

K961458



510(k) Summary

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SCIENTIFIC CORPORATION

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(2) **Device trade or proprietary name:** AVL 9180 Electrolyte Analyzer

Device common or usual name or classification name

Ion-specific electrolyte analyzer for sodium, potassium and chloride or ionized calcium or lithium.

<u>Product Nomenclature</u>	<u>Classification Number</u>	<u>Class</u>	<u>Panel</u>
ELECTRODE, ION-SPECIFIC, CALCIUM	75 JFP	II	CHEMISTRY
ELECTRODE, ION-SPECIFIC, CHLORIDE	75 CGZ	II	CHEMISTRY
FLAME PHOTOMETER, LITHIUM	75 JIH	II	TOXICOLOGY
ELECTRODE, ION-SPECIFIC, POTASSIUM	75 CEM	II	CHEMISTRY
ELECTRODE, ION-SPECIFIC, SODIUM	75 JGS	II	CHEMISTRY

(3) **Substantial Equivalence**

The AVL 9180 is an improved design of our ISE electrolyte analyzer line to provide the user an ability to only exchange electrodes to change configuration between sodium, potassium and chloride to sodium, potassium and ionized calcium or sodium, potassium and lithium. The 9180, configured for sodium, potassium and chloride is equivalent to the AVL 983 Na/K/Cl Analyzer [K861087]; for sodium, potassium and ionized calcium, to the AVL 984 Na/K/iCa Analyzer [K862819] and; for sodium, potassium and lithium to the AVL 985 Na/K/Li Analyzer [K870657]. Additionally, for sodium, potassium and lithium the AVL 9180 is substantially equivalent to the I.L. Model 943 Flame Emission Photometer and for chloride, to the Labconco Digital Chloridometer.

(4) **Description of the new device**

The AVL 9180 Electrolyte Analyzer is a microprocessor-based instrument using ion-selective electrodes for the measurement of sodium, potassium, chloride, ionized calcium and lithium. The user is able to select any one of the measurement modes: whole blood, serum, urine, standard, QC material, acetate or bicarbonate dialysate, depending on the sample type to be analyzed. The analyzer automatically processes the sample through the necessary steps, then prints and displays the results.

In the blood, serum and QC measuring modes, the results for sodium and potassium are reported by default as flame photometry equivalent; chloride, ionized calcium and lithium are reported as ISE direct potentiometric values. The urine mode allows for the measurement of prediluted urine samples for sodium, potassium and chloride. The acetate, bicarbonate and standard modes allow for the measurement of aqueous standards and dialysate solutions and reports as ISE direct potentiometric values.

(5) Intended use of the device.

The AVL 9180 Electrolyte Analyzer is intended to be used for the measurement of sodium, potassium, chloride, ionized calcium and lithium in whole blood, serum or plasma, urine, dialysate solutions, or QC materials as appropriate by minimally trained personnel qualified to perform and to report these values in a clinical laboratory setting. These analytes are commonly used in the diagnosis and management of patients with a broad range of renal, metabolic and cardiovascular disorders and, as such, have come to be among those which are considered by the American Association of Clinical Chemistry to have the potential of being life threatening if left uncontrolled.

(6) Technological characteristics of the device.**Principles of Measurement**

The principles of measurement used in the AVL 9180 Electrolyte Analyzer are identical to those principles existing in the electrolyte analyzers to which substantial equivalence is claimed in paragraph (a)(3) above.

Calibration

The AVL 9180 contains software which permits operation in one of six parameter configurations: Na⁺/K⁺/Ca⁺⁺, Na⁺/K⁺/Cl⁻, Na⁺/K⁺/Li⁺, Na⁺/K⁺, Na⁺/Li⁺ or Li⁺. A 2-point calibration is performed automatically every 4 hours in READY mode, and a 1-point calibration is performed automatically with each measurement.

Technical Specifications**Measured Values**

Parameter	Range	Display Resolution	units
<i>whole blood, serum, plasma, dialysate and aqueous solutions</i>			
Sodium	40 - 205	0.1	mmol/L
Potassium	1.5 - 15	0.1 or 0.01	mmol/L
Chloride	50 - 200	0 or 0.1	mmol/L
ionized Calcium	0.2 - 5.0	0.01 or 0.001	mmol/L
Lithium	0.1 - 6.0	0.01 or 0.001	mmol/L
<i>urine</i>			
Sodium	1-300	0	mmol/L
Potassium	4.5 - 120 (60 - 120 with additional dilution)	0.1	mmol/L
Chloride	1 - 300	0	mmol/L

Operating Conditions

- Minimum Sample Size: 95 μ L
- Sample Type:..... heparinized whole blood, serum, plasma, urine
aqueous standards and acetate or bicarbonate
dialysate solutions
- Sample Application:.....syringe, capillary or AVL Microsampler,
collection tube or sample cup
- Sample Inputautomatic aspiration
- Ambient Temperature:.....+15 - +32 °C (59 - 90 °F)
- Relative Humidity:.....5% to 95% (non-condensing)
- Type of Measurement:.....direct potentiometry

Data Management

- PrintoutBuilt-in thermal printer
- Interface RS 232 C with selectable baud rate
- Format8 bits, no parity, 1 stop bit, ASCII or ASTM (bi-directional)

Electrical Supply

- Voltage 100 - 240 VAC (50-60 Hz)
- Power Consumption 1.4 VA max., 375 max.

Dimensions and Weight

- Height x width x depth 13.2 x 12.4 x 12.0 inches (33.5 x 31.5 x 29.5 cm)
- Weight 13 lb. (6 kg)

Classifications

- Safety category I
- Device typeB (according to ÖVE-MG/EN 60601-1, IEC 601-1)
- Mode of operation..... continuous operation
- Protection classification IP 20
- Explosion protection..... the device is not designed for operation
in explosive environments
- Approvals..... CSA, IEC 1010 (TÜV/GS), CE

(b) (1) Summary of nonclinical tests submitted with the premarket notification for the device.

Precision

Typical Within-Run (S_{wr}) Between-Day (S_{bd}) and Total (S_{τ}) Precision is determined from 2 runs per day with 2 replicates per run for 20 days on two model AVL 9180 analyzers in each of its three main configurations using samples of each of the specimen types suitable for measurement on the 9180.

Linearity in Aqueous Standard Solutions

Aqueous linearity standards were gravimetrically prepared from N.I.S.T. traceable salts and measured on each of six AVL 9180 instruments, two of each configuration: Na/K/Cl, Na/K/iCa and Na/K/Li.

Parameter	Slope	Intercept	Correlation Coefficient	Sy*x	Range	n
Sodium	0.99993	0.0128	0.99995	0.666	51 - 196	300
Potassium	0.99838	0.0119	0.99919	0.194	2.0 - 12.6	300
Chloride	0.97556	-0.1775	0.99994	0.674	56 - 194	100
ionized Calcium	1.01552	-0.0078	0.99980	0.037	0.4 - 3.3	100
Lithium	0.99850	0.0087	0.99985	0.038	0.3 - 5.3	100

Linearity in Serum

Linearity in serum was established with the analysis of two specimen sets in non-clinical tests: commercially prepared serum linearity standards for sodium, chloride and potassium with normal protein content, and a group of random patient serum samples. All samples were analyzed in pairs on each of two of AVL 9180 instruments in each configuration: Na/K/Cl, Na/K/iCa and Na/K/Li. and in pairs on each of several instrument types for comparison to various methods:

vs. Flame Absorbance Emission Spectroscopy (IL 943 Flame Photometer)

Parameter	Slope	Intercept	Correlation Coefficient	Sy*x	Range	n
Sodium	0.9617	5.83	0.9908	2.04	104 - 178	50
<i>normalized to Na=140</i>		0.47				
Potassium	1.0249	0.015	0.9991	0.075	1.8 - 11.5	50
<i>normalized to K=4.0</i>		0.11				
Lithium	0.9803	0.011	0.9822	0.028	0.11 - 0.71	15

vs. ISE Direct Potentiometry (AVL 983, AVL 984, AVL 985 Electrolyte Analyzers)

Parameter	Slope	Intercept	Correlation Coefficient	Sy*x	Range	n
Sodium	0.9895	-6.35	0.9992	0.61	110 - 186	50
Potassium	1.0223	-0.25	0.9996	0.05	2.0 - 11.6	50
Chloride	0.9631	-1.01	0.9995	0.51	70 - 152	50
ionized Calcium	0.8898	0.107	0.9960	0.021	0.67 - 1.66	50
Lithium	0.9923	0.008	0.9985	0.010	0.11 - 0.71	15

vs. ISE Direct Potentiometry with flame correlation (AVL 9130, AVL 9140 Electrolyte Analyzers)

Parameter	Slope	Intercept	Correlation Coefficient	Sy*x	Range	n
Sodium	0.9856	-2.02	0.9856	1.21	104 - 179	50
Potassium	0.9992	0.02	0.9994	0.05	1.9 - 11.8	50
Chloride	1.0026	-5.31	0.9989	0.73	70 - 152	50
ionized Calcium	1.0023	0.040	0.9954	0.022	0.62 - 1.54	50

Linearity in Urine

Linearity in urine was evaluated with the analysis of random patient urine specimens on two, AVL 9810 Electrolyte Analyzers in the Na/K/Cl configuration and, in duplicate on two AVL 983 Na/K/Cl Electrolyte Analyzers for sodium, potassium and chloride; on a IL 943 Flame Photometer for sodium and potassium; and on a Labconco Digital Chloridometer for chloride.

vs. direct ISE (AVL 983) in urine

Parameter	Slope	Intercept	Correlation		Range	n
			Coefficient	Sy*x		
Sodium	1.0173	-7.4382	0.9973	5.55	4 - 262	56
Potassium	1.0312	-0.1539	0.9976	2.24	6 - 147	56
Chloride	0.9817	2.4630	0.9972	5.64	16 - 299	56

vs. flame absorbance emission spectroscopy (IL 943 Flame Photometer) in urine

Parameter	Slope	Intercept	Correlation		Range	n
			Coefficient	Sy*x		
Sodium	0.9173	0.5627	0.9901	10.64	7 - 285	56
Potassium	1.0312	-0.1539	0.9976	2.24	6 - 147	56

vs. chloridometry (Labconco Digital) Chloridometer in urine

Parameter	Slope	Intercept	Correlation		Range	n
			Coefficient	Sy*x		
Chloride	0.9817	2.4630	0.9972	5.64	16 - 299	56

(b) (2)

Summary of clinical tests submitted with the premarket notification for the device.

Three field tests were conducted to demonstrate the correlation of the AVL 9180 to legally marketed predicate devices in a clinical setting, operated by personnel trained to perform and report these analyses. Specimens analyzed in these tests were remnant from patient specimens collected for routing analysis on existing instrumentation.

In all evaluations, there was no difference in mean values ($P < 0.05$) obtained on measurement by the AVL 9180 and the predicate device. The table below provides data representative of that collected in these field tests.

vs. thin-film slide; KODAK Ektachem XR700 in serum

Parameter	Slope	Intercept	Correlation		Range	n
			Coefficient	Sy*x		
Sodium	1.0459	-6.6196	0.9495	1.67	125 - 158	103
Potassium	1.0895	-0.2740	0.9873	0.10	2.8 - 6.2	103
Chloride	0.9505	6.2577	0.9762	1.32	85 - 125	103

Parameter	Slope	Intercept	Correlation Coefficient	Sy*x	Range	n
Sodium	0.9208	10.1267	0.9485	1.19	112 - 142	102
Potassium	0.9820	0.0879	0.9933	0.16	3.2 - 12.3	102
Chloride	0.8346	13.3572	0.9674	1.45	83 - 118	102
ionized Calcium	1.0020	0.0800	0.9783	0.02	0.78 - 1.37	102

vs. direct ISE (AVL 984 Electrolyte Analyzer) in whole blood

Parameter	Slope	Intercept	Correlation Coefficient	Sy*x	Range	n
Sodium	0.9918	-6.4874	0.9682	0.94	123 - 149	102
Potassium	0.9671	-0.0380	0.9974	0.10	3.3 - 12.8	102
ionized Calcium	0.9491	0.0374	0.9825	0.02	0.87 - 1.47	102

vs. direct ISE (AVL 985 Electrolyte Analyzer) in whole blood

Parameter	Slope	Intercept	Correlation Coefficient	Sy*x	Range	n
Lithium	1.0799	-0.0203	0.9986	0.03	0.19 - 3.34	104

vs. flame absorbance emission spectroscopy (IL 943 Flame Photometer) in serum

Parameter	Slope	Intercept	Correlation Coefficient	Sy*x	Range	n
Lithium	0.9720	0.0163	0.9957	0.02	0.23 - 1.13	15

(b) (3) Conclusions drawn from the clinical and nonclinical trials.

Analysis of the comparative measurement presented in the 510(k) for this device, together with the linearity and precision data collected during these clinical and nonclinical trials demonstrates that the AVL 9180 in any of the available configurations for measurement, is safe and effective. There is no significant difference in the measurement values obtained on whole blood, serum or urine with the AVL 9180 and those obtained with predicate devices in this study and the precision and linearity demonstrated both in clinical and non clinical trials is within the manufacturers claims and expectations.