Instructions for use

Sanquin Reagents B.V.
Plesmanlaan 125
1066 CX Amsterdam
The Netherlands

Phone: +31 20 5123599
Fax: +31 20 5123570
Reagents@sanquin.nl
www.sanquin.org/reagents

Magister C24	REF **K7320**	IVD CE
Magister Analysis Software	REF **K7320S1**	IVD CE
Magister Control Software	REF **K7320S2**	IVD CE

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For professional use only

Quick start reference manual for Magister C24

The instrument should only be used as intended, in perfect technical condition, by qualified persons and under strict observation of current safety and accident prevention standards. For detailed instructions please refer to the Magister C24 Operations Manual, the Magister C24 Service Manual and the IFU of products mentioned below. Magister C24 instruments comply with relevant directives as stated in Sanquin Reagents Declaration of Conformity (available on request).

General information

The Magister C24 is a fully automated system to handle Cellbind micro column cards. The use of PeliControl (REF K1379) is required at least once every day when using the system. In the event of failure to pass the quality control tests, the reason for this must be identified. The laboratory tests should not be considered reliable until the problem has been resolved.

The following reagents can be used in combination with Magister:

Cellbind Screen	REF K7000	CE
Cellbind Direct	REF K7011	CE
Cellbind Direct Type	REF K7012	CE
Cellbind LISS	REF K7110/7130	CE
Cellbind P2	REF K7200	CE 0344
Cellbind P3	REF K7210	CE 0344
Cellbind P3-P (papain)	REF K7211	CE 0344
Cellbind ID16	REF K7230	CE 0344
Cellbind ID16-P (papain)	REF K7231	CE 0344
Cellbind A_1 reagent red cells	REF K7240	CE 0344
Cellbind A_2 reagent red cells	REF K7241	CE
Cellbind B reagent red cells	REF K7242	CE 0344
Cellbind O positive reagent red cells	REF K7243	CE
Pelikloon anti-A (IgM) monoclonal	REF K1188	CE 0344
Pelikloon anti-B (IgM) monoclonal	REF K1189	CE 0344
Pelikloon anti-A,B (IgM) monoclonal	REF K1190	CE 0344
Pelikloon anti-D (IgM) monoclonal	REF K1255	CE 0344
Pelikloon anti-D enhanced (IgM) monoclonal	REF K1151	CE 0344
Pelikloon anti-D mix (IgM) monoclonal	REF K1157	CE 0344
Pelikloon monoclonal control	REF K1156	CE 0344
Pelikloon anti-CDE (IgM/IgG) monoclonal	REF K1113	CE
Pelikloon anti-C (IgM) monoclonal	REF K1195/1202	CE 0344
Pelikloon anti-c (IgM) monoclonal	REF K1196/1203	CE 0344
Pelikloon anti-E (IgM) monoclonal	REF K1191/1204	CE 0344
Pelikloon anti-e (IgM) monoclonal	REF K1197/1205	CE 0344
Pelikloon anti-K (IgM) monoclonal	REF K1199	CE 0344
PeliControl	REF K1379	CE 0344
PeliControl CcEeK	REF K1399	CE 0344

Precautions

The electromagnetic environment should be evaluated prior to operation of the device. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the proper operation.

See IFU of products mentioned above.
Reagents are not cooled on the Magister C24 and it is advised to store the reagents at the required conditions after use. Storage of reagents on the Magister C24, up to ten days and eight hours per day, does not influence the performance of the reagents. To prevent evaporation of the reagents used, Evaporation Caps (Beckman Coulter, REF 447170) can be used during use and storage. If these caps are not used, make sure the reagent vials are closed with the corresponding lid to prevent contamination.
Before use and also before placing the vials into the Magister C24, always resuspend the reagent red cells by gently inverting the vial several times until cells are fully in suspension. Check that the reagent red cells remain in suspension. If there is settling of red cells, resuspend again. To prevent settling of red cells, Stirrer Balls (REF K7390) can be used.

Potential hazards may exist to personnel from the liquids being handled by the instrument. Infectious clinical samples may be present. Although the 'hands-off' operating features of the system minimise exposure to these agents, the potential for hazardous exposure still exists. Respect warning labels and follow safety instructions provided in the Material Safety Data Sheet (MSDS) by the manufacturer of reagents. Liquid and solid wastes may be biohazards and should be handled using universal precautions. Always remove samples, reagents and solvents from the instrument immediately after the run is complete. Always wear protective clothing recommended by the manufacturer.

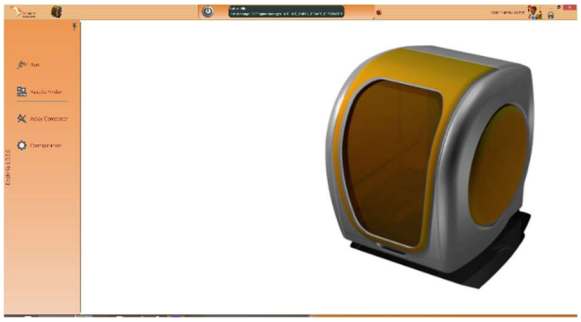
Operating procedure

1. Accessing the program

1.1 To access the Gladstone program, select the **MAGISTER C24** icon as displayed below.

1.2 The "*Log in*" dialogue box will appear asking for *User Name* and *Password* which enables software access.

1.3 The main menu window appears on screen.



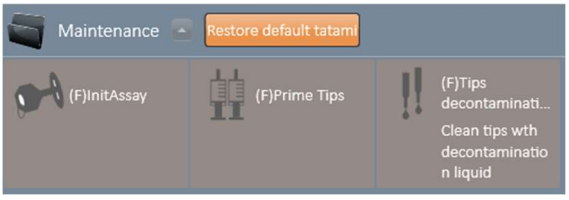
2. Maintenance procedure

2.1 **Prime the system**

At the beginning and end of the workday it is necessary to activate this maintenance procedure. The system liquid, used by Magister for washing and needle decontamination, is a solution which consists of distilled or de-mineralised water with Decon90 detergent. To prepare the system liquid, dilute 3,5 mL of Decon90 into 1L of distilled or de-mineralised water.

2.2 To activate the rinsing procedure, access the "*Maintenance*" window by clicking the **Run** button followed by **Maintenance** button.

2.3 A window with available service and maintenance options appears.



2.4 Double click the "*Prime Tips*" button to start the flush procedure.

2.5 **Tips decontamination**

The Magister system uses a liquid solution (Ethanol or Isopropanol) for the tip decontamination phase before and at the end of an assay execution.

Place the dedicated container with this solution on the left side of the needles washing station.

2.6 Double click the "*Tip Decontamination*" button to start the procedure.

2.7 At the end of the procedure, return to the worklist window by clicking on the **Worklist** button.

2. Maintenance procedure

2.8 Reset consumables counters

The system memorises the number of available consumable materials (predilution tubes and gel cards).

2.9 If you intend to reset the counter for the gel cards, click the **Reset** button and select the option "*Test (support loading) Area*".

2.10 If you intend to reset the predilution position counter, click the **Reset** button and select the option "*Predilution Area*".

3. Programming an analytical session

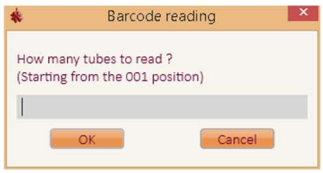
3.1 Programming a new work list consists of the insertion of samples and the scheduling of tests to be executed for each sample.

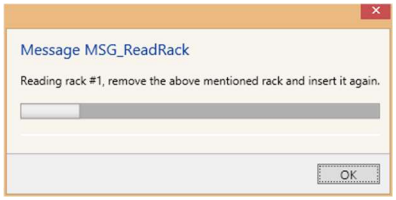
3.2 Local worklists

First remove any old work list by clicking the **Clear List** button that appears in the central part of the main window.

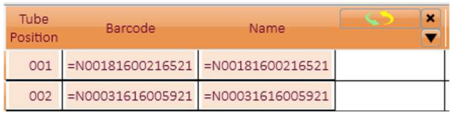
3.3 To create a new work list, click the **Barcode** button.

3.4 Insert the total number of sample tubes that should be scanned (maximum number of tubes is 32). Scanning is executed from the first position on rack 1. A new window appears indicating which rack needs to be read. Follow instructions on screen.





3.5 To add tests to the list, click the **Assays** button and select the assay of interest by clicking the ▼ button.

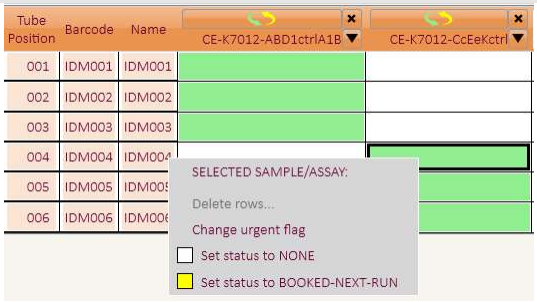


3.6 Scheduling tests

To schedule tests for the samples, click the field that intersects the sample line and the test column concerned.
Each field selected will be colored green.

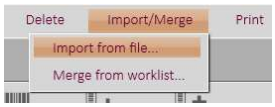
To de-select the samples, right-click the fields concerned and select "*Set status to NONE*".

3. Programming an analytical session



3.7 External Worklists

To import a worklist from a HOST, click the **Import/Merge** button and select *"Import from file"*.



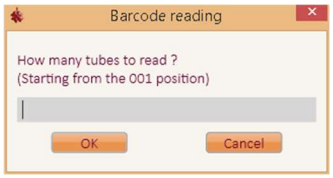
3.8 A new window appears with available work lists. Select the worklist you want to import and click the **Import** button.

3.9 The worklist showing Barcode, name of samples and the list of methods to process is shown in the "*Worklist*" window.

3.10 When importing, it is necessary to scan the barcodes of the samples to match the barcodes of the work list with the one actually loaded on the analyser.

To activate the scanning of barcodes, click the **Barcode** button.

3.11 Insert the total number of sample tubes. Scanning is executed from the first position on rack 1. A new window appears indicating which rack needs to be read. Follow the instruction on screen.

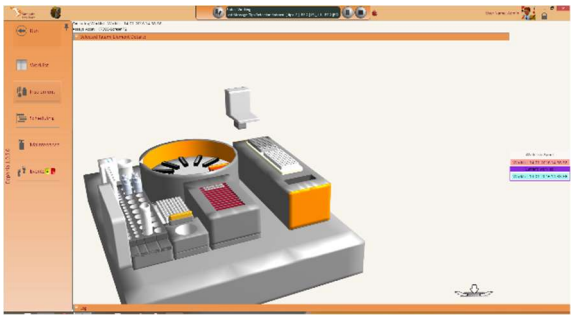


4. Executing the analytical session

4.1 To start the analytical session, click the **Run** button.

4. Executing the analytical session

4.2 The "*Instrument view*" window opens. Here information regarding sample tubes, reagents, predilution tubes and gelcards can be displayed by clicking on the desired item or hovering with the mouse over the desired item.

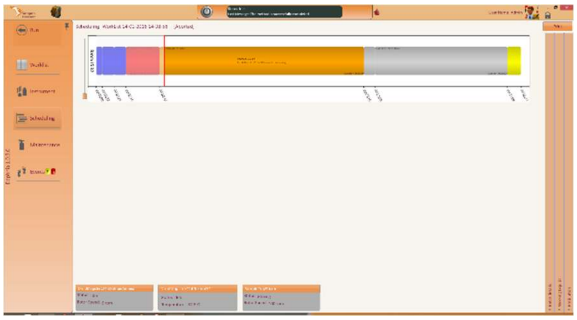


4.3 On the right side of the window a worklist spool is displayed. The current worklist is highlighted in the purple box. Pending worklists will be shown below the purple box.

4.4 **Scheduling view**

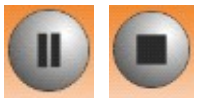
During analysis, it is possible to verify the status of a session in process through the bar graph outline in the "*Scheduling*" window. A red cursor (vertical red line), indicates the actual process in execution, showing the status of the session's progress.

This window also displays real time status of centrifuge speed, incubator temperature and stirrer speed.



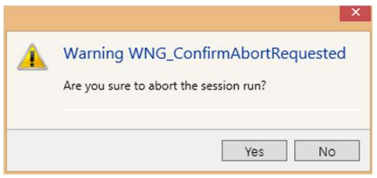
4.5 **Interrupting the analytic process**

The execution of the analytical process can be interrupted at any time by clicking the **Pause** button. Click the **Play** ▶ button to continue the process.



4.6 If you want to stop the execution of the analytical process, click on the **Stop** button.

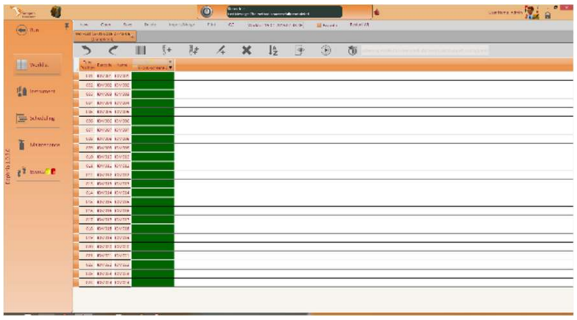
A dialogue box appears showing two buttons. For a temporary pause: click the **No** option button to continue the process. To terminate the process click the **Yes** button



4.7 **Ending the analytical session**

At the end of the execution of an entire analytical session, the status bar at the top of the window will show: "*Status: Idle*" to confirm that the session is terminated.

4.8 The main window will show the worklists processed with tests executed displayed in the color dark green.

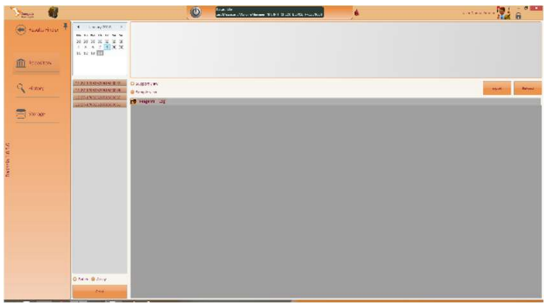


5. Accessing the archive

5.1 The user can view the results in *Results Finder.* Click the **Run** button followed by the **Results Finder** button and the **Repository** button.

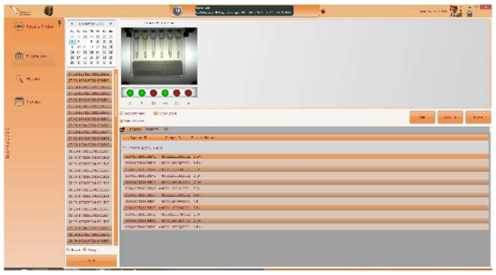
5. Accessing the archive

5.2 Following this selection, a window will appear offering the options for consulting the archive.



5.3 To navigate through the archive, click the arrows in the calendar.

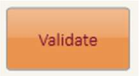
5.4 Selecting a day will display the gel cards processed for the day selected and their results.



5.5 To have a paper report, click the **Print** button.

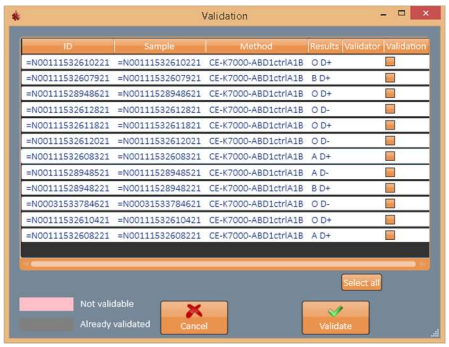
6. Validating and exporting the results

6.1 Once the operator has completed checking the results, it is necessary to validate the results. For this purpose click the **Validate** button.



6.2 In order to validate a sample, flag the relevant box in the "*Validation*" column followed by the **Validate** button.

When it is not possible to link a result to validate a result, then the sample background is pink.



6.3 Once the operator has made the validation, it is possible to export the result to the LIS by clicking the **Export** button.

Interpretation

Positive and negative reactions are interpreted by a ratio calculation of detected pixel numbers. Pixels are detected in two areas, defined on the upper gel matrix level and at the bottom of each column.

Decommissioning and Disposal of Magister C24

If you are permanently taking Magister C24 out of service, first thoroughly clean and decontaminate. Dispose of Magister C24 according to the regulation of the local authorities. Prior to recycling, electrical and electronic components, such as power supply units (PSU), printed circuit boards (PCB), cables etc., should be removed and disposed of according to local regulations. The materials of Magister C24 can be recycled according to local regulations

Limitations

See IFU of products mentioned above.
Sanquin products are guaranteed to perform as described in the original manufacturer's instructions for use. Strict adherence to the procedures, test layouts and recommended reagents and equipment is essential. Sanquin declines all responsibility arising from any deviation thereof.