

The Validation Protocol for the Installation Qualification of the PowerPac™ Universal Power Supply System/Identification Number or Serial Number

Protocol Prepared By: Bio-Rad Laboratories 10/29/03
Date

Protocol Reviewed By: Company Name Date

Protocol Approved By: Enter Department Name 1 Date

Enter Department Name 2 Date

Enter Department Name 3 Date

Enter Department Name 4 Date

1. PURPOSE

This protocol documents the Installation Qualification (IQ) to verify that the PowerPac Universal power supply, identification number, has been properly installed in accordance with design specifications and Company Name's requirements.

2. Power Supply

2.1 Description

The PowerPac Universal power supply is designed to provide constant voltage, current, or power for a wide range of electrophoresis applications, including high throughput electrophoresis with the Dodeca cells and electrophoretic blotting. This power supply also provides the capability of recording, transferring and archiving the data or methods to a Personal Digital Assistant (PDA) and personal computer (PC) for more sophisticated pharmaceutical, QC laboratory and proteomics customers.

Add the description of the specific usage of the PowerPac Universal power supply in the process scheme.

2.2 Validation Approach

Test work for this protocol consists of the Installation Qualification (IQ) for this power supply. The IQ will be executed by completing the IQ Attachments. Completion of these attachments will be performed through field verification.

3. DOCUMENTATION

3.1 Document all information and verifications at the time they are performed. Record data pertaining to the testing described in this protocol on the appropriate attachments or on additional data sheets if specific attachments are not available.

3.2 Upon completion of the test work prepare a final report. Include in this report the following:

3.2.1 All original data or copies of documentation referenced in this protocol or identify the location of the documentation.

3.2.2 Any deviations from this protocol or abnormalities that occurred during the IQ including reasons for deviations and corrective actions, if any.

- 3.3 Perform and document the verifications according to the following list of attachments:
 - 3.3.1 Attachment 1- Packing List Verification
 - 3.3.2 Attachment 2- Power Supply Installation and Safety Verification
 - 3.3.3 Attachment 3- Software Version Verification
 - 3.3.4 Attachment 4- Operation Assessment

4. INSTALLATION QUALIFICATION

- 4.1 Packing List (Attachment 1) - Verify that the PowerPac Universal power supply is safely shipped and items are supplied in accordance with the manufacturer's defined specifications and the content list.
- 4.2 Power Supply Installation and Safety Verification (Attachment 2) – Verify that the power paths are safe to support high power output usages. Verify that the PowerPac Universal Power Supply is installed in accordance with the manufacturer's recommended specifications.
- 4.3 Software Version Verification (Attachment 3) – Verify the software applications are installed in accordance with the manufacturer's specified versions. This applies only if the PowerPac Data Transfer Software and PowerPac Remote Software are in use.
- 4.4 Operation Assessment (Attachment 4) – Document all the cells or electrophoresis apparati to be used with the power supply, including running conditions such as voltage, current, and power, to be applied with the PowerPac Universal power supply

5. ACCEPTANCE CRITERIA

- 5.1 The PowerPac Universal power supply and all the items are appropriately received in accordance with the specifications in the instruction manual.
- 5.2 All the parts in the input power path are qualified for safety standards and the PowerPac Universal power supply is installed in accordance with the specifications in the instruction manual.
- 5.3 All the software applications are installed with correct version (if applicable).
- 5.4 Record all the cells or electrophoresis apparati which will be used with the PowerPac Universal power supply.

ATTACHMENT 1

Installation Qualification
Packing List

System Description: PowerPac Universal Power Supply, System/Identification Number or Serial Number _____

Component Name	Tag No.	Description	Manufacturer/ Model Number	Serial Number	Field Verified (Circle one)	Unit Properly Received (Circle one)	As listed on P.O. or specification sheet (Circle one)
PowerPac Universal Power Supply		Power supply is packed in a protective AirBox™ (Air Packaging technologies, Inc, Valencia, CA, USA) or alternate packaging as determined by the manufacturer			Yes No N/A	Yes No N/A	Yes No N/A
Power Cord		3-Prong AC power cord plugged into 3-Prong AC grounded power outlet			Yes No N/A	Yes No N/A	Yes No N/A
Instruction Manual		Instructs users on proper operation and maintenance of the power supply	N/A	N/A	Yes No N/A	Yes No N/A	Yes No N/A
Warranty Card		Warranty registration	N/A	N/A	Yes No N/A	Yes No N/A	Yes No N/A
Declaration of conformity		Certification of ISO Compliance		N/A	Yes No N/A	Yes No N/A	Yes No N/A

N/A: Not applicable.

Comments: _____

Performed By: _____ Date: _____

Reviewed By: _____ Date: _____

ATTACHMENT 2

Installation Qualification

Power Supply Installation and Safety Verification

System Description: PowerPac Universal Power Supply, System/Identification Number

Supporting Utility Safety

Supporting Utility	Description	Model/ Serial Number	Result (Circle one)	Verified By/Date
Power Outlet	Power is tested using a receptacle analyzer, E-Z Check 61-035 or equivalent.	Receptacle Analyzer:	Pass Fail	
3-Prong AC Power Cord	3-Prong AC Power Cord is tested using a digital voltage meter, Fluke 83-3 DMM or equivalent.	Digital Meter:	Pass Fail	
Two-Prong 4mm Banana Plug	Two-Prong 4 mm Banana Plug attached to a cell or any other electrophoresis apparatus is EN 61010 certified		Pass Fail	

Installation

Place Installed	Description	Installed (Circle one)	Temperature	Humidity	Verified By/Date
	Ensure that there is at least 6 cm clearance around the power supply to ensure adequate cooling of power supply	Pass Fail			

Comments: _____

Performed By: _____

Date: _____

Reviewed By: _____

Date: _____

ATTACHMENT 3
 Installation Qualification
Software Version Verification

System Description: PowerPac Universal Power Supply, System/Identification Number

	Item	Version number (if applicable)		Verified By / Date
		Expected	Actual	
1	Power Supply Firmware (Displayed on unit at power-up)	1.27 or higher		
2	PowerPac Remote software (Found in "Info" on PDA Applications)	2.03 or higher		
3	Palm OS (Found in "Info" on PDA Applications)	4.0 or above		
2	PowerPac Data Transfer software (Found in "About" under "Help" tab)	1.0		
3	PC operating system	Windows® 2000™/XP™		

Comments: _____

Performed By: _____ Date: _____

Reviewed By: _____ Date: _____

ATTACHMENT 4
 Installation Qualification
Operation Assessment

System Description: PowerPac Universal Power Supply, System/Identification Number or Serial Number

The operating range for the PowerPac Universal is as follows:

Output voltage: 10-500 volts
 Output current: 0.01 to 2.5 amperes
 Output power: 1-500 watts

If the expected running conditions for any of the cells or electrophoresis apparati listed in the table below do not fall within the operating range of the PowerPac Universal, use of this cell/ apparatus with the PowerPac Universal is not recommended and may void the warranty.

Number	List of Cells or Electrophoresis Apparati Intended for Use with the PowerPac Universal power supply	Expected Running Conditions			Within Operating Range?
		Voltage	Current	Power	(Circle one)
1					Yes No
2					Yes No
3					Yes No
4					Yes No
5					Yes No
6					Yes No
7					Yes No

Comments: _____

Performed By: _____

Date: _____

Reviewed By: _____

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