



# Mindray BS-240

## Automated Clinical Chemistry Analyzer



## **Qualification Manual:**

**Installation Qualification / Operation Qualification / Performance Qualification**

*IQ/OQ/PQ -BS -240*

## **INSTALLATION QUALIFICATION**

### **INSTRUCTIONS:**

1. This document is to be completed at time the system is unpacked and setup for operation.
2. An authorized Avantor representative will checkout each module and verify the alignment.
3. All deviations from normal specification to include any problems with installation will be noted in the comments section.
4. This document contains proprietary information and is in no way to be copied, photographed or duplicated in any way without expressed written authorization by Mindray.

### **INSTALLATION QUALIFICATION PROTOCOL:**

This Installation Qualification protocol will be performed on the Instrument installed at,  
**PRO BIOTIC DIAGNOSTICS PVT.LTD.**

Add- 3<sup>rd</sup> Floor, C-4/206, Sector 6 Rd, Pocket-4, Sector 6, New Delhi -110085

This protocol will define the documentation that will be used to evaluate the instrument documented in accordance with manufacturer's specifications and identified use.

Installation checks will be performed to verify that the instrumentation has been installed with proper connections and utilities.

Any exceptional conditions encountered during the qualification studies will be identified for review. Exceptional conditions will be investigated & appropriate course of action will be determined.

**INSTALLATION QUALIFICATION**

**SYSTEM CERTIFICATION:**

Study data has determined that the system described in this document meets all criteria outlined in this Installation. Qualification protocol, or exceptional conditions have been identified and documentation included. Exceptional conditions, if any have been addressed. The system is ready for specified usage.

Protocol performed by: **AVIENCE BIOMEDICAL Representative**

**Mr. RAHUL PAL**  
**Customer Service Engineer**  
**IVD-Automation**

**AVIENCE BIOMEDICAL PVT.TLD. DELHI-110058**

Signature: .....

Customer Authorization:

**MS-JIYA MAKKAR**  
**LAB INCHARGE**  
**PRO BIOTIC DIAGNOSTICS PVT.LTD.**

ADD- Add- 3<sup>rd</sup> Floor, C-4/206, Sector 6 Rd,Pocket-4, Sector 6, New Delhi -110085

Signature: .....

**CERTIFICATION OF INSTALLATION – REPORT**

INSTRUMENT NAME: **BS 240**

SERIAL NUMBER: **YX 35007115**

CUSTOMER NAME & ADDRESS: : **MS-JIYA MAKKAR**  
LAB INCHARGE  
**PRO BIOTIC DIAGNOSTICS PVT.LTD.**

ADD- Add- 3<sup>rd</sup> Floor, C-4/206, Sector 6 Rd,Pocket-4, Sector 6, New Delhi -110085

The undersigned performer certifies that the Installation Qualification Protocol has been successfully completed for the instrument stated above.

Authorized Engineer,

**Mr. RAHUL PAL**  
**Customer Service Engineer**  
**IVD-Automation**

**AVIENCE BIOMEDICAL PVT.TLD. DELHI-110058**

Signature .....

Note: Installation Service Report Should be attached with this manual for Documentation.

*IQ/OQ/PQ -BS 240*

## INSTALLATION VERIFICATION REPORT

This is to certify that the following checks mentioned in the installation verification protocol have been performed and found to be satisfactory.

1. Pre-Installation Check	Remark
A) Carton arrival	Checked
B) Spare and accessibility	Checked & Cleared
C) Electrical input	Checked & Passed
D) Ambient temperature and Humidity	Passed
E) Ventilation	Passed
F) Drainage	Checked
2. Unpacking & Console Installation	Passed
3. Electrical Cables Installation	Checked & Passed
4. Unpacking & Installation of the Analytical Unit	Passed
5. Setting up the analyzing unit	Success
6. Alignment Verification	Success

Mr. RAHUL PAL	MS –JIYA MAKKAR
(Signature)	(Signature)

**Installation Qualification Notes & Attachments:**

**OPERATIONAL QUALIFICATION**

**SYSTEM CERTIFICATION:**

Study date has determined that the system described in this document either meets all criteria outlined in this Operational Qualification protocol. All exceptional conditions if any have been addressed. The system is ready for specified usage.

Protocol performed by:

**AVIENCE BIOMEDICAL REPRESENTATIVE**

MR –RAHUL PAL

Customer Service Executive IVD-Automation

DELHI, -110058

**CUSTOMER AUTHORIZATION:-**

**MS-JIYA MAKKAR**

LAB INCHARGE

**PRO BIOTIC DIAGNOSTICS PVT.LTD.**

**ADD- Add- 3<sup>rd</sup> Floor, C-4/206,  
Sector 6 Rd,Pocket-4, Sector 6,  
New Delhi -110085**

Authorized Engineer's Signature

Customer's Signature

Date:

Date:





## **OPERATIONAL QUALIFICATION – SYSTEM VERIFICATION REPORT**

This is to certify that the following checks mentioned in the operational verification protocol have been performed and found to be satisfactory.

<b><u>OPERATIONAL QUALIFICATION PROTOCOL</u></b>	<b><u>REMARKS</u></b>
<b>1] CHECKING THE ANALYTICAL UNIT</b>	
A] SOFTWARE BOOTING & INITIALIZATION	Success
B] BASIC SYSTEM CHECKS & VERIFICATION	Verified
<b>2] IMPORTING &amp; CALIBRATING THE CHEMISTRIES</b>	Success
<b>3] RUNNING CONTROLS</b>	Success
<b>4] TRAINING THE OPERATORS</b>	Completed

Mr. RAHUL PAL  (Signature)	MS JIYA MAKKAR  (Signature)
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## **OPERATIONAL QUALIFICATION PROCEDURES**

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

### **OQ PROCEDURES:**

1. System software loading.
2. System Booting and Initialization
3. Basic System Checks.
4. Importing Chemistries & Calibrating Chemistries.
5. Running Controls.
6. Operators Training Schedule.

### **References:**

1. Operation Manual –BS 240
2. Service Manual – BS 240

### ***Operational Qualification Notes:***

**Operational Qualification Notes:**

**PERFORMANCE QUALIFICATION**

**SYSTEM CERTIFICATION:**

Study data has determined that the system described in this document meets all criteria outlined in this Performance Qualification protocol, or exceptional conditions have been identified and documentation included exceptional conditions, if any have been addressed. The system is ready for specified usage.

Protocol performed by: **AVIENCE BIOMEDICAL**

MR RAHUL PAL  
SR Service Engineer-  
Technical IVD-  
Automation Delhi-  
110058

Customer Authorization:

**MS-JIYA MAKKAR  
LAB INCHARGE  
PRO BIOTIC DIAGNOSTICS PVT.LTD.**

**ADD- Add- 3<sup>rd</sup> Floor, C-4/206,  
Sector 6 Rd,Pocket-4, Sector 6,  
New Delhi -110085**

Authorized Service Engineer's Signature

Customer's Signature

Date:

Date:

**PERFORMANCE QUALIFICATION VERIFICATION REPORT**

This is to certify that the following checks mentioned in the performance verification protocol have been performed and found to be satisfactory.

MR :RAHUL PAL	MS JIYA MAKKAR
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## **PERFORMANCE ANALYSIS**

The following performance protocols have been carried out in **BS -240**, the fully automated clinical chemistry analyzer bearing the serial number : **YX 35007115** installed at GI Laboratory Services

1. **With-in run precision**
2. **Between-run precision**
3. **Accuracy**
4. **Linearity**



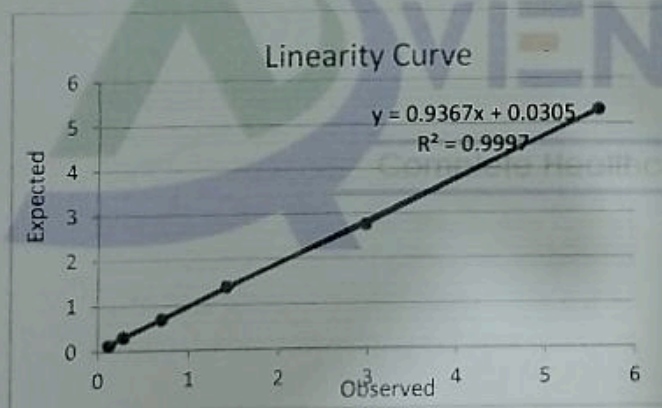
Carryover worksheet													
Run	Ca	Glu	T-Bil	ALT	AST	ALP	TP	ALB	TG	TC	CREATININ	UREA	URIC ACID
H1	12.62	319.4	4.53	111.2	222	497.2	4.42	2.6	85.2	106.7	5.72	109.6	10.39
H2	12.37	317.6	4.62	109	223.6	501	4.31	2.6	86.6	105.6	5.71	108.78	10.99
H3	12.64	317.2	4.63	108.8	222.9	502.8	4.2	2.6	85.6	106.3	5.71	108.96	11.16
L1	10.16	92	1.23	30	42.4	120.8	7.04	4.3	150.7	233.9	1.79	40.98	4.94
L2	10.19	92.2	1.15	29.6	42.4	135	6.95	4.3	152.2	229.7	1.81	40.71	5.03
L3	10.06	93.2	1.22	29.8	41.3	133.2	6.78	4.3	150.9	230.1	1.77	40.84	50.8
% Carryover	4.33	-0.53	0.29	0.25	0.60	-3.37	-10.53	0.00	0.31	-3.05	0.51	0.21	115.20

Instrument - XL1000, SN- 110060



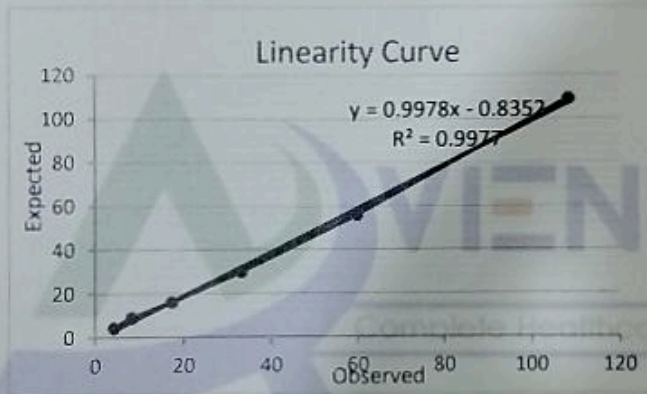


Linearity Curve with R Square Value				
CREATININE				
Sr. No.	Dilutions	Expected Conc	Observed Conc	% Recovery
1	Neat	5.61	5.31	94.7
2	(1:2)	2.98	2.76	92.6
3	(1:4)	1.42	1.39	97.9
4	(1:8)	0.70	0.69	98.6
5	(1:16)	0.28	0.31	110.7
6	(1:32)	0.12	0.13	108.3

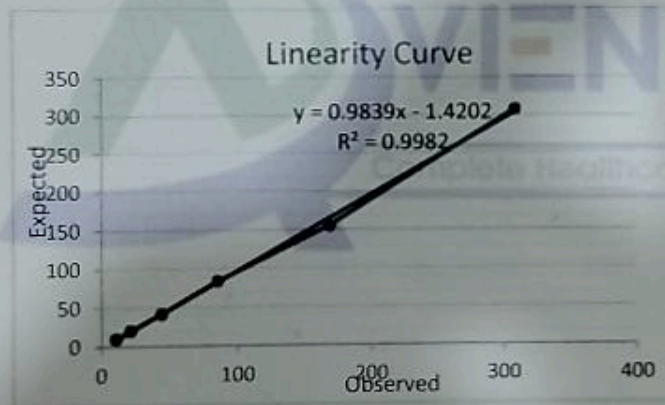




Linearity Curve with R Square Value				
UREA				
Sr. No.	Dilutions	Expected Conc	Observed Conc	% Recovery
1	Neat	108.45	109.24	100.7
2	(1:2)	59.74	56.23	94.1
3	(1:4)	33.06	30.12	91.1
4	(1:8)	17.23	16.24	94.3
5	(1:16)	8.25	9.14	110.8
6	(1:32)	4.21	4.45	105.7

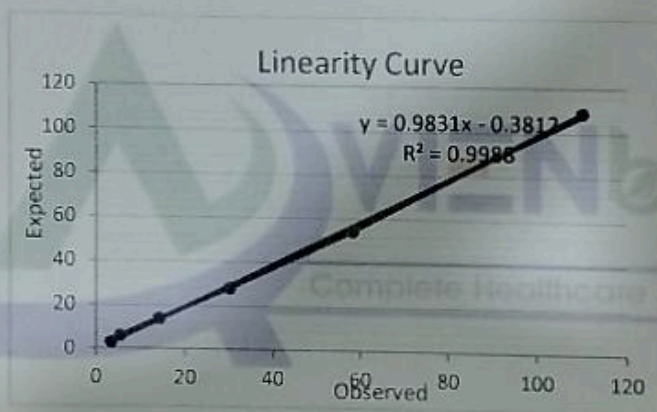


Linearity Curve with R Square Value				
RBS				
Sr. No.	Dilutions	Expected Conc	Observed Conc	% Recovery
1	Neat	310.10	308.21	99.4
2	(1:2)	168.90	155.24	91.9
3	(1:4)	85.20	84.12	98.7
4	(1:8)	43.80	42.06	96.0
5	(1:16)	21.40	21.03	98.3
6	(1:32)	10.60	10.53	99.3





Linearity Curve with R Square Value				
ALT				
Sr. No.	Dilutions	Expected Conc	Observed Conc	% Recovery
1	Neat	110.10	109.24	99.2
2	(1:2)	58.30	54.62	93.7
3	(1:4)	30.20	28.23	93.5
4	(1:8)	14.10	14.11	100.1
5	(1:16)	5.40	6.12	113.3
6	(1:32)	3.30	3.06	92.7



Linearity Curve with R Square Value				
AST				
Sr. No.	Dilutions	Expected Conc	Observed Conc	% Recovery
1	Neat	218.40	217.23	99.5
2	(1:2)	114.60	109.21	95.3
3	(1:4)	54.70	54.61	99.8
4	(1:8)	27.40	27.30	99.6
5	(1:16)	13.30	13.65	102.6
6	(1:32)	4.30	5.12	119.1

