To Whom It May Concern

ISO 15189:2012 REQUIREMENTS REG. "CALIBRATION & VERIFICATION PROCEDURES"[1]

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[2] 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[3], 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

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1 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

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

5 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

Roche Professional Services *(ISO 9001:2015 certified)*

Customer Support Center No: 1800-123-7599 /Toll No: +91-44-30413900

Roche

Case No.	CAS-0013225018	Instrument Model	ELECTROLYTE ANALYZER W/O STARTERKIT 9180
Order No.	ORD-0017062730	Instrument Serial No.	22159
Contract Type	PREVENTATIVE MAINTENANCE & PARTS	Finance Status	CASH
Lab/Inst./hosp.Name		Arth Diagnostics Pvt Ltd	
Customer No.		0052070145	
Contact Name :		ARVINDER Singh	
Contact Number :		+919929093266	
Address :		Plot#4C,Apex Chamber,	
City :		Udaipur	

Call Received Date/Time:	31.03.2021 13:45	Call Attended Date/Time:	12.05.2021 14:00

Job Type	PM Visit
Job Description	PM VisitFlash Comments//////
Action Summary	Workdone:Preventive Maintenance done Calibration Done Customer Satisfaction Ratin5 (1-5):5

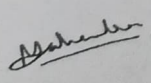
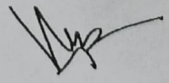
Spare Part Replaced

Part No	Parts Description	Batch No	Batch Expiry Date	Qty	Invoice Type
03074064001(1)	HARNESS, MAIN TUBING, 918X(1)			1	Free of charge

(1): Customer owned

Time Report

Effective Visit Date : 12.05.2021	Complete Date : 12.05.2021	
Date	Type	Time
2021.05.12	Travel Time--Standard	1
2021.05.12	Working Time--Standard	0.75
	Total:	1.75

Customer's Signature Name : Mahendra K Sen	Service Engineer/Application Specialist Name : Manoj Vishwakarma
	
Date: 12.05.2021	Date: 12.05.2021

Disclaimer

1. This Service report has been signed by the authorized representative of your organization.

Preface

The 9180 Electrolyte Analyzer is a powerful tool designed to quickly, accurately and efficiently conduct basic electrolyte testing in the convenience of the laboratory.

This manual has detailed descriptions of 9180 Electrolyte Analyzer features and general operational concepts, specification functions and use of controls, operating techniques, emergency procedures, product labeling and maintenance procedures.

How to use this manual

- Keep this Instructions for Use in a safe place to ensure that it is not damaged and remains available for use.
- This Instructions for Use should be easily accessible at all times.

To help you find information quickly, there is a table of contents at the beginning of the book and each chapter. In addition, a complete index can be found at the end.

Conventions used in this manual

Visual cues are used to help locate and interpret information in this manual quickly. This section explains formatting conventions used in this manual.

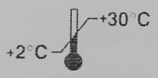
Symbols The following symbols are used:

Symbol	Used for
►	Start of procedure
•	List item
👁	Cross-reference
☞	Call-up (software reference)
💡	Tip
⚠	**Attention** All sections / passages that are marked with this symbol describe procedures and/or indicate conditions or dangers that could damage or lead to a malfunction in the 9180 Electrolyte Analyzer.
⚠	**Warning** Sections marked with this symbol contain information that must be observed to avoid potential injuries (to patients, users and third parties).

Symbol	Used for
	**Risk of infection!** All sections and parts of texts that are marked with this symbol describe procedures that may involve risk of infection.
	**ESD protective measures** All sections / text passages that are marked with this symbol refer to components that require special care with respect to electrostatic discharges. Packaging with this label may be opened by trained personnel only.

IVD symbols

The symbols are used in accordance with DIN EN ISO 15223-1[(a)] and DIN EN ISO 780[(b)].

Symbol	Description
CE	Conformité Européenne: This product complies with the requirements in the guideline for In Vitro Diagnostic 98/79/EC.
LOT	Batch code
	Consumables: use by... (expiry date) The product should not be used after expiry of the specified date. If a day is not indicated, apply the last day of the respective month.
	Temperature limitation The conditions necessary to preserve the product's shelf life before opening.
IVD	In Vitro Diagnostic Medical Device
	Manufacturer (according to In Vitro Diagnostic guidelines 98/79/EG)
REF	Catalogue number
	Caution, consult accompanying documents.
	Consult Instructions for Use.
SN	Serial number (model plate)
	Do not use if package damaged.
STERILE EO	**Valid only for Roche MICROSAMPLER PROTECT:** Method of sterilization using ethylene oxide

(a) DIN EN ISO 15223-1: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

(b) DIN EN ISO 780: Packaging - Pictorial marking for the handling of goods

Measurement and calibration procedures

Measurement procedure

The 9180 Electrolyte Analyzer methodology is based on the ion selective electrode (ISE) measurement to determine the measurement values

see Chapter 4 *Theoretical foundation*, section *Measurement principle* on page A-36.

It is very important that the main door be closed during sampling to provide shielding from sources of electromagnetic and electrostatic interference.

There are six different electrodes used in the 9180 Electrolyte Analyzer: sodium, potassium, chloride, ionized calcium, lithium and a reference electrode. Each electrode has an ion-selective membrane that undergoes a specific reaction with the corresponding ions contained in the sample being analyzed. The membrane is an ion exchanger, reacting to the electrical charge of the ion causing a change in the membrane potential, or measuring voltage, which is built up in the film between the sample and the membrane.

A galvanic measuring chain within the electrode determines the difference between the two potential values on either side of the membrane. The galvanic chain is closed through the sample on one side by the reference electrode, reference electrolyte and the "open terminal".

The membrane, inner electrolyte and inner electrode close the other side.

A difference in ion concentrations between the inner electrolyte and the sample causes an electro-chemical potential to form across the membrane of the active electrode. The potential is conducted by a highly conductive, inner electrode to an amplifier. The reference electrode is connected to ground as well as to the amplifier.

The ion concentration in the sample is then determined by using a calibration curve determined by measured points of standard solutions with precisely known ion concentrations.

Calibration procedure

A 2-point calibration is performed automatically every 4 hours in [READY] mode and a 1-point calibration is automatically performed with every measurement.

An automatic calibration procedure is also performed shortly after power-on or reset. A calibration cycle can also be initiated manually at times when no sample measurements are performed.

Measurement evaluation

The validity of the test results from the 9180 Electrolyte Analyzer must be carefully examined by a clinical-medical specialist who will take the patient's clinical condition into consideration before any clinical decisions are reached based on the test results.

In order to ensure the quality of the measurement results, complete a quality control test on 3 levels (1=low, 2=normal, 3=high) after each electrode exchange, after each replacement of the SnapPak, after startup of the instrument as well as after monthly, semi annual and annual maintenance steps.

Additionally, at least once daily one QC measurement has to be performed in alternating levels (1=low, 2=normal, 3=high) (e.g., day 1 - level 1, day 2 - level 2, day 3 - level 3, day 4 - level 1, etc.). When required by local regulations, QC measurements must be performed more often.

A quality control program for electrolytes includes the analysis of sample materials with known ranges of expected values and the comparison of these values with analyzer results.

For further information, see Chapter 8 *Quality control*.

Important safety instructions

For your own safety and the proper operation of your equipment, always follow these precautions when working with the 9180 Electrolyte Analyzer:

- Keep the analyzer away from all sources of liquids such as sinks and wash basins.

CAUTION

Do not use ammonia-based or alcohol-based cleaners, which can chemically react with plastic, on or around the analyzer.

- Always handle blood samples and collection devices with appropriate care.
- Use approved protective gloves to avoid direct contact with sample.
- Aseptic procedures are required when cleaning the sampling probe to avoid contamination.
- Dispose of SnapPak according to local regulations.

Sample collection and handling

While handling samples, all necessary regulations concerning hygiene must be observed.

Dangerous pathogenic agents could be present.

For further information, see Chapter 7 *Measurement*.