

Customer: HEER CLINICAL LABORATORY

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Equipment: BC760 Auto Hematology Analyzer

Title: IQ,OQ & PQ DOCUMENT

Doc. No. : TMQ/180123/HEER/BC760

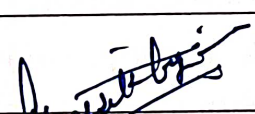
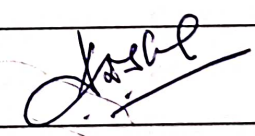
Installation Qualification for Mindray BC760 Sr. No.:- DG7-28000141

Customer Name : HEER CLINICAL LABORATORY
Contact Person : DR. ANIL SHAH
Instrument Model : BC760
Serial No. : DG7-28000141
Date Of installation : 18/01/2023

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: HEER CLINICAL LABORATORY

116,National Plaza,Opp. Aurvadic College,Lal Darwaja Road,Surat.

Service Engineer		Customer	
Signature:		Signature:	

TANISH MEDIQUIP

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Customer: HEER CLINICAL LABORATORY

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Equipment: BC760 Auto Hematology Analyzer

Title: IQ,OQ & PQ DOCUMENT

Doc. No. : TMQ/180123/HEER/BC760

Installation Qualification for Mindray BC760 Sr. No.:- DG7-28000141

Customer Name : HEER CLINICAL LABORATORY

Contact Person : DR. ANIL SHAH

Instrument Model : BC760

Serial No. : DG7-28000141

Date Of installation : 18/01/2023

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.

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.

Installation Qualification for BC760 Sr. No.:- DG7-28000141

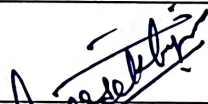
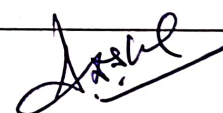
Carried out all the installation procedures as per the installation procedure and checklists.

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

TMQ , Technical Services Department

Service Engineer		Customer	
Signature:		Signature:	

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Equipment: BC760 Auto Hematology Analyzer

Title: IQ,OQ & PQ DOCUMENT

Doc. No. : TMQ/180123/HEER/BC760

Installation Certificate For BC760 Sr. No.- DG7-28000141

This is to certify that the instrument BC760 Sr. No:- DG7-28000141 is successfully installed and commissioned at :



HEER CLINICAL LABORATORY

116,National Plaza,Opp. Aurvadic College,Lal Darwaja Road,Surat

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

Date of Installation : 18/01/2023

TMQ, Technical Services Department

Service Engineer		Customer	
Signature:		Signature:	

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Equipment: BC760 Auto Hematology Analyzer

Title: IQ,OQ & PQ DOCUMENT

Doc. No. : TMQ/180123/HEER/BC760

Operational Qualification:

System Certification:

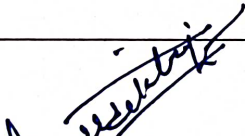
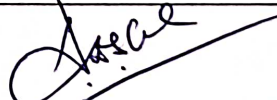
Study data has determined that the system described in this document either meets all criteria outlined in this Operational Protocol, or exceptional conditions have been identified and documentation included.

Exceptional Conditions, If any Have been Addressed.

The System is ready for specific usage.

Customer Authorization : HEER CLINICAL LABORATORY

116,National Plaza,Opp. Aurvadic College,Lal Darwaja Road,Surat

Service Engineer		Customer	
Signature:		Signature:	

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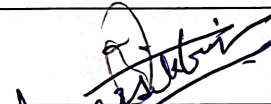
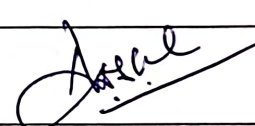
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Equipment: BC760 Auto Hematology Analyzer
Title: IQ, OQ & PQ DOCUMENT
Doc. No. : TMQ/180123/HEER/BC760

Operations Qualifications for BC760 Sr. No.- DG7-28000141

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

TMQ, Technical Services Department

Service Engineer		Customer	
Signature:		Signature:	

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Equipment: BC760 Auto Hematology Analyzer

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Title: IQ,OQ & PQ DOCUMENT

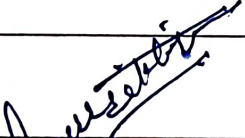

Doc. No. : TMQ/180123/HEER/BC760

Instrument Setup

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

Operational Instpection

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	
Signature:		Signature:	

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Equipment: BC760 Auto Hematology Analyzer

Title: IQ, OQ & PQ DOCUMENT

Doc. No. : TMQ/180123/HEER/BC760

Performance Qualification for Mindray BC760 Sr. No.: -DG7-28000141

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 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.

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Title: IQ,OQ & PQ DOCUMENT

Doc. No. : TMQ/180123/HEER/BC760

BACKGROUND TEST

MODEL : BC760

Serial No. : DG7-28000141

MODE : WB

Serial No.	DG7-28000141						
Mode	CT-WB-CD						
Substance	Blood sample						
Number of Summaries	5						
	Select	Date/Time	Operator	WBC	RBC	HGB	PLT
5	Yes	01-18-2023 04:27	service	0.01	0	0	0
4	Yes	01-18-2023 04:26	service	0	0	0	0
3	Yes	01-18-2023 04:26	service	0	0	0	0
2	Yes	01-18-2023 04:25	service	0	0	0	0
1	Yes	01-18-2023 04:24	service	0	0	0	0
Limit				0.1	0.02	0.1	3
Result				Pass	Pass	Pass	Pass

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Doc. No. : TMQ/180123/HEER/BC760

REPRODUCIBILITY TEST

MODEL : BC760

Serial No. : DG7-28000141

MODE : WB

Serial No.	DG7-28000141							
Mode	AL-WB-CD							
Substance	Blood sample							
Number of Summaries	7							
Lot No.								
	Select	Date/Time	Operator	WBC	RBC	HGB	MCV	PLT
10	Yes	01-18-2023	service	12.8	5.26	11.7	71.8	259
9	Yes	01-18-2023	service	13.48	5.27	11.5	71.6	262
8	Yes	01-18-2023	service	13.31	5.18	11.4	71.9	252
7	Yes	01-18-2023	service	13.15	5.23	11.6	71.7	259
6	Yes	01-18-2023	service	13.14	5.19	11.6	71.5	257
5	Yes	01-18-2023	service	12.96	5.18	11.3	71.8	260
4	Yes	01-18-2023	service	13.18	5.27	11.5	71.7	248
3	Yes	01-18-2023	service	13.26	5.07	11.3	71.8	235
2	Yes	01-18-2023	service	13.15	5.31	11.6	71.8	250
1	Yes	01-18-2023	service	13.28	5.18	11.2	71.6	256
Mean				13.17	5.24	11.6	71.7	255
SD				0.206	0.047	0.1	0.13	5.3
Min				12.8	5.18	11.4	71.5	248
Max				13.48	5.31	11.7	71.9	262
R				0.68	0.13	0.3	0.4	14
d(Min)				0.01	0.01	0	0	2
d(Max)				0.37	0.07	0.2	0.2	7
CV%				1.6	0.9	0.9	0.2	2.1
Limit(%)				2.5	1.5	1	1	4
Result				Pass	Pass	Pass	Pass	Pass

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Doc. No. : TMQ/180123/HEER/BC760

Serial No.	DG7-28000141									
Mode	AL-WB-CD									
Substance	Blood sample									
Number of Summaries	7									
Lot No.										
	Select	Date/Time	Operator	Neu#	Lym#	Mon#	Eos#	Bas#	IMG#	
10	Yes	01-18-2023	service	11.3	0.94	0.48	0.07	0.01	0.05	
9	Yes	01-18-2023	service	11.89	0.99	0.51	0.08	0.01	0.05	
8	Yes	01-18-2023	service	11.73	1.01	0.49	0.06	0.02	0.09	
7	Yes	01-18-2023	service	11.56	0.97	0.49	0.08	0.05	0.09	
6	Yes	01-18-2023	service	11.49	1.04	0.55	0.05	0.01	0.07	
5	Yes	01-18-2023	service	11.46	1	0.45	0.04	0.01	0.15	
4	Yes	01-18-2023	service	11.67	0.99	0.48	0.03	0.01	0.07	
3	Yes	01-18-2023	service	11.7	1.01	0.5	0.04	0.01	0.08	
2	Yes	01-18-2023	service	11.55	1.03	0.5	0.04	0.03	0.13	
1	Yes	01-18-2023	service	11.78	0.95	0.5	0.01	0.04	0.07	
Mean				11.6	1	0.5	0.06	0.02	0.08	
SD				0.188	0.035	0.024	0.02	0.015	0.028	
Min				11.3	0.94	0.48	0.03	0.01	0.05	
Max				11.89	1.04	0.55	0.08	0.05	0.13	
R				0.59	0.1	0.07	0.05	0.04	0.08	
d(Min)				0.04	0.01	0	0	0	0.01	
d(Max)				0.3	0.06	0.05	0.03	0.03	0.05	
CV%				1.6	3.5	4.9	33.3	76.4	35.6	
Limit(%)				6	6	16	20	30	25	
Result				Pass	Pass	Pass	Pass	Pass	Pass	

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Doc. No. : TMQ/180123/HEER/BC760

Serial No.	DG7-28000141								
Mode	AL-WB-CD								
Substance	Blood sample								
Number of Summaries	7								
Lot No.									
	Select	Date/Time	Operator	Neu %	Lym %	Mon %	Eos%	Bas %	IMG %
10	Yes	01-18-2023	service	88.2	7.4	3.8	0.5	0.1	0.4
9	Yes	01-18-2023	service	88.1	7.4	3.8	0.6	0.1	0.4
8	Yes	01-18-2023	service	88	7.6	3.7	0.5	0.2	0.7
7	Yes	01-18-2023	service	87.9	7.4	3.7	0.6	0.4	0.7
6	Yes	01-18-2023	service	87.4	7.9	4.2	0.4	0.1	0.5
5	Yes	01-18-2023	service	88.4	7.7	3.5	0.3	0.1	1.1
4	Yes	01-18-2023	service	88.5	7.5	3.7	0.2	0.1	0.5
3	Yes	01-18-2023	service	88.3	7.6	3.8	0.3	0	0.6
2	Yes	01-18-2023	service	87.9	7.8	3.8	0.3	0.2	1
1	Yes	01-18-2023	service	88.6	7.2	3.8	0.1	0.3	0.5
Mean				88	7.6	3.8	0.4	0.2	0.6
SD				0.34	0.21	0.18	0.15	0.11	0.22
Min				87.4	7.4	3.7	0.2	0.1	0.4
Max				88.5	7.9	4.2	0.6	0.4	1
R				1.1	0.5	0.5	0.4	0.3	0.6
d(Min)				0	0	0	0	0	0.1
d(Max)				0.6	0.3	0.4	0.2	0.2	0.4
CV%				0.4	2.7	4.6	34.1	64.9	36
Limit(%)				6	6	16	20	30	25
Result				Pass	Pass	Pass	Pass	Pass	Pass

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Doc. No. : TMQ/180123/HEER/BC760

Serial No.	DG7-28000141								
Mode	AL-WB-CD								
Substance	Blood sample								
Number of Summaries	7								
Lot No.									
	Select	Date/Time	Operator	HCT	MCH	MCH C	RDW-CV	RDW-SD	MPV
10	Yes	01-18-2023	service	37.8	22.3	31.1	18.2	48.8	10.7
9	Yes	01-18-2023	service	37.7	21.9	30.6	18.1	48.4	10.2
8	Yes	01-18-2023	service	37.3	22	30.6	18.1	48.7	10.5
7	Yes	01-18-2023	service	37.5	22.1	30.8	18.2	48.9	10.6
6	Yes	01-18-2023	service	37.1	22.4	31.3	18.3	49	10.8
5	Yes	01-18-2023	service	37.2	21.8	30.4	18.3	49	10.5
4	Yes	01-18-2023	service	37.8	21.9	30.5	18.2	49	10.4
3	Yes	01-18-2023	service	36.4	22.3	31.1	18.1	48.5	10.3
2	Yes	01-18-2023	service	38.2	21.8	30.4	18.2	49	10.4
1	Yes	01-18-2023	service	37.1	21.6	30.2	18.2	48.8	10.4
Mean				37.6	22.1	30.7	18.2	48.8	10.5
SD				0.36	0.22	0.34	0.07	0.22	0.2
Min				37.1	21.8	30.4	18.1	48.4	10.2
Max				38.2	22.4	31.3	18.3	49	10.8
R				1.1	0.6	0.9	0.2	0.6	0.6
d(Min)				0.1	0	0.1	0	0	0
d(Max)				0.6	0.3	0.6	0.1	0.4	0.3
CV%				1	1	1.1	0.4	0.5	1.9
Limit(%)				1.5	1.5	1.5	2	2	3
Result				Pass	Pass	Pass	Pass	Pass	Pass

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Serial No.	DG7-28000141								
Mode	AL-WB-CD								
Substance	Blood sample								
Number of Summaries	7								
Lot No.									
	Select	Date/Time	Operator	PDW	PCT	P-LCC	P-LCR	NRBC #	NRBC %
10	Yes	01-18-2023	service	16.9	0.289	91	35	0	0
9	Yes	01-18-2023	service	16.6	0.274	85	32.4	0	0
8	Yes	01-18-2023	service	16.6	0.275	88	34.7	0	0
7	Yes	01-18-2023	service	16.7	0.285	87	33.6	0	0
6	Yes	01-18-2023	service	16.9	0.292	91	35.5	0	0
5	Yes	01-18-2023	service	16.8	0.274	86	32.9	0	0
4	Yes	01-18-2023	service	16.5	0.261	81	32.6	0	0
3	Yes	01-18-2023	service	16.6	0.243	76	32.2	0	0
2	Yes	01-18-2023	service	16.7	0.269	82	32.6	0	0
1	Yes	01-18-2023	service	17.1	0.272	86	33.7	0	0
Mean				16.7	0.278	86	33.8	0	0
SD				0.15	0.0113	4	1.29	0	0
Min				16.5	0.261	81	32.4	0	0
Max				16.9	0.292	91	35.5	0	0
R				0.4	0.031	10	3.1	0	0
d(Min)				0	0.003	1	0.2	0	0
d(Max)				0.2	0.017	5	1.7	0	0
CV%				0.9	4.1	4.6	3.8	0	0
Limit(%)				10	5	15	15	25	25
Result				Pass	Pass	Pass	Pass	Pass	Pass

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Equipment: BC760 Auto Hematology Analyzer

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Serial No.	DG7- 28000141					
Mode	AL-WB-CD					
Substance	Blood sample					
Number of Summaries	7					
Lot No.						
	Select	Date/Time	Operator	IPF	PLT-I	PLT-H
10	Yes	01-18-2023	service	7	269	259
9	Yes	01-18-2023	service	7.4	268	262
8	Yes	01-18-2023	service	7.7	261	252
7	Yes	01-18-2023	service	6	269	259
6	Yes	01-18-2023	service	6.4	272	257
5	Yes	01-18-2023	service	6.7	262	260
4	Yes	01-18-2023	service	6.9	252	248
3	Yes	01-18-2023	service	6	237	235
2	Yes	01-18-2023	service	6.2	259	250
1	Yes	01-18-2023	service	6.6	261	256
Mean				6.8	264	255
SD				0.63	7.2	5.3
Min				6	252	248
Max				7.7	272	262
R				1.7	20	14
d(Min)				0.1	3	2
d(Max)				0.9	12	7
CV%				9.3	2.7	2.1
Limit(%)				25	4	4
Result				Pass	Pass	Pass

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EMAIL- TANISHMEDIQUIP@GMAIL.COM

Customer: HEER CLINICAL LABORATORY

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Equipment: BC760 Auto Hematology Analyzer

Title: IQ, OQ & PQ DOCUMENT

Doc. No. : TMQ/180123/HEER/BC760

CARRYOVER TEST

Serial No.	DG7-28000141						
Mode	OV-WB-CBC						
Substance	Blood sample						
	Date/Time	Operator	WBC	RBC	HGB	HCT	PLT
High-Level 1	01-18-2023	service	7.28	4.26	14.8	46.5	200
High-Level 2	01-18-2023	service	7.74	4.29	14.9	46.8	207
High-Level 3	01-18-2023	service	7.52	4.29	14.9	46.6	210
Low-Level 1	01-18-2023	service	0	0	0	0	0
Low-Level 2	01-18-2023	service	0	0	0	0	0
Low-Level 3	01-18-2023	service	0	0	0	0	0
Carryover%			0.00%	0.00%	0.00%	0.00%	0.00%
Limit%			≤1.0%	≤1.0%	≤1.0%	≤1.0%	≤1.0%

Customer: HEER CLINICAL LABORATORY

Page 1 of 5

Equipment: BC760 Auto Hematology Analyzer

Title: Calibration Certificate

Doc. No. : TMQ/180123/HEER/BC760

Calibration Certificate

Customer Name

HEER CLINICAL LABORATORY – SURAT.

Model

Fully Automated 5-Parts Cellcounter Mindray BC760

Serial no.

DG7-28000141

Calibration Date

21/04/2023

This is to certify that the above mentioned product has been calibrated for 5 parameters (WBC,RBC,HGB,MCV and PLT) according to standard procedure provided by Manufacturer.



Service Engineer,

Tanishh MediQuip,

Surat.

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Customer: HEER CLINICAL LABORATORY

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Equipment: BC760 Auto Hematology Analyzer

Title: Calibration Certificate

Doc. No. : TMQ/180123/HEER/BC760

BACKGROUND TEST

MODEL : BC760

Serial No. : DG7-28000141

MODE : WB

Serial No.	DG7-28000141						
Mode	CT-WB-CD						
Substance	Blood sample						
Number of Summaries	5						
	Select	Date/Time	Operator	WBC	RBC	HGB	PLT
5	Yes	04-21-2023 14:54	service	0	0	0	0
4	Yes	04-21-2023 14:53	service	0	0	0	0
3	Yes	04-21-2023 14:53	service	0	0	0	0
2	Yes	04-21-2023 14:52	service	0	0	0	0
1	Yes	04-21-2023 14:51	service	0	0	0	0
Limit				0.1	0.02	0.1	3
Result				Pass	Pass	Pass	Pass

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Customer: HEER CLINICAL LABORATORY

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Equipment: BC760 Auto Hematology Analyzer

Title: Calibration Certificate

Doc. No. : TMQ/180123/HEER/BC760

REPRODUCIBILITY TEST

MODEL : BC760

Serial No. : DG7-28000141

Serial No.	DG7-28000141							
Mode	AL-WB-CD							
Substance	Blood sample							
Number of Summaries	9							
Lot No.								
	Select	Date/Time	Operator	WBC	RBC	HGB	MCV	PLT
10	Yes	04-21-2023 15:05	service	6.01	5.34	14.1	79.9	212
9	Yes	04-21-2023 15:04	service	5.89	5.32	14	79.7	218
8	Yes	04-21-2023 15:04	service	5.73	5.31	14.2	79.7	201
7	No	04-21-2023 15:03	service	5.97	5.39	14.4	79.9	212
6	Yes	04-21-2023 15:02	service	6.05	5.25	14	79.9	203
5	Yes	04-21-2023 15:01	service	5.94	5.29	14.1	80	210
4	Yes	04-21-2023 15:01	service	5.87	5.18	14	79.9	210
3	Yes	04-21-2023 15:00	service	5.93	5.36	14.1	79.8	214
2	Yes	04-21-2023 14:59	service	5.93	5.29	14.2	79.8	215
1	Yes	04-21-2023 14:58	service	6.04	5.2	14.1	79.8	204
Mean				5.93	5.28	14.1	79.8	210
SD				0.099	0.061	0.07	0.1	5.9

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Customer: HEER CLINICAL LABORATORY

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Equipment: BC760 Auto Hematology Analyzer

Title: Calibration Certificate

Doc. No. : TMQ/180123/HEER/BC760

Min				5.73	5.18	14	79.7	201
Max				6.05	5.36	14.2	80	218
R				0.32	0.18	0.2	0.3	17
d(Min)				0	0.01	0	0	0
d(Max)				0.2	0.1	0.1	0.2	9
CV%				1.7	1.2	0.5	0.1	2.8
Limit(%)				2.5	1.5	1	1	4
Result				Pass	Pass	Pass	Pass	Pass

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Customer: HEER CLINICAL LABORATORY

Equipment: BC760 Auto Hematology Analyzer

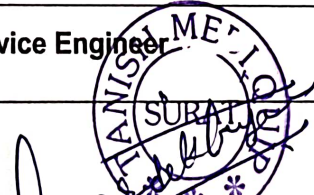
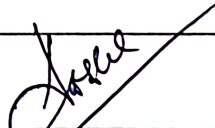
Title: Calibration Certificate

Doc. No. : TMQ/180123/HEER/BC760

Calibration Data

Lot No.	PLUS042 3		Exp. Date	05-05- 2023		
Operator	Admin		Calibration complete time	04-21- 2023		
WB calibration data						
	Select	WBC	RBC	HGB	MCV	PLT
Target		9.02	4.4	12.8	91.4	251
WB 1#	Yes	9.54	4.17	12.9	91.4	238
WB 2#	Yes	9.84	4.18	12.8	91.3	240
WB 3#	Yes	9.36	4.18	12.7	91.3	232
WB 4#	Yes	9.75	4.24	13	91.3	236
WB 5#	No	9.87	4.23	12.8	91.2	249
WB 6#	Yes	9.64	4.25	13	91.3	237
WB 7#	Yes	9.74	4.21	12.9	91.3	235
WB 8#	No	10.07	4.21	12.8	91	237
WB 9#	Yes	9.55	4.19	12.8	91.2	236
WB 10#	Yes	9.65	4.06	12.7	91.1	229
Mean		9.63	4.19	12.8	91.3	235
CV%		1.561	1.391	0.89	0.09	1.5
Old Factor (%)		100	103	100	100	100
New Factor (%)		93.63	105.09	99.71	100.15	106.59

Protocol Performed By:

Service Engineer		Customer	
Signature:		Signature:	

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