

Anexa nr.2 la Formularul Specificații tehnice

Analizator biochimic automat

Descriere	Analizator biochimic automat destinate analizelor biochimice cu sistem închis de reactivi.	
Parametrul	Specificația solicitata	SPECIFICAȚII TEHNICE OFERTATE, model Selectra ProM (Elitech/Olanda)
Tip de lucru	continuu	Continuu
Tip sistem	închis	închis
	random acces	random acces
Capacitatea (teste/oră)	≥150 (teste fotomerice, fara modul ISE)	180 (teste fotomerice, fara modul ISE)
Posibilitatea efectuării analizelor urgente	da	Da
Tipul dispozitivului	staționar	Da, cu calculator integrat
Tip probă	Ser și plasmă	Ser și plasmă
	urină	urină
	sînge integru/hemolizat	sînge integru/hemolizat
	CSF (lichid cefalo-rahidian)	CSF (lichid cefalo-rahidian)
Tip diluare	automat	automatizată
Sistem de spălare	AUTOMAT	Total automatizată (cuvă, ac, sistem de dozare)
	Fara conectare la sursa externa de apa	Fara conectare la sursa externa de apa
	Volum de apa consumat pe ora ≤0.5l	Volum de apa consumat pe ora 0.5l maxim
Program control al calității	Management intern al controlului calitatii	Da
	Grafice Levey-Jennings	Da, Westgard rules Levey-Jennings plots
Compartiment reactivi	Cantitate de reactivi concomitant la bord ≥30	Cantitate de reactivi concomitant la bord 32

	Capacitatea buteliilor cu reactive 20ml si 50ml	Capacitatea buteliilor cu reactive 10ml, 25ml, 50ml – pag 17 ProM User Manual.
	Detectia nivelului de lichide - da	Detectia nivelului de lichide – da - Liquid sensor detection.
	Consumul de reagenti ce poate fi programat 10mcl – 440mcl	Consumul de reagenti ce poate fi programat: – R 1 volume 110 - 399 μ L – R 2 volume 10 - 289 μ L – R 3 volume 10 - 289 μ L – Programmable in 1 μ L steps
Compartiment probe	Cantitate probe la bord ≥ 72	Cantitate probe la bord 72
	Eprubete primare, da	primary and secondary tubes, da
	Eprubete pediatrice, da	Da, pediatric cups
	Eprubete primare si pediatrice pot fi utilizate concomitant, da	Eprubete primare si pediatrice pot fi utilizate concomitant, da
	Volumul probei utilizat 3mcl – 40mcl	– Sample volume 1 - 30 μ L – Programmable in 0.1 μ L steps
Rotor pentru probelor	cu termostat la 37 grade C	Da
	Cantitatea celulelor pentru reactive ≥ 120	Cantitatea celulelor pentru reactive 32
	Cu posibilitatea de utilizare repetata, da	Cu posibilitatea de utilizare repetata, da - 10,000 tests / cuvette rotor.
	Volumul de reactie 200mcl-800mcl	Volumul de reactie 220 μ L -400 μ L
Regimuri de măsurare:	Cinetic	Cinetic
	Mono și bi-cromatic	Mono si bi-cromatic
	Imunoturbidimetric (Turbidity)	Imunoturbidimetric (Turbidity)
	Filtre optice utilizate ≥ 8	Filtre optice utilizate 8

		Diapazonul filtrelor optice 340nm-900nm	Diapazonul filtrelor optice: 340, 405, 505, 546, 578, 620, 660, 700 nm
		Funcție de detectie a prozonei	Funcție de detectie a prozonei, da – ProM User Manual
Sistem operational		Calculator extern, da	Calculator extrn, integrat cu analizatorul biochimic
		Interfata LIS	Interfata LIS, ProM User Manual
		Program intuitive si usor de realizat	Program intuitive si usor de realizat
Sistemul de dozare:	cu sensor de obstacole	da	Dispune de sensor de obstacole
	Volum de dozare	3mcl – 1250mcl	– R 1 volume 110 - 399 μ L – R 2 volume 10 - 289 μ L – R 3 volume 10 - 289 μ L Programmable in 1 μ L steps
	rezolutia	≤ 0.126 mcl	Resolution 0.001 Abs
	Viteza de dozare	≥ 880 mcl/s	Nu se aplica la ProM
Sursa de lumina		Lampa cu halogen 6V, 10W	Quartz-iodine lamp 12V-20W
		Durata de viata ≥ 2000 ore	2000 ore, da ProM User Manual
		Monitorizarea automata a duratei de lucru, da	Monitorizarea automata a duratei de lucru, da
Alimentarea		220 V, 50 Hz	220 V, 50 Hz
Greutatea		≤ 45 kg	95 kg
Certificare		CE – certificate/declaratie	CE – certificate/declaratie
		ISO 13485	ISO 13485
		ISO9001	ISO9001
		Ingineri autorizati de producator pentru mentenenta si suport tehnic	Ingineri autorizati de producator pentru mentenenta si suport tehnic

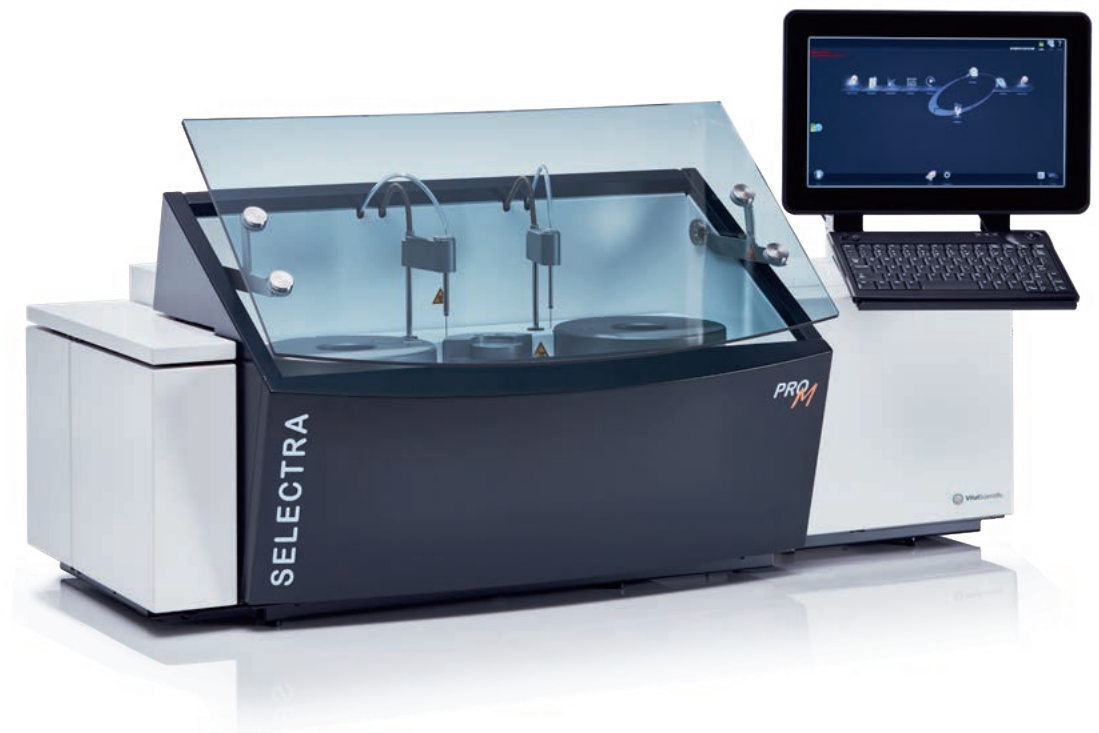
Clinical Chemistry

Selectra ProM™



Selectra Solutions

THE SMARTEST CHOICE
FOR YOUR GROWING
LABORATORY NEEDS



VitalScientific
Diagnostics for Life

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SPECIFICATIONS

THROUGHPUT

- Typically 180 tests/hour¹
- Up to 333 ISE tests/hour (Dry ISE optional)

REAGENT HANDLING

- Refrigerated reagent rotor controlled with Peltier elements
- Cooled to 10°C+/-4°C at normal laboratory conditions
- 32 reagent positions for 10 mL and 25 mL reagent bottles
- Reagent ID and automated programming of assays, calibrators and controls via barcode
- All reagent positions can be assigned as R1, R2 and R3
- Pre-heated needle with level detection, collision protection and integrated mixer

SAMPLE HANDLING

- Sample rotor containing:
 - Outer segment with 50 barcode readable positions
 - Inner segment with 12 auxiliary positions
 - All positions fit 13x75 mm primary and secondary tubes and pediatric cups
 - All positions can be used for calibrators, controls, normal, pediatric and STAT samples
- Sample probe with level detection, integrated mixer and collision protection
- Programmable dilution ratios 1 : 5 up to 1 : 200 in one step increments with 3 possible diluents

PIPETTING SYSTEM

- 1000 µL reagent syringe:
 - R 1 volume 110 - 399 µL
 - R 2 volume 10 - 289 µL
 - R 3 volume 10 - 289 µL
 - Programmable in 1 µL steps
- 100 µL sample syringe:
 - Sample volume 1 - 30 µL
 - Programmable in 0.1 µL steps

CUVETTE ROTOR

- Cost effective, semi-disposable cuvette rotor with 48 cuvettes, path length 7 mm
- >10,000 tests per rotor
- Minimum measuring volume 220 µL
- Measuring temperature 37°C, controlled by Peltier elements

LIGHT SOURCE

- Quartz-iodine lamp 12V-20W

WAVELENGTH RANGE

- 340 - 800 nm
- Optical unit with 8 position filter wheel
- Automatic wavelength selection
- 340, 405, 505, 546, 578, 620, 660, 700 nm standard installed
- Other wavelengths available on request

PHOTOMETRIC RANGE

- -0.1 to 3.0 Absorbance
- Resolution 0.001 Abs

ANALYTICAL MODES (SINGLE, DUAL AND TRIPLE REAGENT SYSTEM)

- Kinetic measurement with linearity check
- Mono and bichromatic end point measurement with or without bichromatic reagent blank and/or sample blank correction
- Two point measurement; with or without slope blank
- Graphic plot of all measuring points
- Predilution, post-dilution and automatic reflex dilution as needed
- Non-linear calibration curves
- Prozone check for immunology tests
- Cut-off declaration
- Calculated tests

QUALITY CONTROL

- Up to 15 different controls can be defined, 3 per test
- Westgard rules
- Levey-Jennings plots
- Quality control statistics

WATER CONSUMPTION

- ~500 mL per hour max, continuous operation

STANDARDS AND REGULATIONS

- CE-IVDR
- USA FDA 510(k)
- CB
- UL

DIMENSIONS & WEIGHT

- 125 cm (50 in) x 59 cm (23 in) x 62 cm (25 in) excl. monitor and panel PC (WxHxD)
- 95 kg (210 lbs)

INTERFACE

- State of the art Host-Query interface available
- Host: RS232 or Ethernet (TCP/IP) through LIS-2A protocol
- Hand held CCD barcode reader used for reagent identification and automated programming of assays, controls, and calibrators

INSTALLATION CONDITIONS

- Temperature: 15 - 32 °C (59 - 90°F)
- Humidity: 15 - 85% RH
- Altitude: up to 2000 m
- Plumbing: no dedicated system water or drain required
- Electrical: Voltage: 100 - 240 Vac; Frequency: 50 / 60 Hz; Power (max): 400 VA

INTEGRATED PC²

- Touch screen navigation
- Operating System: MS Windows 10 IoT

OPTIONS

ISE MODULE²

- Patented Solid State Dry Electrode Technology
- Indirect measurement
- Dilution 1:14
- Measures Sodium, Potassium, Chloride and Bicarbonate

POSITIVE SAMPLE IDENTIFICATION

- Positive Sample Identification (PSID) via integrated barcode reader
- Reads all popular formats including Codes 39, 128, 11, 93, CODABAR and Interleaved 2/5

PRINTER

- Printer supported by MS Windows™

PROACTIVE MAINTENANCE KIT

- Complete parts kit for annual preventive maintenance

¹ Assuming combinations of photometric and ISE tests.

² Please verify the right instrument catalog number for this option from your local representative.

1.2.4 Reagent rotor



In the Selectra ProM, the left rotor holds reagent bottles. Bottles of 10 ml, 25 ml and 50 ml can be placed. The entire rotor can easily be replaced. This may be useful when different sets of reagents are needed. During normal operation, the rotor is covered. The base of the rotor is cooled.


Note
 Optimal cooling can only be reached when the cover is kept closed as much as possible. Only open the cover when access is needed.


Note
 It is possible to use multiple rotors for the same Selectra ProM. Each rotor may hold a different set of reagents. Switching rotors can be done without shutting down the analyzer. See par. 5.2.4. For details on configuring multiple rotors, see par. 6.3.2.

7.3.2 Replacing the cuvette rotor

The cuvette rotor must be replaced when:

- 10 000 tests were performed with it. The counter is available in the **Change cuvette rotor** screen. See step 3 below.
- Too many cuvettes are excluded. A cuvette must be excluded when SD.ERR messages appear after performing a cuvette rotor blank. See par. 7.1.4. ELITechGroup recommends replacing the cuvette rotor when more than 3 cuvettes are excluded.



BIOHAZARD

Observe all common safety precautions (e.g. wear protective clothing and gloves), since this part of the system is potentially infectious. Also make sure that no liquids leak into the analyzer system.

1. Make sure the state of the analyzer is **Stand-by** or **Inactive**.
2. Open the **Rotor/System** screen. This screen is listed in the menu tree.
3. Click **Change cuvette rotor** in the menu to the left. The screen shows two counters. The top counter shows how many tests were performed on the current rotor. The bottom counter shows how many tests were performed on the analyzer.

Tests on this rotor:	798
Total test count:	798

4. Remove cover from the cuvette rotor.
5. Click **F1 Lift WashArm**. The wash arm moves to the highest position.
6. The analyzer asks if the counter should be reset. Click **Yes** to zero the cuvette counter.
7. Gently pull the stirrer unit up with the metal pin [A]. It remains in this position.



8. Carefully remove the cuvette rotor.

7.3.3 Replacing the lamp

The lamp must be replaced after about 2 000 operating hours (approximately one year under normal operating conditions) or earlier if a mechanical or technical defect is found. If the analyzer behaves in an unusual manner, check the intensity of the lamp. It is possible that the lamp deteriorates before it reaches 2 000 operating hours.



WARNING

Make sure the analyzer is switched off before replacing the lamp.



HOT SURFACE

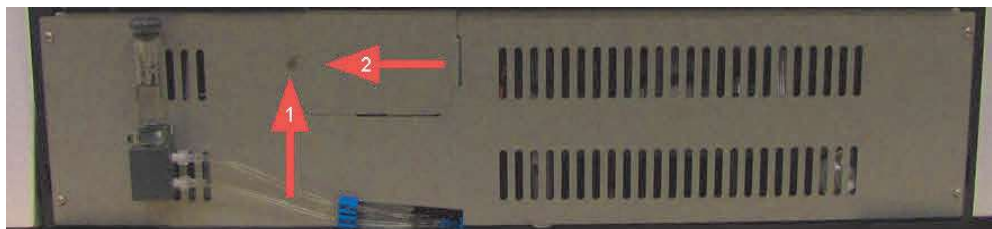
Do not touch the lamp immediately after switching off the analyzer. The lamp is hot and will cause burns. Allow the lamp to cool down for at least 10 minutes after switching off the analyzer.

1. Open the cover.
2. Lift the front panel and remove it from the analyzer.
3. A small sliding panel is held in position by one screw [1] on the left. Loosen the screw. Slide the panel to the left [2], then tilt and lift it out. The lamp support is now exposed.



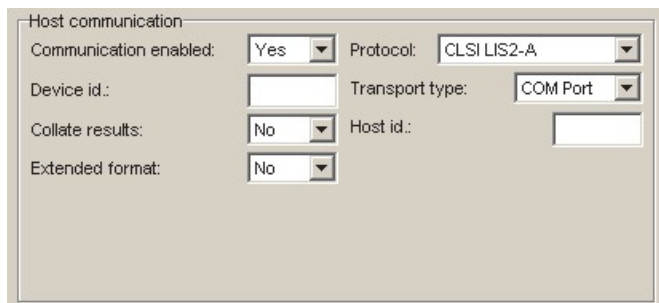
Note

To get better access to the lamp unit, you can remove the entire front panel. Remove the four screws around the sides to do this.



6.6.2 Configuring the LIS host connection

1. Open the **Installation** screen. This screen is listed in the menu tree.
2. Click **Communication** in the menu to the left. The screen shows the current settings.
3. Set the **Host communication** parameters in the bottom section of the screen.



Communication enabled: Select **Yes** to enable communication with the LIS host.

Protocol: Name of the protocol. A document describing the **CLSI LIS2-A** protocol can be provided on request.

Device id.: Six-digit code for identification purposes. All information sent to the host computer will be identified by this code.

Host id.: Four-digit code to identify the host computer to communicate with. This can be used in situations where multiple host systems are connected in the same LIS.

Transport type: Select **COM Port** or **TCP/IP**.

Collate results: Select **Yes** to keep test results until all tests for a sample are ready, before the whole set of test results is sent to the host. Select **No** to have the analyzer send test results as soon as they become available.

Extended format: Select **Yes** to use an extended format in the communications with the host computer (absorbance values are transmitted to the host along with the results).

4. (Optional) If the **Transport type:** is **COM Port**, Click **F3 Port Settings** to change the serial communication port settings. Contact your supplier for details.
5. (Optional) If the **Transport type:** is **TCP/IP**, Click **F3 TCP/IP connection settings** to change the communication settings. If required, click **F9 Network Connections** to open the Windows network configuration section.

Parameters

All values shown to the left are the same as on the **Evaluate Results** screen. See par. 4.2.5. The top right section of the screen shows the measured result and the status of the measurement.



Note

The measurement details are shown in a number of screens. Click on the tabs in the top to view the screen. The screens are described in separate subsections below.

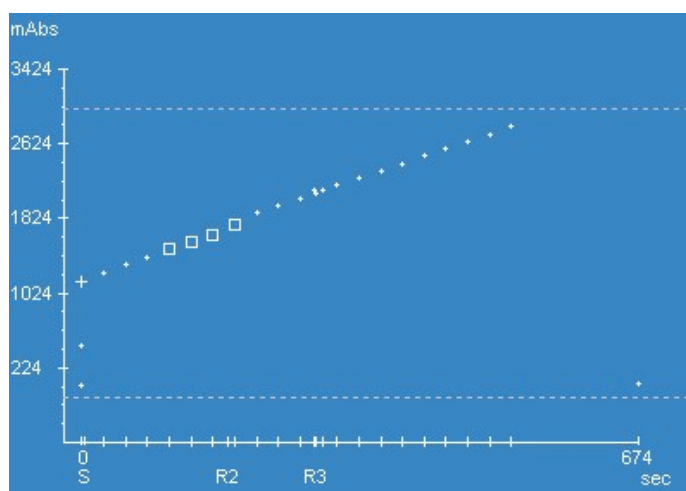


Note

Not all screens listed below are shown for all measurements. Only those that have information to show are visible.

Graph

The graph shows all measurement points. The X-axis shows the timing of measurements. The Y-axis shows the measured absorbances.



Measurement used in the calculation of the test result.



Measurement used in the prozone check. Only shown in prozone graph.



Measurement not used in the calculation of the test result.



Measurement of the first reagent.



Extrapolated value. Only used for sample start methods with falling kinetics.



- In normal graph: slope point used for slope blank calculation.
- In prozone graph: prozone point used in the calculation.

The dashed lines indicate the absorbance limits defined for this test.