



IC System Installation Qualification

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PRINTING HISTORY

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1 Introduction

Validation is becoming increasingly important to analytical laboratories. Documented evidence must be provided to demonstrate the integrity of data collected and validate the results obtained on laboratory instrumentation.

Many laboratories achieve this by formal quality systems, which are generally implemented in accordance with one or more of the three internationally recognized quality standards:

- ❑ **ISO 9001**
- ❑ **Good Laboratory Practice (GLP)**
- ❑ **ISO Guide**

These standards are written in broad terms, to make them as widely applicable as possible. All stipulate general requirements specifying instruments must be fit for purpose, properly maintained and calibrated to national or international standards. The procedure used for Dionex IQ is adapted to these standards.

This procedure provides IQ for the DX-500, DX-600, DX-320, BioLC and DX-120 systems.

2 Installation Qualification (IQ)

Installation Qualification covers all procedures relating to the installation of instruments in a specific environment. IQ Confirms that the instrument(s) were shipped as ordered and that the environment where the system is installed is suitable for operating the instrument.

Performing the IQ is required at the initial installation of the instrument or when a new module is added to an existing instrument.

IQ documents the following items:

- That the instruments, including all modules and accessories, were shipped as ordered and were inspected for shipping damage.
- That the required computer hardware and software were supplied.
- That the laboratory environment is suitable for the system
- That there is sufficient space to install the instrument and the required materials for the installation are available.
- That the installation of the instrument was performed exclusively according to the manufacturer's guidelines.
- That the instrument functions as expected when first operated and that any deviations are recorded.
- That existing peripheral equipment is connected correctly.

3 Performing the Installation Qualification

3.1 Customer and Shipment Information

Fill in the customer information located in Section A of the IQ Worksheet. This documents that the shipment was received according to the actual purchase order placed and all relevant customer information is documented.

3.2 Facility Requirements

Confirm that the facility requirements located in Section B of the IQ Worksheet are available prior to performing the installation. Document item availability in the worksheet.

3.3 System Installation

3.3.1 Unpacking

1. Check all shipping boxes for visible damage. If there is any damage, document the details in Section E of the IQ Worksheet.
2. Place the box on the floor, open it and remove accessory items.
3. Remove the module using the foam packing insert handles.
4. Remove any packing material.
5. Confirm that the module is not damaged. If damage is visible, inform the customer and transport company immediately. If necessary, take photographs and note names of witnesses to prove the damage. Document all details in Section E of the IQ Worksheet.
6. Confirm that the module ship kit and all other necessary accessories have been provided.
7. Record all unpacking information in Section C of the IQ Worksheet.

3.3.2 Placing Modules on Bench

1. Place the base modules on a firm, vibration free surface.
2. Confirm that the bench where the modules are to be installed is not exposed to temperature fluctuations, high humidity, or direct sunlight.

3. Modules may be stacked one on top of each other as long as it is in accordance with the customer's laboratory height requirements. In general, do not stack more than three single stack modules (i.e. one pump and one detector) together.
4. When all modules have been set up on the bench, record this in Section C of the IQ Worksheet.

3.3.3 Electrical and LAN Connections

1. Connect all module power cords and plug into laboratory electrical source.
2. Connect all LAN or 10 Base T cables from the module to the computer or hub box (if applicable).
3. Connect any Relay or TTL cables (if applicable).
4. Make all detector cell connections.
5. When all module connections have been made, record this in Section C of the IQ Worksheet.

3.3.4 Liquid Line Installation and System Equilibration

Note: Do not install columns and suppressors at this time. They will be installed later in the procedure.

1. Using the tubing provided in the module shipkits, make all appropriate liquid line connections between the pump, injection valve, autosampler, accessory modules and the detector cell.
2. Confirm a sink or appropriate waste receptacle is available for system liquid waste.
3. Fill an eluent bottle with 18 meg-ohm deionized, filtered water and connect it to the pump. Prime the pump for approximately 5 minutes, using isopropyl alcohol if needed.
4. Select a flow rate of 1.00 mL/min and flush the entire system for approximately 15 minutes.
5. When the system has completed equilibration, record this in Section C of the IQ Worksheet.

3.3.5 Computer and Software Installation

1. Install computer in appropriate location near instrument or remotely (at the customer's request).
2. If not using a pre-loaded computer with software, install PeakNet or Chromeleon software and then configure a timebase for each system being installed.
3. When the computer/software installation is complete, record this in Section C of the IQ Worksheet.

3.4 General System Function Test

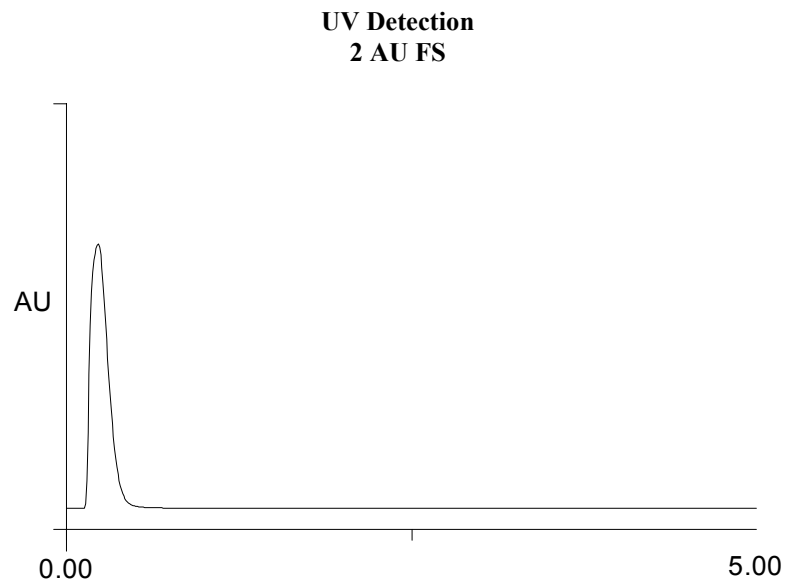
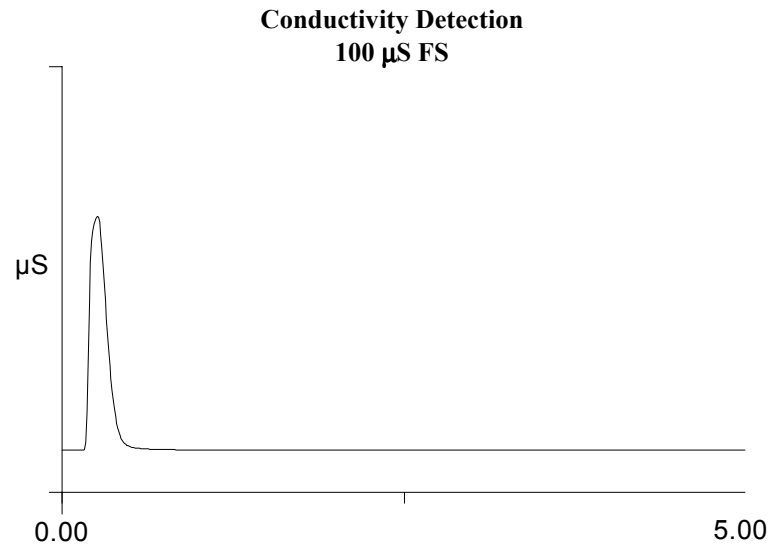
To perform the general system function test, use the Dionex Quality Installation Solution (10 ppm Nitrate, Dionex P/N 052820) included in the pump ship kit. This test sample is used to confirm system operation and can be used with conductivity and absorbance detectors. The Quality Installation Solution should not be used as a quantitative standard.

1. Stop the pump flow.
2. Install the yellow PEEK backpressure tubing, included in the Quality Installation Solution packaging, between the injection valve and the detector cell.
3. Turn on the pump flow and select water as the eluent with a flow rate of 1.00 mL/min.
4. Actuate the injection valve back and forth between LOAD and INJECT to flush the sample loop.
5. **Conductivity Detectors.** The background conductivity reading should not be higher than 1 μ S. If the background reading is higher, find an alternate water source.

Absorbance Detectors. Turn UV lamp on and set wavelength to 210 nm.

6. Check liquid flow paths for leaks, make adjustments where necessary.
7. Allow the system to stabilize, this will take approximately five minutes. The system backpressure should be 1500 – 2500 psi (100 - 170 bar).
8. Inject 15 - 50 μ L of the Quality Installation Solution and run data acquisition. The nitrate peak will elute at approximately 0.2 minutes. If the peak does not appear, confirm proper injection valve operation and that liquid connections are correct, then repeat the injection. Results obtained will be similar to the Example chromatograms in Figure 1.
9. When the general system function test is complete, record this in Section D of the IQ Worksheet.

Figure 1. Example Chromatograms



3.5 Application Installation

1. Prepare the eluents and standards needed for application to be installed.
2. Install columns and suppressors. Flush and equilibrate each according to the installation instructions for the type of column and suppressor being used. This information is located on the Consumables CD-ROM located in any of the module ship kits.
3. Inject the standard and run data acquisition. Confirm the data collected is in accordance with the application specifications.
4. When the application has been installed successfully, record this in Section D of the IQ Worksheet.

3.6 System Information

Record all computer, software and module information in Section D of the IQ Worksheet.

4 IQ Completion

4.1 Customer Review

1. The IQ results should be reviewed by the instrument owner/user. If the qualification is accepted, both the Customer and the Qualification Executor should sign each page of the IQ Worksheet.
2. Leave the IQ documentation with the customer.

5 Installation Qualification Worksheets

Note: If any of the items below result in an answer of 'No', 'not complete' or 'not acceptable', comments must be provided in Section E.

Section A. Customer and Shipment Information

A. Customer and Shipment Information	
Company Name	
Customer Name	
Street Address	
City, State, Zip	
Phone	
Customer Purchase Order	
Dionex Order Number	
Date of Delivery	
Date of Installation	
IQ Executor/Company	
Do the items on Customer Purchase Order Match Dionex Packing List?	Yes No
Are the items on Packing List included with the system shipment?	Yes No

Customer Signature _____

Qualification Executor _____

Date _____

Section B. Facility Requirements

B. Facility Requirements		
Requirement	Specification	Availability (mark N/A if not applicable)
Temperature Range	10°- 40° C	Yes No
Humidity Range	5 to 95% Relative Humidity	Yes No
Gas Supply (if needed)	Nitrogen or Helium at 100 psi	Yes No N/A
Power	Outlets available at appropriate country voltage	Yes No
Bench Space	3" of available space behind modules	Yes No
Water Quality	18 meg-ohm or better	Yes No
Eluents	As specified for application to be installed	Yes No N/A
Standards	As specified for application to be installed	Yes No N/A

Section C. System Installation

C. System Installation		
Item	Status	
3.1 Step 1 - Shipping Box Condition	Arrived undamaged	Yes No
3.1 Step 5 - Module Condition	Arrived undamaged	Yes No
3.1 Step 6 - Module Accessories	Included	Yes No
3.2 Module Set Up	Complete	Yes No
3.3 Electrical and LAN Connections	Complete	Yes No
3.4 Computer and Software Installation	Complete	Yes No
3.5 Liquid Line Installation and System Equilibration	Complete	Yes No
3.7 General system Function Test	Complete	Yes No
3.8 Application Installation	Complete	Yes No

Customer Signature _____

Qualification Executor _____

Date _____

Section D. System Information

D. System Information – IC Hardware					
Module	Model	Serial Number	Moduleware Version	Company Asset #	Installed Options
Pump					<input type="checkbox"/> Degas
Pump					
Detector					
Detector					
Chromatography Module					
Autosampler					<input type="checkbox"/> Sample Prep <input type="checkbox"/> Sample Tray Temp
Autosampler Compartment					<input type="checkbox"/> Column Switching
Accessory					
Accessory					
DX - 120					<input type="checkbox"/> Column Switching

D. System Information – Computer			
Item	Manufacturer	Serial Number	Company Asset #
Monitor			
CPU			
Printer			

Customer Signature _____

Qualification Executor _____

Date _____

D. System Information - Software			
Name	Version	Serial Number	Key Code/License Server*
Installed Features*			
Number of Timebases			
Concurrent Clients			
Device Control	On Off		
Extended Device Control	On Off		
IC Control	On Off		
IC Control SE	On Off		
Multiple Network Control	On Off		
Report Publisher	On Off		
Remote Client	On Off		
Data Reprocessing	On Off		
Library License	On Off		
PDA License	On Off		

* Required for PeakNet 6 Series only

Customer Signature _____

Qualification Executor _____

Date _____

Section E. IQ Comments

E. IQ Comments	
Section	Comment/Action

Customer Signature _____

Qualification Executor _____

Date _____