.2 Important user information

## Read this before operating the product



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

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

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

### Intended use of the ÄKTA readyflux

#### system

ÄKTA readyflux system is intended to be used as development and manufacturing equipment for processing of biomolecules, both upstream and downstream.

#### **Prerequisites**

- You should be acquainted with the use of bioprocessing equipment and with the handling of biological materials.
- You must have read and understood *Chapter 2 Safety instructions, on page 11* of these *Operating Instructions*.
- The system must be installed according to the instructions in *Chapter 4 Installation,* on page 74.
- You must have a working knowledge of the UNICORN<sup>™</sup> software. See the UNICORN manuals for instructions on the software structure and the work flow.
- You must have a working knowledge of Microsoft<sup>®</sup> Windows<sup>®</sup>.

#### Definitions

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



#### WARNING

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



#### CAUTION

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



#### NOTICE

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

#### **Notes and tips**

Note:	A note is used to indicate information that is important for trouble-free and
	optimal use of the product.
Tip:	A tip contains useful information that can improve or optimize your proce-

, dures.

## 1.3 Associated documentation

#### Introduction

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

#### **User documentation**

The user documentation listed in the table below is available in printed, PDF, or electronic Help format.

Documentation	Main contents
ÄKTA readyflux Operating Instructions	Instructions needed to install, operate and maintain ÄKTA readyflux in a safe way.
Site Preparation Guide	Document specifying site require- ments. Contains a checklist as a feed- back tool to the Cytiva personnel prior to installation of the instrument or system.
Unpacking Instructions	Instructions on how to unpack the instrument upon arrival.
Hardware Product Documentation binders	Documents including hardware specifications.
UNICORN 7 documentation package	Overview and detailed descriptions of the system control software for ÄKTA readyflux. The manuals cover the process picture map for real time moni- toring, the method editor, as well as the evaluation and administration modules.
Software manual	Instructions on how to use the software

#### Help in the software

The following help information is available on the workstation software.

Documentation	Main contents
UNICORN 7 software help	Overview and detailed descriptions of menus and functions in UNICORN 7.
	To access the software help, select <i>Help</i> from the menu bar or press the <i>F1</i> key.

#### System-specific documentation

In addition to the *Operating Instructions* manual, the documentation package supplied with ÄKTA readyflux also includes product documentation binders containing detailed specifications and traceability documents.

#### **Component documentation**

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

### 1.4 Abbreviations

#### Introduction

This section explains abbreviations that appear in the user documentation for  $\ddot{\mathsf{A}}\mathsf{KTA}$  readyflux.

### Abbreviations

Abbrevia- tion	Definition (English)	Translation
CFF	Cross-Flow Filtration	Cross-Flow Filtration
GMP	Good Manufacturing Practices	Good Manufacturing Practices
HF	Hollow Fiber	Hollow Fiber
LPM	Liter Per Minute	Liter Per Minute
MAbs	Monoclonal Antibodies	Monoclonal Antibodies
PCV	Pressure Control Valve	Pressure Control Valve
RPM	Revolutions Per Minute	Revolutions Per Minute
SOP	Standard Operation Proce- dures	Standard Operation Proce- dures
ТМР	Transmembrane Pressure	Transmembrane Pressure
UPS	Uninterruptible Power Supply	Uninterruptible Power Supply

## 2 Safety instructions

#### About this chapter

This chapter describes safety precautions, labels and symbols that are attached to the equipment. In addition, the chapter describes emergency and recovery procedures, and provides recycling information.

#### Important



#### WARNING

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

#### In this chapter

Section		See page
2.1	Safety precautions	12
2.2	Labels	23
2.3	Emergency procedures	25

## 2.1 Safety precautions

#### Introduction

ÄKTA readyflux is powered by mains voltage and handles materials that may be hazardous. Before installing, operating or maintaining the system, you must be aware of the hazards described in this manual.

## Follow the instructions provided to avoid personal injuries, damage to the equipment, or to other personnel or equipment in the area.

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

- General precautions on page 12
- Personal protection, on page 14
- Flammable liquids and explosive environment on page 14
- Installing and moving the system on page 15
- Power supply, on page 17
- System operation on page 18
- Maintenance on page 22

#### **General precautions**



#### WARNING

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

4	

#### WARNING

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



#### WARNING

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



Only properly trained personnel may operate and maintain the product.



#### WARNING

**Electrical shock hazard**. All installation, service and maintenance of components inside the electronics cabinet should be done by service personnel authorized by Cytiva. Do not open any covers or replace parts unless specifically stated in the *Operating Instructions*.



#### WARNING

Do not use any accessories not supplied or recommended by Cytiva.



#### WARNING

Do not use ÄKTA readyflux 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

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

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

#### **Personal protection**

#### WARNING

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

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



#### WARNING

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



#### WARNING

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

## Flammable liquids and explosive environment



#### WARNING

**Flammable liquids.** This product is **not approved** for handling flammable liquids.



#### WARNING

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

#### Installing and moving the system



#### WARNING

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



#### WARNING

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



#### WARNING

**Tipping risk**. When lifting and moving the product, make sure that the fork is inserted under the center of gravity of the product. The center of gravity of the product is high and the product may tip over if the forks are offset too far to either side.



#### WARNING

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



#### WARNING

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



#### WARNING

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



#### CAUTION

The product is designed for indoor use only.



#### CAUTION

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



#### CAUTION

Packing crates may have been exposed to pesticides, depending on the regulations of the country of delivery. Recycle packing crates according to local recommendations for pesticide-treated wood.



#### CAUTION

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



#### CAUTION

Make sure that the tubing is not bent along sharp edges. Vibration of bent tubing along sharp edges causes rubbing that may cause the tubing to break and leak.



#### CAUTION

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



#### 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 ÄKTA readyflux without pooling.



#### CAUTION

The maximum weight of the 2D Bag on the Bagkart is 25 kg. Bagkart must only be tared with an empty bag and empty flow kits. Incorrect taring will result in overload of the Bagkart trolley or the bag, which may result in bag burst.



#### CAUTION

Bagkart must be calibrated with a pre-calibrated weight. If the calibration terminated or cancelled partially, re-calibrate before use.



#### CAUTION

Read XDUO and XDM instruction safety procedures and user manual before interfacing and operating with ÄKTA readyflux .



#### NOTICE

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



#### NOTICE

Vents on the ÄKTA readyflux instrument. Do not block the ventilation inlets or outlets of the instrument.

#### **Power supply**



#### WARNING

**Supply voltage.** Before connecting the power cord, make sure that the supply voltage at the wall outlet corresponds to the marking on the instrument.



#### WARNING

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



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



#### WARNING

Fuse replacement should only be performed by an authorized service engineer.



#### WARNING

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



#### WARNING

All electrical installations must be performed by authorized personnel only.

#### System operation



#### WARNING

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



#### WARNING

**Over-pressure.** Never block the outlet tubing with, for instance, stop plugs, since this will create over-pressure and might result in injury.



Do not close valves located downstream of the pump when pump is running.



#### WARNING

During operation, the cabinet door must always be closed and locked.



#### WARNING

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



#### WARNING

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



#### WARNING

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



#### WARNING

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



#### WARNING

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





Never leave a flow kit containing aggressive liquids mounted on the system for longer time periods. Either discard the flow path, or rinse it with water or suitable solution.



#### WARNING

Single use. The flow kit is intended for single use only.



#### WARNING

Never put fingers or any objects other than the intended tubing into the pinch valve opening.



#### WARNING

Emergency stop in XDUO and XDM instruments will pause the system.



#### WARNING

Emergency stop in the system will not pause XDUO and XDM systems.



#### CAUTION

**Hot surface.** When pumping fluid through feed pump, do not touch feed pump until you are sure that this can be done without risk or when the pump has reached a temperature below 40°C. Use protective gloves to touch the hot surface e.g. feed pump pressure plate during run.



#### CAUTION

Frequently check the torque of the screws on the pressure plate (feed pump) if running the system for a longer time period (more than a day).



#### CAUTION

**Check expiry date**. Never use a flow kit that has past its expiry date.



#### CAUTION

The **PAUSE/CONTINUE** button on the status panel of instrument will toggle between pause and run. It corresponds to the **Pause** and **Continue** buttons in UNICORN .



#### CAUTION

Do not insert your fingers into any moving parts. Keep your hands out of the pump openings. Turn off the pump motor before opening the pump.



#### CAUTION

Knowledge of how to use UNICORN is required to safely operate the product. Refer to UNICORN user documentation as required.



#### CAUTION

To avoid contamination, make sure the system is thoroughly cleaned before changing the flow kit.



#### NOTICE

Do not leave a flow kit mounted on the system for an excessively long time. The tubing may be chemically welded when pinched together for longer periods, possibly causing high pressure alarms when running the system.

#### Maintenance

#### WARNING

**Disconnect power.** Always disconnect power from the instrument before performing any maintenance task.

#### WARNING

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

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



#### WARNING

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



#### WARNING

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



#### CAUTION

Connectors on the cabinet, such as connectors for pH, conductivity, network, etc., that are not used, should be plugged to prevent cleaning liquid from entering the connector.



#### CAUTION

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

### 2.2 Labels

#### Introduction

This section describes the system label and other safety or regulatory labels that are attached to the product.

#### System label

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

The following symbols and text may be present on the system label:

Label text	Description
	<b>Warning!</b> Read the user documentation before using the system. Do not open any covers or replace parts unless specifically stated in the user documentation.
Code Number	Ordering number for ÄKTA readyflux
Serial Number	System serial number
Manufacturing Month/Year	Month (MM) and Year (YYYY) of manufacture
Supply Voltage	Supply voltage
Frequency	Supply voltage frequency
Max Power Consumption	Maximum power consumption
Pneumatic Supply	Pneumatic supply pressure requirement
Protection Class	Protection class. Ingress protection according to IEC 60529. This covers the electric cabinet only.

#### **Safety labels**

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

Symbol/text	Description
	<b>Warning!</b> Read the user documentation before using the system. Do not open any covers or replace parts unless specifically stated in the user documentation.

Symbol/text	Description
4	<b>Warning! High Voltage</b> . Always make sure that the system is disconnected from electric power before opening the cabinet doors or disconnecting any electric device.
	<b>Warning! Pinch hazard.</b> This sign is located next to pinch valves. Never put your fingers or any objects other than the intended tubing into the pinch valve openings. Ensure that clothing or other equipment cannot get caught in the pinch valves.
26	<b>Warning! Pinch hazard because of rotating parts.</b> This sign is located next to the pumps. Turn off the pump motor before opening the pump. Keep your hands out of the pump openings.
EMERGENCY STOP	<b>EMERGENCY STOP</b> label, yellow with black text. (Emergency stop button is red). See Section 2.3 Emergency procedures, on page 25 for further information about the <b>EMERGENCY STOP</b> button.

## 2.3 Emergency procedures

#### Introduction

This section describes how to do an emergency shutdown of the ÄKTA readyflux system, and the procedure for restarting the system.

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

#### **Precautions**



#### WARNING

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

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



#### WARNING

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

## Emergency stop button and main power switch



Part	Function
1	Emergency stop button EMERGENCY STOP
2	Main power switch MAIN POWER

#### **Emergency shutdown**

In an emergency situation, follow the steps below to stop the run: ÄKTA readyflux Operating Instructions 29175550 AE

### 2 Safety instructions

2.3 Emergency procedures

lf you want to	then
stop the run	<ul> <li>Press the EMERGENCY STOP button. or</li> <li>To stop the run from UNICORN, click the End button in the System Control module.</li> <li>System Control File Edit View Manual System Tools Help Price Price Price Price Price</li> </ul>
switch off the instru- ment	<ul> <li>Turn the MAIN POWER switch to the O position. or</li> <li>Disconnect the power cord from the wall socket.</li> <li>Result: The run is interrupted immediately.</li> <li>Note: The sample and data may be lost as a result of switching off the power.</li> </ul>

#### **Power failure**

The following table describes the consequences of a power failure.

Power failure to	Will result in
ÄKTA readyflux system	<ul> <li>The run is interrupted immediately.</li> <li>The data collected up to the time of the power failure is available in UNICORN.</li> </ul>
Computer	<ul> <li>The UNICORN computer shuts down.</li> <li>The Power/Communication indicator (white) on the Instrument control panel displays a slowly flashing light.</li> <li>The run is interrupted immediately.</li> <li>Data generated up to 10 seconds before the power failure can be recovered.</li> <li>Note: The UNICORN client may lose connection to the instrument during a temporary overload of the processor and display an error message. This may appear as a computer failure. The run continues and you can restart the UNICORN client to regain control. No data will be lost.</li> </ul>

## Restart after emergency shutdown or power failure

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

Step	Action
1	Make sure that the condition that caused the emergency shutdown or power failure is corrected.
2	If power to the instrument has been lost, restart the instrument.
3	Click the <b>Continue</b> button in the <b>System Control</b> module.

## 3 System description

#### About this chapter

This chapter provides an overview of the technical properties of ÄKTA readyflux.

#### In this chapter

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3.2	Illustrations	31
3.3	Components	40
3.4	Flow system	52
3.5	Filters	56
3.6	UNICORN control system	60

### 3.1 System overview

#### Introduction

ÄKTA readyflux system is a single-use cross flow filtration (CFF) system. It is intended for use in development and GMP production processes of pharmaceuticals. The ÄKTA readyflux system is primarily for the the production of MAbs, but can also be used for vaccines and recombinant proteins. The system shall not be used for diagnostic purposes in any clinical or *in vitro* procedures.

This section gives an overview of the ÄKTA readyflux system.

## Illustration of the ÄKTA readyflux system



Part	Function
1	Bagkart, trolley for 2D hanging bag
2	ÄKTA readyflux main filtration instrument
3	Fluxkart, trolley for placement of flat sheet filter cassette

#### **Areas of application**

ÄKTA readyflux is a single-use cross flow filtration (CFF) system for use in production processes with both hollow fiber filter cartridges and flat sheet membrane cassettes. Applications include concentration, diafiltration (buffer exchange), clarification and cell harvest. All the wetted parts in the system are disposable.

ÄKTA readyflux is designed for downstream operations as well as upstream harvesting in line with cGMP guidelines. Other applications are cell harvesting, cell or lysate clarification, product concentration, normal flow filtration and diafiltration. It can be used with both hollow fiber filter cartridges and flat sheet membrane cassettes.



#### WARNING

**Flammable liquids.** This product is **not approved** for handling flammable liquids.



#### WARNING

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

#### Associated products

ÄKTA readyflux is intended for use with ÄKTA readyflux flow kits that are ordered separately. A flow kit consists of the entire flow path of the system. See <u>Section 8.4 Ordering</u> *information, on page 180* for ordering information. ÄKTA readyflux is designed to operate with ÄKTA ready chromatography systems and mixers.

### 3.2 Illustrations

#### Introduction

This section provides illustrations of the  $\ddot{\mathsf{A}}\mathsf{KTA}$  readyflux system. The main features and components are indicated.

#### ÄKTA readyflux instrument

The illustration below shows the ÄKTA readyflux instrument.



Part	Function
1	ÄKTA readyflux cabinet transfer side
2	ÄKTA readyflux cabinet permeate side
3	ÄKTA readyflux top panel
4	ÄKTA readyflux front panel
5	Swivel casters with brake

#### ÄKTA readyflux top panel

The illustration below shows the top panel of the ÄKTA readyflux instrument.



Part	Function
1	EMERGENCY STOP button
2	POWER, RUN, and PAUSE/CONTINUE indicator lights
3	FLOW KIT INSTALL - RUN - INTEGRITY TEST selector



#### CAUTION

The **PAUSE/CONTINUE** button on the system will toggle between pause and run. It corresponds to the **Pause** and **Continue** buttons in UNICORN .

### ÄKTA readyflux front panel



The illustration below shows the front panel of the ÄKTA readyflux instrument.

Part	Function
1	Transfer valve XV-084
2	Recirculation valve from permeate <b>XV-085</b>
3	Transfer to retentate valve XV-086
4	Pressure control valve PCV-341
5	Retentate valve to bag XV-052
6	Feed/buffer inlet valve XV-004
7	Feed inlet valve from bag <b>XV-005</b>
8	Feed pump P-201
9	Tube supports
10	Integrity valve XV-041 to air supply
11	Retentate valve from filter XV-051
12	Connector for pressure sensor PT-112
13	Connector for conductivity sensor <b>CE-101</b> and temperature sensor <b>TE-161</b>
14	Connector for pressure sensor PT-111
15	Feed inlet valve to filter <b>XV-006</b>
16	Drain valve XV-071

## ÄKTA readyflux cabinet permeate side



The illustration below shows the permeate side of the ÄKTA readyflux instrument.

Part	Function
1	UV sensor AE-131
2	Position for mounting bracket for hollow fiber cartridges, see <i>Section</i> 3.5.2 <i>Hollow fiber (HF) filters, on page 58</i> .
3	Clamp for pH sensor cable
4	Tube supports
5	Connector for pressure sensor PT-113
6	Connector for conductivity sensor <b>CE-102</b> and temperature sensor <b>TE-162</b>
7	Connector for pH sensor AE-121
8	Connector for flow sensor FE-141
9	Dummy connector for flow sensor <b>FE-141</b>
10	Main power switch MAIN POWER

Part	Function
11	Permeate pump P-203
12	Inlet valve XV-034 for permeate pump and UV sensor
13	Permeate recirculation inlet valve XV-033
14	Permeate outlet valve XV-032
15	Permeate drain valve XV-031
16	External connectors, see External connectors on page 37

### ÄKTA readyflux cabinet transfer side

The illustration below shows the transfer side of the ÄKTA readyflux instrument.



Part	Function
1	Air filter clamp
2	Air inlet valve XV-081
3	Air sensor AE-151
4	Buffer inlet valve XV-082
5	Product/Fed batch process inlet valve XV-083
6	Push handle
7	External connectors, see External connectors on page 37
8	Transfer pump P-202
9	Tube supports
10	Feed/buffer inlet valves XV-001, XV-002, XV-003
#### **External connectors**

The illustrations below show the ports for external connectors on ÄKTA readyflux.



Ports on the permeate side:

Part	Function	
POWERSUPPLY	System power supply connector	
PNEUMATIC AIR SUPPLY	Pneumatic air supply	
CUSTOMER I/O - 1	I/O socket, see Section 3.3.4 CUSTOMER I/O connec- tors, on page 50	
SYSTEM COMPUTER	UNICORN Ethernet connector	



Ports on the transfer side:

Part	Function
PROFIBUS OUT	PROFIBUS™ connector out

# 3 System description

3.2 Illustrations

Part	Function	
PROFIBUS IN	PROFIBUS connector in	
WE 176	Weight scale connector	
CUSTOMER I/O - 2	I/O socket, see Section 3.3.4 CUSTOMER I/O connec- tors, on page 50	

# Bagkart

The illustration below shows the Bagkart trolley.



Part	Function	
1	Load cell	
2	Cable from load cell to instrument	
3	Push handle	
4	Storage cabinet	
5	Swivel casters with brake	
6	Bagholder	
7	Dummy connector for load cell	

# Fluxkart

The illustration below shows the Fluxkart trolley.



Part	Function	
1	Push handle	
2	Spillage collector	
3	Swivel casters with brake	

# 3.3 Components

#### About this section

This section provides an overview of the different components of ÄKTA readyflux.

# In this section

Section		See page
3.3.1	Flow kits	41
3.3.2	Pumps and valves	43
3.3.3	Meters and sensors	48
3.3.4	CUSTOMER I/O connectors	50

# 3.3.1 Flow kits

#### **Flow path**

ÄKTA readyflux flow kits consist of tubing, sensors, a pump head, and fittings. The flow kit, including pump head and sensors, is disposable.

The flow path consists of three parts. Each of the three parts are gamma irradiated at delivery and ready for use with the ÄKTA readyflux instrument.

The illustration below shows the parts of the flow path.



No	Color	Function	Description
1	Blue	Permeate and recirculation flow path	Flow path that handles process fluid that passed through the filter.
2	Yellow	Retentate and transfer flow path	Flow path returning from the filter to the feed source. Transfer flow path also adds process fluid to the feed source.
3	Red	Feed flow path	Flow path from the feed source to the filter.

For flow chart and flow path descriptions, see Section 3.4 Flow system, on page 52.

3 System description 3.3 Components

3.3.1 Flow kits

3.3.1 Flow kits

For information on how to install a flow kit, see *Section 5.1 Flow kit installation, on page* 97.

#### **Flow kit tubing**

Flow kit tubing inner diameter (i.d.) dimensions are:

- 3/s inch at drains and low flow circulation paths
- 1/4 inch at the permeate pump
- 1/2 inch at high flow circulation path

Various types of tubing are used for the flow kit:

- Braided tubing at high-pressure paths
- Clear tubing at low-pressure paths, except at the UV-sensor
- Black tubing at the UV sensor
- Pump tubing at the permeate pump and the transfer pump

See also Flow kit specifications on page 173.

3 System description 3.3 Components 3.3.2 Pumps and valves

# 3.3.2 Pumps and valves

#### Introduction

This section describes the components located on the panels of the ÄKTA readyflux instrument:

- Front panel
- Transfer side panel
- Permeate side panel

The components' designations are shown in the flow chart in Section 3.4 Flow system, on page 52.

#### **Pumps**

ÄKTA readyflux has three pumps. Placement is shown in *Section 3.2 Illustrations, on* page 31.

Pump		Pumptype
P-201	Feed pump	Diaphragm pump
P-202	Transfer pump	Peristaltic pump
P-203	Permeate pump	Peristaltic pump

3 System description3.3 Components3.3.2 Pumps and valves

#### **Feed pump**

The feed pump **P-201** installed on ÄKTA readyflux is a four piston diaphragm pump. It uses a single-use pump head that is part of the flow kit and that is disposed of after usage. The Quattroflow™-1200 SU is self-priming and can run dry.

The illustration below shows the feed pump.



Part	Function
1	Motor
2	Ring drive
3	Pump head
4	Hole for screws
5	Pressure plate

#### **Transfer and permeate pumps**

The transfer (**P-202**) and permeate (**P-203**) pump installed on ÄKTA readyflux are peristaltic pumps. Peristaltic pumps can run dry.

The occlusion settings knob on the transfer pump and the permeate pump is by default set to  ${\bf 2}.$ 

The illustration below shows the transfer pump and the permeate pump.

**Note:** Changes to occlusion settings may require a change in gain factor. For more information on how to change the gain factor see Calibration of pumps P-201, P-202 and P-203 on page 146



Part	Function
1	Occlusion settings knob
2	Pump head
3	Opening for inserting the pump tubing
4	Lever for opening the pump head
5	Motor

#### **Pinch valves**

Pinch valves are used to control the path of the liquid flow through the flowpath. There are 20 pinch valves and one PCV. The valves have manually operated safety locks keeping the tubing in place and preventing the valves from accidentally closing during flow kit installation.

During pause, the valves will remain in the same position as during the run. At the end of a method run, or at emergency stop, the valves reset to their default positions.

During no run, changing between **FLOW KIT INSTALL** or **INTEGRITY TEST** will change the valves to different open/close states.

The illustration below shows a pinch valve.





#### WARNING

Never put fingers or any objects other than the intended tubing into the pinch valve opening.

#### **Default positions of valves**

The table below lists the different valves and their default positions.

Valves	Default position
Permeate valves, XV-031 to XV-034	Closed
Air inlet valve, <b>XV-081</b>	Closed
Transfer valves, XV-082 to XV-085	Closed
Transfer to retentate valve, XV-086	Closed
Retentate valves, XV-051 and XV-052	Open
Pressure control valve, <b>PCV-341</b>	Open
Integrity valve, XV-041	Closed
Additional feed inlet valves, <b>XV-001</b> to <b>XV-003</b>	Closed
Feed flow path valves, XV-004 and XV-071	Closed
Feed flow path valves, XV-005 and XV-006	Open

- **Note:** Valves are either open or closed, except for the PCV valve which can be closed gradually.
- **Note: TMP** is controlled by the pressure control valve **PCV-341**, which is regulated by the **TMP** instruction in UNICORN.
- **Note:** Control the PCV valve in manual mode by entering the desired pressure set point in percent (%) in the **PCV341\_%closed** instruction.

# 3.3.3 Meters and sensors

#### Introduction

Sensors that measure pressure, conductivity, temperature, pH, flow and UV are included in the ÄKTA readyflux flow kits. The sensors are disposable and intended for single use only. They are pre-calibrated.

The sensors are connected to meter units inside the instrument cabinet. The sensors must to be connected to the meters via connector cables.

#### **Pressure sensors**

ÄKTA readyflux flow kits have three pressure cells continuously measuring the pressure of the liquid:

Pressure sensor	Location	Function
PT-111	Feed flow path, directly down- stream from the feed pump.	Measures the pressure in the feed flow path.
PT-112	Retentate flow path, directly downstream from the filter.	Measures the pressure in the retentate flow path after the filter.
PT-113	Permeate flow path, directly upstream from the outlet manifold of the filter.	Measures the pressure in the permeate flow path after the filter.

The locations of the pressure sensors are also depicted in *Flow chart on page 52*.

#### **Flow sensor**

ÄKTA readyflux flow kit contains an ultrasonic flow sensor (transducer) **FE-141** that measures the flow in the permeate flow path.

# Conductivity and temperature sensors

ÄKTA readyflux flow kits contain two sensors that measure the conductivity and temperature of the samples during a run. The temperature sensors measure the temperature by measuring the electrical resistance of metal electrodes and is a part of the conductivity sensor.

Sensor	Location
Conductivity sensor <b>CE-101</b> and temperature sensor <b>TE-161</b>	Retentate flow path

Sensor	Location
Conductivity sensor <b>CE-102</b> and temperature sensor <b>TE-162</b>	Permeate flow path

The locations of the conductivity and temperature sensors are also depicted in *Flow* chart on page 52.

Conductivity measurement is temperature compensated and thus dependent on correct temperature readings.

**Note:** A system that is not properly temperature equilibrated may produce incorrect temperature readings. Therefore, if the system or flow kit is moved between rooms with different temperatures, time must be allowed for the equipment to adjust to the new ambient temperature. It can take up to several hours for the flow kit to adjust to room temperature.

#### **Air sensors**

The air sensors **AE-151** and **AE-152** (optional) continuously monitor air bubbles in the flow path. When air is detected, the system is either paused, or performs an action that is set in the method. Air sensor **AE-152** is not part of the ÄKTA readyflux system.

The locations of the air sensors are depicted in *Flow chart on page 52*.

#### **pH** sensor

ÄKTA readyflux flow kit contains a pH sensor (**AE-121**) that measures the pH of the sample in the permeate flow path.

The location of the pH sensor is depicted in Flow chart on page 52.

#### **UV** sensor

ÄKTA readyflux flow kits contain a UV sensor (**AE-131**) that measures UV absorbance of the sample in the permeate flow path.

For correct measurements, it is important that the UV sensor is properly fitted into the its reader.

The location of the UV sensor is depicted in *Flow chart on page 52*.

# 3.3.4 CUSTOMER I/O connectors

# Introduction

The **CUSTOMER I/O** connectors are 9-pole (**CUSTOMER I/O - 1**) and 15-pole (**CUSTOMER I/O - 2**) IP67-proof D-sub pin connectors. Matching socket connectors containing a screw terminal block with water tight housing are supplied with the system. The **CUSTOMER I/O** connector can be used to interface **AE-152** and external scales, an external alarm, and to receive a signal indicating that a UPS has been activated.

This section provides an overview of the ports on each of the **CUSTOMER I/O** sockets.

### CUSTOMER I/O - 1

The table below provides a list of the ports of the **CUSTOMER I/O - 1** connector at the permeate side of the ÄKTA readyflux cabinet.

Pin	Definition of signal
1	Free
2	Free
3	+ve 4-20 mA, <b>WE-179</b>
4	Free
5	-ve 4-20 mA, <b>WE-179</b>
6	Free
7	Free
8	Free
9	Free

This connector supports the following interfaces:

- External weighing scale WE-179
- **Note:** To enable **WE-179** communication with instrument, select the component in component types (see Section 4.4.3 Start UNICORN and connect to system, on page 86).

# CUSTOMER I/O - 2

The table below provides a list of the ports of the **CUSTOMER I/O - 2** connector at the transfer side of the ÄKTA readyflux cabinet.

*Note:* ÄKTA readyflux does not supply power to remote weighing scale readers but accepts analog (2-wire 4-20mA) signals. The system provides input/output signal interface through customer I/O connector.

Pin	Definition of signal
1	+24V Digital output, Remote alarm
2	Free
3	+ve 4-20 mA, <b>WE-177</b>
4	Digital ground, Remote alarm
5	-ve 4-20 mA, <b>WE-177</b>
6	+ve 4-20 mA, <b>WE-178</b>
7	-ve 4-20 mA, <b>WE-178</b>
8	Free
9	Signal H, Air sensor <b>AE-152</b>
10	Signal V, Air sensor <b>AE-152</b>
11	+24V Digital input, UPS On
12	Free
13	+5V, Air sensor <b>AE-152</b>
14	Ground, Air sensor AE-152
15	+24V Digital supply voltage, UPS On

This connector supports the following interfaces:

- Air sensor AE-152
- External weighing scale WE-177
- External weighing scale WE-178
- Remote alarm
- UPS On
- Note: To enable AE-152, WE-177 and WE-178 communication with the instrument, select the components in Component types list (see Section 4.4.3 Start UNICORN and connect to system, on page 86).

# 3.4 Flow system

# **Flow chart**



Symbol	Function
Ø	Pump
R	Pressure control valve
$\bowtie$	Normally closed valve
M	Normally open valve
Δ́	Bag
	Filter
0	Sensor

Symbol	Function
11	Connector
	Air filter
$\bigtriangledown$	Load cell
	Accessory
	Customer I/O
А	Air sensor
С	Conductivity sensor
F	Flow sensor
Р	Pump
pН	pH sensor
Pf	Feed pressure sensor
Рр	Permeate pressure sensor
Pr	Retentate pressure sensor
Т	Temperature sensor
UV	Ultra Violet sensor
W	Weight

#### **Feed flow path description**

The purpose of the feed flow path (red line in the flow chart) is to transfer the feed from the feed source (2D or 3D bag) via the pump to the filter. The feed pump **P-201** generates the desired flow to run the process.

Located on the feed flow path is the pressure sensor **PT-111** that measures the pressure between the pump and the filter.

The feed flow path can be cut off with the **XV-006** valve and drained through the **XV-071** valve.

Sensor **AE-152** can be placed on the tubing between **XV-003** and **XV-004** to continuously monitor air bubbles in the flow path.

#### **Retentate flow path description**

Particles or molecules too large to pass through the filter pores are retained and pass along the filter membrane as retentate. The retentate is guided to the retentate outlet through the **XV-051** valve, from where it can be pumped back to the feed source and recirculated.

The retentate outlet flow path has sensors for pressure (**PT-112**), conductivity (**CE-101**) and temperature (**TE-161**). Transmembrane pressure is controlled by the pressure control valve **PCV-341**.

The entire retentate flow path can be shut off by closing the retentate valves **XV-051** and **XV-086**. The retentate flow path is drained through the **XV-071** valve on the feed flow path.

#### Permeate flow path description

Particles or molecules small enough to pass through the filter pores are collected as permeate. Permeate is collected from the filter through the permeate connection and guided to the permeate outlet through the **XV-032** valve, from where it can be guided back to the recirculation through the **XV-033** valve.

The permeate outlet flow path has sensors for pressure (**PT-113**), conductivity (**CE-102**), temperature (**TE-162**), pH (**AE-121**), flow (**FE-141**) and UV (**AE-131**).

#### **Transfer flow path description**

The transfer flow path adds process fluid and buffer solutions to the feed source.

Located on the transfer flow path is an air filter and air sensor AE-151.

The transfer flow path can be activated by opening the valves **XV-082** or **XV-083**, **XV-084**, and **XV-086**. The transfer flow path can be cut off with the **XV-084** valve.

#### **Maximum pressures**

The pressure is monitored by three pressure sensors, see *Pressure sensors on page 48*. The different pressure levels are illustrated with dashed lines in the flow chart below.



Dash	Description	Pressure
	Low pressure	<0.5 bar (7.25 psi, 0.05 MPa)
	High pressure	≤4 bar (58.02 psi, 0.4 MPa)

# 3.5 Filters

#### **About this section**

This section provides an overview of the different filter types that can be used with  $\ddot{\mathsf{A}}\mathsf{K}\mathsf{T}\mathsf{A}$  readyflux.

# In this section

Section		See page
3.5.1	Flat sheet filters	57
3.5.2	Hollow fiber (HF) filters	58

3 System description 3.5 Filters 3.5.1 Flat sheet filters

# 3.5.1 Flat sheet filters

#### Introduction

The ÄKTA readyflux Fluxkart provides a convenient way to position the filter holder at the correct height to match the length of the flow kit tubing.

For more information about cassette models and sizes, see *Membrane filter cassette specifications, on page 174.* 

#### Filter cassette holder

The filter cassette holder follows industry standard cassette dimensions and accepts other cassettes of standard layout. In some cases an adapter is necessary to connect to the flow kit.

The filter cassette holder mounted on Fluxkart can be replaced by other filter cassette holders.

The illustration below shows a **Kvick Flow™** filter cassette holder placed on Fluxkart.



# 3.5.2 Hollow fiber (HF) filters

## Introduction

The ÄKTA readyflux mounting brackets for HF cartridges provides a convenient way to place and use HF cartridges for filtration.

ÄKTA readyflux is designed to operate with hollow fiber cartridges of different sizes. These cartridges are described in the *Hollow fiber cartridges for membrane separations Operating Handbook*, Cytiva article no. 18116530.

See Section 5.3.2 Hollow fiber (HF) cartridges, on page 137 for more information on how to install the HF cartridges for a filtration.

For more information on cartridge models and sizes, see *Hollow fiber cartridge specifications on page 174*.

#### Hollow fiber cartridges

Hollow fiber (HF) cartridges consist of bundles of cylindrical fibers through which the feed fluid enters via the filter inlet. The fluid that does not pass the permeable membrane is collected as retentate at the filter outlet. The fluid passing through the permeable membrane is collected as permeate.

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

The HF cartridge is mounted vertically, so the lower side connection serves as a drain for the permeate. This allows for more complete recovery of the permeate.

The illustration below shows a HF cartridge mounted on the ÄKTA readyflux cabinet.



3 System description 3.5 Filters 3.5.2 Hollow fiber (HF) filters

# Mounting brackets for hollow fiber cartridges

The mounting brackets for hollow fiber cartridges are located on the permeate side of the ÄKTA readyflux instrument.

The mounting brackets have a hinged arm where the hollow fiber cartridge is inserted. The hinged arm is secured with a knurled nut.

The illustrations below show mounting brackets which can accommodate one or two hollow fibre filters based on selection.



# 3.6 UNICORN control system

#### About this section

This section provides an overview of the UNICORN software that is used to operate the  $\ddot{\mathsf{A}}\mathsf{KTA}$  readyflux system.

# In this section

Section		See page
3.6.1	Introduction	61
3.6.2	Description of UNICORN	62
3.6.3	The <b>System Control</b> module	63
3.6.4	Process picture	65
3.6.5	Warnings and alarms	73

3 System description 3.6 UNICORN control system 3.6.1 Introduction

## 3.6.1 Introduction

#### **Overview**

ÄKTA readyflux is controlled by the UNICORN process control software. UNICORN can save established processes as methods. The methods include the instructions necessary for process operation and documentation.

#### **User access levels**

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

Only personnel with adequate training should be allowed to operate the instrument. Access to system should be controlled by different user-levels with different authorizations.

Only system operators with adequate authorization can be responsible for designing methods that conform to local SOP and GMP if applicable.

UNICORN is compatible with FDA 21 CFR Part 11.

#### **Documentation**

The UNICORN software phases and the UNICORN user documentation provide complete instructions for programming and for using the software for process control.

Contact your local Cytiva representative for advice if required.

# 3.6.2 Description of UNICORN

#### Software modules

The UNICORN control software consists of four modules:

Module	Function
Administration	File handling and administration tasks; for example, definition of systems and managing user profiles.
Method Editor	Method creation and editing for preprog- rammed control of ÄKTA readyflux.
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 the UNICORN system for automatic control includes these general steps:

Step	Action
1	Program an ÄKTA readyflux method run using the UNICORN software. It is possible to use an existing method or modify an existing method to meet the run objectives.
2	Start the run using the created method.
3	Monitor the run's progress using the <b>System Control</b> module. In the <b>System Control</b> module, all the data about the run is displayed in four different panes. The panes can be open one or several at a time, 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 <b>Evaluation Module</b> .

## 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.

# 3.6.3 The System Control module

#### Introduction

The **System Control** module is used to start, view, and control a manual or method run.

#### System Control toolbar buttons

The following table shows the **System Control** toolbar buttons that are referred to in this manual.

Butto n	Function	Butto n	Function
	<b>Open Method Navigator</b> . Opens the <b>Method Navi-</b> <b>gator</b> where available methods are listed.		<b>Run</b> . Starts a method run.
	<i>Hold</i> . Suspends the method run, while current flow rate and valve positions are sustained.	Ш	<b>Pause</b> . Suspends the method run and stops all pumps. The current valve positions are sustained.
	<b>Continue</b> . Resumes for example a held or paused method run.		<b>End</b> . Permanently ends the method run and stops all pumps. The valves reset to their default positions.
<b>V</b>	<b>Customize</b> . Opens the <b>Customize</b> dialog box where curve settings, run data groups and run log contents can be set.	•	<b>Connect to Systems</b> . Opens the <b>Connect to</b> <b>Systems</b> dialog box where systems can be connected, and currently connected users are displayed.

#### System Control panes

As shown in the following illustration, four panes can be displayed in the **System Control** module.

The *Run Log* pane (1) presents all registered actions.

The *Run Data* pane (2) presents current data in numerical values.

The *Chart* pane (3) illustrates data as curves during the entire run.

The current flow path is illustrated in the **Process Picture** pane (4), which allows manual interactions with the system and provides feedback on run parameters. For more information about the process picture, see <u>Section 3.6.4 Process picture</u>, on page 65.

#### 3 System description

3.6 UNICORN control system

3.6.3 The System Control module



# 3.6.4 Process picture

#### Introduction

The process picture is a pictorial representation of the system and is shown in the **Process Picture** pane in the **System Control** module. The process picture displays the current flow path and system parameters during a run and can be used to control the run. The flow paths in the process picture have different colors depending on the state of the system.

#### Panels

The **Process Picture** pane contains four panels, as shown in the illustration below.



Part	Function
1	Process picture
2	System state panel
3	Flow Kit installation wizard button
4	Settings panel

# **Symbols**

The table below describes the various symbols that are used in the process picture.

#### 3 System description

3.6 UNICORN control system

3.6.4 Process picture

Symbol	Description
20 kg Reservoir	Bag
***	Filter
	Flow path
PCV341 40 % 🛱 🗖	Pressure control valve
18.00 L/min	Active pump (green rotating triangle)
0 L/min	Inactive pump (gray triangle)
PT112	Sensor
•	Open valve
1041	Closed valve

#### The Idle state

When the system is powered on, and all the components are initialized to their default states, the process picture shows the *Idle* (ready) state of the system. The system state panel says *Idle* and the different flow paths are illustrated in the colors red, yellow, and blue, as shown in the illustration below.



Color	Indication
Red	Feed flow path
Yellow	Retentate and transfer flow path
Blue	Permeate and recirculation flow path

#### The Running state

When the system is running an instruction in manual, the process picture shows the *Running* state of the system. The system state panel says *Running* and the open flow paths are illustrated in green color, as shown in the illustration below. The closed flow paths are illustrated in gray color.



#### 3 System description

3.6 UNICORN control system

3.6.4 Process picture

Color	Indication
Green	Open flow path
Gray	Closed flow path

**Note:** The optional components are shown in the process picture based on the user selection of components in the **Administration** module of UNICORN.

# The Flow kit installation wizard button

The *Flow kit installation wizard* is launched from the *Flow Kit installation wizard* button above the *Settings* panel.

The illustration below shows the *Flow Kit installation wizard* button.



#### The Settings panel

Different settings can be changed from the **Settings** panel. The illustration below shows the **Settings** panel.

Settings
Units
Pumps
PCV
AutomatedValues
DisplayParameters

The table below describes the settings.

Settings	Description	
Units	Change the units for flow and pr picture. The available options ar Flow: L/h or L/min Pressure: bar or psi Settings Units Flow L/min Pressure bar Pressure bar Choose the preferred settings a	ressure in the process re: nd click <b>OK</b> .
Pumps	Set the values for the three differed: Values for the feed pump <b>Permeate</b> : Values for the perm <b>Transfer</b> : Values for the transfer Flow rate 23.00 L/min Setpoint 0.00 L/min OK Carcel	erent pumps: eate pump or pump Settings Units Pumps Feed Permeate Transfer PCV AutomatedValues DisplayParameters
	Enter the preferred values and c	click <b>OK</b> .

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3.6 UNICORN control system

3.6.4 Process picture

Settings	Description
PCV	Set the values for the pressure control valve.
	Settings Units Pumps PCV Close 40.00 % Setpoint 0.00 % OK Cancel AutomatedValues DisplayParameters
Automated- Values	Set the values for the automated values such as <i>TMP</i> , <i>DeltaP</i> , <i>CFP</i> , <i>Flux</i> , <i>Shear</i> , and <i>CRV</i> . Settings Units Pumps PCV AutomatedValues
	TMP DeltaP
	CFP Flux
	Shear
	DisplayParameters
	Enter the preferred values and click <b>OK</b> .

Settings	Description
DisplayParame- ters	Show or hide all the labels in the process picture.
	Settings
	Units
	Pumps
	PCV
	AutomatedValues
	DisplayParameters
	Show/Hide Labels
	Select the <b>Show/Hide Labels</b> check box to show the labels.

### Pumps



#### WARNING

Make sure that a valid flow path exists before running a pump manually. Running a pump with invalid flow path will create overpressure and may result in tube burst or injury.

The pumps can be started and stopped directly in the process picture:

• To start a pump, click on the gray triangle on the pump symbol.

*Result:* A confirmation dialog is displayed. After confirmation, the pump starts with the set value.



• To stop a pump, click on the green rotating triangle on the pump symbol. *Result:* The value of the flow rate is set to 0 L/min and the pump stops immediately

To change the values of a pump:

• Click on the value on the pump symbol in the process picture. *Result:* The **Settings** panel opens.

3 System description

3.6 UNICORN control system

3.6.4 Process picture

or

• click *Pumps* in the Settings panel.

### Valves

To toggle the valves position between open and close:

• Click on the valve symbol in the process picture.

*Result:* A confirmation dialog is displayed. After confirmation, the valve position is changed.

Confirmation		×
Do you want t	to change the val	lve position?
[	ОК	Cancel

To change the values of the pressure control valve:

• Click on the symbol of the pressure control valve in the process picture. *Result:* The **Settings** panel opens.

or

• click PCV in the Settings panel.

#### Sensors

The locations of the sensors are hidden in the process picture. To show the location of a sensor:

• Point to the value of the sensor in the process picture.

*Result:* The sensor symbol is displayed in the process picture where the sensor is located.


3 System description3.6 UNICORN control system3.6.5 Warnings and alarms

# 3.6.5 Warnings and alarms

#### Warnings

Warnings are generated to warn operating personnel that process parameters have exceeded preset high and/or low limits. The process method continues after the warning has been acknowledged.

#### **Alarm signals**

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

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

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

#### Alarm test

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

#### Alarm reset

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

# 4 Installation

## **About this chapter**

This chapter provides required information to enable users and service personnel to transport, unpack and install the product.

# In this chapter

Section		See page
4.1	Site requirements	75
4.2	Transport	79
4.3	Unpack the product	82
4.4	Setup	83
4.5	Power supply	92

# 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 *Section 2.1 Safety precautions, on page 12* as listed below:

- General precautions on page 12
- Personal protection, on page 14
- Flammable liquids and explosive environment on page 14
- Installing and moving the system on page 15
- Power supply, on page 17

# 4.1 Site requirements

#### **Space requirements**

For space and floor requirement, see external dimensions and weights in *Dimensions* on page 75.

- Make sure that the floor can handle the ÄKTA readyflux 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 ÄKTA readyflux, Bagkart and Fluxkart when installed at the intended production location.

#### **Dimensions**

The following illustration shows the dimensions of the ÄKTA readyflux system.



155 cm (61")

The following table lists the dimensions of the individual products in the ÄKTA readyflux system.

Product	Width (cm)	Depth (cm)	Height (cm)
ÄKTA readyflux instrument	110	88	152
Bagkart	91	81	155
Fluxkart	72	45	100

#### 4 Installation 4.1 Site requirements

# Weight

The following table lists the weights of the individual products in the ÄKTA readyflux system.

Product	Weight (kg)
ÄKTA readyflux instrument	280
Bagkart	87
Fluxkart	40

# **Environmental conditions**

The following general requirements must be fulfilled:

- The ÄKTA readyflux 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 Hardware Product Documentation binders.

Avoid:

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

The installation site must comply with the following specifications:

Parameter	Specification	
Allowed location	Indoor use only	
Ambient temperature, operation	4°C to 32°C	
Max. relative humidity, operation	20% RH to 80% RH, non-condensing	
Ambient temperature, storage	-25°C to 50°C	
Atmospheric pressure	0.84 to 1.06 bar (1218 to 1537 psi, 0.084 to 0.106 MPa)	
Altitude, operation	Up to 2000 m	
Pollution degree of the intended envi- ronment	Pollution degree 2	
Ingress protection	IP45	

## **Electrical power requirements**

Parameter	Specification
Supply voltage	100 to 240 V AC ± 10%
Frequency	50/60 Hz
Max. power consumption	1 kVA
Circuit breaker	16 A



#### WARNING

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

#### **Media supply**

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

See Section 8.1 Specifications, on page 172 regarding requirements on media supply and delivery.

## **Computer requirements**

The use of a Cytiva computer is recommended. A non-Cytiva computer with 64-bit Windows operating system is acceptable if it complies with the requirements in the table below.

Components	Specification
Monitor size	17.3" or higher in case of laptop
	19" or higher in case of monitor
Processor	Intel <sup>®</sup> Core™ i5-2400 with 4 cores, 3.10 GHz
System memory	4 GB
Hard disk drive	250 GB
DVD RW	Unspecified
Network card	Extra Network Interface Card

For other computer requirements, see UNICORN 7Administration and Technical manual, Cytiva article no. 29209687.



#### NOTICE

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

When installing a stand-alone computer, take appropriate precautions to protect the computer from exposure to liquids.

# 4.2 Transport

#### Introduction

This section gives important information that must be considered when transporting the product.

#### **Crate dimensions**

The ÄKTA readyflux instrument is delivered in a crate.



The total crate weight, including the ÄKTA readyflux instrument, is 373 kg.

#### Moving the crate

Use suitable lifting equipment, such as a pallet lift or forklift, with a minimum capacity to match the weight of the ÄKTA readyflux system plus the transport crate. See *Crate dimensions on page* 79 and *Weight on page* 76 for information about crate weight and system weight. Make sure that the load is evenly distributed over the forks of the lifting equipment.

**Note:** Before moving the transport crate, make sure that all openings and apertures that the transport crate is intended to pass through are large enough to allow passage of the transport crate when it is lifted from the floor.

Read and carefully follow the instructions provided by the labels and symbols on the transport crate. The following table shows examples and the meanings of symbols that may be found on the transport crate.

Symbol	Explanation
	CAUTION TOP HEAVY. The center of balance is offset and is higher than the center of the crate.
	Fragile
Ť	Keep dry
<u><u><u></u></u><u></u><u></u><u></u></u>	This side up
	Recyclable material

## Moving when unpacked



#### WARNING

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

ÄKTA readyflux can be rolled by hand on hard and level surface with wheel brakes released. If the floor quality does not allow rolling the ÄKTA readyflux instrument on its own wheels, it can be moved with a pallet jack or fork lift.

**Note:** Before moving the instrument, make sure that all openings and apertures that the instrument is intended to pass through are large enough to allow passage of the instrument when it is lifted from the floor.



Before moving ÄKTA readyflux, make sure that:

- The power supply to ÄKTA readyflux is switched off.
- All power cords to ÄKTA readyflux are disconnected.
- All air supply lines to ÄKTA readyflux are disconnected.
- All process lines to ÄKTA readyflux are disconnected, and no fluids are present in the process lines.
- All communication cables to ÄKTA readyflux are disconnected.

# 4.3 Unpack the product

# Introduction

This section provides general instructions for unpacking the product.

See *Unpacking Instructions* 29178997 attached to the outside of the crate when unpacking the crate.

# Precautions



#### WARNING

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



# WARNING

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



# WARNING

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



# WARNING

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



#### WARNING

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

# 4.4 Setup

## About this section

This section provides required information to set up the ÄKTA readyflux system.

# In this section

Secti	ection	
4.4.1	Position the system	84
4.4.2	Setup of control system and network	85
4.4.3	Start UNICORN and connect to system	86
4.4.4	Connect compressed air supply	89
4.4.5	Bag and filter tubing connections	90

# 4.4.1 **Position the system**

# **Position the system**

The area required for positioning the ÄKTA readyflux system is 310 × 286 cm, allowing for at least 100 cm of free space on all sides of the instrument. The space allotted for the system should be sufficient to accommodate the ÄKTA readyflux instrument, Bagkart, and Fluxkart.



## Lock the wheels

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



# 4.4.2 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.

# Connect the system to a stand-alone computer

Two network cables are delivered with the system and should be connected according to the instruction below:

Step	Action
1	Connect the encapsulated end of the longer (10 m) straight cable to to the <b>SYSTEM COMPUTER</b> connector, see <i>External connectors on page 37</i> .
2	Connect the other end of the long cable to:
	• the controlling computer if a direct connection is used, or
	• the shorter (3 m) crossover cable, which, in turn, is connected to a switch or hub (the shorter cable is only used when connecting to the controlling computer via a network).



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

# Install UNICORN

Make sure that the UNICORN control software is installed on your computer. A system must be defined, and the ÄKTA readyflux configuration or strategy must be installed. See UNICORN 7 Administration and Technical manual for more information.

# Set up Controller Unit 960 (CU-960)

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

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

See UNICORN 7 Administration and Technical manual for more information.

# 4.4.3 Start UNICORN and connect to system

# Introduction

This section describes how to start and  $\log$  on to UNICORN and how to connect the instrument to UNICORN.

**Note:** See UNICORN 7 Administration and Technical manual for more information about how to define a new system, view, import or delete instrument configurations and edit system properties.

# Start UNICORN and log on

Follow the instructions to start UNICORN and log on to the program. A valid e-license must be available for the workstation. See UNICORN 7 Administration and Technical manual for more information about e-licenses.

Step	Action	
1	Double-click the UNICORN icon on the desktop.	
	Result:	

The *Log On* dialog box opens.

#### Note:

If there is no connection to the database it is still possible to log on to UNICORN and control a running system. The **Log On** dialog box will give the option to start **System Control** without a database. Click **Start System Control** to proceed to the next **Log On** dialog box.

2

In the Log On dialog box, select User Name, enter Password and click OK.

#### Note:

It is also possible to select the **Use Windows Authentication** check box and enter a network ID in the **User Name** field.

🖏 Log On - L	NICORN 🗾
🔲 Use <u>W</u> ind	ows Authentication
User Name:	Default 🔹
Domain:	
Access <u>G</u> roup:	Access To Everything
Start:	✓ Administration  ✓ System Control  Method Editor  Evaluation
	QK Qancel Options <<

#### Result:

The selected UNICORN modules open.

4 Installation 4.4 Setup 4.4.3 Start UNICORN and connect to system

#### Set up instrument components

Follow the instructions to open and edit components installed with the ÄKTA readyflux system.

Step	Action			
1	Select a system	m in the <b>System Pr</b>	<b>operties</b> dialog.	
	Note:			
	Only active sy	stems can be edited	d.	
2	Click <b>Edit</b> to v	iew the <b>Componer</b>	nt types list.	
	Result:			
	All available co	omponents are sho	wn.	
	Edit - AKTAreadyflux	_		×
	Instrument configuration	readyflux_1_0_4_test14 (1.0.0.2)	• Information	Import
	Instrument server	HCA-47WJ542	▼ Rename	



3 Select or deselect components in the check boxes under **Component types** in the **Edit** dialog.

#### Note:

The **Edit** dialog is system specific.

4 Click OK.

# **Connect to system**

Follow the instructions to connect the instrument to UNICORN. See Section 3.6.3 The System Control module, on page 63 for more information about the module.

4 Installation4.4 Setup4.4.3 Start UNICORN and connect to system

1

Step Action

In the **System Control** module, click **Connect to Systems**.

Result:

The Connect to Systems dialog box opens.

Connect to Systems		X
Connected systems (1 selected, max 3)		
System name	Control	View
📃 🔳 System1		
🗌 🔳 System2		۲
📉 🔳 System3	۲	0
📄 🔳 System4		0
🔲 🔳 System5		0
🔲 🔳 System6		۲
🔲 🔳 System7		۲
Connected Users	ОК	Cancel

2

In the *Connect to Systems* dialog box, select a system check box, click *Control* for that system, then click *OK*.

Result:

The selected instrument can now be controlled by the software.

# 4.4.4 Connect compressed air supply

### Introduction

This section describes how to connect the compressed air supply.

For requirements on air supply, see Technical specifications on page 172.

**Note:** Specified supply of compressed air should be maintained. Inadequate air supply will cause malfunction of the instrument and may cause hazards.

# Connect compressed air supply to ÄKTA readyflux

Step	Action	
1	Check that specified supply of compressed air is available at point of instal- lation.	
2	Make sure that the supply gauge pressure to the cabinet is between 5.5 to 7 bar. The manometer is set to 6 bar at the factory and must not be changed. Connect the compressed air supply to the <b>PNEUMATIC AIR SUPPLY</b> on the right (permeate) side of the instrument. Use the supplied 5 m air hose with 7.5 mm inner diameter.	
3		
	POWER PNEUMATIC CUSTOMER I/O - 1 SYSTEM	



# 4.4.5 Bag and filter tubing connections

# Introduction

This section provides guidelines for the tubing connections to bags and filters in the ÄKTA readyflux system.

# **Connection diagram**

See *Flow chart on page* 52 for a schematic diagram of the connections in the ÄKTA readyflux system.

# Recommended hoses and connections

Make sure to:

- Use hoses delivered with the ÄKTA readyflux flow kit to connect the flow kit to a 2D hanging bag (Bagkart) and filters.
- Use customer supplied hoses to connect the ÄKTA readyflux flow kit to a 3D bag (XDUO or XDM).

See Section 3.3.1 Flow kits, on page 41 and Flow kit specifications on page 173 for information regarding connection types and sizes.

# **General guidelines for connections**

- Use piping or tubing that has an internal diameter sufficient for the flow rate specified. The inner diameter of the tubing and its connections should be greater than or equal to the corresponding diameter of the system.
- Inlet and outlet containers shall be located and arranged so that back pressure and suction height remains within system specification limits.
- Keep the tubing lengths as short as possible to minimize hold-up volume in the system.
- Route the tubing to minimize the risk of tripping when operating the instrument and connected device.
- If the hoses are violently pulled by accident, they must be checked for damage, leakage and mechanical rigidity before continuing operation.
- The chemical resistance of tubing should meet the conditions specified in *Section* 8.3 *Chemical resistance, on page* 177.
- Make sure that all tubing is not twisted and is kink-free.
- Make sure that tubing clamps are open.

4 Installation 4.4 Setup 4.4.5 Bag and filter tubing connections



# 4.5 Power supply

# Introduction

This section describes the electrical connections to the instrument.

# Precautions



#### WARNING

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



#### WARNING

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



#### WARNING

**Supply voltage.** Before connecting the power cord, make sure that the supply voltage at the wall outlet corresponds to the marking on the instrument.

# **Power requirements**

The power supply requirements are specified in *Electrical power requirements on page* 77.

# Installation

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



#### WARNING

All electrical installations must be performed by authorized personnel only.



#### NOTICE

Do not turn on the **MAINS POWER** switch before all connections are made.

### **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 the power supply.

See *Technical specifications on page 172* or the Hardware Product Documentation binders for information regarding the leakage current for your system.

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

#### **Isolation switch**

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

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

#### **Power supply cable**

- Delivered with a permanent mains power supply cable, equipped with an IEC 60309 connector.
- Accepts 100 to 240 V AC, 50/60 Hz power supply.

The mains power supply must be connected and configured by authorized service personnel. Contact your Cytiva representative for more information.



#### WARNING

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

**Note:** Only authorized Cytiva personnel may perform service, installation and manitenance of components outside the cabinet.

# Main power supply wire colors and tags

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

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

# Protective earth wire cross section area

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

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

# **Ground fault breaker**

ÄKTA readyflux is not equipped with a general Ground Fault Circuit Breaker and it is not an option that is available from Cytiva.

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

- 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 Hardware Product Documentation binders.

#### **Built-in circuit breakers**

The mains power supply to the ÄKTA readyflux system and the pumps are equipped with circuit breakers inside the electrical cabinet. See the Hardware Product Documentation binders for the specific types used in your system.

### **More information**

Wiring diagrams for the system, voltage, power, fuse requirements and the tripping current for the fixed power supply ground fault protector can be found in the Hardware Product Documentation binders.

# 5 Operation

## **About this chapter**

This chapter provides the information required to safely operate the product.

## In this chapter

Section		See page
5.1	Flow kit installation	97
5.2	Baginstallation	128
5.3	Filter installation	134
5.4	Installation test	139
5.5	Calibration	146
5.6	Perform a run	149
5.7	Procedures after a run	154

# 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 *Section 2.1 Safety precautions, on page 12* as listed below:

- General precautions on page 12
- Personal protection, on page 14
- Flammable liquids and explosive environment on page 14
- Power supply, on page 17
- System operation on page 18



#### NOTICE

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

See Section 8.3 Chemical resistance, on page 177 for more information.

# 5.1 Flow kit installation

## About this section

This section provides the information required to install the flow kit.

## In this section

Section		See page
5.1.1	Preparations	99
5.1.2	Flow kit package	100
5.1.3	Install the flow kit	101
5.1.4	Flow kit installation test	124

# Precautions



## WARNING

Never leave a flow kit containing aggressive liquids mounted on the system for longer time periods. Either discard the flow path, or rinse it with water or suitable solution.



#### WARNING

Never put fingers or any objects other than the intended tubing into the pinch valve opening.



#### CAUTION

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



#### CAUTION

To avoid contamination, make sure the system is thoroughly cleaned before changing the flow kit.



#### NOTICE

Do not leave a flow kit mounted on the system for an excessively long time. The tubing walls may stick together where the tubing is squeezed, possibly causing high pressure alarms when running the system.



#### NOTICE

Only use flow kits supplied by Cytiva.

5 Operation 5.1 Flow kit installation 5.1.1 Preparations

# 5.1.1 Preparations

#### **Disinfectant solution**

A suitable disinfectant solution must be available for cleaning the external surfaces of system and flow kit. 70% ethanol or 2-propanol (isopropanol) can be used for sanitization.

**Note:** Desinfection is not necessary for flow kits with ReadyMate<sup>™</sup> end connections.

#### **Test buffers**

Wash and test buffers required for component testing must be prepared before mounting a new flow kit. It is important that buffers containing acetone or ethanol are freshly prepared. For details about volumes and concentrations required, see *Section 5.4 Installation test, on page 139.* A **Test solution preparation protocol** template is available on the ÄKTA readyflux CD.

**Note:** Make sure that the test solution is equilibrated to room temperature.

# 5.1.2 Flow kit package

# Packaging

The flow kit is delivered in three parts.

No.	Part of the flow path
1	Permeate flow path tubing, pump tubing and sensors
2	Retentate and transfer flow path tubing, pump tubing and sensors
3	Feed flow path tubing, feed pump head and sensor

ÄKTA readyflux flow kits are packed and delivered in double plastic bags. All parts are sterilized by gamma-irradiation and ready for use with the ÄKTA readyflux instrument. For information about the irradiation dose, see the flow kit documentation package.

# Labeling of flow kits

The different parts of the ÄKTA readyflux flow kit are labeled with a barcode for traceability.

# 5.1.3 Install the flow kit

#### Introduction

This section contains a step-by-step description of how to install a flow kit onto the ÄKTA readyflux cabinet.

Always use the ÄKTA readyflux **flow kit installation wizard** when installing a new flow kit. The wizard helps to ensure that all the steps are performed in the right order. The following information can be used as a supplement to the ÄKTA readyflux **flow kit installation wizard**.

- *Note:* Before operation, make sure that all safety locks on the pinch valves are closed.
- **Note:** The **Flow kit installation wizard** button will be enabled only when the system is in ready state. The button will be disabled when in running mode.
- **Note:** Always operate the instrument with the feed bag connected to feed and retentive lines. Valves closure during E-Stop, run END or power cycle will reset the valves to default open/close positions with a valid flow path centered on feed bag.

## Start the installation wizard

Follow the instructions below to start the ÄKTA readyflux flow kit installation wizard.

Step	Action
1	Start the UNICORN software.
2	Click the <b>Flow Kit installation wizard</b> button in the <b>System Control</b> module, located in the middle of right corner of process picture.
Tip:	Select <b>Restore to Default</b> under the <b>View</b> tab to maximize the size of the process picture.
Tip:	It is recommended to view the <b>flow kit installation wizard</b> in a maximized window.

#### Installation steps

The installation wizard will go through the following steps:

- Unpacking the flow kit.
  See Unpacking the flow kit, on page 102.
- Installation type and flow kit configuration.
  See Installation type and flow kit configuration on page 102.
- Registration details.
  See Registration details on page 103.
- 4. Prepare the system for flow kit installation.

See Prepare the system for flow kit installation on page 103.

#### 5 Operation

5.1 Flow kit installation

5.1.3 Install the flow kit

- Mount the tubing of the permeate flow path.
  See Mount the tubing of the permeate flow path on page 105.
- Mount the tubing of the retentate and transfer flow path.
  See Mount the tubing of the retentate and transfer flow path, on page 108.
- Mount the tubing of the feed flow path.
  See Mount the tubing of the feed flow path on page 112.
- Connect the sensors.
  See Connect the sensors on page 115.
- 9. Connect the end connections of the flow kit.

For TC end connectors, see Connect the end connections of the flow kit using TC end connectors on page 119.

For ReadyMate end connectors, see Connect the end connections of the flow kit using ReadyMate end connectors on page 120.

Close the pinch valves and the pump heads.
 See Close the pinch valves and the pump heads on page 122.

# Unpacking the flow kit

Follow the instructions below for unpacking the ÄKTA readyflux flow kit.

Step	Action
1	Open the box with the flow kit.
2	Take out the three plastic bags with the flow kit parts. Open the outer plastic bag of each flow path and take out the inner plastic bag.
	Note:
	Do not tear open the inner plastic bag until immediately before mounting the flow kit part onto the system cabinet.
3	Take out the documentation. Keep the documents near the instrument for registration.

# Installation type and flow kit configuration

Follow the instructions below for selecting the installation type and the flow kit configuration.

Step	Action	
1	Select installation type, <b>Quick installation</b> or <b>Step-by-step installation</b> .	
	Note:	
	Quick installation is only recommended for experienced users.	

5 Operation 5.1 Flow kit installation 5.1.3 Install the flow kit

Step	Action
2	Select the type of flow kit, <i>Flow Kit, Flow Kit plus</i> , or <i>Custom Kit</i> , and the type of end connector, <i>TC</i> or <i>ReadyMate</i> .

#### **Registration details**

Follow the instructions below for entering the registration details of the flow kit.

Note:	The Custom kit is by default equipped with ReadyMate end connections.
-------	---

#### Step Action

- 1 Enter the flow kit details manually or with a barcode scanner.
- 2 Enter the pH calibration details manually.



**Note:** The pH calibration slope and zero point values are provided on the sensor.

**Note:** If **Quick installation** has been chosen, the wizard will end here, and display a list of remaining installation steps.

# Prepare the system for flow kit installation

Follow the instructions below for preparation of the system for flow kit installation.

Note: UNICORN must be in ready state.

5 Operation 5.1 Flow kit installation

5.1.3 Install the flow kit



#### Note:

The FLOW KIT INSTALL setting will open all valves.

#### Note:

2

Do not run any method when in the FLOW KIT INSTALL setting.

- Open the safety locks on all pinch valves. Move the black lever on the pinch valves 180 degrees.
  - 6 valves on the transfer side of the instrument
  - 11 valves on the front of the instrument
  - 4 valves on the permeate side of the instrument



5 Operation 5.1 Flow kit installation 5.1.3 Install the flow kit

#### Step Action

3 Open the pump head of transfer pump **P-202** and permeate pump **P-203**. Move the lever on the pumps to the left (counterclockwise).



# Mount the tubing of the permeate flow path

Follow the instructions below to mount the tubing of the permeate flow path.

- **Note:** Leave the permeate pump head open while operating the permeate flow control.
- *Tip:* Align the flow kit tubing with the colored lines on the instrument.
- Step Action
- 1 Tear open the plastic bag.



#### 5 Operation

5.1 Flow kit installation

5.1.3 Install the flow kit

Step	Action
2	• If the flow kit is not supplied with a UV sensor:
	Hold the permeate recirculation tubing and the sensors tubing in one hand and the white pump tubing in the other hand.



• If the flow kit is supplied with the UV sensor **AE-131**:

Hold the permeate recirculation tubing and the sensors tubing in one hand. Use the other hand to place the UV sensor **AE-131** into the support and push the sensor into the reader until it clicks into the correct position.



5 Operation 5.1 Flow kit installation 5.1.3 Install the flow kit

#### Step Action

3 Place the white pump tubing into permeate pump **P-203**.



Use the free hand to insert the tubing into the two pinch valves **XV-033** and **XV-034** on the permeate side.



4

#### 5 Operation

5.1 Flow kit installation

5.1.3 Install the flow kit

5

#### Step Action

Use the free hand to align the permeate recirculation tubing around the cabinet and place it into the tube supports.



6 Insert the tubing into the two pinch valves **XV-031** and **XV-032** on the permeate side and place the sensor tubing into the tube supports.



# Mount the tubing of the retentate and transfer flow path

Follow the instructions below to mount the retentate and transfer flow path.

*Tip:* Align the flow kit tubing to the lines on the instrument.
#### Step Action

#### 1 Tear open the plastic bag.



Hold the air filter tubing to be placed into the clamp **FA-231** and the H-junction tubing in one hand and the air filter tubing to be placed into the **FA-232** clamp in the other hand.



3

2

Insert the tubing into the two pinch valves **XV-041** and **XV-051** on the cabinet front.



5.1 Flow kit installation

5.1.3 Install the flow kit

# Step Action

4

Insert the tubing with the air filter into the air filter clamp **FA-232**.



5 Insert the tubing into the two pinch valves **PCV-341** and **XV-052**.



6

Transfer the H-junction tubing to the other hand.



#### Step Action

7 Align the H-junction tubing and insert it into the three pinch valves **XV-086**, **XV-085**, and **XV-084**.



8

Place the tubing into transfer pump **P-202**.



9

Insert the tubing with the air filter into the air filter clamp **FA-231** on the transfer side.



# Step Action

10 Insert the tubing into the three pinch valves **XV-083**, **XV-082**, and **XV-081** on the transfer side, and into the air sensor **AE-151**.



# Mount the tubing of the feed flow path

Follow the instructions below to mount the feed flow path.

Tip:	Align the flow kit i	tubing to the lines or	the instrument.
	0	0	

#### Step Action

1 Tear open the plastic bag.



#### Step Action

2 Hold the tubing before the feed pump and the braided tubing in one hand and the tubing after the pump head in the other hand.



Insert the tubing into the two pinch valves **XV-006** and **XV-071** on the cabinet front.



4

3

Place the pump head into pump **P-201**.



5.1 Flow kit installation

5.1.3 Install the flow kit

5

# Step Action

Insert the tubing into the two pinch valves **XV-004** and **XV-005**.



Insert the tubing into the three pinch valves **XV-001**, **XV-002**, and **XV-003** on the transfer side.



7

6

Place the pressure plate on pump **P-201**.



#### Step Action

8 Hold the pressure plate and hand tighten the screws into pump by using a hex key.



Attach the drive adapter to the torque wrench and tighten the screws to 8 Nm, diagonally first and circular at the end.



# **Connect the sensors**

9

Follow the instructions below for connecting the sensors.

5.1 Flow kit installation

5.1.3 Install the flow kit

#### Step Action

1

Identify the sensors and their connectors on the permeate side and remove the sensor caps from the system.



Step	Action	
2	Plug in the pressure sensor <b>PT-113</b> cable as follows:	
	a. Align the white lines (A) and (B) on the connectors.	

**b.** Press the connectors together firmly.



Repeat for **PT-111** and **PT-112** on the cabinet front.

5.1 Flow kit installation

5.1.3 Install the flow kit

Step	Action
3	Plug in the conductivity sensor <b>CE-102</b> cable as follows:
	<b>a.</b> Align the keyway (1) on the connector of the sensor with the tab (1) inside the mating connector on the cable.
	<b>b.</b> Press the cable connector onto the sensor firmly.
	c. Turn the twist lock ring (3) to ensure proper connection.



Repeat for **CE-101** on the cabinet front.

Connect the pH sensor **AE-121** cable as follows:

- **a.** Align the keyway (A) on the connector of the sensor with the tab (A) inside the mating connector on the cable.
- **b.** Press the cable connector onto the sensor firmly.
- **c.** Tighten the knurled bushing (B) of the cable connector by hand to ensure proper connection and then push the connector into the clamp.

# Note:

4

A tightening of at least 6 times ¼ turn is necessary to get a good signal.



Step	Action	
5	Plug in the flow sensor <b>FE-141</b> cable as follows:	
	a. Align the arrows on both connectors.	
	b. Press the connectors together firmly.	



# Connect the end connections of the flow kit using TC end connectors

If the flow kit is supplied with TC end connectors, follow the instructions below to connect the end connections of the flow kit.

Step Action
-------------

1 Remove the protective caps from the permeate recirculation and transfer tubing at **XV-085**.



5.1 Flow kit installation

5.1.3 Install the flow kit



2 Insert the O-ring into the tube ends and align the tube ends.



3 Apply a standard plastic sanitary clamp, a disposable TC clamp, or a stainless steel sanitary clamp to the connector assembly for connection.



- 4 Repeat for filter and feed bag connections.
- **Note:** Always operate instrument with the feed bag connected to feed and retentate lines. Valves closure during E-Stop, run END or power cycle will reset the valves to default open/close positions with a valid flow path centered on feed bag.

# Connect the end connections of the flow kit using ReadyMate end connectors

If the flow kit is supplied with ReadyMate end connectors, follow the instructions below to connect the end connections of the flow kit.

# Step Action 1 Remove the protective cap and printed liner from the permeate recirculation and transfer tubing at XV-085. Tilt the connectors to engage the hook of one connector with the slot of the other. Bring the connectors together with an audible click.



Bring the tabs together and pull firmly on both tabs. Pull straight out until the folded membrane is completely removed.



2

Step	Action
3	Apply a standard plastic sanitary clamp, a disposable ReadyClamp, or a stainless steel sanitary clamp to the connector assembly for connection.
	St

- 4 Repeat for filter and feed bag connections.
- **Note:** Always operate instrument with the feed bag connected to feed and retentate lines. Valves closure during E-Stop, run END or power cycle will reset the valves to default open/close positions with a valid flow path centered on feed bag.

# Close the pinch valves and the pump heads

Follow the instructions below to close the pinch valves and the pump heads.

Step	Action
1	Turn the black levers on the pinch valves 180 degrees to close the safety locks on all pinch valves:
	6 valves on the transfer side of the instrument
	<ul> <li>11 valves on the front of the instrument</li> </ul>
	<ul> <li>4 valves on the permeate side of the instrument</li> </ul>



# 5.1.4 Flow kit installation test

# Introduction

The flow kit installation test checks that the flow kit is correctly installed and that the sensors are responding to the test points. The flow kit installation test takes approximately 5 minutes.

- **Note:** Flow kit installation test should always be performed after installing a new flow kit.
- *Note:* Flow kit installation test protocol considers Flow Kit with TC end connections and optional sensors.
- *Note:* Flow kit installation test uses a test solution containing 1% (v/v) acetone and 1.0 M sodium chloride.
- **Note:** For other flow kit configurations and test solutions, it is recommended to customize the method to suite user needs.

# Prerequisites

- Make sure that the Flow Kit optional components are selected in component view.
- Make sure that the latest installation test method is used.
- The flow kit is installed according to the instructions in the ÄKTA readyflux flow kit installation wizard.

# Description of the flow kit installation test

Step	Action
1	The test solution is recirculated to optimize usage.
2	The pressure sensors are tested for response during backpressure created by using <b>PCV%close</b> .
3	The conductivity, temperature, pH and UV sensors are tested by pumping a solution of 1% (v/v) acetone and 1.0 M sodium chloride through the flow kit.
4	The flow sensor is tested with recirculation setpoint of the feed pump.
5	When the test is finished within 5 minutes, it can be considered as PASS. The responses of sensors can be found in the UNICORN result file with a name containing Installation Test Flow Kit which can be accessed using <i>Evaluation</i> module.

For more information about the test report, *Section 5.4.3 The installation test report, on page 144.* 

# **Equipment and chemicals**

The following equipment and chemicals are required for the flow kit installation test:

- Tee connector, O-rings, TC clamps, and flexible tubing
- Test solution: 10 L of 1% (v/v) acetone and 1.0 M sodium chloride in a suitable container. See also the *Test solution preparation protocol* template on the system CD.
- **Note:** The test solution must be freshly prepared before a flow kit installation test is performed, to prevent the acetone from evaporating.
- **Note:** Make sure that the test solution is equilibrated to room temperature.

# Prepare for the flow kit installation test

Follow the steps below to prepare for the flow kit installation test.

Step	Action
1	Use a tee connector to connect the feed outlet to the flow kit permeate and retentate inlets.
2	Connect 1/2" ID flexible tubing on <b>XV-001</b> , 3/8" ID flexible tubing on <b>XV-034</b> ( <b>P-203</b> or <b>AE-131</b> ) outlet and place it in the test solution container.
3	Open the lid of Permeate pump ( <b>P-203</b> ).
4	Place the container next to the system and use only required tubing lengths to connect the flow kit and the container.
	For a description on how to make the connection, see <i>Connect the end</i> connections of the flow kit using TC end connectors on page 119.
5	Follow the instructions on the screen.
Note:	The following warnings can appear during the test and can be ignored:
	The UV led low light intensity warning appears if UV is enabled and the lamp is not switched on.
	The FE141 measurement error warning appears if there is no liquid or air bubble is detected by the <b>FE-141</b> .



#### WARNING

**Over-pressure.** Never block the outlet tubing with, for instance, stop plugs, since this will create over-pressure and might result in injury.

# Start the flow kit installation test

Follow the instructions below to start the flow kit installation test.

5.1 Flow kit installation

5.1.4 Flow kit installation test

Action
Import the Flow Kit installation test method from CD or Web
Open it in <i>Method</i> editor
For Flow Kit plus configuration, update the pH calibration slope and zero point values in <b>AE121_pH calibration settings</b> block located in test instructions tab of method
Save it
Run the method

# Monitor the flow kit installation test

The progress of the installation test can be followed in UNICORN 7. Charts will display the response curves for different sensors. Any time during the test run it is possible to manually add run notes that will be included in the report. To open the **Run Notes** dialog box, click **View**  $\rightarrow$  **Documentation**.

# Flow kit installation test report

When the test is finished within 5 minutes, it can be considered as PASS. The responses of sensors can be found in the UNICORN result file with a name containing Installation Test Flow Kit which can be accessed using *Evaluation* module.

# **Print a test report**

To print the UNICORN test report, go to UNICORN 7 *Evaluation* module. In the *File* menu, click *Report* and select the file name containing Installation Test Flow Kit.

# **Description of a test report**

An installation test report in the Installation Test Flow Kit file contains the following information

<b>Report section</b>	Information
Header	UNICORN 7 version number
	Name of user who ran the test
	Time and date
	Path of the test report file

## 5 Operation 5.1 Flow kit installation 5.1.4 Flow kit installation test

Report section	Information
Questions	Product identification details:
	Bar code of flow kit parts
	pH sensor details
	Protocol for text solution preparation
	Mode for entering codes
Method notes	Name of the system
	• List of steps that were performed during flow kit
	installation
Start notes	Notes entered in the <b>Start Notes</b> panel before the start
	of the component test
Run notes	Notes entered in the <b>Run Notes</b> dialog box during the component test
Evaluation notes	Notes entered after the component test is finished. To
	view the evaluation notes in UNICORN 7, go to the <b>Evalu-</b>
	<b>Notes</b> tab.
Results from installa-	Charts displaying the response over time for each of the
tion test	sensors.
Comments	Space for comments on the paper copy of the report.
Signature	Field for signatures for performance and approval

# Troubleshooting

If one of the sensors does not meet the specification, the test will be in infinite hold condition and will not proceed to the next sensor setpoint. Troubleshooting must be performed to establish the cause of failure and correct the problem. Troubleshooting is performed using the **system control** module or manual instructions. See *Chapter 7 Troubleshooting, on page 164*.

# 5.2 Bag installation

# **About this section**

This section provides required information to install bags in the  $\ddot{\mathsf{A}}\mathsf{KTA}$  readyflux system.

# In this section

Section		See page
5.2.1	2D hanging bag (Bagkart)	129
5.2.2	3D bag (XDUO or XDM)	132

5 Operation 5.2 Bag installation 5.2.1 2D hanging bag (Bagkart)

# 5.2.1 2D hanging bag (Bagkart)

# Introduction

This section describes how to install 5 L, 10 L and 20 L 2D-hanging bags (Bagkart) in the ÄKTA readyflux system.

# Illustration of a 2D hanging bag



Part	Function
1	Mounting rod
2	Bag outlet
3	Bag inlet
4	Flushing outlet
5	Sample port

# Installation

Follow the instruction below to install a 2D hanging bag (Bagkart) in the  $\ddot{\mathsf{A}}\mathsf{K}\mathsf{T}\mathsf{A}$  readyflux system.

5.2 Bag installation

5.2.1 2D hanging bag (Bagkart)





# CAUTION

Bagkart must be calibrated with a pre-calibrated weight. If the calibration terminated or cancelled partially, re-calibrate before use.

## Step Action

- 1 Slide the bag and the mounting rod from the side into the holder.
- 2 Connect the 2D hanging bag's outlet and inlet to the flow kit. See *Connect* the end connections of the flow kit using TC end connectors on page 119 or *Connect the end connections of the flow kit using ReadyMate end connectors on page 120* for a description on how to connect the flow kit to the bag outlet and inlet.

#### Note:

If necessary, move Bagkart to adjust the tubing lengths.

- 3 Connect the cable from the load cell to the ÄKTA readyflux instrument as follows:
  - **a.** Remove the plug on the weight scale connector (**WE 176**) on the transfer side of the ÄKTA readyflux instrument.
  - **b.** Align the keyway (A) on the weight scale connector with the tab (B) inside the mating connector on the cable.
  - c. Press the cable connector onto the weight scale connector firmly.
  - **d.** Tighten the knurled bushing (C) of the cable connector by hand to ensure proper connection.



5 Operation 5.2 Bag installation 5.2.1 2D hanging bag (Bagkart)

Step	Action
4	Make sure that <b>Bagkart (WE176)</b> is selected under <b>Component types</b> → <b>FeedBag Weight</b> , see Set up instrument components, on page 87.
	Note:
	Bagkart is enabled by default.

# 5.2.2 3D bag (XDUO or XDM)

# Introduction

This section describes how to install a 3D bag (XDUO or XDM) in the ÄKTA readyflux system. For more information regarding the XDUO or XDM system, see *FlexFactory XDUO Mixer Operating Instructions* or *FlexFactory XDM S UF Mixer Operating Instructions*.

**Note:** Contact a Cytiva service engineer when connecting XDUO or XDM S UF mixers to the ÄKTA readyflux system.

# Installation

Follow the instruction below to install a 3D bag (XDUO or XDM) in the ÄKTA readyflux system.

- **Note:** XDUO must have weight support and a PROFIBUS connection to work with the ÄKTA readyflux system.
- *Note:* XDM system must have an I/O box with PROFIBUS support to work with the ÄKTA readyflux system.

#### Step Action

1 Connect the 3D bag's outlet and inlet to the flow kit. See *Connect the end connections of the flow kit using TC end connectors on page 119 or Connect the end connections of the flow kit using ReadyMate end connectors on page 120* for a description on how to connect the flow kit to the bag outlet and inlet.

#### Note:

If necessary, align the XDUO or XDM system and the ÄKTA readyflux instrument next to each other to minimize the tubing lengths.

- 2 Connect the cable from the XDUO or XDM system to the ÄKTA readyflux instrument as follows:
  - a. Remove the terminator on the PROFIBUS connector out (**PROFIBUS OUT**) on the transfer side of the ÄKTA readyflux instrument.
  - **b.** Align the keyway on the **PROFIBUS OUT** connector with the tab inside the mating connector on the cable.
  - c. Press the cable connector onto the **PROFIBUS OUT** connector firmly.
  - **d.** Tighten the knurled bushing of the cable connector by hand to ensure proper connection.
- 3 Switch on the XDUO or XDM system. Make sure the XDUO system is in the *Local Control* mode. Initialize the XDUO or XDM system.

5 Operation 5.2 Bag installation 5.2.2 3D bag (XDUO or XDM)

# Step Action 4 **XDUO** For XDUO mixer, make sure the following Component types are selected as listed below, see Set up instrument components, on page 87: Mixer (XDUO/XDM) Options: Mixer (XDUO) • Mixer (XDUO/XDM) Options:Monitor (XDUO/XDM) • Depending on where the mixer is connected, select one of the following: FeedBag Weight: Feed Mixer (XDUO/XDM) or Transfer Weight: Transfer Mixer (XDUO/XDM) or Permeate Weight: Permeate Mixer (XDUO/XDM) Note: Agitator speed control is not available. XDM For XDM S UF mixer, make sure the following Components types are selected as listed below, see Set up instrument components, on page 87: • Mixer (XDUO/XDM) Options: Mixer (XDM) Mixer (XDUO/XDM) Options:Monitor (XDUO/XDM) •

 Depending on where the mixer is connected, select one of the following: FeedBag Weight:Feed Mixer (XDUO/XDM) or

Transfer Weight:Transfer Mixer (XDUO/XDM) or Permeate Weight: Permeate Mixer (XDUO/XDM)

- Mixer (XDM) Size:XDM xxx
- Mixer (XDM) Options:Mixer (XDM) Control
- Mixer (XDM) Options:Conductivity (XDM)
- Mixer (XDM) Options:pH (XDM)
- Mixer (XDM) Options:Temperature (XDM)

# Note:

Agitator speed control is available. During agitator speed control, **Pause** and **End** in UNICORN 7 stops agitation.

**Note:** Initialize the XDUO or XDM system first before connecting and starting a run on ÄKTA readyflux instrument.

# 5.3 Filter installation

# **About this section**

This section provides required information to install filters in the  $\ddot{\mathsf{A}}\mathsf{KTA}$  readyflux system.

# In this section

Section		Seepage
5.3.1	Membrane filter cassettes	135
5.3.2	Hollow fiber (HF) cartridges	137

# 5.3.1 Membrane filter cassettes

## Introduction

This section describes how to place the cassette holder on the Fluxkart and connect to the system.

# **General preparation of the cassettes**

Follow the general preparations below 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 their characteristic air or nitrogen flow.
2	Prepare and check the cassettes according to the manufacturer's instruc- tions.

# Installation

Follow the instruction below to install membrane filter cassettes in the filter cassette holder.

Step	Action
1	Assemble filter cassette in the cassette holder separatly and bring it near Fluxkart.
2	Place the assembled cassette holder on the Fluxkart in such a way that it minimizes tubing length (by facing holder inlet and outlet towards tubing connections).
3	Identify and connect the respective tubings to the feed, retentate and permeate ports on the holder.
4	Make sure that tubing connected to the cassette holder is not kinked or pinched.

# **Filter integrity test**

Follow the instruction below to perform a filter integrity test.

Note: UNICORN must be in End mode.

*Note:* Do not run any method when in the **INTEGRITY TEST** setting.

5.3 Filter installation

5.3.1 Membrane filter cassettes



3 INTEGRITY TEST will open valves XV-031, XV-032 and XV-041 and close valves XV-006 and XV-051. All other valves will remain in their previous state.

#### Note:

For more information about the integrity test, see the instructions of the filter or cassette manufacturer.

5 Operation 5.3 Filter installation 5.3.2 Hollow fiber (HF) cartridges

# 5.3.2 Hollow fiber (HF) cartridges

# Introduction

This section describes how to install HF cartridges in the ÄKTA readyflux system.

# Installation

Follow the instruction below to install a HF cartridge.

Step	Action
1	Make sure that the system is configured for using HF cartridges of the intended size.
2	Prepare the HF cartridge according to the manufacturer's instructions.
3	Open the hinged arm of the lower mounting bracket and let the the bottom clamp of the HF cartridge rest on the bracket and hinged arm. Close the hinged arm and hand-tighten the knurled nut.
4	Open the hinged arm of the upper mounting bracket and insert the HF cartridge into the mounting bracket. Close the hinged arm and hand-tighten



5

Connect the flow kit feed outlet from **XV-006** to the bottom of the HF cartridge.

5.3 Filter installation

5.3.2 Hollow fiber (HF) cartridges

Step	Action
6	Connect the top outlet of the HF cartridge to the flow kit retentate inlet at ${\bf XV-051}.$
	Note:
	If necessary, use adapters or 180 degree tubing to match the end connec- tions.
7	Connect the upper side permeate outlet to the flow kit permeate inlet at <b>PT-113</b> .

## Note:

If necessary, use adapters or Y-tubing to match the end connections.

#### Note:

See Operating Handbook 18116530 for more information about the HF cartridge connections.



# NOTICE

Make sure that the tubing is not kinked or pinched, and that the tubing clamp is open.

# 5.4 Installation test

# About this section

This section provides the information required to perform the system installation test. The test enables users and service personnel to check that all components are functioning after installation of the system, components or flow kit.

# In this section

Section		See page
5.4.1	About the system installation test	140
5.4.2	Running a system installation test	142
5.4.3	The installation test report	144

5 Operation5.4 Installation test5.4.1 About the system installation test

# 5.4.1 About the system installation test

# Introduction

The installation test checks that the system is correctly installed and that the modules are functioning properly. An installation test takes approximately 60 minutes.

- *Note:* An installation test should always be performed after installing a new system or new parts.
- **Note:** System installation test protocol considers Flow Kit containing optional sensors and TC end connections.

# Prerequisites

- Make sure the flow kit optional components and service are selected in component view.
- Make sure that the latest installation test method is used.
- Make sure that the flow kit is installed according to the instructions in the ÄKTA readyflux flow kit installation wizard.
- Make sure that the Bagkart trolley or the weighing scale is calibrated and tared.

# Description of the system installation test

The following table describes the different stages of the system installation test.

Stage	Description
1	Individual valves are opened and closed.
2	Their pressure regulator is checked for warnings during individual valves open/close test.
3	The conductivity, temperature and UV sensors are tested by pumping a solution of 1% (v/v) acetone and 1.0 M sodium chloride through the flow kit. If the UV and conductivity readings are within the specified range, the sensors pass the test.
4	The pH sensor is tested for properties of demineralized water.
5	Pumps are tested for 3 setpoints within the range and when the readings are within the specified range, the pumps pass the test. The flow sensor is simultaneously tested at the minimum setpoint of feed pump.
6	The flow sensor is tested at the minimum setpoint of feed pump.
7	Pressure sensors are tested for response to backpressure created by using <b>PCV%close</b> .
8	TMP control is checked by backpressure creation.

Stage	Description
9	The air bubble detector checks if air bubbles are present in the system during cleaning of the flow kit.
10	When the test is finished, a test report (AKTA_ready-flux_test_report.txt) is generated with a FAIL or PASS result for each module. This report is additional to the UNICORN result file, with a name that contains the phrase Installation Test System which can be accessed from the <b>Evaluation</b> module.

For more information about the test report, *Section 5.4.3 The installation test report, on page 144.* 

5 Operation5.4 Installation test5.4.2 Running a system installation test

# 5.4.2 Running a system installation test

# **Equipment and chemicals**

The following equipment and chemicals are required for the system installation test:

- Flow Kit with TC end connections containing Conductivity, pH & UV on permeate section
- Tee connector, O-rings, TC clamps, and flexible tubing
- 30 L of fresh water
- A container to hold approximately 20 L of waste solution
- Test solution: 10 L of 1% (v/v) acetone and 1.0 M sodium chloride in a suitable container. See also the *Test solution preparation protocol* template on the system CD.
- **Note:** The test solution must be freshly prepared before an installation test is performed, to prevent the acetone from evaporating.
- **Note:** Make sure that the fresh water and the test solution are equilibrated to room temperature.

# Prepare for the system installation test

Follow the steps below to prepare for the system installation test.

Step	Action
1	Connect the feed outlet to the flow kit permeate and retentate inlets with a T-connector.
2	Connect ¾" i.d. flexible tubing on XV-082, XV-083, XV-071, XV-031 and XV-034 (P-203 or AE-131) outlet and place in a fresh water container.
	For a description on how to make the connection, see <i>Connect the end</i> connections of the flow kit using TC end connectors on page 119.
3	Open the lid of the Permeate pump ( <b>P-203</b> ).
4	Place containers next to the system and use only required tubing lengths to connect flow kit and containers.
5	Follow the instructions on the screen.
Note:	The following warnings can appear during the test and can be ignored: The "UV led low light intensity" warning appears if UV is enabled and the lamp is not switched on. The "FE141 measurement error" warning appears if there is no liquid or air bubble detected by the <b>FE-141</b> .



## WARNING

**Over-pressure.** Never block the outlet tubing with, for instance, stop plugs, since this will create over-pressure and might result in injury.

# Start the installation test

Follow the instructions below to start the system installation test.

Step	Action
1	Import the system installation test method from CD or Web.
2	Open it in the <i>Method Editor</i> module.
3	Update the pH calibration slope and zero point values in <b>AE121_pH cali-</b> bration settings block located in the <b>Text Instructions</b> tab.
4	Save it.
5	Run the method.

# Monitor the system installation test

The progress of the system installation test can be followed in UNICORN 7. Charts will display the response curves for different sensors. Any time during the test run it is possible to manually add run notes that will be included in the report. To open the **Run Notes** dialog box, click **View**  $\rightarrow$  **Documentation**.

5 Operation5.4 Installation test5.4.3 The installation test report

# 5.4.3 The installation test report

Two test reports are generated when the test is finished.

- A UNICORN result file with a name containing Installation Test System which can be accessed using *Evaluation* module.
- A summary of PASS or FAIL result in the AKTA\_readyflux\_test\_report.txtfile which is in C:\Program Files (x86)\GE Healthcare\UNICORN\UNICORN 7.1\Temp folder or at a drive where UNICORN was installed.

# Print a test report

To print the UNICORN test report, go to UNICORN 7 *Evaluation* module. In the *File* menu, click *Report* and select the file name containing Installation Test System.

Toprint the file AKTA\_readyflux\_test\_report.txt,gotoC:\Program Files (x86)\GE Healthcare\UNICORN\UNICORN 7.1\Temp.

# **Description of a test report**

An installation test report in <code>AKTA\_readyflux\_test\_report.txt</code> contains the following information:

Report section	Information
Summary	Overall report showing if test has passed ( ${\tt PASS}$ ) or failed ( ${\tt FAIL}$ )
Header	<ul> <li>Installation test file name</li> <li>System name</li> <li>UNICORN 7 version number</li> <li>Time and date</li> <li>Name of user who ran the test</li> <li>Path of the test report file</li> </ul>
Test results	Pass (PASS) or fail (FAIL) result for each of the components

An installation test report in the Installation Test System file contains the following information:

<b>Report section</b>	Information
Header	UNICORN 7 version number
	Name of user who ran the test
	Time and date
	Path of the test report file
#### 5 Operation 5.4 Installation test 5.4.3 The installation test report

Report section	Information
Questions	Product identification details:
	Bar code of flow kit parts
	pH sensor details
	Protocol for text solution preparation
	Mode for entering codes
Method notes	Name of the system
	List of steps that were performed during flow kit instal- lation
Start notes	Notes entered in the <b>Start Notes</b> panel before the start of the component test
Run notes	Notes entered in the <b>Run Notes</b> dialog box during the component test
Evaluation notes	Notes entered after the component test is finished. To view the evaluation notes in UNICORN 7 version number, go to the <i>Evaluation</i> module and click <i>View</i> $\rightarrow$ <i>Run Record</i> and click the <i>Notes</i> tab.
Results from instal- lation test	Charts displaying the response over time for each of the sensors.
Comments	Space for comments on the paper copy of the report.
Signature	Field for signatures for performance and approval

### Troubleshooting

If one of the components failed the installation test, troubleshooting must be performed to establish the cause of failure and correct the problem. A failing component is identified in the test report by a FAIL result. Troubleshooting is performed by using the system control module or manual instructions. See *Chapter 7 Trouble-shooting, on page 164*.

# 5.5 Calibration

#### Introduction

This section describes how to calibrate the components.

#### Calibration of 2D bag

To perform a calibration of the 2D bag, a pre-calibrated hanging weight of known weight must be used.

Follow these steps to perform a calibration:

Step	Action
1	Start a run.
2	Go to System Control $\rightarrow$ Systems $\rightarrow$ Calibrate $\rightarrow$ Cal_WE176.
3	Follow the instructions.

#### **Calibration of flowmeter FE-141**

The flowmeter must be filled with water without air bubbles and must be still before performing the zero calibration.

Follow these steps to perform a calibration:

Step	Action
1	Start a run.
2	Go to <b>System Control →Manual →Special →FE141_AutoZero</b> .
3	Follow the instructions.

# Calibration of pumps P-201, P-202 and P-203

Calibration can only be performed in *Manual Instructions* and shall be calibrated according to the instructions provided in the documentation referenced below. Follow these steps to perform a calibration:

Step	Action				
1	Before calibration, make sure the valid flow path is set for the valid pump under <b>test</b> .				
	It is possible to select any inlets and outlets for liquid flow through the system. It is recommended to run the calibration with water.				
0	Elliste a later contained with an event weter entropy of the				

2 Fill the inlet container with enough water or test solution.

Step	Action
3	Set the RPM of the pump (P20x_RPM) under <b>Manual instruction</b> $\rightarrow$ <b>Special</b> and click <b>Execute the run</b> .
4	Let the pump run for couple of minutes to make sure that no air bubbles are present in the system tubings.
5	Measure the flowrate in LPM using the reference instrument between time point 0 and time point T.
	It is recommended to perform the calibration at different set points.
6	Calculate the GAIN for each set point using the formula GAIN= (Flow (LPM))/ (Speed (RPM)).
7	Calculate the average GAIN from the different set points.
8	Enter the average GAIN under <i>Manual instruction</i> → Special → P20X_Gain.
Note:	Calibrate pumps prior to gain change.
Note:	The GAIN calculation is given in the DVD/CD.

#### Perform a UV stray light calibration

- **Note:** A UV stray light calibration only has to be performed when the installed flow kit includes the UV sensor.
- **Note:** UV stray light calibration is not required for predefined phases and methods.

After a new flow kit has been mounted, a UV stray light calibration has to be performed. UV stray light calibration shuts off the **UV LED** lamp for approximately 10 seconds. During this time, stray light from the outside is measured. The measured light is later subtracted from the UV measurements made during the run.

Follow the instructions below to start a UV stray light calibration manually.

1

2

# Step Action

In the **System Control** module, on the **Manual** menu, click **Execute Manual Instructions**. Select the instruction **AE131UV\_StraylightCalib** and click **Execute**.

structions:	Parameters for AE12116/ OccubeldCalls	Instruc	tion execution list	
Permeate     AE131UV_AutoZero     AE131UV_StrukjetCale     Densty_PermeateRow     Ruc_ZDrop     Manual_PermeateRow     P203_Direction     PCV341_V3Dased     PermeateVolumeTatal_Ret     PermeateVolumeTatal_Ret		h	sent Delete	

A warning message will be displayed when the stray light calibration has started. This warning message is information only. The calibration will proceed regardless of whether the user closes the warning message (by clicking **Acknowledge**) or not.

esocuori canoreson, po nor per-	orm any other instruction	during the next 15 second	<ul> <li>Occurred at tim</li> </ul>	e 2017-01-24

- 3 Click *Execute* to start the stray light calibration.
- **Note:** Do not change anything on the system or in UNICORN 7 during the time stray light is measured (approximately 10 seconds).
- **Note:** If stray light calibration is included in a user-defined method, a delay of at least 15 seconds is required before the next instruction.

# 5.6 Perform a run

#### **About this section**

This section describes the safety aspects of performing a run.

For detailed information about how to run the system, see UNICORN 7 System Control manual and ÄKTA readyflux software manual.

## In this section

Sectio	n	See page
5.6.1	Before you start	150
5.6.2	Start and monitor a method run	152

# 5.6.1 Before you start

#### Introduction

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

#### **Prerequisites**

Make sure that the system is correctly prepared. Check that:

- The system is prepared according to the settings in the method to be run.
- A suitable filter has been selected for the ultrafiltration/diafiltration or microfiltration application.
- The buffer and product inlet tubing is immersed in correct buffer vessels (consider solution identity and volume).
- All waste tubing is immersed in appropriate waste vessels (consider vessel size, placement and material).
- No tubing is twisted and the flow path is free from leakage.

#### Hold, pause or stop the run

At the end of a method the run stops automatically. All pumps stop and an acoustic end signal sounds and **End** is displayed in the **Run Log**.

To interrupt a method during a run you may use the *Hold*, *Pause* or *End* buttons in the *System Control* module. A held or paused method run can be resumed by using the *Continue* button. See the instructions in the table below.

lf you want to	then
temporarily hold the method, with current flow rate and valve positions sustained	click the <b>Hold</b> button.
temporarily pause the method, stop all pumps and with current valve positions sustained	click the <b>Pause</b> button.

If you want to	then
resume a held or paused method run	click the <b>Continue</b> button.
	Note:
	An ended method cannot be continued.
permanently end the run, stop all pumps and reset the valves to their default posi- tions	click the <b>End</b> button.

**Note:** When ending a method run in advance, it is possible to save the partial result.

# 5.6.2 Start and monitor a method run

### Introduction

This section describes how to start a run using a previously created method and how to monitor the run. For more information on method creation, see UNICORN 7 Method manual.

### Choose and start a method

The instruction below describes how to open a method and start a run.

Step	Action
1	Open the System Control module and click the Open Method Navigator
	button.



Result:

The *Method Navigator* pane opens.

Method Navigator				4 ×		
60	Methods, Method ·	Method • 🔟 •				
Folder name		System	Last modified	Created by	*	
· -	DoeMethod		2014-10-05 14:3	Default		
- E	Dvis		2012-11-27 14:5	Default		
	AutoTests 2013-05-3	4	2013-05-31 12:0	Default		
	Dvie1		2012-11-27 14:5	Default		

2

Select the method to run, and click the **Run** button.



Result:

The Start Protocol dialog opens.

- 3 Step through the displayed pages in the **Start Protocol**, add requested input and make appropriate changes if necessary. Click **Next**.
- 4 Click **Start** on the last page of the **Start Protocol** to start the run.

#### Monitor the run

# You can follow the on-going method run in the **System Control** module. The current system state is shown in the **System state** panel in the **Run Data** pane. For example, it may say **Method Run**, **Wash** or **Hold**.



For more information about the data shown in the **System Control** module, see *Section 3.6.3 The System Control module, on page 63*.

For more information about the process picture, see Section 3.6.4 Process picture, on page 65.

# 5.7 Procedures after a run

### Introduction

This section describes how to prepare the flow kit and the filter for disposal and how to shut down the system after a run.

The flow kit and the filter should be disposed of in accordance with local regulations.

# Prepare the flow kit and the filter for disposal



#### WARNING

**Hazardous chemicals during run.** When using hazardous chemicals, run **System CIP** to flush the entire system tubing with distilled water or discard the flowkit, before service and maintenance.

Follow these steps to prepare the flow kit and the filter for disposal:

#### Step Action 1 Connect a bag filled with water to inlet XV-082. Flush all the parts used in the flow path with water by running a cleaning method from the ÄKTA readyflux system. Note: Do not remove the flow kit from the cabinet. 2 After a filter cleaning and storage (multiple-use filters) or after a complete run (for single-use filters), dismantle the filter from the flow kit by disconnecting the feed inlet to the filter at XV-006, the filter outlet to the retentate inlet at XV-051, and the filter outlet to the permeate inlet. 3 Fill the flow kit and filter with air by pumping air from an empty inlet. Use *Manual xxxxxFlow* when filling the system with air. 4 Make sure that UNICORN is in *End* mode and that the flow path is empty and not pressurized. Disconnect all inlet and outlet containers and the filter. Put back protective 5 end caps delivered with the flow kit. Open all valves by turning the FLOW KIT INSTALL - RUN - INTEGRITY TEST 6 selector to the FLOW KIT INSTALL position.

# Dismantle flow kit and the filter for disposal

After preparation, follow these steps to dismantle and remove the flow kit and the filter for disposal:

#### Step Action

1

Disconnect all flow kit sensors from the connector cables.

#### Note:

It is important to pull back the **FE-141** latch to disconnect the cable, as shown in image. If the latch is not pulled back properly to disconnect, the cable will be damaged.



2 Open the following:

- all safety locks on the pinch valves by turning the black levers 180 degrees,
- the permeate pump and transfer pump as described in *Prepare the* system for flow kit installation on page 103,
- the feed pump using only a hex key to remove feed pump head.
- 3 Lift off the flow kit.
- 4 If required, autoclave the flow kit. Remove the protective caps before autoclaving.
- 5 Dispose of the empty flow kit and the filter in accordance with local regulations and consult the instructions in the filter documentation.

#### Log off or exit UNICORN

Follow the instructions to log off or exit UNICORN. This can be performed from any of the UNICORN modules.

lf you want to	then
log off UNICORN	on the <b>File</b> menu, click <b>Log off</b> .
	Exit UNICORN
	<i>Result</i> : All open UNICORN modules close and the <i>Log On</i> dialog box opens.
exit UNICORN	on the <b>File</b> menu, click <b>Exit UNICORN</b> .
	Log off - Eric
	Result: All open UNICORN modules close.

**Note:** If an edited method or result is open and not saved when you try to exit or log off UNICORN, you will see a warning. Click **Yes** to save, **No** to exit without saving, or **Cancel** to stay logged on.

#### Shut down the instrument

Turn the **MAIN POWER** switch to the **O** position to switch off the instrument.



# 6 Maintenance

#### About this chapter

This chapter provides information to enable users and service personnel to clean, maintain, calibrate and store the product. Contact Cytiva service personnel before any maintenance.

#### In this chapter

Section		See page
6.1	Cleaning before planned service	158
6.2	Daily maintenance	159
6.3	Yearly maintenance	161
6.4	Spare parts	162
6.5	Storage	163

#### **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 *Section 2.1 Safety precautions, on page 12* as listed below:

- General precautions on page 12
- Personal protection, on page 14
- Flammable liquids and explosive environment on page 14
- Power supply, on page 17
- Maintenance on page 22

# 6.1 Cleaning before planned service

# Cleaning before planned maintenance/service

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

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

### Health and safety declaration forms

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

# 6.2 Daily maintenance

#### Introduction

Regular maintenance is important for safe and trouble-free operation of the ÄKTA readyflux system. This section provides instructions for daily maintenance by the user. Daily maintenance mainly includes cleaning.



#### WARNING

**Electrical shock hazard**. All installation, service and maintenance of components inside the electronics cabinet should be done by service personnel authorized by Cytiva. Do not open any covers or replace parts unless specifically stated in the *Operating Instructions*.

#### **Always be attentive**

It is important that the user is always attentive about the status and operation of the equipment. The cause of any abnormal behavior or aberrant noise should be examined and removed. If the problem is non-trivial, contact your local Cytiva representative.

### **General cleaning**



#### CAUTION

To avoid contamination, make sure the system is thoroughly cleaned before changing the flow kit.



#### CAUTION

Connectors on the cabinet, such as connectors for pH, conductivity, network, etc., that are not used, should be plugged to prevent cleaning liquid from entering the connector.

For proper function, the system should be kept clean and dry:

- Chemical stains and dust are removed by wiping the outside surfaces of the cabinet and the pump with a clean tissue wetted with water. 70% ethanol or 2-propanol (Isopropanol) can be used for sanitization.
- If salt buffer is spilled on the valves, rinse carefully with water to remove salt crystals and wipe dry.
- Clean the system of infectious or aggressive fluids before service or maintenance. Make sure that the cleaning procedure flushes all possible flow paths in the system.
- To avoid corrosion, wipe the cabinet dry after cleaning.

### **Cleaning after each run**

- Clean the shaft of the feed pump **P-201** after the flow kit has been uninstalled.
- Clean the rollers of the pumps **P-202** and **P-203** after the flow kit has been uninstalled.

### **Clean the filters**

Filters shall be cleaned according to the instructions provided by the respective manufacturer's documentation.

# 6.3 Yearly maintenance

#### Introduction

Preventive maintenance must be performed on a yearly basis by qualified service personnel authorized by Cytiva. Different service agreements are available. Contact your Cytiva representative for more information. This section provides instructions for yearly maintenance.

#### Pneumatic valve opening and closing

Follow these steps to open and close a pneumatic valve:

Step	Action
1	Click on the respective valve that needs to be opened using the process picture or manual instructions.
2	Click again on the same valve symbol in the process picture to close the valve.
	Result:
	The valve should function as intended without raising any alarms or warn- ings.

#### **Pump head**

Be observant of any changes in the sound of the pump, or of vibrations, as these may indicate that the pump rotor needs to be replaced. Normally, the pump rotor is checked and replaced in connection with yearly maintenance.

#### System air vent filters

Replace system air vent filters once a year or earlier according to the service agreement.

# 6.4 Spare parts

### Introduction

Apart from the flow kits, ÄKTA readyflux has very few parts that a user may need to replace. Normally, parts are checked and, if necessary, replaced by service personnel during preventive maintenance. For a list of available accessories and spare parts see *Section 8.4 Ordering information, on page 180*.

#### **Replacing the wheels**

The wheels are screwed onto the system cabinet support from below. Follow these steps to replace a wheel.

Step	Action
1	Lift the cabinet slightly. See <i>Section 4.2 Transport, on page 79</i> for more information on moving and lifting the cabinet.
2	Loosen the four bolts holding the wheel and remove the wheel.
3	Mount the new wheel.
4	Insert the four bolts and tighten them.

# 6.5 Storage

If the system is not used for a longer time period (more than a few days):

- Remove the flow kit (see Section 5.7 Procedures after a run, on page 154).
- Clean the cabinet (see General cleaning on page 159).
- If the system is moved, the system power and air supply must be switched off.

#### Note:

Although the system can be stored at temperatures in the range -25°C to 50°C, room temperature is preferable.

Flow kits should not be stored at temperatures below 0°C.



#### NOTICE

Do not leave a flow kit mounted on the system for an excessively long time. The tubing walls may stick together where the tubing is squeezed, possibly causing high pressure alarms when running the system.



#### NOTICE

Do not use 1 M NaOH (or higher) for more than 2 hours. Flush afterwards with a suitable rinsing liquid to remove the NaOH.

# 7 Troubleshooting

### About this chapter

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

Note that problems related to sensors and valves normally are revealed during the component test, which is discussed in *Section 5.4 Installation test, on page 139*.

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

### 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 *Section 2.1 Safety precautions, on page 12* as listed below:

- General precautions on page 12
- Personal protection, on page 14
- Flammable liquids and explosive environment on page 14
- Power supply, on page 17
- Maintenance on page 22

### Computer

Problem	Corrective action
Communication failure during a run.	<ul><li>Check communication cable and connections.</li><li>Reboot PC and check the communication.</li></ul>
No system found when starting up UNICORN.	<ul> <li>Make sure the system is switched on.</li> <li>Check communication cable and connectors.</li> <li>Make sure there is no IP address conflict.</li> <li>If system is connected to a switch or hub, check that the extra cable (3 m) is connected in series with the long (10 m) cable.</li> <li>Reboot PC: shut down Windows, switch off the system power switch, wait at least 5 sec, and restart the system.</li> </ul>

## Power

Problem	Corrective action
Power failure during a run	Check that the power to the system is available. If the power supply is reaching the system and the system is not powering ON, contact a Cytiva representative.
	Note:
	If the power failure also affects the computer, no data can be stored and the run must be restarted.

# **Compressed air**

Problem	Corrective action
The warning <b>No air supply to</b> <b>the system</b> is displayed and the system raises a warning.	Insufficient air supply caused by, for instance, malfunctioning air supply equipment or a leaking air hose. Rectify the air supply problem.
	If the air leakage sound is audible from inside the system, contact a Cytiva representative.

# Valves

Problem	Corrective action
The Valve error is displayed.	A valve lock may be open. Check the valve locks. Close if necessary.
	To close an open safety lock on a pinch valve:
	1. Open the valve through system control or manual instructions.
	2. Turn the black lever on the pinch valve 180 degrees to close the pinch valve lock. For more information, see <i>Close the pinch valves and the pump heads on page 122</i> .
	3. Close the valve through system control or manual instructions.
	Note:
	When opening the valves, all parts of the flow kit may be filled with liquid, also inlets and outlets that are currently not used. To avoid spillage of liquid, do not remove the end caps from connections that are not used.
	If the <b>Valve error</b> alarm is accompanied by <b>No air supply to the system</b> , the alarm is caused by a compressed air failure.
	Tubing is not properly inserted. Open the valve through <b>System</b> <b>Control</b> or <b>Manual Instructions</b> and align the tubing.

Problem	Corrective action
	Position sensor failure. Check If the valve can be opened/closed with <b>System Control</b> or <b>Manual Instructions</b> . If <b>Valve error</b> persists, contact a Cytiva representative.

# **Feed pump**

Problem	Corrective action
Pump not working	<ul> <li>Emergency button has been pressed. Reset according to Restart after emergency shutdown or power failure on page 27.</li> <li>Incorrect method. Check by entering Manual_FeedFlow &gt; 1 L/min.</li> </ul>
Little or no flow	<ul> <li>Check that connected inlet is used.</li> <li>No liquid is supplied to the pump. Check inlet containers.</li> <li><i>P201_Gain</i> factor is incorrect. Check by setting default value.</li> <li>The pressure plate on the feed pump head is not properly secured. See <i>Mount the tubing of the feed flow path on page 112</i>.</li> <li>Check the aligning surfaces of the feed pump shaft and head and wipe them clean if necessary.</li> <li>Incorrect method. Check by entering <i>Manual_FeedFlow</i> &gt; 1 L/min.</li> <li>Leaking flow kit tubing. Replace flow kit.</li> <li>Kinks or blockages in the flow kit. Remount or replace flow kit. See <i>Section 5.1.3 Install the flow kit, on page 101</i> for mounting instructions.</li> </ul>

# Transfer and permeate pumps

Problem	Corrective action
Pump not working	<ul> <li>Emergency button has been pressed. Reset according to Restart after emergency shutdown or power failure on page 27.</li> <li>Incorrect method. Check by entering Manual_xxxxFlow &gt; 1 L/min.</li> </ul>

Problem	Corrective action
Little or no flow	Check whether pump lid is closed.
	• <b>P20x_Gain</b> factor is incorrect. Check by setting default value.
	Check that the connected inlet is used.
	• No liquid is supplied to the pump. Check the inlet containers.
	<ul> <li>Incorrect method. Check by entering <i>Manual_xxxxFlow</i> &gt; 1 L/min.</li> </ul>
	Leaking flow kit tubing. Replace flow kit.
	• Kinks or blockages in the flow kit . Remount flow kit, see <i>Section</i> 5.1.3 Install the flow kit, on page 101.

## **Pressure control valve**

Problem	Corrective action
<b>PCV</b> not working	• Emergency button has been pressed. Reset according to Restart after emergency shutdown or power failure on page 27.
	Valve lock may be open.
	No air supply to the system.
	<ul> <li>Incorrect method. Check by entering <i>PCV_%Closed</i> to &gt; 10%.</li> </ul>
	If none of the above, contact Cytiva service personnel.
Back pressure not attained	Check by partially closing the valve by entering <b>PCV_%Colsed</b> to > 10%. If the problem persists, contact Cytiva representative.

## **Pressure monitors**

Problem	Corrective action
Incorrect pressure reading	Make sure that the pressure sensor cable is properly connected to the system cable. See Section 5.1.3 Install the flow kit, on page 101 for mounting instructions.

# Conductivity and temperature monitors

Problem	Corrective action
Incorrect conductivity reading	• Make sure that the conductivity and temperature sensor is properly connected to the system cable. See Section 5.1.3 Install the flow kit, on page 101 for mounting instructions.
	Check that the connected inlet is used.
	• Check if there are errors in the temperature readings. Conduc- tivity is temperature compensated and thus dependent on correct temperature readings.
Errors in temperature readings	Possible problem with the temperature measurement is:
	The system temperature is not stable with respect to the surroundings. If the room temperature changes or if the system is moved from one room to another, it must be given time to adjust to current room temperature.

## **Flow monitor**

Problem	Corrective action
Incorrect flow reading	• Make sure that the flow sensor is properly connected to the system cable. See <i>Section 5.1.3 Install the flow kit, on page 101</i> for mounting instructions.
	<ul> <li>Auto zero is not done correctly. Redo auto zero with FE141_AutoZero instruction by filling liquid (no air bubbles and no flow) in permeate flow path.</li> </ul>
Cavitation (small air bubbles produced in flow path)	Cavitation results in unstable flow sensor readings. Remove air bubbles by varying flow.

# pH monitor

Problem	Corrective action
Incorrect pH reading	• Make sure that the pH sensor is properly connected to the system cable. See Section 5.1.3 Install the flow kit, on page 101 for mounting instructions.
	• Make sure that correct calibration factors (gain and slope) are entered. See Section 5.1.3 Install the flow kit, on page 101 for mounting instructions.
	Check that the connected inlet is used.
	• Make sure that a known process liquid is used.

## **UV** monitor

Problem	Corrective action
Incorrect UV reading	• Condensation on the flow cell window. Check that the UV cell and sensor windows are clean and dry. Wipe with a soft tissue if necessary.
	Make sure that the UV cell is properly inserted.
	Check that the connected inlet is used.
	Make sure that a known process liquid is used.

# **Flow path**

Problem	Corrective action
Too high outlet pressure	<ul> <li>Check that the connected outlet is used and that the outlet is not plugged.</li> <li>Kinks or blockages in the flow kit. Remount flow kit. See Section 5.1.3 Install the flow kit, on page 101 for mounting instructions.</li> <li>Too small outlet tubing diameter. Change to a larger tubing.</li> <li>The flow kit has been mounted on the system for too long, causing the inner walls of the tubing to stick together. Replace the flow kit.</li> </ul>
Air bubble is detected	<ul> <li>Air in flow path.</li> <li>Check that the connected inlet is used.</li> <li>Check the inlet containers for process liquid level.</li> <li>Remove any air in the flow path by varying flow.</li> <li>Note:</li> <li>Small amounts of air are handled by a delay timer to avoid unintentional alarm.</li> </ul>

# Bagkart

Problem	Corrective action
Incorrect weight	• Make sure that the weighing scale is properly connected to the system connector. See Section 5.2.1 2D hanging bag (Bagkart), on page 129 for weighing scale connection instructions.
	• Make sure Zero calibration is performed prior to the run with no load condition.
	• Taring is not done correctly. Tare with empty bag.
	• Zero or weight Calibration is not done correctly or partially done. Redo calibration.

# Customer I/O

Problem	Corrective action
Incorrect weight	<ul> <li>Make sure that the weighing scale is properly connected to the system connector. See Section 3.3.4 CUSTOMER I/O connectors, on page 50 for weighing scale connection instructions.</li> <li>Weight space or effect is set incorrectly. Set weight space or effect is set incorrectly.</li> </ul>
	• Weight range or offset is set incorrectly. Set weight range or offset correctly in <b>Settings</b> or <b>instruction</b> .
Air in flow path is not detected	<ul> <li>Make sure that the AE-152 air sensor is properly connected to the customer I/O connector. See Section 3.3.4 CUSTOMER I/O connectors, on page 50 for customer I/O connection instructions.</li> <li>Enable AE-152 in system settings</li> </ul>

# 8 Reference information

### About this chapter

This chapter lists the technical specifications of ÄKTA readyflux. The chapter also includes a list of wetted materials, a chemical resistance guide, ordering information, and Health and Safety Declaration form for service.

## In this chapter

Section	on	See page
8.1	Specifications	172
8.2	Process wetted materials	176
8.3	Chemical resistance	177
8.4	Ordering information	180
8.5	Recycling information	182
8.6	Regulatory information	184
8.7	Health and Safety Declaration Form	194
8.8	More information	196

# 8.1 Specifications

# **Technical specifications**

Property	Value
Dimensions	110 × 86 ×152 cm (width × depth × height)
Weight	280 kg
Control system	UNICORN 7.1 or higher versions of UNICORN
Supplyvoltage	100 to 240 V AC ± 10%
Frequency	50/60Hz
Max. power consumption	1 kVA
Overvoltage category	Category II
Leakage current	≤ 3.5 mA
Ingress protection	IP45
Compressed air interface	6 bar, 50 NL/min, oil- and particle-free
Acoustic noise level	< 70 dB(A)

# **Environmental requirements**

Property	Value
Allowed location	Indoor use only
Ambient temperature	4°C to 32°C
Liquid temperature	4°C to 50°C
Liquid pressure	-0.4 to 4 bar
Fluid density	800 to 1200 kg/m <sup>3</sup>
Fluid viscosity	Up to 5 times of water viscosity
Max. relative humidity, operation	80% RH, non-condensing, up to 32°C
Max. altitude, operation	2000 m
Pollution degree of the intended envi- ronment	Pollution degree 2

# Capacity

Property	Value
Pump, feed, operating flow	Speed: 12 to 2400 rpm Flow: 2 to 18 L/min
Pump, transfer, operating flow	Speed: 20 to 500 rpm Flow: 0.5 to 6 L/min
Pump, permeate	Speed: 10 to 250 rpm Flow: 0.05 to 1.6 L/min

## **Flow kit specifications**

Property	Value
Tubing diameter (i.d.)	Feed and retentate: 12.7 mm = $\frac{1}{2}$ "
	Transfer, permeate and drain: 9.5 mm = ¾"
Inlet manifold diameter (i.d.)	9.5 mm = ¾″
Pump tubing diameter (i.d.)	Feed: 12.7 mm = ½"
	Transfer: 9.5 mm = ¾″
	Permeate: 6.4 mm = 1⁄4″
Flow rate range, feed	0.2 to 18 L/min
Flow rate range, permeate	0.05 to 6 L/min
Flow rate range, transfer	0.5 to 6 L/min
Connectors, type/size	TC/25
No. of inlets/outlets	5/3

## **Sensor specifications**

Sensor	Range	Acceptance range
Pressure, gauge (feed, retentate and permeate)	-0.5 to 5.2 bar	-0.4 to 4 bar
Pressure control valve	0 to 4 bar	0% to 100%
Flow, permeate	0 to 8 L/min	0.05 to 6 L/min
Conductivity (retentate and permeate)	0.001 to 200 mS/cm	0.1 to 200 mS/cm

#### 8 Reference information

#### 8.1 Specifications

Sensor	Range	Acceptance range
Temperature (retentate and permeate) <sup>1</sup>	4°C to 50°C	4°C to 50°C
рН	pH 3 to 10	pH 3 to 10
UV	-	-100 to 1000 mAU
Weight	0 to 50 kg	0 to 25 kg

 $^{1\,}$  The liquid and the surrounding room should be maintained at the same temperature.

# Membrane filter cassette specifications

Property	Value
No of cassette holders	1
No of cassettes	1 to 5
Typical filter area	0.46 to 2.50 m <sup>2</sup>
Recommended feed flow	Refer to membrane manufacturer
Recommended permeate flow	Refer to membrane manufacturer

## Hollow fiber cartridge specifications

Property	Value
Max no of cartridges	2
Cartridge size	5, 6, 8 or 9
Total filter area	0.12 to 0.84 m <sup>2</sup>
Recommended shear rate	0 to 25000 s <sup>-1</sup>

## Hollow fiber flow requirements

The general permeate flow for hollow fiber filters is 1.67 L/min/m<sup>2</sup>.

Filter size	Area	Min feed	Max feed	Perm flow	Perm flow
	range	flow (L/	flow (L/	min area	max area
	(m <sup>2</sup> )	min) <sup>1</sup>	min) <sup>2</sup>	(L/min)	(L/min)
5,6	0.12 to 0.48	≤ 2.1	≤12	~0.2	~0.8

Filter size	Area	Min feed	Max feed	Perm flow	Perm flow
	range	flow (L/	flow (L/	min area	max area
	(m <sup>2</sup> )	min) <sup>1</sup>	min) <sup>2</sup>	(L/min)	(L/min)
8,9	0.36 to 1.2	≤ 5.4	≤ 36 <sup>3</sup>	~0.6	~2.0

<sup>1</sup> At a shear rate of 4000/s, C-lumen

<sup>2</sup> At a shear rate of 12000/s, E-lumen

<sup>3</sup> Hollow fiber sizes 8 and 9 (standard and RTP) can only be used in the ÄKTA readyflux system at a maximum shear rate of 8000/s, because the feed pump cannot provide a feed flow required for higher shear rates.

Hollow fiber flow requirements at different shear rates:

Filter	Lumen	Feed flow (L/min) at a shear rate of					
size	(mm)	2000/ s	4000/ s	8000/ s	10000 /s	12000 /s	16000 /s
5, 6	0.5 <sup>1</sup>	1.1	2.1	4.3	5.35	6.4	8.6
	0.75 <sup>2</sup>	1.4	2.8	5.6	7.0	8.4	11.2
	1.0 <sup>3</sup>	2.0	4.0	8.0	10.0	12.0	16.0
8,9	0.5 <sup>1</sup>	2.7	5.4	10.6	13.3	16.0	21.5 <sup>4</sup>
	0.75 <sup>2</sup>	4.4	8.8	18.0	22.4 <sup>4</sup>	26.8 <sup>4</sup>	35.0 <sup>4</sup>
	1.0 <sup>3</sup>	6.1	12.2	24.5 <sup>4</sup>	30.6 <sup>4</sup>	36.7 <sup>4</sup>	49.0 <sup>4</sup>

<sup>1</sup> C-lumen

<sup>2</sup> D-lumen

<sup>3</sup> E-lumen

<sup>4</sup> Not supported by ÄKTA readyflux flow kit specifications. See Flow rate range, feed in Flow kit specifications on page 173.

<sup>1</sup> Not supported by ÄKTA readyflux flow kit specifications. See *Flow rate range, feed* in *Flow kit specifications, on page 173.* 

**Note:** The 0.5 mm lumen filters require a higher shear rate and flow than the 1.0 mm lumen filters.

# 8.2 Process wetted materials

#### **Materials used**

The materials used in the manufacturing of ÄKTA readyflux have been chosen for their biological and chemical compatibility with the solvents used during operation. The system has also been designed to comply with the varying hygienic requirements at the different stages of development and production. The flow kit tubing has been treated with gamma radiation, except for the pump tubing, which has been autoclaved (the pH electrode has not been treated).

### List of wetted materials

Component	Materials	
Tubing	C-Flex® thermoplastic elastomer (TPE)	
Pump tubing	Platinum-cured silicone	
Connectors	ReadyMate end connector: Polycarbonate, silicone rubber	
	TC end connector: Polypropylene (PP)	
Pressure sensors	Polysulfone (PSU)	
Flow sensor	Polypropylene	
Conductivity sensors	Polysulfone (PSU), gold	
pH sensor	Polysulfone, Marlex™ high-density polyethylene (PE-HD), ethylene-propylene-diene monomer (HDPE), porous zirconia, glass	
UV sensor	Polypropylene	
Sealing materials	Polypropylene, thermoplastic elastomer, ethylene- propylene-diene monomer (EPDM), silicone	

# 8.3 Chemical resistance

# Allowed chemicals for external surfaces, cabinet

The following chemicals shall be used when cleaning the system:

- Water with weak detergent should be used for daily cleaning of the cabinet.
- 70% ethanol or 2-propanol (isopropanol) can be used for sanitization.

The external/outer surfaces of the ÄKTA readyflux system shall be resistant to the following chemicals:

Chemical	Concentration
Acetic acid	25%
Acetone	2.5%
Ethanol	70%
Ethanol/Acetic acid	20%/ 10%
Guanidine hydrochloride	6.0 M
Hydrochloric acid	0.1 M
Phosphoric acid	5%
Isopropanol (2-propanol)	70%
Sodium chloride	0 to 3 M
Sodium hydroxide	0.5 M
Sodium hypochlorite	300 ppm
Triton™ X-100	1%

## Allowed chemicals for wetted surfaces

You must consider the compatibility of the wetted parts and your process chemicals so that no negative interaction takes place. Also make sure that your process chemicals do not damage the system components, compromising the safety of the system.

Contact your local Cytiva representative if you are not sure of the compatibility of your chemicals.

ÄKTA readyflux flow paths are resistant to chemical agents used in protein recovery, including buffer solutions for adsorption, elution and washing, and to solutions effective in cleaning and storage. The following table lists chemicals that may be used with ÄKTA readyflux. The concentrations listed are not normally exceeded during an operating cycle.

# **Note:** The table should be used only as a guide. The effects of a chemical will generally be more severe at higher temperatures. The combined effects of agents have not been taken into account.

The wetted surfaces in the ÄKTA readyflux system shall be resistant to the following chemicals under the described conditions:

Chemical	Concentra- tion	Time/cycle	No. of cycles	Tempera- ture
Acetic acid	25%	8 h	3	25°C
Acetone	2.5%	8 h	3	25°C
Ammonium sulfate	2.5 M	8h	3	25°C
Aqueous buffers, pH 3 to 10	<0.3 M	8 h	3	25°C
Arginine	2 M	8h	3	25°C
EDTA	100 mM	8h	3	25°C
Ethanol	20%	8h	3	25°C
Ethanol/ Acetic acid	20%/ 10%	8 h	3	25°C
Formalde- hyde	0.10%	8h	3	25°C
Guanidine hydro- chloride	6 M	8 h	3	25°C
Hydrochloric acid	0.1 M	8h	3	25°C
Imidazole	0.5 M	8 h	3	25°C

Chemical	Concentra- tion	Time/cycle	No. of cycles	Tempera- ture
Isopropanol	50%	8h	3	25°C
Mercaptoe- thanol	20 mM	8 h	3	25°C
PEG 500	5%	8h	3	25°C
PEG 1000	1%	8h	3	25°C
PEG 5000	1%	8 h	3	25°C
Phosphoric acid	5%	8h	3	25°C
Pluronic® F-68	1%	8h	3	25°C
SDS	1%	8h	3	25°C
Sodium chloride	5 M	8h	3	25°C
Sodium hydroxide (static)	0.01 N	7 days	1	25°C
Sodium hydroxide (dynamic)	1.0 M	2 h	3	25°C
Sorbitol	1 M	8 h	3	25°C
Sucrose	1 M	8h	3	25°C
Triton X-100	1%	8h	3	25°C
Tween™20	1%	8 h	3	25°C
Tween 80	1%	8 h	3	25°C
Urea	8 M	8h	3	25°C

# 8.4 Ordering information

### Introduction

This section contains ordering information for ÄKTA readyflux flow kits and ÄKTA readyflux accessories and spare parts, and for related literature.

# ÄKTA readyflux accessories

Product	Product code
Bagkart	29151500
Fluxkart	29245919
Hollow fiber filter holder, Single filter	29258287
Hollow fiber filter holder, Two filters	29256166

# **ÄKTA readyflux flow kits**

Product	Product code
Flow Kit RM, ÄKTA readyflux	29187381
Flow Kit TC, ÄKTA readyflux	29187383
Flow Kit plus RM, ÄKTA readyflux	29187382
Flow Kit plus TC, ÄKTA readyflux	29151600

# ÄKTA readyflux flow kit accessories

Product	Product code
ReadyMate, 0.75 IN TC	28936695
ReadyClamp	28936690
Clamp, TC, 0.5-0.75-IN	29002800
Clamp, TC, 1.0-1.5-IN	29002799
Gasket, TC, 0.75 IN	28952743
Gasket, TC, 1.5 IN	28952744
Reducer, 1.5-IN TC TO 0.75-IN TC	28952829
RMRM Jumper 0.5INx1 FT RS1PK	12410135
Product	Product code
------------------------	--------------
RMRM Jumper Y manifold	12410195

# ÄKTA readyflux IQ/OQ

Product	Product code
IQOQ Performance	28992657

# ÄKTA readyflux spare parts

Product	Product code
CU-960	28938854
PCV controller	29226930
Quattroflow pump assembly	29168412
Peristaltic pump assembly	29168417
Load cell	29191023

# 8.5 Recycling information

# Introduction

This section contains information about the decommissioning of the product.



# CAUTION

Always use appropriate personal protective equipment when decommissioning the equipment.

# Decontamination

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

# **Disposal of the product**

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

# **Disposal of electrical components**



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

# Instructions for disposal of the instrument

Follow the instructions below for disposal of the ÄKTA readyflux instrument.

Step	Action
1	Separate all electronic components (terminal strips, power supplies, trans- mitters, pumps, probes/sensors, etc.) from the Electrical Cabinet.
2	Decontaminate the ÄKTA readyflux Cabinet and Electrical Cabinet following appropriate procedures depending on what type of environment the unit was located in. Follow local and/or national/federal requirements for disposal of the ÄKTA readyflux Cabinet and the Electrical Cabinet.

Step	Action
3	Dispose of electronic components as specified by local regulations depending on material used in the construction of the components. Follow local and/or national/federal requirements for disposal of the electronic components.

# Instructions for disposal of the flow kit

Follow the instructions below for disposal of the flow kit.

Step	Action
1	Decontaminate the flow kit following appropriate procedures depending on what type of environment the unit was located in. Follow local and/or national/federal requirements for disposal of the flow kit.
2	Separate all electronic components (the sensors) from the flow kit.
3	Dispose of electronic components as specified by local regulations depending on material used in the construction of the components. Follow local and/or national/federal requirements for disposal of the electronic components.
4	Dispose of the remaining parts of the flow kit in accordance with local regu- lations regarding chemical or biohazardous waste.

# 8.6 Regulatory information

# Introduction

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

# In this section

Section		See page
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8 Reference information 8.6 Regulatory information 8.6.1 Contact information

# 8.6.1 Contact information

# **Contact information for support**

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

# **Manufacturing information**

The table below summarizes the required manufacturing information.

Requirement	Information
Name and address of manufacturer	Cytiva Sweden AB
	Björkgatan 30
	SE 751 84 Uppsala
	Sweden
Telephone number of manufacturer	+ 46 771 400 600

# 8.6.2 European Union and European Economic Area

# Introduction

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

# **Conformity with EU Directives**

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

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

# **CE** marking



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

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

8 Reference information 8.6 Regulatory information 8.6.3 Eurasian Economic Union Евразийский экономический союз

# 8.6.3 Eurasian Economic Union Евразийский экономический союз

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

#### Introduction

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

#### Введение

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

# Manufacturer and importer information

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

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

## Информация о производителе и импортере

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

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

8 Reference information

8.6 Regulatory information

8.6.3 Eurasian Economic Union

Евразийский экономический союз

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

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

# EHE

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

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

# 8.6.4 Regulations for North America

#### Introduction

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

## **FCC** compliance

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

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

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

# 8.6.5 Regulatory statements

# Introduction

This section shows regulatory statements that apply to regional requirements.

# EMC emission, CISPR 11: Group 1, Class A statement



## NOTICE

This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

# South Korea

Regulatory information to comply with the Korean technical regulations.



#### NOTICE

Class A equipment (equipment for business use).

This equipment has been evaluated for its suitability for use in a business environment.

When used in a residential environment, there is a concern of radio interference.



# 주의

A급 기기 (업무용 방송통신 기자재)

이기기는 업무용환경에서 사용할 목적으로 적합성평가를 받 은 기기

로서 가정용 환경에서 사용하는 경우 전파간섭의 우려가 있습 니다.

# 8.6.6 Other regulations and standards

## Introduction

This section describes the standards that apply to the product.

# Biological and chemical compatibility

The Wetted parts of the ÄKTA readyflux system meet the material requirements of the following standards and regulations:

Requirement	Description
USP <88> Class VI	Material requirements from United States Pharmacopeia. Biological Reactivity Tests, "In Vivo".
EMEA/410/01	Guidance on minimising the risk of transmitting animal spon- giform encephalopathy agents via human and veterinary medicinal products. Animal origin-free material.

8 Reference information 8.6 Regulatory information 8.6.7 Declaration of Hazardous Substances (DoHS)

# 8.6.7 Declaration of Hazardous Substances (DoHS)

根据 SJ/T11364-2014《电子电气产品有害物质限制使用标识要求》特提供如下 有关污染控制方面的信息。

The following product pollution control information is provided according to SJ/ T11364-2014 Marking for Restriction of Hazardous Substances caused by electrical and electronic products.

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



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

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

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

本产品在使用寿命结束时不可作为普通生活垃圾处理,应被单独收集妥善处理。

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

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

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

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

# 有害物质的名称及含量 Name and Concentration of Hazardous Substances

#### 产品中有害物质的名称及含量

Table of Hazardous Substances' Name and Concentration

部件名称 Component name	有害物质 Hazardous substance					
	铅 (Pb)	汞 (Hg)	镉 (Cd)	六价铬 (Cr(VI))	多溴联苯 (PBB)	多溴二苯醚 (PBDE)
29151000	x	0	0	0	0	0
29151500	х	0	0	0	0	0
29151600	0	0	0	0	0	0
29245919	0	0	0	0	0	0
29187381	0	0	0	0	0	0
29187382	0	0	0	0	0	0
29187383	0	0	0	0	0	0

- 0: 表示该有害物质在该部件所有均质材料中的含量均在 GB/T 26572 规定的 限量要求以下。
- X: 表示该有害物质至少在该部件的某一均质材料中的含量超出 GB/T 26572 规定的限量要求。
- 此表所列数据为发布时所能获得的最佳信息.
- **0:** Indicates that this hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in GB/T 26572.
- X: Indicates that this hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirement in GB/T 26572
- Data listed in the table represents best information available at the time of publication.

#### 8.7 Health and Safety Declaration Form

# On site service



## **On Site Service Health & Safety Declaration Form**

Service Ticket #:

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

Yes	No	Review the ac Provide expla	Review the actions below and answer "Yes" or "No". Provide explanation for any "No" answers in box below.				
0	С	) Instrument h Rinse tubing of Make sure the suitable survey	Instrument has been cleaned of hazardous substances. Rinse tubing or piping, wipe down scanner surfaces, or otherwise make sure removal of any dangerous residue. Make sure the area around the instrument is clean. If radioactivity has been used, perform a wipe test or other suitable survey.				
0	С	Adequate spa installation. In prior to Cytiva	Adequate space and clearance is provided to allow safe access for instrument service, repair or installation. In some cases this may require customer to move equipment from normal operating location prior to Cytiva arrival.				
0	С	Consumables any area that	Consumables, such as columns or gels, have been removed or isolated from the instrument and from any area that may impede access to the instrument.				
0	С	All buffer / wa	All buffer / waste vessels are labeled. Excess containers have been removed from the area to provide access.				
Provide explanation for any "No" answers here:							
Equipm	Equipment type / Product No: Serial No:						
I hereby confirm that the equipment specified above has been cleaned to remove any hazardous substances and that the area has been made safe and accessible.							
Name:				Company or institution:			
Positio job title	n or e:			Date (YYYY/MM/DD):			
Signed	:						
Cytiva and the	tiva and the Drop logo are trademarks of Global Life Sciences IP Holdco LLC or an affiliate.						

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6 ZOJO cytwic All goods and services are sold subject to the terms and conditions of sale of the supplying company operating within the Cytwa business. A copy of those terms and conditions is available on request. Contact your local Cytwa representative for the most current information.

For local office contact information, visit cytiva.com/contact.

28980026 AD 04/2020

## **Product return or servicing**



#### **Health & Safety Declaration Form** for Product Return or Servicing

<b>Return authorization</b>	and/or	
number:	Service Ticket/Request:	

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

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

Yes	No	Specify if the equipment has been in contact with any of the following:				
0	$\bigcirc$	Radioactivity (spec	ify)			
0	$\bigcirc$	Infectious or hazar	dous biological substances (specify)			
0	$\bigcirc$	Other Hazardous Chemicals (specify)				
Equipm you for	ent mus addition	t be decontaminat al information con	ed prior to servi cerning the syst	ce / return. l tem / equipr	Provide a telephone n nent.	umber where Cytiva can contact
Telepho	one No:					
Liquid and/or gas in equipment is:			Water			
				Ethanol		
				None, em	pty	
				Argon, He	lium, Nitrogen	
				Liquid Nit	rogen	
			Other, specify	,		
Equipm	nent type	/ Product No:			Serial No:	
I hereby confirm that the equipment specified above has been cleaned to remove any hazardous substances and that the area has been made safe and accessible.						
Name:					Company or institution:	
Positio	n or job 1	itle:			Date (YYYY/MM/DI	)
Signed						
					To	o ivo o voturn outboringtion numbo

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

© 2020 Option. All goods and services are sold subject to the terms and conditions of sale of the supplying company operating within the Optiva business. A copy of those terms and conditions is available on request. Contact your local Optiva representative for the most current information.

For local office contact information, visit cytiva.com/contact. 28980027 AD 04/2020

# 8.8 More information

## **Spare parts and accessories**

Additional information regarding spare parts and acccessories can be found in the Hardware Product Documentation binders. For lists of documents, see Section 1.3 Associated documentation, on page 8.

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

## **Remaining aspects**

Contact your local Cytiva representative for advice regarding:

- Service
- Method optimization
- Ordering information (first, see Section 8.4 Ordering information, on page 180)
- Other issues not covered by this manual

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

# Training

Cytiva recommends that all new operators attend the training courses available from Cytiva. The courses will provide all information necessary for inexperienced operators to safely operate ÄKTA readyflux. Courses in the field of bioprocess development and manufacturing are available from Cytiva Fast Trak™ Training & Education.

For more information about training, please contact your local Cytiva representative.

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