VISTA VIEW®

Instructions for Use

Hand-Held Mydriatic Fundus Camera

Volk VistaView®
Instructions for Use for VistaView Hand-Held Mydriatic Fundus Camera

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Contents

1 Product Description 5
1.1 General 5
1.2 Important Symbols 5
1.3 Warnings and Cautions 6
1.4 Contraindications of Use 8
1.5 Usage Environment Requirements 8
1.6 Package Contents 9

2 Operating Instructions 10
2.1 Unpacking the Product 10
2.2 Charging the Device 10
2.3 Eye Cup Installation 10
2.4 Powering On the Device 11
2.5 Start Up Messages 11
2.6 Setting Up the VistaView App 13
2.7 Selecting a Patient 19
2.8 Capturing Images 20
2.9 Reviewing Images and Adding Notes 24
2.10 Creating a Report 25
2.11 Managing Patients 26
2.12 Transfer Patient Files 27
2.13 Wireless Transfer of Patient Data 29
2.14 Wired Transfer to Windows PC 32
2.15 Wired Transfer to Mac 33
2.16 Re-encrypting Patient Data 35
2.17 Disable Encryption 36
2.18 Sync Files for Export 37
2.19 Telemedicine Mode 38
2.20 Updating the App 43
2.21 Reinstalling the App 44

3 Maintenance 45
3.1 General Maintenance 45
3.2 Cleaning Instructions 45

4 Technical Description 46
4.1 Specifications 46
4.2 Operating and Storage Environments 47
4.3 Transportation Environment 47
4.4 Expected Service Life 47
4.5 Disposing of the Device 47

5 Compatibility and Compliance 48
5.1 Electromagnetic Compatibility 48
5.2 Compliance 54
5.3 FCC Regulations 54

6 Troubleshooting 56
6.1 Device Errors 56
6.2 Image Quality 57
6.3 System Messages 58

7 Warranty 61
7.1 Warranty Terms 61

8 Support and Servicing 62

1. Product Description

1.1 General

The Volk VistaView is a mydriatic fundus camera that is intended to capture and store images of the fundus of the dilated eye. The device is capable of taking high quality images with large 55° field of view. The device uses precision optics and on-board electronics coupled with an integrated smartphone to capture images of the retina, macula, and optic disc.

Rx only

The Volk VistaView requires the eye to be dilated and is intended to be used by trained professionals in professional healthcare environments only. Note: The Volk VistaView is a prescription device which 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 the Volk VistaView 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
CE	The device has been tested and conforms to the provisions noted within the EU Medical Devices Regulation 2017/745.
	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.
	A part of the device which in normal use comes into physical contact with the patient.
	Mandatory to refer to this IFU.
MD	Indicates that the item is a medical device.
	Indicates the date when the medical device was manufactured.

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

Radio frequency radiation: Electromagnetic interference may occur in the vicinity of equipment.

The symbol is accompanied by the name and the address of the manufacturer.

Dispose of device in the proper manner and ensure to comply with all laws and regulations applicable to your area.

Authorized representative in the European Community accompanied by the name and the contact information of the authorized representative.

Fragile, handle with care.

Keep dry.

Symbols found on and in the smartphone are not included. Please visit the smartphone manufacturer website for instructions on how to use the smartphone.

1.3 Warnings and Cautions

The Volk VistaView should be used in accordance with the instructions, warnings, and caution statements presented in this IFU for the most effective and safe results. Before using the device, you must familiarize yourself with all warnings, cautions, and with all sections of this IFU. Specific warnings and cautions are also found throughout this IFU.

The device requires dilation of the patient's eye for imaging.

The Volk VistaView device is only intended to be used for mydriatic imaging of the retina.

It is the responsibility of the user to make sure that they are creating regular backups of data to prevent loss of data.

It is the responsibility of the user to keep track of the data encryption password to prevent loss of data.

Deleting the pre-installed Volk VistaView smartphone application will delete all patient data and images because the application stores all the data in the encrypted application memory. The user should never delete or uninstall the smartphone application off of the VistaView.

User should not change the smartphone's Bluetooth settings. The Bluetooth connection should be active and connected automatically. This is needed for the device to function properly and must be connected at all times. If there is an issue with Bluetooth settings, please reference Section 6.1 Device Errors.

Only use the accessories and parts provided or specified by Volk Optical with this product.

No unauthorized modification of the device is allowed.

Only use the power supply provided in the sales package or a certified ITE-grade power supply. If you need a replacement power supply, please contact Volk Optical Inc. or your local distributor.

Do not connect the device to computers, laptops, power supplies, or electrical equipment while the device is inside the patient environment (within 4 feet of the patient).

The device cannot be used to capture any images of the fundus while plugged into a computer or power supply.

All servicing and repair of this equipment is to be performed by Volk Optical Inc. or by a center approved by Volk Optical Inc. only.

Only use cleaning instructions provided in this IFU, Section 3. Maintenance.

The device is not intended to be sterilized using autoclave, ETO gas, or any other sterilization means beyond the cleaning and sanitation procedures discussed in this IFU, Section 3. Maintenance.

To avoid the risk of cross-contamination and irritation, clean the eye cup after each patient exam using the cleaning instructions provided in this IFU, Section 3. Maintenance.

1.4 Contraindications of Use

To avoid prolonged light exposure, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization and imaging of the target structures.

The Volk VistaView is classified as Group 1 light exposure limits based on the standard ANSI Z80.36-2016. The Volk VistaView is classified as Group 2 light exposure limits based on the standard ISO 15004-2:2007.

The light emitted from this instrument is potentially hazardous by way of causing ocular damage if the exposure duration exceeds 7 hours and 7 minutes of continuous use at the maximum setting.

1.5 Usage Environment Requirements

The Volk VistaView is intended to be used indoors in normal temperature and humidity conditions by trained professionals in professional healthcare environments only.

Volk VistaView is not suitable for use in the presence of flammable anesthetics and/or a mixture of air, oxygen, or nitrous oxide; in oxygen enriched environments; or in any other potentially explosive/flammable environment.

Avoid leaving the eye cup in direct sunlight, as there may be a risk of skin burn.

Avoid using the device in a dusty environment.

Do not expose the device to rain or high moisture environments.

Do not submerge the device in liquid or allow liquid to enter the interior of the device.

Avoid subjecting the device to vibrations or electrical shocks.

Use only CE marked USB-C cables with this device.

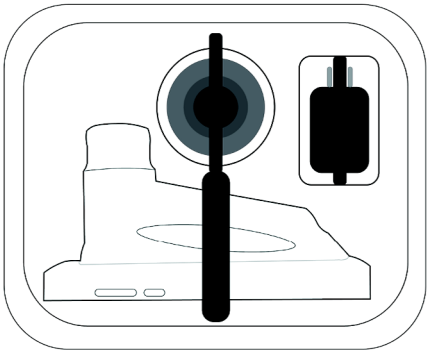
Only connect the device to computers, laptops, and power supplies outside the patient environment that have passed the safety standard for information technology equipment IEC 60950-1, EN 60950-1, and UL 60950-1 to ensure the safety of the USB-C electrical connection.

If operated within an electromagnetic environment, the device must be used in accordance with instructions and guidelines set forth in Section 5. Compatibility and Compliance.

1.6 Package Contents

The Volk VistaView product package includes the following items.

- Volk VistaView device
- Silicone eye cup
- Lens cap
- Volk VistaView IFU
- Volk VistaView Quick Start Guide
- Charger
- International plug adapters
- USB-C cable
- Volk VistaView case



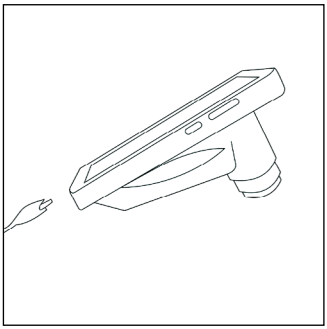
2. Operating Instructions

2.1 Unpacking the Product

Confirm that all purchased items are included in the packaged case, and there is no visible damage to any of the parts.

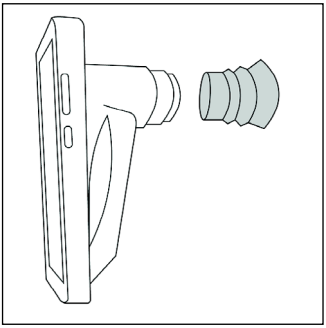
2.2 Charging the Device

Charge the device with the USB-C cable as shown, connecting one end to the USB-C connector on the Volk VistaView and the other end to the wall charger or USB-C on computer. When the device is fully charged, disconnect the charger from the USB-C connector on the device.



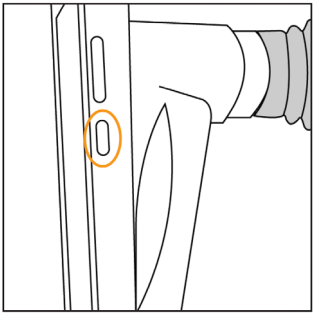
2.3 Eye Cup Installation

Mount the eye cup onto the end of the VistaView as shown. Use of the eye cup is optional as it helps block stray room light and stabilizes the device during alignment.



2.4 Powering On the Device

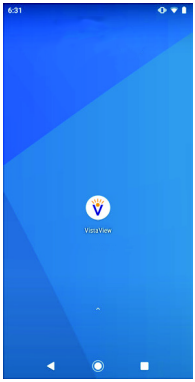
Power on the device by pressing the power button as shown.



The default password is 1234. To change the password, navigate to phone settings by swiping down from the top of the screen, clicking the settings gear button, and searching for “screen lock”.

2.5 Start Up Messages

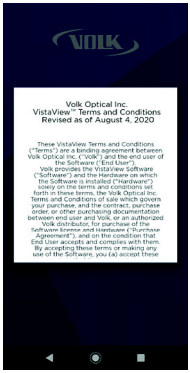
Once the device is on, navigate to the VistaView application installed on the device. The home screen should be visible on the screen as shown below.

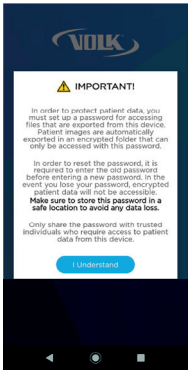


Upon set up, the application will request user to carefully read and understand the Volk Optical Inc. VistaView® Terms and Conditions. The user must scroll to the bottom and select **I Understand and Agree** before proceeding.

After agreeing to the Volk Optical Inc. VistaView® Terms and Conditions, the user is informed of warnings associated with encrypted file storage and password protected report. Ensure that the password is stored in a safe location and only share the password with trusted individuals. Select **I Understand** to continue.

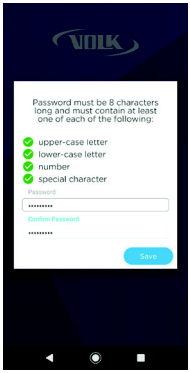
Please note that it is the responsibility of the user to use the data export in a manner compliant with their practices.

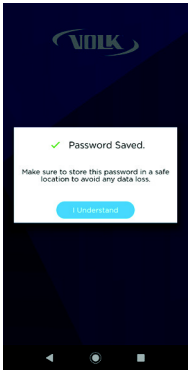




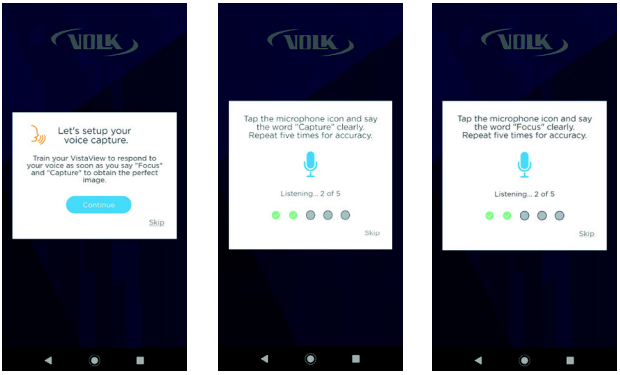
The user is prompted to input a password at least 8 characters long with at least one of each of the following: upper-case letter, lower-case letter, number, and special character.

Please note that it is the responsibility of the user to store the password in a safe location to avoid loss of any data.



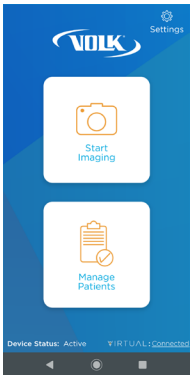


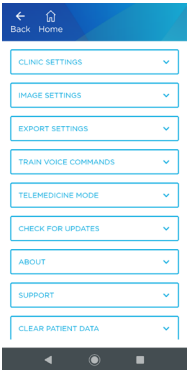
For best results when using the **Voice Activation** feature on the VistaView, the user can train the device to recognize their voice and pronunciation of the word “Capture” and “Focus”. Press **Continue** to begin training. When you are ready, tap the microphone icon and repeat the word “Capture” five (5) times, following repeat the word “Focus” five (5) times. The screen will update after each successful training attempt. You can also repeat this training at any time by following the steps under Train Voice Commands Settings in the next section of this IFU.



2.6 Setting Up the VistaView App

Before starting an imaging session with a patient, the user must always check that the device status is **Active** in the bottom left-hand corner on the home screen. If the device status is Inactive, please refer to the troubleshooting tips in Section 6.1 Device Errors.





Once the application has started, navigate to the settings menu by selecting the **Settings** icon in the top right-hand corner, as shown. It is recommended that the user only change or update the **Clinic Settings, Image Settings**, **Export Settings**, **Train Voice Commands**, **Telemedicine Mode**, and **Test Mode**.

Clinic Settings

The user can add and edit clinic information in **Clinic Settings** to organize information and data obtained from multiple clinics. To add a clinic, select **Add Clinic** under the **Clinic Settings**.

Image Settings

The user can change **Image Settings** to export either **JPEG** or **DICOM** compressed images and raw images.

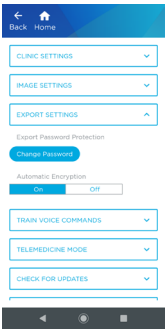
If DICOM files are needed, choose the **DICOM** setting before imaging. Images cannot be converted to DICOM after imaging.

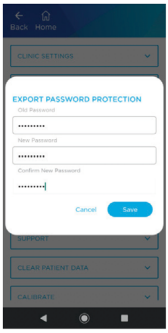
The **Raw Image Acquisition** setting allows the user to automatically export the raw images in a digital negative format (DNG) that correspond to the compressed JPEG or DICOM images. If raw image export is turned Off, the user risks losing raw image traceability.

Export Settings

The user can change **Export Settings** to enable or disable encrypted file storage. To change the password for password encrypted file storage and the patient report password, select **Change Password**. Input the old password, enter a new password, and confirm new password.

It is the responsibility of the user to keep track of passwords to avoid loss of data.





Train Voice Commands Settings

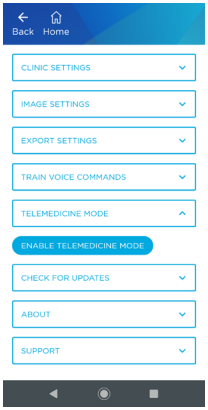
For best results when using the **Voice Activation** feature on the VistaView, the user can train the device to recognize their voice and pronunciation of the word “Capture” and “Focus”. To train the device, select **Train Capture** or **Train Focus** under Train Voice Commands. If Train Capture selected, repeat the word “Capture” five (5) times, if Train Focus selected repeat the word “Focus” five (5) times when prompted.

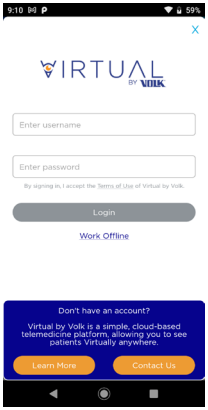
Telemedicine Mode

The user can turn on **Telemedicine Mode** to connect to Virtual by Volk. The user can only **Enable Telemedicine Mode** with valid login credentials given to Virtual by Volk users.

Telemedicine Mode allows users to access Scheduled Patients and upload VistaView images to the Virtual by Volk platform. Please reference Section 2.19 Telemedicine Mode for more details.

To enable Telemedicine Mode, click the **Enable Telemedicine Mode** button. A login window will appear with username and password fields. You can contact Volk directly using the Contact Us button to learn more about Virtual by Volk.



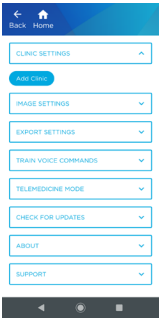


Default Settings

The screenshots below indicate the default settings for **Clinic Settings** and **Image Settings.**

The device has been calibrated and paired via Bluetooth during manufacturing by Volk. The user is advised not to change the **Calibrate** or **Bluetooth** settings unless instructed to do so by Volk Optical customer care.

Please reference Section 6.1 Device Errors for troubleshooting tips.



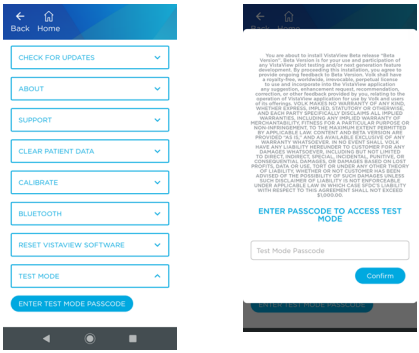
Reset VistaView Software

The Reset VistaView Software option deletes all patient data from the application memory and from the exported data folder. Transfer patient data to a PC, as well as a safe location, before performing the Reset, to avoid loss of important data.

Reset VistaView Software resets all user settings, except Bluetooth and Calibration Settings. Reset VistaView Software can be used to reset the encrypted file storage and patient report password if it is lost or forgotten, but will lead to loss of all data.

Test Mode

The Test Mode option allows users to test new application features before they are released. Test Mode can only be accessed with a password given by Volk to select users.



To enable Test Mode, click **Enter Test Mode Passcode** and enter the password. Test Mode can be disabled at any time to return to the released VistaView app version. Test Mode is automatically disabled after 30 days of use.

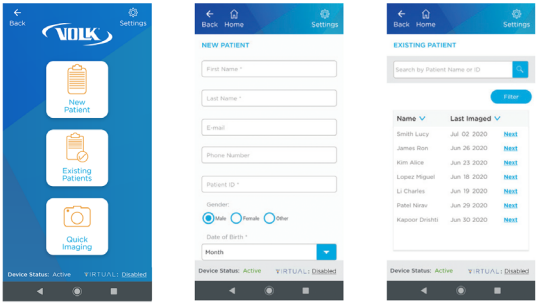
Setting	Function
Clinic Settings	Add and edit clinic information to organize information and data obtained from multiple clinics.
Image Settings	Adjust JPEG quality, enable DICOM export and enable Raw Image Acquisition.
Export Settings	Change encrypted data storage and patient report password and turn off encrypted data storage.
Train Voice Commands	Train the device to recognize the user's voice when they say "Capture" and "Focus".
Telemedicine Mode	Enable connection to Virtual by Volk.
Check for Updates	Manually check for application updates.
About	VistaView application version number.
Regulatory	View FCC ID for the RF module included in VistaView. See Section 5.3 for additional information.
Support	Open the digital IFU, Terms and Conditions, Third Party Licenses, and Volk customer care contact information.
Clear Patient Data	Erase all patient information and images from the application.
Calibrate	Calibrate the VistaView imaging window.
Bluetooth	Pairing and connection to device.
Reset VistaView Software	Reset all data and settings.
Test Mode	Access unreleased app features for beta testing

It is the responsibility of the user to make sure they are creating regular backups of data to prevent loss of data, especially before using Reset VistaView Software.

2.7 Selecting a Patient

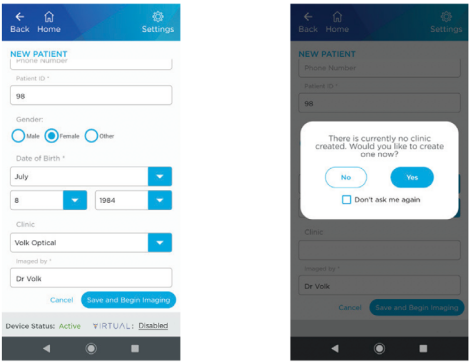
Select **Start Imaging** on the home screen. Choose between **New Patient** and **Existing Patients** depending on the patient being examined. Choose **Quick Imaging** to begin an imaging session without entering patient data first.

When imaging a new patient, enter the requested patient information. Mandatory fields are First Name, Last Name, Patient ID, Gender, Date of Birth, and “Imaged By” (name of operator/user). Each patient should have a unique Patient ID.



When imaging an existing patient, search the patient database and select the patient to image.

Once all details have been entered, select **Save and Begin Imaging** to proceed to the imaging screen.

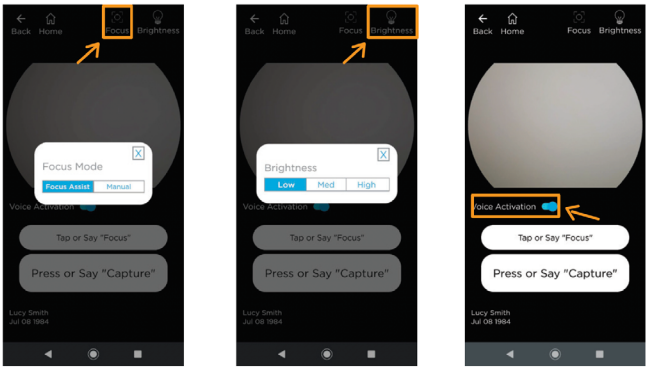


Images captured using **Quick Imaging** can be assigned to a New or Existing Patient following the imaging session.

Note: If no clinic has been set up, the device will prompt the user to add a clinic. Select **Yes** to set up a clinic before proceeding or select **No** to proceed without a clinic. Check **Don't Ask Me Again** if you do not want to see this message again. The user can still add a clinic by accessing the clinic settings through the settings gear icon on the home screen.

2.8 Capturing Images

On the imaging screen, select desired settings. The focus mode and brightness are user adjustable.

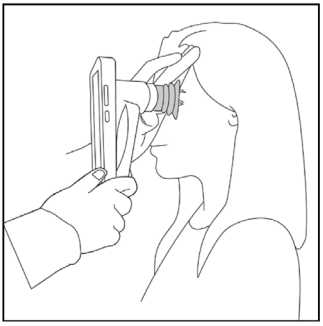


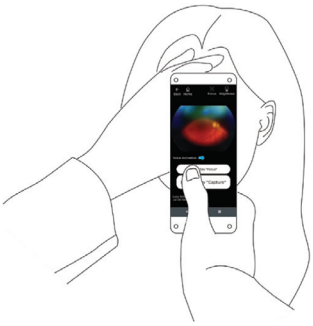
To adjust the focus mode, select the **Focus** icon then select **Focus Assist**, or **Manual** mode.

To adjust the brightness, select the **Brightness** icon. Start with the lowest brightness and increase as needed.

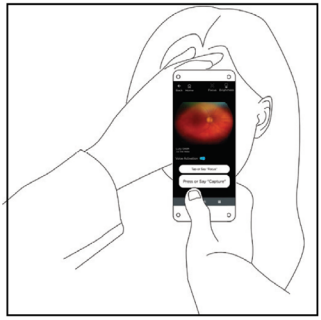
If needed, turn on the **Voice Activation** feature by activating the toggle button, as shown. Simply say the word "Focus" to focus and lock the focus, say the word "Capture" to capture an image once lined up and the retina is in full field. Voice activation feature best performs when the user trains their VistaView to recognize their voice by saying "capture" and "focus" five times during the first use of the application or at any time through the VistaView settings.

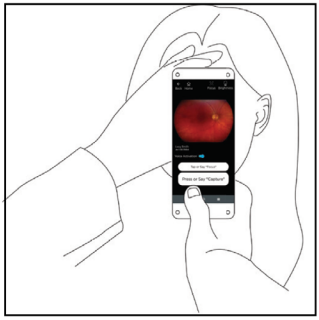
To image a patient, the patient and examiner should be seated facing each other. Use your dominant hand to hold the VistaView and use your non-dominant hand to stabilize the device by positioning the fingers just behind the eye cup.





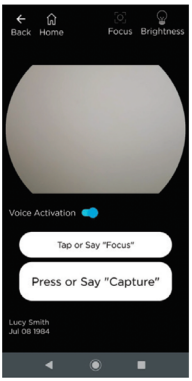
Ask the patient to look over your shoulder or to fixate at a spot near your ear. Approach the pupil, keeping the device vertical and in a portrait orientation. Slowly, move the device closer to the eye while keeping the pupil in the center of the screen. Locate the retina, which can be seen as a small reflection within the pupil. If focus-assist is enabled, tap the **Tap or Say "Focus"** button on the screen or say "focus" when you can see the optic disk. The right focus is then locked for the eye. When the focus is locked, if needed, you can readjust the position of the camera. Keep the retina reflection in the middle of the display screen and slowly advance the device closer to the patient's forehead.

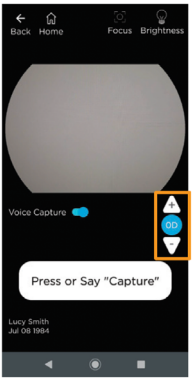




The correct imaging distance is reached when the retina completely fills the imaging window. Do not be afraid to gently push the device closer to the patient to fill the field of view - the eye cup is flexible and the device will not touch the patient's eye.

If using manual focus, use the buttons on the right-hand side of the screen to increase or decrease the focus by increments of one diopter to match the patient's refractive power before you begin imaging.

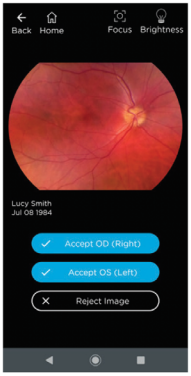


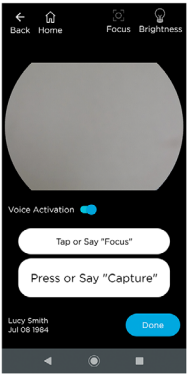


To capture an image, ensure that the retina fills up the full field-of-view and is illuminated with no dark spots, reflections, or shaded regions appearing toward the boundaries during preview. Press the **Capture** button on screen. The device will flash and capture an image. If **Voice Activation** is on, take an image by saying the word “Capture”.

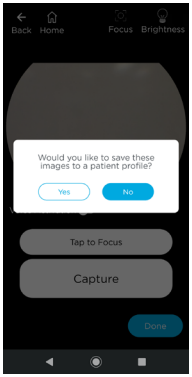
Note: Inform the patient that they will see a bright flash of light and to keep their eyes open. This will help prepare them and attempt to avoid reflex movements that may compromise the image.

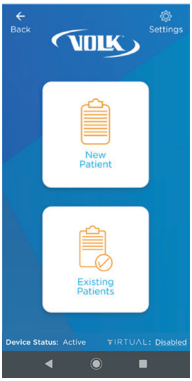
An image preview will appear. The user can zoom into the image by spreading two fingers to check for quality before accepting the image and assigning it to the OD (right) eye, or the OS (left) eye, or to reject the image. All options return the user to the imaging screen where more images can be captured if desired.





Once all images have been captured, select **Done** on screen, which will take the user to the exam review screen for **New Patients** or **Existing Patients**. Selecting Done for **Quick Imaging** will lead to a pop-up asking the user if they want to assign the images to a patient. Clicking **Yes** allows the user to assign the images to a New or Existing Patient. Clicking **No** saves the images to an "Unknown Patient" profile.



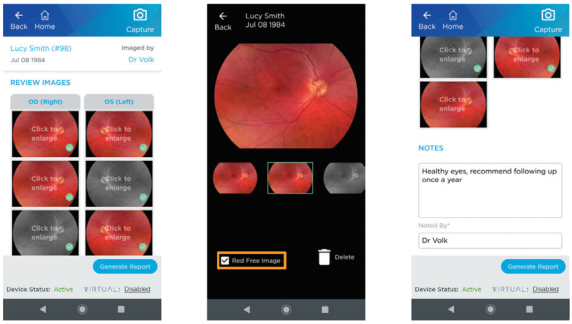


2.9 Reviewing Images and Adding Notes

On the patient exam review screen, the user can tap on the thumbnail to enlarge the image. The user can also spread and pinch to zoom in and out of the image.

Checking the red free box below the image adds a red free version of the original retina image for ease of analysis if needed.

Tap the **Delete** icon to delete the image from the device if needed.



On the patient exam review screen, the user can add optional notes. The user is responsible for the accuracy of any notes.

The content of exam notes represents the opinion of the person who entered the notes, and does not reflect the opinions, views, or recommendations of Volk Optical Inc.

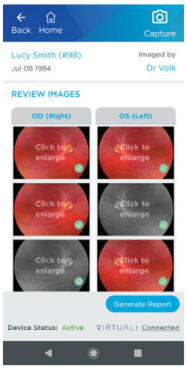
The user will be required to fill “Noted By” (name of operator/user) if notes are added. Then, select Generate Report or Home.

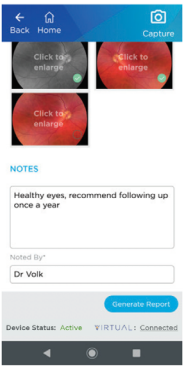
To enhance traceability, report notes cannot be edited or deleted once saved. Additional notes can be added.

2.10 Creating a Report

The user can select the images to include in a report from the patient exam review screen, add optional notes, then select **Generate Report.**

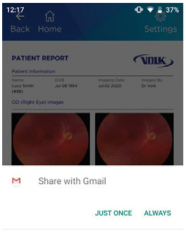
This report is meant to be used as an aid for record keeping and is not a substitute for medical diagnosis or treatment.





To select the images to be added to the report, select the circle in the lower right corner of the image to add a green check mark. After selecting the images and pressing Generate Report, the user can review the report to verify that all the information is accurate.

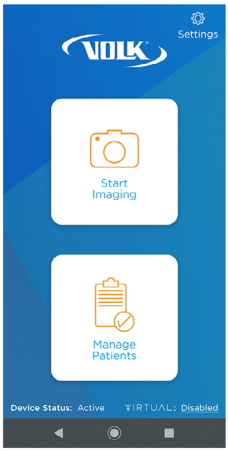
After a report is generated, the user has three options: Share the report via applications on the device, as shown below; Save & Close, which saves the report to the patient database inside the software application; or Edit to edit the report.



The generated report will contain patient information, images, and notes from the time of report generation. Any change to patient information, exams, or notes will require the user to re-generate the report to ensure that the report is up-to-date.

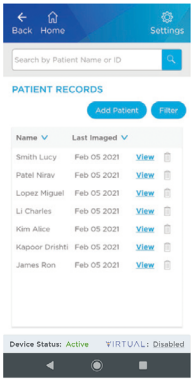
2.11 Managing Patients

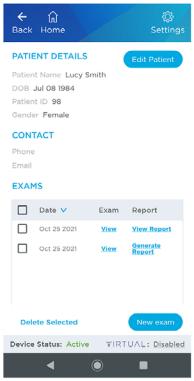
The user can review patients and images later, after saving the exam. From the home screen, select **Manage Patients** followed by **Patient List**. The user has the option to select the patient to review by searching the database.



After the user selects a patient by selecting **View**, the patient profile opens, where previous exams are available for review and patient information can be edited. Click **Edit Patient** to change patient information, including Name, Date of Birth, Patient ID, and Gender.

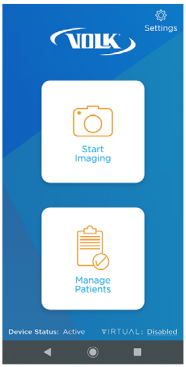
In the Report column, the user can view a previously generated report by selecting **View Report**. If a report has not been generated, the user can select **Generate Report**. The user can also start a **New Exam**. A new exam does not overwrite existing data but adds an exam to a patient.





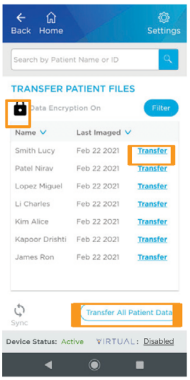
2.12 Transfer Patient Files

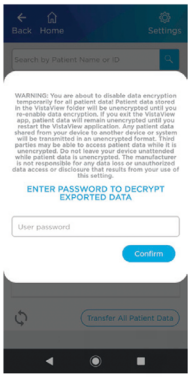
All patient data is automatically exported to an encrypted folder in the device memory after each exam. This data can be accessed, transferred, and downloaded via wireless or through connection to a computer by USB cable provided with the device. All exported data is encrypted by default. To access the data, select **Manage Patients** followed by **Transfer Patient Files**.



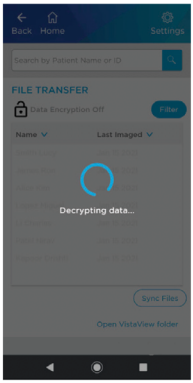
When the user is on the **Transfer Patient Files** screen, the user will see the words **Data Encryption On** next to a lock icon at the upper left-hand corner indicating exported data is currently encrypted. This is the default setting to add extra security while handling patient data. When data encryption is on, the user won't be able to access patient files. To proceed to transfer or share patient files, **the user must decrypt** the patient data.

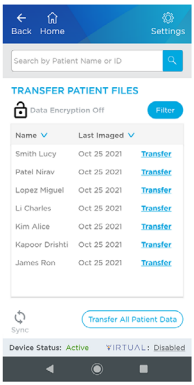
The user can decrypt the exported data by tapping the lock icon, transfer button next to each listed patient, or transfer all patients data button. A pop up will appear, asking for the user password to decrypt the data. This password pop-up will also automatically appear if the device is plugged in to a PC. The user will input their password then select **Confirm** to decrypt stored data. A loading icon will appear, indicating that data is being decrypted.





When data is successfully decrypted, the lock icon will unlock, labeled with the words **Data Encryption Off**. If the user presses the **Transfer** button next to any listed patient, or the **Transfer All Patient Data** button in the bottom right, they will be directed to the patient folders containing their data.





2.13 Wireless Transfer of Patient Data

When the exported data is decrypted as instructed in Section 2.12 Transfer Patient Files, the user can access and share the data. When the user clicks on a **Transfer** button next to a patient name in the list or clicks **Transfer All Patient Data**, the associated data folder opens. This allows the user to share patient folder or files.

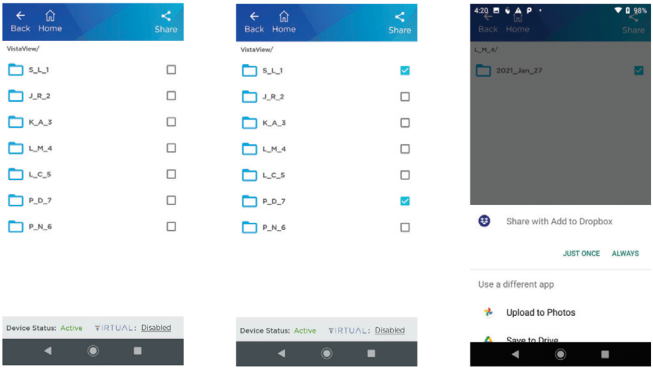
Depending on the file size you attempt to share, you may not be able to share your data through email. Please make sure to check your preferred email service's file size requirements for the best results.

Selected Patients

To share selected patients, press the **Transfer All Patient Data** button. Select the check box right next to each patient folder to select a patient. Select all the patient folders you would like to share. As you select patient folders, a check mark will appear within the check box next to each selected patient folder.

When you complete your patient folder selection, press the **Share** icon in the upper right-hand corner. The share menu pops up. Select the preferred method to share the data.

When the share menu pops up, the user can select the 'Always' option to set a sharing method as the default setting. The user can always reset this selection in Android settings to allow additional options.



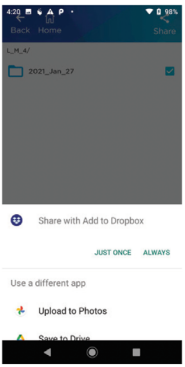
Individual Patient

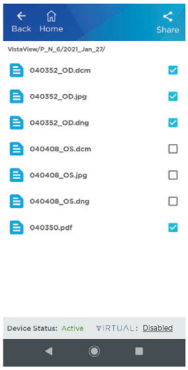
When the exported data is decrypted as instructed in Section 2.12 Transfer Patient Files, the user can access and share the data.

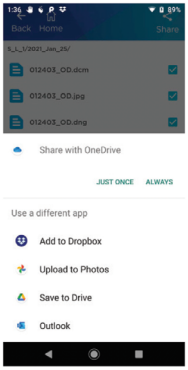
Tap on a transfer button next to any patient in the list. This allows the user to see the associated patient folder. To share the entire patient folder, select the check box and a check mark will appear. Select the share icon. The share menu pops up. Select the preferred methods to share the patient folder. To share a single exam or multiple files in the patient exam folder, select the patient folder. This will allow the user to see the files in the folder. Press on a check box next to each file to select a file and check mark will appear in the box. Press the Share icon. The share menu pops up. Select the preferred method to share the file.

When the share menu pops up, if the user selects 'Always', then this method becomes the default sharing method and the user needs to reset this selection in Android settings to allow additional methods to appear as a choice.

Although the data is decrypted, the PDF reports are still password protected. Your password to open patient reports is the same as your decryption password.







Bluetooth transfer to a PC

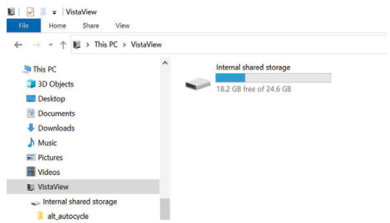
When transferring the data to a PC via Bluetooth, the user needs to ensure that their PC is in data receiving mode. To enable data receiving in a PC, select the Bluetooth icon on your PC, and select 'Receive a File' before initiating a share from the VistaView. The user needs to pair their VistaView to the PC to share the data. The data will be sent to the PC and saved in a directory specified by the user.

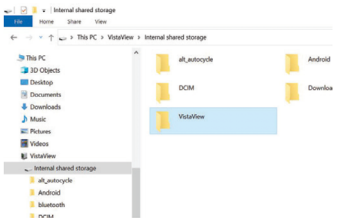
2.14 Wired Transfer to Windows PC

To transfer files to a PC, make sure to **connect the device via USB-C cable, provided with the device, to a PC** and make sure that **your VistaView application is running**. Upon connecting the device, the VistaView application on the device will display the patient data decryption screen. Make sure patient data is decrypted following Section 2.12 Transfer Patient Files. To transfer patient data, the user must decrypt the VistaView folder.

When the user connects the device, the VistaView will be recognized by the PC as an external storage device. To open files on a Windows PC, go to “This PC” and select “VistaView”, then select “Internal File Storage”. Then open the VistaView folder among folders in the internal file storage. Patient folders are named by the patient’s LastInitial_ FirstInitial_PatientID. Image files are labeled hhmmss_OD or hhmmss_ OS where hh is hour, mm is minute, and ss is second. PDF files are labeled as hhmmss. Copy and paste the patient folders or exam files to your PC in any directory location.
Then, the Patient Folders and files can be shared to a desired location, such as Dropbox or Google Drive.

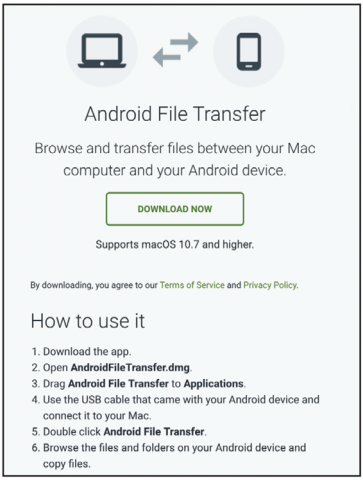
Although the data is decrypted, the patient reports are always password protected. Your password to open patient reports is the same as your decryption password.





2.15 Wired Transfer to Mac

To transfer files to a Mac, make sure to connect the device via USB-C cable to a Mac and make sure patient data is decrypted following Section 2.12 Transfer Patient Files. The application “Android File Transfer” will need to be downloaded to the Mac from the Android website (www.android.com/filetransfer/). This screenshot was taken directly from the application “Android File Transfer”.



To open files on a Mac, open the Android File Transfer application. Then open the VistaView folder. Patient Folders are named by LastInitial_FirstInitial_PatientID. Image files are labeled as hhmmss_OD or hhmmss_OS where hh is hour, mm is minute, and ss is second. PDF files are labeled hhmmss.

The Patient Folders and files can be shared to a desired location, such as Dropbox or Google Drive.

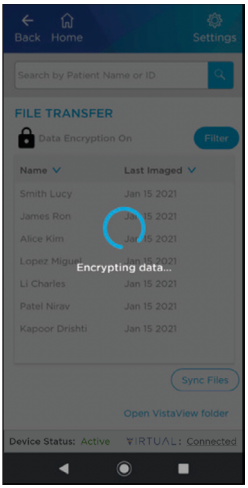
The Patient Folders and files can be shared to a desired location, such as Dropbox or Google Drive.

Although the data is decrypted, the PDFs are always password protected.

2.16 Re-Encrypting Patient Data

After file transfer is complete, patient data will be re-encrypted to ensure safety of the files. There are four ways in which data can be re-encrypted:

1. Unplug the device from the PC, if applicable
2. Tap the lock icon on the File Transfer screen
3. Start a new imaging session by clicking Start Imaging
4. Relaunch the application



Once the data is re-encrypted in one of the four listed ways, the data will not be accessible. To access the data for transfer or sharing again, the user will need to follow Section 2.12 Transfer Patient Files.

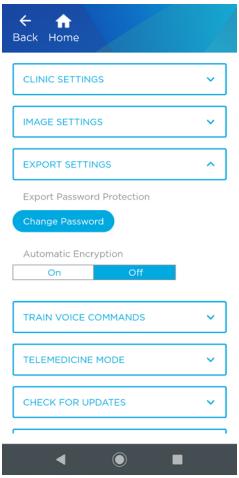
2.17 Disable Encryption

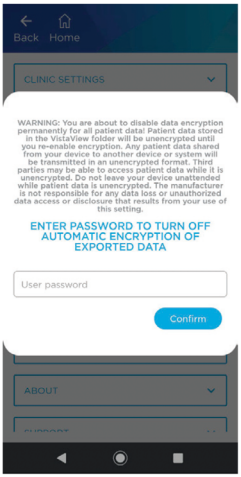
Users can turn off the automatic encryption of their files through the App Settings. Select 'Settings' in the VistaView app then scroll to **Export Settings**. Under **Automatic Encryption** select 'Off'.

A pop up will appear warning the user that data can be exported or shared without a password. The user should enter their password then click **Confirm** to turn off automatic encryption.

Although the data is decrypted, the PDFs are still password protected while **Automatic Encryption** is turned off.

The manufacturer is not responsible for any data loss or unauthorized data access or disclosure that results from turning off automatic encryption.

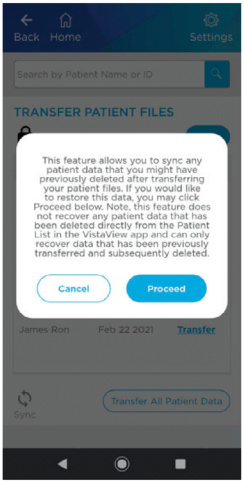


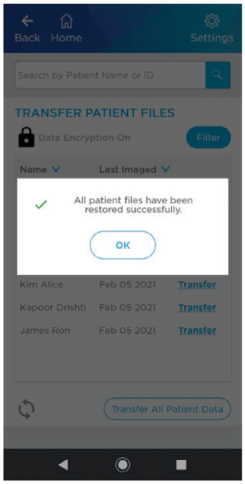


2.18 Sync Files for Export

The Sync button on the Transfer Patient Files screen is available for users who deleted or lost files from the VistaView folder. The Sync button will duplicate the application memory in the VistaView folder to restore any lost files. Please note, the data will still have to exist within VistaView in order to be accessible.

The sync button does not need to be used unless the user wants to restore deleted files back to VistaView folder for export.



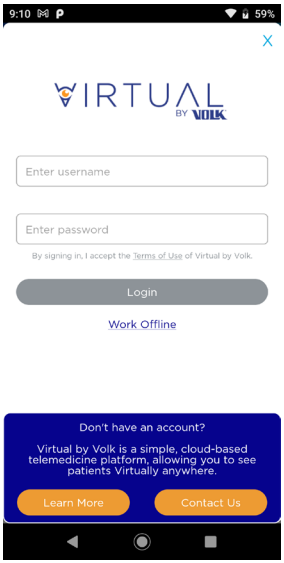


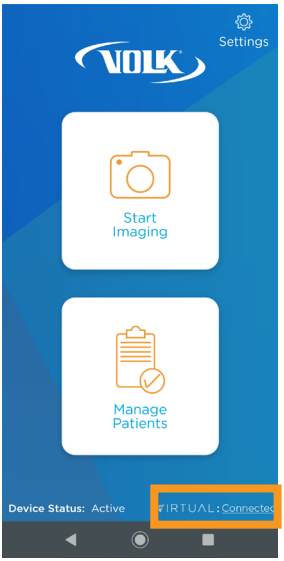
2.19 Telemedicine Mode

Telemedicine Mode allows the user to connect to Virtual by Volk. See Section 2.6 Setting Up the VistaView App for instructions on enabling Telemedicine Mode. The user will be prompted to log in to their camera technician account each time the VistaView app is launched while Telemedicine Mode is still enabled.

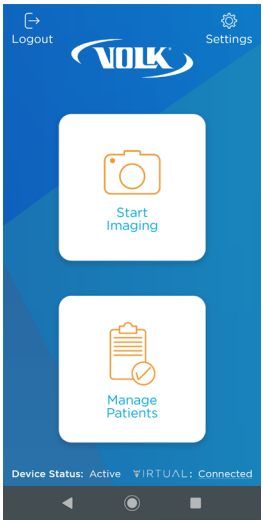
Virtual by Volk status is indicated in the lower right-hand corner of the home screen. Virtual status can be ‘Disabled’, ‘Connected’, ‘Go Online’, and ‘Offline’.

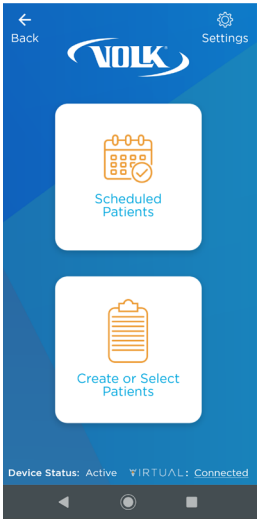
‘Disabled’ status means Telemedicine Mode is Disabled. ‘Connected’ status means Telemedicine Mode is Enabled and a Camera Technician is currently logged in. ‘Go Online’ status means that the camera technician has lost internet connection. Images cannot be uploaded to Virtual by Volk without a stable internet connection. ‘Offline’ status means that the images will be stored locally in the device until a camera technician logs in and assigns those patients to their account. The Virtual status is clickable and leads to the Virtual by Volk login screen.



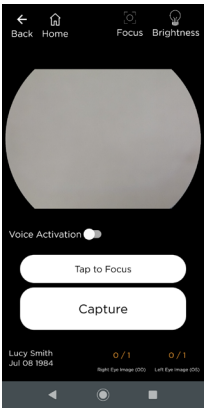


The user can access Scheduled Patients via Start Imaging > Scheduled Patients. Patients can be scheduled by the administrator for the camera technician. The user can also create New Patients or image Existing Patients via Start Imaging > Create or Select Patients.

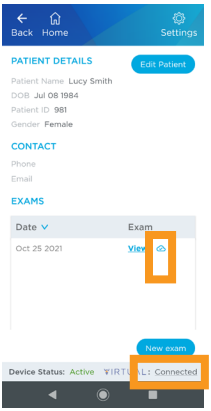




All images captured in Telemedicine Mode will be uploaded to the Telemedicine platform if the image number requirement defined by the administrator is met. The image number requirement is displayed on the imaging screen for Scheduled, New, and Existing Patients.

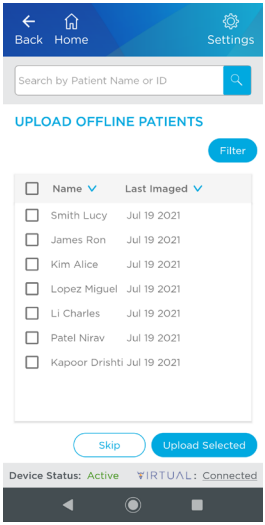


The user can check upload status of their images via Manage Patients > View. On the Patient Details screen, each exam will have a cloud icon. If the icon is blue with a checkmark, the patient's images were successfully uploaded to Virtual by Volk. If the icon is red with a slash through it, the patient's images have not been uploaded to Virtual by Volk. The red cloud icon can be clicked to direct the user to WiFi settings.

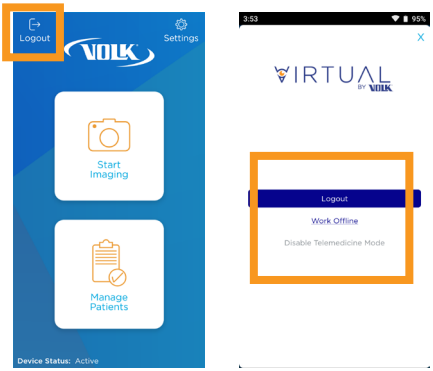


The user can choose to work offline if there is not a stable internet connection. To work offline, click the Work Offline button on the initial log in screen. All images captured in Offline Mode will be stored locally in the VistaView app.

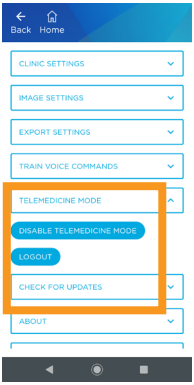
To assign Offline Mode images to a Virtual by Volk user profile, establish a stable internet connection and log in to the user's Virtual by Volk account. The screen below will appear with all Offline Mode patients listed. Select any Offline Mode patients that belong to the Virtual by Volk user and click Upload Selected. The patient information and images will be uploaded to the user's Virtual by Volk profile and will be removed from the Offline Mode local profile.



The user will be automatically logged out of their Virtual by Volk account after 30 minutes of inactivity. The user can log out manually via the Logout button in the upper left-hand corner of the home screen or via Settings > Telemedicine Mode > Logout.



The user can Disable Telemedicine Mode to exit Telemedicine Mode and enter the regular VistaView app. To Disable Telemedicine Mode, the user can click the Virtual by Volk status in the lower right-hand corner of the home screen and click Disable Telemedicine Mode. Alternatively, the user can Disable Telemedicine Mode via Settings > Telemedicine Mode > Disable Telemedicine Mode.



Telemedicine mode will not generate any reports or export any data to the device memory. If the user needs to decrypt non-Telemedicine mode images, they will first need to Disable Telemedicine Mode.

2.20 Updating the App

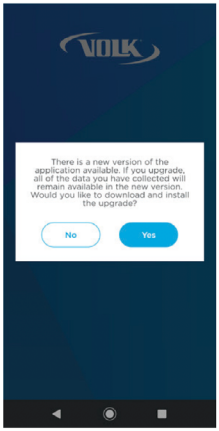
Ensure that the app is up-to-date for the best VistaView experience. Updating the app will not delete any patient data, but it is recommended to create a backup before updating.

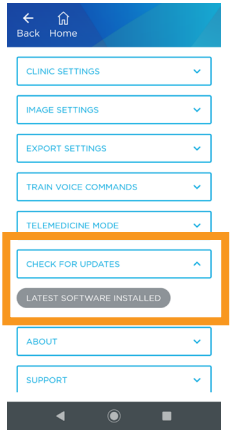
To update the application, the user must be connected to a Wi-Fi network through the device settings. Swipe down from the top of the screen and check to see if left-most icon for Wi-Fi is on, indicated by a green color. If Wi-Fi is off and greyed out, select the icon to turn on Wi-Fi.

Select **Settings** in the VistaView app then scroll down to select **Check for Updates**.

If there is no update available, the button will be gray and say **Latest Software Installed**.

If there is an update available, the button will be blue and say **Update Available**. The update will be automatically downloaded and installed if the user clicks the blue button and confirms the upgrade.





The app will automatically relaunch after the update has finished installing. The device status should be Active. Bluetooth or Calibration settings do not need to be adjusted. If Device Status is Inactive, please refer to Section 6.1 Device Errors for troubleshooting tips.

2.21 Reinstalling the App

If the VistaView app is accidentally uninstalled from the device, navigate to the Files app. The Download folder of the VistaView will open. Navigate to the VistaView folder. If there is file named **VistaView.apk**, install the app.

If a file named **VistaView.apk** is not available here, please reach out to Volk for assistance.

3. Maintenance

3.1 General Maintenance

The VistaView mydriatic fundus camera is a medical device that should be handled with care. Only manual non-immersion cleaning should be used for this instrument. Do not immerse in cleaning fluids. Do not sterilize using autoclave, ETO gas, or any other sterilization means. Always disconnect all electrical connections before cleaning.

Do not attempt to perform any maintenance while the device is being used on a patient.

Avoid touching the optical surfaces except when required for cleaning.

Do not force objects inside the exposed USB-C connector. Only use compressed air for cleaning dust from recessed and inaccessible areas of the device.

If the device becomes non-functional or stops working as intended, do not attempt to repair or make changes to the device. Contact Volk Optical for support at volk@volk.com. Only Volk Optical is authorized to repair or make changes to the device.

3.2 Cleaning Instructions

To clean the exterior of the device, wipe the surface with a clean, absorbent, non-shedding, cotton cloth dampened with a water/detergent solution (2% detergent by volume). To prevent fluids from entering the device, do not spray the device with water/detergent solution. Avoid touching the USB-C connector and optical lens. Ensure that surfaces are carefully hand dried using a clean, non-shedding, cotton cloth.

The optical lens component can be cleaned using Volk Precision Optical Lens Cleaner. Do not use synthetic fiber lens cleaning cloths (e.g. microfiber) on optical surfaces.

Clean the eye cup before each use on a new patient. The eye cup can be cleaned using a clean, absorbent, non-shedding, cotton cloth with a 70% ethanol solution.

4. Technical Description

4.1 Specifications

Parameter	Description
Device Model	Volk VistaView
Imaging Modality	Mydriatic
Minimum Pupil Size	4 mm
Field of View	Static: 55° horizontal, 42° vertical
Weight	560 grams
Focus Adjustment	Auto-focus, manual focus
Diopter Correction	-15 to +15 diopter
Light Source	White light LED
Image Resolution	31 pixels/degree
Image Format	JPEG, DNG, DICOM
Dimensions	88 x 202 x 103 mm
Connector Type	USB-C
Device Power Rating	5 V (DC), 2 A
Battery Capacity	4630 mAh
Software	VistaView smartphone application
Operating System	Android OS
Compatible Smartphone	Nokia XR20
Switching Power Supply	Input: 100-240 V (AC), 50/60 Hz Output: 5 V (DC), 2 A

4.2 Operating and Storage Environments

Temperature	+10 °C to +35 °C
Relative Humidity	30% to 80%
Atmospheric Pressure	800 hPa to 1060 hPa

4.3 Transportation Environment

Temperature	-20 °C to +50 °C
Relative Humidity	10% to 90%
Atmospheric Pressure	500 hPa to 1060 hPa

4.4 Expected Service Life

The expected service life of the device is 2 years.

4.5 Disposing of the Device

Disposal of this product in an unlawful manner may have a negative impact on human health and on the environment. Do not dispose of the Volk VistaView as unsorted municipal waste. When disposing of this product, delete all patient data and follow the procedure which conforms with the laws and regulations applicable to your area.

5. Compatibility and Compliance

5.1 Electromagnetic Compatibility

The Volk VistaView mydriatic fundus camera requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the following section.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Volk VistaView mydriatic fundus camera, including cables specified by the manufacturer. Otherwise, performance of this equipment could be degraded.

A risk of increased emissions or decreased immunity may result if any additional cables are attached.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Volk VistaView mydriatic fundus camera is intended for use in the electromagnetic environment specified below. The customer or the user of the Volk VistaView mydriatic fundus camera should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Volk VistaView mydriatic fundus camera uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The Volk VistaView mydriatic fundus camera is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: ⚠This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the Volk VistaView or shielding the location.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Volk VistaView mydriatic fundus camera is intended for use in the electromagnetic environment specified below. The customer or the user of the Volk VistaView mydriatic fundus camera should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	+8 kV contact +15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power supply should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line ±2 kV line(s) to earth	±1 kV line(s) to line ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle 70 % U_T; 25/30 cycles h Single phase: at 0° 0 % U_T; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle 70 % U_T; 25/30 cycles h Single phase: at 0° 0 % U_T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Volk VistaView mydriatic fundus camera requires continued operation during power mains interruptions, it is recommended that the Volk VistaView mydriatic fundus camera be powered from an uninterrupted power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the A.C. mains voltage prior to application of the test level.

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 0.15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0.15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Volk VistaView ophthalmic camera, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	Recommended separation distance $d = [3.5/3] \sqrt{P}$ 80 MHz to 800 MHz $d = [7/3] \sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Volk VistaView mydriatic fundus camera is used exceeds the applicable RF compliance level above, the Volk VistaView mydriatic fundus camera should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Volk VistaView mydriatic fundus camera.

Immunity Test	IEC 60601 Test Level and Compliance			Electromagnetic Environment - Guidance
	MHz	Modulation	Field Strength	
Immunity to proximity fields from RF wireless communications equipment	385	18 Hz	27 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Volk VistaView ophthalmic camera, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $E = [6/d]\sqrt{P}$ $d = [6/E]\sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the field strength in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
	450	18 Hz	28 V/m	
	710	217 Hz	9 V/m	
	745	217 Hz	28 V/m	
	780	217 Hz	28 V/m	
	810	18 Hz	28 V/m	
	870	18 Hz	28 V/m	
	930	18 Hz	28 V/m	
	1720	217 Hz	28 V/m	
	1845	217 Hz	28 V/m	
	1970	217 Hz	28 V/m	
	2450	217 Hz	28 V/m	
	5240	217 Hz	9 V/m	
	5500	217 Hz	9 V/m	
	5785	217 Hz	9 V/m	

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended Separation Distances

This section covers the recommended separation distances of portable and mobile RF communications equipment as well as RF wireless communications equipment from the Volk VistaView mydriatic fundus camera. The Volk VistaView mydriatic fundus camera is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Volk VistaView mydriatic fundus camera can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Volk VistaView mydriatic fundus camera as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)			
	80 MHz to 800 MHz d = [3.5/3] √P	800 MHz to 2.7 GHz d = [7/3] √P	710, 745, 780, 5240, 5500, 5785 MHz d = [6/9] √P	385, 450, 810, 870, 930, 1720, 1845, 1970, 2450 MHz d = [6/28] √P
0.01	0.117	0.233	0.067	0.021
0.1	0.369	0.738	0.211	0.070
1	1.170	2.333	0.667	0.214
10	3.689	7.379	2.108	0.700
100	11.667	23.333	6.670	2.143

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

5.2 Compliance

The Volk VistaView complies with the following standards

- IEC 60601-1:2005+A1:2012
- IEC 60601-1-2:2014
- ISO 10940:2009
- ISO 15004-2:2007
- ANSI Z80.36:2016

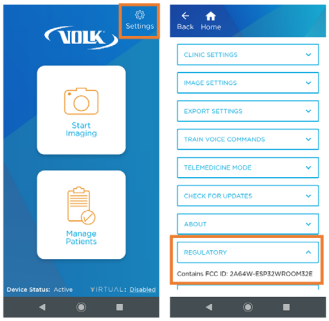
The FDA classification is Class II and 510(k) exempt.
The EU Medical Devices Regulation 2017/745 classification is Class I.

This declaration shall be rendered invalid if changes are made to the Volk VistaView without the manufacturer's authorization.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

5.3 FCC Regulations

To view the FCC ID for the RF module within VistaView, click **Regulatory** within the VistaView app Settings.



The FCC ID for the RF module within VistaView is also listed on the package label on the VistaView box.

WARNING: The Federal Communications Commission warns that changes or modifications of the radio module within this device not expressly approved by Volk Optical Inc. could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his expense.

6. Troubleshooting

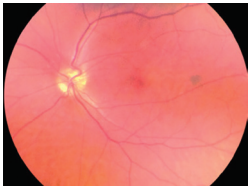
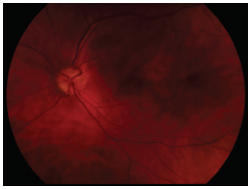
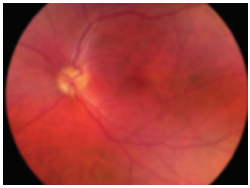
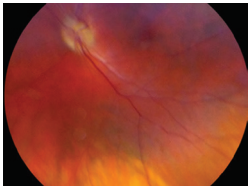
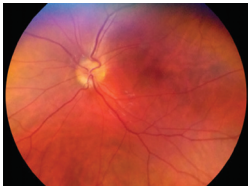
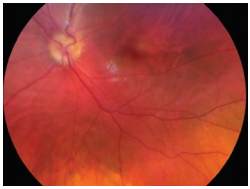
6.1 Device Errors

The following are a list of errors the user may encounter while using the device and the recommended solutions to address them.

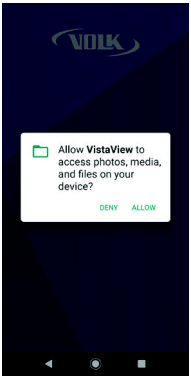
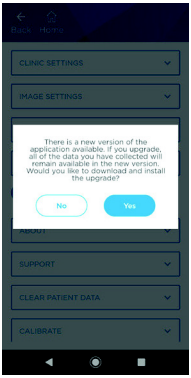
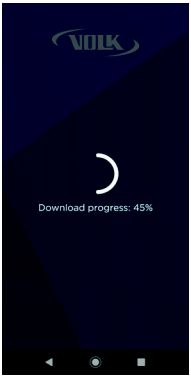
Error	Cause	Troubleshooting tip
Device Status: Inactive	Device plugged into external power source via USB-C	Unplug device from USB-C connection and wait for 30 seconds for Device Status to change to Active.
	Bluetooth connection failure	Navigate to Settings > Bluetooth > Seek Devices and connect to the device shown in connections with name 'Fundus I' with 12-digit MAC address displayed.
	Bluetooth connection turned off	Navigate to Phone Settings > Connected Devices > Connection Preferences > Bluetooth. Ensure toggle switch is On.
Small or skewed image while capturing and reviewing images	Device is not calibrated *Note: The device has already been calibrated by Volk Optical before shipping. The user should only use this function if instructed by Volk Optical.*	Navigate to the settings menu on screen and select the Calibrate function. Once the device enters camera mode, point the device at any flat white surface and press calibrate. Once calibration is successful, user can verify that visualization on device screen is acceptable.

If the above solutions do not work, contact Volk Optical at volk@volk.com and we will be happy to assist you.

6.2 Image Quality

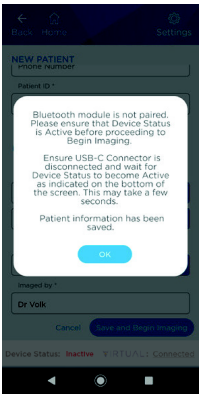
Image Quality	Problem and Correction
	**Image is too bright:** Correct this by changing the **Brightness** settings. Decrease the brightness level found on the imaging screen to decrease the image brightness.
	**Image is too dark:** Correct this by changing the **Brightness** settings. Increase the brightness level found on the imaging screen to brighten the image brightness.
	**Image is not in focus:** If using focus-assist mode, tap the focus button when the optic disk is visible to trigger and lock the focus before capturing the image. If focus assist mode does not work, switch to manual focus mode. Adjust the diopter value until the image is clear.
	**Image is blurry:** This may be a result of the patient's eye movements. Ask the patient to fixate at a point above your shoulder or at your ear to help keep their gaze steady. Hold the device steady when capturing the image.
	**Glare on image:** If there is a glare at the top of the image, the imaging distance is too far away. Shorten the working distance to remove the glare. If there is a glare at the bottom of the image, move further away from the eye.
	**Macula not centered:** Ask the patient to fixate at a point above your shoulder or at your ear to help keep their gaze steady. Adjust the angle of the device such that the face of the device is parallel to the patient. If issue persists, follow calibration steps of this IFU.

6.3 System Messages

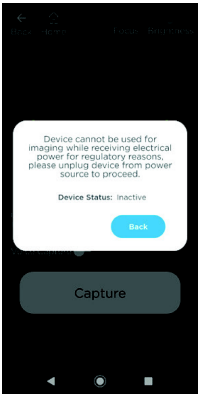
System Message	Interpretation
	When first using the device, the application will request the user to allow permission to take pictures. Press **Allow** to use the device for its intended purpose.
	Device has found a new version of VistaView software available for update. Updating the app will not delete any patient data but it is recommended to create a backup before updating. The user is prompted whether they would like to continue with updating. Refer to Section 2.20 Updating the App.
	If user selected yes to continue with application update, screen shows the download progress.

System Message

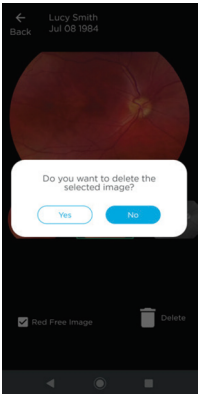
Interpretation



When the device is Inactive, imaging mode is not accessible. The user will see “Bluetooth module is not paired. Please ensure that Device Status is Active before proceeding to Begin Imaging. Ensure USB-C Connector is disconnected and wait for Device Status to become Active as indicated on the bottom of the screen. This may take a few seconds. Patient information has been saved.” Connect to Bluetooth or unplug the device to image.



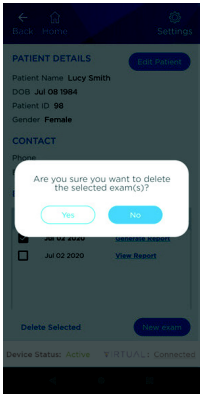
While the device is plugged in, imaging mode is not accessible. The user will see “Device cannot be used for imaging while receiving electrical power for regulatory reasons. Please unplug device from power source to proceed.” The user must unplug the device to image.



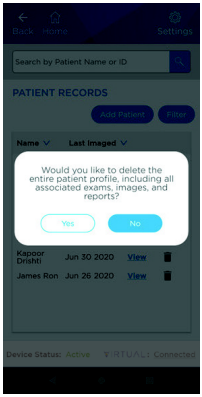
When the user attempts to delete an image, the user will see “Do you want to delete the selected image?” The user is prompted to choose between No to cancel the deletion and Yes delete the image.

System Message

Interpretation



When attempting to delete a patient exam, the user will see “Are you sure you want to delete the selected exam(s)?” within an individual patient database. Choosing No will prevent deletion. Choosing Yes will delete all information associated with that specific study.



When attempting to delete a patient, the user will see “Would you like to delete the entire patient profile, including all associated exams, images, and reports?” if confirming deletion of a patient from the patient database. Choosing No will prevent deletion. Choosing Yes will delete all information associated with that particular patient.

7. Warranty

Volk Optical provides a 1-year warranty as standard with the Volk VistaView. The warranty covers the external lens attachment, Android application, and Android device.

7.1 Warranty Terms

Volk provides a limited warranty against manufacturing defects for the VistaView for a period of one (1) year from the date of delivery of the VistaView to the customer. The obligation of Volk and the customer's sole exclusive remedy hereunder, shall be limited, at Volk's option, to replacement or repair of the defective VistaView unit. The customer must not return goods unless authorized in writing by Volk. Volk shall have the right to inspect the goods at the customer's installation. Customer's failure to give prompt written notice (30 days) upon discovery of any alleged defect shall constitute acceptance of the VistaView as delivered, and a waiver by customer of all claims with respect thereto.

Notwithstanding the foregoing warranties and remedies, Volk shall have no obligation hereunder if the VistaView becomes defective as a result of the customer's disassembly or modification of the goods, unauthorized service or repair, misuse or abuse of the VistaView hardware or software, or combination with unauthorized software, hardware, or systems, or improper storage, accidents, contamination, adulteration, improper configuration, improper use or misapplication after delivery thereof to the customer, or customer's failure to use the VistaView consistent with the Instructions for Use and any other documentation provided, including but not limited to failure to follow the recommended cleaning instructions and/or warnings contained in the Instructions for Use or customer's breach of any Volk Terms and Conditions of Sale or VistaView Terms and Conditions which can be found on www.volk.com.

The customer shall be responsible for returning products for warranty service to Volk Optical, 7893 Enterprise Drive, Mentor, Ohio 44060 - USA. In the event the VistaView is not eligible for warranty service, the customer is solely responsible for all costs of shipping and handling.

Warranty repairs will include all labor, adjustments, and replacement parts. Replacement parts may be re-manufactured or contain re-manufactured materials. The warranty service will not be provided without proof the product was purchased directly from Volk Optical, an authorized Volk distributor, or a Volk-authorized e-commerce platform. In the event of a product recall during the warranty period, the VistaView will be replaced at no cost to the customer. Any repair for issues not covered by the above warranty may be conducted at the sole discretion of Volk at a cost to be determined by Volk.

VOLK MAKES NO OTHER WARRANTY, EXPRESS OR IMPLIED, REGARDING THE HARDWARE OR SOFTWARE, INCLUDING WITHOUT LIMITATION, IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT, AND FITNESS FOR A PARTICULAR PURPOSE, AND ALL SUCH WARRANTIES ARE HEREBY EXPRESSLY EXCLUDED.

8. Support and Servicing

New orders may be placed directly with Volk Optical via our website www.volk.com or by calling us at the numbers listed at the end of this section. You may also order directly through a Authorized Volk Optical Distributor in your region. Authorized Distributor contact information is available directly from Volk Optical at volk.com.

For servicing and repairs, contact the Authorized Volk Optical Distributor from whom you purchased the device or contact us at rma.support@volk.com or the numbers listed at the end of this section.

If you have any questions about how to set-up, use or troubleshoot your device, please contact our Customer Care Team at volk@volk.com or the numbers listed at the end of this section.

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