

IQ, OQ & PQ PROTOCOL

FOR

CBS 400

Na/K/Cl/iCa Electrolyte Analyser

Imported & Marketed by:

B&E Diagnostics India Pvt. Ltd.

Shed No.18, 19/& 20, Shankheshwar Industrial Estate, Tajpur Road, Sarkhej-Bavla Highway
Changodar - 382213 Ahmedabad - India

Authorised Distributor – Sales & Service:

Brundavana Bio Medicals, Hubli

Customer Name:

SUMUKH PRAYOGALAYA

QC DATA REPORT

MODEL: CBS400

S/N: BE023945

LOT NO. I0064

EXP: November 2023

K+	Accuracy & Precision		
QC Level	Low	Norma I	High
Target value:	2.12	3.97	6.05
Low limit:	1.60	3.46	5.53
High limit:	2.64	4.48	6.57
Date:	28/1/2023		
	2.09	3.97	6.09
	2.11	3.98	6.09
	2.10	3.98	6.09
Mean	2.23	4.05	6.15
SD	0.01	0.00	0.00
CV	0.00	0.00	0.00
CV Limit	1.00	1.00	1.00
Accuracy	Pass	Pass	Pass
Precision	Pass	Pass	Pass

Na+	Accuracy & Precision		
QC Level	Low	Norma I	High
Target value:	118.00	140.6	160.2
Low limit:	112.40	134.93	154.53
High limit:	123.6	146.27	165.87
Date:	28/1/2023		
	119.5	142.5	161.7
	119.8	142.5	161.7
	119.8	142.5	161.7
Mean	119.5 3	139.17	161.50
SD	0.17	0.00	0.00
CV	0.00	0.00	0.00
CV Limit	1.00	1.00	1.00
Accuracy	Pass	Pass	Pass
Precision	Pass	Pass	Pass

Cl-	Accuracy & Precision		
QC Level	Low	Norma I	High
Target value:	81.5	102.10	120.00
Low limit:	76.91	97.62	115.51
High limit:	86.09	106.58	124.49
Date:	28/1/2023		
	83.0	103.2	120.1
	83.0	103.5	120.5
	83.3	103.2	120.5
Mean	80.1 7	100.57	119.3 7
SD	0.17	0.17	0.23
CV	0.00	0.00	0.00
CV Limit	1.00	1.00	1.00
Accuracy	Pass	Pass	Pass
Precision	Pass	Pass	Pass

iCa	Accuracy & Precision		
QC Level	Low	Norma I	High
Target Valve:	0.75	1.16	1.59
Low limit:	0.56	0.97	1.40
High limit:	0.94	1.35	1.78
Date:	28/1/2023		
	0.77	1.17	1.60
	0.78	1.18	1.61
	0.76	1.17	1.59
Mean	0.77	1.17	1.59
SD	0.10	0.04	0.05
SV	0.00	0.00	0.00
CV Limit	1.00	1.00	1.00
Accuracy	Pass	Pass	Pass
Precision	Pass	Pass	Pass

Performance Qualification

INSTRUMENT PERFORMANCE:

Slope Values: K 63.2
 Na 61.7
 Cl -63.9
 iCa 26.2

Air Sensor: Liquid:921 (NR> 700)
 Air: 460 (NR< 540)

Pump
 Calibration: Pump Rate: 1.046
 (0.9-1.1)

Accuracy: Mean must fall within Low and High Limit.

K+	Accuracy & Precision		
	Low	Normal	High
QC Level			
Target value:	2.12	3.97	6.05
Low limit:	1.60	3.46	5.53
High limit:	2.64	4.48	6.57
Date:	28/1/2023		
	2.09	3.97	6.09
	2.11	3.98	6.09
	2.10	3.98	6.09
Mean	2.10	3.98	6.09
SD	0.01	0.00	0.00
CV	0.00	0.00	0.00
CV Limit	1.00	1.00	1.00
Accuracy	Pass	Pass	Pass
Precision	Pass	Pass	Pass

Precision: CV must be equal to or less than the CV Limit.

Na+	Accuracy & Precision		
	Low	Normal	High
QC Level			
Target value:	118.00	140.6	160.2
Low limit:	112.40	134.93	154.53
High limit:	123.6	146.27	165.87
Date:	28/1/2023		
	119.5	142.5	161.7
	119.8	142.5	161.7
	119.8	142.5	161.7
Mean	119.7	142.5	161.7
SD	0.17	0.00	0.00
CV	0.00	0.00	0.00
CV Limit	1.00	1.00	1.00
Accuracy	Pass	Pass	Pass
Precision	Pass	Pass	Pass

CI-	Accuracy & Precision		
QC Level	Low	Normal	High
Target value:	81.5	102.10	120.00
Low limit:	76.91	97.62	115.51
High limit:	86.09	106.58	124.49
Date:	28/1/2023		
	83.0	103.2	120.1
	83.0	103.5	120.5
	83.3	103.2	120.5
Mean	83.1	103.30	120.37
SD	0.17	0.17	0.23
CV	0.00	0.00	0.00
CV Limit	1.00	1.00	1.00
Accuracy	Pass	Pass	Pass
Precision	Pass	Pass	Pass

iCa	Accuracy & Precision		
QC Level	Low	Normal	High
Target Value:	0.75	1.16	1.59
Low limit:	0.56	0.97	1.40
High limit:	0.94	1.35	1.78
Date:	28/1/2023		
	0.77	1.17	1.60
	0.78	1.18	1.61
	0.76	1.17	1.59
Mean	0.77	1.17	1.59
SD	0.10	0.04	0.05
CV	0.00	0.00	0.00
CV Limit	1.00	1.00	1.00
Accuracy	Pass	Pass	Pass
Precision	Pass	Pass	Pass

CONTENTS:

- (1) GENERAL INSTRUCTIONS.**
- (2) A. INSTALLATION QUALIFICATION (I.Q.)**
B. INSTALLATION PROCEDURE.
- (3) A. OPERATIONAL QUALIFICATION (O.Q)**
B. OPERATOR MAINTENANCE PROTOCOL.
- (4) PERFORMANCE QUALIFICATIONS (P.Q.)**

(1) GENERAL INSTRUCTIONS:

- Authorised distributor of B&E Diagnostics India Pvt. Ltd. is responsible for installation of CBS 400, Fully Automated Na/K/Cl/iCa Electrolyte Analyser, at **SUMUKH PRAYOGALAYA** as per the attached protocol.
- An authorized B&E Diagnostics India Pvt. Ltd., representative will physically check the system and proceed for the installation.
- This installation protocol will be followed as specified by the manufacturer.
- Installation checks will also be performed to verify that the instrument has been installed with proper connections and utilities.
- An authorized B&E Diagnostics India Pvt. Ltd. representative will also perform the precision check on the system to check if it is as per the claim of the manufacturer.
- The results obtained for Precision checks will be verified by the qualified trained employee of Brundavana Bio Medicals. Along with an authorized B&E Diagnostics India Pvt. Ltd. representative.
- On completion of the Installation all the necessary documents of the System checks will be used to evaluate the instrument installation in accordance with the manufacturer's protocol and intended use.
- An authorized B&E Diagnostics India Pvt. Ltd. representative will verify the documents of the system checks and approve the same.
- Successful completion of this protocol will verify that this instrument has been installed in accordance with the intended usage

(2) A. INSTALLATION QUALIFICATION

1. Installation Requirement:

Sr. No.	Description	Compliance Yes/No	Verified by & Date
1.	Environmental conditions as per required. Ref: (Instrument User Manual)	Yes	28/01/2023
2.	Physical Space Requirement as per Ref: (Instrument User Manual)	Yes	28/01/2023
3.	Electrical Requirements Ref: (Instrument User Manual)	Yes	28/01/2023
4.	UPS connection available.	Yes	

2. The instrument has been checked for the following:

Sr. No.	Verification	Provided Yes/No	Verified by & Date
1.	Instrument is identified Instrument Serial No (Customer)	Yes BE 02 39 45	28/01/2023
2.	Specifications are included : Ref: (Instrument User Manual)	Yes	28/01/2023
3.	Accessories / consumables are listed as per checklist	Yes	28/01/2023

4.	System checked for any External / physical damage.	Ye s	28/01/202 3
5.	Instrument User Manual	Ye s	28/01/202 3

3. Equipment Description:

CBS 400, Fully Automated Na/K/Cl/iCa Electrolyte Analyser

Instrument Identification	Verified Yes/No	Verified by / Date
Equipment Type : Na/K/Cl/iCa Electrolyte Analyser	Yes	28/01/2023
Model : CBS 400	Yes	
Manufacturer : B&E Bio-technology Co. Ltd.	Yes	
Marketed By : B&E Diagnostics India Pvt. Ltd.	Yes	28/01/2023
Equipment # : One	Yes	28/01/2023
Serial Number :	BE023945	
Dimensions : 455*275*480 mm (H*W*D)	Yes	
Power Supply: AC 110V to 220V 50Hz to 60Hz Power Consumption: ≤80W	Yes	28/01/2023

4. Accessories/Consumables:

The accessories were supplied with the instrument as per the check list. Check & verified in case they are found to be in order.

Qualified trained employee name	Verified By	Date
Maheshgouda T Patil		28/01/2023

5. Preventive Maintenance:

The routine preventive maintenance of the system will be carried out by Brundavana Bio Medicals engineer at a specified time interval as recommended by the manufacturer.

6. Spare Parts:

B&E Diagnostics India Pvt. Ltd. strongly recommends the end user & Brundavana Bio Medicals to maintain a basic consumable parts onsite to minimize down time due to minor failures. We will provide the list of such consumable parts to the user on request.

(2)B. INSTALLATION PROCEDURE:

1. Putting the system at the predefined and pre inspected location
2. Removal of the internal packing material of the system.
3. Place the Instrument on the bench top.
4. Connect the Power cord to the CBS 400.
6. Connect the reagents tubing and reagent to the Instrument.
7. All the operating software has been loaded in to CBS 400.
8. Now from back of the instrument turn the power switch ON. CBS 400 goes through its power up and self-test sequence.
9. The CBS 400 **Main Menu** is displayed after the start up sequence is complete

Conclusion: Instrument has been qualified for Installation. Hence it has been taken for Installation Qualification.

(3) A. OPERATIONAL QUALIFICATION:

1. Instrument Identification:

Instrument Name: CBS 400

Serial Number: BE023945

2. Following is the list of actions performed and verified for running the system routinely.

Please refer Instrument programming in operation manual step by step

Test No.	Test Name	Test Purpose	Method	Verified Date
1.	SYSTEM SWITCH ON	TO CHECK THE ERROR FREE POWER UP.	Switch on the main, switch on the system. System will perform the self-test Sequence. CBS 400 MAIN MENU is displayed after the completion. Check for any errors on the screen.	28/01/2023
2.	PRINTER TEST	TO CHECK STATUS OF THE PRINTER.	Initiate a self-test of printer or run a sample to check the print.	28/01/2023
3.	REAGENT STATUS	TO CHECK ADEQUATE REAGENT IS AVAILABLE FOR ANALYSIS	Manually check in the reagent bottles.	28/01/2023

3. Operator Training Record:

Operator Training: The users responsible for the operation of this instrument will be trained on the proper usage of the system. Training will focus on the basic operation and maintenance of the system. The training of the operators will be documented and the training records will be filled as indicated below:

Sr · N o.	Operator s	Designation	Name & Sign of the Trainer.	Date
1.	Nagaraj Hosamani	Lab Technician	Maheshgouda T Patil	28/01/2023
2.	Anjaneya.K	Lab Technician		28/01/2023
3.	Bhargavi	Lab Technician		28/01/2023
4.	Veena B.K	Lab Technician		28/01/2023
5.	Revan Belageri	Lab Technician		28/01/2023

4. Comments:

Training has been given successfully to all the responsible laboratory staff of Sumukh Prayogalaya to handle the software, operation and maintenance of this system.

(3)B. OPERATOR MAINTENANCE PROTOCOL : As per S.O.P. given.

Conclusion:

Instrument has been qualified for Operation. Hence it has been taken for Operational Qualification.

(4) PERFORMANCE QUALIFICATION:



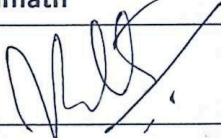
Instrument Name: CBS 400

Serial Number: BE023945

B. Following is the list of test performed and verified

Repeatability, tests for Precision. Checked and found to be acceptable.
Calibration Value: Tested and found to be acceptable.
Quality Control (QCB-1, 2, 3): Checked and found to be acceptable.

Report Sign Off

Prepared by:		
Name:	Maheshgouda T Patil	
Title: Engineer Sales and Service		Date: 28/01/2023
Reviewed by:		
Name:	Dr. Vaishali Choukimath	
Title: Consultant Pathologist	Sign: 	Date: 28/01/2023
Approved by:		
Name:	Dr. Vashali Choukimath	
Title:	Sign: 	Date: 28/01/2023

Conclusion:

Instrument has been qualified for Performance. Hence it has been taken for Performance Qualification.

For, B & E Diagnostics India Private Limited


(Authorised Signatory)