

# **QUALIFICATION WORKBOOK**

**FOR**

# **PL-ELS 1000**

## **EVAPORATIVE LIGHT SCATTERING DETECTOR**

Version 2.0 November 2001



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***Polymer Laboratories***

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## Introduction

This Qualification documentation for the PL-ELS 1000 contains procedures and documents required to validate your PL-ELS 1000 throughout the four 4 stages of the instrument life in a user's laboratory: The four stages are as follows:-

- ***Design Qualification (DQ)***
- ***Installation Qualification (IQ)***
- ***Operational Qualification (OQ)***
- ***Performance Qualification (PQ)***

The workbook is designed to assist in keeping the instrument working correctly and provide the necessary procedures and information to qualify the instrument during audits or inspection. It is thus important to keep this documentation regularly up-dated. The documents in the Design Qualification section demonstrate the qualification of the vendor and the instrument's functional and performance specifications.

Because system qualification is not a one-time event PL has setup processes to enable qualification during the entire product life. The User should feel free to add further documents whenever appropriate.

### **The Four Stage Qualification System**

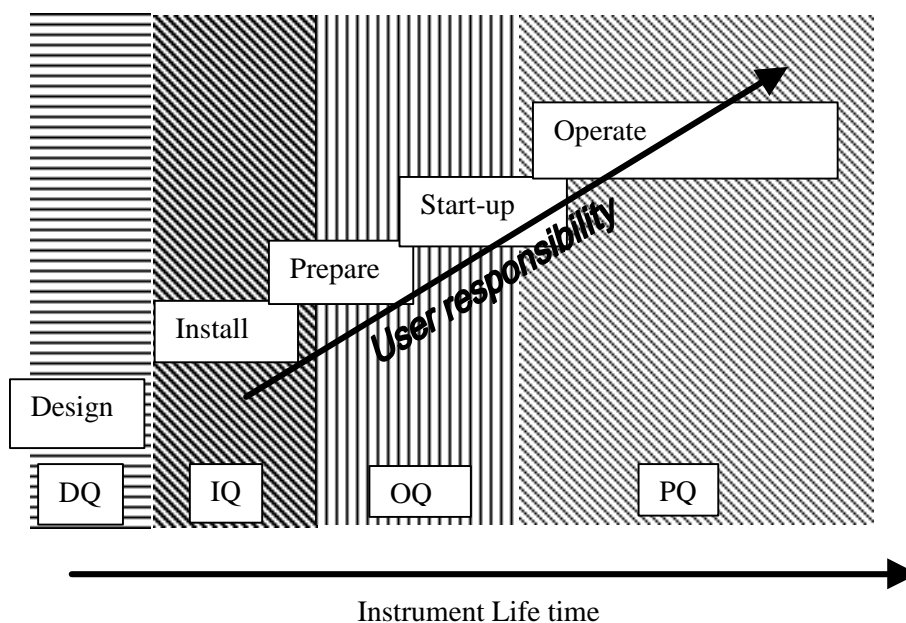
Consistency, reliability and accuracy are paramount in analytical practices and thus it is vital that the equipment used in such work are functioning and performing correctly.

The term qualification can be broken down into four major sections, which cover the entire life of the product

- **Design Qualification (DQ)** for setting functional and performance specifications
- **Installation Qualification (IQ)** for performing and documenting the installation in the selected User environment
- **Operational Qualification (OQ)** for testing the equipment in the selected User environment to ensure that it meets the previously defined functional and performance specifications
- **Performance Qualification (PQ)** for testing that the system consistently performs as intended for the selected application

The diagram below shows how each of these stages are combined to ensure complete instrument quality spanning the entire life of the product. Each stage sets a platform for the next and therefore missing a stage makes it increasingly difficult to satisfy the requirements of the next. As indicated by the arrow, diagonally across the diagram, the instrument quality status becomes increasingly the onus of the user.

Figure 2.1 Instrument Qualifications



### **Design Qualification**

#### *Definition and frequency*

Design qualification (DQ) defines the functional and operational specifications of the equipment and details the conscious decisions in the selection of the supplier. The DQ stage is completed with the purchase of the equipment.

#### *Who performs the design qualification?*

The User should always perform DQ. The instrument's functional and performance specifications from the vendor can be used as a source for information. These documents can then be supplemented with details of the conscious decision made by the user in selecting the vendor.

#### *Qualification Workbook*

The qualification workbook provides the instrument brochure, performance specifications and quality documents supporting the manufacture of the PL-ELS 1000. The PL-ELS 1000 is developed and produced in accordance with a managed quality system, which ensures the instrument is suitability inspected and tested prior to shipment. Each PL-ELS 1000 is fully tested both electronically and chromatographically in the factory and is shipped together with

- Declaration of Conformity, which declares that the instrument has successfully passed all production quality tests
- Declarations of CE compliance declaring that the instrument is compliant with the European instrument directives that apply and therefore is worthy of a CE stamp

## **Installation Qualification (IQ) Phase**

### *Definition and Frequency*

Installation qualification (IQ) establishes that the instrument is received as designed and specified, that it is properly installed in the selected environment, and that this environment is suitable for the operation of the instrument. The IQ phase is finished after the successful installation and signing of the installation qualification protocols.

### *Who performs the installation qualification?*

The PL-ELS 1000 can be installed by the User. However, please read the Operators' manual before and during the installation so that the correct installation procedures are adopted.

### *How does PL recommend the IQ is performed?*

The installation of the PL-ELS 1000 follows a documented procedure checking that the instrument functions correctly after installation. PL provides a protocol for IQ, including a test certificate, which is signed by the installer during the installation and verified by the laboratory manager or supervisor. The tests are limited to the functionality of the PL-ELS 1000, its location and correct extraction and ventilation requirements. Although a detector output is monitored as part of the functionality test, no chromatography is performed. The chromatography test, which tests and validates the whole of the chromatography system, is restricted to OQ stage.

### *Qualification Workbook*

The IQ section of the workbook contains the documents that detail the equipment installed, including the control software and firmware, the IQ protocol and the check sheet. This section should be up-dated as necessary if instrument modifications are made.

## **Operational Qualification**

### *Definition and frequency*

Operational qualification (OQ) is the process of demonstrating that an instrument will function according to the operational specification in the selected environment. This process is called operational qualification (OQ) in the Pharmaceutical/FDA environment and performance verification (PV) in the ISO/EN/Accreditation environment.

The tests, must be performed by the user on a regular basis to satisfy quality procedures. The frequency of the tests depends on the instruments' operation but should be conducted at a frequency that will ensure the instrument parameters are still within operational specifications. Typically it is recommended that the tests be performed:

- After installation
- After a change to the system
- After a major repair
- At a defined regular time interval; one-year time intervals are most appropriate.

### *Who performs the operational qualification/performance verification?*

OQ is typically performed by the user. Please consult your Operators' manual for the correct operation of the PL-ELS 1000.

### *The recommended approach to OQ for the PL-ELS 1000*

The PL-ELS 1000 control software (version 3.0) includes a facility to rigorously test the functionality of the instrument, providing a performance test on-site. A report is generated detailing the results with acceptance criteria. The report should be printed out and filed in the qualification documentation. We recommend that this automated performance test is supported by a chromatographic run so that the complete chromatograph is tested.

The documentation in the section operational qualification describes the automatic system test facility, its set-up and operation.

## **Performance Qualification (PQ)**

### *Definition and Frequency*

Performance qualification (PQ) is the process of demonstrating that an instrument consistently performs according to a specification appropriate for its routine use. The test frequency can be every day, every week, every month or whenever the system is used, but is much more frequent than the OQ. The PQ should always be performed under conditions that are the same or similar to the routine analysis.

### *Who does performance qualification?*

The user should always perform PQ. PL will assist if necessary with the design and frequency of the tests required.

*The Recommended Approach to PQ*

It is recommend that a chromatography test is performed for the PQ utilising one of the calibration standards that form part of the general experiment. By routinely monitoring the signal-to-noise of this standard the detector performance would be verified. Tabulating or graphing each result in the qualification workbook will demonstrate performance verification.

## **Design Qualification (DQ)**

### **List of Contents**

- PL-ELS 1000 sales brochure
- CE Certificate
- Declaration of Conformity
- Specifications
- Customer documentation





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## **Polymer Laboratories**

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### **Declaration of Conformity**

We herewith inform you that the product PL-ELS 1000 with serial number

003-123

has successfully passed all our production quality tests.

During final instrument performance verification the following general characteristics were tested to our internal specifications:

Electrical functional tests



Chromatography tests



Electrical safety tests

Example

Date

12<sup>th</sup> October 1999

Test Technician

Paul Claes

Approved

S. D. M.



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**Polymer Laboratories**

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**DECLARATION OF CONFORMITY**

We, Polymer Laboratories Ltd  
Essex Road  
Church Stretton  
Shropshire SY6 6AX  
U.K.

declare that the product:

**Evaporative Light Scattering Detector**

***PL-ELS 1000***

***Part # 091/24797***

conforms with the requirements of EC Directives 89/392, 91/368 & 89/336 by complying with the following Harmonised European Standards:

Safety:	EN61010 - 1	Class I Installation category II Pollution degree 2
	EN61010 -2 - 010	Class 2
EMC:	EN 61000-4-2; 4-3; 4-4; 4-5; 4-6; 4-11; 3-3	Electromagnetic compatibility and Mains voltage and flicker emissions
	ENV 50204	Electromagnetic compatibility
	EN 55022	Conducted emissions: Class B
		Radiated emissions: Class B*
	EN 60555-2	Harmonic emissions

1st April, 1998

Dr. S.O'Donohue,  
Instrument Development Manager

## Instrument Specifications

Light Source		Tungsten/Halogen Lamp
Detector		Photodiode
Temperature Range*	Evaporator	30-300°C
	Nebulizer	30-220°C
	Heated Transfer Line	30-220°C
Gas Flow		0-2 SLM @60 psi @25°C (PL-ELS 1000)
		0-1 SLM @100 psi @25°C (PL-ELS 1000μ)
	Pressure operating range	60 – 100 psi (4-6.7 bar)
	Maximum Pressure	150 psi (10 bar)
Eluent Flow		0-5.0ml/min (PL-ELS 1000)
		0-0.5ml/min (PL-ELS 1000μ)
Analogue Output		0-10V
		0-1V
Communication		Serial I/O
	Outputs	2 Contact closures
		1 TTL +ve
		1 TTL –ve
		Heated Transfer line control
	Input	Remote auto-zero control
Instrument Control		Microprocessor
Instrument Interface		Detachable IR remote control
		Windows based PC control
Detector Status		Sleep, Gas Save, Standby, Heating, Ready and Error
Size	wxdxh	175x480x430mm
	Packaged wxdxh	670x340x580mm
Weight		15kg
	Packaged	22kg

\* To achieve the maximum operating temperature, the unit must be supplied with either 110V or 240V as indicated. Voltage supplies below these values will limit the maximum operational temperature of the instrument.

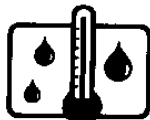
## **Installation Qualification (IQ)**

### **List of Contents**

- ⇒ Site preparation check list
- ⇒ Installation qualification protocol
- ⇒ Instrument Qualification Data Sheet
- ⇒ Installation certificate
- ⇒ Customer Documentation

## Site Preparation Check List

### Environmental Conditions



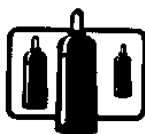
Temperature 15 to 35°C (59 to 86°F)  
At constant temperature  
Avoid positioning in direct sunlight  
Humidity 40-80%

### Power



USA and Japan	115V (AC) $\pm 10$ 50/60 Hz, 6A max.
Europe	230V (AC) $\pm 10\%$ 50/60 Hz, 3A max.

### Gas Supply



Gas: Nitrogen (98% purity or better and filtered to 0.2 $\mu$ m)

*Notes:*

- $\Rightarrow$  Air can be used for non flammable solvents
- $\Rightarrow$  The mass flow controller is not calibrated for use with gases other than Air or Nitrogen
- $\Rightarrow$  For operation with other inert gases contact Polymer Laboratories for advice.

Gas flow 0-2 SLM @ 60 psi @ 25°C (PL-ELS 1000)  
Gas flow 0-1 SLM @ 100 psi @ 25°C (PL-ELS 1000 $\mu$ )  
Pressure operating range: 0 – 100 psi (4-6.7 bar)  
Maximum Pressure: 150 psi (10 bar)

### Extraction Requirements



During the normal operation the carrier solvent is evaporated as it passes through the instrument and must be extracted safely at the rear of the unit.

The exhaust from the instrument (10mm ID convoluted PTFE tubing) must be extracted to a fume hood or similar solvent disposal unit.

If the extraction tube provided with the instrument is to be extended it is recommended that the diameter of the extension is increased to at least 50mm (2") diameter tubing so the extraction quality is not inhibited

## Installation Qualification Protocol

### Purpose

This installation qualification protocol should be performed on the PL-ELS 1000 at the time it is installed in the laboratory. The installation qualification will document the physical placement of the instrument into the laboratory and verify it is properly connected and is functional. The installation qualification also ensures the customer is properly familiarized with the operation and control systems of the instrument. Successful completion of this protocol will verify that the PL-ELS 1000 has been correctly installed to PL's specification.

### Exceptional Conditions

Should the PL-ELS 1000 fail to comply with the installation qualification protocol, the exceptional conditions encountered should be documented and reported to Polymer Laboratories. Exceptional conditions will be investigated and a remedial action determined. Should the instrument fail again, then assuming it can not be repaired and its use is compliant with the terms of the warranty the system will be replaced.

### Procedure

1. Install the PL-ELS 1000 in accordance with Chapter 1 of the installation manual, paying particular attention to the instrument extraction.
2. Switch on the instrument and ensure the displayed version agrees with the information detailed on the Instrument Qualification Sheet provided with the instrument. (A specimen copy of this sheet can be found at the end of this section and should be replaced with the one supplied with your instrument). Version 2.0 will be reported on the instrument for all 2.XX releases, but later releases will report the actual revision.
3. Load method #2 using the handset or the graphical users interface (GUI) and set the instrument in RUN mode. Verify the instrument is operating correctly by observing the temperature readouts on the instrument and the GUI.
4. Ensure that the instrument can be controlled by both the handset, on and off the instrument, and the GUI.
5. Once the instrument is at equilibrium according to the conditions of method #2, collect a 10min baseline using an acquisition system. **Note Solvent should not be flowing through the instrument at this time.**
6. Measure and record the baseline noise for this baseline. This is the *gas only noise* and should be typically <0.2mV.
7. The system is now ready for the operational qualification.



## Polymer Laboratories

### Instrument Qualification Data Sheet

INSTRUMENT	PL-ELS 1000
Manufacturer	Polymer Laboratories Ltd
Serial Number	030-777
Customer Identification Number	
System Number	
Firmware Revision #	Version <a href="#">3.0</a>
EPROM	1/24929
ARCOM PCB	1/24929
Interface PIC	1/24929
Interface PCB	1/24929
Handset PIC	1/24929
Handset PCB	1/24804
Temperature Controller	1/24924
Temperature Controller PCB	1/24800
Control software (CCT)	Version <a href="#">4.0</a>

## **Upgrade Information**

Date	Upgraded Component	Engineer	Authorized
	As received		



## Installation Qualification Test Certificate

This is to certify that the PL-ELS 1000 has successfully been installed, satisfying the following requirements:-

*Site requirements:-*

Location

\_\_\_\_\_  
[Laboratory number and department]

Operating Voltage

\_\_\_\_\_

Gas Supply

\_\_\_\_\_

Extraction

\_\_\_\_\_

*Functional tests:-*

Instrument functioned correctly

☐

Instrument handset control

☐

Instrument GUI control

☐

Gas only baseline (mV)

\_\_\_\_\_

*Operation Training/Basic understanding the instrument controls:-*

Basic principals of system

☐

Handset operations

☐

GUI operations

☐

\_\_\_\_\_  
Installation Technician

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Laboratory Supervisor/Manger

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

## **Operational Qualification (OQ)**

### **List of Contents**

- ⇒ Operational Qualification Protocol
  - ◆ System Test reports
  - ◆ Chromatography test reports
- ⇒ Certification of Instrument Operational Qualification
- ⇒ Customer Documentation

## Operational Qualification Protocol

### **Purpose**

This Operational Qualification protocol should initially be performed on the PL-ELS 1000 at the time the instrument is installed. The following protocol describes the recommended Operational Qualification tests for the PL-ELS 1000. Successful completion of this protocol will verify the instrument is performing to the acceptance criteria defined by the individual test.

A qualified operator, knowledgeable in the operation of the PL-ELS 1000 and system should only perform these tests.

### **Exceptional Conditions**

Should the PL-ELS 1000 fail all or any part of the operational qualification protocol, the exceptional conditions encountered should be documented and reported to Polymer Laboratories. Exceptional conditions will be investigated and a remedial action determined. Should the instrument require service or repair to satisfy the Operational Qualification or Performance Verification tests then contact your Polymer Laboratories representative for assistance. Should the instrument fail outside the instrument's warranty period any necessary service will be chargeable in accordance with our standard service tariff.

If a new instrument fails the OQ/PV it will be covered under the manufacturer's warranty providing the conditions of the warranty have been met.

### **Automated System Test**

The system test included in the PL-ELS 1000 graphical user interface (version 3.0) operates rigorous performance tests of the instrument control systems and measures the accuracy and stability of the control parameters. All operation modes are evaluated (Standby, Gas Save and Run) with verification of operating temperature, temperature stability, set gas flow and gas flow stability and photodetector output.

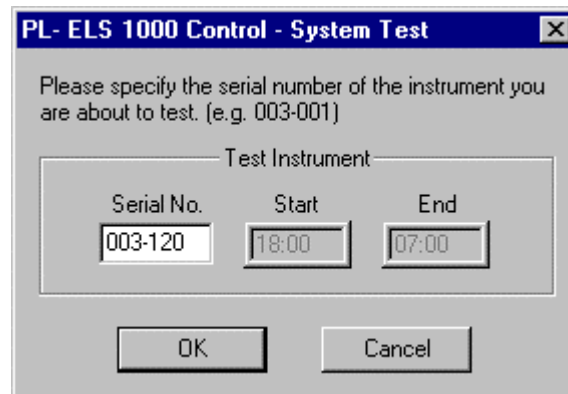
The tests are pre-programmed to commence at 6 o'clock (18.00) in the evening and complete at 7 o'clock (7.00) the following morning.

### **Procedure**

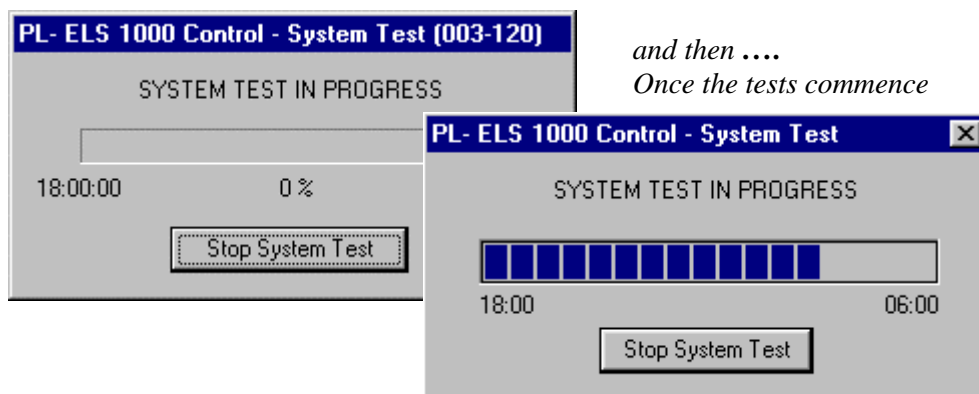
- 1 To prepare the instrument for the test, ensure it is turned on, and set-up for normal operation; supplied with gas flow, adequately extracted and the nebuliser waste tube submerged in solvent contained in the waste bottle. The instrument should be set to the STANDBY mode and ideally at room temperature. Connect the instrument to the control PC via the serial cable supplied and set-up the system test according to the following instructions before 18.00 as displayed by the computer system clock.
- 2 In the software select System test found in the *Tools* menu



- 3 Enter the serial number of your instrument in the box provided and click the ok button



- 4 The control system is now disabled and the following dialog is displayed on the PC screen.

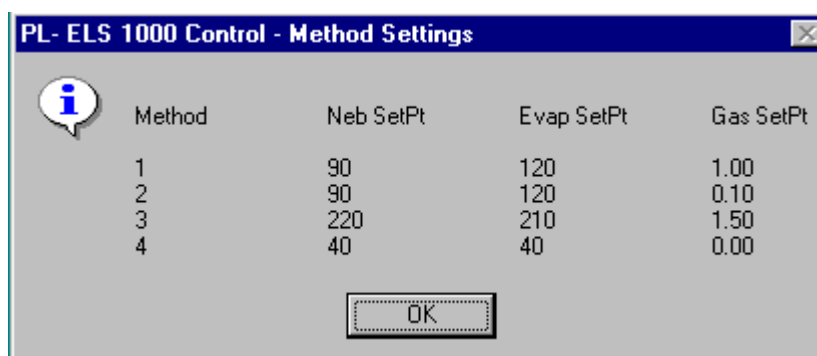


- 5 Once the computer clock reaches 18.00 hours the tests will automatically commence. During the 13-hour test period the instrument is taken through the stages tabulated below.

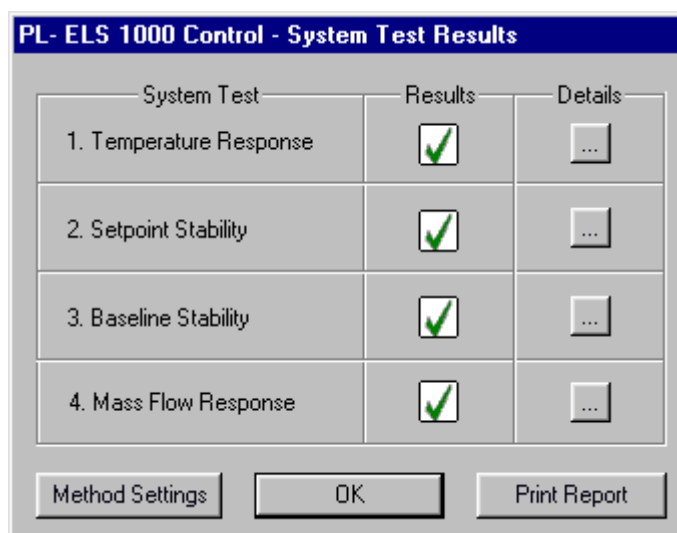
	Time period	Operation Mode	Evaporation Temperature	Nebuliser Temperature	Gas Flow
Stage 1	18.00-20.00	RUN	120	90	1.0
Stage 2	20.00-21.00	RUN	120	90	0.1
Stage 3	21.00-3.00	RUN	210	220	1.5
Stage 4	3.00-6.00	GAS SAVE	40	40	0.0
Stage 5	End	STANDBY	120	90	1.0

From 18.00 (start of the test) to 20.00 the instrument is set to operate according to method 1 in the RUN mode. From 20.00 to 21.00 method 2 in the RUN mode, from 21.00 to 3.00 method 3 in the RUN mode and from 3.00 to 6.00 method 4 in GAS SAVE mode, finishing with method 1 settings in STANDBY mode at 7.00. These methods, time durations and mode changes have been carefully selected so that the instrument is completely exercised giving accurate performance data.

The method settings appropriate to this test are stored in a file called “Test.mtd” and can be displayed by selecting the *Method Settings* button from the System Test result dialog



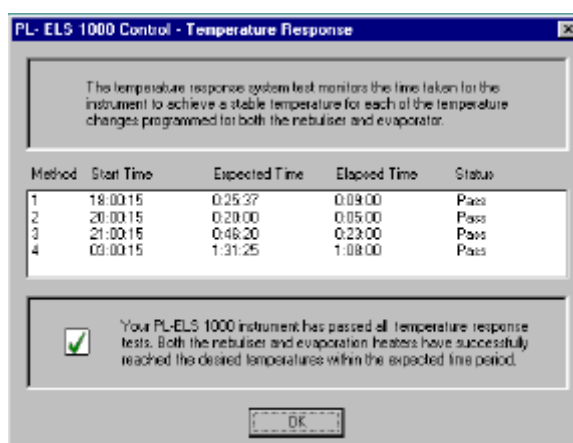
- On completion of the test period the operational log that is recorded throughout the tests is saved and automatically analyzed to give a summary report similar to the one shown below.



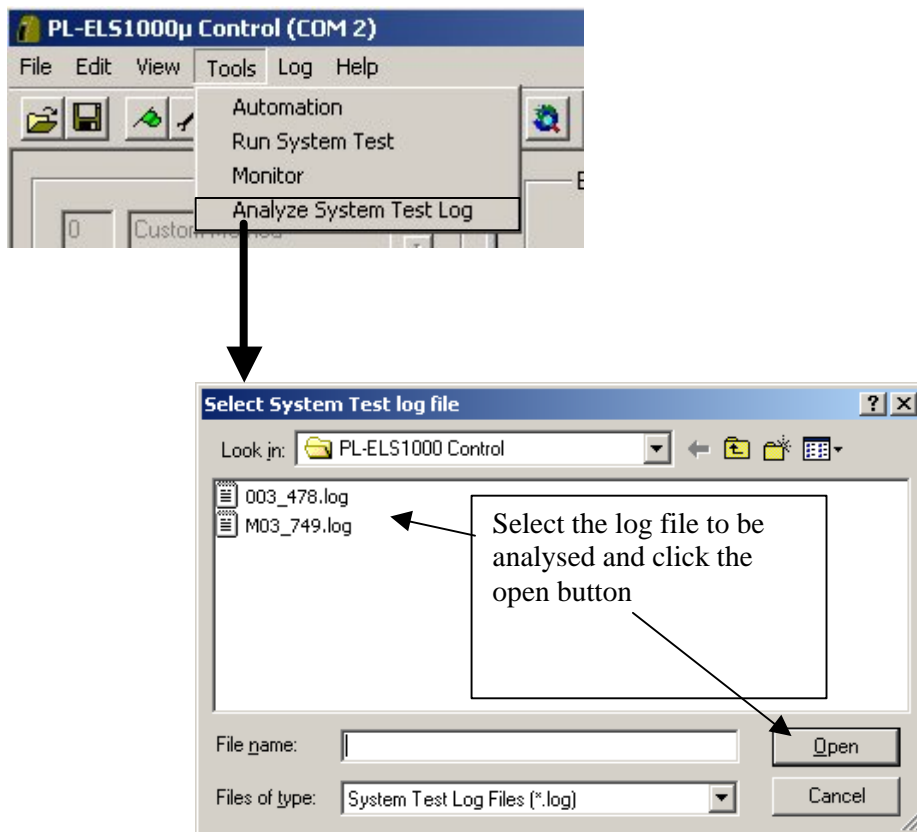
- A green tick denotes the instrument as passed the system test whereas a red cross would indicate the instrument had failed to meet the test specifications. The test specifications are tabulated for each of the tests below.

System test	Test Criteria	Tolerance
1. Temperature Response	Measures the time required for both heaters to reach set condition at each stage of the test all stages of the test	Stage 1 - 25mins Stage 2 - 20mins Stage 3 - 47mins Stage 4 – 1hr 30mins
2. Setpoint Stability	Calculates the offset and the % deviation from the set temperature for each heater at each set temperature	Offset $\pm 0.5^{\circ}\text{C}$ RSD - $\leq 1\%$
3. Baseline stability	Monitors the offset for each step increase in temperature	$<0.15\text{V}$
4. Mass Flow response	Measures the time taken to reach set point	$<270$ secs

- 8 A detailed on screen report for each of the tests can be viewed by selecting the *Details...* button. An example of the Temperature response details is shown below.



- 9 Selecting the *Print Report* button gives a hard copy of the results for filing in your workbook. An example of this three-page report is shown at the end of this section.  
**Important: The report can only be printed from this dialog. Selecting the Ok button before printing the report will close the dialogue and conclude the test without a printed report.**
- 10 If any part of the system test was deemed a failure please send the log file to your Polymer Laboratories service center or PL representative for further analysis. The log file is saved to a file name "serial\_ number".log (eg 003\_120.log in the example shown here) in the C:\program files\Polymer Laboratories\ELS 1000 Control directory or in the directory the control software was installed. A test report can also be generated from the log file at Polymer Laboratories Ltd if required.
- 11 The log file can be reanalyzed directly from the control interface at any time and a system test report generated. To do this open the log file using the "Analyse System test Log" in the *Tools* menu.



## INSTRUMENT PERFORMANCE REPORT

**Manufacturers Name :** Polymer Laboratories Ltd.

**Manufacturers Address :** Essex Road  
Church Stretton  
Shropshire  
SY6 6AX

**Instrument Name :** PL-ELS 1000

**Serial Number :** 003\_240

*The following functional characteristics of the PL-ELS 1000 instrument have all been individually tested for conformance with our internal specifications.*

**Temperature Response :** PASSED

Both the nebuliser and evaporation heaters have successfully reached the desired temperature within the expected time period.

**Temperature Accuracy :** PASSED

Both the nebuliser and evaporation heaters have successfully maintaining a constant temperature at the desired setpoints.

**Baseline Stability :** PASSED

The output of your PL-ELS 1000 instrument has shown to satisfy the test criteria of the baseline test.

**Mass Flow Response :** PASSED

The mass flow controller was successfully reaching and maintaining the desired gas flow rates set.

**Report Date :** Tuesday, October 05, 1999

**Test Technician :** \_\_\_\_\_



**INSTRUMENT PERFORMANCE REPORT**

Method 1			
Neb SetPt : 120 C		Evap SetPt : 90 C	Gas SetPt : 1.0 SLM
Test	Limit	Measured Result	Status
1. Temperature Response (hh:mm:ss)	0:29:32	0:13:30	Pass
2. Temperature Stability			Pass
2.1. Nebuliser (Average Offset C)	± 0.50	0.00	Pass
2.2. Evaporator (Average Offset C)	± 0.50	0.00	Pass
2.3. Nebuliser (RSD %)	1.00	0.22	Pass
2.4. Evaporator (RSD %)	1.00	0.21	Pass
3. Baseline Stability (Photo Output V)	0.15	0.04	Pass
4. Mass Flow Response (sec)	270	0	Pass

Method 2			
Neb SetPt : 120 C		Evap SetPt : 90 C	Gas SetPt : 0.1 SLM
Test	Limit	Measured Result	Status
1. Temperature Response (hh:mm:ss)	0:29:32	0:05:00	Pass
2. Temperature Stability			Pass
2.1. Nebuliser (Average Offset C)	± 0.50	0.00	Pass
2.2. Evaporator (Average Offset C)	± 0.50	0.00	Pass
2.3. Nebuliser (RSD %)	1.00	0.15	Pass
2.4. Evaporator (RSD %)	1.00	0.17	Pass
3. Baseline Stability (Photo Output V)	0.15	0.04	Pass
4. Mass Flow Response (sec)	270	30	Pass

Method 3			
Neb SetPt : 210 C		Evap SetPt : 220 C	Gas SetPt : 1.5 SLM
Test	Limit	Measured Result	Status
1. Temperature Response (hh:mm:ss)	0:37:59	0:28:00	Pass
2. Temperature Stability			Pass
2.1. Nebuliser (Average Offset C)	± 0.50	-0.10	Pass
2.2. Evaporator (Average Offset C)	± 0.50	0.00	Pass
2.3. Nebuliser (RSD %)	1.00	0.13	Pass
2.4. Evaporator (RSD %)	1.00	0.12	Pass
3. Baseline Stability (Photo Output V)	0.15	0.05	Pass
4. Mass Flow Response (sec)	270	0	Pass

**INSTRUMENT PERFORMANCE REPORT**

Method 4			
Neb SetPt : 40 C		Evap SetPt : 40 C	Gas SetPt : 1.0 SLM
Test	Limit	Measured Result	Status
1. Temperature Response (hh:mm:ss)	1:29:25	0:57:00	Pass
2. Temperature Stability			Pass
2.1. Nebuliser (Average Offset C)	± 0.50	0.00	Pass
2.2. Evaporator (Average Offset C)	± 0.50	0.00	Pass
2.3. Nebuliser (RSD %)	1.00	0.35	Pass
2.4. Evaporator (RSD %)	1.00	0.32	Pass
3. Baseline Stability (Photo Output V)	0.15	0.04	Pass
4. Mass Flow Response (sec)	270	60	Pass

Example

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**Chromatography Test**

To verify that the instrument is performing correctly chromatographically, we recommend the following simple test, utilizing a PL aquagel-OH Guard column. Injecting a fixed concentration of glucose solution into the detector via this column gives a direct measurement of the detector sensitivity from the peak area. Although the guard column does not perform any separation it is used to prevent injection spikes that are prevalent with direct injection and helps to suppress pump pulsations by slightly increasing system back pressure. Thus, this method gives a measurement of detector performance chromatographically without the added complication of column performance. We strongly recommend that this test should be immediately followed up with a chromatographic test utilizing your standard conditions and a routinely used internal laboratory standard. This later test can now form the basis of the PQ for this system and thus the results entered into the PQ documentation.

The performance specification reported for this test is based on the results of many tests performed on different systems and using different columns. However, it should be noted that the quality of the HPLC pump, test probe, eluent, extraction facilities, data acquisition system and instrument operational conditions all have a large influence on the final result and thus the tolerances set take these factors into account.

The PL-ELS 1000 should be tested for sensitivity and baseline noise according to the following test procedure.

1. Weigh accurately 5mg of Glucose into a 25ml volumetric flask. Add 15mls of water to dissolve the glucose. Once the glucose has dissolved make up to the mark with water.
2. Setup the instrument in accordance with the Operator's Manual and set the conditions as follows:-

**Detector Settings** (*Default method #2*)

<i>Nebulizer Temperature:</i>	90°C
<i>Evaporator Temperature</i>	120°C
<i>Gas flow rate:</i>	1.5 SLM@≥60PSI
<i>Time Constant:</i>	Off [0]
<i>Detector Output</i>	<i>Output (<u>not</u> 1/10<sup>th</sup> scale)</i>

3. Prepare the chromatographic system according to the conditions shown. If the sample is to be introduced by a manual injection we recommend a calibrated 50µl loop is fitted to the injection valve, so that a full loop injection is performed. The test column is available from Polymer Laboratories, part number 1149-1840

**Chromatography Conditions**

Test probe:	Glucose (10µg injected)
Concentration:	0.2 mg/ml
Injection Volume:	50µl (full loop injection)
Column:	PL aquagel-OH 8µm Guard 50 x 7.5 mm
Eluent:	Water (18 MΩ, filtered to 0.2µm and degassed)
Eluent flow rate:	1.0 ml/min

4. Allow at least 1-2hours for the instrument to stabilize at the set temperatures before making any injections. The eluent should be flowing during this time.
5. Set the data acquisition to collect for a total of 10mins with a collection rate of at least 5pts/sec and at 1V full scale deflection.
6. Inject 50µl of the test solution into the system. If this is performed by a manual injection, rather than an autosampler, it is recommended that 0.5ml of sample is injected so that the loop is over filled and thoroughly flushed.
7. Start the data acquisition system and inject at 2min intervals resulting in a 10min chromatogram with 5 peaks.
8. Calculate the area of each peak, average the value and compare the result with the one shown in the table below.
9. The noise should be measured from a 10min baseline run with the eluent flowing at 1ml/min.

Pass Specifications for the Glucose/water test

Area (mV.sec)	Typically the average area should be >3000 mV.sec but not <2500 mV.sec
Noise (mV)	<0.3

**Note:** Different data acquisition systems report the area using a variety of units. If you are using the HP Chemstation the area is reported in mV.sec and thus can be used directly. For other systems the units may not be mV.secs and a conversion factor will need to be applied. For example the PL Caliber SEC software reports the area (calculated using the Overlay module) in **response.min**. To convert the PL-Caliber area from response.min to mV. Sec, the number must be multiplied by 0.0488 (assuming the data was collected on a 1V range). If you unsure of the area units generated from your data acquisition software contact your software vendor.

## Certification of Instrument Operational Qualification (1 of 2)

Certificate Type

Initial

☐

Requalification

☐

(Installation)

(Reoccurring)

SUMMARY OF RESULTS		
All qualification tests were successfully completed	PASS	
Some of the qualification tests or measurements required correction to successfully complete*	PASS AFTER CORRECTION	
Some of the qualification tests or measurements were not successfully completed**	FAIL	
*A Deviation Report must be attached showing the corrective action taken. The Deviation Reports associated with this document are listed below.		
**It is recommended that the PL-ELS 1000 is taken out of service until suitable repairs have been made		

\_\_\_\_\_  
Test Technician

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Laboratory Supervisor/Manager

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**Certification of Instrument Operational Qualification (2 of 2)**

**Deviation Report**

DEVIATION #	DESCRIPTION OF PROBLEM	CORRECTIVE ACTION	REPORT ATTACHED (YES/NO)	RESOLUTION DATE

## **Performance Qualification (PQ)**

### List of Contents

- ⇒ Maintenance Log book
- ⇒ Instrument PQ reports (Customer contributed)

