

Csense 100 IQ/OQ/PQ

<p>IQ/OQ/PQ Protocol</p> <p>Installation Qualification</p> <p>Operational Qualification</p> <p>Performance Qualification</p>
--

<p>Instrument name: Csense 100</p> <p>Serial No.: 31210199</p> <p>D.O.I. : 14.05.2022</p> <p>Warranty: 12 months</p>
--

Customer Details
<p>HEALTHCARE PATH LABORATORY</p> <p>OPP. GOVT ITI, BAHADURGARH</p> <p>HARYANA-124507</p> <p>CONTACT NO- 9350966190</p>



Corporate office: Plot No109, HSIIDC, Sector-31,  
Faridabad - 121003 (Haryana), Phone: +91-129-4286600/612  
Email [mail@ozonebio.com](mailto:mail@ozonebio.com), Website: [www.ozonebio.com](http://www.ozonebio.com).

## Csense 100 IQ/OQ/PQ

<b>Installation Qualification</b>
-----------------------------------

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.

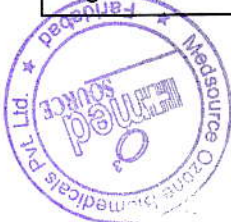
S.No.	Parameter	Expected Result	Observed	Remarks
1	Ground voltage (voltage between neutral and earth)	< 3V	2.1 V	OK.
2	Line voltage (voltage between line and neutral)	180V to 245V	223 V	OK.
3	Capacity of online ups	>1000W	2 kVA	OK
<b>Unpacking</b>				
Caution: Unpacking and lifting is 2 persons job				
4	Package inspection	No damage and sealed		OK
		Inspection of accessory supplied		OK
		Accessory box included computer		OK

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

Special Note: Installation report attached.

Engineer name and signature

Customer name and signature



**med**  
SOURCE  
Medsource Ozone Biomedicals Pvt. Ltd.

Corporate office: Plot No109, HSIIDC, Sector-31,  
Faridabad - 121003 (Haryana), Phone: +91-129-4286600/612  
Email [mail@ozonebio.com](mailto:mail@ozonebio.com), Website: [www.ozonebio.com](http://www.ozonebio.com).

## Csense 100 IQ/OQ/PQ

<b>Operational Qualification</b>
----------------------------------

**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:

Engineer name and signature

Customer name and signature



Corporate office: Plot No109, HSIIDC, Sector-31,  
Faridabad - 121003 (Haryana), Phone: +91-129-4286600/612  
Email [mail@ozonebio.com](mailto:mail@ozonebio.com), Website: [www.ozonebio.com](http://www.ozonebio.com).

## Csense 100 IQ/OQ/PO

<b>Performance Qualification</b>
----------------------------------

**Purpose:** The purpose of the performance qualification (PQ) is to confirm that the instrument is installed and performed as per requirement.

S no	Parameter	Expected result	Obtained value	Result
1	AD Values of 340nm	30,000 to 60,000	48578	OK
2	AD Values of 405nm	30,000 to 60,000	49788	OK
3	AD Values of 450nm	30,000 to 60,000	51678	OK
4	AD Values of 510nm	30,000 to 60,000	48225	OK
5	AD Values of 546nm	30,000 to 60,000	49578	OK
6	AD Values of 578nm	30,000 to 60,000	51788	OK
7	AD Values of 630nm	30,000 to 60,000	52135	OK
8	AD Values of 700nm	30,000 to 60,000	49726	OK
9	Accuracy study	The results of both QC samples should be in the specified range	within the range.	OK
10	Precision study	The CV in % should be lesser than 5% for each test	<1%	OK

Reports Print out	Expected	Remarks
Reports of both QC performed	Attached printout/ Saved file name and location	Printed
Reports of precision study done	Attached printout/ Saved file name and location	Printed

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

Special note:

Engineer name and signature

Customer name and signature



Medsource Ozone Biomedicals Pvt. Ltd.

Corporate office: Plot No109, HSIIDC, Sector-31,  
Faridabad - 121003 (Haryana), Phone: +91-129-4286600/612  
Email [mail@ozonebio.com](mailto:mail@ozonebio.com), Website: [www.ozonebio.com](http://www.ozonebio.com).