



Installation Qualification

For Mindray BC-20s Sr No- TK-36015006

Customer Name : PRO BIOTIC DIAGNOSTICS PVT.LTD.
Customer Address : 3rd Floor, C-4/206, Sector 6 Rd, Pocket-4, Sector 6, New Delhi -110085
Contact Person : MS - JIYA MAKKAR
Instrument Model : BC-20S – Auto Hematology Analyser
Serial No. : SR.No.-TK- 36015006
Date of Installation : 15TH DEC-2023

Site survey done and pre-installation checklist was made and found that the site is complying to all the requirements. The instrument packaging was checked and opened for installation.

Initial Inspection of the unit carried out and the details are as follows:

System Condition Report:

System delivered in satisfactory condition and no external physical damage 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 are present.

Attached are the Check-Lists for the same.

AVIENCE BIOMEDICALS PVT.LTD

Technical Services Department

Engineer Name : RAHUL PAL
Designation: Sr. Service Engineer-IVD

Signature :

PRO BIOTIC DIAGNOSTICS PVT.LTD.

Lab Services

Contact Person : MS-JIYA MAKKAR

Signature:

1. Installation Site Checklist

S.No.	Inspection Item	Description	Acceptance Criteria	Result	Remarks	
1	Working Environment	Ambient Temperature	Within normal operation temperature	10°C to 30°C	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
		Humidity	Within operating humidity range	20% to 85%	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
		Atmospheric Pressure	Within operating atmospheric pressure	70KPa to 106 Kpa	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
		Electromagnetic Interferences	Keep Away from electromagnetic interference sources		<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
2	Space Requirements	Space	Meet the Space Requirements	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK	
3	Heat Dissipation	Space requirement for Radiator Fan	At least 100mm to each side of the analyzer	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK	
4	Power Requirements of the main unit and pneumatic unit	Power Supply Voltage and Frequency	Meet the requirements	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK	



2. Instrument Installation Checklist

S.No.	Inspection Item	Description	Acceptance Criteria	Result	Remarks
1	The package box and appearance of the main unit	Package and Appearance	Package and Appearance	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
2	The package box and appearance of the pneumatic unit	Package and Appearance	Package and Appearance	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
3	The package box and appearance of the autoloader unit	Package and Appearance	Package and Appearance	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
4	Item Packing List	Package and Appearance	All Items are included	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
5	Removing the fixing components of the pneumatic unit	Remove the fixing screws	The fixing screws are removed	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
6	Removing the fixing components of the Analyzer	Stop bar of the Front Cover	Cut the cable ties	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
		Manual Sampling Assembly	Cut the cable ties	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
		Cylinder of the mixing assembly	Cut the cable ties	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
		Piercing probe residual liquid tray	Cut the cable ties	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK



Contd..

S.No.	Inspection Item	Description	Acceptance Criteria	Result	Remarks
7	Removing the plastic ties fixing the autoloader	Removing the plastic ties on autoloader	Ties are cut off	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
8	Remove the separator plate of the SRV	Separator plate of the SRV	Separator Plate of the SRV removed	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
11	Connection of Waste	Waste tube and sensor	Tube connected properly and not bent	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
12	Connection of Diluent	Connection of diluent container cap	Tube connected properly and not bent	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
13	Connections of the Optional Equipments	Connection of Printer	Connected Properly and working	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK





Operational Qualification

For Mindray BC-20s Sr No- TK-36015006

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Customer Address : 3rd Floor, C-4/206, Sector 6 Rd, Pocket-4, Sector 6, New Delhi -110085
Contact Person : MS -JIYA MAKKAR
Instrument Model : BC 20S – Auto Hematology Analyser
Serial No. : SR.NO-TK-36015006
Date of Installation : 15TH DEC 2023

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

Initial Inspection of the unit carried out after installation:

All the checks of the instrument were performed as per the Operational Checklist. Analyzer configuration and status for Temperature, Pressure and other test points was checked.

Attached are the Check-Lists for the same.

AVIENCE BIOMEDICALS PVT.LTD

Technical Services Department

Engineer Name : RAHUL PAL

Designation: Sr. Service Engineer –IVD

Signature :



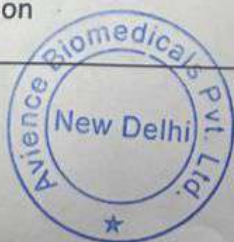
PRO BIOTIC DIAGNOSTICS PVT.LTD
Lab Services

Contact Person : JIYA MAKKAR

Signature

1. Instrument Operational Setup Checklist

S.No.	Inspection Item	Description	Acceptance Criteria	Result	Remarks
1	Analyzer Version Information	Version Information	Correct Version	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
2	Analyzer Pressure Status	250Kpa	250Kpa \pm 5Kpa	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
		-70Kpa	No Alarms or Warnings	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
		106Kpa	106Kpa \pm 2Kpa	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
		70Kpa	70Kpa \pm 1Kpa	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
		40Kpa	40Kpa \pm 1Kpa	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
		-38Kpa	-38Kpa \pm 0.5Kpa	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
3	Analyzer Temperature Status	Temperature Values	Meet Requirements	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
4	Voltage and Current	Voltage and Currents	Meet Requirements	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
5	Software function configuration	Configurations	Correct	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK



S.No.	Inspection Item	Description	Acceptance Criteria	Result	Remarks
6	Confirm the Pierce Probe Piercing Depth	Pierce Probe Piercing Depth	Analyzer can well aspirate from a 1ml Sample	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
7	SRV Hole Alignment Verification	The pin is properly aligned with the positioning hole	Meet Requirement	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
8	Sample Aspiration	Aspiration Position	Meet Requirement	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
9	Piercing	Piercing Position	Meet Requirement	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
11	Date Format	Date Setup	Meet Client's Requirement	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
12	Auxiliary Setup	Auxiliary Setup Items	Meet Client's Requirement	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
13	Reagent Setup	Reagent Barcode and Lot number Information	Reagent Barcode and Lot number Information entered correctly	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
14	Maintenance Setup	Settings of the maintenance setup	Settings are suitable for the laboratory	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK



S.No.	Inspection Item	Description	Acceptance Criteria	Result	Remarks
15	HgB Blank Voltage Check	Hgb Blank Voltage Value	$4.5V \pm 0.1V$	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
16	Advanced Setup	Settings of the advanced setup	Correctly Setup	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
17	Sensor Level Setup	Blood Sample Sensor	2.30V to 2.4V	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
		Fluorescent Reagent Sensor	2.30V to 2.4V	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK



2. Instrument Installation Operational Performance Checklist

a. Background Test

S.No.	Inspection Item	Description	Acceptance Criteria	Obtained Value	Result	Remarks
1	Background	WBC	$\leq 0.2 \times 10^9 / L$	$0.0 \times 10^9 / L$	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
		RBC	$\leq 0.02 \times 10^{12} / L$	$0.0 \times 10^{12} / L$	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
		Hgb	$\leq 0.1 \text{ gm} / L$	$0.0 \text{ gm} / L$	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
		PLT	$\leq 10 \times 10^9 / L$	$0 \times 10^9 / L$	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK



b. Carry-Over Test

S.No.	Inspection Item	Description	Acceptance Criteria	Obtained Value	Result	Remarks
2	Carryover	WBC	$\leq 0.50\%$	0.10%	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
		RBC	$\leq 0.50\%$	0.00%	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
		Hgb	$\leq 0.60\%$	0.00%	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
					<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	
		PLT	$\leq 1.00\%$	0.00%	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK



c. Repeatability Test

S.No.	Inspection Item	Description	Acceptance Criteria	Obtained Value	Result	Remarks
3	Repeatability	WBC	$\leq 2.5\%$	0.8%	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
		RBC	$\leq 1.5\%$	0.9%	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
		Hgb	$\leq 1.5\%$	0.5%	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK
		PLT	$\leq 4.0\%$	2.1%	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail	OK

