



MULTI ARRAY XPLOERER (MAX) 45k AND 9k INSTRUCTION FOR USE

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I. DISCLAIMER

MacroArray Diagnostics has validated the provided instructions, reagents, instrument, software, and customizable features for this analyser to optimize product performance and meet product specifications. User defined modifications are not supported by MacroArray Diagnostics as they may affect performance of the analyser and test results. It is the responsibility of the user to validate any modifications made to these instructions, instruments, reagents, or software provided by MacroArray Diagnostics.

Please consult the relevant instructions for use of ALEX² and FOX tests before processing!

II. LIABILITY STATEMENT

This guide was checked for correctness. The instructions and descriptions for the MAX devices were correct at the time this guide was written. Subsequent guides may be changed without prior notice; however, MacroArray Diagnostics assumes no liability for harm caused directly or indirectly by errors from the guide. The MAX devices *in-vitro* diagnostic devices which is intended to be used by trained laboratory personnel only.

This guide and the software described are protected by copyright. No part of this guide or of the software described may be duplicated, reproduced, or copied to an electronic medium or machine-readable format without prior written permission from MacroArray Diagnostics.

III. TERMS AND DEFINITIONS

Damage	Physical injury or damage to human health, damage to goods or the environment.
Intended Operation	Operation, including readiness for operation, in accordance with the operating instructions or the intended use.
Intended Use	Use of a product, method, or service in accordance with the specifications and instructions defined by MacroArray Diagnostics (MADx).
Obvious damage	Damage that can be recognized with the naked eye alone by careful observation of the analyser or its component, or by monitoring available displays, signals, or transmitted data.
Operator	Individual or group responsible for the usage and maintenance of the device. The operator makes sure the users have been appropriately instructed about how to operate the device.
Process	Resources and activities that interact to convert inputs into results.



Trained personnel	Employees who have completed a recognized education program for the task that has been assigned to them, who are familiar with the special aspects and hazards of their work environment and who continue their education with regular training sessions about changes and developments (such as standards and guidelines) that are relevant to their education and their work.
User	Person using the device in accordance with the specifications.
Validation	Confirmation by providing objective evidence that the requirements for a specifically intended use or specifically intended application have been fulfilled.
Verification	Confirmation by providing objective evidence that defined requirements have been fulfilled.

IV. INTENDED USE FOR MAX 45k AND MAX 9k

The MAX 45k is an instrument and intended as accessory to ALEX technology-based products. The IVD medical product automatically processes ALEX technology-based arrays and acquires pictures of those. The product is used by trained laboratory personnel and medical professionals in a medical laboratory.

The MAX 9k is an instrument and intended as accessory to ALEX technology-based products. The IVD medical product automatically processes up to 10 ALEX technology-based arrays in one run and acquires pictures of those. It is used by trained laboratory personnel and medical professionals in a medical laboratory.

The MAX 45k and MAX 9k are categorized in class A according to the In Vitro Diagnostics Regulation IVDR (2017/746) and will be used by trained laboratory personnel only. Concerning IVDD (98/79/EG) the instrument is not classified according to list A, B, or self-testing devices.

V. MANUFACTURER AND LABELING

V.1 MANUFACTURER

The MAX devices are manufactured by MacroArray Diagnostics (MADx)



MacroArray Diagnostics
Lemböckgasse 59/Top 4
A-1230 Vienna, Austria



V.2 IDENTIFICATION OF THE DEVICES

An identification label is placed at the rear side of the MAX devices.



Figure 1: Identification label details placed on the rear side of the MAX 45k

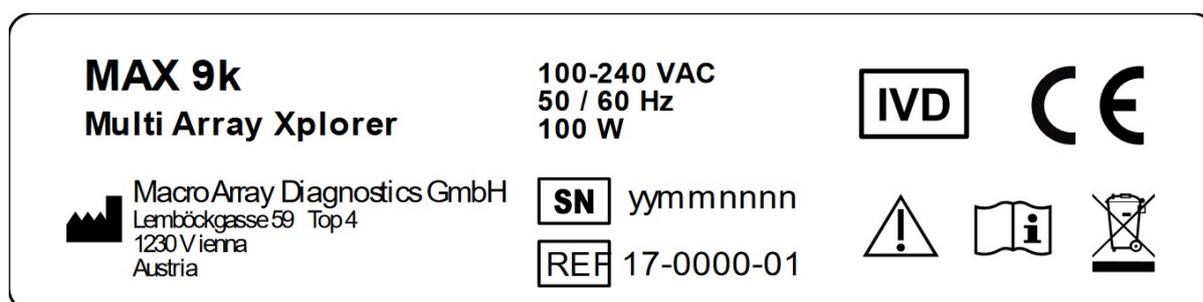


Figure 2: Identification label placed on the rear side of the MAX 9k

VI. PERFORMANCE DATA

VI.1 ASSAY CALIBRATION

For the Assay Calibration refer to the respective IFU of the ALEX² or FOX test.

VI.2 MEASURING RANGE

For the Measuring Range refer to the respective IFU of the ALEX² or FOX test.

VI.3 QUALITY CONTROL

Record keeping for each assay:

According to good laboratory practice it is recommended to record the lot numbers of all reagents used. Lot numbers of all reagents are saved for each run and the information can be retrieved retrospectively for each Run ID via RAPTOR SERVER Analysis Software.

Control Specimens:

According to good laboratory practice it is recommended that quality control samples are included within defined intervals. MacroArray Diagnostics produces a quality control sample



for ALEX² tests: the **QualityXplorer** (REF 31-0800-02). As an alternative, Lyphochek® sIgE Control Panel A (by Bio-Rad) can also be applied.

Acceptance ranges for the QualityXplorer and the most recent batches of Lyphochek® sIgE Control Panel A are stored and displayed on RAPTOR SERVER.

See section XVII.11 for further details on how the quality control system is implemented on the MAX devices.

VI.4 DATA ANALYSIS

ALEX² and FOX images are automatically analysed using MADx's RAPTOR SERVER and a report is generated summarizing the results for the user.

VI.5 RESULTS

ALEX² is a quantitative method for specific IgE and a semi-quantitative method for total IgE determination. Allergen- specific IgE antibodies are expressed as IgE response units (kU_A/L), total IgE results as kU/L. MADx's RAPTOR SERVER Analysis Software automatically calculates and reports sIgE results (quantitatively) and tIgE results (semi- quantitatively).

FOX is a semi-quantitative method for specific IgG determination. Specific IgG antibodies are expressed as IgG response units (µg/ml). MADx's RAPTOR SERVER Analysis Software automatically calculates and reports sIgG results semi-quantitatively as classes (low, intermediate, and highly elevated).

VI.6 LIMITATION OF THE PROCEDURE

For the Limitation of the procedure refer to the respective IFU of the ALEX² test or FOX test.

VI.7 EXPECTED VALUES

For the expected values refer to the respective IFU of the ALEX² test or FOX test.

VI.8 PERFORMANCE CHARACTERISTICS

ALEX² test:

Precision:

The lot-to-lot variation was determined on three MAX 45k and MAX 9k devices in three separate ALEX² runs. Three selected multi-sensitized samples were tested covering the majority of priority components at 3 different levels: >10 kU_A/L, 1-10 kU_A/L and 0,3-1 kU_A/L.

For the selected allergen components, the CV (in %) was calculated between runs and between instruments (= total CV).



	CV (0.3 - 1 kU _A /l)	CV (1 - 10 kU _A /l)	CV (> 10 kU _A /l)	CV (> 1 kU _A /l)
Total CV% MAX 45k	24.0	11.0	9.1	10.6
Total CV% MAX 9k	20.6	10.1	8.8	9.4

Homogeneity:

The homogeneity of the ALEX² results within a MAX test run was tested on three separate MAX 45k and MAX 9k devices. A single multi-sensitized positive test sample was tested at all positions of the cartridge carousel.

	CV (0.3 - 1 kU _A /l)	CV (1 - 10 kU _A /l)	CV (> 10 kU _A /l)	CV (> 1 kU _A /l)
CV% MAX 45k	33.6	12.3	9.2	11.5
CV% MAX 9k	28.1	10.3	9.3	9.8

Analytical Sensitivity:

For the Limit of Detection refer to the section performance characteristics in the IFU of the ALEX² test.

Analytical Specificity:

For the Analytical Specificity refer to the section performance characteristics in the IFU of the ALEX² test.

Interference:

For the interference with other substances refer to the section performance characteristics in the IFU of the ALEX² test.

FOX test:

Precision:

The lot-to-lot variation was determined on three MAX 45k and MAX 9k devices in three separate FOX runs. Three selected multi-sensitized samples were tested covering the majority of priority antigens. For the selected antigens, the CV (in %) was calculated between runs and between instruments (= total CV).



	CV (10.0 – 19.9 µg/ml)	CV (> 20 µg/ml)	CV (> 10,0 µg/ml)
Total CV% MAX 45k	9.1	4.3	6.3
Total CV% MAX 9k	8.8	5.0	6.2

Homogeneity:

The homogeneity of the FOX results within a MAX 9k test run was tested on three separate MAX 9k devices. A single multi-sensitized positive test sample was tested at all positions of the cartridge carousel.

	CV (10.0 – 19.9 µg/ml)	CV (> 20 µg/ml)	CV (> 10.0 µg/ml)
CV% MAX 45k	n.a.	n.a.	n.a.
CV% MAX 9k	8.3	5.6	6.3

Analytical Sensitivity:

For the Limit of Detection refer to the performance characteristics in the IFU of the FOX test.

Interference:

For the interference with other substances refer to the performance characteristics in the IFU of the FOX test.



VII. PRINCIPLE OF THE PROCEDURE

VII.1 ALEX² TEST PRINCIPLE

ALEX² is a solid-phase immunoassay. Allergen extracts or molecular allergens, which are coupled to nanoparticles, are deposited in a systematic fashion onto a solid phase, forming a macroscopic array. First, the particle bound allergens react with specific IgE that is present in the patient's sample. After incubation, non-specific IgE is washed off. The procedure continues by adding an enzyme labelled anti-human IgE detection antibody which forms a complex with the particle bound specific IgE. After a second washing step, substrate is added which is converted to an insoluble, coloured precipitate by the antibody-bound enzyme. Finally, the enzyme-substrate reaction is stopped by adding a blocking reagent. The amount of precipitate is proportional to the concentration of specific IgE in the patient sample. The assay procedure is followed by an automated image acquisition and analysis which is integrated in the MAX device. The test results are analysed with MADx's RAPTOR SERVER Analysis Software and reported in IgE response units (kU_A/L). Total IgE results are also reported in IgE response units (kU/L).

VII.2 FOX TEST PRINCIPLE

FOX is a solid-phase immunoassay. Food extracts, which are coupled to nanoparticles, are deposited in a systematic fashion onto a solid phase forming a macroscopic array. First, the particle bound proteins react with specific IgG that is present in the patient's sample. After incubation, non-specific IgG is washed off. The procedure continues by adding an enzyme labelled anti-human IgG detection antibody which forms a complex with the particle bound specific IgG. After a second washing step, substrate is added which is converted to an insoluble, coloured precipitate by the antibody-bound enzyme. Finally, the enzyme-substrate reaction is stopped by adding a blocking reagent. The amount of precipitate is proportional to the concentration of specific IgG in the patient sample. The lab test procedure is followed by an automated image acquisition and analysis which is integrated in MAX device. The test results are analysed with MADx's RAPTOR SERVER Analysis Software and reported in µg/ml and in IgG classes.

VIII. SERVICE

MacroArray Diagnostics or its local distributors are available to repair the device during normal local office hours. In case a service is required at any other time, contact the MacroArray Diagnostics service (support@macroarraydx.com) or your local distributor. The scope of agreed service is included in your service contract.



IX. WARRANTY

MacroArray Diagnostics and its local distributors guarantee that the device will show no defects during operation if it is installed and operated according to this manual by qualified and trained personnel. For further information about warranty, contact the MacroArray Diagnostics service or its distributors. The warranty is not valid for damage that occurs because of non-compliance with this manual, whereby repairs and servicing must only be carried out by persons trained and certified by MacroArray Diagnostics. Maintenance needs to be performed as described in this manual. Improper interventions on the device void the warranty and can result in service charges. Only use the device as intended. If the device is not used as intended, MacroArray Diagnostics disclaims all liability for damage to the device.

X. ORDERING INFORMATION

Use only consumables, accessories and spare parts provided by or recommended by MacroArray Diagnostics. Order these items only from MacroArray Diagnostics or local distributors. For ordering information, see the MacroArray Diagnostics brochure for one of our MAX devices or contact the MacroArray Diagnostics team at orders@macroarraydx.com or your local distributor.

The MADx article number (REF) for the MAX 45k device is 16-0000-01.

The MADx article number (REF) for the MAX 9k device is 17-0000-01.

XI. SAFE HANDLING

The device has been inspected for technical safety before shipment. To maintain this status and to ensure hazard-free operation:

- Always follow the instructions in this manual.
- Always follow good laboratory practice.
- Make sure the electrical and environmental conditions described in section XXI are met.

In addition, MacroArray Diagnostics clearly states that using the analyser in a manner not specified by this manual or elsewhere by MacroArray Diagnostics may affect the safety measures implemented by the manufacturer and may also result in a hazardous situation or lead to wrong test results.

XI.1 OPERATOR QUALIFICATION

The analyser must only be operated by persons whose skills, knowledge and practical experience qualify them to do so, and who have read and understood this manual to avoid the risk of death and serious injury due to the lack of knowledge.



XI.2 ELECTRICAL SAFETY

To prevent the risk of electric shocks when touching parts of the device - even when the system is switched off - please apply the following guidelines:

- The analyser must be connected only to a socket with ground (earth).
- Only correctly rated extension cables with enough power capacity and a protective conductor and ground contact shall be used.
- Never disconnect the ground contacts from the power line.
- Never interrupt the protective conductor inside or outside of the system.
- Never remove protective guards or fused components.
- Ensure that all surfaces, including the floor, are dry when using the system.
- Make sure that the power switch of the system is easily accessible.
- If the analyser needs to be opened before maintenance, repair, or replacement work, switch off the analyser and disconnect it from all voltage sources as described in the relevant procedure.

Please avoid damage to the system due to eventual short-circuit, caused by spilled liquids that get into contact with live parts, by applying the following guidelines:

- Never pour liquids or place containers with liquid on top of the system.
- Disconnect the mains plug immediately if liquid is spilled into the system.

Please do not operate strong electromagnetic transmitters, for example, mobile phones, door openers, or elevators, in the vicinity of the analyser to prevent the risk of malfunctions of the MAX devices.

Please note that the delivered power cord shall not be replaced by any other inadequately specified or sized power cord.

XI.3 MECHANICAL SAFETY

To avoid serious injury by moving mechanical parts, the analyser is equipped with an internal interlock that prevents the opening of the main cover (cover) during operation and during other activities involving movement of mechanical parts.

	Never bypass this internal locking mechanism, otherwise the instrument will be de-energized to prevent injury due to the movements of the pipettor or rotors. If this occurs, all measurements that have already been performed are lost
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XI.4 OPERATIONAL SAFETY

To avoid property damage due to inaccurate handling of the system, rough handling or dropping, improper interventions on the system which void the warranty and can result in service work to be separately charged, please apply the following guidelines:

- Always handle the system with care.
- Switch off the instrument and secure it against accidental operation if there is visible damage to the system.
- Only carry out maintenance and repair work or replace parts as described in this manual.
- Only use spare parts recommended by MacroArray Diagnostics.

XI.5 SAFE HANDLING OF ALL NEEDED CONSUMABLES

Please ensure that you read and observe any instructions for use that are supplied with the consumables, product manufacturer's warnings and manufacturers information regarding the compatibility of laboratory gloves with the materials and liquids used in order to avoid the following:

- Infection by potentially infectious material
- Irritation of skin by cleaning agent
- Inaccurate handling of consumables
- Pollution by improper waste disposal

XI.6 OPERATIONAL CONDITIONS

When operating the MAX device, ensure compliance with the specified ambient conditions (see section XXI); these must be strictly adhered to. See also section XV.2 prior to installation. The operator is not allowed to exchange any fuses. In case of a defect fuse, a technical defect is assumed that must be fixed by MacroArray Diagnostics or your local distributor only, and not by the operator.

XI.7 DECONTAMINATION

If hazardous materials are spilled on or into the analyser, an appropriate decontamination procedure must be performed. If you have any questions or doubts concerning the compatibility of decontamination- or cleaning agents with analyser components or component materials, please contact MacroArray Diagnostics or your local distributor. For safety reasons, the MAX device must be disinfected/decontaminated before repairs and service work are performed. Make sure you follow the instructions for decontaminating the analyser. Before decontamination and/or disinfection, switch off and disconnect the analyser

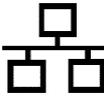
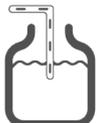


from the power supply (pull the plug). The operator is solely responsible for the effectiveness of the disinfection and decontamination methods used and their validation.

XII. GLOSSARY OF SYMBOLS

	Caution, hot surface
	Caution, biohazard
	Caution, hand/finger injuries
	Consult instruction for use
	In vitro diagnostic medical device
	CE mark
	Manufacturer
	Serial number
	Waste electrical and electronic equipment
	Power on
	Power off



	Ethernet port
	Fuse characteristics
	Biohazard
	System Water
	Washing Solution
	1 Litre Level
	10 Litre Level (MAX 45k)
	2 litre Level (MAX 9k)
	Protective Grounding
	<p>Catalogue number Indicates the manufacturer's catalogue number so that the medical device can be identified.</p>
	<p>Temperature limit Indicates the temperature limits to which the medical device can be safely exposed.</p>
	Caution



XIII. SAFETY MESSAGES

All safety messages must be observed to avoid hazardous situations which may result in death, injury, or damage to the equipment.

	Indicates a hazardous situation which, if not avoided, will result in death, serious or minor injury.
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XIV. LEGAL REQUIREMENTS

XIV.1 INTERNATIONAL STANDARDS

The MAX devices have been developed, tested, and manufactured in accordance with EN ISO 13485, EN IEC 61010-2-101, EN ISO 14971, EN IEC 61326-2-6, EN ISO 62304 and EN ISO 62366.

XIV.2 CE CONFORMITY

The MAX devices hold a CE mark which certifies that the devices meet the essential requirements of the following European directives:

- In Vitro Diagnostic Medical Devices Directive 98/79/EC
- Directive on Waste Electrical and Electronic Equipment 2012/19/EU
- Directive on Restriction of Hazardous Substances 2011/65/EC

XIV.3 ELECTROMAGNETIC COMPATIBILITY (EMC), RADIO INTER-FERERENCE SUPPRESSION AND IMMUNITY TO INTERFERENCE

The MAX devices have been tested in accordance with EN IEC 61326-2-6 and correspond to CISPR 11 Class B.

XIV.4 OBLIGATIONS OF THE OWNER OF THE DEVICE

The owner of the device takes on the obligations arising from the national legislation about the operation of in-vitro diagnostic medical devices.



XV. LIFE CYCLE

This section describes the stages the MAX devices go through, beginning from delivery to disposal, and the requirements involved for the operator within each stage.

XV.1 DELIVERY

XV.1.1 DAMAGES DURING TRANSPORT

The outer packaging of the device ensures the best possible protection against transport damage. Nevertheless, please check each shipment immediately upon receipt for visible transport damage. Additionally, check the tilt/shock sensors on the outer packaging whether they are triggered in red colour. If you receive an incomplete or damaged shipment, please directly contact MacroArray Diagnostics or your local distributor. Please notify the carrier about apparent damage.

XV.1.2 SCOPE OF DELIVERY

Included Items
1x MAX analyser
1x System-Water Container
1x Set of Tubing and Cabling for the System-Water-Container
1x Wastewater Container
1x Set of Tubing and Cabling for the Wastewater-Container
1x Washing Solution Container
1x Image Acquisition Module (in MAX 9k already mounted)
1x Steel Pipettor Needle (in MAX 9k Assembled in Pipetting Robot)
5x Segments (MAX 45k)
2x Segments (MAX 9k)
1x Cartridge Rotor – Front Cover (MAX 45k)
1x Cartridge Rotor – Rear Cover (MAX 45k)
1x Power Cord
1x Ethernet Cable
1x Syringe Set for dosing pump (MAX 9k)

Table 1 List of items available for delivery



For the operation of the MAX analysers, an ALEX² (50x: REF 02-5001-01) or FOX (REF 80-5001-01) assay kit is required, which is not included in the shipment of the MAX device and must be ordered separately.

It is possible to use the MAX 9k with the ALEX² 20x kit (REF 02-2001-01) as well; in that case a bottle of Stop Solution (REF 00-5007-01) and a bottle of Washing Solution (REF 00-5003-01) is additionally required.

For the optimal setting of the camera exposure, the application of a ConfigXplorer (REF 30-0100-01) is obligatory.

The device control, test-setup, and result analysis is carried out on the web-based RAPTOR SERVER analysis software (see Chapter XVII). Therefore, the MAX devices are only to be used in combination with the web-based RAPTOR SERVER analysis software and the corresponding MAX Agent desktop software, connected to a PC. Please consult the current IFU of RAPTOR SERVER.

XV.2 INSTALLATION

XV.2.1 SITE PREPARATION PRIOR TO INSTALLATION

The MAX devices are intended for indoor use only and should be operated in a room with a controlled temperature. Before the device is powered on, ensure that the device is at room temperature. Make sure that the electrical and environmental conditions are met (see section XXI).

The minimum clearance dimensions surrounding the devices shall be as follows:

- Left and right side of the analyser: > 200 mm
- Back side: > 120 mm
- Space on top (for lid opening): > 500 mm
- Suggested bench height: max. 750 mm

Please note, that there might be additional space required for a PC connected to the device, and for external fluid containers to be placed under the bench or next to the device on the bench. Apart from the requirements in Section XXI, following additional conditions are required for the use of the MAX:

- Availability of waste sink on site
- Availability of Demineralized water on site
- PC with at least windows 10
- Display of at least 1080p
- Admin rights to configure connection to the MAX, and to install and update software



- Permanent and stable internet connection, with access to (outgoing port):
 - <https://www.raptor-server.com>
 - <https://api.raptor-server.com>
 - <https://resultshare.raptor-server.com>
 - <https://www.macroarraydx.com>

XV.2.2 UNPACKING AND SETTING UP INSTRUMENT

	<p>The MAX 45k device shall be unpacked and lifted out of the packaging only by MacroArray Diagnostics or a local distributor and only be operated by specialized personnel (laboratory personnel) who have previously undergone training in how to use the analyser. This training can only be provided by MacroArray Diagnostics or a local distributor. By these means, injury of the operator resulting from overload such as pulled muscles or disk lesion will be avoided.</p>
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For the **MAX 9k** proceed as follows (**ask for the tutorial video from your local distributor!**):

1. Make sure there are no damages on the packaging (Section XV.1.1)
2. Carefully cut the straps and take off the top of the cardboard box
3. Take out the flat accessories box from the top.
4. Remove the outer cardboard-box wrapping around the instrument.
5. Remove the top foam panel.
6. Remove the two foamed side parts on the front and back of the instrument.
7. Remove the two foamed side parts on the left and right sides of the instrument.
8. Dismount and unfold the plastic bag at the base of the device and remove the bag.
9. With two people, carefully remove the unit from the box and place it on a table.

	<p>The instrument must be lifted by two persons standing to the right and left by holding it with their hand underneath the instrument. Do not use the handle of the main cover lid when carrying the instrument!</p>
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10. Remove the plastic protector layer from the top of the device.
11. Open the main cover by bypassing the lock (See Figure 16 in section XVI.4.3)
12. According to the illustrations below:
 - Remove (pull out) the plastic needle holder, yellow on the illustration, (1), from the pipettor needle
 - Lift up and hold the pipettor (2) to remove the plastic holder ring (3) from the pipettor parking hole. There is also a polystyrol foam to remove.



- Remove the bubble wrap from underneath the pipettor and put back the pipettor needle (2) to the parking hole.

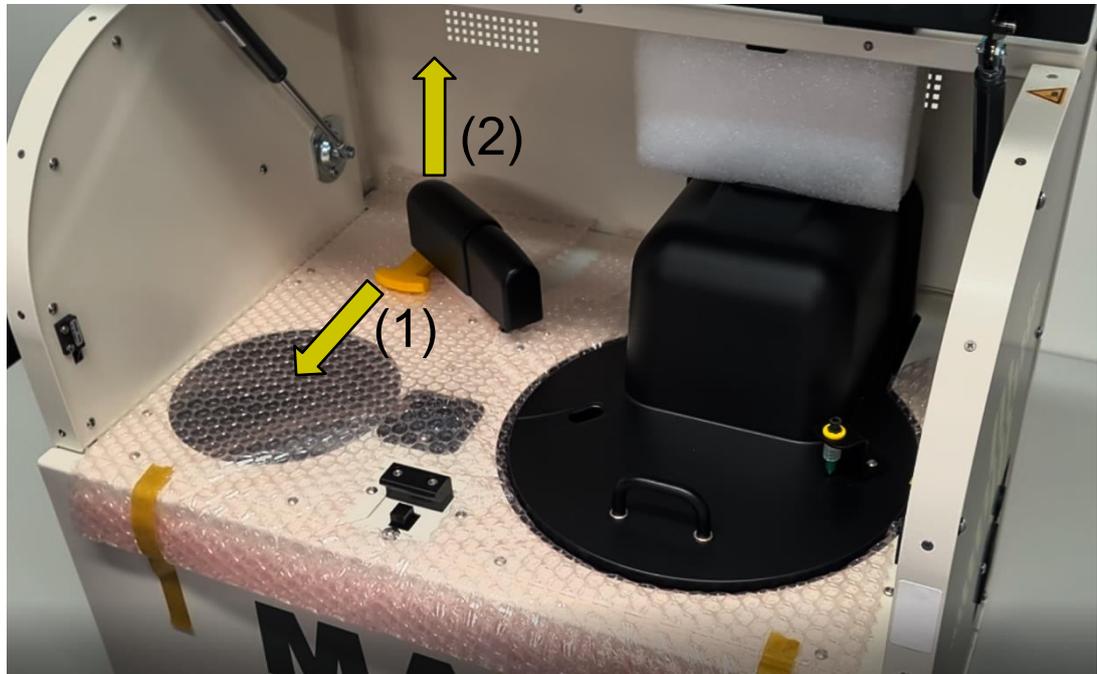


Figure 3: Installing MAX 9k

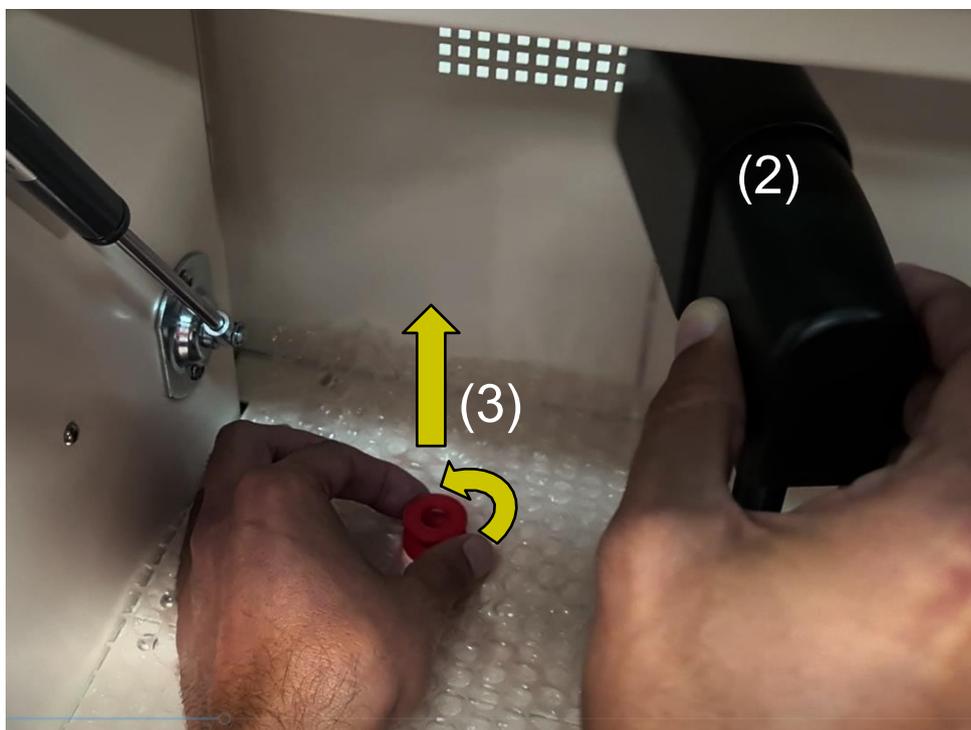


Figure 4: Installing MAX 9k



- Remove the plastic foam place holder (4) from the top of the cartridge rotor cover

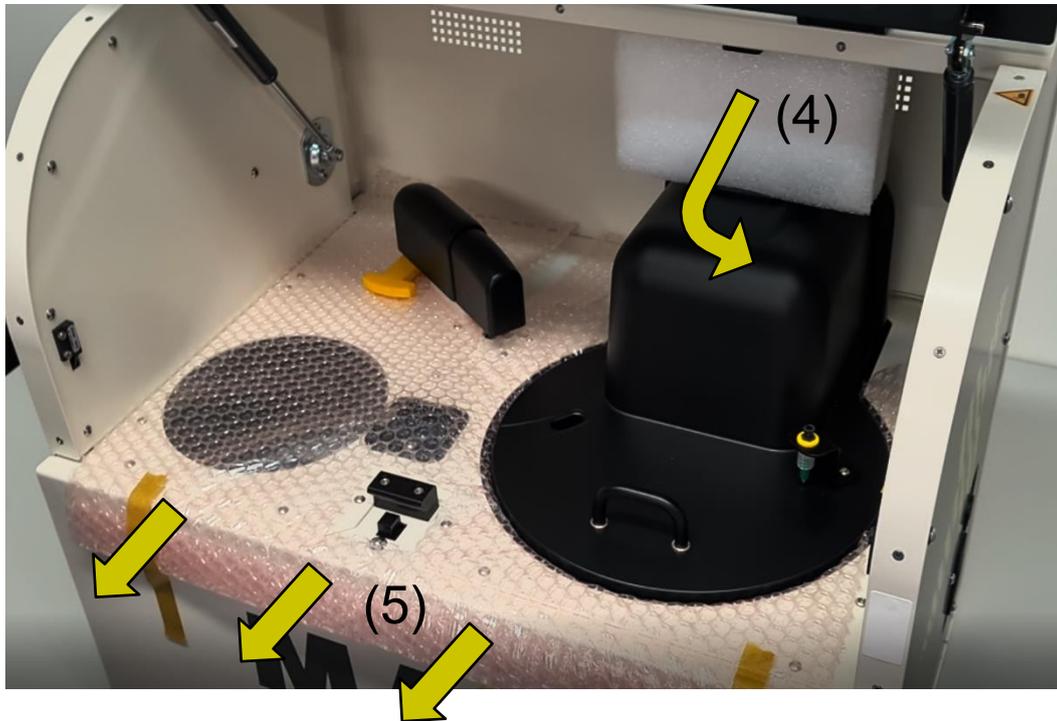


Figure 5: Installing MAX 9k

- Lift the cartridge rotor cover and remove the plastic protector foil (5)
- Remove the tapes which hold the Washing Solution tube (6) and mount the tubing to the luer lock of the washing solution dispenser needle by the regular thread mount (7). Make sure the needle fitting is tight and not moving easily.

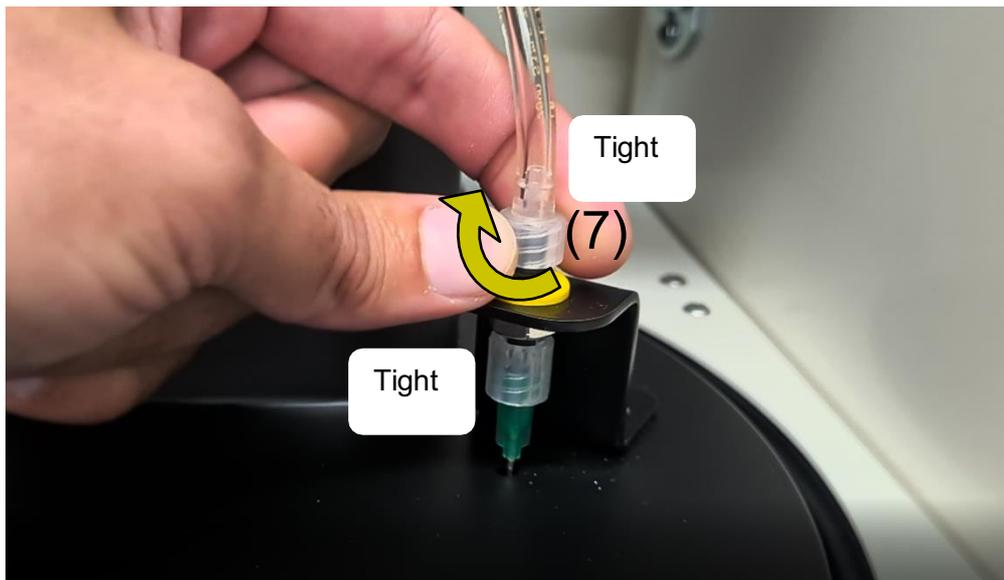


Figure 6: Installing MAX 9k



- Fix the tubing at the holder mount on the rotor cover, by sliding the black rubber ring onto the holder (8)

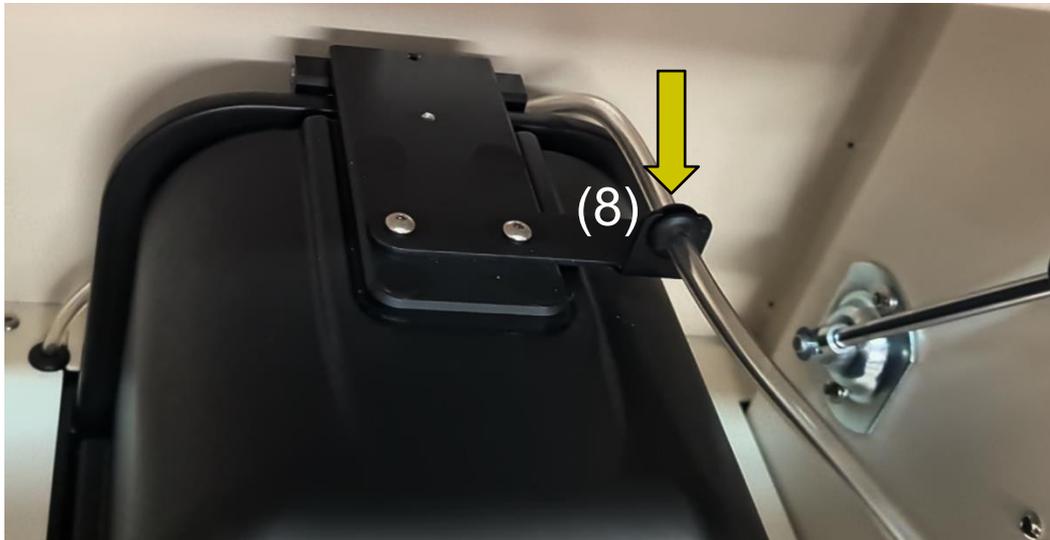


Figure 7: Installing MAX 9k

- Insert the segments into the cartridge rotor, see section XVI.6.2.
- Insert the sample rotor carousel to the sample rotor tub by sliding it onto the shaft.



Please check to ensure that a needle is installed in the Pipetting Robot (for details see section XVI.7). Tighten the needle at the grip additionally, if necessary. If no needle is installed, it is not allowed to start the device, otherwise decontamination may occur. In this case, please contact MacroArray Diagnostics or its local distributors.



XV.2.3 **MAX 9k - PREVENTIVE PRESSURIZED FLUSHING OF THE WASH SOLUTION PUMP**

Before initial operation of the MAX 9k instrument, preventive pressurized flushing of the Washing Solution pump is strongly recommended to ensure smooth instrument operation. To do this, use the syringe set and first fill the syringe with 4 ml of air. Then connect the syringe set to the connection for the wash solution (yellow). Now apply multiple short pressure pulses by pushing the syringe.

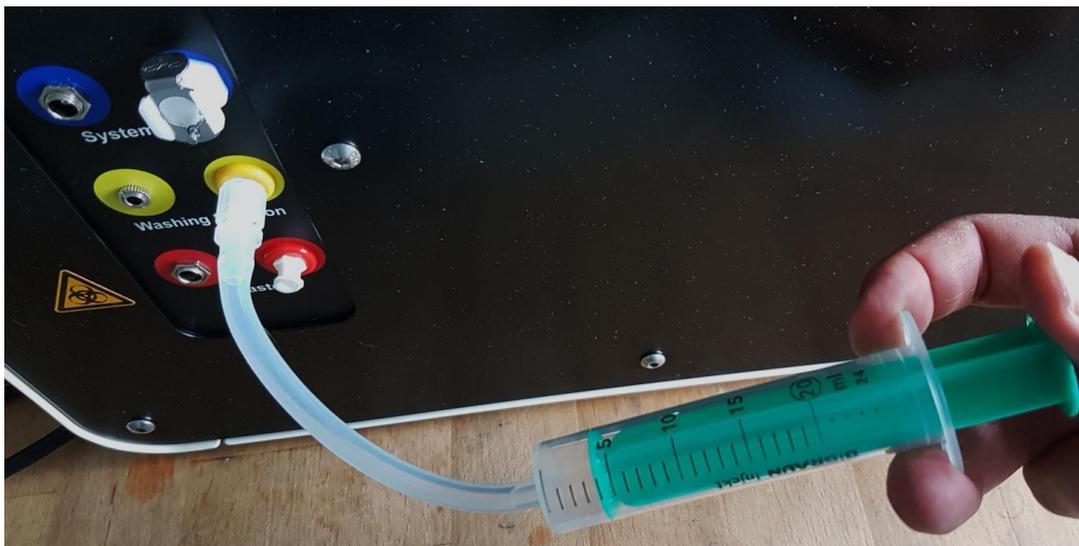


Figure 8: Preventive Pressurized Flushing with the Syringe Set

XV.2.4 **CONNECT THE EXTERNAL FLUIDIC SUPPLIES AND THEIR FILL-LEVEL SENSORS**

- On the left side of the device, plug the container tubing into the corresponding sockets, see container connection panel in section XVI.4.1.
- On the left side of the device, connect the cables for the fill level sensors of the containers, see container connection panel in section XVI.4.1.

XV.2.5 **CONNECT POWER SOURCE**

- At the right side of the device, plug the power cord into the socket, see power module in section XVI.4.4.
- Plug the power cord into a power outlet with a ground contact as shown in section XVI.4.4.

XV.2.6 **CONNECT ETHERNET COMMUNICATION**

- At the right side of the device, plug the ethernet cable into the socket, see Ethernet panel in section XVI.4.4.
- Plug the other end of the Ethernet cable into a PC (use an USB-to-Ethernet adapter if necessary)



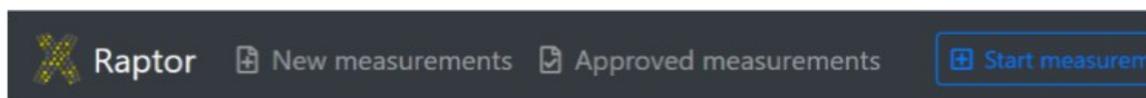
XV.2.7 START DEVICE

- Close the main cover, see section XVI.4.3. On the right side of the device, set the main switch to position I, see section XVI.4.4.
- Start the analyser and perform a ConfigXplorer Scan to confirm the proper function of the device and release it for operation (see Section XVII.5).

XV.3 NON-OPERATION

To prepare the device for a longer period of standstill, proceed as follows:

- Open the main cover and remove all sample tubes, reagent bottles and cartridges.
- Apply the decontamination routine according to the instructions provided in RAPTOR SERVER Analysis Software. Click on “Tenant Admin → “Manage MAX devices” → “Configure” → “Decontamination”



Configure MADxMAX003



- Shutdown the analyser via RAPTOR SERVER Analysis Software, see section XVII.9.
- At the right side of the analyser, set the mains switch to position 0, see section XVI.4.
- At the right side of the analyser, unplug the power cord from the socket, see Power module switch in section XVI.4.
- At the right side of the analyser, unplug the ethernet cable from the socket, see Ethernet panel in section XVI.4.
- At the left side of the analyser, unplug the container tubing and fill level sensor cables from the corresponding sockets (see section XVI.4.).
- Empty and clean all containers.
- Remove the cartridge rotor front and rear cover.
- Remove the segments.
- Clean the cartridge rotor, see section 0.
- Insert cartridge rotor rear and front cover.
- Clean the sample and reagent rotor, see section 0.
- Clean the exterior surfaces, see section 0.
- Close the main top cover.



XV.4 DE-INSTALLATION

To de-install the analyser, proceed as follows:

- Prepare the device for non-operation (see section XV.3).
- If you want to store the analyser, make sure that the storage location meets the storage and transportation conditions, see the technical specifications in section XXI.

XV.5 TRANSPORT

The device shall be transported under the conditions that are shown on the corresponding cardboard box.

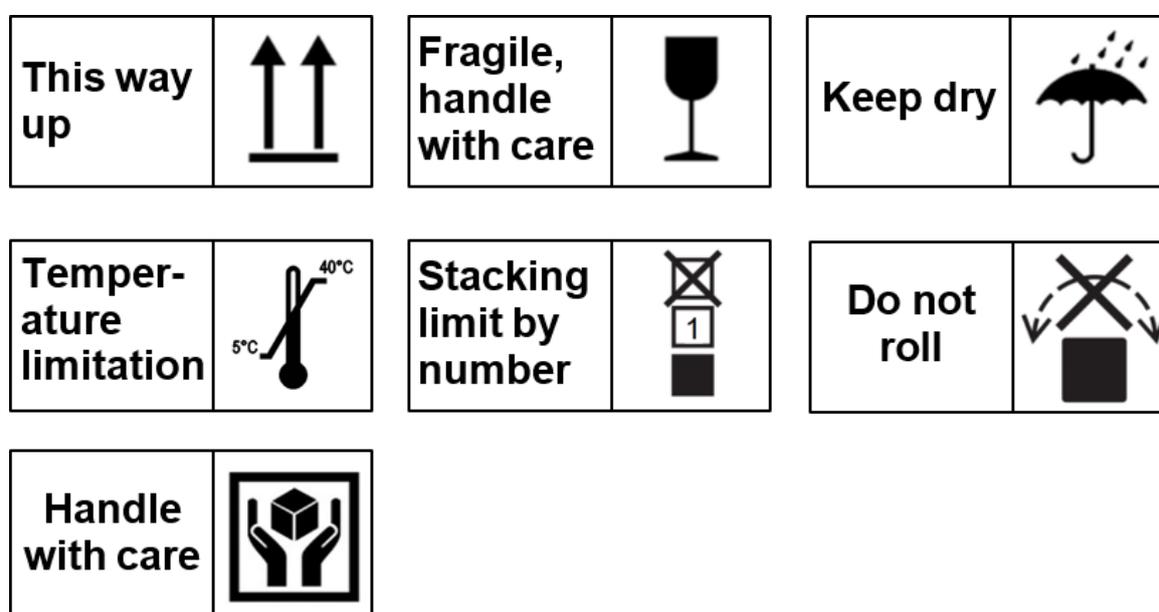


Figure 9: Transport Conditions

XV.6 DISPOSAL

In the European Union, disposal of the analyser is regulated by Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) and corresponding national transpositions.

MacroArray Diagnostics is committed to take back and recycle electrical and electronic equipment in areas where the above-mentioned directive is enforced. In areas where the above-mentioned directive is not enforced, contact the MacroArray Diagnostics service or a local distributor regarding disposal of the analyser.

Depending on the applications, parts of the device may be contaminated with biohazardous or hazardous chemical material.



	<p>Treat contaminated material according to national and local standards and regulations. Before transport or disposal, disinfect parts of the analyser that may be contaminated according to national and local standards and regulations. If you need assistance, contact MacroArray Diagnostics or a local distributor</p>
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	<p>Do not treat electrical and electronic equipment as unsorted municipal waste and check with your local waste disposal contractor for specific requirements regarding disposal. Please collect waste electrical and electronic equipment separately and return them to MacroArray Diagnostics or a local distributor in areas where the above-mentioned directive is enforced.</p>
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To dispose the device, proceed as follows:

- De-install the device, see section XV.4.
- Contact support of MacroArray Diagnostics or your local distributor regarding disposal of the device.
- Dispose of the device according to national and local standards and regulations.



XVI. DESCRIPTION

XVI.1 OVERVIEW OF THE MAX 45k DEVICE

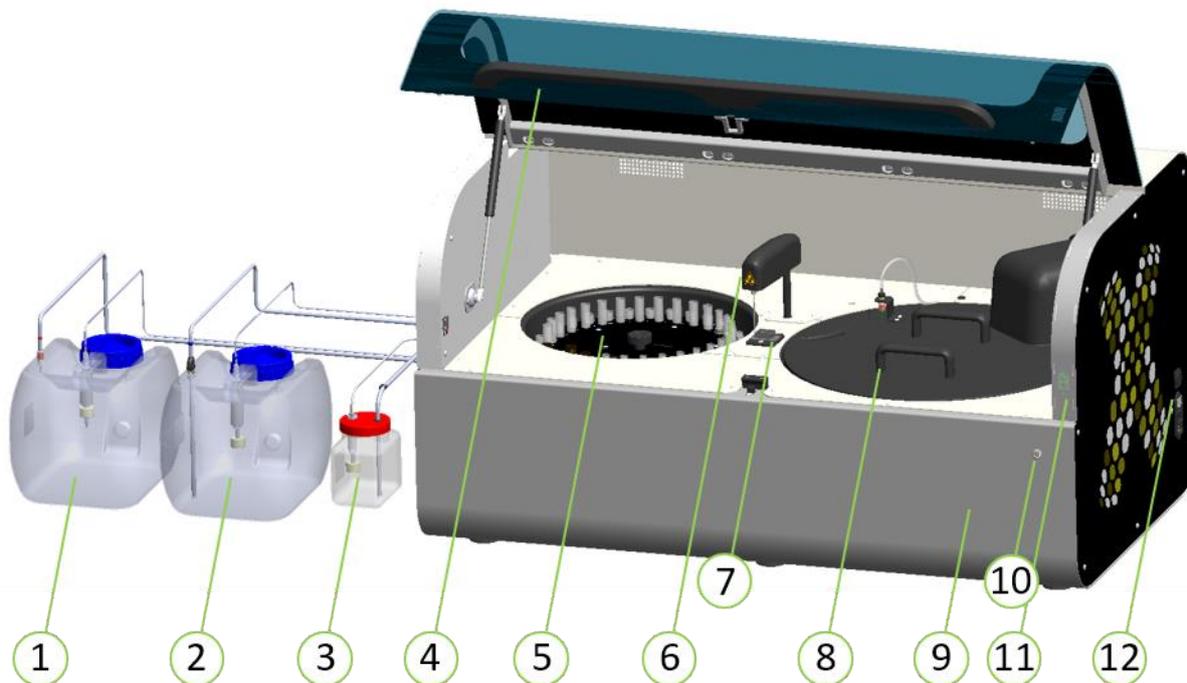


Figure 10: Functional sub-systems MAX 45k

- 1 Wastewater Container incl. Fill-Level Sensor
- 2 System-Water Container incl. Fill-Level Sensor
- 3 Washing Solution Container incl. Fill-Level Sensor
- 4 Main Cover
- 5 Sample and Reagent Rotor
- 6 Pipetting Robot
- 7 Pipettor Needle Rinsing Station
- 8 Cartridge Rotor
- 9 Housing
- 10 Recover Push Button
- 11 Status LEDs
- 12 Power and Ethernet Connector, Main Power Switch



XVI.2 OVERVIEW OF THE MAX 9k DEVICE

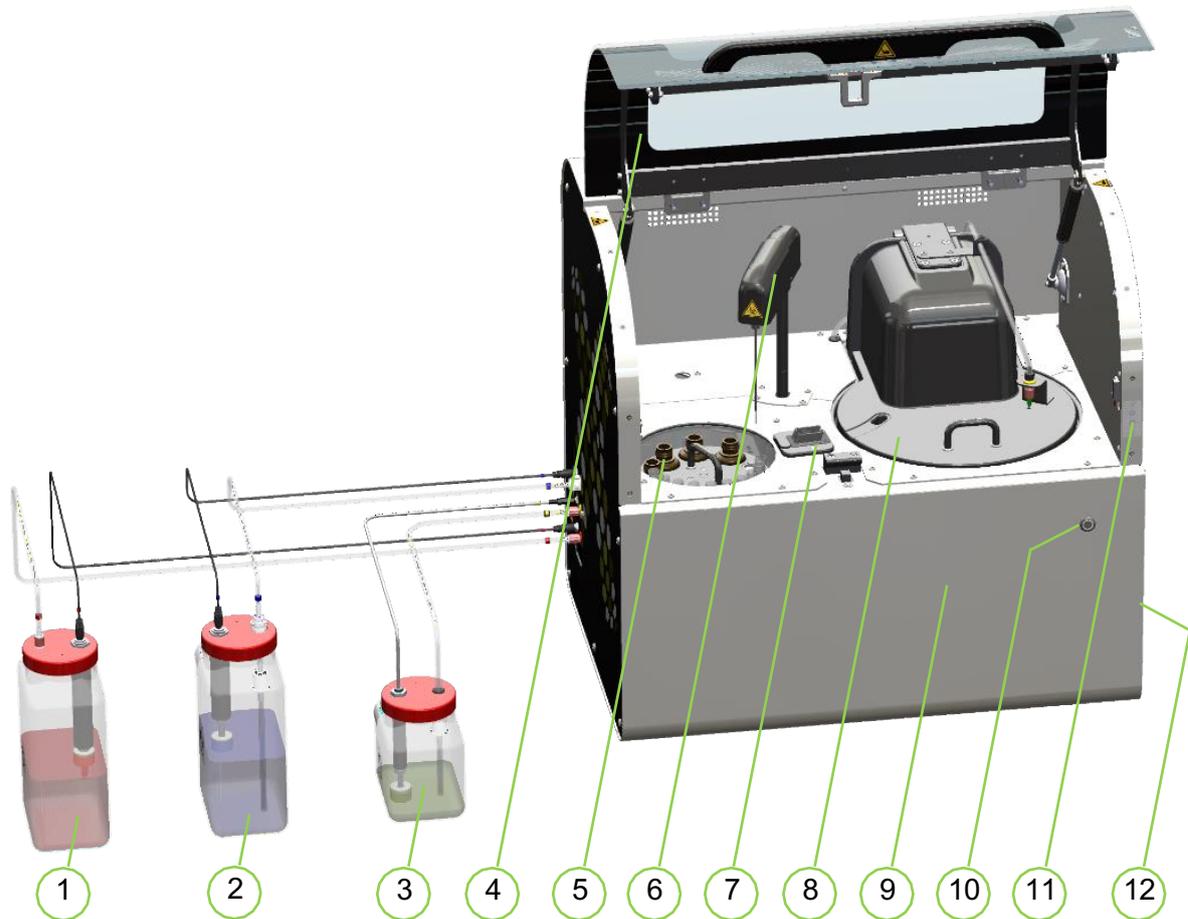


Figure 11: Functional sub-system MAX 9k

- 1 Wastewater Container incl. Fill-Level Sensor (red colour code)
- 2 System-Water Container incl. Fill-Level Sensor (blue colour code)
- 3 Washing Solution Container incl. Fill-Level Sensor (yellow colour code)
- 4 Main Cover
- 5 Sample and Reagent Rotor
- 6 Pipetting Robot
- 7 Pipettor Needle Rinsing Station
- 8 Cartridge Rotor
- 9 Housing
- 10 Recover Push Button
- 11 Status LEDs
- 12 Power and Ethernet Connector, Main Power Switch



XVI.3 PRINCIPLE OF THE OPERATION

NOTE: The Instruction for Use for the ALEX² (REF 02-5001-01 and REF 02-2001-01) and FOX assay kits (REF 80-5001-01) can be obtained online at www.macroarraydx.com and should be consulted before any assay run is performed on a MAX device.



Either ALEX² or FOX tests can be processed in one run. A combination of ALEX² and FOX cartridges or reagents is prohibited.

- Sample tubes that contain serum or plasma, and ALEX² or FOX reagents are loaded manually to the reagent and sample positions on the sample rotor.
- ALEX² or FOX kit cartridges are manually loaded to the cartridge rotor.
- Assignment of the patient samples to the respective cartridges is done via the software application RAPTOR SERVER.

When the test run is started, dilution medium (in case of an ALEX² test) is pipetted from the corresponding bottle to the cartridges. Next, the samples are pipetted to the cartridge according to the assignment in RAPTOR SERVER, then mixed and incubated for a certain duration. Optionally, manually pre-diluted samples can be processed as well; in that case, the protocol skips the dilution step accordingly.

NOTE: FOX tests can only be processed pre-diluted.

The sample substance is removed from the cartridges by centrifugation (spinning of the cartridge rotor) and a Washing Solution is applied on the cartridges multiple times.

Next, the secondary antibody (ALEX² or FOX Detection Antibody) solution is pipetted from the corresponding reagent bottle to the cartridges sequentially, mixed and incubated for a certain time period.

The secondary antibody solution is removed from the cartridges and Washing Solution is applied on the cartridges multiple times.

The substrate solution (ALEX² or FOX Substrate Solution) is pipetted from the corresponding reagent bottle to the cartridges sequentially and incubated for a certain time period.

The Stop Solution is pipetted from the corresponding reagent bottle to the cartridges sequentially to stop the chemical reaction on the cartridges.

Afterwards, the substrate and stop solution mixture is removed from the cartridges and a final washing step is performed.

The cartridges are then dried and finally, image acquisition of each cartridge is performed. The images are analysed by RAPTOR SERVER.

It is possible to recapture already processed cartridge images independently from a Run. Make sure you carry out the recapture in the device in which the tests took place.



XVI.4 HOUSING

XVI.4.1 LEFT SIDE OF THE DEVICE

Figure 12 shows the different fluidics and electronics ports which are located on the left side of the device and their purpose. Each container is equipped with a fill-level sensor. The fill-level sensor ports and the tubing connectors for the System Water, Waste Water and Washing Solution container are highlighted in different colours to prevent any misplacement of tubing and fill-level sensor connectors (red – Waste, blue – System Water, yellow – Washing Solution). In addition, all fluidics and electrical connectors are different in shape and size and therefore prevent misplacement by design. If the level sensor cables of the level sensors are not attached, the RAPTOR SERVER Analysis Software will indicate a missing critical fill-level and will not allow to perform any cartridge processing with the analyser.

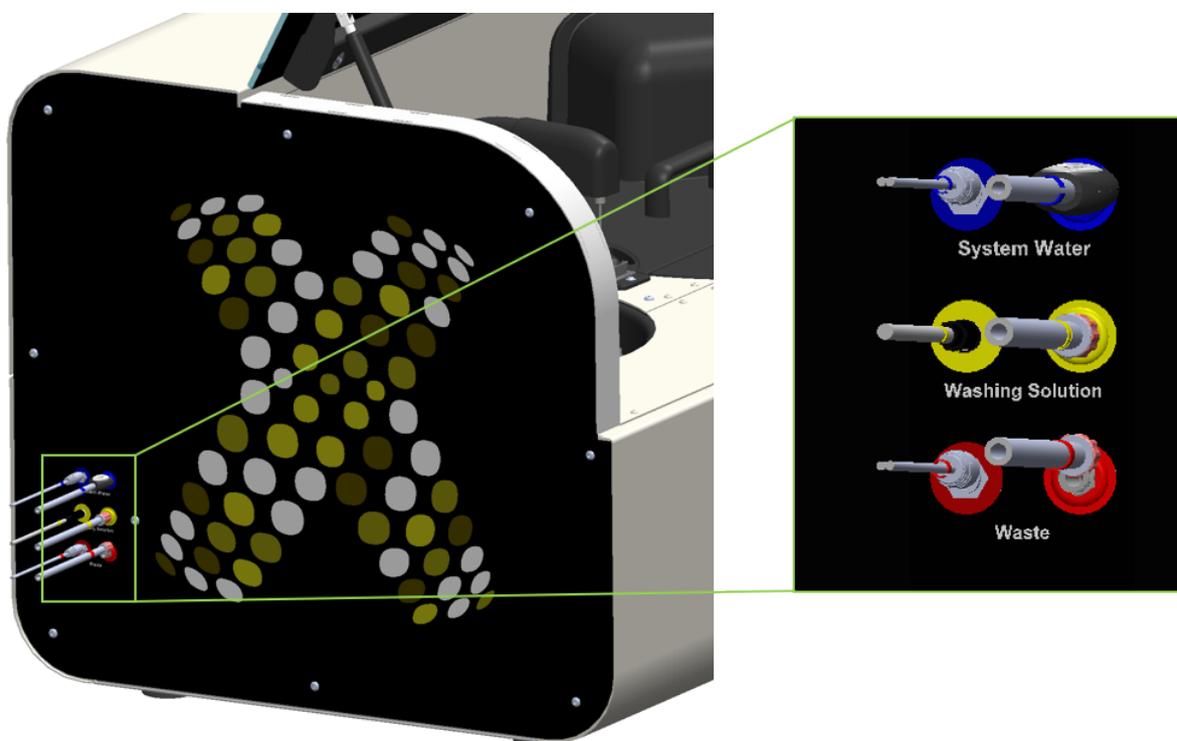


Figure 12: Left side of the device



XVI.4.2 REAR SIDE OF THE DEVICE

Figure 13 shows the rear side of the device. The rear side includes air inlets and outlets which must not be covered to ensure sufficient cooling and functionality of the corresponding units.



Figure 13: Rear side of the device

XVI.4.3 FRONT SIDE OF THE DEVICE

Figure 14 shows the front side of the analyser with closed main cover. On the right side of the analyser's front panel, a recovery button (circular silver push button) and two status LEDs are located. The lower status LED is red, the upper status LED green and the button is illuminated in white colour. Both status LEDs and the push button can change their status from permanently illuminated to a flashing state and reverse, indicating the different working status of the analyser as shown in Table 2.

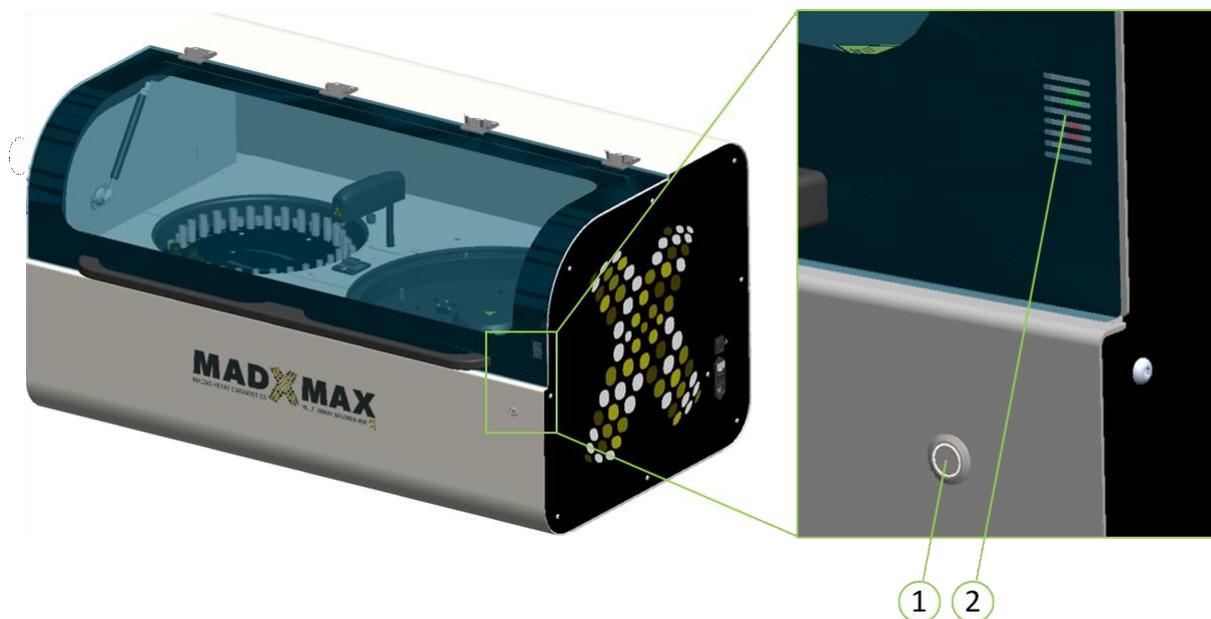


Figure 14: Front side of the device

- 1 Recover Push Button
- 2 Status LEDs (Green and Red)

Working Status	Description
Off	Analyzer is off. Push button LED and the status LEDs are off.
Booting	While turning on, the push button LED flashes quickly until the operating system of the instrument is booted, and the device’s sub systems are powered on. Finally, the white push button LED is turned on permanently and both status LEDs are off.
Processing	During any ongoing activities of the analyser, the white push button LED is permanently on, and the green LED is flashing, whereas the red LED is off.
Standby	Upon initialization, and after completing any activities, the green LED will turn from flashing to “permanent on” status. The red LED is still off. The push button LED is permanently on.
Shut down	After the device is shut down via the RAPTOR SERVER Analysis Software, the push button LED turns from permanent on to slow flashing status (flashing interval of approx. 5s) The green LED goes off. The red LED is off. In this state, the device can be turned off by the main switch or recovered by pressing the silver push button.
Stop state	Whenever the device is in a Stop state (main cover opened, leakage, or crash error), the push button LED and red LED are permanently on. Green LED is off.

Table 2: Explanation of different working status of the device



The “Main Cover”, which allows the user to access the working deck, is equipped with two sensors, detecting if the main cover is in an “opened” or a “closed” state. In case of an “opened” state, the analyser stops all mechanical motions immediately. Any activities can only be executed when the main cover is in a “closed” state.

To prevent any unforeseen opening of the “Main Cover” during operation, the main cover is secured by an interlock system (see Figure 15) which can only be unlocked via the RAPTOR SERVER Analysis Software. The interlock is designed in a way that in case of a software- or electrical malfunction, the main cover stays permanently locked, and the user gets no access to the working deck.

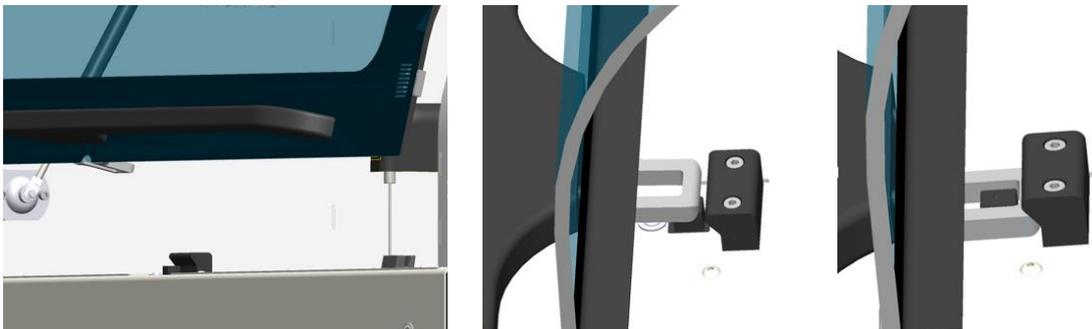


Figure 15: Illustration of interlock functionality of the main cover

In this case, the user can bypass the interlock with a screwdriver via the opening (1) on Figure 16 of the main cover by pushing down the spring lock (2) and pulling the main cover upwards.

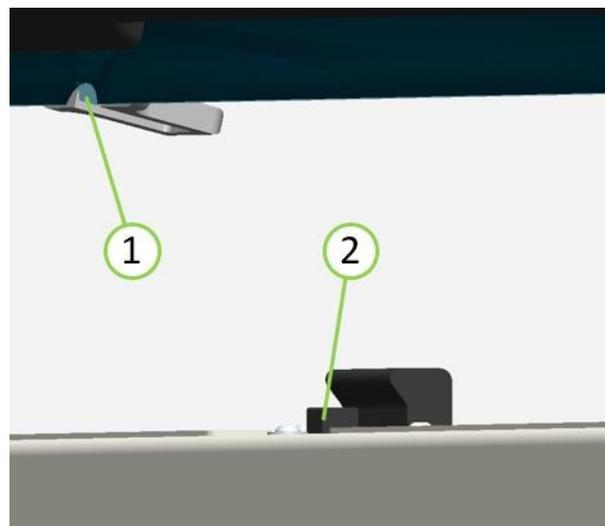


Figure 16: Bypassing the interlock

In case the lock is bypassed during operation and the main cover is opened, the analyser will stop all mechanical motions immediately. MacroArray Diagnostics disclaims all liability for damage to the analyser by manually bypassing the interlock during operation.



For a proper handling of the main cover, the following rules must be applied:

	To open or close the main cover, grab the handle only with both hands as shown below.
--	---



Figure 17: Closing Main Cover



Additional warning symbols in front of the opened main cover, on both sides of the analyser and on top of the main cover - as shown in the following pictures (highlighted with green circles) - shall warn the user or any third person to keep their fingers and hands off the analyser when the main cover is getting closed.

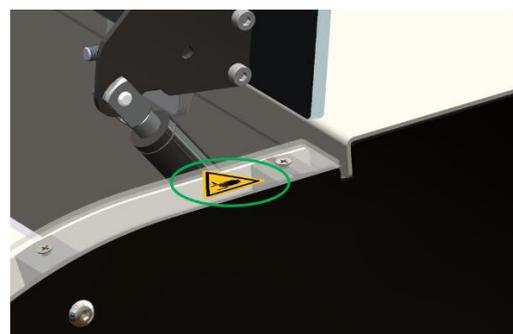
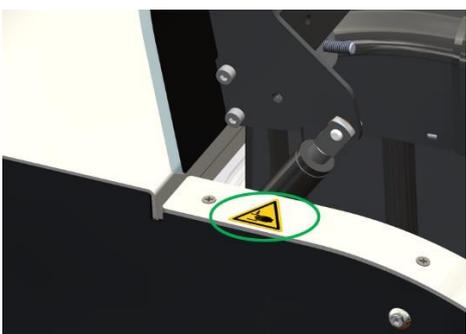
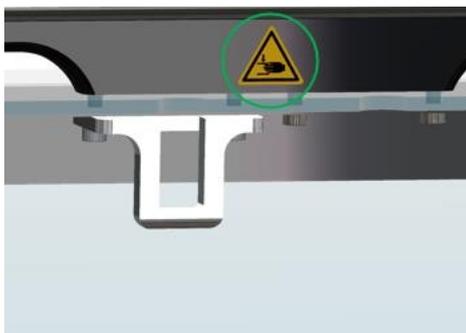


Figure 18: Warnings of Injuries to hands



XVI.4.4 RIGHT SIDE OF THE DEVICE

Figure 19 shows the main power entrance module incl. fuse drawer and Ethernet connection port, which are located on the right side of the analyser.

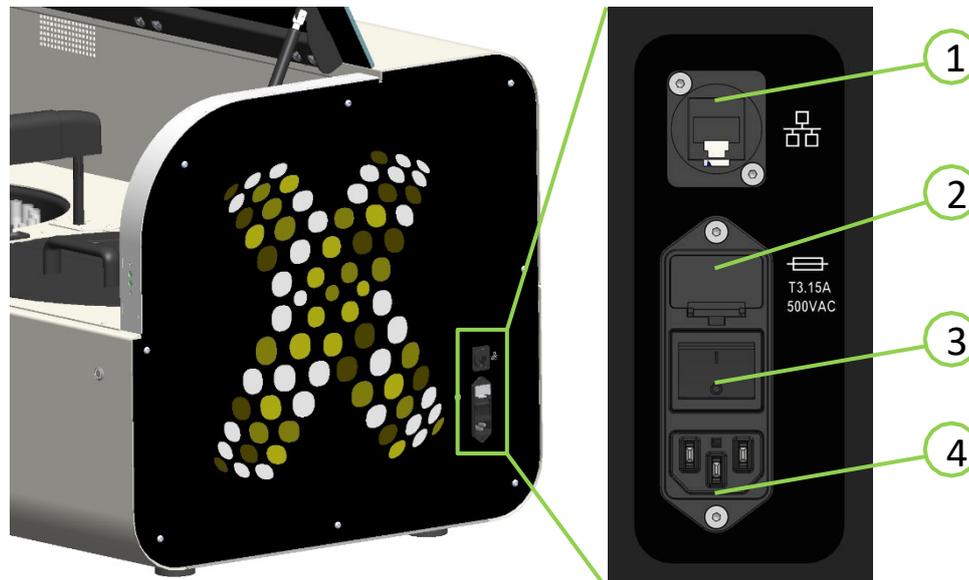


Figure 19: Right side of the device

- 1 Ethernet Port
- 2 Fuse Drawer Including Fuses with Characteristics as Shown Below.
- 3 Main Power Switch
- 4 Main Power Connector

The analyser must be equipped with 2 fuses according to the following specifications:

Manufacturer: Littelfuse® Cartridge Fuse
Type: 5*20 mm > Time-Lag > 477 Series
AMP-Code: T3.15A / 500V AC



XVI.5 WORKING DECK OF THE MAX 45k DEVICE

By opening the main cover, the user will get direct access to the main functional modules on the working deck for loading the ALEX² or the FOX test (see Figure 20).

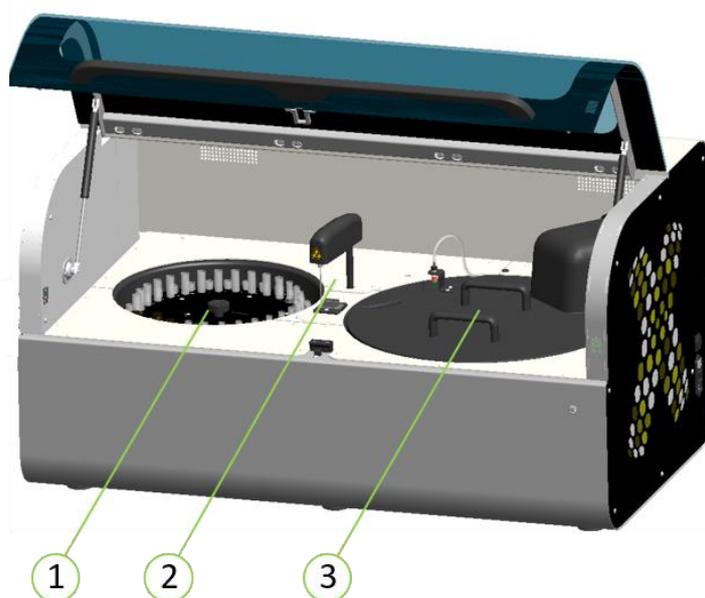


Figure 20: Main functional modules on the working deck of the MAX 45k

- 1 Sample and Reagent Rotor
- 2 Pipetting Module and Needle Rinsing Station
- 3 Cartridge Rotor and Imaging Module

The main cover, which allows the user to access the working deck, is equipped with two sensors, detecting if the main cover is in an “opened” or a “closed” state. In case of an “opened” state, the analyser will stop all mechanical motions immediately. Mechanical motions can only be executed when the main cover is in a “closed” state.



XVI.5.1 SAMPLE AND REAGENT ROTOR

Figure 21 shows the sample and reagent rotor of the analyser. Only the 30 ml (large) and 10 ml (small) reagent bottles provided in the 50x ALEX² or the FOX kit can be loaded, and all caps must be removed. The sample and reagent rotors include three openings to load large reagent bottles and one opening for loading the small reagent bottle. The RAPTOR SERVER Analysis Software will localize and identify the type of the reagent loaded by reading the barcode label on the bottle.

	<p>Either ALEX² or FOX tests can be processed in one run. A combination of ALEX² and FOX cartridges or reagents is prohibited.</p>
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Up to 50 sample tubes can be loaded into the MAX 45k device with a nominal diameter of 13 mm or 16 mm whereby the 13 mm tubes shall be loaded with a tube adapter only. Tubes with a height of minimum 75 mm and maximum 100 mm can be loaded.

Please consult section XXI for the specification of the sample tubes and minimum volumes.

	<p>Samples and reagents shall be handled according to the respective Instruction for Use of ALEX² and FOX kits. Avoid air bubbles which can potentially lead to wrong pipetting steps and test results. Clotted samples must not be used.</p>
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	<p>If the tube adapter is not applied for the 13 mm tubes, damage to the needle can be caused by a tilted tube. When a vertical movement is blocked by the tilted tube, the analyser will stop all movements automatically to prevent further damage, and the analyser will transit into "Stop State". The assay run is aborted.</p>
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	<p>If tubes are loaded with a height of more than 100 mm, a collision during horizontal movement of the needle can occur, damaging the needle and the analyser.</p>
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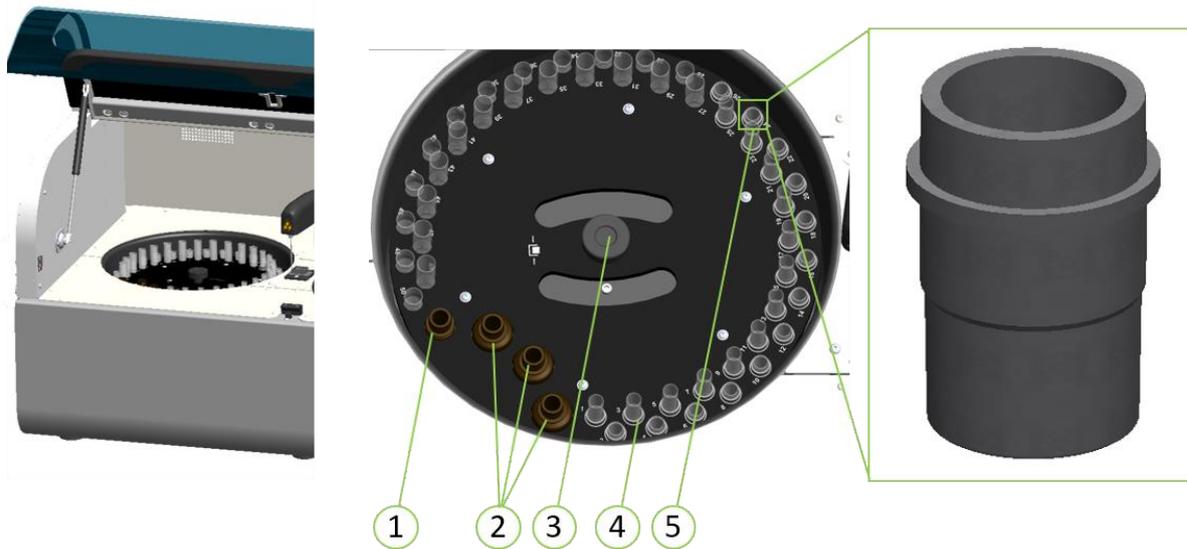


Figure 21: Left: Positioning of the sample and reagent rotor. Middle: Overview of loading positions and its marking. Right: Schematics of the sample tube adapter

- 1 15ml Reagent Bottle
- 2 30ml Reagent Bottle
- 3 Thumbscrew
- 4 Sample Tube
- 5 Sample Tube Adapter

In case of cleaning or loading, the sample and reagent rotor disc can be removed from the analyser by removing the thumb screw on top of the sample and reagent rotor disc and pulling the rotor disc upwards.

The sample and reagent rotor disc are equipped with a tongue and groove mechanism to secure the rotor disc at the correct position. The groove positioning is highlighted with a white marking to easily find the match between the tongue and the groove for convenient placement as shown in Figure 22. After insertion of the rotor disc, the thumb screw must be tightened.

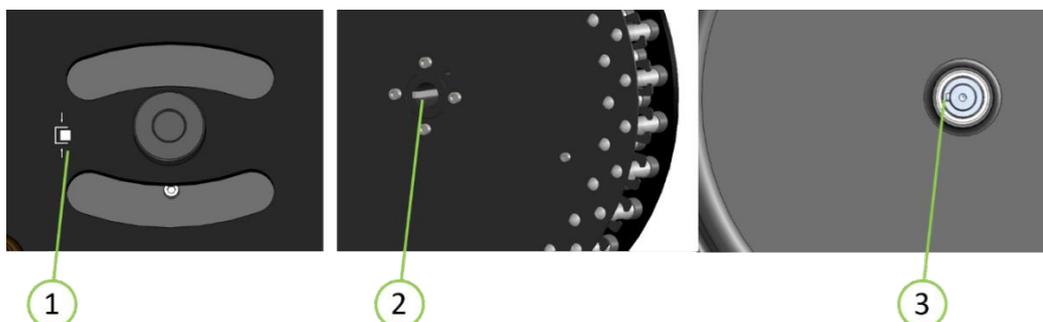


Figure 22: Left: Marking on top of the rotor disc. Middle: Groove shown from underneath the rotor disc. Right: Tongue included in the rotor axis visible after rotor disc is removed



The sample and reagent rotor discs are surrounded by a plastic pot (functioning as a liquid collector tub) to prevent spilled liquids leaking into the instrument. By removing the rotor disc, the user has easy access to clean the tub. In addition, the sample and reagent rotor is equipped with a barcode reader to read the sample and reagent barcode labels.

	<p>No spray-cleaning of the tub is allowed due to the risk of spraying liquids against the barcode reader resulting in a malfunction of the barcode reader optics as shown in Figure 23.</p>
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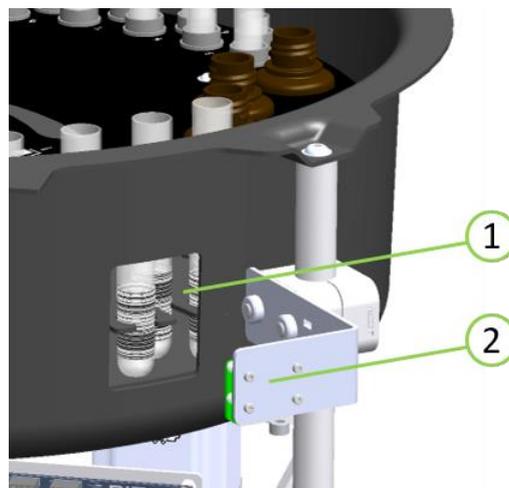


Figure 23: Detailed schematics of barcode reading capability of the sample and reagent rotor

- 1 Barcode reader window
- 2 Barcode reader electronics and optics



XVI.5.2 CARTRIDGE ROTOR AND IMAGE ACQUISITION MODULE

Figure 24 shows the heated cartridge rotor including the image acquisition module. The cartridge rotor and image acquisition module are covered by two lids, the front and rear rotor cover lids. The cartridge rotor has a capacity of 50 cartridges that can be loaded via 5 cartridge segments with a maximum capacity of 10 cartridges each. To load or unload cartridges via the cartridge segments, remove only the front lid of the rotor.

	<p>The front lid must be placed back again on the MAX 45k before a new assay run is started. Otherwise, wrong results might be obtained.</p>
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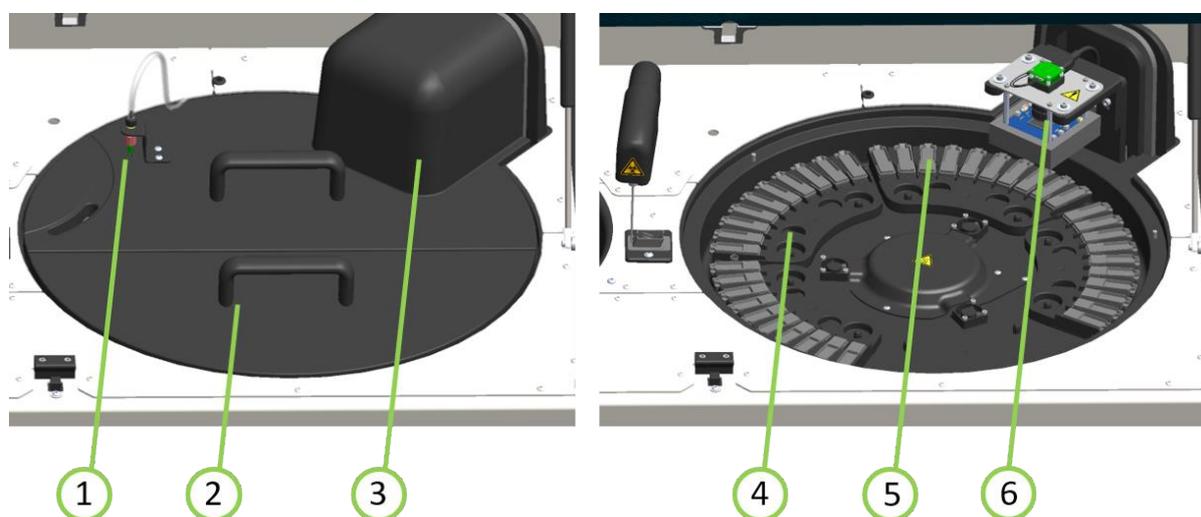


Figure 24: Overview of cartridge rotor assembly on the MAX 45k

- 1 Washing solution dispenser needle
- 2 Front Rotor Cover
- 3 Rear Rotor Cover
- 4 Cartridge Segment
- 5 Cartridge
- 6 Image Acquisition Module

The segments are equipped with a metal sheet part and are pressed against the rotor plate by magnetic forces. To correctly position the segments, the user should take a segment between the forefinger and thumb through the large holes, and insert it so, that the two alignment pins of the rotor plate correspond to the alignment holes in the segment (see Figure 25).

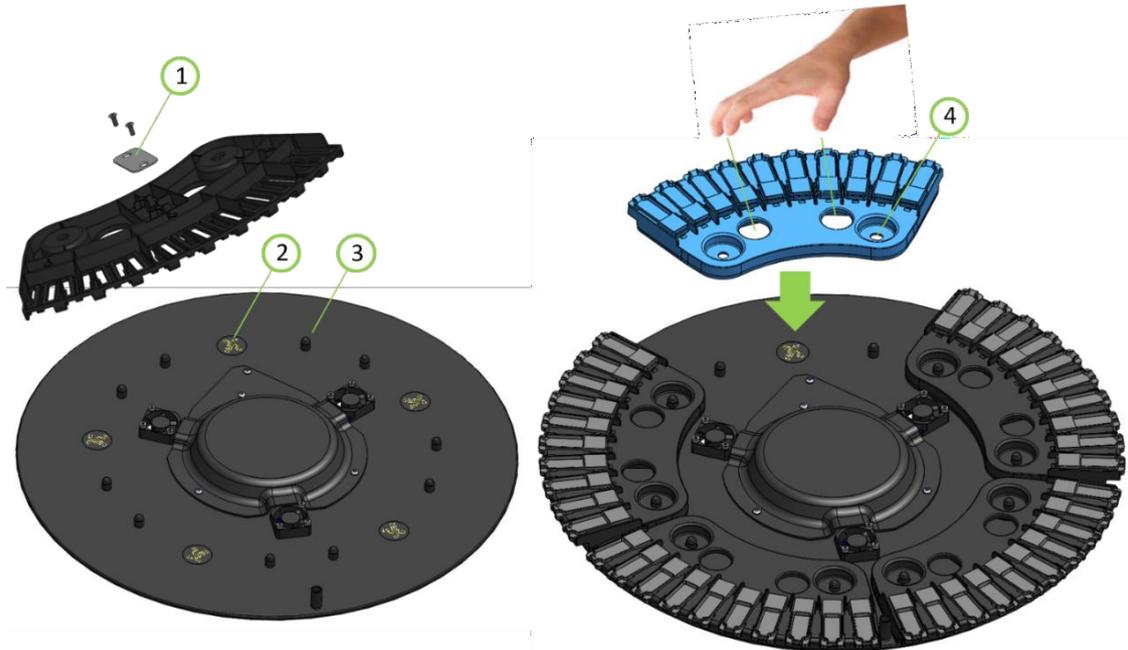


Figure 25: Schematic for handling/loading of cartridge segments

- 1 Metal Sheet Part
- 2 Magnet covered by a sticker
- 3 Alignment Pin
- 4 Alignment Holes

The ALEX² or FOX cartridges can be loaded on to the segments outside or inside the instrument. The loading procedure is shown in Figure 26. To insert the cartridge, the user must take the cartridge with the fingers touching only the side or QR-Code part of the cartridge, and slide it into the segment slot radially outwards, until its final position is indicated by a click sound.

	<p>The cartridge must be discarded if the user touches the surface of the nitrocellulose membrane in the cartridge due to potential malfunction of the array.</p>
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	<p>It is recommended to insert the cartridges into the segments outside of the MAX.</p>
--	---

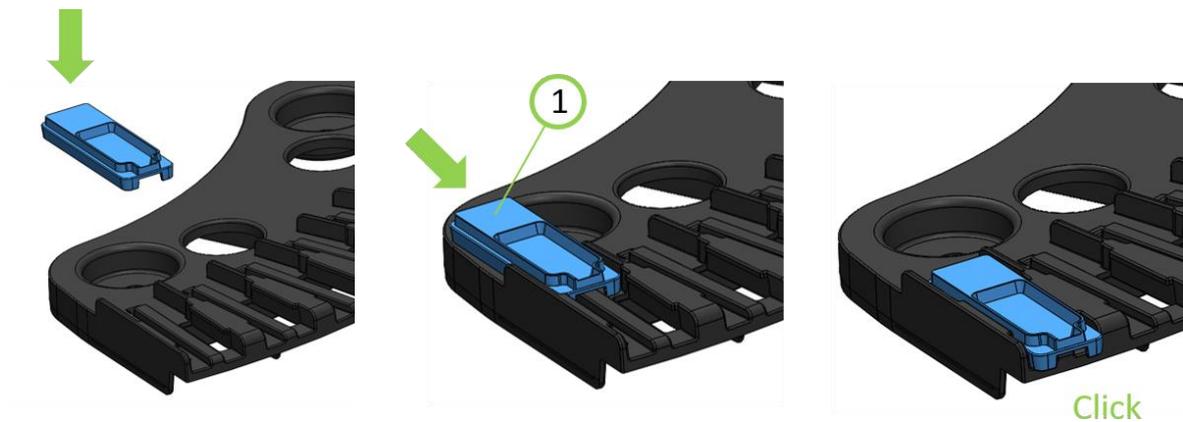
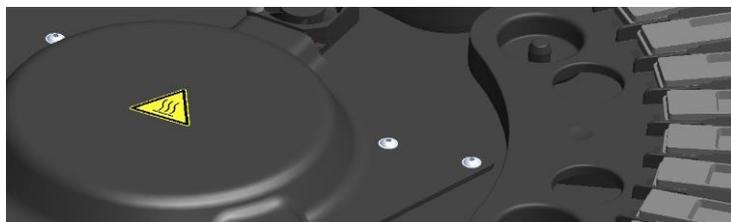


Figure 26: Schematic for loading the cartridge into the segment

1 QR-Code Area of the Cartridge

The cartridge rotor plate is generally heated between to 37 °C for the incubation and drying of the cartridges. To prevent any skin irritation during the loading of the segments onto the heated rotor plate, a warning label is placed on the centre part of the rotor plate.



Caution, hot surface!

By removing the rear rotor lid, the user gets access to the image acquisition module. When all segments are removed, the user can easily clean/wipe the waste drain channel (waste rim) as shown in Figure 27.

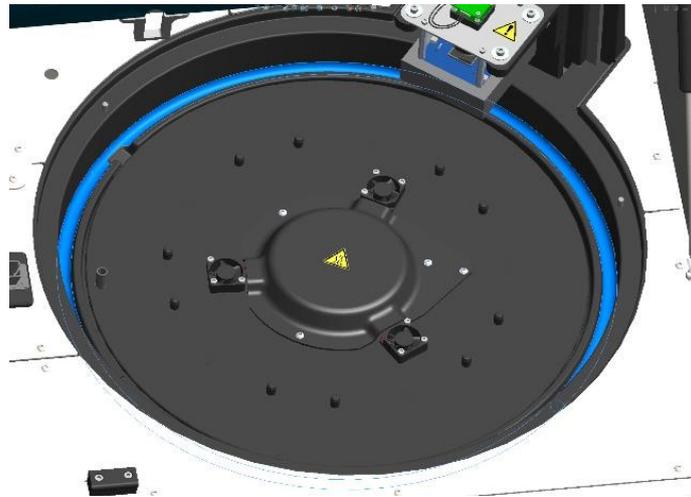


Figure 27: Waste drain channel of cartridge rotor highlighted in blue

The image acquisition module (Figure 28) shows a warning label, which shall indicate that the user must be careful when a cleaning procedure of the waste rim is performed. When the rear rotor lid is removed for cleaning purpose, the user must not touch the optical and electrical elements of the image acquisition module.

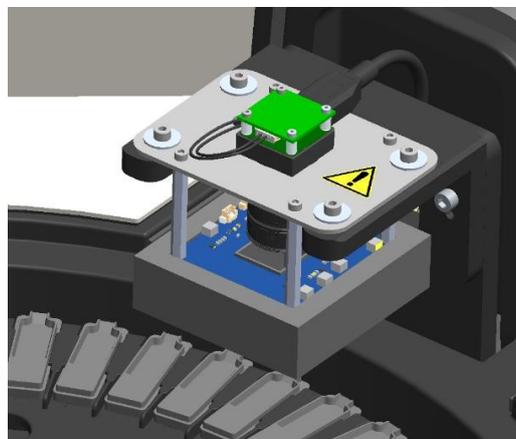


Figure 28: Image acquisition module

	<p>Caution, do not use sprays for cleaning the waste rim and rotor plate! Instead, only wipe cleaning is allowed, otherwise the image acquisition module may malfunction. Please do not touch the optics and electrical elements, otherwise both may malfunction. Make sure you use a wiping method without any residues.</p>
--	---

To correctly insert the rear rotor lid, two alignment pins located around the rotor and two corresponding holes in the rear lid as shown in Figure 29 (highlighted in red) must be aligned with each other.

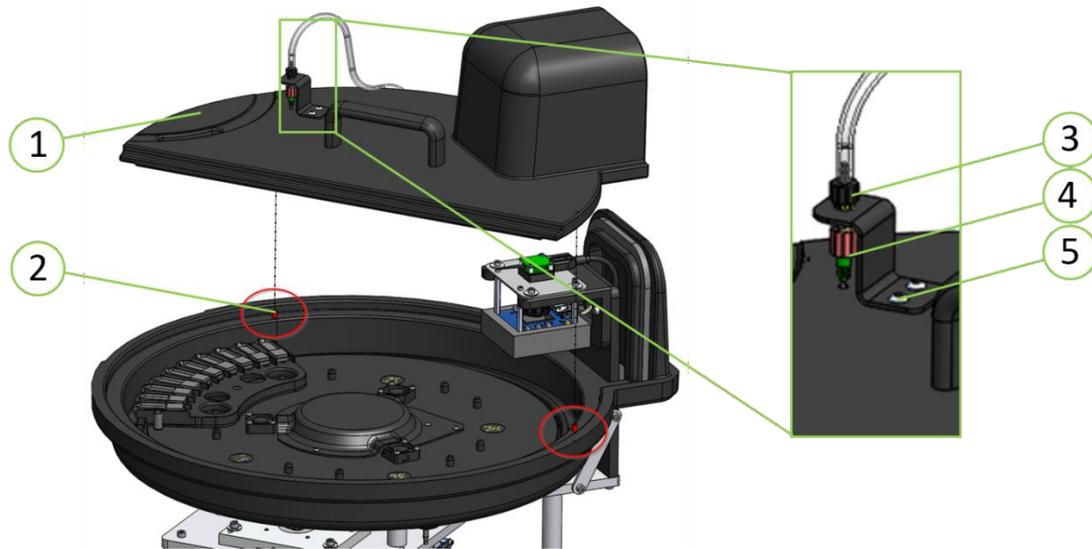


Figure 29: Illustration for alignment of rotor rear lid and waste rim structure

- 1 Alignment Hole
- 2 Alignment Pins
- 3 Luer Lock fitting
- 4 Washing Solution dispenser needle
- 5 Washing Solution needle holder

	<p>The rear lid must be inserted correctly, otherwise the washing solution needle is not aligned correctly to the rotor resulting in insufficient cartridge washing, and consequently, wrong results may occur.</p>
--	---

	<p>Prior to the removal of the rear lid, the washing solution tubing needs to be dismantled via the Luer lock from the washing solution needle holder.</p>
--	--



XVI.6 WORKING DECK OF THE MAX 9k DEVICE

By opening the main cover, the user will get direct access to the main functional modules on the working deck for loading the ALEX² or the FOX test (see Figure 30).

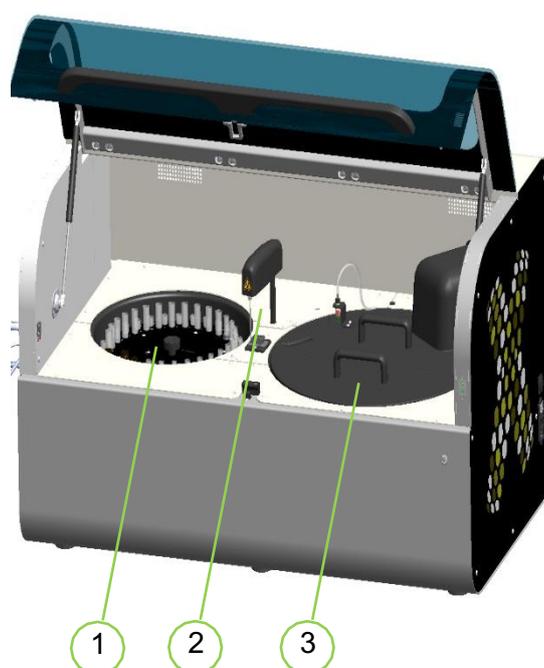


Figure 30: Main functional modules on the working deck of the MAX 9k

- 1 Sample and Reagent Rotor
- 2 **Pipetting Robot and Needle Rinsing Station**
- 3 Cartridge Rotor and Imaging Module

The main cover, which allows the user to access the working deck, is equipped with two sensors, detecting if the main cover is in an “opened” or a “closed” state. In case of an “opened” state, the analyser will stop all activities immediately. Any operation can only be executed when the main cover is in a “closed” state.



XVI.6.1 SAMPLE AND REAGENT ROTOR

Figure 31 shows the sample and reagent rotor of the analyser. Only the reagent bottles provided in the ALEX², or the FOX kit shall be loaded, and all caps must be removed. The sample and reagent rotor includes 3 openings to load large (30 ml) reagent bottles and one opening for loading the small (10ml) reagent bottle. Using a special adapter, it is also possible to insert small reagent bottles of the 20x ALEX² kit into the 3 large openings. The RAPTOR SERVER Analysis Software will localize and identify the type of the reagent which has been loaded by the barcode presented on the reagent labels.

	<p>Either ALEX² or FOX tests can be processed in one run. A combination of ALEX² and FOX cartridges or reagents is prohibited.</p>
---	--

Up to 10 sample tubes can be loaded with a nominal diameter of 13mm and a height of 75mm.

Please consult section XXI for the specification of the sample tubes and minimum volumes.

	<p>Samples and reagents shall be handled according to the respective Instruction for Use of ALEX² and FOX kits. Avoid air bubbles which can potentially lead to wrong pipetting steps and test results. Clotted samples must not be used.</p>
---	---

	<p>If the small reagent bottles are placed in the larger openings used for the 30ml bottles without using the adapter, damage to the needle can be caused by a tilted or not correctly positioned bottle. When a vertical movement is blocked by the tilted or not correctly positioned bottle, the analyser will stop all movements automatically to prevent further damage, and the device will transit into "Stop State". The assay run will be aborted.</p>
---	---

	<p>If tubes are loaded with a height of more than 75mm, a collision with the horizontal movement of the needle can occur, damaging the needle and the device.</p>
---	---

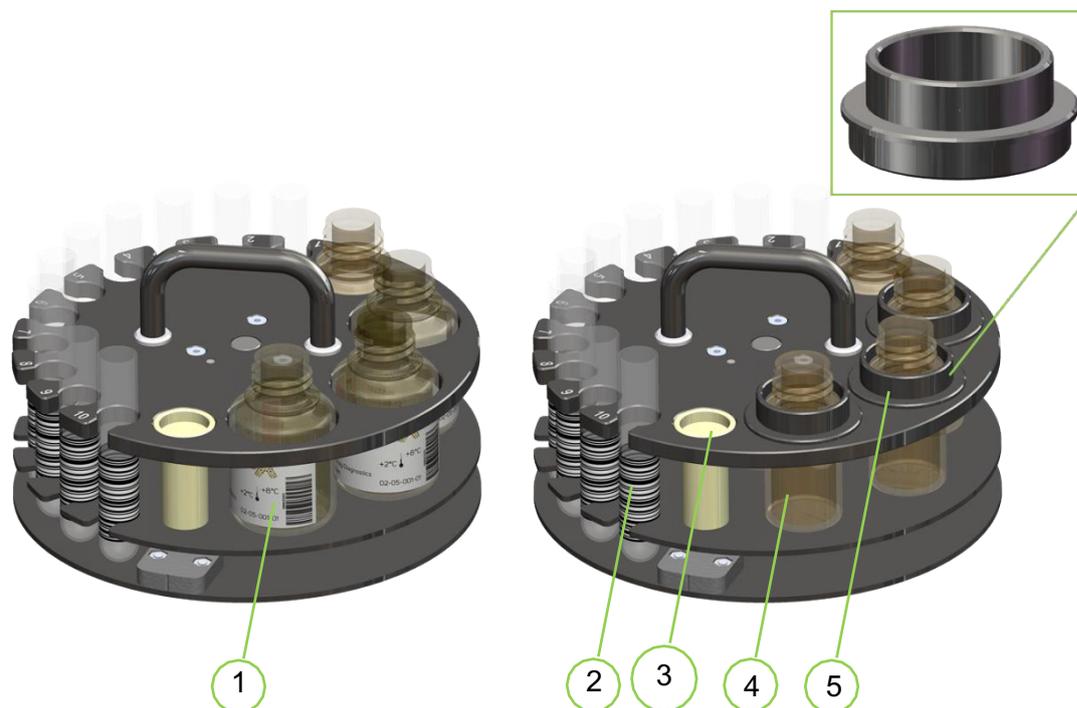


Figure 31: Overview of loading possibilities (left: 50x ALEX² kit or FOX, right: 20x ALEX² kit)

- 1 Large (30ml) Reagent Bottle
- 2 Sample Tube
- 3 Fixture for auto-alignment
- 4 Small (15ml) Reagent Bottle
- 5 Reagent Bottle Adapter

The rotor is equipped with a metallic fixture that is required for auto-alignment.



Attention must be paid to keeping the metal fixture clean and free of deposits. Otherwise, the proper function of the auto-alignment cannot be guaranteed. Use 70% ethanol to clean the fixture of contamination and particles.

The sample and reagent rotor disc is surrounded by a plastic tub (working as a collector for spilled liquids) to prevent liquids leaking into the instrument. By removing the rotor disc, the user has easy access to clean the tub. This can be easily done by pulling the rotor disc upwards.

To reinsert the sample and reagent rotor disc, simply place the rotor back into the rotor tub. The rotational position does not have to be observed here. The instrument determines the correct position as soon as the main cover is closed again.

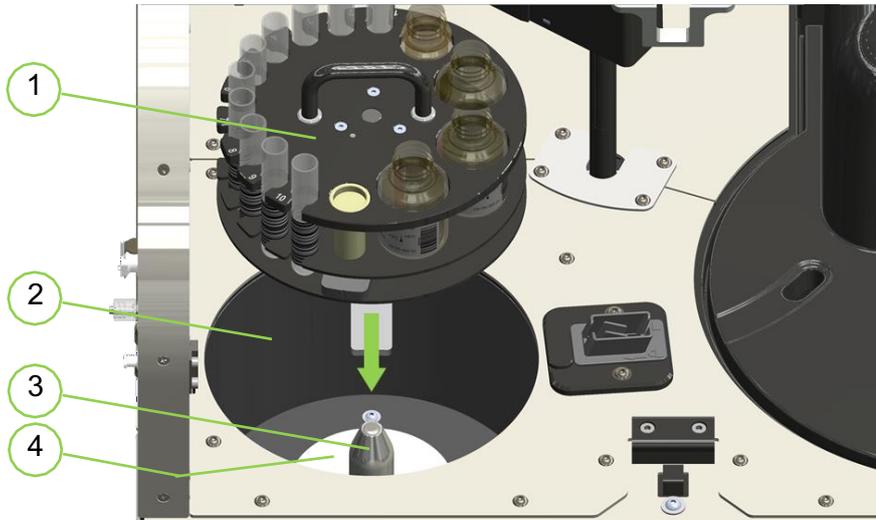


Figure 32: Inserting the Sample and Reagent Rotor Carousel

- 1 Sample and reagent carousel
- 2 Rotor tub
- 3 Conical pin
- 4 Neoprene rotor plate

	<p>The insertion of the sample and reagent carousel must be done carefully. Place the carousel onto the conical pin centrally and let slide guided by hand until the carousel is firmly seated on the neoprene rotor plate. Never let go of the carousel above that point, otherwise the liquids in the tubes and bottles may spill out and decontaminate the rotor.</p>
--	--

	<p>When inserting the carousel, make sure that the underside of the carousel and the neoprene rotor plate is dry. Otherwise, the rotor carousel may slip during movement.</p>
--	---

The sample and reagent rotor is equipped with a barcode reader to read the sample and reagent barcodes.

	<p>No spray-cleaning of the tub is allowed due to the risk of spraying liquids onto the barcode reader resulting in a malfunction of its optics as shown in Figure 33.</p>
--	--

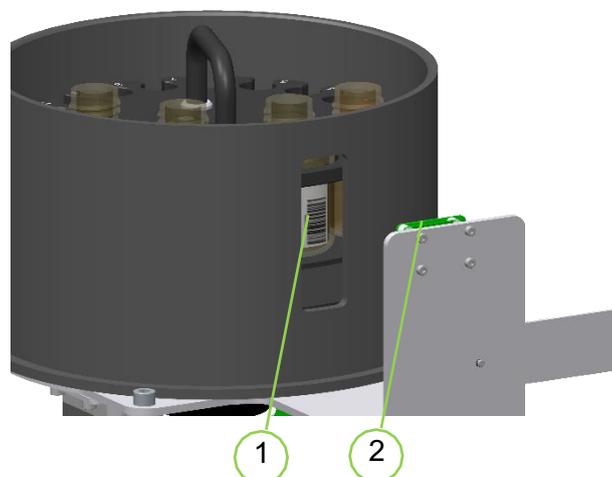


Figure 33: Schematics of the Barcode Reading in the Sample and Reagent Rotor

- 1 Barcode reader window in the tub
- 2 Barcode reader electronics and optics



XVI.6.2 CARTRIDGE ROTOR AND IMAGE ACQUISITION MODULE

Figure 34 shows the heated cartridge rotor including the image acquisition module. The cartridge rotor and the image acquisition module are covered by a rotor cover. The cartridge rotor has a capacity for 2 cartridge holder segments, which can be loaded each with 5 cartridges (10 tests altogether).

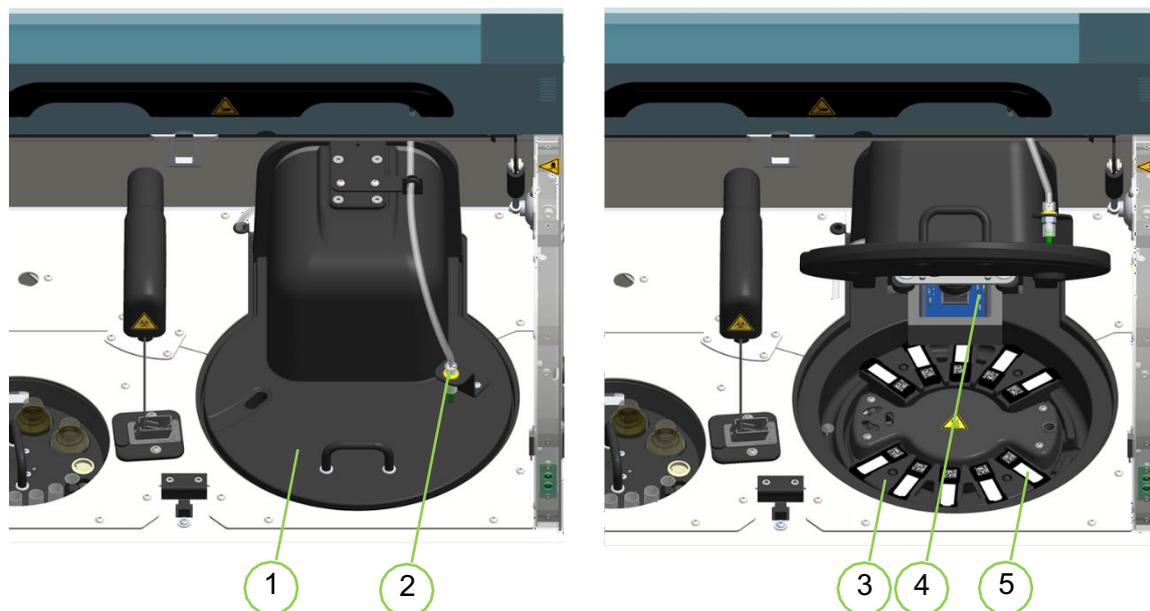


Figure 34: Overview of cartridge rotor assembly

- 1 Rotor Cover
- 2 Wash-buffer solution dispenser needle
- 3 Cartridge Holder Segment
- 4 **Image Acquisition Module**
- 5 Cartridge

The loading procedure is shown in Figure 35. To insert the cartridge, the user must take the cartridge with the fingers touching only the side of the cartridge, and slide it into the segment slot radially outwards, until its final position is indicated by a click sound.



Figure 35: Schematics for Loading the Cartridge into the Segment

1 QR-Code Area of the Cartridge

	<p>The cartridge must be discarded if the user touches the surface of the nitrocellulose membrane in the cartridge due to potential malfunction of the test.</p>
--	--

	<p>It is recommended to insert the cartridges into the segments outside of the MAX.</p>
--	---

As soon as the segments are loaded with the cartridges, the segments can be inserted into the instrument. For this purpose, the rotor cover must be opened. Please note that the cartridge rotor is intended to be operated with two hands. One hand is used to open the rotor cover and hold it in the open position, the other hand is used to insert the segments into or remove them from the rotor.



Figure 36: Two-Hand Operation of the Cartridge Rotor



The segments are equipped with a metal sheet part and are pressed against the rotor plate by magnetic forces. To correctly position the segments, the user should take a segment between the forefinger and thumb through the large holes, and insert it so, that the two alignment pins of the rotor plate correspond to the alignment holes in the segment (see Figure 37).

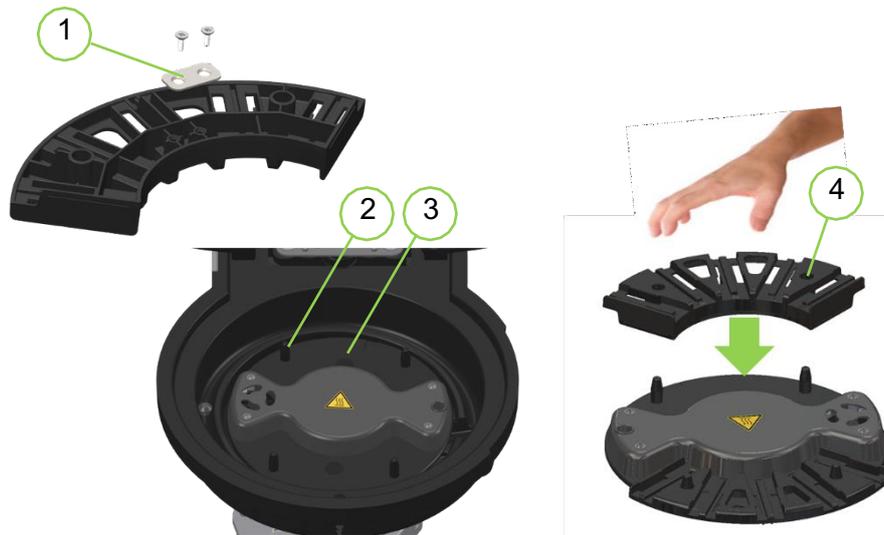


Figure 37: Schematic for Handling and Loading of cartridge segments

- 1 Metal Sheet Part
- 2 Magnet
- 3 Alignment Pin
- 4 Alignment Holes

	Attention must be paid that the pins (marked red in Figure 38) are in the correct segment holes, otherwise proper results cannot be generated.
--	--



Figure 38: Correct Position of segment holes and pins (highlighted in red)



After the segments with the cartridges have been inserted into the rotor, the rotor cover and the main cover must be closed again before the measurement can be started.

The rotor is equipped with a metallic fixture that is required for auto-alignment.

	Attention must be paid to ensuring that the metal fixture is clean and free of debris. Otherwise, it cannot be ensured that the auto-alignment works properly. Use 70% ethanol to clean the fixture of contamination and particles.
--	---

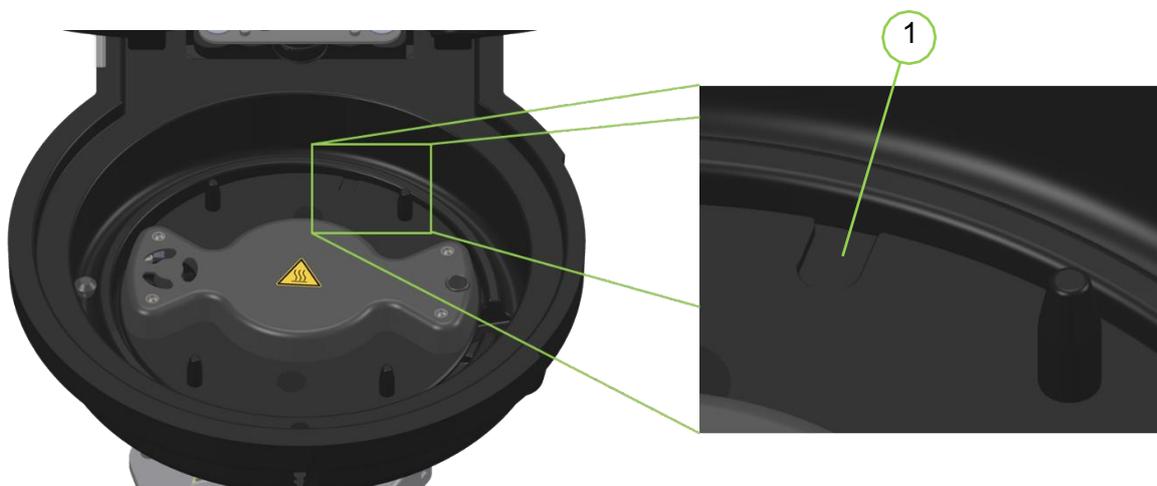


Figure 39: Fixture for the Use of the Auto Alignment

1 Fixture for the use of the auto alignment

The cartridge rotor plate is generally heated to 37 °C for the incubation and drying of the cartridges.



Caution, hot surface!

By opening the rotor cover, the user gets access to the image acquisition module. When all segments are removed, the user can easily clean/wipe the waste drain channel (waste rim) as shown in Figure 40 highlighted in blue.



Figure 40: Waste drain channel of cartridge rotor highlighted in blue

The image acquisition module shows a warning label, which warns the user to be careful when cleaning the waste rim. When the rear rotor lid is removed for cleaning, the user should avoid touching the optical and electrical elements of the image acquisition module.

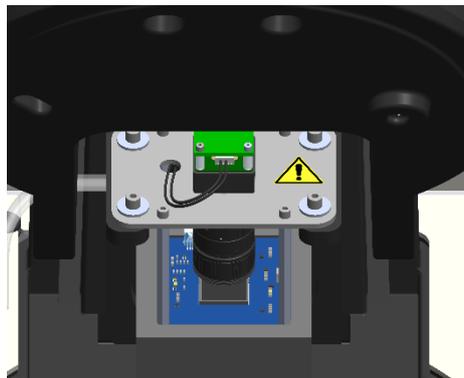


Figure 41: Image acquisition module



Caution, do not use sprays for cleaning the waste rim and rotor plate! Instead, only wipe cleaning is allowed, otherwise the image acquisition module may malfunction. Please do not touch the optics and electrical elements, otherwise both may malfunction. When wiping, avoid using clothes which leave residues.

When manual activities in the cartridge rotor are completed and the instrument is to be operated, the rotor cover must be closed. The rotor cover is equipped with a sensor that detects whether it is in an "open" or "closed" state. In the case of an "open" state, the analyser cannot be operated. When closing the rotor cover, make sure that the lid is closed correctly. If the rotor cover is not closed correctly and the device is started, an error will occur (see Section XX).



Figure 42: Illustration for Closing the Rotor Cover

	<p>To close the rotor cover, carefully push the cover down by the handle, making sure that there are no objects on the rotor which prevent the cover from closing correctly. The rotor cover must be seated completely and flat on the rotor. Otherwise, the analyser cannot be started.</p>
--	--

	<p>Before closing the main cover, the rotor cover must be closed, otherwise the rotor cover may be damaged.</p>
--	---

	<p>The rotor cover must be closed correctly, otherwise the Washing Solution needle is not aligned correctly resulting in insufficient washing and wrong results.</p>
--	--

XVI. 7PIPETTING ROBOT

The pipetting robot (Figure 43) carries out the pipetting of samples or reagents from the sample and reagent rotor to the cartridge rotor. The robotic arm is equipped with a steel needle and liquid level detection (LLD) electronics which are protected by a plastic cover. The LLD is used to minimize outer needle contamination within the sample tube and reagent bottle liquids. The steel needle will be cleaned on the inner and outer surface through the active rinsing station between each pipetting step.

In MAX 9k, the Pipetting Robot uses a metallic fixture on the rinsing station module for auto-alignment.

	<p>Attention must be paid to keeping the fixture clean and free of deposits. Otherwise, it cannot be guaranteed that the auto alignment will function properly</p>
--	--



Figure 43: Pipetting robot

- 1 Head of Pipettor Robot with Cover
- 2 Robotic Shaft for Vertical and Rotational Movement
- 3 Steel Pipettor Needle
- 4 Active Rinsing Station

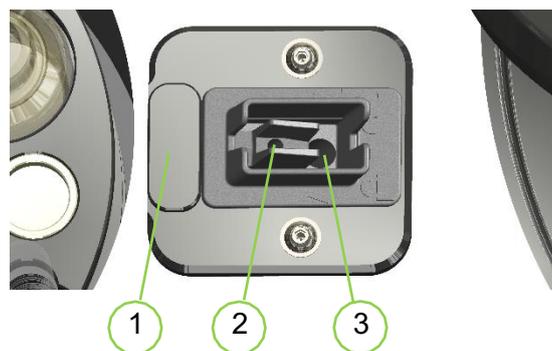


Figure 44: Active rinsing station

- 1 Fixture for the use of the auto alignment (MAX 9k only)
- 2 System Water Supply
- 3 Waste Drain



The upper arm of the pipetting robot is labelled with a biohazard warning symbol to remind the user to avoid touching the needle due to the risk of cutting or puncturing the skin resulting in a potential infection.

The pipettor needle can be replaced by the user by unscrewing the needle from the thread and inserting a new one. The new needle needs to be fastened tight to seal the fluidic system (see Figure 45).

	Do not remove the upper arm cover
	Only touch the needle on its grip, Figure 45 (4).
	Make sure there is a gap, Figure 45 (5) between the housing and the grip of the needle after tightening. If you do not see a gap, contact MADx Support or your local distributor.

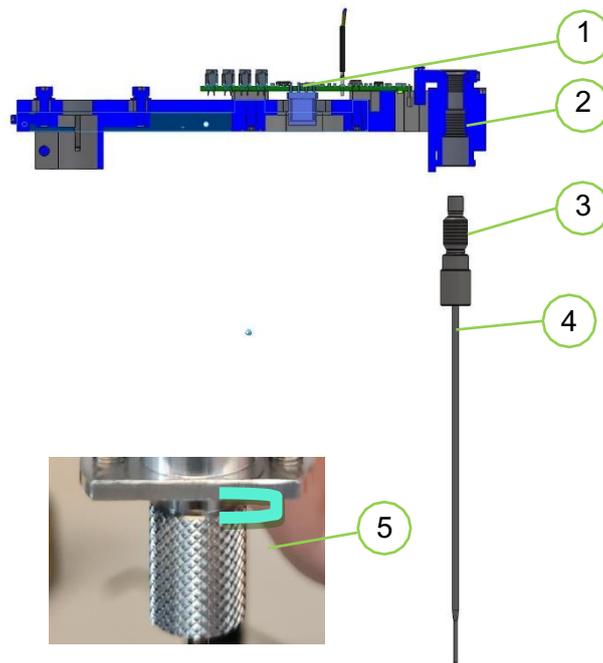


Figure 45: Schematics for the Needle Fluidics Sealing

- 1 LLD and Crash Detection Electronics
- 2 Upper Arm threaded housing
- 3 Needle Thread
- 4 Needle Grip
- 5 Gap between grip and housing



XVI.8 SUPPLIES

XVI.8.1 SYSTEM- AND WASTEWATER CONTAINERS

For the MAX 45k 10 litres, for the MAX 9k 2 litres of demineralized water must be filled into the system water container. Before operation, the container must be filled up to the marking as shown below, otherwise the RAPTOR SERVER will potentially restrict the run-setup due to a low fill level.

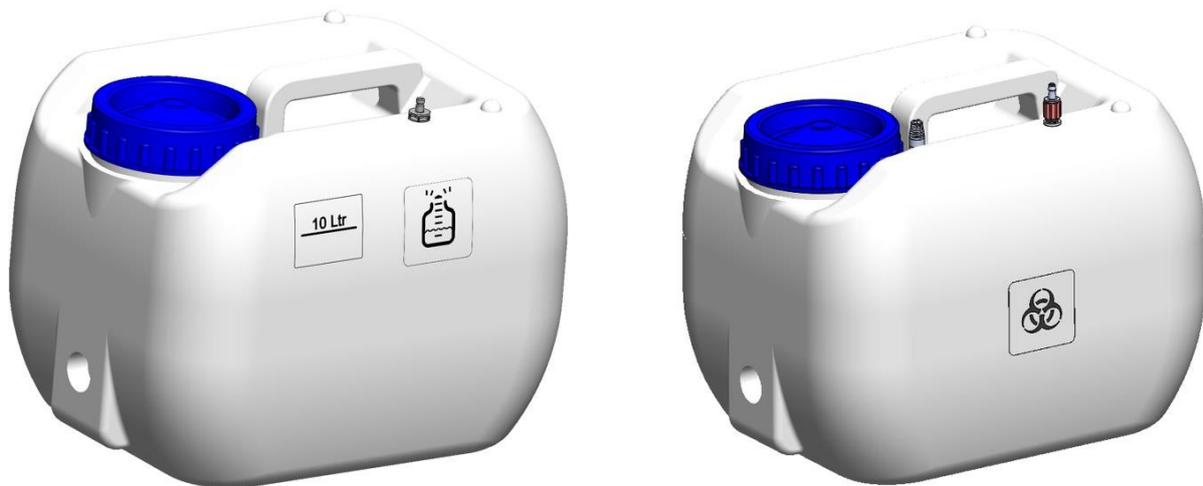


Figure 46: 10L System Water Container (left) and Waste Container (right) for the MAX 45k



Figure 47: 2L System-Water Container (left) and Waste Container (right) for the MAX 9k



Caution, the tube of the waste container must be connected to the instrument and to the waste container **before** starting the analyzer, otherwise a potential biohazard contamination of the environment and the operator may occur by spillage from the waste tubing of the device.

XVI.8.2 WASHING SOLUTION CONTAINER

The device requires Washing Solution, which is provided separately by MacroArray Diagnostics or a local distributor. To prepare 1L Washing Solution, empty the 250 ml concentrate into the Washing Solution container, and fill it up to the 1 litre marking with demineralized water. Before use, the fill-level is controlled by the instrument for the number of tests to be processed. If the fill level is not sufficient, the RAPTOR SERVER software will restrict the test run.

In the MAX 45k, the provided 1L Washing Solution is sufficient for 4 runs. In the MAX 9k, 1L of Washing Solution is sufficient for 7 runs.



Figure 48: Washing Solution Container



XVI.8.3 ASSAY KIT SUPPLIES

The ALEX² assay components, consisting of the Washing Solution, ALEX² Sample Diluent, ALEX² Detection Antibody, ALEX² Substrate Solution and ALEX² Stop Solution as well as the ALEX² cartridges, are provided separately in the ALEX² Assay Kit (REF 02-5001-01 / 02-2001-01) by MacroArray Diagnostics or your local distributor.

	If you use the MAX 9k device with the ALEX ² 20x kit (REF 02-2001-01), a bottle of Stop Solution (REF 00-5007-01) and a bottle of Washing Solution (REF 00-5003-01) is additionally required.
--	--

The FOX assay components, consisting of the Washing Solution, FOX Sample Diluent, FOX Detection Antibody, FOX Substrate Solution and FOX Stop Solution as well as the FOX cartridges, are separately provided via the FOX Assay Kit (REF 80-5001-01) by MacroArray Diagnostics or your local distributor.

NOTE: Please ensure to read and observe the instructions for the applied Assay Kit and handle substances and cartridges appropriately in connection with the analyser.



XVII. OPERATION

XVII.1 PREREQUISITES

The following equipment and settings are needed to run ALEX² or FOX tests on a MAX device:

- MAX device installed (see Section XV.2)
- Optional equipment: uninterrupted power supply (UPS) with 500 VA
- An ALEX² (REF 02-5001-0101 / 02-2001-01) or a FOX (REF 80-5001-01) Assay Kit. Please consult the Instruction for Use of these IVD products before you run any assays on the instrument.

NOTE: If you use the MAX 9k device with the ALEX² 20x kit (REF 02-2001-01), a bottle of Stop Solution (REF 00-5007-01) and a bottle of Washing Solution (REF 00-5003-01) is additionally required.

NOTE: Either ALEX² or FOX arrays can be processed in one run. A combination of ALEX² and FOX cartridges or reagents in one assay run is not possible.

- Serum samples or plasma samples (no EDTA plasma) – **please check the minimum volumes and applicable tube sizes in section XXI.**
- PC with Windows version 10 or higher and a web browser (currently only Google Chrome is supported) installed.
- “Raptor MAX Agent” software installed on the PC – see section XVII.2 on how to install this software package.
- The PC needs two separate network connections: one with a stable Internet connection (usually done via WIFI) to connect to the web-based RAPTOR SERVER Analysis Software and an Ethernet cable connection used for the connection between PC and MAX via LAN cable. If the PC does not have a LAN cable socket, a USB – RJ45 (LAN) adapter can be used, see an example device below:





- To connect the PC with the MAX device, use the LAN cable which is included in the MAX shipment. Any high-speed LAN cable with 2 RJ45 connectors can be used.
- Configure the connection in your Windows (10) network settings:
 - In “Network Settings” choose the appropriate Ethernet connection
 - Enter the “Properties”, and change settings:
 - Change the setting to “Manual” instead of “DHCP” and choose “IPv4”
 - Manually set the IP address for to 192.168.183.10
 - Set the Subnet mask to 24
 - Set the gateway to 192.168.183.1
 - Click on “ok”

Edit IP settings

Manual

IPv4

On

IP address

192.168.183.10

Subnet prefix length

24

Gateway

192.168.183.1

Figure 49: Network settings of the Ethernet connection for the MAX on Windows 10



XVII. 2 LOG-IN TO RAPTOR SERVER

In your web browser, enter the URL for the web-based RAPTOR SERVER Analysis Software (<https://www.raptor-server.com/>) and press “Enter”. The Login page will show up. Please use the login method and user credentials as instructed by your local distributor or by MADx support team. **Please consult the RAPTOR SERVER IFU before starting to use the software.**



Welcome to RAPTOR-SERVER, the analysis software for the [ALEX and FOX multiplex test](#). Please log in below to continue.

<p>Log in with Azure AD / Office 365</p> <p>If your organization integrates the software into its Microsoft Azure/Office 365 user directory (single-sign-on) click the button below. You will be redirected to the Microsoft login screen.</p> <p> Log in</p>	<p>Log in with Username & password</p> <p>Please enter your username and password.</p> <p>Your username</p> <p>Your password</p> <p> Log in</p> <p>Forgot your password? No problem, you can request a new one.</p>
--	--

If the log-in was successful, the homepage of the RAPTOR SERVER Analysis Software shows up with the dashboard displaying the latest new and approved measurements as well as the currently connected devices. If you are working on a completely new Tenant, these are empty.



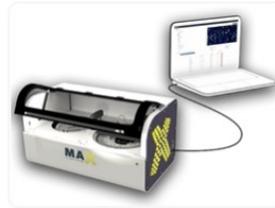
New Measurements

Last 7 days

QC	QR-Code	Sample Code	Analysis Date		
OK	02APK398	Ic_22640	9/30/2022 09:55 AM	Details	Report
OK	02APK3A3	Ic_22640	9/30/2022 09:54 AM	Details	Report
OK	02AVP1C8	Ic_22640	9/28/2022 01:48 PM	Details	Report
OK	02AVP09C	Ic_22640	9/28/2022 01:48 PM	Details	Report

View all new measurements

Connected Devices



MAX 45k_20010006

Running tests

Cancel

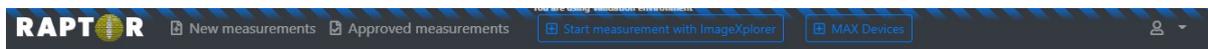
View all Automats

View all ImageExplorers

Approved Measurements

QR-Code	Sample Code	Analysis Date		
02APK395	Fechter Ch	9/30/2022 09:55 AM	Details	Report
02AVP151	Verena	9/28/2022 01:49 PM	Details	Report

By clicking “New Measurements” all results from previous ALEX² and FOX assay runs on the MAX device are shown. If you also have an ImageXplorer imaging device (RE 11-0000-01) in use, the results obtained with this device will be shown as well.

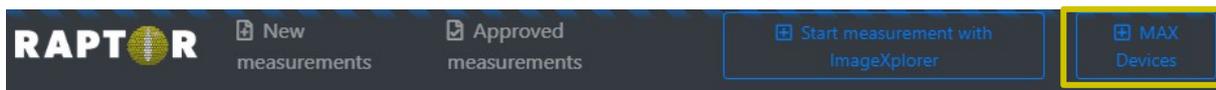


New Measurements

Search by QR-Code, patient, sample, tag, analysis date, approval date ...

	Source	QC	Tags	Product type	QR-Code	Sample Code	Patient Code Pet Name	Patient Name Pet Owner	Analysis Date
<input type="checkbox"/>	Recaptured	OK	recaptured	ALEX2	02APU349				10/3/2022 02:13 PM
<input type="checkbox"/>	Recaptured	OK	recaptured	ALEX2	02APU34A				10/3/2022 02:13 PM
<input type="checkbox"/>	Recaptured	OK	recaptured	ALEX2	02APU341				10/3/2022 02:13 PM
<input type="checkbox"/>	Recaptured	OK	recaptured	ALEX2 ASIT	53AAA317				10/3/2022 02:13 PM
<input type="checkbox"/>	MAX 45k	OK		ALEX2	02APU349	008 FAT during Validation 22650 APU 27.09.2022			9/29/2022 09:42 AM
<input type="checkbox"/>	MAX 45k	OK		ALEX2	02APU34A	008 FAT during Validation 22650 APU 27.09.2022			9/29/2022 09:43 AM
<input type="checkbox"/>	MAX 45k	OK		ALEX2	02APU341	008 FAT during Validation 22650 APU 27.09.2022			9/29/2022 09:42 AM
<input type="checkbox"/>	MAX 45k	OK		ALEX2	02APU342	008 FAT during Validation 22650 APU 27.09.2022			9/29/2022 09:42 AM
<input type="checkbox"/>	MAX 45k	OK		ALEX2	02APU343	008 FAT during Validation 22650 APU 27.09.2022			9/29/2022 09:42 AM

On top of the page, click on the blue button “MAX devices” highlighted in yellow in the screenshot below.



New Measurements

Search by QR-Code, patient, sample, tag, analysis date, approval date ...



On the following page, an overview of the status of all automated systems (MAX devices) can be seen. If there is only one device installed and configured in your lab, it will only show one line with the name and status of the MAX device.

If you have not registered your device to your RAPTOR SERVER Tenant yet, this page is empty.

The screenshot shows the RAPTOR interface with a navigation bar at the top containing 'New measurements', 'Approved measurements', 'Start measurement with ImageXplorer', and 'MAX Devices'. Below the navigation bar, the 'MAX Devices' section contains a table with the following data:

Name	Type	Status
MAX 45k TEST 5702	Max45k	Agent disconnected
MAX test	Max45k	Agent disconnected
MAX test1	Max45k	Agent disconnected
MAX_on_Five	Max45k	Agent disconnected

XVII.3 INSTALLING AND STARTING THE AGENT SOFTWARE

Before starting a new assay run on the MAX device with RAPTOR SERVER on www.raptor-server.com, make sure that the “Raptor MAX Agent” software is running. The agent should automatically be launched during Windows start-up. If the agent app is not yet installed, an installation package can be downloaded from the Administration page on www.raptor-server.com (“Tenant Admin” -> “Manage MAX devices” -> “Download MAX Agent Software”).

The screenshot shows the 'MAX devices for "MADx Tenant"' section of the RAPTOR interface. It features two buttons: 'Add new MAX device' and 'Download MAX Agent Software'. Below the buttons is a table with the following data:

Name	Type	Key	Serialnumber	Last connection	Last activity
MAX 45k TEST 5702	Max45k	pM6Gg88ZgwI2yp4QbZ4Qjoxk6d47I6	19090008	22 hours ago	never
MAX test	Max45k	Q9A8MNTp2GDjCpumr4KMafPRkc1vsa	20030020	one month ago	2 months ago
MAX test1	Max45k	dGQMhqDogV96SGDWAqPdmPyDhy1195	19090008	27 days ago	5 months ago

On the same webpage, your new MAX device can be registered, and a corresponding unique key can be generated. For every MAX device in use, a separate key is generated automatically.

To register the new device, press “Add new MAX” and enter a name for your MAX device in the corresponding field. The MAX key should be copied (STRG + C) from the field below.

The device type can be chosen in the dropdown menu next to “Device Type”.



Add new MAX device

General Information

Last seen serialnumber

Last seen firmware version

Agent connected at

Agent disconnected at

Name

Machine Type

Key

This key is required when installing an Agent.

Besides the name of the device, the status (enabled or disabled) and the default sample tube types can be set. Additional information can be written into the Notes and Internal Notes fields. Press “Save” to create your new MAX device on RAPTOR SERVER.

Notes

Internal Notes

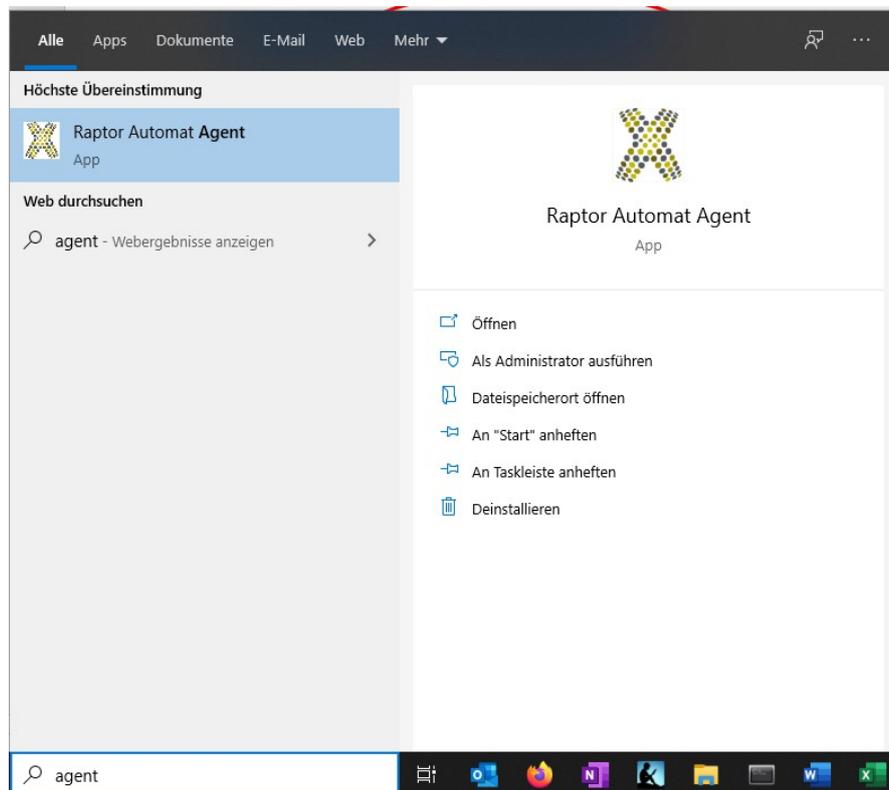
For internal use only.

Disabled

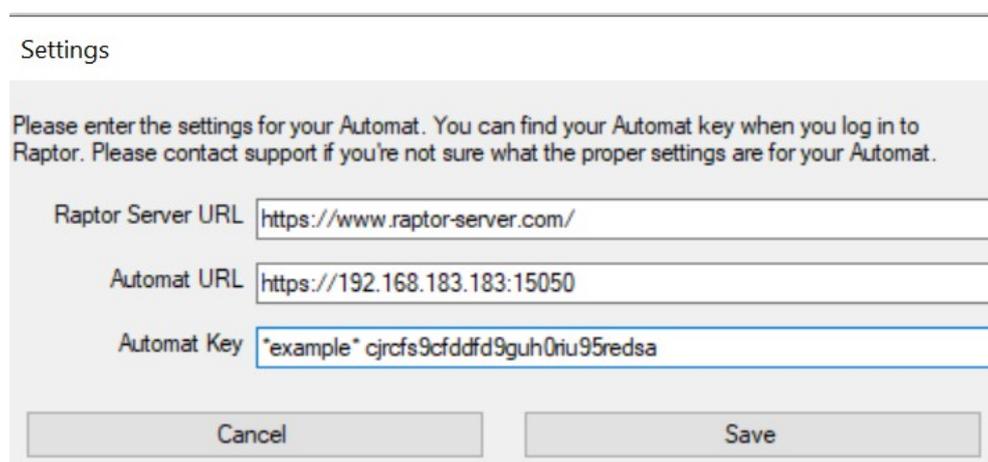
Default Sample Tubes

If the Agent software is not launched automatically during Windows start up, you can launch the app manually:

- Search for “agent” in the search window on the bottom of the Windows desktop.
- Click on “Raptor Agent for MAX” to launch the agent app.



After the Raptor MAX Agent app has started for the first time, click on “Settings”, and enter the Key, you have generated on RAPTOR SERVER at the device configuration (copy – paste).

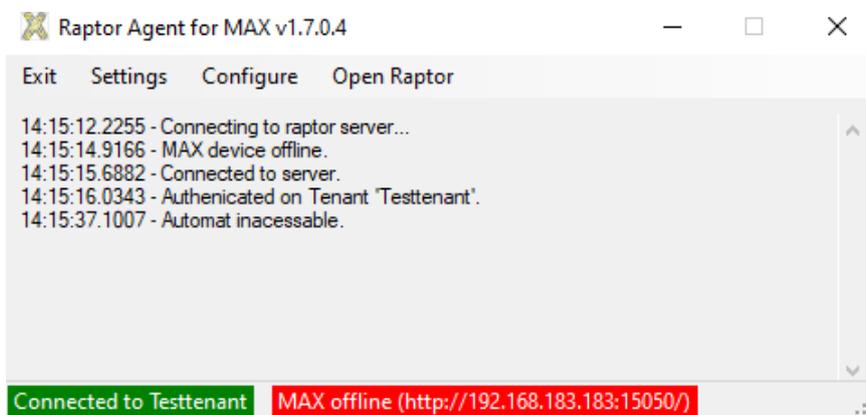


Click on “Save” to apply the settings. After about 30 seconds, both status fields on the bottom of the Settings window should be green:



If one or both status fields on the bottom of the Raptor MAX Agent window are red, please check that the “Settings” are set correctly. Also check if you have entered the correct key for your device (MAX Key) and that the device is properly connected with the PC.

In the example below, the Agent was not able to connect to the MAX device. Check in “Settings”, if you put the correct key for the MAX in the corresponding fields. Also make sure that the MAX device is directly linked to the PC, where you have the Raptor MAX Agent installed and running, with the Ethernet cable provided in the MAX device shipment.





XVII.4 MAX CONFIGURATION PAGE

Open the Administration menu in the upper right corner of the RAPTOR SERVER browser window. Click on "Tenant Admin" and select "Manage MAX devices" on the next page.



MAX devices

Use this to configure MAX devices or add new ones. Each MAX device needs to be known by the Raptor-Server, otherwise connections will be refused.



Click on "Configure" for the instrument which you want to configure.



MAX devices for "MADx Tenant"



Name	Type	Key	Serialnumber	Last connection	Last activity	QC	Configure	Disable
MAX 45k TEST 5702	Max45k	pM6Gg88ZgwI2yp4QbZ4Qjoxk6d47I6	19090008	9 minutes ago	never	QC	Configure	Disable
MAX test	Max45k	Q9A8MNTp2GDjCpumr4K1afPRkc1vsa	20030020	one month ago	2 months ago	QC	Configure	Disable
MAX test1	Max45k	dGQmHqDogV96SGDwAqPdmPyDhy1195	19090008	27 days ago	5 months ago	QC	Configure	Disable

The "Configure" page for the selected MAX device is shown. Besides the general information like name, key notes, tube type etc., the following information can be obtained:

□ Run logs:

Run Logs

RunId	Batch Id	Triggered at	Results received at	Operator	View
30	02AIU	10/4/2022 03:38 PM	10/4/2022 03:49 PM	Kandybovich (Kandybovich@macroarraydx.com)	View
28	02APU	9/27/2022 05:15 PM	9/27/2022 08:23 PM	Kandybovich (Kandybovich@macroarraydx.com)	View
27	02APK	9/27/2022 10:54 AM	9/27/2022 11:04 AM	Kandybovich (Kandybovich@macroarraydx.com)	View
26	02APK	9/27/2022 09:34 AM	9/27/2022 09:43 AM	Kandybovich (Kandybovich@macroarraydx.com)	View
25	90AAG	9/27/2022 09:20 AM	9/26/2022 07:49 PM	distributore (distributore@server.com)	View
23	02APK	9/26/2022 10:52 AM	9/26/2022 11:04 AM	Kandybovich (Kandybovich@macroarraydx.com)	View
19	90AAG	8/11/2022 05:49 PM	8/11/2022 08:55 PM	Kandybovich (Kandybovich@macroarraydx.com)	View
18	02ARW	8/8/2022 06:12 PM	8/8/2022 09:19 PM	Kandybovich (Kandybovich@macroarraydx.com)	View
17	02AIU	8/8/2022 04:35 PM	8/8/2022 04:46 PM	Kandybovich (Kandybovich@macroarraydx.com)	View
16	02AIU	8/8/2022 03:52 PM	8/8/2022 04:03 PM	Kandybovich (Kandybovich@macroarraydx.com)	View



By clicking on the blue eye symbol on the right, detailed information about processed assay runs can be obtained (run info, errors, sample- and cartridge ID's in use, cartridge rotor temperature).



□ Maintenance:

Maintenances

There are no maintenances yet.

Shows information on past monthly maintenance procedures (see section 6 for further explanations).

□ ConfigXplorer Scans:

ConfigXplorer Scans

Version	Started at	Offset X	Offset Y	Width	Height	Exposure	Applied
✓ V1	vor 7 Tagen	400	316	650	350	992	
✓ ConfigXplorer	vor 7 Tagen	400	316	650	350	974	6/30/2022 05:35 AM

In order to adjust the exposure and the alignment of the imaging, a ConfigXplorer Scan must be performed after a new installation of the instrument and periodically every 60 days. The results of these scans are stored and can be looked into in detail and downloaded in a PDF format. Further information about the ConfigXplorer procedure can be obtained from the section XVII.5.

□ QR-Code image exposure:

It is possible to adjust the exposure, with which the QR-Codes of the cartridges are captured. This is useful when there is a reading failure during a ConfigXplorer scan or the cartridge inventory. Be careful, that you do not change the exposure for the array image. This is calibrated automatically by the ConfigXplorer scan.

QR-Code image configuration

QR-Code Exposure:



Calibration configuration

Mode:

Exposure:

Any changes, which were made in the configuration of the MAX, can be finalized by pressing the blue “Save” button.



XVII.5 CONFIGXPLOER SCANS

A ConfigXplorer scan needs to be performed:

- For every new MAX device before it is used to analyse patient samples.
- For devices already in use: every 60 days. RAPTOR SERVER Analysis Software will notify the user if a new ConfigXplorer scan is needed.

In order to perform the ConfigXplorer scan, a special cartridge is needed, which can be ordered from MacroArray Diagnostics or your local distributor. Please check the expiry date, which is printed on the pouch label, before you put the cartridge into the instrument. If you just received a new device, the ConfigXplorer should be included in the shipment.



Remove the ConfigXplorer from the pouch. Do not touch the surface of the cartridge membrane!



Put the ConfigXplorer cartridge into the cartridge rotor on the instrument. The ConfigXplorer shall always be placed in Position 1 in the cartridge rotor. Position 1 (marked by the arrow in the picture below) is counter clockwise to the cylindrical drain hole on the cartridge rotor. The rotor can be manually moved in both directions when the top cover is open.



Figure 50: Position 1 on the MAX 45k



Figure 51: Position 1 on the MAX 9k

Make sure that the instrument is switched on and initialized that the system water and washing solution containers are filled according to section XVI.8 and connected and the waste container is empty and connected to the instrument.

To start the ConfigXplorer scan, select “Configure” in the “Manage MAX devices” menu, as described in the previous section and click on “Start ConfigXplorer Scan”. The procedure runs automatically and is finished after approximately 2 minutes, depending on the quality of the internet connection.



The results of the current and all past ConfigXplorer scan can be investigated on the configuration page of the instrument. Click on the blue eye symbol and check if the ConfigXplorer scan was performed successfully (“Acceptance Criteria: Passed”). If the scan has passed, click on “Apply Settings”.



ConfigXplorer run report for val 170

[← Back to MAX device](#)
[Download Report](#)
[Apply detected settings](#)

Please check the automatically detected values for plausibility before applying them to your device.

Results

Device	21120004
QR-Code	30BAB05B24022023;52988;
Exposure	890
Offset X	354
Offset Y	316
Width	650
Height	350
Linearity Test [R ²] (> 0.95)	0.9997458203594268
Homogeneity Test [CV] (< 5)	1.003133517125027
Duration	00:01:16.7363721
Completed	now
Acceptance Criteria (R ² and CV ok)	Passed

XVII.6 STARTING A NEW ASSAY RUN

Please note that a maximum number of 4 assay runs can be performed with the MAX 45k, and a maximum of 5 runs on the MAX 9k with one assay kit due to Washing Solution use.

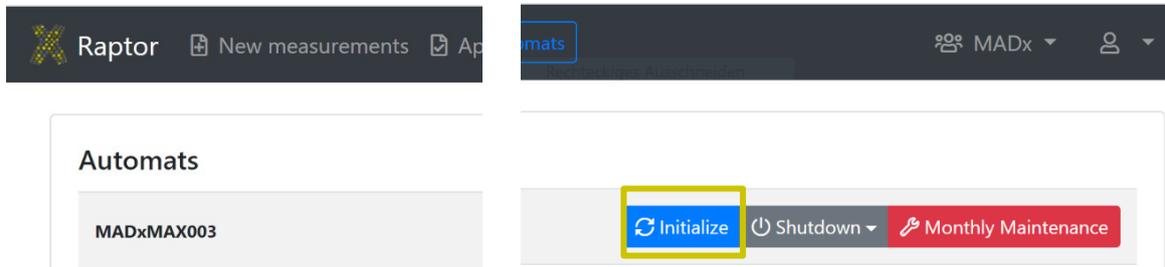
Before starting a new assay run, make sure that the waste container is empty, the system water container is filled with demineralized water and the washing solution container is filled with diluted Washing Solution of your assay kit (ALEX² or FOX). Please consult the Instruction for Use of ALEX² or FOX on how to correctly prepare the Washing Solution for the MAX device. The main cover must be firmly closed before proceeding with the operation of the device.

Click on “MAX devices” to get an overview of all MAX devices that are currently linked to your laboratory tenant.

Click on “Initialize” to perform the initialization process for the instrument which will be used for the upcoming assay run. During the initialization procedure, the pipette is rinsed several times in the rinsing station.

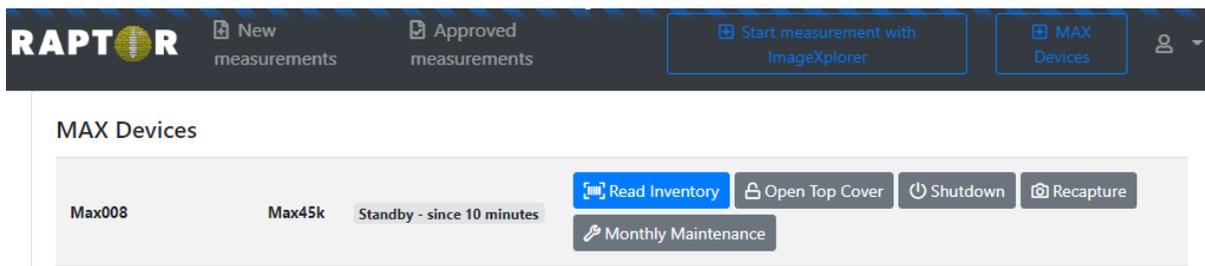


NOTE: the MAX 9k additionally carries out automated position alignment (auto-alignment) steps of the pipettor during initialization.



XVII.7 LOADING INVENTORY FOR AN ASSAY RUN

After the initialization of the instrument has finished, the menu items “Read Inventory” and “Open Top Cover” appear.



Click “Open Top Cover”, so that the interlock system releases the main cover after a short rinse of the pipette. Wait for the “click” sound on the instrument before you pull the lever of the cover. RAPTOR SERVER will prompt when the “Top Cover can be opened”.

	Please consult the safety instructions in section XVI.4.3 to avoid injuries when opening the main cover.
--	--

	The top cover of the MAX 9k might open up by itself after clicking the Open button on RAPTOR SERVER. Stand clear of the device.
--	---

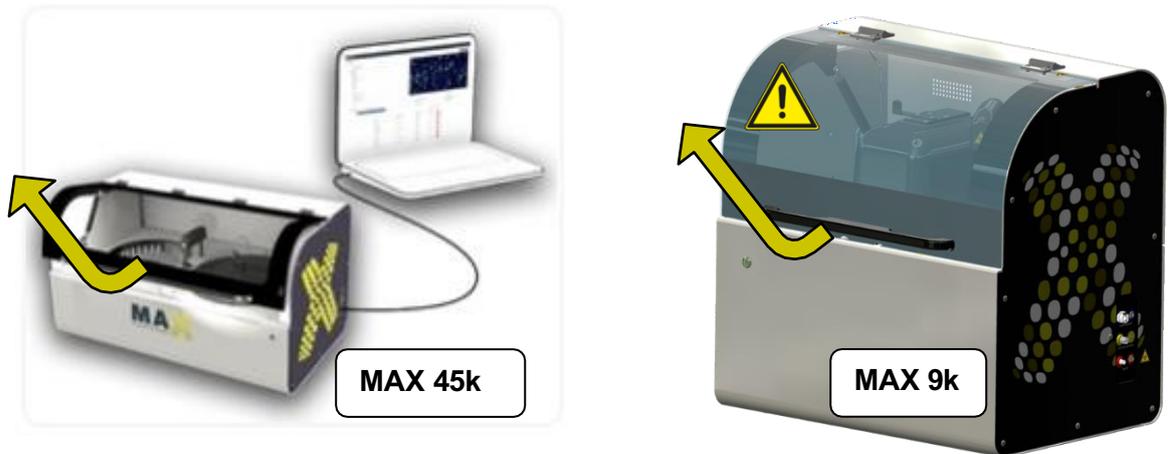


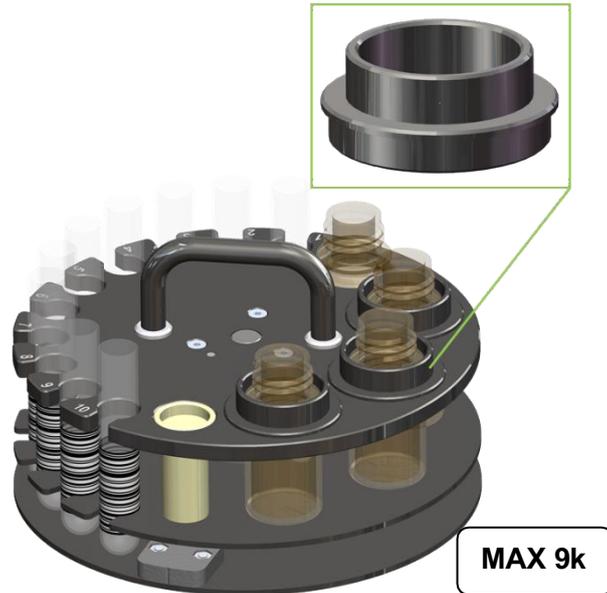
Figure 52: Opening main cover of devices

Put the reagent bottles Sample Diluent, Detection Antibody, Substrate Solution, and Stop Solution in the corresponding holes on the sample rotor. Make sure that the barcode on the labels is facing radially outwards and that no bubbles are visible. Note that if you use manually prediluted samples, you do not need to put the Sample Diluent into the instrument.

Make sure the size of the bottle exactly matches the size of the hole you place the bottle into (See Section XVI). The exact order of the reagent bottles does not matter since the barcode reader identifies each reagent based on its barcode. **The Stop Solution can only be placed in the narrower opening.**



If you use the 20x ALEX² kit with the MAX 9k device, apply the narrow adapters for the corresponding reagent bottles as below.



 Reagents can be loaded from either only an ALEX² or only a FOX kit. A combination of ALEX² and FOX cartridges or reagents within one assay run is not possible.

Put the sample tubes with 13mm diameter into the sample carousel, starting with position 1. For MAX 45k, use the provided adapters for inserting the 13mm tubes. Ensure that the barcode is facing outwards. For barcode specifications, see Section XXI.



Figure 53: Loading of devices

The MAX 45k can also be used with 16 mm diameter tubes (without adapter).



Use false-bottom 13 mm tubes, for low sample volumes. **See Section XXI for suitable tube types!**



	Always check the minimum sample volumes first before you start an assay run! Make sure that the test samples do not include visible particles like clotted fibrin. See section XXI for minimum sample volumes for each tube type.
--	---

	Make sure that the barcode on the labels of each sample tube is facing outwards so it can be easily detected by the barcode scanner of the instrument.
--	--

	The maximum applicable barcode length is 3 cm. The label itself can be longer. The barcode must have 1cm clearance from the bottom and 1.5cm from the top. This ensures a safe identification of the code.
--	--

After all reagents and samples have been loaded, take the necessary number of ALEX² / FOX cartridges (usually one cartridge per sample) from the ALEX² or FOX cartridge box.



 Only use FOX cartridges in combination with FOX reagents, and ALEX² cartridges only with ALEX² reagents. A combination of ALEX² and FOX cartridges or reagents within one assay run is not possible.

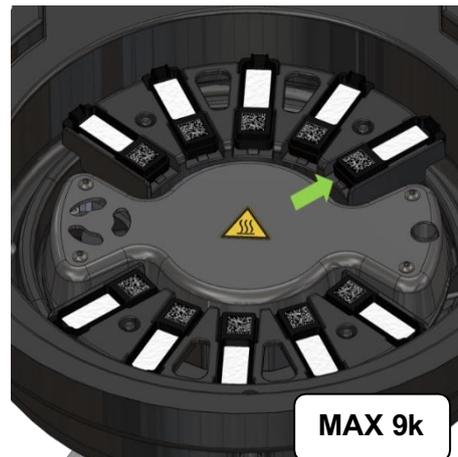
Remove/open the front cover from the cartridge rotor to get access to the cartridge holders.

Remove a cartridge segment from the cartridge rotor and insert the cartridges into the cartridge segment outside of the instrument. Slide the cartridge into its slot from the centre outwards until it is fixed, and you hear a “click” sound.

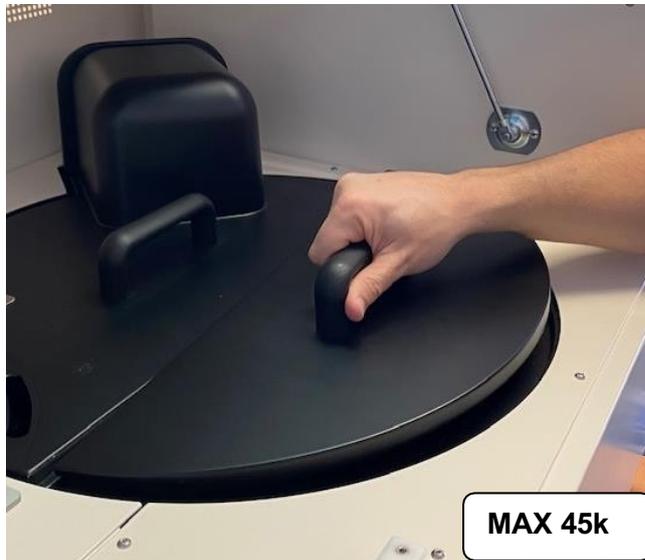


 **Do not touch the surface of the cartridges!**

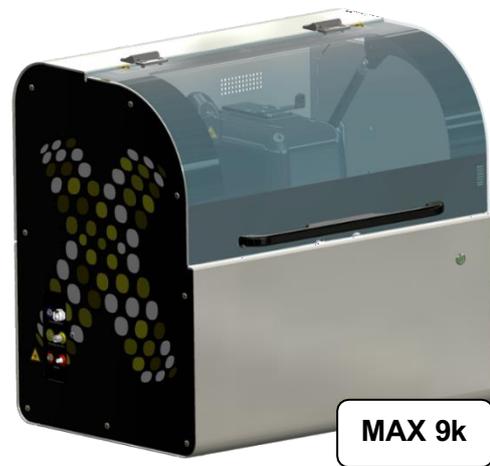
The cartridges can be placed in any free position. Preferably start loading of the cartridges at Position 1 as shown in the picture below marked with an arrow.



Make sure you insert the cartridge holder segments back to their position onto the corresponding alignment pins. After all cartridges have been loaded, close the cover of the cartridge rotor.



Make sure that all caps from reagent bottles and sample tubes have been removed. **Close the main top cover of the device manually.**



After closing, click the “Initialize” button on RAPTOR SERVER.

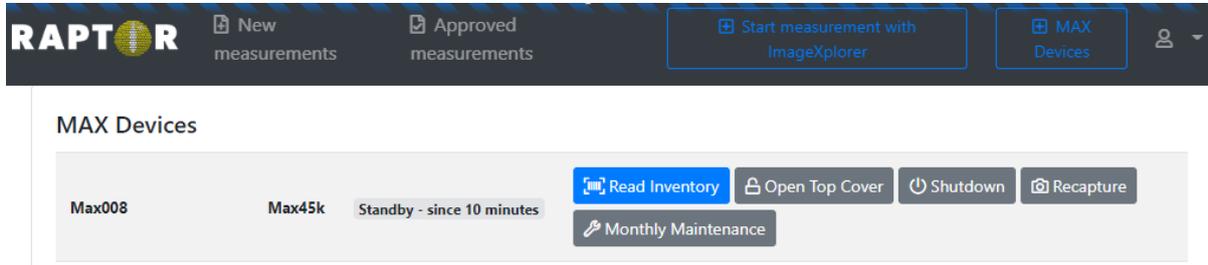
MAX Devices

Max008	Max45k	Stopped, initialization can be started - since a minute	Initialize
--------	--------	---	----------------------------



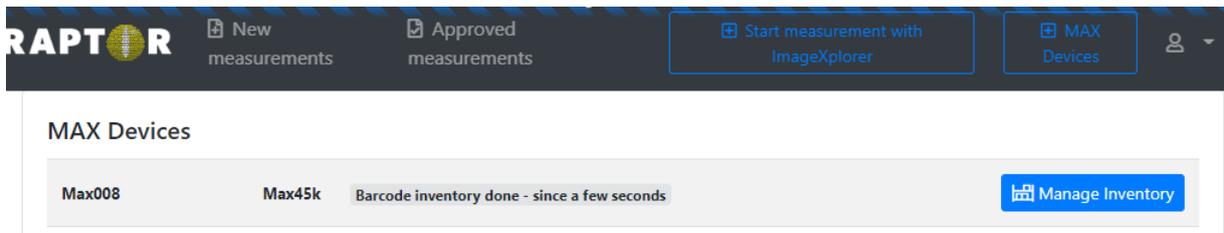
XVII.8 INVENTORY READING AND VOLUME CHECK

After Initialization, click on the blue button “Read Inventory” on RAPTOR SERVER.



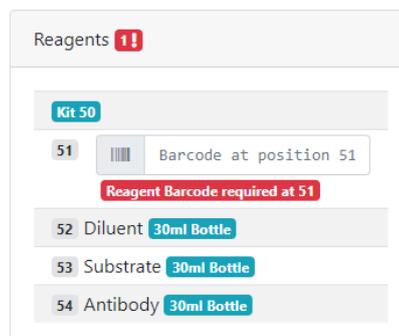
Upon clicking on Read Inventory, the instrument reads all barcodes on the reagent bottles, the sample tubes, and the ALEX² or FOX cartridges.

When the process is finished, click the blue button “Manage Inventory” to manage your recognized inventory of cartridges, samples, and reagents.



In the example below, the user forgot to put the Stop Solution into the sample rotor. A red warning message tells the user that no reagent barcode for position 51 could be detected. Open the main cover (click on “Open Top Cover”) and put the missing reagent bottle(s) into the corresponding holes of the sample rotor.

Inventory for Max008





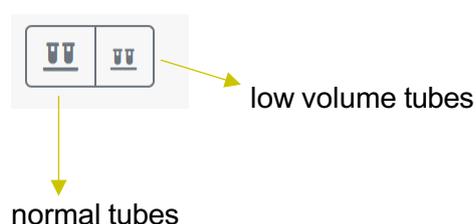
If there are reagents and samples which are correctly positioned but the barcode still cannot be read, contact your local distributor or MADx Support to check the barcode reader function. It is also possible to manually enter the barcode from the label of reagents and samples. In that case, please take care that you enter the barcode exactly the way it appears on the label of the reagent or sample. Show the label image with the yellow button “See Image”.



In case of an ALEX² assay, choose whether your samples are manually prediluted, or undiluted. With the option “Not prediluted”, the samples will be diluted by the device during the assay run (Sample Diluent bottle is required in the reagent holder). With the option “Prediluted”, the user confirms that they loaded manually prediluted samples in the sample rotor; thus, no further dilution step will take place during the run. You cannot apply both options in one run.

	<p>For a FOX assay, only prediluted samples can be used (default option).</p>
--	---

Select the tube type (standard tube or low volume tube) by clicking on the corresponding icon on top of the sample list (to select the tube type for all samples), or by clicking on the symbol at a specific sample position to set the tube type only for a specific sample. You can also change the default size of the test tubes in the configuration page of the MAX device.

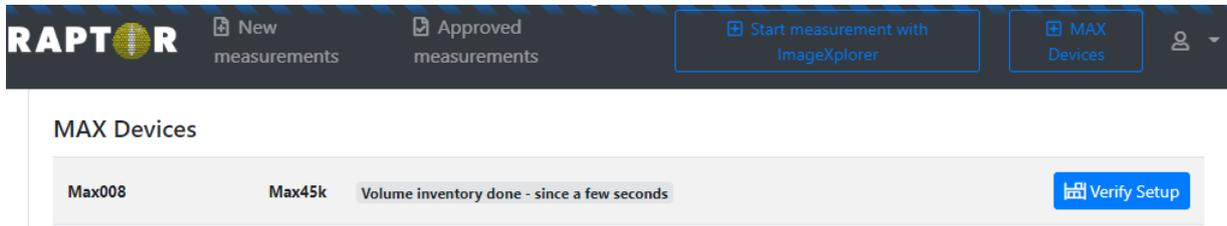


The assignment of each ALEX² / FOX cartridge to a sample is done automatically by the RAPTOR SERVER software based on the position numbers; however, you can change this assignment by clicking on the cartridge QR-Code, located in every line of sample on the right side, and move the QR-Code with the mouse up or down to the desired position by drag and drop. If you want to test the same sample on multiple cartridges, it is possible by drag-n-drop.



After you confirmed the correct codes and positions of your samples, and cartridges, press the blue “Check Volumes” button. Now the instrument captures all volumes in the sample rotor.

After the process has finished, click on “Verify Setup”.



In the example below, the instrument has detected enough volume in the reagent bottles, sample tubes and containers to start an assay run. (All volumes marked as “green”). The volumes in the reagent bottles are quantified, and the fill levels in the external containers are monitored. If the volume in one vessel is insufficient it will be marked in red, and a run cannot be started. Make sure you have sufficient reagents in your kit for the test run, and that you filled the washing solution and system water containers. Make sure the waste is empty.

	The user must take care they fill up the sample tubes with the minimum required volumes as specified in Section XXI.
--	--

Inventory for Max008



Options

Predilution of samples ⓘ **Not prediluted**

Reagents

Kit 50

- 51 Stop solution **6,579µl**
- 52 Diluent **13,678µl** **Edited**
- 53 Substrate **15,851µl** **Edited**
- 54 Antibody **16,407µl**

System State

- Washing Solution container **Ok**
- System water container **Ok**
- Waste container **Ok**

If prediluted samples are loaded into the instrument (“Predilution of Samples” option is set to “Prediluted”), you can ignore any error messages referring to the availability of the Sample Diluent, since the samples have been already incubated with the Sample Diluent.

Click on the blue button “Start Run” to begin with the assay run.



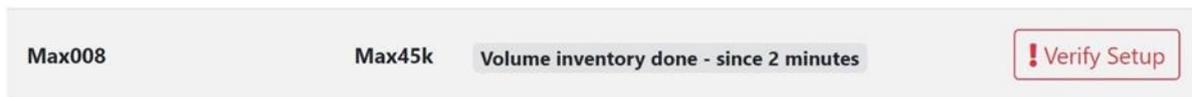
XVII.8.1 INTEGRITY CHECK

At the start and end of every run, the machine performs a control for the integrity of the fluidic system. If the Integrity Check in the beginning of the run fails for the first time, a “retry” button is available, where the MAX makes a 2nd attempt to carry out the integrity check and start the run.



For this 2nd try, the integrity check is carried out automatically on the cartridge on Position 2, to avoid complications with a semi-wet cartridge on Position 1. If this fails, you will jump back to the “Verify Setup” step as before and can start the whole process again. In that case an inspection is suggested.

MAX Devices



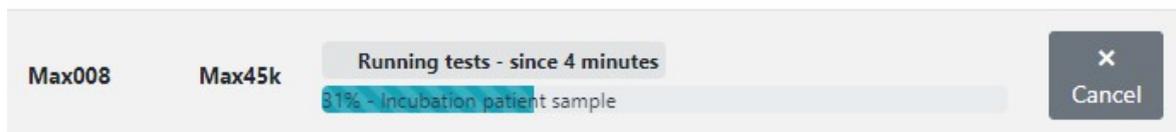
Inventory for Max008

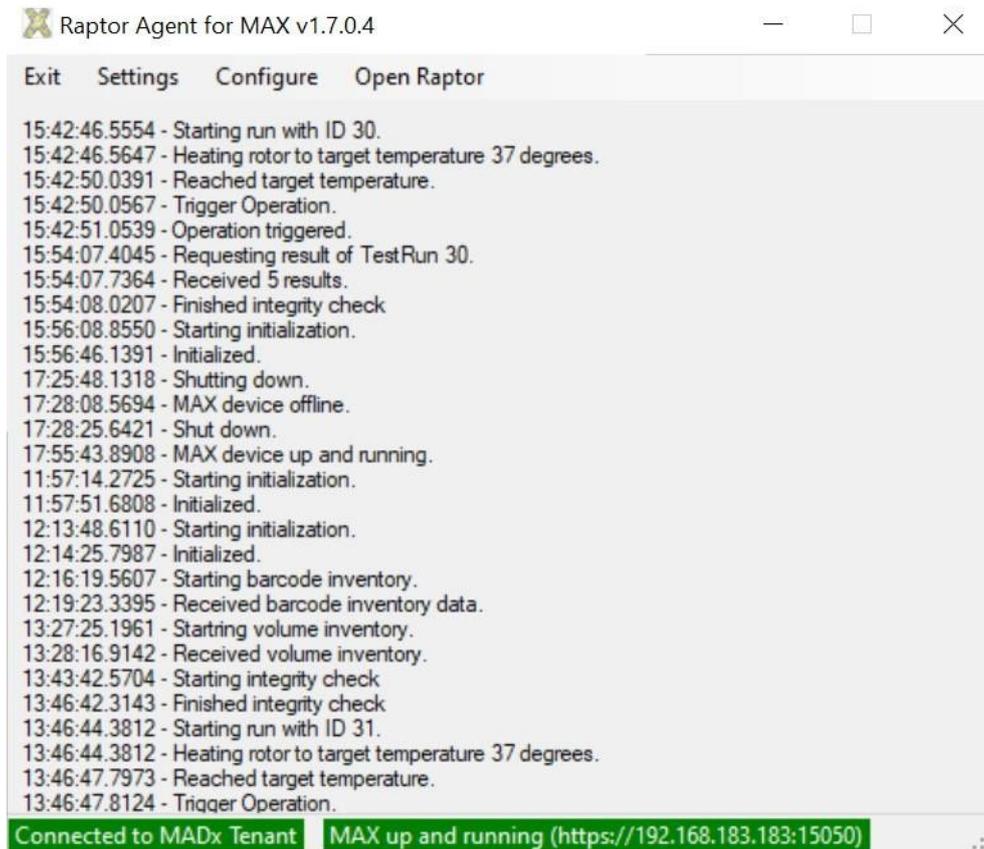


If the integrity check at the end of the run fails, the test results will be uploaded to RAPTOR SERVER as usual, but with a warning at the measurement detail page.

The status field of the instrument shows the current status and provides a progress bar to estimate the residual run time of the assay run. The status of operation can also be checked in the “Raptor Agent for MAX”.

MAX Devices





Do not close the “Raptor Agent for MAX” app during an assay run. If for any reason the application crashes, restart the program.

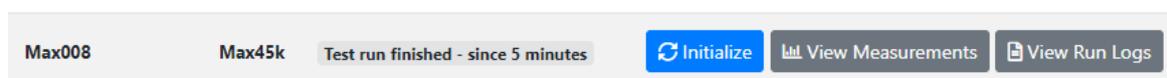
XVII.9 END OF ASSAY RUN AND SHUTDOWN

When the assay is finished, the status field will indicate “Test run finished”. By clicking on “View Measurements”, the result page is opened, and the sample results can be verified and approved, according to the RAPTOR SERVER user manual.

To view the run logs and potential error messages, click on “View Run Logs”. To start a new assay run or to shut down the instrument, click “Initialize”.

Before starting a new assay run, make sure that you remove all processed cartridges from the cartridge rotor.

MAX Devices





To perform a shutdown of the instrument:

- Open Top Cover after Initialization
- Remove all reagents and sample tubes from the sample rotor
- Remove all cartridges from the cartridge rotor
- Close the Top Cover and initialize
- Click on “Shutdown” on RAPTOR SERVER.



- After (!) the recovery push button starts flashing slowly, the device can be powered off with the main switch. **Never press the main switch while the MAX is still active!**
- Consult section XIX for required maintenance procedures of the instrument.





XVII.10 RECAPTURE

It is possible to carry out an imaging sequence of test cartridges, without a Run. In the standby (initialized) state of the machine, the “Recapture” button is visible. By clicking the button “Recapture” a user confirmation will be required (screenshot below); after that all cartridge positions will be read, and the tests found will be imaged and their results will be uploaded to the New Measurements list on RAPTOR SERVER, with the Tag “recapture”.

	Make sure you only recapture tests in the MAX 9k which were originally processed with the MAX 9k. Similarly, with the MAX 45k it is only allowed to recapture tests which were processed originally with a MAX 45k.
--	---

	Make sure you do not use the recapture function of the MAX device on manually processed tests!
--	--

Confirm Recapture for MAX device **Max008**

 **WARNING:** It is only allowed to recapture tests which were originally processed with an automated instrument (MAX). Using manually processed arrays is prohibited due to a possibly false result.

Please confirm that all of the inserted tests were originally processed with a MAX.

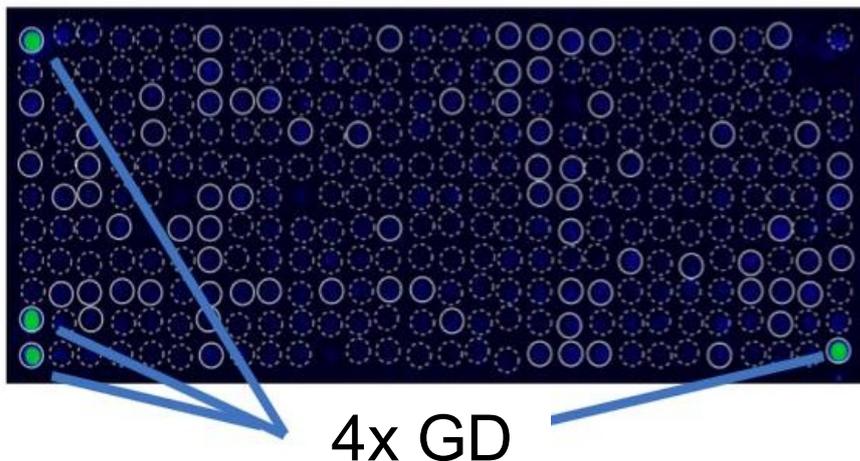


XVII.11 INTERNAL QUALITY CONTROL

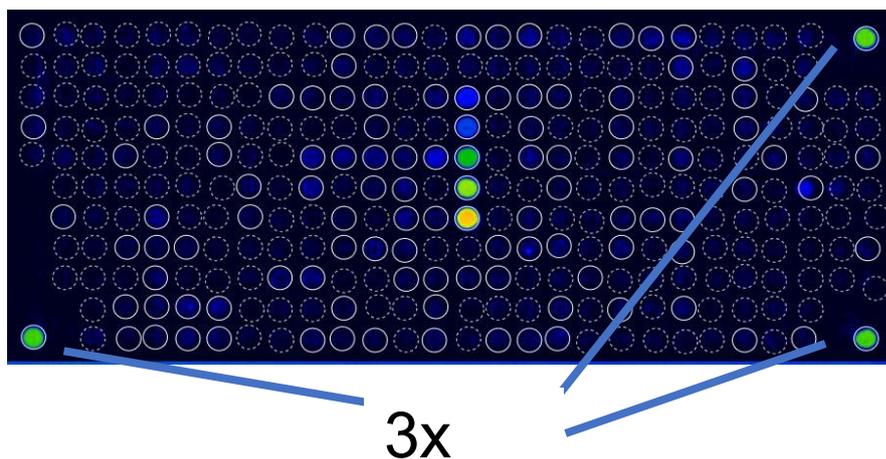
ALEX² and FOX cartridges have an inbuilt assay run control, represented by so called “Guide Dots” (GD) on the cartridge surface.

ALEX² cartridges work with 4 Guide Dots, while FOX cartridges work with 3 Guide Dots, in the positions as depicted below

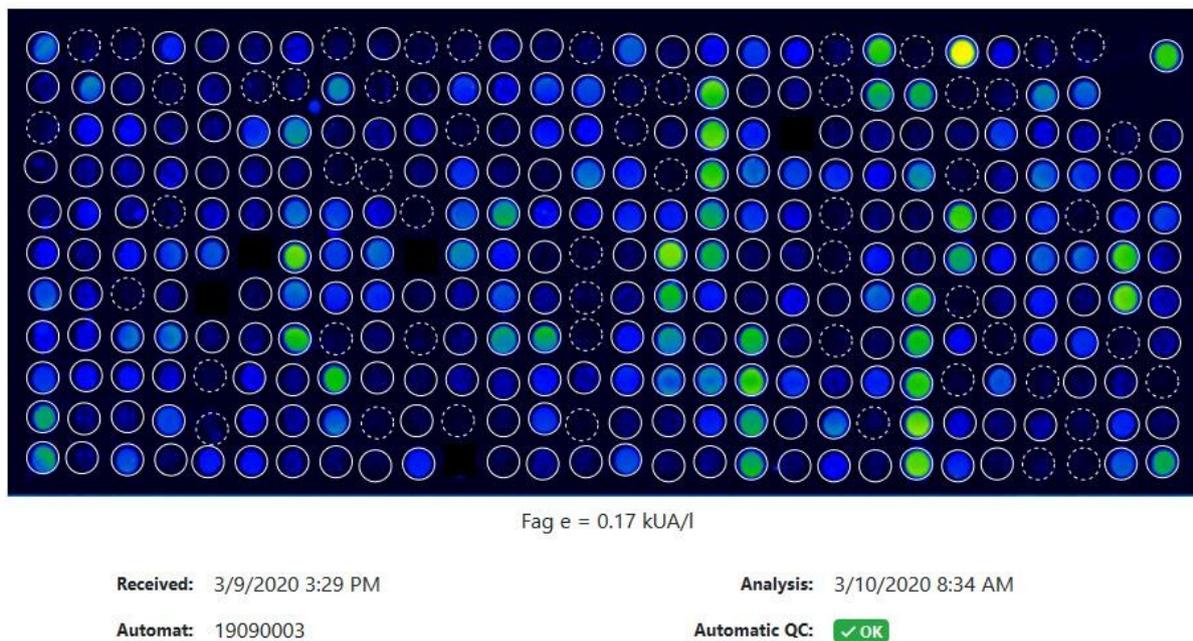
ALEX²



FOX



During the image acquisition of an ALEX² or FOX cartridge, RAPTOR SERVER evaluates the signal of all Guide Dots as well as the background signal of the membrane surface. If all quality criteria are fulfilled, the “automatic QC” field under the image is set to “OK”. Please consult the RAPTOR SERVER user manual for further information about the QC of the test. If QC fails, contact MADx support or your local distributor.



Additionally, it is recommended to run at least one negative and one positive quality control sample with every assay run. Currently, the QC module in RAPTOR SERVER is only available for ALEX², not for FOX.

RAPTOR SERVER contains a basic QC module which can monitor QC performance with the two supported quality control samples:

The QualityXplorer (REF 31-0800-02), manufactured by MacroArray Diagnostics, is the preferred product for a quality control sample. It includes 8 QC samples in barcoded low-volume tubes with 200µl fill volume. To use the QualityXplorer as a sample, unscrew the cap, and put the sample tube into the sample rotor as you set up a regular run. The sample code, starting with the number 31, will be recognized by RAPTOR SERVER as a QC sample. For further information, consult the IFU of the QualityXplorer.

The “Lyphocheck® sIgE Control, Panel A” is distributed by the company Bio-Rad. Please consult the Instruction for Use of the manufacturer on how to use this control material. In its liquid state, it can be used as a sample in MAX runs. In order to use Lyphocheck® sIgE Control Panel A as an internal quality control during an assay run with a MAX device, use the lot number with the proceeding product ID “32” of the control as the barcode for the sample, for example “3222640” for Lyphocheck® sIgE Control Panel A lot 22640. RAPTOR SERVER will recognize this barcode as a QC sample.

The acceptance ranges for the most recent batches of the QualityXplorer and Lyphocheck® sIgE Control Panel A are stored in RAPTOR SERVER and cannot be edited by the user.

QC results can be reviewed from the MAX device settings page (“Tenant Admin” → “Manage MAX devices”). Click on the blue button “QC” to see an overview of QC results for a particular MAX device.

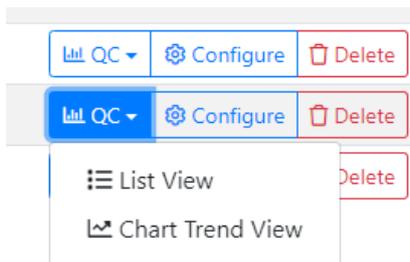


MAX devices for "MADx Tenant"

[Add new MAX device](#) [Download MAX Agent Software](#)

Name	Type	Key	Serialnumber	Last connection	Last activity	
MAX 45k TEST 5702	Max45k	pM6Gg88ZgwI2yp4QbZ4Qjoxk6d47I6	19090008	23 hours ago	never	QC Configure Disable
MAX test	Max45k	Q9A8MNTp2GDjCpumr4KMafPRkc1vsa	20030020	one month ago	2 months ago	QC Configure Disable

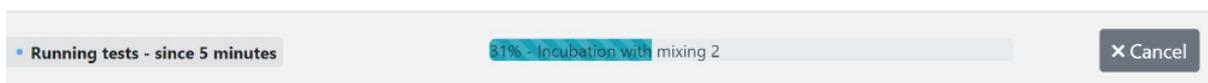
The QC results can be examined in "List View" or in "Chart Trend View":



XVII.12 ABORTION OF AN ASSAY RUN

In case of a severe error, the instrument changes to status "stop". In status "stop" all motors stop their movement and all pumps are switched off. The status "stop" is displayed to the user via the instrument status page. The assay run is aborted, no results are reported.

During an assay run, the procedure can be manually aborted by the user by clicking the "Abort run" button at the status bar of the instrument. Please note that after the Sample Diluent has been dispensed, the cartridges cannot be reused and must be discarded.



If a leakage is detected and reported by the RAPTOR SERVER Analysis Software, the MADx support team or its local distributors need to be contacted. The instrument should be switched off immediately and the power cord should be unplugged for safety reasons.

If a vertical movement crash of the steel needle is detected, all mechanical motions of the stepper motors and all pumps will immediately stop running. The operator is informed about the event via the instrument status page. A "System Prepare" via the "Initialize" button in the RAPTOR SERVER Analysis Software will recover the instrument to perform further steps. If the same crash is detected twice - although an "Initialize" procedure was executed in between - the MADx support team or your local distributor need to be contacted before performing any new assay run.



In case of an uncontrolled main cover opening, all mechanical motions and pumps immediately stop. After closing the cover, the user can recover the analyser with the “Initialize” button of the GUI. In case of an uncontrolled opening (bypassing of lock) of the main cover, MADx disclaims all liability for damage to the analyser.

XVII.13 AUTO-ALIGNMENT WITH THE MAX 9K

Each time the MAX 9k device is started or the “Initialize” button is pressed, a position alignment is performed. During this alignment process, the needle is checked for bending and the positions at the sample rotor, cartridge rotor and rinsing station are precisely aligned. This process is fully automated. After completion of the alignment process, the user is informed if it was unsuccessful. See section XX.7 for a detailed description of the possible error causes

XVII.14 ERROR HANDLING

Section XX describes troubleshooting of MAX devices and lists all the possible error messages. Errors can be categorized by their severity (0-3): Errors with a severity of 0 to 2 allow the test run to be continued and obtain at least partial test results, whereas severe errors (level 3) cause the instrument to stop immediately and abort the assay run – no test results can be achieved.

If errors occur during an assay run, they are displayed in the RAPTOR SERVER Analysis Software on the screen (error code and severity level). The User should contact MADx support or their local distributor for the analysis and identification of the error codes.

At the end of the assay run (or after the instrument aborted the assay run due to a severe error), an error log is created by the system. A hyperlink to the error log is provided on the user interface. By clicking on this link, the user can download the log file in text format and send it to MacroArray Diagnostics or your local distributor for further analysis via E-Mail.

The MAX should be active and online to download the Agent and MAX logs on the configuration page of the device. First, click on “MAX logs” or “Agent logs” for a dropdown, and choose “request”. Wait 1-2 minutes and a “download” option will appear in the same dropdown. Click “download” and send the file to your local distributor.

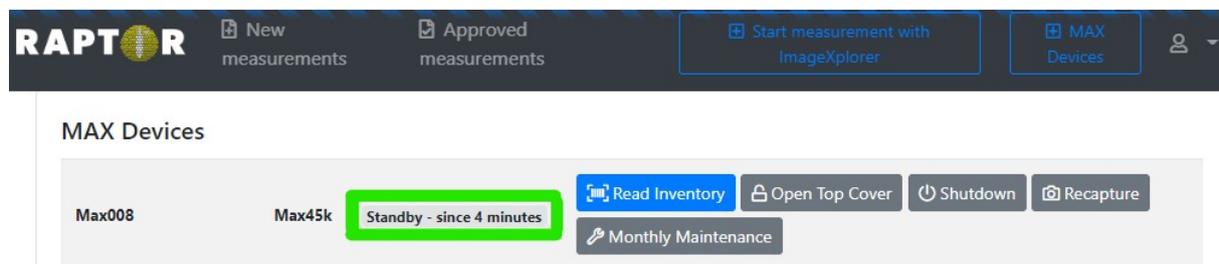
Configure MADxMAX003





XVII.15 INSTRUMENT STATUS

The current instrument status is displayed in the RAPTOR SERVER Analysis Software (see green rectangle in the screenshot below) and the operator is always informed about the actual step in the workflow of the MAX device.



The following status messages for the MAX devices are available:

WaitingForStatus	Agent is connected to RAPTOR SERVER and status of instrument needs to be requested by Agent.
AutomatInaccessable	Agent is connected to RAPTOR SERVER, but instrument cannot be accessed.
NotInitialized	Agent is connected to both, RAPTOR SERVER and instrument. Instrument recently switched on and needs to be initialized.
UserRequestedInititalization	Agent is connected to both, RAPTOR SERVER and instrument. User sent request for initialization. Initialization option disappears for all users of tenant, and command is sent to agent and waits for the acknowledge of the agent.
Initialization	Agent is connected to both, RAPTOR SERVER and Automat. This status is shown, while the instrument prepares itself before it achieves the standby state.
Standby	Agent is connected to both, RAPTOR SERVER and instrument. Instrument is in a safe state. Barcode inventory procedure can be started. Top cover can be opened.
UserRequestedOpenTopCover	Agent is connected to both, RAPTOR SERVER and instrument. User sent request for top cover to be opened. Actions disappear for all users of tenant.
Homing	Agent is connected to both, RAPTOR SERVER and instrument. User sent request for top cover to be opened. Before it can be opened, actors (=mechanical moving parts) need to be homed (= prepared).



TopCoverCanBeOpened	Agent is connected to both, RAPTOR SERVER and instrument. Main cover is physically opened. This state appears, until main cover is closed.
TopCoverOpen	Agent is connected to both, RAPTOR SERVER and instrument. Main cover is physically opened. This state appears, until main cover is closed.
UserRequestedbarcodeInventory	Agent is connected to both, RAPTOR SERVER and instrument. User sent request for barcode inventory. Actions disappear for all users of tenant.
BarcodeInventoryCapturing	Agent is connected to both, RAPTOR SERVER and instrument. Automat executes barcode inventory procedure.
BarcodeInventoryDone	Agent is connected to both, RAPTOR SERVER and instrument. Automat finished barcode inventory procedure and is ready for next step.
UserRequestedVolumeInventory	Agent is connected to both, RAPTOR SERVER and instrument. User sent request for volume inventory. Actions disappear for all users of tenant.
VolumeInventoryCapturing	Agent is connected to both, RAPTOR SERVER and instrument. Automat executes volume inventory procedure.
VolumeInventoryDone	Agent is connected to both, RAPTOR SERVER and instrument. Automat finished volume inventory procedure and is ready for next step.
UserRequestedTestRun	Agent is connected to both, RAPTOR SERVER and instrument. User sent request to start test run. Actions disappear for all users of tenant.
RunningTests	Agent is connected to both, RAPTOR SERVER and instrument. Automat executes test run.
ResultTransmissionStarted	Agent is connected to both, RAPTOR SERVER and instrument. Operation procedure stopped and results are transmitted from instrument to RAPTOR SERVER via Agent.
TestRunFinished	Agent is connected to both, RAPTOR SERVER and instrument. All results sent to RAPTOR SERVER. User can see details of test run, view results or prepare instrument for next run.
UserRequestedCancel	Agent is connected to both, RAPTOR SERVER and instrument. User sent request to cancel current procedure. Actions disappear for all users of tenant.
Cancelling	Agent is connected to both, RAPTOR SERVER and instrument. Current operation is canceled. This state appears while cancel procedure is executed.



Stop	Agent is connected to both, RAPTOR SERVER and instrument. Either user canceled an operation, or a severe error was detected by the instrument, and it moves into state Stop.
Integrity Check Failed	Agent is connected to both RAPTOR SERVER and MAX instrument. The integrity check in the beginning of the run failed. The user can either press “retry” to try and start the run again, or “skip” and get back to the previous step.

Table 3 Status messages of MAX devices

In case of a fatal error, the instrument status changes to status “stop” (status “5”). The operator is informed about the detailed cause of the fatal error (e.g., crash, leakage, top cover opened during the assay run) via the instrument status page.

XVII.16 IMAGE ANALYSIS AND REPORT GENERATION

For a detailed description of Image Analysis and Report Generation please refer to the Instructions for Use of the RAPTOR SERVER Analysis Software.



XVIII. CLEANING

By following the preparatory, operational and maintenance instructions for the instrument, you will keep the analyser in good shape and significantly prolong its working life. If your device malfunctions, please contact MacroArray Diagnostics or your local distributor.

XVIII.1 CLEANING OF THE OUTER SURFACE

To clean the outer surfaces of the analyser, please wear gloves and use only mild detergents or alcoholic disinfectants. Autoclaving or soaking parts of the instrument into cleaning agents is prohibited. Please see the product-specific inserts for safety instructions of the cleaning agents.

For the disinfection of the surfaces, a 2% solution of Terralin® Protect (available from Schülke & Mayr GmbH Norderstedt), or Microcide SQ (Global BioTechnologies, inc., USA) is recommended.



Please refer to the safety data sheet of the disinfectant solution in use for handling instructions and turn off the instrument prior to the outer cleaning.

XVIII.2 WEEKLY CLEANING

The weekly cleaning of the analyser should basically include the following steps:

- Open the main cover of the device via RAPTOR SERVER
- Remove / lift the front cover lid of the cartridge rotor and remove all cartridge segments (you can turn the rotor by hand).
- Visually check if the washing solution needle on the bottom side of the rotor cover shows any residues (in case of MAX 45k, take the rear cover lid of the cartridge rotor after detaching the tube from the washing solution needle). If residues are visible, please replace the needle.
- Clean the waste rim of the cartridge rotor with a cloth moistened (non-dripping) with Terralin® Protect or Microcide SQ in a 2% solution.



Do not use a spray for cleaning, otherwise the optics may malfunction.

- Clean the illumination module of the cartridge rotor at the illuminated surface with a cloth moistened with the above recommended disinfectant to remove potential dust. Do not touch the camera lens!
- In case of the MAX 9k, clean the metallic knob on the sample rotor carousel, in the cartridge rotor, the metallic jig at the rinsing station, and the metallic alignment jig at



the home-position of the pipettor with 70% ethanol as seen in Figure 54 and Figure 55.

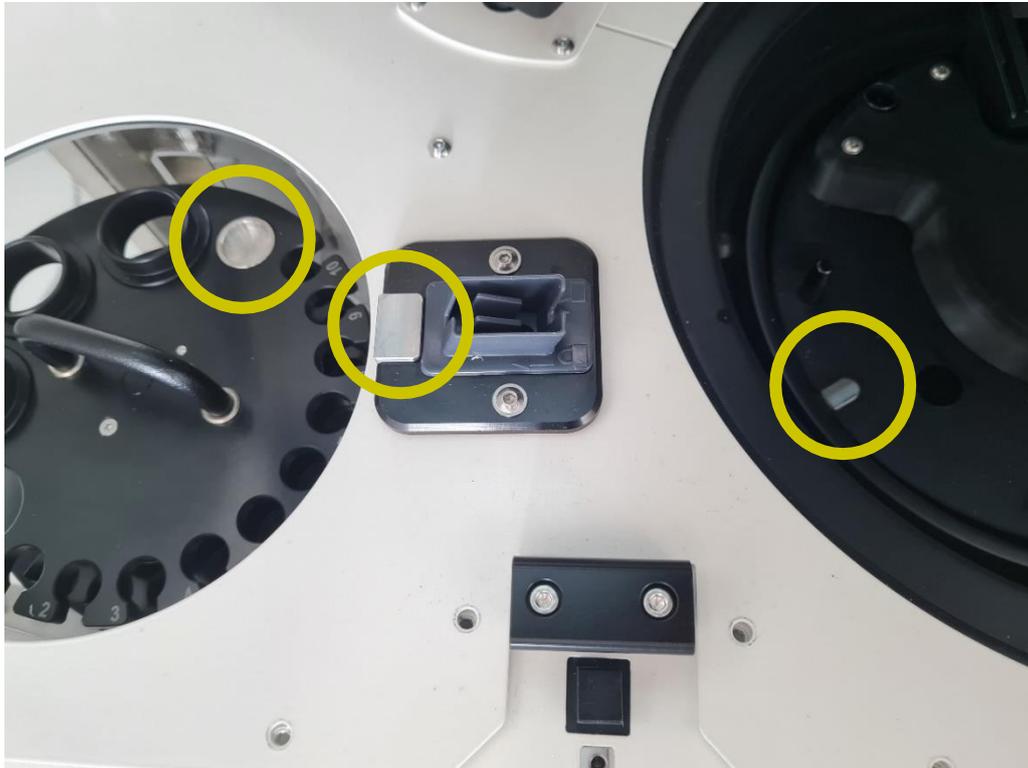


Figure 54: Metallic alignment jigs to be cleaned with 70% Ethanol in the MAX 9k



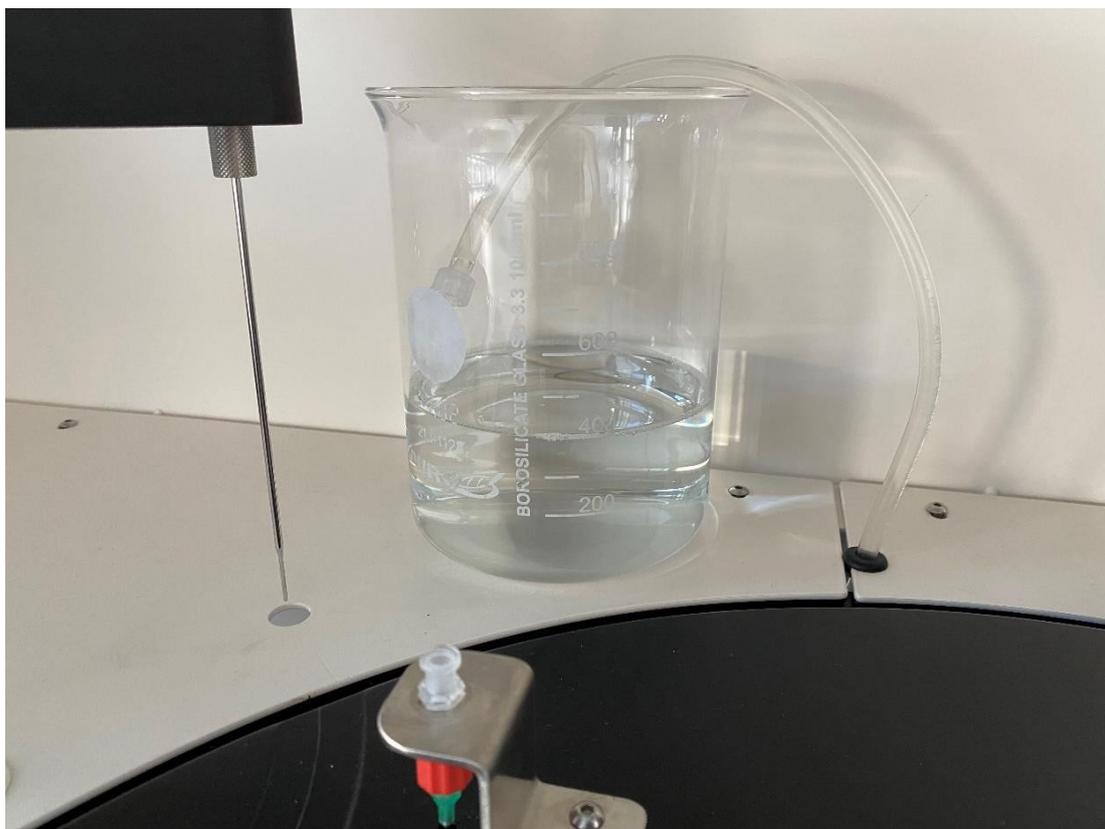
Figure 55: Metallic alignment feature to be cleaned with 70% Ethanol in the MAX 9k



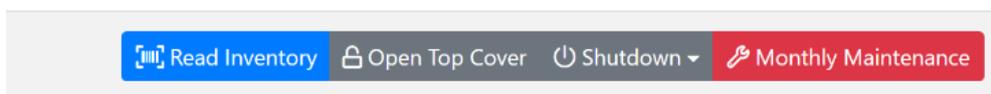
XVIII.3 MONTHLY MAINTENANCE

The monthly cleaning of the analyser is mandatory, and to be carried out by the User. The due date of a necessary monthly maintenance is tracked and prompted by the RAPTOR SERVER Analysis Software.

Before starting the procedure, open the main top cover (RAPTOR SERVER) and disconnect the washing solution tubing from the Luer-lock connector. Place the tubing safely into a vessel with at least 1 litre fill volume. Make sure that the vessel is not in the way of the pipettor arm and that the tubing is fixed in the vessel to prevent leakage.



Close the main cover, and press Initialize. To start the maintenance and work with the provided online-checklist, go to the MAX device control page, and press the red button “Monthly Maintenance”.



The maintenance page for the selected instrument is shown. Please follow the instructions on the screen carefully and click the corresponding checkbox after completing each step.



Prepare monthly maintenance routine for MAX device Max008

⚠ After the monthly maintenance routine has been started, it must be executed until it is finished by the current operator. Please make sure to reserve enough time for this procedure (approx. 2 hours).

① Before the monthly maintenance routine can be started, all three containers (system-water, waste and Washing Solution) need to be cleaned. Please ensure that the following tasks are done in advance.

- Before you start the monthly maintenance procedure, open the main top cover of the device and disconnect the inner washing solution tubing from the Luer-lock connector of the washing solution dispenser needle. Place the tubing into a vessel with at least 1 liter capacity. Make sure that the vessel is not in the way of the pipettor arm and that the tubing is fixed in the vessel to prevent leakage. To do the above, press "back" on the bottom of this page to get back to the MAX control buttons and use the button "open top cover".
- Empty the system-water- and the waste-water container. Transfer the content of the washing-solution container to a separate vessel, like a beaker.
- Add Terralin® Protect or Microcide SQ solution in 2% dilution with demineralized water to all containers (system-water, waste, and washing solution container). Fill the waste and system water containers of the MAX 45k with 2L of the disinfectant solution. In case of the MAX 9k, add only 1L disinfectant solution in the 2 containers. The Washing Solution container should be filled with 500 ml of the 2% disinfectant solution for MAX 9k as well as MAX 45k. Swivel the containers so that all surfaces inside the containers are get in contact with the disinfectant solution. Incubate for approx. 30 minutes.
- Visually check if the floats of the container are clotted. A clotted float will not freely fall down when released after it was pushed manually to the top.
- In case of a clotted float, please refill the containers to half with 2% of the disinfectant solution for at least 24 hours and manually push the float back and forth several times. If a float is still clogged, please call MacroArray Diagnostics or its official distributor.
- Empty all containers and rinse them with demineralized water.
- Add Terralin® Protect or Microcide SQ solution in 2% dilution with demineralized water again but only to the system-water and washing solution container. Fill the system water container of the MAX 45k with 2L of the disinfectant solution. In case of the MAX 9k, add only 1L disinfectant solution. The Washing Solution container should be filled with 500 ml of the 2% disinfectant solution for MAX 9k as well as MAX 45k.
- Attach the screw caps of the system-water, washing-solution and waste containers properly.

[X Back](#) [Start monthly maintenance routine](#)

Estimated duration for this step is 35 minutes.

The monthly maintenance procedure includes the following steps:

- After emptying the system water and waste containers and transferring the content of the washing solution container to a separate clean vessel, fill all containers (system-water, waste, and washing solution) with Terralin® Protect or Microcide SQ in 2% dilution as prompted by RAPTOR SERVER. Incubate for approx. 30 minutes at room temperature. Fill the waste and system water containers with 2L in the MAX 45k, and 1L in the MAX 9k. Fill the Washing Solution container with 500 ml.
- Remove the disinfectant solution from all containers and wash them thoroughly, using demineralized water. Empty all containers.
- Visually check if any of the float balls of the container is clotted and will not easily fall back when released after it was pushed manually to the top.
- In case of a clotted float ball, please refill the containers with 2% disinfectant solution for at least 24 hours and manually push the float back and forth several times. Finally, wash out all containers thoroughly using demineralized water and empty all containers. If a float ball is still clogged, please call the service team of MacroArray Diagnostics or your local distributor.
- Fill the system-water and Washing Solution containers as prompted by RAPTOR SERVER with Terralin® Protect or Microcide SQ in 2% dilution (system water container with 2L in the MAX 45k, and 1L in the MAX 9k; Washing Solution container



with 500 mL) and start the monthly maintenance routine on the RAPTOR SERVER platform. Follow the instructions given by the RAPTOR SERVER Analysis Software.

- If you did not put the washing solution tube in a vessel before starting, you can use the “back” button to jump back to the control page of the MAX device and trigger opening the cover to be able to do the following: detach the washing solution tube from the washing solution dispenser needle, and safely place the tube in a vessel of at least 1L fill volume. The vessel (like a glass beaker) should stand stable inside the machine, but not in the way of the pipettor arm. Make sure the tube remains inside the vessel and does not easily move – eventually to be fixed with a labelling tape. Then close the cover and start the first step of the monthly maintenance.
- After you have proceeded through all steps instructed by the RAPTOR SERVER Software, the main cover will be unlocked in the last step (Step 6). Open the cover and clean the rotor plate of both rotors using a cloth moistened with Terralin® Protect or Microcide SQ in 2% dilution. Make sure you take out and thoroughly clean the cartridge holder segments as well.
- Remove the sample rotor carousel and clean the tub using a cloth moistened with the 2% disinfectant solution. Do not clean the neoprene surface of the sample rotor disc in the MAX 9k.



Do not use a spray for cleaning, otherwise the barcode reader may malfunction.

- Clean the waste rim around the cartridge rotor using a cloth moistened with the 2% disinfectant solution.



Do not use a spray for cleaning, otherwise the optics and electronics of the image acquisition module may malfunction.

- In case of the 9k, clean the metallic knob on the sample rotor disc, the metallic jig at the rinsing station, and the metallic alignment jig at the home-position of the pipettor with 70% ethanol (see section XVIII.2).

In case an error is detected in any of the steps during the maintenance routine, e.g., by excess foam at the rinsing station, the maintenance routine is interrupted, and it can be either aborted or repeated from the current step. In this case, RAPTOR SERVER offers the two above options to be chosen by the user.

- If the “repeat” option is chosen, the maintenance routine will be continued from the step in which it was interrupted. In that case, the operator should double-check if the necessary amount of currently applied fluids is still available in the system-water and Wash Solution containers.



- If the cause of the error can only be resolved by a manual intervention or by opening the cover of the analyser, the “abort” option shall be chosen by the operator. Thereby, the operator can quit the maintenance routine in three steps, as guided by RAPTOR SERVER.

	In either case the operator shall be cautious about the fluid level in the waste container, to avoid its overfilling.
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XVIII.4 REPAIRS

All maintenance work or repairs not listed in this instruction manual must always be carried out by MacroArray Diagnostics or its local distributors.

PLEASE NOTE

For safety reasons, a return of the instrument to MacroArray Diagnostics or its local distributors is only possible after the instrument has been cleaned and decontaminated by the user.



XIX. PERFORMING MAINTENANCE

XIX.1 ANNUAL MAINTENANCE/PARTS EXCHANGE BY SERVICE TECHNICIAN

Annual preventive maintenance must be performed for the instrument and will be carried out by qualified service personnel of MacroArray Diagnostics or its local distributors. The parts which are replaced within this regular interval are:

- Syringe body
- Waste tubing
- Waste pump head
- Washing solution dispenser needle
- Pipette needle
- External tubing and filters for each container
- Annual clean-up of the SD card in the instrument

Additional activities to be applied are described in the service manual.

XIX.2 EXCHANGE OF STEEL NEEDLE OF PIPETTOR ARM BY THE OPERATOR

The steel needle of the robotic pipettor arm should be replaced annually or if damaged. The replacement can be performed by the user according to the following procedure. It is recommended to wear gloves for the following steps:

1. Please turn off the instrument and open the main cover according to section XVI.4.3.
2. Manually lift the robotics pipettor arm to the top and turn it to the front so that the needle tip is positioned above the drain channel of the needle rinsing station. Keep holding the arm in this position.



3. Hold the arm at the mentioned position and unscrew the needle slowly by turning it counter clockwise with your other hand. Liquid will drop into the drain channel. Make sure you only touch the needle at its grip (see XVI.7).



4. Gently screw a new steel needle into the holder by turning it clockwise until it is fixed. Tighten it firmly and make sure you still have a gap between the housing and the grip after tightening (see XVI.7)
5. Move the arm carefully and slowly horizontally through the external rinsing station and check if the needle is touching the side walls.



6. In case the needle is touching one of both side walls, please contact your local distributor or MADx support.
7. Finally, the needle must be positioned over the parking position where the needle can slowly fall in without any collision with the working deck (see figure below).

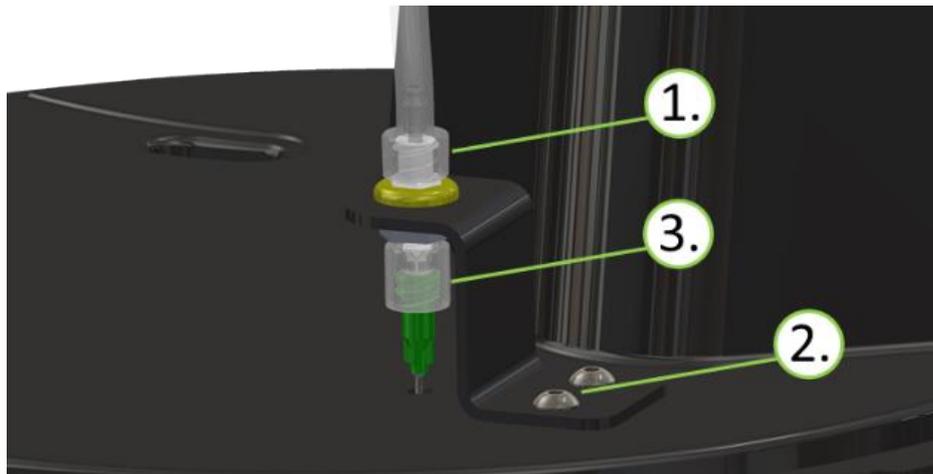


If this procedure is correctly applied, no further alignment is necessary.

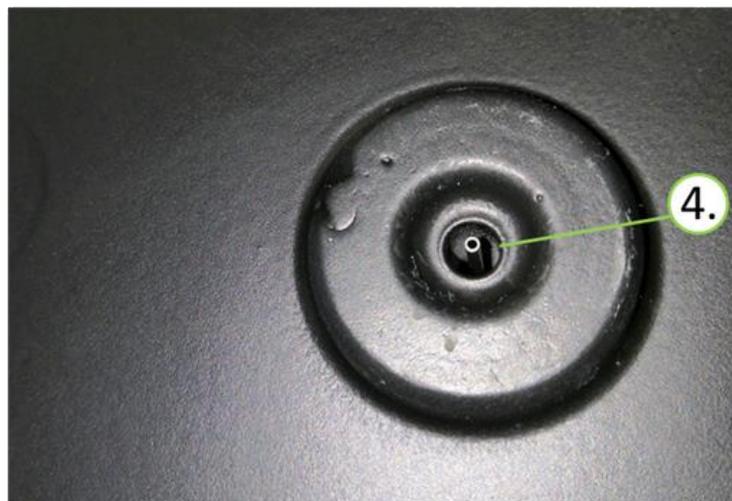


XIX.3 EXCHANGE OF THE WASHING SOLUTION NEEDLE

The washing solution needle of the cartridge rotor should be replaced annually or if damaged. The replacement can be also performed by the user according to the following procedure. It is recommended to wear gloves for the following steps:



1. Remove Luer-lock connector from fitting.
2. Remove needle holder by unscrewing the screws
3. Exchange wash needle
4. Mount needle adapter so that needle is centrally aligned on the bottom of the rear lid of the cartridge rotor and tight the two screws firmly.





XX. Troubleshooting MAX devices

Error messages from the analyser will be presented by the RAPTOR SERVER Analysis Software as described in section XVII.13. When a serious error occurs, the analyser gets into a “stop-state”; this can be caused by the following events:

XX.1 LEAKAGE SENSOR

The cartridge rotor is equipped with a leakage detector underneath to detect a drain overflow.



If a leakage is detected, the MAX stops, and the error is reported by RAPTOR SERVER. Switch off the instrument with the main switch and disconnect the power cable. Contact MADx or your local distributor.

XX.2 CRASH SENSOR

The pipetting robot is equipped with a crash detection unit to detect vertical crashes of the pipettor needle. If the sensor is triggered, the MAX stops all motions and pumps. The user can examine the position where the crash took place to potentially identify the root cause. By performing the “Initialize” procedure via the RAPTOR SERVER Analysis Software (see section XVII.6) the user can recover the analyser to perform further steps. A run cannot be resumed.



If a second vertical movement crash is detected after an “Initialize”, please contact MADx service or your local distributor.

XX.3 UN-AUTHORIZED MAIN COVER OPENING

The main cover is secured with an interlock system. If the cover gets opened while the instrument is active, all mechanical motions and pumps stop. Therefore, only open the top cover authorized via the button on RAPTOR SERVER. After closing the cover, the user can recover the analyser to perform further steps by performing the “Initialize” procedure via the RAPTOR SERVER Analysis Software (see section XVII.6).



If an un-authorized main cover opening occurs, MacroArray Diagnostics disclaims all liability for damage to the analyser or uncomplete test results.



XX.4 PIPETTOR NEEDLE RINSING STATION: MISSING SYSTEM WATER

As the needle outer rinse is performed via the waterfall at the rinsing station, the existence of System Water – which is necessary to ensure the proper cleaning of the outer needle surface - is controlled. If no Liquid Level Detection (LLD) occurs, an error is recorded for the corresponding cartridge.

	<p>If the rinsing station regularly lacks sufficient System Water for the exterior needle cleaning, contact MADx service or your local distributor.</p>
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XX.5 WASHING SOLUTION FLUIDICS INTEGRITY

The function of the dosing pump (washing solution) is automatically controlled at the start and in the end of a run, by imaging a cartridge after Washing Solution dispensation. Thereby, the risk of an undetected malfunction (air leaks in the washing solution fluidics) during the run is decreased.

If the control fails before the run, the run does not start, and the user sees the “integrity check failed” screen. The user can then either retry to start the run again (including a repeated integrity check) or press “Skip” to jump back to the “verify setup” page.

<p>Max45k Integrity check failed - since a minute</p>	<p> Integrity check failed. Would you like to retry?</p>	<p><input type="button" value="Retry"/> <input type="button" value="Skip"/></p>
---	---	---

If the error occurs for the second time, and/or air inclusions can be observed in the tubing of the Washing Solution, contact MADx Support or your local distributor. If the control fails at the end of the run, the results will still be uploaded, but tagged automatically and with the error noted in the measurement details. The User should be cautious about the quality of the results.

	<p>If the dosing pump does not apply enough washing solution to the cartridges, perform a preventive pressurized flushing of the dosing pump, as described in section XV.2.4. If the error prevails even after flushing, please contact MADx support or your local distributor.</p>
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XX.6 WASTE PUMP MALFUNCTION

After a series of pipetting steps is finished (e.g., sample pipetting) the device controls the fill level of the drainage of the active rinsing station to ensure that no clogging or waste pump malfunction occurs. If a liquid surface is detected, the analyser transits into the “Stop State”.

	<p>If the rinsing station drainage does not work, please contact MADx Support or your local distributor.</p>
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XX.7 AUTO-ALIGNMENT MALFUNCTION (MAX 9K)

Each time the instrument is started, or the “Initialize” button is pressed, a position alignment is performed. During this alignment process, the needle is checked fully automatically for bending and its main positions are checked and adjusted if necessary. In the following possible errors are shown and their possible causes and solutions are described.

XX.7.1 ERROR DETECTED DURING REFERENCING AT RINSING STATION, SAMPLE ROTOR OR CARTRIDGE ROTOR

Possible Causes:

- Sample Rotor is not inserted
- Cartridge rotor movement malfunction
- Sample rotor positioning malfunction
- Unknown error in the process

Possible Solution:

- Insert the Sample Rotor and restart the initialization process.
- Contact your local distributor or MADx support

XX.7.2 ERROR DETECTED DURING ALIGNMENT AT THE PARKING (HOME) POSITION OF THE PIPETTE

Possible Cause:

- Needle is bent
- Error during movement of pipettor to parking (home) position
- Error during finding the centre with LLD

Possible Solution:

- Replace the needle (see section XVI.7)
- Contact your local distributor or MADx support

XX.7.3 ERROR DETECTED DURING ALIGNMENT AT THE RINSING STATION

Possible Cause:

- Error during movement of pipettor at rinsing station

Possible Solution:

- Contact your local distributor or MADx support



XX.7.4 ERROR DETECTED DURING ALIGNMENT AT THE SAMPLE ROTOR

Possible Cause:

- Error during movement of pipettor or sample rotor
- Too many iterations needed to align sample rotor

Possible Solution:

- Insert Sample Rotor
- Contact your local distributor or MADx support

XX.7.5 ERROR DETECTED DURING ALIGNMENT AT THE CARTRIDGE ROTOR

Possible Cause:

- Given position cannot be reached for cartridge rotor
- Cartridge rotor movement malfunction
- Cartridge rotor cover not properly closed

Possible Solution:

- Contact your local distributor or MADx support

XX.7.6 ALIGNMENT ERROR WHEN READING CONFIG FILES

Possible Cause:

- Config files corrupt

Possible Solution:

- Contact your local distributor or MADx support

XX.8 FURTHER ERROR MESSAGES

In addition to the above-mentioned severe errors, the analyser is capable to provide further error codes.

Severity	Description	Instrument Operation
Severe	The highest error severity (3)	Instrument stops all movements, no test results can be achieved, no test run can be started.
Error	A middle error severity (2)	Instrument stops partial movement, test run can be continued, partial test results can be achieved.
Warning	The lowest error severity (1)	Instrument does not stop movement, test run can be continued, all or partial test results can be achieved.
Info	Information to be logged (without error severity (0))	Information is logged and there is no impact on instrument movement.

Table 4 Error severities



XXI. TECHNICAL SPECIFICATION

Item	Specification MAX 45k	Specification MAX 9k
Throughput	Up to 100 tests per working day (8h) and 150 tests including 1 overnight run	Up to 20 tests per working day (8h) and 30 tests including 1 overnight run
Sample pipetting volume	100 µl to 399 µl	
Reagent pipetting volume	100 µl to 400 µl	
Low Volume sample tubes	Sarstedt false-bottom tubes 2.5 ml, 75x13 (round), Order number: 60.614.010	
13 mm Standard Tubes	Height: 75-100 mm For example: Sarstedt tubes 5 ml, 75x13 mm, PS Order number: 55.475 Use with provided adapter	Height: 75mm. For example: Sarstedt tubes 5ml, 75x13mm (Order No.: 55.475)
16 mm standard tubes	Minimum height: 75 mm, maximum height: 100 mm For example: Sarstedt tubes 13 ml, 100x16 mm, PS Order number: 55.459	
NOTE: Before using any other tube than specified above, please contact MADx support or your distributor.		
Minimum sample volume for 1 ALEX ² test, 13/16 mm standard tube	Not prediluted: 400 µl Prediluted manually: 145 µl serum + 580 µl Sample Diluent	
Minimum sample volume for 1 ALEX ² test, Low Volume tube	Not prediluted: 200 µl Prediluted manually: 120 µl serum + 480 µl Sample Diluent	
Minimum sample volume for 1 FOX test, Low Volume tube only	Prediluted ONLY: 600 µl (12 µl serum + 588 µl Sample Diluent)	
Maximum number of onboard samples	50	10
Maximum number of assay runs with one ALEX ² / FOX kit (Washing Solution)	4	5



Item	Specification MAX 45k	Specification MAX 9k
Sample container	Sample tubes with a nominal height of 75 mm - 100 mm and a nominal outer diameter of 13 mm (with adapter) or 16 mm (13 mm tubes with adapter)	Sample tubes with a nominal height of 75mm and a nominal outer diameter of 13mm
Sample barcode size	Max. 3 cm	
Sample barcode types	code128 code39 ean8 codabar code25	
Reagent container	15 ml, 30 ml	
Max number of onboard cartridges	50	10
Incubation temperature	37 °C ± 0.5 °C accuracy	
Mixing method	Non-Invasive	
Dimensions	Depth: 65 cm, Width: 115 cm, Height: 60 cm (closed main cover)	Depth: 42cm, Width: 59.2cm, Height: 58cm (closed main cover)
Ambient temperature	During operation: 18 to 30 °C During transportation and storage: 5 to 40 °C.	
Ambient humidity	During operation: 30 to 85 % RH (non-condensing) (relative humidity) During transportation and storage: 10 to 95% RH (relative humidity)	
Appropriate degree of pollution	2	
Altitude	-400 m to 2000 m above sea level	
Weight	~ 100 kg	37.1 kg
Power Management*	100-240 V, 150 W, 50/60 Hz	100-240V, 100 W, 50/60Hz
Noise Level	< 65 dB in 1m distance	

Table 5 Technical specification

* Any mains voltage fluctuations must not exceed +/- 10% of the rated voltage. Transient over-voltages must be within the limits normally encountered in the power grid. The rated level of the transient overvoltage is the voltage impulse withstand according to the overvoltage category II of IEC-60364-4-443.



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