

INSTALLATION & TRAINING REPORT

Customer Name : TATA IMG
Department : PATHOLOGY
Address : Tata Steel Meramandali, DHENKANAL
City : DHENKANAL Pin : 759121 State : ODISHA
Territory : CUTTACK Zone : EZ-D
Telephone & Fax : 9871741808 email : _____
Contact Person : Nicky Anand Mobile No. : 9871741808
Instrument Model : EC-90 Sr. No. : 5628-2-202302
Installation Date : 11/08/23

The above mentioned instrument has been satisfactorily installed by Service Engineer / Product Specialist of Transasia Bio-Medicals Ltd. Operational Training & User Maintenance of the instrument was provided to the following staff members on date (s) : 11/08/23.....

Name (s)	Designation/ Dept.
1. <u>Nicky Anand</u>	<u>Lab tech.</u>
2. <u>Sipak Kumar</u>	<u>Lab tech.</u>
3. <u>Sharan Jit</u>	<u>Lab tech.</u>
4. <u>Chandan Kumar</u>	<u>Lab tech.</u>

Test/ Parameters Demonstrated : _____
Customer Comments (If any) : _____

Engineer / Product Specialist : EC90 Customer Signature : [Signature]

Signature : [Signature] Customer Name : MADHUK SINHA

Name : Avinash Kumar Jena / Uddhab Nayak Designation : Manager

Date : 11/08/23 Customer Seal : [Seal]

Arbitration Clause
All disputes, Differences, controversies and questions directly or indirectly arising at any time under, out of, in connection with or in relation to the payment of this instrument / reagents / service shall be referred to the sole arbitrator to be appointed by Transasia Bio-Medicals Limited under the Arbitration and Conciliation Act 1996. The venue and seat of arbitration shall be at Mumbai. The award rendered by the arbitrator(s) shall be final and binding upon both Parties.

www.transasia.co.in
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TRANSASIA BIOMEDICALS LIMITED**INSTALLATION QUALIFICATION****TRANSASIA**
Bio-Medicals Ltd.Customer Name: TATA IimgModel: EC 90Serial
Number:

5628-2-202302

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1. APPROVAL:**1.1 Prepared By:**

Name	Designation	Date
Mr. Abhinash Jena	Sr. Service Engineer	11/08/2023

1.2 Checked By:

Name	Designation	Signature	Date
Nicky Anand	S.S.O	Nicky Anand	11/08/23
Deepak Kumar	S.O	Deepak Kumar	11/08/23
Dharamjeet	A.O	Dharamjeet	11/08/23

1.3 Approved By:

Name	Designation	Signature	Date
Nicky Anand	S.S.O	Nicky Anand	11/08/23



TRANSASIA BIOMEDICALS LIMITED
INSTALLATION QUALIFICATION

TRANSASIA
Bio-Medicals Ltd.

Customer Name: TATA Iimg

Model: EC 90

Serial
Number:

5628-2-202302

2 OBJECTIVE:

The objective of this protocol is to establish documented evidence for the Installation Qualification of EC-90.

3 PRE-REQUISITES:

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

- **Analyzer Condition Report:**
Found the Analyzer along with accessories to have been delivered in satisfactory condition and no external physical damaged observed.
- **External Requirements for Installation:**
- Input voltage of 100-240VAC 50/60Hz 60W
- Recommended Operational Conditions 15-35 °C / 15-90% Humidity
- In order to ensure the safety of the analyzer and the operator, following conditions must be guaranteed.
- The power supply system (Protection Class B & Category II) must be compatible with the voltage and current specifications indicated on the serial number plate attached to the rear of the analyzer; and it is recommended to check the efficiency of the electrical system from time to time.
- The material for the operator's safety (gloves, containers for disposing of used expendable items, surface disinfectants) must always be available.

4 UNPACKING AND PLACEMENT :

- The unpacking & positioning of the analyzer must comply with the instructions indicated in user manual.

5 INSTALLATION :

- The installation of the analyzer must be in accordance to the instructions indicated in the EC 90_Quick Start Guide (Available in Accessory box along with the analyzer).
- After verification of the installation of the analyzer, flip toggle the power switch to ON (I).
- Once switched on, the analyzer guides the operator to perform 11 relevant steps needed to install the analyzer.
- On confirming the final step, the analyzer performs a Start Up Completion (Prime Up followed by 2P Calibration)
- The analyzer returns to Home Screen after successful Start Up completion process indicating readiness for sample measurement.

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

TRANSASIA BIOMEDICALS LIMITED
OPERATIONAL QUALIFICATION

TRANSASIA[®]
Bio-Medicals Ltd.

Customer Name: TATA Img

Model: EC 90

Serial Number: 5628-2-202302

ANNEXURE-A

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1. APPROVAL:

1.1 Prepared By:

Name	Designation	Date
Mr. Abhinash Jena	Sr. Service Engineer	11/08/2023

1.2 Checked By:

Name	Designation	Signature	Date
Nicky Anand	S.S.O	Nicky Anand	11/08/23
Deepak Kumar	S.O	<i>Deepak</i>	11/08/23
Dharamjeet	A.O	Dharamjeet.	11/08/23

1.3 Approved By:

Name	Designation	Signature	Date
Nicky Anand	S.S.O	Nicky Anand	11/08/23

Signature

TRANSASIA BIOMEDICALS LIMITED
OPERATIONAL QUALIFICATION

TRANSASIA[®]
Bio-Medicals Ltd.

Customer Name: TATA 1mg

Model: EC 90

Serial
Number:

5628-2-202302

2. OBJECTIVE:

The objective of this protocol is to establish documented evidence for the Operational Qualification of EC 90

3. PRE-REQUISITES:

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

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

4. TEST PLAN:

- Setting up the System settings by selecting date, time and language.
- Checked Tubes inserted, found OK.
- Checked EC Cartridge inserted with Biosensor found OK.

5. ACCEPTANCE CRITERIA:

Prime Up and 2P Calibration are resulted with NO ERROR.

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

TRANSASIA BIOMEDICALS LIMITED**PERFORMANCE QUALIFICATION****TRANSASIA**[®]
Bio-Medicals Ltd.

Customer Name: TATA Img

Model: **EC 90**Serial
Number:

5628-2-202302

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1. APPROVAL:**1.1 Prepared By:**

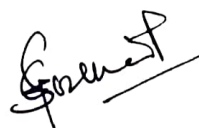
Name	Designation	Date
Mr. Siba Sankar Acharya	Application Specialist	11/08/2023

1.2 Checked By:

Name	Designation	Signature	Date
Nicky Anand	S.S.O	Nicky Anand	11/08/23
Deepak Kumar	S.O	Deepak	11/08/23
Dharamjeet	Accessioning Officer	Dharamjeet.	11/08/23

1.3 Approved By:

Name	Designation	Signature	Date
Nicky Anand	S.S.O	Nicky Anand	11/08/23



TRANSASIA BIOMEDICALS LIMITED**PERFORMANCE QUALIFICATION****TRANSASIA**
Bio-Medicals Ltd.

er Name: TATA lmg

Model: EC 90Serial
Number:

5628-2-202302

2. OBJECTIVE:

The objective of this protocol is to establish documented evidence for the Performance Qualification of EC 90 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:

Perform precision study for Erba Norm or Erba Path controls and check the recovery (for any one level QC) & CV% during the Performance Qualification of EC 90.

- Follow the EC 90 Quick Start Guide for Test procedure.

5. ACCEPTANCE CRITERIA:

Acceptance criteria are based on the precision studies conducted by manufacturer for EC 90.

6. SUMMARY:

PRECISION CHECK DATA			
	Sodium(Na+)	Pottasium(K+)	Chloride(Cl-)
Run-1	136.2	3.87	100.8
Run-2	136.2	3.88	100.8
Run-3	136.4	3.89	100.8
Run-4	136.7	3.90	101.3
Run-5	136.1	3.89	100.9
Run-6	136.4	3.91	101.0
Run-7	137.3	3.93	101.0
Run-8	136.9	3.94	101.3
Run-9	137.3	3.96	100.9
Run-10	137.0	3.92	101.2
Mean	136.7	3.91	101.0
SD	0.46	0.028	0.20
CV%	0.333	0.728	0.198
Acceptble Range(%)	1.00	1.00	1.00
Status	Pass	Pass	Pass

TRANSASIA BIOMEDICALS LIMITED**PERFORMANCE QUALIFICATION****TRANSASIA**
Bio-Medicals Ltd.

Owner Name: TATA Img

Model: EC 90Serial
Number:

5628-2-202302

Control Data			
Erba Nrom			
Control Level	Normal		
Lot No.:	S062243		
Exp. Date:	11/2024		
Parameter	Na	K	Cl
Contro Range	118.0-142.0	3.65-4.43	89.5-109.3
Control Result	128	3.99	98.1
Status	Pass	Pass	Pass

Traceability: Instrument Raw Data printouts.

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

Annexure-B

Instrument Raw Data to be attached as printout attachments in Annexure-B.