



Agilent BioTek BioSpa 8
Automated Incubator

Qualification and Maintenance Procedures



ERRATA NOTICE: This document contains references to BioTek. Please note that BioTek is now Agilent. For more information, go to www.agilent.com/lifesciences/biotek.

Notices

Document Identification

1411018

Revision E. February 2024

Copyright

© Agilent Technologies, Inc. 2021-2024

No part of this manual may be reproduced in any form or by any means (including electronic storage and retrieval or translation into a foreign language) without prior agreement and written consent from Agilent Technologies, Inc. as governed by United States and international copyright laws.

Agilent Technologies, Inc.
5301 Stevens Creek Blvd.
Santa Clara, CA 95051
USA

Instrument Manufacturing



Manufactured by
Agilent Technologies, Inc.
5301 Stevens Creek Blvd.
Santa Clara, CA 95051
USA



Warranty

The material contained in this document is provided "as is," and is subject to being changed, without notice, in future editions. Further, to the maximum extent permitted by applicable law, Agilent disclaims all warranties, either express or implied, with regard to this manual and any information contained herein, including but not limited to the implied warranties of merchantability and fitness for a particular purpose. Agilent shall not be liable for errors or for incidental or consequential damages in connection with the furnishing, use, or performance of this document or of any information contained herein. Should Agilent and the user have a separate written agreement with warranty terms covering the material in this document that conflict with these terms, the warranty terms in the separate agreement shall control.

Technology Licenses

The hardware and/or software described in this document are furnished under a license and may be used or copied only in accordance with the terms of such license.

Restricted Rights Legend

U.S. Government Restricted Rights. Software and technical data rights granted to the federal government include only those rights customarily provided to end user customers.

Agilent provides this customary commercial license in Software and technical data pursuant to FAR 12.211 (Technical Data) and 12.212 (Computer Software) and, for the Department of Defense, DFARS 252.227-7015 (Technical Data - Commercial Items) and DFARS 227.7202-3 (Rights in Commercial Computer Software or Computer Software Documentation).

Safety Notices

CAUTION

A **CAUTION** notice denotes a hazard. It calls attention to an operating procedure, practice, or the like that, if not correctly performed or adhered to, could result in damage to the product or loss of important data. Do not proceed beyond a **CAUTION** notice until the indicated conditions are fully understood and met.

WARNING

A **WARNING** notice denotes a hazard. It calls attention to an operating procedure, practice, or the like that, if not correctly performed or adhered to, could result in personal injury or death. Do not proceed beyond a **WARNING** notice until the indicated conditions are fully understood and met.

Contact Information



Agilent Technologies, Inc.
5301 Stevens Creek Blvd.
Santa Clara, CA 95051

Worldwide Sales and Support

www.agilent.com/en/contact-us/page

Technical Support and Service

Service Toll-Free US and Canada: (800) 227-9770

www.agilent.com/en/support

Email: bio.tac@agilent.com

Instrument service and repair is available worldwide at one of our international service centers and in the field at your location.

Customer Care

Email: bio.CustomerCare@agilent.com

Contents

Notices	i
Contact Information	ii
Worldwide Sales and Support	ii
Technical Support and Service	ii
Customer Care	ii
Contents	iii
Section 1 Introduction	1
Overview	2
Recommended Qualification Schedule	3
Recommended Maintenance Schedule	3
Design Qualification (DQ)	4
Section 2 Installation Qualification	5
IQ-1: Unpack and Inspect	6
IQ-2: Check Required Components	7
Package Contents	7
IQ-3: Check Optional Accessories	8
IQ-4: Select an Appropriate Location	9
IQ-5: Remove the Shipping Hardware	10
Remove the Shipping Platform	11
Install a Cytation with an Isolation Table	11
Installing a Synergy Neo2 or Cytation (without an isolation table) on the Left Side	12
Install Feet to Support Right-Side Rotating Base Installation	14
Remove the Shipping Brackets	14
IQ-6: Set up the BioSpa	15
Install Internal Components	15
Insert the Baffles	17
Install the HEPA Filter	18
Install Plate Holders	19
Install the Water Pan	20
Close Lid and Install Cover	21
Install External Components	21
Install the Deck Spacers	22
Install the Gripper and Robot Covers	23
Install the Platform/Cover and Guard Rail	23
Install the Rotating Base	27
Rotating Base: install alignment plate	28

Rotating Base Installation	28
Rotate base to access internal components	30
Clamp tubing together	32
IQ-7: Install Companion Instruments	33
Integration Kits	34
Cytation 1/5/7 Right-Side Installation	35
Cytation 1/5/7 with Isolation Table Installation	36
Cytation C10 with Isolation Table Installation	38
Cytation 1/5/7 Left-Side Installation	42
Epoch 2 Installation	43
Synergy H1 Installation	44
Synergy Neo2 Right-Side Installation	45
Synergy Neo2 Left-Side Installation	46
405 TS-LS Installation	47
EL406 Installation	48
MultiFlo FX Installation	49
IQ-8: Install BioSpa Software	50
Minimum System Requirements	50
Disable Sleep Mode	51
Turn Off Automated Updates	51
Launch the BioSpa Software	51
IQ-9: Install Gas Tanks and Regulators	52
IQ-10: Connect Required Components	54
IQ-11: Connect Host Computer to Incubator and Reader	54
IQ-12: Connect Power	55
IQ-13: Configure Companion Instruments	55
IQ-14: Configure Instruments for BioSpa	56
Configure Instruments	56
Record BioSpa Software Info	56
IQ-15: Align Instruments	56
Align the Gripper	58
Verify Alignment	58
IQ-16: Create and Run a Test Session	59
Define a Reader-Imager Session	59
Define a Washer-Dispenser Session	60
Run a Session	62
Environment	62
Assay Steps	63
Load Plates	63

Start Time	64
Section 3 Operation Qualification	65
OQ-1: Run a System Test	66
Record BioSpa Software Info	66
OQ-2: Verify Alignment	66
OQ-3: Verify Gas Sensors	66
OQ-4: Verify Temperature Sensor	69
OQ-5: Verify Water Level Sensor	71
Section 4 Performance Qualification	72
PQ-1: Run a System Test	73
Record BioSpa Software Info	73
PQ-2: Verify Alignment	73
Section 5 Periodic Maintenance	74
Daily Maintenance	75
Daily Safety Checks	75
Weekly Maintenance	75
Required Materials	75
Clean the Water Pan	76
Fill the Water Pan	77
Replace the HEPA Filter	78
Clean the Internal Chamber and Plate Holders	78
Replace the Gas Line Tubing and Filter	80
Clean the Fan Inlet Filter	81
Decontamination	81
Tools and Supplies	81
Decontaminate Exterior Surfaces	82
Shut-Down Procedure	82
Section 6 Specifications	84
Physical Specifications	85
Environmental Conditions	85
Labware	85
Plate Dimensions	86
Performance Specifications	86
Temperature Control	86
CO2 Control	87
O2 Control	87
Humidity	87
Power Usage	87

Contents

IQ Checklist	88
OQ Checklist	93
PQ Logbook	95
PM Logbook	96
Traceability Logbook	97
In This Book	98



Section 3 Operation Qualification

This section provides instructions for confirming the BioSpa operates according to specification.

The gas sensor, temperature sensor, and water-level sensor were fully tested in the factory before shipment. You do not need to perform the sensor verification steps for new instruments. Instead, perform these tests at the first and subsequent annual operation qualifications.

OQ-1: Run a System Test	66
OQ-2: Verify Alignment	66
OQ-3: Verify Gas Sensors	66
OQ-4: Verify Temperature Sensor	69
OQ-5: Verify Water Level Sensor	71

Section 3 Operation Qualification

OO-1: Run a System Test

OO-1: Run a System Test



- 1 Click the Utilities button (or select **Tools > Utilities**).
- 2 **Run a Self-Test** Click the link to run a self-test.

Also, verify that the correct software versions are installed.

Record BioSpa Software Info

In the BioSpa software, select **Help > About BioSpa** and record relevant data in the OQ Checklist.

- ✓ Use the OQ Checklist to confirm that the BioSpa passed its self-test and the required software versions are installed.

OO-2: Verify Alignment

Follow instructions for [IQ-15: Align Instruments](#), except choose the **Verify current alignment positions** option. Follow the prompts to complete the test.

- ✓ Use the OQ Checklist to confirm that the BioSpa passed its alignment verification.

OO-3: Verify Gas Sensors

Tools > Utilities > Advanced Utilities > Calibrate Gas Sensors

Use these controls to verify the accuracy of the CO₂ and O₂ sensors and recalibrate them, if needed. Before the incubator leaves our factory, Agilent calibrates the sensors. Verifying the BioSpa's gas sensors once per year is considered good laboratory practice.

Recalibrating the sensors is required only when the sensor reports values that differ $\pm 0.5\%$ compared to the known composition. The Verify activity checks the calibration.

Three ways to perform this task: To do it yourself, you can use calibration gas, which is recommended and described here, or a gas meter. Using a traceable calibration gas standard is typically more reliable than using a gas meter. If calibration gas is not available, you can use a stand-alone gas meter, or employ the third option: let Agilent do it.

NOTE

An alternative to calibrating the gas sensors yourself is sending the gas sensor box to Agilent for recalibration. Contact Technical Support and follow instructions to Remove the Gas Sensor in the user's manual.

Section 3 Operation Qualification

OQ-3: Verify Gas Sensors

The following do-it-yourself instructions to **Verify** gas sensor performance require calibration gas.



Figure 3-1: Using a Calibration Gas is the recommended method.

Install Gas Cap on Gas Sensors:

- 1 Remove the top cover to expose the tools: hex wrench and gas calibration cap on the lid.
- 2 Loosen thumbscrews to release the gas cap.



Figure 3-2: Hex wrench and gas calibration cap location.

Section 3 Operation Qualification

OQ-3: Verify Gas Sensors

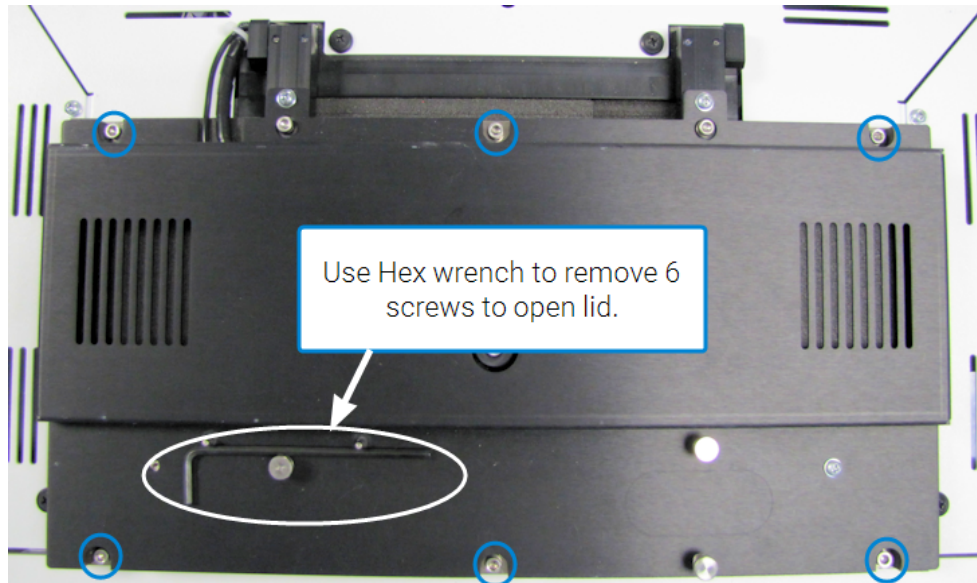


Figure 3-3: Hex wrench and the six hex screws.

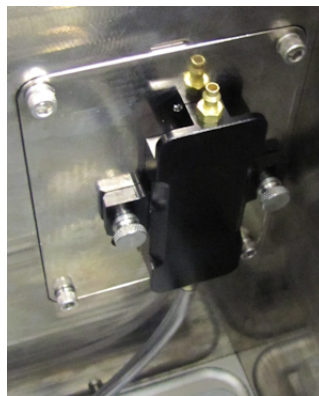


Figure 3-4: Gas Cal Cap on Gas Sensor.

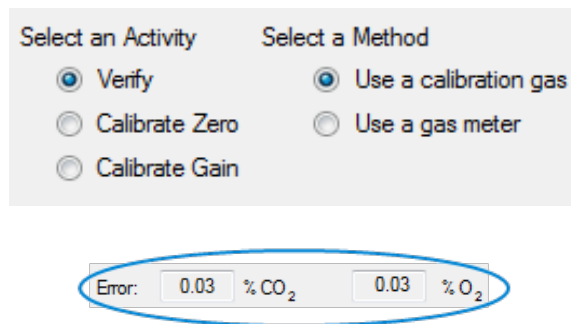


Figure 3-5: Setting the Activity and settings.

- 3 Use the hex wrench to open the top lid.
- 4 In the BioSpa software, select **Tools > Utilities > Advanced Utilities > Calibrate Gas Sensors**. In the lower left corner, select **Open all drawers**.
- 5 Remove the HEPA filter: twist counterclockwise.
- 6 Remove the bottom baffle and right baffle.
- 7 Put the gas calibration cap on the gas sensor and tighten thumbscrews to hold it in place. (The extra tubing connected to the gas cap helps reduce errors during calibration by preventing air from diffusing into the sensors.)
- 8 Connect the calibration gas, set to 0.9 slpm, and turn on flow.
- 9 Set the Activity to **Verify** and the Method to "Use a calibration gas."
- 10 At Step 1: Select CO₂ or O₂ or both to match your equipment.
- 11 At Step 2: Specify the gas composition as defined by its manufacturer.
- 12 At Step 3: Select **Start Test** and follow prompts.
- 13 At Step 4: Select **Capture Test** when sufficient time (at least 3 minutes) has elapsed to trust the sensor readings .

Section 3 Operation Qualification

OQ-4: Verify Temperature Sensor

Verification passes if the **Error** values reported are within the $\pm 0.5\%$ range.

Remove the gas cal cap from the sensor and reassemble the incubator to its normal state.

- ✓ Use the OQ Checklist to confirm that the BioSpa's gas sensor is operating as expected.
- If the gas sensor needs to be recalibrated, follow instructions in the user manual.

OQ-4: Verify Temperature Sensor

Tools > Utilities > Advanced Utilities > Calibrate Temperature

Use these controls to verify the incubator's temperature reading and recalibrate the sensor, if needed. Before it leaves our factory, Agilent calibrates the temperature sensor. Verifying the BioSpa's temperature sensor once per year is considered good laboratory practice.

Recalibration is only required when the sensor reports values $\pm 0.5\text{ }^{\circ}\text{C}$ compared to the measured temperatures.

You need an **Immersion thermometer**, 1/4" (6.4 mm) diameter or smaller with $\pm 0.1\text{ }^{\circ}\text{C}$ gradient that can sink 4-6" (100-160 mm) into the chamber or a **temperature test plate** comparable to Pyro QC Pak by Innovative Instruments, Inc.

NOTE

Various devices that measure temperature can be used to perform this step, some take much longer than others to produce an accurate reading. For example, immersion thermometers designed for measurements in air perform faster than test plates: 1/2 hour vs. 1 hour. Give sufficient time for your device to stabilize to the environment and capture an accurate measurement.

Step 1: Insert your thermometer or test plate.

Immersion Thermometer

- 1 Use the hex wrench provided to open the top port on the incubator.



Figure 3-6: Opening the port with the hex wrench.

Temperature Test Plate

Always put the test plate in the same drawer and position, for example, position 3, drawer 2.

- 1 Insert the test plate.

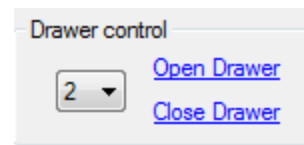


Figure 3-8: Drawer controls.



Section 3 Operation Qualification

OQ-4: Verify Temperature Sensor

Immersion Thermometer

- 2 Open the port to insert the thermometer, immersing it, letting it sink 4"-6" into the chamber.

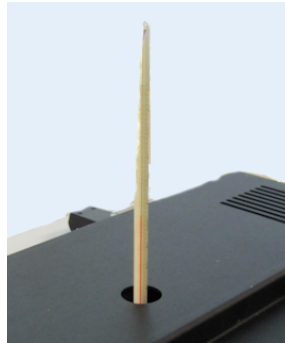


Figure 3-7: Inserting the thermometer.

- 3 Click **Start Calibration process now**.

Temperature Test Plate

Figure 3-9: Test plate inserted into the drawer.

- 2 Click **Start Calibration process now**.

Step 2: Capture Incubator Temperature

Let the system stabilize for 2 hours. Then, select **Capture Current Temperature**.



TIP

Exception: if you are verifying temperature sensor performance during a period when the incubator is in regular use at a steady temperature for a significant duration. In this case, observe a stable temperature for 30 minutes before recording the temperature, if that is sufficient time for your measuring device.

End of Temperature Verification

- 1 Retrieve temperature from your measuring device. Compare it to the **Current Temperature**.
 - 2 If the measured temperature is within the range ± 0.5 °C compared to the current temperature, sensor performance is verified.
 - 3 When performance is verified, select **Cancel Calibration**.
- ✓ Use the OQ Checklist to confirm that the BioSpa's temperature sensor is operating as expected. If the temperature sensor needs to be recalibrated, follow instructions in the user manual.

Section 3 Operation Qualification
OQ-5: Verify Water Level Sensor

OQ-5: Verify Water Level Sensor

The BioSpa highlight's the "% Humidity" field in the control panel (and during a session displays a warning message) when the water level drops in the water pan. Perform this test to verify that the float sensor is performing as expected.



% Humidity 80.5

Figure 3-10: Humidity level.

- 1 Click **Blank** and say **Yes** to the prompt to "Use Lids."
 - 2 Empty the water pan. Hold onto the water-level sensor in its housing to keep it from falling out. Make sure it is correctly oriented: "up" is visible. Replace the pan and add 100 mL sterile distilled water.
 - 3 Observe the control panel, the **Humidity** field should be highlighted orange indicating low water level.
 - 4 Fill the pan with 300 mL (or add another 200 mL) sterile distilled water and verify that the **Humidity** field in the control panel appears normal.
- ✓ Use the OQ Checklist to confirm that the water-level sensor is operating as expected.

IQ Checklist for BioSpa 8, All Models

Model:	
Serial Number:	
Date:	
Location:	

#	Step	Result or Information
IQ-1	Unpack/Inspect the Incubator Shipping container and instrument intact and undamaged? Record information as applicable: Order Number: _____ Ship Date: _____	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____ <i>If NO, contact your carrier and Agilent or your supplier</i>
IQ-2	Check Required Components Components intact and undamaged?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____ <i>If NO, contact your carrier and Agilent or your supplier</i>
IQ-3	Check Optional Components Components intact and undamaged? If YES, list or attach documentation:	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____ <i>If NO, contact your carrier and Agilent or your supplier</i> _____ _____ _____
IQ-4	Select an Appropriate Location Incubator located on level surface with temperature and humidity in acceptable range?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____
IQ-5	Remove Shipping Hardware Shipping hardware removed and stored? Including: <ul style="list-style-type: none"> • shipping platform • robot shipping bracket • drawer shipping brackets Left-side reader installation steps performed? <ul style="list-style-type: none"> • feet and alignment plate installed 	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____ <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____

IQ Checklist for BioSpa 8, All Models

#	Step	Result or Information
IQ-6	<p>Set up the BioSpa</p> <p>Install internal components? Including:</p> <ul style="list-style-type: none"> • Baffles • HEPA filter • Plate holders • Water pan (gas models only) • Close lid and install cover <p>Install external components? Including:</p> <ul style="list-style-type: none"> • Deck spacers • Gripper cover • Robot cover • Platform/cover • Guard rail 	<p><input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p><input type="checkbox"/> N/A _____</p> <p><input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p><input type="checkbox"/> N/A _____</p>
IQ-7	<p>Install Companion Instruments</p> <p>Fluidics instrument installed on left-side platform?</p> <p>Detection instrument installed?</p>	<p><input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p><input type="checkbox"/> N/A _____</p> <p><input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p><input type="checkbox"/> N/A _____</p>
IQ-8	<p>Install PC Software</p> <p>BioSpa software installed?</p> <p>Gen5 software/upgrade installed?</p> <p>LHC software/upgrade installed?</p>	<p><input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p><input type="checkbox"/> N/A _____</p> <p><input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p><input type="checkbox"/> N/A _____</p> <p><input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p><input type="checkbox"/> N/A _____</p>
IQ-9	<p>Install Gas Tanks & Registers</p> <p>CO2 and N2 gas canisters installed?</p>	<p><input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p><input type="checkbox"/> N/A _____</p>

IQ Checklist for BioSpa 8, All Models

#	Step	Result or Information
IQ-10	Connect Components to the Incubator Required components connected? Including: <ul style="list-style-type: none"> • CO2 & N2 tubing? • Platform/cover cable? • Liquid handler USB cable? • Power cable? 	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____
IQ-11	Connect Host Computer to Incubator and Reader Companion reader and incubator connected to the host computer? If required: Record computer specifications (e.g., processor, operating system), or attach documentation.	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____
IQ-12	Connect Power Up to three power supplies/cords connected to power receptacles that provide voltage and current within the specified rating for the system?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____
IQ-13	Configure Companion Instruments Reader configured in Gen5? Liquid handler configured in LHC?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____ <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____
	Establish Communication Communication with reader tested in Gen5? Communication with washer or dispenser tested in LHC?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____ <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____
	Create & Test Run Protocols Gen5 protocols tested? LHC protocols tested?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____ <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____
IQ-14	Configure Instruments for BioSpa BioSpa software configured to use liquid handler and/or reader? All self-tests successful?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____ <input type="checkbox"/> PASS <input type="checkbox"/> FAIL <input type="checkbox"/> N/A _____

IQ Checklist for BioSpa 8, All Models

#	Step	Result or Information
	Record BioSpa Software Info Model: _____ Serial Number: _____ Installation Version: _____ PC Software Version: _____ Motor Controller Basecode: _____ Gas Controller Basecode: _____ Temperature Controller Basecode: _____ Gen5 Version: _____ LHC Version: _____	<input type="checkbox"/> N/A _____ _____ _____ _____ _____ _____ _____ _____ _____
IQ-15	Align Instruments Gripper aligned to deliver and retrieve microplates to companion instruments?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____
IQ-16	Create and Run a Test Session Define a Reader-Imager session? Define a Washer-Dispenser session? Gas-flow test pass? Session completed successfully? Including: <ul style="list-style-type: none"> • Temperature at set point • CO2/N2 at set point • Humidity at expected level 	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____ <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____ <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____ <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____
	Review Safety Information Information pertaining to Warnings, Hazards, Precautions, and Safety Symbols reviewed (or will be reviewed, as a part of training)?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____
	Product registered with Agilent?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____

IQ Checklist for BioSpa 8, All Models

Comments:

Installation Qualification conducted by:	Date:
---	--------------

PRINT Name:

<i>If required, reviewed/approved by:</i> <input type="checkbox"/> N/A	Date:
--	--------------

PRINT Name:

OQ Checklist for BioSpa 8

Model:		
Serial Number:		
Date:		<input type="checkbox"/> Installation or <input type="checkbox"/> Shipping Date:
Location:		

#	Step	Result/Information
OQ-1	Run the System Test System Test pass?	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL <input type="checkbox"/> N/A _____
	Verify Software Information Correct/expected versions of software installed on the host computer, and BioSpa?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A _____
	Record BioSpa Software Info Model: _____ Serial Number: _____ Installation Version: _____ PC Software Version: _____ Motor Controller Basecode: _____ Gas Controller Basecode: _____ Temperature Controller Basecode: _____ LHC Version: _____ Gen5 Version: _____	<input type="checkbox"/> N/A _____
OQ-2	Verify Alignment Alignment verification test pass?	<input type="checkbox"/> PASS <input type="checkbox"/> FAIL <input type="checkbox"/> N/A _____
OQ-3	Verify Gas Sensor Gas sensor verification test pass?	<input type="checkbox"/> Not required at initial installation <input type="checkbox"/> PASS <input type="checkbox"/> FAIL <input type="checkbox"/> N/A _____
OQ-4	Verify Temperature Sensor Temperature sensor verification test pass?	<input type="checkbox"/> Not required at initial installation <input type="checkbox"/> PASS <input type="checkbox"/> FAIL <input type="checkbox"/> N/A _____
OQ-5	Verify Water Level Sensor Water level verification test pass?	<input type="checkbox"/> Not required at initial installation <input type="checkbox"/> PASS <input type="checkbox"/> FAIL <input type="checkbox"/> N/A _____

NOTE The gas, temperature, and water-level sensors were fully tested at the factory before shipment. You do not need to perform these sensor verification steps for new instruments. Instead, perform these tests at the first and subsequent annual operation qualifications.

OQ Checklist for BioSpa 8

Comments:

--

Operational Qualification Conducted By:

Date:

--	--

PRINT Name:

If required, reviewed/approved by: N/A

Date:

--	--

PRINT Name: