

CALIBRATION REPORT

Customer Name : Lotus Diagnostics

Address : Shop No. 5, Chandresh CHS,
Next to Lotus Multi Speciality Hospital,
Opp. ST Lawrence School, Devki Nagar,
Borivali -West, Mumbai -400103

Instrument Model : ST-200 Plus Electrolyte Analyzer


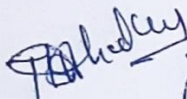
Serial no : ST -3789

Calibration Date : 12.06.2017

As per the Standard Operating procedure of ST-200 Plus Electrolyte Analyzer, the instrument has been calibrated.

As per method mentioned into manuals/sop, the Known Value Sample/Control run on the analyzer. All obtained values were within a normal range as mentioned in performance certificate. This indicated that an instrument is performing accurately and precisely.

Hence, we certified that ST-200 Plus Electrolyte Analyzer is calibrated.



Makarand Thakur
(Service Engineer)

Annexure - 1

ANALYZE TYPE: QUALITY CONTROL
Jun-12-17 12:28:24

LEVEL 1

ANALYZE QC

Na = 119.7 mmol/L HIGH
K = 1.99 mmol/L HIGH
Cl = 84.7 mmol/L HIGH

Jun-12-17 12:32:40

LEVEL 2

ANALYZE QC

Na = 138.7 mmol/L HIGH
K = 3.79 mmol/L HIGH
Cl = 103.7 mmol/L HIGH

Jun-12-17 12:34:48

LEVEL 3

ANALYZE QC

Na = 157.2 mmol/L HIGH
K = 5.80 mmol/L HIGH
Cl = 120.5 mmol/L HIGH

Jun-12-17 12:36:46

Performed By.



Jaini

APPROVED BY

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INSTALLATION QUALIFICATION – IQ

OPERATIONAL QUALIFICATION – OQ

&

PERFORMANCE QUALIFICATION - PQ



**ST-200 Plus
Electrolyte Analyzer**

INSTALLATION QUALIFICATION

FOR

Lotus Diagnostics.

Shop No. 5, Chandresh CHS,
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BY


NIRMAAN BIOMEDICALS

CERTIFICATION OF INSTALLATION


INSTRUMENT NAME : ST-200 Plus Electrolyte Analyzer
SERIAL NUMBER : ST -3789
CUSTOMER NAME : Lotus Diagnostics
ADDRESS : Shop No. 5, Chandresh CHS,
Next to Lotus Multi Speciality Hospital,
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Borivali -West, Mumbai -400103.

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

SERVICE DIVISION :

Signature :  *Makarand Thakur*
Name : Mr. Makarand Thakur
Designation : (Service Engineer)
Distributor : Nirmaan Biomedicals

QUALITY DIVISION :

Signature :  *Makarand Thakur*
Name : Mr. Makarand Thakur
Designation : (QC Engineer)
Distributor : Nirmaan Biomedicals

INSTALLATION REPORT

CUSTOMER NAME : Lotus Diagnostics
PLACE : Mumbai
DEPARTMENT : DIAGNOSTICS CENTER.
INSTRUMENT NAME : ST-200 Plus Electrolyte Analyzer
SERIAL NUMBER : ST - 3789
INSTALLATION DATE : 12.06.2017

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.

FOR NIRMAAN BIOMEDICALS



Makarand Thakur
(Service Engineer)

INSTRUMENT SETUP

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

OPERATION INSPECTION

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

FOR NIRMAAN BIOMEDICALS



Makarand Thakur
(Service Engineer)

INSTALLATION QUALIFICATION

INSTRUMENT NAME : ST-200 Plus Electrolyte Analyzer
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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	15-45 degree	37 degree

FOR NIRMAAN BIOMEDICALS



Makarand Thakur
(Service Engineer)



**ST-200 Plus
Electrolyte Analyzer**

OPERATIONAL QUALIFICATION

FOR

Lotus Diagnostics.

Shop No. 5, Chandresh CHS,
Next to Lotus Multi Speciality Hospital,
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BY

NIRMAAN BIOMEDICALS

CERTIFICATION OF OPERATION

INSTRUMENT NAME : ST-200 Plus Electrolyte Analyzer
SERIAL NUMBER : ST -3789
CUSTOMER NAME : Lotus Diagnostics
ADDRESS : Shop No. 5, Chandresh CHS,
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Opp. ST Lawrence School, Devki Nagar,
Borivali -West, Mumbai -400103.

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

SERVICE DIVISION :

Signature :

Name :

Designation :

Distributor :



Mr. Makarand Thakur

(Service Engineer)

NIRMAAN BIOMEDICALS

QUALITY DIVISION :

Signature :

Name :

Designation :

Distributor :



Mr. Makarand Thakur

(QC Engineer)

NIRMAAN BIOMEDICALS

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 NIRMAAN BIOMEDICALS



Makarand Thakur
(Service Engineer)

PERFORMANCE ANALYSIS

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

The control Level 1 & Level 2 & Level 3 have been run and the results are 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

SERVICE DIVISION :

Signature :



Name : Mr. Makarand Thakur

Designation : (Service Engineer)

Distributor : NIRMAAN BIOMEDICALS

QUALITY DIVISION :

Signature :



Name : Mr. Makarand Thakur

Designation : (QC Engineer)

Distributor : NIRMAAN BIOMEDICALS