VIRTUAL

BY **VOLK** ®

Instructions for Use

Cloud-Based Retinal Screening Platform

Virtual by Volk ™
Instructions for Use for Virtual by Volk Cloud-Based Retinal Screening Platform

Volk Optical Inc.
7893 Enterprise Drive
Mentor, OH 44060 USA

volk.com
volk@volk.com

Toll Free USA: +1 (800) 345-8655
Phone: +1 (440) 942-6161

Contents

1. Product Description

1.1 General

Virtual by Volk is a cloud-based telemedicine solution that enables the secure transfer and storage of retinal images and clinical data. Retinal images are uploaded to the cloud and routed to a clinician or a qualified reader for analysis. The system is designed to ensure adherence to HIPAA compliance guidelines. Virtual by Volk can be accessed by various levels of users such as Volk Administrator, Client Administrator, Clinic Administrator, Camera Technician, Clinician, and Payer. Virtual by Volk allows these different users to remotely interact and perform eye screenings.

The Virtual by Volk is a prescription device that is only intended to be used under the supervision of a physician or licensed practitioner.

It is the responsibility of the health care provider to protect patient health information and comply with local regulations regarding patient health information. The images on Virtual by Volk may contain identifiable patient information, and it is the responsibility of the health care provider to ensure that data safeguards are implemented to protect patient health information.

1.2 Important Symbols

Symbol	Description
	Important operating instructions are included in this Instructions for Use (IFU). Failure to follow these instructions could place the patient or operator at risk.
	Consult this IFU for important cautionary information. The user is advised of important operating and maintenance instructions.
	Indicates the date when the medical device was manufactured.

Rx only   Prescription Device symbol. Caution: Federal law restricts this device to sale by or on the order of a physician or licensed practitioner.

    This symbol is accompanied by the name and the address of the device's manufacturer.

GTIN   Notes the Global Trade Item Number of the product.

1.3 Intended Use

Virtual by Volk is a web-based software system application intended for use in storing, managing, and displaying patient data, diagnostic data, and images from computerized diagnostic instruments or systems. Original and enhanced images can be viewed by trained healthcare professionals.

1.4 Intended Users

Virtual by Volk is intended to be used by medically qualified, trained healthcare professionals. Secondary intended users include biomedical personnel, IT professionals, and both Volk and third-party service personnel. The instructions contained within this document only target this set of users.

1.5 Overview

Virtual by Volk enables various roles and functions to be carried out by different users. This allows different tasks such as patient creation, patient management, retinal imaging, and retinal image analysis to be assigned to appropriate users. These different users can interact via the cloud, streamlining the retinal imaging process. A client or clinic administrator can create a camera technician and then schedule a patient for screening by the camera technician. At the appointment, the camera technician will use a retinal camera to capture images of the patient which can then be submitted for review by a clinician. The clinician can view the patient's retinal images, assess them, and advise a management plan for the patient. Once reviewed, the clinician can generate a report for the patient and send it to the client or clinic administrator who can view the report and share it with the patient.
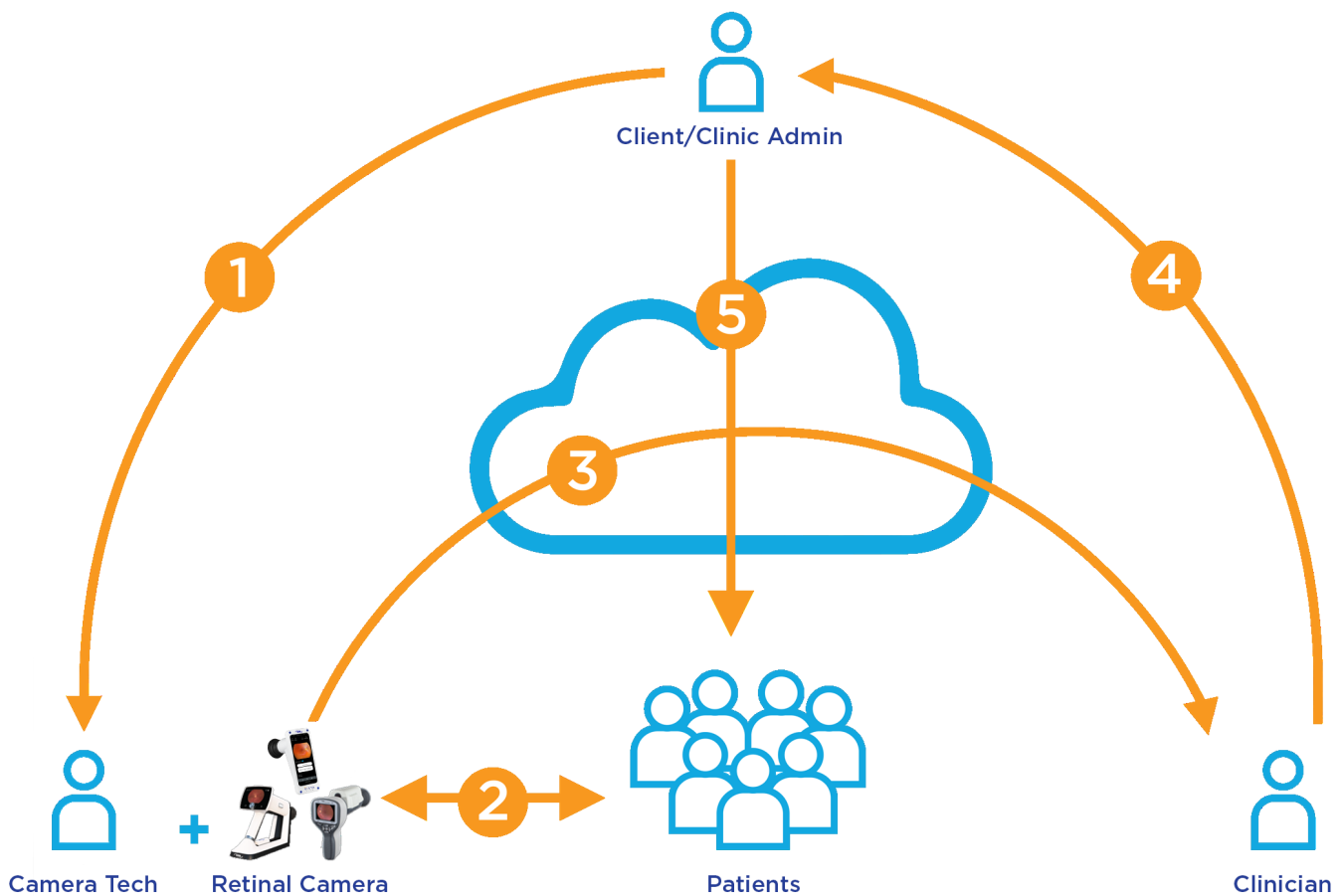

Figure 1: Workflow of Different User Roles

2. Getting Started

2.1 Logging In

Virtual by Volk's web version can be accessed using an internet browser. When choosing a browser, please refer to Section 3.3 for more details about performance and compatibility. To begin, navigate to your browser and enter "https://ce-io.com/VolkProdA/login.html" in the search bar as illustrated below. The log-in page for Virtual by Volk is located at this URL.

All Virtual by Volk accounts are accessed with a username and password. The web version requires users to specify their role via the drop-down along with their username and password. Your Volk Client Success team will create your account and an authorization email will be sent from "no-reply@verificationemail.com" to the account's email. Please make sure to add "no-reply@verificationemail.com" to your contacts list to prevent the authorization email from being directed to your spam folder. The authorization email will provide a username and password that can be used to begin setting up your user profile. After entering the given username and password, you will be prompted to create a new password.
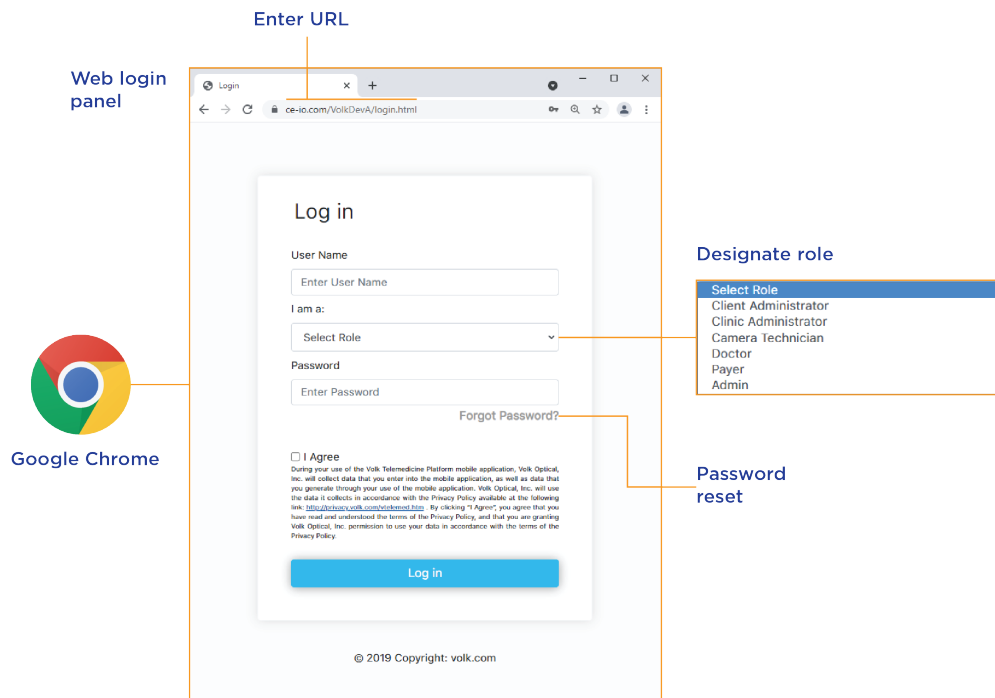

Figure 2: Web Version Login Screen

2.2 IT Network Security

All devices used to connect to Virtual by Volk should be set up and maintained following IEC 80001 or similar IT Network security practices.

These include:

- physical security of the computer and any connected peripherals to prevent theft, tampering, unauthorized use, or unintended disclosure of private data shown on the computer screen

- individual user authentication using strong passwords and, if possible, some form of multi-factor authentication

- idle-session timeouts with either screen locking or automatic logout

- user access rights/permissions limited to those required for the user's assigned role

- timely installation of all computer and operating system vendor's security patches and updates

- anti-virus, anti-malware, and/or intrusion detection/prevention software from a trusted vendor installed and regularly updated

- periodic system backups, with regular testing of system recovery procedures

- secure network connection, either wired or wireless. Wired network connections should be physically secured and/or protected by 802.1X network access control and/or IPsec. Wireless network connections should use WPA2-PSK or WPA2- Enterprise security with strong username/password or X.509 certificate based authentication.

2.3 System Requirements

Item	Requirement description
Web Browser	Google Chrome 60.0.3112+ or Internet Explorer _____+
High-Speed Internet Connection	Broadband Internet Connection with minimum download speed ___ Mbps.
Transport Security	Ability to connect to ce-io.com with TLS 1.2.
Firewall	Ability to connect to ce-io.com server. Allows to access Virtual by Volk on the web platform.
Certificates	_____

2.4 Managing Passwords

Please do not share your login/password details with other users.

When creating a new password, the minimum password length is 8 characters. Furthermore, the new password must contain **at least one lower case alphabetic character**, **one upper case alphabetic character**, **one special character**, and **one number.**

Every user should renew their password as required by their organization's settings. The default renewal period is set to 90 days. When a renewal period has expired, change the password from the account drop-down. See Figure 4 for the location of the account options drop-down for all user roles.

If a user forgets their password, it can be reset via the "Forgot Password" option on the login screen. On the web version, enter a valid username and role on the login screen, select "Forgot Password" as illustrated in Figure 2, and a reset code will be sent to the user's email. The login screen will then prompt the user for the reset code and a new password.
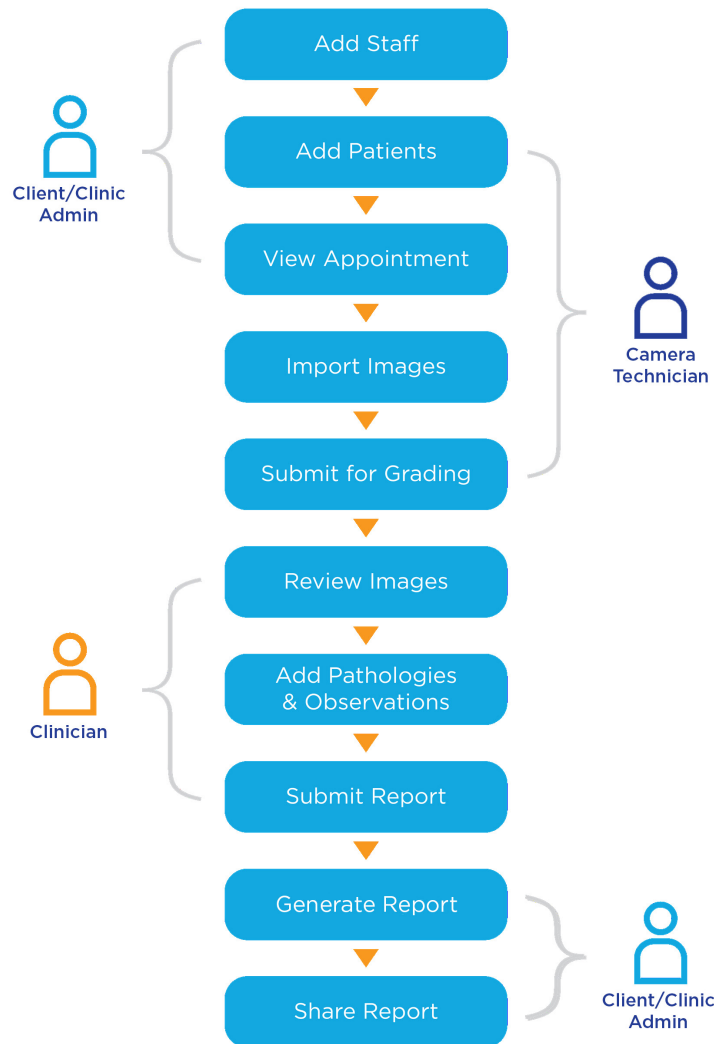
3. User Roles

3.1 Workflow

Figure 3: Schematic Representation of Typical Workflow

Virtual by Volk assigns responsibilities to specific user types, allowing for the efficient creation, scheduling, imaging, and reviewing of patients. A client or clinic administrator can add and schedule patients and can allow their camera technicians to manage these tasks as well. These patients and appointments are then wirelessly transferred to camera technicians who can view their patients and appointments, perform the imaging, and send the retinal photos over the cloud for review by a clinician. Clinicians receive this information, log their observations and diagnoses, and generate reports that can be reviewed and shared by users.

3.2 Client Administrator

The client administrator manages and designates user roles at the client site.

Add Patients ▶ Schedule Patient ▶ Add Patients ▶ Generate Report

Their primary responsibilities include adding and managing patients and staff, as well as viewing and downloading reports.

They can add staff, including camera technicians, clinicians, and payers. Client administrators can then manage the scheduling and assignments of their staff, receive patient reports from clinicians, and view audit trails.

3.3 Clinic Administrator

A clinic administrator role manages patients at the clinic.

Add Patients ▶ Schedule Patient ▶ Add Patients ▶ Generate Report

Clinic administrators are primarily intended to add patients, schedule them, and view and download reports.

They can add camera technicians and patients, schedule patients, receive reports from clinicians, and share reports with patients and/or insurance providers.

3.4 Camera Technician

Camera technicians are the on-ground operators of retinal cameras.

View/Add Appointment ▶ Import Images ▶ Submit for Grading

The primary function of the camera technician is to schedule patients, manage patients, image them, and submit their images.

They can view their patients and appointments assigned by their client administrator. Given permission by their client administrator, they can also create and schedule patients independently.

3.5 Clinician

Clinicians receive retinal images of their patients and perform analysis.

| Review Images | ▶ | Add Pathologies & Observations | ▶ | Submit Report |

The clinician reviews images captured by the camera technician, analyzes the images, and records observations to include in submitted reports.

Clinicians can annotate fundus images for pathology, list diagnoses, and provide a management plan within their reports.

3.6 Payer

The payer is an administrator at an insurance provider.

| Add Patients | ▶ | Transfer Patients |

The primary responsibility of a payer is to import lists of patients and transfer them to the Client Administrator.

4. Client Administrator

4.1 Introduction

As a Client Administrator, you can add and schedule Patients as well as view their reports after they are examined. Furthermore, Client Administrators can edit their Patients' information and reschedule them. Client Administrators are capable of viewing and downloading their Patients' reports once they have been reviewed. Staff such as Camera Technicians, Clinicians, and Payers can also be created by the Client Administrator. Camera Technicians can be given Patients by the Client Administrator. Client Administrators can also view all user activities through Audit Trails.

Figure 4: Client Administrator Interface

4.2 Adding Patients

To create a Patient, select the Patient from the left-hand menu and click the "Add Patient" button in the upper right corner. From there, information about the Patient can be entered and saved. Mandatory fields will be represented with "(*)".

4.3 Scheduling or Changing Appointments

When adding a new Patient, you will automatically be directed to schedule the Patient. It is not required that a Patient be scheduled upon creation, they can be scheduled by accessing Section 6 of their Patient profile at any time. These scheduling options can be accessed by clicking on the "..." icon, selecting "Edit," and scrolling to the bottom for Section 6 "Schedule". If the Patient has not been scheduled, Section 6 can be quickly accessed by clicking on "Schedule Now" for the corresponding Patient.

When scheduling a Patient, the location, clinic, Camera Technician, and time slot are required. Available time slots are white, occupied times are grey, the selected slot is blue, and when rescheduling, the Patient's current reservation is yellow.
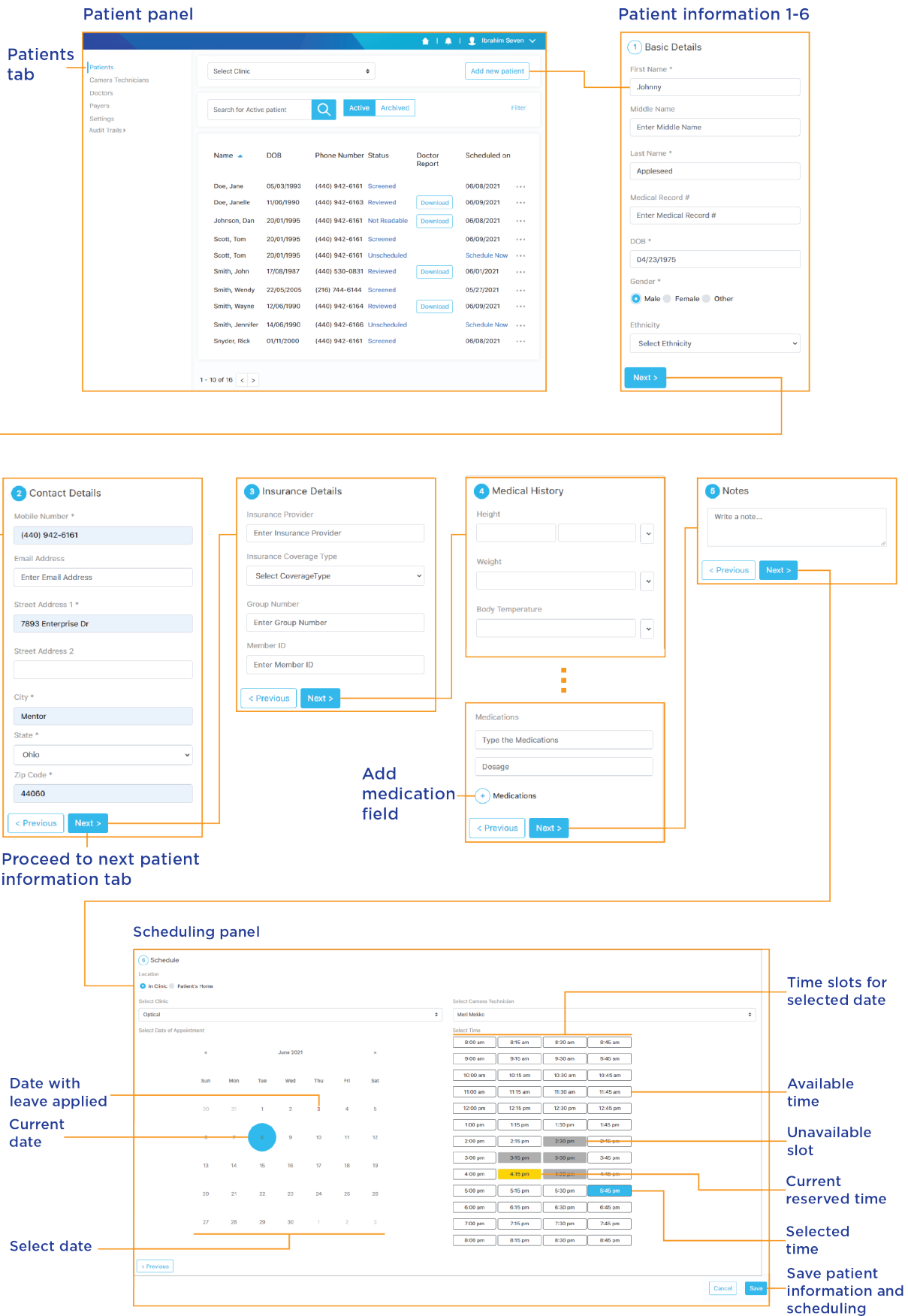
Figure 5: Adding a Patient

4.4 Locating Reviewed Patients and Generating Reports

Client Administrators can filter their Patient list to view all reviewed Patients. On their home screen, this can be done by clicking on "Reviewed" in the Patient Statistics dock.

A similar list of reviewed Patients can be accessed by selecting the "Patients" list from the left-hand menu and filtering with "Filter" to view only Patients with "Reviewed" status.

A Client Administrator's lists can be searched via the search bar and filtered by clicking "Filter". Within "Filter", the Client Administrator has options to invert the alphabetization and filter by state, zip code, or status. Within the "status" filter options, the Patient list can also be narrowed to reviewed patients. The reviewed Patient list can also be filtered to entries within a certain time frame with the drop-down menu in the upper right-hand corner.

Once a Patient has been imaged by a Camera Technician and reviewed by a Clinician, the Patient's report can be generated. This report will contain the Patient's information, their retinal images, and the Clinician's assessments. As illustrated in Figure 5- Adding a Patient, a successfully screened and reviewed Patient will have a "Download" button on their entry in the list under "Doctor Report". When clicked, a pdf of the Patient's report will be generated and downloaded to the Client Administrator's computer. This file can be found on the computer under "Downloads".
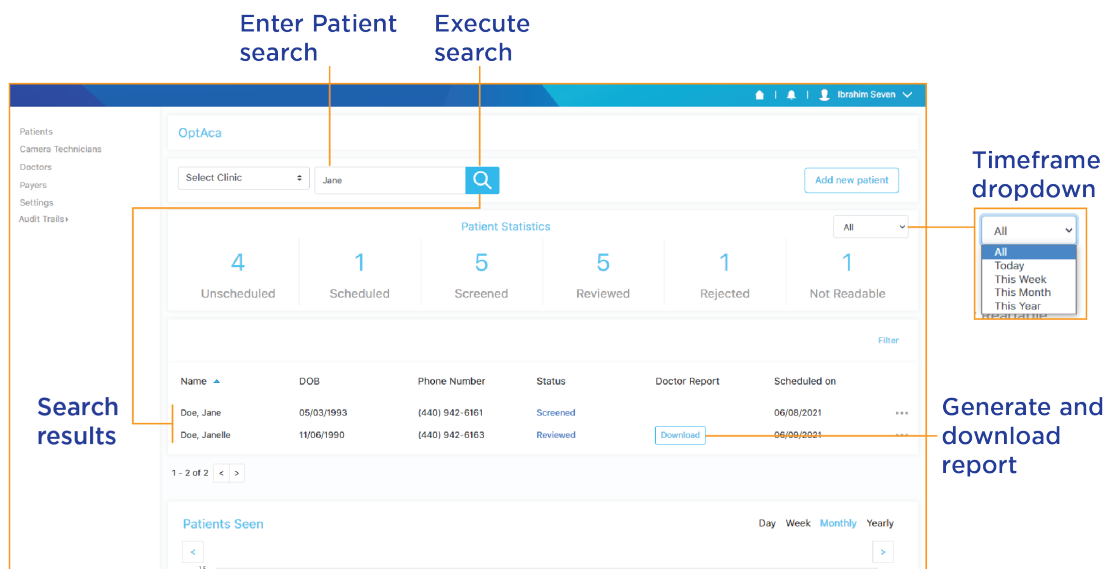

Figure 6: Searching Patients and Generating Reports

4.5 Adding Staff

Client Administrators can also create Camera Technicians, Clinicians, and Payers. The Client Administrator should populate their staff in the database before scheduling and assigning Patients. Every Camera Technician that is added to the system is assigned to one or multiple clinics, the amount can be determined by the Client Administrator. Like Camera Technicians, every Clinician added to the system must be assigned to at least one clinic.

Adding Staff can be executed like adding other types of users, where the desired role menu is accessed from the left-hand menu and selecting "Add Staff" in the top right corner begins the creation process.

When creating a Camera Technician, basic details, contact details, and the Camera Technician's clinic will be required. When creating a Clinician, their clinic, NPI, and license number are required. Clinics can be added by a Volk Administrator if a Clinician's clinic is not listed. NPI and license number are both Clinician identifiers, and license number will require the specification of the Clinician's state of practice.

4.6 Editing and Archiving Users

After adding a Camera Technician, Clinician, or Patient you can edit their information, including email and username. Select the tab on the left-hand panel that corresponds to the desired user's type. This will populate the dashboard with a list of all users of that type. Search or filter the list via the search bar and "filter" buttons respectively. Once the desired user is located, click on the "..." icon to the right of the user followed by "Edit", and then modify their information. Once complete, click "Update" at the end of the form to save the changes.

Client administrators can also archive users to remove them from their workflow. Click on the "..." icon for the target user and then "Archive". This will move the target user out of the "Active" section and into "Archived". To restore an archived user, navigate to the "Archived" tab to see a list of all archived users of the current type. Clicking "Restore" next to the desired user will return them to the active list of users.

4.7 Audit Trails

The Client Administrator will have access to audit logs to allow traceability of all actions. The Audit Trail tab is broken into Access Logs and Login Activity and can be accessed by clicking on "Audit Trails" on the left-hand panel beneath the user types.

The Access Log presents information about all user activities within the system. Each event will note the user involved, role, action, description, source IP, page accessed, and the time it occurred.

Login Activity records and displays all logins for the Client Administrator and any of its users. Entries on the Login Activity page contain a username, role, login and logout time, if successful, block time, and timestamp.

4.8 Settings

From the left-hand panel, select the settings tab to access options about capture requirements, image types, and Camera Technician permissions.

"Image Requirements" allows the Client Administrator to specify the number of required images per label their Camera Technicians must submit.

The file type of submitted images can be specified under "Image Type", either DICOM or JPEG. DICOM is the standard filetype for medical imaging, while JPEG is a more compressed filetype that allows for efficient data transfers.

If DICOM images are required, ensure that DICOM is selected before imaging. JPEGS cannot be converted to DICOM.

The "Adding Patients" feature specifies whether the Client Administrator's Camera Technicians can create Patients themselves.

5. Clinic Administrator

5.1 Introduction

Clinic Administrators can create Patients and schedule them for examinations by Camera Technicians, which they also can create.

The Clinic Administrator's home screen displays a Patient dashboard with information about Patients of all statuses.
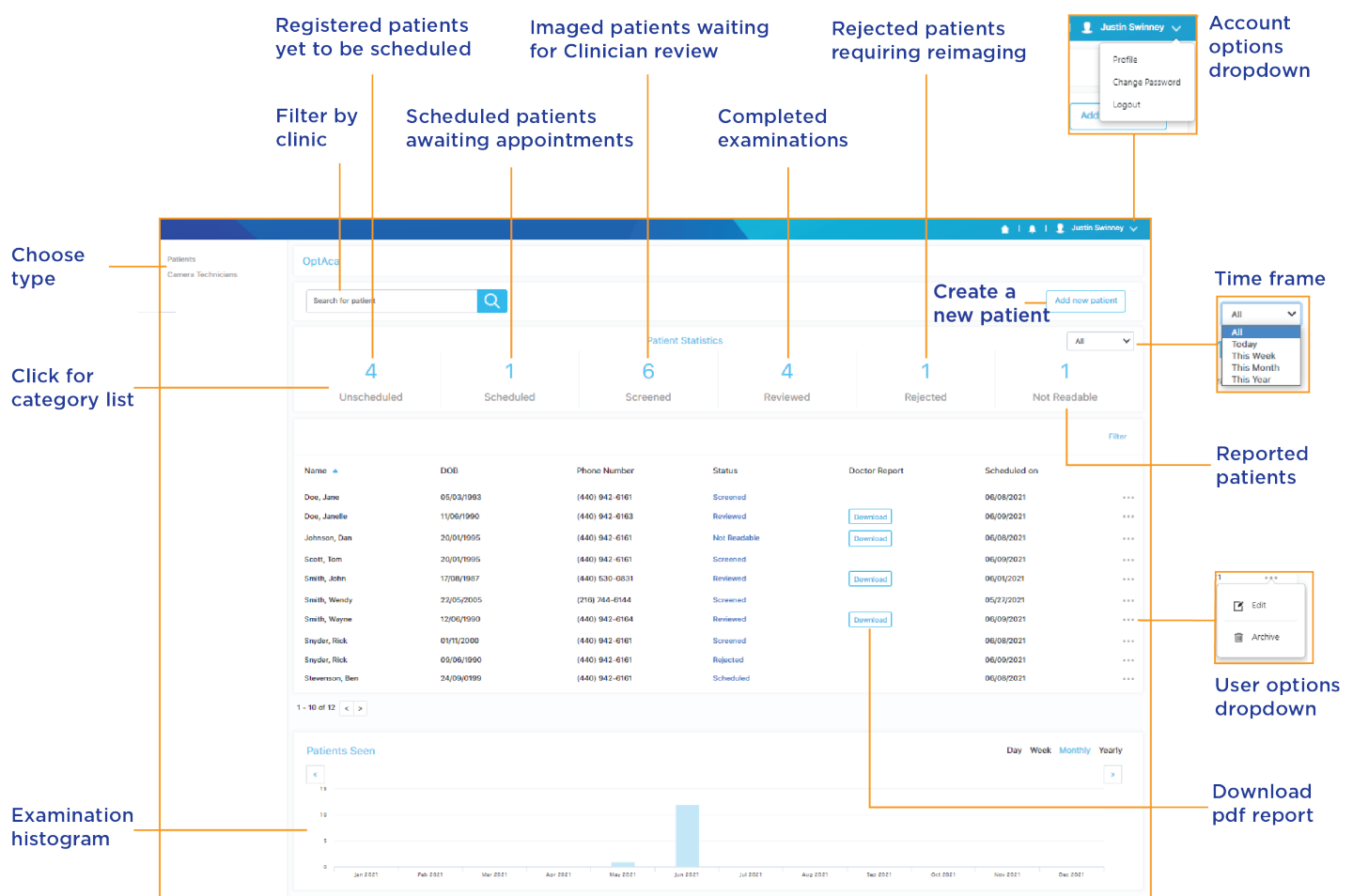
Registered patients yet to be scheduled

Imaged patients waiting for Clinician review

Rejected patients requiring reimaging

Account options dropdown

Filter by clinic

Scheduled patients awaiting appointments

Completed examinations

Choose type

Create a new patient

Time frame

Click for category list

Reported patients

User options dropdown

Examination histogram

Download pdf report

Figure 7: Clinic Administrator Interface

5.2 Adding Users and Patients

Clinic Administrators can add Camera Technicians and Patients like Client Administrators. For information about adding and editing those user types, refer to sections 4.2 and 4.5.

5.3 Scheduling or Changing Appointments

For information on how to schedule or change an appointment, please refer to Section 4.3.

6. Camera Technician

As the on-ground operators of retinal imaging devices, Camera Technicians are responsible for performing examinations as well as uploading them via the Virtual by Volk platform for assessment by Clinicians.

Camera Technicians have four ways of interacting with Virtual by Volk. They can use Virtual by Volk's web version, iOS app, VistaView, or Prestige retinal cameras.

In-browser
Sections 6.1-6.5
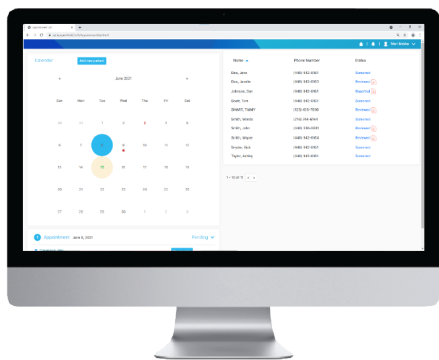
Mobile app
Sections 6.6-6.11
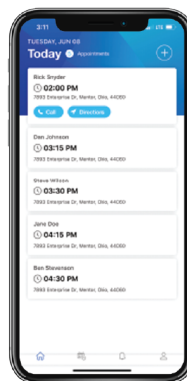
VistaView
Sections 6.12-6.15

Pictor Prestige
Sections 6.16-6.20

Figure 8: Camera Technician Interfaces

Web-Based

6.1.1 Introduction

Virtual by Volk's in-browser solution allows Camera Technicians to create and manage Patients as well as upload imagery from a retinal camera after performing an examination.

The Camera Technician's home page displays a calendar, appointments, and a Patient information table with the Patient's name, phone number, status, and a PDF icon which can be clicked to view the Patient's report.

Account options and training

Appointment list

Create a new patient (if enabled)

Screened or reviewed patients

View report

Filter appointments

Change appointment time
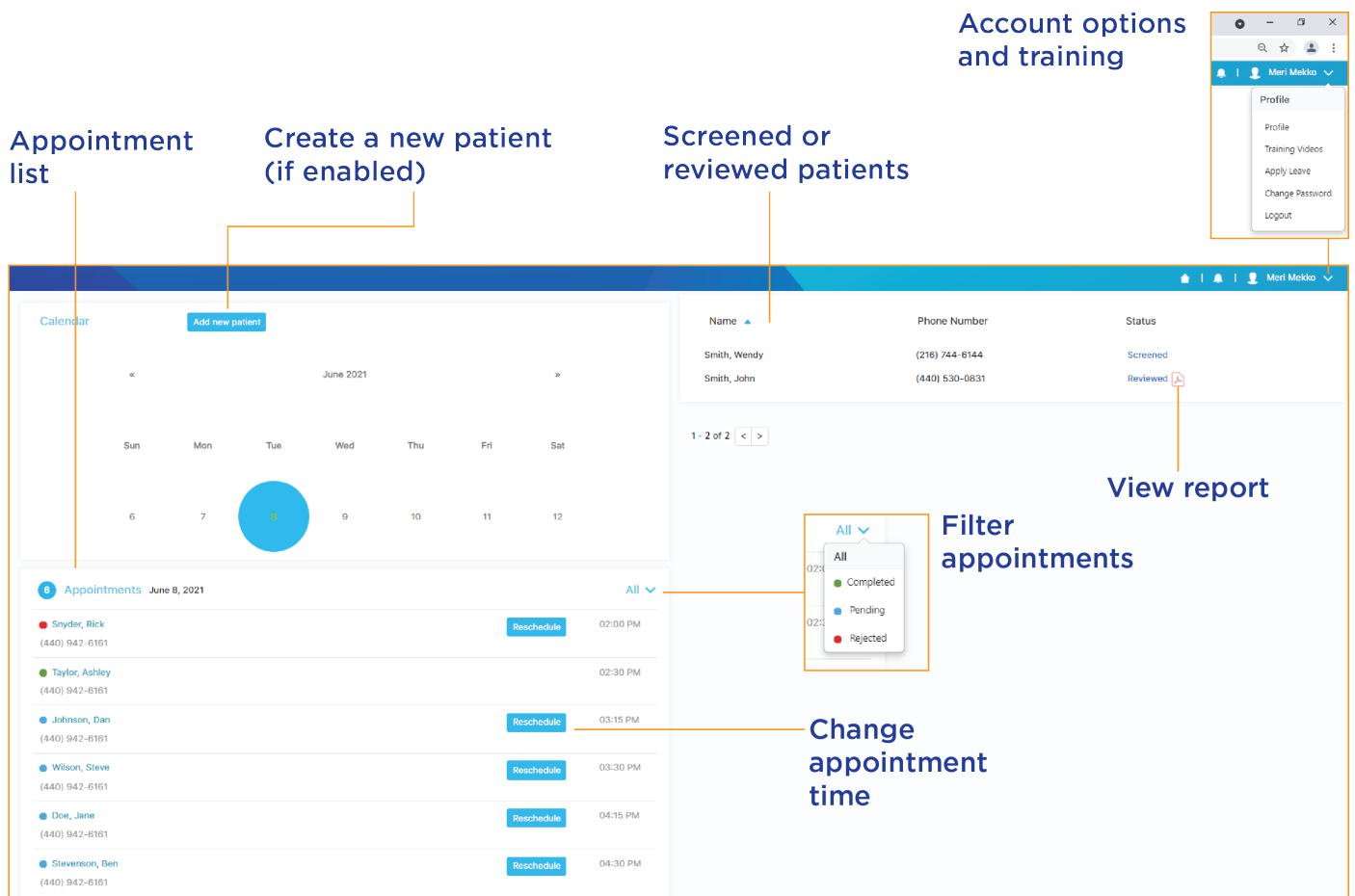
Figure 9: Camera Technician Home Screen

6.1.2 Adding Patients

Camera Technicians can add new Patients to their site locations when permitted by their Client Administrator. Select the 'Add new patient' button above the calendar. Populate the Patient profile with mandatory fields represented by an asterisk (*). In Section 6 "Schedule" select a time slot to schedule an appointment for that Patient. Figure 5 illustrates Section 6 of the Patient creation process. As a Camera Technician, you can only view and schedule timeslots that belong to you. Click the save button to add the Patient profile to the database. If the "Add new patient" button does not appear on the Camera Technician's home screen; a request will need to be made to the Client Administrator to enable the functionality.

6.1.3 Appointments

A Camera Technician's appointments are displayed on the left-hand side of the dashboard. By default, the current day's appointments will populate the schedule. If no appointments are scheduled on the current day, the calendar will inform the Camera Technician of the next scheduled appointment. Camera Technicians can also click on a date to view appointments for that day.

Filter what kind of upcoming appointments are visible using the drop-down illustrated in Figure 9. Pending appointments are noted with a blue dot, completed appointments are green, and rejected or incomplete Patients get a red dot.

The Camera Technician can reschedule a Patient by selecting the "Reschedule" button on the Home screen next to the Patient's name on the pending list. Proceed to reselect a time slot for the new appointment and click "Save". Available time slots are colored in white; unavailable time slots are grey, and the currently reserved appointment time is yellow.

6.1.4 Importing Retinal Images

Once the Camera Technician selects an appointment by clicking on a Patient, the following screen appears requiring the retinal images to be imported from a retinal camera.

Data import window

Figure 10: Importing Data from a Retinal Camera

Always review the retinal images and confirm that they are matched with the correct label (OD-Right Eye vs OS-Left Eye) to prevent confusion. At this point, the Camera Technician must ensure the retinal camera is powered up. The images can be transferred to a PC via wireless methods or through a USB connection. Please refer to the compatible retinal camera's user manual for a detailed description of transfer methods. This transfer method is not recommended by the manufacturer due to the multiple additional steps required to transfer images. Please refer to Camera Technician iOS App and Prestige direct connectivity sections for recommended image transfer methods.

Once an image is uploaded, a thumbnail will be displayed in the image field and the Camera Technician can proceed to submit images. The Camera Technician can also add a note to an image to inform the Clinician about the details of the image. By clicking "Done" in the lower left, the Camera Technician submits the screening for observation by a Clinician.

If a Patient cannot be seen or rescheduled, the Patient pack can be rejected to the Client or Clinic Administrator. From the data import screen, select "Reject Patient", describe the reason for rejection, and submit the report with the "Report" button.

6.1.5 Apply for Leave

Camera Technicians have the ability to "Apply for Leave." This enables a Camera Technician to inform the Client Administrator when they are unavailable to conduct screenings.

After selecting "Apply Leave" under their Profile, the Camera Technician must select a day, provide a reason, and submit by clicking "Apply Leave". A date on the calendar will be noted in red when the Camera Technician has successfully submitted for leave on that day.

Mobile App

6.2.1 Introduction
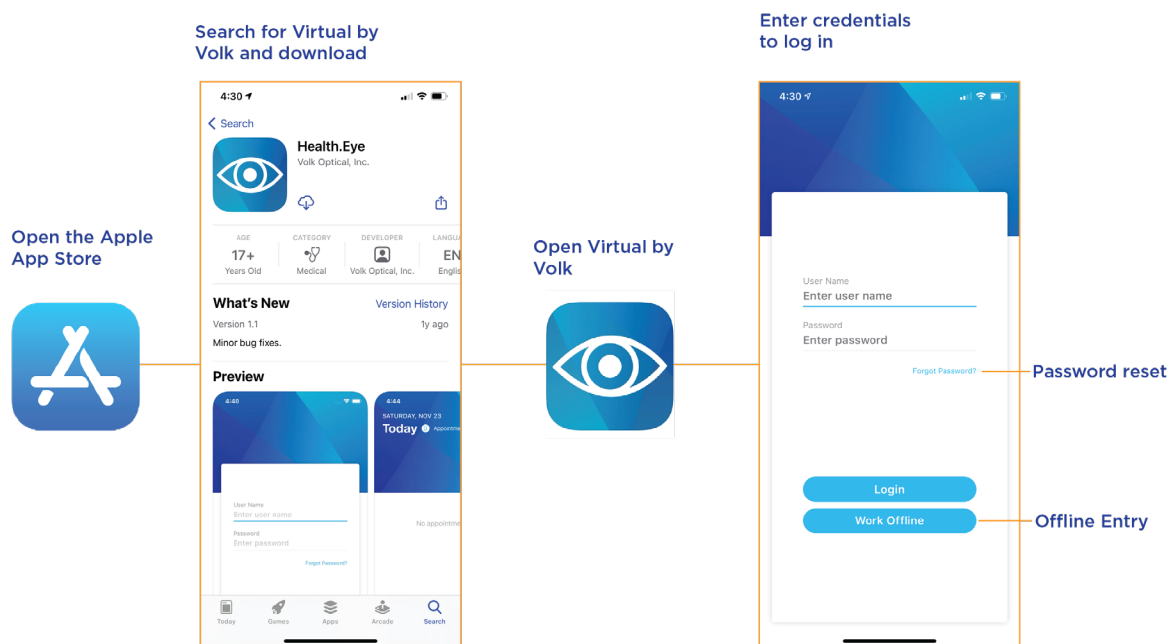
Figure 11: Mobile Version Access

Virtual by Volk's mobile version allows Camera Technicians to continue adding, managing, and imaging their Patients on the go. Through the iOS app, the Camera Technician's mobile phone can be paired to a Vista View, Pictor Prestige, or Pictor Plus. The app can be located within the App Store by navigating to the search tab and searching for Virtual by Volk. The app is free to download but requires an Apple ID to proceed. Once downloaded, it can be found on the user's Home Screen and tapped to open. Virtual by Volk's mobile platform is intended for exclusive use by Camera Technician users, no other user roles will be able to log in on the app.

Upon opening the app, the Camera Technician will need to sign in with their credentials. Unlike the web application, there is no need to specify user type, as all mobile users are Camera Technicians. Selecting "Forgot Password" on the login screen will lead to a prompt for a username. See Figure 10 for the location of "Forgot Password". Following the entry of a valid username, an account reset link will be sent to the user's email. Once opened, the user can create a new password.
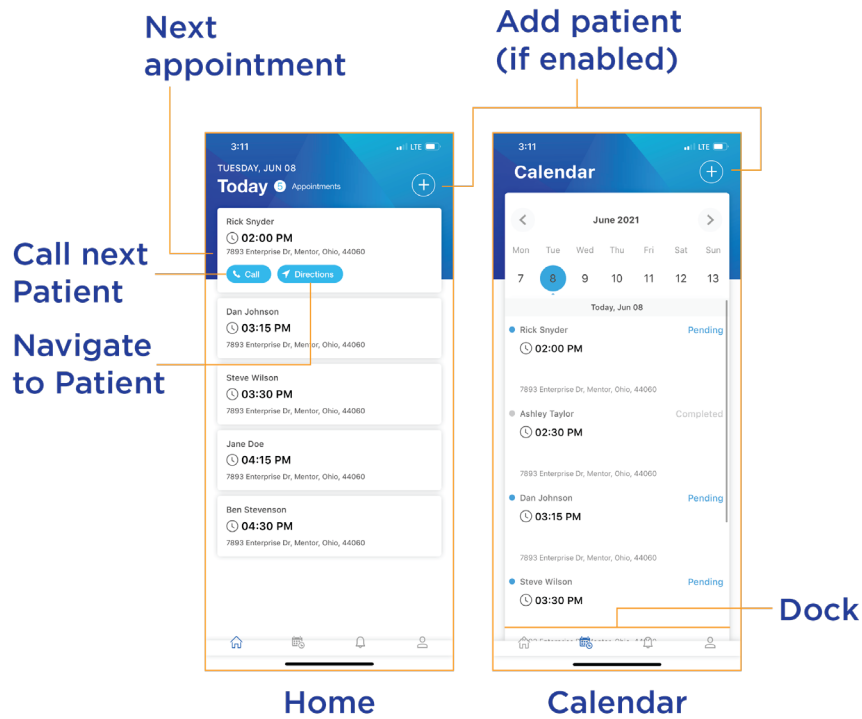
Figure 12: Home and Calendar Views

6.2.2 Home Menu

Once successfully logged in, the Camera Technician will see their appointments for the day. If there are no appointments on the current day, the next available appointment will be shown on the home screen. Tapping on the appointment will load the Patient's name, appointment schedule, and address. The Patient can be called via the "Call" button. For non-ambulatory Patients, the Camera Technician can also get navigation to the Patient's home via the "Directions" button.

6.2.3 Viewing Appointments

Click on the "Calendar" icon located on the bottom dock to access the calendar screen. Here, the Camera Technician can easily view their schedule on a daily/weekly/monthly basis. Appointments are displayed for the selected day unless none are scheduled. In that case, the calendar will inform the Camera Technician of the next scheduled appointment. Pending appointments are noted with a blue dot, completed appointments with a green dot, and rejected or incomplete appointments are red. A day marked with a blue dot has at least one pending Patient needing Camera Tech's attention, while a day marked with a grey dot has no pending Patient. A red dot indicates that all Patients were rejected by the Camera Technician on this day.

6.2.4 Adding and Scheduling Patients

Camera Technicians can add new Patients to their site locations by clicking the (+) as displayed in Figure 12. Adding a new Patient as a Camera Technician is no different than adding a Patient as a Client Administrator. Please reference Section 5.2 for details on Patient creation. If the 'plus' button does not appear on the Camera Technician Home Page, a request will need to be made by the Client Administrator to Volk Administrator to enable the functionality.

After all basic Patient information and contact details have been entered the following screen enables the Camera Technician to schedule an appointment for the Patient. An appointment's location can be selected as "In Clinic" (default) or "Patient's Home". A Camera Technician can only schedule an appointment on their calendar. Available time slots are noted with a white border, while unavailable times are grey.
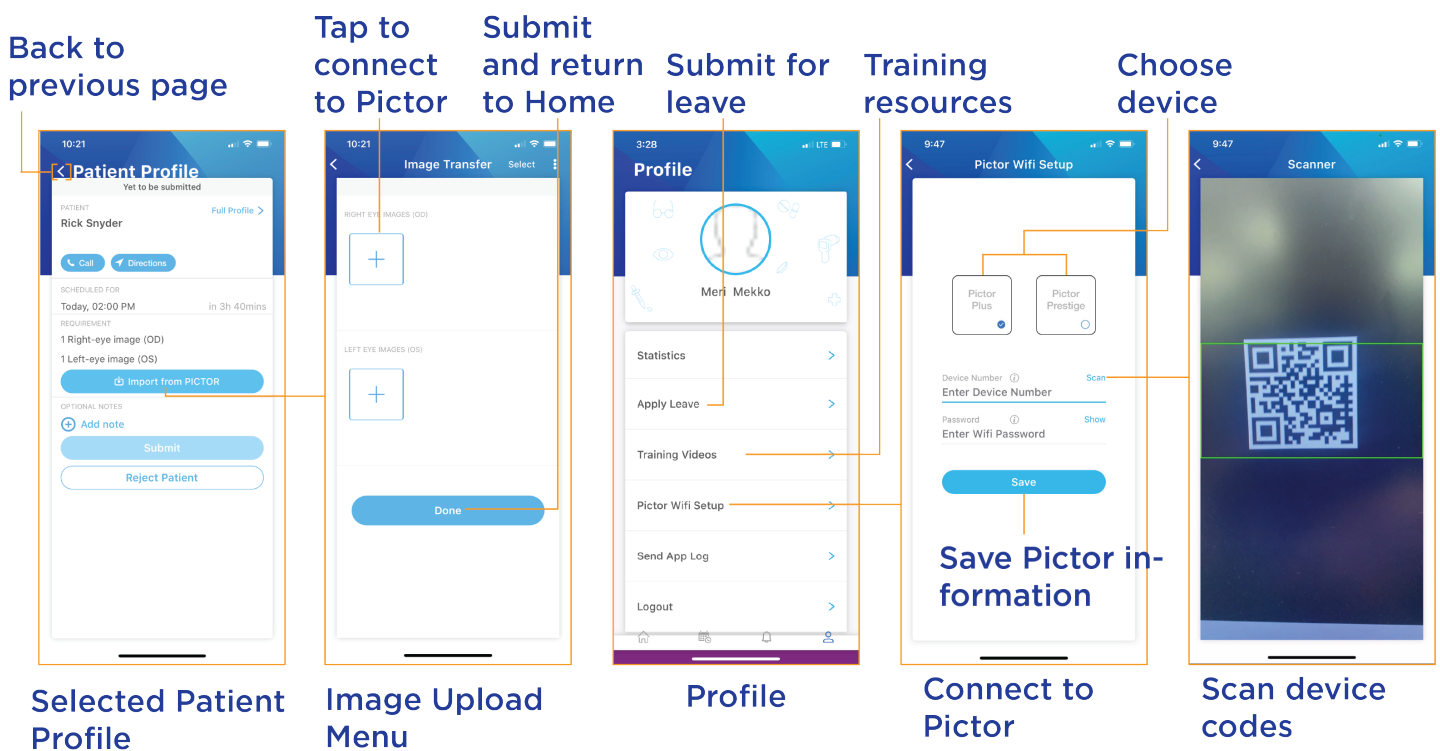
Figure 13: Patient Image Upload and Profile Options

6.2.5 Pairing and Using Pictor

The camera must be paired to the iOS device before any images can be imported. Failure to properly pair your camera to the iOS device may prevent the transfer of retinal images to the telemedicine software. For Pictor Plus and Pictor Prestige pairing, begin by clicking on "Profile," the rightmost icon on the dock. After selecting the appropriate device, a barcode scanner will appear to scan the serial number and password QR codes found in the device's case. Please contact your Volk Client Success team member if you have any difficulty in this process. After successfully scanned, click done and ensure that a "Connection is Successful" message is received.

Once the Camera Technician selects an appointment, an option to upload retinal images from Pictor will become available.

Click "Import from PICTOR" to transfer images captured by the retinal camera onto the mobile app. If you are not familiar with Pictor Plus or Pictor Prestige, it is recommended to refer to the Instructions for Use for your device.

Ensure the Pictor camera is turned on, turn on the device by pressing and holding the power button. The Camera Technician can select retinal images from the camera and associate them with the Patient currently being reviewed. A Camera Technician can also tap on the three dots in the top right of the screen to import images via their device's gallery.

The Camera Technician can scan for the retinal camera over Wi-Fi, browse Pictor's gallery, and select the Patient's images to upload. When importing retinal images, you can select the laterality of the pictures to associate them with either the left or right eye. Camera Technicians can then submit the Patient file to the Clinician for review.

6.2.6 Apply for Leave

Camera Technicians have the ability to "Apply for Leave" when they are unavailable to conduct screenings on Patients. This feature enables a Camera Technician to remotely inform their Client Administrator when they cannot accept Patients. This feature can be found in the "Profile" menu accessed by the rightmost icon in the bottom dock. Refer to Figure 13 for the location of "Apply Leave". The Camera Technician must select a day, provide a reason, and submit with the "Apply Leave" button. A date will be noted in red when an "Apply Leave" request has been submitted for it.

VistaView

6.3.1 Logging In
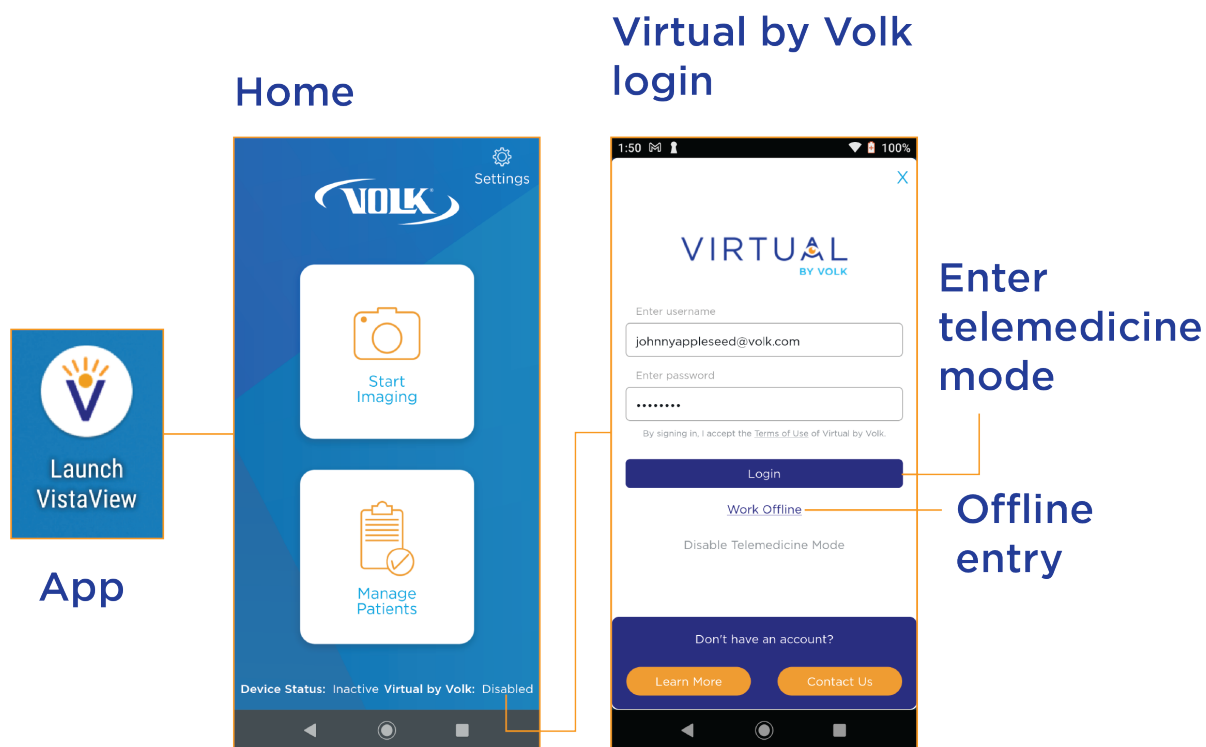
Figure 14: VistaView Entry

A "Launch VistaView" application can be found in the center of the device's home screen. After tapping the application to launch it, the Camera Technician will be on the Home menu, where they can begin imaging, manage Patients, access settings, and enter telemedicine mode. Without entering Virtual by Volk, the VistaView can be operated with limited functionality. To enter telemedicine mode, tap the "Virtual by Volk: Disabled" indicator in the bottom right corner. Then, the VistaView will ask the Camera Technician to enter their login credentials. After successfully logging in, the VistaView main menu will appear, with the bottom right indicator now stating "Virtual by Volk: Enabled". From here, the Camera Technician can start imaging a new or existing Patient, manage Patients, or access settings like before, but now with cloud-based functionalities.

6.3.2 Start Imaging
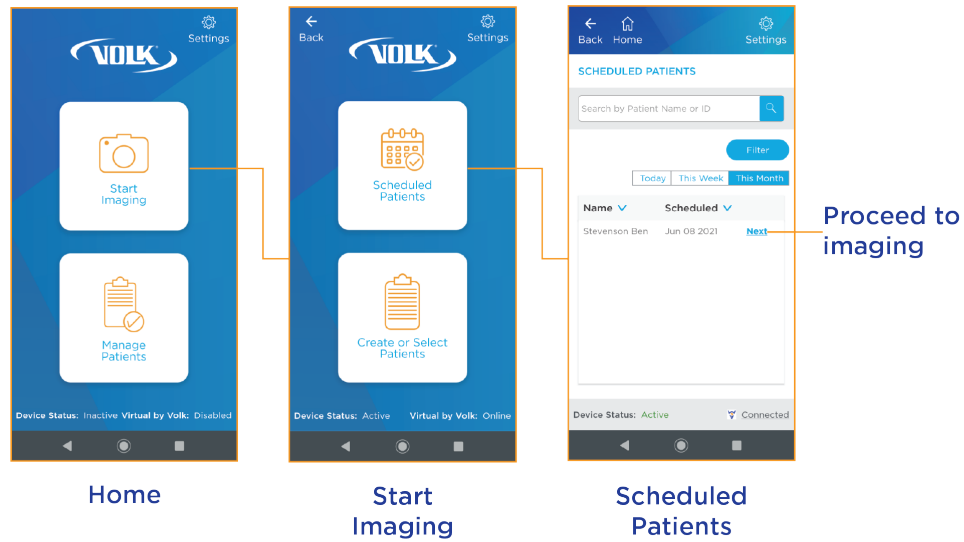
Figure 15: Start Imaging

If the desired Patient is already registered and scheduled, they can be selected by navigating to the "Scheduled Patients" menu and tapping "Next" on the desired Patient.
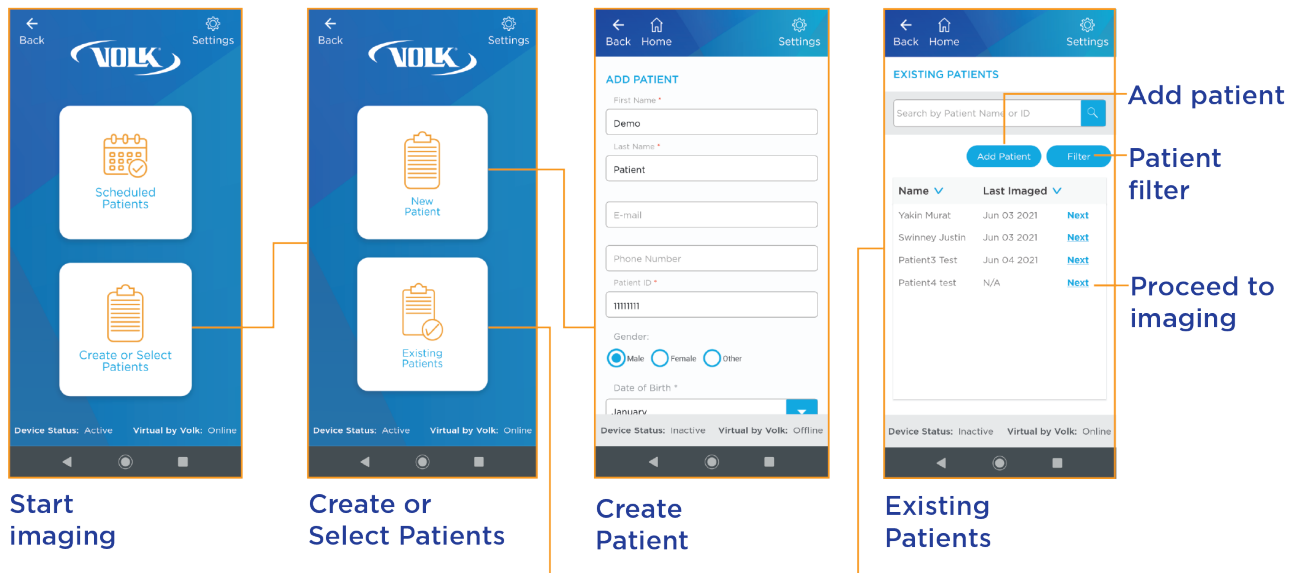
Figure 16: Create or Select Existing Patients

If the Patient is new or unscheduled, the Camera Technician can navigate to "Create or Select Patients". From "New Patient," all information about a new Patient can be entered, and then the technician can proceed to imaging. An unscheduled Patient can be found in "Existing Patients," where a list of all registered Patients will appear. The desired Patient can be selected by pressing "Next," or a Patient can be added via the "Add Patient" button.

6.3.3 Manage Patients
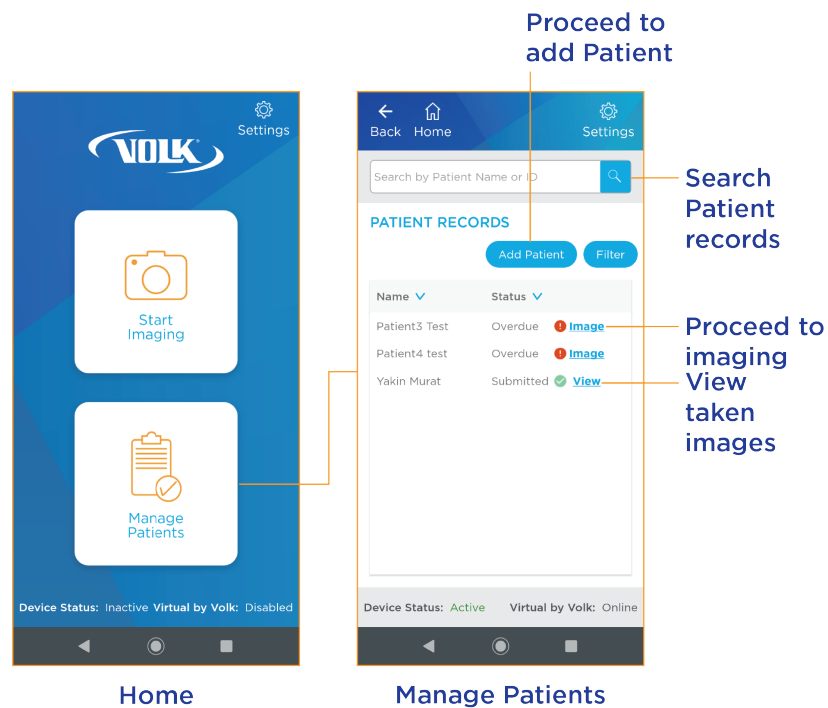
Figure 17: Managing Patients

Selecting "Manage Patients" will navigate the user to the "Patient Records" screen. Here, all registered Patients are displayed along with their status. This status indicates whether they are scheduled for imaging, overdue, or if their imaging has been successfully submitted. Overdue and scheduled Patients can be imaged from this menu by selecting "Image", while "Submitted" Patients' exams can be reviewed by selecting "View".

6.3.4 Imaging

| Imaging mode | Laterality notation | Capture progress | Capture complete | Submission |
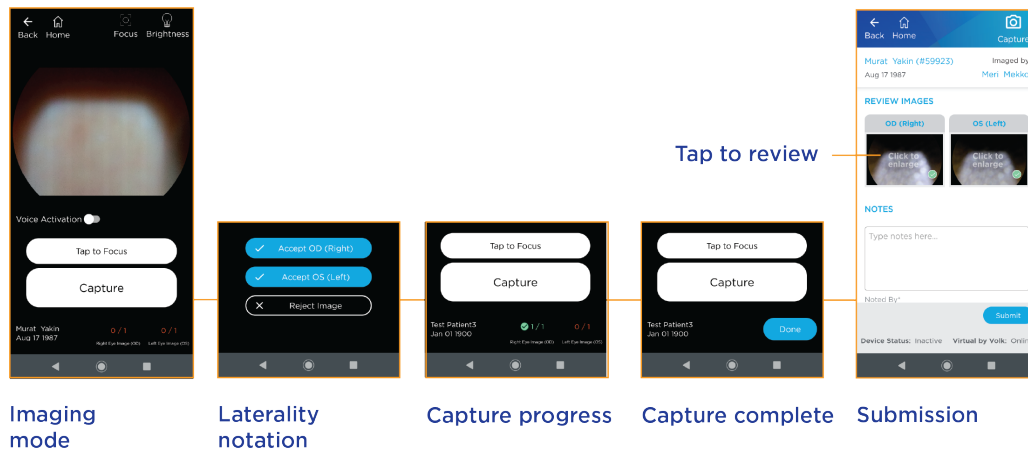
Figure 18: Capturing

Once the desired Patient has been selected for an exam, VistaView will proceed to the imaging mode. Here, along with the displayed camera view, VistaView offers several functionalities. Once the subject is in focus, the image can be recorded with the "Capture" button. "Tap to Focus" refreshes the camera's autofocus. This feature will only appear when VistaView is in Focus Assist mode. Manual focus adjusts the camera's focus from -15D to 15D using the up and down arrows. This functionality will only appear when VistaView is in Manual Focus mode. The user can capture images and focus the camera via trained voice commands when "Voice Activation" is enabled. Selecting "Focus" opens a popup menu to toggle between Focus Assist and Manual. The "Brightness" menu changes the brightness of the captured image. The technician can choose between "Low", "Medium", and "High" exposure.

After the desired retinal image has been captured, the picture can either be accepted and notated as either OD or OS respectively, or the image can be rejected and VistaView will return to the capture screen to try again.

Upon acceptance, the image will be added to the count in the bottom right for its respective eye. When the desired number of pictures is met, the progress will turn from red to green. This threshold is determined by the Camera Technician's Client Administrator in their Capture Settings. Once all required imagery has been submitted, the progress tallies will be replaced with "Done" and the Camera Technician can proceed to the submission page.

Before submission, the images can be reviewed by tapping on them. Notes can be added to the exam in the below fields. Once complete, press "Submit" in the lower right-hand corner. Then Vista View will return to the main menu and a confirmation of a successful submission will appear along the bottom.

Pictor Prestige

6.4.1 Getting Started

To interact with Pictor, there are 4 buttons. The Navigation Roller is used to make selections and navigate menus through scrolling and clicking. On the left and right of the Navigation Roller are the Power Button and Back Button respectively. The Power Button Powers on the device and gains additional functionalities on menus where a press function is displayed above it. The Back Button is used to move backward through menus and gains additional uses when an alternative function is displayed above it. A dual-action Shutter located on the back of the handle is used when capturing images and can detect whole and half presses.

Figure 19: Pictor Prestige Controls

To turn on the Pictor Prestige, press and hold the power button. If there are multiple users, the technician will be prompted to select their user account and log in if it is password protected. The Pictor Prestige will then advance to the main capture view.

6.4.2 Connect to Internet

From the main view, clicking the Navigation Roller will open the Main Menu. The Main Menu contains five options. Enter the rightmost option, settings, with a click of the Navigation Roller. From Settings, select the rightmost option, Camera. The Camera menu contains several options used to configure the system. Wireless Settings are under the fourth option from the left, the Wi-fi bands. Within Wireless Settings, the third option is the Cloud Menu. From the Cloud Menu, Network Selection allows the Camera Technician to select a Wi-Fi network and connect to it. Network passwords will be entered on a keyboard using the Navigation Roller to select characters.

6.4.3 Log in to Virtual by Volk

Once successfully connected to a network, the Camera Technician can log in to their Virtual by Volk account to access their cloud-based account. From the Cloud Menu, Cloud Login will allow the Camera Technician to enter their Virtual by Volk username and password. A success message will confirm the Pictor Prestige's connection to Virtual by Volk.

6.4.4 Download Patient List

From the Main Menu, the Patient menu is fourth from the left. In Patient, the third option, Update Worklist, will fetch the Camera Technician's Patient list from the cloud. A success confirmation will indicate if the fetch was executed. Then, all of the Patients added to the Camera Technician's schedule will populate in the Patients menu to the right of all previously available options.

6.4.5 Start Imaging

Images can be taken from the Main View for the next available Patient, or a New Study/Four-Image Sequence can be begun for a specific Patient. This can be accessed from the Patient Menu. The roster of all added and fetched Patients will be to the right of the New option and can be selected to use for imaging or deleted.

Once the Camera Technician has either selected a Patient or navigated to the Main View, a circular view of the Prestige's camera will populate the center of the screen.

Concentric image quality indicators will remain red until proper image conditions are met. They will turn green and a rectangular focus box will appear over the camera view when the subject is in focus and the Prestige is ready to take a photo. Images are taken by pressing the shutter, and a beep will confirm that an image has been taken. When in auto-focus, a half-press of the shutter will activate the autofocus to adjust to the distance of the subject.

Once taken, a preview of the image will appear. A press of the Navigation Roller will proceed the user to options for the photo. Three image quality indicators will populate the upper right corner of the screen. The indicators are brightness, focus, and sharpness from top to bottom. Each can be green, yellow, or red to indicate the quality of that aspect of the image.

If the Camera Technician confirms the image is successful and the Patient has been fetched from Virtual by volk, then the Pictor Prestige will then begin uploading the retinal capture to the cloud. When in progress, the cloud icon on the Main View will have ellipses within it. Once complete, the cloud will become empty again.

7. Clinician

7.1 Home Screen

Figure 20: Clinician Interface

7.2 Reviewing
7.2.1 Assessment

Once the review option is selected on a pending Patient, the assessment screen appears. If a Clinician decides that the given information and quality of the images is not sufficient, they can report the profile under the right or left eye sections. This will report the Patient back to the Clinic Admin and the Patient will be rescheduled to repeat the imaging.

Figure 21: Clinician Assessment Panel

7.2.2 Annotation

The Clinician can click on the retinal images to inspect them, add pathology and take notes by clicking "Start Annotation". The scale on the left side allows the Clinician to zoom in and out of the image. Color filters and contrast adjustment are available and can be activated by checking their respective boxes. Remember to click "Save and Exit" when done.
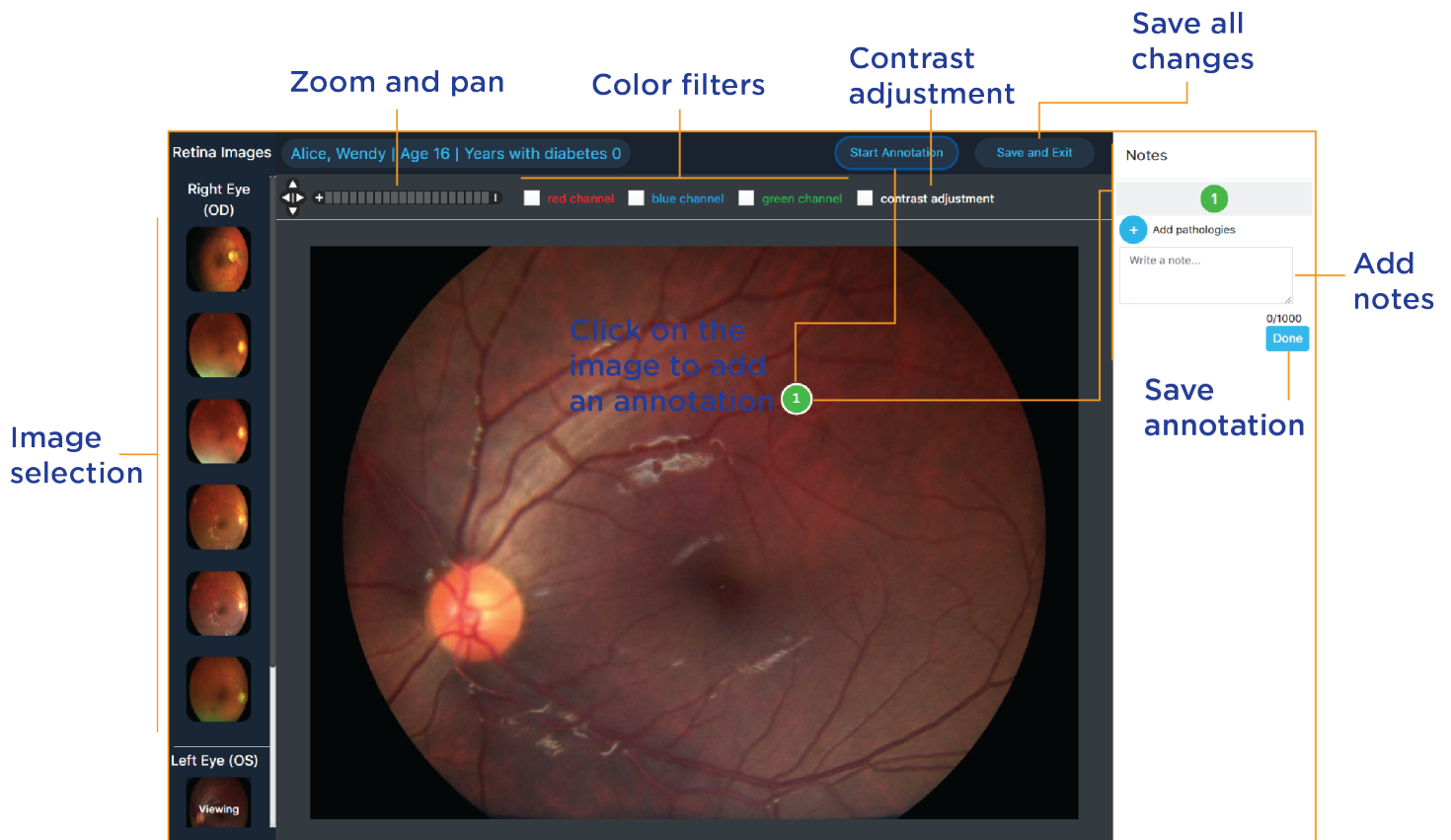
Figure 22: Clinician Annotation Panel

7.2.3 Clinical Assessment and Management Plan

On the Patient profile screen, the Clinician will be able to select pre-populated clinical assessment fields next to the right and left eye image sections. If no prepopulated field covers the assessment, the Clinician can add their text into the "Other" box in each eye section.

When the Clinician completes their clinical assessment in each eye section, they can enter the appropriate management plan, referral, and timeframe under the "Clinical Assessment and Management Plan" section. Once all these fields are completed, the "Submit" button will turn blue, allowing the Clinician to finish generating the report.

Figure 23: Clinician Management Menu

7.2.4 Report

Completed reports can be downloaded or viewed in a pdf format by clicking on the download or view buttons for each Patient. If a Clinician wants to review a Patient again, they can click "Review Again" next to the desired Patient in the "Reviewed Patient" list. Previous selections will be displayed to the Clinician. If any changes are made by the Clinician through "Review Again", a new report will be generated and the old reported will be appended to it for traceability. The contents of the Patient report summarize the screening information and are not intended as a substitute for diagnosis.

Assessment results

Assessment generated ICD-10 codes

Clinician's signature

Figure 24: Patient Report

8. Payer

8.1 Interface

Payers can see the number of screened and unscreened Patients in their clinic, diabetic retinopathy status, and Patient import history on their homepage.

Figure 25: Payer Interface

8.2 Adding New Patients

Payers can add new Patients to their site locations. Adding a new Patient as a Payer is no different than adding one as a Client Administrator. Please refer to Sections 5.2.

Payers can also add Patients in batches using a .csv file. To begin, click on "Sample .csv file" in the upper right-hand corner. Fill out the downloaded .csv file accordingly, making sure to fill in all the required fields in the specified formats. You will be notified of all the required fields when you clicked on "Sample .csv file". Once complete, select "Import CSV" in the upper right-hand corner of the Home screen. Either click on "Upload" and choose the .csv filled out .csv to upload or drag and drop the file onto the page. You will be notified whether the upload was successful or not. If the .csv file does not meet the format requirements; an error message will appear stating which required fields are missing or incorrect.

Appendix

User permissions and scope for each role are as defined by the table below.

Feature	Client Administrator	Clinic Administrator	Camera Technician	Clinician	Payer
View Clients	✓				
Add Camera Technician	✓	✓			
Add Clinician	✓				
Archive Staff	✓				
Edit Staff Email	✓				
Archive Patient	✓	✓			
View Clinic	✓				
View OPH	✓				
View Camera Technician	✓	✓			
Add Payer	✓				
View Payer	✓				
Add Patient	✓	✓	(if enabled)		✓
Schedule Appointment	✓	✓	✓		
View Appointment	✓	✓	✓		
Screen Patient			✓		
View Screened Patient	✓	✓	✓	✓	
Submit Images			✓		
Reject Patient			✓	✓	
Review Images				✓	
Make Observations				✓	
Make Clinical Assessment and Plan				✓	
Send Report to Client Administrator				✓	
Configure Capture Requirements	✓	✓			
View Training Videos			✓	✓	
Notifications	✓	✓	✓	✓	
View Audit Trails	✓				
View and Edit Profile	✓	✓	✓	✓	
Change Password	✓	✓	✓	✓	✓
Apply Leave			✓		
Patient Import History				✓	✓
OPH Dashboard				✓	
Payer Dashboard					✓
Client Administrator Dashboard	✓				
Clinic Administrator Dashboard	✓	✓			