

CALIBRATION REPORT

Customer Name : Primus Pathology & Diagnostics LLP
Shop No 14, 15 & 16, Gr floor ,
Sheetal Darshan CHS Ltd, Mira Road, Thane – 401107

Instrument Model : Mindray BS 240 E

Serial Number : BC8-35000404

Calibration Date : 10/08/2023

Calibration Due Date: 09/08/2024

As per Standard Operating Procedure of Mindray BS 240E Automated Chemistry Analyzer mentioned the instrument has been calibrated

As per method mentioned into manuals / SOP, the known value sample / control run on the Analyzer as per protocol. All obtained values are in the range and CV values were checked. CV values were within a normal range as mentioned in performing accurately and precisely

Hence, we certified that Mindray BS 240E Automated Chemistry Analyzer is calibrated

M. P. Dorrade

Service Engineer

Customer: Primus Pathology & Diagnostics LLP		Page 1 of 8
Equipment: BS 240 E Fully Auto Biochemistry Analyzer		
Title: IQ,OQ & PQ DOCUMENT	Doc. No. : MBQ/NKZ/031072023/BS240E	

Installation Qualification for Mindray BS-240 E Sr. No.:- BC8-35000404

Hospital/ Laboratory Name : Primus Pathology & Diagnostics LLP

Address : Shop No 14, 15 & 16, Gr floor ,

Sheetal Darshan CHS Ltd , Mira Road , Thane – 401107

Contact Person : Dr. Niraj Gujar

Instrument Model : BS-240 E

Serial No. : BC8-35000404

Date Of installation : 10-08-2023

The instrument was installed and was found to be working satisfactory. Preliminary Operator 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.

Authorized Person Hospital/ Laboratory:

Name : Mahesh Darade

Contact Person : Dr. Niraj Gujar

Designation : Service Engineer

Designation : Pathologist

Signature :

M. P. Darade

Signature :

Customer: Primus Pathology & Diagnostics LLP	Page 2 of 8
Equipment: BS 240 E Fully Auto Biochemistry Analyzer	
Title: IQ,OQ & PQ DOCUMENT	Doc. No. : MBQ/NKZ/031072023/BS240E

Installation Certificate For BS-240 E Sr. No.- BC8-35000404

This is to certify that the instrument **BS-240 E** Sr. No.- **BC8-35000404** is successfully installed and commissioned at : Primus Pathology & Diagnostics LLP , Shop No 14, 15 & 16, Gr floor ,Sheetal Darshan CHS Ltd , Mira Road , Thane – 401107 and the Installation Protocol/ checklist has been Successfully completed for the above Instrument.

Date of Installation: 10-08-2023

Authorized Person



Name : Mahesh Darade

Designation : Service Engineer

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Equipment: BS 240 E Fully Auto Biochemistry Analyzer	
Title: IQ,OQ & PQ DOCUMENT	Doc. No. : MBQ/NKZ/031072023/BS240E

Installation Qualification for Mindray BS-240 E Sr. No. - BC8-35000404

Hospital/ Laboratory Name : Primus Pathology & Diagnostics LLP

Address : Shop No 14, 15 & 16, Gr floor ,
Sheetal Darshan CHS Ltd , Mira Road , Thane – 401107

Contact Person : Dr. Niraj Gujar

Instrument Model : BS-240 E

Serial No. : BC8-35000404

Date Of installation : 10-08-2023

Customer: Primus Pathology & Diagnostics LLP		Page 4 of 8
Equipment: BS 240 E Fully Auto Biochemistry Analyzer		
Title: IQ,OQ & PQ DOCUMENT	Doc. No. : MBQ/NKZ/031072023/BS240E	

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 accessories as required.

External Requirement for Installation:

1. Input voltage of 220V-240V/50Hz or 60 Hz.
 2. Recommended operating Temperature is 15-30 degree Celsius, with in Relative Humidity 30-85% and Atmospheric pressure 70-106kPa.
- Carried out all the installation procedures as per the installation procedure and checklists.
 - Carried out all the necessary checks and alignments.
 - Carried out all the necessary system checks and tests.
 - Handover the Instrument for Operator Training And Qualifications

For Authorized Person

M.P. Darade

Name : Mahesh Darade

Designation : Service Engineer

Customer: Primus Pathology & Diagnostics LLP		Page 5 of 8
Equipment: BS 240 E Fully Auto Biochemistry Analyzer		
Title: IQ,OQ & PQ DOCUMENT	Doc. No. : MBQ/NKZ/031072023/BS240E	

Performance Qualification for BS-240 E Sr. No.: BC8-35000404

Calibration Parameters

- Checked and found all the control parameters to be within the acceptable CV limits and in range.
- Checked and found all controls to be within The acceptable SD.

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 Study has been performed by AG Diagnostic Protocol for ALB,ALP,ALT,AST,CA parameters and the results found within the acceptable limit which is mentioned in there protocol. The Same data attached in Performance Qualification.

The system is ready for Specific Usage

Protocol Performed By

Name : Mahesh Darade

M.P. Darade

Designation : Application Specialist/ Service Engineer

PERFORMANCE QUALIFICATION DONE BY

Name : Mahesh Darade

M.P. Darade

Designation : Application Specialist/ Service Engineer

Customer: Primus Pathology & Diagnostics LLP		Page 6 of 8
Equipment: BS 240 E Fully Auto Biochemistry Analyzer		
Title: IQ,OQ & PQ DOCUMENT	Doc. No. : MBQ/NKZ/031072023/BS240E	

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 : Authorized Person

Name : Mahesh Darade

Designation : Service Engineer/ Application Specialist

M.P. Darade

Hospital/ Laboratory Authorization

Name : Dr. Niraj Gujar

Designation : Pathologist

**Company Representative Name And Sign
And Sign**

Hospital/ Laboratory Name

M.P. Darade

Date: 10-08-2023

Date: 10-08-2023

Customer: Primus Pathology & Diagnostics LLP	Page 7 of 8
Equipment: BS 240 E Fully Auto Biochemistry Analyzer	
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Operations Qualifications for BS-240 E Sr. No.- BC8-35000404

1. Verified all the Mechanical Movements : Done
2. Verifeied Hydraulics : Done
3. Verified Electrical Systems : Done
4. Verified the all reagents Systems : Done

Authorized Person

Name : Mahesh Darade

M. P. Darade

Designation : Service Engineer/ Application Person

Date : 10-08-2023

Instrument Setup

1. Assembled the instrument accessories.
2. Removed the shipping Clamps.
3. Installed the Reagent/ Sample probes .
4. Installed the Reagent/Sample mixers.
5. Prepared and connected the Detergent Solution
6. Connected the Waste Tubing
7. Connected the Communication Cable.
8. Connected the Power cord and connection cord.
9. Connected the PC And CPU
10. Install the software.
11. Initialize the machine and follow the installation procedure.

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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.

Authorized Person

M.P. Darade

Name : Mahesh Darade

Designation : Service Engineer