

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 in unpacked and setup for operation.
- 2. An authorized Avantor representative will checkout each module and verifies 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- 3rd 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 manufacture'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.

IQ/OQ/PQ -BS -240

INSTALLATION QUALIFICATION

SYSTEM CERTIFICATION:

IQ/OQ/PQ -BS -240

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 BIOT	TIC DIAGNOSTICS PVT.LTD.
ADD- Add- 3 rd 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 rd 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.
IC)/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.

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

CUSTOMER AUTHORIZATION:-

MR –RAHUL PAL

MS-JIYA MAKKAR

Customer Service Executive IVD-Automation

LAB INCHARGE PRO BIOTIC DIAGNOSTICS PVT.LTD.

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

DELHI, -110058

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.

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

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

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- 3rd 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 nave been performed and found to be satisfactory.							
MR :RAHUL PAL	MS JIYA MAKKAR						

IQ/OQ/PQ -BS 240

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

						Inte	er Assa	y Precision		2-3-5				
1	D - Hankland	T.BILIRUBIN	ALT	AST	ALP	TP	ALB	CREATININE	UREA	URIC ACID	CALCIUM	RBS	CHOLESTEROL	TG
.N.	Replications	The state of the s	109.8	221.5	483.7	4.45	2.6	5.79	108.63	10.74	12.88	321.5	112	85.4
1	Run1	4.95	109.8	221.8	488.7	4.33	2.7	5.85	106.26	10.33	12.82	317.2	114.9	87.9
2	Run2	4.88	110.7	222.3	492.3	4.23	2.7	5.81	108.18	10.34	12.91	322.4	105.7	87.3
3	Run3	4.91	108.2	221.6	484.5	4.26	2.7	5.76	108.46	10.54	12.97	321.1	107.5	88.6
4	Run4	4.88	- The second second second	219.2	489.8	4.24	2.7	5.8	106.66	10.44	12.76	317.3	106.8	87.4
5	Run5	4.57	109.9	222.7	484.2	4.25	2.7	5.79	104.94	10.44	12.92	323.2	105.8	87
6	Run6	4.83	-	223.5	481.1	4.3	2.7	5.79	107.23	10.32	12.87	325.5	105	88.6
7	Run7	4.63	110	221.9	486.7	4.31	2.7	5.82	106.35	10.36	12.77	319.6	105.5	85.9
8	Run8	4.62	109.8		487.3	4.31	2.7	5.81	108.14	10.58	12.66	319	108.2	88.8
9	Run9 Run10	4.76	111.5	222.2	486.6	4.27	2.7	5.78	106.25	10.35	12.75	322.5	107.6	87.3
	Mean	4.77	109.86	222.01	486.49	4,30 0.06	2.69	5.80	107.11	10.44	12.83	320.93 2.66	107.90	87.4. 1.13
	SD	0.14	0.86	0.54	3.27 0.67	1.49	1.18	0.02	1.14	1.32	0.74	0.83	2.94	1.29

Instrument - XL1000, SN- 110060



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
нз	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
12	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

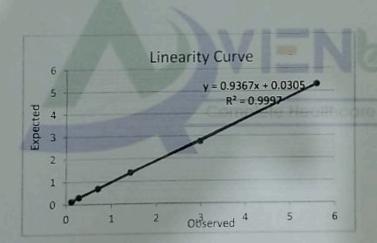




H.O.: C-11, 1st Floor, C Block, Community Center, Janakpuri, New Delhi-110058 Unit Add.: G-1, Sector-11, Noida, Distt. Gautam Budh Nagar, Uttar Pradesh-201301

CIN No:- U74999DL2019PTC359158 aviencebiomedicals@gmail.com 011-46074944, 18001204636 www.avienbio.com

	Linearity	Curve with R S	quare Value	11/2	
		CREATININ	IE		
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	







H.O.: C-11, 1st Floor, C Block, Community Center, Janakpuri, New Delhi-110058 Unit Add.: G-1, Sector-11, Noida, Distt. Gautam Budh Nagar, Uttar Pradesh-201301

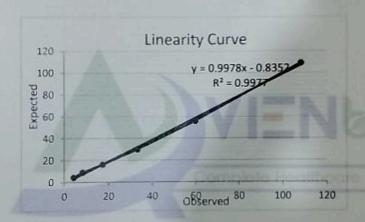
CIN No:- U74999DL2019PTC359158

60 II	avi	enc	ebio	medi	calso	e) an	nail.	com
	100		لموارحاه	ablababab	industria.	C 10.	And the last	-

011	-46	07/	1944	4.5	200	10
V 1 1		خلك	1244	100	UU	r

204636 📵 www.avienbio.com

17.51	Linearity	Curve with R S	quare 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	



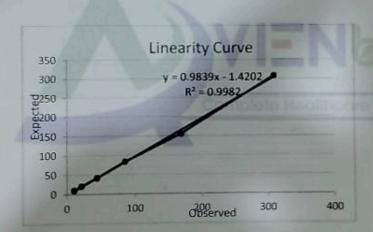




H.O.: C-11, 1st Floor, C Block, Community Center, Janakpuri, New Delhi-110058 Unit Add.: G-1, Sector-11, Noida, Distt. Gautam Budh Nagar, Uttar Pradesh-201301

CIN No:- U74999DL2019PTC359158 (a) aviencebiomedicals@gmall.com (b) 011-46074944, 18001204636 (b) www.avienbio.com

	Linearity	Curve with R S	quare 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	



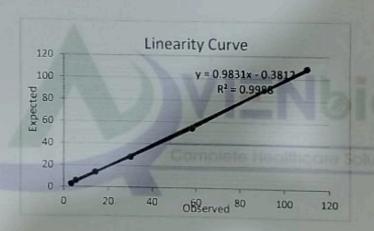




H.O.: C-11, 1st Floor, C Block, Community Center, Janakpuri, New Delhi-110058 Unit Add.: G-1, Sector-11, Noida, Distt. Gautam Budh Nagar, Uttar Pradesh-201301

CIN No:- U74999DL2019PTC359158 avienceblomedicals@gmail.com 011-46074944, 18001204636 www.avienbio.com

	Linearity	Curve with R S	quare 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	







H.O.: C-11, 1st Floor, C Block, Community Center, Janakpuri, New Delhi-110058 Unit Add.: G-1, Sector-11, Noida, Distt. Gautam Budh Nagar, Uttar Pradesh-201301

CIN No:- U74999DL2019PTC359158 📵 aviencebiomedicals@gmail.com 🕒 011-46074944, 18001204636 📵 www.avienbio.com

	Linearity	Curve with R S	quare 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	

