



STAR BIOMED PVT. LTD.

Calibration Certificate

Following values have been checked & adjusted on BS 240 (Sl. No.: YX- 9A003144) installed at KVR HOSITAL, Near Reliance Petrol Pump, Moradabad Road, Kashipur, Uttarakhand-244713

System voltages are in the specified range –Checked by Digital Multimeter are as below:

S.No.	Module	Observed Value	Acceptable Range
1	24 Voltage Supply	24.3 VDC	24.0 +/- 1.0 VDC
2	12 Voltage Supply	12.2 VDC	12.0 +/- 0.5 VDC
3	5 Voltage Supply	5.04 VDC	5.00 +/- 0.1 VDC
4	Liquid Level Sensor Board Supply	4.03 VDC	4.0 +/- 0.1 VDC

System Temperature values are in the specified range –Checked and are as below:

S.No.	Module	Observed Value	Acceptable Range
1	Reagent Preheater Temp.	45.3 °C	45 +/- 0.5 °C
2	Reaction Disk Temp.	37.1 °C	37 +/- 0.4 °C
3	Reagent Compartment Temp.	10 °C	8 to 12 °C

Photometer Adjustment Values are within range as recommended:

S.No.	Module	Observed Value	Acceptable Range
1	Background Count for all Wavelength	51,500 +/-40	48,000 to 55,000

Pipetting Syringes are Ok volume dispensed measured on Digital Weighing Machine:


S.No.	Module	Observed Value	Acceptable Range
1	Reagent/Sample Syringe	500 uL	500 +/-1uL

Washing Dispense are Ok volume dispensed measured on Digital Weighing Machine

S.No.	Module	Observed Value	Acceptable Range
1	Interior Washing	3.10 mL	3.00 +/- 500uL
2	Exterior Washing	3.15 mL	3.00 +/- 500uL

- > All other mechanisms have been checked through software and found working OK.
- > Performed calibration for End Point, Kinetic & Fixed Time Kinetic. Run control & sample, Results were satisfactory.
- > Next Calibration will be performed on 19/05/2022

For,
Star Biomed Pvt. Ltd.


Amit Thakur
Service Engineer

Date: 20/05/2021



STAR BIOMED PVT. LTD.

AUTO CHEMISTRY ANALYZER

Mindray BS-240

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

KVR HOSITAL

**Near Reliance Petrol Pump
Moradabad Road, Kashipur,
Uttarakhand-244713**

BY:

Star Biomed Pvt. Ltd

Date: 12/09/2020



STAR BIOMED PVT. LTD.

CERTIFICATE OF INSTALLATION

INSTRUMENT NAME : MINDRAY BS240 AUTO CHEMISTRY ANALYZER

SERIAL NUMBER : YX- 9A003144

CUSTOMER NAME : KVR Hospital

ADDRESS : Near Reliance Petrol Pump, Moradabad Road, Kashipur 244713

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

Engineer

Signature :

Name : Amit Thakur

Designation : Service Engineer

Company : Star Biomed Pvt. Ltd.,

Quality Manager

Signature :

Name : Ritesh Mishra

Designation : Quality Manager

Company : Star Biomed Pvt. Ltd.,

Date: 12/09/2020



STAR BIOMED PVT. LTD.

INSTALLATION REPORT

Customer Name : KVR Hospital,
Near Reliance Petrol Pump,
Moradabad Road, Kashipur 244713

Place : Uttrakhand

Department : Laboratory

Contact Person : Dr. Bharat Bhushan

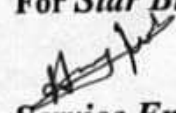
Instrument Name : Mindray BS240

Serial Number : YX- 9A003144

Date of Installation : 12/09/2020

The Analyzer was installed along with the necessary standard accessories. All basic requirements and adjustments were checked and are found to be satisfactory. The preliminary standardization of the analyzer and the training were provided to the complete satisfaction of the customer. The analyzer is found to be working satisfactorily.

For Star Biomed Pvt. Ltd


Service Engineer

Date: 12/09/2020



STAR BIOMED PVT. LTD.

INSTALLATION QUALIFICATION/IQ PROTOCOL

- 1. System Unpacking*
- 2. System Checking For any Damages*
- 3. All accessories as per check List verification*
- 4. Space Requirement*
- 5. Power Requirement*
- 6. Reagents, Control, Calibrators verification.*

1. SYSTEM UNPACKING & 2. SYSTEM CHECKING

Unpack D5 instrument carefully and check for any physical Damages.

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 on below the countertop to accommodate the reagents & pneumatic unit and waste containers.

DIMENSIONS		
PARAMETER	Analyzer OV	Pneumatic Unit
Width mm	690	650
Depth mm	570	520
Height mm	595	520
Weight Kg	100	75



STAR BIOMED PVT. LTD.

5. POWER REQUIREMENT -

<i>Requirement</i>	<i>Acceptable Range</i>	<i>Observed Ranged</i>
Input Voltage	220 +/- 10 V	225 V
Line Frequency	50 HZ	50 HZ
Ambient Temperature	15 C - 30 C	23

7. Reagents . Calibrators Check-

Auto Cal Lot. No H014 Exp. April/2021

REAGENT CALIBRATION CHECK		
NAME	Auto Cal value	Remark
Glucose Human	218	OK
ALP Human	465	OK
TP Human	7.36	OK
CHO Human	265	OK
TG Human	252	OK
UREA Human	46.5	OK
CRE MINDRAY	4.70	OK
UA Human	10.5	OK
ALB Human	5.48	OK
SGOT Human	130	OK
SGPT Human	134	OK
CALCIUM MINDRAY	13.0	OK
T BILL Human	4.0	OK
D BILL Human	3.0	OK



STAR BIOMED PVT. LTD.

PRE-INSTALLTION VERIFICATION REPORT :

PRE-INSTALLATION VERIFICATION REPORT		
S/N	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 Operational Qualification procedure specifies the methodology for installation of specified system after successful installation qualification. Successful completion of procedure identifies that system is ready for operation and subsequent performance analysis.

OO PROTOCOL

1. System Connections
2. Reagent & Waste Connections
3. Customizing the Analyzer Software
4. System Booting , Initialization & Check
5. Maintenance procedures.
6. Customer Training – Operation & Maintenance.

1. SYSTEM CONNECTION –

SYSTEM CONNECTIONS			
S/N	NAME	Check	Remark
1	Pneumatic Unit	Yes	OK
2	Input Power supply	Yes	OK
4	Printer Connection	Yes	OK

2. REAGENT & WASTE CONNECTIONS -

REAGENT CONNECTION CHECK		
NAME	CHECK	Remark
Glucose Human	YES	Ok
ALP Human	YES	Ok
TP Human	YES	Ok
TCHO Human	YES	Ok
TG Human	YES	Ok
UREA Human	YES	Ok
CRE MINDRAY	YES	Ok
UA Human	YES	Ok
ALB Human	YES	Ok
SGOT Human	YES	Ok
SGPT Human	YES	Ok
CALCIUM MINDRAY	YES	Ok
T BILL Human	YES	Ok
D BILL Human	YES	Ok

Date: 12/09/2020



3. CUSTOMIZING ANALYZER SOFTWARE –

CUSTOMIZING ANALYZER SOFTWARE			
S/N	Parameters	Check	Remark
1	Date & Time	Operating Manual 5.2.1	OK
2	Reagents	Operating Manual 5.2.1	OK
3	Reference Ranges	Operating Manual 5.3.1	OK
4	Reference Units	Operating Manual 5.3.1	OK
5	Printing format	Operating Manual 5.3.1	OK
6	Creating New User	Operating Manual 5.3.2	OK

4. SYSTEM BOOTING, INITIALIZATION & Check -

Power ON System and check instrument Initialization successfully.

Check following Parameters.

TEMPERATURES & PRESSURES				
S/N	Parameters	Actual°C	Range°C	Remark
1	Preheat Bath	40	30 to 50	Ok
2	Reaction Bath	36.9	30 to 45	Ok
3	Ambience	25.4	15 to 35	Ok
4	Laser Diode	35.9	15 to 45	Ok

MAINTENANCE PROCEDURES:-

MAINTENANCE			
S/N	Parameters	Check	Remark
1	Using Maintenance Menu	Yes	Ok
2	Replacing Priming Reagents	Yes	Ok
3	Cleaning	Yes	Ok
4	Maintenance	Yes	Ok
5	Overall Maintenance	Yes	Ok
6	Version Information	Yes	Ok
7	Temperature & Pressure	Yes	Ok
8	Touch Screen Calibration	Yes	Ok
9	Cleaning SRV Manually	Yes	Ok
		Yes	Ok

Date: 12/09/2020



STAR BIOMED PVT. LTD.

ADJUSTMENT			
S/N	Parameters	Check	Remark
1	Vacuum & Pressure	Yes	Ok
2	Error Messages & Recommendations	Yes	Ok

PERFORMANCE QUALIFICATION-

Serodos Control Level I (Lot. No.0005 Exp. Feb/2021)			
TEST	Mean conc.	SD (Calc)	
Glucose Human	88.3	13.9	
ALP Human	238	55.5	
TP MINDRAY	6.37	0.53	
UREA Human	33.1	7.3	
CRE MINDRAY	2.50	0.202	
ALB Human	3.80	0.67	
SGOT Human	35.5	6.1	
SGPT Human	32.8	7.5	
CALCIUM MINDRAY	9.49	0.706	
PHOS HUMAN	3.77	0.68	
Serodos control Level-Plus (Lot. No.0015 Exp.Feb/2021)			
TEST	Mean conc.	SD (Calc)	
Glucose Human	223	36.0	
ALP Human	475	119.0	
TP Human	6.52	0.71	
CHO Human	264	37.0	
TG Human	186	33.5	
UREA Human	46.2	10.05	
CRE MINDRAY	5.59	0.506	
UA Human	10.9	1.52	
ALB Human	4.47	1.03	
SGOT Human	135	30.5	
SGPT Human	13.5	31.0	
CALCIUM MINDRAY	12.15	0.81	
PHOS Human	8.45	1.52	

For Star Biomed Pvt. Ltd


Service Engineer

Date: 12/09/2020

Calibration Result List

Chemistry	Cal Status	R0	K	A	B	C	D	Cal Date/Time
Glu-G	Calibrated	43.7370						15-04-2022 02:31:04
			0.0236					
UREA	Calibrated	11.6504						21-04-2022 18:05:46
			0.1370					
CREA-S	Calibrated	112.0682						17-04-2022 12:45:07
			0.0031					
UA	Calibrated	26.8588						15-04-2022 00:50:13
			0.0074					
T-bil-D II	Calibrated	2.0041						17-04-2022 12:46:01
			0.0111					
D-bil-D II	Calibrated	0.3399						17-04-2022 12:46:19
			0.0016					
AST	Calibrated	-0.0699						04-04-2022 21:00:00
			0.5355					
ALT	Calibrated	4.3057						28-04-2022 11:10:12
			0.5024					
ALP	Calibrated	46.2431						23-04-2022 11:16:54
			0.7575					
Y-GT	Calibrated	16.2362						24-04-2022 11:11:39
			0.1984					
TP	Calibrated	35.3688						21-04-2022 18:09:22
			0.0034					
ALB	Calibrated	139.0604						03-04-2022 15:22:38
			0.0006					
TC	Calibrated	12.6898						04-04-2022 21:03:00
			0.0459					
TG	Calibrated	15.6526						04-04-2022 21:08:24
			0.0471					
HDL-C	Calibrated	13.3467						12-04-2022 19:48:33
			0.0377					
LDH H	Calibrated	-16.9215						04-04-2022 21:06:00
			-0.7224					
CRP II	Calibrated	441.1954		-5.1338		0.0030		29-04-2022 16:57:58
			5503.2875		0.9048			
T BIL H	Calibrated	19.2338						03-04-2022 15:18:26
			0.0076					
D BIL H	Calibrated	0.1092						03-04-2022 15:16:02
			0.0038					
U ACID H	Calibrated	217.8794						17-04-2022 12:39:43
			0.0058					
AMYLASE H	Calibrated	0.8117						10-04-2022 14:53:52