

IQ/OQ

for DECADE II, Elite, Lite
and ROXY

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C H A P T E R 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 qualification must be filed together in one location.

CHAPTER 2

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	○	
Delivery is undamaged	○	
All items on checklist(s) are included	○	
Certificates of performance are included		
- detector	○	
- flow cell(s)	○	
User manual(s) is (are) included	○	

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

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	○	
Functionality in DIAG and CONFIG is understood	○	
Concept of time files has been explained (ROXY)	○	
Functional characteristics of I/O contacts on rear panel have been explained	○	
It has been explained how to perform a dummy cell test, stop flow test	○	
Polishing and maintenance of flow cell has been explained	○	
Functional characteristics of options have been explained (if applicable)		
External valve	○	
Dual cell	○	
Dialogue software	○	
Syringe pump	○	

Information regarding these issues is in the user manual.

Verified by (customer):

Deviations (Y/N):

Comments:

CHAPTER 3

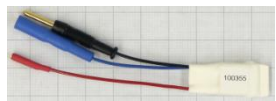
OQ procedure

Introduction

The Operation Qualification (OQ) consist of two electronic tests: the dummy cell test and the analogue output test. These electronic tests check the noise, output and stability performance of the device.

Required part, tools and software

Required parts and tools

Part no	Description
250.0040	Dummy cell (part of detector accessories; one per cell) 
250.0128*	Output cable (part of Antec's 'OQ PQ PM cal hardware kit' for engineers)
	AD convertor or calibrated voltmeter

* 250.0128B for Elite

Software

An automated dummy cell test and report generator is implemented in Antec's 'Dialogue Elite' software (for Windows only). To unlock this feature, one of the following software dongles is necessary and the computer should have Microsoft Excel installed. In case a suitable Dialogue Elite software dongle is not available it is allowed to evaluate the noise trace in other HPLC data acquisition software.

Dialogue Elite software, and one of the listed Dialogue software dongles:	
Pn	Description
171.9005	Dialogue, PQ version
171.9002	Dialogue, OQ/PQ/ROXY version
171.9015	Dialogue Elite Standard
171.9012	Dialogue Elite Professional
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.

Dummy cell noise test

A dummy cell consists of a resistor and capacitor, which will result in a specific current and noise level when applying the settings as given in Table IV. The test consists of recording a stable baseline signal for 15 min, and evaluating its noise level. The dummy cell noise test will also test temperature stability, as the dummy cell requires constant temperature to meet the specifications.

Evaluation of the **noise** level is done by averaging 30 peak to peak values from segments of 30 s (total of 15 min):

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

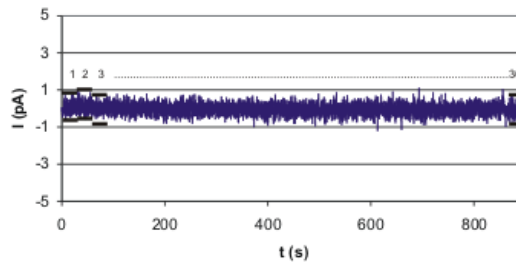


Fig. 1. Baseline noise measurement.

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 setting given in Table IV

Procedure

1. In Dialogue software, select Options/Dummy cell noise test. Correct settings are set automatically; verify them.
2. Record the baseline during 15 minutes.
The Dialogue software test script will automatically output the data to an Excel template that calculates the noise level according to the peak-to-peak method.
3. Read the cell current (I cell) from the display and write it down.
4. Process/print the data.
5. Enter the results of the dummy cell test in the results table on page 10.

Settings

Table IV. Dummy cell test settings.

Parameter	Setting
Cell potential	800 mV
Oven	35 °C for at least 1 hour
Compensation	ON/SET (Autozero)
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

Analogue output test

The analogue output of the detector is tested by applying the conditions as specified in Table V on a dummy cell and measuring the rear panel Output voltage.

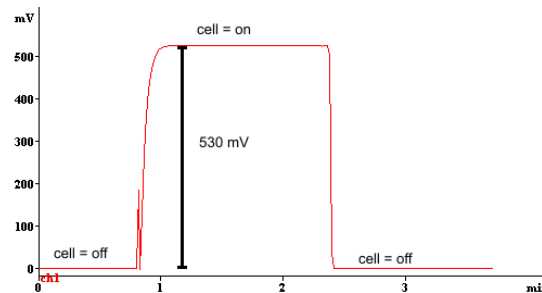


Fig. 2. Measurement of output from a dummy cell

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 setting given in Table V. Perform the measurements with the connected AD convertor, or alternatively with a calibrated voltmeter and cable 250.0128(B).

Settings

Table V. Analogue output test settings.

Parameter	Setting
Cell potential	800 mV
Oven	35 °C for at least 1 hour
Compensation	OFF (Autozero)
Offset	0%
Range	5 nA
Output test	INTRO/DECADE: REC output DECADE II, Elite or ROXY: Output

Procedure

1. Apply the settings from Table V.
2. Measure the analogue output with cell ON and cell OFF, and calculate the difference in output voltage (Fig. 2)
3. Enter the result in the table on page 10.

What to do if failed

Steps to take when the device fails the OQ test:

1. Double check all applied settings
2. Check the knowledge base on our website and/ or contact Antec for support.

CHAPTER 4

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	<* pA pA
Analog output test			
Output at 5 nA/V	530 ± 10 mV mV

*ROXY: < 4 pA, all others < 2.0 pA

Test results Cell 2

For DCC detectors 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	<* pA pA
Analog output test			
Output at 5 nA/V	530 ± 10 mV mV

*ROXY: < 4 pA, all others < 2.0 pA

Final result (passed / failed) _____

Verified by (customer):

Deviations (Y/N):

Comments:

CHAPTER 5

IQ & OQ certification

The undersigned reviewer/customer is authorized to sign and accepts that the engineer is trained and qualified to perform the Qualification procedures on Antec devices.

The undersigned engineer certifies that he/she is trained and qualified to perform the Qualification procedures on Antec devices.

All tests and procedures as described in this document have been completed, and all results are within specifications or clearly indicated if not.

The installation and operation testing has been carried out in accordance to the IQ and OQ procedures and to the satisfaction of both parties.

Engineer

Name
Initials
Company

.....
Date Signature

Reviewer/customer

Name
Initials
Job title
Company & Dept.

.....
Date Signature

Operators

The following operator(s) have been trained and familiarized with the unit during the installation.

Name
Name
Name

Instrument

DECADE Elite / ROXY p/n: s/n:

Instrument has DCC option (Y/N)
External valve option installed (Y/N)

Flow cell 1 p/n: s/n:

Working electrode type:
Reference electrode type:

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

Working electrode type:
Reference electrode type:

** if aquired*

Manufacturer Antec Scientific
Supplier

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

OQ test devices

Dummy cell* p/n: 250.0040 s/n:

Volt meter or AD signal s/n:

*s/n: entering more than one s/n is allowed for DCC detectors.

Other relevant information

Verified by (customer):

Deviations (Y/N):

Comments:

Comments

Verified by (customer):

Deviations (Y/N):

Comments:

CHAPTER 6

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: