

ICS-5000 System Installation Qualification

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1 Introduction

Instrument qualification 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 stipulated 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 ICS-5000 systems and ICS-Series detectors.



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 received 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 received 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.
- 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 two single stack modules (i.e., one pump and one EG, or one DC and one VWD or PDA detector, or one TC, one VWD or one PDA) together.
- 4 When all modules have been set up on the bench, record this in Section C of the IQ Worksheet.

3.3.3 Computer and Software Installation

- 1 Install the computer in an appropriate location near the instrument or remotely (at the customer's request).
- 2 If not using a pre-loaded computer with software, install Chromeleon software. 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.



3.3.4 Electrical Connections, USB Connections, and Software Configuration

- 1 Connect all module power cords and plug into laboratory electrical source.
- 2 Connect all USB cables from the module to the computer or USB hub box (if applicable)
- 3 Connect any Relay or TTL cables (if applicable).
- 4 Make all detector cell connections (if applicable).
- 5 When all module connections have been made, configure the modules in a Timebase in Chromeleon 6 or in an Instrument in Chromeleon 7.
- 6 When all module connections have been made and the modules have been configured in the software, record this in

Section C of the IQ Worksheet.

3.3.5 Liquid Line Installation and System Equilibration (Capillary and Analytical Conductivity or Absorbance Detectors)

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

- 1 Confirm that an appropriate waste receptacle is available for system liquid waste. Fill an eluent bottle with 18.2 megohm-cm deionized, filtered water and connect it to the pump. Prime the pump for approximately 5 minutes.
- 2 A) Analytical System:

1. Connect the pump eluent line to a backpressure coil (P/N 049715). Select a flow rate of 1.00 mL/min and flush the pump for approximately 5 minutes.

2. Connect the pump eluent line to the conductivity detector. Flush for approximately 5 minutes. B) Capillary Conductivity Detectors:

- 1. Connect the pump eluent line to a backpressure coil (P/N 074572). Select a flow rate of 0.01 mL/min and flush the pump for approximately 15 minutes.
- 2. Connect the pump eluent line to the conductivity detector. Flush for approximately 15 minutes.
- 3 When the system has completed equilibration, record this in Section C of the IQ Worksheet (#3.5).
- 4 Using the tubing provided in the module ship kits, make all appropriate liquid line connections between the pump, injection valve, autosampler, accessory modules, and detector cell.

3.3.6 Liquid Line Installation and System Equilibration ED (Electrochemical Detector on ICS-5000 systems only)

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

- 1 Using the tubing provided in the module ship kits, make all appropriate liquid line connections between the pump, injection valve, auto sampler, accessory modules, and electrochemistry detector cell (assembled with disposable gold working electrode).
- 2 Confirm that an appropriate waste receptacle is available for system liquid waste. Fill an eluent bottle with 50 mM NaOH made from filtered, degassed 18.2 megohm-cm deionized water and connect it to the pump. Prime the pump for approximately 5 minutes.
- A) Analytical Systems: Select a flow rate of 1.00 mL/min and flush the entire system for approximately 15 minutes.
 B) Capillary Systems: Select a flow rate of 0.01 mL/min and flush the entire system for approximately 15 minutes.
- 4 Set the Electrochemical cell to Integrated Amperometry Mode. Use an appropriate waveform for the application the system will be used for. The following waveforms are supported depending whether your system is configured with Ag/AgCl or PdH reference electrode.



Electrode/Waveforms	Ag/Ag Cl Analytical	Ag/AgCl Capillary	PdH Analytical	PdH Capillary
AAA – AgCl	Yes	Yes	*	No
AAA – pH	Yes	Yes	*	No
Carbohydrate quadruple PDH	No	No	*	Yes
Carbohydrate quadruple potential	Yes	Yes	*	Yes

* PdH Reference electrode use in analytical ED is not supported at this time.

5 Turn the Electrochemical Cell on.

6 When the system has completed equilibration, record the system status in Section C (#3.5) of the IQ Worksheet.

3.4 General System Function Test

3.4.1 General System Function Test (Conductivity or Absorbance Detectors)

To perform the general system function test, use the Dionex Quality Installation Solution Dionex P/N 052820 which is included in the pump shipkit for Conductivity or Absorbance, 10 ppm Nitrate. 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 **Analytical Conductivity Detectors or Absorbance Detectors:** Turn on the pump flow and use water as the eluent with a flow rate of 1.00 mL/min. Actuate the injection valve back and forth three times between LOAD and INJECT to flush the sample loop.

Capillary Conductivity Detectors: Turn on the pump flow and use water as the eluent with a flow rate of 0.01 mL/min. Actuate the injection valve back and forth three times between LOAD and INJECT to flush the sample loop.

4 Detectors

a. Conductivity Detectors. The background conductivity reading should not be higher than 1 µS. If the background reading is higher, find an alternate water source. Dionex recommends ASTM Type 1 (or better) deionized water (18.2 megohm-cm, filtered)

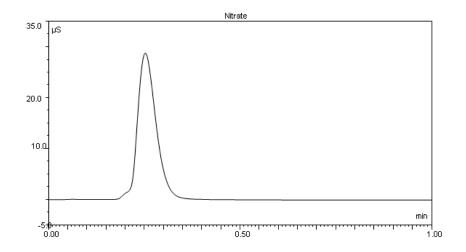
b. Absorbance Detectors. Turn on the UV Lamp and set the wavelength to 210 nm.

- 5 Check liquid flow paths for leaks, make adjustments where necessary.
- 6 Allow the system to stabilize, this will take 5 minutes. The system backpressure should be 1500 to 2500 PSI (100 to 170 bar).
- 7 Inject 15 to 50 μL of the Quality Installation Solution and run data acquisition. The analyte 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. The valves should start as load and switch to inject during injection. Results obtained will be similar to the example chromatograms in Figure 1.
- 8 When the general system function test is complete, record this in Section C of the IQ Worksheet.

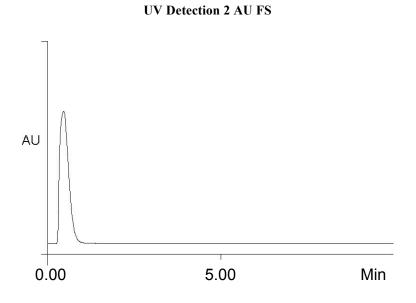


Figure 1. Example Chromatograms

Analytical and Capillary Systems



Analytical Systems Only





3.4.2 General System Function Test (Electrochemical Detectors)

To perform the general system function test, use the Dionex MonoStandard (043162 ordered separately) or equivalent. Follow the directions that are shipped with the standard to make a 0.1 mM mix of monosaccharide standards. Dilute the 0.1 mM mix 100X to produce a 1 µM mix of monosaccharide standards; this will be the "Quality Installation Solution". Use only ASTM Type 1 (or better) deionized water (18.2 megohm-cm, filtered). This test sample is used to confirm system operation and can be used with electrochemical detectors. This is a mixed standard, but since there is no separation device in the system, it will yield a single peak. The Quality Installation Solution should not be used as a quantitative standard.

1 Turn off the ED cell and 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 **Analytical Systems**: Turn on the pump flow and use 50 mM NaOH as the eluent with a flow rate of 1.00 mL/min.

Capillary Systems: Turn on the pump flow and use 50 mM NaOH as the eluent with a flow rate of 0.01 mL/min.

4 Set the Electrochemical cell to Integrated Amperometry Mode. Use an appropriate waveform for the application the system will be used for. The following waveforms are supported depending whether your system is configured with Ag/AgCl or PdH reference electrode.

Electrode/Waveforms	Ag/Ag Cl Analytical	Ag/AgCl Capillary	PdH Analytical	PdH Capillary
AAA – AgCl	Yes	Yes	*	No
AAA – pH	Yes	Yes	*	No
Carbohydrate quadruple PDH	No	No	*	Yes
Carbohydrate quadruple potential	Yes	Yes	*	Yes

* PdH Reference electrode use in analytical ED is not supported at this time

5 Turn the Electrochemical Cell on.

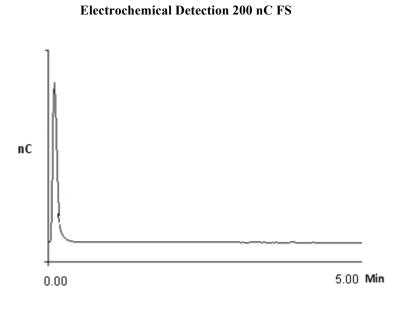
6 Actuate the injection valve back and forth between LOAD and INJECT to flush the sample loop.

- 7 Check liquid flow paths for leaks, make adjustments where necessary.
- 8 Allow the system to stabilize; this will take approximately 10 minutes. The system backpressure should be 500 to 1500 psi (35 to 100 bar).
- 9 Inject 10 to 25 µL of the mixed monosaccharide Quality Installation Solution and run data acquisition. The analyte 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 2.

10 When the general system function test is complete, record this in Section C of the IQ Worksheet.



Figure 2. Example Chromatograms





3.5 Application Installation

- 1 Prepare the eluents and standards needed for the application to be installed. 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 Dionex Reference Library CD-ROM located in any of the module ship kits.
- 2 Inject the standard and run data acquisition. Confirm that the data collected is in accordance with the application specifications.
- 3 No sign-off is necessary on the IQ Worksheet as part of the IQ procedure.

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 Worksheets.
- 2 Leave the original IQ documentation with the customer and retain a copy.



5 Installation Qualification Worksheets

Note: If the answer to any item is 'No', 'not complete' or 'not acceptable,' an explanation 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 Custome	er Purchase Order match Dionex Packing List?	Yes No			
Are the items on Packing	J List included with the system shipment?	Yes No			

Customer Signature



Section B. Facility Requirements

B. Facility Requirements							
Requirement	Specification S			on			
Temperature Range	10° to 40° C	Yes	No				
Humidity Range	5 to 80% Relative Humidity	Yes	No				
Gas Supply (if needed)	Nitrogen or Helium as specified	Yes	No	N/A			
Power	Outlets available at appropriate country voltage	Yes	No				
Bench Space	3" (8 cm) of available space behind modules	Yes	No				
Water Quality	18.2 megohm-cm 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 setup	Complete	Yes	No			
3.3 Electrical and USB 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			

Customer Signature _____

 Qualification Executor
 Date



Section D. System Information

D.1 ICS-5000 System Information								
Name of Timel	oase:				=	Chromeleon		
Name of 2 nd Timebase:			N/A	Software:	N/A Other:_			
Instrument:	Model:		Instrument Serial Number:	Company A Numb	Asset Tag ber:	Provided by Customer:	N/A	
Pump	Capillary Capillary Analytic: Analytic: Other:	/ DP al SP			□ N/A			
Compartment	TC TC Cap DC Cap DC Anal IC Cube CD Dete ED Dete Other:	lytical right left ector			□ N/A			
Eluent Generation	EG				□ N/A			
Autosampler	AS AS-DV AS-HV				□ N/A			
UV Detector	VWD PDA Other:				N/A			
Other	MSQ Other:				N/A			
Customer Sig	nature		·					
Qualification E	xecutor]	Date				



D.1.1 ICS-5000 Detector Chromatography Module Information						
Model:	ICS-5000 DC	Installed		N/A		
Heating Options	Two Zone Heating					
Upper Compartment	IC Cube High Pressure Valve 1: High Pressure Valve 2: Low Pressure Valve 1: Low Pressure Valve 2: RCH-1 Heater Installed:	Left 6-Port 2-Port 2-Port Yes	☐ 10-F ☐ 3-Pc	Port N Port N Port N	I/A I/A I/A I/A	
Middle Compartment	Detector 1 (Left):	Analytical CD Analytical CD	Capillary		ED ED	
Lower Compartment	Injection Valve 1 (Left) p Injection Valve 2 (Right)		6 ☐ 10 6 ☐ 10			
Module Serial No:			Firmware Ve	rsion:		
Connection :	USB	Address	s:			

D.1.2 ICS-5000 Thermal Compartment Module Information						
Model:	ICS-5000 TC	Install	ed 🗌		N/A]
Injection Valves	Injection Valve 1 (Left) po Injection Valve 2 (Right)		☐ 6 ☐ 6			
Module Serial No:				Firmware	Version:	
Connection:	USB		Addres	ss:		

D.1.3 ICS-5000 Pump Module Information							
Model:	ICS-5000 SP	ICS-5000 DP		Installed		N/A	
Pump 1 (Lower)	Isocratic Analytical	Gradient Analytica	Ca	pillary Isocratic			
Pump 2 (DP Only)	Isocratic Analytical	Gradient Analytica	I 🗌 Ca	pillary Isocratic			
Operational Mode	Two Separate Systems		Post Column		Regen	erant 🗌	
(DP Only)	Loading	Other:					
Module Serial No:			Firmware	Version:			
Connection:	USB	Addres	s:				

Customer Signature _	
Qualification Executor	 Date



D.1.4 ICS-5000 Eluent Generator Module Information							
Module:	ICS-5000 EG	Insta	alled			Capillary 🔲	
Module Serial No:	Firmware Version:						
Connection:	USB		Add	ress:			

D.1.5 ICS-Series Variable Wavelength Detector Module Information

Module:	ICS-Series VWD	Installed		N/A	
Channel(s):	Single Channel	Multiple Ch	nannel 🗌		
Module Serial No:			Firmwa	re Version:	
Connection:	USB	Addr	ess:		

D.1.6 ICS-Series Photodiode Array Detector Module Information					
Module:	ICS-5000 PDA	Installed		N/A	
Module Serial No:			Firmv	vare Version:	
Connection:	USB	Add	ress:		

D.1.7 ICS-Series Autosampler Module Information				
Model:	AS 🔲 AS-DV 🗌 AS-HV 🗌	Installed	N/A	
Options:	Sample Prep Thermal Controls	Simultaneous 🗌 Sequent	tial 🔲 N/A 🔲	
Valve Installed	6-port 10-port	None		
Module Serial No:		Firmware Version:		
Connection:	USB 🔲 TTL/Relay 🗌 RS-232 🗌	Address / Port:		

D.1.8 Computer System Information				
Item		Manufacturer	Serial Number	Company Asset #
Monitor				
CPU				
Printer	N/A 🔲			

Customer Signature	



D.2a System Information – Software Chromeleon 6 Versions					
Name	Version	Serial Number		Key Code	
Chromeleon					
Installed Featur	es				
Server License				On	Off
Timebase Class 1					
Timebase Class 2					
Timebase Class 3					
Multiple Network C	ontrol			On	Off
MS Control				On	Off
IC Control SE				On	Off
3D Data Acquisitio	n			On	Off
ICS-3000 Gradient	Generation			On	Off
Fraction Collection				On	Off
Purification (Extended Fractionation)			On	Off	
Control Only			On	Off	
DDK Development				On	Off
Client Features					
Client License				On	Off
Server Control				On	Off
Concurrent Clients	i			On	Off
Report Publisher				On	Off
GLP Compliance			On	Off	
Virtual Column – Basic			On	Off	
Virtual Column – Complete			On	Off	
Xpress Mode	Xpress Mode			On	Off
SDK Features	SDK Features				
ASAP				On	Off
Analyzer			On	Off	

Customer Signature



D.2b System Information – Software Chromeleon 7 Versions					
Name	Version	Serial Number	License File Location		
Chromeleon					
Instrument Con	troller Optic	ons			
Instrument Control	ler License		Available	Not Available	
Class 1 Instrument	ts				
Class 2 Instruments					
Class 3 Instruments					
3D Data Acquisition			Available	Not Available	
IC Control SE			Available	Not Available	
Data Client Opt	Data Client Options				
Data Client			Available	Not Available	
Instrument Operation			Available	Not Available	
Report Designer Pro			Available	Not Available	
Compliance Tools		Available	Not Available		

Customer Signature	
Qualification Executor	 Date



Section E. IQ Comments

E. IQ Comments			
Section	Comment/Action		

Customer Signature