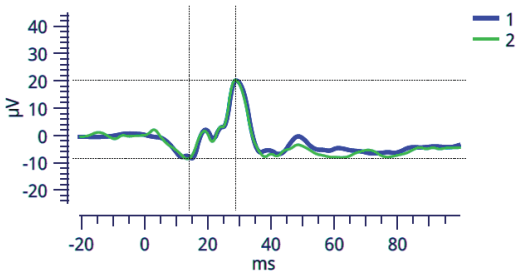
LKC TECHNOLOGIES
VISION *DEFINED*™

RET*eval*®

VISUAL ELECTRODIAGNOSTIC SYSTEM



- INTUITIVE
- OBJECTIVE
- REPEATABLE

TEST RETINA FUNCTION ANYTIME, ANYWHERE

The **RET***eval* device brings comprehensive electrophysiology testing to any office or clinical setting. Run standard flicker and flash ERGs and VEPs to better define retina function with efficiency and proven efficacy.

INTUITIVE ELECTRORETINOGRAM (ERG) TECHNOLOGY

An ERG test provides reliable guidance for medical professionals to understand and assess functional changes that may impact a patient's vision by evaluating the retina's response to light. The **RET***eval* device helps doctors obtain objective, functional information.

COMMON USES FOR FULL FLASH AND FLICKER ERG TESTS

- Glaucoma[3,7]
- Diabetic Retinopathy[1,2]
- Central Retinal Vein Occlusion[4]
- Acquired and Inherited Retinal Diseases[5,6]
- Unexplained Vision Loss
- Pediatric Nystagmus[8]
- Trouble Seeing in the Dark
- Changes in Color Vision

NORMATIVE DATA AVAILABLE TO AID IN INTERPRETATION

Flash: 85 Td·s, Chromaticity (0.33, 0.33) at 28.3 Hz

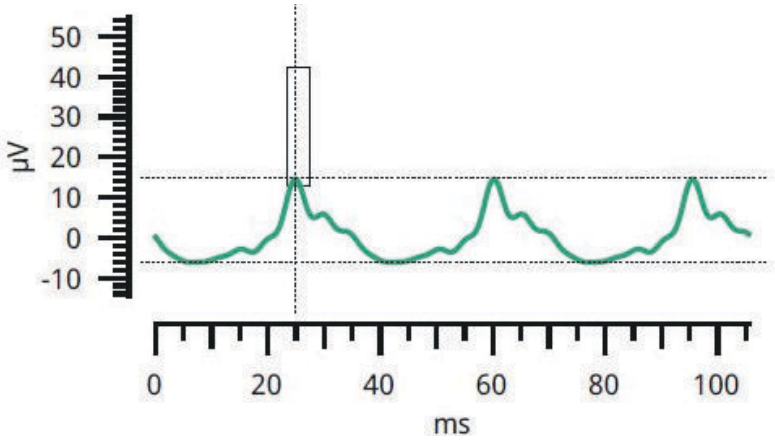
Background: 850 Td, Chromaticity (0.33, 0.33)

Right Eye

ms	μV
23.3 ↔ 27.4	19.1 ↔ 48.4
25.8 (81%)	17.7 (1%)

Age Adjusted Reference Intervals

Example Patient: Age 27



1 Maa et al. A novel device for accurate and efficient testing for vision-threatening diabetic retinopathy. *Journal of Diabetes and Its Complications*, 2015.

2 Fukuo et al. Screening for diabetic retinopathy using new mydriasis-free, full-field flicker ERG recording device. *Scientific Reports*, 2016.

3 Wu et al. Photopic negative response obtained using a handheld electroretinogram device: determining the optimal measure and repeatability, *Translational Vision Science & Technology*, 2016.

4 Yasuda et al. Flicker electroretinograms before and after intravitreal ranibizumab injection in eyes with central retinal vein occlusion. *Acta Ophthalmologica*, 2015.

5 Nakamura et al. Evaluation of cone function by a handheld non-mydriatic flicker electroretinogram device. *Clinical Ophthalmology*, 2016.

6 Ullah et al. Mutations in phosphodiesterase 6 identified in familial cases of retinitis pigmentosa. *Human Genome Variation*, 2016.

7 Preiser et al. Photopic Negative Response versus Pattern Electroretinogram in Early Glaucoma. *Investigative Ophthalmology & Visual Science*, 2013.

8 Grace, et al. Portable nonsedated electroretinogram evaluation of children with nystagmus in the pediatric ophthalmology clinic. *Journal of AAPOS*, 2017.

THE RET*eval* DEVICE IS THE ONLY DEVICE THAT OFFERS FULL ISCEV-COMPLIANT ERG TESTING IN A COMPLETELY PORTABLE DEVICE.

Clearly define your diagnosis with the right information in hand.

1. **Soft eye cup for patient comfort**
2. **IR camera to view eye during testing**
3. **Immediate test results right on the device**
4. **Simple joystick control**
5. **Ergonomic to fit comfortably in hand**
6. **Small charging base**
7. **Lithium Ion battery for up to 8 hours* of use**
8. **Docking station offers USB connectivity**

**Approximately 70 patients before recharging, depending on protocol used.*

Multilingual user interface for global use

Infield calibration ensures accurate settings for testing

Built-in pupilometer to measure and (optionally) compensate for pupil size, allowing for tests on dilated or undilated eyes depending on patient needs

Standard ganzfeld functionality in a hand-held device

Non-invasive testing with the optional use of patented LKC Sensor Strip electrodes that can be applied directly on the skin, a great alternative for those who cannot tolerate corneal electrodes

RETeval DEVICE 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 – 3000	0.2 – 3500	0.03 – 1200	0.4 – 6000
	To convert to Trolands, multiply luminance by the pupil area in mm².				
Input type	Custom 3 pin connector with positive, negative, and right leg drive signals				
Noise	< 0.1 µV 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)	< ±0.1 ms				
Timing precision † (human eye, 1σ)	Typically < ±1 ms				
Pupil measurements	1.3 mm – 9.0 mm, < 0.1 mm resolution, 28.3 Hz				
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)				
Weight	8.5 oz. (240 g)				
Docking station	Convenient storage location, charging stand, and USB connectivity to your computer and network				
Protocols	Based on software options, choose from retinal illuminance (Td) and luminance (cd/m²) versions of ISCEV standard protocols, flicker protocols, and other protocols.				

† For Troland-based flicker protocols having a retinal illuminance energy ≥ 4 Td·s. All specifications are subject to change.

ADVANCED TESTING FOR ALL YOUR NEEDS

RET*eval* features arbitrary wave forms and extended protocols, including:

- ISCEV compliant 5 and 6 step protocols
- Flash VEP
- S-Cone
- On/Off
- Photopic negative response (PhNR)
- Custom protocols to meet your specific needs

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LKC Technologies, Inc., established in 1975, is an ISO 13485:2003 & 2016 and MDSAP certified, FDA-registered medical device manufacturer with quality products installed worldwide in over 70 countries. RETeval is trademarked by LKC Technologies and the device is CE marked and FDA cleared.
The project described was supported by Award Number R44EY021121 from the National Eye Institute.
The content is solely the responsibility of LKC and does not necessarily reflect the views of the National Eye Institute of the National Institutes of Health.
The RETeval 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 device Sensor Strips may be covered by one or more of the following US patents and their foreign counterparts: 9,510,762 and 10,010,261.
Additional patents pending. RETeval DR is not currently available in the United States.
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