



## **SAGE SCIENCE INC**

BluePippin IQ/OQ

460012 Rev. B

Originated: July 18, 2023

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 BluePippin instrument.

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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 BluePippin upon installation, and ongoing operation.

### **1.3 Reference Documents**

460011, BluePippin Installation Guide, 460013 BluePippin Operations Manual

All at the latest revision.

### **1.4 Responsibilities**

The Sage Science 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>	BluePippin DNA Size Selection System
<b>Instrument Description:</b>	Automated Preparative Agarose Gel Electrophoresis
<b>Manufacturer:</b>	Sage Science, Inc. 500 Cumming Center Suite 2400 Beverly, MA 01915 978.922.1832 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>BluePippin 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	
Rinse Cassette	
<b>LCD Display</b>	
LCD Display	
Power Supply	
Power Cord	
VGA video cable	



Calibration fixture with protective cover .



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

<b>Manufacturers Recommendations</b>	
Ambient Temperature between 17-23°C	
~30 x 30 in. bench space	
Proximity to 2 x 110V or 220V outlets	

**Comments:**

**2.4 IQ Signature**

**Refer to Installation Guide, 460011**

**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 (section 4)

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

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

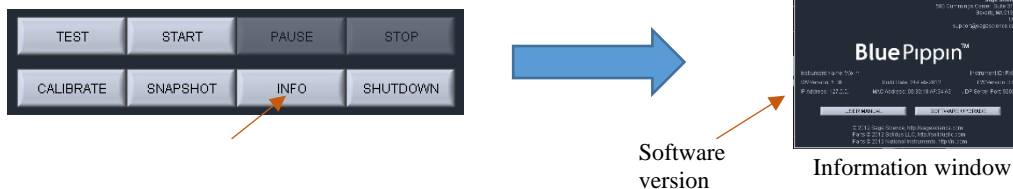
Is the LCD Display on ? Yes  No

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

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

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

*Click the "INFO" on the bottom of the Main screen to pop up the Information Window.*



Record the software version: \_\_\_\_\_

*Click the Information window to exit.*



### 3.2 Optical Calibration

Refer to Operations Manual (section 9)

Has the optical calibration fixture been placed over the detector array?

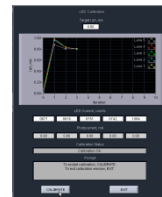
Yes  No

Is the lid closed?

Yes  No

*Go to the Main screen*

*Press the CALIBRATE button (opens the calibration pop-up window)*

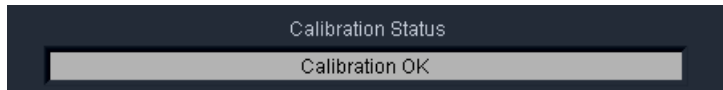


*Press the CALIBRATE button in the pop-up window*



Does the Calibration Status window display “Calibration OK”:

Yes  No



**Comments:**

### 3.3 Continuity Test

Refer to BluePippin Operations Manual (section 10.1 and 10.2 for the gel preparation procedure, and 10.3 for the Continuity Test.)

Prepare a gel cassette as outlined in Section 10.1 and 10.2 of the Operations Manual

Place the gel cassettes onto the instrument nest and close the lid.

Has the cassette been prepared and the adhesive tapes removed? Yes  No

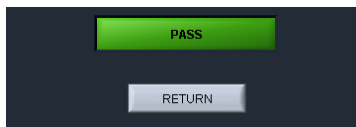
Is the lid closed? Yes  No

*Go to the Main screen*

*Press the TEST button. This will open the continuity test pop-up window and automatically start the test routine.*



Did the cassettes pass the Continuity Test? 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:**