



SAGE SCIENCE INC

PippinHT IQ/OQ

460006 Rev. B
December 4, 2014, 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 PippinHT 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 PippinHT upon installation, and ongoing operation.

1.3 Reference Documents

460004, PippinHT Installation Guide, 460005 PippinHT 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

Instrument:	PippinHT 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:	

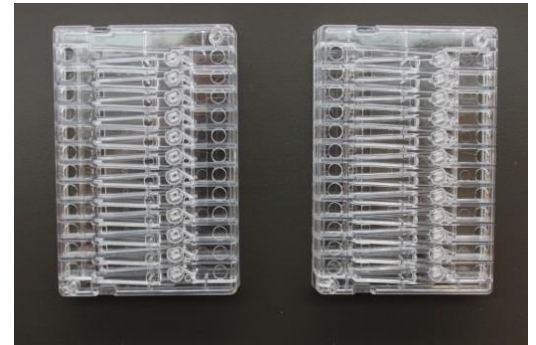
2.2 Instrument Delivery and Documentation

Verify that the following items have been received.

PippinHT Instrument	
Power Supply	
Power Cord	
Documentation	
Operations Manual	
Accessories	
USB Computer Keyboard	
USB Mouse	
Mouse Pad	
USB Flash Drive	
Calibration Fixture 1	
Calibration Fixture 2	
Rinse Cassette 1	
Rinse Cassette 2	
LCD Display	
LCD Display	
Power Supply	
Power Cord	
HDMI/VGA video cable	



Calibration fixtures with protective covers.



Rinse Cassettes

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, 460004 Rev.B

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 PippinHT software successfully launch (Main Tab)? Yes No

Click the PippinHT logo on the bottom right of the Main screen 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 both the detector arrays ? Yes No

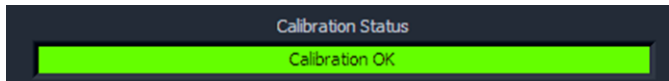
Is the lid closed? Yes No

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 PippinHT Operations Manual (pages 7-1 to 7-3 for the gel preparation procedure, and 8-1 to 8-2 for the Continuity Test.)

Prepare two gel cassettes as outlined in Section 7 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

Go to the Main screen

Press the TEST button (opens the continuity test pop-up window)

Press the CALIBRATE button in the 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: