



Handheld,
Full-Field ERG

RETeval[®]

The RETeval device brings comprehensive electrophysiology testing to any office or clinical setting, allowing you to quickly test with standard flicker and flash ERGs and VEPs and define retina function with ease, efficiency, and proven efficacy.

Portable, powerful ERG testing in the palm of your hand. Easily integrates into your current practice.

RETeval is the first completely self-contained, hand-held, mobile visual electrophysiology device.

It is efficient and intuitive to administer, requires minimal (if any) changes in workflow, and allows physicians to perform visual electrophysiology testing almost anywhere.

Utilizing a miniature integrated Ganzfeld with multiple flash and flicker protocols, RETeval provides an objective, robust assessment of retinal function.

Full-field ERG is complementary to OCT, extended color vision diagnostics (ColorDx[®] CCT-HD[™]), pattern VEP + ERG (EvokeDx[®]), retinal imaging, and standard automated perimetry.

RETeval includes:

- A soft eyecup that is comfortable for patients while minimizing interference from external light sources
- High quality, robust materials with excellent shielding from electromagnetic interference
- Dynamic luminance that allows for testing of dilated and un-dilated pupils (based on patient/physician's needs) while maintaining constant luminance



Quickly test retina function

The RETeval device brings comprehensive electrophysiology testing to any office or clinical setting, allowing you to quickly test with standard flicker and flash ERGs and VEPs and define retina function with ease, efficiency, and proven efficacy.

"The RETeval device brings my practice a truly portable, easy to use ERG solution. We have the option of obtaining a standard ERG with skin electrodes or corneal electrodes. We were impressed with the ease of acquisition, the quality of the automatic reporting function and the affordability. The ability to download reports into our EMR facilitates timely record keeping and communication with referring doctors. We appreciate the overall quality of the device."

Dr. Monique Leys MD, EBO
West Virginia University Eye Institute



- 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.

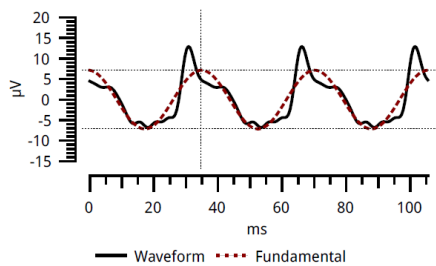
HOW FULL-FIELD ELECTRORETINOGRAM (ffERG) TESTING ASSISTS IN TREATING PATIENTS WITH DIABETIC RETINOPATHY

Diabetic retinopathy (DR) is the most common cause of vision reduction among individuals with diabetes and a leading cause of blindness among working-age adults.¹

In the US, less than 50% of the patients with diabetes receive an annual DR examination.²



28 Hz implicit time: 34.7 ms
28 Hz amplitude: 14.3 μV



The 8 Td-s flicker test is often utilized for DR assessment to aid in diagnosis.



The RETeval device offers a portable, self-contained, integrated device that performs the 8 Td-s flicker test as well as all ISCEV-standard testing protocols for diabetic retinopathy.

RECENT STUDIES HAVE SHOWN:

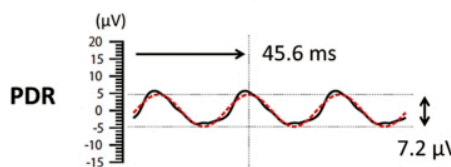
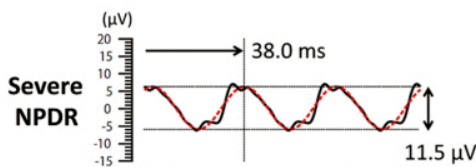
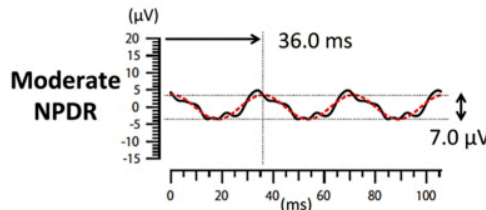
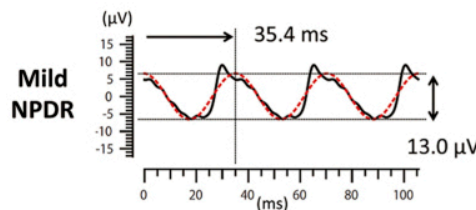
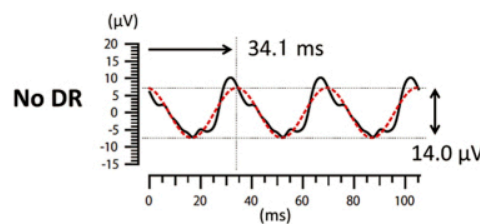
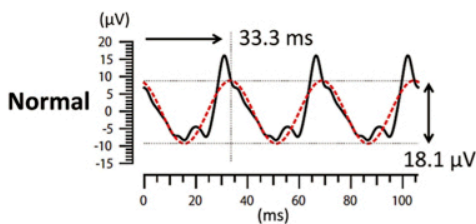
The implicit times in eyes with DR were significantly longer than that of normal eyes and eyes with no DR (P < 0.001)¹

The implicit time of flicker ERG may be a more useful index to compensate for the drawbacks of fundus examinations¹

- The RETeval device was more suitable for mass screening than the conventional ERG recordings systems¹
- The RETeval is a small portable device that can record the flicker ERG without mydriasis¹

BENEFITS OF ERG TESTING WITH RETeval

- No dilation required¹
- Immediate results vs. potentially ungradable fundus images²
- No issues with pupil size¹
- Unaffected by cataracts²



CPT CODE ERG: 92275

¹ Fukuo et al. Screening for diabetic retinopathy using new mydriasis-free, full-field flicker ERG recording device. *Scientific Reports*, 2016.
² Maa et al. A novel device for accurate and efficient testing for vision-threatening diabetic retinopathy. *Journal of Diabetes and Its Complications*, 2015.

Specifications

Light source (LED):	Dynamic flash luminance energies (cd·s/m ²)	Background luminance (cd/m ²)
- Red (621 nm)	0.0001-15	0.03-3000
- Green (530 nm)	0.001-17	0.2-3500
- Blue (470 nm)	0.0001-5	0.03-1200
- White (RGB)	0.002-30	0.4-6000
Input Type	< 0.1 μ V 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	< ± 0.1 ms	
Timing accuracy* (electronic eye)	< ± 0.1 ms	
Timing precision* (human eye, 1 σ)	Typically < ± 1 ms	
Pupil measurements	1.3 mm – 9.0 mm, < 0.1 mm resolution, 28.3 Hz	
Safety	Battery-powered and complies with optical, electrical, and biocompatibility safety standards	
Regulatory	FDA 510(k) cleared and CE Marked	
Distributed in the USA by Konan Medical USA, Inc.	Manufactured by LKC Technologies, Inc.	

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