

Ref No: Avantor/Calibration /1713/03

Date: 01/07/2022

CALIBRATION CERTIFICATE

Customer Name	HEALTHHEART DIAGNOSTICS.
Address	BUILDING-07, HARDEVPURI, NATHU CHOWK ,SHAHDARA ,DELHI-110093

CALIBRATION Report for

Machine	FULLY AUTO CHEMISTRY ANALYZER
Model	BS 240Pro
Serial Number	BC7-22001739

CALIBRATION Validity

Calibration performed date	01-07-2022
Calibration validity	1 Year
Next Calibration Due on	30-06-2023

CHECKS BEFORE CALIBRATION

PHYSICAL CHECKS:

Outer Casing/Chassis O.K. (No Damage)	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
CPU, Keyboard, Monitor O.K.	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
UPS Power supply OK	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
Water Unit OK	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>

ENGINEERING CHECKS:

Mechanical fittings O.K.	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
Screws tightening O.K.	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
Computer functioning normal	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
On/off switch working normally.	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
Instrument Switching On normally.	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
Software checks (All Programs working OK)	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
No abnormal and unusual sound coming.	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
Lamp switching on & off normal	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
Reagent and sample Arm Action correct	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
Input Voltage O.K.	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
Temperature O.K.	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>
Any abnormal noise	Yes: <input checked="" type="checkbox"/> / No: <input type="checkbox"/>

CALIBRATION

Sample probe action and movement	CALIBRATED
Reagent probe action and movement	CALIBRATED
Cuvette wash probe action and up/down movement	CALIBRATED
Reaction Cuvette positioning and movement	CALIBRATED
Sample Tray Positioning action and movement	CALIBRATED
Reagent Tray Positioning action and movement	CALIBRATED
Optical Unit	CALIBRATED
Temperature- Heating and Cooling	CALIBRATED
Water Supply Module motor function	CALIBRATED
Wash Unit Motor function	CALIBRATED
Waste Unit Motor Function	CALIBRATED
Mixing Unit Motor function	CALIBRATED
ISE Unit	CALIBRATED

CALIBRATOR NAME	CALIBRATOR LOT	EXPIRY
Multi Sera Calibrator	150121006	2022-12-31

PERFORMANCE CHECKS AFTER CALIBRATION

<p><u>Photometric Unit performance after calibration</u> Wavelength 340, 380, 412,450, 505, 546, 570, 605, 660, 700, 740, 800</p> <p><u>Segment wise performance after calibration:</u></p>	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Sample probe action and movement	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Reagent probe action and movement	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Cuvette wash probe action and up/down movement	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Reaction Cuvette positioning and movement	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Sample Tray Positioning action and movement	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Reagent Tray Positioning action and movement	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Optical Unit	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Temperature- Heating and Cooling	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Water Supply Module motor function	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Wash Unit Motor function	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Waste Unit Motor Function	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
Mixing Unit Motor function	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
ISE Unit	GOOD: <input checked="" type="checkbox"/> /POOR: <input type="checkbox"/>
<u>Overall performance</u>	Satisfactorily <input checked="" type="checkbox"/> Not satisfactorily <input type="checkbox"/>

Calibration performed by:



Name: Sanjeev Kumar
Customer Service
Executive Mobile: +91
9811459701
Email: sanjeev.kumar@avantorsciences.com

Signature:

Date: 01-07-2022

PERFORMANCE ANALYSIS

Model: BS-240Pro

Serial no. BC7-22001739

The performance of the analyzer has been verified for the accuracy and precision analysis of the parameters specified below with Bio Red control and human sample.

Quality Control performance

S No.	Chemistry Parameters	Unit	Bio rad level - 1 Lot no. 26491		Bio rad level – 2 Lot no. 26492	
			Mean Value	Results	Mean Value	Results
1	TG	mg/dl	164.2	177.8	75.1	75.2
2	TRP	g/dl	6.1	6.48	3.76	3.89
3	ALP	U/l	121.2	114.5	435.3	417.5
4	D BILL	mg/dl	0.37	0.38	1.64	1.63
5	T BILL	mg/dl	0.92	0.9	4.46	4.39
6	SGPT	U/l	26.1	26	107.6	106.8
7	SGOT	U/l	29.7	29.1	177.9	198.1
8	CHOL	mg/dl	249.3	242.8	104.5	100.8
9	GLU	mg/dl	81.5	84.7	266.9	280.1
10	URIC ACID	mg/dl	4.44	4.53	8.74	8.69
11	ALB	g/dl	3.37	3.82	2.54	2.53
12	UREA	mg/dl	30.9	34.6	92	97.1
13	CREAT	mg/dl	1.93	2.28	4.24	4.7
14	CAL	mg/dl	9.89	10.13	11.45	11.49
15	PHOS	mg/dl	3.12	3.34	7.09	7.49
16	HDL	mg/dl	65.8	68.3	21.4	20.6
17	TRIG	mg/dl	164.2	177.8	75.1	75.2
18	GGT	U/l	59.2	59.6	149.1	151.1

For Avantor Performance Materials India Ltd.

Signature: - 

Name: Sanjeev Kumar
Customer Service
Executive Mobile: +91
9811459701
Email: sanjeev.kumar@avantorsciences.com

Signature:

Date: 01-07-2022

Date:01.07.2022

CALIBRATION CERTIFICATE

To whom So Ever It May Concern

This is to certify that the below mentioned instrument installed HEALTHHEART DIAGNOSTICS., BUILDING-07,HARDEV PURI,NATHU CHOWK ,SHAHDARA ,DELHI-110093 Has Been Calibrated by Us On 01/07/2022, The Next Calibration is due on before 30/06/2023, The values are falling within the specified range.

The calibration is done by the service team of Avantor performance materials India ltd.

The next calibration is due on 30th JULY 2023
Validity: -One year for Calibration factor data.

For Avantor Performance Materials India Limited

A handwritten signature in blue ink that reads 'Sanjeev'.

Sanjeev Kumar
Sr. Customer Service Executive
+91 9811459701
Email: sanjeev.kumar@avantorsciences.com



Avantor Performance Materials India Limited

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Web: www.avantorinc.com

CIN: U24209HR1991PLC048501

MINDRAY BS 240 PRO

BIOCHEMISTRY ANALYSER

INSTALLATION QUALIFICATION (IQ) / OPERATIONAL QUALIFICATION (OQ)

FOR

WELLNESS DIAGNOSITC PVT. LTD.

BY


AVANTOR PERFORMANCE MATERIALS INDIA LIMITED



CERTIFICATE OF INSTALLATION

INSTRUMENT NAME	MINDRAY BS 240 PRO
SR. NO.	BC7-22001739
CUSTOMER NAME	HEALTHHEART DIAGNOSTICS.
ADDRESS	BUILDING-07, HARDEV PURI, NATHU CHOWK ,SHAHDARA ,DELHI- 110093

THE UNDERSIGNED PERFORMERS CERTIFY THAT THE INSTALLATION QUALIFICATION PROTOCOL HAS BEEN SUCCESSFULLY COMPLETED FOR THE INSTRUMENT STATED ABOVE.

ENGINEER	
SIGNATURE	
NAME	SANJEEV KUMAR
DESIGNATION	CUSTOMER SERVICE EXECUTIVE
COMPANY	AVANTOR PERFORMANCE MATERIALS INDIA LIMITED

QUALITY MANAGER	
SIGNATURE	
NAME	DR.POOJA
DESIGNATION	DIRECTOR
COMPANY	HEALTHHEART DIAGNOSTICS.

**INSTALLATION REPORT**

CUSTOMER NAME	HEALTHHEART DIAGNOSTICS.
PLACE	BUILDING-07, HARDEV PURI, NATHU CHOWK ,SHAHDARA ,DELHI- 110093
DEPARTMENT	Laboratory
CONTACT PERSON	DR.POOJA
INSTRUMENT NAME	MINDRAY BS 240 PRO
SERIAL NUMBER	BC7-22001739
DATE OF INSTALLATION	29/06/2022
WARRANTY EXPIRY	28/06/2027

THE ANALYZER WAS INSTALLED ALONG WITH THE NECESSARY STANDARD ACCESSORIES, ALL BASIC REQUIREMENTS AND ADJUSTMENTS WERE CHECKED AND 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 AVANTOR PERFORMANCE MATERIALS INDIA LIMITED

SANJEEV KUMAR
CUSTOMER SERVICE EXECUTIVE



INSTRUMENT SETUP

INSTALLATION QUALIFICATION

IQ PROTOCOL

1. SYSTEM UNPACKING
2. CHECK FOR ANY PHYSICAL DAMAGE
3. VERIFY ACCESSORIES LIST
4. SPACE REQUIRMENT
5. POWER REQUIREMENT
6. OPERATING ENVIRONMENT

1 SYSTEM UN PACKING / 2 CHECK FOR ANY PHYSICAL DAMAGE

BS 240 PRO WAS UNPACKED AND CHECKED FOR ANY PHYSICAL DAMAGES. FOUND TO BE INTACT

3 VERIFY ACCESSORIES LIST

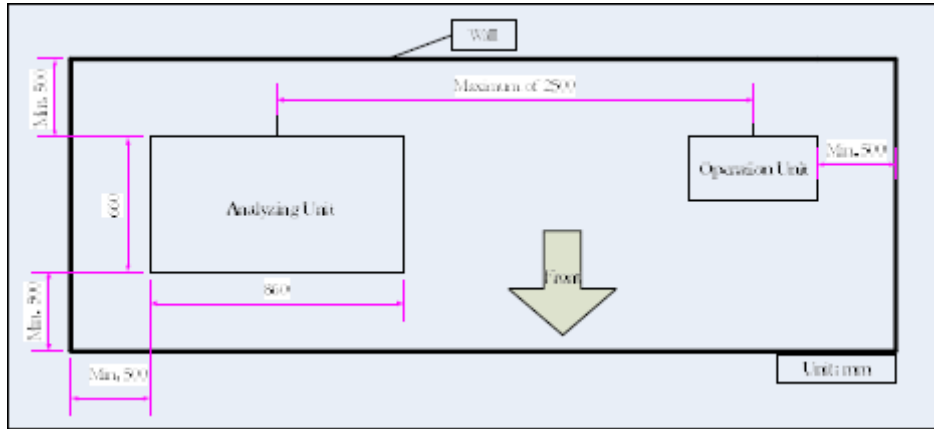
ACCESSORIES LIST WAS COMPARED WITH THE PHYSICALLY AVAILABLE ITEMS AND FOUND TO BE OK

S No	ITEM DESCRIPTION	STATUS
1	COMPUTER UNIT	INSTALLED
2	USER SOFTWARE	INSTALLED
3	INTEGRATED PROBE	INSTALLED
4	MIXER UNIT	INSTALLED
5	DEIONIZED WATER TANK WITH SENSOR	INSTALLED
6	WATER UNIT	INSTALLED
7	DETERGENT CAN WITH SENSOR	INSTALLED
8	H-WASTE CAN WITH SENSOR	INSTALLED
9	PRINTER UNIT	NA



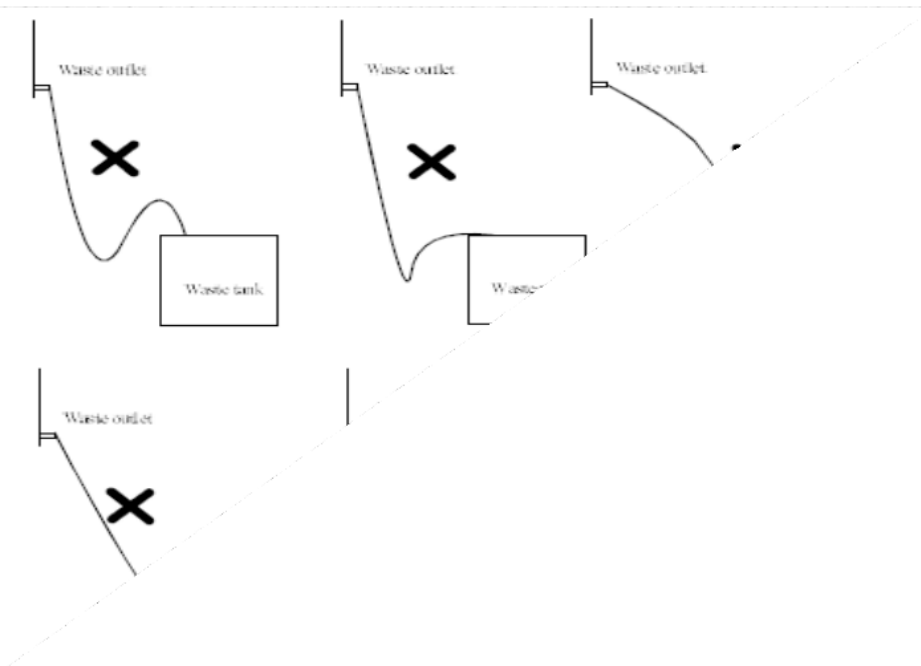
4 SPACE REQUIREMENTS

A: MAIN INSTRUMENT



ALL UNITS IN MM

B: WATER SUPPLY & DRAIN





5 POWER REQUIREMENT / 6 OPERATING ENVIRONMENT

REQUIREMENT	REQUIREMENT	REMARKS
INPUT VOLTAGE	220 ± 10V AC	OK
LINE FREQUENCY	50/60 HZ	OK
AMBIENT TEMPERATURE	15°C - 30°C	OK
UPS	3 KVA ONLINE	OK
GROUNDING	< 5VAC	OK
WATER QUALITY	CONDUCTIVITY - < 1µS/CM	OK

THE INSTALLATION QUALIFICATION POINTS WERE CHECKED AND FOLLOWED AND FOUND TO BE OK AND FURTHER CERTIFIES THE INSTRUMENT TO BE INSTALLED AT THE GIVEN PREMISES

FOR AVANTOR PERFORMANCE MATERIALS INDIA LIMITED


SANJEEV KUMAR
CUSTOMER SERVICE EXECUTIVE



CERTIFICATE OF OPERATION

INSTRUMENT NAME	MINDRAY BS 240 PRO
SR. NO.	BC7-22001739
CUSTOMER NAME	HEALTHHEART DIAGNOSTICS.
ADDRESS	BUILDING-07, HARDEV PURI, NATHU CHOWK ,SHAHDARA ,DELHI- 110093

THE UNDERSIGNED PERFORMERS CERTIFY THAT THE OPERATION QUALIFICATION PROTOCOL HAS BEEN SUCCESSFULLY COMPLETED FOR THE INSTRUMENT STATED ABOVE.

ENGINEER	
SIGNATURE	
NAME	SANJEEV KUMAR
DESIGNATION	CUSTOMER SERVICE EXECUTIVE
COMPANY	AVANTOR PERFORMANCE MATERIALS INDIA LIMITED

QUALITY MANAGER	
SIGNATURE	
NAME	DR.POOJA
DESIGNATION	DIRECTOR
COMPANY	HEALTHHEART DIAGNOSTICS.



OPERATIONAL QUALIFICATION OF THE INSTRUMENT:

DESCRIPTION	REMARKS
POWER UP	PASSED
LOGIN	PASSED
FLUID PRIME	PASSED
MAINTENANCE RECORD SET UP	DONE
START UP INITIALIZATION	PASSED
IMPORTING & CONFIGURING CHEMISTRY PARAMETERS	NA
SYSTEM PERFORMANCE TEST	PASSED

OPERATIONAL QUALIFICATION VERIFICATION WAS CARRIED OUT AS PER THE PROTOCOL AND INSTRUMENT WAS DEEMED FIT FOR PERFORMANCE QUALIFICATION.

FOR AVANTOR PERFORMANCE MATERIALS INDIA LIMITED

SANJEEV KUMAR
CUSTOMER SERVICE EXECUTIVE

Control		ALL	QC Date		11-07-2022	11-07-2022	Results		Summary	QC Setup
Control	Lot No.	Chem	Sample Type	Lot No.	Result	Unit	Set Mean	Set SD	Flag	Run Da
BioRad 1	26491	T-bil-D II	Serum		0.86					
BioRad 1	26491	D-bil-D II	Serum		0.39	mg/dL	0.89	0.03		11-07-2
BioRad 1	26491	Urea AV	Serum		28	mg/dL	0.388	0.017		11-07-2
BioRad 1	26491	Creat AV	Serum		4.30	mg/dL	32.64	2.31		11-07-2
BioRad 1	26491	Creat AV	Serum		4.31	mg/dL	2.16	0.13	2.7s	11-07-2
BioRad 1	26491	TP Avantor	Serum		6.4	mg/dL	2.16	0.13	2.7s	11-07-2
BioRad 1	26491	ALT/PT AV	Serum		29	g/dL	6.74	0.345		11-07-2
BioRad 1	26491	AST/OT AV	Serum		40	U/L	31.13	2.88		11-07-2
BioRad 1	26491	ALB AV	Serum		3	U/L	37.5	2.37		11-07-2
BioRad 1	26491	Glu-G	Serum		82.3	g/dL	3.59	1.43		11-07-2
BioRad 1	26491	UA	Serum		4.38	mg/dL	88.01	8.8		11-07-2
										11-07-2

Chem	Flag	Cal Status	Cal Date/Time	R0	K	A
T-bil-D II		Calibrated	15-07-2022 13:45:40	0.6954	0.0125	
Creat AV		Calibrated	29-07-2022 14:40:00	767.1796	0.0021	
Creat AV		Calibrated	29-07-2022 14:12:36	779.8102	0.0021	
Creat AV		Calibrated	15-07-2022 13:38:24	732.1905	0.0020	
HbA1C AV		Calibrated	11-07-2022 17:02:40	2.7353		104.60
				536.2400		162.98
				1198.4690		126.28
CHOL AVE		Calibrated	11-07-2022 16:58:25	1594.9949		146.80
TG AVE		Calibrated	11-07-2022 16:58:10	-23.5882	0.0559	
				3.0579	0.0668	

ent refrigeration temperature is out of range

