

UNMATCHED SERVICE  
SINCE 1979...

## CALIBRATION CERTIFICATE

**Neethi Lab****Kunnamangalam**

1. Model Name & Sr. No : . EM 200- B200462
2. Range of the instrument: Optical density Linear form 0-2.5 A
3. Precision & Accuracy study on EM 200 done on 15.6.2022
4. Calibration Due Date: 14.6.2023
5. Calibration Done By : Mr. Biju Mathew

Reagent / Sample ratio -

Cup Position	Replicates	Absorbance (X)	SD	CV
Cup 1	20	1.5438 OD	0.0054	0.40%
Cup 2	20	1.5438 OD	0.0052	0.42 %
Cup 3	20	1.5449 OD	0.0047	0.38%

### Test of Potassium Dichromate ( $K_2Cr_2O_7$ ) on EM 200

Pipetted / Measured by EM 200		Manually Pipettes EM 200		Manually pipetted & read in Auto span	
Low	High	Low	High	Low	High
0.2005	1.8670	0.1975	1.8710	0.2025	1.7630



This instrument is manufactured in accordance with the European law in force, in particular to "Electricity Safety" EN 610101 and "Electromagnetic Compatibility" EN 61326 Standards.

	Ideal	Actual
Pressure	0.9 bar	0.93bar
Lamp Voltage	11.87 V	11.8V
Temperature	37 <sup>0</sup> C	37 <sup>0</sup> C

Photometer Calibration Check	Ok
Cuvette Blank Check	Ok

Wavelength	Off Set	Gain
340	255	120
405	255	140
505	255	122
546	255	160
578	255	144
600	255	162
660	255	180
700	255	165

The instrument does photometer check before each batch of tests is run. It will give an error message if the photometer test fails and it will not run any samples.

Thanking you and assuring of our prompt attention at all times.

Yours faithfully,  
For Transasia Bio- Medicals Ltd,

**Biju Mathew**  
Area Service Manager



**TRANSASIA BIO-MEDICAL LTD.**

**EM-200**

**SR. NO :B200462**

**IQ,OQ AND PQ**

For

**NEETHI LAB  
KUNNAMANGALAM**

Marketed by:  
Transasia Bio-Medicals Ltd.,  
Transasia House,  
Chandivali Studio road,  
Andheri (E),  
MUMBAI - 400 072

## Installation Qualification for EM200, Sr. No.:- B200462

**Customer Name** : NEETHI LAB KUNNAMANGALAM  
**Address** : Town branch building,Kunnamangalam.  
**Instrument Name** : EM-200  
**Serial Number** : B200462

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

### **System Condition Report:**

Found the System to have been delivered in satisfactory condition and no external physical damaged observed on the same. Package was kept in Good Condition as per the directional indicators like not tilt, indicating the System has not been subjected to mechanical shocks or stored in any manner, so as to cause any damage to the same.

Found all the required accessories as required.

Installation Procedure & Checklist Attached for records.

### **External Requirements for Installation:**

1. Input voltage of 220V-240V / 50Hz or 60Hz.
2. Recommended Operating Temperature is 15-30 °C, with Relative Humidity 30-85% and Atmospheric Pressure 70-106 kPa.

## **Installation Certificate for EM-200, Sr. No.:- B200462**

This is to certify that the instrument **EM-200 Sr. No.:- B200462** is successfully Installed and Commissioned at **NEETHI LAB Kunnamangalam** and the Installation Protocol / checklist has been successfully completed for the Above instrument.

Date of Installation : 23/12/2017

**Protocol Performed By:**

**Transasia Bio-Medical Ltd., Technical Services Department**

**Name** : Mr. Biju Mathew

**Designation** : Service Engineer

**Signature** : 

**Installation Qualifications for EM-200, Sr. No.:- B200462**

Performed/Verified

Installation Procedures as per Checklists.  
Necessary checks and alignments.  
Priming and Cleaning Operations  
Check the results by running the controls.  
Hand over the Instrument for Operators Training & Qualifications


**Protocol Performed By:**

**For TBM, Technical Services Department**

**Name** : Mr. Biju Mathew

**Designation** : Service Engineer

**Signature** : 

## Installation Qualification for EM-200, Sr. No.: -B200462

**Customer Name** : NEETHI LAB KUNNAMANGALAM  
**Address** : Town branch building, Kunnamangalam  
**Contact Person** : Sruthi B Pillai , Quality Manager  
**Instrument Model** : EM-200  
**Serial Number** : B200462  
**Date of Installation** : 23/12/2017

The instrument was installed and was found to be working satisfactorily. Preliminary Customer Training was provided and standardization of the parameters were done. The results were found to be within the expected range and System found to be working satisfactorily.

### Protocol Performed By:

**TBM, Technical Services Department**      **CUSTOMER : PRADO PVT. LTD.**

Name : Mr. Biju Matew

Contact Person : Sruthi B Pillai

Designation : Service Engineer

Designation : Quality manager

Signature : 

Signature : 

## Instrument Setup

1. Assembled the instrument accessories.
2. Removed the Shipping Clamps
3. Connected the Sampler
4. Set the Reagent Tubings
5. Connected the Reagents
6. Connected the waste Tank
7. Connected the Waste Tubings
8. Connected the Power Cord and Connection Cord.
9. Connected the External Printer
10. Perform the setting sequence

Result/Checks

<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>

## Operational Inspection

1. Mechanical Movements.
2. Hydraulics.
3. Electricals.
4. Controls and samples ,Results.

Result/Checks

<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>

**Protocol Performed By:**

**TBM, Technical Services Department**

**Name** : Mr. Biju Matew

**Designation** : Service Engineer

**Signature** : 



**Operations Qualifications for EM-200, Sr. No.:- B200462**

1. Mechanical Movements : Verified
2. Hydraulics. : Verified
3. Electrical Systems : Verified
4. Controls : Verified

**Protocol Performed By:**

**TBM, Technical Services Department**

**Name** : Mr.Biju Matew

**Designation** : Service Engineer

**Date** : 16/8/22

**Signature** : 

## Operational Qualification:

### System Certification:

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

Exceptional conditions, if any, have been addressed.

**The System is ready for specific usage.**

Protocol Performed By: Transasia Bio-Medical Ltd.

Name: Mr. Shabeer.T

Designation: Sr.Application Specialist

Customer Authorization: NEETHI LAB KUNNAMANGALAM

Name: SRUTHI B PILLAI

Designation: Quality manager

Company Representative Name & Sign



Customer Name & Sign

SRUTHI-B-PILLAI



Date: 16/08/2022

Date: 16/08/2022

## Performance Qualifications for EM-200, Sr. No.:- B200462

1. **CONTROLS:** - Run QC Erba Normal and High of all the parameters, found within acceptable limit.
2. **PRECISION CHECK:** - Run the precision of all the parameters, calculate mean, and SD, found within range.

### **System Certification:**

Study data has determined that the System described in this document either meets the necessary 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:**

**Name** : Mr. Biju Matew

**Designation** : Sr. Service Engineer

**Signature** : 

**Date** : 16/8/22.

### **PERFORMANCE QUALIFICATION DONE BY**

**Name** : Mr. Shabeer.T

**Designation**: Sr. Application Specialist

**Signature** : 

**Date** : 16/08/2022.