

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-200Pro
Electrolyte Analyzer**

INSTALLATION QUALIFICATION

FOR

MKAS HEALTH CARE SERVICE
Sunjay Heights,
Proof Road,
Balasore, Odisha

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.
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CERTIFICATION OF OPERATION

INSTRUMENT NAME : ST-200Pro
SERIAL NUMBER : STP-001727
CUSTOMER NAME : MKAS Health Care Pvt. Ltd.
ADDRESS : **Balasore, Odisha**

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.

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 DATTA
(National Manager-Service)

Sensa Core Medical Instrumentation Pvt. Ltd.

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CERTIFICATION OF INSTALLATION

INSTRUMENT NAME : ST-200Pro
SERIAL NUMBER : STP-001727
CUSTOMER NAME : MKAS Health Care Pvt. Ltd.
ADDRESS : Balasore, Odisha

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
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QUALITY MANAGER

Signature : V. POSI BABU
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INSTALLATION REPORT

CUSTOMER NAME : MKAS Health Care Pvt. Ltd
PLACE : Balasore, Odisha.
DEPARTMENT : Pathology Laboratory
INSTRUMENT NAME : ST 200Pro
SERIAL NUMBER : STP-01727
INSTALLATION DATE : 30.07.2021
WARRANTY EXPIRY : 29.07.2022

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 SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.



KIRAN DATE
(National Manager-Service)

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INSTRUMENT SETUP

S No	ITEM DESCRIPTION	STATUS
1	SOFTWARE VERSION (AS6.USF.M021)	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.



KIRAN DATE
(National Manager-Service)

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INSTALLATION QUALIFICATION

INSTRUMENT NAME : ST-200Pro
SERIAL NUMBER : STP-01727
CUSTOMER NAME : MKAS Health Care Pvt. Ltd.
ADDRESS : Balasore, Odisha.

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

FOR SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.



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(National Manager-Service)

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**ST-200Pro
Electrolyte Analyzer**

PERFORMANCE QUALIFICATION

FOR

MKAS HEALTH CARE SERVICE
Sunjay Heights,
Proof Road,
Balasore, Odisha

BY

SENSACORE MEDICAL INSTRUMENTATION Pvt. Ltd.

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INSTALLATION REPORT

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.

INSTALLATION REPORT

F02/SC/FQC/SOP/001-00

NAME & ADDRESS OF THE INSTALLATION PLACE:

"MKAS HEALTHCARE, APOLLO CLINIC",
The land mark, Sanjay Heights, DR Mahesh Biswal
Proof Road, Balasore, Odisha - 756003, Odisha
(M): 9328059856, 874 Ver.

NAME OF THE ANALYZER: ST-200 PRO S. No.: STP-1727

PARAMETERS:

SODIUM (Na⁺): Na 2103 B 01 POTASSIUM (K⁺): K 2103 F 17

CHLORIDE (Cl⁻): Cl 2104 C 23 LITHIUM (Li⁺):

IONIZED CALCIUM (iCa⁺⁺): iCa 2104 L 10 pH: HCO₃⁻:

BUBBLE DETECTOR: US 53 D 2103 002 REFERENCE: Ref 5 Ch 2103 B 4.3

INSTALLED ON: 30th JULY 2021

WARRANTY ENDS ON: to 29th JULY 2022

COMMENTS IF ANY: "ST-200 PRO Analyzer installed successfully
with Shine Wave UPS & valid grounding
and, All parameter's behavior's Normality"

INSTALLED BY

(NAME): Dhanuram Mohanty

NAME OF THE
DISTRIBUTOR:

Care & Care
S. B. Pathan

DATE: 30-07-2021

SEAL:

INSTALLED MKAS Healthcare

AT: Balasore

SIGNATURE: Kanakalata Swain

NAME: Kanakalata Swain

DESIGNATION: Lab. Technician

SEAL:

MKAS HEALTHCARE SERVICES PVT. LTD.

The Land Mark, Sanjay Heights
Proof Road, Balasore-756003, Odisha
M.: 9439454650

Sensa Core Medical Instrumentation Pvt. Ltd.

Plot No: 3, Export Promotion Industrial Park, Pashamylaram, Sangareddy (District) - 502307,
Hyderabad, Telangana, INDIA. Telephone : +08455 - 223400 www.sensacore.com

SENSA CORE

INSTALLATION

S.No	DESCRIPTION	STATUS	REMARKS
1	Physical Check	✓	Yes
2	Short Supply of accessories	✓	NO
3	Check the voltage and earthing at the supply point.	✓	Yes
4	Check the internal parts of the system for any loose connections	✓	NO
5	Check the input Voltage	✓	Yes
6	Install printer paper with its Axel	✓	Yes
7	Switch ON the system	✓	Yes
8	Check the Date & Time	✓	Yes
9	Check any leakage is present	✓	NO
10	Run a calibration & Test	✓	Yes
11	Make a copy of the documents enclosed with Analyzer	✓	Yes
12	Get a signature of acceptance of accessories	✓	Yes
13	Submit Installation report & warranty Card	✓	Yes


 Signature: _____
 Date: 30/07/2021

Karakalata swain
 Signature: _____
 Date: 30/07/2021

MKAS HEALTHCARE SERVICES PVT. LTD.
 The Land Mark, Sanjay Heights
 Proof Road, Balasore-756003, Odhisha
 M.: 9439454650

SENSA CORE

Plot No.3, FPIP Zone, Pashamylaram, Sanga Reddy District - 502307. www.sensacore.com

F01-R01/SC/FQC/SOP.001

Instrument Name : ST 200 Pro Na/K/iCa/Li/pH/Cl Electrolyte Analyzer

Instrument Number :	STP-202103001727	Date of Testing	24/03/2021
Software Version :	ASW5.USF.M007	"Na" Electrode :	Na2103B01
Tested Reagent Lot :	R2103B	"K" Electrode :	K2103F17
Bubble Detector :	US5BD2103002	"iCa" Electrode :	_____ iCa2104L10
"Ref" Electrode :	Ref 5ch2103B43	"Li" Electrode :	_____
		"pH" Electrode :	_____
		"Cl" Electrode :	_____ Cl2104C23

MB NUMBER: UABG4V2103158

Calibration Slope :

S.No	Na+	K+	iCa	Li	pH	Cl-
1	68.73	69.90	36.46	73.12	73.91	57.04
2	68.59	68.78	36.25	72.79	73.86	57.04
3	68.42	68.49	36.25	72.65	73.63	57.10
Mean	68.58	69.06	36.32	72.85	73.80	57.06
Ranges	35 - 100 mV/decade	35 - 100 mV/decade	15 - 50 mV/decade	30 - 100 mV/decade	30 - 100 mV/decade	30 - 100 mV/decade
Status	OK	OK	OK	OK	OK	OK

Quality Control (I) :

Lot:UQC2103A-L1

Exp:Jan 2023

S.No	Na+	K+	iCa	Li	pH	Cl-
1	121.40	2.16	1.97	0.50	7.02	78.98
2	122.02	2.17	1.95	0.51	7.01	79.78
3	121.35	2.12	1.95	0.52	7.01	80.01
Mean	121.59	2.15	1.96	0.51	7.01	79.59
Ranges	110 - 128 mmol/L	1.47 - 2.47 mmol/L	1.34-2.34 mmol/L	0.17-0.87 mmol/L	6.98-7.08	72 - 90 mmol/L
Status	OK	OK	OK	OK	OK	OK

Quality Control (II) :

Lot:UQC2102A-L2

Exp: Jan 2022

S.No	Na+	K+	iCa	Li	pH	Cl-
1	140.95	4.14	1.24	1.68	7.24	100.21
2	141.21	4.08	1.24	1.67	7.23	101.32
3	140.32	4.16	1.23	1.71	7.23	101.25
Mean	140.83	4.13	1.24	1.69	7.23	100.93
Ranges	133 - 147 mmol/L	3.45 - 4.45 mmol/L	0.71 - 1.71 mmol/L	1.10-1.85 mmol/L	7.16-7.26	93 - 107 mmol/L
Status	OK	OK	OK	OK	OK	OK

Quality Control (III) :

Lot:UQC2103A-L3

Exp: Jan 2022

S.No	Na+	K+	iCa	Li	pH	Cl-
1	162.01	6.17	0.74	2.35	7.44	121.74
2	162.41	6.17	0.75	2.37	7.43	121.85
3	162.03	6.17	0.75	2.37	7.44	121.36
Mean	162.15	6.17	0.75	2.36	7.44	121.65
Ranges	151 - 169 mmol/L	5.51 - 6.51 mmol/L	0.22 - 1.22 mmol/L	1.74-2.74 mmol/L	7.35-7.45	112 - 130 mmol/L
Status	OK	OK	OK	OK	OK	OK

S.No	Na+	K+	iCa	Li	pH	Cl-
1	-----	-----	-----	-----	-----	-----
2	-----	-----	-----	-----	-----	-----
3	-----	-----	-----	-----	-----	-----
Mean	-----	-----	-----	-----	-----	-----
Ranges	-----	-----	-----	-----	-----	-----
Status	-----	-----	-----	-----	-----	-----

BIO RAD Level (I) : Lot: 26471 Exp: Feb 2023

S.No	Na+	K+	iCa	Li	pH	Cl-
1	147.42	4.07	0.83	0.79	-----	97.52
2	148.63	4.02	0.81	0.78	-----	96.32
3	147.05	4.06	0.82	0.68	-----	96.21
Mean	147.70	4.05	0.82	0.75	-----	96.68
Ranges	133 - 153 mmol/L	3.65 - 4.26 mmol/L	0.75 - 1.12 mmol/L	0.37 - 0.87 mmol/L	-----	90 - 106 mmol/L
Status	OK	OK	OK	OK	-----	OK

BIO RAD Level (II) : Lot: 26472 Exp: Feb 2023

S.No	Na+	K+	iCa	Li	pH	Cl-
1	131.24	6.21	1.11	1.68	-----	87.32
2	131.25	6.15	1.13	1.65	-----	86.24
3	130.26	6.18	1.12	1.64	-----	85.41
Mean	130.92	6.18	1.12	1.66	-----	86.32
Ranges	118 - 135 mmol/L	5.54 - 6.41 mmol/L	0.90 - 1.32 mmol/L	1.30 - 2.55 mmol/L	-----	78 - 94 mmol/L
Status	OK	OK	OK	OK	-----	OK

Urine Quality Control (I) : Lot:UQC2103A-UL-1 Exp: Jan 2023

S.No	Na+	K+	iCa	Li	pH	Cl-
1	362.98	69.35	-----	-----	-----	369.12
2	359.98	69.64	-----	-----	-----	366.87
3	361.87	69.49	-----	-----	-----	368.92
Mean	361.61	69.49	-----	-----	-----	368.30
Ranges	280 - 450 mmol/d	55 - 85 mmol/d	-----	-----	-----	300-450 mmol/d
Status	OK	OK	-----	-----	-----	OK

Urine Quality Control (II) : Lot:UQC2103A-UL-2 Exp: Jan 2023

S.No	Na+	K+	iCa	Li	pH	Cl-
1	675.32	388.13	-----	-----	-----	824.03
2	675.36	393.45	-----	-----	-----	824.87
3	675.78	393.05	-----	-----	-----	823.51
Mean	675.49	391.54	-----	-----	-----	824.14
Ranges	580 - 750 mmol/d	280 - 550 mmol/d	-----	-----	-----	700 - 900 mmol/d
Status	OK	OK	-----	-----	-----	OK

NOTE: iCa/pH/Li/Cl results are the results tested by internal QC Electrodes.

Tested By

Rajesh
24/03/2021

Reviewed By:

D. Durgarao
24/03/2021

Approved By:

[Signature]
24/03/2021

SENSA CORE

Healthcare and Diagnostic Products

F03-R01/SC/QA/SOP/004

CERTIFICATE OF ANALYSIS

PRODUCT:	ST-200 Pro ELECTROLYTE ANALYZER	
SERIAL NUMBER:	STP-1727	
SOFTWARE VERSION:	ASW5.USF.M007	
CHECK OF SETTING IN "SYSTEM" AND "SETUP" MENU:	PASSED	√
CALIBRATION DATA TEST:	PASSED	√
MEASUREMENT PROCESS TEST:	PASSED	√
INTERNAL PRINTER TEST:	PASSED	√
SERIAL COMMUNICATION TEST:	PASSED	√
CHECK OF SN CONFORMITY IN LABEL, PACKAGE AND PRINTOUT CE LOGO:	PASSED	√
APPEARANCE CHECK OF INSTRUMENT AND ACCESSORIES:	PASSED	√
COMPARISON OF PACKAGE CONTENT TO PACKING CHECKLIST:	PASSED	√

The unit with the serial number indicated above has been checked and released for sale by Sensacore Medical Instrumentation Pvt Ltd. The specified values of the "internal check" (see user manual) are within the acceptable confidence range and the unit is able to function correctly under the conditions described in the user manual.

24.03.2021

Department Incharge: _____

