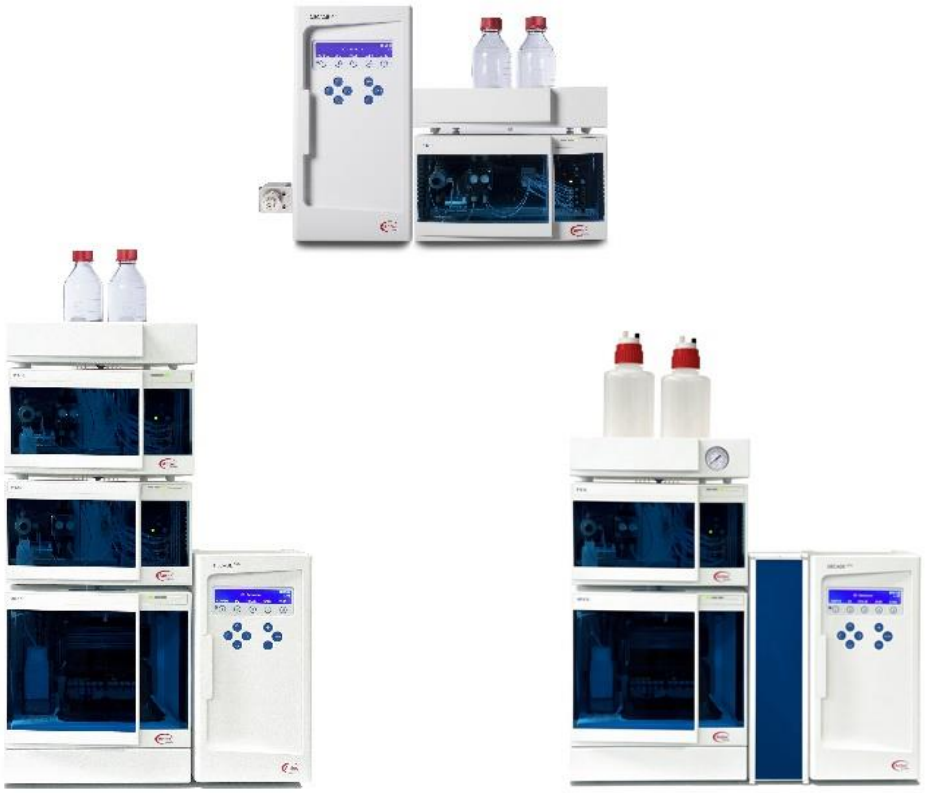
# Installation checklist

for ALEXYS Analyzers
with Clarity software

180.0011W, Edition 4, 2025



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## Symbols

The following symbols are used in this guide:


The danger sign warns about a hazard. It calls attention to a procedure or practice which, if not adhered to, could result in injury or loss of life. Do not proceed beyond a danger sign until the indicated conditions are fully understood and met.


The warning sign denotes a hazard. It calls attention to a procedure or practice which, if not adhered to, could result in severe injury or damage or destruction of parts or all of the equipment. Do not proceed beyond a warning sign until the indicated conditions are fully understood and met.


The caution sign denotes a hazard. It calls attention to a procedure or practice which, if not adhered to, could result in damage or destruction of parts or all of the equipment. Do not proceed beyond a cautions sign until the indicated conditions are fully understood and met.


The biohazard sign draws attention to the fact that use of biological materials, viral samples and needles may carry a significant health risk.

The attention sign signals relevant information. Read this information, as it might be helpful.

The note sign signals additional information. It provides advice or a suggestion that may support you in using the equipment.

## Safety practices

The ALEXYS installation may only be performed by a qualified service engineer trained by the manufacturer. The following safety practices and protective measures are intended to ensure safe operation of the instrument.

### Electrical hazards


Never open a device when it is connected to an electrical power source! Removal of protective panels on the instrument can result in exposure to potentially dangerous voltages which may lead to **severe injury or loss of life**! The instrument may only be opened by authorized service engineers of the manufacturer or a company authorized by the manufacturer.

WARNING - RISK OF ELECTRIC CHOCK
DISCONNECT POWER BEFORE SERVICING

AVERTISSEMENT - RISQUE DE CHOC ELECTRIQUE
COUPER L'ALIMENTATION AVANT LA MAINTENANCE

### Solvents


Organic solvents are highly flammable. Since capillaries can detach from their screw fittings and allow solvent to escape, it is prohibited to have any open flames near the analytical system.
If a leakage occurs, turn of the power of the instrument and remedy the situation immediately. Regularly check for leaks and clogged LC tubing and connections. Do not close or block drains or outlets. Do not allow flammable and/or toxic solvents to accumulate. Follow a regulated, approved waste disposal program. Never dispose of such products through the municipal sewage system.


### Toxicity:

Organic solvents are toxic above a certain concentration. Ensure that work areas are always well-ventilated! Wear protective gloves, safety glasses and other relevant protective clothing when working on the device!
Use proper eye and skin protection when working with solvents. Additional safety requirements or protection may be necessary depending on the chemicals used in combination with this equipment. Make sure that you understand the hazards associated with the chemicals used and take appropriate measures with regards to safety and protection.


### General precautions

Use of this product outside the scope of this guide may present a hazard and can lead to personal injury.

## Spare parts and service availability

Manufacturer provides operational spare parts of instruments and current accessories for a period of five years after shipment of the final production run of the instrument. Spare parts will be available after this five years period on an 'as available' basis.
Manufacturer provides a variety of services to support her customers after warranty expiration. Repair service can be provided on a time and material basis. Contact your local supplier for servicing. Technical support and training can be provided by qualified chemists on both contractual or as-needed basis.

C H A P T E R 1

# Introduction

This document is intended as a **general master checklist** to guide the technical engineer through the process in preparation of and during an installation of an ALEXYS Analyzer. This document will highlight the most efficient order of actions and refers to the installation sections of the user manuals for details. This document also contains a section with Appendixes with details for Clarity software installation and the passivation or rinsing details.


This document is by no means a replacement of the installation sections described in the user manuals supplied with the system.

C H A P T E R 2

# Preparing for installation

## IQ

A printed copy of an Installation Qualification (IQ) document (pn. 180.0024) is provided with each ALEXYS Analyzer (and available for download from our website). This document is a guideline, sign-off document and checklist covering important details of the installation and content of the training/instruction that has to be given to the end user.

A completed and signed IQ document will serve as an objective proof that the installation was completed successful and was carried out to the satisfaction of both parties.

- Familiarize yourself with its contents, perform the installation according to the guides given herein, and fill in the IQ document during the installation.

## OQ

A printed copy of an Operation Qualification (OQ) document (pn. 180.0023x) is provided with the DECADE Elite (and available for download from our website). This document describes the OQ tests and is used for sign-off.

A completed and signed OQ document will serve as an objective proof that the detector is performing within specs after having been on transport.

- Familiarize yourself with its contents, perform the tests according to the guides given herein, and fill in the OQ document during the installation.

## PQ

A Performance Qualification (PQ) is a procedure that checks the complete ALEXYS Analyzer. If a PQ is required by the customer as part of the installation at the customers site, double check if the correct set of PQ consumables were ordered, in advance of an installation. See the info on our website for details about PQ.

## Info to send to a customer in advance of an installation

This paragraph highlights the set of documents that should be sent to the customer well in advance of an installation, as it takes time to prepare all the required items.

**PC requirements document**

The ALEXYS Analyzer does not cover a personal computer and router. **A PC and router have to be organized separately by the customer.** A list with specific requirements and settings for the PC and router are given in this document:

- ‘PC requirements’(pn. 195.7000)

**General installation requirements document**

Before installation, the laboratory where the system is going to be installed should have a certain set of chemicals, consumables, facilities and free bench space to run the analysis of interest. A list with specifications and requirements is given in this document:

- ‘General requirements for installation of ALEXYS systems’ (pn. 180.7070C)

**Application specific requirements document**

Application associated requirements are listed in specific documents. We regularly update/add new documents when new applications have been developed, and therefore we recommend to check the website for the latest versions and download it! Check www.antecscientific.com and search for *‘site preparation documents’.*

- Download the latest version of the correct application specific requirements documents from our website and verify the content before forwarding

## Download most recent versions of software

To assure that the system will be installed with the most recent software version available we recommend to

- download a copy of the relevant software (Table 1) from the Antec and DataApex website shortly before installation to a transportable disk.

*Table 1. List of software programs recommended for download before an installation of an ALEXYS system.*

| Software program | pn | website | Remark |
|---|---|---|---|
| Clarity | C50 | DataApex | Acquisition and data processing software for ALEXYS |
| Dialogue Elite | 175.9007 | AntecScientific | Service software and direct control over DECADE Elite |

## Documents to read before installation

When preparing for an installation, we advise to

- familiarize yourself with the contents of the IQ OQ PQ documents, the system related manuals and this checklist document.

In the tables below all relevant user manuals and installation manuals are listed. ALEXYS systems are shipped with all manuals on a USB stick, and a few manuals are provided as well in print.

*Table 2. Part numbers and titles of the manuals that are shipped in print with each ALEXYS Analyzer.*

| pn | Title |
|---|---|
| 180.0011W | ALEXYS installation checklist |
| 171.0023 | IQ OQ for D2 Elite Lite and ROXY |
| 180.0024 | IQ for ALEXYS |
| 171_0023O* | OQ for D2 Elite Lite and ROXY* |
| 171_0023P* | PQ for D2 Elite Lite* |
| 180.7001W | LC connections installation guide |
| 191_0011 | AS6.1L user manual |
| 194.0010 | P6.1L pump user manual |
| 116.0014 | SenCell Quick-start guide |

** provided in PQ consumables kit, if ordered*

*Table 3. Part numbers and titles of current user manuals and installation related documents.*

| pn | Title |
|---|---|
| 175.0010 | DECADE Elite user manual |
| 102.0010a | Flexcell user manual |
| 250.7010 | Flexcell metal WE flattening-polishing kit |
| 116.0010 | SenCell flow cell user manual |
| 180_7070C | General requirements for installation of ALEXYS systems |
| 195.7000 | PC requirements and settings |

C H A P T E R 3

# Installation

**General guidelines**

- Start with checking the exterior of the transport boxes and inform the transport company immediately in case of visible damage.
- Store the transport boxes as they have custom fit cushions and may be needed again.
- For each instrument check the contents of accessory kits etc. using the supplied checklist to assure it is complete
- Install each instrument according to the instructions of its user manual
- Check that all parts are undamaged.
- Write down the part number and serial number of each unpacked unit in the IQ document.

## Unpacking

**Instrument assembly schematics**

- First open the **ALEXYS LC connections kit** and take the schematic LC drawing out as a guide where each instrument is placed relative to the other.

**Unpacking order of instruments/parts**


**Make sure that the placement of the instruments will not obstruct the air flow of fans in the equipment because this could impair the cooling capability (pump and autosampler: back-side, detector: bottom).**

- Unpack the **DECADE Elite** and place it on the bench.
- Unpack the **autosampler** and place it on the bench (or mount it on the side panel in case of an electrical valve)
- Unpack the **pump(s)** and place it (them) on the bench or on top of the autosampler.
- Unpack the **eluent tray** and place it on top of the pump.
- Unpack the **pulse damper(s)** and mount it on the side of the pump.

## Powering up

### Power cables

- ❑ Each instrument's ship kit contains an EU and US style power cable; organize enough alternative power cables in advance if necessary.


**When it is necessary to use a different mains cable than supplied, make sure that the cable meets all relevant safety and EMC requirements (CE, CSA and UL). The manufacturer is not liable if power cords are used that do not meet the relevant safety and EMC requirements.**

### Connecting the power cables and powering on

- ❑ Make sure the power button of the instrument is set to OFF before making a connection.
- ❑ **DECADE Elite detector**– power it on, and manually set the oven temperature to 35 °C. Connect the dummy cell to the cell cable and let it stabilize at 800 mV (the OQ dummy cell test setting)
- ❑ **AS6.1L autosampler** – first remove the transport tape securing the sample trays inside the sample compartment, then power it on.
- ❑ **P6.1 pump** – remove the stoppers from the pump head and install the pump piston wash tubing and piston wash solution (see 'LC connections installations guide') before powering on the pump.

## Digital communication between ALEXYS and computer

### LAN

For software control over the ALEXYS Analyzer, a dedicated local area network (LAN) has to be created with a network switch and the 'LAN connection kit' (pn. 250.0180) that contains the dedicated LAN-cables.

- ❑ Verify if the PC specifications and operating system are in compliance with the PC requirements document (p/n 195.7000). Adapt the PC energy saving settings and virus scanner settings where necessary.

- Follow the instructions in the LAN connection kit install guide (pn. 250.7018) to set the correct IP address to the LAN-port.
- Use the cables from the LAN connection kit to connect with the LAN switch box. Do not use the LAN cables from the instrument's individual ship kits!

## Perform the DECADE Elite OQ test

### Install Dialogue Elite software

- Install the Dialogue Elite software according to the instructions given in the manual 'Dialogue Elite user manual' (document. 175_0015).

### Run the analogue output and dummy cell test

- Follow the instructions in the (IQ)OQ document 171_0023(O)
- Use Dialogue Elite software for generating automated dummy cell noise test output
- Use a voltmeter for the Analogue output test
- Check and sign the results.

## Place the ALEXYS system under Clarity software control

### Clarity software

- Install the Clarity software according to the instructions given in 'Appendix I' of this document.

### Antec pre-configured Clarity files

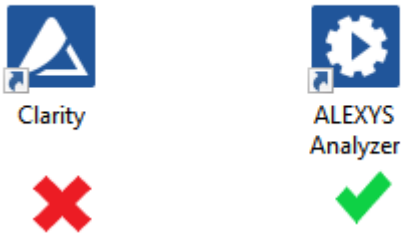
- Install the Clarity software according to the instructions given in 'Appendix II' of this document or make the configuration and methods from scratch.

### Check and adjust the pre-configured Clarity method files

Before actually using the methods and sending the settings to the instruments, the settings have to checked carefully, confirmed and understood.

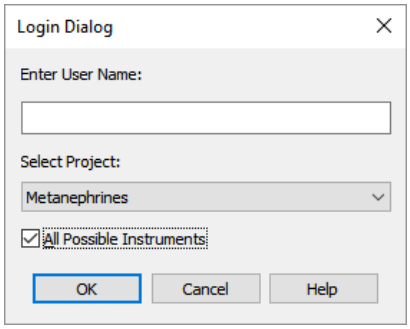

**Only "Send method to instrument" after having installed the whole system, having checked the method settings and running with the correct mobile phase.**

- ❑ Start the Clarity software program with the dedicated Clarity short-cut key with the ALEXYS application name (not with the 'Clarity' key as this evokes the default settings).




*If for any reason the 'Cancel' button was chosen, close down and restart Clarity again to make all the preconfigured links functional.*

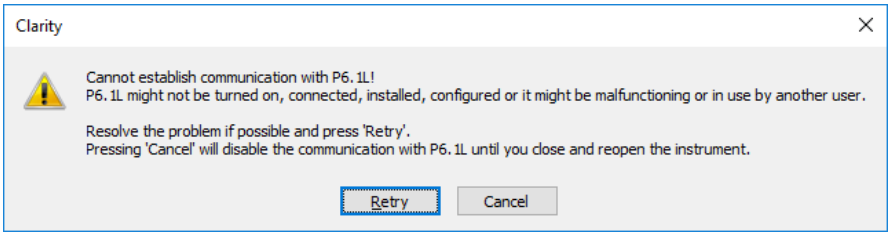
- ❑ Click on the 'Login' dialog' box in the middle of the system picture, and make sure to check the 'All possible Instruments' checkbox every time you log into the instrument.




- ❑ Open, check and update all the tabs in each method where necessary.

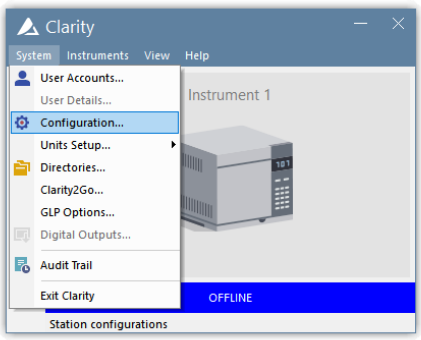
**Update the instrument's serial number in the Clarity preconfigured files before first use**

If the default instrument serial number is not updated to that of the connected instrument, this will prompt the following dialogue box (example for the pump):

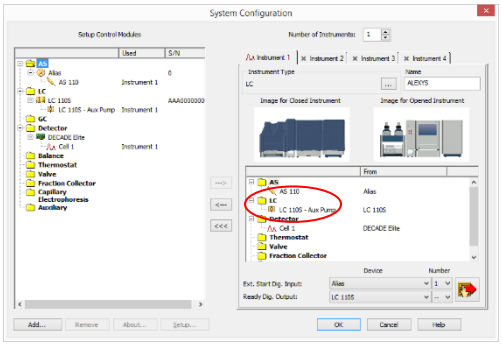



The update for each instrument's serial number should be done at the level of the instrument control module:

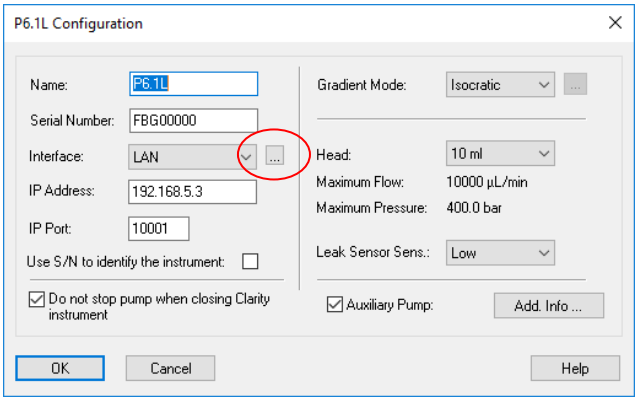
- ❑ Start up the software using the dedicated Clarity short-cut key with the ALEXYS application name.
- ❑ From the Main window, open the system configuration window (System/Configuration).



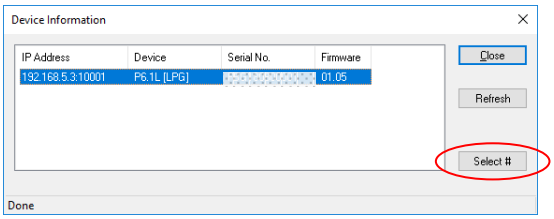

- ❑ Open each instrument's driver by double clicking it.




- ❑ In the example of the pump control module screen, double click on the '. . .' button. This works the same for the autosampler:




- ❑ Click the ‘Select #’ button to update the serial number.




- ❑ Close all the Clarity windows by clicking Close or OK
- ❑ Close Clarity software (which saves the changes)

The ALEXYS Analyzer is now under control of the Clarity software.

### Starting up the application with manual control over the instruments

The Clarity window ‘Device Monitor’ gives direct control over the individual instruments when connected to Clarity. This window is useful when the pump has to be purged or when the initial wash command has to be given to the autosampler.

# Liquid connections

**Drain tubing**

Make sure that all drain tubing are connected:

- Funnels and drain tubing at the frontside of the pump front
- A tube to a waste container below the system in case the pumps are set directly on the bench.
- A funnel to on top of the autosampler in case the pumps are set on top of it.
- One drain on the side of the AS6.1L autosampler.

The main source of liquid from drains will be the wash solvent and condensation water from the autosampler.

**Flow path part 1**

Follow the instructions in the 'LC connections installation guide' (pn 180.7001W) to build the LC flow path:

- Install the liquid flow path as depicted in the schematic drawing **up to the injector**.
- Connect the PQ-FIA tubing coil to the injector in preparation of the PQ and to generate some backpressure while rinsing.
- Open the Clarity Device monitor from the instrument window (from the menu: Monitor/Device monitor; or use the icon)
- Execute 'Initial wash' to remove air from the flow path of the autosampler.

# Passivation/rinsing

- Use the Clarity Device Monitor Window for direct control over the pump and autosampler.
- For metal containing system, apply the passivation procedure with nitric acid, including the cleaning step with water (see Appendix III)
- For metal-free systems apply the rinsing procedure with 2 M NaOH (see Appendix IV)

## Perform the PQ test

### Prepare the system for PQ

- ❑ Make sure to flush the lines thoroughly clean of rinsing/passivation solutions
- ❑ Follow the instructions in the PQ document 171_0023(O) and equilibrate the system with the correct mobile phase

### Connect the flow cell

- ❑ Follow the instructions in the flow cell manual to install the cell in the flow path, but not before the system has completely equilibrate in mobile phase.

### Run the system PQ tests

- ❑ Follow the instructions in the PQ document 171_0023(O)
- ❑ Use Clarity software for running the PQ test
- ❑ Check and sign the results.

## Connecting the column and flow cell

### Flow path part 2

- ❑ If the PQ was run, remove the PQ FIA tubing and the flow cell from the system.
- ❑ Make the flow path as depicted in the schematic drawing **up to the column**.
- ❑ Flush the lines with a solution that is compatible with the transport solution that is inside the column (see column care instruction).
- ❑ Connect the column to the injector and the waste line to the column outlet
- ❑ Flush the column with the appropriate solutions and let it equilibrate in mobile phase.
- ❑ For **separations based on ion pairing** and a new C18 column, run the mobile phase for at least 16 hours (overnight) through the column to flush and equilibrate it before installing the flow cell.

- For **separations based on anion exchange** chromatography, the column should be flushed and equilibrated according the column instructions before installing the flow cell.

**Connect the flow cell**

- Follow the instructions in the flow cell manual to install the cell in the flow path, but not before the column has completely equilibrate in mobile phase.


**Do NOT turn ON the cell if it is not yet primed with mobile phase.**

## Test injections

**Analyze standards**

- Run some test injections and tweak the system settings if needed.

## Clarity training

To make the customer acquainted with the Clarity software, a presentation about the **concept** of Clarity for use with ALEXYS, and a **hands-on training document** are available on our website:

Clarity - Antec Scientific

- The Clarity hands-on training manual (pn. 195.7010) helps to learn working with this software.
- The example-chromatograms for hands-on training are available from the ‘Clarity Antec Analyzers.zip’ (for installation see Appendix II).

A P P E N D I X I

# Installation of Clarity acquisition software

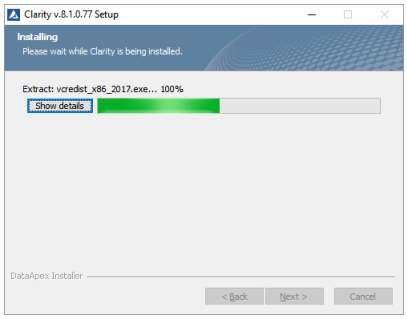

## General guidelines

**Do <u>NOT</u> insert the Clarity dongle before the Clarity installation process is completely finished!**

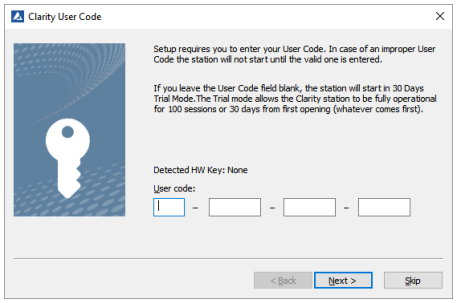

**Make sure to install the newest Clarity version (check DataApex website), as the Clarity user key code is not backwards compatible with older versions.**

## Instructions

- Start the installation using the exe-file for Clarity installation.
- Accept the default settings:
  - location for Clarity software (computer C-drive)
  - location for data
- The software installation can take a few minutes.

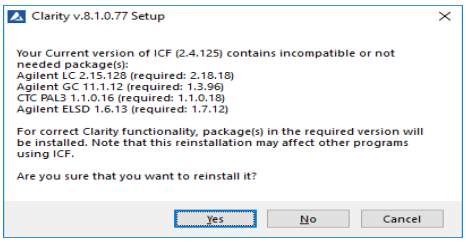



- When prompted for the User code, insert the hardware key and enter the correct code, which can be found on the front of the box and also inside the paper copy of the Clarity booklet.

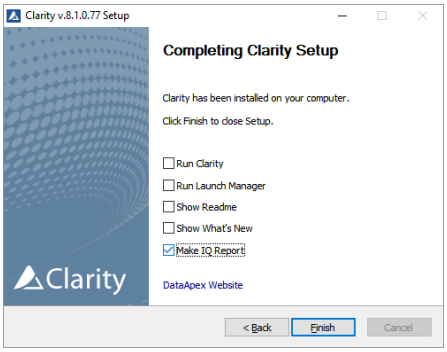


If this step is skipped, the user code can also be entered at a later stage after restarting the Clarity software (Main menu/About/User code).

- ❑ In case a message pops up asking to allow the reinstallation of some driver, select 'Yes'.




- ❑ Accept the additional pop-up requests for installation of drivers during the installation process.
- ❑ At the end of the installation check the "Make IQ report now" box to generate the Clarity IQ report.




- ❑ Run the 3rd party package validation and print both IQ reports.

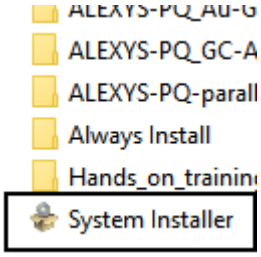

*Example of a Clarity IQ report*

A P P E N D I X I I

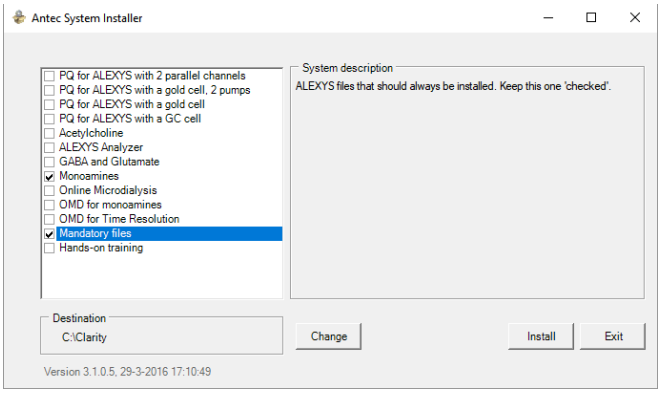
# Installation of pre-configured Clarity files

For different applications with ALEXYS LC-ECD analyzers, pre-configured Clarity files are available. The correct set of application-specific files can be installed from the Antec USB stick:

- Open the folder '195_0035 - Clarity Antec Analyzers' and run the 'System Installer'.




- Select the right application.
  - The right part of the installer window (Feature description) gives details about to which set of hardware the files apply.
  - More than one application can be selected at this point.
  - Make sure to select the 'Mandatory files' and the 'Hands-on training' in addition to any other files





**Be aware that any changes made to the installed files will be overwritten with the original settings when 'adding' other method installers after initial installation.**

A P P E N D I X I I I

# Passivation of new metal-containing systems

For optimal performance of the ALEXYS Analyzer, some parts of the LC system should be rinsed with an appropriate solution before the system is used.

The systems that contain metal parts in the flow path are the ALEXYS Neurotransmitter Analyzer and the ALEXYS Clinical Analyzer.

All new metal parts in the system should be passivated before use. Metal parts that are in contact with the mobile phase are:

- the pump head
- metal tubing on the pump
- the pulse dampener
- valve
- metal sample loops

In principle, the procedure consists of running (preferably) a 15% nitric acid solution through the metal parts for 20 minutes and rinsing it clean afterward with water.

Make sure that all non-metallic parts that are not acid-resistant (nylon Whatman inlet filters, degasser channels, column and flow cell) are disconnected during this procedure.

**(Dis)connection instructions**

- First make sure that all the connections are leak-tight by pumping water through the lines and inspecting each connection.
- If already attached, disconnect the tubing between the injector and (pre)column at the (pre)column side and lead the tubing outlet into a dedicated waste bottle.
- Disconnect the 1/8” OD outlet tubing from the degasser, slide the connector away from the tubing end (if already attached), and place the open end in a small bottle with about 50 mL of 15% nitric acid.
- A schematic picture of the connected tubing is given in Figure 1.

**Procedure**

- Set the flow rate of the pump to a reasonable setting (resulting in a backpressure between 5-50 bar), check if there is enough solution in the bottle to run 20 min at the chosen flow rate and run the acid through the system for 20 minutes.
- **Regularly switch** the valve of the injector to assure that both Load and Inject positions will be passivated!

- After running the acid through the system, flush the system thoroughly with water, with the injector **regularly switching** between Inject and Load positions.
- Check the pH of the waste solution (with pH paper) to confirm that all nitric acid has been flushed out of the system. The pH should be around 7 (water) before continuing with the installation.

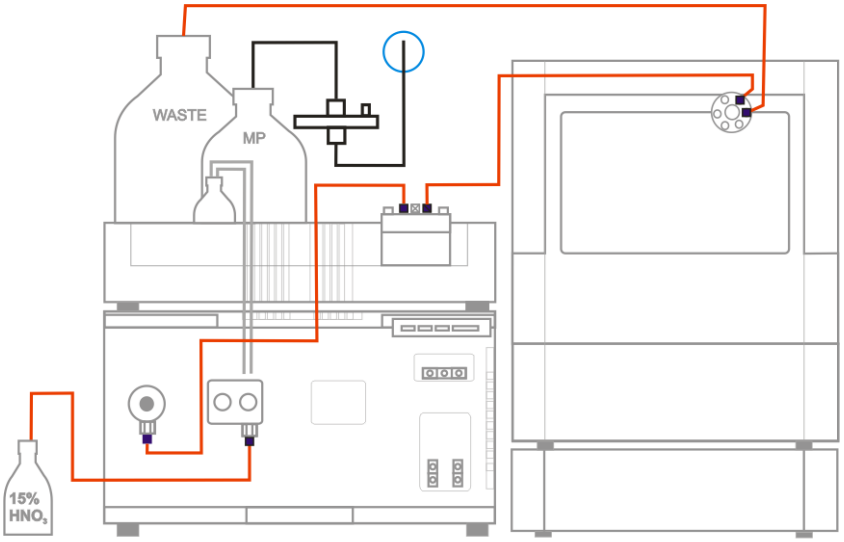



*Figure 1. Flow path configuration schematics for passivation of the metal parts in an ALEXYS system. Note that the nitric acid is not going through the Whatman in-line filter, the detector, nor the degasser channels. In case of a dual channel system or gradient set-up the same principle is applied.*

A P P E N D I X  I V

# Rinsing procedure for new metal-free systems

A new ALEXYS Carbohydrate Analyzer should be flushed with a high concentration of NaOH before installing a column. The column and cell can be installed after the rinse.

**Procedure**

- First make sure that all the connections are leak-tight by pumping water through the lines and inspecting each connection.
- Connect one of the eluent lines from the degasser channel to the bottle filled with 2 M NaOH solution.
- Set the flow rate of the pump to a reasonable setting (resulting in a backpressure between 5-50 bar), check if there is enough solution in the bottle to run 20 min at the chosen flow rate and run 2 M NaOH through the system for 20 minutes.
- Make sure to flush the high concentration of NaOH away with 0.1 M NaOH solution (check the column specification sheet for the flushing instructions) before continuing with the installation and connecting the column.

**Do not let the system stand still for a prolonged period after using NaOH as the mobile phase to avoid the formation of NaOH salts and system blockage.**

A P P E N D I X V

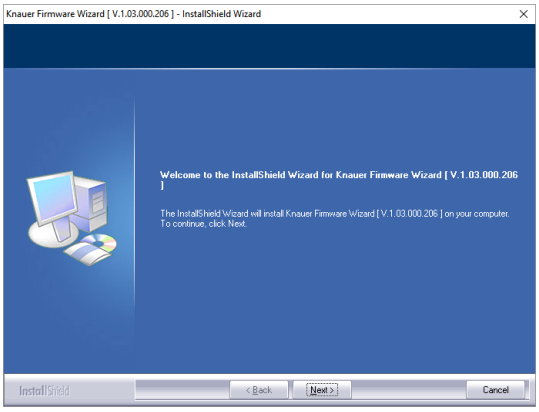
# Adjustment of internal pump settings

All new P6.1L pumps are preconfigured to communicate over LAN using IP address 192.168.5.3. In case of an ALEXYS system with an additional pump, the IP address 192.168.5.4 is used as a factory setting. In case two instruments in an ALEXYS system share the same IP address, Clarity will not be able to control them, and one of them will need adjustment. This appendix shows how to modify the pump IP address.

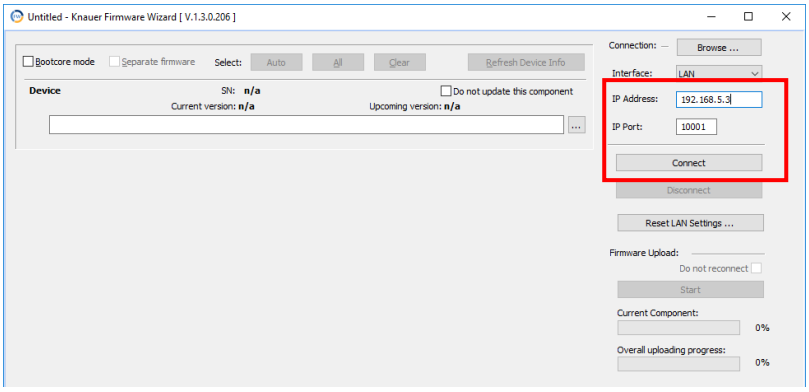
## Changing the IP address of a pump

- Install the 'Knauer_FirmwareWizard' software tool to access the internal pump settings
  - a copy of this installer is on the Antec USB stick folder:

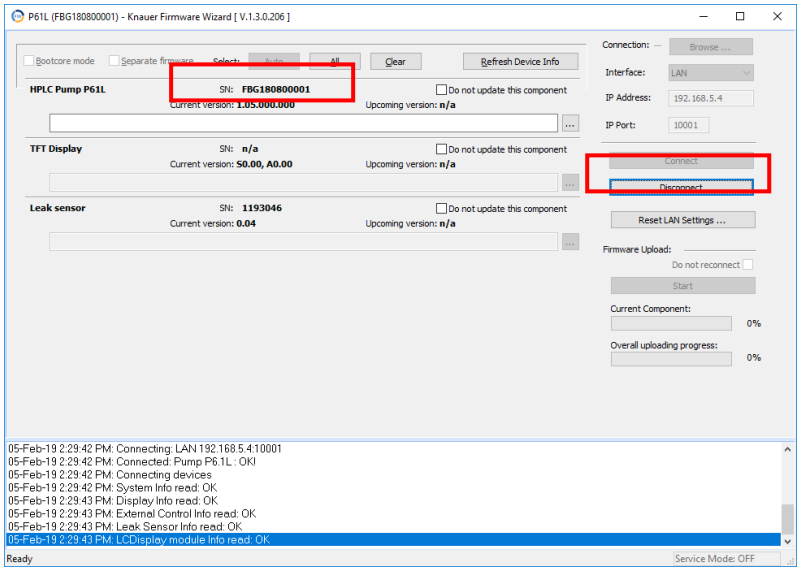
    *software\srv\P6.1L_tools.zip\P6.1L_tools*



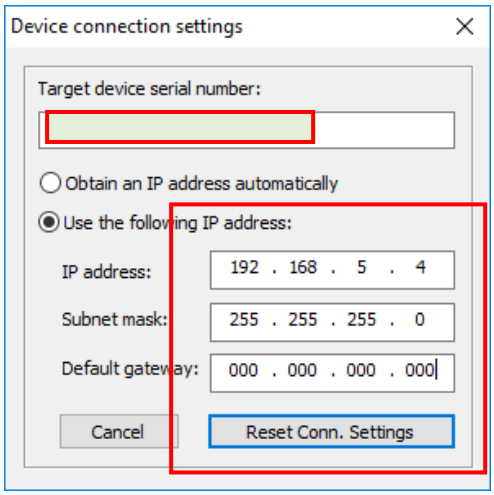

- Make sure only one pump is connected with a LAN-cable at this point.
- Start the 'Knauer_FirmwareWizard', fill in the current IP address of the pump and click 'Connect'.



- ❑ Note/copy the serial number of the pump and click the ‘Disconnect’ button




- ❑ With the target pump ‘Disconnected’ from the software, click the ‘Reset LAN settings’ button, fill in the serial number of the pump, the new IP address, Subnet mask (255.255.255.0) and default gateway (000.000.000.000).




- ❑ Click the button ‘Reset Conn. Setting’, and the IP address will be changed.
- ❑ Doublechecking for a successful change can be done with the ‘Connect’ button after typing the new IP address.