

Welch Allyn® RETeval-DR™



Directions for use

WelchAllyn®

Advancing Frontline Care™

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The RETeval-DR device may be covered by one or more of the following US patents and their foreign counterparts: 7,540,613 and 9,492,098. Additional patents pending.

The RETeval-DR Sensor Strips may be covered by one or more of the following US patents and their foreign counterparts: 9,510.762. Additional patents pending.

For information about any Welch Allyn product, contact Welch Allyn at www.welchallyn.com/about/company/locations.

LKC is an ISO13485:2003 and EN ISO13485:2012 certified corporation.

DIR 80020080 Ver. F Revised 2018-02

This manual applies to

REF

 RETeval.

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WelchAllyn[®]
Advancing Frontline Care[™]

For non-English RETeval-DR *Directions for use*, go to www.RETeval-DR.com.

Register your device at www.welchallyn.com/warranty.

Download firmware updates at www.welchallyn.com/softwaredownloads.

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Introduction

RETeval-DR™ Electroretinograph is designed as an aid in diagnosis and disease management of visual pathway dysfunctions or ophthalmic disorders such as diabetic retinopathy (DR). The DR Assessment Protocol has been clinically validated to match the diagnosis from seven-field stereoscopic fundus images.

Test results are visible immediately on the device screen. The device automatically creates PDF reports that include test results, patient information and your practice or institution information. These PDF reports can be transferred to any PC via a USB cable.

Before using the device, read the sections of the manual that pertain to your use of the RETeval-DR.

For information about any Welch Allyn product, contact Welch Allyn at www.welchallyn.com/about/company/locations.

Intended use

The RETeval-DR device is intended to generate photic signals and measure and display evoked responses generated by the retina and the visual nervous system.

The operators of the device are intended to be physicians, optometrists, medical technicians, clinical medical assistants, nurses, and other health-care professionals.

Indications for use

RETeval-DR is indicated for use in the measurement of visual electrophysiological potentials, including electroretinogram (ERG). RETeval is also indicated for use in the measurement of pupil diameter.

RETeval-DR is intended as an aid in diagnosis and disease management in visual pathway dysfunctions or ophthalmic disorders (e.g., diabetic retinopathy).

Contraindications

Use of the RETeval-DR device is contraindicated under these conditions:

- Do not use with patients diagnosed with photosensitive epilepsy.
- Do not use with patients who are allergic to the sensor strip gel.
- Avoid use when the orbit structure is damaged or surrounding soft tissue has an open lesion.

Some patients may feel discomfort when viewing the flickering light that the RETeval-DR device creates to test their eyes. This discomfort usually subsides quickly when the test procedure completes.

Latex statement

The components of the RETeval-DR device that could contact the user or patient were not made with natural rubber latex. This includes all items that could be contacted during normal operation, and all other functions, such as user maintenance and cleaning, as are defined in the *Directions for use*.

No internal components are known to be made with natural rubber latex.

Applicability

Regulatory and Safety requirements are occasionally revised. Please refer to the user manual that originally accompanied your RETeval device for regulatory and safety information relevant to that specific device.

Symbols and definitions

Documentation symbols



WARNING The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death. Warning statements 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. This definition applies to both yellow and black and white symbols.



Consult operating instructions/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.



Mandatory - Consult Directions for Use

Power symbols



Power button

















Direct current (DC)

Connectivity symbols



USB

Miscellaneous symbols

	Manufacturer		Date of manufacture
	Product Identifier		Reorder Number
	Do not re-use	R_x ONLY	By prescription or order of physician
	Type BF applied parts	CE	Meets essential requirements of European Medical Device Directive 93/42/EEC
	ETL Listed mark indicating proof of product compliance. Conforms To: AAMI Std ES 60601-1, CENELEC EN Std 60601-1, IEC Std 60601-1-6, IEC Std 60601-1, IEC Std 62366, ISO Std 15004-1, ISO Std 15004-2, IEC 60601-2-40 Certified To: CSA Std No. 60601-1		Temperature limit
	Keep away from rain	LOT	Lot Code
	Expiration Date	GTIN	Global Trade Identification Number
	Do not dispose of in trash, Contains Li-Metal batteries		Not made with natural rubber latex
	Serial Number		Contains lithium-Ion. This symbol indicates general recovery / recyclable and must not be disposed of as unsorted municipal waste and must be collected separately.

Equipment serial number

Each RETeval-DR device has a unique equipment serial number. The equipment serial number may appear in one of two formats.

The serial number takes the form R # # # # # #.

R	Product code is R
---	-------------------

#####	Production sequence number (5 or 6 digits)
-------	--

Locate the serial number on the device

1. Remove the battery cover.
2. Pivot the battery away from the device to locate the serial number.

The serial number begins with the letter "R."

Locate the serial number in Systems

1. Scroll to **Settings** and then press the joystick.
2. Scroll to **System** and then press the joystick.

The System Information screen appears showing the following information.

- The firmware version
- The serial number
- The number of tests completed

About warnings and cautions

Warning and caution statements can appear on the Welch Allyn RETeval-DR device, the packaging, the shipping container, or in this Directions for use.

The RETeval-DR 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. In addition to reviewing the general warnings and cautions presented in the next section, you must also review the more specific warnings and cautions that appear throughout the manual in conjunction with setup/startup, operation, and maintenance tasks.

- 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 or operator injury risk. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Use of most commercial electrodes with leads 1 meter or less in length should work.



WARNING Patient injury risk. Dispose of single-use components (for example, sensor strips) after using them one time.



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





















WARNING Fire and explosion hazard. Do not operate the monitor 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.



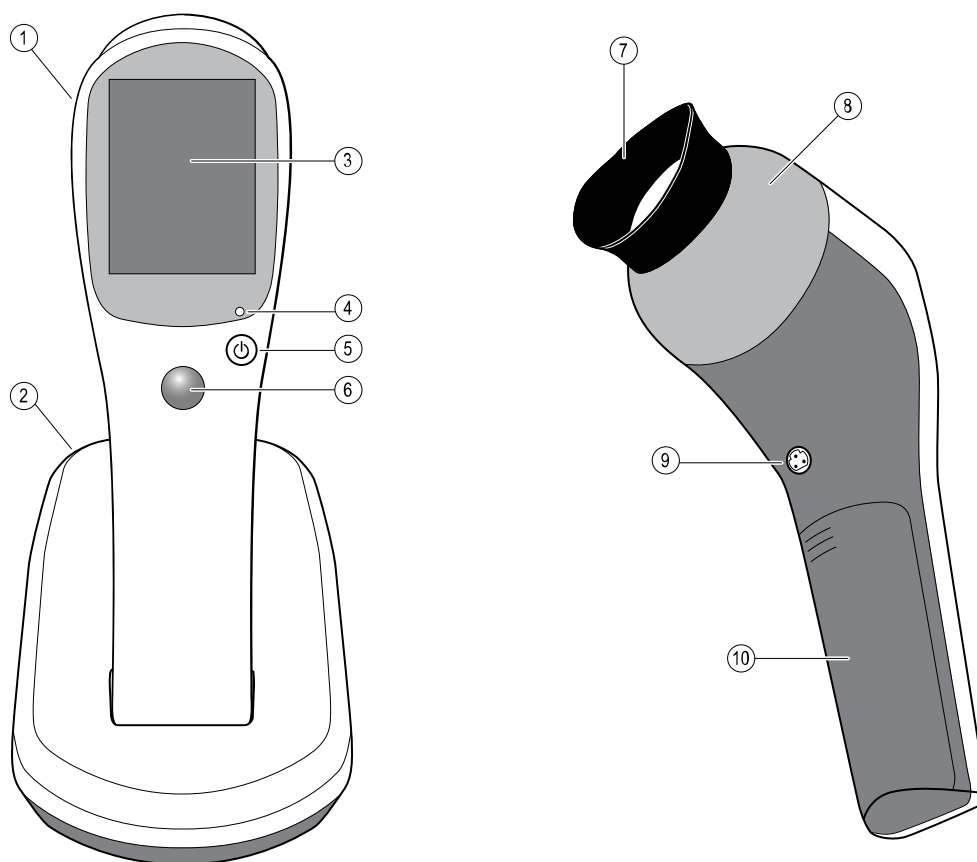
WARNING Patient injury risk. Reference intervals should only be changed under physician direction.

-  **CAUTION** Do not sterilize the device or sensor strips.
-  **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 RETeval-DR 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** Do not connect the RETeval-DR device to the docking station while measuring a patient. This will compromise the quality of recordings and subject isolation.
-  **CAUTION** Results deleted on the device cannot be recovered. Save results you want to keep on a computer or laptop before deleting them from the RETeval-DR device.
-  **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** Use only the provided power brick described in Accessories.
-  **CAUTION** Only connect the RETeval-DR device 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** Liquid cleaners may damage the LED lights and camera.
-  **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



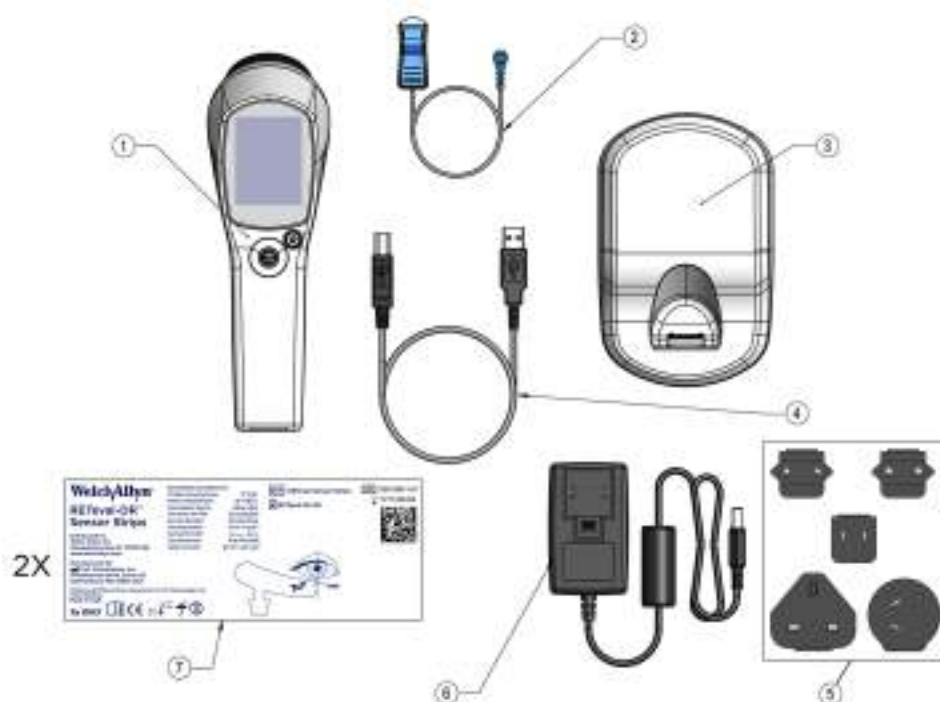
No.	Feature	Description
1	RETeval-DR device	Used to test for diabetic retinopathy
2	Docking station	Charges RETeval-DR and enables data transfer to a PC. Connect to an electrical outlet using the supplied power brick
3	LCD display	Displays information for charging, testing, and adjustments to the device

No.	Feature	Description
4	Power indicator	When the light is steady, it indicates that the device is powered on. When it is blinking, it indicates that the device is in the process of shutting down.
5	Power button	Push button to turn the device on and off
6	Thumb joystick	Allows you to move through menus, perform functions, and select parameters by moving the joystick up/down/right/left/select
7	Eyecup	Blocks ambient light during testing
8	Bezel	Area to which the eyecup attaches
9	Sensor strip lead connector	Connects the RETeval-DR device to the sensor strip
10	Battery cover	Covers the battery compartment

Setup

Unpack the system

The RETeval-DR device is packaged with the following items. Confirm that all items are included.



Number	Item	Description
1	RETeval-DR device	Used to test for diabetic retinopathy.
2	Sensor strip lead	Connects the device to sensor strips for testing
3	Docking station	Charges the RETeval-DR device and enables data transfer to a computer or laptop. Connect to a mains outlet using the supplied power brick.

Number	Item	Description
4	USB cable	Connects the device to a computer or laptop to transfer results.
5	Mains outlet plates	Mains outlet plate options that matches available mains outlets.
6	Power brick	Connects the device to a mains outlet.
7	Sensor strips	Used to test the eye for diabetic retinopathy.
Not shown	Dust cover	Protects the device from dust while not in use.
Not shown	<i>RETeval-DR Directions for use</i>	This document. The <i>Directions for use</i> (DFU) is also available as a portable document format (.pdf) file located in the root directory of the RETeval-DR device when the device is connected to a computer or laptop via the USB cable.

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.

Docking station

You can place the device in the docking station to charge the device or to connect and transfer data to a computer or laptop.

Charge the battery

When the RETeval-DR device battery charge is low, a warning message is shown on the device screen. Return the device to the docking station and let it charge. Do not attempt to test a patient after this message appears.

The device is powered by an integrated, rechargeable lithium-ion battery. A full charge permits testing of approximately 70 patients.

The battery icon in the upper-right corner of the screen displays the amount of charge remaining. The amount of green in the battery icon indicates the remaining capacity.

Note Misalignment of the USB plug and socket can cause damage. The plug and socket should be visually inspected prior to each installation of the charging cable. If you see damage, contact Welch Allyn Technical Support: www.welchallyn.com/service.

Connect the power cord

The RETeval-DR device is shipped with a partial charge. However, it is strongly recommended that you fully charge the device prior to testing.

1. Attach the power brick plate that matches your mains outlet to the power brick power plug.
2. Insert the power cord receptacle into the power brick port on the back of the docking station.
3. Insert the power brick power plug into the mains outlet. The power supply accepts 100 – 240 VAC, 50/60 Hz.

Charge the battery using the power brick

The RETeval-DR lithium-ion battery charges when in the docking station from either the computer or laptop via the USB cable or the power brick connection to a mains outlet. If the power brick is connected, charging will be significantly faster than if a USB connection is used. The charging status is shown on the display. If the display is blank, press the power button to turn it on. The RETeval-DR device is shipped with a partial charge.

1. Insert the power cord receptacle for the power brick into the power brick port on the back of the docking station.
2. Insert the power brick plate that is appropriate for your location into the power brick power plug.
3. Insert the power brick power plug into the mains outlet.

Charge the battery using the USB port

Charging the RETeval-DR device using the USB cable is significantly slower than charging the device using the power brick and a mains outlet. The charging status is shown on the display. If the display is blank, press the power button to turn it on. The RETeval-DR device is shipped with a partial charge.

1. Insert the USB connector into the port on the back of the docking station.
2. Insert the USB connector into an available USB port on your computer or laptop.

Connect the sensor strip lead

The RETeval-DR sensor strip lead connection is above the battery compartment on the front of the device.

Connect the sensor strip lead to the blue sensor strip lead connector.

Thumb joystick

The joystick provides a simple and intuitive user interface. Use your thumb to push the joystick in the desired direction.

Press the joystick...	To...
UP	Move the selection up
DOWN	Move the selection down
LEFT when the cursor is at the left edge of the screen	Go back one screen
RIGHT when the cursor is at the right edge of the screen	Go forward one screen
CENTER	Select a highlighted item

Device settings

The device menus enable you to change many of the device settings or functions. These settings include:

- Language
- Date/Time
- Backlight
- Practice information
- Page size
- Memory
- System

Change the language

The LANGUAGE menu enables you to select the language used in the device.

1. Scroll to **Settings > Language**, and then press the joystick.
2. Scroll either up or down to advance to the desired language, and then press the joystick.
3. Scroll left to return to the Main display.

Change the date and time

The device uses the date and time to label results and to compute the patient's age. The time appears in country-specific format.

1. Scroll down with the joystick to **Settings > Date / Time**, and then press the joystick.
The Set Date menu appears.
2. Scroll up or down to select the Month, and then press the joystick.
The display advances to the Day field.
3. Scroll up or down to select the Day, and then press the joystick.
The display advances to the Year field.
4. Scroll up or down to select the Year, and then press the joystick.
The display advances to the Time screen.

5. Scroll up or down to select the Hour, and then press the joystick.
The display advances to the Minute field.
6. Scroll up or down to select the Minute, and then press the joystick.
The display advances to the AM / PM field.
7. Scroll up or down to select AM or PM, and then press the joystick.
The display automatically returns to the Main menu.


Adjust the backlight

The backlight can be adjusted to three different levels of intensity—high, medium, and low. You can also adjust the backlight for the display to red. Brighter settings may be more visible, but will use more battery power and require you to charge the battery more often.

1. Scroll down to **Settings > Backlight**, and then press the joystick.
2. Scroll down to select the desired intensity, and then press the joystick.
The device automatically returns to the Settings menu.
3. Scroll left to return to the Main menu.

Practice information


Practice information is used to label reports. It includes your medical practice name and three lines for the practice address. You also can use these lines for other information. Practice information is displayed on the report above the patient information.


Pressing  on the bottom row of the Practice information keyboard enables practice information to be scanned from an external display, such as a computer or laptop monitor. Scanning is automatic and does not require the joystick to be pressed. Follow the instructions in the "RETeval-DR Utilities" section to download and install software utilities for the device.



Change practice information

1. Scroll down to **Settings > Practice information**, and then press the joystick.

The device keyboard appears with the Welch Allyn, Inc. name and address as the default practice information shown on the Practice Name screen.

2. Scroll down to , and then press  repeatedly to delete the default practice name.
3. Use the joystick to navigate the keyboard to enter the name of your practice.

When the practice name is complete, navigate to , and then press the joystick to move to the first address screen.

4. Use the joystick to navigate the keyboard to enter the first line of the practice address.
5. When the first address line is complete, navigate to , and then press the joystick. The second address line appears.
6. Continue to use the joystick to complete the second and third address fields.
7. If you choose not to use all of the address fields, scroll to  and press the joystick on each of the remaining address screens.

The device automatically returns to the Main screen.

Change the paper size

The PDF reports created by the RETeval-DR device can be formatted for either A4 or letter (8.5" x 11") paper.

1. Scroll down to **Settings > Page size**, and then press the joystick.
2. Scroll up or down to the desired page size, and then press the joystick. The device returns to the Settings menu.
3. Scroll left to return to the Main display.

Memory



CAUTION Results deleted on the device cannot be recovered. Save results you want to keep on a computer or laptop before deleting them from the RETeval-DR device.

The RETeval-DR device can store up to 50 test results. You must remove old results to make room for new results. There are three ways to remove results.

- Remove selected records from the device
- Remove all results from the device
- Remove results using a computer or laptop

Go to "Erase test results" for further information.

System information

View GTIN

The Global Trade Item Number (GTIN) is a globally unique 14-digit number used to identify trade items, products, or services.

1. Scroll down to **Settings > System > GTIN**.
2. Press the joystick.

The GTIN is displayed.

Change system settings

1. Scroll down to **Settings > System > Change settings**.
2. Press the joystick.

Update firmware

Follow the instructions in the firmware update notice to download the firmware update. Additional information on managing firmware updates can be found in the “Manage firmware” section of this manual.

1. Scroll down to **Settings > System > Change settings > Update firmware**.
2. Press the joystick.
3. Select the firmware update you would like to use and press the joystick to select **Next**.
4. Wait while the firmware updates.

The device will restart automatically when the firmware is updated.

Adjust reference interval

The score produced by the DR Assessment Protocol correlates with the presence and severity of diabetic retinopathy and clinically significant macular edema. Patients with more-severe levels of diabetic retinopathy will typically have higher test scores (Maa et al. 2016).

The default reference interval for RETeval-DR is set at 7.0-19.9; this reference interval can be adjusted to trade off sensitivity, specificity, and negative predictive values by varying the upper point of the reference interval, as shown in the examples below.

Sensitivity, specificity, and predictive values at multiple cutoff values

Upper interval	Sensitivity	Specificity	Predictive power of test	
			Positive	Negative
17.5	93%	52%	8%	99.5%
18.0	90%	57%	9%	99.2%
19.0	88%	67%	11%	99.1%
19.9 (default)	83%	78%	15%	99%
21.1	73%	84%	17%	99%

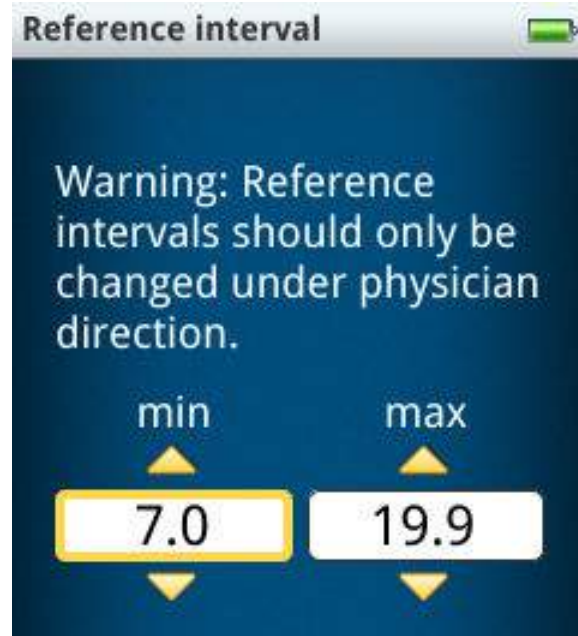
The default lower point of the reference interval is set at 7.0 and is three standard deviations below the mean for the patients without retinopathy (Maa et al. 2016); typically, the lower point of the reference interval is not changed.



WARNING Patient injury risk. Reference intervals should only be changed under physician direction.

Go to “DR assessment protocol” for information on the DR assessment protocol.

1. Scroll down to **Settings > System > Change settings > Reference interval**.
2. Press the joystick.
3. Scroll up or down to select the new lower point of the reference interval (Min) and scroll right.
4. Scroll up or down to select the new upper point of the reference interval (Max) and press the joystick.



Reset device to factory default settings

You can reset the device to the factory default settings. Follow the steps below if there are problems with the device or if you are advised to do so by Technical Support.

1. Power on the device and ensure that the device is charged.
2. Scroll down to **Settings > System > Change settings > Reset settings**.
The Reset Settings menu appears.
3. If you do not want to erase everything, scroll left to select **No** and press the joystick.
4. To reset the device to factory default settings, press the joystick to select **Yes**.

All settings are reset to the initial factory settings. Select **Next** to restart the device.

5. Go to “Device settings” for information on setting site-specific settings.

Return device to initial factory condition

Returning your device to its initial factory condition erases everything from the device, including patient information, test results, and settings. To do a “factory reset”, you need to do both “Erase everything” and “Reset settings”.



CAUTION Results deleted on the device cannot be recovered. Save the results you want to keep on a computer or laptop before deleting them from the device.

1. Power on the device and ensure that the device is charged.
2. Scroll to **Settings > Memory > Erase everything**.
A confirmation screen appears asking if you want to erase everything.
3. If you do not want to erase everything, scroll left to select **No**, and press the joystick.
4. To erase everything, press the joystick to select **Yes**.

Operating instructions

Turn the RETeval-DR on and off



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.

1. Press the Power button to turn the device on.
The Initializing screen appears as the device powers on.
2. Press the Power button to turn the device off.

The screen shuts off immediately, but the green power indicator light blinks as the device cycles off.

Note If you want to turn the device on again, wait a few seconds after the power indicator light stops blinking.

Perform a test

Testing overview



WARNING Patient injury risk. Dispose of single-use components (for example, sensor strips) after using them one time.



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



CAUTION Do not connect the RETeval-DR device to the docking station while measuring a patient. This will compromise the quality of recordings and subject isolation.

Performing a test with the RETeval-DR device includes a series of steps.

1. Prepare the device
2. Prepare the patient
3. Test the right and left eye
4. Remove the sensor strips from each eye
5. View the results
6. Clean patient-contact parts

Ask the patient to relax and to try not to blink. The patient should not talk, smile, or move during the test. Doing so will increase the test time.

Ensure that there is no hair between the sensor strip and the skin. The sensor strips must be able to adhere firmly to the skin. If the patient has oily skin, heavy makeup, or any other condition that causes the sensor strips not to adhere well, clean the patient's skin with soap and water or an alcohol wipe. Use alcohol-based products with caution; alcohol fumes may cause irritation to the eye.

Prepare the device

1. Remove the RETeval-DR device from the docking station; the device turns on automatically. If the device is not in the docking station, press the Power button to power on the device.
2. Press the joystick to select **New Test**.
3. Enter patient information as prompted by the device (name or identifier and date of birth).
4. Confirm that the patient information is correct.

Prepare the patient

The RETeval-DR sensor strips are specific for the right and left eye. Erroneous results will occur if the sensor strips are used with the wrong eye; timings will be wrong by about 18 ms. If you suspect the sensor strips were used with the wrong eye, repeat the test with a new pair of correctly applied sensor strips. The sensor strips packaging has a pictograph to guide you in proper placement.



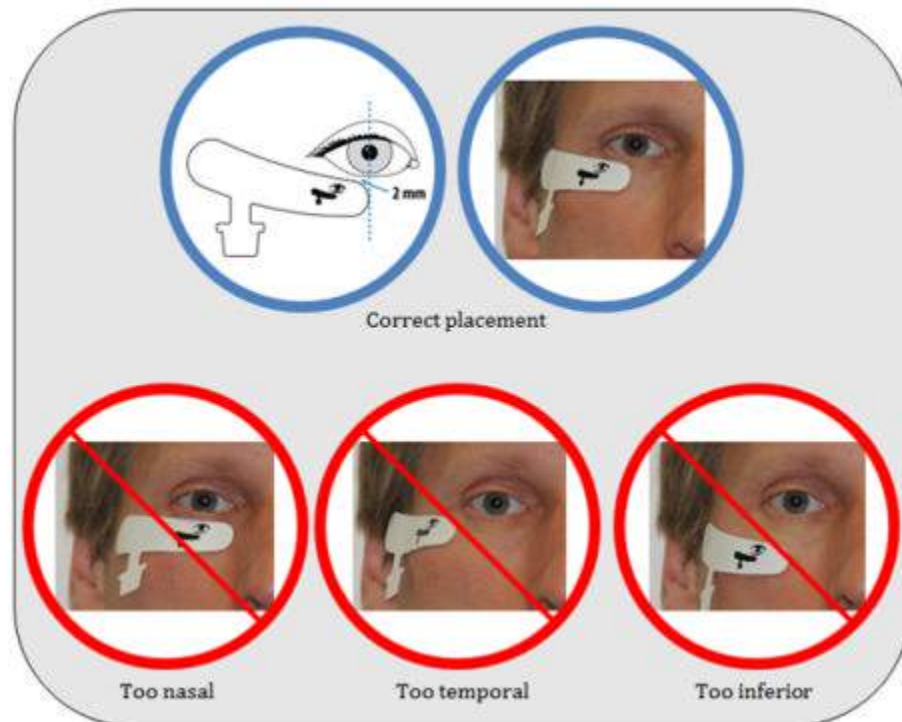
WARNING Patient injury risk. Dispose of single-use components (for example, sensor strips) after using them one time.

RETeval-DR sensor strips are to be used for a single examination only. Sensor strips may not adhere well if re-used, causing an excessively high electrode impedance and potentially preventing the device from producing a result.

1. Scan a sensor strip packet barcode by placing the device eyecup on or very near the barcode. Scanning is automatic and does not require you to press the joystick.

The barcode is designed to prevent use of expired sensor strips and prevent reuse across multiple examinations. During the same examination, however, adjustment to sensor strip positioning and one retest on the same patient can be conducted.

2. Ask the patient to remove their eyeglasses. Contact lenses may be left in place.
3. Apply the right and left sensor strips as shown below.



Device testing options

When running a test, you may be presented with choices described below.

Option	Description
Cancel	Ends the test without saving results
Next	Proceeds to the next step in the protocol
Restart	Returns to the beginning of the current eye, discarding any partial results accumulated for that eye
Skip or Skip eye	Skips the eye displayed for testing

Test each eye

The RETeval-DR device is designed to measure the patient's right eye first. The default is to test both eyes. If you only want to measure a patient's left eye, use the **Skip** button to proceed past the right eye screen without testing the patient. By using the skip button you can test only the right eye or only the left eye.

Note Patients should not talk during the test to minimize muscle-generated signal interference.

1. Ask the patient to cover the selected eye with the palm of their hand.
This improves their focus on the red light in the ganzfeld and opens their eyelids wider to make the pupil more visible.
2. Connect the lead to the sensor strip below the patient's right eye, and then select **Next**.
If the Next button is not present, the electrical connection to the patient is poor or the device is not connected properly to the electrode. See "Troubleshooting" for suggestions to resolve this issue.
3. Instruct the patient to open their eye as wide as possible and look at the red fixation light in the device.
4. Press the device against the patient's face, positioning the device so that the patient's pupil is inside the large green circle.
5. Swivel the device to minimize gaps between the eyecup and the patient's face in order to reduce the amount of ambient light reaching the eye.
6. Press the joystick to select **Start Test** after the device has properly located the pupil. This is shown on the display as a circle with a red crosshair.
If the device erroneously indicates something else as the pupil, reposition the device and ensure that the eyelids are sufficiently open until the pupil is properly identified. If Start Test is not highlighted, go to "Troubleshooting" for suggestions to resolve this issue.

Note At the beginning of each test, the device automatically recalibrates the light intensity and color, during which time the patient will see brief red, green, and blue flashes. This process takes about one second. If recalibration is unsuccessful, an “Unable to calibrate” or “Excessive ambient light” error will display. See “Troubleshooting” for suggestions to resolve this issue.

7. Wait while the device conducts the test.
The device provides feedback on the device display to the clinician on the progress of the testing. Communicate this progress with the patient as it occurs.
8. After the device has indicated that the testing is complete, disconnect the lead from the sensor strip.
9. Repeat Steps 1–8 to test the opposite eye.
10. Clean the eyecup, sensor strip lead, and other patient-contact parts of the device after each patient.

A results summary is shown on the device. While the results are being shown, the data is saved in the device. A Next button and notification of successful storage appears upon completion of the save, which can take several seconds.

Remove the sensor strips

1. Remove the sensor strips from the patient’s face, starting with the end under the eye. Alternatively, ask the patient to remove the sensor strips.
2. Dispose of the sensor strips in accordance with local guidelines.

Test results

The DR Assessment Protocol combines implicit time, amplitude, age, and pupil response. The protocol creates a unified result score, which is shown immediately after test completion. Patients with more-severe levels of diabetic retinopathy will typically have a higher test result (Maa et al. 2016).

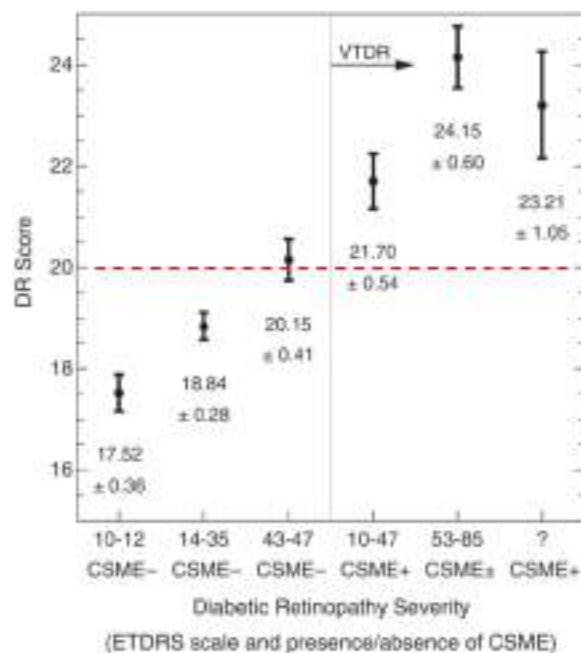
The DR Assessment Protocol will classify the test result as either High, Normal, or Low depending upon the reference interval selected. The default reference interval is set at 7.0-19.9; This reference interval can be adjusted; refer to “Adjust reference interval” for more information.

DR assessment protocol result scoring¹

Result	High	Normal	Low
	≥ 20.0	19.9 – 7.0	≤ 6.9

1. Default reference interval

High test results—greater than or equal to 20.0 using the default reference interval—are indicative of more-severe levels of diabetic retinopathy, as shown below.



The image above shows the dependence of RETeval-DR measurements on diabetic retinopathy severity level. Plots show the mean and standard error of the mean for each severity group listed in the table below.

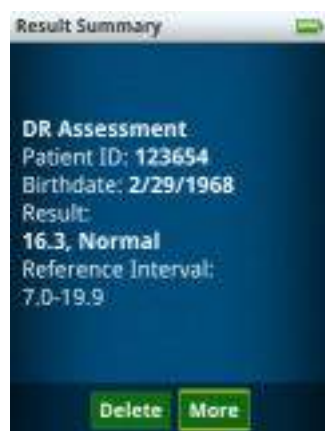
Severity group definitions

International clinical classification (Wilkinson et al. 2003)	ETDRS level	CSME
No NPDR	10 - 12	-
Mild NPDR	14 - 35	-
Moderate NPDR	43 - 47	-
CSME with no, mild, or moderate NPDR	10 - 47	+
Severe NPDR or proliferative DR	53 - 85	+ / -
Ungradable ETDRS level	?	+

View results

You can view test results either from the device or from a computer or laptop.

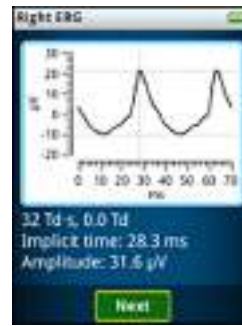
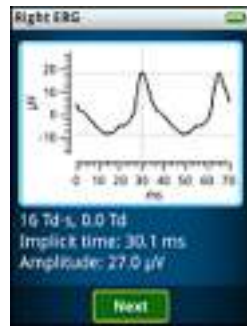
Test result details can be viewed on the device from the Results screen. Alternatively, results can be transferred to the PC in PDF format for viewing.



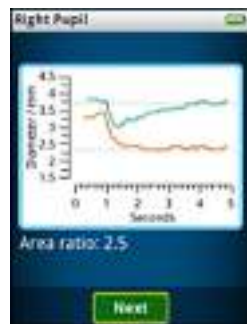
Results from the device

The results are stored in chronological order with the most recent result first. After showing the same summary page, the electrical and pupil responses are displayed.

The figures below show the results from the right eye; left eye results are similarly shown.



Two periods of the electrical response, as measured from the Sensor strip, to a 32 Td-s (left) and 16 Td-s (right) white flickering stimulus are shown. The light flashes stimulating the retina occurred at time = 0 ms and near time = 35 ms. The dotted lines indicate the measurement points for the peak-to-peak amplitude and implicit time (time-to-peak).



The pupil size as a function of time is shown for the 4 and 32 Td-s white flickering stimuli. The stimuli start at time = 0. The dotted lines show the extracted pupil diameters for the two stimuli. The ratio of pupil areas is quantitated in the plot.

Results from a computer or laptop

Results can be transferred to a computer or laptop in PDF format.

The file naming convention for results, patientID_birthdate_testdate.pdf, includes these parameters.

- Patient ID
- Birth date (yymmdd: year, month, day)
- Test date (yymmddhhmmss: year, month, day, hour, minute, seconds)

With this file naming convention, past patient results sort next to patient's current results.

The PDF displays:

- Practice information, specified in Settings
- Patient information, entered during the test
- Date and time of the test
- A description of the stimulus used. Chromaticities are reported in the (x,y) colorspace from CIE 1931. Brightness is reported in photopic units.
- Patient results

You can print, fax, or email these PDF files from your computer or laptop.

The PDF shows three periods of the electrical response recorded by the Sensor strips. In the electrical response, the light flashes stimulating the retina occurred at time = 0 ms, 35 ms and 70 ms.

Transfer results to a computer

1. Connect the USB connector to the docking station and the USB connector to the computer or laptop.
2. Place the RETeval-DR device in the docking station.

The device appears in the computer or laptop directory as a thumb drive or external drive.

3. Select the external drive on the computer or laptop that represents the device.

You can view results or copy them to your computer or laptop as you would files in any directory on your computer or laptop. Patient results are located in the Reports directory in the device.

View results on the device

The Results menu enables you to select the results you wish to view.

1. Scroll to **Results**, and then press the joystick.
2. Scroll through the list for the desired result, and then press the joystick.

The result appears in the device display screen.

Delete results from the device



CAUTION Results deleted on the device cannot be recovered. Save results you want to keep on a computer or laptop before deleting them from the RETeval-DR device.

The RETeval-DR device can store up to 50 test results. You must remove old results to make room for new results. There are three ways to remove results.

Erase selected test results from the device

Make sure that any results you want to keep have been copied to a computer or laptop.

1. Press the Power button to power up the device.
2. Scroll down to **Results**, and then press the joystick.
3. Select the desired test results to be deleted, and then select **Delete**.

A confirmation screen appears asking if you want to delete the selected results.

4. Select **Yes**.
5. If you choose not to delete the selected results, scroll to **No**, and then press the joystick.

The device automatically returns to the Results screen.

6. Scroll left to return to the Main display.

Erase all test results from the device

Make sure that any results you want to keep have been copied to a computer or laptop.

Note If, during Step 2, you choose **Erase everything**, then the data storage area reformats the user partition, deleting results and protocols. “Erase everything” does not affect settings; it does not affect language, paper size, backlight, or practice information.

1. Press the Power button to power on the RETeval-DR device.
2. Scroll down to **Settings > Memory > Erase all test results**, and then press the joystick.

A confirmation screen appears asking if you want to erase all test results. It also reinforces that all test results will be removed permanently.

3. Select **Yes**.
4. If you choose not to delete all test results, scroll left to select **No**, and then press the joystick.

The device automatically returns to the Memory screen.

5. Scroll left to return to the Main display.

Delete test results using a computer or laptop

To save time, you can delete test results that have been saved to your computer or laptop from the computer directory.

Make sure that all test results have been copied to a computer or laptop.

1. Place the RETeval-DR device into the docking station.
2. Wait for the device to appear as an external drive on your computer or laptop.
3. Navigate to the Reports directory on your computer or laptop.
4. Select the desired test results from the Reports directory on your computer or laptop.
5. Delete the selected reports as you would any file on your computer or laptop.

Manage firmware and software

Update firmware

Periodically Welch Allyn publishes an update to the device firmware. You must download the update to the computer or laptop first, connect the RETeval-DR device to the computer or laptop, and complete the firmware update process.

Download the firmware update

Find firmware updates at www.welchallyn.com/softwaredownloads. Alternatively, follow the instructions in the firmware update notice to find and download the update to your computer or laptop.

Copy the firmware to the device

1. Connect the USB connector to the docking station and the USB connector to the computer or laptop.
2. Power on the device and ensure that the device is charged.
3. Place the RETeval-DR device in the docking station.
Wait for the device to appear in the computer or laptop directory as an external drive.
4. Copy the firmware update file from the computer directory to the device Firmware directory on the computer.
5. Eject the external drive from the computer or laptop that represents the device.
6. Remove the device from the docking station.
7. Disconnect the USB connector from the docking station and the USB connector from the computer or laptop.

Update the firmware on the device

Follow instructions in the firmware update notice to find and download the update.

1. Scroll to **Settings** > **System** > **Update Firmware**, and then press the joystick.
2. Select the firmware update you want, and then press the joystick to select Next.
3. Wait while the firmware is updated.

After the firmware update completes, the device restarts automatically.

If the RETeval-DR update fails, verify that the firmware update file was downloaded and copied to the device correctly by repeating “Copy the firmware” and “Update the firmware on the device.”

RETeval-DR utilities

Optional software utilities available for your RETeval device include the following:

RETeval Data Entry Barcode Generator	For data-entry convenience, the RETeval Data Entry Barcode Generator software utility enables entry of patient information, practice information, and comments on a PC using the computer’s keyboard. This information is converted by the utility to a barcode on the PC screen that is scanned with RETeval-DR to transfer the information.
RETeval Data Analyst	Once installed on a PC connected to a RETeval-DR device, the RETeval Data Analyst software utility runs in the background to collect test results in a format that qualifies as de-identified health information for the purpose of evaluating distributions of test results in various populations.

1. Connect the USB connector to the RETeval docking station and the USB connector to the computer or laptop.
2. Place the RETeval-DR device in the docking station.
The device appears in the computer or laptop directory as a thumb drive or external drive.
3. Select the external drive on the computer or laptop that represents the device.
4. Click **Install the RETeval-DR Utilities**.
5. You will be directed to the Welch Allyn RETeval-DR Utilities Download webpage. Follow the instructions on this webpage to download and install the RETeval-DR Utilities.

Clean and disinfect

Clean and disinfect



CAUTION Do not sterilize the device or sensor strips.



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



CAUTION Liquid cleaners may damage the LED lights and camera.



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.

The white interior sphere that the patient looks into (the ganzfeld), should be cleaned when there is visible dust inside or when the device fails to calibrate at the start of a test.

Welch Allyn recommends that you clean the eyecup and sensor strip lead between each patient.

The RETeval-DR device is chemically compatible to wipes containing 70% isopropyl alcohol and with wipes containing alkyl dimethyl benzyl ammonium chloride. The use of other wipes may damage the device.

Clean the ganzfeld

1. Remove the eyecup by grasping the rubber nearest the silver bezel and pulling gently.
2. Clean the ganzfeld with a compressed gas air duster to remove dust.
3. If compressed gas does not work, a damp cloth may be used.
4. To replace the eyecup, orient the eyecup so that the slots on the white plastic rim of the eyecup are aligned with the bumps on the silver bezel.
5. Push gently until the eyecup clicks onto the silver bezel.

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.

The RETeval-DR device runs internal tests and self-checks frequently. Device failures are obvious; the device will stop functioning and warn the user rather than producing erroneous or unexpected results.

If the device displays an error message, follow the instructions on the screen to correct the error, or contact Welch Allyn Technical Support: www.welchallyn.com/service. Note any error number shown.

The device doesn't show the Next button after I connect to the sensor strip or after pressing the Start test button, I get an "The electrodes have been disconnected" error

The RETeval-DR device monitors the electrical impedance of the connection between pads on the sensor strip. If the impedance is too high, the Next button won't be displayed. During a test, if the electrical impedance gets too high or the inputs saturate the analog-to-digital converter, the "electrodes disconnected" message is displayed. The impedance can be too high because of the following reasons.

Problem	Solution
The sensor strip lead is not correctly connected to the sensor strip.	Unclip and reconnect the lead.
The sensor strip isn't connected to the patient's skin.	Ensure the sensor strip is not resting on the patient's sideburns or on heavy makeup. Press down lightly on the three electrode gel pads on each sensor strip to ensure the sensor strip is sticking well. Clean the skin with soap and water or an alcohol wipe and reapply the sensor strip.
The sensor strip may be defective.	Use a new sensor strip.

The device won't let me press the Start test button when I can see the eye or after pressing the Start test button, I get an "The pupil can no longer be found" error

The RETeval-DR device measures the pupil size and adjusts the brightness of the flickering light for each flash based upon the pupil size. The Start test button is only enabled after the pupil is located. During a test, if the device cannot find the pupil for

durations longer than a typical blink, the device generates the “pupil can no longer be found” error. The device may not be able to locate the pupil for the following reasons.

Problem	Solution
The eyelids are closed.	Ask the patient to open their eyes.
An eyelid is obscuring all or part of the pupil.	<ul style="list-style-type: none"> • 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 red light.	The bright glint dot should be inside or near the pupil if the patient is looking at the red light. Ask the patient to look at the red light.
If the device cannot find the patient’s pupil, testing cannot be performed.	<ul style="list-style-type: none"> • If you believe that the device should be able to find a pupil, please run the Record Video option in Protocol. • Afterwards, dock the device to a computer or laptop, browse to the Data directory on the device, and copy the resulting .rff file to your computer or laptop (named null_*_*.rff, where the *’s are numbers). • Contact Welch Allyn Technical Support: www.welchallyn.com/service for instructions on how to send Welch Allyn the file.

After pressing the Start test button, I get an “Excessive ambient light” error

The flicker implicit time changes with illumination levels. External light that reaches the eye under test can therefore affect results (making the timing faster). The eyecup is designed to block external light from reaching the eye. If the RETeval-DR device senses too much ambient light, an error message will display on the screen. After pressing **Restart** to reduce the amount of ambient light reaching the eye, perform the following.

Problem	Solution
“Excessive ambient light” error	<p>Rotate the RETeval-DR device so the eyecup better contacts the skin around the eye.</p> <hr/> <p>Hold your hand near the patient’s temple to block the light with your hand</p> <hr/> <p>Move to a darker location or turn off any room lighting.</p>

After pressing the Start test button, I get an “Unable to calibrate” error

The RETeval-DR device, after checking for ambient light, recalibrates the flash intensity and color to match the factory-calibrated settings. The white interior sphere that the

patient looks into (the ganzfeld) redirects light from red, green, and blue LEDs to create a uniform, diffuse white light. A small change in the light reflectance of the ganzfeld will create a large change in the color or intensity of the light output, which is corrected by this recalibration. If the correction is too large, the RETeval-DR device will create an error.

Problem	Solution
"Unable to calibrate" error	Remove the eyecup for better access to the ganzfeld for cleaning.
	Clean the ganzfeld with compressed gas.
	If compressed gas does not work, clean the ganzfeld with a damp cloth.

The screen is blank but the power light is on

You can turn the device off at any time by pressing the power button. The screen goes blank immediately, but the device takes a few more seconds to turn off completely. If the power button is pressed just after the last blink, the display will fail to turn back on.

Problem	Solution
The screen is blank but the power light is on	Press the power button again to turn the device off. Wait 5 seconds after the power indicator has stopped blinking, and then turn the device back on.
	If the power button fails to turn back on, hold the power button for 15 seconds, then release and press the power button to turn the device off.
	If this does not resolve the issue, remove and reinstall the battery.

An error code is reported

Error codes are reported for failures unlikely to be correctable in the field.

When error codes are displayed, the RETeval-DR device may give the option of performing a factory reset. The factory reset option may also occur if the USB file system has been corrupted due to removing the device from the docking station while files were being transferred or other occurrences. A factory reset returns the device to the as-shipped condition by reformatting the device, deleting all data, custom protocols, and customization in order to attempt to return the device to working order.

Problem	Solution
An error code appears	Record the error code and contact Welch Allyn Technical Support at www.welchallyn.com/service to obtain information on returning the product and obtaining warranty service. You must obtain a return authorization from Welch Allyn to arrange for the return of your RETeval-DR product before you send it to the designated Welch Allyn service center for repair or replacement.

Specifications

Specifications

Light source	Red LED (621 nm)	Green LED (530 nm)	Blue LED (470 nm)	White (RGB)
Flash luminance energies (cd·s/m ²)	0.0001 – 15	0.001 – 17	0.0001 – 5	0.002 – 30
Background luminance (cd/m ²)	0.03 – 3000	0.2 – 3500	0.03 – 1200	0.4 – 6000
To convert to Trolands, multiply luminance by the pupil area in mm ² .				
Input Type	Custom 3 pin connector with positive, negative, and right leg drive signals.			
Noise	< 0.1 μ Vrms at the flicker frequency for flicker protocols			
CMRR	> 100 dB at 50-60 Hz			
Frequency Range	DC-coupled			
Flicker Frequency	Approximately 28.3 Hz			
Data Resolution	Approximately 71 nV / bit			
Input Range	± 0.6 V			
Sampling rate	Approximately 2 kHz			
Timing accuracy (electronic eye) ¹	< ± 0.1 ms			
Timing precision ¹ (human eye, 1 σ)	Typically < ± 1 ms			
Pupil measurements	1.3 mm – 9.0 mm, < 0.1 mm resolution			

Safety	Battery-powered. Complies with optical, electrical, and biocompatibility safety standards.
Power source	Li-Ion battery allows testing of approximately 70 patients before recharging, depending on the protocol used
Recharge time	4 hours – charger included
Size	2.8" W x 3.8" D x 9" H (7 cm x 10 cm x 23 cm)
Docking station	Convenient storage location, charging stand, and USB connectivity to your computer or laptop and network
Protocol	DR Assessment

All specifications are subject to change.

¹ For Troland-based flicker protocols having a retinal illuminance energy ≥ 4 Td-s.

Operating environment

Temperature	10 °C – 35 °C (50 °F – 95 °F)
Humidity	10% – 90% non-condensing
Air pressure	62 kPa – 106 kPa (-80 m / -260 feet – 4000 m / 13,000 feet)

Product performance

The RETeval-DR device's normal operation includes measuring flicker implicit time with a single-patient, single-day standard deviation that is typically less than or equal to 1.0 ms; therefore, the RETeval-DR device must operate with no unintended deviations in settings and with typical operation.

Contact Welch Allyn Technical Support: www.welchallyn.com/service if changes in performance are noted.

Essential performance

The RETeval-DR device is neither life supporting nor life sustaining nor is it a primary diagnostic device, its function is to aid a physician in making a diagnosis in combination with other data and in light of the physician's knowledge and experience, as such the RETeval-DR device has no Essential Performance as pertains to risk.

Device lifetime

The lifetime of the device is five (5) years or 10,000 test protocols performed, whichever comes first. The manufacture date of the device can be found on the device labels.

Welch Allyn will service RETeval-DR devices that are within their lifetime. 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 RETeval-DR device fails to hold a charge, a new battery can be ordered.

Maintenance

User maintenance

The RETeval-DR device contains no user serviceable parts other than the eyecup and battery, both of which can be replaced without the need of tools.

To maintain proper function and compliance to regulatory requirements, do not attempt to disassemble the device.

Other than the replacement parts mentioned above and cleaning as described elsewhere in this manual, no user maintenance is required to maintain proper function and regulatory compliance.

Remove the eyecup

To remove the eyecup, grasp the rubber nearest the silver bezel and pull gently.

Replace the eyecup

1. To replace the eyecup, orient the eyecup so that the slots on the white plastic rim of the eyecup are aligned with the raised areas on the bezel.
2. Push gently until the eyecup clicks onto the bezel.
3. Clean the eyecup before testing your next patient.

For information about any Welch Allyn product, contact Welch Allyn Technical Support: www.welchallyn.com/service.

Biocompatibility

The patient-contact portion of the RETeval-DR device and sensor strips comply with biocompatibility standard ISO 10993-1.

Calibration and storage

Item	Description
Calibration	The RETeval-DR device includes automated internal flash calibration and QC checks. No testing can be carried out by users.
Storage	<p>Store the device in the docking station and place the dust cover over the device when not in use.</p> <p>Store the device at temperatures between -40 °C and 35 °C (-40 °F and 95 °F).</p> <p>Store sensor strips between temperatures between -40 °C and 35 °C (-40 °F and 95 °F).</p> <p>Short-term shipping conditions can be between -40 °C and 70 °C (-40 °F and 158 °F).</p> <p>Store and ship the device and/or sensor strips at humidity between 10% and 90% non-condensing, and atmospheric pressure between 62 kPa and 106 kPa (-4000 m to 13,000 m).</p>

Standards and compliance

General compliance and standards

Many local laws and regulations require special procedures to recycle or dispose of electrical equipment-related waste including batteries and other elements of electronic devices. Follow all of your respective local laws and regulations for the proper disposal of batteries and any other parts of this system. 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..



WARNING Batteries may explode or cause burns, if disassembled, crushed or exposed to fire or high temperatures.



WARNING To disconnect mains from the device, remove the power brick from the mains connector to assure simultaneous disconnection of all poles.

EMC compliance

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

- 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 monitor complies with all applicable and required standards for electromagnetic interference.

Guidance and Manufacturer's Declaration – Emissions

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

Emissions test	Compliance	Electromagnetic environment–guidance
RF emissions CISPR 11	Group 1	The RETeval-DR device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Class B
Harmonics IEC 61000-3-2	Class A	Class A
Flicker IEC 61000-3-3	Complies	Complies
<p>The RETeval-DR device is suitable for use in all establishments, other than domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</p>		
<p>To assure continued effectiveness, only use cables and accessories supplied by Welch Allyn which are specifically designed for use with the RETeval-DR device.</p>		

Guidance and Manufacturer's Declaration – Immunity

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

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment–guidance
ESD IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT IEC 61000-4-4	±2kV Mains ±1kV I/Os	±2kV Mains ±1kV I/Os	Mains power quality should be that of a typical home, commercial, or hospital environment
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical home, commercial, or hospital environment

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment—guidance
Voltage Dips/Dropout IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° % UT; 1 cycle 70 % UT; 25/30 cycles for 50 Hz and 60Hz, respectively Single phase: at 0° 0 % UT; 250/300 cycle for 50 Hz and 60 Hz, respectively Single phase: at 0°	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° % UT; 1 cycle 70 % UT; 25/30 cycles for 50 Hz and 60Hz, respectively Single phase: at 0° 0 % UT; 250/300 cycle for 50 Hz and 60 Hz, respectively Single phase: at 0°	Mains power quality should be that of a typical home, commercial, or hospital environment. If the user of the RETeval-DR requires continued operation during power mains interruptions, it is recommended that the RETeval-DR be powered from an uninterruptible power supply or battery.
Power frequency 50/60Hz Magnetic field IEC 61000-4-8	30 A/m, 50 Hz or 60 Hz	30 A/m, 50 Hz or 60 Hz	Power frequency magnetic fields should be that of a typical home, commercial, or hospital environment.
Conducted RF IEC 61000-4-6	3 V, 0.15 MHz – 80 MHz 6 V in ISM radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 V, 0.15 MHz – 80 MHz 6 V in ISM radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile communications equipment should be separated from the RETeval-DR device by no less than the distances calculated/listed below: $D = (1.17) \sqrt{P}$, 150kHz to 80MHz $D = (1.17) \sqrt{P}$, 80 to 800 MHz $D = (2.33) \sqrt{P}$, 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.
Radiated RF IEC 61000-4-3	3 V, 0.15 MHz – 80 MHz 6 V in ISM radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 V, 0.15 MHz – 80 MHz 6 V in ISM radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile communications equipment should be separated from the RETeval-DR device by no less than the distances calculated/listed below: $D = (1.17) \sqrt{P}$, 150kHz to 80MHz $D = (1.17) \sqrt{P}$, 80 to 800 MHz $D = (2.33) \sqrt{P}$, 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment—guidance
			vicinity of equipment containing a transmitter.

Recommended Separations Distances for the RETeval-DR device

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

Max Output Power (Watts)	Separation (m)	Separation (m)	Separation (m)
	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 $D = (2.33) \sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.7	11.7	23.3

Appendices

Approved accessories

Part number	Item
RETeval-001	Welch AllynRETeval-DR Visual Electrodiagnostic Device, including Disposable Sensor Strips (2 packages—50 Pairs per package), Charging Dock, and USB Cable; 100-240 V, 50-60 Hz, Lithium-Ion Battery (#RETeval-ACC-02); IEC Plug Types A, G, E/F, and I (RETeval-ACC-05); English Directions for use
RETeval-SS-50	Disposable Sensor Strips for Welch Allyn RETeval-DR Visual Electrodiagnostic Device; Quantity 50 Pairs
RETeval-ACC-04	Eyecup Accessory for Welch Allyn RETeval-DR Visual Electrodiagnostic Device
RETeval-ACC-01	Lead-Wire Accessory for Welch Allyn RETeval-DR Visual Electrodiagnostic Device
RETeval-ACC-05	Power Transformer Accessory Kit for Welch Allyn RETeval-DR Visual Electrodiagnostic Device; 100-240 V, 50-60 Hz IEC Plug Types A, G, E/F, I and C
RETeval-ACC-03	Dust Cover Accessory for Welch Allyn RETeval-DR Visual Electrodiagnostic Device
RETeval-ACC-02	3.6 V Battery for Welch Allyn RETeval-DR Visual Electrodiagnostic Device; Lithium-Ion

For information about any Welch Allyn product, contact Welch Allyn at www.welchallyn.com/about/company/locations.

DR assessment protocol

The DR Assessment Protocol is designed to aid in the detection of vision threatening diabetic retinopathy (DR), which is defined as severe non-proliferative DR (ETDRS level 53), proliferative DR (ETDRS levels 61+), or clinically significant macular edema (CSME). This definition of vision-threatening DR (VTDR) is the same as used in the NHANES 2005-2008 epidemiology study (Zhang et al. 2010) sponsored by the United States National Center for Health Statistics (NCHS) and the Centers for Disease Control and Prevention (2011).

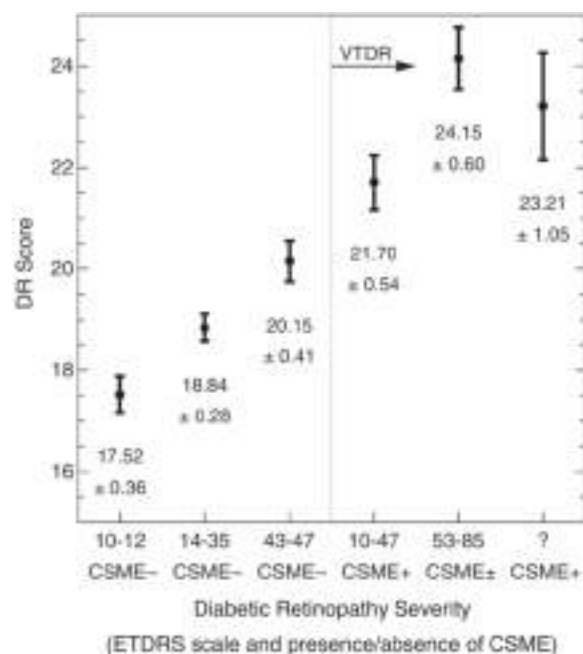
The DR assessment protocol was developed using measurements of 467 people with diabetes aged 23 – 88 (Maa et al. 2016). The gold standard, 7-field, color, stereo, ETDRS-compliant fundus photography with non-physician expert grading (double-read with adjudication), classified each subject into a severity group (Table 1) based on the subject's worst eye. The study had a planned oversampling of low-prevalence retinopathy levels, and the subject population included 106 diabetics with VTDR in at

least one eye. The average testing time for the RETeval-DR device during the clinical trial was 2.3 minutes to test both eyes.

Severity group definitions

International clinical classification (Wilkinson et al. 2003)	ETDRS level	CSME
No NPDR	10 - 12	-
Mild NPDR	14 - 35	-
Moderate NPDR	43 - 47	-
CSME with no, mild, or moderate NPDR	10 - 47	+
Severe NPDR or proliferative DR	53 - 85	+ / -
Ungradable ETDRS level	?	+

The score produced by the DR Assessment Protocol correlates with the presence and severity of diabetic retinopathy and clinically significant macular edema, as shown below (Maa et al. 2016).



The DR Assessment Protocol uses two or three sets of 4, 16, and 32 Td-s flickering white stimuli (28.3 Hz) with no background light. The number of sets is determined by the device's internal precision metrics. The Troland unit (Td) describes retinal illuminance, which is the amount of luminance that enters the pupil. The RETeval-DR device measures the pupil size in real time and continuously adjusts the flash luminance to deliver the desired amount of light into the eye regardless of the size of the pupil. The light stimuli are white light (1931 CIE x, y of 0.33, 0.33).

The patient's result is a combination of the following:

- Age of the patient

- The timing of the electrical response to the 32 Td-s stimulus
- The amplitude of the electrical response to the 16 Td-s stimulus
- The ratio of the pupil area between the 4 Td-s stimulus and the 32 Td-s stimulus

To help ensure accurate results, enter the correct birth date.

Individuals with diabetes who have severe retinopathy typically have pupils that change size less than the pupils of healthy individuals. If the patient is on medications or has other conditions that impair the pupil response, extra care must be taken to properly interpret the RETeval-DR device results, as these individuals are more likely to be erroneously classified as likely to have vision threatening DR. Further, ensure the contralateral eye is covered by the patient’s hand to prevent uncontrolled light stimulation of the contralateral eye from affecting the pupil being measured. Do not use the DR Assessment Protocol on patients whose eyes are pharmacologically dilated.

The result from the DR Assessment Protocol is interpreted as being low, normal, or high. Default “Normal” results are within the reference interval 7.1 – 19.9. A result greater than or equal to 20 (which by default is interpreted as “high” by the device) was indicative of vision- threatening DR in the study population. When weighted for the prevalence found in a typical diabetic population, the device has a sensitivity of 83%, a specificity of 78%, and a negative predictive value (NPV) of 99%, assuming the NHANES 2005-2008 prevalence of 4.4% (Zhang et al. 2010). Using the same cutoff of 20, if CSME is ignored and only patients with ETDRS 53+ are considered, the sensitivity improved to 87%, the NPV improved to 99.2%, while the specificity remained the same.

The reference interval can be adjusted (see "Device Settings") to trade off sensitivity, specificity, and negative predictive values as described in the following table for varying the upper point of the reference interval. The default lower point of the reference interval is three standard deviations below the mean for the patients without retinopathy. Thus, only about one person per thousand should fall below the lower limit and be interpreted as low.

Performance metrics with primary care prevalence

RETeval cutoff value	Sensitivity	Specificity	Percent of tested sample					
			Predictive power of test		Positive test		Negative test	
			Positive	Negative	True	False	True	False
17.6	93%	52%	8%	99.5%	4.1%	46%	50%	0.2%
LCL	73%	47%	5%	97%	2.4%	41%	45%	0.0%
UCL	99.9%	57%	13%	100.0%	6.5%	51%	55%	1.3%
18.1	90%	57%	9%	99.2%	3.8%	41%	55%	0.5%
LCL	65%	52%	5%	97%	2.2%	36%	50%	0.1%
UCL	99%	62%	14%	99.9%	6.2%	46%	59%	1.7%
19.1	88%	67%	11%	99.1%	3.8%	31%	64%	0.5%

Performance metrics with primary care prevalence

RETEval cutoff value	Sensitivity	Specificity	Percent of tested sample					
			Predictive power of test		Positive test		Negative test	
			Positive	Negative	True	False	True	False
LCL	65%	62%	6%	97%	2.2%	27%	59%	0.1%
UCL	99%	72%	17%	99.9%	6.2%	36%	69%	1.7%
20.0	83%	78%	15%	99%	3.6%	21%	75%	0.7%
LCL	59%	74%	9%	97%	2.0%	17%	71%	0.1%
UCL	96%	82%	23%	99.9%	5.9%	25%	79%	2.1%
21.2	73%	84%	17%	99%	3.1%	15%	80%	1.2%
LCL	47%	80%	9%	97%	1.7%	12%	76%	0.4%
UCL	90%	87%	27%	99.5%	5.3%	19%	84%	2.8%

LCL and UCL represent the lower and upper 95% confidence limits, respectively.

References

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Warranty

Welch Allyn, Inc. warrants that the RETeval-DR product meets its labeled specifications and will be free from defects in materials and workmanship that occur within 1 year of shipment. This warranty does not cover damage caused by: 1) attempted disassembly or repair by anyone not authorized by Welch Allyn, 2) failure to follow instructions for use and maintenance, or 3) accidental drops or impacts. If the RETeval-DR product covered by this warranty malfunctions due to a defect in material or workmanship within the 1

year warranty period, Welch Allyn will, at its discretion, repair or replace the product free of charge.

You must obtain a return authorization from Welch Allyn to arrange for the return of your RETeval-DR product before you send it to the designated Welch Allyn service center for repair or replacement. Contact Welch Allyn Technical Support at www.welchallyn.com/about/company/locations.htm to obtain information on returning the product and obtaining warranty service.

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DEFECTS OCCURRING AFTER WARRANTY PERIOD.

Charges for repairs after the warranty period, but within the product's service life, will be based upon actual hours spent on the repair at the prevailing rate, plus the price of parts required and transportation charges. You may also elect to purchase an extended warranty. Continued support beyond the warranty period may require an annual support and update fee. For information about purchasing an extended warranty on your RETeval-DR product, contact Welch Allyn Technical Support: www.welchallyn.com/about/company/locations.htm.

