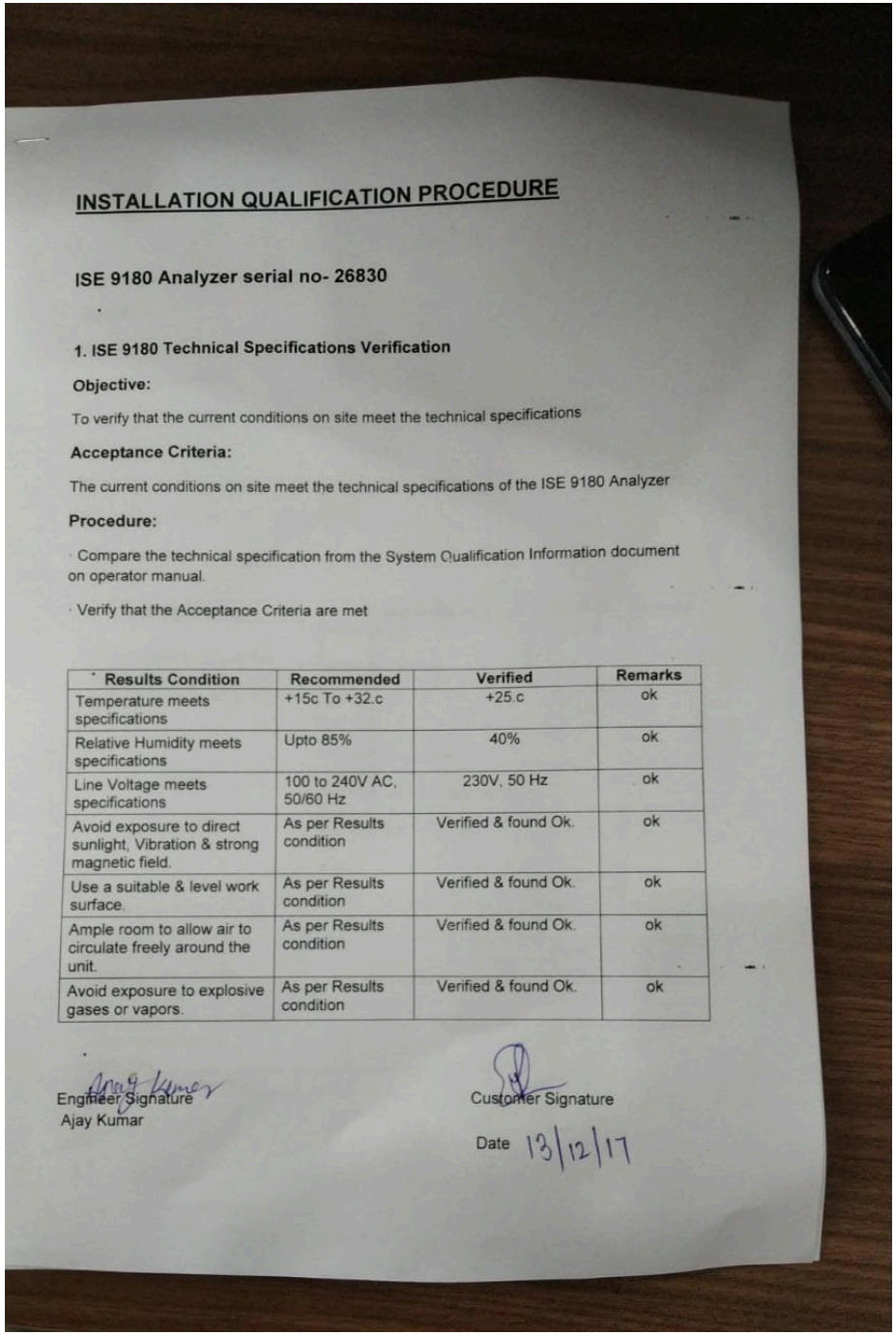


INSTALLATION QUALIFICATION PROCEDURE

ISE 9180 Analyzer serial no- 26830

1. ISE 9180 Technical Specifications Verification

Objective:

To verify that the current conditions on site meet the technical specifications

Acceptance Criteria:

The current conditions on site meet the technical specifications of the ISE 9180 Analyzer

Procedure:

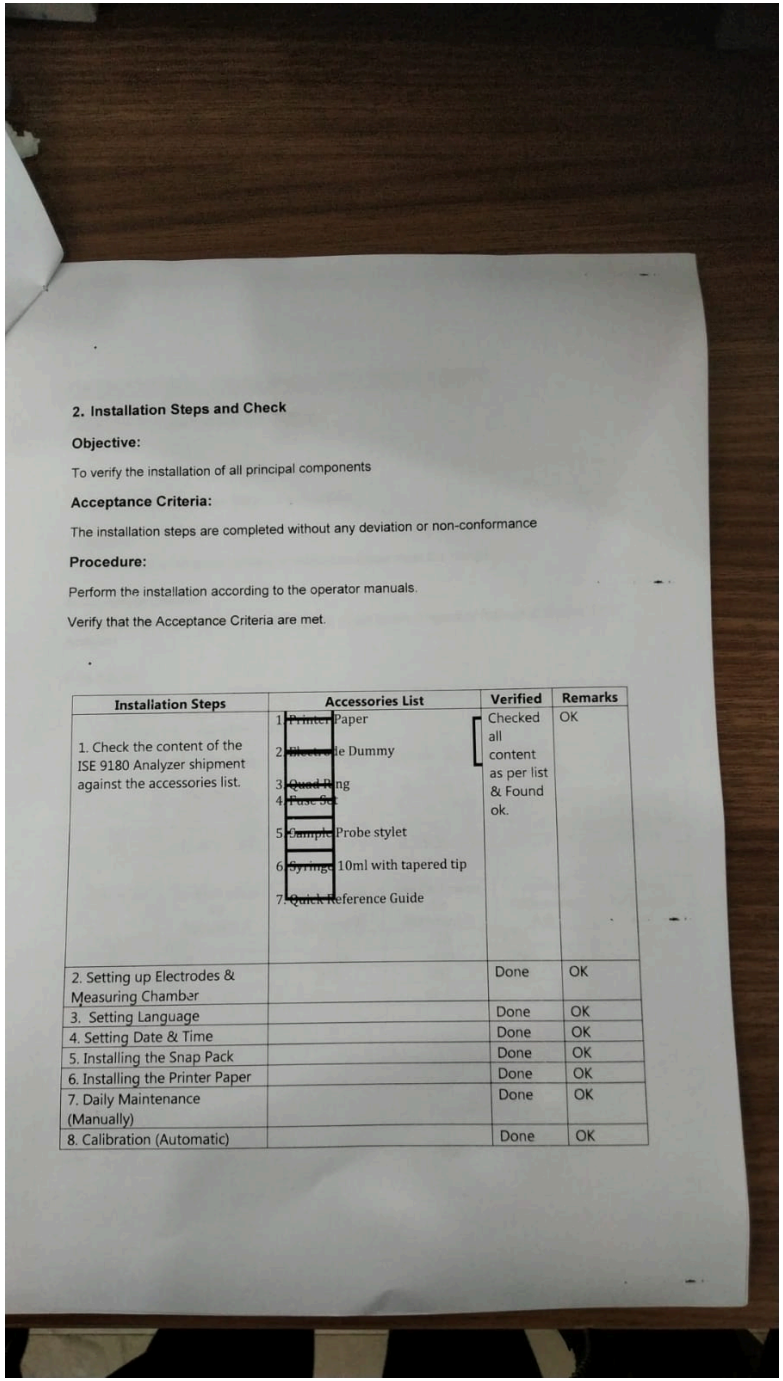
- Compare the technical specification from the System Qualification Information document on operator manual.
- Verify that the Acceptance Criteria are met

Results Condition	Recommended	Verified	Remarks
Temperature meets specifications	+15c To +32.c	+25.c	ok
Relative Humidity meets specifications	Upto 85%	40%	ok
Line Voltage meets specifications	100 to 240V AC, 50/60 Hz	230V, 50 Hz	ok
Avoid exposure to direct sunlight, Vibration & strong magnetic field.	As per Results condition	Verified & found Ok.	ok
Use a suitable & level work surface.	As per Results condition	Verified & found Ok.	ok
Ample room to allow air to circulate freely around the unit.	As per Results condition	Verified & found Ok.	ok
Avoid exposure to explosive gases or vapors.	As per Results condition	Verified & found Ok.	ok

Engineer Signature
Ajay Kumar

Customer Signature

Date 13/12/17



2. Installation Steps and Check

Objective:

To verify the installation of all principal components

Acceptance Criteria:

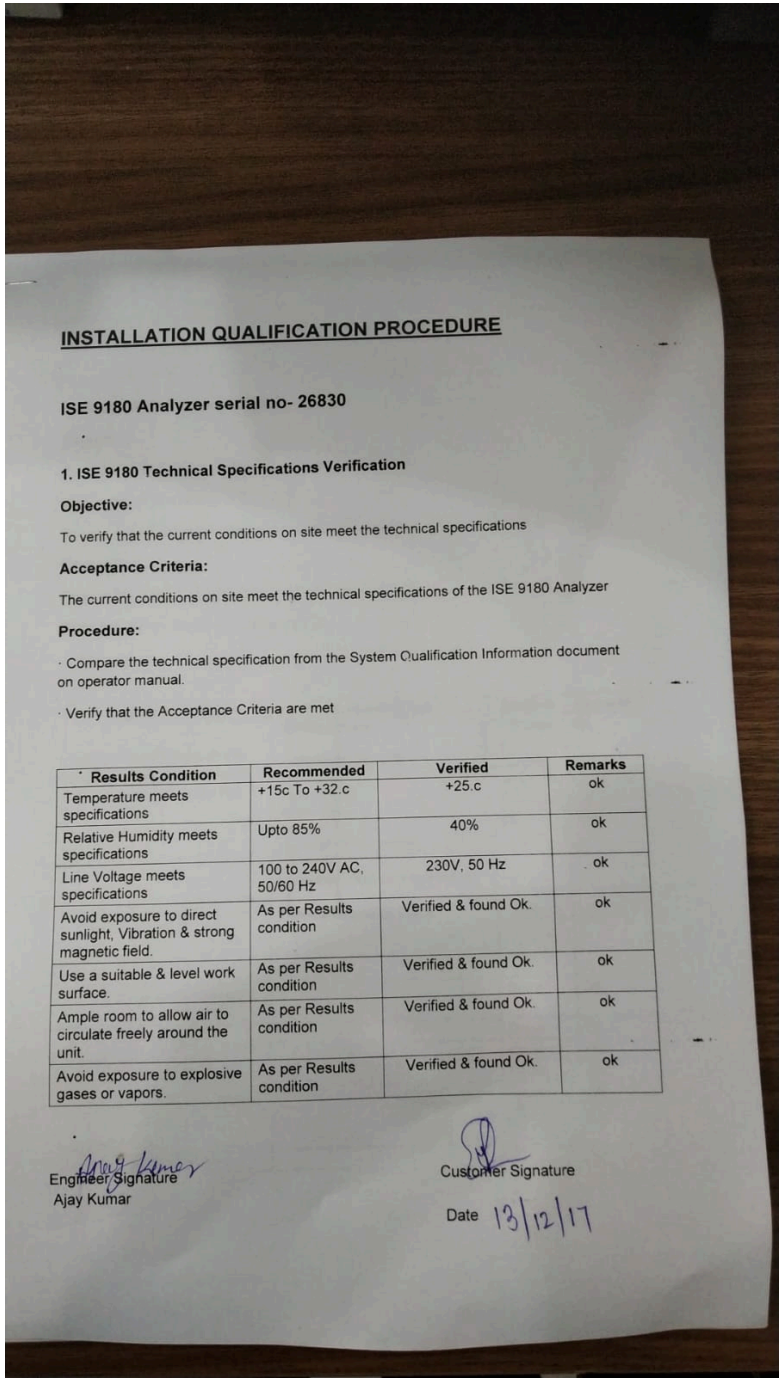
The installation steps are completed without any deviation or non-conformance

Procedure:

Perform the installation according to the operator manuals.

Verify that the Acceptance Criteria are met.

Installation Steps	Accessories List	Verified	Remarks
1. Check the content of the ISE 9180 Analyzer shipment against the accessories list.	1 [redacted] Paper 2 [redacted]e Dummy 3 [redacted] ng 4 [redacted] 5 [redacted] Probe stylet 6 [redacted] 10ml with tapered tip 7 [redacted] eference Guide	Checked all content as per list & Found ok.	OK
2. Setting up Electrodes & Measuring Chamber		Done	OK
3. Setting Language		Done	OK
4. Setting Date & Time		Done	OK
5. Installing the Snap Pack		Done	OK
6. Installing the Printer Paper		Done	OK
7. Daily Maintenance (Manually)		Done	OK
8. Calibration (Automatic)		Done	OK



INSTALLATION QUALIFICATION PROCEDURE

ISE 9180 Analyzer serial no- 26830

1. ISE 9180 Technical Specifications Verification

Objective:

To verify that the current conditions on site meet the technical specifications

Acceptance Criteria:

The current conditions on site meet the technical specifications of the ISE 9180 Analyzer

Procedure:

· Compare the technical specification from the System Qualification Information document on operator manual.

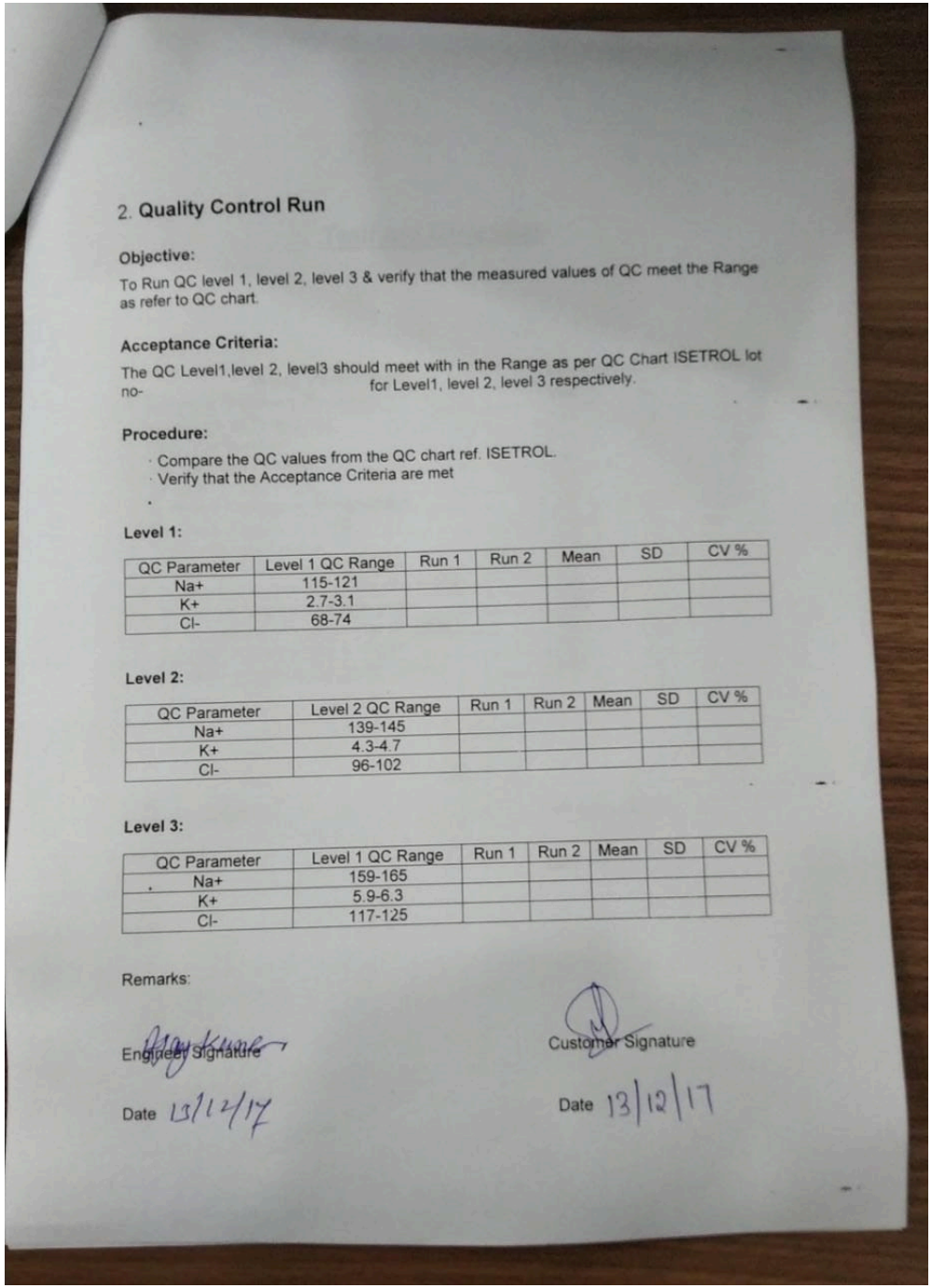
· Verify that the Acceptance Criteria are met

Results Condition	Recommended	Verified	Remarks
Temperature meets specifications	+15c To +32.c	+25.c	ok
Relative Humidity meets specifications	Upto 85%	40%	ok
Line Voltage meets specifications	100 to 240V AC, 50/60 Hz	230V, 50 Hz	ok
Avoid exposure to direct sunlight, Vibration & strong magnetic field.	As per Results condition	Verified & found Ok.	ok
Use a suitable & level work surface.	As per Results condition	Verified & found Ok.	ok
Ample room to allow air to circulate freely around the unit.	As per Results condition	Verified & found Ok.	ok
Avoid exposure to explosive gases or vapors.	As per Results condition	Verified & found Ok.	ok

Engineer Signature
Ajay Kumar

Customer Signature

Date 13/12/17



2. Quality Control Run

Objective:

To Run QC level 1, level 2, level 3 & verify that the measured values of QC meet the Range as refer to QC chart.

Acceptance Criteria:

The QC Level1,level 2, level3 should meet with in the Range as per QC Chart ISETROL lot no- for Level1, level 2, level 3 respectively.

Procedure:

- Compare the QC values from the QC chart ref. ISETROL.
- Verify that the Acceptance Criteria are met

Level 1:

QC Parameter	Level 1 QC Range	Run 1	Run 2	Mean	SD	CV %
Na+	115-121					
K+	2.7-3.1					
Cl-	68-74					

Level 2:

QC Parameter	Level 2 QC Range	Run 1	Run 2	Mean	SD	CV %
Na+	139-145					
K+	4.3-4.7					
Cl-	96-102					

Level 3:

QC Parameter	Level 1 QC Range	Run 1	Run 2	Mean	SD	CV %
Na+	159-165					
K+	5.9-6.3					
Cl-	117-125					

Remarks:

Engineer Signature

Date 13/12/17

Customer Signature

Date 13/12/17

OPERATIONAL QUALIFICATION PROCEDURE

ISE 9180 Analyzer serial no- 26830

1. ISE 9180 Calibration Slope Verification

Objective:

To verify that the measured values of calibration Slope meet the Range

Acceptance Criteria:

The Calibration slope meet with in the Range as per given in operator manual of the ISE 9180 Analyzer

Procedure:

- Compare the slope values from the System Qualification Information document on operator manual.
- Verify that the Acceptance Criteria are met

Electrode	Allowed value for Standard A	Allowed value for Standard B	Allowed value for Standard C	Allowed Difference A-B	Allowed Difference A-C
Na+	-600 to +2400	-1600 to +2400	-600 to +2400	+250 to +680	-50 to +50
K+	-700 to +1000	-2500 to +500	-700 to +100	+470 to 1200	-40 to +40
Cl-	-3100 to -100	-1000 to +3000	-3100 to -100	-370 to -86	unused

Electrode	Verified value for Standard A	Verified value for Standard B	Verified value for Standard C	Verified Difference A-B	Verified Difference A-C
Na+	692	117	726	575	34
K+	-420	-1519	-416	1099	-4
Cl-	265	973	267	-708	2
Remarks	ok ☐	ok ☐	ok ☐	ok ☐	ok ☐

Engineer Signature

Date 13/12/17

Customer Signature

Date 13/12/17

Maintenance Schedule

Daily Maintenance:

1. Perform Daily Cleaning
2. Perform Daily Conditioning

Weekly Maintenance

1. Clean Sample probe & fill port
2. Clean Analyzer surfaces.

Monthly Maintenance

1. Clean the reference electrode housing.

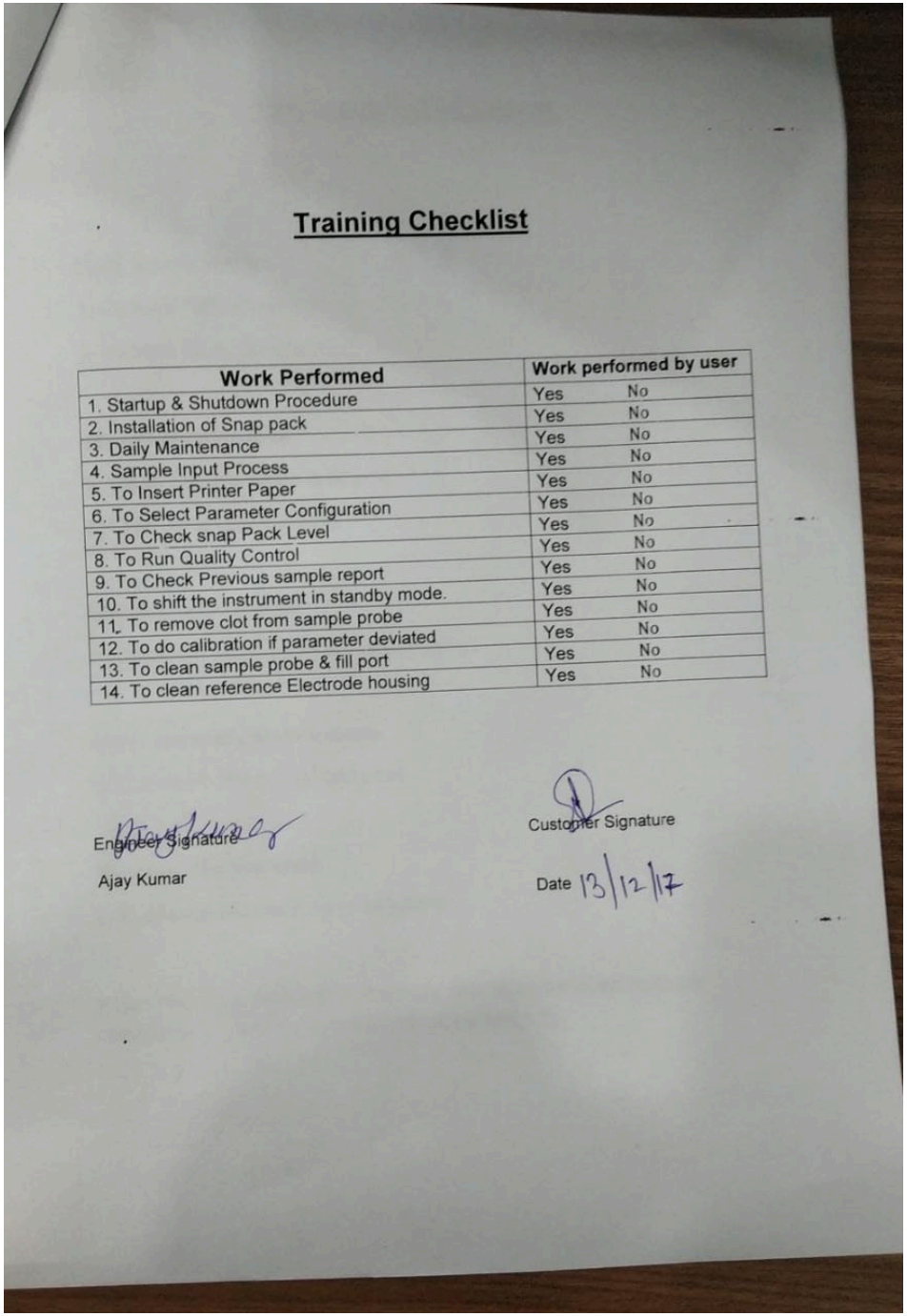
Semi- Annually Maintenance

1. Exchange the pump tubing set.

Annually Maintenance

1. Exchange the main harness tubing.

Note: The semi- annually & annually maintenance work must be completed by fully qualified technical person only.



Training Checklist

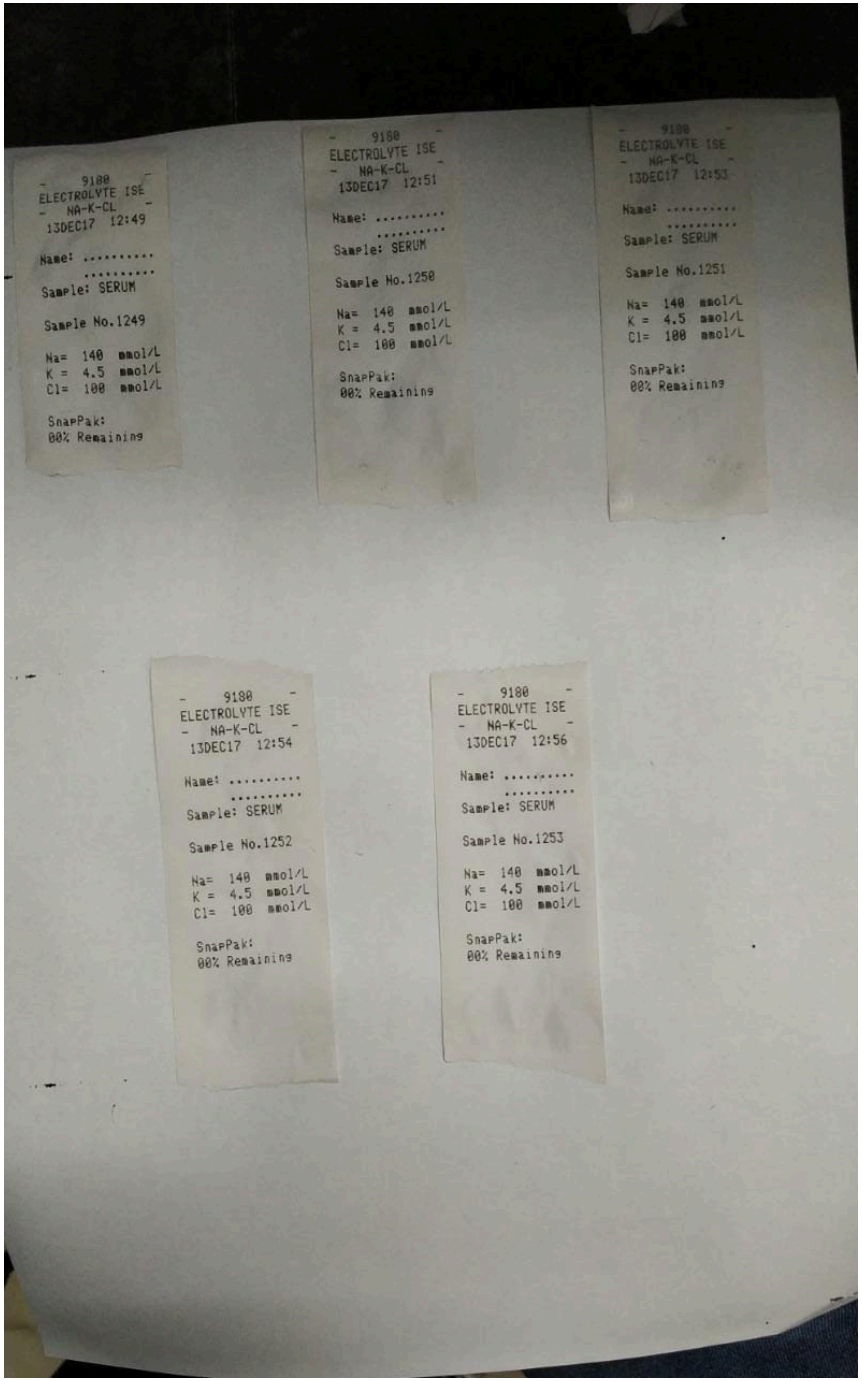
Work Performed	Work performed by user	
1. Startup & Shutdown Procedure	Yes	No
2. Installation of Snap pack	Yes	No
3. Daily Maintenance	Yes	No
4. Sample Input Process	Yes	No
5. To Insert Printer Paper	Yes	No
6. To Select Parameter Configuration	Yes	No
7. To Check snap Pack Level	Yes	No
8. To Run Quality Control	Yes	No
9. To Check Previous sample report	Yes	No
10. To shift the instrument in standby mode.	Yes	No
11. To remove clot from sample probe	Yes	No
12. To do calibration if parameter deviated	Yes	No
13. To clean sample probe & fill port	Yes	No
14. To clean reference Electrode housing	Yes	No

Engineer Signature

Ajay Kumar

Customer Signature

Date 13/12/17


9180
ELECTROLYTE ISE
NA-K-CL
13DEC17 12:49
Name: .....
Sample: SERUM
Sample No.1249
Na= 140 mmol/L
K = 4.5 mmol/L
Cl= 100 mmol/L
SnapPak:
00% Remaining
9180
ELECTROLYTE ISE
NA-K-CL
13DEC17 12:51
Name: .....
Sample: SERUM
Sample No.1250
Na= 140 mmol/L
K = 4.5 mmol/L
Cl= 100 mmol/L
SnapPak:
00% Remaining
9180
ELECTROLYTE ISE
NA-K-CL
13DEC17 12:53
Name: .....
Sample: SERUM
Sample No.1251
Na= 140 mmol/L
K = 4.5 mmol/L
Cl= 100 mmol/L
SnapPak:
00% Remaining
9180
ELECTROLYTE ISE
NA-K-CL
13DEC17 12:54
Name: .....
Sample: SERUM
Sample No.1252
Na= 140 mmol/L
K = 4.5 mmol/L
Cl= 100 mmol/L
SnapPak:
00% Remaining
9180
ELECTROLYTE ISE
NA-K-CL
13DEC17 12:56
Name: .....
Sample: SERUM
Sample No.1253
Na= 140 mmol/L
K = 4.5 mmol/L
Cl= 100 mmol/L
SnapPak:
00% Remaining

REVISION DATE :10 12.2021

To Whom It May Concern

ISO **15189:2012 REQUIREMENTS REG. "CALIBRATION & VERIFICATION PROCEDURES"'**

All Roche Diagnostics products which are distributed and for which a Free-Sales-Certificate is issued, are CE-marked. The In-Vitro-Diagnostics Directive of the European Union' requires for all CE marked products that the manufacturer assures compliance of the products with the requirements of the In-Vitro-Diagnostics Directive. This means that all processes in the development and manufacturing of Roche Diagnostics products are guided by a Quality Management System. Our Quality Management System is in compliance with the requirements from ISO 9001:2008', ISO 13485:2003 + AC: 2007[4], and QSReg[5].

The mentioned regulations require that the production systems and measuring devices used are qualified and the manufacturing and test procedures are validated[6]. This status has to be assured by scheduled maintenance and by regular qualification resp. validation reviews and updates.

All physical quantities, calibrators and controls used in Roche Diagnostics systems are fully traceable to certified standards or reference materials. The performance of all Roche Diagnostics systems at the customer site is assured if regular QC measurements, cleaning and maintenance procedures as described in the instructions for use or service documentation are performed. By having controlled internal procedures and by running the tasks required in the respective user documentation, all Roche Diagnostics systems will perform as specified during their defined lifetime.

Additional calibration or verification procedures are NOT required of the user in order to assure the specified performances of every Roche Diagnostics system. Only if a user deviates from these manufacturer's recommendations does he have to establish site-specific calibration and verification procedures as part of his accreditation process.

Graz, 26-Feb-2013

Dr. Johann Harer
Head of Quality Management & Regulatory Affairs

ISO 15189:2012, Medical laboratories - Requirements for quality and competence

[2] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

[3] ISO 9001:2008, Quality Management Systems - Requirements

ISO 13485:2003 + Cor.1:2009, Medical Devices — Quality Management Systems — Requirements for Regulatory Purposes)

Quality System Regulations, 21 CFR Part 820, requirements on medical devices

[6] 21 CFR Part 809, 21 CFR Part 210, 21 CFR Part 11; GAMP 5 guideline; Annex 15 to the EU Guide to cGMP