



IMAGE XPLOER INSTRUCTIONS FOR USE

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I. DISCLAIMER

MacroArray Diagnostics 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 MacroArray Diagnostics 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 MacroArray Diagnostics.

Please consult the relevant instructions for use of applicable ALEX technology-based tests before processing, <https://www.madx.com/extras!>

The following products are within the scope of this document and are hereinafter referred to as “tests” or “test kits”:

Product name	REF-Number	CE Mark
ALEX ²	02-2001-01	
ALEX ³	03-2001-01	
FOX	80-5001-01	

II. LANGUAGE DISCLAIMER

These Instructions for Use (IFU) are provided in multiple languages according to regulation (EU) 2017/746. In the event of any discrepancies or inconsistencies between the English version and any translated version, the English version shall prevail and be considered the authoritative reference.

III. LIABILITY STATEMENT

This IFU has been reviewed for accuracy. The instructions and description for the ImageXplorer were correct at the time of publication. Subsequent versions of this guide may be updated without prior notice.

The ImageXplorer is an in-vitro diagnostic device intended for use by trained laboratory personnel only. The ImageXplorer may only be used for its intended purpose in accordance with this IFU. The IFU must be observed without exception. If you are unfamiliar with the use of the ImageXplorer, you are obliged to obtain information from MacroArray Diagnostics (MADx) before using it. MADx assumes no liability for improper use of the ImageXplorer. MADx shall only be liable for any harm or damage to property directly or indirectly resulting from errors in this IFU in the event of gross negligence or intent, and for personal injury only within the scope of the mandatory statutory provisions.

If any term or provision in this IFU shall be held to be illegal or unenforceable, in whole or in part, under any enactment or rule of law, such term or provision or part shall to that extent be



deemed not to form part of this IFU but the enforceability of the remainder of this IFU shall not be affected.

This guide is protected by copyright. No part of it may be duplicated, reproduced, or copied in any electronic or machine-readable format without prior written permission from MADx.

IV. TERMS AND DEFINITIONS

Damage	Physical injury or damage to human health, damage to goods or the environment.
Intended Operation	Operation, including readiness for operation, in accordance with the operating instructions or the intended use.
Intended Purpose	Use of a product, method, or service in accordance with the specifications and instructions defined by Macro Array Diagnostics (MADx).
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.
Operator	Individual or group responsible for the usage and maintenance of the device. The operator makes sure the users have been appropriately instructed about how to operate the device.
Process	Resources and activities that interact to convert input into results.
Trained personnel	Employees who have completed a recognized education program for the task that has been assigned to them, who are familiar with the special aspects and hazards of their work environment and who continue their education with regular training sessions about changes and developments (such as standards and guidelines) that are relevant to their education and their work.
User	Person using the device in accordance with the specifications.
Validation	Confirmation by providing objective evidence that the requirements for a specifically intended use or specifically intended application have been fulfilled.
Verification	Confirmation by providing objective evidence that defined requirements have been fulfilled.



V. INTENDED PURPOSE FOR IMAGEEXPLORER

The ImageXplorer is an instrument and intended as accessory to ALEX technology-based products.

The IVD medical product acquires pictures of the ALEX technology-based arrays and is used by trained laboratory personnel and medical professionals in a medical laboratory.

This Instruction for Use is applicable for the following products:

Basic UDI-DI	REF	Product
91201229211JR	11-0000-01	ImageXplorer

VI. MANUFACTURER

The ImageXplorer is manufactured by MacroArray Diagnostics (MADx).



MacroArray Diagnostics
Lemböckgasse 59, Top 4
1230 Vienna, Austria

VII. PERFORMANCE DATA

VII.1 ASSAY CALIBRATION

For the Assay Calibration refer to the respective IFU of the ALEX², ALEX³ or FOX test.

VII.2 MEASURING RANGE

For the Measuring Range refer to the respective IFU of the ALEX², ALEX³ or FOX test.

VII.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. Lyphochek® slgE Control Panel A (by Bio-Rad) can be applied. Acceptance ranges for the most recent batches of Lyphochek® slgE Control Panel A are stored and displayed on RAPTOR SERVER.



VII.4 DATA ANALYSIS

ALEX², ALEX³ and FOX images are automatically analyzed using RAPTOR SERVER and a report is generated summarizing the results for the user.

VII.5 RESULTS

ALEX² and ALEX³ are quantitative methods for specific IgE and a semi-quantitative method for total IgE determination for ALEX². For ALEX³, total IgE is measured quantitatively between 2-1000 kU/l, and semi-quantitatively from 1001-2500 kU/l. Allergen- specific IgE antibodies are expressed as IgE response units (kU_A/l), total IgE results as kU/l. RAPTOR SERVER Analysis Software automatically calculates and reports sIgE results (quantitatively) and tIgE results accordingly.

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

VII.6 LIMITATION OF THE PROCEDURE

For the Limitation of the procedure refer to the respective IFU of the ALEX², ALEX³ test or FOX test.

VII.7 EXPECTED VALUE

For the expected values refer to the respective IFU of the ALEX², ALEX³ test or FOX test.

VII.8 PERFORMANCE CHARACTERISTICS

The performance characteristics can be found at: <https://www.madx.com/extras>.

VIII. PRINCIPLE OF THE PROCEDURE

VIII.1 ALEX² AND ALEX³ TEST PRINCIPLE

ALEX² and ALEX³ are solid-phase immunoassays. 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 the ImageXplorer. The test results are analyzed with 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).

VIII.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 the ImageXplorer. The test results are analyzed with RAPTOR SERVER Analysis Software and reported in µg/ml and in IgG classes.

IX. SERVICE

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

X. WARRANTY

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



XI. ORDERING INFORMATION

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

The MADx article number (REF) for the ImageXplorer is 11-0000-01.

XII. SAFE HANDLING

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.

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

This equipment is designed for use in the PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to malfunction if used in the HOME HEALTHCARE ENVIRONMENT. Performance is expected to be affected by electromagnetic fields; proper operation can be restored by increasing the distance between the equipment and the source of interference.

XII.1 OPERATOR QUALIFICATION

The ImageXplorer should be operated by or under the supervision of a technician or operator who is sufficiently qualified for laboratory work. Before operating the ImageXplorer and the RAPTOR SERVER Analysis Software, the operator should:

- Read these Instructions for Use carefully
- Be aware of all relevant laboratory procedures
- Be aware of all relevant safety rules and regulations

Carefully follow the procedure specified in these Instructions for Use for the operation and maintenance of the system. Maintenance which is not described in the Instructions for Use should be left to qualified service engineers.



Do NOT open the instrument housing!



	Electronic equipment can be a source of electric shocks!
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	Service and Repair should only be carried out by MacroArray Diagnostics or its local distributors.
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XII.2 OPERATIONAL SAFETY

As with any mechanical system, certain precautions must be taken when operating the imager.

	Do NOT load humid or wet cartridges!
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Any liquid spilled on the instrument may result in the malfunction of the system. If liquid is spilled on the instrument, wipe it off immediately and contact technical support.

XII.3 DECONTAMINATION

For safety reasons, the ImageXplorer 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.

XIII. GLOSSARY OF SYMBOLS

	Consult instruction for use
	In vitro diagnostic medical device
	CE mark
	Manufacturer



	Serial number
	Waste electrical and electronic equipment
	Caution
	Unique device identifier
	MacroArray Diagnostics (MADx)

XIV. SAFETY MESSAGES

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

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

XV.1 INTERNATIONAL STANDARDS

The ImageXplorer has been developed, tested, and manufactured in accordance with EN ISO 13485, EN ISO 14971 and EN IEC 61326-2-6.

XV.2 CE CONFORMITY

The ImageXplorer bears a CE mark certifying that the device meets the general safety and performance requirements of Annex I to Regulation (EU) 2017/746 (IVDR).

The device further complies with European Directive 2011/65/EU on the Restriction of Hazardous Substances (RoHS).



XV.3 ELECTROMAGNETIC COMPATIBILITY (EMC), RADIO INTERFERENCE SUPPRESSION AND IMMUNITY TO INTERFERENCE

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

XVI. LIFE CYCLE

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

XVI.1 DELIVERY

XVI.1.1 DAMAGES DURING TRANSPORT

The outer packaging of the ImageXplorer ensures the best possible protection against transport damage. Nevertheless, please check each shipment immediately upon receipt for visible transport damage. If you receive an incomplete or damaged shipment, please directly contact MacroArray Diagnostics or your local distributor. Please notify the carrier about apparent damage.

XVI.1.2 SCOPE OF DELIVERY

Included Items
1x ImageXplorer
1x ImageXplorer Carriage
1x Connecting cable (PC to ImageXplorer)

Table 1: List of items available for delivery

For the operation of the device, an ALEX² (REF 02-2001-01), ALEX³ (REF 03-2001-01), or FOX (REF 80-5001-01) assay kit is required, which is not included in the shipment of the ImageXplorer and must be ordered separately.

XVI.2 DISPOSAL

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

MacroArray Diagnostics is committed to take back and recycle electrical and electronic equipment in areas where the above-mentioned directive is enforced.

In areas where the above-mentioned directive is not enforced, contact the MacroArray Diagnostics service or a local distributor regarding disposal of the analyzer.



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

	Treat contaminated material according to national and local standards and regulations. Before transport or disposal, disinfect parts of the analyzer that may be contaminated according to national and local standards and regulations. If you need assistance, contact MacroArray Diagnostics or a local distributor.
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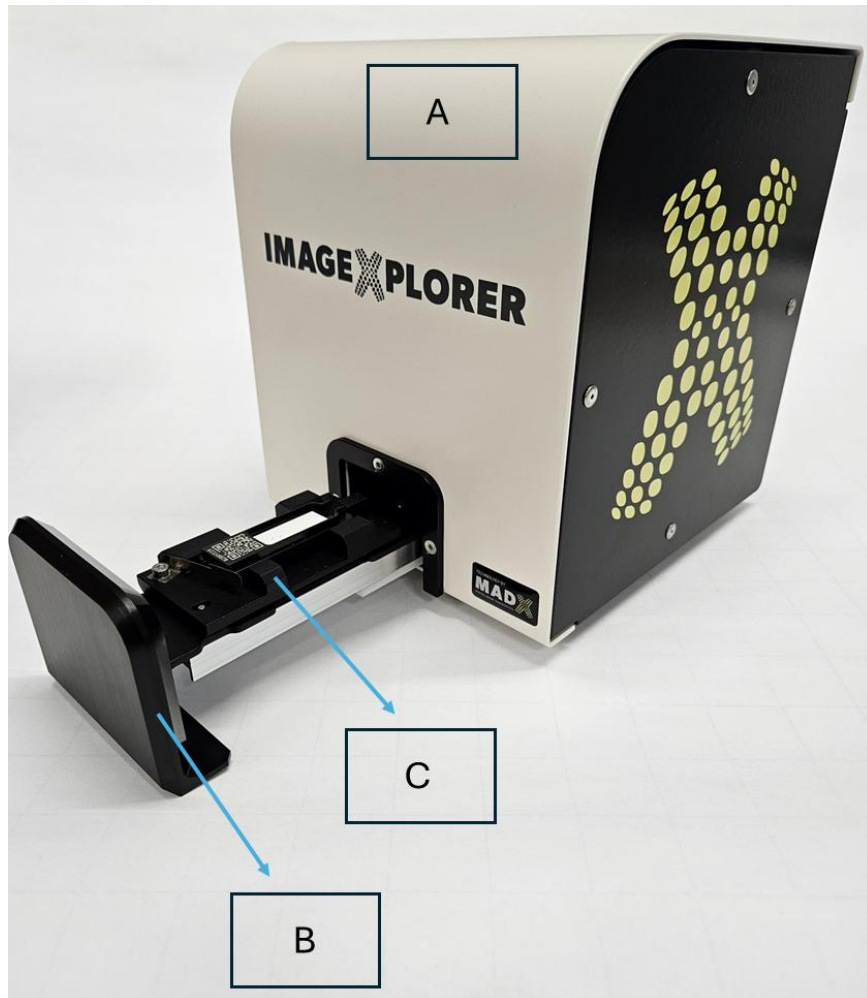
	Do not treat electrical and electronic equipment as unsorted municipal waste and check with your local waste disposal contractor for specific requirements regarding disposal. Please collect waste electrical and electronic equipment separately and return it to MacroArray Diagnostics or a local distributor in areas where the above-mentioned directive is enforced.
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XVI.3 DATA BACKUP

When using RAPTOR SERVER Analysis Software, all analytical and patient related data are stored according to the MADx Terms of Service Agreement in the Microsoft Azure Online Portal. Please also refer to the Online Services Terms (OST) of Microsoft, available at <https://www.microsoft.com/en-us/licensing/product-licensing/products>. For the RAPTOR SERVER on-premise version, the customer/user is responsible for carrying out backups, please consult with your local IT administrator.



XVII. DESCRIPTION



- A: chassis
B: slider
C: carriage

The relevant system components of the ImageXplorer are:

- CCD (charge-coupled device) Camera for image acquisition
- Custom LED light circuit board
- Carriage for inserting cartridges
- Stage for sliding the cartridge holder
- USB 2.0 or USB 3.0 cable



XVII.1 CONNECTING THE IMAGEEXPLORER TO THE PC

The ImageXplorer is not a standalone device and must always be used in combination with RAPTOR SERVER Analysis Software. The ImageXplorer is plugged into a computer via the provided USB 2.0 or USB 3.0 cable, and both the connection and the power supply are managed through the computer's USB 3.0 port by the USB cable provided.

NOTE: The device can also be used on a USB 2.0 port, but the analysis will require longer time because of lower data transmission rates.





XVII.2 RAPTOR SERVER SOFTWARE SETUP

Google Chrome is recommended as a browser for using the RAPTOR SERVER. The graphical user interface of RAPTOR SERVER can be accessed on the website: <https://www.raptor-server.com>.

The RAPTOR SERVER instance is designed for SaaS operation and therefore supports multiple independent tenants. Each tenant is logically differentiated from all other tenants and no exchange of data between tenants is possible in any way. If measurements should be transferred from one tenant to another one, it must be done actively in the RAPTOR SERVER Analysis Software.

For further information on the RAPTOR SERVER please refer to the corresponding Instructions for Use.



XVII.3 DOWNLOAD OF THE IMAGEEXPLORER AGENT SOFTWARE AND IMAGEEXPLORER DEFINITION

To set up an ImageXplorer for your tenant, go to the Tenant Admin area and click "Manage ImageExplorers". To add a new ImageXplorer, please select "Add new ImageXplorer" and assign a name to it. An ImageXplorer key will be generated automatically.



ImageExplorers
Use this to configure ImageExplorers, or add new ones. Every ImageXplorer needs to be known to Raptor Server, otherwise it won't be able to connect.

[Manage ImageExplorers](#)

RAPTOR [New measurements](#) [Approved measurements](#) [Start measurement](#) [Automats](#)

Add new ImageXplorer

General information

Name:

Key:
This key is required when installing an Agent.

ImageXplorer Serialnumber:
Serialnumber of connected ImageXplorer.

Notes:

Internal Notes:
For internal use only.

Disabled:

QR-Code image configuration

QR-Code Exposure:

Calibration configuration

Mode:

Array image configuration

Array Offset X:

Array Offset Y:

Array Width:

Array Height:

Array Exposure:

[Save](#) [Cancel](#) [Debug information](#)

After clicking on "Save" you will return to the overview page of the respective ImageXplorer. Here you shall download the ImageXplorer Agent software.



ImageXplorers for "MADx"

Add new ImageXplorer

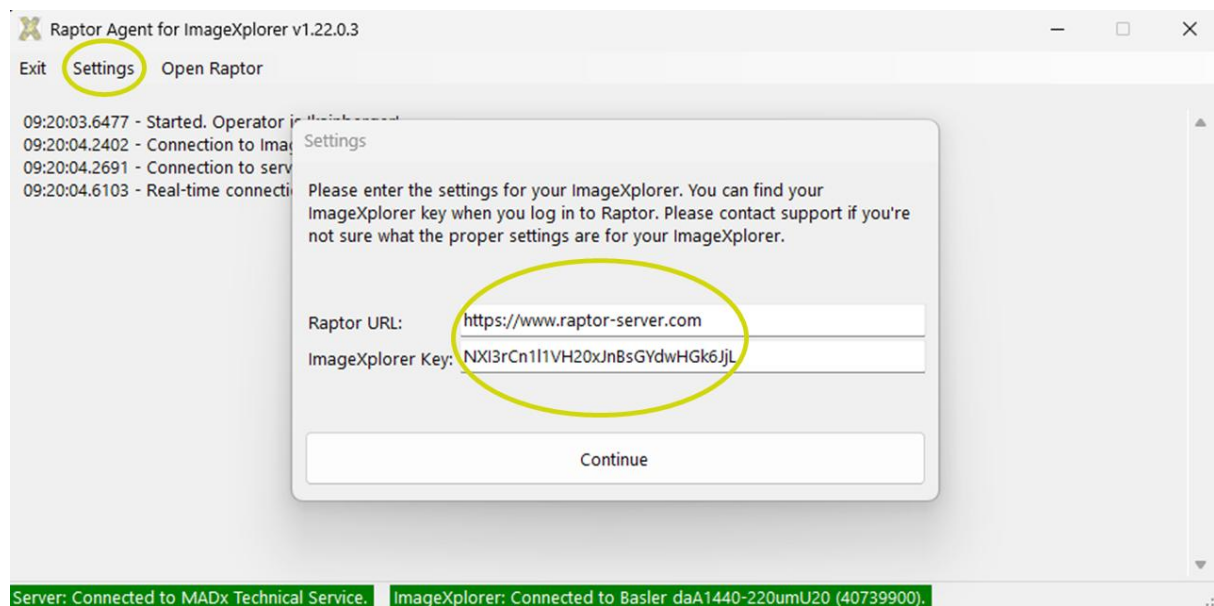
 Download ImageXplorer Agent Software

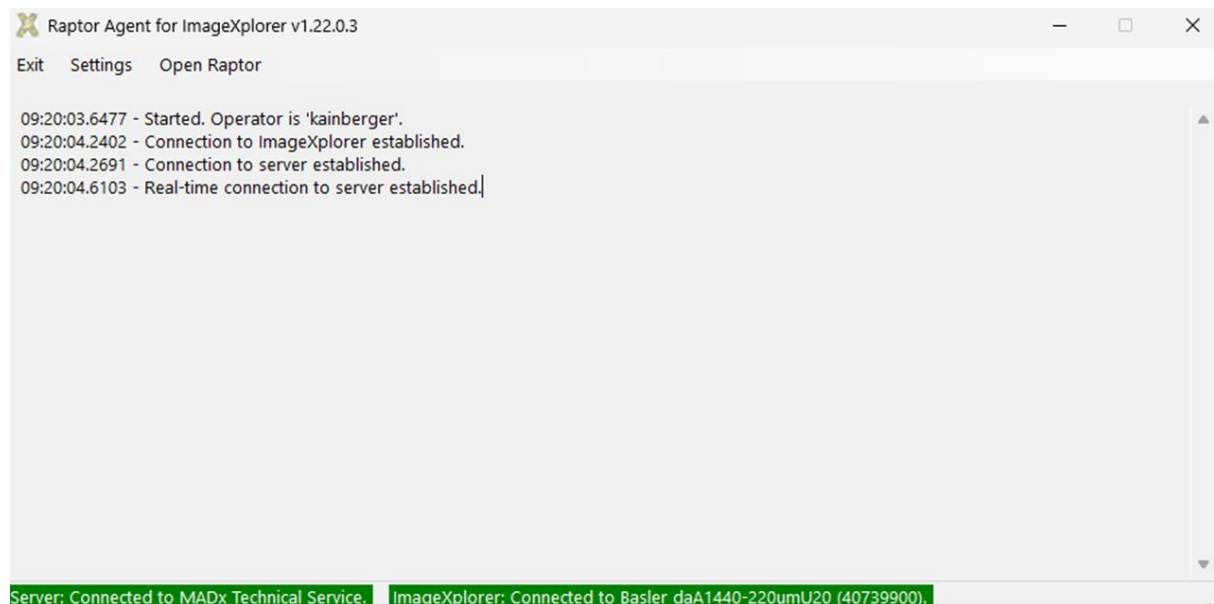
Carry out the installation of the ImageXplorer agent, as a regular installation process.

NOTE: The use of the ImageXplorer requires the presence of the software "Pylon Runtime 6.1.1, by Basler. If you install the "full" version of the ImageXplorer Agent, the software is included. If you already have this software, it is enough to install the "slim" version of the Software.

NOTE: It is suggested to remove any other Pylon software from the PC before installing the ImageXplorer Agent, such as previous versions of the Pylon Runtime.

To activate the Agent and connect it to ImageXplorer and RAPTOR SERVER, please go to Settings and type in the RAPTOR SERVER URL: <https://www.raptor-server.com> and your ImageXplorer Key and click "Continue".



**A****B**

A: Connection to RAPTOR SERVER

B: Connection to ImageXplorer

If a connection to both the RAPTOR SERVER and the ImageXplorer is established, both fields are highlighted in green. If one connection fails, refer to the troubleshooting section for further instructions.

If the Log in was successful, the homepage of the RAPTOR SERVER Analysis Software shows up with the dashboard, which includes new and approved measurement results from previous ALEX², ALEX³ and FOX assay runs on the ImageXplorer and the date of the last ConfigXplorer scan and/or monthly maintenance (for MAX devices only).



New Measurements

Last 7 days

QC	Product type / Source	QR-Code	Sample Code	Analysis Date	
X Failed	ALEX ² MAX 45k	02XYZ08E	9362743916	28.01.2026 08:58	Details Report
X Failed	ALEX ² MAX 45k	02XYZ08B	ZD43174941	28.01.2026 08:58	Details Report
X Failed	ALEX ² MAX 45k	02XYZ0A6	539753490	28.01.2026 08:58	Details Report
X Failed	ALEX ² MAX 45k	02XYZ03C	0124307518	28.01.2026 08:58	Details Report
OK	ALEX ² IX	02BRY119		26.01.2026 09:34	Details Report
X Failed	ALEX ² MAX 45k	02XYZ095	0124307518	23.01.2026 08:50	Details Report
X Failed	ALEX ² MAX 45k	02XYZ0A6	539753490	23.01.2026 08:50	Details Report
X Failed	ALEX ² MAX 45k	02XYZ08B	ZD43174941	23.01.2026 08:50	Details Report
X Failed	ALEX ² MAX 45k	02XYZ08E	9362743916	23.01.2026 08:50	Details Report
X Failed	ALEX ² MAX 45k	02XYZ095	0124307518	22.01.2026 08:46	Details Report

In total there are 17 new measurements in the selected time period.

[View all new measurements](#)

Approved Measurements

QR-Code	Product type / Source	Sample Code	Analysis Date	
OK 02CBY109	ALEX ² MAX 45k	AR	27.11.2025 22:43	Details Report
OK 02BRY104	ALEX ² IX		27.03.2025 14:20	Details Report
OK 02AND319	ALEX ² IX		15.01.2024 17:01	Details Report

Connected Devices

IX IFU

Standby

[Start Measurement](#) [Start new ConfigXplorer scan](#)

Last ConfigXplorer scan: 26.01.2026 10:16

[Start QC sample scan](#) [QC History](#) [Configure](#)

MAX45k QC device

Inaccessible

Last ConfigXplorer scan: 21.01.2026 10:40
Last monthly cleaning: 21.01.2026 10:42

[QC History](#) [Configure](#)

[View all MAX devices](#) [View all ImageXplorers](#)

XVII.4 ADJUSTING THE IMAGEEXPLORER SETTINGS

Each ImageXplorer has unique image settings that need to be calibrated using the ConfigXplorer during the first Installation and then every 60 days.

Upon the first installation or upon starting the new RAPTOR SERVER version for the first time, no measurement can be made with the ImageXplorer without a ConfigXplorer scan.

[New measurements](#)
[Approved measurements](#)
[Start measurement with ImageXplorer](#)

The ImageXplorer IX training cannot be used, because it requires a ConfigXplorer scan.

[Go to ImageXplorer configuration](#)

Every new ImageXplorer system will include a calibration ConfigXplorer with a special barcode starting with the digits "30" on the label (e.g., 30AAF267). The calibration array is delivered in a resealable pouch and should always be stored in a dark place at room temperature.



After clicking "Configure" in the menu "Manage ImageXplorers" you are directed to the area where you can run a ConfigXplorer Scan.

ImageXplorers for "MADx - Quality Control "

Add new ImageXplorer Download ImageXplorer Agent Software

Name	Key	Serialnumber	Last connection	Last activity	
PT4 ImageXplorer QC	K0gUp2HsuS40eAwkBPbkivo0qbL8bj	22124136	one year ago	2 seconds ago	Delete Configure

By clicking on "Start new ConfigXplorer scan", the calibration of the setting-adjustments starts (takes about 1-2 minutes).

Configure "IX IFU"

General information

Name: IX IFU

Key: WQQZIF8xIJ7WBamER1MvTXtpRKv4y5
This key is required when installing an Agent.

ImageXplorer Serialnumber: 40739900
Serialnumber of connected ImageXplorer.

ConfigXplorer scans

[Start new ConfigXplorer scan](#)
[Start customized ConfigXplorer scan](#)
[View manually taken images](#)

Please make sure that the ImageXplorer is connected, idle and that you have a ConfigXplorer cartridge inserted.

There are no ConfigXplorer scans yet.

This calibration measurement will identify and adjust the optimal settings for x, y, width and height of the array edges and the optimal exposure. After the calculation is finished, a report of the ConfigXplorer Scan is displayed. The user shall apply the new ImageXplorer settings by clicking "Apply detected settings."

NOTE: If the calibration ConfigXplorer Scan gets stuck and does not update the state for a couple of minutes, click on abort. On the configure page of the ImageXplorer, click "Start ConfigXplorer scan" again. If this problem occurs in the long term, check your connections, as described in chapter XVII.10.



ConfigXplorer run report for ImageXplorer

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

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

Results

Device	22124137
QR-Code	30BAC11E24122024;53173;
Exposure	1546
Offset X	402
Offset Y	370
Width	618
Height	288
Linearity Test [R ²] (> 0.95)	0.999479013663686
Homogeneity Test [CV] (< 5)	1.3903116236964623
Duration	00:00:42.1146637
Completed	now
Acceptance Criteria (R ² and CV ok)	Passed

Running the ConfigXplorer Scan on a regular basis will ensure that the ImageXplorer uses the optimal configuration. Therefore, after 60 days a message will appear, which prompts you to repeat the ImageXplorer ConfigXplorer Scan within 30 days.

Raptor

New measurements

Approved measurements

Start measurement

Automats

Adliance ▼

The last testarray scan for this ImageXplorer is more than 68 days ago. Please make sure to complete another ImageXplorer testarray scan in the next 22 days.

You requested a new measurement from ImageXplorer "Hannes' ImageXplorer". Please wait until the measurement is completed ...

Contacting ImageXplorer ...

If you do not repeat the ConfigXplorer test, no new measurements will be possible after 90 days. Previous results will be accessible as before.

The current ImageXplorer settings are to be found in the "Tenant Administration" area → "Manage ImageXplorers" → "Configure". If the QR-Code is not recognized during the ConfigXplorer Scan, the standard "QR-Code Exposure" of 3.000 can be increased.



Configure "Neuer IX "

General information

Name:	Neuer IX
Key:	hOfOxvDXlxF1xrp4p9ttjmNfH9qait
	This key is required when installing an Agent.
ImageXplorer Serialnumber:	23167844
	Serialnumber of connected ImageXplorer.
Notes:	
Internal Notes:	
	For internal use only.
Disabled:	Not disabled
Ignore ConfigXplorer scan checks:	☒ Enforce to ignore ConfigXplorer scan checks (required e.g. > 60 days) on this device.

QR-Code image configuration

QR-Code Exposure:	3000
-------------------	-----------------------------------

Calibration configuration

Mode:	Use automatic exposure
-------	---

Array image configuration

Array Offset X:	362
Array Offset Y:	326
Array Width:	634
Array Height:	298
Array Exposure:	834

The Calibration configuration is set by default to "Use automatic exposure", which stays for an exposure of 2500. However, it can be set to "Use manual exposure". With this mode, the exposure can be corrected up or down.



Add new ImageXplorer

General information

Name:

Key:
This key is required when installing an Agent.

ImageXplorer Serialnumber:
Serialnumber of connected ImageXplorer.

Notes:

Internal Notes:
For internal use only.

Disabled:

QR-Code image configuration

QR-Code Exposure:

Calibration configuration

Mode:

Array image configuration

Array Offset X:

Array Offset Y:

Array Width:

Array Height:

Array Exposure:



RAPTOR [New measurements](#) [Approved measurements](#) [Start me](#)

Add new ImageXplorer

General information

Name: ImageXplorer

Key: U7gPsUGvNeP00306Kd9CupIKFYub4o
This key is required when installing an Agent.

ImageXplorer Serialnumber:
Serialnumber of connected ImageXplorer.

Notes:
For internal use only.

Internal Notes:
For internal use only.

Disabled: Not disabled

QR-Code image configuration

QR-Code Exposure: 3000

Calibration configuration

Mode: Use manual exposure

Exposure: 2500

Array image configuration

Array Offset X: 400

Array Offset Y: 350

Array Width: 600

Array Height: 280

Array Exposure: 1600

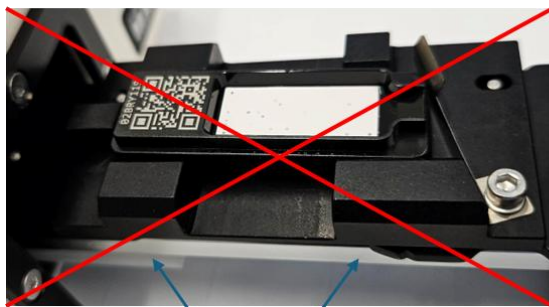
[Save](#) [← Cancel](#) [🔍 Debug information](#)



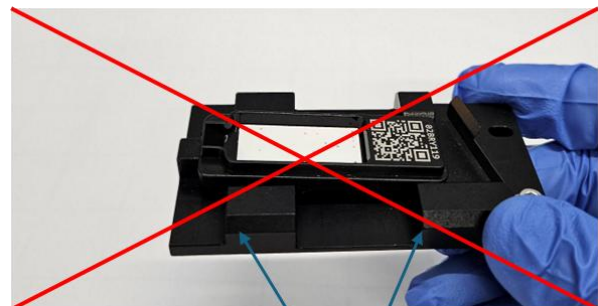
XVII.5 IMAGING AND ANALYSIS OF MEASUREMENTS

XVII.5.1 INSERTING A CARTRIDGE INTO THE IMAGEXPLOER

The ImageXplorer has an insertion mechanism for loading one processed cartridge at a time into the device. Carefully take the cartridge (do not touch the membrane of the cartridge) and insert it by facing the QR-Code to the MADx logo on the ImageXplorer into the carriage. Make sure that the cartridge is completely inserted into the carriage and neither in front nor in the back raised up (see pictures below). After inserting a cartridge, close the slider by moving it forward gently until it stops.



A



B

A: slider

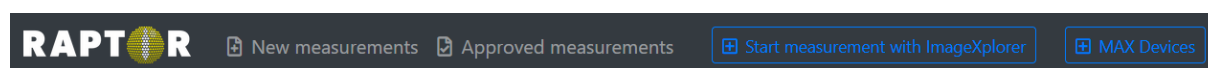
B: carriage



XVII.5.2 IMAGE ACQUISITION, QR-CODE READING AND GRID FINDING

On the overview page you will find a tab "New measurements", a tab "Approved measurements", a button for "Start measurement with ImageXplorer" and a button for MAX devices. The tab "New measurements" contains all new and unapproved measurements, the tab "approved measurements" contains all hitherto approved measurements.

Click on "Start Measurement" in the RAPTOR SERVER browser window to acquire an image and start the analytic sequence.



If only one ImageXplorer is connected, the analysis will start immediately. If several ImageXplorers are connected to the tenant on RAPTOR SERVER, the user must first select which ImageXplorer they want to use. RAPTOR SERVER automatically recognizes the QR-Code, which is the basis of all further processing and assigns the identified QR-Code to the new measurement.

Attention: Be aware of which ImageXplorer you are using, to have the correct test results for a given patient!

The QR-Code on each cartridge contains the following information:

- type of test array (ALEX² / ALEX³ / FOX)
- corresponding allergen layout
- QC information
- Lot number of cartridge

For further information on the features of the RAPTOR SERVER Analysis Software such as customizing reports and approving/exporting measurements please refer to the corresponding Instructions for Use.



XVII.6 INTERNAL QUALITY CONTROL

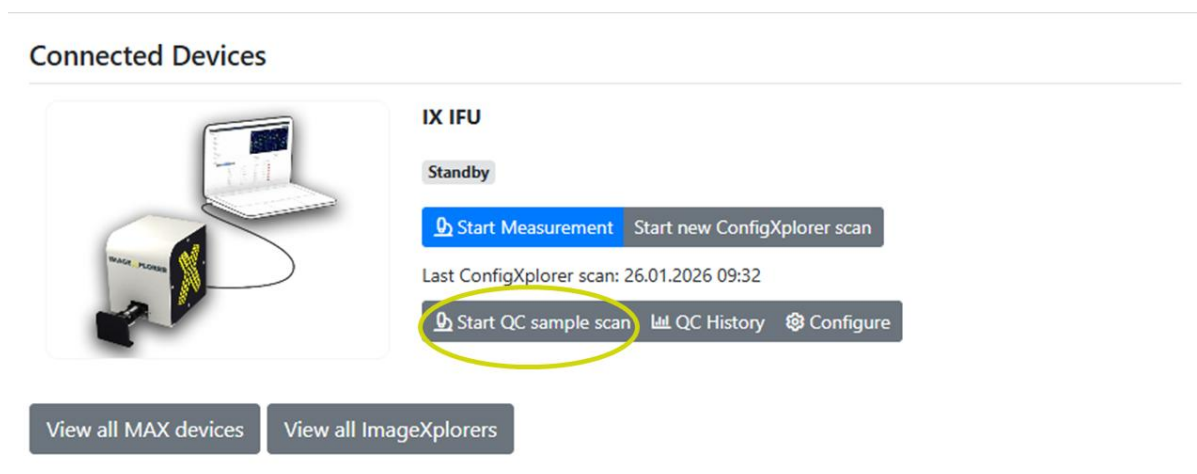
ALEX², ALEX³ and FOX cartridges have an inbuilt assay run control, represented by so called Guide Dots (GD) on the cartridge surface. ALEX² cartridges work with 4 guide dots, there are 2 guide dots and 2 dots for sample pipetting control (SPC) on ALEX³, while FOX cartridges work with 3 guide dots. During the image acquisition of an ALEX², ALEX³ or FOX cartridge, RAPTOR SERVER evaluates the signal of all guide dots as well as the background signal of the membrane surface. If all quality criteria are fulfilled, the “automatic QC” field under the image is set to “OK”.

Please consult the user manual of the individual test kit for further information about the QC of the test. If QC fails, contact MADx support or your local distributor.

The frequency and scope of quality control testing should follow the applicable national or regional quality guidelines and your laboratory's internal quality management requirements. A dedicated negative control sample is not available for ALEX³.

It is recommended to run a positive quality control sample at intervals defined by those requirements, and in particular whenever a new ALEX³ lot is put into use, in order to verify consistent performance across lots.

When connecting an ImageXplorer it will provide you with an option to run a QC sample scan.



The “Lyphocheck® slgE Control, Panel A” is distributed by the company Bio-Rad. Please consult the Instruction for Use of the manufacturer on how to use this control material. MacroArray Diagnostics provides the acceptance ranges for the most recent batch. These values are also stored in the RAPTOR SERVER. If you want to use Lyphocheck® slgE Control Panel A as a quality control during an analysis with ImageXplorer, choose product ID “32” and enter the lot of the Lyphocheck® slgE Control Panel A (for example 22640). RAPTOR SERVER will recognize this barcode as a QC sample.



Currently, the QC module in RAPTOR SERVER is only available for ALEX² and ALEX³, not for FOX.

Independently from the QC results, the ImageXplorer settings page shows results of recent ConfigXplorer scans ("Tenant Admin" → "Manage ImageXplorers" → "Configure").

Configure "IX IFU"

General information

Name: IX IFU

Key: WQQZIF8xJ7WBamER1MvTXtpRKv4y5
This key is required when installing an Agent.

ImageXplorer Serialnumber: 40739900
Serialnumber of connected ImageXplorer.

Notes:

Internal Notes:

Disabled: Not disabled

Require ImageXplorer ConfigXplorer scan: Warn after 60 days, enforce after 90 days.

Ignore ConfigXplorer scan checks: ☐ Enforce to ignore ConfigXplorer scan checks (required e.g. > 60 days) on this device.

ConfigXplorer scans

View manually taken images

Version	Started	Duration	Offset X	Offset Y	Width	Height	Exposure	Applied	
✓ ConfigXplorer	2 days ago	2 minutes	484	364	716	372	2144	26.01.2026 10:16	
✓ ConfigXplorer	2 days ago	1 minute	484	364	716	376	2144	26.01.2026 10:12	
✓ ConfigXplorer	2 days ago	1 minute	488	364	712	376	2146		
✗ ConfigXplorer	2 days ago		488	364	712	372			
✗ ConfigXplorer	2 days ago								
✓ ConfigXplorer	2 days ago	2 minutes	484	372	716	372	2128	26.01.2026 09:32	

XVII.7 TECHNICAL SUPPORT

If you have any questions, experiences or difficulties concerning the ImageXplorer or RAPTOR SERVER Analysis Software, please contact your local distributor.

XVII.8 TECHNICAL DATA AND REQUIREMENTS

Features	Parameters
Compatible Test Formats	ALEX ² , ALEX ³ or FOX cartridges
Cartridge Dimensions (W x D x H)	53 x 18 x 7 mm
Maximum Scan Area (W x D)	50 x 30 mm
Light Source	White light LED
Applicable Dyes	Colorimetric Dyes
Scan Resolution	Up to 600 dpi
Scan Speed	CPU dependent, < 5 s per cartridge
Dynamic Range	2.5 logs
Repeatability	R2 ≥ 99 %, CV ≤ 5 %
Focus Distance	80 ± 10 mm
Image File Format	BMP 16 Bit
Voltage	5 V USB



Features	Parameters
Power	< 5 Watts
Power supply	The device is powered either by the supplied +5V USB 2.0 cable or an USB 3.0. No additional power supply is needed.
Size (W x D x H)	160 x 180 x 180 mm
Weight	2.5 kg
Barcode Identification	QR-Code
Operating System	PC with MS Windows® 10 or higher
Required software (Incl. with the full version of the Agent installer)	Pylon Runtime v6.1.1
Connection	USB 2.0 or higher
Temperature Range	Room Temperature (15 – 30°C)
Humidity	30 – 85%, non-condensing
Dust	Dust-free environment recommended

XVII.9 MAINTENANCE

The ImageXplorer is a sensitive imaging device and should be handled carefully. For accurate results, it is essential that the instrument be maintained dust-free state as much as possible. To this end, the external ImageXplorer housing must be regularly cleaned with lint-free cloth. Do not use any detergents for cleaning. The carriage which holds the cartridges can be separately cleaned if necessary, using mild detergents or alcoholic solutions.

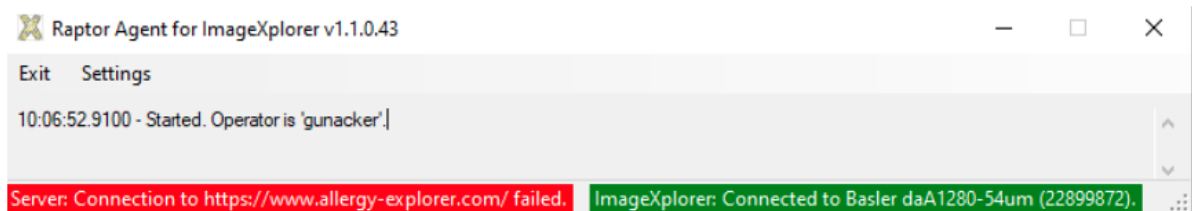
	Do NOT open the instrument chassis!
--	--



XVII.10 TROUBLESHOOTING

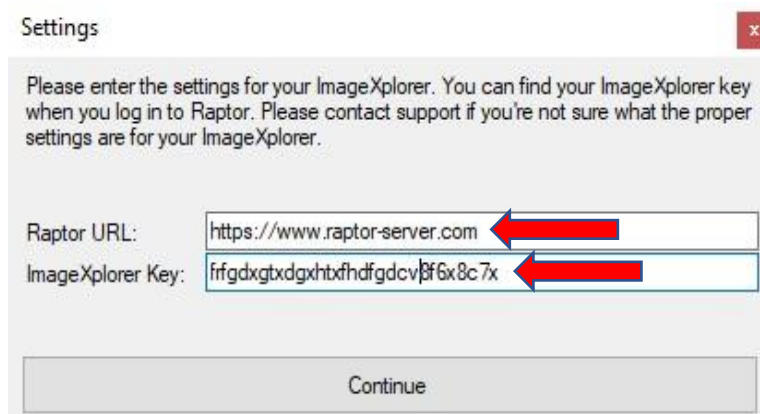
The following errors are the most common ones and therefore explained here in more detail.

Server Connection to www.raptor-server.com failed (Agent flags connection in red color)



Possible Solutions:

- Check internet connection
- Click settings and check if RAPTOR SERVER URL (www.raptor-server.com) is correct



ImageXplorer Connection failed (Agent flags connection in red color):





Possible Solutions:

- Check if ImageXplorer is connected to the computer
- Reconnect ImageXplorer to the computer (pull out and plug in the USB cable again).
- Click settings and check if the ImageXplorer key is correct and the same as on RAPTOR SERVER

Settings

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

Raptor URL:

ImageXplorer Key:

Continue

Start Measurement is not possible:

RAPTOR New measurements Approved measurements Start measurement with ImageXplorer

The ImageXplorer IX training cannot be used, because it requires a ConfigXplorer scan.

Go to ImageXplorer configuration

Possible Solutions:

- Check if ImageXplorer is connected
- Check if the last required ConfigXplorer Scan has been performed

If you still have problems or have any other questions about the products and services of MacroArray Diagnostics, please contact your local distributor.



XVIII. CHANGE HISTORY

Version	Description	Date of Issue	Replaces
01	First compilation	08-2017	N/A
02	Spelling mistakes corrected, formal issues corrected, page numbering added, German named report exchanged by English named	09-2017	01
03	Installation added, typos fixed, new pictures added for a better explanation, Raptor version added in title, print function on export deleted, MOD described in more detail	11-2017	02
04	For changes see AA_29112017 Raptor Software Update (Version 1.2); Typos corrected, pictures updated	03-2018	03
05	New Raptor version, typos and formatting errors fixed, Raptor version added, images updated from necessary, Short Cut G added, new MOD "Without Venoms", result release extended, new languages added (RU, UK), tlgE reference values added, report display extended, custom header in report extended, export diagnostic package, table with unusual spots added.	05-2018	04
06	Raptor Version 1.3. New: ImageXplorer test using test array small bugfixes<	07-2018	05
07	Raptor Software Update 1.3.1 (Testarray, Export Excel, error messages, report changes)	12-2018	06
08	Update of .NET Framework 4.6.1 to 4.7.2 included, update of Basler Pylon camera driver included, new export format available: TIFF Report, XLSX (Excel) export option: values of IgE Standards and Guide Dots are now displayed, an updated version of the information on cross-reactive allergen families is available (in the report settings tab), information on NPC2 & CCD included, positive results are stated in table form along the allergen family text, QC "OK" is now displayed in the ALEX lab report (page 1), update of test array procedure to provide better traceability in the test array report	05-2019	07
09	Intended use change according to AA_03072019, geplantes Raptor Bugfix Update CA_04072019 (Header linking has been updated, new languages + codes have been added)	07-2019	08
10	Update Raptor 1.5.2 and ALEX ²	10-2019	09
10.1	A typing error was discovered in the intended use (CA_15112019 Raptor Intended Use), all affected people have already been informed in the course of the CAPA, so no explicit release is necessary here. As it was only a typing error, only an interim version will be released.	11-2019	10
11	Address changed according to AA_16122019 MADx Umzug in neue Facility, url updated, company name corrected, typos corrected	04-2020	10.1
12	A separate IX IFU was created to provide outmost customer clarity and to comply with requests from authorities. Parts solely concerning the ImageXplorer were taken from the current RAPTOR SERVER IFU and included in this IFU.	10-2022	11
13	Label updated; REF No. Added; for details see AA_04102022 Änderung des Etiketts des ImageXplorer	10-2022	12
14	Pictures and technical data adapted to new IX camera. intended use updated Design aligned to other IFUs	11-2022	13
15	QualityXplorer added	12-2022	14
16	Basic UDI-DI and REF number added in tabular form; Intended Use changed to Intended Purpose; glossary of symbols updated; URL updated to madx.com; Address and label standardized according to AA_01022023; change history added	09-2024	15
17.1	Section II Language disclaimer added; ALEX ³ added and any reference to ALEX ² (50 tests) removed in the whole document; label removed in section VI; QualityXplorer removed in the whole document; further statement added in section XII according to EN IEC 61326-2-6; infos about specific guide dots removed; screenshots updated in the whole document; whole change history added in section XVIII; XVII.6 Adjustment to the Quality Control Testing clause (identical in IX & MAX 9/45k)	09-2026	16



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