

Customer: Vioma Lifesciences Pvt Ltd

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Equipment: CL900i Immunoassay Analyzer

Title: IQ,OQ & PQ DOCUMENT

Doc. No. : MBQ/031072023/NKZ/CL900i

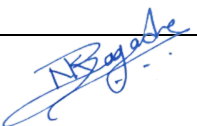
Installation Qualification for Mindray CL900i Sr. No.:- BK2-32000532

Customer Name : VIOMA LIFESCIENCES PVT LTD
Contact Person : DR.NIRAJ GUJAR
Instrument Model : CL900i
Serial No. : BK2-32000532
Date Of installation : 26/06/2023

The instrument was installed And was found to be working satisfactory. Preliminary Customer 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.

Customer: VIOMA LIFESCIENCES PVT LTD

**Indofill Industries Ltd , Off Swami Vivekanand Road , Azad Nagar , Sandoz Baug ,
P.O. Thane West, Thane , Maharashtra - 400607**

Service Engineer		Customer	
Name:	Nandkumar Zagade	Name:	Dr Niraj Gujar
Signature:		Signature:	

Customer: Vioma Lifesciences Pvt Ltd

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Installation Certificate For CL900i Sr. No.- BK2-32000532

This is to certify that the instrument CL900i Sr. No:- BK2-32000532 is successfully installed and commissioned at :

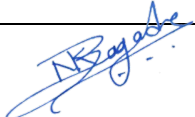
VIOMA LIFESCIENCES PVT LTD

**Indofill Industries Ltd , Off Swami Vivekanand Road , Azad Nagar , Sandoz Baug ,
P.O. Thane West, Thane , Maharashtra - 400607**

and the Installation Protocol/ checklist has been Successfully completed for the above Instrument.

Date of Installation : 26/06/2023

MBQ , Technical Services Department

Service Engineer		Customer	
Name:	Nandkumar Zagade	Name:	Dr Niraj Gujar
Signature:		Signature:	

Installation Qualification for Mindray CL900i Sr. No.:- BK2-32000532

Customer Name : VIOMA LIFESCIENCES PVT LTD

Contact Person : DR.NIRAJ GUJAR

Instrument Model : CL900i

Serial No. : BK2-32000532

Date Of installation : 26/06/2023

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.

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Found all the required accessories as required.

Installation Procedure And Checklist Attached for the records.

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.

Installation Qualification for CL900i Sr. No.:- BK2-32000532

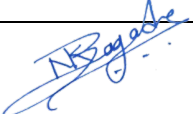
Carried out all the installation procedures as per the installation procedure and checklists.

Carried out all the necessary checks and alignments.

Carried out all the necessary system checks and tests.

Handover the Instrument for operatos Training And Qualifications

MBQ , Technical Services Department

Service Engineer		Customer	
Name:	Nandkumar Zagade	Name:	Dr Niraj Gujar
Signature:		Signature:	

Performance Qualification for Mindray CL900i Sr. No.:-BK2-32000532

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.

Customer: Vioma Lifesciences Pvt Ltd

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Equipment: CL900i Immunoassay Analyzer

Title: IQ, OQ & PQ DOCUMENT

Doc. No. : MBQ/031072023/NKZ/CL900i

Operational Qualification:

System Certification:

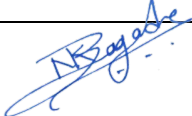
Study data has determined that the system described in this document either meets all criteria outlined in this Operational Protocol, or exceptional conditions have been identified and documentation included.

Exceptional Conditions, If any Have been Addressed.

The System is ready for specific usage.

Customer Authorization : **VIOMA LIFESCIENCES PVT LTD**

**Indofill Industries Ltd , Off Swami Vivekanand Road , Azad Nagar ,
Sandoz Baug , P.O. Thane West, Thane , Maharashtra - 400607**

Service Engineer		Customer	
Name:	Nandkumar Zagade	Name:	Dr Niraj Gujar
Signature:		Signature:	

Customer: Vioma Lifesciences Pvt Ltd

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Operations Qualifications for CL900i Sr. No.- BK2-32000532

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

TMQ, Technical Services Department

Service Engineer		Customer	
Name:	Nandkumar Zagade	Name:	Dr Niraj Gujar
Signature:		Signature:	

Customer: Vioma Lifesciences Pvt Ltd

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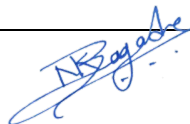
Instrument Setup

1. Assembled the instrument accessories.
2. Removed the shipping Clamps.
3. Installed the Substrate Solution
4. Installed the Reaction Cuvette
5. Prepared and connected the Wsh Buffer 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.
11. Initialize the machine and follow the installation procedure.

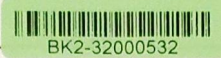
Operational Instection

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.

Service Engineer		Customer	
Name:	Nandkumar Zagade	Name:	Dr Niraj Gujar



参数配置表 (主机) Parameter List (Main Unit)

机器序列号 Instrument Serial Number		 BK2-32000532	软件版本 Software Version	08.01.24.20800	
序号 No	单元 Unit	参数 Parameter	默认值 Default Value	调试范围 Parameter Range	补偿值 Compensation Value
1	试剂盘单元 Reagent Carousel Unit	试剂盒Ra位距试剂盒位置偏移 Position Offset of Ra from Reagent Pack Home Position	/	(-100, 540)	0
2	试剂盘单元 Reagent Carousel Unit	试剂盒Rb位距试剂盒位置偏移 Position Offset of Rb from Reagent Pack Home Position	/	(-224, 416)	24
3	试剂盘单元 Reagent Carousel Unit	试剂盒Rc位距试剂盒位置偏移 Position Offset of Rc from Reagent Pack Home Position	/	(-336, 304)	21
4	试剂盘单元 Reagent Carousel Unit	试剂盒Rd位距试剂盒位置偏移 Position Offset of Rd from Reagent Pack Home Position	/	(-400, 240)	20
5	样本盘单元 Sample Carousel Unit	盘逆时针运动位置偏移 Position Offset of Counter-clockwise Movement	/	(-190, 180)	-5
6	样本盘单元 Sample Carousel Unit	盘顺时针运动位置偏移 Position Offset of Clockwise Movement	/	(-190, 180)	0
7	样本盘单元 Sample Carousel Unit	盘45#样本位位置偏移 Position Offset of Sample Disk 45#.	/	(-140, 140)	0
8	样本盘单元 Sample Carousel Unit	盘41#样本位位置偏移 Position Offset of Sample Disk 41#.	/	(-140, 140)	0
9	样本盘单元 Sample Carousel Unit	盘35#样本位位置偏移 Position Offset of Sample Disk 35#.	/	(-140, 140)	0
10	样本盘单元 Sample Carousel Unit	盘31#样本位位置偏移 Position Offset of Sample Disk 31#.	/	(-140, 140)	0
11	样本盘单元 Sample Carousel Unit	盘25#样本位位置偏移 Position Offset of Sample Disk 25#.	/	(-140, 140)	0
12	样本盘单元 Sample Carousel Unit	盘21#样本位位置偏移 Position Offset of Sample Disk 21#.	/	(-140, 140)	0
13	样本盘单元 Sample Carousel Unit	盘15#样本位位置偏移 Position Offset of Sample Disk 15#.	/	(-140, 140)	0
14	样本盘单元 Sample Carousel Unit	盘11#样本位位置偏移 Position Offset of Sample Disk 11#.	/	(-140, 140)	0
15	样本盘单元 Sample Carousel Unit	盘5#样本位位置偏移 Position Offset of Sample Disk 5#.	/	(-140, 140)	0
16	样本盘单元 Sample Carousel Unit	盘1#样本位位置偏移 Position Offset of Sample Disk 1#.	/	(-140, 140)	0
17	磁分离盘单元 Dispersion Unit	杯位偏移-停止位置 Cuvette Position Offset - Stop Position	/	(-255, 255)	0
18	磁分离盘单元 Dispersion Unit	反转停止位置补偿 Reversed Rotation Stop Position Compensation	/	(-40, 40)	0

序号 No	单元 Unit	参数 Parameter	默认值 Default Value	调试范围 Parameter Range	补偿值 Compensation Value
19	磁分离盘单元 Dispersion Unit	Z初始位置偏移 Position Offset from Vertical Home Position	/	(-460, 460)	0
20	磁分离盘单元 Dispersion Unit	注液位置 Dispense Position	/	(-255, 255)	40
21	磁分离盘单元 Dispersion Unit	吸液杯底位置 Aspirate Cuvette Bottom Position	/	(-255, 255)	0
22	磁分离盘单元 Dispersion Unit	混匀速度参数 Mixing Speed	/	(20,80)	67
23	磁分离盘单元 Dispersion Unit	蠕动泵吸液限速台阶 Aspirating Pump Velocity Step	/	[1,16]	7
24	抓杯手单元 Gripper Unit	X轴右杯盒右下角位置偏移 Pos. Offset from Lower-right Corner of Right Cuvette Box in X-axis	/	/	-21
25	抓杯手单元 Gripper Unit	X轴右杯盒左下角位置偏移 Pos. Offset from Lower-left Corner of Right Cuvette Box in X-axis	/	/	-20
26	抓杯手单元 Gripper Unit	X轴右杯盒左上角位置偏移 Pos. Offset from Upper-left Corner of Right Cuvette Box in X-axis	/	/	3
27	抓杯手单元 Gripper Unit	X轴左杯盒右下角位置偏移 Pos. Offset from Lower-right Corner of Left Cuvette Box in X-axis	/	/	-88
28	抓杯手单元 Gripper Unit	X轴左杯盒左下角位置偏移 Pos. Offset from Lower-left Corner of Left Cuvette Box in X-axis	/	/	-81
29	抓杯手单元 Gripper Unit	X轴左杯盒左上角位置偏移 Pos. Offset from Upper-left Corner of Left Cuvette Box in X-axis	/	/	-23
30	抓杯手单元 Gripper Unit	X轴孵育块右下角位置偏移 Pos. Offset from Lower-right Corner of Incubation Module in X-axis	/	/	-27
31	抓杯手单元 Gripper Unit	X轴孵育块左下角位置偏移 Pos. Offset from Lower-left Corner of Incubation Module in X-axis	/	/	-16
32	抓杯手单元 Gripper Unit	X轴孵育块左上角位置偏移 Pos. Offset from Upper-left Corner of Incubation Module in X-axis	/	/	-25
33	抓杯手单元 Gripper Unit	X轴混匀位1位置偏移 Pos. Offset from Mixing Pos. 1 in X-axis	/	/	-134
34	抓杯手单元 Gripper Unit	X轴混匀位2位置偏移 Pos. Offset from Mixing Pos. 2 in X-axis	/	/	-133
35	抓杯手单元 Gripper Unit	X轴混匀位3位置偏移 Pos. Offset from Mixing Pos. 3 in X-axis	/	/	0
36	抓杯手单元 Gripper Unit	X轴磁分离IO位位置偏移 Pos. Offset from I/O Pos. of Dispersion Carousel in X-axis	/	/	-1
37	抓杯手单元 Gripper Unit	X轴测光位位置偏移 Pos. Offset from Photometric Pos. in X-axis	/	/	-28
38	抓杯手单元 Gripper Unit	X轴排废液位位置偏移 Pos. Offset from Waste Liquid Aspirating Pos. in X-axis	/	/	-28

序号 No	单元 Unit	参数 Parameter	默认值 Default Value	调试范围 Parameter Range	补偿值 Compensation Value
39	抓杯手单元 Gripper Unit	X轴抛弃杯位位置偏移 Pos. Offset from Discarding Pos. in X-axis	/	/	-302
40	抓杯手单元 Gripper Unit	Y轴右杯盒右下角位置偏移 Pos. Offset from Lower-right Corner of Right Cuvette Box in Y-axis	/	/	-169
41	抓杯手单元 Gripper Unit	Y轴右杯盒左下角位置偏移 Pos. Offset from Lower-left Corner of Right Cuvette Box in Y-axis	/	/	-178
42	抓杯手单元 Gripper Unit	Y轴右杯盒左上角位置偏移 Pos. Offset from Upper-left Corner of Right Cuvette Box in Y-axis	/	/	-160
43	抓杯手单元 Gripper Unit	Y轴左杯盒右下角位置偏移 Pos. Offset from Lower-right Corner of Left Cuvette Box in Y-axis	/	/	-138
44	抓杯手单元 Gripper Unit	Y轴左杯盒左下角位置偏移 Pos. Offset from Lower-left Corner of Left Cuvette Box in Y-axis	/	/	-144
45	抓杯手单元 Gripper Unit	Y轴左杯盒左上角位置偏移 Pos. Offset from Upper-left Corner of Left Cuvette Box in Y-axis	/	/	-122
46	抓杯手单元 Gripper Unit	Y轴孵育块右下角位置偏移 Pos. Offset from Lower-right Corner of Incubation Module in Y-axis	/	/	-85
47	抓杯手单元 Gripper Unit	Y轴孵育块左下角位置偏移 Pos. Offset from Lower-left Corner of Incubation Module in Y-axis	/	/	-66
48	抓杯手单元 Gripper Unit	Y轴孵育块左上角位置偏移 Pos. Offset from Upper-left Corner of Incubation Module in Y-axis	/	/	-56
49	抓杯手单元 Gripper Unit	Y轴混匀位1位置偏移 Pos. Offset from Mixing Pos. 1 in Y-axis	/	/	78
50	抓杯手单元 Gripper Unit	Y轴混匀位2位置偏移 Pos. Offset from Mixing Pos. 2 in Y-axis	/	/	83
51	抓杯手单元 Gripper Unit	Y轴混匀位3位置偏移 Pos. Offset from Mixing Pos. 3 in Y-axis	/	/	0
52	抓杯手单元 Gripper Unit	Y轴磁分离IO位位置偏移 Pos. Offset from I/O Pos. of Dispersion Carousel in Y-axis	/	/	26
53	抓杯手单元 Gripper Unit	Y轴测光位位置偏移 Pos. Offset from Photometric Pos. in Y-axis	/	/	-69
54	抓杯手单元 Gripper Unit	Y轴排废液位位置偏移 Pos. Offset from Waste Liquid Aspirating Pos. in Y-axis	/	/	-64
55	抓杯手单元 Gripper Unit	Y轴抛弃杯位位置偏移 Pos. Offset from Discarding Pos. in Y-axis	/	/	162
56	抓杯手单元 Gripper Unit	右杯盒抓放杯与中光耦位置偏移 Pos. Offset from Middle Optocoupler in Right Cuvette Box	/	(-320, 80)	-12
57	抓杯手单元 Gripper Unit	左杯盒抓放杯与中光耦位置偏移 Pos. Offset from Middle Optocoupler in Left Cuvette Box	/	(-320, 80)	1
58	抓杯手单元 Gripper Unit	孵育块抓放杯与中光耦位置偏移 Pos. Offset from Middle Optocoupler in Incubation Module	/	(-320, 70)	12

序号 No	单元 Unit	参数 Parameter	默认值 Default Value	调试范围 Parameter Range	补偿值 Compensation Value
59	抓杯手单元 Gripper Unit	磁分离抓放杯与中光耦位置偏移 Pos. Offset from Middle Optocoupler in Dispersion Carousel	/	(-285, 150)	48
60	抓杯手单元 Gripper Unit	混匀位抓放杯与中光耦位置偏移 Pos. Offset from Middle Optocoupler in Mixing Pos.	/	(-320, 150)	24
61	抓杯手单元 Gripper Unit	手指张开最大时凸轮挡片与光耦的位置偏移 Pos. Offset of Flap from Optocoupler when Finger Opens the Max	/	(-80, 80)	-8
62	采样针单元 Probe Unit	试剂Ra位置偏移 Position Offset from Ra Position	/	(-190,190)	85
63	采样针单元 Probe Unit	试剂Rb位置偏移 Position Offset from Rb Position	/	(-190,190)	54
64	采样针单元 Probe Unit	试剂Rc位置偏移 Position Offset from Rc Position	/	(-190,190)	60
65	采样针单元 Probe Unit	试剂Rd位置偏移 Position Offset from Rd Position	/	(-190,190)	47
66	采样针单元 Probe Unit	50#样本位位置偏移 50# Position Offset from Sample Position	/	/	80
67	采样针单元 Probe Unit	45#样本位位置偏移 45# Position Offset from Sample Position	/	(-170,170)	67
68	采样针单元 Probe Unit	41#样本位位置偏移 41# Position Offset from Sample Position	/	(-170,170)	80
69	采样针单元 Probe Unit	35#样本位位置偏移 35# Position Offset from Sample Position	/	(-170,170)	75
70	采样针单元 Probe Unit	31#样本位位置偏移 31# Position Offset from Sample Position	/	(-170,170)	80
71	采样针单元 Probe Unit	25#样本位位置偏移 25# Position Offset from Sample Position	/	(-170,170)	67
72	采样针单元 Probe Unit	21#样本位位置偏移 21# Position Offset from Sample Position	/	(-170,170)	80
73	采样针单元 Probe Unit	15#样本位位置偏移 15# Position Offset from Sample Position	/	(-170,170)	67
74	采样针单元 Probe Unit	11#样本位位置偏移 11# Position Offset from Sample Position	/	(-170,170)	80
75	采样针单元 Probe Unit	5#样本位位置偏移 5# Position Offset from Sample Position	/	(-170,170)	67
76	采样针单元 Probe Unit	1#样本位位置偏移 1# Position Offset from Sample Position	/	(-170,170)	80
77	采样针单元 Probe Unit	清洗位位置偏移 Position Offset from Wash Position	/	(-190,190)	5
78	采样针单元 Probe Unit	混匀位I位置偏移 Position Offset from Mixing Position I	/	(-120,120)	51

序号 No	单元 Unit	参数 Parameter	默认值 Default Value	调试范围 Parameter Range	补偿值 Compensation Value
79	采样针单元 Probe Unit	混匀位2位置偏移 Position Offset from Mixing Position 2	/	(-120,120)	18
80	采样针单元 Probe Unit	针初始位位置偏移 Position Offset from Vertical Home Position	/	(-400, 136)	-259
81	采样针单元 Probe Unit	针到试剂盘垂直极限位置偏移 Probe to Reagent Carousel Vertical Extreme	/	(-972, 972)	103
82	采样针单元 Probe Unit	针到样本位垂直极限位置偏移 Probe to Sample Position Vertical Extreme	/	(-1203, 1203)	334
83	采样针单元 Probe Unit	针到混匀位1垂直极限位置偏移 Probe to Mixing Position 1 Vertical Extreme	/	/	256
84	采样针单元 Probe Unit	针到混匀位2垂直极限位置偏移 Probe to Mixing Position 2 Vertical Extreme	/	/	258
85	混匀单元 Mixer Unit	初始位位置偏移 Position Offset from Home Position	/	[-13, 320]	0
86	温控单元 Temp. Control Unit	孵育块传感器1温度偏差 Incubation Module Sensor 1 Temperature Offset	/	(-5, 5)	-0.6
87	温控单元 Temp. Control Unit	孵育块传感器2温度偏差 Incubation Module Sensor 2 Temperature Offset	/	(-5, 5)	-0.6
88	温控单元 Temp. Control Unit	磁分离盘传感器R0 Dispersion Carousel Sensor R0	/	/	999
89	温控单元 Temp. Control Unit	磁分离盘传感器R37 Dispersion Carousel Sensor R37	/	/	1139.28
90	温控单元 Temp. Control Unit	磁分离盘传感器R100 Dispersion Carousel Sensor R100	/	/	1374.41
91	温控单元 Temp. Control Unit	磁分离盘传感器 Δ AD Dispersion Carousel Sensor Δ AD	/	/	-211
92	温控单元 Temp. Control Unit	磁分离盘传感器温度偏差DT Dispersion Carousel Sensor Temperature Offset DT	/	[-1, 1]	0
93	温控单元 Temp. Control Unit	底物预热传感器R0 Substrate Preheat Sensor R0	/	/	999.79
94	温控单元 Temp. Control Unit	底物预热传感器R37 Substrate Preheat Sensor R37	/	/	1140.54
95	温控单元 Temp. Control Unit	底物预热传感器R100 Substrate Preheat Sensor R100	/	/	1376.31
96	温控单元 Temp. Control Unit	底物预热传感器 Δ AD Substrate Preheat Sensor Δ AD	/	/	-215
97	温控单元 Temp. Control Unit	底物预热传感器温度偏差DT Substrate Preheat Sensor Temperature Offset DT	/	[-5, 5]	0
98	测光单元 Photometric Unit	遮光盖下位位置偏移 Position Offset of Shading Cover from Lower Position	/	/	-17

序号 No	单元 Unit	参数 Parameter	默认值 Default Value	调试范围 Parameter Range	补偿值 Compensation Value
99	测光单元 Photometric Unit	PMT高压DA PMT High Voltage DA	/	[160, 255]	200
100	测光单元 Photometric Unit	光计数线性校准参数 τ_1 Photon Counting Linear Calibration Factor τ_1	/	[0, 300]	102
101	测光单元 Photometric Unit	光计数线性校准参数 τ_2 Photon Counting Linear Calibration Factor τ_2	/	[0, 300]	109
102	测光单元 Photometric Unit	K (光计数一致性补偿系数) K(Photon counting consistency compensation coefficient)	/	[0.0, 2.0]	1.021
103	测光单元 Photometric Unit	Save AD Save AD	/	[0, 65535]	14249
104	测光单元 Photometric Unit	Save Count Save Count	/	[2550000, 3450000]	3256620
105	测光单元 Photometric Unit	LED初始DA LED Initial DA	/	[32767, 65535]	40428
106	液路系统 Hydraulic System	底物回吸空气量 Substrate Unit Back Aspirate Air	/	(0, 275)	217
107	液路系统 Hydraulic System	底物注液气泡数字电位器DA值 Substrate Air Bubble Potentiometer DA Value	/	[0, 255]	177
108	液路系统 Hydraulic System	吸液气泡数字电位器DA值 Aspirating bubble potentiometer DA value	/	[0, 255]	157
109	液路系统 Hydraulic System	底物管路状态 Substrate Tubes Status	/	[0, 1]	0
110	液路系统 Hydraulic System	加样针管路状态 Probe Tubes Status	/	[0, 1]	0
111	液路系统 Hydraulic System	磁分离清洗管路状态 Dispersion Wash Tubes Status	/	[0, 1]	0
112	液路系统 Hydraulic System	磁分离注液管路状态 Dispersion Dispense Tubes Status	/	[0, 1]	0

记录人 Recorded by:

张四代

日期 Date: 2023-03-01