

Antec®

ROXY™ EC system

IQ manual

210.7024, Edition 1, 2010



Antec Proven Performance!

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Identification

The undersigned engineer certifies that he/she is trained and qualified to perform an Installation Qualification on the ROXY™ EC system.

Performer:
Name Signature Initials

Company

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

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

Reviewer/
Customer:
Name Signature Initials

Company:

Title:
(Owner-designated authorized person)

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

Comments:

Instruments and identification

- | | | | |
|--------------------------|--------------------|------------|------------|
| <input type="checkbox"/> | ROXY™ potentiostat | p/n: | s/n: |
| <input type="checkbox"/> | ReactorCell™ | p/n: | s/n: |
| <input type="checkbox"/> | Syringe pump | p/n: | s/n: |
| <input type="checkbox"/> | | p/n: | s/n: |
| | | | |

*s/n: entering more than one s/n is allowed if more than one unit is used.
On the empty location please fill in the type of mass spectrometer to which the system will be coupled.

- | | | |
|--------------------------|---------------------------|-------|
| <input type="checkbox"/> | Dialogue for ROXY version | |
| <input type="checkbox"/> | Dialogue dongle Y/N | |
| <input type="checkbox"/> | | |

Manufacturer Antec
Supplier

Date of delivery

Warranty until

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

Comments:

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Verified by (customer):

Deviations (Y/N):

Comments:

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 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, 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.

Verified by (customer):

Deviations (Y/N):

Comments:

Verified by (customer):

Deviations (Y/N):

Comments:

C H A P T E R 2

Installation

Unpacking and installation checks

Inspect the *transport boxes* for possible damage on arrival. Immediately inform the transport company in case of damage, 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, your system has been inspected and tested to ensure the best possible performance. The results of all tests are included.

Table I

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

** User manuals: 210.7010, 210.7014, 210.7017 and 188.0010. All user manuals can be found in the shipping boxes of the corresponding instruments.

| Check | In conf. | Non conf. ref. * |
|---|-----------------------|------------------|
| Delivery is in accordance with order | <input type="radio"/> | |
| Delivery is undamaged | <input type="radio"/> | |
| All items on checklist(s) are included | <input type="radio"/> | |
| Certificates of performance are included: | | |
| - ROXY potentiostat | <input type="radio"/> | |
| - ReactorCell | <input type="radio"/> | |
| - Syringe pump | <input type="radio"/> | |
| User manuals are included** | <input type="radio"/> | |

Verified by (customer):

Deviations (Y/N):

Comments:

Installation procedure

A ROXY[®] system installation checklist is supplied with every ROXY EC system. It is a general check list to guide you through the installation of an ROXY[®] EC system. The full instrument installation procedure of the supplied equipment is described in the corresponding user manuals (Chapter "Installation Guide"). Installation details of the ReactorCell are described in the ReactorCell user manual (Chapter "Installation of .."). It is the users' responsibility to prepare an installation site according to environmental specifications as described in the ROXY user manuals.

For a successful installation a few preparations must be made. This is a responsibility of the end-user. Note that all these issues are explained in detail in the "Installation Guide" of the user manual.

1. The mass spectrometer (MS) can be controlled by the ROXY EC system by contact-closure. The end-user should make sure that all required preparation with respect to the MS are accomplished:
 - [a] An open-ended IO cable or screw terminal connector should be available on the MS side to connect the ROXY trigger cable.
 - [b] The MS software should be configured in slave mode to be able to start runs controlled via contact closure by means of the Dialogue software.
2. A number of operating supplies and consumables should be available. Chemicals (including water) used for preparation of mobile phase must be of HPLC grade or better.
3. 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 and MS only.
4. If the ROXY is used in the reductive mode (at a negative working potential) additional steps should be taken to remove oxygen from the mobile phase.

Verified by (customer):

Deviations (Y/N):

Comments:

Table II

| 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 | ○ | |
| ROXY EC system trigger cable is correctly connected & configured to the start input of the mass spectrometer. | ○ | |
| All tubing & connections are leakage-free installed in accordance with the corresponding LC connection kit installation drawing. | ○ | |
| Purity of all mobile phase chemicals are HPLC grade or better | ○ | |
| Installation procedure is done in accordance to user's manuals. | ○ | |

Verified by (customer):

Deviations (Y/N):

Comments:

Operational familiarisation

The ROXY EC system has been designed for maximum functionality and ease of use. Most of the operational issues are intuitive and do not need further explanation. A few issues require explanation.

Table III

| Check | In conf. | Non conf. ref. * |
|---|----------|------------------|
| Concept of electrochemical conversion (oxidation/reduction) and detection has been explained. | ○ | |
| Concept of recording of mass voltammogram is explained. | ○ | |
| It has been explained how to perform a ROXY potentiostat dummy cell test | ○ | |
| Disassembly/assembly of the ReactorCell has been explained | ○ | |
| Maintenance of ReactorCell (working and reference electrode) has been explained | ○ | |
| Functional characteristics have been explained (if applicable) of: | | |
| - ROXY potentiostat | ○ | |
| - ReactorCell | ○ | |
| - Syringe pump | ○ | |
| - Dialogue software | ○ | |

Information regarding these issues can be found in the corresponding user manual.

Verified by (customer):

Deviations (Y/N):

Comments:

C H A P T E R 3

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 ROXY EC or EC/LC system during the installation.

Antec representative

| | |
|---------------------------|-------|
| Engineer name & signature | |
| Company | |
| Date | |

Customer (authorised to sign)

| | |
|------------------|-------|
| Name & signature | |
| Company/dept. | |
| Date | |

Operator(s) trained for ROXY EC or EC/LC System

| | |
|-----------------|-------|
| Name & initials | |
| Name & initials | |
| Name & initials | |

Verified by (customer):

Deviations (Y/N):

Comments:

Comments

Verified by (customer):

Deviations (Y/N):

Comments:

C H A P T E R 4

Non conformance record

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

Table IV

| Ref. | Non-conformance and action taken | Signature customer | Sign. Antec rep. |
|------|----------------------------------|--------------------|------------------|
| 1 | | | |
| 2 | | | |
| 3 | | | |
| 4 | | | |
| 5 | | | |
| 6 | | | |

Verified by (customer):

Deviations (Y/N):

Comments: