

TRANSASIA BIOMEDICALS LIMITED			TRANSASIA Bio-Medicals Ltd.
IQQQPQ of Easylyte Plus (Pathkind Diagnostics Bulandshahr)			
Instrument Name	Easylyte Plus	SN	55777CNKC

Installation Certificate for Easylyte Plus (Na/K/Cl)


This is to certify that the Easylyte Plus Instrument Serial No. **55777CNKC** is successfully Installed and Commissioned at **Pathkind Diagnostics Bulandshahr** and the Installation Protocol / checklist has been successfully completed for the above instrument.

TRANSASIA BIOMEDICALS LTD, MUMBAI.

Name : Rajnish Singh

Designation : Sr. Service Engineer

Date : 10/11/2017

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IQOQPQ of Easylyte Plus (Pathkind Diagnostics Bulandshahr)			
Instrument Name	Easylyte Plus	SN	55777CNKC

Installation Qualification for Easylyte Plus

Customer Name : Pathkind Diagnostics Bulandshahr

Address : Bulandshahr

Instrument Name : Easylyte Plus Na/K/Cl

Serial Number : 55777CNKC

Initial Inspection of the unit carried out and the details are as follows:

System Condition Report:

Removed the EasyLyte and accessories from shipping containers and place on solid work surface.
 Visually inspected EasyLyte for any damage sustained during shipment.

External Requirements for Installation:

1. The power cord of the EasyLyte was connected to a matching grounded outlet
 Supply of 220 VAC, 50/60 Hz, as indicated on the label on the rear of the analyzer.
2. Checked the mains supply and found the Earth, neutral voltage 0 V
3. The environment is free from dust, mechanical vibrations, and electrical interference.
4. Ambient Conditions Maintained : 15-32 degree Celsius(60-90F), < 85% Humidity

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UNPACKING

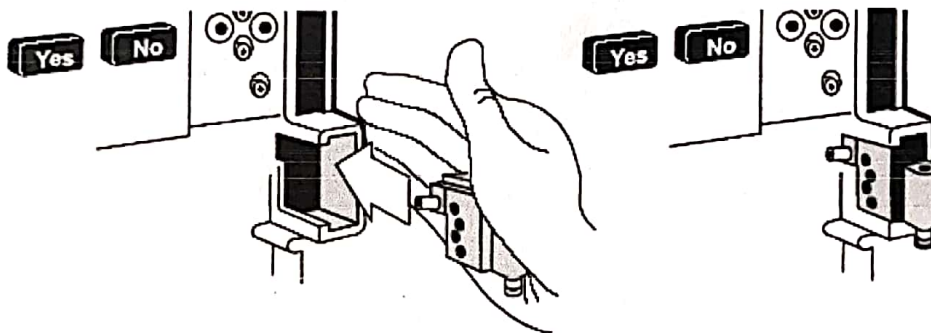
Removed the EasyLyte and accessories from shipping containers and placed on solid work surface. Visually inspected EasyLyte for any damage sustained during shipment.

INSTALLATION/REPLACEMENT

For installation or replacement instructions of EasyLyte components, followed the procedures in this section..

1.Solutions Valve

Installed the SOLUTIONS VALVE into the EasyLyte by pushing firmly on the rounded front of the valve.



2.Probe Wiper-

Installed the PROBE WIPER by pushing it firmly onto the mounting post on the bottom of the SOLUTIONS VALVE.

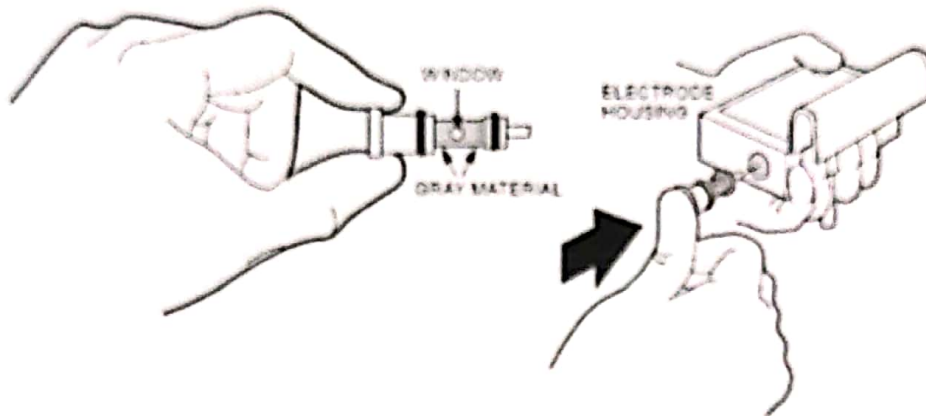
3.Sample Probe

Rotated the SAMPLE PROBE until the side PROBE HOLE(near the rounded tip) faced forward. Then, gently inserted the rounded tip of the SAMPLE PROBE downward into the top of the SOLUTIONS VALVE. Aligned the probe collar ring with the white notch on the PROBE ARM.

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Membrane Assembly

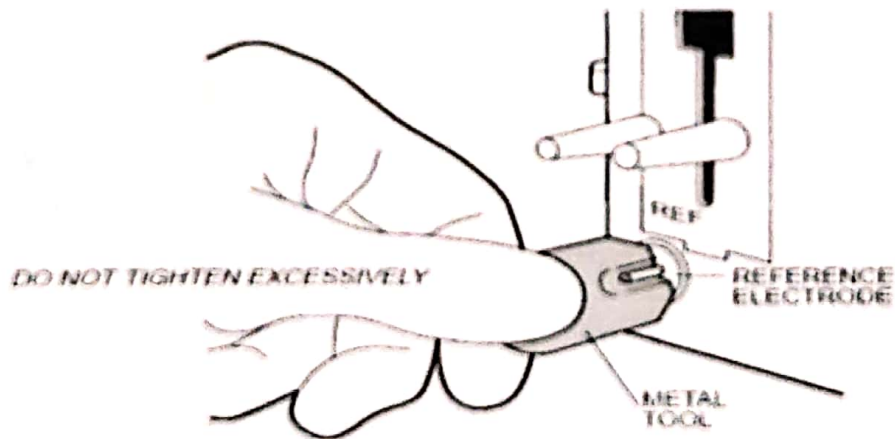
Removed the MEMBRANE ASSEMBLY from holding it by the large end. Note the small, installed the membrane assembly with round window visible to the operator in the electrode housing.



5. Reference Electrode

Removed the REFERENCE ELECTRODE from its package. Remove and discard the red vinyl cap and packaging.

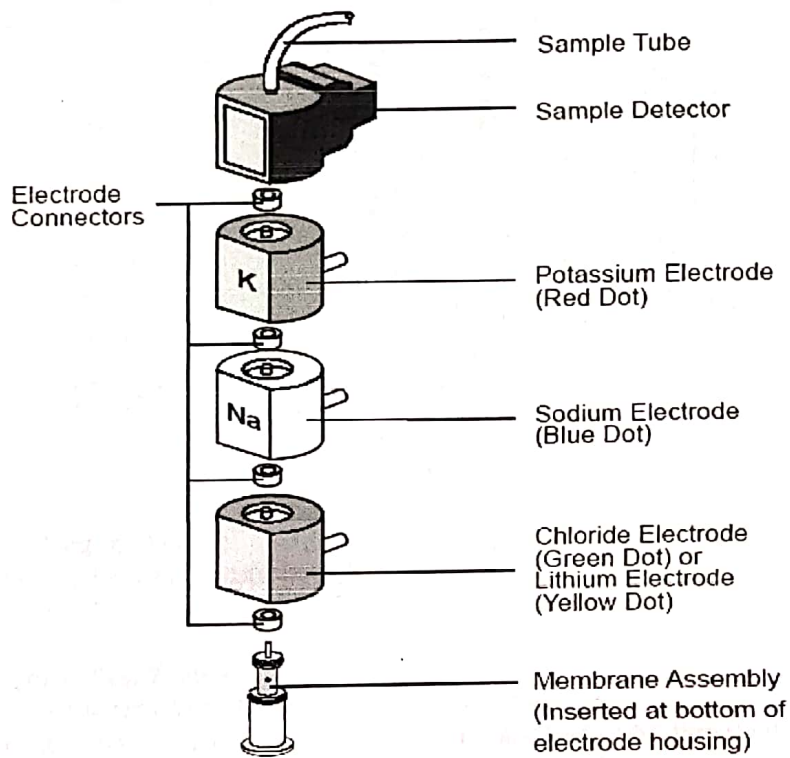
Screwed the new REFERENCE ELECTRODE into the ELECTRODE HOUSING using the METAL TOOL.



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6. Building Electrode Stack

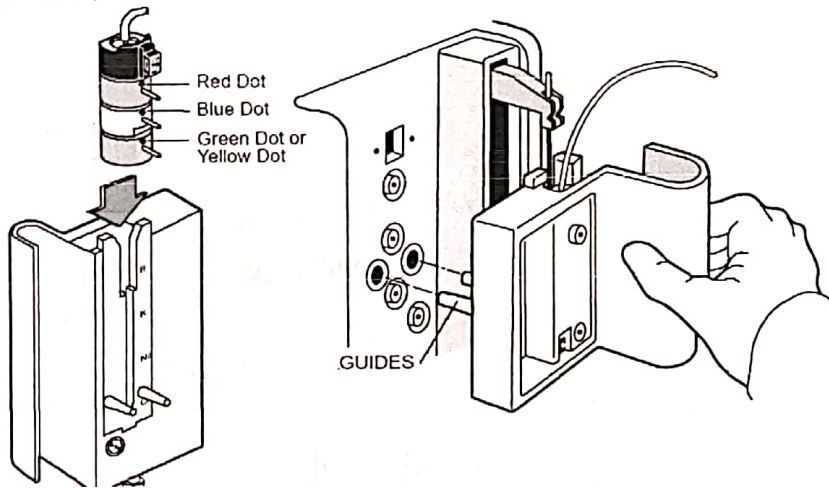
Assemble the ELECTRODE CONNECTORS, ELECTRODES, and SAMPLE DETECTOR. Make sure each component is clean and dry, and the electrode symbols, "Na", "K", "Cl" or "Li", are right-side up. Connected the SAMPLE TUBE to the metal connector on the SAMPLE DETECTOR at the top of the ELECTRODE STACK.



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7. Loading Electrode Stack

Slid the ELECTRODE STACK into the ELECTRODE HOUSING. PUSHED DOWN firmly until the SAMPLE DETECTOR snaps into position.

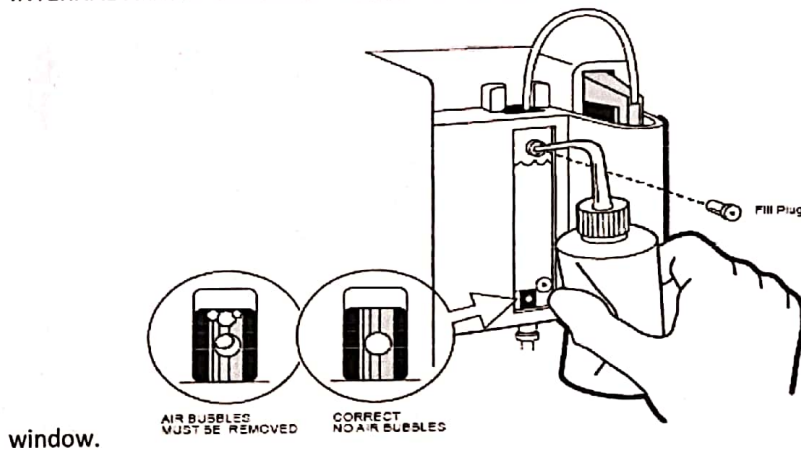


8. Installing the Tubing

Connected the SAMPLE TUBE to the top of the SAMPLE PROBE.

9. Internal Filling Solution

Removed the cap on the INTERNAL FILLING SOLUTION bottle. Place the spout cap on the bottle. Filled the ELECTRODE HOUSING through the fill plug hole until the INTERNAL FILLING SOLUTION reached the "fill line" on the

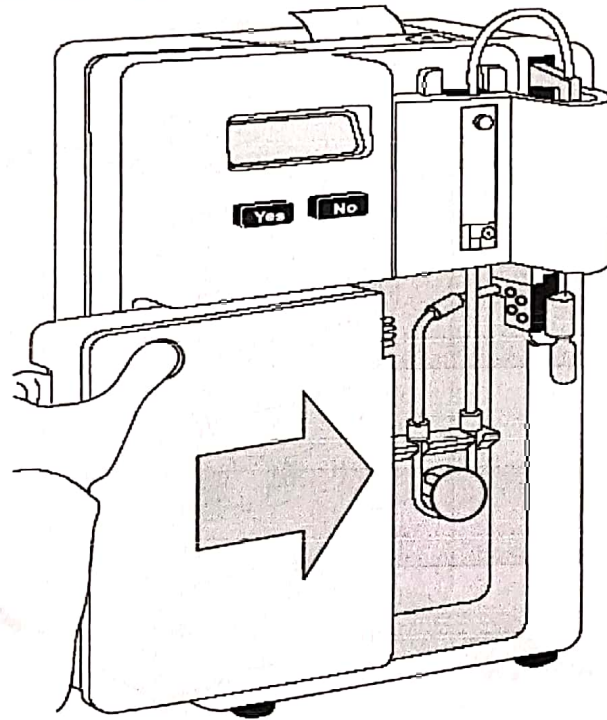


window.

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10. Solutions Pack Installation

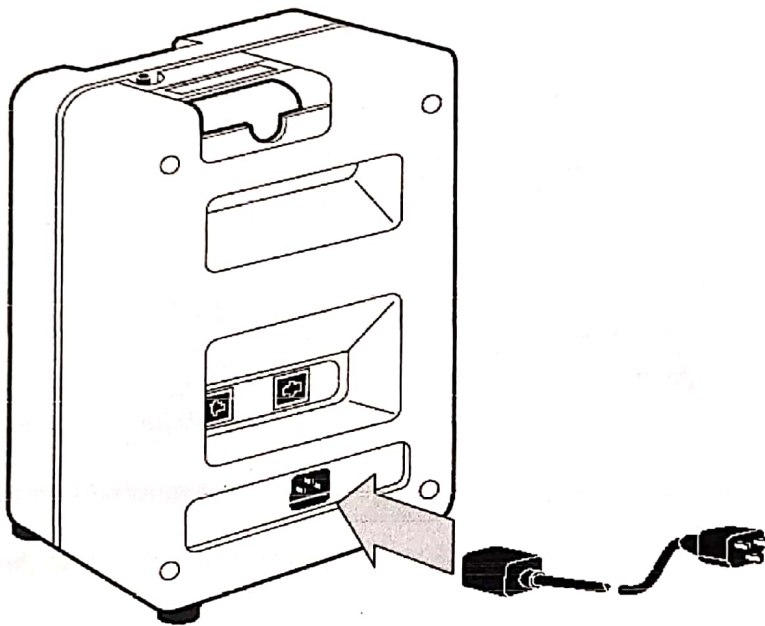
Placed SOLUTIONS PACK into the front of the analyzer, and slided the SOLUTIONS PACK firmly to the right, plugging it into the SOLUTIONS VALVE.




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11. Power Up

After assembling all the components, plugged the EasyLyte into a GROUNDED outlet. A beep sound alongwith with . ****Na/K**** or ****Na/K/Cl**** or ****Na/K/Li**** appeared on the display. The EasyLyte displayed **CALIBRATE NOW?**, installation is completed.

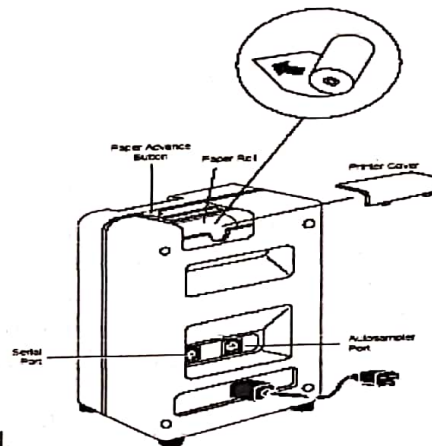


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12. Printer Paper/Accessories Installation

To install the roll of paper into the printer, Cut the new edge to a point in the center of the paper, forming a V. Gently pushed this leading edge of the paper into the slot behind the printer until the paper tip reached the plastic tear bar. Pull the paper by hand until the full width appears at the tear bar.

After installing the paper, replaced the small cover on top of the



housing to protect the printer paper roll.

Protocol Performed By: Rajnish Singh

Designation: Sr Sarvice Engineer


Signature:

Date: 10/11/2017

Customer Authorization: Pathkind Diagnostics Bulandshahr

Name : Dr Faheem Javed

Designation : Pathologist

Signature : 

Date: 10/11/2017

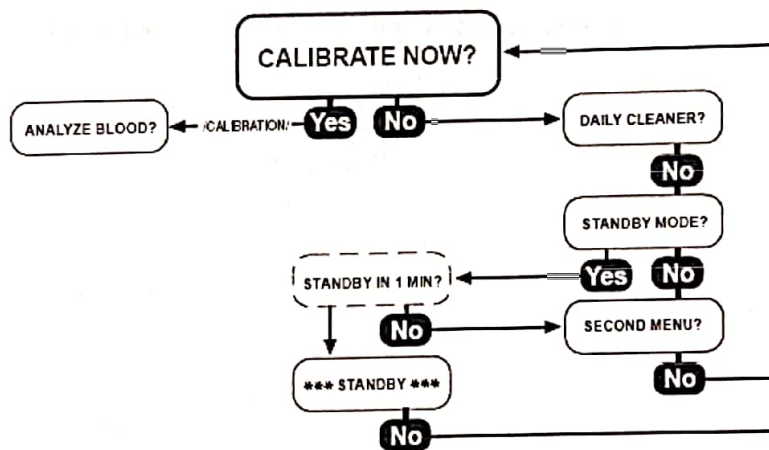
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Operational Qualification

1.SOLUTION PURGE.

This procedure was required, as SOLUTIONS PACK was newly installed.
After purging, the display returned to CALIBRATE NOW?

2.CALIBRATION.



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Verified proper installation, and the display showed **CALIBRATE NOW?**.

Successfully calibrated the instrument and it displayed **ANALYZE BLOOD?**.

Protocol Performed By: Rajnish Singh

Designation: Sr Service Engineer

Signature:

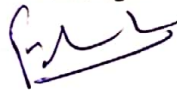
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Customer Authorization: Pathkind Diagnostics Bulandshahr

Name : Dr Faheem Javed

Designation : Pathologist

Signature :



Date: 10/11/2017

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Performance Qualification

1. Checked Cal values and results are within the range.
2. Checked electrodes values and results are within the range.
3. Checked Precision with 1 normal sample in 11 Replications and CV % results are within acceptable criteria.
4. Checked QC Results in Replications and all results are within the range.

Precision Study			
Run Seq.	NA	K	CL
1	137.8	4.24	100.4
2	137.8	4.23	106.1
3	137.8	4.24	106.4
4	137.9	4.24	106.2
5	137.7	4.24	106.5
6	137.8	4.26	106.3
7	137.6	4.25	106.7
8	137.8	4.23	106.3
9	137.6	4.25	106.7
10	137.8	4.24	106.3
11	137.8	4.24	106.5
Mean	137.76	4.24	105.85
SD	0.09	0.01	1.82
CV%	0.07	0.21	1.72
Acceptable Limit CV %	< 1.0	< 2.0	< 2.0

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QUALITY CONTROL

NORMAL CONTROL

Na 139.2 K 3.65 Cl 105.4

STORE RESULTS

NOV-10-17; 12:03

QUALITY CONTROL

NORMAL CONTROL

Na 139.3 K 3.68 Cl 105.7

STORE RESULTS

NOV-10-17; 12:05

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System Certification:

Study data has determined that the System described in this document either meets all criteria outlined in this Performance Qualification Protocol, or exceptional conditions have been identified and documentation included.

The System is ready for specific usage.

Protocol Performed By: Lavkush Lal

Designation: Application Specialist

Signature:


Date: 10/11/2017

Customer Authorization: Pathkind Diagnostics Bulandshahr

Name : Dr Faheem Javed

Designation : Pathologist

Signature :



Date: 10/11/2017