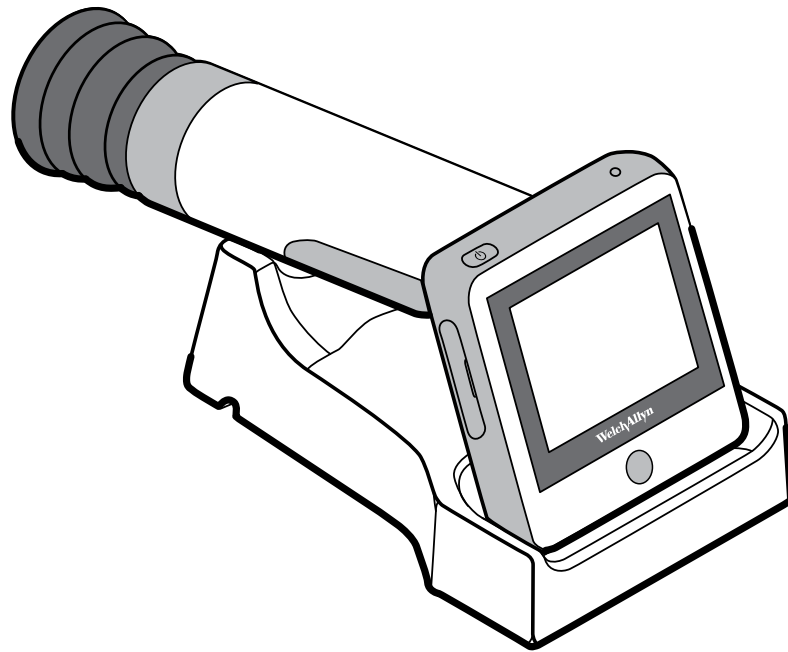


Welch Allyn RetinaVue™ 100 Imager



Directions for use

Software version 4.5.XX

WelchAllyn®

Advancing Frontline Care™

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Caution Federal US law restricts sale of the device identified in this manual to, or on the order of, a licensed physician.

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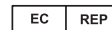
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Manufactured for Welch Allyn, Inc.
Medimaging Integrated Solution Inc. (MiiS)
1F, No. 7, R&D Rd II, Hsinchu Science Park,
Hsinchu, TAIWAN 30076, R.O.C.

Made in Taiwan

This manual applies to the REF 901103 Fundus Camera



Obelis S.A.
Bd. General Wahis 53,1030,
Brussels, Belgium

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Symbols

Documentation symbols



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

Power symbols



Power button



Direct current (DC)



Rated power input, DC



Rated power output, DC



Fuse



Rechargeable battery

Li-ion



Battery Charging - Non-AC powered

Connectivity symbols



USB



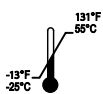
Wireless signal strength (requires optional software)

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



- No connection (X)

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



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"



Non-ionizing electromagnetic radiation



Serial Number

FCC ID

The identification number assigned by the Federal Communication Commission

Battery charge level indicators

	Device is running on battery and charge is above ninety percent.		Device is running on battery and charge is above seventy-five percent.
	Device is running on battery and charge is above fifty percent.		Device is running on battery and charge is above twenty percent.
 	Device is running on battery and charge is below twenty 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.

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 and cautions



WARNING Patient injury risk. The eye cup should be cleaned after each patient.



WARNING Fire and explosion hazard. Do not operate 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.



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



WARNING When using the RetinaVue 100 Imager, no acute optical radiation hazards are identified. However, Welch Allyn recommends limiting the intensity of the light directed into the patient's eye to the minimum level that is necessary for diagnosis. Infants, aphakes, and persons with diseased eyes are at a greater risk. The risk is also increased if the examined person has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source within the previous 24 hours. This will apply particularly if the eye has had exposure to retinal photography. The intended use of this device is for routine ophthalmic exams on the order of typically less than 60 seconds per eye. Although there is a benefit versus risk factor in any medical procedure, these more complicated exams should not exceed a three minute exam time in 24 hours. Significant use of this device beyond its intended use is not recommended; it may cause harm to the eyes.



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



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 Only connect 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.

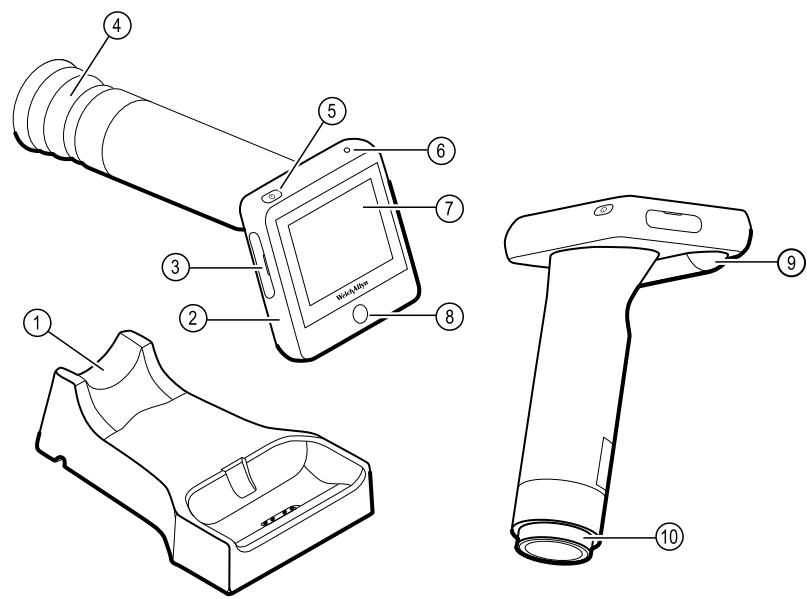


CAUTION Consult the cleaning agent and germicidal cleaner agent manufacturer instructions for their proper use and germicidal efficacy prior to their use.



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

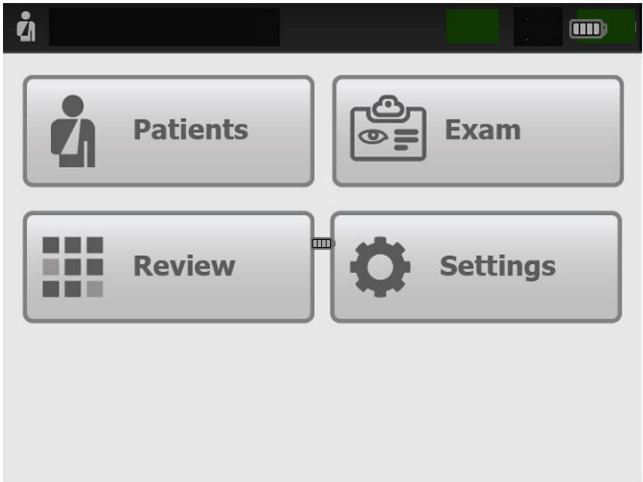
Controls and connectors



No.	Feature	Description
1	Docking station	Charges the RetinaVue 100 Imager and enables data transfer to a PC running the RetinaVue™ Network software. (Requires optional software). Connect to an electrical outlet or to a USB port of a computer.
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	SD Card slot. Insert SD Card for data storage.
4	Eye cup	Blocks ambient light during testing
5	Power button	Push button to turn the device on and off.
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

RetinaVue 100 Imager screens

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



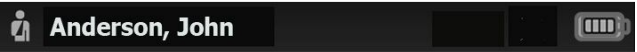
Item	Area
1	Device status
2	Content

Device Status Area

The Device Status Area, located at the top of the *Home screen*, displays the following information from left to right:

- Patient Icon
- Battery condition. Estimated battery capacity is displayed in a charged or discharged status format.

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



- Patient Icon and Patient name. The format of the Patient name is last name, first name.
- Connection status. The icons indicate which connection type, if any, is currently active.

Note Your model might not contain all of these features.

Icon	Connection type
	USB
X	No connection

- Battery condition. Estimated battery capacity is displayed in a charged or discharged status format.

Content Area

The Content Area includes four workflow selection buttons. Touching one of the four buttons navigates to the next screen associated with that workflow.

- **Patients:** Presents a list of patients created on the RetinaVue 100 Imager or transferred from the RetinaVue™ Network (requires optional software).
- **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. (The Exam Workflow requires optional RetinaVue™ Network software to submit images to an overread service.)
- **Review:** Presents images and exams from a list of patients contained on the RetinaVue 100 Imager.
- **Settings.** Provides controls to view or change the following:
 - Volume
 - Time
 - Date
 - Advanced Settings:
 - Device access code
 - Advanced settings code
 - Format SD
 - Factory reset
 - Export log
- About
 - Software Version

Pre-, post-, and acquisition navigation

The Navigation area is located at the bottom of the RetinaVue 100 Imager screen. Navigation controls change with the mode and include:

Pre-acquisition



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

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

Image acquisition navigation: Navigates to images within the prescribed sequence. Provides a visual representation of the prescribed sequential capture, 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:  or  Navigates to the *Acquisition screen*.

Accept image:  Navigates to the *Exam summary screen* when the last exam in the sequence is accepted.

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

Exam summary and Settings

Back:  Navigates to a previous dialog or step.

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 <i>Home screen</i> .
2.	 (Image Acquisition Settings) navigates to the <i>Advanced image capture settings</i> 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 in the image capture sequence or navigates to the <i>Exam summary screen</i> if this is the last image.

About image quality scores

Good quality 	If the image is of good quality, it is very likely to be read by a specialist. (Scores of 60 +)
Acceptable quality 	If the image is of good enough quality, it is likely to be read by a specialist. (Range of 40 — 59)
Unacceptable quality 	If the image is lacking in quality, it is highly unlikely that a specialist will be able to read it. (Range of 1 — 39)

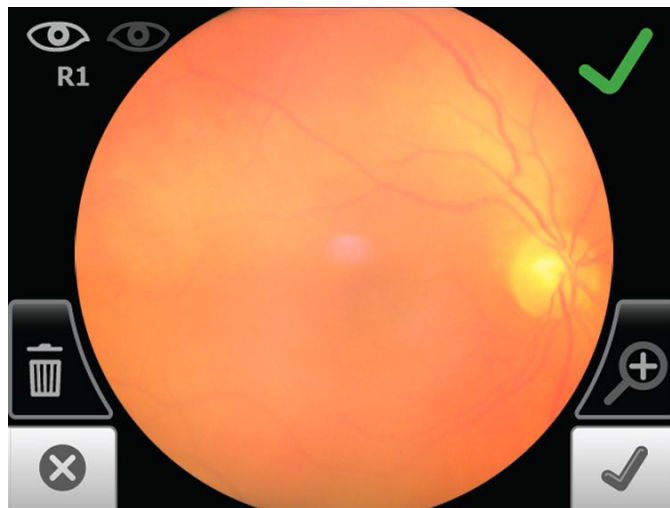
Controls (Post-acquisition)

On the *Post-acquisition screen*, images with a green check (✓) are of good quality (scores of 60 +), images with a yellow check (✓) are of acceptable quality (scores of 40 — 59), and those with a red x (✗) are of unacceptable quality (scores of 1 — 39).

Use the RetinaVue 100 Imager touchscreen inspection control



to navigate to the *Inspection screen*, then zoom in or out with a pinch or pull.



On the *Post-acquisition screen*, touch  (Trash) or  (Discard) to discard the image. At the dialogue screen, touch **Delete** to confirm the discard and to return to the *Pre-*

acquisition screen to acquire again. On the *Image inspection screen*, touch  (Close) to return to *Post-acquisition screen* and accept or reject the acquired image.

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 captured.

Exam summary controls (Post-acquisition and Review modes)

Exam summary from the *Post-acquisition screen*

From the *Post-acquisition screen*, touch the  (Image accepted button) to navigate to the *Exam summary screen*. Each image on the *Exam summary screen* contains a quality score and status. For images with a low quality score (range 1—39), touch **Override** to accept the image.



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



CAUTION Unsaved images are discarded if the RetinaVue 100 Imager loses battery power or if it enters deep sleep mode.

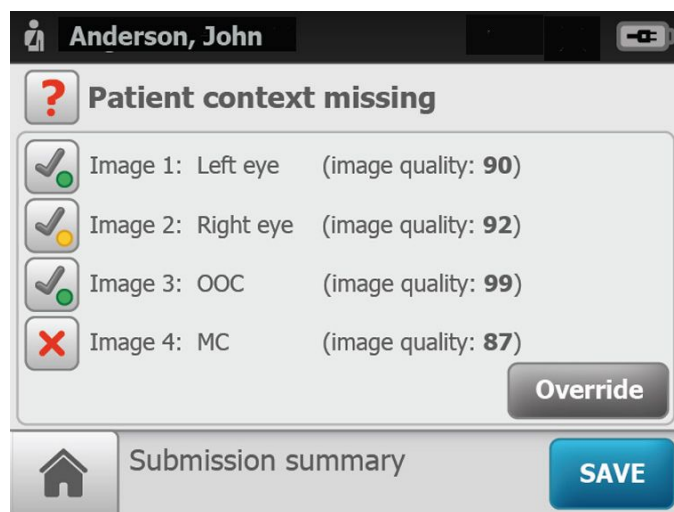
Note

If the RetinaVue 100 Imager enters stand by mode when left idle for approximately two minutes, wake up the RetinaVue 100 Imager by touching the LCD screen or by pressing the Home button. When prompted to leave the screen and discard the image, touch **Cancel**.

Add the missing patient context information. Touch  and then touch  to create the patient.

Note

For images with a low quality score (range 1—39), the Save option is disabled until **Override** is touched.



Touch  (Accepted good) to view that image.
Image accepted, good quality. Quality scores of 60+.

Touch  (Accepted OK) to view that image.
Image accepted, quality OK. Quality scores ranging from 40 — 59.

Touch  (Rejected) to view that image.
Image rejected. Quality scores ranging from 1—39.

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

Exam summary from the *Review screen*

Touch Review.

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

Touch  (Accepted good) to view that image.

Touch  (Accepted OK) to view that image.

Touch  (Rejected) to view that image.

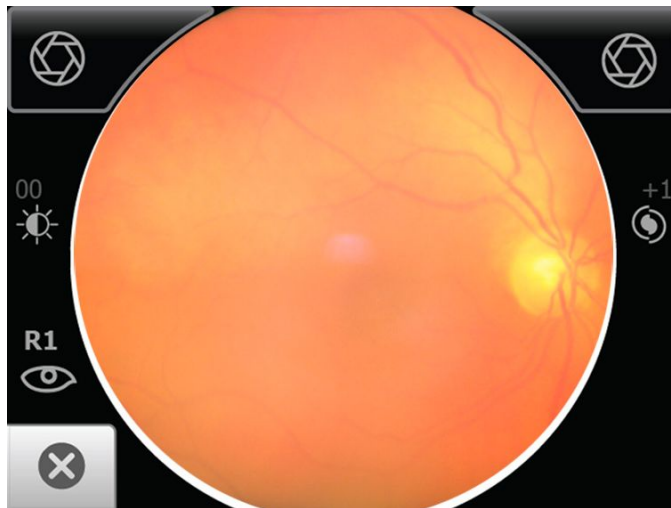
Touch  (Patient) to review patient demographics on the *Patient summary* screen.

Touch  (Back) to return to the *Review screen*.

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

About the Auto and Manual modes

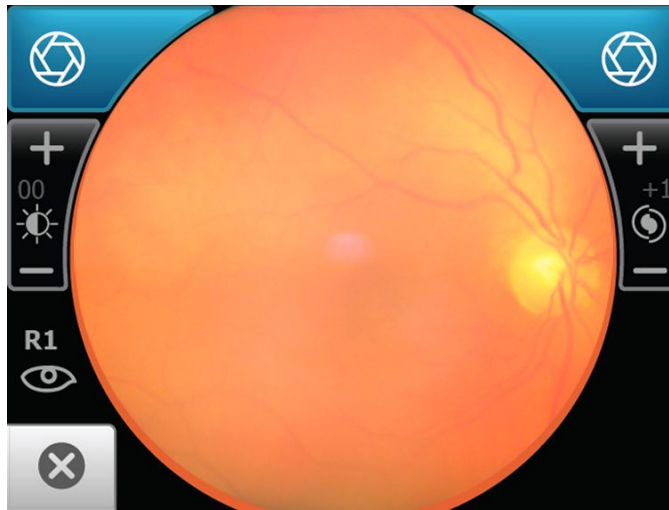
Auto Mode



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

- Image capture
- Focus adjustment (from the *Advanced image capture settings* screen, values range from -1 to +1)
- Flash brightness adjustment (from the *Advanced image capture settings* screen, values range from -2 to +2)
- 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.

Manual Mode

Manual mode contains advanced image capture options.

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

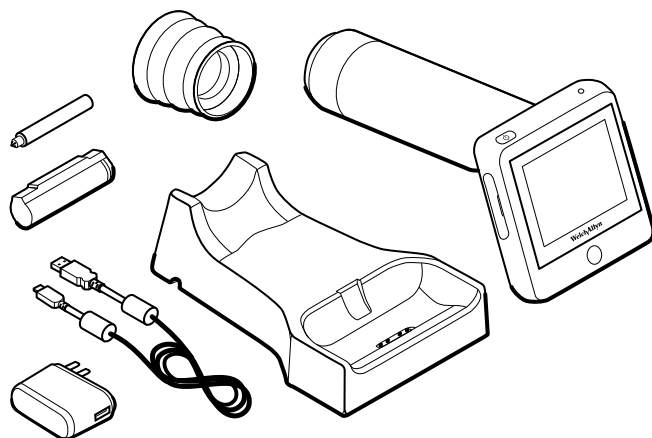
Available manual features include:

- Image capture
 - Focus adjustment (from the *Acquisition screen*, values range from -1 to +1)
 - Flash brightness adjustment (from the *Acquisition screen*, values range from -2 to +2)
-

Using the RetinaVue 100 Imager

Unpack the system

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



Number	Item	Description
1	RetinaVue 100 Imager device	Digital hand-held eye-fundus camera used to record digital photographs and video of the fundus of the human eye and surrounding area.
2	Docking station	Charges the RetinaVue 100 Imager 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.
5	Eye cup	Blocks ambient light during testing
6	Battery	Rechargeable lithium ion battery

Number	Item	Description
7	Screwdriver	Phillips screwdriver to remove battery cover screws
Not shown	RetinaVue 100 Imager <i>Directions for use</i>	This document. The <i>Directions for use</i> (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

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.

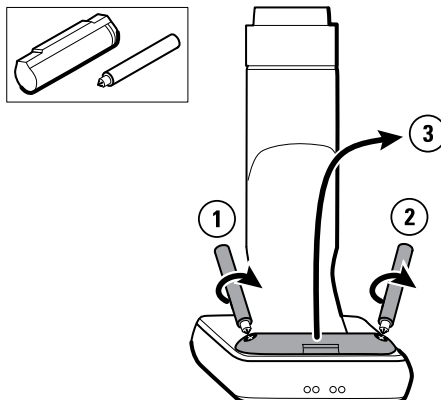


WARNING Personal injury risk. Improper handling of the battery can lead to heat generation, smoke, explosion, or fire. Do not short-circuit, crush, incinerate, or disassemble the battery. Never dispose of batteries in refuse containers. Always recycle batteries according to national or local regulations.

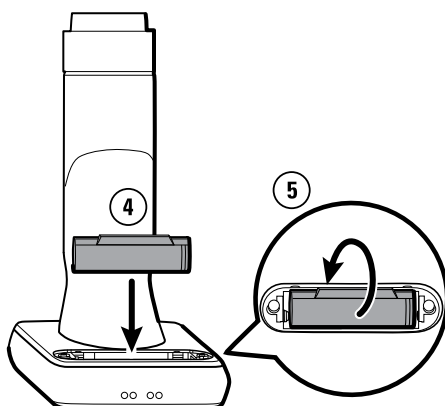


WARNING Use only Welch Allyn approved accessories, and use them according to the manufacturer's directions for use. Using unapproved accessories with the camera can affect patient and operator safety and can compromise product performance and accuracy, and void the product warranty.

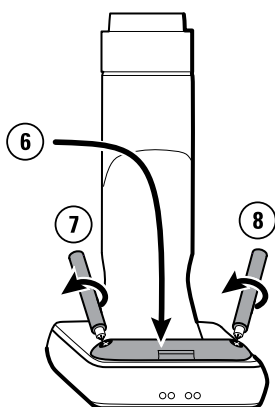
1. Loosen the screw at the left side of the battery cover.
2. Loosen the screw at the right side of the battery cover.
3. Push in the battery cover tab and then lift up the battery cover. Slide open the battery cover by tilting the cover upward.



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.



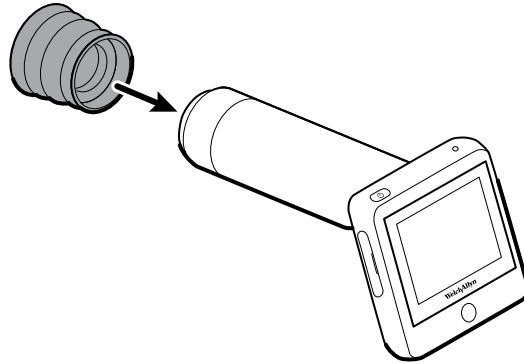
Note Do not over-tighten the screws.

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



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

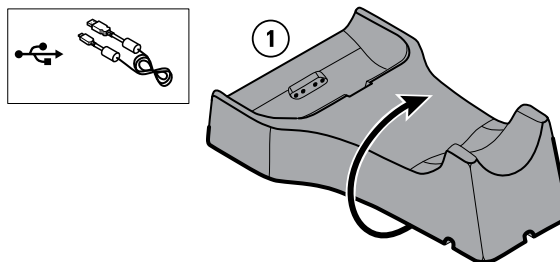


Docking station

Place the device in the docking station to charge the device or to connect and transfer data to a computer or laptop PC running the RetinaVue Network™ Client software. (Requires optional software).

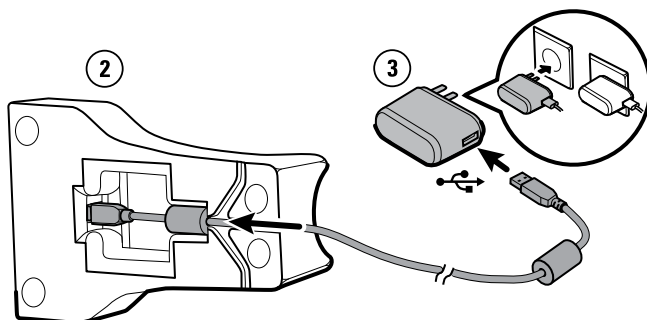
Set up the docking station for charging

1. Turn the docking station over.

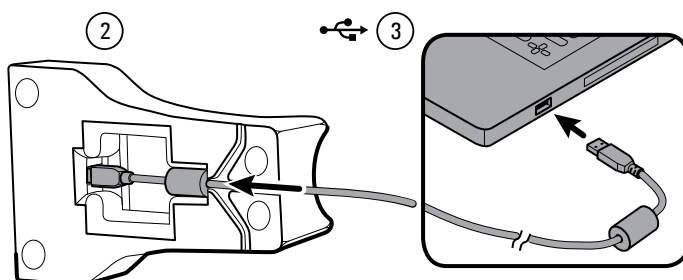


2. Connect the USB cable to the docking station.
3. Either plug the USB cable into the wall adapter plug and then plug the wall adapter into an AC outlet, or plug the USB cable into an open USB port on a computer.

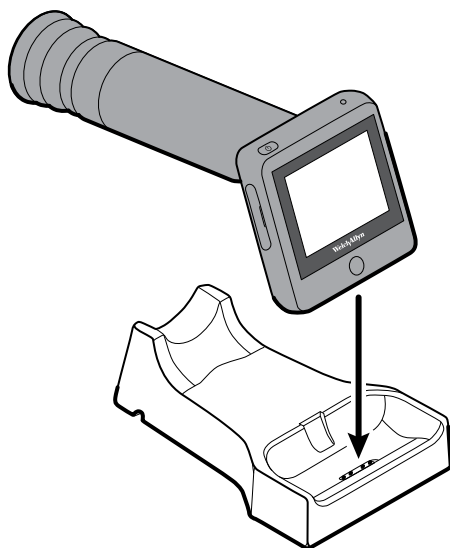
- a. Plug the USB cable into the wall adapter plug and then plug the wall adapter into an AC outlet.



- b. (Optional) Plug the USB cable into an open USB port on a computer.



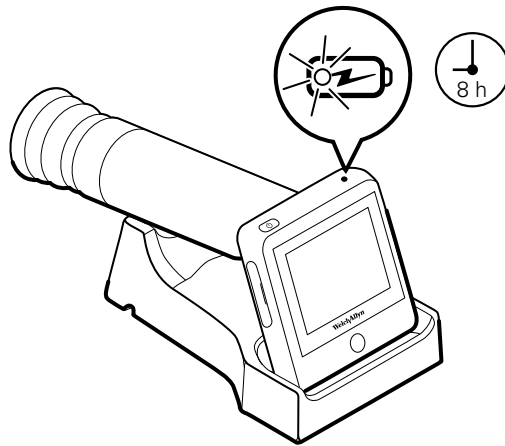
4. Place the RetinaVue 100 Imager on the docking station charger with the contact pins of the RetinaVue 100 Imager touching the contact pins of the docking station charger.



5. Before the first use, allow the RetinaVue 100 Imager to charge for 8 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 reseal the RetinaVue 100 Imager into the docking station. Charging is impacted if the pins are not properly touching.



Patient data management

Create a list of patients on the RetinaVue 100 Imager.

To create a new patient:

1. From the *Home screen*, touch **Patients**. The *Patient list screen* appears.



2. Touch  (New patient) The *New Patient screen* appears.

The screenshot shows the 'New Patient screen' with several input fields. Each field has a 'Required' label and a keyboard icon. At the bottom, there is a navigation bar with a back arrow, a 'New patient' label, and an 'OK' button.

Field	Label
Last name	Required
First name	Required
Middle initial	Required
Date of birth	Required
Patient ID	Required

3. Touch within the Patient's Last name, First name, or Middle name entry box to launch the on-screen keyboard. Enter the patient's information and touch **OK**.
4. Enter the patient's last name and first name. Touch **OK**. (Middle name is optional.)
5. 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. Enter the patient's gender using the radio button to select male or female.
7. Enter the patient's ID. Touch **OK**.
8. Once all the required fields are complete, touch **OK** to open a new exam.

To select a patient from the Patient list:

1. From the *Home screen*, touch **Patients**. The *Patient list screen* appears.



2. Touch the Patient's name to view a summary of the patient information on the *Patient Summary screen*.
3. Touch **OK** to open a new exam for that patient.

Required fields include Patient's Last name, First name, Date of birth, and Identification number.

The screenshot shows a mobile application interface for a patient summary form. At the top, there is a status bar with a signal strength icon, a battery level icon, and a time display. Below the status bar is a header bar with a person icon on the left and a battery icon on the right. The main content area displays a form with the following fields:

Last name	Anderson
First name	John
Middle initial	
Date of birth	03/21/1972
Patient ID	123456

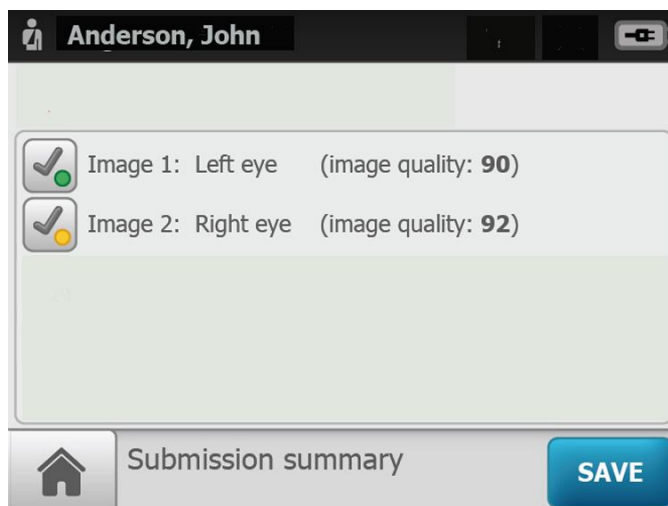
At the bottom of the screen, there is a navigation bar with a back arrow icon, a 'Patient summary' label, and an 'OK' button.

Review patient tests:

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



2. Touch on a patient's information to review the patient demographics and to view images associated with a patient.
3. The most current set of images associated with a patient appears 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*.

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.

- Ensure that the SD card is installed into the RetinaVue 100 Imager.
- Ask your patient to remove their glasses.
- 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.
- 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 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 lens the same height as the patient's examined eye.
- Approach the patient from directly in front of the tested eye. Ensure that the RetinaVue 100 Imager is level and straight with the patient's eye the during the approach into the eye.
- Keep the RetinaVue 100 Imager device level and make any fine adjustments to the patient end of RetinaVue 100 Imager rather than the LCD display end.

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



1. Press the power button .

Note To conserve power, the RetinaVue 100 Imager enters stand by mode and returns to the Home screen if it remains idle for approximately two minutes. Touch the LCD screen to wake up the RetinaVue 100 Imager from stand by mode.

Note After 10 minutes of inactivity the RetinaVue 100 Imager will enter deep sleep mode. Press the Home button to activate the RetinaVue 100 Imager.

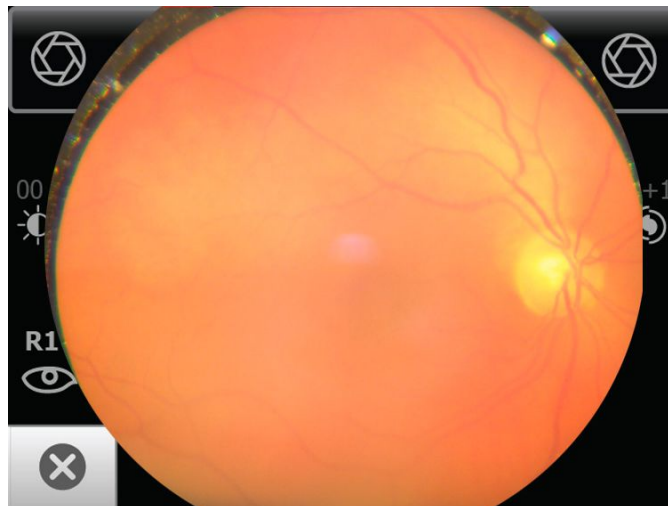
2. From the Home screen, touch **Exam**.

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. Ask your patient to look straight forward and to cover (but not close) their unexamined eye. Stabilize the RetinaVue 100 Imager so that it is the same height as the patient's examined eye.

Note

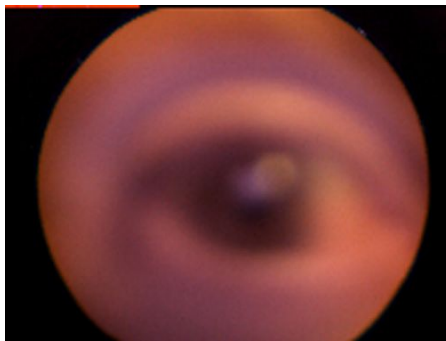
Hold the RetinaVue 100 Imager with one hand and use your other hand to make fine adjustments at the patient's eye. Cradle the lens between your thumb and index finger and then put your fingers on the patient's forehead.



6. Ask the patient to stare at the green fixation lights.

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

7. Start with the eye cup about two to three inches from the eye to be tested.
 - a. Continue to compress the eye cup against the examined eye.
 - b. Identify the white/purple reflection inside the pupil.



WARNING Patient injury risk. The eye cup should be cleaned after each patient.

8. Line up the cross hair and move the image directly toward the reflection, allowing the white reflection to fill the screen as you approach the eye.
9. Continue to move forward slowly until the white reflection fills the whole screen.

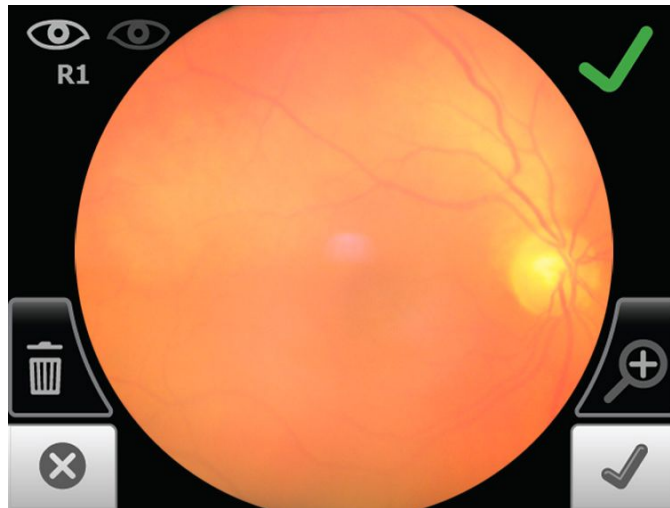
Note Compress the eye cup slightly to surround the eye socket.

10. Continue to move the RetinaVue 100 Imager forward by slightly compressing the eye cup until a ghost-like bubble appears on the screen.

Note If necessary, move the patient end of the RetinaVue 100 Imager toward the ghost-like bubble and direct the ghost-like bubble into the diamond shape located in the upper part of the LCD touchscreen.

11. The RetinaVue 100 Imager automatically captures the image. The RetinaVue 100 Imager plays an acquire tone similar to the sound of a camera shutter.

The image appears on the LCD touchscreen for review.



12. Touch  to begin the second exam of the patient's left eye (L1) and repeat the steps until the second image is automatically captured.
13. When the two images are captured and contain a green quality acceptance check mark, proceed to the patient's Exam summary screen.

Note

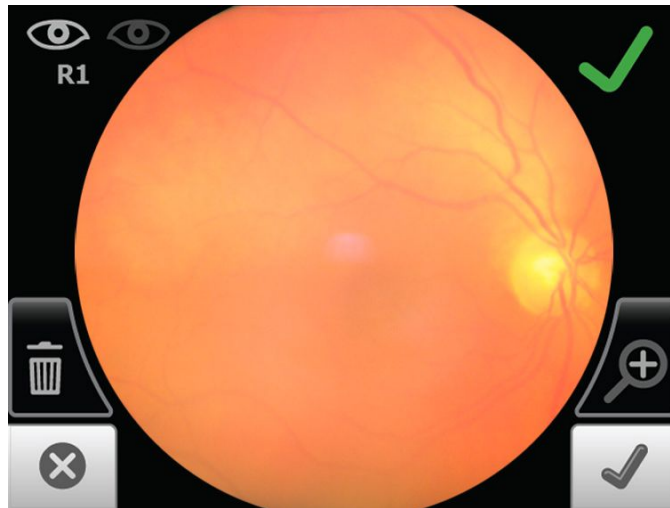
Touch  to review the current image. Images with a red X  denote low quality images. Touch  or  to dispose of an image and touch  to begin an exam capture of a replacement image.

Perform a manual image capture while in Auto exam mode

1. From the *Pre-acquisition screen*, touch **Start**.

2. Touch  (image capture) to manually capture an image.

The RetinaVue 100 Imager plays an acquire tone similar to the sound of a camera shutter. The image appears on the LCD touchscreen for review.



Skip an image capture while in exam mode

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

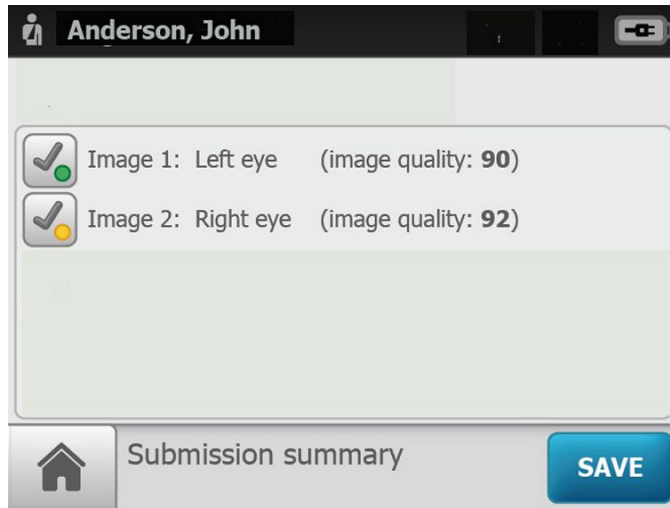
The *Pre-acquisition screen* appears.



2. Touch  (Next) or touch  (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  (Next) again to navigate to the *Exam summary screen*.



Perform a manual image capture while in Manual exam mode

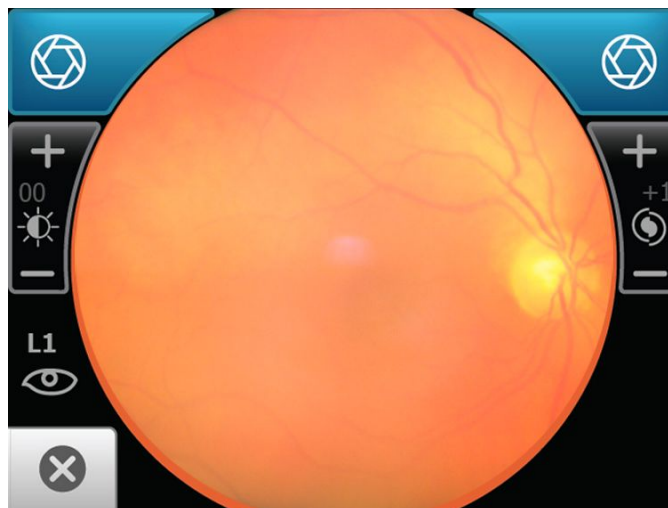
1. From the Home screen, touch **Exam**.

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. Start with the eye cup about two to three inches from the eye to be tested.
 - a. Continue to compress the eye cup against the examined eye.
 - b. Identify the white/purple reflection inside the pupil.

5. Continue to move forward slowly until the white reflection fills the whole screen.

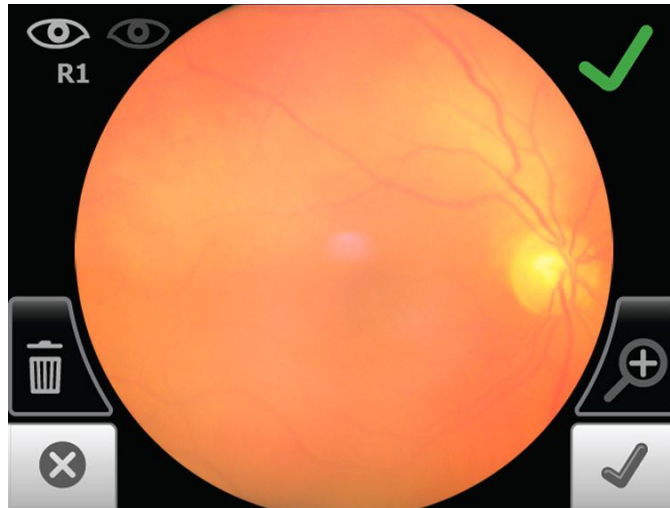
Note Compress the eye cup slightly to surround the eye socket.

6. Continue to move the RetinaVue 100 Imager forward by slightly compressing the eye cup until a ghost-like bubble appears on the screen.

Note If necessary, move the patient end of the RetinaVue 100 Imager toward the ghost-like bubble and direct the ghost-like bubble into the diamond shape located in the upper part of the LCD touchscreen.

7. Touch  (image capture) to manually capture an image.

The RetinaVue 100 Imager plays an acquire tone similar to the sound of a camera shutter. The image appears on the LCD touchscreen for review.



Update the RetinaVue 100 Imager software

Note Patient list changes will only be made to the RetinaVue 100 Imager after it is undocked from the docking station charger. (Transferring patient list information requires the optional RetinaVue Network software.)

Note DICOM files will be available to the RetinaVue Network once the RetinaVue 100 Imager is docked.



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

Before you begin, you will need the following :

- The SD card with the downloaded software update.
 - A computer with an Internet connection.
 - The RetinaVue 100 Imager you plan to update.
 - The docking station charger with a USB cable connected to AC power.
1. Power down the RetinaVue 100 Imager and remove the SD card.
 2. Insert the SD card into an open SD card reader port on the computer.
 3. Download the software update from the Welch Allyn website and transfer the software update to a computer.
 4. Transfer the software update from the computer to the SD card.
 5. Remove the SD card from the computer.
 6. Insert the SD card into the RetinaVue 100 Imager.
 7. Place the RetinaVue 100 Imager on the docking station charger, connect to AC power, and then power up the RetinaVue 100 Imager.
 8. After the RetinaVue 100 Imager boots up, confirm the software upgrade.
 - a. Touch **Settings**.
 - b. Touch **About** to view the software version.

You are ready to use the updated software.

Troubleshooting software updates

Note The RetinaVue 100 Imager boots up normally after a successful software update, however if a software update fails, the RetinaVue 100 Imager displays a failed update error message.

Power loss during software update:

- If a power loss occurs during the software update or if there are hardware issues, the RetinaVue 100 Imager posts a blank screen. Remove the battery, reinstall it, and restart RetinaVue 100 Imager. By performing this power cycle, the RetinaVue 100 Imager reverts to a previous version of software. Repeat the steps to perform the update again.

Corrupted software files:

- If the software update on the SD card is corrupted, the RetinaVue 100 Imager displays a failed update error message indicating that the RetinaVue 100 Imager 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.

Viewing or changing the RetinaVue 100 Imager settings

To view or change the settings

Touch **Settings**.

- Touch **Volume**.

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

- Touch **Time**.

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



Touch (Back) to return to the *Settings screen*.

- Touch **Date**.

Touch  to enter the month, day, and year in the MM/DD/YYYY format. Touch **OK**.



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*.
- **Factory reset.** Touch **OK** to reset the device to the default settings and touch **OK** again to return to the *Advanced Settings screen*.
- **Export log.** The log files are exported to the SD card. Touch **OK** to return to the



Advanced Settings screen. Touch **OK**. Touch

(Back) to return to the *Settings screen*.

Touch **About** to view the software version. Touch **OK**.



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

Troubleshooting

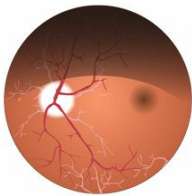
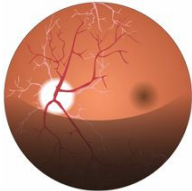


CAUTION A defective device should not be used. Parts which may be broken or missing or are visibly worn, distorted, or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from Welch Allyn.

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

Troubleshooting image quality

A quality image will appear without any problems

Problem	Solution
Full dark circle around the outside	Move the RetinaVue 100 Imager closer to the eye slowly until the screen is filled with the white/gray circle.
Dark semi circle on top 	Move the patient side of the RetinaVue 100 Imager down and away from dark semi-circle.
Dark semi circle on bottom 	Move the patient side of the RetinaVue 100 Imager up and away from dark semi-circle.
Bubble is too wide for Auto-capture to capture image	Back the RetinaVue 100 Imager away from patient eye slowly until a smaller bubble is visible and inside the circular alignment target.

Problem	Solution
The eyelids are closed.	Ask the patient to open their eyes.
An eyelid is obscuring all or part of the pupil.	• Ensure that the patient is covering their other eye with the palm of their hand. • Ask the patient to open their eyes wider. Drooping eyelids that cover part of the pupil may require the clinician to manually hold them open wider during the test. • Use the eyecup to keep the eyelid open by using the thumb and forefinger to simultaneously gently lift the patient's eyebrow upwards and gently pull down on the skin below the eye while securing the eyecup in place.
The patient isn't looking at the green fixation lights.	The green fixation lights should be near the pupil. If the patient is not looking at the green fixation lights, ask the patient to look at the green fixation lights. Ask the patient to cover their unexamined eye.

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 Do not use chemicals other than isopropyl or ethyl alcohol on the lens.

The RetinaVue 100 Imager can be cleaned and an intermediate-level of disinfection can be achieved using the following method.

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

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.

Disinfecting the RetinaVue 100 Imager

Use a pre-moistened wipe or soft cloth slightly moistened with an approved disinfectant to disinfect the RetinaVue 100 Imager. Follow the manufacturers recommendations.

Note After cleaning or disinfecting, wait at least 10 minutes before taking another measurement.

Approved cleaning agents

Use only the following approved cleaning agents on the RetinaVue 100 Imager:

CaviWipes	Super HDQ® L10
Sani-Cloth® Plus	Cleancide
Super Sani-Cloth®	Clorox HealthCare Bleach Germicidal Cleaner
Sani-Cloth® Bleach	Virex II (256)
Oxiver Tb	Tuffie5 Cleaning Wipes
Clinell® Universal Wipes	70% IPA
Accel INTERVention	10% bleach (.5% - 1% Sodium Hypochlorite)
Accel TB	

Welch Allyn has validated 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.

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 / video flash light	Natural White Light Emitting Diode (LED)
Focus	Auto Focus and Manual Focus
Camera Resolution	1920 × 1080 pixels
LCD Monitor	3.5 inch Full Color TFT-LCD
Image Format	JPEG (Photograph)
Interface	Micro USB, AV out port
File Transfer	Micro USB Port to PC running RetinaVue Network Client (requires additional software)
File Storage	SD Card, default 8GB. Supports 2G to 32GB by FAT32 format.
Power Source	Rechargeable Lithium Battery 3.6V / 2000mAh
External Power	Source: 100~240 VAC, 50/60 Hz
Power Adapter Spec.	Input Spec. : 100~240 VAC, 50/60 Hz, 0.3A; Output Spec. : 5V DC, 2A
Charger Station Input Spec.	5V DC, 1.2A
Operating Time	3 hours at at 5 minutes working mode and 15 minutes deep sleep mode as one cycle

Charging Time	5 hours through docking station
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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 1 060 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 1 060 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 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 device fails to hold a charge, a new battery can be ordered.

Device radio

The RetinaVue 100 Imager's radio operates on Welch Allyn FlexNet™ or other 802.11 networks. For information regarding the configuration of network connections and recommended settings, see the best practices documents at www.welchallyn.com/promotions/Network_Installation_Best_Practices.htm. **Note:** Your model might not contain all of these features.

WLAN standard	IEEE802.11b/g/n, Wi-Fi compliant
Frequency Range	2.412 to 2.484 GHz
Data Rate	802.11b: 11, 5.5, 2, 1 Mbps DSSS 802.11g: 54, 48, 36, 24, 18, 12, 9, 6 Mbps OFDM 802.11n: HT20 MCS0~7, HT40 MCS0~7
Modulation	802.11b: CCK, DQPSK, DBPSK 802.11g: 64 QAM, 16 QAM, QPSK, BPSK 802.11n: BPSK, QPSK, 16-QAM, 64-QAM
Host interface	USB 2.0
Encryption	WPA, WPA-PSK, WPA2, WPA2-PSK, WEP 64bit & 128bit, IEEE 802.11x, IEEE 802.11i
Channel availability	2.4GHz: (Ch. 1-11) – United States (Ch. 1-13) – Europe (Ch. 1-14) – Japan
Antenna	PCB-37x6-15U.FL with I-PEX cable, Max Gain: 1.3 dBi
Agency approvals	US: FCC 15.247:2014, KDB 558074 V3, Part 18, ANSI C63.10.2013 Europe: Annex 3.2 R&TTED in 2.4 GHz bands, EN 300 328 V1.9.1:2015, EN 301 489-17 V2.2.1:2012, EN 301 489-01 V1.9.2:2011, EN62479 Canada: (IC) RSS-210:2010 RSS-Gen:2014, RSS-02:2015

Channel restrictions in the 5-GHz band are determined by country.
Marking by the symbol (!) indicates that usage restrictions apply.

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

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

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

Note Effective Isotropic Radiated Power (EIRP).

Note Some countries restrict the use of 5-GHz bands. The 802.11a radio in the RetinaVue 100 Imager uses only the channels indicated by the access point with which the radio associates. The hospital IT department must configure access points to operate with approved domains.

General compliance and standards

The RetinaVue 100 Imager complies with the following standards:

IEC 60601-1 : 2005 (EN 60601-1 : 2006)

IEC 60601-1-2 : 2007 (EN 60601-1-2 : 2007)

ISO 15004-1 : 2006

ISO 15004-2 : 2007

ISO 10940 : 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.

General radio compliance

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

This device complies with Part 15 of the FCC rules and with the rules of the Canadian ICES-003 as described below.

Federal Communications Commission (FCC)

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.

- This device must accept any interference received, including interference that may cause undesired operation.

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

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

The user may find the following booklet prepared by the Federal Communications Commission helpful:

The Interference Handbook

This booklet is available from the U.S. Government Printing Office, Washington, D.C. 20402. Stock No. 004-000-0034504.

Welch Allyn is not responsible for any radio or television interference caused by unauthorized modification of the devices included with this Welch Allyn product, or the substitution or attachment of connecting cables and equipment other than specified by Welch Allyn.

The correction of interference caused by such unauthorized modification, substitution, or attachment will be the responsibility of the user.

The device is designed and tested to meet the applicable limits for radio frequency (RF) exposure established by the Federal Communications Commission (U.S.A.) Specific Absorption Rate; (SAR) refers to the rate at which the body absorbs RF energy.

The maximum allowable SAR limit is 4.0 W/kg, averaged over 10 gram of tissue for the device. The following SAR values were measured during product certification, 0.012 W/kg with a (0mm gap) a value well below the maximum allowable limit of 4.0 W/kg.

Industry Canada (IC) emissions

This device complies with RSS 210 of Industry Canada.

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

L'utilisation de ce dispositif est autorisée seulement aux conditions suivantes: (1) il ne doit pas produire de brouillage et (2) l'utilisateur du dispositif doit être prêt à accepter tout brouillage radioélectrique reçu, même si ce brouillage est susceptible de compromettre le fonctionnement du dispositif.

This Class B digital apparatus complies with Canadian ICES-003.

Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.

RF Radiation Hazard Warning

Using higher gain antennas and types of antennas not certified for use with this product is not allowed. The device shall not be co-located with another transmitter.

Cet avertissement de sécurité est conforme aux limites d'exposition définies par la norme CNR-102 at relative aux fréquences radio.

This radio transmitter (Contains IC ID: 3147A-BT800) has been approved by Industry Canada to operate with the antenna types listed in table above with the maximum permissible gain and required antenna impedance for each antenna type indicated. Antenna types not included in this list, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.

Le présent émetteur radio (Contains IC ID: 3147A-BT800) a été approuvé par Industrie Canada pour fonctionner avec les types d'antenne énumérés ci-dessous et ayant un gain admissible maximal et l'impédance requise pour chaque type d'antenne. Les types d'antenne non inclus dans cette liste, ou dont le gain est supérieur au gain maximal indiqué, sont strictement interdits pour l'exploitation de l'émetteur.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada. Dans le but de réduire les risques de brouillage radioélectrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

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

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

EMC compliance

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment. This device complies with IEC EN 60601-1-2:2007.

- 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.
Harmonic emissions IEC 61000-3-2	Class A	 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.
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	±6 kV contact ± 8 kV air	± 6 kV contact ± 8 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.

Electromagnetic immunity

Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95% dip in 0.5 cycle 60% dip in 5 cycles 30% dip for 25 cycles >95% dip in 5 seconds	>95% dip in 0.5 cycle 60% dip in 5 cycles 30% dip for 25 cycles >95% dip in 5 seconds	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

$$d = (2.33) \sqrt{P} \text{ 800 MHz to 2,5 GHz}$$

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.

^aField strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To

Electromagnetic immunity

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 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.

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

Recommended separation distances between portable and mobile RF communications equipment and the 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 2.5 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.

Approved accessories

The following table lists the approved RetinaVue 100 Imager accessories.



WARNING Use only Welch Allyn approved accessories and use them according to the manufacturer's directions for use. Using unapproved accessories with the RetinaVue 100 Imager can affect patient and operator safety and can compromise product performance and accuracy, and void the product warranty.

Accessories

Miscellaneous items

Part number	Description
RV100	RetinaVue 100 Imager with lithium-ion battery
106401	Charging Dock for Welch Allyn RetinaVue 100 Imager; 100-240 V, 50-60 Hz
106404	Reusable Eye Cups for Welch Allyn RetinaVue 100 Imager: Qty. 5
106405	Battery for Welch Allyn RetinaVue 100 Imager; Lithium-Ion
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)
106541	RetinaVue 100 Imager Chin rest adapter
106547	RetinaVue 100 Imager Chin rest
236200-2	Welch Allyn RetinaVue 100 Imager replacement screwdriver for battery cover. #1 Phillips Screwdriver w/ Logo
106558	Laptop for RetinaVue Network Client

Service

Part number	Description
S1-RV100-1	Welch Allyn Partners in Care Comprehensive Partnership Program Service Agreement for RetinaVue 100 Imager; 1 year
S1-RV100-2	Welch Allyn Partners in Care Comprehensive Partnership Program Service Agreement for RetinaVue 100 Imager; 2 year
S1-RV100-5	Welch Allyn Partners in Care Comprehensive Partnership Program Service Agreement for RetinaVue 100 Imager; 5 year
S4-RV100-1	Welch Allyn Partners In Care Extended Warranty Program for RetinaVue 100 Imager; 1 year
S4-RV100-2	Welch Allyn Partners In Care Extended Warranty Program for RetinaVue 100 Imager; 2 year
S4-RV100-5	Welch Allyn Partners In Care Extended Warranty Program for RetinaVue 100 Imager; 5 year

Literature/Documentation

Part number	Description
411492	RetinaVue 100 Imager Directions for use
723617	RetinaVue 100 Imager Startup guide
724147	RetinaVue 100 Imager System network guide
411513	Chin rest assembly guide
724146	RetinaVue 100 Imager Technique guide

Warranty

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

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

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

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

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

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

