



Antec
Industrieweg 12
2382 NV Zoeterwoude
The Netherlands

DECADE Elite

IQ manual

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Identification

The undersigned engineer certifies that he/she is trained and qualified to perform an IQ on the DECADE Elite™.

Performer:
Name Signature Initials

Company

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

The undersigned reviewer/customer accepts that the above-mentioned engineer is trained and qualified to perform an IQ on the DECADE Elite.

Reviewer/
Customer:
Name Signature Initials

Company:

Title:
(Owner-designated authorized person)

Instruments

- DECADE Elite* p/n: s/n:
 Flow cell p/n: s/n:
 REF electrode 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.

DECADE Elite options installed:

- External valve
 Dual cell control (DCC)
 Triple cell control (TCC)

Manufacturer Antec

Supplier

Date of delivery

Warranty until

Other relevant hardware

Description	Serial no

Verified by (customer):

Deviations (Y/N):

Comments:

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CHAPTER 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 practices. 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 and installation qualification must be filed together in one location.

As regulations and customer requirements may change, manufacturer reserves the right to introduce changes without prior notice.

Important information on safety practices, intended use, installation, operation and maintenance is provided in the DECADE Elite user manual. Before using your instrument or accessories, you must thoroughly read this information and safety practices. This manual is written for laboratory technicians who use the DECADE Elite detector for (U)HPLC analysis.



Unskilled, improper, or careless use of this instrument can create fire hazards, or other hazards which can cause death, serious injury to personnel, or severe damage to equipment and property. Observe all relevant safety practices at all times. Only use the device for applications that fall within the scope of the specified intended use. Else the protective and safety equipment of the device could fail.

CHAPTER 2

Installation**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	<input type="radio"/>	
Delivery is undamaged	<input type="radio"/>	
All items on checklist(s) are included	<input type="radio"/>	
Certificates of performance are included		
- detector	<input type="radio"/>	
- flow cell(s)	<input type="radio"/>	
User manual(s) is (are) included	<input type="radio"/>	

* 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 DECADE Elite user manual (chapter 2 "Installation"). Installation details of all different type of flow cells are described in the user manual delivered with your flow cell. It is the users' responsibility to prepare an installation site according to environmental specifications as described in the DECADE Elite user manual.

For a successful installation a few preparations must be made. This is a responsibility of the user. Note that all these preparations are explained in detail in chapter 2 of the DECADE Elite 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 used for preparation of mobile phase must be of HPLC grade or better (resistivity of 18 MOhm-cm). 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 DECADE Elite 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" and "safety practices" and "maintenance" in user manual(s) are 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 the 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	○	
The installation is done in accordance with the instructions in the DECADE Elite user manual rev no. ...	○	
Installation of optional parts is done in accordance with the instructions (if applicable)		
External valve doc. rev. no	○	
Dialogue software doc. rev. no	○	

Verified by (customer):

Deviations (Y/N):

Comments:

Operational familiarization

The DECADE Elite has been designed for maximum functionality and ease of use. Most of the operational parameters are intuitive and do not need further explanation. A few require explanation.

Table III

Check	In conf.	Non conf. ref. *
Concept of DC, Scan and Pulse mode has been explained	<input type="radio"/>	
Functionality in DIAG and CONFIG is understood	<input type="radio"/>	
Correct measurement range	<input type="radio"/>	
Functional characteristics of I/O contacts on rear panel have been explained	<input type="radio"/>	
It has been explained how to perform a dummy cell test	<input type="radio"/>	
Stop flow test has been explained	<input type="radio"/>	
Polishing of flow cell has been explained	<input type="radio"/>	
Maintenance of reference electrode has been explained	<input type="radio"/>	
Functional characteristics of options have been explained (if applicable)		
External valve	<input type="radio"/>	
Dual cell	<input type="radio"/>	
Dialogue software	<input type="radio"/>	

For detailed information regarding instrument operation, measurement modes, maintenance and trouble-shooting refer to the DECADE Elite or Flow cell user manual or the user manual of the accessories.

Verified by (customer):

Deviations (Y/N):

Comments:

CHAPTER 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 familiarized with the DECADE Elite electrochemical detector during the installation.

Antec representative

Technician name & signature
Company	
Date	

Customer (authorized to sign)

Name & signature
Company/dept.	
Date	

Operator(s) trained for DECADE Elite

Name & initial
Name & initial
Name & initial

Comments

Verified by (customer):

Deviations (Y/N):

Comments:

CHAPTER 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 Leyden rep.
1	
2	
3	
4	
5	
6	

Verified by (customer):

Deviations (Y/N):

Comments:

