Done



2. Clean the rotory valave

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#### MANJERI CLINICAL LABORATORY &IDEAL X-RAYS, MANJERI

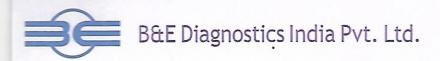
PPM CHECKLIST FOR ELECTROLYTE ANALYZER

#### CBS 300 ELECTROLITE ANALYZER SERIAL NO: BE010802 I. SPECIAL PRECAUTIONS If there is evidence of blood or serum contamination, submit the device for cleaning and decontamination before inspecting it. Wear appropriate Personnel Protection Equipment (PPE) during work. Refer to the Safety procedure for additional precautions and guidance. **II. TEST APPARATUS REQUIRED** 1.ELECTROLYTE ANALYZER Model: CBS 300 Serial:BE010314 Description status Description status Passed Passed 1. AC Plug 8. Rotory Valve Passed 2. Line Cord Passed 9. Fluid Flow 3. Fuse Passed 10. Indicator Passed 4. Tubes Passed 11. Display Passed 5. Connectors Passed 12. User Calibration Passed 6. Electrode Value Passed Passed 13. Pump Tube 7. Controls Passed 14. Pinch Valve Passed 15. Air Sensor Passed **III. PREVENTIVE MAINTENANCE TASKS** status Description Description status 1. Clean the whole tubings Done 3. Replace Deteriorated components Done

4. Lubricate

Done

			IV. G	UALITY CO	ONTROL DAT	·A			
	1	N-		I					
Quality Control	Target	Na+ Measured Value	Range	Target	K+ Measured Value	Range	Target	CI- Measured Value	Range
Level -1	118.0	118.2	1.87	2.12	2.28	0.17	81.5	81.6	1.53
Level -2	140.6	140.6	1.89	3.97	4.05	0.17	102.1	101.5	1.49
Level -3	160.2	161	1.89	6.05	6.03	0.17	120	119.5	1.5
				V. SUM	IMARY				
NOTES				v. 30W	IIWAN				
		the instrumnet			el Quality Cont	trols. Instrur	ment is worl	king perfectly.	
Completed by Customer Signa		nature:			Date :				
						17-09-2021			
Verified by:					Time: 4.30 PM				





# IQ, OQ & PQ PROTOCOL

F

0

R

CBS 300

Na/K/Cl 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:
Insignia Biomedical

## 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 300, Fully Automated Na/K/Cl Electrolyte Analyser, at (Insignia Biomedical) 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 Insignia Biomedical. 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. <u>Installation Requirement:</u>

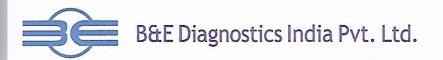
Sr. No.	Description	Complian ce Yes/No	Verified by & Date
1.	Environmental conditions as per required.  Ref: (Instrument User Manual)	Yes	15/09/2 021
2.	Physical Space Requirement as per Ref: (Instrument User Manual)	Yes	15/09/2 021
3.	Electrical Requirements Ref: (Instrument User Manual)	Yes	15/09/2 021
4.	UPS connection available.		

## 2. The instrument has been checked for the following:

Sr. No.	Verification	Provided Yes/No	Verified by & Date	
	Instrument is identified	Yes		
1.	Instrument Serial No (Customer)	BE 01 08	15/09/2 021	



		02	
2.	Specifications are included : Ref:  (Instrument User Manual )	Yes	15/09/2
3.	Accessories / consumables are listed as per checklist	Yes	15/09/2
4.	System checked for any External / physical damage.	Yes	15/09/2 021
5.	Instrument User Manual	Yes	15/09/2 021



## 3. Equipment Description:

CBS 300, Fully Automated Na/K/Cl Electrolyte Analyser

Instrument Identification	Verifie d Yes/N	Verified by / Date
Equipment Type : Na/K/Cl Electrolyte Analyser	Yes	
Model: CBS 300	Yes	15/09/2
Manufacturer : B&E Bio-technology Co. Ltd.	Yes	021
Marketed By : B&E Diagnostics India Pvt. Ltd.	Yes	15/09/2 021
Equipment # : One	Yes	7
Serial Number :	BE01080 2	15/09/2
Dimensions : 455*275*480 mm (H*W*D)	Yes	021
Power Supply: AC 110V to 220V 50Hz to 60Hz Power Consumption: ≤80W	Yes	15/09/2 021

## 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.

Verified By	Dat e
	Verified By



#### 5. Preventive Maintenance:

The routine preventive maintenance of the system will be carried out by Insignia Biomedical 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 & Insignia Biomedical 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 300.
- 6. Connect the reagents tubing and reagent to the Instrument.
- 7. All the operating software has been loaded in to CBS 300.

- 8. Now from back of the instrument turn the power switch ON. CBS 300 goes through its power up and self-test sequence.
- 9. The CBS 300 Main Menu is displayed after the start up sequence is complete

<u>Conclusion:</u> Instrument has been qualified for Installation. Hence it has been taken for Installation Qualification.



### (3) A. PERATIONAL QUALIFICATION:

0

#### 1. Instrument Identification:

Instrument Name:

CBS 300 Serial

Number: BE010802

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

Please refer Instrument programming in operation manual step by step

Tes	Test Name	Test Purpose	Method	Verifie
t		•		d
No.		·		Date



# B&E Diagnostics India Pvt. Ltd.

		<b>-</b>	- Annual
SYSTEM	TO CHECK	Switch on the	
SWITCH	THE	main, switch on	
ON	ERROR	the system.	
	FREE	System will	
	POWER	perform the self-	15/09/202
	UP.	test Sequence.	1
		CBS 300 MAIN	
		MENU is	
		displayed after	
		the completion.	
		Check for any	
		errors on the	
		screen.	
PRINTER TEST	TO CHECK	Initiate a self-	
	STATUS OF	test of printer	15/09/2021
	THE PRINTER.	or run a sample	- 0, 0 1, 2021
		to check the	
		print.	
REAGE	TO CHECK	Manually	
NT	ADEQUATE	check in the	
STATU	REAGENT	reagent	15/09/202
S	IS	bottles.	1
	AVAILABLE		
Table 1	FOR .		
	ANALYSIS		
	SWITCH ON  PRINTER TEST  REAGE NT STATU	SWITCH ON  THE ERROR FREE POWER UP.  PRINTER TEST TO CHECK STATUS OF THE PRINTER.  REAGE NT ADEQUATE STATU S IS AVAILABLE FOR	SWITCH ON  THE ERROR FREE POWER UP.  System will POWER UP.  System will perform the self- test Sequence. CBS 300 MAIN MENU is displayed after the completion. Check for any errors on the screen.  PRINTER TEST TO CHECK STATUS OF THE PRINTER.  REAGE NT ADEQUATE STATU S INITIATE ADEQUATE STATU S AVAILABLE FOR  main, switch on the system. System will perform the self- test Sequence. CBS 300 MAIN MENU is displayed after the completion. Check for any errors on the screen.  Manually check in the reagent bottles.

## 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. No.	Operato rs	Designation	Name & Sign of the Trainer.	Date
1.				
2.				
3.				
4.	•			L. Carlotte
5.				



## 4.<u>Comments:</u>

Training has been given successfully to all the responsible laboratory staff of (Manjeri Clinical Laboratory & Ideal X-Rays, Manjeri) to handle the software, operation and maintenance of this system.



III. B. <u>PERATOR MAINTENANCE PROTOCOL</u>: As per S.O.P. given.

#### Conclusion:

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

#### (4) PERFORMANCE QUALIFICATION:

#### A. Instrument Identification:

Instrument Name: CBS

300 Serial Number:

BE010802

## 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:	Hareesh	
Title: Service Manager	Sign:	Date:
Reviewed by:		
Name:	-	
Title:	0.	Date:
Consultant Patho	ologist Sign:	
Approved by:		
Name:		
Title:	Sign:	Date:

## Conclusion:

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