

**MANJERI CLINICAL LABORATORY & IDEAL X-RAYS, MANJERI**  
**PPM CHECKLIST FOR ELECTROLYTE ANALYZER**

<b><u>CBS 300 ELECTROLITE ANALYZER</u></b>		<b><u>SERIAL NO: BE010802</u></b>	
<b>I. SPECIAL PRECAUTIONS</b>			
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.			
<b>II. TEST APPARATUS REQUIRED</b>			
<b>1.ELECTROLYTE ANALYZER</b>		<b>Model: CBS 300</b>	<b>Serial:BE010314</b>
<b>Description</b>	<b>status</b>	<b>Description</b>	<b>status</b>
1. AC Plug	Passed	8. Rotary Valve	Passed
2. Line Cord	Passed	9. Fluid Flow	Passed
3. Fuse	Passed	10. Indicator	Passed
4. Tubes	Passed	11. Display	Passed
5. Connectors	Passed	12. User Calibration	Passed
6. Electrode Value	Passed	13. Pump Tube	Passed
7. Controls	Passed	14. Pinch Valve	Passed
		15. Air Sensor	Passed
<b>III. PREVENTIVE MAINTENANCE TASKS</b>			
<b>Description</b>	<b>status</b>	<b>Description</b>	<b>status</b>
1. Clean the whole tubings	<b>Done</b>	3. Replace Deteriorated components	<b>Done</b>
2. Clean the rotary valave	<b>Done</b>	4. Lubricate	<b>Done</b>

**IV. QUALITY CONTROL DATA**

Quality Control	Na+			K+			Cl-		
	Target	Measured Value	Range	Target	Measured Value	Range	Target	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. SUMMARY**

**NOTES**

Calibrated the instrument. Analyzed the Tri Level Quality Controls. Instrument is working perfectly.  
**Next calibration is due on 16-09-2022**

Completed by	Customer Signature:	Date :
Verified by:		17-09-2021
		Time: <b>4.30 PM</b>



B&E Diagnostics India Pvt. Ltd.



## *IQ, OQ & PQ PROTOCOL*

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*CBS 300*

*Na/K/Cl Electrolyte Analyser*



B&E Diagnostics India Pvt. Ltd.

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*



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(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*



## B&E Diagnostics India Pvt. Ltd.

- *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	15/09/2021
2.	Physical Space Requirement as per Ref: (Instrument User Manual )	Yes	15/09/2021
3.	Electrical Requirements Ref: (Instrument User Manual )	Yes	15/09/2021
4.	UPS connection available.		

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 01 08	15/09/2021





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



### 3. Equipment Description:

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

<i>Instrument Identification</i>	<i>Verified Yes/No</i>	<i>Verified by / Date</i>
<i>Equipment Type : Na/K/Cl Electrolyte Analyser</i>	<i>Yes</i>	
<i>Model : CBS 300</i>	<i>Yes</i>	<i>15/09/2021</i>
<i>Manufacturer : B&amp;E Bio-technology Co. Ltd.</i>	<i>Yes</i>	
<i>Marketed By : B&amp;E Diagnostics India Pvt. Ltd.</i>	<i>Yes</i>	<i>15/09/2021</i>
<i>Equipment # : One</i>	<i>Yes</i>	
<i>Serial Number :</i>	<i>BEO10802</i>	<i>15/09/2021</i>
<i>Dimensions : 455*275*480 mm (H*W*D)</i>	<i>Yes</i>	
<i>Power Supply: AC 110V to 220V 50Hz to 60Hz Power Consumption: ≤80W</i>	<i>Yes</i>	<i>15/09/2021</i>

### 4. Accessories/Consumables:

*The accessories were supplied with the instrument as per the*



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*check list. Check & verified in case they are found to be in order.*

<i>Qualified trained employee name</i>	<i>Verified By</i>	<i>Dat e</i>



### 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.

## A) 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.



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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

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



3) A. PERATIONAL QUALIFICATION:

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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

Test No.	Test Name	Test Purpose	Method	Verified Date
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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 300 MAIN MENU is displayed after the completion. Check for any errors on the screen.	15/09/2021 1
2.	PRINTER TEST	TO CHECK STATUS OF THE PRINTER.	Initiate a self-test of printer or run a sample to check the print.	15/09/2021
3.	REAGENT STATUSES	TO CHECK ADEQUATE REAGENT IS AVAILABLE FOR ANALYSIS	Manually check in the reagent bottles.	15/09/2021 1



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:*

<i>Sr. No.</i>	<i>Operators</i>	<i>Designation</i>	<i>Name &amp; Sign of the Trainer.</i>	<i>Date</i>
1.				
2.				
3.				
4.				
5.				





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4. Comments:

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. PERATOR MAINTENANCE PROTOCOL : As per S.O.P.

o given.

Conclusion:

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

(A) 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*

<i>Prepared by:</i>			
<i>Name:</i>	<i>Hareesh</i>		
<i>Title:</i> <i>Service Manager</i>	<i>Sign:</i>	<i>Date:</i>	
<i>Reviewed by:</i>			
<i>Name:</i>			
<i>Title:</i> <i>Consultant Pathologist</i>	<i>Sign:</i>	<i>Date:</i>	
<i>Approved by:</i>			
<i>Name:</i>			
<i>Title:</i>	<i>Sign:</i>	<i>Date:</i>	

*Conclusion:*

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