

VOLK®



Instructions for Use

Hand-Held Non-Mydriatic Fundus Camera

Volk Viva
Instructions for Use for Hand-held non-mydriatric fundus camera

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1. Product Description

1.1 General

The Viva device is intended to be a high-quality, affordable, portable, and easy-to-use fundus camera that enables healthcare workers to capture and manage images of the general population. The device is handheld and non-mydriatic, making the technology accessible to many users and patients.

R_x only

The Volk Viva does not require the eye to be dilated and is intended to be used by trained medical professionals in professional healthcare environments only. The Volk Viva 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 Viva 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.

1.1.1 Intended Use

The Viva device is an ophthalmic camera intended to capture and store images of the eye and the surrounding area.

1.1.2 Indications for Use

The Volk Viva is intended for use by qualified healthcare professionals in capturing high-resolution, non-mydriatic digital images of the retina. The device is designed to aid in the visualization, documentation, and analysis of the ocular fundus, including the optic nerve head, macula, and peripheral retina.

Healthcare professionals should follow the manufacturer's instructions and guidelines for proper operation and maintenance of the Volk Viva.

1.2 Important Symbols

Symbol

Description



The device has been tested and conforms to the provisions noted within the EU Medical Devices Regulation 2017/745.



Read accompanying user documentation indicates that important operating instructions are included in this User's and Maintenance Manual. Failure to follow these instructions could place the patient or operator at risk.



Caution. Consult the instructions for use for important cautionary information. The user is advised of important operating and maintenance instructions.



Type BF applied part: Applied part is a part of device that in normal use necessarily comes into physical contact with the patient.



Mandatory to refer to instructions for use



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



Disposal specification
European directive on waste electrical and electronic equipment (WEEE) 2012/19/EU specifies the disposal.



Fragile, handle with care



Keep Dry



Indicates that the item is a medical device.



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.



Indicates the date when the medical device was manufactured.



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

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 Viva is safe for patients and clinicians when used in accordance with the instructions, warnings, and caution statements presented in this instruction for use. **Before using the device, you must familiarize yourself with all warnings and cautions and with the sections of this Instructions for Use that pertain to your use of the device.** Specific warnings and cautions are also found throughout this document.



Factory resetting the smartphone will remove the Viva application and associated calibration data, rendering the device useless.



Use only the accessories and parts provided or specified by Volk Optical with this product.



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



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



No modification of the device is allowed.



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



The device is not intended to be sterilized.



Only use cleaning instructions provided in the maintenance section of this document.



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



Deleting the pre-installed Volk Viva smartphone application will delete all patient data and images, since the application stores all the data in the encrypted application memory. The user should never delete or uninstall the smartphone application from the Viva.



Inspect device before each use.



Do not use the device if there are signs of damage.



Caretakers should assess patients for adverse reactions on the skin where the device has contact, such as redness (erythema), swelling (edema), irritation, sensitization (delayed Type IV hypersensitivity), allergy, immune response, or other reactions.



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



This product contains a chemical known in the State of California to cause cancer, birth defects, or other reproductive harm.



Do not remove the product label from the device.

1.4 Contraindications of Use

Because prolonged intense light exposure can damage the retina, 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 of the target structures.

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



CAUTION – The light emitted from this instrument is potentially hazardous. The longer the duration of exposure and the greater the number of pulses, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum output will exceed the safety guideline after:

Retina mode

- 30,303 images

External mode

- 9 hours, 15 minutes of illumination or 50 images



CAUTION - Do not capture more than 50 images per patient per day.



CAUTION – The following conditions may complicate or prevent imaging: cataract, corneal opacity, and nystagmus.

1.5 Usage Environment Requirements

The Volk Viva is intended to be used by trained medical professionals in professional healthcare environments only.



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



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



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



Avoid using the device in a dusty environment.



Avoid subjecting the device to vibration or shock.



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



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, UL 60950-1 to ensure the safety of the USB electrical connection.



The device must be operated in the electromagnetic environment indicated in this document.

1.6 Package Contents

The Volk Viva product package includes the following items.

- Volk Viva device
- Volk Viva case & shoulder strap
- USB cable
- Eye cup
- Lens cap
- Volk Viva Quick Start Guide



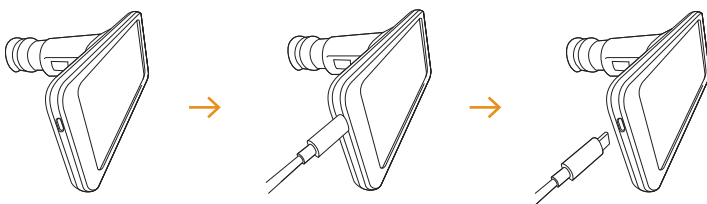
2. Operating Instructions

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.

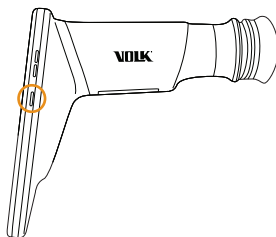
2.2 Charging the Device

Charge the device with the USB cable as shown, connecting one end to the USB connector on the Volk Viva and the other end to an IEC 60950-1, EN 60950-1 or UL 60950-1 certified power supply, until the device is fully charged. Then disconnect the charger from the USB connector on device.



2.3 Using the Device

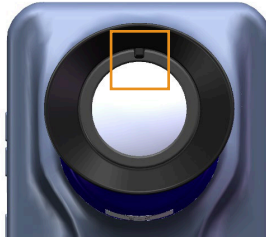
Power on the device by pressing the power button as shown.



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

To reinstall the eye cup after cleaning, check for the notch inside the eye

cup, then match the notch with the slot on the end of the Viva camera. Carefully stretch the eye cup over the black ring, being careful not to touch the lens surface.



2.4 Viva Software Configuration

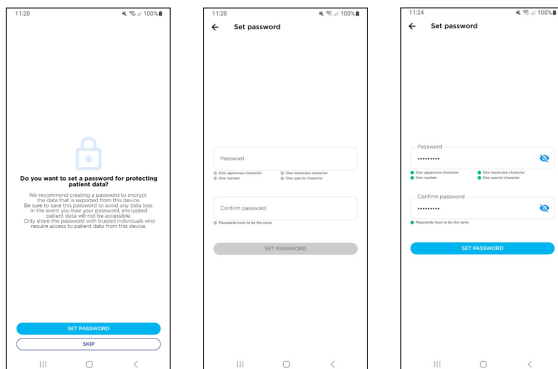
Once the device has been powered on, the Viva application will open automatically. The Viva application can be opened at any time by clicking the Viva icon on the smartphone home screen. Upon first use, the Volk Viva Terms of Use must be reviewed and accepted.



The device will prompt the creation of a password that will be used to decrypt exported data for transfer out of the device. If the user creates a password, all exported data will be encrypted by default. The password must include one uppercase character, one lowercase character, one number, and one special character.



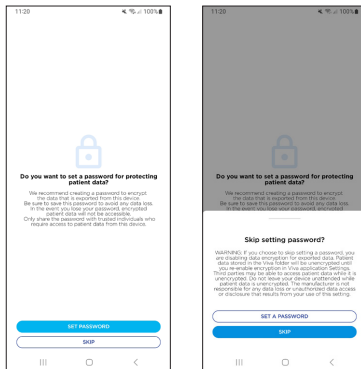
WARNING: If the user creates a password, patient data will be exported to the Viva folder in an encrypted format. The user will need to enter the password to decrypt the data prior to transfer out of the Viva device. Be sure to save this password to avoid any data loss. In the event the password is lost, encrypted data will not be accessible.



This step may be skipped at the user's discretion. If the user skips creating a password, all exported data will be unencrypted and accessible by default.

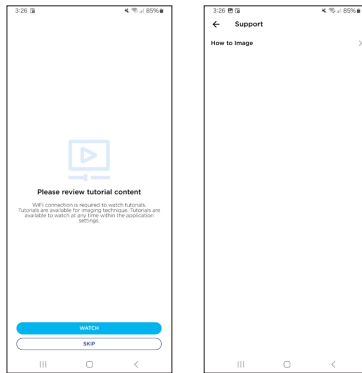


WARNING: If the user skips creating a password, patient data will be exported to the Viva folder in an unencrypted format. The manufacturer is not responsible for any data loss or unauthorized data access or disclosure that results from the user of this setting.



The device will then prompt the user to adjust the digital mask. Point the device at a white sheet of paper. Use the arrows on the screen to shift the mask up/down/left/right. When the internal components are properly masked, click Save Calibration.

A set of tutorials will be available to preview prior to first use. These videos are available to review at any time on-device within the Settings menu.



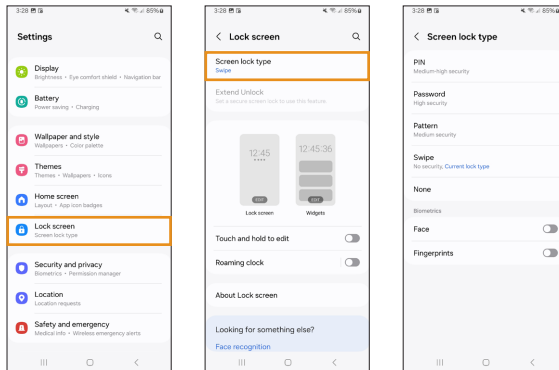
After reviewing the optional tutorials, the software will launch to the Home Screen.

2.5 Smartphone Security Settings



WARNING: It is advised that a user also adds security lock to the smartphone itself. This is the best way to ensure that all data that is stored on the device is not accessible to unauthorized users.

To set a Security Lock. Navigate out of the Volk Viva App to the Smartphone Home Screen. Open **Settings** and Select **“Lock screen”** followed by **“Screen lock type”**.



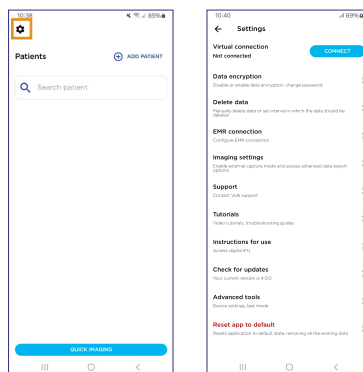
The available Screen lock options include PIN, Password, Pattern and Face ID. Fingerprint Lock is not Compatible with the Volk Viva Device.



WARNING: In the event the security lock is lost or forgotten, the device will be rendered unusable.

2.6 Viva Software Settings

The Viva software settings can be accessed from the Home Screen by clicking the gear icon in the top left corner. Before first use, ensure that each setting is configured as desired.



Setting

Virtual connection

Data encryption

Delete data

EMR connection

Imaging settings

Support

Tutorials

Instructions for Use

Check for updates

Advanced tools

Reset app to default

Description

Connect to Virtual by Volk
(Telemedicine software)

Disable or enable data encryption &
change password

Manually delete data or set interval in
which data will be automatically deleted

Configure EMR connection

Enable external capture mode and access
advanced data export options

Contact Volk support

Access tutorial videos and
troubleshooting guides

Access digital IFU

Check for application updates

Access firmware version and device
calibration & install Test Mode. Only to
be used when advised by Volk Optical
customer care.

Resets application to default state,
removing all the existing data.

2.6.1 Virtual Connection

The user can connect to Virtual by Volk with valid login credentials given to Virtual by Volk users. Virtual connection allows users to access Scheduled Patients and to upload Viva images to the Virtual by Volk platform. The user will need to re-login after 30-minutes of inactivity. Please refer to Section 2.14 for more details.

2.6.2 Data encryption

The user can enable or disable data encryption. To disable data encryption for exported data, the current password must be input. To enable encryption for exported data, a new password must be created.



WARNING: If encryption is enabled, patient data will be exported to the Viva folder in an encrypted format. The user will need to enter their password to decrypt the data prior to transfer out of the Viva device. Be sure to save this password to avoid any data loss. In the event the password is lost, encrypted data will not be accessible.



WARNING: If encryption is disabled, patient data will be exported to the Viva folder in an unencrypted format. The manufacturer is not responsible for any data loss or unauthorized data access or disclosure that results from the use of this setting.

The data encryption password can be changed by inputting the current password and creating a new password. Passwords must include one uppercase character, one lowercase character, one number, and one special character.



WARNING: Be sure to save this password to avoid any data loss. In the event the password is lost, encrypted data will not be accessible.

The four screenshots show the following steps:

- Data encryption screen:** The 'Encrypt exported data (recommended)' option is selected with a blue circle. Below it is a 'CHANGE PASSWORD' button. The 'Disable encryption for exported data' option is unselected.
- Change password screen:** The 'Current password' field is filled with '*****'. The 'New password' field is empty. Below the fields are checkboxes for password requirements: 'At least 8 characters', 'At least one uppercase character', 'At least one lowercase character', 'At least one number', and 'At least one special character'. A 'CONFIRM NEW PASSWORD' button is at the bottom.
- Confirm new password screen:** The 'Confirm new password' field is filled with '*****'. A 'CHANGED PASSWORD' button is at the bottom.
- Disable encryption screen:** The 'Disable encryption for exported data' option is selected with a blue circle. Below it is a 'DISABLE ENCRYPTION' button. A warning message is displayed: 'Warning! Before this device is by the Viva folder will be unprotected. The manufacturer is not responsible for any data loss or unauthorized data access or disclosure that results from your use of this setting.'

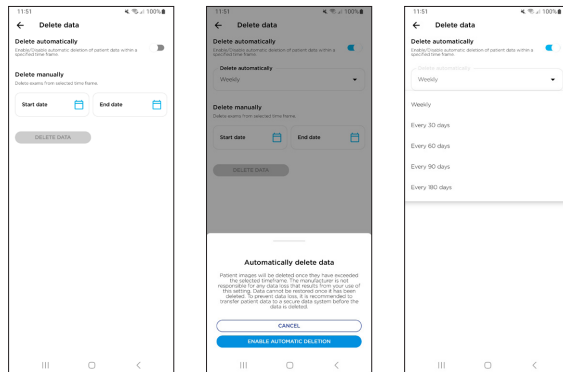
If data encryption is enabled, all PDF reports will be password protected. If data encryption is disabled, all PDF reports will be accessible without a password.



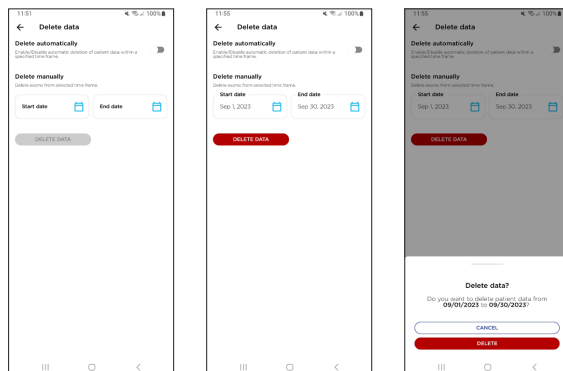
WARNING: The manufacturer is not responsible for any data loss or unauthorized data access or disclosure that results from the use of this setting.

2.6.3 Delete data

The Viva device is able to automatically delete data to optimize device storage. Data can be deleted once it reaches a certain expiration date by selecting Delete automatically > enable automatic deletion > selecting an interval. Data can be automatically deleted after 7 days, 30 days, 60 days, 90 days, or 180 days.



The user is able to manually bulk delete data from a selected timeframe by selecting a start date > selecting an end date > delete data > delete.





WARNING: The manufacturer is not responsible for any data loss that results from your use of this setting. Data cannot be restored once it has been deleted. To prevent data loss, it is recommended to transfer patient data to a secure data system before the data is deleted.

2.6.4 EMR connection

The user can connect to their DICOM-compatible Electronic Medical Record (EMR) system via AE Title, IP Address, and Port information for their Modality Work List and Remote DICOM Receiver. Configuration with a DICOM-compatible EMR allows users to access Scheduled Patients and to upload Viva images automatically into the EMR. Configuration is required one-time only. Please refer to Section 2.13 for more details.

2.6.5 Imaging settings

The user may enable External capture mode. These images are intended to capture and store images of the eye and surrounding area for documentation purposes only.

The Viva camera exports JPEG images by default. The user may enable DICOM and/or BMP export. If DICOM export is enabled, the device will generate a .dcm image without direct connection to the user's EMR (Refer to Section 2.6.4 for instructions on connecting directly to an EMR). This image can then be manually uploaded to the user's EMR.

If BMP export is enabled, the device will generate a .bmp image for each compressed JPEG image.

2.6.6 Support

The user may contact Volk Optical customer care via email on-device or via phone call on a separate device.

2.6.7 Tutorials

Access tutorial videos and troubleshooting guides.

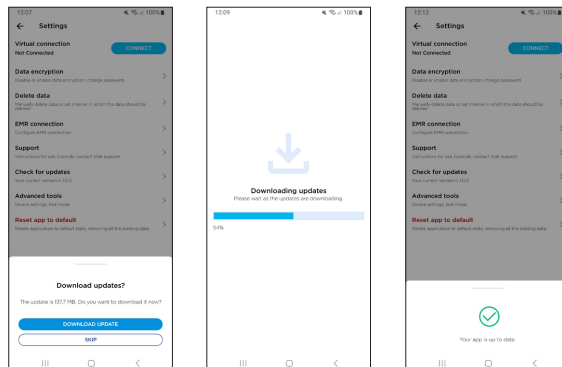
2.6.8 Instructions for Use

Access the digital IFU. The digital IFU may also be accessed on Volk's website.

2.6.9 Check for updates

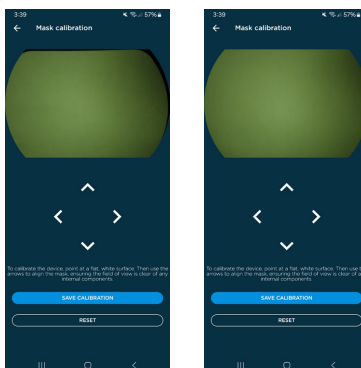
The current software version is listed under Check for updates. Click Check for updates to access available application updates. Connection to a Wi-Fi network is required.

If an update is available, the user may download now or wait to install later. If the user chooses to download now, a loading indicator will show download status. Once the update has been downloaded, it will be automatically installed. If there are no updates available, the application will indicate that it is up to date.



2.6.10 Advanced tools

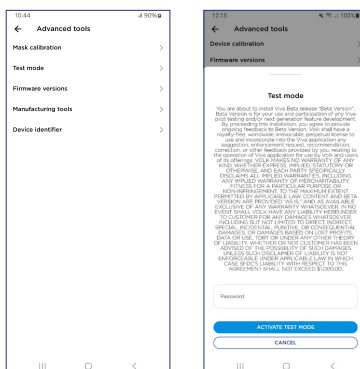
To adjust the digital mask, click Mask calibration. Point the device at a white sheet of paper. Use the arrows on the screen to shift the mask up/down/left/right. When the internal components are properly masked, click Save Calibration.



The device is calibrated during manufacturing using Manufacturing Tools. The user is advised not to change the calibration settings unless instructed to do so by Volk Optical customer care. A passcode given by Volk Optical customer care is required to access these calibration options.

The current firmware versions are listed under Firmware versions menu.

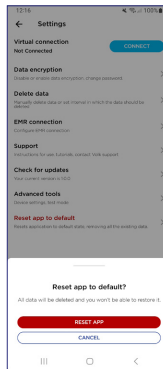
Test mode can be installed after instruction and access code given by Volk to select users. Test mode allows users to access new application features prior to release. To enable, enter the Test mode passcode and click Activate Test Mode. Test mode can be disabled at any time to return to the released Viva app version. Test mode is automatically disabled after 30 days of use.



2.6.11 Reset app to default

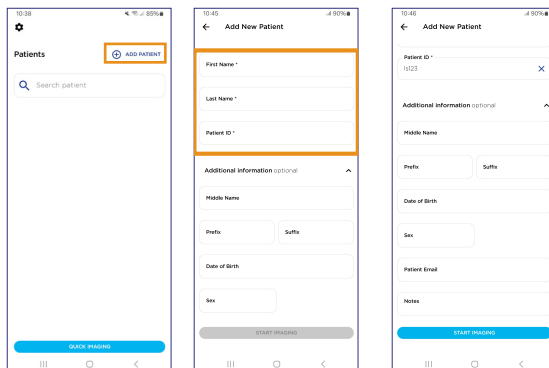
Resetting app to default deletes all patient data from the application memory and exported folder. Before performing a factory reset, transfer all patient data to a secondary location to avoid loss of data.

Resetting app to default resets all user settings and can be used to reset the data encryption password if it is lost or forgotten. However, all current data will be lost.

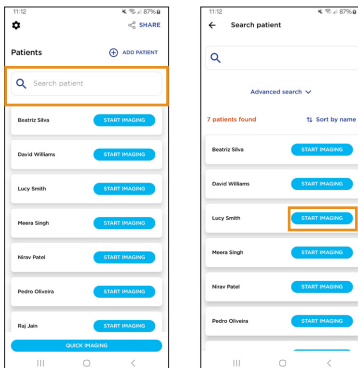


2.7 Creating and Selecting Patients

To create a patient, select **Add Patient**. When creating a new patient, enter the requested patient information. Mandatory fields are First Name, Last Name, and Patient ID. Each patient must have a unique Patient ID. Once mandatory fields have been filled in, select **Start Imaging** at the bottom of the new patient form to begin imaging.



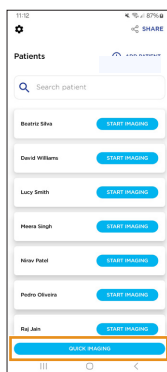
To image an existing patient, search and/or filter the patient database and select **Start Imaging** next to the patient's name.



To begin an imaging session without first entering patient data, **Quick Imaging** may be selected. Images captured using this feature can be assigned to a New or Existing Patient following the imaging session. Quick imaging sessions not assigned to a New or Existing Patient will be stored under an anonymous patient profile.



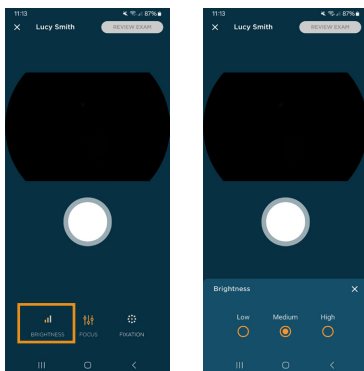
WARNING: It is the user's responsibility to ensure that traceability to patient information is not lost by using the Quick Imaging feature.



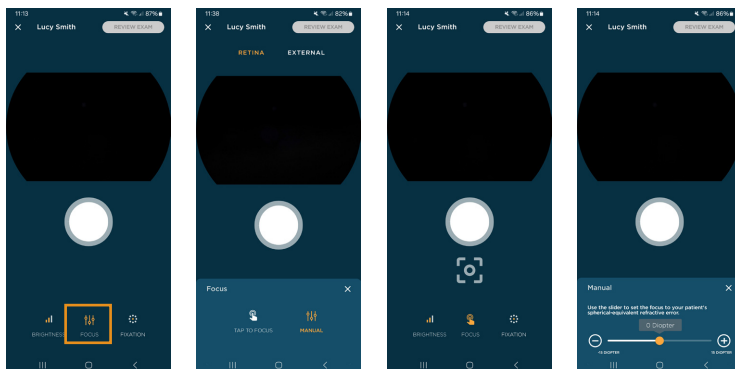
2.8 Imaging Settings

Select **Start Imaging** or **Quick Imaging** to begin imaging. On the imaging screen, select the desired settings. Brightness, Focus, and Fixation are user adjustable.

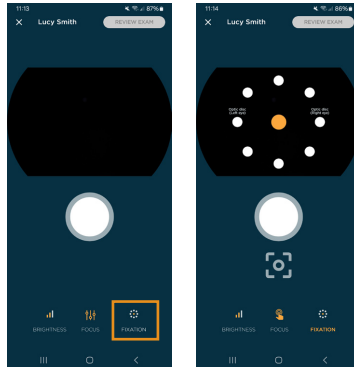
To adjust the brightness, select the **Brightness** icon. If captured images are too bright, reduce the brightness. If captured images are too dark, increase the brightness.



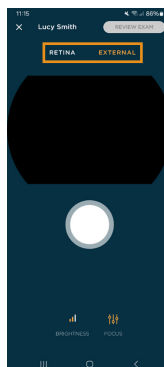
To adjust the focus mode, select the **Focus** icon. In Tap to Focus mode, tap the image preview or autofocus trigger button to focus. In Manual focus mode, select the patient's spherical-equivalent refractive error on the slider. The device will set the focus position corresponding to the refractive error input.



The device includes 9 fixation targets which allows imaging of different areas on the retina by adjusting the patient's fixation. Select the desired fixation target from the **Fixation** menu. By default, the fixation target is in the center of the screen to obtain a macula-centered photo.

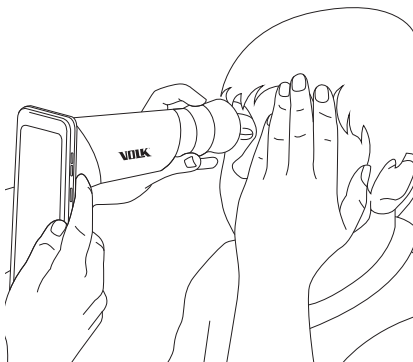


The user is able to capture and store images of the eye and surrounding area using the **External capture** mode. Refer to Section 2.6.5 for instructions on how to enable External capture mode. Once this mode is enabled, select the desired mode above the image preview. For **Retina** mode, the eye will be illuminated with infrared light during alignment and briefly flashed with white light to capture the image. In **External** mode, the device uses white light to align, then a brief white light flash to capture the image. There is no fixation target for External mode.

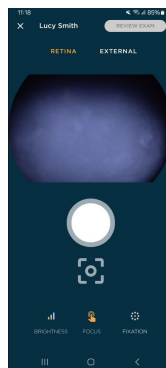
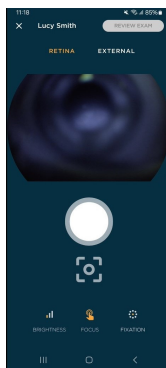
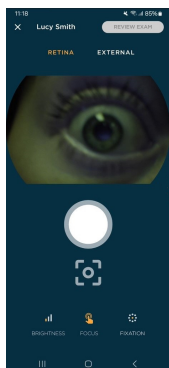


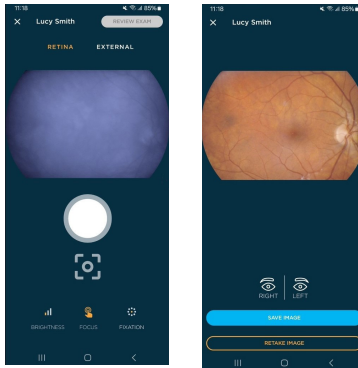
2.9 Capturing Images

To capture retina photos, the patient and examiner should be seated facing each other. Use your dominant hand to hold the Viva and use your non-dominant hand to stabilize the device by positioning your thumb and index finger on the grey grip behind the eye cup. Use your other fingers to stabilize against the patient's face.



Ask the patient to cover their other eye and fixate on the red light inside the device. Approach the pupil, keeping the device vertical and perpendicular to the patient's eye. 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 purple reflection within the pupil. Push the device in until the retina fills the entire field of view. If using **Tap to Focus** mode, tap the retina preview or autofocus trigger button to focus the device. Do not be afraid to gently push the device closer to the patient to fill the field of view- the eye cup is flexible.





Once correct alignment is achieved, press the **Capture** button on the screen. Images may also be captured by pressing the volume buttons on the side of the device. The camera will flash and capture an image.



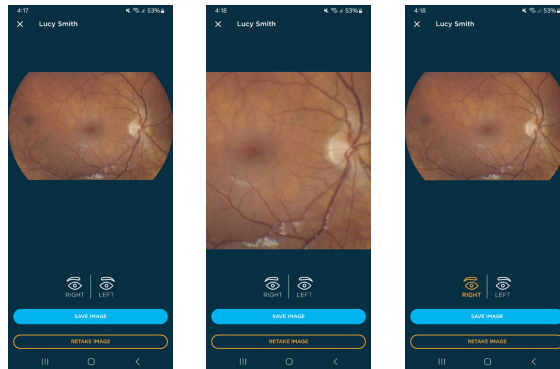
TIP: Inform the user that they will see a brief bright flash of light and to keep their eye open. This will help prepare them and attempt to avoid reflex movements that may compromise the image.

To capture External images, switch to **External** mode. Hold the device as you would for retina images, but with a longer working distance. Ask the patient to look over your shoulder or to fixate at a spot near your ear. Focus the device on the cornea, then capture the image.

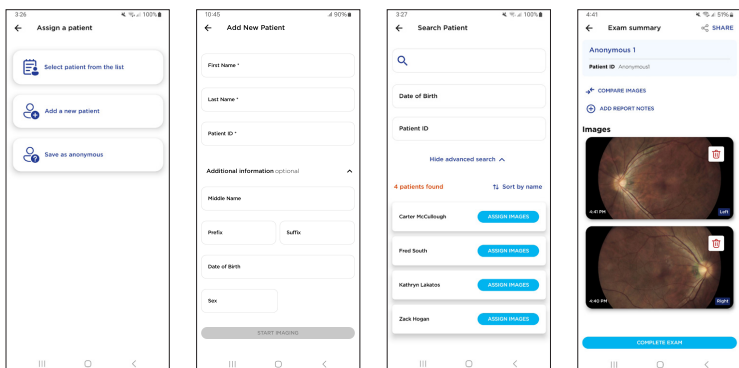


TIP: For best results, capture external images in a dimly lit room avoiding sunlight.

For both **Retina** and **External** modes, a preview image will appear. The user may zoom into the image to verify quality before accepting or rejecting the image. The image must be assigned to a Right or Left eye before saving. All options return the user to the imaging screen where more images can be captured if desired.

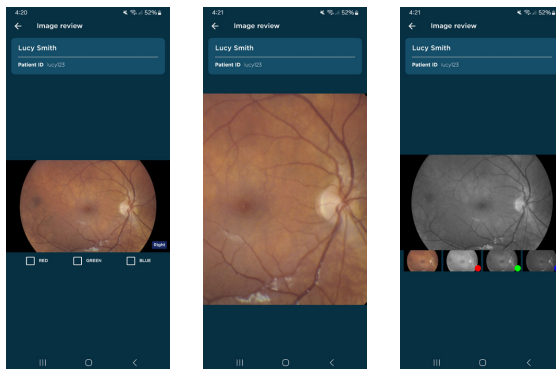


Once all images have been captured, select **Review Exam** on the imaging screen. If imaging was completed using **Quick Imaging**, the user will be prompted to assign the images to a New, Existing, or anonymous patient. To assign images to an existing patient, choose **Select patient from the list** > find patient from the application database > select Assign images. To assign images to a new patient, select **Add a new patient** then enter the patient's information. If images are saved to an anonymous patient profile, the patient's name and ID are autogenerated. The patient information can be added to the profile at any time after the exam (Refer to Section 2.11).

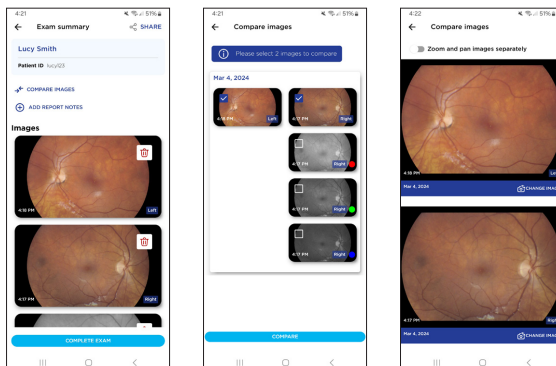


2.10 Reviewing Images

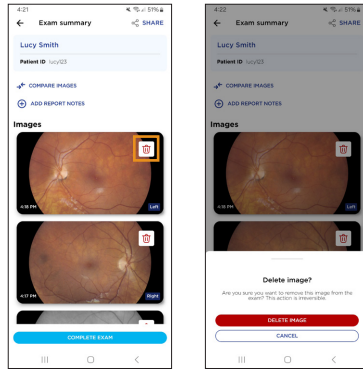
On the **Exam summary** screen, the user can review all images captured during the exam. Tap on any image to enlarge for expanded review or to add filters to the image. Select Red, Green, or Blue to add a copy of the image with red, green, or blue channels only.



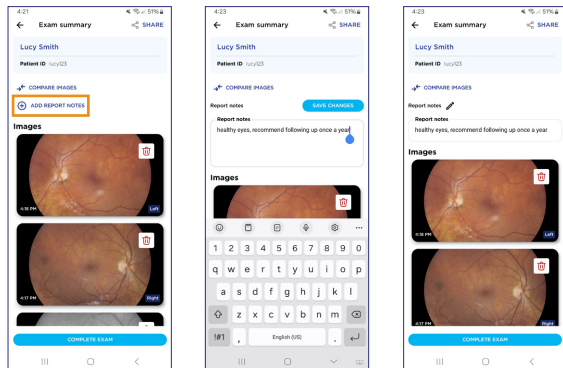
The user may select Compare Images to review two images simultaneously. Click **Compare Images** then select two images from the exam. The user has the option to zoom and pan the images together or separately.



Images can be deleted from the exam by clicking the trash can icon overlaying the image and selecting **Delete**.



Report notes may be added to the exam by selecting **Add Report Notes**. These notes will be retained in the patient exam on-device and will be added to the PDF exam report.



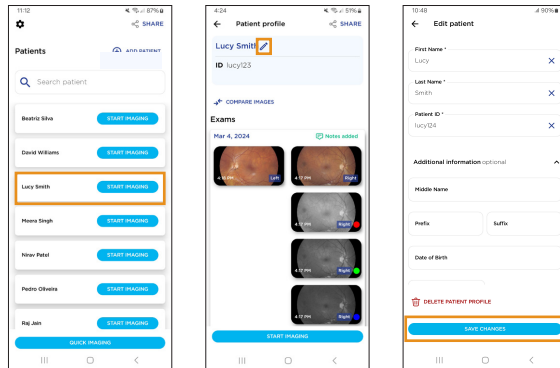
WARNING: The content of exam notes represents the option of the person who entered the notes, and does not reflect the opinions, views, or recommendations of Volk Optical Inc.

You may capture additional images within the same exam by selecting the Back button in the top left. Images and/or reports can be shared from here using the **Share** icon in the top right. Refer to Section 2.12 for more details.

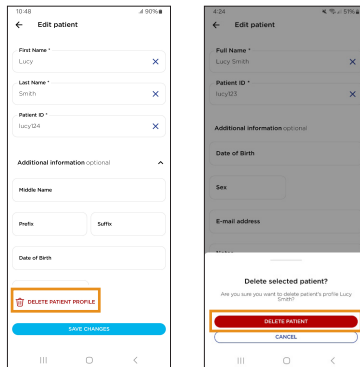
Once all images have been captured, reviewed, and notes added, select **Complete Exam** to save and close the exam.

2.11 Patient Management

The user is able to review previous exams at any time by selecting the patient from the Existing Patients list. This will open the **Patient Profile**. Patient information can be edited and/or added by selecting the pencil icon next to the patient's name. This tool can be used to assign anonymous images to a patient post-exam.

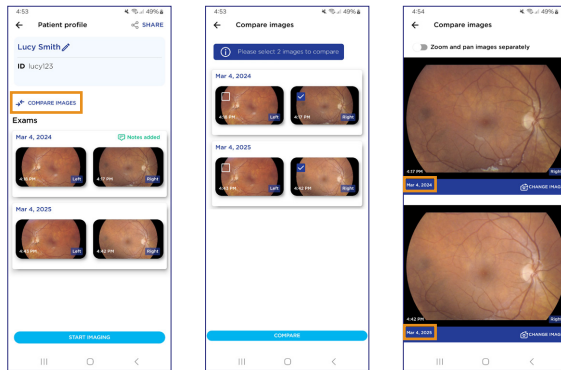


From this **Edit Patient** menu, the patient profile may be deleted. All associated exams will be deleted if the patient profile is deleted.

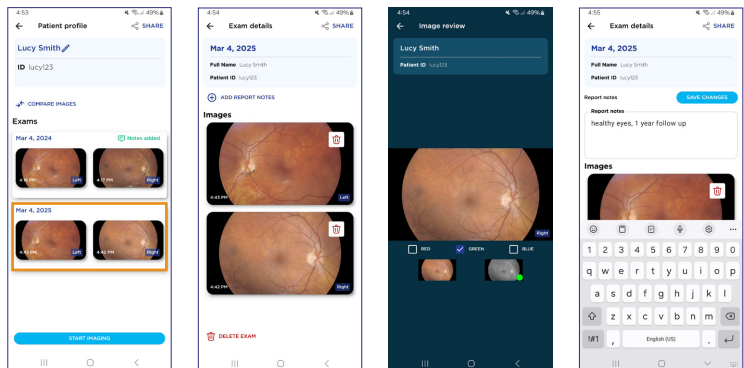


WARNING: The manufacturer is not responsible for any data loss that results from your use of this setting. Data cannot be restored once it has been deleted. To prevent data loss, it is recommended to transfer patient data to a secure data system before the data is deleted.

From the **Patient Profile**, you may use the Compare Images feature to review images from separate exams. Select two images to compare and select Compare. The comparison images can be changed by selecting Change Image.



Click an individual exam to expand for in-depth review. From this **Exam Details** view, the user may add filtered images, perform detailed review of images, delete images and add/edit report notes.

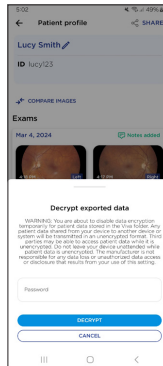


2.12 Sharing Patient Data

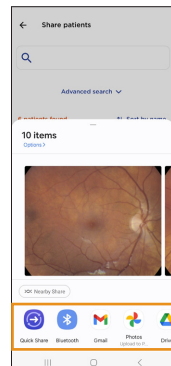
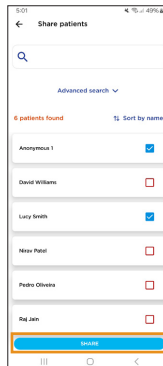
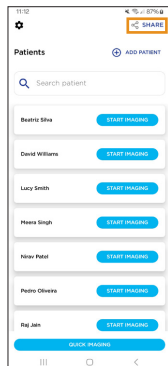
All images captured using the Viva device are exported to the smartphone's memory after each exam. The default file type for images in JPEG. Refer to Section 2.6.5 for instructions on how to enable DICOM and/or BMP image files. The images and reports can be accessed, transferred, and downloaded via wireless (i.e., Bluetooth, upload to file storage application on-device) or through connection to a computer by USB cable provided with the device.

If the user selected a password during application setup (see Section 2.4), the patient data in this folder will be encrypted. If the user did not select a password, the patient data in this folder will be unencrypted. This setting can be managed at any time, including changing the password or turning on/off encryption (see Section 2.6.2).

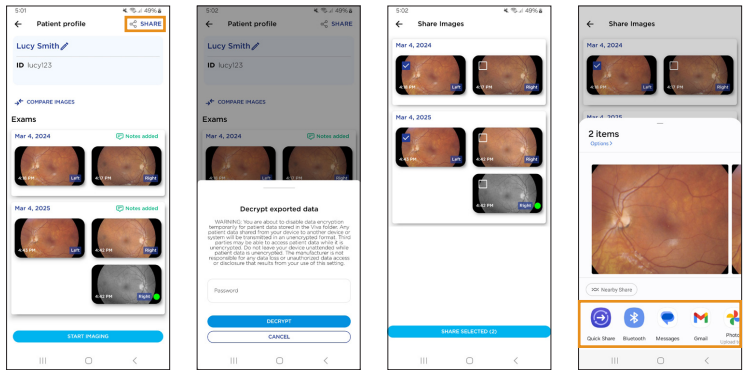
To decrypt the data in the Viva folder, you must enter the password in-app by clicking **Share** on the Home screen, Patient profile, or Exam details screen or plugging the device into a PC. The images and reports can then be copied out of the device memory.



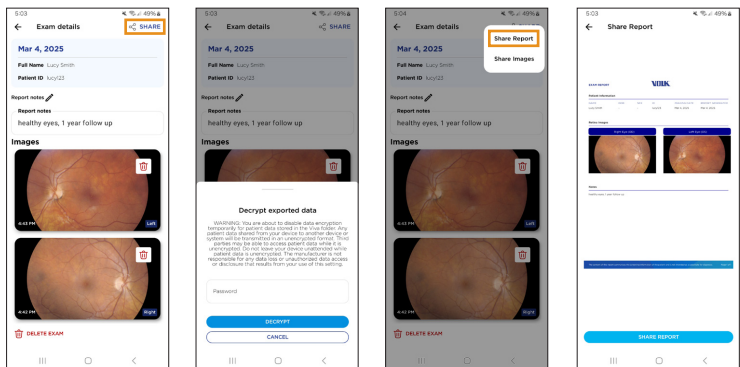
To share multiple patients wirelessly, select **Share** on the Home Screen. Select the patients to export and select Share. If encryption is enabled, enter your password. Then select any number of patients and click **Share Selected**. When you share multiple patients, all of their images and reports are shared.

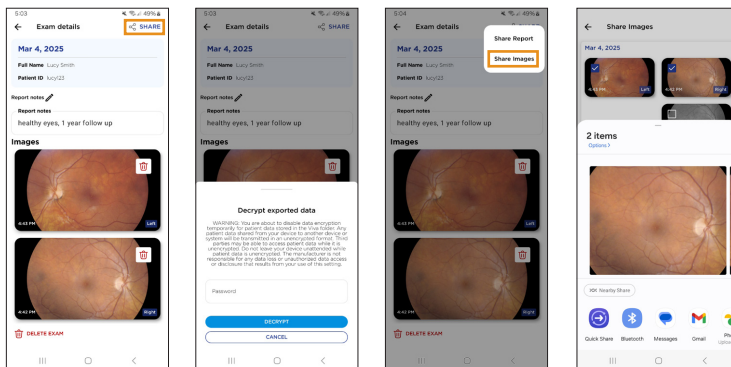


To share images for individual patients, open their Patient Profile then select **Share** in the top right.



To share images and reports for specific exams, open the Exam details. Select **Share** in the top right. You have the option to Share Report or Share Images. Select **Share Report** to generate a PDF report with selected images and exam notes. Select **Share Images** to export images only. This workflow can be performed immediately after the exam on the Exam review screen.

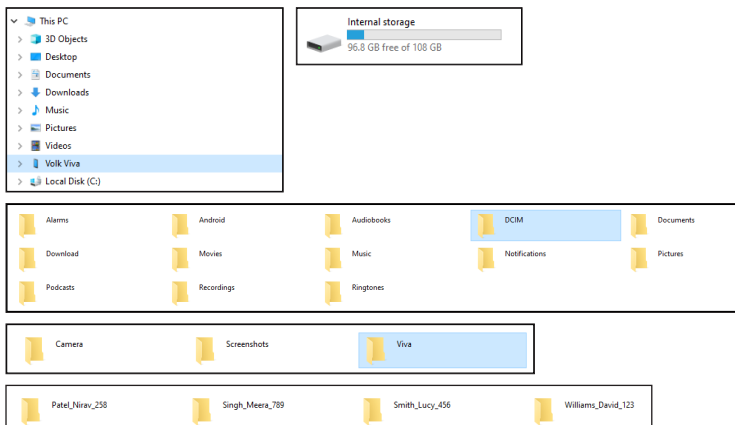




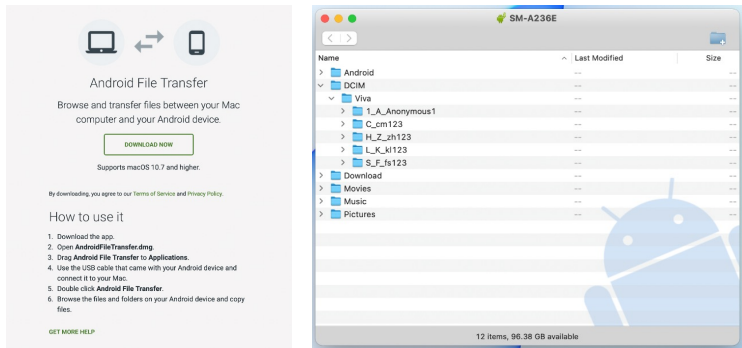
If data encryption is enabled, patient data will be automatically re-encrypted following the wireless transfer.

To complete wired transfer of files, connect the Viva device via USB-C (cable provided with the device) to your PC. If encryption is enabled, enter your password within the Viva application to decrypt the exported data.

When the device is connected to a PC, the Volk Viva will be recognized as an external storage device. To open files on a Windows PC, open **This PC > Volk Viva > Internal File Storage > DCIM > Viva**. Patient folders are named by the patient's LastName_FirstName_PatientID. Image files are labeled with a timestamp including YearMonthDay and HourMinuteSecond (YYYYMMDD_hhmmss) and suffix for OD, OS, and/or external. Copy and paste the folder(s) to your PC or any desired location, such as Dropbox or Google Drive.



To open files on a Mac PC, you must first install the Android File Transfer application from the Android website. Once installed, open this application, and plug your Viva device into the Mac PC. Use the Android File Transfer application to copy the Viva folder and patient data onto your Mac.



If data encryption is enabled, patient data will be automatically re-encrypted when the device is unplugged from USB.

2.13 DICOM

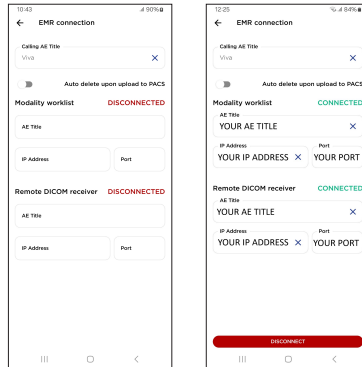
The Viva is capable of integrating with DICOM-compatible Electronic Medical Records (EMR) via communication with your EMR's remote Picture Archiving and Communication System (PACS) server. This allows you to pull a list of patients scheduled in your EMR directly into the Viva via a modality worklist server. Additionally, patient images can be uploaded to the EMR via a remote DICOM Receiver. The Modality Worklist server and remote DICOM Receiver hosted by your EMR can communicate with the Viva by entering the AE Title, IP Address, and Port Number for each system.



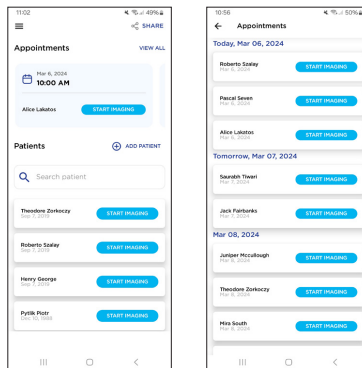
NOTE: the Viva must be connected to a wireless network that can be discovered by the EMR. Please consult with your IT department to identify the system credentials for your EMR, and other communication requirements that may affect the use of this feature.

The EMR configuration page can be found by going to Settings > EMR Connection.

When the Viva app is able to successfully connect to a system, it will change its status from **Disconnected** to **Connected**.



Once both the Modality Worklist Server and Remote DICOM Receiver are configured, your scheduled patients will be shown under the **Appointments** section. To view all of your scheduled patients, select **View All**.



Select the patient from the appointment menu to begin imaging. After capturing and reviewing the patient images, the images will be automatically sent to the remote DICOM receiver once the **Complete Exam** button is selected. A pop-up will appear confirming how many images were sent to the EMR.

FAQ:

Q: What is the AE Title, IP Address, and Port number for my EMR?

A: Please contact your IT department to provide that information to you.

Q: Can I connect only the modality worklist server, or do I need to also connect the Remote DICOM Receiver?

A: Both are required to be connected in order to use the EMR integration feature.

Q: I've entered the right credentials, and the Viva says "Connected" but my EMR is still not working.

A: Please contact your IT department to confirm that there are no other restrictions on your network that would impact the functionality of the EMR feature.

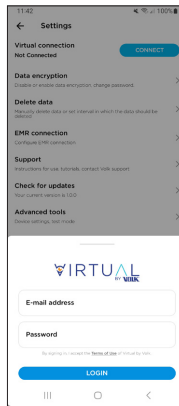
2.14 Virtual by Volk

The Viva app is able to be integrated with Volk's cloud-based telemedicine platform **Virtual by Volk**. This platform allows scheduled patients to be viewed directly in the Viva and the images will be automatically uploaded into the Virtual platform for healthcare professional consultation.



NOTE: Virtual by Volk is a separate paid service and a network connection is required in order to use it with the Viva camera.

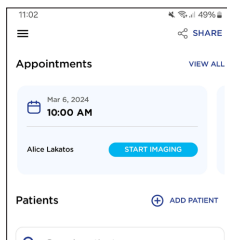
To access Virtual, go to Settings > **Virtual Connection** > Then tap the **Connect** button to login. The user must log in using their camera technician credentials each time the Viva app is to be used in Virtual by Volk mode.



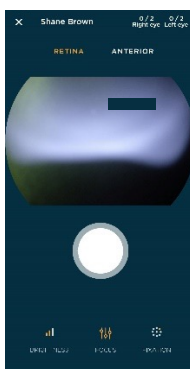
Virtual by Volk's status is indicated in the settings page underneath the Virtual Connection. Virtual status can be **Not Connected**, **Connected**, and **Working Offline**. **Not Connected** status means Virtual by Volk is not in use or not logged in. **Connected** status means Virtual by Volk is Enabled, and a Camera Technician is currently logged in. A Wi-Fi indicator with a slash through it will appear next to the Connected status if the user has lost connection to the internet. 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 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 Viva app. To assign Offline Mode images to a Virtual by Volk user profile, establish a stable internet connection and log in to the technician's account. The user will be prompted to assign the Offline Mode patients to the technician's account. 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.

Scheduled patients will be displayed underneath the Appointments tab at the top of the main menu. To view all of your patients, select **View All**. Patients can be scheduled by the administrator for the camera technician. The user can also create New Patients or image Existing Patients in Virtual by Volk mode.



All images captured while Virtual by Volk is connected will be uploaded to the Virtual platform if the image number requirement defined by the administrator is met. The image number requirement is displayed on the imaging screen.



The user will be automatically logged out of their Virtual by Volk account after 30 minutes of inactivity. The user can log out manually by going to the Settings page and tapping **Disconnect**.

Virtual by Volk will not generate any reports or export any data to the device memory. If the user needs to decrypt non-Virtual captured images, they will first need to disconnect from Virtual first.

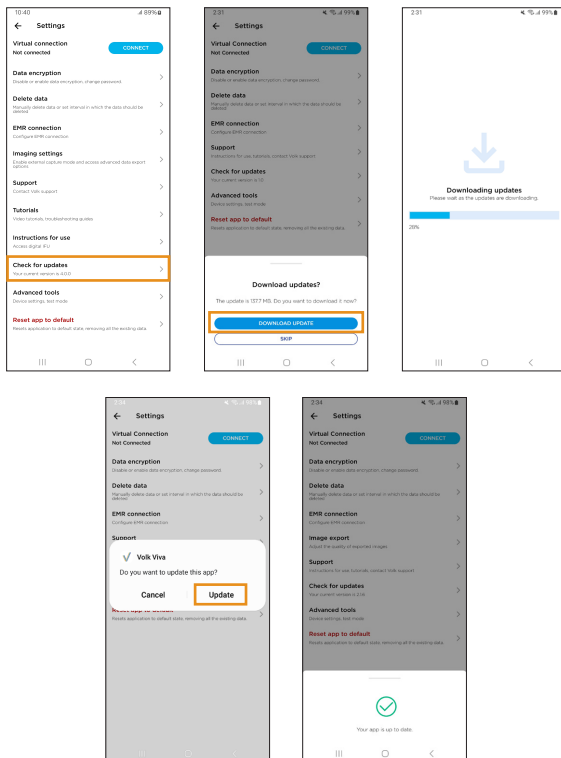
2.15 App Updates

For the best experience, regularly connect to a Wi-Fi network and restart the Viva application to ensure that it is up to date, including the most recent version of this user manual. Updating the app will not delete any patient data, but it is recommended to create a backup before updating.

The device must be connected to a Wi-Fi network to download and install updates. Use the smartphone settings menu to connect to a network.

If an update is available, the device is connected to a Wi-Fi network, and you newly launch the app, you will receive a prompt to download and install an available update. You have the option to skip or download. If you choose to download, the app will automatically download and install the update. The app will automatically relaunch after the update has finished installing.

You have the option of checking for updates or installing any skipped updates at any time by opening Settings > **Check for Updates**.



3. Maintenance

3.1 General Maintenance

The Volk Viva camera is a medical device that should be handled with care. Only manual non-immersion cleaning should be used for this instrument. Do not autoclave or immerse in cleaning fluids. Do not disinfect or sterilize the device. Always disconnect all electrical connections before cleaning.

Avoid touching the optical lens surface except when required for cleaning.

Do not force objects inside the exposed USB connector.

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

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

If the device is showing signs of significant overheating, do not continue using the device. Power the device down and allow it to cool.

3.2 Cleaning Instructions

To clean the non-optical plastic surfaces and non-electrical components on device, wipe the external surface of housing with a clean absorbent, non-shedding, cotton cloth dampened with a water/detergent solution (2% detergent by volume) or water/isopropyl alcohol solution (70% IPA by volume). Ensure that surfaces are carefully hand dried using a clean, non-shedding, cotton cloth.

To disinfect the Silicone Eye cup, use an alcohol wipe (70% alcohol), or soak the eye cup in a glutaraldehyde, hydrogen peroxide, or peracetic acid solution. Rinse eye cup under running water. Dry the eye cup using a clean cloth before use.

Do not use synthetic fiber lens cleaning cloths (e.g. microfiber) on optical surfaces. Cosmetic blemishes (i.e. fingerprints) may be removed using a lens wipe.

Repeated reprocessing of the silicone eye cup has minimal impact on the composition when the instructions are followed. It is important to discontinue the use of any parts or components of the medical device that are showing signs of damage or significant wear or tear.

4. Technical Descriptions

4.1 Specifications

Parameter	Description
Device Name	Volk Viva
Imaging modality	Non-Mydriatic
Minimum pupil size	3 mm
Field of view	45°
Focus adjustment	Autofocus, manual focus
Diopter correction	-15 to +15 diopter
Light source	Infrared LED
	White light LED
	9x Red LEDs
Camera Resolution	16 MP
Image Size	1920x1080 pixels (2.07 MP)
Image format	BMP, DICOM
Dimensions	7.25" x 3.25" x 8.75"
Weight	600 grams
Interface	USB-C
Battery Capacity	Li-Po 5000 mAh
Charging	25 W: max 9 V, 2.77 A
Software	Volk Viva smartphone application
Operating system	Android OS

4.2 Operating & Storage Environment

Temperature	+10°C to +35°C
Relative humidity	30% to 80%
Atmospheric pressure	800 hPa to 1060 hPa



The device is intended for use indoors. Do not store or use the device in ambient conditions other than those prescribed.



This instrument does not meet the requirements of ISO 15004-01 for storage. Do not store this instrument in conditions where the temperature may rise above +35°C or fall below +10°C



Avoid using the device in a dusty environment.



Avoid subjecting the device to vibration and shock.

4.3 Transportation Environment

Temperature	-30°C to +40°C
Relative humidity	10% to 90%
Atmospheric pressure	600 hPa to 1060 hPa

4.4 Expected Service Life

The expected service life of the device is 1 year.

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 Viva as unsorted municipal waste. When disposing of this product, follow the procedure which conforms with the laws and regulations applicable to your area.

5. Electromagnetic Compatibility

5.1 General

Medical electrical systems need special precautions regarding EMC and need to be installed and put into service according to the EMC information provided.



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 Viva, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



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



This device has not been tested for compatibility with all other potential RF Emitters such as X-ray, Metal Detectors, Electrosurgical Equipment, Diathermy Equipment, 5G Cellular, NFC, WPT, or Electronic Article Surveillance (EAS) devices. Caution should be used if such emitters are present within the use environment.



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.

5.2 Emissions and Information

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

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Volk Viva, 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 B	The Volk Viva, 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: Warning: 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 re-orienting or relocating the Volk Viva, 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 Viva is intended for use in the electromagnetic environment specified below. The customer or the user of the Volk Viva, 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	+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 (2)	+1kV line(s) to line (2)	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 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Volk Viva, requires continued operation during power mains interruptions, it is recommended that the Volk Viva, be powered from an uninterruptible 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 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 Viva, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = [3.5/10] \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = [7/10] \sqrt{P} \text{ 800 MHz to 2.7 GHz}$ 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. b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 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 Viva, is used exceeds the applicable RF compliance level above, the Volk Viva, 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 Viva.

Immunity Test

IMMUNITY
to proximity fields
from RF wireless
communications
equipment

IEC 60601 Test Level
and Compliance

MHz	Modulation	Field Strength
385	18 Hz	27 V/m
450	18 Hz	28 V/m
710	217 Hz	9 V/m
745	217 Hz	9 V/m
780	217 Hz	9 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
0.1342	2.1 kHz	65 A/m
13.56	50 kHz	7.5 A/m
0.030	CW	8 A/m

Electromagnetic
Environment - Guidance

Portable and mobile RF communications equipment should be used no closer to any part of the Volk Viva, 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 manu-facturer, 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: 

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

The Volk Viva, is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Volk Viva, can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Volk Viva, 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 $d = [3.5/10] \sqrt{P}$	800 MHz to 2.7 GHz $d = [7/10] \sqrt{P}$	710, 745, 780, 5240, 5500, 5785 MHz $d = [6/9] \sqrt{P}$	385, 450, 810, 870, 930, 1720, 1845, 1970, 2450 MHz $d = [6/28] \sqrt{P}$
0.01	0.035	0.070	0.067	0.021
0.1	0.110	0.221	0.211	0.070
1	0.350	0.700	0.667	0.214
10	1.107	2.213	2.108	0.700
100	3.500	7.000	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 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

5.3 Compliance

The Volk Viva complies with the following standards

- IEC 60601-1:2005+A1:2012+AMD2:2020
- IEC 60601-1-2:2014+A1:2020
- ISO 10940:2009
- ISO 15004-2:2007
- ANSI Z80.36:2016

The US FDA classification is Class II and 510(k) exempt.

The EU Medical Devices Regulation 2017/745 classification is Class I.

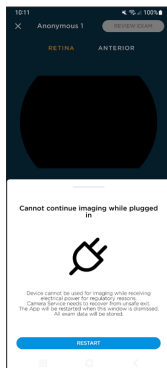
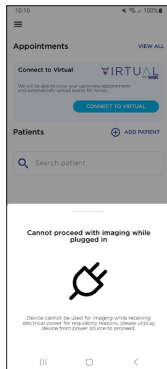
This declaration shall be rendered invalid if changes are made to the Volk Viva without the manufacturer's authorization.

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.

6. Error Messages and Troubleshooting Tips

The following are a list of system and error messages the user could encounter while using the device:

System message

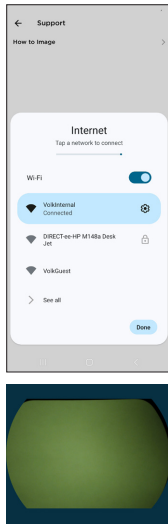


Interpretation

The device cannot be used to image while plugged in to charger or PC. Ensure that the USB-C connector is disconnected before proceeding to image.

The device cannot be used to image while plugged in to charger or PC. The camera must be restarted, and USB-C connector must be disconnected before continuing to image.

System message



Interpretation

The use of the requested feature requires an internet connection. Use the Internet prompt in-app to connect to your Wi-Fi network.

Internal components are visible when imaging. Recalibrate the mask by following instructions in Section 2.6.10.

7. Warranty

Volk Optical provides a 1-year warranty as standard with the Volk Viva.

7.1 Warranty Terms

Volk provides a limited warranty against manufacturing defects for the Viva for a period of one (1) year from the date of delivery of the Viva 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 Viva 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. The customer's failure to give prompt written notice (30 days) upon discovery of any alleged defect shall constitute acceptance of the Viva 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 Viva becomes defective as a result of the customer's disassembly or modification of the goods, unauthorized service or repair, misuse or abuse of the Viva 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 Viva 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 Viva 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 Viva 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 remanufactured 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 Viva 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, NONINFRINGEMENT, AND FITNESS FOR A PARTICULAR PURPOSE, AND ALL SUCH WARRANTIES ARE HEREBY EXPRESSLY EXCLUDED.

8. Support and Servicing

Orders may be placed with the Authorized Volk Optical Distributor in your region. Authorized Distributor contact information is available directly from Volk Optical.

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, or to request Instructions for Use in paper form at no additional cost, please contact our Customer Care Team at volk@volk.com or the numbers listed at the end of this section.

Toll free within the United States: +1 (800) 345-8655

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9. Revision History

Revision	Release Date	Description	Revision Necessary for Safety Reasons?
B	April 4, 2024	Initial release	No
C	April 12, 2024	Update instructions related to external capture mode and export filetype options	No
D	June 19, 2024	No change in content, design update only	No
E	August 23, 2024	Updates for European Union registration, update Patient Folder naming convention	No
F	October 13, 2025	Screenshot updates	No



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