

ERBA - EM 200

FULLY AUTOMATED BIOCHEMISTRY ANALYZER

SerialNo. V200050



INSTALLATION QUALIFICATION

For

Customer Name: H CLOUD HEALTH CARE #161B 6TH MAIN
3RD CROSS ROAD 3RD PHASE JP NAGAR BANGALORE-560078

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1.0 PRE APPROVAL

1.1 Prepared By

Name	Designation	Signature	Date
ESHWAR	SERVICE ENGINEER		19/3/22

1.2 Checked By

Name	Designation	Signature	Date
ESHWAR	SERVICE ENGINEER		19/3/22

1.3 Approved By

Name	Designation	Signature	Date
MR. RAVINDRA BABU	RSM		19/3/22

Note: After the Pre-Approval, this document is effective for the execution.



2.0 OBJECTIVE

The objective of this document is to provide an outline for the inspection of EM 200 (Bio-Chemistry Random Analyzer) and to verify that the following boundaries:

- Each Installed subcomponent complies with the engineering design and instrument data sheet / design specifications & manufacturer's recommendations.
- To ensure that all the safety features are defined before the start up of operational qualification exercise.
- The system meets the current regulatory requirements.
- To identify the Standard operating procedures for Operational Qualification.

3.0 SCOPE

The scope of this protocol is to outline procedure for Installation qualification of the subjected instrument within the following boundaries:

- Identification and verification of its Major components / Accessories
- Identification, Classification and Verification of Process Control Instruments / Gauges / Devices
- Identification and verification of Material of Construction
- Identification and verification of Supporting Utilities
- Identification of Standard Operating Procedures
- Identification and Verification of Documents



4.0 EXECUTION TEAM

Name	Department	Designation	Signature



5.0 INSTRUMENT DESCRIPTION

The Clinical Chemistry Analyzer is an open, full automated, discrete, patient prioritized, random access, computerized analyzer.

Technical Specifications:

System Type	Open, Automated, Discrete, Random Access, Patient Prioritized, 1/2 Reagents
Analysis Speed	200 Biochemistry tests per hour 400 tests per hour (with ISE) for a cycle time of 18 seconds
Display resolution	1024 X 768
Analyzer Dimensions	810 (W) x 800 (D) x 600 (H) mm
Number of tests on board	Maximum: 50
Assay Modes	1-point, 2-point, Rate-A and Rate -B, ISE optional
Calibration	Linear (two point and multi point), Factorized and Non-linear multipoint
Sample (Tubes / Cups)	Primary tubes of 5, 7 or 10mL & sample cups
Photometric Optics	Mono and Bi-chromatic measurement using 8 wavelengths
Absorbance Range	0 - 2.5
Auxiliary Data	10,000 results
Interface	RS-232 C port for Bi-directional Communication
Stat Sampling	Total 30 positions



Purpose:

The purpose of this instrument is to analyze the bio-chemical parameters, such as Sugar, Cholesterol, Tri-glycerides, Proteins, etc.

The working unit of the analyzer comprises the following:

- Basic operating unit with an intelligent photometer
- Sophisticated robotics combined with an operating console and a central processing unit (CPU).

Operating Unit:

The operating unit of the analyzer includes the sample and reagent handling systems. The sample handling system consists of a sample tray, sample arm, sample syringe and a wash station for the sample probe.

Photometric System:

The photometric system consists of 45 hard glass cuvettes, multi wavelength diffracting photometer and a halogen lamp.

Operating Console:

The operating console consists of a touch screen (optional) color TFT monitor, a key board and a mouse.

CPU (Central Processing Unit):

CPU consists of Pentium – IV 1.7 GHz processor (or Higher) with a 48 x CD Drive, and minimum 256 MB memory. The application software can be installed on computers with operating systems of Windows XP.

Besides the above mentioned, this analyzer has got the unique Software and Hardware features.




5.0 IDENTIFICATION OF MAJOR COMPONENTS / ACCESSORIES

Details of each major component identified in this section, is recorded in a data sheet under the section 08.0.

Name of Component / Accessories	Present	Verified by Signature	Observations
	Yes / No		
Sample Tray / Disk	Yes		
Sample Syringe	Yes		
Sample Probe	Yes		
Wash Station for Sample Probe	Yes		
Reagent Tray / Disk	Yes		
Reagent Bottles	Yes		
Reagent Probe	Yes		
Stirrer	Yes		
Permanent Reaction Cuvette	Yes		
9 Stage Laundry System	Yes		
Light Source	Yes		
Sample Cups	Yes		
Software of EM 200	Yes		



7.0 INSTALLATION CHECK / REVIEW

S. No.	Statement	Yes / No	Verified by Signature
1.	Verify that the "as built" drawings are complete and represent the design concept	YES	
2.	Verify that major components / accessories are securely anchored and shock proof.		
3.	Verify that there is no observable physical damage.		
4.	Verify that there is sufficient room of servicing provided		
5.	Verify that all utilities and electrical connections have been done according to the drawings.		
6.	Walking access to ground mounted instrument provided.		
7.	Required electric connections are tight, weather proof and earthed.		
8.	Instrument identification nameplate visible.		
9.	Units installed on foundation and secure in place as per manufacturer's recommendations.		
10.	Verify that the instruments installed and leveled properly on the floor.		
11.	Verify that the Material of Construction is proper and meeting the requirements.		



INSPECTION CHECK / REVIEW

Instructions for completing the check / review

1. For each **data sheet**, record the required information with pen. Wherever required record "Yes" for acceptance, "No" for non-compliance and "NA" for not applicable.
"No" replies must be explained / justified.
2. When more than one component of same specification/type exists in the same equipment, individual data sheets should be filled for each component.
3. When a list of acceptable options is presented, tick (✓) the option that is actually present.
4. In the "**Method of Verification**" column indicate that item is installed and inspected according to manufacturer's specifications, such as by Visual / Physical, SOP, Test Certificate, Manual, etc.



Instrument/ Component Name: Sample Tray / Disk

Date :19-03-2022

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of patient cups / samples	30 positions	30	MANUAL	
Standards / Stat	30 positions	30+9	MANUAL	
Blank	Can be put on any position		YES	
ISE positions (Optional)	Can be programmed on any positions	NA	NA	
Controls	Can be programmed on any positions		YES	



Instrument/ Component Name: Sample Syringe

Date :19-03-2022

Description	Specified	Actual	Method of Verification	Verified by Signature
Dispensing Volume	2 – 70 μ L	2-70	AUTOMATED	
Installed Location	Behind the instrument on the right side			
Quantity	01 No.	01		
Increase in dispensing volume	0.2 μ L	0.2		

Instrument/ Component Name: Sample Probe

Date :19-03-2022



Description	Specified	Actual	Method of Verification	Verified by Signature
Aspiration Volume	2 - 70 μ L	2-70		
MOC	Teflon coated	Teflon coated		
Quantity	01 No.	01		
Increase in aspiration volume	0.2 μ L	0.2		

Instrument/ Component Name: Wash Station for Sample Probe

Date :19-03-2022

Description	Specified	Actual	Method of Verification	Verified by Signature
No. of position	01 No	1	MANUSAL	
Type of positions	i) Drain ii) Trough		MANUAL	



Instrument/ Component Name: Reagent Tray / Disk

Date :19-03-2022

Description	Specified	Actual	Method of Verification	Verified by Signature
Cool reagent disk	50 positions		MANUAL	
Outer Rings	25 positions		MANUAL	
Inner Rings	25 positions		MANUAL	
Adaptors of 5mL	50 positions		MANUAL	
Maintenance of Temperature	8-12°C ± 2°C		MANUAL	
Rotation of disk	Counter-Clockwise		MANUAL	
Time for Rotation of one Cuvette	Every 18 seconds		MANUAL	



Instrument/ Component Name: Reagent Bottles

Date :19-03-2022

Description	Specified	Actual	Method of Verification	Verified by Signature
Minimum Capacity	20 mL	20 mL	MANUAL	
Maximum Capacity	50 mL	50 mL	MANUAL	
Quantity (Large)	25 Nos'	25 Nos'	MANUAL	
Quantity (Smaller)	25 Nos'	25 Nos'	MANUAL	
Type	Screw Capped	Screw Capped	MANUAL	
Outer ring position	20 mL bottles & 5ml adaptors	20 mL bottles & 5ml adaptors	MANUAL	
Inner ring position	20 mL & 50 mL bottles & 5ml adaptors	20 mL & 50 mL bottles & 5ml adaptors	MANUAL	
MOC	Plastic	Plastic	MANUAL	
Adaptor	50 Nos'	50 Nos'	MANUAL	
Adaptor Capacity	5 mL	5 mL	MANUAL	
Identification of Reagents	Barcode labels on the reagent containers	Barcode labels on the reagent containers	MANUAL	



Instrument/ Component Name: Reagent Probe

Date :19-03-2022

Description	Specified	Actual	Method of Verification	Verified by Signature
Aspiration/Dispensing Volume	R1: 50 – 300 μ L	R1: 50 – 300 μ L	AUTOMATED	
	R2: 0 or 10 – 300 μ L	R2: 0 or 10 – 300 μ L	AUTOMATED	
MOC	Teflon coated	Teflon coated	MANUAL	
Quantity	02 Nos.	02 Nos.	MANUAL	
Increase in aspiration/dispensing volume	1 μ L	1 μ L	MANUAL	

Instrument/ Component Name: Reagent Syringe

Date :19-03-2022

Description	Specified	Actual	Method of Verification	Verified by Signature
Maximum capacity	500 μ L	500 μ L	MANUAL	
Installed Location	At the back of the instrument on the right side	At the back of the instrument on the right side	MANUAL	
Quantity	01 No.	01 No.	MANUAL	
Increase in dispensing volume	1 μ L	1 μ L	MANUAL	



Instrument/ Component Name: Stirrer

Date :19-03-2022

Description	Specified	Actual	Method of Verification	Verified by Signature
Type	Single Stirrer	01	MANUAL	
No. of paddles	01 No.	01	MANUAL	

Instrument/ Component Name: Permanent Reaction Cuvette

Tag/Identification No.:

Date :19-03-2022

Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	45 No's	45 No's	MANUAL	
MOC	Hard Glass	Hard Glass	MANUAL	
Capacity	770 µL	770 µL	MANUAL	



Instrument/ Component Name: 7 Stage Laundry System

Date :19-03-2022

Description	Specified	Actual	Method of Verification	Verified by Signature
Nozzles	Nozzle - 1		MANUAL	<i>[Signature]</i>
	Nozzle - 2		MANUAL	
	Nozzle - 3		MANUAL	
	Nozzle - 4		MANUAL	
	Nozzle - 5		MANUAL	
	Nozzle - 6		MANUAL	
	Nozzle - 7		MANUAL	

Instrument/ Component Name: Light Source

Date :19-03-2022

Description	Specified	Actual	Method of Verification	Verified by Signature
Watts	12 W		MANUAL	<i>[Signature]</i>
Volts	12 V		MANUAL	
MOC	Halogen		MANUAL	
Quantity	01 No		MANUAL	

Instrument/ Component Name: Sample Cups

Date :19-03-2022



Description	Specified	Actual	Method of Verification	Verified by Signature
Quantity	500 No's		MANUAL	
MOC	Plastic		MANUAL	
Capacity	2 mL		MANUAL	

Instrument/ Component Name: Software of EM 200

Date :19-03-2022

Description	Specified	Actual	Method of Verification	Verified by Signature
Version			MANUAL	
CD number			MANUAL	
Product	EM- 200	EM- 200	MANUAL	
Make	Erba Transasia	Erba Transasia	MANUAL	



IDENTIFICATION AND VERIFICATION OF MATERIAL OF CONSTRUCTION

Identify and list down all components of the equipment for its material of construction.

Method of Test may be Molybdenum Test, Test Certificate, Manual, etc.

Component (s)	Material of Construction	Actual	Method of Verification	Verified by Sign & Date
Sample Probe	Teflon coated	Teflon coated	MANUAL	
Reagent Probe	Teflon coated	Teflon coated	MANUAL	
Permanent Reaction Cuvette	Hard Glass	Hard Glass	MANUAL	
Light Source	Halogen	Halogen	MANUAL	
Reagent Bottle	Plastic	Plastic	MANUAL	
Sample Cups	Plastic	Plastic	MANUAL	

10.0 IDENTIFICATION AND VERIFICATION OF SUPPORTING UTILITIES

List the supporting utilities and record whether or not they are properly connected and identified.

Utilities	Observation / Result	Verified by Sign & Date
Power	MANUAL	
Distilled Water	MANUAL	
Wash Solution	MANUAL	
UPS	MANUAL	



12.0 IDENTIFICATION AND VERIFICATION OF DOCUMENTS

12.1 DRAWINGS

Title	Drawing No.	Verified by Sign & Date
As-built Drawing		<i>[Signature]</i> 12/12/18

11.0 IDENTIFICATION OF STANDARD OPERATING PROCEDURE

SOP No.	Title
Operation	Operation of Bio-Chemistry Random Analyzer
Calibration	Calibration of Parameters
Controls	Checking of Controls for Parameters
Maintenance	Maintenance / Checking of Distilled water, Waste, Wash solution, Cuvette rinse, Sample probe wash and Water save
Cleaning	Cleaning of Instrument surface



12.2 GENERAL DOCUMENTS

Title	Document No.	Verified by Sign & Date
General		
Purchase Order No.		
Warranty Certificate		
Invoice		
Test Certificates		
Material of Construction		
Electrical Motor		

15.0 ABBREVIATIONS

SOP	Standard Operating Procedure
MOC	Material of Construction
IQ	Installation Qualification



16.0 POST APPROVAL:

16.1 Checked by

Name	Designation	Signature	Date
MS.ANITHA			

16.2 Approved by

Name	Designation	Signature	Date
DR.VENUS KUMAR	Lab HEAD		

Note: This report is effective from the date of approval.



ERBA-EM 200 FULLY AUTOMATED BIOCHEMISTRY ANALYZER Serial No. V200050

OPERATIONAL QUALIFICATION

For

Customer Name: H CLOUD HEALTH CARE #161B 6TH MAIN 3RD CROSS ROAD 3RD PHASE JP
NAGAR BANGALORE-560078

As part of Operational qualification, the following checks shall be done and each test shall be recorded:

Instrument Start-up

To check and establish the standard sequence to be followed, during start-up of the subjected instrument in Auto / Manual mode, to propose for correct operation and to avoid any damage to the instrument and personnel.

Functional Checks

To check and ensure that different functions (such as switching devices, indication / monitoring / recording devices, feedback system, etc.) for correct operation of the subjected instrument are working as expected.

Interlocks and Alarms Check

To check and ensure that the interlocks and alarms (such as status indication system, negative feed back system, control loops, sound alarms, etc.) for correct control and monitoring of the operation cycle are working as expected.

Safety / Security Checks

To check and ensure that the safety / security functions (such as program logging, process control, personnel safety systems, password check, etc.) to protect the instrument and personnel are working as expected.

Instrument Shut-down

To check and establish the standard sequence to be followed, during shut-down of the subjected instrument in Auto / Manual mode, to propose for correct operation and to avoid any damage to the instrument and personnel.



1.0 INSTRUMENT START-UP:

Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by (Sign & Date)	Remarks
Ensure that all the required electrical connections are properly connected.	yes		
Ensure the proper filling of double distilled / de-ionized water and Cleaning solution in the respective cans.	yes		
Ensure the availability of XL Wash.	yes		
Ensure the availability of Biohazard Waste.	yes		
Ensure the availability of Normal Waste.	yes		
Switch ON the rear switch of the analyzer.	yes		
Switch ON the side switch of the analyzer.	yes		
Switch ON the computer and start the analyzer application software.	yes		
Initialization	yes		



2.0 FUNCTIONAL CHECKS:

2.1 Maintenance:

Refer the Operator's Manual for the procedures, for the following activities:

Activity	Observation	Verified by (Sign & Date)	Remarks
Photometer functioning	yes		
Cuvette Rinse	yes		

2.2 Loading of Reagents:

Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by (Sign & Date)	Remarks
Reagent Level Scan, Dead Volume Check & 2 Reagent Chemistry	yes		



2.3 Calibration:

Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by (Sign & Date)	Remarks
Blank (Distilled Water)	yes	<i>[Signature]</i> 01/12/22	
Standard (Multical)	yes		

3.0 INTERLOCKS AND ALARMS CHECK:

Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by (Sign & Date)	Remarks
Less volume of Distilled Water	yes	<i>[Signature]</i> 01/12/22	
Less volume of Wash Solution	yes		
More volume of Bio-Hazard waste	yes		
More volume of Normal / General waste	yes		



4.0 SAFETY / SECURITY CHECKS:

Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by (Sign & Date)	Remarks
Password Check for Test Parameters	NA	<i>[Signature]</i>	
Password Check for QC Mode	NA		

5.0 INSTRUMENT SHUT-DOWN:

Refer the Operator's Manual for the procedures, for the following activities:

Action	Observation	Verified by (Sign & Date)	Remarks
Sample Probe Wash	yes	<i>[Signature]</i>	
Water Save	yes		
Switch OFF the computer.	yes		
Switch OFF the side switch of the analyzer.	yes		
Switch OFF the rear switch of the analyzer.	yes		



Customer Name: H CLOUD HEALTH CARE CENTER
 #161B 6TH MAIN 3RD CROSS ROAD 3RD PHASE JP
 NAGAR BANGALORE-560078

Model: EM-200

Serial Number:

V200050

ANNEXURE-A

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1. APPROVAL:

Prepared By:

Name	Designation	Signature	Date
RUPESH N	APPLICATION MANAGER		12/2/22

Checked By:

Name	Designation	Signature	Date
MS.ANITHA	LAB TECHNICIAN		

Approved By:

Name	Designation	Signature	Date
DR.VENUS KUMAR	LAB HEAD		





Customer Name: H CLOUD HEALTH CARE CENTER
 #161B 6TH MAIN 3RD
 CROSS ROAD 3RD PHASE JP NAGAR
 BANGALORE-560078

Model: EM-200 Serial Number:

V200090

2. OBJECTIVE:

The objective of this protocol is to establish documented evidence for the Performance Qualification of Fully Automated Biochemistry Analyzer and to Ensure that the results obtained are within the pre-determined Acceptance Criteria.

3. PRE-REQUISITES:

Following Pre-requisites are required before the execution of Performance Qualification.

- Completion of Installation Qualification (IQ) prior to PQ.
- Completion of Operational Qualification (OQ) prior to PQ.

4. TEST PLAN:

Following any of 3 available test parameters precision shall be performed (N=10 for each parameter each level) on Mono-Level &/or Bi-Level controls and check the CV% during the Performance Qualification of Fully Automated Biochemistry Analyzer.

Sr.No	Test Parameter
1	ALBUMIN
2	CHOLESTEROL
3	GAMMA GT
4	GLUCOSE
5	SGPT
6	PROTEIN
7	UREA

5. ACCEPTANCE CRITERIA:

Acceptance criteria are based on the precision studies conducted as per *CLSI Guideline EP 05-A3*.

6. SUMMARY:

Test Name	ALBUMIN		SGPT		GLUCOSE	
	ERBA NORM	ERBA PATH	ERBA NORM	ERBA PATH	ERBA NORM	ERBA PATH
Level	3.54	5.14	39.7	80.2	91.9	273.4
Mean	0.02	0.03	0.94	1.27	0.87	1.14
SD	0.59	0.65	2.36	1.58	0.94	0.42
CV%						
Acceptable Criteria (Max.value)						
Status	PASS	PASS	PASS	PASS	PASS	PASS

Traceability: Instrument Raw Data from Test Statistics Menu.
 Note: This report is effective from the date of approval.



Transasia Bio-Medicals Ltd., No. 43, Chhatrapati Shivaji Maharaj Road, Andheri (E), Mumbai - 400 025
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TRANSASIA BIOMEDICALS LIMITED

PERFORMANCE QUALIFICATION

Customer Name: H CLOUD HEALTH CARE
CENTER #161B 6TH MAIN 3RD
CROSS ROAD 3RD PHASE JP NAGAR
BANGALORE-560078

Model: EM-200

Serial Number:



Annexure-B

Instrument Raw Data from Test Statistics Menu to be attached as printout attachments in Annexure-B.

