

# BHAGWATI SCIENTIFIC

Deals in : Laboratory and Industrial Chemicals, Instrument and Lab. Items

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Mob.: 9811194562

REF. NO. ....

DATED .....

## AUTO CHEMISTRY ANALYZER

### Mindray BS-240

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

### DHAM'S DIAGNOSTIC CENTRE

No 3856/23, Arya Samaj Road, Reghar Pura , New Delhi, Delhi 110005

**BY:-**  
***Bhagwati Scientific***

**Date-12/07/2021**



## **CERTIFICATE OF INSTALLATION**

**INSTRUMENT NAME : MINDRAY BS240 AUTO CHEMISTRY ANALYZER**

**SERIAL NUMBER : XR-64000030**

**CUSTOMER NAME : DHAM'S DIAGNOSTIC CENTRE**

**ADDRESS : No 3856/23, Arya Samaj Road, Reghar Pura, New Delhi, Delhi  
110005**

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

### **Engineer**

**Signature :**

**Name : Shivam Gupta**

**Designation : Service Engineer**

**Company : Bhagwati Scientific**

### **Quality Manager**

**Signature :**

**Name : Manoj Sharma**

**Designation : Quality Manager**

**Company : Bhagwati Scientific**

**Date-12/08/2021**



## **INSTALLATION REPORT**

**Customer Name** : DHAM DIAGNOSTIC CENTRE  
No 3856/23, Arya Samaj Road, Regar Pura, New Delhi, Delhi 110005

**Place** : New Delhi

**Department** : Laboratory

**Contact Person** : Mr.Sandeep

**Instrument Name** : Mindray BS-240

**Serial Number** : **YX-64000027**

**Date of Installation** :

*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 Bhagwati Scientific**

**Service Engineer**



## **INSTALLATION QUALIFICATION/IO 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



## **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-**

***XL MULTI CAL Lot. No 2005093E Exp.-12/2021***

REAGENT CALIBRATION CHECK		
NAME	MALTI CAL VALUE	Remark
Glucose AGD	202	OK
ALP ERBA	256	OK
TP ERBA	5.1	OK
CHO ERBA	157	OK
TG BIOGENESIS	139	OK
UREA ERBA	99.1	OK
CRE MINDRAY	3.88	OK
URIC ACID BIOGENESIS	5.83	OK
ALB ERBA	3.23	OK
SGOT MINDRAY	102	OK
SGPT ERBA	92.7	OK
CALCIUM BIOGENESIS	11.3	OK
T BIL MINDRAY	5.18	OK
D BIL MINDRAY	2.28	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 –**

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

### **2. REAGENT & WASTE CONNECTIONS -**

<b>REAGENT CONNECTION CHECK</b>		
<b>NAME</b>	<b>CHECK</b>	<b>Remark</b>
Glucose AGD	YES	Ok
ALP ERBA	YES	Ok
TP ERBA	YES	Ok
TCHO ERBA	YES	Ok
TG BIOGENESIS	YES	Ok
UREA ERBA	YES	Ok
CRE MINDRAY	YES	Ok
UA BIOGENESIS	YES	Ok
ALB ERBA	YES	Ok
SGOT MINDRAY	YES	Ok
SGPT ERBA	YES	Ok
CALCIUM BIOGENESIS	YES	Ok
T BILL MINDRAY	YES	Ok
D BILL MINDRAY	YES	Ok

**Date-12/07/2021**



### **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-12/07/2021**



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

**PERFORMANCE QUALIFICATION-**

ERBA NORM Control Level-1 (Lot. No. S052024A Exp. 12/2022)			
TEST	Mean conc.	SD (Calc)	
Glucose AGD	86.5	4.32	
ALP ERBA	120.64	8.04	
TP ERBA	6.37	0.32	
UREA ERBA	40.68	2.03	
CRE MINDRAY	1.22	0.09	
ALB ERBA	3.55	0.18	
SGOT MINDRAY	47.05	3.14	
SGPT ERBA	38.97	2.60	
CALCIUM BIOGENESIS	7.52	0.50	
ERBA PATH control Level-2 (Lot. No. S052025A Exp. 11/2022)			
TEST	Mean conc.	SD (Calc)	
Glucose AGD	228.06	11.40	
ALP ERBA	335.58	22.37	
TP ERBA	10.10	0.50	
CHO ERBA	327.72	16.39	
TG BIOGENESIS	181.62	9.08	
UREA ERBA	104.92	5.25	
CRE MINDRAY	3.15	0.22	
UA BIOGENESIS	10.37	0.52	
ALB ERBA	4.68	0.23	
SGOT MINDRAY	135.16	9.01	
SGPT ERBA	128.18	8.55	
CALCIUM BIOGENESIS	10.42	0.52	

**For Bhagwati Scientific**

**Service Engineer**

**Date-12/07/2021**

