Welch Allyn RetinaVue™ 100 Imager Pro

Directions for use

Software version 6.XX

Welch Allyn®

Advancing Frontline Care™

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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

	Power button		Direct current (DC)
	Rated power input, DC		Rated power output, DC
	Fuse		Rechargeable battery
	Battery Charging - Non-AC powered		

Connectivity symbols

	USB

Wireless radio symbols

	Non-ionizing electromagnetic radiation		Australian Communications and Media Authority (ACMA) Radio Compliance Mark (RCM)
FCC ID 	The identification number assigned by the Federal Communication Commission 2AFB3WA-WEC100	**IC ID**	Industry Canada identification number. The equivalent governing body to the FCC in the United States 21375-WAWEC100 CAN ICES-3 (B)/NMB-3(B)

Shipping, storing, and environment symbols

	Temperature limit		Keep Dry
	Separate collection of Electrical and Electronic Equipment. Do not dispose as unsorted municipal waste.		Fragile
	Humidity limitation		Atmospheric pressure limitation
	This way up		Stacking limit by number
	Recyclable		

Miscellaneous symbols

	Product Identifier		Reorder Number

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	SN	Serial Number
EC REP	Authorized Representative in the European Community		

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 25 percent.
	Device is running on battery and charge is below 10 percent. Device blinks with alternating icons.		Device is connected to a power supply and is docked.

Introduction

Intended use

The Welch Allyn RetinaVue 100 Imager is a digital hand-held eye-fundus camera used to record digital photographs of the fundus (including retina, macula and optic disc) of the human eye and surrounding area.

Prescription only or "For Use by or on the order of a licensed medical professional".

Note It is the responsibility of the health care provider to protect patient health information and to meet regulatory and HIPAA compliance. The images on the RetinaVue 100 Imager Pro may contain identifiable patient information and it is the responsibility of the health care provider to ensure that data safeguards are implemented to protect patient health information.

For information on configuring the RetinaVue 100 Imager Pro device to connect to the RetinaVue Network system, contact Welch Allyn support to discuss setting up a RetinaVue Network account.

About warnings and cautions

Warning and caution statements can appear on the RetinaVue 100 Imager device, the packaging, the shipping container, or in this *Directions for use*.

The RetinaVue 100 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 100 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 eye cup after each patient to avoid the risk of cross-contamination.

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.

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 100 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 100 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 100 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.

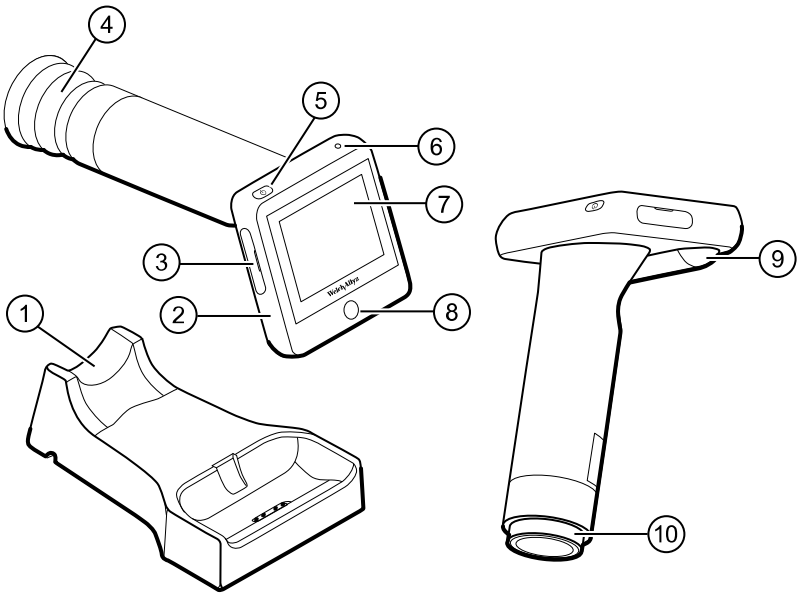
CAUTION Do not use automatic cleansing machines or sterilization.

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 100 Imager can be used on patients with eye implants and intraocular lenses. While the RetinaVue 100 Imager can be used on patients with cataracts and other eye opacities, the use of the RetinaVue 100 Imager may result in a lower quality image due to the increased reflection of the flash off the patient's intraocular lens.

Controls and connectors



No.	Feature	Description
1	Docking station	Charges the RetinaVue 100 Imager Pro and enables data transfer to a computer. Connect to an electrical outlet or to the "Always On" USB port of a computer. **Note** USB ports supply power only when the computer is on. However, many newer computers contain a yellow "Always On" USB port that can supply power even when the computer is sleeping, hibernating, or turned off. See you computer manufacturer's user documentation for instructions on changing the power management options and for identifying the "Always On" USB port.
2	RetinaVue 100 Imager device	Digital hand-held eye-fundus camera used to record digital photographs of the fundus of the human eye and surrounding area.
3	SD Card port/service port	SD Card slot. Insert SD Card for data storage. **Note** The service port under the SD Card cover is for factory use only and is not for customer use.
4	Eye cup	Blocks ambient light during testing
5	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 off ○ Sleep

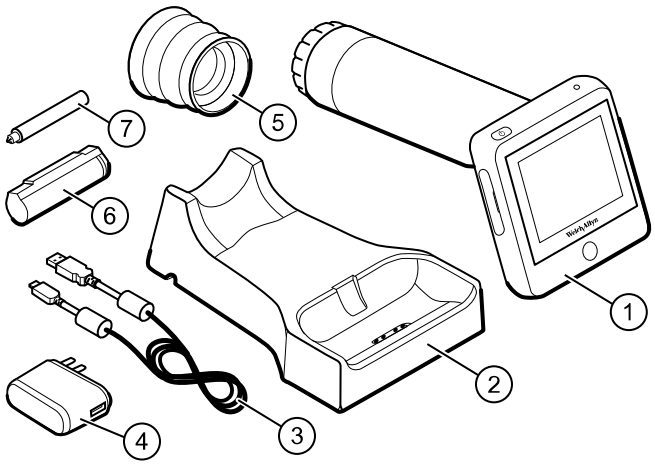
No.	Feature	Description
		○ Cancel
6	Power indicator	• When the LED light is green, it indicates that the device is docked and is fully powered. • When the LED light is amber, it indicates that the device is docked and is in the process of charging. • When the device is not docked the LED is off.
7	LCD touchscreen	3.5" color HD LCD touchscreen. Displays information for charging, testing, and adjustments to the device.
8	Home button	Press the Home button to navigate to the Home screen (workflow selection) from any screen on the device.
9	Battery cover	Covers the battery compartment
10	Bezel	Area to which the eye cup attaches

Using the RetinaVue 100 Imager Pro

View images saved to the RetinaVue 100 Imager Pro on the LCD touchscreen. The images saved on the SD card are in unencrypted (.jpg) format and a DICOM (.dcm) format. To view images on a computer, use photo viewer software.

Unpack the system

The RetinaVue 100 Imager Pro device is packaged with the following items. Confirm that all items are included.



Number	Item	Description
1	RetinaVue 100 Imager Pro device	Digital hand-held eye-fundus camera used to record digital photographs of the fundus of the human eye and surrounding area.
2	Docking station	Charges the RetinaVue 100 Imager Pro device and enables USB data transfer to a computer or laptop. Connect to region-specific AC wall outlet.
3	USB cable	Connects the docking station to a computer or laptop to transfer results. Connects the docking station to the wall adapter plug for AC charging.
4	Wall adapter plug	Connects to USB cable. Match to region-specific AC wall outlet.

Number	Item	Description
5	Eye cup	Blocks ambient light during testing
6	Battery	Rechargeable lithium ion battery
7	Screwdriver	Phillips screwdriver to remove battery cover screws
Not shown	RetinaVue 100 Imager Pro *Directions for use*	This document. The *Directions for use* (DFU) is also available on the Welch Allyn web site.
Not shown	SD Card	SD Card installed in the SD Card slot for data storage
Not shown	Lens spray	RetinaVue 100 Imager lens cleaner
Not shown	Lens cloth	RetinaVue 100 Imager lens cleaning 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. The battery is charged through contact pins on the device and the docking station.

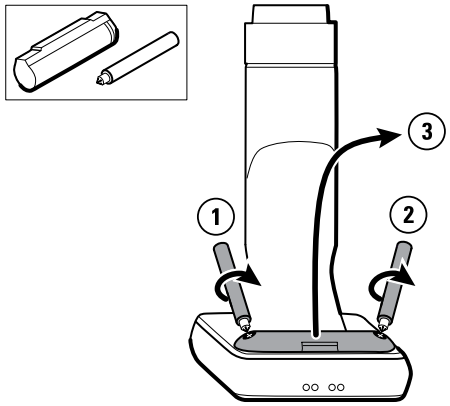
Install the battery/replace the battery

Set the RetinaVue 100 Imager on a flat, clean surface with the LED display facing down.

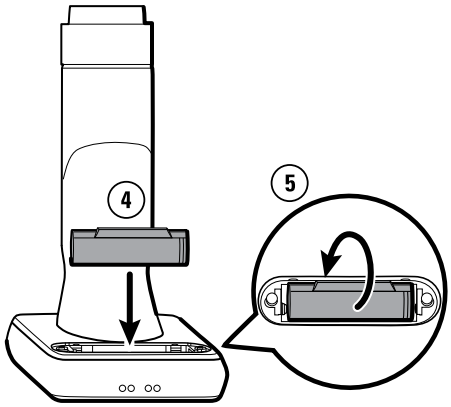
WARNING Personal injury risk. Improper handling of the battery can lead to heat generation, smoke, explosion, or fire. Do not short-circuit, crush, incinerate, or disassemble the battery. Never dispose of batteries in refuse containers. Always recycle batteries according to national or local regulations.

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.

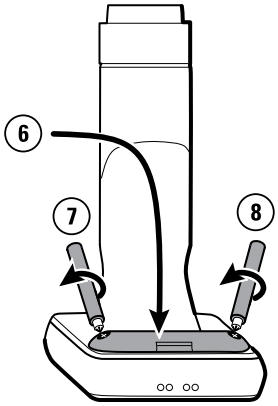
1. Loosen the screw at the left side of the battery cover.
2. Loosen the screw at the right side of the battery cover.
3. Push in the battery cover tab and then lift up the battery cover. Slide open the battery cover by tilting the cover upward.



4. For first-time setup of the RetinaVue 100 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.
   a. This procedure applies to first-time setup of the RetinaVue 100 Imager. Insert the battery into the battery compartment. Match the polarity of the battery to the + and - markings on the RetinaVue 100 Imager.
   b. This procedure only applies to battery replacement. Remove the existing battery from the battery compartment and insert the new replacement battery into the battery compartment. Match the polarity of the battery to the + and - markings on the RetinaVue 100 Imager.
5. Rotate the raised flat edge of the battery until it sets in the back notch of the battery compartment.



6. Insert the two battery cover tabs into the slot, then push in the tab to close the battery compartment.
7. Tighten the screw at the left side of the battery cover.
8. Tighten the screw at the right side of the battery cover.



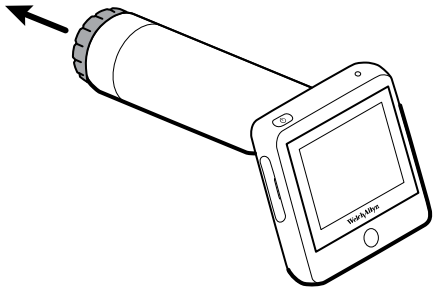
Note Do not over-tighten the screws.

Eye cup

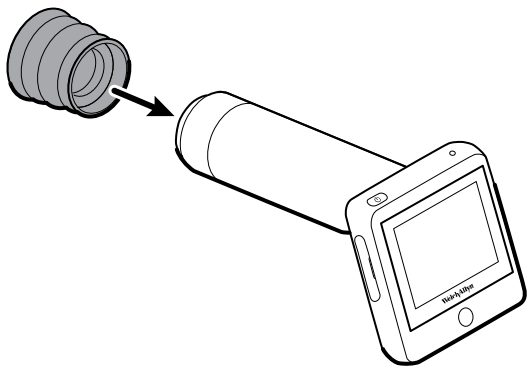
The eye cup blocks ambient light during testing and covers the patient's eye socket to allow them to best focus on the green fixation lights. The eye cup works on the patient's left and right eye.

Set up the eye cup for a patient exam

1. Remove the lens cap from the RetinaVue 100 Imager.



2. Slide the eye cup over the bezel on the RetinaVue 100 Imager.



3. Use the eye cup to cover the patient's examined eye and allow them to focus on the green fixation lights.

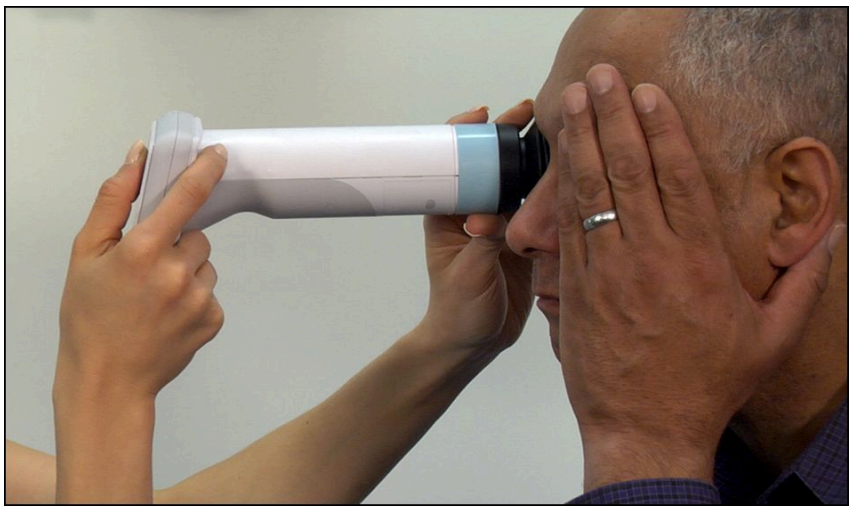
Hold the RetinaVue 100 Imager for a patient exam

The RetinaVue 100 Imager must be held level and in line with your patient's eye.

There are two recommended techniques to properly hold the RetinaVue 100 Imager for a quick and successful retinal exam:

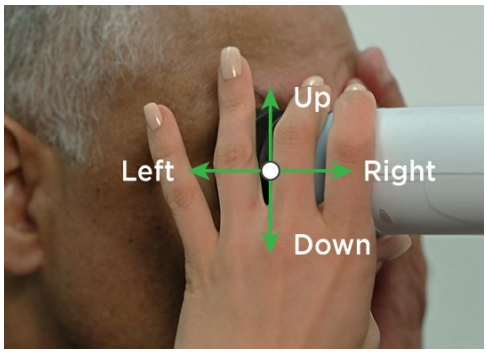
Telescope Grip

Smart phone Grip



Make micro adjustments with your guide hand to fine tune the focus of the RetinaVue 100 Imager.

Guide (Patient End) Hand



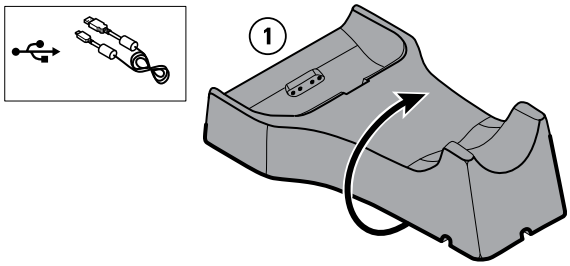
Hold the patient end of the RetinaVue 100 Imager with just the thumb and forefinger. Use the small and ring finger to steady the RetinaVue 100 Imager by anchoring them gently on the patient's forehead.

Docking station

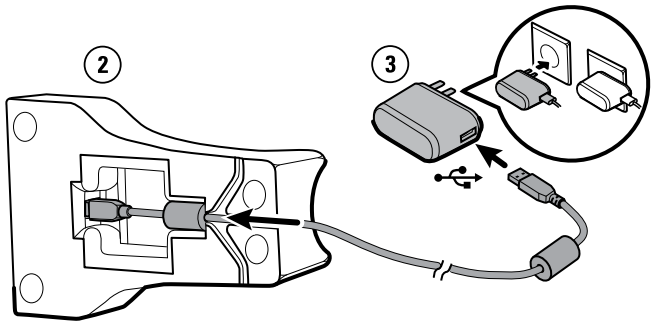
Place the device into the docking station to charge the device or to connect and transfer data to a computer or laptop.

Set up the docking station for charging

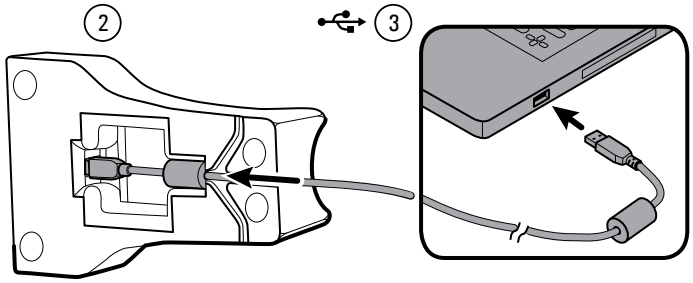
1. Turn the docking station over.



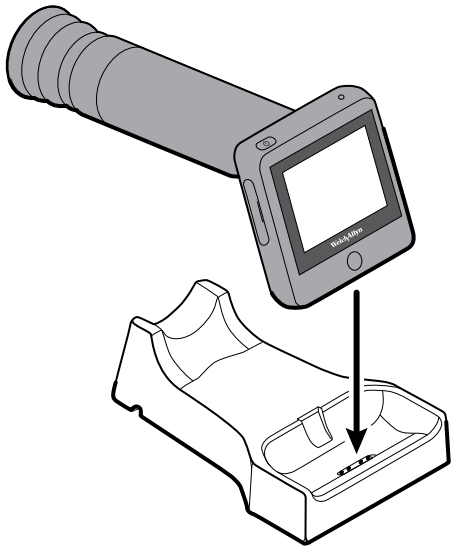
2. Connect the USB cable to the docking station.
3. Either plug the USB cable into the wall adapter plug and then plug the wall adapter into an AC outlet, or plug the USB cable into the "Always On" USB port on a computer.
   a. Plug the USB cable into the wall adapter plug and then plug the wall adapter into an AC outlet.



   b. (Optional) Plug the USB cable into the "Always On" USB port on a computer.

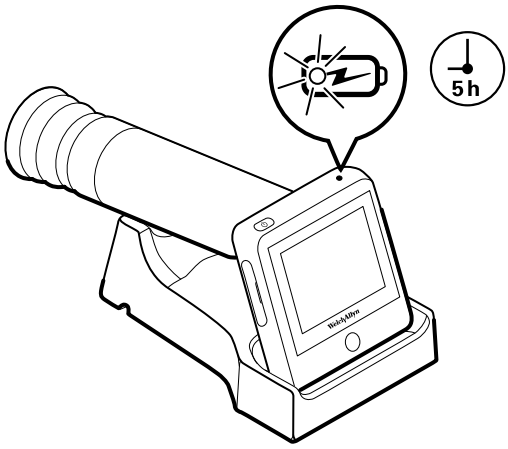


4. Place the RetinaVue 100 Imager on the docking station charger with the contact pins of the RetinaVue 100 Imager touching the contact pins of the docking station charger.



5. Before the first use, allow the RetinaVue 100 Imager to charge for 5 hours on the docking station charger.

Note The power indicator light turns amber to indicate that the RetinaVue 100 Imager is in the processing of charging. If the power indicator light does not turn on, ensure that the contact pins of the RetinaVue 100 Imager are touching the contact pins of the docking station charger and reseat the RetinaVue 100 Imager into the docking station. Charging is impacted if the pins are not properly touching.



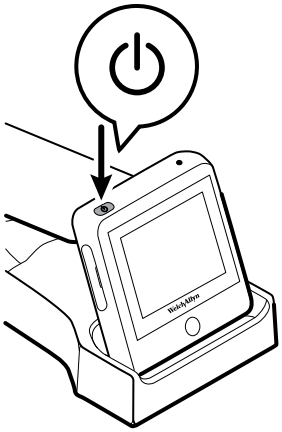
Note The removal of the plug from the socket provides the means of isolation from the mains power supply. The user is reminded to keep this means of disconnection easily accessible in case of emergency.

First time set up of the RetinaVue 100 Imager Pro

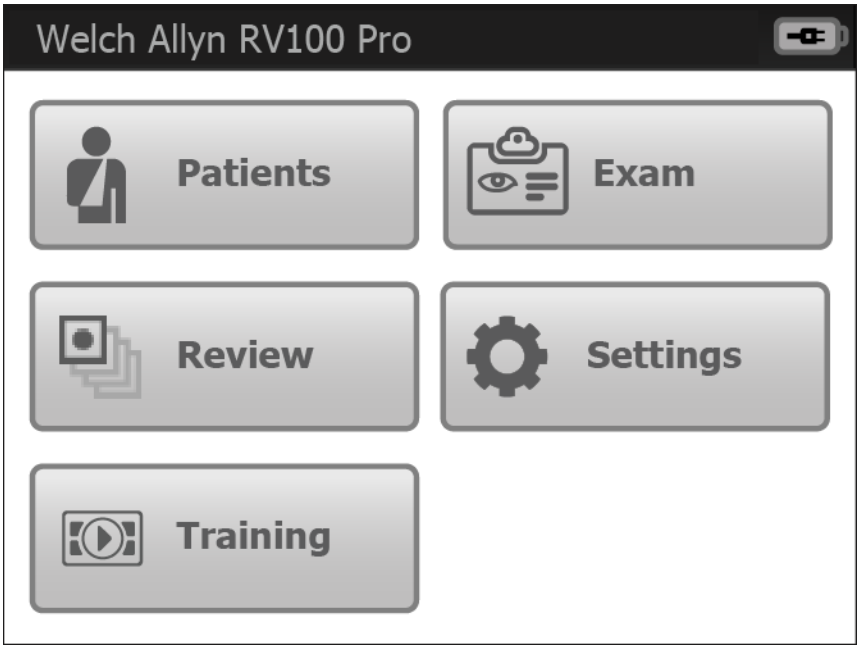
The RetinaVue 100 Imager Pro runs a brief diagnostic self-test each time it powers up.

CAUTION Always use the RetinaVue 100 Imager Pro with an adequately charged and properly functioning battery.

1. Press ⏻ to power up the RetinaVue 100 Imager Pro.



As the device is powering up, the RetinaVue 100 Imager Pro displays the Welch Allyn logo and the model number. After powering up, the *Home* screen appears.

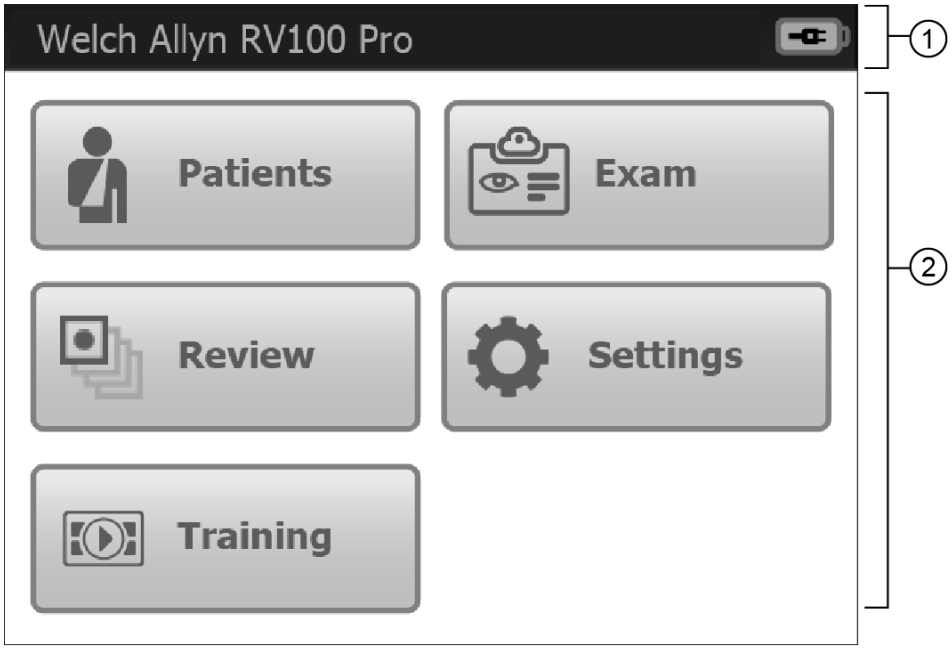


Note If the battery is in a discharged state, the time and date need to be set.

2. Touch ▲ (up) or ▼ (down) to adjust the hour, minute (Min), Continent, and Location. Use the radio buttons to select the 24-hour or 12-hour format. Touch ← (Back) to return to the *Settings screen*.
3. Touch **Date**.
4. Touch ▲ (up) or ▼ (down) to adjust the day, month, and year in the DD/MM/YY format. Touch ← (Back) to return to the *Settings screen.*

RetinaVue 100 Imager Pro Home screen

The RetinaVue 100 Imager Pro *Home screen* includes the following areas:

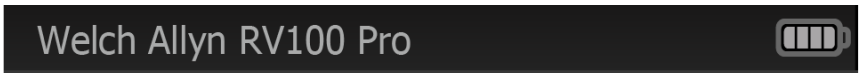


Item	Area
1	Device status
2	Content

Device Status Area

The Device Status Area, located at the top of the *Home screen*, displays the Battery condition and the device model number. Estimated battery capacity is displayed in a charged or discharged status format.

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



- the device model number
- the battery condition

Content Area

The Content Area includes four workflow selection buttons and a Training button. Touching one of the five buttons navigates to the next screen associated with that workflow or training.

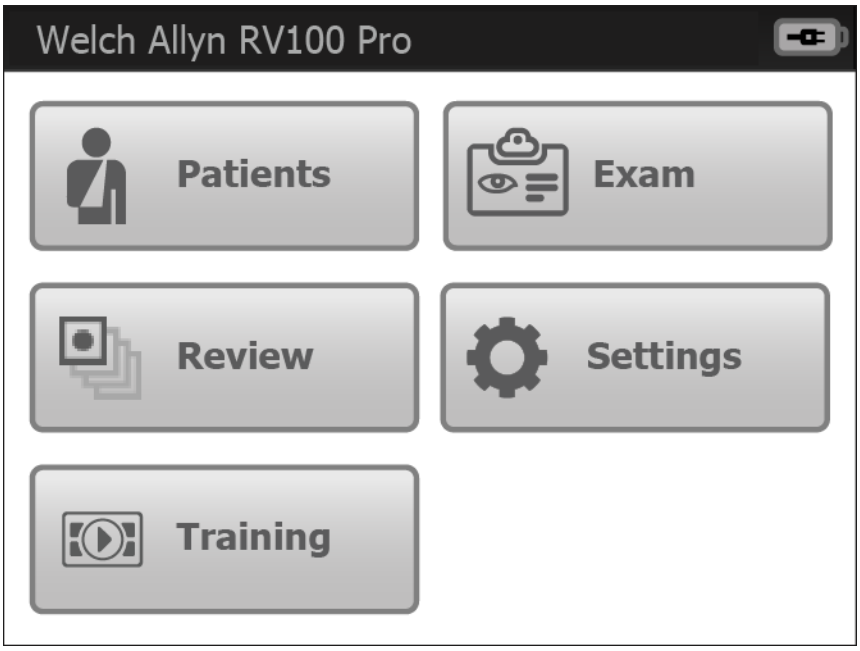
- **Patients:** Presents a list of patients created on the RetinaVue 100 Imager Pro until the exams are completed.
- **Exam:** The Exam workflow provides a guided approach to image capture. To maintain consistent and complete exam submissions, a prescribed image acquisition

sequence is used to complete an exam. The Exam workflow also presents controls, status, and previews of images.

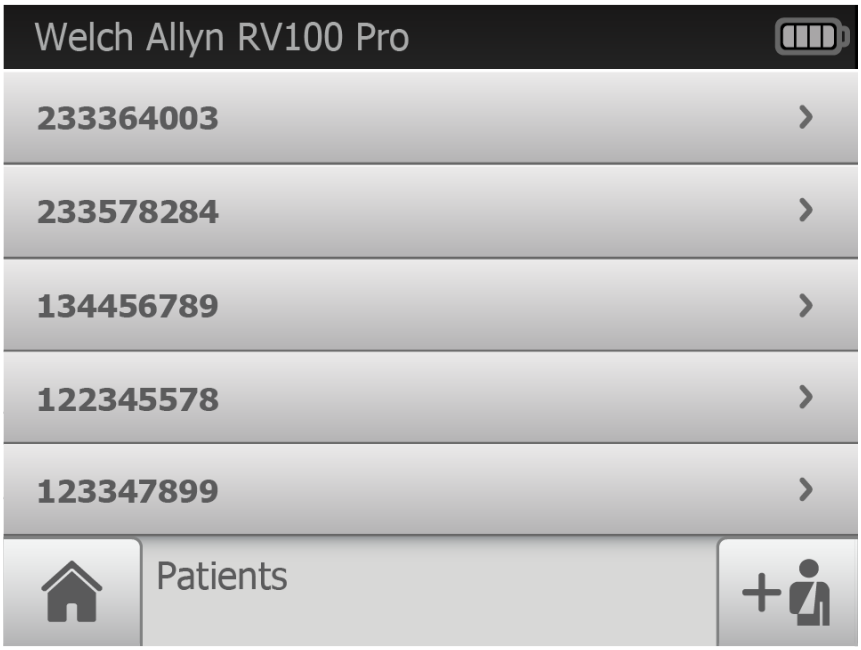
- **Review:** Presents images and exams from a list of patient IDs contained on the RetinaVue 100 Imager Pro .
- **Settings.** Provides controls to view or change the following:
  - Volume
  - Time
  - Date
  - Advanced settings:
    - Device access code
    - Advanced settings code
    - Format SD
    - Restore factory defaults
  - Exam setup
    - 1-image (Macula-centered)
    - 2-image (Macula and Optic Disc-centered)
  - Camera configuration
    Switch between RV100/RV100 Pro
    - RV100 Pro
      Unencrypted images only (no RetinaVue Network compatibility)
    - RV100
      RetinaVue Network required (USB or Wireless)
    - Export log
  - About
    - Software version
  - Regulatory Information
- **Training:** Provides demonstrations and interactive training exercises on the RetinaVue 100 Imager Pro. Short video clips and interactive training help you practice the three key steps necessary to master the RetinaVue 100 Imager Pro.

Create a new patient on the RetinaVue 100 Imager Pro camera

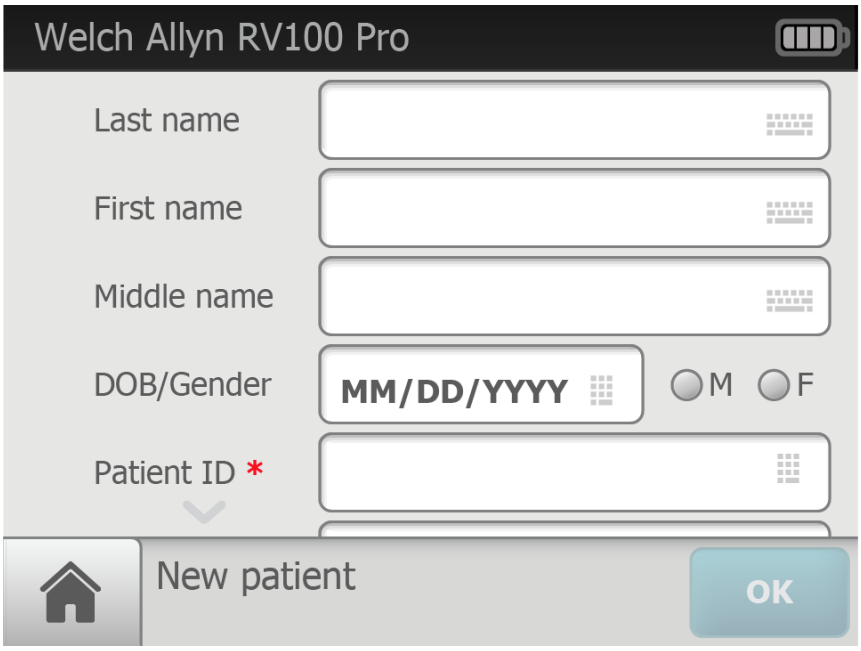
1. From the *Home screen*, touch **Patients**.



2. After the *Patients screen* appears, touch (New patient).



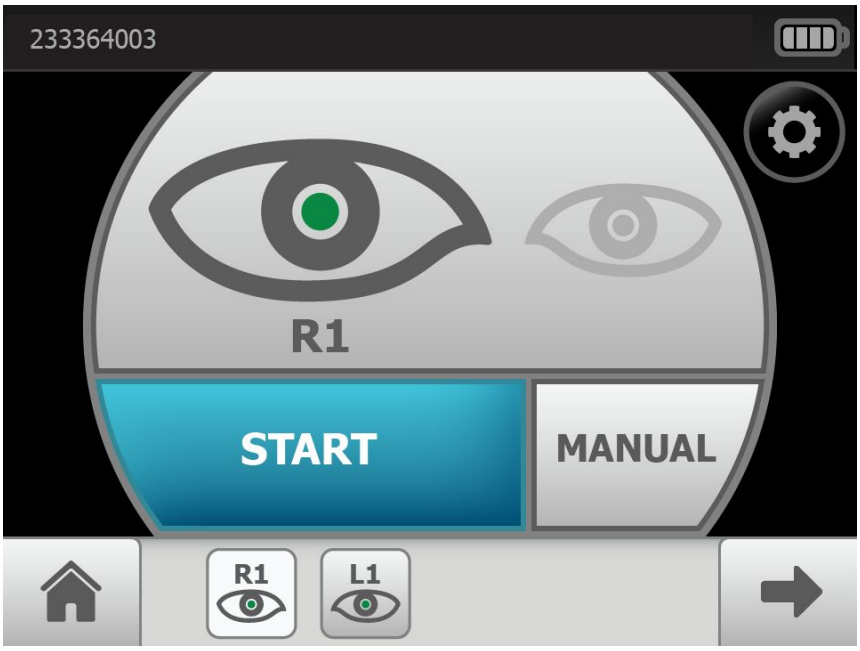
The *New Patient screen* appears.



The Patient ID field is the only Required field and is noted with a red asterisk. Once added, the required Patient ID will appear in the top left of the *Pre-acquisition* screen as the camera enters the Pre-acquisition mode.

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

3. Touch within the Patient ID field to launch the on-screen keyboard. Enter the Patient ID and touch **OK**.
4. (Optional) Touch within the Patient's Last name, First name, or Middle initial to enter the patient's last name, first name and middle initial. Touch **OK**.
5. (Optional) Enter the patient's Date of Birth. Touch within the DOB/Gender field to launch the on-screen keyboard and to enter the patient's Date of Birth. Touch **OK**.
6. (Optional) Enter the patient's gender using the radio button to select male (M) or female (F).
7. Once all the required fields are complete, touch **OK** to open a new exam. The *Pre-acquisition* screen appears.

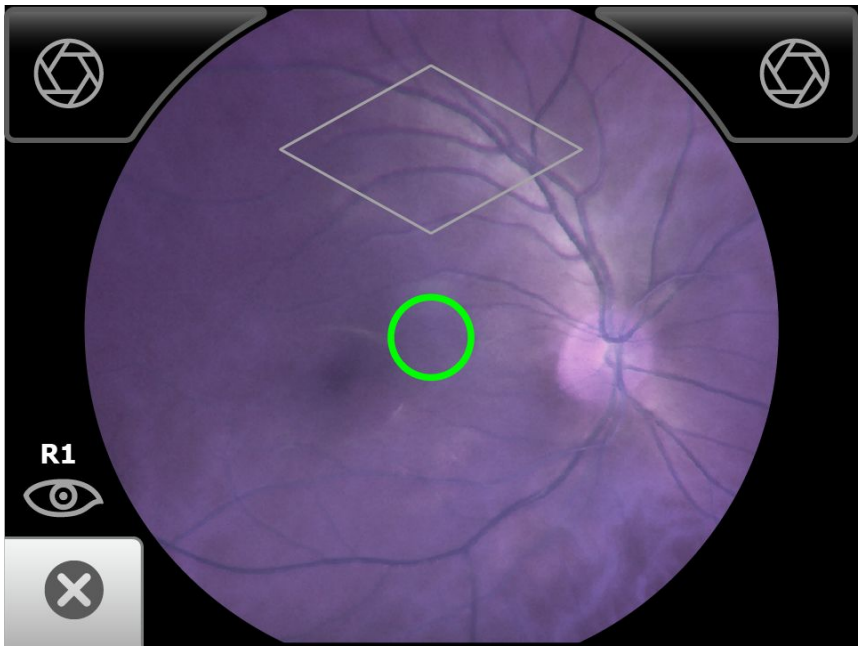


Note The Patient ID appears in the top left of the *Pre-acquisition* screen.

8. Refer to the topic *Perform an eye exam using the Auto exam mode* for instructions on performing exams and acquiring images.

About the Auto and Manual Exam modes

Auto Mode

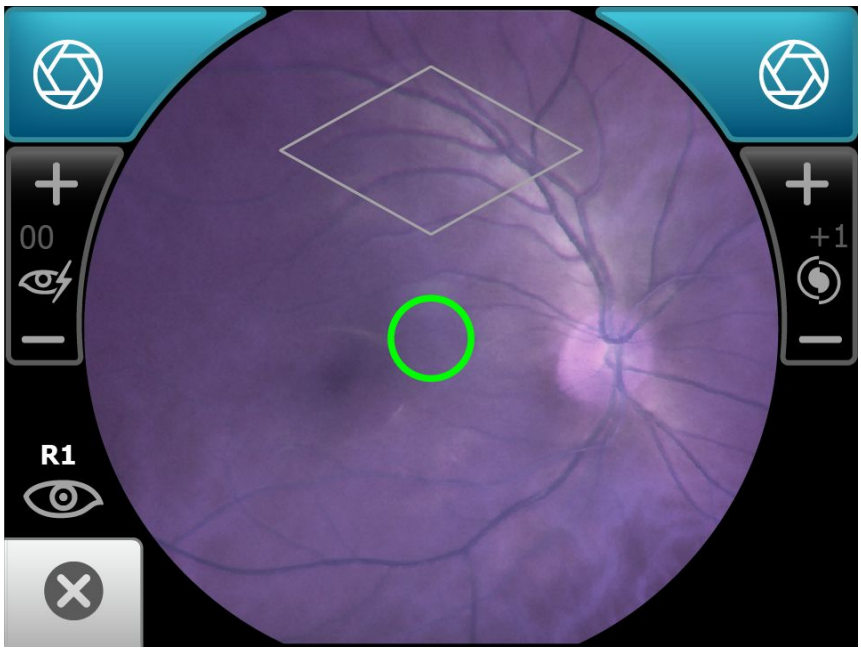


Auto Mode is the default image capture mode. Available automatic features include:

- Image capture
- Focus
- Flash brightness
- Sequential image capture order of the right and left eye
- Navigation to the image *Inspection screen*

In addition to the automatic features, manual capture, manual focus adjustment, and manual flash brightness adjustment are also available. (Manual focus adjustment and flash brightness are accessed from the *Capture settings screen*.)

Manual Mode



Manual mode contains advanced image capture options.

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

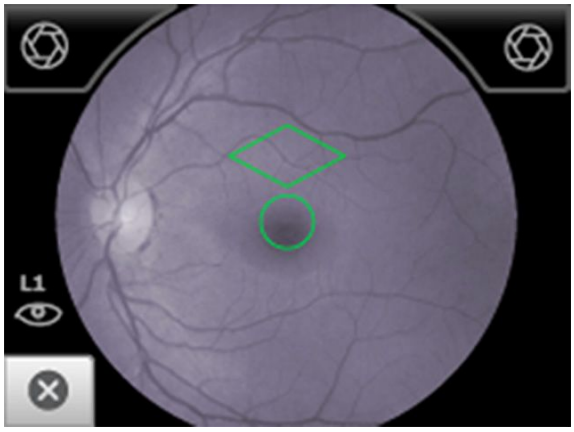
Available manual features include:

- 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

Adaptive software in the Auto exam mode for software 6.10.02 and higher

Auto exam mode first stage

Once the view is in-fundus, the adaptive software will enlarge the on-screen diamond at specific time intervals.

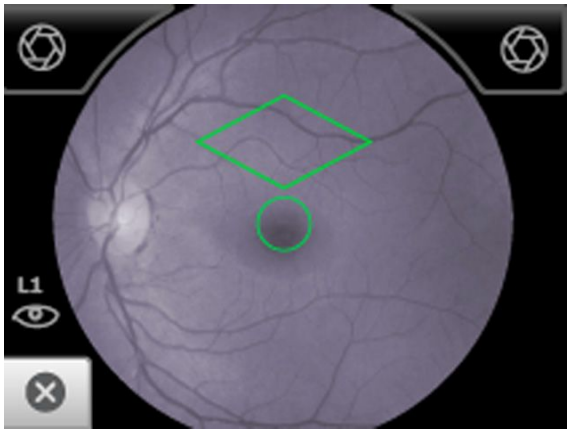


Note The best image quality is obtained while the diamond is at the beginning smallest size.

Note The diamond will reset to its smallest size each time the view moves out of the fundus.

Auto exam mode second stage

As the image capture sequence continues, the diamond on the LCD touchscreen increases in size.



Perform an eye exam using the Auto exam mode

Auto exam mode is the default image capture mode.

Available automatic features include:

- Image capture
- Focus adjustment
- Flash brightness adjustment
- Sequential image capture order of the right and left eye
- Navigation to the image Inspection screen
    - In addition to automatic image capture, manual capture is also available.

Note To ensure that the patient's pupils sufficiently dilate to at least 3.5 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.

Note While the RetinaVue 100 Imager Pro can be used on patients with cataracts and other eye opacities, the use of the RetinaVue 100 Imager Pro may result in a lower quality image due to the increased reflection of the flash off the patient's intraocular lens.

- Ensure that the SD card is installed into the RetinaVue 100 Imager Pro.
- Ask your patient to remove their glasses, contacts can remain in place.
- Ensure that the patient sits on the edge of an exam table and stand in front of the patient to take the image.

Alternatively, 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.

- 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 100 Imager Pro 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 100 Imager Pro lens the same height as the patient's examined eye.
- Approach the patient from directly in front of the examined eye.
- Make slight, micro adjustments with your guide hand to fine tune the position of the RetinaVue 100 Imager Pro. Do not use your hand on the LCD side to make minor adjustments.

Note For additional information about techniques to capture the highest quality image, see the *Technique guide* and the *Training video* that came with the RetinaVue 100 Imager Pro.

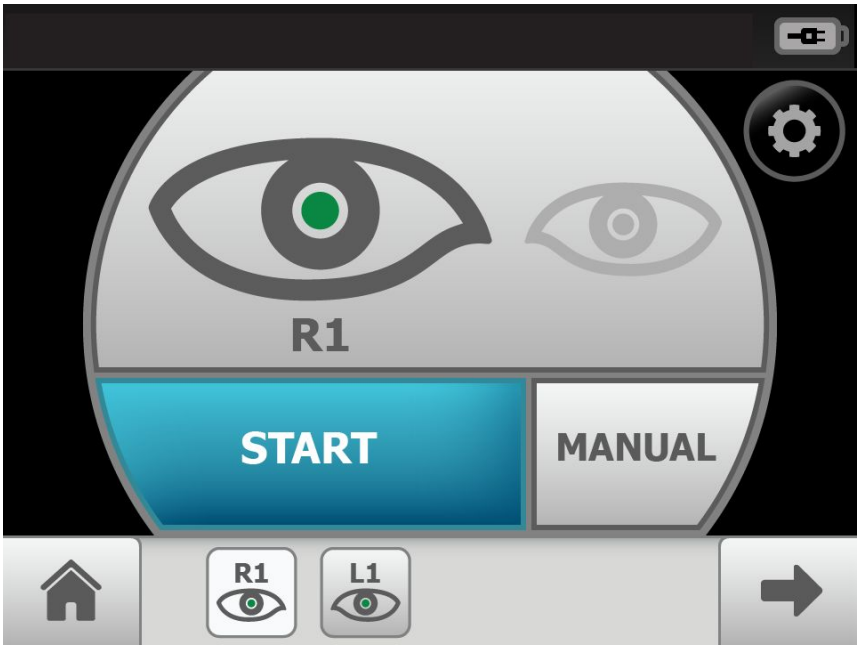
1. Press the power button .

   Note To conserve power, the RetinaVue 100 Imager Pro enters Sleep mode if it remains idle for approximately 2 minutes. Touch the LCD screen, press the power button, or press the Home button to wake up the RetinaVue 100 Imager Pro from Sleep mode.

   Note After 10 minutes of inactivity in Sleep mode, the RetinaVue 100 Imager Pro powers down. Press the power button to activate the RetinaVue 100 Imager Pro.

2. From the Home screen, touch **Exam**.

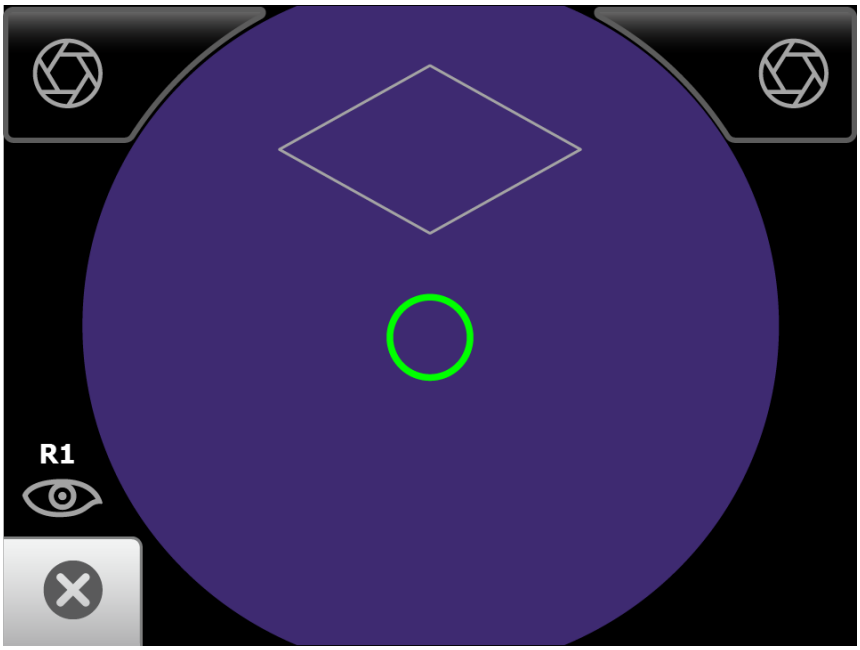
   The *Preacquisition screen* appears.



3. (Optional), If necessary, touch (Settings) to adjust the illumination, or the focus. Touch the up or down arrows in the *Advanced image capture settings* and touch **OK**.

4. Touch **Start** to enter the *Image acquisition mode* and begin the first exam of the patient's right eye (R1).

   The *Exam acquisition screen* appears.



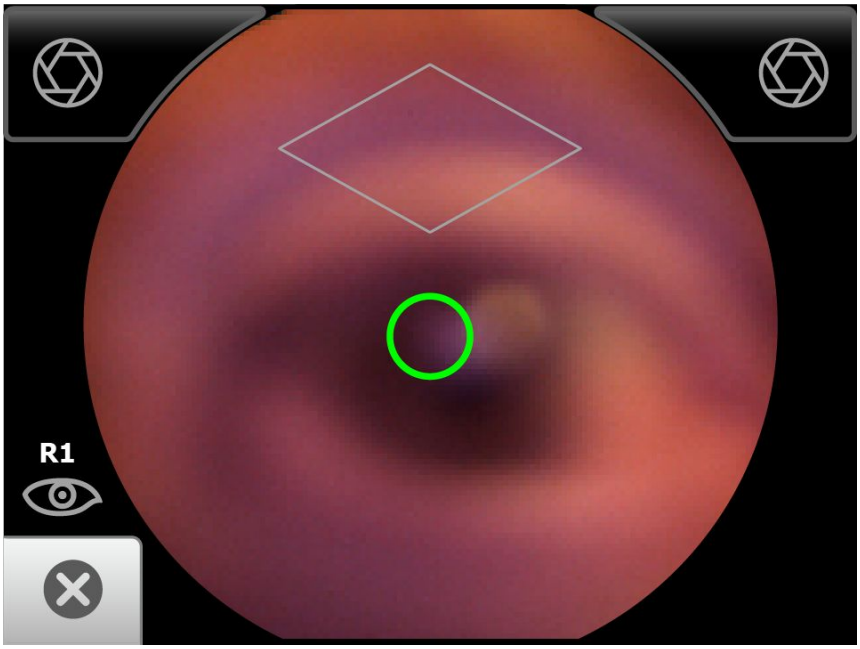
5. Hold the patient end of the RetinaVue 100 Imager Pro two to three inches directly in front of the patient's examined eye. Continue forward to compress the eye cup against the examined eye.

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

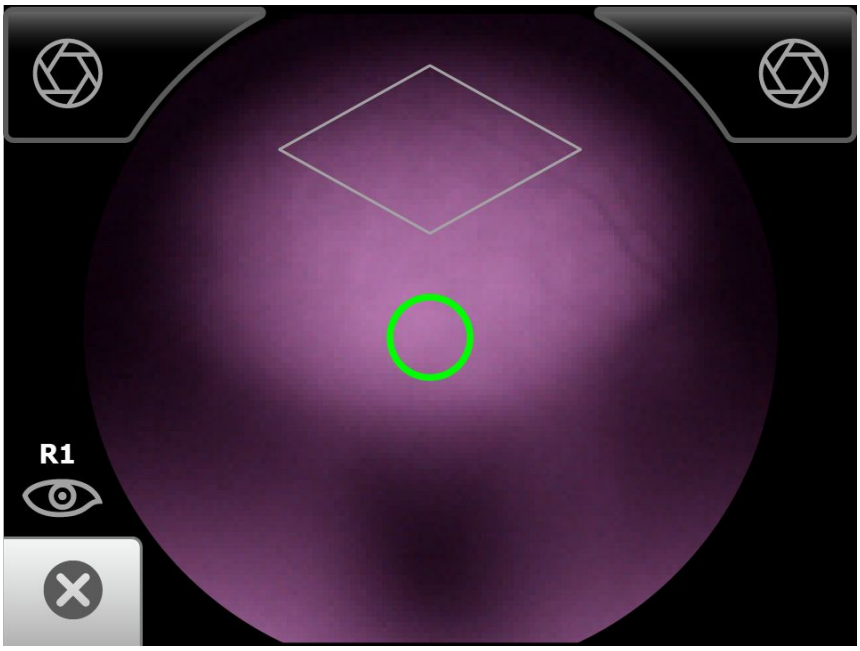
6. Direct the patient to focus on the green fixation lights inside the barrel of the RetinaVue 100 Imager Pro.

   Note Instruct the patient to cover, but not close, their unexamined eye. This will help the patient to focus on the green fixation lights.

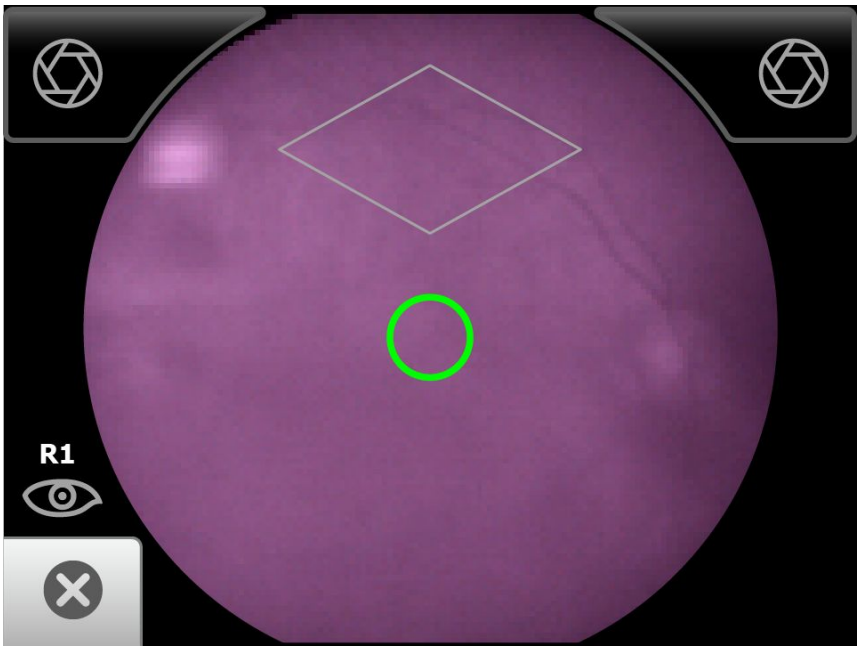
7. Look for a white circular reflection at the top of the eye's image on the LCD touchscreen. This is your initial target.



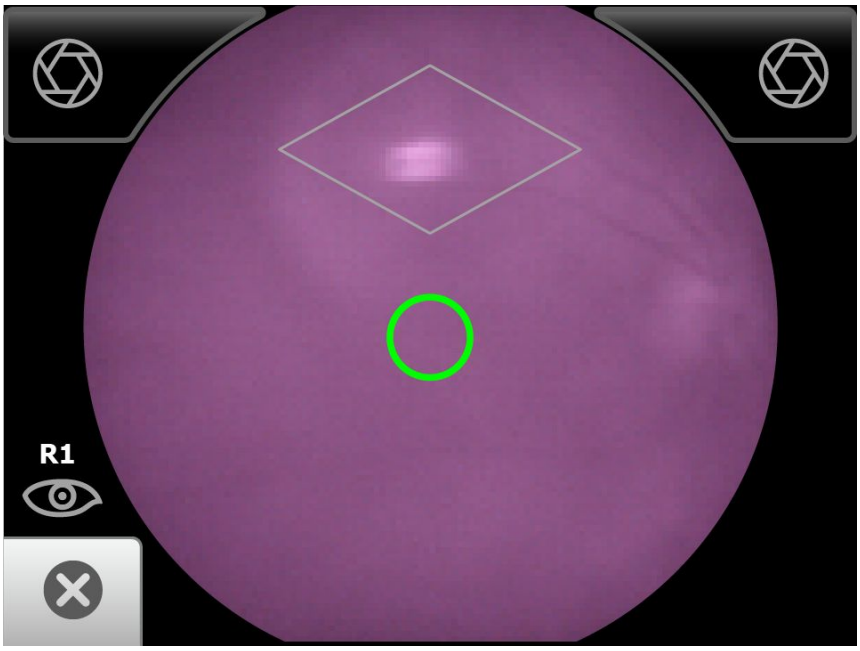
8. Guide the green circle on the RetinaVue 100 Imager Pro LCD touchscreen towards the initial target by slowly moving the RetinaVue 100 Imager Pro towards the eye.



9. Once the reflection has filled the screen, push slightly forward until a “bubble” appears.
10. Keep the RetinaVue 100 Imager Pro in line. Slightly adjust the RetinaVue 100 Imager Pro away from any shadows that appear.
11. Move the patient end of the RetinaVue 100 Imager Pro toward the bubble.

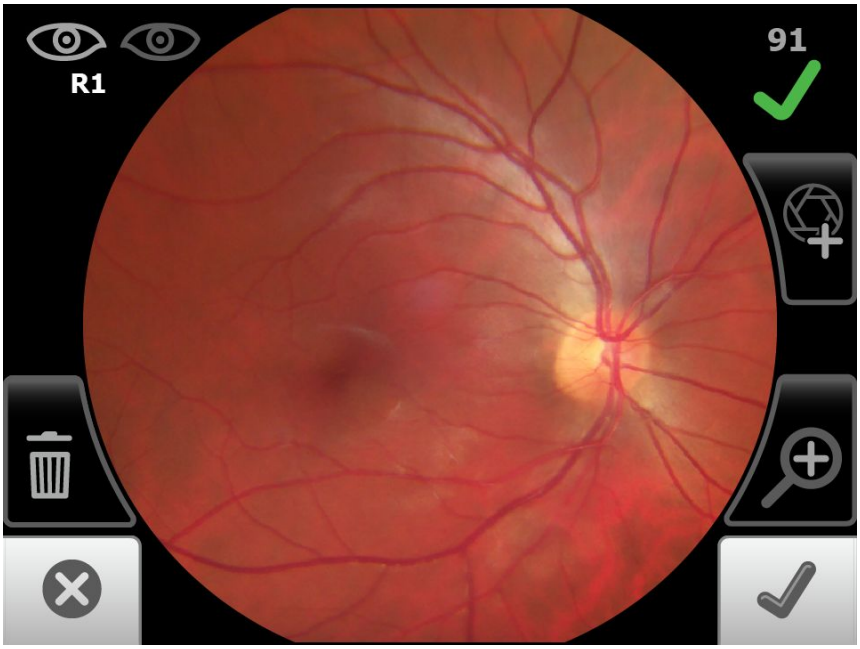


12. Align the bubble inside the diamond icon.



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

    The acquired image appears on the LCD touchscreen for review in about five seconds.



14. Touch (Accept) to begin the second exam of the patient's left eye (L1) and wait at least 1 minute before repeating the steps until the second image is automatically captured.
    - (Optional) If the 2-image, Macula +Optic Disc-center exam setup is selected in Advanced settings, wait at least 1 minute before repeating the steps until all the images are automatically captured (R1, L1, R2, L2 and up to 4 additional images).

Note Touch to review the current image. Images with a red X ( ) denote low quality images. Touch (navigates to the *Acquisition screen*) or touch (navigates to the *Pre-acquisition screen*) to dispose of an image and then touch (Add image) to begin a capture of another image.

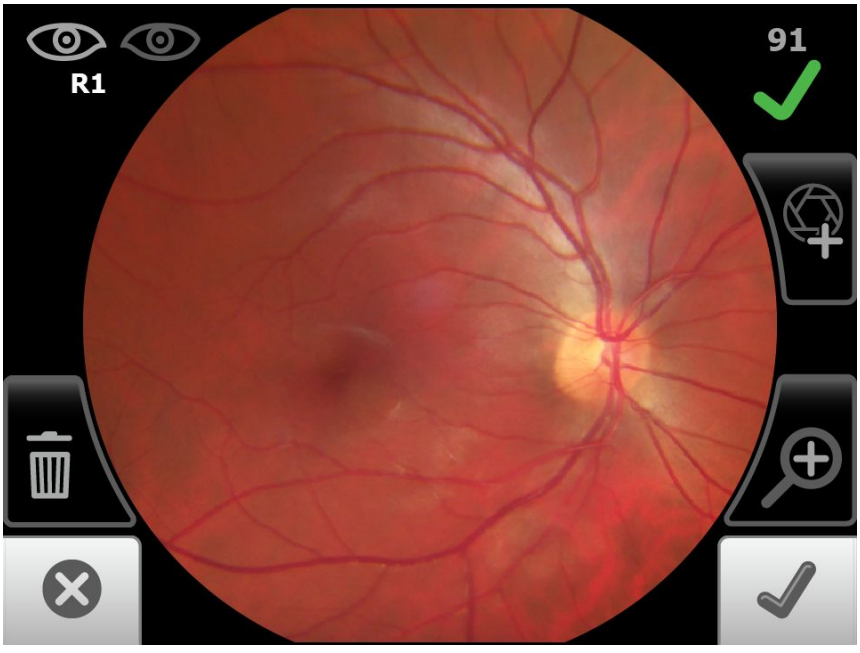
15. When the sequential image capture is complete and the images contain a green or yellow quality acceptance check mark, proceed to the *Exam summary screen*.

Note To add missing patient context information touch and then touch to create a new patient, or touch on an existing patient's name from within the *Patients screen* to select that patient. Touch **Save** to save the exam images.

Perform a manual image capture while in Auto exam mode

1. From the *Pre-acquisition screen*, touch **Start**.
2. Touch or (image capture) to manually capture an image.

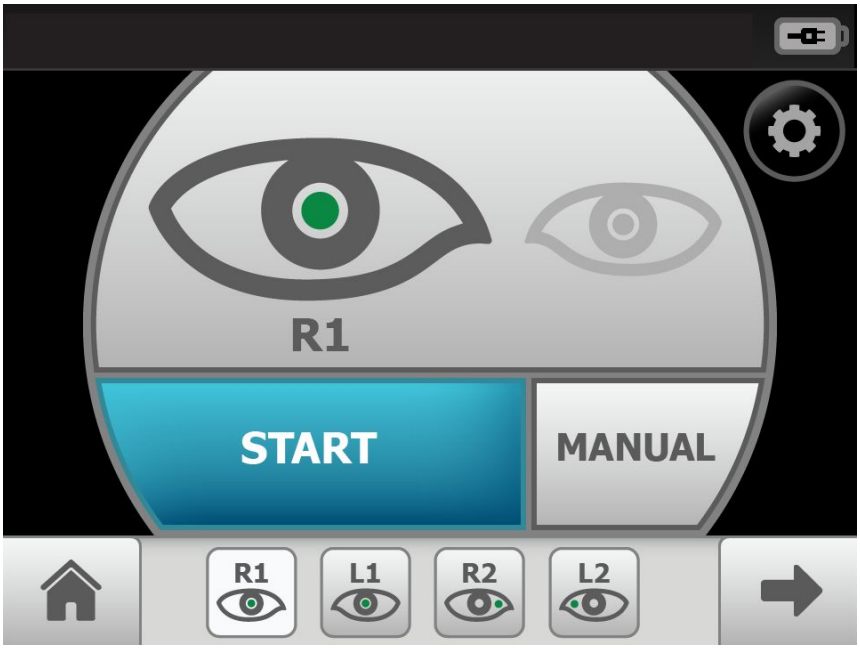
   An audible tone alerts you that the image has been captured. The acquired image appears on the LCD touchscreen for review in about five seconds.



Skip an image capture while in Auto exam mode

1. From the Home screen, touch **Exam**.

   The *Pre-acquisition screen* appears.



2. Touch (Next) or touch , or , or (Image Order) to skip to the next image in the sequence.
3. Touch **Start** to enter *Image acquisition mode* and begin the exam of the patient's eye using the next image in the sequence. The *Exam acquisition screen* appears.
4. If this is the last image in the sequence, touch (Accept) on the *Image inspection screen* and navigate to the *Exam summary screen*. If an image is missing in the 1-image, Macula-centered Exam setup, touch **Override** to access the Save button and to save the image. Or, touch **Override** to access the Save button and to save multiple images in the 2-image, Macula + Optic Disc-centered Exam setup.

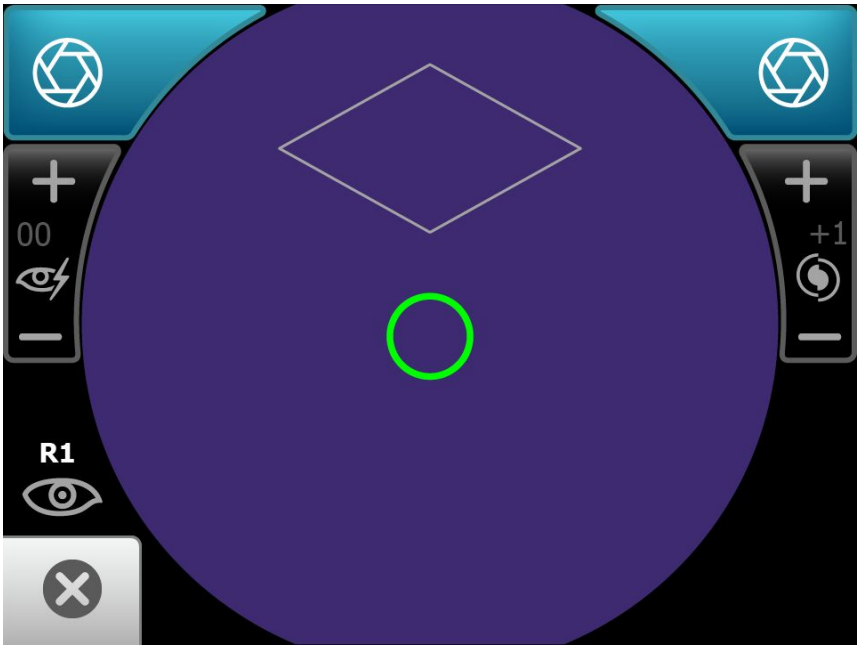
Perform a manual image capture while in Manual exam mode

1. From the Home screen, touch **Exam**.

   The *Pre-acquisition screen* appears.

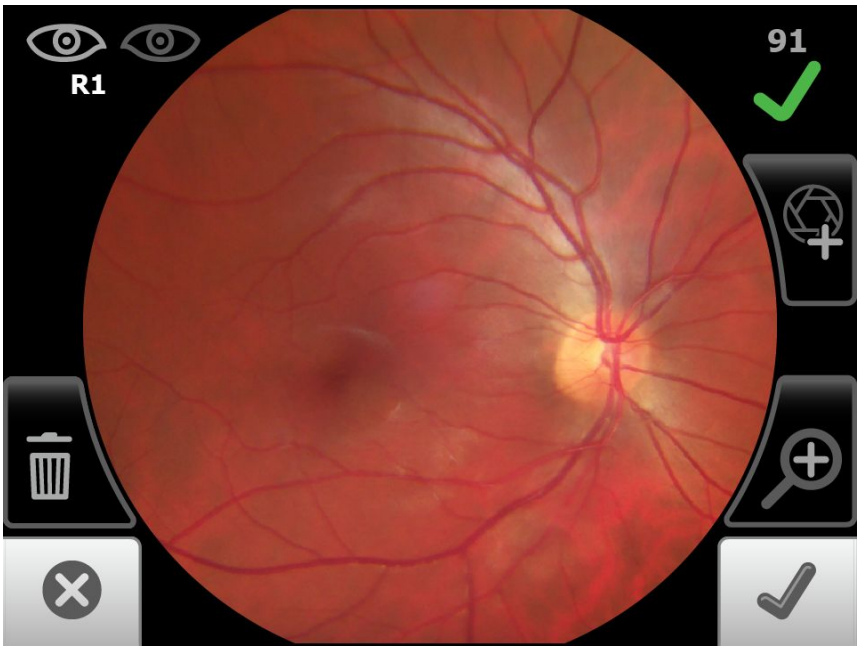
2. Touch **MANUAL** to enter *Image acquisition mode* and begin the exam of the patient's eye.

   The *Exam acquisition screen* appears.



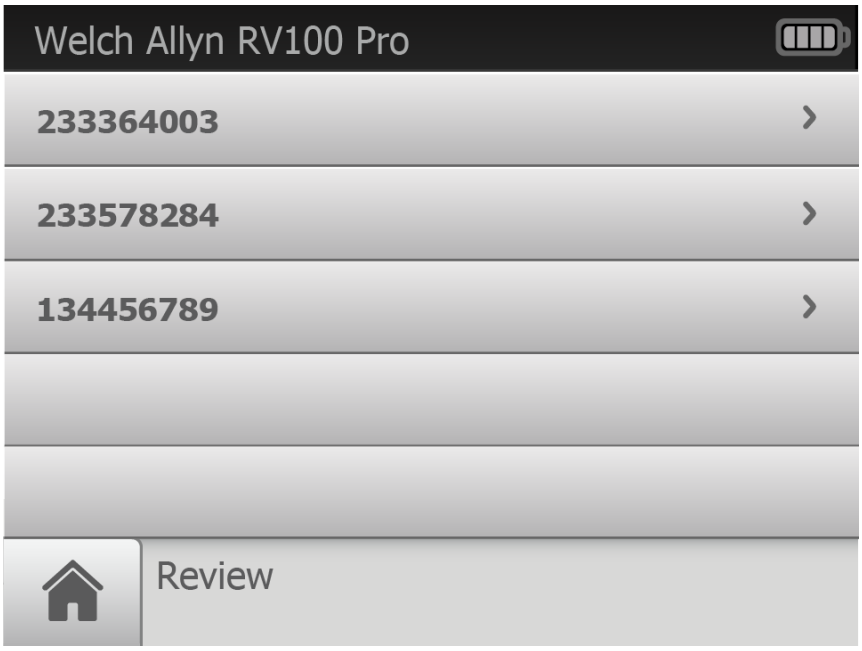
3. (Optional), If necessary, touch to adjust illumination, or touch to adjust the focus.
4. Hold the patient end of the RetinaVue 100 Imager two to three inches directly in front of the patient's examined eye. Continue forward to compress the eye cup against the examined eye.
5. Direct the patient to focus on the green fixation lights inside the barrel of the RetinaVue 100 Imager.
6. Look for a white circular reflection at the top of the eye's image on the LCD touchscreen. This is your initial target.
7. Guide the green circle on the RetinaVue 100 Imager LCD touchscreen towards the initial target by slowly moving the RetinaVue 100 Imager towards the eye.
8. Once the reflection has filled the screen, push slightly forward until a “bubble” appears.
9. Move the patient end of the RetinaVue 100 Imager toward the bubble.
10. Align the bubble inside the diamond icon.
11. Touch or (image capture) to manually capture an image.

    An audible tone alerts you that the image has been captured. The acquired image appears on the LCD touchscreen for review in about five seconds.

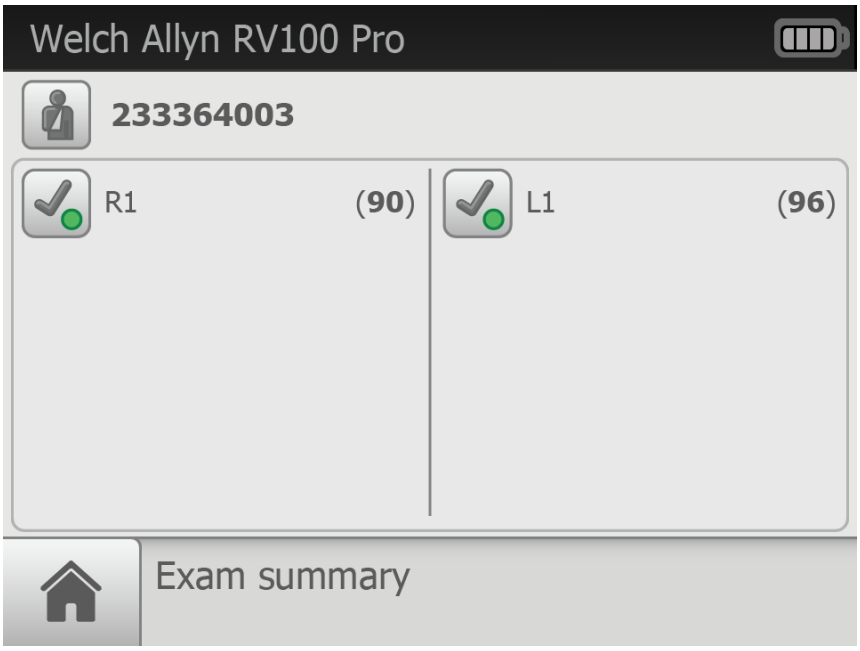


Review patient exams on the RetinaVue 100 Imager Pro

1. From the *Home screen*, touch **Review**. The *Review screen* appears.



2. Touch on a patient's ID to review the patient demographics (*Patient summary* screen) and to view images associated with a patient.
3. Any saved images appear on the *Exam summary screen*.



4. After the review is complete, touch (Back) to return to the *Review screen* and then touch (Home) to return to the *Home screen.*

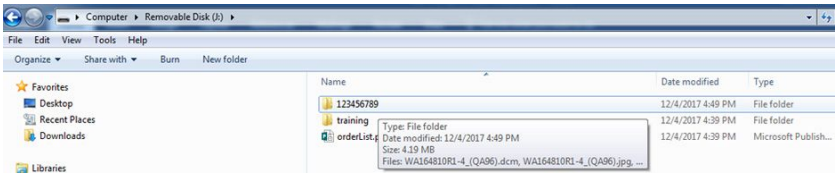
Transfer patient exams from the RetinaVue 100 Imager Pro to a computer

1. Place the RetinaVue 100 Imager Pro into the cradle and ensure that the cradle is connected to a computer by the USB cable.

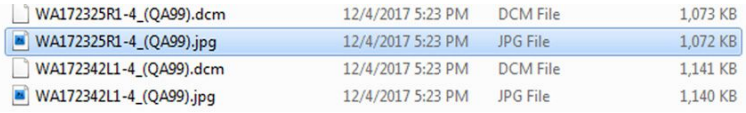
2. Power on the computer and the RetinaVue 100 Imager Pro.
3. If using a computer on a network, enter your credentials.

Note It is the responsibility of the health care provider to protect patient health information and to meet regulatory and HIPAA compliance. The images on the RetinaVue 100 Imager Pro may contain identifiable patient information and it is the responsibility of the health care provider to ensure that data safeguards are implemented to protect patient health information.

4. Within a few seconds, an Autoplay pop-up window appears on the computer screen, indicating that a new storage volume (the RetinaVue 100 Imager Pro camera's SD card) was detected.



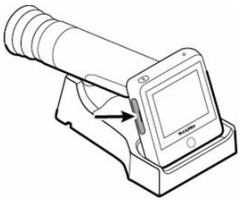
5. Click on the storage volume. Click on the folder with the Patient ID that you created previously on the RetinaVue 100 Imager Pro camera.
6. Double-click on the .jpg image to open an exam image in your installed photo viewer program.



7. Select the image and copy the image and paste it into the desired location.

Use the RetinaVue 100 Imager Pro SD Card to transfer patient exams to a computer

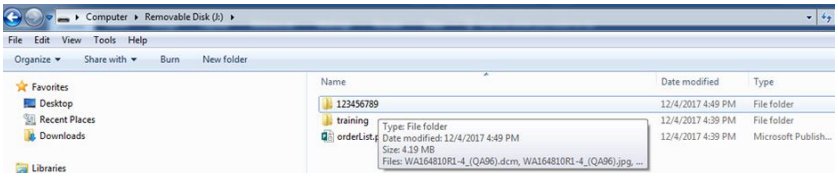
1. Power down the RetinaVue 100 Imager Pro and remove the SD Card.



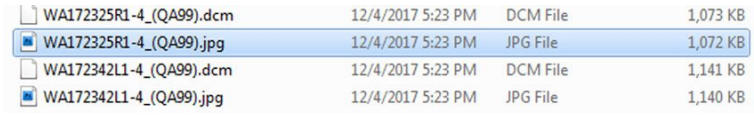
2. Insert the SD Card into an open SD Card reader port on the computer.
3. Within a few seconds, an Autoplay pop-up window appears on the compter screen, indicating that a new storage volume (the RetinaVue 100 Imager Pro camera's SD card) was detected.

Note It is the responsibility of the health care provider to protect patient health information and to meet regulatory and HIPAA compliance. The images on the RetinaVue 100 Imager Pro may contain identifiable patient information and it is the responsibility of the health care provider to ensure that data safeguards are implemented to protect patient health information.

4. Click on the storage volume. Click on the folder with the Patient ID that you created previously on the RetinaVue 100 Imager Pro camera.



5. Transfer the exam images from the SD Card to the computer.



6. Select the image and copy the file from the SD Card and paste it into the desired location.

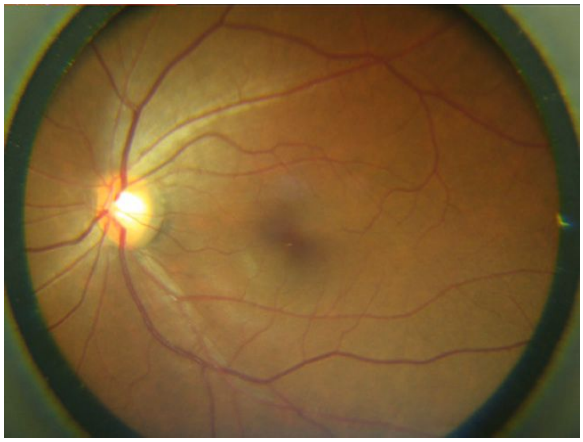
Troubleshooting

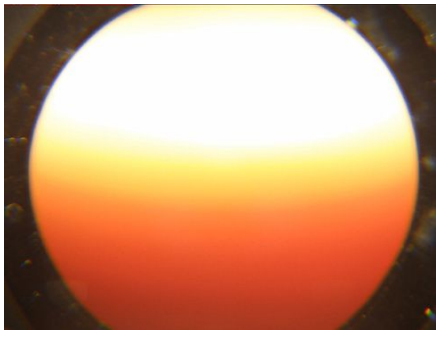
CAUTION A defective device should not be used. A device with parts which may be broken or missing, visibly worn, distorted, or contaminated should be replaced immediately.

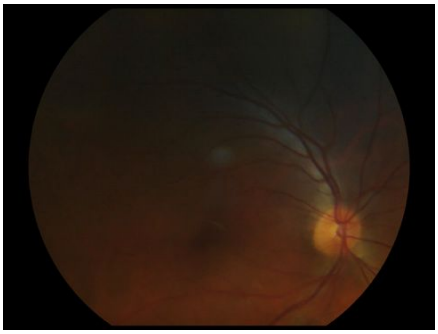
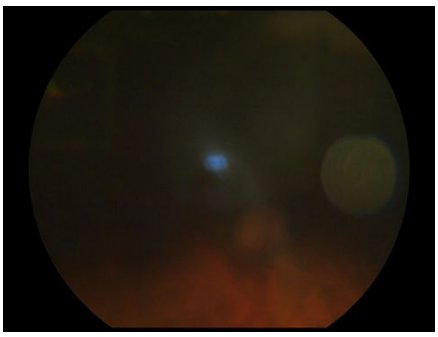
To correct an error, follow these instructions or contact Welch Allyn Technical Support: www.welchallyn.com/service.

Troubleshooting image quality

Good quality image



Problem	Solution
Partial blink 	Ask the patient to keep his or her eye open.

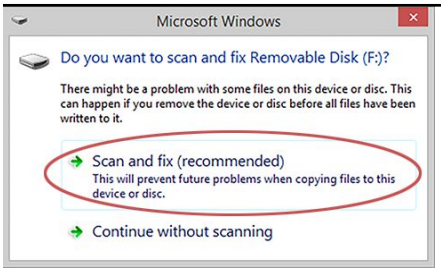
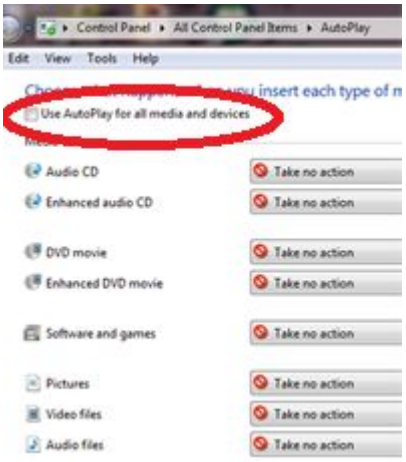
Problem	Solution
Dark semi-circle on top 	Move the patient side of the RetinaVue 100 Imager down and away from dark semi-circle.
Dirty lens 	Clean the lens with an appropriate cleaning cloth.

Error messages

Error message/problem	Solution
There is no SD card inserted. Please insert an SD card to continue.	Insert SD card.
SD card access error	Check the write-protection switch on the SD card and ensure that it is in the forward position. Reinsert SD card to ensure the card is seated correctly.
The space left in the SD card is not enough. Please replace the SD card.	Replace the SD card with a formatted SD card.
Update file extraction failed. Power off device and restart.	Check the write-protection switch on the SD card and ensure that it is in the forward position. Reinsert SD card to ensure the card is seated correctly. If the SD card does not have sufficient space, remove all files (except the update image) from the SD card. Perform the update again.
Failed saving files to the SD card.	Check the write-protection switch on the SD card and ensure that it is in the forward position. Reinsert or replace the SD card and click Retry.

Error message/problem	Solution
Camera is docked. Remove camera from docking station to access camera functions.	Remove the camera from the docking station.
The battery is running low. Please recharge.	When the battery charge level is below 25 percent, the low battery error message appears. Place the camera into the docking station to charge the battery. To reduce the likelihood of a low battery charging state, ensure that the USB cable is plugged into a "Always On" USB port on the computer. If the low battery message continues to display after the camera is docked in the docking station for several hours and while it is plugged into a USB port of your computer, plug the USB cable into an "Always On" USB port on the computer. (Only "Always On" USB ports continue to charge the camera when the computer enters sleep mode or power-saving mode.) **Note** See you computer manufacturer's user documentation for instructions on changing the power management options and for identifying the "Always On" USB port.
The battery level is too low to acquire any image. Please recharge now.	When the battery charge level is below ten percent and the battery icon blinks, the low battery error message appears. Place the camera into the docking station to charge the battery.

Problem	Solution
Battery is not installed. Camera will not charge. The power indicator LED light on the camera blinks between green and amber when placed in the docking station.	Install the battery and check to ensure that the polarity on the battery matches the + and - polarity on the device.
Battery is installed with the polarity reversed. Camera will not charge. The power indicator LED light on the camera blinks between green and amber when placed in the docking station.	Re-install the battery and check to ensure that the polarity on the battery matches the + and - polarity on the device. Set the camera into the docking station and wait for the power indicator LED light to turn amber indicating that the device is charging.
The power indicator light does not turn on when the camera is set into the docking station. Charging is impacted if the pins are not properly touching.	Ensure that the contact pins of the camera are touching the contact pins of the docking station charger. If necessary, reseat the camera into the docking station.
The Windows® operating system may display the *Scan and fix* or *Continue without scanning* message once the camera is set in the cradle or when the USB cable is removed from the laptop or PC.	Select *Scan and fix* if this Windows message appears in situations when the camera is connected to a laptop or PC by the USB cable.

Problem	Solution
	
The Windows® operating system may display the Autoplay notification popup dialogue box each time the camera is placed into the docking station when 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**. 

Reset the codes and data

Problem	Solution
Locked out of the RetinaVue 100 Imager Pro. Cannot recall the Device access code or the Advanced settings code.	**CAUTION** Resetting the codes will result in a loss of any images and patient data stored on the RetinaVue 100 Imager Pro. When the *Please enter access code* screen appears, press and hold the Home button for approximately 10 seconds. Touch **Confirm** at the dialogue screen prompt *Reset all the settings to defaults?*

Problem	Solution
	Note The reset process typically takes a few minutes to cycle through the complete reset. During the reset process, it is normal for the Confirm button to remain active before the reset confirmation dialogue screen appears. Do not remove the SD card or power off the device. Touch **OK** at the *All settings were restored to factory defaults* confirmation dialogue screen.

Maintenance

Clean and disinfect

CAUTION Never submerge the RetinaVue 100 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 100 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 docking station 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 docking station charger and the device.

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

The RetinaVue 100 Imager has been tested to verify that it is compatible with the approved cleaning agents.

Cleaning the RetinaVue 100 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 RetinaVue 100 Imager and eye cup

Power off the RetinaVue 100 Imager before cleaning it.

Use a pre-moistened wipe or soft cloth slightly moistened with an approved cleaner to gently clean the RetinaVue 100 Imager and eye cup.

Cleaning the docking station charger

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

Disinfecting the RetinaVue 100 Imager, eye cup, and docking station 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 100 Imager, eye cup, and docking station charger. Follow the manufacturers recommendations.

Approved cleaning agents

Use only the following approved cleaning agents on the RetinaVue 100 Imager, eye cup, and docking station charger:

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

The RetinaVue 100 Imager has been tested to verify these instructions as being capable of preparing the RetinaVue 100 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.

RetinaVue 100 Imager Pro Specifications

Specifications

View Angle	45 Degree (Typical)
Diopter	-20 ~ +20D (Typical)
Dimensions	L 8.8 inches (224.2 mm) × W 4.2 inches (106.7 mm) × H 4.1 inches (105.2 mm)
Weight	565 Grams ±5%
Search Fundus Lighting	Infrared LED
Camera flash light	Natural White Light Emitting Diode (LED)
Captures	Auto capture and Manual capture
Camera Resolution	2048 x 1536 pixels
LCD Monitor	3.5 inch Full Color TFT-LCD
Image Format	Unencrypted JPEG/DICOM (standalone use)
Interface	Micro USB
RetinaVue 100 Imager Pro File Transfer	Docking station, micro USB cable to a computer SD Card transfer to a computer SD Card Reader
File Storage	SD Card, default 8GB. Supports 8GB to 32GB by FAT32 format. Supports 1,200 exams Supports up to 200 patients
Power Source	Rechargeable Lithium Battery 3.6V / 3350mAh
External Power	Source: 100~240 VAC, 50/60 Hz
Power Adapter Spec.	Input Spec. : 100~240 VAC, 50/60 Hz, 0.2A - 0.1A; Output Spec. : 5V DC, 2A
Charger Station Input Spec.	5V DC, 1.2A

Operating Time	3 hours at 5 minutes working mode. The device enters Sleep mode if idle for 2 minutes. Once the device is idle for 2 minutes it enters Sleep mode and if it remains idle in Sleep mode for another 10 minutes the device powers down.
Charging Time	5 hours (through the docking station using a Welch Allyn approved battery)

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 100 Imager Pro 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 100 Imager Pro device fails to hold a charge, a new battery can be ordered.

Enable the RetinaVue Network

Note The RetinaVue 100 Imager Pro model is a stand alone camera with unencrypted images and is designed for use independent of the Welch Allyn RetinaVue Network.

Note Account registration with the Welch Allyn RetinaVue Network is required to use the RetinaVue 100 Imager camera with wireless or USB connectivity. To change to a RetinaVue 100 Imager camera configuration with encrypted images and a USB or wireless connection to the Welch Allyn RetinaVue Network:

- In North America, please call the following number: 865.622.8380 from 8:00 AM – 5 PM EST to create an account with the Welch Allyn RetinaVue Network. For additional inquires use the following link: www.welchallyn.com/support.
- In the Australian region, contact Australia Technical Support at the following number: 1800 650 083 from 08:30 – 17:00 Monday – Friday AEDT. For additional inquires use the following link: techsupport.au@welchallyn.com.

To change the camera configuration from the RV100 Pro to the RV100 (USB or Wireless):

1. Touch **Settings**.
2. Touch **Advanced settings**.
3. Touch **Camera configuration**.
4. To convert the RV100 Pro to a RV100, touch **RV100** to use the RetinaVue Imager camera with encrypted images and with the RetinaVue Network:
   a. Touch **Yes** at the prompt: *I already have an account*.
   b. Touch **OK** at the prompt: *Saved exams stored on this camera will be discarded.***Note:** This prompt only appears if saved exams have not been transferred.
   c. At the RetinaVue 100 Imager camera set up screen, select whether your camera will be used with Wi-Fi or USB connectivity.
   - For Wi-Fi set up, touch the **RetinaVue Network - Wi-Fi** radio button and see the RetinaVue 100 Imager *Directions for use* topic *First time selection of Wi-Fi connectivity workflow* for instructions on setting up the camera for a wireless connection to the RetinaVue Network Customer Portal.

- For USB set up, touch the **RetinaVue Network - USB** radio button and see the manual *Software installation instructions* for instructions on downloading the RetinaVue Network software application onto your PC.

To change the camera configuration from the RV100 (USB or Wireless) to the RV100 Pro:

1. Touch **Settings**.
2. Touch **Advanced settings**.
3. Touch **Camera configuration**.

   Note The RetinaVue 100 Imager Pro camera provide a means to revert back to the RetinaVue 100 Imager Pro model at this point in the configuration.

4. Touch **RV100 Pro** to convert the RV100 to the RV100 Pro and to use the RetinaVue 100 Imager Pro camera with unencrypted images without using the RetinaVue Network:
   a. Touch **OK** at the prompt: *Saved exams stored on this camera will be discarded.***Note:** This prompt only appears if saved exams have not been transferred.
   b. At the RetinaVue 100 Imager camera set up screen, touch the **RV100 Pro** radio button to revert back the RetinaVue 100 Imager Pro model.

Viewing or changing the RetinaVue 100 Imager Pro settings

To view or change the settings

Touch **Settings**. Modify the settings as desired.

- Touch **Volume**.

Touch (up) or (down) to adjust the device sound volume. Touch (Back) to return to the *Settings screen.*

- Touch **Time**.

Touch (up) or (down) to adjust the hour, minute (Min), 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 **Date**.

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

Touch **Advanced settings**.

Modify the settings as desired

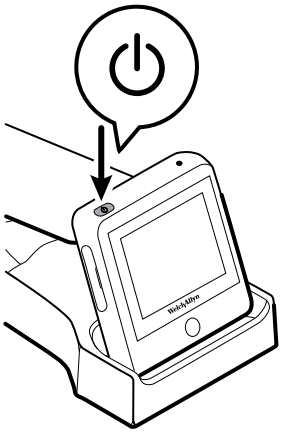
- **Device access code**. Set the Device access numeric code, retype the code to confirm, and touch **OK** to return to the *Advanced Settings screen.*
- **Advanced settings code**. Set the Advanced settings numeric code, retype the code to confirm, and touch **OK** to return to the *Advanced Settings screen*.
- **Format SD**. Touch **OK** to format the SD card to the default settings and touch **OK** again to return to the *Advanced Settings screen*.
- **Restore factory defaults**. Touch **Confirm** to reset the device to the default settings and touch **OK** to return to the *Advanced Settings screen*.
- **Exam setup.** Touch **Exam setup**. Touch 1-image (Macula-centered) to use the one image per eye exam workflow or touch 2-image (Macula and Optic Disc-centered) to use the two images per eye exam workflow . Touch (Back) to return to the *Settings screen.*

- **Camera configuration.** Touch **Camera configuration**. Touch **RV100 Pro** to use the RetinaVue 100 Pro Imager with unencrypted images only without the RetinaVue Network. See the topic *Enable the device with the RetinaVue Network* for further instructions on configuring the device.
- **Export log**. The log files are exported to the SD card. Touch **OK** to return to the Advanced Settings screen. Touch (Back) to return to the *Settings screen*.
- Touch **About** to view the software version. Touch **OK**.
- **Regulatory Information**. Touch **Regulatory Information** to view Regulatory Information. Touch (Back) to return to the *Settings screen*.

Touch (Home) to return to the *Home screen*.

Power down the RetinaVue 100 Imager

1. Press .



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

3. Touch one of the options.

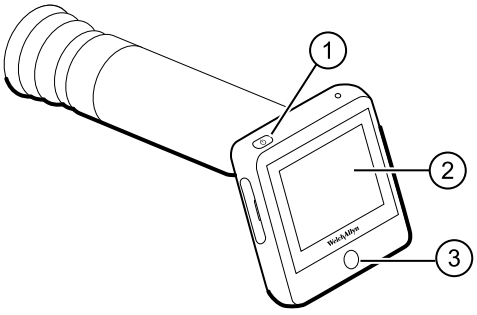
   The RetinaVue 100 Imager will power off, go into Sleep mode, or return to the prior screen, depending on the option you choose.

Sleep mode

To conserve power, the RetinaVue 100 Imager enters Sleep mode if approximately 2 minutes have passed since the last screen press.

To bring the RetinaVue 100 Imager out of Sleep mode, use any of these methods:

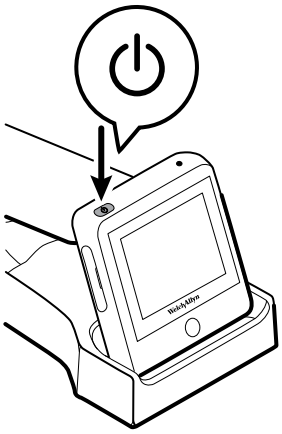
1. Touch the power button.
2. Touch the LCD touchscreen.
3. Press the Home button.



Note Lifting or moving the RetinaVue 100 Imager also brings the RetinaVue 100 Imager out of Sleep mode.

Enter Sleep mode

1. Press ⏻.



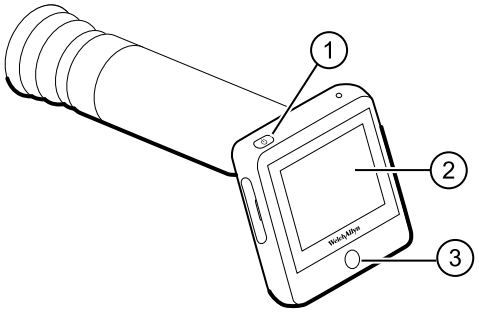
2. A dialogue box appears with three options:
   - Power Off
   - Sleep
   - Cancel

3. Touch **Sleep.**

   The RetinaVue 100 Imager enters Sleep mode.

Exit sleep mode

1. Perform one of these options: (1) Press ⏻, (2) touch the LCD touchscreen, or (3) press the Home button.



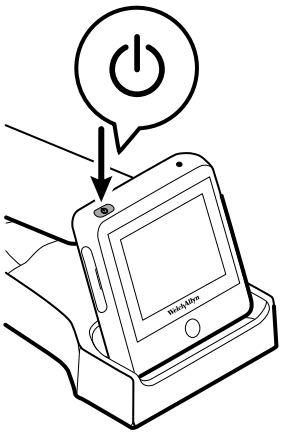
Note Lifting or moving the RetinaVue 100 Imager also brings the RetinaVue 100 Imager out of Sleep mode.

2. After performing one of the options, the RetinaVue 100 Imager will awaken from Sleep mode, or return to the prior screen.

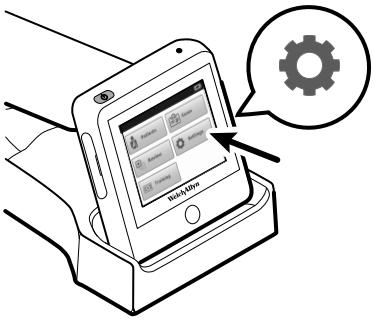
Set the date and time

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 to turn the device on.

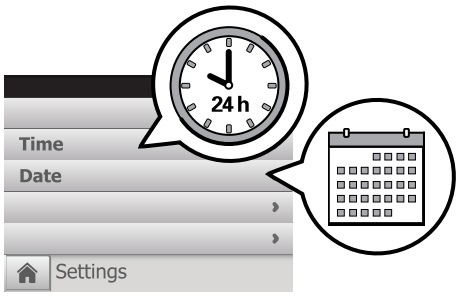


2. Touch **Settings** on the RetinaVue 100 Imager Home screen.



3. Touch **Time**. Touch (up) or (down) to adjust the hour, minute, Continent, and location.

Note The default time appears in the 24-hour format. Use the radio buttons to select the 24-hour or 12-hour format.

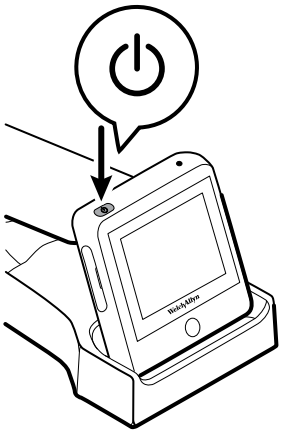


4. Touch (Back) to return to the *Settings screen*.
5. Touch **Date**. Touch (up) or (down) to adjust the day, month, and year in the DD/MM/YY format.
6. Touch (Back) to return to the *Settings screen*.
7. Touch (Home) to return to the RetinaVue 100 Imager *Home screen*.

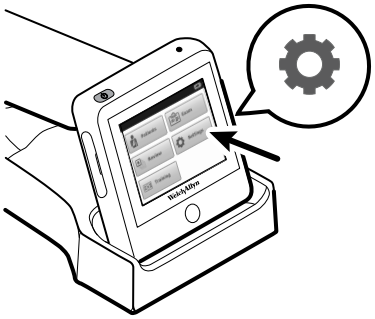
Set the Device Access Code

Note Setting the Device Access Code before first use provides additional security features in the RetinaVue 100 Imager Pro to prevent unintended access to patient information by unauthorized individuals**.**

1. Follow the steps in the *Battery installation and replacement* section to install the battery and then press and hold the power button to turn the device on.



2. Remove the RetinaVue 100 Imager Pro from the docking station charger.
3. Touch **Settings** on the RetinaVue 100 Imager Pro Home screen.



4. Touch **Advanced Settings**.
5. Touch **Device Access Code** to enter an access code for the RetinaVue 100 Imager Pro.
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.

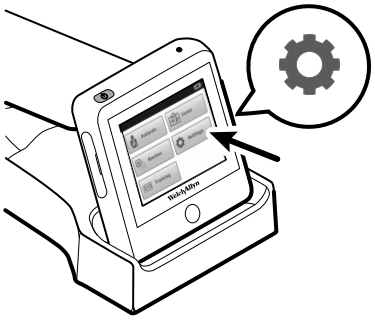
   Note The access code password can contain a minimum of 1-digit and a maximum of 18-digits. Characters are only numeric from 0 through 9.

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 *Settings screen*.
9. Touch (Home) to return to the RetinaVue 100 Imager Pro *Home screen*.

Reset the Device access code

Note See the *Troubleshooting section* if you cannot recall your RetinaVue 100 Imager Pro access code and need to erase the access code.

1. Remove the RetinaVue 100 Imager Pro from the docking station charger.
2. If you are not already logged in, enter the existing access code for the RetinaVue 100 Imager Pro.
3. Touch **Settings** on the RetinaVue 100 Imager Pro Home screen.



4. Touch **Advanced Settings**.
5. Touch **Device access code**.
6. Touch **Reset** to clear the existing access codes.

7. 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.

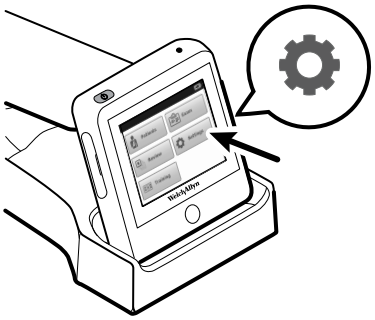
   Note Alternatively, after the code reset, touch (Back), (Back), and (Home) to return to the RetinaVue 100 Imager Pro *Home screen* without using a Device access code.

8. Touch **OK** to accept the code and touch **OK** again at the confirmation screen to return to the *Advanced Settings* screen.
9. Touch (Back) to return to the *Settings screen*.
10. Touch (Home) to return to the RetinaVue 100 Imager Pro *Home screen*.

Reset the Advanced settings code

Note See the *Troubleshooting section* if you cannot recall your RetinaVue 100 Imager Pro Advanced settings code or the Device access code and need to erase the code.

1. Remove the RetinaVue 100 Imager Pro from the docking station charger.
2. If the RetinaVue 100 Imager Pro 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.
3. Touch **Settings** on the RetinaVue 100 Imager Pro *Home screen*.



4. Touch **Advanced Settings**.
5. Enter the existing Advanced settings code for the RetinaVue 100 Imager Pro.
6. Touch **Advanced settings code**.
7. Touch **Reset** to clear the existing Advanced settings codes.
8. 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), and (Home) to return to the RetinaVue 100 Imager Pro *Home screen* without using an Advanced setting code.

9. Touch **OK** to accept the code and touch **OK** again at the confirmation screen.
10. Touch (Back) to return to the *Settings screen*.
11. Touch (Home) to return to the RetinaVue 100 Imager Pro *Home screen*.

General compliance and standards

The RetinaVue 100 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

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.

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 901103 Imager 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 901103 Imager in extremely close proximity to other equipment.
- It is not safe to operate the 901103 Imager in the presence of high-frequency surgical equipment.

Emissions and immunity information

Electromagnetic emissions

The 901103 is intended for use in the electromagnetic environment specified below. The customer or user of the 901103 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The 901103 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 901103 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. **WARNING** This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment [a]. It may be necessary to take mitigation measures, such as re-orienting or relocating the 901103 or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

[a] The 901103 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 R&TTE Directive (1995/5/EC). 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 901103 is intended for use in the electromagnetic environment specified below. The customer or the user of the 901103 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 contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge	± 1 kV differential mode	± 1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.

Electromagnetic immunity

IEC 61000-4-5	± 2 kV common mode	± 2 kV common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	100% dip in 0.5 cycle 100% dip in 1 cycles 30% dip in 25 cycles 100% interruption in 250 cycles	100% dip in 0.5 cycle 100% dip in 1 cycles 30% dip in 25 cycles 100% interruption in 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 901103 requires continued operation during power mains interruptions, it is recommended that the 901103 be powered from an uninterruptible power supply or a battery.

Electromagnetic immunity

The 901103 is intended for use in the electromagnetic environment specified below. The customer or the user of the 901103 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 901103, 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	$d = (1.17)\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 1 GHz	3 V/m	$d = (1.17)\sqrt{P}$ 80 to 800 MHz
			$d = (2.33)\sqrt{P}$ 800 MHz to 2,7 GHz 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:

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.

[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 901103 is used exceeds the applicable RF

Electromagnetic immunity

compliance level above, the 901103 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 901103.

[b]Over 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 901103

The 901103 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the 901103 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 901103 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 transmitter (W)	**150 kHz to 80 MHz** $d = (1.17)\sqrt{P}$	**80 MHz to 800 MHz** $d = (1.17)\sqrt{P}$	**800 MHz to 2.7 GHz** $d = (2.23)\sqrt{P}$
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.3333

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.

Navigation controls

Navigation controls in the Training mode

From the *Home screen* touch **Training**. The RetinaVue 100 Imager *Interactive Training Video screen* appears.

Note Navigation controls change with each mode.

Touch anywhere within the RetinaVue 100 Imager touchscreen to display the training navigation controls. The navigation controls appear within the middle of the RetinaVue 100 Imager touchscreen.

The navigation controls for the Interactive Training video include:

Step back to beginning: Touch to navigate to the first scene within the training section.

Step back to previous scene: Touch to navigate to the previous scene within the training section.

Home: Displays the RetinaVue 100 Imager workflow selection buttons and navigates to the *Home screen*.

Play: Touch to resume the training.

Skip forward to next scene: Touch to navigate to the next scene within the training section.

Skip forward to last: Touch to navigate to the last scene within the training section.

Note In addition to the control buttons, touch anywhere within the RetinaVue 100 Imager touchscreen to pause the training or to display the training navigation controls.

Navigation controls in the Exam mode

The Navigation area is located at the bottom of the RetinaVue 100 Imager screen. Navigation controls change with the mode. The navigation controls for Pre-, post-, and acquisition in Exam mode include:

Pre-acquisition

1-image

Macula-centered

2-image

Macula + Optic Disc-centered

Home: Displays the RetinaVue 100 Imager workflow selection buttons and navigates to the *Home screen*.

Next: Navigates to the next image acquisition within a prescribed image acquisition sequence or to the next step in a sequence of steps.

Image acquisition navigation: Navigates to the image acquisition position within the prescribed sequence. Provides a visual representation of the prescribed sequential acquisition, including the right eye ( ) and the left eye ( ). Provides a status of acquired images for acceptance or dismissal.

Acquisition

Exit: Navigates to the *Pre-acquisition screen*.

Post-acquisition

Discard image: Navigates to the *Pre-acquisition screen*. Or Navigates to the *Acquisition screen*.

Accept image: Navigates to the *Exam summary screen* when the last exam in the sequence has been accepted. Also navigates to *Pre-acquisition screen* if there are more images to be captured.

Image inspection: Navigates to the *Image inspection screen*.

Add image: Navigates to the *Acquisition screen*

Navigation controls in the Settings mode

The navigation controls for the Settings mode include the back, home, and advance to next buttons. The primary navigation area is located at the bottom of the RetinaVue 100 Imager screen. While on the *Settings* screen, the **>** (Advance to next screen) button navigates to the next dialogue. The button is located on the same line as the setting.

Back: Navigates to a previous dialogue or step.

Home: Displays the RetinaVue 100 Imager workflow selection buttons and navigates to the *Home* screen.

>: (Advance to next screen) Navigates to a next dialogue while on the *Settings* screen.

Navigation controls in the Review mode

The navigation controls for the Review mode include the back, home, advance to next screen, and image quality buttons. The primary navigation area is located at the bottom of the RetinaVue 100 Imager screen. In addition, the **>** (Advance to next screen) button navigates to an image. The button is located on the same line as the patient's name on the *Review* screen. The image quality button also navigates to an image. The button is located below the patient's name on the *Exam summary* screen.

Back: Navigates to a previous dialogue or step.

Home: Displays the RetinaVue 100 Imager workflow selection buttons and navigates to the *Home screen*.

>: (Advance to next screen) Navigates to an image while on the *Review* screen.

Good quality green: From the *Exam summary* screen, touch the good quality icon to navigate to the image on the *Post-acquisition* screen.

Acceptable quality yellow: From the *Exam summary* screen, touch the acceptable quality icon to navigate to the image on the *Post-acquisition* screen.

Unacceptable quality red: From the *Exam summary* screen, touch the unacceptable quality icon to navigate to the image on the *Post-acquisition* screen.

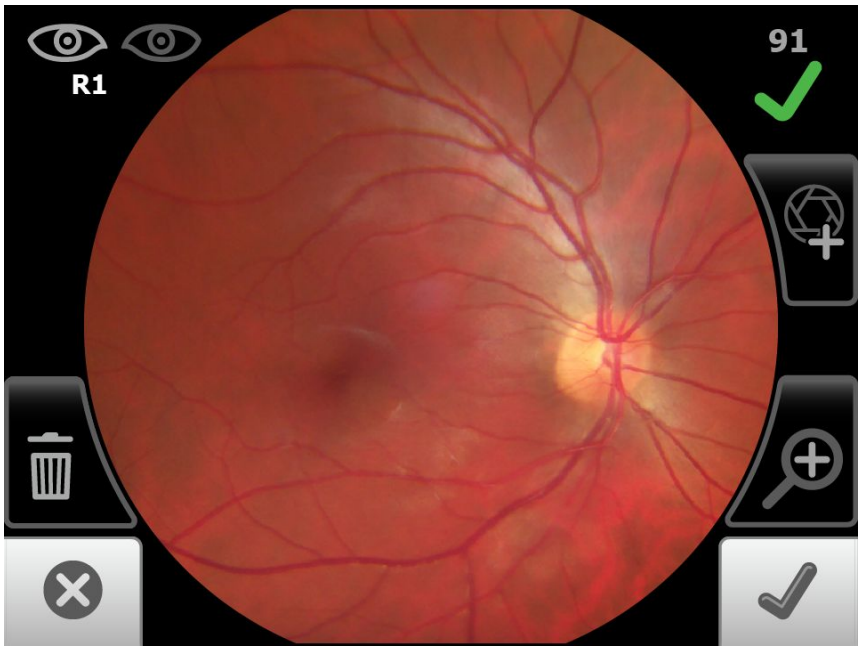
Image Pre-acquisition controls (Auto mode)

From the *Home screen* touch **Exam**. The Exam *Pre-acquisition screen* appears.

No.	Feature	No.	Feature
1.	**START** enters automatic image acquisition mode.	4.	Navigates to the *Home screen.*
2.	(Image Acquisition Settings) navigates to the *Capture settings* screen. Adjust the flash brightness (-2 to +2) or the focus settings (-1 to +1).	5.	**MANUAL** switches to advanced image capture options.
3.	(Image Order) skips to the next image in the sequence.	6.	(Next) skips to the next image acquisition within a prescribed image acquisition sequence or navigates to the *Exam summary screen* if the last image has been acquired.

Controls (Post-acquisition)

On the *Post-acquisition screen*, images with a green check ( ) are of good quality (scores of 40 +), images with a yellow check ( ) are of acceptable quality (scores of 20 — 39), and those with a red x ( ) are of unacceptable quality (scores of 0 — 19).



Use the RetinaVue 100 Imager touchscreen inspection control to navigate to the *Inspection screen*, then zoom in or out with a pinch or pull. Touch (Back) to navigate to the *Post-acquisition* screen. Or, touch (Trash) and then touch **Delete** at the dialogue screen: Do you wish to discard this image and acquire again? to confirm the discard and to return to the *Acquisition screen* to acquire again. Touch (Add image) to navigate to the *Acquisition screen* and take an additional image.

Note The initial captured image is saved.

Touch (Discard) then touch **Yes** at the dialogue: *Do you wish to discard this image?* to discard the image. Alternatively, touch **No** at the dialogue screen to return to the *Post-acquisition* screen to save the initial captured image.

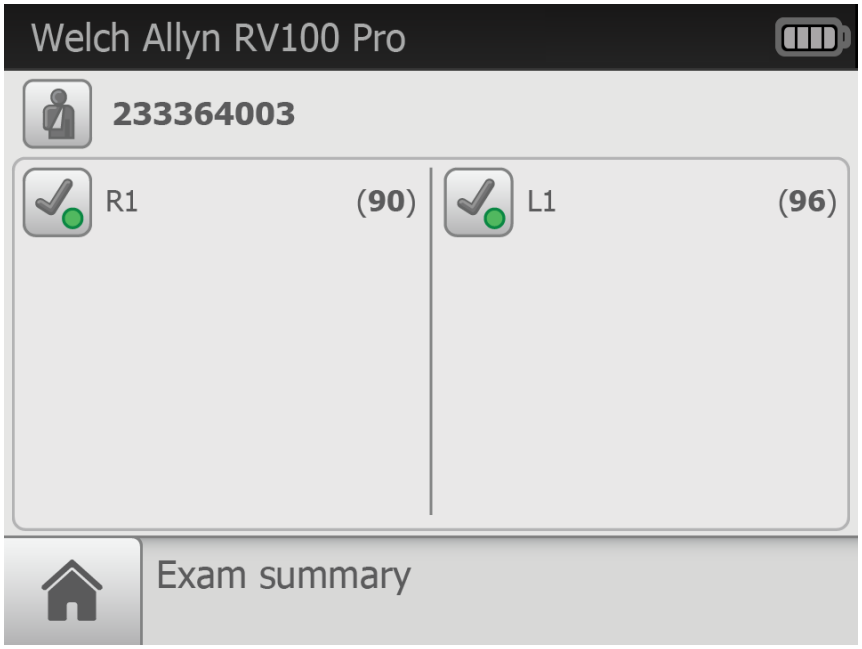
On the *Post-acquisition screen*, touch (Trash) and then touch **Delete** at the dialogue screen: *Do you wish to discard this image and acquire again?* to confirm the discard and to return to the *Acquisition screen* to acquire again.

Touch (Accept) to accept the image and to navigate to the next image. Or touch (Accept) to navigate to the *Exam summary screen* once the last image of the exam is acquired.

Exam summary controls (Post-acquisition and Review modes)

Exam summary from the *Post-acquisition screen*

From the *Post-acquisition screen*, touch (Accept) to navigate to the *Exam summary screen*. Each image on the *Exam summary screen* contains a quality score and status.



Touch (Good quality green) to view that image. Image accepted, good quality. Quality scores of 40+.

Touch (Acceptable quality yellow) to view that image. Image accepted, quality OK. Quality scores ranging from 20 – 39.

Touch (Unacceptable quality red) to view that image. Image rejected. Quality scores ranging from 0 – 19.

CAUTION Captured images require patient context before the images can be saved.

Note To add missing patient context information touch .

Touch to create a new patient, or touch on an existing patient's ID from within the *Patients screen*.

Touch **SAVE** to accept all images and to return to the *Home screen*.

If an image is missing touch **Override** to access the Save button and to save a single image in the 1-image, Macula-centered Exam setup, or touch **Override** to save multiple images in the 2-image, Macula + Optic Disc-centered Exam setup.

Exam summary from the *Review screen*

Touch **Review**.

Touch on a patient's ID. The *Exam summary screen* appears for that patient.

Touch (Good quality green), (Acceptable quality yellow), or (Unacceptable quality red) to view the image. Touch (Patient) to review patient demographics on the *Patient summary* screen. Touch (Back) to return to the *Review screen.* Touch (Home) to return to the *Home screen*.

Update the RetinaVue 100 Imager Pro software to version 6.XX and above

CAUTION Do NOT remove the SD Card or the power source from the device during boot up.

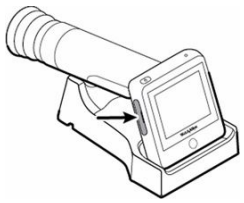
Take note of the current software version:

1. Touch **Settings**.
2. Touch **About** to view the software version.

Before you begin, you will need the following :

- A computer with an Internet connection.
- The docking station charger with a USB cable connected to the power source.
- The RetinaVue 100 Imager Pro containing the SD card that you plan to update. (Alternatively, you can use a blank, formatted, 8GB to 32GB SD Card to transfer the downloaded software update to the RetinaVue 100 Imager Pro).

1. Ensure that any patient data that you want to save is transferred by docking the RetinaVue 100 Imager Pro into the docking station charger with a USB cable connected to a laptop or PC.
2. Remove the RetinaVue 100 Imager Pro from the docking station charger, touch **Settings** then touch **Advanced settings**.
3. Touch **Format SD**.
4. Touch **OK**.
5. Power down the RetinaVue 100 Imager Pro and remove the SD Card.



6. Insert the SD Card into an open SD Card reader port on the computer.
7. Download the software update and transfer the software update to a computer.
8. Transfer the software update from the computer to the SD Card.

Note Use a safe eject method when ejecting the SD card to ensure a complete software transfer to the SD card. (Options include right-clicking on the *Start Menu > Open Windows Explorer> right-click on SD card> click Eject*. Or, click on the *Taskbar> Show hidden icons >* click*Safely Remove Hardware and Eject Media>* click *Eject SDHC*). If an eject menu is not available with your system settings, wait until the files have completely copied before manually ejecting the SD Card.

9. Remove the SD Card from the computer.
10. Insert the SD Card into the RetinaVue 100 Imager Pro.
11. Place the RetinaVue 100 Imager Pro on the docking station charger, connect the docking station charger via a USB cable to the power source, and then power up the RetinaVue 100 Imager Pro.

    Note The update process typically takes a few minutes to cycle through the complete update. During the update process, it is normal to see both a blank screen and an update screen that appear several times before the RetinaVue 100 Imager Pro automatically reboots.

12. After the RetinaVue 100 Imager Pro boots up to the *Home* screen, confirm the software update.
    a. Touch **Settings**.
    b. Touch **About** to view the software version.
13. Touch **OK**.

    You are ready to use the updated software.

Troubleshooting software updates

Note The RetinaVue 100 Imager Pro boots up normally after a successful software update, however if a software update fails, the RetinaVue 100 Imager Pro 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 100 Imager Pro posts a blank screen. Remove the battery, reinstall it, and restart RetinaVue 100 Imager Pro. By performing this power cycle, the RetinaVue 100 Imager Pro reverts to a previous version of software. Repeat the steps to perform the update again.

Corrupted software files:

- If the software update on the SD Card is corrupted, the RetinaVue 100 Imager Pro displays a failed update error message indicating that the RetinaVue 100 Imager Pro is unable to load the software from the SD Card. Remove the SD Card, reformat it on a PC. Repeat the steps to perform the update again.

Update extraction file error

If the RetinaVue 100 Imager Pro displays the failed update error message, *Update file extraction failed. Power off device and restart,* the SD Card does not have sufficient space. Remove all files (except the update image) from the SD Card. Perform the update again.

RetinaVue 100 and 100 Imager Pro Accessories

Miscellaneous items

Part number	Description
RV100PRO-B	RetinaVue 100 Imager Pro with lithium-ion battery
RV100-B	RetinaVue 100 Imager with lithium-ion battery
RV100-6	RetinaVue 100 Imager with lithium-ion battery and Australian plug
RV100PRO-6	RetinaVue 100 Imager Pro with lithium-ion battery and Australian plug
106401	Charging Dock for Welch Allyn RetinaVue 100 Imager; 100-240 V, 50-60 Hz
106405	Battery for Welch Allyn RetinaVue 100 Imager; Lithium-Ion 3.6V / 3350mAh
106406	Replacement USB Cable for Welch Allyn RetinaVue 100 Imager
106507	Power supply wall adapter for Welch Allyn RetinaVue 100 Imager. 100-240 V, 50-60 Hz; IEC Plug Type B (US)
106508	Power supply wall adapter for Welch AllynRetinaVue 100 Imager. 100-240 V, 50-60 Hz; IEC Plug Type C (EU)
106509	Power supply wall adapter for Welch Allyn RetinaVue 100 Imager. 100-240 V, 50-60 Hz; IEC Plug Type G (UK)
106530	Power supply wall adapter for Welch Allyn RetinaVue 100 Imager. 100-240 V, 50-60 Hz; IEC Plug Type I (AU)
106710	RetinaVue 100 Imager Lens cap
106711	RetinaVue 100 Imager Battery cover

Part number	Description
236200-2	Welch Allyn RetinaVue 100 Imager replacement screwdriver for battery cover. #1 Phillips Screwdriver w/ Logo
723481	Laptop for RetinaVue Network
724224	RetinaVue 100 Imager camera case
723484	Lens spray
723671	Lens cloth

Applied parts

Part number	Description
106404	Reusable Eye Cups for Welch Allyn RetinaVue 100 Imager: Qty. 5

Service

Part number	Description
S1-RV100-1	Welch Allyn Partners in Care Comprehensive Partnership Program Service for RetinaVue 100 Imager; 1 year
SV-RV100-2	Welch Allyn Partners in Care Comprehensive Partnership Program Service for RetinaVue 100 Imager; 2 years
SV-RV100-3	Welch Allyn Partners in Care Comprehensive Partnership Program Service for RetinaVue 100 Imager; 3 years
S1-RV100-1P	Welch Allyn Partners in Care Comprehensive Partnership Program Premium Service for RetinaVue 100 Imager; 1 year
S1-RV100-2P	Welch Allyn Partners in Care Comprehensive Partnership Program Premium Service for RetinaVue 100 Imager; 2 years
S1-RV100-3P	Welch Allyn Partners in Care Comprehensive Partnership Program Premium Service for RetinaVue 100 Imager; 3 years

Literature/Documentation

Part number	Description
411492	RetinaVue 100 Imager Directions for use
727803	RetinaVue 100 Imager Pro Directions for use

Part number	Description
724146	RetinaVue 100 Imager Technique guide

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