
Gene Pulser Xcell Electroporation Systems

Recommended Installation Qualification and Operational Qualification Protocols

Catalog #1652660
#1652661
#1652662



BIO-RAD

Gene Pulser Xcell Electroporation System

Recommended Installation Qualification and Operational Qualification Protocol Guidelines

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Section 1: General Instructions

1.1 Scope

These Installation Qualification and Operational Qualification (IQ and OQ) protocol guidelines are applicable to the Gene Pulser Xcell Electroporation System. These are designed to guide customers by providing recommended protocols for IQ and OQ that can be performed by the customer for the following systems:

- Gene Pulser Xcell Total System (catalog #1652660)
- Gene Pulser Xcell Eukaryotic System, CE System (catalog #1652661)
- Gene Pulser Xcell Microbial System, PC System (catalog #1652662)

Within this document, the IQ protocol provides guidance on how to document the proper installation of the Gene Pulser Xcell, and the OQ protocol is allows you to verify Gene Pulser Xcell operations (for example, that the system is properly delivering pulses based on user input.

Test result tables and signature documentation are provided to document results. However, they can be adapted as per individual lab needs and requirements.

1.2 Protocol Guidelines

The IQ sections of this document should be completed after receipt of the instrument. OQ sections can be completed after the IQ is completed or on a regular basis.

If an element in this protocol does not apply, it shall be indicated by N/A (not applicable). If a section has not been successfully completed, indicate the appropriate protocol exceptions and action taken in Section 5.1.

1.3 General Safety Information

The Gene Pulser Xcell Electroporation System is designed and certified to meet safety requirements of EN61010 and the EMC requirements of EN61326 (for Class A) and conforms to the Class A standards for electromagnetic emissions intended for laboratory equipment applications.

Do not use any part of the Gene Pulser Xcell Electroporation System if obvious external case damage has occurred, or the electronic displays are not functioning as described in the manual. Use this instrument only with the components provided (or their authorized additions or replacements), including, but not limited to, supplied cables and the Gene Pulser Xcell ShockPod cuvette chamber.

There are no user-serviceable parts within the unit. The operator should make no attempt to open any case cover or defeat any safety interlock. Do not alter or modify the instrument in any way.

Bio-Rad is not responsible for any injury or damage caused by the use of this instrument not performed by Bio-Rad or an authorized agent.

For detailed safety information and precautions, refer to the Gene Pulser Xcell Electroporation System Instruction Manual (#4006217), which you can download from <http://www.bio-rad.com>.

Note: This instrument is intended for research use as a laboratory application only.

1.4 Executor and Reviewer Identification and Signature

This section identifies the persons executing and reviewing the recommended IQ protocol.

Executor

Printed name	Institution/company	Signature	Date

Reviewer

Printed name	Institution/company	Signature	Date

This section identifies the persons executing and reviewing the recommended OQ protocol.

Executor

Printed name	Institution/company	Signature	Date

Reviewer

Printed name	Institution/company	Signature	Date

1.5 Site Information

Table 1.5 Site Information

Date of installation	
PO number	
Primary contact name	
Primary contact phone number	
Primary contact email address	
Installation site (department/lab)	
Company or institution name	
Address	
Executor initial and date	

1.6 Section 1 Signatures

Upon acceptance of this section, the executor and reviewer shall indicate results and sign and date below. If any of this section has not been successfully completed, indicate the appropriate protocol exceptions and action taken in Section 5.1.

Section 1 completed successfully		Executor signature	Date
Yes	No		
Section 1 completed successfully		Reviewer signature	Date
Yes	No		

Section 2: Installation Requirements

2.1 Delivery Confirmation

Table 2.1 Delivery Confirmation

Document	Present (executor initial)
Shipping documentation (packing list)	
Itemized purchase order	
Observations/comments:	

2.2 Inspection/Identification of Components

Inspect the shipment for receipt of all items listed in Table 2.2-1 and any shipping damage. Record serial or lot numbers (where applicable) of items listed.

Table 2.2-1 Inspection Results

Instrument Box Contents	Present (yes, no, or N/A)	Serial or Lot Number (if applicable)
Gene Pulser Xcell electroporation main unit		
Gene Pulser Xcell CE module (if applicable)		
Gene Pulser Xcell PC module (if applicable)		
Gene Pulser Xcell ShockPod cuvette chamber		
Power cord		N/A
Cuvettes (specify size received)		
Instruction manual		N/A
Warranty card		N/A
Declaration of conformity		N/A
Observations/comments:		
Executor initial and date		

If any damage is present, contact Bio-Rad Laboratories Technical Support to report damage and obtain Return Authorization approval and a Return Authorization number. If an item is missing, contact Bio-Rad Laboratories Technical Support to replace the missing item.

Table 2.2-2 Return Authorization

RA number	
Issued by	
Date arranged for collection	
Summary of damage or missing items	

2.3 Section 2 Signatures

Upon acceptance of this section, the executor and reviewer shall indicate results, and then sign and date below. If any part of this section was not successfully completed, indicate the appropriate protocol exceptions and action taken in Section 5.1.

Section 2 completed successfully		Executor signature	Date
Yes	No		
Section 2 completed successfully		Reviewer signature	Date
Yes	No		

Section 3: Recommended Installation Qualification Protocol

Before proceeding with this recommended IQ Protocol, unpack and set up the instrument in accordance with the Gene Pulser Xcell Electroporation System Instruction Manual, Section 2: Unpacking and System Installation.

3.1 Environment Requirements

The Gene Pulser Xcell Electroporation System shall be located on a sturdy, flat, and dry surface where there is no obstruction of the instrument vents per the environment specifications in Table 3.1. You must connect the system to a properly grounded receptacle.

Important: Do not use a 2-prong plug adaptor; it will void the safety certification of this product. Avoid use of extension cords, which can compromise the safety of the operator.

Table 3.1 Environment Requirements

Parameter	Requirement	Verification
Ventilation clearance	No obstruction to ventilation openings, vents found on front of Gene Pulser Xcell main unit	
Environment	Clean, free of excessive dust or moisture, stable, level surface	
Room temperature	Operate instrument within 0–35° C	
Room humidity	0–95%, without condensation	
Power circuit	Properly grounded receptacle	
Observations/comments:		

3.2 Hardware Installation

Install the Gene Pulser Xcell system in accordance with the instruction manual and record the results in Table 3.2.

Table 3.2 Hardware Installation

Description	Specification	Verification
System setup	Place the main unit on the lab bench.	
	Place the CE module (if applicable) on top of the main unit.	
	Place the PC module (if applicable) on top of the CE module, or the main unit if no CE module exists. Note: CE and PC modules are stackable in any order.	
	Insert the red/black connector that is attached to the back of the CE module (if applicable) into the appropriately labeled receptacle on the back of the main unit (Figure 3.2-1).	
	Insert the red/black connector that is attached to the back of the PC module (if applicable) into the appropriately labeled receptacle on the back of the main unit (Figure 3.2-2).	
	Insert the ShockPod leads into left and center output jacks located on the front of the main unit (Figure 3.2-3).	
System startup	Plug the power supply into the main unit and into a power outlet.	
	Turn the main unit power switch to the On position.	
	Verify the system initializes and the power light illuminates. Note: The display quickly shows the Bio-Rad name, product name, and interface version number.	
	Verify the system display lists items 1-10 (Figure 3.2-4).	
Gene Pulser Xcell ShockPod chamber open/close	Press the tab on the front of the chamber to release the latch, and verify the lid opens.	
	Gently press down on the chamber to verify the lid closes.	
Observations/comments:		

Note: All menu functions can be accessed from these screens.

Figure 3.2-1 Rear view (back panel) of CE module showing connection to the main unit

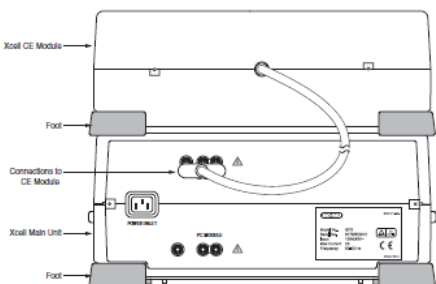


Figure 3.2-2 Rear view (back panel) of PC module showing connection to the main unit

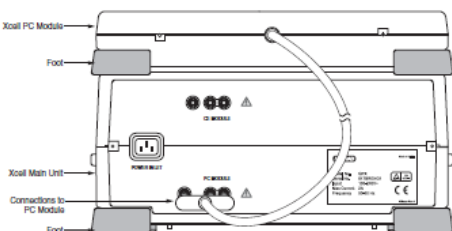


Figure 3.2-3 Front view of main unit showing ShockPod connection

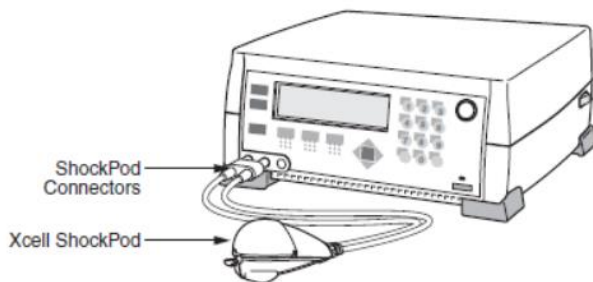


Figure 3.2-4 Gene Pulser Xcell main unit Home screens

Home Screen

```
HOME
1. Exponential protocol
2. Time constant protocol
3. Square wave protocol
4. Pre-set protocols
>5. User protocols
```

```
HOME
<6. Last pulse
7. Optimize
8. Data management
9. Measurements
10. User preferences
```

Executor initial and date	
----------------------------------	--

3.3 Section 3 Signatures

Upon acceptance of this section, the executor and reviewer shall indicate results and sign and date below. If any of this section has not been successfully completed, indicate the appropriate protocol exceptions and action taken in Section 5.1.

Section 3 completed successfully		Executor signature	Date
Yes	No		
Section 3 completed successfully		Reviewer signature	Date
Yes	No		

Section 4: Recommended Operational Qualification Protocol

This recommended OQ Protocol consists of a series of internal tests that verify that the internal capacitors and resistors are working properly, along with full system tests with the ShockPod to confirm full system performance.

4.1 Required Materials

This protocol requires the materials specified in Table 4.1 below, some of which are not included with the Gene Pulser Xcell system. Bio-Rad recommends that testers wear safety glasses when using this instrument, and avoid spilling any liquids on the instrument.

Table 4.1 Required Materials

Description	Serial or lot number	Expiration date
Gene Pulser Xcell Main Unit (#1652666)		N/A
Gene Pulser Xcell PC Module (if applicable) (#1652668)		N/A
Gene Pulser Xcell CE Module (if applicable) (#1652667)		N/A
Gene Pulser Xcell ShockPod Cuvette Chamber (#1652669)		N/A
Gene Pulser/Micro Pulser Cuvettes, 0.2 cm gap (#1652086)		
ReadyPrep Proteomics Grade Water (#1632091) (or similar)		
10x Phosphate Buffered Saline (PBS) (#1662043)		
1x PBS (made by mixing 1ml 10x PBS with 9 ml water)		

4.2 Gene Pulser Xcell Internal System Test

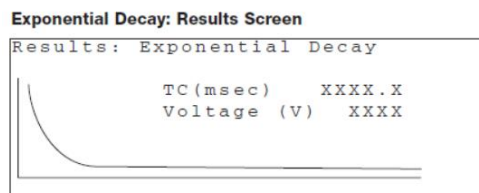
4.2.1 Internal System Exponential Decay and Square Wave Test List

All system tests for exponential decay and square wave require a main unit, along with the module specified in the test title.

Exponential Decay Tests

- 1: 3000 Volt PC Module Exponential Test A
- 2: 3000 Volt PC Module Exponential Test B
- 3: 3000 Volt PC Module Exponential Test C
- 4: 200 Volt PC Module Exponential Test
- 5: 500 Volt PC Module Exponential Test
- 6: 500 Volt CE and PC Module Exponential Test
- 7: 200 Volt CE and PC Module Exponential Test
- 8: 160 Volt CE and PC Module Exponential Test

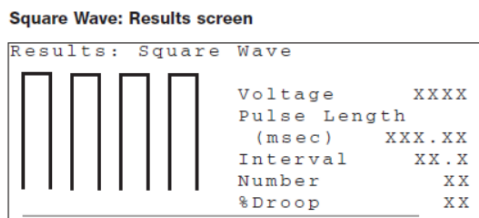
Figure 4.2.1-1 Example of exponential decay pulse results on main unit



Square Wave Tests

- 9: 3000 Volt Square Wave Test (use when testing the main unit)
- 10: 160 Volt CE Module Square Wave Test

Figure 4.2.1-2 Example of square wave pulse results on main unit



4.2.2 Internal System Test Protocols

The following sections contain detailed protocols for each of the tests listed in Section 4.2.1.

IMPORTANT: Detach the ShockPod before starting the tests. A connected ShockPod results in test failure.

► Turn off the Gene Pulser Xcell main unit power and wait 10 sec before turning it back on to begin testing.

Wait 1 min between tests to allow capacitors to fully discharge. If any test fails, wait 1 min, confirm the ShockPod is detached, and verify the correct testing values are entered into each screen before repeating.

1: 3000 Volt PC Module Exponential Test A

Step	Description	Pass/Fail
1	On the Home screen, select 1. Exponential Protocol.	
2	Set Voltage to 3000 and press Enter.	
3	Set Capacitance to 25 μ F and press Enter.	
4	Set Pulse Controller Resistance to 200 Ω and press Enter.	
5	Press Pulse.	
6	Verify the Results screen displays an exponential waveform, and record results in Table 4.2.3 on page 20.	

2: 3000 Volt PC Module Exponential Test B

Step	Description	Pass/Fail
1	On the Home screen, select 1. Exponential Protocol.	
2	Set Voltage to 3000 and press Enter.	
3	Set Capacitance to 50 μ F and press Enter.	
4	Set Pulse Controller Resistance to 1000 Ω and press Enter.	
5	Press Pulse.	
6	Verify the Results screen displays an exponential waveform, and record results in Table 4.2.3 on page 20.	

3: 3000 Volt PC Module Exponential Test C

Step	Description	Pass/Fail
1	On the Home screen, select 1. Exponential Protocol.	
2	Set Voltage to 3000 and press Enter.	
3	Set Capacitance to 10 μ F and press Enter.	
4	Set Pulse Controller Resistance to 50 Ω and press Enter.	
5	Press Pulse.	
6	Verify the Results screen displays an exponential waveform, and record results in Table 4.2.3 on page 20.	

4: 200 Volt PC Module Exponential Test

Step	Description	Pass/Fail
1	On the Home screen, select 1. Exponential Protocol.	
2	Set Voltage to 200 and press Enter.	
3	Set Capacitance to 10 μ F and press Enter.	
4	Set Pulse Controller Resistance to 50 Ω and press Enter.	
5	Press Pulse.	
6	Verify the Results screen displays an exponential waveform, and record results in Table 4-2.3 on page 20.	

5: 500 Volt PC Module Exponential Test

Step	Description	Pass/Fail
1	On the Home screen, select 1. Exponential Protocol.	
2	Set Voltage to 500 and press Enter.	
3	Set Capacitance to 25 μ F and press Enter.	
4	Set Pulse Controller Resistance to 200 Ω and press Enter.	
5	Press Pulse.	
6	Verify the Results screen displays an exponential waveform, and record results in Table 4.2.3 on page 20.	

6: 500 Volt CE and PC Module Exponential Test

Step	Description	Pass/Fail
1	On the Home screen, select 1. Exponential Protocol.	
2	Set Voltage to 500 and press Enter.	
3	Set Capacitance to 3275 μ F and press Enter.	
4	Set Pulse Controller Resistance to 1000 Ω and press Enter.	
5	Press Pulse. Note: The results may take longer to appear than other tests.	
6	Verify the Results screen displays an exponential waveform, and record results in Table 4.2.3 on page 20.	

7: 200 Volt CE and PC Module Exponential Test

Step	Description	Pass/Fail
1	On the Home screen, select 1. Exponential Protocol.	
2	Set Voltage to 200 and press Enter.	
3	Set Capacitance to 125 μ F and press Enter.	
4	Set Pulse Controller Resistance to 50 Ω and press Enter.	
5	Press Pulse.	
6	Verify the Results screen displays an exponential waveform, and record results in Table 4.2.3 on page 20.	

8: 160 Volt CE and PC Module Exponential Test

Step	Description	Pass/Fail
1	On the Home screen, select 1. Exponential Protocol.	
2	Set Voltage to 160 and press Enter.	
3	Set Capacitance to 500 μ F and press Enter.	
4	Set Pulse Controller Resistance to 200 Ω and press Enter.	
5	Press Pulse.	
6	Verify the Results screen displays an exponential waveform, and record results in Table 4.2.3 on page 20.	

9: 3000 Volt Square Wave Test (Main Unit)

Tip: It is normal to hear a snapping or popping sound at the high voltage range when performing the square wave tests. The sound is noticeably louder at the high voltage range for square wave pulse than exponential pulse.

Step	Description	Pass/Fail
1	On the Home screen, select 3. Square Wave Protocol.	
2	Set Voltage to 3000 and press Enter.	
3	Set Pulse Length to 0.1 ms and press Enter.	
4	Set Number of Pulses to 1 and press Enter.	
5	Set Pulse Interval to 0.0 sec and press Enter.	
6	Press Pulse.	
7	Verify the Results screen displays an exponential waveform, and record results in Table 4.2.3 on page 20.	

10: 160 Volt CE Module Square Wave Test

Step	Description	Pass/Fail
1	On the Home screen, select 3. Square Wave Protocol.	
2	Set Voltage to 160 and press Enter.	
3	Set Pulse Length to 25.0 ms and press Enter.	
4	Set Number of Pulses to 1 and press Enter.	
5	Set Pulse Interval to 0.0 sec and press Enter.	
6	Press Pulse.	
7	Verify the Results screen displays an exponential waveform, and record results in Table 4.2.3 on page 20.	

4.2.3 Internal System Test Data

Use this section to record the results of the Internal System Test Protocol, per Yes/No notations in previous sections.

Note: If the system does not have the applicable unit component, then the user may skip this test and should enter N/A for measured values.

Table 4.2.3 Internal System Test Data

Test Number	Test Name	Applicable Unit	Expected Values	Measured Values	Pass/Fail
1	3000 Volt PC Module Exponential Test A	Main + PC	TC: 3.75-6.25 Voltage: 2700-3300	TC: Voltage:	
2	3000 Volt PC Module Exponential Test B	Main + PC	TC: 37.5-62.5 Voltage: 2700-3300	TC: Voltage:	
3	3000 Volt PC Module Exponential Test C	Main + PC	TC: .375-.625 Voltage: 2700-3300	TC: Voltage:	
4	200 Volt PC Module Exponential Test	Main + PC	TC: 0.375-0.625 Voltage: 180-220	TC: Voltage:	
5	500 Volt PC Module Exponential Test	Main + PC	TC: 3.75-6.25 Voltage: 450-550	TC: Voltage:	
6	500 Volt CE and PC Module Exponential Test	Main + CE + PC	TC: 2456-4094 Voltage: 450-550	TC: Voltage:	
7	200 Volt CE and PC Module Exponential Test	Main + CE + PC	TC: 4.7-7.8 Voltage: 180-220	TC: Voltage:	
8	160 Volt CE and PC Module Exponential Test	Main + CE + PC	TC: 75-125 Voltage: 144-176	TC: Voltage:	
9	3000 Volt Square Wave Test	Main	Voltage: 2700-3300 %Droop: 0-1	Voltage: %Droop:	
10	160 Volt CE Module Square Wave Test	Main + CE	Voltage: 144-176 %Droop: 0-1	Voltage: %Droop:	

4.3 Gene Pulser Xcell ShockPod Test

All system tests for the ShockPod require a main unit. Refer to Table 4.3 to ensure you have the appropriate system modules specific to your test needs.

4.3.1 ShockPod Test List

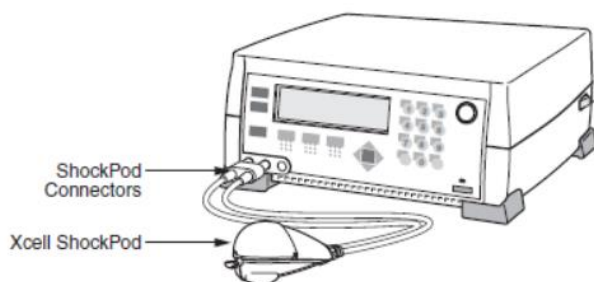
- 1: ShockPod Resistance Test
- 2: ShockPod PC Module Test A
- 3: ShockPod PC Module Test B
- 4: ShockPod CE Module Test A
- 5: ShockPod CE Module Test B

4.3.2 ShockPod Test Protocols

The following section contains detailed protocols for each of the tests listed in 4.3.1.

► Turn off the instrument. Insert the ShockPod leads into left and center output jacks located on the front of the main unit.

Figure 4.3.2



Test Protocol Notes

- Create a separate cuvette containing the indicated buffer (1x PBS or ReadyPrep proteomics-grade water) for each test.

IMPORTANT: Reuse of cuvettes and buffer may result in test failure.

- If any test fails, wait for one minute and repeat a second time. Confirm that the ShockPod is attached, that correct values are entered to each screen, and that each cuvette contains 200 μ l of correct buffer.

1: ShockPod Resistance Test

Step	Description	Pass/Fail
1	Add 200 µl of 1x PBS to a 2mm cuvette.	
2	Place the cuvette into the ShockPod and close the lid.	
3	On the Home screen, select 9. Measurement and press Enter.	
4	Select 1. Sample Resistance and press Enter.	
5	Measure resistance of cuvette and record results in Table 4.3.3 on page 24.	

2: ShockPod PC Module Test A

Step	Description	Pass/Fail
1	Add 200µl of ReadyPrep proteomics-grade water to a 2mm cuvette.	
2	Place the cuvette into the ShockPod and close the lid.	
3	On the Home screen, select 4. Pre-Set Protocols and press Enter.	
4	Select 1. Bacterial and press Enter.	
5	Select 3. E. coli-2 mm, 3.0 kV and press Enter.	
6	Confirm that Voltage is 3000 V, the Capacitance is 25 µF, Resistance is 200 Ω and Cuvette mm is 2.	
7	Press Pulse.	
8	Verify that the Results screen displays an exponential waveform and record results in Table 4.3.3 on page 24.	

3. ShockPod PC Module Test B

Step	Description	Pass/Fail
1	Add 200 µl of ReadyPrep proteomics-grade water to a 2 mm cuvette.	
2	Place the cuvette into the ShockPod and close the lid.	
3	On the Home screen, select 4. Pre-Set Protocols and press Enter.	
4	Select 1. Bacterial and press Enter.	
5	Select item 7. B.Cereus and press Enter.	
6	Confirm that Voltage is 1000 V, Capacitance is 50 µF, the Resistance is 200 Ω and Cuvette mm is 2.	
7	Press Pulse.	
8	Verify that the Results screen displays an exponential waveform, and record results in Table 4.3.3 on page 24.	

4. ShockPod CE Module Test A

Step	Description	Pass/Fail
1	Add 200µl of 1x PBS to a 2mm cuvette.	
2	Place the cuvette into the ShockPod and close the lid.	
3	On the Home screen, select 4. Pre-Set Protocols and press Enter.	
4	Select 3. Mammalian and press Enter.	
5	Select 1. CHO and press Enter.	
6	Confirm that Voltage is 160 V, Pulse Length is 15.0 ms, Number of Pulses is 1, Pulse Interval is 0.0 and Cuvette mm is 2.	
7	Press Pulse.	
8	Verify that the Results screen displays a square waveform and record results in Table 4.3.3 on page 24.	

5. ShockPod CE Module Test B

Step	Description	Pass/Fail
1	Add 200µl of 1x PBS to a 2mm cuvette.	
2	Place the cuvette into the ShockPod and close the lid.	
3	On the Home screen, select 4. Pre-Set Protocols and press Enter.	
4	Select 3. Mammalian and press Enter.	
5	Select 11. Jurkat and press Enter.	
6	Confirm that Voltage is 140 V, Capacitance is 1000 µF, Resistance is ∞ and Cuvette mm is 2.	
7	Press Pulse.	
8	Verify that the Results screen displays an exponential waveform and record results in Table 4.3.3 on page 24.	

4.3.3 ShockPod Test Data

Use this section to record the ShockPod test protocol results. If any test fails, repeat a second time using new cuvettes and reagents. Confirm the ShockPod is properly inserted into the main unit, the lid is closed, correct values are entered on each screen, and 200µl of the correct buffer is in each cuvette.

If the system does not have the applicable unit component, then the user may skip this test and should enter N/A for measured values.

Table 4.3.3 ShockPod Test Data

Test Number	Test Name	Applicable Unit	Expected Values	Measured Values	Pass/Fail
1	ShockPod Resistance Test	Main	Resistance: 5-22	Resistance:	
2	ShockPod PC Module Test A Bacterial protocol #3	Main + PC	TC: 4-6 Voltage: 2700-3300	TC: Voltage:	
3	ShockPod PC Module Test B Bacterial Protocol #7	Main + PC	TC: 9-11 Voltage: 900-1100	TC: Voltage:	
4	ShockPod CE Module Test A Mammalian Protocol #1	Main + CE	Voltage: 144-176 %Droop: 20-35	Voltage: %Droop:	
5	ShockPod CE Module Test B Mammalian Protocol #11	Main + CE	TC: 13.5-18 Voltage: 126-154	TC: Voltage:	

4.4 Section 4 Signatures

Upon acceptance of this section, the executor and reviewer shall indicate results and sign and date below. If any of this section has not been successfully completed, indicate the appropriate protocol exceptions and action taken in Section 5.1.

Section 4 completed successfully		Executor signature	Date
Yes	No		
Section 4 completed successfully		Reviewer signature	Date
Yes	No		

Section 5: Protocol Exceptions and Action Taken

5.1 Protocol Exceptions and Action Taken

If an exception or deviation was made to the protocol, the executor must comment on the reason for each exception and list what actions were taken to correct the situation. The executor should provide a description, including the section in which the problem occurred and/or any parts replaced.

Table 5.1 Protocol exceptions and actions taken

Exceptions		
1.		
2.		
3.		
Actions taken		
1		
2.		
3.		
Executor name	Signature	Date

Section 6: Attachment Log Summary

6.1 Attachment Log Summary

Generate all required attachments (data, certification training, and so forth), and list them below, in “attachment name, attachment description” format. Ensure all attachments are paginated, and cite the pages in the Attachment Log Summary below.

Table 6.1 Attachment log summary

Attachment description	Page __ of __
Executor initial and date	

Section 7: Final Approval and Signatures

7.1 Final Approval

By signing in the appropriate section below, the executor and reviewer confirm the successful or unsuccessful completion of the installation qualification and operational qualification system test. Further, acknowledgement of successful completion indicates the instrument has been completely installed and qualified for operational purposes.

For unsuccessful completion of test results, contact Bio-Rad Laboratories Technical Support to report issues requiring service or repair. Include copies of passed and failed test results.

Section 7 completed successfully		Executor signature	Date
Yes	No		
Section 7 completed successfully		Reviewer signature	Date
Yes	No		



**Bio-Rad
Laboratories, Inc.**

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Group

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