

# IQ

## for ALEXYS LC-ECD systems

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## C H A P T E R 1

## Introduction

This document describes the installation procedure as advised by the manufacturer. It is a result from our interpretation of many regulations and laboratory practices. In addition, feedback from users and representatives helped us to finalize this procedure.

All qualification checks have to be approved, or should be marked "n/a" if not applicable. Any deviation observed must be documented in the 'non-conformance' record. All relevant documents regarding system delivery and installation qualification must be filed together in one location.

As regulations and customer requirements may change, the manufacturer reserves the right to introduce changes without prior notice. For details on functionality, operation and theory, reference is made to the instruments user manuals.

## CHAPTER 2

## Identification

## ALEXYS instruments

Mark the installed product and its details or fill in n.a..

**Detector:** ..... p/n: ..... s/n: .....

**Flow cell:** ..... p/n: ..... s/n: .....

Working electrode type: .....

Reference electrode type: .....

**Flow cell 2:** ..... p/n: ..... s/n: .....

Working electrode type: .....

Reference electrode type: .....

**Injector:** ..... p/n: ..... s/n: .....

Size of valve ports:  1/16"  1/32" Nr. of ports: .....

**Pump:** P6.1L p/n: ..... s/n: .....

Installed options:  degasser  SSV  LPG

Installed pulse damper:  PEEK  stainless steel  n.a.

Pulse damper style:  tube  with membrane  n.a.

**Pump 2:** P6.1L p/n: ..... s/n: .....

Installed options:  degasser  SSV  LPG

Installed pulse damper:  PEEK  stainless steel  n.a.

Pulse damper style:  tube  with membrane  n.a.

**Eluent tray:** ..... p/n: ..... s/n: .....

**Column thermostat:** CT 2.1 p/n: ..... s/n: .....

**Additional valve:** ..... p/n: .....

Verified by (customer): ..... Deviations (Y/N): .....

Comments:

### ALEXYS control software and drivers

**Software\***

*Clarity* Ver. ....  
 Software license key p/n: ..... s/n: .....  
 Dongle user code: .....

*Chromeleon* Ver. ....  
 *OpenLab*  
 DECADE Elite driver Ver. ....  
 Knauer P6.1L driver Ver. ....  
 Knauer AS6.1L driver Ver. ....  
 Knauer CT2.1 driver Ver. ....

\* Mark the installed product and its details or fill in n.a.

### IO connection details (if made)

.....  
 .....

### Other relevant information

.....  
 .....

Manufacturer Antec Scientific  
 Supplier .....

Date of delivery .....  
 Date of installation .....  
 Warranty until .....

Verified by (customer): ..... Deviations (Y/N): .....

Comments:

## CHAPTER 3

**Installation****Preparations**

For a successful installation a few **preparations** must be made. Dedicated installation requirements documents are available that have to be sent to the customer in advance of the installation to prepare the site correctly. Relevant installation issues are explained in detail in the "Installation Guide" sections of the user manuals.

1. The installation site should meet the environmental specifications as described in the ALEXYS users manuals.
2. The chemicals (and water) used for preparation of mobile phase must be of specific grade (or better). Any trace of impurity will lead to elevated background current and an increase of noise.
3. Operating supplies and consumables should be available.
4. In a multi-purpose lab (that is not ECD-only) precautions should be taken to avoid contamination of high purity chemicals. We advise to keep a separate set of buffer salts, standards, glass ware and other small supplies for ECD only.

**Table I**

Check	In conf.	Non conf. ref. nr *
Section "installation guide" and "safety practices" in user manual(s) is noticed	<input type="checkbox"/>	
Environmental conditions are in accordance to recommendations in manual	<input type="checkbox"/>	
Purity of all mobile phase chemicals is HPLC grade or better	<input type="checkbox"/>	
The water used for preparation of mobile phase has a resistivity > 18 MOhm.cm and TOC<10ppb	<input type="checkbox"/>	

\* Any deviation observed must be documented in the 'non-conformance' record.

Verified by (customer): .....

Deviations (Y/N): .....

Comments:

## Unpacking

Before opening, inspect the transport boxes for external damage. In case of damage, immediately inform the transport company, otherwise she may not accept any responsibility. Keep the transport boxes as it is designed for optimum protection during transport and it may be needed again.

Carefully unpack the system and inspect it for completeness and for possible damage. Contact the supplier in case of damage or if not all marked items on the checklist(s) are included.

Prior to shipment, the system was inspected and tested to ensure the best possible performance. The results of all tests are included.

**Table II**

Check	In conf.	Non conf. ref. nr *
Delivery is in accordance with order	<input type="checkbox"/>	
Delivery is undamaged	<input type="checkbox"/>	
All items on checklist(s) are included	<input type="checkbox"/>	
Certificates of performance are included		
- P6.1L pump(s)	<input type="checkbox"/>	
- injector	<input type="checkbox"/>	
- detector(s)	<input type="checkbox"/>	
- flow cell(s)	<input type="checkbox"/>	
- column(s)	<input type="checkbox"/>	
User manuals are included (USB stick)	<input type="checkbox"/>	

\* Any deviation observed must be documented in the 'non-conformance' record.

Verified by (customer): .....

Deviations (Y/N): .....

Comments:

## Installation

The **installation** procedure of the different instruments and parts of the system is described in the users manuals (Chpt. "Installation Guide").

Some points to highlight:

1. The stainless steel parts of the ALEXYS system must be passivated and metal-free systems for use in HPAEC-PAD set-up need to be rinsed with NaOH solution as part of the installation.
2. The column and mobile phase must be electrochemically clean.
3. Flush the (new)column according to the manufacturers recommendations before running mobile phase through.
4. If the mobile phase contains ion-pairing agent, stabilize a new unused C18 column overnight with running mobile phase before attaching the flow cell.
5. If a flow cell with ISAAC™ type reference electrode is used, the ISAAC requires a fixed concentration (2 or 8 mmol/L) chloride ions (KCl or NaCl) in the mobile phase.

**Table III**

Check	In conf.	Non conf. ref. nr *
Installation procedure is done in accordance to user's manuals.	<input type="checkbox"/>	
System with stainless steel parts is passivated in accordance to recommendations in manual	<input type="checkbox"/>	
Metal-free system is rinsed with NaOH solution in accordance to recommendations in manual	<input type="checkbox"/>	
Column conditioned according to the manufacturer's recommendations	<input type="checkbox"/>	
In case of ion pairing separation, the column was additionally stabilized for >10h with running mobile phase before connecting the flow cell.	<input type="checkbox"/>	
In case of using an ISAAC reference: fixed concentration (... mmol/L) Cl <sup>-</sup> in mobile phase	<input type="checkbox"/>	

\* Any deviation observed must be documented in the 'non-conformance' record.

Verified by (customer): .....

Deviations (Y/N): .....

Comments:

## CHAPTER 4

**Operational familiarization****Basics and theory**

The ALEXYS LC-EC System has been designed for maximum functionality and ease of use. Most of the operational issues are intuitive, but a few issues require additional explanation.

Information regarding these issues is in the corresponding user manual.

**Table IV**

Check	In conf.	Non conf. ref. nr *
Concept of HPLC separation has been explained	<input type="checkbox"/>	
Concept of electrochemical detection has been explained	<input type="checkbox"/>	
Functional characteristics have been explained (if applicable) of: - P6.1L pump - injector - electrochemical detector - flow cell(s) - column(s) - chromatographic data software - column thermostat - inert gas blanketing using the eluent tray	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
Application specific details have been explained - Analysis of ...	<input type="checkbox"/>	

\* Any deviation observed must be documented in the 'non-conformance' record.

Verified by (customer): .....

Deviations (Y/N): .....

Comments:

## Maintenance instructions

The ALEXYS LC-EC System has been designed for maximum functionality and ease of use. Performing proper maintenance is key to prolonging the correct functioning of the system.

Receiving detailed information regarding maintenance is part of the training/instructions. For reference purpose, the instructions are also given in the corresponding user manuals of the instrument.

**Table V**

Check	In conf.	Non conf. ref. nr *
Daily maintenance routines were explained: - Autosampler needle wash - Check for leaks	<input type="checkbox"/> <input type="checkbox"/>	
Weekly maintenance routines were explained: - Refreshing the piston wash solution	<input type="checkbox"/>	
Half-yearly maintenance routines were explained: - Replacement of the in-line filter(s)	<input type="checkbox"/>	
Flow cell maintenance were explained: - Polishing of the working electrode - Polishing of the auxiliary electrode - Maintenance of the reference electrode	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
Storage procedures were explained	<input type="checkbox"/>	
The use of a daily checklist** was explained	<input type="checkbox"/>	

\* Any deviation observed must be documented in the 'non-conformance' record.

\*\* See Appendix I

Verified by (customer): .....

Deviations (Y/N): .....

Comments:

## Troubleshooting instructions

Two tests are explained that an end-user should be able to do before contacting the manufacturer in case of detector related issues.

Detailed information is in the detector user manual.

**Table VI**

Check	In conf.	Non conf. ref. nr *
Troubleshooting tests were explained: - Dummy cell test - Stop flow test (only for analyses in DC mode)	<input type="checkbox"/>  <input type="checkbox"/>	

\* Any deviation observed must be documented in the 'non-conformance' record.

Verified by (customer): .....

Deviations (Y/N): .....

Comments:



## C H A P T E R 6

**Non-conformance record**

Any case of non-conformance found during installation should be documented and signed for acceptance or corrective action taken.

**Table VII**

Ref.	Non-conformance and action taken	Signature customer	Sign. Antec Scientific rep.
1		.....	.....
2		.....	.....
3		.....	.....

Verified by (customer): .....


Deviations (Y/N): .....

Comments:

## A P P E N D I X I

## ALEXYS Operator Checklist

The newest digital version of our ALEXYS Operator Checklist can be downloaded from our website (document nr. 180\_0029).

		Date:			
<b>Mobile phase and waste</b>					
Enough mobile phase in the bottles					
Mobile phase not expired					
No microbial growth visible in the mobile phase bottle					
Waste bottle emptied					
Mobile phase replaced (at least every 3 days)					
<b>In-line Whatman filter</b>					
No air in the Whatman filter inlet					
No dots/stains/discoloration visible on membrane?					
Filter replaced (once/6 months)					
<b>Pump</b>					
Degasser lights green					
No air pockets in the inlet lines					
No wetness/salt build-up at the connectors of the degasser					
No wetness/salt build-up at the connectors of the pump head					
Piston wash level did not change					
Piston wash solution replaced (once/week)					
Piston seals replaced (once/year)					
<b>Auto sampler</b>					
Performed Initial wash					
No air on top of syringe or stuck in the buffer tubing					
Enough needle wash solution					
Check/empty the autosampler waste bottle					
No wetness/salts at valve connectors					
Needle wash solution replaced (at least once/week)					
Syringe tip replaced (once/year)					
<b>Flowcell</b>					
Crystals/no air visible (in an sb ref)					
Maintenance of reference - ISAAC or sb (at least once/3 months)					
<b>Before starting a complete sequence</b>					
Calibration file name cloned in method to match today's date					
Correct method 'Sent to instrument' and system is stabilizing					
Waste line lowered all the way into the Waste bottle					
Performed a system suitability test run and results are OK					
Any modifications to the integration table updated to the method					
Check marks applied to all sequence lines					
Bypass' mode set for lines used for stabilization or standby time					
<b>System values</b>					
Detector Ecell setting (mV)					
Detector I-cell reading					
Detector oven temperature (°C)					
Set vs. actual sample tray temperature (°C)					
Flow rate (µL/min)					
Pressure reading (bar)					
System suitability test run peak height					
System suitability test run plate count/m					
Baseline noise level estimation (visual peak-to-peak)					
Operator initials					
Remarks					