

TRANSASIA[®]

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CIN: U33110MH1985PLC036198



TRANSASIA BIO-MEDICAL LTD.

EM-200

SR. NO : B150406

IQ, OQ AND PQ

For

**NEYVELI DIAGNOSTICS CENTER,
NEYVELI - 605006**

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



Installation Qualification for EM200, Sr. No.: B150406

Customer Name : NEYVELI DIAGNOSTICS CENTER
Address : Dr. Ambedkar road, Block – 12, Neyveli – 605006
Instrument Name : EM-200
Serial Number : B150406

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.:- B150406

This is to certify that the instrument **EM-200 Sr. No.:- B150406** is successfully Installed and Commissioned at **NEYVELI DIAGNOSTICS CENTER, Neyveli**, and the Installation Protocol / checklist has been successfully completed for the Above instrument.

Date of Installation: 15/06/2015

Protocol Performed By:

Transasia Bio-Medical Ltd., Technical Services Department

Name : Mr. Shaik Ajmeer

Designation : Service Engineer

Signature : For
M. Shankar

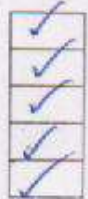




Installation Qualifications for EM-200, Sr. No.:- B150406

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. Shaik Ajmeer

Designation : Service Engineer

Signature :





Installation Qualification for EM-200, Sr. No.:- B150406

Customer Name : NEYVELI DIAGNOSTICS CENTER,
Address : Dr. Ambedkar road, Block - 12, Neyveli - 605006
Contact Person : Mrs. J. Umarani
Instrument Model : EM-200
Serial Number : B150406
Date of Installation : 15-06-2015

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
CENTER**

Name : Mr. Shaik Ajmeer

Designation : Service Engineer

Signature : *Ferd*

CUSTOMER : NEYVELI DIAGNOSTICS

Contact Person : Mrs. J. Umarani

Designation : Lab in charge

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. M. Sankar

Designation: Sr.Application Specialist

Customer Authorization: **NEYVELI DIAGNOSTICS CENTER**

Name: Mrs. J. Umarani

Designation: Lab in charge

Company Representative Name & Sign

Date: 23/06/2015

Customer Name & Sign

Date: 23/06/2015





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

✓
✓
✓
✓
✓
✓
✓
✓
✓
✓

Operational Inspection

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

Result/Checks

✓
✓
✓
✓

Protocol Performed By:

TBM, Technical Services Department

Name : Mr. Shaik Ajmeer

Designation : Service Engineer

Signature :





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

Operations Qualifications for EM-200, Sr. No.:- B150406

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

Protocol Performed By:

TBM, Technical Services Department

Name : Mr. Shaik Ajmeer

Designation : Service Engineer

Date : 23-06-2015

Signature : *For*





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

Operations Qualifications for EM-200, Sr. No.:- B150406

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

Protocol Performed By:

TBM, Technical Services Department

Name : Mr. Shaik Ajmeer

Designation : Service Engineer

Date : 23-06-2015

Signature : *For*

Al. Hankey





Performance Qualifications for EM-200, Sr. No.:- B150406

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. Shaik Ajmeer

Designation : Service Engineer

Signature : *M. Shaik Ajmeer*

Date : 23/06/2015

PERFORMANCE QUALIFICATION DONE BY

Name : Mr. M. Sankar

Designation: Sr.Application Specialist

Signature : *M. Sankar*

Date : 23/06/2015

