RETEVETTM PORTABLE ERG

USER MANUAL



Item no. 173610



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LKC Technologies, Inc., established in 1987, is ISO 13485:2016 (MDSAP) certified and an FDA-registered medical device manufacturer with quality products installed in over fifty countries.

1. WELCOME TO RETEVET™

Congratulations on your acquisition of the RETevet[™] visual electrodiagnostic device. With the RETevet[™] device, you can offer your patients a convenient retinal diagnostic evaluation. The RETevet[™] device is the veterinary version of the RETeval device, which is a visual electrodiagnostic device approved for use in humans in over 70 countries.

Every RETevet[™] device comes with flicker protocols and single-flash protocols for veterinary use. Protocols are available through a protocol chooser that enables electroretinogram (ERG) testing.

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

What's in the Box

The RETevet[™] device is packaged with these items. Check that all items are present.



RETevet™ device	Measures the response of the eye to light.
Docking station	Charges the RETevet™ device and enables data transfer to a PC.
Dust cover	Not shown. Protects the device from dust while not in use.
3-plug electrode lead	Connects the device to electrodes for testing.
USB cable	Connects the device to a PC to transfer results.
Power brick and plates	Connects the device to an electrical outlet. Use the wall-plug option that matches available electrical outlets.
User Manual	This document. The manual is available as a PDF located on the root directory of the RETevet™ device.
Electrodes	Not shown. Depending on what was ordered, electrodes could be ERG Jet electrodes for large animals, or smaller electrodes sized for rats or mice. Ten needle electrodes as reference and ground are provided when a primary electrode is ordered.

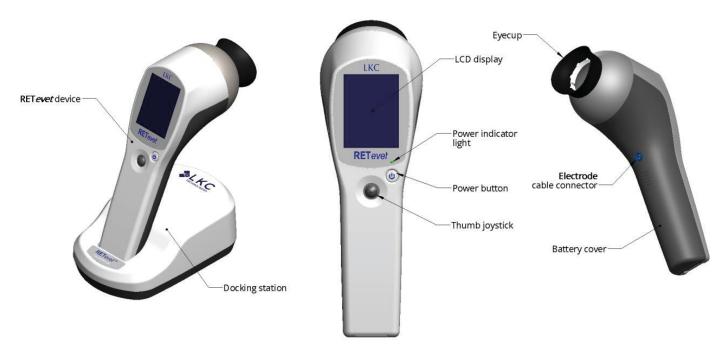
2. GETTING STARTED

Connect the Cord to the Docking Station and Plug-in

- Attach the power brick plate that matches your electrical outlet to the power brick.
- Connect the power cord to the docking station.
- Connect the power brick to an electrical outlet. The power supply accepts 100 240 VAC, 50/60 Hz.

Let the Device Charge

The RETevet[™] device charges its battery when in the docking station from either the USB or power brick connection. If the power brick is connected, charging will be significantly faster than if only a USB connection is present. The charging status is shown on the display. If the display is blank, press the power button to turn it on. The RETevet[™] device is shipped with a partial charge.



Connect the Electrodes

Connect the 3-plug electrode lead to the blue lead connector shown in the figure above, and then connect the electrodes in the following way: corneal electrode to the red plug, reference electrode to the black plug and the ground electrode to the green plug.

Device Controls

The RETevet™ device has an up/down/right/left/select joystick and an on-off power button.

Turning the Device Off

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. Wait a few seconds after the power indicator light stops blinking before turning the device back on.

Joystick

The joystick provides a simple and intuitive user interface. Use your thumb to push the joystick in the desired direction. UP and DOWN move the selection highlight up or down.

Go back one screen: Press **LEFT** when the cursor is at the left edge of the screen. Press **RIGHT** when the cursor is at the right edge of the screen.

Select a highlighted item: Press **SELECT**.

Main Menu

The RETevet[™] device main menu has a top status bar, four buttons and at the bottom a description of the currently-selected protocol. The status bar shows the time, date, and battery charge state. The four buttons enable the operator to start a new test, view previous results, change system settings, and choose the protocol that will run when starting a new test. At the bottom of the screen, the currently selected protocol is displayed.



Settings

Set up the RETevet[™] device for use in your practice.

- 1. Turn on the device.

 The device goes through a brief internal test and initialization.
- 2. Select Settings.
- 3. Adjust each setting as you prefer.

Language

Use the joystick to scroll through the languages and select the one you want to use for the device's user interface and PDF reports.

If you select a right-to-left language (i. e., Arabic), the **RIGHT** and **LEFT** joystick directions are swapped from the description in this manual.



Date/Time

Use the joystick to select each element of the current date. Use the **RIGHT** and **LEFT** joystick directions to move between pages. The device uses the date and time to label results and to compute the patient's age.

Backlight

The display backlight can be adjusted to three different levels. Brighter settings may be more visible but will slightly reduce the number of patients you can test before needing to recharge in the docking station. There is also a "red" option that makes the display only use red light. For tests requiring dark-adaptation, the display backlight is automatically dimmed and reddened during the appropriate portion of the protocol.

Practice Information

Practice information is used to label reports. It includes the practice name and three lines for practice address. You can use these lines for other information if you like. Text is inserted at the blinking vertical cursor. Use the delete key to move to the left. Practice information is displayed on the report above the patient information as shown in the sample report on Page 22. That sample report has LKC Technologies and its address as the practice information, which is the default for all devices. Pressing the barcode symbol enables practice information to be scanned from an external display such as a PC monitor. Scanning is automatic and does not require the joystick to be pressed. Look in the downloads section of https://www.lkc.com/products/RETevet™ to download the free data entry software. If the RETevet™ device has trouble scanning the barcode, ensure the eyecup is on or very close to the display, the display brightness is set to maximum, and the mouse cursor is not superimposed on the barcode.

Page Size

The PDF reports created by the RETevet™ device can be formatted for either A4 sized paper or letter (8.5" x 11") sized paper.

Device Serial Number and Options

To view the device's serial number and what options are present, select **System** under **Settings**.

Under **Settings** there is also a **Report formats** menu, where you can select if you want PDF, JPEG, or PNG output formats for the reports. More than one option can be selected. PDF is the preferred format for printing. JPEG may be more convenient for uploading results to certain EMR systems.



3. CHOOSING A PROTOCOL

The RETevet[™] device enables you to change the stimulus conditions (called protocols) to best meet your needs via a protocol chooser. The RETevet[™] protocols have flicker and single flash stimuli to provide the complete assessment of the retinal function.



Flicker ERG Testing

The RETevet[™] device supports flicker ERG testing, as a fast and easy way to assess the functioning of the cone pathways. The RETevet[™] device measures flicker implicit time quickly and accurately by flashing light into the patient's eye and measuring the time delay (implicit time) and amplitude of the retina's electrical response as detected on the eye electrode.

Brief flashes of light are provided at the beginning of each 28.3 Hz stimulus period. Background illumination, where present, uses a pulse-width-modulation (PWM) frequency near 1 kHz. Flicker protocols typically record between 5 and 15 seconds of data for each stimulus condition stopping after an internal precision metric is reached. Some protocols have multiple stimulus conditions which are presented sequentially with a short (< 1 s) dark pause between the conditions. A counter on the screen shows progress for these multi-stimulus protocols.

The RETevet[™] device provides flicker intensities of 3 and 10 cd·s/m² without a background light and the ISCEV standard 3 cd·s/m² flash with a 30 cd/m² background. If you are unsure which stimulus to use, the ISCEV standard is recommended.

Flicker: 3 cd·s/m ²							
Description	Eye	Flash Luminance Energy (0.33, 0.33 White)	Background Luminance (0.33, 0.33 White)	# Flashes			
Light adapted 3.0 flicker	Right	3 cd·s/m² @ 28.3 Hz	Off	141-424			
Light adapted 3.0 flicker	Left	3 cd·s/m² @ 28.3 Hz	Off	141-424			

Flicker: 10 cd-s/m ²							
Description	Eye	Flash Luminance Energy (0.33, 0.33 White)	Background Luminance (0.33, 0.33 White)	# Flashes			
Light adapted 10.0 flicker	Right	10 cd·s/m² @ 28.3 Hz	Off	141-424			
Light adapted 3.0 flicker	Right	10 cd·s/m² @ 28.3 Hz	Off	141-424			

Flicker: 3 cd·s/m², 30 cd/m² bg								
Description	Eye	Flash Luminance Energy (0.33, 0.33 White)	Background Luminance (0.33, 0.33 White)	# Flashes				
Light adapted 10.0 flicker	Right	3 cd·s/m² @ 28.3 Hz	30 cd/m ²	141-424				
Light adapted 3.0 flicker	Left	3 cd·s/m² @ 28.3 Hz	30 cd/m ²	141-424				

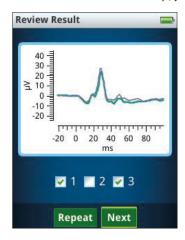
Flash ERG Testing

For more complete retinal function testing (including issues of seeing in dim light situations), flash testing can be used in addition to the flicker testing.

- 1. Dark-adapted rod response (DA 0.01): provides information about rod system, night vision and therefore is useful in detecting rhodopsin-related mutations and SARDS for example.
- 2. Dark-adapted, mixed, rod and cone response (DA 3.0): both, rod and cones are assessed. Photoreceptors are evaluated separately (a-wave) from their pathways in the inner retina (b-wave) providing generalized yet complete evaluation of the retinal function.
- 3. Dark-adapted mixed, rod and cone response to a higher intensity flash (DA 10.0): in addition to the information acquired in the previous step, the response to the higher intensity flash allows for the evaluation of the impact the opacity of the media such as a cataract has on the retinal function.
- 4. Dark-adapted Oscillatory Potentials (OPs) extracted from the mixed response by using the 85–190 Hz bandpass filter provide more subtle and consistent information about the diffused changes in the inner retina caused by e. g., ischemic events or amacrine cell function. These test results are mainly used for research purposes. Up to 5 cursors are automatically placed on the oscillatory potential peaks and troughs and are indicated on the report as black dots on the waveform. Implicit times (time to peak) and amplitudes (peak to following trough) are reported for each individual cursor. The sums of implicit times and amplitudes for all cursors are also reported. When interpreting the summed cursor times and amplitudes, you should examine the cursor dots on the waveform to ensure that no waves are missed.
- 5. Light adapted cone response (LA 3.0) provides an overall assessment of outer and inner retina in the day vision.
- 6. Light adapted flicker (LA 3.0 flicker) is a robust response of the cone pathway and an excellent tool for a quick assessment of the retinal function.

Flash conditions in those steps depend on the species, particularly on their behavioral time of activity (nocturnal vs. diurnal). Therefore, **protocols are built based on the individual customer's needs.**

Subtests in these protocols display the waveform results after each measurement period and enable the operator to repeat the step as many times as desired. Automated cursor placements are computed to the average cursor placement across all repetitions. Any subtest can be skipped without affecting the rest of the protocol. On the review screen, the operator has the option of selecting which replicates to keep from the reports. This option enables replicates to be deleted in the event, for example, of poor patient compliance or excess noise in some replicates. To remove a replicate, simply uncheck the box associated with that replicates can be selected or removed anytime while collecting replicates. After you have moved to the next test step, you no longer can alter the replicate selection for previous steps.



For dark-adapted tests, the display is automatically dimmed and reddened. The green power status LED is also turned off to assist in dark-adaptation. The display and LED are automatically brightened at the end of the dark-adaptation tests.

To create the visual stimulus, the RETevet[™] device generates variable-duration flashes of white light, made from red, green, and blue LEDs all being on for the same duration. The maximum energy flash of white light is 30 cd·s/m², which has a flash duration of 5 ms.

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The signal processing for the non-flicker tests uses the followings steps. A zero-phase 0.3 Hz high-pass filter reduces electrode drift and offset while preserving waveform timing. Measurements from multiple flashes are combined to improve the signal to noise ratio using a trimmed mean to reduce the effect of outliers after removing outlier replicates whose amplitudes exceed 1 mV. The resulting waveform is then processed using wavelet-based denoising (Ahmadi and Rodrigo 2013) where wavelets are attenuated based on the signal to noise power between the post-stimulus (signal) and pre-stimulus (noise) portions of the waveform. Oscillatory potential analysis does not use the wavelet denoising

Ecvo-Based ERG Protocols for Veterinary Use

The RETevet[™] device has a series of protocols based on the guidelines for testing dogs (Ekesten et al. 2013). These protocols all use the acronym ECVO, which stands for European College of Veterinary Ophthalmologists, which were the original basis for the guidelines.

The protocol **ECVO 5-step** can be used to assess the functioning of the rod and cone pathways in the retina. Rod function is assessed with a series of dim flashes after a period dark-adaptation (20 minutes is recommended). Next, cone function is tested after 10 minutes of light adaption. Waiting or examination room ambient light is close to 30 cd/m² which is likely sufficient or the built-in 30 cd/m² can be used per each eye. This protocol is recommended for anesthetized or sedated animals, as the test duration is fairly long.

ECVO 5-step				
Description Eye		Flash Luminance Energy (0.33, 0.33 white)	Background Luminance (0.33, 0.33 white)	# Flashes
Dark-adaptation timer	Both	Off	Off	
Dark-adapted 0.01	Right	0.01 cd·s/m² @ 0.2 Hz	Off	4
Dark-adapted 3.0	Right	3 cd·s/m² @ 1/15 Hz	Off	4
Dark-adapted 10.0	Right	10 cd·s/m² @ 0.05 Hz	Off	1
Dark-adapted 0.01	Left	0.01 cd·s/m² @ 0.2 Hz	Off	4
Dark-adapted 3.0	Dark-adapted 3.0 Left		Off	4
Dark-adapted 10.0	Left	10 cd·s/m² @ 0.05 Hz	Off	1
Light adaptation timer	Right	Off	30 cd/m ²	
Light adapted 3.0	Right	3 cd·s/m² @ 2 Hz	30 cd/m ²	20
Light adapted 3.0 flicker	Right	3 cd·s/m² @ 28.3 Hz	30 cd/m ²	141-424
Light adaptation timer	Left	Off	30 cd/m ²	
Light adapted 3.0	Left	3 cd·s/m² @ 2 Hz	30 cd/m ²	20
Light adapted 3.0 flicker	Left	3 cd·s/m² @ 28.3 Hz	30 cd/m ²	141-424

Protocol **ECVO 5-step single flash** is a modified version of the ECVO 5-step protocol described above. The difference is while the **ECVO 5-step** uses 4 flashes in the DA 0.01 and DA 3.0 steps in order to used averaging to improve signal quality, this **single flash** version only uses 1 flash to minimize testing time. Replicates can be made in both protocols, and artefactual results deleted. This protocol is recommended for NON-anesthetized or NON-sedated animals.

ECVO 5-step single flash					
Description Eye		Flash Luminance Energy (0.33, 0.33 white)	Background Luminance (0.33, 0.33 white)	# Flashes	
Dark-adaptation timer	Both	Off	Off		
Dark-adapted 0.01	Right	0.01 cd·s/m² @ 0.2 Hz	Off	1	
Dark-adapted 3.0	Right	3 cd·s/m² @ 1/15 Hz	Off	1	
Dark-adapted 10.0	Right	10 cd·s/m² @ 0.05 Hz	Off	1	
Dark-adapted 0.01 Left		0.01 cd·s/m² @ 0.2 Hz	Off	1	
Dark-adapted 3.0 Left		3 cd·s/m² @ 1/15 Hz	Off	1	
Dark-adapted 10.0 Left		10 cd·s/m² @ 0.05 Hz Off		1	
Light adaptation timer	Right	Off	30 cd/m ²		
Light adapted 3.0	Right	3 cd·s/m² @ 2 Hz	30 cd/m ²	20	
Light adapted 3.0 flicker	Right	3 cd·s/m² @ 28.3 Hz	30 cd/m ²	141 – 424	
Light adaptation timer	Left	Off	30 cd/m ²		
Light adapted 3.0	Left	3 cd·s/m² @ 2 Hz	30 cd/m ²	20	
Light adapted 3.0 flicker	Left	3 cd·s/m² @ 28.3 Hz	30 cd/m ²	141 – 424	

Protocol **ECVO short, yes/no protocol** is a modified version of the **ECVO 5-step single protocol**. Only the dark-adapted steps are performed. This protocol is recommended for NON-anesthetized or NON-sedated animals when only rod- and mixed rod-cone retinal function is required to be assessed.

ECVO short, yes / no protocol						
Description Eye		Flash Luminance Energy (0.33, 0.33 white)	Background Luminance (0.33, 0.33 white)	# Flashes		
Dark-adaptation timer	Both	Off	Off			
Dark-adapted 0.01	Right	0.01 cd·s/m² @ 0.2 Hz	Off	1		
Dark-adapted 3.0 Right		3 cd·s/m² @ 1/15 Hz	Off	1		
Dark-adapted 10.0 Right		10 cd·s/m² @ 0.05 Hz	Off	1		
Dark-adapted 0.01	Left	0.01 cd·s/m² @ 0.2 Hz	Off	1		
Dark-adapted 3.0 Left		3 cd·s/m² @ 1/15 Hz	Off	1		
Dark-adapted 10.0	Left	10 cd·s/m² @ 0.05 Hz	Off	1		

In the protocol Cone function testing, only light-adapted tests are performed. At least 10 minutes exposure to the ambient light close to 30 cd/m² (outside or examination room) should be done before testing. This protocol is recommended for quick, cone-based general assessment of the retinal function, for example, for pre-cataract testing. We also recommend this procedure for the inexperienced users.

Cone function testing						
Description	Eye	Flash Luminance Energy (0.33, 0.33 White)	Background Luminance (0.33, 0.33 White)	# Flashes		
Light adaptation timer	Right	Off	30 cd/m ²			
Light adapted 3.0	Right	3 cd·s/m² @ 2 Hz	30 cd/m ²	20		
Light adapted 3.0 flicker	Right	3 cd·s/m² @ 28.3 Hz	30 cd/m ²	141 – 424		
Light adaptation timer	Left	Off	30 cd/m ²			
Light adapted 3.0	Left	3 cd·s/m² @ 2 Hz	30 cd/m ²	20		
Light adapted 3.0 flicker	Left	3 cd·s/m² @ 28.3 Hz	30 cd/m ²	141 – 424		

In the protocol ECVO long protocol for PRA diagnosis, dim flash ERGs are performed during dark adaption in order to assess the rate of rod recovery in the dark. Measurements occur every 4 minutes starting at time 0. The choice of which eye to test eye is offered at the beginning of the test, as only one eye is tested. Light adaptation of 10 minutes occurs after the right and left eyes dark-adapted tests are completed. Waiting or examination room ambient light close to 30 cd/m² is likely sufficient or one can use the built-in light-adaptation 10-min period. This protocol is recommended for anesthetized or sedated animals when the progression of dark-adaptation needs to be evaluated, for example in Progressive Retinal Atrophy (PRA) (Miyadera, Acland, and Aguirre 2012). PRA is a bilateral disease so that evaluating one eye is sufficient (Ekesten et al. 2013).

ECVO long protocol for PRA dia	agnosis			
Description	Eye	Flash Luminance Energy (0.33, 0.33 White)	Background Luminance (0.33, 0.33 White)	# Flashes
Dark-adapted 0.01	Operator's choice	0.01 cd·s/m² @ 0.2 Hz	Off	4
Wait remain	der of 4 minutes, ol	oserve count-down timer, press "Sta	art Test" to continue	
Dark-adapted 0.01		0.01 cd·s/m² @ 0.2 Hz	Off	4
Wait remain	der of 4 minutes, ol	oserve count-down timer, press "Sta	art Test" to continue	
Dark-adapted 0.01		0.01 cd·s/m² @ 0.2 Hz	Off	4
Wait remain	der of 4 minutes, ol	oserve count-down timer, press "Sta	art Test" to continue	
Dark-adapted 0.01		0.01 cd·s/m² @ 0.2 Hz	Off	4
Wait remain	ider of 4 minutes, ol	oserve count-down timer, press "St	art Test" to continue	
Dark-adapted 0.01		0.01 cd·s/m² @ 0.2 Hz	Off	4
Wait remain	nder of 4 minutes, ol	oserve count-down timer, press "St	art Test" to continue	
Dark-adapted 0.01		0.01 cd·s/m² @ 0.2 Hz	Off	4
Dark-adapted 3.0		3 cd·s/m² @ 1/15 Hz	Off	4
Dark-adapted 10.0		10 cd·s/m² @ 0.05 Hz	Off	1
Light adaptation timer		Off	30 cd/m ²	
Light adapted 3.0		3 cd·s/m² @ 2 Hz	30 cd/m ²	20
Light adapted 3.0 flicker		3 cd·s/m ² @ 28.3 Hz	30 cd/m ²	141 - 424

Protocol **ECVO** with **ERG-measured DA** single is a shorted version of **ECVO** long protocol for **PRA** diagnosis protocol where the dark-adapted tests use only 1 flash instead of 4. Replicates can be made in both protocols, and artefactual results deleted. This protocol is recommended for NON-anesthetized or NON-sedated animals.

ECVO long protocol for PRA dia	agnosis single flash			
Description	Eye	Flash Luminance Energy (0.33, 0.33 White)	Background Luminance (0.33, 0.33 White)	# Flashes
Dark-adapted 0.01	Operator's choice	0.01 cd·s/m² @ 0.2 Hz	Off	1
Wait remain	nder of 4 minutes, ol	bserve count-down timer, press "St	art Test" to continue	
Dark-adapted 0.01		0.01 cd·s/m² @ 0.2 Hz	Off	1
Wait remain	nder of 4 minutes, ol	bserve count-down timer, press "St	art Test" to continue	
Dark-adapted 0.01		0.01 cd·s/m² @ 0.2 Hz	Off	1
Wait remain	nder of 4 minutes, ol	bserve count-down timer, press "St	art Test" to continue	
Dark-adapted 0.01		0.01 cd·s/m² @ 0.2 Hz	Off	1
Wait remain	nder of 4 minutes, ol	bserve count-down timer, press "St	art Test" to continue	
Dark-adapted 0.01		0.01 cd·s/m² @ 0.2 Hz	Off	1
Wait remain	nder of 4 minutes, ol	bserve count-down timer, press "St	art Test" to continue	
Dark-adapted 0.01		0.01 cd·s/m² @ 0.2 Hz	Off	1
Dark-adapted 3.0		3 cd·s/m² @ 1/15 Hz	Off	1
Dark-adapted 10.0		10 cd·s/m² @ 0.05 Hz	Off	1
Light adaptation timer		Off	30 cd/m ²	
Light adapted 3.0		3 cd·s/m² @ 2 Hz	30 cd/m ²	20
Light adapted 3.0 flicker		3 cd·s/m² @ 28.3 Hz	30 cd/m ²	141 -424

PupilLightReflex protocol generate 1000 cd/m² red (621 nm) or blue (470 nm) light, as selected by the operator so the pupil responses can be observed on the display and noted down. No report is generated. This protocol should not be used if the animal has been artificially dilated, as the pupils will be unresponsive.

Iscev-Based ERG Protocols for Animal Use

These protocols are created for research and pharmaceutical testing. They use standards published for humans by International Society for Clinical Electrophysiology of Vision (ISCEV) and are most suitable for basic discovery, pre-clinical, and toxicology studies.

The following tables describe other ERG protocols for animal use.

In the protocol **Dog, Cat, Nonhuman Primate 6 step, light adapted first**, light adapted tests are performed first. The 10-min light adaptation in the waiting or examination room ambient light is often considered sufficient. A minimum dark-adaptation period of 20 minutes is suggested to measure rod function.

Oscillatory potentials, the 6th step in the protocol, are automatically extracted and measured from the dark-adapted 3.0 test.

Dog, Cat, Nonhuman Primate, 6-step, light adapted first					
Description	Eye	Flash Luminance Energy (0.33, 0.33 White)	Background Luminance (0.33, 0.33 White)	# Flashes	
Light adapted 3.0	Right	3 cd·s/m² @ 2 Hz	30 cd/m ²	20	
Light adapted 3.0 flicker	Right	3 cd·s/m² @ 28.3 Hz	30 cd/m ²	141 – 424	
Light adapted 3.0	Left	3 cd·s/m² @ 2 Hz	30 cd/m ²	20	
Light adapted 3.0 flicker	Left	3 cd·s/m² @ 28.3 Hz	30 cd/m ²	141 – 424	
Dark-adaptation timer	Both	Off	Off		
Dark-adapted 0.01	Right	0.01 cd·s/m² @ 0.5 Hz	Off	3	
Dark-adapted 3.0	Right	3 cd·s/m² @ 0.1 Hz	Off	3	
Dark-adapted 10.0	Right	10 cd·s/m² @ 0.05 Hz	Off	3	
Dark-adapted 0.01	Left	0.01 cd·s/m² @ 0.5 Hz	Off	3	
Dark-adapted 3.0	Left	3 cd·s/m² @ 0.1 Hz	Off	3	
Dark-adapted 10.0	Left	10 cd·s/m² @ 0.05 Hz	Off	3	

Alternatively, the dark-adapted steps can be performed first, as done in the **Dog, Cat, Nonhuman Primate, 6-step, dark-adapted first** protocol.

Dog, Cat, Nonhuman Primate, 6- step, dark-adapted first					
Description	Eye	Flash Luminance Energy (0.33, 0.33 White)	Background Luminance (0.33, 0.33 White)	# Flashes	
Dark-adaptation timer	Both	Off	Off		
Dark-adapted 0.01	Right	0.01 cd·s/m² @ 0.5 Hz	Off	3	
Dark-adapted 3.0	Right	3 cd·s/m² @ 0.1 Hz	Off	3	
Dark-adapted 10.0	Right	10 cd·s/m² @ 0.05 Hz	Off	3	
Dark-adapted 0.01	Left	0.01 cd·s/m² @ 0.5 Hz	Off	3	
Dark-adapted 3.0	Left	3 cd·s/m² @ 0.1 Hz	Off	3	
Dark-adapted 10.0	Left	10 cd·s/m² @ 0.05 Hz	Off	3	
Light adaptation timer	Right	Off	30 cd/m ²		
Light adapted 3.0	Right	3 cd·s/m² @ 2 Hz	30 cd/m ²	20	
Light adapted 3.0 flicker	Right	3 cd·s/m² @ 28.3 Hz	30 cd/m ²	141 – 424	
Light adaptation timer	Left	Off	30 cd/m ²		
Light adapted 3.0	Left	3 cd·s/m² @ 2 Hz	30 cd/m ²	20	
Light adapted 3.0 flicker	Left	3 cd·s/m² @ 28.3 Hz	30 cd/m ²	141 – 424	

For testing rabbits and mini-pigs, **Rabbit**, **mini pig**, **photopic 2 step and Rabbit**, **mini pig**, **scotopic 4 step** were designed (McGee, Dembinska, and Gruebbel 2005). Photopic and scotopic tests can be performed separately or together depending on the study design.

Rabbit, mini pig, photopic 2 step					
Description	Eye	Flash Luminance Energy (0.33, 0.33 White)	Background Luminance (0.33, 0.33 White)	# Flashes	
Light adapted 8.0	Right	8 cd·s/m² @ 2 Hz	30 cd/m ²	20	
Light adapted 8.0 flicker	Right	8 cd·s/m² @ 28.3 Hz	30 cd/m ²	141 – 424	
Light adapted 8.0	Left	8 cd·s/m² @ 2 Hz	30 cd/m ²	20	
Light adapted 8.0 flicker	Left	8 cd·s/m² @ 28.3 Hz	30 cd/m ²	141 – 424	

For the dark-adapted testing, dark adaption can be done overnight before the test starts or for at least 20 minutes before testing. Use the red backlight option in **Settings** (see page 6) to start the test with a red screen. Oscillatory potentials are automatically calculated from the DA 8.0 test, which is the 4th step in the protocol.

Rabbit, mini pig, scotopic 4 step					
Description	Eye	Flash Luminance Energy (0.33, 0.33 White)	Background Luminance (0.33, 0.33 White)	# Flashes	
Dark-adapted 0.6	Right	0.06 cd·s/m² @ 0.5 Hz	Off	3	
Dark-adapted 8.0	Right	8 cd·s/m² @ 0.1 Hz	Off	3	
Dark-adapted 25	Right	25 cd·s/m² @ 0.05 Hz	Off	3	
Dark-adapted 0.06	Left	0.06 cd·s/m² @ 0.5 Hz	Off	3	
Dark-adapted 8	Left	8 cd·s/m² @ 0.1 Hz	Off	3	
Dark-adapted 25	Left	25 cd·s/m² @ 0.05 Hz	Off	3	

For testing rats and mice, dimmer stimuli are typically used (Dembinska et al. 2001, Dembinska et al. 2002, Polosa et al. 2019). Photopic and scotopic tests can be performed separately or together depending on the study design, there are separate protocols for measuring just the animal's right or left eye.

Rat, mouse photopic 2 step left eye					
Description	Eye	Flash Luminance Energy (0.33, 0.33 White)	Background Luminance (0.33, 0.33 White)	# Flashes	
Light adapted 8.0	Left	8.0 cd·s/m² @ 2 Hz	30 cd/m ²	20	
Light adapted 8.0 flicker	Left	8.0 cd·s/m² @ 28.3 Hz	30 cd/m ²	141 – 424	

Rat, mouse photopic 2 step right eye						
Description	Eye	Flash Luminance Energy (0.33, 0.33 White)	Background Luminance (0.33, 0.33 White)	# Flashes		
Light adapted 8.0	Right	8.0 cd·s/m² @ 2 Hz	30 cd/m ²	20		
Light adapted 8.0 flicker	Right	8.0 cd·s/m² @ 28.3 Hz	30 cd/m ²	141 – 424		

Overnight dark-adaptation is recommended in rodents. Oscillatory potentials are automatically calculated from the DA 8.0 test, which is the 3rd step in the protocol.

USER MANUAL RETEVET™ PORTABLE ERG

Rat, mouse scotopic 3 step left eye					
Description	Eye	Flash Luminance Energy (0.33, 0.33 White)	Background Luminance (0.33, 0.33 White)	# Flashes	
Dark-adapted 0.002	Right	0.002 cd·s/m² @ 0.5 Hz	Off	3	
Dark-adapted 8.0	Right	8.0 cd·s/m² @ 0.1 Hz	Off	1	

Rat, mouse scotopic 3 step right eye						
Description	Eye	Flash Luminance Energy (0.33, 0.33 White)	Background Luminance (0.33, 0.33 White)	# Flashes		
Dark-adapted 0.002	Left	0.002 cd·s/m² @ 0.5 Hz	Off	3		
Dark-adapted 8.0	Left	8.0 cd·s/m² @ 0.1 Hz	Off	1		

Other Protocols

The RETevet[™] device has two protocols for which measurements are not obtained: The other two protocols are "flashlight" protocols where the device creates either 30 cd/m² or 300 cd/m² white light.

Custom Protocols

If there is a protocol that you would like to run that is not built in the RETevet™ device, a custom protocol can be created for you. Contact EICKEMEYER® for more information on how to obtain and use a custom protocol. Typically, custom protocols should define, which tests will be run and what will be the conditions of those tests such as the stimuli intensity, frequency, color, duration, and type (on-off, ramp, or sinusoidal stimuli).

Custom protocols must be transferred in the Protocols folder on the device. The built-in protocols can be viewed on the device in the folder EMR/Built-in protocols, which can be a starting point for creating your own custom protocols. Protocols are written in the full-featured Lua programming language.

Reference Intervals

The RETevet[™] device has built-in infrastructure to handle and report your reference interval data. We doe not provide non-human reference data, as there are dependencies on species, breed, and electrode type used. However, if in your practice you have tested many subjects with normal vision, contact EICKEMEYER® support for assistance in incorporating your own reference data.

4. BEFORE PERFORMING AN ERG TEST

Anesthesia

An ERG can be obtained without anesthesia or sedation in dogs. In other animals, anesthesia may be needed in order to complete the test. Anesthesia usually will affect the ERG, and the literature should be consulted for recommendations. Make sure the eyes of anesthetized animal will not roll down, which may occur with certain pharmacological agents or by a physical block. Typically, for research purposes animals (mice, rats, rabbits, dogs, pigs, NHP) can be anesthetized with a Ketamine/Xalazine combination for ERG recordings. Tenneson and Vezina studied 6 different anesthetic agents in a 2017 ARVO poster, a copy of which is https://www.criver.com/sites/default/files/resource-files/SP-ARVO-17-effect-of- anesthetic-selection-for-ERG.pdf.

Monocular or Binocular Recording

Consider whether you would like to obtain an electroretinogram from one eye (monocular) or from both eyes (binocular). Monocular recording is faster, and may be sufficient when there is a strong possibility that the eyes are similar, for example: in systemic exposure models in rats and mice in research or in toxicology safety evaluations in rabbits. With monocular interventions, recording from both eyes enable the untreated eye to be a control if binocular recordings are made.

Preparing the Animal

Preform ERG testing before photography or indirect ophthalmoscopy if dark-adapted recordings are desired, because 60 minutes are needed for the rods to fully recover from bright light exposures (Tuntivanich et al. 2005).

Dilate the pupils using, for example, a combination of 0.5 % proparacaine and 1 % of tropicamide. Wait 20 – 30 minutes for full dilation. Cautiously verify dilation, especially in black-eyed animals. Anesthetize the cornea around 5 minutes prior to the recording.

Use goniosol or other methylcellulose solution to provide a conductive path between a contact lens electrode and the cornea. If needed, plan ahead for the location and how the animal will be dark-adapted. Use dim red lights in the dark room because rods are insensitive to red light.

Ensure normal body temperature is maintained if the animal is anesthetized. Electroretinograms are temperature-dependent.

Make sure you have all the electrodes and eye speculum if needed.

Electrode Choice

Choose the electrode based on the size of the animal to be tested. ERG-Jet and DTL electrodes are common in larger animals (Mentzer et al. 2005) as well as the newer RM-canine electrode. For smaller animals such as mice and rats, DTL or contact lens electrodes can be used. All these electrodes are available from EICKEMEYER®. While individual preferences vary, we recommend ERG-Jet or RM-canine electrodes for the larger animals. Stainless-steel needle electrodes are used as reference and ground electrodes and they are also available from EICKEMEYER®.

5. PERFORMING AN ERG TEST

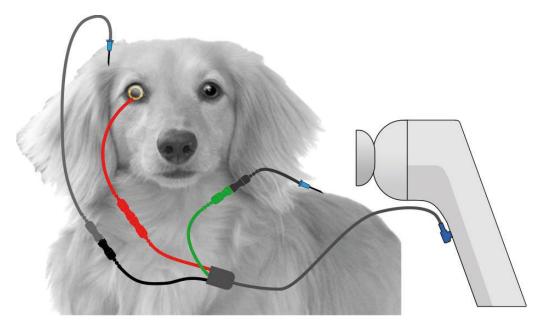
- 1. Remove the RETevet[™] device from the docking station.
- 2. Confirm the protocol is the one desired by looking at the protocol title at the bottom of the screen. If not, select Protocol on the device and change it to the desired protocol. See manual section **Choosing a protocol** on page 8.
- 3. Select **New Test** on the device.
- 4. Enter patient information as prompted by the device (name or identifier and date of birth). Pressing the barcode symbol enables patient information to be scanned from an external display such as a PC monitor. Scanning is automatic and does not require the joystick to be pressed. Look in the downloads section of https://www.lkc.com/products/RETevet™ to download the free data entry software. If the RETevet™ device has trouble scanning the barcode, ensure the eyecup is on or very close to the display, the display brightness is set to maximum, and the cursor is not superimposed on the barcode.
- 5. Confirm that the protocol and patient information are correct.
- 6. Make sure animal has dilated pupils and anesthetized corneas.
- 7. Place electrodes for the right eye.
 - A Proper placement for un-anesthetized pets and larger, anesthetized experimental animals is shown in figure A: active ERG-Jet electrode on the cornea, reference electrode 1–2 cm from the tested lateral canthus in veterinary clinic or at the base of the ear in research or pharmaceutical testing, and ground electrode on the top of the head or between the shoulder blades. Place the electrodes in the following order: ground, reference, active electrode. If the ERG-Jet electrode is used fill half of it just before positioning it on the cornea. An eye retractor (speculum) can be used or the eye must be kept open by the operator. For dark-adapted tests, collect the ERGs from the right eye while the left eye is covered.

Remember: the reference electrode must be placed on the tested side: 1-2 cm from the right lateral canthus or at the base of the right ear when the right eye is tested and 1-2 cm from the left lateral canthus or at the base of the left ear when the left eye is tested. Other places such as cheek or mouth can be used to place the reference electrode. **Keep it consistent throughout all your tests.** Consider using the Mounting Arm instead of holding RETevetTM with anesthetized animal.

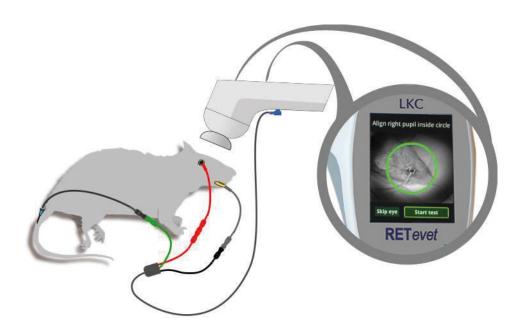
B Proper placement of the electrodes for small, anesthetized, experimental animals is shown in figure B: active jet (loop or DTL) electrode on the cornea, reference electrode at the base of the ear on the tested side, or in the mouth and ground electrode in the tail.

If the electrical connection is noisy, the RETevet[™] device will warn you of the poor connection so that it can be improved before proceeding. Make sure the Jet electrode is adhering to the cornea, add goniosol solution (or similar), replace the electrode(s) or see the **Troubleshooting** section of this manual for suggestions on how to resolve the issue.

A



В



8. Test the right eye.

Select Next.

Position the device so that the animal's pupil is inside the large green circle and the RETevet[™] device is as close as possible and not interfering with the electrodes Remove the eye cup if needed.

Select **Start Test** to start the test after the pupil has been placed in the green circle. At the beginning of each test, the RETevetTM device automatically recalibrates the light intensity and color. This process takes about one second. Wait while the device conducts the ERGs. Testing time depends on the protocol that you have selected and can be less than 10 seconds or as long as a couple of minutes. Cover the left eye if dark-adapted ERGs are recorded.



9. Test the left eye

After the device has indicated that the testing is complete for the right eye, switch active and reference electrodes to the left eye. Ground electrode stays at the same position in the back. Repeat Step 6 for the left eye. There is no need to cover the already tested right eye.

Remove the electrodes while the device is saving the results. A **Next** button appears along with a notification of successful storage upon completion of the save, which can take several seconds.

If any of the steps could not be completed as described above, and error messages are displayed see the Troubleshooting section of this manual to resolve those problems.

Clean the eyecup and other animal-contact parts of the device.

6. VIEWING RESULTS

General

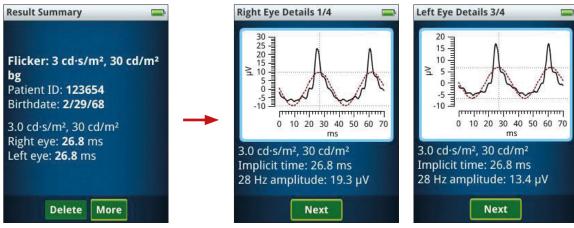
Results are shown on the RETevet™ device and are ready to print on a PC when the ERG tests are completed successfully. The ISCEV standard states that each laboratory should establish or confirm typical reference values for its own equipment, recording protocols, and patient populations. When referring to the literature for clinical interpretation, it is important to verify the material and methods before drawing conclusions.

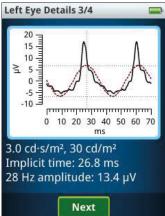
Viewing the results on the device is used to quickly assess the results and decide upon the next steps without printing the results.

Examining the results on a PC, displayed as a ready-to-print pdf file, allows for more detailed data analysis, printing, archiving and file sharing after the patient examination.

Results on the Device

Results Summary is displayed on the screen at the end of the test as pictured below. Results details are also visible from the main menu Results option. Scroll up and down through the list and select the desired test result. The results are stored in chronological order; with the most recent result first. By pressing "More" button, waveform, testing condition, implicit times, and amplitudes for each eye can be seen.





Results on a PC

Results can be transferred to the PC in PDF format.

- 1. Place the RETevet[™] device into the docking station.
- 2. Connect the USB cable to the docking station and to the PC.
- 3. The device appears on the PC like a thumb drive or external USB drive.

You can now view results or copy them to the PC as you would see files in any directory on the PC. If the RETevet™ device does not connect as a USB drive (called RETeval) on your PC, see the Troubleshooting section below.

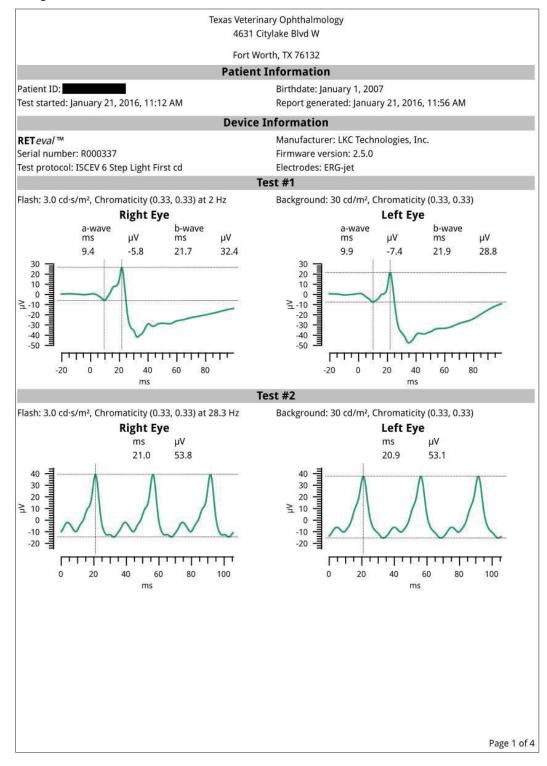
Patient results are located in the/Reports directory on the device. For each PDF report, there are two corresponding data files found in the/Data folder. These data files have the same file name with a different extension (.rff and .rffx rather than .pdf). The .rffx file is in an XML format that can be used to extract numerical information from the test programmatically. The .rff file is a binary file that contains all the raw data collected during the test procedure. Keeping the .rff data files is recommended in case you require technical support from EICKEMEYER®.

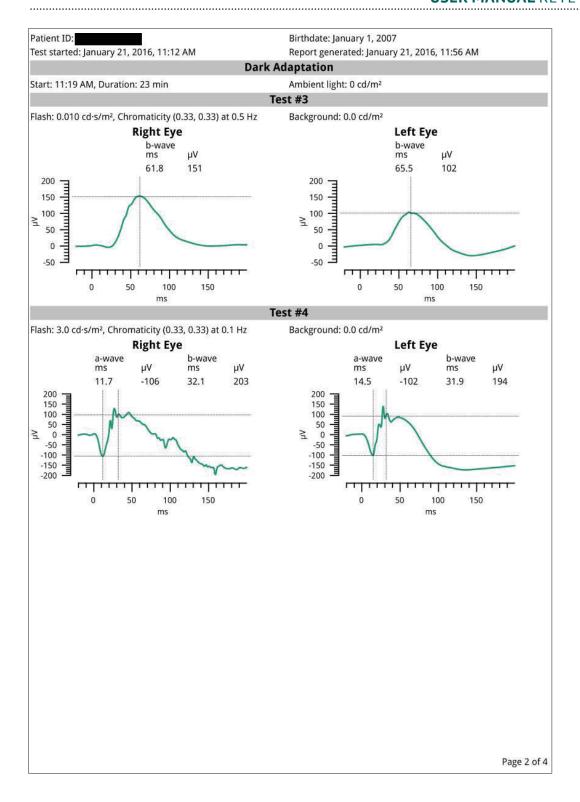
The file naming convention for results is patient ID_birthdate_testdate.pdf, where the birthdate is yymmdd (2-digit year, month, day), and the test date ("testdate") is yymmddhhmmss (2-digit year, month, day, hour, minute, second). With this file naming convention, past patient results will sort next to their current results. Any spaces in the patient ID are removed in the filename.

The PDF displays

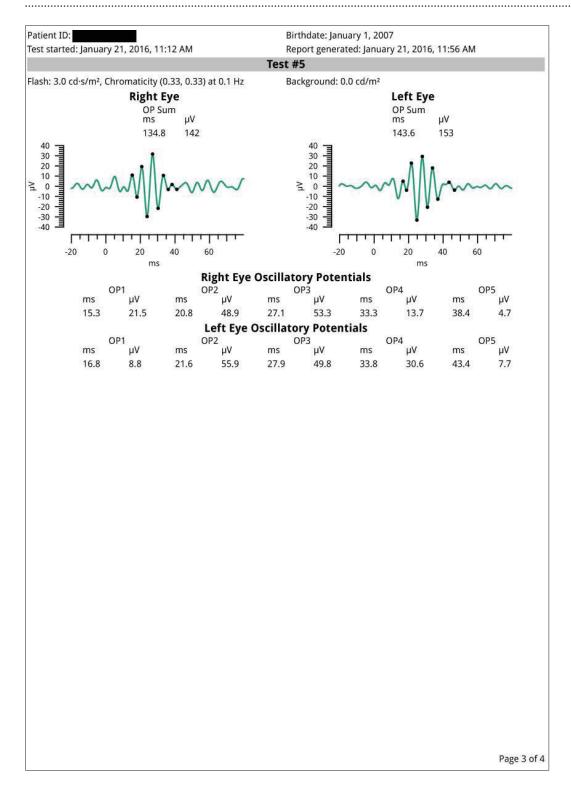
- Practice information, as specified in Settings (See page 6 for changing practice information.)
- Patient information, as entered during the test
- Date and time of the test
- A description of the stimulus used. Chromaticities are reported in the (x,y) colorspace from CIE 1931. Brightness of the flash is reported in photopic units in candela/m²/sec, while background light intensity is reported in candela/m². In some cases, rather than reporting chromaticity (x,y) the stimulus will be described as the brightness of the red, green, and blue LEDs separately.
- Patient results

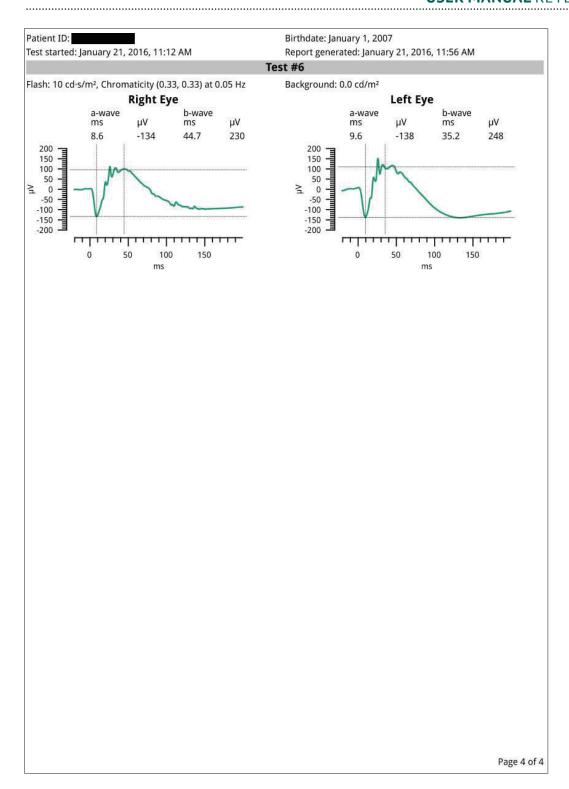
You can print, fax, or email these PDF files just as you would any file on your PC. An example PDF report is shown below from a dog.





USER MANUAL RETEVET™ PORTABLE ERG





USER MANUAL RETEVET™ PORTABLE ERG

Flicker Results on the Device Versus on a PC

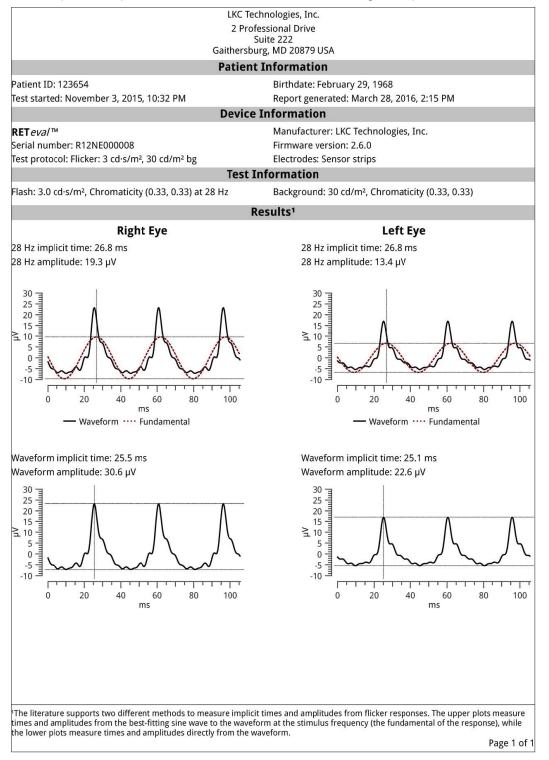
Flicker results are presented as 2 curves. The black curve represents the electrical response of the retina to the flickering light while the red dashed curve represents the fundamental (or best-fitting sine wave) of the electrical response.

When viewing the flicker results **on the device**, two periods are shown. The light flashes stimulating the retina occurred at time = 0 ms and near time = 35 ms. Peak-to-peak amplitudes and timing measurements use the fundamental because this measure has been reported to be more accurate for managing patients with ischemia (Severns, Johnson, and Merritt 1991) and more robust to the lighting conditions the patient experienced before the test (McAnany and Nolan 2014). The dotted lines indicate the measurement values extracted from the waveforms.

When viewing the results on the PC the PDF shows three periods. In the electrical response, the light flashes stimulating the retina occurred at time = 0 ms, 35 ms and 70 ms. The PDF report shows the timing and peak-to-peak amplitude for the electrical response as well as for the fundamental of the electrical response.

It is up to the investigator to choose one of the two ways of evaluating flicker responses and sticking to it for consistency and data comparability.

An example PDF report for the 3 cd·s/m² with a 30 cd/m² background protocol are shown below.



7. ADDITIONAL ACTIVITIES

Removing Old Results from the Device

The RETevet[™] device can store up to 50 test results. You must remove old results to make room for new tests. There are three ways to remove results.



Warning!

Results deleted on the device cannot be recovered. Save results you want to keep on a PC before deleting them off the RETevet™ device.

Removing Selected Results from the Device

To remove individual results from the device, follow these steps:

- 1. Make sure that any results you want to keep have been copied to the PC.
- 2. Turn on the RETevet™ device.
- 3. Select Results.
- 4. Select the desired result to be erased.
- 5. Select Delete.
- 6. Select Yes.

Removing All Results from the Device

To remove all stored results from the device, follow these steps:

- 1. Make sure that any results you want to keep have been copied to the PC.
- 2. Turn on the RETevet™ device.
- 3. Select Settings then Memory.
- 4. Select Erase all test results.
- 5. Select Yes.

If during Step 4 you chose Erase everything, then the data storage area (including patient results and custom protocols) would be deleted and reset to factory condition.

Removing Results Using the PC

To remove results from the device using a PC, follow these steps:

- 1. Place the RETevet[™] device into the docking station.
- 2. Connect the USB cable.
- 3. Wait for the device to appear as an external drive on the PC.
- 4. Navigate to the Reports directory on the device.
- 5. Make sure that any results you want to keep have been uploaded to the PC. Copy the files just as you would copy any file from a thumb drive or other external device to a PC. If desired, also copy the corresponding raw data file (.rff) and XML file (.rffx) from the/Data folder to archive the results in machine-readable formats for programmatic analysis.
- 6. Delete results from the Reports directory to remove them from the device. If you are saving results in multiple formats (e.g., PDF and JPEG), all formats have to be deleted in order to remove the result from the device and make space for future tests.

Removing and Replacing the Eyecup

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

To replace the eyecup, orient the eyecup so the slots in the white plastic on the eyecup are aligned with the bumps on the device. Push gently until the eyecup clicks into the device. Replacement eye cups can be ordered from EICKEMEYER®.

Updating Firmware

Periodically LKC publishes an update to the device firmware. Firmware updates are provided at no charge for the first year, afterward an annual support fee will be required for continued support and firmware updates.

You must download the update to the PC first, connect the RETevet[™] device to the PC, and carry out the firmware update process. Follow these steps:

- 1. Download the firmware update to the PC (follow instructions in the firmware update notice to find and download the update).
- 2. Connect the USB cable to the PC.
- 3. Place the device into the docking station.
- 4. Wait for the device to appear as an external drive on the PC.
- 5. Copy the firmware update file from the directory on the PC to the Firmware directory on the device.
- 6. Eject the external drive that represents the device from the PC.
- 7. Remove the device from the docking station.
- 8. Select Settings, then System, then Change settings, then Update Firmware.
- 9. Select the firmware update you want.
- 10. Select Next.
- 11. Wait while the firmware is updated.
- 12. After the firmware update completes, the device will restart automatically.

If the RETevet[™] device fails during the firmware update, verify that the firmware update file was downloaded and copied to the device correctly by repeating steps 5 through 12.

8. TROUBLESHOOTING HINTS

The RETevet[™] 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 remediate the error, or contact the EICKEMEYER® customer service. Note any error number shown in your email message.

Charge the Battery when the Charge is low

When the RETevet[™] 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 try to test a patient after seeing this message.

A full charge permits testing of approximately 70 patients, depending on the protocol used. The device takes approximately 4 hours to charge completely.

The battery's state of charge can be seen on most screens via the battery icon in the upper right corner. The amount of green in the icon represents the remaining capacity.



Measure the Patient's Right Eye First

The RETevet[™] device is designed to measure the patient's right eye first. 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. The default is to test both eyes. Using the skip button you can test only the right eye or only the left eye.

The Device doesn't Show the Next Button after I connect the Electrode or after pressing the Start Test Button, I get an "The Electrodes have been disconnected" Error

The RETevet™ device monitors the electrical impedance of the connection between the electrodes. 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 and/or electrode noise can be too high because of the following reasons:

- 1. 3-plug lead is not correctly connected to the electrodes. Check the connection and try reconnecting the lead. Don't pull on wires as the connection can break at either end without being visible.
- 2. The electrodes are poorly connected to the patient. Ensure the active electrode is well placed on the cornea and secured with viscous solution (typically hydroxypropyl methylcellulose 2.5), and both, reference and ground electrodes are inserted all the way in.
- 3. Any of the electrodes may be defective, try another electrode when in doubt.

The Device Shows "Excessive electrode noise"

The RETevetTM device monitors the electrical noise of the connection between electrodes. The electrode noise (including power-line interference) is found by computing $2\sqrt{2}$ times the standard deviation of the electrical response in the bandwidth 48-186 Hz to robustly estimate the peak-to-peak noise. If the electrode noise exceeds 5,600 μ V for flicker tests, the noise level is displayed. It is recommended that you try to reduce the noise before pressing the Next button to ensure quality recordings. The noise may be high for the following reasons:

- 1. The patient may be generating excessive electromyogram noise by moving or not being deeply anesthetized.
- 2. The impedance of the electrodes is too high. Check the placement of the corneal electrode, add gonioscopic solution, make sure needles are fully inserted and were not bend, change electrodes if nothing else works.

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 RETevet™ 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, try the following items:

- Rotate the RETevet[™] device so the eyecup better contacts the skin around the eye.
- Hold your hand near the patient's temple to block the light with your hand.
- Move to a darker location and/or turn off any room lighting.

After pressing the Start Test Button, I get an "Unable to Calibrate" Error

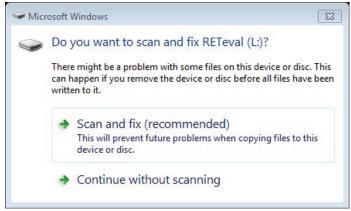
The RETevet[™] device, after checking for ambient light, recalibrates the flash intensity and color to match the factory-calibrated settings. The white interior sphere that the patient looks into (the ganzfeld) redirects light from red, green, and blue LEDs to create a uniform, diffuse white light. A 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 RETevet[™] device will create this error. Cleaning the ganzfeld with compressed gas usually will fix the problem. A damp cloth moistened with water or isopropyl alcohol may be used if compressed gas doesn't work. Removing the eyecup (See page 28) will improve the access to the ganzfeld for cleaning.

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. Press the power button again to turn the device off. 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 all else fails, remove and reinstall the battery.

The RETevet™ Device won't connect to my PC

The RETevet™ device shows on the PC as RETeval. It acts like a USB drive, and therefore should connect to any modern PC that has a USB port, independent of the operating system. The device connects to you PC through the provided USB cable through the docking station and into the hand-held portion. USB power is indicated on the RETevet™ screen with one of the following two images. If one of these images aren't present, check to ensure that the USB cable is connected on both ends, and that the device is fully seated in the docking station. It is possible that the USB data connection has not been made even though the USB power lines are connected, for example, if a poor- quality USB cable is being used or if your IT department has blocked the use of external USB drives. Always use the USB cable provided and check with your IT department about not blocking USB drives. You can test the USB port with any other USB drive to ensure the computer is working. You can also try removing and re-seating the device from the docking station to reset the USB connection. If an alternative USB drive works in the same USB port, but the RETevet™ device won't connect, then the USB cable, docking station, or device may be defective. Try swapping out components to isolate the failure if you have any replacement components; otherwise, contact the EICKEMEYER® customer service.







I get a "Scan and Fix" Error from Windows® when placing the RETevet™ Device in the Docking Station

When removing the RETevet[™] device from the docking station, always eject the external drive that represents the device from the PC. Otherwise, the USB drive in the RETevet™ device may become corrupted. Let your PC "Scan and fix" the RETevet™ device if a problem is detected.

Results are "not measurable"

The RETevet™ device attempts to quantify ERG results with automatically-placed cursors. In some cases, with low signal-tonoise ratios or unexpected waveform shapes, the cursor placement fails and "not measurable" is reported. In some types of retinal dysfunction, the retina's response is very weak and "not measurable" cursor placements are expected. In

certain animals, the waveform timing may be sufficiently different than expected that "not measurable" is reported even though the waveform looks good by eye. Contact customer support to see if a custom protocol can be made to modify the cursor placement algorithm. In other cases, the waveform looks worse than expected based on other clinical history. For these cases, you can try the steps suggested above under The device shows "Excessive electrode noise".

Reset Settings

You can reset the RETevet™ device to the factory default settings. Follow these steps if there are problems with the device or if advised to do so by Support:

Turn on the RETevet™ device.

Select Settings, then System, then Change settings, then Reset Settings. Select Next.

All settings are reset to the initial factory settings and you will have to reset them manually as indicated in the "Getting Started" section of this manual, including:

- Display language
- Date
- Time
- Practice Name
- Practice Address
- Backlight
- Protocol

To put the RETevet[™] device back to its initial-factory condition, perform a **Reset Settings** and an **Erase everything** under Settings, then Memory.

Device Language is set to an unfamiliar Language

If the device is set to a language you do not know, follow these steps to change languages. Turn on the RETevet™ device. If the device is already on, turn it off, wait 5 seconds, then turn it back on. Select the second to the bottom of the 4 menu items (Settings) from the menu. Select the top menu item (Language). Select a language that is familiar to you.

An Error Code is Reported

Error codes are reported for failures unlikely to be correctable in the field. Record the error code and contact the EICKEMEYER® customer service. In addition, save and send to EICKEMEYER® any files found in the/Diagnostics folder on the device. When error codes are displayed, the RETevet™ 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, for example, removing the device from the docking station while files were being transferred. 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. We recommend not performing a factory reset on the first time an error code is reported.



9. REFERENCES

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10. REGULATORY AND SAFETY INFORMATION

Applicability

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

Intended Use

The RETevet[™] 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 veterinary professionals and scientists.

Indications for Use

RETevet[™] is indicated for use in the measurement of visual electrophysiological potentials, including electroretinograms (ERG). RETevet[™] is intended as an aid in diagnosis and research of visual pathway dysfunctions or ophthalmic disorders (e.g., diabetic retinopathy, glaucoma).

Latex Statement

The components of the RETevet[™] 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 User Manual.

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

Specifications

Light source		Red LED (621 nm)	Green LED (530 nm)	Blue LED (470 nm)	White (RGB)	
	Flash luminance energies (cd·s/m²)	0.0001-15	0.001 – 17	0.0001 – 5	0.002 – 30	
	Background luminance (cd/m²)	0.03 – 3,000	0.2 – 3,500	0.03 –1,200	0.4 – 6000	
	To convert to Trolan	ds, multiply luminan	ce by the pupil area	in mm²		
Input Type	Custom 3 pin conne	ctor with positive, ne	egative, and right leg	drive signals		
Noise	$< 0.1 \mu V rms$ at the f	licker frequency for f	licker protocols			
CMRR	> 100 dB at 50-60	Hz				
Frequency Range	DC-coupled					
Flicker Frequency	Approximately 28.3	Hz				
Data Resolution	Approximately 71 n	Approximately 71 nV/bit				
Input Range	± 0.6 V	± 0.6 V				
Sampling rate	Approximately 2 kH	Z				
Timing accuracy † (electronic eye)	< ± 0.1 ms	< ± 0.1 ms				
Timing precision † (human eye, 1σ)	Typically < ±1 ms	Typically < ±1 ms				
Safety	Battery-powered. Co	omplies with optical,	electrical, and biocor	npatibility safety sta	ndards	
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	W 2.8" x D 3.8" x H 8	3.4" (W 7 cm x D 10 c	m x H 21 cm)			
Weight	8.5 oz. (240 g)					
Docking station	Convenient storage location, charging stand, and USB connectivity to your computer and network					
Protocols	Choose from flash a	nd flicker protocols	adapted for various a	nimal species		

All specifications are subject to change.

Cleaning and Disinfection



Warning!

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



Caution!

- Do not submerge the device in liquid or allow liquid to enter the interior of the device as this could damage the electronics. Do not use automatic cleansing machines or sterilization.
- Follow these instructions and only use the cleaning or germicidal cleaner agent types listed or damage may occur.

Cleaning the Ganzfeld

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.

The ganzfeld can be cleaned with a compressed gas air duster to remove dust. A damp moistened with water or isopropyl alcohol cloth may be used if compressed gas doesn't work. Liquid cleaners may damage the LED lights and camera inside it.

Cleaning and Disinfecting the Exterior

Cleaning of the patient contacting parts of the device (eyecup and sensor strip lead) is recommended between patient uses.

The RETevet[™] 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.

- 1. Remove all visible soil by wiping all exterior surfaces with a compatible wipe. Ensure that all visible contamination has been removed.
- 2. Disinfect using a germicidal wipe labeled suitable for use on healthcare equipment and capable of low or intermediate level disinfection, following the procedures and contact time recommended by the germicidal wipe manufacturer.
- 3. Inspect for any visible damage prior to use. Discontinue use if any abnormalities are found.

Replacement eyecups and sensor three plug electrode leads are available. See Purchasing Supplies and Accessories on page 45.

Sterilization

The RETevet[™] device is not intended to be sterilized.

Biocompatibility

The patient-contact portion of the RETevet[™] device complies with biocompatibility standard ISO 10993-1.

Calibration and Storage

Calibration:	The RETevet [™] device includes automated internal flash calibration and QC checks. No testing can be carried out by users.
Storage:	Store the device in the docking station and place dust cover over the device when not in use. Store the device at temperatures between -40 °C and 35 °C (-40 °F and 95 °F), humidity between 10 % and 90 % non-condensing, and atmospheric pressure between 62 kPa and 106 kPa (-4,000 m to 13,000 m). Short-term shipping conditions can be between -40 °C and 70 °C (-40 °F and 158 °F), humidity between 10 % and 90 % non-condensing, and atmospheric pressure between 62 kPa and 106 kPa (-4,000 m to 13,000 m).

Product Performance

The RETevet[™] 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 RETevet[™] device must operate with no unintended deviations in settings and with typical operation.

Contact the EICKEMEYER® customer service if changes in performance are noted.

Essential Performance

The RETevet[™] 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 RETevet[™] device has no Essential Performance as pertains to risk.

Operating Environment

Temperature: 10-35 °C (50-95 °F) Humidity: 10-90 % non-condensing

Air pressure: 62 – 106 kPa (-80 m / -260 feet / 4,000 m / 13,000 feet)

Lifetime

The lifetime of the device is 7 years or 10,000 test protocols performed, whichever comes first. The manufacture date of the device can be found on the device labels. The number of protocols performed will appear on the **System/Settings** screen beginning after the first 200 protocols have been performed.

EICKEMEYER® will service RETevet™ devices that are within their lifetime. Firmware updates and support may require an annual subscription service after the initial one-year warranty period.

The expected battery life is at least 1 year. If the RETevet[™] device fails to hold a charge, a new battery can be ordered.

Precautions

- All servicing of this equipment is to be performed by EICKEMEYER®.
- Medical Electrical Equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided herein.
- Portable and mobile RF communications equipment can affect RETevet™ performance.
- Input overload can occur in proximity to defibrillator or electrocautery devices.
- Do not connect the animal to a high frequency (HF) surgical equipment simultaneously with the RETevet[™], as it may result in burns at the site of the electrodes and may damage the RETevet[™].
- Operation of the RETevet™ in close proximity to a shortwave or microwave therapy equipment may produce instability in the RETevet™ recordings.



Warning!

To avoid the risk of electric shock, avoid accidental contact between an electrode connected to the RETevetTM and other conductive parts (e. g., metal) before applying the electrode to the animal. For example, connect electrodes to the animal before plugging them into the RETevetTM.

- The eyecup should be cleaned after each patient.
- 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.
- This device is not suitable for use in the presence of a flammable anesthetic mixture of air, or with oxygen or nitrous oxide.
- Do not connect the RETevet[™] device to the docking station while measuring a patient! This will compromise the quality of recordings and subject isolation.
- Do not modify this equipment without authorization of the manufacturer.
- Do not use batteries from other sources, as it may result in a hazard such as excessive temperatures, fire, or explosion.
- Do not use the device in direct sunlight. Strong ambient light may affect results.
- Use only the provided power brick with this device. The power brick provided is a 5 VDC 1.2 A medical grade power supply, part number GTM41076-0605, made by GlobTek Inc.
- To simultaneously disconnect all mains supply, remove the power brick from the mains outlet.
- Only connect the RETevet[™] device to PCs 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.

Electromagnetic Compatibility (EMC)

The RETevet[™] device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.



Warning!

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 long should work.

Guidance and Manufacturer's Declaration – Emissions

The RETevet[™] device is intended for use in the electromagnetic environment specified below. The customer or user of the RETevet[™] device should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The RETevet [™] 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
		The RETevet [™] 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.
		To assure continued effectiveness, only use cables and accessories supplied by EICKEMEYER® which are specifically designed for use with the RETevet™ device.

Guidance and Manufacturer's Declaration - Immunity

The RETevet™ device is intended for use in the electromagnetic environment specified below. The customer or user of the RETevet[™] device should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD	±8 kV Contact	±8 kV Contact	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
IEC 61000-4-2	±15 kV Air	±15 kV Air	
EFT	±2 kV Mains	±2 kV Mains	Mains power quality should be that of a typical commercial, hospital, or home environment
IEC 61000-4-4	±1 kV I/Os	±1 kV I/Os	
Surge	±1 kV Differential	±1 kV Differential	Mains power quality should be that of a typical commercial, hospital, or home environment
IEC 61000-4-5	±2 kV Common	±2 kV Common	
Voltage Dips/Dropout IEC 61000-4-11	0 % U _T ; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° % U _T ; 1 cycle 70 % U _T ; 25/30 cycles for 50 Hz and 60 Hz, respectively Single phase: at 0° 0 % U _T ; 250/300 cycle for 50 Hz and 60 Hz, respectively Single phase: at 0°	0 % U _T ; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° % U _T ; 1 cycle 70 % U _T ; 25/30 cycles for 50 Hz and 60 Hz, respectively Single phase: at 0° 0 % U _T ; 250/300 cycle for 50 Hz and 60 Hz, respectively Single phase: at 0°	Mains power quality should be that of a typical commercial, hospital, or home environment If the user of the RETevet™ requires continued operation during power mains interruptions it is recommended that the RETevet™ be powered from an uninterruptible power supply or battery.
Power Frequency 50/60 Hz 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 commercial, hospital, or home environment.

Guidance and Manufacturer's Declaration - Immunity

The RETevet[™] device is intended for use in the electromagnetic environment specified below. The customer or user of the RETevet[™] device should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V, 0.15 – 80 MHz 6 V in ISM radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz 3 V/m Professional 80 MHz – 2,7 GHz 80 % AM at 1 kHz Table 9 of IEC 60601-1-2:2014	(V1) = 3 Vrms (E1) = 3 V/m	Portable and mobile communications equipment should be separated from the RETevet TM device by no less than the distances calculated/listed below: $D = \frac{3.5}{V1} \text{ VP}, 150 \text{ kHz to } 80 \text{ MHz}$ $D = \frac{3.5}{E1} \text{ VP}, 80 \text{ to } 800 \text{ MHz}$ $D = \frac{7}{E1} \text{ VP}, 800 \text{ MHz to } 2.5 \text{ GHz}$ 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.
			To assure continued effectiveness, only use cables and accessories supplied by EICKEMEYER® which are specifically designed for use with the RETevet™ device.

Recommended Separations Distances for the RETevet™ device

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

Max Output Power (Watts)	Separation (m) 150 kHz to 80 MHz $D = \frac{3.5}{V1} \sqrt{P}$	Separation (m) 80 MHz to 800 MHz $D = \frac{3.5}{E1} \sqrt{P}$	Separation (m) 800 MHz to 2.5 GHz $D = \frac{7}{E1} \sqrt{P}$
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

RoHS

RoHS2 Compliance Statement

The RETevet™ product line is RoHS compliant in accordance with EU RoHS Directives 2002/95/EC – 2011/65/EU and the Council of 8 June 2011 on The restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directives). We hereby declare the restricted materials or substances are not contained therein (the material/substance is not found above the threshold level listed other than exemptions approved by RoHS). RETevet™ devices are also labeled with the CE mark indicating compliance with RoHS2.

The RoHS directives allow certain exemptions from its declared limits. The RETevet[™] complies with exemption 6(a) which allows Lead as an alloying element in steel for machining purposes and in galvanized steel containing up to 0,35 % lead by weight.



China RoHS2 Compliance Statement

The RETevet™ product line is RoHS compliant in accordance with the China RoHS Directive GB/T 26572-2011 on **Requirements** of concentration limits for certain restricted substances in electrical and electronic products (RoHS Directives). We hereby declare the restricted materials or substances are not contained therein (the material/substance is not found above the threshold level listed except as specifically indicated below).

The stainless-steel weight contained within the RETevet[™] charging base may contain trace amounts of lead that comply with the acceptable limits of the EU RoHS exemption 6(a). Due to the possible presence of trace amounts of lead in this component the RETevet[™] has been categorized with an Environment Friendly Use Period (EFUP) of 25 years.



Symbols

Symbols	
Symbol	Description / Function
CE 0086	Council Directive Compliance
C	Power button. Press to turn device on and off when not in docking station. Turn screen on and off when in the docking station.
†	Type BF applied part, as defined in IEC 60601-1. The applied parts are the electrodes.
	Direct current
Ţ i	Refer to the operating instructions (i.e., this manual).
②	Do not reuse.
T	Keep dry.
X	WEEE directive. In applicable countries, the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.
Ψ	USB port
Li-lon	Contains "Lithium Ion". This symbol indicates "General recovery/recyclable" and must not be disposed of as unsorted municipal waste and must be collected separately.
•••	Manufacturer
M	Manufacture date
1	Storage temperature range
LOT	Lot number
REF	Catalog number
	Use by date
c	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 Std 60601-2-40
Intertek	Certified To: CSA Std No. 60601-1
	Refer to the operation instructions (i.e. this manual) to assure proper and safe operation.

Equipment Identification

Each RETevet[™] device has a unique serial number for identification. The serial number can be seen by choosing Settings, then **System** on the user interface. The serial number can also be found on the bottom of the docking station and under the battery, viewable after removing the battery cover and pivoting the battery away from the device. The serial number has the form R#####, interpreted as follows:

R	Product code is R
######	Production sequence number (5 or 6 digits)

Approvals

This product has been tested for and complies with the requirements of the following standards:

- ISO 15004-1 Ophthalmic instruments, General requirements ISO 15004-2 Ophthalmic instruments, Light protection hazard IEC 60601-2-40 Medical electrical equipment (2nd edition)
- IEC 60601-1 Medical electrical equipment (3.1 edition) CB Scheme IEC 60601-1 Medical electrical equipment (3rd edition) CB Scheme AAMI ES60601-1 Medical electrical equipment
- CSA C22.2#60601-1 Medical electrical equipment
- CENELEC EN60601-1 Medical electrical equipment (3rd edition)
- IEC 60601-1-2 Electromagnetic compatibility, including Japan deviations (4th edition) IEC 60601-1-6 Usability
- IEC 62366 Usability
- IEC 60601-1 Medical electrical equipment (2nd edition) CB Scheme
- UL 60601-1 UL Standard for Safety medical electrical equipment (2nd edition) CSA C22.2#601.1 Medical electrical equipment (2nd edition)
- CENELEC EN60601-1 Medical electrical equipment (2nd edition) IEC 60601-1-6 Usability (2nd edition)
- ANSI/AAMI/ISO 10993-1 Biological evaluation of medical devices

11. INTELLECTUAL PROPERTY

The RETevet[™] device may be covered by one or more of the following US patents and their foreign counterparts: 9,492,098.

RETevet[™] and RETeval[™] are trademarks of LKC Technologies, Inc.

The firmware contained in the RETevet[™] device is copyrighted © 2011–2019 by LKC Technologies, Inc. Use of the firmware outside of the RETevet[™] device is prohibited. All rights reserved.

12. CONTACT INFORMATION

Support

Contact support staff via the contact details on the back.

Warranty

EICKEMEYER® unconditionally warrants this instrument to be free from defects in materials and workmanship, provided there is no evidence of abuse or attempted repairs without authorization from EICKEMEYER®. This Warranty is binding for one year from date of shipment and is limited to servicing and/or replacing any instrument, or part thereof, returned to the factory for that purpose with transportation charges prepaid and which are found to be defective. This Warranty is made expressly in lieu of all other liabilities and obligations on the part of EICKEMEYER®.

Attempts to disassemble the device will result in breakage and voids the warranty.

DAMAGE UPON ARRIVAL. Each instrument leaves our plant, after rigorous tests, in perfect operating condition. The instrument may receive rough handling and damage in transit. The shipment is insured against such damage. The Buyer must immediately report, in writing, any concealed or apparent damage to the last carrier as well as to us and issue an order for replacement or repair.

DEFECTS OCCURRING WITHIN WARRANTY PERIOD. Parts of the unit may develop defects which were not revealed during comprehensive testing. The price of our instru- ments makes provision for such service, but it does not:

- 1. Provide for transportation charges to our factory for service,
- 2. Provide for services not performed or authorized by us,
- 3. Provide for the cost of repairing instruments that have obviously been abused, subjected to unusual environments for which they have not been designed, or an attempt has been made to disassemble the device resulting in damage to the device.

We will be happy at any time to discuss by phone, letter, FAX, or e-mail suspected defects or aspects of instrument operation that may be unclear. We advise you to inform us by phone, letter, FAX, or e-mail of the nature of the defect before returning an instrument for repair as a RMA authorization is necessary prior to returning a device to EICKEMEYER® for repair or service. Many times, a simple suggestion will solve the problem without returning an instrument to the factory. If we are unable to suggest something that solves the problem, we will advise you as to what parts of the equipment should be returned to the factory for service.

DEFECTS OCCURRING AFTER WARRANTY PERIOD. Charges for repairs after the warranty period and within product lifetime policy will be based upon actual hours spent on the repair at the prevailing rate, plus cost of parts required and transportation charges; or you may elect to purchase an extended warranty. Continued support and firmware updates beyond the warranty period may require an annual support and update fee.

We will be happy to discuss by phone, letter, FAX, or e-mail any problem you may be experiencing.

Purchasing Supplies and Accessories

Users may purchase supplies and accessories by contacting your local distributor. Refer to this parts list:

Item No. Item

173610 RETevet™ visual electrodiagnostic device (i.e., this product)

E17361001 RETevet[™] adapter cable for DIN electrodes (3-plug electrode lead)

E17361002 Battery E17361003 Eyecup E17361004 Dust Cover

USER MANUAL RETEVET™ PORTABLE ERG

Service/Repairs

The RETevet[™] device contains no user serviceable parts other than the eyecup and battery, both of which can be replaced without the need to 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.

	USER MANUAL RETEVET™ PORTABLE ERG
NOTES	



GERMANY

EICKEMEYER KG Eltastraße 8 78532 Tuttlingen T +49 7461 96 580 0 F +49 7461 96 580 90 info@eickemeyer.de www.eickemeyer.de

SWITZERLAND

EICKEMEYER AG Sandgrube 29 9050 Appenzell T +41 71 788 23 13 F +41 71 788 23 14 info@eickemeyer.ch www.eickemeyer.ch

UNITED KINGDOM

EICKEMEYER Ltd.
3 Windmill Business Village
Brooklands Close
Sunbury-on- Thames
Surrey, TW16 7DY
T +44 20 8891 2007
info@eickemeyer.co.uk
www.eickemeyer.co.uk

POLAND

EICKEMEYER Sp. z o.o. Al. Jana Pawła II 27 00-867 Warszawa T +48 22 185 55 76 F +48 22 185 59 40 info@eickemeyer.pl www.eickemeyer.pl

DENMARK

EICKEMEYER ApS Solbakken 26, Hammelev 6500 Vojens T +45 7020 5019 info@eickemeyer.dk www.eickemeyer.dk

NETHERLANDS

EICKEMEYER B.V. Bellweg 44 4104 BJ Culemborg T +31 345 58 9400 info@eickemeyer.nl www.eickemeyer.nl

ITALY

EICKEMEYER S.R.L. Via G. Verdi 8 65015 Montesilvano (PE) T +39 0859 35 4078 F +39 0859 35 9471 info@eickemeyer.it www.eickemeyer.it

CANADA

EICKEMEYER Inc.
617 Douro Street, Suite #205
Stratford, Ont. Canada
N5A 0B5
T +1 519 273 5558
F +1 519 271 7114
info@eickemeyervet.ca
www.eickemeyer.com