



## **SAGE SCIENCE INC**

SageELF IQ/OQ

460002 Rev. A  
August 26, 2014

Sheet **1** of **11**

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### **SUMMARY**

This document provides instructions and records for Installation Qualification (IQ) and Operational Qualification (OQ) for the SageELF platform .

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## **1.0 INTRODUCTION**

### **1.1 Purpose**

This guideline documents requirements and procedures for users or Sage Science Staff for installation qualifications and operational qualification (IQ/OQ)

### **1.2 Scope**

This document provides a checklist of items and procedures to qualify the correct function of the SageELF upon installation, and ongoing operation.

### **1.3 Reference Documents**

460001, SageELF Installation Guide, 460003 SageELF Operations Manual

All at the latest revision.

### **1.4 Responsibilities**

The Applications Lab Director or designee will be responsible to ensure that this procedure is implemented.

2.0 INSTALLATION QUALIFICATION (IQ)

2.1 Instrument Origin and Identification

<b>Instrument:</b>	SageELF Fractionator
<b>Instrument Description:</b>	Agarose Gel Electrophoresis, Preparative Fractionation of DNA or protein samples.
<b>Manufacturer:</b>	Sage Science, Inc. 500 Cumming Center Suite 2400 Beverly, MA 01915 617.922.1832 www.sagescience.com
<b>Service Contact:</b>	Tel: 888.744.0144 Email: support@sagescience.com
<b>Serial Number:</b> (see back panel)	
<b>Date Received:</b>	
<b>Installation Location:</b>	
<b>Purchase Order Number:</b>	
<b>ID or Asset Number:</b>	

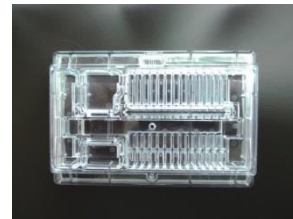
**2.2 Instrument Delivery and Documentation**

Verify that the following items have been received.

<b>SageELF Instrument</b>	
Power Supply	
Power Cord	
<b>Documentation</b>	
Operations Manual	
<b>Accessories</b>	
USB Computer Keyboard	
USB Mouse	
Mouse Pad	
USB Flash Drive	
Calibration Fixture 1	
Calibration Fixture 2	
Rinse Cassette 1	
Rinse Cassette 2	
<b>LCD Display</b>	
LCD Display	
Power Supply	
Power Cord	
HDMI/RS232 video cable	



Calibration Fixtures



Rinse Cassette

**2.2 Instrument Delivery and Documentation (cont'd)**

Is there any damage to the instrument or accessories?  
Yes  No  **Comments:**

Has the manufacturer been informed of damage or missing items?  
Yes  No  **If yes, corrective action taken::**

**2.3 Environment and Siting**

Manufacturers Recommendations	
Ambient Temperature between 17-25°C	
~30 x 30 in. bench space	
Proximity to 2 x 110V or 220V outlets	

**Comments:**

**2.4 IQ Signature**

**Refer to Installation Guide, SSIXMXXXX Rev.A  
Installed by:**

User  Sage Science Representative

**IQ Completed By:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Comments:**

### 3.0 OPERATIONAL QUALIFICATION (OQ)

#### 3.1 Powering On the Instrument

Refer to Operations Manual (page 3-2)

Are the instrument and LCD display connected to power outlets ? Yes  No

Are the blue LEDs on the Cassette nests activated? Yes  No

Is the LCD Display on ? Yes  No

*Press power switch located on the rear of the instrument, and wait for software to launch  
(approximately 30 seconds)*

Is the blue LED on the front panel activated? Yes  No

Did the SageELF software successfully launch (Main Tab)? Yes  No

*Press the "Display Info" button to pop up the Information Window.*

Software version: \_\_\_\_\_

*Click the pop up window to exit.*



**3.2 Optical Calibration**

Refer to Operations Manual (pages 6-1 and 6-2)

Have both calibration fixtures been placed over the detectors ? Yes  No

Is the Lid Closed? Yes  No

*Press the "Clear Run Data" Button*

*Press the "Calibrate Detector" Button*

*Select both nests in the Detector Calibration pop up window*

*Press "Start"*

Did both nests pass the Calibration Test Yes  No

**Comments:**

### 3.3 Current Test

Refer to Operations Manual (pages 8-1 and 8-2, and 9-1 to 9-4)

Prepare two gel cassettes as outlined in Section 8 of the Operations Manual

Place the two gel cassettes onto the instrument Nests 1 and 2 and close the lid.

Have the cassettes been prepared and the adhesive tape removed ? Yes  No

Is the lid closed? Yes  No

*Press the "Clear Run Data" Button*

*Press the "Check Current" Button*

*Select both cassette in the Current pop up window*

*Press "Start"*

Did both cassettes pass the Separation Test Result? Yes  No

Did both cassettes pass the Elution Test Result? Yes  No

**Comments:**

**3.4 OQ Signature**

**Assessed by:**

User  Sage Science Representative

**OQ Completed By:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Serial Number:** \_\_\_\_\_

Have there been any deviations?

Yes  No  **Comments:**

Has the manufacturer been informed of the deviations?

Yes  No  **If yes, corrective action taken::**

**Comments:**