

TRANSASIA[®]

Transasia Bio-Medicals Ltd., Transasia House, 8 Chandivali Studio Road, Andheri (East), Mumbai - 400 072
Tel: +91 22 4030 9000 Fax: +91 22 2857 3030 Email : transasia@transasia.co.in CIN : U33110MH1985PLC036198



TRANSASIA

EM- 200

SR. NO B2001038

FULLY AUTOMATIC BIOCHEMISTRY ANALYZER

IQ,OQ AND PQ

For

Inlaks General Hospital, Chembur

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



Installation Qualification for EM200 Sr. No.:- B2001038

Customer Name : Inlaks General Hospital I
Address : Chembur Colony, Indira Nagar, Chembur, Mumbai, Maharashtra 400074
Instrument Name : EM-200
Serial Number : B2001038
Date of Installation : 08/10/2018

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.:- B2001038

This is to certify that the instrument **EM-200 Sr. No.:- B2001038** is successfully Installed and Commissioned at Inlaks General Hospital, Chembur and the Installation Protocol / checklist has been successfully completed for the above instrument.

Date of Installation : 08/10/2018

TBM, Technical Services Department

Name : Ms.Swati Srivastava
Designation : Engineer



Installation Qualifications for EM-200, Sr. No.:- B2001038

Carried out all the Installation Procedures as per the Installation Procedure & Checklists.

Carried out all the necessary checks and alignments.

Carried out all the necessary system checks and tests.

Carried out Priming and Cleaning Operations

Checked the results by running the controls and found OK.

Handed over the Instrument for Operators Training & Qualifications

For TBM, Technical Services Department

Name : Ms. Swati Srivastava

Designation : Engineer



Installation Qualification for EM-200, Sr. No.:- B2001038

Customer Name : Inlaks General Hospital Chembur

Instrument Name : EM-200

Serial Number : B2001038

Date of Installation : 08/10/2018

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, Mumbai

Name: Ms. Swati Srivastava

Designation: Engineer

Customer Authorization: Inlaks General Hospital Chembur

Name: Dr. Aparna Jaïram

Designation: HOD

Company Representative

Name & Sign

Ms. Swati Srivastava

Date: 15/11/21

Name & Sign

Dr. Aparna Jaïram

Date: 15-11-21



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.

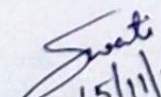
The System is ready for specific usage.

Protocol Performed By: TBM, Mumbai
Name: Ms. Swati Srivastava
Designation: Service Engineer

Customer Authorization: Inlaks General Hospital
Name: Dr. Aparna Jairam
Designation: HOD

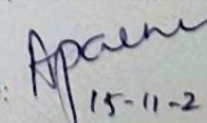
Company Representative Name & Sign

Mr. Swati Srivastava

Date: 
15/11/21

Customer Name & Sign

Dr. Aparna Jairam

Date: 
15-11-21



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

Operational Inspection

1. Checked and found Mechanical Movements OK
2. Checked and found Hydraulics OK.
3. Checked and found Electricals OK.
4. Checked with controls and samples ,results are found OK.

TBM, Technical Services Department

Name : Ms. Swati Srivastava
Designation : Engineer



Operations Qualifications for EM-200, Sr. No.:- B2001038

1. Verified all the Mechanical Movements : Done
2. Verified Hydraulics. : Done
3. Verified Electrical Systems : Done
4. Verified with Controls : Done

TBM, Technical Services Department

Name : Ms. Swati Srivastava
Designation : Engineer



Performance Qualifications for EM-200, Sr. No.:- B2001038

1. **CONTROLS:** - Run Biochemistry control of all the parameters, found within acceptable limit.
2. **PRECISION CHECK:** - Run the precision of the parameters for 10 times; calculate mean, CV% . found within range.

Parameters Values for Verification:

TEST PLAN:

The following tests shall be followed, during the performance Qualification of EM200 instrument.
(Bio-Chemistry Random Analyzer).

Test Parameter	Acceptance Criteria (CV%)	Test Procedure/ Reference(Results Obtained)
PHOS	Less than 5.0 %	0.89 %
UA	Less than 5.0 %	1.06 %
ALBD	Less than 5.0 %	0.77 %
ALPU	Less than 5.0 %	0.91 %
HDLC	Less than 5.0 %	1.20 %
GGT	Less than 5.0 %	2.07 %
TRIG	Less than 5.0 %	0.83 %
CA	Less than 5.0 %	2.72 %
UREA	Less than 5.0 %	1.27 %
GOTHL	Less than 5.0 %	1.61 %
LDH	Less than 5.0 %	1.07 %
CHOL	Less than 5.0 %	2.24 %
GLU	Less than 5.0 %	1.70 %
GPTHL	Less than 5.0 %	1.57 %
CHOL	Less than 5.0 %	2.04 %



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: TBM, Mumbai
Name: Mr. Krishnakant Seegarla
Designation: Application Manager
Customer Authorization: Inlaks General Hospital Chembur

Name: Dr. Aparna
Designation: HOD

Company Representative Name & Sign

Mr. Krishnakath Seegarla

Date: 15/11/21

Name & Sign

Dr. Aparna Jairam

Date: 15-11-21



CERTIFICATE OF CALIBRATION/VERIFICATION

Customer Name: Inlaks General Hospital, Chembur
Model: Fully Automated Bio-Chemistry Analyzer-EM 200
Serial No: S2001038
Calibration Date: 15-11-2021
Next Calibration due on before : 16-11-2022
Calibrator Used: Multical Lot Number: 2204083
Quality Control Used: Lot Number:S062125B/S062131B

This is to certify that the above mentioned instrument has been verified of calibration according to the procedures provided by the manufacturer -

General Parameters:

Parameter	Measured Value	Acceptable Range	
Line Voltage	230V	230 V +/- 5%	Pass
Logic Voltage	5.0 V	4.9 V to 5.1 V	Pass
Lamp Voltage	12.0 V	11.8 V to 12.2 V	Pass
Flow cell Temperature	37.0 deg	37 +/- 0.5	Pass
45 Cuvette blank value for for all filter	Enclose value sheet for all cuvette	Abs 0.02-0.2	Pass



Photometer Filter Gain Levels:

s.no	Filter Value in nm	Filter Gain in mv
1	340	578
2	405	517
3	505	528
4	546	516
5	578	495
6	600	498
7	660	478
8	700	460

Technical Service Department
Transasia Bio-medical Limited

Swat.

