

**CALIBRATION CERTIFICATE**

|                      |  |                               |            |
|----------------------|--|-------------------------------|------------|
| <b>Customer Name</b> | <b>KRM Healthcare</b>  |                               |            |
| <b>Department</b>    | <b>Department of Haematology Laboratory</b>  |                               |            |
| <b>Address</b>       | Laxmi Plaza, 436/437, Laxmi Industrial Estate, Suresh Nagar,<br>Andheri West, Mumbai, Maharashtra 400053 |                               |            |
|                      |  | <b>Date of Calibration</b>    | 26.12.2023 |
| <b>Instrument</b>    | <i>MINDRAY<br/>BC 760<br/>ANALYZER</i>   | <b>Next Calibration Date</b>  | 24.06.2024 |
| <b>Serial No</b>     | <b>DE5-27000160</b>  | <b>Calibrator Lot Number</b>  | PLUS-0324  |
|                      |  | <b>Calibrator Expiry date</b> | 05/04/2024 |

|                                  | <u>Parameter</u>              | <u>Target</u> | <u>Range</u> | <u>Mean of Measured Values</u> | <u>New Factor</u> | <u>Old Factor</u> |
|----------------------------------|-------------------------------|---------------|--------------|--------------------------------|-------------------|-------------------|
| <b><u>Calibration Values</u></b> | <b>WBC x 10<sup>9</sup>/L</b> | 9.29          | 9.09-9.42    | 9.26                           | 101.23            | 100.0             |
|                                  | <b>RBC x10<sup>12</sup>/L</b> | 4.59          | 4.51-4.67    | 4.59                           | 100.00            | 100.0             |
|                                  | <b>HGB g/L</b>                | 13.4          | 13.2-13.6    | 13.34                          | 100.45            | 100.0             |
|                                  | <b>MCV fl</b>                 | 94.2          | 92.2- 96.2   | 93.29                          | 101.02            | 100.0             |
|                                  | <b>PLT x 10<sup>9</sup>/L</b> | 247           | 235-259      | 246                            | 100.40            | 100.0             |

This is to certify that the Mindray BC 700[B] Hematology Analyzer Sr. No: **DE5-27000160** system, installed at **KRM Healthcare, Laxmi Plaza, 436/437, Laxmi Industrial Estate, Suresh Nagar, Andheri West, Mumbai, Maharashtra 400053** has been calibrated using the standard reference material SC CAL PLUS-0324 Calibrator. Traceability of SC CAL PLUS Calibrator material from the manufacturer is attached along with this certificate.

*M. P. Darade*

Mahesh Darade

Date: 26-12-2023

Service & Application  
Specialist

Medvision Biomedicals Pvt. Ltd.

## Whole Blood Calibration

| Calibrator Calibration      |                     |            |                         |                   |            |
|-----------------------------|---------------------|------------|-------------------------|-------------------|------------|
|                             |                     |            |                         |                   |            |
| <b>Lot No.:</b>             | <b>PLUS-0324</b>    |            | <b>Exp. Date:</b>       | <b>05/04/2024</b> |            |
|                             |                     |            |                         |                   |            |
| <b>Analyzer SN:</b>         | <b>DE5-27000160</b> |            | <b>Calibration Date</b> | <b>26/12/2023</b> |            |
|                             |                     |            |                         |                   |            |
| <b>Parameter</b>            | <b>WBC</b>          | <b>RBC</b> | <b>HGB</b>              | <b>MCV</b>        | <b>PLT</b> |
| Target                      | 9.29                | 4.59       | 13.4                    | 94.2              | 247        |
| 1                           | 9.26                | 4.57       | 13.2                    | 94.4              | 256        |
| 2                           | 9.3                 | 4.58       | 13.2                    | 93.5              | 242        |
| 3                           | 9.24                | 4.58       | 13.5                    | 92.3              | 240        |
| 4                           | 9.33                | 4.61       | 13.5                    | 95.6              | 257        |
| 5                           | 9.34                | 4.60       | 13.4                    | 95.5              | 241        |
| 6                           | 9.12                | 4.59       | 13.6                    | 89.6              | 239        |
| 7                           | 9.1                 | 4.64       | 13.2                    | 92.7              | 244        |
| 8                           | 9.4                 | 4.61       | 13.3                    | 93.8              | 236        |
| 9                           | 9.25                | 4.54       | 13.2                    | 92.8              | 252        |
| 10                          | 9.28                | 4.63       | 13.3                    | 92.7              | 255        |
| Mean                        | 9.26                | 4.59       | 13.34                   | 93.29             | 246        |
| CV%                         | 0.01                | 0.02       | 0.00                    | 0.00              | 0.00       |
| Old Calibration Factors (%) | 100.0               | 100.0      | 100.0                   | 100.0             | 100.0      |
| New Calibration Factors (%) | 101.23              | 100.0      | 100.45                  | 101.02            | 100.40     |

## ESR Calibration

|                               |          |  |                           |            |
|-------------------------------|----------|--|---------------------------|------------|
| Lot No.                       | PLUS0324 |  | Exp. Date                 | 5/04/2024  |
| Operator                      | Service  |  | Calibration complete time | 26/12/2023 |
| Low level calibration data    |          |  |                           |            |
|                               | ESR      |  |                           |            |
| Target                        | 13.23    |  |                           |            |
| Low level 1#                  | 16.58    |  |                           |            |
| Low level 2#                  | 16.57    |  |                           |            |
| Low level 3#                  | 16.58    |  |                           |            |
| Mean                          | 16.58    |  |                           |            |
| CV%                           | 0.029    |  |                           |            |
| Normal level calibration data |          |  |                           |            |
|                               | ESR      |  |                           |            |
| Target                        | 31.37    |  |                           |            |
| Normal level 1#               | 40.02    |  |                           |            |
| Normal level 2#               | 39.97    |  |                           |            |
| Normal level 3#               | 39.84    |  |                           |            |
| Mean                          | 39.94    |  |                           |            |
| CV%                           | 0.228    |  |                           |            |
| High level calibration data   |          |  |                           |            |
|                               | ESR      |  |                           |            |
| Target                        | 47.33    |  |                           |            |
| High level 1#                 | 84.5     |  |                           |            |
| High level 2#                 | 85.27    |  |                           |            |
| High level 3#                 | 84.51    |  |                           |            |
| Mean                          | 84.76    |  |                           |            |
| CV%                           | 0.519    |  |                           |            |
| Old calibration slope k       | 0.737    |  |                           |            |
| New calibration slope k       | 0.482    |  |                           |            |
| Old calibration intercept b   | 2.229    |  |                           |            |
| New calibration intercept b   | 7.94     |  |                           |            |

Customer: KRM Healthcare

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Equipment: BC-700[B] Auto Hematology Analyzer

Title: IQ,QQ & PQ DOCUMENT

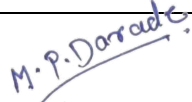
Doc. No: 240217/MEDV/IQQQPQ/BC700/V1

## Installation Qualification for Mindray BC-700[B] Sr. No: DE5-27000160

Customer Name : KRM Healthcare  
Contact Person : Kumudini Rawool  
Instrument Model : BC-700[B]  
Serial No. : DE5-27000160  
Date Of installation : 05/04/2023

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: KRM Healthcare**

| Service Engineer |   | Customer   |                 |
|------------------|---|------------|-----------------|
| Name:            | Mahesh Darade   | Name:      | Kumudini Rawool |
| Signature:       |  | Signature: |                 |

Customer: KRM Healthcare

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Equipment: BC-700[B] Auto Hematology Analyzer

Title: IQ, OQ & PQ DOCUMENT

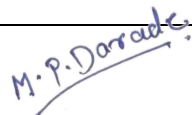
Doc. No: 240217/MEDV/IQOQPQ/BC700/V1

## Installation Certificate For BC-700[B] Sr. No.:- DE5-27000160

This is to certify that the instrument BC-700[B] Sr. No.:- DE5-27000160 is successfully installed and commissioned at : KRM Healthcare, Laxmi Plaza, 436/437, Laxmi Industrial Estate, Suresh Nagar, Andheri West, Mumbai, Maharashtra 400053 and the Installation Protocol/ checklist has been Successfully completed for the above Instrument.

Date of Installation : 05/04/2023

MBQ , Technical Services Department

| Service Engineer |   | Customer   |                 |
|------------------|---|------------|-----------------|
| Name:            | Mahesh Darade   | Name:      | Kumudini Rawool |
| Signature:       |  | Signature: |                 |

**Customer: KRM Healthcare**

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**Equipment: BC-700[B] Auto Hematology Analyzer**

**Title: IQ, OQ & PQ DOCUMENT**

**Doc. No: 240217/MEDV/IQOQPQ/BC700/V1**

## **Installation Qualification for Mindray BC-700[B] Sr.No.:DE5-27000160**

Customer Name : **KRM Healthcare**  
Contact Person : **Kumudini Rawool**  
Instrument Model : **BC-700[B]**  
Serial No. : **DE5-27000160**  
Date Of installation : **05/04/2023**

**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: KRM Healthcare

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Equipment: BC-700[B] Auto Hematology Analyzer

Title: IQ, OQ & PQ DOCUMENT

Doc. No: 240217/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.:- DE5-27000160

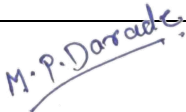
Carried out all the installation procedures as per the installation procedure and checklists.

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:      | Kumudini Rawool |
| Signature:       |  | Signature: |                 |

**Customer:** KRM Healthcare

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**Equipment:** BC-700[B] Auto Hematology Analyzer

**Title:** IQ,QQ & PQ DOCUMENT

**Doc. No:** 240217/MEDV/IQQQPQ/BC700/V1

## **Performance Qualification**

**for**

**Mindray BC-700[B] Sr. No.: -DE5 -27000160**

### **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 system is ready for Specific Usage.**



Customer: KRM Healthcare

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Equipment: BC-700[B] Auto Hematology Analyzer

Title: IQ, OQ & PQ DOCUMENT

Doc. No: 240217/MEDV/IQOQPQ/BC700/V1

## Operational Qualification:

### System Certification:

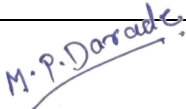
Study data has determined that the system described in this document either meets all criteria outlined in this Operational Protocol, or exceptional conditions have been identified and documentation included.

Exceptional Conditions, If any Have been Addressed.

**The System is ready for specific usage.**

Customer Authorization: **KRM Healthcare**

**KRM Healthcare, Laxmi Plaza, 436/437, Laxmi Industrial Estate,  
Suresh Nagar, Andheri West, Mumbai, Maharashtra 400053**

| Service Engineer |   | Customer   |                 |
|------------------|---|------------|-----------------|
| Name:            | Mahesh Darade   | Name:      | Kumudini Rawool |
| Signature:       |  | Signature: |                 |

Customer: KRM Healthcare

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Equipment: BC-700[B] Auto Hematology Analyzer

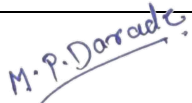
Title: IQ, OQ & PQ DOCUMENT

Doc. No: 240217/MEDV/IQOQPQ/BC700/V1

## Operations Qualifications for BC-700[B] Sr. No.: -DE5-27000160

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

### Technical Services Department

| Service Engineer |   | Customer   |                 |
|------------------|---|------------|-----------------|
| Name:            | Mahesh Darade   | Name:      | Kumudini Rawool |
| Signature:       |  | Signature: |                 |

Customer: KRM Healthcare

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Equipment: BC-700[B] Auto Hematology Analyzer

Title: IQ, OQ & PQ DOCUMENT

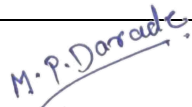
Doc. No: 240217/MEDV/IQOQPQ/BC700/V1

## 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. Initialized 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:      | Kumudini Rawool |
| Signature:       |  | Signature: |                 |