epsilon diagnostics

To Whomsoever It May Concern

05.03.2022

CALIBRATION CERTIFICATE

EPSILYTE Electrolyte Analyser Na/K/Cl

Serial No: 1601137 installed at Doctors Laboratory

Tested for the following with Calibrator pack Lot no: 20210315; Exp: 14.09.2022

Slope of Na (Sodium)	- 57.0 (Range 27-67)
Millivolts of K (Potassium)	- 52.3 (Range 27-67)
Millivolts of Cl (Chloride)	- 48.2 (Range 27-60)

Ran Quality Control having Lot no: 20210315; Exp: 14-03-2023 and found results satisfactory.

Na	-	140	Range (136-148)
K	-	3.92	Range (3.68-4.16)
Cl	-	96.2	Range (91-105)

Next Calibration due on 05th September 2022.

For Epsilon Diagnostics

M. Simson Rathnaraj

Regional Manager

EPSILON DIAGNOSTICS Chennai 600 020

F2-2, Shan Complex, 2nd Floor, Near Changampuzha Park, Edappally P.O, Cochin – 682 024. Phone: 0484-2337076, 9947017444

E-mail: mail@epsilondiagnostics.com Web: www.epsilondiagnostics.com

epsilyte

XI 921

ELECTROLYTE ANALYZER

INSTALLATION QUALIFICATION

INSTALLATION QUALIFICATION

INSTRUCTIONS

1. This document is to be completed at time the system in unpacked and setup for operation.

2. An authorized Epsilon Diagnostics representative will checkout each module and verify the alignment.

3. All deviations from normal specification to include any problems with installation will be noted in the comments section.

4. This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization by Epsilon Diagnostics.

INSTALLATION QUALIFICATION

This installation Qualification protocol will be performed on the installation located at Sree Ranga Hospital, 12 Varada Reddy Street, Vedhachalam Nagar, Chengalpattu-603001.

This protocol will define the documentation that will be used to evaluate the instrument documentation that will be used to evaluate the instrument documented in accordance with manufacture's specifications and identified use. Successful completion of this protocol will verify that the instrumentation identified has been installed in accordance with intended usage.

Installation checks will be performed to verify that the instrumentation has been installed with proper connections and utilities.

Trained knowledgeable personnel will perform qualification studies as mentioned in Epsilon Diagnostics Service bulletin.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated and appropriate course of action will be determined.

EPSILON DIAGNOSTICS Chennai 600 020

epsilyte

INSTALLATION QUALIFICATION

SYSTEM CERTIFICATION

Study data has determined that the system described in this document meets all criteria outlined in this Installation. Qualification protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any have been addressed. The system is ready for specified usage.

Protocol performed by; **Epsilon Diagnostics Representative**

Name: M Simson Rathnaraj

Title: Regional Manager

Company: Epsilon Diagnostics

Customer Authorization:

Name : Dr.M.Gandhi

Title : Laboratory In charge

ENGINEER SIGNATURE

DATE 03.12.2021

CUSTOMER SIGNATURE

DATE 03.12.2021

epsilyte

CERIFICATION OF INSTALLATION - REPORT

INSTRUMENT NAME: XI 921 - ELECTROLYTE ANALYSER

SERIAL NUMBER: 1601137

CUSTOMER NAME & ADDRESS: Doctors Laboratory
14Q2 Nethaji Bypass road,
Opp to Government medical college and hospital,
Dharmapuri-636701

The undersigned performer certifies that the installation Qualification protocol has been successfully completed for the instrument stated above.

ENGINEER

SIGNATURE:

NAME: M Simson Rathnaraj

DESIGNATION: Regional Manager

COMPANY: Epsilon Diagnostics

EPSILON DIAGNOSTICS Chennai 600 020

INSTALLATION VERIFICATION REPORT

This is to certify that the following checks mentioned in the installation verification protocol have been performed and found to be satisfactory.

3.10 PRE- INSTALLATION CHECK	
A) Carton arrival	
B) Spare and accessibility	
C) Electrical input	
D) Ambient temperature and Humidity	
E) Ventilation	
F) Drainage	
3.11 INVENTORY VERIFICATION & UNPACKING	
A) Inventory and inspection. Checklist (attached)	
B) Unpacking Analytical Station	
3.12 INSTALLING THE ELECTRICAL CABLES	
3.13 INSTALLING ELECTRODES	
3.14 INSTALLING TUBINGS	
3.15 INSTALLTING REAGENT PACK	

SIMSON RATHNARAJ. M ENGINEER NAME AND SIGNATURE	CUSTOMER NAME AND SIGNATURE

EPSILON DIAGNOSTICS Chennai 600 020

Appendix

Checklist of shipment
Engineer training certificate
DMM calibration certificate

INSTALLATION QUALIFICATION

3.10 XI 921 - ELECTROLYTE ANALYSER PREINSTALLATION CHECKLIST

Before you install the instrument, verify the following conditions are met. Report any discrepancies on the Installation Report.

Operator Training

✓ An operator is trained or is scheduled to be trained within the next two weeks.

Carton Arrival and Condition

✓ All the cartons on the shipping list have arrived.

✓ All the cartons are intact and undamaged. If any cartons are damaged, confirm that a claim was filed with the carrier.

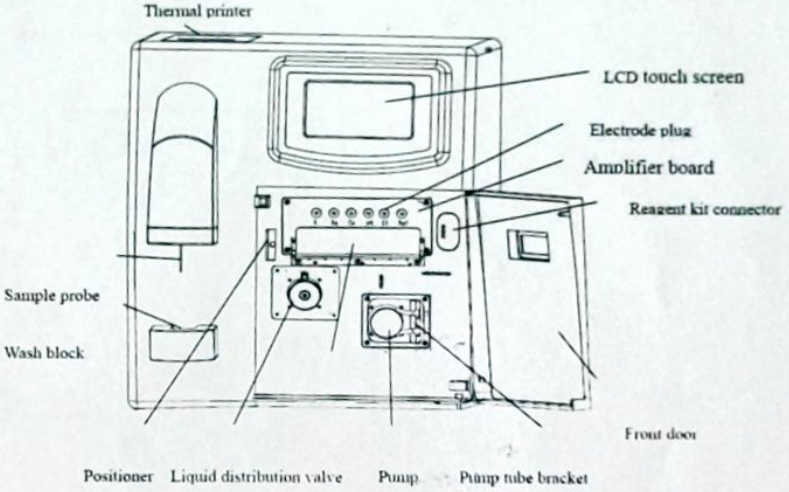
Instrument Site

Space and Accessibility

✓ The designated instrument area is easily accessible for maintaining and servicing the instrument, such as an island or a movable table.

✓ The space is sufficient for the individual units. The dimensions and requirements for accessibility and ventilation are shown in Figures 3.10-1, 3.10-2, and 3.10-3.

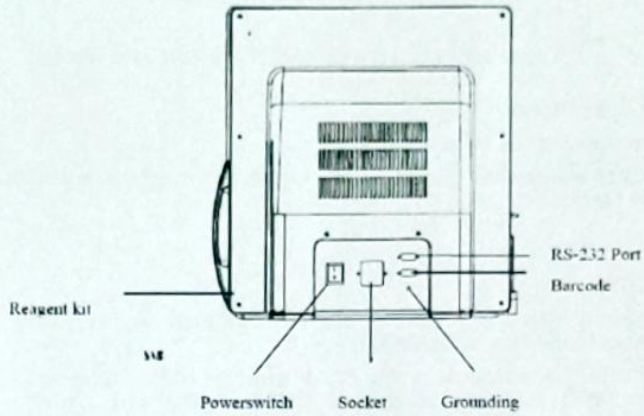
Figure 3.10 -1 Space and Accessibility Requirements for the XI 921 - ELECTROLYTE ANALYSER

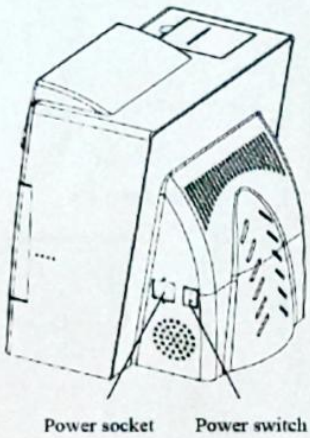


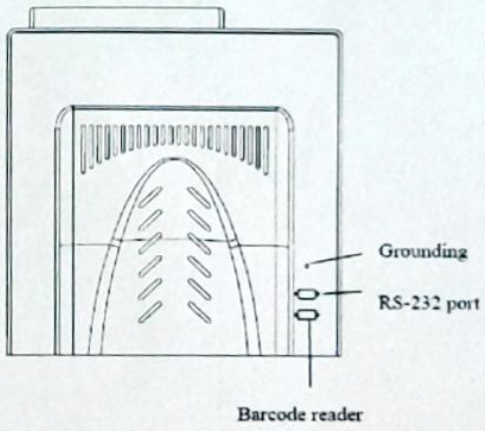
Ventilation

✓ The vents at the rear are not obstructed. See Figure 3.10-2 for the location of the vents.

Figure 3.10-2 Location of Vents on the XI 921 - ELECTROLYTE ANALYSER







Electrical Requirements

CAUTION Heat damage. Using an extension cord on the Power Supply could cause heat damage to the main ac power cable. Designate an area for the Power Supply close enough to an electrical outlet that an extension cord is not needed.

✓ The female ac outlet for the main Power Supply is within 3 m (10 ft) of the area designated for the instrument.

✓The main ac outlet is a three-wire outlet supplying a 230 VAC, 50/60Hz, 100 W, single-phase input power.

✓The ground is a confirmed third-wire earth ground that can carry the full current of the circuit.

✓The circuit is independent and protected.

Environmental Requirements

- Ambient Temperature (15- 30 C)
- Relative Humidity (20- 85 %)
- Atmospheric Pressure (86- 106 kPa)

Installation Supplies

✓The instrument reagents, calibrators and controls are available and within expiration limits.

✓The paper supplies and blood collection tubes are available. Refer to the Appendix in the Operator's Guide for a list of blood collection tubes that can be used on the instrument.

Installation

1) The instrument should be installed on a stable and solid platform that is free of mechanical vibration and away from vibration source.
2) The environment should be as free as possible from dust, corrosive gas, loud noises and electrical interference.
3) Avoid placing the instrument in direct sunlight or in front of a source of heat or vent.
4) Ambient temperature: 15~32℃, relative humidity: <85%.
5) The power supply should be AC220/110V±10%, 50/60Hz±1Hz
6) Power supply and grounding should be connected correctly.

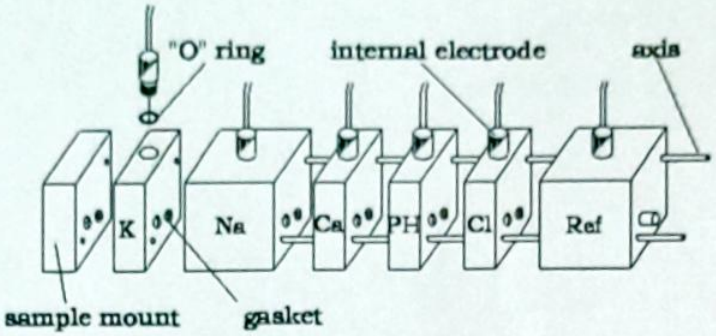
Installation of new electrodes

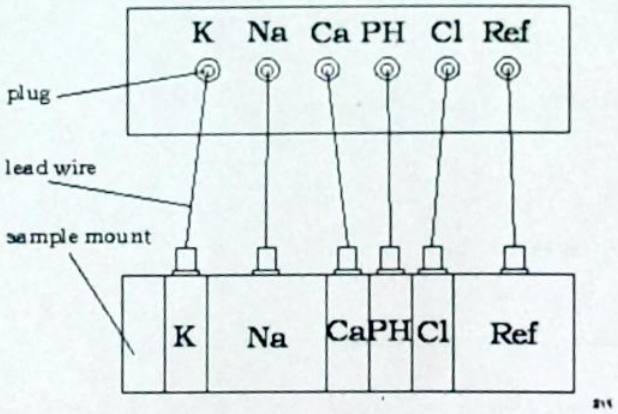
1) Electrode assembly of new instrument has been installed and tested in good condition, before shipping.
2) Check if the filling solutions are sufficient or carry bladders.

Replace & check electrodes

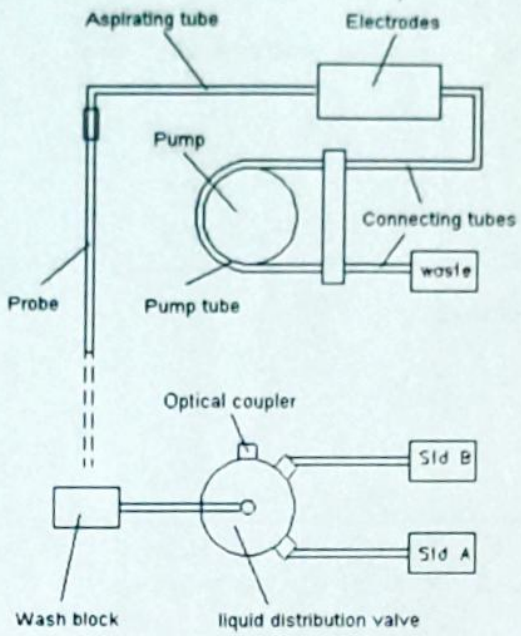
1) Assemble the electrodes with the rubber gasket according to figure.
2) Put them through the axis, and then tighten the nuts firmly.
3) If the filling solutions are insufficient, remove the internal electrodes and fill in correct filling solutions (K filling solution for K electrode, Ca filling solution for Ca electrode, Na/Cl filling solution for Na, Cl and pH electrodes, and reference filling solution for reference electrode).
4) Clean and dry the electrodes with soft tissue.
5) Install the whole electrode assembly to the electrode holder.
6) Connect the electrode lead wires and the grounding wire to the corresponding plugs according to figure 3.

1) **Do not mix up the electrodes!**
2) **Replaced internal electrode must not be used without distilled water rinsing.**
3) **Away from metal goods**
4) **80~90% solution is sufficient**
5) **Do not touch electrode membranes by any hard subjects.**
6) **Lapping electrodes to eliminate bladder**
7) **Electrode installation must be follow figure 2.**
8) **Do not mix up K、Ca、Na、PH、Cl solutions**

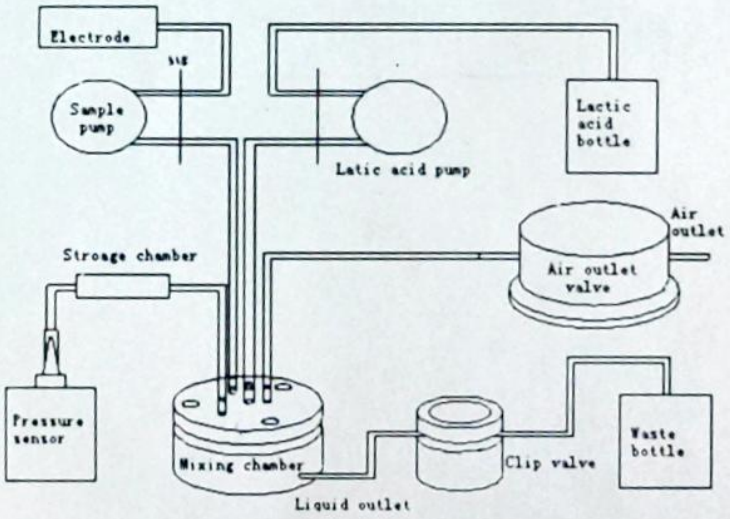

"O" ring
internal electrode
axis
K
Na
Ca
PH
Cl
Ref
sample mount
gasket


K Na Ca PH Cl Ref
plug
lead wire
sample mount
K
Na
CaPH
Cl
Ref

Installation of Tubes



Installation of Tubes for HCO3



Installation of Reagents

For external reagent pack user: take off rubber cap of external reagents, connect tubes according to outlet marks.
For internal reagent pack user: stretching the rubber cap, insert reagent package.
XI-921BT、XI-921DT model user, should discharge waste water into the external waste bottle (W).
Reagent bottle user: open each bottle cap (A std、B std、Lactic acid solution) insert covered pipette into reagent bottle, screw down cap, and then connect corresponding inhaling tube to the stainless steel tube.
Insert waste water tube to "W" waste bottle, screw down cap.
Finally, check out the whole tubing system.

After taking out standard、control、filling solutions or other reagents from the refrigerator, please wait for a moment until they warm up to the room temperature, to prevent the damage of the electrodes. Be careful not to contaminate the reagents during the installation or replacing.

Installation of Printer paper

1. Insert the paper support on the stand.

2. Insert the paper into the guide slot.
3. Make sure the thermal side of the paper faces downward.
4. Pull up the lever on the right, rotate the knob until the paper comes out, then push the lever down; or touch "Paper" on the service menu until the paper comes out.

epsilyte

XI 921

ELECTROLYTE ANALYZER

PERFORMANCE QUALIFICATION

epsilyte

PERFORMANCE QUALIFICATION

SYSTEM CERTIFICATION

Study date has determined that the system described in this document either meets all criteria outlined in this Performance Qualification protocol. All exceptional conditions if any have been addressed. The system is ready for specified usage.

Protocol performed by: **Epsilon Diagnostics Representative**

Name: M Simson Rathnaraj

Title: Regional Manager

Company: Epsilon Diagnostics

Customer Authorization:

Name: Dr.M.Gandhi

Title: Laboratory In charge

ENGINEER SIGNATURE

DATE 03.12.2021

CUSTOMER SIGNATURE

DATE 03.12.2021

EPSILON DIAGNOSTICS Chennai 600 020

epsilyte

PERFORMANCE QUALIFICATION VERIFICATION REPORT

This is to certify that the following checks mentioned in the performance verification protocol have been performed and found to be satisfactory.

PERFORMANCE VERIFICATION	
1] INITIALIZING	
2] PRECISION CHECK	
3] CARRYOVER	
4] LINEARITY CHECK	

SIMSON RATHNARAJ. M ENGINEER NAME AND SIGNATURE	CUSTOMER NAME AND SIGNATURE

EPSILON DIAGNOSTICS Chennai 600 020

Appendix

Performance Verification results

PERFORMANCE QUALIFICATION

SYSTEM CERTIFICATION

Study data has determined that the system described in this document meets all criteria outlined in this Performance Qualification protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any have been addressed. The system is ready for specified usage.

Protocol performed by; **Epsilon Diagnostics Representative**

Name: M Simson Rathnaraj

Title: Regional Manager

Company: Epsilon Diagnostics

Customer Authorization

Name: Dr.M.Gandhi

Title: Laboratory In charge

ENGINEER SIGNATURE

DATE 03.12.2021

EPSILON DIAGNOSTICS Chennai 600 020

CUSTOMER SIGNATURE

DATE 03.12.2021

Performance Specifications-- *XI 921 Electrolyte analyser*
Reference Information

SPECIFICATIONS

The analyzer utilizes Ion Selective Electrode (ISE) technology. Ion Selective Electrode is a type of electrochemical sensor. It converts the ion activity to the electric potential of the electrode. The relation conforms to the NERNST equation, that the Logarithm of the ion activity has a linear relation with the electrode potential. In addition, different electrode is sensitive to different ions, for example, sodium electrode is only sensitive to Na ions, and potassium electrode is only sensitive to K ions. If potassium electrode, sodium electrode, and chloride electrode are being combined together, then K ions, Na ions, and chloride ions in the sample can be measured at the same time.

The key part of the electrode is the sensitive membrane. On one side, it is in contact with the sample, responds to the change of the concentration of certain ions in the sample. On the other side, it is in contact with the internal filling solution, and converts the ionic conduction to the electronic conduction through a silver thread i.e. internal electrode. In addition, there is a reference electrode providing reference potential and forming a complete measuring circuit. Inside the reference electrode there is also an internal electrode. Its potential remains constant when the concentration of the solution changes, so it provides a reference point to measure the potential differences.

2.2 Measuring principles

The instrument measures the electrode potentials, and the data is processed by the microprocessor to obtain the concentration of a given ion. The measure method is called "standard comparison". It uses two kinds of standard solutions, one for the calibration of the base point, and the other for the calibration of the slope. The result is obtained from the potentials of the sample and two standard solutions.

Following are the equations:

$$C_X = C_A * EXP[(E_X - E_A) / S] \qquad (1)$$

$$S = \frac{E_B - E_A}{Log\ (C_B / C_A)} \qquad (2)$$

Note:

C_X, E_X: the concentration and potential of the sample

C_A, E_A: the concentration and potential of standard A

C_B, E_B: the concentration and potential of standard B

S: the slope of electrode

In order to improve the precision, the contents of the standard solutions should be similar with the blood samples as much as possible.

Measuring Range

Electrode	Measuring range/(mmol/L)	Slope range (mV/dec)
K^+	0.50～15.0	27～70
Na^+	30.0～200.0	27～70
Cl^-	30.0～200.0	27～70
Ca^{2+}	0.10～5.00	15～35
pH	7.0～9.0(Unit)	27～70
Li^+	0.3～3.0	12～67
HCO_3^- (AB)	6.0～50.0	4～20

Sample Type

Serum, Plasma, Whole Blood, Urine

Measuring Speed

60 Samples /hour

Index (Table 4.0)

Parameters	Accuracy(B)	Precision(CV)	Linearity(D)	Stability(S)	Carryover(C)
K^+	≤3.0%	≤1.0%	≤3.0% or ±0.08 mmol/L	≤2.0%	≤1.5%
Na^+	≤3.0%	≤1.0%	≤3.0% or ±2.0 mmol/L	≤2.0%	≤1.5%
Cl^-	≤3.0%	≤1.0%	≤3.0% or ±2.0 mmol/L	≤2.0%	≤1.5%
Ca^{2+}	≤5.0%	≤3.0%	≤3.0% or ±0.04 mmol/L	≤3.0%	≤1.5%
pH	≤1%	≤2.0%	≤5.0%	≤2.0%	≤1.5%
Li^+	≤5.0%	≤5.0%	≤5.0% or ±0.1mmol/L	≤5.0%	≤5.0%
HCO_3^-	≤6.0%	≤3.0%	≤5.0% or ±1.0mmol/L	≤3 mmol/L	≤10%

Accuracy Qualification

Accuracy is tested on a minimum of 150 normal & 50 abnormal samples for all parameters, Distributional abnormal samples should be included.

Carryover

High-to-Low Carryover on the XI 921 Electrolyte Analyser should meet the limits set in Table 4:

Mode-to-Mode Comparison (for Auto Sampler if present)

Automatic (closed vial) and Manual (open vial) mode-to-mode differences of the means of 10 "normal" specimens, measured in triplicate, or 50 samples from accuracy testing should be less than or equal to the following:

Na	5%, whichever is greater
K	2%, whichever is greater
Ca	2%, whichever is greater
Cl	5%, whichever is greater
Li	5%, whichever is greater

Operating and Reportable Ranges

The operating ranges reflect the range of values over which the instrument displays, prints and transmits results. Values that are between the linear range and the operating range, and values outside the reportable range, are displayed, printed and transmitted with an over linear range flag (+).

	Measuring Range	Precision (CV %)
K^+	0.50 – 15.00 mmol/L	≤1.0%
Na^+	30.0 – 200.0 mmol/L	≤1.0%
Cl^-	30.0 – 200.0 mmol/L	≤1.0%
Ca^{2+}	0.10 – 5.00 mmol/L	≤2.0%
Li^+	0.20 – 3.00 mmol/L	≤3.0%
pH	4.00 – 9.00 unit	≤1.0%

5.5 PRECISION VERIFICATION

Purpose

Use this procedure to verify the reproducibility (precision) of the results.

Tools/Supplies Needed

Fresh normal, serum sample Determine the quantity needed based on the number of tests modes to be run (Minimum 10)

Procedure

1. At the Instrument, Select Sampling.
2. Enter Sample Number
3. Present tube under sample probe and press aspirate
4. Sample will be aspirated.
5. Record the results
6. Similarly repeat a minimum of 10 aspirations using the same sample
7. Record results and calculate the % CV
8. Verify that the results are within the limits specified in Table 4.0
9. Please ensure
   a. No parameters are trending. A trend could indicate air leaks.
   b. If any parameter does not meet the criteria:
   c. Correct the problem.
   d. Repeat the test.

epsilyte

XI 921

ELECTROLYTE ANALYZER

OPERATIONAL QUALIFICATION

OPERATIONAL QUALIFICATION

SYSTEM CERTIFICATION

Study date has determined that the system described in this document either meets all criteria outlined in this Operational Qualification protocol. All exceptional conditions if any have been addressed. The system is ready for specified usage.

Protocol performed by: **EPSILON DIAGNOSTICS Representative**

Name: M Simson Rathnaraj

Title: Regional Manager

Company: **EPSILON DIAGNOSTICS**

Customer Authorization:

Name: Dr.M.Gandhi

Title: Laboratory In charge

ENGINEER SIGNATURE

CUSTOMER SIGNATURE

DATE 03.12.2021

DATE 03.12.2021

epsilyte

OPERATIONAL QUALIFICATION – SYSTEM VERIFICATION REPORT

This is to certify that the following checks mentioned in the operational verification protocol have been performed and found to be satisfactory.

3.16 CHECKING THE ANALYTICAL STATION	
3.16.1 SUPPLYING AC INPUT	
3.16.2 POWER ON THE SYSTEM	
3.17 TESTING THE SYSTEM	
3.17.1 ELECTRODE INSTALLATION	
3.17.2 SYSTEM CONDITION AFTER SHUTDOWN	
3.17.3 SYSTEM CONDITION AFTER STARTUP	
3.18 INSTALLATION CHECKLIST	
5.1 SYSTEM VERIFICATION REPORT	

SIMSON RATHNARAJ. M ENGINEER NAME AND SIGNATURE	CUSTOMER NAME AND SIGNATURE

Appendix

Start-up report

OPERATIONAL QUALIFICATION

SYSTEM CERTIFICATION

Study data has determined that the system described in this document meets all criteria outlined in this Operational Qualification protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any have been addressed. The system is ready for specified usage.

Protocol performed by; **EPSILON DIAGNOSTICS Representative**

Name: Simson Rathnaraj

Title: Regional Manager

Company: **EPSILON DIAGNOSTICS**

Customer Authorization:

Name: Dr.M.Gandhi

Title: Laboratory In charge

ENGINEER SIGNATURE

DATE 03.12.2021

CUSTOMER SIGNATURE

DATE 03.12.2021

EPSILON DIAGNOSTICS Chennai 600 020

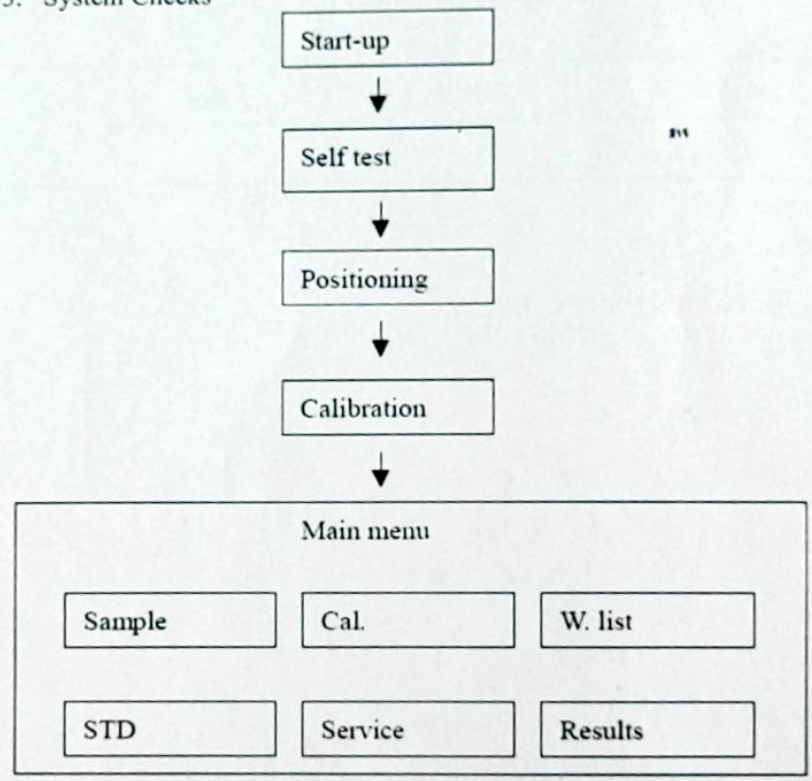
XI 921
ELECTROLYTE ANALYZER

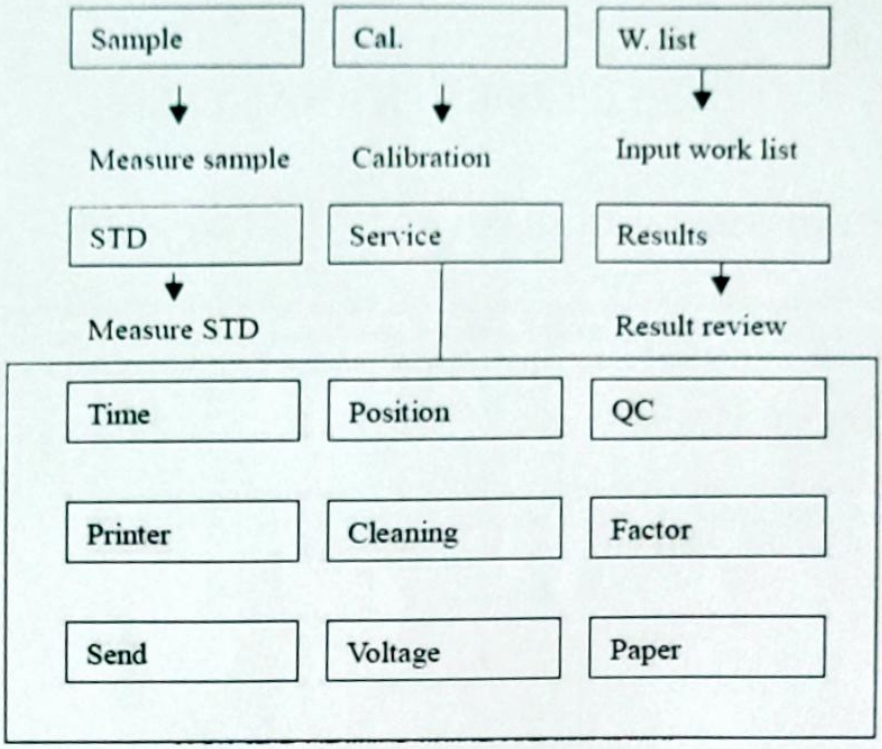
OPERATIONAL QUALIFICATION

The operational qualification procedure specifies the methodology for the installation of the specified system after successful installation qualification. Successful completion of the specified protocols and is ready for operation and subsequent performance analysis.

REFRENCE OQ Protocol

1. System software loading
2. System Booting and Initialization
3. System Checks





Reference

Operation manual XI 921 ELECTROLYTE ANALYZER
Service manual XI 921 ELECTROLYTE ANALYZER

OPERATIONAL QUALIFICATION

3.16 CHECKING THE XI 921 ELECTROLYTE ANALYZER

Power up Checks

CAUTION Heat damage. Using an extension cord on the Power Supply could cause heat damage to the main ac power cable. Do not use an extension cord. Plug the main ac power cable from the Power Supply directly into a dedicated wall outlet.

1. Plug the main ac power cable for the Power Supply into the dedicated wall outlet.
2. Turn on the MAIN POWER circuit breaker.
3. Press **POWER ON**,

The Screen Displays ..... **INITIALIZING**.....

The instrument carries out the self-test for the positioner, printer and auto sampler. The sample probe will lift up, and the screen displays:

Auto position OK Printer OK

Notes:

1. For auto sampler models, it will show "Sample tray "OK" if the auto sampler is correctly installed.
2. The initialization will halt if any error detected on the liquid distribution valve, elevator switch or optical couplers.

When the initialization finishes successfully, the sample probe comes down, and a few seconds later, the screen displays:

Measure ISE STD.....

It indicates the instrument is carrying out the calibration. The system checks the positioner' voltage, pump pulse numbers and electrode potentials. The screen displays:

1032 ... *(the positioner's voltage (in mV) when calibrating without liquid, up to 3 readings)*

127 ... *(the positioner's voltage (in mV) when calibrating with liquid, up to 3 readings)*

2094 2100 ... *(the pump pulse number corresponding to the sample volume, up to 4 readings)*

70.36 68.08 73.77 33.75 69.1 *(the potential of each electrode when Standard B aspirated)*

53.98 73.56 66.59 26.15 95.1 *(the potential of each electrode when Standard A aspirated)*

.....

..... *(The potentials with standard B and standard A displayed in turn, up to 3 times)*

When the calibration finish, the screen displays:

Slope		
K:	54.5	OK
Na:	52.3	OK

And the results will also be printed out as below:

TIME: 2005-03-30 10:08
SLOPE

K:	54.5	(27-70)
Na:	52.3	(27-70)
Cl:	51.6	(27-70)
Ca:	25.5	(15-35)
pH:	55.6	(26-70)
AB:	11.4	(4- 20)

Note: if the slope of an electrode is unstable, it will display "Fluc."on the right side. If the slope of an electrode is abnormal, it will display "X" on the right side.

The normal ranges of the slopes are:

K:	27-70 mV/dec	Ca:	15-35 mV/dec
Na:	27-70 mV/dec	pH:	27-70 mV/dec
Cl:	20-70 mV/dec	Li:	12-67 mV/dec
AB:	4-20 mV/dec		

After the calibration, the screen will display the main menu: