GE Healthcare
Life Sciences

ÄKTAprocess™

Operating Instructions

Original instructions

Table of Contents

1 Introduction

About this chapter

This chapter contains important user information, descriptions of safety notices, regulatory information, intended use of ÄKTAprocess, and lists of associated documentation.

In this chapter

1.1 About this manual

Purpose of this document

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

Scope of this document

This manual is valid for all variants of standard ÄKTAprocess. Your system is either CE-classified or UL-classified. The system configuration for your system is described in the General Specification and on the system label.

Detailed information regarding columns, media and buffer tanks is not covered.

Typographical conventions

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

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

1.2 Important user information

Read this before operating ÄKTAprocess

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

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

Do not operate ÄKTAprocess 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 ÄKTAprocess

ÄKTAprocess is a low-pressure automated liquid chromatography system intended for the precision transportation of fluids to and from chromatography columns of varying sizes. The system is intended for process scale-up and large-scale pharmaceutical manufacturing.

ÄKTAprocess is not suitable for operation in a potentially explosive atmosphere or for handling flammable liquids.

WARNING

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

Prerequisites

In order to operate ÄKTAprocess safely, and according to the intended purpose, the following prerequisites must be met:

- You should be acquainted with the use of bioprocessing equipment and with the handling of biological materials.
- You must read and understand the Safety chapter of these *Operating Instructions*.
- The system must be installed according to the instructions in *Chapter 4 Installation, on page 81*.
- A working knowledge of UNICORN™ software is required. Refer to the UNICORN manuals for instructions on the software structure and the work flow.

Safety notices

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

Warnings

WARNING

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

Cautions

CAUTION

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

Notices

NOTICE

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

Notes and tips

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

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

1.3 Regulatory information

Introduction

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

Manufacturing information

The table below summarizes the required manufacturing information. For further information, see the EC Declaration of Conformity (DoC) document.

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

CE Conformity

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

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

Directive	Title
2006/42/EC	Machinery Directive (MD)
2004/108/EC	Electromagnetic Compatibility (EMC) Directive
2006/95/EC	Low Voltage Directive (LVD)

International standards

Harmonized standard requirements fulfilled by this product are summarized in the table below.

Standard	Description	Notes
EN 61010-1, IEC 61010-1, UL 61010-1, CAN/CSA-C22.2 No. 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use	EN standard is harmonized with 2006/95/EC
EN 61326-1	EMC emissions and immunity requirements for electrical equipment for measurement, control and laboratory use. Emission according to CISPR 11, Group 1, class A	EN standard is harmonized with 2004/108/EC
EN ISO 12100	Safety of machinery. General principles for design. Risk assessment and risk reduction.	EN ISO standard is harmonized with 2006/42/EC

Additional regulatory compliance

The table below lists additional regulatory requirements that are fulfilled by ÄKTAprocess.

Requirement	Description	Notes
ASME-BPE	All steel piping welds, including contact welds	Applicable for systems with steel piping
USP <88> class VI	United States Pharmacopia (USP) Bio reactivity testing, In Vivo	Applicable for polymeric materials in contact with process stream
CFR 21 § 177 FDA	Code of Federal Regulations, Food and Drugs Title 21, Part 177 FDA	Applicable for polymeric materials in contact with process stream

Requirement	Description	Notes
Animal Origin Free or in compliance with EMA 410/01	Free from animal derived ingredients or in compliance with EMA 410/01 part 6.4 Tallow derivates	Applicable for polymeric materials in contact with process stream *and* for the manufacturing process of whatever part (even non-polymeric) in contact with process stream
EN 287:1, 1418, EN ISO 15607, 15609-1, 15614-1, 5817, 6520, 3834-2	Welding	Applicable for systems with steel piping

Environmental conformity

ÄKTAprocess complies with the following environmental regulations.

Regulation	Title
2011/65/EU	Restriction of Hazardous Substances (RoHS) Directive
2002/96/EC	Waste Electrical and Electronic Equipment (WEEE) Directive
Regulation (EC) No 1907/2006	Registration, Evaluation, Authorization and restriction of CHemicals (REACH)
ACPEIP	Administration on the Control of Pollution Caused by Electronic Information Products, China Restriction of Hazardous Substances (RoHS).

CE marking

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

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

UL conformity

The system is listed according to UL508a.

A *UL inspection report* is provided in the *documentation package*.

Regulatory compliance of connected equipment

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

1.4 Associated documentation

System-specific documentation

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

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

Document	Abbreviation	Purpose/Contents
Piping and Instrument Diagram	P&ID	Schematic overview of the entire process flow, all components and instruments and the control system.
General Specification	GS	Technical data for the system
Assembly Drawing	AD	Physical layout. Provides all dimensional data.
Equipment List	EQL	Description of process-related components, including wetted materials and specifications.
Functional Specification	FS	UNICORN function description.
Declaration of Conformity	DoC	EC declaration of conformity.
Spare Part List	SPL	List of spare parts available from GE Healthcare.

Software documentation

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

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

Component documentation

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

2 Safety instructions

About this chapter

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

Important

WARNING

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

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

In this chapter

2.1 Safety precautions

Introduction

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

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

General precautions

WARNING

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

WARNING

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 ÄKTAprocess and the entire process.

WARNING

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

WARNING

Protective earth. ÄKTAprocess must always be connected to protective earth when energized.

WARNING

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

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

WARNING

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

WARNING

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

Flammable liquids and explosive environment

WARNING

Flammable liquids. ÄKTAprocess is **not approved** to handle flammable liquids.

WARNING

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

Personal protection

WARNING

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

WARNING

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

WARNING

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

CAUTION

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

CAUTION

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

CAUTION

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

Installing and moving

WARNING

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

WARNING

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

WARNING

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

WARNING

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

WARNING

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

WARNING

Heavy object. Take great care to avoid the wheels slipping off the edge of the ramp, especially the higher wheels of 1" systems.

WARNING

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

WARNING

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

WARNING

If 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 while it is operating.

CAUTION

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

CAUTION

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

CAUTION

ÄKTAprocess is designed for indoor use only.

CAUTION

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

CAUTION

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

CAUTION

Before moving ÄKTAprocess, make sure that:

1 The power supply to ÄKTAprocess is switched off.

2 All power cords to ÄKTAprocess are disconnected.

3 All air supply lines to ÄKTAprocess are disconnected.

4 All process lines to ÄKTAprocess are disconnected.

5 All Ethernet cables to ÄKTAprocess are disconnected.

CAUTION

Make sure that the common waste outlet is:

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

CAUTION

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

CAUTION

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

CAUTION

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

CAUTION

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

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

Flush out the denaturated alcohol before assembling, testing or integrating ÄKTAprocess into the intended process context.

Power supply

WARNING

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

WARNING

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

WARNING

All electrical installations must be performed by authorized personnel only.

CAUTION

Do not use an Uninterruptible Power Supply (UPS) outside the range 100 to 240 V. For UL-classified systems, do not use a UPS supply exceeding 120 V.

CAUTION

Connection of an Uninterruptible Power Supply (UPS) shall only be performed by authorized personnel to avoid mismatching or connection errors. Contact your local GE Healthcare representative for more information.

Sample pump

WARNING

Always move or lift the sample pump separately and disconnected from the ÄKTAprocess system. The units must always be moved individually.

WARNING

Take extra care to make sure that the sample pump trolley does not overturn when moving the trolley.

WARNING

The sample pump must be positioned so that it does not interfere with access to the emergency stop buttons.

WARNING

The sample pump must be powered from the system. It must not be connected directly to mains power.

CAUTION

The handles on the sample pump trolley must not be used for lifting.

System operation

WARNING

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

WARNING

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

WARNING

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

WARNING

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

WARNING

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

WARNING

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

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

WARNING

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

WARNING

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

WARNING

Use columns that withstand expected pressures. If not, the columns might rupture, resulting in injury.

WARNING

Never operate ÄKTAprocess with pressure control valves (PCVs) completely closed. A pressure increase may result, and cause leakage.

WARNING

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

WARNING

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

CAUTION

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

CAUTION

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

CAUTION

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

CAUTION

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

CAUTION

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

CAUTION

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

Maintenance

WARNING

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

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

WARNING

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

WARNING

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

WARNING

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

- After assembly or maintenance
- Before operation or CIP

WARNING

To avoid injury when servicing the valves on 1" systems, make sure that no body parts are caught when turning the valve assemblies.

CAUTION

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

CAUTION

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

2.2 Labels

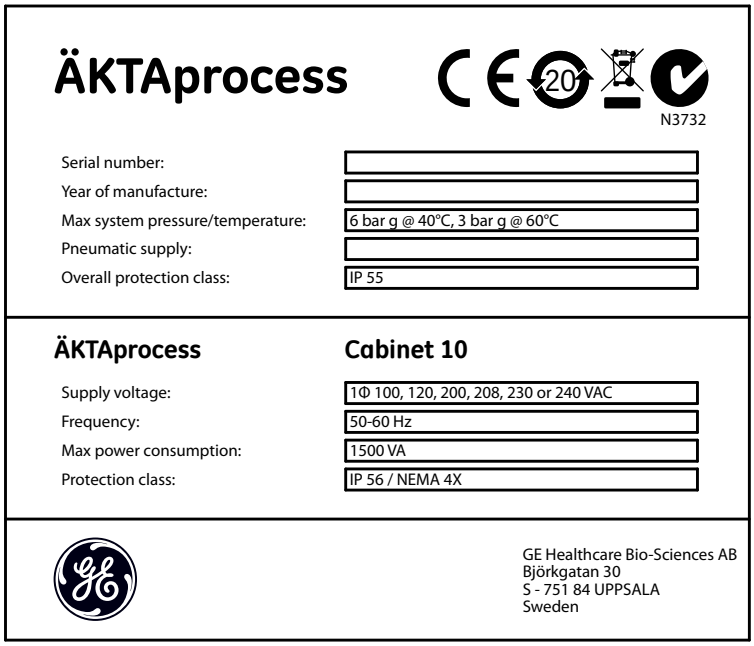
Introduction

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

System label

The illustration below shows an example of a system label.

Note: *The specific data shown on the system label below is only an example. Actual data is specific for each individual system and may vary from system to system.*



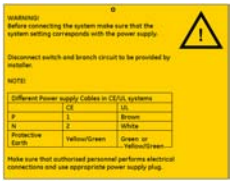
The system label information is explained in the following table.

Label text	Description
	The system complies with applicable European directives. Refer to *International standards, on page 11*.
	This symbol indicates that the product contains hazardous materials in excess of the limits established by the Chinese standard SJ/T11363-2006 Requirements for Concentration Limits for Certain Hazardous Substances in Electronics.
	This symbol indicates that waste electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of equipment.
	The system complies with the requirements for electromagnetic compliance (EMC) in Australia and New Zealand.
Serial number	System serial number.
Year of manufacture	Manufacturing year.
Max system pressure/temperature	Max system pressure at temperature
Pneumatic supply	Pneumatic supply pressure requirement
Overall protection class	Overall protection class. Ingress protection according to IEC 60529. This cover all components of the system except the electric cabinet.
Cabinet 10 / Cabinet 30	Cabinet 10 / Cabinet 30. Indicates the system cabinet type. Refer to *Cabinet type specific data, on page 165*.
Supply voltage	Supply voltage
Frequency	Supply voltage frequency
Max power consumption	Max power consumption
Protection class	Protection class. Ingress protection according to IEC 60529. This covers the electric cabinet only.

Safety labels

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

Symbol/text	Description
	**Warning!** Read the user documentation before using the system. Do not open any covers or replace parts unless specifically stated in the user documentation.
	**Warning! High Voltage**. Always make sure that the system is disconnected from electric power before opening the cabinet doors or disconnecting any electric device.
	**EMERGENCY STOP** label, yellow with black text. (emergency stop button is red). See *Section 2.3 Emergency procedures, on page 34* for further information regarding the emergency stop.
	**WARNING! High voltage inside cabinet!** Authorized personnel only! For continued protection against fire, only replace fuses with the same type and rating.
	**CAUTION!** Pressure control valve shall be set to 5.5 – 7 bar g for instrument air supply.

<table>
<tr><th>Symbol/text</th><th>Description</th></tr>
<tr><td> 
</td><td>Warning! Before connecting the system, make sure that the system setting corresponds with the power supply.
Disconnect switch and branch circuit to be provided by installer.
NOTE!
<table><tr><td colspan="3">Different power supply cables in CE/UL systems</td></tr><tr><td></td><td>CE</td><td>UL</td></tr><tr><td>P</td><td>1</td><td>Brown</td></tr><tr><td>N</td><td>2</td><td>White</td></tr><tr><td>Protective Earth</td><td>Yellow/green</td><td>Green or Yellow/green</td></tr></table>Make sure that authorized personnel perform electrical connections and use appropriate power supply plug.</td></tr>
<tr><td> 
</td><td>Attention: cleaning only when USB cover is closed!
Note:
This label is located beside the USB port on the side panel of the monitor.</td></tr>
</table>

2.3 Emergency procedures

Introduction

This section describes how to perform an emergency shutdown of ÄKTAprocess, the result in the event of power failure, and the procedure for restarting ÄKTAprocess in this case.

Precautions

WARNING

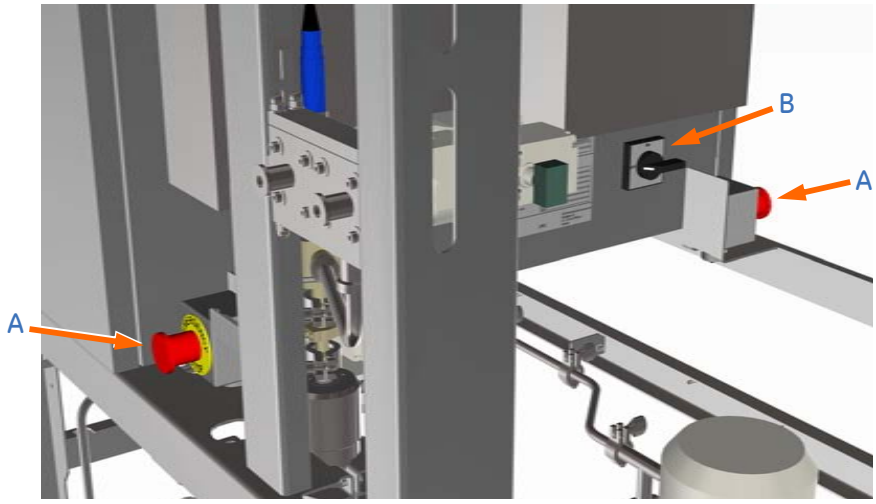
Emergency stop. Pressing the **EMERGENCY STOP** will not shut off mains power to the cabinet.

WARNING

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

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

Emergency shutdown



Step	Action	Result
1.	Press one of the **EMERGENCY STOP** buttons (A).	• All motors and externally moving components stop immediately. • The built-in computer and other components remain powered. • No data is lost. • The valves will shut down in a specific order, for details see *Valve shutdown order* below.
2.	If required, also switch off the mains power supply using the **SYSTEM POWER SWITCH** (B), disconnect the power cord or switch off the fixed power supply circuit breaker.	• Power to the entire system, including the computer, is lost. • Data and run status may be lost. • All valves will shut immediately and not in sequence.

Valve shutdown order

If an **EMERGENCY STOP** button is used, the valves will shut in the following order:

1 CIP/AxiChrom Column packing valves

2 InletA valves / InletB valves (optional) / Sample inlet valves (optional)

3 Air trap valves

4 Filter valves (optional)

5 Sample connection valves (optional)

6 Column 1 valves

7 Column 2 valves (optional)

8 Outlet valves

Power failure

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

All pumps stop if the electrical power to the system is lost. All valves will immediately revert to ***Closed*** positions.

If only the system is affected by the power failure and not the computer, UNICORN will display text saying that communication has been broken and that no data has been recovered. When power returns to normal, the system will be in ***End*** state (i.e., it will not resume the run).

The UNICORN interface control unit, **CU-960**, has capabilities to store real time data during short disconnection from the computer. Data stored on the **CU-960** can be uploaded to the computer once communication to the computer is re-established. Upload of data from the **CU-960** to the computer will be indicated on the monitor. The system can be controlled again once the upload of data from the **CU-960** is completed. Data upload can take several minutes to complete.

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

Restart after emergency shutdown or power failure

Follow the instruction below to restart ÄKTAprocess after emergency shutdown or power failure.

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

2.4 Recycling information

Introduction

This section contains information about the decommissioning of ÄKTAprocess.

Decontamination

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

Disposal, general instructions

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

Recycling of hazardous substances

ÄKTAprocess contains hazardous substances. Detailed information is available from your GE Healthcare representative.

Disposal of electrical components

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

2.5 Declaration of Hazardous Substances (DoHS)

Introduction

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

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

Symbols used in pollution control label

电子信息产品污染控制标志说明

Label	Meaning
	This symbol indicates the product contains hazardous materials in excess of the limits established by the Chinese standard SJ/T11363-2006 Requirements for Concentration Limits for Certain Hazardous Substances in Electronic Information Products. The number in the symbol is the Environment-friendly Use Period (EFUP), which indicates the period during which the toxic or hazardous substances or elements contained in electronic information products will not leak or mutate under normal operating conditions so that the use of such electronic information products will not result in any severe environmental pollution, any bodily injury or damage to any assets. The unit of the period is "Year". In order to maintain the declared EFUP, the product shall be operated normally according to the instructions and environmental conditions as defined in the product manual, and periodic maintenance schedules specified in Product Maintenance Procedures shall be followed strictly. Consumables or certain parts may have their own label with an EFUP value less than the product. Periodic replacement of those consumables or parts to maintain the declared EFUP shall be done in accordance with the Product Maintenance Procedures. This product must not be disposed of as unsorted municipal waste, and must be collected separately and handled properly after decommissioning.

Label	Meaning
	该标志表明本产品含有超过SJ/T11363-2006《电子信息产品中有毒有害物质的限量要求》中限量的有毒有害物质。标志中的数字为本产品的环保使用期，表明本产品在正常使用的条件下，有毒有害物质不会发生外泄或突变，用户使用本产品不会对环境造成严重污染或对其人身、财产造成严重损害的期限。单位为年。 为保证所申明的环保使用期限，应按产品手册中所规定的环境条件和方法进行正常使用，并严格遵守产品维修手册中规定的期维修和保养要求。 产品中的消耗件和某些零部件可能有其单独的环保使用期限标志，并且其环保使用期限有可能比整个产品本身的环保使用期限短。应到期按产品维修程序更换那些消耗件和零部件，以保证所申明的整个产品的环保使用期限。 本产品在使用寿命结束时不可作为普通生活垃圾处理，应被单独收集妥善处理

List of hazardous substances and their concentrations

产品中有毒有害物质或元素的名称及含量

Indication for each major part if substance exceeds limit

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

List of hazardous substances

Component name 部件名称	Hazardous substance 有毒有害物质或元素					
	Pb 铅	Hg 汞	Cd 镉	Cr6+ 六价铬	PBB 多溴联苯	PBDE 多溴二苯醚
ÄKTAprocess [1]	X	0	0	0	0	0

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

3 System description

About this chapter

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

In this chapter

3.1 Configurations

Introduction

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

Components

Standard ÄKTAprocess components are described in *Section 3.3 Standard components, on page 53*.

Optional ÄKTAprocess components are described in *Section 3.4 Optional components, on page 65*.

The UNICORN control system is described in *Section 3.6 UNICORN control system, on page 77*. The product documentation package includes the Software Configuration Description, which describes all functions of the control software in detail.

Tubing and cabinet

ÄKTAprocess can be delivered with tubing dimensions from 6 mm to 1" and with a cabinet type of Cabinet 10 or Cabinet 30. The differences between the cabinet types are specified in *Cabinet type specific data, on page 165*.

Process tubing materials can be stainless steel or polypropylene. Temperature and pressure limits for the these materials are specified in *Temperature and pressure limits, on page 166*.

3.2 Illustrations of ÄKTAprocess

Introduction

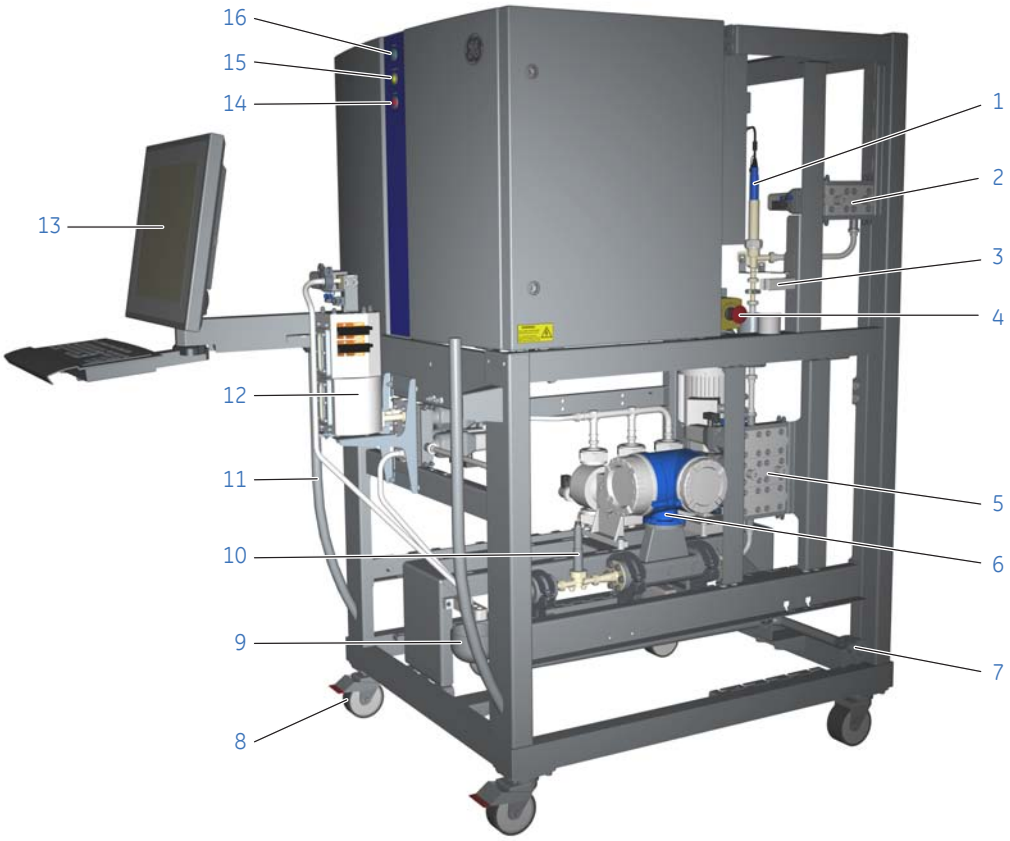
This section provides illustrations of ÄKTAprocess in both the basic configuration and with all options. The main features and components are indicated.

Battery limits

The term 'battery limit' appears in the tables that explain the illustrations of ÄKTAprocess. Battery limit is used to indicate a delimitation point between ÄKTAprocess and the customer process equipment. Battery limits denote the points where functional responsibility is handed over from the plant to the instrument or *vice versa*.

System with standard configuration: front view

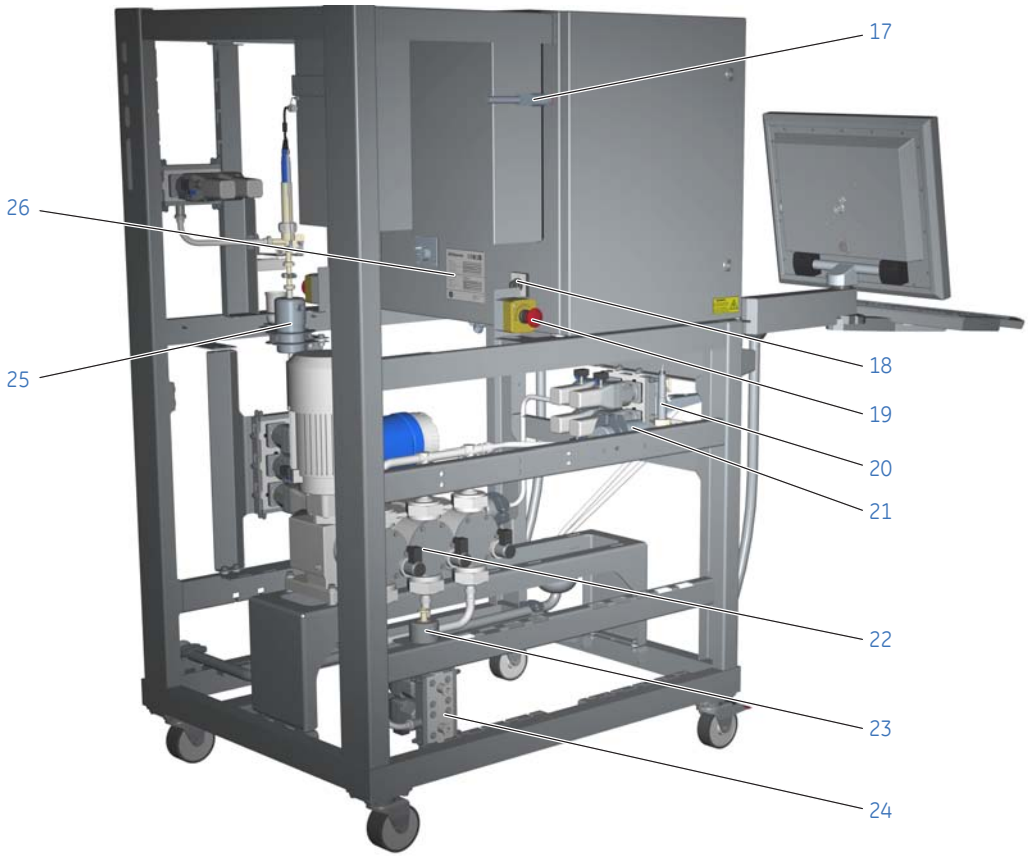
The illustration below shows a front view of the standard configuration of ÄKTAprocess.



Part	Function
1	pH probe
2	Battery limit: System outlets (2)
3	pH probe calibration holder
4	**EMERGENCY STOP**
5	Battery limit: Column 1 connections (2)
6	Flow meter
7	Battery limit: Common waste outlet
8	Swiveling wheel with brake (4)
9	Common waste collection cup
10	Pre-column pressure meter
11	Skid maneuvering handle (2)
12	Air trap
13	Operator console with keyboard and monitor
14	Indicator lamp - **ALARM**
15	Indicator lamp - **RUN/PAUSE**
16	Indicator lamp - **POWER**

System with standard configuration: rear view

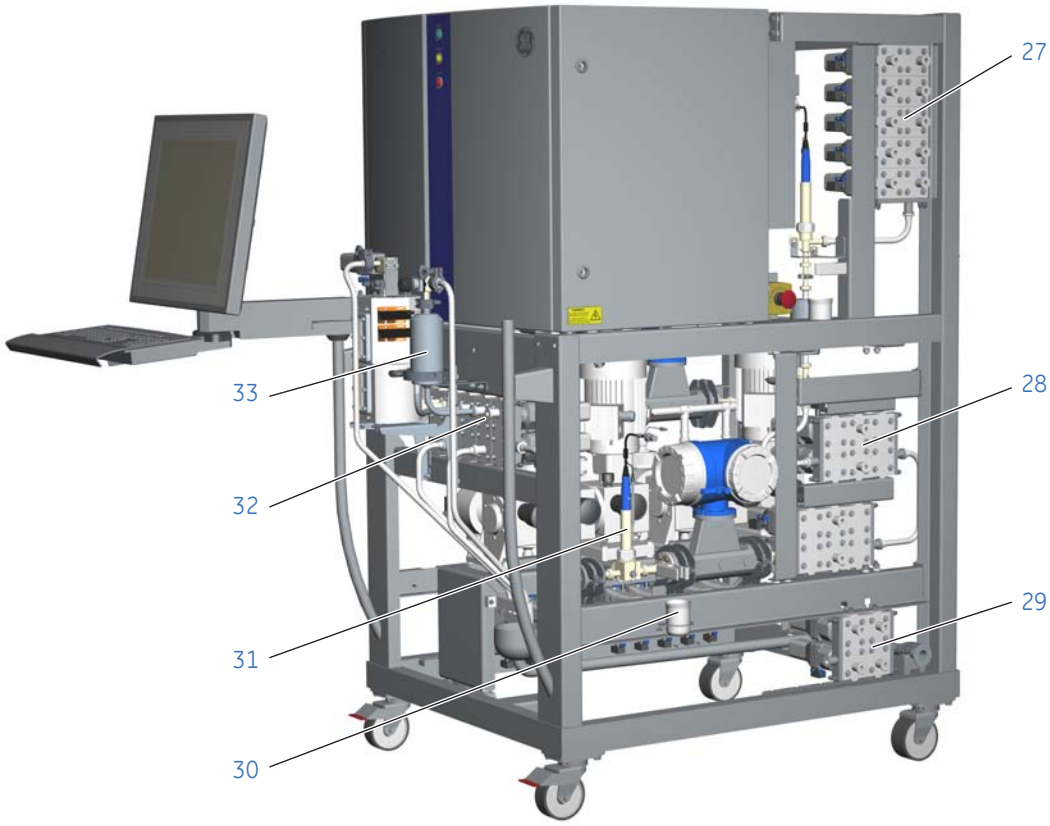
The illustration below shows a rear view of the standard configuration of ÄKTAprocess.



Part	Function
17	Pneumatic air supply connection port
18	**SYSTEM POWER SWITCH**
19	**EMERGENCY STOP**
20	Pressure meter
21	Pre-column conductivity meter
22	System pump A
23	Moveable air sensor
24	Battery limit: System inlets (2)
25	Post-column conductivity meter
26	System label

System with all options: front view

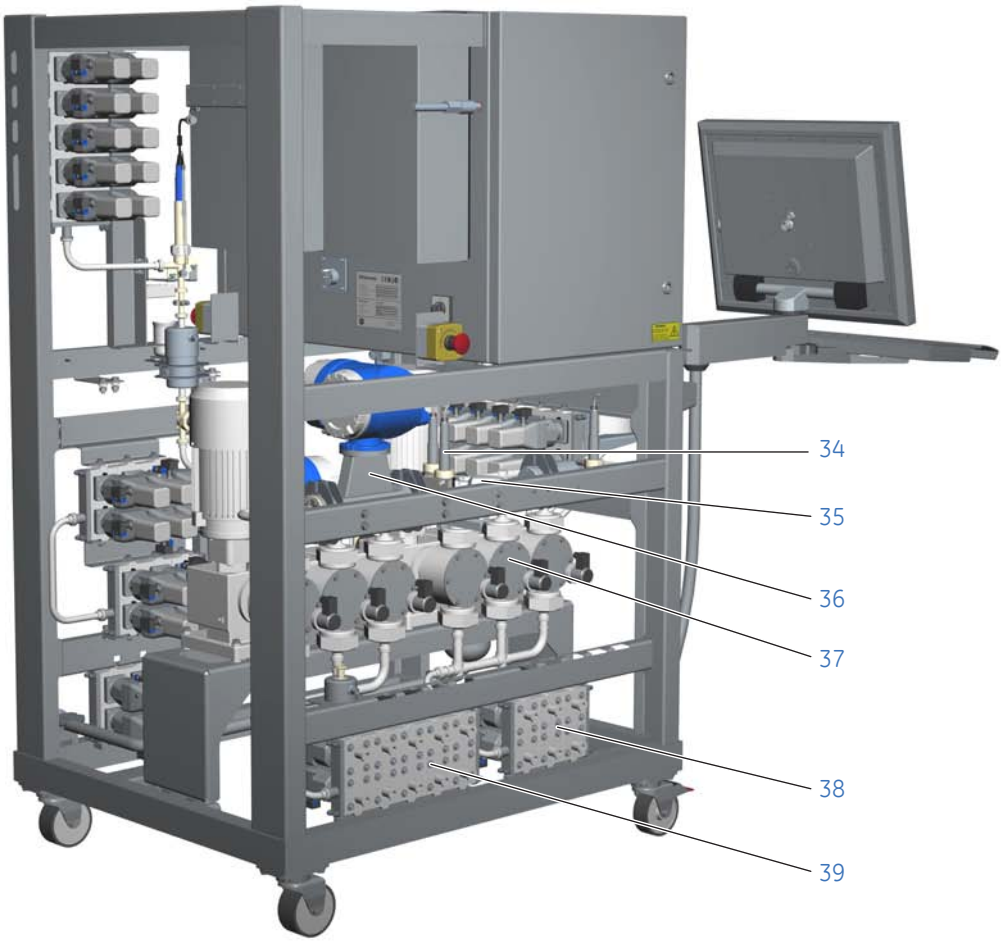
The illustration below shows a front view of an example of ÄKTAprocess with all optional components.



Part	Function
27	Battery limit: System outlets (10)
28	Battery limit: Column 2 connections (2)
29	Battery limit: CIP / AxiChrom™ valves
30	Pre-column pH probe calibration cup
31	Pre-column pH probe
32	Sample pump inlet
33	In-line filter

System with all options: rear view

The illustration below shows a rear view of an example of ÄKTAprocess with all optional components.



Part	Function
34	Pressure meter with PCV option (2)
35	Pressure control valve
36	Flow meter
37	System pump B
38	Battery limit: Buffer B inlets (6)
39	Battery limit: Buffer A inlets (10)

3.3 Standard components

Introduction

This section provides an overview of the standard components of ÄKTAprocess.

In this section

3.3.1 Structural components

Electric cabinet

The electric cabinet serves as the container for all electrical and pneumatic equipment.

Skid

The rigid stainless steel structure supports all process components and the electric cabinet.

The structure is designed for handling in a production environment and to be easy to move and keep clean.

The steel structure protects all installed components while still allowing easy access.

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

3.3.2 Control system components

Introduction

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

Control system

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

Refer to *Section 3.6 UNICORN control system, on page 77* for information on the UNICORN control system.

Control unit

A **CU-960** control unit is the controlling interface between UNICORN and the components of ÄKTAprocess.

The **CU-960** control unit is located inside the cabinet.

Computer

The computer is built into the cabinet and fully protected from the outside environment.

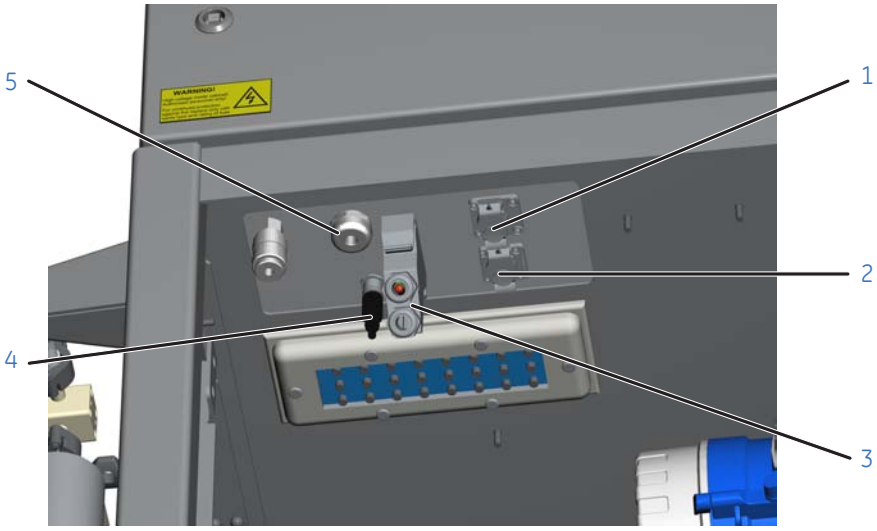
User console

The display and input equipment is ergonomically designed for usage in a clean production environment.

Communications

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

The PROFIBUS connection and other communication ports are located on the underside of the electrical cabinet, as shown in the illustration below. For information on where to connect the PROFIBUS signal cable to the AxiChrom Master, see the *AxiChrom User Manual*.



Part	Function
1	USB connection port
2	Ethernet connection port
3	Customer I/O connection
4	PROFIBUS connection
5	UPS Power

3.3.3 Inlets and outlets

Introduction

This section describes the inlets and outlets, including the drain outlet, of ÄKTAprocess that are provided in the standard configuration.

Connections

The standard configuration of ÄKTAprocess has two inlets, two outlets and connections for one column. As shown in the flowchart in *Section 3.5 Flowchart, on page 72* ÄKTAprocess has a moveable air sensor that may be connected to any inlet.

For standard ÄKTAprocess configurations the pressure on the inlets should be in the range 0 to 0.2 bar. The outlets can handle backpressure up to 1 bar.

Drains

All drains from ÄKTAprocess are collected to a single drain outlet. The drains are first collected in an open cup to ensure that no back pressure is applied on any parts of the processing system.

3.3.4 Meters and sensors

Introduction

This section describes the meters and sensors that are installed as standard components of ÄKTAprocess.

Overview

ÄKTAprocess is provided with a set of sensors and meters that provide data to the control system, enabling it to control the progress and detect the performance of the process in a satisfactory way.

The basic system setup includes meters and sensors that measure pressure, flow, conductivity (Cond), pH, air, temperature and UV. Measurement of these parameters enables basic isocratic operation and the air sensor before the column also makes sure that no air enters the column during processing.

Flow meter measurement principle

The measuring principle of the flow meter is based on the controlled generation of Coriolis forces. Refer to the flow meter manual in the product documentation package for more information.

3.3.5 System pump

Introduction

This section describes the basic ÄKTAprocess system pump. In the standard configuration, a single system pump is provided that supports isocratic operation.

Pump type

The system pump is a triple head diaphragm pump, or a 5-headed diaphragm pump for flow rates 45 to 2000 l/h. The process wetted parts of the pump heads are effectively sealed from non-sanitary components of the pump.

The pump is provided with stroke length adjustment knobs. These are factory preset at delivery and must not be adjusted by the user.

Pump stroke frequency

The pump stroke frequency is controlled by the flow that is set in the UNICORN control software.

Safety monitoring

The system is protected from exceeding the high pressure limit by the electronic module **ALP-900**, an air, level and pressure monitoring system that is situated inside the cabinet.

The **ALP-900** monitors:

1 The pressure in each pressure sensor

2 The pressure difference between each pressure sensor

3 The temperature in the process liquid

If any of the monitored parameters reaches a critical limit, the **ALP-900** will shut down the pumps independently from the UNICORN control system.

3.3.6 Air trap

Introduction

An air trap is installed in the flow path of ÄKTAprocess. This section describes the air trap and the sensors that are used for liquid level control.

Air trap function

The function of the air trap is to de-gas buffers. A vortex is created in the air trap and the liquid in the air trap is pressed downwards and outwards by the centrifugal force generated while air is separated in the center of the chamber. The rotation eliminates pockets of stagnant liquid, which prevents unwanted build-up of solids (e.g., bacterial cells) and simplifies the cleaning of the air trap.

Level sensors

Two sensors for automatic liquid level control are installed in the air trap. This sensor assembly consists of a high and a low level sensor. The sensors must be re-calibrated if the LED indicator displays a red light while the liquid level is still far from the low or high level markers.

Note: *It is recommended that after a power down a calibration of the level sensors should always be performed. See Section 6.6.2 Air trap calibration, on page 153.*

Note: *When the air trap is filled with liquid that foams easily, for example liquids containing detergents and protein solutions (sample), large volumes of air should not be allowed to enter into the air trap. If foam is formed it may interfere with the automatic liquid level control.*

Always position a movable air sensor at the inlet of the sample or detergent-containing liquid. The air sensor will set the system to ***Pause*** *when air is detected, which will prevent the build up of foam in the air trap or can trigger the next step in the method.*

3.3.7 Valves

General description

With the exception of the filter housing options that have either one or three manual air outlet valves, all valves are diaphragm valves that are actuated by compressed air. The valve actuators are controlled by an ASi bus.

The inlet and outlet valve configurations are identical. Each valve consists of a valve body, a diaphragm and an actuator. Two valves are combined into a valve block.

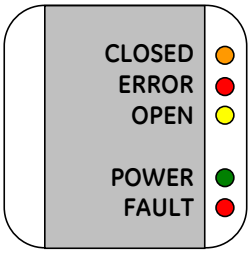
Due to their size and weight, the valves for 1" systems are mounted in turnable cradles.

WARNING

To avoid injury when servicing the valves on 1" systems, make sure that no body parts are caught when turning the valve assemblies.

Valve LED indicator lights

The valve LED indicator lights are illustrated below.



Label	Color	Description (when applicable)
CLOSED	Orange	Steady light: Actuator in closed position
ERROR	Red	Steady light: Programming, sensor or internal error
OPEN	Yellow	Steady light: Actuator in open position
POWER	Green	Voltage on
FAULT	Red	Steady light: Slave address error

Note: *Refer to the product documentation package for other possible indications and more information about their meaning. Some indications are only relevant for service personnel.*

Valve default positions

When the system is powered up and connected to compressed air, the default positions for the various valves are given in the table below. If no control signal is present, for example if the mains power is shut off, the valves will revert to ***Closed*** positions.

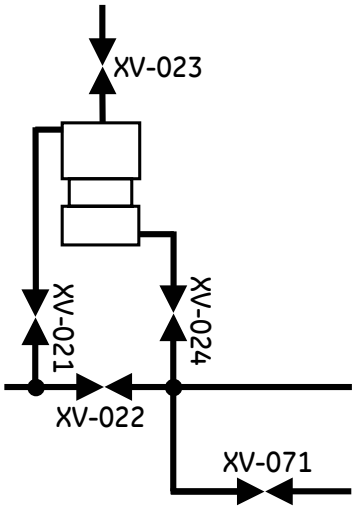
Valves	Default position
Inlet valves	***Closed***
Outlet valves	***Closed***
Sample inlet valves	***Closed***
CIP/AxiChrom column packing valves	***Closed***
Air trap valves	***Inline***
Filter valves	***Bypass***
Column valves	***Bypass_Both***

Note: *Inlet valves should always be closed when not in use. This is essential to ensure gradient accuracy and to prevent buffers from mixing.*

Air trap valves

The air trap valve blocks are directly connected, either to the optional filter valve blocks or to tubing going to the pre-column air sensor, in order to minimize the dead volume that is caused by connecting valve blocks with tubing.

The layout of the air trap valves is illustrated below.



Valve positions	Open valve(s)
Bypass	XV-022
Inline (Default)	XV-021 + XV-024
Fill	XV-021 + XV-023
Fill_Inline	XV-021 + XV-023 + XV-024
Out_through_drain	XV-021 + XV-024 + XV-071
Drain (No flow)	XV-023 + XV-024 + XV-071

The ***Drain*** valve position is used for example when the air trap is emptied before disassembly or to lower the liquid level in the air trap. The pump(s) must be set to 0.0 l/h when the ***Drain*** valve position is used.

Note: *The UNICORN instruction **ManFlow** must be used when running **Out_through_drain** unless the system has a flow meter before the air trap. However, it is possible to use **Flow** for short periods of time even if the system is not equipped with a flow meter.*

Note: *If the system is set for max flow when **Fill** is used, the air trap may not be able to close quickly enough and in that case it will overflow. Reduce the flow to avoid this.*

The UNICORN instruction ***Alarms:AirTrapLevelControl*** can be used to enable or disable the automatic liquid level control. The other settings outlined in the table below automatically disable the level control.

Instruction	Setting
Valves:AirTrap	***Bypass***
	Fill
	Fill_Inline
	Drain
	Out_through_drain

The instruction ***System:Settings:Specials:AirTrapPauseFunction*** defines if the valve goes back to the default position (Inline) or if it remains in position when the system is set to Pause.

Sample connection valves

The optional sample pump is connected to the sample connection valve, where the feed from System pump A and the optional gradient pump B is also connected, after the air trap and the optional filter. Sample inlet valves are available only on systems that are delivered with a sample pump.

When an inlet valve is open (A, B or Sample inlet valves), the corresponding sample connection valve will also open. The sample connection valves cannot be controlled independently by the operator.

Note: *The alarm for the sample inlet valves must be disabled if the sample pump is disconnected. See Section 5.1.5 Final checks, on page 123 for UNICORN settings.*

Column valves

The column valve sets (column 1 and the optional column 2) each consist of six valves. Similar to the inlet valve blocks, the blocks are connected directly to each other to enable the shortest possible flow path.

To define if the valve goes back to the default position (***Bypass_Both***) or if it remains in position when the system is set to ***Pause***, see *UNICORN instruction notes, on page 170* for instructions.

3.4 Optional components

Introduction

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

Extra system pump inlets

Up to eight extra inlets with individually controlled valves can be installed.

This means that ÄKTAprocess is able to manage up to ten individual inlets for system pump A.

Extra system outlets

Up to eight extra system outlets with individually controlled valves can be installed.

This means that ÄKTAprocess is able to manage up to ten individual outlets in total.

System pump B

ÄKTAprocess can be provided with a second system pump. The addition of a second system pump enables ÄKTAprocess to operate as a gradient system.

The B-pump can be provided with up to six individually controlled inlets.

If the System pump B option is selected, an extra flow meter can also be provided to enable the individual pump flows, as well as the total system flow, to be measured.

The B-pump type is identical to the A-pump.

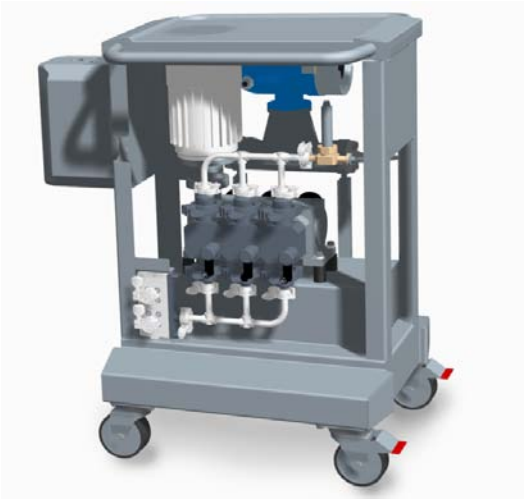
In-line filter

A filter can be installed between the air trap and the column to prevent foreign objects from contaminating the column. Different types of in-line filter are available, including a disposable capsule filter option. Filter housings may be made of steel or polypropylene.

Two columns

ÄKTAprocess can be configured to incorporate a second column. With this option, the ÄKTAprocess can supply two columns, one after the other with mobile phase.

Sample pump



The sample pump allows sample to be injected into the column without the need to use any of the system pumps for this purpose.

There are two optional inlets feeding the sample pump. The sample pump is also provided with an extra pressure meter that protects the system against over pressure.

Extra pressure meter

An extra pressure meter can be installed after the column to accurately measure the pressure drop over the column.

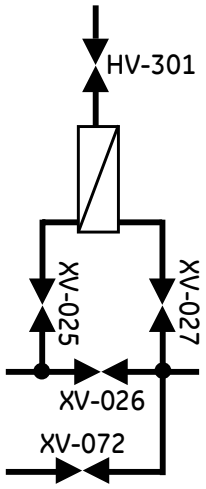
Extra pH meter

An extra pH-meter can be installed before the column on a gradient system to enable the gradient to be monitored.

Filter valves

The optional in-line filter valve block set is identical to the air trap valve block set. There is also a manual valve for air evacuation, HV-301.

The layout of the filter valves is illustrated in the following diagram.



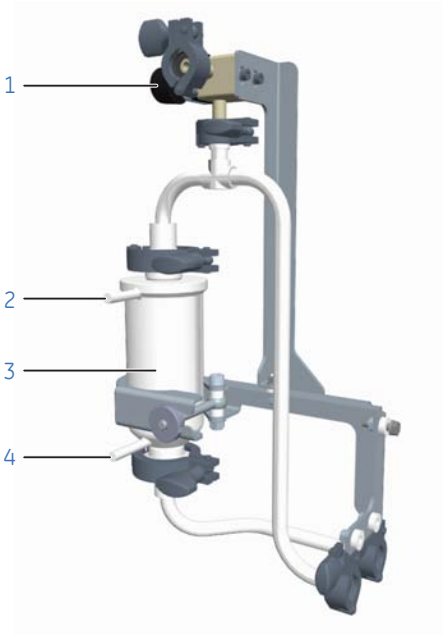
Valve positions	Open valve(s)
Bypass (default)	XV-026
Inline	XV-025 + XV-027
Out_through_drain	XV-025 + XV-027 + XV-072
Drain (No flow)	HV-301 + XV-027 + XV-072

The ***Drain*** valve position is used, for example, when the filter housing is emptied before replacing the filter. The pump(s) must be set to 0.0 l/h when the ***Drain*** valve position is used.

Note: *The UNICORN instruction **ManFlow** must be used when running **Out_through_drain** unless the system has a flow meter before the air trap. However, it is possible to use **Flow** for short periods of time even if the system is not equipped with a flow meter.*

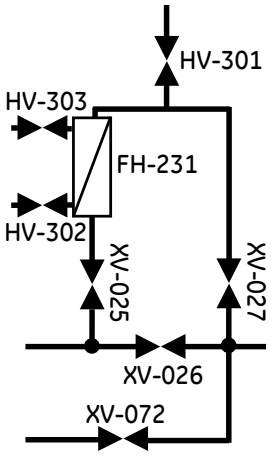
Capsule filter and valves

A disposable capsule filter option may be selected instead of the in-line filter option described above. The disposable capsule filter housing is made of polypropylene and includes two additional manual valves for air evacuation, as illustrated below.



Part	Function
1	Manual valve **HV-301**
2	Outlet to manual valve **HV-303**
3	Capsule filter housing
4	Outlet to manual valve **HV-302**

The layout of the capsule filter valves is illustrated in the following diagram.



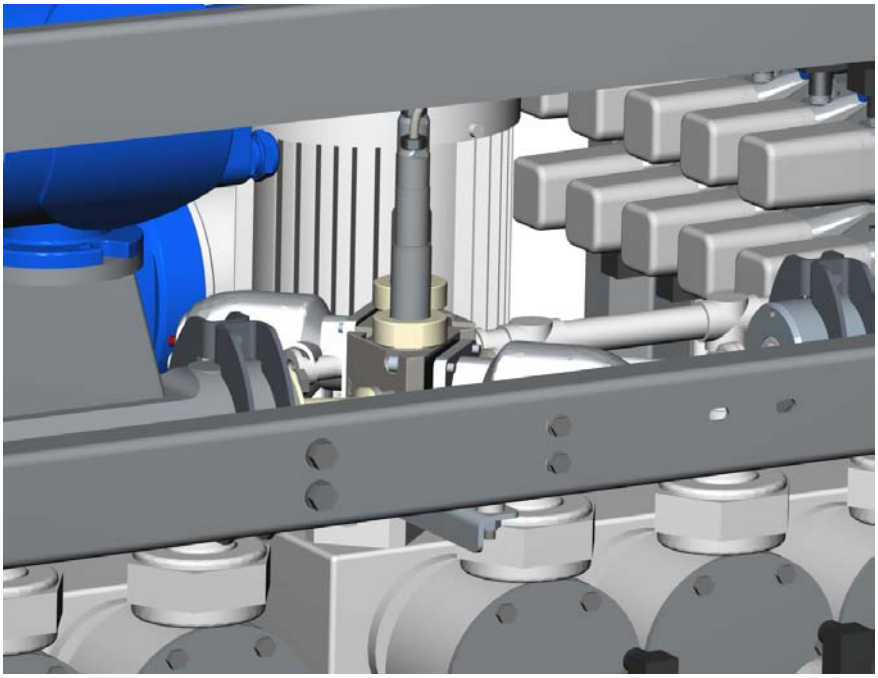
Valve positions	Open valve(s)
Bypass (default)	XV-026
Inline	XV-025 + XV-027
Out_through_drain	XV-025 + XV-027 + XV-072
Drain (No flow)	HV-301 + HV-302 + HV-303 + XV-027 + XV-072

The ***Drain*** valve position is used, for example, when the filter housing is emptied before replacing the filter. The pump(s) must be set to 0.0 l/h when the ***Drain*** valve position is used.

Note: *The UNICORN instruction **ManFlow** must be used when running **Out_through_drain** unless the system has a flow meter before the air trap. However, it is possible to use **Flow** for short periods of time even if the system is not equipped with a flow meter.*

Pressure control valves (PCV)

ÄKTAprocess can be provided with up to two optional pressure control valves, **PCV-341** and **PCV-342**, as shown in the illustration below.



Note: *The illustration shows **PCV-341** and **PCV-342** positioned horizontally.*

The function of the PCVs is to protect the system from 'free flow' if the inlets are fed with a higher pressure than 0.2 bar.

The pressure control valve option allows the pressure on the inlets to be regulated and the flow through the system via individual system pumps to be controlled.

ALP2 PCV safety monitoring

If ÄKTAprocess is optionally configured to include a pressure control valve, or valves, the system will also be equipped with an **ALP2** air, level and pressure monitoring system.

The **ALP2** unit protects against exceeding maximum operating pressures by monitoring pressure between the pumps and the PCVs.

CIP / AxiChrom manifold

A CIP / AxiChrom manifold with four individually controlled valves enables UNICORN to control CIP with up to four inlets and control processing together with a connected AxiChrom column.

See *Using the CIP/AxiChrom manifold option, on page 139* for more information about connections for CIP. For Intelligent Packing with AxiChrom columns, see AxiChrom manuals for details on connection.

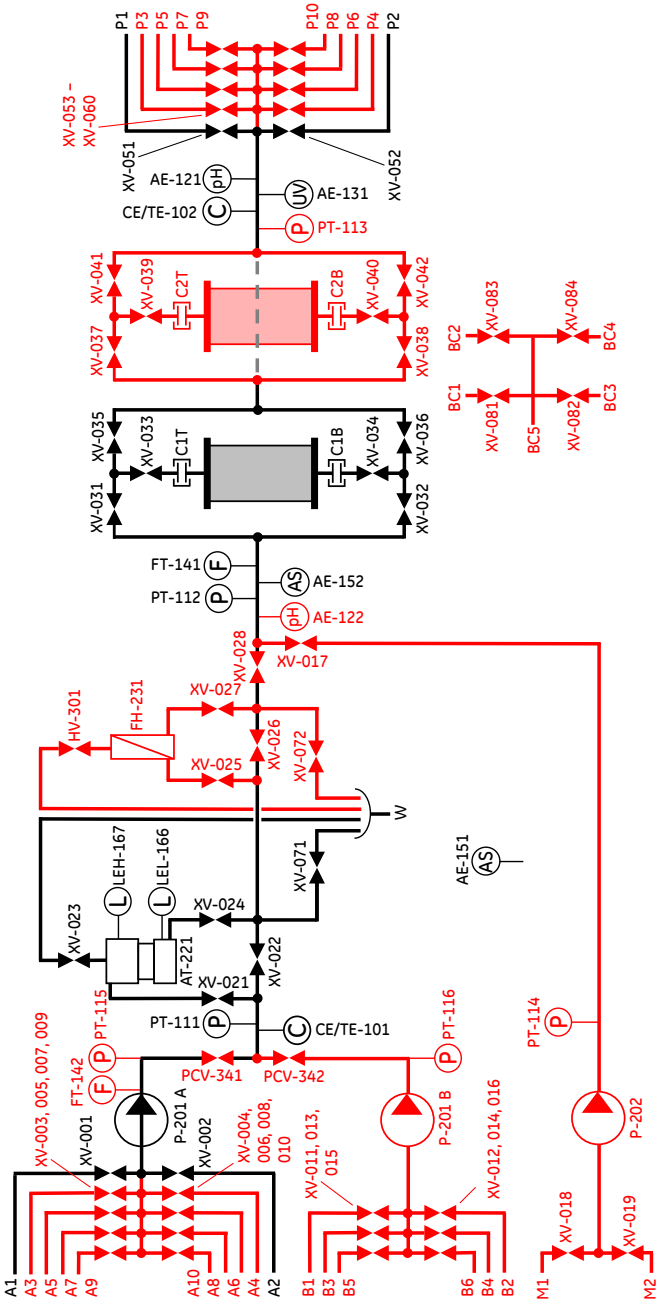
Anybus™ X-gateway

The system can be provided with an optional Anybus X-gateway to enable communication between ÄKTAprocess and the customer network. The signals transferred can both be analog process readings, digital status and handshake signals. The Anybus X-gateway is located inside the electrical cabinet. The interface to the gateway is PROFIBUS Slave through a M12 connector in the bottom of the electrical cabinet.

The Anybus X-gateway copies I/O-data in both directions, thus enabling data exchange between two optically isolated PROFIBUS networks. The Anybus X-gateway connections can be used for many different applications. See the PROFIBUS Communication Interface documenation for a description of how the different I/O-data is addressed in the memory space.

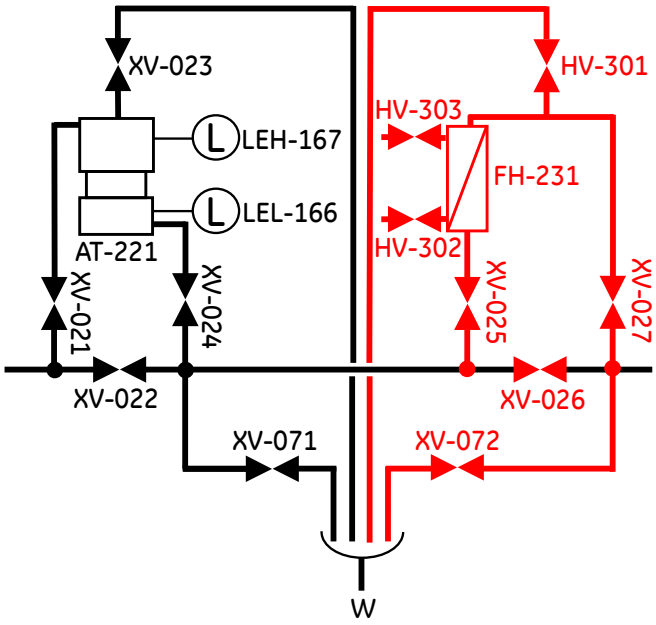
Contact your local GE Healthcare representative for more information.

3.5 Flowchart



Capsule filter option

The illustration below shows the corresponding air trap and filter block alternative section of the flowchart if the capsule filter option is selected.



Note: *Black represents standard components; Red represents optional components.*

Process components

The following table lists the process components that are shown in the flow chart.

Tag	Function (qty)	Note
1, **2**	Outlets	
3 to **10**	Outlets	Optional
A1, **A2**	Buffer A inlets	
A3 to **A10**	Buffer A inlets	Optional
AT-221	Air trap	
B1 to **B6**	Buffer B inlets	Part of system pump B option
C1T	Column 1 top connection	

Tag	Function (qty)	Note
C1B	Column 1 bottom connection	
C2T	Column 2 top connection	Part of column 2 option
C2B	Column 2 bottom connection	Part of column 2 option
CIP1 to **CIP4**	CIP inlets	
CIP C	CIP common inlet	
FH-231	Filter	Option
HV-301	Filter vent valve	Part of filter option, manual
HV-302	Capsule filter bottom manual valve	Capsule filter option only
HV-303	Capsule filter top manual valve	Capsule filter option only
M1, **M2**	Sample inlets	Part of sample pump option
P-201 A	System pump A	
P-201 B	System pump B	Option
P-202	Sample pump	Option
PCV-341	Pressure control valve, A inlets	Option
PCV-342	Pressure control valve, B inlets	Option
W	Common waste	
XV-001, **XV-002**	Buffer A inlet valves	
XV-003 to **XV-010**	Buffer A inlet valves	Optional
XV-011 to **XV-016**	Buffer B inlet valves	Part of system pump B option
XV-017	Sample connection valve	Part of sample pump option
XV-018, **XV-019**	Sample inlets valves	Part of sample pump option
XV-021	Air trap inlet valve	
XV-022	Air trap bypass valve	
XV-023	Air trap vent valve	
XV-024	Air trap outlet valve	
XV-025	Filter inlet valve	Part of filter option

Tag	Function (qty)	Note
XV-026	Filter bypass valve	Part of filter option
XV-027	Filter outlet valve	Part of filter option
XV-028	System connection valve	Part of sample pump option
XV-031	Column 1 top inlet valve	
XV-032	Column 1 bottom inlet valve	
XV-033	Column 1 top valve	
XV-034	Column 1 bottom valve	
XV-035	Column 1 top outlet valve	
XV-036	Column 1 bottom outlet valve	
XV-037	Column 2 top inlet valve	Part of column 2 option
XV-038	Column 2 bottom inlet valve	Part of column 2 option
XV-039	Column 2 top valve	Part of column 2 option
XV-040	Column 2 bottom valve	Part of column 2 option
XV-041	Column 2 top outlet valve	Part of column 2 option
XV-042	Column 2 bottom outlet valve	Part of column 2 option
XV-051, **XV-052**	Outlet valves	
XV-053 to **XV-060**	Outlet valves	Optional
XV-071	Air trap drain valve	
XV-072	Filter drain valve	Part of filter option
XV-081 to **XV-084**	CIP / AxiChrom manifold	Option

Meters and sensors

The following table lists the meters and sensors that are shown in the flow chart.

Tag	Function	Note
AE-151	Buffer inlet air sensor	Movable
AE-152	Pre-column air sensor	Final check that no air enters the column
AT-121	Post-column pH-meter	
AT-131	Post-column UV-meter	Peak detection
CE/TE-101	Pre-column conductivity meter	Also includes a temperature meter
CE/TE-102	Post-column conductivity meter	Peak detection and CIP-control, also includes a temperature meter
FT-141	System flow meter	Measures the total system flow
LEH-167	Air trap high level meter	
LEL-166	Air trap low level meter	
PT-111	Pre-filter pressure meter	Option
PT-112	Pre-column pressure meter	Guards the column from over pressure, detects clogged column
PT-114	Sample pump pressure meter	Part of sample pump option
PT-115	PCV pressure meter, A inlets	part of PCV option
PT-116	PCV pressure meter, B inlets	part of PCV option

3.6 UNICORN control system

Introduction

ÄKTAprocess is controlled by UNICORN software.

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

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

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

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

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

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

Prerequisite knowledge

At least basic knowledge of UNICORN is required to operate ÄKTAprocess safely.

This manual does not cover how to use UNICORN.

Information on how to use UNICORN can be obtained from the UNICORN manuals.

Contact your local GE Healthcare representative for advice if required.

System networks

UNICORN can be installed on a stand-alone computer to control locally attached systems. Multiple computers can view the output data from one system.

Software modules

The UNICORN control software consists of four modules:

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

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

Workflow

The table below outlines the general workflow for using UNICORN for automatic control.

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

Manual instructions

Parameters can be entered manually in UNICORN for selected categories of instructions.

To access the dialog where the manual instructions can be set, select the ***Manual*** menu in the ***System Control*** module, then select one of the instruction categories from the following list:

- ***Pump***
- ***Valves***
- ***Monitors***
- ***Alarms***
- **Others**

The ***Manual*** menu can also be accessed using the shortcut **Ctrl + M**.

Indicators on the system

The table below describes the meaning of the indicators on the system.

Image	Label	Color	Function
	**POWER**	Green	**Power is on**: *Flashing*: UNICORN starting up. *Steady*: UNICORN ready.
	RUN/PAUSE	Yellow	**UNICORN method is active**: *Flashing*: UNICORN in state ***Pause***. *Steady*: UNICORN in state ***Run***.
	ALARM	Red	**System alarm**: Check UNICORN for detailed information.

Warnings

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

Alarms

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 exceeds the predetermined alarm level, several things happen at once:

- An audible alarm sounds (according to user preference settings).
- The system enters ***Pause*** mode.
- The valves and other components on the system revert to their default positions.

The ***Valve Pause Function*** can be enabled in UNICORN for certain components (air trap, filter, column 1, column 2) to retain the original valve positions. The system indicator lights will also indicate alarms.

Alarm test

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

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

Reset alarms

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

More information

All required manuals are available from the ***Help*** menu in the UNICORN user interface.

4 Installation

About this chapter

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

Precautions

WARNING

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

- *General precautions, on page 17*
- *Personal protection, on page 19*
- *Installing and moving, on page 20*
- *Power supply, on page 23*

In this chapter

This chapter contains the following sections:

4.1 Site requirements

Space and floor load

For space and floor requirements, see external dimensions and weights in *Section 8.1 Specifications, on page 164*.

Note: *Make sure that the floor can handle ÄKTAprocess 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.*

Note: *In order to allow convenient working conditions for the operator, sufficient space should be provided on all sides of ÄKTAprocess when installed at the intended production location.*

Ambient environment

The following should be avoided.

- Direct sunlight
- Strong magnetic or electric fields
- Vibrations
- Corrosive gas
- Dust
- Temperatures outside recommended operating ranges. For ambient environment temperature range, see *Section 8.1 Specifications, on page 164*.

Electrical power

Refer to *Section 4.5 Power supply, on page 105* and *Section 8.1 Specifications, on page 164* for power, voltage and phase requirements.

Compressed air

ÄKTAprocess requires dry and particle free air for system supply.

Refer to *Section 8.1 Specifications, on page 164* regarding capacity requirements.

Refer to *Section 4.4.3 Connect compressed air supply, on page 98* regarding connections to the instrument.

Media supply

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

Refer to *Section 8.1 Specifications, on page 164* regarding media supply and delivery requirements.

Computer

An external computer is not required. ÄKTAprocess is provided with a built-in industrial computer.

4.2 Transport

Introduction

This section outlines important information that must be considered when transporting ÄKTAprocess.

Transport in crate

Use a pallet jack or forklift with a minimum capacity to match the weight of the system plus the transport box. Refer to *Section 8.1 Specifications, on page 164* regarding system weight.

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

The crate dimensions are shown below.

- *Cabinet 10: 111 (w) x 207 (l) x 173 (h) cm*
- *Cabinet 30: 131 (w) x 268 (l) x 193 (h) cm*

Moving when unpacked

WARNING

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

NOTICE

Operator console

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

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

- ÄKTAprocess can be rolled by hand on hard and level surfaces with wheel brakes released.
- If the floor quality does not allow rolling ÄKTAprocess on its own wheels, it can be moved with a pallet jack or forklift.
- For minimum door aperture size, refer to the Assembly Drawing (AD) in the documentation package.

4.3 Unpack ÄKTAprocess

Precaution

CAUTION

To prevent bacterial growth, ÄKTAprocess may be partly filled with denaturated alcohol (18% C_2H_5OH (ethanol), 2% C_3H_7OH (iso-propanol) and 80% H_2O (water)) at delivery.

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

Flush out the denaturated alcohol before assembling, testing or integrating ÄKTAprocess into the intended process context.

Tools required

- 13 mm wrench (or ratchet wrench with 13 mm socket)
- Electrical screwdriver with Phillips no. 2 bit
- Knife
- Wooden lever (enclosed in crate)

Visual inspection

Check

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

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

Procedure

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

Step	Action
1.	Remove the front, side and back panels by loosening the bolts/brackets marked with black paint.
2.	Loosen bolts/brackets holding the equipment to the crate bottom.
3.	Roll the system out of the crate using the ramp that is found inside the crate.

WARNING

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

4.4 ÄKTAprocess Setup

Precaution

CAUTION

To prevent bacterial growth, ÄKTAprocess may be partly filled with denaturated alcohol (18% C_2H_5OH (ethanol), 2% C_3H_7OH (iso-propanol) and 80% H_2O (water)) at delivery.

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

Flush out the denaturated alcohol before assembling, testing or integrating ÄKTAprocess into the intended process context.

In this section

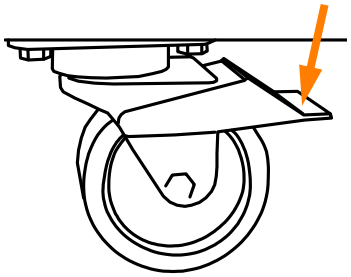
4.4.1 Assembly of ÄKTAprocess

Introduction

Apart from the operator console, the ÄKTAprocess is delivered fully assembled. This section describes the steps needed to mount the operator console, and how to lock the wheels.

Lock the wheels

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



Operator console

CAUTION

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

CAUTION

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

The operator console is packed separately in a cardboard box which is enclosed in the system crate.

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

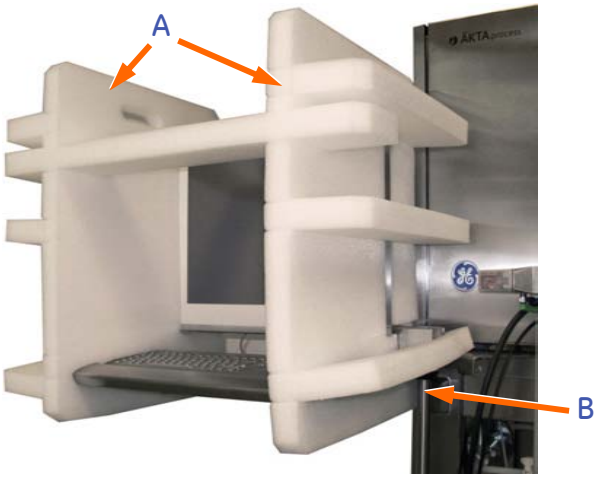
These two cables are attached to the system, and are located underneath the electrical cabinet.

The operator console can be mounted on either the left or right system handle. A rotation stop is fitted to prevent the console from colliding with the system cabinet. Instructions for mounting the console are given below.

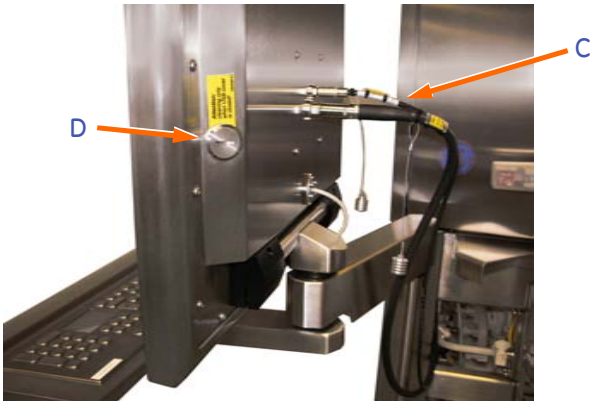
Mount operator console on left side

Follow the instruction below to mount the operator console on the left side.

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



3	Remove the polystyrene foam protection.

Step	Action
4	 Mount the two cables (C) to the console as illustrated in the picture.

NOTICE

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

5 Fix the cables neatly together with the existing cables underneath the cabinet using cable ties, as illustrated below.

Step	Action
6	Fix the rotation stop onto the cabinet, behind the console arm. The bolts holding it in place should be positioned below the plane of the rotation stop plate. The position of the rotation stop is shown below viewed from the front and back.

Mount the operator console on right side

The operator console is mounted on top of the right system handle as described above, with the following differences.

- Place the operator console arm carefully over the right system handle, instead of the left.

- The rotation stop is fixed to the cabinet with the bolts holding it in place above the plane of the rotation stop plate, as illustrated below.

NOTICE

Operator console

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

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

4.4.2 Setup of control system and network

Control system

ÄKTAprocess is delivered with the UNICORN control system pre-installed and configured on the built-in computer. No specific actions are required with respect to the control system.

Network connection

An external socket for Ethernet connection to a network (optional) is available on the bottom panel of the cabinet, marked **ETHERNET IN**.

CAUTION

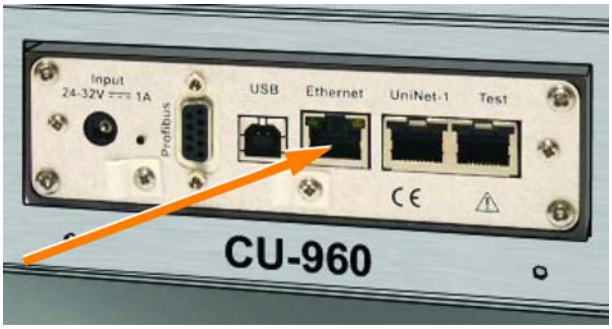
Use the supplied network cable with encased RJ45 connectors to protect from liquids. Do not replace this cable with an unprotected cable.

Connecting an external computer

Follow the instruction below to connect an external computer to the system.

Step	Action
1	Connect the external computer to the socket marked **ETHERNET IN** underneath the bottom panel of the electronics cabinet.
2	Remove the computer's external network cable from the corresponding Ethernet network socket on the inside of the cabinet. This socket is located in the bottom panel of the cabinet immediately in front of the built-in computer.

Step	Action
3	Connect the crossover Ethernet cable from CU-960 to the network socket at the bottom of the cabinet by moving the cable connector from the internal computer's LAN2 outlet to the network socket.



WARNING

If 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 while it is operating.

Peer-to-peer computer connection

An external computer may be connected directly to the built-in computer for simple peer-to-peer control and communication. The connection is similar to a regular network connection, using the external **ETHERNET IN** socket located on the bottom panel of the cabinet.

Note: *The Ethernet cable connecting the external computer and the system computer must be a crossover cable, specifically configured for peer-to-peer type connections. To make sure that the protection of the cabinet is not compromised, it is a recommendation that the enclosed encapsulated network cable is used from the cabinet and extended with a crossover cable, which is connected to the external computer. An alternative is to use a hub or switch. For this connection straight cables may be used.*

OPC client operation

ÄKTAprocess may be connected to an OPC (OLE for Process Control) client to enable the use of a uniform interface between other software systems (e.g. DeltaV™, LIMS - laboratory information systems etc.) and UNICORN. UNICORN OPC server is included in the regular installation and the software may be set up either for full OPC client access to all UNICORN data items or access that is limited. The UNICORN OPC features are described in the UNICORN OPC Server data file (document no 11-0004-15). The UNICORN OPC settings are described in the UNICORN *Administration and Technical Manual* and the *UNICORN OPC manual*.

Customer I/O connections

Customer I/O connections are located on the communications panel on the underside of the electrical cabinet. There are many different applications for the Customer I/O connections. Refer to the product documentation package or contact your local GE Healthcare representative for more detailed technical information.

The external 15-pin D-sub connector on the underside of the cabinet is available for programmable general purpose DC signals, both inbound and outbound.

Mapping between pins and signal types are given in the following table.

Signal	Pin
Digital In 1	**15**
Digital In 2	**8**
Digital In 3	**14**
Digital In 4	**6**
Digital In Common	**7**
Digital Out 1	**2**
Digital Out 2	**3**
Digital Out 3	**5**
Digital Out 4	**10**
Digital Out Common	**4**
Remote alarm output	**1**
Remote alarm output	**9**
UPS On input +	**11**
UPS On input -	**12**

The following notes apply:

- Input voltages in the 5 to 24 V range are acceptable.
- The maximum digital output signal is 24 V/0.10 A.
- For sourcing output, the Out Common is connected to a positive voltage. For sinking output, the Out Common is connected to the Common used by the customer's application.
- Pins **1** and **9** provide a closing relay contact (max 24 V/0.10 A) for an alarm module, e.g. a warning light, a buzzer or similar unit. The external alarm will be triggered when the internal buzzer is activated.
- Pins **11** and **12** are used to receive an On signal from an optional UPS, i.e. active during a power failure when a UPS is working.

4.4.3 Connect compressed air supply

Introduction

This section describes how to connect the compressed air supply.

For requirements on air supply, refer to *Section 4.1 Site requirements, on page 82* and *General technical data, on page 164*.

Connect compressed air supply to ÄKTAprocess

Step	Action
1	Connect the compressed air as shown in the image above.
2	Make sure that the supply pressure to the cabinet is between 5.5 and 7 bar g. The manometer is set to 6 bar g at the factory and shall not be changed.

4.4.4 Guidelines for connections

Introduction

This section provides guidelines for the connection of process components to ÄKTAprocess.

Process 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, refer to *Section 8.1 Specifications, on page 164* and the technical information in the system-specific documentation package.
- 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 equipment.
- If any tubing or hose should be violently pulled by an accidental tripping, check for damage, leakage and mechanical rigidity before continuing operation.
- The chemical properties of the tubing used must meet or exceed the properties specified in *Section 8.2 Chemical resistance, on page 167*.

4.4.5 Connect sample pump

Overview

If ÄKTAprocess is delivered with the sample pump option, connect the sample pump with the enclosed tubing using TC-connectors. Refer to the *Section 3.5 Flowchart, on page 72* for sample pump connection location.

The sample should be fed via the inlet air sensor.

Precaution

WARNING

Read and understand all precautions in *Sample pump, on page 24* before attempting any actions described in this section.

Preparations

Follow the instruction below to prepare for connecting the sample pump.

Step	Action
1	Position the sample pump trolley beside the system. ***Note:*** *The best position is adjacent to the right-hand corner of the system when facing the operator console. Make sure that the sample pump trolley is positioned so that it does not block the column valves and the emergency stop switch.*
2	Log out of UNICORN, turn off the computer and shut down the system. See Procedures after usage. ***Note:*** *The system must be re-started after the sample pump has been connected in order for the monitoring of the sample pump pressure sensor to be activated.*
3	Disconnect the compressed air supply from the system.

Connections

Follow the instruction below to connect the sample pump to ÄKTAprocess.

Step	Action
1	Connect the sample pump air supply hose (marked **P2**) to the T-connector (marked **P1**) on the system air supply hose.
2	Connect the sample pump ASi cable (marked **E2**) to the system ASi cable T-connector (marked **E1**).
3	Connect the pump diaphragm switch cable (marked **E6**) to the corresponding system cable (marked **E5**). ***Note:*** *The pump diaphragm switch cable should be fitted with a terminating connector. If the system has been used without a sample pump, this connector will be terminating the pump diaphragm switch daisy chain on the system. Move this connector from the system to the sample pump cable.*
4	Connect the pump motor power cable (marked **E4**) to the corresponding system cable (marked **E3**).
5	Connect the pressure sensor cable (marked **E8**) to the corresponding system cable (marked **E7**). ***Note:*** *The sample pump air supply hose, ASi cable, motor power cable, pressure sensor cable and pump diaphragm switch cable are all tied together. The corresponding cables on the system side are either T-connectors or loose cable ends, all protected by caps when not in use.*
6	Connect tubing from the sample pump outlet to the sample inlet valve on the system.
7	If required, connect the system's movable air sensor to one of the sample pump inlets.
8	Connect tubing to the sample pump inlets.

Finalization

The following steps need to be performed after connecting the sample pump.

Step	Action
1	Reconnect the compressed air supply to the system.
2	Turn on the system using the **SYSTEM POWER SWITCH**.

4.4.6 Connect a column

Introduction

This section outlines the steps needed to connect a column to ÄKTAprocess.

Important

NOTICE

Make sure that the connections to the column and system comply with the requirements in the column and system *Operating Instructions*.

Considerations for AxiChrom columns

AxiChrom columns can be packed using ÄKTAprocess and Intelligent Packing.

Small diameter columns, up to 200 mm diameter, use ÄKTAprocess pumps to drive the adapter hydraulically.

Larger AxiChrom columns, 300 mm diameter and above, use an AxiChrom Master connected to the ÄKTAprocess Profibus connector.

See respective AxiChrom column manuals for information on hose connections.

For more details regarding using AxiChrom with ÄKTAprocess, refer to the AxiChrom user manual.

Preparations

The air sensor alarm(s) before the column must be disabled before filling the system/column with liquid (***Alarms:Air_Alarm:Disabled***).

Connect an empty column

Follow the instruction below to connect an empty column to ÄKTAprocess.

Step	Action
1	Connect tubing between the system valve marked **COLUMN BOTTOM** and the column bottom.
2	Connect tubing between the system valve marked **COLUMN TOP** and the column top.

Connect a packed column without bypass lines/valves

Follow the instruction below to connect a pre-packed column without by-pass lines/valves to ÄKTAprocess.

Step	Action
1	Connect tubing to the system valve marked **COLUMN BOTTOM**, but do not connect the other end of the tubing to the bottom of the column at this time.
2	Set the system column valves to the ***UpFlow*** position.
3	Using the pump, fill the system with an appropriate liquid for column installation.
4	When the system, including the tubing connected to the column bottom system valve, is filled with liquid, connect the other end of the tubing to the bottom of the column.
5	Connect tubing between the top of the column and the system valve marked **COLUMN TOP**. ***Note:*** *If the column will be run in downwards mode after the connection, the tubing connected to the column top must also be filled with liquid before it is connected to the column top.*

Connect a packed column with bypass lines/valves

Follow the instruction below to connect a pre-packed column with bypass lines/valves to ÄKTAprocess.

Step	Action
1	Connect tubing between the column bottom and the system valve marked **COLUMN BOTTOM**.
2	Connect tubing between the column top and the system valve marked **COLUMN TOP**.
3	Set the system column valves to the ***UpFlow*** position.
4	Using the pump, fill the system with an appropriate liquid for column installation.
5	When the system, including the tubing connected to the column, is filled with liquid, stop the pump.
6	Use the manual valves on the column to change from bypass to in-line.

Final considerations

Once the column is connected, the following should be taken into consideration.

- Make sure to activate the system alarm(s) again after the filling sequence.
- When the pump is started, the system must be in ***Column UpFlow*** position.

4.5 Power supply

Introduction

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

Power requirements

The power supply requirements are specified in *Section 8.1 Specifications, on page 164*.

WARNING

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

WARNING

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

WARNING

All electrical installations must be performed by authorized personnel only.

Installation

The system power cord is connected in one of the following ways:

- A fixed power supply by means of a permanent connection with a safety switch (UL or CE classified systems)
- A connector compliant with IEC 60309-2 (CE classified systems only)

UPS power supply

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

CAUTION

Do not use an Uninterruptible Power Supply (UPS) outside the range 100 to 240 V. For UL-classified systems, do not use a UPS supply exceeding 120 V.

CAUTION

Connection of an Uninterruptible Power Supply (UPS) shall only be performed by authorized personnel to avoid mismatching or connection errors. Contact your local GE Healthcare representative for more information.

Grounding and protective earth

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

  Refer to the product documentation package for information regarding the leakage current for your system.
- The integrity of all ground connections must be periodically checked.

Circuit breaker

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

Breaking the power supply to the instrument by using this breaker must be the regulatory equivalent to disconnecting the power cord for a non-fixed connected instrument.

Power supply cable

The mains power supply cable is shielded ÖLFLEX™ of type:

- **CE-classified**: 150CY Quattro (3 x 2.5 mm^2)
- **UL-classified**: CRF (3 x 14AWG)

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

Main power supply wire colors and tags

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

Function	USA (UL marking)	EU (CE marking)	Terminal label
Live (Phase)	Black	1 (Black or brown)	L
Neutral	White	2 (Blue or black)	N
Protective ground (earth)	Green or Yellow/green	Yellow/green	PE = GND 

Live and neutral wire cross section area

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

Mains current up to	Mains and neutral conductor minimum area
10 A	16 AWG or 1 mm^2
16 A	14 AWG or 1.5 mm^2
25 A	12 AWG or 2.5 mm^2

Protective earth wire cross section area

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

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

Ground fault breaker

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

However, if ground fault protection for the system is required:

- A Ground Fault Circuit Interrupter 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 earth leakage current as stated in the *Test protocol* in the product documentation package.

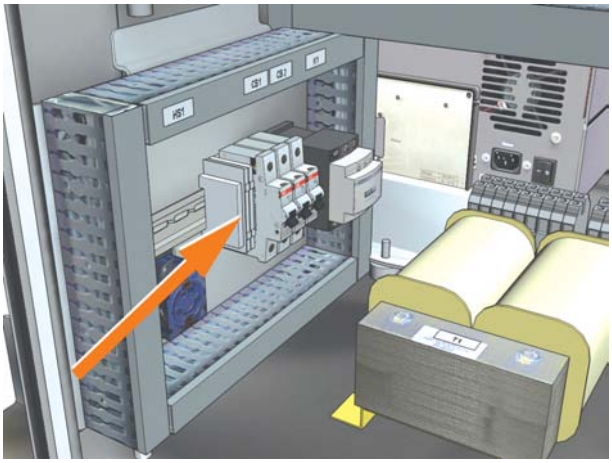
ÄKTAprocess built according to UL is equipped with a ground fault protector to protect the UV-monitor.

Built-in circuit breakers

The mains power supply to ÄKTAprocess and the pumps are equipped with circuit breakers inside the cabinet. Refer to the system documentation for the specific types used in your system.

Circuit breakers for the pumps (**CB1**, **CB2** and **CB3**, one for each pump) are located adjacent to the power transformer in the cabinet, as illustrated below. All pump circuit breakers are rated 10 A.

Circuit breaker **CB4**, located in the opposite side of the cabinet, controls the main power to the rest of the system components. This circuit breaker is also rated 10 A.



UL standard systems

UL standard systems are equipped with additional circuit breakers, **CB5**, **CB6** and **CB7**, protecting the DC power supply to the built-in computer, LCD monitor and instruments in the electric cabinet.

More information

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

5 Operation

About this chapter

This chapter provides the information required to safely operate ÄKTAprocess.

In this chapter

This chapter contains the following sections:

Precautions

WARNING

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

- *General precautions, on page 17*
- *Personal protection, on page 19*
- *System operation, on page 25*

WARNING

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

NOTICE

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

Refer to *Section 8.2 Chemical resistance, on page 167* for more information.

5.1 Prepare the system

Introduction

This section describes the steps that should be performed to prepare ÄKTAprocess for a run.

Prerequisites

Before ÄKTAprocess is taken into operation, make sure that all procedures in the relevant chapters and sections have been performed, including:

- *Chapter 4 Installation, on page 81* and
- Actions before operation in *Section 6.1 User maintenance schedule, on page 130*

In this section

5.1.1 Start the system and software

Start ÄKTAprocess

CAUTION

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

Step	Action
1	Make sure that the air supply to the system is turned on.
2	Turn on the UPS if used.
3	Make sure that the cabinet doors are closed and locked.
4	Switch on power to ÄKTAprocess by turning the **SYSTEM POWER SWITCH** to the "**ON**" position. See *Section 3.2 Illustrations of ÄKTAprocess, on page 44* for location.

After this sequence is completed, the following occurs:

- The built-in computer is turned on
- The **POWER** indicator lamp flashes.

Note: *When communication with UNICORN software is established, the **POWER** indicator lamp will show a steady green light.*

Start UNICORN

Refer to *Section 3.6 UNICORN control system, on page 77* for more information regarding the UNICORN control system, warnings and alarms.

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

5.1.2 Prepare system components

Introduction

This section outlines the steps needed to prepare the pH meter, UV monitor and air sensors before a run.

pH calibration

The pH meter is removed from the flow path for calibration. Calibrate the pH meter according to *Section 6.5 Calibration of pH probe, on page 148*.

Install the pH electrode

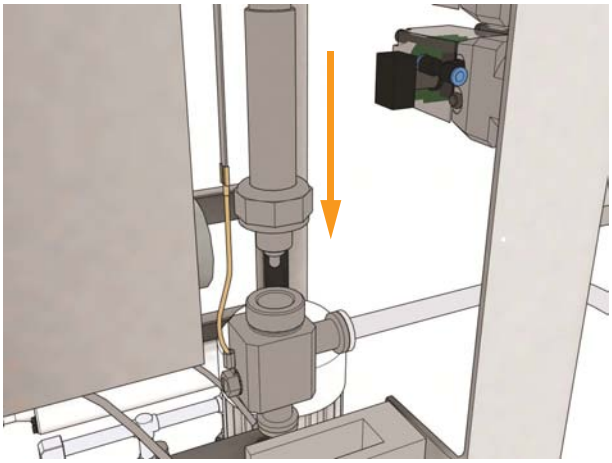
Follow the instruction below to install the pH electrode into the pH flow cell.

CAUTION

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

Note: *Organic solvents will cause pH electrode degeneration. When running methods using organic solvents it is recommended that the pH electrode is not inserted in the flow cell.*

Step	Action
1	Unscrew the plastic fastening nut from the pH cell and remove the pH plug.
2	Move the O-ring from the pH plug to the electrode adapter.
3	Remove the pH electrode adapter from its holder.
4	If the electrode is not mounted in the adapter, remove the protective cap, rinse the electrode with pure water and insert the electrode into the adapter. ***Note:*** *The pH plug may be placed in the pH electrode holder while the electrode is in use.*

Step	Action
5	Insert the assembled pH electrode into the pH flow cell and fasten the nut. Make sure that the electrode is tightened correctly to prevent leakage. 
6	Connect the monitor cable to the electrode.
7	Connect the reference electrode to the grounding wire connected to the pH cell.

UV monitor

The UNICORN instruction ***Monitors:AutoZeroUV*** can be used to set the relative AU to zero.

The ***Monitors:Wavelength*** instruction can be used to set wavelength(s).

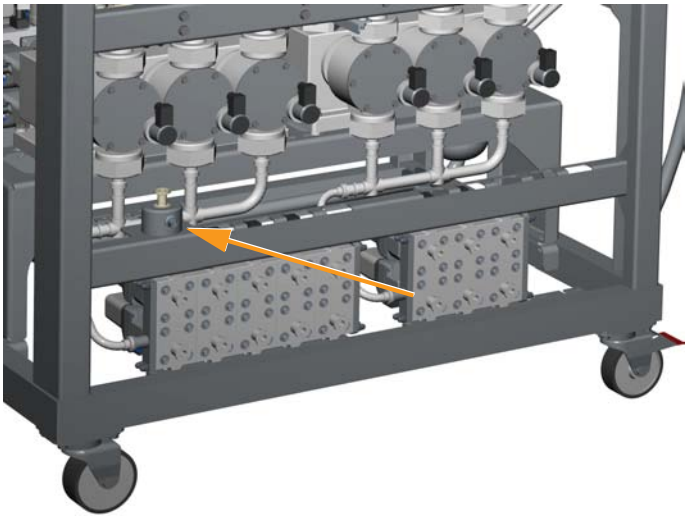
One to three wavelengths (UV1, UV2 and UV3) can be set within the range 190 to 700 nm for UV-900 monitors.

The wavelength can be set to 215, 260, 280 (default), 405 or 546 nm for UVis-920 monitors by changing filters in the monitor.

Note: *The UNICORN instruction is used for method documentation only.*

Air sensors

The movable air sensor may be optionally mounted on any inlet. When not in use, it should be placed in the recessed holder on the inlet side of the system frame as illustrated below.



The UNICORN instruction ***Alarms:Air_Alarm*** can be used to enable the air alarm. The system will be set to ***Pause*** if the sensor detects air. The instruction ***Monitors:AirSensor_Sensitivity*** can be used to control the sensitivity of the air sensors, as outlined in the table below.

Note: *Make sure that the air sensors are filled with liquid before the alarms are enabled, otherwise the alarm will immediately be triggered and cause the system to be set to* ***Pause****.*

Sensitivity set to...	detects bubbles with diameter greater than...
High	4 mm (~34 µl)
Medium (default)	7 mm (~180 µl)
Low	16 mm (~2.1 ml)

The default position for the movable air sensor is ***Disabled***.

The default position for the air sensor located before the column(s) is ***Enabled***.

5.1.3 Priming and leakage test

Introduction

Before a run is started the system should be primed and tested for possible leakage. This section describes a procedure for priming and testing for leakage.

Important

NOTICE

All system parts must be correctly filled with liquid before any functional tests are performed. A suitable liquid is a storage or running buffer for the column.

NOTICE

During the procedure described below, check all valves and tubing connections carefully for air or liquid leakage. If there is any evidence of leakage, attend to the leak and then repeat the filling sequence.

Note: *Each pump must be tested separately if more than one is used (Optional Gradient pump B and/or Sample pump in addition to the standard pump A).*

Prepare for priming and leakage test

Follow the instruction below to prepare ÄKTAprocess for priming and leakage test.

Step	Action
1	Check that the inlet and outlet tubing are correctly connected.
2	Check that the buffer tank(s) are filled with a sufficient amount of a suitable liquid for the procedure.
3	Check that valves to the buffer tanks are open.

Step	Action
4	When the tubing from the buffer tanks is connected to the corresponding inlets, carefully open the clamp at the system inlet valve connection to prime/fill the tubing as much as possible. When the liquid has reached the connection, tighten the clamp again. ***Note:*** *This procedure is performed to avoid pumping too much air into the system.*
5	When applicable, check that the air sensor is connected at the inlet that will be used as the sample inlet.
6	When applicable, insert filter cartridge(s) into the in-line filter housing.
7	When applicable, insert the pH electrode (packed separately) into the pH flow cell as described in *Install the pH electrode, on page 115*.

Run priming and leakage test

The priming and leakage test steps are performed by using the ***Manual control*** module in the UNICORN process control software, as described below.

Step	Action
1	Open an appropriate inlet and outlet, e.g., ***Valves:InletA1*** and ***Valves:Outlet1***.
2	If a column is connected to the system, check that the column is bypassed (e.g., ***Valves:Column:Bypass_Both***).
3	Using the pressure sensor located closest to the inlet used, check that the pressure alarm is set less than or equal to the maximum allowed system pressure. Furthermore, the air sensor alarms before the column must be disabled (***Alarms:Air_Alarm:Disabled***).
4	Start the pump (without feedback) at approximately 20% of maximum capacity (***Pump:ManFlow:20%***).
5	Check that the air trap is in-line (***Valves:AirTrap:Inline***) and check that automatic level control is enabled ***Alarms:AirTrapLevelControl:Enabled***).
6	When applicable, put the filter in-line (***Valves:Filter:Inline***) and then open the manual valve on top of the filter housing. When liquid comes out through the manual valve, close the manual valve.
7	Increase the flow rate to 50% and flush all flow paths and inlets/outlets thoroughly.

Step	Action
8	Check that the flow meter signal is stable and has a reasonable reading.
9	Increase the flow rate stepwise to maximum system capacity. Check for leaks and inspect that pressure sensors and the other instrument readings (e.g., pH/conductivity) are at an acceptable level.
10	Verify that the air sensor before the column indicates no air (the air sensor symbol in the UNICORN ***System Control*** module flow scheme must be green).
11	Decrease the flow rate to less than 50% of the maximum system capacity and monitor the flow rate value in the UNICORN ***System Control*** module to verify that the pump(s) regulates down and the rate decreases smoothly.
12	End the manual session (using the ***END*** command in UNICORN) so that the pump(s) stop and all valves close.

The column connections can now be tested for leakage at a flow rate and pressure that is appropriate for the column/absorbent.

Before putting the column in-line, make sure that the air sensor alarm, for the air sensor located immediately before the column, is enabled prior to the test (***Alarms:Air_Alarm:Enabled***).

5.1.4 Set pressure control valve parameters

Introduction

After the priming and leakage test, and before a run is started, the pressure control valve (PCV) or valves on the system need to be adjusted. The purpose of this adjustment is to achieve correct flow through the system as a result of the feed pressure on the inlets.

This section describes procedures for pressure control valve adjustment and describes how to set two other parameters for the PCV valves, (***Hold backpressure*** and ***Boost***).

PCV adjustment

Pressure control valve set up is performed using UNICORN functions to adjust the low flow limit of the valve.

Follow the instructions in this section in the order presented below (start by adjusting **PCV-341** and then **PCV-342** if your system has this option).

Step	Action
1	Start with opening the flow path (inlet needs to be pressurized).
2	Switch the **PCV-341** valve positioner to manual mode.
3	Close the valve slowly, until no flow is detected by **FT-141**. The valve can be operated manually through instruction ***PCV-341 valvepositioner***.
4	Open the valve slowly until flow is detected by **FT-141**.
5	Close the valve slowly until no flow is detected by **FT-141**. The valve is opened and closed once more for accuracy.
6	Take the percentage (%) value obtained in the step before and lower the result by 4%.
7	Write the calculated result into the instruction ***PCV-341 valvepositioner***. *Result:* This value is the low limit of the valve.
8	Record the value in ***PCV-341 settings*** as the lower limit.

Note: ***PCV-342*** *is set in the same way as described above, using pressure transmitter* ***PT-116*** *instead of* ***PT-115***.

Set other valve parameters

To set the parameters ***Hold backpressure*** and ***Boost*** in the PCV instruction settings, follow the steps described below:

Step	Action
1	Set ***Hold backpressure*** to 0.5 bar over the buffer pressure. ***Note:*** *The valve adjusts the pressure to the Inlet A Hold back tank pressure parameter, so it must not be set lower than the buffer pressure.*
2	Set the ***Boost*** parameter to 5% or 6%. **Tip:** ***Boost***, when added to the PCV signal, minimizes pressure spikes when the pump starts. Although 5% or 6% is usually preferred, this should be adjusted according to requirements.

PCV close limits

Pressure control valves must never be completely closed during a run.

The UNICORN control system will fully open the PCV when the system is in ***End*** mode. When the system is in ***Run*** or ***Pause*** mode UNICORN will set the PCV to its ***Close_limit***.

The ***Close_limit*** for the PCV must be entered in UNICORN according to the flow rate to be used.

Note: *If the **Close_limit** is set to 0.0 the PCV will close completely. As the limit setting depends on the flow rate used, however, it should be noted that a **Close_limit** of 0.5 may also result in a closed PCV.*

WARNING

Never operate ÄKTAprocess with pressure control valves (PCVs) completely closed. A pressure increase may result, and cause leakage.

5.1.5 Final checks

Checklist

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

- Check the condition of all connections and gaskets.
- Check that no chemicals that may be harmful to the system will be used.
- Check that the pump is filled with the correct lubricant oil. Refer to the pump supplier information included in the ÄKTAprocess documentation package for details.
- Check that all inlets and outlets to the system are connected, closed or in the state that they are supposed to be before the system is started.
  - Inlets that are not in use must be closed.
  - Outlets that are not in use must be capped with blind caps or fitted with tubing directed to waste.
- For systems that have a sample pump, check that all protection caps are mounted on the sample pump cable connectors and that a blind plug is mounted on the pneumatic connector if the system is run with the sample pump disconnected.
- If the sample pump is disconnected, the alarm for the sample inlet valves must be disabled. To avoid having to repeat this instruction, the alarm should be disabled in the System Settings in UNICORN: ***System:Settings:Alarms:InletSample_Valves_Alarm:Disable***. Do not forget to enable the alarm when the sample pump is connected again.
- Check that the column connection complies with the requirements in the column instruction manual.
- Check that the air sensor alarm function is enabled when a column is connected. If air is detected an alarm will sound and the system will pause the current operation, thereby protecting the column from air.
- Perform an alarm test according to *Alarm test, on page 80*.

High pressure safety monitoring

The **ALP-900** safety module that monitors the pump/system pressure is a **protection for the system** and **not the column**.

If the pressure limit of the column is lower than that of the system the high pressure alarm settings in UNICORN must be changed accordingly.

Column protection from overpressure can be accomplished, for example, by adding a relief valve or burst disc before the column.

5.2 Perform a run

Precautions

WARNING

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

WARNING

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

CAUTION

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

NOTICE

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

NOTICE

Operator console

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

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

Start a run

Follow the instruction below to start a run.

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

Monitor the run

During the run, the ***System Control*** module will display the run progress of the method being executed.

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

If you want to...	then...
temporarily hold the method, with current flow rate and valve positions sustained	click the ***Hold*** icon.
temporarily pause the method, and stop all pumps	click the ***Pause*** icon.
resume, for example, a held or paused method run.	click the ***Continue*** icon. ***Note:*** *An ended method cannot be continued.*
permanently end the run	click the ***End*** icon.

Note: *When ending a method run prematurely, it is possible to save the partial results.*

More information regarding UNICORN capabilities during the method run is available in the UNICORN user documentation.

End the run

Normal completion

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

End before method has finished

If the method needs to be terminated before it has run to completion, follow the instruction below.

Step	Action
1	Click the ***End*** button at the top of the ***Control module*** window. *Result*: A confirmation dialog will open.
2	Click ***OK*** in the confirmation dialog to end the run, or click ***Cancel*** to continue the run. ***Note:*** *In the dialog, you can choose to save the (partial) results from the run.* ***Note:*** *If the run is part of a scouting run series, you will be given the choice to end the entire scouting run. If you do not end the scouting run, then the next run in the series will start automatically.*

5.3 Shut down the system and software

Introduction

This section describes the steps that should be taken when shutting down ÄKTAprocess and the UNICORN control software.

WARNING

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

Shutdown procedure

Step	Action
1	In UNICORN, select ***File:Exit UNICORN*** in any module, or select ***File:Quit Program*** in ***UNICORN Manager***, depending on the UNICORN version used.
2	Shut down the computer from the Windows ***Start*** menu.
3	When the computer screen has switched off, turn off the **SYSTEM POWER SWITCH**. ***Note:*** *Since the system power will be shut down, the system cannot be operated from another workstation before the system is powered up again, regardless if it is locked or unlocked at shutdown.*
4	Prepare the system for storage as described in *Section 6.3 Storage, on page 144* as required.

6 Maintenance

About this chapter

This chapter provides information to enable users and service personnel to clean, maintain, calibrate and store ÄKTAprocess.

In this chapter

This chapter contains the following sections:

Precautions

WARNING

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

- *General precautions, on page 17*
- *Personal protection, on page 19*
- *Power supply, on page 23*
- *Maintenance, on page 28*

WARNING

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

- After assembly or maintenance
- Before operation or CIP

CAUTION

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

6.1 User maintenance schedule

Introduction

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

Maintenance in connection to each run or weekly

The table below describes maintenance actions required for each run or weekly (depending on which happens first).

Component	Action
UV monitor	Set auto-zero by using the function in UNICORN
pH monitor	Clean, calibrate and store the pH electrode adequately, refer to *Section 6.5 Calibration of pH probe, on page 148*.
In-line filter (if present)	Clean or replace the filter cartridge.
Alarm buzzer	Check the function ***Alarms:BuzzerTest***
Air sensor (if present)	Check the function by running some air through the system and verify that the alarm is triggered and that the system is set to ***Pause***. ***Note:*** *The movable air sensor is disabled in UNICORN by default and must be enabled to be tested.* ***Note:*** *The movable air sensor must be disabled when testing the air sensor that is permanently installed before the column valve blocks.*
Complete system	Clean/sanitize the system according to the procedure described in *Section 6.2.2 Cleaning-in-place (CIP), on page 138*.
Protective earth	Make sure that the protective earth wiring is not disconnected or damaged.

Monthly maintenance

The table below lists maintenance actions that are required monthly.

Component	Action
Air trap level sensors	Check the function and calibrate if needed *Section 6.6.2 Air trap calibration, on page 153* and following pages for more information. ***Note:*** *It is recommended that after a power down a calibration of the level sensors should always be performed.*
Pump	Check for oil leakage. (If the pump leaks, contact your local GE Healthcare representative).
Connections and seals	Check for leakage. Replace seals if needed. Perform a leakage test at maximum operating pressure.

Maintenance annually or as needed

The table below lists maintenance actions that are required annually or as needed.

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

Component	Action
pH monitor	Replace the pH electrode if difficulties are experienced during calibration. ***Note:*** *When replacing the pH electrode, do not use the plastic spacer.*
Conductivity monitor	Clean and calibrate the conductivity monitor.
Flow meter	Adjust the zero-point of the flow meter. This should be done when the actual flow rate deviates from the flow rate displayed in the UNICORN ***System Control*** module or if a flow rate is displayed in ***System Control*** when the pumps are off. ***Note:*** *It is important that the zero-point adjustment of the flow meter is performed properly or the actual flow rate may deviate from the displayed. It is recommended that the adjustment is performed by a GE Healthcare service engineer.* Prior to the adjustment it is very important to fill the system completely with liquid so that no air is trapped in the flow meter. This is best achieved by applying a slight back pressure when the system is filled by using, for example, a relief valve on the outlet valve used. When the system is properly primed, the zero-point adjustment is performed by using the UNICORN instruction ***System:Calibrate:Flow_FT141*** (and when applicable also ***System:Calibrate:Flow_FT142***). ***Note:*** *The flow meter calibration should be checked every time the system is moved.*

Component	Action
Valves	Perform a valve calibration if: • A valve membrane has been changed or • The valve has been interfered with If a "***Valve error***" has been triggered, a valve calibration may restore the valve function. If a valve calibration does not help, contact your local GE Healthcare representative. To perform a valve calibration, use the instruction ***Valves:Calibrate_Valves:XVxxx*** (select the valve that is to be calibrated). Only one valve can be selected and calibrated at a time. ***Note:*** *During the calibration of the valve, the connection to the valve is broken and an alarm is triggered. To complete the calibration, acknowledge the alarm in the* ***Alarm*** *box and then press* ***Continue****.*

6.2 Cleaning

Introduction

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

Precautions

WARNING

Flammable liquids. ÄKTAprocess is **not approved** to handle flammable liquids.

WARNING

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

WARNING

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

- After assembly or maintenance
- Before operation or CIP

NOTICE

Replace the pH electrode with the pH CIP cap (pH plug) before performing CIP with strong acids or alkali.

NOTICE

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

In this section

This section contains the following subsections:

6.2.1 Important considerations for cleaning

Cleaning frequency

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

Cleaning before maintenance/service

The system must be thoroughly cleaned to remove any infectious or aggressive fluids before maintenance or service.

Recommended cleaning agents

All components can be cleaned with the most commonly used agents, such as detergents, ethanol, weak acids, sodium hydroxide and salt solutions.

Refer to *Section 8.2 Chemical resistance, on page 167*.

NOTICE

Avoid sodium chloride solutions below pH 4.0. Rinse the system thoroughly with water immediately after it has been in contact with salt solutions.

Clean the UV and conductivity cell

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

Clean external surfaces

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

Regularly, wipe the outside of ÄKTAprocess with a clean cloth. Use a mild cleaning agent such as water, followed by 70% ethanol. Regular wiping and care of the equipment will help keep the surfaces free from corrosion.

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

6.2.2 Cleaning-in-place (CIP)

Introduction

This section provides general information about the CIP procedure, and provides some general guidelines for CIP procedures. For a detailed instruction, refer to *Section 6.2.3 General procedure for CIP and sanitization, on page 141*.

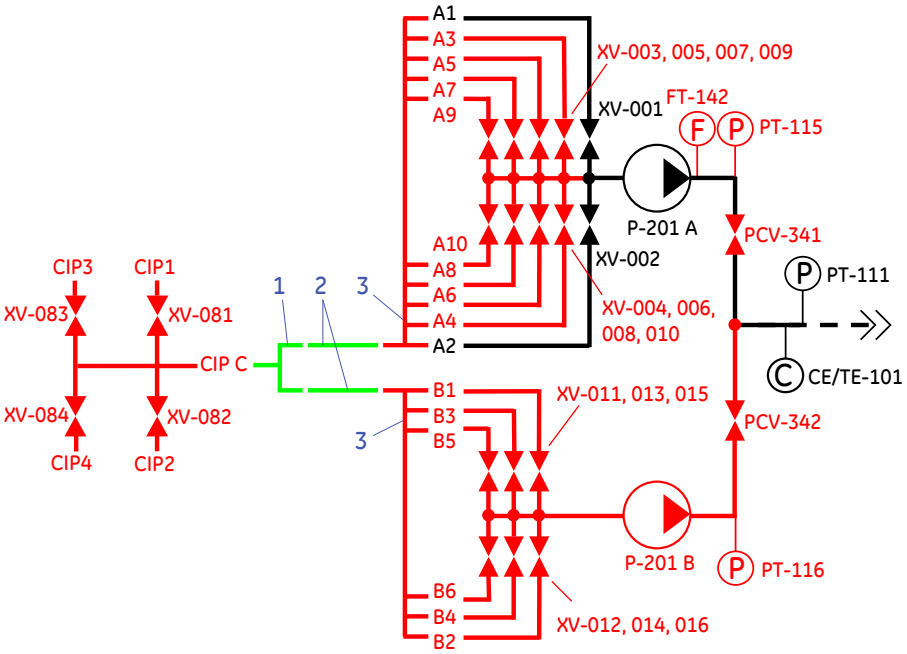
CIP hook-up

During the CIP procedure, the column can be replaced with a bypass manifold or spool piece.

Refer to the column instructions for column specific cleaning recommendations.

Using the CIP/AxiChrom manifold option

This flow scheme shows an example of how to use the CIP/AxiChrom manifold option for CIP on a system configured with the B-pump option.



Part	Function
1	CIP distribution manifold, provided by customer.
2	CIP connection hoses, provided by customer.
3	CIP-manifold, provided by GE Healthcare. Specific manifolds are available as optional equipment for each system battery limit.

For a detailed description of the process components, see *Section 3.5 Flowchart, on page 72*.

Refer to the *Section 6.2.3 General procedure for CIP and sanitization, on page 141* for comprehensive instructions regarding the sanitizing/CIP procedure.

CIP methods in UNICORN

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

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

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

Extended cleaning performance

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

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

Rinsing

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

6.2.3 General procedure for CIP and sanitization

Introduction

The system can be cleaned using 1 M sodium hydroxide as outlined in the procedure below.

Note: *The system owner must qualify a cleaning and sanitizing procedure that is suitable for the required application.*

Preparations

- All tubing including the sanitary fittings must resist sodium hydroxide.
- The filter may have to be removed from the filter housing when certain solutions are used for CIP/Sanitizing. Refer to the documentation from the filter manufacturer to determine if the filter should be removed or not.

  Note: *If there is noticeable build-up of biofilm on the bottom plate of the filter housing when the filter is removed, perform the following actions:*

  1 *Spray the surface with 70% ethanol*
  2 *Wipe off the surface by hand*
  3 *Re-mount the filter casing*
  4 *Run the CIP method*
- The column (and medium) should be cleaned separately and is therefore removed before system cleaning.
- The pH electrode should be replaced with a pH CIP cap (pH plug) before system cleaning. Refer to *Install the pH electrode, on page 115*.
- To make sure that the system does not leak during CIP/Sanitization, perform a combined method and leakage test by performing the CIP/Sanitization procedure using water.
- The optional sample pump, if included in the system, shall always be cleaned first.
- If a capsule filter is used, remove the filter and put the spool piece in place before performing CIP.

Inlets

If the system has optional CIP valves and CIP manifolds:

- Connect tubing between the CIP valves and tanks filled with suitable solutions for system CIP. For example 1 M sodium hydroxide in CIP 1, water in CIP 2 and 20% ethanol in CIP3.
- Connect the manifold(s) to the inlet(s).
- Connect flexible tubing (supplied with the CIP manifolds) between the manifolds and the side inlet of the CIP valve set. If the system contains more than one set of inlet valves, the flexible tubing from each valve set is connected to a manifold on the side inlet of the CIP valve set. Refer to the figure in *Using the CIP/AxiChrom manifold option, on page 139* for the complete set-up.

Note: *If the system does not contain the optional CIP valves, connect tubing to each inlet valve. The tubing from each system inlet then has to be moved manually between tanks filled with the different CIP solutions.*

Column valves

With the column removed, connect the column manifold between the Column top and Column bottom system valves.

Note: *If the system does not have the CIP valves option, connect tubing with sanitary fittings between the Column top and Column bottom system valves.*

Outlets

- Connect the manifold to the outlet (to Outlet 1-10 in the example below)
- Connect tubing from the manifold and lead to waste.

Note: *If the system does not contain the CIP valves, connect tubing to each outlet valve and lead to waste.*

Method

Step	Action
1	Use for example 75% of the max flow of the system and design a method with which each outlet and component pathway is flushed with CIP/Sanitization liquid for at least 30 seconds.

Step	Action
2	When the filling sequence is completed, let the system stand for 60 minutes.

See Section *Section 8.5 UNICORN method for system CIP/Sanitization/Rinsing, on page 172* for an example of a UNICORN method for a two-pump, 10 mm inner diameter system.

After cleaning

- After CIP/Sanitization, rinse all flow paths in the system with water or suitable liquid until these are completely free from cleaning solution (when applicable, the system conductivity monitors can be used as detectors).
- The UNICORN method used for filling the system with 1 M sodium hydroxide can also be used for rinsing. However, the CIP inlet valve has to be changed in the method (to CIP 2 - water - in this example).
- Do not leave sodium hydroxide or other cleaning solutions in the system.
- If the system is to be stored after the CIP/Sanitization, the same UNICORN method, again with a changed CIP inlet (CIP 3 - 20% ethanol - in this example) can be used to fill the system with a suitable storage solution. Refer to *Section 6.3 Storage, on page 144*.

6.3 Storage

Precautions

NOTICE

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

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

NOTICE

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

NOTICE

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

Short term storage

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

Step	Action
1	Perform cleaning as described in *Section 6.2 Cleaning, on page 134*.

Step	Action
2	Replace the pH electrode with the pH CIP cap (pH plug). The electrode should be stored in 3 M potassium chloride. Place the pH electrode in the pH electrode holder, with the end submerged in storage solution. ***Note:*** *Do not store the pH electrode in water only.*
3	Seal off ÄKTAprocess to prevent contamination caused by the surrounding environment.
4	Fill ÄKTAprocess with the storage solution of choice. The air trap should be filled to approximately one quarter of the maximum operating volume to prevent microbial growth.
5	Store columns and absorbents according to the instructions that are applicable in each case.

Long term storage

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

Step	Action
1	Perform the actions described for Short term storage, above.
2	Place ÄKTAprocess in a dust free environment with well-controlled climate. The temperature should be stable and in the range 4°C to 25°C. The air humidity and air temperature differences should be kept as low as possible to prevent condensation and corrosion.
3	For long term storage periods, store any unused TC-rubber gaskets in a cool dark place. This prevents them from aging and drying out.

Note: *To prevent microbial growth, the storage solution shall be replaced regularly if ÄKTAprocess is stored for long periods of time.*

6.4 Disassembly and assembly

Introduction

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

Precautions

WARNING

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

WARNING

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

WARNING

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

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

WARNING

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

- After assembly or maintenance
- Before operation or CIP

User-allowed actions

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

- **The filter cartridge** (optional)
- **TC-connection gaskets**, in cases where the TC-connection can be dismantled without the need to remove any components from the system.
- **The operator panel**. This might be required for protection or space reasons if the system shall be moved.
- **The pH probe**, see *Section 6.5 Calibration of pH probe, on page 148* and *Section 6.6 Repair and calibration, on page 151*.

Other components

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

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

6.5 Calibration of pH probe

Required equipment

The following solutions and equipment are required for calibration of the pH probe:

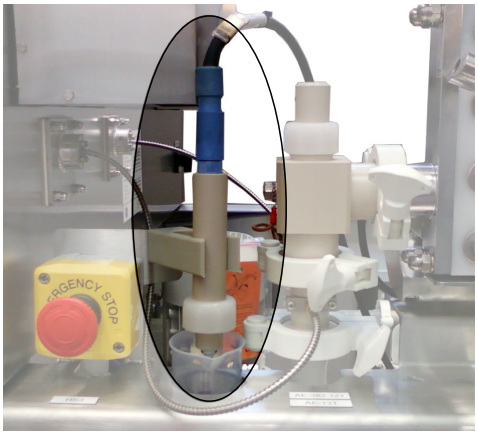
- pH reference solution for low pH-measuring point, preferably pH 4.00
- pH reference solution for high pH-measuring point, preferably pH 7.00

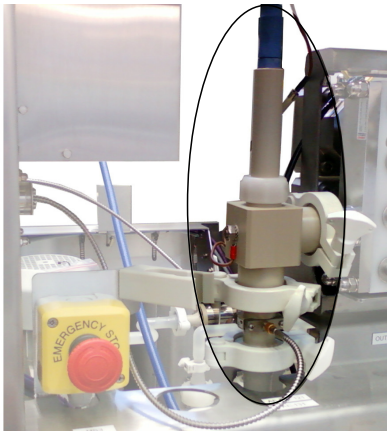
- Clean cloth
- Clean water in spray bottle

Images of pH probe

The left image below shows the pH probe located for storage and calibration. A cup has been placed in the cup holder.

The right image below shows the pH flow cell for operation.





Off-line pH calibration

The table below describes how to calibrate the pH probe.

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

Step	Action
1	Prepare two cups with buffers representing the actual required pH range.
2	Place the cup with the highest pH solution in the cup holder. Insert the pH probe into the holder, with the end submerged in the buffer. ***Note:*** *Attach the cap to the pH flow cell to prevent foreign objects from entering the flow path.*
3	Select ***System:Calibrate*** in UNICORN ***System Control*** module.
4	Enter the pH value for the first buffer (with the highest pH solution) in the ***Reference value 1*** field, wait for the value to stabilize, and press ***Read value 1***.
5	Remove the pH probe from the holder and rinse it with distilled water.

Step	Action
6	Remove the cup with the first buffer from the holder and replace it with the cup with the second buffer.
7	Re-insert the pH probe into the holder, with the end submerged in the buffer.
8	Enter the pH value for the second buffer (with the lowest pH solution) in the ***Reference value 2*** field, wait for the value to stabilize, and press ***Read value 2***.
9	Wait for response and, if the electrode passed, press ***Close***. Otherwise, press ***Close***, refresh/change the pH electrode, and repeat the calibration procedure.
10	Remove the cup from the holder.
11	Relocate the pH probe in the flow cell.

6.6 Repair and calibration

Introduction

This section describes component checks, repair and calibration of components other than the pH probe that the user can perform without GE Healthcare support. Calibration of the pH probe is described in *Section 6.5 Calibration of pH probe, on page 148*.

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

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

WARNING

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

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

In this section

This section contains the following subsections:

6.6.1 Pump calibration

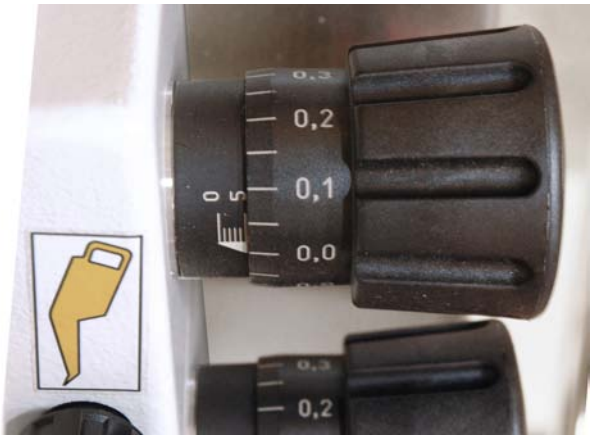
Introduction

Pumps are multiple head diaphragm pumps. Each pump is provided with adjustment knobs controlling the stroke length of the pump head cylinders.

Check the stroke length

The stroke length is factory set to maximum for optimum performance according to the system specifications and should never be changed by the user.

It is recommended to check the stroke length setting on a regular basis to make sure that it is set correctly. To achieve maximum stroke length, all knobs for all pumps shall be set to the outermost index. The illustration below shows an example of a knob that is set to its outermost index:



6.6.2 Air trap calibration

Introduction

The air trap contains sensors that control the liquid level within the air trap, see *Section 3.3.6 Air trap, on page 60*. This section includes a function test for the air level sensors, and two procedures for calibration of the sensors, both automatic and manual.

Air trap level sensor function test

Follow the instruction below to test the air trap level sensors.

Step	Action
1	Empty the air trap from liquid using the ***Drain*** instruction (see *Air trap valves, on page 62*).
2	Verify that only the green LED indicator (for both the low level sensor and high level sensor) is activated (displays a steady green light). If the red and/or yellow LED indicators are also activated, the sensors must be calibrated as described below.
3	By pumping in liquid using the ***Fill_Inline*** instruction for the air trap (see *Air trap valves, on page 62*), slowly increase the liquid level in the air trap. Use the ***Fill*** instruction if the air trap doesn't fill due to a too low flow rate or pressure.
4	Verify that the low level sensor displays a red light when the liquid level approaches the sensor.
5	Verify that the low level sensor also displays a yellow light when the liquid level is within the area of the low level sensor.
6	Verify that the red light of the low level sensor is turned off when the liquid level is well above the area of the low level sensor.
7	Repeat steps 4 to 6 for the high level sensor.

Note: *If lights are not displayed as described above, the level sensors must be calibrated as described below.*

Automatic calibration of level sensors

Follow the instruction below to calibrate the air trap sensors automatically.

Step	Action
1	Empty the air trap completely from liquid using the ***Drain*** instruction for the air trap (see *Air trap valves, on page 62*).
2	Use the instruction ***System:Calibrate:LS_air*** to perform the calibration.
3	Fill the air trap until liquid comes out through the top valve by pumping in liquid using the ***Fill*** instruction. Turn off the pump.
4	Use the instruction ***System:Calibrate:LS_liquid*** to perform the calibration.

Manual calibration of level sensors

Follow the instruction below to calibrate the air trap sensors manually.

Step	Action
1	Empty the air trap from liquid using the ***Drain*** instruction for the air trap (see *Air trap valves, on page 62*).
2	Hold a tool made of iron (e.g. a wrench) close to the cross hairs on the side of the level sensor for a few seconds (< 5 sec), until the green indicator light is flashing.
3	Remove the iron tool. The flashing will end and the LED indicator light will display a steady green light.
4	Repeat steps 2 and 3 for the high level sensor.
5	Fill the air trap until liquid comes out through the top valve by pumping in liquid using the ***Fill*** instruction. Turn off the pump.

Step	Action
6	Hold the iron tool close to the cross hairs on the side of the level sensor for a few seconds (> 5 sec but < 10 sec), until the green indicator light starts flashing at a higher rate than above (approximately 2 Hz). ***Note:*** *The duration of the time that the iron tool is held close to the level sensors decides how the sensors are calibrated:* • *For an empty air trap the tool should be held < 5 seconds* • *For an air trap filled with liquid, the tool should be held > 5 seconds (but not more than 10 seconds)* ***Note:*** *If the iron tool is held close to the level sensors for more than 10 seconds, the sensors will lock and cannot be calibrated as described above. To unlock the sensor, hold the tool close to the sensors for more than 10 seconds once again until the green light goes off. When the tool is removed the green light will come on again.* ***Note:*** *If the surface of the sensors is touched by a hand, the red LED indicators may come on. The red lights will go off when the hand is removed and this will not affect the performance of the level sensors.*
7	Remove the iron tool. The flashing will end and the LED indicator light will display a steady green and yellow light. The sensor is now calibrated.
8	Repeat steps 6 and 7 for the high level sensor.

NOTICE

It is recommended that a calibration of air trap level sensors is performed after every power down.

6.6.3 Component replacement

Replacement of filter

Many optional filters may be used with ÄKTAprocess. Please refer to the filter documentation for instructions on how to replace the filter.

Replacement of batteries

The built-in computer is equipped with a long-life Lithium battery for BIOS functions. Refer to the product documentation package for instructions concerning replacement and operational life.

7 Troubleshooting

About this chapter

This chapter provides information to assist users and service personnel to identify and correct problems that may occur when operating ÄKTAprocess.

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

Precautions

WARNING

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

- *General precautions, on page 17*
- *Personal protection, on page 19*
- *Power supply, on page 23*
- *Maintenance, on page 28*

System

The table below describes problems that may occur with ÄKTAprocess, together with possible corrective actions.

Component	Problem	Possible cause/corrective action
Computer	No system found when starting up UNICORN	• Make sure the system is switched on. • Check communication cable and connectors. • Reboot PC: shut down Windows, switch off the **SYSTEM POWER SWITCH**, wait at least 5 sec, restart system.

Component	Problem	Possible cause/corrective action
Computer	No connection between the system and UNICORN	1 Open a ***System Control*** module. 2 • Select the ***System:Connect*** menu command. or • Click the ***Connect to system*** toolbar icon. *Result*: The System Connect dialog box opens. 3 Select the system you want to connect. 4 Click ***OK***.
Power	Power failure during a run	Check circuit breaker, both in system and for external supply, as applicable.
Compressed air	Compressed air failure during a run. The alarm "No air supply to the system" is displayed and the system enters ***Pause*** mode.	Check if there is insufficient air pressure, caused for instance by malfunctioning air supply equipment or a leaking air hose. a) Rectify the air supply problem. b) Restart the run by pressing the **Continue** button.
Valves	Alarm "***Valve error"*** is displayed	Perform a valve calibration. If a "***Valve error"*** is triggered, a valve calibration may restore the valve function. For instructions on how to perform a valve calibration, see *Maintenance annually or as needed, on page 131*. If a valve calibration does not help, contact your local GE Healthcare representative. If the "***Valve error***" alarm is accompanied by "***No air supply to the system***", the alarm is caused by a compressed air failure (see above).

Component	Problem	Possible cause/corrective action
Pump	Pump not working	• Emergency button has been pressed. • Air pressure too low. Check the pressure of air supply. Adjust if necessary. • No inlet or outlet valve open. Check method and valves. • Incorrect method. Check by entering ***Pump:ManFlow*** > 1%. • If none of the above, contact GE Healthcare service personnel.
	Little or no flow	• Check that the connected inlet is actually used. • Inlet containers are placed too low relative to the pump. Check inlet containers. • No liquid is supplied to the pump. Check inlet containers. • Tubing from inlet container causes pressure or flow loss. Reasons may be too long tubing, too small internal diameter, tube may have a narrow section or is partly plugged. • Malfunctioning valve at container battery limit.
Pump	Too high outlet pressure	• Check that connected outlet is actually used. • Outlet containers are placed too high relative to the pump. • Tubing to outlet container causes pressure or flow loss. Reasons may be too long tubing, too small internal diameter, tube may have a narrow section or may be partly plugged. Check also for non-functioning valve(s). • Malfunctioning valve at container battery limit.

Component	Problem	Possible cause/corrective action
Pump	Pump damage	In the case of pump damage an error text ***Pump diaphragm damage*** will be displayed on the screen. To determine which pump head diaphragm is damaged, perform the following actions: 1 Disable the interlock in UNICORN by acknowledging the Alarm and then press ***Continue***. 2 Increase the flow rate until the system pressure reaches 1.5 bar (pressure sensor PT-111). *Result*: A LED indicator will light up on the pump head with the damaged diaphragm. Refer to the pump manual in the product documentation package for replacement instructions. However, it is recommended that you contact your service representative from GE Healthcare for pump maintenance. ***Note:*** *The alarm for the pump diaphragms (**Pump_Alarm**) may be enabled or disabled in UNICORN.*
Flow meter	The actual flow rate deviates from the displayed flow rate or a flow rate is displayed when the pumps are off	The actual flow rate may deviate from the set flow rate if the running conditions change, such as for example pressure, ambient temperature or air content in the solutions. It can also deviate if there is a build-up of dirt in the flow meter. Other reasons for unintended flow are siphoning through the system or too high inlet pressure. If this occurs, a zero-point adjustment of the flow meter should be performed, see *Maintenance annually or as needed, on page 131*.

UV curve

The table below describes error symptoms that may occur with UV measurements, together with possible corrective actions.

Error symptom	Possible cause	Corrective action
Ghost peak	Dirt or residues in the flow path from previous runs	Clean the system
	Residues in the column from previous runs	Clean the column according to the column instructions

Error symptom	Possible cause	Corrective action
Noisy UV-signal, signal drift or instability	Bad UV fiber connections	Check the connections of the UV cell optical fiber (replace if necessary)
	Dirty UV cell	Clean the UV cell as described in *Clean the UV and conductivity cell, on page 136*

Pressure curve

The table below describes error symptoms that may occur with pressure measurements, together with possible corrective actions.

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

Conductivity

The table below describes error symptoms that may occur with conductivity measurements, together with possible corrective actions.

Error symptom	Possible cause	Corrective action
Baseline drift or noisy signal	Leaking tube connections	Tighten the clamps. If necessary, replace the clamps.
	Bad pump	See separate manual
	Dirty conductivity cell	Clean the conductivity cell, refer to *Clean the UV and conductivity cell, on page 136*
Absolute conductivity value is wrong	Bad calibration	Calibrate the conductivity cell, see separate manual
	Calibration solution not correctly prepared	Recalibrate using a new calibration solution
Incorrect or unstable reading	Bad pump or valve action	Check the pump and the valves
	Temperature compensation not properly set	Check the temperature compensation, see separate manual

pH curve

The table below describes error symptoms that may occur with pH measurements, together with possible corrective actions.

Error symptom	Possible cause	Corrective action
No response to pH changes	The cable to the electrode not properly connected	Check the cable connection
	The electrode membrane might be cracked	Replace the electrode
Small or slow response to pH changes	The electrode membrane might be contaminated	Clean the electrode, see manufacturers's manual
pH reading appears to be incorrect	pH sensor not properly calibrated	Calibrate the pH sensor as described in *Section 6.5 Calibration of pH probe, on page 148*

8 Reference information

About this chapter

This chapter provides reference information that may become useful when installing, operating, maintaining and troubleshooting ÄKTAprocess. Further information to assist in ordering parts and accessories is also provided.

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

To understand the specific configuration that applies to ÄKTAprocess, please refer to the product documentation package supplied with the instrument.

In this chapter

This chapter contains the following sections:

8.1 Specifications

Introduction

This section contains technical data pertaining to the ÄKTAprocess and its components. For complete technical data, refer to the GS in the product documentation package.

General technical data

The following table provides general technical data for the complete system.

Property	Value
Process operating limits	Inlet feed pressure: 0 to 0.2 bar (g) Outlet back pressure: 0 to 1 bar (g) Flammable liquids: Not allowed Operation in EX-rated environment: Not allowed
Electric power	Refer to *Cabinet type specific data, on page 165*
Compressed air	Pressure 5.5 to 7 bar Airflow min. 50 Nl/min during normal operation
Ingress protection EN 60529	System: IP55 Cabinet: IP56, NEMA 4X
Noise level	≤ 72 dBA
Floor inclination	Horizontal +/- 1°
Altitude	Up to 2000 m
Ambient environment	Temperature: 2°C to 26°C Air humidity: 20% to 95%, non-condensing

Cabinet type specific data

The following table provides technical data pertaining to the cabinet type.

Property	Cabinet 10	Cabinet 30
Voltage rating	100, 120, 200 to 208, 230 or 240V / 50-60 Hz	200 to 208, 230 or 240V / 50-60 Hz
Max power consumption	1500 VA	2300 VA
Minimum power supply fuse rating	100, 120V: 15/16 A 200, 230, 240V: 10 A	15/16 A
Transient level	Overvoltage category II	Overvoltage category II

System type specific data

The following table provides capacity and dimension information for the system.

Property	Cabinet 10	Cabinet 30
Tubing	6 or 10 mm polypropylene tubing, 3/8" or 1/2" stainless steel tubing	1" polypropylene or stainless steel tubing
Max flow rate	180 l/h (6 mm or 3/8" tubing), 600 l/h (10 mm or 1/2" tubing)	2000 l/h
Weight, approxi-mately	430 kg	825 kg
Dimensions, operators console excluded	125 x 105 x 165 cm	220 x 105 x 189 cm

Temperature and pressure limits

The table below gives temperature and pressure limits for various types of tubing.

Tubing material	Tubing diameter	Fluid temperature	Maximum pressure
Polypropylene	All	4°C to 40°C	6 bar*
		40°C to 60°C	3 bar
Stainless steel	3/8", 1/2"	4°C to 40°C	10 bar*
	1"		6 bar*
	All	40°C to 60°C	3 bar
		60°C to 80°C	1 bar

Footnote

* When a capsule filter is used the maximum pressure is 5 bar.

System volume

The values presented in this table represents approximate hold-up volumes for indicated sections of the system. Values may vary between individual systems.

Flow path section	System tubing diameter		
	6 mm to 3/8"	10 mm to 1/2"	1"
From the inlets to the column (Air trap, Filter and Column(s) bypassed)	300 ml	550 ml	2250 ml
From the column to the UV cell	22 ml	47 ml	590 ml
From the UV cell to the outlets	23 ml	33 ml	350 ml
Air trap	1200 ml	1200 ml	1800 ml
Filter housing (empty)	440 ml	450 ml	2700 ml

8.2 Chemical resistance

Introduction

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

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

WARNING

Flammable liquids. ÄKTAprocess is **not approved** to handle flammable liquids.

WARNING

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

List of allowed chemicals

Chemical	Concentration	Max time / cycle	Max acc. expos.	Usage
Acetic acid	25%	3 h	3000 h	CIP
Acetone	10%	1 h	Unlimited	UV cell test
Citric acid	pH 2 to 2.5	1 h at temp ≤ 60°C	1000 h	CIP
Ethanol	20%	12 months	Unlimited	Storage
Ethanol / acetic acid	20%	3 h	3000 h	CIP
Guanidine hydrochloride	6 M	5 h	5000 h	CIP
Hydrochloric acid	0.1 M at pH=1	1 h	1000 h	CIP

Chemical	Concentration	Max time / cycle	Max acc. expos.	Usage
Phosphoric acid	5%	Overnight	Unlimited	For stainless steel passivation
2-propanol	30%	1 h	1000 h	CIP
Sodium chloride	0 to 3 M	3 h	3000 h	Purification, CIP
Sodium hydroxide	1 M at pH=14 0.5 M 0.01 M at pH=12	24 h at temp ≤40°C 3 h at temp ≤ 60°C 12 months	1000 days 3000 h Unlimited	CIP CIP Storage
Sodium hypochlorite	300 ppm	3 h at temp ≤ 60°C	3000 h	CIP
Sodium hydroxide/ethanol	1 M or 20%	3 h	3000 h	CIP
Urea	8 M	5 h	5000 h	Purification, CIP
Cleaning solutions	1% to 6% STERIS™ CIP 100™, 0.5% Henkel P3™-11, 0.2% Micro, 0.2% Terg-a-zyme™, 0.1% Tween™ 80	3 h at temp ≤ 60°C	3000 h	CIP

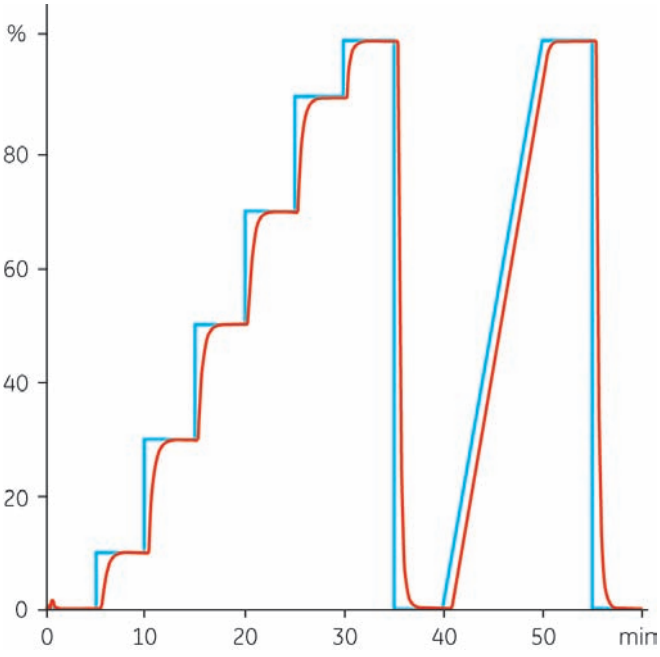
8.3 Gradient performance

Introduction

This section contains information on how the system can be configured to develop gradients using feedback loop technology.

Gradient performance

ÄKTAprocess can be configured to develop gradients at any flow rate using feedback loop technology with an accuracy better than ± 2% within the operating range (see GS in the product documentation package). The illustration below shows the programmed (blue) and the resulting (red) step gradients (left) and linear gradients (right).



Parameters used:

- System: 1" system
- Gradient mode: Feedback on flow
- Flow rate: 500 l/h
- Back pressure: 3 bar

UNICORN instruction notes

Pump:Flow:	0.0 to XX l/h. The pump is regulated by feedback from the flow meter. XX is for example 180 l/h for a 6 mm inner diameter system.
Pump:ManFlow:	0.0 to 100% of the maximum pump capacity. Sets the pump speed to a fixed value. The pump is not regulated by feedback from the flow meter (or conductivity monitor). The actual flow rate can be observed as the reading from the flow meter.
Pump:Gradient:	• Target 0 to 100% B • Length 0 to 100000 min
Pump:GradientRange:	When the ***Gradient Mode*** is set to ***Conductivity***: 0 to 999.99 mS/cm for inlet A and B
Pump:GradientMode:	• ***Flow*** When the system is equipped with two flow meters, the pump is regulated by feedback from the flow meter. • ***Conductivity*** The pump is regulated by feedback from the conductivity meter. • ***Off***
System:Settings:Specials: ColumnPauseFunction:	Defines if the valve goes back to the default position (***Bypass_Both***) or if it remains in position when the system enters ***Pause***. The ***ColumnPauseFunction*** can also be defined for the optional column 2.

8.4 Decontamination report

A Decontamination report, such as shown in the example below, must be used to record decontamination details before a service.

Decontamination Report

1. Equipment that is returned, for service or any other reason when personnel connected to GE Healthcare must handle the equipment (at any location), should be cleaned.
2. This form must be used to log the decontamination of the equipment.
3. A completed copy of this form should be faxed or sent by first class post to the person who will come in contact with the equipment, to ensure that he/she has the information before handling the equipment.
4. Failure to complete the form or comply with the procedure will lead to costs for decontamination and delays in handling the equipment.

5. Company:..... Address:.....
   Phone:..... Fax number:.....

6. Please complete the following sections

6.1 Equipment type..... 6.2 Serial number .....

6.3 Details of substances used on the inside/outside of the equipment

6.3.1 Substance name(s):

.....

.....

6.3.2 Precautions to be taken in handling these substances:

.....

.....

6.3.3 Action to be taken in the event of human contact:

.....

.....

6.3.4 Cleaning fluid to be used if residue of chemicals is found during handling:

.....

.....

6.4 Any further relevant information:

.....

7. If any substances used in the system are hazardous or toxic, these must be highlighted under 6.3.1.

   I hereby confirm that the equipment has been thoroughly cleaned, whether or not the equipment has been in contact with toxic and hazardous substances, and that the equipment has been filled with a suitable solution. I have also attached a description of the cleaning method.

   Storage solution in equipment:.....

   Signed:..... Name:.....

   Position:..... Date:.....

Document number: 04-0051-11
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8.5 UNICORN method for system CIP/Sanitization/Rinsing

Introduction

This section provides an example of a complete method that may be used for system cleaning.

Main method

The method outlined here is an example designed for a 2-pump, 10 mm inner diameter system (max flow 600 l/h). CIP solution in this example is 1 M sodium hydroxide.

Note: *The CIP method below does not include the optional sample pump. If a sample pump is part of the system, it should always be cleaned first. The UNICORN method must be changed accordingly, so that it starts with the sample pump inlets.*

(Main)

0.00 Base Time

0.00 Air_Alarm Disabled Disabled

0.00 Gradient 0.0 {%B} 0.00 {base}

0.00 InletCIP InletCIP1

0.00 InletA InletA1

0.00 AirTrap Inline

0.00 Filter Inline

0.00 Column UpFlow

0.00 Outlet Outlet1

0.00 Flow 450 {l/hour}

0.00 Block Fill_CIP_inlet

(Fill_CIP_inlet)

0.00 Base SameAsMain

0.00 InletCIP InletCIP1

1.00 End_Block

0.00 Block Fill_all_A_inlets

(Fill_all_A_inlets)

0.00 Base SameAsMain

0.00 InletA InletA1

0.50 InletA InletA2

1.00 InletA InletA3
1.50 InletA InletA4
2.00 InletA InletA5
2.50 InletA InletA6
3.00 InletA InletA7
3.50 InletA InletA8
4.00 InletA InletA9
4.50 InletA InletA10
5.00 InletA InletA1
5.00 End_Block
0.00 Block Fill_all_B_inlets
(Fill_all_B_inlets)
0.00 Base SameAsMain
0.00 Gradient 100 {%B} 0.00 {base}
0.00 InletA Closed
0.00 InletB InletB1
1.00 InletB InletB2
1.50 InletB InletB3
2.00 InletB InletB4
2.50 InletB InletB5
3.00 InletB InletB6
3.50 Gradient 0.0 {%B} 0.00 {base}
3.50 InletB Closed
3.50 InletA InletA1
3.50 End_Block
0.00 Block Fill_air_trap
(Fill_air_trap)
0.00 Base SameAsMain
0.00 AirTrap Bypass
1.00 AirTrap Out_through_drain
1.50 AirTrap Fill
2.00 AirTrap Inline
2.00 End_Block
0.00 Block Fill_filter_housing
(Fill_filter_housing)

0.00 Base SameAsMain
0.00 Filter Bypass
0.50 Filter Out_through_drain
1.00 Filter Inline
1.00 Message "Open manual filter valve" Screen "No sound"
1.00 Pause INFINITE {Minutes}
2.00 Message "Close manual filter valve" Screen "No sound"
2.00 Pause INFINITE {Minutes}
2.00 End_Block
0.00 Block Fill_all_column_valves
(Fill_all_column_valves)
0.00 Base SameAsMain
0.00 Column Bypass_Both
1.00 Column Bypass_Under
1.50 Column DownFlow
2.00 Column Bypass_Over
2.50 Column UpFlow
2.50 End_Block
0.00 Block Fill_all_outlets
(Fill_all_outlets)
0.00 Base SameAsMain
0.00 Outlet Outlet1
0.50 Outlet Outlet2
1.00 Outlet Outlet3
1.50 Outlet Outlet4
2.00 Outlet Outlet5
2.50 Outlet Outlet6
3.00 Outlet Outlet7
3.50 Outlet Outlet8
4.00 Outlet Outlet9
4.50 Outlet Outlet10
5.00 Outlet Outlet1
5.00 End_Block
0.00 End_Method

8.6 Further information

Process wetted materials

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

Spare parts and accessories

Additional information regarding spare parts and accessories can be found in the product documentation package.

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

Remaining aspects

Regarding

- Training
- Service
- Method optimization
- Ordering information
- Other issues not covered by these *Operating Instructions*.

Please contact your local GE Healthcare representative for advice.

Contact information is found on the back cover of these *Operating Instructions*.

Index

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