

# MedVision Biomedicals Pvt. Ltd.

Customer: Shri Mahavir Medical Centre		Page 1 of 8
Equipment: BS 240 Fully Auto Biochemistry Analyzer		
Title: IQ, OQ & PQ DOCUMENT	Doc. No. : 231201/MEDV/IQOQPO/BC240/V1	

Installation Qualification for Mindray BS-240 Sr. No.:- YX-35007169

Hospital/ Laboratory Name : Shri Mahavir Medical Centre

Address : Shop No: 4/5, Bhanukant Complex, Aarey CheckNaka,  
Goregaon (East), Mumbai-400063, Maharashtra, India

Contact Person : Sapan Godre

Instrument Model : BS-240

Serial No. : YX-35007169

Date Of installation : 02/12/2023

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 : Sapan Godre

Designation : Service Engineer

Designation : Lab Director

Signature :

Signature :



Customer: Shri Mahavir Medical Centre

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Equipment: BS 240 Fully Auto Biochemistry Analyzer

Title: IQ, OQ & PQ DOCUMENT

Doc. No. : 231201/MEDV/IQOQPQ/BC240/V1

## Installation Certificate For BS-240 Sr. No.- YX-35007169

This is to certify that the instrument **BS-240** Sr. No.-YX-35007169<sup>9</sup> is successfully installed and commissioned at : , Shop No: 4/5, Bhanukant Complex, Aarey CheckNaka, Goregaon (East), Mumbai-400063, Maharashtra, India and the Installation Protocol/ checklist has been Successfully completed for the above Instrument.

Date of Installation: 02/12/2023

### Authorized Person

*M. P. Darade*

Name : Mahesh Darade

Designation : Service Engineer

# MedVision Biomedicals Pvt. Ltd.

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Installation Qualification for Mindray BS-240 Sr. No.- **YX-35007169**

Hospital/ Laboratory Name : Shri Mahavir Medical Centre

Address : Shop No: 4/5, Bhanukant Complex, Aarey CheckNaka,  
Goregaon (East), Mumbai-400063, Maharashtra, India

Contact Person : **Sapan Godre**

Instrument Model : BS-240

Serial No. : **YX35007169**

Date Of installation : **02/12/2023**

Customer: Shri Mahavir Medical Centre

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Equipment: BS 240 Fully Auto Biochemistry Analyzer

Title: IQ, OQ & PQ DOCUMENT

Doc. No. : 231201/MEDV/IQOQPQ/BC240/V1

**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: Shri Mahavir Medical Centre

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Equipment: BS 240 Fully Auto Biochemistry Analyzer

Title: IQ, OQ & PQ DOCUMENT

Doc. No. : 231201/MEDV/IQOQPQ/BC240/V1

Performance Qualification for BS-240 Sr. No.- YX-35007169

## Calibration Parameters

- Checked and found all the control parameters to be within the acceptable range.

## 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 and results for parameters found within the acceptable limit.

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: Shri Mahavir Medical Centre

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Equipment: BS 240 Fully Auto Biochemistry Analyzer

Title: IQ, OQ & PQ DOCUMENT

Doc. No. : 231201/MEDV/IQOQPQ/BC240/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.**

Protocol Performed by : Authorized Person  
Name : Mahesh Darade *M.P. Darade*  
Designation : Service Engineer/ Application Specialist

Hospital/ Laboratory Authorization

Name : *Sapan Godre*  
Designation : *Lab Director*

Company Representative Name And Sign  
And Sign *[Signature]*

Hospital/ Laboratory Name

Date: 01-12-2023

Date: 01-12-2023

Customer: Shri Mahavir Medical Centre

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Equipment: BS 240 Fully Auto Biochemistry Analyzer

Title: IQ,OQ & PQ DOCUMENT

Doc. No. : 231201/MEDV/IQOQPQ/BC240/V1

## Operations Qualifications for BS-240 Sr. No.- *YX-35007169*

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

### Authorized Person

Name : Mahesh Darade

*M.P. Dorade*

Designation : Service Engineer/ Application Person

Date : 01-12-2023

### 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.

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9. Connected the PC And CPU
10. Install the software.
11. 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.

Authorized Person

*M.P. Darade*

Name : Mahesh Darade

Designation : Service Engineer



# QC Result

Control	Lot No.	Chemistry	Lot No.	Unit	Measured	Set		Flag	Run Date/Time
					Result	Mean	SD		
CON L1	059323009	P	3004	mg/dL	4.42	4.22	0.22		12/05/2023 01:15:54 PM
CON L1	059323009	Ca	3010	mg/dL	8.31	8.58	0.32		12/05/2023 01:09:36 PM
CON L1	059323009	Glu-G	3002	mg/dL	99.4	105	5		12/05/2023 01:17:42 PM
CON L1	059323009	T-bil-D II	3005	mg/dL	1.11	1.11	0.08		12/05/2023 01:18:00 PM
CON L1	059323009	D-bil-D II	3005	mg/dL	1.08	1.08	0.08		12/05/2023 01:18:18 PM
CON L1	059323009	ALT	3019	U/L	57.0	55.2	2.8		12/05/2023 01:17:24 PM
CON L1	059323009	AST	3011	U/L	49.3	47.9	2.4		12/05/2023 01:17:42 PM
CON L1	059323009	CRP II	3007	mg/L	5.41	6.31	0.63		12/05/2023 03:04:53 PM
CON L1	059323009	ALP	3009	U/L	97.8	97.9	4.9		12/05/2023 01:14:06 PM
CON L1	059323009	γ-GT	2010	U/L	47.8	48.7	2.4		12/05/2023 01:14:24 PM
CON L1	059323009	TP	3005	g/dL	5.26	5.23	0.26		12/05/2023 01:20:06 PM
CON L1	059323009	ALB II	3005	g/dL	3.18	3.2	0.16		12/05/2023 01:16:12 PM
CON L1	059323009	LIP	3008	U/L	45.1	46.7	3.1		12/05/2023 03:03:05 PM
CON L1	059323009	α-AMY	3005	U/L	89.0	86.7	4.3		12/05/2023 01:19:30 PM
CON L1	059323009	TG	3009	mg/dL	113.5	113	5		12/05/2023 01:21:36 PM
CON L1	059323009	TC	3009	mg/dL	106.9	107	5		12/05/2023 01:17:06 PM
CON L1	059323009	HDL-C	3010	mg/dL	32.1	32.8	2.5		12/05/2023 03:06:23 PM
CON L1	059323009	CREA-S	3028	mg/dL	1.06	1.04	0.05		12/05/2023 01:24:00 PM
CON L1	059323009	UA	2010	mg/dL	5.12	5.21	0.24		12/05/2023 01:24:54 PM
CON L1	059323009	UREA	3008	mg/dL	39.34	42	2.1		12/05/2023 01:20:24 PM

# QC Result

Control	Lot No.	Chemistry	Lot No.	Unit	Measured Result	Set		Flag	Run Date/Time
						Mean	SD		
CON L2	059423007	P	3004	mg/dL	8.43	8.49	0.43		12/05/2023 01:24:54 PM
CON L2	059423007	Ca	3010	mg/dL	12.77	13	0.5		12/05/2023 01:18:00 PM
CON L2	059423007	Glu-G	3002	mg/dL	237.2	247	13		12/05/2023 01:26:06 PM
CON L2	059423007	T-bil-D II	3005	mg/dL	4.26	4.19	0.32		12/05/2023 01:26:24 PM
CON L2	059423007	D-bil-D II	3005	mg/dL	2.69	2.65	0.2		12/05/2023 01:26:42 PM
CON L2	059423007	ALT	3019	U/L	149.5	149	7		12/05/2023 01:25:30 PM
CON L2	059423007	AST	3011	U/L	154.1	153	8		12/05/2023 01:26:24 PM
CON L2	059423007	CRP II	3007	mg/L	58.80	56.5	5.7		12/05/2023 03:06:41 PM
CON L2	059423007	ALP	3009	U/L	241.7	245	12		12/05/2023 01:23:06 PM
CON L2	059423007	γ-GT	2010	U/L	196.1	203	10		12/05/2023 01:23:42 PM
CON L2	059423007	TP	3005	g/dL	8.36	8.22	0.41		12/05/2023 01:29:06 PM
CON L2	059423007	ALB II	3005	g/dL	4.88	4.98	0.25		12/05/2023 01:25:30 PM
CON L2	059423007	LIP	3008	U/L	91.3	99.7	6.7		12/05/2023 03:04:53 PM
CON L2	059423007	α-AMY	3005	U/L	208.5	212	11		12/05/2023 01:28:48 PM
CON L2	059423007	TG	3009	mg/dL	197.0	205	9		12/05/2023 01:32:06 PM
CON L2	059423007	TC	3009	mg/dL	170.5	170	8		12/05/2023 01:27:36 PM
CON L2	059423007	HDL-C	3010	mg/dL	50.3	51	3.9		12/05/2023 03:07:53 PM
CON L2	059423007	CREA-S	3028	mg/dL	4.39	4.14	0.2		12/05/2023 01:37:30 PM
CON L2	059423007	UA	2010	mg/dL	10.59	10.5	0.5		12/05/2023 01:37:48 PM
CON L2	059423007	UREA	3008	mg/dL	121.93	128	7		12/05/2023 01:33:18 PM

Patient:	Sample ID:	1
Patient ID:	Sample Type:	Serum
Date of Birth:	Bar Code:	NAMITA GHORPADE
Age:	Collection Date:	12/05/2023
Gender:	Collection Time:	
Physician:	Department:	
Diagnosis:	Comment:	

Chemistry	Result	Unit	Flag	Ref Range
Glu	101.8	mg/dL		
Glu	103.0	mg/dL		
Glu	103.1	mg/dL		
Glu	102.3	mg/dL		
Glu	101.4	mg/dL		
Glu	100.6	mg/dL		
Glu	101.6	mg/dL		
Glu	101.8	mg/dL		
Glu	100.7	mg/dL		
Glu	101.9	mg/dL		
Glu	100.9	mg/dL		
Glu	101.0	mg/dL		

Ordering Date/Time: 12/05/2023

Test Date/Time: 12/05/2023

Print Date/Time: 12/05/2023 02:17:56 PM

Operator:

Reviewer:

The result are for this sample only

# *Certificate of Training*

This is to certify that

Ms Fruti Gupta

of

**Shree Mahavir Medical Centre**

Has attended and successfully completed the training on  
April 10, 2024 of

**Mindray BS-240**

*M.P. Darade.*

**Mahesh Darade**

**Service & Application Specialist**