Welch Allyn RetinaVue™ 700 Imager



Directions for use

Software version 1.XX



Advancing Frontline Care™

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This manual applies to the REF 901103 Fundus Camera





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Symbols

Documentation symbols

For information on the origin of these symbols, visit http://www.welchallyn.com/symbolsglossary for the Welch Allyn symbols glossary.



WARNING The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death. Warning symbols will appear with a grey background in a black and white document.



Caution The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.



Consult directions for use (DFU). A copy of the DFU is available on this website. A printed copy of the DFU can be ordered from Welch Allyn for delivery within 7 calendar days.



Meets essential requirements of the European Medical Device Directive 93/42/EC.

Power symbols

Ф	Power button
	Direct current (DC)
-	Rated power input, DC
$\bigcirc \overline{\Rightarrow}$	Rated power output, DC

Fuse

Rechargeable battery

Li-ion

(+/←

Connectivity symbols

~

USB

Ψ

Wireless

Wireless radio symbols



Non-ionizing electromagnetic radiation

Ψ...Ι

Wireless signal strength

- Best (4 bars)
- Good (3 bars)
- Fair (2 bars)
- Weak (1 bar)
- No signal (no bars)

FCC ID

The identification number assigned by the Federal Communication Commission

E IC ID

Industry Canada identification number. The equivalent governing body to the FCC in the United States



Australian Communications and Media Authority (ACMA) Radio Compliance Mark (RCM)

Shipping, storing, and environment symbols



Temperature limit



Keep Dry

Directions for use Symbols 3

<u> </u>	Separate collection of Electrical and Electronic Equipment. Do not dispose as unsorted municipal waste.	
<u>-</u> T	Fragile	
Ø	Humidity limitation	
	Atmospheric pressure limitation	
<u>11</u>	This way up	
	Stacking limit by number	
0	Recyclable	
Misce	llaneous symbols	
REF	Product Identifier	
#	Reorder Number	
GTIN	Global Trade Item Number	
<u>~</u>	For indoor use only	

GTIN Global Trade Item Number For indoor use only Type BF applied part R_X ONLY Prescription only or "For Use by or on the order of a licensed medical professional" Clock; time switch; timer Serial Number EC REP Authorized Representative in the European Community

•••	Manufacturer
F	Call for maintenance
**	Process indicator for activities like connecting to network or connecting to computer
Battery	charge level indicators
	Device is running on battery and charge is between 75 and 100 percent.
	Device is running on battery and charge is below 75 percent.
	Device is running on battery and charge is below 50 percent.
	Device is running on battery and charge is below 50 percent. Device is running on battery and charge is below 25 percent.

Introduction

Intended use

The RetinaVue 700 Imager (RV700) is a high-resolution ophthalmic camera used to acquire, save and transmit digital images of the human eye. Anterior and posterior ocular structures such as the surface of the eye, cornea, and fundus including retina, macula and optic disc can be imaged. It is a prescription use only medical device.

No sterility requirements apply to this product.

About warnings and cautions

Warning and caution statements can appear on the RetinaVue 700 Imager device, the packaging, the shipping container, or in this *Directions for use*.

The RetinaVue 700 Imager is safe for patients and clinicians when used in accordance with the instructions and the warning and caution statements presented in this *Directions for use*.

Before using the device, you must familiarize yourself with all warnings and cautions, with the steps to power up the device, and with the sections of this *Directions for use* that pertain to your use of the device. Specific warnings and cautions are also found throughout this manual.

- Failure to understand and observe any warning statement in this manual could lead to patient injury or illness.
- Failure to understand and observe any caution statement in this manual could lead to damage to the equipment or other property, or loss of patient data.

General warnings, cautions, and notes



WARNING Exposure to the RetinaVue 700 Imager flash, in rare cases, may contribute to migraines or temporary visual disturbances, particularly in patients with a history of light sensitivity or migraines. Multiple flashes per eye in a single exam may increase the likelihood of occurrence.



WARNING Clean and disinfect the face cup after each patient to avoid the risk of crosscontamination.



WARNING Operating the device in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide; in oxygen-enriched environments; or in any other potentially explosive environment may cause a fire and explosion hazard.



WARNING Do not use batteries from other sources. This may result in excessive temperatures, fire, or explosion.



WARNING To prevent fire or electrical shock, do not expose the device to rain or moisture.



CAUTION When manually entering patient information, do not use the same patient identifier for multiple patients. This may result in inaccurate data association.



CAUTION Avoid subjecting the device to vibration or shock.



CAUTION Avoid using the device in a dusty environment.



CAUTION Keep the power cord away from any heat source.



CAUTION Do not sterilize the device.



CAUTION All servicing of this equipment is to be performed by Welch Allyn, Inc. or by a center approved by Welch Allyn, Inc.

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CAUTION This device needs to be installed and put into service according to the EMC information provided herein.



CAUTION Portable and mobile RF communications equipment can affect the RetinaVue 700 Imager performance.



CAUTION Input overload can occur in proximity to defibrillator or electrocautery devices.



CAUTION This device is not protected against the ingress of water and should not be used in the presence of liquids which may enter the device.



CAUTION Results deleted on the device cannot be recovered.



CAUTION Do not modify this equipment without authorization of the manufacturer.



CAUTION Do not use the device in direct sunlight. Strong ambient light may affect results.



CAUTION Within the patient environment, only connect the equipment (the RetinaVue 700 Imager) to computers or laptops that have passed the safety standard for information technology equipment IEC 60601-1, EN 60601-1, ANSI/AAMI ES 60601-1 to ensure the safety of the USB electrical connection. Outside the patient environment, only connect the equipment (the RetinaVue 700 Imager) to computers or laptops 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.



CAUTION Do not turn off the device while saving data from a patient test. Turning off the device while saving patient data may delete the data.



CAUTION Do not use the device adjacent to or stacked with other equipment. If the device is used adjacent or stacked with other equipment, the device should be observed to verify normal operation in the configuration in which it will be used.



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



CAUTION Do not use automatic cleansing machines or sterilization



CAUTION Consult the cleaning agent and germicidal cleaner agent manufacturer instructions for their proper use and germicidal efficacy prior to their use.



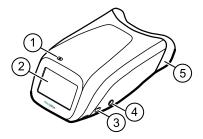
CAUTION Only use the cleaning or germicidal cleaner agent types listed or damage may occur.

Note

The RetinaVue 700 Imager can be used on patients with eye implants and intraocular lenses. While the RetinaVue 700 Imager can be used on patients with cataracts and other eye opacities, the use of the RetinaVue 700 Imager may result in a lower quality image due to the increased reflection of the flash off the patient's intraocular lens.

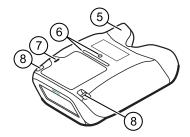
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Controls and connectors



No.	Feature	Description	
1	Power button	 Push button to turn the device on and off. Push button to bring the device out of Sleep mode. Push button to launch a dialogue box with three options: Power down Sleep Cancel 	
2	LCD touchscreen	6" color LCD touchscreen with a 16x9 aspect ratio. Displays information for charging, testing, and adjustments to the device.	
3	USB port	Data transfer port	
4	Charging port and power indicator	Connect AC power supply When the LED light is green, it indicates that the device is fully powered. When the LED light is orange, it indicates that the device is in the process of charging. When the device is not charging the LED is off.	
5	Face cup	Blocks ambient light during testing	

Bottom



No.	Feature	Description	
5	Face cup	Blocks ambient light during testing	
6	(Optional) Pedestal mounting	Pedestal mounting well and attachment slot	
7	Battery cover	Covers the battery compartment	
		Note The two service ports under the battery cover are for factory use only and are not for customer use.	
8	Wrist or neck strap bracket	Wrist or neck strap mounting bracket	

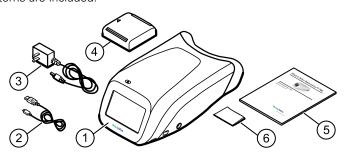
First time set up of the RetinaVue 700 Imager

Use the following topics when setting up the RetinaVue 700 Imager for the first time.

View images saved to the RetinaVue 700 Imager on the LCD touchscreen. The images saved on the RetinaVue 700 Imager are encrypted. To view the images on the PC, install the RetinaVue Network software application. For information on the RetinaVue Network Software visit www.RetinaVue.com.

Unpack the system

The RetinaVue 700 Imager device is packaged with the following items. Confirm that all items are included.



Number	Item	Description
1	RetinaVue 700 Imager device	Digital hand-held eye-fundus camera used to record digital photographs of the fundus of the human eye and anterior and posterior ocular

Number	Item	Description
		structures such as the cornea, lens and fundus including retina, macula and optic disc.
2	USB cable	Connects the device to a computer or laptop to transfer results.
3	Wall adapter plug and AC power cord	Connects the device to the wall adapter plug for AC charging. Match to region-specific AC wall outlet.
4	Lithium-ion battery	Battery
5	RetinaVue 700 Imager <i>Directions for use</i>	This document. The <i>Directions for use</i> (DFU) is also available on the Welch Allyn web site.
6	Lens cloth	RetinaVue 700 Imager lens cloth

If any item is missing, contact Welch Allyn Technical Support: www.welchallyn.com/service. We recommend that you save the shipping box and packing materials in case you need to store or ship the system.

Battery installation and replacement

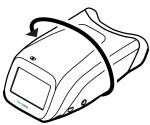
Use the device on battery power once the battery is installed and charged.

Note

The battery is charged when the AC power cable is plugged in to the device and the AC power supply.

Install the battery/replace the battery

Turn the RetinaVue 700 Imager over to access the battery cover and set the RetinaVue 700 Imager on a flat, clean surface.





WARNING Personal injury risk. Improper handling of the battery can lead to heat generation, smoke, explosion, or fire. Do not short-circuit, crush, incinerate, or disassemble the battery. Never dispose of batteries in refuse containers. Always recycle batteries according to national or local regulations.

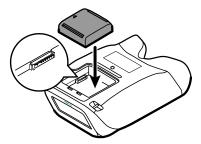


WARNING Use only Welch Allyn approved accessories, and use them according to the manufacturer's directions for use. Using unapproved accessories with the camera can affect patient and operator safety and can compromise product performance and accuracy, and void the product warranty.

- 1. Use a coin to loosen the screw at the edge of the battery cover.
- 2. Slide open the battery cover by tilting the cover upward.



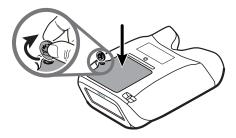
3. For first-time setup of the RetinaVue 700 Imager, insert the battery into the battery compartment.



For battery replacement, remove the existing battery and then insert the new replacement battery into the battery compartment.

Insert the two battery cover tabs into the slots, then push in the tab to close 4. the battery cover.

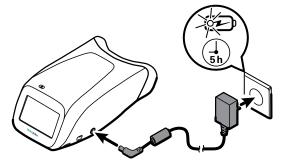
5. Tighten the screw at the edge of the battery cover.



Note Do not over-tighten the screw.

Connect the power supply to the Retina Vue 700 **Imager**

Locate the power connector charging port on the RetinaVue 700 Imager and plug the power supply connector plug into the RetinaVue 700 Imager.





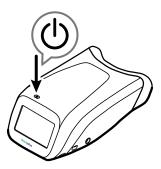
CAUTION The power supply connector easily inserts into the RetinaVue 700 Imager. Using force to connect the power supply connector plug can damage the device and will void the warranty.

Plug the power cord into an available wall outlet to charge the device. When 2. the power indicator LED light is orange, it indicates that the device is in the process of charging.

Note For first time use, the device needs to be charged for 5 hours before use.

Startup

Power



The Power button, located on the upper-left corner of the RetinaVue 700 Imager, performs multiple functions:

- powers up the RetinaVue 700 Imager
- wakes the RetinaVue 700 Imager from Sleep mode
- opens a dialogue screen with controls to power down, enter Sleep mode, or to cancel and return to the prior screen, depending on the option you choose

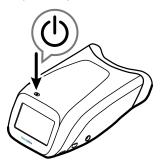
Power up the RetinaVue 700 Imager

The RetinaVue 700 Imager runs a brief diagnostic self-test each time it powers up.



CAUTION Always use the RetinaVue 700 Imager with an adequately charged and properly functioning battery.

1. Press 0 to power up the RetinaVue 700 Imager.



As the device is powering up, the RetinaVue 700 Imager displays the Welch Allyn logo.

If this is the first time set up, select your preferred language from the drop-2. down list and then touch Next.

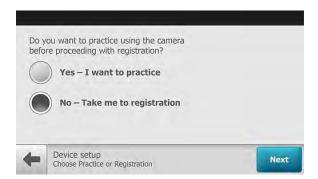


- 3. Touch (up) or (down) to enter, or adjust, the Day, Month, and Year.
- Touch (up) or (down) to enter, or adjust, the Hour, Minute (Min), 4. Continent, and Location. Touch Next.



Note Use the radio buttons to select the 24-hour or 12-hour format.

- 5. If you want to use the camera in practice mode before registering the camera, touch Yes - I want to practice.
 - a. If you want to proceed to registering the camera, touch **No - take** me to registration and then touch Next.



First time selection of USB connectivity workflow

Touch RetinaVue Network - USB to select the USB workflow and touch Next.



Touch **OK** at the Setup completed screen and follow the touchscreen instructions to connect the camera to a computer.

Note

For the USB workflow, the RetinaVue 700 Imager must be connected to a computer running the RetinaVue Network software application (requires additional software) to transfer exams.

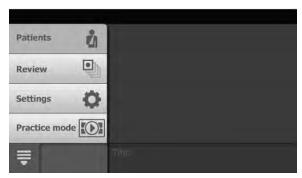
Note

To change the connectivity workflow settings after the initial set up, touch **Settings** > **Advanced settings** > **Reset** factory defaults. Touch All device settings at the dialog: "Select the settings to reset to factory defaults." and then touch **OK** at the dialog "Reset all settings to defaults? All exams stored on this camera will be deleted."

How to set up the camera, then acquire and submit images — Retina Vue 700 Imager camera and RetinaVue Network software application (USB only)

Before you begin

Power on the Retina Vue 700 Imager and touch Practice on the main Patients screen.



- 2. See the *Practice mode* topic for further instructions.
- 3. Practice with interactive feedback from the integrated RetinaVue 700 Imager Practice mode.



Set up the RetinaVue 700 Imager

Power on the computer and the RetinaVue 700 Imager.

Note If prompted to log in to Windows enter your Windows credentials.

2. Ensure the RetinaVue Network software application is running.

If the RetinaVue Network software application is not Note already open, double-click the desktop icon.

Ensure that the RetinaVue 700 Imager is powered on and connected to the computer by the USB cable. Once the camera is connected to the computer, a notification appears on the RetinaVue 700 Imager display indicating that it is connected to the computer: "Camera is connected to computer, disconnect camera from computer to access camera functions."

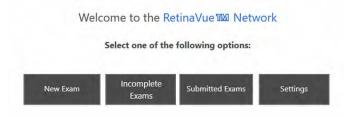




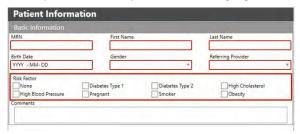


Start a new exam

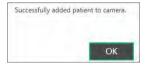
- 1. Have the patient sit in a dark room for 5 minutes to dilate their pupils.
- 2. Click **New Exam** in the RetinaVue Network software application.



3. Complete all required fields. Required fields are highlighted in red.



Click **NEXT** to save the patient information. A message appears indicating the patient has been added to the camera. Click OK.



5. Disconnect the RetinaVue 700 Imager from the computer and USB cable.



CAUTION Do not disconnect the RetinaVue 700 Imager from the USB cable while the RetinaVue Network software application is transferring data. Data may be lost. The process status icon appears while data is being transferred.



6. The new patient appears on the RetinaVue 700 Imager main *Patients* screen.



- 7. Select the patient from the Patients list.
- Ensure that the correct patient is selected and that the demographic information is correct.
- 9. Touch **Exam**.



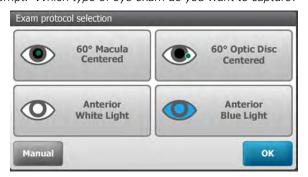


Acquire images

To proceed with the default Exam protocol, touch **START.** 1.



(Optional) If creating the exam on the camera, touch (Settings) a. or touch within the currently displayed exam protocol launch the Exam protocol selection dialog box and to select the desired Exam protocol. Select the new protocol at the dialog screen prompt: "Which type of eye exam do you want to capture?"

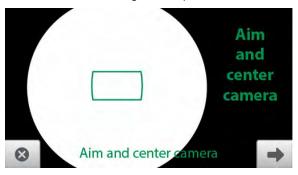


Touch OK.

2. Approach the patient from directly in front of the examined eyes and firmly press the facecup of the RetinaVue 700 Imager against the patient's forehead and nose. A message appears on the LCD touchscreen: "Get ready to aim and center camera" as the camera is entering the live preview mode.



3. Instruct the patient to look at the green fixation light inside the RetinaVue 700 Imager. A message appears on the LCD touchscreen: "Aim and center camera" as the camera is entering the live preview mode.

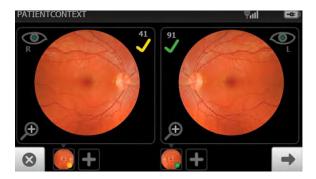




WARNING Clean and disinfect the face cup after each patient to avoid the risk of cross-contamination.

- 4. Keep the RetinaVue 700 Imager in line.
- 5. While the camera is locating the eye and self-adjusting to capture the best image, the "Keep camera steady and in place" message appears on the LCD touchscreen for each eye along with an animation.
- 6. On the LCD touchscreen, the camera prompts to "Aim and center the camera" until the images for each eye are captured.
- 7. An audible tone alerts you that the images have been captured.

The acquired images appear on the LCD touchscreen for review after a few seconds.



- If the image is of good quality (scores of 40 +) \checkmark , it is very likely to be read.
- If the image is of good enough quality (range of 20 39) \checkmark . it is likely to be read.
- If the image is lacking in quality (range of 0 19) \times , it is highly unlikely to be read.
- If the quality indicator is green or yellow, touch (next) in the bottom right 8. corner.

If the quality indicator is red, touch (Discard) in the bottom left corner. Wait at least 1 minute and then acquire a new image, or images.

Touch Save to save the exam for further review on the RetinaVue 700 Imager 9. or touch **Complete** to transfer the exam to the computer running the RetinaVue Network software application.



10. Connect the RetinaVue 700 Imager to the computer with a USB cable.

Note

If the exam does not transfer or if a syncing error message appears in the RetinaVue Network software application, see the *Troubleshooting* topic for further information.





Transfer exam images

- 1. Connect the RetinaVue 700 Imager to the computer with a USB cable.
- 2. Ensure that the camera remains powered on until the exams are transferred to the RetinaVue Network software application.
- 3. In the RetinaVue Network software application, click **Incomplete Exams**.



A list of patients with incomplete exams appears on the *Incomplete Exams* screen.



Select your patient and click **Next**.

If all required fields have been completed, click **Next**. 4.



Review the images and then click **Next** again.



From the Exam Workflow Complete screen, click Submit Exam. 5.



6. Once the exam has been submitted, a message appears indicating the exam was successfully submitted. Click **OK**.

View New Reports - RetinaVue Network **Customer Portal**

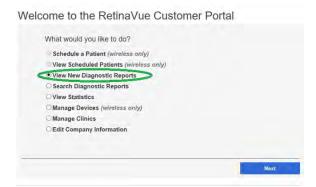
Once images are submitted from the computer running the RetinaVue Network software application and the images are evaluated, a new report is available on the RetinaVue Network Customer Portal.

1. Log in to the RetinaVue Network Customer Portal.

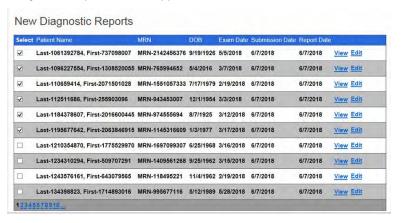


The Welcome screen appears.

2. Select View New Diagnostic Reports and click Next.



The New Diagnostic Reports screen appears.



Select your patient and click **View** to view report. 3.

First time selection of Wi-Fi connectivity workflow

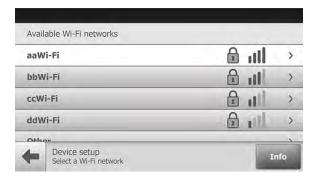
Note

The Wi-Fi camera setup only needs to be completed once unless a change to the connectivity workflow is desired.

Touch RetinaVue Network - Wi-Fi to select the wireless workflow and touch Next.



From the list of available networks, touch on the Wi-Fi connection that you 2. want to connect to.



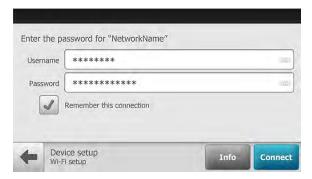
Note *Wi-Fi network names shown here are examples.

Note If you don't see the desired Wi-Fi network that you want to connect to, you may need to scroll down.

Note

During Wi-Fi communication, the RetinaVue 700 Imager supports the use of the following secure authentication types: WPA2-PSK and WPA2 Enterprise. If you don't see the network name in your list it might be a hidden network. Select "Other" and enter the network name. See the *Troubleshooting* section for further information.

3. Using a secured network, enter your network Wi-Fi Username and Password or a Passphrase and touch Connect. Note: if you are using PSK, leave the Username field blank.

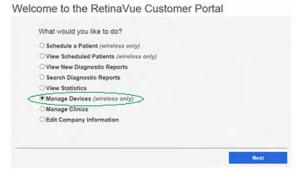


- (Optional). Touch **Remember this connection** and touch **Connect** to a. use the selected network for subsequent Wi-Fi connections.
- To continue setup, launch an internet browser from a computer and enter the 4. following address: https://www.retinavue.net/RN_CustomerPortal/.
- 5. On your RetinaVue 700 Imager, touch Next.
- 6. On the RetinaVue Network Customer Portal, enter your RetinaVue Network Username and Password then click Log In.



Note If prompted, click I agree to accept the End User License Agreement on the RetinaVue Network Customer Portal.

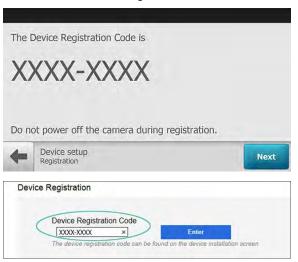
7. On the RetinaVue Network Customer Portal, select Manage Devices (wireless only) and click Next.



Click Add Device 8



- On your RetinaVue 700 Imager, touch **Next** to generate a Device Registration Code
- 10. On the RetinaVue Network Customer Portal, enter the Device Registration Code from the RetinaVue 700 Imager and then click Enter.



Note *The Device Registration Code shown here is an example.

Note The *Next* button is greyed out until the Device Registration Code is received by the RetinaVue 700 Imager from the RetinaVue Network Customer Portal.

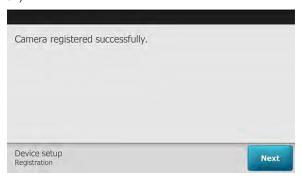
Note The Device Registration Code needs to be entered into the RetinaVue Network Customer Portal as it appears on the RetinaVue 700 Imager device installation screen including the dash (-).

Note The code expires after 30 minutes.

11. On the RetinaVue Network Customer Portal, enter a Device Name (optional) and select a clinic, or clinics, where the RetinaVue 700 Imager will to be used. Select each clinic by clicking the check box next to the clinic name and then click Add Device



- (Optional) Test the WiFi and EMR connection by sending images to a a. test server. This mode is not intended to be used for patient exams.
- (Optional) To select multiple clinics where the RetinaVue 700 Imager will be used at, select each clinic by clicking the check box next to the clinic name.
- (Optional) To enable a Device Access Code for the RetinaVue 700 Imager, select the **Device Access Code** checkbox and enter your code into the Device Access Code field. The RetinaVue 700 Imager and the RetinaVue Network Customer Portal support from 4 to 6digits in the Device Access Code.
- Note Setting the Device Access Code before first use provides additional security features in the RetinaVue 700 Imager to prevent unintended access to patient information by unauthorized individuals.
 - 12. On your RetinaVue 700 Imager, touch Next on the screen: Camera registered successfully.



- 13. (Optional) If a Device Access Code was selected at the RetinaVue Network Customer Portal, touch **OK** at the dialogue: A new device access code has been downloaded. The camera will require this code on next encounter.
- 14. (Optional) If multiple clinics were selected at the RetinaVue Network Customer Portal, use the drop-down menu to select the primary clinic where exams will be performed and then touch **Next**.
- 15. Touch **OK** at the *Setup completed* screen.
- 16. (Optional) If a Device Access Code was set at the RetinaVue Network Customer Portal, enter the Device access code on the RetinaVue 700 Imager and touch **OK**



Note

To change the connectivity workflow settings after the initial set up, touch Settings > Advanced settings > Reset factory defaults. Touch All device and radio settings at the dialog: "Select the settings to reset to factory defaults." and then touch OK at the dialog "Reset all settings to defaults? All exams stored on this camera will be deleted."

About the Auto and Manual Exam modes

Auto Mode



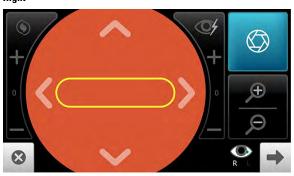
Auto Mode is the default image capture mode. Available features include:

- Automatic image capture
- Exam protocol selection
- Sequential image capture order of the right and left eye
- Navigation to the *Image Inspection* screen
- One touch exit

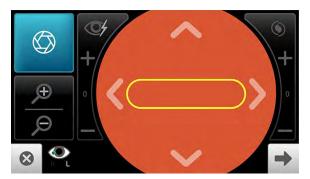
In addition to the automatic features, manual capture, manual focus adjustment, exam protocol selection, and manual flash brightness adjustment are also available.

Manual Mode

Right



Left



Manual mode contains advanced image capture options.

Note A manual touch of the capture button is required to obtain an image.

Available manual features include:

- Focus adjustment (values range from -1 to +1)
- Flash brightness adjustment (values range from -2 to +2)
- Sequential image capture order of the right and left eye
- Image capture
- X-axis control (horizontally movement)
- Y-axis control (vertically movement)
- Zoom
- Auto focus
- One touch exit
- One touch advancement to next screen

About image quality scores

Good quality green (Inspection screen)	Good quality green (Exam summary	
	screen)	If the image is of good quality, it is very _likely to be read.
✓		(Scores of 40 +)
Acceptable quality yellow	Acceptable quality yellow	
(Inspection screen)	(Exam summary screen)	If the image is of good enough quality, it islikely to be read.
✓	√ ₀	(Range of 20 — 39)
Unacceptable quality red	Unacceptable quality red	
(Inspection screen)	(Exam summary screen)	If the image is lacking in quality, it is highly unlikely to be read.
×	J •	(Range of 0 — 19)

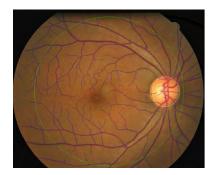
About Exam protocols

Available Exam protocols include:

- 60 ° Macula centered
- 60 ° Optic disc centered
- Anterior white light

Macula centered imaging:

Evaluate and document the central retina and macula for clinical signs of Diabetic Retinopathy.

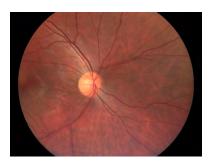


60 ° Macula centered



Optic disc centered imaging:

Evaluate and document the optic disc for clinical signs of glaucoma.



60 ° Optic disc centered



Anterior white imaging:

Evaluate and document anterior ocular structures like lids, lashes, and cornea.



Anterior white liaht





CAUTION Failure to install the face cup spacer plate before a patient anterior image exam may result in unacceptable image quality or failure to capture an image.

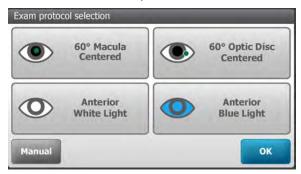


CAUTION Failure to remove the face cup spacer plate before a patient 60 ° Macula centered or 60 ° Optic disc centered exam may result in unacceptable image quality or failure to capture an image.

Accessing exam protocols

From the *Pre Acquisition* screen, touch (Settings) or touch within the current to launch the Exam protocol selection dialog box and to exam protocol select the desired Exam protocol.

Touch the desired Exam protocol button and touch **OK** at the prompt.



Note

The currently selected Exam protocol becomes the default protocol for future exams on the RetinaVue 700 Imager until another protocol is selected.

Note

If a patient has been scheduled from the RetinaVue Network Customer Portal in wireless mode, no changes can made to the Exam protocol once the administrator has locked the protocols.

Face cup

The face cup blocks ambient light during testing and covers both of the patient's eye sockets to allow them to best focus on the green fixation light.

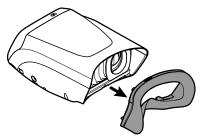
Use the face cup for a patient exam

Use the face cup to cover the patient's examined eyes and allow them to focus on the green fixation light.

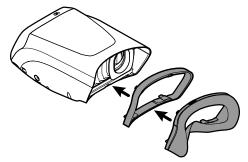


Use the face cup spacer plate for a patient anterior image exam

When performing anterior imaging of the ocular structures (lids, lashes, and cornea) using the blue light or white light protocol, remove the face cup from the RetinaVue 700 Imager,



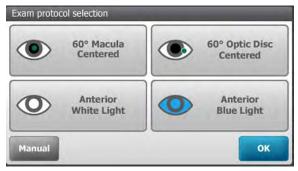
attach the face cup spacer plate to the RetinaVue 700 Imager, and then attach the face cup to the spacer plate.





CAUTION Failure to install the face cup spacer plate before a patient anterior image exam may result in unacceptable image quality or failure to capture an image.

- 2. From the *Pre Acquisition* screen, touch (Settings) or touch within the to launch the *Exam protocol selection* dialog current exam protocol box and to select the Anterior white light or Anterior blue light Exam protocol.
- 3. Touch the Anterior white light or Anterior blue light Exam protocol button and touch **OK** at the prompt.



- Touch **OK** at the prompt: "The imaging ring is required for anterior imaging. Remove ring for regular imaging."
 - If the next patient exam is for an Anterior white light or Anterior blue light Exam protocol leave the face cup spacer plate on the RetinaVue 700 Imager
 - If the next patient exam is for a 60 ° Macula centered or 60 ° Optic disc centered protocol, see the instructions for

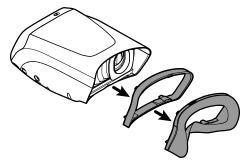
removing the face cup spacer plate from the RetinaVue 700 **Imager**



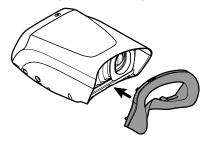
CAUTION Failure to remove the face cup spacer plate before for a patient 60 ° Macula centered or 60 ° Optic disc centered exam may result in unacceptable image quality or failure to capture an image.

Remove the face cup spacer plate for a patient a 60 ° Macula centered or 60 ° Optic disc centered exam

1. When performing a 60 ° Macula centered or 60 ° Optic disc centered exam, remove the face cup and the face cup spacer plate from the RetinaVue 700 **Imager**



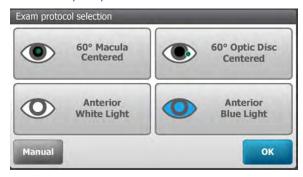
and then reattach just the face cup to the RetinaVue 700 Imager.





CAUTION Failure to remove the face cup spacer plate before for a patient 60 ° Macula centered or 60 ° Optic disc centered exam may result in unacceptable image quality or failure to capture an image

- 2. From the *Pre Acquisition* screen, touch (Settings) or touch within the current exam protocol to launch the *Exam protocol selection* dialog box and to select either the 60 ° Macula centered or 60 ° Optic disc centered Exam protocol.
- 3. Touch the 60 ° Macula centered or 60 ° Optic disc centered protocol button and touch **OK** at the prompt.



Using the RetinaVue 700 Imager

The following topics describe using the RetinaVue 700 Imager for exams, creating new patients, deleting exams and reviewing exams.

Perform an eye exam (wireless workflow)

Note

To ensure that the patient's pupils sufficiently dilate to 3 mm, adjust the room lighting to the lowest possible level. If necessary, have the patient sit in a dark room for 5 minutes to dilate their pupils.

Note

While the RetinaVue 700 Imager can be used on patients with cataracts and other eye opacities, the use of the RetinaVue 700 Imager may result in a lower quality image due to the increased reflection of the flash off the patient's intraocular lens.

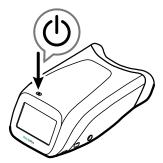
- Ask your patient to remove their glasses, contacts can remain in place.
- If using the RetinaVue 700 Imager without the pedestal, ask the patient to sit in a chair and sit directly across from the patient with your legs together on the same side as the examined eye.
- If using the RetinaVue 700 Imager without the pedestal, ask the patient to sit up straight and hold their head in a stationary position during the entire procedure.
- Ensure that the patient is sitting in a position that allows for a straight and level approach of the RetinaVue 700 Imager into the patient's eyes. A stable approach minimizes the loss of the view of the eye and repeated image capture attempts.
- Keep the RetinaVue 700 Imager lens the same height as the patient's examined eye.

- Approach the patient from directly in front of the examined eyes and firmly press the face cup against the patient's forehead and nose.
- Ask the patient to focus on the fixation light.

Note

For additional information about techniques to capture the highest quality image, see the Technique quide that came with the RetinaVue 700 Imager.

1. Press the power button.



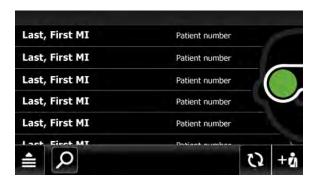
Note

To conserve power, the RetinaVue 700 Imager enters Sleep mode if it remains idle for the time set during set up. (Sleep mode settings include 2, 5, 7, 10 minutes, and Never). Touch the LCD screen or press the power button to wake up the RetinaVue 700 Imager from Sleep mode.

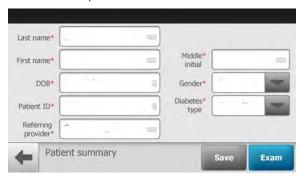
Note

Unless Never is selected, the RetinaVue 700 Imager powers down after 10 minutes of inactivity in Sleep mode. Press the power button to activate the RetinaVue 700 Imager. (See the *Settings* sections for information about changing the Sleep mode settings.)

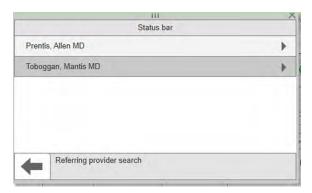
2. From the *Patients* screen, touch + 1 to create a new patient.



- Touch P to search for a patient with an existing exam within the a. Scheduled patients or Saved exams list.
- Touch to refresh the patient list from the RetinaVue Network Customer Portal Scheduled Patients list.
- 3. Touch within the Patient's Last name, First name, or Middle initial entry box to launch the on-screen keyboard.



- Enter the patient's last name and first name. (Middle initial is optional.) 4.
- Enter the patient's DOB (Date of Birth). (Touch within the DOB field to launch 5 the on-screen keyboard and to enter the patient's Date of Birth.)
- Enter the patient's gender using the drop-down menu to select Male, Female, 6 Other, or Unspecified.
- 7. Enter the patient's ID.
- 8. Touch within the Referring provider field entry box to launch the on-screen keyboard and search for your clinic's Referring provider.



- Enter the patient's Diabetes type using the drop-down menu to select Type I, 9. Type II, None, or Unspecified.
- 10. Once all the required fields are complete, touch **Exam** to open a new exam.

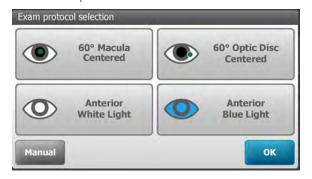


Optionally, to save the patient information without starting an exam, touch Save

11. To proceed with the default Exam protocol, touch START.



(Optional) If creating the exam on the camera, touch (Settings) or touch within the currently displayed exam protoco launch the Exam protocol selection.

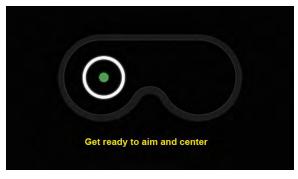


Touch OK.

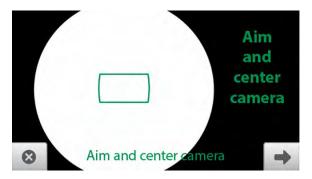
Note

If a patient has been scheduled from the RetinaVue Network Customer Portal in wireless mode, no changes can made to the Exam protocol once the administrator has locked the protocols.

12. Approach the patient from directly in front of the examined eyes and firmly press the facecup of the RetinaVue 700 Imager against the patient's forehead and nose. A message appears on the LCD touchscreen: "Getting ready to aim and center camera" as the camera is entering the live preview mode.



13. Instruct the patient to look at the green fixation light inside the RetinaVue 700 Imager. A message appears on the LCD touchscreen: "Aim and center camera" as the camera is entering the live preview mode.

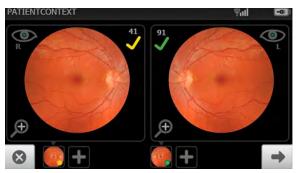




WARNING Clean and disinfect the face cup after each patient to avoid the risk of cross-contamination.

- 14. Keep the RetinaVue 700 Imager in line.
- 15. While the camera is locating the eye and self-adjusting to capture the best image, the "Keep camera steady and in place" message appears on the LCD touchscreen for each eye along with an animation.
- 16. On the LCD touchscreen, the camera prompts to "Aim and center the camera" until the images for each eye are captured.
- 17. An audible tone alerts you that the images have been captured.

The acquired images appear on the LCD touchscreen for review after a few seconds.



- If the image is of good quality (scores of 40 +) ✓, it is very likely to be read.
- If the image is of good enough quality (range of 20 39) \checkmark , it is likely to be read.
- If the image is lacking in quality (range of 0 19) \times , it is highly unlikely to be read.

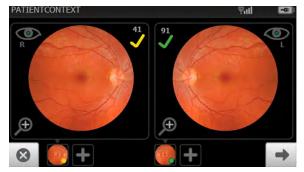
18. Touch to review the displayed image on the *Inspection mode* screen.



Images with a red X (\times) and low score denote low quality images. Touch

igotimes to navigate back to the *Inspection mode* screen. Touch lacksquare (trash) to dispose of an image and to begin a capture of another image. Touch **OK** at the dialog prompt "Do you wish to discard this image and acquire again?". The Live acquisition screen appears.

19. Touch (Next) after all images are automatically captured.



- 20. When the sequential image capture is complete and the images contain a green or yellow quality acceptance check mark, proceed to the Exam summary screen.
 - Touch Save to save the exam to the device for further review or editing.
 - Touch **Submit** to send the exam to the RetinaVue Network b. Customer Portal for a reading.



Perform an eye exam (USB workflow)

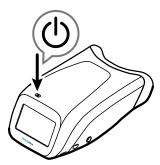
Note

To ensure that the patient's pupils sufficiently dilate to 3 mm, adjust the room lighting to the lowest possible level. If necessary, have the patient sit in a dark room for 5 minutes to dilate their pupils.

Note

While the RetinaVue 700 Imager can be used on patients with cataracts and other eye opacities, the use of the RetinaVue 700 Imager may result in a lower quality image due to the increased reflection of the flash off the patient's intraocular lens.

- Ask your patient to remove their glasses, contacts can remain in place.
- If using the RetinaVue 700 Imager without the pedestal, ask the patient to sit in a chair and sit directly across from the patient with your legs together on the same side as the examined eye.
- If using the RetinaVue 700 Imager without the pedestal, ask the patient to sit up straight and hold their head in a stationary position during the entire procedure.
- Ensure that the patient is sitting in a position that allows for a straight and level approach of the RetinaVue 700 Imager into the patient's eyes. A stable approach minimizes the loss of the view of the eye and repeated image capture attempts.
- Keep the RetinaVue 700 Imager lens the same height as the patient's examined eye.
- Approach the patient from directly in front of the examined eyes and firmly press the face cup against the patient's forehead and nose.
- Ask the patient to focus on the fixation light.
- 1. Press the power button.



Note

To conserve power, the RetinaVue 700 Imager enters Sleep mode if it remains idle for the time set during set up. (Sleep mode settings include 2, 5, 7, 10 minutes, and Never). Touch the LCD screen or press the power button to wake up the RetinaVue 700 Imager from Sleep mode.

Note

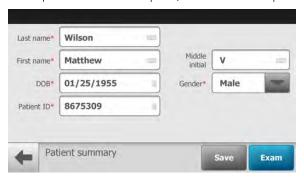
Unless Never is selected, the RetinaVue 700 Imager powers down after 10 minutes of inactivity in Sleep mode. Press the power button to activate the RetinaVue 700 Imager. (See the Settings sections for information about changing the Sleep mode settings.)

2. From the main *Patients screen*, touch + 1 to create a new patient.



- 3. The Patient summary screen appears. Required fields are noted with a red asterisk.
- Touch within the patient's last name or first name field to launch the onscreen keyboard. Enter the patient's last name and first name. (Middle initial is optional.)

- 5. Enter the patient's DOB (Date of Birth). (Touch within the DOB field to launch the on-screen keyboard and to enter the patient's Date of Birth.)
- Enter the patient's gender using the drop-down menu to select Male, Female, 6. Unknown, or Other.
- 7. Enter the patient's ID.
- 8. Once all the required fields are complete, touch **Exam** to open a new exam.

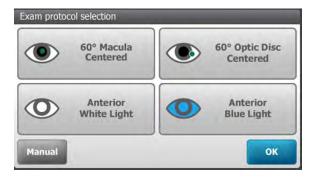


The *Pre-acquisition* screen appears.

9. To proceed with the default Exam protocol, touch **START**.



(Optional) If creating the exam on the camera, touch (Settings) or touch within the currently displayed exam protocol launch the Exam protocol selection.

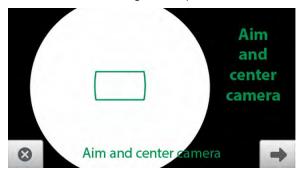


Touch OK.

10. Approach the patient from directly in front of the examined eyes and firmly press the facecup of the RetinaVue 700 Imager against the patient's forehead and nose. A message appears on the LCD touchscreen: "Getting ready to aim and center camera" as the camera is entering the live preview mode.



11. Instruct the patient to look at the green fixation light inside the RetinaVue 700 Imager. A message appears on the LCD touchscreen: "Aim and center camera" as the camera is entering the live preview mode.





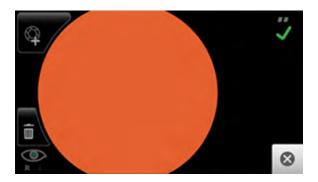
WARNING Clean and disinfect the face cup after each patient to avoid the risk of cross-contamination.

- 12. Keep the RetinaVue 700 Imager in line.
- 13. While the camera is locating the eye and self-adjusting to capture the best image, the "Keep camera steady and in place" message appears on the LCD touchscreen for each eye along with an animation.
- 14. On the LCD touchscreen, the camera prompts to "Aim and center the camera" until the images for each eye are captured.
- 15. An audible tone alerts you that the images have been captured.

The acquired images appear on the LCD touchscreen for review after a few seconds.



- If the image is of good quality (scores of 40 +) \checkmark , it is very likely to be read.
- If the image is of good enough quality (range of 20 39) \checkmark , it is likely to be read.
- If the image is lacking in quality (range of 0 19) \times . it is highly unlikely to be read.
- 16. Touch to review the displayed image on the *Inspection mode* screen.



Images with a red X (X) and low score denote low quality images. Touch igspace to navigate back to the *Inspection mode* screen. Touch lacksquare (trash) to

dispose of an image and to begin a capture of another image. Touch **OK** at the dialog prompt "Do you wish to discard this image and acquire again?". The Live acquisition screen appears.

17. Touch (Next) after all images are automatically captured.



- 18. When the sequential image capture is complete and the images contain a green or yellow quality acceptance check mark, proceed to the Exam summary screen.
 - a. Touch **Save** to save the exam to the device for further review or editing.
 - b. Touch **Complete** and use a USB cable to transfer the exam to a computer running the RetinaVue Network software application to send the exam to the Customer Portal for a reading.

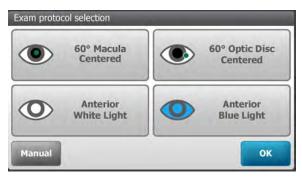


Perform a manual image capture while in Auto exam mode

From the Pre Acquisition screen, touch MANUAL.



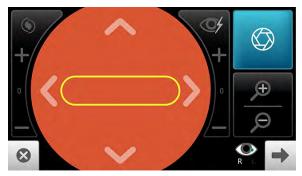
Select the desired manual Exam protocol from the Exam protocol selection 2. screen.



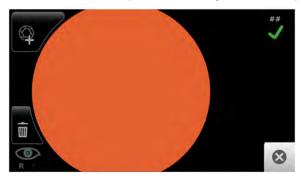
Note

To adjust settings before capturing an image, see the topic About the Auto and Manual Exam modes for additional information about using advanced image capture options (such as Focus adjustment, Flash brightness adjustment, or X-axis and Y-axis adjustment).

3. Touch (image capture) to manually capture an image of the right or left eye. (Right eye manual capture shown.)

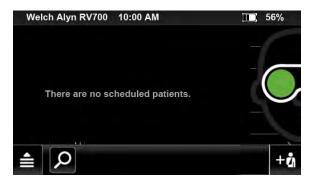


An audible tone alerts you that the image has been captured.

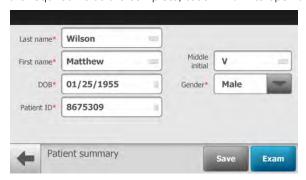


Create a new patient on the RetinaVue 700 Imager (USB)

From the main *Patients screen*, touch + to create a new patient. (USB workflow images shown)



- 2. The Patient summary screen appears. Required fields are noted with a red asterisk.
- 3. Touch within the patient's last name or first name field to launch the onscreen keyboard. Enter the patient's last name and first name. (Middle initial is optional.)
- Enter the patient's DOB (Date of Birth). (Touch within the DOB field to launch 4. the on-screen keyboard and to enter the patient's Date of Birth.)
- Enter the patient's gender using the drop-down menu to select Male, Female, 5. Unknown, or Other.
- 6. Enter the patient's ID.
- 7. Once all the required fields are complete, touch **Exam** to open a new exam.



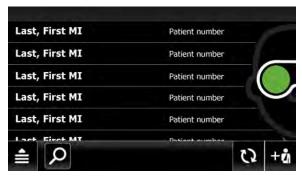
The *Pre-acquisition* screen appears.



8. Refer to Perform an eye exam for instructions on performing exams and acquiring images.

Create a new patient on the RetinaVue 700 Imager (wireless)

From the main *Patients screen*, touch + to create a new patient. (Wireless workflow images shown)



2. The Patient summary screen appears. Required fields are noted with a red asterisk.



- 3. Touch within the patient's last name or first name field to launch the onscreen keyboard. Enter the patient's last name and first name. (Middle initial is optional.)
- Enter the patient's DOB (Date of Birth). (Touch within the DOB field to launch 4. the on-screen keyboard and to enter the patient's Date of Birth.)
- Enter the patient's gender using the drop-down menu to select Male, Female, 5. Unknown, or Other.
- 6. Enter the patient's ID.
- 7. Touch within the Referring provider field entry box to launch the on-screen keyboard and search for your clinic's Referring provider.



- Enter the patient's Diabetes type using the drop-down menu to select Type I, 8. Type II, None, or Unspecified.
- Once all the required fields are complete, touch **Exam** to open a new exam. 9.



The Pre-acquisition screen appears.



10. Refer to Perform an eye exam for instructions on performing exams and acquiring images.

Select or change a clinic on the RetinaVue 700 Imager (wireless only)

- Touch (Navigation Menu) from the main Patients screen.
- 2. Touch **Settings**.



Touch Clinic / States.

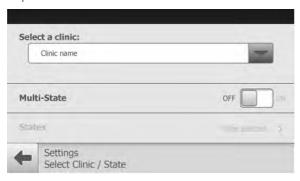
Note

With saved exams on the camera, switching a clinic is not permitted. Either save or delete the exam to switch clinics.

Note

If the "Wi-Fi connection not available." message appears, see the Troubleshooting section.

Use the drop-down menu to select a clinic.



5. Touch (Back) to return to the main *Patients* screen.

Select or change a Multi-State clinic on the RetinaVue 700 Imager (wireless only)

1. Touch (Navigation Menu) from the main *Patients* screen.



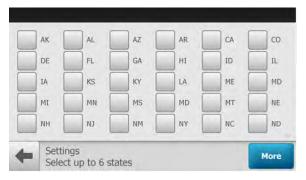
2. Touch Settings



- 3. Touch Clinic / States.
- 4. If multiple clinics are set up, use the drop-down menu to select the clinic you would like to set up for Multi-State use.
- 5. Touch Multi-State. The switch changes from Off to On.



Touch **States** to select between 2 and 6 States for the clinic. Touch **More** to 6. see additional States and to proceed to OK when the desired number of States are selected.

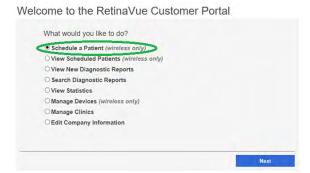


- Touch **OK** to return to the *Clinic/State Settings* screen. 7.
- Touch (Back) to return to the main *Patients* screen. 8.

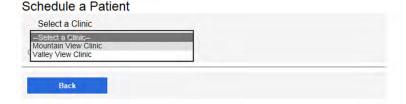
Note For each exam performed in multi-state use, select the state where the exam was performed. Touch **OK** to confirm.

Schedule a patient from the RetinaVue **Network Customer Portal (wireless only)**

Select Schedule a Patient (wireless only) from the RetinaVue Network Customer Portal Welcome screen and then click **Next**.

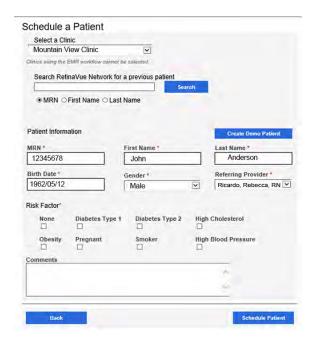


2. Use the drop-down menu to select a clinic.



The Schedule a Patient screen appears for your clinic.

Complete the required fields and click Schedule Patient.



Note

Required fields contain a red asterisk. Required fields include: MRN, First and Last Name, Date of Birth, Gender, and Referring Provider. Optional Risk factor fields include: None, Diabetes Type, Obesity, Pregnant, Smoker, High Cholesterol, and High Blood Pressure.

Note

To search for a patient who has had images captured in the past, select MRN, First Name, or Last Name and enter either the patient's MRN, or their First Name, or their Last Name in the Search field and click Search. Any previous patients of your clinic (within the Retina Vue Network) meeting any of the search parameters appear on the Patients Search screen.

- 4 Ensure that the RetinaVue 700 Imager is powered on and connected to a secure Wi-Fi network. Touch Patients. The Patients screen appears.
 - (Optional) Touch to refresh the patient list from the RetinaVue Network Customer Portal Scheduled Patients list.
- Select the patient from the patient list. Selected patients are highlighted in 5. color.
- 6. Confirm the patient demographics on the *Patient summary* screen.



7. Touch **Exam** to start a new exam. The *Pre-acquisition* screen appears.



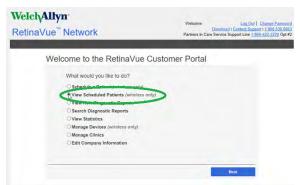
Refer to Perform an eye exam for instructions on performing exams and acquiring images.

Delete a patient scheduled from the RetinaVue Network Customer Portal (wireless only)

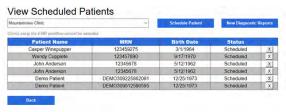


From the Patient summary screen, touch **Delete**. A patient scheduled from 1. the RetinaVue Network Customer Portal is also deleted from the Scheduled patient's list.

2. To confirm that the patient deleted at the RetinaVue 700 Imager is deleted at the RetinaVue Network Customer Portal, log in and select View Scheduled Patients (wireless only) from the Welcome screen and then click Next.

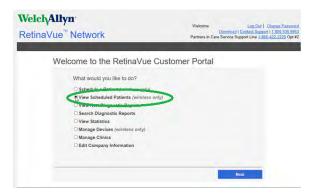


3. Use the drop-down menu to select a clinic and then confirm that the patient no longer appears in scheduled patients list.



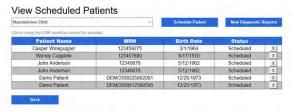
View Scheduled Patients on the RetinaVue Network Customer Portal (wireless only)

Select View Scheduled Patients (wireless only) from the RetinaVue Network Customer Portal Welcome screen and then click **Next**.



The View Scheduled Patients screen appears.

2. Use the drop-down menu to select a clinic and then view scheduled patients.

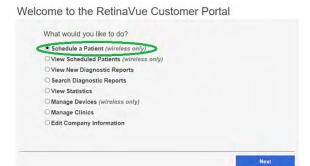


Note

Scheduled patients appear as *Scheduled* in the Status column. If the patient's exam has been completed the patient record appears as Submitted until the patient's report is returned.

Schedule a Demo patient from the RetinaVue Network Customer Portal without submitting an exam for over-read (wireless only)

Select Schedule a Patient (wireless only) from the RetinaVue Network Customer Portal Welcome screen and then click Next.



2. Use the drop-down menu to select a clinic.

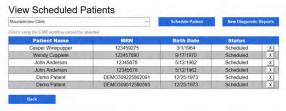
Schedule a Patient	
Select a Clinic	
Select a Clinic— Mountain View Clinic Valley View Clinic	
Back	

The Schedule a Patient screen appears for your clinic.

3. Click Create Demo Patient, complete all required fields, and then click Schedule Patient.



4 The View Scheduled Patients screen appears.



Ensure that the Retina Vue 700 camera is powered on and connected to a secure Wi-Fi network. Touch Patients. The Patients screen appears.



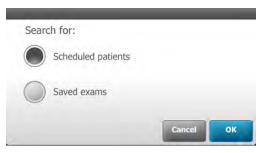
- Touch on **Patient, Demo** to select the Demo Patient. The *Patient Summary* screen appears.
- Touch **OK** to start a new exam to practice with a demo patient without submitting the exam for over-read on the RetinaVue Network Customer Portal.
- Refer to Perform an eye exam for instructions on performing exams and acquiring images.

Search for a patient in the Scheduled Patients list on the RetinaVue 700 Imager (wireless)

From the main *Patients screen*, Touch ρ to search for a patient. (Wireless workflow images shown)



Search for Scheduled patients downloaded to the RetinaVue 700 Imager from 2. the RetinaVue Network Customer Portal (the Patients list search).



Touch **OK** to launch the on-screen keyboard and begin typing the patient's last 3. name, first name, or Patient ID (MRN #) into the entry field box and then touch **OK** on the on-screen keyboard.



The Patients list search screen appears.



4. Touch on a patient's name or ID to select that patient. Selected patients are highlighted in color. The Patient summary screen appears.



Note Patient information is not editable for patients created on the RetinaVue Network Customer Portal.

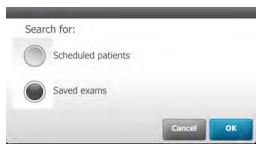
Refer to Perform an eye exam for instructions on performing exams and acquiring images.

Search for a patient in the Saved exams list on the RetinaVue 700 Imager (wireless)

From the main *Patients screen*, Touch P to search for a patient. (Wireless workflow images shown)



2. Touch **Saved exams** to search for patients in the *Saved exams* list of patients already contained on the camera and then touch **OK** to launch the on-screen keyboard.



Note Patients in the Saved Exams list already have completed or partially completed exams.

3. Begin typing the patient's last name, first name, or Patient ID (MRN #) into the Search entry field and then touch **OK** on the on-screen keyboard.



The Saved/Submitted list of patients appears on the Review screen based on search parameters.



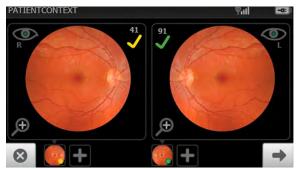
Touch on a patient's name or ID to select that patient. The Exam summary 4. screen appears.



From the Exam summary screen, exams can be deleted or submitted. 5.

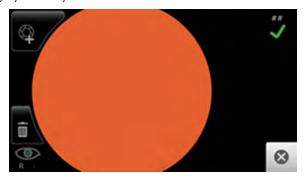
Delete an image during an eye exam

From the Post Acquisition screen, 1.



touch to review the current image on the *Inspection mode* screen.

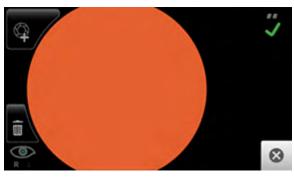
- If the image is of good quality (scores of 40 +) \checkmark , it is very likely to be read.
- If the image is of good enough quality (range of 20 39) \checkmark , it is likely to be read.
- If the image is lacking in quality (range of 0 19) \times , it is highly unlikely to be read.



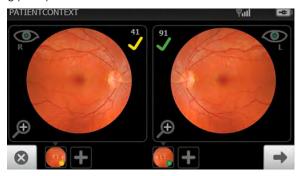
Images with a red X (imes) and a low score denote low quality images and should be deleted.

Either touch twice to discard unsaved images and return to the *Patients* 2 list screen to begin another exam, or touch III (trash) to dispose of an image and return to the Acquisition screen to begin a capture of another image.

From the *Image Inspection* screen, touch **S** to navigate back to the Post Acquisition screen. (Right eye Image Inspection screen shown).

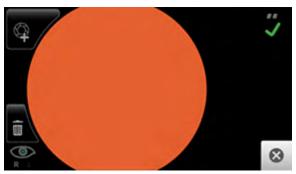


From the *Post Acquisition* screen, touch **8** again to discard unsaved images. Touch **OK** at the "Discard unsaved images and patient data?" dialog prompt.



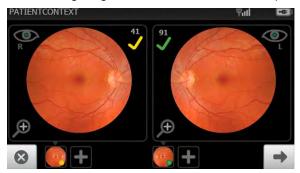
The home Patients screen appears.

From the *Image Inspection* screen, touch (trash) to dispose of an b. image and to begin a capture of another image.



Touch **OK** at the dialog prompt "Do you wish to discard this image and acquire again?". The Acquisition screen appears.

Capture the remaining images and touch (Next) to complete the exam. 3.



4. (Wireless option). When the image capture is complete and the images contain a green or yellow quality acceptance check mark, proceed to the Exam summary screen and touch **Save** or **Submit**.



- Touch **Save** to save an exam to the device for further review or editing. The Exam Saved dialog appears.
- Touch **Submit** to send the exam to the RetinaVue Network for a reading.

In the Wireless mode, the "Exam is gueued up to be Note submitted." message appears.

5. (USB option). When the sequential image capture is complete and the images contain a green or yellow quality acceptance check mark, proceed to the Exam summary screen and touch Save or Complete.



- Touch Save to save exam to the device for further review or editing. The Exam Saved dialog appears.
- Touch **Complete** and connect the USB cable to transfer the exam by USB cable to the RetinaVue Network Software application for a submission from software application on the computer to the RetinaVue Network Customer Portal for a reading.

Delete a patient from the RetinaVue 700 **Imager**

From the main Patients screen, touch on Patient's name or ID number. The selected patient is highlighted in color. (Wireless workflow images shown)

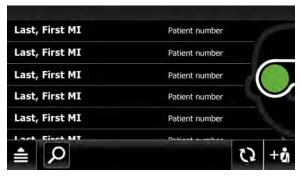


2 Touch Delete.

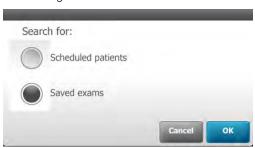


Touch **OK** at the prompt: "Are you sure you want to delete the patient file?".

(Optionally), from the main *Patients screen*, touch \nearrow to search for a patient. 3. (Wireless workflow images shown)



Search for Scheduled patients downloaded to the RetinaVue 700 Imager from 4. the RetinaVue Network Customer Portal (the Patients list search). Or search for patients from the Saved Exams list of patients already contained on the RetinaVue 700 Imager.



5. Touch **OK** to launch the on-screen keyboard and begin typing the patient's last name, first name, or Patient ID (MRN #) into the entry field box and then touch **OK** on the on-screen keyboard.



Either the Patients list search



or the Saved/Submitted (Wi-Fi)



or the Saved/Completed(USB) list



screen appears depending on the option chosen.

Touch on a patient's name or ID to select that patient. The Exam summary 6. screen appears.



Note Patient information is not editable for patients created on the RetinaVue Network Customer Portal.

7. Touch (delete) to remove a patient from the RetinaVue 700 Imager. Touch **OK** at the screen dialog: "Are you sure you want to delete the patient file? This patient will also be deleted on the portal" (Wi-FI). Or, "Are you sure you want to delete this patient's information and exam?"(USB).

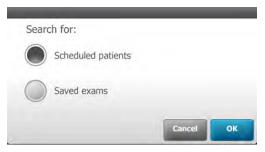
Note See the Troubleshooting section if the following error message appears: "Failure to connect to the portal. Unable to delete patient information".

Delete a patient and exam from the RetinaVue 700 Imager

From the main *Patients screen*, Touch P to search for a patient. (Wireless workflow images shown)



Search for patients from the Scheduled patients/Saved exams list of patients already contained on the RetinaVue 700 Imager.



3. Touch **OK** to launch the on-screen keyboard and begin typing the patient's last name, first name, or Patient ID (MRN #) into the entry field box and then touch **OK** on the on-screen keyboard.



The Saved/Submitted(Wi-FI)

Saved	St	bmitte	d)	
Kinglongname, Katie M	9109830108	Jan 12	9:22 AM	>
Baumlonglastname, W	9109830108	Jan 12	10:42 AM	>
Stevens, Johnathan C	9109830108	Jan 12	12:38 PM	>
Wagner, Michael R	9109830108	Jan 13	1:38 PM	>
Somelongname, Thomas Review	9109830108	1an 14	3:38 PM	

or the Saved/Completed (USB) list screen appears.



4. For Saved exams, touch on a patient's name or ID to select that patient. The Exam summary screen appears.



Touch \blacksquare (delete) to remove the patient and the exam from the RetinaVue 700 Imager. Touch **OK** at the screen dialog: "Are you sure you want to delete this patient's information and exam?".

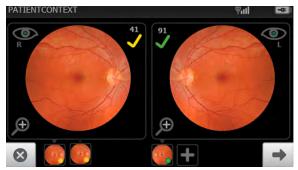
Capture additional images using the same protocol

1. From the Post Acquisition screen,



touch (Missing Image) to capture an additional image using the existing protocol.

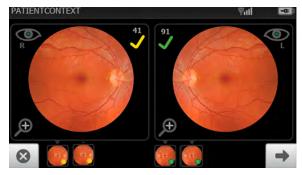
- If the image has a yellow or blue information message, observe the tips to capture another image to improve the image quality of the new image.
- 2. As the new images are captured by the RetinaVue 700 Imager, the new image icon appears in the place of the image capture icon. Touch (Next) after all images are captured.



(Wireless option). When the image capture is complete and the images 3. contain a green or yellow quality acceptance check mark, proceed to the Exam summary screen and touch Save or Submit. However, if there is a missing image on the Exam summary screen,



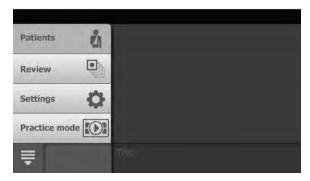
(add optional) to capture an additional image using the existing protocol. The "Get ready to aim and center" and the *Pre Acquisition* screens appear. As the new images are captured by the RetinaVue 700 Imager, the new image icon appears in place of the image capture icon. Touch (Next) after all images are captured.



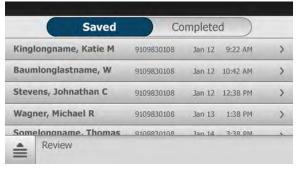
(Wireless option). Touch Save to save the exam to the device or touch **Submit** to send the exam to the RetinaVue Network for a reading. (USB option). Touch Save or touch Complete and connect the USB cable to transfer the exam by USB cable to the RetinaVue Network Software application for a submission from software application on the computer to the RetinaVue Network Customer Portal for a reading.

Review (USB workflow)

From the main Patients screen touch Review.



The patient's Review screen appears.



- 2. Touch on a patient's information to review the patient demographics and to view images associated with a patient.
- Any images which have not been sent for overread appear on the Exam 3. summary screen.



- After the review is complete, touch **Save** to save any changes or touch 4. Complete to sent for overread using USB.
- Touch (Back) to return to the *Review screen* and then touch 5. (Navigation Menu) to return to the main Patients screen.

Review (Wi-Fi workflow)

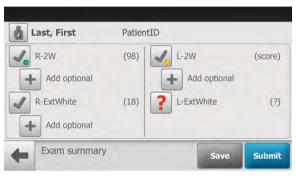
1. From the main Patients screen touch Review.



The patient's *Review* screen appears.



- 2. Touch on a patient's information to review the patient demographics and to view images associated with a patient.
- 3. Any images which have not been sent for overread appear on the *Exam* summary screen.



- After the review is complete, touch **Save** to save any changes or touch Submit to sent for overread using Wi-Fi.
- 5. From the patient's Review screen,



click on the following icons for additional status messages:

- Waiting to upload

- submitted

- report available

Note Once exam has been viewed on the RetinaVue Network customer portal it will be deleted from the device.

Touch (Back) to return to the main *Patients* screen. 6.

Note

Update the RetinaVue 700 Imager software

Note (USB only) Patient list changes will only be made

to the RetinaVue 700 Imager after the USB cable is reattached and connected to a computer running the RetinaVue Network software application.

(USB only) DICOM files will be available to theRetinaVue Network once the RetinaVue 700 Imager is reattached and connected to a computer running the RetinaVue Network software application.

Take note of the current software version:

- From the main Patients screen, touch 1.
- 2 Touch **Settings**.
- Touch **About** to view the software version. 3.
- Touch (Back) to return to the Settings screen. 4

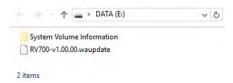
Before you begin, you will need the following:

- A computer with an Internet connection.
- The RetinaVue 700 Imager connected to a computer with a USB cable.
- 1. Download the software update from https://www.retinavue.net/ RN CustomerPortal/ and transfer the software update to a computer.
- From the main *Patients screen*, touch . 2
- 3. Touch **Settings**.
- 4. Touch Advanced settings.
- 5. Touch **software update**.
- 6 Touch Load firmware
- 7. Touch **OK** at the prompt: "Using a USB cable, plug the device into the computer to put the new software file on the device."
- 8. Plug the USB cable into the computer and the RetinaVue 700 Imager.

The screen prompt appears: "Device plugged into the computer. When finished loading file, unplug the device from the computer."

Keep the RetinaVue 700 Imager plugged into the computer and transfer the 9 software update from the computer to the RetinaVue 700 Imager by copying or dragging the file from the computer location into the RetinaVue 700 Imager device drive.

Note (In this example, "DATA (E:)".)



Note

Use a safe eject method when ejecting the RetinaVue 700 Imager to ensure a complete software transfer to the RetinaVue 700 Imager. (Options include rightclicking on the Start Menu > Open File Explorer> rightclick on EXAM, click Eject. Or, click on the Taskbar> Show hidden icons > click Safely Remove Hardware and Eiect Media> click Eiect RetinaVue Imager.

> If an eiect menu is not available with your system settings, wait until the files have completely copied before manually ejecting the RetinaVue 700 Imager.

- 10. Remove the USB cable from the RetinaVue 700 Imager.
- 11. Touch **OK** at the prompt: "Would you like to install the new version of software you just loaded to the device?"

Note The update process typically takes a few minutes to cycle through the complete update. During the update process, it is normal to see a process update icon that appears while the RetinaVue 700 Imager update successfully completes.

- 12. Touch **OK** at the prompt: "Successful update. Touch OK to restart device."
- 13. After the RetinaVue 700 Imager boots up to the main Patients screen, confirm the software update.
 - From the main Patients screen, touch = . a.
 - b. Touch **Settings**.
 - Touch **About** to view the software version.
- 14. Touch (Back) to return to the Settings screen.

Troubleshooting software updates

Note

The RetinaVue 700 Imager boots up normally after a successful software update, however if a software update fails, the RetinaVue 700 Imager displays a failed update error message.

Power loss during software update:

If a power loss occurs during the software update or if there are hardware issues, the RetinaVue 700 Imager posts a blank screen. Remove the battery, reinstall it, and restart RetinaVue 700 Imager. By performing this power cycle, the RetinaVue 700 Imager reverts to a previous version of software. Repeat the steps to perform the update again.

Corrupted software files:

If the software update on the RetinaVue 700 Imager is corrupted, the RetinaVue 700 Imager displays a failed update error message indicating that the RetinaVue 700 Imager is unable to load the software from the computer. Repeat the steps to perform the update again.

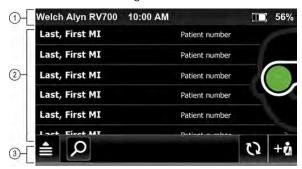
Unsuccessful update error

If the RetinaVue 700 Imager displays the failed update error message, Unsuccessful update. Try downloading the new software update again and redo the install. Ensure that the update file successfully completed the download from the https://www.retinavue.net/RN_CustomerPortal/ site and perform the update again.

Controls

Retina Vue 700 Imager main Patient screen

The RetinaVue 700 Imager main Patients screen includes the following areas:



Item	Area
1	Device status
2	Patients list or Content Area
3	Navigation

1. Device Status Area

The Device Status Area, located at the top of the main *Patients screen*, displays the:

- Device Model
- Clinic Name (if in Wi-Fi workflow and the clinic is selected at the RetinaVue Network customer portal). The clinic text indicates which clinic is selected.
- Time. Displayed in an HH:MM format.

 Connection status. The icons indicate which connection type, if any, is currently active.

Icon	Connection type
Ψ	Wireless signal strength

Battery condition. Percentage of charge is displayed.

In the *Live Preview, Exam Summary* and *Review screens*, the Device Status Area displays:



- Patient Icon and Patient name. The format of the Patient name is last name, first name, and middle initial.
- Clinic Name (The clinic text indicates which clinic is selected once it is entered at the RetinaVue Customer portal). The Clinic Name only displays until a patient is selected.
- Time. Displayed in an HH:MM format.
- Connection status. The icons indicate which connection type, if any, is currently active.
- Battery condition. Estimated battery capacity is displayed in a charged or discharged status format.

2. Patients list/Content Area

At the main *Patients* screen, the **Context Area** shows patients.



The pop up navigation menu provides access to the *Patients, Review, Settings*, and *Practice mode* menus within the **Context Area** of the RetinaVue 700 Imager user interface.

Directions for use Controls 101



- **Patients:** Presents a list of patients created on the RetinaVue 700 Imager or transferred from the RetinaVue Network (requires Wi-Fi connection to the RetinaVue Network or an additional software application).
- Review: Presents images and exams from a list of patients contained on the RetinaVue 700 Imager.
- Settings. Provides controls to view or change the following in the Wi-Fi configuration:
 - Wi-Fi Off/On
 - Wi-Fi
 - Clinic / States
 - Device defaults
 - Volume
 - Sleep mode
 - Date and time
- Wi-Fi configuration Advanced settings:
 - Advanced settings code
 - Software upgrade
 - Reset factory defaults
 - Camera configuration
 - RV700 PRO Unencrypted images only (no RetinaVue Network compatibility)
 - RV700 RetinaVue Network required (USB or Wireless)
 - Exam display settings
 - Animation
 - Transparent UI
 - Enable Flash

- Disable Flash
- Disable Second Start
- **Enable Second Start**
- Export log
- **Settings.** Provides controls to view or change the following in the USB configuration:
 - Device defaults
 - Volume
 - Sleep mode
 - Date and time
- Advanced settings:
 - 0 Device access code
 - 0 Advanced settings code
 - Software upgrade
 - Reset factory defaults
 - Camera configuration 0
 - RV700 PRO Unencrypted images only (no RetinaVue Network compatibility)
 - RV700 RetinaVue Network required (USB or Wireless)
 - Exam display settings
 - Animation
 - Transparent UI
 - **Enable Flash**
 - Disable Flash
 - Disable Second Start
 - **Enable Second Start**
 - Export log
- About
 - Software version
- Regulatory Information
- Network Information
- Open source software information
- Practice mode: Provides interactive training help to practice the steps necessary to master the RetinaVue 700 Imager.

Directions for use Controls 103

3. Navigation Area

In the Wi-Fi workflow, the Navigation Area, located at the bottom of the main *Patients screen*, displays the:

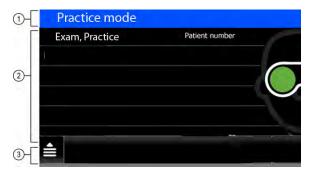
- Navigation menu. Touch and then touch Patients to navigate to the Patients menu, touch Review to navigate to the Review menu, touch Settings to navigate to the Settings menu, touch Practice to navigate to the Practice menu. (See Content Area or Patients list for further details).
- Search. Touch to navigate to the Patient list search or the Saved/
 Submitted Review menus.
- Refresh. Touch to see new patients downloaded from the RetinaVue Network Customer Portal. Wi-Fi Connection must be activate and theRetinaVue 700 Imager must be connected to the RetinaVue Network.
- Create new patient on the RetinaVue 700 Imager. Touch + to navigate to the Patient summary screen.

In the USB workflow, the Navigation Area, located at the bottom of the main *Patients screen*, displays the:

- Navigation menu. Touch and then touch Patients to navigate to the Patients menu, touch Review to navigate to the Review menu, touch Settings to navigate to the Settings menu, touch Practice to navigate to the Practice menu. (See Content Area or Patients list for further details).
- Create a new patient on the RetinaVue 700 Imager. Touch † to navigate to the *Patient summary* screen.

Device Status Area in Practice mode

The Device Status Area in Practice mode is located at the top of the main *Patients screen* and is colored blue. It prominently displays "Practice mode" and it also contains the time and the battery condition.



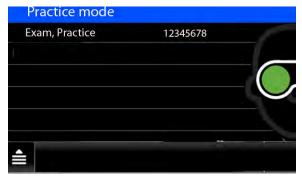
ltem	Area
1	Device status colored blue
2	Single patient "Exam, Practice"
3	Navigation — touch Patients , Review , or Exit

Practice mode

1. From the main Patients screen, touch

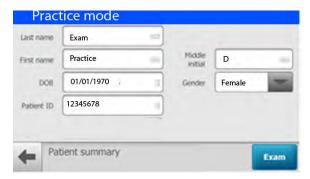


2. Touch **Practice** to enter Practice mode. Touch **OK** at the prompt: "You are about to enter practice mode. This is not a place to capture a real exam." The Practice mode screen appears.

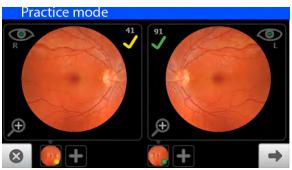


3. Touch on the "Exam, Practice" patient name or the patient number (12345678) to begin practicing with a patient exam.

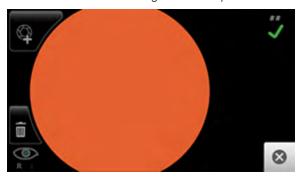
The Practice mode Patient summary screen appears.



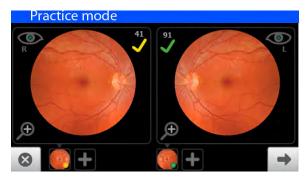
- Touch Exam.
- 5. On the LCD touchscreen, the camera prompts to "Aim and center the camera" until the images for each eye are captured.
- 6. An audible tone alerts you that the images have been captured. The acquired images appear on the LCD touchscreen for review after a few seconds.



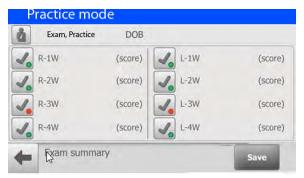
7. Touch igopha to review the current image on the *Inspection mode* screen.



8. Touch (Next) after all images are automatically captured.



Touch Save. 9.



- 10. When you complete your practice experience, touch = and then touch Exit.
- 11. Touch **OK** at the prompt: "Are you sure you want to exit practice mode?" to leave Practice mode and to return to the main Patients screen.

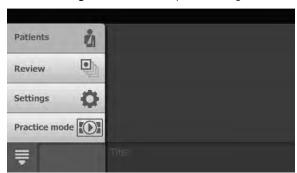
Directions for use Controls 107

Viewing or changing the RetinaVue 700 Imager settings

To view or change the settings, touch (Navigation Menu) from the main *Patients* screen.



Touch **Settings** and then modify the settings as desired.



In the Wi-Fi workflow:

- Touch Wi-Fi Off/On.
 - Touch "OFF" or "ON" to turn the wireless radio off or on.
- Touch Wi-Fi to view or reset available Wi-Fi networks. The list of available
 wireless networks in range appears. The currently selected network appears
 with a checkmark next to the network name.

Touch > to view or modify the wireless network settings from the list of available wireless networks in range. Touch **Info** to view network information. The *Network Information* screen appears:

MAC address 00:17:23:e5:d5:a5

IP address 10.20.200.70

Subnet mask 244,244,244,1

Gateway 10.20.244.1

Version 2.00.02

SSID (Your Network)

Access Point MAC B2:DE:31:OC:32:B2

RSSI -70

Touch (Back) to return to the Settings screen.

- Touch . The Wi-Fi Radio settings screen appears. See "Troubleshooting" for more information on updating Wi-Fi Radio settings.
- Touch Clinic / States. Up to 6 States may be selected for a clinic.
 - Touch **Multi-State**. The switch changes from Off to On.
 - Touch States. Touch the box next to the State abbreviation to select it.
 - Touch More. Touch OK.
 - Touch (Back) to return to the *Settings screen*.
- Touch Device defaults
 - Touch (up) or (down) to adjust the device sound volume. Touch (Back) to return to the Settings screen. Touch (down) to adjust the device sleep time. Use the scroll bar to select 5 minutes, 7 minutes, 10 minutes, or Never. Touch (Back) to return to the Settings screen.
- Touch **Date and time**.

Touch ▲ (up) or ▼ (down) to adjust the hour, minute, Continent, and Location. Use the radio buttons to select the 24-hour or 12-hour format. Touch (Back) to return to the Settings screen.

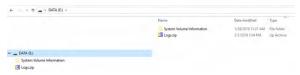
Touch **Advanced settings** and then modify the settings as desired.

- Advanced settings code. Set the Advanced settings numeric code, retype the code to confirm, and touch **OK** to return to the *Advanced settings screen*.
- **Software upgrade**. Touch **Load firmware** and touch **OK** at the prompt to load the software from a computer.
- Reset factory defaults. For Wi-FI, select "All device and radio settings" and touch **OK** to reset the device to the default setting.
- **Exam display setting.** Use the radio buttons to select **Animation**, Transparent UI, Enable Flash, Disable Flash, Disable Second Start, or

Directions for use Controls 109

Enable Second Start at the prompt: "Select what will be displaying on screen during an automatic acquisition." Touch (Back) to return to the Settings screen.

• Export Log. Exports logs into a viewable zip file. Touch **OK** at the prompt: "The log files were exported. Using a USB cable, plug the device in to the computer to copy the exported logs. When finished copying the file, unplug the device from the computer." After the RetinaVue 700 Imager is connected to a computer by the USB cable, navigate to the drive ["DATA (E:)" in the sample screen] and copy the compressed zip file to a location on the computer where the files can be viewed in a text file.



Touch (Back) to return to the Settings screen.

- Network Information. Touch Network Information to view the wireless radio (Wi-Fi) MAC address, IP address, Subnet mask, and Gateway addresses.
 Touch (Back) to return to the Settings screen.
- Touch **About** to view the software version. Touch **(Back)** to return to the *Settings screen*.
- **Regulatory Information**. Touch **Regulatory Information** to view Regulatory Information. Touch (Back) to return to the *Settings screen*.
- Open Source information. Touch Open Source information to view this open source information message: "This product may contain software known as "free" or "open source" software (FOSS). Welch Allyn uses and supports the use of FOSS. We believe that FOSS makes our products more robust and secure, and gives us and our customers greater flexibility. To learn more about FOSS that may be used in this product, please visit our FOSS website at http://www.welchallyn.com/opensource. Where required, a copy of FOSS source code is available on our FOSS website." Touch (Back) to return to the Settings screen.

In the USB workflow:

- Touch Device defaults.
 - Touch (up) or (down) to adjust the device sound volume.

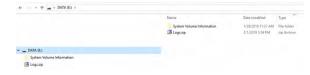
 Touch (Back) to return to the Settings screen.

0 Touch **Date and time**.

Touch (up) or (down) to adjust the hour, minute, Continent, and Location. Use the radio buttons to select the 24-hour or 12-hour format. Touch (Back) to return to the Settings screen.

0 Touch **Advanced settings**.

- **Device access code**. Set the Device access numeric code, retype the code to confirm, and touch **OK** to return to the Advanced settings screen. (USB only)
- **Advanced settings code**. Set the Advanced settings numeric code, retype the code to confirm, and touch **OK** to return to the Advanced settings screen.
- Software upgrade. Touch Load firmware and touch OK at the prompt to load the software from a computer.
- Reset factory defaults. Touch OK and select "All device settings" to reset the device to the default setting and touch **OK** again to return to the *Advanced settings screen*.
- **Exam display setting.** Use the radio buttons to select Animation, Transparent UI, Enable Flash, Disable Flash, Disable Second Start, or Enable Second Start at the prompt: "Select what will be displaying on screen during an automatic acquisition." Touch (Back) to return to the Settings screen.
- **Export Log**. Exports logs into a viewable zip file . Touch **OK** at the prompt: "The log files were exported. Using a USB cable, plug the device in to the computer to copy the exported logs. When finished copying the file, unplug the device from the computer." After the Retina Vue 700 Imager is connected to a computer by the USB cable, navigate to the drive ["DATA (E.)" in the sample screen] and copy the compressed zip file to a location on the computer where the files can be viewed in a text file.



Touch (Back) to return to the Settings screen.

Touch **About** to view the software version. Touch **(Back)** to return to the Settings screen.

Directions for use Controls 111

 Regulatory Information. Touch Regulatory Information to view Regulatory Information. Touch (Back) to return to the Settings screen.

Open Source information. Touch Open Source information to view this open source information message: "This product may contain software known as "free" or "open source" software (FOSS). Welch Allyn uses and supports the use of FOSS. We believe that FOSS makes our products more robust and secure, and gives us and our customers greater flexibility. To learn more about FOSS that may be used in this product, please visit our FOSS website at http://www.welchallyn.com/opensource. Where required, a copy of FOSS source code is available on our FOSS website." Touch (Back) to return to the Settings screen.

Power down the RetinaVue 700

- 1. Press \bigcirc .
- 2. A dialogue box appears with three options:
 - Power down
 - Sleep
 - Cancel



Touch Power down.

Enter Sleep mode

1. Press \bigcirc .

- 2. A dialogue box appears with three options:
 - Power down
 - Sleep
 - Cancel



3. Touch Sleep.

The RetinaVue 700 enters Sleep mode.

Exit sleep mode

1. Press \bigcirc or touch the LCD touchscreen.

Note Lifting or moving the RetinaVue 700 Imager also brings the RetinaVue 700 Imager out of Sleep mode.

2. After performing one of the options, the RetinaVue 700 Imager will awaken from Sleep mode, or return to the prior screen.

Set the date and time

Before first use, set the date and time:

- 1. Follow the steps in the Battery installation and replacement section to install the battery and then press and hold the power button 0 to turn the device on.
- 2. Touch **Settings** on the RetinaVue 700 Imager main *Patients* screen.
- Touch Date/Time. Touch (up) or (down) to adjust the hour, minute, Continent, and location.

Directions for use Controls 113

Note Use the radio buttons to select the 24-hour or 12-hour format.

- Touch (up) or (down) to adjust the day, month, and year in the DD/ MM/YY format.
- 5. Touch (Back) to return to the Settings screen.

Set the Device access code at the RetinaVue 700 Imager (USB only)

Note Setting the Device access code before first use

provides additional security features in the RetinaVue 700 Imager to prevent unintended access to patient information by unauthorized individuals.

Note

See First time selection of Wi-Fi connectivity workflow for instructions on setting the Device access code on the RetinaVue 700 Imager from the RetinaVue Network Customer Portal.

- 1. If not already powered on, press and hold the power button to turn the Retina Vue 700 Imager on.
- 2. From the main *Patients* screen, touch (Navigation menu).
- 3. Touch **Settings**.
- 4. Touch Advanced settings.
- Touch **Device access code** to enter an access code for the RetinaVue 700 Imager.
- 6. Use the touchscreen numeric keypad to enter an access code into the *Access code* field and then retype the same code into *Access code* (retype) field.

Note The access code password can contain a minimum of 1-digit and a maximum of 18-digits. Characters are only numeric from 0 through 9.

- 7. Touch **OK** to accept the code and touch **OK** again at the confirmation screen to return to the *Advanced settings* screen.
- 8. Touch (Back) to return to the *Patients screen*.

Reset the Device access code (USB only)

Note

See the *Troubleshooting section* if you cannot recall your RetinaVue 700 Imager access code and need to erase the access code.

- 1. If you are not already logged in, enter the existing access code for the RetinaVue 700 Imager.
- 2. Touch **Settings** on the RetinaVue 700 Imager main *Patients* screen.
- 3. Touch Advanced settings.
- Touch Device access code.
- 5. Touch **Reset** to clear the existing access codes.
- 6. Use the touchscreen numeric keypad to enter an access code into the *Access code* field and then retype the same code into the *Access code* (retype) field.

Note

The access code password can contain a minimum of 1-digit and a maximum of 18-digits. Characters are only numeric from 0 through 9.

Note

Alternatively, after the code reset, touch (Back), (Back), and to return to the RetinaVue 700 Imager main *Patients* screen without using a Device access code.

- 7. Touch **OK** to accept the code and touch **OK** again at the confirmation screen to return to the *Advanced settings* screen.
- 8. Touch (Back) to return to the Settings screen.

Reset the Advanced settings code

Note

See the *Troubleshooting section* if you cannot recall your RetinaVue 700 Imager Advanced settings code or the Device access code and need to erase the code.

- If the RetinaVue 700 Imager is set with a Device access code (in addition to the Advanced settings code) and you are not already logged in, enter the existing Device access code.
- 2. Touch **Settings** on the RetinaVue 700 Imager main *Patients* screen.
- 3. Touch Advanced settings.
- 4. Enter the existing Advanced settings code for the RetinaVue 700 Imager.
- Touch Advanced settings code.
- 6. Touch **Reset** to clear the existing Advanced settings codes.

Directions for use Controls 115

7. Use the touchscreen numeric keypad to enter a code into the *Advanced* settings code field and then retype the same code into the *Advanced settings* code (retype) field.

Note The Advanced settings code password can contain a minimum of 1-digit and a maximum of 18-digits.

Characters are only numeric from 0 through 9.

Note Alternatively, after the code reset, touch (Back), (Back) to return to the RetinaVue 700 Imager main Patients screen without using an Advanced setting code.

- 8. Touch **OK** to accept the code and touch **OK** again at the confirmation screen.
- 9. Touch (Back) to return to the Settings screen.

Troubleshooting

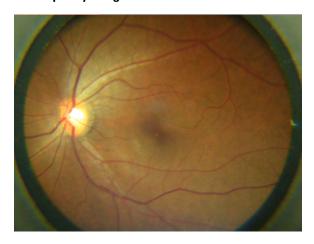


CAUTION A defective device should not be used. A device with parts which may be broken or missing, visibly worn, distorted, or contaminated should be replaced immediately.

To correct an error, follow these instructions or contact Welch Allyn Technical Support: www.welchallyn.com/service.

Troubleshooting image quality

Good quality image



Problem

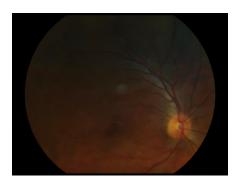
Solution

Partial blink



Ask the patient to keep his or her eye open.

Dark semi-circle on top



Move the patient side of the camera down and away from dark semi-circle.

Dirty lens



Clean the lens with an appropriate cleaning cloth.

Directions for use Troubleshooting 11

Information messages

Information message/problem

Solution



Dirty lens

Clean the camera lens with the recommended cleaner such as Thorlabs Inc. found in the topic Cleaning the RetinaVue 700 lens

Small pupil

To ensure that the patient's pupils sufficiently dilate to at least 3.0 mm diameter, adjust the room lighting to the lowest possible level. If necessary, have the patient sit in a dark room for 5 minutes to dilate their pupils.

Refer to instructions to improve score

See the *Directions for use* and the *Technique guide* for further detail.



If an image is missing touch (Image Missing) to capture an image.

Missing image

The battery is running low. Please recharge.

When the battery charge level is below 10 percent, the low battery error message appears. Connect the camera

Information message/problem	Solution	
	to the power supply to charge the battery.	
The battery level is too low to acquire any image. Please recharge now.	Connect the camera to the power supply to charge the battery.	
There are unsubmitted exams that need to be sent so your patients can be diagnosed.	See the <i>Review</i> topic for further information on submitting exams.	
Error message/problem	Solution	
Error message/problem Error connecting to the network.	Confirm that the network signal strength is sufficient.	
	Confirm that the network signal	

Computer information messages (USB only)

Problem	Solution
The Windows® operating system may display the Scan and fix or Continue without scanning message once the camera USB cable is removed from the laptop or PC.	message appears in situations when
The Windows® operating system may display the	By default, the AutoPlay notification is

The Windows® operating system may display the Autoplay notification popup dialogue box each time the camera the USB cable is connected to the laptop or PC.

By default, the AutoPlay notification is displayed when a USB storage device is connected to the laptop or PC. To disable this notification, select **Control Panel > AutoPlay** from the Windows® Start menu. Uncheck the *Use AutoPlay* for all media and devices checkbox. Click **Save**.

Directions for use Troubleshooting 121

Problem Solution



Problem Solution

Battery is not installed. Camera will not charge.

The power indicator LED light on the camera blinks between green and amber when charging.

Install the battery and check to ensure that the connector pins on the battery and the device are properly seated.

Wireless connectivity

Problem Solution

Cannot connect to the network.

Connection drops.

Ensure that the signal strength is sufficient. The signal strength appears in the top right corner of the device status bar.



Wireless signal strength

- Best (4 bars)
- Good (3 bars)

Problem	Solution
	- Fair (2 bars)
	- Weak (1 bar)
Cannot connect to the RetinaVue Network Server.	Ensure that Wi-Fi is connected.
	Touch Settings .
Message: Error connecting to the network using	
the supplied credentials.	Touch Wi-Fi .
	Ensure that a network name appears. If
	no name appears, then select a
	network name again, enter a Username
	and Password and touch OK .
	Wi-FI Off/On
	Wi-Fi Status >
	Clinic / States) Device defaults)
	Date and time
	Advanced settings Settings
	i settings
	Ensure that IP address is populated and
	shows a valid IP address other than 00:
	00:00:00:00:00.
	Touch Settings .
	Touch Network Information . The
	Network Information screen appears.
	MAC address 00:17:23:e5:d5:a5
	IP address 10.20.200.70
	Subnet mask 255.255.255.1
	Gateway 10.20.244.1

Version 2.00.02

Directions for use Troubleshooting 123

Problem Solution **SSID Your Network** Access Point MAC B2:DE:31:OC: 32:B2 **RSSI-70** Message: Failure to connect to the portal. Unable Follow all steps for connecting to RetinaVue Network Server. to delete patient information. Clinic network does not appear in the Wi-Fi list. Ensure that your network meets the supported credentials type. Check with your network administrator and ensure the network you are attempting to connect with has one of the following security types: Enterprise WPA2-PSK, PEAP-MSCHAPv2, EAP-TLS with certificates

Hidden SSID networks

Manually enter the network name.

Touch Settings.

Touch Wi-Fi.

Scroll to the bottom of the list. Touch Other and launch the keyboard to enter the network name, followed by password, and then select security type.



Solution



Camera does not connect to the network.

Ensure that correct network credentials are used.

For PSK, ensure that the correct Username and Password are entered.

Touch **Settings**.

Touch Wi-Fi.

Select a network name from the list, enter your Username and Password, and check the "Remember this connection" checkbox. Every time you reboot the camera, it will connect to the network automatically.

For TLS, ensure that the correct Username is entered.

Touch **Settings**.

Touch Wi-Fi.

Select a network name from the list, enter your credentials and check the "Remember this connection" checkbox. Every time you reboot the camera, it will connect to the network automatically.

Directions for use Troubleshooting 12

Problem Solution



Patient List is empty.

Follow all steps for connecting to RetinaVue Network Server.

Touch to refresh the scheduled patients



Exam was not sent to the RetinaVue Network Server.

Follow all steps for connecting to RetinaVue Network Server.

To view or change the settings, touch



Touch Review.

From the Submitted status, click on the following icons for additional status messages:

- Waiting to upload

- submitted

- report available

Note: After exam has been over-read it will be removed from submitted column.

Check your network connection. If your saved exam does not appear in the Review list, then it was successfully submitted to the RetinaVue Network

Solution

Server. Check the "View New Diagnostic Reports" area on the RetinaVue Network Customer Portal. Select your clinic name from the dropdown menu. Find your patient and check the Report column. A "Submitted" status confirms that the exam was successfully received by the RetinaVue Network Server.



Maintenance

Clean and disinfect



CAUTION Never submerge the RetinaVue 700 Imager in water or any other liquid.



CAUTION Never use abrasive cleaning agents, thinners or benzene for cleaning and never immerse the instrument in water or other cleaning liquids.



CAUTION Never insert a sharp object into the device or any open surface on the RetinaVue 700 Imager.



CAUTION Do not use unapproved cleaning or disinfection agents. Use of these agents may cause damage to components.



CAUTION When cleaning the device and the battery charger, avoid using cloths or solutions that include quaternary ammonium compounds (ammonium chlorides) or glutaraldehyde-based disinfectants.



CAUTION Do not use bleach solutions of any kind when cleaning metal electrical contacts. They will damage the battery charger and the device.

Note

Clean on a routine basis according to your facility's protocols and standards or local regulations.

The RetinaVue 700 Imager has been tested to verify that it is compatible with the approved cleaning agents.

Cleaning the RetinaVue 700 Imager lens

Wipe the surface of the lens with a cleaning cloth or a lens cleaning tissue such as Thorlabs Inc.. Avoid touching the lens except when cleaning is required.

Cleaning the Retina Vue 700 Imager and face cup

Power off the RetinaVue 700 Imager before cleaning it.

Use a pre-moistened wipe or soft cloth slightly moistened with an approved cleaner to gently clean the RetinaVue 700 Imager and face cup.

Cleaning the battery charger

Use a pre-moistened wipe or soft cloth slightly moistened with an approved cleaner to gently clean the battery charger.

Disinfecting the RetinaVue 700 Imager, face cup, and battery charger

Note Disinfect according to your facility's protocols and standards or local regulations.

Use a pre-moistened wipe or soft cloth slightly moistened with an approved disinfectant to disinfect the RetinaVue 700 Imager, face cup, and battery charger. Follow the manufacturers recommendations.

Approved cleaning agents

Use only the following approved cleaning agents on the RetinaVue 700 Imager, face cup, and battery charger:

- 70 percent isopropyl alcohol
- CaviWipes
- Sani-Cloth® Plus
- Super Sani-Cloth®

The RetinaVue 700 Imager has been tested to verify these instructions as being capable of preparing the RetinaVue 700 Imager for re-use. You must ensure that cleaning and disinfection as actually performed by your personnel, with your equipment and materials, achieves the desired result. This may require validation and routine monitoring of your actual process.

Specifications

Specifications

Field of View	60 degrees ±5% horizontal
	45 degrees ±5% vertical
Pupil size	3.0 mm (minimum)
Working distance	19 - 21 mm from objective lens to cornea
Dimensions	Width: 6.6 inches (167 mm)
	Height: 4.2 inches (106 mm)
	Length without adapter spacer: 11.4 inches (290.2 mm)
	Length with adapter spacer: 12 inches (305.4 mm)
Weight	2.8 pounds (with 2 cell battery, without adapter spacer)
Search Fundus Lighting	Infrared LED
Camera flash light	2 Light Emitting Diodes (LEDs)

Captures	Auto capture and Manual capture	
	Anterior image	
Camera Resolution	2048 x 1536 pixels	
LCD Monitor	6 inch Full Color TFT-LCD	
Image Format	DICOM compliant	
Interface	Micro USB	
File Transfer	Wired	USB to PC by micro USB cable to PC running RetinaVue Network (requires additional software)
	Wireless	WPA2, FIPS certification to Welch Allyn server
File Storage	Integrated storage Ability to save a minimum of 2000 images (500 standard exams, both eyes, using the default protocol) with patient context and camera settings of each image in Integrated storage.	
Power Source	Rechargeable Lithium-ion Battery	
External Power	Source: 100~240 VAC, 50/60 Hz	
Power Adapter Spec.	Input Spec. : 100~240 VAC, 50/60 Hz, 0 3A	0.5A-1.0A; Output Spec. : 12V DC,

Directions for use Specifications 131

Operating Time	3 hours at 5 minutes working mode.
	Once set, the device enters Sleep mode if idle for the set time of 2, 5, 7, or 10 minutes.
	Unless <i>Never</i> is selected, the RetinaVue 700 Imager powers down after 10 minutes of inactivity in Sleep mode.
Charging	5 hours to full charge via 3A @12V
Time	3 hours to full charge the empty 2-cell battery via 3A@12V DC adapter in power off.
	5 hours to full charge the empty 4-cell battery via 3A@12V DC adapter in power off.

All specifications are subject to change.

Operating environment

Criterion	Environmental conditions	
Temperature	+ 10 °C to + 35 °C	
Relative humidity	30 % to 90 %	
Atmospheric pressure	800 hPa to 1060 hPa	

Storage environment

Criterion	Environmental conditions	
Temperature	– 10 °C to + 55 °C	
Relative humidity	10 % to 95 %	
Atmospheric pressure	700 hPa to 1060 hPa	

Transportation environment

Criterion	Environmental conditions
Temperature	– 40 °C to + 70 °C
Relative humidity	10 % to 95 %
Atmospheric pressure	500 hPa to 1060 hPa

Device lifetime

The lifetime of the device is five (5) years. The manufacture date of the device can be found on the device labels.

Welch Allyn will service RetinaVue 700 Imager devices that are within their lifetime. Firmware updates and support may require an annual subscription service after the initial one (1) year warranty period. The expected battery life is at least one (1) year. If the RetinaVue 700 Imager device fails to hold a charge, a new battery can be ordered.

Device radio

The RetinaVue 700 Imager's radio operates on 802.11 networks.

Feature	Descritption		
Regulatory	FCC (Americas, Parts of Asia, and Middle East)		
Domain Support	ETSI (Europe, Middle East, Africa, and Parts of Asia)		
	MIC (Japan) (formerly TELEC)		
	KC (Korea) (formerly KCC)		
2.4 GHz	ETSI: 2.4 GHz to 2.483 GHz	MIC: 2.4 GHz to 2.495 GHz	
Frequency Bands	FCC: 2.4 GHz to 2.483 GHz	KC: 2.4 GHz to 2.483 GHz	
2.4 GHz	ETSI: 13 (3 non-overlapping)	MIC: 14 (4 non-overlapping)	
Operating Channels	FCC: 11 (3 non-overlapping)	KC: 13 (3 non-overlapping)	
5 GHz	ETSI: 5.15 GHz to 5.35 GHz	MIC: 5.15 GHz to 5.35 GHz	
Frequency Bands	5.47 GHz to 5.725 GHz	KC: 5.47 GHz to 5.725 GHz	
	FCC: 5.15 GHz to 5.35 GHz	MIC: 5.15 GHz to 5.35 GHz	
	5.47 GHz to 5.725 GHz	KC: 5.47 GHz to 5.725 GHz	

Feature	Descritption		
	5.725 GHz to 5.825 GHz		
5 GHz	ETSI: 19 non-overlapping	MIC:	19 non-overlapping
Operating Channels	FCC: 24 non-overlapping	KC:	19 non-overlapping
WLAN standard	IEEE802.11a/b/g/n, Wi-Fi compl	iant	
Data Rate	802.11a: 54, 48, 36, 24, 18, 12, 9, 6 Mbps OFDM 802.11b: 11, 5.5, 2, 1 Mbps DSSS 802.11g: 54, 48, 36, 24, 18, 12, 9, 6 Mbps OFDM 802.11n: HT20 MCS0~7, OFDM		
Modulation	BPSK @ 1, 6, 6.5, 7.2 and 9 Mbps QPSK @ 2, 12, 13, 14.4,18, 19.5 and 21.7 Mbps CCK @ 5.5 and 11 Mbps 16-QAM @ 24, 26, 28.9, 36, 39 and 43.3 Mbps 64-QAM @ 48, 52, 54, 57.8, 58.5, 65, and 72.2 Mbps		
Host interface	USB 2.0		
Encryption	Wireless Equivalent Privacy (WEP), Wi-Fi Protected Access (WPA), IEEE 802.11i (WPA2)		
Antenna	PCB Dipole, IPEX MHF, Max Gain: 2.4-2.5 GHz: 2 dBi 5.15-5.35 GHz: 3.9 dBi 5.6 GHz: 4 dBi		
Agency approvals	US: FCC Part15 Subpart B, Part (DFS) Europe: EN 301 893 V2.1.1:207 V2.2.0:2017, EN 301 489-17 V3 Australia and New Zealand: A Authority (ACMA) Radio Compli	7, EN 300 3 .2.0:2017 .ustralian Co	28 V2.1.1:2017, EN 301 489-1

Directions for use Device radio 135

Feature	Descritption
	New Zealand maintains a Mutual Recognition Agreement (MRA) with Australia.

To ensure compliance with local regulations, be sure the correct country in which the access point is installed is selected. This product can be used with the following restriction(s):

Norway - Does not apply for the geographical area within a radius of 20 km from the center of Ny-Ålesund.

France - Outdoor use is limited to 10 mW EIRP within the band 2454 to 2483.5 MHz.

Note Effective Isotropic Radiated Power (EIRP).

General compliance and standards

The RetinaVue 700 Imager complies with the following standards:

IEC 60601-1:2005/A1:2012 (EN 60601-1:2006/A1:2013)

IEC 60601-1-2: 2014 (EN 60601-1-2: 2015)

ISO 15004-1: 2006

ISO 15004-2: 2007

ISO 10940: 2009

ISO 10993-1: 2009

ISO/EN 14971

IEC/EN 62304+AC

IEC 62366

EN 1041



Directive 2002/96/EC-WEEE:

Disposal of noncontaminated electrical and electronic equipment

This product and its accessories must be disposed of according to local laws and regulations. Do not dispose of this product as unsorted municipal waste. Prepare this product for reuse or separate collection as specified by Directive 2002/96/EC of the European Parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE). If this product is contaminated, this directive does not apply.

For more specific disposal or compliance information, see www.welchallyn.com/ weee, or contact Welch Allyn Customer Service at +44 207 365 6780.

General radio compliance

The wireless features of this device must be used in strict accordance with the manufacturer's instructions as described in the user documentation that comes with the product.

Federal Communication Commission Interference Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. This device meets all the other requirements specified in Part 15E, Section 15.407 of the FCC Rules.

Innovation, Science and Economic Development Canada (ISED) – Canada Statement:

This device complies with ISED license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d' ISED applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

For product available in the USA/Canada market, only channel 1~11 can be operated. Selection of other channels is not possible.

Pour les produits disponibles aux États-Unis / Canada du marché, seul le canal 1 à 11 peuvent être exploités. Sélection d'autres canaux n'est pas possible.

- (i) the device for operation in the band 5150-5250 MHz is only for indoor use to reduce the potential for harmful interference to co-channel mobile satellite systems;
- (ii) the maximum antenna gain permitted for devices in the bands 5250-5350 MHz and 5470-5725 MHz shall comply with the e.i.r.p. limit.
- (iii) the maximum antenna gain permitted for devices in the band 5725-5825 MHz shall

comply with the e.i.r.p. limits specified for point-to-point and non point-to-point operation as appropriate.

- (iv) the worst-case tilt angle(s) necessary to remain compliant with the e.i.r.p. elevation mask requirement set forth in Section 6.2.2(3) shall be clearly indicated.
- (v) users should also be advised that high-power radars are allocated as primary users (i.e. priority users) of the bands 5250-5350 MHz and 5650-5850 MHz and that these radars could cause interference and/or damage to LE-LAN devices.
- (i) les dispositifs fonctionnant dans la bande 5150-5250 MHz sont réservés uniquement pour une utilisation à l'intérieur afin de réduire les risques de brouillage préjudiciable aux systèmes de satellites mobiles utilisant les mêmes canaux:

- (ii) le gain maximal d'antenne permis pour les dispositifs utilisant les bandes 5250-5350 MHz et 5470-5725 MHz doit se conformer à la limite de e.i.r.p.
- (iii) le gain maximal d'antenne permis (pour les dispositifs utilisant la bande 5725-5825 MHz) doit se conformer à la limite de e.i.r.p. spécifiée pour l'exploitation point à point et non point à point, selon le cas.
- (iv) les pires angles d'inclinaison nécessaires pour rester conforme à l'exigence de la e.i.r.p. applicable au masque d'élévation, et énoncée à la section 6.2.2 3), doivent être clairement indiqués.
- (v) de plus, les utilisateurs devraient aussi être avisés que les utilisateurs de radars de haute puissance sont désignés utilisateurs principaux (c.-à-d., qu'ils ont la priorité) pour les bandes 5250-5350 MHz et 5650-5850 MHz et que ces radars pourraient causer du brouillage et/ou des dommages aux dispositifs LAN-EL.

Operations in the 5.25-5.35 GHz band are restricted to indoor usage only.

Les opérations dans la bande de 5.25-5.35 GHz sont limités à un usage intérieur seulement.

Radiation Exposure Statement

These requirements set a SAR limit of 1.6 W/kg averaged over one gram of tissue. The highest SAR value reported under this standard during product certification for use when properly worn on the body is 0.97 W/kg.

Ces exigences établissent une limite SAR de 1.6 W / kg en movenne sur un gramme de tissu. La valeur SAR la plus élevée déclarée selon cette norme lors de la certification du produit à utiliser lorsqu'il est correctement porté sur le corps est de 0.97 W/kg.

European Union

Czech	Medimaging Integrated Solution Inc. (MiiS) tímto prohlašuje, že tento vysílač s nízkým výkonem je v souladu se základními požadavky a dalšími příslušnými ustanoveními směrnice 2014/53/ ES
Danish	Medimaging Integrated Solution Inc. (MiiS) erklærer herved, at denne lavt strøm transmitter er i overensstemmelse med de væsentlige krav og andre relevante bestemmelser i direktiv 2014/53/EF
Dutch	Hierbij verklaart Medimaging Integrated Solution Inc. (MiiS) dat deze low power transmitter voldoet aan de essentiële eisen en andere relevante bepalingen van Richtlijn 2014/53/EG
English	Hereby, Medimaging Integrated Solution Inc. (MiiS) declares that this low power transmitter is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EC.

Estonian	Käesolevaga Medimaging Integrated Solution Inc. (MiiS) teatab, et see väikese võimsusega saatja on vastavus olulistele nõuetele ja teistele asjakohastele sätetele direktiivi 2014/53/ EÜ	
Finnish	Näin ollen Medimaging Integrated Solution Inc. (MiiS) vakuuttaa, että tämä pienitehoinen lähetin on direktiivin 2014/53/EY olennaisten vaatimusten ja muiden asiaa koskevien säännösten mukainen	
French	Par conséquent, Medimaging Integrated Solution Inc. (MiiS) déclare que cet émetteur de faible puissance est conforme aux exigences essentielles et autres dispositions pertinentes de la directive 2014/53/CE	
German	Hiermit erklärt Medimaging Integrated Solution Inc. (MiiS), dass dieser Niedrigleistungssender den grundlegenden Anforderungen und anderen relevanten Bestimmungen der Richtlinie 2014/53/EG entspricht	
Greek	Με αυτό τον τρόπο, η Medimaging Integrated Solution Inc. (MiiS) δηλώνει ότι αυτός ο πομπός χαμηλής ισχύος είναι σύμφωνος με τις βασικές απαιτήσεις και άλλες σχετικές διατάξεις της οδηγίας 2014/53/ΕΚ	
Hungarian	A Medimaging Integrated Solution Inc. (MiiS) ezúton kijelenti, hogy ez az alacsony teljesítményű adó megfelel a 2014/53/EK irányelv alapvető követelményeinek és egyéb vonatkozó rendelkezéseinek	
Italian	In questo modo, Medimaging Integrated Solution Inc. (MiiS) dichiara che questo trasmettitore di bassa potenza è conforme ai requisiti essenziali e alle altre pertinenti disposizioni della direttiva 2014/53/CE.	
Latvian	Ar šo, Medimaging Integrated Solution Inc. (MiiS) paziņo, ka šis mazjaudas raidītājs atbilst būtiskajām prasībām un citiem attiecīgiem noteikumiem Direktīvā 2014/53/EK	
Lithuanian	Šiuo dokumentu Medimaging Integrated Solution Inc. (MiiS) deklaruoja, kad šis mažas energijos siųstuvas atitinka esminius reikalavimus ir kitas susijusias nuostatas Direktyva 2014/53/EB	
Malti	Hawnhekk, Medimaging Integrated Solution Inc. (MiiS) jiddikjara li din trasmettitur enerģija baxxa hija konformi mar-rekwiżiti essenzjali u dispożizzjonijiet rilevanti oħra tad-Direttiva 2014/53/KE	
Polish	Niniejszym Medimaging Integrated Solution Inc. (MiiS) oświadcza, że ten nadajnik o małej mocy jest zgodny z zasadniczymi wymaganiami i innymi istotnymi przepisami dyrektywy 2014/53/ WE	
Portuguese	Por este motivo, a Medimaging Integrated Solution Inc. (MiiS) declara que este transmissor de baixa potência está em conformidade com os requisitos essenciais e outras disposições relevantes da Diretiva 2014/53/CE	
Slovak	Medimaging Integrated Solution Inc. (MiiS) týmto vyhlasuje, že tento vysielač s nízkym výkonom je v súlade so základnými požiadavkami a ďalšími príslušnými ustanoveniami smernice 2014/53/ES	
Slovene	S tem, Medimaging Integrated Solution Inc. (MiiS) izjavlja, da je ta nizka moč oddajnik v skladu z bistvenimi zahtevami in drugimi ustreznimi določbami Direktive 2014/53/ES	
Spanish	Por este medio, Medimaging Integrated Solution Inc. (MiiS) declara que este transmisor de baja potencia cumple con los requisitos esenciales y otras disposiciones pertinentes de la Directiva 2014/53/EC	
Swedish	Medimaging Integrated Solution Inc. (MiiS) förklarar härigenom att denna låg effekt sändare överensstämmer med de väsentliga kraven och andra relevanta bestämmelser i direktiv 2014/53/EG	

EMC compliance

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment. This device complies with IEC 60601-1-2: 2014 (EN 60601-1-2: 2015).

- All medical electrical equipment must be installed and put into service in accordance with the EMC information provided in this *Directions for use*.
- Portable and mobile RF communications equipment can affect the behavior of medical electrical equipment.

The device complies with all applicable and required standards for electromagnetic interference.

- It does not normally affect nearby equipment and devices.
- It is not normally affected by nearby equipment and devices.
- However, it is good practice to avoid using the device in extremely close proximity to other equipment.
- It is not safe to operate the device in the presence of high-frequency surgical equipment.



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



WARNING Use only Accessories recommended by Welch Allyn for use with the device. Accessories not recommend by Welch Allyn may affect the EMC emissions or immunity.



WARNING Maintain minimum separation distance between the device and portable RF communication equipment. Performance of the device may be degraded if proper distance is not maintained

Emissions and immunity information

necessary to take mitigation measures, such as re-orienting or relocating the device or

Electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The customer or user of the device should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance		
RF emissions CISPR 11	Group 1	The device 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 device is suitable for use in all establishments, including domestic establishments and those directly—connected to the public low voltage power supply network		
Harmonic emissions	Class A	that supplies buildings used for domestic purposes.		
IEC 61000-3-2		WARNING This equipment/system is		
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	intended for use by healthcare profession only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment a. It may be a support of the control		

shielding the location. ^a The device contains a 5-GHz orthogonal frequency-division multiplexing transmitter or a 2.4-GHz frequency hopping spread-spectrum transmitter for the purpose of wireless communication. The radio is operated according to the requirements of various agencies, including FCC 47 CFR 15.247 and Radio Equipment Directive 2014/53/EU. The transmitter is excluded from the EMC requirements of 60601-1-2, but should be considered when addressing possible interference issues between this and other devices.

Electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst	±2 kV for power supply lines	±2 kV	Mains power quality should be that of a typical professional
IEC 61000-4-4	±1 kV for input/output lines	±1 kV	healthcare facility environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV Line- to -line	±1 kV	Mains power quality should be that of a typical professional healthcare facility environment.

Electromagnetic immunity

±0.5 kV, ±1 kV, ±2 kV Line-to-ground	±2 kV		
0 % U _T ; 0.5 cycle	0 % U _T ; 0.5 cycle	Mains power quality should be that of a typical professional healthcare facility environment. It was the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.	
At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°			
0 % U _T ; 1 cycle	0 % U _T ; 1 cycle		
70 % U _T ; 25/30 cycles Single phase: at 0°	70 % U _T ; 25/30 cycles		
0 % U _T ; 250/300 cycle	0 %U _T ; 250/300 cycle	_	
30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical professional healthcare facility environment.	
	Line-to-ground 0 % U _T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U _T ; 1 cycle 70 % U _T ; 25/30 cycles Single phase: at 0° 0 % U _T ; 250/300 cycle	Line-to-ground 0 % U _T ; 0.5 cycle 0 % U _T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U _T ; 1 cycle 0 % U _T ; 1 cycle 70 % U _T ; 25/30 cycles Single phase: at 0° 0 % U _T ; 250/300 cycle 0 % U _T ; 250/300 cycle	

Electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$
	6Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz.	6Vrms .	$d = \left[\frac{12}{V_2}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/M, 80 MHz to 2.7 GHz	10 V/M	$d = \left[\frac{23}{E1}\right]\sqrt{P}$ 800 MHz to 2.7 GHz
			$d = \left[\frac{12}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz
			where P is the maximum output power rating of the transmitter in watts (W) and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , 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:
			$((\bullet))$

Note1: 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.

^aField 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

Electromagnetic immunity

^bOver the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (m)			
Rated max. output power of	150 kHz to 80 MHz 150 kHz to 80 MHz outside ISM bands in ISM bands			
transmitter (W)	$d = [\frac{3.5}{V1}]\sqrt{P}$	$d = [\frac{12}{V_2}]\sqrt{P}$	$d = \left[\frac{12}{E_1}\right]\sqrt{P}$	$d = \left[\frac{23}{E_1}\right] \sqrt{P}$
0.01	0.12	0.20	0.12	0.23
0.1	0.37	0.63	0.38	0.73
1	1.17	2.00	1.20	2.30
10	3.69	6.32	3.79	7.27
100	11.67	20.00	12.00	23.00

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.

Test specifications	for enclosure po	ort immunity to I	RF wireless	communicatio	ns equipment

Test frequency (MHz)	Band ^a MHz	Service ^a	Modulation ^b	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380 - 390	TETRA 400	Pulse modulation ^b 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM ^c ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE band 13, 17	Pulse modulation ^b	0.2	0.3	9

745			217 Hz			
780						
810	800 - 960	GSM 800/900,	Pulse	2	0.3	28
870		TETRA 800, iDEN 820,	modulation b			
930		CDMA 850, LTE Band 5	18 Hz			
1720	1700 - 1990	GSM 1800;	Pulse	2	0.3	28
1845		CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	modulation ^b 217 Hz			
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^b 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/		0.2	0.3	9
5500		n	modulation b			
5785			217 Hz			

^a For some services, only the uplink frequencies are included.

^c As an alternative to FM modulation, 50 percent pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.



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

The minimum separation distance for higher immunity test levels shall be calculated using the following

 $E = \frac{6}{d} \sqrt{P}$, where P is the maximum power in watts (W), d is the minimum separation distance in meters (m), and E is the immunity test level in V/m.

^b The carrier shall be modulated using a 50 percent duty cycle square wave signal.

Retina Vue 700 Imager Accessories

Pedestal stand

Part number	Description
107145	RetinaVue 700 Imager Pedestal stand

Miscellaneous items

Part number	Description
RV700-B	RetinaVue 700 Imager with lithium-ion battery and US plug
106145	RetinaVue 700 Imager neck strap
106146	RetinaVue 700 Imager wrist strap
107142	Battery (standard capacity) for RetinaVue 700 Imager; Lithium-Ion 3200mAh
107143	Battery (high capacity) for RetinaVue 700 Imager; Lithium-Ion 6400mAh
107144	Battery charger for RetinaVue 700 Imager
107147	Power supply wall adapter for RetinaVue 700 Imager. 100-240 V; IEC Plug Type B (US)
107148	Power supply wall adapter for RetinaVue 700 Imager. 200-240 V; IEC Plug Type C (EU)
107149	Power supply wall adapter for RetinaVue 700 Imager. 200-240 V; IEC Plug Type G (UK)
107180	Power supply wall adapter for RetinaVue 700 Imager. 200-240 V; IEC Plug Type I (AU)

Part number	Description
107181	Replacement USB Cable for RetinaVue 700 Imager
728139	RetinaVue 700 Battery cover
723481	Laptop for RetinaVue Network
723671	Lens cloth
729097	RetinaVue 700 Imager Spacer, Anterior Imaging

Applied parts

Part number **Description**

107146 Reusable Face Cup for RetinaVue 700 Imager: Qty. 1

Service

Part number	Description
S1-RV700-1	Welch Allyn Partners in Care Comprehensive Partnership Program Service for RetinaVue 700 Imager; 1 year
SV-RV700-2	Welch Allyn Partners in Care Comprehensive Partnership Program Service for RetinaVue 700 Imager; 2 years
S1-RV700-5	Welch Allyn Partners in Care Comprehensive Partnership Program Service for RetinaVue 700 Imager; 5 years
S1-RV700-1P	Welch Allyn Partners in Care Comprehensive Partnership Program Premium Service for RetinaVue 700 Imager; 1 year
S1-RV700-2P	Welch Allyn Partners in Care Comprehensive Partnership Program Premium Service for RetinaVue 700 Imager; 2 years
S1-RV700-5P	Welch Allyn Partners in Care Comprehensive Partnership Program Premium Service for RetinaVue 700 Imager; 5 years

Literature/Documentation

Part number	Description
728140	RetinaVue 700 Imager Startup guide
728141	RetinaVue 700 Imager Technique guide

Part number	Description
728142	RetinaVue 700 Imager Quick start guide
728143	RetinaVue 700 Imager Patient education poster

Carry Case

Part number	Description
107200	RetinaVue 700 Imager Premium carry case with shoulder strap

Warranty

Welch Allyn warrants the product to be free of defects in material and workmanship and to perform in accordance with manufacturer's specifications for the period of one year from the date of purchase from Welch Allyn or its authorized distributors or agents.

The warranty period shall start on the date of purchase. The date of purchase is: 1) the invoiced ship date if the device was purchased directly from Welch Allyn, 2) the date specified during product registration, 3) the date of purchase of the product from a Welch Allyn authorized distributor as documented from a receipt from said distributor.

This warranty does not cover damage caused by: 1) handling during shipping, 2) use or maintenance contrary to labeled instructions, 3) alteration or repair by anyone not authorized by Welch Allyn, and 4) accidents.

Shipping cost to return a device to a Welch Allyn Service center is not included.

A service notification number must be obtained from Welch Allyn prior to returning any products or accessories to Welch Allyn's designated service centers for repair. To obtain a service notification number, contact Welch Allyn Technical Support.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. WELCH ALLYN'S OBLIGATION UNDER THIS WARRANTY IS LIMITED TO REPAIR OR REPLACEMENT OF PRODUCTS CONTAINING A DEFECT. WELCH ALLYN IS NOT RESPONSIBLE FOR ANY INDIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM A PRODUCT DEFECT COVERED BY THE WARRANTY.



Advancing Frontline Care $^{\scriptscriptstyle\mathsf{TM}}$

Material No.

729216