9180 Electrolyte analyzer

Short Guide for dialysis solution version 1.0

Publication information

Revision history

Publication version	Software version	Revision date	Change description
1.0	n/a	September 2022	First version

Table 1 Revision history

Introduction The **9180 Electrolyte Analyzer** is capable of measuring acetate and bicarbonate containing dialysis solutions for the quantitative measurement of sodium, potassium, chloride, and calcium. The goal of this document is to provide the necessary information for the measurement of dialysate samples.

Edition notice This publication is intended for operators of the **9180 Electrolyte Analyzer**.

Every effort has been made to ensure that all the information contained in this publication is correct at the time of publishing. However, Roche may need to update the publication information as output of product surveillance activities, leading to a new version of this publication.

General attention

To avoid serious or fatal injury, ensure that you are familiar with the system and safety information before you use the system.

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the instrument in a way that is not described in this publication.
- Store all publications in a safe and easily retrievable place.

Training Do not carry out operation tasks or maintenance actions unless you have received training from Roche Diagnostics. Leave tasks that are not described in the user documentation to trained Roche Service representatives.

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Feedback Every effort has been made to ensure that this publication fulfills the intended use. All feedback on any aspect of this publication is welcome and is considered during updates. Contact your Roche representative, should you have any such feedback.

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Preface

For content areas listed below refer to the **9180 Electrolyte Analyzer** Instructions for Use document.

- Safety information
- Configuring a correlation factor
- Quality control
- General QC concept
- Material setup
- Performing a QC measurement
- Printing a QC report

Dialysate

The Dialysis solution measurement mode allows to analyze dialysis solutions for non-clinical purposes. Dialysis solutions are defined as the buffer solution used by dialysis machines to dialyse patient blood and therefore are not considered as in-vitro-diagnostic sample types.

Please note that this sample type is not considered as in-vitro diagnostic sample type according to the Regulation 2017/746 and therefore is not covered under the scope of this Regulation.

Dialysate Measurement

Measurement principles

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

There are five different electrodes used in the **9180 Electrolyte Analyzer**: sodium, potassium, chloride, calcium, 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, which reacts to the electrical charge of the ion. This causes 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 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 the amplifier.

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

Consumables

Electrodes To measure sodium, potassium, calcium or chloride in dialysate solutions, the following products are required:

	Cl^-	Na^+	K^+	Ca^{2+}
Chloride Electrode 03110451180	X	+	+	+
Sodium Electrode 03110419180	+	X	+	+
Potassium Electrode 03110338180	+	+	X	+
Calcium Electrode 03110354180	+	+	+	X
Reference Electrode 03112306180	X	X	X	X
Reference Electrode Housing 03112284180	X	X	X	X

Table 2 Electrodes

	Cl^-	Na^+	K^+	Ca^{2+}
Dummy Electrode[(a)] 03110192055	+	+	+	+

Table 2 Electrodes

(a) replaces an unused electrode

X	Has to be inserted
+	Dummy electrode has to be used for proper filling of the measuring chamber

Parameter configurations

Possible parameter configurations for the measurement of Dialysate Solutions are:

Electrode position	Parameter configurations			
Na^+	Na^+	Na^+	Na^+	Na^+
K^+	K^+	K^+	Dummy	K^+
Cl^- / Ca^{2+}/ Li^+	Dummy	Cl^-	Cl^-	Ca^{2+}

Table 3 Parameter configurations

Solutions

	Cl^-	Na^+	K^+	Ca^{2+}
Deproteinizer 03110435180	0	0	0	0
Sodium Electrode Conditioner 03110362180		0		
Cleaning Solution 03111555180	0	0	0	0
SnapPak 03112349180	0	0	0	0

Table 4 Solutions order information

0	Can be used

QC material

	Parameters			
	Cl^-	Na^+	K^+	Ca^{2+}
ISETROL 03112888180	0	0	0	0

Table 5 QC material order information

0	Can be used

Supplementary equipment

	Parameters			
	Cl^-	Na^+	K^+	Ca^{2+}
Printer paper 03112292018	0	0	0	0

Table 6 Supplementary order information

0	Can be used

Sample handling

When measuring ionized calcium values, make sure that the sample is not exposed to ambient air. Incorrect ionized calcium values will occur if the sample is exposed to ambient air. Contact with ambient air results in a loss of CO2 in the sample. As a result, the pH values rise in the sample and ionized calcium values are reduced.

Either acetate or bicarbonate dialysate fluids may be analyzed. Dialysate samples can be stored preferably capped and placed in the refrigerator. Prior to measurement, always bring the sample to room temperature.

Measuring procedure

Daily maintenance (manual)

Before performing the first calibration or measurement, the **9180 Electrolyte Analyzer** needs to undergo a simple cleaning and conditioning procedure that ensures the analyzer will perform properly. This daily maintenance has to be performed each day before the analyzer is used.

The process involves cleaning and conditioning the sample path and electrodes, which prepares the **9180 Electrolyte Analyzer** for calibration. The bottles containing Cleaning Solution and Sodium Electrode Conditioner should be ready, along with a package of lint-free tissues that will be used to dry the probe.

Contact with the sample probe may result in infection

Contact with the sample probe during measurements or maintenance actions may result ininfection.

- When you wipe the sample probe, use several layers of gauze and wipe from the top down.
- Take care not to puncture yourself.
- Wear appropriate personal protective equipment.

Do not use Deproteinizer or Sodium Electrode Conditioner after their expiration date.

To start the daily maintenance

1. Press the **NO** key until **DAILY MAINTENANCE?** is displayed, and **YES** to select it. Press **YES** to select **Perform Daily Cleaning?**.
2. Pour a small amount of Cleaning Solution into a clean container.
3. At the prompt **Open Sample Door Introduce Sample**, lift the sample door. The pump will begin to aspirate.

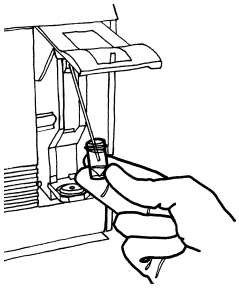

Figure 1

4 Hold the Cleaning Solution under the probe until **Wipe Probe/Close Sample Door** is displayed. Use a lint-free tissue to remove the Cleaning Solution from the probe. Close the sample door.

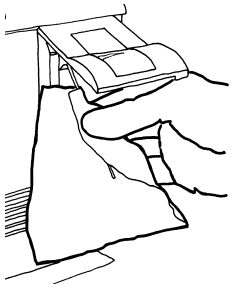

Figure 2

5 While the analyzer displays **Thank You!** and a brief countdown, pour a small amount of Sodium Electrode Conditioner into a clean container.

6 Answer the prompt **Perform Daily Conditioning?** and press **YES**.

7 At the prompt **Open Sample Door Introduce Sample**, lift the sample door and the pump will begin to aspirate.

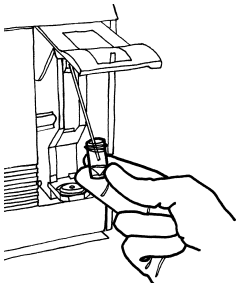

Figure 3

8 Hold the Sodium Electrode Conditioner under the probe until **Wipe Probe/Close Sample Door** is displayed. Use a lint-free tissue to remove the Sodium Electrode Conditioner from the probe. Close the sample door.

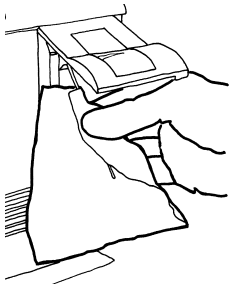

Figure 4

9 After the analyzer displays **Thank You!** and a brief countdown, the prompt **Remain in Daily Maintenance?** can be answered by pressing the **NO** key. Then an automatic calibration will start.

10 After the calibration finishes, the analyzer returns to **READY** and is ready for a QC measurement.

■

Selecting parameter configuration

After the initial daily maintenance, the analyzer starts an automatic calibration for sodium and potassium.

To select a different parameter configuration, interrupt the calibration by pressing **NO**.

To select a parameter configuration

1 Continue pressing **NO** until **OPERATOR FUNCTIONS?** is displayed.Press **YES**.

2 Press **NO** until the prompt **Select Parameter Configurations?** is displayed. Press **YES** and the current configuration will be displayed. The default configuration is:

Sel. Parameter;

- **[Na][K][]ok?**

3 Press **NO** until the desired configuration is displayed. Press **YES** to accept this selection.

If lithium is selected, the dialysate mode is not available.

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QC

Perform QC measurements on 3 levels.

The **9180 Electrolyte Analyzer** is now ready to operate.

WARNING

Failure to follow QC protocols or ignoring QC results may lead to incorrect results

Failure to follow QC protocols or ignoring QC results may lead to incorrect results.

- Follow quality control practices according to local regulations.
- Perform a minimum of one QC measurement each day. In addition, alternate through the 3 levels of available QC materials over the course of 3 days. For example, perform a QC measurement on day 1 with a level 1 QC material, on day 2 with a level 2 QC material and on day 3 with a level 3 QC material.
- Perform QC tests on 3 levels after each of these actions: electrode replacement, SnapPak replacement, start-up of the analyzer, pump tubing set replacement, main tubing harness replacement, sample probe and fill port replacement, and cleaning of the reference electrode housing
- If QC results do not match their expected results, perform the QC measurements again. If QC results still do not to match their expected results, contact Roche Technical Support.
- Do not use the analyzer for diagnostic purposes until QC results match their expected results.
- The impact of wrong results must be carefully assessed by the operator.

Sample measurement

Dialysate samples have to be measured in the dialysate mode. Separate correlation factors for bicarbonate and acetate, which may be necessary for certain dialysate compositions, are only available in dialysate mode.

To enter the dialysate mode:

- Press **NO** until **QC/STD/DIALYSATE/URINE SAMPLE?** appears. Press **YES**.
- Press **NO** until **Bicarbonate Sample?** or **Acetate Sample?** appears.

If lithium is selected, the dialysate mode is not available.

Due to interfering substances found in some dialysate solutions, it may be necessary to establish correlation factors to obtain correct results.

The **9180 Electrolyte Analyzer** provides fast and easy operation. Whenever **READY** appears, the analyzer is ready to perform sample measurements.

WARNING

Incorrect results due to mismatch between sample type and analyzer mode

If the analyzer mode does not match your measured sample type, incorrect results may be generated. This may lead to errors. The impact of wrong results must be carefully assessed by the operator.

- After each measurement, confirm that the analyzer mode on your measurement report matches your sample type.

CAUTION

Loss of sample due to insufficient sample volume

If your sample volume is less than 100 µL, you may not obtain a measurement for your sample and it will be lost.

- Ensure that you use sample collection containers with a maximum volume greater than 100 µL.

To measure a sample

1 Open the sample door. The prompt **Introduce Sample** will be displayed and the pump will start to aspirate.

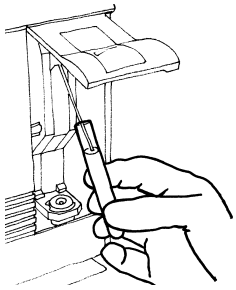

Figure 5

2 Hold the ampoule under the probe until **Wipe Probe Close Sample Door** is displayed.

3 Use a lint-free tissue to clean the probe. Then, close the sample door when prompted.

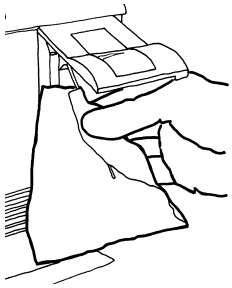

Figure 6

WARNING

Incorrect results due to carryover of analytes and reagents

Traces of analytes or reagents may be carried over from one measurement to the next. This may lead to incorrect results. The impact of wrong results must be carefully assessed by the operator.

- Wipe the sample probe immediately after each measurement on the analyzer. When you wipe the sample probe, use several layers of gauze and wipe from the top down.
- Perform the daily cleaning and conditioning procedure before performing the first measurement of each day. In addition, clean the sample probe and fill port on a weekly basis.

CAUTION

Personal injury due to contact with the paper tear bar

A paper tear bar is located on the front panel of the analyzer, where reports are printed out. Contact with the tear bar may result in personal injury.

- When tearing off reports, leave enough space between your hand and the analyzer.

4 The analyzer will display **Thank You!** and a brief countdown will begin. After the analysis is finished, the test results will be displayed and printed out.

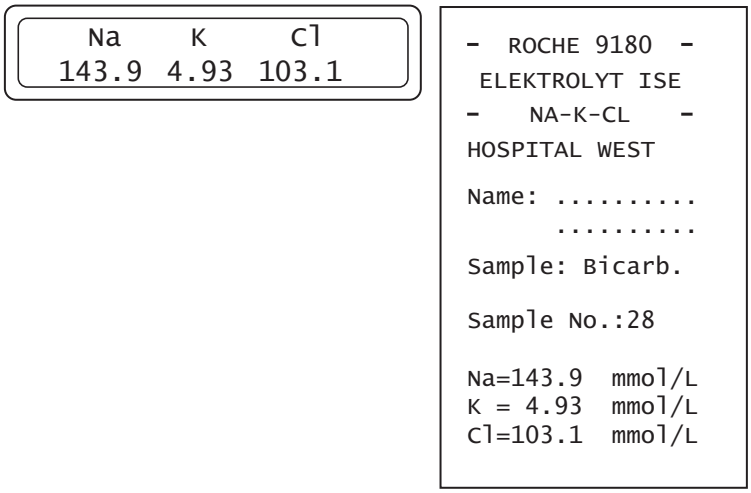

Figure 7

5 If an additional sample report is desired or the automatic sample report is turned off, the results may be printed out by following these steps:

- Press **NO**.
- The prompt **PRINT FUNCTIONS?** appears.
- Press **YES**.
- The prompt **Print last Sample Report?** is displayed.
- Press **YES**.
- The measurement results will be displayed, and the report will print out.
- The analyzer returns to **READY**.

■

Correlation factors

Correlation factors allow you to correlate measurement results from the **9180 Electrolyte Analyzer** to other electrolyte analyzers. Activated correlation values are only considered when measuring whole blood, serum, plasma and QC samples in standard mode. They are not used for standard samples analyzed in **QC/STD/DIALYSATE/URINE SAMPLE** modes. Separate correlation factors for dialysate samples are available.

If Na^+/ K^+, Na^+/ K^+/ Cl^-, or Na^+/ K^+/ Ca^{2+} are activated, a separate set of bicarbonate and acetate correlation factors can be programmed. At the prompt **Program Bicarb. Corr Factors?** and/or **Program Acetate Corr Factors?**, press **YES**. Program these factors as described in the Instructions for Use document. The programmed factors are automatically applied to acetate and bicarbonate measurements.

If QC samples were switched to report direct ISE values using service code QCC, these values are not affected by correlation factors.

Displayed values are always compared to measurement ranges, QC ranges and reference values. You may have to adjust the QC ranges and reference values to your correlation factors.

For safety and security, the analyzer can only be programmed or have existing parameters changed by entering the correct password.

Performance parameters

Measurement parameters

Parameter	specified range: [mmol/L]
Sodium (Na^+)	40 - 205
Potassium (K^+)	0.8 - 15
Chloride (Cl^-)	50 - 200
Calcium (Ca^{2+})	0.2 - 5.0

Table 7 Measurement parameters

Reproducibility

Typical within-run (S_{wr}), between-day (S_{dd}) and total (S_T) precision is determined from 2 runs per day with 2 replicates per run for 20 days on 2 **9180 Electrolyte Analyzer**.

Values for sodium and potassium are the average of all instruments. Values of chloride, ionized calcium and lithium are determined from the measurement of two of each respective unit configuration.

All values are reported in mmol/L.

Material: Acetate Dialysate Solution, n=80

Parameter	Mean	S_{wr}	(CV %)	S_{dd}	(CV %)	S_T	(CV %)
Sodium	86.1	0.85	0.98	1.81	2.10	1.78	2.07
Potassium	2.09	0.029	1.41	0.041	1.94	0.049	2.32
Chloride	107.8	0.25	0.24	0.23	0.21	0.40	0.37
Ionized calcium	1.77	0.020	1.13	0.092	5.20	0.015	6.50

Table 8 Acetate dialysate solution

Material: Bicarbonate Dialysate Solution, n=80

Parameter	Mean	S_{wr}	(CV %)	S_{dd}	(CV %)	S_T	(CV %)
Sodium	135.2	0.45	0.33	0.59	0.44	0.72	0.54
Potassium	1.58	0.023	1.46	0.031	1.95	0.037	2.37
Chloride	107.3	0.37	0.35	0.63	0.59	0.86	0.80
Ionized calcium	1.68	0.012	0.72	0.016	0.96	0.027	1.63

Table 9 Bicarbonate dialysate solution

Method comparison

A method comparison between the **9180 Electrolyte Analyzer** and the Siemens RAPIDPoint 500e system was conducted in dialysate samples.

For the measurements, bicarbonate samples were used and measured both in bicarbonate- and acetate measuring mode. This was done to confirm the ability of the **9180 Electrolyte Analyzer** to obtain similar results in both modes.

The measurement data was compared to the acceptance criteria given by the specifications for 'Accuracy'.

Parameter	Dialysis solution type	Claimed percentage of values within acceptance criteria	Obtained percentage of values within acceptance criteria
Sodium	Acetate	95.00	100.00
	Bicarbonate	95.00	99.18
Potassium	Acetate	95.00	97.60
	Bicarbonate	95.00	99.20
Chloride	Acetate	95.00	99.20
	Bicarbonate	95.00	100.00
Calcium	Acetate	95.00	100.00
	Bicarbonate	95.00	99.20

Table 10 Method comparison