

@PSR

TIN NO.: 07250335324 CIN NO.: U52602DL2009PTC192788

TO,
PATHOLOGY LAB KVR HOSPITAL,
SHIV NAGAR, NEAR SPACTRUM COURT ROAD,
KASHIPUR-244713

CALIBRATION CERTIFICATE

This is to certify that ST-200 AQUA Electrolyte Analyzer (Sr.No.-STAQW-00224) is exclusively marketed in India by PSR Diag. Pvt. Ltd. is installed at **Pathology Lab KVR Hospital**.

We are solely responsible for maintenance (preventive and breakdown) and calibrations as recommended by the manufacturers in the operator manual and updates received from them time to time.

Instrument hardware calibration is checked & done by our Instrument Engineer on 09.03.2022 & next calibration is due on 08.09.2022.

PSR DIAG, PVL Ltd.,

Authorized Signatory

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Instrument hardware calibration is checked & done by our Instrument Engineer on 10.09.2021 & next calibration is due on 09.03.2022.

PSR DIAG PVt Ltd.,

DELHI

Authorized Signatory



To,
PATHOLOGY LAB KVR HOSPITAL
SHIV NAGAR, NEAR SPACTRUM COURT ROAD
KASHIPUR-244713

CALIBRATION CERTIFICATE

This is to certify that ST-200 aQua Electrolyte Analyzer (Sr.No.-STAQW-00224) is exclusively marketed in India by PSR Diag. Pvt. Ltd. is installed at PATHOLOGY LAB KVR HOSPITAL

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Instrument hardware calibration is checked & done by our Instrument Engineer on 11.03.2021 & next calibration is due on 10.09.2021.

PSR DIAG7PAL Ltd.,

Authorized Signatory



Installation qualification for ST-200 aQua

Customer Name

: PATHOLOGY LAB KVR HOSPITAL

Address

: SHIV NAGAR, NEAR SPACTRUM COURT ROAD

KASHIPUR-244713

Instrument Model: ST-200 aQua

Serial Number

: STAQW-00224

Initial Inspection of the Unit carried out and the details are as below:

System Condition Report:

Found the System to have been delivered in satisfactory condition and no external physical damaged observed on the same. The Tilt-Indicator and the Shock-Indicators on the Packaging were found to be in Good Condition, indicating the System has not been subjected to mechanical shocks or stored in any manner, so as to cause any damage to the same.

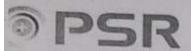
Found all the required accessories as required.

Installation Procedure & Checklist attached for records.

External requirements for Installation:

Input Voltage of 220V / 50 Hz (UPS out-put);

2 Recommended Operating temperatures is 22 - 30 Degree Celsius, with relative Humidity 20 - 80% (No Condensation);



Installation certificate for ST-200 aQua

This is to Certify that the ST-200 aQua Instrument Serial No. STAQW-00224 is successfully installed and Commissioned at PATHOLOGY LAB KVR HOSPITAL and the Installation Protocol / checklist has been successfully completed for the above Instrument.

PSR Diag. Pvt. Ltd.,

Customer: PATHOLOGY LAB KVR HOSPITAL

Name

Mr. Ramendra Sharma

Designation

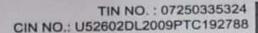
Service. Engineer

Signature

DELHI -

Date

11.03.2021





Installation qualifications for ST-200 aQua

Carried out all the Installation Procedures as per the Installation Procedure & Checklists.

Carried out all the necessary checks.

Carried out all checks and tests for Movement of Pump & Valve.

Carried out set up procedure as per the customer requirement.

Checked the Probe & Pump Tubing leakage.

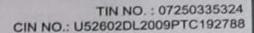
Handed over the Instrument for Operators Training & Qualifications.

For PSR Diagnostics Pvt. Ltd.

Name : Mr. Ramendra Sharma

Designation: Service Engineer

Date : 11.03.2021





Installation Report for ST-200 aQua

Customer Name

: PATHOLOGY LAB KVR HOSPITAL

Department

: Electrolyte Analyzer

Contact Person

Instrument Model : ST-200 aQua

Serial Number

: STAQW-00224

Date of Installation: 11.03.2021

Installation Checks & Protocol done as per Checklist attached.

The Instrument was installed and was found to be working satisfactorily. Preliminary Customer Training was provided and standardization of some parameters were done. The results were found to be within the expected range and the System found to be working satisfactorily.

PSR Diagnostics Pvt. Ltd.

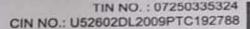
CUSTOMER:

Name: Mr. Ramendra Sharma

Name: PATHOLOGY LAB KVR HOSPITAL

Designation: Service Engineer

Designation:





Instrument Set Up

- 1 Installed the Na+ Electrode;
- 2 Installed the K+ Electrode;
- 3 Installed the ICa+ Electrode
- 4 Installed the Ph+ Electrode
- 5 Installed the CI- Electrode
- 3 Installed the Ref. Electrode:
- 4 Installed the Reagent Module;
- 5 Installed the Printer Paper;
- 6 Installed the Pump Tube Kit;

Operational Inspection

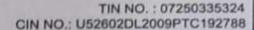
- 1 Checked the Leakage in Electrodes
- 2 Checked the Flow of Cal A;
- 3 Checked the Flow of Cal B;
- 4 Checked the Flow of Cal C;
- 5 Checked the Pump Tube Kit Tension;
- 6 Checked the Valve Movement
- 7 Checked the Probe Sensor & Bubble Detector;

PSR Diagnostics Pvt. Ltd.

Name : Mr Ramendra Sharma

Designation : Service Engineer

Date : 11.03.2021





Performance Qualifications for ST-200 aQua

1. Controls -

- a. Quality Control Level 1(Low)
- b. Quality Control -Level 2(Normal)
- c. Quality Control -Level 3(High)

Checked and found all level Controls to be within the acceptable SD

Datasheet of Calibration and Controls attached.

Li/pH/Cl Electrode

Test Report

(Certificate Of Analysis)

Product Name : LipHCI Electrode

Lot No : S3AQN2006A14

Quality Control's Lot : AQC2004A Reagent Pack Lot : R20067

Bio Rad-1 Lot

Bio Rad-2 Lot

26471

Date: 04/07/2020

		Slope		Qual	Quality Control-1	1-1	Qualit	Quality Control-2	1-2	Qualit	Quality Control-3	1-3	B	Bio Rad-1		Bic	Bio Rad-2	
Sr.no	בי	Hd	ט	רי	Hd	ט	13	Hd	ū	'n	Н	כ	n	Hd	ū	'n	Hd	U
1	81.58	60.64	06.99	0.54	7.02	78.7	1.42	7.23	101.1	2.10	7.39	123.3	0.59		95.0	1.30	*	81.2
2	79.8	69.09	66.83	0.54	7.02	80.9	1.41	7.23	101.2	2.12	7.39	123.3	0.58	13	94.4	1.29		81.9
3	80.32	60.75	66.90	0.54	7.02	6'08	1.41	7.23	101.2	2.14	7.39	123.5	0.59		93.8	1.33		82.4
Mean		69.09	66.88	0.54	7.02	30.2	1.41	7.23	101.2	2.12	7.39	123.4	0.59	0	94.4	1:31	,	81.8
ange	30-100	30-100	35-100	0	6.96-7.06	71-89	71-89 0,90-1.60	7.19-7.29	93-107	7.19-7.29 93-107 1.66-2.66 7.35-7.45 110-128	7,35-7,45		0.50-0.71		90.2-106 1.0-1.60	1.0-1.60		76-89.3
Ilnite	2	À	VIII	mmol/L		mmol/L	mmol/L mmol/L		mmol/L	mmol/L mmol/L	,	mmol/L mmol/L	mmol/L		mmol/L mmol/L	mmol/L		mmol/L

Status

PASSED

Product Specification: Quantitative Estimation In Human Blood, Serum & Urine Using Ion Selective Method.

Tested by: Atarath Date: 04 109 10020

Verified by :

Date: Oct



Operations Qualifications for ST-200 aQua

1.	Verified the Calibrations of Electrodes	:	Done
2.	Carried out set-up of parameters	:	Done
3.	Carried out Daily Cleaning Procedures	:	Done
4.	Carried out manual set-up	:	Done
5.	Carried out Calibration of Moving Table	:	Done
6.	Imparted Operator's training and maintenance	:	Done



Operational Qualification:

System certification

Study Data has determined that the System described in this document either meets all criteria outlined in this Operational Qualification Protocol, or exceptional conditions have been identified and documentation included.

Exceptional conditions, if any, have been addressed.

The System is ready for specific usage.

Protocol Performed By:

PSR Diagnostics Pvt. Ltd.

Name

: Mr. Ramendra Sharma

Customer Authorization

: PATHOLOGY LAB KVR HOSPITAL

Company Representative Name & Sign:

Date: 11.03.2021



SENSACORE LEVEL 1 ANALYZE QC

Na :123.0 mmol/L K :2.32 mmol/L iCa:1.43 mmol/L Li:0.52 mmol/L pH:6.936 Cl:82.8 mmol/L

Apr-21-22 13:33:38

Reagent: 27% Samples: 446

SENSACORE LEVEL 2 ANALYZE QC

Na :143.4 mmol/L K :4.12 mmol/L iCa:1.20 mmol/L Li :1.35 mmol/L pH :7.247 CI :102.5 mmol/L

Apr-21-22 13:35:28

Reagent: 27% Samples: 447

SENSACORE LEVEL 3 ANALYZE QC

Na :165.0 mmol/L K :6.11 mmol/L iCa:0.81 mmol/L Li :2.09 mmol/L pH :7.385 CI :122.4 mmol/L

Apr-21-22 13:36:52

Reagent: 27% Samples: 448

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May-11-22 13:19:31
Reagent: 28% Samples: 439
CALIBRATION SLOPE
Na :59.30
K :66.61
ICa:36.03
Li :73.70
pH :52.21
01 :77.48
May-11-22 13:21:29
Reagent: 28% Samples: 439
SENSACORE
LEVEL 1
ANALYZE QC
 Na :122.6 mmol/L
 K :2.26 mmol/L
iCa:1.48 mmol/L
Li:0.56 mmol/L
pH:6.930
 CI:82.6 mmol/L
 May-11-22 13:22:53
 Reagent:28% Samples:440
 SENSACORE
 LEVEL 2
 ANALYZE QC
 Na :143.2 mmol/L
 K :4.12 mmol/L
iCa:1.20 mmol/L
Li:1.39 mmol/L
pH:7.242
 CI =102.0 mmol/L
 May-11-22 13:24:34
 Reagent: 28% Samples: 441
  SENSACORE
  LEVEL 3
  ANALYZE QC
  Na :165.6 mmol/L
  K :6.06 mmol/L
  10a:0.80 mmol/L
  Li :2.11 mmol/L
pH :7.381
  CI =122.1 mmol/L
  May-11-22 13:25:56
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Reagent: 28% Samples: 442