

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

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

**ST-200 aQua
Electrolyte Analyzer**

INSTALLATION QUALIFICATION

FOR

Medivision Hospital

P.No:1,2&3, IDA Phase-1

Shapur Nagar

Jeedimetla, Hyderabad.

BY

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CERTIFICATION OF OPERATION

INSTRUMENT NAME : ST-200aQua
SERIAL NUMBER : STAQW-1540
CUSTOMER NAME : Medivision Hospital
ADDRESS : Jeedimetla, Hyderabad.

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.

QUALITY MANAGER

Signature : V. POSI BABU
Name : MR. POSI BABU V
Designation : QA/QC TEAM LEADER
Company : SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.

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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.



KIRAN DATE
(National Manager-Service)

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Electrolyte Analyzer**

**OPERATIONAL QUALIFICATION
FOR**

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P.No:1,2&3, IDA Phase-1
Shapur Nagar
Jeedimetla, Hyderabad.

BY
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CERTIFICATION OF INSTALLATION

INSTRUMENT NAME : ST-200 aQua
SERIAL NUMBER : STAQW-1540
CUSTOMER NAME : Medivision Hospital
ADDRESS : Jeedimetla, Hyderabad.


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

ENGINEER



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INSTALLATION REPORT

CUSTOMER NAME : Medivision Hospital
PLACE : Jeedimetla Hyderabad.
DEPARTMENT : Pathology Laboratory
INSTRUMENT NAME : ST 200 aQua
SERIAL NUMBER : STAQW-1540
INSTALLATION DATE : 14.04.2021
WARRANTY EXPIRY : 13.04.2026

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.

FOR SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.



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INSTALLATION QUALIFICATION

INSTRUMENT NAME : ST-200AQUA
SERIAL NUMBER : STAQW-1540
CUSTOMER NAME : Medivision Hospital
ADDRESS : Jeedimetla, Hyderabad.

INSTALLATION REQUIREMENTS FOR THE INSTRUMENT:

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

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**ST-200AQUA
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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



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