




**SINBIOMEDIX INC**

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MINDRAY BC 5000 – HEMATOLOGY ANALYZER

INSTALLATION QUALIFICATION  
OPERATIONAL QUALIFICATION  
PERFORMANCE QUALIFICATION  
(IQ/OQ/PQ)


For SINBIOMEDIX INC.

  
Auth. Signatory

***BY Sinbiomedix Inc.***

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## INSTALLATION QUALIFICATION

### IQ Protocol

1. System Unpacking
2. System Checking for any Damages
3. All accessories as per checklist verification
4. Space requirement
5. Power requirement
6. Reagent's control, calibrators verification

### 1. SYSTEM UNPACKING & 2. SYSTEM CHECKING

Mindray BC 5000 Haematology Analyzer instrument carefully and check for any physical damage.

### 3. ACCESSORIES CHECK

Check all accessories as per check list

### 4. SPACE REQUIREMENT

- Checked site for proper space allocation. At least 100 cm on each side and enough room below the countertop to accommodate the reagent & pneumatic unit and waste containers.

DIMENSIONS	
PARAMETER	ANALYZER OV
Width mm	514
Depth mm	594
Height mm	645
Weight mm	24.5

### 5. POWER REQUIREMENT

Requirement	Acceptable Range	Observed Ranged
Input voltage	220 +/- 10V	225 v
Line Frequency	50 HZ	50 HZ
Ambient Temperature	15C- 30 C	23

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**6. Regents, Control, Calibrator's Check**

NAME	CHECK	Remark
Diluent	Ok	Ok
Lyse	Ok	Ok
EZ Cleanser	Ok	Ok
Probe Cleanser	Ok	Ok

**PRE-INSTALLATION VERIFICATION REPORT**

PRE-INSTALLATION VERIFICATION REPORT		
S.NO	PARAMETER	REMARK
1	Unpacking Instrument	Ok
2	System Checking for Damages	Ok
3	Accessories Check	Ok
4	Space Check	Ok
5	Power check	Ok
6	Reagents Check	Ok

**OPERATIONAL QUALIFICATION**

The operation Qualification procedure specifies the methodology for installation for installation of specified system after successful installation qualification. Successful completion of procedure identifies that system is ready for operation and subsequent performance analysis.

**OQ Protocol**

- a. System Connections
- b. Strip and control Preparation
- c. Customizing the analyzer software
- d. System Booting, Initializing & Check
- e. Maintenance Procedures
- f. Customer Training- Operation & Maintenance

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**1. SYSTEM CONNECTION**

SYSTEM CONNECTION			
S/N	NAME	CHECK	REAMRK
1	Main Unit	Operating Manual	Ok
2	Input Power supply	Connect	Ok

**2. Reagent & Waste Connection**

REAGENT CONNECTION CHECK		
NAME	CHECK	REMARK
Diluent	Operating Manual	ok
Lyse	Operating Manual	ok
Waste	Operating Manual	ok

**3. CUSTOMIZING ANALYZER SOFTWARE**

CUSTOMIZING ANALYZER SOFTWARE			
S/N	Parameters	Check	Rearmrk
1	Date & Time	Operating Manual 2	ok
2	Alarm	Operating Manual 2	ok
3	Reference Ranges	Operating Manual 2	ok
4	Control	Operating Manual 2	ok
5	Printing Format	Operating Manual 2	ok

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#### 4. SYSTEM BOOTING, INITIALIZATION CHECK

Power on System and check instrument Initialization Successfully  
Check following Parameters.

SYSTEM SETUP				
S/N	Parameter	Actual	Range	Remark
1	Calibration Setup	As per system	As per sheet	Ok
2	Control Setup	Actual	As per sheet	Ok
3	Calibration	1	Auto	Ok
4	Hardware Setup	As per user	As per User	Ok

#### MAINTENANCE PROCEDURES

MAINTENANCE			
S/N	Parameter	Check	Reamrk
1	Flush	Operator Manual 3	Ok
2	Enhanced flush	Operator Manual 3	Ok
3	Cleaning	Operator Manual 3	Ok
4	Price chamber	Operator Manual 3	Ok
5	Drain chamber	Operator Manual 3	Ok
6	Touch screen calibration	Operator Manual 3	Ok

ADJUSTMENT			
S/N	Parameter	Check	Reamrk
1	Control adjustment	Operator Manual 4	Ok
2	Alarm adjustment	Operator Manual 3.3	Ok
3	Limits	Operator Manual 3	Ok

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## PERFORMANCE QUALIFICATION

LOW CONTROL					
S/N	PARAMETER	Actual	Target	Range	Remark
1	WBC	3.49	3.53	± 1.00	PASS
2	RBC	2.48	2.56	± 0.18	PASS
3	HGB	5.43	5.6	± 4.00	PASS
4	MCV	71.8	72.7	± 5.00	PASS
5	PLT	48	50	± 20.00	PASS
NORMAL CONTROL					
S/N	PARAMETER	Actual	Target	Range	Remark
1	WBC	7.81	7.79	± 1.50	PASS
2	RBC	5.21	5.11	± 0.24	PASS
3	HGB	13.6	13.4	± 6.00	PASS
4	MCV	88.01	87.31	± 5.00	PASS
5	PLT	284	283	± 40.00	PASS
HIGH CONTROL					
S/N	PARAMETER	Actual	Target	Range	Remark
1	WBC	19.1	18.08	± 2.50	PASS
2	RBC	5.71	5.63	± 0.30	PASS
3	HGB	17.1	16.9	± 8.00	PASS
4	MCV	97.01	96.27	± 5.00	PASS
5	PLT	538	532	± 60.00	PASS

IN THIS PQ SECTION I NEED TO ADD CONTROL DATA WITH CONTROL DETAILS AND CALIBRATION FACTORS.