

Customer: Vioma Lifesciences Pvt Ltd	Page 1 of 8
Equipment: BS 240 E Fully Auto Biochemistry Analyzer	
Title: IQ,OQ & PQ DOCUMENT	Doc. No. : MBQ/NKZ/031072023/BS240E

Installation Qualification for Mindray BS-240 E Sr. No.:- BC8-35000385

Hospital/ Laboratory Name : Vioma Life science Pvt Ltd

Address : Indofill Industries Limited, off Swami Vivekananda Road,
Azad Nagar, Sandoz Baug P.O., Thane West, Mumbai
400607

Contact Person : Dr. Niraj Gujar

Instrument Model : BS-240 E

Serial No. : BC8-35000385

Date Of installation : 23-06-2023

The instrument was installed and was found to be working satisfactory. Preliminary Operator Training was provided and standardization of the parameters were done. The results were found to be within the expected range and system found to be working satisfactorily.

Authorized Person Hospital/ Laboratory:

Name : Nandkumar Zagade

Contact Person :Dr. Niraj Gujar

Designation : Service Engineer

Designation : Pathologist

Signature :



Signature :


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Installation Certificate For BS-240 E Sr. No.- BC8-35000385

This is to certify that the instrument **BS-240 E** Sr. No.- **BC8-35000385** is successfully installed and commissioned at : Vioma Lifescience Pvt Ltd , Indofill Industries Ltd , Off Swami Vivekananda , Azad Nagar ,Sandoz Baug , Thane and the Installation Protocol/ checklist has been Successfully completed for the above Instrument.

Date of Installation: 23-06-2023

Authorized Person



Name : Nandkumar Zagade

Designation : Service Engineer

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Installation Qualification for Mindray BS-240 E Sr. No.- BC8-35000385

Hospital/ Laboratory Name : Vioma Lifesciences Pvt Ltd

Address : Near Bitwise Terratower, Mumbai Pune Bypass Rd.,
Pune, Maharashtra - 411045

Contact Person : Dr. Niraj Gujar

Instrument Model : BS-240 E

Serial No. : BC8-35000385

Date Of installation : 23-06-2023

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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 accessories as required.

External Requirement for Installation:

1. Input voltage of 220V-240V/50Hz or 60 Hz.
 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 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 Authorized Person

Name :  Nandkumar Zagade

Designation : Service Engineer

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Performance Qualification for BS-240 E Sr. No.: BC8-35000385

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 Study has been performed by AG Diagnostic Protocol for ALB,ALP,ALT,AST,CA parameters and the results found within the acceptable limit which is mentioned in there protocol. The Same data attached in Performance Qualification.

The system is ready for Specific Usage

Protocol Performed By 

Name : Nandkumar Zagade

Designation : Application Specialist/ Service Engineer

PERFORMANCE QUALIFICATION DONE BY

Name : Nandkumar Zagade

Designation : Application Specialist/ Service Engineer

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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.

The System is ready for specific usage.

Protocol Performed by : Authorized Person

Name : Nandkumar Zagade

Designation : Service Engineer/ Application Specialist

Hospital/ Laboratory Authorization

Name : Dr. Niraj Gujar

Designation :Pathologist

**Company Representative Name And Sign
And Sign**



Date: 23-06-2023

Hospital/ Laboratory Name

Date: 23-06-2023

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Operations Qualifications for BS-240 E Sr. No.- BC8-35000385

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

Authorized Person

Name : Nandkumar Zagade

Designation : Service Engineer/ Application Person

Date : 23-06-2023

Instrument Setup

1. Assembled the instrument accessories.
2. Removed the shipping Clamps.
3. Installed the Reagent/ Sample probes .
4. Installed the Reagent/Sample mixers.
5. Prepared and connected the Detergent Solution
6. Connected the Waste Tubing
7. Connected the Communication Cable.
8. Connected the Power cord and connection cord.
9. Connected the PC And CPU
10. Install the software.

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11. Initialize the machine and follow the installation procedure.

Operational Inspection

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.

Authorized Person


Name : Nandkumar Zagade

Designation : Service Engineer

Mindray-BS-240E

H-046-011279-00-3.0



046-011279-00(3.0)

参数配置表Parameter List

Instrument Serial Number 机器序列号			Software Version 软件版本	30.0.7.15322	
NO. 序号	Unit 单元	Parameter 参数	Default Value 默认值	Parameter Range 参数范围	Actual Value 实际值
1	Sample Reagent Unit 样本试剂盘单元	Sample/Reagent Carousel Outer Ring Aspirate Stop Position Offset 样本试剂盘外圈吸样停止位置偏移量	112	[85,193]	116
2	Sample Reagent Unit 样本试剂盘单元	Sample/Reagent Carousel Middle Ring Aspirate Stop Position Offset 样本试剂盘中圈吸样停止位置偏移量	44	[22,66]	53
3	Sample Reagent Unit 样本试剂盘单元	Sample/Reagent Carousel Inner Ring Aspirate Stop Position Offset 样本试剂盘内圈吸样停止位置偏移量	146	[115,169]	146
4	Sample Reagent Unit 样本试剂盘单元	Outer Ring Bar Code Scanning Offset 外圈条码扫描动态扫描偏移量	44	[34,54]	44
5	Sample Reagent Unit 样本试剂盘单元	Middle Ring Bar Code Scanning Offset 中圈条码扫描动态扫描偏移量	130	[120,140]	130
6	Sample Reagent Unit 样本试剂盘单元	Bar code scanning deviation on outer ring - Stop position 外圈条码扫描偏移量-停止位置	44	[34,54]	44
7	Sample Reagent Unit 样本试剂盘单元	Bar code scanning deviation on middle ring - Stop position 中圈条码扫描偏移量-停止位置	130	[120,140]	130
8	Sample Reagent Unit 样本试剂盘单元	ISE Vertical Position 加ISE样本垂直位置	1276	[1156,1396]	1276
9	Sample Reagent Unit 样本试剂盘单元	Above ISE sample injection port 加ISE样本水平位置	-1608	[-1633,-1583]	-1608
10	Sample Reagent Unit 样本试剂盘单元	Probe Positive Horizontal Wash Position 采样针清洗正向水平位置	153	[128,178]	149
11	Sample Reagent Unit 样本试剂盘单元	Probe Negative Horizontal Wash Position 采样针负向清洗水平位置	153	[128,178]	152
12	Sample Reagent Unit 样本试剂盘单元	Probe Vertical Wash Position 采样针清洗垂直位置	86	[26,146]	84
13	Sample Reagent Unit 样本试剂盘单元	Probe Vertical Wash Position for Whole Blood Test 采样针全血清洗垂直位置	1562	[1506,1622]	1560
14	Sample Reagent Unit 样本试剂盘单元	Horizontal Aspirate Position on Sample/Reagent Carousel Outer Ring 样本试剂盘外圈吸液水平位置	-155	[-180,-130]	-152
15	Sample Reagent Unit 样本试剂盘单元	Horizontal Aspirate Position on Sample/Reagent Carousel Middle Ring 样本试剂盘中圈吸液水平位置	-254	[-279,-229]	-252
16	Sample Reagent Unit 样本试剂盘单元	Horizontal Aspirate Position on Sample/Reagent Carousel Inner Ring 样本试剂盘内圈吸液水平位置	-376	[-416,-336]	-374
17	Sample Reagent Unit 样本试剂盘单元	Reaction Carousel Horizontal Position 1 (Dispense R1 and Dilute Sample) 反应盘水平位置1 (排R1和稀释样本)	743	[723,763]	746
18	Sample Reagent Unit 样本试剂盘单元	Reaction Carousel Horizontal Position 2 (Dispense Sample and Aspirate Diluted Sample and R2) 反应盘水平位置2 (排样本、吸稀释样本和R2)	491	[471,511]	493

19	Sample Reagent Unit 样本试剂盘单元	Sample Carousel Vertical Extreme Position 样本盘垂直极限位置	2857	[2787,2977]	2891
20	Sample Reagent Unit 样本试剂盘单元	Reaction Carousel Vertical Extreme Position 反应盘垂直极限位置	1418	[1348,1488]	1428
21	Sample Reagent Unit 样本试剂盘单元	Reagent Carousel Vertical Extreme Position 试剂盘垂直极限位置	2939	[2869,3009]	2971
22	Mixer Unit 搅拌杆单元	Mixer Horizontal Wash Position 搅拌杆清洗水平位置	-246	[-266,-226]	-230
23	Mixer Unit 搅拌杆单元	Sample Mixing Horizontal Position 搅拌杆样本搅拌水平位置	836	[816,856]	838
24	Mixer Unit 搅拌杆单元	Reagent Mixing Horizontal Position 搅拌杆试剂搅拌水平位置	266	[246,286]	267
25	Mixer Unit 搅拌杆单元	Sample Mixing Vertical Position 搅拌杆搅拌垂直位置	730	[688,772]	731
26	Reaction Carousel Unit 反应盘单元	Photo electricity Gain Channel 340 #光电增益参数340	127	[31,255]	216
27	Reaction Carousel Unit 反应盘单元	Photo electricity Gain Channel 380 #光电增益参数380	127	[31,255]	85
28	Reaction Carousel Unit 反应盘单元	Photo electricity Gain Channel 412 #光电增益参数412	127	[31,255]	82
29	Reaction Carousel Unit 反应盘单元	Photo electricity Gain Channel 450 #光电增益参数450	127	[31,255]	87
30	Reaction Carousel Unit 反应盘单元	Photo electricity Gain Channel 505 #光电增益参数505	127	[31,255]	80
31	Reaction Carousel Unit 反应盘单元	Photo electricity Gain Channel 546 #光电增益参数546	127	[31,255]	102
32	Reaction Carousel Unit 反应盘单元	Photo electricity Gain Channel 570 #光电增益参数570	127	[31,255]	87
33	Reaction Carousel Unit 反应盘单元	Photo electricity Gain Channel 605 #光电增益参数605	127	[31,255]	71
34	Reaction Carousel Unit 反应盘单元	Photo electricity Gain Channel 660 #光电增益参数660	127	[31,255]	71
35	Reaction Carousel Unit 反应盘单元	Photo electricity Gain Channel 700 #光电增益参数700	127	[31,255]	64
36	Reaction Carousel Unit 反应盘单元	Photo electricity Gain Channel 740 #光电增益参数740	127	[31,255]	64
37	Reaction Carousel Unit 反应盘单元	Photo electricity Gain Channel 800 #光电增益参数800	127	[31,255]	58
38	Reaction Carousel Unit 反应盘单元	Reaction Carousel Calibration (Stop Offset) 反应盘位置校正(停止偏移量)	33	[10,50]	33
39	Reaction Carousel Unit 反应盘单元	Automatic Wash best Adjust Cuvette segment Offset 自动清洗的最佳杯联调试位	1	[1,8]	1

40	Reaction Carousel Unit 反应盘单元	Automatic Wash Max forward deviation segment Position Offset 正向最大偏差杯限	1	[1,8]	4
41	Reaction Carousel Unit 反应盘单元	Automatic Wash Max Negative deviation segment Position Offset 负向最大偏差杯限	1	[1,8]	8
42	Reaction Carousel Unit 反应盘单元	Channel 340 Photo electricity Gain Minimum 340nm波长增益参数下限值	76	[31,76]	56
43	Temp Unit 温控单元	Reaction Carousel Sensor 1 R0 传感器1 R0	1000	[/]	1000.343689
44	Temp Unit 温控单元	Reaction Carousel Sensor 1 A 传感器1 A	0.00375	[/]	0.003813000
45	Temp Unit 温控单元	Reaction Carousel Sensor 1 B 传感器1 B	0	[/]	-0.000001000
46	Temp Unit 温控单元	Reaction Carousel Sensor 1_ΔAD 传感器1 ΔAD	0	[/]	-150
47	Temp Unit 温控单元	Reaction Carousel ΔT 反应盘 ΔT	0	[-1.0,1.0]	0.2
48	Auto Wash Unit 自动清洗单元	Reaction carousel dispensing position 反应盘排注(中间)位置	807	[744,857]	812
49	Auto Wash Unit 自动清洗单元	Reaction carousel washing position 反应盘清洗(底部)位置	1563	[1500,1613]	1568
50	Auto Wash Unit 自动清洗单元	Fluidic Prime Complete 液路灌注是否完成	0	[/]	0

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记录人 Recorded by: 何磊 日期 Date: 2023-05-20