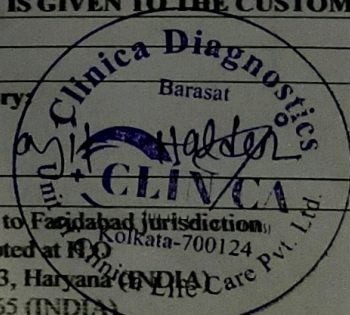




Medsources Ozone Biomedicals Pvt. Ltd.

## INSTRUMENT INSTALLATION REPORT

<b>Hospital/Lab Name:</b> CLINICA DIAGNOSTICS		<b>District:</b> NORTH 24 PGS		<b>State:</b> WEST BENGAL	
<b>Address:</b> KRISHNAGAR ROAD (NH34), NOAPARA, BARASAT		<b>Pin:</b> 700124		<b>Ph. No.:</b> 8240623506	
<b>Model:</b> CSENSE 200CD		<b>Instrument:</b> CLINICAL CHEMISTRY ANALYZER			
<b>Serial No.:</b> 0532502018 IEC		<b>Challan No.:</b>		<b>Date:</b>	
<b>QC No.:</b>		<b>Invoice No.:</b>		<b>Date:</b>	
<b>Customer Code:</b>		<b>Instrument Delivery date:</b>		<b>Instrument Installation Date:</b>	
<b>Pre-Installation report made by:</b> SELF		<b>Report No.:</b>		<b>Date:</b> 09-NOV-2023	
<b>Warranty:</b> ONE YEAR		<b>Site Status:</b> Ready			
(Warranty starts either from the date of delivery or installation of Instrument whichever is earlier)					
<b>Contact Person:</b>					
S/N	NAME	DESIGNATION	PHONE/CELL NO.	EMAIL ID	
1.	DR. AVIK GUPTA	CO-OWNER	9433540998		
2.	MR. ARIJIT DEY	CO-OWNER	9674980112		
<b>Site Output Voltage:</b> (Kindly check the recommended power supply voltage or voltage range mentioned Backside of the Instrument or in Service or User manual and should be maintain the same always)					
<b>Power Source:</b> UPS (Source voltage should be constant)					
<b>Site Earthing Voltage:</b> 1.5 V (Earthing voltage should be 0VAC, otherwise suggest customer to take the necessary steps for it)					
<b>Line/Neutral:</b> 228 V , <b>Line/Earth:</b> 229 V , <b>Earth/Neutral:</b> 1.5 V (leakage voltage should be 0VAC)					
<b>Humidity:</b> NORMAL <b>Site condition:</b> READY <b>Ventilation:</b> GOOD <b>Room size:</b> 300 SQ. FT.					
<b>Engineers Remarks regarding Power source and Site conditions and suggestions to customer :</b>					
SITE IS READY FOR INSTALLATION.					
<b>Test Performed:</b>					
TEST NAME	RESULT	REMARK			
CREA-MR	33.04				
SGOT	35.08	ALL RESULTS ARE SATISFACTORY. QC AND SAMPLE PRECISION			
SGPT	1.09	RESULTS ARE ATTACHED.			
<b>Persons' Trained:</b> RINA MAHATO, BISWAJIT HALDER					
<b>Customer's Remarks:</b>					
<b>Engineer's Remarks:</b> INSTRUMENT IS INSTALLED SUCCESSFULLY; TRAINING IS GIVEN TO THE CUSTOMER. INSTRUMENT IS WORKING SATISFACTORY.					
<b>Service Engineer's name:</b> ASTIK MISHRA			<b>Authorized Signatory:</b>		
<b>Signature:</b> <u>Astik Mishra</u>			<b>Name:</b> Biswajit Halder		
<b>Date (DD/MM/YY):</b> 11/11/2023			<b>(with Seal), Date:</b> 11/11/23		
<b>Note:</b> 1. Please fill the form in Capital Letters only. 2. Annexure is mandatory, 3. Subject to Faridabad jurisdiction.					
<b>Imp:</b> Please note that in case of non-compliance of above points, report shall not be accepted at NO					
HEAD OFF.: Plot No. 109 HSIIDC, Sector - 31, Faridabad - 121003, Haryana (INDIA)					
REGD. OFF.: 238, Santnagar, East of Kailash, Delhi - 110065 (INDIA)					
Mob.: 09650064495, E-mail: <a href="mailto:mail@ozonebio.com">mail@ozonebio.com</a> , <a href="mailto:service@ozonebio.com">service@ozonebio.com</a> Website: <a href="http://www.ozonebio.com">www.ozonebio.com</a>					
Original: H.O. 1 <sup>st</sup> Copy -B.DO/AM, 2 <sup>nd</sup> Copy-Z.M, 3 <sup>rd</sup> Copy Self					





IQ/OQ/PQ Protocol

Installation Qualification

Operational Qualification

Performance Qualification

Instrument name: Csense 200<sup>CD</sup>

Serial No.: 0532502018 IEC

D.O.I. : 11.11.2023

Warranty: 12 months


Customer Details

Clinica Diagnostics

Krishnagar Road ( NH 34), Noapara,  
Barasat, North 24 Pgs- 700124

CONTACT NO- 9433540998



**med** 

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)



### 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)	< 5V	1V	OK
2	Line voltage (voltage between line and neutral)	180V to 245V	222V	OK
3	Capacity of online ups	>2 KVA	5KVA	OK
4	Installation space	The gap between the analyzer and wall must not be less than 0.5m		OK
<b>Unpacking</b>				
Caution: Unpacking and lifting is 2 persons job				
4	Package inspection	No damage and sealed	No damage	OK
		Inspection of accessory supplied	All supplied	OK
		Accessory box included computer	Computer received without damage	OK

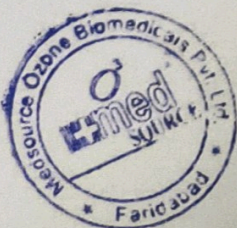
- The analyzer passed the installation qualification  
 The analyzer didn't pass the installation qualification


Special Note: Installation report attached.

*Astik Mishra*  
 Engineer name and signature

11/11/2023

*Biswanjit Halder.*  
 Customer name and signature



**med**   
 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)



<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	No error,ok
2	Check the reagent cooling	Reagent components starts cooling	Cooling found ok
3	Position of Probe	Probe should be in the wash station	Yes
4	Functionality of Probe level sensor	Responding with green LED ON/OFF	Functioning
5	Functionality check of mixer motor.	Judge whether the mixer is in the centre of the test cuvette/cleaning pool and whether you can hear the sound of rubbing up against the wall at the time of rotation	Checked and found OK
6	Installation of all system pack reagents, Calibration and QC data	Installed	Yes, installed
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 200 <sup>CD</sup> ?	Done, OK

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

Special note:

*Astik Mishra*

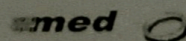
Engineer name and signature

11/11/2023



*Biswanjit Halder*

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).



Performance Qualification
---------------------------

**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	20,000 to 60,000	48400	OK
2	AD Values of 405nm	20,000 to 60,000	50700	OK
3	AD Values of 510nm	20,000 to 60,000	52200	OK
4	AD Values of 546nm	20,000 to 60,000	52600	OK
5	AD Values of 578nm	20,000 to 60,000	49500	OK
6	AD Values of 630nm	20,000 to 60,000	54000	OK
7	AD Values of 670nm	20,000 to 60,000	51500	OK
8	Accuracy study	The results of both QC samples should be in the specified range	Performed	OK
9	Precision study	The CV in % should be lesser than 5% for each test	Performed	OK

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

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

Special note:

*Astik Mishra*  
 Engineer name and signature



4/11/2023

*Biswanjit Halder*  
 Customer name and signature

**med**

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).



### Quality control data list

No.:OZONORM

BatchNo:OZN-2311

Itemname	Result	Prompt	Ref. Range	Unit	Test Date:
SGOT-OZ	33.043		25.0 - 41.0	U/L	2023-11-09 16:44:27
SGPT-OZ	35.087		29.0 - 45.0	U/L	2023-11-09 17:16:04
CREAT MR-OZ	1.095		0.84 - 1.36	mg/dL	2023-11-09 16:44:09

Astik Mishra  
09/11/2023



ZOPATH

BatchNo:OZP-2307

	Result	Prompt	Ref. Range	Unit	Test Date:
...OZ	140.895		114.0 - 170.0	U/L	2023-11-09 16:45:22
...T-OZ	118.666		99.0 - 151.0	U/L	2023-11-09 17:16:23
HEAT MR-OZ	4.766		3.70 - 5.50	mg/dL	2023-11-09 16:45:04

Astik Mishra

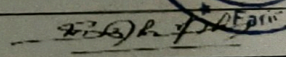
09/11/2023

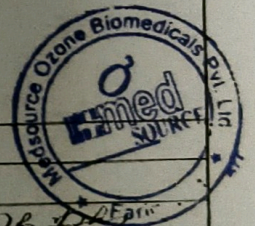


Sample Position	Sample No.	Item	Result
1	PRECISION001	SGOT-OZ	31.8 U/L
1	PRECISION001	SGOT-OZ	33.2 U/L
1	PRECISION001	SGOT-OZ	32.4 U/L
1	PRECISION001	SGOT-OZ	32.6 U/L
1	PRECISION001	SGOT-OZ	32.5 U/L
1	PRECISION001	SGOT-OZ	33.2 U/L
1	PRECISION001	SGOT-OZ	33.4 U/L
1	PRECISION001	SGOT-OZ	33.7 U/L
1	PRECISION001	SGOT-OZ	33.6 U/L
1	PRECISION001	SGOT-OZ	33.4 U/L
1	PRECISION001	CREAT MR-OZ	1.25 mg/dL
1	PRECISION001	CREAT MR-OZ	1.22 mg/dL
1	PRECISION001	CREAT MR-OZ	1.21 mg/dL
1	PRECISION001	CREAT MR-OZ	1.25 mg/dL
1	PRECISION001	CREAT MR-OZ	1.16 mg/dL
1	PRECISION001	CREAT MR-OZ	1.23 mg/dL
1	PRECISION001	CREAT MR-OZ	1.17 mg/dL
1	PRECISION001	CREAT MR-OZ	1.34 mg/dL
1	PRECISION001	CREAT MR-OZ	1.35 mg/dL
1	PRECISION001	CREAT MR-OZ	1.35 mg/dL

Astik Mishra  
09/11/2023



Calibration Certificate				
Product Name	Auto analyzer	Model	CSENSE 200 <sup>CO</sup>	
Tested Date	11.11.2023	SN	0532502018 IEC	
No.	Item	Standard and Demand	Obtained	Conclusion
1	Basic Function	Effective	Working Satisfactory	✓ QC pass
2	Callbration and QC programming	Effective	Done	✓ QC pass
3	Sample entry	Effective	Done	✓ QC pass
4	All wavelength readings	20k to 50k	Working Satisfactory	✓ QC pass
5	Reaction well temperature	37°C ± 0.3	37.1°C	✓ QC pass
6	Reagent cooling	15°C lesser than RT	Checked	✓ QC pass
7	Functionality check of mixer motor.	Judge whether the mixer is in the centre of the test cuvette/cleaning pool and whether you can hear the sound of rubbing up against the wall at the time of rotation	Checked	✓ QC pass
8	Mechanical co-ordinate values	Instrument specific	Checked	✓ QC pass
9	level sensor	Effective	Checked	✓ QC pass
10	Collision sensor	Effective	Checked	✓ QC pass
11	Input power source	210 to 240 V, 50Hz	232 V, 50HZ	✓ QC pass
Testing Result : <b>Passed</b>				
QC PASS				
Instrument calibrated as per the factory standard and the performed check values are satisfactory.				
<b>Next calibration on: 10.11.2024</b>				
Remarks:				
The Tester: <b>Astik Charan Mishra</b>			The Auditor: 	



### Medsource Ozone Biomedicals Pvt. Ltd.

Head Office: Plot No. 109, HSIIDC, Sector-31, Faridabad-121003, (Haryana), INDIA  
 Registered Office: 238, Sant Nagar, East of Kailash, New Delhi-110065, INDIA  
 Telephone: +91-129-4286600 | E-mail: mail@ozonebio.com | Website: www.ozonebio.com  
 CIN: U85100DL2003PTC120213