



Installation Qualification for Mindray BC-20S Sr. No.:- TK-94006141

Customer Name : SAANVI PATHOLOGY
Customer Address : Infront of district hospital chhatarpur Madhya Pradesh- 471001
Contact Person : Mr. Bhuvan shantanu
Instrument Model : BC 20S
Serial No. : TK-94006141
Date Of installation : 01-03-2023

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: Saanvi pathology, Infront of district hospital Chhatarpur Madhya Pradesh- 471001

MRIN, Technical Services Department

Name	: Kali	Contact Person	: Varun K Sharma
Designation	: Sr. Service Engineer	Designation	: Asst. Application Manager
Signature	: 		: 

Installation Certificate For BC-20S Sr. No.:- TK-94006141

This is to certify that the instrument BC-20S Sr. No.:- TK-94006141 is successfully installed and commissioned at : Saanvi pathology, Infront of district hospital Chhatarpur Madhya Pradesh- 471001, : and the Installation Protocol/ checklist has been Successfully completed for the above Instrument.

Date of Installation : 01/03/2020

MRIN, Technical Services Department

Name : Kali



Designation : Sr. Service Engineer

Installation Qualification for Mindray BC-20S Sr. No.:- TK-94006141

Customer Name : Saanvi pathology, Infront of district hospital Chhatarpur

Madhya Pradesh- 471001

Instrument Name : BC-20S

Serial No : TK-94006141

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 required accessories as required.

Intallation 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.**

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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 operators Training And Qualifications

For MRIN, Technical Services Department

Name : Kali

Designation : Sr. Service Engineer

Performance Qualification for BC-20S Sr. No.:- TK-94006141

Calibration Parameters

Checked and found all the control [parameters to be with in 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 thenecessary criteria outlined inthis Performance Qualification Protocol, or exceptional conditions have been identified and documentation included.

The system is ready for Specific Usage.

Protocol Performed By:

Name : Varun Kumar Sharma

Designation :Asst. Application Manager

PERFORMANCE QUALIFICATION DONE BY

Name : Varun Kumar Shrama

Designation : Asst. Application Manager


Operation Qualification for BC-20S Sr. No.:- TK-94006141

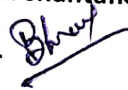
System Certification:

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 : MRIN, Ahmedabad
Name: Kali 
Designation: Sr. Service Engineer

Customer Authorization : Saanvi pathology, Infront of district hospital Chhatarpur
Madhya Pradesh- 471001
Name : Mr. Bhuvan shantanu
Designation : Lab Owner 

Company Representative Name And Sign

Mr. Kali 

Date: 01/03/2020

Customer Name And Sign

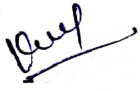
Mr. Bhuvan Shantanu 

Date: 01/03/2020

Operation Qualification for BC-20S Sr. No.:- TK-94006141

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

MRIN, Technical Services Department

Name : Kali 

Designation : Sr. Service Engineer

Date : 01/03/2020

Instrument Setup

1. Assembled the instrument accessories.
2. Removed the shipping Clamps.
3. Connected the LYSE REAGENT .
4. Connected the DILUENT REAGENT.
5. Connected the Waste Tubing
6. Connected the Power cord and connection cord.
7. Initialise the machine and follow the installation procedure.

Bill

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.

MRIN, Technical Services Dpartment

Name : Kali 

Designation : Sr. Service Engineer

Calibration Certificate BC 20S			
Customer Name	SAANVI PATHOLOGY	Date	05.06.2023
Address	Infront of district hospital Chhatarpur, Madhya Pradesh-471001		
Instrument Model	Mindray BC 20S	Date of Calibration	05.06.2023
Serial No	TK-94006141	Calibrator Lot Number	PLUS0318
		Calibrator Expiry date	28/8/2023

Calibration Values	Parameter	Target	Range	Mean of Measured Values	Factor	Old Factor
	WBC x 10 ³ /μl	9.5	9.3-9.70	9.817	100	96.77
	RBC x10 ⁶ /μl	4.5	4.47-4.63	4.497	100	101.18
	HGB g/dl	13.8	13.6-14	14.17	98	95.39
	MCV fl	96	94-98	92.75	100	103.5
	PLT x 10 ³ /μl	254	242-266	248.6	105	97.17

It is hereby certified that the Mindray BC 20S hematology analyzer installed at SAANVI PATHOLOGY has been calibrated using the standard reference material PLUS 0318. This certificate is valid for 1 year from date of calibration.

With Regards,



Mindray India Pvt Ltd.

L-J QC Table

File No.: 3
 Lot No.: DH2307H
 Mode: Whole Blood
 Exp. Date: 05/09/2023
 Level: High
 QC Type: QC Sample In.

Date	Time	WBC	Neu#	Lym#	Mon#	Eos#	Bas#	Neu%	Lym%	Mon%	Eos%	Bas%
04/08/2023	12:06	20.70	12.60	4.12	1.11	2.24	0.41	62.8	20.5	5.5	11.1	2.0
		2.50	2.45	1.45	1.11	2.24	0.41	12.0	7.0	5.5	11.1	2.0
		17.82	11.78	2.96	1.12	1.96	0.41	66.1	16.6	6.3	11.0	2.3

NLR	PLR	RBC	HGB	HCT	MCV	MCH	MCHC	RDW-CV	RDW-SD	PLT	MPV	PDW-CV	PDW-SD	PCT	P-LCC	P-LCR
3.98	150.00	4.49	16.9	53.6	100.0	31.5	31.5	15.4	56.0	484	8.9	0.137	13.6	0.431	110	22.7
		0.30	8.0	2.4	5.0	2.5	3.0	3.0	8.0	60	3.0	0.050	5.0	0.200	35	10.0
		16.2	1	45.5	101.3	1	36.0	13.7	50.7	444	9.1	0.133	12.9	0.405	100	22.4

L-J QC Table

File No.: 2
 Lot No.: DH2307N
 Mode: Whole Blood
 Exp. Date: 05/09/2023
 Level: Normal

Date	Time	WBC	Neu#	Lym#	Mon#	Eos#	Bas#	Neu%	Lym%	Mon%	Eos%	Bas%
04/08/2023	12:04	8.73	4.92	2.65	0.44	0.73	0.43	56.4	30.3	5.0	8.3	5.0
		1.00	1.05	0.70	0.44	0.73	0.43	12.0	8.0	5.0	8.3	5.0
		8.03	4.54	2.44	0.42	0.63	0.46	56.5	30.4	5.2	7.9	5.7

NLR	PLR	RBC	HGB	HCT	MCV	MCH	MCHC	RDW-CV	RDW-SD	PLT	MPV	PDW-CV	PDW-SD	PCT	P-LCC	P-LCR
1.86	90.16	3.87	13.2	42.1	90.6	28.4	31.4	16.8	55.1	242	8.6	0.137	13.3	0.209	51	21.2
		2.24	6.0	2.0	5.0	2.5	3.0	3.0	8.0	40	3.0	0.050	5.0	0.100	25	10.0
		12.8	1	35.3	91.2	1	33.2	15.0	49.9	220	8.9	0.136	12.9	0.195	48	21.9

L-J QC Table

File No.: 1
 Lot No.: dh2307
 Mode: Whole Blood
 Exp. Date: 05/09/2023
 Level: Low
 QC Type: CBC-5

Date	Time	WBC	Neu#	Lym#	Mon#	Eos#	Bas#	Neu%	Lym%	Mon%	Eos%	Bas%
04/08/2023	12:01	3.72	1.87	1.44	0.18	0.23	0.31	50.0	38.6	4.9	6.3	8.2
		0.50	0.45	0.35	0.18	0.23	0.31	12.9	9.0	4.9	6.3	8.2
		3.46	1.69	1.38	0.14	0.25	0.27	49.1	39.8	4.0	7.1	7.8

NLR	PLR	RBC	HGB	HCT	MCV	MCH	MCHC	RDW-CV	RDW-SD	PLT	MPV	PDW-CV	PDW-SD	PCT	P-LCC	P-LCR
1.22	37.68	1.97	5.6	18.1	78.8	24.6	31.2	18.4	52.5	44	8.2	0.138	13.2	0.360	8	17.9
		0.18	4.0	1.5	5.0	2.5	3.0	3.0	8.0	20	3.0	0.050	5.0	0.360	8	10.0
		5.3	1	15.4	78.2	26.7	34.2	17.3	48.9	52	8.0	0.136	11.6	0.041	9	17.2