Instructions for Use

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Magister C24 REF **K7320** IVD CE

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For laboratory professional use only

1. Intended purpose

The Magister C24 instrument (K7320) is an in vitro diagnostic medical device for automated blood grouping assays. The assays are performed using Cellbind gel cards in combination with Cellbind buffers, antibodies and Cellbind reagent red cells supplied by Sanquin Reagents B.V. In general, the assays are for: semi-quantitative blood grouping and detection, screening and identification of red cell antibodies and complement components using human red blood cells and EDTA-plasma.
Magister C24 is intended for professional use only.

1.1. General information

The instrument contains all mechanical components necessary to automate a column agglutination assay. By means of barcodes, the system identifies and recognizes reagent samples or gel cards used in the assay. The following devices can be used in combination with Magister:

Device	Description
K7000	Cellbind Screen
K7012	Cellbind Direct Type
K7110 | K7130	Cellbind LISS
K7180	Cellbind Diluent
K7200	Cellbind P2
K7210	Cellbind P3
K7230	Cellbind ID16
K7240	Cellbind A_1 reagent red cells
K7242	Cellbind B reagent red cells
K1188	Pelikloon anti-A (IgM) monoclonal
K1189	Pelikloon anti-B (IgM) monoclonal
K1190	Pelikloon anti-A,B (IgM) monoclonal
K1255	Pelikloon anti-D (IgM) monoclonal
K1151	Pelikloon anti-D enhanced (IgM) monoclonal
K1157	Pelikloon anti-D mix (IgM/IgG) monoclonal
K1156	Pelikloon control monoclonal
K1195 | K1202	Pelikloon anti-C (IgM) monoclonal
K1196 | K1203	Pelikloon anti-c (IgM) monoclonal
K1191 | K1204	Pelikloon anti-E (IgM) monoclonal
K1197 | K1205	Pelikloon anti-e (IgM) monoclonal
K1199	Pelikloon anti-K (IgM) monoclonal
K1236	anti-Fy^a (IgG) monoclonal AGT method
K1379	PeliControl

1.2. Package contents

The following system and software components are included with the Magister C24 instrument:

System components/modules	Description
PipettingArm	Robotic arm for pipetting purposes, including two tips with independent capacitor-based liquid sensors and clot detection.
GripperArm	Robotic arm for handling Cellbind micro column cards to different positions on the instrument deck.
WashStation	Module for washing the PipettingArm tips. Also includes a position for decontamination purpose of both tips.
SampleTray	Module, including barcode scanner, for reading barcodes from sample tubes and reagent vials.
GelCardReader	Component for reading barcodes from Cellbind micro column cards.
PreDilPlate	Component for diluting samples cells, performed in a deep-well block with 96 positions.
Incubator	Pipetting position for 12 Cellbind micro column cards, doubling as a heating block when incubation is required.
Amonix	Module for centrifuging 12 Cellbind micro column cards according to a fixed protocol.
Cyclops6	Complete module for capturing Cellbind micro column cards, and used as storage for used and unused gel cards.
System Liquid Container	Plastic (5 litre) container with liquid sensing containing liquid solution for use with the instrument.
Magister C24 Computer System (K7320-PC)	All-in-One - pre-installed - computer, including keyboard and mouse, running the Magister C24 software components (highlighted below).

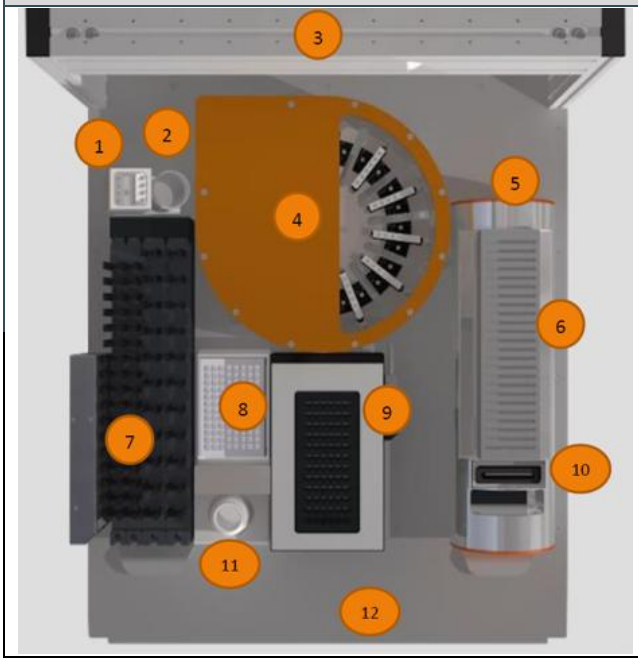
Software components	Description
Gladstone	Used to control the main Magister C24 (K7320) hardware.
QCaptHR	Through an automatic set of actions, this component creates a mask of pixels for each detected spot i.e., agglutination area, either at the top and/or at the bottom of the gel matrix. The ratio between these area's is then calculated and converted into a semi-quantitative agglutination score.
ResultsFinder	Programme that allows for navigating through the gel card images produced by the camera module i.e., Cyclops6.

1.3. Materials required (not provided)

- Standard laboratory materials and equipment
- Distilled or demineralised water
- Cellbind buffers
- Reagents
- Cellbind reagent red cells

Device	Description
K7390	Stirrer balls
K7391	Deepwell tubes
K7392	Reusable tube holder
K7393	Decon90
K7394	Evaporation caps

1.4. Instrument layout

	Position and description	
	1	Wash station
	2	Loading area for decontamination solution
	3	X-rail for Pipetting- and Gripper arms
	4	Centrifuge
	5	Camera
	6	Gel card loading area
	7	Sample- and reagent loading area
	8	Sample cell predilution area
	9	Incubator
	10	Position for dummy gel card
	11	Alternative Cellbind LISS position
	12	Instrument deck

2. Specimen collection and handling

Blood samples should be withdrawn aseptically with or without the addition of anticoagulants. It is required to centrifuge blood collection tubes at 3000 rcf prior to collection of serum samples (for 10 minutes) or plasma samples (for 5 minutes). Collection of serum or plasma samples should be performed using a pipette and not by pouring the plasma or serum. The plasma or serum samples must remain free of white cells, gel fragments and/or fibrin residues to avoid blocking of the gel matrix. For the detection or identification of red cell antibodies it is advised to use fresh plasma or serum (within 48 hours after drawing). Serum or plasma samples that are not immediately tested may be stored for 48 hours at 2–8°C, or longer at <–18°C. It is also advised to centrifuge the serum or plasma samples after thawing for 5 minutes at 3000 rcf prior to testing to remove any precipitate (repeated freeze-thaw cycles should be avoided). For the modified direct antiglobulin test fresh blood should be used (within 48 hours after drawing), preferably drawn into EDTA, to prevent in vitro coating of red cells with complement components. Plasma is not suitable for the detection of complement-binding antibodies since anticoagulants will inhibit complement activation.

2.1. Test principle

The instrument contains all mechanical components necessary to aid an automated column agglutination assay, including the evaluation of Cellbind micro column cards for:

- Determining AB0/Rh-D blood type (including reverse typing)
- Phenotyping of Rhesus and Kell
- Irregular antibody screening and identification
- Compatibility tests (cross match)
- Performing DAT (direct antiglobulin test)

2.2. Calibrators and controls

The use of PeliControl (K1379 is required at least once every day when using the system. An equivalent control will need to be validated by the user first. In the event of failure to pass the quality control tests, the reason for this must be identified. The laboratory tests should not be taken into consideration until the problem has been resolved.

2.3. Decommissioning and Disposal

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

3. Precautions and warnings

3.1. Symbols and conventions

The table below illustrates a glossary of symbols used on the Magister C24 and in this manual. Please observe appropriate safety procedures when these symbols are shown:

Symbol	Explanation
	Pay attention to this part for further information and/or proceed with caution.
	Indicates the presence of high voltage and warns the user to proceed with caution.
	Risks associated with (biological and chemical) biohazards.
	Risks associated with puncture hazard.
	Risks associated with hot surfaces.
	Risks associated by the presence of a laser in class 2 or higher.
	Risks associated with electrostatic discharge. This may result in (main)board and/or instrument malfunctions.

3.2. Potential safety hazards

Mechanical
The instrument is a robotic device that operates under computer control. As with most robotic devices, there is potential for injury from moving mechanical components whenever the instrument is in operation. The robotic arm can exert enough force to be a pinch hazard. The pipetting tips are sharp enough to be a puncture hazard. These hazards are minimized using encoders on each axis, which immediately detects incorrect positioning. Never reach or lean into the instrument during operation, unless the system has paused and displays a dialog box indicating that user-intervention is required. A front cover on the instrument should be always closed and prevents accidental contact with moving components. Therefore, the instrument will stop whenever the front cover is opened during operation. Reaching inside the instrument at any time during operation may result in injury to the user and/or damage the instrument. Pop-up messages provided by the software will inform the user in case of malfunction and in choosing the correct course of action.

Biological and chemical
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 waste may be biohazards and should be handled using universal precautions. Remove samples, reagents, and solvents from the instrument immediately after the run is complete. Always wear protective clothing as recommended by/issued at the site where the instrument is installed.

Electrical
Standard electrical safety precautions should be applied. Do not touch any switches or outlets with wet hands. Switch the instrument off before disconnecting its power cable, and always unplug the instrument's power cable prior to cleaning up any major liquid spills and/or prior to servicing any of the electrical or internal components. Only qualified personnel should perform electrical servicing. Replace all access covers before operating the instrument. The electromagnetic environment should be evaluated prior to operation of the device. Do not use this device near sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these can interfere with the proper operation.

About processed results
*Processed sample results can be exported to a LIS (Laboratory Information System). Exporting results can **only** be performed after validation of the results and is the sole responsibility of the user. Bi-directional communication is the sole responsibility of the IT-department according to their own security policies where the instrument is installed. Connection to an IT-network that includes other equipment could result in unidentified risks to patients It is therefore the sole responsibility of the installed location to identify, analyse, evaluate, and control these risks.*

3.3. Compliance

It is required to use only reagents and disposables from Sanquin Reagents B.V. as mentioned in the general information and within their expiation date. Sanquin Reagents B.V. does not take any responsibility for possible malfunction resulted in the use of non-validated and/or expired reagents and disposables, including sample tubes that have not been tested and validated prior. The instrument should only be operated by qualified users and technicians who have followed suitable training and should only be used for its intended purpose.

Changes and/or modifications to the instrument and its software are prohibited, including adaptions to assay parameters! All users assume full responsibility and consequences for any changes and/or modifications performed on the instrument without prior consent of Sanquin Reagents B.V.

Decon90 (K7390) is a detergent that many automated pipetting instruments use for washing and decontamination of fixed tips. This detergent might contain substances that carry a chemical risk. Refer to the Decon90 MSDS for more information.

The Magister C24 should only be used in perfect technical condition and under strict observation of current safety and accident prevention standards. If daily controls are tested first, carry-over may not be immediately visible. It is prohibited to use the instrument in potentially explosive environments where risk of fire exists. 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, as required by the technical specifications.

The Magister C24 is designed for use in a professional healthcare facility environment as described in IEC 61326. It is not intended for use in residential environments and is likely to perform incorrectly if used in a home healthcare environment as this may not provide adequate protection to radio reception in such environments. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference. Do not use the Magister C24 in proximity to sources of strong electromagnetic radiation.

The manufacturer is responsible for providing equipment electromagnetic compatibility information to the customer or user. The user is responsible for ensuring a compatible electromagnetic environment for the equipment can be maintained in order for the device to perform as intended. The calculation formula to determine the separation distance between an IVD medical device and a mobile phone is given by $d = 6/E \cdot \sqrt{P}$*, where [**d**] is the minimum separation distance in metres, [**P**] is the maximum power in watts, and [**E**] is the immunity test level in V/m.*

4. Test procedure

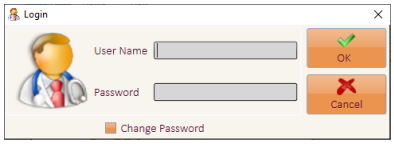
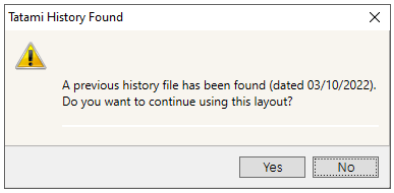
4.1. Before use

The instrument should ***only*** be installed by qualified and trained technicians, and should only be used by qualified and trained laboratory professionals, whilst taking care of the following:

- Check that all parts of the instrument are available by verifying the components mentioned in the packing list.
- Remove the packaging material and check that all parts are not damaged in any way.
- Make sure a strong and stable laboratory table is available for the instrument and its accessories. The working space of table should have a minimum dimension of 85 x 200 cm and should be able to carry at least 150 kg.
- It is critical that the instrument is set up as intended, and that no unnecessary items are present on its instrument deck during operation
- An earthed 110/240 V AC connection is required and must be connected to a sine wave UPS (Uninterruptible Power Supply), which will allow the instrument to operate for at least 30 minutes. This will also prevent potential damage to the instrument and its computer system due to power interruption, surges, and/or loss of power
- Demineralized or distilled water, Decon90 and 70/80% ethanol are required for installation purposes.
- It is critical that the instrument is set up as intended, and that no unnecessary items are present on its instrument deck during operation.
- Unless when connected directly to a drain, the system waste reservoir must be emptied at least once a day. If the container is allowed to fill up completely to the level of the waste tubing inside the container, the waste solution will flow back into the instrument's wash station and may spill onto the instrument deck, resulting in contamination of the instrument, and may affect results.
- Ensure that the System Waste Tubing does not have any kinks, and that there are no loops in the tubing path that would prevent the system waste solution from flowing freely downwards.
- Ensure that the System Liquid Tubing from the System Liquid Container is also free of kinks.
- Ensure that the System Liquid Container is adequately filled prior to the start of each worklist run and is placed on the same level as the instrument.
- Make sure the instrument is located as such that the user can hear the audible alarm from the system, allowing for immediate attention in the event intervention is needed.
- The computer keyboard must be placed within reach of the Magister C24 to ensure access to the escape key when needed.
- Allow Cellbind gel cards and reagents to reach room temperature (18-25 °C) before use on the Magister C24.

- Cellbind gel cards and reagents are not cooled on the Magister C24. It is therefore advised to store these at the required conditions after use. Please refer to the corresponding product IFUs for information on-board stability of Cellbind gel cards, reagents, and samples.
- Before use and before placing reagent red cells into the Magister C24, always gently resuspend the vials several times until the reagent red cells are fully in suspension, and that no air bubbles are present on top of the suspension. Check that the reagent red cells remain in suspension before each use, and if there is settling of red cells, resuspend again.

4.2. Accessing the program

To access the Gladstone program, double-click on the ***Magister C24*** icon on the desktop. An additional shortcut can also be found in the Windows taskbar.	
A splash-screen and login window will appear to provide access to the program. Click [**OK**] after entering the correct user credentials.	
The software will remember the previous state of the instrument. Selecting [**No**] will reset all previous used disposables and start the instrument with a clean layout.	
After login, the main menu appears on screen. If the instrument is switched on during login, software will initialise the instrument and check that all the modules are available. When successful, the main status bar will display "*Idle*". 	
Clicking the [**Power**] button will repeat the initialisation procedure. This could be an option if the instrument was not switched on after login. In this instance, the status bar will display *Offline*, indicating that there is no communication with the instrument.	
The upper right part of the main window will display the user currently logged in. A user can log out at any time by clicking on the [**Padlock**] icon, next to the user's avatar.	User Name: Admin

By default, a user will automatically be logged out after 7 minutes of inactivity.

4.3. Maintenance procedures

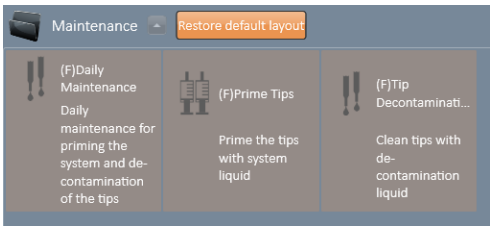
The system liquid used by instrument for washing and decontaminating the internal tubing and tips is a solution consisting of distilled or de-mineralised water with Decon90 detergent. Correctly preparing system liquid is essential for correct operation. To prepare this, dilute 3,5 mL of Decon90 into 1L of distilled or de-mineralised water (3.5% Decon90 solution). Check that the System Liquid Container is sufficiently filled before initiating the Daily Maintenance procedure, and never (re)move the System Liquid Container from its position whilst performing priming procedures.

For correct decontamination purposes, the instrument uses a 70% ethanol solution (e.g., isopropanol). Place a container with this solution in the dedicated position on the right side of the wash before initiating the Daily Maintenance procedure.

Maintenance procedures should only be carried out by qualified users who have followed suitable training. All users assume full responsibility and consequences that may lead to malfunctioning of the instrument when not following correct maintenance procedures, using other Decon90 concentrations than 3.5%, or using solutions other than Decon90 and distilled or de-mineralised water.

4.3.1. Daily maintenance

*To maintain the analyser's hydraulic system, it is necessary to perform a maintenance procedure on the instrument at the **start and end** of **each day**, or after every eight (8) hours of continuous operation.*

To activate the *Daily Maintenance* procedure from the main menu, click [Run], followed by [Maintenance].	
A window with available service and maintenance options will appear on the right side of the screen. Double-click the [**Daily Maintenance**] button to start the maintenance procedure.	

During this procedure the system will flush the instrument with 3 wash cycles. Each cycle will clean the interior of the tips above the wash station first, afterwards moving into the wash station to clean the exterior of the tips. This procedure will also remove any air trapped in the system liquid tubing. After the third wash cycle has completed, the interior of the tips are decontaminated with the 70% ethanol solution by aspirating and dispensing this solution above the wash station, also with 3 wash cycles. Finally, one more cycle with system liquid removes the excess of 70% ethanol solution.

4.3.2. Weekly maintenance

This maintenance procedure should be performed every 7 days or after a long period of inactivity, and is used to maintain the analyser's hydraulic system and clean/remove any accumulated debris:

- Clean the instrument's worktable and both tips.
- Empty and clean the System Liquid Container and prepare a new solution of system liquid.
- Decontaminate the System Liquid Tubing, including filters.
- Check the System Waste Tubing and if applicable, empty the System Waste Container.
- Perform the "***Daily Maintenance***" procedure.

4.3.3. Monthly maintenance

The procedure for monthly maintenance adds the decontamination of the *WashStation* to list of maintenance procedures, next to performing both daily- and weekly maintenance.

4.4. Creating a worklist

A worklist can be either programmed by the user, or automatically generated via a management system when reading the sample barcodes. When creating/modifying a worklist, the following menu items are available:

Icon	Explanation	Icon	Explanation
New	Create a new worklist	Import/Merge	Import or merge worklists that have been uploaded to a local directory
Open	Open an existing worklist	Print	Print an overview of the current worklist
Save	Save the current worklist	QC	Control panel for updating quality control panels
Delete	Delete the current worklist	WorkList 11-10-2022 07-51-34	Auto-generated worklist name, which can be modified

Icon	Explanation	Icon	Explanation
Favorite	Mark the current worklist as favourite	Restart Worklist	Restart a previous worklist
	Undo action		Redo action
	Read sample tube barcodes		Add a new sample
	Add multiple sample rows		Add a new assay column
	Read reagent vial barcodes		Clear the current worklist
	Order samples by tube positions *		Start
	Preview scheduling information on the current worklist	Reset Disposables	Reset currently used disposables

** This icon is hidden by default.*

4.4.1. Adding samples

To create a new worklist from the main menu, click [**Run**], followed by [**Worklist**].

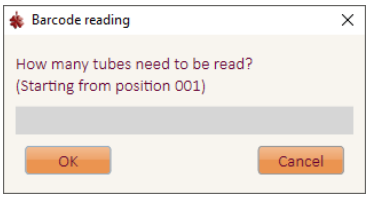
A new worklist will normally be automatically generated upon starting the software but can also be initiated by clicking on [**New**] from the main menu.

The contents of a (previous) worklist can be removed by clicking the [**Clear List**] icon:

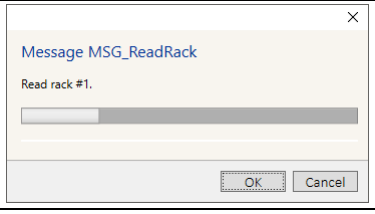
When adding samples to a worklist that do not have a barcode on the sample tube, use the [**Add a new sample**] or [**Add multiple sample rows**] buttons. This will create a worklist with software-generated sample-IDs in the following format: "***IDMxxx***".

To create a worklist with sample barcodes, click on the [**Barcode**] icon.

Insert the total number of sample tubes that should be scanned (with a maximum of 32 sample tubes), click [**OK**].

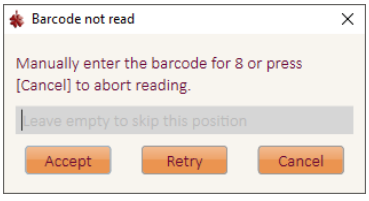


The software will ask to re-insert the appropriate sample rack(s). Follow the on-screen instructions.



If the software was not able to read a barcode correctly i.e., damaged barcode or no barcode present on the sample tube, a message will be displayed to indicate which position(s) has (have) been affected.

- Enter the barcode either manually or via a manual barcode scanner and click [**Accept**] to input the barcode. Leave this field empty to skip this position.
- Click [**Retry**] to repeat the sample barcode reading.
- Click [**Cancel**] to abort the sample barcode reading.



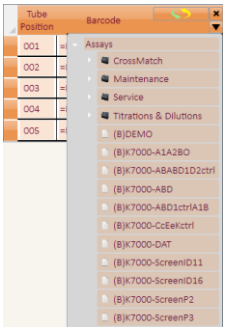
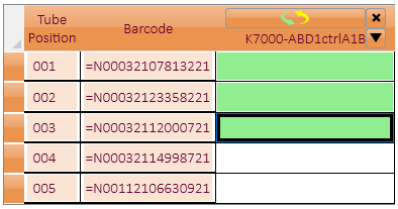
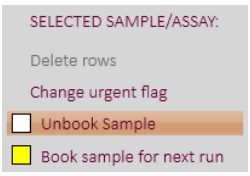
*It is necessary to always use the [**Barcode**] for reading sample barcodes to automatically create worklists from either a LIS (Laboratory Information System) or host-system (FTP). The HL7 protocol is used for bi-directional communication.*

When connected and configured correctly, the worklist will be automatically generated showing which assays are paired with which samples. It remains possible to manually (de)select assays when needed. Please contact your local distributor for more information on how to set-up and configure your instrument when connecting to such systems.

Maximum barcode length is set to 25 digits and can consist of the following 1D barcode types: Code 128, EAN UPC, Code 39, 2/5 Interleaved, and Codabar.

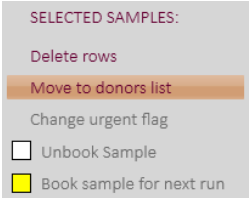
It is required to only use sample tubes that have been pre-defined as default, or has been setup during instrument installation by a qualified service technician.

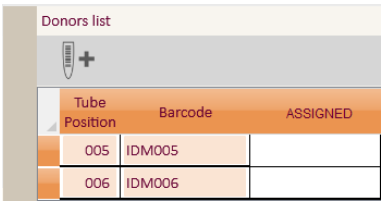
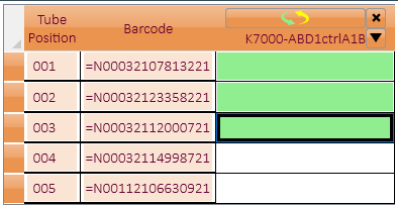
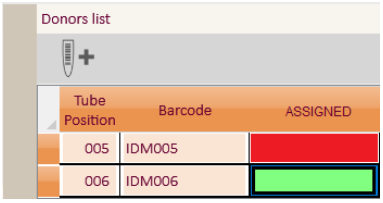
4.4.2. Adding an assay

To add an assay to the worklist, click the [**Add assay**] icon".	
By selecting the drop-down menu (▼ button) an assay of choice can be selected.	
To schedule an assay for the added samples, click the field that intersects the sample line and the assay column. Selecting a field will schedule the test for that sample, which will then be highlighted in light green. It is also possible to "*drag-and-select*" all samples for an assay by holding the left mouse button down and dragging until all appropriate cells have been selected.	
To deselect the assay for a particular sample, right-click the applicable field and select "*Unbook Sample*". If needed, using this button changes the scheduling for a sample (or multiple samples when selected) from ***Booked*** to ***Unbook*** to ***Book sample for next run***.	

4.4.3. Cross match assay

*If one or more cross matches have been selected in the worklist, users must pair a patient's sample tube to the donor tube. Although it is possible to select and perform different cross match assays, it is only possible to select **one** donor tube for **one** patient.*

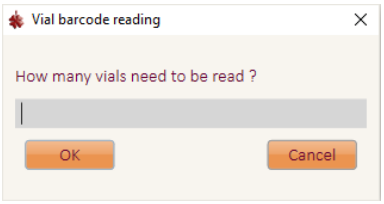
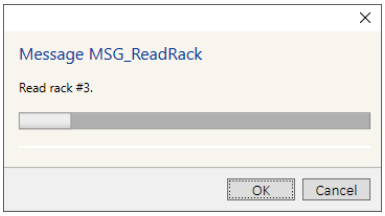
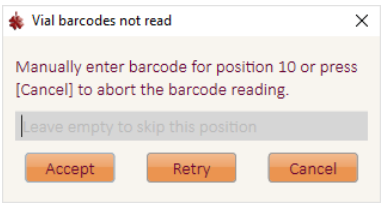
If a cross match assay has been selected from the assay list, a [**Donors booking**] tab on the right side of the window will be generated. By right-clicking on the left orange row header in the worklist – next to the sample row – users can add this to the donor tab.	

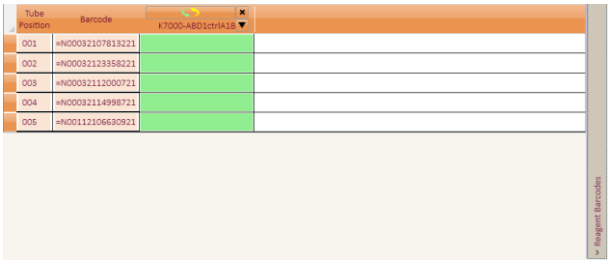
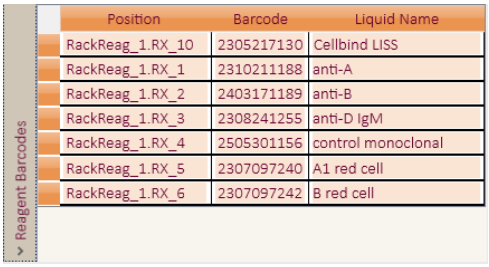
Additionally, it is also possible to add a donor to this list manually by clicking on the [**Add a new sample**] button.	
By highlighting the patient in the left part of the worklist, and then by selecting the appropriate sample tube from the donor list, the cross match is selected.	
When switching to another patient in the left part of the worklist, the previous allocated donor tube will be highlighted in red.	

4.4.4. Manual barcode reading for reagent vials

By default, the reagent vials are dynamically loaded by the software on the instrument according to the order of assays that have been programmed in the worklist. A user therefore must insert the reagents according to the on-screen instructions.

With the "***Read vial barcodes***" functionality it is possible to (temporarily – if the software has been programmed to use fixed reagent positions) allocate reagent position by reading the reagents racks prior to starting the worklist, therefore being able to position reagents according to user wishes.

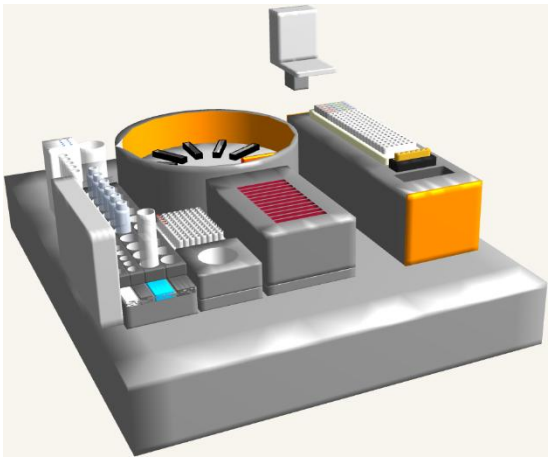
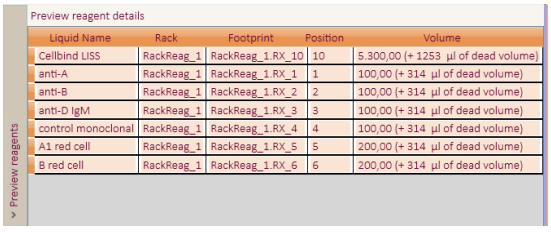
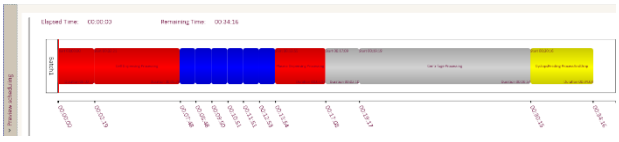
Click on [**Read reagent vial barcodes**] to start the procedure.	
Insert the number of vials that need to be read.	
The software will ask to re-insert the appropriate reagent rack(s). Follow the on-screen instructions.	
If the software was not able to read a barcode correctly i.e., damaged barcode or missing reagent on that position, a message will be displayed to indicate which position(s) has (have) been affected. • Enter the barcode either manually or via a manual barcode scanner and click [**Accept**] to input the barcode. Leave this field empty to skip this position. • Click [**Retry**] to repeat the reagent vial barcode reading. • Click [**Cancel**] in order to abort the reagent vial barcode reading.	

When performed, a [**Preview reagents**] tab will be generated on the right side of the window, where a user can identify the reagents and their positions on the reagent rack(s).	
Clicking on the [**Preview reagents**] tab will show the reagent barcode information, and their position on the reagent rack.	

Reagent Barcodes

Position	Barcode	Liquid Name
RackReag_1.RX_10	2305217130	Cellbind LISS
RackReag_1.RX_1	2310211188	anti-A
RackReag_1.RX_2	2403171189	anti-B
RackReag_1.RX_3	2308241255	anti-D IgM
RackReag_1.RX_4	2505301156	control monoclonal
RackReag_1.RX_5	2307097240	A1 red cell
RackReag_1.RX_6	2307097242	B red cell

4.4.5. Previewing the worklist

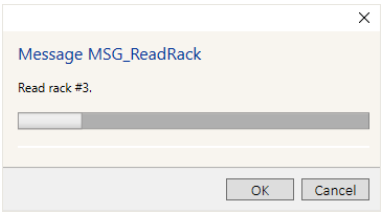
The worklist can be previewed by using the [**Preview instrument and scheduling**] to button. This will generate *information tabs* on the right side of the window.	
Clicking on [**Preview instrument**] from the first available tab will open a 3D representation of the instrument and provides useful information to the user regarding sample-, reagent-, predilution- and gel card positions. Detailed information can be seen when hovering over a desired item.	
Clicking on [**Preview reagent**] from the third tab will open the reagent list: the reagents needed for the programmed assay(s) and their positions on the reagent racks(s), including total volume needed to complete the worklist.	
The [**Preview scheduling**] tab will provide a time estimate regarding worklist duration.	

Preview reagent details

Liquid Name	Rack	Footprint	Position	Volume
Cellbind LISS	RackReag_1	RackReag_1.RX_10	10	5.300,00 (+ 1253 µl of dead volume)
anti-A	RackReag_1	RackReag_1.RX_1	1	100,00 (+ 314 µl of dead volume)
anti-B	RackReag_1	RackReag_1.RX_2	2	100,00 (+ 314 µl of dead volume)
anti-D IgM	RackReag_1	RackReag_1.RX_3	3	100,00 (+ 314 µl of dead volume)
control monoclonal	RackReag_1	RackReag_1.RX_4	4	100,00 (+ 314 µl of dead volume)
A1 red cell	RackReag_1	RackReag_1.RX_5	5	200,00 (+ 314 µl of dead volume)
B red cell	RackReag_1	RackReag_1.RX_6	6	200,00 (+ 314 µl of dead volume)

When using reagent red cells, gently resuspend the appropriate vials several times before each assay until the red cells are fully in suspension. Check that no air bubbles are present on top of the suspension before use. The use of Stirrer Balls (K7393) is highly recommended to ensure red cell reagents are kept in a continuous suspension. Non-homogenised red blood cells can lead to unexpected results.

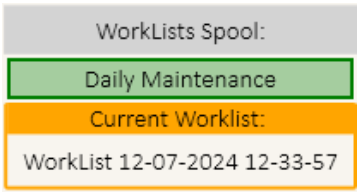
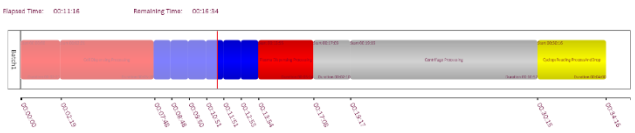
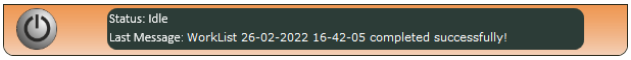
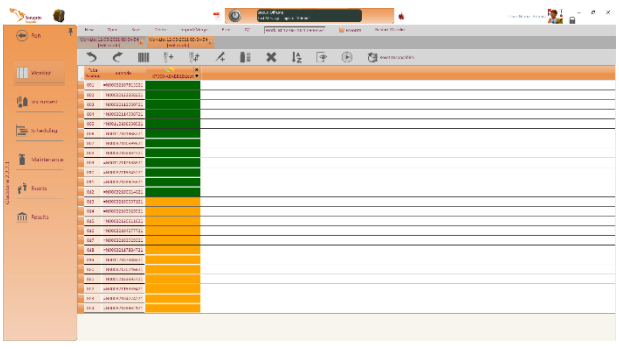
4.4.6. Starting the worklist

To start the worklist, click [**Run**].	
The "*Instrument*" window will open, and the software will ask to re-insert the appropriate reagents rack(s). Follow the on-screen instructions and close the door when done. The instrument will now start the worklist! ***Note**: This action is not applicable when the user has manually read the reagent vials prior to starting the worklist.*	

After the applicable reagent rack(s) have been reinserted (to read the reagent barcodes) the instrument will perform an "InitAssay". This assay will initialise the instrument and perform a wash- and decontamination step (each time) before the worklist is started.

4.5. Instrument operation

Before starting instrument operation, please make sure the front shield is fully closed. The instrument will not start if the front shield is not fully closed.

The worklist spool is displayed in the [***Instrument***] view. The previous worklist is highlighted in a dark-green box. The worklist which is currently running will be highlighted in a orange box below the previous ran worklist.	
It is possible to check/verify the current scheduling (status) of the worklist by clicking on [**Scheduling**]. A vertical red line indicates the current process step within the worklist, including elapsed- and remaining time for when the work list will be completed.	
During operation, clicking on the [**Pause**] button will stop the instrument after the current performing action has been completed.	This [Pause] icon will then change into a pulsating [**Play**] icon. Clicking on the "*Play/Pause*" icon a second time continues the worklist.
When the worklist has successfully finished, [**Idle**] will be shown in the status bar at the top of the main window.	
Clicking on [**Worklist**] displays all samples that have been successfully run. This will be highlighted in dark green. Different colours in the assay field(s) will indicate the status of samples in a particular worklist (see below).	

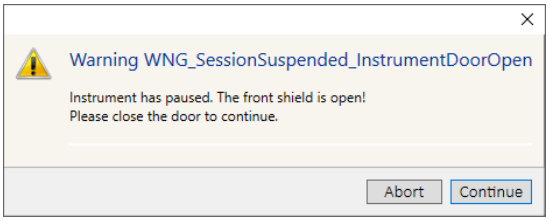
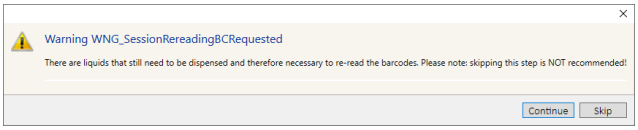
To restart a previous worklist, click [**Restart Worklist**]. This will re-open the worklist, and can be edited accordingly.	Restart Worklist

The colours in the worklist will indicate what status is given to (specific) samples. These are:

Status	Colour	Description
None	White	No tests have been selected
Booked	Light green	Samples selected for the current worklist
Booked for next run	Yellow	Samples selected for another worklist
Running	Orange	Worklist/samples currently being processed
Processed	Dark green	Worklist/samples completed successfully
Aborted	Red	Worklist/samples aborted

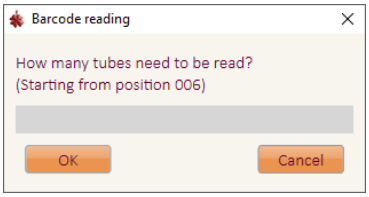
4.5.1. Pausing instrument operation

When the instrument is paused or in operation and the instrument's front shield is opened, the instrument will stop immediately to prevent any damage or injury to the instrument and/or user respectively.

A warning message will be displayed when the instrument's front shield is opened. • To continue instrument operation, close the instrument's front shield and click [**Continue**]. • The currently running worklist can be aborted when clicking on [**Abort**].	
Because the instrument's front shield has been opened during operation, it is strongly recommended to re-read the sample- and reagent racks in order to verify that sample- and reagent positions have not been altered. Click [**Continue**] to re-read the necessary sample- and reagent racks and follow the on-screen instructions.	

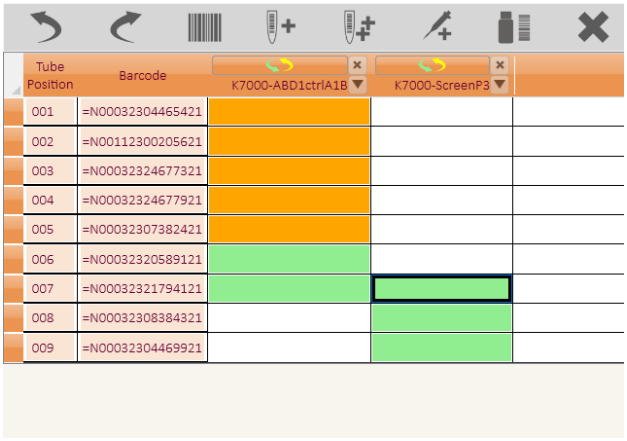
*A user is always able to [**Skip**] this procedure and continue instrument operation without verifying the sample- and reagent positions. This is however not recommended as mistakes could lead to unexpected results. Such actions will always be logged and are fully traceable in the worklist log.*

4.5.2. Continuous loading

During operation, samples can be added to the current worklist by clicking on the [**Continuous Loading**] icon.	The icon will turn green when a continuous loading request has been initiated. The instrument will pause after the current performing action has been completed.
Users are now able to add additional samples through the worklist editor as described. Click on the [**Barcode**] icon and enter the number of additional samples to be added.	

When the current worklist already has the correct assay loaded for the samples that have just been added, click the field that intersects the sample line and the assay column. Selecting a field will schedule the test for that sample, which will then be highlighted in light green.

If a different assay is required for the samples that have just been added, click on the [**Add assay**] icon, and choose the desired assay.



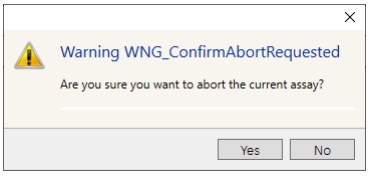
After the worklist has been updated, click the [**Play**] button to resume the worklist.

4.5.3. Stopping instrument operation

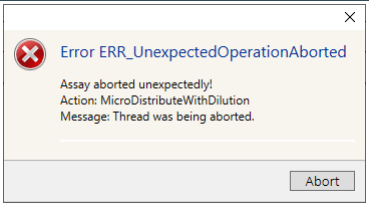
The [**Stop**] button will stop instrument operation immediately.

The software will display a message verifying the current worklist is being aborted.

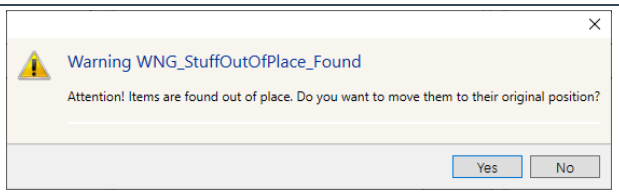
- Click [**No**] to continue instrument operation.
- To abort the current worklist, click [**Yes**].



A final message will be reported that the worklist has been aborted. Click [Abort] to initialise and return the instrument to its "*Idle*" state.

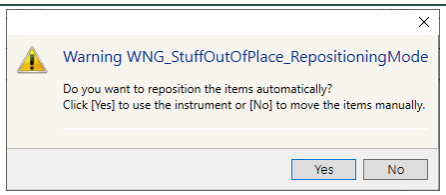


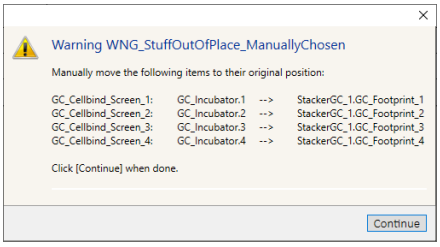
After the instrument has re-initialised, the software will ask the user to move items to their original location in case these items are still present in different module locations e.g., Cellbind gel cards in the Incubator module. Click [**Yes**] to place these items back to their original location.



*[**No**] will not move these items back and will keep these positions occupied within the software, therefore unable to be used when a new worklist is started.*

The instrument can automatically move items to their original location by clicking on [**Yes**]. When successful, the instrument's deck will be cleared



It is also possible to perform this action manually when [**No**] has been selected in the previous step. The software will then generate a report indicating where the items are located. If all items are (re)moved from their current location to their original position, clicking on [**Continue**] clears the instrument's deck.	

It is always recommended to automatically move items to their original location, as the software knows the current position of all items that need to be moved to their original position. This will also prevent a future instrument failure in the event users do not remove all items from the instrument correctly.

4.6. Capturing gel card images

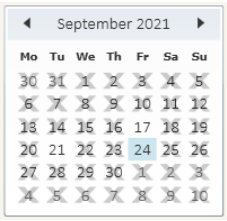
When the centrifugation step of an assay has been completed, ***an automatic set of actions*** will provide the healthcare professional with an aid in calculating the reaction scores from gel card images.

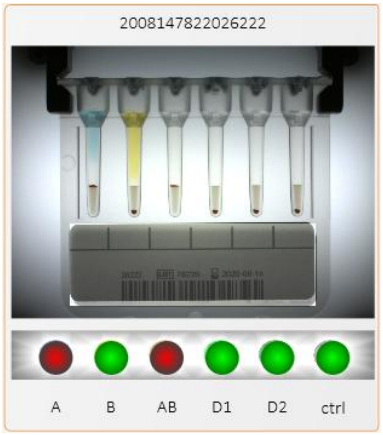
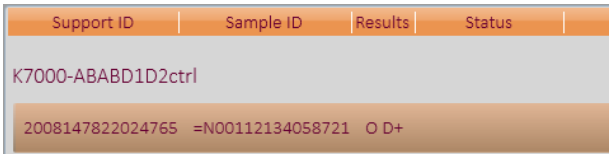
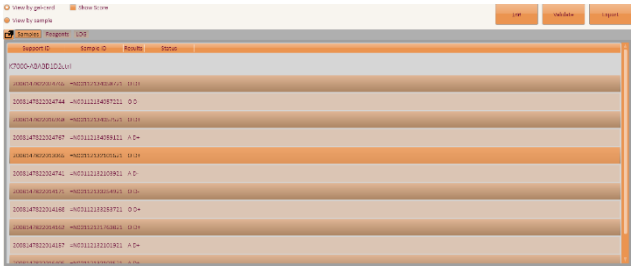
1. The gel card will be picked up and moved to barcode reader to verify if the gel card for which the result will be calculated for, is the correct one. 2. After the gel card is verified, it is positioned inside the camera module where **QCaptHR** will acquire the gel card image. 3. Immediately thereafter, the software will process the gel card, first checking that the individual gel card columns can be located. 4. Then, using a validated set of parameters pre-programmed for the assay, **QCaptHR** uses pixel detection to measure the ratio between agglutinated cells on the upper gel matrix level and non-agglutinated cells at the bottom of each column. This is then converted into a semi-quantitative agglutination score. To this score it connects a blood grouping result (A/B/O/Rh-D etc) which the laboratory professional needs to evaluate.	

4.7. Accessing gel card images

Users can view sample results in the (sub)menu [**Results**]. This can be accessed from the main menu by going to [**Results Finder**] and clicking on [**Results**].	
A shortcut to the [**Results**] menu is also available within the [**Run**] menu.	

Within the results menu a user can navigate through the results, and confirm, edit, validate, and export these results. This screen can be divided into 4 parts.

A calendar is shown in the top-left part of the screen. By clicking on a desired date, the window on the right will update automatically to show the user the sample results from that specific date. Dates will be crossed out if no tests have been performed on those dates.	

Worklists that have been performed by the instrument are shown in the bottom-left of the screen. Sample results belonging to the same worklist have the same colour, therefore being distinguishable between different worklists.	
A gel card image (or images) for the sample result selected in the worklist will be shown in the top-right part of the screen, next to the calendar. The reaction strengths are colour coded and is displayed just below the gel card image. The reaction score can be enabled by clicking on [**Show reaction score**]. 	
All relevant information on samples, reagents, relevant worklist logs, all processed gel cards, and the results suggested by the device as outlined in the table below with reactions scores can be accessed on the right. 	
To print out a hardcopy of the results, click [**Print**]. This will print a report from the current selected worklist.	

*The colours shown just below the gel card indicate the reaction strength, and ranges from dark red (strong positive reaction) to green (negative reaction). See also **chapter 4.6.***

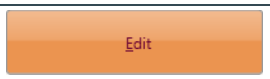
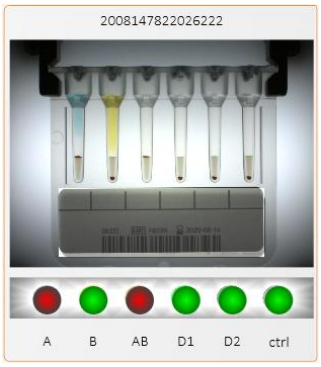
Colour	Score	Description
Red	4+	All cells on top of the gel matrix
Dark Orange	3+	Majority of red cells on top, a minor amount at the bottom of the gel matrix
Orange	2+	Evenly distributed red cells on top and at the bottom of the gel matrix
Dark yellow	1+	Small number of red cells on top, the majority will be at the bottom of the gel matrix
Yellow	?	Nearly all red cells at the bottom, and a minor number of red cells on top of the gel matrix
Green	-	All cells at the bottom of the gel matrix
Grey	N/A	No reactions score can be interpretated

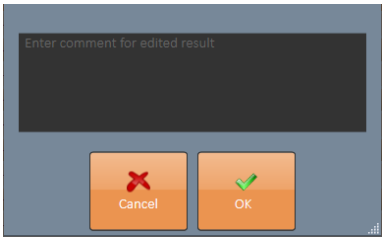
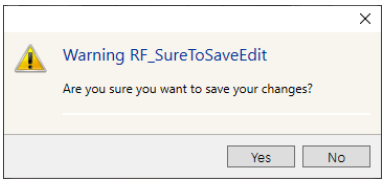
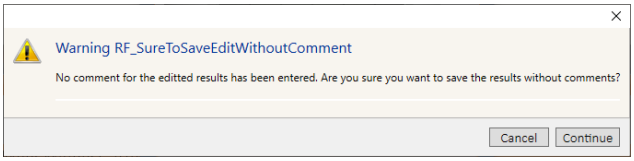
Icons might be appended next to a sample result indicating different statuses. These can be the following:

Icon	Explanation
	Sample result has been edited.
	Sample result has not yet been validated
	Sample result has been evaluated and validated by laboratory professionals.
	Sample result has been exported to a either a LIS (Laboratory Information System) or host-system (FTP).
	Barcode was not read correctly during instrument operation and therefore manually entered.
	Barcode did not match previous read barcode.
	Low liquid level for either sample and/or reagent.
	Gel card has been re-read by the camera module.
	Quality control results are OK.
	Quality control results are OK, ***but*** the panel itself is expired.
	Results for the quality control are ***not*** OK.
	Results for the quality control are ***not*** OK, ***and*** the panel itself is expired.
	Original data for these results has been moved to an archive.

4.7.1. Edit results

Whereas the results shown by the device are suggestive and are only an aid, the laboratory professional themselves must enter the right result interpretation/evaluation using edit option. Gel cards should be considered as compromised when presence of air bubbles or debris in the gel card is witnessed.

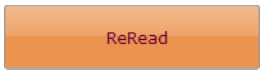
Results can be edited by clicking on [**Edit**] from the main part of the results window.	
A window will open where the result(s) for a particular gel card can be edited. Select a coloured reaction score and left click with a mouse to scroll through the possible reaction scores. Once clicked, the scores will be editable from negative to 4+	

It is then possible to input a comment when editing a result. When finished, click [**OK**] to save the new result.	
A message window will appear asking the user if they want to save their changes. • Click [**Yes**] to save the edited result(s). • Select [**No**] to return to the main results screen and discard changes made to the result(s).	
If saving an edited result and no comment has been noted in the input field, the software will verify saving the result without a comment • Click [**Continue**] to save the edited result(s) without adding a comment. • Click [**Cancel**] to return to the previous window.	

*An edited result, including any comments added to the comment field, will always be logged and are fully traceable in the worklist log. If a reaction is restored to its original score, the result will remain marked as edited, denoted by a [**Pencil**] icon next to the result. Comments will also be shown on the printed reports.*

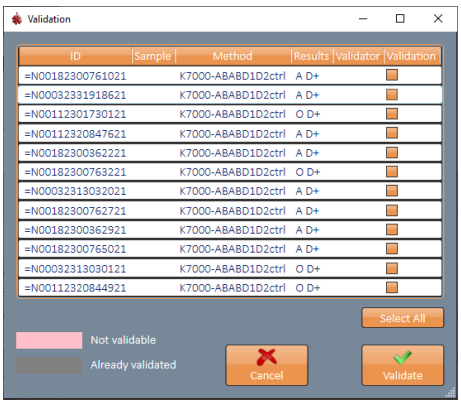
4.7.2. Re-reading gel cards

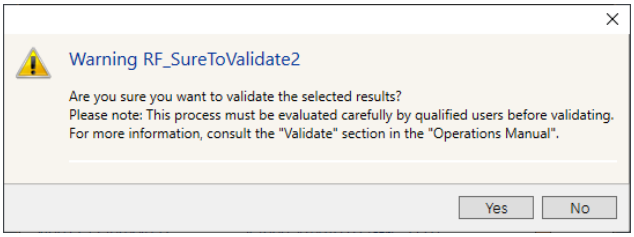
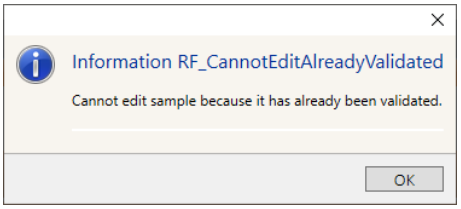
It is possible to re-read gel cards that have been previously calculated by the software. This option will only be available when the instrument is switched on and initialised, and only on the same day of testing.

 Re-reading can be initiated by clicking on the [**Re-Read**] button in the top right corner of the main results window and follow the on-screen instructions.	 An icon will be appended to the result once the gel card has been re-read by the instrument.

When the door has not been opened after the worklist has been completed, the gel card can be directly read from its original position (loading area) on top of the camera module. In the event the front door has been opened, or any other circumstance during the day, the gel card in question must be placed in the "*Balance card*" position for re-reading the gel card.

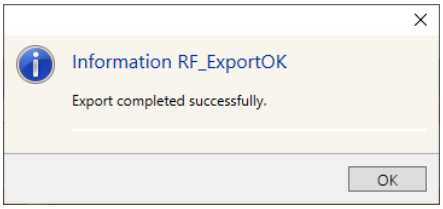
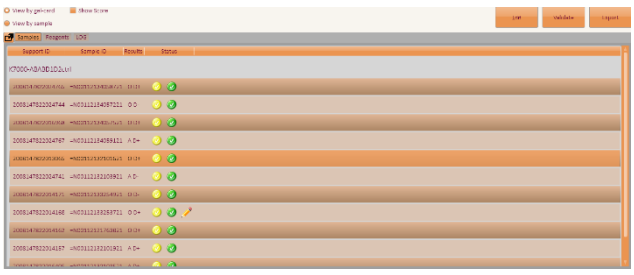
4.7.3. Validating results

Once results have been evaluated by the laboratory professional, they can be secured by confirming the reaction scores. Select the appropriate worklist and click on [**Validate**].	
 Samples from the worklist can be either checked *one-by-one*, or the complete worklist can be selected by checking the [**Select all**] button. Samples that cannot be linked to a result, will show a [N/A] score in the results window. Such samples cannot be validated and will therefore be highlighted in pink.	

When all applicable results have been selected, click [**Validate**].	
A message window will appear asking the user if they want to save their changes. • Click [**Yes**] to validate the result(s). • Select [**No**] to return to the main results screen and not validate the selected samples results).	
Once validated, results will be appended with a yellow check-mark icon. ***Note**: after validation, sample results cannot be edited anymore.*	

4.7.4. Exporting results

*Processed sample results can be exported to a LIMS (Laboratory Information Management System). Exporting results can **only** be performed **after** validation of the results and is the sole responsibility of the user. For this purpose, the Magister C24 uses the HL7 (Health Level Seven) protocol for interfacing between the system and a LIMS. Setting up this bi-directional communication is the sole responsibility of the IT-department according to their own security policies where the instrument is installed. Please contact your local distributor and IT-department for more information on how to set-up and configure your instrument when connecting to a LIMS (Laboratory Information System) or host-system (FTP).*

Click [**Export**] to send results to a LIS (Laboratory Information System) or host-system (FTP).	
Once exported, results will be appended with a green check-mark icon.	

4.8. Instrument Configuration

Some instrument and software parameters can be configured according to user requests and/or requirements. However, critical parts of the software are non-configurable and/or password protected. Therefore, only qualified, and fully trained (key)users and engineers are able, to some extent and with the necessary login credentials, configure instrument- and software parameters upon their wishes.

The instrument should only be used for its intended purpose. Changes and/or modifications to the instrument and its software is prohibited! All users assume full responsibility and consequences for any changes and/or modifications that may lead to malfunctioning of the instrument when not following correct procedures. Only with prior consent of Sanquin Reagents B.V., (key)users and technicians who have followed qualified training can perform any such actions.

5. Limitations

Installation of the software may only be performed by a certified application specialist and/or service engineer in accordance with the instructions in the Service Manual.

6. Analytical performance

On-board stability	Outcome
Cellbind gel cards	Cellbind gel cards can be stored up to 3 months at 18-25°C when kept in their original polystyrene box. Additionally, Cellbind gel cards can be stored up to 6 days at 25°C and 6.5 hours at 28°C in the original trays when outside their polystyrene box.
Cellbind LISS	Cellbind LISS can be stored up to 2 weeks.

Trueness of measurement	Outcome
Crossmatch testing	Positive percentage agreement : 100% (95 – 100% CI 95%) Negative percentage agreement : 95% (88 – 98% CI 95%)
A1 reverse testing	Positive percentage agreement : 99.8% (98.6 - 100% CI 95%) Negative percentage agreement : 100% (98.8 - 100.0% CI 95%)
B reverse testing	Positive percentage agreement : 99.6% (98.5 - 99.9%CI 95%) Negative percentage agreement : 100% (98.3 - 100.0%CI 95%)

Reproducibility	Outcome
Reverse testing	Comparison between automated and manual testing by evaluation of the difference in the number of highest counts showed a maximum of 1 agglutination step difference, indicating that the acceptance criteria are met for positive sample. All negative samples were negative in both systems.
Antibody Screening and Identification	Comparison between automated and manual testing by evaluation of the difference in the number of highest counts showed a maximum of 2 agglutination steps difference, indicating that the acceptance criteria are met. All negative samples were negative in both systems

Carry-over	Outcome
	Absence of carry-over of sample or reagent by the two pipetting tips.

Please refer to the Instruction for Use of the reagents used with the instrument for more information on analytical performance and on-board stability information

7. Clinical Performance

No clinical performance studies have been performed specifically for IVDR. Studies performed for IVDD showed a specificity of 100% with 48 negative samples and a sensitivity of 100% with 10 positive samples in screening and identification of antibodies. Please refer to the Instruction for Use of the reagents used with the instrument for more information.

8. Notice

Any serious incident that has occurred in relation to this product should be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or the patient is established.

9. References

1. Race R.R. and Sanger R.; Blood Groups in Man, 6th ed. Oxford Blackwell Scientific Publishers 1975.
2. Issit P.D.; Applied Blood Group Serology, 3rd ed. Montgomery Scientific Publications, Miami, Florida, USA, 1985.
3. Daniels G.; Human Blood Groups. Blackwell Science Ltd. 1995.
4. Mollison P.L. et al.; Blood Transfusion In Clinical Medicine, 9th ed. Blackwell, Oxford, 1993.
5. Mujahid, A. & Dickert, F. L. Blood Group Typing: From Classical Strategies to the Application of Synthetic Antibodies Generated by Molecular Imprinting. *Sensors (Basel).* **16**, (2015).
6. Li, H.-Y. & Guo, K. Blood Group Testing. *Front. Med.* **9**, 827619 (2022).
7. Bhagwat, S. N., Sharma, J. H., Jose, J. & Modi, C. J. Comparison Between Conventional and Automated Techniques for Blood Grouping and Crossmatching: Experience from a Tertiary Care Centre. *J. Lab. Physicians* **7**, 96–102 (2015).

10. Disclaimer

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. Strict adherence to the Instructions for Use is required to obtain reliable results. Always consult the most recent Instructions for Use before use.

11. Changes to previous version

This is the first version under the IVDR 2017/746.