



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



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



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



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



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.**

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



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



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



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

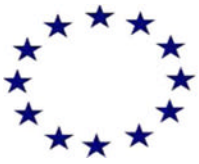
PERFORMANCE QUALIFICATION-

Serodos Control Level 1 (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



AUTO CHEMISTRY ANALYZER

Mindray BC-5130

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



CERTIFICATE OF INSTALLATION

Instrument Model : MINDRAY BC5130

Serial No. : TR-980003002

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



Installation Report

Customer Name : KVR Hospital
Address : Near Reliance Petrol Pump, Moradabad Road,
Kashipur 244713
Contact Person : DR Bharat Bhushan
Instrument Model : MINDRAY BC5130
Serial No. : TR-980003002
Date Of installation : 12/09/2020

The instrument was installed at customer place and was found to be working satisfactory. Preliminary Customer Training was provided and standardization of the parameters were done as per requirement. The results were found to be within the expected range and system found to be working satisfactorily.

For **STAR BIOMED PVT.LTD.**

Name : Amit Thakur
Designation : Service Engineer

Signature :

Date: 12/09/2020



Installation Qualification

Customer Name : KVR Hospital
Address : Near Reliance Petrol Pump, Moradabad Road,
Kashipur 244713
Contact Person : DR Bharat Bhushan
Instrument Model : MINDRAY BC5130
Serial No. : TR-980003002
Date Of installation : 12/09/2020

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 required accessories in place as per requirement.

Installation Procedure and Checklist Attached for the records

External Requirement for Installation:

- 1. Uninterrupted Power Supply Input voltage of 220V-240V/50Hz.**
- 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 recommended by Mindray Manual 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 STAR BIOMED PVT.LTD.

Name : Amit Thakur

Designation : Service Engineer

Date: 12/09/2020



Performance Qualification

Calibration Parameters

Checked and found all the control parameters to be within the acceptable CV limits and in range.

Checked and found all controls to be within the acceptable SD.

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 system is ready for Specific Usage.

Protocol Performed By:

Name : Amit Thakur

Designation : Service Engineer

Date: 12/09/2020



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.

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

The System is ready for specific usage.

STAR BIOMED PVT.LTD.

Protocol Performed By:

Name : Amit Thakur

Designation : Service Engineer

Date: 12/09/2020



Instrument Setup

1. Assembled the instrument accessories.
2. Removed the shipping Clamps.
3. Connected the LH LYSE REAGENT .
4. Connected the DILUENT REAGENT.
5. Connected the Leo I REAGENT
6. Connected the Leo II REAGENT
7. Connected the Waste Tubing
8. Connected the Communication Cable.
9. Connected the Power cord and connection cord.
10. Coonected the External Printer.
11. Connected the PC And Cpu.
12. Install the software.
13. Initialise the machine and follow the installation procedure.

Operational Instection

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.

STAR BIOMED PVT.LTD.

Protocol Performed By:

Name : Amit Thakur

Designation : Service Engineer

Date: 12/09/2020