



ELECTROLYTE ANALYZER
ELECT3 / ELECT 5

INSTALLATION QUALIFICATION
OPERATIONAL QUALIFICATION
PERFORMANCE QUALIFICATION
(IQ/OQ/PQ)

BY:-

Star Bio Med Pvt. Ltd



Date: - 27.02.2024

25-B/7, W.E.A. New Rohtak Road, Near Liberty Cinema, Karol Bagh, New Delhi-110005
Tel. : 9643207024, 20, 9810028448 • Email : starbiomed@rediffmail.com, info@starbiomed.com






STAR BIOMED PVT. LTD.

CERTIFICATE OF INSTALLATION

INSTRUMENT NAME : ELECTROLYTE ANALYZER "ELECT3"
SERIAL NUMBER : 0122112013
CUSTOMER NAME : WELL CARE PATH LAB,
ADDRESS : SCO Shree Balaji Enclave Dhakoli Zirkipur Panjab 160104

The undersigned performers certify that the Installation Qualification Protocol has been successfully completed for the instrument stated above.

Engineer

Signature : 
Name : Vishnu Sharma
Designation : Service Engineer
Company : STAR BIOMED PVT. LTD.

Quality Manager

Signature : 
Name : Manoj Shroff
Designation : Quality Manager
Company : STAR BIOMED PVT. LTD.



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INSTALLATION REPORT

Customer Name : WELL CARE PATH LAB
Place : SCO Shree Balaji Enclave Dhakoli Zirapur Panjab 160104
Contact Person : Mr. Gurnam Singh
Instrument Name : Electrolyte Analyzer
Serial Number : 0122112013

The Analyzer was installed along with the necessary standard accessories. All basic requirements and adjustments were checked and are found to be satisfactory. The preliminary standardization of the analyzer and the training were provided to the complete satisfaction of the customer. The analyzer is found to be working satisfactorily.

For Star Biomed Pvt. Ltd



Service Engineer

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INSTALLATION QUALIFICATION/IQ PROTOCOL

1. System Unpacking
2. System Checking For any Damages
3. All accessories as per check List verification
4. Space Requirement checked and verify.
5. Power / Working Requirement check.
6. Reagents, Calibrators and Control verification.

1. SYSTEM UNPACKING & 2. SYSTEM CHECKING

Unpacked the instrument carefully and check for any physical Damages. No damage found.

3. ACCESSORIES CHECK

Check all accessories as per check List and verified OK.

4. SPACE REQUIREMENT

- Checked site for proper space allocation. At least 20CM on each side and enough room on the countertop, Checked and found OK.

DIMENSIONS		
PARAMETER	Analyzer (mm)	Working Area
Width mm	490	510
Depth mm	400	420
Height mm	470	500
Weight Kg	8.100Kg	



POWER / WORKING REQUIREMENT

Requirement	Acceptable Range	Observed Ranged
Input Voltage	220 +/- 10 V	223 V
Neutral to Earth Voltage	<5.0V	3.8V
Line Frequency	50 HZ	50 HZ
Ambient Temperature	10 C – 30 C	23
Relative Humidity	20-85 %	63%

6.1 Reagents Loading

After checking instrument physically and before switching on the analyser, first check the pump tubing for any pinch. If no pinch found and in well condition pull the connector and load it on the lock so that pump sets to aspiration. Now unpack the Reagent pack and open the safety cap of pack. Load the reagent up to the end in the reagent load area.

Checked and found OK and Regent Loaded in the Slot of Instrument.

6.2 Electrode Loading

Before Loading all Electrode to the instrument insure that all electrodes has its internal filling Solution properly fill with enough Volume. If required fill up with respective filling solutions. Now load all electrode by loosing the gripping nut / Notch, Load electrodes in proper order and re fix the Gripping Nut.

Checked all Electrodes and its filling Solutions found OK, After loading Verified for proper fixing in Slot.

6.3 Calibration

Switch ON the Instrument and wait till instrument performs the initial checks of Probe movement, Liquide check, Solution Pack registration and finally Calibration of Solution Pack.

Electrode	Slope range (mV/dec)	Observed Slope (mV/dec)
K+	27~70	53.2
Na+	27~70	63.3
Cl-	27~70	41.7
Ca ²⁺	15~35	NA
CO ₂	4~20	NA
pH	27~70	NA



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OPERATIONAL QUALIFICATION

The Operational Qualification procedure specifies the methodology for installation of specified system after successful installation qualification. Successful completion of procedure identifies that system is ready for operation and subsequent performance analysis.

OQ PROTOCOL

1. System Connections
2. Reagent & Waste Connections
3. Customizing the Analyzer Software
4. System Booting , Initialization & Check
5. Maintenance procedures.
6. Customer Training – Operation & Maintenance.

1. SYSTEM CONNECTION –

SYSTEM CONNECTIONS			
S/N	NAME	Check	Remark
1	Main Unit	Yes	OK
2	Input Power supply	Yes	OK
4	Pump and Electrode Connection	Yes	OK

2. REAGENT & WASTE CONNECTIONS -

REAGENT CONNECTION CHECK		
NAME	CHECK	Remark
Solution Pack Installation	YES	Ok
Waste Connection	YES (it is inside Solution pack)	Ok
Electrode connection	YES	Ok

3. CUSTOMIZING ANALYZER SOFTWARE

CUSTOMIZING ANALYZER SOFTWARE			
S/N	Parameters	Check	Remark
1	Date & Time	Check to current date and time	Done
2	Standby and Calibration timeout	Set to required value	Done
3	Reference Ranges	Set as per lab requirement	Done
4	Reference Units	Set as per lab requirement	Done



4. SYSTEM BOOTING, INITIALIZATION & Check

Power ON System and check instrument Initialization successfully.
Check following Parameters.

S/N	Parameters	Check Status	Remark
1	Startup check	Pass	Pass
2	Solution Pack Registry	Check required Volume	Pass
3	Calibration	Check Status (27-70)	Pass

5. MAINTENANCE PROCEDURES

Train Operator for the following procedure and Guide for its schedule

MAINTENANCE			
S/N	Parameters	Check	Remark
1	Using Maintenance Menu	Yes	Ok
2	Replacing Reagents Pack	Yes	Ok
3	Cleaning of Fluid path	Yes	Ok
4	Weekly Maintenance	Yes	Ok
5	Overall Maintenance	Yes	Ok
6	Checking Electrode filling solution and filling it	Yes	Ok
7	Replacing Membrane of Reference Electrode	Yes	Ok
8	Touch Screen Calibration	Yes	Ok
9	Cleaning Pump Tubing and checking	Yes	Ok

6. CUSTOMER TRAINING – OPERATION & MAINTENANCE

Training Provided to Operator and Administrator for System Routine Operations
Quality Control running and Troubleshooting.

Date: 27/02/2024

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PERFORMANCE QUALIFICATION

System Control Lot No. 201801222 Exp. 21/01/2020			
TEST	Target		Observed
	Mean conc.	SD	Value
Na Sodium	145.0 mmol/L	+/- 2.5	143.4
K Potassium	5.00 mmol/L	+/- 0.2	4.89
Cl Chloride	105.0 mmol/L	+/- 2.0	103.8

Control 1			
TEST	Target		Observed
	Mean conc.	SD	Value
Na Sodium			
K Potassium			
Cl Chloride			

Control 2			
TEST	Target		Observed
	Mean conc.	SD	Value
Na Sodium			
K Potassium			
Cl Chloride			

QC run performed on System and results found Satisfactory.
System Working OK

For Star Biomed Pvt. Ltd



Service Engineer
Date: 27.02.2024

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Certificate of Calibration

Date: 27 Mar, 2024

This is to certify that the below mentioned instrument in **WELL CARE PATH LAB**, SCO Shree Balaji Enclave Dhakoli Zirkpur Panjab 160104 has been calibrated by us on 27 Mar, 2024. The next calibration is due on before 26th Mar, 2025. The values are falling within the specified range.

Instrument Model Name: Electrolyte Analyzer

Instrument Serial No. : 0122112013

Thanking you and assuring the best of our services always.

For **STAR BIOMED PVT. LTD.**

Service Engineer



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