VISTA
VIEW™

Instructions for Use

Hand-Held Mydriatic Fundus Camera

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1. Product Description

1.1 General

The Volk VistaView is a mydriatic fundus camera 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.

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.

Rx only

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

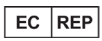
Symbol	Description
CE	The device has been tested and conforms to the provisions noted within the 93/42/EEC Medical Device Directive.
	Important operating instructions are included in this Instructions for Use (IFU). Failure to follow these instructions could place the patient or operator at risk.
	Consult 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.

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 exporting, saving, and creating regular backups of data to prevent loss of data.

It is the responsibility of the user to keep track of the data export 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 functional properly and must be connected at all times. If there is an issue with Bluetooth settings, please reference Section 6.1 Device Errors of this IFU.

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. 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 Section 3. Maintenance of this IFU.

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 Section 3. Maintenance of this IFU.

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

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.

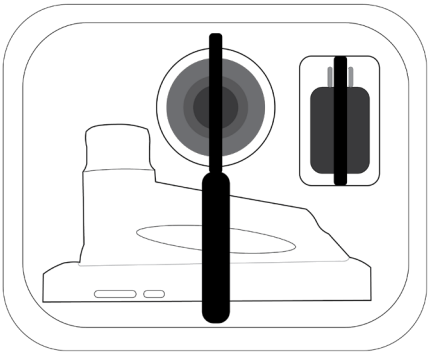
Only connect the device to computers, laptops, and power supplies outside the patient environment that have passed the safety standard for information technology equipment IEC 60950-1, EN 60950-1, and UL 60950-1 to ensure the safety of the USB-C electrical connection.

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 of this IFU.

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
- USB-C cable
- Volk VistaView case



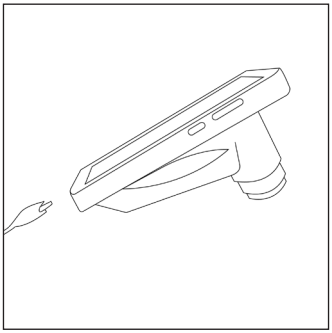
2. Operating instructions

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.

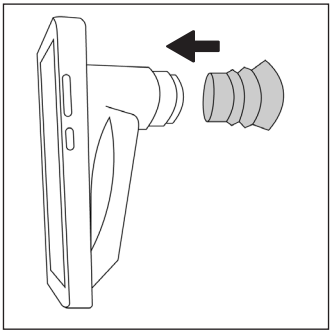
2.2 Charging the Device

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.



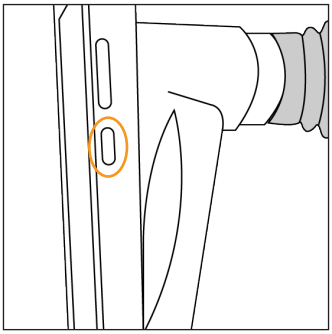
2.3 Eye Cup Installation

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”.

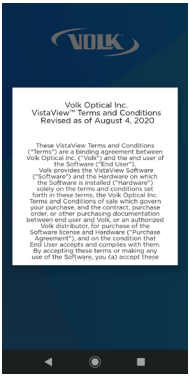
2.5 Start Up Messages

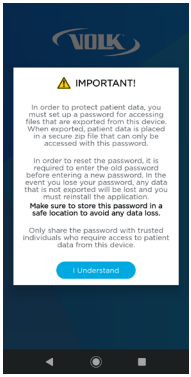
Once the device is on, navigate to the VistaView application installed on the device. The home screen should be visible on the screen as shown below.

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 password protected exports. Ensure that the password is stored in a safe location and only share the password with trusted individuals. Select **I Understand** to continue.

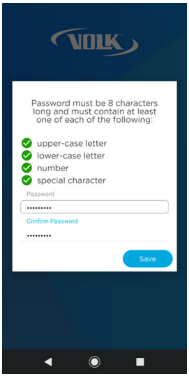
Please note that it is the responsibility of the user to use the password protected export in a manner compliant with their practices.

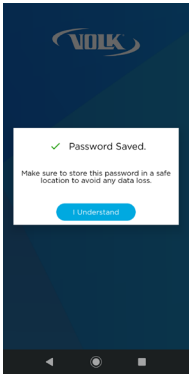


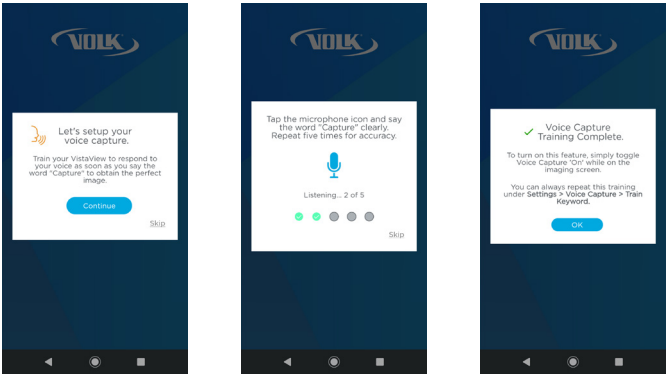


The user is prompted to input a password at least 8 characters long with at least one of each of the following: upper-case letter, lower-case letter, number, and special character.

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



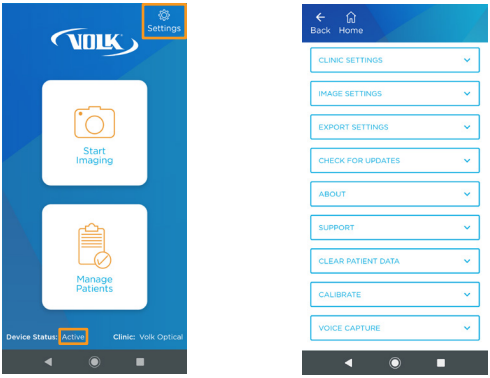




For best results when using the **Voice Capture** feature on the VistaView, the user can train the device to recognize their voice and pronunciation of the word “Capture”. Press **Continue** to begin training. When you are ready, tap the microphone icon and repeat the word “Capture” five (5) times. The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



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,** and **Voice Capture**.

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.

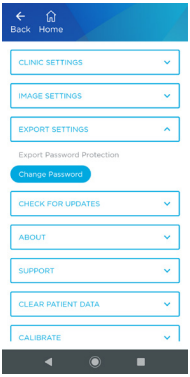
If DICOM files are needed, choose the **DICOM** setting before imaging. Images cannot be converted to DICOM after imaging.

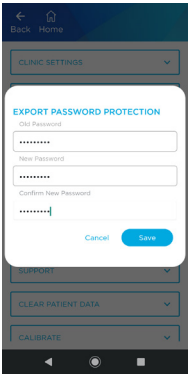
The **Raw Image Acquisition** setting allows the user to automatically export the raw images in a digital negative format (DNG) that correspond to the compressed JPEG or DICOM images. If raw image export is turned **Off**, the user risks losing raw image traceability.

Export Settings

The user can change **Export Settings** to enable password protected export. To change the password for password protected export, 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.





Voice Capture Settings

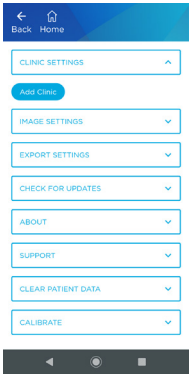
For best results when using the **Voice Capture** feature on the VistaView, the user can train the device to recognize their voice and pronunciation of the word “Capture”. To train the device, select **Train Keyword** under Voice Capture. When prompted, repeat the word “Capture” five (5) times.

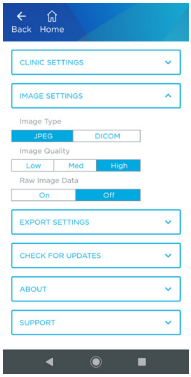
Default Settings

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 of this IFU for troubleshooting tips.





Factory Reset

The **Factory Reset** 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 Factory Reset to avoid loss of important data.

Factory Reset resets all user settings, except Bluetooth and Calibration Settings. Factory Reset can be used to reset the data export password if it is lost or forgotten, but will lead to loss of all data.

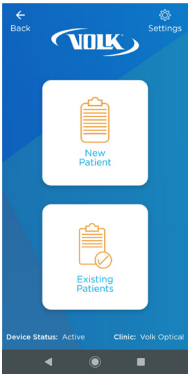
Setting	Function
Clinic Settings	Add and edit clinic information to organize information and data obtained from multiple clinics.
Image Settings	Adjust JPEG quality, enable DICOM export and enable Raw Image Acquisition.
Export Settings	Change password for password protected export.
Check for Updates	Manually check for application updates.
About	VistaView application version number.
Support	Link to online 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.
Voice Capture	Train the device to better recognize the word “Capture” as said by the user during voice activated image capture.
Bluetooth	Pairing and connection to device.
Factory Reset	Reset all data and settings.

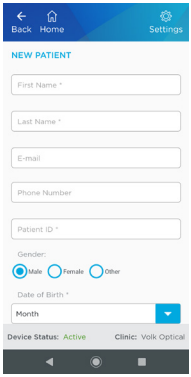
It is the responsibility of the user to make sure they are exporting, saving, and creating regular backups of data to prevent loss of data, especially before a factory reset.

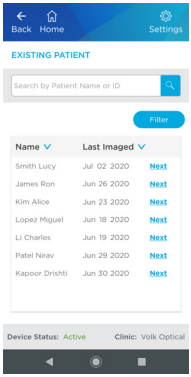
2.7 Selecting a Patient

Select **Start Imaging** on the home screen. Choose between **New Patient** and **Existing Patients** depending on the patient being examined.

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.

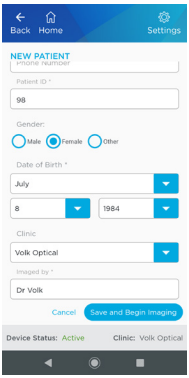


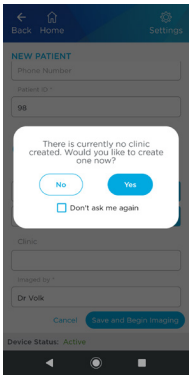




When imaging an existing patient, search the patient database and select the patient to image.

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

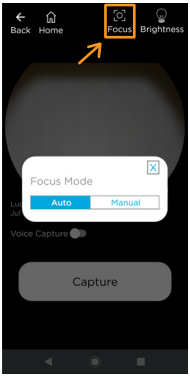


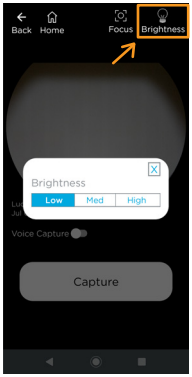


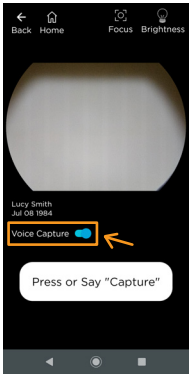
Note: If no clinic has been set up, the device will prompt the user to add a clinic. Select **Yes** to set up a clinic before proceeding or select **No** to proceed without a clinic. Check **Don't Ask Me Again** if you do not want to see this message again. The user can still add a clinic by accessing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







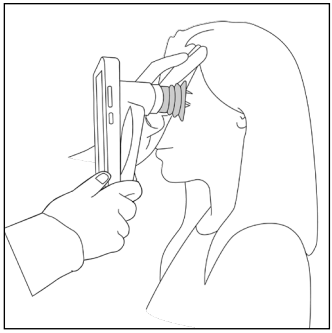
To adjust the focus mode, select the **Focus** icon then select **Auto** or **Manual** mode.

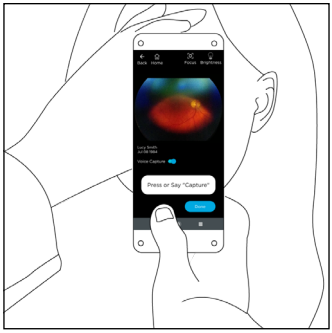
To adjust the brightness, select the **Brightness** icon. Start with the lowest brightness and increase as needed.

If needed, turn on the **Voice Capture** feature by activating the toggle button, as shown. Simply say the word "Capture" to capture an image once lined up and in focus.

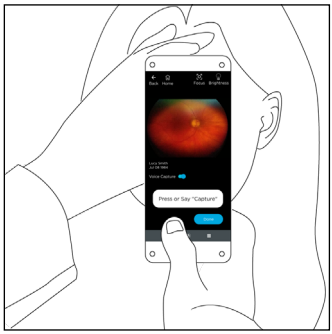
To image a patient, the patient and examiner should be seated facing each other. Use your dominant hand to hold the VistaView and use your non-dominant hand to stabilize the device by positioning the fingers just behind the eye cup.

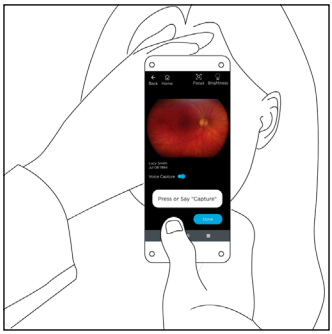
Ask the patient to look over your shoulder or to fixate at a spot near your ear. Approach the pupil, keeping the device vertical and in a portrait orientation. Stabilize by resting fingers on patient's forehead.





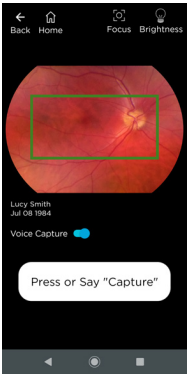
Slowly, move the device closer to the eye while keeping the pupil in the center of the screen. Locate the retina, which can be seen as a small reflection within the pupil. Keep the retina reflection in the middle of the display screen and slowly advance the device closer to the patient's eye.

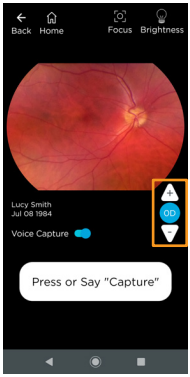




The correct imaging distance is reached when the retina completely fills the imaging window. Do not be afraid to gently push the device closer to the patient - the eye cup is flexible and the device will not touch the patient's eye. If auto-focus is enabled, tap anywhere on the screen to focus, except for a button. A green box will appear when the retina is in focus.

A green box appears when in focus. If using manual focus, use the buttons on the right-hand side of the screen to increase or decrease the focus by one diopter increments.

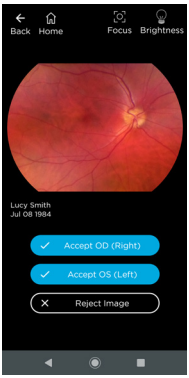


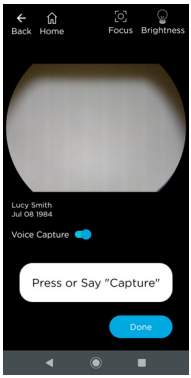


To capture an image, ensure that the full field-of-view is illuminated with no dark spots, reflections, or shaded regions appearing toward the boundaries during preview. Press the **Capture** button on screen. The device will flash and capture an image. If **Voice Capture** is on, wait for the green box to appear if using auto focus then take an image by saying the word “Capture”.

Note: Inform the patient being imaged that they will see a bright flash. This will help them to be prepared 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.





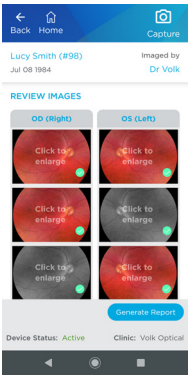
Once all images have been captured, select **Done** on screen, which will take the user to the patient exam review screen.

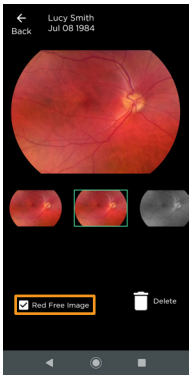
2.9 Reviewing Images and Adding Notes

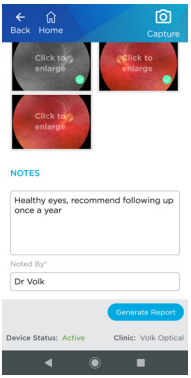
On the patient exam review screen, the user can tap on the thumbnail to enlarge the image. The user can also spread and pinch to zoom in and out of the image.

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.







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.

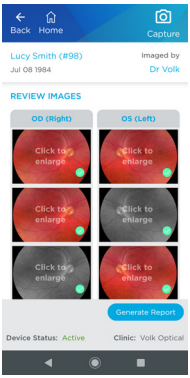
The user will be required to fill “Noted By” (name of operator/user) if notes are added. Then, select **Generate Report** or **Home**.

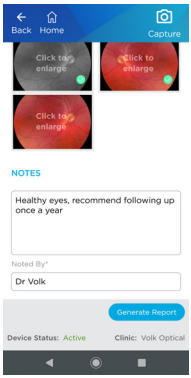
Report notes cannot be edited or deleted once saved to enhance traceability. Additional notes can be added.

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**.

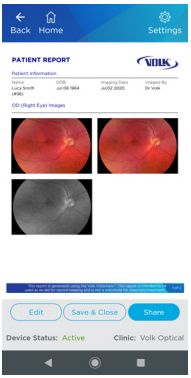
This report is meant to be used as an aid for record keeping and is not a substitute for medical diagnosis or treatment.

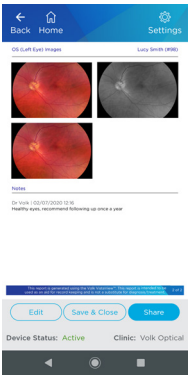


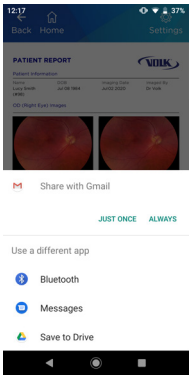


To select the images to be added to the report, select the circle in the lower right corner of the image to add a green check mark. After selecting the images and pressing **Generate Report**, the user can review the report to verify that all the information is accurate.

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.



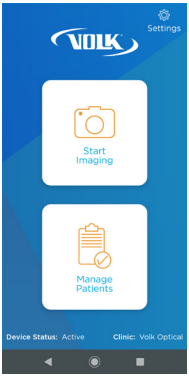




The generated report will contain patient information, images, and notes from the time of report generation. Any change to patient information, exams, or notes will require the user to re-generate the report to ensure that the report is up-to-date.

2.11 Managing Patients

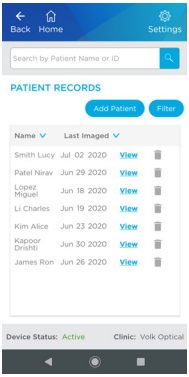
The user can review patients and images later after saving the exam. From the home screen, select **Manage Patients** followed by **Patient List**. The user has the option to select the patient to review by searching the database.

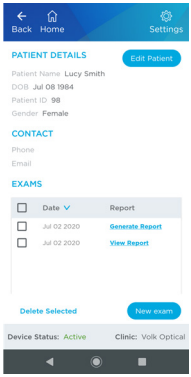


After the user selects a patient by selecting **View**, patient profile opens where previous exams are available for review and patient information can be edited. Click **Edit Patient** to change patient information, including Name, Date of Birth, Patient ID, and Gender.

All reports will need to be re-generated to reflect any changes to patient information.

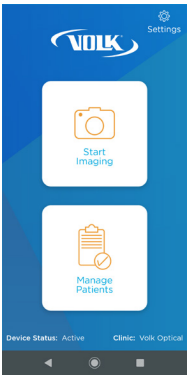
In the Report column, the user can view a previously generated report by selecting **View Report**. If a report has not been generated, the user can select **Generate Report.** The user can also start a **New Exam**. A new exam does not overwrite existing data but adds an exam to a patient.





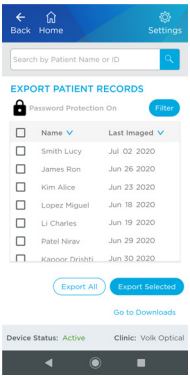
2.12 Exporting Patient Data

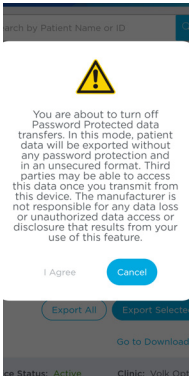
The user can export patient data to the device memory. Exported data can be accessed, transferred, and downloaded through connection to a computer by the USB-C cable provided with the device. This can be done by selecting **Manage Patients** followed by **Export Patient Data**.

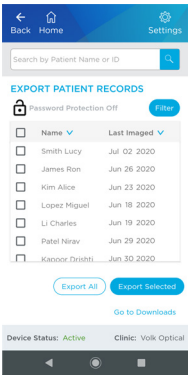


When accessing the Export Patient Records screen, the user will see the words **Password Protection On** next to a lock icon at the upper left-hand corner indicating password protected export is on. This is the default setup to add extra security while handling patient data.

The user can turn off password protected export by tapping the lock. When a user taps the lock, a pop-up appears confirming that the user wants to export without a password. Select **I Agree** to turn off password protected export.

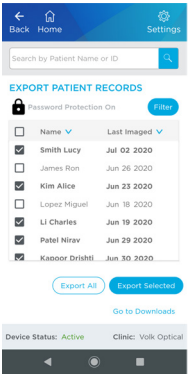


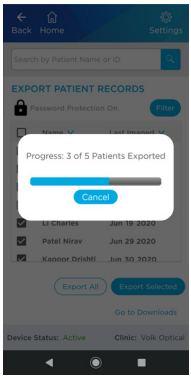


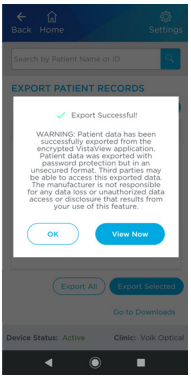


The user can choose which patient(s) to export and select **Export Selected**. The user can also export all patients by choosing **Export All**.

An export bar will show the status of the export. Once the export is finished, a pop-up will inform the user of completion. Select **View Now** to view the exported data on the device. Select **OK** to dismiss the notification.







2.13 Wireless Transfer of Patient Data

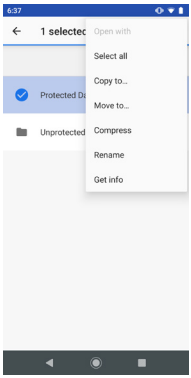
Protected Data

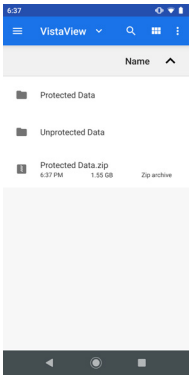
When the user selects **View Now** after exporting data or **Go to Downloads** from the export screen, the Download folder on the VistaView opens. Select the VistaView folder. Since wireless sharing is restricted to only files, folders must be compressed into a zip file if the user wants to share multiple patients.

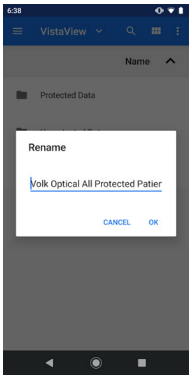
All Patients

To share all protected patient data, press and hold the **Protected Data** folder until a check mark appears. Press the ⋮ Menu icon in the upper right-hand corner. A menu of options appears. Choose **Compress** to make the folder into a zip file.

A zip file appears named Protected Data.zip. If the user wants to rename the zip file, press and hold the Protected Data.zip file. Then, press the Menu icon and choose **Rename**. Type in a new name for the zip file and press **OK**.

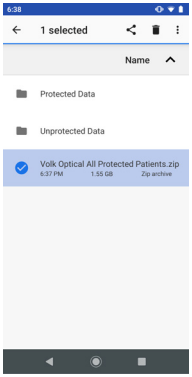


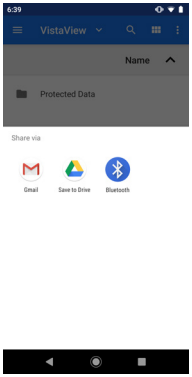




After the zip file is rename, press and hold the zip file. Choose the Share icon in the upper right-hand corner. The share menu pops up. Select the preferred method to share the zip file.

The zip file is locked and needs a password to access. Only share the password with authorized individuals allowed to have access to patient data.





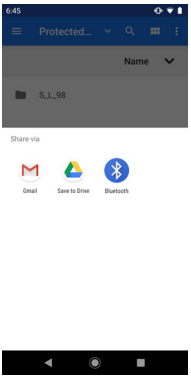
Selected Patients

To share selected patients, open the Protected Data folder. Press and hold each patient folder you wish to share until a check mark appears. Press the ⋮Menu icon in the upper right-hand corner. A menu of options appears. Choose **Compress** to make the folders into a zip file.

A zip file appears named Protected Data.zip. If the user wants to rename the zip file, press and hold the Protected Data.zip file. Then, press the Menu icon and choose **Rename**. Type in a new name for the zip file and press **OK**.

After the zip file is renamed, press and hold the zip file. Choose the Share icon in the upper right-hand corner. The share menu pops up. Select the preferred method to share the zip file.

The zip file is locked and needs a password to access. Only share the password with authorized individuals allowed to have access to patient data.

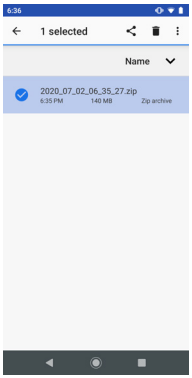


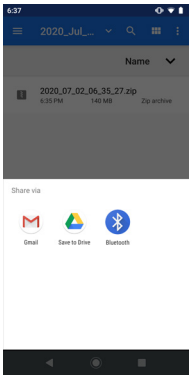
Individual Patient

To share an individual patient, select Protected Data > the patient to share > the zip file of the date to share. Press and hold the zip file until a check mark appears.

Select the Share icon. The share menu pops up. Select the preferred method to share the zip file.

The zip file is locked and needs a password to access. Only share the password with authorized individuals allowed to have access to patient data.





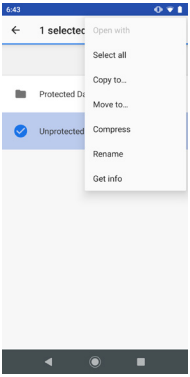
Unprotected Data

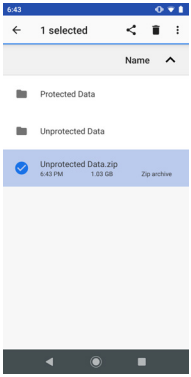
When the user selects **View Now** after exporting data or **Go to Downloads** from the export screen, the Download folder on the VistaView opens. Select the VistaView folder. Since wireless sharing is restricted to only files, folders must be compressed into a zip file if the user wants to share multiple patients.

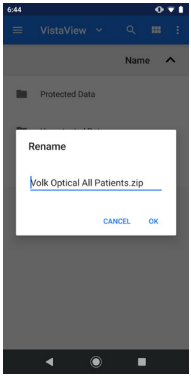
All Patients

To share all unprotected patient data, press and hold the **Unprotected Data** folder until a check mark appears. Press the ⋮ Menu icon in the upper right-hand corner. A menu of options appears. Choose **Compress** to make the folder into a zip file.

A zip file appears named Unprotected Data.zip. If the user wants to rename the zip file, press and hold the Unprotected Data.zip file. Then, press the Menu icon and choose **Rename**. Type in a new name for the zip file and press **OK**.

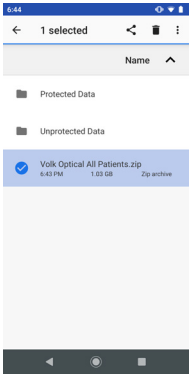


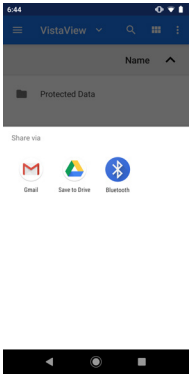




After the zip file is renamed, press and hold the zip file. Choose the Share icon in the upper right-hand corner. The share menu pops up. Select the preferred method to share the zip file.

Although the data is unprotected, the PDFs are still password protected.





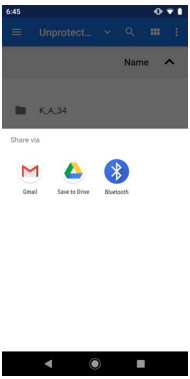
Selected Patients

To share selected patients, open the Unprotected Data folder. Press and hold each patient folder you wish to share until a check mark appears. Press the ⋮ Menu icon in the upper right-hand corner. A menu of options appears. Choose **Compress** to make the folders into a zip file.

A zip file appears named Unprotected Data.zip. If the user wants to rename the zip file, press and hold the Unprotected Data.zip file. Then, press the Menu icon and choose **Rename**. Type in a new name for the zip file and press **OK**.

After the zip file is renamed, press and hold the zip file. Choose the Share icon in the upper right-hand corner. The share menu pops up. Select the preferred method to share the zip file.

Although the data is unprotected, the PDFs are still password protected.

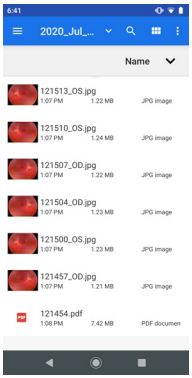


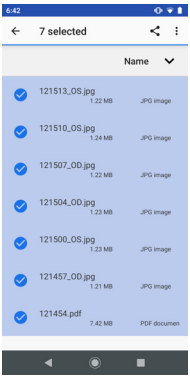
Individual Patient

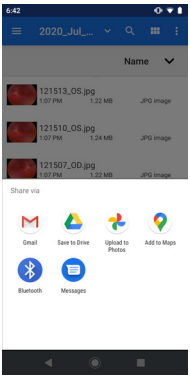
To share an individual patient, select Unprotected Data > the patient to share > the date to share. Press and hold the images and reports until a check mark appears.

Select the Share icon. The share menu pops up. Select the preferred method to share the zip file.

Although the data is unprotected, the PDFs are still password protected.

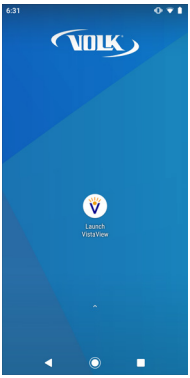


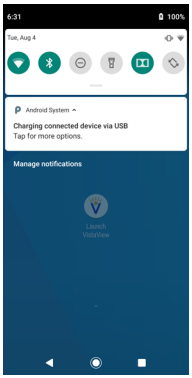


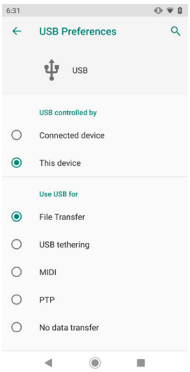


2.14 Wired Transfer to Windows PC

To transfer files to a PC, make sure patient data is exported following Section 2.12 Exporting Patient Data of this IFU. Connect the device via USB-C cable to a PC. Pull down from the top of the phone homepage to view the Android system options and select **Tap for more options**. Make sure to select the File Transfer option on this screen to connect the VistaView to a PC.



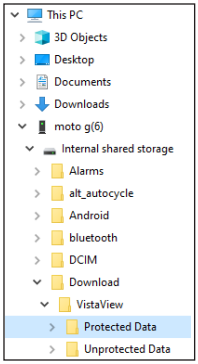




To open files on a Windows PC, open “This PC” and select moto g(6) (the Motorola Moto G6 external drive folder) to access the exported patient data. Open the Download folder followed by the VistaView folder.

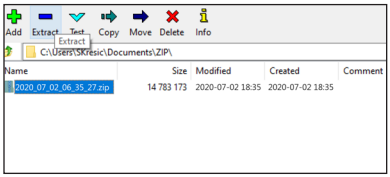
Protected Data

To access patient data, follow the pathway moto g(6) > Internal shared storage > Download > VistaView. Copy the Protected Data folder to a desired location.



In the copied location, open Protected Data > the patient to access > the date to access. The ZIP files are labeled as Year_Month_Date_hh_mm_ss. Select a ZIP file to access.

From there, open an application such as Winrar or 7-Zip and navigate to the copied folder. Select the zip folder and click the extract option. Select the destination to extract the zip file to and input the password created in Section 2.5 Start Up Messages of this IFU.



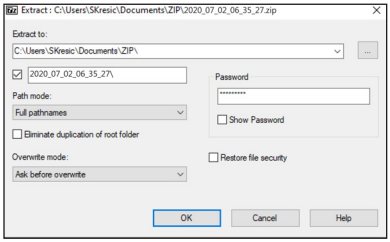
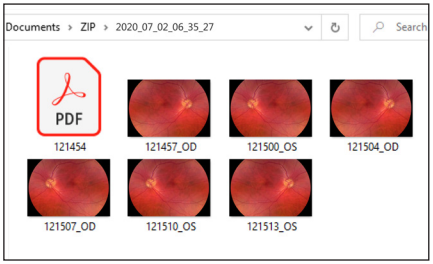
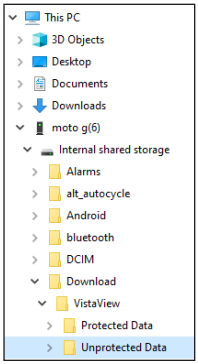


Image files are labeled as hhmmss_OD or hhmmss_OS where hh is hour, mm is minute, and ss is second. PDF files are labeled hhmmss.



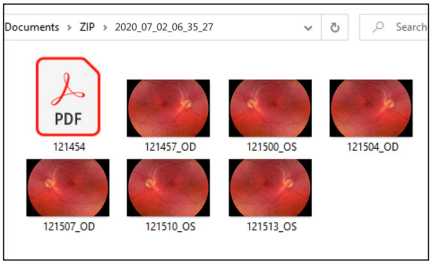
Unprotected Data

To access patient data, follow the pathway moto g(6) > Internal shared storage > Download > VistaView. Copy the Unprotected Data folder to a desired location.



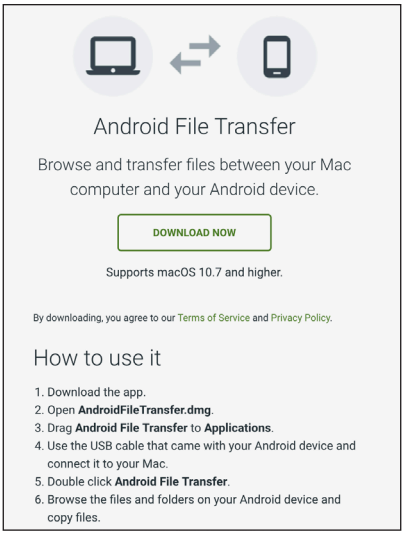
In the copied location, open Unprotected Data > the patient to access > the date to access. Image files are labeled as hhmmss_OD or hhmmss_OS where hh is hour, mm is minute, and ss is second. PDF files are labeled hhmmss.

Although the data is unprotected, the PDFs are still password protected.

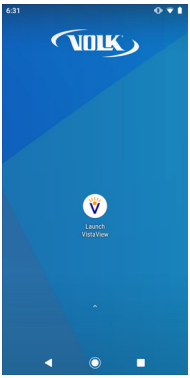


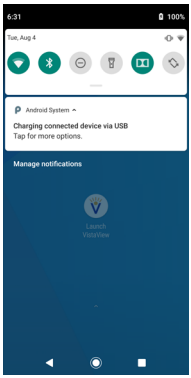
2.15 Wired Transfer to Mac

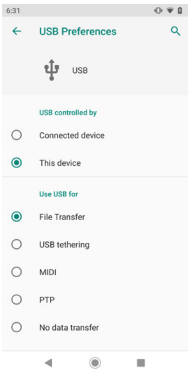
To access exported data on a Mac, make sure patient data is exported following Section 2.12 Exporting Patient Data of this IFU. The application “Android File Transfer” will need to be downloaded to the Mac from the Android website. This screenshot was taken directly from the application “Android File Transfer”.



Connect the device via USB-C cable to a Mac. Pull down from the top of the phone homepage to view the Android system options and select **Tap for more options**. Make sure to select the File Transfer option on this screen to connect the VistaView to a PC.





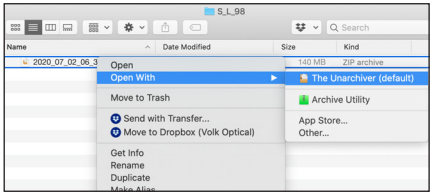


Protected Data

To access patient data, open the Android File Transfer application on the Mac. Follow the pathway Download > VistaView. Copy the Protected Data folder to a desired location.

In the copied location, open Protected Data > the patient to access > the date to access. The ZIP files are labeled as Year_Month_Date_hh_mm_ss. Select a ZIP file to access.

From there, right-click to **Open With -> The Unarchiver.** When Unarchiver opens, click **Extract** and select the destination to extract the zip file. Input the password created in Section 2.5 Start Up Messages of this IFU.



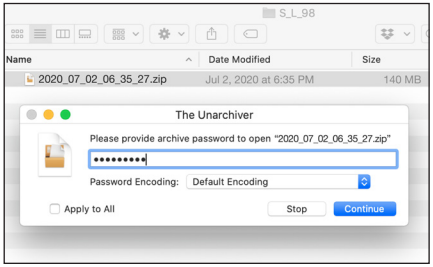
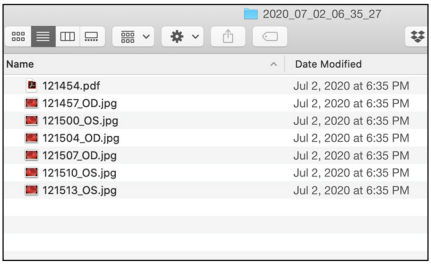


Image files are labeled as hhmmss_OD or hhmmss_OS where hh is hour, mm is minute, and ss is second. PDF files are labeled hhmmss.

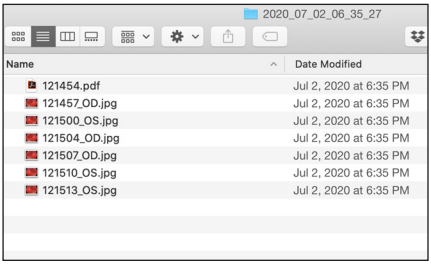


Unprotected Data

To access patient data, open the Android File Transfer application on the Mac. Follow the pathway Download > VistaView. Copy the Unprotected Data folder to a desired location.

In the copied location, open Unprotected Data > the patient to access > the date to access. 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.

Although the data is unprotected, the PDFs are still password protected.



2.16 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.

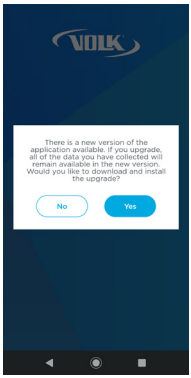
Select **Settings** in the VistaView app then scroll down to select **Check for Updates**.

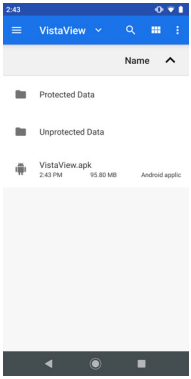
If there is no update available, there will be a pop-up confirming the user is running the latest app.

If there is an update available, a pop-up will prompt the user. Select **Yes** on the app update pop-up to download and install the update.

The Download folder of the VistaView device will open. Look for the VistaView folder. Open the VistaView folder and select **VistaView.apk**.

There will be a pop-up message about downloading an unknown app. Select **Continue**. There will be another pop-up message about installing an update to the VistaView application. Select **Install**.





After the app has finished installing, select **Open**. The VistaView app will launch and is ready to use. 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 of this IFU for troubleshooting tips.

2.17 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 followed by Application Update folder. If there is file named **VistaView.apk**, install the app as described at the bottom of Section 2.16 Updating the App of this IFU.

If a file named **VistaView.apk** is not available here, make sure Wi-Fi is turned on. Swipe down from the top of the screen and select the left-most icon to turn on Wi-Fi if not already enabled. Search for volk.com in the Chrome app on the VistaView.

On volk.com, search for “VistaView”. Click on **VistaView App Download** and the app will automatically download to the Download folder.

Navigate to the Files app. The Download folder will open. Navigate to the VistaView folder followed by Application Update folder. Install the file named **VistaView.apk** as described at the bottom of Section 2.16 Updating the App of this IFU.

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	5 mm
Field of view	55° static
Weight	500 grams
Focus adjustment	Auto-focus, manual focus
Diopter correction	-15 to +15 diopter
Light source	White light LED
Image resolution	3072 x 2122 pixels
Image format	JPEG, DNG, DICOM
Dimensions	78 x 185 x 102 mm
Connector Type	USB-C
Device Power Rating	5 V (DC), 3 A
Battery Capacity	3000 mAh
Software	VistaView smartphone application
Operating system	Android OS
Compatible smartphone	Motorola Moto G6
Switching Power Supply	Motorola SC-22
	Input: 100-240 V (AC), 50/60 Hz
	Output: 5 V (DC), 3 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	±8kV contact ±15kV air	+8kV contact +15kV 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 610004-4	±2kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV line(s) to line ±2kV line(s) to earth	+1kV line(s) to line +2kV 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 % U_T; 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 % U_T; 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 a 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 for portable and mobile RF communications equipment as well as RF wireless communications equipment 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 93/42/EEC Medical Device Directive classification is Class I.

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

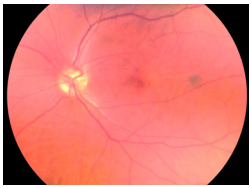
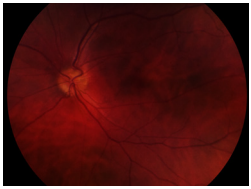
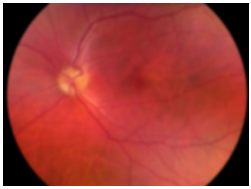
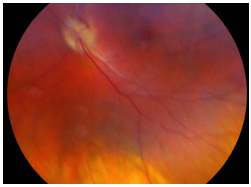
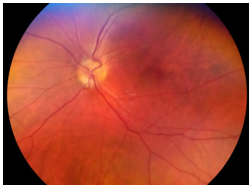
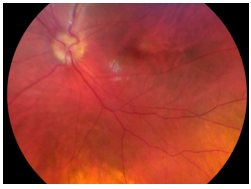
6. Troubleshooting

6.1 Device Errors

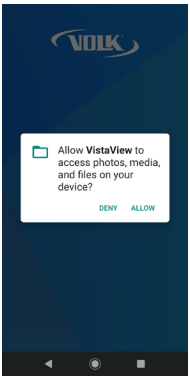
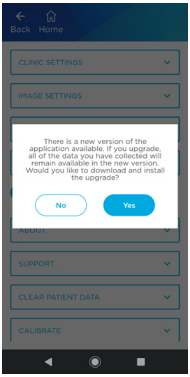
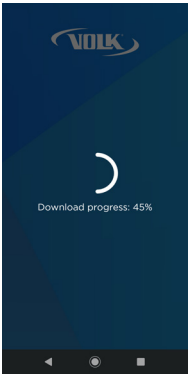
The following are a list of errors the user may encounter while using the device and the recommended solutions to address them.

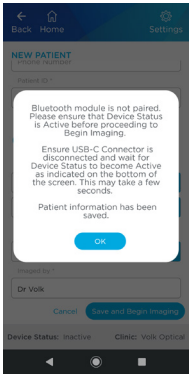
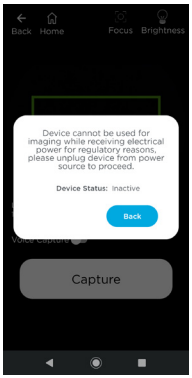
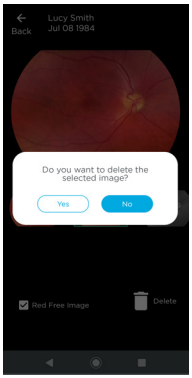
Error	Cause	Troubleshooting tip
Device Status: Inactive	Device plugged into external power source via USB-C	Unplug device from USB-C connection and wait for 30 seconds for Device Status to change to Active.
	Bluetooth connection failure	Navigate to Settings > Bluetooth > Seek Devices and connect to the 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.

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 auto-focus mode, wait until the focus is locked and the green box appears before capturing the image. If auto-focus 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.

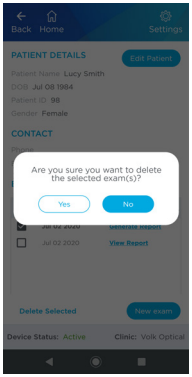
6.3 System Messages

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 2.16 Updating the App of this IFU.
	If user selected yes to continue with application update, screen shows the download progress.

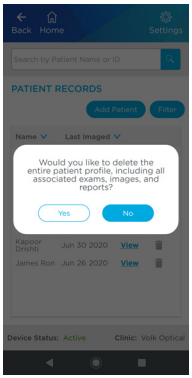
System Message	Interpretation
	When the device is Inactive, imaging mode is not accessible. The user will see “Bluetooth module is not paired. Please ensure that Device Status is Active before proceeding to Begin Imaging. Ensure USB-C Connector is disconnected and wait for Device Status to become Active 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 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, EXPRESSED 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

For servicing and repairs, contact the Authorized Volk Optical Distributor from who you purchased the device or contact us at rma@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.