

INSTALLATION QUALIFICATION - IQ
&
OPERATIONAL QUALIFICATION - OQ
PERFORMANCE QUALIFICATION - PQ





**ST-200 aQua
Electrolyte Analyzer**

INSTALLATION QUALIFICATION

FOR

**Life Well Diagnostics
#1st Floor Lajpat Nagar,
New Delhi.**

BY

SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.

Sensa Core Medical Instrumentation Pvt. Ltd.
Plot, No: 3, Export Promotion Industrial Park, Pashamylaram, Medak (Dist), 502307, T.S. INDIA.
Tel: +08455 - 223400, www.sensacore.com

CERTIFICATION OF OPERATION

INSTRUMENT NAME : ST-200aQua

SERIAL NUMBER : STAQWB-0425

CUSTOMER NAME : Life Well Diagnostics

ADDRESS : Lajpat Nagar, New Delhi.

THE UNDERSIGNED PERFORMERS CERTIFY THAT THE OPERATIONAL
QUALIFICATION PROTOCOL HAS BEEN SUCCESSFULLY COMPLETED FOR
THE INSTRUMENT STATED ABOVE.

ENGINEER

Signature :



Name : MR. KIRAN DATE

Designation :

NATIONAL SERVICE MANAGER

Company :

SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.

Signature :

V. Posi Babu

Name : MR. POSI BABU V

Designation :

QA/QC TEAM LEADER

Company :

SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.

Sensa Core Medical Instrumentation Pvt. Ltd.

Plot, No: 3, Export Promotion Industrial Park, Pashamylaram, Medak (Dist), 502307, T.S. INDIA.
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OPERATIONAL QUALIFICATION OF THE INSTRUMENT:

DESCRIPTION	STATUS	REMARKS
POWER SUPPLY	SELF CHECK	PASSED
ELECTRONICS	SELF CHECK	PASSED
REAGENT PACK	SELF CHECK	PASSED
HARDWARE	SELF CHECK	PASSED
FLOW PATH	SELF CHECK	PASSED

FOR SENSACORE MEDICAL INSTRUMENTATION PVT. LTD.



(National Manager-Service)



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CERTIFICATION OF INSTALLATION

INSTRUMENT NAME : ST-200 aQua

SERIAL NUMBER : STAQW-0425

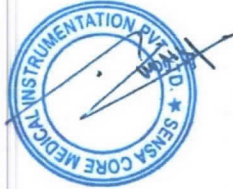
CUSTOMER NAME : Life Well Diagnostics.

ADDRESS : Lajpat Nagar, New Delhi.

THE UNDERSIGNED PERFORMERS CERTIFY THAT THE INSTALLATION QUALIFICATION PROTOCOL HAS BEEN SUCCESSFULLY COMPLETED FOR THE INSTRUMENT STATED ABOVE.

ENGINEER

Signature



Name

MR. KIRAN DATE

Designation

NATIONAL SERVICE MANAGER

Company

SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.

QUALITY MANAGER

Signature

V. Posi Babu

Name

MR. POSI BABU V

Designation

QA/QC TEAM LEADER

Company

SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.

INSTALLATION REPORT

CUSTOMER NAME : Life Well Diagnostics.
PLACE : Lajpat Nagar, New Delhi.
DEPARTMENT : Pathology Laboratory
INSTRUMENT NAME : ST 200 aQua
SERIAL NUMBER : STAQWB-0425
INSTALLATION DATE : 10.02.2023
WARRANTY EXPIRY : 09.02.2025

THE ELECTROLYTE ANALYZER WAS INSTALLED ALONG WITH THE NECESSARY STANDARD ACCESSORIES, ALL BASIC REQUIREMENTS AND ADJUSTMENTS WERE CHECKED AND FOUND TO BE SATISFACTORY. THE PRELIMINARY STANDARDIZATION OF THE ELECTROLYTE ANALYZER AND THE TRAINING WERE PROVIDED TO THE COMPLETE SATISFACTION OF THE CUSTOMER. THE ELECTROLYTE ANALYZER IS FOUND TO BE WORKING SATISFACTORILY.

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INSTRUMENT SETUP

S No	ITEM DESCRIPTION	STATUS
1	SOFTWARE VERSION	INSTALLED
2	REAGENT PACK	INSTALLED
3	QUALITY CONTROL	TESTED

OPERATION INSPECTION

- POWER SUPPLY CHECKED.
- NO UNUSUAL NOISE PRODUCED IN THE SYSTEM.

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INSTALLATION QUALIFICATION

INSTRUMENT NAME : ST-200AQUA

SERIAL NUMBER : STAQWB-0425

CUSTOMER NAME : Life Well Diagnostics

ADDRESS : Lajpat Nagar, New Delhi.

INSTALLATION REQUIREMENTS FOR THE INSTRUMENT:

REQUIREMENTS	ACCEPTABLE RANGE	OBSERVED RANGE
Input Voltage	220±10AC	217±5V AC
Line Frequency	50/60 HZ	50HZ
Ambient Temperature	10-35 degree	24 degree

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PERFORMANCE ANALYSIS

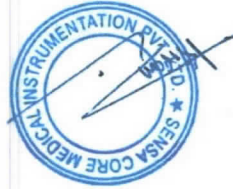
The performance of the system has been verified by the following process.

Ten replicates of the control Level 1 & Level 2 & Level 3 have been run and the statistical analysis of the data is performed. The results should be within control range with following precision limits.

THE UNDERSIGNED PERFORMERS CERTIFY THAT THE PERFORMANCE QUALIFICATION PROTOCOL HAS BEEN SUCCESSFULLY COMPLETED FOR THE INSTRUMENT STATED ABOVE.

A separate annexure has been attached along with this document

ENGINEER



Signature :

Name :

MR. KIRAN DATE

Designation :

NATIONAL SERVICE MANAGER

Company :

SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.

QUALITY MANAGER

Signature :

V. Posi Babu

Name :

MR. POSI BABU V

Designation :

QA/QC TEAM LEADER

Company :

SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.

ST-200AQUA-CALIBRATION CERTIFICATE

CUSTOMERS NAME:

Life Well Diagnostics

ADDRESS:

1st Floor, Lajpat Nagar, New Delhi

CONTACT NO:

.....

SERIAL NO OF THE INSTRUMENT:

STAQWB-0425

CALIBRATION DATE: 10/02/2023

VALID TILL: 09/02/2024

CALIBRATION DONE BY:

Mr. Kiran Date

Calibration Slopes:

S.No	Na+	K+	!Ca	pH	Cl	Pco2	HC03
1	72.19	70.28	44.53	67.60	6.69	-----	131.95
2	71.78	69.84	45.00	67.85	69.19	-----	132.87
3	71.00	70.20	44.72	68.80	68.83	-----	132.87
Mean	71.99	70.11	44.72	68.08	68.90	-----	132.56
Ranges	35-100 mV/dec	35-100 mV/dec	15-50 mV/dec	30-100 mV/dec	30-100 mV/dec	-----	40-150 mV/dec
Status	OK	OK	OK	OK	OK	-----	OK

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Quality Control - 1 : LotNo:AQC2210A-L1 Exp: Apr 2024

S.No	Na+	K+	iCa	pH	Cl	HCO3	pCO2
1	117.98	1.97	1.97	7.11	69.78	29.31	88.27
2	117.05	1.94	1.94	7.10	69.78	28.07	89.44
3	116.75	1.96	1.96	7.12	68.52	30.16	87.10
Mean	117.26	1.96	1.96	7.11	69.36	29.18	88.27
Ranges	106-124	1.45-2.45	1.49--2.49	7.01-7.27	56-74	23-31	77-98
Status	OK	OK	OK	OK	OK	OK	OK

Quality Control - 2 : LotNo:AQC2210A-L2 Exp: Apr-2024

S.No	Na+	K+	iCa	pH	Cl	HCO3	pCO2
1	143.12	4.00	1.24	7.27	99.02	29.55	65.07
2	143.52	4.00	1.23	7.27	99.87	31.26	64.27
3	142.26	3.98	1.23	7.28	99.03	30.94	63.43
Mean	142.97	3.99	1.23	7.27	99.31	30.58	64.26
Ranges	133-151	3.46-4.46	0.73-1.73	7.18-7.36	87-105	25-33	52-74
Status	OK	OK	OK	OK	OK	OK	OK

Quality Control - 3 : LotNo:AQC2210A-L3 Exp: Apr-2024

S.No	Na+	K+	iCa	pH	Cl	HCO3	pCO2
1	169.12	6.03	0.69	7.61	119.87	30.67	27.46
2	171.01	6.09	0.71	7.63	121.12	30.53	25.71
3	170.65	6.10	0.72	7.62	120.47	30.61	26.67
Mean	170.26	6.07	0.71	7.62	120.49	30.60	26.61
Ranges	160-178	5.71-6.71	0.21-1.21	7.54-7.72	111-129	28-36	12-34
Status	OK	OK	OK	OK	OK	OK	OK



Signature of Engineer
DATE: 10/02/2023



Signature of Doctor
DATE: 10/02/2023