



# **ICS-3000 System Installation Qualification**

© 2006 Dionex Corporation

Document No. 065080 Revision 02  
September 2006

© 2006, Dionex Corporation  
All rights reserved worldwide.  
Printed in the United States of America

This publication is protected by federal copyright law. No part of this publication may be copied or distributed, transmitted, transcribed, stored in a retrieval system, or transmitted into any human or computer language, in any form or by any means, electronic, mechanical, magnetic, manual, or otherwise, or disclosed to third parties without the express written permission of Dionex Corporation, 1228 Titan Way, Sunnyvale, California 94088-3606 USA.

#### **DISCLAIMER OF WARRANTY AND LIMITED WARRANTY**

**THIS PUBLICATION IS PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND. DIONEX CORPORATION DOES NOT WARRANT, GUARANTEE, OR MAKE ANY EXPRESS OR IMPLIED REPRESENTATIONS REGARDING THE USE, OR THE RESULTS OF THE USE, OF THIS PUBLICATION IN TERMS OF CORRECTNESS, ACCURACY, RELIABILITY, CURRENCY, OR OTHER-WISE. FURTHER, DIONEX CORPORATION RESERVES THE RIGHT TO REVISE THIS PUBLICATION AND TO MAKE CHANGES FROM TIME TO TIME IN THE CONTENT HEREIN WITHOUT OBLIGATION OF DIONEX CORPORATION TO NOTIFY ANY PERSON OR ORGANIZATION OF SUCH REVISION OR CHANGES.**

#### **PRINTING HISTORY**

Revision 01, April 2005  
Revision 02, September 2006

## Table of Contents

<b>1</b>	<b>Introduction</b>	<b>4</b>
<b>2</b>	<b>Installation Qualification (IQ)</b>	<b>5</b>
<b>3</b>	<b>Performing the Installation Qualification</b>	<b>6</b>
3.1	Customer and Shipment Information	6
3.2	Facility Requirements	6
3.3	System Installation	6
3.3.1	Unpacking	6
3.3.2	Placing Modules on Bench	7
3.3.3	Computer and Software Installation	7
3.3.4	Electrical and USB Connections	7
3.3.5	Liquid Line Installation and System Equilibration (Cond. Or Abs detector)	8
3.3.5	Liquid Line Installation and System Equilibration (ED detector)	8
3.4	General System Function Test	9
3.5	System Information	12
<b>4</b>	<b>IQ Completion</b>	<b>13</b>
4.1	Customer Review	13
<b>5</b>	<b>Installation Qualification Worksheets</b>	<b>14</b>
	Section A. Customer and Shipment Information	14
	Section B. Facility Requirements	15
	Section C. System Installation	15
	Section D. System Information	16
	Section E. IQ Comments	21

# 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 ICS-3000 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 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.
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 EG, or one DC and one VWD or PDA detector, or one TC, one VWD and 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. 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.

### **3.3.4 Electrical and USB Connections**

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 a timebase in Chromeleon
6. When all module connections have been made and the timebase has been configured record this in Section C of the IQ Worksheet.

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

**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 ship kits, make all appropriate liquid line connections between the pump, injection valve, autosampler, accessory modules, and detector cell.
2. Confirm that an appropriate waste receptacle is available for system liquid waste.
3. Fill an eluent bottle with 18 megohm deionized, filtered water and connect it to the pump. Prime the pump for approximately 5 minutes.
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.

### 3.3.6 Liquid Line Installation and System Equilibration ED (Electrochemical Detector on ICS-3000 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.
3. Fill an eluent bottle with 50 mM NaOH made from filtered, degassed 18 megaohm deionized water and connect it to the pump. Prime the pump for approximately 5 minutes.
4. Select a flow rate of 0.25 mL/min and flush the entire system for approximately 30 minutes.
5. Set the Electrochemical cell to Integrated Amperometry Mode. Use one of the following waveforms:
  - AAA – AgCl
  - AAA – pH
  - Carbohydrate quadruple potential
  - Carbohydrate triple potential
6. Turn the Electrochemical Cell on.
7. When the system has completed equilibration, record this in Section C of the IQ Worksheet.

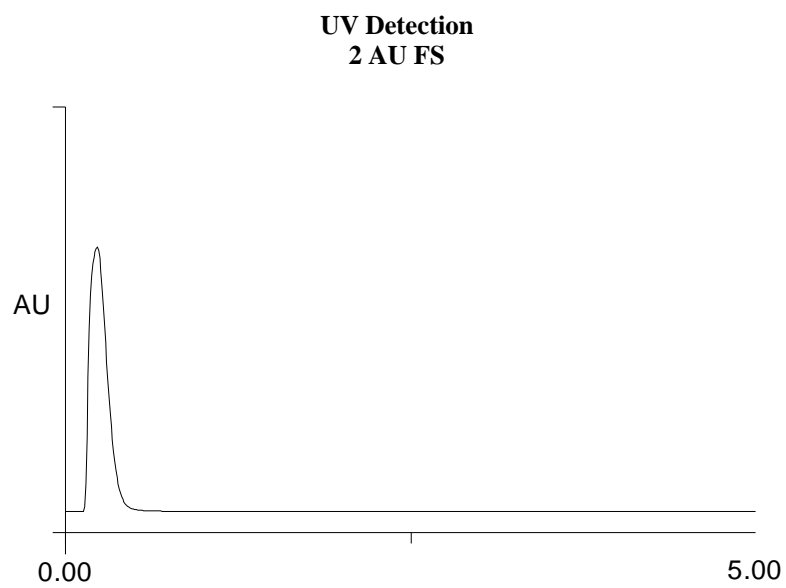
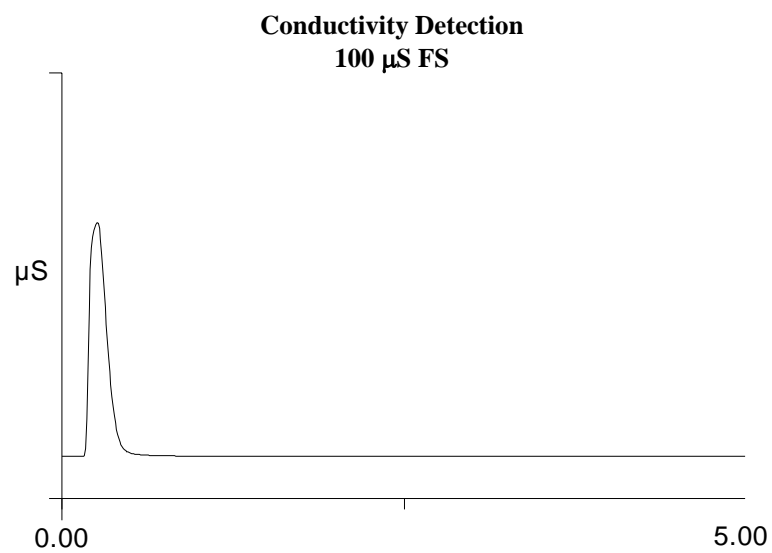
## 3.4 General System Function Test

### 3.4.1 General Systems Function Test (Conductivity or Absorbance Detectors)

To perform the general system function test, use the Dionex Quality Installation Solution (For Conductivity or Absorbance 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. **Conductivity Detectors or Absorbance Detectors:** 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  $\mu$ S. If the background reading is higher, find an alternate water source.  
**Absorbance Detectors.** Turn on the UV lamp and set the 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 5 minutes. The system backpressure should be 1500 to 2500 psi (100 to 170 bar).
8. Inject 15 to 50  $\mu$ L 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. 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 C of the IQ Worksheet.

**Figure 1. Example Chromatograms**



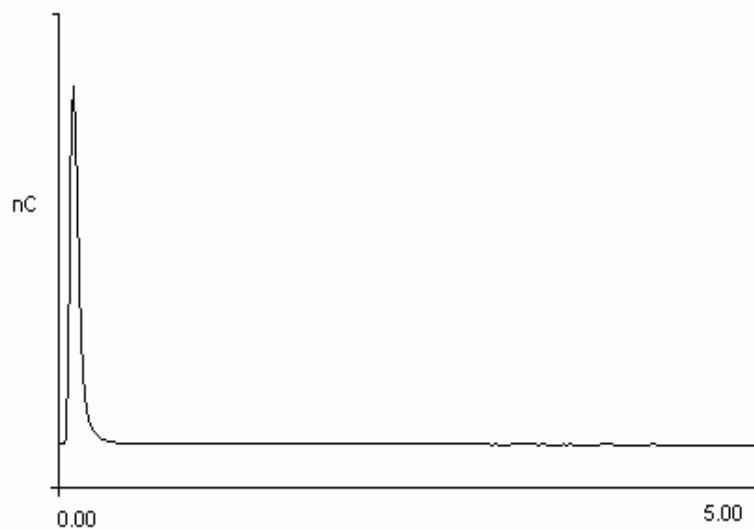
### 3.4.2 General System Function Test (Electrochemical Detectors)

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 uM mix of monosaccharide standards, this will be the "Quality Installation Solution". This test sample is used to confirm system operation and can be used with electrochemical detectors. This is a mix 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. Stop the pump flow and turn off the ED cell if it is on.
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 50 mM NaOH as the eluent with a flow rate of 0.25 mL/min.
4. Set the Electrochemical cell to Integrated Amperometry Mode. Use one of the following waveforms:
  - AAA – AgCl
  - AAA – pH
  - Carbohydrate quadruple potential
  - Carbohydrate triple potential
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  $\mu$ L of the appropriate 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 1.
10. When the general system function test is complete, record this in Section C of the IQ Worksheet.

**Figure 1. Example Chromatograms**

**Electrochemical Detection  
200 nC FS**



### 3.5 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 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 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° 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" of available space behind modules	Yes No
Water Quality	18 megaOhm 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
3.8 Application installation	Complete	Yes No

Customer Signature \_\_\_\_\_

Qualification Executor \_\_\_\_\_

Date \_\_\_\_\_

## Section D. ICS-3000 System Information

D. ICS-3000 System Information					
Name of Timebase (1):		<input type="checkbox"/> CM <input type="checkbox"/> CMX <input type="checkbox"/> Not applicable			
Name of Timebase (2):					
Instrument:	Model:	Serial No.:	Address (if applicable):	Provided. by Customer:	N/A
Pump:	<input type="checkbox"/> SP <input type="checkbox"/> DP Other:		<input type="checkbox"/> N/A		<input type="checkbox"/>
Compartment	<input type="checkbox"/> DC <input type="checkbox"/> TC <input type="checkbox"/> Other:		<input type="checkbox"/> N/A		<input type="checkbox"/>
DC Left Detector	<input type="checkbox"/> CD <input type="checkbox"/> ED		<input type="checkbox"/> N/A		<input type="checkbox"/>
DC Right Detector	<input type="checkbox"/> CD <input type="checkbox"/> ED		<input type="checkbox"/> N/A		<input type="checkbox"/>
Eluent Generation:	<input type="checkbox"/> EG <input type="checkbox"/> Other		<input type="checkbox"/> N/A		<input type="checkbox"/>
Autosampler:	<input type="checkbox"/> AS <input type="checkbox"/> AS40 <input type="checkbox"/> AS-HV <input type="checkbox"/> Other:		<input type="checkbox"/> N/A		<input type="checkbox"/>
UV Detector:	<input type="checkbox"/> VWD <input type="checkbox"/> PDA <input type="checkbox"/> Other:		<input type="checkbox"/> N/A	<input type="checkbox"/> Type:	<input type="checkbox"/>
Detector 2:	<input type="checkbox"/> RF 2000 <input type="checkbox"/> Other:		<input type="checkbox"/> N/A	<input type="checkbox"/> Type:	<input type="checkbox"/>
Detector 3:	<input type="checkbox"/> RI101 <input type="checkbox"/> Other:		<input type="checkbox"/> N/A	<input type="checkbox"/> Type:	<input type="checkbox"/>
UCI:	<input type="checkbox"/> 100		<input type="checkbox"/> N/A		<input type="checkbox"/>

Customer Signature \_\_\_\_\_

Qualification Executor \_\_\_\_\_

Date \_\_\_\_\_

D. ICS-3000 Detector Chromatography Module Information			
Model:	ICS-3000 DC	<input type="checkbox"/> Installed	<input type="checkbox"/> N/A
Heating Options	<input type="checkbox"/> One Zone Heating <input type="checkbox"/> Two Zone Heating		
Lower Compartment	Injection Valve 1 (Left) ports: <input type="checkbox"/> 6 <input type="checkbox"/> 10 <input type="checkbox"/> N/A Injection Valve 2 (Right) ports: <input type="checkbox"/> 6 <input type="checkbox"/> 10 <input type="checkbox"/> N/A		
Middle Compartment	Detector 1 (Left): <input type="checkbox"/> CD <input type="checkbox"/> ED <input type="checkbox"/> N/A Detector 2 (Right): <input type="checkbox"/> CD <input type="checkbox"/> ED <input type="checkbox"/> N/A		
Upper Compartment	<input type="checkbox"/> Automation Manager Installed <input type="checkbox"/> N/A HP Valve 1: <input type="checkbox"/> 6 <input type="checkbox"/> 10 <input type="checkbox"/> N/A HP Valve 2: <input type="checkbox"/> 6 <input type="checkbox"/> 10 <input type="checkbox"/> N/A LP Valve 1: <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A LP Valve 2: <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> N/A <input type="checkbox"/> RCH-1 Column Heater Installed		
Module Serial No:			
Firmware Version:			
Connection	<input type="checkbox"/> USB		

D. ICS-3000 Thermal Compartment Module Information			
Model:	ICS-3000 TC	<input type="checkbox"/> Installed	<input type="checkbox"/> N/A
Injection Valves	Injection Valve 1 (Left) ports: <input type="checkbox"/> 6 <input type="checkbox"/> N/A Injection Valve 2 (Right) ports: <input type="checkbox"/> 6 <input type="checkbox"/> 10 <input type="checkbox"/> N/A		
Module Serial No:			
Firmware Version:			
Connection	<input type="checkbox"/> USB		

D. ICS-3000 Pump Module Information			
Model:	ICS-3000 Pump	<input type="checkbox"/> Installed	<input type="checkbox"/> N/A
Pump Type:	<input type="checkbox"/> SP <input type="checkbox"/> DP		
Pump 1 (Lower)	<input type="checkbox"/> ISO <input type="checkbox"/> GRAD		
Pump 2 (DP Only)	<input type="checkbox"/> GRAD		
Operational Mode (DP Only):	<input type="checkbox"/> Second Channel Chromatography <input type="checkbox"/> Auxiliary Dependent <input type="checkbox"/> Auxiliary Independent		
Serial No.:			
Firmware Version:			
Connection:	<input type="checkbox"/> USB		

Customer Signature \_\_\_\_\_

Qualification Executor \_\_\_\_\_

Date \_\_\_\_\_

D. ICS-3000 Eluent Generator Module Information			
Module:	ICS-3000 EG	<input type="checkbox"/> Installed	<input type="checkbox"/> N/A
Module Serial No.:			
Firmware Version:			
Connection:	<input type="checkbox"/> USB		

D. ICS-Series Variable Wavelength Detector Module Information			
Module:	ICS-Series VWD	<input type="checkbox"/> Installed	<input type="checkbox"/> N/A
Channel(s):	<input type="checkbox"/> Single Channel <input type="checkbox"/> Multiple Channel		
Module Serial No.:			
Firmware Version:			
Connection:	<input type="checkbox"/> USB		

D. ICS-Series Photodiode Array Detector Module Information			
Module:	ICS-3000 PDA	<input type="checkbox"/> Installed	<input type="checkbox"/> N/A
Module Serial No.:			
Firmware Version:			
Connection:	<input type="checkbox"/> USB		

D. ICS-Series Autosampler Module Information					
Model:	<input type="checkbox"/> AS	<input type="checkbox"/> AS40	<input type="checkbox"/> AS-HV	<input type="checkbox"/> Installed	<input type="checkbox"/> N/A
Options:	<input type="checkbox"/> SP <input type="checkbox"/> ST <input type="checkbox"/> Simultaneous Kit <input type="checkbox"/> Sequential Kit <input type="checkbox"/> N/A				
Firmware Version:					
Module Serial No.:					
Connection:	<input type="checkbox"/> USB <input type="checkbox"/> TTL/RELAY <input type="checkbox"/> RS-232				

Customer Signature \_\_\_\_\_

Qualification Executor \_\_\_\_\_

Date \_\_\_\_\_

<b>D. Computer System Information</b>			
<b>Item</b>	<b>Manufacturer</b>	<b>Serial Number</b>	<b>Company Asset #</b>
<b>Monitor</b>			
<b>CPU</b>			
<b>Printer</b>			

Customer Signature \_\_\_\_\_

Qualification Executor \_\_\_\_\_

Date \_\_\_\_\_

D. System Information – Software			
Name	Version	Dongle Serial Number	Key Code/License Server
Chromeleon			
Installed Features			
Server License			On Off
Timebase Class 1			
Timebase Class 2			
Timebase Class 3			
Multiple Network Control			On Off
MS Control			On Off
IC Control SE			On Off
3D Data Acquisition			On Off
ICS-2000 Gradient Generation			On Off
Fraction Collection			On Off
Purification			On Off
Control Only			On Off
DDK Development			On Off
Client Features			
Client License			On Off
Server Control			On Off
Concurrent Clients			On Off
Report Publisher			On Off
GLP Compliance			On Off
Virtual Column – Isocratic			On Off
Virtual Column – Linear Gradient			On Off
Xpress Mode			On Off
SDK Features			
ASAP			On Off
Analyzer			On Off

Customer Signature \_\_\_\_\_

Qualification Executor \_\_\_\_\_

Date \_\_\_\_\_

