



## MAX (Multi Array Xplorer) 45k

# Instruction Manual

- Instruction for Use -

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## Preface

Dear User,

We at MacroArray Diagnostics want to thank you for choosing our Multi Array Xplorer 45k analyzer (MAX 45k) for an automated analysis of ALEX<sup>2</sup> tests. The MAX 45k analyzer is ideal for small to medium-sized labs but can also be used in large labs for fully automatic quantitative determination of allergen specific Immunoglobulin E (sIgE) and semi-quantitative determination of total IgE (tIgE). This user guide contains step-by-step instructions for operating the analyzer and will help you with all the applications and enables you to use the functions of the MAX 45k. If you have any further questions that are not answered in this user guide, our MAX 45k team and our local business partners will be happy to help you. Please contact us at [support@macroarraydx.com](mailto:support@macroarraydx.com). We hope that the MAX 45k will meet your expectations.

Sincerely yours,

**Dr. Christian Harwanegg, MBA**

Chief Executive Officer MacroArray Diagnostics GmbH

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## 1. Introduction

This manual describes the use of the MAX 45k in laboratories with trained personnel. The following pages of this manual will guide you through the proper usage of the MAX 45k analyzer.

### 1.1. Terms and Definitions

Here is a description of the terms and symbols used in this guide and on the analyzer.

<b>User</b>	Person using the analyzer in accordance with the specifications.
<b>Intended use</b>	Use of a product, method, or service in accordance with the specifications, directions and instructions defined by MacroArray Diagnostics GmbH.
<b>Intended operation</b>	Operation, including readiness for operation, in accordance with the operating instructions or the intended use.
<b>Operator</b>	Individual or group responsible for the usage and maintenance of the analyzer. The operator makes sure the users have been appropriately instructed about how to operate the analyzer.
<b>Trained personnel</b>	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.
<b>Obvious damage</b>	Damage that can be seen with naked eye alone by careful observation of the analyzer or component, or that can be recognized by monitoring available displays, signals, or transmitted data.
<b>Process</b>	Resources and activities that interact to convert inputs into results.
<b>Damage</b>	Physical injury or damage to human health, damage to goods or the environment
<b>Verification</b>	Confirmation by providing objective evidence that defined requirements have been fulfilled.
<b>Validation</b>	Confirmation by providing objective evidence that the requirements for a specifically intended use or specifically intended application have been fulfilled.

## 1.2. Manufacturer

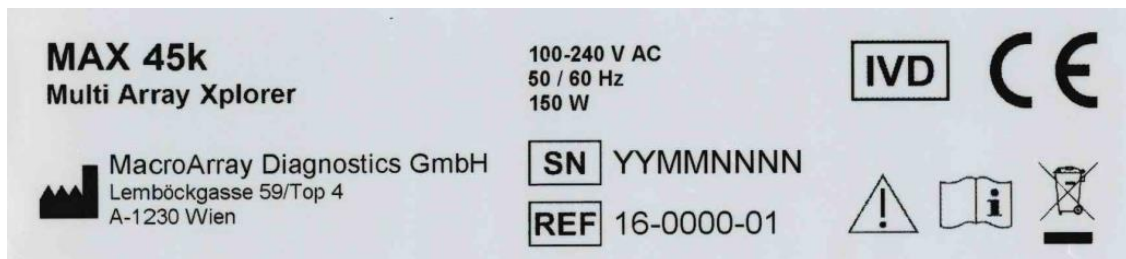
The MAX 45k is manufactured by MacroArray Diagnostics GmbH



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## 1.3. Identification of the Analyzer

An identification label is placed at the rear side of the MAX 45k analyzer.



**Figure 1**

Identification label details placed on the rear side of the analyzer.

## 1.4. Performance Data

### 1.4.1. Assay Calibration

For the Assay Calibration refer to the IFU of the ALEX<sup>2</sup> test

### 1.4.2. Measuring Range

For the Measuring Range refer to the IFU of the ALEX<sup>2</sup> test

### 1.4.3. 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 GmbH provides acceptance ranges for the most recent batches of Lyphochek® sIgE Control Panel A. These values are stored in RAPTOR SERVER and cannot be edited by the user.

See section 5.10 for further details on how the quality control system is implemented on MAX 45k.

#### 1.4.4. Data Analysis

ALEX<sup>2</sup> images are automatically analyzed using MADx's RAPTOR SERVER and a report is generated summarizing the results for the user.

#### 1.4.5. Results

ALEX<sup>2</sup> is a quantitative method for specific IgE and semi-quantitative method for total IgE. Allergen specific IgE antibodies are expressed as IgE response units (kU<sub>A</sub>/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).

#### 1.4.6. Limitation of the Procedure

For the Limitation of the procedure refer to the IFU of the ALEX<sup>2</sup> test

#### 1.4.7. Expected Values

For the expected values refer to the IFU of the ALEX<sup>2</sup> test

#### 1.4.8. Performance Characteristics

Precision (lot-lot variation):

The lot-to-lot variation was determined on three MAX 45k instruments in three separate runs. Multi-sensitized samples covering 220 allergens of the ALEX<sup>2</sup> allergen panel were included in the study. The study comprised 451 allergen per sample combinations at three different levels: >10 kU<sub>A</sub>/L, 1-10 kU<sub>A</sub>/L and 0,3-1 kU<sub>A</sub>/L. For the selected allergen components, the CV (in %) was calculated between runs and between instruments (= total CV).

	CV (betw. 0,3-1 kU <sub>A</sub> /l)	CV (betw. 1-10 kU <sub>A</sub> /l)	CV (>10 kU <sub>A</sub> /l)	CV (>1 kU <sub>A</sub> /l)
Total CV%	24.0	11.0	9.1	10.6

Homogeneity (within-run precision):

The homogeneity of the results within a MAX 45k test run was tested on three separate MAX 45k instruments. The same multi-sensitized positive test sample (107 allergens > 0,3 kUA/L) was tested at all positions of the cartridge carousel of the MAX 45k instruments.

	CV (betw. 0,3-1 kU <sub>A</sub> /l)	CV (betw. 1-10 kU <sub>A</sub> /l)	CV (>10 kU <sub>A</sub> /l)	CV (>1 kU <sub>A</sub> /l)
CV%	33.6	12.3	9.2	11.5

Analytical Sensitivity:

For the Limit of Detection refer to the section performance characteristics in the IFU of the ALEX<sup>2</sup> test



**Analytical Specificity:**

For the Analytical Specificity refer to the section performance characteristics in the IFU of the ALEX<sup>2</sup> test

**Interference:**

For the interference with other substances refer to the section performance characteristics in the IFU of the ALEX<sup>2</sup> test

**1.5. Principle of the Procedure**

ALEX<sup>2</sup> is a solid-phase immunoassay. MAX 45k is an IVD device which is intended to automatically perform all steps for up to 50 ALEX<sup>2</sup> tests in one assay run. 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, colored 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 MAX 45k. The test results are analyzed with MADx's RAPTOR SERVER Analysis Software and reported in IgE response units (kU<sub>A</sub>/L). Total IgE results are also reported in IgE response units (kU/L).

**1.6. Service**

MacroArray Diagnostics GmbH or its authorized representatives are available to repair the analyzer during normal local office hours. Should a service be required at any other time, contact the MacroArray Diagnostics GmbH service or a local representative authorized by MacroArray Diagnostics GmbH. You will receive information about how to reach the MacroArray Diagnostics GmbH service when the analyzer is installed, or visit <https://www.macroarraydx.com/> to find contact information. The scope of agreed service is included in your service contract.

**1.7. Warranty**

MacroArray Diagnostics GmbH and its representatives guarantee that the analyzer 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 GmbH service or its representatives. 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 authorized by MacroArray Diagnostics GmbH. Maintenance needs to be performed as described in this manual and in den RAPTOR SERVER Analysis Software documentation. Improper interventions on the analyzer void the warranty and can result in service charges. Only use the analyzer as intended. If the analyzer is not used as intended, MacroArray Diagnostics GmbH disclaims all liability for damage to the analyzer.

## 1.8. Ordering information

Use only consumables, accessories and spare parts provided by or recommended by MacroArray Diagnostics GmbH. Order these items only from MacroArray Diagnostics GmbH or representatives authorized by MacroArray Diagnostics GmbH. For ordering information, see the MacroArray Diagnostics GmbH brochure for the MAX 45k or contact the MacroArray Diagnostics GmbH service team at [support@macroarraydx.com](mailto:support@macroarraydx.com).

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

## 2. Safe Handling

### 2.1. Intended Use

The MAX 45k analyzer is intended for an automated in-vitro diagnostics (IVD) use for quantitative determination of allergen specific Immunoglobulin E (sIgE) and semi-quantitative determination of Total IgE (tIgE). The MAX 45k is suitable for human serum or plasma (Heparin, Citrate, but no EDTA). MAX 45k is intended to be used only in conjunction with RAPTOR SERVER Analysis Software and ALEX based technology arrays.

The semi-quantitative and quantitative determination is intended as an aid in the clinical diagnosis of patients with allergies in conjunction with other clinical and laboratory findings. For that reason, the final diagnosis must be realized by a medical expert under consideration of all available clinical findings and other laboratory parameter.

The MADX Cartridge Analyzer instrument is 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.

### 2.2. General Safety Information

The analyzer 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 9 are met.

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

#### 2.2.1. Operator Qualification

The analyzer 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.

#### 2.2.2. Electrical Safety

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

- The analyzer 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 MAX 45k needs to be opened before maintenance, repair or replacement work, switch off the analyzer and disconnect it from all voltage sources as described in the relevant procedure.

Please avoid damage to the system because of short-circuit by spilled liquids that gets 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 analyzer to prevent the risk of malfunctions of the MAX 45k analyzer.

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

### **2.2.3. Mechanical Safety**

To avoid serious injury by moving mechanical parts, the analyzer is equipped with an internal interlock that prevents the opening of the main cover during the movement of mechanical parts. Never bypass this internal interlock mechanism!

### **2.2.4. 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 GmbH.

### **2.2.5. 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

### 2.2.6. Operational Conditions







When operating the MAX 45k, ensure compliance with the specified ambient conditions (see section 9); these must be strictly adhered to. See also section 3.2. - **Site Preparation 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 GmbH or their authorized representative only, and not by the operator.




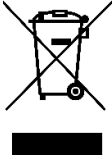


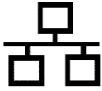



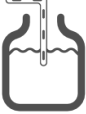
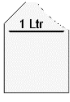
### 2.2.7. Decontamination










If hazardous materials are spilled on or into the analyzer, an appropriate decontamination procedure must be performed. If you have any questions or doubts concerning the compatibility of decontamination- or cleaning agents with analyzer components or component materials, please contact MacroArray Diagnostics GmbH. For safety reasons, the MAX 45k analyzer must be disinfected/decontaminated before repairs and service work are performed. Make sure you follow the instructions for decontaminating the analyzer. Before decontamination and/or disinfection, disconnect the analyzer 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.

## 2.3. Safety Symbols/Warning Labels on the Analyzer

The following safety warning labels or other symbols are placed on the analyzer or described in detail in this manual.

	Caution, consult accompanying description in this manual
	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
 T3.15A 500VAC	Fuse characteristics
	Biohazard
	System-Water
	Wash-Buffer Solution
	1 Liter Level

	10 Liter Level
	Protective Grounding
	Catalogue number Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Temperature limit Indicates the temperature limits to which the medical device can be safely exposed.
	Use-by date Indicates the date after which the medical device is not to be used.
	Batch code Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Do not re-use Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Warning (GHS pictogram)
	Do not use if package is damaged

**Table 1**  
Symbols on the analyzer and container.

#### 2.4. Safety Messages/Signal Words within this Manual

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.

## **2.5. Legal Requirements**

### **2.5.1. International Standards**

The MAX 45k analyzer has 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.

### **2.5.2. CE Conformity**

The MAX 45k analyzer holds a CE mark which certifies that the MAX 45k analyzer meets 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

### **2.5.3. Electromagnetic Compatibility (EMC), Radio Interference Suppression and Immunity to Interference**

The MAX 45k has been tested in accordance with EN IEC 61326-2-6 and corresponds to CISPR 11 Class B.

## **2.6. Obligations of the Owner of the Analyzer**

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



### 3. Life Cycle

This section describes the stages the MAX 45k analyzer goes through, beginning from delivery to disposal, and the requirements involved for the operator within each stage.

#### 3.1. Delivery

##### 3.1.1. Checking for Damages during Transport

The analyzer outer packaging ensures the best possible protection against transport damage. Nevertheless, please check each shipment immediately upon receipt for visible transport damage. If you receive an incomplete or damaged shipment, please directly contact MacroArray Diagnostics GmbH or its official representative. Please notify the carrier about apparent damage.

##### 3.1.2. Unpacking



Caution

The MAX 45k shall be unpacked and lifted out of the packaging only by MacroArray Diagnostics GmbH or its authorized partners and only be operated by specialized personnel (laboratory personnel) who have previously undergone training in how to use the analyzer. This training can only be provided by MacroArray Diagnostics GmbH or its authorized partners. By these means, injury of the operator resulting from overload such as pulled muscles or disk lesion will be avoided.

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

Left and right side of the analyzer:	> 200 mm
Back side:	> 120 mm
Space on top (for lid opening):	> 500 mm

##### 3.1.3. Scope of Delivery

Included Items
1x MAX 45k Analyzer
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 Wash-Buffer Solution Container
1x Image Acquisition Module
1x Steel Needle
5x Segments
1x Cartridge Rotor – Front Cover
1x Cartridge Rotor – Rear Cover
1x Power Cord
1x Ethernet Cable

**Table 2**

List of items available for delivery.

An ALEX<sup>2</sup> assay kit (REF 02-5001-01), which is not included in the shipment of the MAX 45k instrument, is required for operation and must be ordered separately.

## 3.2. Installation

### 3.2.1. Site Preparation prior to Installation

The MAX 45k is intended for indoor use only and should be operated in a room with a controlled temperature. Before the analyzer is powered on ensure that the analyzer is at room temperature. Make sure that the electrical and environmental conditions are met, (see section 9).

### 3.2.2. Connect Fluidics Supplies and its Fill-Level Sensors

1. On the left side of the analyzer, plug the container tubing into the corresponding sockets, see container connection panel in section 4.3.1.
2. On the left side of the analyzer, connect the power cord for the fill level sensors of the container, see container connection panel in section 4.3.1.

### 3.2.3. Connect Power Source

1. At the right side of the analyzer, plug the power cord into the socket, see power module in section 4.3.4.
2. Plug the power cord into a power outlet with a ground contact as shown in section 4.3.4.

### 3.2.4. Connect Ethernet Communication

1. At the right side of the analyzer, plug the ethernet cable into the socket, see Ethernet panel section 4.3.4.
2. Plug the other end of the Ethernet cable into a PC or into the lab network ethernet connector socket (see section 4.3.4.).

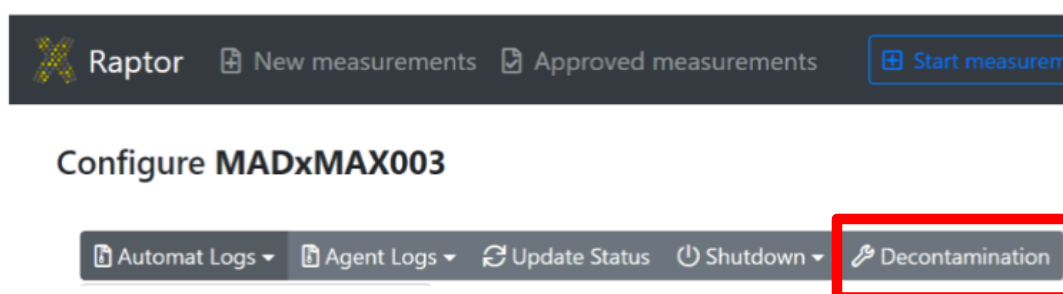
### 3.2.5. Start Analyzer

1. Close the main flap, see section 4.3.3.
2. At the right side of the analyzer, set the mains switch to position I, see section 4.3.4.
3. Start the analyzer and perform a function test for proper installation, see section 5.

### 3.3. Non-Operation

To prepare the analyzer for a longer period of non-operation, proceed as follows:

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



3. Shutdown the analyzer via RAPTOR SERVER Analysis Software, see section 5.9.
4. At the right side of the analyzer, set the mains switch to position 0, see section 4.3.
5. At the right side of the analyzer, unplug the power cord from the socket, see Power module switch in section 4.3.
6. At the right side of the analyzer, unplug the ethernet cable from the socket, see Ethernet panel in section 4.3.
7. At the left side of the analyzer, unplug the container tubing and fill level sensor cable from the corresponding sockets (see section 4.3.).
8. Empty and clean all container.
9. Remove the cartridge rotor front and rear cover.
10. Remove the segments.
11. Clean the cartridge rotor, see section 6.
12. Insert cartridge rotor rear and front cover.
13. Clean the sample and reagent rotor, see section 6.
14. Clean the exterior surfaces, see section 6.
15. Close main flap.

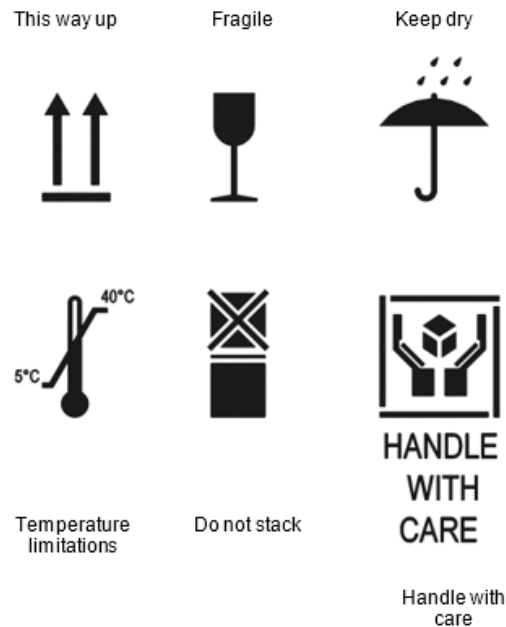
### 3.4. De-Installation

To de-install the analyzer, proceed as follows:

1. Prepare the analyzer for non-operation (non-operation, see section 3.3.).
2. If you want to store the analyzer, make sure that the storage location meets the storage and transportation conditions, see the technical specifications in section 9.

### 3.5. Transport

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



### 3.6. Disposal

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

MacroArray Diagnostics GmbH 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 GmbH service or its authorized partners regarding disposal of the analyzer.

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



Treat contaminated material according to national and local standards and regulations. Before transport or disposal, disinfect parts of the analyzer that may be contaminated according to national and local standards and regulations. If you need assistance, contact MacroArray Diagnostics GmbH or its partners.



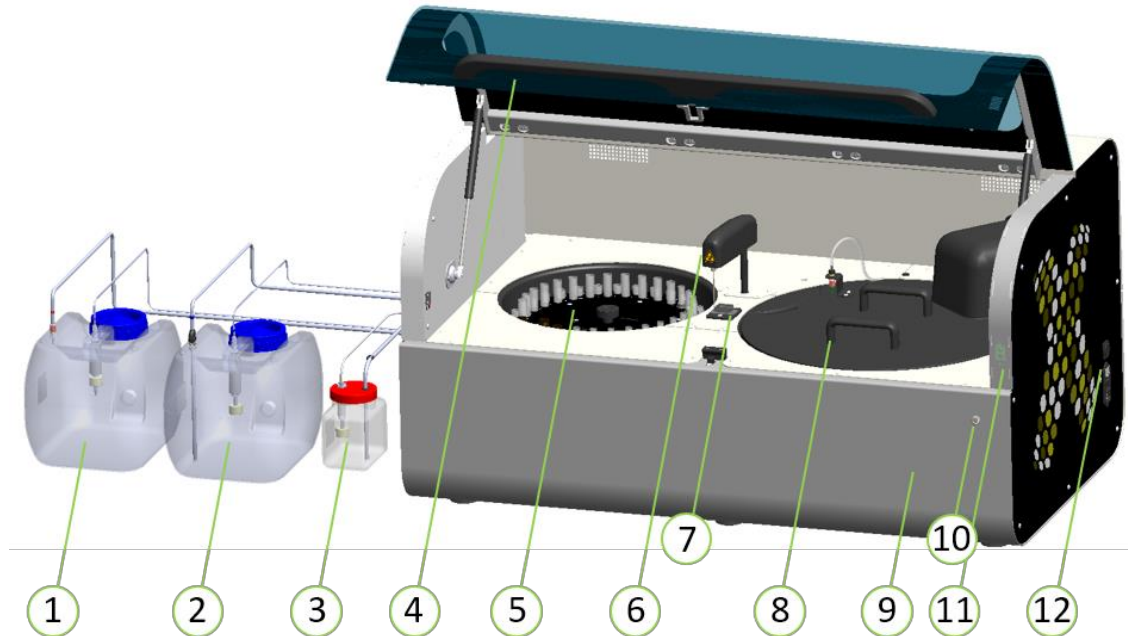
Do not treat electrical and electronic equipment as unsorted municipal waste and check with your local waste disposal contractor for specific requirements regarding disposal. Please collect waste electrical and electronic equipment separately and return them to MacroArray Diagnostics GmbH or its partners in areas where the above-mentioned directive is enforced.

To dispose of the analyzer, proceed as follows:

1. De-install the analyzer, see section 3.4.
2. Contact the MacroArray Diagnostics GmbH service or its authorized partners regarding disposal of the analyzer.
3. Dispose of the analyzer according to national and local standards and regulations.

## 4. Description

### 4.1. Overview of the Analyzer



- 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 Flap
- 5 Sample and Reagent Rotor
- 6 Pipetting Robot
- 7 Needle Wash Station
- 8 Cartridge Rotor
- 9 Housing
- 10 Recover Push Button
- 11 Status LEDs
- 12 Power and Ethernet Connector, Main Power Switch

**Figure 1**  
Functional sub-systems.

## 4.2. Principle of the Operation

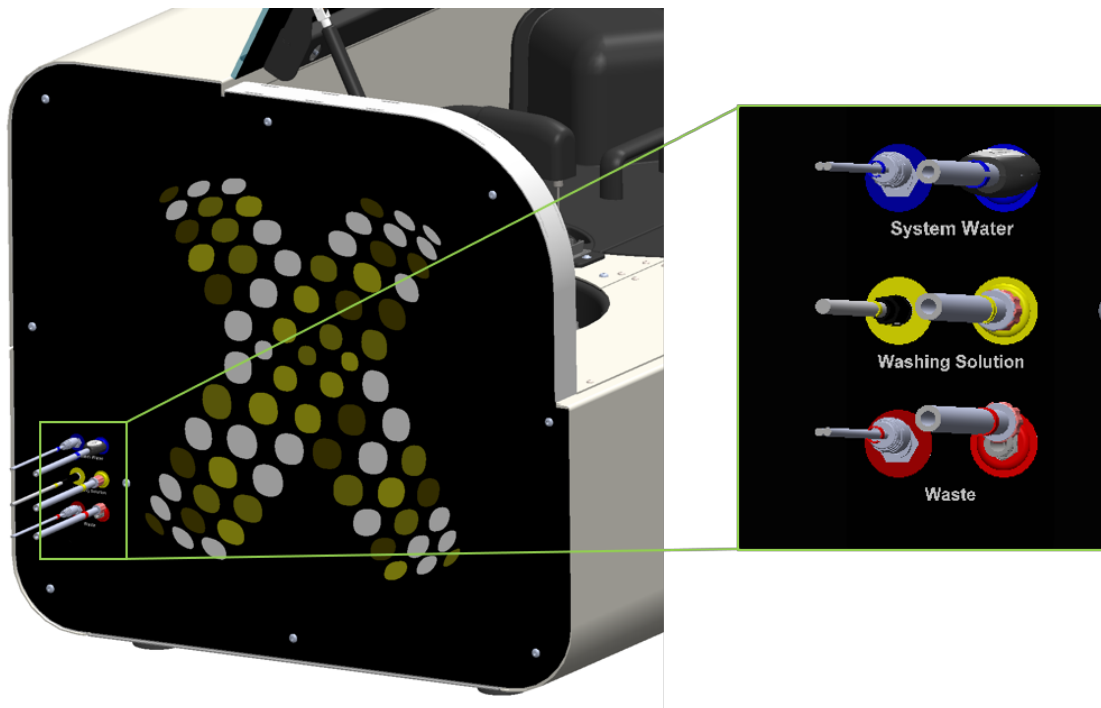
Note: The Instruction for Use for the ALEX<sup>2</sup> reagent kit (REF 02-5001-01) can be obtained online at [www.macroarraydx.com](http://www.macroarraydx.com) and should be consulted before any assay run is performed on the MAX 45k instrument.

- Sample tubes that contain serum or plasma and ALEX<sup>2</sup> kit reagents are loaded manually to the reagent and sample rotor.
- ALEX<sup>2</sup> kit cartridges are manually loaded to the cartridge rotor.
- Assignment of the sample (patient) to the cartridge is done via the software application RAPTOR SERVER.
- When the ALEX<sup>2</sup> process is started, dilution medium (ALEX<sup>2</sup> Sample Diluent) will be pipetted from the corresponding bottle to the loaded cartridges. Next, the samples are pipetted to the cartridge according to the software assignment, mixed and incubated for a certain period of time.
- The sample liquid is removed from the cartridges by centrifugation forces (fast spinning of the cartridge rotor) and wash-buffer solution (ALEX<sup>2</sup> Washing Solution) is applied on the cartridges multiple times.
- Secondary antibody (ALEX<sup>2</sup> Detection Antibody) solution will be pipetted from the corresponding reagent bottle to the cartridges sequentially, mixed and incubated for a certain time period.
- Secondary antibody solution will be removed from the cartridges and wash-buffer solution (ALEX<sup>2</sup> Washing Solution) is applied on the cartridges multiple times.
- Substrate solution (ALEX<sup>2</sup> Substrate Solution) will be pipetted from the corresponding reagent bottle to the cartridges sequentially and incubated for a certain time period.
- Stop solution (ALEX<sup>2</sup> Stop Solution) will be 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 will be removed from the cartridges and the cartridges and a final washing step will be performed.
- The cartridges are then dried and finally, image acquisition of each cartridges will be performed. The images are analyzed by RAPTOR SERVER.
- The operation principle allows a second protocol where manually pre-diluted samples can be loaded, and no diluent solution will be pipetted in the first place.

## 4.3. Housing

### 4.3.1. Left side of the Analyzer

**Figure 2** shows the different fluidics and electronics ports which are located on the left side of the analyzer 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, wastewater and wash-buffer solution container are highlighted in different colors 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 analyzer.



**Figure 2**  
Left Side of the analyzer.



### 4.3.2. Rear Side of the Analyzer

**Figure 3** shows the rear side of the analyzer. The rear side includes air inlets and outlets which must not be covered to ensure sufficient cooling and functionality of the corresponding units.



**Figure 3**  
Rear side of the analyzer.

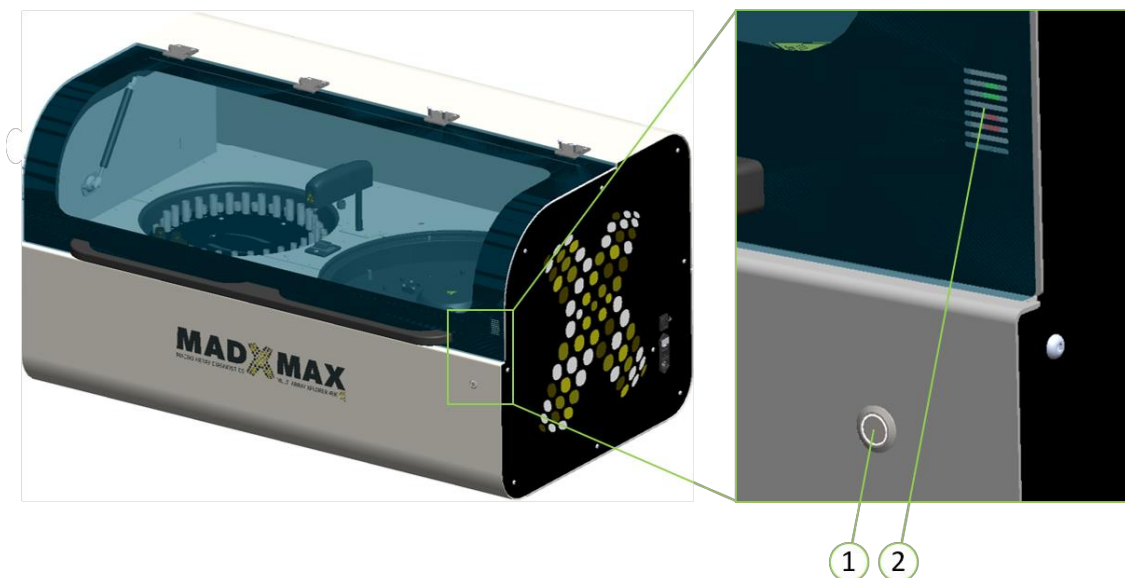
### 4.3.3. Front Side of the Analyzer

**Figure 4** shows the front side of the analyzer with closed main flap. On the right side of the analyzer's front panel, a recovery switch (circular push button) and two status LEDs are located. The lower LED is red, the upper LED green and the button is illuminated in white color. Both LEDs and the switch (push button) can change its status from permanently illuminated to a flashing state and reverse, indicating the different working status of the analyzer as shown in **Table 3**.

Working Status	Description
1	Analyzer is off. Push button LED and the status LEDs are switched off.
2	After the main power switch is turned on, the push button LED will flash quickly until the operating system of the instrument is loaded and analyser's sub systems are powered. Finally, the push button LED is turned on permanently and both status LEDs are off.
3	During initialization of the analyser, the push button LED is permanently on and the green LED is flashing, where else the red LED is off.

4	After the analyser initialization is finished, the green LED will turn from flashing to “permanent on” status. The red LED is still off. The push button LED is permanently on.
5	If the analyser is in operation, the push button LED is permanently on. The green LED is flashing, and the red LED is off.
7	When the analyser will be shut down via RAPTOR SERVER Analysis Software, the push button LED turns from permanent on to slow flashing status (flashing interval of approx. 5 s) The green LED goes off. The red LED is still off. In this state, the analyser can be turned off by the main switch or recovered by pressing the push button.
8	Whenever the analyser is in a Stop state (main flap opened or error), the push button LED and red LED are permanently on. Green LED is off.

**Table 3**  
Explanation of different working status of the analyzer.

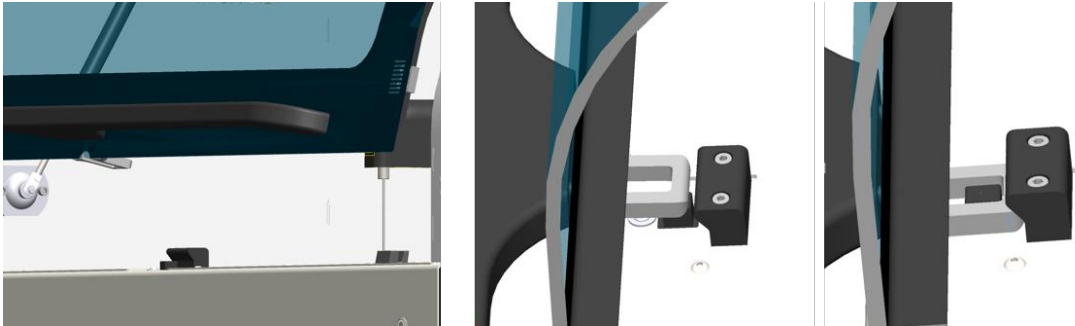


- 1 Recover Push Button
- 2 Status LEDs (Green and Red)

**Figure 4**  
Front side view of the analyzer.

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

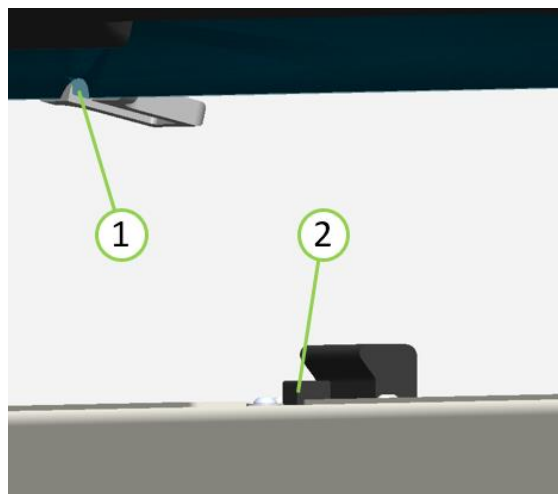
To prevent any unforeseen opening of the “Main Flap” during operation (mechanical movements), the main flap is secured by an interlock system (see **Figure 5**) which can only be opened via the RAPTOR SERVER Analysis Software. The design of the interlock is designed in a way that in case of a software- or electrical malfunction, the main flap will be permanently locked, and the user gets no access to the working deck.



**Figure 5**

Illustration of interlock functionality of the main flap.

In this case, the user can bypass the interlock with a screwdriver via the recess (see **Figure 6**) of the main flap by pushing down the integrated spring lock and pulling the main flap upwards.



**Figure 6**

Bypassing the interlock.

In case a tool is used during operation and the main flap is opened, the analyzer will stop all mechanical motions immediately. MacroArray Diagnostics GmbH disclaims all liability for damage to the analyzer by manually bypassing the interlock during operations.

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

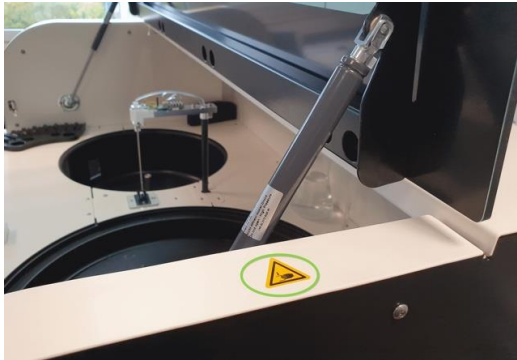
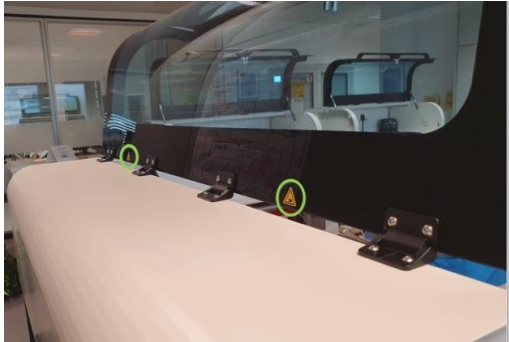


Caution

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

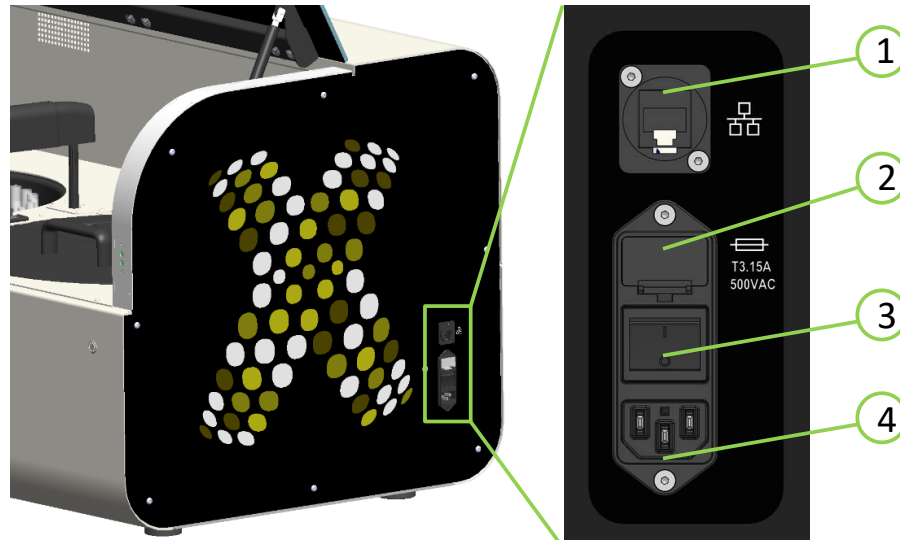


Additional warning symbols in front of the opened main flap, on both sides of the analyzer and on top of the main flap - as shown in the following pictures (highlighted with green circles) - shall warn the user and third person to keep off fingers and hands from the analyzer when main flap will be closed by the user.



#### 4.3.4. Right Side of the Analyzer

**Figure 7** shows the main power entrance module incl. fuse drawer and Ethernet connection port, which are located on the right side of the analyzer.



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

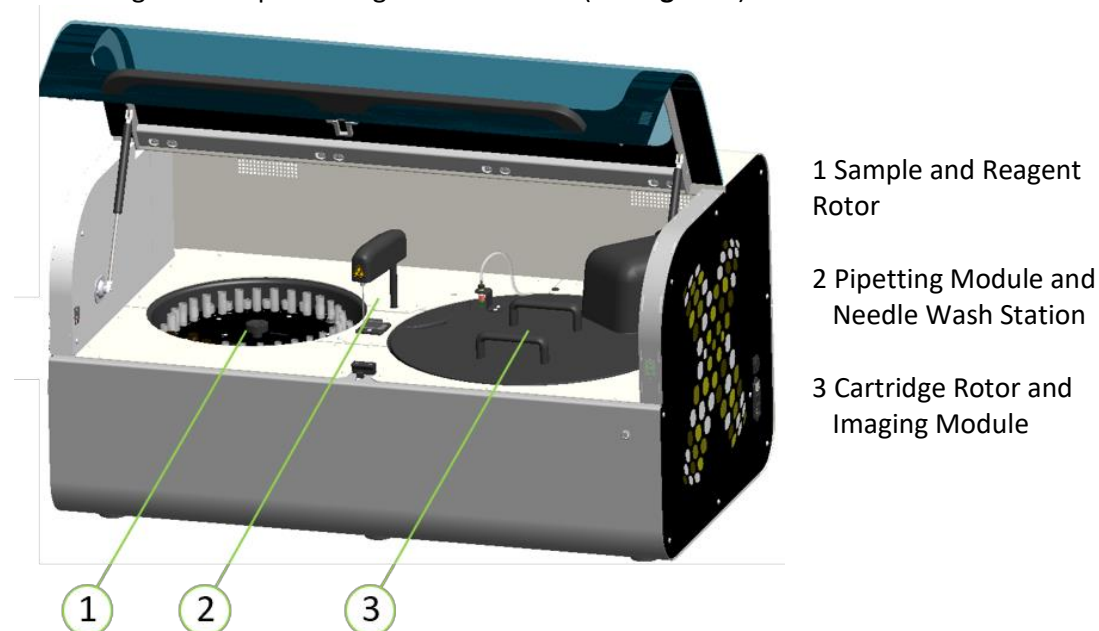
**Figure 7**  
Right side of the analyzer.

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

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

#### 4.4. Working Deck of the Analyzer

By opening the main flap, the user will get direct access to the main functional modules on the working deck for processing the ALEX<sup>2</sup> tests (see **Figure 8**).



**Figure 8**

Main functional modules on the working deck.

##### 4.4.1. Sample and Reagent Rotor

**Figure 9** shows the sample and reagent rotor of the analyzer. Only the reagent bottles (30ml and 15ml) provided in the ALEX<sup>2</sup> kit shall be loaded, all caps must be removed. The sample and reagent rotors include three openings to load 30ml reagent bottles and one opening for loading the 15ml reagent bottle. The RAPTOR SERVER Analysis Software will localize and identify the type of the reagent which has been loaded with the barcode presented on the reagent labels.

In addition, up to 50 sample tubes can be loaded with a nominal diameter of 13mm or 16mm whereby the 13 mm tubes shall be loaded with a tube adapter only. Tubes with a height of minimum 75mm and maximum 100mm can be loaded. **Please consult section 9 for the specification of the sample tubes and minimum volumes.**



Caution

Samples and reagents shall be handled according to the ALEX<sup>2</sup> kit Instruction for Use. Avoid air bubbles which potentially can lead to wrong pipetting steps and test results accordingly. **Clotted samples must not be used.**



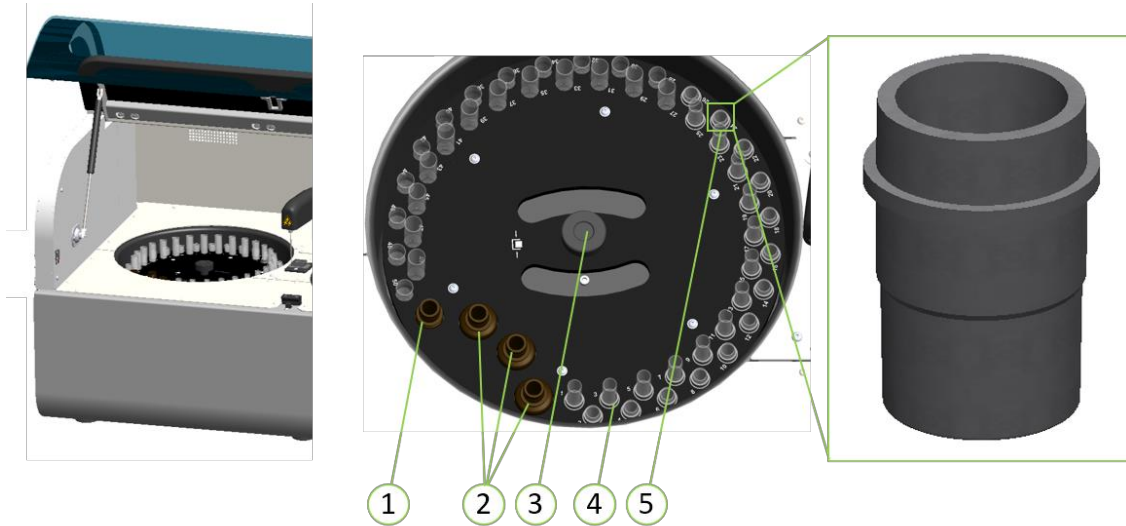
Caution

If the tube adapter is not applied for the 13mm tubes, damage to the needle can be provoked by a tilted tube. When a vertical movement is blocked by the tilted tube, the analyzer will stop all movements automatically to prevent further damage, and the analyzer will transit into "Stop State". The assay run is aborted.



Caution

If tubes are loaded with a height of more than 100mm, a collision with the horizontal movement of the needle can be provoked, resulting in a damage of the needle and the analyzer.



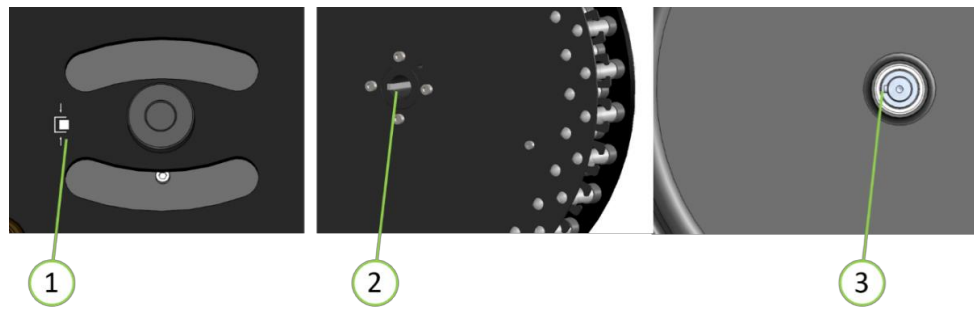
- 1 15 ml Reagent Bottle
- 2 30ml Reagent Bottle
- 3 Thumbscrew
- 4 Sample Tube
- 5 Sample Tube Adapter

**Figure 9**

**Left:** Positioning of the sample and reagent rotor. **middle:** Overview of loading positions and its marking. **Right:** Schematics of the sample tube adapter.

For cleaning and loading purpose, the sample and reagent rotor disc can be removed from the analyzer 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 discs are equipped with a tongue and groove mechanism to insert 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 10**. After insertion of the rotor disc, the thumb screw must be tightened.



**Figure 10**

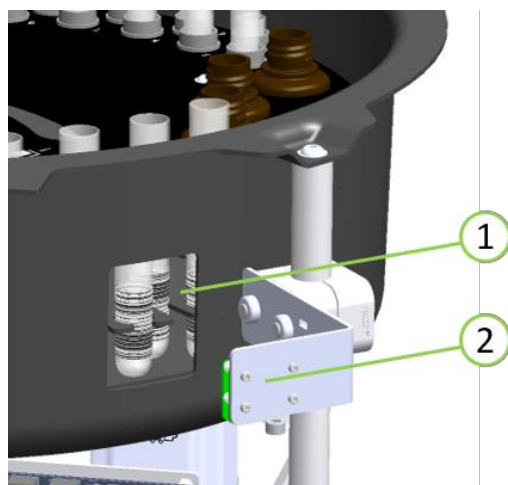
**Left:** Marking on top of the rotor disc. **Middle:** Groove shown from underneath the rotor disc. **Right:** Tongue included in the rotor axis visible after rotor disc is removed.

The sample and reagent rotor discs are surrounded by a plastic pot (working as a tub for liquids) to prevent leakage of spilled over liquids into the instrument. By removing the rotor disc, the user has easy access to clean the tub. In addition, the sample and reagent rotor are equipped with a barcode reader to read the sample and reagent barcodes.



Caution

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 11**.



1 barcode reading cut out in the tub.

2 barcode electronics and optics.

**Figure 11**

Detailed schematics of barcode reading capability of the sample and reagent rotor.

#### 4.4.2. Cartridge Rotor and Image Acquisition Module

**Figure 12** 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. 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 carousel.



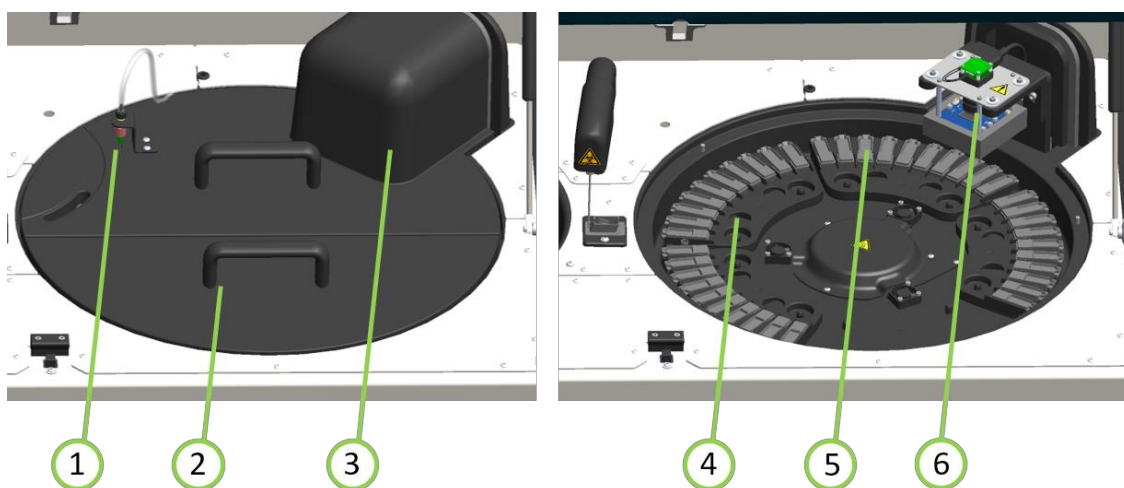


Caution

The front lid must be placed back again before a new assay run is started. Otherwise wrong results may be obtained.

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 the segment between the forefinger and thumb into the big cut outs and loading the segments so that the two alignment pins of the rotor plate correspond to the alignment holes in the segment (see **Figure 13**).

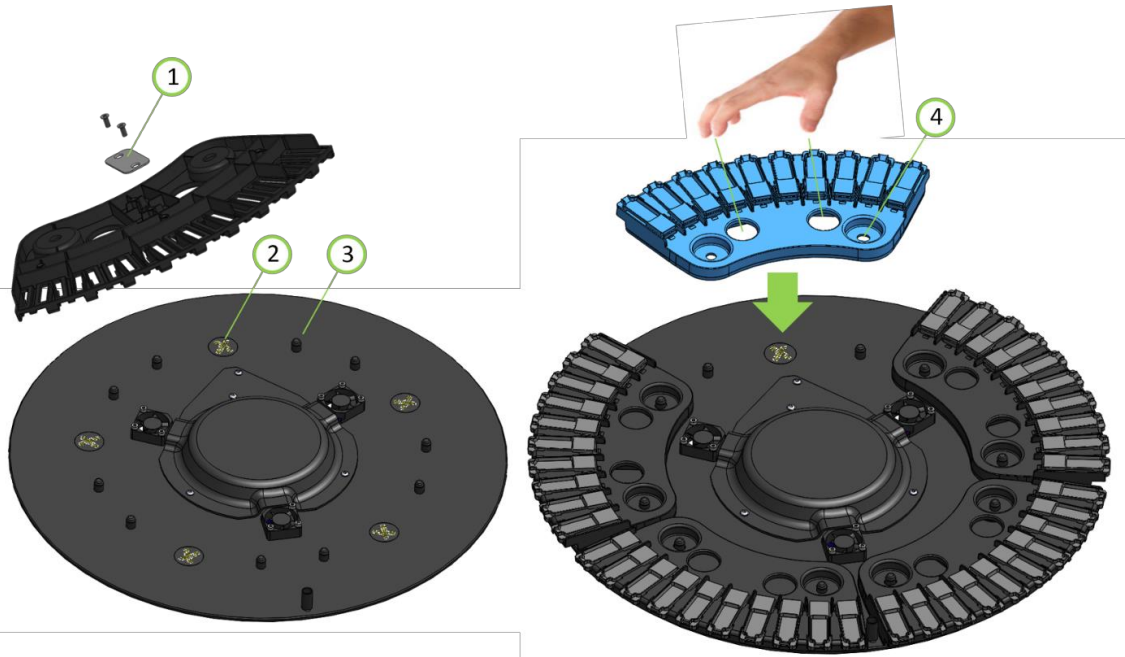
The ALEX<sup>2</sup> cartridges can be load on to the segments outside or inside of the instrument. The loading procedure is shown in **Figure 14**. To load the cartridge, the user has to take the cartridge with the fingers touching only the side or barcode part of the cartridge. By putting the cartridge into the segment slot and sliding from the inner to the outer position the final fixation point is indicated by a click sound.



- 1 Wash-buffer solution dispensing needle
- 2 Front Rotor Cover
- 3 Rear Rotor Cover
- 4 Cartridge Segment
- 5 Cartridge
- 6 Image Acquisition Module

**Figure 12**

Overview of cartridge rotor assembly.



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

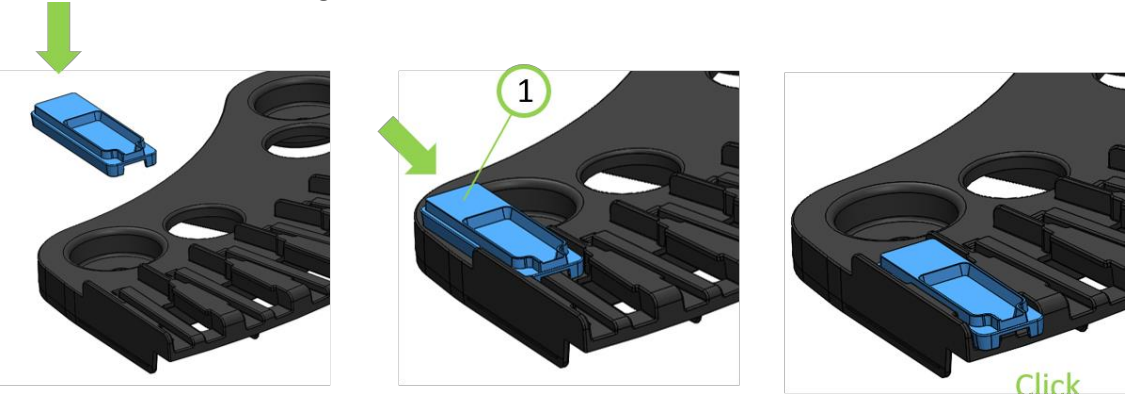
**Figure 13**

Schematic for handling/loading of cartridge segments.



Caution

The cartridge must be discarded if the user touches the surface of the nitro cellulose matrix in the cartridge due to potential malfunction of the cartridge.

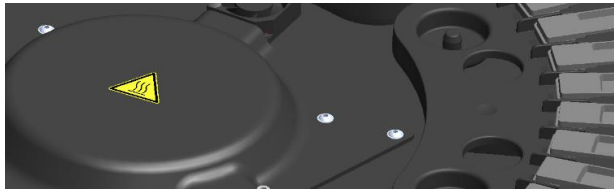


- 1 barcode Area of the Cartridge

**Figure 14**

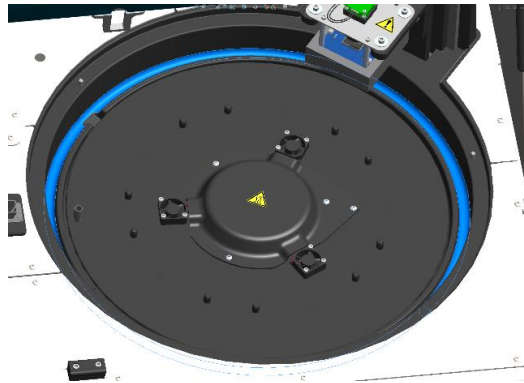
Schematic for loading the cartridge into the segment.

The cartridge rotor plate is generally heated between 30°C and 50°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 center part of the rotor plate.



Caution, hot surface!

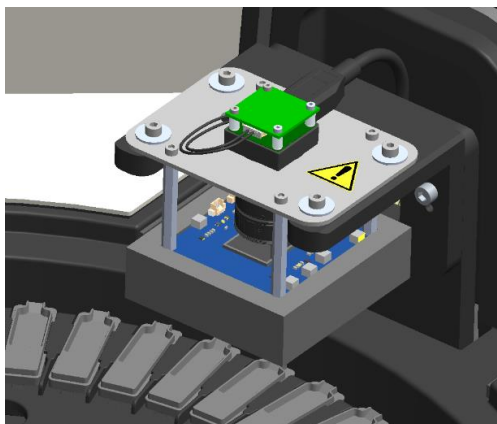
By removing the rear rotor lid, the user gets access to the image acquisition module. When all segments are removed, the user can easily clean/wipe the waste drain channel (waste rim) as shown in **Figure 15** highlighted in blue.



**Figure 15**

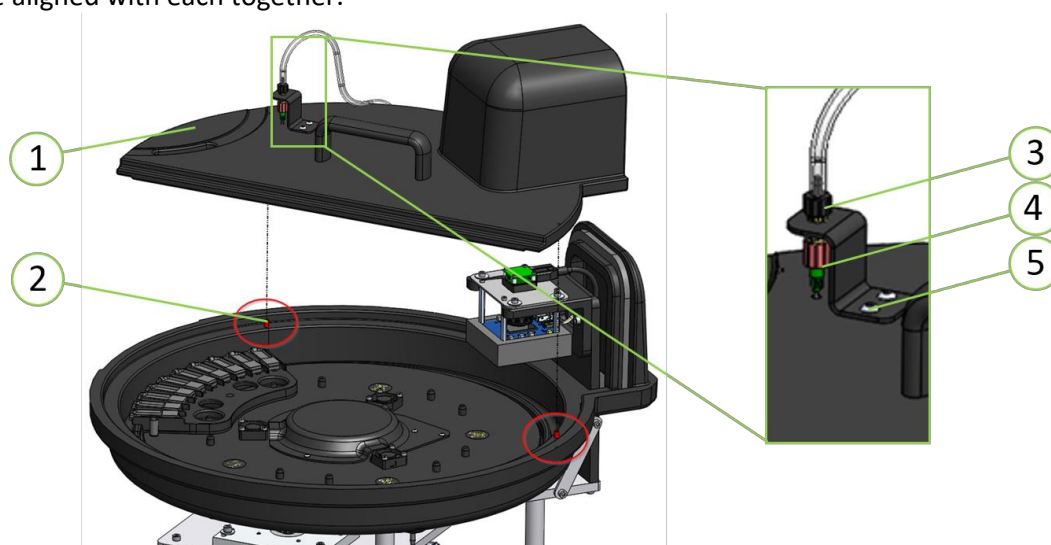
Waste drain channel of cartridge rotor highlighted in blue.

The image acquisition module shows a warning label, that 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 shall not touch the optical and electrical elements of the 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.

To correctly insert the rear rotor lid, two alignment pins located in the waste rim structure and two corresponding holes in the rear lid as shown in **Figure 16** (highlighted in red) have to be aligned with each other.



- 1 Alignment Hole
- 2 Alignment Pins
- 3 Luer Lock Adapter
- 4 Wash-Buffer Solution Luer Lock Needle
- 5 Screws for Unmounting the Wash-Buffer Solution Needle Holder for Replacement of Needle

**Figure 16**

Illustration for alignment of rotor rear lid and waste rim structure.



Caution

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

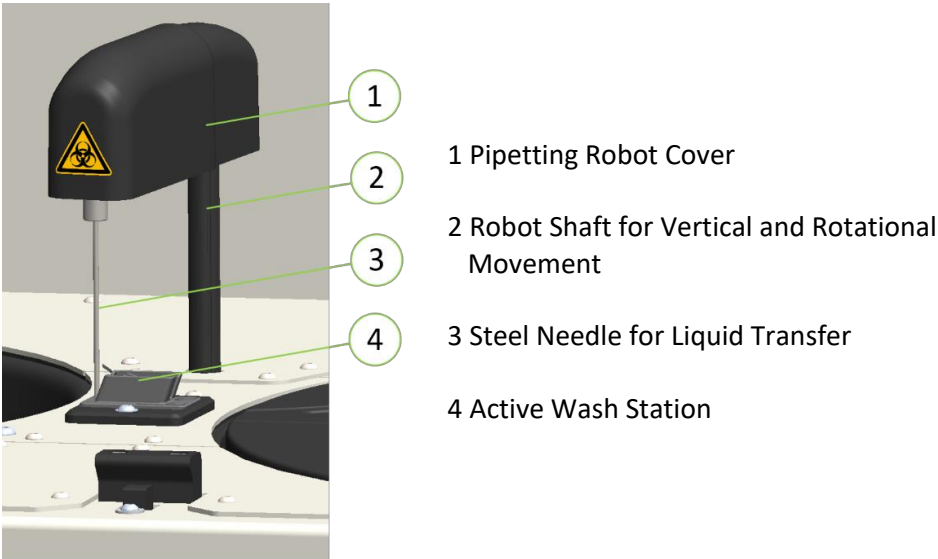


Caution

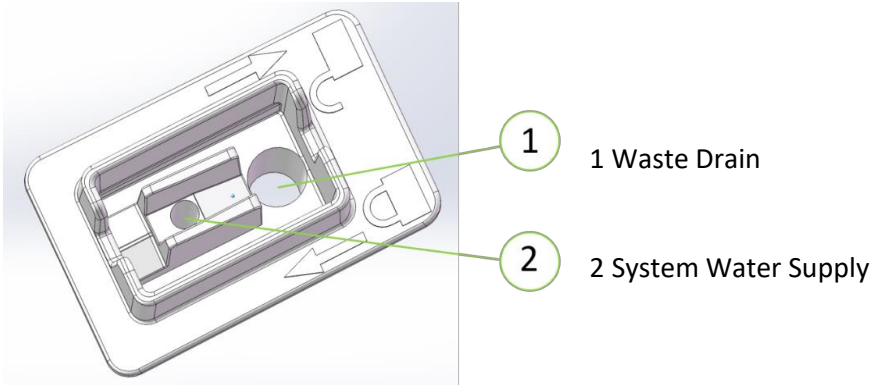
Prior to the removal of the rear lid, the wash-buffer solution tubing needs to be dismantled via the Luer lock from the wash-buffer solution needle holder.

#### 4.4.3. Pipetting Robot

The pipetting robot as shown in **Figure 17** enables the pipetting of sample or reagent from the sample and reagent rotor to the cartridge rotor. The robotics is equipped with a steel needle and a liquid level detection electronics that is protected by a plastic cover. The liquid level detection 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 inside the active wash station between the pipetting steps of different liquids.



**Figure 17**  
Pipetting robot.



**Figure 18**  
Active wash station.

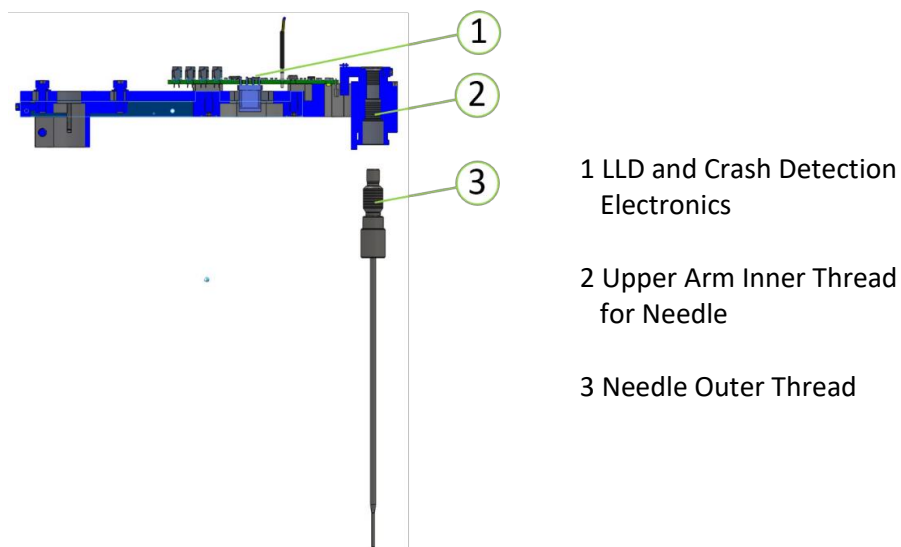
The upper arm of the pipetting robotics is labeled with a biohazard warning symbol to carefully remind the user not to touch the needle end part and potentially cut or puncture the skin resulting in a potential infection.



The needle can be replaced by the user by unscrewing the needle and inserting a new one. The new needle needs to be fastened tightly to seal the fluidics system (see **Figure 19**).



The user is not allowed to remove the upper arm cover due to the potential risk of pulling the pipetting tubing so that the ferrule for sealing the fluidics transition between the tubing and steel needle may be lost, resulting in a leakage and therefore potentially wrong pipetting.



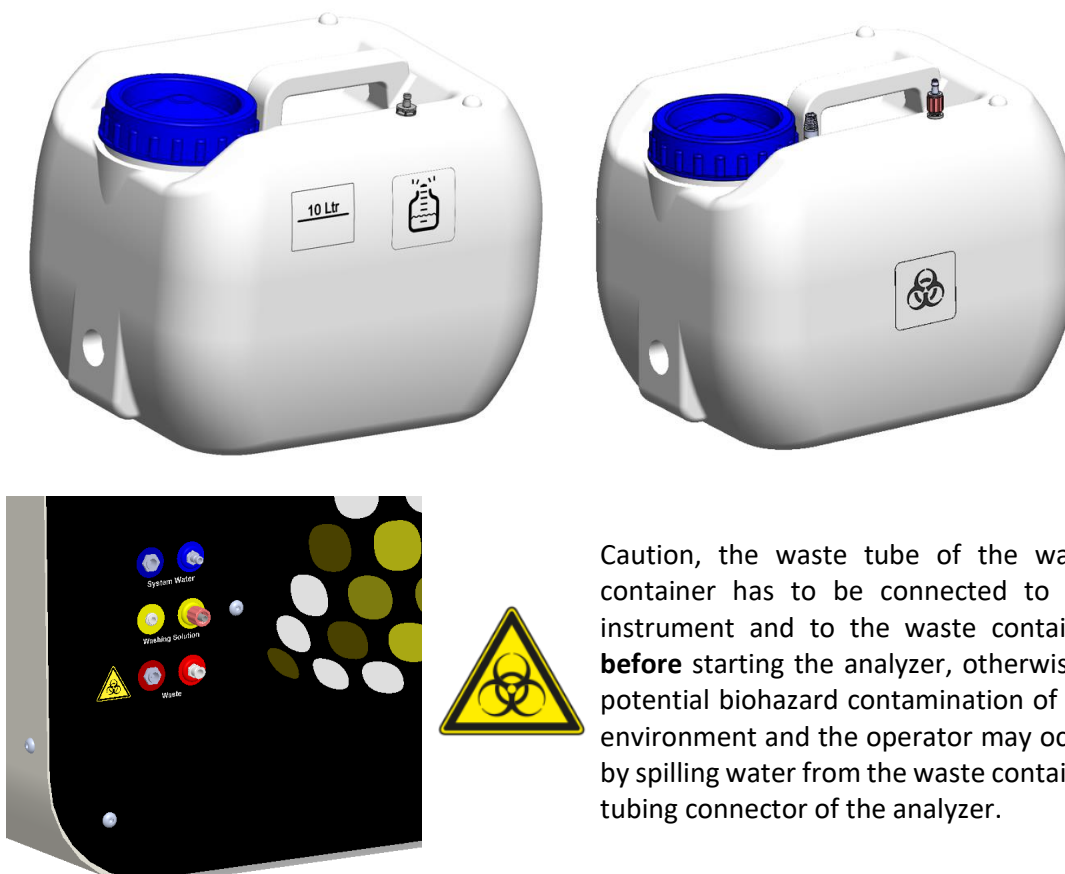
**Figure 19**

Schematics for the needle fluidics sealing by screwing the needle into the upper arm.

## 4.5. Supplies

### 4.5.1. System- and Wastewater Container

10 l of demineralized water must be filled into the corresponding system water container. Prior to a daily usage, the container must be filled up to the 10 Ltr marking as shown below, otherwise the RAPTOR SERVER will indicate that no further test can be performed with 50 cartridges loaded into the cartridge rotor.



Caution, the waste tube of the waste container has to 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 spilling water from the waste container tubing connector of the analyzer.

**Figure 20**

(Left) system-water container and (right) wastewater container and corresponding warning message in case of no waste tubing connection.

### 4.5.2. Wash-Buffer Solution Container

The analyzer needs to be equipped with 1l of wash-buffer solution provided separately by MacroArray Diagnostics GmbH or their authorized distributors. The washing solution needs to be prepared according to the ALEX<sup>2</sup> Instruction for Use and filled manually into the corresponding wash- buffer container. Prior to a daily usage, the container must be filled up to the 1 l marking as shown below, otherwise the instrument software will indicate that no further test can be performed when 50 cartridges are loaded into the instrument.



**Figure 21**  
Wash-Buffer Solution Container

#### 4.5.3. Assay Kit Supplies

The assay components, consisting of the ALEX<sup>2</sup> Sample Diluent, ALEX<sup>2</sup> Detection Antibody, ALEX<sup>2</sup> Substrate Solution and ALEX<sup>2</sup> Stop Solution as well as the ALEX<sup>2</sup> cartridges, are provided via the ALEX<sup>2</sup> Assay Kit (REF 02-5001-01) by MacroArray Diagnostics GmbH or their authorized distributors separately. Please ensure to read and observe any instructions for use for this assay Kit and handle these liquids and cartridges appropriately in connection with the analyzer.



## 5. Operating

### 5.1. Prerequisites

The following equipment and settings are needed to run ALEX<sup>2</sup> on MAX 45k:

- MAX 45k analyzer, properly installed by MADx or its distributors
- ALEX<sup>2</sup> reagent kit (REF 02-5001-01). Please consult the Instruction for Use of this IVD product before you run any assays on the instrument
- Serum samples or plasma samples (no EDTA plasma) – please check the minimal volumes in section 9 (technical specifications)
- PC with Windows version 7 or higher and a web browser (currently only Google Chrome is supported) installed
- “Raptor Agent for Automat” software installed on the PC – see section 5.2 on how to install this software package
- The PC needs two separate network adapters: one with a **stable Internet connection** (usually done via WIFI adapter) to connect to the cloud-based RAPTOR SERVER Analysis Software and a second network adapter used for the local area network (LAN) which connects the PC with the MAX 45k instrument via the LAN cable. If the PC does not provide 2 separate built-in network adapters, any USB – to – RJ45 adapter can be used, see an example device below:



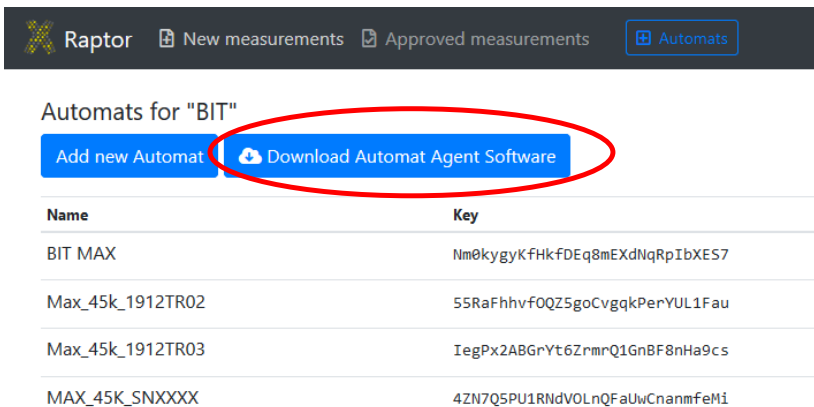
- To connect the PC with the MAX 45k, use the LAN cable which is included in the MAX 45k shipment. However, any high-speed LAN cable with 2 RJ45 connectors can be used.
- Configure the LAN Adapter in your Windows settings:
  - o In “Network Settings” choose “Change Network adapter options”
  - o You should see a window which shows all available Network connections, including your WIFI and the LAN adapter
  - o Right-click on the LAN adapter and choose “Properties”. Please note that you need Admin privileges on your PC in order to change the network settings
  - o Click on “Internet protocol Version 4” and then on “Properties”
  - o Manually change the IP address for the adapter and choose 192.168.183.10
  - o Change the Subnet mask to 255.255.255.0
  - o Click on “ok”

Optional equipment:

- uninterrupted power supply (UPS) with 500 VA

## 5.2. Installing and Starting the Software

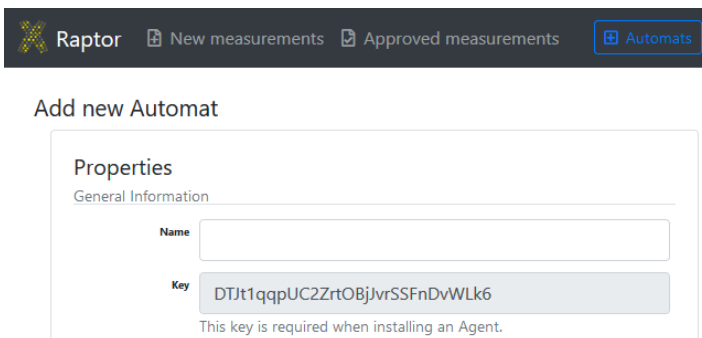
Before starting a new assay run on the MAX 45k with RAPTOR SERVER on [www.allergy-explorer.com](http://www.allergy-explorer.com), make sure that the “Raptor Agent for Automat” app is running. The agent should automatically be launched during Windows startup. If the agent app is not yet installed, an installation package can be downloaded from the Administration page on [www.allergy-explorer.com](http://www.allergy-explorer.com). (“Administration” -> “Tenant Admin” -> “Manage Automats” -> “Download Automat Agent Software”).



The screenshot shows the Raptor web interface with the 'Automats for BIT' page. The navigation bar includes 'Raptor', 'New measurements', 'Approved measurements', and 'Automats'. Below the navigation bar, there are two buttons: 'Add new Automat' and 'Download Automat Agent Software', with the latter being circled in red. Below the buttons is a table listing existing automats.

Name	Key
BIT MAX	Nm0kygyKfHkfDEq8mEXdNqRpIbXES7
Max_45k_1912TR02	55RaFhhvf0QZ5goCvgqkPerYUL1Fau
Max_45k_1912TR03	IegPx2ABGrYt6ZrnrQ1GnBF8nHa9cs
MAX_45K_SNXXXX	4ZN7Q5PU1RNdV0LnQFaUwCnanmfeMi

On the same webpage, a new instrument (Automat) and a corresponding unique key can be generated. For every MAX 45k in use, a separate key need to be generated. To obtain a new key, press “Add new Automat” and enter a name for your MAX 45k instrument in the corresponding field. The Automat key should be copied (STRG + C) from the field below.



The screenshot shows the Raptor web interface with the 'Add new Automat' page. The navigation bar includes 'Raptor', 'New measurements', 'Approved measurements', and 'Automats'. Below the navigation bar, there is a form titled 'Add new Automat' with a 'Properties' section. The 'General Information' section has a 'Name' field and a 'Key' field. The 'Key' field is pre-filled with the unique key 'DTJt1qqpUC2ZrtOBjvrSSFndvWlk6'. Below the 'Key' field, there is a note: 'This key is required when installing an Agent.'

Besides the name of the instrument, the status (enabled or disabled) and the default sample tube types can be changed. Additional information can be written into the Notes and Internal Notes fields.

Notes

Internal Notes

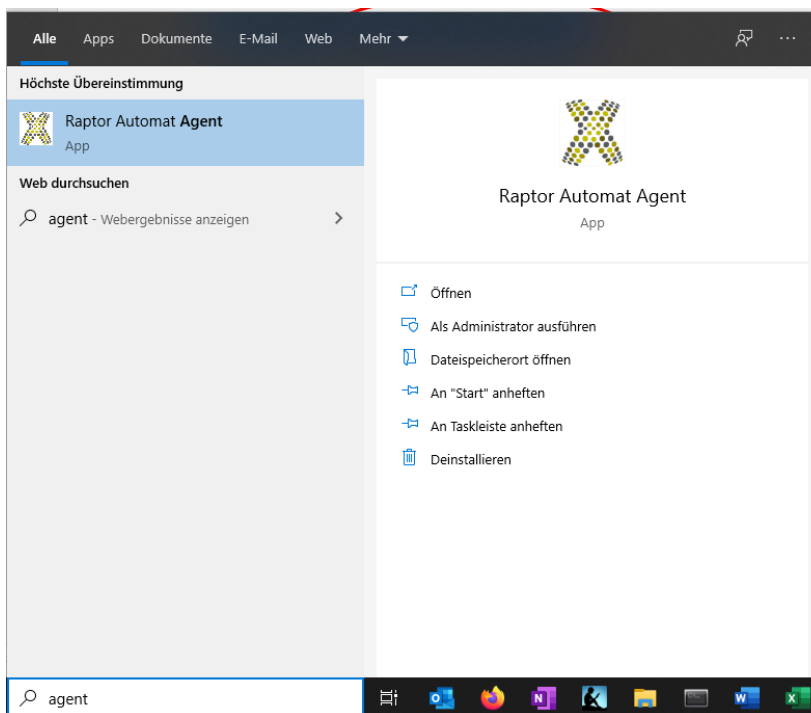
For internal use only.

Disabled

Default Sample Tubes

If the agent software is not launched automatically during Windows startup, you can launch the app manually:

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



After the Raptor Automat Agent app has started for the first time, click on “Settings” and enter the Raptor Server URL and Automat URL as shown in the Screenshot below. For the Automat Key, enter the key you have generated and copied before (STRG + v).

Settings

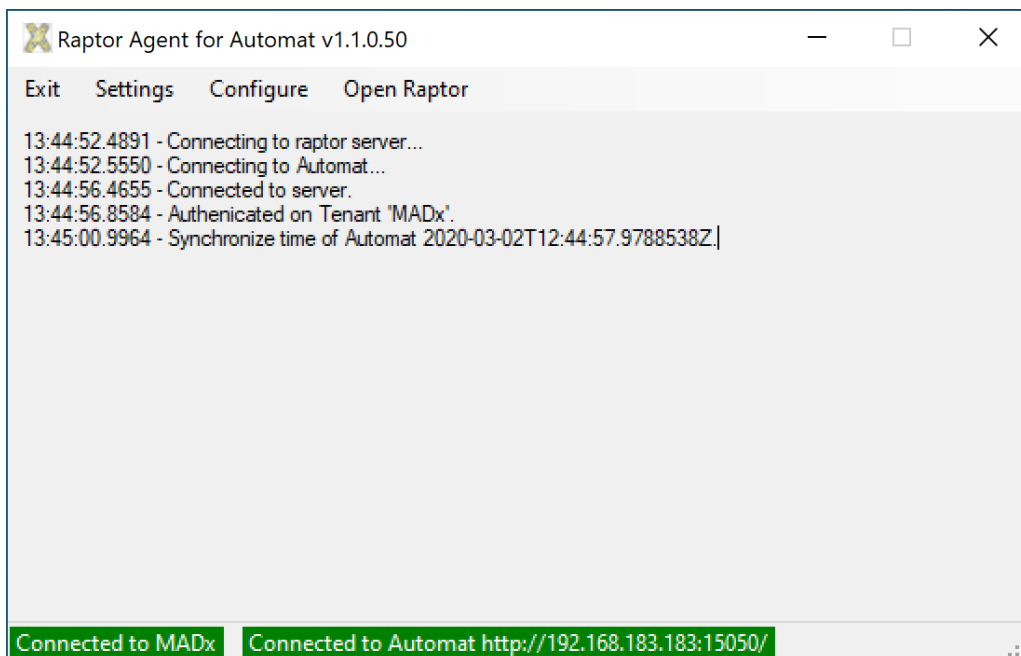
Please enter the settings for your Automat. You can find your Automat key when you log in to Raptor. Please contact support if you're not sure what the proper settings are for your Automat.

Raptor Server URL

Automat URL

Automat Key

Click on “Save” to store 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 Automat Agent window are red, please check that the “Settings” are set correctly. Also check if you have entered the correct key for your analyzer (Automat Key) and the analyzer is properly connected with the PC.

In the example below, the Raptor Agent for Automat was not able to connect to the MAX 45k instrument. Check in “Settings”, if you put the correct Automat URL and Automat key in the corresponding fields. Also make sure that the MAX 45k instrument is directly linked to the PC where you have Raptor Agent installed with the Ethernet cable provided in the MAX 45k delivery box.

### 5.3. Log-In to RAPTOR SERVER

In your web browser, enter the URL for the cloud 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 System Administrator or by MADx support team.



Welcome to Raptor, the analysis software for the [ALEX multiplex allergy test](#).  
Please log in below to continue.

**Log in with Azure AD / Office 365**

If your organization integrates Raptor into its Microsoft Azure/Office 365 user directory (single-sign-on) click the button below. You will be redirected to the Microsoft login screen.

**Log in**

**Log in with Username & password**

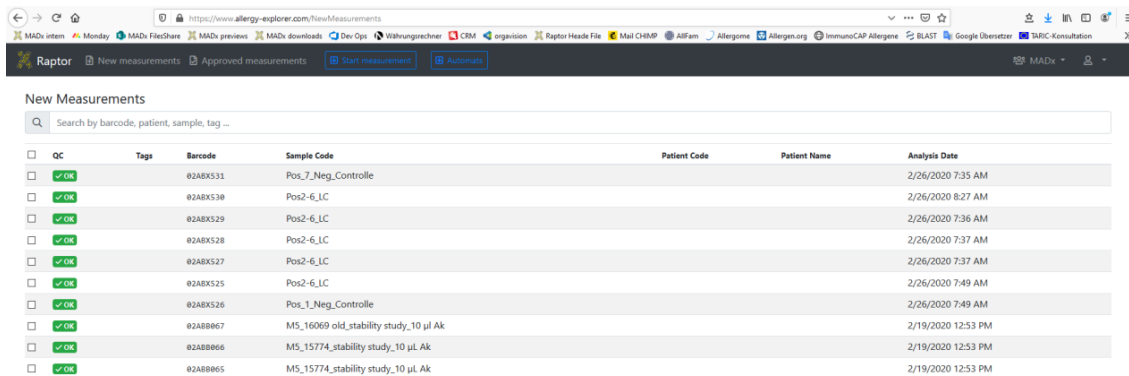
Please enter your Raptor username and password.

**Log in**

Forgot your password? No problem, you can [request a new one](#).

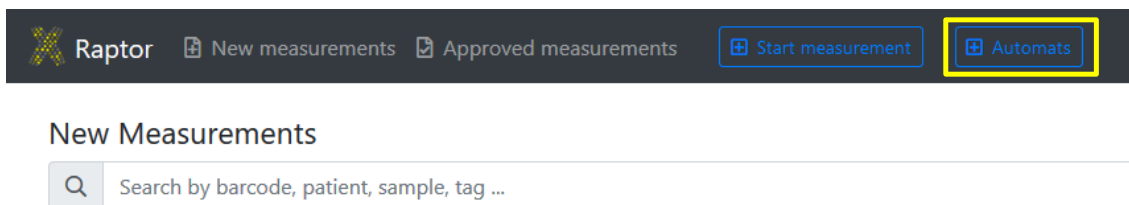
If the Login was successful, the homepage of the RAPTOR SERVER Analysis Software shows up with the ALEX<sup>2</sup> measurement results from previous MAX 45k assay runs. If you also have an

ImageXplorer imaging device (RE 11-0000-01) in use, the results obtained with this device will be shown as well.

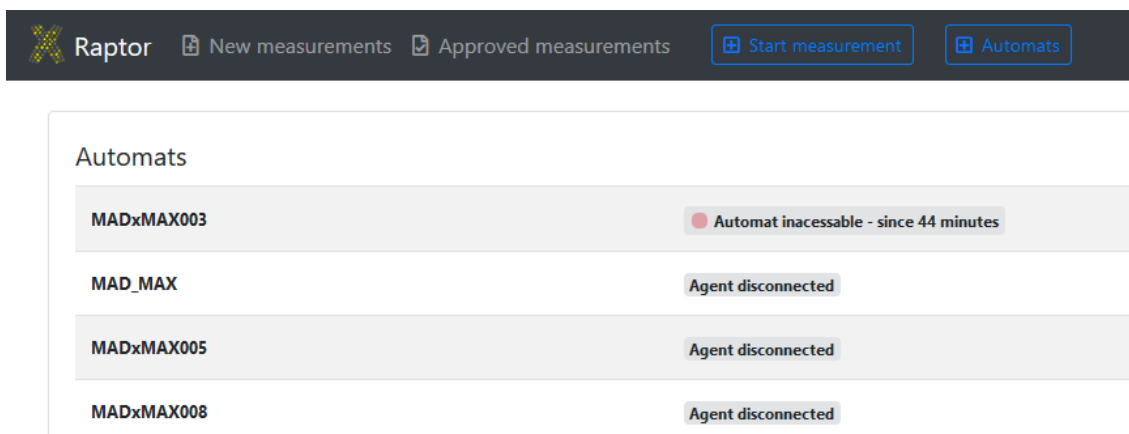


QC	Tags	Barcode	Sample Code	Patient Code	Patient Name	Analysis Date
<input checked="" type="checkbox"/>		02ABX531	Pos_7_Neg_Controller			2/26/2020 7:35 AM
<input checked="" type="checkbox"/>		02ABX530	Pos2-6_LC			2/26/2020 8:27 AM
<input checked="" type="checkbox"/>		02ABX529	Pos2-6_LC			2/26/2020 7:36 AM
<input checked="" type="checkbox"/>		02ABX528	Pos2-6_LC			2/26/2020 7:37 AM
<input checked="" type="checkbox"/>		02ABX527	Pos2-6_LC			2/26/2020 7:37 AM
<input checked="" type="checkbox"/>		02ABX525	Pos2-6_LC			2/26/2020 7:49 AM
<input checked="" type="checkbox"/>		02ABX526	Pos_1_Neg_Controller			2/26/2020 7:49 AM
<input checked="" type="checkbox"/>		02AB8867	MS_16069_old_stability study_10 µl Ak			2/19/2020 12:53 PM
<input checked="" type="checkbox"/>		02AB8866	MS_15774_stability study_10 µl Ak			2/19/2020 12:53 PM
<input checked="" type="checkbox"/>		02AB8865	MS_15774_stability study_10 µl Ak			2/19/2020 12:53 PM

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



On the following page, an overview of the status of all analyzer systems (automats) can be seen. If there is only one analyzer installed and configured in your lab, it will only show one line with the name and status of the MAX 45k instrument (automat).

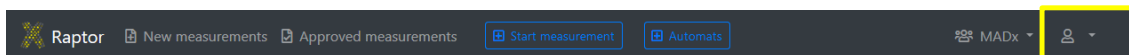


Automats

MADxMAX003	Automat inaccessible - since 44 minutes
MAD_MAX	Agent disconnected
MADxMAX005	Agent disconnected
MADxMAX008	Agent disconnected

#### 5.4. Configuring the MAX 45k Instrument

Open the Administration menu in the upper right corner of the RAPTOR SERVER browser window. Click on “Tenant Admin” and select “Manage Automats” on the next page.



**Automats**

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

[Manage Automats](#)

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

Automats for "MADx"

[Add new Automat](#) [Download Automat Agent Software](#)

Name	Key	Last connection	Last activity	
MAD_MAX	0F2mBu4a1k4wIFjcPC641ThUkc4s2	yesterday	never	<a href="#">QC</a> <a href="#">Configure</a> <a href="#">Delete</a>
MADxMAX003	CnKyr1pE9hwZ188A1QRVfrbo8fNwSM	51 minutes ago	2 months ago	<a href="#">QC</a> <a href="#">Configure</a> <a href="#">Delete</a>
MADxMAX005	VaOYeCjHFJ0gawUE7JQy1RderamFb	7 days ago	2 months ago	<a href="#">QC</a> <a href="#">Configure</a> <a href="#">Delete</a>
MADxMAX008	qJZAwcjCAHrg3kVCng5s09yf18P8LE	22 days ago	2 months ago	<a href="#">QC</a> <a href="#">Configure</a> <a href="#">Delete</a>

The "Configure" page for the selected MAX 45k instrument 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	Started At (UTC)	Finished At (UTC)	Operator	
302	02ABX	2/25/2020 9:38:00 AM	2/25/2020 1:57 PM	mitterer@macroarraydx.com (mitterer@macroarraydx.com)	<a href="#">👁</a>
301	02AAR	2/19/2020 9:10:28 AM	2/19/2020 2:03 PM	mitterer@macroarraydx.com (mitterer@macroarraydx.com)	<a href="#">👁</a>
300	02AAB	2/18/2020 3:17:53 PM	2/19/2020 8:43 AM	mitterer@macroarraydx.com (mitterer@macroarraydx.com)	<a href="#">👁</a>
299	02AAB	2/18/2020 10:44:01 AM	2/18/2020 2:19 PM	mitterer@macroarraydx.com (mitterer@macroarraydx.com)	<a href="#">👁</a>
298	02ABB	2/14/2020 9:48:51 AM	2/14/2020 12:59 PM	Mats Nystrand (mats.nystrand@macroarraydx.com)	<a href="#">👁</a>
297	02AAC	2/10/2020 3:12:37 PM	2/11/2020 7:36 AM	mitterer@macroarraydx.com (mitterer@macroarraydx.com)	<a href="#">👁</a>
296	02ABB	2/10/2020 10:23:54 AM	2/10/2020 1:29 PM	mitterer@macroarraydx.com (mitterer@macroarraydx.com)	<a href="#">👁</a>
295	02AAC	2/6/2020 10:40:34 AM	2/6/2020 2:16 PM	mitterer@macroarraydx.com (mitterer@macroarraydx.com)	<a href="#">👁</a>
294	02ABB	2/5/2020 9:40:19 AM	2/5/2020 12:48 PM	mitterer@macroarraydx.com (mitterer@macroarraydx.com)	<a href="#">👁</a>
293	02ABB	2/4/2020 9:26:13 AM	2/4/2020 12:34 PM	mitterer@macroarraydx.com (mitterer@macroarraydx.com)	<a href="#">👁</a>

[All Run Records](#)

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 maintenance procedures (see section 6 for further explanations)

## - Testarray

Scans:

Testarray scans

Started	Offset X	Offset Y	Width	Height	Exposure	
✓ 2 months ago	400	316	650	350	974	
✓ 3 months ago	400	316	650	350	960	
3 months ago						
✓ 6 months ago	400	316	650	350	914	
✗ 6 months ago						

[All Calibration Records](#)

In order to adjust the imager device on the MAX 45k, a test array run must be performed after a new installation of the instrument and periodically every 6 weeks. The results of these testarray scans can be inspected in detail and downloaded as a report file in PDF format. Further information about the testarray run procedure can be obtained from the section 5.5.

## 5.5. Testarray Scans

A testarray scan needs to be performed:

- For every new MAX 45k instrument before it is used to analyze patient samples
- For instruments in use: every 60 days. RAPTOR SERVER Analysis Software will notify the user if a new testarray run is needed

In order to perform the testarray run, a special cartridge is needed, which can be ordered from MacroArray Diagnostics or its distribution partners. Please check the expiry date, which is printed on the pouch label, before you put the cartridge into the instrument.



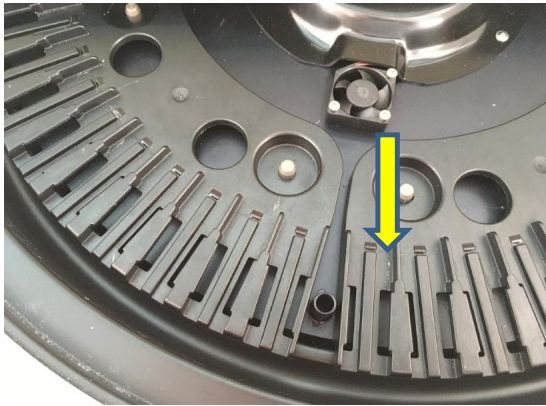
Remove the testarray from the pouch. Do not touch the surface of the cartridge membrane!



Put the testarray cartridge into the cartridge rotor on the instrument. Make a note of the position where you put the cartridge (1-50): Position 1 (marked by the yellow arrow in the



picture below) is next to the drilled hole in the cartridge rotor, the positions 2, 3,...etc. are located counter-clockwise. The rotor can be manually moved in both directions.



Make sure that the instrument is switched on and that the system water and washing solution containers are filled according to section 4.5 and connected and the waste container is empty and connected to the instrument.

To start the testarray run, select “Configure” in the “Automats” menu, as described in the previous section. Enter the selected position of the testarray and click on “Start auto-adjustment”. The procedure runs automatically and is finished after approximately 15 minutes.

Choose Position of Test-Assay

Start auto-adjustment

Please make sure that the Automat is connected, idle and that you have a calibration ALEX chip inserted.

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

## Results

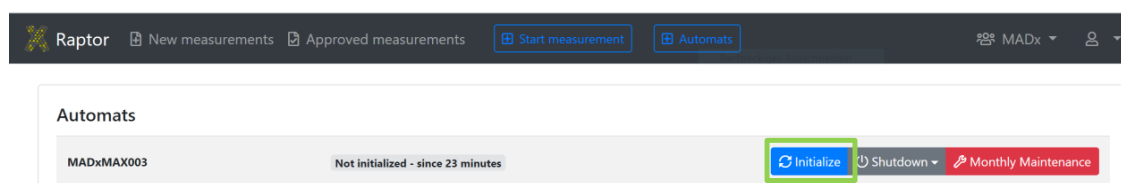
<b>Detected offset X</b>	400
<b>Detected offset Y</b>	316
<b>Detected width</b>	650
<b>Detected height</b>	350
<b>Detected exposure</b>	974
<b>Device Serialnumber</b>	19090003
<b>Acceptance Criteria</b>	Passed

## 5.6. Starting a new Assay Run

**Please note that a maximum number of 5 assay runs can be performed with each ALEX<sup>2</sup> kit! For example, 5 assay runs á 10 test samples (normal priming) are possible with the content of an ALEX<sup>2</sup> test kit (02-5001-01).**

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 container is filled with diluted ALEX<sup>2</sup> Washing Solution. Please consult the Instruction for Use of ALEX<sup>2</sup> on how to correctly prepare the ALEX<sup>2</sup> Washing Solution for MAX 45k. The main flap must be firmly closed before any movement in the MAX 45k instrument occurs.

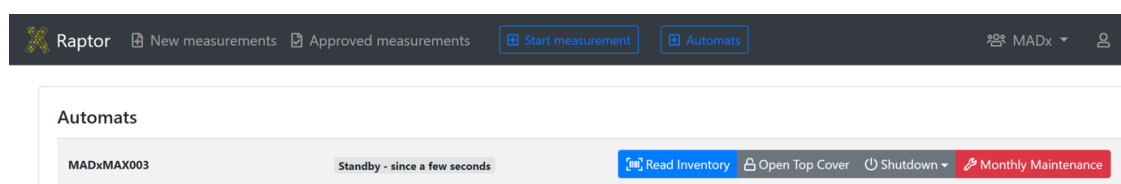
Click on “Automats” to get an overview of all MAX 45k instruments (Automats) that are currently linked to your laboratory tenant. Click on “Initialize” to perform the initialization process for the instrument which will be used for the upcoming assay run.



During the initialization procedure, the pipette will be washed several times in the washing station.

## 5.7. Load Inventory for Assay Run

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



Click “Open Top Cover” and the interlock system releases the main flap after a short priming of the pipette. Wait for the “click” sound on the instrument before you pull the lever of the flap. **Please consult the safety instructions in section 4.3.3. to avoid injuries when opening the main flap.**

Remove the front lid from the sample rotor to get access to the cartridge holders.

Put the 30 ml reagent vials (ALEX<sup>2</sup> Sample Diluent, ALEX<sup>2</sup> Detection Antibody, ALEX<sup>2</sup> Substrate Solution) in the corresponding holes on the sample rotor. Make sure that the barcode on the labels is facing outwards and that no air bubbles are visible.



Put the 15 ml reagent vial (ALEX<sup>2</sup> Stop Solution) in the corresponding hole on the sample rotor. Make sure that the barcode on the labels is facing outwards and that no air bubbles are visible.



Put the sample tubes with 16 mm diameter directly into the sample carousel, starting with position 1.



Use 13 mm vials only with the provided adapters.



You can also insert small-volume tubes, which are often used for QC samples or if only a small amount of patient specimen is available. Use the same adapters as for the 13 mm tubes.



**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 9 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.

After all reagents and samples are loaded, remove the necessary number of ALEX<sup>2</sup> cartridges (usually one cartridge per sample) from the ALEX<sup>2</sup> cartridge box.

Insert the ALEX<sup>2</sup> cartridges into the cartridge rotor: Move the cartridge from center outwards until 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 above.



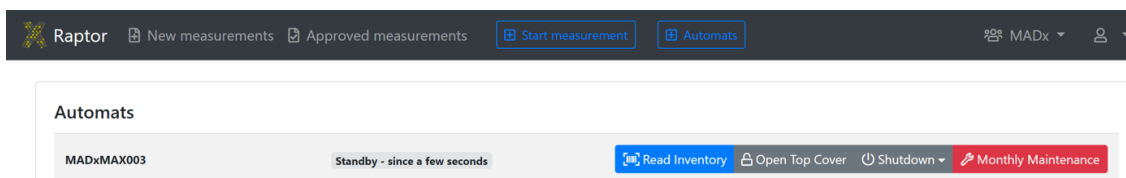
After all cartridges have been loaded, close the front lid of the cartridge rotor.



Make sure that all caps from reagent vials and sample tubes have been removed. **Close the main flap of the instrument.**



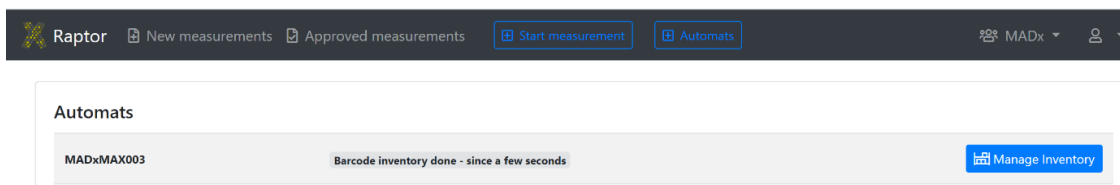
Click on the blue button “Read Inventory” in RAPTOR SERVER Analysis Software.



## 5.8. Inventory Reading and Volume Check

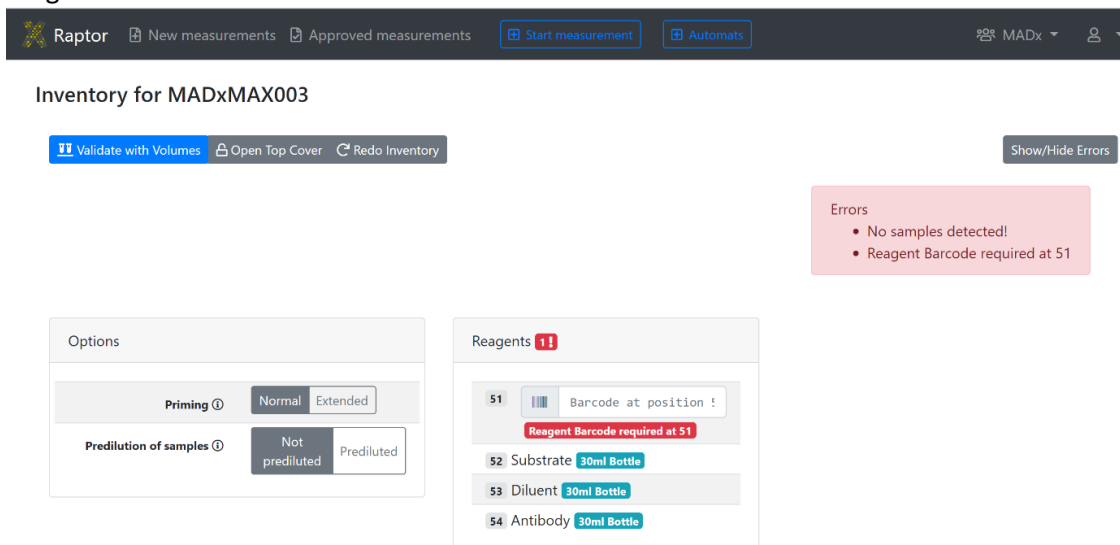
The instrument reads all barcodes provided on the labels of the reagent bottles, the sample tubes and the ALEX<sup>2</sup> cartridges.

When the process is finished, click the blue button “Manage Inventory” to check if the automatic reading of the barcodes did work properly.



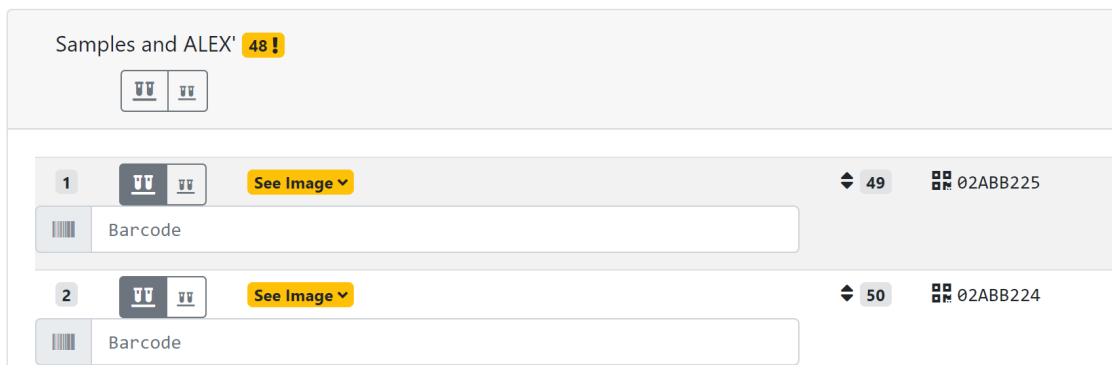
In the example below, the user forgot to put the ALEX<sup>2</sup> Stop Solution into the sample rotor. A red warning message tells the user that no reagent barcode for position 51 could be detected. Open the main flap (click on “Open Top Cover”) and put the missing reagent bottle(s) into the corresponding holes of the sample rotor.

If all reagents have been put into place and you still get an error message (no barcode detected), the barcode can be entered manually into the corresponding text field. Please take care that you write the letters and digits exactly the way they appear on the label of the reagent bottle.

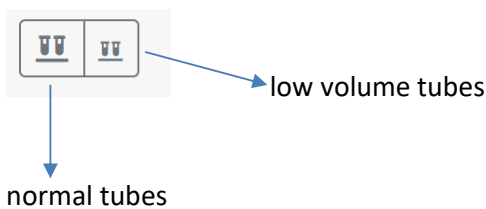


If no barcode could be detected on the sample tubes – as shown in the example above – a barcode or ID for the sample must be entered manually in the corresponding text field.

By clicking on the yellow button “See Image”, a picture from the scanned barcode can be examined.



You can either select standard tubes (13 or 16 mm diameter) or low volume tubes by clicking on the corresponding icon on top of the sample list – to select the vial type for all samples – or by clicking on the symbol at a specific sample position to set the vial type only for this sample. You can also change the default size of the test tubes in the settings of the MAX 45k instrument.



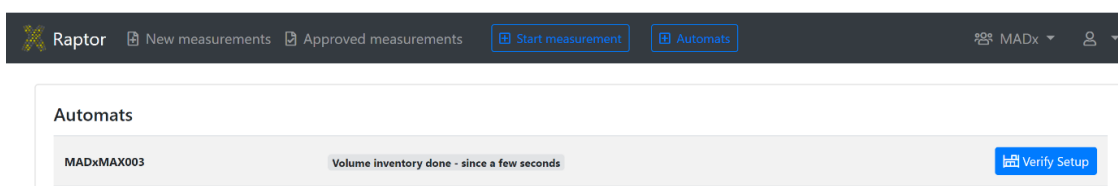
The assignment of the ALEX<sup>2</sup> cartridges to the sample is done automatically by the software, however, you can change this assignment by clicking on the cartridge barcode, located in every line of sample on the right side, and move the barcode with the mouse up or down to the desired position. If you want to use the same sample for more than one cartridge, the barcode of another cartridge needs to be moved to this sample.



If all barcodes and assignments have been set, press the blue “Validate with Volumes” button and the instrument starts to check all liquid volumes in the sample rotor.

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





In the example below, the instrument has detected enough volume in the reagent vials, sample tubes and containers to start an assay run. (All volumes marked as “green”)

### Inventory for MADxMAX003

Start Run Edit Inventory Open Top Cover Redo Inventory

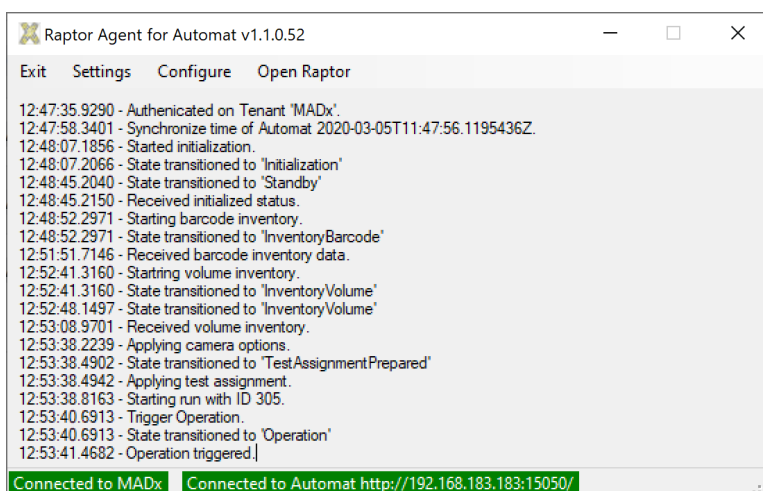
Options		Reagents		System State	
Priming ⓘ	Normal Extended	51 Stop solution	16,867µl	Wash solution container	Ok
Predilution of samples ⓘ	Not prediluted Prediluted	52 Substrate	25,842µl	System water container	Ok
		53 Diluent	39,545µl	Waste container	Ok
		54 Antibody	25,930µl		

Before starting the actual assay run, you can change the priming behavior from default (“Normal”) to “Extended”. Use “Extended” priming behavior to remove visible air bubbles from the wash-buffer solution tubing. **Please note that excessive usage of extended priming will reduce the number of assay runs which can be performed with one ALEX<sup>2</sup> kit.**

If you use prediluted samples (samples which have been preincubated with ALEX<sup>2</sup> Sample Diluent), change “Predilution of Samples” setting to “Prediluted”. Please note that these settings are applied to ALL samples in the assay run!

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

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 Automat”.



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

## 5.9. End of Assay Run and Shutdown

When the assay is finished, the status field will indicate “Test run finished”.

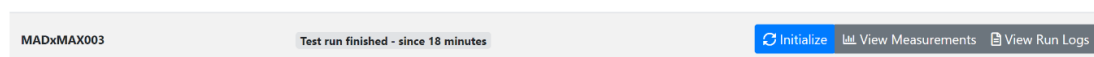
By clicking on “View Measurements”, the result page is opened, and the sample results can be verified and approved. See section 5.14

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”

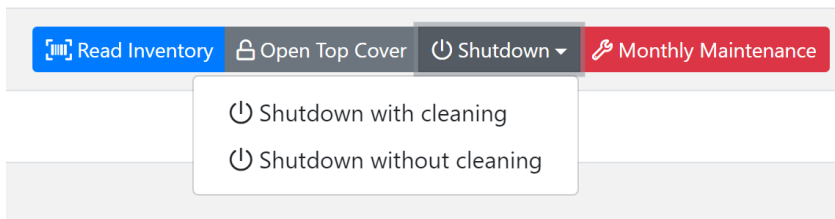
**Before starting a new assay run, make sure that you remove all processed cartridges from the cartridge rotor.**

Automats



To perform a shutdown of the instrument:

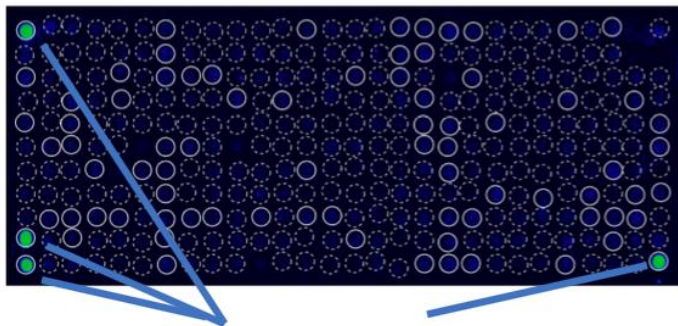
- Remove all reagents and sample tubes from the sample rotor
- Remove all cartridges from the cartridge rotor
- Click on “Shutdown” and perform either a “Shutdown with cleaning” or a “Shutdown without cleaning”. If you are planning to start another assay run on the same day, you can select “Shutdown without cleaning”. Otherwise, choose “Shutdown with cleaning”.
- After (!) the recovery push button starts flashing, the instrument can be powered off with the main switch.
- Consult section 6 for required maintenance procedures of the instrument



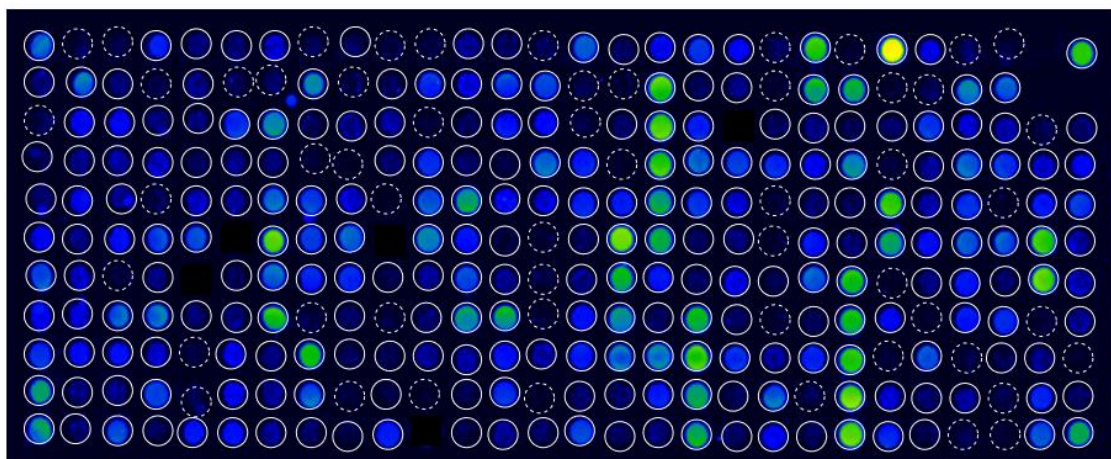
### 5.10. Internal Quality Control

Every ALEX<sup>2</sup> cartridge has an inbuilt assay run control, which consists of 4 so called “Guide Dots” at 3 corners on the cartridge surface:

#### ALEX<sup>2</sup>



During the image acquisition of the ALEX<sup>2</sup> 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 section 5.14 for further information about QC attached to the cartridge.



Fag e = 0.17 kUA/l

Received: 3/9/2020 3:29 PM

Analysis: 3/10/2020 8:34 AM

Automat: 19090003

Automatic QC: ✔ OK

Additionally, it is recommended to run at least one negative and one positive quality control sample with every assay run. RAPTOR SERVER contains a basic QC module which can monitor QC performance with the commercial quality control sample “Lyphochek® Allergen IgE sIgE Control, Panel A” from the company Bio-Rad. Please consult the Instruction for Use from the manufacturer on how to use this control material.

MacroArray Diagnostics provides acceptance ranges for the most recent batch of Lyphochek® sIgE Control Panel A. These values are stored in RAPTOR SERVER and cannot be edited by the user.

In order to use Lyphochek® sIgE Control Panel A as an internal quality control during an assay run with MAX 45k, use the lot number with the proceeding product ID “32” of the control as the barcode for the sample, for example “3222630” for Lyphochek® sIgE Control Panel A lot 22630. RAPTOR SERVER will recognize this barcode as a QC sample.

For lot# 22630, the following allergens and acceptance limits have been predefined in RAPTOR SERVER analysis software:

Feature Name	Min Threshold	Max Threshold
Ara h 9	0,95	3,05
Bet v 1	2,33	7,08
Der p 1	3,38	10,21
Fel d 1	6,43	27,83
Phl p 2	1,58	6,22

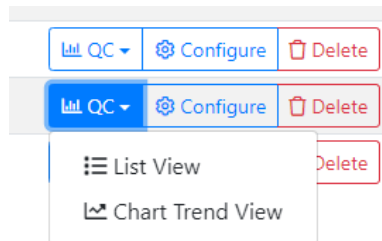
QC results can be obtained from the Automat settings page (“Tenant Admin” → “Manage Automats”). Click on the blue button “QC” to see an overview of QC results for a particular MAX 45k instrument.

## Automats for "MADx"

[Add new Automat](#)
[Download Automat Agent Software](#)

Name	Key	Last connection	Last activity	
MAD_MAX	0F2mBu4a1k4wIFjcPC641ThUkcd4s2	13 days ago	never	<a href="#">QC</a> <a href="#">Configure</a> <a href="#">Delete</a>
MADxMAX003	CnKyr1pE9hwZ188A1QRVfrbo8fNWSM	14 minutes ago	2 months ago	<a href="#">QC</a> <a href="#">Configure</a> <a href="#">Delete</a>

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



### 5.11. 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 stopped by the user by clicking the "cancel" button on the status page of the instrument. Please note that after the Sample Diluent and patient sera have been dispensed, the cartridges cannot be reused and must be discarded.

## Automats

MADxMAX003	Running tests - since 5 minutes	81% incubation with mixing 2	Cancel
------------	---------------------------------	------------------------------	--------

If a leakage is detected and presented by the RAPTOR SERVER Analysis Software, the MADx support team or its authorized partners 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 its authorized partners need to be contacted before performing any new assay run.

In case of an unsecured main flap opening all mechanical motions and pumps immediately stop. With a "System Prepare" via the "Initialize" button of the GUI the user can recover the analyzer to perform further steps. If an un-granted access takes place MADx disclaims all liability for damage to the analyzer.

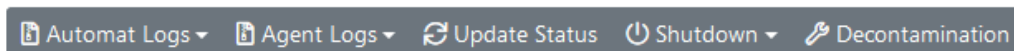
## 5.12. Error Handling

Section 8 describes troubleshooting of MAX 45k 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), so that the user can easily identify them and take appropriate actions if necessary.

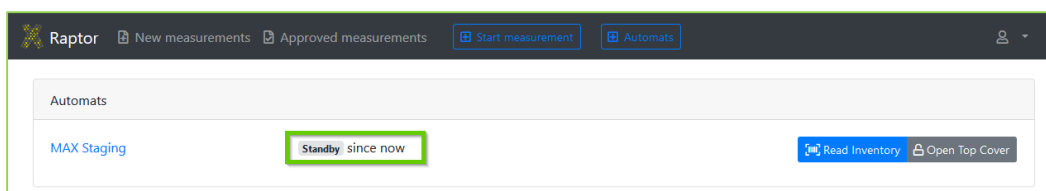
At the end of the assay run (or after the instrument aborted the assay run due to a severe error), an error log is created by the system. A hyperlink to the error log is provided on the user interface. By clicking on this link, the user can download the log file in text format and send it to MacroArray Diagnostics or its representative for further analysis via E-Mail. On the configuration page of the instrument, log files for the instrument itself (“Automat Logs”) and for the agent software (“Agent Logs”) can be downloaded if requested by technical service employees from MacroArray Diagnostics or its service partners. In a first step, the log file has to be created in RAPTOR SERVER and in the second step the file can be downloaded and saved on the local PC for further analysis or sent via E-Mail to technical service.

### Configure MADxMAX003



## 5.13. 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 45k instrument.



The following status messages for the MAX 45k instrument are available:

WaitingForStatus	Agent is connected to RAPTOR SERVER and status of instrument needs to be requested by Agent
AutomatInaccessible	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 disappears for all users of tenant.
HomeingActors	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) needs to be homed (= prepared).
TopCoverCanBeOpened	Agent is connected to both, RAPTOR SERVER and instrument. Main flap is physically opened. This state appears, until main flap is closed.
TopCoverOpen	Agent is connected to both, RAPTOR SERVER and instrument. Main flap is physically opened. This state appears, until main flap is closed.
UserRequestedbarcodeInventory	Agent is connected to both, RAPTOR SERVER and instrument. User sent request for barcode inventory. Actions disappears 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 disappears for all users of tenant.

VolumInventoryCapturing	Agent is connected to both, RAPTOR SERVER and instrument. Automat executes volume inventory procedure.
VolumInventoryDone	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 disappears for all users of tenant.
RunningTests	Agent is connected to both, RAPTOR SERVER and instrument. Automat executes operation procedure.
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 disappears 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.

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.

## 5.14. Image Analysis and Report Generation

The results of the recent assay runs can be obtained by clicking on “New measurements” on the menu bar on top of the RAPTOR SERVER Analysis Software. Each line represents one result of a processed ALEX<sup>2</sup> cartridge.

The barcode on each cartridge contains the following information:

- version of ALEX<sup>2</sup> test kit
- corresponding allergen layout
- QC information
- Lot number of ALEX<sup>2</sup> cartridge
- batch specific correction of calibration for specific and total IgE



By clicking on one of the cartridge barcodes, a detailed overview of the measurement is displayed with the patient information fields and sample information fields on the left, an analytic image of the array on the right and a detailed result view of allergens below.

The screenshot shows the Raptor software interface. On the left, there is a 'Details' section with various input fields for patient and sample information. A box labeled 'A' highlights the 'Sample Code' field, which contains 'Positive Control'. Below this are fields for 'Sampling Date', 'Assay Date', 'Patient Code', 'Patient Name', 'Date of Birth', 'Info', and 'Doctor Info'. At the bottom of this section are buttons for 'Report', 'Save', and 'Save and approve'. On the right, there is an analytic image of the array, a grid of colored circles representing individual measurements. A box labeled 'B' highlights this image. Below the image, there is a 'Mal d 2 = 0.08 kUA/l' label, and further down, 'Received: 3/5/2020 11:11 AM', 'Automat: 19090003', 'Analysis: 3/5/2020 11:11 AM', and 'Automatic QC: ✓OK'. At the bottom, there is a table of allergens with columns for 'I1 Name', 'Code', 'Biochemical', 'Tissue & Exposure', 'E/M', 'Feature', and 'kUA/L'. A box labeled 'C' highlights the 'Code' column. The table lists three allergens: Acarus siro (Code d70, Feature 1.71), Akazie (Code t19, Feature 0.73), and Alternaria alternata (Code m229, Feature 24.54).

I1 Name	Code	Biochemical	Tissue & Exposure	E/M	Feature	kUA/L
Acarus siro <i>Acarus siro</i>	d70		Milben Inhalation	E	Aca s	1.71
Akazie <i>Acacia mimosa</i>	t19		Pollen Inhalation	E	Aca m	0.73
Alternaria alternata <i>Alternaria alternata</i>	m229	Alt a 1-Familie	Mikroorganismen & Pilzsporen Inhalation	M	Alt a 1	24.54

A: Patient and sample information fields

B: Analytic image

C: Result view

In addition, date of analysis, serial number of the instrument (automat), Automatic QC and possibly also an error log are displayed below the analytical image.


Additional sample and patient information can be added manually:


- sample code
- sampling date
- assay date
- patient code
- name of the patient
- date of birth
- additional information
- name of the referring physician and
- a tag
- MOD panel

## Details

Barcode: 02AD0942


Sample Code: 12

Sampling Date: 11.11.2019 

Assay Date: 02.07.2020 

Patient Code: MA

Patient Name: Martina




Date of Birth: 01.10.2000 

Info: Info

Doctor Info: Dr. A

Tags: Tag Info

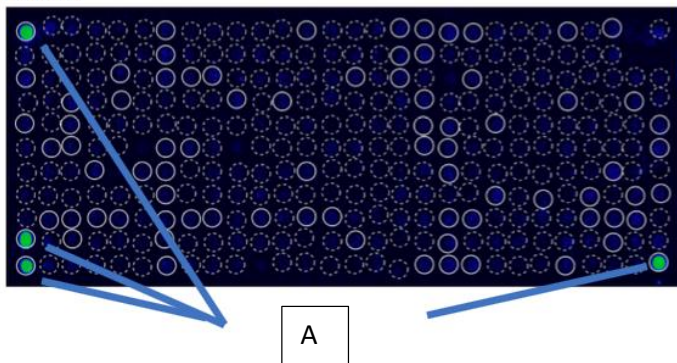
MOD: < No MOD >

 Report  Save  Save and approve

If you click on "Save" the entered information will be saved.

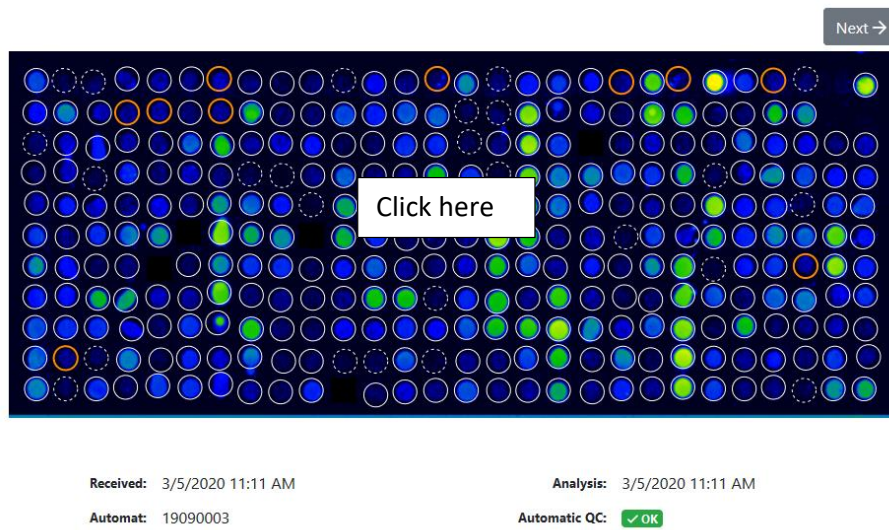
The array of the measurement with grid is displayed in the analytical image area. The software automatically identifies the position of the array in the image data based on the guide dots. There are 4 guide dots on ALEX<sup>2</sup>.

### ALEX<sup>2</sup>

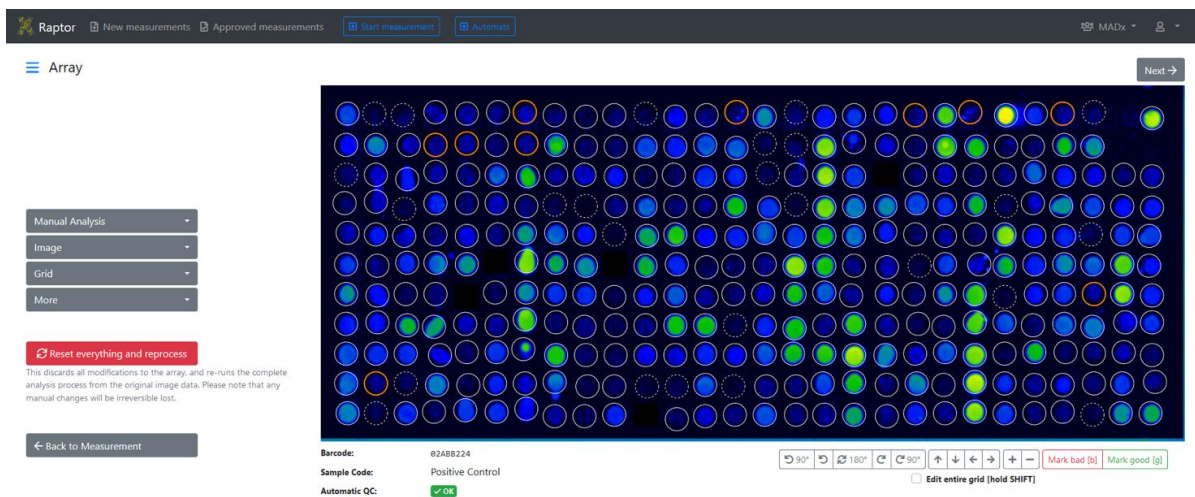


A: 4 Guide Dots

To enter the image processing mode, click directly into the image.

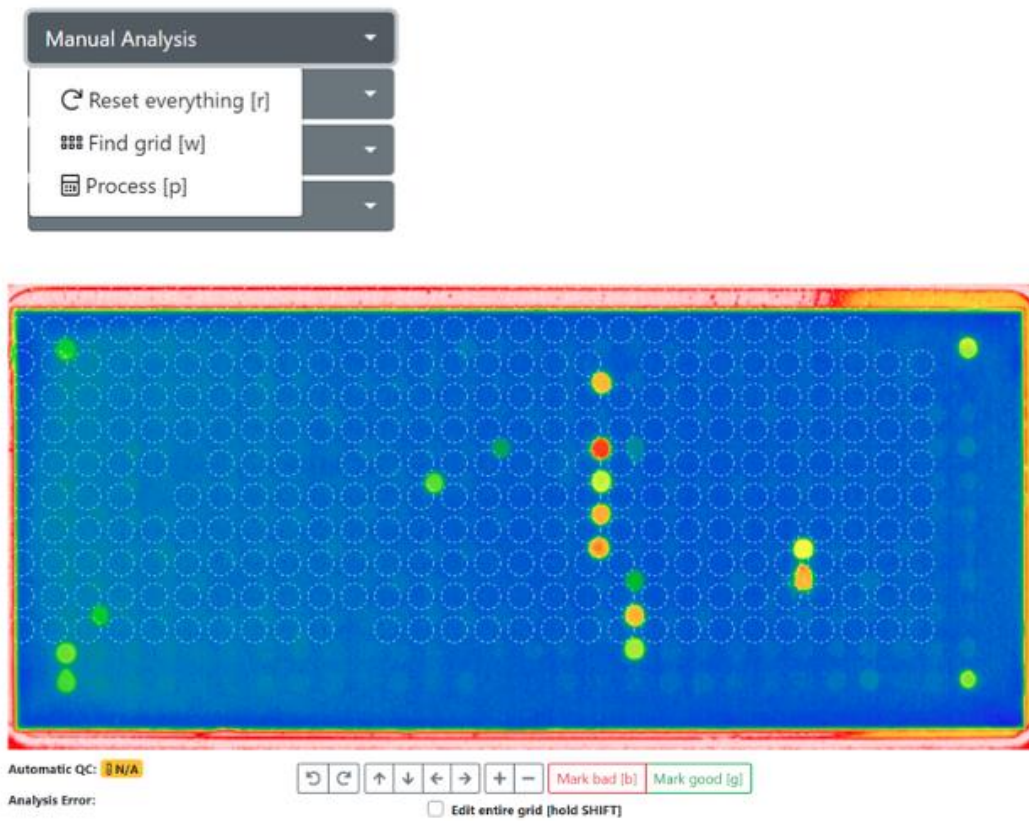


### Image Processing Mode:

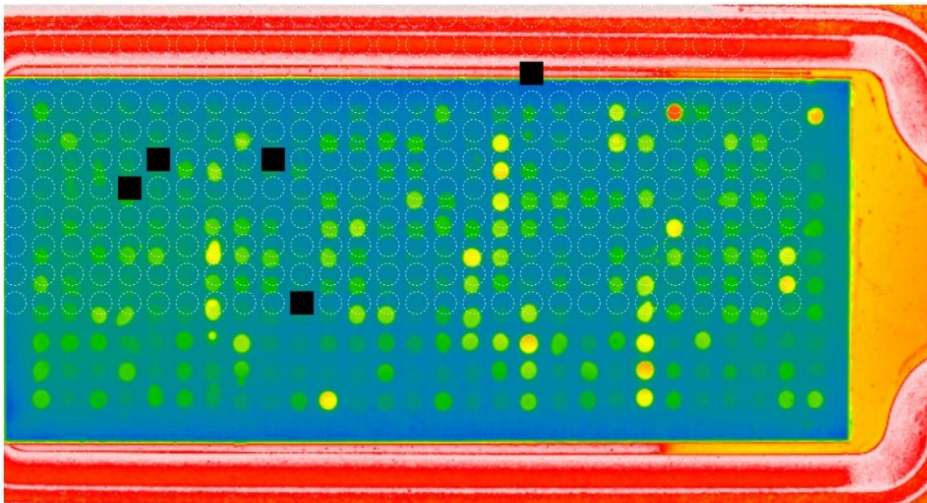


If the automatic position finding fails, the user will be alerted and the measurement quality control (inbuilt assay run control, see section 5.10) will be set to FAIL. In this case, the user can try to manually position the array by resetting the grid by pressing “R” or go to “Manual Analysis --> Reset Grid”. After resetting, you can move the whole grid with the mouse by additionally pressing “Shift”, or by setting a check mark at “edit entire grid”. The grid can also be found automatically by selecting “Manual Analysis --> “Find grid” or by pressing “W”. To turn the grid clockwise or counterclockwise, click the buttons according to the picture above. The position of the grid can be confirmed by pressing “P” or “Manual Analysis --> Process”.

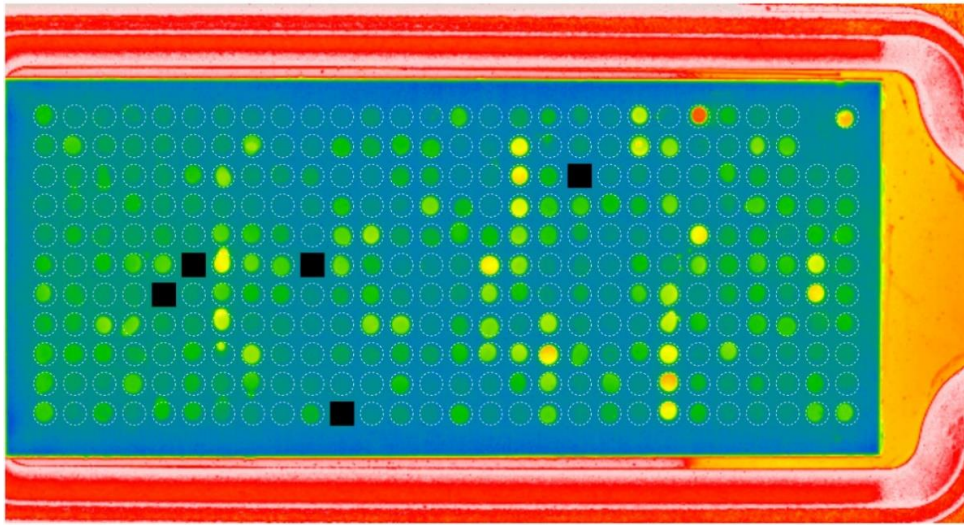
Press “R” or “Manual Analysis --> Reset everything”:



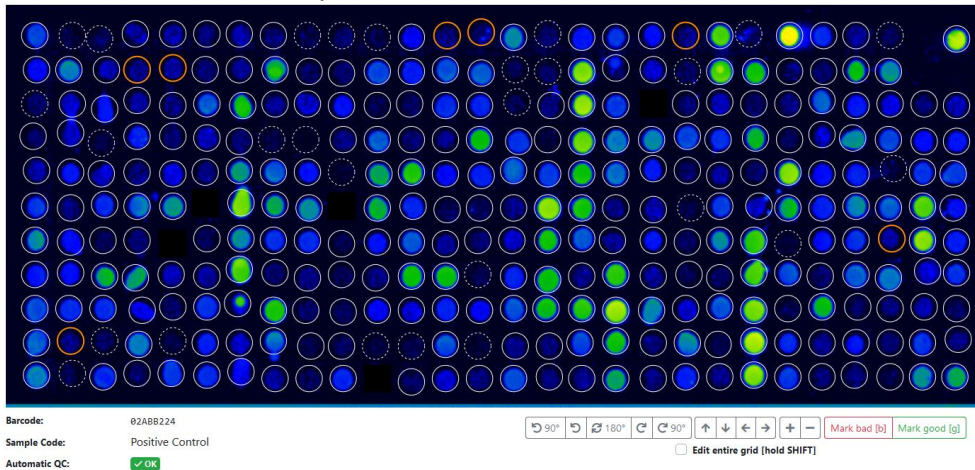
Press "R" or "Manual Analysis --> Reset Grid"



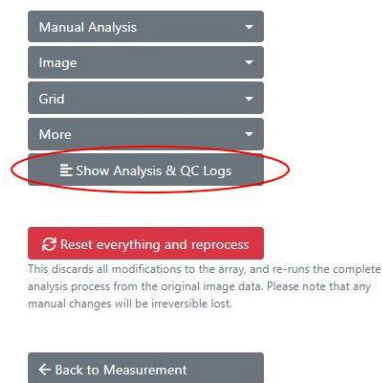
Press "W" or "Manual Analysis --> Find Grid" or manually move the whole grid:



Press "P" or "Manual Analysis --> Process":



If the image is reset manually, or with the button "Reset everything and reprocess", a button "Show analysis & QC logs" appears:



If you click this button, a text area will open with the explanation for QC fail or QC OK. For ALEX<sup>2</sup>, the background signal must be within a certain range and all 4 guide dots must achieve a certain value.

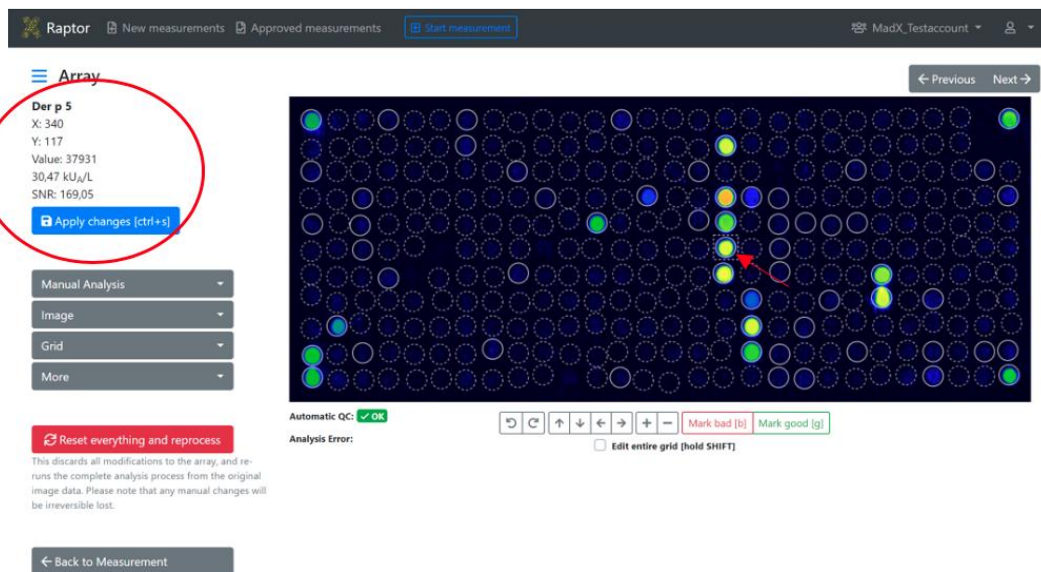
<p><b>Analysis Log</b></p> <p>Parsing calibration string ...          Total Igt (tIgt) normalized by calculating <math>1,38E-06x^4+0,013109999956677246x^3-20,14980078125 (x=16242)</math>, which results in 557.          'ReQuantify' took 426ms.</p>	<p><b>QC Log</b></p> <p>These are the values used for QC (ALEX v2): Curve Correction=0,9999008677496417, tIgt=16242, GD1=17802 (SNR=109.09), GD2=14754 (SNR=70.66), GD3=16849 (SNR=65.77), GD4=17381 (SNR=60.36)          QC (ALEX v2) succeeded.</p>
<p><b>Background Log</b></p> <p>Calculated background statistics for 204 pixels (from a total of 226, skipped smallest 11, and highest 11 pixels). The average is 9 970, the minimum 7822 and the maximum 12187 (minimum and maximum is calculated including skipped pixels). This results in an average difference of 516, which is an SD of 35,23 and a CV of 0,36%.          For comparison, there is an overall total of 171360 pixels. The overall average is 15 663, the minimum 5 197 and the maximum 65 187.</p>	

## Image Analysis

The analytic image of the selected ALEX technology-based array is displayed in a false color code to allow for a clear visualization. The false color intensity can be adjusted in three steps. Go to “Image” and select one of the 3 levels (low color correction, medium color correction or high color correction).

Pictures above from left to right: High color correction (default) - Medium color correction - Low color correction.

By clicking inside one spot, name, x and y coordinates of the image, raw and result value of the spot and the signal-to-noise ratio (SNR) are displayed.



Each allergen is surrounded by a circle. The graphic depiction of the circle represents the automatic interpretation by the software or the modification by the user:

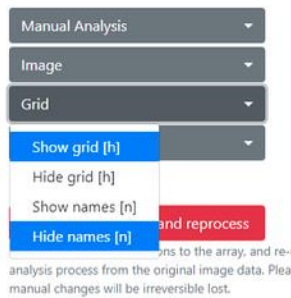
1. Circle with dotted line: not yet analyzed or below cut-off
2. Circle with a solid thin line: positive spot automatically found
3. Circle with solid thick line: spot set to good by user
4. Circle with a solid thin line and an X in the center: spot set to bad by the user
5. Circle with a thick dashed orange line: Spots to be inspected by the user with poor signal-to-noise ratio but a quantitative result above the system cut-off. Those spots should be set to "good" or "bad" by the user.
6. Research Use Only Spots (RUO) are marked with a "R" inside of the circle and will not be displayed in the PDF report, but are exported in the CSV, EXCEL or ASTM file. The RUO spots can be displayed by changes in the personal settings.



Spots are editable by the user:

- A single spot is selected by clicking on a spot.
- If you simultaneously press "SHIFT" or select "edit entire grid", all spots will be selected.
- Single spots or all spots can be moved with the arrow keys (left, right, up, down) or with the mouse.
- A selected spot can be set to Good by pressing "G"
- A selected spot can be set to Bad by pressing "B"
- By clicking on "H" the grid can be hidden and displayed again.
- By clicking on "N", all spots are annotated, and the abbreviated name of each allergen is displayed. This can be undone by pressing "N" again.

The last two features can also be used by selecting “Grid” --> “show or hide grid” and “show or hide names”.



### Short-Cut Summary:

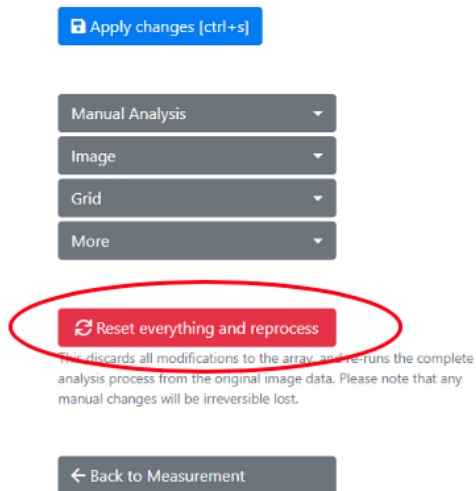
Short Cut	Execution
R	Reset analysis
W	Find grid
P	Process
G	Set feature to good
B	Set feature to bad
N	Annotate allergen features
H	Hide/unhide grid
SHIFT	Select all measurements

Orange marked spots need to be inspected and set to Good or Bad by the user. Otherwise, they will be marked by an orange triangle with an exclamation mark in the report. If the spot was set to “good” or “bad”, this will not be displayed.

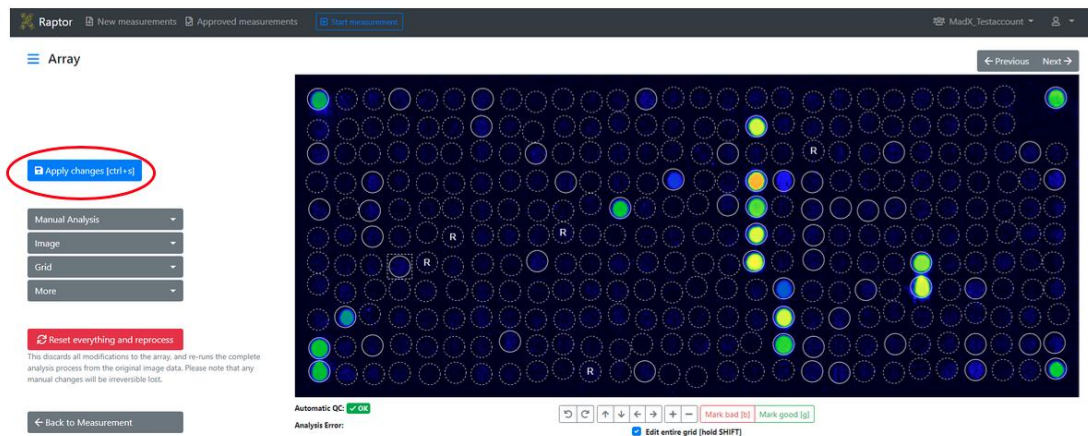
Milk				
Cow, milk	Bos d 4	M	α-Lactalbumin	0,38
Cow, milk	Bos d 5	M	β-Lactoglobulin	0,90
Cow, milk	Bos d 8	M	Casein	6,04
Cow, milk	Bos d_milk	E		3,40

It is also possible to open an image of the barcode, an image of the unprocessed or the processed array. To do this, go to "More" and select the desired image. A complete reset is also possible by pressing the "Reset everything and reprocess" button.

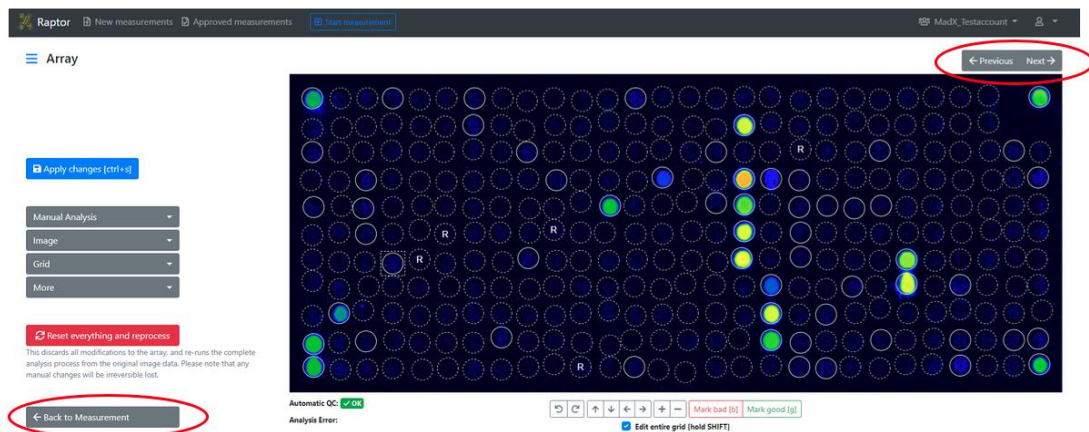




To return to the detail page of the measurement, press "Back to measurement". You can also click "Next/Preview" to go to the editing page of the following image. If the user changes the position or the interpretation of the spot or the whole grid, the analytic data will be erased, and the QC set to NA. After the analysis, press "Apply Changes" to save the modifications.



To return to the detail page of the measurement, press "Back to measurement". You can also click "Next/Preview" to go to the editing page of the following image.



### Analytical results

In the detailed results list, below the patient information and the analytic image, the results of the selected measurement will be displayed. The analytic result will display a list containing the following information:

- Allergen name & species
- Allergen code
- Biochemical function
- Tissue & exposure route
- Allergen extract or molecular allergen
- Feature name
- IgE value expressed as kU<sub>A</sub>/l (color coded)

All allergens

Name	Code	Biochemical	Tissue & Exposure	E/M	Feature	kU <sub>A</sub> /L
Acacia <i>Acacia mimos</i>	t19		Pollen Inhalation	E	Aca m	0.00
Acarus siro <i>Acarus siro</i>	d70		Mites Inhalation	E	Aca s	0.39
Alder <i>Alnus glutinosa</i>	t100	PR-10	Pollen Inhalation	M	Aln g 1	0.00
Alder <i>Alnus glutinosa</i>	t101	Polcalcin	Pollen Inhalation	M	Aln g 4	0.00
Almond <i>Prunus dulcis</i>	f20		Plant Food Food	E	Pru du	0.00
Alternaria alternata <i>Alternaria alternata</i>	m229	Alt a 1-Family	Microorganisms & Spores Inhalation	M	Alt a 1	0.00
Alternaria alternata <i>Alternaria alternata</i>	m230	Enolase	Microorganisms & Spores Inhalation	M	Alt a 6	0.00
American Cockroach <i>Periplaneta americana</i>	i206		Insects Inhalation	E	Per a	0.00
American Cockroach <i>Periplaneta americana</i>	i300	Tropomyosin	Insects Inhalation	M	Per a 7	0.11
American house dust mite <i>Dermatophagoides farinae</i>	d100	Cysteine protease	Mites Inhalation	M	Der f 1	3.69
American house dust mite <i>Dermatophagoides farinae</i>	d101	NPC2 Family	Mites Inhalation	M	Der f 2	30.01

By clicking on the drop-down menu “All allergens/Only positive allergens”, the information to be displayed in the analytic results window can be selected. This is independent of those results that are displayed in the PDF report.

All allergens		← All allergens
Only positive allergens		kUA/L
E	Aca m	0.00
E	Aca s	0.39

## Overview of measurements

New and unapproved measurements can be displayed in the “New Measurements” overview.

QC	Tags	Barcode	Sample Code	Patient Code	Patient Name	Analysis Date
OK		02AAB320				14.11.2019 10:54
OK		02AAB386				14.11.2019 10:54
OK		02AAB387				14.11.2019 10:54
OK		02AAB388				14.11.2019 10:53
Failed		02AAB389				14.11.2019 10:53

Clicking on the barcode or the analysis date takes you to the detail area of the measurement. Patient information and tags can also be entered in the overview page. To do this, simply click in the corresponding field of the measurement and insert it. With "TAB" you automatically enter the next field and your entry will be saved.

QC	Tags	Barcode	Sample Code	Patient Code	Patient Name	Analysis Date
OK		02AAB320	<input type="text"/>			14.11.2019 10:54
OK		02AAB386				14.11.2019 10:54
OK		02AAB387				14.11.2019 10:54
OK		02AAB388				14.11.2019 10:53
Failed		02AAB389				14.11.2019 10:53

In the search field, measurements can be searched for by according barcode, patient name, sample code or tag.

QC	Tags	Barcode	Sample Code	Patient Code	Patient Name	Analysis Date
OK		02AAB320				14.11.2019 10:54

It is possible to duplicate the barcode and the measurement data in the data repository if cartridge is acquired several times. However, this is indicated by a triangle with an exclamation mark during measurement.

QC	Tags	Barcode	Sample Code	Patient Code	Patient Name	Analysis Date
OK		02AAB320				16.12.2019 13:26
OK		02AAB386				16.12.2019 13:26
OK		02AAB387				16.12.2019 13:26
OK		02AAB388				16.12.2019 13:26

## Approving and exporting measurements

After analysis and careful revision of the results, the measurements can be approved by two ways:

1. One or more measurements can be selected by ticking and then approved in the drop-down menu together:

Selected measurements

- Download CSV format
- Download Excel format
- Approve**
- Update interpretation
- Delete

Unapproved measurements can also be downloaded as CSV or EXCEL.

2. A measurement can also be approved on the detail page of a measurement. Simply click on "Save and approve".

Barcode: 02AAB320

Sample Code:

Sampling Date:

Assay Date: 14.11.2019

Patient Code:

Patient Name:

Date of Birth:

Info:

Doctor Info:

Tags:

Report Save **Save and approve**

Received: 14.11.2019 10:54  
ImageExplorer: 22124136

Name	Code	Biochemical	Tissue & Exposure
Acacia <i>Acacia mimosa</i>	t19		Pollen Inhalation
Acarus siro <i>Acarus siro</i>	d70		Mites Inhalation

If the QC of a measurement is "ok", the measurement simply moves to the "Approved Measurements" tab. If the QC of a measurement is "Failed", the user will get a notification that the "Measurement QC is not OK". In addition, it will also be stated on the report that the internal QC (plausibility check for GD and background signal) was not successful.

#### Approve measurements

You are about to approve the following measurements.

Barcode	Analysis Date	Warnings
02AAB320	14.11.2019 10:54	

Approved measurements are stored in the "Approved measurements" tab. No patient information can be changed or added. The details of a measurement can be displayed by clicking on a measurement.

Tags	Barcode	Sample Code	Patient Code	Patient Name	Date of Birth	Approval Date
	02AAB319	119				10.12.2019 14:58
	02AAB318	118				10.12.2019 09:17
	02AAB317	117				10.12.2019 09:17

Selected measurements in the approved measurements tab can be downloaded as PDF report, as EXCEL, CSV or ASTM file.

#### Approved Measurements

Search by barcode, patient, sample, tag ...

Download selected measurements ▾

Tags	Barcode	Sample Code
<input checked="" type="checkbox"/>	02AAB319	119
<input checked="" type="checkbox"/>	02AAB318	118
<input checked="" type="checkbox"/>	02AAB317	117

#### Approved Measurements

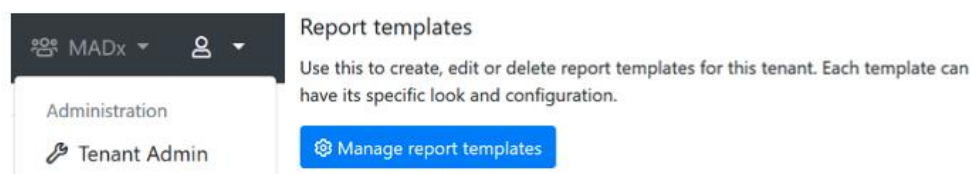
Search by barcode, patient, sample, tag ...

Download selected measurements ▾

Report (PDF format)	Barcode	Sample Code
CSV format	02AAB319	119
Excel format	02AAB318	118
ASTM format	02AAB317	117

## Report Settings

In the "Tenant Admin" and "Manage report templates" the report settings can be selected.



The following settings can be selected:

- Name of the report template
- Preferred language (you can still change the language for every report separately)

- Allergens summary: tIgE  
Total IgE (tIgE) is highlighted in blue on the summary page of the report. It is possible to hide tIgE in the report if you deselect tIgE.
- Dates shown on the report:
  - Sample date
  - Assay date
  - Test date
  - Approval date
  - Print date
- Allergen details:
  - Include allergens (all allergens or only the positive ones)
  - Allergen sort order: The allergen details in the report (in one allergen group) can be sorted in three different ways:
    - Alphabetical order by allergen codes
    - Descending from the highest to the lowest value
    - Alphabetically order by allergen name (common name)
  - Cross-reactive information: By selecting “include cross-reactive information”, explanatory sentences will be added to the end of the report describing those allergen families that are positive on the first page. (see “cross-reactive allergens”). It is possible to include the information as text only or the information and a table of all positive allergens).
  - Include interpretation (RAVEN)
- Export settings of PDF Report:
  - Setting Type: Automatic --> choose from the following options:
    - Patient ID
    - Patient Name
    - Sample ID
    - Measurement barcode
    - Date & Time
  - Setting Type: Manual --> select options the way you prefer  
Example: Report\_{PatientID}\_{DateAndTime}
- Header: To upload a logo on the left or right side, please press “Browse” and select a JPG or TIFF format.
- Signature: In addition, a picture of a signature can be uploaded to be added at the end of the report.

The screenshot shows the 'Add new report template' configuration window. It includes the following sections:

- General configuration:** Name (New report template), Preferred language (English).
- Dates shown:** Checkboxes for 'Include sample date', 'Include assay date', 'Include test date', 'Include approval date', and 'Include print date'.
- Export Settings:** Setting Type (Automatic), and checkboxes for 'Include Patient ID', 'Include Patient Name', 'Include Sample ID', 'Include Measurement Barcode', and 'Include Date & Time'.
- Allergens Summary:** 'Include final list' checkbox.
- Allergen Details:** 'Include allergens', 'Allergens sort order' (Alphabetically by allergen), 'Cross-reactive information', and 'Include interpretation' checkboxes.
- Header:** 'Logo left', 'Text' (with a preview area showing contact information), and 'Logo right' fields.
- Signatures:** 'Left', 'Center', and 'Right' signature fields.

Buttons for 'Save' and 'Cancel' are located at the bottom left.

After the change, the report template can be saved by clicking the “Save” Button.

The following languages are available:

- Arabic
- Bulgarian
- Chinese
- Croatian
- Czech
- Dutch
- English
- French
- Georgian
- German
- Greek
- Hungarian
- Italian
- Latvian
- Lithuanian
- Persian
- Polish
- Portuguese
- Romanian
- Russian
- Slovak
- Slovenian
- Spanish
- Spanish-Mexico
- Turkish
- Ukrainian

To define your “default” template that is used as standard template, you need to have at least “basic tenant” rights. If you go to "Configure Tenant" in the Tenant Admin area, you can select your default language and template.

The screenshot shows the 'Tenant configuration' page. The sidebar on the left has 'Administration' and 'Tenant Admin' (with a key icon). The main content area is titled 'Tenant configuration' and contains a 'Configure Tenant' button. Below this is a section titled 'Configure "MADx"' with a 'General configuration' sub-section. The 'General configuration' section includes the following fields:

- \* Name: MADx
- Default timezone: (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna
- Default report template: New report template
- Default report language: English

The 'Default report language' field is highlighted with a red oval.

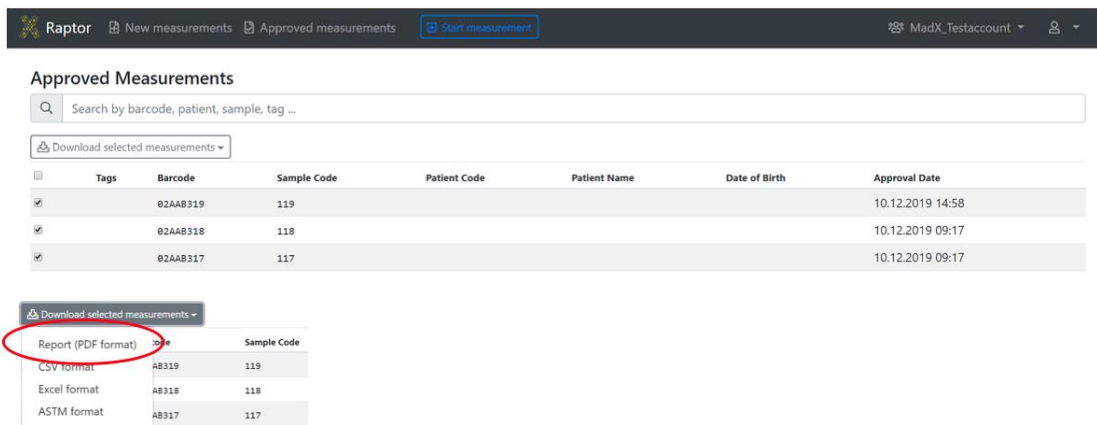
A report of an unapproved measurement can be displayed by clicking on one measurement from the “New measurement” tab and selecting “Report”.

The screenshot shows the 'Raptor' interface with the 'Details' page for a measurement. The page displays various fields for the measurement, including Barcode, Sample Code, Sampling Date, Assay Date, Patient Code, Patient Name, Date of Birth, Info, Doctor Info, and Tag. At the bottom, there are three buttons: 'Report', 'Save', and 'Save and approve'. The 'Report' button is highlighted with a red oval.

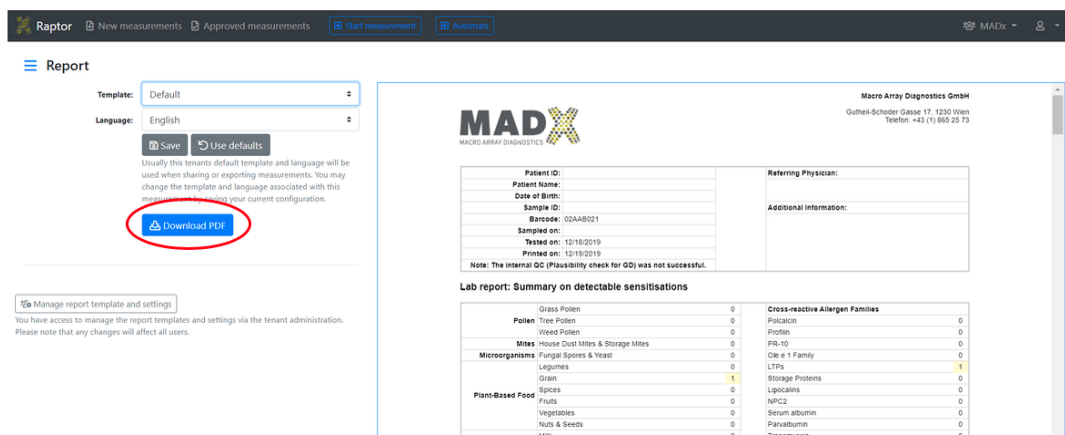
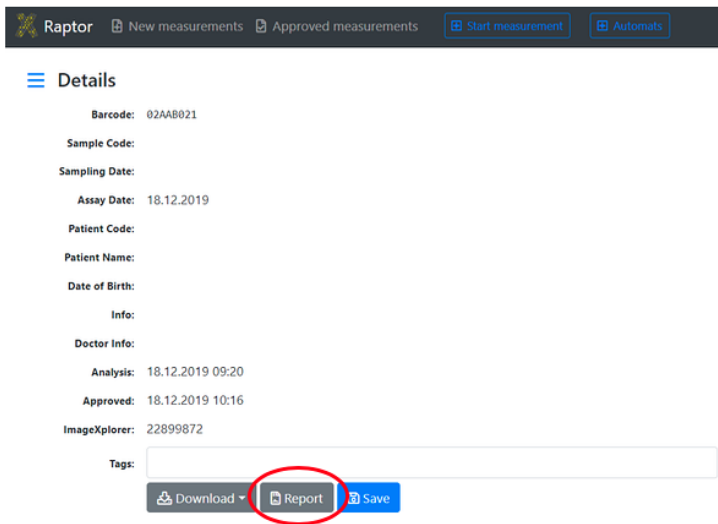
Then you see a preview of the report, where you can select a report template (default or customized) and set the default language. However, it is not possible to download this PDF report. For this purpose, it is necessary to approve the measurement first. You can select either “Version 1” or “Version 2” for the template.

Approved measurements can either be downloaded together or individually. To download measurements together, first go to the "Approved measurements" tab and select the measurements you want to download. Then select PDF Report from the drop-down menu and a zip folder containing the PDF Reports will be saved locally on your computer.





If you click on a measurement, you get to the detail area of this measurement. From there, you can also display a preview of the report and change the settings for the header and language of this report. You can then download the report directly from there.



## Requesting Interpretation Guidance

A special software module has been implemented to support the interpretation of ALEX technology-based results: RAVEN interpretation. For using this service, a license key has to be requested by your local distributor or by sending a request to support@macroarraydx.com.

The license key received must be entered in the Tenant Admin area under "Configure Tenant". To add a license key, full company details, a data processing agreement document and a term of service document has to be uploaded.

The image shows two parts of a web interface. The top part is titled "Tenant configuration" and contains the text "The general configuration settings for your tenant." and a blue button labeled "Configure Tenant". The bottom part is titled "Interpretation" and features a text input field labeled "License Key:" which is circled in red.

An interpretation query with RAVEN is possible both for approved and unapproved measurements. The report can only be downloaded for approved measurements. Select a measurement for an interpretation query to get to the detail page of a measurement, then click on the icon and select "View interpretation".

The image shows a measurement detail page for ID "02AAB019". A dropdown menu is open, showing options: "View array", "View report", "View interpretation" (circled in red), and "Approve measurement" (a blue button). Below the menu are input fields for "Patient Code:" and "Patient Name:". A red circle highlights the menu icon in the top left corner.

This opens a window in which the settings (language) specific patient information (such as age, gender and environment) and patient symptoms can be entered.

**Interpretation**

**Settings**

Language: English

**Patient information**

Gender: Female

Age: 30 years

Environment: Continental

**Patient symptoms**

Asthma: None

Rhinitis: None

Conjunctivitis: None

Urticaria: None

Angioedema: None

Oral Allergy Syndrome: None

Eczema: None

Anaphylaxis: None

GastroentericSymptoms: None

Request interpretation

After entering these, the query can be started with the button "Request interpretation".

**Interpretation**

**Patient information**

Gender: Female

Age: 30 years

Environment: Continental

Asthma: None

Rhinitis: None

Conjunctivitis: None

Urticaria: None

Angioedema: None

Oral Allergy Syndrome: None

Eczema: None

Anaphylaxis: None

GastroentericSymptoms: None

**Interpretation**

**Raven Interpretation Summary**

**Sample Information**

The sample was tested on ALEX<sup>2</sup> Barcode 02AAB019, interpretation date 12/19/2019.

Of the tested 295 allergens, 25 were above the detection limit of 0.3 kU<sub>A</sub>/L. A sensitization can be an indicator of an allergy. For selected allergens, comments for interpretation are listed below.

**Total IgE: 512 kU/L**

The measured total IgE was 512 kU/L. Above a total IgE of 100 kU/L, allergy is likely.

**Cross-Reactive Allergen Sensitization detected**

Sensitization against allergen molecules which are markers of (broad) cross-reactivity between different allergen sources.

Detected cross-reactive allergen sensitizations:

- PR-10s: Aln g 1, Bet v 1, Cor a 1.0103, Fag s 1
- Polcalcins: Aln g 4, Pfl p 7

**PR-10 Proteins (PR10)**

PR-10 inhalative: The major birch pollen allergen, Bet v 1, represents the prototype of all PR-10 allergens and is the primary sensitizer in regions with birch pollen exposure. The presence of PR-10 allergens in Fagales tree pollen explains IgE cross-reactivity between pollen from hazel, alder, beech, oak and hornbeam. PR-10 nutritive: PR-10 allergens in raw fruits, nuts, vegetable and legumes can induce oral allergy syndrome and sometimes severe allergic reactions in sensitized individuals. PR-10 allergens are not stable to heat and digestion.

**Polcalcins (Ca++ binding proteins, PC)**

Members of the PC family can cause inhalative symptoms. PC allergens can be found in pollen from grasses, trees and weeds. Inhalative symptoms manifest as allergic rhino-conjunctivitis and/or allergic asthma.

Request new interpretation

This measurement already has an interpretation stored. Usually, it should not be necessary to request those again, but it could be necessary when the patients information has changed.

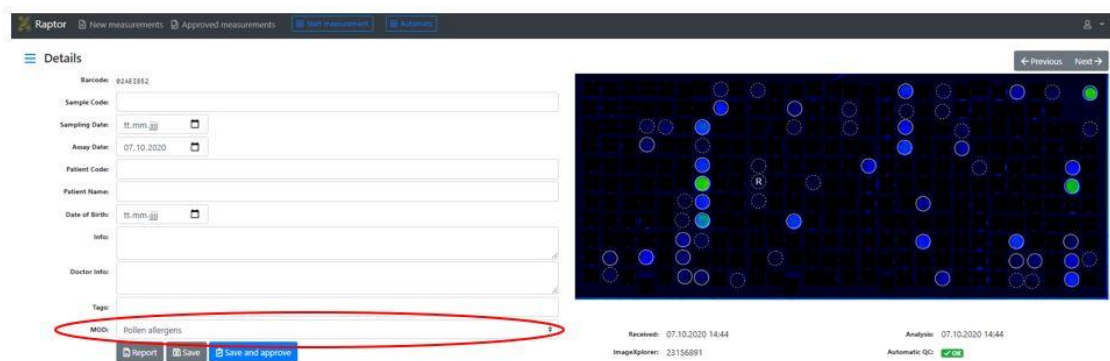
The interpretation is automatically inserted at the end of the report and is also displayed in a preview window. Measurements which have already received an interpretation query are indicated by the following symbol:



### Multiplex on Demand

#### Selecting Multiplex on Demand

The user can select which analytical parameters should be considered for the analysis. In the detail window of a measurement, a global predefined panel can be selected. If a panel is selected, the software will only display the allergen spots and results of the selected panel.



After approval of the measurements, the unselected allergen results will be deleted from both image and data. The unselected allergens are then listed in the report as “-“. To reset the selection, select "no panel".

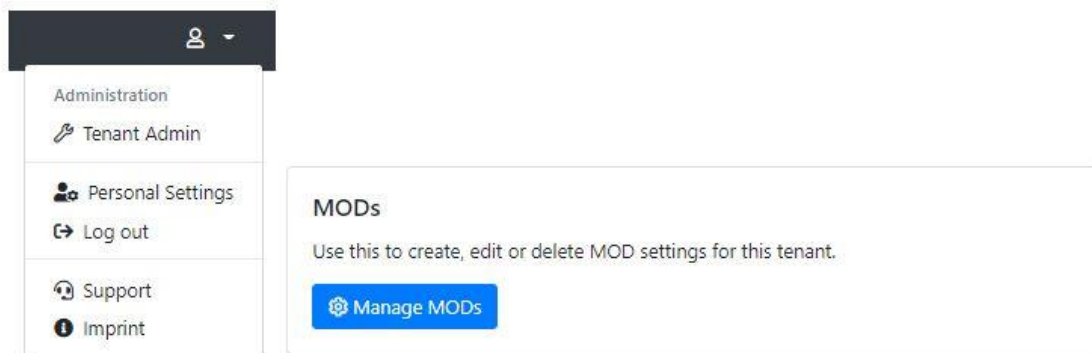
Predefined MODs:

The following allergen panels can be selected:

- AIT relevant
- ALEX2 without venoms
- Animal based food
- Cockroaches, mites & insects
- Contact allergens
- Egg & milk
- Food allergens
- Fruit allergens
- Furry animals
- Inhalative allergens
- Legumes, nuts & seeds
- Molecular allergens
- Plant based food
- Pollen allergens
- Venom allergens

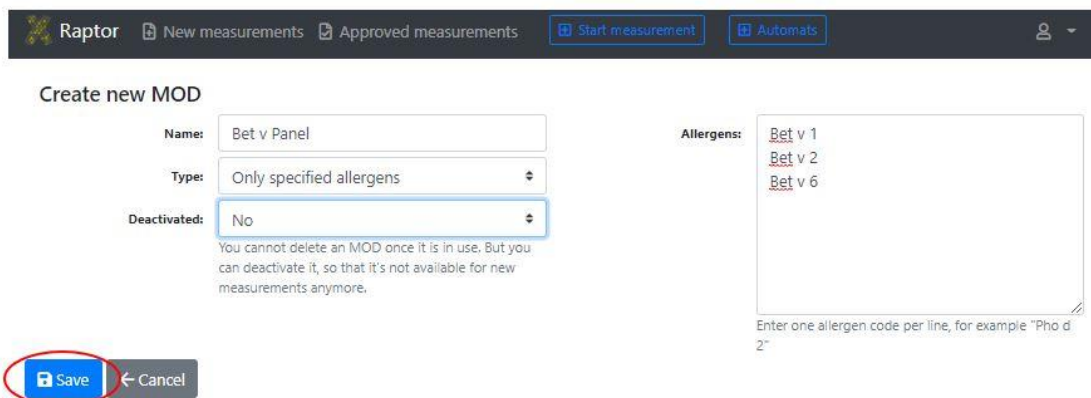
Defining new MOD Panels:

Each tenant can define his own MOD panels. To do this, go to "Tenant Admin" --> click on "Manage MODs" and create a tenant-specific MOD panel by clicking on "Add new MOD".



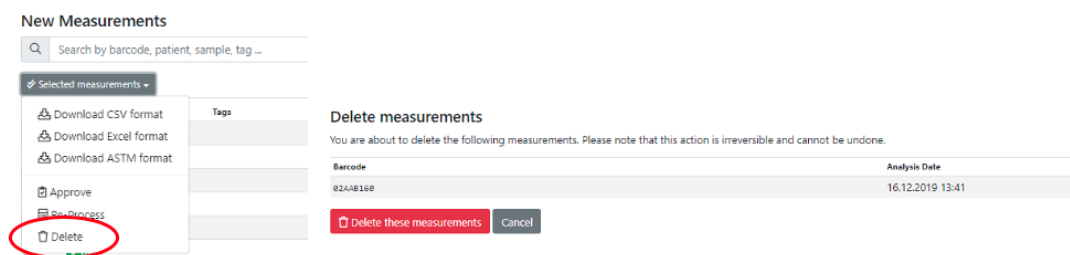
### MODs for "MADx" and global ones

Add new MOD



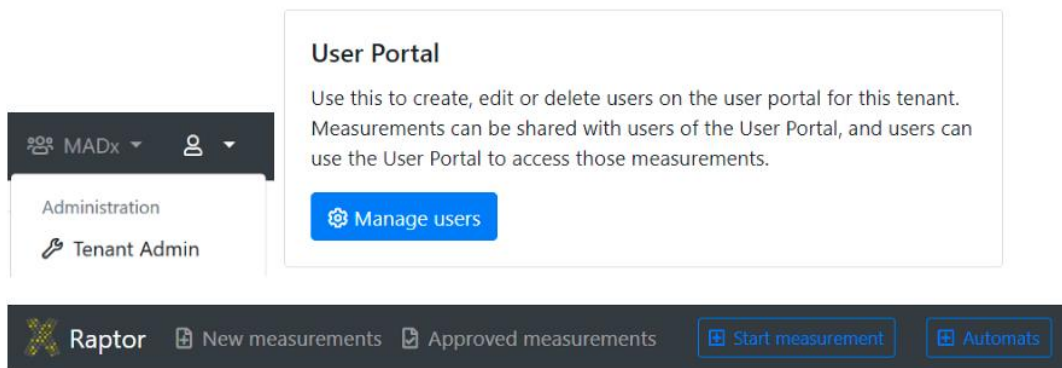
### Deleting measurements

Non-approved measurements can be deleted by selecting the measurement that should be deleted and select in the drop-down menu "delete". Before a measurement is permanently deleted, a warning appears that has to be approved. Deleted measurements will be permanently erased and cannot be restored.

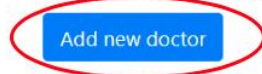


## User Portal

Measurements can be shared with a physician or other user. To do this, you must first create a physician or user. To create a physician or user, go to "Tenant Admin --> User Portal", click on "Manage Users" and add a new doctor or user.

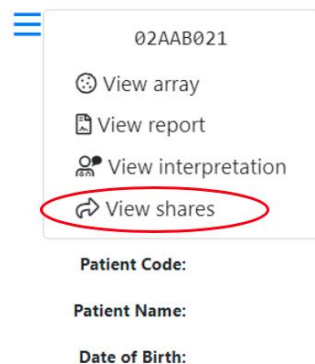


### Users of User Portal for "MADx"



Enter the user information and send an E-mail to create a password. Alternatively, you can define the password for the user.

Only already approved measurements can be shared. For this purpose, please go to the tab "Approved measurements", click on the detail page of a measurement, go to the icon and select "View Shares".



Then select the user with whom you want to share the measurement and click “Share”. After that you can either send a link by E-mail, with which the user can access this measurement. Or the user can log in with his access data on the following website (<https://doctorportal.raptor-server.com/>) and see the measurement shared with him.

### ☰ Share


You are about to share a measurement with a user of the User Portal. Please note that the doctor will have access to the results of the measurement until your measurement. Once you share a measurement you'll be provided with a link to access the shared information via the encrypted User Portal.

Barcode: 02AAB021

Share with: X Dr. (testuser2@macroarraydx.com) ▾

If you can't find a specific user of the User Portal, go to the [tenant administration](#) to configure the list of available users of the User Portal.

[Share](#) [Cancel](#)

 User Portal
English ▾

## Welcome to the User Portal

The Allergy Explorer User Portal allows users to view shared measurements. You will need a username and password to log in, and view all measurements that have been shared with you. Also, a sharing link will allow to view specific shared measurements.

Please enter your username and your password:

Did you forget your password? No problem, you can [request a new one](#).

Imprint Privacy
v0.0.1.10

After log-in, the user can view the patient details of the shared measurements and open the report. However, the user cannot change anything.

User Portal English Log out

## Shared Measurements

These are the measurements that have been shared with you. You may view the details of each measurement, or download the report PDF file.

Measurement	Patient	Sample
02AAB021		<a href="#">View Details</a> <a href="#">View Report</a>

Imprint Privacy v0.0.1.10

Measurements that have been shared are marked with the following symbol. Measurements that have been shared can also be withdrawn by a tenant.

### Log-out

To log out of the RAPTOR SERVER, click on "Log out" and close the window.

MADx

- Administration
- Tenant Admin
- System Admin
- Personal Settings
- [Log out](#)
- Support
- Imprint

### 5.15. Storage and Transportation

For storage and transportation of the MAX 45k, please follow the procedure described in Section 6.3 step 1. to 7.



## 6. Cleaning/Maintenance

By following the preparatory and follow-up work instructions for the instrument, you will keep the analyzer in good shape and significantly prolong its working life. If your analyzer malfunctions, please contact MacroArray Diagnostics or its authorized service partners.

### 6.1. Cleaning of the Outer Surface

To clean the outer surfaces of the analyzer, please wear gloves and use only mild detergents or alcoholic disinfectants. Autoclaving or putting parts which have been removed from the instrument into cleaning agents or disinfectants is not permitted. Please see the product-specific inserts for safety instructions on handling cleaning agents.

For the disinfection of the surfaces, terralin® protect (available from Schülke & Mayr GmbH Norderstedt) in a concentration of 2% is recommended.



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

### 6.2. Weekly Cleaning

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

1. Remove the front and rear lid of the cartridge rotor with wash-buffer solution tube disconnected and remove all cartridge segments.
2. Clean the waste rim of the cartridge rotor with a cloth moistened (non-dripping) with terralin® protect 2%.



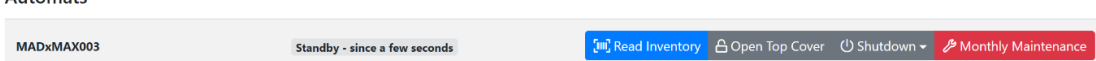
**Do not use a spray for cleaning, otherwise the optics may malfunction.**

3. Clean the illumination module of the cartridge rotor at the illuminated surface with a cloth moistened with terralin® protect 2% (non-dripping) to remove potential dust.
4. Remove the rear lid of the cartridge rotor and visually check if the wash needle shows any residuals. If residuals are visible, please exchange the wash needle.

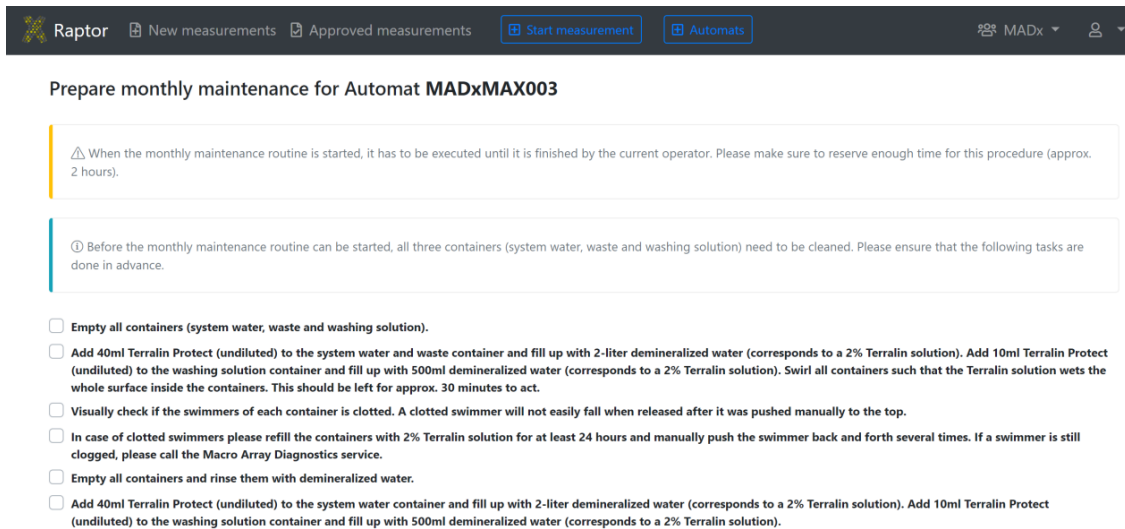
### 6.3. Monthly Cleaning

The monthly cleaning of the analyzer is mandatory and activated and tracked by RAPTOR SERVER Analysis Software. To start the procedure and work with the provided online-check list, go to the instrument main page and press the red button “Monthly Maintenance”.

Automats



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



Prepare monthly maintenance for Automat **MADxMAX003**

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

⌚ 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.

- Empty all containers (system water, waste and washing solution).
- Add 40ml Terralin Protect (undiluted) to the system water and waste container and fill up with 2-liter demineralized water (corresponds to a 2% Terralin solution). Add 10ml Terralin Protect (undiluted) to the washing solution container and fill up with 500ml demineralized water (corresponds to a 2% Terralin solution). Swirl all containers such that the Terralin solution wets the whole surface inside the containers. This should be left for approx. 30 minutes to act.
- Visually check if the swimmers of each container is clotted. A clotted swimmer will not easily fall when released after it was pushed manually to the top.
- In case of clotted swimmers please refill the containers with 2% Terralin solution for at least 24 hours and manually push the swimmer back and forth several times. If a swimmer is still clogged, please call the Macro Array Diagnostics service.
- Empty all containers and rinse them with demineralized water.
- Add 40ml Terralin Protect (undiluted) to the system water container and fill up with 2-liter demineralized water (corresponds to a 2% Terralin solution). Add 10ml Terralin Protect (undiluted) to the washing solution container and fill up with 500ml demineralized water (corresponds to a 2% Terralin solution).

The monthly maintenance procedure includes the following steps:

1. Fill all containers (system-water, wastewater, and wash-buffer solution) with terralin<sup>®</sup> protect 2% up to the labeled marking. Incubate for approx. 30 minutes at room temperature.
2. Remove the terralin<sup>®</sup> protect solution from all containers and wash them thoroughly, using demineralized water. Empty all container.
3. 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.
4. In case of a clotted float ball please refill the containers with terralin protect 2% for at least 24 hours and manually push the swimmer back and forth several times and finally wash all containers out thoroughly using demineralized water and empty all container. If a float ball is still clogged, please call the service team from MacroArray Diagnostics or its representatives.
5. Fill the system-water and Washing Solution container up to the labeled marking with terralin<sup>®</sup> protect 2% and start the monthly maintenance routine RAPTOR SERVER Analysis Software and follow the instructions in the RAPTOR SERVER Analysis Software.
6. Clean the rotor plate of both rotors using a cloth moistened with terralin<sup>®</sup> protect 2%.
7. Remove sample and cartridge rotor disk and clean the tub using a cloth moistened with terralin<sup>®</sup> protect 2%.



Caution

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

- Clean the waste rim using a cloth moistened with *terralin*<sup>®</sup> *protect* 2%.



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

#### 6.4. Repairs

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

##### PLEASE NOTE

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

## 7. Performing Maintenance

### 7.1. Annual Maintenance/Parts Exchange by Service Technician

Annual maintenance must be performed for the instrument and will be carried out by qualified service employees from MacroArray Diagnostics GmbH or its qualified and authorized service partners. The parts that need to be exchanged within this regular interval are:

- Syringe body
- Waste tube line
- Waste pump head
- Inline filter from system waste line from pipetting needle wash station and rim.
- Annual clean-up of the SD card in the instrument

Additional activities to be applied are described in the service manual and will be done by a service engineer.

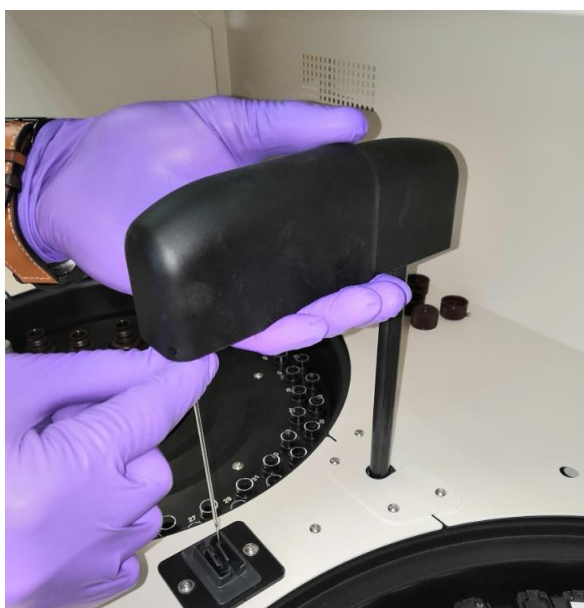
### 7.2. Exchange of Steel Needle of Robotic Arm by the Operator

The steel needle of the robotics 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:

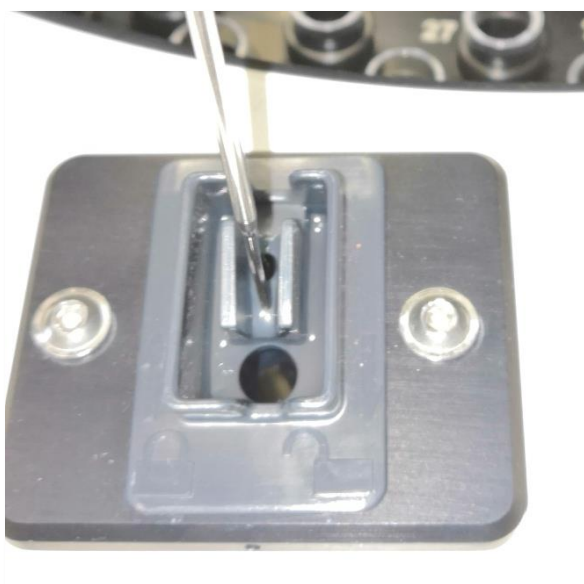
1. Please turn off the instrument and open the main flap according to **Section 4.3.3**.
2. Manually lift the robotics arm to the top and turn it to the front so that the needle tip is positioned above the drain channel of the needle wash station. Keep holding the arm in this position.



3. Hold the arm at the mentioned position and unscrew the needle slowly by turning it counterclockwise with your other hand. Liquid will drop into the drain channel.



4. Gently screw a new steel needle into the holder by turning it clockwise until it is fixed.
5. Move the arm carefully and slowly horizontally through the external wash station and check if the needle is touching the side walls.



6. In case the needle is touching one of both side walls, the instrument must not be used until a realignment has been performed by a service technician. Please call technical service from MADx or its authorized partners.

Finally, the needle has to be positioned over the parking position where the needle can slowly fall down without any collision with the working deck (see figure below).

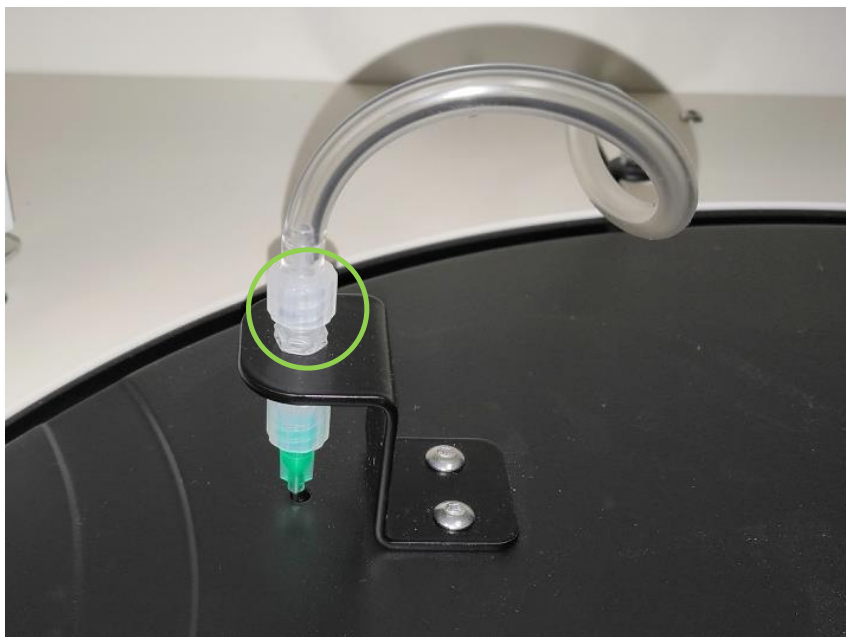


If this procedure is correctly applied no further alignment is necessary.

### 7.3. Exchange of the Wash Solution Needle

The wash solution needle of the cartridge rotor 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:

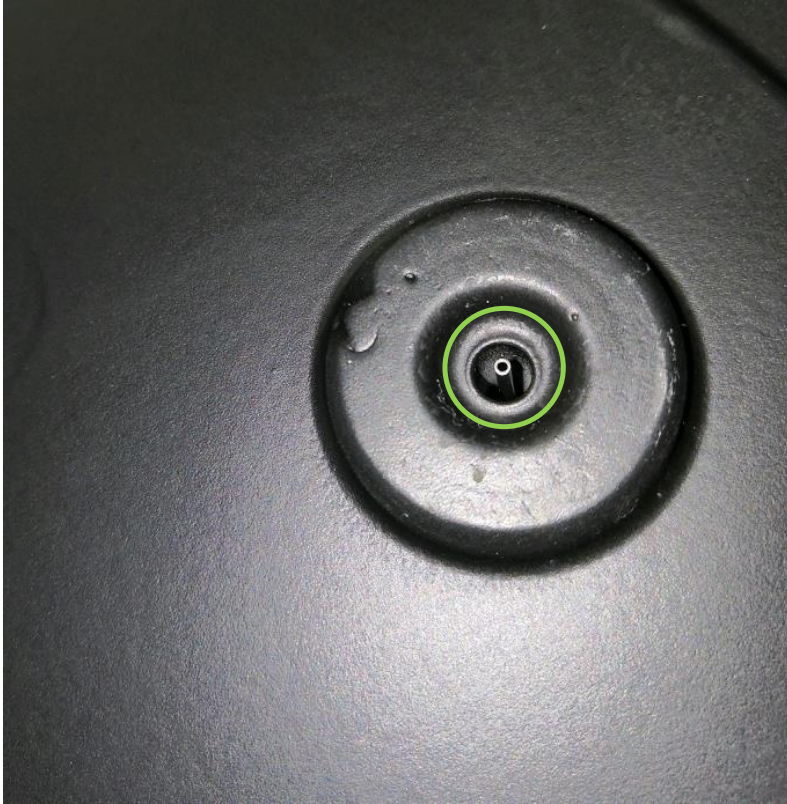
1. Remove Luer-lock connector from needle.



2. Remove needle adapter and exchange wash needle.



3. Mount needle adapter so that needle is centrally aligned on the bottom of the rear lid of the cartridge rotor and tight the screw firmly.





## 8. Troubleshooting MAX 45k

Error messages from the analyzer will be presented by RAPTOR SERVER Analysis Software as described in **section 5.12**. When a serious error occurs, the analyzer gets into a “stop-state”, caused by the following events:

### 8.1. Leakage Sensor

The cartridge rotor is equipped with a leakage detector that will stop all mechanical movements and pumps immediately when a leakage is detected.



Caution

If a leakage is detected and presented by RAPTOR SERVER Analysis Software, switch off the instrument and disconnect the power cable. Contact MacroArray Diagnostics service or its authorized partners.

### 8.2. Crash Sensor

The pipetting robot is equipped with a vertical movement crash detection unit. It will stop all mechanical motions and pumps immediately after a vertical crash of the steel pipette has been detected. 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 5.6**) the user can recover the analyzer to perform further steps.



Caution

If a second vertical movement crash is detected, although an “Initialize” procedure was executed in between, please contact MacroArray Diagnostics service or its authorized partners.

### 8.3. Un-authorized Main Flap Opening

The main flap is secured with an interlock system. Whenever the user compromises the security mechanism while the instrument is turned on, all mechanical motions and pumps immediately stop working. By performing the “Initialize” procedure via the RAPTOR SERVER Analysis Software (see **Section 5.6**), the user can recover the analyzer to perform further steps.



Caution

If an un-authorized main Flap Opening occurs, MacroArray Diagnostics GmbH disclaims all liability for damage to the analyzer or incomplete test results.

### 8.4. Needle Wash Station: Missing System Water

When the outer needle wash is performed, the existence of System Water – which is necessary to ensure the proper cleaning of the outer needle surface - will be checked. If no Liquid Level Detection (LLD) occurs, the analyzer transits into the “Stop State”, or an error is recorded for the corresponding cartridge in case this issue occurs during an assay run.



If the wash station does not provide System Water for the exterior needle cleaning, please contact MacroArray Diagnostics service or its authorized partners.

### 8.5. Waste Pump Malfunction

After a series of pipetting steps is finished (e.g. sample pipetting) the device will check the fill level of the drain channel of the active wash station to ensure that no clogging or waste pump malfunction took place. If a critical fill level is detected, the analyzer transits into the “Stop State” with a corresponding error message.



If the wash station does not apply enough wastewater draining, please contact MacroArray Diagnostics service or its authorized partners.

### 8.6. Further Error Messages

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

#### Error Severity

Severity	Description	Instrument Operation
Severe	The highest error severity (3)	Instrument stops all movement, 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

## 9. Technical Specification

Item	Specification
Throughput	Up to 100 test per working day (8h) and 150 tests including 1 overnight run
Sample pipetting volume	100µl to 500µl
Reagent pipetting volume	100 to 500µl
Low volume sample tubes	Sarstedt ZB-Röhre 2,5ml, 75x13 (round), Order number: 60.614.010
13 mm standard tubes (with adapter)	Minimum height: 75 mm, maximum height: 100 mm For example: Sarstedt Röhre 5ml, 75x13mm, PS Order number: 55.475
16 mm standard tubes	Minimum height: 75 mm, maximum height: 100 mm For example: Sarstedt Röhre 13ml, 100x16mm, PS Order number: 55.459
Minimum sample volume for 1 test, 13/16 mm standard tubes	400 µl (145 µl serum + 580 µl Sample Diluent with manual predilution)
Minimum sample volume for 1 test, low volume tubes	200 µl (110 µl serum + 440 µl Sample Diluent with manual predilution)
Maximum number of onboard samples	50
Maximum number of assay runs with one ALEX <sup>2</sup> kit	5
Sample container	Sample tubes with a nominal height of 75mm and 100mm and a nominal outer diameter of 13mm and 16mm (13mm tubes with adapter)
Reagent container	15mL, 30mL
Max number of onboard cartridges	50
Incubation temperature	37°C ± 0.5 °C accuracy
Mixing method	Non-Invasive
Dimensions	Depth: 65 cm, Width: 115 cm, Height: 60 cm (closed main flap)
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	-400m – 2000 m above sea level
Weight	~ 100kg
Power Management*	100-240V, 150 W, 50/60Hz
Noise Level	< 65dB in 1m distance

**Table 12**  
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.

## 10. References

1. Hamilton RG. Assessment of human allergic disease. In: Rich RR et al ed. Clinical Immunology, Principles and Practice, 3:rd ed. Mosby Elsevier; 2008:1471-84
2. Harwanegg C, Laffer S, Hiller R, Mueller MW, Kraft D, Spitzauer S, Valenta R. Microarrayed recombinant allergens for diagnosis of allergy. Clin Exp Allergy. 2003 Jan; 33(1):7-13
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