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IQ/OQ

for DECADE II, Elite, Lite and ROXY

171.0023, Edition 7, 2017

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CHAPTER 1

Introduction

This document describes the Qualification 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.

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 user manuals.

In this document, 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 this operational qualification must be filed together in one location.

C H A P T E R 2

Identification

Engineer

The undersigned engineer certifies that he/she is trained and qualified to perform an IQ/OQ/PQ on Antec devices.

Performer: _____ _____ _____
Name Signature Initials

Company _____

Title: _____
(Anted Leyden 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 an IQ/OQ/PQ on Antec devices.

Reviewer/
Customer: _____ _____ _____
Name Signature Initials

Company: _____

Title: _____
(Owner-designated authorized person)

Instruments

☐ DECADE II, Elite, Lite, or ROXY p/n: ..... s/n: .....

☐ Dummy cell* p/n: ..... s/n: .....

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

Device options installed:

☐ External valve

☐ Dual cell control

☐ Syringe pump

Manufacturer Antec

Supplier .....

Other relevant hardware

Description	**Serial no**

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

Comments:

C H A P T E R 3

IQ Procedure

Unpacking and installation checks

Inspect the *transport box* for possible damage as it arrives. Immediately inform the transport company in case of damage, otherwise she may not accept any responsibility. Keep the transport box 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 are included.
Prior to shipment, your detector has been inspected and tested to ensure the best possible performance. The results of all tests are included in the ship kit.

Table I

Check	**In conf.**	**Non conf. ref. ***
Delivery is in accordance with order	O	
Delivery is undamaged	O	
All items on checklist(s) are included	O	
Certificates of performance are included - detector - flow cell(s)	 O O	
User manual(s) is (are) included	O	

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

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

Comments:

Installation procedure

The full instrument installation procedure is described in the user's manual (Chpt. "Installation Guide"). Installation details of all different type of flow cells are in the flow cell manual (Chpt. "Installation of ..").
It is the users' responsibility to prepare an installation site according to environmental specifications as described in the user's manual.

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

1. To fully exploit the enormous linear dynamic range and detection sensitivity of the electrochemical detector an optimized and dedicated HPLC system must be applied. The system hardware must be passivated and column and mobile phase must be electrochemically clean prior to installation.
2. Passage of air bubbles through the flow cell will lead to unacceptable noise levels and 'spikes'. Therefore, the use of an in-line degasser is required.
3. If a flow cell with ISAAC type reference electrode is used, the ISAAC requires a fixed concentration (2 mmol/L) chloride ions (KCl or NaCl) in the mobile phase.
4. 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. Any trace of impurity will lead to elevated background current and an increase of noise.
5. 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.
6. If the device is used for reductive ECD (at a negative working potential) additional steps should be taken to remove oxygen from the mobile phase.

Table II

Check	**In conf.**	**Non conf. ref. ***
Section "installation guide" and "safety practices" in user's manual(s) is noticed	O	
Environmental conditions are in accordance to recommendations in manual	O	
System passivated in accordance to recommendations in manual	O	
HPLC column has been preconditioned in accordance to recommendations in manual	O	
HPLC system is equipped with in-line degasser	O	
Reductive measurement: steps are taken to suppress oxygen in mobile phase	O	
In case of ISAAC: fixed concentration (2 mmol/L) Cl- in mobile phase	O	
Purity of all mobile phase chemicals is HPLC grade or better	O	
Installation procedure is done in accordance to the user's manual rev no. ……	O	
Installation of options is done in accordance to instructions (if applicable) External valve doc. rev no …… Dialogue software doc. rev no ……	 O O	

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

Comments:

Operational familiarization

The Antec electrochemical detectors and potentiostats have been designed for maximum functionality and ease of use. Most of the operational issues are intuitive and do not need further explanation.

Table III

Check	**In conf.**	**Non conf. ref. ***
Concept of DC, Scan and Pulse mode has been explained	O	
Functionality in DIAG and CONFIG is understood	O	
Concept of time files has been explained	O	
Functional characteristics of I/O contacts on rear panel have been explained	O	
It has been explained how to perform a dummy cell test, stop flow test	O	
Polishing and maintenance of flow cell has been explained	O	
Functional characteristics of options have been explained (if applicable) External valve Dual cell Dialogue software Syringe pump	 O O O O	

Information regarding these issues is in the user manual.

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

Comments:

C H A P T E R 4

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 familiarized with the unit during the installation.

Antec Leyden representative

Technician name & signature	……... ……..….
Company	
Date	

Customer (authorized to sign)

Name & signature	……... ……..….
Company/dept.	
Date	

Operator(s)

Name & initial	……... ……..….
Name & initial	……... ……..….
Name & initial	……... ……..….

CHAPTER 5

OQ procedure

Introduction

Noise and stability performance of the device is checked using a dummy cell. With this test also temperature stability is checked, as the dummy cell consists of a resistor and capacitor that both require constant temperature to meet the noise and stability specifications.
We define **noise** as the average of 30 peak to peak noise measurements over a period of 30 s (total of 15 min).

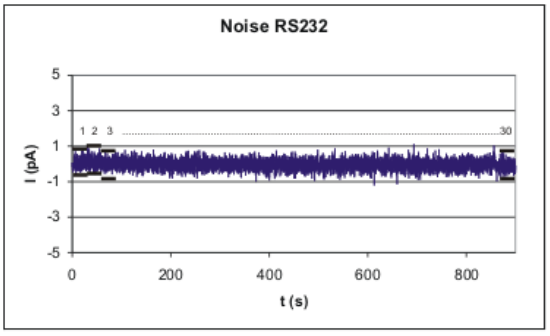


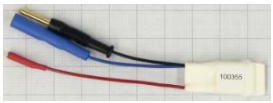
Fig. 1. Noise measurement.

$$\text{Noise} = \frac{n_1 + n_2 + n_3 \ldots\ldots\ldots\ldots\ldots + n_{30}}{30}$$

Drift is measured as the slope of the baseline during 15 minutes measurement.

Required part, tools and software

Required tools

Part no	Description
250.0040	Dummy cell (part of detector accessories; one per cell) 
250.0128*	Output cable (part of detector accessories)
	AD convertor or calibrated voltmeter

*) 250.0128B for Elite

Required software

A OQ noise test and report generator is implemented in Dialogue software (for Windows only). To unlock this feature, one of the following software dongles is necessary and the computer should have Microsoft Excel installed.

Part no	Description
171.9005 or 171.9002	Dialogue, PQ version (since 2015 suitable for OQ) Dialogue, OQ/PQ/ROXY version
171.9015 or 171.9012	Dialogue Elite Standard Dialogue Elite Professional (distributors)
	Microsoft Excel 2003 or newer for automated output

Alternative data acquisition software can be used, but all measurements have to be processed manually in that case.

For the DECADE Elite, the new Dialogue Elite software is required. This software is backward compatible with the other (old) Dialogue dongles.

In case the Dialogue software is not available it is allowed to evaluate the noise trace in other HPLC data acquisition software.

Dummy cell test procedure

Preparations

Before running the test make sure the system has **stabilized for more than an** hour with a dummy cell installed and ON, at the right temperature, working potential E, and range setting (see Setting below in Table IV.

Settings

Table IV. Dummy cell test settings.

Parameter	**Setting**
Cell potential	800 mV
Oven	35 °C for at least 1 hour
Zero	ON/SET
Filter	First available filter setting (0.1 s, or 0.5 Hz)
Range	Between 100 pA - 1 nA
Acquisition	Data rate < 10 Hz
Output test	INTRO/DECADE: REC output DECADE II, Elite or ROXY: Output

Procedure

1. For detailed instructions on running a Dummy cell test with Dialogue software, see the Dialogue manual.
2. Make sure the unit has stabilized for at least one hour before running the test.
3. In Dialogue, select Options/Dummy cell noise test. Correct settings are set automatically, verify these.
4. Measure the noise during 15 minutes. Acquisition frequency must be set to less than 10 Hz.
5. Read the cell current from the display (I cell)
6. Enter the results of the dummy cell test in the results table on page 13.

Analogue output test

The analogue output of the detector is tested by measuring the difference in output signal from a dummy cell with the working potential switched off (zero level) and on. The measurement is taken from the rear panel Output connector, which is either connected to some software through an AD convertor or alternatively measured with a calibrated voltmeter.

1. Use the settings from Table IV, but set the detector range to 5 nA/V and set the compensation (auto zero) to OFF. Offset % must be zero.
2. Measure the analogue output with cell off.
3. Switch on the cell and measure the analogue output.
4. Calculate the difference in output voltage measured with ‘Cell on’ and ‘Cell off’ (Fig. 2).
5. Enter the results of the Analogue output test in the results table on page 13.

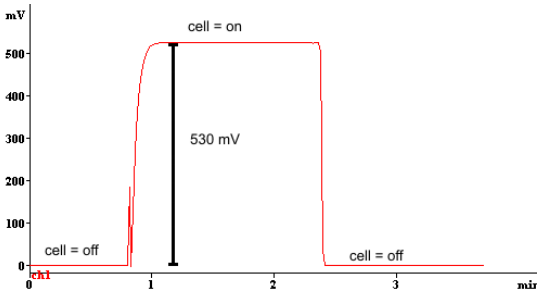


Fig. 2. Measuring output with dummy cell off and on at 5 nA/V, for other settings see Table IV.

What to do if failed

Steps to take when the device fails the OQ test:

1. Double check all settings.
2. Check our knowledge base, search for “noise”
3. If not successful in fixing the problem contact Antec for support.

C H A P T E R 6

OQ results summary

Test results cell 1

	Specified	Measured	Result
Dummy cell test			
Current (I-cell)	2.67 ± 0.05 nA	……. nA	……
Noise p-p	< 2.0 pA	……. pA	……
Analog output test			
Output at 5 nA/V	530 ± 10 mV	……. mV	……

Test results 2nd cell

For 2-channel configurations only, otherwise fill in n.a. (not applicable).

	Specified	Measured	Result
Dummy cell test			
Current (I-cell)	2.67 ± 0.05 nA	……. nA	……
Noise p-p	< 2.0 pA	……. pA	……
Analog output test			
Output at 5 nA/V	530 ± 10 mV	……. mV	……

Final result (passed / failed) _____

C H A P T E R 7

OQ certification

The Operational Qualification has been carried out in accordance to the OQ procedure and has been carried out to the satisfaction of both parties. All tests as described in this document have been successfully completed, and all results are within specifications.

Executing engineer

Company ……

Performer ……

…… ……..……

Date Signature

Customer (authorized to sign)

Company & Dept. ……

Reviewer/Customer ……

…… ……..……

Date Signature

Comments

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

Comments:

C H A P T E R 8

Non-conformance record

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

Table 2. Non-conformance record.

Ref.	Non-conformance and action taken	Signature customer	Sign. executing technician
1		……	……
2		……	……
3		……	……
4		……	……
5		……	……
6		……	……

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

Comments: