

Anexa 21 Analizator ionoselectiv Na K, Cl

Caracteristici solicitate	Caracteristici oferite EasyLyte Plus Na/K/Cl, Medica Corporation, SUA
Analizator ionoselectiv Na, K, Cl Cod 150610 Descriere Analizatoarele de electroliți testează unul sau mai multi electroliți folosind electrozi iono-selectivi. Parametrul Specificația Tip probă Ser da Urină da Plasmă da Sînge integru da Tip analize Na da K da Cl da Spălare automată da Display LCD sau LED da Printer da Data management da Interfața PC da Reagenți Reagenți "Să fie inclus toți reagenții necesari cît și alte accesorii, piese necesare pentru efectuarea analizelor și buna funcționare" ≥ 1000 analize Perioada de valabilitate a reagentilor din momentul livrării ≥ 6 luni	Analizator ionoselectiv Na, K, Cl Cod 150610 Descriere Analizatoarele de electroliți testează unul sau mai multi electroliți folosind electrozi iono-selectivi. Parametrul Specificația Tip probă Ser da Urină da Plasmă da Sînge integru da Tip analize Na da K da Cl da Spălare automată da Display LCD sau LED da Printer da Data management da Interfața PC da Reagenți Reagenți " inclusi toți reagenții necesari cît și alte accesorii, piese necesare pentru efectuarea analizelor și buna funcționare" - 1000 analize Perioada de valabilitate a reagentilor din momentul livrării ≥ 6 luni

Anexa 22 Analizator ionoselectiv Na K, Ca++

Caracteristici solicitate	Caracteristici oferite EasyLyte Calcium Na/K/Ca++Ph, Medica Corporation, SUA
Analizator ionoselectiv Na, K, Ca++ Cod 150620 Descriere Analizatoarele de electroliți testează unul sau mai multi electroliți folosind electrozi iono-selectivi. Parametrul Specificația Tip probă Ser da Urină da Plasmă da Sînge integru da Tip analize Na da K da Ca++ da Spălare automată da Display LCD sau LED da Printer da Data management da Interfața PC da Reagenți Reagenți "Să fie inclus toți reagenții necesari cît și alte accesorii, piese necesare pentru efectuarea analizelor și buna funcționare" $\geq$ 1000 analize Perioada de valabilitate a reagentilor din momentul livrării $\geq$ 6 luni	Analizator ionoselectiv Na, K, Ca++ Ph Cod 150620 Descriere Analizatoarele de electroliți testează unul sau mai multi electroliți folosind electrozi iono-selectivi. Parametrul Specificația Tip probă Ser da Urină da Plasmă da Sînge integru da Tip analize Na da K da Ca++ da Ph da Spălare automată da Display LCD sau LED da Printer da Data management da Interfața PC da Reagenți Reagenți "inclusi toți reagenții necesari cît și alte accesorii, piese necesare pentru efectuarea analizelor și buna funcționare" - 1000 analize Perioada de valabilitate a reagentilor din momentul livrării $\geq$ 6 luni



Medica Corporation
5 Oak Park Drive
Bedford, Massachusetts 01730
Tel 781 275 4892
Fax 781 275 2731
www.medicacorp.com

Declaration of Conformity

Product Name:

EasyLyte and accessories per attachment

EasyElectrolytes and accessories per attachment

Model/Type:

EasyLyte Na/K, Na/K/Cl, Na/K/Li, Na/K/Cl/Li,
Na/K/Ca/pH, Na/K/Cl/Ca/Li

EasyElectrolytes Na/K/Cl, Na/K/Li

Manufacturer

 Medica Corporation
5 Oak Park Drive, Bedford, Massachusetts, 01730, USA

Representative

 Emergo Europe, Prinsessegracht 20,
2514 AP The Hague, The Netherlands
Tel: +31 70 345 8570
Fax: +31 70 346 7299

Means of Conformity

Medica Corporation declares that the products listed are covered by Annex III of Directive 98/79/EC. These products are self-certified since they are for professional use only and are not listed on Annex II, List A or Annex II, List B of Directive 98/79/EC. In addition, they are in conformity with the Annex I, "Essential Requirements" and provisions of council Directive 98/79/EC for In Vitro Diagnostic Medical Devices, Directive 2011/65/EU Restriction of Hazardous Substance in Electrical and Electronic Equipment, and the corresponding national laws of the Member States.

Place and Date: Bedford, Massachusetts, USA, September 27, 2018

Signature:



Name: Photios Makris, Ph.D.

Title: VP, Regulatory Affairs

EasyLyte Accessories

Catalog No.	Accessory	EDMA Code
2004	EasyLyte Na/K Analyzer	21 07 11 02
2014	EasyLyte Plus Na/K/Cl Analyzer	21 07 11 02
2015	EasyLyte Lithium Na/K/Li Analyzer	21 07 11 02
2016	EasyLyte Calcium Na/K/Ca/pH Analyzer	21 07 11 02
2021	EasyLyte Na/K/Cl/Li Analyzer	21 07 11 02
2030	EasyLyte EXPAND Analyzer, Na/K/Cl/Ca-Li	21 07 11 02
2070	EasyLyte EasySampler	21 07 11 02
2101	EasyLyte K+ Electrode	11 04 01 06
2102	EasyLyte Na+ Electrode	11 04 01 07
2113	EasyLyte Cl- Electrode	11 04 01 03
2106	EasyLyte Li+ Electrode	11 04 01 04
2150	EasyLyte Ca++ Electrode	11 04 01 02
2151	EasyLyte pH Electrode	11 70 31 02
2152	EasyLyte Disposable Reference Electrode	11 04 04 01
2103	EasyLyte Reference Electrode	11 04 04 01
2258	EasyLyte Membrane Assembly	21 07 11 02
2120	EasyLyte Na/K 800 ml Solutions Pack	11 04 04 02
2121	EasyLyte Na/K/Cl 800mL Solutions Pack	11 04 04 02
2122	EasyLyte Na/K/Li 800mL Solutions Pack	11 04 04 02
2123	EasyLyte Na/K/Ca/pH 800mL Solutions Pack	11 04 04 02
2028	EasyLyte Na/K/Cl/Li 400mL Solution Pack	11 04 04 02
2109	EasyLyte Na/K 400mL Solutions Pack	11 04 04 02
2112	EasyLyte Na/K/Cl 400mL Solutions Pack	11 04 04 02
2115	EasyLyte Na/K/Li 400mL Solutions Pack	11 04 04 02
2114	EasyLyte Na/K/Ca/pH 400mL Solutions Pack	11 04 04 02
2026	EasyLyte Na/K/Cl/Li 800mL Solution Pack	11 04 04 02
2124	EasyLyte Na/K/Cl/Ca-Li 800ml Solutions Pack	11 04 04 02
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04
2843	EasyLyte Quality Control Sample Cups (60)	21 07 11 02
2118	Daily Cleaning Solution Kit	11 01 01 27
2598	EasyLyte Daily Cleaner Cup	21 07 11 02
2108	EasyLyte Solutions Valve	21 07 11 02
2107	EasyLyte Sample Probe	21 07 11 02
2257	EasyLyte Sample Detector	21 07 11 02

EasyLyte Accessories, continued

Catalog No.	Accessory	EDMA Code
2104	EasyLyte Tubing Kit	21 07 11 02
2100	EasyLyte Calcium Tubing Kit	21 07 11 02
2492	EasyLyte Internal Filling Solution (125mL)	11 04 04 90
2309	EasyLyte Wash Solution (50mL)	11 04 04 90
2111	EasyLyte Urine Diluent (500mL)	11 04 04 90
2577	EasyLyte Standard Solution, Urine (50mL)	11 04 04 90
2323	EasyLyte Probe Wipers (6)	21 07 11 02
2541	EasyLyte Printer Paper (3 rolls)	21 07 11 02
2595	EasyLyte EasySampler Sample Cups, 500uL (500)	21 07 11 02
2596	EasyLyte Sample Cups 2.0mL (500)	21 07 11 02
10745	Anti-Evaporation Caps (500)	21 07 11 02
2293	EasyLyte Capillary Tubes	21 07 11 02
2590	EasyLyte Capillary Adaptor Kit	21 07 11 02
2292	EasyLyte Capillary Adaptor Cleaning Kit	21 07 11 02
2578	EasyLyte Red Dye Test Solution (50mL)	11 30 01 11
2572	EasyLyte Troubleshooting Kit	21 07 11 02
2571	EasyLyte Troubleshooting Kit (Na/K/Ca/pH and Na/K/Cl/Li)	21 07 11 02
2105	EasyLyte Quarterly Operating Kit	21 07 11 02
2095	EasyLyte Maintenance Kit	21 07 11 02
2076	EasyLyte Sample Tray	21 07 11 02
2074	EasyLyte Sample Cup Retainer Ring	21 07 11 02
7118	Daily Rinse/Cleaning Solution Kit	11 01 01 27
2544	EasyLyte C Series Printer Paper (5 rolls)	21 07 11 02
2934	EasyLyte Barcode Reader Kit	21 07 11 02

EasyElectrolytes Accessories

Catalog No.	Accessory	EDMA Code
4002	EasyElectrolyte Na/K/Cl Analyzer	21 07 11 02
4003	EasyElectrolyte Na/K/Li Analyzer	21 07 11 02
4102	Reagent Module, Na/K/Cl	11 04 04 02
4103	Reagent Module, Na/K/Li	11 04 04 02
7205	EasyElectrolyte/EasyStat Na+ Electrode	11 04 01 07
7206	EasyElectrolyte/EasyStat K+ Electrode	11 04 01 06
4203	EasyElectrolyte Cl- Electrode	11 04 01 03
4204	EasyElectrolyte Li+ Electrode	11 04 01 04
6204	EasyElectrolyte/EasyStat/EasyBloodGas Reference Electrode	11 04 04 01
4207	EasyElectrolyte Spacer Electrode	11 04 01 90
4301	EasyElectrolyte Troubleshooting Kit	21 07 11 02
2118	Daily Cleaning Solution Kit	11 01 01 27
4402	EasyStat/EasyBloodGas/EasyElectrolyte Red Test Dye Solution	11 30 01 11
4403	EasyElectrolyte Urine Diluent	11 04 04 90
2814	Bi-Level Quality Control Kit	11 50 02 04
2815	Tri-Level Quality Control Kit	11 50 02 04
4405	EasyElectrolyte Na/K/Cl Demonstration Kit	21 07 11 02
4406	EasyElectrolyte Na/K/Li Demonstration Kit	21 07 11 02
4404	EasyElectrolyte Capillary Tube Kit	21 07 11 02
4306	EasyElectrolyte Sampler	21 07 11 02
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 07 11 02
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper	21 07 11 02
4506	EasyElectrolyte Sensor Module	21 07 11 02
4507	EasyElectrolyte Valve Module	21 07 11 02
4508	EasyStat/EasyBloodGas/EasyElectrolyte Compression Plate	21 07 11 02
7302	Probe Wipers	21 07 11 02
4522	EasyElectrolyte Daily Cleaner Sample Cups	21 07 11 02
4539	EasyElectrolyte Sensor Module, Li+	21 07 11 02
6537	EasyElectrolyte/EasyStat/EasyBloodGas Serial Cable, 9-pin	21 07 11 02
6520	EasyElectrolyte/EasyStat/EasyBloodGas Barcode Reader Kit	21 07 11 02

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Medica Corporation

(FIN F002402)

Main Site: 5 Oak Park Drive, Bedford, Massachusetts, 01730, United States

Additional Site: 3 Oak Park Drive, Bedford, Massachusetts, 01730, United States

has been registered by Intertek, an MDSAP recognized auditing organization,
as conforming to the requirements of:

ISO 13485:2016

Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012;
RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

The management system is applicable to:

*Design, Development, Manufacture, Service, Installation and Distribution of
in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro
diagnostic reagents, in-vitro diagnostic analyzers/software used in diagnosis
and management of cancer, immune status, disease status, autoimmune
status, cardiac markers, protein metabolism, endocrine disorders, blood
analytes, urinalysis, blood gases.*

Certificate Number:

0089217

Initial Certification Date:

2019-04-19

Certification Effective Date:

2019-04-19

Certification Expiry Date:

2022-04-18



Calin Moldoveanu

President, Business Assurance

Intertek Testing Services NA, Inc.
900 Chelmsford Street
Lowell, MA, USA 01851



MEDICA

Products for Health Care

EasyLyte www.medicacorp.com

Na^+/K^+

$\text{Na}^+/\text{K}^+/\text{Cl}^-$

$\text{Na}^+/\text{K}^+/\text{Li}^+$

$\text{Na}^+/\text{K}^+/\text{Ca}^{++}/\text{pH}$



EasyLyte

easy inside and out

- **Easy to Use**

Simple, menu-driven, Yes/No prompted operation

Whole blood, serum, plasma or urine samples

Results printed automatically in less than 60 seconds

Automatic or on-demand calibration

Automatic probe wiping

- **Easy to Maintain**

All calibrants contained in convenient, disposable solutions pack

All waste collected in solutions pack

Disposable electrodes require no maintenance

Modular design makes maintaining analyzer simple and fast

- **Easy to Afford**

Low analyzer purchase price

Low cost per test

- **Available in four models:**

- **EasyLyte** Na^+/K^+
- **EasyLytePLUS** $\text{Na}^+/\text{K}^+/\text{Cl}^-$
- **EasyLyteLithium** $\text{Na}^+/\text{K}^+/\text{Li}^+$
- **EasyLyteCalcium** $\text{Na}^+/\text{K}^+/\text{Ca}^{++}/\text{pH}$





Modular, maintenance-free electrodes



Cl⁻



Internal printer prints patient results, calibration values, quality control data, and results summaries, flagging abnormal results

Pressing Yes or No buttons is all that is required to analyze serum, plasma or whole blood



K⁺



Self-contained Solutions Pack contains liquid calibrants and collects all waste, eliminates sample contact



Capillary sampler is removable and disposable



EasySampler

The modular EasySampler connects quickly to the EasyLyte Na/K, Na/K/Cl, and Na/K/Li analyzers, enhancing laboratory performance.

- 21 sample positions
- Dedicated Stat position
- Normal/Abnormal QC positions
- Optional auto-repeat of out-of-range values

Li+

pH

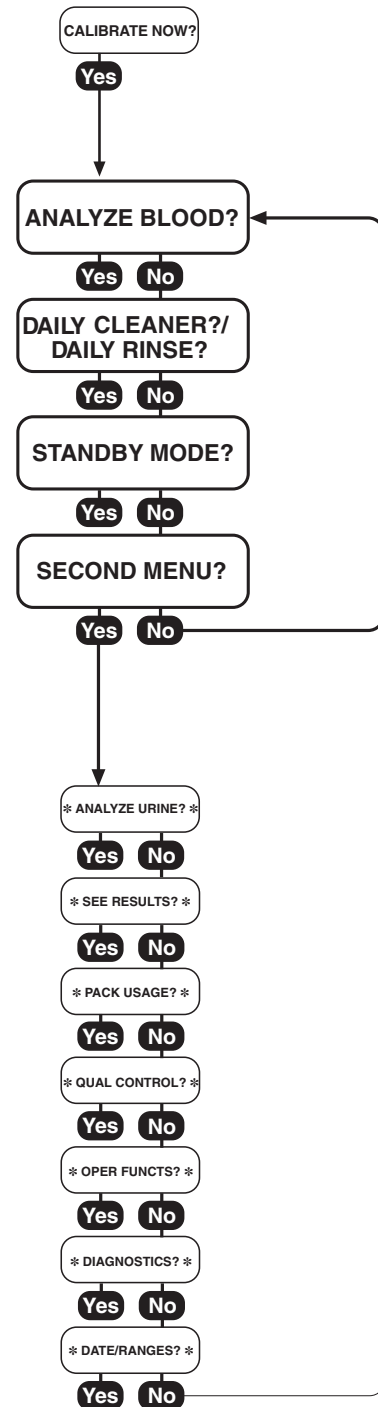
Analyzer software insures ease of operation

Software computes quality control statistics, flags abnormal results, and monitors performance.

- Two button operation
- Automatic calibration
- User-friendly menu

Ca++

Na+



Specifications

(Na⁺/K⁺, Na⁺/K⁺/Cl⁻, Na⁺/K⁺/Li⁺, Na⁺/K⁺/Ca⁺⁺/pH)

MEDICA

Products for Health Care

CLIA Classification: Moderate Complexity
Sample Type: Whole Blood, Serum, Plasma or Urine
Sample Size: 100 µL Whole Blood, Serum, Plasma, 60 µL capillary or 400 µL diluted (1:10) Urine

Method: Direct measurement by Ion Selective Electrode (ISE)

Measurement Range:	Blood	Urine
	Na ⁺ : 20 – 200 mmol/L	Na ⁺ : 25 – 1000 mmol/L
	K ⁺ : 0.2 – 40 mmol/L	K ⁺ : 1.0 – 500 mmol/L
	Cl ⁻ : 25 – 200 mmol/L	Cl ⁻ : 25 – 500 mmol/L
	Li ⁺ : 0.2 – 5.0 mmol/L	
	Ca ⁺⁺ : 0.1 – 6.0 mmol/L	
	pH: 6.0 – 8.0 Units	

Display Resolution: Na⁺: 0.1 mmol/L K⁺: 0.01 mmol/L Cl⁻: 0.1 mmol/L
 Li⁺: 0.01 mmol/L Ca⁺⁺: 0.01 mmol/L pH: 0.005 units

	Na ⁺ /K ⁺	Na ⁺ /K ⁺ /Cl ⁻	Na ⁺ /K ⁺ /Li ⁺	Na ⁺ /K ⁺ /Ca ⁺⁺ /pH
Analysis time (blood)	55 sec	55 sec	55 sec	60 sec
Urine Mode	Yes	Yes	Yes	No
Analysis time (urine)	90 sec	90 sec	90 sec	N/A
EasySampler	Yes	Yes	Yes	No
Capillary Samples	Yes	Yes	Yes	No

Data Storage: Patient results — up to 128 samples
 QC results — up to 20 each Normal, Low, and High

Calibration: Automatic or On-Demand

Output: 128 x 64 pixel graphic display
 24 column thermal printer
 Serial port (RS-232), EasySampler port

Ambient Conditions: 15–32°C (60–90°F), <85% humidity

Power: 100-240 VAC 50/60 Hz, 0.8A

Size & Weight: 9.5"W x 16.5"H x 8.0"D (24 cm W x 42 cm H x 20 cm D) 13 lbs. (5.8 kg)

Medica Corporation
 5 Oak Park Drive
 Bedford, MA 01730-1413
 USA

Continental US Telephone
800 777 5983

International Telephone
781 275 4892

Fax
781 275 2731

sales@medicacorp.com

www.medicacorp.com

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