


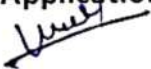
Installation Qualification for Mindray BC-20S Sr. No.:- TK-94006141

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.

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 BC -20S Sr. No.:- TK-94006141

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

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. Appplication Manager


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

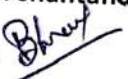
System Certification:

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

L-J QC Table

File No.: 3
 Lot No.: DH2307N
 Mode: Whole Blood
 Exp.Date: 05/09/2023
 Level: High

QC Type: High
 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	2.74	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

L-J QC Table

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

QC Type: 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
186	90.16	4.65	13.2	42.1	90.6	28.4	31.4	16.8	55.1	242	8.6	0.137	13.3	0.209	51	212
		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	100
		3.87	12.8	1 35.3	91.2	1 33.2	1 36.3	15.0	49.9	220	8.9	0.136	12.9	0.195	48	219

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
122	37.68	2.30	5.6	18.1	78.8	24.6	31.2	18.4	52.5	44	8.2	0.138	13.2	0.360	8	179
		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	100
		1.97	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	172

CALIBRATION DATA

SMP NO/TIME	WBC	RBC	HGB	HCT	PLT
SCS1	6.80	4.41	12.3	34.00	258
SCS2	6.90	4.42	12.3	34.00	261
SCS3	6.90	4.38	12.3	33.60	257
SCS4	6.70	4.36	12.3	33.40	259
SCS5	6.80	4.42	12.3	33.90	264
MEAN	6.82	4.398	12.30	33.78	259.8
Acceptable Limits	6.51 - 7.09	4.320 - 4.497	12.11 - 12.36	33.06 - 34.55	250.3 - 276.7
Result	PASS	PASS	PASS	PASS	PASS

(Traceability System) :

The traceability system of Mindray Hematology analyzers are shown in attached sheet.



Sheetal Dixit
(Head- Products & Marketing)For

MIN/MED/2023-2024/105535
05th june 2023

CALIBRATION CERTIFICATE

This is to certify that the Hematology Analyzer VectorVec5deff bearing serial number:
TX94006141 installed at Saanvi Pathology Lab
as calibrated on 05th june 2023.

Calibrator : ABX
MINOCALLot No. :
CX460
Expiry Date : 25th oct 2023

The reports of Blank Cycle, Repeatability and Calibration Values were all found unacceptable range.

Next calibration cycle is due on 04th june 2024.



Sheetal Dixit
(Head- Products & Marketing)
For