IMAGEXPLORER
INSTRUCTION FOR USE

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I. DISCLAIMER

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

Please consult the relevant instructions for use of ALEX^2 and FOX tests before processing!

II. LIABILITY STATEMENT

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

III. TERMS AND DEFINITIONS

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

IV. INTENDED USE FOR IMAGEXPLORER

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.

V. MANUFACTURER AND LABELING

V.1 MANUFACTURER

The ImageXplorer is manufactured by MacroArray Diagnostics (MADx)

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

V.2 IDENTIFICATION OF THE DEVICES

An identification label is placed at the rear side of the ImageXplorer.

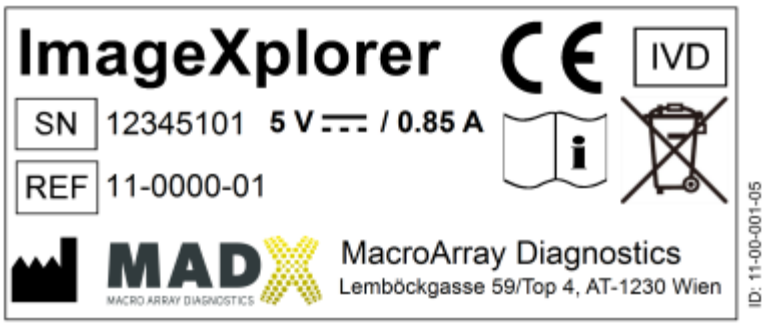


Figure 1: Identification label details placed on the ImageXplorer

VI. PERFORMANCE DATA

VI.1 ASSAY CALIBRATION

For the Assay Calibration refer to the respective IFU of the ALEX^2 or FOX test.

VI.2 MEASURING RANGE

For the Measuring Range refer to the respective IFU of the ALEX^2 or FOX test.

VI.3 QUALITY CONTROL

Record keeping for each assay:

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

Control Specimens:

According to good laboratory practice it is recommended that quality control samples are included within defined intervals. MacroArray Diagnostics provides its own quality control sample for ALEX² tests – QualityXplorer (REF 31-0800-02). Furthermore, Lyphochek® sIgE

Control Panel A (by Bio-Rad) is also a supported control. Acceptance ranges for the QualityXplorer and the most recent batches of Lyphochek® sIgE Control Panel A are stored in RAPTOR SERVER.

VI.4 DATA ANALYSIS

ALEX^2 and FOX images are automatically analysed using MADx's RAPTOR SERVER and a report is generated summarizing the results for the user.

VI.5 RESULTS

ALEX^2 is a quantitative method for specific IgE and a semi-quantitative method for total IgE determination. Allergen- specific IgE antibodies are expressed as IgE response units (kU_A/L), total IgE results as kU/L. MADx's RAPTOR SERVER Analysis Software automatically calculates and reports sIgE results (quantitatively) and tIgE results (semi- quantitatively).

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

VI.6 LIMITATION OF THE PROCEDURE

For the Limitation of the procedure refer to the respective IFU of the ALEX^2 test or FOX test.

VI.7 EXPECTED VALUES

For the expected values refer to the respective IFU of the ALEX^2 test or FOX test.

VI.8 PERFORMANCE CHARACTERISTICS

ALEX² test:

Precision:

For the precision, we refer to the section performance characteristics in the IFU of the ALEX^2 test.

Repeatability (within-run precision):

In the repeatability study, multi-sensitized samples were tested 10 times by the same operator on different days. The study comprised 319 allergens per sample combinations covering 165 individual allergens at 3 different levels (>10 kU_A/L, 1-10 kU_A/L and 0.3-1 kU_A/L).

Concentration – kU_A/L	Total CV %
≥ 0.3 - < 1.0	25.6
≥ 1 - < 10	13.8
≥ 10	10.7
≥ 1	13.5

Analytical Sensitivity:
For the Limit of Detection, we refer to the section performance characteristics in the IFU of the ALEX^2 test.

Analytical Specificity:
For the Analytical Specificity, we refer to the section performance characteristics in the IFU of the ALEX^2 test.

Interference:
For the interference with other substances, we refer to the section performance characteristics in the IFU of the ALEX^2 test.

FOX test

Precision (lot-lot variation):
The lot-to-lot variation was determined on 3 cartridge lots in three separate runs. Multi-sensitized samples were included in the study. The study comprised 867 allergen/sample combinations covering 121 individual allergens over the entire measuring range.

Concentration - µg/ml	Intra CV %	Inter CV %	Total CV %
10.0 – 19.9	6.9	11.2	9.1
≥ 20	3.1	5.5	4.3
≥ 10	4.8	7.9	6.3

Repeatability (within-run precision):
In the repeatability study, multi-sensitized samples were tested 10 times by the same operation on different days. The study comprised 862 antigen/sample combinations covering 115 individual antigens over the entire measuring range.

Concentration - µg/ml	Total CV %
10.0 – 19.9	11.3
≥ 20	5.4
≥ 10	7.2

Analytical Sensitivity:
For the Limit of Detection, we refer to the section performance characteristics in the IFU of the FOX test.

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

VII. PRINCIPLE OF THE PROCEDURE

VII.1 ALEX^2 TEST PRINCIPLE

ALEX^2 is a solid-phase immunoassay. Allergen extracts or molecular allergens, which are coupled to nanoparticles, are deposited in a systematic fashion onto a solid phase, forming a macroscopic array. First, the particle bound allergens react with specific IgE that is present in the patient's sample. After incubation, non-specific IgE is washed off. The procedure continues by adding an enzyme labelled anti-human IgE detection antibody which forms a complex with the particle bound specific IgE. After a second washing step, substrate is added which is converted to an insoluble, coloured precipitate by the antibody-bound enzyme. Finally, the enzyme-substrate reaction is stopped by adding a blocking reagent. The amount of precipitate is proportional to the concentration of specific IgE in the patient sample. The assay procedure is followed by an automated image acquisition and analysis which is integrated in the ImageXplorer. The test results are analysed with MADx's RAPTOR SERVER Analysis Software and reported in IgE response units (kU_A/L). Total IgE results are also reported in IgE response units (kU/L).

VII.2 FOX TEST PRINCIPLE

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

the concentration of specific IgG in the patient sample. The lab test procedure is followed by an automated image acquisition and analysis which is integrated in the ImageXplorer. The test results are analysed with MADx's RAPTOR SERVER Analysis Software and reported in µg/ml and in IgG classes.

VIII. SERVICE

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

IX. WARRANTY

MacroArray Diagnostics and its local distributors guarantee that the 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 analyser.

X. ORDERING INFORMATION

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

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

XI. SAFE HANDLING

The analyser 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 analyser in a manner not specified by this manual or elsewhere by MacroArray Diagnostics may affect the safety measures implemented by the manufacturer and may also result in a hazardous situation or lead to wrong test results.

XI.1 OPERATOR QUALIFICATION

The 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!

	Service and Repair should only be carried out by Macro Array Diagnostics or its local distributors.

XI.2 OPERATIONAL SAFETY

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

	Do NOT load humid or wet cartridges!

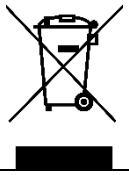
Any liquid spilled on the instrument may result in the malfunction of the system. If liquid is spilled on the instrument, wipe it off immediately and contact technical support.

XI.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 analyser. Before decontamination and/or disinfection, disconnect the analyser from the power supply (pull the plug). The operator is solely responsible for the effective

eness of the disinfection and decontamination methods used and their validation.

XII. GLOSSARY OF SYMBOLS

	Consult instruction for use
	In vitro diagnostic medical device
	CE mark
	Manufacturer
	Serial number
	Waste electrical and electronic equipment
	Caution

XIII. SAFETY MESSAGES

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

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

XIV. LEGAL REQUIREMENTS

XIV.1 INTERNATIONAL STANDARDS

The ImageXplorer 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.

XIV.2 CE CONFORMITY

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

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

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

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

XV. 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.

XV.1 DELIVERY

XV.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.

XV.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 ALEX^2 (50x: REF 02-5001-01 or 20x: REF 02-2001-01) 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.

XV.2 DISPOSAL

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

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

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

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

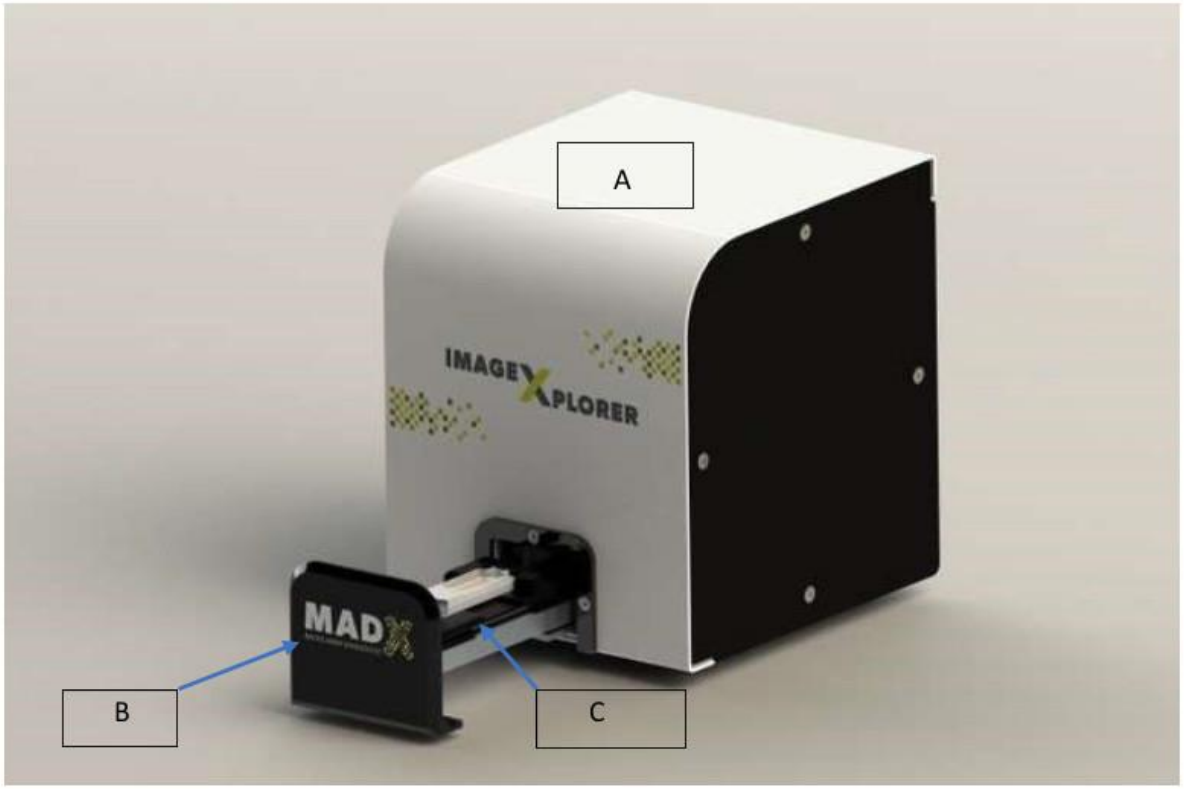
	Treat contaminated material according to national and local standards and regulations. Before transport or disposal, disinfect parts of the analyser that may be contaminated according to national and local standards and regulations. If you need assistance, contact MacroArray Diagnostics or a local distributor.

	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 MacroArray Diagnostics or a local distributor in areas where the above-mentioned directive is enforced.

XV.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, please consult with your local IT administrator.

XVI. 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

XVI.1 CONNECTING THE IMAGEXPLORER 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 2.0or USB 3.0 cable, and both the connection and the power supply are managed through the computer's USB 3.0 port by the provided USB cable.

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

XVI.2 RAPTOR SERVER SOFTWARE SETUP

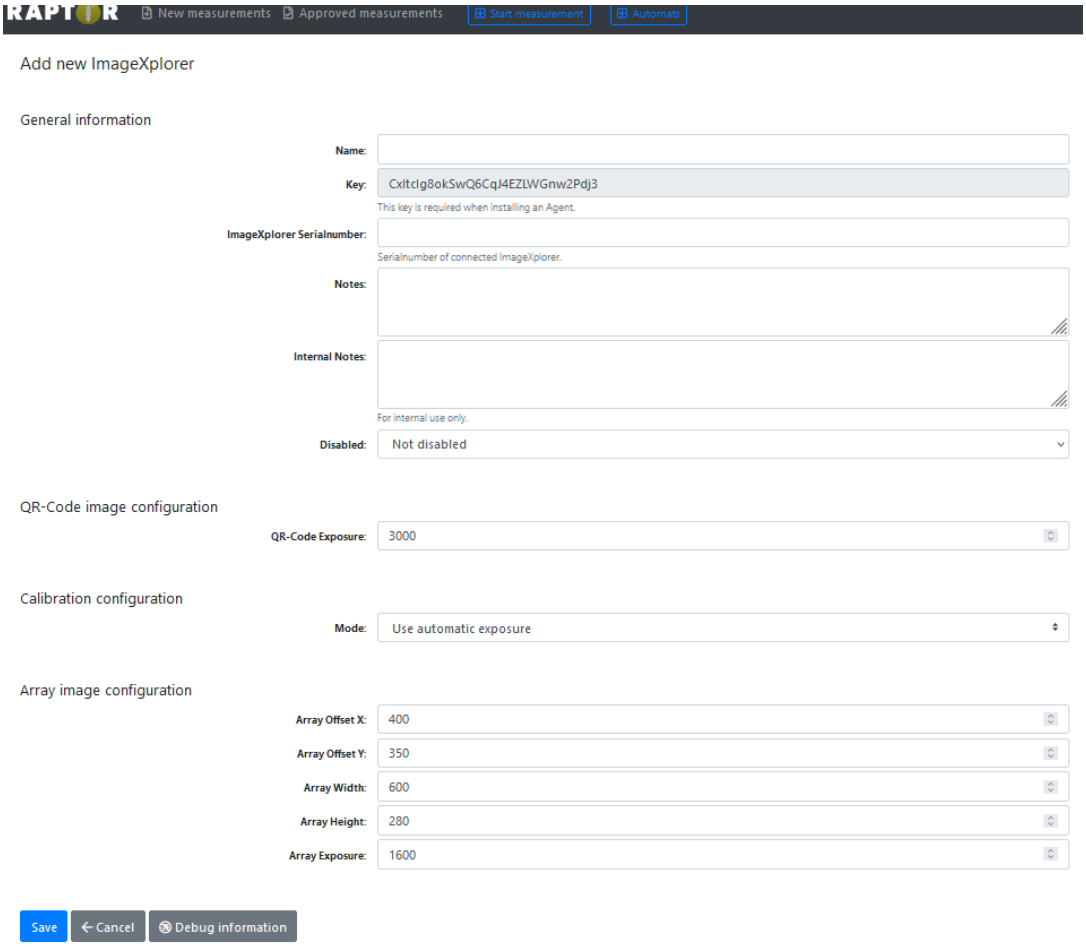
Google Chrome is recommended as a browser for using the RAPTOR SERVER. The graphical user interface of RAPTOR SERVER can be accessed on the website: https://www.raptor-server.com.

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 has to be done actively in the RAPTOR SERVER Analysis Software.

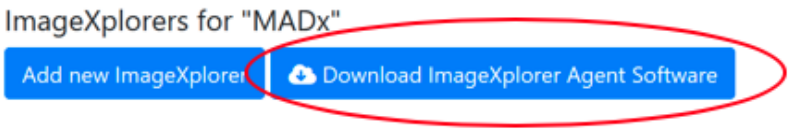
For further information on the RAPTOR SERVER please refer to the corresponding Instructions for Use.

XVI.3 DOWNLOAD OF THE IMAGEXPLORER AGENT SOFTWARE AND IMAGEXPLORER DEFINITION

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



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

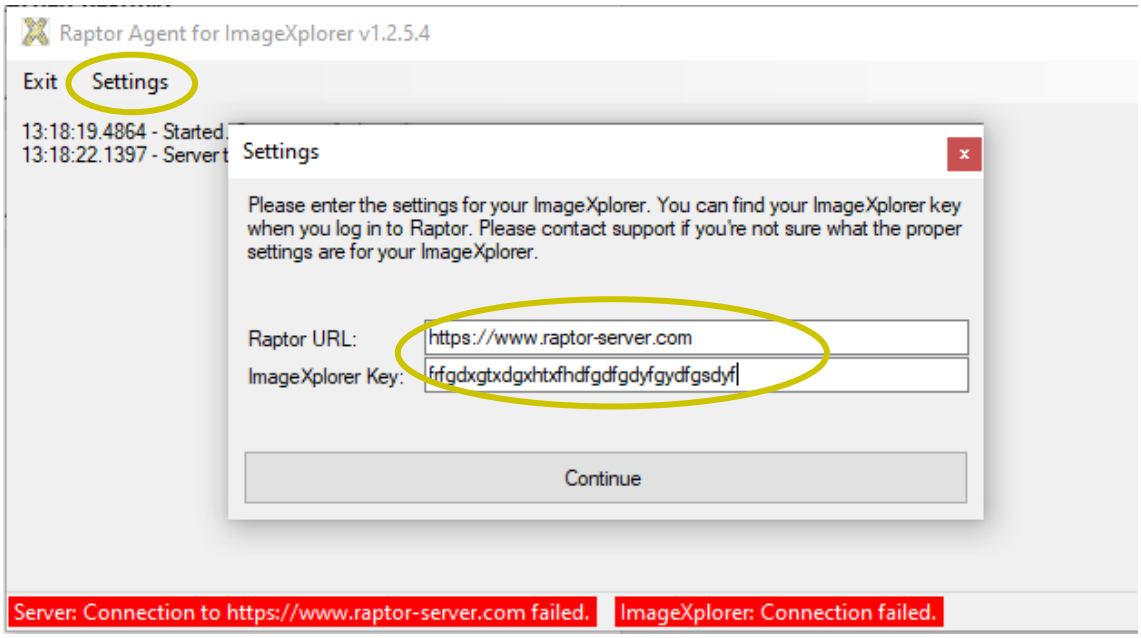


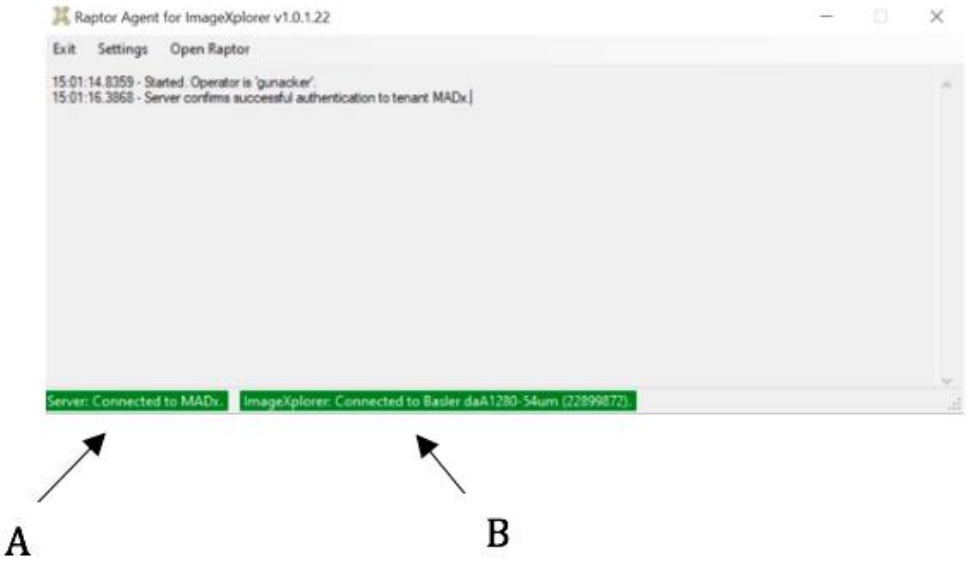
Carry out the installation of the ImageXplorer agent, as a regular installation process.

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”.

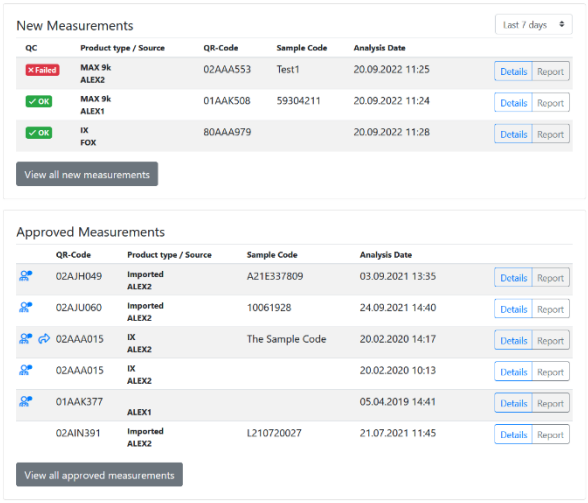


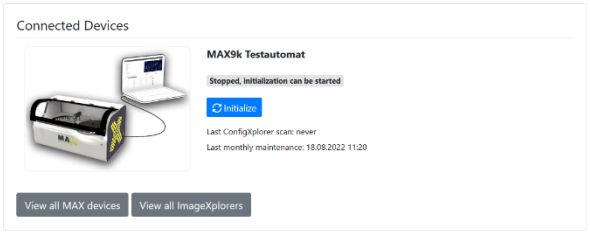


A: Connection to RAPTOR SERVER
B: Connection to ImageXplorer

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 ALEX^2 and FOX assay runs on the ImageXplorer. and the date of the last ConfigXplorer scan and/or monthly maintenance (for MAX devices only).

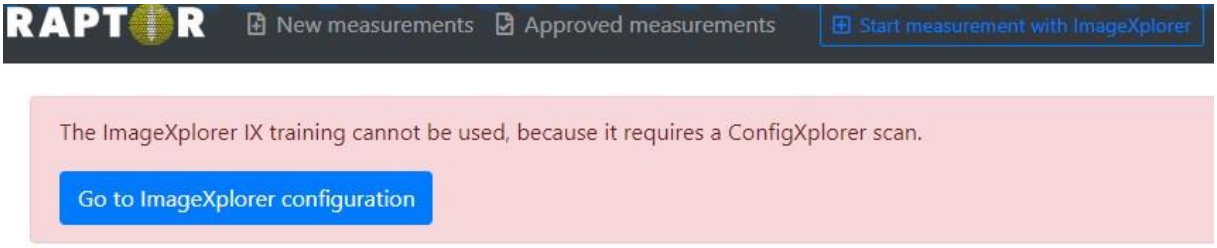




XVI.4 ADJUSTING THE IMAGEXPLORER SETTINGS

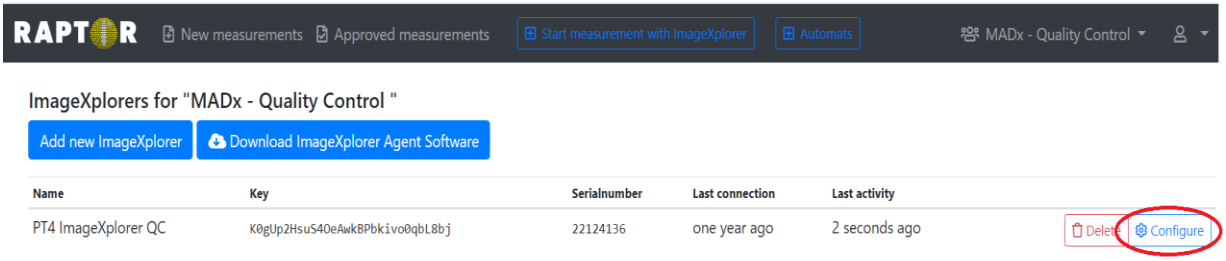
Each ImageXplorer has unique image settings that need to be calibrated using the ConfigXplorer during the first I nstallation and then every 60 days.

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.

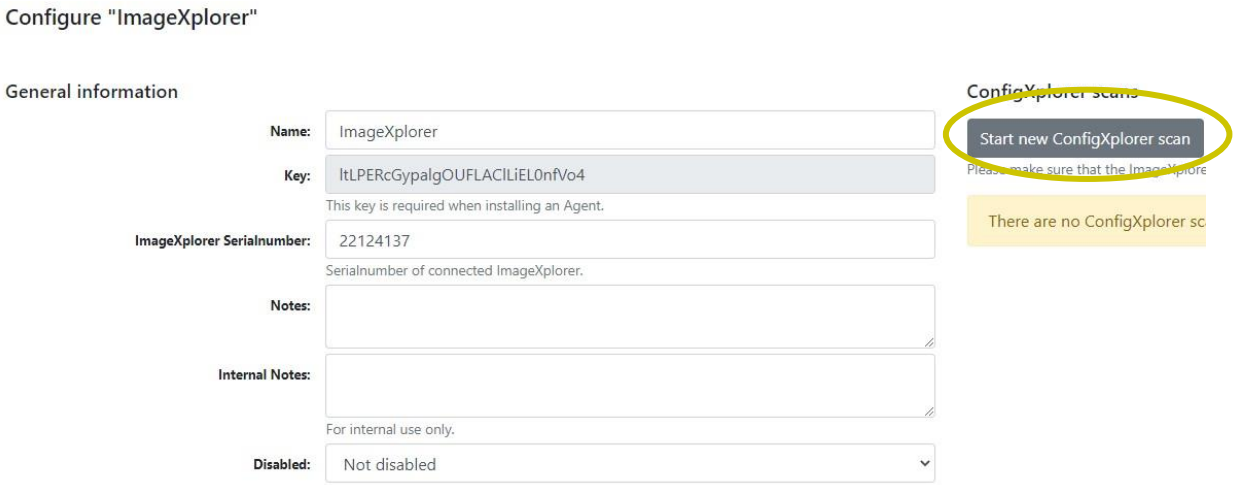


Every new ImageXplorer system will include a calibration ConfigXplorer with a special barcode starting with the digits "30" on the label (e.g., 30AAF267). The calibration array is delivered in a resealable pouch and should always be stored in a dark place at room temperature.

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

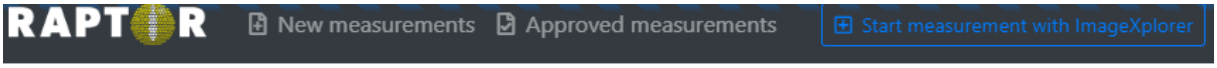


By clicking on “Start new ConfigXplorer scan”, the calibration of the setting-adjustments starts (takes about 1-2 minutes).



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 XVI.10.



ConfigXplorer run report for ImageXplorer

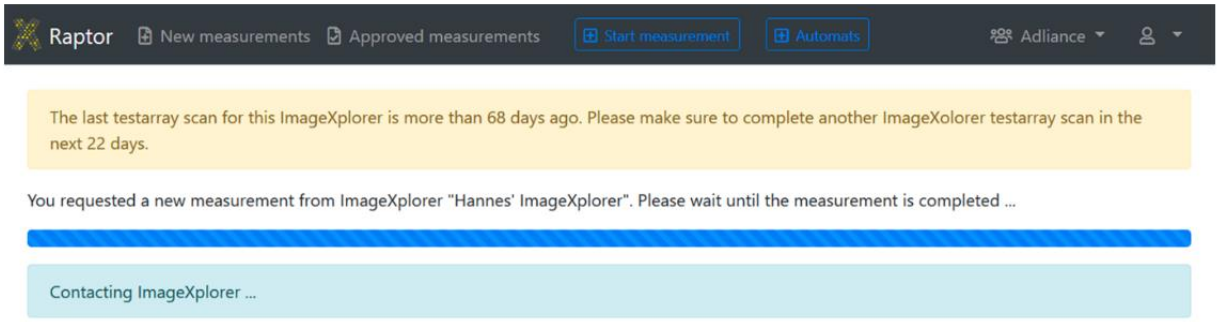
← Back to ImageXplorer | Download Report | Apply detected settings

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

Results

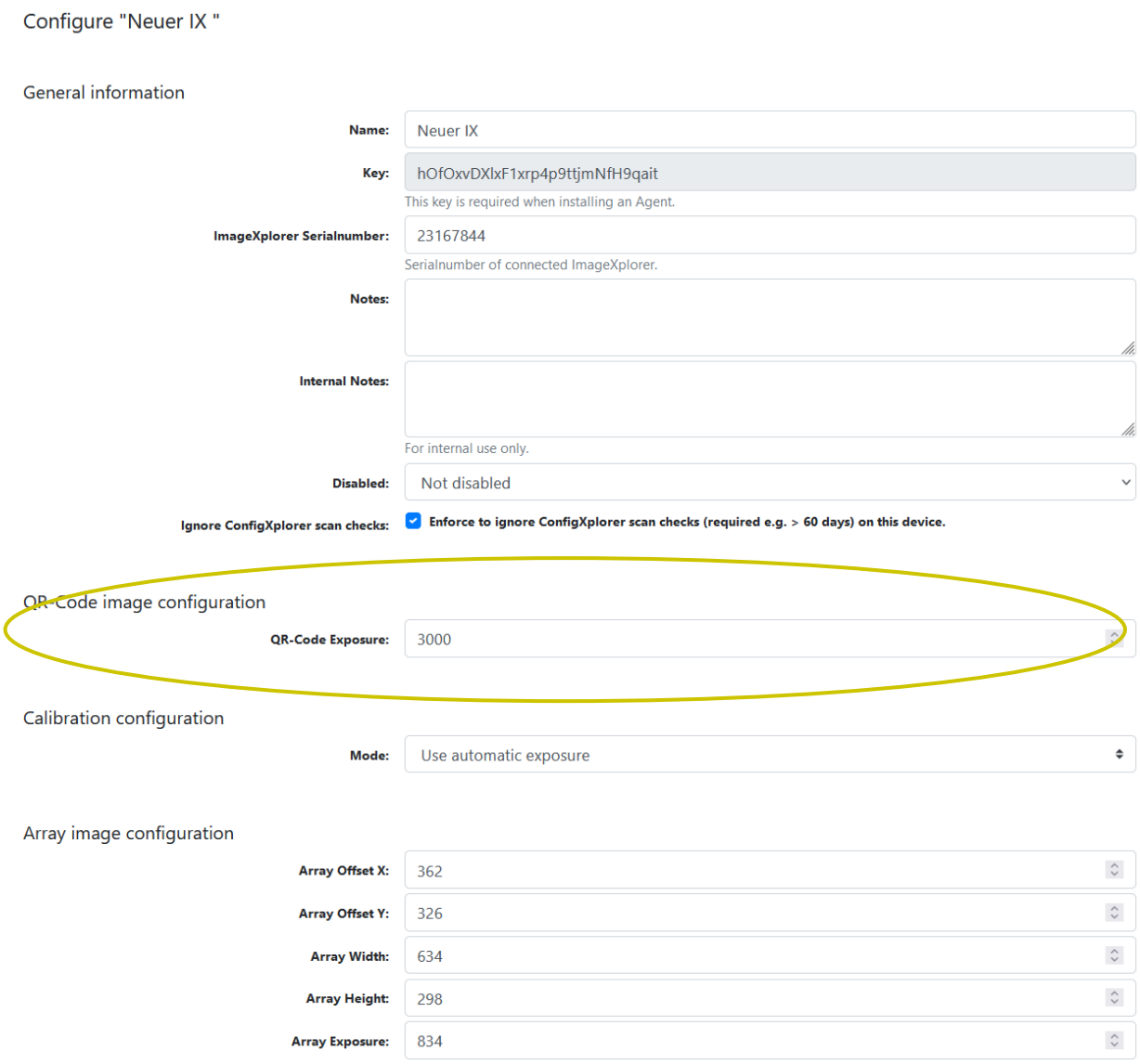
Device	22124137
QR-Code	30BAC11E24122024;53173;
Exposure	1546
Offset X	402
Offset Y	370
Width	618
Height	288
Linearity Test [R^2] (> 0.95)	0.999479013663686
Homogenity Test [CV] (< 5)	1.3903116236964623
Duration	00:00:42.1146637
Completed	now
Acceptance Criteria (R^2 and CV ok)	Passed

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.

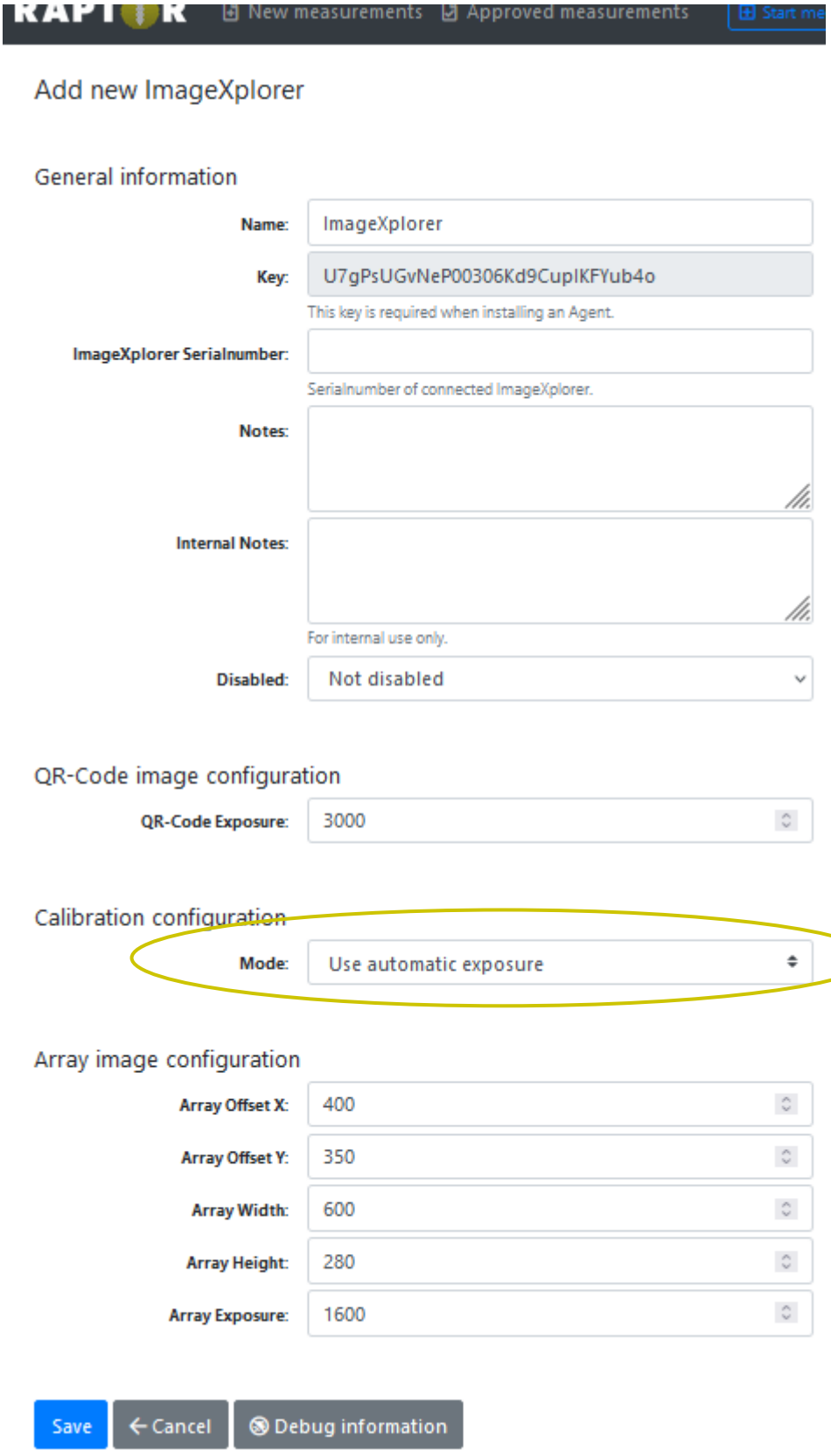


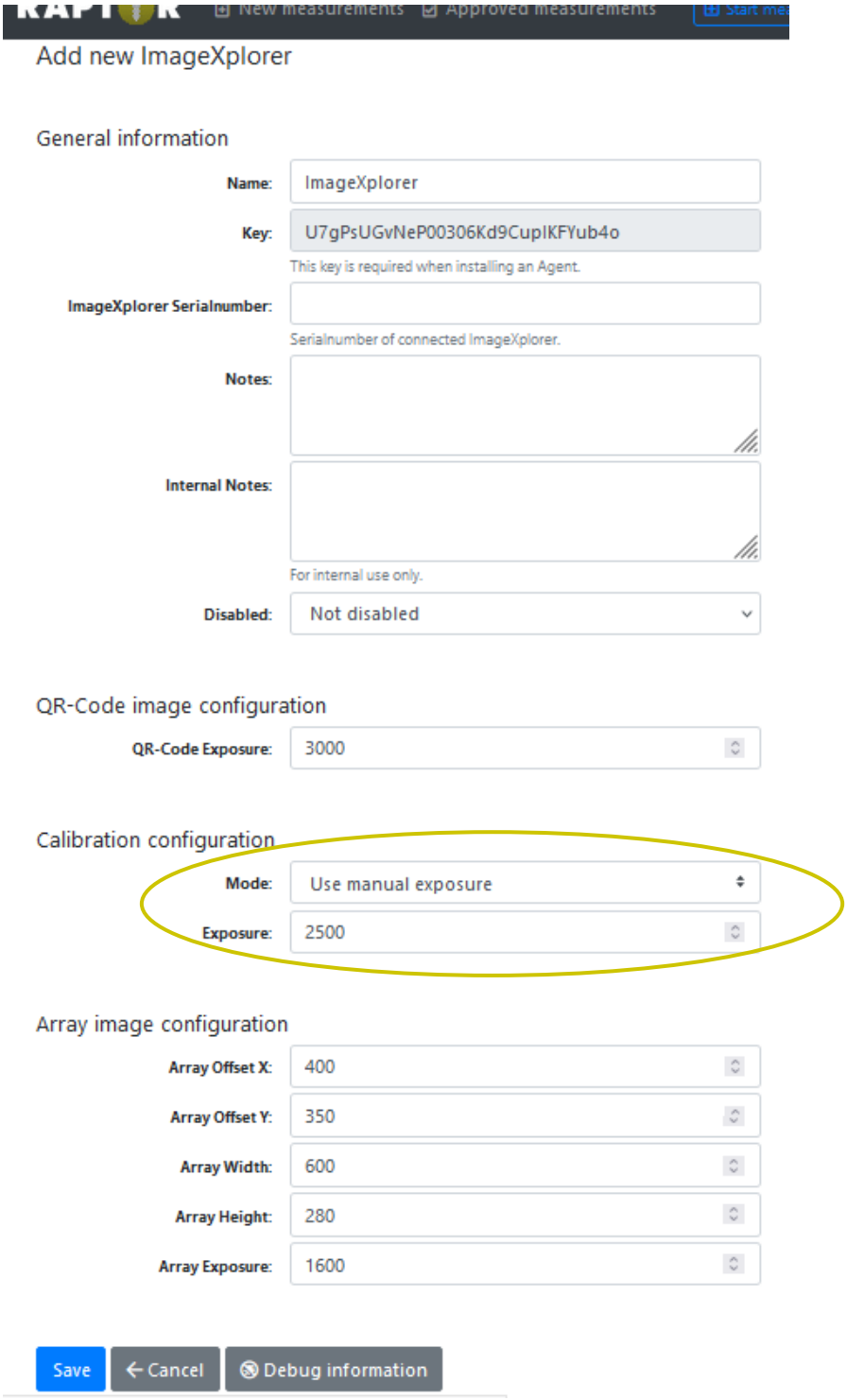
If you do not repeat the ImageXplorer test, no new measurements will be possible after 90 days. Previous results will be accessible as before.

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.



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.

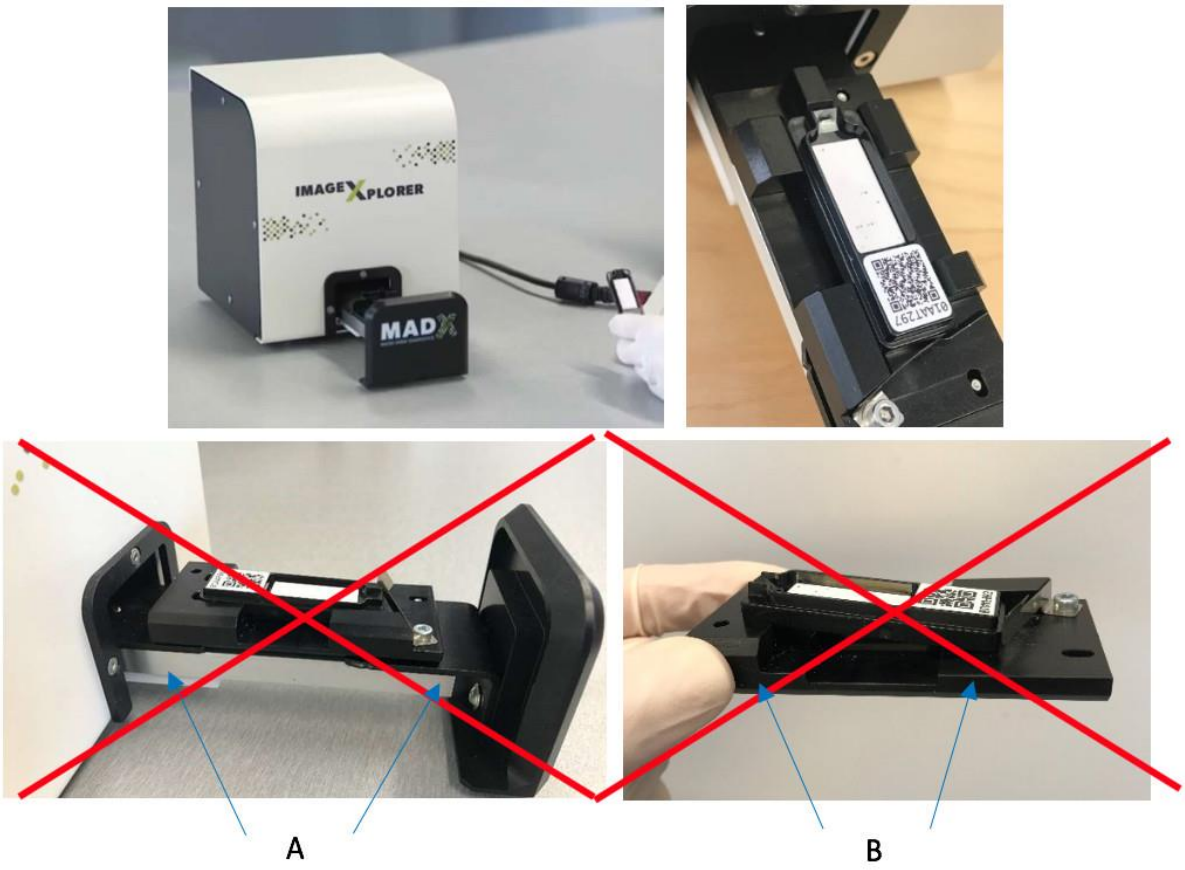

RAPTOR
New measurements
Approved measurements
Start me
Add new ImageXplorer
General information
Name:
ImageXplorer
Key:
U7gPsUGvNeP00306Kd9CupIKFYub4o
This key is required when installing an Agent.
ImageXplorer Serialnumber:
Serialnumber of connected ImageXplorer.
Notes:
Internal Notes:
For internal use only.
Disabled:
Not disabled
QR-Code image configuration
QR-Code Exposure:
3000
Calibration configuration
Mode:
Use automatic exposure
Array image configuration
Array Offset X:
400
Array Offset Y:
350
Array Width:
600
Array Height:
280
Array Exposure:
1600
Save
Cancel
Debug information


New measurements
Approved measurements
Add new ImageXplorer
General information
Name:
ImageXplorer
Key:
U7gPsUGvNeP00306Kd9CuplKFYub4o
This key is required when installing an Agent.
ImageXplorer Serialnumber:
Serialnumber of connected ImageXplorer.
Notes:
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

XVI.5 IMAGING AND ANALYSIS OF MEASUREMENTS

XVI.5.1 INSERTING A CARTRIDGE INTO THE IMAGEXPLORER

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.

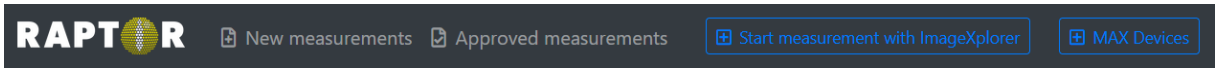


A: slider
B: carriage

XVI.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!

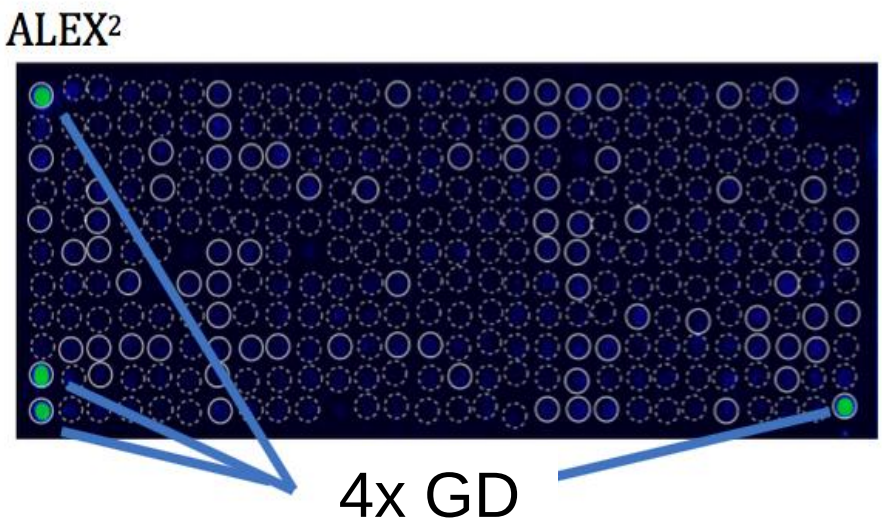
The QR-Code on each cartridge contains the following information:

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

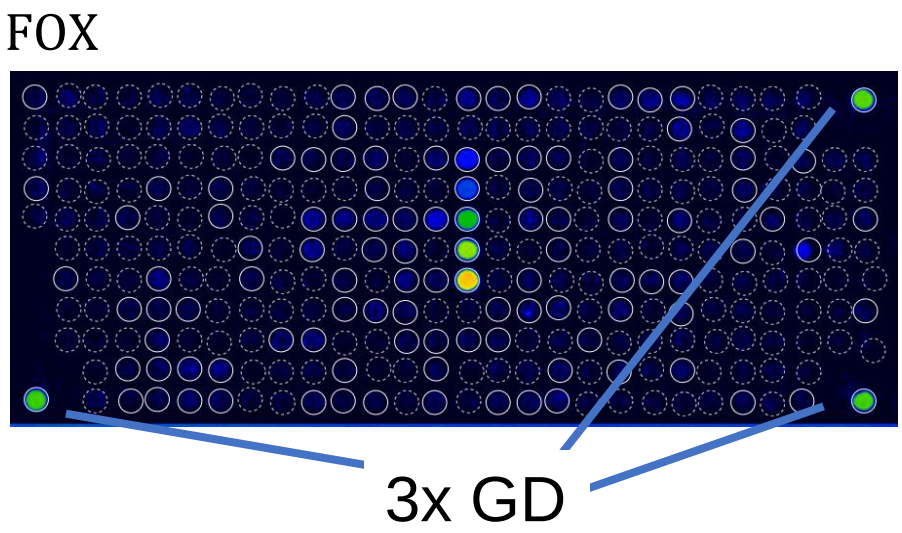
For further information on the features of the RAPTOR SERVER Analysis Software such as customizing reports and approving / exporting measurements please refer to the corresponding Instructions for Use.

XVI.6 INTERNAL QUALITY CONTROL

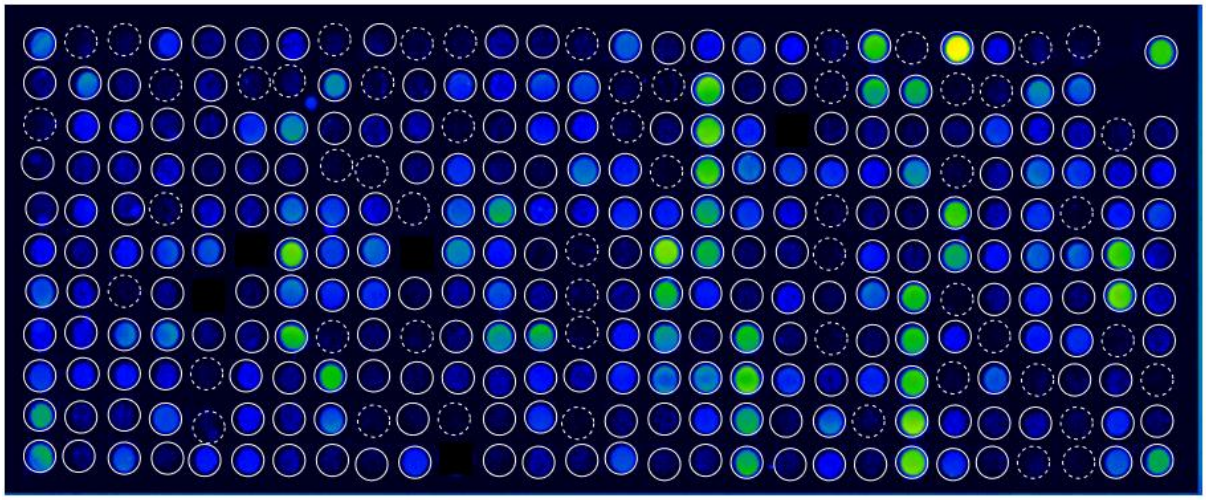
ALEX^2 and FOX cartridges have an inbuilt assay run control, represented by so called “Guide Dots” (GD) at 3 corners on the cartridge surface. ALEX^2 cartridges work with 4 Guide Dots, while FOX cartridges work with 3 Guide Dots, in the positions as depicted below



.



During the image acquisition of an ALEX^2 or FOX cartridge, RAPTOR SERVER evaluates the signal of all Guide Dots as well as the background signal of the membrane surface. If all quality criteria are fulfilled, the “automatic QC” field under the image is set to “OK”. Please consult the RAPTOR SERVER Analysis Software Instructions for Use 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

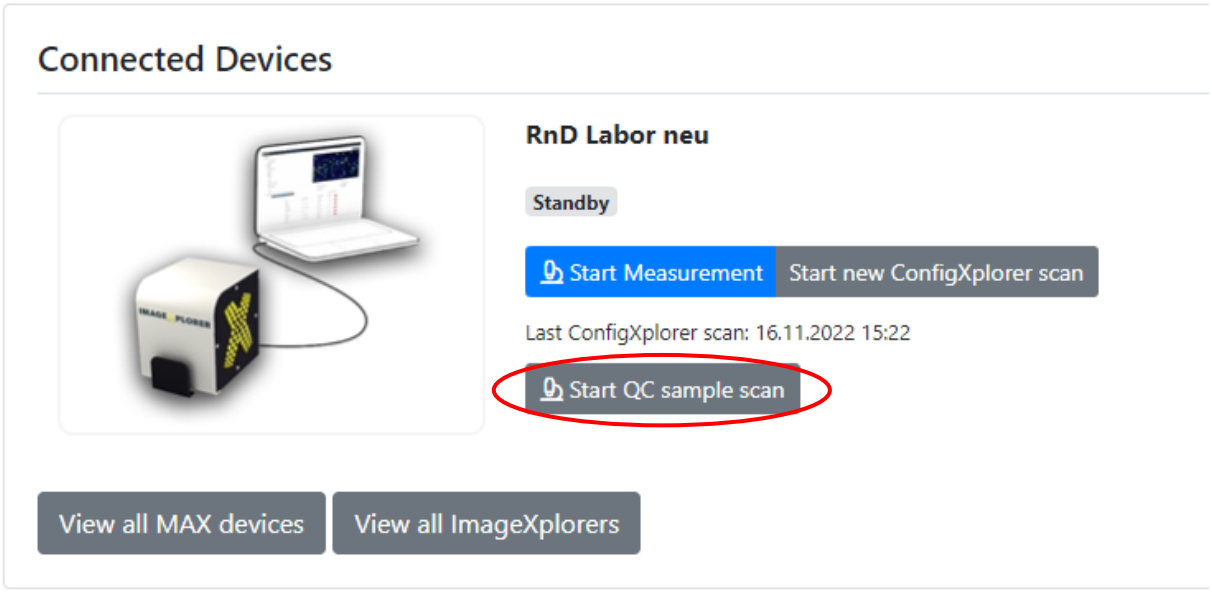
Received: 3/9/2020 3:29 PM **Analysis:** 3/10/2020 8:34 AM

Automat: 19090003 **Automatic QC:** ✓ OK

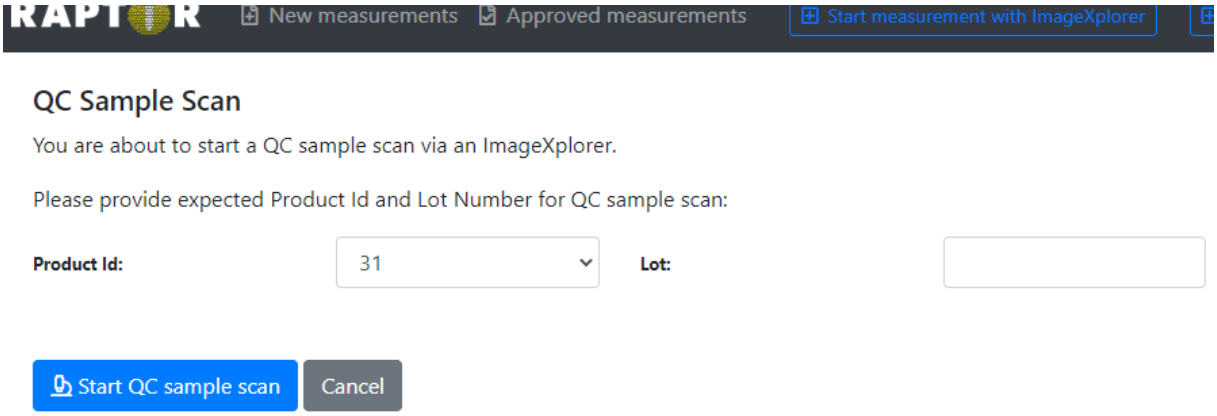
Additionally, it is recommended to run at least one negative and one positive quality control sample with every assay run.

MacroArray Diagnostics provides its own quality control sample for ALEX² tests – the QualityXplorer (REF 31-0800-02), which includes 8 QC samples (for detailed information, please consult the IFU of the QualityXplorer).

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



After choosing the Product ID (31) and entering the Lot Number of the QualityXplorer, the QC sample scan can be started.

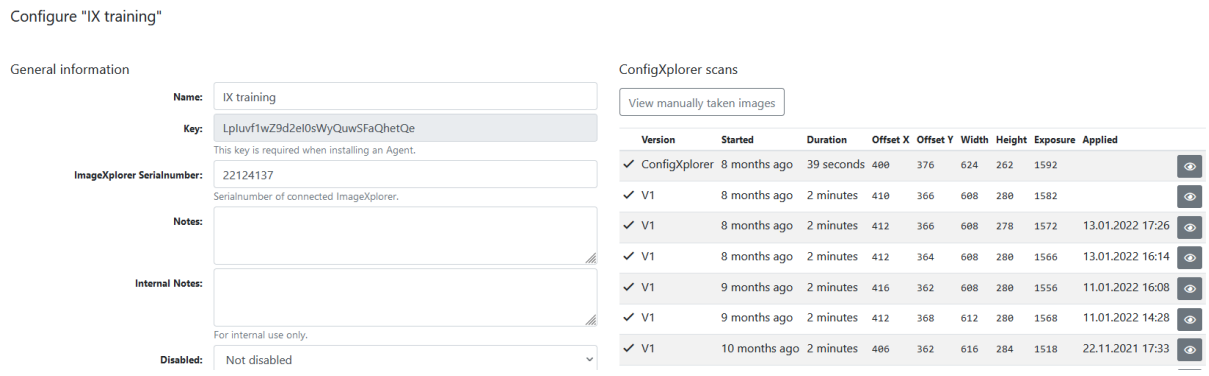


MacroArray Diagnostics provides acceptance ranges for its own QualityXplorer and these values are stored in the RAPTOR SERVER and cannot be edited by the user. The RAPTOR SERVER also contains a basic QC module which can monitor QC performance with the QualityXplorer. These QC results can be obtained from the ImageXplorer settings page ("Tenant Admin" → "Manage ImageXplorers" → "QC") – for further details, please consult the IFU of the RAPTOR SERVER.

Alternatively, the quality control product "Lyphochek® sIgE Control, Panel A" from the company Bio-Rad can be used as a QC sample (please consult the Instruction for Use from 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 Lyphochek® sIgE Control Panel A as a quality control during an analysis with ImageXplorer, choose product ID "32" and enter the lot of the Lyphochek® sIgE 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 ALEX^2, not for FOX.

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



XVI.7TECHNICAL SUPPORT

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

XVI.8 TECHNICAL DATA AND REQUIREMENTS

Features	Parameters
Compatible Test Formats	ALEX^2 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	$R^2 \geq 99$ %, CV ≤ 5 %
Focus Distance	80 ± 10 mm
Image File Format	BMP 16 Bit
Voltage	5 V USB
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	1.2 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

XVI.9 MAINTENANCE

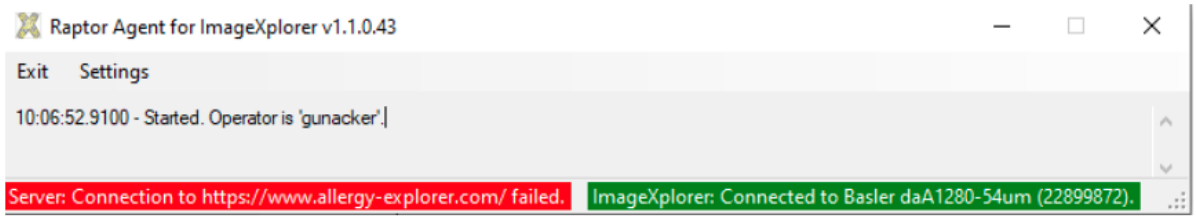
The ImageXplorer is a sensitive imaging device and should be handled carefully. For accurate results, it is essential that the instrument be maintained dust-free state as much as possible. To this end, the external ImageXplorer housing must be regularly cleaned with a lint-free cloth. Do not use any 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!**

XVI.10 TROUBLESHOOTING

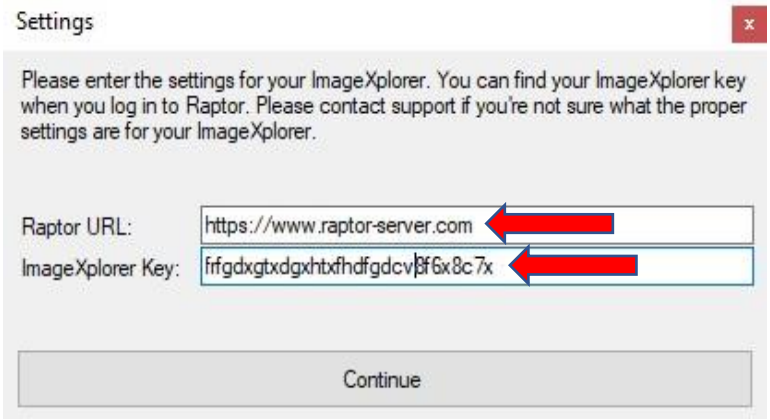
The following errors are the most common ones and therefore explained here in more detail.

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



Possible Solutions:

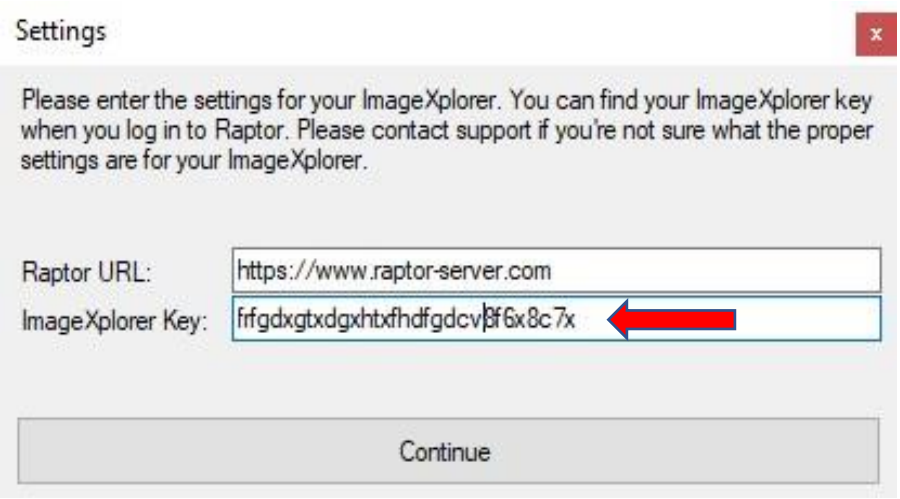
- Check internet connection
- Click settings and check if RAPTOR SERVER URL (www.raptor-server.com is correct
- Click settings and check if ImageXplorer key is correct and corresponds to the one specified for the Tenant on RAPTOR SERVER



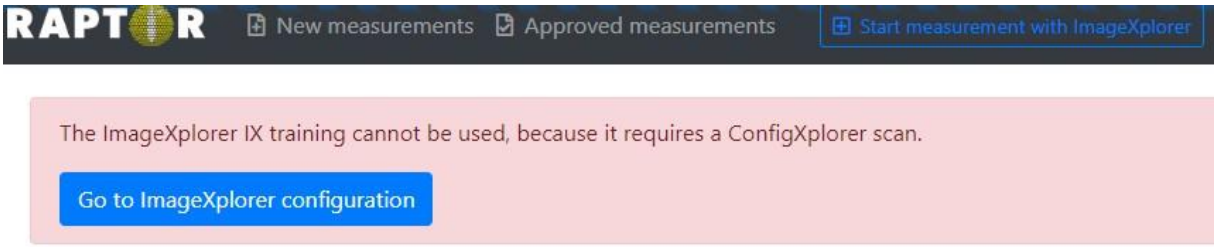
ImageXplorer Connection failed (Agent flags connection in red colour):

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



Start Measurement is not possible:



Possible Solutions:

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

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



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