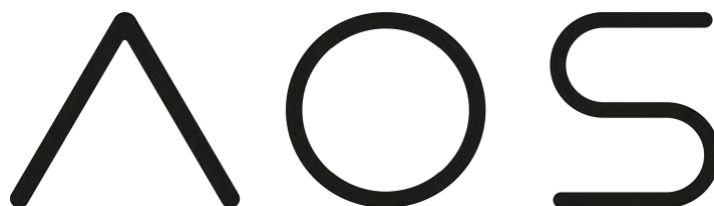


AOS V3 – User Guide

User Manual – Medical Product/Medical Software - AOS V3.1
Advanced Ophthalmic Systems Ltd (AOS)



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This user guide is subject to periodic review, update, and revision. Customers are cautioned to verify that This medical product performs as described in this manual.

The user of this medical product shall have the sole responsibility for any problem that results from improper use or alteration by anyone other than AOS.

The safety, reliability, and performance of this medical product can only be assured under the following conditions:

- The medical product has been used according to the accompanying operating instructions in this user guide.

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Advanced Ophthalmic Systems Ltd, The Old Rectory, Church Street, Weybridge, Surrey KT13 8DE, UK.

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1 Introduction

1.1 About this guide

This document describes how to use the AOS V3 software package for analysis of digital images of the eye and for conducting video sessions.

This document also describes any system requirements and potential limitations due to image size, image quality and visible artefacts contained within the image.

The results given are intended as a diagnostic support tool for clinicians. Please refer to our Terms and Conditions for information on usage, licensing and subscription.

1.2 System Requirements

The specification below represents the minimum requirements for AOS V3 software. AOS V3 is a web application and can be run via online browsers.

Supported Browser	Chrome, Firefox, MS Edge
Supported Operating Systems	PC or Mac
Recommended min resolution	1024 x 768

1.3 Supported image and video file types

Description	File extensions
Windows Bitmaps	BMP
Joint Photographic Exports Group	JPG
Portable Network Graphics	PNG
Graphics Interchange Format	GIF
Moving Picture Exports Group	MP4
Quick Time Movie	.MOV

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1.4 Support Information

The updates and new features that the user receive are dependent on the package or subscription level that the user purchased. The www.aos-hub.com website provides all support documentation, including tutorial videos and support portal.

1.5 Website maintenance

Updates and maintenance for the AOS V3 software are provided via scheduled and unscheduled maintenance. Please review to the Terms & Conditions for AOS V3.

1.6 Mobile application maintenance

Updates and maintenance for the AOS V3 mobile applications are provided via scheduled and unscheduled maintenance. AOS V3 mobile applications are available on the relevant app stores and any update will be provided via standard app updates.

1.7 Using slit lamp cameras

The system has not yet been tested with images captured from newer LED slit lamps. You may notice results vary if you switch between devices, though if you use a single machine your results will remain consistent.

2 Safety



Medical product AOS V3 is CE marked.
AOS V3, CE Class I CE registration number
MHRA registration number: 2021032301196322

FDA Registration

AOS V3, Class I medical device
FDA registration number: 3014329625



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Authorised European Representative:
Medical Device Safety Service (MDSS) GmbH,
Schiffgraben 41, 30175 Hannover, Germany



Please read this document before using the AOS product.
Changes or modifications not approved by Advanced Ophthalmic Systems Ltd could affect the safety and effectiveness of the medical product and will void the system's warranty.



<https://aos-hub.com/support/>

If the user require further information regarding this medical product, please contact Advanced Ophthalmic Systems Ltd.

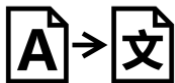


<https://aos-hub.com/support/>

If the user require further information regarding this medical product, please contact Advanced Ophthalmic Systems Ltd.



- GMDN: 65168
- EMDN: V92
- GMN: 5065017576AOS5C Basic UDI-DI
- UDI-DI (GTIN13): 5065017576004 / 5065017576011 / 5065017576028 / 5065017576035 / 5065017576042 / 5065017576059



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3 Logging in to the AOS service

The AOS V3 software is a web-based platform that can be used inside and outside of the clinic. To login into the software please visit www.aos-hub.com and click the login button on the home page.

3.1 Account registration and purchasing

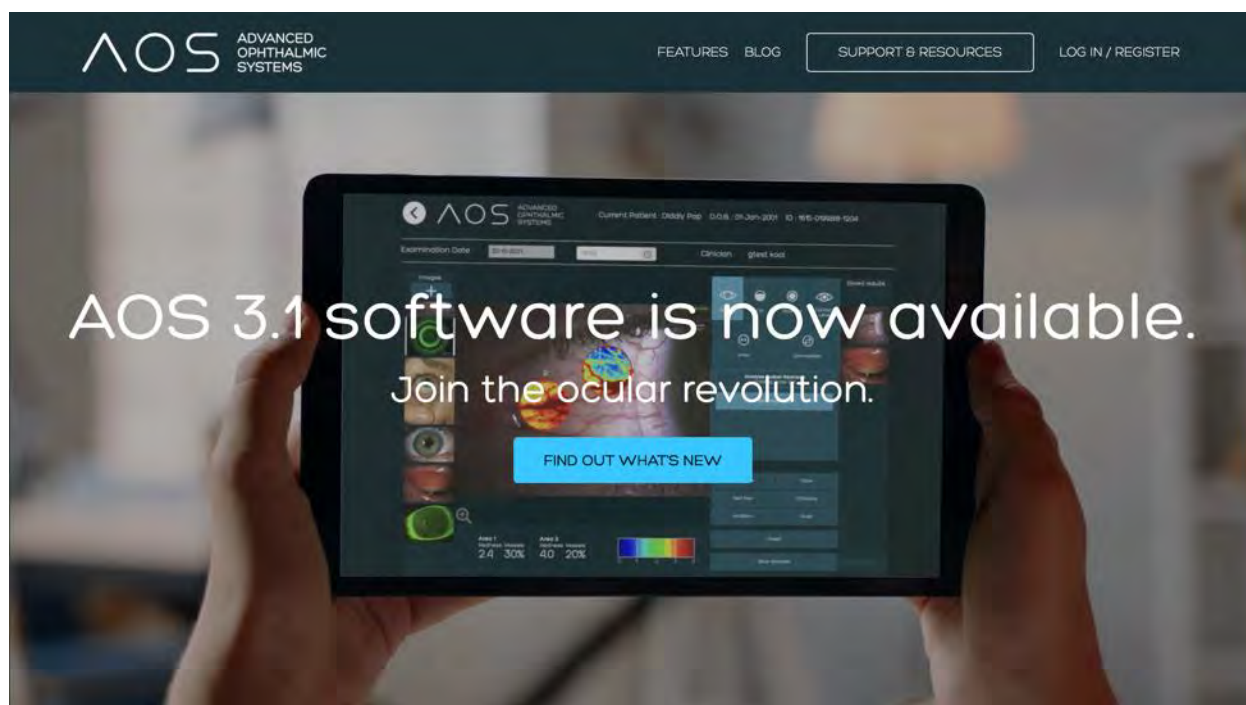
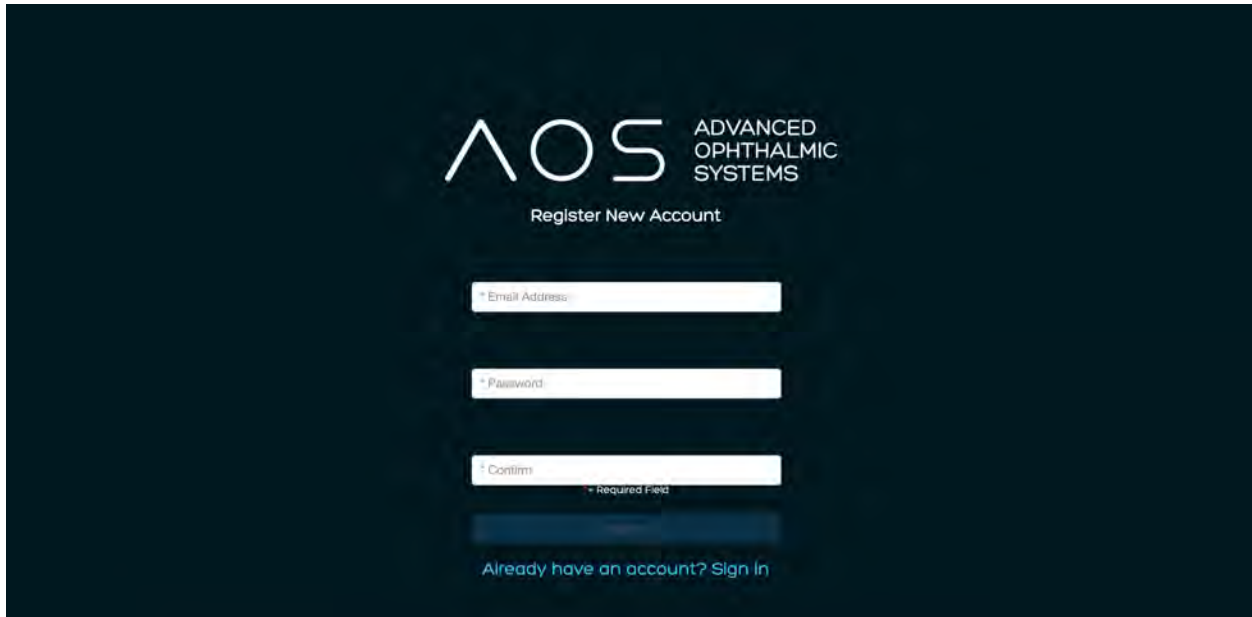


Figure 1. aos-hub.com website.

To purchase access to the AOS V3 online software and mobile applications a user will need to register online via the aos-hub.com website, see figure 1 above. Purchasers will be directed to register a new account and then subsequently purchase their preferred number and types of licenses, see figure 2, 3,4. Once selected the new user will then provide their payment details and have an active account, see figure 5.

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The screenshot shows the 'Register New Account' page for AOS (Advanced Ophthalmic Systems). The page has a dark blue background. At the top, the AOS logo is displayed next to the text 'ADVANCED OPHTHALMIC SYSTEMS'. Below the logo, the text 'Register New Account' is centered. The form consists of three input fields: 'Email Address', 'Password', and 'Confirm'. The 'Confirm' field has a red asterisk and the text '* Required Field' below it. A blue button is positioned below the 'Confirm' field. At the bottom of the form, there is a link that says 'Already have an account? Sign In'.

Figure 2. Register a new account.



The screenshot shows the 'Create New Customer Account' page for AOS (Advanced Ophthalmic Systems). The page has a dark blue background. At the top, the AOS logo is displayed next to the text 'ADVANCED OPHTHALMIC SYSTEMS'. Below the logo, the text 'Create New Customer Account' is centered. The form consists of several input fields: 'Company Name', 'First Name', 'Last Name', 'Username', 'Email' (with a green checkmark next to it), 'Address Line 1', 'Address Line 2', 'Town/City', 'Country', 'Postcode/Zip Code', 'Field (Country)' (with a dropdown arrow), 'Mobile Number', and 'Phone Number'. A 'Select Image' button is located to the right of the 'Phone Number' field. A red asterisk and the text '* Required Field' are located below the 'Phone Number' field. A small profile picture placeholder is visible at the bottom left of the form.

Figure 3. Register a new account (information)

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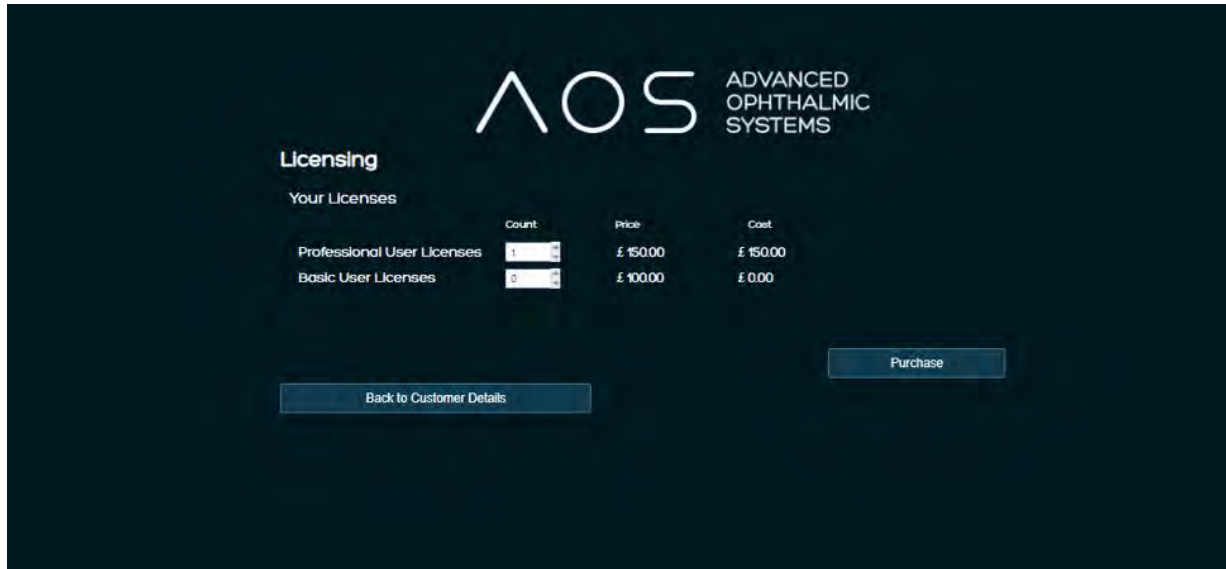


Figure 4. Purchasing preferred number and type of licensing.

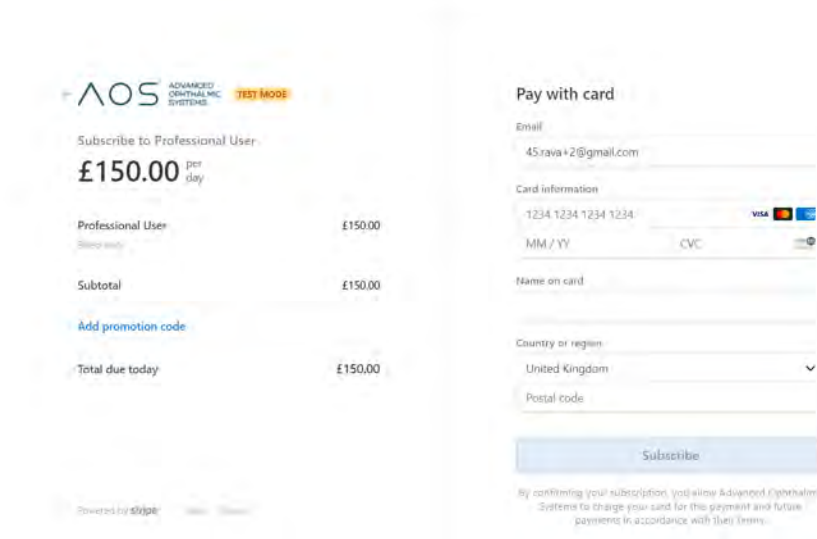


Figure 5. Payment details and account activation.

3.2 Accessing the AOS software and mobile application

Upon purchasing AOS V3 software the user will be directed to a login page where the user will be asked to enter the user username (the email address which the user used to register the user account) and password, see figure 6 below.

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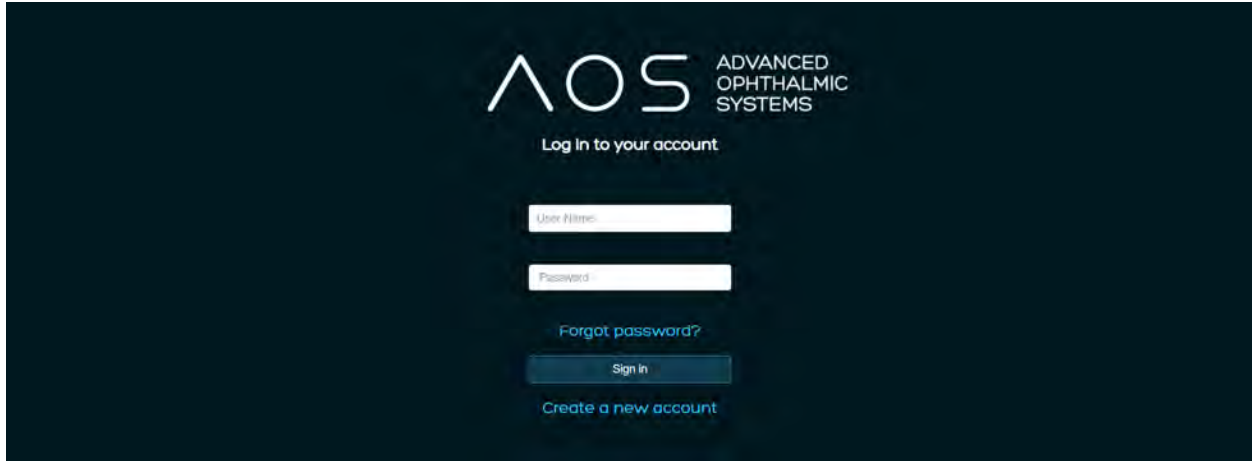


Figure 6. AOS V3 software login page.

3.3 Installation of mobile app – Eye Care Provider

Installation is per account. Once an account has been created and licenses purchased, the user will be sent an email with download and login details for the user AOS Vision mobile app (Provider version). Follow these steps to install AOS Vision to the mobile

Click on the link to the appropriate app store in the email provided to begin the download and automated installation. On first use of the app, the user will be asked to enter a 10-digit code which is in the registration email, see figure 7 below. The user will need to safeguard and keep the pin.

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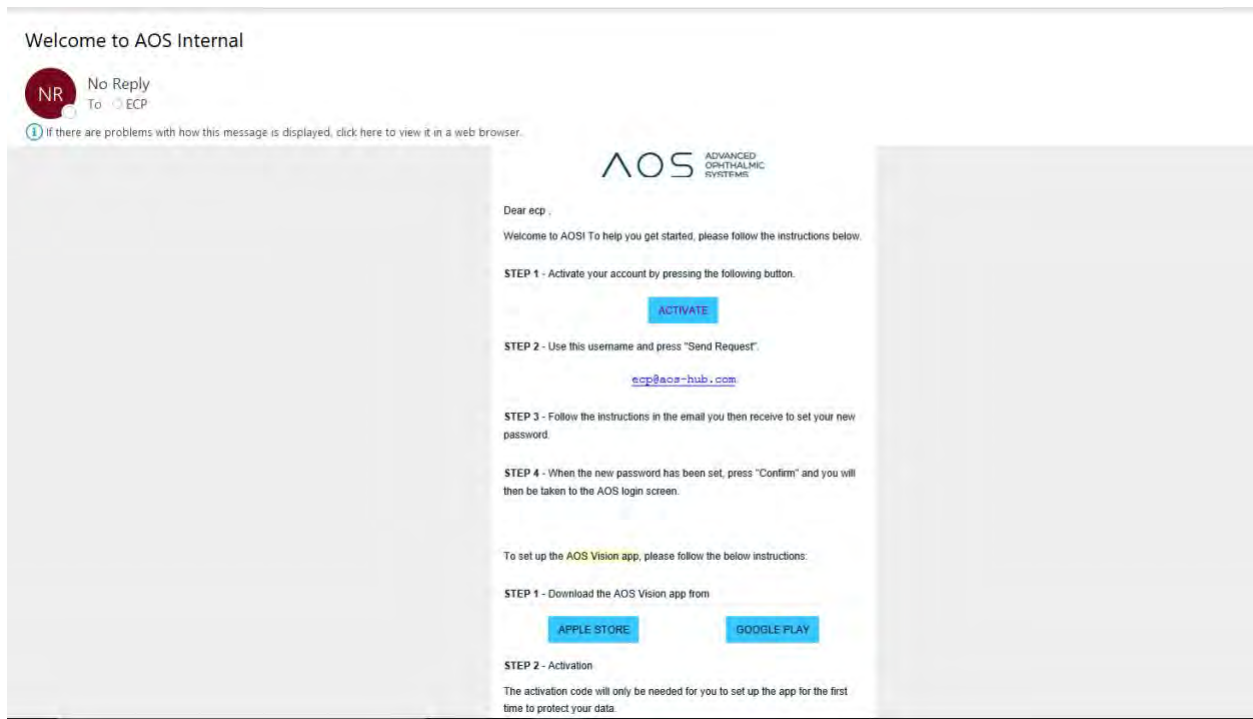
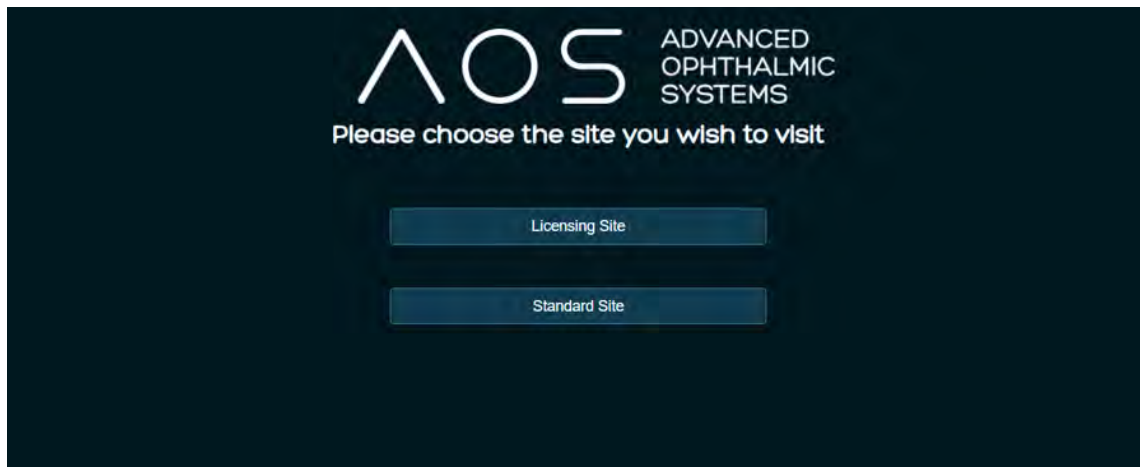


Figure 7. Registration email with 10-digit code.

4 Getting started with the admin functions

4.1 Admin controls

When a new user account is created for a customer that account creator is the global administrator for the system and has all the rights and controls associated. Admin controls include the ability to add and remove users (both pro and basic) as well as control the payment details. When the global administrator logs into their user account via the AOS V3 login they will be directed to choose between the standard site and the licensing site, see figure 8 below.



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Figure 8. Global administrator’s site selection page.

4.2 Licensing site

The licensing site is where the global administrator can continue to edit their user account (and subsequent user accounts under their control). They will have the ability to create new users, adjust payment details, purchase new licenses and reset login details for users. To add or remove licenses the global administrator only needs click on the up or down arrows on the page. See figure 9 below. The number of each associated license on the licensing page reflects the number of licenses available for the user and the associated billing amount.

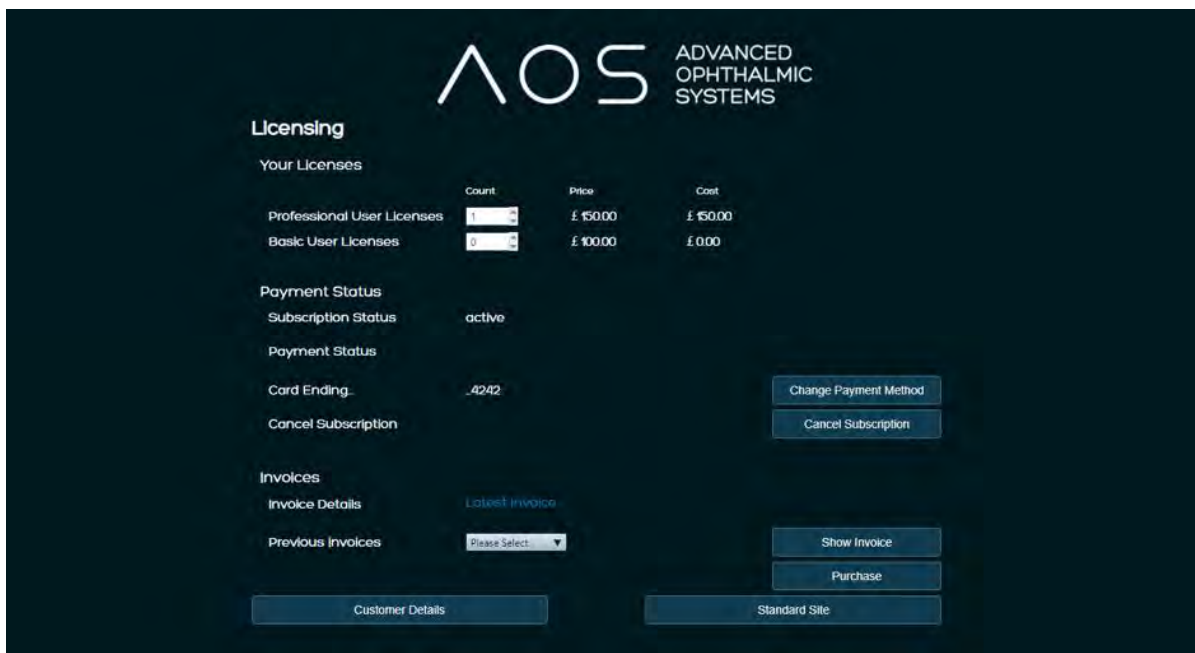


Figure 9. Licensing site.

4.3 Definitions of types of user

A Professional user can use every aspect of the AOS software except for rights associated to the global administrator.

A Basic user can use every aspect of the AOS software but is unable to perform new exams.

A Global admin is responsible for admin of the main customer account and can add/edit/delete groups and users. A Professional and/or Basic user can have global administrator rights.

A local admin is responsible for admin of the group they are in and can add/edit/delete users within this group. A Professional and/or Basic user can have local administrator rights.

4.4 How to add groups

All users within a single account are in the same group by default. The global administrator has the ability to add subsequent groups under their customer account. Groups are defined as a set

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of users who can see a patient database. If the user/global administrator would like for a set of users to see a patient database and test results they must be added to the same group within the software. See figure 10 below.

*****IF A USER IS A GLOBAL ADMINISTRATOR AND HAS MULTIPLE USER GROUPS THEY CANNOT ADD NEW PATIENTS**** This is a system security protocol to ensure each patient is sent to the correct database.

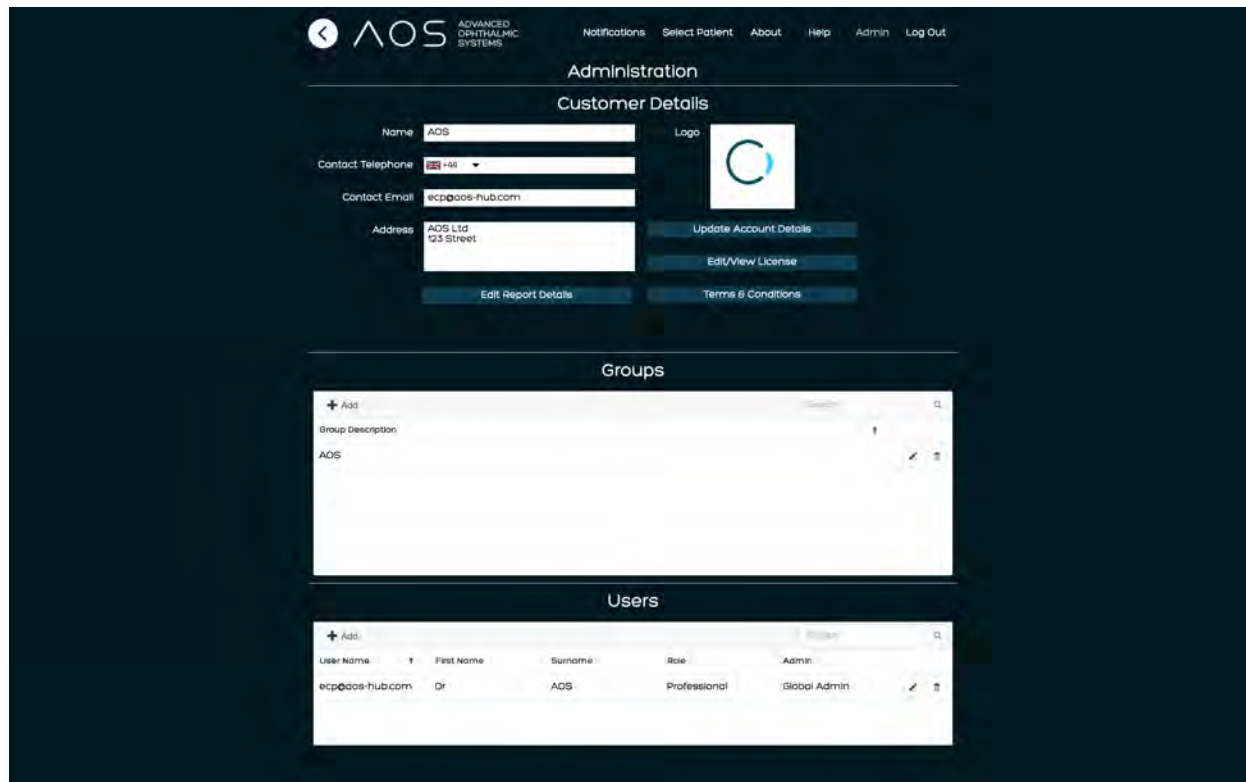


Figure 10. Groups.

4.5 How to add a user

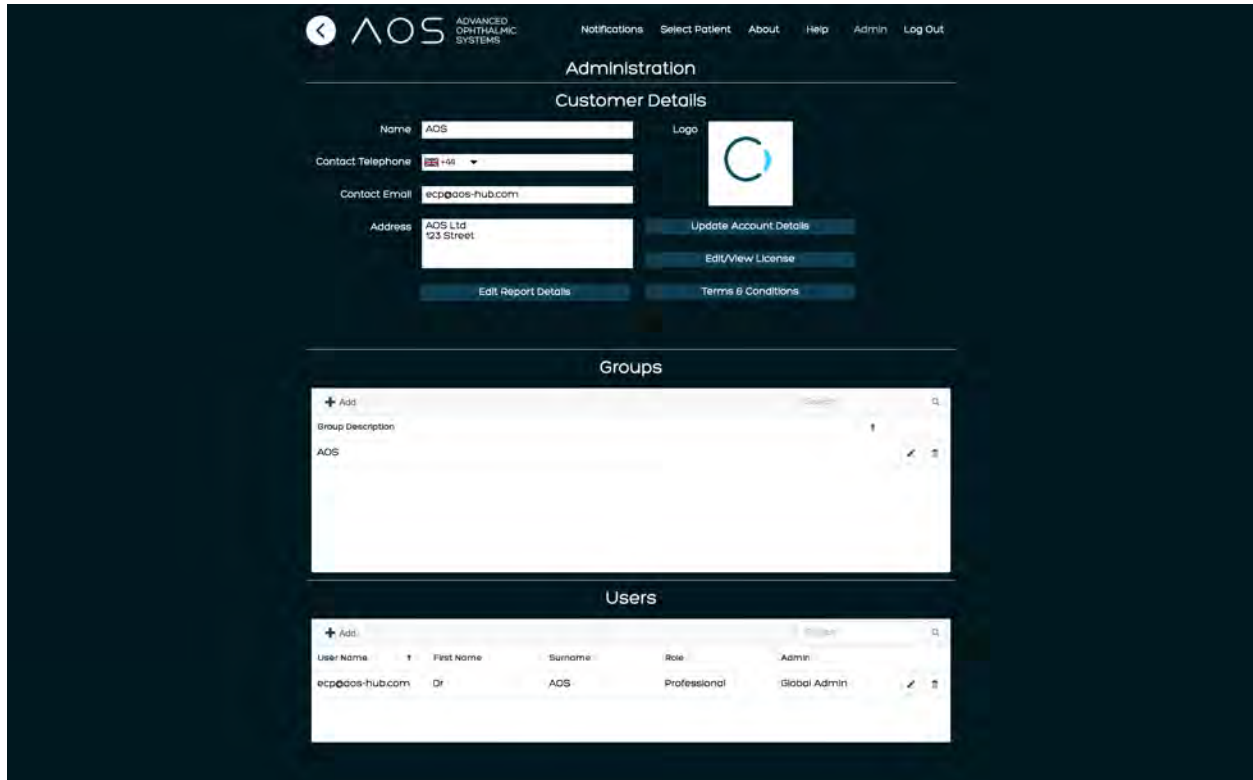
To add a new user (either Pro or Basic) the global (*or local*) admin must visit the licensing site which is accessible via the Edit/view license button in the Admin page. See figure 10 above.

Use the arrow tabs next to the required account (Pro or Basic) to increase the number of users within the user group (if they need additional licenses), see figure 9 above. Click Purchase and Back to AOS home and go to the Admin page, see figure 10 below. The user is now able to add new users.

Once the user has the appropriate number of licenses (Pro or Basic) associated with their account and they return to the Admin control page they can add the users according to their

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needs and responsibilities. To add a user, click on the ADD button in the top left hand corner of the users box and supply the appropriate details.



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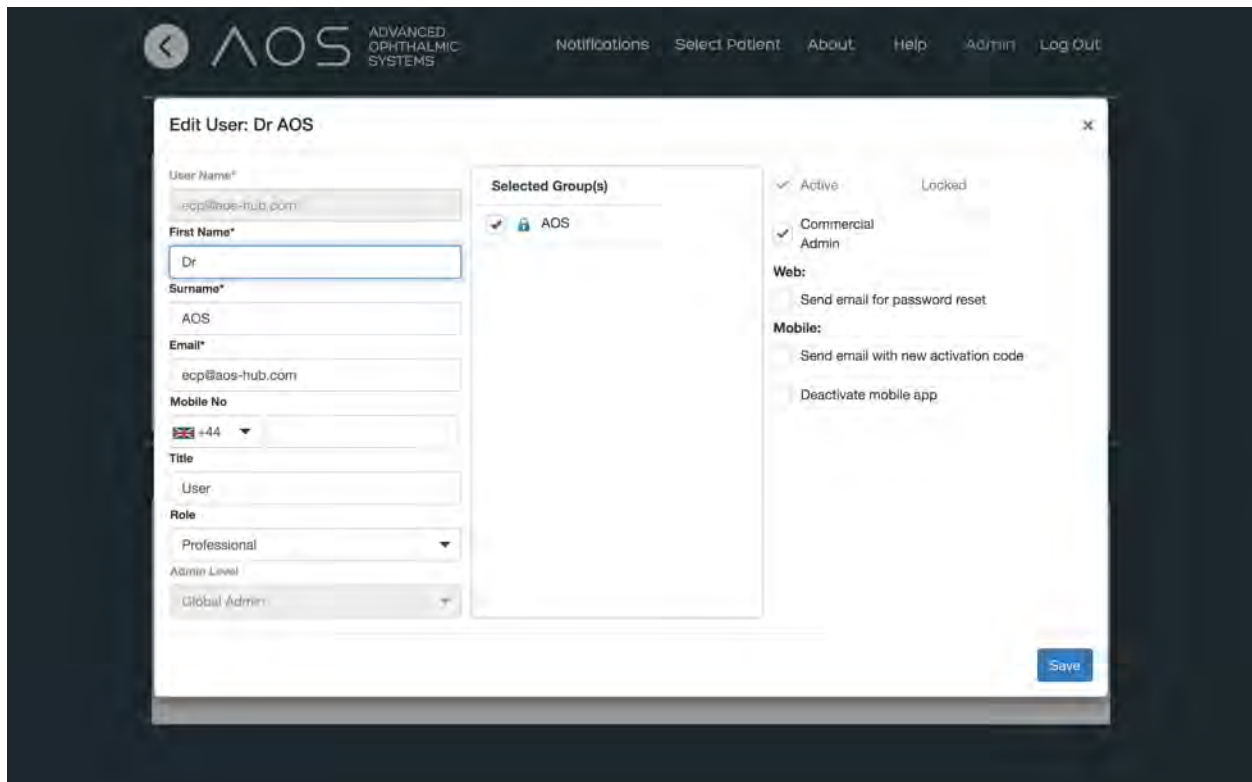


Figure 11-12. Add new users.

4.6 User settings

Username – enter the registered email address in the username field. If an incorrect address is entered into this field, delete the user and add again using the correct email address. **Once accounts are created, they are unable to be deleted, please ensure the details the user enters are correct.**

Role – select either professional or basic user. The role you select effects what the user can do within the software.

Admin level – if the user would like the user to be able to add new users select local admin.

Selected Groups – if there is more than one group within the user organisation the admin will need to select the group the user is to be part of. User groups define what patient data base the user can see (or cannot see). AOS recommend contacting support if the user is in need of multiple groups.

When the admin adds a new user, the Active box will be checked as default. If the user wishes to deactivate the account for a period of time, un-check this box.

Commercial admin – if this box is checked, the user will be able to purchase new licenses for their group.

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Send email with new activation code – if this box is clicked and confirmed for any user (pro, basic and patient) the user will be supplied an email with new mobile app login instructions. The user must click save for this to take effect.

Deactivate mobile app – When clicked and confirmed terminates the mobile account related to the user (pro, basic and patient) and they will no longer be able to use the mobile app. The user must click save for this to take effect.

Send email for password reset (ECP) – If the user enters the incorrect password 3 times they will be locked out of their account. To activate the account and reset the password, the admin for that user will need to un-check the Locked box in the user page and click the Password reset button. See figure 13 below.

New activation code (patient) - If a patient forgets the login PIN for the AOS Vision mobile app and/or needs a new activation code, they will need to contact the eye care professional (ECP) they are registered with. The ECP (admin, pro or basic user) will then need to open the patient record and Request Patient Image. The patient will then be sent a new email and/or text message with their PIN and a new activation code.

The screenshot displays the 'Edit User: Dr AOS' interface. The form contains the following fields and options:

- User Name***: ecp@aos-hub.com
- First Name***: Dr
- Surname***: AOS
- Email***: ecp@aos-hub.com
- Mobile No**: +44
- Title**: User
- Role**: Professional
- Admin Level**: Global Admin
- Selected Group(s)**: AOS
- Active**:
- Locked**:
- Commercial Admin**:
- Web:**
 - Send email for password reset:
- Mobile:**
 - Send email with new activation code:
 - Deactivate mobile app:

A blue 'Save' button is positioned at the bottom right of the form.

Figure 13. Add new users.

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5 Getting started with AOS

5.1 Application basics

5.1.1 Starting a patient session – existing patient

To start a session with an existing patient, log into the web service and select the preferred patient from the database. Upon clicking the arrow on the right-hand side of the 'Select a patient' field the user will be presented with a dropdown list of all the user patients. Click on the patient and the user will be taken to their patient summary page. Alternatively, the user can start typing the name of the patient in the empty field underneath 'Select a patient' and an intelligent search of the database will take place, see figure 14 below. The patient list the user sees in the menu is directly related to the group they are in (see admin controls).

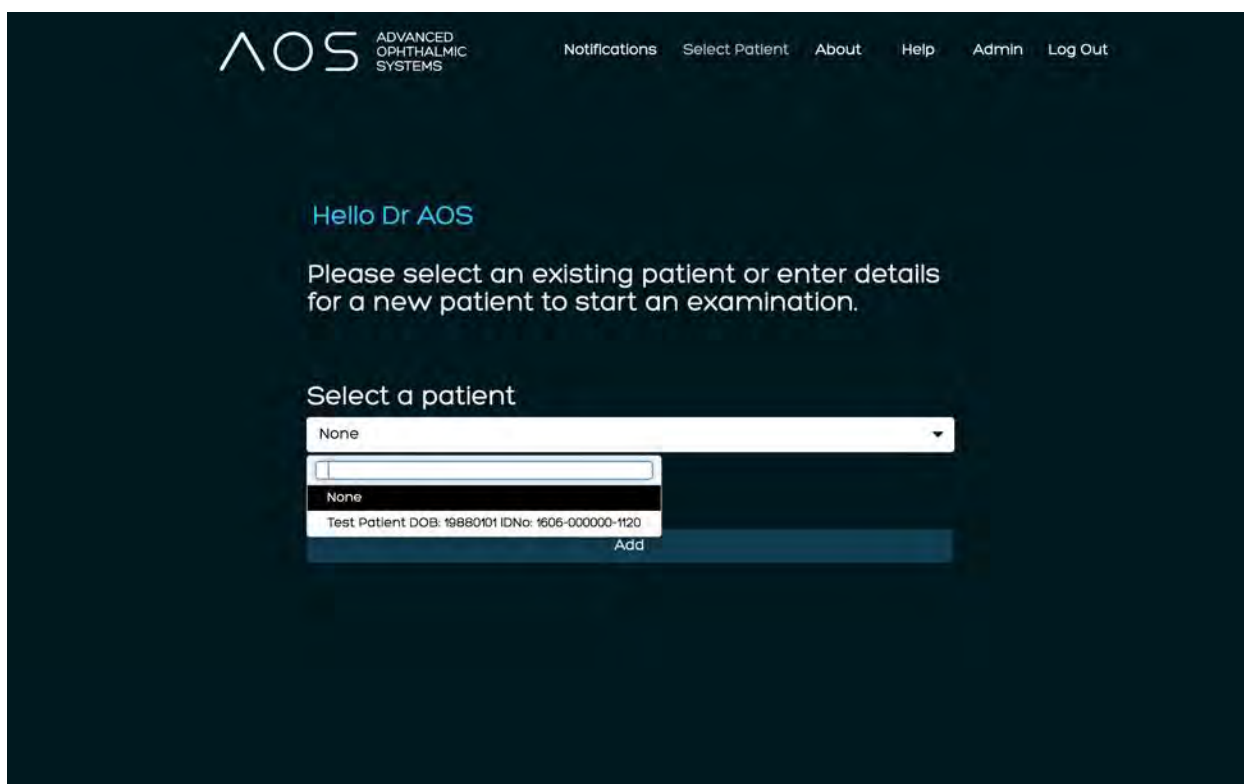


Figure 14. Selecting existing patient.

5.1.2 Starting a patient session – new patient

To start a new patient session with a new patient log into the web service and choose “add a patient”, see figure 15 below. Enter the patient details into the empty fields. There are 6 required fields: title, first name, surname, date of birth, gender, email, see figure 15 below. If the new patient is a dependent of an existing patient and their contact email address is the same as this existing patient, the user will need to enter a unique username which they can be

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identified by. FirstnameSurnameDOB is our suggestion for this username, i.e. JohnSmithYYYYMMDD. To add a unique user name click on the alternative user name text and an additional text field will appear.

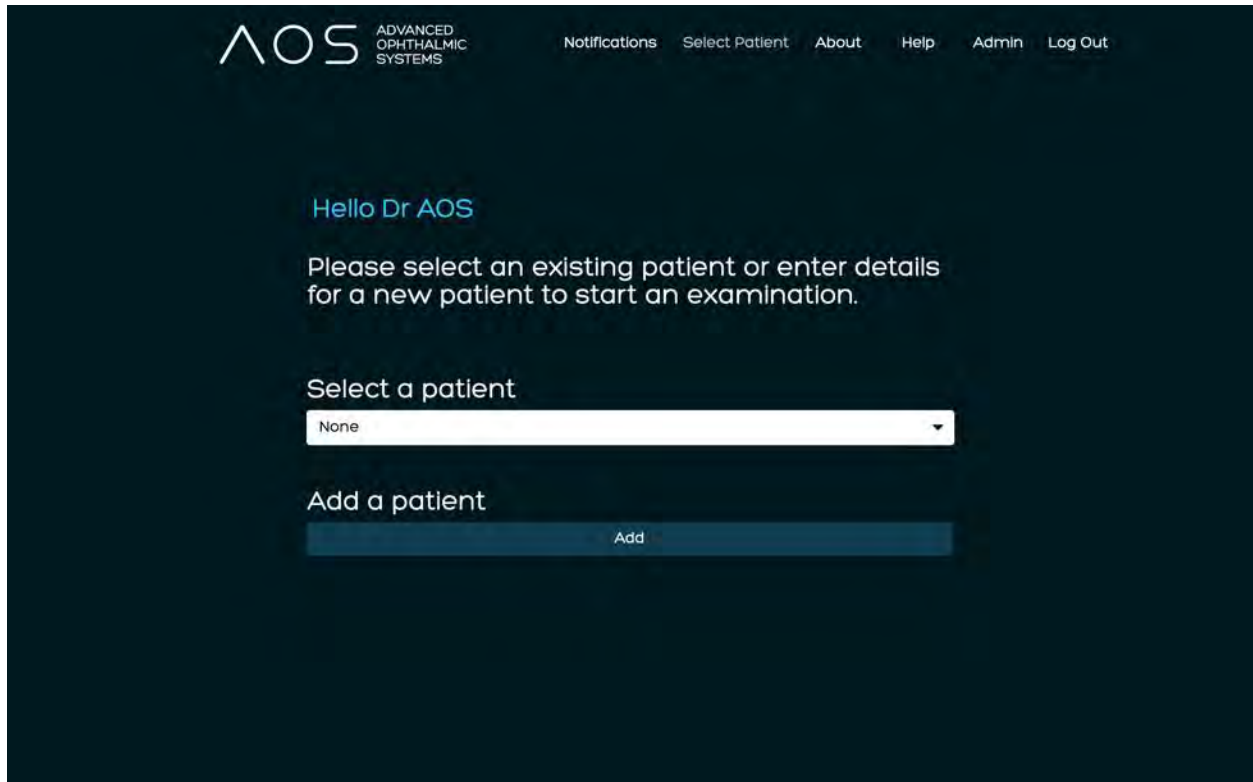


Figure 15. Selecting adding a new patient.

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The screenshot shows the 'Patient Record' form in the AOS V3 system. The form is set against a dark blue background with white text and input fields. At the top left is the AOS logo and 'ADVANCED OPHTHALMIC SYSTEMS'. At the top right are navigation links: 'Notifications', 'Select Patient', 'About', 'Help', 'Admin', and 'Log Out'. The form title 'Patient Record' is centered. The 'Patient ID' is '1606-000000-1120'. The form contains the following fields: 'Title' (Mrs), 'First Name' (Test), 'Surname' (Patient), 'Date of Birth' (01-01-1988) with an 'Age' field (34), 'Gender' (Female), 'NHS ID', 'MRN', 'Address line 1', 'Address line 2', 'Town/City', 'County', 'Country', 'Postcode / Zip code', and 'Phone Number' (+44 7123456678). There is a 'Note' field with the placeholder 'Add a note about the patient'. At the bottom, there are 'Email' and 'Confirm email' fields (both patient@aos-hub.com) and a 'Save' button. A small note at the bottom states: 'Saving a new email address will create a new record. Once created it cannot be changed.'

Figure 16. Adding a new patient's details.

When all required fields have been complete, click 'Save' and the user will be taken to the Patient Summary page. The users are now ready to start a session. See figure 17 below.

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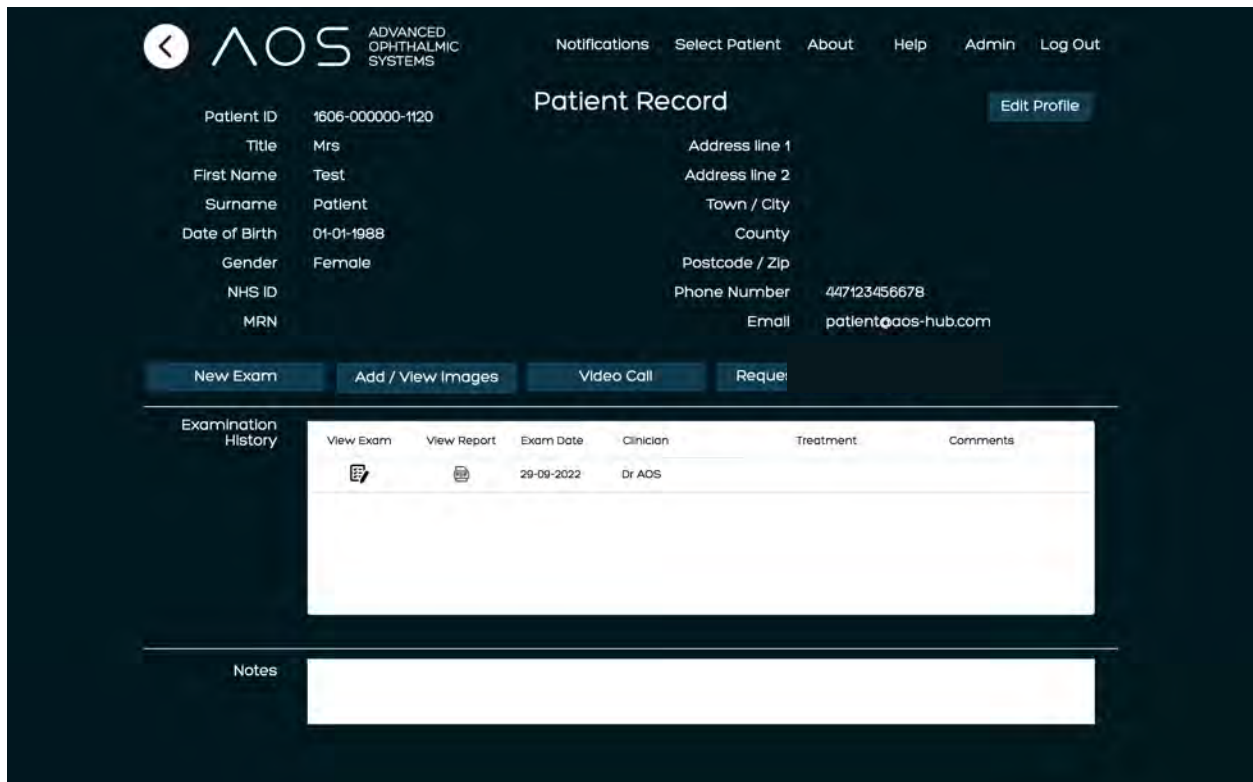


Figure 17. Patient Summary Page.

5.1.3 Choosing the user images to analyse

Before the user can start an exam, they will need to select the images or videos to analyse. In the patient summary page, click the 'Add/View Images' button. This will take the user to the media gallery for this patient. See figure 18 below.

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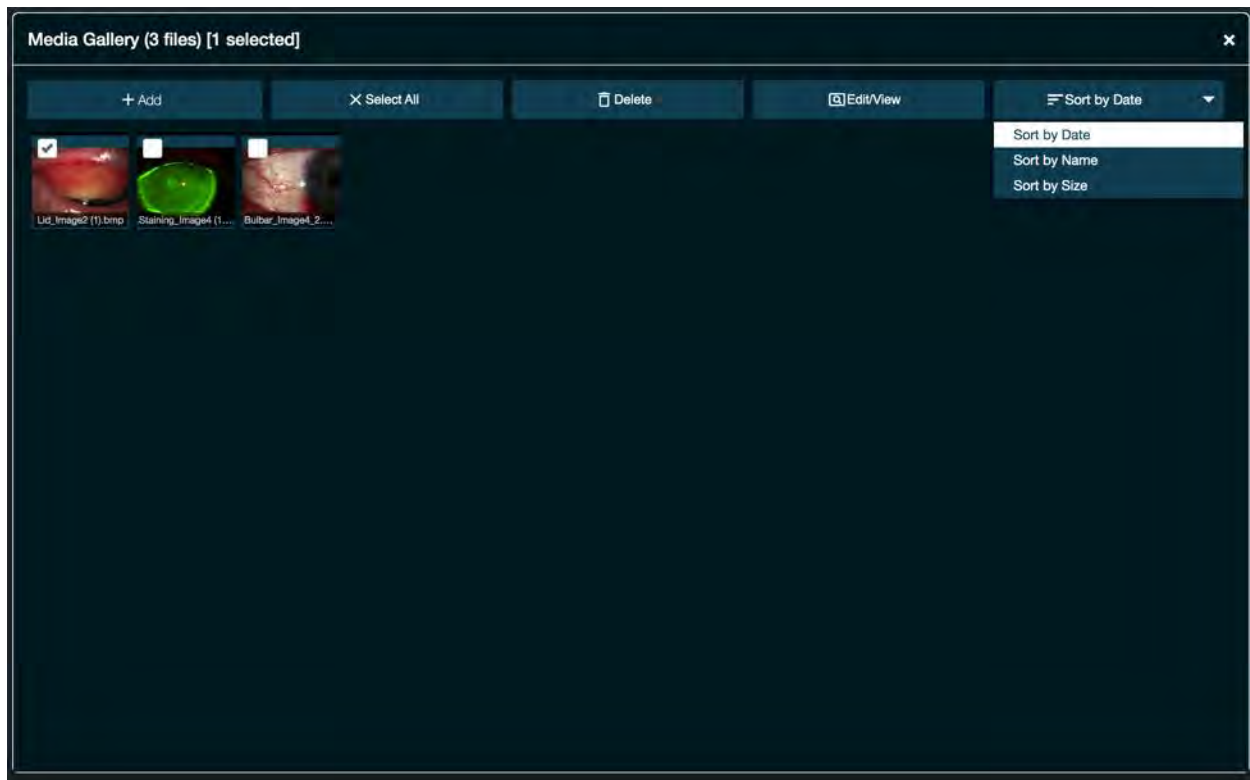


Figure 18. Media gallery for a specific patient.

The add/view images page contains all media related to that patient. Every image or video taken by the AOS Vision mobile app, either by the patient or by the ECP, will be transferred and stored in this location. Media from an alternative source can be added by clicking the '+ Add' button. This will open a file picker and the file of choice can be selected and added to this page.

The media gallery can be sorted by date, name and file size using the drop down menu.

Note: To transfer images from the mobile app, see section 14.

5.1.4 Editing an image

Select an image and click the 'Edit/View' button to edit the image. The following tools can be used:

- Rotate left
- Rotate right
- Crop the image
- Save the image
- Mark as OD/OS

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Note: saving an edited image will create a copy and the original image will still be saved. Use the cancel button to remove any editing before saving.

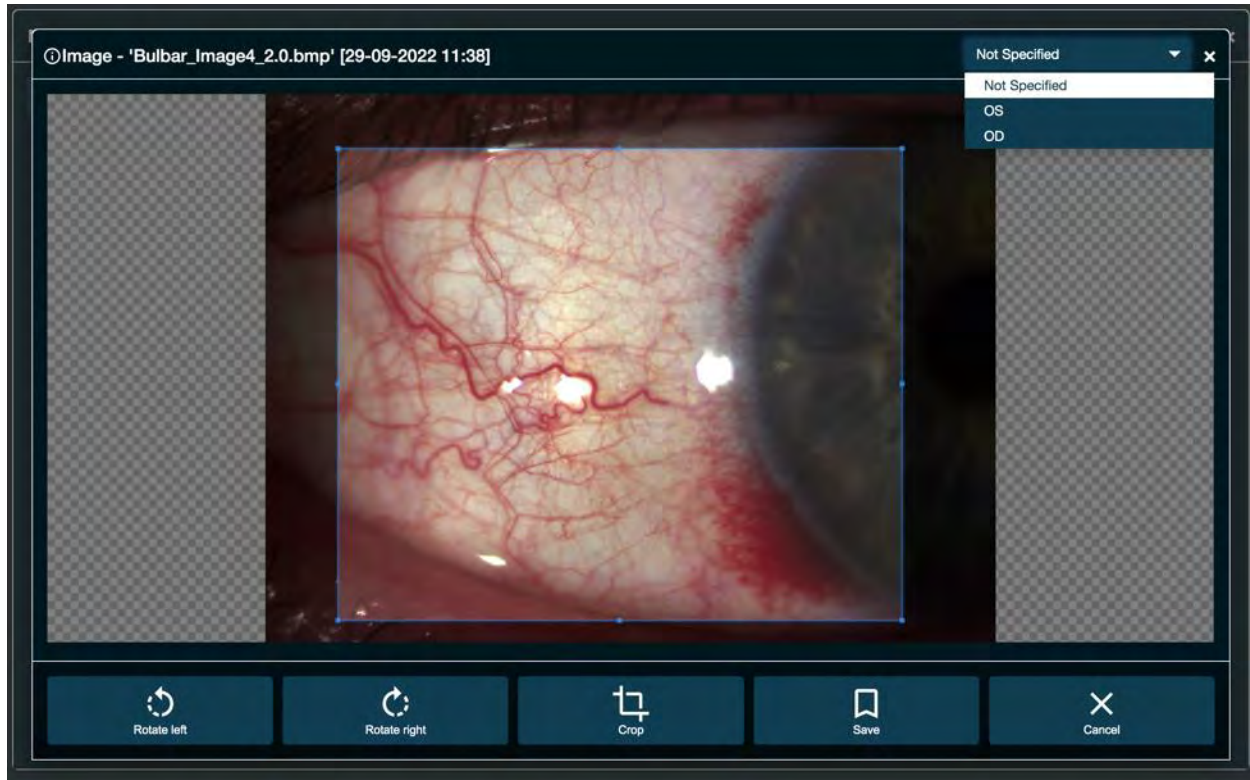


Figure 19. Editing an image.

5.1.5 Editing a video

For contact lens analysis, the user may want to capture still images from a video. Select the video to edit and click the 'Edit/View' button. The user can then use the following tools to capture the desired still image:

- Play/pause
- Stop – this moves the playback position to the beginning of the clip
- Change the playback speed to half speed, quarter speed, 1/10th speed
- Move frame by frame
- Capture still image

Note: a still image can only be captured when the video is paused. The new image will be saved to the media gallery.

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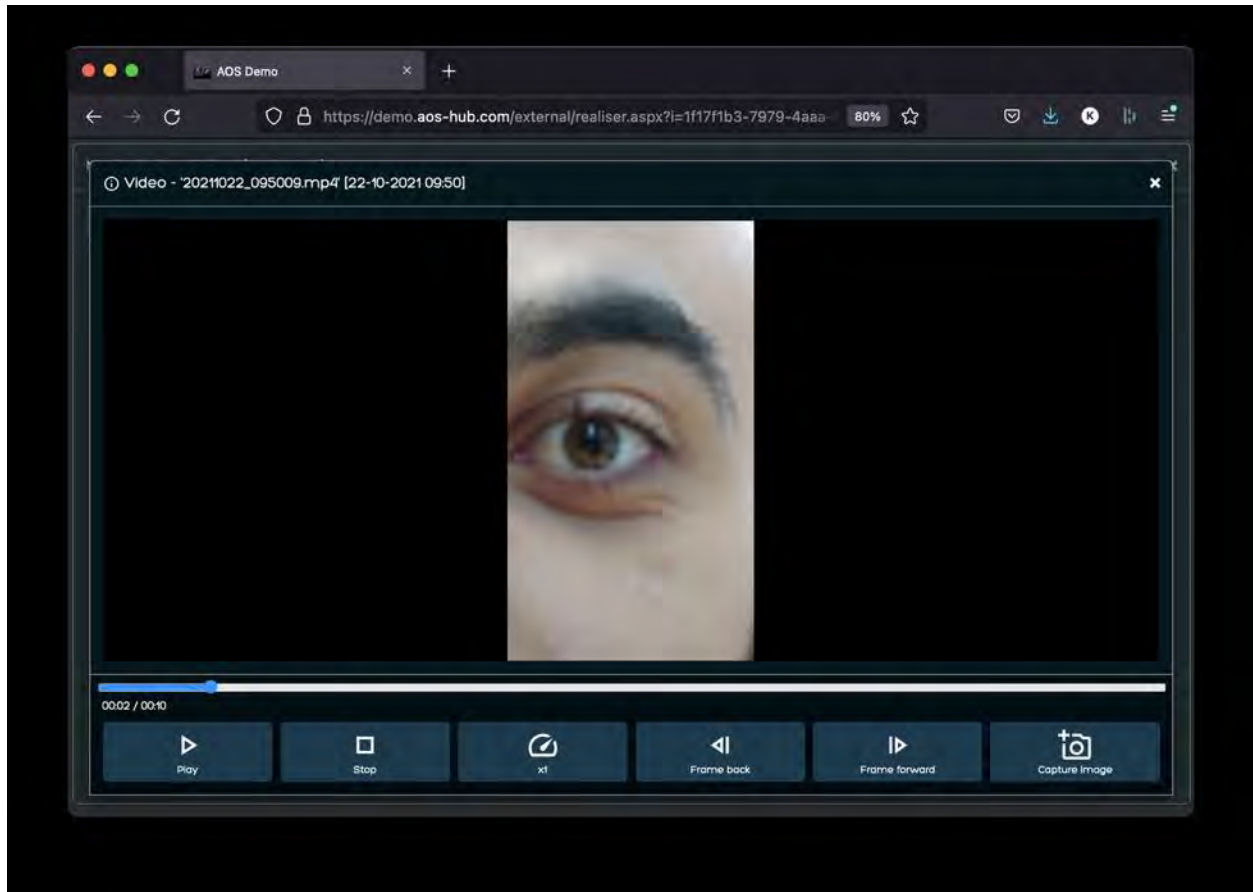


Figure 20. Editing a video.

5.1.6 Deleting unwanted images

To remove media from the gallery, the user selects the images/videos they wish to delete and clicks the 'Delete' button on the media gallery banner. A pop up will appear asking the user to confirm, click 'Yes' to delete and 'No' to return to the media gallery. Once the image is deleted it will be removed completely from the AOS system. See figure 21 below.

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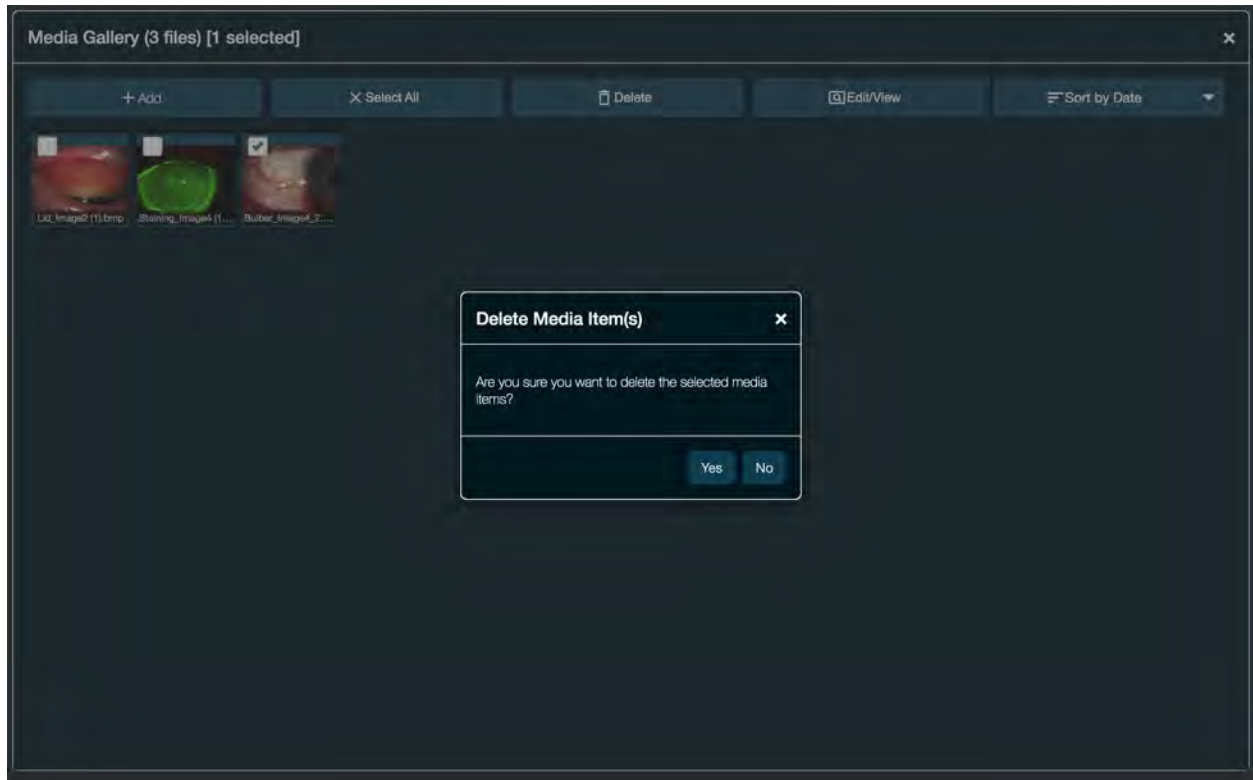


Figure 21. Delete image.

5.1.7 How to start an exam

To start an exam, follow these steps:

- From the patient summary page, select the New Exam button.
- Select the '+' button to open the media gallery

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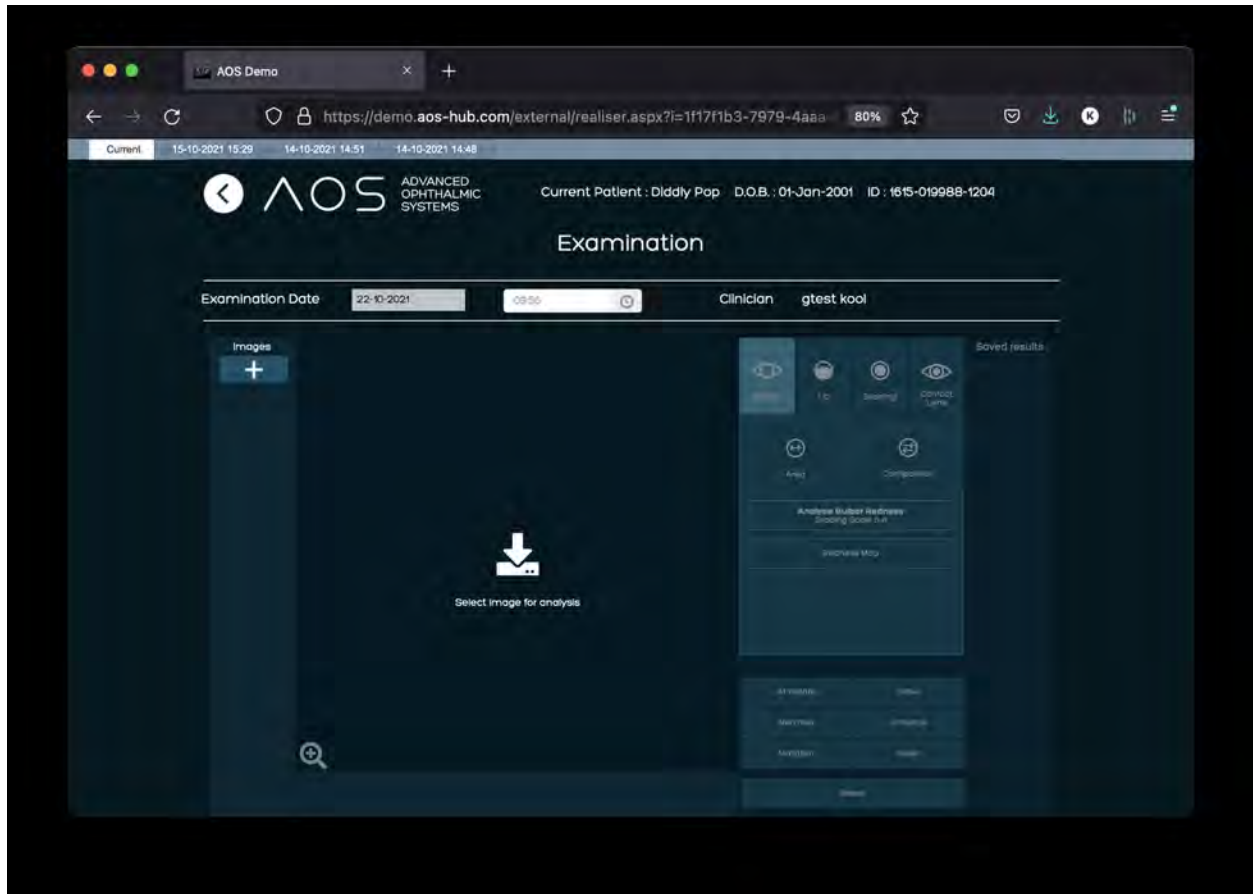


Figure 22. Starting a new exam.

- Select the images to analyse by clicking the check boxes
- Click the 'Use selected media' button to start the exam

Note: videos cannot currently be imported into the exam page for analysis.

Users can also add new images from the device's file storage at this stage. To do this open the media library from the exam page by clicking the big '+' button. Then select '+ Add' and follow the steps to add an image. The images can then be selected to be used in the exam but the original will not be saved to the media gallery.

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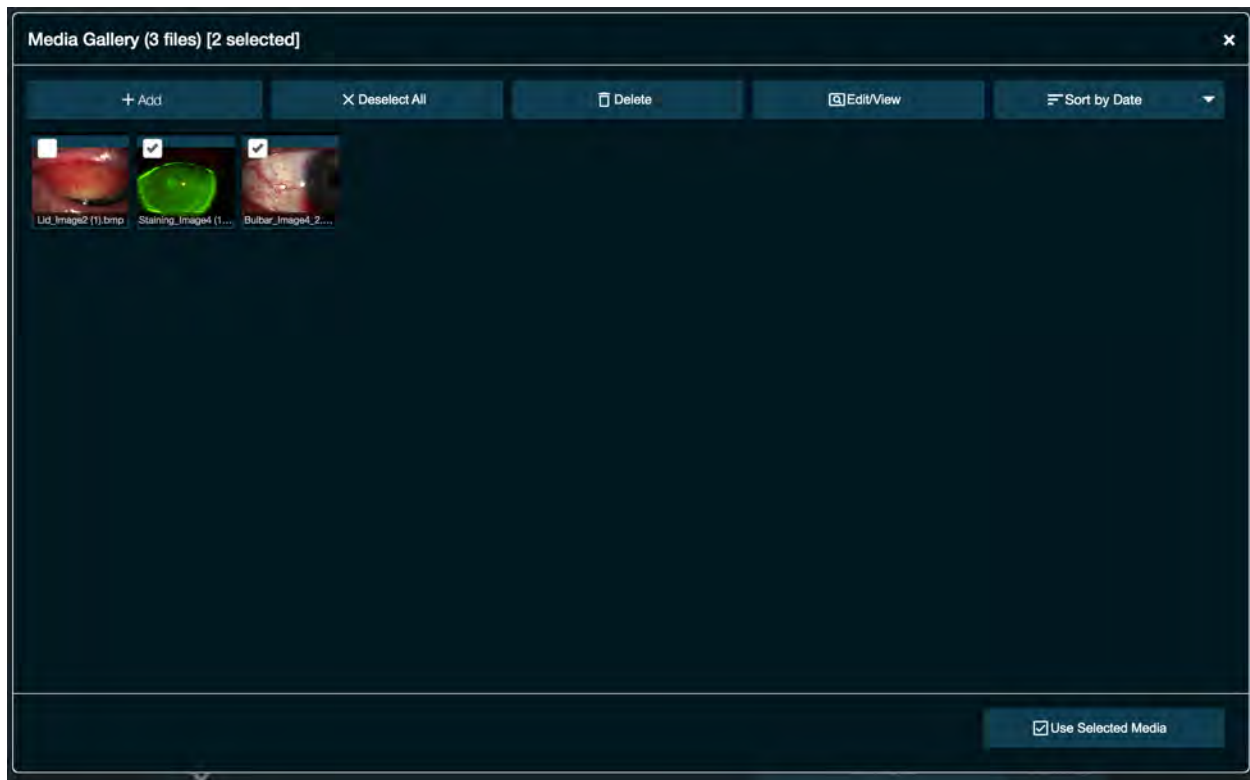


Figure 23. Selecting images to be analysed.

All images selected from the media gallery will appear in the left-hand column of the analysis screen. Click on the image to be analysed and it will appear in the main screen, see figure 24 below.

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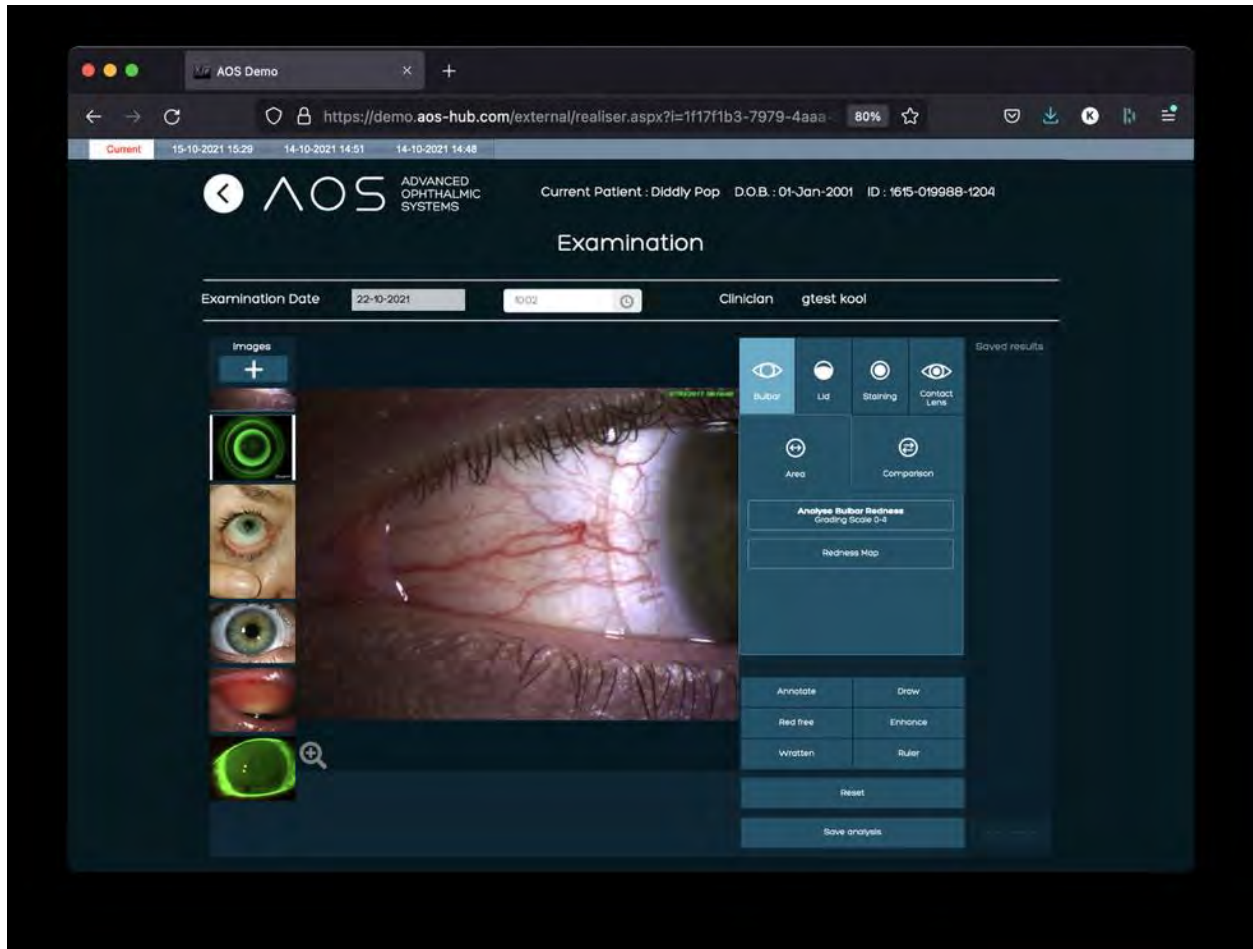


Figure 24. New Exam. Image to be analysed on the main screen.

5.1.8 How to use analysis tools

When the mode (Bulbar, Lid or Staining) has been selected, the user then clicks on the 'Area' button followed by the activation button which appears below ('Detect Staining' in Staining mode; 'Detect lid redness' in Lid mode; 'Analyse Bulbar Redness' or 'Redness Map' in Bulbar mode). The image in the main analysis screen has now been activated and the drawing can start, see figure 25-26 below.

There are two options available:

- Left click the user mouse to add the user's first anchor point, release and continue to drop anchor points by left clicking each time. Left click on the user starting point to complete the area of analysis.
- Alternatively, when the first anchor point has been dropped, the user can hold the left button of the mouse down and trace the area of interest, completing the drawing by returning to the first anchor point and releasing the left button on the mouse.
- An anchor point can also be dragged around the image to increase accuracy.

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- To correct an error or start over, click outside of the area and the user will be prompted to start over.

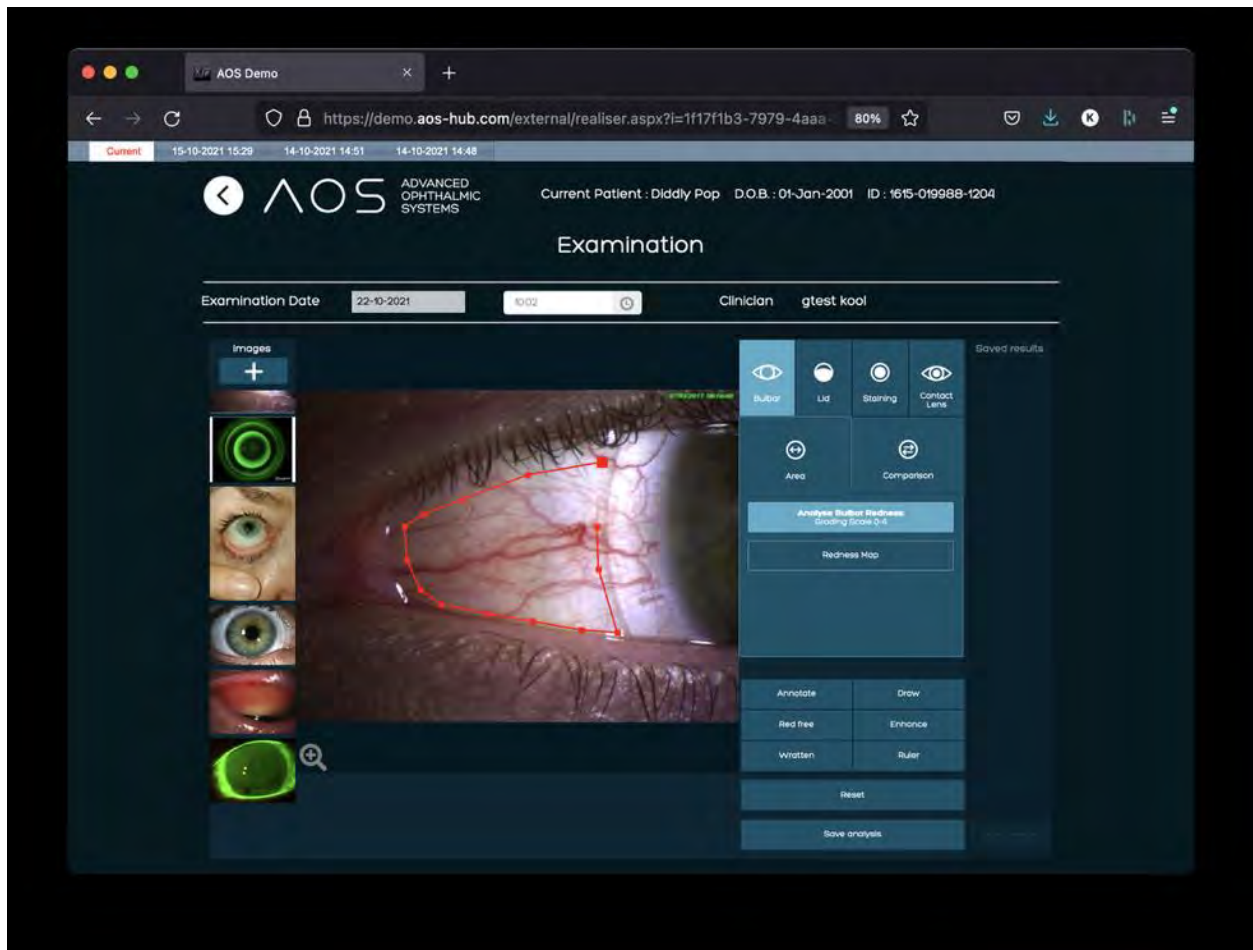


Figure 25. Drawing an area in bulbar function.

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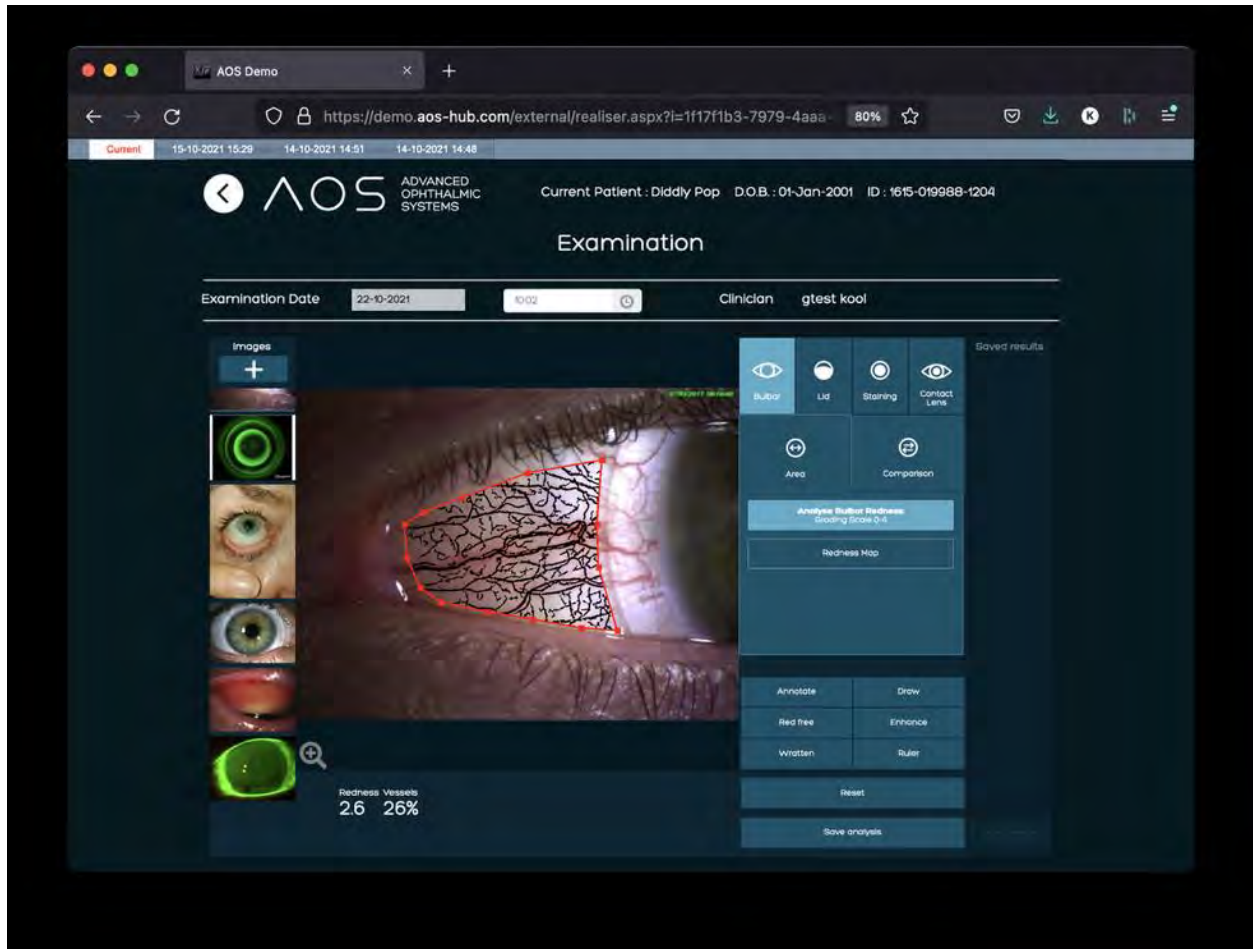


Figure 26. Area in bulbar function.

5.2 RESULTS PANEL

Results from the analysis are displayed automatically in the panel below the main analysis screen. See figure 26 above.

5.3 Saving the user analysis

When the analysis of an image is complete the user hits the 'Save analysis' button and the analysed image, along with the results, are saved and will be added to the report. This image will now appear in the 'Saved results' panel to the right of the screen. See figure 27 below.

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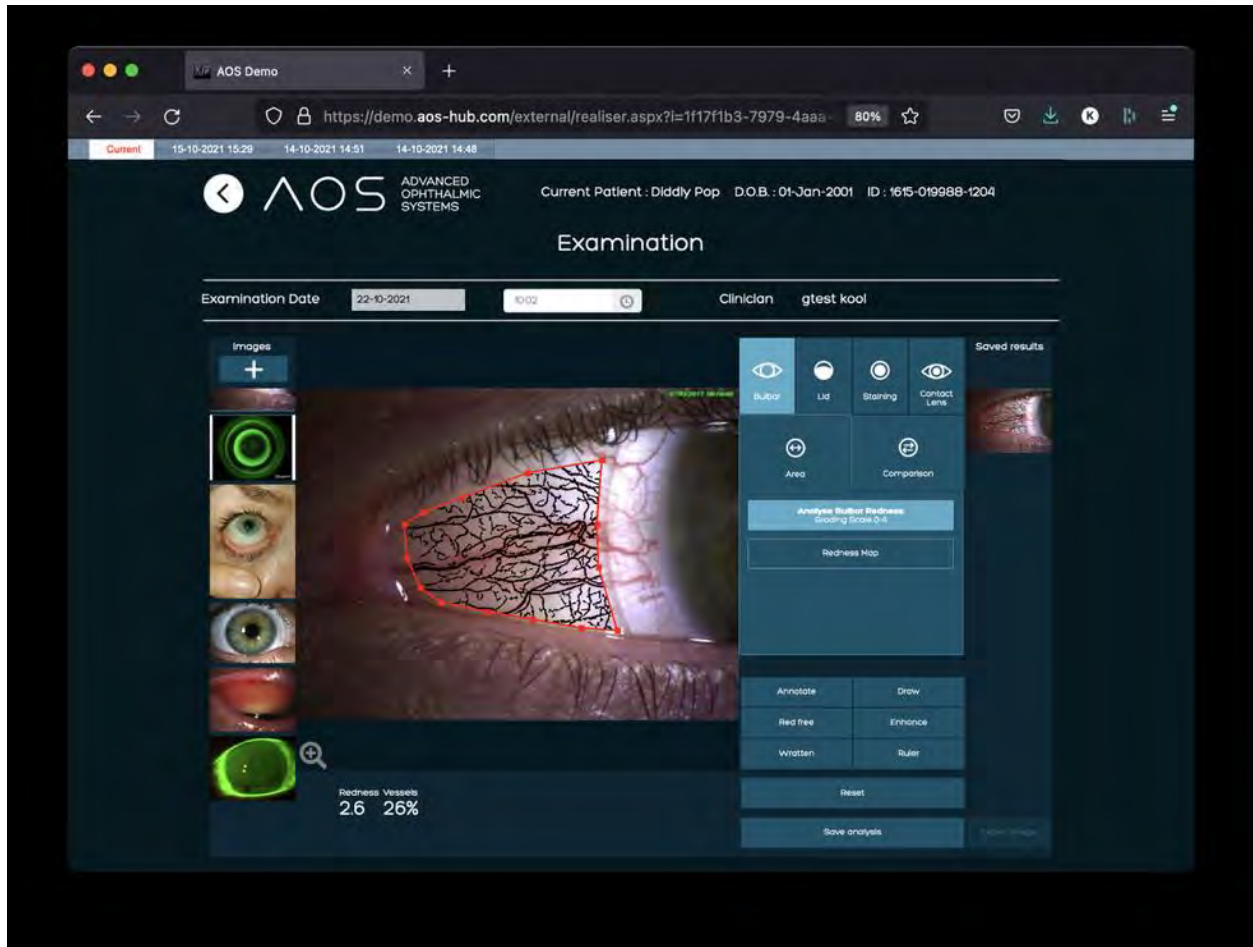


Figure 27. Saved results.

5.4 Exporting an image

To export images from the saved results panel, follow these steps:

- Select the image from the right hand panel (only one image can be selected at a time)
- The rest of the screen will become inactive
- Click the 'Export Image' button
- The image will download to your device as a .jpeg
- Select a new image to analyse from the left hand image column

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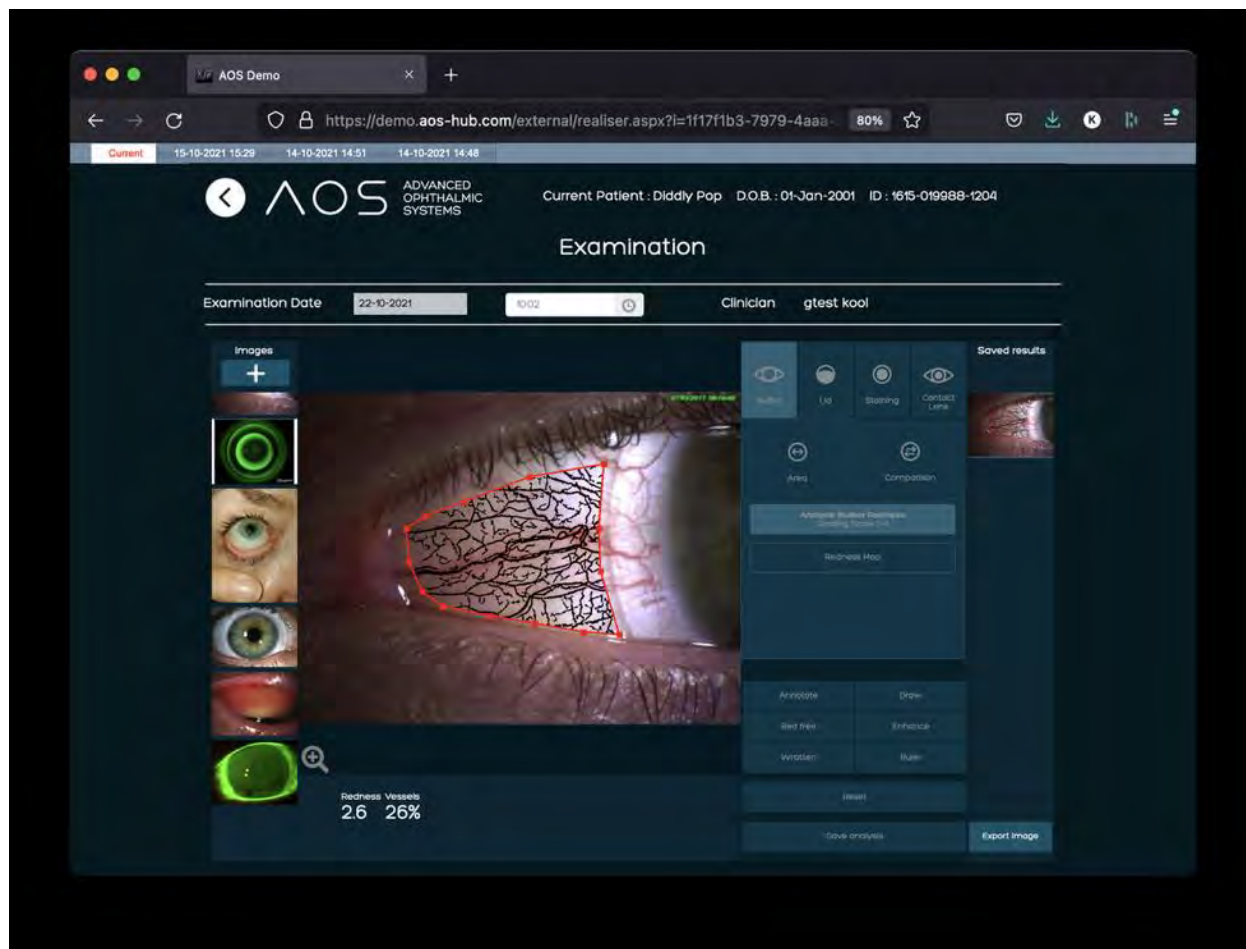


Figure 28. Export image.

6 Reporting

6.1 How reporting works

Reports are built with every patient analysis session and are accessible from the patient summary page. As well as the analysis results, the report contains any notes made in the 'Comments' and 'Treatment pathway' fields, and annotations made to the image.

Note: only analyses that have been saved to the saved results column will be included in the report.

6.1.1 Generate a report from a session

When a patient session is complete, the user can create a report by following these steps:

- Click the 'Generate Report' button at the bottom of the screen
- All images from the saved results column will be selected automatically
- The user can deselect images they do not want to be included

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- When the correct images are selected, click the 'Generate report' button
- Select the PDF icon to view the report in a new browser tab
- To store the report in the patient file, select 'Save and Finish' to complete the exam

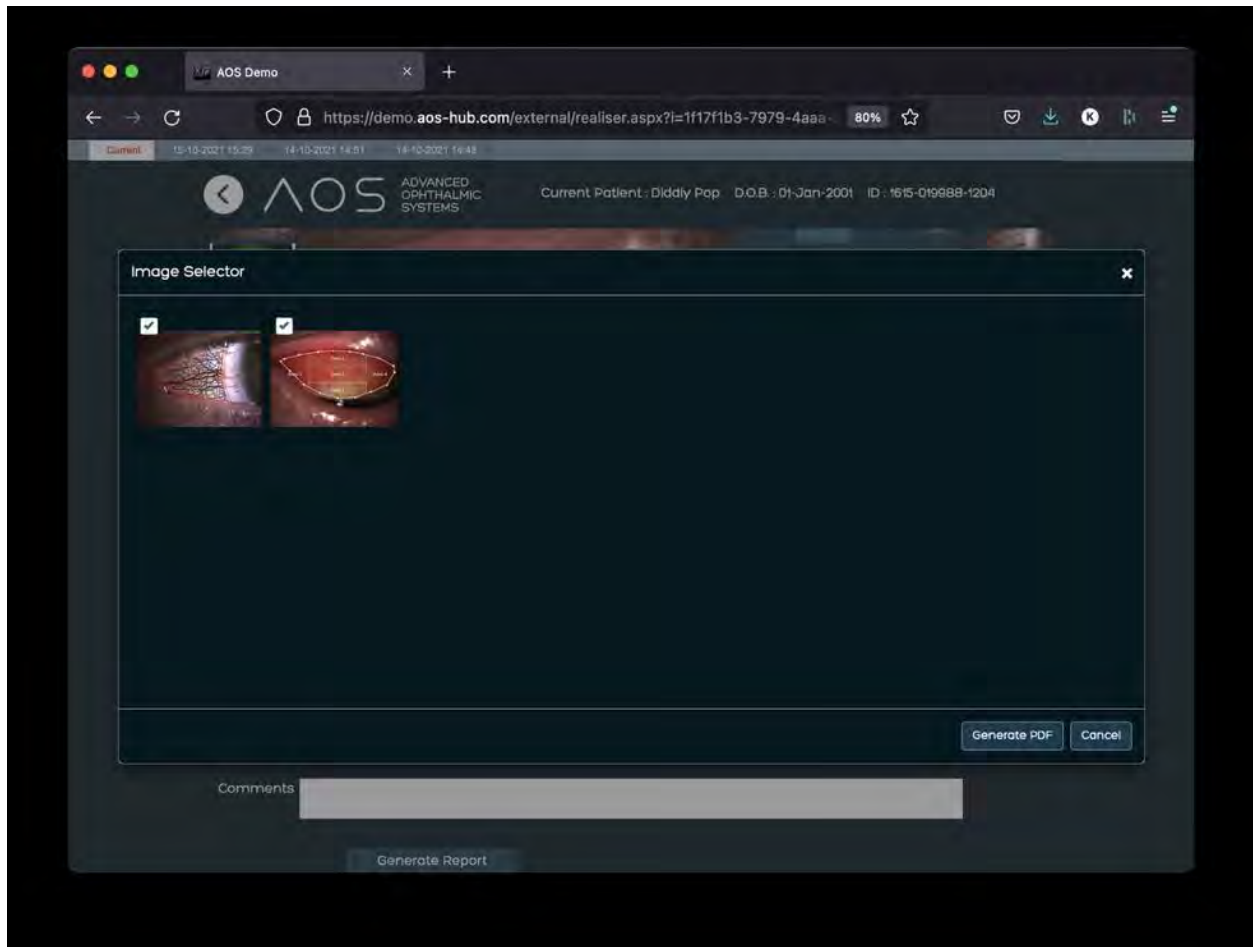


Figure 29. Generating a report

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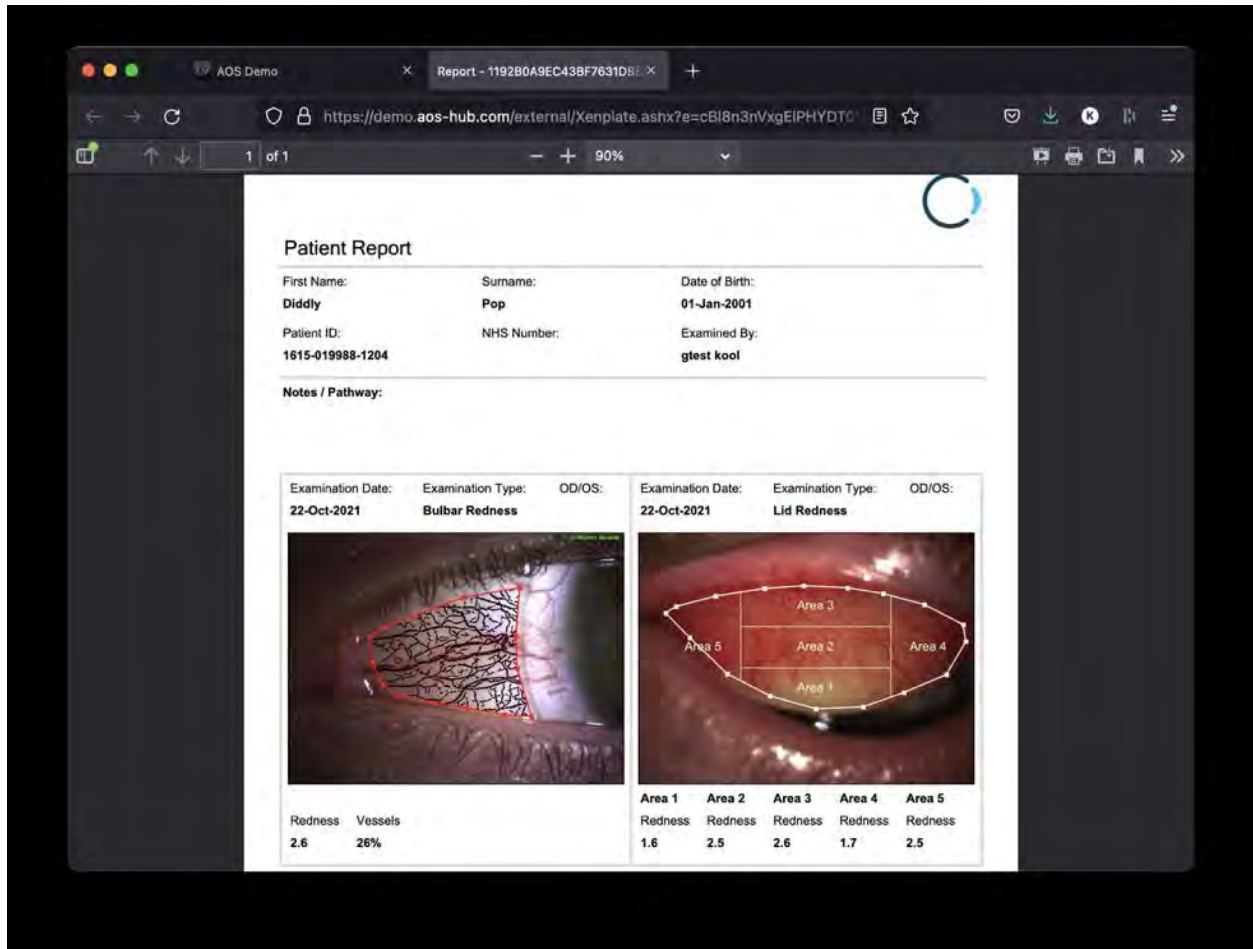


Figure 30. Viewing the PDF in a new browser

6.1.2 Viewing previous reports

The analysis from the last session, along with all previous sessions, are stored in the 'View Exam' column of the Patient Record screen. Reports can be opened directly into a new tab from the 'View Report' column, see figure 31 below.

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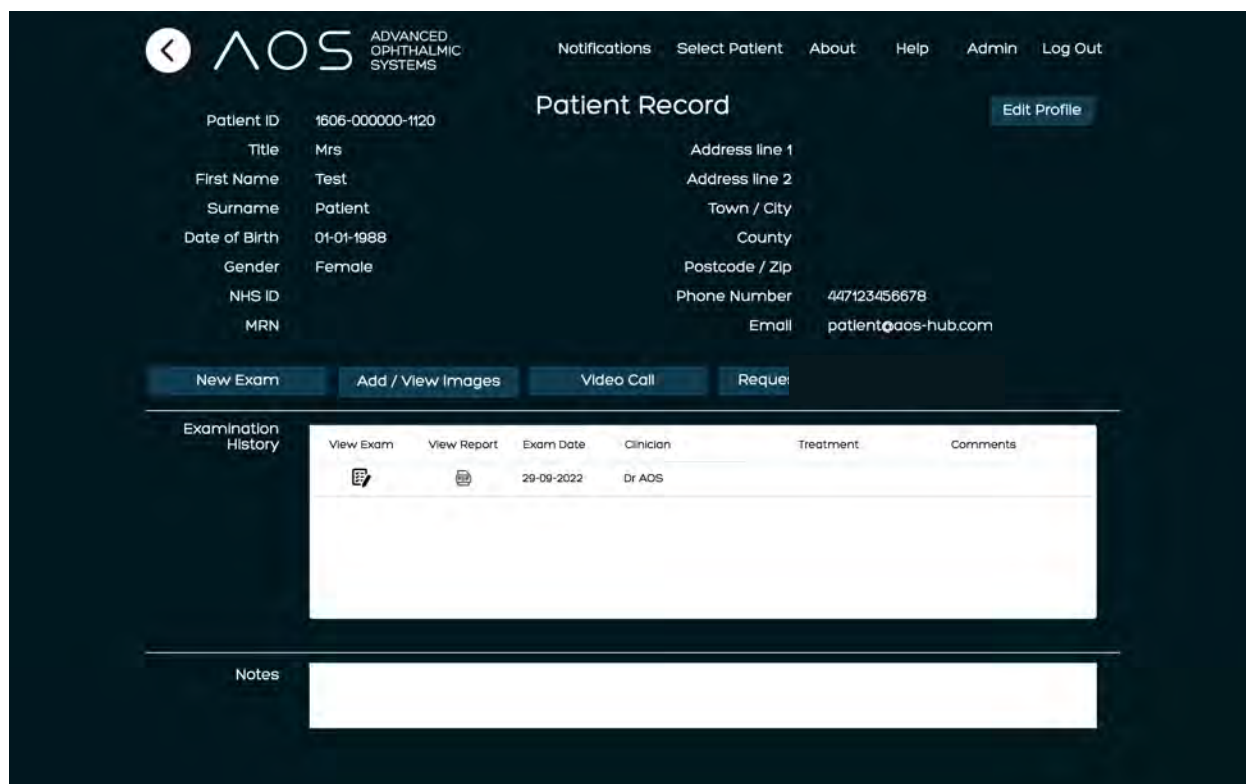


Figure 31. View exams in Examination History box.

6.1.3 Report layout

The AOS V3 software will automatically generate a report using the following fields once the user selects the 'Generate report' button. See figure 32 below.

- Patient details
- Treatment pathway
- Comments
- Saved images

If updated in the global administrator admin page, all reports within that Customer group will also include:

- User logo
- Company name
- Company email
- Company contact number
- Company address

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Patient report

First name: Ben	Last name: Kool	Date of birth: 14 Mar, 1979
Patient ID: 123456789	HNS Number: 123456789	Examined by: Dr. Smith

Notes / Pathway:

- Notes captures here for ALL images. Not individual examinations.
- Amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua lorem ipsum dolor sit.
- Consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua lorem ipsum dolor sit amet cipsum dolor sit amet.
- Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua incididunt ut labore et dolore magna aliqua.
- Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua.
- Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua.
- Adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua.

Examination date: 12 Aug, 2020	Examination type: Lid Redness	OD / OS: R Eye		
				
Area 1 Redness 1.8	Area 2 Redness 1.7	Area 3 Redness 1.5	Area 4 Redness 2.5	Area 5 Redness 2.5

Examination date: 12 Aug, 2020	Examination type: Bulbar redness	OD / OS: R Eye	
			
Area 1 Redness 0.5	Vessels 1.8	Area 2 Redness 0.5	Vessels 1.8

Figure 32. Patient report example.

6.2 Saving a new patient exam

To save an exam the user clicks on the 'Save/Finish' button on the bottom right-hand side of the screen. It is imperative that the user clicks the 'Save/Finish' button to save an exam or no data will be saved. Once clicked the exam will be saved and the user will be returned to the patient summary tab. See figure 33 below.

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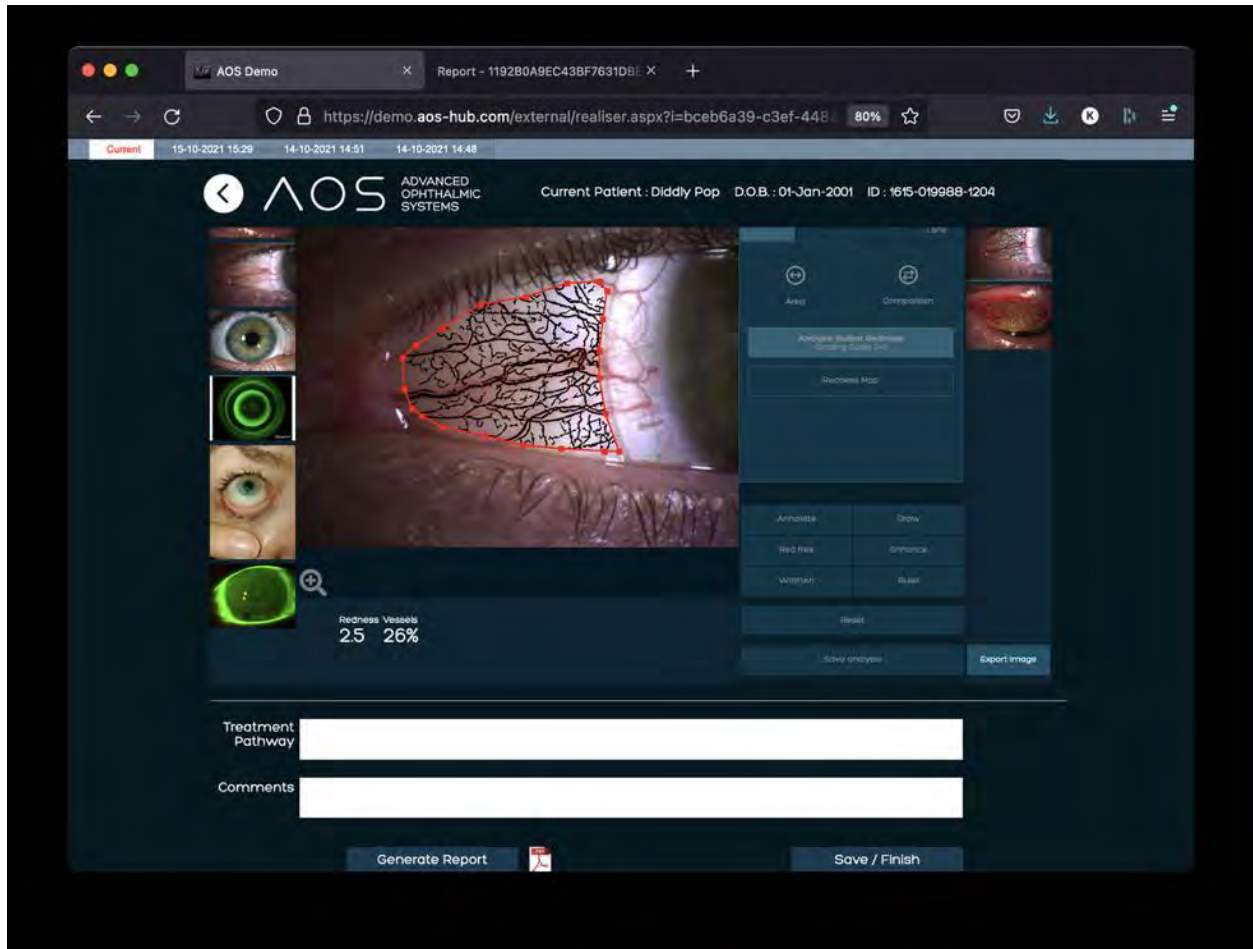


Figure 33. Save/Finish to return to the Patient Summary tab.

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7 Using AOS application features

7.1 Using the Bulbar Redness tool

The Bulbar Redness tool presents results showing the Conjunctival Total Redness on a 0-4 scale and maps the vascularity for the selected area. Results are shown in the Panel at the bottom of the screen.

There are two features in Bulbar Redness mode; **Area** and **Comparison**.

7.1.1 Using Area mode

To use the area mode, select an image to analyse (see section 5.1.8), click on bulbar redness and then select 'Analyse bulbar redness'. Place the cursor on the image in the analysis screen and left click to draw an area of interest. Results are displayed in results panel at bottom of screen, see figure 34 below. The user can draw a new area of interest by clicking outside the drawn area or resetting the image.

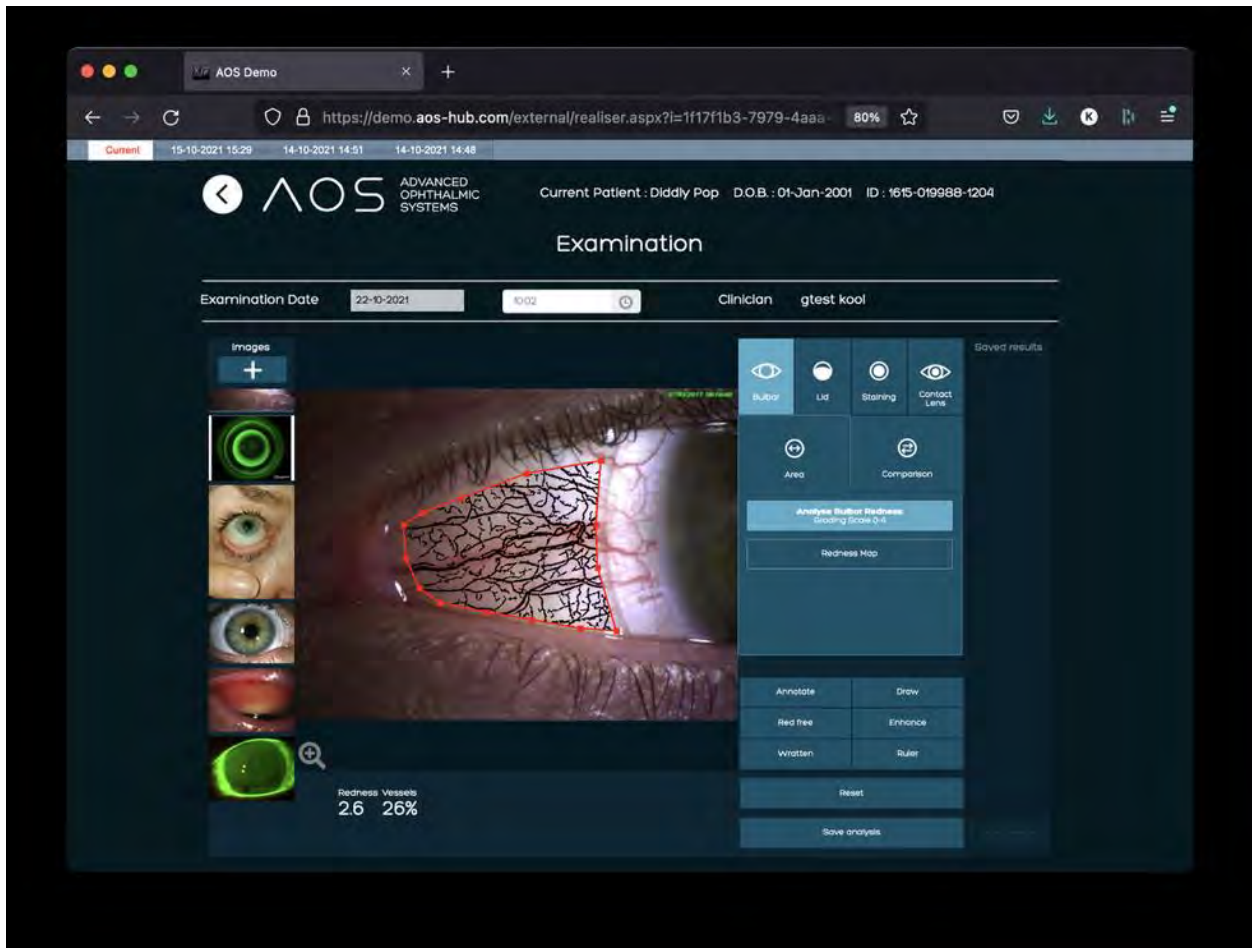


Figure 34. Bulbar Redness mode's feature: Area. Reset button in bottom right corner enable to draw a new area.

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7.1.2 Using the Redness Map

The drawn area can also be displayed using a colour heatmap. Simply activate 'Redness Map' by clicking on the 'redness map' button and the drawn area will display a heat map, the grading chart for which appears in the results panel at the bottom of the screen. See figure 35 below.

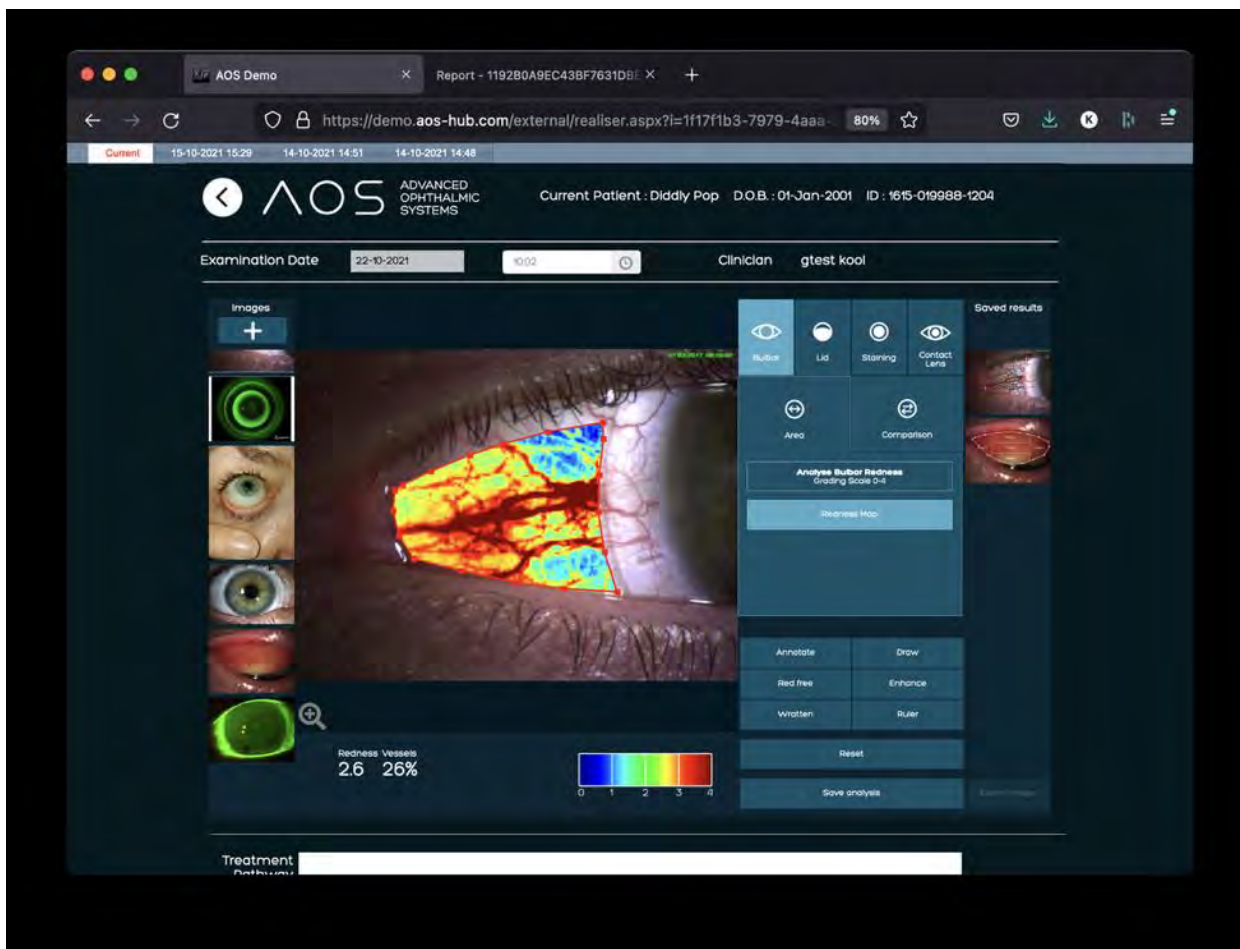


Figure 35. Bulbar Redness mode's feature: Redness map.

7.2 The Area comparison tool

The comparison tool allows the user to place two identical circles on the image. They can be moved independently, but both resize or reshape together. Activate the Comparison button and click twice on the image to input the two circles. Move each circle using the 'hand' cursor to reshape or resize both simultaneously. Results are displayed in the panel at the bottom of the screen. See figure 36-37 below. The software can display the comparison in redness values or colour map.

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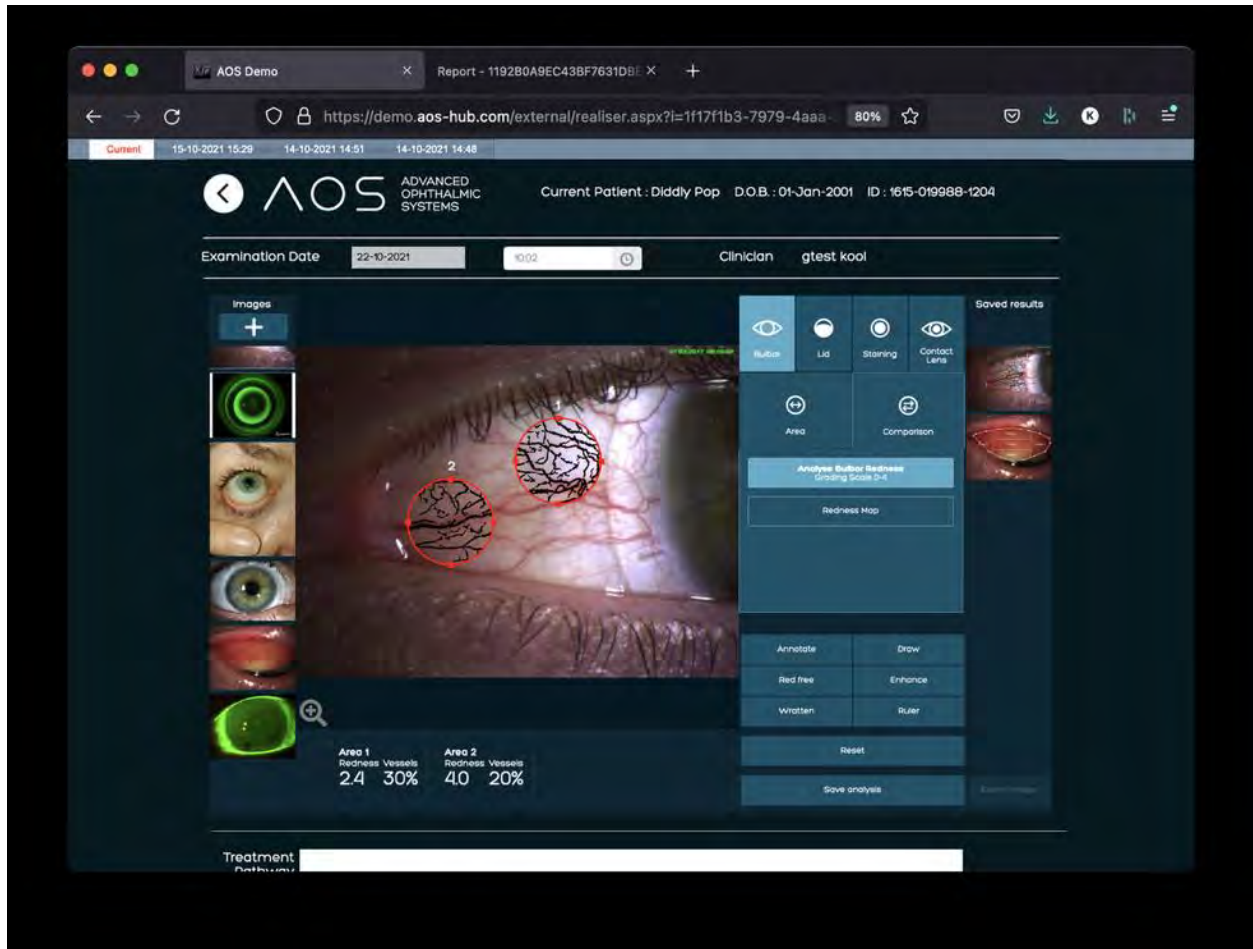


Figure 36. Area comparison tool.

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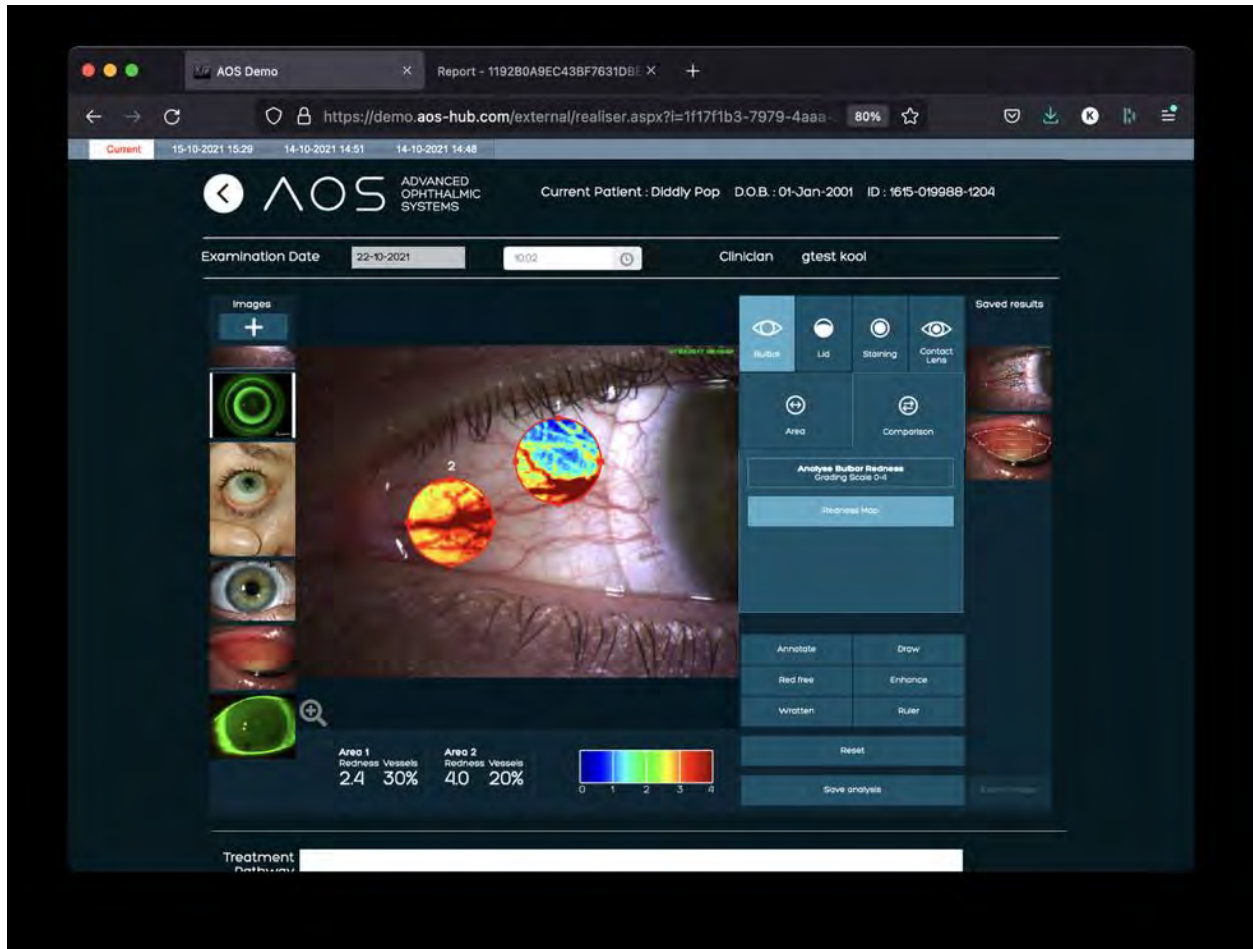


Figure 37. Area comparison tool.

7.3 The Draw tool

It is possible to simply draw a line over the captured image to highlight an area. See section 5.4 for further detail. To use the draw function select it from the tools section and left click to draw an area of interest. Continue to left click to drop anchor points and draw the wanted shape. See figure 38 below.

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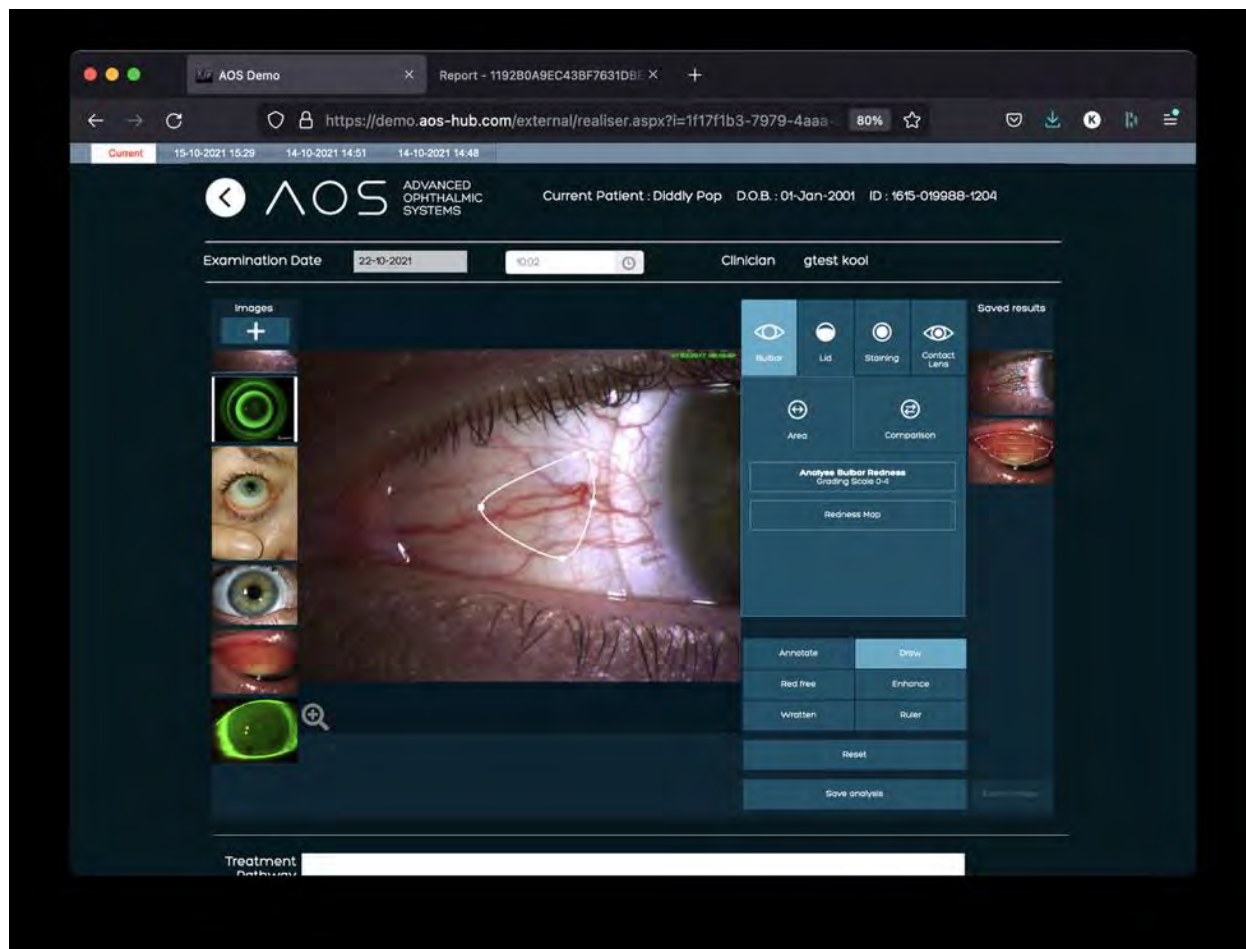


Figure 38. Draw tool.

7.4 Lid Redness

The Lid Redness tool detects Palpebral Conjunctival Redness, again using the 0–4 scale. It presents results in the industry standard 5 sector grid. Lid Redness mode is activated using the 'Detect lid redness' button.

7.4.1 Detect Palpebral Conjunctival Redness

Draw an area to analyse using the Area tool (See section 5.1.8). Results are displayed within the image in the 5-sector grid and in the results panel at the bottom of the screen. To use the lid mode, select an image to analyse (see section 5.1.8), click on 'lid' icon on the right-hand side of the screen, and then select 'Detect lid redness'. Place the cursor on the image in the analysis screen and left click and hold or left click and drop the anchor points to draw an area of interest. Results are displayed in results panel at bottom of screen. See figure 39 below.

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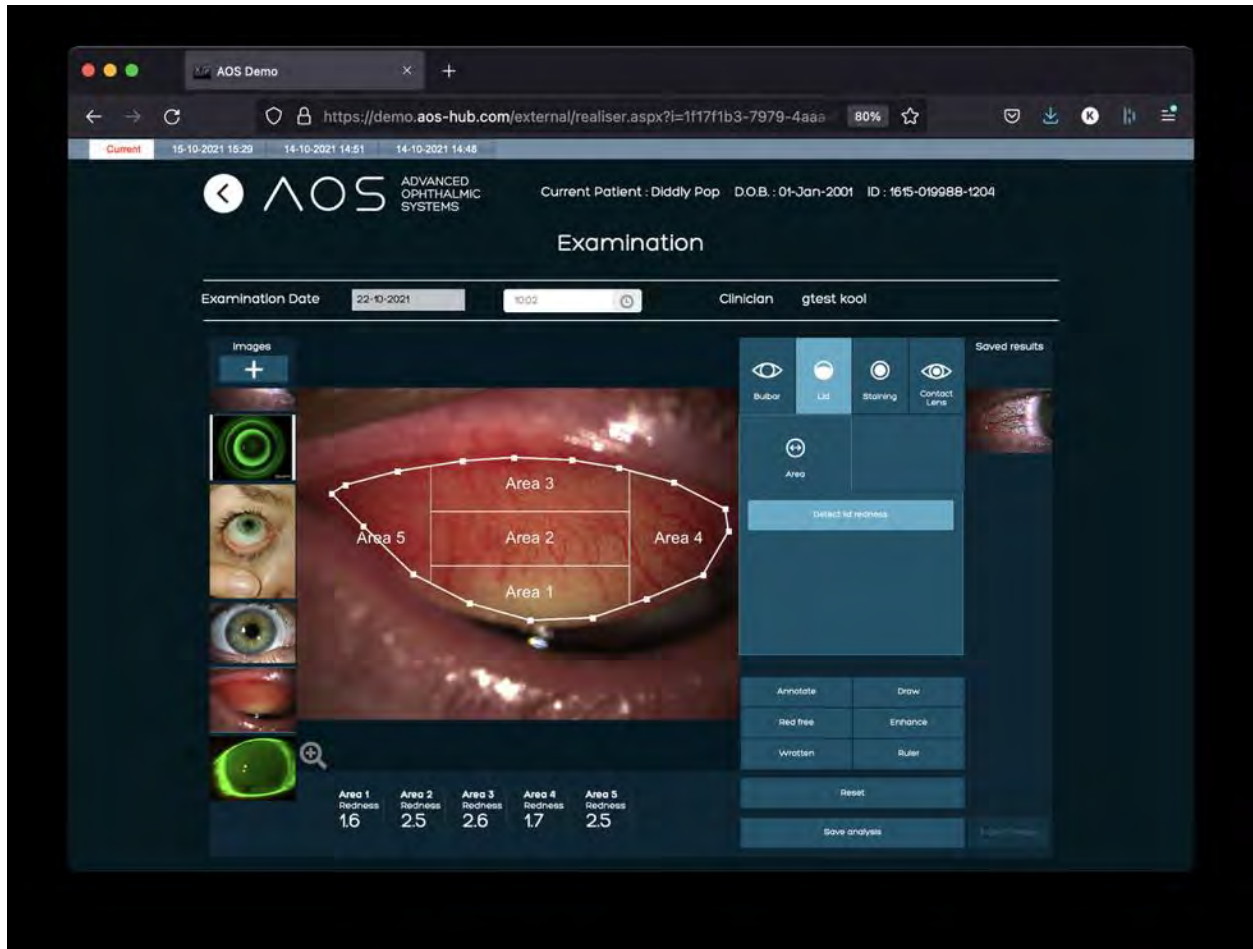


Figure 39. Detecting lid redness.

7.5 Staining tool

7.5.1 Punctate count within a user specified area

Use the Area drawing tool to draw an area (see section 5.1.6). The image highlights the **punctate** in red. Results are displayed in the results Panel at the bottom of the screen. To use the punctate count click on the 'Staining' function on the right-hand side of the analysis screen. The user will need to select the 'detect staining' button and then draw an area of interest on the image in the analysis screen. Once the user closes the area the AOS software will provide the objective output in the results tab. See figure 40 below.

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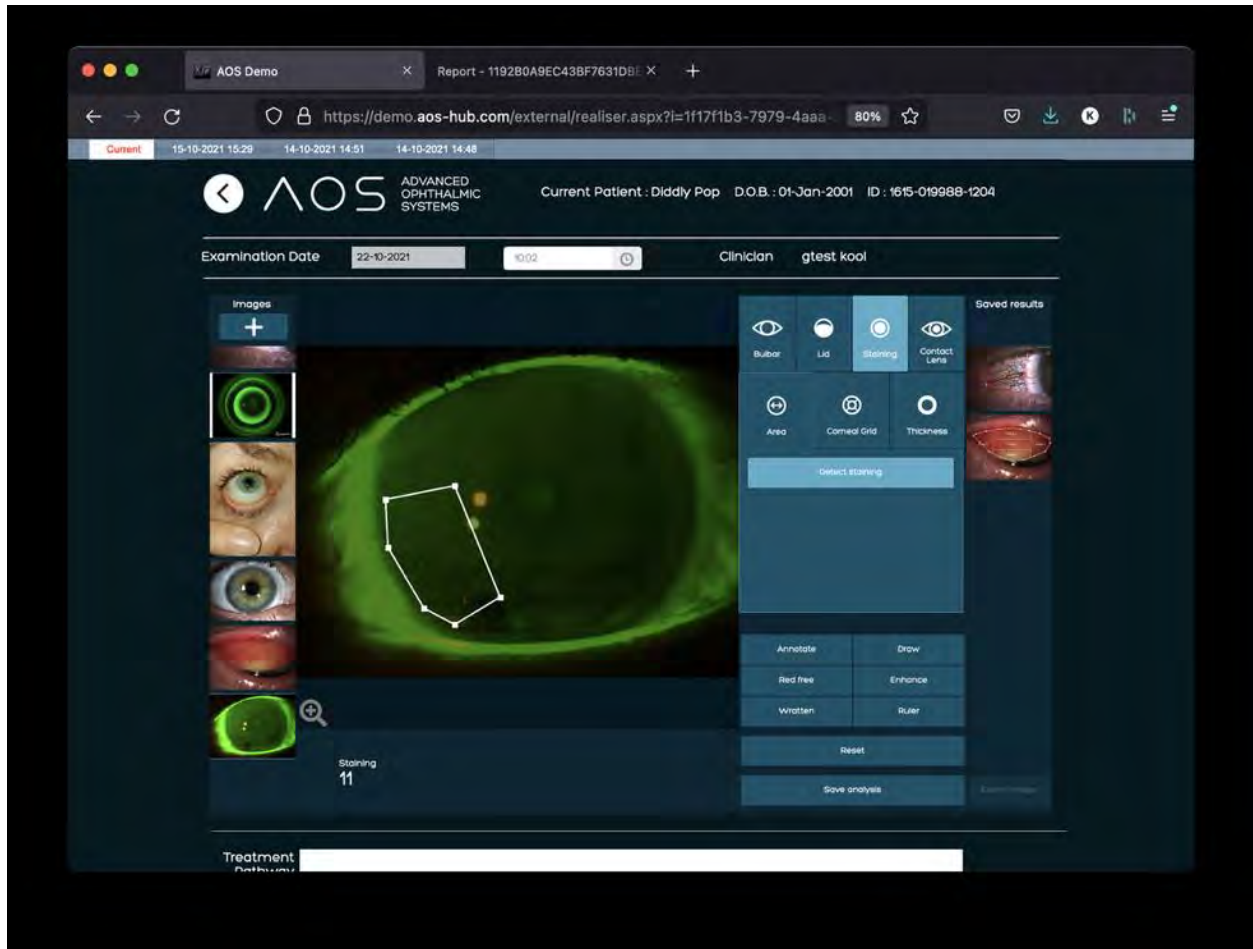


Figure 40. Punctate count with area.

7.5.2 Using the Corneal grid

To use the corneal grid punctate count click on the 'Staining' function on the right-hand side of the analysis screen, then choose 'corneal grid'. Then click on the staining image the corneal grid will be placed on the image. To position the grid over the image, drag the arrow cursor whilst positioned in the central sector of the grid. To resize and reshape, 'grab' one of the circles on the edge of the grid to resize and reshape. Results will be provided in the results tab. See figure 41 below.

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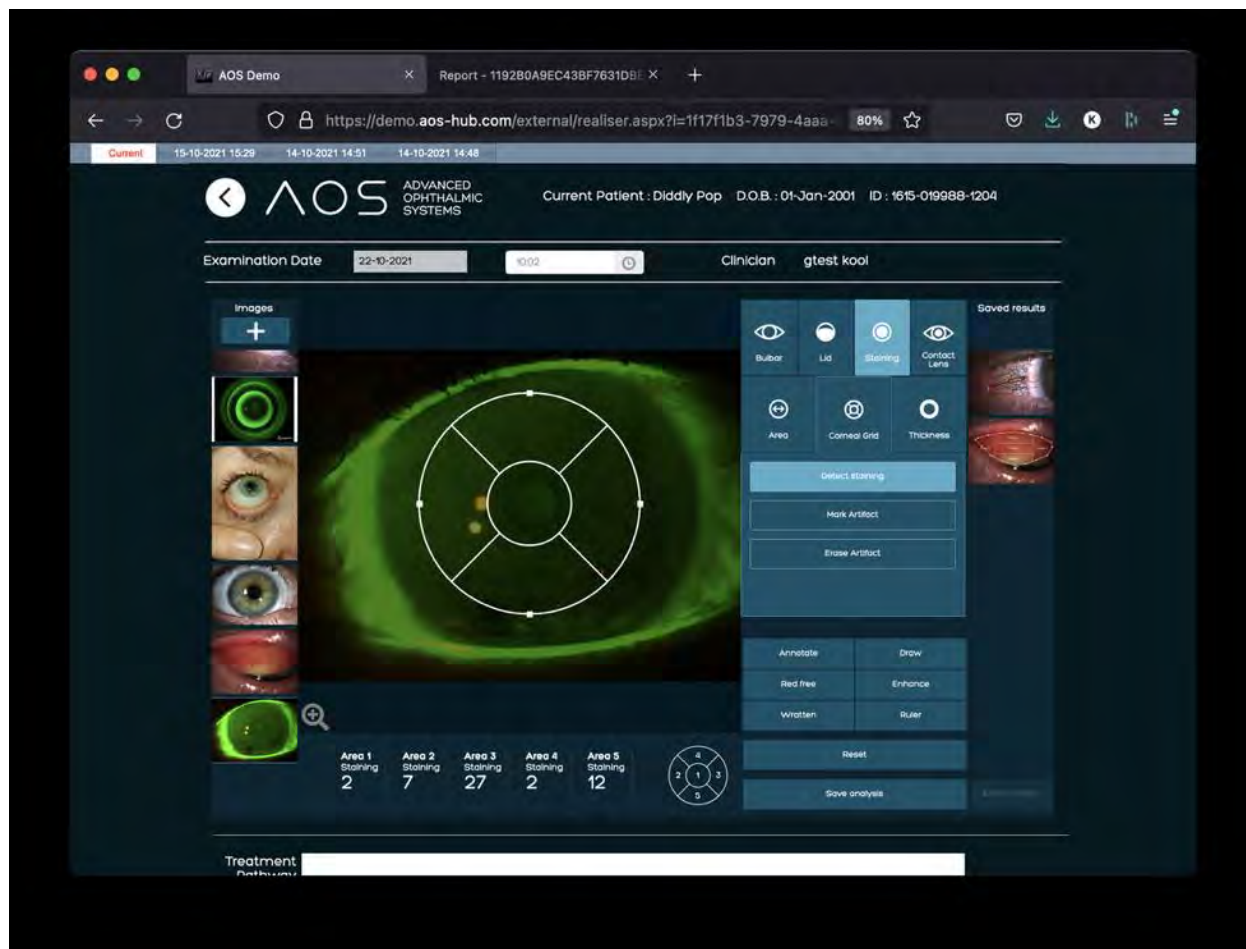


Figure 41. Punctate count with corneal grid.

7.6 Thickness

AOS can help visualise the depth of fluorescein over the eye by creating a heat map. Cold colours (blue) refer to thin levels of Fluorescein; while, hot colours (red) indicates thicker levels of fluorescein. To use the fluorescein thickness functionality, click on the 'Staining' function on the right-hand side of the analysis screen and choose 'thickness'.

7.7 2D Fluorescein thickness Level

To associate the heat map colours to the thickness of fluorescein, click on the "2D" button. This function will apply a staining depth 2D representation to the whole image. See figure 42 below.

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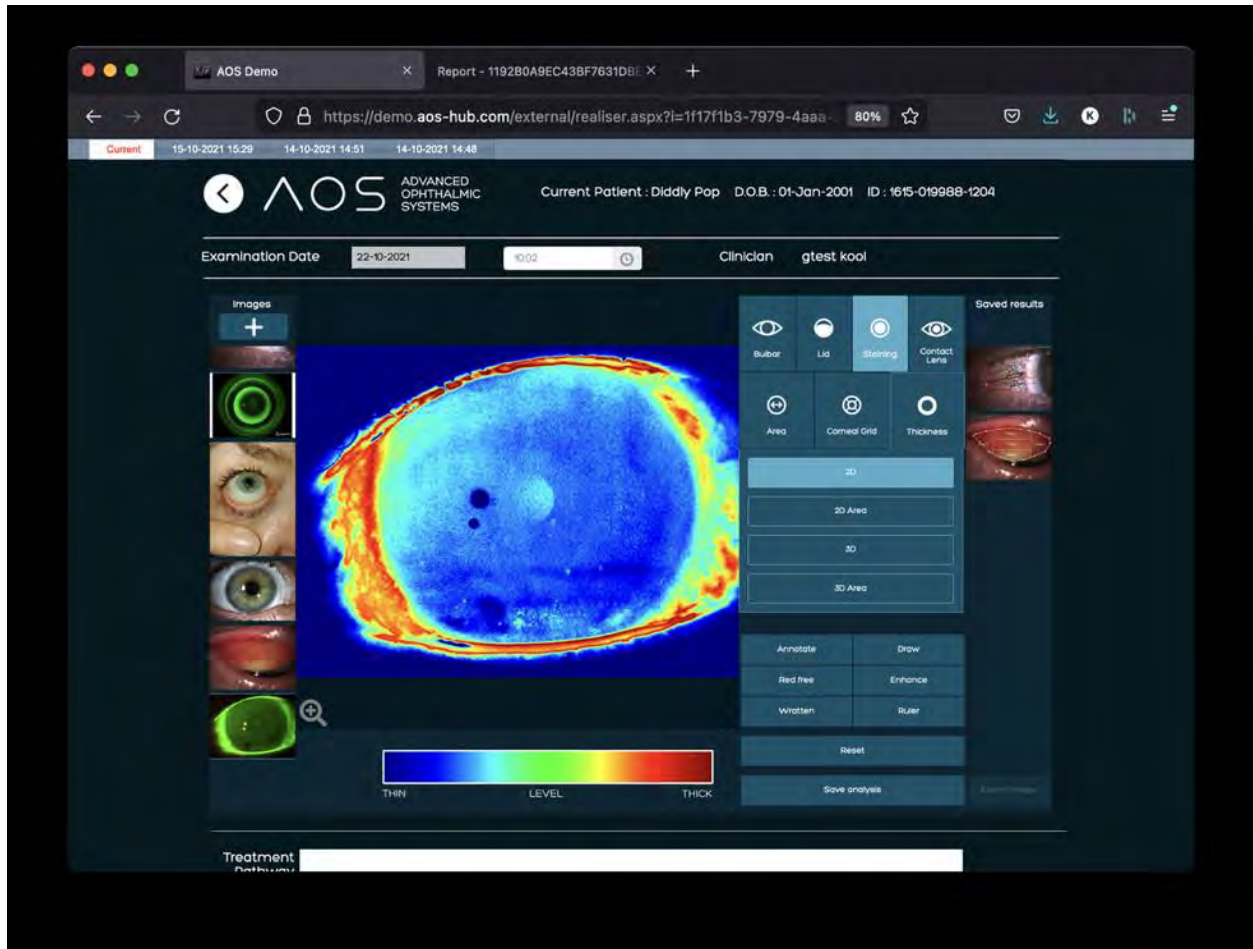


Figure 42. 2D fluorescein thickness level.

Alternatively, the user can draw an area of interest and generate the heat map over the selected area only; select '2D area', draw the area over the heatmap, when the area is closed, the heatmap is applied only to the area drawn. See figure 43 below.

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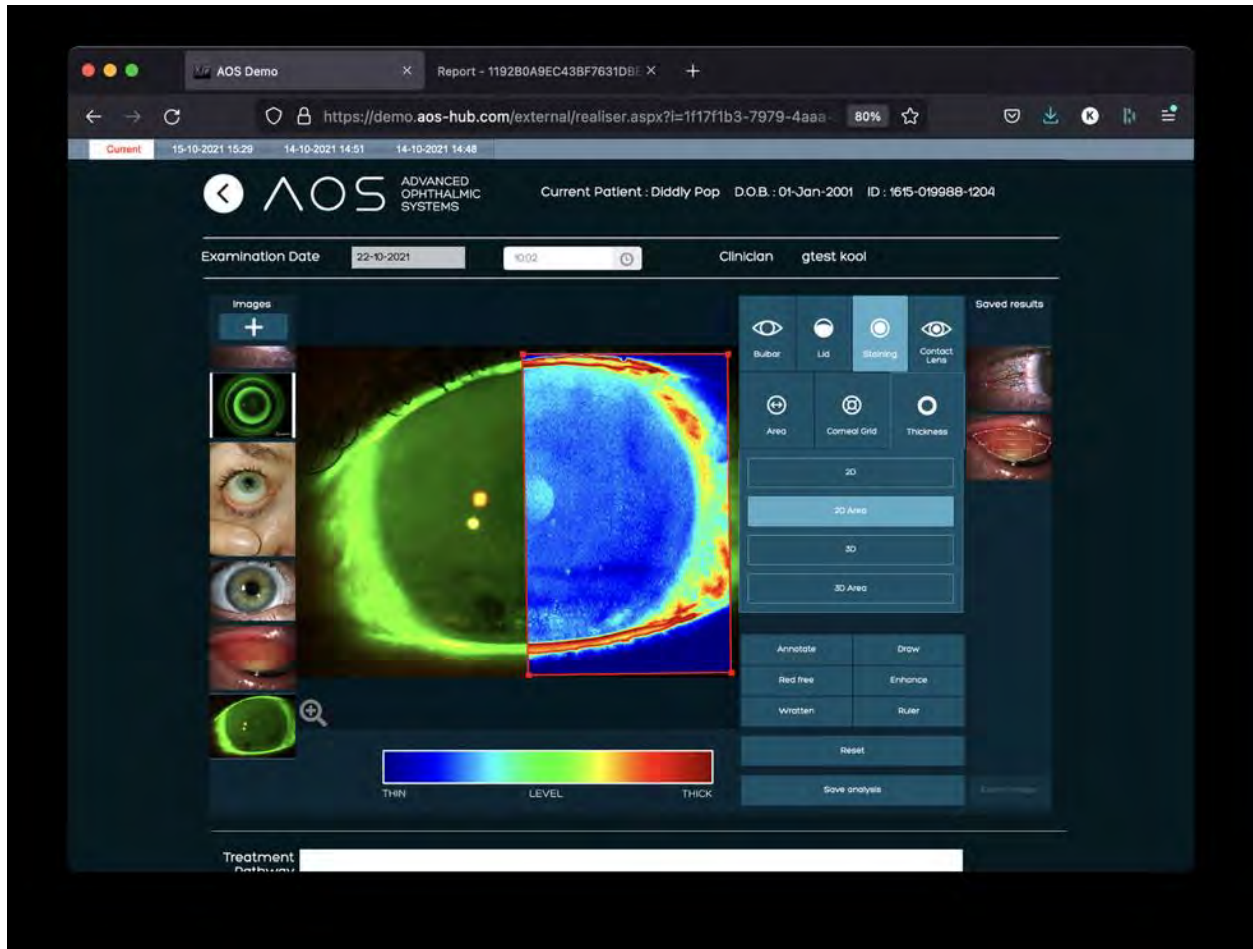


Figure 43. 2D fluorescein thickness level (area).

7.8 3D Fluorescein thickness Level

By clicking on the “3D” button, it is also possible to recreate a 3D view of the fluorescein thickness and the heat map, the red representing the higher levels of fluorescein. This function will apply a staining depth 3D representation to the whole image. See figure 44 below.

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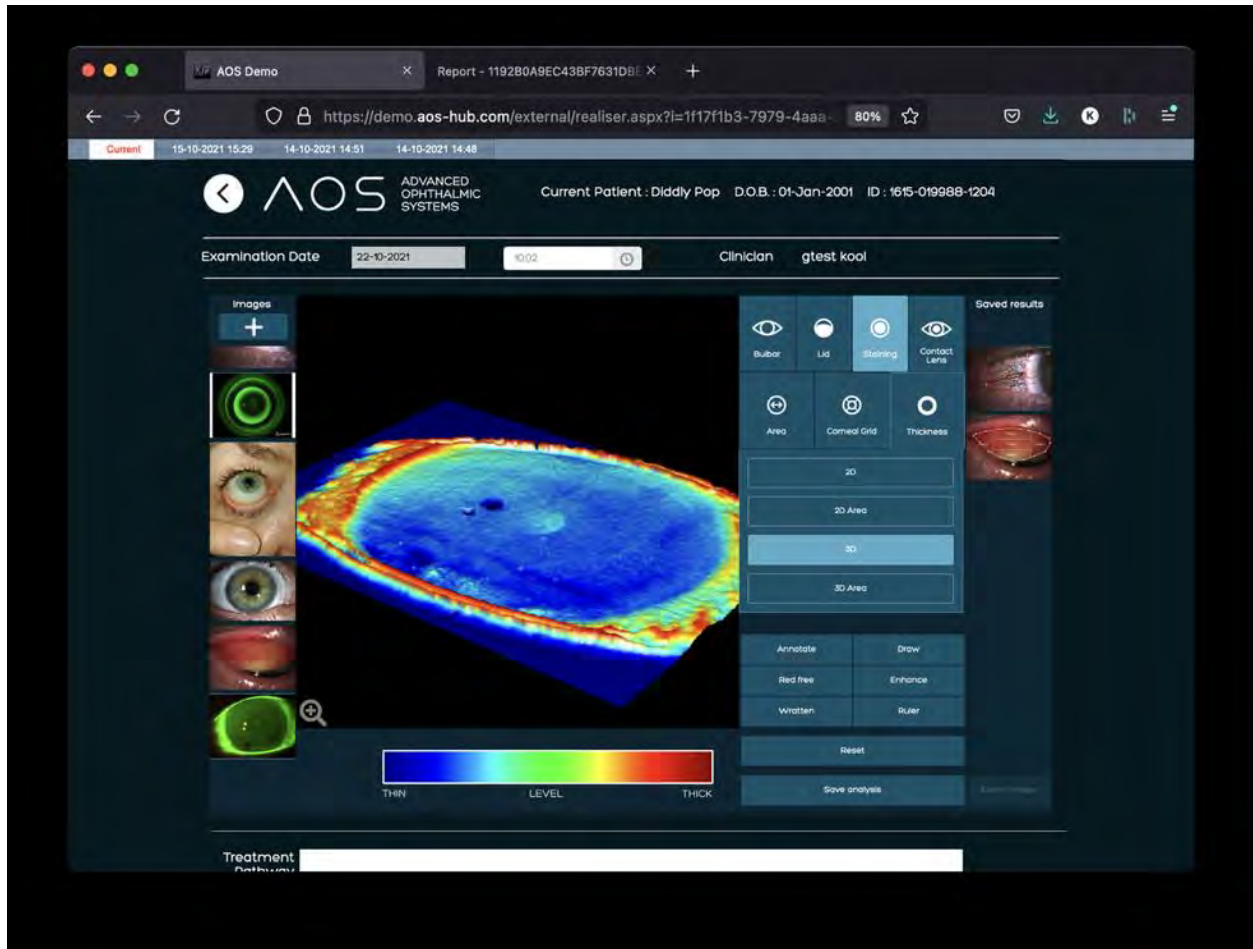


Figure 44. 3D fluorescein thickness level.

Similarly, the user can draw an area of interest and generate the 3D model on the selected area only by activating the '3D Area' button, draw the area over the heatmap, when the area is closed, the heatmap is applied only to the area drawn. See figure 45 below. To draw the area of interest, click 3D area, then left click on the image to highlight the area of interest.

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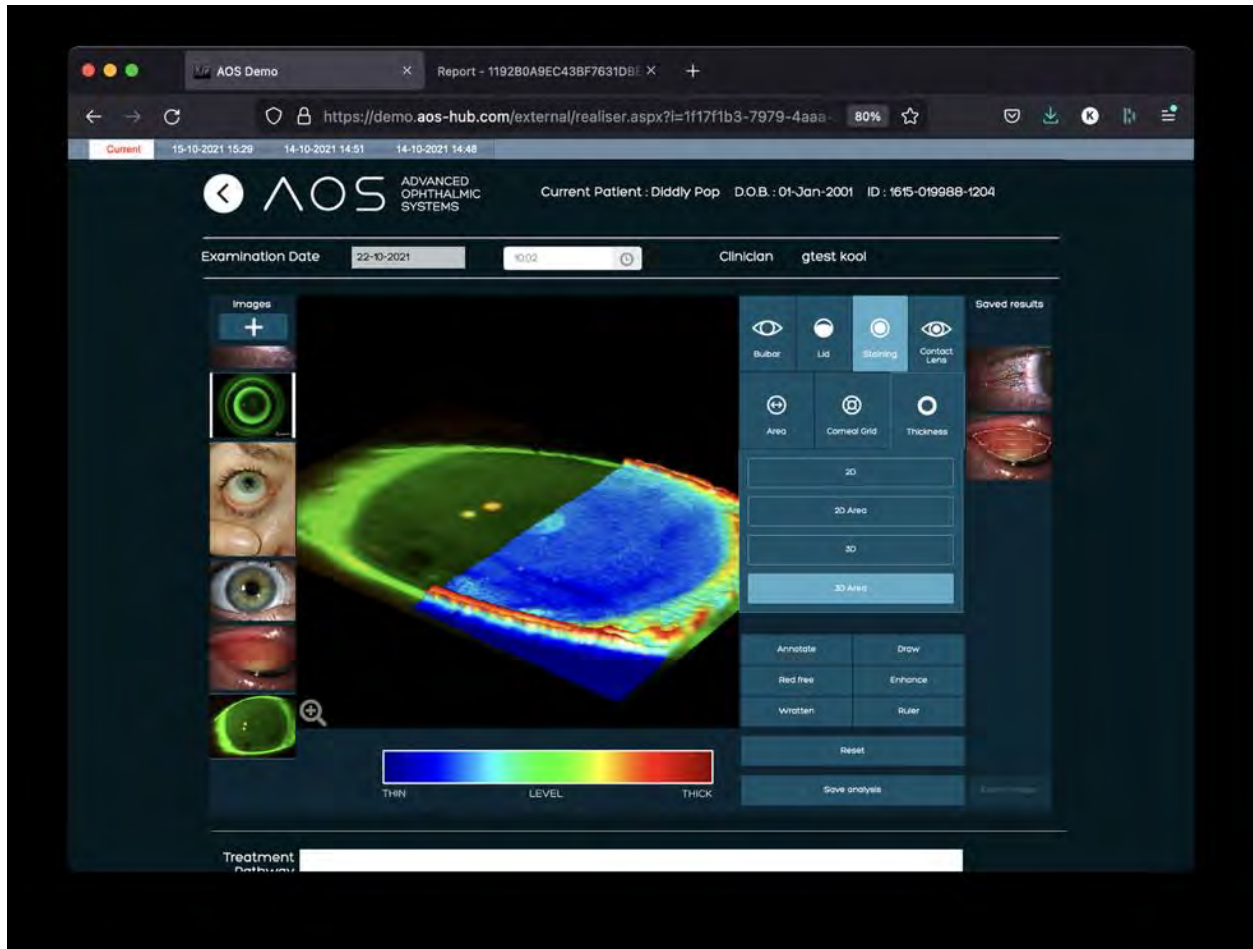


Figure 45. 3D fluorescein thickness level (area).

7.9 Contact Lens Analysis Tool

The contact lens analysis tool allows the ECP to assess the centralisation of the lens and accurately measure the angle of the toric lens against the prescribed angle.

To position the lens perimeter, follow these steps:

- Select an image and click on the contact lens tab
- Click the 'Identify lens perimeter' button and click on the image to activate the perimeter
- A green circle will appear with markings to show 0, 90, 180, 270 degrees
- The square markings can be used to resize the perimeter to the correct size
 - Use the markings to drag and resize the perimeter
- The triangular markings can be used to rotate the image so 0 degrees is in the correct place
 - Use the markings to drag vertically to rotate the perimeter

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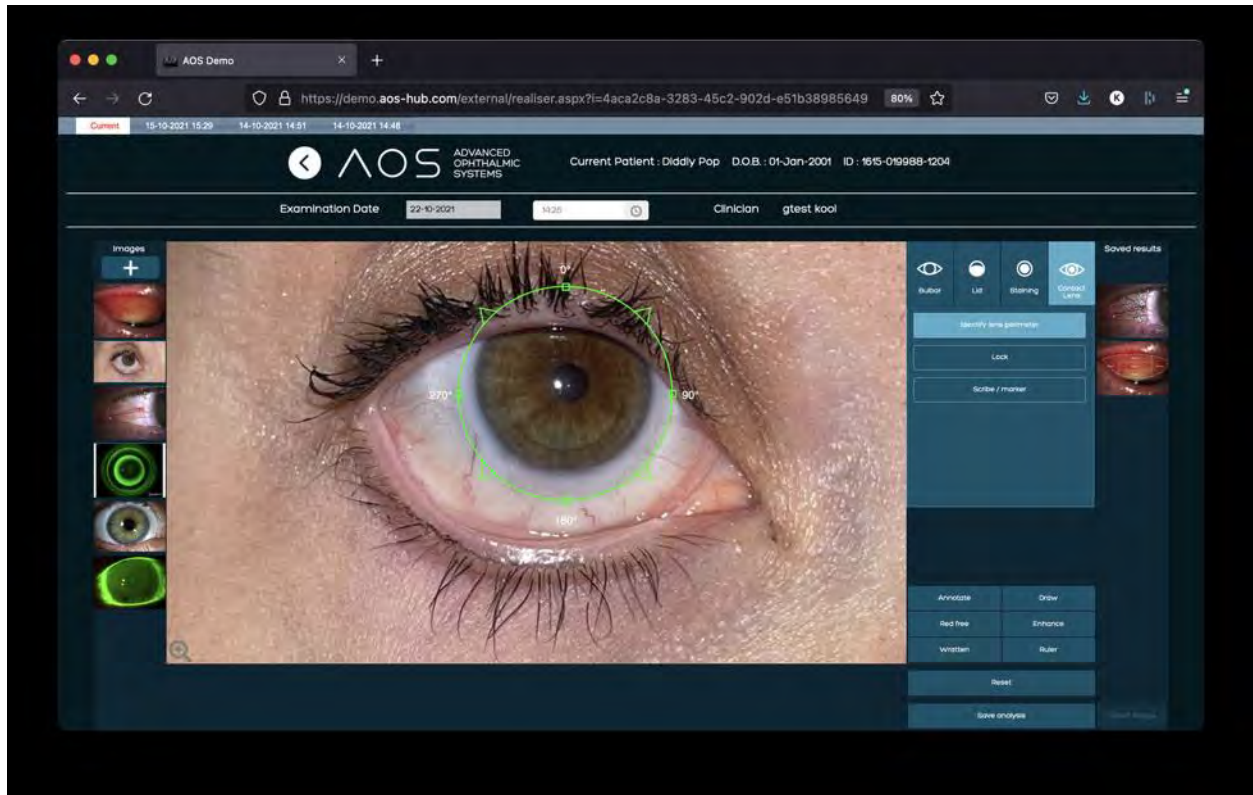


Figure 46. Contact lens analysis - identify lens perimeter

When the perimeter is in the correct position, find the toric angle by following these steps:

- Select the 'Lock' button to keep the perimeter in place
- Click on the 'Scribe / marker' button - the cursor will become a crosshair icon
- Using the crosshair, select the toric marker on the lens
- The toric angle is measured and displayed next to the red marker and below the image
- The scribe/marker can be re-placed and the toric angle will be automatically re-calculated
- To move, resize or rotate the lens perimeter, the user must unlock the position by de-selecting the 'Lock' button and following the process again.

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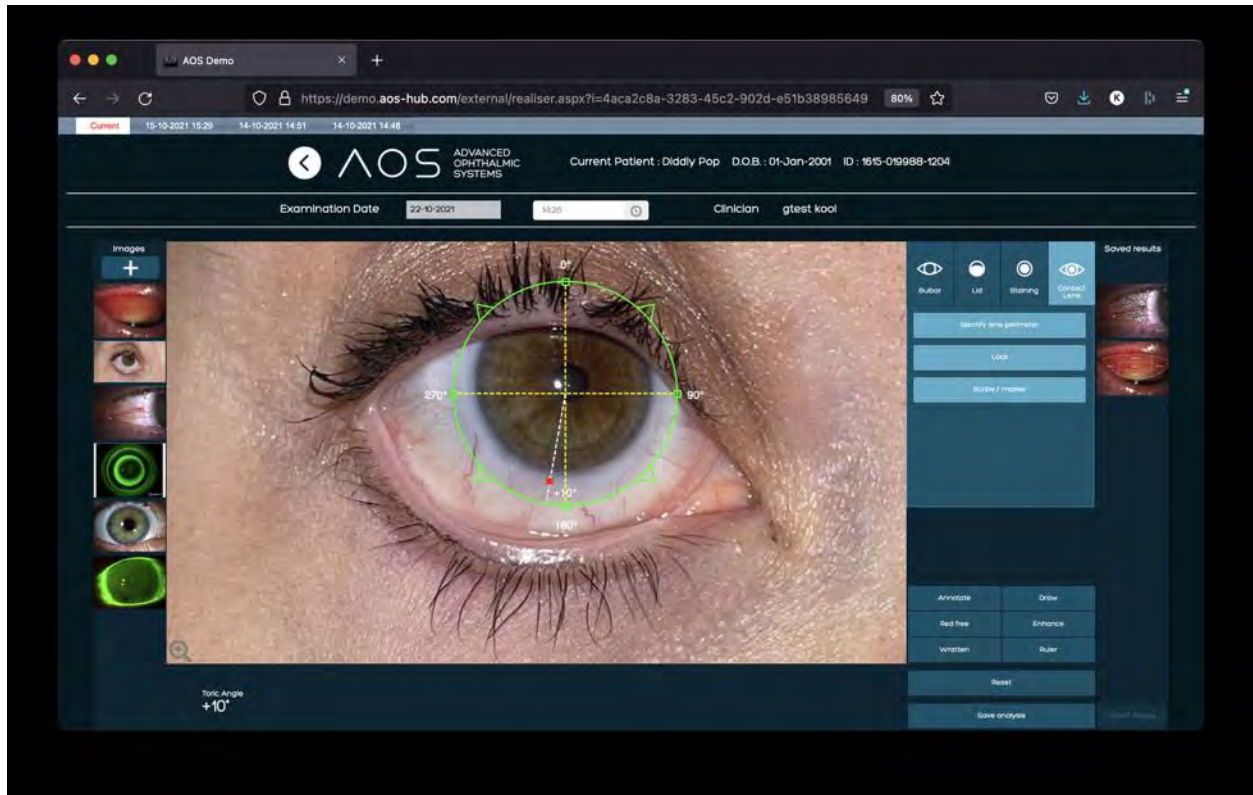


Figure 47. Contact lens analysis – toric angle measurement

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8 Additional tools

8.1 Annotate

The Annotate function works in all modes and on un-analysed images. When the Annotate function is activated, the user left clicks on the area of the image they wish to add a note to. This will open up a text box which the user can then type in to. When the note has been finished hit Enter. The annotation can be moved around the image by left clicking on the text and dragging. A user can add multiple annotations to the same image.

8.2 Draw

The draw function allows the user to select an area for reference and document it. To use the draw tool, click on the draw button so that it becomes active, move the cursor over the main image in the analysis screen and left click to begin to draw. Continue to move the cursor and left click to draw to surround an area of interest. Click on the original anchor point to close the drawing.

8.3 Enhancement

Click on the Enhancement to obtain a better visualisation of the blood vessels and total image enhancement. The enhance function will bring out greater detail within the image analysis. To use the enhance function click on the enhance button, this will activate the filter and apply it to the entire image. To deactivate the filter simply click the enhance button again.

8.4 Red Free

Click on the Red Free button to visualise a Red-Free image. The red free function will apply a red free filter to the entire image in the analysis screen. To use the red free function, click on the red free button, this will activate the red free filter. To deactivate the filter simply click the red free button again.

8.5 Wratten Filter

The AOS Wratten Filter allows an enhancement of the fluorescein over the anterior segment. The wratten will bring out greater detail within the image analysis when using NaFl. To use the wratten filter click on the wratten button, this will activate the filter. To deactivate the filter simply click the wratten button again.

8.6 Zoom

To zoom in on an image, click the plus magnifying glass icon in the bottom left of the image and use the mouse pad or mouse roller to zoom in and out of the image. The image itself can be moved by holding the left button of the mouse down. To lock the image, click the magnifying glass icon again to disable zoom.

8.7 Ruler

The Ruler tool calculates distance and area and is available in any mode. Select ruler, left click to drop the anchor point and drag the line across the image, this will allow the user to manually input a known distance, ie the diameter of a contact lens. The user can adjust the length of the line by double clicking in the line numeric and entering a different value. This value is used as a baseline measurement.

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Measurements can be taken in cm, mm, μm , nm, by selecting the measurement and using the dropdown. Once the ruler is on the image the user can left click to apply another distance and or area measurement. See figure 48-49 below.

8.8 Segment measurement

- Take an external measurement across the eye, for example a contact lens
- Click on ruler to make the tool active
- Choose start and end point of calibration line with a left mouse click
- Click on the numeric placed above the line and enter the exact measurement in mm
- The user will see the ruler now has a value applied. Move the primary ruler to the area measured externally and adjust its length to suit
- The user can now use the secondary ruler to measure other areas of the image
- To add further rulers left click on the image to choose New Ruler Item and select “Line”. Select start and end point of the distance you want to measure.”

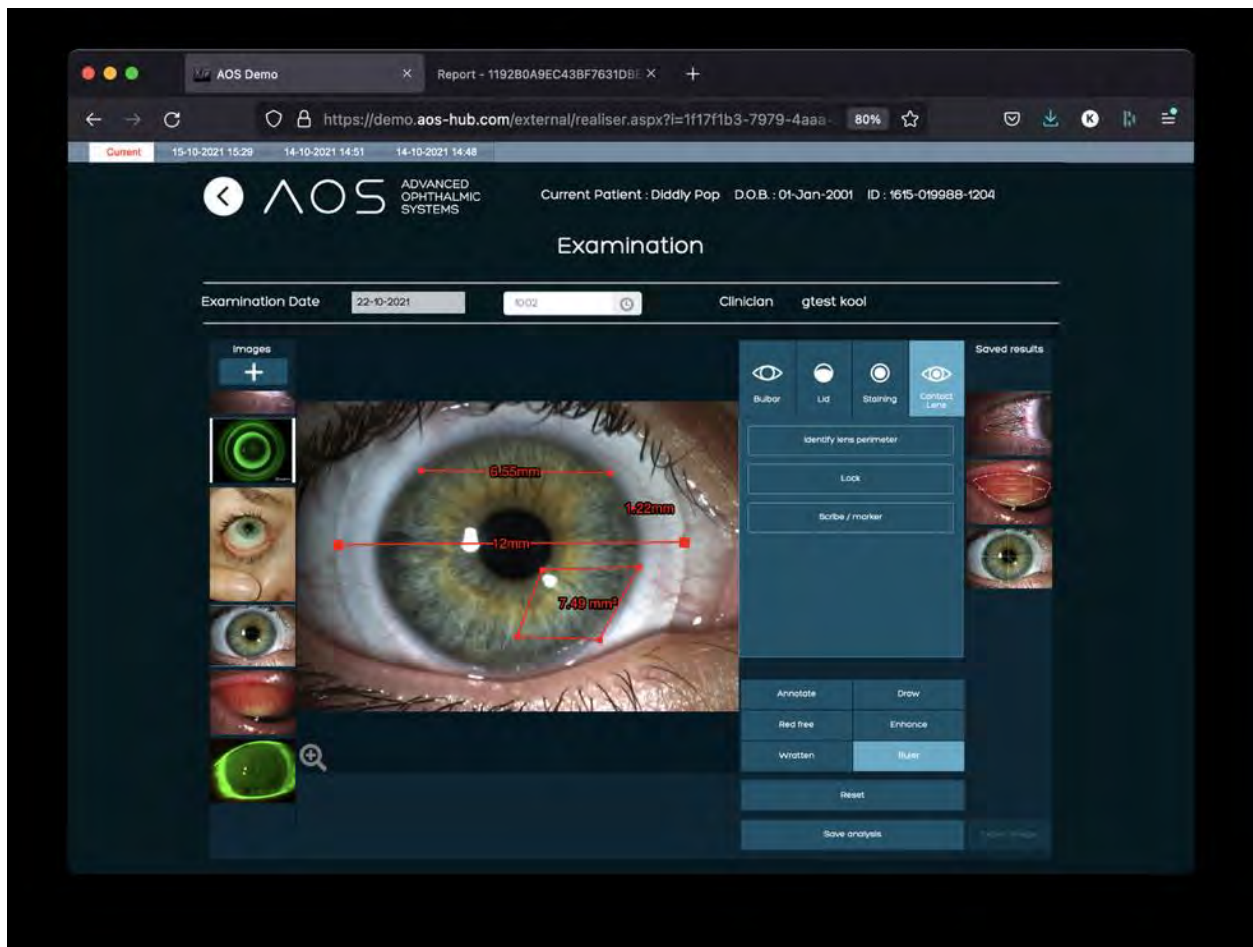


Figure 48. Ruler function - line

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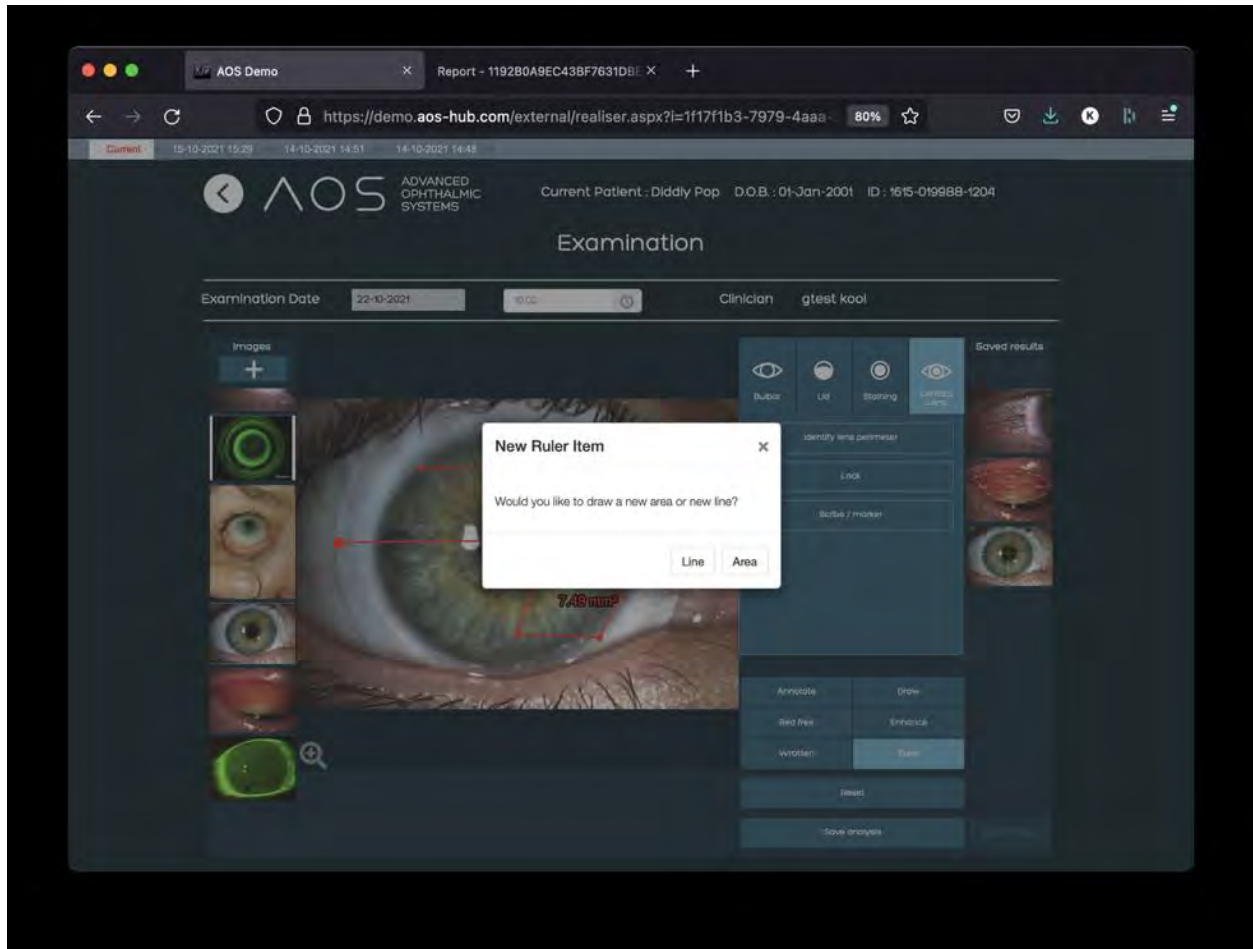


Figure 49. Ruler function - line

8.9 Area measurement

- Take an external measurement across the eye, for example a contact lens
- Click on ruler to make the tool active
- Choose start and end point of calibration line with a left mouse click
- Click on the numeric placed above the line and enter the exact measurement in mm
- Draw the area the user wants to calculate and once the area is complete the measurement is displayed.
- To add further area measurements left click on the image to choose “New Ruler Item” and select “Area”. Select the area you want to measure.”

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Figure 50. Ruler function - area

9 Video call

How to start a patient video call

When the patient has been selected the user will be taken to the patient summary page. If the user selects the 'Video Call' button they will be asked if they want to open a session with the named patient, see figure 51-52 below. Upon clicking 'OK' an email and/or text message will be sent to the patient which contains a link which will start the video session via a web browser, see figure 53 below.

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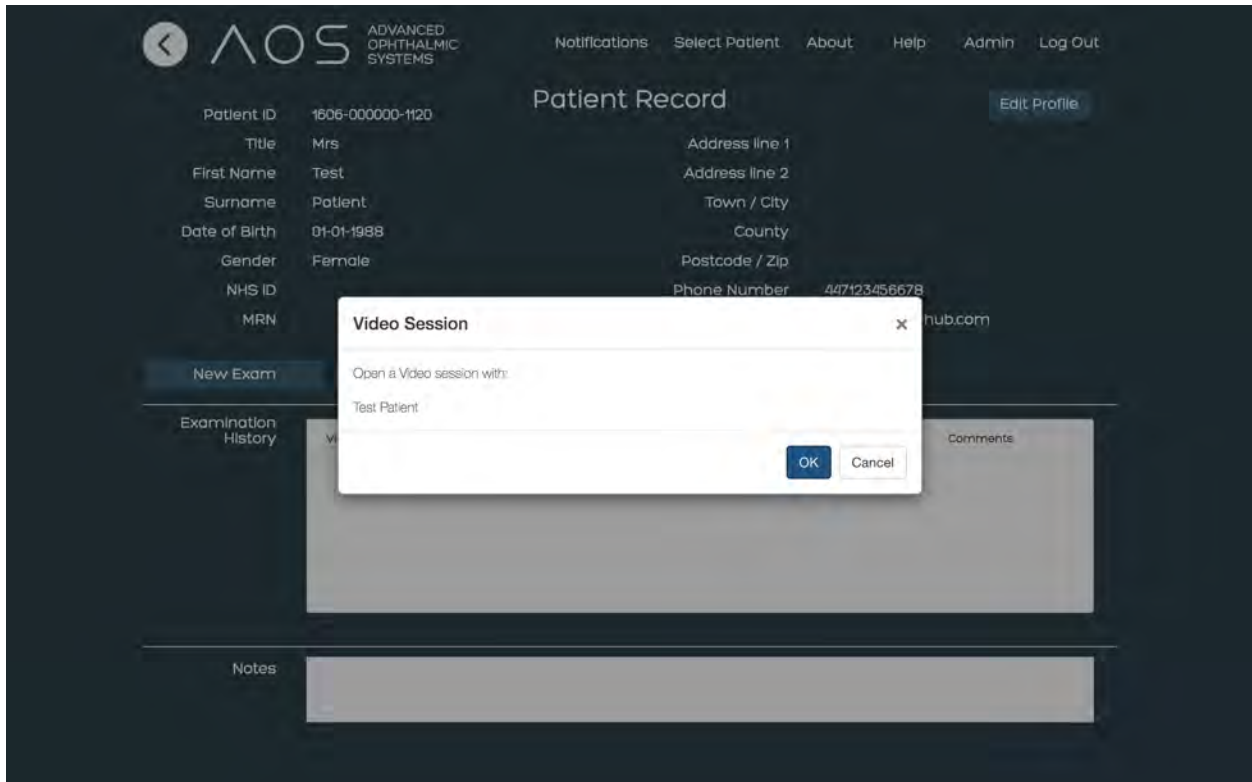


Figure 51. Selecting videocall button

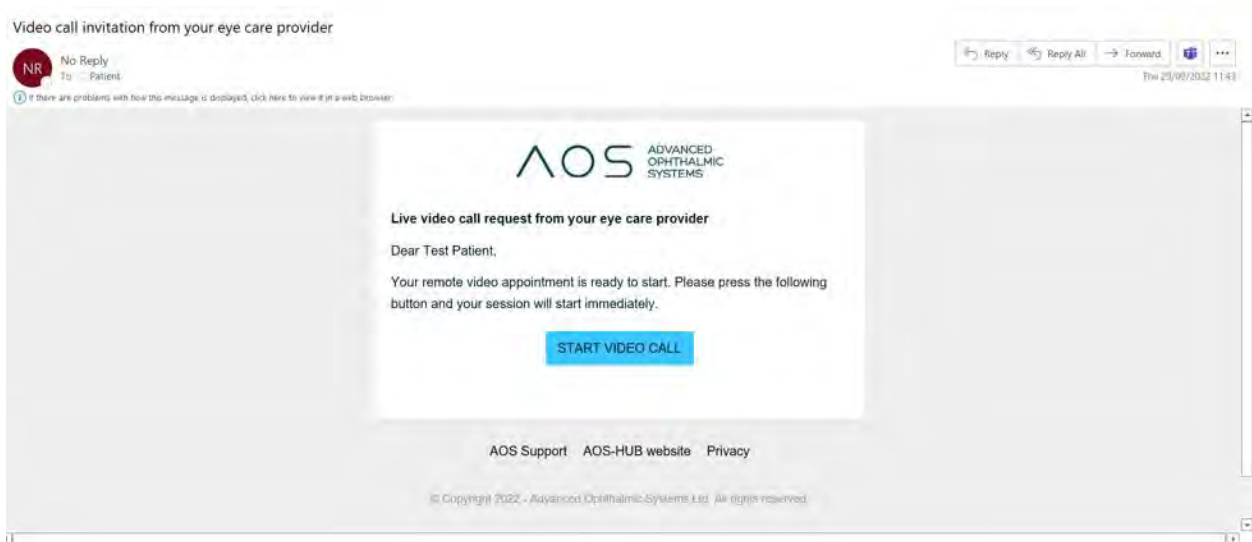


Figure 52. Mail/message received by the patient.

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At this point the user will be taken to their live video screen which will open in a new window, see figure 53 below. During the video call, the user can add other users within their group to the call by selecting them from the 'registered users' dropdown, see figure 54 below.

Users are able to perform basic video call functionality:

- Screen share
- Blur background
- Apply background image

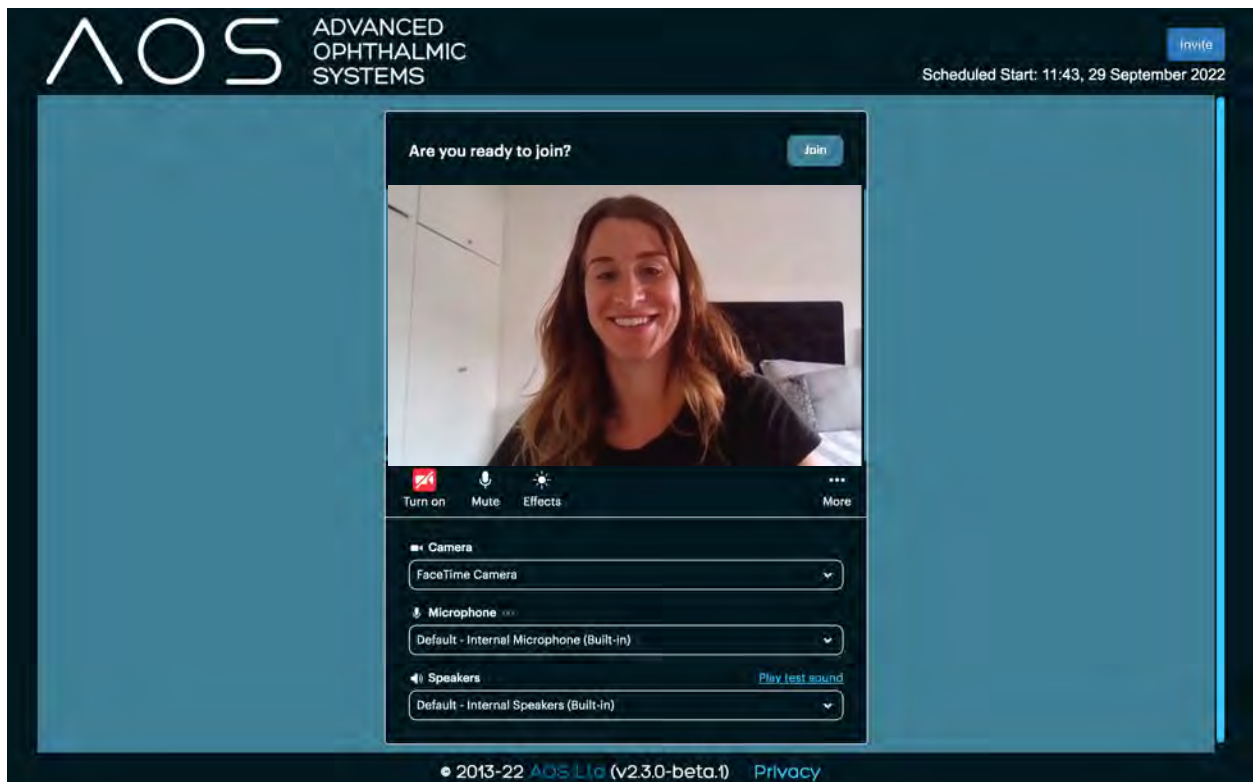


Figure 53. Another browser will open for the provider/user.

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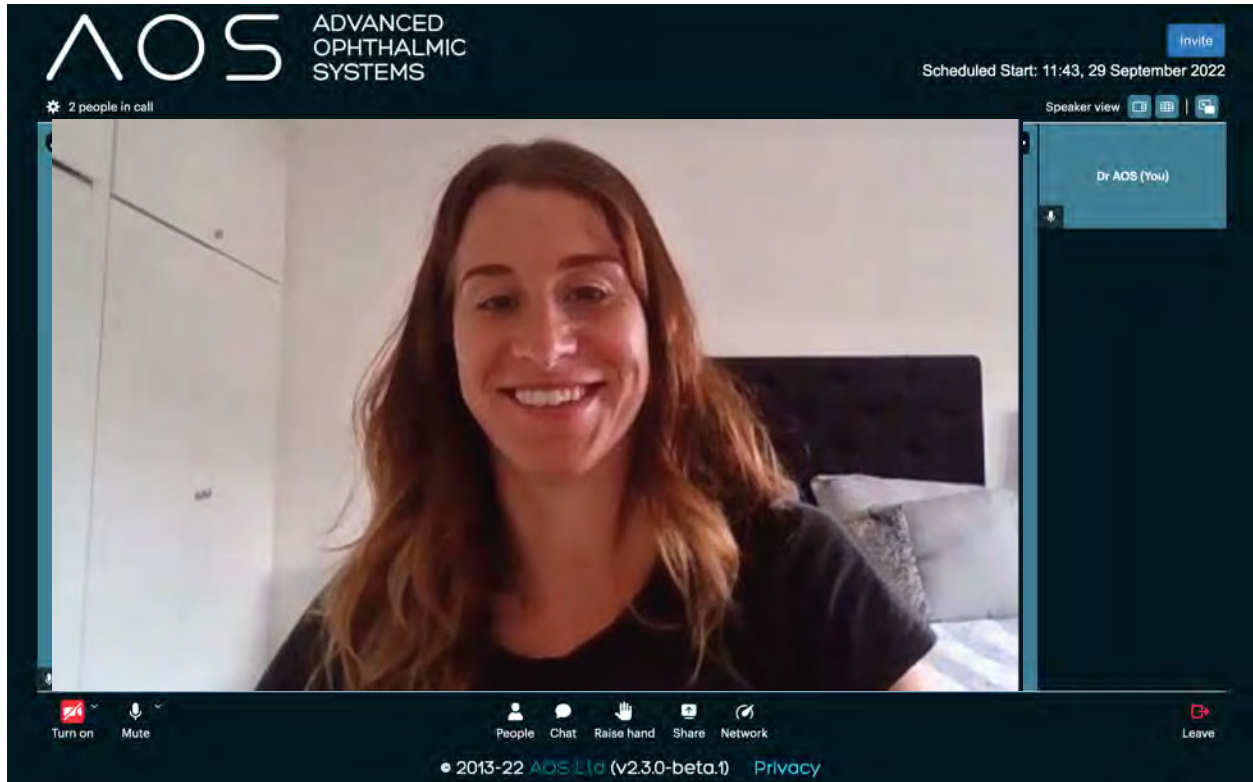


Figure 54. Telemed session.

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10 How to request a remote image from the patient

When the patient has been selected the user will be taken to the patient summary page. If the user selects the 'Request Patient Image' button an email and/or text message will be sent to the patient. The message contains a link which will download and open the patient app, see figure 55-56 below. All images captured and transferred by the patient will be sent to the patient image database in their file.

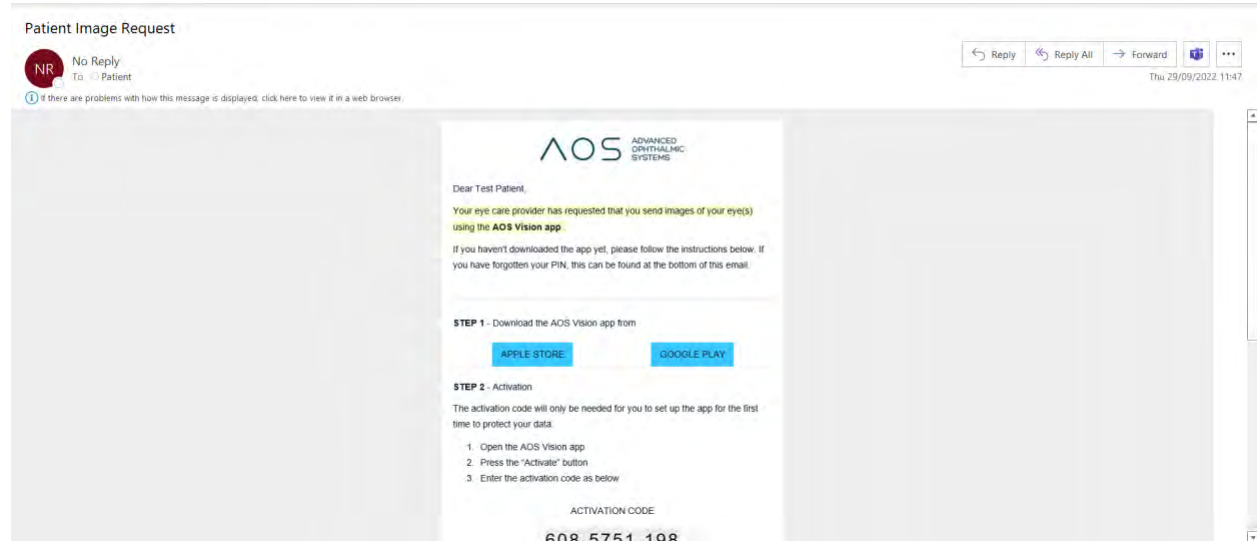


Figure 55. Email/message containing link for the patient app.

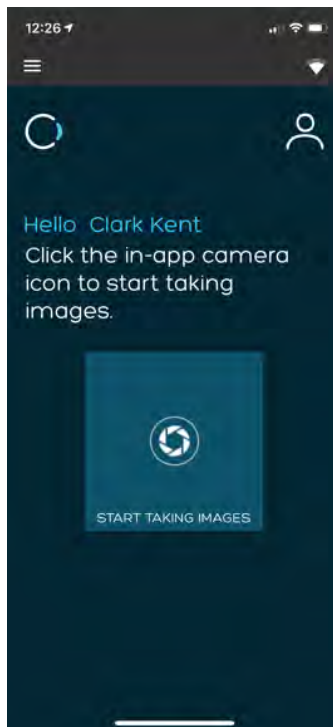


Figure 56. Patient app.

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11 Professional and Basic users mobile app

The AOS V3 system provides users (professional and basic) a mobile app (AOS Vision) for both android and iPhone. This app is designed to allow users the ability to take images of a patient and share them with the AOS V3 software. When a user is setup in AOS V3 they can receive an email that provides them all the details related to their mobile app, login details and activation codes. Access to the mobile app is driven by the admin controls in the V3 software.

11.1 Downloading and Logging in as a Pro or Basic user

In order to login the user will need to follow a simple procedure to download and login to the app. The mobile application will automatically recognize the user based on their user permissions. The procedure for the mobile app and download are as follows, see figure 58-62 below:

- Open the email provided to the user from the AOS system.
- In the email there is a 10-digit activation code – write down or copy the code to your clipboard
- Follow the link for either the android or apple store depending on the device you use.
- Download the app from the store
- Open the mobile app and click the activate button at the bottom of the screen
- Put in the 10-digit activation code
- Allow the system to activate the account and connect the user to the appropriate web account
- The user is now logged in as a pro or basic user for the app

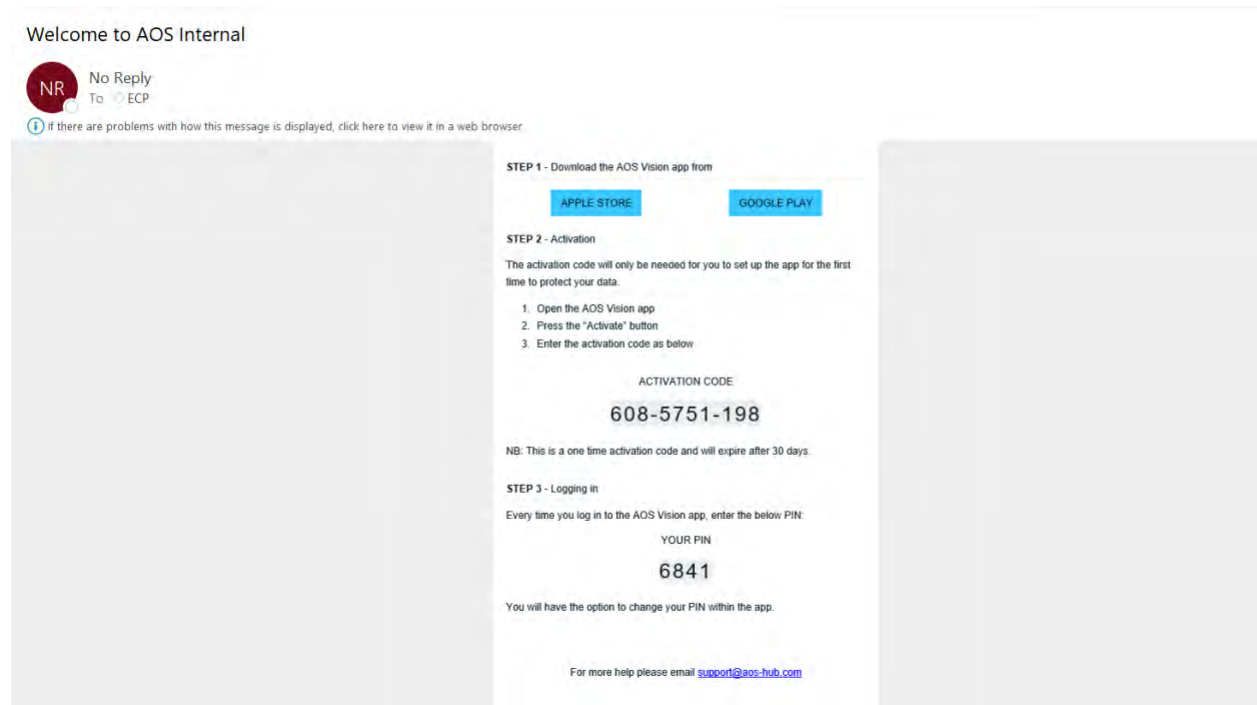


Figure 58. AOS Vision mobile app email.

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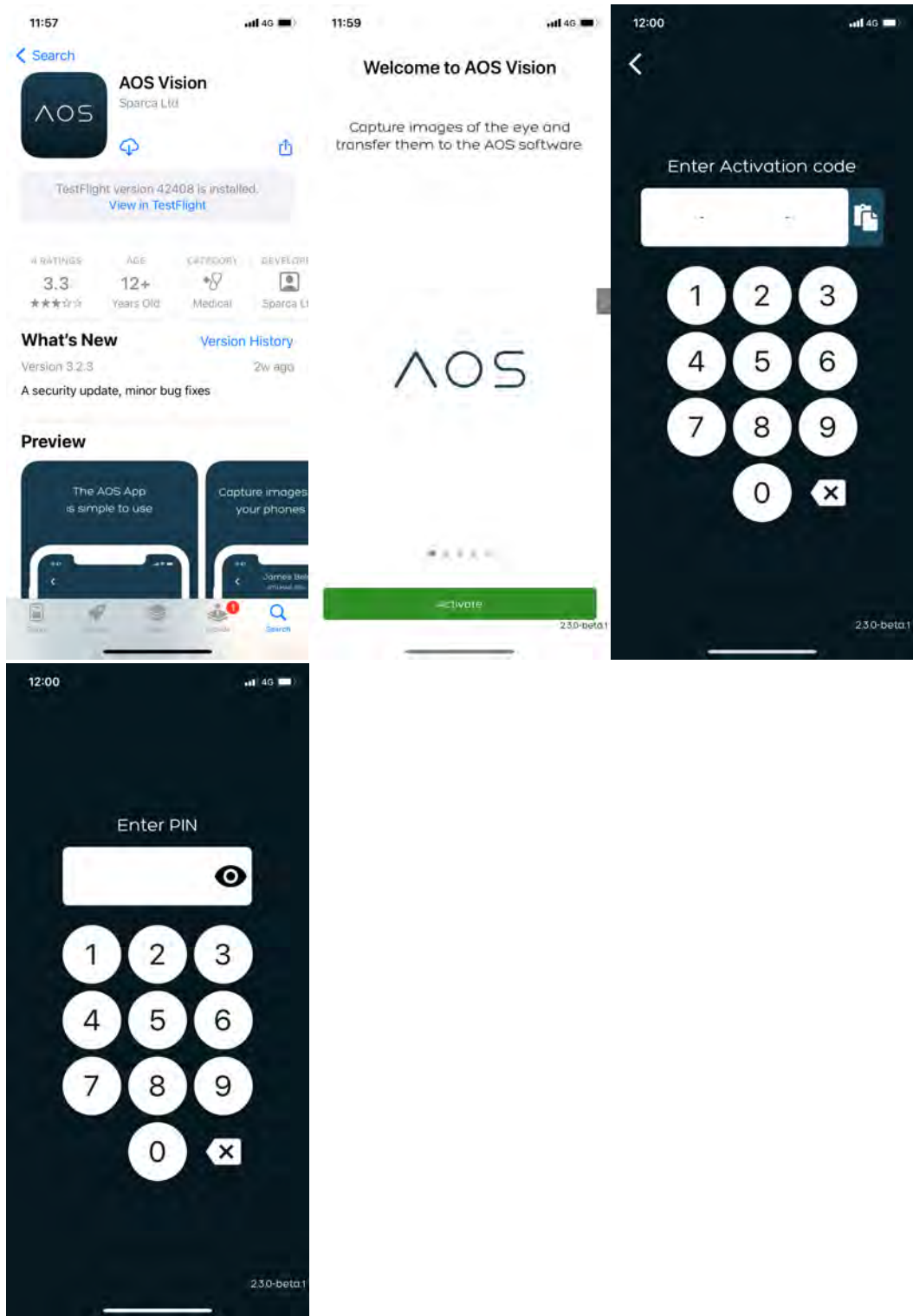


Figure 59-62. Downloading and logging as a Pro/Basic user.

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11.2 Confirming the patient

Once the user is logged into the mobile app they have access to the patient database using the drop down menu in the middle of the screen. Users can tap the drop-down menu to see the list of patients or type to search. Once the user has selected the patient, they are asked to confirm the patient details prior to taking images. See figure 63-64 below.

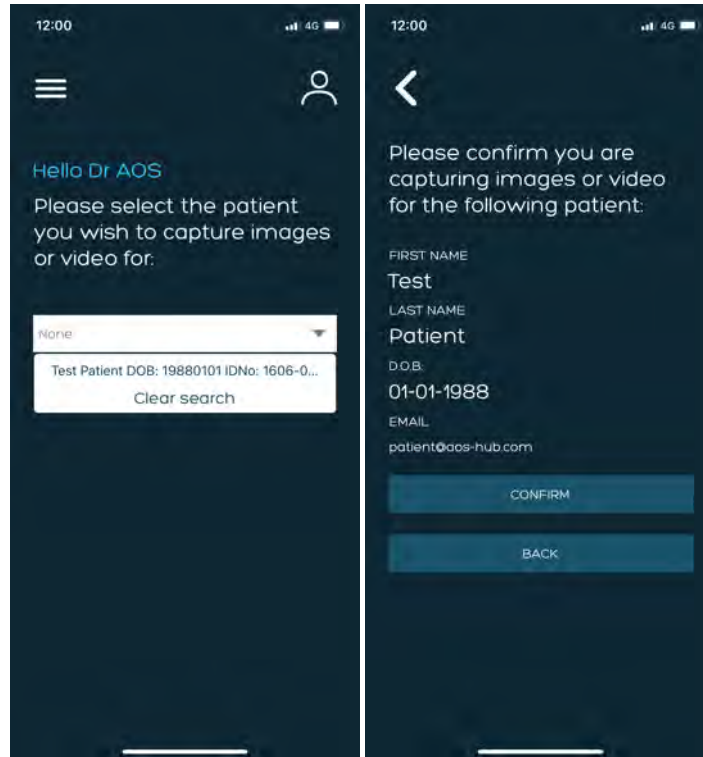


Figure 63-64. Selecting and confirming the patient.

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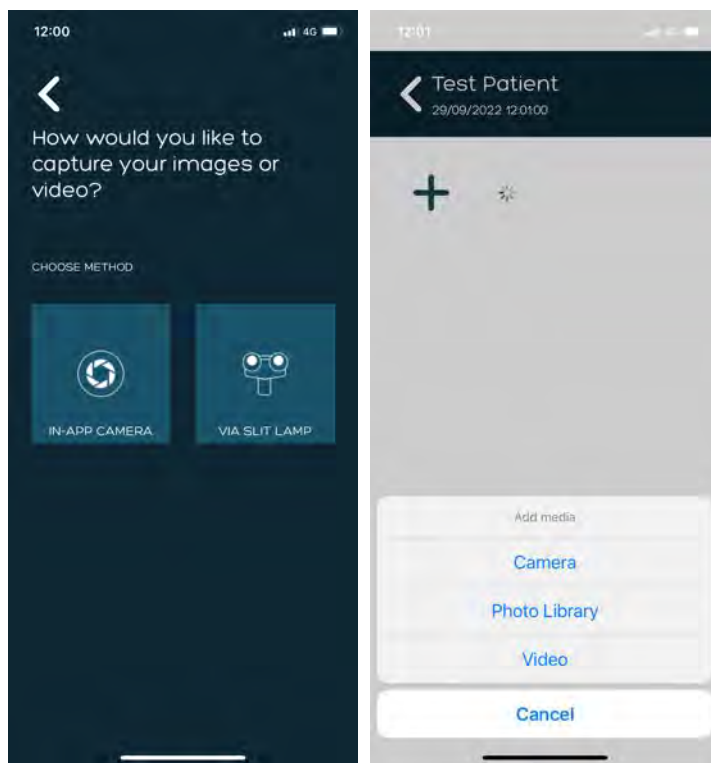
12 Video and Image capture

Once the user has selected and confirmed the patient, they have the option to take an image or video of the patient's eye using the camera on their device. The user can capture that image/video using the in-app camera and holding the phone or by connecting the mobile device to a slit lamp. The steps to take the image/video are as follows, see figure 65-66 below.

- Select the patient
- Confirm the patient details
- Choose either in-app camera or slit lamp (if using the slit lamp function connect the mobile device to the slit lamp)
- Press the + button
- Select either camera or video
- Use the native camera controls to get the best image – auto focus, flash, brightness
- Capture using the devices native controls
- Review and select 'Use photo' or 'Use video'

Images and videos can also be uploaded from the existing photo/video library. Note: it is recommended that all images/videos are captured through the app for best results. For guidance on how to take the best images/videos, navigate to the 'Guidance' page using the hamburger menu. To use existing images, press the + button and then select 'Photo library' or 'Video library'.

Images and videos can be viewed and edited in the app before transferring to the patient file in AOS.



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Figure 65-66. Image capture.

12.1 Using with a slit lamp adapter

If the user connects their mobile device to the slit lamp using an adapter, they will need to ensure the adapter and the mobile device is aligned with the oculars and the patient's eye is in focus. When using an adapter, the user should use the screen of the mobile device to drive the slit lamp and focus. No adapter is the same and they may need additional time to align the system to ensure quality imaging.

12.2 Editing an image in the app

The user can edit an image in the app before transferring it to the patient file. Follow these steps to edit an image:

- Select the image thumbnail
- Press the edit icon in the bottom left below the image
- To crop the image:
 - o Select the crop icon
 - o Crop the desired section
 - o Select the tick icon in the bottom right
 - o Click save
- Select the rotate icon if needed
- Select the invert icon if needed
- Click save
- Click done
- The edited image will be saved in place of the original image

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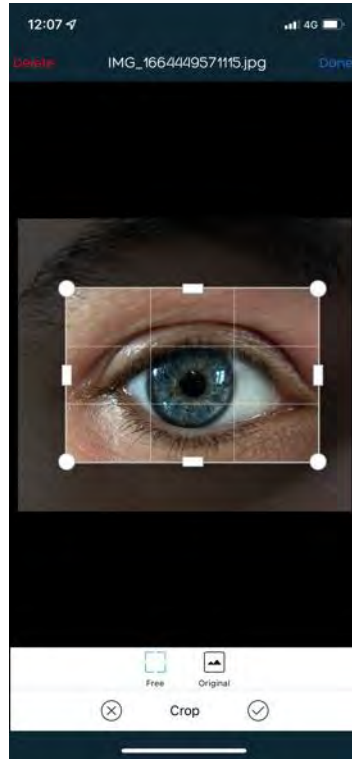


Figure 67. Editing an image.

12.3 Deleting an image/video in the app

Users can delete an image from the app before transferring to the patient file in AOS. To delete:

- Select the image/video thumbnail
- Select the delete button in the top left corner of the screen

13 Image/video transfer

Once the image/video of the patient is taken by the user, they have the ability to transfer images directly to the patient file in the AOS V3 software. To transfer media from the mobile device the user must click the 'Transfer' button at the bottom of the app. All media that can be seen as thumbnails on the app will automatically be transferred to the patient file.

13.1 What happens to the transferred images

Transferred images appear under the 'Add/View' images function on the AOS V3 software. See figure 68 below.

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Figure 68. Patient image database – add/view images.

14 Mobile app for Patients

14.1 Sending app download to patients

When in the Patient Record page, the user will need to click the 'Request Patient Image' button, see figure 58 below. An email (and text message if patient mobile number is included in their profile) will be sent to the patient with active links to download the AOS Vision app. The patient can then download the app and begin taking images. See figure 69 below.

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The screenshot displays the AOS V3 Patient Record interface. At the top left is the AOS logo (Advanced Ophthalmic Systems) and navigation links: Notifications, Select Patient, About, Help, Admin, and Log Out. The main content area is titled "Patient Record" and includes an "Edit Profile" button. Patient information is organized into two columns:

Patient ID	1606-000000-1120	Address line 1	
Title	Mrs	Address line 2	
First Name	Test	Town / City	
Surname	Patient	County	
Date of Birth	01-01-1988	Postcode / Zip	
Gender	Female	Phone Number	447123456678
NHS ID		Email	patient@aos-hub.com
MRN			

Below the patient information are four buttons: "New Exam", "Add / View Images", "Video Call", and "Request Patient Image". Underneath is an "Examination History" table with columns: View Exam, View Report, Exam Date, Clinician, Treatment, and Comments. A single entry is visible for 29-09-2022 by Dr AOS. At the bottom is a "Notes" section with a text input area.

Figure 69. Request patient image.

The screenshot shows an email titled "Patient Image Request" from AOS (Advanced Ophthalmic Systems) to a patient. The email body contains the following text:

Dear Test Patient,

Your eye care provider has requested that you send images of your eyes) using the **AOS Vision app**.

If you haven't downloaded the app yet, please follow the instructions below. If you have forgotten your PIN, this can be found at the bottom of this email.

STEP 1 - Download the AOS Vision app from

[APPLE STORE](#) [GOOGLE PLAY](#)

STEP 2 - Activation

The activation code will only be needed for you to set up the app for the first time to protect your data.

1. Open the AOS Vision app
2. Press the "Activate" button
3. Enter the activation code as below

ACTIVATION CODE

60R_5751_19R

Figure 70. Patient email.

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14.2 Logging in – Activation for first use

When the patient clicks the active link in the email or text message, the AOS Vision app will automatically download and open. The patient will then need to enter the activation code that was in the email/text message and they will be taken to a camera screen and can begin taking images.

Upon completion, the patient will click Transfer Images and the images are transferred into the patient database in the AOS V3 software. See figure 71 below



Figure 71. Patient transfer images.

14.3 Logging in – after activation

The patient needs to enter the PIN to login into the app. Once logged in they will need to select the 'take images' icon which will allow the patient either take an image or upload an image from the photo library.

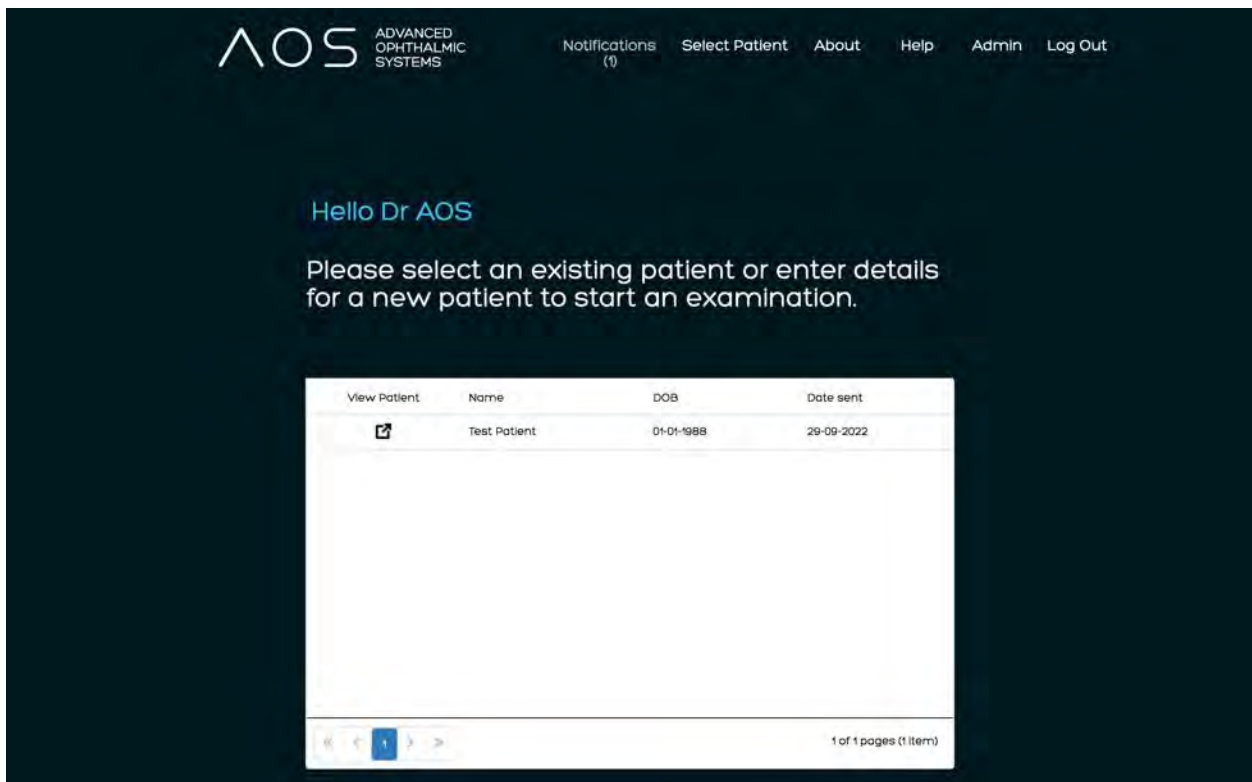
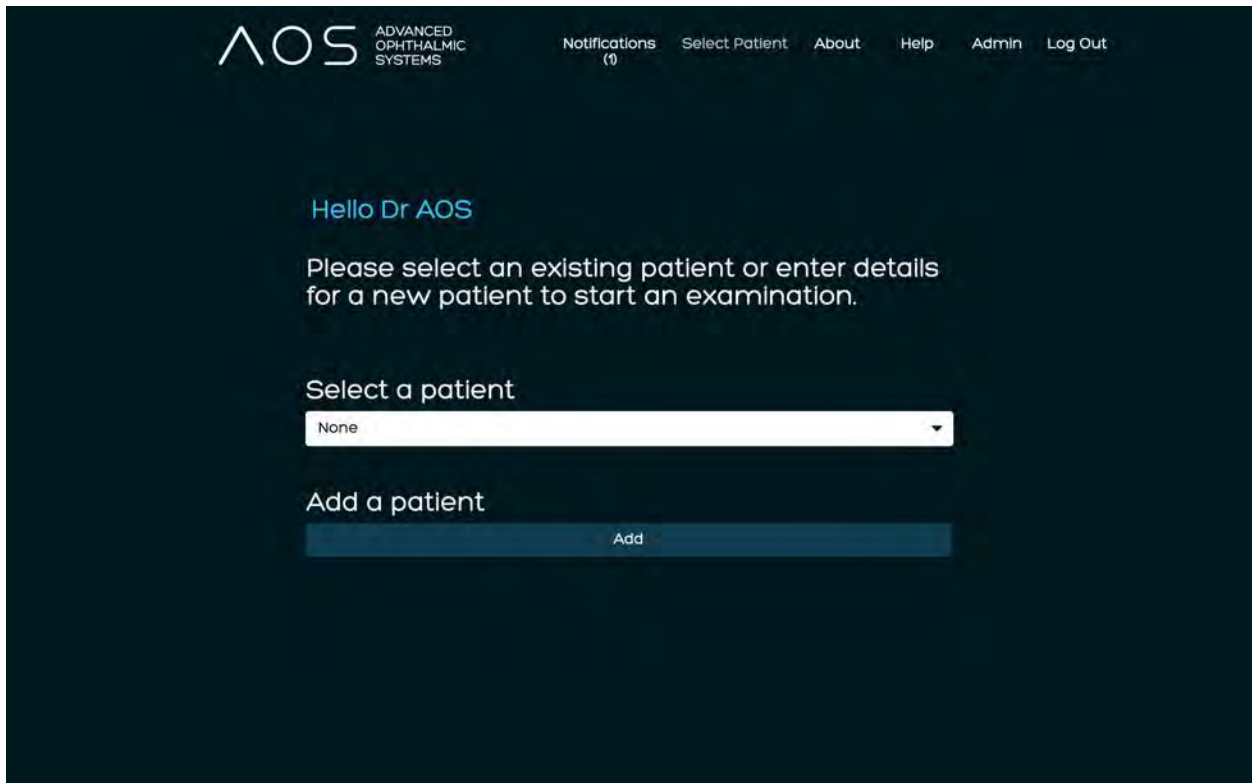
Upon completion, the patient will click Transfer Images and the images are transferred into the patient database in the AOS software under add/view images.

14.4 Notification of patient transfers

When patient's transfer images/videos from their AOS app, a notification will appear on the AOS system. This will appear for all users within the same user group. When 'Notifications' is selected, a list of patients who have transferred images/videos will be displayed with the most recent transfer at the top.

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Once a patient is selected and their patient summary is viewed, the notification will be cleared from all users. See figures 72-73 below.



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Figure 72-73. Notification of patient image transfer

15 Billing and invoicing

The AOS V3 software allows the global administrator to control their account for billing and invoicing. The global administrator for the account can access this information in two ways, by either logging into their account and going to the licensing site or by clicking on the admin page and then the licensing button. See figure 74 below.



Figure 74. Show invoice

The global account administrator also has the ability to review previous invoices for their account and update any pertinent information using the admin or licensing page. See figure 75 below.

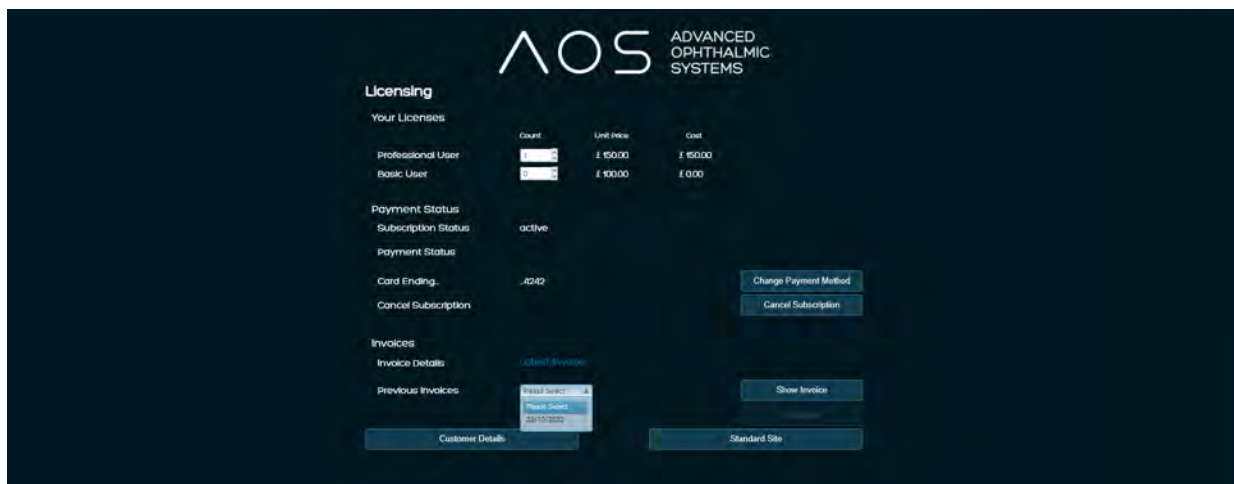


Figure 75. Previous invoices

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16 Getting help and support

16.1 The AOS website

<https://www.aos-hub.com>. For all supporting documentation for AOS products, go to the contact page and use the feedback widget or mail us direct support@aos-hub.com

16.2 Requesting product support

Should the user have a question regarding application support or specific product use, please contact our Support Centre via the online form on the AOS Contact web pages and or live chat on our website.

16.3 Finding support documentation online for other AOS products

At www.aos-hub.com all product documentation is logically stored and available for download in pdf format.

16.4 Update notifications

Notifications of product updates and new features will be advertised on the website. All documentation will be updated accordingly. If the user has a subscription product updates and features will download automatically each time the application is started.

17 FAQ's

17.1 Where do I and /or my patient find my activation code for the app

All users of the system (including patients) will receive a welcome email that provides all the relevant information for their user account including the app login details. If the user is unable to find the email the global administrator can reset password and activation codes.

17.2 Which smartphones does the AOS Vision app work with?

The AOS vision app works with both android and iPhone mobile devices and tablets. For the minimum restrictions for Android and iPhone devices, please visit the support pages on the AOS website, or contact AOS for more information.

17.3 Printing the user result files

Result files are saved in PDF format and can be opened and printed from any PDF viewer. The PDF reports are available by opening a patient file to the summary tab and clicking on the 'View exams' report icon. The PDF for the file/session is in the bottom left hand corner of the page.

17.4 I can't open my results file

This is likely that there is no PDF viewer application installed on the computer. A viewer is available for download from www.adobe.com.

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17.5 Database integration

If the user uses a database to manage the user patient files outside of the AOS database, the AOS report can be saved within the same patient folders. This is dependent on the folders not being locked for access via file explorer.

17.6 What image file types can AOS analyse

AOS can load and analyse many image file types including;

- Windows bitmaps - BMP, DIB
- JPEG files - JPEG, JPG, JPE
- Portable Network Graphics – PNG
- Portable image format - PBM, PGM, PPM
- TIFF files - TIFF, TIF

18 Contact AOS

Information on all AOS applications is available online. Please contact us via the online contact forms. For any further information or enquiries regarding AOS and our products, please contact;

enquiries@aos-hub.com