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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 operational qualification must be filed together in one location.

CHAPTER 2

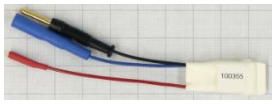
OQ procedure

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 stabile 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):

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

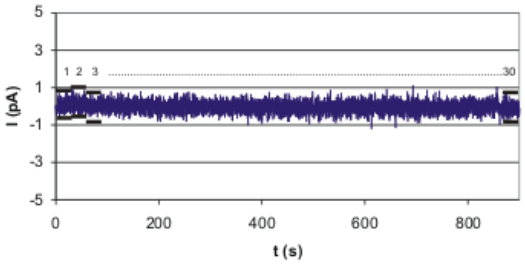


Fig. 1.Baseline noise measurement.

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 I

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 5.

Settings

Table I. 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.

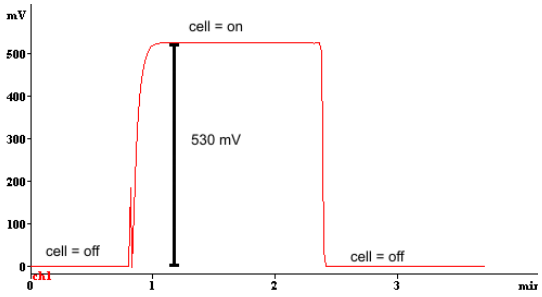


Fig. 2. Measurement of output from a dummy cell

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 II. 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 II.
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 5.

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 3

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 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	< ……* 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:

C H A P T E R 4

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 operational testing has been carried out in accordance to the 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

Instrument

DECADE (Elite, Lite, II) Intro or ROXY p/n: ……. s/n: …….

Instrument has DCC option (Y/N) …….

OQ test devices

Dummy cell*	p/n:	250.0040	s/n:	…….
Volt meter or AD signal		…….	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:

C H A P T E R 4

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: