

Operational Qualification

Purpose: The purpose of the operational qualification (OQ) is to ensure that the system can be operated as expected and to devise the standard operating procedure.

S no	Parameter	Expected result	Result
1	Switch ON the instrument and Run self check	Software started with no error message	OK
2	Check the reagent cooling	Reagent components starts cooling	OK
3	Position of Probe	Probe should be in the wash station	OK
4	Functionality of Probe level sensor	Responding with green LED ON/OFF	OK
5	Functionality of probe collision sensor	Aligned with 1mm height of sensor	OK
6	Installation of all system pack reagents, Calibration and QC data	Installed	OK
7	Place any of three reagent bottle and test volume	All volumes have to be recognized.	OK
8	Training	Have all users been properly trained on the safety, theory of operation and maintenance of the Csense 100?	OK

- The analyzer passed the operational qualification
- The analyzer didn't pass the operational qualification

Special note:

Praveen Kumar

Engineer name and signature

Customer name and signature



Installation Qualification

To verify that the facilities provided for the installation of fully automated Biochemistry analyzer meets the requirements for the system and that all components of the system have been delivered, ready for installation in accordance with the standard for the system and other appropriate regulations.

Purpose: The purpose of the installation qualification (IQ) is to confirm that the instrument is installed as per the requirement.

S.No.	Parameter	Expected Result	Observed	Remarks
1	Ground voltage (voltage between neutral and earth)	< 3V	0.1V	SATISFACTORY
2	Line voltage (voltage between line and neutral)	180V to 245V	234V	SATISFACTORY.
3	Capacity of online ups	>1000W	5KVA	SATISFACTORY.
Unpacking				
Caution: Unpacking and lifting is 2 persons job				
4	Package inspection	No damage and sealed	OK	OK
		Inspection of accessory supplied	OK	OK
		Accessory box included computer	OK	OK

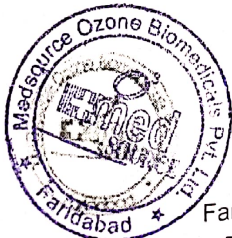
- The analyzer passed the installation qualification
- The analyzer didn't pass the installation qualification

Special Note: Installation report attached.

[Handwritten Signature]

Engineer name and signature

Customer name and signature



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