



Date: November 22, 2022

To

Neethi Lab & X-Ray
Kunnamangalam

CALIBRATION CERTIFICATE

The routine calibration of the following instrument which is installed at your laboratory is performed as per specifications. The calibration of various mechanism, etc has been done. Please find the annexure enclosed.

Instrument Name : **EASY LYTE.**
Serial no : 55226
Calibration Date : 22.11.2022
Next Calibration Due : 21.11.2023
Performed at customer site by : Mr Biju Mathew

For Transasia Bio Medicals Ltd.

Shiju K. John
Regional Service Manager
Calicut

ANNEXURE-A

| SI NO | DESCRIPTION | TARGET | VALUE OBTAINED |
|--------------|---|------------------------|-----------------------|
| 1 | CALIBRATION | Na 50-64 K 50-64 | Na 56 K 58 |
| 2 | ELECTRODE VALUES | Na 100-160 K 35-125 | Na 130 K 75 |
| 3 | Mechanical alignment Of sample probe | Check for Alarm | OK |
| 4 | Sample Detector | 150-250 | 176 |



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

This is to certify that the Easylyte Plus Instrument Serial No.55226 is successfully Installed and Commissioned at NEETHI LAB KUNNAMANGALAM and the Installation Protocol / checklist has been successfully completed for the above instrument.

TRANSASIA BIO-MEDICALS LTD, MUMBAI

Name : Mr .BIJU MATHEW & Mr .SHABEER

Designation : Service Engineer & Sr.Application Specialist

Installation Date : 23-12-2017

Installation Qualification for Easylyte Plus

Customer Name : NEETHI LAB KUNNAMANGALAM.

Address : Town branch building, Kunnamangalam.

Instrument Name : Easylyte Plus Na/K/Cl

Serial Number : 55226

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 placed it 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 and installation manual on the rear of the analyzer.
2. Checked the mains supply and found the Earth, neutral voltage at 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

UNPACKING

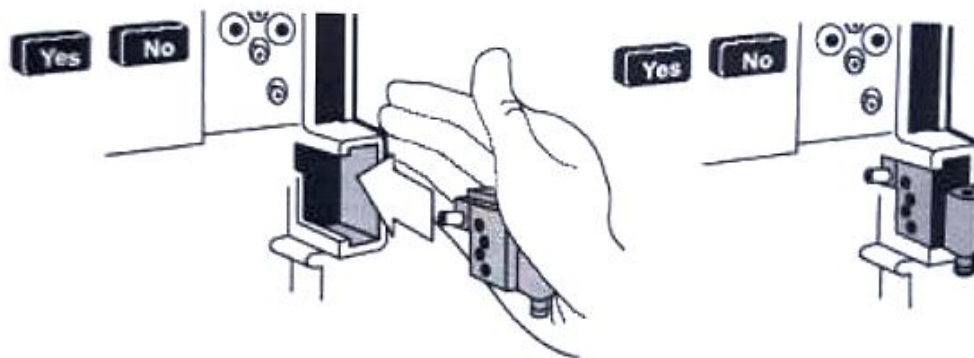
Removed the EasyLyte and accessories from shipping containers and placed on solid work surface. Visually inspected EasyLyte for any damage sustained during shipment.

INSTALLATION/REPLACEMENT

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

1. Solutions Valve

The SOLUTIONS VALVE was installed into the EasyLyte by pushing firmly on the rounded front of the valve.



2. Probe Wiper-

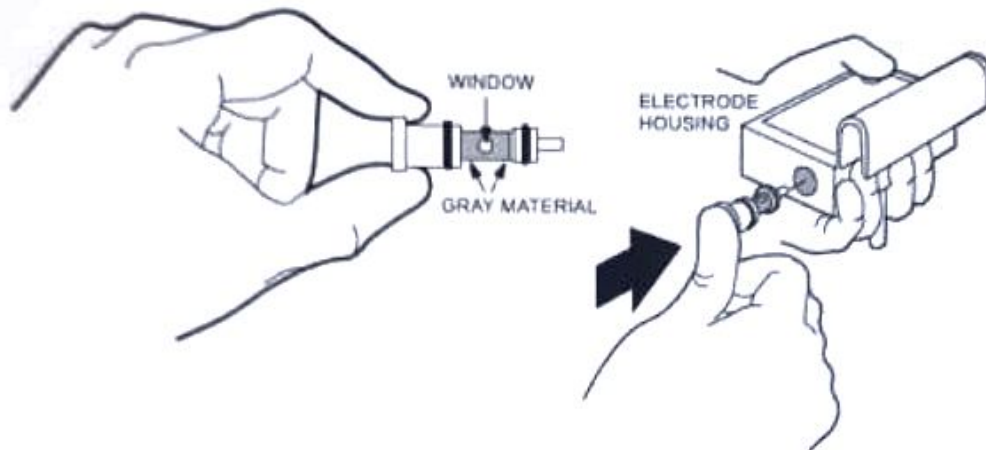
The PROBE WIPER was installed by pushing it firmly onto the mounting post on the bottom of the SOLUTIONS VALVE.

3. Sample Probe

The SAMPLE PROBE was rotated until the side PROBE HOLE (near the rounded tip) faced forward. Then the rounded tip of the SAMPLE PROBE was gently inserted into the rounded tip of the SAMPLE PROBE downward on top of the SOLUTIONS VALVE. Alignment of the probe collar ring was made with the white notch on the PROBE ARM.

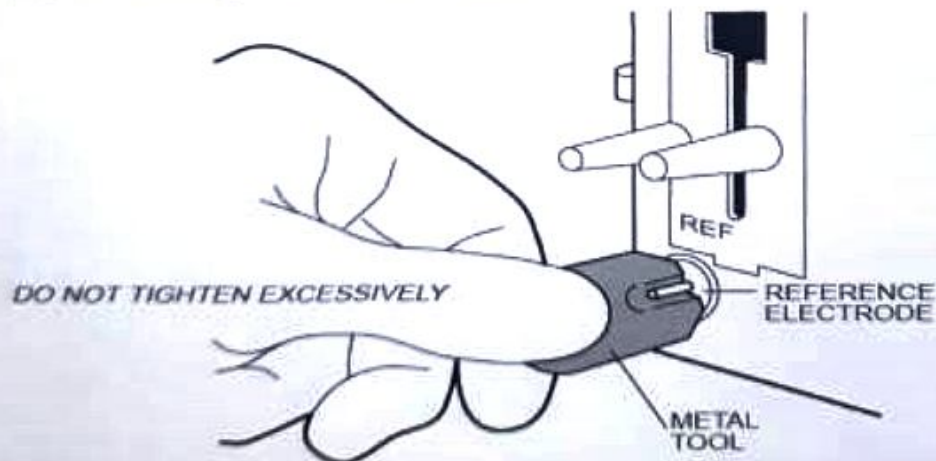
Membrane Assembly

The MEMBRANE ASSEMBLY was removed from holding it by the large end. Note the small, Installed the membrane assembly with round window is visible to the operator in the electrode housing.



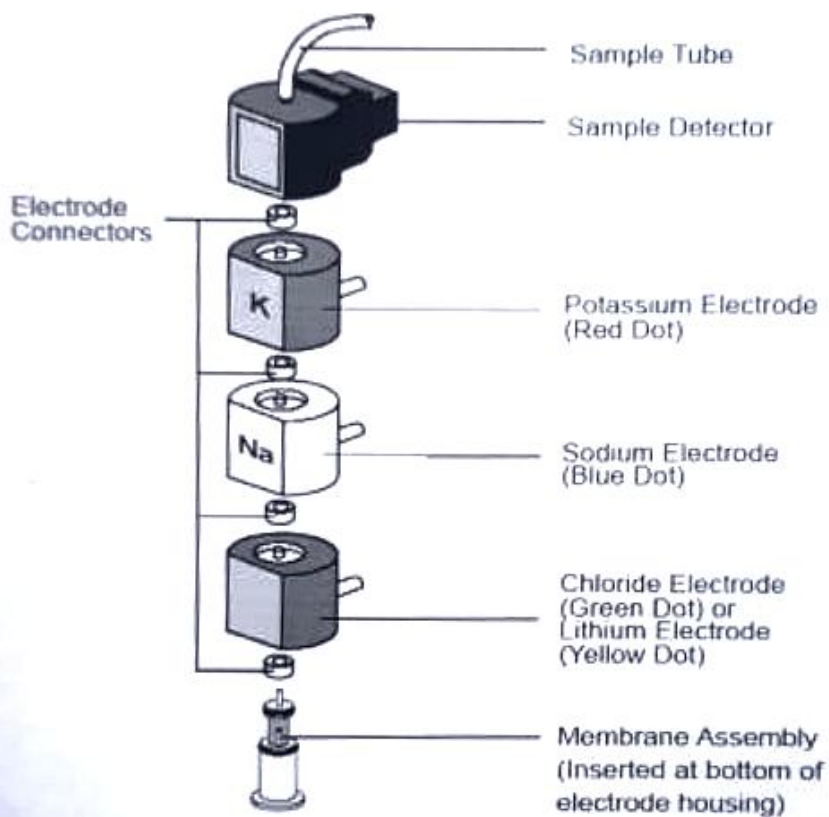
5. Reference Electrode

The REFERENCE ELECTRODE was removed from its package and the the red vinyl cap removed and discarded from the package
The new REFERENCE ELECTRODE was screwed into the ELECTRODE HOUSING using the METAL TOOL.



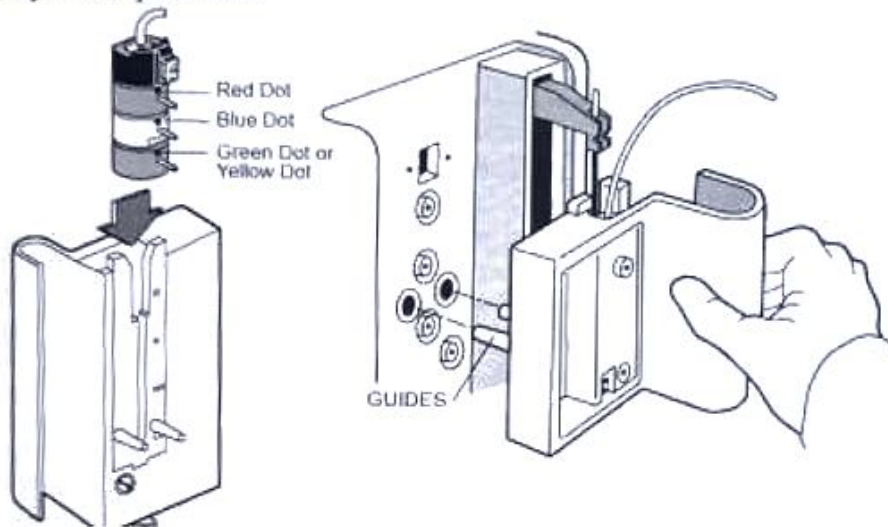
6. Building Electrode Stack

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



7. Loading Electrode Stack

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

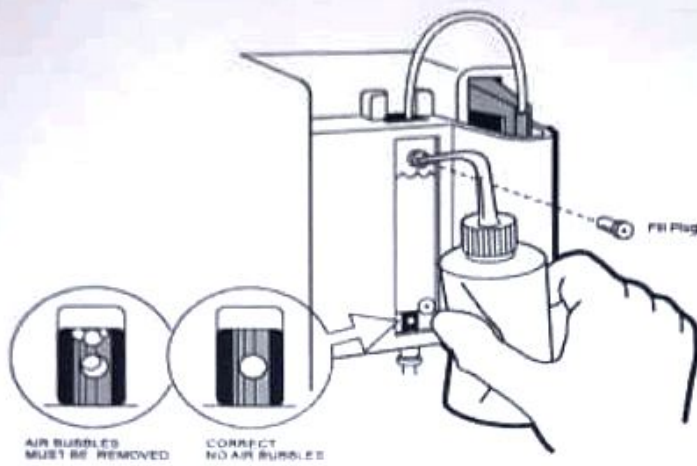


8. Installing the Tubing

The SAMPLE TUBE was connected to the top of the SAMPLE PROBE.

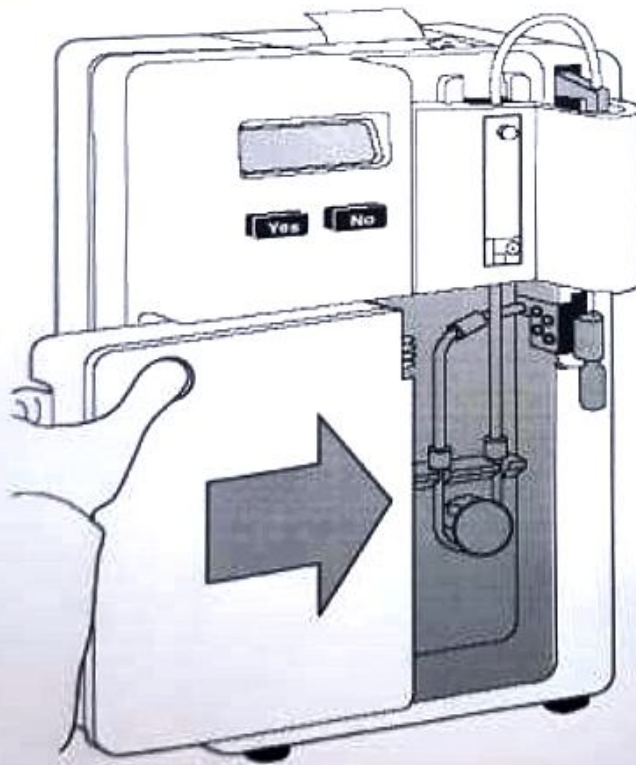
9. Internal Filling Solution

The cap on the INTERNAL FILLING SOLUTION bottle was removed. Placed was the spout cap on the bottle. The ELECTRODE HOUSING was filled through the fill plug hole until the INTERNAL FILLING SOLUTION reached the "fill line" on the window.



10. Solutions Pack Installation

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



11. Power Up

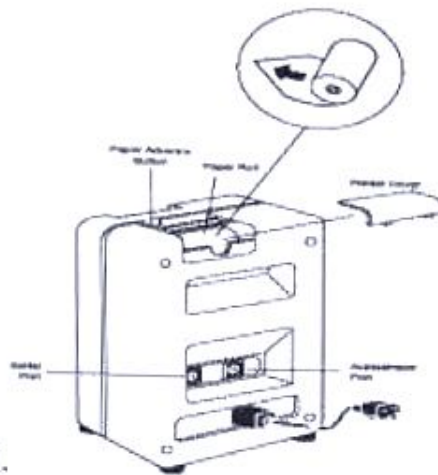
After assembling all the components, the EasyLyte was plugged into a GROUNDING outlet.

A beep sound along with "****u/k**" in "****u/k/1**" in "****u/k/1A**" appeared on the display. The EasyLyte displayed "ALIBUATE NOW!". This completes installation of EasyLyte instrument.



12. Printer Paper/Accessories Installation

To install roll the paper into the printer, Cut the new edge to a point in the center of the paper, forming a V. Gently pushed was the leading edge of the paper into the slot behind the printer until the paper tip reached the plastic tear bar. The paper was Pulled 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 : BIJU MATHEW & SHABEER.T

Designation : Service Engineer & Sr.Application Specialist

Signature

:  

Date

: 16-08-2022

Customer Authorization : NEETHI LAB KUNNAMANGALAM

Name

: SRUTHI B PILLAI

Designation

: Quality Manager

Signature

: 

Date

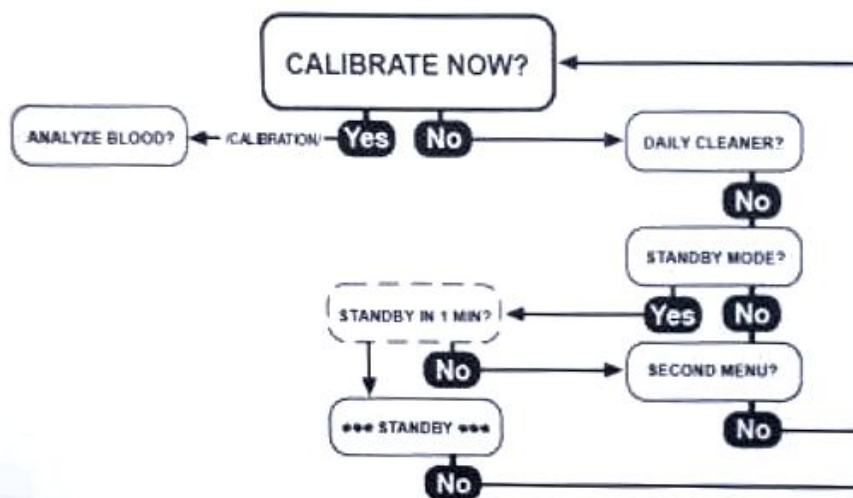
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Operational Qualification:

1. SOLUTION PURGE.

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

2. CALIBRATION.



Proper installation was Verified, and the display characteristics were as per manual instructions, showed **CALIBRATE NOW?**.

After Successful calibration of the instrument it displayed **ANALYZE BLOOD?**. The instrument also printed every step as per the manual instructions and the results were found within range.

Summary: Operation of the instrument is as per expectations. It was checked and found ok.

Protocol Performed By : BIJU MATHEW & SHABEER.T

Designation : Service Engineer & Sr.Application Specialist

Signature :  

Date : 16-08-2022

Customer Authorization : NEETHI LAB KUNNAMANGALAM

Name : SRUTHI B PILLAI

Designation : Quality Manager

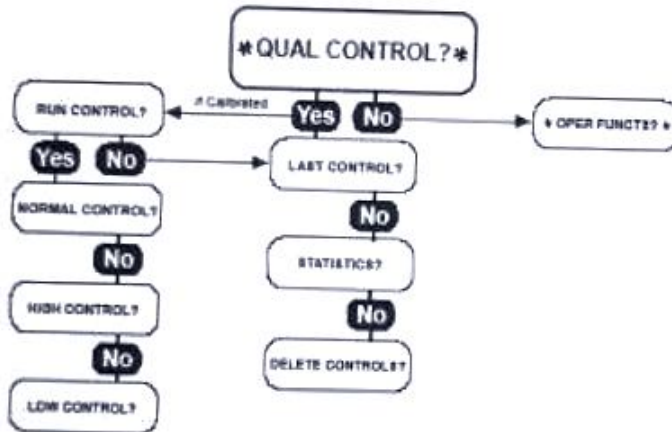
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Date : 16-08-2022

Performance Qualification:

QUALITY CONTROL

After calibrating the instrument, checked with Quality Control (Level 1 & 2) and found the results and precision within specified ranges.



Biorad Lyphocheck Quality Control was used to verify the accuracy and precision of the Easylyte Analyzer. Results are attached.

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 : SHABEER.T

Designation : Sr.Application Specialist

Signature : 

Date : 16-08-2022

Customer Authorization : NEETHI LAB KUNNAMANGALAM

Name : SRUTHI B PILLAI

Designation : Quality Manager

Signature : 

Date : 16-08-2022