INSTRUCTIONS FOR USE

RAPTOR SERVER

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

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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.

The herein described procedure is only for using the RAPTOR SERVER Analysis Software in combination with the ImageXplorer. For using the RAPTOR SERVER Analysis Software with the MAX 45k refer to the Instructions for Use for MAX 45k.

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







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LIABILITY STATEMENT

This guide was checked for correctness. The instructions and descriptions for the RAPTOR SERVER Software and ImageXplorer 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 ImageXplorer and Raptor Server are in-vitro diagnostic devices that is intended to be used by trained laboratory personnel only.

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ABBREVIATIONS 1

DPA **Data Protection Agreement**

Guide dots - special spots at the corners of the array. Used for plausibility GD

checks by RAPTOR SERVER Analysis Software.

IFU Instructions for use

IgE Immunoglobulin E

IgG Immunoglobulin G

In-vitro diagnostics IVD

Multiplex On Demand MOD

QC Quality control

Research use only **RUO**

Terms of Service ToS

2 INTENDED USE

2.1 ImageXplorer

The ImageXplorer is an imaging device to be used in combination with the RAPTOR SERVER Analysis Software to acquire images of ALEX² & FOX arrays after they have been processed by the laboratory user or medical professional.

2.2 RAPTOR SERVER Analysis Software

The RAPTOR SERVER Analysis Software (RAPTOR SERVER) is intended for in vitro diagnostic (IVD) use in combination with the ALEX² & FOX test kits. The cloud-based RAPTOR SERVER performs a quantitative analysis of allergen-specific Immunoglobulin E (slgE) of processed ALEX² arrays, a semiquantitative analysis of total lgE (tlgE) of processed ALEX² arrays, or a semi-quantitative analysis of Immunoglobulin G (IgG) of processed FOX arrays. Additionally, it offers basic interpretation and comments for decision support. The testing system is an aid in the clinical diagnosis of patients with allergies in conjunction with other clinical and laboratory findings. The software is to be used in clinical laboratories by trained operators or medical professionals. The software can either be used in conjunction with ImageXplorer or MAX 45k, as an analysis tool and for sharing results with other users/referring physicians.

Currently available test kits for use with RAPTOR SERVER:

ALEX² -REF 02-2001-01, REF 02-5001-01

FOX -REF 80-5001-01

SUMMARY AND EXPLANATION

RAPTOR SERVER Analysis Software is a web-based alternative to Raptor Analysis Software. RAPTOR SERVER is a cloud-based application and is operated via the browser. RAPTOR SERVER is a software for the acquisition and analysis of medical device images taken by the ImageXplorer device from processed ALEX2 or FOX test arrays. RAPTOR SERVER is developed as a standalone solution which also performs the storage of data and creation of reports based on the diagnostic lab results.

The software consists of

- web-based server software that provides graphical user interface control via the user's web browser. This server software is commonly referred to as RAPTOR SERVER.
- a standalone application for data transmission between the ImageXplorer device and the server software. This application is commonly referred to as "AGENT".

The software has been specifically developed for the analysis and reporting of results of ALEX² & FOX tests.

3.1 Operation

Ideally, the operation of RAPTOR SERVER should be centralized, in the form of a cloudbased SaaS (Software as a Service) application. However, a purely local operation on a customer-owned data center (RAPTOR SERVER "on-premise") is also possible, though with much limited support and features.

IMPORTANT USER INFORMATION:

For the correct use of the ImageXplorer and the RAPTOR SERVER software, it is necessary for the user to carefully read and follow these instructions for use. The manufacturer assumes no liability for any use of this test system which is not described in this document or for modifications by the user of the test system.

This version of the IFU is valid from the RAPTOR SERVER Version 1.2.7 onwards.

PRINCIPLES OF PROCEDURE

ALEX² & FOX tests 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 (ALEX²) or IgG (FOX) antibodies which are present in the patient sample. After incubation, non-specific IgE/IgG is washed off. The procedure continues by adding an enzyme labelled antihuman detection antibody which forms a complex with the particle bound specific IgE/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 antibodies in the patient sample.

The lab test procedure is followed by image acquisition and analysis using the ImageXplorer. The test results are analyzed with MADx's RAPTOR SERVER. ALEX² test results are reported in allergen specific IgE units (kU_A/I), along with the total IgE results in IgE units (kU/I). FOX test results are reported in specific IgG units (µg/ml).

5 **ENVIRONMENTAL CONDITIONS AND SHIPMENT**

To ensure trouble-free operations of the ImageXplorer, it is important to place the instrument in an appropriate environment. Following specifications must be fulfilled:

Environmental conditions	Specifications
Operating Temperature:	15 to 30 °C
Humidity:	30 - 85%, non-condensing
Power supply:	The device is powered by a +5V USB 3.0 or USB 2.0 cable from either a personal computer or a USB power supply. No additional power supply is needed.
Weight and dimensions of workplace:	The device fits on a normal work bench or desk, weight and dimension do not require special support structures
Dust: Operating system:	Dust-free environment recommended Windows 10

6 WASTE DISPOSAL

Waste disposal of the ImageXplorer must be performed in accordance with local guidelines.

GLOSSARY OF SYMBOLS 7

Symbol

Description



CE Mark



In vitro diagnostic medical device - Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.



Consult instructions for use - Indicates the need for the user to consult the instructions for use.



Serial number - Indicates the manufacturer's serial number so that a specific medical device can be identified.



Manufacturer - Indicates the medical device manufacturer



Symbol for the marking of EEE



Important Note

8 PRODUCT CONTENTS

Equipment	REF	Quantity
ImageXplorer	11-0000-01	1
ImageXplorer carriage	-	1
Connecting cable (PC - ImageXplorer)	-	1
RAPTOR SERVER Analysis Software	22-0000-01	1
USB Power Hub for constant +5V supply	-	optional

9 SAFETY INSTRUCTIONS

9.1 Operator Qualification

The ImageXplorer and the RAPTOR SERVER 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 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 authorized and qualified personnel manufacturer!

9.2 Data Backup

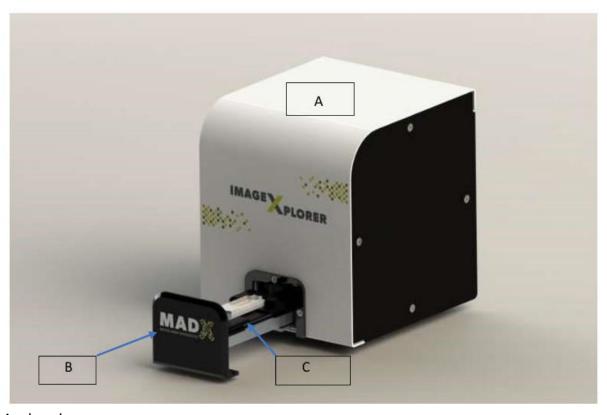
When using RAPTOR SERVER, all analytical and patient related data are stored according to the MADx Terms of Service Agreement in the Microsoft Azure Online Portal. Please also refer to the Online Services Terms (OST) of Microsoft, available at https://www.microsoft.com/en-us/licensing/product-licensing/products.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

9.3 Electromagnetic Compatibility

The ImageXplorer fulfils the requirements of Electromagnetic Compatibility (EMC) according to EN 61326 (Electrical equipment for measurement, control, and laboratory use).

Devices that emit electromagnetic waves may affect measurement data or cause the instrument to malfunction.

10 SYSTEM COMPONENTS



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 cable

11 WORKFLOW

- 1. Connect ImageXplorer to computer
- 2. Go to www.raptor-server.com in a web-browser
- 3. Start the ImageXplorer Agent on the PC and provide the ImageXplorer key
- 4. Log in to your tenant account
- 5. Start measurement
- 6. Enter patient information
- 7. Analyze and verify results, then approve results
- 8. Export the data, or download report

12 INSTRUCTIONS

12.1 Connecting the ImageXplorer to the PC

The ImageXplorer is not a standalone device and must always be used in combination with RAPTOR SERVER. The ImageXplorer is plugged into a computer via the provided USB cable, and both the connection and the power supply are managed through the computer's USB 3.0 port by the provided USB cable. The thicker USB plug (USB B) is attached to the back of the ImageXplorer, whereas the thinner USB port (USB A) is attached to the computer.

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.





12.2 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.

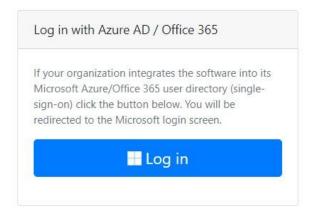
12.2.1 Log-In

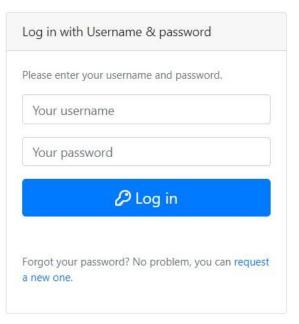
A Tenant is the online entity for a single laboratory within the RAPTOR SERVER. Tenants are created by MADx and access is provided by your local distributor.

Multiple users can log in to a Tenant platform. Access to a Tenant on RAPTOR SERVER will only be available to users with a valid username and password specified by MADx or by an external directory service (Office 365/Azure Active Directory). User accounts are created by the tenant administrator (Local distributor, or MADx).

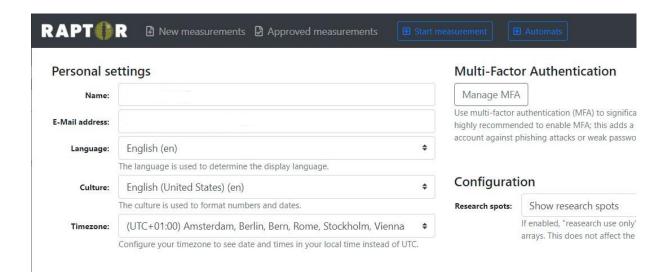


Welcome to RAPTOR-SERVER, the analysis software for the ALEX and FOX multiplex test. Please log in below to continue.





After successful login, the user has access to their tenant. A password can also be reset if forgotten.



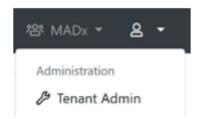
12.2.2 Personal Settings

In "Personal Settings" you can select the user language, the culture (e.g. English (UK)) and the time zone. ALEX² contains 5 Research Use Only (RUO) allergen spots. These are deactivated by default. To make the RUO spots visible, the user can select "show research spots" in the drop-down menu. In addition, the display language can be selected, once the translation is available.

Raptor Server supports Multiple Factor Authentication (MFA) of users with given username and password. It can be set up in the personal settings, using an authenticator app (Google or Microsoft) installed on the smartphone of the user. Clicking on Manage MFA in the Personal Settings page, the user will be guided to set up the MFA.

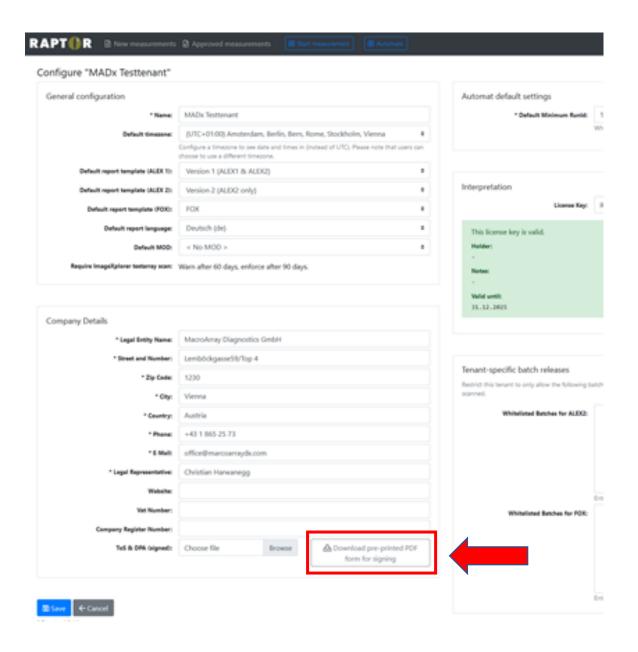
12.2.3 Tenant Admin

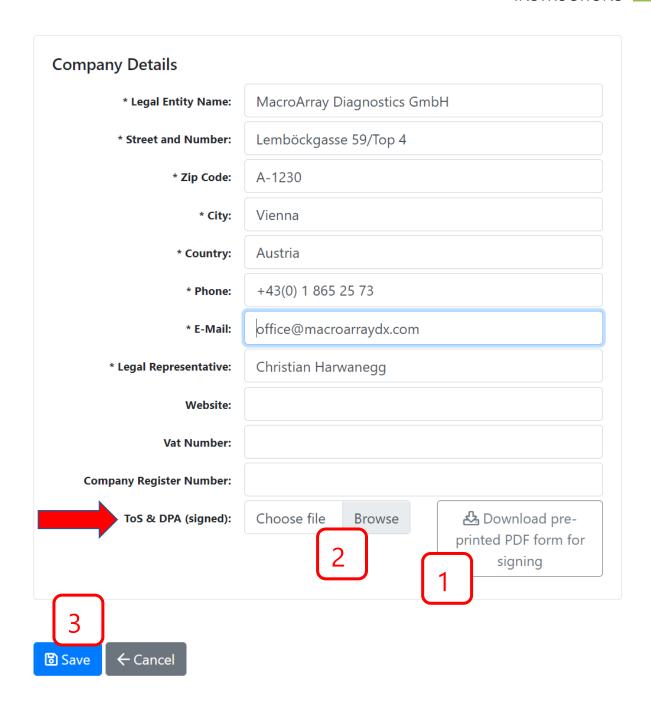
If you click on the menu icon in the upper right corner and select Tenant Admin, you will be directed to the Tenant Admin area, where you can set the preferences for your tenant.



First, please access the Tenant Configuration page and fill out the company details accordingly. Make sure the company details represent official data, since these details are included in the Data Protection Agreement (DPA) and Terms of Service (ToS). Download the documents, add your signature, and upload the signed documents by clicking on "Browse".

NOTE: The use of RAPTOR SERVER is officially enabled only after submitting the signed DPA and ToS.



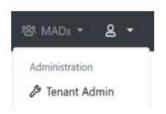


Other important pages of the Tenant Admin area are:

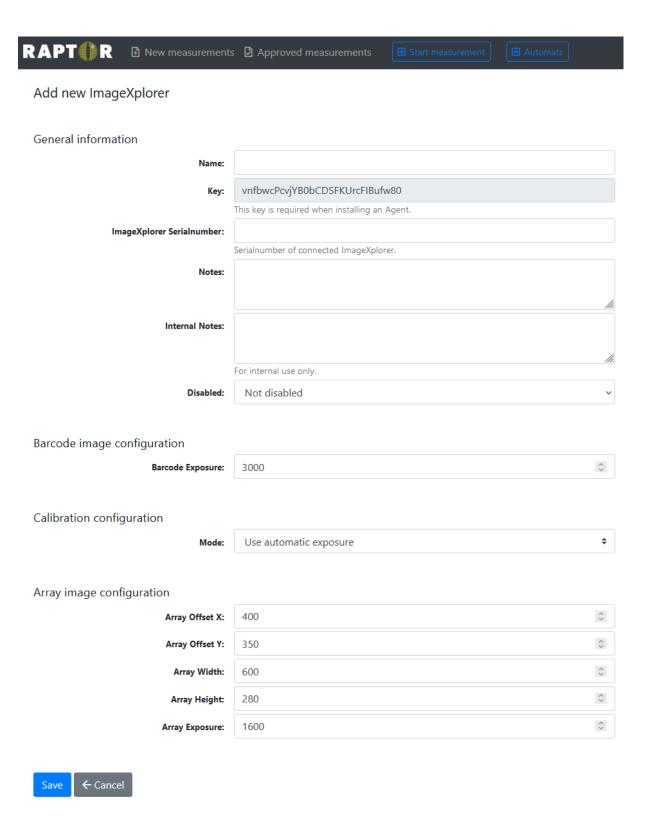
- ImageXplorers: Use this to configure existing ImageXplorers or add new ones. Every ImageXplorer needs to be registered as an entity to the Tenant on RAPTOR SERVER, otherwise a connection is not possible.
- Report Templates: Use this to create, edit or delete report templates for this tenant. Each template can have its specific look and configuration
- Measurement data completion: Manage pre-defined patient information that can be assigned to a measurement
- User Portal: Use this to create, edit or delete users on the user portal for this tenant. Measurements can be shared with users of the User Portal, and users can use the User Portal to access those measurements.

12.2.4 Download of the ImageXplorer Agent Software & 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.

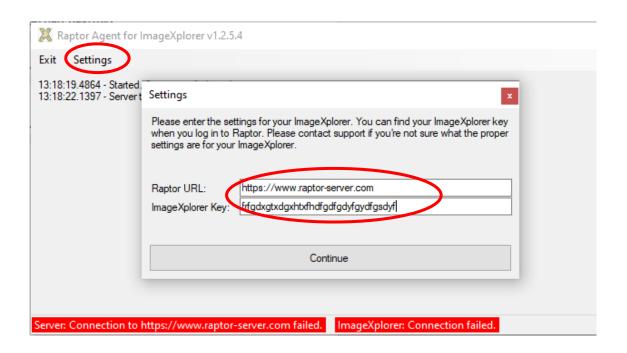


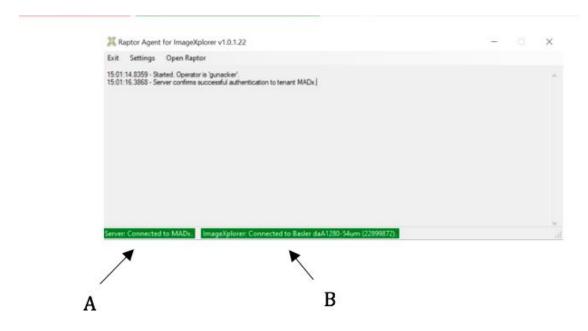
Carry out the installation of the ImageXplorer agent, as a regular installation process.

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.

12.2.4.1 Adjusting the ImageXplorer Settings

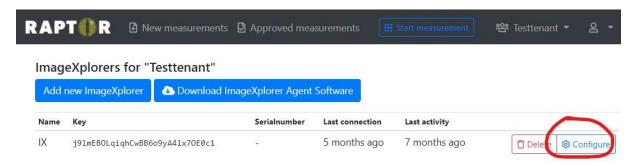
Each ImageXplorer has unique image settings that need to be calibrated (Test Array) during the first installation and then every 60 days.

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 Test Array run.



Every new ImageXplorer system will include a calibration test array with a special barcode starting with the digits "30" on the label (e.g. 30AAF267). The calibration test 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 test array.

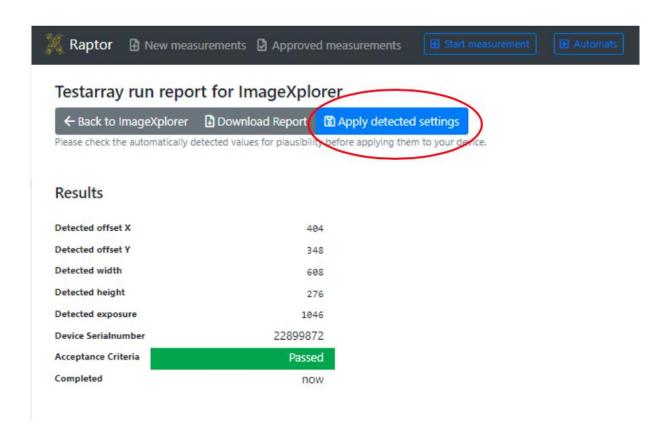


By clicking on "Start new test array scan", the calibration of the setting-adjustments starts (takes about 2-3 minutes).

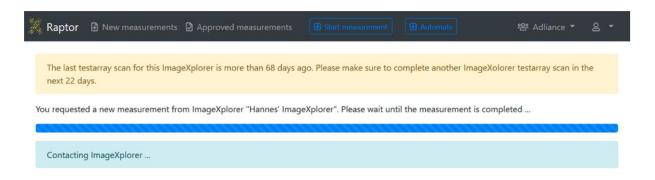


This calibration measurement will identify and adjust the optimal settings for x, y, width and height of the array edges and the optimal exposure. After the calculation is finished, a report of the test array run is displayed. The user shall apply the new ImageXplorer settings by clicking "Apply detected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

NOTE: If the calibration testarray run hangs and does not update the state for a couple of minutes, click on abort. On the Configure page of the ImageXplorer, click "Start new testarray scan" again. If this problem occurs in the long term, check your connections, as described in chapter 12.12.



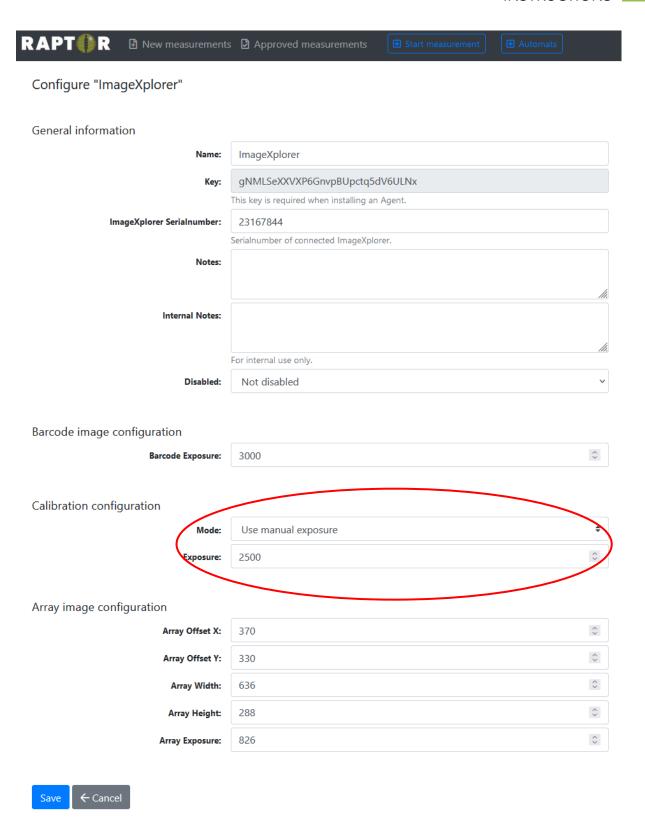
Running the test array on a regular basis will ensure that the ImageXplorer uses the optimal configuration. Therefore, after 60 days a message will appear, which prompts you to repeat the ImageXplorer test array run within 30 days.

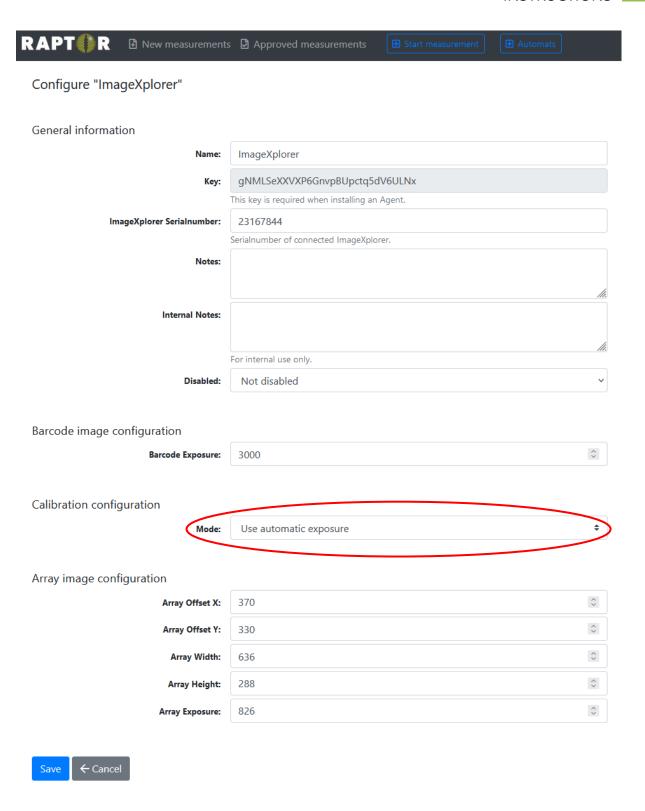


If you do not repeat the ImageXplorer test, no new measurements will be possible after 90 days. Previous results will be accessible as before.

The current ImageXplorer settings are to be found in the "Tenant Administration" area --> "Manage ImageXplorers" --> "Configure"

If the barcode is not recognized during the test array run, the "automatic exposure" under calibration configuration can be changed to --> "manual exposure". The Calibration Exposure is set to 2500 by default. However, it can be corrected a little bit up or down.

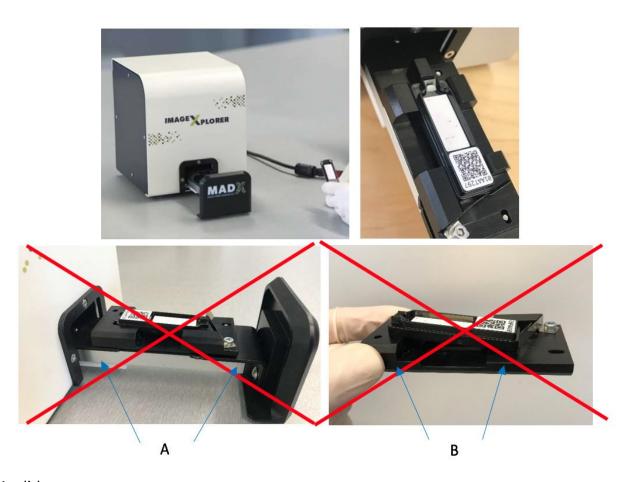




12.3 Imaging and Analysis of measurements

12.3.1 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 (don't touch the membrane of the cartridge) and insert it by facing the barcode 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.

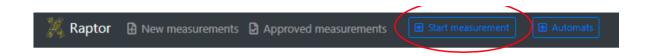


A: slider B: carriage

12.3.2 Image Acquisition, Barcode Reading and Grid Finding

On the overview page you will find a tab "New measurements", a tab "Approved measurements", a button for "Start measurement" and if there is a MAX 45k (automated processing unit), a button for Automat. 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.



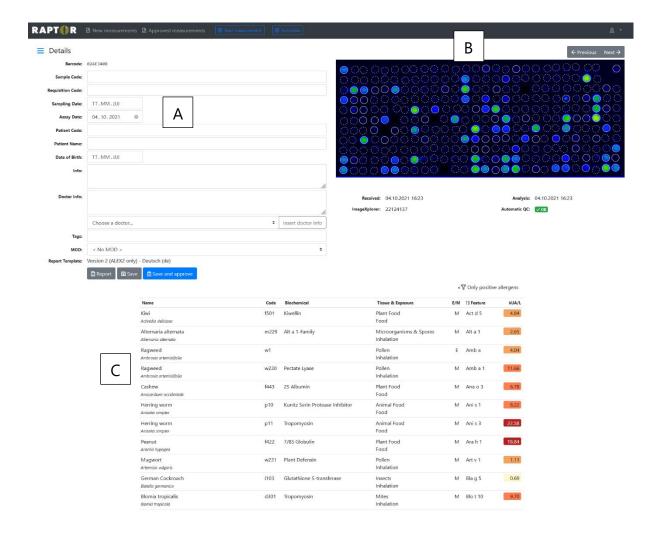
If only one ImageXplorer is connected, the analysis will start immediately. If several ImageXplorers are connected to the tenant on RAPTOR SERVER, the user must first select which ImageXplorer they want to use. RAPTOR SERVER automatically recognizes the barcode, which is the basis of all further processing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

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

The barcode on each cartridge contains the following information:

- type of test array (ALEX² / FOX)
- corresponding allergen layout
- QC information
- Lot number of cartridge
- batch specific correction of calibration for specific and total IgE

After imaging and analysis, a detailed overview of the measurement is displayed with the patient information fields and sample information fields on the left, an analytic image of the array on the right and a detailed result view of allergens below.



A: Patient and sample information fields

B: Analytic image

C: Result view

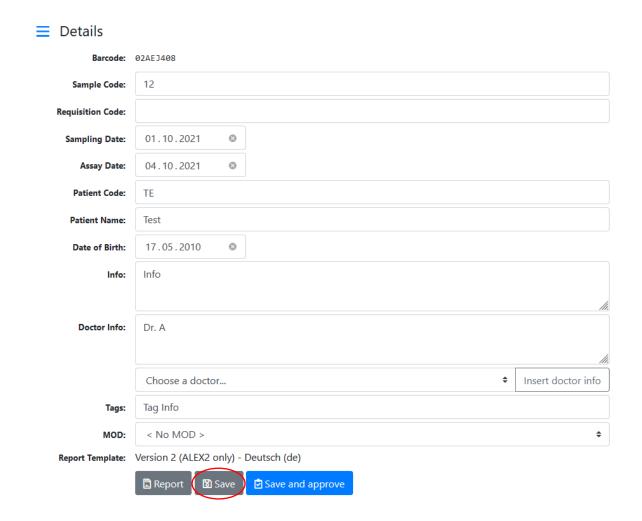
In addition, date of analysis, serial number of the ImageXplorer, QC and possibly also an error log are displayed below the analytical image.

Additional sample and patient information can be added manually:

- sample code
- requisition code
- sampling date
- assay date
- patient code
- name of the patient
- date of birth
- additional information (Info)
- name of the referring physician (Doctor Info)
- tags
- MOD panel

The entries in "Info" and "Doctor Info" can be formatted to appear bold, cursive and/or underlined. This is done as follows:

- _Info_ will appear underlined
- *Info* will appear cursive
- **Info** will appear **bold**

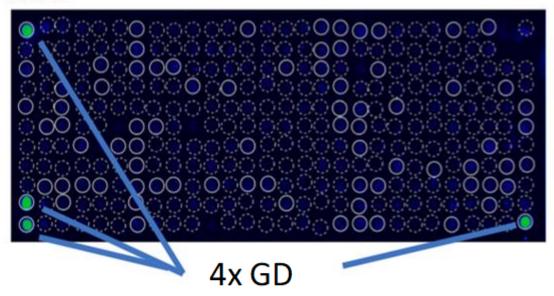


If you click on "Save" the entered information will be saved.

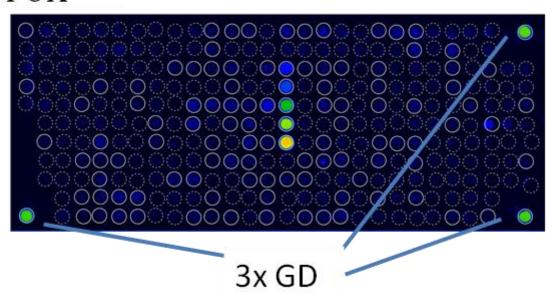
The array of the measurement with grid is displayed in the analytical image area. The software automatically identifies the position of the array in the image data based on the guide dots. There are 4 guide dots on ALEX², and 3 guide dots on FOX.

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".

ALEX²

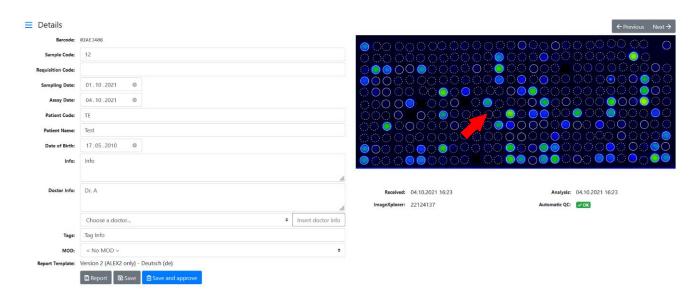


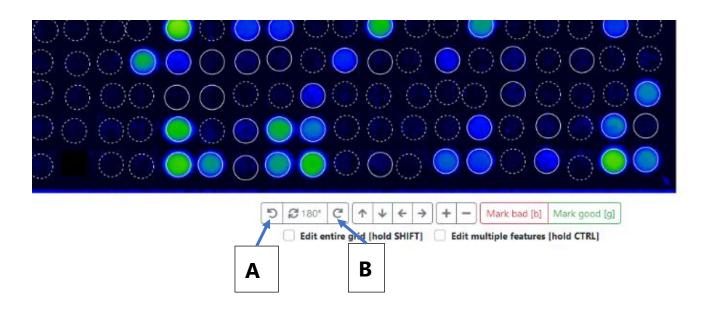
FOX



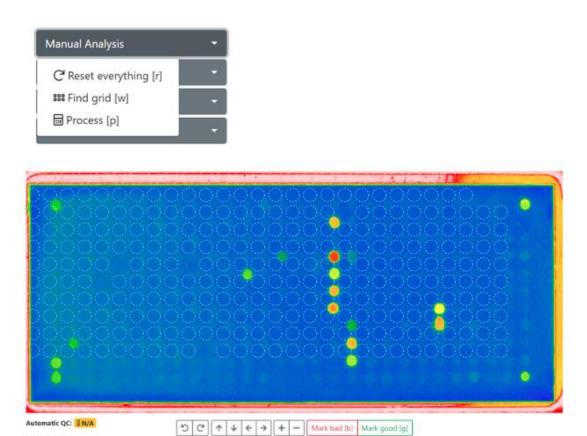
12.3.3 Image Processing Mode

To enter the image processing mode, click on the image.





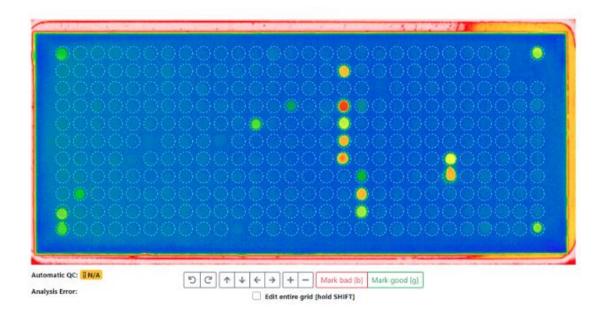
If the automatic position finding fails, the user will be alerted, and the measurement quality control (QC) will be set to FAIL. In this case, the user can try to manually position the array by resetting the grid by pressing "R" or go to "Manual Analysis --> Reset Grid". After resetting, you can move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



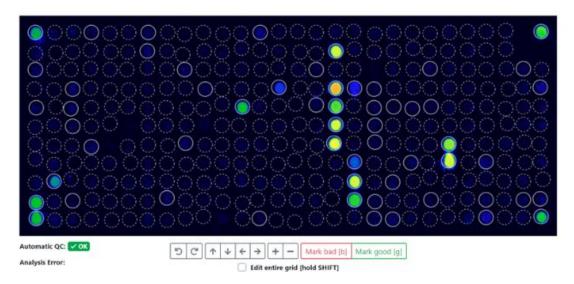
Edit entire grid [hold SHIFT]

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

Analysis Error:

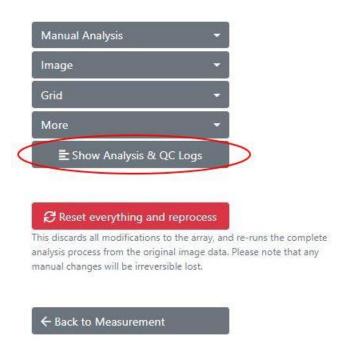


Press "W" or "Manual Analysis --> Find Grid" or manually move the entire grid

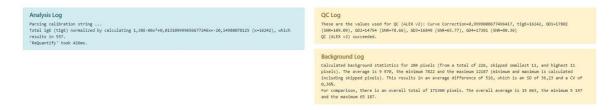


Press "P" or "Manual Analysis --> Process"

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

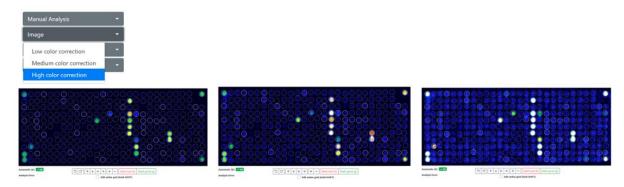


If you click on this button, an area will open with the explanation for QC fail or QC OK. For the QC to be OK, the background must be within a certain range and all guide dots must reach a special value. If these QC criteria are still not fulfilled after manually adjusting the spots on the image, please contact your local distributor.



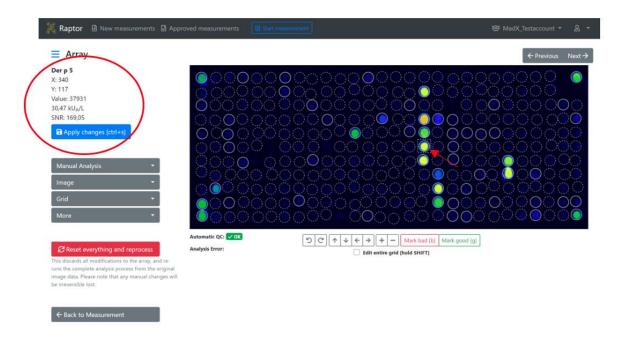
12.3.3.1 Image Analysis

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



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

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



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

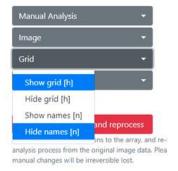
- 1. Circle with dotted line: not yet analyzed or below cut-off
- 2. Circle with a solid thin line: positive spot automatically found
- 3. Circle with solid thick line: spot set to good by user
- 4. Circle with a solid thin line and an X in the center: spot set to bad by the user
- 5. Circle with a thick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



Spots are editable by the user:

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

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



12.3.3.2 Shortcut Summary

SHIFT

Short Cut	Execution
R	Reset analysis
W	Find grid
P	Process
G	Set feature to good
В	Set feature to bad
N	Annotate allergen features
Н	Hide/unhide grid

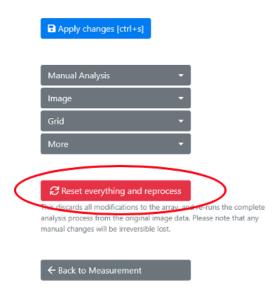
Orange marked spots need to be inspected and set to Good or Bad by the user.

Select all measurements

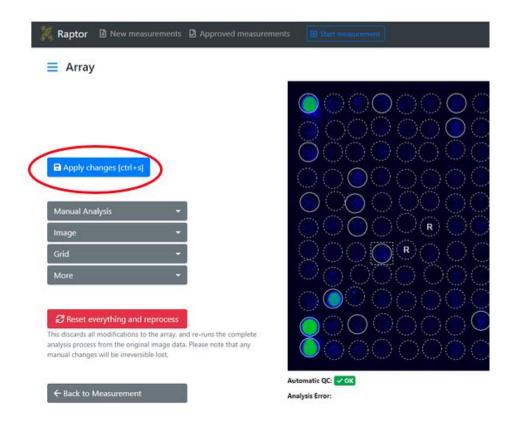
Otherwise, they will be marked by an orange triangle with an exclamation mark in the report. If the spot was set to "good" or "bad", this will not be displayed.



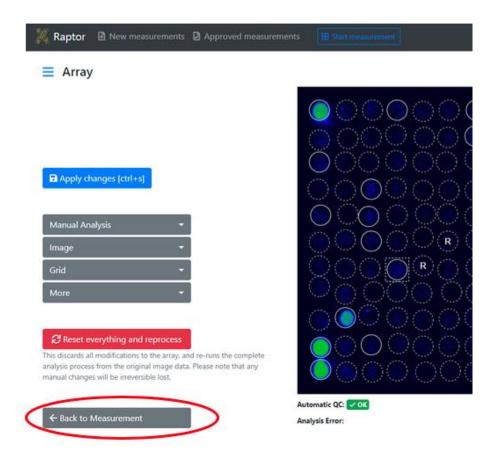
It is also possible to open an image of the barcode, an image of the unprocessed or the processed array. To do this, go to "More" and select the desired image. A complete reset is also possible by pressing the "Reset everything and reprocess" button.



If the user changes the position or the interpretation of the spot or the whole grid, the analytic data will be erased, and the QC set to NA. After the analysis, press "Apply Changes" to save the modifications.



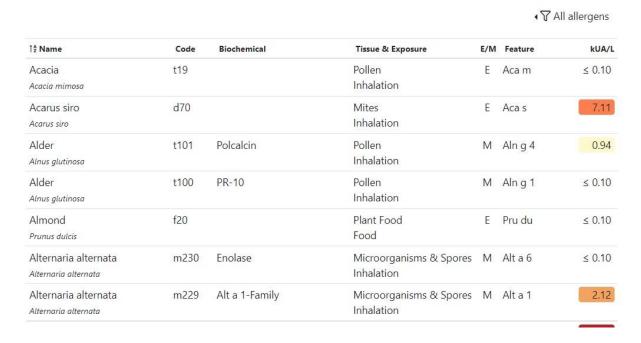
To return to the detail page of the measurement from the image processing mode, press "Back to measurement". You can also click "Next/Previous" to go to the editing page of the following image.



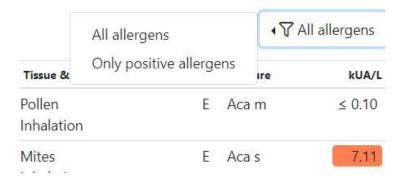
12.3.3.3 Analytical Results

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

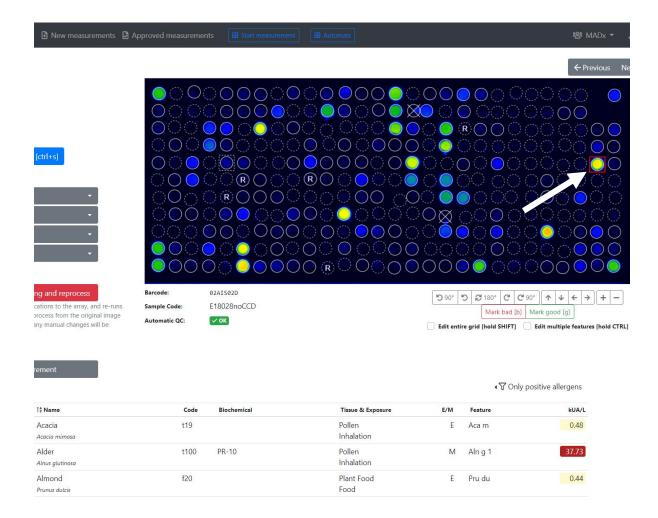
- Allergen name & species
- Allergen code
- Biochemical function
- Tissue & exposure route
- Allergen extract or molecular allergen
- Feature name
- In case of ALEX² IgE value expressed as kU_A/I (color coded)
- In case of FOX IgG value expressed as μg/ml (color coded)



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



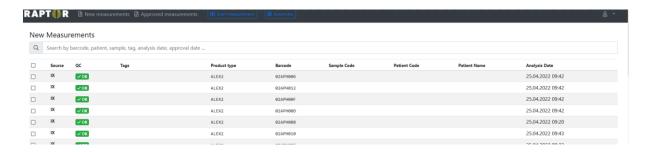
By clicking on the name of one or more allergens in the list of allergen results, the corresponding spots on the array image are highlighted by a red rectangular box.



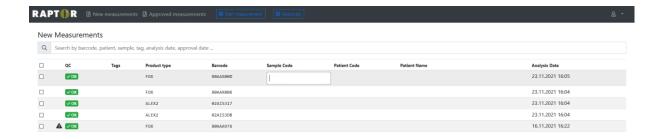
12.3.4 Overview of Measurements

New and unapproved measurements can be displayed in the "New Measurements" overview, which also displays the following information for each measurement:

- · Source of measurement
- QC status
- Tags
- Product Type
- Barcode
- Sample Code
- Patient Code
- Patient Name
- Analysis Date



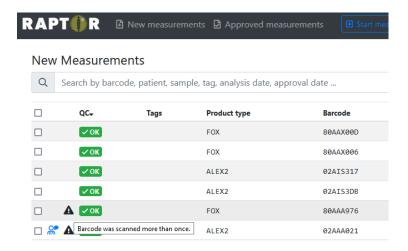
Clicking on the barcode or the analysis date takes you to the detail area of the measurement. Patient information, sample code and tags can also be entered in the overview page. To do this, simply click in the corresponding field of the measurement and insert it. Press the "Tab" button to automatically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



In the search field, measurements can be searched for by their tag, product type, barcode, sample code, patient code and patient name and analysis date.



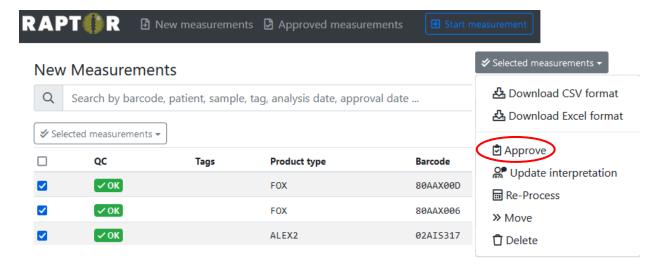
It is possible to duplicate the barcode and the measurement data in the data repository if cartridge is acquired several times. However, this is indicated by a triangle with an exclamation mark during measurement.



12.3.5 Approving and Exporting Measurements

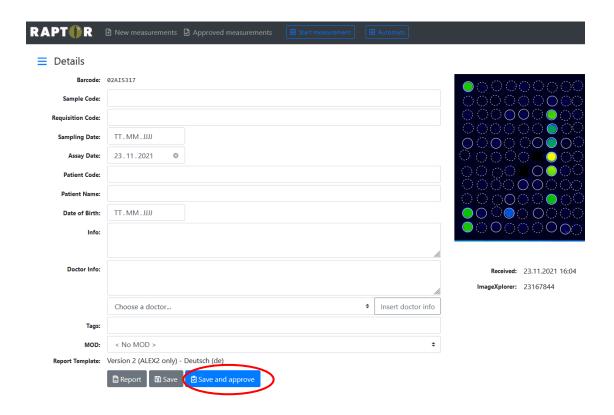
After analysis and careful revision of the results, the measurements can be approved by two ways:

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

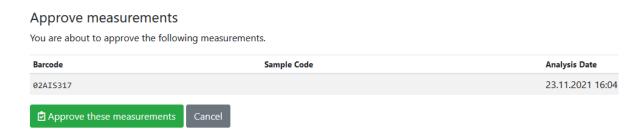


Unapproved measurements can also be downloaded as CSV or EXCEL.

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



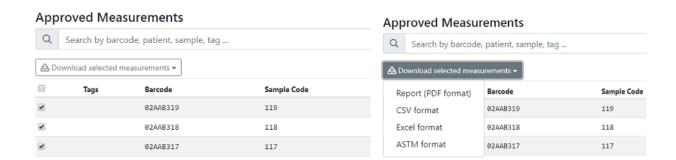
If the QC of a measurement is "OK", the measurement simply moves to the "Approved Measurements" tab upon approval. If the QC of a measurement is "Failed", the user will get a notification that the "Measurement QC is not OK". In addition, it will also be stated on the report that the internal QC (plausibility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



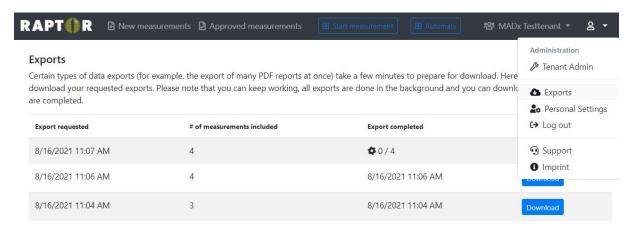
Approved measurements are stored in the section "Approved measurements". No patient information can be changed or added here. The details/result of a measurement can be displayed by clicking on a measurement. The features of the image can also be displayed but cannot be adjusted anymore.



The results of selected measurements in the approved measurements section can be downloaded as PDF report, as EXCEL, CSV or ASTM file. Values under 0.1 kUA will be displayed as < 0.1, and values over 50 kUA as >50 instead of the absolute value.



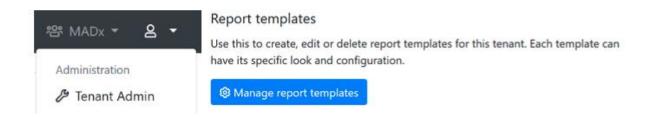
If a larger amount of data is requested for export, for example multiple .pdf reports, an export download link will be generated in a separate window. The export process then runs in the background and can be viewed by clicking on the menu in the upper right corner. A finished export can be downloaded by clicking on "download".



12.4 Report

Creating a Custom Report Template 12.4.1

Reports can be customized by clicking on "Tenant Admin" and then "Manage report templates".



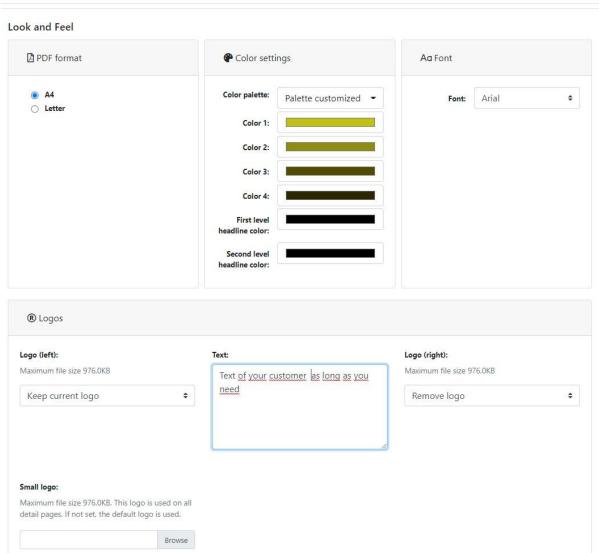
The following settings can be selected:

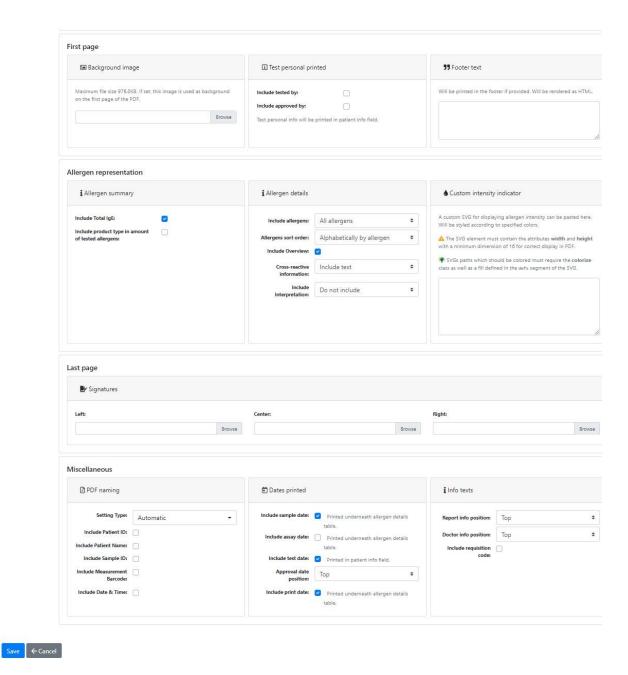
- Name of the report template
- Base template (ALEX² Version 1 or Version 2, FOX)
- Preferred language (you can still change the language for every report separately)
- PDF Format
- The base colors of the template and the result classes can be customized across the entire color palette for Version 2 (ALEX² only)
- Font
- Header: To upload a logo on the left or right side of the front-page header, please press "Browse" and select a JPG or TIFF format.
- Additional to the Logos on both sides of the front-page header, a miniature logo can be added to the headnote of all pages. By default, this is a miniature of the left-side header logo.
- Additionally, it is possible to add a custom explanatory text for providing the QC result (failed or OK)
- Background image: it is possible to add a watermark background to all pages.

- For Version 2 (ALEX² only) information on test personal can be enabled as well (include tested by, include approved by)
- Text can be added to the footnote of all pages
- Allergen Summary:
 - o tlgE (ALEX²) In case of an ALEX² test, total IgE (tlgE) is highlighted on the last page of the report. It is possible to hide tlgE in the report if you deselect tlgE.
 - Product type Option to display the product type (ALEX / FOX) on the report
- Allergen details:
 - Include allergens (which results to include)
 - o Allergen sort order: The allergen details in the report (in one allergen group) can be sorted in three different ways:
 - Alphabetical order by allergen codes
 - Descending from the highest to the lowest value
 - Alphabetically order by allergen name (common name)
 - Include Overview
 - o Cross-reactive information: By selecting "include cross-reactive information", explanatory sentences will be added to the end of the report describing those allergen families that are positive on the first page. (see "cross-reactive allergens"). It is possible to include the information as text only or the information and a table of all positive allergens).
 - Include interpretation (RAVEN) See corresponding Chapter. Here can be selected whether an interpretation shall be included automatically in the report, or only by request.
 - Include allergens overview
 - Include RUO spots
- Custom intensity indicator (a custom SVG for displaying allergen intensity can be added)
- Signature: In addition, a picture of a signature can be uploaded to be added at the end of the report.
- PDF naming:
 - Setting Type: Automatic --> choose from the following options:
 - Patient ID
 - Patient Name
 - Sample ID

- Measurement Barcode
- Date & Time
- o Setting Type: Manual --> select options the way you prefer Example: Report_{PatientID}_{DateAndTime}
- Dates printed on the report:
 - o Sample date
 - Assay date
 - Test date
 - Approval date
 - Print date
- "Info" and "Doctor Info" entries of the measurement can be displayed on the top and/or bottom of the front page. The requisition code can be added as well.







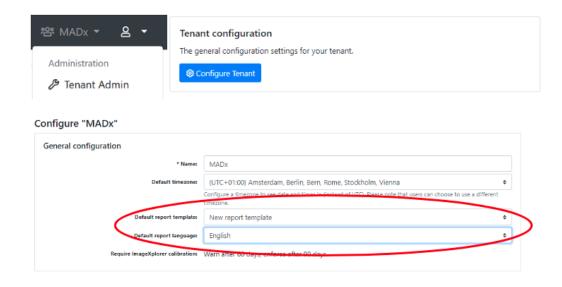
After the change, the report template can be saved by clicking the "Save" Button.

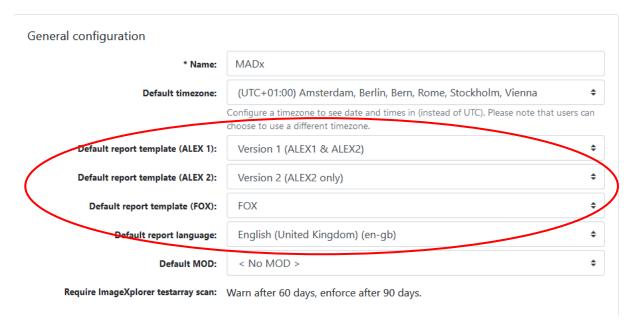
The following languages are available:

- Azerbaijani
- Albanian
- Arabic
- Arabic (Saudi Arabia)
- Bulgarian
- Chinese
- Croatian
- Czech

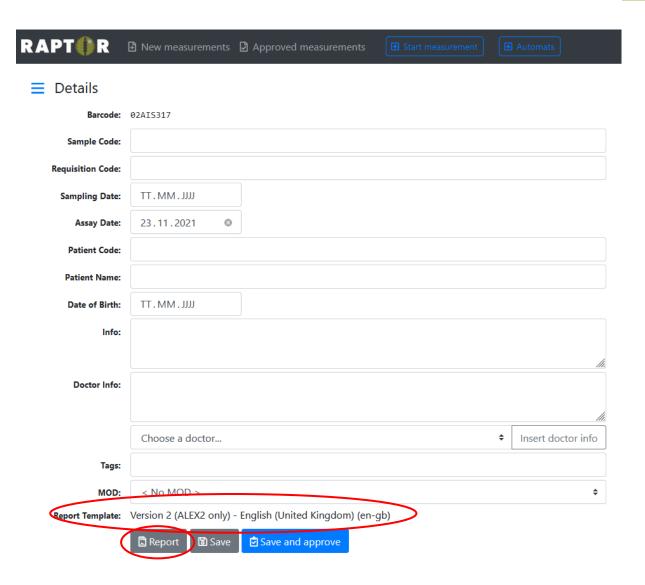
- Dutch
- English (India)
- English (United Kingdom)
- English (United States)
- Estonian
- Farsi (Iran)
- French
- Georgian
- German
- Greek
- Hindi
- Hungarian
- Italian
- Latvian
- Lithuanian
- Norwegian
- Persian
- Polish
- Portuguese
- Romanian
- Russian
- Slovak
- Slovenian
- Spanish
- Spanish (Mexico)
- Swedish
- Turkish
- Ukrainian

To define your "default" template, that is used as standard template, you need to have the corresponding user rights. Then, if you go to "Configure Tenant" in the Tenant Admin area, you can select your default language and templates for ALEX² and FOX.

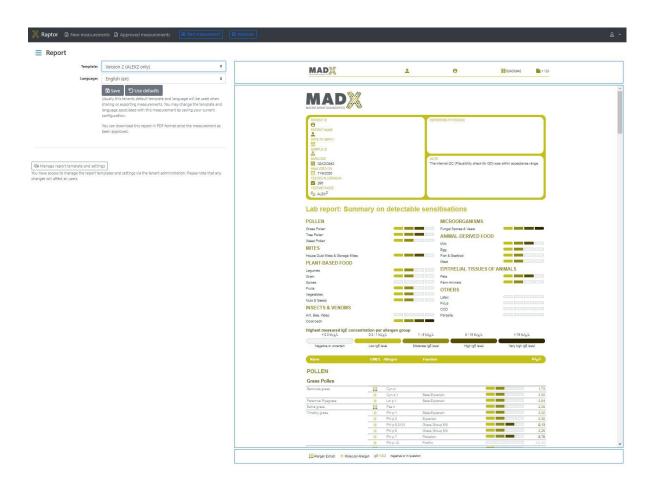




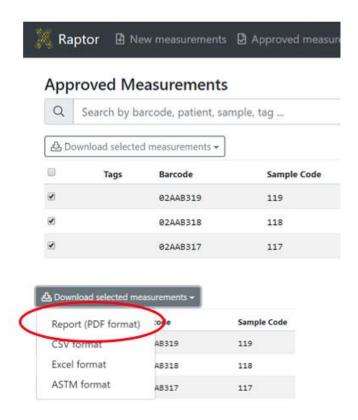
A report of an unapproved measurement can be viewed by clicking on the measurement barcode under in the "New measurements" tab; Select the desired report template and click "Report".



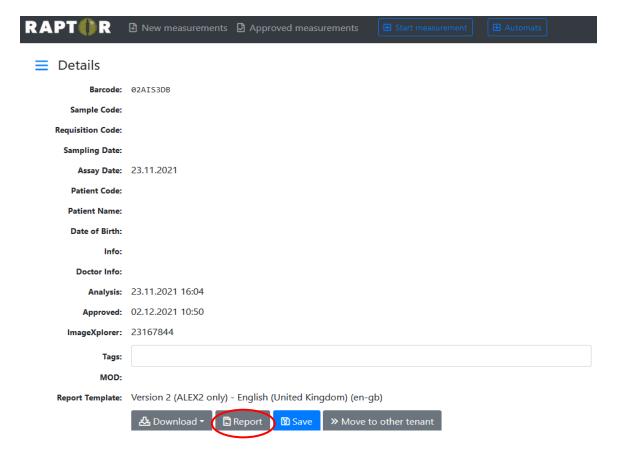
Then you see a preview of the report, where you can select a report template (default or customized) and set the default language. However, it is not possible to download this PDF report. For this purpose, it is necessary to approve the measurement first.

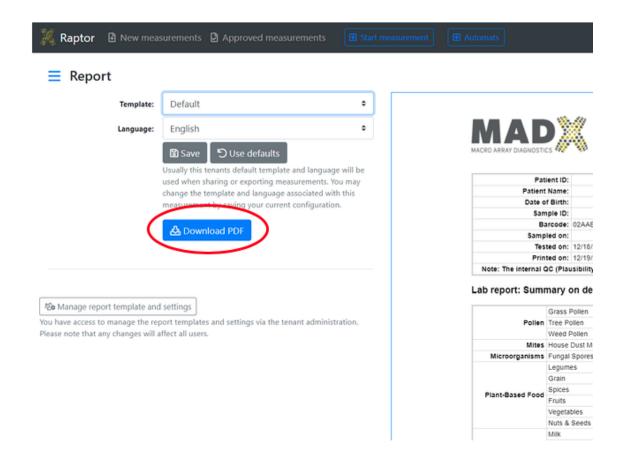


Approved measurements can either be downloaded together or individually. To download measurements together, first go to the "Approved measurements" tab and select the measurements you want to download. Then select PDF Report from the drop-down menu and a zip folder containing the PDF Reports will be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



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





12.4.2 Requesting Interpretation Guidance

A special software module has been implemented to support the interpretation of ALEX² results: RAVEN interpretation guidance.

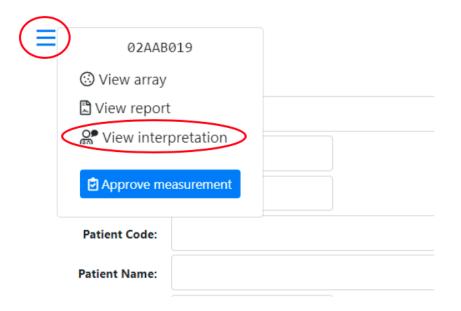
For using this service, a license key must be requested from your local distributor.

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

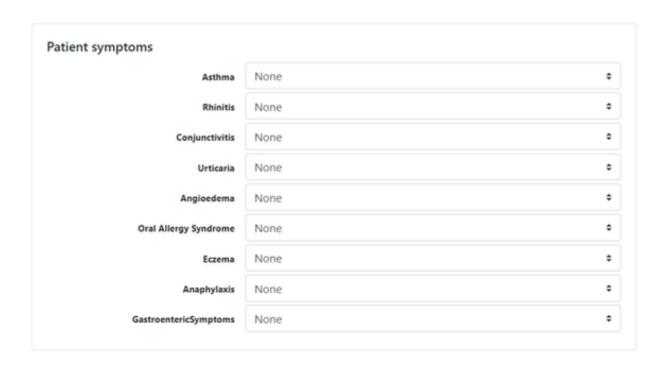
Tenant configuration	
The general configuration settings for your tenant.	
Configure Tenant	
Interpretation	
License Key:	

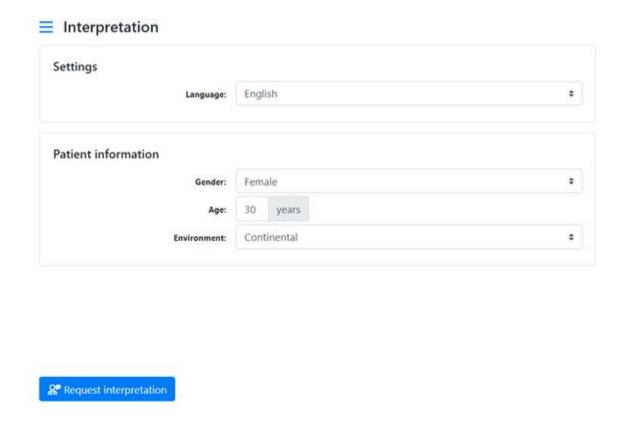
An interpretation query with RAVEN is possible for both - approved and unapproved - measurements. The report can only be downloaded for approved measurements. The interpretation is added automatically to the report, if a report template is chosen for which the option "Automatically include interpretation" was specified.

In case for your report template the Interpretation option "Include manually triggered interpretation" was selected, you must trigger the interpretation manually for a measurement by getting to the detail page of a measurement, then clicking on the menu icon and selecting "View interpretation".

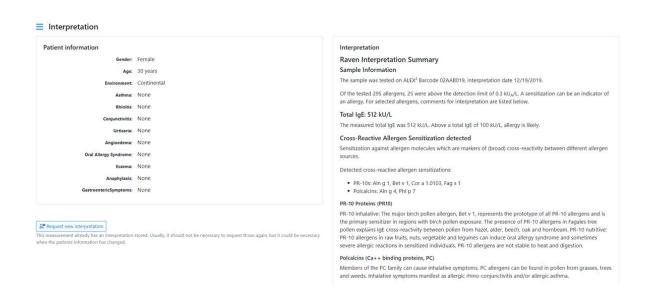


This opens a window in which the settings, such as language, specific patient information (age, gender, environment) and patient symptoms can be entered.





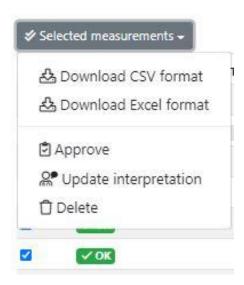
After entering these, the query can be started with the button "Request interpretation".



The interpretation will be then inserted at the end of the report and is also displayed in a preview window. Measurements which have already received an interpretation are

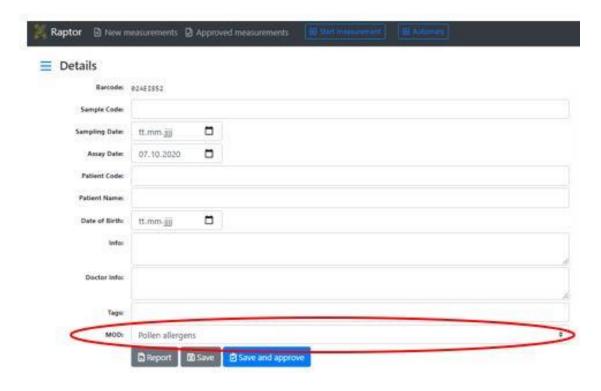
indicated by the following symbol: After clicking on the symbol, the interpretation can be reviewed as above, with the possibility to update (request new) or delete the existing interpretation.

In addition, several interpretation queries can also be triggered in a batch. If you select several measurements on the overview page (of both unapproved and approved measurements) and click with the mouse on the 3 lines in the upper left corner, you can select "Update Interpretation" to perform the query in batch.



12.4.3 Multiplex on Demand

The user has the option to choose a defined group of allergens to be considered for the result. In the detail window of a measurement, a predefined panel can be selected. If a panel is selected, the software will only display the allergen spots and results of the selected panel. To reset the selection and display all allergens, select "no MOD".



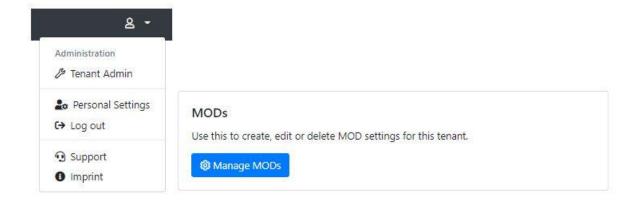


CAUTION! After approval of the measurement, the allergen results, which were not included in the MOD, will be deleted from both image and data. The unselected allergens are then listed in the report as "-".

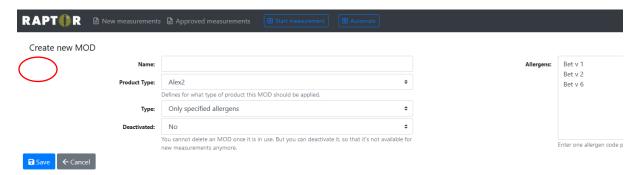
The following allergen panels can be selected as the predefined MODs:

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

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

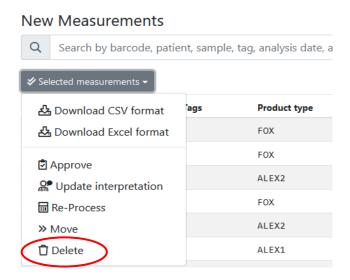


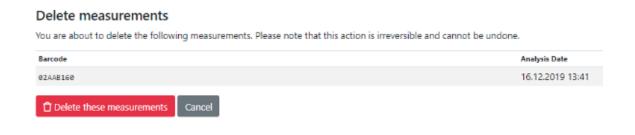
Enter the name of the panel, the product type, the MOD type (only specified allergens, or all allergens except the specified ones), and the allergens (by their code) you would like to include in the panel.



12.5 Deleting Measurements

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

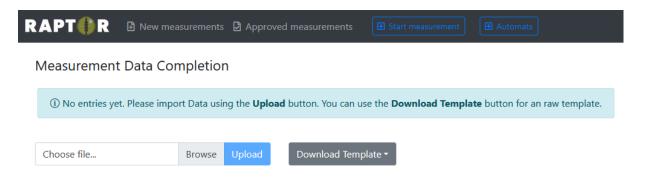




12.6 Importing the patient information from a file

Patient information corresponding to a certain test barcode can be added in an Import-Template .csv or .xls file. To download this file, go to the Tenant Admin area and click on "Manage Measurement Data Completion" under "Measurement data completion". There you can choose between the .csv and .xls formats (xls is suggested).

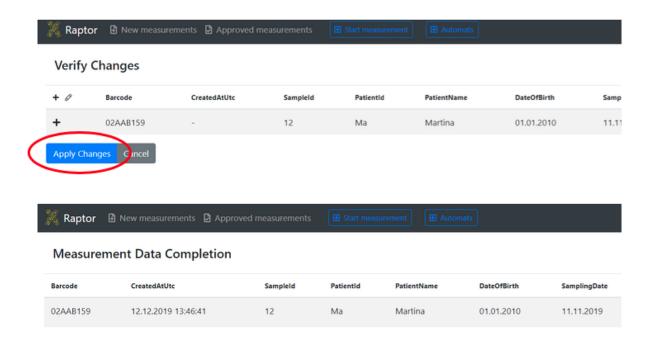




After downloading the Template file, you can type in patient information for the corresponding barcode, save it on your computer, upload the document again and click "Apply Changes".



After uploading this file, the entered information will be displayed. This information can be further edited, and changes can be applied.



If an image is acquired and the information for the corresponding test barcode was uploaded before, the patient information is automatically imported into the software.

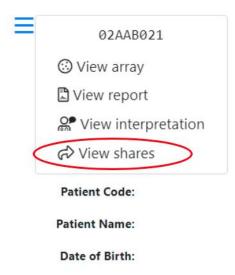
12.7 User Portal

Measurements can be shared with a doctor or a user who is not registered to any Tenant on Raptor Server. To do this, you must first create a user account on the User Portal for the doctor. To create the account, go to "Tenant Admin --> User Portal", click on "Manage Users" and add a new doctor.

Enter the user information and send an E-mail for password creation. Alternatively, you can predefine the password for the user. Make sure you change the status of the user to "enabled".

eneral configura	ation		
First name:	Dr. X	Last name:	Υ
E-Mail address:	testuser@email.com		
Username:	testuser@email.com	Password:	Send an invitation e-mail to user \$
	It is a good idea to use the users e-mail- address as username as well.		
Status:	Locked (user cannot log in) \$	Doctor Info Text:	
	Enabled (user can log in)		
	Locked (user cannot log in)		This information will be printed on a patient report.

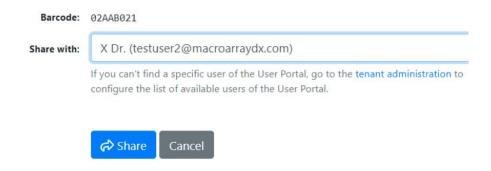
Only already approved measurements can be shared. For this purpose, please go to the tab "Approved measurements", click on the detail page of a measurement, click on the menu icon and select "View Shares".

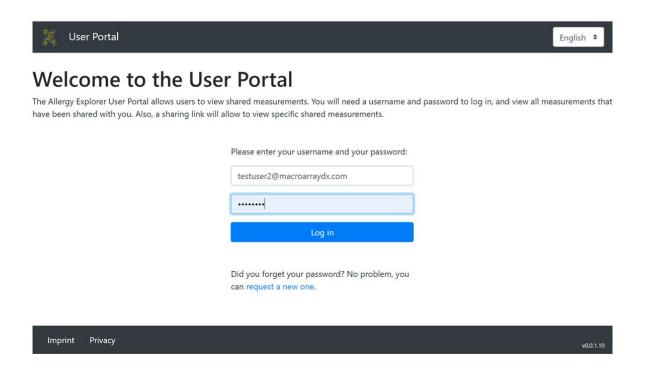


Then select the user with whom you want to share the measurement and click "Share". After that you can either send a link by E-mail, with which the user can access this measurement. Alternatively, the user can log in to their account on the following website (https://doctorportal.raptor-server.com and see the measurement shared with him.

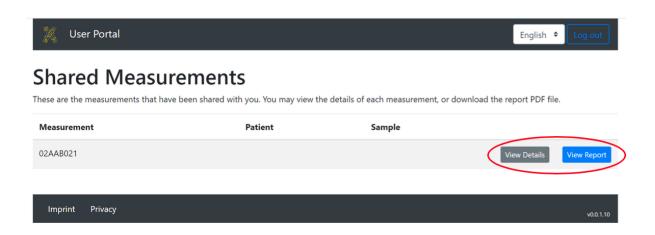
Share

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

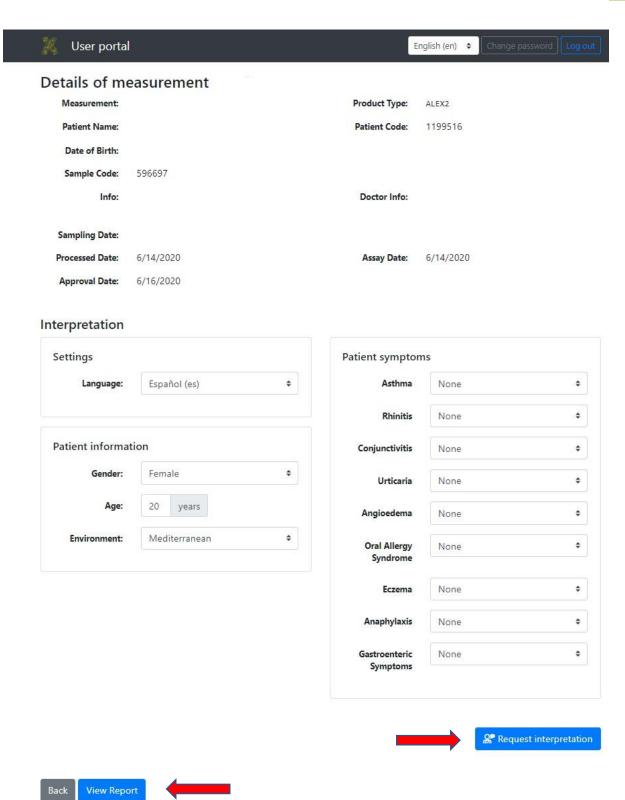




After logging in, the user can view the patient details of the measurements which have been shared with them and open the report. However, the user cannot change anything. The user can also change their password if desired by clicking on "Change password".



It is possible to request a RAVEN interpretation guidance for shared measurements too. For this purpose, fill out the patient data accordingly and click on "Request interpretation". Then, to view the patient report, click on "View Report".



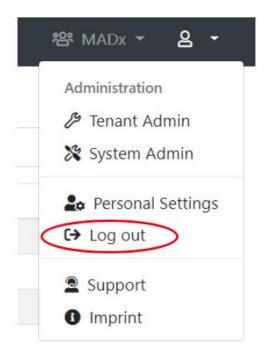
Measurements that have been shared are marked with the following symbol in the list of approved measurements:

Shared measurements can also be withdrawn by a tenant user, by clicking on Revoke:



12.8 Log-out

To log out of RAPTOR SERVER, click on the personal menu symbol in the upper right corner, choose "Log out" and close the window.



12.9 Technical Support

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

12.10 Technical Data & Requirements

This chapter summarizes the specifications of the ImageXplorer and Raptor SERVER.

<u>ImageXplorer</u>

Features Parameters

ALEX² or FOX cartridges **Compatible Test Formats**

Cartridge Dimensions (W \times D \times 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 $R^2 \ge 99 \%$, $CV \le 5 \%$

 $80 \pm 10 \, \text{mm}$ Focus Distance BMP 16 Bit Image File Format Voltage 5 V USB

Power < 5 Watts

Size $(W \times D \times H)$ 160 x 180 x 180 mm

Weight 1.2 kg Barcode Identification OR Barcode

Operating System PC with MS Windows® 10

Required software

Pylon Runtime v6.1.1 (Incl. with the full version of the Agent installer)

Connection USB 2.0 or higher Room Temperature Temperature Range

Raptor Server

The GUI of Raptor SERVER can be accessed in a single web-browser. The application is optimized for Google Chrome on Windows 10. Following access rights must be enabled for the use, at least on the outgoing port 443:

- o www.raptor-server.com
- o api.raptor-server.com
- o doctorportal.raptor-server.com
- o www.macroarraydx.com

12.11 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.



12.12 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
- o 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

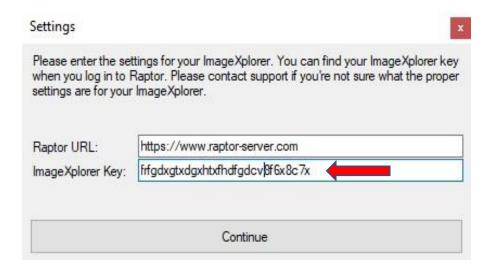


ImageXplorer Connection failed (Agent flags connection in red color):

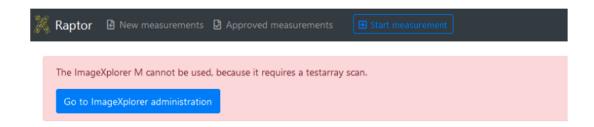


Possible Solutions:

- Check if ImageXplorer is connected to the computer
- o 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
- o Check if the last required Test Array run has been performed

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



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