AntecScientific.com | info@AntecScientific.com | T +31 71 5813333

OQ

for DECADE II, Elite, Lite and ROXY

171.0023O, Edition 7, 2016

Antec Scientific | Industrieweg 12 | 2382 NV Zoeterwoude | The Netherlands

Table of contents

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

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).

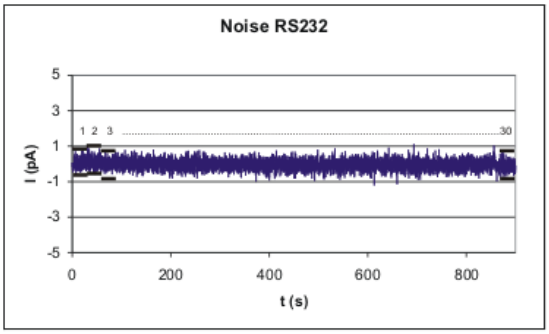


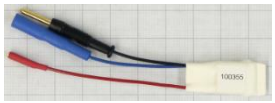
Fig. 1. Noise measurement.

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

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 I.

Settings

Table I. 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 8.

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 I, 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 8.

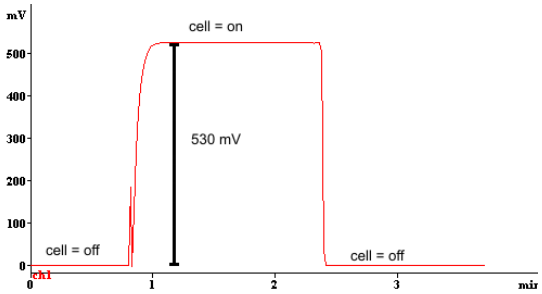


Fig. 2. Measuring output with dummy cell off and on at 5 nA/V, for other settings see Table I.

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 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	< 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) _____

CHAPTER 5

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 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: