Installation Qualification/Operational Qualification Protocols and Instructions

Experion™ Automated Electrophoresis Station and Software

Validation Kit
(Catalog #700-7051)

Security Edition Software
(Catalog #700-7052)
(includes 700-7051)

BIO-RAD

Bio-Rad Technical Support

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Protocol Acceptance by Customer and List of Tests Performed

Bio-Rad Laboratories recommends that the IQ/OQ protocols be performed in total when the Experion automated electrophoresis station and software are initially installed. Installation qualification should also be performed when the Experion electrophoresis station is moved to a new location, when the software is upgraded, and when the computer that runs the electrophoresis station is changed or modified. Operational qualification should also be run on a regular basis to confirm that the system is performing to specifications, and also when there is a question that the instrument is not performing to specifications.

I have reviewed the IQ/OQ document and agree that it provides the appropriate procedures for the Installation Qualification/Operational Qualification of the Experion automated electrophoresis station and software.

_____   _____   _____

Customer Name (print)   Signature   Date

_____   _____   _____

Reviewer Name/Title (print)   Signature   Date

Contents

Section 1
Introduction

Qualification of analytical instruments is a formal process of documenting that an instrument is fit for its intended use and that it is kept maintained and calibrated. The Experion IQ/OQ kit is used to qualify the installation and operation of the Experion automated electrophoresis station and software. As a part of the system setup and check, a number of tables are completed and printed. A completed IQ/OQ test report consists of: 1) cover protocol acceptance page with a list of appended test reports; 2) the completed test documents; 3) printed test reports. All documentation should be signed and filed in a notebook for audit review. Such documentation provides a valuable tool that allows the user to discriminate between assay and instrument problems.

Fig. 1. The Experion system includes the following components: (1) automated electrophoresis station, (2) priming station (3) vortex station for nucleic acid analysis (4) system operation and data analysis software and (5) analysis kits (sold separately), which include the (a) chips and (b) reagents for protein, standard sensitivity RNA, high sensitivity RNA analysis, DNA 1K and 12K.

1.1 System Description

The Experion automated electrophoresis system consists of an electrophoresis station, a priming station, an optional vortex station (when used with the RNA electrophoresis kits), and software for data acquisition and analysis (Figure 1).

1.2 Packing List Verification

The Experion automated electrophoresis system is shipped in multiple boxes. The number of boxes will vary depending upon the catalog number ordered. Refer to the packing list (Section 1.3) to ensure receipt of all components.

Upon receipt of the complete system and accessories, verify that all boxes and parts are present by filling out **Table I**. Record the serial numbers of the components, and the information for the computer that will operate the instrument, in **Table II**. (See Section 6)

Please note the following when removing the contents from each shipping box:
- Carefully lift the electrophoresis station (Figure 2) by grasping the underside of the unit (between the green feet) and the top of the unit


Fig. 2. The Experion automated electrophoresis station.

- Remove all instruments from the protective plastic bags and inspect for any external damage. If any part is missing or damaged, contact Bio-Rad Laboratories immediately
- Remove the plastic film (sticky protective layer of foam) from the green lids of the electrophoresis and priming stations

1.3 Packing List Verification Software Packages

The Validation kit (catalog #700-7051) and the Security Edition software (catalog #700-7052) are available separately. Both kits provide access to the validation menus of the Experion 3.0 software. Only the Security Edition kit allows access to the security features necessary for compliance with U.S. FDA 21 CFR part 11. Both kits contain:
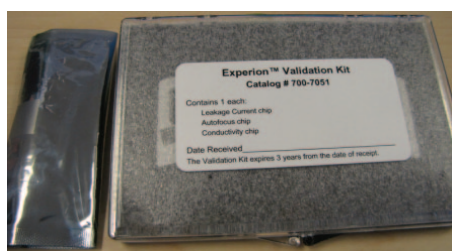
A plastic box containing 3 Experion test chips:

- Focus chip
- Conductivity chip
- Current chip

Hardware protection key (HPK) or dongle

Quick Guide containing specific password information

This instruction manual

Confirm receipt of each component and that there is no apparent damage. Fill in date received on sticker on lid of Experion Validation kit containing the three test chips. Please report any damage at once to Bio-Rad Technical Support.

Section 2
Installation Qualification

Installation Qualification (IQ) determines if the Experion automated electrophoresis station and software are properly installed. Installation Qualification tests should be performed at the following times:

- When the system is installed
- When the station is moved to a new location
- Every time the software is upgraded
- Any time the associated computer is changed or modified
- Prior to running OQ tests

These tests are accessed through the Experion software and are available to customers who have purchased the IQ/OQ package.

2.1 Software IQ

It is necessary to install and test the software prior to installation of the Experion electrophoresis station. The computer system must be setup and minimum operating requirements must be verified, before the software is installed (refer to **Table III** in Section 6). Proper installation of the software is verified by running the automated software IQ test found in **Table V** (See Section 6).

Software Installation

Place the Experion electrophoresis station and computer on a bench that is free of excessive dust, moisture, strong magnetic fields, ionizing radiation and vibrating instrumentation (i.e., shakers, centrifuges, etc). All equipment should be away from heat sources. It is best to have a dedicated computer for running and analyzing files from the Experion electrophoresis station. If a computer cannot be dedicated, and multiple pieces of instrumentation are connected to the same computer, capability limitations and communication problems may occur. Some systems require a dedicated computer as they will dominate the USB ports and restrict communication with other instrumentation. Other systems will require a specific setup sequence before communicating properly. Compatibility of systems and computers must be determined prior to running the system. The computer configuration is first confirmed by completing the equipment identification. Then follow the instructions in **Table IV** (See Section 6) to install the software.

The software IQ test verifies that all of the Experion software files are installed and properly configured. The test is accessed through the Experion software and available to customers who have purchased the IQ/OQ package. Follow the instructions in **Table V** (See Section 6) to run the Experion software IQ test.

2.2 Hardware IQ

The hardware IQ describes proper setup of the Experion electrophoresis station. The hardware IQ procedure ensures that the electrophoresis station is able to be powered up and will communicate with the software installed on the computer. Follow the instructions in **Tables VI** and **VII** (See Section 6) to perform the hardware IQ setup and test.

2.3 List of IQ Documents

Protocol Approval and List of Tests Performed

Table I: Packing List Verification
Table II: Equipment Identification (Parts and Serial Numbers)
Table III: Computer Minimal Operating Requirements

Software IQ

Table IV: Software Installation
Table V: Software IQ Test
Sample Software Installation Qualification Results

Hardware IQ

Table VI: Experion Electrophoresis Station Setup
Table VII: Hardware IQ Test
Sample Hardware Operational Qualification Results

Section 3
Operational Qualification

Operational Qualification (OQ) demonstrates that the Experion automated electrophoresis station and software are functioning to specification. Operational Qualification tests should be performed:

- Once upon receipt of the instrument
- When the instrument is moved to a new location
- When the computer or software that runs the instrument is changed or modified

Operational Qualification tests should also be run on a regular basis to confirm the system continues to function to specifications. We recommend performing OQ tests at 3 month intervals, and when there is a question that the instrument is not performing to specifications. **Software and hardware IQ tests should be performed prior to the OQ tests in order to verify that the software and hardware are installed properly.**

3.1 Software OQ

Software OQ verifies that the calculations used to analyze data files are complete and are functioning correctly. Calculations are performed on a data file where the results are known. Test results are compared to the expected results to verify the software is functioning properly. Run the software OQ as described in **Table VIII** (See Section 6).

3.2 Hardware OQ

Hardware OQ demonstrates that the electrophoresis station is performing to specifications. Tests are performed to confirm that the laser and detector are operational. Additional tests demonstrate that the electrophoretic functions of the instrument are functioning to specifications. Run the hardware OQ as described in **Table IX** (See Section 6).

3.3 List of OQ Documents
Protocol Approval and List of Tests Performed
Software OQ

> **Table VIII**: Software OQ Test
> Sample Software Results

Hardware OQ

> **Table IX**: Hardware OQ Test
> Sample Hardware Results

Section 4
Introduction to the Experion Security Edition Software

This is a brief overview of the additional features available with the Experion Security Edition software (catalog #700-7052). For more information, consult the software help section. To begin, follow the installation instructions on the software Quick Guide included with the security kit. This guide will provide the administrator password necessary to set all software parameters.

4.1 Additional Validation Feature

The Security Edition software offers an additional option in the validation menu to allow the user to print all IQ/OQ results as a single file. The Experion Validation kit software (catalog #700-7051) requires printing results at the time of execution.
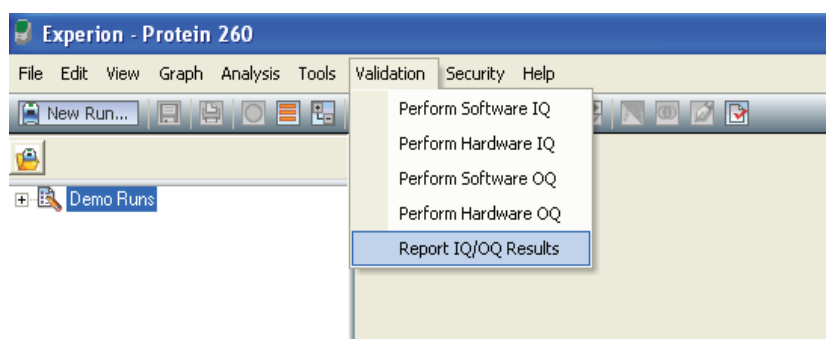
4.2 Security Menu and Administrator Functions

The security menu options are intuitive. The interface will guide you through the process of creating users, setting access levels and customizing security requirements and policies. For more information, consult the online help included with the software.
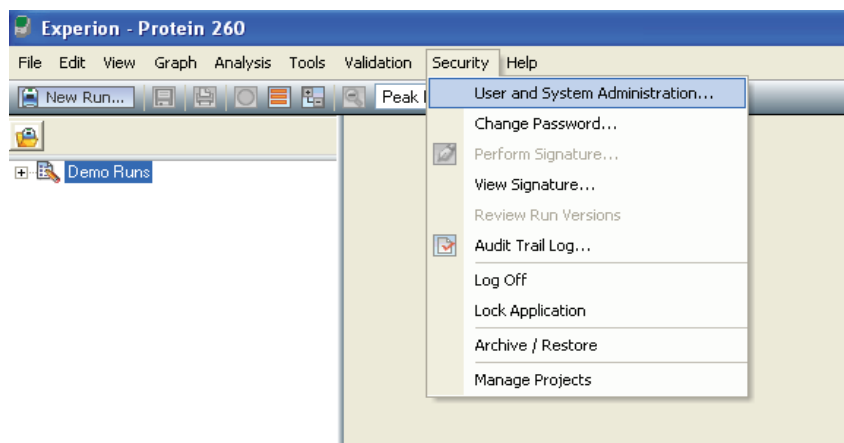
4.2.1 User Name and System Administration Interface

On the Administration Interface window, the administrator must create all users, then establish access levels and global policies. This is the first screen to create all users.
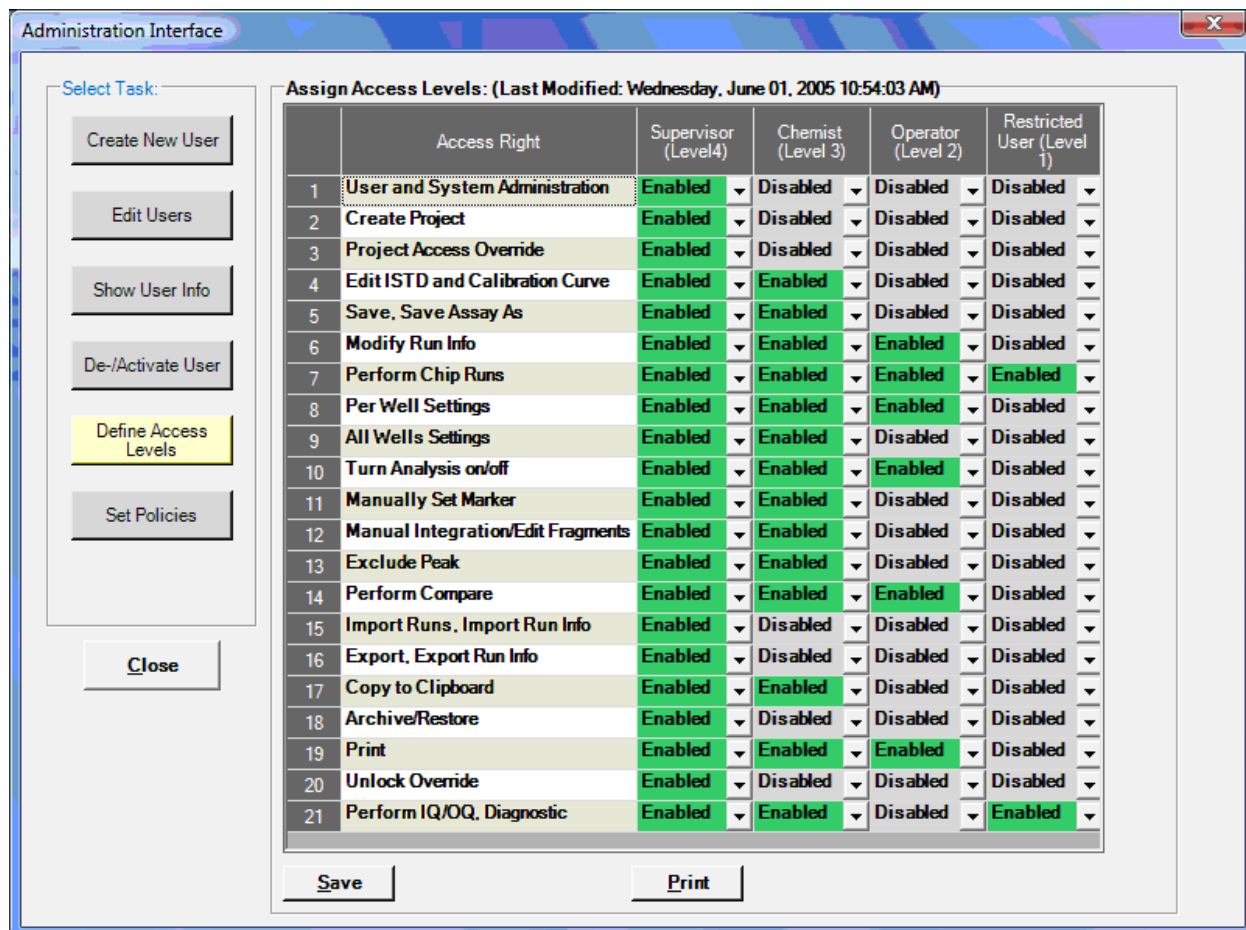

4.2.2 Access Levels

There are 5 different access levels. Each user is assigned a username, unique password and specific level of access. The access levels are named:

- Administrator
- Supervisor
- Chemist
- Operator
- Restricted User

The administrator determines which activities are accessible for each level. The following image shows the default settings to illustrate the parameters available for each level.

Administration Interface

Select Task:
- Create New User
- Edit Users
- Show User Info
- De-/Activate User
- Define Access Levels
- Set Policies
- Close

Assign Access Levels: (Last Modified: Wednesday, June 01, 2005 10:54:03 AM)

	Access Right	Supervisor (Level 4)	Chemist (Level 3)	Operator (Level 2)	Restricted User (Level 1)
1	User and System Administration	Enabled	Disabled	Disabled	Disabled
2	Create Project	Enabled	Disabled	Disabled	Disabled
3	Project Access Override	Enabled	Disabled	Disabled	Disabled
4	Edit ISTD and Calibration Curve	Enabled	Enabled	Disabled	Disabled
5	Save, Save Assay As	Enabled	Enabled	Disabled	Disabled
6	Modify Run Info	Enabled	Enabled	Enabled	Disabled
7	Perform Chip Runs	Enabled	Enabled	Enabled	Enabled
8	Per Well Settings	Enabled	Enabled	Enabled	Disabled
9	All Wells Settings	Enabled	Enabled	Disabled	Disabled
10	Turn Analysis on/off	Enabled	Enabled	Enabled	Disabled
11	Manually Set Marker	Enabled	Enabled	Disabled	Disabled
12	Manual Integration/Edit Fragments	Enabled	Enabled	Disabled	Disabled
13	Exclude Peak	Enabled	Enabled	Disabled	Disabled
14	Perform Compare	Enabled	Enabled	Enabled	Disabled
15	Import Runs, Import Run Info	Enabled	Disabled	Disabled	Disabled
16	Export, Export Run Info	Enabled	Disabled	Disabled	Disabled
17	Copy to Clipboard	Enabled	Enabled	Disabled	Disabled
18	Archive/Restore	Enabled	Disabled	Disabled	Disabled
19	Print	Enabled	Enabled	Enabled	Disabled
20	Unlock Override	Enabled	Disabled	Disabled	Disabled
21	Perform IQ/OQ, Diagnostic	Enabled	Enabled	Disabled	Enabled

Save   Print

4.2.3 Global Policies

The Administrator will set global policies for all login and signature passwords. The onscreen menu will guide the administrator through this process.

4.2.4 Other Functions

For more information on the other options, audit trails, audit trail views, archiving, and managing projects, consult the Help section included in the software.

Section 5
Definitions

Conductivity Diagnostics Test: Verifies the conductivity of each channel (pin to pin) is within limits. The maximum allowed voltage difference is 1000 ± 2 V and current difference is ± 0.04 μA. High conductivity between channels could cause samples to leak between channels and contaminate another sample.

Current Diagnostics Test: Measures the current leakage of all channels using a wet chip. Electrodes are set to 1000 V and the current measured should be 0.01 μA. As with the conductivity test, a high current leakage may allow samples to leak between channels.

Focus Diagnostics Test: Runs an autofocus of the laser and verifies the horizontal and vertical offsets are within specification. The test also measures the signal and noise of the background as well as the peak intensity and variability of the laser. Taken together, the tests indicate whether the systems laser is operating as specified and is able to focus on the electrophoresis channel. If any of the specifications are not met, detection of the sample may be compromised.

Systems Electronics Test: Verifies functionality of the instrument electronics.

Systems Communications Test: Verifies communication of the instrument with the software.

Systems Fan Test: Verifies functionality of the instrument fan.

Systems Heater Test: Verifies temperature sensor functionality and heating rate of the plate using internal sensors.

Systems Lid Sensor Test: Verifies functionality of the lid sensors.

Section 6
IQ and OQ Documentation

IQ/OQ Protocol Checklist

The following IQ/OQ report contains the following tests:

Test/Title	Check if Performed and Appended	Performed by/Date
Table I: Packing List Verification		
Table II: Equipment Identification (Parts and Serial Numbers)		
Table III: Computer Minimal Operating Requirements		
Table IV: Software Installation		
Table V: Software IQ Test		
Validation Software Installation Qualification Results		
Table VI: Hardware IQ Electrophoresis Station Setup		
Table VII: Hardware IQ Test		
Validation Hardware Installation Qualification Results		
Table VIII: Software OQ Test		
Validation Software Operation Qualification Results		
Table IX: Hardware OQ Test		
Validation Hardware Operational Qualification Results		

Comments:_____

Performed by:_____ Date:_____

Reviewed by:_____ Date:_____

Installation Qualification
Experion Automated Station – Serial Number_____

Table I: Packing List Verification

Box	Component	Performed by/Date
1	Electrophoresis Station	
	Power Cord	
	USB 2.0 Cable	
	Instruction Manual	
	Warranty Card	
	Declaration of Conformity	
2	Priming Station	
	Power Adaptor Cable	
	Extra Priming Seals (Qty 2)	
	Warranty Card	
	Declaration of Conformity	
3	Experion Software CD version _____	
4	Vortex Station (optional)	
	Power Cord	
	Warranty Card	
	Declaration of Conformity	
5	Validation Kit or Security Edition Kit	
	IQ/OQ Procedures and manual	
	Focus Test Chip	
	Current Test Chip	
	Conductivity Test Chip	
	Dongle	

Comments:_____

Performed by:_____   Date:_____

Reviewed by:_____   Date:_____

Installation Qualification
Experion Automated Station – Serial Number_____

Table II: Equipment Identification (Parts and Serial Numbers)

Description	Manufacturer	Model	Serial #	Asset #	Performed by/Date
Electrophoresis Station	Bio-Rad Laboratories	N/A			
Priming Station	Bio-Rad Laboratories				
Vortex Station (optional)	Bio-Rad Laboratories	N/A			
Computer System	Bio-Rad Laboratories				

NA = Not Applicable

Validation Kit Expiration Date (3 years from date of receipt)_____

Test Chips	Manufacturer	Lot #	O/S, INT Valves (back of the focus chip)
Focus chip	Caliper Life Sciences		O/S: _____ INT: _____
Conductivity chip	Caliper Life Sciences		N/A
Current chip	Caliper Life Sciences		

Comments:_____

Performed by:_____ Date:_____

Reviewed by:_____ Date:_____

Installation Qualification
Experion Automated Station – Serial Number_____

Table III: Computer Minimal Operating Requirements

1) Open "My Computer"> Select "System Properties".
   Use the information from the computer to complete this table.

2) Turn on the computer and monitor.

Description	Minimum Requirement	Actual Specification	Performed by/Date
Computer	PC		
Processor (CPU)	Pentium 4 3 GHz processor		
RAM	1 GB		
Operating System	Windows XP, Windows Vista or Windows 7 (32-bit)		
USB 2.0	2 ports		
Drives	CD-ROM, 80 GB hard drive		
Printer	None		

Comments:_____

Performed by:_____ Date:_____

Reviewed by:_____ Date:_____

Installation Qualification
Experion Electrophoresis Station – Serial Number_____

Table IV: Software Installation

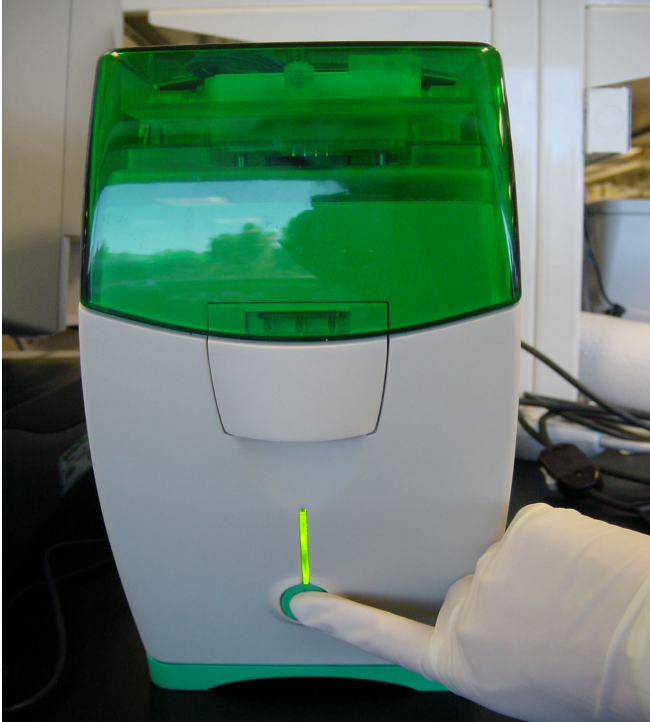| Item	Description	Performed by/date
1	Attach the software protection USB dongle to one of the USB 2.0 ports.	
2	Turn on the computer.	
3	Place the CD into the CD-ROM drive. Installation will begin automatically.	
4	Follow the instructions for Experion software installation. See the Quick Installation Guide provided with the electrophoresis station.	
5	If installation does not begin automatically; double click on the **"My Computer"** desktop icon. Select the CD drive by double clicking, then double click on the setup.exe file.	

Comments:_____
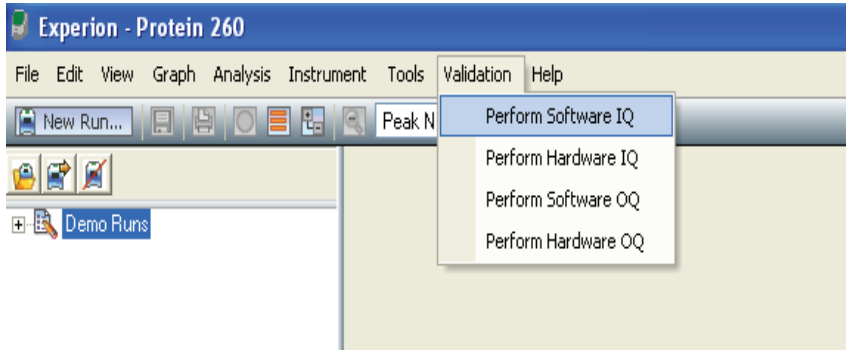
Performed by:_____ Date:_____

Reviewed by:_____ Date:_____

Installation Qualification
Experion Electrophoresis Station – Serial Number_____

Table V: Software IQ Test

Item	Description	Performed by/date
1	Double-click the **Experion Software** desktop icon on the computer to launch the software.	
2	Select **Perform Software IQ** from the **Validation** menu. 	
3	Select **Start IQ**. If any part of the test fails, uninstall the software then reinstall and repeat the test. If there is a repeated failure, call Bio-Rad Technical Support.	
4	Select the **Print** button to print the report on the next page. Security Edition only: If further IQ/OQ tests will be performed, print all test results together through **Report IQ/OQ Results**.	
5	Append the printed report to this IQ/OQ records binder.	

Comments:_____

Performed by:_____ Date:_____

Reviewed by:_____ Date:_____

Software Installation Qualification(IQ) Results Report

Software Version: 3.0.216.0
License Level: Sanity
Validation Date/Time: Friday, June 13, 2008 4:30:01 PM
Overall Result: ✓ Pass

System

Tests	Passed	Warning	Failed	Comment †
Software Installation Information	✓			
Directory	✓			

Files

Tests	Passed	Warning	Failed	Comment †
Application Assays	✓			
Application Configuration	✓			
Application DLLs	✓			
Application Exe	✓			
Application Resources	✓			
Application Symbols	✓			
Database	✓			
Docs	✓			
Instrument	✓			
Microsoft	✓			
Others	✓			
Schemas	✓			
Software Configuration	✓			
Solobug	✓			
Third Party	✓			
Windows	✓			

SAMPLE

Performed by: _____   Date: _____
Reviewed by: _____   Date: _____

† For more details on the IQ results select the 'View Details' button in the Software IQ dialog box

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Installation Qualification
Experion Electrophoresis Station – Serial Number_____

Table VI: Hardware IQ Electrophoresis Station Setup

Item	Description	Performed by/date
1	Connect one end of the supplied power cable to the electrophoresis station and the other end to a grounded AC outlet rated 10 A/100–240 VAC.	
2	Connect the electrophroresis station to your PC via the USB 2.0 cable.	

Comments:_____

Performed by:_____ Date:_____

Reviewed by:_____ Date:_____

Installation Qualification
Experion Electrophoresis Station – Serial Number_____

Table VI (Cont): Hardware IQ Electrophoresis Station Setup

Item	Description	Performed by/date
3	Turn on the power to the electrophoresis station by pushing the green button in the front of the station. The illuminated green LED, above the green button, indicates the unit is on. If the LED is not lit, then the unit is not receiving power (refer to Section 4, Troubleshooting, in the Experion Instruction Manual).	

Comments:_____

Performed by:_____ Date:_____

Reviewed by:_____ Date:_____

Installation Qualification
Experion Electrophoresis Station – Serial Number_____

Table VII: Hardware IQ Test

Item	Description	Performed by/date
1	Turn on the Experion Station. Boot up the Experion software. Select **Hardware IQ** through the **Validation** Menu. Select **Electronic and Communication Tests.**	
2	Select **Start**. All tests must be executed. It is not possible to deselect a test. If a failure results, repeat test. If a second failure occurs, call Bio-Rad Technical Support.	
3	Select **Next** to view details. Select **Print** to print the report on the next page. Security Edition only: If further IQ/OQ tests will be performed, print all test results together through **Report IQ/OQ Results**.	
4	Append print report to IQ/OQ records binder.	

Comments:_____

Performed by:_____ Date:_____

Reviewed by:_____ Date:_____

Hardware Installation Qualification(IQ) Results Report

Instrument ID: 001249
Serial Number: 001249
Firmware Version: A.01.10
Diagnostics Log Version: 2.01
License Level: Security
Validation Date/Time: Friday, June 13, 2008 4:31:35 PM
Overall Result: ✔ Passed

Tests	Passed	Failed	Comment
Communications	✔		
Electronics	✔		

SAMPLE

Performed by: _____ **Date:** _____
Reviewed by: _____ **Date:** _____

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Operational Qualification
Experion Electrophoresis Station – Serial Number_____

Table VIII: Software OQ Test

Item	Description	Performed by/date
1	Double-click the **Experion Software** icon on the computer desktop to launch the software.	
2	Select **Perform Software OQ** from the **Validation** menu.	
3	Select **Start OQ**. If any part of the test fails, uninstall the software, reinstall, and repeat first the Software IQ test and then the OQ test. If there is a repeated failure, call Bio-Rad Technical Support. Details can only be viewed when there is a failure.	
4	Select **Next** to view details. Select **Print** to print the report on the next page. Security Edition only: If further IQ/OQ tests will be performed, print all test results together through **Report IQ/OQ Results**.	
5	Append printed report to IQ/OQ records binder.	

Comments:_____

Performed by:_____ Date:_____

Reviewed by:_____ Date:_____

Software Operational Qualification(OQ) Results Report

Software Version:	3.0.216.0
License Level:	Security
Validation Date/Time:	Friday, June 13, 2008 4:33:10 PM
Overall Result:	✔ Passed

Assay	Passed	Failed	Comment
Protein 260	✔		
Prokaryote Total RNA Standard Sensitivity	✔		
Prokaryote Total RNA High Sensitivity	✔		
Eukaryote Total RNA Standard Sensitivity	✔		
Eukaryote Total RNA High Sensitivity	✔		
mRNA Standard Sensitivity	✔		
mRNA High Sensitivity	✔		
DNA 1K	✔		
DNA 12K	✔		

SAMPLE

Performed by:	_____	**Date:**	_____
Reviewed by:	_____	**Date:**	_____

Printed: Friday, June 13, 2008 4:35:47 PM

Operational Qualification
Experion Electrophoresis Station – Serial Number_____

Table IX: Hardware OQ Test

Item	Description	Performed by/date
1	Boot up software. Select **Perform Hardware OQ** through the Validation menu.	
2	All **System Validation** tests must be selected and executed. If a failure of any test results, repeat tests. If failure occurs a second time, call Bio-Rad Technical Support.*	
3	Select **Next**, then follow directions to run **Focus Diagnostics** test. The screen will guide the operator through each step. Check the box when action is complete to toggle to next step. If a failure is reported, repeat test. If continued failure occurs, call Bio-Rad Technical Support.	
4	Select **Next**, then follow directions to run **Conductivity Diagnostics** test. Check each box when action has been completed to toggle to the next step. If a failure is reported, repeat test. If continued failure occurs, call Bio-Rad Technical Support.	
5	Select **Next**, then follow directions to run **Current Diagnostics** test. If a failure is reported, repeat test. If continued failure occurs, call Bio-Rad Technical Support.	
6	Select **Next** to view details. Select **Print** to print the report on the next page. Security Edition only: If further IQ/OQ tests will be performed, print all test results together through **Report IQ/OQ Results.**	
7	Append printed report to IQ/OQ records binder.	

* **Heater plate test:** If this test is repeated for any reason, follow the procedure below:

a) Power off the Experion™ station

b) Open the lid

c) Wait 30 min to let heater plate cool to room temperature

d) Power Experion station on and let it pre-warm for 5 min

e) Start the heater test

Comments:_____

Performed by:_____   Date:_____

Reviewed by:_____   Date:_____

Hardware Operational Qualification(OQ) Results Report

Instrument ID:	001249
Serial Number:	001249
Firmware Version:	A.01.10
Diagnostics Log Version:	2.01
License Level:	Security
Validation Date/Time:	Friday, June 13, 2008 5:23:19 PM
Overall Result:	✔ Passed

Tests	Passed	Failed
Communications	✔	
Electronics	✔	
Fan	✔	
Lid	✔	
Heater	✔	
Focus	✔	
Conductivity	✔	
Leakage	✔	

SAMPLE

Performed by:	_____	**Date:**	_____
Reviewed by:	_____	**Date:**	_____

Printed: Friday, June 13, 2008 5:59:46 PM

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