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 |
|--------------------------|-------------------------|----------|
| Frepareu by. | BIO-RAU LABORATORIES | 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.

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ATTACHMENT 1

Operational Qualification

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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| Performed By: | Date: |
| Reviewed By: | Date: |

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ATTACHMENT 1

Operational Qualification

Front Panel Keys Verification
PowerPac Universal Power Supply System/Identification Number System Description:

| 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 | |

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| Reviewed By: | Date: |

ATTACHMENT 2

Operational Qualification

Methods on Power Supply

System Description: PowerPac Universal Supply System/Identification Number

| Step | Method | Description | Progran as spe (Circle | cified | 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 | |

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| Performed By: | Date: |
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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: | |

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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 |
|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|---------------------|
| 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 | |

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| Performed By: | Date: |
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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 | |

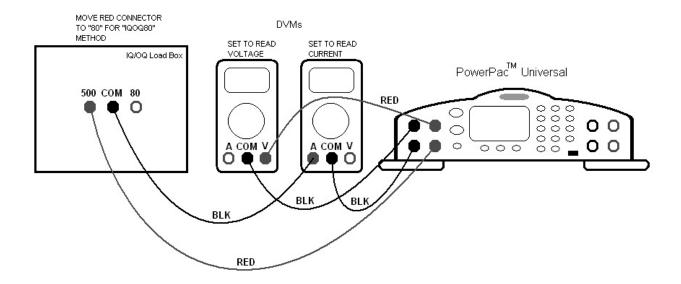
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ATTACHMENT 4 Output Accuracy

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 | Controlled Parameter | Second Parameter | Third Parameter | Time |
|------|----------------------|------------------|-----------------|--------|
| No: | | | | |
| 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.

| Comments: | |
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| Performed By: | Date: |
| Reviewed By: | Date: |

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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 | Controlled Parameter | Second Parameter | Third Parameter | Time |
|------|----------------------|------------------|-----------------|--------|
| No: | | | | |
| 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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| Reviewed By: | Date: |

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ATTACHMENT 4

System Description:

Output Accuracy
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. | 0 |
| 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. | e other cells calculate |
| 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 watts. | by the UUT (in |
| 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. | e the formulas down |
| | |

|] | | | | | | | | | | | | | | | |
|--------------------|------------------------------|--------------------------------------|-------------------------|----------------|---------------------------|-------------------------|---------------------|--------------------|-------------------|------------------------|--------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|--------------------------------------------------------------------|
| | Powe | PowerPac Universal IQ/OQ Spreadsheet | iiversa | | Sprea | idshee | | | | | | | | | |
| | | | | This | document is | a template |) for a spreadsheet | that is use | d to analyz | e the data g | jathered using the OQ proced | 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 | rsal and the IQ/OQ Load Box | | |
| Print o the pox | ut this spre wer produci | adsheet, a ed during e | nd write c each step | own the d | lata gathe display the | e percent | nunning the pro | cedure. n measu | After the rement. | method is The upper | s run on the PowerPac L r limit for the percent erro | niversal, enter the data g or for the controlled paran | 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 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. | . The formulas in the | cells below. The formulas in the other cells calculate othe right. |
| Vmete milliam | r is the volt ps), and Pp | age read b opu is the I | y the DVA | 4 during the | nat step in the UUT | n the run, in watts: | lmeter is the cu | rrent rea | d (in milli | Amps) du | ring that step in the run, | 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 UU milliamps), and Pppu is the power displayed by the UUT in watts. | ayed by the UUT, lppu is t | T, lppu is the current displayed by the UUT (in | d by the UUT (in |
| The form the page | mulas liste je. | d must be | entered ir | nto the ap | propriate | cells as s | hown. The eas | iest way | to do this | is to ente | rthe top row first, highlig | th the cells underneath, | 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. | n" option to duplica | te the formulas down |
| Note: | Underlined | paramete | s for Vset | , Iset, and | d Pset ind | licate the | parameter that i | s the cor | ntrolled its | em: Voltag | Note: Underlined parameters for Vset, Iset, and Pset indicate the parameter that is the controlled item: Voltage, Current, or Power. | | | | |
| Note: | Underlined | paramete | s for Verr | %, lerr%, | and Pen | % indicat | e the percentage | error of | the para | meter that | t actually is controlled by | Note: Underlined parameters for Verr%, lerr%, and Perr% indicate the percentage error of the parameter that actually is controlled by the UUT, based on operating conditions | ating conditions. | | |
| Note: | Tests indic | ated by V t | 01, I to P | and P to | V indicati | e crossov | er tests, where i | he unit's | operatini | g point co | nstraints require operatio | 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 | n programmed. | | |
| | 500 O | 500 Ohm Test | 3357 | | | İ | | | | | | | | | |
| Î | Þ | œ | ဂ | 0 | т | 71 | ရ | I | -13 | ے | _ | | × | z | 0 |
| | Test | Vset | Iset | Pset | Vmeter | lmeter | Pmeter | Vppu | DB DB | Pppu | Ven% | len% | Perr% | Controlled Parameter Error | Controlled Parameter Error Limit |
| 1 | < | 500 | 2500 | 500 | ш | | =E11*F11/1000 | | | | =(H11-E11)*100/E11 | =(111-F11)*100/F11 | =(J11-G11)*100/G11 | =K11 | Verr%<2 ± 2% |
| 12 | - | 500 |) [0] | 500 | | | =E12*F12/1000 | | | | =(H12-E12)*100/E12 | =(112-F12)*100/F12 | =(J12-G12)*100/G12 | =F12-I12 | Imeter-Ippu < ± 5mA |
| 14 | - | 500 | 700 | 500 | | - 10 | =E14*F14/1000 | | 06 | | =(H 14-E 14)*100/E 14 | =(114-F14)*100/F14 | =(J14-G14)*100/G14 | =L14 | lerr%< + 2% |
| 15 | < | 50 | 2500 | 500 | | | =E15*F15/1000 | | | | =(H15-E15)*100/E15 | =(115-F15)*100/F15 | =(J15-G15)*100/G15 | =E15-H15 | Vmeter-Vppu < ± 1V |
| 16 | < 8- | 500 | 150 | 500 | | | =E16*F16/1000 | | | | =(H16-E16)*100/E16 | =(116-F16)*100/F16 | =(J16-G16)*100/G16 | =F12-112 | Imeter-Ippu < + 5mA |
| 18 7 | 7 d d | 200 | 2500 | 500 Tu | | | =E18*F18/1000 | | | | =(H 18-E 18)*100/E 18 | =(112+17)*100/F18 | =(J18-G18)*100/G18 | #X18 | Verr%< + 2% |
| 19 | ъ | 500 | 2500 | 250 | | | =E19*F19/1000 | | | | =(H19-E19)*100/E19 | =(119-F19)*100/F19 | =(J19-G19)*100/G19 | =M19 | Perr%< + 2% |
| | 80 Oh | 80 Ohm Test | | | | | | | | | | | | | |
| | A | œ | ဂ | 0 | т | п | o | H | _ | ٦ | | | M | N | 0 |
| 21 | < | 200 | 2500 | 500 | | | =E21*F21/1000 | | | | =(H21-E21)*100/E21 | =(I21-F21)*100/F21 | =(J21-G21)*100/G21 | =K21 | Verr%≤±2% |
| 3 2 | j - | 200 | 200 | 300 | | | =E22*F22/1000 | | | | =(H22-E22)*100/E22 | =(122-F22*1UUF22 | =(J22-G22)*100/G22 | =F 22422 | Imeter-Ippu ≤ ± 5mA |
| 24 | - 1 | 200 | 1800 | 500 | | | =E 24*F 24/1000 | | | | =(H 24-E 24)*100/E 24 | =(124-F24)*100/F24 | =(J24-G24)*100/G24 | =124 | lerr%< + 2% |
| 25 | < | 20 | 2500 | 500 | | | =E25*F25/1000 | | | | =(H25-E25)*100/E25 | =(125-F25)*100/F25 | =(J25-G25)*100/G25 | =E25-H25 | Vmeter-Vppu≤±1V |
| 26 | , e | 200 | 500 | 500 | | | =E26*F26/1000 | | | | =(H26-E26)*100/E26 | =(126-F26)*100/F26 | | =L26 | lerr% <u><</u> ± 2% |
| 28 | P # C | 80 | 2500 | 500 | | | =E28*F28/1000 | | | | =(H 28-E 28)* 100/E 28 | =(128-F28)*100/F28 | =(J28-G28)*100/G28 | =K28 | Verr%< + 2% |
| 29 | 0 | 200 | 2500 | 250 | | | =E29*F29/1000 | | 72 | | =(H29-E29)*100/E29 | =(129-F29)*100/F29 | =(J29-G29)*100/G29 | =M29 | Perr%< + 2% |

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ATTACHMENT 5

Operational Qualification **Data Organization Verification**

| | System Description: | PowerPac Universal pe | ower supply S | ystem/Identification Num |
|--|---------------------|-----------------------|---------------|--------------------------|
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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 2000TM or Windows XPTM
- 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: | |
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| 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/D ate |
|------|-----------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|-------------------------|
| 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: | |
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| Performed By: | Date: |
| Reviewed By: | Date: |

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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 |
|------|--------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|---------------------|
| 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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| Performed By: | Date: |
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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: | | | |
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