Anexa nr. 9 la Formularul Specificații tehnice
Lot nr. 9 Analizator biochimic automat 200

Specificarea tehnică solicitată	**Specificarea tehnică deplină ofertata**, model **Selecta Mach5** (nr. catalog 6004-301)
Descriere Analizator automat destinat analizelor biochimice. Sistem analitic automat cu calculator integrat sau exterior (procesor, monitor, tastatura + mouse, imprimanta) Tip de lucru continuu Tip sistem randoom acces Capacitatea (teste/oră) ≥ 200 (teste fotometrice, fara modul ISE) Posibilitatea efectuării analizelor urgente Obligatoriu Tipul dispozitivului staționar Tip probă Ser plasmă urină sânge integru CSF (lichid cefalo-rahidian) lichide biologice Tip diluare automat Sistem de spălare total automat Obligatoriu Program complex de control al calității Obligatoriu Compartiment reactivi cu răcire Rotor cu Cuva pentru reacție cu încălzire la 37°C Tip Reutilizabil (indicati ciclurile posibile de reutilizare) Sistem fotometric cu sursa de lumina LED/Halogen Cu minim 12 lungimi de unda in intervalul 340 până la 800nm Regimuri de măsurare Cinetic Mono și bi-cromatic Imunoturbidimetric (Turbidity) Controlul cantitatii de reagent ramas obligatoriu Semnalizare lipsă reagent și probă Obligatoriu Sistemul de dozare: Reagenții Utilizarea a minim 2 metodici: mono și bireagent Volumul reagentului programabil cu pasul 1 µl Cu senzor de obstacol detectia automata a cheagurilor de sange Obligatoriu Conectare LIS Bi-directional Alimentarea 220 V, 50 Hz **Note:** Oferta de preț trebuie să includă reactivii necesari pentru testele indicate, soluțiile QC și calibrare Cantitatea soluțiilor propuse trebuie să asigure efectuarea procedurilor de control al calității și calibrare, ori de câte ori este necesar. **Furnizorul va asigura:** Transmiterea către spital documentația completă privind conectarea analizatorului la sistemul informatic (H3 SIA AMS/AMP) și să asigure suportul tehnic necesar echipei desemnate de spital sau firmei de software care realizează efectiv conectarea. Instruirea personalului. Mentenanța preventivă și corectivă gratuită pe toată durata contractului atât pentru analizator cât și pentru dispozitivele auxiliare livrate (ex. Calculator, UPS, sistem filtrare). Seturile de mentenanță și piesele de schimb gratuite pe toată durata contractului atât pentru analizator cât și pentru dispozitivele auxiliare livrate (ex. Calculator, UPS, sistem filtrare apă). Toate consumabilele necesare gratuite pe toată durata contractului atât pentru analizator cât și pentru dispozitivele auxiliare livrate (ex. Calculator, UPS, sistem filtrare apă), dacă acestea nu au fost incluse în oferta inițială. Timpul de intervenție în caz de defect: maxim 24 ore de la solicitarea telefonică. Preț pentru reactivi nemodificat pentru toată perioada contractului. Perioada de valabilitate pentru reagenții livrați: La momentul livrării: Minim 6 luni, dar nu mai puțin de 80% din termenul total de valabilitate. Să se indice timpul de stabilitate a reactivilor după deschidere. Termenele mai mari vor fi considerate un avantaj. Operatorul Economic va include în oferta prețul dispozitivului medical și prețurile pentru fiecare test considerând: - Efectuarea controlului calității pentru fiecare test în fiecare zi lucrătoare. - Efectuarea calibrării ori de cate ori va fi necesar (în baza rezultatului	Descriere Analizator automat destinat analizelor biochimice. Sistem analitic automat cu calculator integrat (procesor, monitor, tastatura+mouse), *pag. 4 Selectra Mach5 Brochure* Tip de lucru continuu - **CONTINUOUS REAGENT AND SAMPLE LOADING,** ***pag. 4 Selectra Mach5 Brochure*** Tip sistem randoom acces – da pag.4 *Selectra Mach5 Brochure***.** Capacitatea (teste/oră fara modul ISE): **250 tests/hour for dual reagent tests; 500 tests/hour for mono-reagent tests**, *Selectra Mach5_User Manual, A.1 Technical specifications;* Posibilitatea efectuării analizelor urgente da – **STAT capability -** *pag. 4 Selectra Mach5 Brochure; Selectra Mach5_User Manual, pag. 256.* Tipul dispozitivului staţionar – da, benchtop, *pag. 4 Selectra Mach5 Brochure* Tip probă: Ser, plasmă, urină, sânge integru, CSF, lichide biologice – da, *pag. 4 Selectra Mach5 Brochure; Selectra Mach5_User Manual, pag. 189***.** Tip diluare automat: **Dilution**, *pag. A-15 Selectra Mach5_User Manual, A.2.3.3***; automatic onboard dilution,** *pag. 4 Selectra Mach5 Brochure;* Sistem de spălare total automat - **Wash station Fully automated with overflow level detector,** *Selectra Mach5_User Manual, A.1.1.4 Measurement system;* Program complex de control al calității Obligatoriu – da, **QC rules: Westgard, Basic, Separation;** *Selectra Mach5_User Manual, A.2.3.2 QC rules;* Compartiment reactivi cu răcire **Up to 65 Bar Code Readable (BCR) positions, cooled at 8 ± 4 °C**, *Mach5 prospect, pag. 4* Rotor cu Cuva pentru reacție pentru probe cu încălzire la 37°C – da, **cap 3.2 Cuvette rotor**, *Selectra Mach5_User Manual, pag 3-3*; Tip Reutilizabil – **30 000 teste**, *Selectra Mach5_User Manual, cap. 6.2 Maintenance schedule.* Sistem fotometric cu sursa de lumina **LED based photometer,** *Selectra Mach5_User Manual, A.1.1.4 Measurement system;* Cu 12 lungimi de unda in intervalul: **340, 405, 415, 490, 505, 546, 570, 600, 625, 660, 700, 800nm -** *Selectra Mach5_User Manual, A.1.1.4 Measurement system;* Regimuri de măsurare Cinetic - ***Selectra Mach5_User Manual, 8.4.2 Tests screen - General page;*** Mono și bi-cromatic– **da,** *Selectra Mach5_User Manual pag 8-9***;** Imunoturbidimetrc (Turbidity) – **da,** *ASSAY TECHNOLOGY – Turbidimetric, Mach5 prospect, pag. 4;* **(IFU atasat);** Controlul cantitatii de reagent ramas obligatoriu – da, **Selectra Mach5_User Manual, 4-13** Semnalizare lipsă reagent și probă – **da - Reagent Low Volume Warning,** *Selectra Mach5_User Manual, pag. 189.* Insuficient sample, *Selectra Mach5_User Manual, 7-7; 7-9***.** Sistemul de dozare: Reagenții Utilizarea a 2 metodici: **mono-reagent tests si dual reagent tests -** *A.1 Technical specifications, Selectra Mach5_User Manual;* Volumul reagentului programabil cu pasul 1 µl - **da, Selectra** *Mach5_User Manual, A.1.1.4 Measurement system;* detectia automata a cheagurilor de sange – **Clot detection, A.1.1.2** *Selectra Mach5_User Manual, pag A-3;* Cu senzor de obstacol – **da, colision detection**, *Selectra Mach5_User Manual, pag A-3;* Conectare LIS Bi-directional – da, **8.11.5 LIS screen** *Selectra Mach5_User Manual, pag 8-41;* Alimentarea **100 - 240 Vac ±10%, 50/60 Hz, Selectra Mach5_User Manual, A-6;** **Note:**

controlului calității). - Toate piesele si kiturile de mentenanță necesare bunei funcționării pe întreaga perioada a contractului. - Sistemul de filtrare (stație purificare apa) și toate filtrele necesare pentru funcționarea stației de purificare al apei pe toată perioada contractului. -UPS (Sursa neîntreruptibilă de alimentare) și costurile acumulatoarelor necesare pe toata perioada contractului. - Calculator (PC), monitor, tastatura, mouse cu garanție deplină și înlocuire în caz de defectare. - Toate consumabilele, inclusiv: soluții de spălare, soluții de buffer, electrozi/modul ISE, cuve/rotor pentru reacție, lămpi și tot spectrul de consumabile necesare bunei funcționări pentru efectuarea tuturor testelor solicitate de IMSP. - Toate serviciile de mentenanță preventivă și corectivă necesare bunei funcționări pe perioada contractului. Respectiv, se vor lua în calculul toate cheltuielile care ar putea apărea în întreaga perioada a contractului.	Oferta de preț include reactivii necesari pentru testele indicate, soluțiile QC și calibrare. Cantitatea soluțiilor propuse va asigura efectuarea procedurilor de control al calității și calibrare, ori de câte ori este necesar. **GBG-MLD va asigura:** Transmiterea către spital documentația completă privind conectarea analizatorului la sistemul informatic (H3 SIA AMS/AMP) și să asigure suportul tehnic necesar echipei desemnate de spital sau firmei de software care realizează efectiv conectarea. Instruirea personalului. Mentenanța preventivă și corectivă gratuită pe toată durata contractului atât pentru analizator cât și pentru dispozitivele auxiliare livrate (ex. Calculator, UPS, sistem filtrare). Seturile de mentenanță și piesele de schimb gratuite pe toată durata contractului atât pentru analizator cât și pentru dispozitivele auxiliare livrate (ex. Calculator, UPS, sistem filtrare apă) Toate consumabilele necesare gratuite pe toată durata contractului atât pentru analizator cât și pentru dispozitivele auxiliare livrate (ex. Calculator, UPS, sistem filtrare apă), dacă acestea nu au fost incluse în oferta inițială. Timpul de intervenție în caz de defect: maxim 24 ore de la solicitarea telefonică. Preț pentru reactivi nemodificat pentru toată perioada contractului. Perioada de valabilitate pentru reagenții livrați: La momentul livrării: Minim 6 luni, dar nu mai puțin de 80% din termenul total de valabilitate. Să se indice timpul de stabilitate a reactivilor după deschidere – 8saptamani. GBG-MLD a inclus în oferta prețul dispozitivului medical și prețurile pentru fiecare test considerând: - Efectuarea controlului calității pentru fiecare test în fiecare zi lucrătoare. - Efectuarea calibrării ori de cate ori va fi necesar (în baza rezultatului controlului calității). - Toate piesele si kiturile de mentenanță necesare bunei funcționării pe întreaga perioada a contractului. -UPS (Sursa neîntreruptibilă de alimentare) și costurile acumulatoarelor necesare pe toata perioada contractului. - Calculator (PC), monitor, tastatura, mouse cu garanție deplină și înlocuire în caz de defectare – este integrat in analizor. - Toate consumabilele, inclusiv: soluții de spălare, soluții de buffer, electrozi, cuve/rotor pentru reacție, lămpi și tot spectrul de consumabile necesare bunei funcționări pentru efectuarea tuturor testelor solicitate de IMSP. - Toate serviciile de mentenanță preventivă și corectivă necesare bunei funcționări pe perioada contractului. Respectiv, se vor lua în calculul toate cheltuielile care ar putea apărea în întreaga perioada a contractului.

***Edit* -** Edit the test parameters of the selected test. You cannot edit a test if it is mentioned in a worklist. Reagents may remain loaded.

***Delete* -** Delete the selected test. You can only delete tests that are not being used elsewhere in the system. If the deleted test was linked to a calibrator or control, it will automatically be unlinked. If the deleted test was included in a panel, it will be removed from the panel.

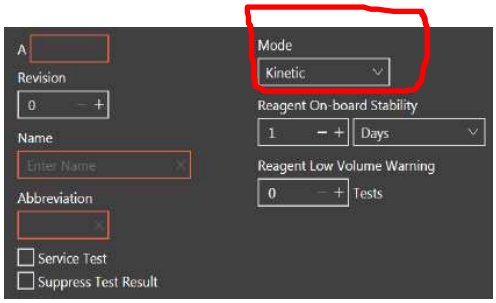
***Accept* -** Confirm the changes in all test configuration pages.

***Cancel* -** Discard the changes in all test configuration pages.

See also:
'Importing data' on page 5-46
'Exporting data' on page 5-47
'System Parameters screen' on page 8-36

8.4.2 Tests screen - General page

Fields



Test Code - A three-digit code that represents the test in the analyzer software. The character in front of the code indicates the creator, Predefined tests are identified by a digit or by D (distributor) or S (service). User-defined tests are identified by A (administrator).

***Revision* -** The version number of the test, with a maximum of 9.

***Name* -** The test name, with a maximum of 20 characters. This name appears in screens and reports. When this page shows the word 'closed' after the name of the test, the test is predefined and cannot be fully edited at administrator (or lower) user level.

***Abbreviation* -** A unique abbreviated test name, with a maximum of 4 characters. This name is used in lists, on buttons and in other places where space is limited.

***Service Test* -** When selected, the test is not included in communications with an optional LIS (the test cannot be requested from the LIS and no results are passed to the LIS when the test is requested manually). This option is used for tests that have no diagnostic function but are scheduled for servicing and maintenance of the system.

***Suppress Test Result* -** When selected, the test results are ignored. They are excluded from reports and are not sent to the LIS.

***Mode* -** The available test methods:

- ***Kinetic***: A continuous measurement of the reaction rate (dAbs/m)
- ***Two-Point***: Difference between two specified points (dAbs)
- ***End-Point***: Measurement at the end of the reaction (Abs)

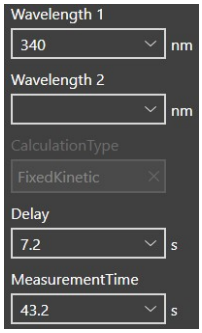
***Reagent On-board Stability* -** Reagent usage period, in days or hours, after loading on the rotor. Maximum is 90 days.

See also:
'Calibrators screen - General page' on page 8-22
'Calibrators screen - Lot page' on page 8-22
'Z - Duplicate Difference Limit Error' on page 7-9

8.4.4 Tests screen - Measurement page

The fields shown in this page depend on the selected test ***Mode*** in the ***General*** page.

Kinetic and Two-Point tests



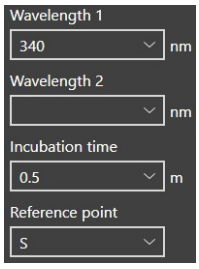
Wavelength 1 **and** ***Wavelength 2*** **-** Select the wavelength(s) to be used in the calculation of absorbance results. For bichromatic tests, two wavelengths must be selected. If only ***Wavelength 1*** is entered, a monochromatic test is done.

Mode **-** The test mode selected in the ***General*** page.

Delay **-** Select the delay (in seconds) between pipetting the sample (or the last reagent in case of multi-reagent tests) and the first measurement.

Measurement Time **-** Select the minimum duration (in seconds) covered by the measurement (from the time specified by ***Delay*** to the last measurement).

End-Point tests



Wavelength 1 **and** ***Wavelength 2*** **-** Select the wavelength(s) to be used in the calculation of absorbance results. For bichromatic tests, two wavelengths must be selected. If only ***Wavelength 1*** is entered, a monochromatic test is done.

Incubation Time **-** Select the time between pipetting the sample (or the last reagent in case of multi-reagent tests) and the measurement.

Reference Point **-** Measurement point used as baseline in the calculation of the result. S means the point just **before** sample is added, R2/R3/R4 means just **before** reagent 2/3/4 is added. If you want to calculate using the point **after** addition of the last ingredient, select ***Mode Two-Point***.

3.2 Cuvette rotor

1	*Photometer units*	*4*	*Cuvette rotor cover*
2	*Cuvette rotor*	*5*	*Mixer*
3	*Cuvette wash station*		

Fig.3-2 Cuvette rotor

The cuvette rotor [2] contains 128 cuvettes. The measuring volume must be between 110 and 400 µl. The cuvette rotor is heated from below and has an insulated cover [4]. The cuvette rotor temperature is kept at 37 °C. The mixer [5] ensures that the reaction mixture in the cuvettes is well mixed.

The cuvette rotor rotates to bring each sample into the measurement position. Light from the photometer LED [1] passes through the cuvette. After the last measurement, the cuvette is washed and dried by the cuvette wash station [3]. The waste is disposed in a waste container.

3.8 User interface and integrated pc

Fig.3-8 Selectra Mach5 with touchscreen

The Selectra Mach5 is fitted with a touchscreen on an adjustable mounting arm. The touchscreen offers an easy-to-use and direct user interface to the system functions. A keyboard is supplied for entering data where needed.

The integrated PC runs the operating system and the user interface software for the system.

It is possible to connect the system to a Laboratory Information System (LIS). In that case, test requests can be retrieved from the LIS host computer and test results are transferred back automatically when the tests are completed.

NOTICE

HANDLE WITH CARE

Make sure your fingers (or gloves) are clean when touching the screen. A clean, plastic stylus may also be used. Never use metal or sharp objects to touch the screen.

⚠ CAUTION

TAKE CARE

Mains connected equipment connected to the USB port shall be certified to IEC60950-1 or IEC62368-1.

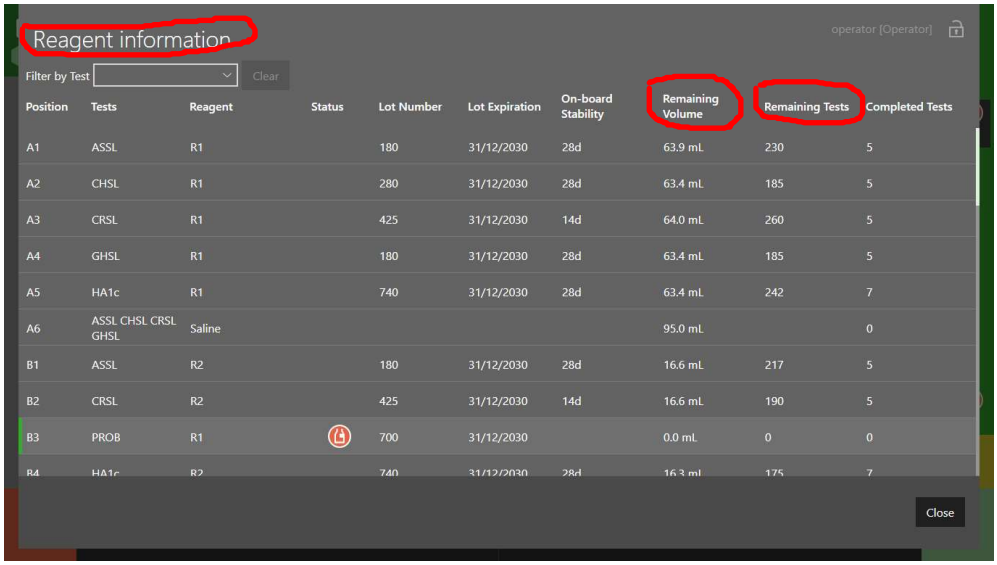


Fig.4-6 ***Reagent Information*** *dialog*

Fields

Filter by Test **-** Select a test to only show the reagents for the selected test.

Position **-** Position of the reagent on the rotor, consisting of a combination of the segment (A-E) and a number (1-6 or 1-16).

Tests **-** Test for which the reagent is used.

Reagent **-** Role of reagent: first (R1), second (R2), third (R3), fourth (R4) or diluent or dummy reagent (for sample blank). For special fluids, the name of the fluid is listed instead.

Status **-** State of the reagent. See the table above.

Lot Number **-** Lot number of the loaded reagent.

Lot Exp. **-** Expiration date of the reagent lot. After this date the reagent can no longer be used for testing and must be replaced.

On-board Stability **-** Remaining time during which the reagent can still be used when it is kept on the system.

Remaining Volume **-** The remaining volume in the reagent container. After refilling or replacing the reagent container, the volume information is reset to the nominal container volume.

Info

If the reagent is loaded via barcode (PRID), the volume information is based on the test counter field (0-9) in the barcode, which should correspond to the fill volume of the container.

Remaining Tests **-** Number of tests that can be performed with the remaining reagent volume.

Completed Tests **-** Number of tests that were performed using the reagent. The number is reset when the reagent is replaced.

6.2 Maintenance schedule

Table 6-1: Maintenance schedule

Interval	Task	Note
1 day	Start of Day procedure	
1 day	End of Day procedure	
As needed	Clean system exterior	
As needed	Clean system liquid and waste containers	
1 week	Rinse probes	
6 months	Replace drying block and tube	
12 months	Replace system liquid filter	[1]
12 months	Clean system interior	[1]
30,000 tests	Replace cuvette rotor	

[1] Yearly maintenance is normally performed by service engineers of your supplier.

The maintenance intervals for your system can also be viewed by tapping ••• **> *Tasks* > *Maintenance* > *Overview***.

NOTICE

PLEASE NOTE

Some maintenance work may be performed by service engineers of the system supplier. If you have doubts about the work you need to do, contact your supplier's support department.

Info

Your laboratory may have additional maintenance requirements for the system. The table shows the minimum maintenance tasks and frequency as recommended by the manufacturer.

See also:
'Maintenance procedures' on page 6-4

M, m - High Absorbance Limit Violation / Low Absorbance Limit Violation

The test result was above the configured upper absorbance limit (M) or below the configured lower absorbance limit (m).

Action:

- In case of an M flag, rerun the test with a diluted sample, by tapping ***Dilute***. If the ***Automatic Re-run*** option is set for this flag (***Flag Customization*** screen) and if the system state allows processing, the test will be automatically diluted (based on the configured dilution ratio) and processed.
- Check the ***Absorbance Limits*** in the test configuration (***Tests*** screen - ***Abs Check*** page).
- Check the ***Reagent Blank Absorbance Limits*** in the test configuration (***Tests*** screen - ***Calibration*** page).

See also:
'Tests screen - Abs Check page' on page 8-10
'Tests screen - Calibration page' on page 8-14

N+, N- - High Reference Limit Violation / Low Reference Limit Violation

The test result was above (N+) or below (N-) the applicable reference range (male, female or pediatric). This is a 'normal use' flag.

Possible cause:

- Patient concentration outside defined ranges.
- Incorrect reference ranges (if flagged for multiple patients).

Action:

- Optional: if result is suspicious, then repeat test to confirm.
- Correct the ***Reference ranges [units]*** for the fields ***Male***, ***Female*** or ***Pediatric*** in the test configuration (***Tests*** screen - ***Result Calculation*** page).

Info

This error is not shown if Y, y - ***Reference Panic High Limit Error*** or ***Reference Panic Low Limit Error*** also occurred.

See also:
'Tests screen - Result Calculation page' on page 8-12

R- - Insufficient Reagent

The test was not performed due to an empty or missing reagent bottle. Once the problem is resolved, interrupted tests will be scheduled with the next sample run.

Possible causes:

- Empty bottle.
- No proper aspiration possible.
- Missing reagent bottle.
- The liquid detection system is malfunctioning.

Actions:

- Fill or (re)place the reagent bottle. Carefully remove any bubbles or foam with a disposable pipette.
- Check if the reagents are in the correct rotor positions.
- Rinse the probes and let dry.
- Contact your supplier's Support Department.

See also:
'Rinsing the probes' on page 6-7

X, x - Concentration High Error / Concentration Low Error

The test result is above the configured concentration range (X) or below the analytical sensitivity (x).

Actions:

- In case of an X flag, rerun the test with a diluted sample, by tapping ***Dilute***. If the ***Automatic Re-run*** option is set for this flag (***Flag Customization*** screen) and if the system state allows processing, the test will be automatically diluted (based on the configured dilution ratio) and processed.
- Check the concentration ***Limits*** in the test configuration (***Tests*** screen - ***Result Calculation*** page).

See also:
'Tests screen - Result Calculation page' on page 8-12

Y, y - Reference Panic High Limit Error / Reference Panic Low Limit Error

The test result is above the configured upper panic limit (Y) or below the configured lower panic limit (y).

Actions:

- Immediate action is required in treatment of the patient.
- If the result is incorrectly labeled as 'panic', then check the ***Reference ranges [units]*** for the ***Panic*** field in the test configuration (***Tests*** screen - ***Result Calculation*** page) and rerun the test.

See also:
'Tests screen - Result Calculation page' on page 8-12

Z - Duplicate Difference Limit Error

The difference between the results of a replicated test is too high.

Possible cause:

- Contamination in the sample or reagent.
- Incorrect test parameter.

Actions:

- Check the sample and reagent for visual contamination.
- Repeat with new or fresh reagent.
- Check the limit parameter of the ***Duplicate Difference*** in the test configuration (***Tests*** screen - ***Processing*** page).

See also:
'Tests screen - Processing page' on page 8-7

- Insufficient Sample Error

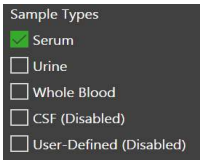
Pipetting is not possible due to insufficient sample.

Possible causes:

- The sample tube is empty.
- The sample tube is not loaded.
- The sample tube is not in the correct sample position.
- Air bubbles are preventing aspiration.
- The liquid detection system is malfunctioning.

Reagent Low Volume Warning **-** A reagent low volume warning appears in the notification bar when this number of tests can still be performed (calculated with the test that uses the highest volume of this reagent).

Sample Types Fields



Serum, ***Urine***, ***Whole Blood***, ***CSF***, ***User-Defined*** **-** When selected, the sample type can be tested with the test. The available sample types correspond with those defined via ••• **>** ***Configure > Sample Types***.

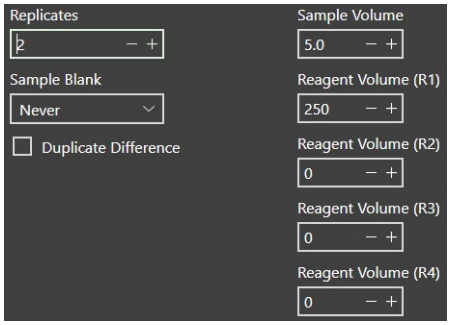
Info

Sample types that are disabled, can be enabled in the ***Sample Types*** screen.

See also:
'Checking and loading reagents' on page 5-17

8.4.3 Tests screen - Processing page

Fields



Replicates **-** Number of times the test will be performed for each sample. The results of these tests are averaged. Maximum number is 3.

Info

If it is not necessary to run replicates for every test request, you can also set replicates when you request a specific patient test.

Sample Blank **-** When selected, the result is corrected with the sample blank result. A sample blank measurement is used to correct for tinted or cloudy samples. The measurement is performed on a sample with a dummy reagent. Select an option from the list: ***Never***, ***Always*** or ***On Request***. The option ***On Request*** enables the ***Request Sample Blank*** option in the ***New Patient Sample Request*** screen.

Duplicate Difference **-** When selected, enter maximum allowable absorbance difference between the results of the replicated test. The unit depends on the ***Mode*** field in the ***General*** page. If the difference is above this value, the flag ***Duplicate Difference Limit***

A.1 Technical specifications

A.1.1 System specifications

A.1.1.1 Performance

Maximum throughput	250 tests/hour for dual reagent tests 500 tests/hour for mono-reagent tests
Programmable tests	Maximum 1000, depending on the system configuration
Sample processing	Random access
Quality control	6 per parameter
Noise emission	Balanced noise criterium at NCB-58 Sound pressure 58 dB(A) max. when in use

See also:
'Accuracy and precision' on page A-7

A.1.1.2 Sample system

Sample rotor	65 positions for barcode readable sample tubes, on 5 replaceable outer segments (each 13 positions) 20 positions for barcode unreadable calibrators, controls, blanks, special fluids and pediatric cups, on non-replaceable special sample segment
Sample tubes	Diameter: 12 - 16 mm Height: 75 - 100 mm; 75 mm in non-replaceable special sample segment
Sample cups	As recommended and supplied by ELITechGroup B.V.
Probe	Level detection Collision detection Clot detection Heater with temperature sensor
Pipetting capacity	1 - 30 µL (increments of 0.1 µL)

A.1 Technical specifications

A.1.1 System specifications

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See also:
'Accuracy and precision' on page A-7

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Sample rotor	65 positions for barcode readable sample tubes, on 5 replaceable outer segments (each 13 positions) 20 positions for barcode unreadable calibrators, controls, blanks, special fluids and pediatric cups, on non-replaceable special sample segment
Sample tubes	Diameter: 12 - 16 mm Height: 75 - 100 mm; 75 mm in non-replaceable special sample segment
Sample cups	As recommended and supplied by ELITechGroup B.V.
Probe	Level detection Collision detection Clot detection Heater with temperature sensor
Pipetting capacity	1 - 30 µL (increments of 0.1 µL)

A.1.1.3 Reagent system

Reagent rotor	30 to 80 positions on 5 replaceable segments (6 or 16 positions each) Segments with 6 positions are for barcode readable reagent containers with a capacity of 90mL Segments with 16 positions are for 13 barcode readable containers (30 mL), 2 barcode unreadable containers and 1 barcode unreadable bottle (10 mL)
Reagents containers or bottles	Wedge shaped containers: 90 mL Rectangle shaped containers: 30 mL Round bottles: 10 mL Adapter allowed for small bottles in large positions
Volumes per test	Reagent 1: 50 - 370 µL Reagents 2, 3 and 4: 10 - 349 µL
Refrigeration	7 ± 3 ºC Ambient temperature 15 - 25 ºC
Probe	Level detection Collision detection Heater with temperature sensor
Pipetting capacity	400 µL (increments of 1 µL)

A.1.1.4 Measurement system

Cuvette rotor	Replaceable rotor with 128 positions
Optical path length	5 mm
Total volume range (sample and reagent)	110 to 400 µL
Wash station	Fully automated with overflow level detector
Cuvette rinsing	4 x 500 µL system liquid
Light source	LED based photometer
Photometers	16, each measuring absorbance at a single wavelength
Wavelengths	340, 405, 415, 490, 505, 546, 570, 600, 625, 660, 700, 800 nm
Central wavelength accuracy	± 2 to ± 15 nm, depending on the wavelength
Measuring range	0 to 3.0 Abs.

A.1.1.3 Reagent system

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Refrigeration	7 ± 3 ºC Ambient temperature 15 - 25 ºC
Probe	Level detection Collision detection Heater with temperature sensor
Pipetting capacity	400 µL (increments of 1 µL)

A.1.1.4 Measurement system

Cuvette rotor	Replaceable rotor with 128 positions
Optical path length	5 mm
Total volume range (sample and reagent)	110 to 400 µL
Wash station	Fully automated with overflow level detector
Cuvette rinsing	4 x 500 µL system liquid
Light source	LED based photometer
Photometers	16, each measuring absorbance at a single wavelength
Wavelengths	340, 405, 415, 490, 505, 546, 570, 600, 625, 660, 700, 800 nm
Central wavelength accuracy	± 2 to ± 15 nm, depending on the wavelength
Measuring range	0 to 3.0 Abs.

CISPR 11 Class A	This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case it may be necessary to take measures to mitigate the interference. The system is tested and certified by UL according IEC 61010-1:2010 (incl. AMD1:2016), IEC 61010-2-010:2014, IEC 61010-2-051:2015 and IEC 61010-2-101:2015. The CB-certificate is available upon request.

Info

The approvals listed here refer only to the instrument and operator console, not to additional devices. For the approvals for these devices, see the corresponding manuals.

A.1.2 Requirements

A.1.2.1 Power requirements

Mains inlet	1 x IEC60320/C13 input connector
Line Voltage	100 - 240 Vac ±10%
Line Frequency	50/60 Hz
Max. Power Consumption	700 VA
Overvoltage category	II (in accordance with IEC 61010-1)
Main fuses	2 x 10 A, time delay, high breaking capacity, 250 Vac

A.1.2.2 Environmental requirements

Ambient temperature	15 to 32 ºC (59 to 90 ºF)
Relative humidity	30 - 85%, non-condensing
Operating environment	Indoor use
Maximum altitude	3000 meter / 10.000 feet
Pollution degree	2 (in accordance with IEC 664)
Degree of protection	IP X0

Sample blank

Measurement performed on a sample with a dummy reagent added. The result is used to correct for tinted or cloudy samples.

Slope blank

Measurement of the slope before the final reagent is added. This only applies to kinetic tests. The result is used to adjust for drift in the sample with the initial reagent.

STAT

STAT samples are scheduled before any other samples, and are displayed in the notification bar. They are often called “emergency” samples.

Substrate depletion

The substrate starts running out before measurements are completed.

System liquid

A 1 to 400 dilution of System Solution in purified water (ASTM type II grade or better). Used to wash the cuvettes and probes, also used for the pipetting system (system fluidics).

System Solution

Fluid used diluted with purified water (ASTM type II grade or better) at 1/400. When diluted, fluid is called system liquid.

Wash Solution

Wash Solution A and Wash Solution B are fluids on the sample and reagent rotors, used in reagent probe cleaning, probe rinsing and links and incompatibility wash tests.

Clinical Systems

selectra

MACH 5

Make work flow

ELITechGroup

EMPOWERING IVD

Selectra **Mach®5**

An innovative benchtop solution to match your laboratory's needs now and into the future

- Quality and sturdiness – synonymous with the Selectra brand
- Maximum efficiency through consolidation of routine and special testing
- The accuracy required to help clinicians provide the best patient outcomes
- Economical benchtop solution

Now, how can Selectra Mach®5 add additional value for your clinical chemistry laboratory?

Choose your next benchtop system wisely

When choosing the right solution for your clinical chemistry laboratory, features that directly impact your laboratory's productivity will be critically important.

You will look for the best option to complete your workload with the existing or even less resources.

Simply making side by side comparisons of published technical specifications does not provide the critical information for your unique situation.

An integrated approach, that combines the critical productivity elements in a benchtop system, provides the additional insight required to make your work flow.

An integrated approach to benchtop system efficiency: The Benchtop System Workflow Index™

Efficient workflow depends on much more than a system's published specifications

Benchtop System Workflow (BSW) Index is a different way to compare the overall efficiency of benchtop systems using published specifications

The higher the BSW Index™, the more efficient the workflow in your laboratory

$$\frac{\text{SAMPLE CAPACITY \%}^{1} \times \text{ONBOARD MENU CAPACITY \%}^{2} \times \text{TPH}_{CALC}{}^{3}}{100} = \textbf{BSW INDEX}$$

1 Sample Tray Capacity divided by the capacity needed to perform your daily workload.

2 Onboard Menu Capacity divided by the capacity needed to load your complete routine test menu.

3 Calculated theoretical Tests Per Hour performing your typical daily workload.

How the BSW Index works

The BSW Index assesses the overall workflow in a lab by incorporating three productivity elements of the benchtop system.

In short, it is a measure of benchtop speed ("calculated Tests Per Hour") combined with measurements of benchtop-staff interactions during instrument operating time.

The higher the BSW Index, the more efficient the workflow in your laboratory

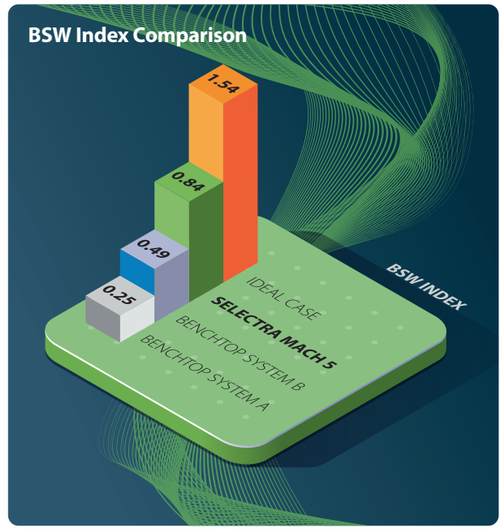
Let's look at the following scenario:

A routine clinical chemistry laboratory needs a new benchtop clinical chemistry system. Demand is expected to grow to 300 samples/day, requiring a menu of 40 parameters[3], with an average of 12 tests/sample. The laboratory is operational 12 hours/day.

A "top 3" of benchtop systems is selected, based on published specifications meeting the current and future productivity needs: Selectra Mach5, Benchtop system A and Benchtop system B.

To determine which system will be most efficient, the BSW Index for all 3 systems is calculated.

Conclusion: for this laboratory, the Selectra Mach5 would be the best fit.



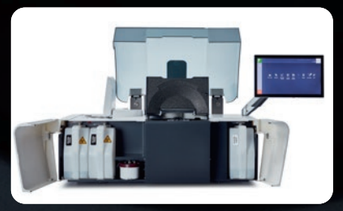
The values for the Ideal Case and the 3 selected instruments are displayed in the table below:

Top 3 selected Benchtop Systems:	SELECTRA MACH5	SYSTEM A	SYSTEM B	IDEAL CASE[1]
SAMPLE CAPACITY	83	40	50	110 (C[2])
ON BOARD REAGENT CAPACITY[3]	68	50	100	100 (B)
CALCULATED TPH (based on cycle time values)	314	270	216	300
BSW INDEX	0.84	0.25	0.49	1.54

1. The Ideal Case is calculated by selecting the maximum score for each efficiency element, from all the instruments used in the comparison, and the desired throughput (in this case 300 Tests Per Hour).
2. Instrument C has the most optimal sample capacity but, because of insufficient throughput, did not make the short list.
3. Reagent positions required for the selected menu for non-ELITech Systems are based on publicly available information. For the Selectra Mach5, 70 reagent positions are required for the selected test menu.

Make work flow with Selectra Mach®5. A new approach to benchtop system efficiency

Other key features of the Selectra Mach®5



System completeness: Unlike many other systems, Selectra Mach®5 has everything included in the system, minimizing footprint. A built-in computer system including touchscreen monitor enabling better cyber security. An integrated supply of system liquid, simplifying system handling for the operator, or, in other words, optimizing human-system interventions.

Water usage: Selectra Mach5 has an onboard water capacity of 10L and typically uses up to 2.5L/h. The system is designed to perform efficiently, therefore both the water and waste containers can be replaced without interrupting the analytical process.

Photometric module: The unique photometers of Selectra Mach5 are LED-based and have a significantly longer life span than the halogen lamp in lamp-based photometers used in many other clinical chemistry systems. Moreover, the LED photometric cartridge technology provides more flexibility and adaptability for future assay developments, as up to 16 individual LED photometer cartridges with a specific wavelength can be accommodated (12 included as standard).

GENERAL SPECIFICATIONS

INSTRUMENTS	
SYSTEM	Fully automated, random access, benchtop clinical chemistry system with STAT capability
COUNTRY OF ORIGIN	Netherlands
DIMENSIONS	105 cm (w) x 70 cm (d) x 65 cm (h)
WEIGHT	110 Kg
OPERATING ENVIRONMENT	Between 15-32 °C; 30-85 % relative humidity (non condensing); and up to 3,000 m above sea level
INTEGRATED PLATFORM	Instrument with inbuilt PC, software, reagents, calibrators, controls and consumables
ANALYSIS MODES	Quantitative, Semi-Quantitative and Qualitative
ASSAY TYPES	Quantitative Kinetic Rate, Fixed Point Rate, End Point; Semi-quantitative; and Qualitative (cut-off)
ASSAY TECHNOLOGIES	Colorimetric (UV-Visible spectra), Turbidimetric

TEST MENU	
PROGRAMMABLE TESTS	1,000
ON BOARD REAGENT CAPACITY	Up to 65 Bar Code Readable (BCR) positions, cooled at 8 ± 4 °C
ON BOARD TEST CAPACITY	At least 39 Parameters when using ELITechGroup system reagents
SYSTEM REAGENT MENU	At least 40 CE marked system reagents
USE OF THIRD PARTY REAGENTS	Yes, capability of running third party assays not available from ELITechGroup

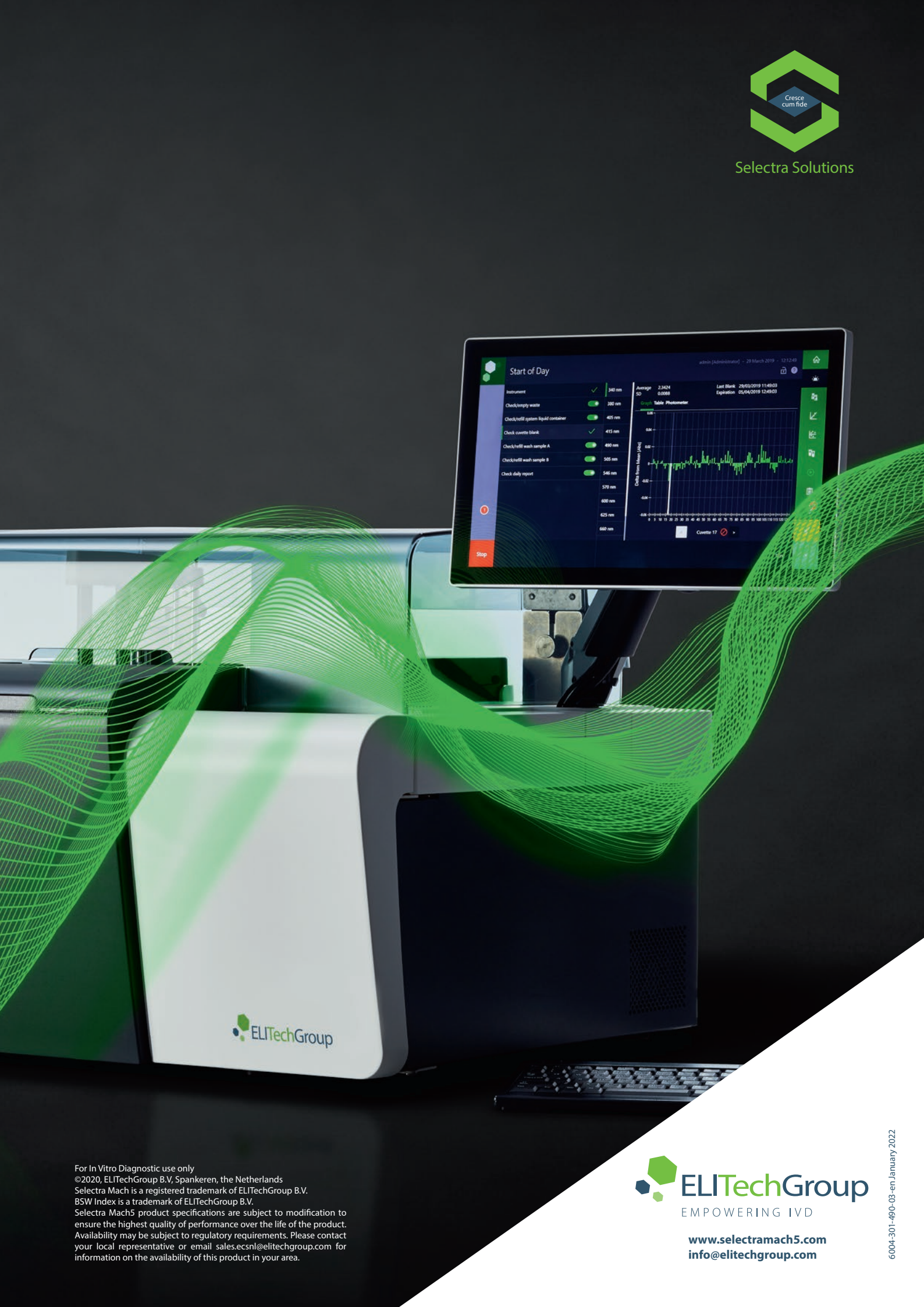
WORK FLOW	
PRIMARY TUBE SAMPLING	Primary- tube diameter ranging from 12 to 16 mm and a height ranging from 75 to 100 mm
CONTINUOUS REAGENT AND SAMPLE LOADING	Yes, samples and reagents, via dedicated sample and reagent access covers (maximum pause time for sample of 2 minutes)
ON BOARD SAMPLE CAPACITY	85 sample positions. 65 BCR and 20 auxiliary positions (inner ring)
THROUGHPUT RANGE (PHOTOMETRICS)	250 to 500 photometric TPH
THROUGHPUT /M²	340 to 680 photometric TPH/m^2
TIME TO FIRST RESULT (PHOTOMETRICS)	< 5 minutes when using ELITech system reagents (assay dependent)
STAT LOADING	Utilising pause function, so no interruption to tests already in progress
AUTOMATIC REPEAT TESTING	Yes, automatic onboard dilution of out of range results
WALK AWAY TIME	Up to 4 hours using ELITechGroup system reagents
VALIDATED SAMPLE TYPES	Serum, Plasma, Whole Blood and Urine (assay dependent)
SAMPLE INTEGRITY	Sample clot detection
SAMPLE AND REAGENT IDENTIFICATION	Inbuilt BCR for risk free loading of samples and reagents

SYSTEM CONTROL	
OPERATING SYSTEM	Windows 10 based operating system
USER COMMANDS	15.6 inch capacitance Touch and Swipe screen, resolution 1366 x 768 pixels and widescreen (16:9) aspect ratio
APPLICATIONS	Automatically downloaded from 2D barcode on IFU with handheld BCR
CONTROL AND CALIBRATOR DATA	Automatically downloaded from 2D barcode on IFU with handheld BCR
STATUS DISPLAY	Instrument status, time for completion are displayed in real time
START UP PROCEDURE	System can be programmed for automated start up outside routine hours to prevent interruptions to workflow
SHUT DOWN PROCEDURE	System can be programmed for automated shut down outside routine hours to prevent interruptions to workflow
STORAGE CAPACITY	256 GB solid state hard disk

OPERATOR SAFETY	
ACCESS WHEN OPERATING	Cover open /closed detection. Transparent instrument cover, so moveable parts are visible during operation
MAIN COVER	Open/Closed detection
SAMPLE COVER	Open/Closed detection
REAGENT COVER	Open/Closed detection
CUVETTE ROTOR COVER	Open/Closed detection
NOISE EMISSION	Balanced noise criterium at NCB-58; Sound pressure 58 dB(A)max. when in use

REGULATORY COMPLIANCE	
IVD MEDICAL DEVICES	CE-marked in accordance with EU IVD Regulation 2017/746
ROHS	CE-marked in accordance with EU Directive 2011/65/EU
SAFETY	Tested and certified according to: IEC 61010-1:2010 (incl. AMD1:2016), IEC 61010-2-010:2014, IEC 61010-2-051:2015, IEC 61010-2-101:2015
ELECTROMAGNETIC COMPATIBILITY	Tested and certified by DEKRA according to: IEC 61326-1:2012, IEC 61326-2-6:2012

CE



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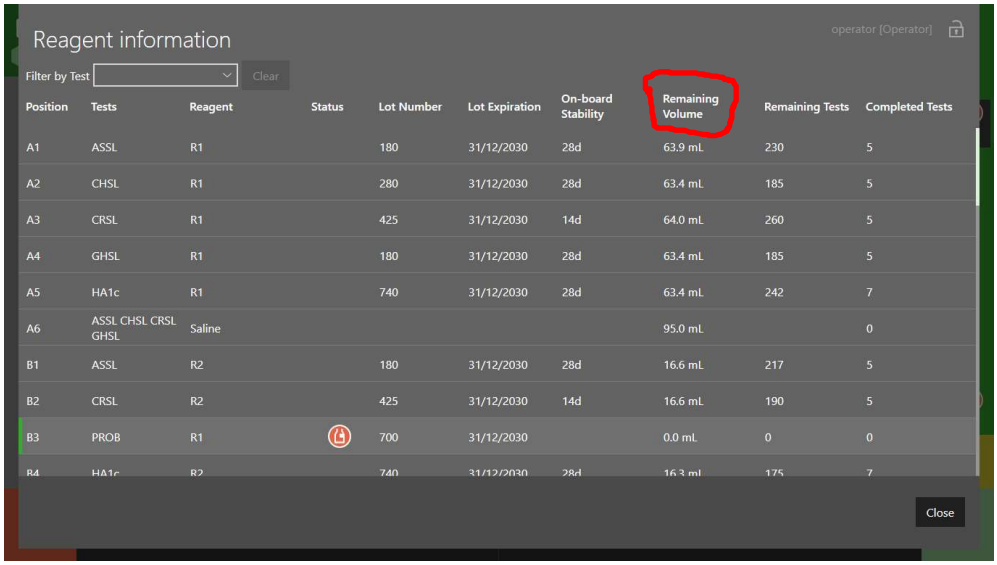


Fig.4-6 ***Reagent Information*** *dialog*

Fields

Filter by Test **-** Select a test to only show the reagents for the selected test.

Position **-** Position of the reagent on the rotor, consisting of a combination of the segment (A-E) and a number (1-6 or 1-16).

Tests **-** Test for which the reagent is used.

Reagent **-** Role of reagent: first (R1), second (R2), third (R3), fourth (R4) or diluent or dummy reagent (for sample blank). For special fluids, the name of the fluid is listed instead.

Status **-** State of the reagent. See the table above.

Lot Number **-** Lot number of the loaded reagent.

Lot Exp. **-** Expiration date of the reagent lot. After this date the reagent can no longer be used for testing and must be replaced.

On-board Stability **-** Remaining time during which the reagent can still be used when it is kept on the system.

Remaining Volume **-** The remaining volume in the reagent container. After refilling or replacing the reagent container, the volume information is reset to the nominal container volume.

Info

If the reagent is loaded via barcode (PRID), the volume information is based on the test counter field (0-9) in the barcode, which should correspond to the fill volume of the container.

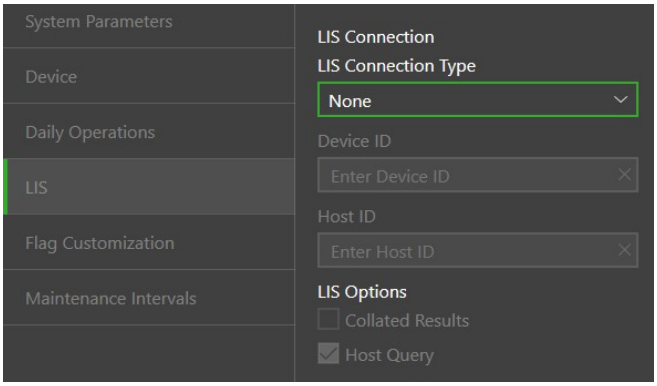
Remaining Tests **-** Number of tests that can be performed with the remaining reagent volume.

Completed Tests **-** Number of tests that were performed using the reagent. The number is reset when the reagent is replaced.

8.11.5 LIS screen

If your system is connected to a Laboratory Information System, define all connection settings in this screen.

LIS Connection fields



LIS Connection Type **-** Select ***RS-232*** or ***TCP/IP*** to enable a LIS. Select ***None*** if you want to disable a LIS.

Device ID **-** Code (maximum 20 characters) to identify the system to the LIS host computer. Used when multiple devices are connected to the same LIS host computer.

Host ID **-** Code (maximum 20 characters) to identify the LIS host computer connected to the system. Used when multiple LIS host computers are available on the network.

LIS Options fields

Collated Results **-** Select this field to gather all sample test results when they are finished and send them as a set to the LIS host computer. Deselect to send individual test results as soon as they become available.

Host Query **-** Select this field to enable sending a query for the test requests to the LIS. If enabled, a host query is possible manually (when requesting a new patient test) or automatically (after the sample rotor cover was closed and all barcodes were scanned).

TCP/IP Settings fields

Host Name **-** Name of the LIS host computer on the TCP/IP network.

Port Number **-** The number of the port on the LIS host computer that handles the communication.

RS-232 Settings

Com Port **-** The communication port that handles the LIS communication.

Bits per Second **-** The bitrate of the communication.

Data Bits **-** The number of data bits per character.

Stop Bits **-** The duration of the stop period.

Parity **-** The type of parity bit.

CISPR 11 Class A	This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case it may be necessary to take measures to mitigate the interference. The system is tested and certified by UL according IEC 61010-1:2010 (incl. AMD1:2016), IEC 61010-2-010:2014, IEC 61010-2-051:2015 and IEC 61010-2-101:2015. The CB-certificate is available upon request.

Info

The approvals listed here refer only to the instrument and operator console, not to additional devices. For the approvals for these devices, see the corresponding manuals.

A.1.2 Requirements

A.1.2.1 Power requirements

Mains inlet	1 x IEC60320/C13 input connector
Line Voltage	100 - 240 Vac ±10%
Line Frequency	50/60 Hz
Max. Power Consumption	700 VA
Overvoltage category	II (in accordance with IEC 61010-1)
Main fuses	2 x 10 A, time delay, high breaking capacity, 250 Vac

A.1.2.2 Environmental requirements

Ambient temperature	15 to 32 ºC (59 to 90 ºF)
Relative humidity	30 - 85%, non-condensing
Operating environment	Indoor use
Maximum altitude	3000 meter / 10.000 feet
Pollution degree	2 (in accordance with IEC 664)
Degree of protection	IP X0

A.2.3.2 QC rules

Westgard rules

When the Westgard option is selected, the high and low limits are automatically set from the standard deviation that is entered by the user.

The Westgard rules are violated if one or more of the following conditions apply:

- 1 control result is more than 3 standard deviations from the target.
- The last 2 control results are more than 2 standard deviations from the target in the same direction (+ or –).
- The last 4 control results are more than 1 standard deviation from the target in the same direction (+ or –).
- The last 10 control results are all located either on the '+' or the '–' side to the target.

The Westgard rules are not violated in any other case.

Basic rules

When the basic option is selected, a low and high limit can be set. If the result is outside these limits, a flag is raised.

Separation rules

Separation checks if the control result has a minimal distance from the fixed cut-off or calibrator result. If the result is too close, a flag is raised.

See also:
'Controls screen - General page' on page 8-27
'Controls screen - Lot page' on page 8-28

A.2.3.3 Dilution

The 'sample predilution' option is used for samples that would normally fall outside the measurable absorbance, concentration or calibration range. The sample is prediluted by the system, using diluent available on the rotor.

The 'rerun dilution' option is a post-dilution available for a flagged test result. If requested, the test is repeated with diluted sample. Dilution options and ratios are defined in the test configuration settings.

It is possible to dilute a calibrator into one or more diluted calibrator levels.

Info

In this manual and in the analyzer software, the dilution ratios are given as parts of the sample to parts of the resulting solution. Thus, a dilution ratio of 1/5 means 1 part of the sample diluted with 4 parts of diluent, resulting in 5 parts of solution.

Example

A test uses a calibrator with 5 standards, for concentrations 0, 10, 20, 50 and 100. Measuring a sample with a concentration of 200 would mean that the actual concentration cannot be obtained by interpolation on the calibration curve. In this case, predilution of the sample with a factor of 1/5 brings the concentration within the calibrator range. The measured concentration (40) is corrected with the predilution factor to obtain the actual concentration which is shown on screen (uncorrected concentrations are not shown).