



SAGE SCIENCE INC

BluePippin IQ/OQ

460012 Rev. A

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

Prepared by: Alex Vira

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

Instrument:	BluePippin DNA Size Selection System
Instrument Description:	Automated Preparative Agarose Gel Electrophoresis
Manufacturer:	Sage Science, Inc. 500 Cumming Center Suite 2400 Beverly, MA 01915 617.922.1832 www.sagescience.com
Service Contact:	Tel: 888.744.0144 Email: support@sagescience.com
Serial Number: (see back panel)	
Date Received:	
Installation Location:	
Purchase Order Number:	
ID or Asset Number:	

2.2 Instrument Delivery and Documentation

Verify that the following items have been received.

BluePippin Instrument	
Power Supply	
Power Cord	
Documentation	
Operations Manual	
Accessories	
USB Computer Keyboard	
USB Mouse	
Mouse Pad	
USB Flash Drive	
Calibration Fixture	
Rinse Cassette	
LCD Display	
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

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, 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 (page 3-2)

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

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

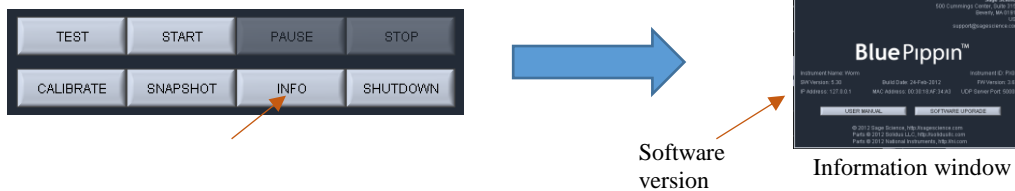
Is the LCD Display on ? Yes No

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 (pages 6-1 and 6-2)

Has the optical calibrator 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)

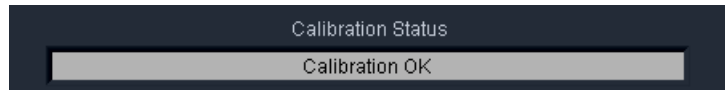


Press the CALIBRATE button in the pop-up window



Does the Calibration Status window display “Calibration OK”:

Yes No



Comments:

3.3 Continuity Test

Refer to BluePippin Operations Manual (pages 6.1 to 6.2 for the gel preparation procedure, and 6-3 for the Continuity Test.)

Prepare a gel cassettes as outlined in Section 6.1 and 6.2 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

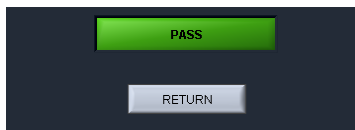
Is the lid closed? Yes No

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: