



USER'S MANUAL / INSTRUCTIONS FOR USE

Volk iNview

Retinal Camera

Product description

The Volk iNview is an ophthalmic camera device to be used by healthcare professionals to acquire wide-angle digital color images of the retina using an Apple iPhone or iPod Touch. Volk iNview is a combination product comprised of a mobile application (app) and an indirect ophthalmoscopic lens attachment for an Apple iPhone or iPod Touch.

The Volk iNview mobile app is accessible to users via the Apple App Store (Apple Inc.) for use on select iOS devices; specifically, iPhone 5s and 6, or iPod Touch (6th Generation). The Volk iNview mobile app, operating on an iPhone or iPod Touch, integrates with a mechanical adaptor with a telescopic feature that houses a high-quality glass fundusoscopic lens. The combination of the mobile app-powered smartphone / camera and the ophthalmoscope provide a clinician with the ability to image the retina of the human eye using the native high-resolution camera and white-light LED of the iPhone or iPod Touch.

Table of Contents

PRODUCT DESCRIPTION	2
1. PACKAGE CONTENTS	4
2. ACCESSORIES PURCHASED SEPARATELY	4
VOLK INVIEW CARRY CASE	4
ADAPTER KIT FOR VOLK INVIEW	4
VOLK PRECISION OPTICAL LENS CLEANER	5
VOLK LENS PEN	5
3. APPLICATION INSTRUCTIONS	6
LOADING THE APPLICATION	6
USING THE APPLICATION	7
DATA EXPORT	20
4. INDICATIONS FOR USE	23
5. CONTRAINDICATIONS	23
6. WARNINGS AND PRECAUTIONS	23
EYE SAFETY	23
7. IMPORTANT SYMBOLS	24
8. ERROR MESSAGES	25
9. DEVICE PARTS	26
APPLIES TO:	26
10. LABELING	27
11. CLEANING INSTRUCTIONS	28
12. TECHNICAL DESCRIPTION	29
13. INTELLECTUAL PROPERTY INFORMATION	30
14. DISPOSING OF THE VOLK INVIEW	30
15. DEVICE CLASS	30
16. CONTACT	31
17. WARRANTY	32
18. ORDERING INFORMATION	34

1. **Package contents**

Packaging contents will vary by part number:

Part Number	Camera	Camera Supplied
VINVIEW-TCH	iPod Touch	None
VINVIEW-5S	iPhone 5S	None
VINVIEW-6	iPhone 6	None
VINVIEWWC-TCH	iPod Touch	iPod Touch 6th Gen

Included as part of the electronic camera device (if supplied):

- USB power and sync cord
- Apple Wall Power Charger (US sockets)

2. **Accessories purchased separately**

Volk iNview Carry Case

Model Number: *VINVIEW-CASE*

Official Pelican™ Watertight and Dustproof Case – supplied with fitted foam interior

Adapter Kit for Volk iNview

Part Number	Description	Camera
VINVIEWADPT-TCH	Adapter Kit for iNview – iPod Touch	iPod Touch
VINVIEWADPT-5S	Adapter Kit for iNview – iPhone 5S	iPhone 5S
VINVIEWADPT-6	Adapter Kit for iNview – iPhone 6	iPhone 6

The camera holder case may be replaced to accommodate any of the cameras specified above. Orders may be placed with an Authorized Volk Optical Distributor in your region, or directly from Volk Optical Inc. The Adapter Kit will include instructions for camera holder replacement.

Volk Precision Optical Lens Cleaner

Model Number: *VPOLC*

Volk Precision Optical Lens Cleaner consists of a highly absorbent, lint-free optical towellette moistened to an exact saturation level with a unique combination of oil removers and cleaning agents.

<http://www.volk.com/index.php/volk-products/accessories/lens-cleaner/precision-optical-lens-cleaner.html>

Volk Lens Pen

Model Number: *VLENSPEN*

Volk LensPen ophthalmic lens cleaning instrument utilizes a remarkable lens cleaning compound which removes finger prints, smudges and grease marks with ease.

<http://www.volk.com/index.php/volk-products/accessories/lens-cleaner/lens-pen.html>

3. Application Instructions

This section contains instructions for setting up your new Volk iNview Retinal Camera, capturing images, and exporting the images from the device.

As an alternative to reading these instructions, setup and use of the iNview is covered in a tutorial video available on the Volk website at <http://www.volk.com/iNview/training>.

Loading the application

Personal iOS device

1. Visit the App Store on your Apple device and download the application “Volk iNview.”
2. Place your device into the Volk iNview indirect lens holder as pictured in Figure 1, below.



Figure 1

Prepackaged iOS device

1. Charge the device fully before use.
2. Power on the iPod Touch using the Sleep button located on top of the electronic camera device.
3. Connect the camera WiFi your local network.

Note - Full instructions to connect to WiFi can be found on the Apple website.

Starting the Application

The Volk iNview software application is launched by selecting the Volk iNview application icon (Figure 2).

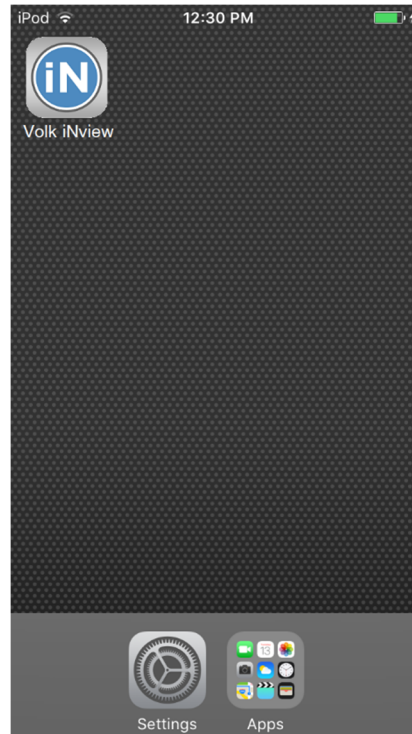


Figure 2

Using the application

Instructions for First Use of the Application

This section contains instructions for setting up the Volk iNview application for the first time. It is strongly recommended that this section is read entirely before using your new Volk iNview.

Adjusting Electronic Camera Device Settings

During normal operation of the Volk iNview Retinal Imager, the electronic camera device display (iPod Touch, iPhone 5s, or iPhone 6) is used to help the user to align the device with the patient's eye as well as to review acquired retinal images. To aid in these functions, it is recommended that the display brightness setting of the electronic camera device be set to a fixed, full-brightness setting. This can be done by accessing Settings → Display & Brightness where one could then turn Auto-Brightness Off and position the brightness slider on High (Figure 3).

It is advantageous to restrict calls and texts from being pushed onto the electronic camera device while it is being used to acquire retinal images. This can be accomplished by placing the electronic camera device in Airplane Mode prior to taking retinal images.

Note – to receive access to software updates, the electronic camera device needs to establish occasional access to the internet. This cannot be done while the device is in Airplane Mode unless WiFi is enabled.

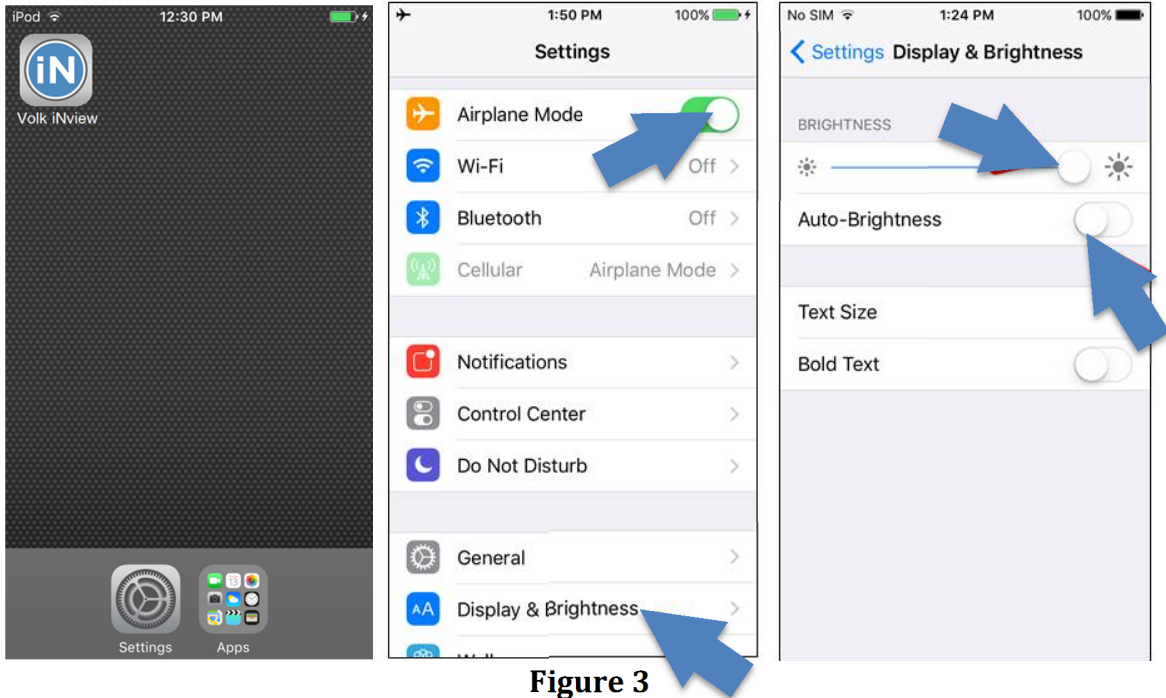


Figure 3

Summary Check List

1. Turn device to airplane mode
2. Adjust Screen Brightness setting to maximum
3. Disable Auto-Brightness

Using Application with Patient Information Encryption

On first startup of the application, you will be presented with the choice to use the application in either encrypted mode or unencrypted mode (Figure 4).

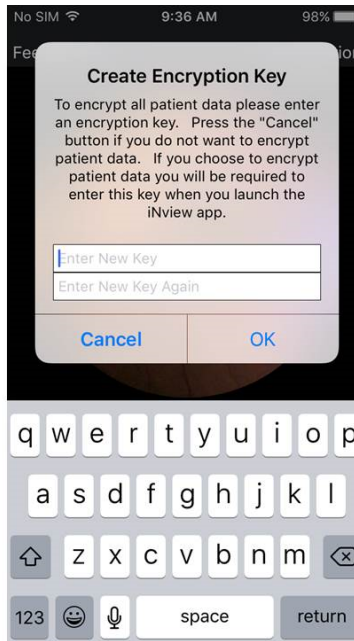


Figure 4

IMPORTANT NOTE – THERE IS NO PASSWORD RESET AVAILABLE SHOULD THE ENCRYPTION KEY BE FORGOTTEN. ALL DATA STORED WITHIN THE APPLICATION WILL BE LOST.

This is an important decision for the user. In the encrypted-mode, all of the patient imagery and data is stored locally within the memory of the electronic camera device as encrypted data. The encryption method that is used is sufficient to allow the Volk iNview Retinal Imager to meet HIPAA requirements. To operate in an encrypted-mode, the user is required to provide a password. Once an encryption password has been entered, the user is then required to enter that same password every subsequent time the Volk iNview software application is launched. Failure to enter the proper password will lock out non-authorized users.

Note – users who choose to operate the Volk iNview Retinal Imager in an encrypted-mode need to take care ensuring that the entered password is securely retained. If an encryption password is ever forgotten, the only recourse is to first delete the Volk iNview software application (and all the patient data contained within the application), and then reload the Volk iNview application.

It is not possible to change from encrypted or unencrypted mode without deleting the application from the iOS device. This will remove all images and patient data located in the application. Use the data export function (see page 19).

Summary Checklist for Encrypted vs. Unencrypted mode

Encrypted	Unencrypted
A password will be required each time the application is started.	No password will be required when using the application.
Patient information and images are encrypted. Data is stored within the application.	Patient information and images are not encrypted. Data is stored within the application.
Data is stored in a HIPAA compliant manner.	Data storage is not HIPAA compliant.

Calibrating the Camera

The camera must be calibrated before imaging a patient for the first time.

After software initialization has taken place and the user has moved past Data Encryption Selection, the user is presented with the Main Program Display (Figure 5).

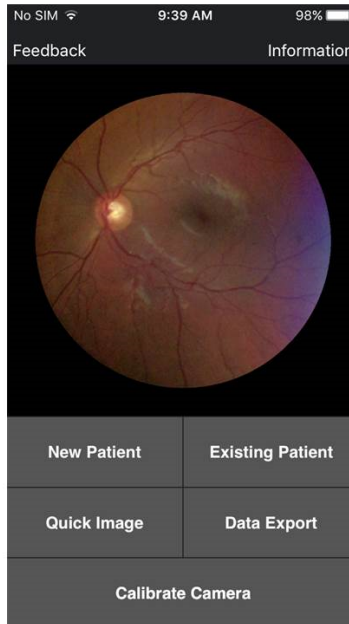


Figure 5

Before the Volk iNview Retinal Imager can be used to acquire retinal images, the camera must first be calibrated. The camera calibration process aligns the smart device field-of-view (FOV) and the point of focus with the Primary Imaging Lens.

Note – the Volk iNview software application will only operate if the smart device in which it is installed is used with / calibrated to a Volk-supplied iNview retinal imaging attachment.

To calibrate the camera, the user selects the Camera Calibration icon from the Main Program Display.

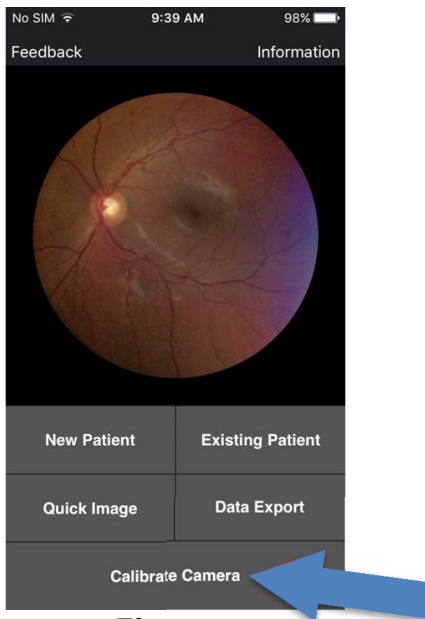


Figure 6

A dialog box then instructs the user to point the Volk iNview Retinal Imager (camera) at a piece of plain white paper – such as the reverse of this manual. After a few seconds, a second dialog box will be presented that indicates that the camera calibration has been successfully completed. After successful calibration, the Volk iNview software application will be automatically exited. The iNview software application needs to be re-launched for the camera calibration parameters to be successfully applied.

Note – contact Volk if the camera calibration process fails to calibrate with your Volk iNview device.

Undertaking an Image Session

Note – the Volk iNview Retinal Imager requires that the patient’s pupil diameter be 5mm or greater. The larger the patient pupil size, the easier it is to properly align the Volk iNview device to the patient’s eye.

Imaging Technique

Utilizing the correct technique will make a great difference to the ease of imaging. The method of holding the Volk iNview Retinal Imager when it is being used during an imaging session is illustrated in Figure 7, below.



Figure 7

This method allows access to the screen of the device while providing the best control of the device to capture images.

- The device can be used with either the left or right hand at the front.
- The front hand should be placed on the lens grip at the very front of the device for the best control.

Anyone trained to perform an eye examination using a Volk indirect BIO lens will be able to quickly master operation of the Volk iNview Retinal Imager. The Primary Imaging Lens that is used within the Volk iNview Retinal Imager is a 25D lens and it has a working distance of approximately 50mm. The large end of the Lens Tube is fashioned like an indirect BIO lens with the intention that the user position and stabilize the device using the patient's forehead as a steady reference as illustrated in Figure 8, below.



Figure 2

Note – the Volk iNview Retinal Imager should not come into contact with the patient. The working distance of the Primary Imaging Lens is approximately 50mm. This ensures that there is always a comfortable amount of distance between the device and patient.

The most effective way of properly aligning the Volk iNview Retinal Imager is to use the lead hand (the one in contact with the patient’s forehead) to make all the required adjustments in space. The hand closer to the electronic camera device should be held reasonably stable as the positioning adjustments are being made with the lead hand.

When an imaging session is underway, the operator uses the live video displayed on the electronic camera device to align the device with the patient’s eye. Within a couple of seconds from the time the imaging session is initiated, the user is instructed to position the Volk iNview Retinal Imager about 100mm in front of the eye to be imaged. At this distance the eye socket should fill the display as illustrated in Figure 9, below.

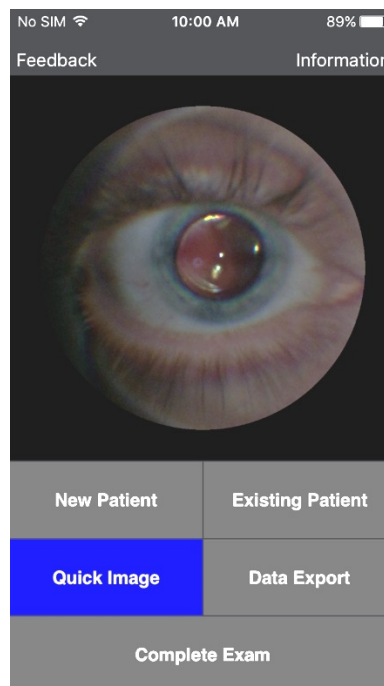


Figure 9

At this distance, it is easy to keep the eye centered in display. If the patient’s eye is dilated sufficiently (5mm diameter or greater), a red reflex should be visible. At this distance, the red reflex is slit-like in nature – not circular. The width of the slit will be dependent on the diameter of the patient’s pupil. The greater the pupil size, the greater the width of the red reflex. With a red reflex present, the user is further instructed to smoothly move the Volk iNview Retinal Imager towards the patient’s eye while attempting to keep the red reflex centered on the display. Figure 10 shows the image seen as the user pushes closer to the eye.

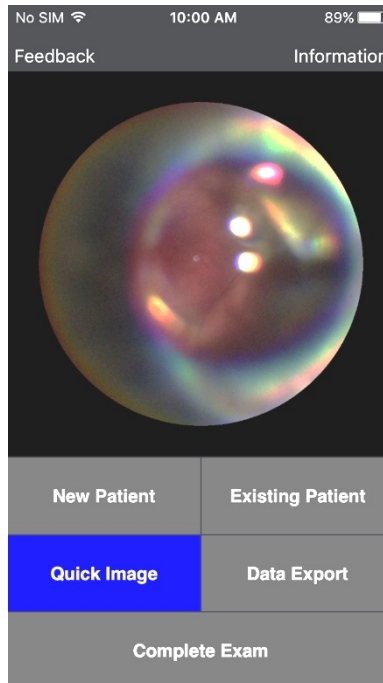


Figure 10

Note – the most effective way to align the Volk iNview Retinal Imager is to rely on the lead hand to make the necessary positioning adjustments.

At the sweet spot of operation, the red reflex will quickly expand from a slit to fill the entire field-of-view (FOV) of the Primary Lens Element. This action is similar to how a properly aligned indirect BIO behaves as it is aligned with an eye (Figure 11):

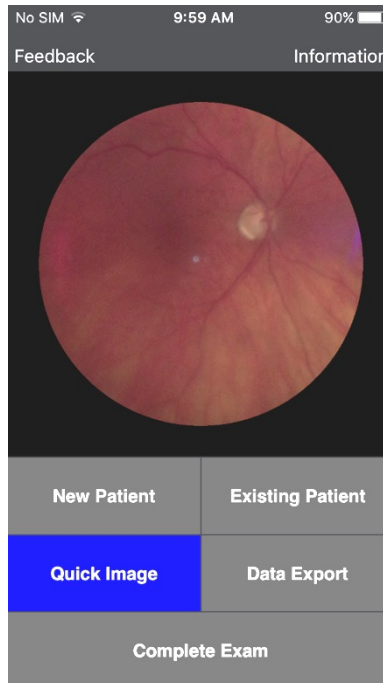


Figure 11

During the entire time the Volk iNview Retinal Imager is being aligned with the eye, the video stream is being analyzed. When an aligned and focused retina is detected, retinal images are automatically acquired and saved by the Volk iNview software application. Acquisition is demonstrated through a 'camera shutter click' audio notification and flashing screen.

Image Capture

During an imaging session, a total of up to 9 images will automatically be captured and saved by the device. These images will be automatically acquired and saved based on an internal algorithm that grades the quality of the image. Using the auto-acquisition functionality of the Volk iNview Retinal Imager, proper alignment between the device and the patient's eye only has to be maintained for a fraction of a second in order for high-quality images to be acquired and saved. In addition to the auto-acquisition feature, the Volk iNview Retinal Imager always gives the user the option of capturing an image on command. The user can capture a retinal image by touching anywhere in the Image Display Section of the Main Program Display (Figure 12).

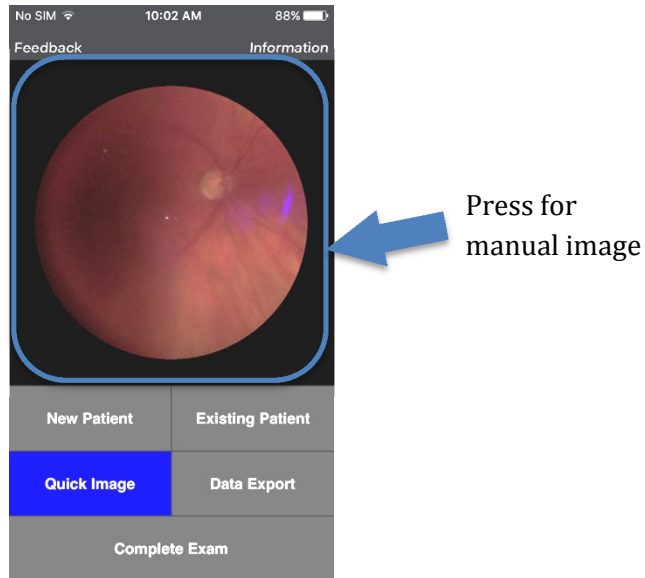


Figure 3

All user-captured images are retained within the Volk iNview image memory space – not the device’s DCIM memory space, which is accessed through the Photos App.

Auto-acquired images do not over-write any images specifically taken by the user.

Patient Imaging

New Patients

The Volk iNview software application allows the user to attach the patient’s name, first and last name, or unique patient ID to the retinal images that are taken. When a new patient is to be imaged and archived using the Volk iNview Retinal Imager, the user selects New Patient from the Main Program Display. This enables the Patient Information Display (Figure 13).

The screenshot shows a mobile application interface titled "Patient Information". At the top, the status bar indicates "No SIM", "10:29 AM", and "100%" battery. The form contains the following elements:

- Patient ID:** A text input field.
- Last Name:** A text input field.
- First Name:** A text input field.
- Patient Birth Date:** A table with three columns: Month, Day, and Year.

December	1	2013
January	2	2014
February	3	2015
March	4	2016
April	5	2017
- Image Left Eye** and **Image Right Eye**: Two buttons for selecting the eye to be imaged.
- Cancel**: A button at the bottom of the form.

Figure 4

Two different methods are available to attach patient information to the images taken using the Volk iNview Retinal Imager. One method is to enter a unique patient ID for every new patient being imaged and managed. Alternately, patient images can be managed by entering the patient's first and last name, and birth date. It is not possible for the Volk iNview application to simultaneously accommodate both a first and a last name, and a patient ID. Once the appropriate patient data has been entered, the imaging session is started by selecting either Image Left Eye or Image Right Eye from the Patient Information Display.

Existing Patients

For existing patients (patients who have had their patient information entered during a previous imaging session), an imaging session is started by selected Existing Patient from the Main Program Display. This loads the Patient Record Identifier Display. The existing patient can be searched by either Patient Birth Date and Name, or Patient ID Number – whichever is applicable. Reaching the Patient Exam Date Display (Figure 14), the user has the option of reviewing images from previous imaging sessions or performing a New Exam (Left Eye) or New Exam (Right Eye).

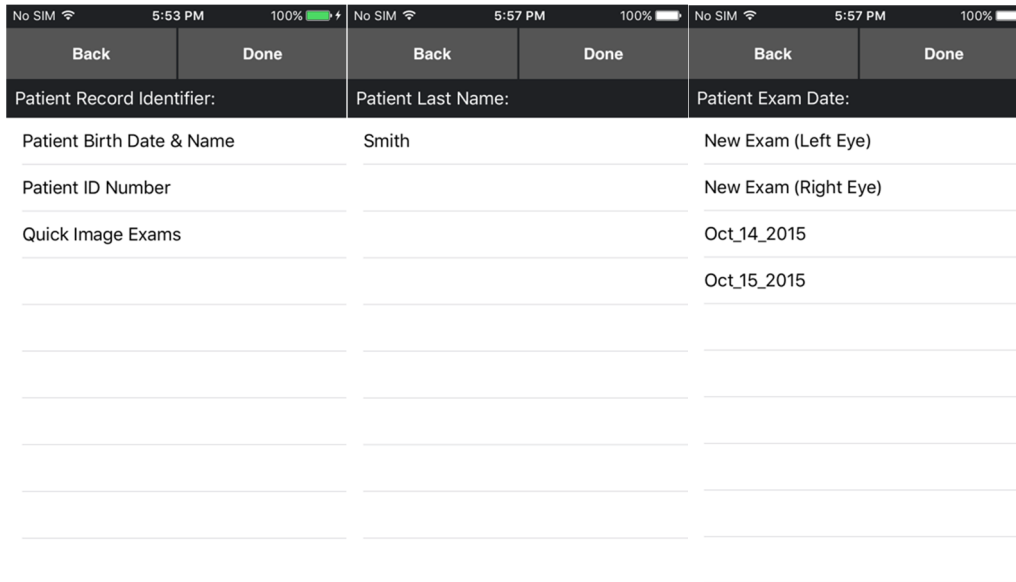


Figure 5

Once an imaging session is selected, the internal illumination source is turned on and the device is made ready to acquire retinal images. A total of up to 9 images will automatically be captured and saved by the device during each imaging session. These images will be automatically acquired and saved based on an internal algorithm that grades the quality of the image. The auto-acquisition feature of the Volk iNview Retinal Imager is a powerful capability that makes the product unique within the marketplace. It greatly eases the job of acquiring high-quality retinal images using a hand held device. Using the auto-acquisition functionality of the Volk iNview Retinal Imager, proper alignment between the device and the patient’s eye only has to be maintained for a fraction of a second for high-quality images to be acquired and saved. In addition to the auto-acquisition feature, the Volk iNview Retinal Imager always gives the user the option of capturing an image on command. The user can capture a retinal image by touching anywhere in the Image Display Section of the Main Program Display (Figure 12).

All user-acquired images are retained within a 9 image memory space. Auto-acquired images are not allowed to over-write any images specifically taken by the user.

To end an imaging session, select Complete Exam from the Main Program Display. The user should always remember to select Complete Exam as soon as possible following completion of the session. Completing the session turns off the high-power illumination and processing functions and this, in turn, maximizes battery lifetime. Additional imaging sessions can be started by repeating the Image Left Eye / Image Right Eye selection.

To review the retinal images obtained during a Quick Image session, the user touches on the User Display Section of the Main Program Display. This will bring up a thumbnail display of all of the images collected during the just concluded Quick Image session shown below in Figure 15.

Press to view image capture gallery.

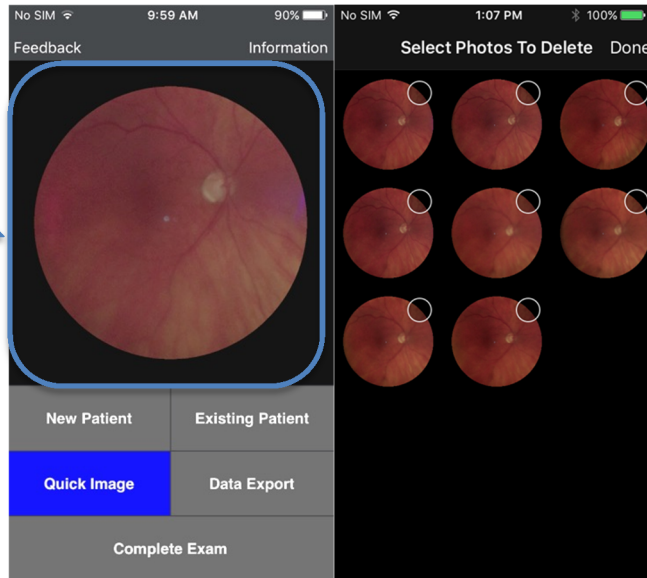
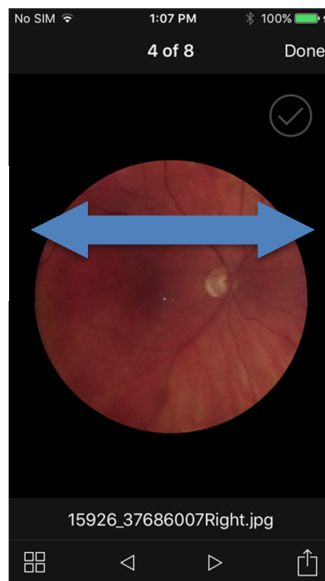


Figure 6

To delete one or more of the images, the user marks images by selecting the small circle positioned in the right-upper quadrant of the image and then selects Done. Alternately, a full screen display of any of the images can be commanded by simply selecting that image. The user can move through the complete image memory simply by swiping the display side-to-side. From the full screen display, the user can choose to upload the image to various destinations by selecting the upload icon (Figure 16).



Swipe left or right to navigate through images.

Figure 7

Imaging Steps Summary

1. Select either New Patient or Existing Patient from the Main Program Display.
 - a. If New Patient – enter either the patient ID or first name/last name and birth date of the patient.
 - b. If Existing Patient – select patient starting from the Patient Record Identifier Display.
2. Select (Image Left Eye / New Exam (Left Eye)) or (Image Right Eye / New Exam (Right Eye)).
3. Position the Volk iNview Retinal Image approximately 100mm from the patient’s eye.
4. Center the red reflex on the display.
5. Move the Volk iNview Retinal Imager towards the patient keeping the red reflex centered on the display.
6. When the red reflex fills the Primary Imaging Lens FOV, stabilize the device as the auto-acquisition capability begins to acquire and save retinal images (indicated by momentary flash of the screen and/or audible snap).
7. After auto-acquisitions start to occur, Quick Image memory will quickly fill with up to 9 aligned and focused retinal images.
8. At the user’s discretion, user-acquired images can be obtained by touching anywhere in the Image Display Section of the Main Program Display (see Figure 12).
9. Select Complete Examination from the Main Program Display.

Quick Image

Pressing the Quick Image button will start an imaging session and provide the user with a quick way to conduct an imaging session. However, the images that are stored during a Quick Image session have no patient information attached. Every time a Quick Image session is run, it writes over previously acquired Quick Image results.

Data Export

Note – Exporting data from the application may not comply with current HIPAA regulations. Although data stored in the encrypted mode conforms to HIPAA requirements; exported data is not necessarily HIPAA compliant.

Sharing an Image

Individual images can be shared using the Share button from the image viewing gallery.

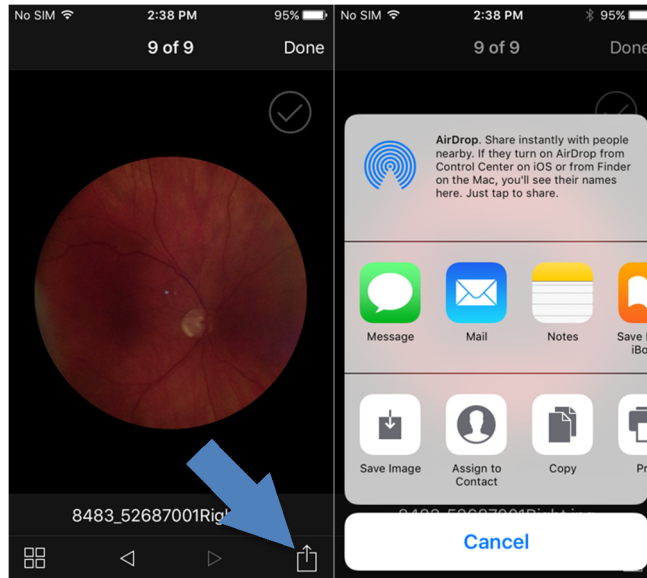


Figure 8

Transferring Data to a PC or Mac

The Volk iNview application can also be used to transfer images with patient information to your PC or Mac using iTunes.

Before You Start

- If it is not installed already, download iTunes to your PC by going to <http://www.apple.com/itunes/download/>. Follow the instructions to complete the installation process.

Data Export Process

1. In the Volk iNview app, press the “Data Export” button.
2. The first time the Data Export button is pressed, Volk iNview will generate a compressed (zip) file containing all image data. Subsequent Data Export operations will give you the following options:
 - a. Export All Images (same as first activation)
 - b. Export Images Since Last Export (creates new export file with only new data)
 - c. Delete Export File
 - d. Cancel (return to Volk iNview)
3. Once you have selected an export option, Volk iNview will display a message indicating that a data export file has been created and is available for transfer to a PC. Press OK.
4. Activate iTunes.
5. Connect the Volk iNview device to the PC using a USB cable.
6. Select the Volk iNview device by clicking on the iPhone button (Figure 18).

Note – view the tutorial videos and help on the application for further information on using the application.

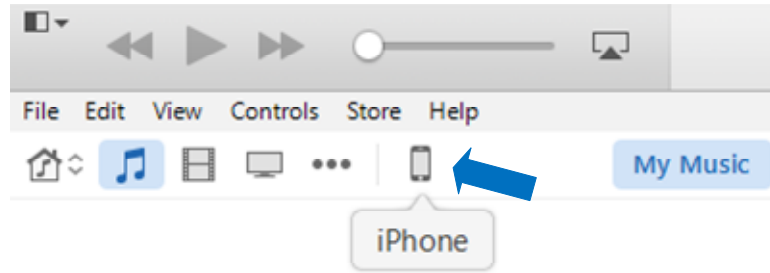


Figure 9

- Select the “Apps” menu item on the left side of iTunes. Scroll down until the File Sharing section is visible. Select the Volk iNview app and the file iNviewDataExport.zip will appear under the Volk iNview Documents heading.
- Now select the Volk iNviewDataExport.zip document, and click on the Save to... button. This will open a dialog box that will allow you to navigate to the location of your choosing to save the data.

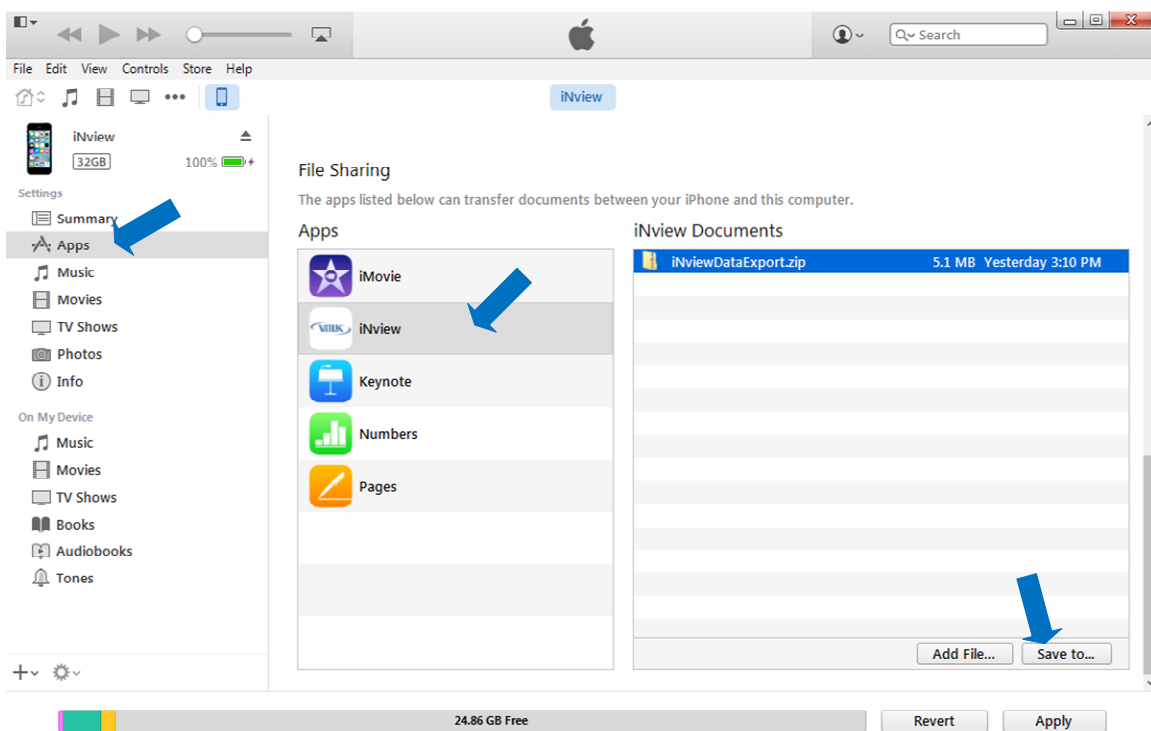


Figure 19

- Once the data is on your computer, you can choose to “unzip” the data by right clicking on it and selecting the “Extract All...” option.

4. Indications for Use

The Volk iNview ophthalmic camera is intended to take photographs of the retina of the eye for the purposes of general visualization and patient education.

NOTE: The Volk iNview can either be supplied as a complete ophthalmic camera device or can be used with an existing iPod Touch (6th Generation), iPhone 5S, or iPhone 6.

5. Contraindications

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 iNview is deemed to have a maximum safety exposure for use on a patient of two hours.

The Volk iNview is not intended to provide visualization for the purposes of diagnosis.

6. Warnings and Precautions

Use only Apple products that are listed as compatible with the Volk iNview.

No modifications to the Volk iNview hardware are permitted.










The Volk iNview application cannot be used unless the device is within the Volk iNview camera system.

The Volk iNview must be used in adherence to the daily maximum exposures listed in Eye Safety below.

Eye Safety

All versions of the Volk iNview retinal imager (iPod Touch, iPhone 5s, iPhone 6) have been tested against ISO 15004-2:2007 – Ophthalmic Instruments – Fundamental requirements and test methods Part 2: Light hazard protection. The illumination levels of all supported Volk iNview implementations have been shown to comply with Group 1 classification as per the referenced standard. Group 1 classification of the Volk iNview product assumes a continuous light exposure time of less than 2 hours. Group 1 ophthalmic instruments require no external product labeling for light hazards.

7. Important Symbols

	<p>Caution. Consult the instructions for use for important cautionary information. The user is advised of important operating and maintenance instructions.</p>
	<p>Consult the instructions for use. Indicates that important operating instructions are included in this User Manual. Failure to follow these instructions could place the patient or operator at risk.</p>
	<p>Do not operate or leave this assembly in any environment that may exceed +10°C to 40°C.</p>
	<p>Dispose of device in the proper manner and ensure to comply with all laws and regulations applicable to your area.</p>
	<p>The CE mark on this product indicates it has been tested and conforms to the provisions noted within the 93/42/EEC Medical Device Directive.</p>
	<p>Indicates the medical device manufacturer, as defined in the EU Directive 93/42/EEC.</p>
	<p>Indicates the Authorized representative in the European Community.</p>
	<p>Indicates the manufacturer's lot number so that the lot can be identified.</p>
	<p>Indicates the manufacturer's product code so that the medical device can be identified.</p>

Symbols found in the electronic camera device are not included. Please visit www.apple.com to learn how to use your device. The iPod Touch and iPhone user guides are available on the Apple website.

8. Error messages

The following table shows the error messages within the Volk iNview application. For error messages that concern the iOS device or operating system, consult the iPod Touch or iPhone user guide available on the Apple website.

Message present in application	Description of error message and action to be taken.
Please press the "Calibrate Camera" button to calibrate your camera before performing an exam for the first time.	Application requires calibration before first use. Press the calibrate button in the application and point the camera at the floor to start the calibration process.
Alphabetic Patient First/Last Name or Patient ID is required	In order to use the patient data function of the application, a Patient ID <u>or</u> Patient Name (comprised of A-Z only) is required.

9. Device Parts

Applies to:

- VINVIEW-TCH (Volk iNview for iPod Touch)
- VINVIEW-5S (Volk iNview for iPhone 5S)
- VINVIEW-6 (Volk iNview for iPhone 6)

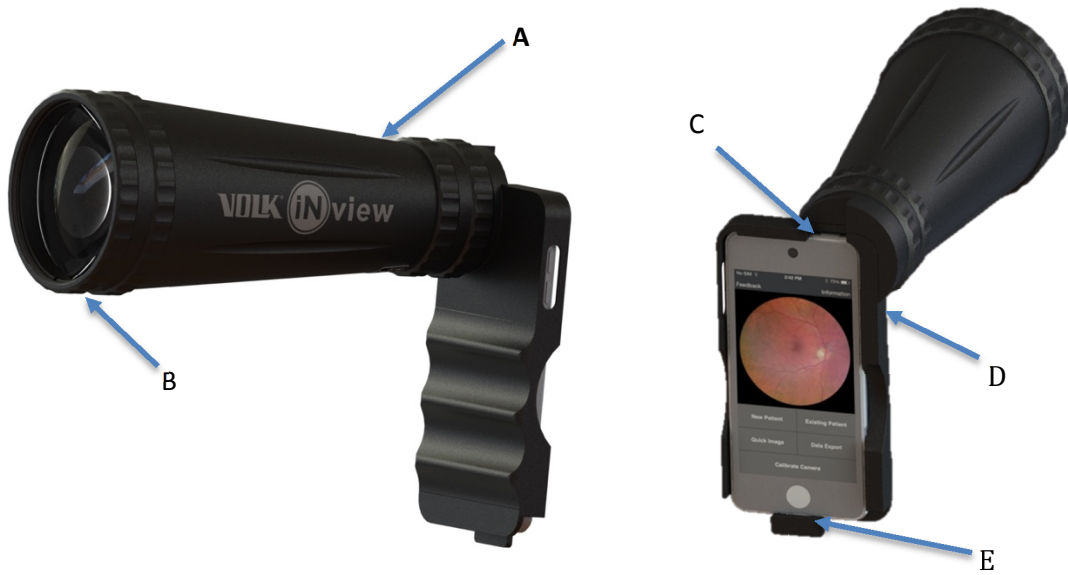


Figure 20

Key	Description
A	Indirect Lens Holder
B	Indirect Lens
C	Camera Sleep button (iPod Touch)
D	Camera Sleep Button (iPhone)
E	Camera charging port

10. Labeling

Part and lot number information is located on the lower portion of the Lens Tube (Figure 21). This information is required to complete the Product Registration Card that is supplied with the Volk iNview Retinal Imager.



Figure 10

11. Cleaning instructions

The Volk iNview Retinal Imager is a precision medical device that should be handled with care. Only manual non-immersion cleaning as described should be used for this instrument. Do not autoclave or immerse in cleaning fluids. Always disconnect power supply from source before cleaning. Do not use synthetic fiber lens cleaning cloths (e.g., microfiber) on optical surfaces.

1. Remove the electronic camera device from the external indirect lens attachment.
2. Shut down electronic camera device.
3. Wipe the external surface 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).
4. The Primary Imaging Lens can be cleaned using Volk Precision Optical Cleaner or the Volk Optical LensPen.

Note - further instructions and cleaning options can be found in the Volk Cleaning and Care guide on the Volk website. Methods A and B are applicable to the Volk iNview.

5. Ensure that excess solution does not enter the instrument. Use caution to ensure cotton cloth is not saturated with solution.
6. Surfaces must be carefully hand-dried using a clean, non-shedding, cotton cloth.
7. Safely dispose of used cleaning materials.
8. The electronic camera device can be cleaned in the following fashion:
 - a. Unplug all cables and turn off iOS device (press and hold the Sleep / Wake button, and then slide the onscreen slider).
 - b. Using a soft, slightly damp, lint-free cloth, wipe the external surface. Avoid getting moisture in openings. Do not use window cleaners, household cleaners, compressed air, aerosol sprays, solvents, ammonia, abrasives, or cleaners containing hydrogen peroxide to clean the iPhone or iPod Touch.

Note – the Volk iNview Retinal Imager is not intended to be disinfected.

Note – the Volk iNview Retinal Imager is not intended to be sterilized.

12. Technical description

Supported Electronic Camera Devices

- iPod Touch (6th Gen)
- iPhone 5s
- iPhone 6
- iPhone SE

Patient Pupil Size	5mm diameter or greater
Field of View	50°
Illumination	White light LED (provided by electronic camera device)
Working Distance	50mm
Diopter Correction	-20D to +20D autofocus accommodation
Operating Modes	User selectable – either Encrypted/Unencrypted Data Mode
Image Size	918 x 918 Pixels (843 Kpixel total, 466 Kpixel retina area) 100 Kbyte (compressed file size)
Image Format	JPEG
Battery Life (Qty of 2 minute exams)	50 (iPod Touch) 70 (iPhone 5s) 85 (iPhone 6)
Software	Downloaded from App Store
Image Capture Modes	Both automatic-capture and forced-capture modes supported
Lens Tube Length	180mm 134mm (iPod Touch)
Camera Case Length	135mm (iPhone 5s) 149mm (iPhone 6)
Overall Width	94mm
Weight	325g (lens tube/case only) 413g (integrated iPod Touch system)
Camera Memory	16 Gbyte (integrated iPod Touch system)
Image Export	Lightning-type to USB cable
Power Source	Internal electronic camera device battery operates all imager functions 100-240VAC, 50-60 Hz input
Battery Charger	5 VDC output Lightning connector type (Integrated iPod Touch system only)
Operating Temperature	0° to 35°C
Non-Operating Temperature	-20° to 45°C
Relative Humidity	5% to 95% non-condensing
Operating Altitude	Up to 3000m

13. Intellectual Property Information

Patents

The Volk iNview Retinal Imager is protected by international patents. Patents have been issued in Japan and China. Patents are pending in the US, India, and the EU.

Trademark

Volk iNview is a registered trademark of Volk Optical Inc.

iPod Touch, iPhone 5s, and iPhone 6 are registered trademarks of Apple Inc.

14. Disposing of the Volk iNview

Disposal of this product in an unlawful manner may have a negative impact on human health and on the environment. Therefore, when disposing of this product, be absolutely certain to follow the procedure which conforms with the laws and regulations applicable to your area.

15. Device Class

This product has been tested to meet the requirements under ISO 15004-2:2007(E) as a Group I exempt product.

This product is registered in the US with the FDA as a general-use ophthalmic camera under the following proprietary names:

- iNview for iPod Touch (VINVIEW-TCH)
- iNview for iPhone 5s (VINVIEW-5S)
- iNview for iPhone 6 (VINVIEW-6)
- iNview Touch Camera (VINVIEWWC-TCH)

This product is self-declared in the EU as a Class I Accessory in accordance with Council Directive 93/42/EEC, Article 1.

16. Contact

Information on the Volk iNview Retinal Camera can be found on the Volk website at www.volk.com.

If you have any questions or require service contact us at volk@volk.com for service or call us at (+1) 800-345-8655.

Feedback on the application is always appreciated and any suggested improvements can be made using the *Feedback* button shown in Figure 22.

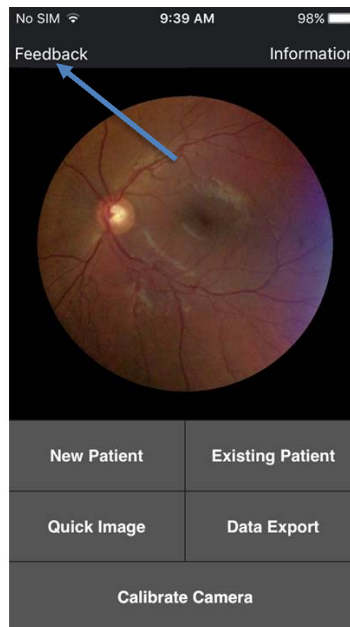


Figure 22

17. Warranty

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

For Volk iNview Camera devices (purchased including camera) the warranty covers the external indirect lens attachment, iOS application, and iOS device.

1. Volk iNview Touch Camera (VINVIEWC-TCH)

For Volk iNview Attachment devices (purchased excluding camera) the warranty covers the external indirect lens attachment and iOS application:

- 1. Volk iNview for iPod Touch (VINVIEW-TCH)**
- 2. Volk iNview for iPhone 5s (VINVIEW-5S)**
- 3. Volk iNview for iPhone 6 (VINVIEW-6)**

Warranty Terms

The Seller warrants to the Purchaser that the goods furnished hereunder will, for the appropriate periods of product warranties, as defined on our user instructions shipped with each product, conform to Sellers' agreed to specifications. The obligation of the Seller, and the Purchaser's sole and exclusive remedy hereunder, shall be limited, at the Seller's option, to replacement of defective goods or refund of the purchase price thereof. Purchaser shall not return goods unless authorized in writing by Seller. Seller shall have the right to inspect the goods at Purchaser's installation. Purchaser's failure to give prompt written notice (30 days) upon discovery of any alleged defect shall constitute a waiver by Purchaser of all claims with respect thereto. Notwithstanding the foregoing warranties and remedies, seller shall have no obligation hereunder if the goods become defective as a result of improper storage, contamination, adulteration, improper use, or misapplication after delivery thereof to Purchaser. If the product fails to function due to defects in either materials or workmanship, Volk will, at its option, either repair or replace the product without charge, subject to the Warranty Limitations.

Volk Optical warrants its iNview Retinal Imager against defects in material or workmanship for a period of 1 year from receipt by end-user.

Customers shall be responsible for returning products for warranty service to Volk Optical Inc., 7893 Enterprise Drive, Mentor, Ohio 44060 - USA.

Warranty repairs will include all labor, adjustments, and replacement parts. Replacement parts may be remanufactured or contain remanufactured materials.

Warranty service may not be provided without proof the product was purchased from Volk Optical Inc. or an Authorized Volk Distributor.

This Warranty becomes null and void if the customer fails to return the product in packaging that is consistent with the original protective packaging and it results in shipping damage.

This Warranty becomes null and void if the customer fails to follow the recommended cleaning instructions and/or cautions contained in the product instruction manual.

This Warranty does not cover service required because of disassembly, unauthorized modifications or service, misuse, or abuse.

SELLER MAKES NO OTHER WARRANTY, EXPRESS OR IMPLIED, OF THE PRODUCT SUPPLIED HEREUNDER, INCLUDING, WITHOUT LIMITATION, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND ALL SUCH WARRANTIES ARE HEREBY EXPRESSLY EXCLUDED. SELLER SHALL HAVE NO LIABILITY FOR LOSS OF PROFITS, OR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES UNDER ANY CIRCUMSTANCES OR LEGAL THEORY, WHETHER BASED ON NEGLIGENCE, BREACH OF WARRANTY, STRICT LIABILITY, TORT, CONTRACT, OR OTHERWISE. SELLER SHALL IN NO EVENT BE LIABLE IN RESPECT OF THIS ORDER AND/OR PRODUCT DELIVERED ON ACCOUNT OF THIS ORDER FOR ANY AMOUNT GREATER THAN THAT PAID TO SELLER ON ACCOUNT OF THIS ORDER. THE PURCHASER ACKNOWLEDGES THAT IT IS PURCHASING THE GOODS SOLELY ON THE BASIS OF THE COMMITMENTS OF THE SELLER EXPRESSLY SET FORTH HEREIN.

18. Ordering Information

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

For Volk iNview Camera devices (purchased including camera) the warranty covers the external indirect lens attachment, iOS application, and iOS device.

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

Toll free within the United States: 1.800.345.8655
Phone: 440.942.6161
Fax: 440.942.2257
Email: volk@volk.com
Website: www.volk.com

EU REPRESENTATIVE

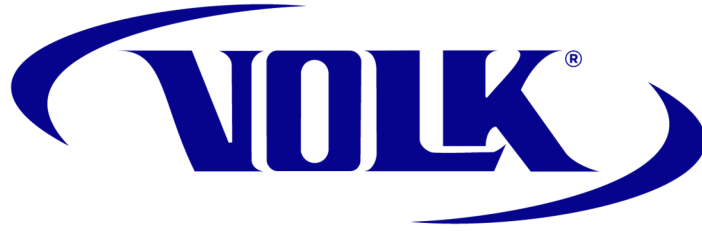
The Volk authorized representative based in the European Union (EU) is:

Rudolf Riester GmbH
Bruckstraße 31
72417 Jungingen, Germany

Email: info@riester.de
Phone: +49 74 77 / 92 70-0
Fax: +49 74 77 / 92 70-70



Members of the European Union should contact their authorized Volk Distributor for disposal of this unit.



Volk Optical Inc.

7893 Enterprise Drive
Mentor, Ohio 44060
USA

Toll free within the United States: 1.800.345.8655

Phone: 440.942.6161

Fax: 440.942.2257

Email: volk@volk.com

Website: www.volk.com

IM-088
Revision: D