diatron

Pictus 500 IQ, OQ, PQ Guideline and Documentation

Name/Address of Lab: CCL, Kolkatta 51/8, Roy Bahadur Rd, Chamrapatti, Behala, Kolkatta, West Bengal, 700034	
Phone#:	**Contact Person:** Mr. Jayanta
FAX:	**Contact Email:**
Instrument Model: Diatron P500	**Instrument Serial #:** 18086922
Installation Date: 13/10/2018	**Software Revision #:** P500 (V2-SP)
Install Technician Name: Mukesh Kumar	**Signature:**

Instrument Installation Qualification:

The Installation Qualification (IQ) procedure verifies that the equipment and its sub-systems have been installed in accordance with the specifications. These requirements must all be satisfied before the IQ can be completed and the qualification process is allowed to progress to the Operational Qualification (OQ) procedure.

INSTALLATION QUALIFICATION CHECKLIST:

Shipping Boxes Received

☑ No external damage.

Documentation

☑ Matched Serial # Packing List.
☑ Matched Serial # Final Check Report.
☑ Operator's Manual.

Accessories

☑ As per attached list.

Instrument Location

☑ The analyzer is a heavy instrument (more than 95 Kg). At least two persons are needed to move it. The lifting arms must be used.
☑ The instrument is installed on a solid horizontal table that can support the weight of the instrument.
☑ The location is well-ventilated and dust free.
☑ The instrument is properly levelled.
☑ The instrument is not expose to direct sunlight.
☑ The instrument is not placed near or in front of heat sources.
☑ The pressure is above 600 hP.
☑ The room temperature is lower than 30°C.
☑ Main electric is close to the instrument (less than two meters) and must fulfill local regulations.
☑ There is a free access to main switch and main cable's plug. A distance of 50 cm from the left side of instrument to nearest table or wall is advisable. The right side must have at least 30 cm of free space for ventilation purposes.
☑ The instrument must have 2.10 m of free space above it. Avoid using shelves, walls or screens above the instrument.
☑ Reagent storage under the instrument is easily accessible.
☑ Space for computer, printer and UPS to be hooked.

Power Requirements

- ☑ 100/240 Vac, 50/60 Hz, 600VA maximum.
- ☑ Female receptacle outlet with single-phase input power and ground.
- ☑ Building outlet properly grounded and electrical panel protected against power fluctuations.
- ☑ Confirmed third-wire earth ground capable of carrying full current of circuit.
- ☑ UPS system hooked up to properly rated and grounded outlet, battery is connected and powered on.

Connections and Setup

PC setup and connections

- ☑ Peripherals (mouse, keyboard) connected to the computer.
- ☑ Computer power cord connected.
- ☑ Power cord connectedto UPS.
- ☑ USB/serial port adapter connectedto computer and serial cable connected to instrument.

Instrument setup and connections

- ☑ Biohazard waste container tubing properly connected to container and to instrument.
- ☑ Biohazard waste container located on floor or shelf lower than instrument.
- ☑ Reagent tubing properly connected to all reagent containers and to instrument.
- ☑ Tubes cut to length in order to prevent a U shape below bottle level.
- ☑ Peristaltic pumps tubing connected.
- ☑ The plastic protection tubefrom the vertical shaft of the probe arm and tip protector removed.
- ☑ DI water and cleaner bottles filled.
- ☑ Instrument and scale connected to the computer.
- ☑ Instrument's power cord connected to instrument and plugged into electrical outlet.

Installation Qualification is now complete. You may begin the Operation Qualification Procedure.

OPERATION QUALIFICATION CHECKLIST:

The definition of operational qualification is: Establishing confidence that the equipment and sub-systems are capable of operating within the stated limits and tolerances. In practice, the operational qualification is the executed test protocol documenting that a system meets the defined requirements or that the system does what it's supposed to do.

Instrument and PC Startup:

- ☑ Computer powered on and USB/serial port adapter driver installed.
- ☑ Computer settings configured for proper date/time, display, hibernation and hard drive per installation guide.
- ☑ Windows activation performedwhen prompted.
- ☑ Windows updated prior to software installation.
- ☑ Software installed.
- ☑ Instrument turned on.
- ☑ Software started and reconnected (Do not initialize)
- ☑ Filter wheel calibrated (remember to remove cuvettes if any inserted).
- ☑ Reaction cuvettes inserted.
- ☑ Full mechanical calibration performed.
- ☑ System flush performed.
- ☑ Washer volume calibration performed.
- ☑ Photometer calibration performed.
- ☑ Scale calibrated.
- ☑ Initialization performed.

System tests:

In order to check whether the instrument works within given specification the instrument is equipped in a batch of tests to check analyzers performance. To ensure that the instrument meets all measuring requirements all the tests should pass.

All the System Tests protocols are included in the Operator's Manual (Chapter 9). Follow the instruction given in the OM as well as on the screen during performing the tests.

Reagent used for system tests:

1. Calibration set VA0003SL:
   - 5 g/l Potassium dichromate
   - Sodium nitrate
   - 0,1 g/l Potassium dichromate
   - 2 g/l Potassium dichromate
2. Additive for Wash Solution VA0002SL
3. Cleaning SolutionVA0000SL

Additional reagents:

1. Distilled water

System Tests results:

	Passed	Failed	Comments
• Temperature	☑	☐	Passed
• Stray light	☑	☐	0.001% T ≤ 0.04 T - Passed
• Noise	☑	☐	0.00052 Abs ≤ 0.01 abs - Passed
• Stability	☑	☐	Passed
• Tip pump	☑	☐	2150 ul >= 1400 ul - Passed
• Level detection	☑	☐	In reaction / In reagent - Passed
• Washer hydraulics	☑	☐	Passed
• Washer	☑	☐	0.0146 abs ≤ 0.02 abs - Passed
• Dilution	☑	☐	0.7472 % ≤ 1.5 % - Passed
• Photometer linearity	☑	☐	1.72 % ≤ 5 % / 0.9997 ≥ 0.95 - Passed
• Diluter linearity	☑	☐	linear Departure / corellation passed
• Clot detector	☑	☐	All parameters passed.

Refer to the *Operator's Manual*, for detailed information regarding the reagents composition, storage requirements, usage, etc.

INSTRUMENT PERFORMANCE QUALIFICATION:

The definition of performance qualification is: Establishing confidence through appropriate testing that the installed product meets all performance requirements for functionality and safety and that results are effective and reproducible. In practice, the performance qualification is the executed test protocol documenting that a system meets the defined requirements to function in the clinicallaboratory environment.

NEW INSTRUMENT VALIDATION:

All new instruments, upon installation, must be tested to validate the manufacturer's claims for accuracy and precision.

New operators will be instructed and assisted by the individual(s) who install and train the operator(s) in the routine use of the new analyzer. Instructions and guidance in the validation of accuracy and precision will be will be included in the training process. These validations must be reviewed and approved by the Lab Director before the instrument can be used to test and report patient samples.

Perform the dichromate end tests as part of the system tests upon installation, after maintenance procedure or during root cause investigations on any kind of measurement inconsistencies.

Dichromate tests are useful to check syringe reproducibility, mixing function, photometer stability and overall quantify total analytical error caused by the mechanical parts of the instrument

Two types of test should be performed

- Potassium dichromate solution used as reagent, distilled water as sample
- Potassium dichromate solution used as sample, distilled water as reagent

Used solutions.

- **Potassium dichromate solution (5 g/l)**
- **Potassium dichromate solution (0,1 g/l)**
- **Distilled water**

Performing potassium dichromate tests:

1. Define the reqiured methods on the Methods definition page. Use 340 nm filter and incubation time of 300 sec. Please see excel sheet with detailed protocol.

Method ID	Filter	Sample type/volume	Reagent type/volume	Limits	Mode	Decimals	Factor	Offset
Dichromate S2	340 nm	5g/l potassium dichromate, 2 µl	Distilled water 300 µl	0-10	End point	4	1	0
Dichromate S10	340 nm	5g/l potassium dichromate, 10 µl	Distilled water 300 µl	0-10	End point	4	1	0
Dichromate R100	340 nm	distilled water 5 µl	0,1 g/l potassium dichromate 300 µl	0-10	End point	4	1	0

2. Fill the sample tubes and reagent vials with the required solution or distilled water. Two sample tube with 5 g/l Potassium dichromate solution, one sample tube with distilled water, Two reagent vials with distilled water, one with 0,1 g/l potassium dichromate solution.

3. Program the samples on the samples page, 20 replicates/ method

4. Place reagents and samples into the analyzer

5. Make sure that instruments maintenance procedures have been all performed and is properly flushed and ready to use

6. Start the measurement

Recommended Limits

	Dichromate S2	Dichromate S10	Dichromate R100
Expected Abs recovery	0,28-0,42 (0,35)	1,256-1,884 (1,57)	0,64-0,96 (0,8)
Acceptable CV:	<1,%	<0,5%	<0,3%

REPORTING RESULTS

Results will be reported according to established laboratory procedure.

INOPERABLE TEST SYSTEM:

Refer to established laboratory policies for what to do when the instrument is out of service.

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INSTRUMENT VALIDATION EVALUATION

Laboratory Name:	CCL, Kolkatta
Address:	51/8, Roy Bahadur Rd, near James long Crossing, Chamrapatti, Behala, WB
Phone:	98307 79122 / 93310 20610
Contact person:	Mr. Jayanta Bhadra
Contact email:	

Instrument Serial No.:	18086922	**Date installed:**	13/10/2018
Date(s) validated:	14/10/2018		

Material used for Accuracy & Precision:	
Lot Number & Expiration Date:	
Material used for Reportable Range:	
Lot Number & Expiration Date:	

Instructions:

1. The Lab Director must review this data and determine if the results of the Accuracy andPrecision testing are acceptable to validate the manufacturer's claims.
2. The Lab Director must review the Reportable Range study and accept or reject the reportable ranges established. No Reportable Ranges may be established that exceed themanufacturer's linear testing range.
3. The Reference Ranges must be validated by the Lab Director and the laboratory as beingappropriate for the lab's patient population. There are numerous ways to do this: empiricevaluation, comparison to area hospitals' and practices' ranges, Internet research, research of literature, or by methods outlined in the *CLSI Document C28-A3E "How to Define and Determine Reference Intervals in the Clinical Laboratory."*

I have evaluated the validation data for this analyzer and find the accuracy, precision, reportable range and referenceranges are within the limits stated by the manufacturer. ☑ *YES* ☐ *NO*

I approve this instrument for use in this clinical lab. ☑ *YES* ☐ *NO*

Lab Director's Signature: [signature]

Date approved: 14/10/2018