



MAX (Multi Array Xplorer) 45k

User Manual

- Instruction for Use -

Version number: 16-IFU-01-EN-07

Date of Issue: 2022-07

Applicable MAX 45k firmware version: 1.3.2

We reserve the right to make changes in the course of technical development without previous notice.

© 2022 Macro Array Diagnostics GmbH. All rights reserved.
Lemböckgasse 59/Top 4
1230 Wien
Austria

Neither this manual nor any parts of it may be duplicated or transmitted in any way without the written approval of Macro Array Diagnostics GmbH.

Disclaimer

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



Macro Array Diagnostics GmbH
Lemböckgasse 59/Top 4
A-1230 Vienna
Austria
<https://www.macroarraydx.com/>

Liability statement

This guide was checked for correctness. The instructions and descriptions for the MAX 45k were correct at the time this guide was written. Subsequent guides may be changed without prior notice; however, Macro Array Diagnostics GmbH assumes no liability for harm caused directly or indirectly by errors from the guide. The MAX 45k is an in-vitro diagnostic device that will be used by trained laboratory personal only.

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

Preface

Dear User,

We at Macro Array Diagnostics want to thank you for choosing our Multi Array Xplorer 45k analyzer (MAX 45k) for an automated analysis of ALEX² and FOX 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, ALEX²) and semi-quantitative determination of total IgE (tIgE, ALEX²) or semi-quantitative IgG (FOX). 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 MADx team (support@macroarraydx.com) and our local distributors will be happy to help you. We hope that the MAX 45k will meet your expectations.

Sincerely yours,

Dr. Christian Harwanegg, MBA

Chief Executive Officer Macro Array Diagnostics GmbH

Contents

1. INTRODUCTION.....	6
1.1. TERMS AND DEFINITIONS	6
1.2. MANUFACTURER	7
1.3. IDENTIFICATION OF THE ANALYZER	7
1.4. PERFORMANCE DATA	7
1.5. PRINCIPLE OF THE PROCEDURE	10
1.6. SERVICE	10
1.7. WARRANTY	11
1.8. ORDERING INFORMATION.....	11
2. SAFE HANDLING.....	12
2.1. INTENDED USE	12
2.2. GENERAL SAFETY INFORMATION.....	12
2.3. SAFETY SYMBOLS/WARNING LABELS ON THE ANALYZER.....	15
2.4. SAFETY MESSAGES/SIGNAL WORDS WITHIN THIS MANUAL	16
2.5. LEGAL REQUIREMENTS.....	17
2.6. OBLIGATIONS OF THE OWNER OF THE ANALYZER	17
3. LIFE CYCLE	18
3.1. DELIVERY	18
3.2. INSTALLATION	20
3.3. DEACTIVATION	21
3.4. DE-INSTALLATION.....	22
3.5. TRANSPORT	22
3.6. DISPOSAL.....	23
4. DESCRIPTION	24
4.1. OVERVIEW OF THE ANALYZER.....	24
4.2. PRINCIPLE OF THE OPERATION.....	25
4.3. HOUSING	26
4.4. WORKING DECK OF THE ANALYZER	32
4.5. SUPPLIES.....	41
5. OPERATION.....	43
5.1. PREREQUISITES.....	43
5.2. INSTALLING AND STARTING THE SOFTWARE.....	44
5.3. LOG-IN TO RAPTOR SERVER.....	48
5.4. CONFIGURING THE MAX 45K INSTRUMENT.....	50
5.5. CONFIGXPLORER SCANS.....	52
5.6. STARTING A NEW ASSAY RUN.....	54
5.7. LOAD INVENTORY FOR ASSAY RUN	54
5.8. INVENTORY READING AND VOLUME CHECK.....	60
5.9. END OF ASSAY RUN AND SHUTDOWN	64
5.10. RECAPTURE	65
5.11. INTERNAL QUALITY CONTROL.....	65
5.12. ABORTION OF AN ASSAY RUN	68
5.13. ERROR HANDLING.....	69
5.14. INSTRUMENT STATUS	70
5.15. IMAGE ANALYSIS AND REPORT GENERATION	72
5.16. STORAGE AND TRANSPORTATION.....	72
6. CLEANING/MAINTENANCE.....	73
6.1. CLEANING OF THE OUTER SURFACE	73
6.2. WEEKLY CLEANING	73
6.3. MONTHLY MAINTENANCE	74

6.4.	REPAIRS	76
7.	PERFORMING MAINTENANCE	77
7.1.	ANNUAL MAINTENANCE/PARTS EXCHANGE BY SERVICE TECHNICIAN	77
7.2.	EXCHANGE OF STEEL NEEDLE OF ROBOTIC ARM BY THE OPERATOR	77
7.3.	EXCHANGE OF THE WASH SOLUTION NEEDLE	80
8.	TROUBLESHOOTING MAX 45K	82
8.1.	LEAKAGE SENSOR	82
8.2.	CRASH SENSOR	82
8.3.	UN-AUTHORIZED MAIN FLAP OPENING.....	82
8.4.	NEEDLE WASH STATION: MISSING SYSTEM WATER.....	83
8.5.	WASHING SOLUTION FLUIDICS INTEGRITY.....	83
8.6.	WASTE PUMP MALFUNCTION	83
8.7.	FURTHER ERROR MESSAGES	83
9.	TECHNICAL SPECIFICATION	84
10.	REFERENCES.....	86

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.

User	Person using the analyzer in accordance with the specifications.
Intended use	Use of a product, method, or service in accordance with the specifications and instructions defined by Macro Array Diagnostics GmbH (MADx).
Intended operation	Operation, including readiness for operation, in accordance with the operating instructions or the intended use.
Operator	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.
Trained personnel	Employees who have completed a recognized education program for the task that has been assigned to them, who are familiar with the special aspects and hazards of their work environment and who continue their education with regular training sessions about changes and developments (such as standards and guidelines) that are relevant to their education and their work.
Obvious damage	Damage that can be recognized with the naked eye alone by careful observation of the analyzer or its component, or by monitoring available displays, signals, or transmitted data.
Process	Resources and activities that interact to convert inputs into results.
Damage	Physical injury or damage to human health, damage to goods or the environment.
Verification	Confirmation by providing objective evidence that defined requirements have been fulfilled.
Validation	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 Macro Array Diagnostics GmbH (MADx)



Macro Array Diagnostics GmbH
Lemböckgasse 59/Top 4
A-1230 Vienna, Austria

1.3. Identification of the Analyzer

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

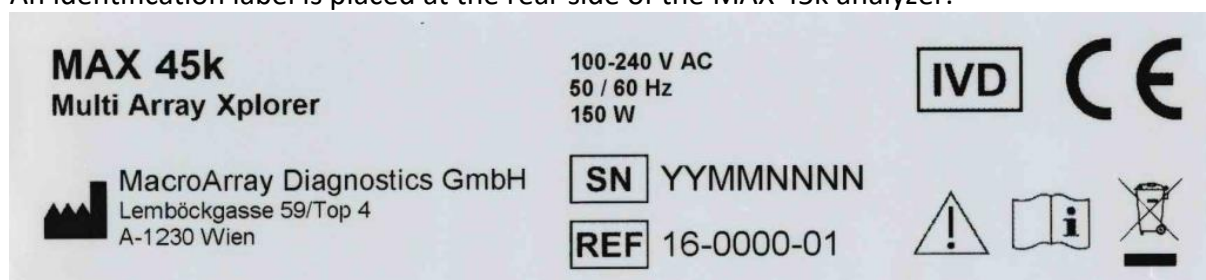


Figure 1

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 respective IFU of the ALEX² or FOX test.

1.4.2. Measuring Range

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

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

1.4.5. Results

ALEX² 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_A/L), total IgE results as kU/L. MADx's RAPTOR SERVER Analysis Software automatically calculates and reports slgE results (quantitatively) and tIgE results (semi-quantitatively).

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

1.4.6. Limitation of the Procedure

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

1.4.7. Expected Values

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

1.4.8. Performance Characteristics

ALEX² test

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 ALEX² allergen panel were included in the study. The study comprised 451 allergen per sample combinations at three different levels: >10 kU_A/L, 1 - 10 kU_A/L and 0.3 - 1 kU_A/L. For the selected allergen components, the CV (in %) was calculated between runs and between instruments (= total CV).

	CV (0.3 - 1 kU _A /l)	CV (1 - 10 kU _A /l)	CV (> 10 kU _A /l)	CV (> 1 kU _A /l)
Total CV%	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 kU_A/L) was tested at all positions of the cartridge carousel of the MAX 45k instruments.

	CV (0,3 - 1 kU _A /l)	CV (1 - 10 kU _A /l)	CV (>10 kU _A /l)	CV (>1 kU _A /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 ALEX² test.

Analytical Specificity:

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

Interference:

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

FOX test**Precision (lot-lot variation):**

The lot-to-lot variation was determined on three cartridge lots in three separate runs. Multi-sensitized samples were included in the study. The study comprised 867 antigen/sample combinations covering 121 individual antigens over the entire measuring range.

Concentration - µg/ml	10.0 – 19.9	≥ 20.0	≥ 10.0
Total CV - %	9.1	4.3	6.3

Homogeneity (within-run precision):

In the homogeneity study, multi-sensitized samples were tested 10 times by the same operator on different days. The study comprised 862 antigen/sample combinations covering 115 individual antigens over the entire measuring range.

Concentration - µg/ml	10.0 – 19.9	≥ 20.0	≥ 10.0
Total CV - %	11.3	5.4	7.2

Analytical Sensitivity:

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

Interference:

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

1.5. Principle of the Procedure

1.5.1. ALEX² test principle

ALEX² is a solid-phase immunoassay. MAX 45k is an IVD device which is intended to automatically perform all steps for up to 50 ALEX² 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_A/L). Total IgE results are also reported in IgE response units (kU/L).

1.5.2. FOX test principle

FOX is a solid-phase immunoassay. Food extracts, which are coupled to nanoparticles, are deposited in a systematic fashion onto a solid phase forming a macroscopic array. First, the particle bound proteins react with specific IgG that is present in the patient's sample. After incubation, non-specific IgG is washed off. The procedure continues by adding an enzyme labelled anti-human IgG detection antibody which forms a complex with the particle bound specific IgG. After a second washing step, substrate is added which is converted to an insoluble, 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 IgG in the patient sample. The lab test 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 IgG classes.

1.6. Service

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

1.7. Warranty

Macro Array Diagnostics GmbH and its local distributors 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 Macro Array Diagnostics GmbH service or its distributors. The warranty is not valid for damage that occurs because of non-compliance with this manual, whereby repairs and servicing must only be carried out by persons authorized by Macro Array 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, Macro Array 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 Macro Array Diagnostics GmbH. Order these items only from Macro Array Diagnostics GmbH or local distributors. For ordering information, see the Macro Array Diagnostics GmbH brochure for the MAX 45k or contact the Macro Array Diagnostics GmbH team at orders@macroarraydx.com or your local distributor.

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 use as an automated in-vitro diagnostic tool (IVD) for the quantitative determination of allergen-specific Immunoglobulin E (sIgE, ALEX²) and for the semi-quantitative determination of total IgE (tIgE, ALEX²) and specific Immunoglobulin G (sIgG, FOX). The MAX 45k is suitable for human serum or plasma (Heparin, Citrate, but no EDTA). The MAX 45k is intended to be used only in conjunction with the RAPTOR SERVER Analysis Software, and ALEX² or FOX test arrays.

The semi-quantitative and quantitative IgE determination is intended as an aid in the clinical diagnosis of patients with allergies in conjunction with other clinical and laboratory findings. The semi-quantitative IgG determination can be used to support dietary clarification and to monitor dietary compliance, hence as an aid in the clinical diagnosis of patients with suspected immunologically caused food intolerance, by all means in consultation with a medical expert. Thus, the final diagnosis must be realized by a medical expert under consideration of all available clinical findings and other laboratory parameters.

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, Macro Array Diagnostics GmbH clearly states that using the analyzer in a manner not specified by this manual or elsewhere by Macro Array 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 Macro Array 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

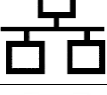
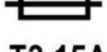
When operating the MAX 45k, ensure compliance with the specified ambient conditions (see section 9); these must be strictly adhered to. See also section 3.2. - Site Preparation prior to installation. The operator is not allowed to exchange any fuses. In case of a defect fuse, a technical defect is assumed that must be fixed by Macro Array Diagnostics GmbH or your local distributor 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 Macro Array Diagnostics GmbH or your local distributor. 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

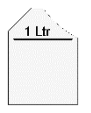
	System-Water
	Wash-Buffer Solution
	1 Liter Level
	10 Liter Level
	Protective Grounding
	Catalogue number Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Temperature limit Indicates the temperature limits to which the medical device can be safely exposed.
	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.



Caution

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 owner of the analyzer device 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 Macro Array Diagnostics GmbH or your local distributor. 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 Macro Array Diagnostics GmbH or a local distributor 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 Macro Array Diagnostics GmbH or a distributor. 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

For the operation of the device, an ALEX² (REF 02-5001-01), or FOX (REF 80-5001-01) assay kit is required, which is not included in the shipment of the MAX 45k instrument 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 cables for the fill level sensors of the containers, 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.).

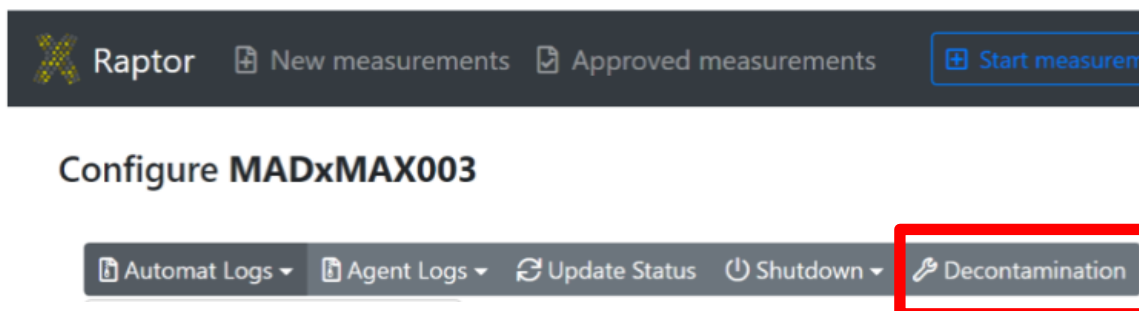
3.2.5. Start Analyzer

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. Deactivation

To prepare the analyzer for a longer period of switch-off, 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 cables from the corresponding sockets (see section 4.3.).
8. Empty and clean all containers.
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.

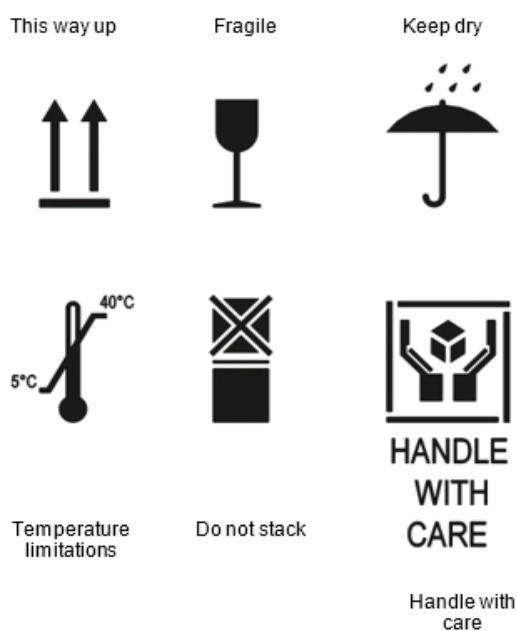
3.4. De-Installation

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.

Macro Array 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 Macro Array Diagnostics GmbH service or a local distributor 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 Macro Array Diagnostics GmbH or a local distributor.



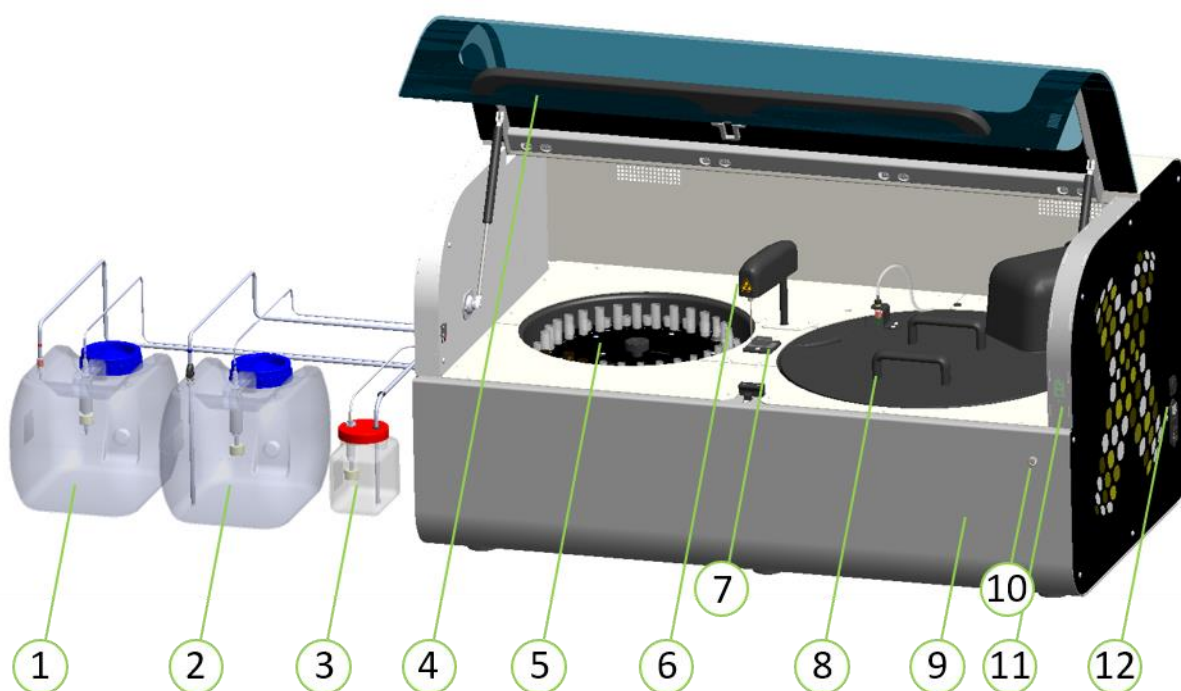
Do not treat electrical and electronic equipment as unsorted municipal waste and check with your local waste disposal contractor for specific requirements regarding disposal. Please collect waste electrical and electronic equipment separately and return them to Macro Array Diagnostics GmbH or a local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

To dispose the analyzer, proceed as follows:

1. De-install the analyzer, see section 3.4.
2. Contact support of Macro Array Diagnostics GmbH or your local distributor 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 ALEX² (REF 02-5001-01) and FOX assay kits (REF 80-5001-01) can be obtained online at www.macroarraydx.com and should be consulted before any assay run is performed on the MAX 45k instrument.

CAUTION: Either ALEX² or FOX arrays can be measured in one run. A combination of ALEX² and FOX cartridges or reagents is prohibited.

- Sample tubes that contain serum or plasma, and ALEX² or FOX reagents are loaded manually to the reagent and sample positions on the sample rotor.
- ALEX² or FOX kit cartridges are manually loaded to the cartridge rotor.
- Assignment of the patient samples to the respective cartridges is done via the software application RAPTOR SERVER.
- When the test run is started, dilution medium (in case of an ALEX² test) is pipetted from the corresponding bottle to the loaded cartridges. Next, the samples are pipetted to the cartridge according to the assignment in RAPTOR SERVER, then mixed and incubated for a certain time period. Optionally, manually pre-diluted samples can be processed as well; in that case, the protocol skips the dilution step accordingly.

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

- The sample substance is removed from the cartridges by centrifugation forces (fast spinning of the cartridge rotor) and a wash-buffer solution (ALEX² or FOX Washing Solution) is applied on the cartridges multiple times.
- Next, the secondary antibody (ALEX² or FOX Detection Antibody) solution will be pipetted from the corresponding reagent bottle to the cartridges sequentially, mixed and incubated for a certain time period.
- The secondary antibody solution is removed from the cartridges and wash-buffer solution (ALEX² or FOX Washing Solution) is applied on the cartridges multiple times.
- The substrate solution (ALEX² or FOX Substrate Solution) is pipetted from the corresponding reagent bottle to the cartridges sequentially and incubated for a certain time period.
- The stop solution (ALEX² or FOX Stop Solution) is pipetted from the corresponding reagent bottle to the cartridges sequentially to stop the chemical reaction on the cartridges.
- Afterwards, the substrate and stop solution mixture is removed from the cartridges and a final washing step is performed.
- The cartridges are then dried and finally, image acquisition of each cartridge is performed. The images are analyzed by RAPTOR SERVER.
- It is possible to recapture already processed cartridge images independently from a Run.

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.

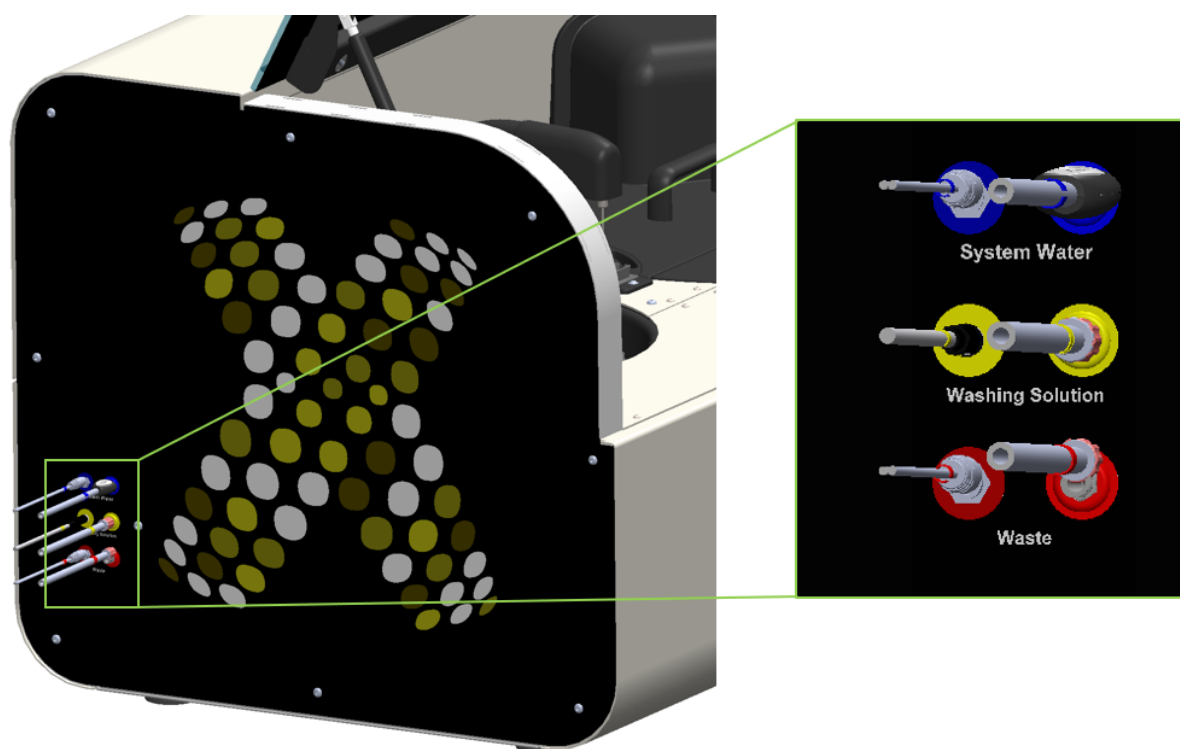


Figure 2
Left Side of the analyzer.

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.

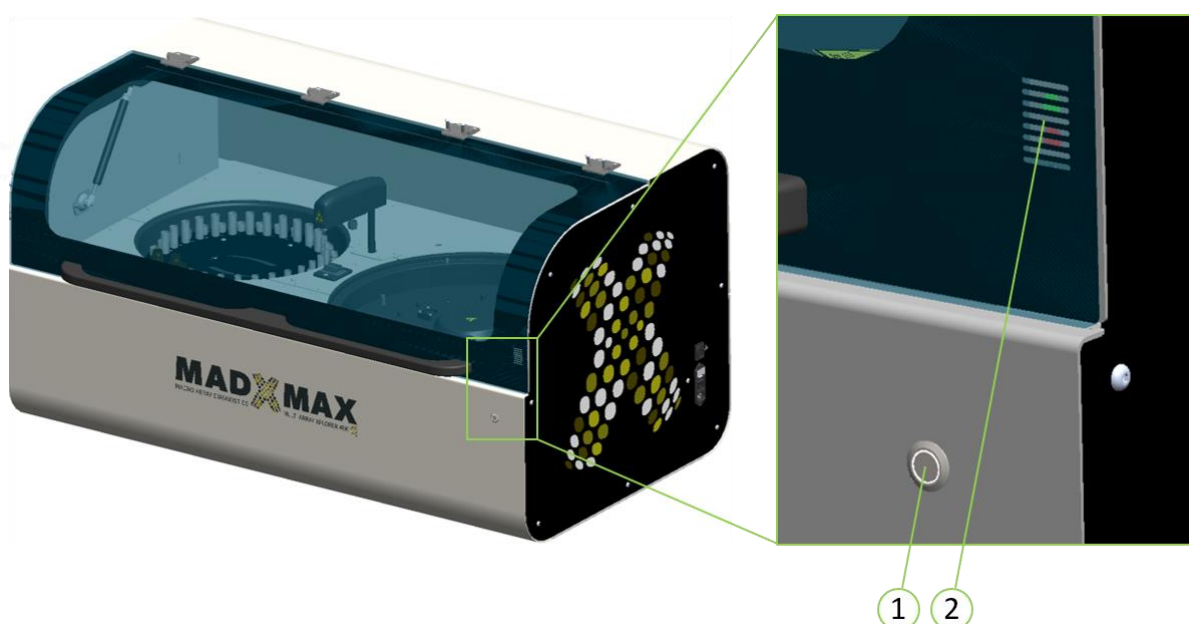
4.3.3. Front Side of the Analyzer

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.
6	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. 5s) 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.
7	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.

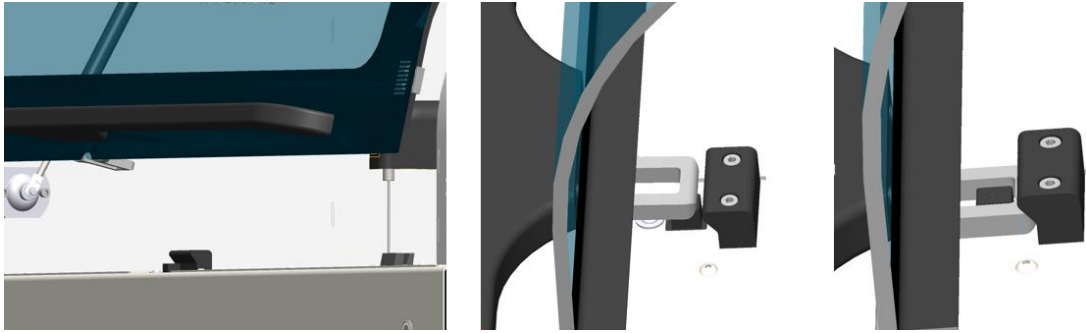


Figure 5

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.

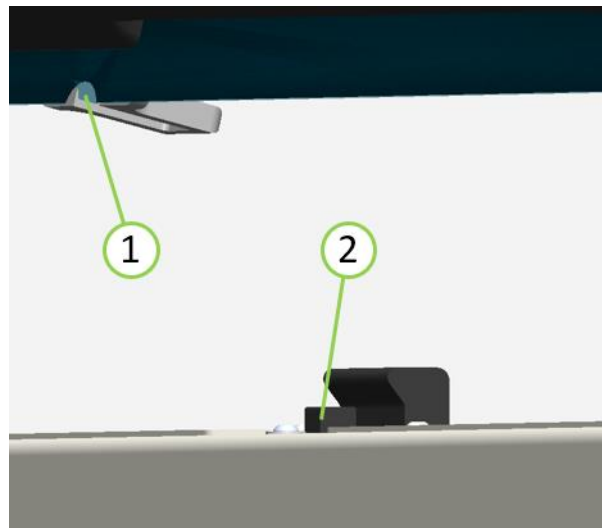


Figure 6

Bypassing the interlock.

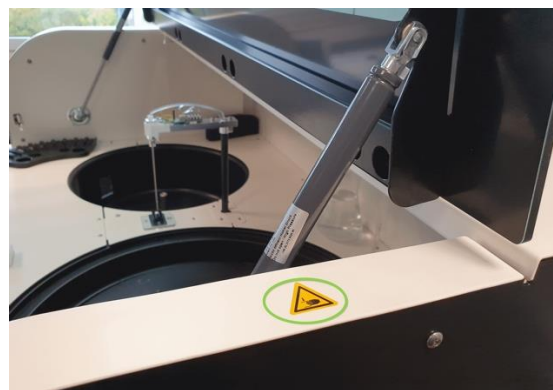
In case a tool is used during operation and the main flap is opened, the analyzer will stop all mechanical motions immediately. Macro Array Diagnostics GmbH disclaims all liability for damage to the analyzer by manually bypassing the interlock during operations. For a proper handling of the main flap, the following rules must be applied:



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

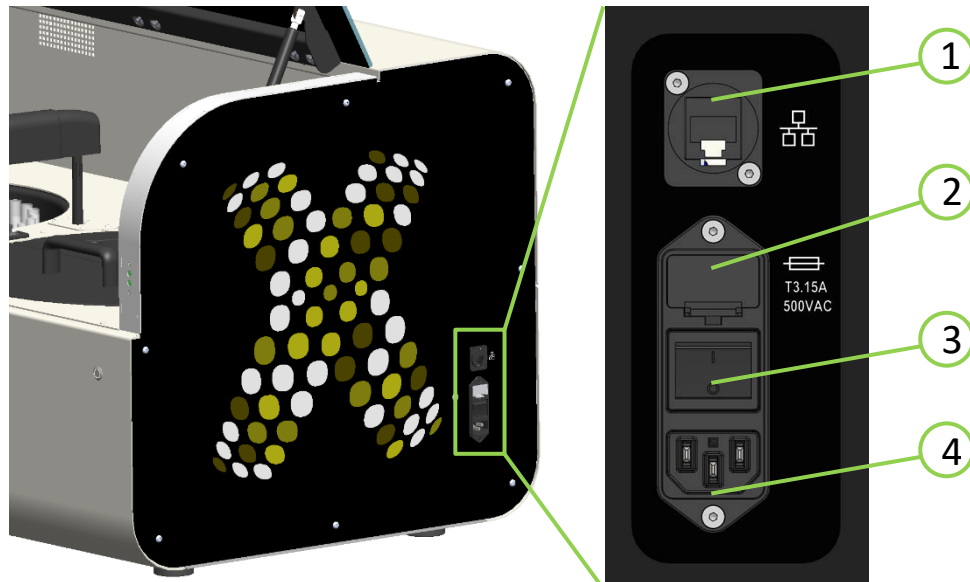


Additional warning symbols in front of the opened main flap, on both sides of the analyzer and on top of the main flap - as shown in the following pictures (highlighted with green circles) - shall warn the user and third person to keep off fingers and hands from the analyzer when main flap will be closed 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 loading the ALEX² or the FOX test (see **Figure 8**).

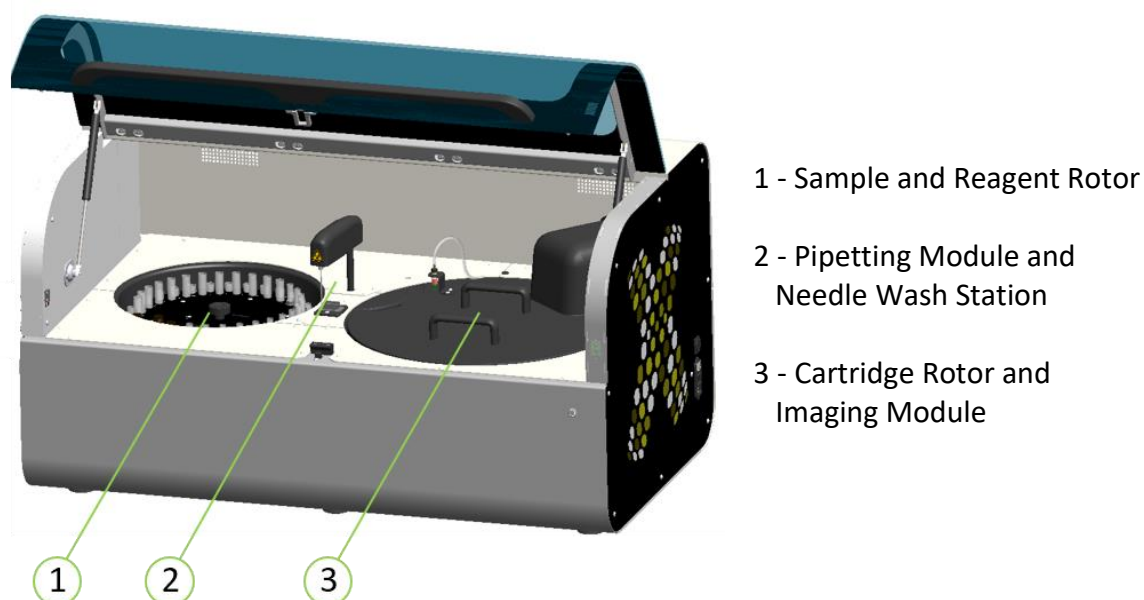


Figure 8

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 (30 ml and 15 ml) provided in the ALEX² or the FOX kit shall be loaded, and all caps must be removed. The sample and reagent rotors include three openings to load 30 ml reagent bottles and one opening for loading the 15 ml 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.



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

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



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



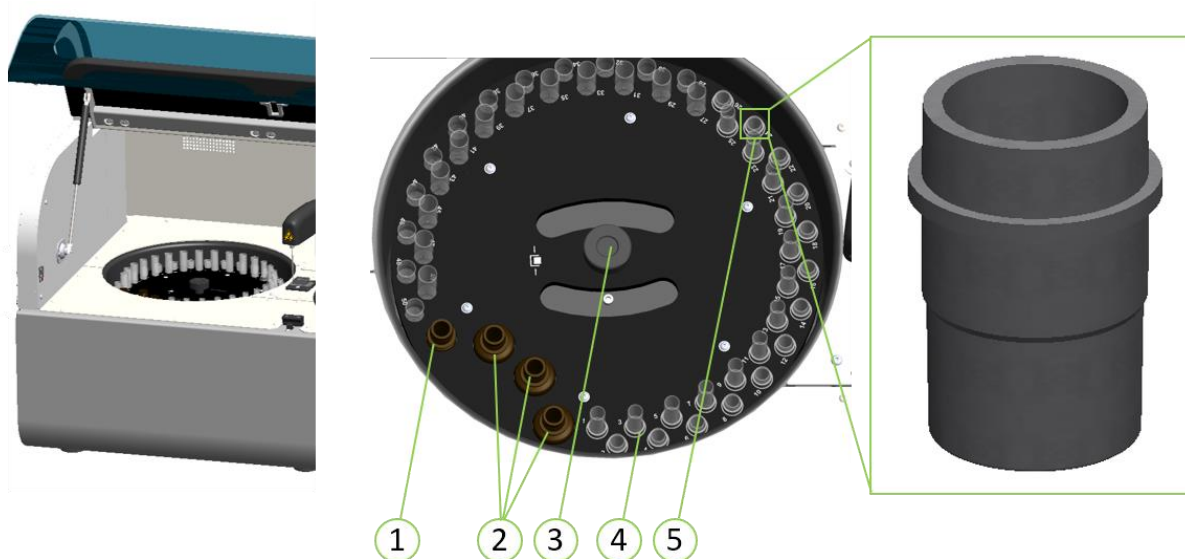
Caution

If the tube adapter is not applied for the 13 mm tubes, damage to the needle can be caused by a tilted tube. When a vertical movement is blocked by the tilted tube, the 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 100 mm, a collision during horizontal movement of the needle can occur, damaging the needle and the analyzer.



- 1 15ml 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.

In case of cleaning or loading, 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 disc are equipped with a tongue and groove mechanism to secure the rotor disc at the correct position. The groove positioning is highlighted with a white marking to easily find the match between the tongue and the groove for convenient placement as shown in **Figure 10**. After insertion of the rotor disc, the thumb screw must be tightened.

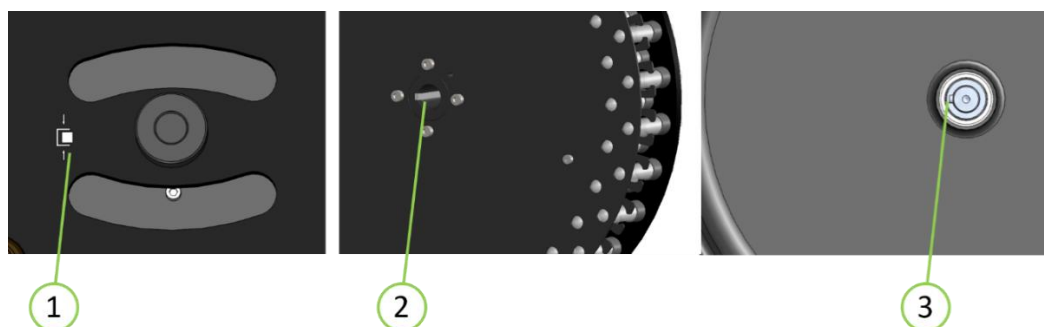


Figure 10

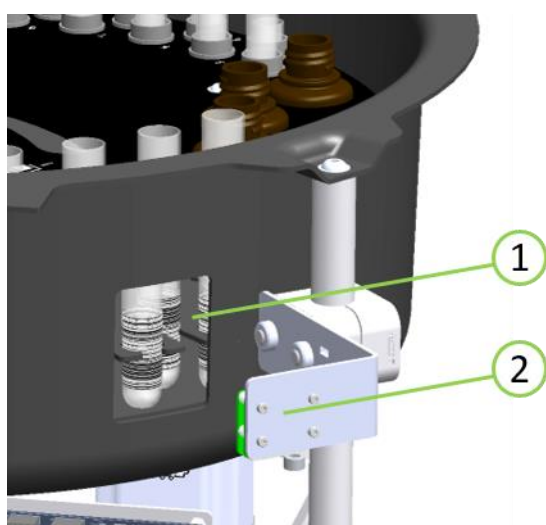
Left: Marking on top of the rotor disc. **Middle:** Groove shown from underneath the rotor disc. **Right:** Tongue included in the rotor axis visible after rotor disc is removed.

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.

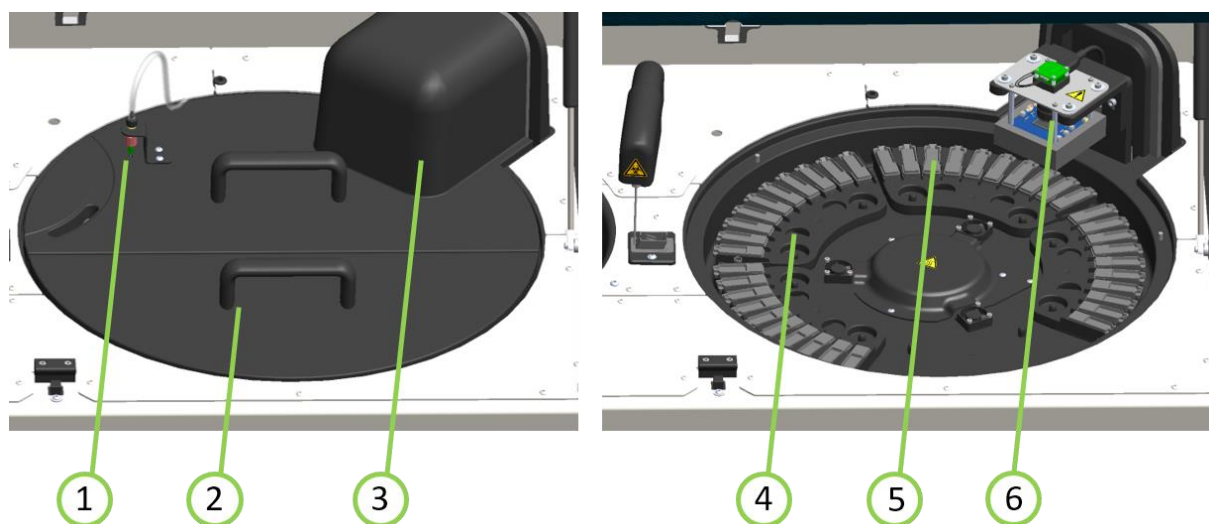
4.4.2. Cartridge Rotor and Image Acquisition Module

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.

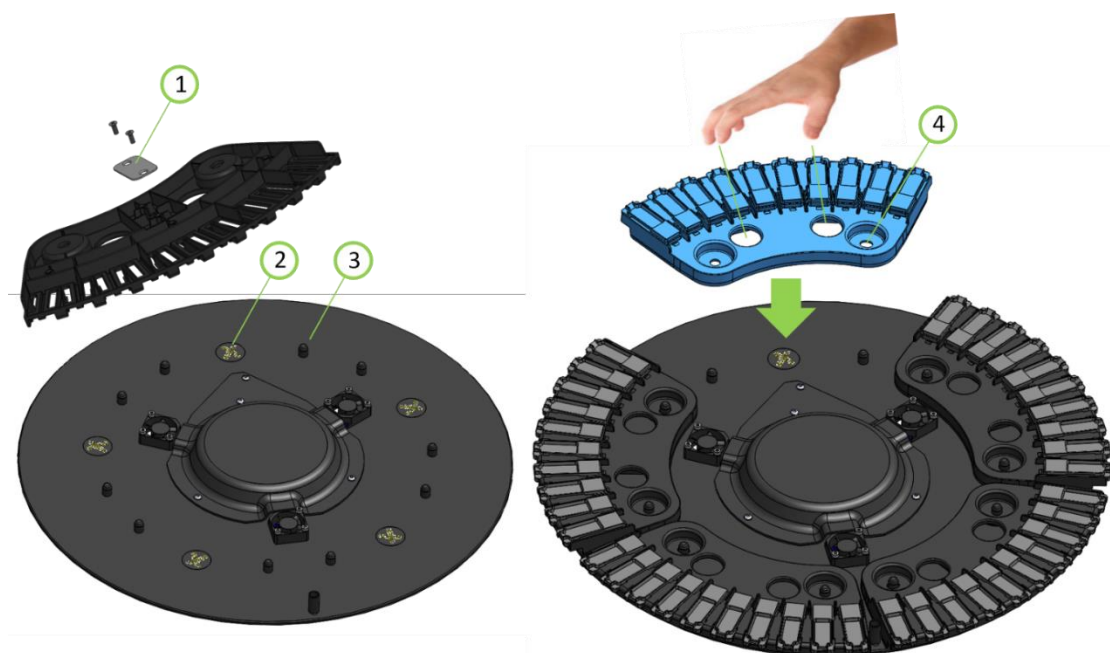


- 1 Wash-buffer solution dispensing needle
- 2 Front Rotor Cover
- 3 Rear Rotor Cover
- 4 Cartridge Segment
- 5 Cartridge
- 6 Image Acquisition Module

Figure 12

Overview of cartridge rotor assembly.

The segments are equipped with a metal sheet part and are pressed against the rotor plate by magnetic forces. To correctly position the segments, the user should take a segment between the forefinger and thumb through the large holes, and insert it so, that the two alignment pins of the rotor plate correspond to the alignment holes in the segment (see **Figure 13**).



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

Figure 13

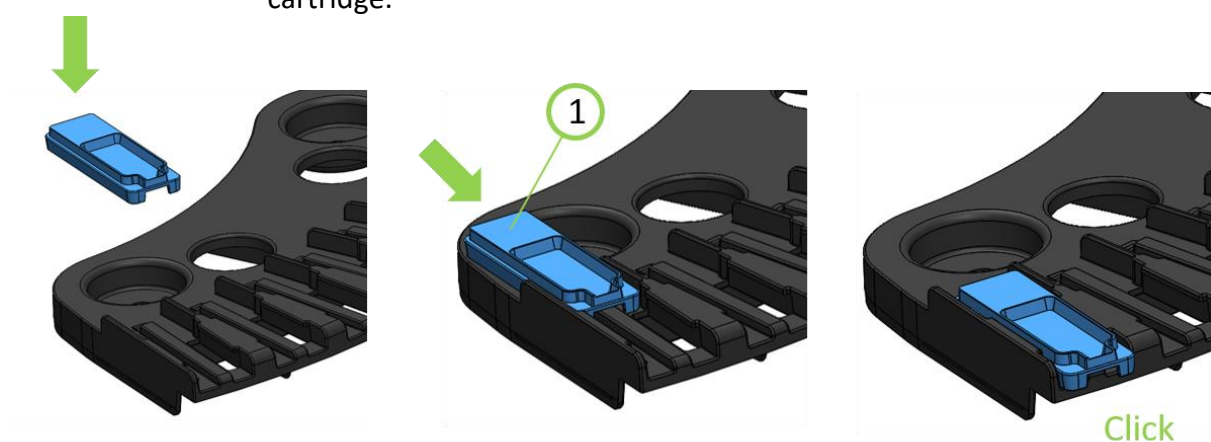
Schematic for handling/loading of cartridge segments.

The ALEX² or FOX cartridges can be loaded on to the segments outside or inside the instrument. The loading procedure is shown in **Figure 14**. To insert the cartridge, the user must take the cartridge with the fingers touching only the side or QR-Code part of the cartridge, and slide it into the segment slot radially outwards, until its final position is indicated by a click sound.



Caution

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

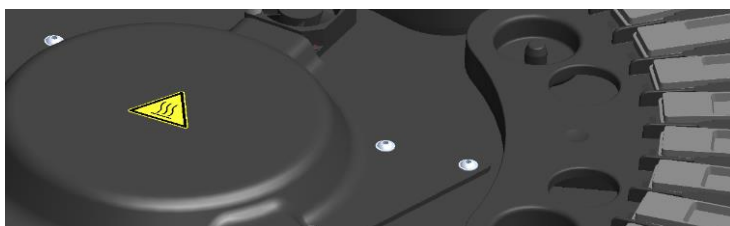


- 1 - QR-Code Area of the Cartridge

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.

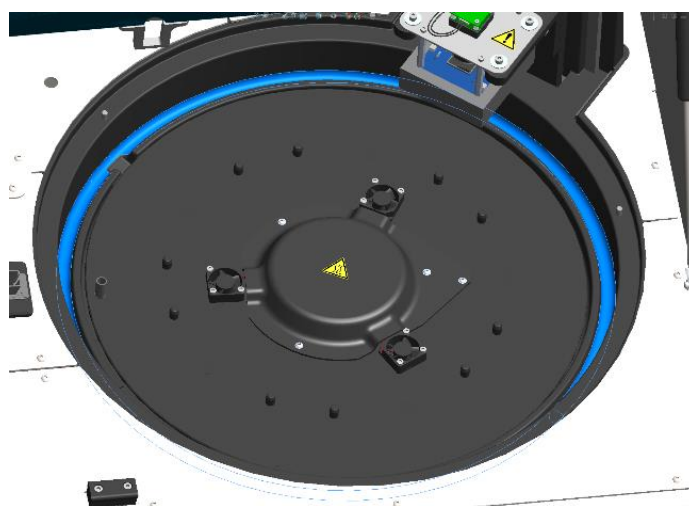
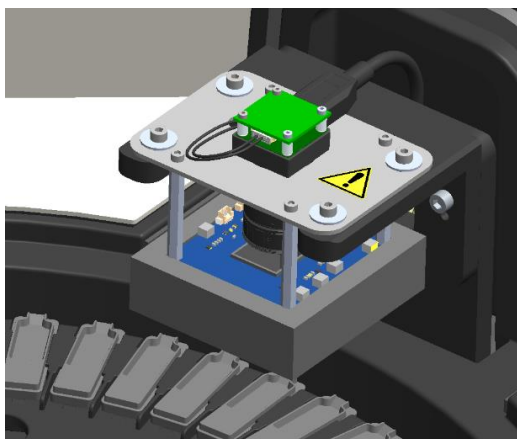


Figure 15

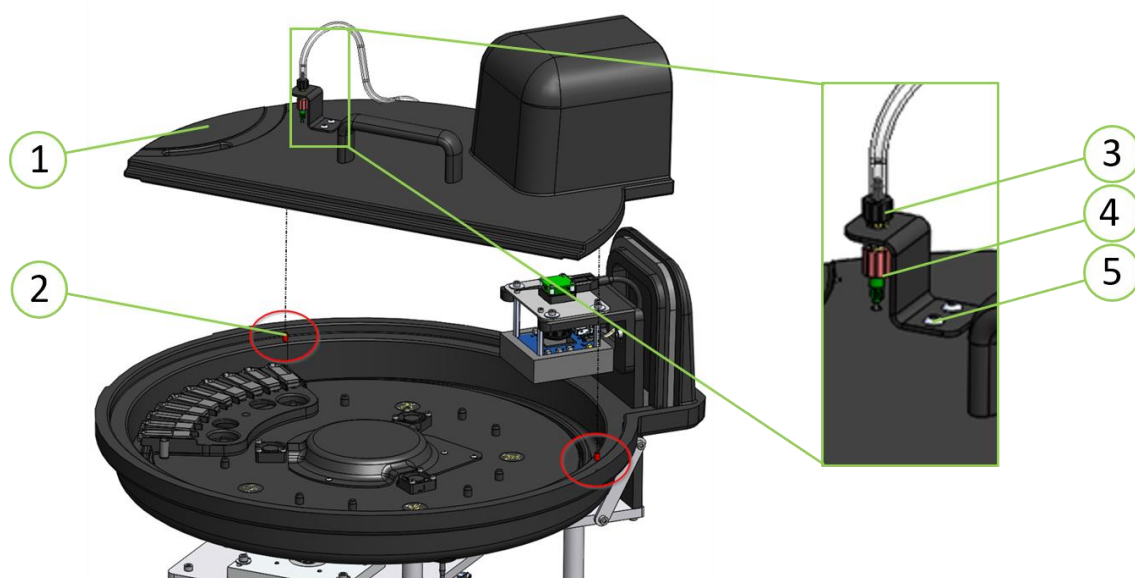
Waste drain channel of cartridge rotor highlighted in blue.

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



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) must 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.



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 samples or reagents from the sample and reagent rotor to the cartridge rotor. The robotic arm is equipped with a steel needle and liquid level detection (LLD) electronics which are protected by a plastic cover. The 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.

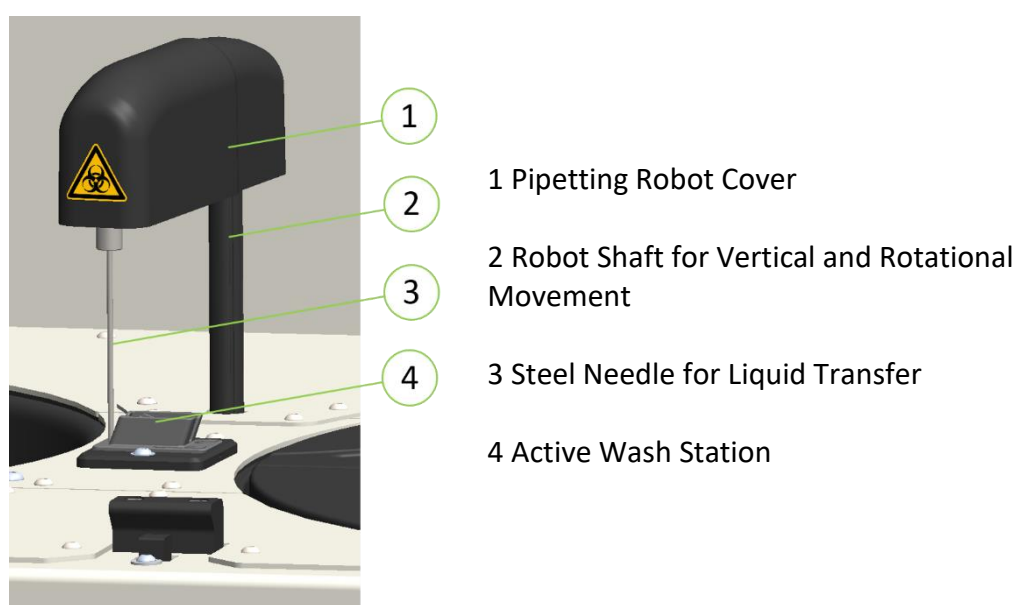


Figure 17
Pipetting robot.

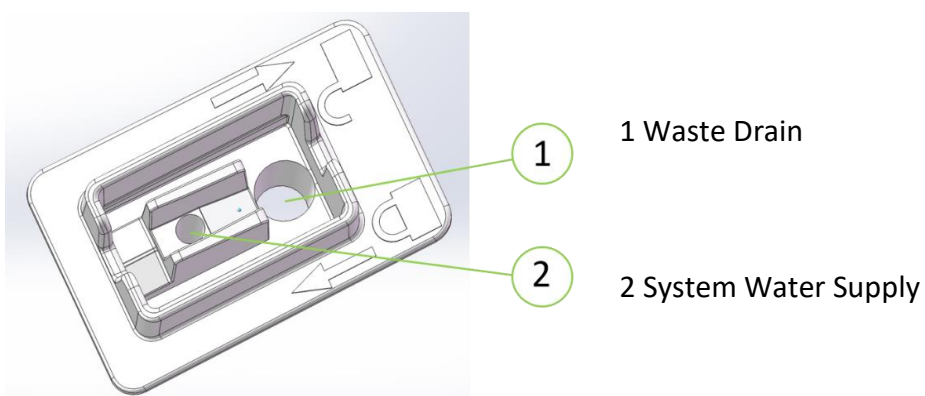


Figure 18
Active wash station.



The upper arm of the pipetting robotics is labeled with a biohazard warning symbol to remind the user not to touch the needle end part and potentially cut or puncture the skin resulting in a potential infection (**Figure 17**).

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.

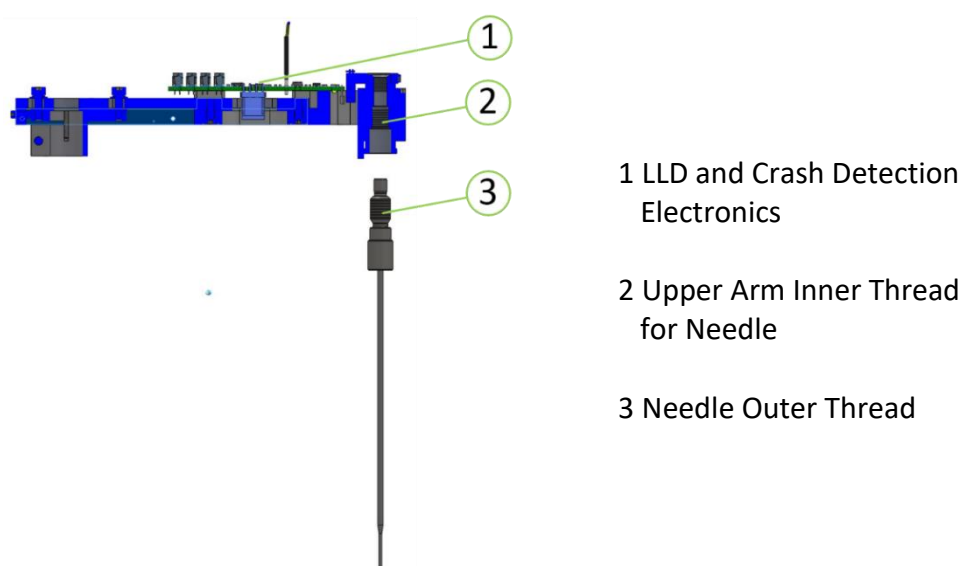


Figure 19

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

4.5. Supplies

4.5.1. System- and Wastewater Containers

10 liters 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 liter 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.

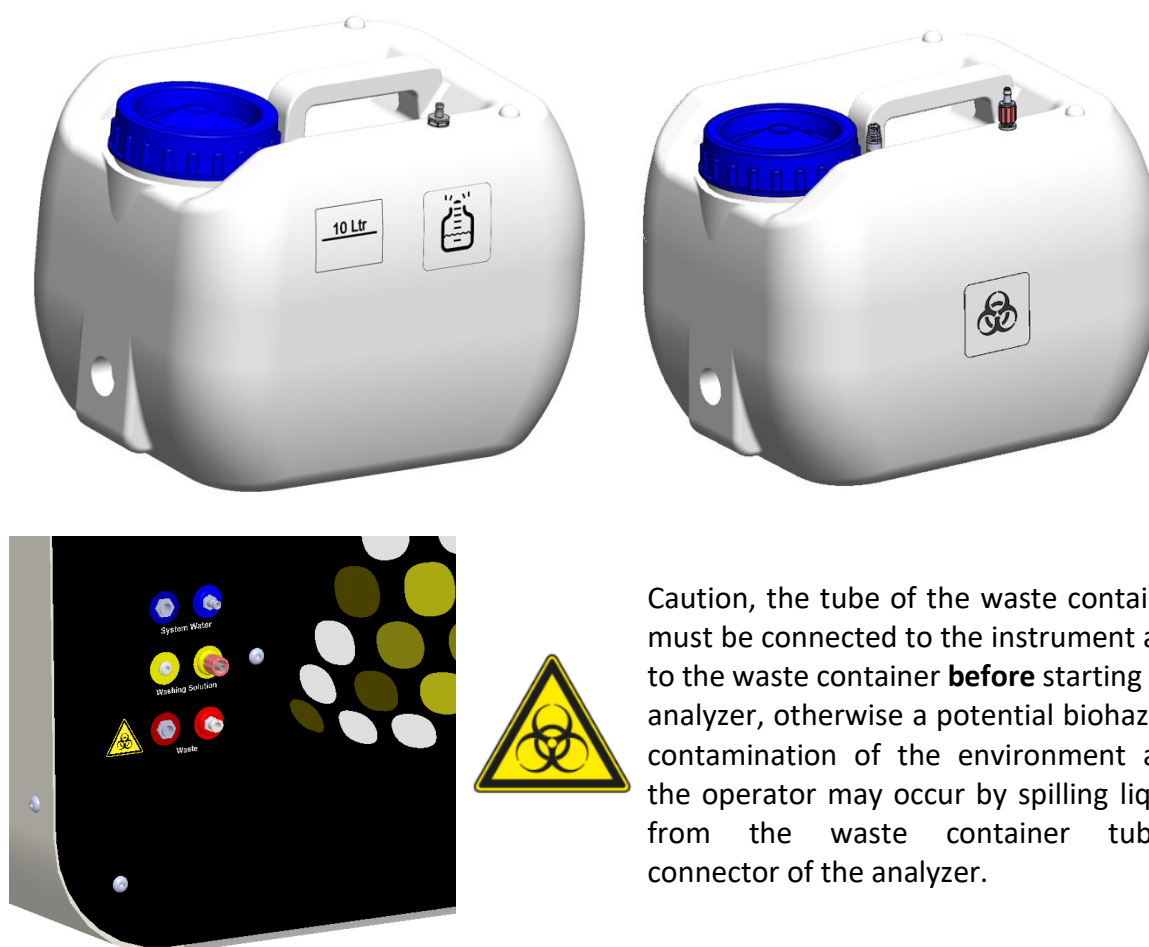


Figure 20

(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 Macro Array Diagnostics GmbH or a local distributor. To prepare the washing solution, empty the 250 ml concentrate into the wash-buffer container, and fill it up to the 1 liter marking with demineralized water. Before use, the fill-level is controlled by the instrument for the number of tests to be processed. If the fill level is not sufficient, the RAPTOR SERVER software will indicate that no test can be performed. It is suggested to use up the 50x test kit in not more than 4 runs, otherwise the provided washing buffer might run out.



Figure 21
Wash-Buffer Solution Container

4.5.3. Assay Kit Supplies

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

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

NOTE: 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. Operation

5.1. Prerequisites

The following equipment and settings are needed to run ALEX² or FOX tests on MAX 45k:

- MAX 45k analyzer, properly installed by MADx or its distributors.
- An ALEX² (REF 02-5001-01) or a FOX (REF 80-5001-01) Assay Kit. Please consult the Instruction for Use of these IVD products before you run any assays on the instrument.

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

- Serum samples or plasma samples (no EDTA plasma) – **please check the minimal volumes and applicable tube sizes 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:



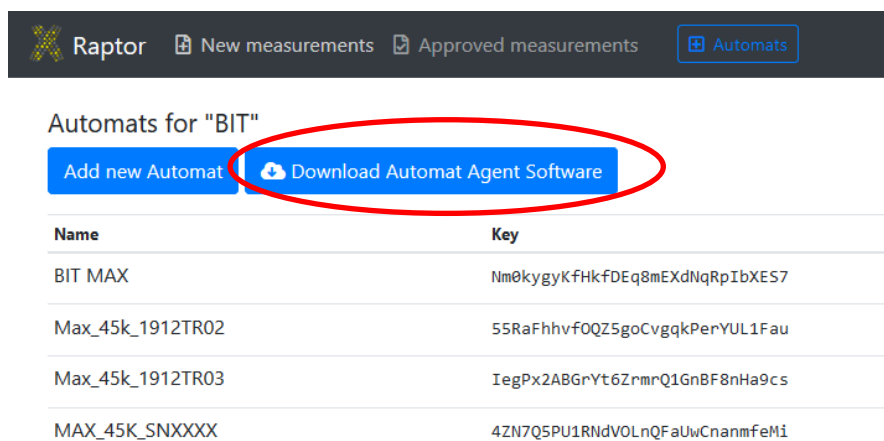
- To connect the PC with the MAX 45k, use the LAN cable which is included in the MAX 45k shipment. However, any high-speed LAN cable with 2 RJ45 connectors can be used.

Configure the LAN Adapter in your Windows settings:

- In “Network Settings” choose “Change Network adapter options”
 - You should see a window which shows all available Network connections, including your WIFI and the LAN adapter
 - 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
 - Click on “Internet protocol Version 4” and then on “Properties”
 - Manually change the IP address for the adapter and choose 192.168.183.10
 - Change the Subnet mask to 255.255.255.0
 - Click on “ok”
- Optional equipment: uninterrupted power supply (UPS) with 500 VA

5.2. Installing and Starting the Software

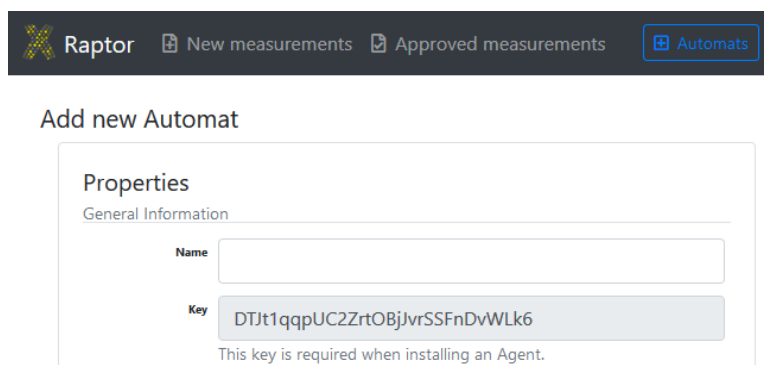
Before starting a new assay run on the MAX 45k with RAPTOR SERVER on www.raptor-server.com, make sure that the “Raptor Agent for Automat” app is running. The agent should automatically be launched during Windows startup. If the agent app is not yet installed, an installation package can be downloaded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



The screenshot shows the Raptor web interface with the 'Automats' tab selected. Under 'Automats for "BIT"', there are two buttons: 'Add new Automat' and 'Download Automat Agent Software'. The latter is circled in red. Below the buttons is a table listing existing automats.

Name	Key
BIT MAX	Nm0kygyKfHkfDEq8mEXdNqRpIbXES7
Max_45k_1912TR02	55RaFhhvf0QZ5goCvgqkPerYUL1Fau
Max_45k_1912TR03	IegPx2ABGrYt6ZrmrQ1GnBF8nHa9cs
MAX_45K_SNXXXX	4ZN7Q5PU1RNdVOLnQFaUwCnanmFeMi

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 needs 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 'Add new Automat' form. It has a 'Name' input field and a 'Key' input field. The 'Key' field contains the value 'DTJt1qqpUC2ZrtOBjJvrSSFnDvWLk6'. 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

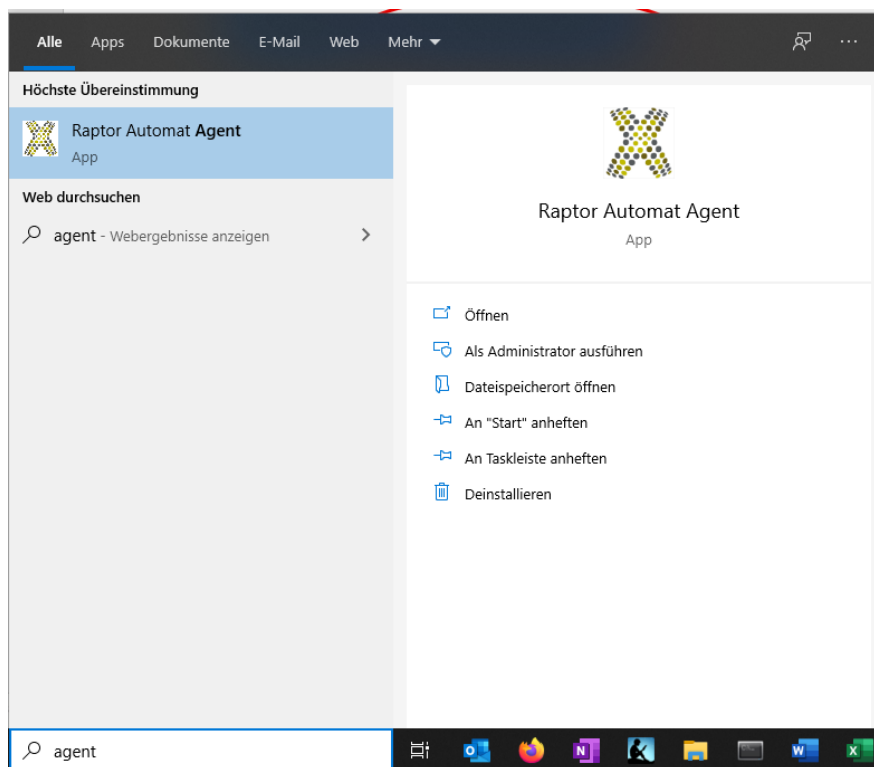
For internal use only.

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

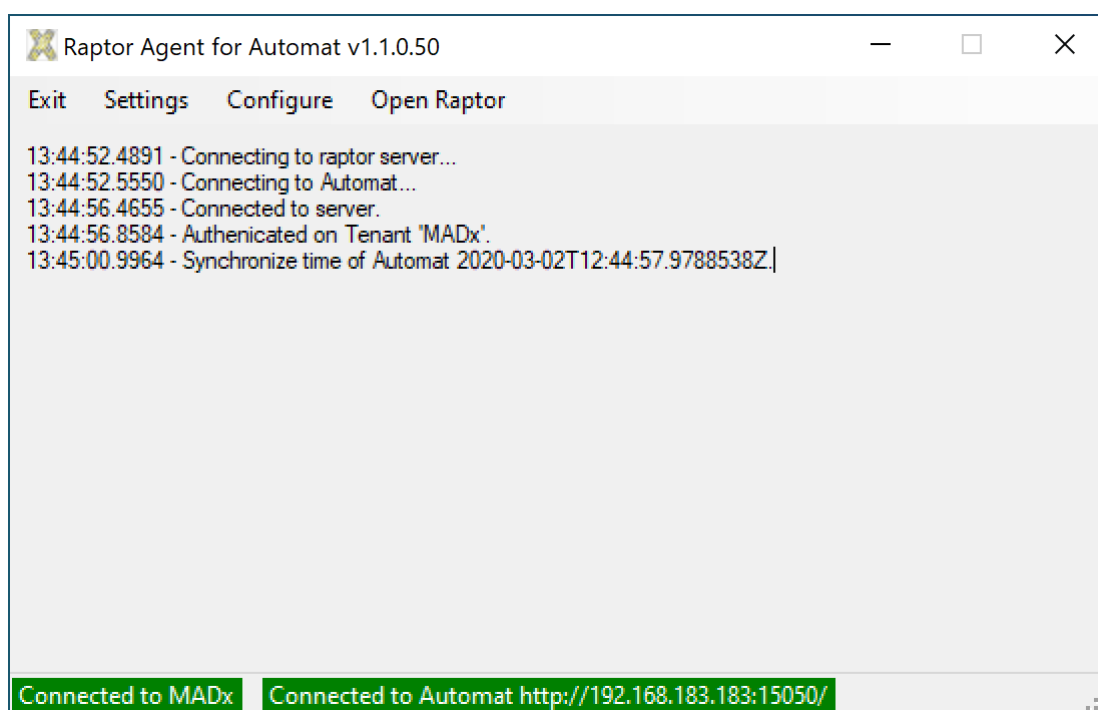
Please enter the settings for your Automat. You can find your Automat key when you log in to Raptor. Please contact support if you're not sure what the proper settings are for your Automat.

Raptor Server URL

Automat URL

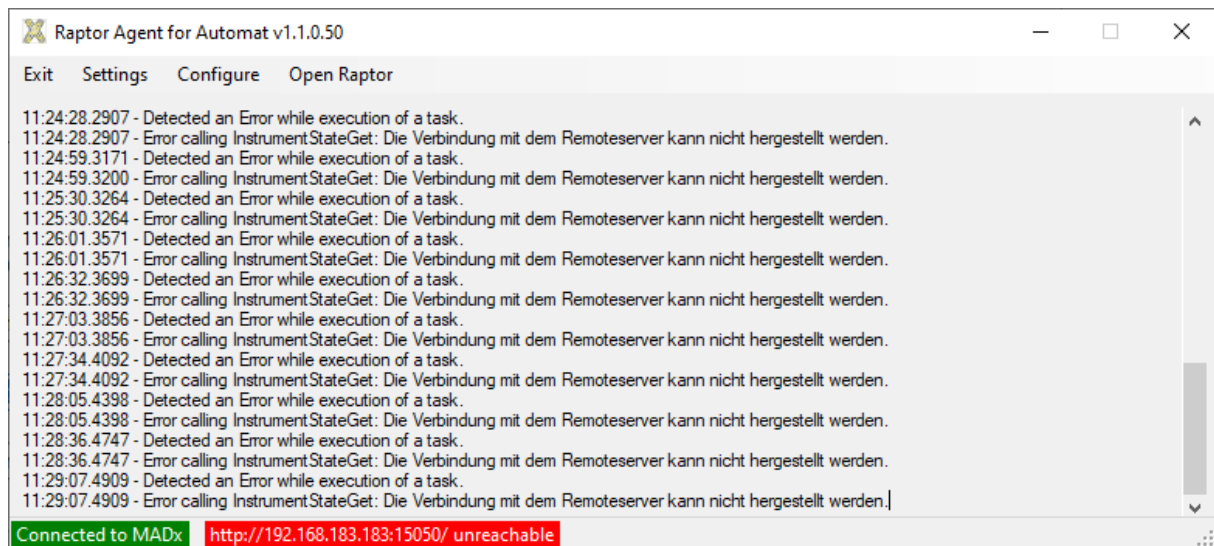
Automat Key

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

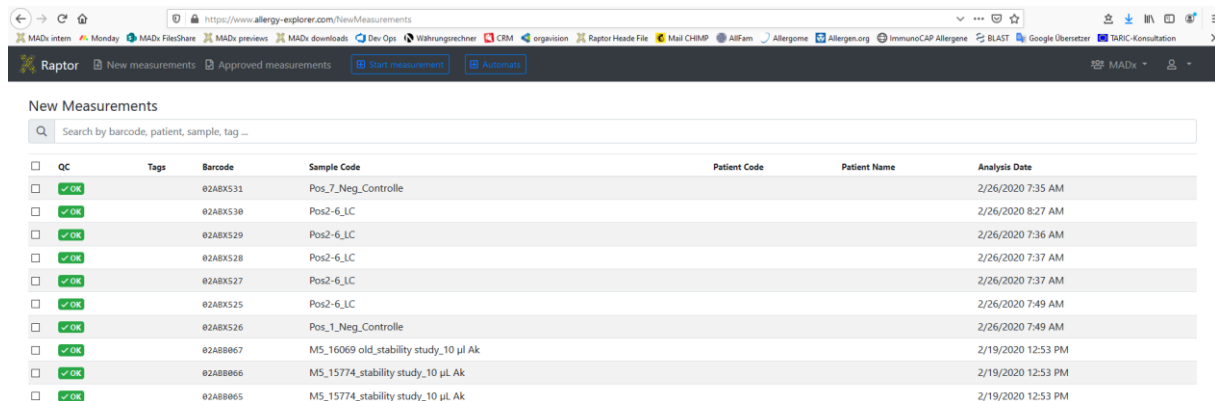
In your web browser, enter the URL for the cloud-based RAPTOR SERVER Analysis Software (<https://www.raptor-server.com/>) and press “Enter”. The Login page will show up. Please use the login method and user credentials as instructed by your System Administrator, by MADx support team or your local distributor.



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

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

If the Log in was successful, the homepage of the RAPTOR SERVER Analysis Software shows up with the measurement results from previous ALEX² and FOX assay runs on the MAX 45k. 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.



https://www.allergy-explorer.com/newMeasurements

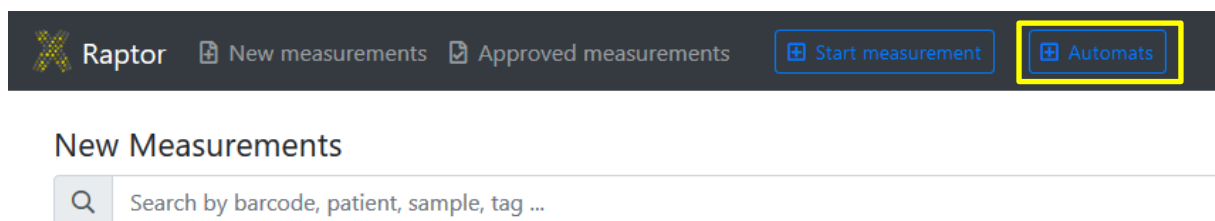
Raptor New measurements Approved measurements Start measurement Automats

New Measurements

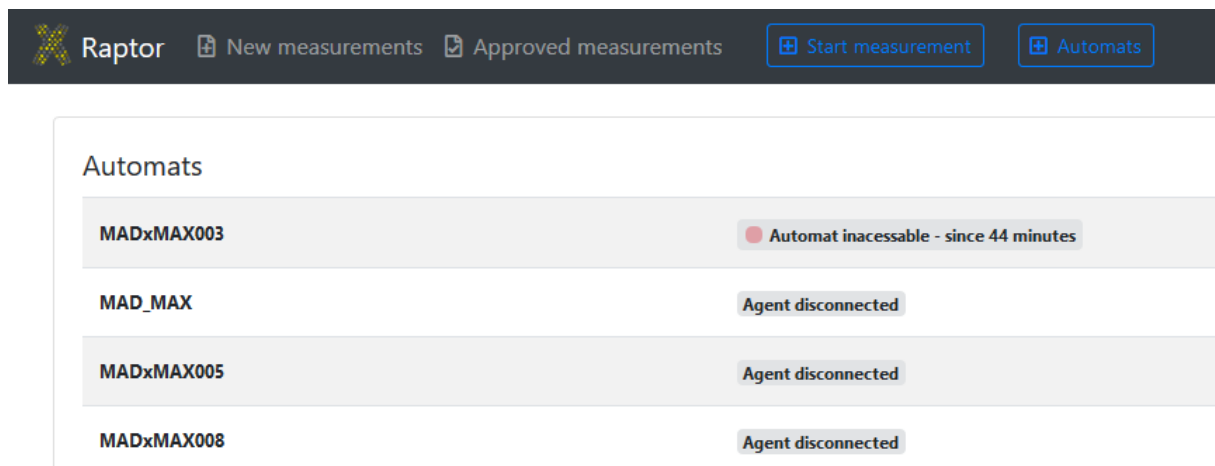
Search by barcode, patient, sample, tag ...

QC	Tags	Barcode	Sample Code	Patient Code	Patient Name	Analysis Date
☐	OK	02ABX531	Pos_7_Neg_Controlle			2/26/2020 7:35 AM
☐	OK	02ABX530	Pos2-6_LC			2/26/2020 8:27 AM
☐	OK	02ABX529	Pos2-6_LC			2/26/2020 7:36 AM
☐	OK	02ABX528	Pos2-6_LC			2/26/2020 7:37 AM
☐	OK	02ABX527	Pos2-6_LC			2/26/2020 7:37 AM
☐	OK	02ABX525	Pos2-6_LC			2/26/2020 7:49 AM
☐	OK	02ABX526	Pos_1_Neg_Controlle			2/26/2020 7:49 AM
☐	OK	02AB8067	M5_16069_old_stability study_10 µl Ak			2/19/2020 12:53 PM
☐	OK	02AB8066	M5_15774_stability study_10 µl Ak			2/19/2020 12:53 PM
☐	OK	02AB8065	M5_15774_stability study_10 µl Ak			2/19/2020 12:53 PM

On 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).



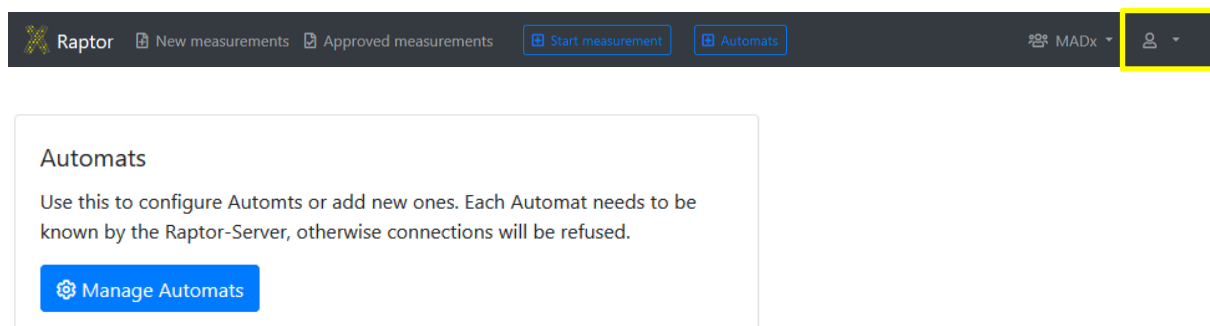
Raptor New measurements Approved measurements Start measurement Automats

Automats

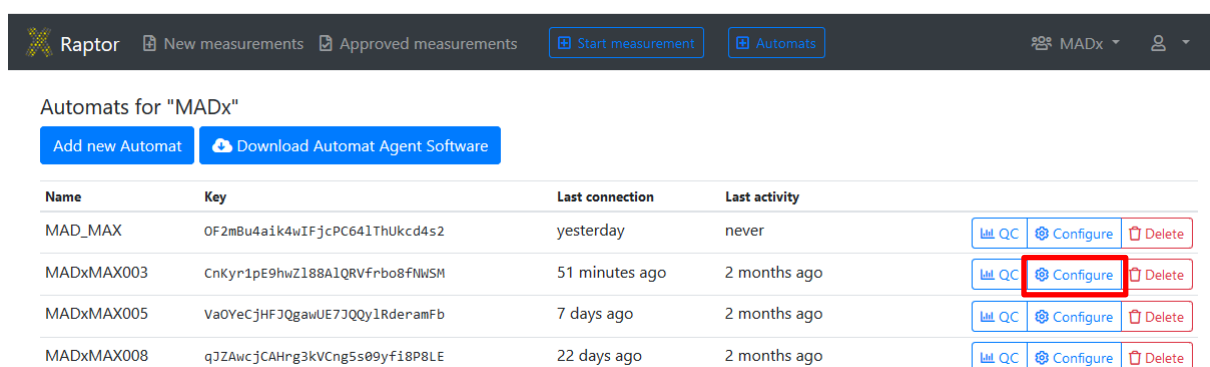
MADxMAX003	Automat inaccessible - since 44 minutes
MAD_MAX	Agent disconnected
MADxMAX005	Agent disconnected
MADxMAX008	Agent disconnected

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.



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



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)
301	02AAR	2/19/2020 9:10:28 AM	2/19/2020 2:03 PM	mitterer@macroarraydx.com (mitterer@macroarraydx.com)
300	02AAB	2/18/2020 3:17:53 PM	2/19/2020 8:43 AM	mitterer@macroarraydx.com (mitterer@macroarraydx.com)
299	02AAB	2/18/2020 10:44:01 AM	2/18/2020 2:19 PM	mitterer@macroarraydx.com (mitterer@macroarraydx.com)
298	02ABB	2/14/2020 9:48:51 AM	2/14/2020 12:59 PM	Mats Nystrand (mats.nystrand@macroarraydx.com)
297	02AAC	2/10/2020 3:12:37 PM	2/11/2020 7:36 AM	mitterer@macroarraydx.com (mitterer@macroarraydx.com)
296	02ABB	2/10/2020 10:23:54 AM	2/10/2020 1:29 PM	mitterer@macroarraydx.com (mitterer@macroarraydx.com)
295	02AAC	2/6/2020 10:40:34 AM	2/6/2020 2:16 PM	mitterer@macroarraydx.com (mitterer@macroarraydx.com)
294	02ABB	2/5/2020 9:40:19 AM	2/5/2020 12:48 PM	mitterer@macroarraydx.com (mitterer@macroarraydx.com)
293	02ABB	2/4/2020 9:26:13 AM	2/4/2020 12:34 PM	mitterer@macroarraydx.com (mitterer@macroarraydx.com)

[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).

- ConfigXplorer Scans:

ConfigXplorer Scans

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

In order to adjust the exposure and the alignment of the imaging device on the MAX 45k, a ConfigXplorer run must be performed after a new installation of the instrument and periodically every 60 days. The results of these scans can be inspected in detail and downloaded as a report file in PDF format. Further information about the ConfigXplorer procedure can be obtained from the section 5.5.

- QR-Code image exposure:

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

QR-Code image configuration

QR-Code Exposure:



Calibration configuration

Mode:

Exposure:

Any changes, which were made in the configuration of the Automat, are finalized by pressing the blue "Save" button.

5.5. ConfigXplorer Scans

A ConfigXplorer 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 ConfigXplorer run is needed.

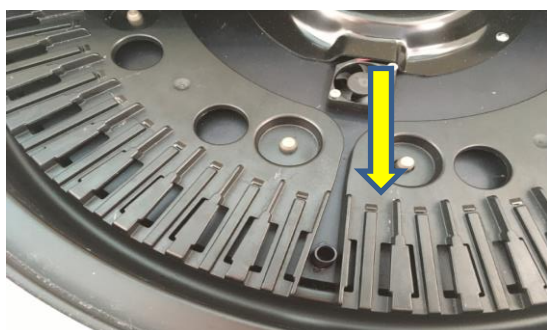
In order to perform the ConfigXplorer run, a special cartridge is needed, which can be ordered from Macro Array Diagnostics or your local distributor. Please check the expiry date, which is printed on the pouch label, before you put the cartridge into the instrument.



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



Put the ConfigXplorer cartridge into the cartridge rotor on the instrument. 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 counterclockwise. The rotor can be manually moved in both directions when the top cover is open.



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 ConfigXplorer run, select "Configure" in the "Automats" menu, as described in the previous section. Enter the selected position of the ConfigXplorer 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 ConfigXplorer runs can be investigated on the configuration page of the instrument. Click on the blue eye symbol and check if the ConfigXplorer run was performed successfully ("Acceptance Criteria: Passed"). If the test has passed, click on "Apply Settings".

Results

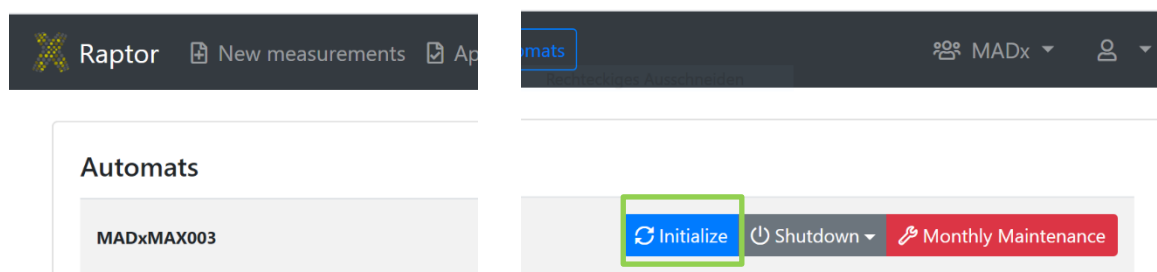
Detected offset X	400
Detected offset Y	316
Detected width	650
Detected height	350
Detected exposure	974
Device Serialnumber	19090003
Acceptance Criteria	Passed

5.6. Starting a new Assay Run

Please note that a maximum number of 4 assay runs can be performed with each assay kit!

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 Washing Solution of your assay kit (ALEX² or FOX). Please consult the Instruction for Use of ALEX² or FOX on how to correctly prepare the Washing Solution for the MAX 45k. The main flap must be firmly closed before any operation of the MAX 45k.

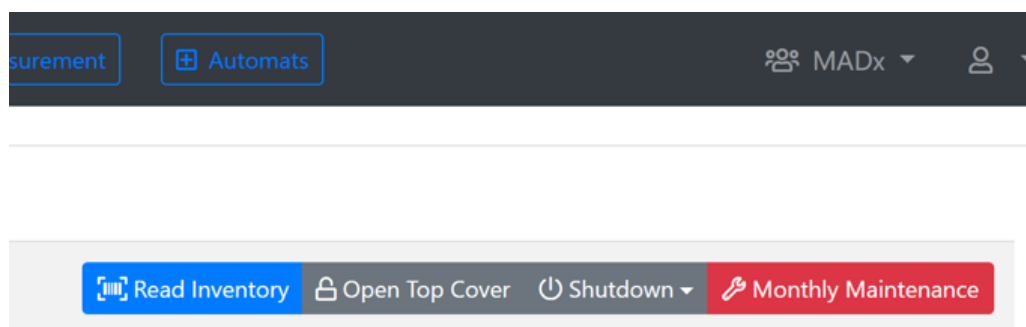
Click on “Automats” to get an overview of all MAX 45k instruments (Automats) that are currently linked to your laboratory tenant. Click on “Initialize” to perform the initialization process for the instrument which will be used for the upcoming assay run.



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”, so that 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.**



Put the 30ml reagent vials (ALEX² / FOX Sample Diluent, ALEX² / FOX Detection Antibody, ALEX² / FOX 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. Please note that if you use manually prediluted samples, you do not need to put the Sample Diluent into the instrument.



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



Put the 15ml reagent vial (ALEX² / FOX Stop Solution) in the corresponding hole on the sample rotor. Make sure that the barcode on the label 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 13mm vials only with the provided adapters.



You can also insert false-bottom low 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 13mm 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.



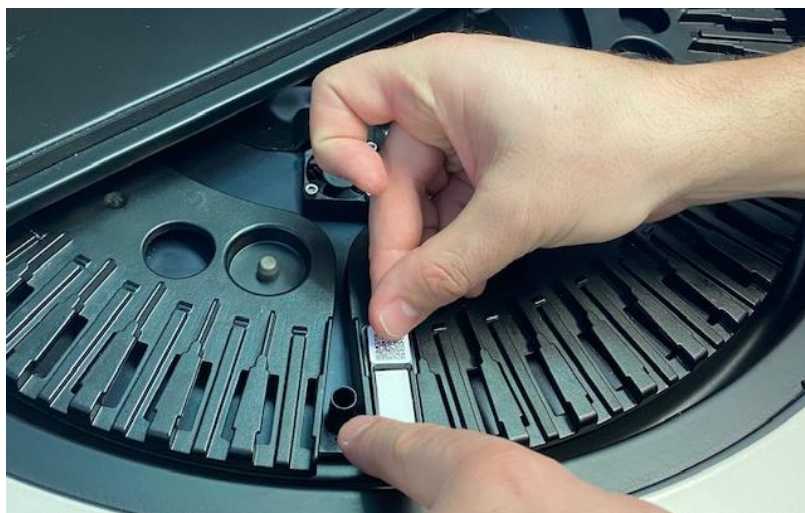
Caution

The maximum applicable barcode length is 3cm. Make sure that your barcode is attached in a position where it is not covered by the adapter tube, and still has 1cm clearance from the bottom of the tube. This ensures a safe identification of the code.

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

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

Insert the 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!**



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

The cartridges can be placed in any free position. Preferably start loading of the cartridges at position 1 as shown in the picture above.



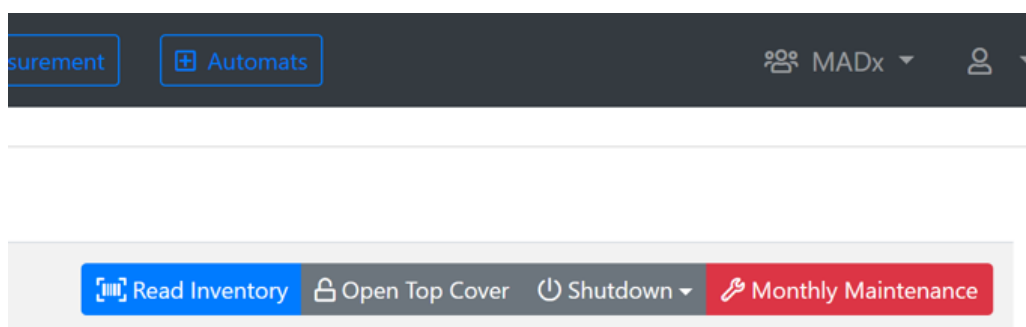
After all cartridges have been loaded, close the front lid of the cartridge rotor.



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



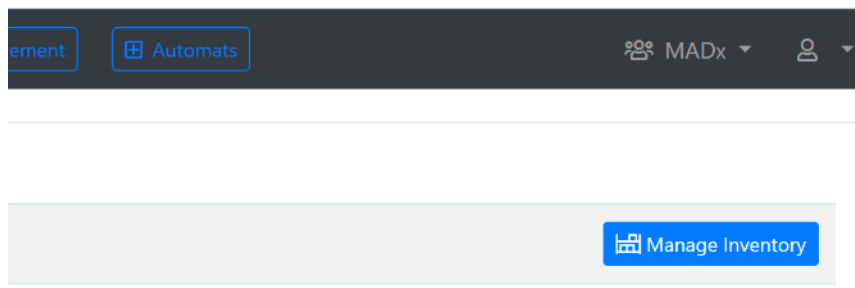
Click on the blue button “Read Inventory” in RAPTOR SERVER Analysis Software.



5.8. Inventory Reading and Volume Check

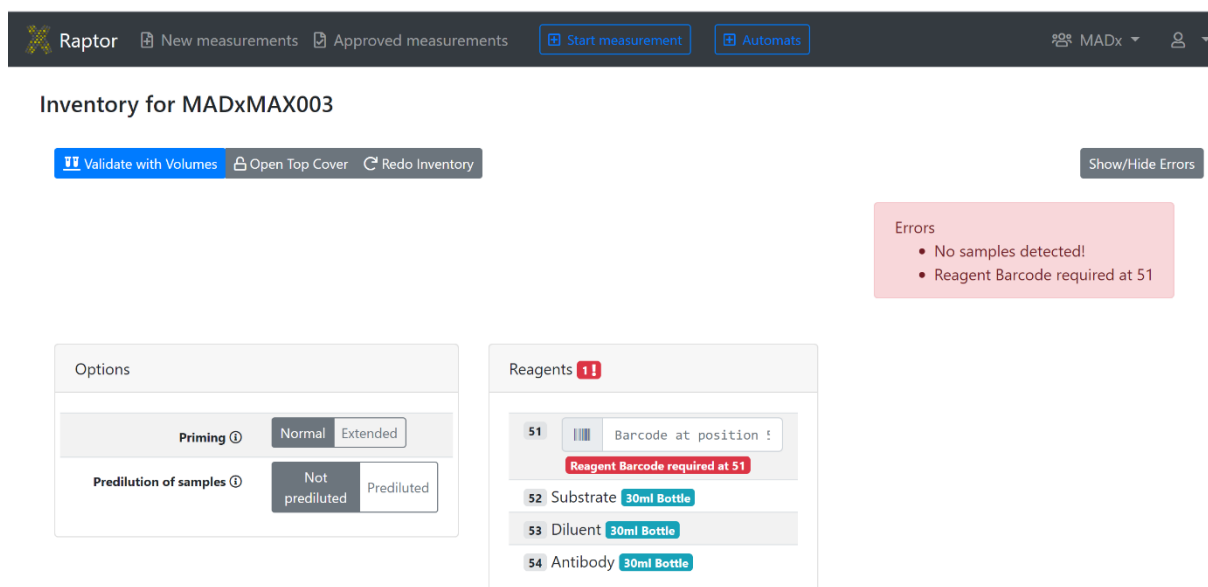
The instrument reads all barcodes/QR-Codes provided on the labels of the reagent bottles, the sample tubes, and the ALEX² / FOX cartridges.

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 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.

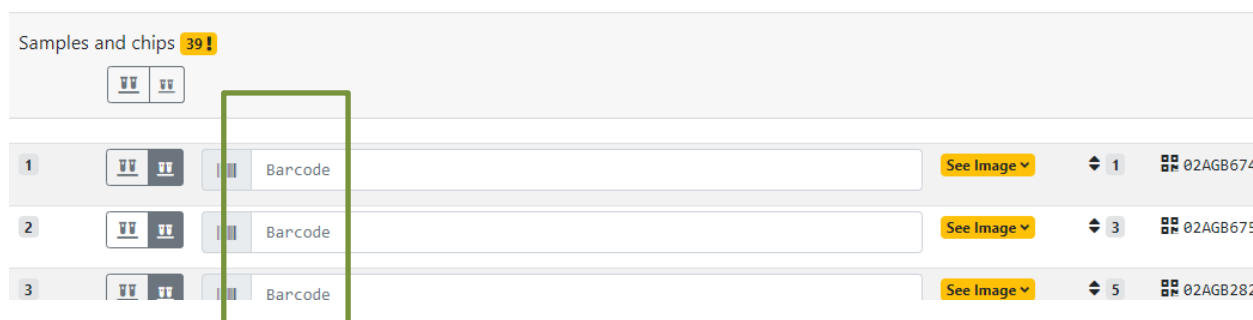
If all reagents have been put into place and you still get an error message (no barcode detected), the barcode can be entered manually into the corresponding text field. Please take care that you write the letters and digits exactly the way they appear on the label of the reagent bottle.



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

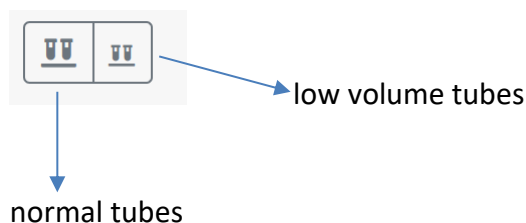
cannot apply both options in one assay run. In case of a FOX assay, only prediluted samples can be used (default option).

If one of the QR-Codes on the test-cartridges fails to be read, it is suggested to adjust the exposure for reading the barcodes by 300 upwards or downwards: see “configuration barcode exposure” 5.4).



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.

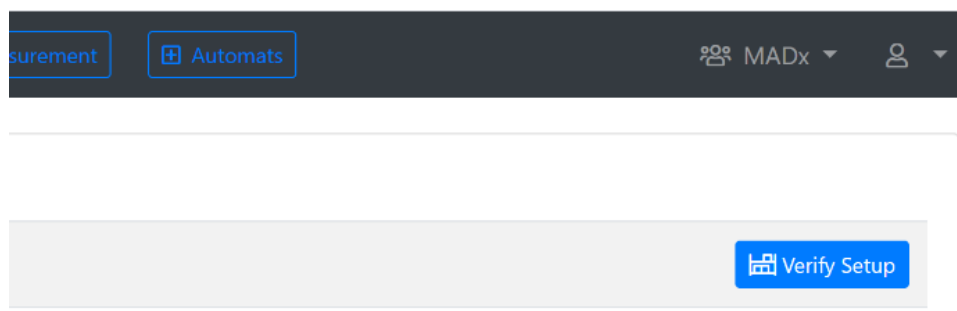
You can either select standard tubes (13 mm or 16 mm diameter) or low volume tubes by clicking on the corresponding icon on top of the sample list – to select the vial type for all samples – or by clicking on the symbol at a specific sample position to set the vial type only for this sample. You can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



The assignment of each ALEX² / FOX cartridge to a sample is done automatically by the RAPTOR SERVER software based on the position numbers; however, you can change this assignment by clicking on the cartridge QR-Code, located in every line of sample on the right side, and move the QR-Code with the mouse up or down to the desired position. If you want to use the same sample for more than one cartridge, the QR-Code of another cartridge needs to be moved to this sample, by clicking and dragging with the mouse.

If all barcodes / QR-Codes 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”. **Always use the extended priming option after at least 4 days out of operation for the MAX, and after handling the washing solution container or tubing, also after a fresh refill. If you need to detach any of the external tubes to refill containers just before a run, go back to “edit inventory”, and choose extended priming. By detaching the tubes, air can get into the system which is undesired. This can be counteracted by the extended priming option.**

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

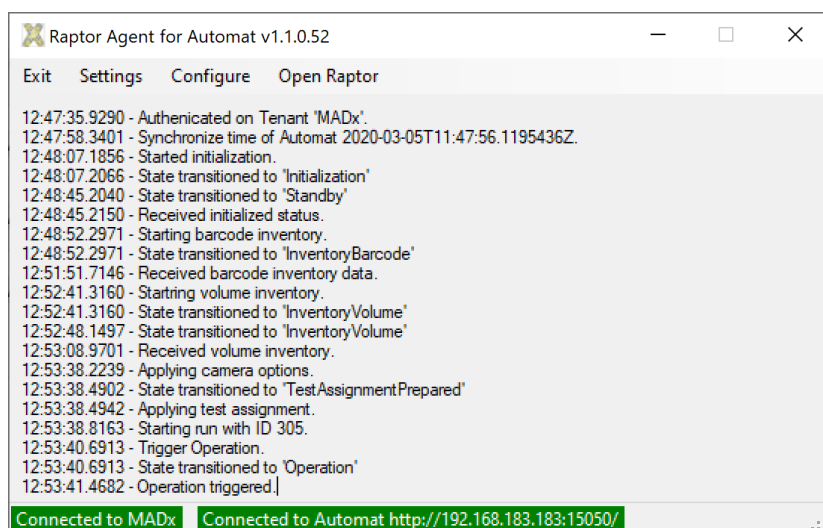
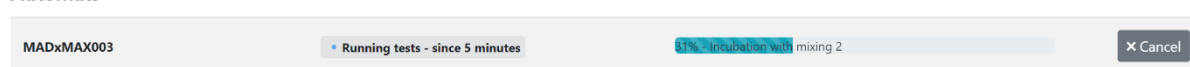
Click on the blue button “Start Run” to begin with the assay run.

5.8.1. Integrity Check

At the start and end of every run, the machine performs a control for the integrity of the fluidic system. If that fails at the start, the User will jump back to the “verify setup” step and can start again. If it fails for the second time, try to use the extended priming option, check for any air inclusions in the washing solution tubing, and contact your local distributor. If the integrity check at the end of the run fails, the test results will be uploaded to RAPTOR SERVER as usual, but with a warning at the measurement detail page.

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

Automats



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

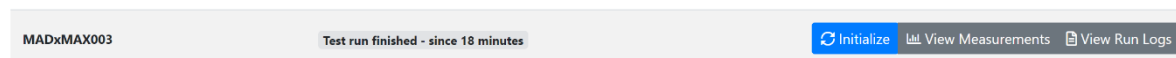
5.9. End of Assay Run and Shutdown

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”.

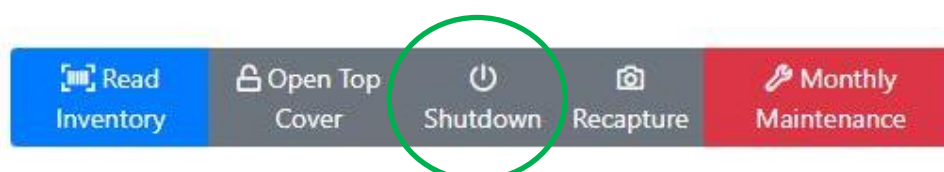
Before starting a new assay run, make sure that you remove all processed cartridges from the cartridge rotor.

Automats



To perform a shutdown of the instrument:

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



- After (!) the recovery push button starts flashing slowly, the device can be powered off with the main switch. **Never press the main switch while the MAX is still active!**
- Consult section 6 for required maintenance procedures of the instrument.



5.10. Recapture

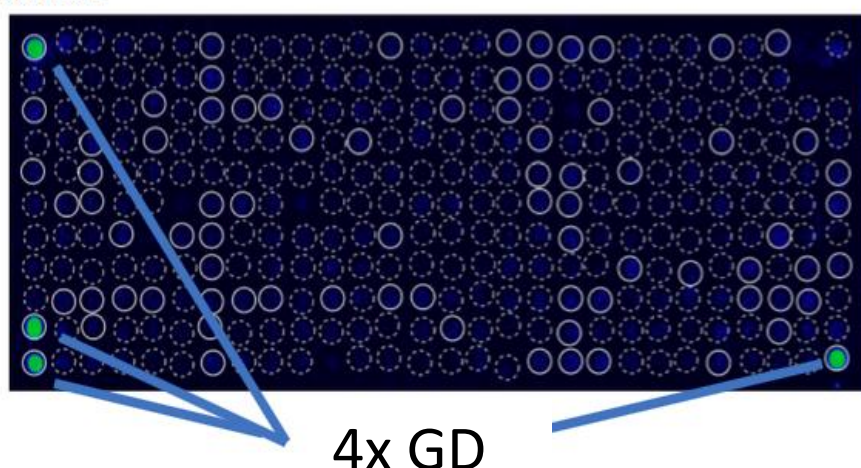
It is possible to carry out an imaging sequence of test cartridges, without a Run. In the standby (initialized) state of the machine, the “recapture” button is visible. By clicking the button, all cartridge positions will be read, and the tests found will be uploaded to the New Measurements tab on RAPTOR SERVER, with the Tag “recapture”. Note, if you have barcoded samples in the sample positions, the sample codes will be paired with the cartridge positions.

5.11. Internal Quality Control

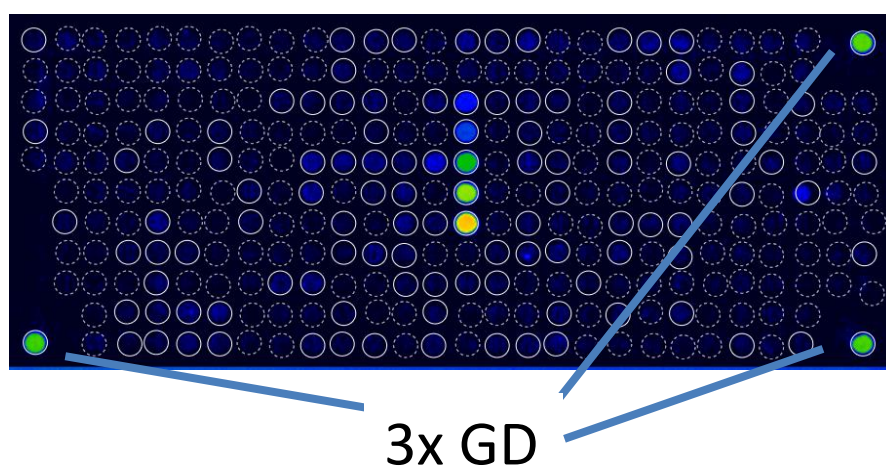
ALEX² and FOX cartridges have an inbuilt assay run control, represented by so called “Guide Dots” (GD) on the cartridge surface.

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

ALEX²

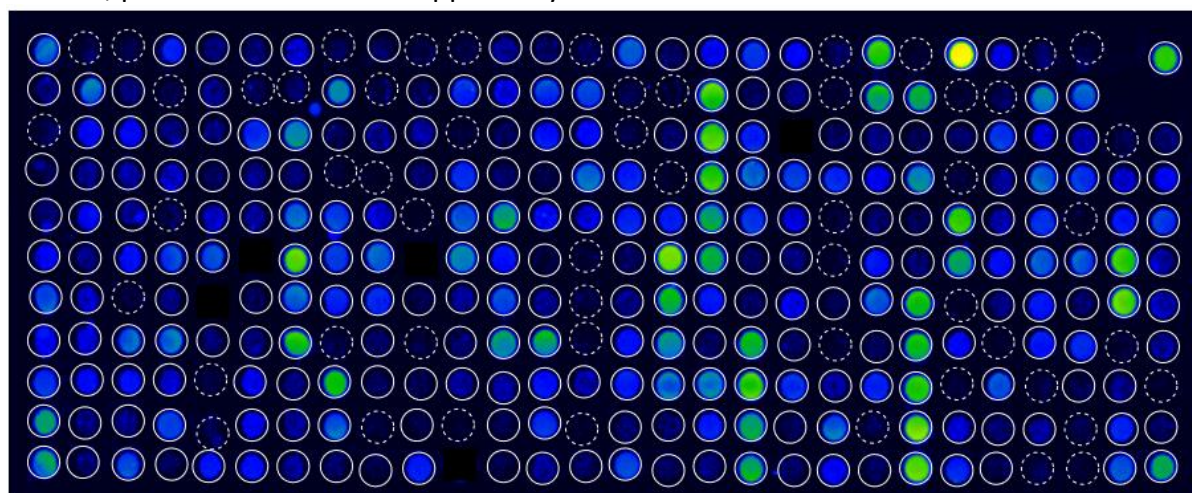


FOX



During the image acquisition of an ALEX² or FOX cartridge, RAPTOR SERVER evaluates the signal of all Guide Dots as well as the background signal of the membrane surface. If all quality

criteria are fulfilled, the “automatic QC” field under the image is set to “OK”. Please consult section 5.14 for further information about QC attached to the cartridge. If QC criteria are not fulfilled, please contact MADx support or your local distributor.



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 “Lyphocheck® 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. Currently, the QC module in RAPTOR SERVER is only available for ALEX², not for FOX.

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

In order to use Lyphocheck® 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 Lyphocheck® 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

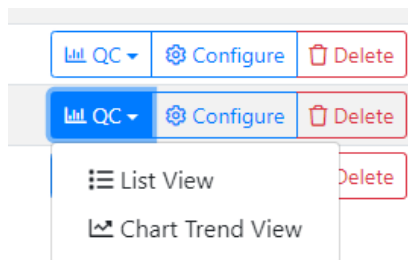
QC results can be obtained from the Automat settings page (“Tenant Admin” → “Manage Automats”). Click on the blue button “QC” to see an overview of QC results for a particular MAX 45k instrument.

Automats for "MADx"

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

Name	Key	Last connection	Last activity	
MAD_MAX	0F2mBu4aik4wIFjcPC641ThUkcd4s2	13 days ago	never	QC Configure Delete
MADxMAX003	CnKyr1pE9hwZ188A1QRVfrbo8fNwSM	14 minutes ago	2 months ago	QC Configure Delete

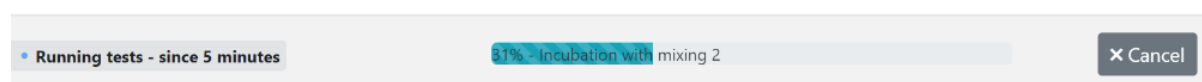
QC results can be examined in “List View” or in “Chart Trend View”:



5.12. Abortion of an assay run

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

During an assay run, the procedure can be manually 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.



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

If a vertical movement crash of the steel needle is detected, all mechanical motions of the stepper motors and all pumps will immediately stop running. The operator is informed about the event via the instrument status page. A “System Prepare” via the “Initialize” button in the RAPTOR SERVER Analysis Software will recover the instrument to perform further steps.

If the same crash is detected twice - although an “Initialize” procedure was executed in between - the MADx support team or your local distributor need to be contacted before performing any new assay run.

In case of an 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.

5.13. 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.

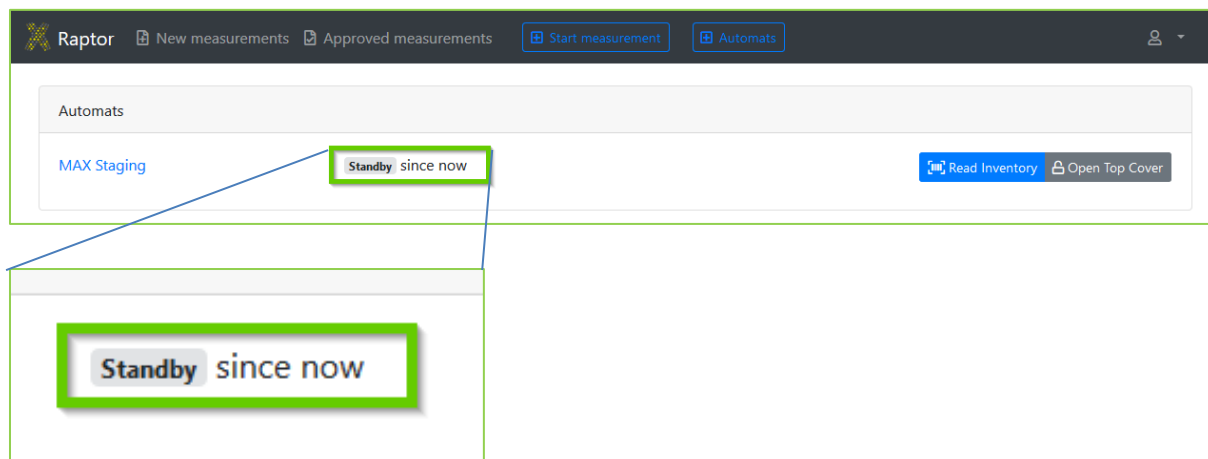
At the end of the assay run (or after the instrument aborted the assay run due to a severe error), an error log is created by the system. A hyperlink to the error log is provided on the user interface. By clicking on this link, the user can download the log file in text format and send it to Macro Array Diagnostics or your local distributor 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 Macro Array Diagnostics or its local distributors. In a first step, the log file has to be requested 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**

 Automat Logs ▾  Agent Logs ▾  Update Status  Shutdown ▾  Decontamination

5.14. 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 disappear 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) need 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 disappear for all users of tenant.
barcodeInventoryCapturing	Agent is connected to both, RAPTOR SERVER and instrument. Automat executes barcode inventory procedure.
barcodeInventoryDone	Agent is connected to both, RAPTOR SERVER and instrument. Automat finished barcode inventory procedure and is ready for next step.
UserRequestedVolumeInventory	Agent is connected to both, RAPTOR SERVER and instrument. User sent request for volume inventory. Actions disappear for all users of tenant.
VolumeInventoryCapturing	Agent is connected to both, RAPTOR SERVER and instrument. Automat executes volume inventory procedure.
VolumeInventoryDone	Agent is connected to both, RAPTOR SERVER and instrument. Automat finished volume inventory procedure and is ready for next step.
UserRequestedTestRun	Agent is connected to both, RAPTOR SERVER and instrument. User sent request to start test run. Actions disappear for all users of tenant.
RunningTests	Agent is connected to both, RAPTOR SERVER and instrument. Automat executes test run.
ResultTransmissionStarted	Agent is connected to both, RAPTOR SERVER and instrument. Operation procedure stopped and results are transmitted from instrument to RAPTOR SERVER via Agent.
TestRunFinished	Agent is connected to both, RAPTOR SERVER and instrument. All results sent to RAPTOR SERVER. User can see details of test run, view results or prepare instrument for next run.
UserRequestedCancel	Agent is connected to both, RAPTOR SERVER and instrument. User sent request to cancel current procedure. Actions disappear for all users of tenant.
Cancelling	Agent is connected to both, RAPTOR SERVER and instrument. Current operation is canceled. This state appears while cancel procedure is executed.
Stop	Agent is connected to both, RAPTOR SERVER and instrument. Either user canceled an operation, or a severe error was detected by the instrument, and it moves into state Stop.

Table 4 Status messages of MAX 45k

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.

5.15. Image Analysis and Report Generation

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

5.16. Storage and Transportation

For storage and transportation of the MAX 45k, please follow Sections 3.3, 3.4 and 3.5.

6. Cleaning/Maintenance

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

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



Caution

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

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 or Microcide SQ in a 2% solution.



Caution

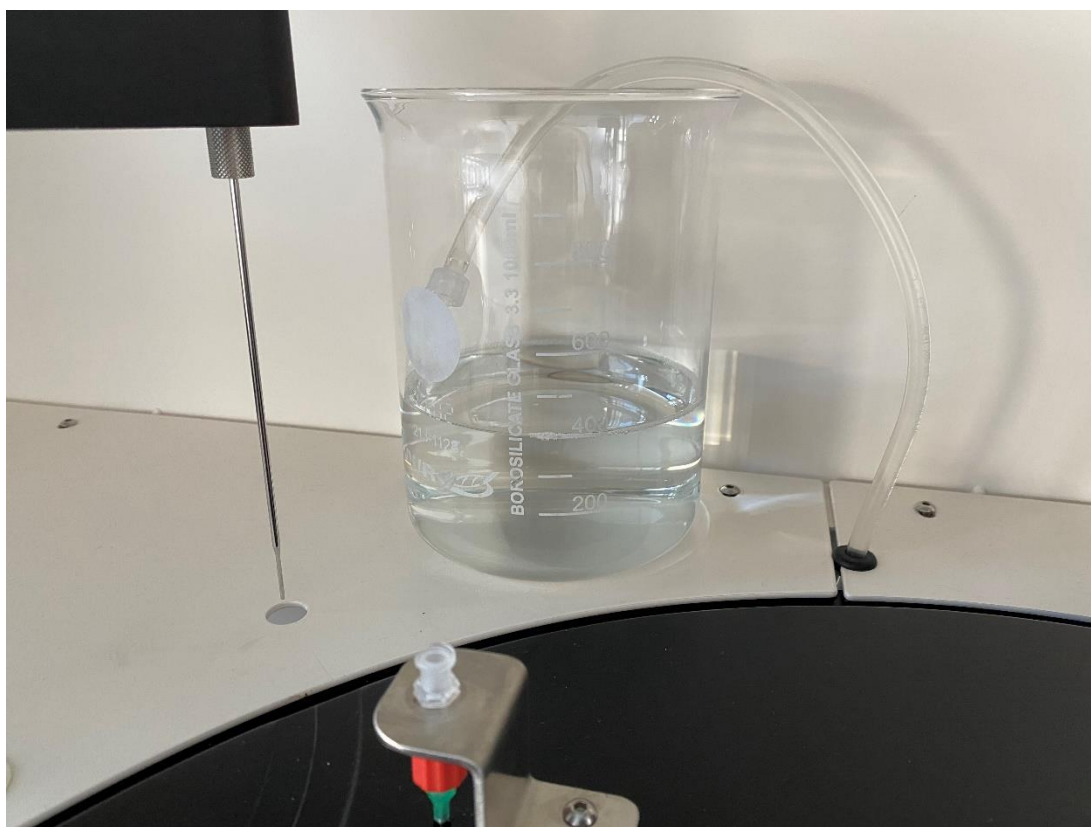
Do not use a spray for cleaning, otherwise the optics may malfunction.

3. Clean the illumination module of the cartridge rotor at the illuminated surface with a cloth moistened with the above recommended disinfectant 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.

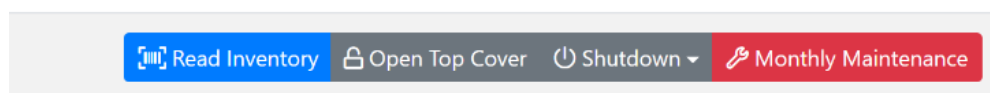
6.3. Monthly Maintenance

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

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



To start the maintenance and work with the provided online-checklist, go to the automat control page, and press the red button “Monthly Maintenance”.



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

Prepare monthly maintenance routine for automat MADx Test Automat

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

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

- ☐ Disconnect the wash-solution tubing from the Luer-lock connector and place the tubing into a vessel with at least 1 litre filling volume. Make sure that the vessel is not in the way of the pipettor arm and that the tubing is fixed in the vessel to prevent leakage. To open the top cover, press "back" on the bottom of this page to get back to the Automat controls and use the button "open top cover" after initialization.
- ☐ Empty the system-water- and the waste-water container. Transfer the content of the washing-solution container to a separate vessel, like a beaker.
- ☐ Add 40ml Terralin Protect (undiluted) to the system-water and waste-water container and fill it up with 2 liters of demineralized water (corresponds to a 2% Terralin solution). Add 10ml Terralin Protect (undiluted) to the wash-solution container and fill it up with 500ml demineralized water (corresponds to a 2% Terralin solution). Swivel the containers so that all surfaces inside the containers are moistened with the Terralin solution. Incubate for approx. 30 minutes.
- ☐ Visually check if the floats of the container are clotted. A clotted float will not freely fall down when released after it was pushed manually to the top.
- ☐ In case of a clotted float, please refill the containers with 2% Terralin solution for at least 24 hours and manually push the float back and forth several times. If a float is still clogged, please call MacroArray Diagnostics or its official distributor.
- ☐ Empty all containers and rinse them with demineralized water.
- ☐ Add 40ml Terralin Protect (undiluted) to the system-water container and fill it up with 2 liters of demineralized water (corresponds to a 2% Terralin solution). Add 10ml Terralin Protect (undiluted) to the wash-solution container and fill it up with 500ml demineralized water (corresponds to a 2% Terralin solution).
- ☐ Attach the screw caps of the system-water, wash-solution and waste-water containers properly.

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

Estimated duration for this step is 35 minutes.

The monthly maintenance procedure includes the following steps:

1. After emptying the system water and waste containers and transferring the content of the washing solution container to a separate clean vessel, fill all containers (system-water, waste, and washing solution) with Terralin® Protect or Microcide SQ in 2% dilution up to the labeled marking. Incubate for approx. 30 minutes at room temperature.
2. Remove the disinfectant solution from all containers and wash them thoroughly, using demineralized water. Empty all containers.
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 2% disinfectant solution for at least 24 hours and manually push the float back and forth several times. Finally, wash out all containers thoroughly using demineralized water and empty all containers. If a float ball is still clogged, please call the service team of Macro Array Diagnostics or your local distributor.
5. Fill the system-water and Washing Solution containers up to the labeled marking with Terralin® Protect or Microcide SQ in 2% dilution and start the monthly maintenance routine on the RAPTOR SERVER platform. Follow the instructions given by the RAPTOR SERVER Analysis Software.
6. If you did not put the washing solution tube in a vessel before starting, you can use the "back" button to jump back to the control page of the automat and trigger opening the cover to be able to do the following: detach the washing solution tube from the washing needle, and safely place the tube in a vessel of at least 1L fill volume. The vessel (like a glass beaker) should stand stable inside the machine, but not in the way of the pipettor arm. Make sure the tube remains inside the vessel and does not easily move – eventually to be fixed with a labeling tape. Then close the cover and start the first step of the monthly maintenance.

7. After you have proceeded through all steps instructed by the RAPTOR SERVER Software, the main flap will be unlocked in the last step (Step 6). Open the cover and clean the rotor plate of both rotors using a cloth moistened with Terralin® Protect or Microcide SQ in 2% dilution. Make sure you take out and thoroughly clean the cartridge holder segments as well.
8. Remove the sample rotor disk and clean the tub using a cloth moistened with the 2% disinfectant solution.



Caution

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

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



Caution

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

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

- If the “repeat” option is chosen, the maintenance routine will be continued from the step in which it was interrupted. In that case, the operator should double-check if the necessary amount of currently applied fluids is still available in the system-water and Wash Solution containers.
- If the cause of the error can only be resolved by a manual intervention or by opening the cover of the analyzer, the “abort” option shall be chosen by the operator. Thereby, the operator can quit the maintenance routine in 3 steps, as guided by RAPTOR SERVER.



Caution

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

6.4. Repairs

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

PLEASE NOTE

For safety reasons, a return of the instrument to Macro Array Diagnostics GmbH or its local distributors 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 of Macro Array Diagnostics GmbH or its local distributors. The parts which are replaced within this regular interval are:

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

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

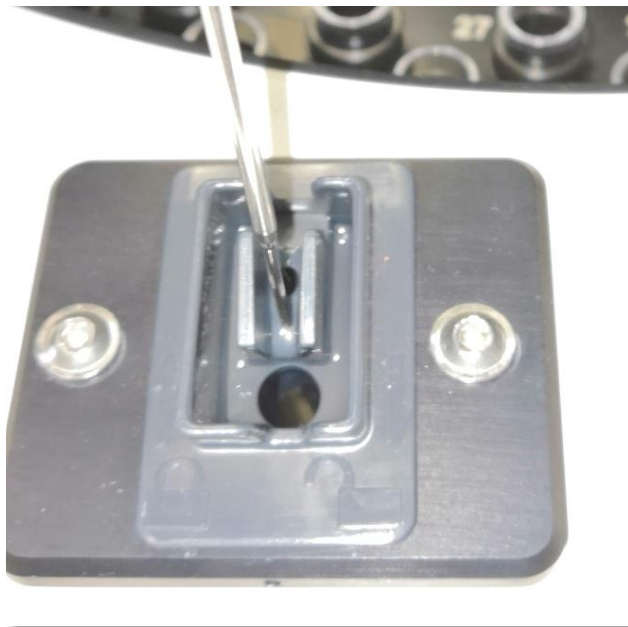
1. Please turn off the instrument and open the main flap according to **Section 4.3.3**.
2. Manually lift the robotics arm to the top and turn it to the front so that the needle tip is positioned above the drain channel of the needle wash station. Keep holding the arm in this position.



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 your local distributor.

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



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

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 also performed by the user according to the following procedure. It is recommended to wear gloves for the following steps:

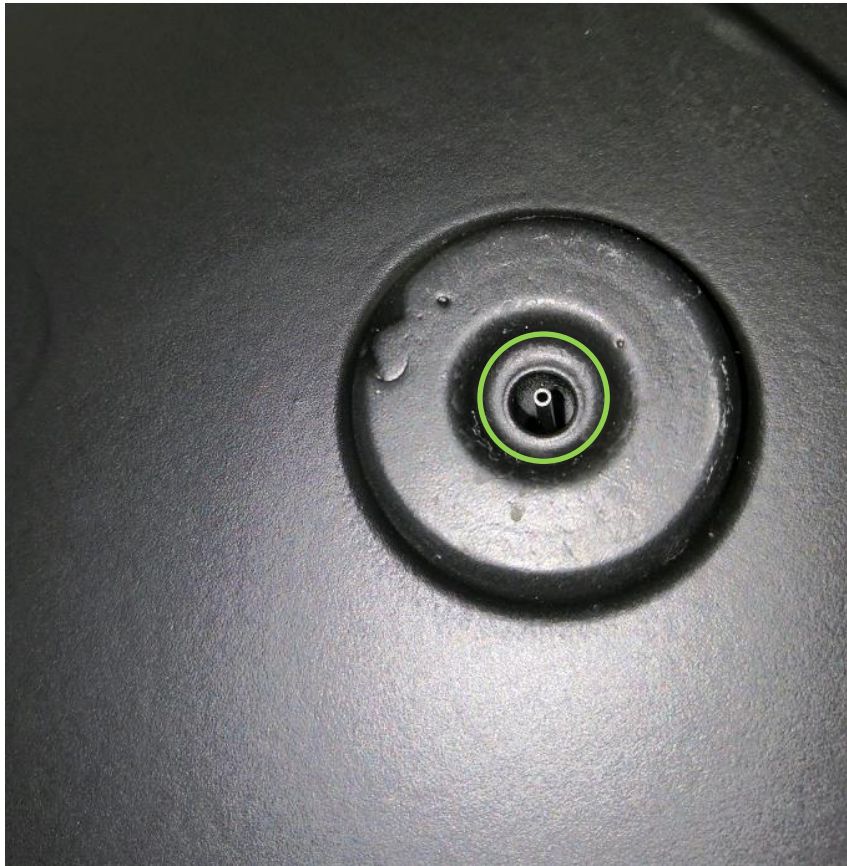
1. Remove Luer-lock connector from needle.



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.



If a leakage is detected and reported by RAPTOR SERVER Analysis Software, switch off the instrument and disconnect the power cable. Contact Macro Array Diagnostics service or your local distributor.

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.



If a second vertical movement crash is detected, although an “Initialize” procedure was executed in between, please contact Macro Array Diagnostics service or your local distributor.

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.



If an un-authorized main Flap Opening occurs, Macro Array Diagnostics GmbH disclaims all liability for damage to the analyzer or uncomplete 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 Macro Array Diagnostics service or your local distributor.

8.5. Washing solution fluidics integrity

The function of the dosing pump (washing solution) is controlled before and after a run, by imaging a cartridge after washing solution dispensation. Thereby, the risk of an undetected malfunction (air leaks in the washing solution fluidics) during the run is decreased. If the control fails before the run, the run does not start, and the user will jump back to the “verify setup page”; if the control fails at the end of the run, the results will still be uploaded, but tagged automatically and with the error noted in the measurement details.

8.6. 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 Macro Array Diagnostics service or your local distributor.

8.7. Further Error Messages

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

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

Table 5 Error severities

9. Technical Specification

Item	Specification
Throughput	Up to 100 tests per working day (8h) and 150 tests including 1 overnight run
Sample pipetting volume	100 µl to 399 µl
Reagent pipetting volume	100 µl to 400 µl
Low volume sample tubes	Sarstedt false-bottom tubes 2.5 ml, 75x13 (round), Order number: 60.614.010
13 mm standard tubes (with adapter)	Minimum height: 75 mm, maximum height: 100 mm For example: Sarstedt tubes 5 ml, 75x13 mm, PS Order number: 55.475
16 mm standard tubes	Minimum height: 75 mm, maximum height: 100 mm For example: Sarstedt tubes 13 ml, 100x16 mm, PS Order number: 55.459
NOTE: Before using any other tube than specified above, please contact MADx support or your distributor.	
Minimum sample volume for 1 ALEX ² test, 13/16 mm standard tubes	Not prediluted: 400 µl Prediluted manually: 145 µl serum + 580 µl Sample Diluent
Minimum sample volume for 1 ALEX ² test, low volume tubes	Not prediluted: 200 µl Prediluted manually: 120 µl serum + 480 µl Sample Diluent
Minimum sample volume for 1 FOX test, low vol. tube only	Prediluted ONLY: 600 µl (12 µl serum + 588 µl Sample Diluent)
Maximum number of onboard samples	50
Maximum number of assay runs with one ALEX ² / FOX kit	4
Sample container	Sample tubes with a nominal height of 75 mm and 100 mm and a nominal outer diameter of 13 mm and 16 mm (13 mm tubes with adapter)
Sample barcode size	Max. 3 cm
Sample barcode types	code128 code39 ean8 codabar code25
Reagent container	15 ml, 30 ml
Max number of onboard cartridges	50
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)

	humidity)
Appropriate degree of pollution	2
Altitude	-400 m to 2000 m above sea level
Weight	~ 100 kg
Power Management*	100-240 V, 150 W, 50/60 Hz
Noise Level	< 65 dB in 1m distance

Table 6 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, R.G.. (2008). Assessment of human allergic diseases. *Clinical Immunology*. 1471-1484. doi: 10.1016/B978-0-323-04404-2.10100-9.
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. doi: 10.1046/j.1365-2222.2003.01550.x. PMID: 12534543.
3. Hiller R, Laffer S, Harwanegg C, Huber M, Schmidt WM, Twardosz A, Barletta B, Becker WM, Blaser K, Breiteneder H, Chapman M, Crameri R, Duchêne M, Ferreira F, Fiebig H, Hoffmann-Sommergruber K, King TP, Kleber-Janke T, Kurup VP, Lehrer SB, Lidholm J, Müller U, Pini C, Reese G, Scheiner O, Scheynius A, Shen HD, Spitzauer S, Suck R, Swoboda I, Thomas W, Tinghino R, Van Hage-Hamsten M, Virtanen T, Kraft D, Müller MW, Valenta R. Microarrayed allergen molecules: diagnostic gatekeepers for allergy treatment. *FASEB J*. 2002 Mar;16(3):414-6. doi: 10.1096/fj.01-0711fje. Epub 2002 Jan 14. PMID: 11790727
4. Ferrer M, Sanz ML, Sastre J, Bartra J, del Cuvillo A, Montoro J, Jáuregui I, Dávila I, Mullol J, Valero A. Molecular diagnosis in allergology: application of the microarray technique. *J Investig Allergol Clin Immunol*. 2009;19 Suppl 1:19-24. PMID: 19476050.
5. Ott H, Fölster-Holst R, Merk HF, Baron JM. Allergen microarrays: a novel tool for high-resolution IgE profiling in adults with atopic dermatitis. *Eur J Dermatol*. 2010 Jan-Feb;20(1):54-61. doi: 10.1684/ejd.2010.0810. Epub 2009 Oct 2. PMID: 19801343.
6. Sastre J. Molecular diagnosis in allergy. *Clin Exp Allergy*. 2010 Oct;40(10):1442-60. doi: 10.1111/j.1365-2222.2010.03585.x. Epub 2010 Aug 2. PMID: 20682003.
7. CLSI Protocols for Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline Second Edition CLSI Document EP5-A2 (ISBN 1-56238-542-9) 2004.
8. CLSI Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guidelines. CLSI document EP17-A (ISBN 1-56238-551-8), 2004.