

A

QUALIFICATION DOCUMENTS

FOR

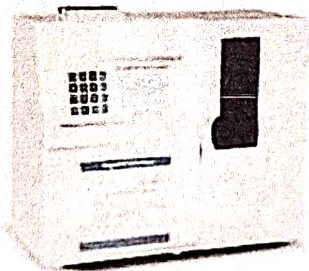
SENSACORE

ST-100B

ELECTROLYTE ANALYZER SYSTEM

Software Version

24W1.3B.M021



SCOPE OF SENSACORE MEDICAL ST-100B ELECTROLYTE ANALYZER

The procedures contained in this document will verify the functional performance of Sensacore Medical ST-100B Electrolyte Analyzer instruments and systems for accuracy, linearity and precision.

To complete the protocols contained within this document a Sensacore Medical ST-100B Electrolyte Analyzer system will require Reagent pack, Quality Control Material, Daily cleaner, Waste bottle, Urine dilute etc.

GENERAL DESCRIPTION:

The ST-100B is an automated microprocessor-controlled analyzer for measurement of sodium, potassium, ionized calcium, Lithium, Chloride, pH & Bicarbonate in serum, plasma, whole blood, diluted urine and cerebrospinal fluid.

To obtain accurate results, the ST-100B must be operated with Our Company's specially packaged Calibrant.

The Instrument is fitted with the flow system of Electrode housing which ensures a low level of carry over even with limited sample volume.

The peristaltic pump guarantees a high level of precision in the aspirated volume.

The Instrument is having Keypad to enter the settings requested on the display. The display shows instrument status and error malfunctioning signals.

The test results are shown directly in the measure unit and are printed on heat sensitive paper.

TECHNICAL SPECIFICATIONS (Na/K/iCa/Li/Ph/HCO₃/Cl) :

Sample : Whole heparin blood, Serum, Plasma, Cerebrospinal fluid & Diluted Urine.

Sample size : 130 micro liters of Whole heparin blood, Serum, Cerebrospinal fluid, Plasma & 500 micro liters of diluted (1:5) Urine.

Method : Direct Measurement by Ion Selective Electrode (ISE)

Ion Selective Electrodes (ISE)

[The Ion Selective Electrode (ISE) measurement principle is based on the interaction of freely moving ions in the sample with an active sensor material or membrane. In contrast to older technologies such as Flame Photometry which measure the concentration of an ion in the whole

sample, an ISE determines the free unbound ions, or more precisely, the activity of the ions in the aqueous phase of the sample.

The activity (A) of an ion in solution is defined as the product of its concentration (C) and its activity coefficient (γ).

$$A = \gamma \cdot C$$

Following parameters can be measured in this particular analyzer

Sodium(Na⁺), Potassium(K⁺), Ionised Calcium(iCa⁺), Chloride(CL), Lithium(Li⁺), Potential of Hydrogen(Ph), Bicarbonate(HCO₃)

Detection Range :

Parameters	Blood (mmol/L)	Urine (mmol/L)	Serum and Plasma (mmol/L)
Na ⁺	50.0 – 250.0	35 – 1000	50.0 – 250.0
K ⁺	0.5 – 20.0	5 – 200	0.5 – 20.0
iCa ⁺	0.25 – 5.0	2.4 – 7.5	0.25 – 5.0
Cl ⁻	45.0 – 200.0	25 – 500	45.0 – 200.0
Li ⁺	0.3 – 5	-	0.3 – 5
pH	7.20 – 7.60	-	4.0 – 9.0
Hco ₃	18 – 30	-	18 – 30

Analysis Time : 70 sec. (Blood) / 80 sec. (Urine)

Data Storage : 600 Patient results, QC and Urine up to 100 results each.

Calibration : Automatic or on Demand.

Output : 128×64 Graphics display With Y/N Numeric keypad 24 columns thermal Printer

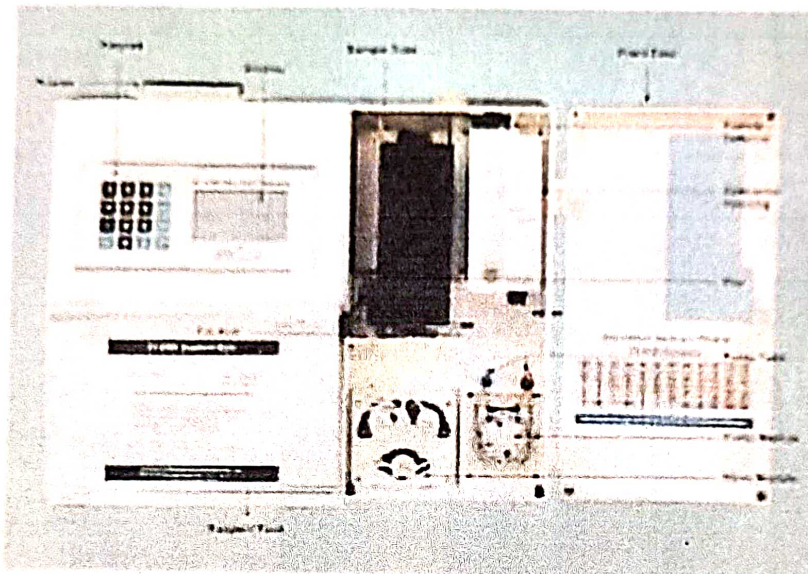
Ambient Conditions: 10-32 °C (60-90°F), < 85% humidity.

Power : 100/115~VAC, 50-60HZ, or 220~VAC

Size & Weight : 13(H), 15(W), 38(L) cm 9 kg

INTRODUCTION:-

Electrolyte play multiple roles in the maintenance of body functions such as sustaining proper body Ph, regulating function of the heart and other muscles, and participating in enzymatic functions. Electrolytic imbalances can result in congestive heart failure, diabetes insipidus, and kidney diseases. For these reasons electrolytic analysis is a key factor in patient diagnosis and treatment. Electrolyte analyzers measure electrolytes in serum, plasma and urine. The procedures contained in this document will verify the functional performance Analyzer instrument and system for accuracy, linearity and precision.



PARTS, FUNCTIONS AND IDENTIFICATIONS

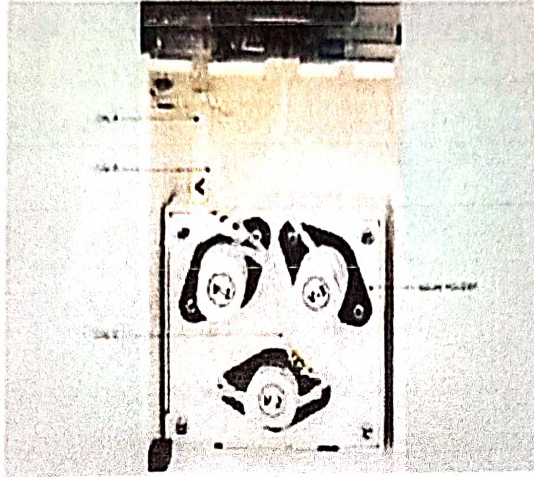
Parts of the Analyzer:

- Valve module
- Reference housing
- Electrode stack
- Bubble detector
- Pump module
- Reagent pack

Introduction Of Valve Module:

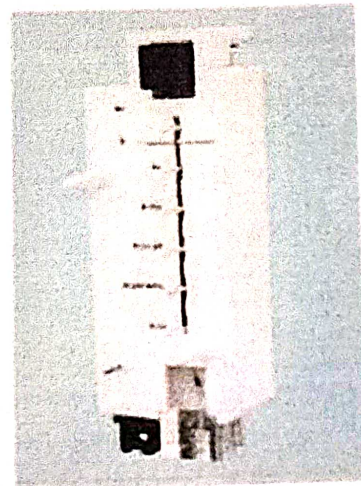
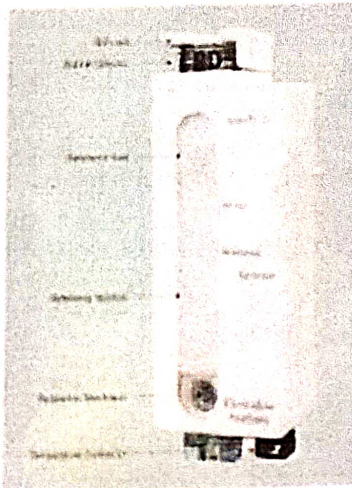
Valve module is mounted in ST-100B for the supply of Calibrant A, Calibrant B & Calibrant C solutions as per requirement.

- Valve 1 for A/B Calibrant solution.
- Valve 2 for AIR & output of Valve 1.
- Valve 3 for Calibrant C & output of Valve 2



Reference Housing:

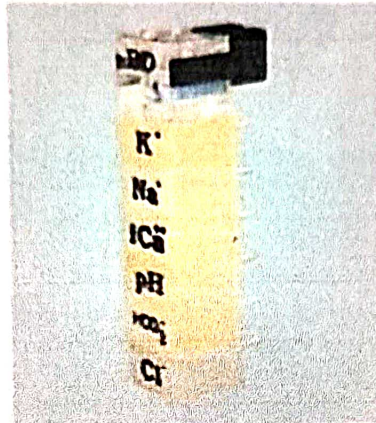
All Electrodes are staging in Reference housing, it consist of Potassium chloride (KCl) solution & temperature sensor. Connector is present at the bottom of reference housing to connect temperature sensor to motherboard.



Electrode Stack:

Electrode stack is placed inside the Electrode Housing. Electrode housing must be in place to ensure proper operation. Between every electrode, it is mandatory to place a rubber seal. The seals must be clean and dry.

Electrodes are arranged in the following manner as shown in fig.



Bubble Detector:

Bubble detector is used to check bubbles in the flow. It is very important to check clear flow of electrolyte analyzer.

The bubble detector detects the difference between liquid and air, which is important for proper sample positioning in the ST-100B.

- MODEL 1 -- K/ Na
- MODEL 2 -- K/ Na /Cl
- MODEL 3 -- K/ Na /iCa
- MODEL 4 -- K/ Na /iCa /pH
- MODEL 5 -- K/ Na /iCa /Cl
- MODEL 6 -- K/ Na /iCa /Li
- MODEL 7 -- K/ Na /iCa /Li/pH
- MODEL 8 -- K/ Na /iCa /pH/Cl
- MODEL 9 -- K/ Na /iCa /Li/Cl
- MODEL 10 -- K/ Na /iCa /Li /pH/Cl
- MODEL 11 -- K/ Na /iCa /pH/HCO₃/Cl
- MODEL 12 -- K/ Na /pH /HCO₃/Cl

Electrolyte Analyzer Models

Electrode Parameters

ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
K	K	K	K	K	K	K	K	K	K	K	K
Na	Na	Na	Na	Na	Na	Na	Na	Na	Na	Na	Na
n	n	ICa	ICa	ICa	ICa	ICa	ICa	ICa	ICa	ICa	n
n	n	n	n	LI	pH	LI	pH	LI	LI	pH	pH
n	n	n	n	n	n	pH	n	n	pH	uCO ₂	uCO ₂
n	Cl	n	Cl	n	n	n	Cl	Cl	Cl	Cl	Cl
1	2	3	4	5	6	7	8	9	10	11	12

Note: Please Arrange The Electrodes As Per The Parameter Selection

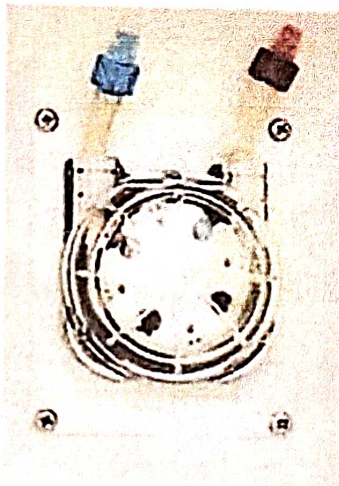
Notes:

1. Model 1 to Model 10 is compatible with ST-100B General reagent pack.
2. Model 11 & 12 is compatible with ST-100B Bicarbonate reagent pack.
3. If we select model 11 or model 12 then only temperature sensor will be activated & CAL C is used in calibration. If not then temperature sensor will be in idle state & CAL C will not be used.

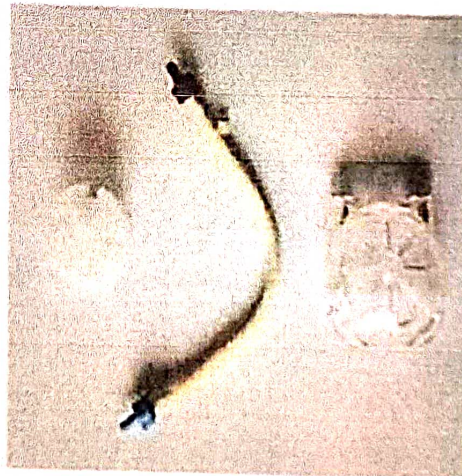
Pump module:

Pump tube: The pump tube has two stoppers. One red stopper is connected at the base of the electrode housing and another blue stopper is connected to the reagent pack socket (i.e.) to the waste on valve module block or external waste.

Front View



Pump Assembly Modules



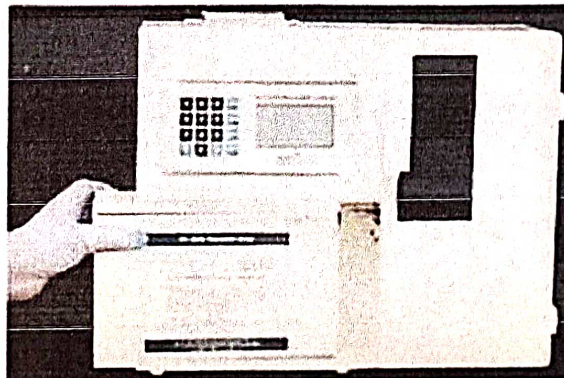
Pump module installation procedure:

- 1. Module base:** It is fixed to the chassis through a lock at the top of base as shown in the figure. We need to place the base bottom side first followed by the top, which consists of lock.
- 2. Rollers:** It consists of groove at its bottom and a knob on the front side. Groove side should be inserted to the base knob.
- 3. Pump tubing:** Insert the tubing as per the direction by holding the roller firmly as shown in the figure.
- 4. Front cover:** It is used to lock the rollers and pump tubing as shown in the figure. Ensure that the tag of pump tubing should be above the front cover lock.

Reagent Pack :

The ST-100B has an RFID (Radio Frequency Identification System) which keeps track of the reagent pack usage. The ST-100B will indicate the availability of reagents in a decreasing manner i.e., 100% to 0% at every analysis.

When 15% of the reagent has remained in the reagent pack, instrument will indicate that **INSUFFICIENT PACK PLEASE REPLACE** percentage till it reaches 5%. Below 5% the instrument will displays **REPLACE PACK** and there is no possibility for calibration and analysis.



Note: Do not place the ST-100B (Bicarbonate) reagent pack open to atmosphere. CAL C is highly affected by air, ensure to insert stoppers when reagent pack left ideally. Because, it gets escape from the pack

Section – A

IDENTIFICATION OF INSTRUMENTS/SYSTEMS BEING QUALIFIED

System identification:

Location : Heer Clinical Laboratory – Surat

Owner identification Number/ Company Assets Analyser

Consisting of:

Instrument: Sensacore medical make Electrolyte Analyser

- Type of Instrument-Model Name: Electrolyte Analyser
- Model Number : ST-100B
- Firmware Revision Number: Software Version_24W1.3BM021
- Primary Module Serial Number: Analyser Serial No: ST 100B-512
- Controller Module Serial Number: ST 100B-512
- Owner Equipment Number : ST 100B-512
- Original Manufacturer: SENSACORE MEDICAL INSTRUMENTATION PVT LTD HYDERBAD

Section Review Completed (Test: Pass (Fail () Initial _____

Comments: _____

Performed By: W.S.

Date: 1/12/20

Reviewed By: J. Patel

Date: 01/12/2020

Required Tools And Supplies

	Present	Initial	Date
1. Consumable for Testing Analysis	Yes		
2. Calibration Reagent pack for Calibration	yes		
3. Liquid QC Levels Analytical Balance	Yes		
4. Urine Diluent	yes		
5. Daily Cleaners	Yes		

() This page has been reviewed and instruction followed initial

Steel

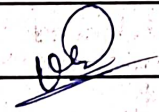

Date: 11/11/20

INSTALLATION QUALIFICATION OF ELECTROLYTE ANALYSER

- Unbox and inspect all components for physical damage. Check the system as per the packing list
- Install system as per the standard instruction in the installation manual
- Electrical / Signal connections power cords are connected to the modules
- System Powered ON. – Powered ON and Initialization Diagnostics Passed.
- Power is ON and system found all system components.

Section Review () Completed () Test: Pass () Fail () Initial _____

Comments: _____

Performed By:  Date: 1/12/20 Reviewed By:  Date: 01/12/2020

LIST OF COMPONENTS OF THE ELECTROLYTE ANALYSER SYSTEM

ITEMS	DESCRIPTION	SERIAL NO	REV NO
Main Unit	Electrolyte 100-B Analyser	ST - 100 B- 512	N /A
Reagent Pack for Calibration	ST -100 B Reagent Pack	U19485	11.2021
Software Version	24w1.3B.M021		

Section Review Completed Test: Pass Fail () Initial _____

Comments: _____

Performed by: [Signature] Date: 11/12/20 Reviewed by: [Signature] Date: 01/12/2020

PURPOSE :-

The documentation that accompanies the ST - 100B Electrolyte Analyzer includes practical and theoretical information regarding the function and use of the analyzer. Contains all the information required for everyday operation of the analyzer. Describes the functions of the analyzer and how to set it up according to customer's / End User's needs and requirements. Provides detailed information about the operating principles of the analyzer. Provides information about how the performance of the analyzer is tested.

SCOPE:-

The procedures contained in this document will verify the Operational performance of Sensacore's ST-100B instrument and systems for accuracy, linearity and precision.

To complete the protocols contained within this document a complete Sensacore's ST-100B Electrolyte Analyzer system will be required. Samples to be analyzed, Calibration Reagent pack, Sampling devices, Syringes, Capillaries etc.

For instruments which have power-up calibration and diagnostic features, a successful power-up sequence will indicate proper function of CPU, ROM, RAM, associated controller circuitry and internal calibration. Successful power-up sequences will be noted as appropriate.

INSTRUMENT QUALIFICATION TEST SPECIFICS**ELECTROLYTE ANALYSIS INSTRUMENT:-**

Accuracy : Timed collection of a fixed volume of mobile phase.

Linearity : (Accuracy across expected operational range)

Timed collection of Sample volume of mobile phase, measurement across expected operational range.

Precision : Determined from the reproducibility of arterial whole blood samples, the replicate injections of the owner designated standard sample preparation.

Co-relation : Results of Patient samples on ST-100B Analyzer

VERIFICATION NEED OF MAINTENANCE FREQUENCY

Analyzer cleaning and disinfection

Introduction:-

Periodic cleaning and disinfection of the touch screen, inlet probe, waste drain and the analyzer casing is recommended. Performing preventative maintenance during reagent pack replacement is also recommended.

Disinfection:-

Disinfection of outer surfaces is performed when appropriate. Disinfection frequency depends on local requirements and the use of the instrument. Prior to disinfection ensure that the analyzer surfaces are clean and without residue from blood and/or liquids.

Cleaning the inlet probe:- After each analysis, wipe the outside of the inlet probe with a tissue or gauze.

Cleaning the analyzer casing:- The analyzer casing can be cleaned, as needed, with a damp cloth.

Disinfecting the analyzer casing :- The analyzer casing can be disinfected periodically using a dilute bleach solution (a 1:9 ratio of sodium hypochlorite to deionized water) or other disinfecting agents such as 70 % isopropyl alcohol, 70 % ethanol or 4 % Diversol BX. These disinfecting agents may also be used in the analyzer areas noted below under Cleaning during solution pack installation and Cleaning during sensor cassette installation.

Cleaning the touch screen :- Use a clean, damp, non-abrasive cloth to clean the touch screen. Never allow moisture to settle at the bottom of the screen. Any commercially available window cleaner may also be used. All liquids should be first applied to a cloth. Never apply liquids directly to the screen.

Disinfecting the touch screen :- An alcohol-based cleaner (e.g. 70 % isopropyl alcohol), followed by a water-dampened cloth can be used periodically to disinfect the screen.

Cleaning during solution pack installation:- During the installation of a new solution pack, clean and dry the manifold in the analyzer's solution pack cavity. The luers can be cleaned with a damp, lint-free cloth.

VERIFICATION OF CLEANING AND OPERATION SOP

Analyzer Cleaning And Disinfection:-

Blood and other bio-hazardous substances contact only limited areas of the analyzer system during normal use. These areas include the waste drain, waste tubing and the reagent pack. The reagent pack can be discarded in appropriate contaminated waste receptacles. The waste drain and waste tubing can be disinfected by performing the following procedure.

TRAINING FOR OPERATION OF EQUIPMENT/INSTRUMENT/SYSTEM

The ST-100B Electrolyte analyzer provides instructions to the user for a variety of commonly performed procedures. The instructions are presented in a video tutorial format which includes video clips with accompanying descriptive text and audio.

Perform a sample from Syringe OR Glass Capillary:-

- There must be measurement within predefined range by mfg. & resolution within limit claimed must be achieved.
- Use balanced Heparinized arterial whole blood to complete this procedure
- Although any measurement within acceptable measurement range is accepted on the instrument, ensure the instrument is running at approximately achievable measurement ranges and resolution claimed by manufacturer.

NON CONFIRMATIVES

ACTIONS Taken, If Any

ATTACHMENTS

CONCLUSION:

The ST-100B Electrolyte analyzer demonstrated good precision with CVs of analytics in within run and between day's trials within acceptable limits and recovery percentages close to 100%. These analyzer showed acceptable correlation when compared with hospital analyzer currently in use.

Section Review () Completed () Test: Pass () Fail () Initial _____

Comments: _____

Performed by: [Signature]

Date: 11/11/20

Reviewed by: [Signature]

Date: 01/12/20

Section – B

Owner Approval of qualification Protocol

This certifies that Heer Laboratory – Surat management and /or persons have approval these protocols which will be used to qualify ,the functional performance of the ELECTROLYTE ANALYSER instruments ,system and its Consumables, Calibrators,

It also certifies that an owner designated responsible persons will approve all completed protocols, collected data and results by signing all approval forms indicating an action be taken by the reviewer,

Comments Approved

Title: Dr

Shel

Name: Dr. Anil D. Shel

Title QA Manager

Madhuri Pratik Dargjee .

Name:

Title; HOD

Falguni Parekh.

Name:

SECTION - C

PROTOCOL COMPLETION INSTRUCTIONS

The personnel performing and reviewing instrument and system qualification protocols are trained, qualified personnel as defined below:

Performer - Trained and qualified person (e.g. Sensacore's services Engineer-Service Engineer) who can determine proper instrument function, diagnose and repair any problems which may be found during the performance of these procedures and is authorized to certify the proper functionality of the Electrolyte Analyzer instrument.

Reviewer - Instrument owner designated person who is qualified as defined by NABL and other Quality Accreditation Authority in India to acknowledge the successful completion of the performer's tasks.

Form Completion Requirements - The performer and reviewer must complete all form items in full except for the comment section which is optional.

Correction of Form Entries - To correct any entry item the following protocol must be followed:

1. Draw a single diagonal line, bottom left to upper right corner through the mis-entered Or incorrect information.
2. Initial and date the diagonal line.
3. In the case of short entry error write the correct entry to upper right of the original entry, initial and date correct entry.
4. In the case of a long entry error, write the correct entry on a separate page, initial and date. Correct entry, number the page alphanumerically (for example, if the error occurred on page 6 of 10, number correction page 6A of 10) and locate correction page immediately following original page.
5. Log reason for corrected entry in comment section at the bottom of page.

() This page has been reviewed and instruction followed initial

[Signature]

Date: 11/12/20

PERFORMANCE QUALIFICATION

This section describes the automatic method of the on-board quality control system. With this method, the ST-100B Electrolyte analyzer provides automatic quality control analysis for each parameter, measuring at least two levels of quality control material (two levels for hematocrit) at user-defined intervals.

Recommended Procedures For System Suitability Analysis

Schedule:

These automatic quality control measurements are performed during each System Cycle. The interval of these events can be determined by user.

Acceptable ranges:

The assigned value and acceptance range for each parameter and level is entered automatically into the analyzer each time a new lot being installed. These values can be viewed and printed from the System Information.

Acceptance Criteria:

The ST-100B Electrolyte analyzer automatically assesses all automatic QC results and flags any result that is outside the acceptance range. The user can choose, among several options, how the system should react when a result falls outside the acceptance range for a parameter.

QC records :

All automatic quality control results are stored in the analyzer's database in Data logs for downloading and printing these records.

1. Identify complete electrolyte Analyzer system being used (Main Unit , Consumables, data system and software)
2. Use a well documented System Performance Qualification test condition such as:
Preparation of collection of Biological Samples collection procedure transport of sample
Preservation of the sample.

DOCUMENT ELECTROLYTE ANALYSER SYSTEM PRECISION RESULTS IN TERMS OF: LEVEL – 1

- Instrument Precision : Reproducibility of defined QC measurements time over a minimum of 3-5 analysis / runs
- Control Name and Level : Sensa Stat control Level – 1
- Lot No : UQC 2010A1.2
- Expiry date : 30/09/2022

Test	Ph	Na+	K+	Cl -	Ica++	
1	6.940	119.5	1.940	85	1.85	
2	6.880	121.8	1.890	87	1.88	
3	6.850	122.0	1.880	86	1.86	
4	6.920	121.2	1.930	88	1.79	
5	6.878	120.9	1.910	87	1.87	
Average	6.893	121.08	1.911	86.6	1.85	
Std Deviation	0.028	0.512	0.022	0.8	0.040	
CV %	0.41	0.42	1.15	0.92	2.1	
Claim Pass / Fail	Pass	Pass	Pass	Pass	Pass	

Section Review () Completed (✓) Test: Pass (✓) Fail () Initial _____

Comments: _____

Performed by: [Signature]

Date: 11/12/20

Reviewed by: [Signature]

Date: 01/12/20


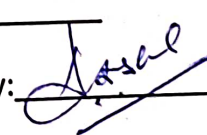
DOCUMENT ELECTROLYTE ANALYSER SYSTEM PRECISION RESULTS IN TERMS OF: LEVEL - 2

- Instrument Precision : Reproducibility of defined QC measurements time over a minimum of 3-5 analysis / runs
- Control Name and Level : Sensa Stat control Level -2
- Lot No : UQC 2010A1.2
- Expiry date : 30/09/2022

Test	Ph	Na+	K+	Cl -	Ica++	
1	7.19	139.2	3.95	100	1.32	
2	7.21	141.5	4.15	103	1.29	
3	7.23	140.7	4.12	101	1.31	
4	7.20	142.1	4.08	105	1.34	
5	7.24	141.6	4.12	103	1.32	
Average	7.21	141.0	4.08	102	1.31	
Std Deviation	0.018	0.57	0.028	1.63	0.020	
CV %	0.25	0.41	0.7	1.52	1.58	
Claim Pass / Fail	Pass	Pass	Pass	Pass	Pass	

Section Review Completed Test: Pass Fail () Initial _____

Comments: _____

Performed by:  Date: 11/12/20 Reviewed by:  Date: 01/12/20

PROTOCOL PERFORMER'S / QULIFIER'S CREDENTIALS

QA Manager: Madhuri Pratik Dajjee _____

Signature 

Initials

Title: _____

Owner designated responsible person

Date

11/12/20

Reviewer: Madhuri Pratik Dajjee _____

Signature 

Initials

Performer Madhuri Pratik Dajjee _____

Signature 

Initials

Title Amish Lamb _____

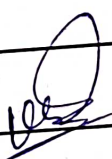
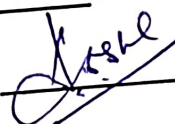
Service Engineer

Date

11/12/20.

Section Review Completed (Test: Pass (Fail () Initial _____

Comments: _____

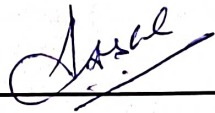
Performed by:  Date: 11/12/20 Reviewed by:  Date: 01/12/20

QUALIFICATION FINAL APPROVAL

This certifies that Heer Clinical Laboratory – Surat management and/or designated responsible persons have approvable the successful completion of these protocols which were used to qualify the functional performance of the Sensacore's ST -100 B Electrolyte Instruments and Systems.

It also certifies that an owner designated responsible persons has approval all completed protocols , collected data results by signing and dating all approval forms indicating an action be taken by reviewer.

Comments _____

<u>Doctor</u> _____	<u></u> _____	_____
Title	Signature	Date
_____	_____	_____
Title	Signature	Date
_____	_____	_____
Title	Signature	Date