

IQ

for ALEXYS LC-ECD systems

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Introduction

This document describes the installation procedure as advised by the manufacturer. It is a result from our interpretation of many regulations and laboratory practises. 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 an installation qualification must be filed together in one location.

As regulations and customer requirements may change, the manufacturer reserves the right to introduces changes without prior notice. For details on functionality, operation and theory reference is made to the instrument users manual.

C H A P T E R 1

Identification

Engineer

The undersigned engineer certifies that he/she is trained and qualified to perform an Installation Qualification on the ALEXYS® LC-EC System.

Company:

Performer:
Name Initials

Position:

Signature:
(Antec representative trained and qualified to perform PQ procedures)

Reviewer/customer

The undersigned reviewer/customer accepts that the above-mentioned engineer is trained and qualified to perform a Installation Qualification on the ALEXYS LC-EC System.

Company:

Department:

Reviewer/
Customer:
Name Initials

Position:

Signature:
(Owner-designated authorized person)

Instruments

- | | | | |
|--------------------------|-----------------|------------|------------|
| <input type="checkbox"/> | LC 110S 1 | p/n: | s/n: |
| <input type="checkbox"/> | LC 110S 2 | p/n: | s/n: |
| <input type="checkbox"/> | OR 110 | p/n: | s/n: |
| <input type="checkbox"/> | DECADE Elite™ | p/n: | s/n: |
| <input type="checkbox"/> | AS 110 | p/n: | s/n: |
| <input type="checkbox"/> | Valve | p/n: | s/n: |
| <input type="checkbox"/> | Flow cell 1 | p/n: | s/n: |
| <input type="checkbox"/> | REF electrode 1 | p/n: | s/n: |
| <input type="checkbox"/> | Flow cell 2 | p/n: | s/n: |
| <input type="checkbox"/> | REF electrode 2 | p/n: | s/n: |
| <input type="checkbox"/> | Column 1 | p/n: | s/n: |
| <input type="checkbox"/> | Column 2 | p/n: | s/n: |

*s/n: entering more than one s/n is allowed if more than one unit is used.

- | | | |
|--------------------------|-----------------------------|-------|
| <input type="checkbox"/> | Clarity data system version | |
| <input type="checkbox"/> | Clarity dongle s/n | |

Manufacturer	Antec Scientific
Supplier

Date of delivery
Warranty until

Verified by (customer):

Deviations (Y/N):

Comments:

CHAPTER 2

Preparations

For a successful installation a few **preparations** must be made. Note that part of this is also a responsibility of the user. Relevant issues are explained in detail in the "Installation Guide" sections of the user manuals and for some applications there is a Requirements document that can be sent to the customer in advance of installation to prepare correctly.

1. The installation site should meet the environmental specifications as described in the ALEXYS users manuals.
2. The water used to prepare mobile phase must have a resistivity of >18 MOhm.cm and a TOC level < 5 ppb.
3. Chemicals used for preparation of mobile phase must be of HPLC grade or better. Any trace of impurity will lead to elevated background current and an increase of noise.
4. Operating supplies and consumables should be available.
5. In a multi-purpose lab (that is not ECD-only) precautions should be taken to avoid contamination of high purity chemicals. We advice 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. *
Section "installation guide" and "safety practices" in users manual(s) is noticed	○	
Environmental conditions are in accordance to recommendations in manual	○	
In case of reductive analysis: steps are taken to suppress oxygen in mobile phase	○	
Purity of all mobile phase chemicals is HPLC grade or better	○	
The water used for preparation of mobile phase has a resistivity > 18 MOhm.cm and TOC<10ppb	○	

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

Verified by (customer):

Deviations (Y/N):

Comments:

CHAPTER 3

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 your 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. *
Delivery is in accordance with order	○	
Delivery is undamaged	○	
All items on checklist(s) are included	○	
Certificates of performance and user manuals are included		
- LC 110S HPLC pump	○	
- AS 110 autosampler	○	
- DECADE Elite detector	○	
- OR 110 organiser rack	○	
- Flow cell(s)	○	
- Column(s)	○	

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

** User manuals: see check list for included documents.

Verified by (customer):

Deviations (Y/N):

Comments:

CHAPTER 4

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 system hardware must be passivated as part of the installation
2. The column and mobile phase must be electrochemically clean.
3. Passage of air bubbles through the flow cell will lead to unacceptable noise levels and 'spikes'. Therefore, the use of the in-line degasser is required.
4. If a flow cell with ISAAC™ type reference electrode is used, the ISAAC requires a fixed concentration (2 or 8 mmole/L) chloride ions (KCl or NaCl) in the mobile phase.

Table III

Check	In conf.	Non conf. ref. *
System passivated in accordance to recommendations in manual	○	
Installation procedure is done in accordance to user's manuals.	○	
In case of reductive analysis: steps are taken to suppress oxygen in mobile phase	○	
In case of using an ISAAC reference: fixed concentration (... mmole/L) Cl ⁻ in mobile phase	○	

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

Verified by (customer):

Deviations (Y/N):

Comments:

CHAPTER 5

Operational familiarisation

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. *
Concept of electrochemical detection has been explained	<input type="radio"/>	
Dummy cell test has been explained	<input type="radio"/>	
Stop flow test has been explained	<input type="radio"/>	
Polishing of flow cell has been explained	<input type="radio"/>	
Maintenance of reference electrode has been explained	<input type="radio"/>	
Functional characteristics have been explained (if applicable) of:		
- LC 110S pump	<input type="radio"/>	
- AS 110 autosampler	<input type="radio"/>	
- DECADE Elite electrochemical detector	<input type="radio"/>	
- OR 110 organiser rack	<input type="radio"/>	
- Clarity data system software	<input type="radio"/>	

* 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

IQ certification

The installation has been performed in accordance to the Installation Qualification and has been carried out to the satisfaction of both parties. Designated operator has been trained and familiarised with the ALEXYS LC-EC System during the installation.

Antec Scientific representative

Company:

Performer:

.....
Date

.....
Signature

Customer (authorised to sign)

Company & Dept:

Reviewer/Customer:

.....
Date

.....
Signature

Operator(s) trained for working with the ALEXYS system

Name:

Name::

Name:

Verified by (customer):

Deviations (Y/N):

Comments:

CHAPTER 7

Non conformance record

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

Table V

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

Comments

Verified by (customer):

Deviations (Y/N):

Comments: