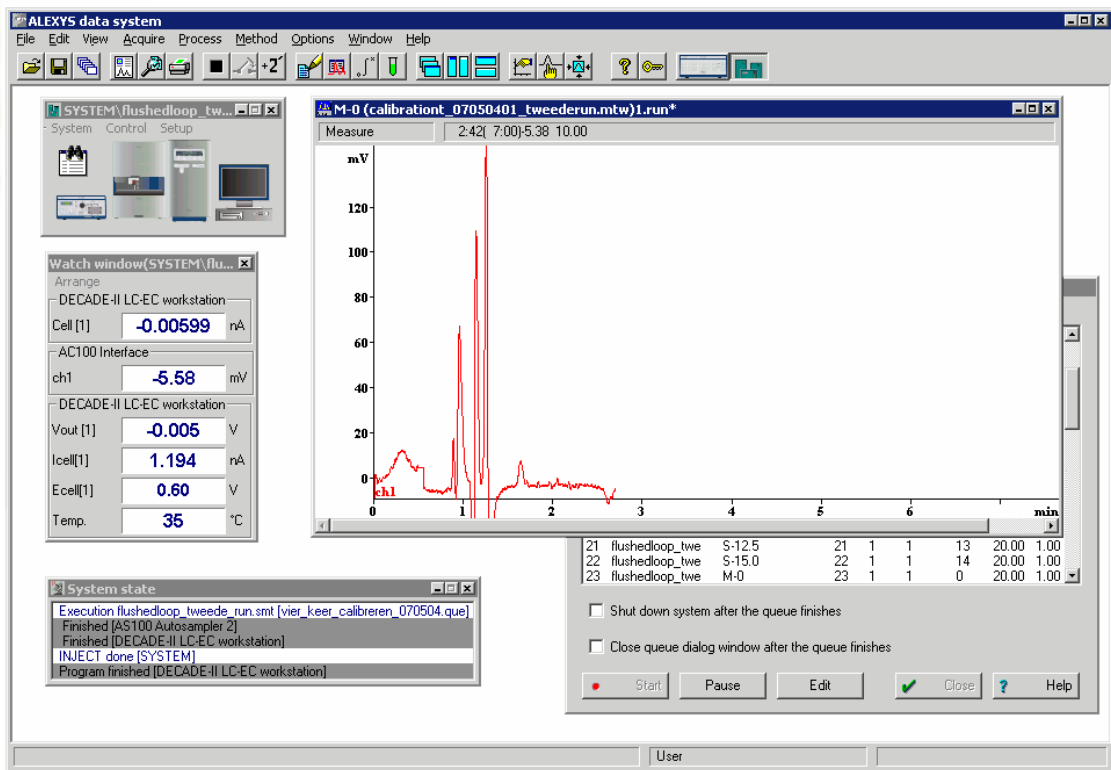


# ALEXYS data system

IQ





# Identification

The undersigned engineer certifies that he/she is trained and qualified to perform an IQ on the ALEXYS data system software.

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 ALEXYS data system software.

Reviewer/  
Customer: .....  
Name Signature Initials

Company: .....

Title: .....  
(Owner-designated authorized person)

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

Comments:

## Software

ALEXYS version	
Dongle s/n	

Manufacturer	Antec Leyden
Supplier	

Date of delivery	
------------------	--

Verified by (customer): .....

Deviations (Y/N): .....

Comments:

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Verified by (customer): .....

Deviations (Y/N): .....

Comments:

## C H A P T E R 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 practises.

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 an installation qualification must be filed together in one location.

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 software user manual.

Verified by (customer): .....

Deviations (Y/N): .....

Comments:

## 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.

The ALEXYS data system set includes following parts:

- Installation CD with ALEXYS data system and drivers
- USB license dongle
- User manual

Carefully unpack the box 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.

**Table I**

<b>Check</b>	<b>In conf.</b>	<b>Non conf. ref. *</b>
Delivery is in accordance with order	○	
Delivery is undamaged	○	
All items on checklist(s) are included	○	
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 software installation procedure is described in the ALEXYS data system user manual (Chpt. "Installation & Configuration"). It is the users responsibility to meet the computer & hardware requirements for installation. The minimum requirements for basic configuration are listed below:

- 800 MHz Pentium computer with 256 Mb memory
- Windows 98, Windows NT, Windows 2000 or Windows XP operating system. The 21CFR part 11 support version only operates under Windows 2000 or Windows XP Professional Edition using an NTFS disk partition
- 15 Mb free space on hard disk (is needed for installation only)
- 100 Mb free space on hard disk drive for data storage
- Monitor resolution 1024x768 with 16-bit colour depth
- One free RS232 port to connect the AC 100 interface
- One free USB port to connect a USB license dongle

Important installation information:

- Before inserting the USB dongle in the PC it is important that the USB license key drivers are installed.
- Always switch off AC 100 when starting up Windows or PC
- When upgrading:
  - Always uninstall previous ALEXYS version
  - Remove ALEXYS folder from PC (or copy to a safe place)
  - Download and install ALEXYS system files installer containing all new developed system files for a quick start.

**Table II**

Check	In conf.	Non conf. ref. *
Section "installation & Configuration" in user manual(s) is noticed	○	
The PC & hardware requirements for installation are met	○	
Installation of software is performed in accordance with user manual rev no. ...	○	

Verified by (customer): .....

Deviations (Y/N): .....

Comments:



## Software IQ utility

Upon installation (ALEXYS versions 1.0.195 >) the ALEXYS data system automatically installs a software Installation Qualification utility to verify that all software components are correctly installed. A report is generated and can be printed out (see screen dump below).

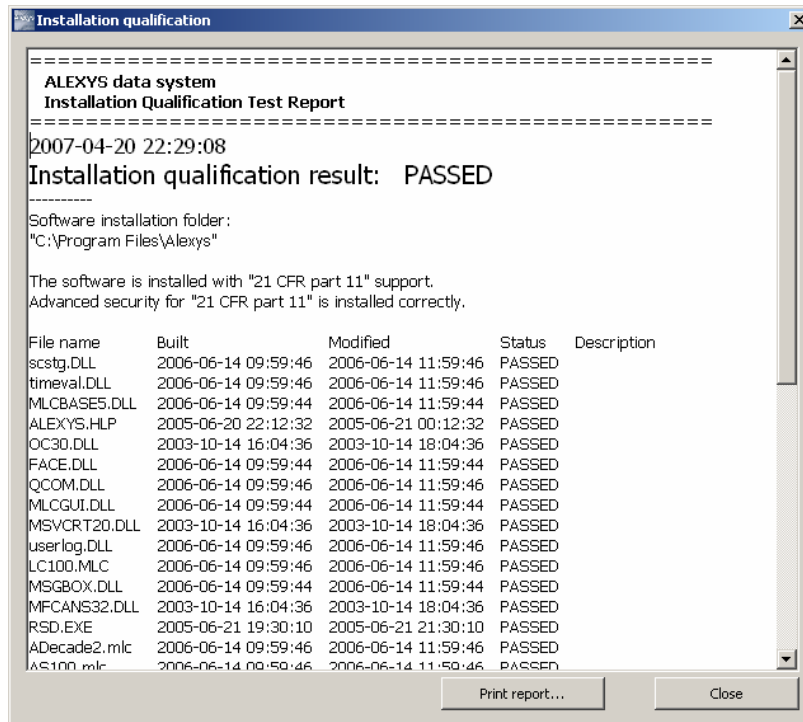


Table III

Check	In conf.	Non conf. ref. *
An IQ test report is printed and all installed software files are 'passed'	○	
In case of an 21CFRpart11 support installation the advanced security feature is installed correctly.	○	

Verified by (customer): .....

Deviations (Y/N): .....

Comments:

## Operational familiarisation

The ALEXYS data system software has been designed for maximum functionality and ease of use. Most of the operational issues are intuitive and do not need further explanation. A few software features require a basic explanation.

**Table IV**

<b>Check</b>	<b>In conf.</b>	<b>Non conf. ref. *</b>
Concept of a system and method file has been explained	<input type="radio"/>	
An example system & method configuration has been build from scratch and explained	<input type="radio"/>	
A sample queue has been programmed and explained.	<input type="radio"/>	
Explanation of (manual) integration and setting peak table and calibration curve has been given	<input type="radio"/>	
Batch-reprocessing of a series of sample queue chromatograms has been performed	<input type="radio"/>	
Report and summary report functionality has been demonstrated	<input type="radio"/>	
Global preferences are explained	<input type="radio"/>	
If applicable the 21CFRpart 11 support features are explained	<input type="radio"/>	

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 familiarised with the ALEXYS data system software during the installation.

### Antec Leyden representative

Technician name & signature	.....
Company	
Date	

### Customer (authorised to sign)

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

### Operator(s) trained for the ALEXYS data system

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

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 installation should be documented and signed for acceptance or corrective action taken.

**Table V**

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: