The Validation Protocol for the Operational 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 Operational Qualification (OQ) to verify that the PowerPac Universal power supply, , operates in accordance with Name's requirements and that Company Name's requirements do not exceed manufacturer's equipment specification.

2. SYSTEM

2.1 Description

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 PDA and PC for more sophisticated pharmaceutical, QC laboratory and proteomics customers.

Modify the system description to reflect actual system configuration. Add the description of the specific usage of the PowerPac Universal power supply in the

2.2 Validation Approach

Test work for this protocol consists of the Operational Qualification (OQ) for this power supply. The OQ will include verification of power supply functional testing, as well as overall system testing. Functional testing will include keystrokes, method generation, operation and controls, power output accuracy, and data organization testing associated with the power supply.

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, which occurred during the OQ 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- Front Panel Keys Verification
3.3.2 Attachment 2- Methods on Power Supply
3.3.3 Attachment 3- Operational and Controls Verification
3.3.4 Attachment 4- Output Accuracy Verification
3.3.5 Attachment 5- Data Organization Verification

4. OPERATIONAL QUALIFICATION

4.1 Front Panel Keys Verification (Attachment 1) - Verify the functionality of each front panel key equipped on PowerPac Universal Power Supply.

4.2 Methods on Power Supply (Attachment 2) - Verify that the PowerPac Universal power supply can generate a single step in manual mode and method(s) in method mode. This protocol also verifies that the power supply can manage the method(s) in accordance with the manufacturer's design.

4.3 Operation and Controls Verification (Attachment 3) - Verify that the operations and controls of PowerPac Universal power supply meet the user’s requirements and operating criteria specified by the manufacturer.

4.4 Output Accuracy Verification (Attachment 4) - Verify that the output readings of voltage, current and power displayed on the front panel display of PowerPac Universal power supply are consistent with the actual output.

4.5 Data Organization Verification (Attachment 5) - Verify that the management of data files on a PDA and PC is in accordance with the manufacturer’s design.

5. ACCEPTANCE CRITERIA

5.1 Each front panel key on the PowerPac Universal power supply carries out the function completely as defined by the manufacturer.

5.2 PowerPac Universal power supply generates a single step in manual mode or methods in method mode successfully. The methods created are appropriately managed (such as edit, delete, rename, save, etc).

5.3 PowerPac Universal power supply operates according to the manufacturer's defined specifications.

5.4 The consistency between the actual output readings (voltage, current and power) and displayed output readings on the front panel are within the tolerances of the manufacturer's defined specifications.

5.5 The run data and methods are appropriately edited, saved and transferred on the PowerPac Universal power supply, PDA and PC. The correct information carried by run data and methods are completely retained during the process of transfer.

ATTACHMENT 1
Operational Qualification
Front Panel Keys Verification

System Description: PowerPac Universal Power Supply System/Identification Number

Key	Function	Results (Circle One)	Verified By / Date
Power Switch	Move power switch to the "|" position to turn on the PowerPac Universal power supply.	Pass Fail	
Run/Pause	Starts or pauses a run. When paused, the run parameters for the current or subsequent steps may be edited.	Pass Fail	
Stop/Home	Terminates the run in progress, or if no run is active, changes the display to the Home screen.	Pass Fail	
Setup	Used to set the PowerPac Universal power supply default settings such as: power failure detection, rapid resistance change detection, no load detection as well as clock, contract and key chirp settings.	Pass Fail	
Edit	Moves the cursor between entry fields used to set the run mode (constant voltage, constant current, or constant power), run limits (voltage, current, or power) and time mode (hours volt-hours or untimed).	Pass Fail	
CE	Deletes alphanumeric characters from a parameter value or method name, or restore previous numeric value.	Pass Fail	

Comments: _____

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ATTACHMENT 1
Operational Qualification
Front Panel Keys Verification

System Description: PowerPac Universal Power Supply System/Identification Number

Key	Function	Results (Circle One)	Verified By / Date
Arrow keys	Used to scroll through method list or method protocol.	Pass Fail	
Alpha-numeric keypad	Used to enter parameter values and method names.	Pass Fail	
Soft Keys	Used to select commands on the LCD screen immediately above the soft keys	Pass Fail	

Comments: _____

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ATTACHMENT 2
Operational Qualification
Methods on Power Supply

System Description: PowerPac Universal Supply System/Identification Number

Step	Method	Description	Programmable as specified (Circle One)	Verified By / Date
1	Constant voltage in manual mode	Create manual run with constant voltage and choose time: VHOURS	Yes No	
2	Constant current in manual mode	Create manual run with constant current and choose time: HRS	Yes No	
3	Constant watts in manual mode	Create manual run with constant power and choose time: UNTIMED	Yes No	
4	One method in method mode	Create a method with nine steps, then save and view the method	Yes No	
5	Edit the method in method mode	Delete any two steps in the method created in step 4 and replace one step with new parameters. Save the method with new name and view the method.	Yes No	
6	Nine methods in method mode	Create another seven methods and save them with different names. Nine methods (include two methods in step 4 and 5) should be stored in mathematical/ alphabetical order.	Yes No	
7	Delete method in method mode	Delete a method and verify that eight methods remain in the list.	Yes No	
8	Change method name	Change a method name and verify that the steps in that method are not affected.	Yes No	

Comments: _____

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ATTACHMENT 3
Operational Qualification
Operational and Controls verification

System Description: PowerPac Universal Supply System/Identification Number

The following operational and controls qualifications are performed using an electrophoresis cell with gels. A Criterion™ cell (165-6001) or Mini-PROTEAN® 3 cell manufactured by Bio-Rad Laboratories with two precast SDS gels is recommended.

Operation	Description	Operate as specified	Verified By/Date
Constant voltage in manual mode	Create a single constant voltage step with a duration of 1 hour in manual mode. Record the variation of voltage and the elapsed time.	Cell and gel used: Range of volts: Elapsed time:	
Constant current in manual mode	Create a single constant current step with a duration of 1.5 hours in manual mode. Record the variation of current and the elapsed time.	Cell and gel used: Range of current: Elapsed time:	
Constant power in manual mode	Create a single, constant power step with a duration of 30 minutes in manual mode. Record the variation of power and the elapsed time.	Cell and gel used: Range of watts: Elapsed time:	
Constant voltage in method mode	Create a single, constant voltage step with a duration of 5 hours in method mode. Record the variation of voltage and the elapsed time.	Cell and gel used: Range of volts: Elapsed time:	
Constant current in method mode	Create a single, constant current step with a duration of 40 minutes in method mode. Record the variation of current and the elapsed time.	Cell and gel used: Range of current: Elapsed time:	
Constant power in method mode	Create a single constant power step with 2 hours duration in method mode. Record the variation of power and the elapsed time.	Cell and gel used: Range of watts: Elapsed time:	

Comments: _____

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Performed By: _____ Date: _____

Reviewed By: _____ Date: _____

ATTACHMENT 3
Operational Qualification
Operational and Controls Verification

System Description: PowerPac Universal Power Supply System/Identification Number

Operation	Description	Operate as specified	Verified By/Date
Continuous hour in manual mode	Create a single step, constant voltage (or current , or power) step with an "untimed" duration in manual mode. Stop the run five minutes later and record the elapsed time.	Run duration matches display within 2 seconds: Yes No **Start Time:** **Stop Time:**	
Continuous hour in method mode	Create a single, constant voltage (or current , orpower) method with an "untimed" duration in method mode. Stop the run five minutes later and record the elapsed time.	Run duration matches display within 2 seconds: Yes No **Start Time:** **Stop Time:**	
Volt-hour in manual mode	Create a single, constant voltage step method with a duration of 1 volt-hour in manual mode. Record the elapsed volt-hours.	Cell and gel used: Elapsed volt-hours:	
Volt-hour in method mode	Create a single, constant voltage step method with a duration of 1 volt-hour in method mode. Record the elapsed volt-hours.	Cell and gel used: Elapsed volt-hours:	
Power failure	Turn "PFd" on in the Setup menu. Create a method in method mode and start the run. Unplug the power cord from the AC power source, wait a few moments, then reconnect it.	Run is resumed: Yes No	
Pause run editing in manual mode	Create a step in manual mode and start the run. Pause the run, change the controlled parameter, then continue the run.	Run continues under new setting: Yes No	

Comments: _____

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ATTACHMENT 3
Operational Qualification
Operational and Controls Verification

System Description: PowerPac Universal Power Supply System/Identification Number

Operation	Description	Operate as specified	Verified By/Date
Pause run editing in method mode	Create a multi-step method in method mode and start the run. Pause the run, edit the step settings and continue the run.	Run continues under new settings: Yes No	
Automatic crossover	Create a single constant voltage step in manual mode: Volt=200V; LimitA = 50mA; LimitW =100w.	Run mode changes to 50mA constant current: Yes No	
Rapid resistance change	Turn “RRCd-NLDd“ on in the Setup menu. Create a run in manual mode and start the run. Unplug the load (cells, etc.).	An alarm sounds and run pauses: Yes No	
No load detection	Turn “RRCd-NLDd“ on in the Setup menu. Create a single step run in manual mode and start the run without a load.	An error message “NOLOAD DETECTED”: appears: Yes No	

Comments: _____

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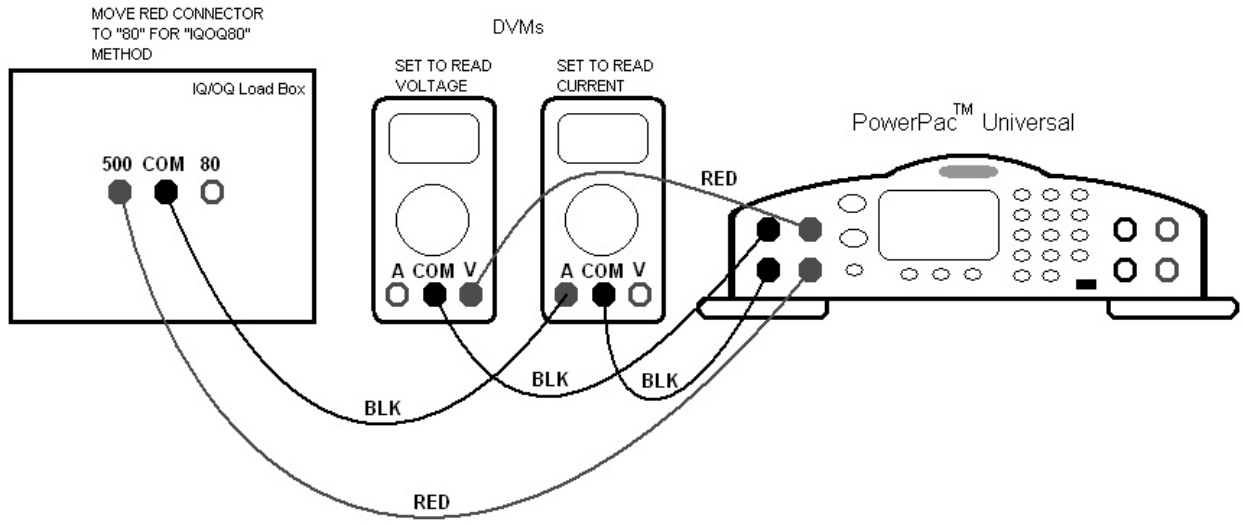
ATTACHMENT 4
Output Accuracy

System Description: PowerPac Universal Power Supply System/Identification Number

The following Operational and Controls Qualifications are performed using an IQ/OQ Test Box (164-5069) and two calibrated Digital Multimeters or DVMs (Note: Meters should be Calibrated Fluke True RMS Multimeters Model 189 or equivalent with 0.1% DCV and 0.15% DC mA accuracy). Connect the box and the two DVMs to the PowerPac Universal power supply as shown in the following diagram:



After connection, power up the PowerPac Universal power supply and the two DVMs. Set the DVMs as shown in the diagram, one to read voltage on a scale that will accommodate 500VDC, and the other to read current on a scale that will accommodate 2500mADC. Then, program the following method, called "IQOQ500" on the PowerPac Universal power supply, or use a PDA to load the method into the PowerPac Universal power supply's memory.

Comments: _____

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ATTACHMENT 4
Output Accuracy

System Description: PowerPac Universal Power Supply System/Identification Number

Step No:	Controlled Parameter	Second Parameter	Third Parameter	Time
1	500V	2500mA	500W	1 Min.
2	60mA	500V	500W	1 Min.
3	20W	500V	2500mA	1 Min.
4	700mA	500V	500W	1 Min.
5	50V	2500mA	500W	1 Min.
6	500V	500mA	500W	1 Min.
7	2500mA	500V	100W	1 Min.
8	500W	200V	2500mA	1 Min.
9	250W	500V	2500mA	1 Min.

IQOQ500

Before running the method, use the CD included with this product to load the Microsoft Excel™ spreadsheet named "IQOQCalc.xls". Print out a copy of this spreadsheet to collect data. A sample spreadsheet that contains the formulas to be used is shown in Table 1.

Run the method, and, while each step is running, write down the voltage and current measured on the DVMs and the voltage, current, and power displayed on the PowerPac Universal on a copy of the spreadsheet shown in Table 1. When the method is complete, transfer the data collected into a copy of "IQOQCalc.xls".

After entering the data, compare the number in the "Controlled Parameter Error" to the number in the column labeled "Controlled Parameter Limit". If the number in the "Error" column is less than or equal to the number in the "Limit" column, the PowerPac Universal power supply meets the requirements of that test. If any of the numbers in the "Error" column exceed its corresponding number in the "Limit" column, the PowerPac Universal power supply must be calibrated by Bio-Rad Service.

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ATTACHMENT 4
Output Accuracy

System Description: PowerPac Universal Power Supply System/Identification Number

Then, move the red wire that is connected to the "500" connector on the IQ/OQ Test Box to the "80" connector.

Step No:	Controlled Parameter	Second Parameter	Third Parameter	Time
1	200V	2500mA	500W	1 Min.
2	200mA	200V	500W	1 Min.
3	20W	200V	2500mA	1 Min.
4	1800mA	200V	500W	1 Min.
5	20V	2500mA	500W	1 Min.
6	200V	150mA	500W	1 Min.
7	2500mA	200V	100W	1 Min.
8	500W	80V	2500mA	1 Min.
9	250W	200V	2500mA	1 Min.

IQOQ80

Run the method, and, while each step is running, write down the voltage and current measured on the DVMs and the voltage, current, and power displayed on the PowerPac Universal power supply on a copy of the spreadsheet shown in Table 1. When the method is complete, transfer the data collected into a spreadsheet with the formulas shown in Table 1.

After entering the data, compare the number in the "Controlled Parameter Error" to the number in the column labeled "Controlled Parameter Limit". If the number in the "Error" column is less than or equal to the number in the "Limit" column, the PowerPac Universal power supply meets the requirements of that test. If any of the numbers in the "Error" column exceed its corresponding number in the "Limit" column, the PowerPac Universal power supply must be calibrated by Bio-Rad Service.

Comments: _____

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ATTACHMENT 4
Output Accuracy

System Description: PowerPac Universal Power Supply System/Identification Number

PowerPac Universal IQ/OQ Spreadsheet

This document is a template for a spreadsheet that is used to analyze the data gathered using the OQ procedure with the PowerPac Universal and the IQ/OQ Load Box.

Print out this spreadsheet, and write down the data gathered while running the procedure. After the method is run on the PowerPac Universal, enter the data gathered in the cells below. The formulas in the other cells calculate the power produced during each step, and will display the percentage error of each measurement. The upper limit for the percent error for the controlled parameter is listed to the right.

Vmeter is the voltage read by the DVM during that step in the run, Imeter is the current read (in milliAmps) during that step in the run, Vppu is the voltage displayed by the UUT, Ippu is the current displayed by the UUT (in milliamps), and Pppu is the power displayed by the UUT in watts.

The formulas listed must be entered into the appropriate cells as shown. The easiest way to do this is to enter the top row first, highlight the cells underneath, and then use the "Fill Down" option to duplicate the formulas down the page.

Note: Underlined parameters for Vset, Iset, and Pset indicate the parameter that is the controlled item: Voltage, Current, or Power.

Note: Underlined parameters for Verr%, Ierr%, and Perr% indicate the percentage error of the parameter that actually is controlled by the UUT, based on operating conditions.

Note: Tests indicated by V to I, I to P, and P to V indicate crossover tests, where the unit's operating point constraints require operation in a different mode than programmed.

500 Ohm Test

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
	Test	Vset	Iset	Pset	Vmeter	Imeter	Pmeter	Vppu	Ippu	Pppu	Verr%	Ierr%	Perr%	Controlled Parameter Error	Controlled Parameter Error Limit
11	V	500	2500	500			=E11*F11/1000				=(H11-E11)*100/E11	=(I11-F11)*100/F11	=(J11-G11)*100/G11	=K11	Verr% ≤ ± 2%
12	I	500	60	500			=E12*F12/1000				=(H12-E12)*100/E12	=(I12-F12)*100/F12	=(J12-G12)*100/G12	=F12-I12	Imeter-Ippu ≤ ± 5mA
13	P	500	2500	20			=E13*F13/1000				=(H13-E13)*100/E13	=(I13-F13)*100/F13	=(J13-G13)*100/G13	=M13	Perr% ≤ ± 2%
14	I	500	700	500			=E14*F14/1000				=(H14-E14)*100/E14	=(I14-F14)*100/F14	=(J14-G14)*100/G14	=L14	Ierr% ≤ ± 2%
15	V	50	2500	500			=E15*F15/1000				=(H15-E15)*100/E15	=(I15-F15)*100/F15	=(J15-G15)*100/G15	=E15-H15	Vmeter-Vppu ≤ ± 1V
16	V to I	500	150	500			=E16*F16/1000				=(H16-E16)*100/E16	=(I16-F16)*100/F16	=(J16-G16)*100/G16	=F12-I12	Imeter-Ippu ≤ ± 5mA
17	I to P	500	2500	100			=E17*F17/1000				=(H17-E17)*100/E17	=(I17-F17)*100/F17	=(J17-G17)*100/G17	=M17	Perr% ≤ ± 2%
18	P to V	200	2500	500			=E18*F18/1000				=(H18-E18)*100/E18	=(I18-F18)*100/F18	=(J18-G18)*100/G18	=K18	Verr% ≤ ± 2%
19	P	500	2500	250			=E19*F19/1000				=(H19-E19)*100/E19	=(I19-F19)*100/F19	=(J19-G19)*100/G19	=M19	Perr% ≤ ± 2%

80 Ohm Test

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
21	V	200	2500	500			=E21*F21/1000				=(H21-E21)*100/E21	=(I21-F21)*100/F21	=(J21-G21)*100/G21	=K21	Verr% ≤ ± 2%
22	I	200	200	500			=E22*F22/1000				=(H22-E22)*100/E22	=(I22-F22)*100/F22	=(J22-G22)*100/G22	=F22-I22	Imeter-Ippu ≤ ± 5mA
23	P	200	2500	20			=E23*F23/1000				=(H23-E23)*100/E23	=(I23-F23)*100/F23	=(J23-G23)*100/G23	=M23	Perr% ≤ ± 2%
24	I	200	1800	500			=E24*F24/1000				=(H24-E24)*100/E24	=(I24-F24)*100/F24	=(J24-G24)*100/G24	=L24	Ierr% ≤ ± 2%
25	V	20	2500	500			=E25*F25/1000				=(H25-E25)*100/E25	=(I25-F25)*100/F25	=(J25-G25)*100/G25	=E25-H25	Vmeter-Vppu ≤ ± 1V
26	V to I	200	500	500			=E26*F26/1000				=(H26-E26)*100/E26	=(I26-F26)*100/F26	=(J26-G26)*100/G26	=L26	Ierr% ≤ ± 2%
27	I to P	500	2500	100			=E27*F27/1000				=(H27-E27)*100/E27	=(I27-F27)*100/F27	=(J27-G27)*100/G27	=M27	Perr% ≤ ± 2%
28	P to V	80	2500	500			=E28*F28/1000				=(H28-E28)*100/E28	=(I28-F28)*100/F28	=(J28-G28)*100/G28	=K28	Verr% ≤ ± 2%
29	P	200	2500	250			=E29*F29/1000				=(H29-E29)*100/E29	=(I29-F29)*100/F29	=(J29-G29)*100/G29	=M29	Perr% ≤ ± 2%

Table 1

ATTACHMENT 5
Operational Qualification
Data Organization Verification

System Description: PowerPac Universal power supply System/Identification Number

The PowerPac Universal power supply is capable of transmitting methods to and from a PDA (Personal Digital Assistant), and transmitting run data to a personal computer (PC) or PDA through the IR port located on the front of the power supply. To verify the data transfer correctly, the following items are required to perform the verification:

- One IrDA Port
- One compatible PC with Windows 2000™ or Windows XP™
- PowerPac Data Transfer Software and PowerPac Remote Software (164-5067) loaded on a PC and PDA respectively
- One PDA with Palm OS Version 4.0 or above

Step	Function	Description	Operate as specified	Verified By/Date
1	Transfer 20 run data files from the power supply to PDA	Create a run with a unique name in method mode, run it, and transfer it to a PDA. Repeat until 20 runs are transferred.	20 Run data transferred: Yes No	
2	Transfer 5 run data flies from the power supply to PC	Create a run with a unique name in method mode. Run it and transfer it from the power supply to a PC. Repeat until 5 runs are transferred.	5 Run data transferred: Yes No	
3	Transfer 10 run data files from PDA to PC	Transfer a run data file from step 1 to a PC. Repeat until 10 data files are transferred.	10 Run data transferred: Yes No	
4	Delete a run data files from PDA	Select a run data file from the list of run data files in a PDA and delete the data file.	One run data deleted: Yes No	

Comments: _____

Performed By: _____ Date: _____

Reviewed By: _____ Date: _____

ATTACHMENT 5
Operational Qualification
Data Organization Verification

System Description: PowerPac Universal power supply System/Identification Number

Step	Function	Description	Operate as specified	Verified By/Date
5	Extract a method from the run data file in the PDA	Select a run data file from the list of run data files in the PDA, extract the method and save it with a new name.	Method is extracted and saved: Yes No	
6	Transfer 3 methods from power supply to PDA	Beam in a current method to the PDA. Repeat until 3 methods are transferred.	Three methods are transferred: Yes No	
7	Edit 2 methods in PDA	Select an existing method from the list of methods in the PDA, edit step(s) and save it with a new name. Repeat until two methods are edited and saved.	Two methods are edited and saved: Yes No	
8	Create 2 new methods in PDA	Create two new methods and save them with unique names	Two new methods are created and saved: Yes No	
9	Transfer 9 methods from PDA to power supply	Select a method from the list of methods in PDA and beam to the power supply. Repeat until nine methods are transferred.	9 methods are transferred: Yes No	
10	Import 5 run data files to PowerPac Data Transfer program	Create three new projects named as Test1, Test2 and Test3. Import two data files to Test1, two data files to Test2 and one data files to Test3.	Five data files are imported to the projects: Yes No	

Comments: _____

Performed By: _____ Date: _____

Reviewed By: _____ Date: _____

ATTACHMENT 5
Operational Qualification
Data Organization Verification

System Description: PowerPac Universal power supply System/Identification Number

Step	Function	Description	Operate as specified	Verified By/Date
11	Method in PC and method in power supply correlation	Create a run in method mode on power supply and import it to project Test1. Compare the method in the PC with the method in the power supply. Repeat two times for projects Test2 and Test3 and compare the methods.	Method in the PC and the method in the power supply are consistent:Yes No	
12	Data and method correlation	Compare the run data file (from step 11) in the time course table with the method in the PC and the method in the power supply. Repeat comparison for the file in projects Test2 and Test3	Run data is consistent with the method in the PC and the method in the power supply: Yes No	
13	Data, method, and graph correlation in PowerPac Data Transfer program	Open a run data file from project Test1 and compare the run data, method and graph. Repeat for one file from project Test2 and one file from Test3.	Run data, method, and graph are consistent: Yes No	
14	Data Report	Print reports for one run data file in each project of Test1, Test2 and Test3. The each report should includes Method, Edited method, comments Graph and run data.	Reports are printed with correct information: Yes No	
15	Data Export	Open a run data file and export the run data to MicroSoft Excel™. Open the file from Excel and compare run data in Excel with the run data in PowerPac Data Transfer program.	Run data is transferred with correct values: Yes No	

Comments: _____

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ATTACHMENT 5
Operational Qualification
Data Organization Verification

System Description: PowerPac Universal power supply System/Identification Number

Step	Function	Description	Operate as specified	Verified By/Date
16	Graph Export	Open a run data file and export the graph as a Bitmap to the Clipboard. Open the graph and compare the graph with the graph in PowerPac Data Transfer program.	Graph is transferred with correct profile: Yes No	

Comments: _____

Performed By: _____ Date: _____

Reviewed By: _____ Date: _____