

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 BC 700

Serial Number : BC 700[B]

Calibration Date : 11/10/2023

Calibration Due Date:10/10/2024

As per Standard Operating Procedure of Mindray BC 700 Heamatology 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 BC 700 Analyzer is calibrated



Service Engineer

Customer: Primus Pathology & Diagnostics LLP

Page 1 of 9

Equipment: BC700[B] Auto Hematology Analyzer

Title: IQ, OQ & PQ DOCUMENT

Doc. No: 231124/MEDV/IQOQPQ/BC700/V1

Installation Qualification for Mindray BC-700[B] Sr. No: DE5-28000211

Customer Name : Primus Pathology & Diagnostics LLP

Contact Person : Dr. Niraj Gujar


Instrument Model : BC 700 [B]

Serial No. : DE5-28000211

Date Of installation : 11/10/2023

The instrument was installed And was found to be working satisfactory. 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.

Customer: Primus Pathology & Diagnostics LLP

Service Engineer		Customer	
Name:	Mahesh Darade	Name:	Dr. Niraj Gujar
Signature:		Signature:	

Customer: Primus Pathology & Diagnostics LLP

Page 2 of 9

Equipment: BC700[B] Auto Hematology Analyzer

Title: IQ, OQ & PQ DOCUMENT

Doc. No: 231124/MEDV/IQOQPQ/BC700/V1

Installation Certificate For BC-700[B] Sr. No.- DE5-28000211

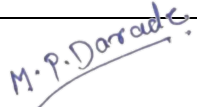
This is to certify that the instrument BC-700[B] Sr. No:- DE5-28000211 is successfully installed and commissioned at :

Primus Pathology & Diagnostics LLP, B-001, Gr. Floor, Sheetal Ddarshan CHS Ltd, MTNL Rd, opp. Shahi Restaurant & Juganu Watch, Sheetal Nagar, Mira Road East, Maharashtra 401107

and the Installation Protocol/ checklist has been Successfully completed for the above Instrument.

Date of Installation : 11/10/2023

AC , Technical Services Department

Service Engineer		Customer	
Name:	Mahesh Darade	Name:	Dr. Niraj Gujar
Signature:		Signature:	

Customer: Primus Pathology & Diagnostics LLP

Page 3 of 9

Equipment: BC700[B] Auto Hematology Analyzer

Title: IQ,QQ & PQ DOCUMENT

Doc. No: 231124/MEDV/IQOQPQ/BC700/V1

Installation Qualification for Mindray BC-700[B] Sr. No.:- DE5-28000211

Customer Name : Primus Pathology & Diagnostics LLP
Contact Person : Dr. Niraj Gujar
Instrument Model : BC-700[B]
Serial No. : DE5-28000211
Date Of installation : 11/10/2023

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 And Checklist Attached for the records.

Customer: Primus Pathology & Diagnostics LLP

Page 4 of 9

Equipment: BC700[B] Auto Hematology Analyzer

Title: IQ, OQ & PQ DOCUMENT

Doc. No: 231124/MEDV/IQOQPQ/BC700/V1

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.

Installation Qualification for BC-700[B] Sr. No.:- DE5-28000211


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 operators Training And Qualifications

Technical Services Department

Service Engineer		Customer	
Name:	Mahesh Darade	Name:	Dr. Niraj Gujar
Signature:		Signature:	

Customer: Primus Pathology & Diagnostics LLP

Page 5 of 9

Equipment: BC700[B] Auto Hematology Analyzer

Title: IQ, OQ & PQ DOCUMENT

Doc. No: 231124/MEDV/IQOQPQ/BC700/V1

Performance Qualification for Mindray BC-700[B] Sr. No.: -DE5-28000211

Calibration Parameters

Checked and found all the control [parameters to be with in 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 system is ready for Specific Usage.

Customer: Primus Pathology & Diagnostics LLP

Page 6 of 9

Equipment: BC700[B] Auto Hematology Analyzer

Title: IQ,QQ & PQ DOCUMENT

Doc. No: 231124/MEDV/IQOQPQ/BC700/V1

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.

Customer Authorization: **Primus Pathology & Diagnostics LLP**

**B-001, Gr. Floor, Sheetal Ddarshan CHS Ltd, MTNL Rd, opp. Shahi
Restaurant & Juganu Watch, Sheetal Nagar, Mira Road East,
Maharashtra 401107.**

Service Engineer		Customer	
Name:	Mahesh Darade	Name:	Dr. Niraj Gujar
Signature:		Signature:	

Customer: Primus Pathology & Diagnostics LLP

Page 7 of 9

Equipment: BC700[B] Auto Hematology Analyzer

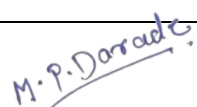
Title: IQ, OQ & PQ DOCUMENT

Doc. No: 231124/MEDV/IQOQPQ/BC700/V1

Operations Qualifications for BC-700[B] Sr. No.- DE5-28000211

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

Technical Services Department

Service Engineer		Customer	
Name:	Mahesh Darade	Name:	Dr. Niraj Gujar
Signature:		Signature:	

Customer: Primus Pathology & Diagnostics LLP

Page 8 of 9

Equipment: BC700[B] Auto Hematology Analyzer

Title: IQ, OQ & PQ DOCUMENT


Doc. No: 231124/MEDV/IQOQPQ/BC700/V1

Instrument Setup

1. Assembled the instrument accessories.
2. Removed the shipping Clamps.
3. Connected the LD LYSE REAGENT .
4. Connected the LH LYSE REAGENT
5. Connected the FD DYE REAGENT
6. Connected the DILUENT REAGENT.
7. Connected the Waste Tubing
8. Connected the Power cord and connection cord.
9. Initialize the machine and follow the installation procedure.

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.

Service Engineer		Customer	
Name:	Mahesh Darade	Name:	Dr. Niraj Gujar
Signature:		Signature:	