RETeval™

User Manual

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LKC TECHNOLOGIES

CE 2797

Rx only

Part no. 96-023-EN

EN - Printable Instructions for Use (IFU) in multiple languages are stored on your RET*eval* device as PDF files. Connect the RET*eval* to a computer using the provided docking station and USB cable. The RET*eval* will appear on your computer as a flash-disk. Select the IFU you need, or go to www.lkc.com/IFUs
BG - Инструкциите за употреба (ИУ) за печат на няколко езика се съхраняват на Вашето устройство RET*eval* като PDF файлове. Свържете RET*eval* към компютър с помощта на предоставената докинг станция и USB кабел. RET*eval* ще се появи на компютъра Ви като флаш диск. Изберете ИУ, от които се нуждаете, или отидете на www.lkc.com/IFUs
HR - Upute za uporabu (IFU) na više jezika pohranjene su na vaš RET*eval* uređaj kao PDF datoteke i dostupne su za ispis. Povežite RET*eval* na računalo pomoću priložene priključne stanice i USB kabela. RET*eval* će se na vašem računalu prikazati kao memorijski flash uređaj. Odaberite potrebne Upute za uporabu ili posjetite www.lkc.com/IFUs
CS - Tisknutelné návody k použití v několika jazycích jsou uloženy v zařízení RET*eval* ve formě souborů PDF. RET*eval* můžete připojit k počítači pomocí dodané dokovací stanice a kabelu USB. RET*eval* se v počítači zobrazí jako flashdisk. Vyberte požadovaný návod k použití nebo přejděte na stránku www.lkc.com/IFUs.
DA - Brugsanvisninger (IFU) på flere sprog, der kan udskrives, er lagret på din RETeval-enhed som PDF-filer. Slut RETeval til en computer ved hjælp af den medfølgende dockingstation og USB-kabel. RETeval vises på din computer som en flash-disk. Vælg den brugsanvisning, du har brug for, eller gå til www.lkc.com/IFUs
NL - Op uw RET*eval* -apparaat zijn afdrukbare gebruiksaanwijzingen (IFU) in meerdere talen opgeslagen als PDF-bestanden. Sluit het RET*eval* -apparaat aan op een computer met het meegeleverde dockingstation en de USB-kabel. Het RET*eval* -apparaat wordt op uw computer weergegeven als een flashstation. Selecteer de gewenste gebruiksaanwijzing of ga naar www.lkc.com/IFUs.
ET - Teie RET*evali* seadmesse on PDF-failidena salvestatud prinditavad kasutusjuhised mitmes keeles. Ühendage RET*evali* seade arvutiga, kasutades selleks dokki ja USB-juhet. RET*evali* seade kuvatakse teie arvutiekraanil välkmäluseadmena. Valige sobiv kasutusjuhend või külastage veebilehte www.lkc.com/IFUs
FI - RETeval -laitteeseen on tallennettu tulostettavat käyttöohjeet PDF-tiedostoina monella kielellä. Yhdistä RETeval tietokoneeseen oheisella telakalla ja USB-kaapelilla. RETeval näkyy tietokoneella muistitikkuna. Valitse tarvitsemasi käyttöohjeet tai siirry osoitteeseen www.lkc.com/IFUs.
FR - Des instructions d'utilisation à imprimer (IFU) dans plusieurs langues sont stockées sur votre appareil RET*eval* sous forme de fichiers PDF. Connectez le dispositif RET*eval* à un ordinateur en utilisant la station d'accueil fournie et un câble USB. Le dispositif RET*eval* apparaîtra sur votre ordinateur comme disque amovible. Sélectionnez l'IFU dont vous avez besoin ou visitez www.lkc.com/IFUs.
DE - Druckbare Nutzungsanweisungen (IFU) in mehreren Sprachen werden als PDF-Dateien auf Ihrem RET*eval* -Gerät gespeichert. Verbinden Sie mithilfe der bereitgestellten Dockingstation den RET*eval* über ein USB-Kabel mit einem Computer. Der RET*eval* wird als Wechseldatenträger auf Ihrem Computer erscheinen. Wählen Sie die benötigte IFU aus, oder besuchen Sie www.lkc.com/IFUs
EL - Οι εκτυπώσιμες Οδηγίες χρήσης σε πολλαπλές γλώσσες είναι αποθηκευμένες στη συσκευή RET*eval* ως αρχεία PDF. Συνδέστε το RET*eval* σε υπολογιστή χρησιμοποιώντας τον παρεχόμενο σταθμό τοποθέτησης και το καλώδιο USB. Το RET*eval* θα εμφανιστεί στον υπολογιστή σας ως μονάδα flash. Επιλέξτε τις οδηγίες χρήσης που χρειάζεστε ή μεταβείτε στον ιστότοπο www.lkc.com/IFUs.
HU - A több nyelven elérhető, nyomtatható használati utasításokat RET*eval* eszközén találhatja PDF fájlokként. Csatlakoztassa a RET*eval* egy számítógéphez a mellékelt dokkolóegység és USB-kábel használatával. A RET*eval* flash-lemezként jelenik majd meg számítógépén. Válassza ki a szükséges használati utasítást, vagy látogasson el a www.lkc.com/IFUs oldalra
GA - Tá Treoracha Inphriontáilte Úsáide i dteangacha difriúla á stóráil ar d'fheiste RET*eval* i bhformáid PDF. Bain úsáid as an stáisiún nasctha agus cábla USB arna gcur ar fáil chun RET*eval* a nascadh le ríomhaire. Beidh RET*eval* le feiceáil ar an ríomhaire mar fhlaisdiosca. Roghnaigh na Treoracha Inphriontáilte Úsáide atá uait, nó téigh go dtí www.lkc.com/IFUs
IT - Le istruzioni per l'uso stampabili (IFU) in più lingue sono archiviate sul dispositivo RET*eval* come file PDF. Collegare il dispositivo RET*eval* a un computer utilizzando la docking station e il cavo USB in dotazione. Il computer visualizzerà il dispositivo RET*eval* come unità flash. Selezionare le istruzioni necessarie o visitare l'indirizzo www.lkc.com/IFUs
LV - Drukājamas lietošanas instrukcijas (IFU) vairākās valodās tiek glabātas jūsu RET*eval* ierīcē PDF failu formātā. Pieslēdziet RET*eval* ierīci datoram, izmantojot komplektā iekļauto dokstaciju un USB vadu. Jūsu datorā RET*eval* ierīce tiks parādīta kā zibatmiņa. Atlasiet IFU vai apmeklējiet vietni www.lkc.com/IFUs
LT - Jūsų „ RET*eval* " prietaise yra naudojimo instrukcijos (IFU) keliomis kalbomis, pateiktos kaip PDF failai. Prijunkite „ RET*eval* " prietaisą prie kompiuterio naudodami komplekte esančią sujungimo stotelę ir USB

laidą. Kompiuterio ekrane „ RET*eval* " aplanką matysite kaip atmintinės piktogramą. Pasirinkite reikiamą IFU arba instrukcijų ieškokite adresu www.lkc.com/IFUs
MT - Struzzjonijiet għall-Użu (IFU, Instructions for Use) li jistgħu jiġu stampati f'lingwi differenti huma maħżuna fuq l-apparat RET*eval* tiegħek bħala PDF files. Ikkonnettja r- RET*eval* ma' kompjuter billi tuża l-istazzjon għad-dokkjar (docking station) u l-kejbil tal-USB ipprovduti. RET*eval* se jidher fuq il-kompjuter tiegħek bħala flash-disk. Agħżel l-Istruzzjonijiet li teħtieġ, jew mur fuq www.lkc.com/IFUs
PL - Instrukcje obsługi (IFU) do druku w wielu językach przechowywane są na urządzeniu RET*eval* jako pliki PDF. Podłącz RET*eval* do komputera za pomocą dołączonej stacji dokującej i przewodu USB. RET*eval* pojawi się na komputerze jako dysk flash. Wybierz odpowiednią instrukcję obsługi lub przejdź na stronę www.lkc.com/IFUs
PT - Instruções de Utilização imprimíveis (IFU) em várias línguas são armazenadas no seu dispositivo RET*eval* como ficheiros PDF. Ligue o RET*eval* a um computador utilizando a estação de ancoragem fornecida e o cabo USB. O RET*eval* aparecerá no seu computador como um disco flash. Seleccione o IFU de que necessita, ou vá a www.lkc.com/IFUs
RO - Instrucțiunile de utilizare (IFU) imprimabile în mai multe limbi sunt stocate pe dispozitivul dvs. RET*eval* sub formă de fișiere PDF. Conectați RET*eval* la un computer folosind stația de andocare și cablul USB furnizate. RET*eval* va apărea pe computerul dvs. ca o unitate flash. Selectați IFU de care aveți nevoie sau accesați www.lkc.com/IFUs
SK - Tlačiteľné návody na použitie (IFU) vo viacerých jazykoch sú uložené v zariadení RET*eval* ako súbory PDF. Pripojte zariadenie RET*eval* k počítaču pomocou dodanej dokovacej stanice a kábla USB. Zariadenie RET*eval* sa zobrazí v počítači ako flashdisk. Vyberte požadovaný návod na použitie alebo prejdite na stránku www.lkc.com/IFUs
SL - Natisljiva navodila za uporabo v več jezikih so v obliki datotek PDF shranjena v napravi RET*eval*. Za povezavo naprave RET*eval* in računalnika uporabite priloženo priklopno postajo in kabel USB. Naprava RET*eval* bo v računalniku prikazana kot bliskovni pogon. Izberite želena navodila za uporabo ali obiščite www.lkc.com/IFUs
ES - En su dispositivo RET*eval* hay almacenadas como archivos PDF instrucciones imprimibles de uso en varios idiomas. Conecte el dispositivo RET*eval* a un ordenador con la base de carga y el cable USB proporcionados. El dispositivo RET*eval* aparecerá en su ordenador como una unidad de disco externa. Seleccione las instrucciones que necesite o visite www.lkc.com/IFUs
SV - Utskrivbara bruksanvisningar (IFU) på flera språk lagras som PDF-filer på din RET*eval* -enhet. Anslut RET*eval* till en dator med hjälp av medföljande dockningsstation och USB-kabel. RET*eval* kommer att visas på din dator som ett flashminne. Välj den IFU du behöver eller gå till www.lkc.com/IFUs.

European Regulatory Data

Basic UDI-DI (for EUDAMED database searches) – 0857901006RETeval53
Instructions for USE (IFUs) in other languages may be found at www.lkc.com/IFUs
To request a printed copy of this manual please send an email to support@lkc.com and include the following information:

1) Company name
2) Your name
3) Mailing address
4) The serial number of your device
5) The part number of the manual you need
   To find the correct part number, open the PDF file in the IFU in the language you want and find the part number. The part number will appear on either the front or back of the IFU. The manual part number will look something like 96-123-AB. Your manual will be shipped to you within 7 days.

LKC Technologies, Inc., established in 1987, is ISO 13485:2016 certified and holds MDSAP and FDA registrations and a CE certificate as a medical device manufacturer with quality products installed in over fifty countries.

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TABLE OF CONTENTS

Welcome to RETeval

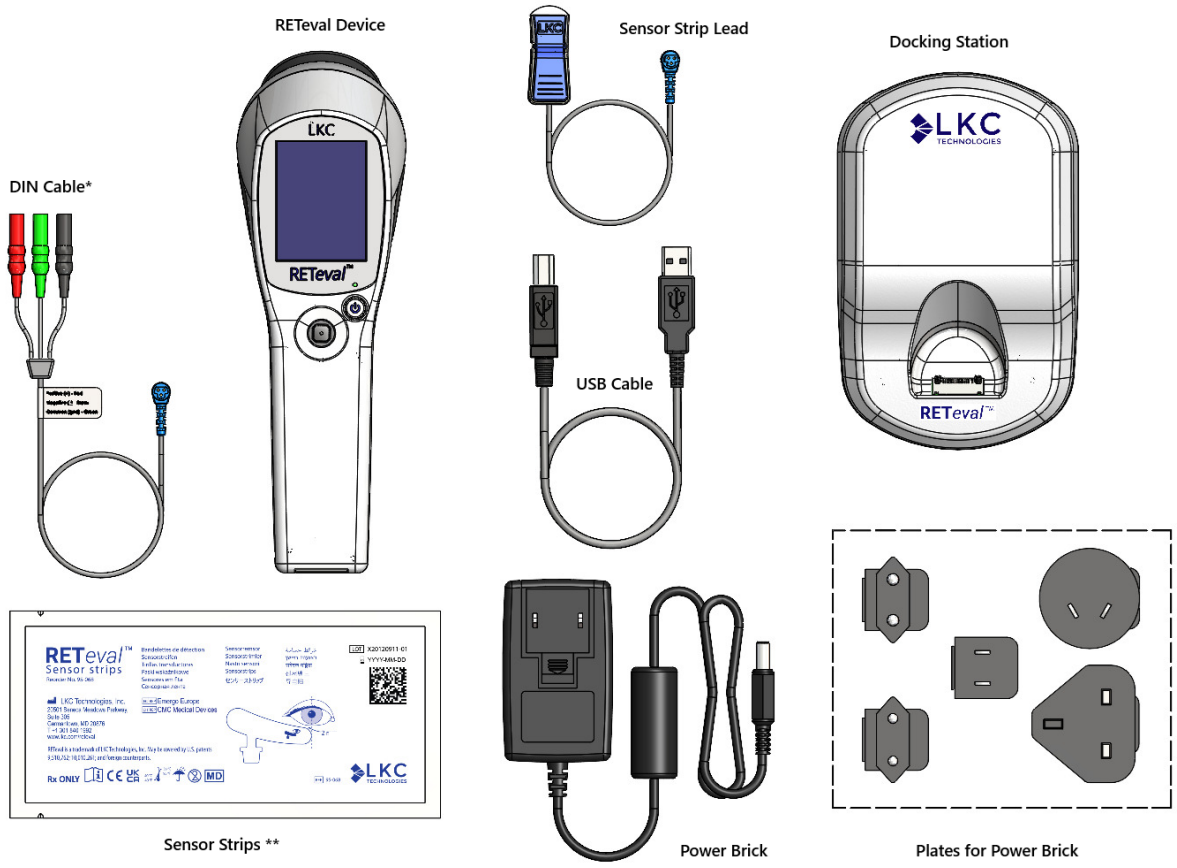
Congratulations on your purchase of the RETeval visual electrodiagnostic device. With the RETeval device, you can offer your patients a convenient retinal diagnostic evaluation.

Every RETeval device comes with flicker-based protocols, and through optional upgrades, single-flash based protocols become available through a protocol chooser that enables other electroretinogram (ERG) and visual evoked potential (VEP) 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. The RETeval device has an electronic medical record interface to digitally order tests for a patient and transfer results into a supported EMR / EHR system.

What's in the Box

The RETeval device is packaged with these items. Check that all items are present.



RETeval device	Measures the response of the eye to light.
Docking station	Charges the RETeval device and enables data transfer to a PC.
Dust cover (not shown)	Protects the device from dust while not in use.
DIN adapter cable *	Connects the device to DIN electrodes.
Sensor Strip lead	Connects the device to Sensor Strips for testing.
Sensor Strips **	Skin electrode arrays for measuring the eye's electrical response. See instructions for use, 95-025 Sensor Strip Product Insert, provided with Sensor Strips.
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 RETeval device.

* This item is only supplied with RETeval Complete.
** This item is not supplied when a "no-electrodes" version is ordered.

Getting Started

Connect the cord to the docking station and plug in

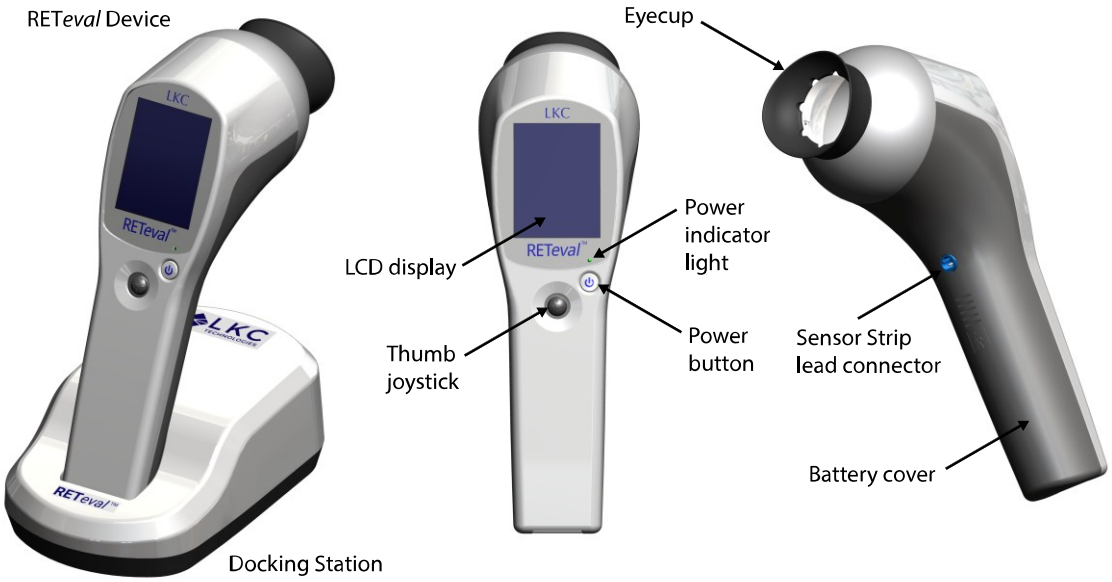
Attach the power brick plate that matches your electrical outlet to the power brick.

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 RETeval 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 RETeval device is shipped with a partial charge.



Placing the device into the docking station

Inserting the device into the docking station enables recharging the battery and transferring results to a computer via a USB connection. To insert the device, slide the device at the appropriate angle down the back of the opening in the docking station to reduce the mechanical stress on the connector at the bottom.

Connect the Sensor Strip lead

Connect the Sensor Strip lead to the blue Sensor Strip lead connector. The Sensor Strip lead for Sensor Strips has one Sensor Strip clip. The Sensor Strip lead for the Small Sensor Strips has two Sensor Strip clips.

The Sensor Strip lead is long enough for most circumstances; however, if your application requires additional length, a 24” (61 cm) long extension is available (see Purchasing Supplies and Accessories). If an extension cable is used, it is necessary to loop the cable over the patient’s ear or tape the cable to the patient’s cheek to prevent the weight of the extension from impacting test measurements.

Device controls

The RETeval 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 and holding it down for at least 1 second.

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.

Auto Power-Down

When not being charged, the RETeval device will power itself down after at least 10 minutes of inactivity, pressing the power button will reawaken the device.

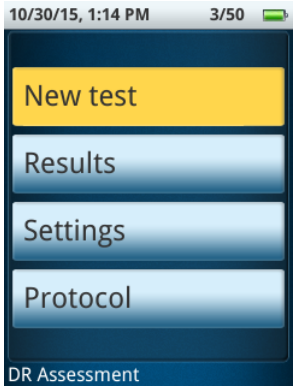
Joystick

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.

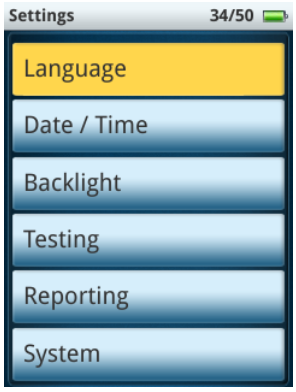
Go back one screen:	Press **LEFT** when the cursor is at the left edge of the screen.
Go forward one screen:	Press **RIGHT** when the cursor is at the right edge of the screen.
Select a highlighted item:	Press **SELECT**.

Main menu



The RETeval 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 date, time, remaining storage capacity, 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 RETeval device for use in your practice.

Step 1. Turn on the device.

The device goes through a brief internal test and initialization.

Step 2. Select Settings.

Step 3. Adjust each setting as you prefer.

Language

Select the language 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.

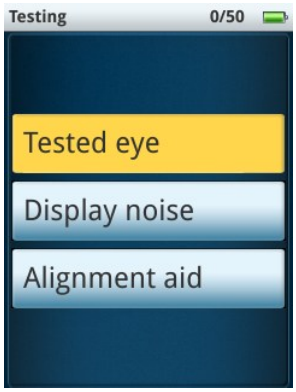
Date / Time

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. The date and time can also be updated via scanning a barcode at the beginning of a test using the free data barcode application which runs on Windows and smartphones (go to https://lkc.com/barcode or search for RETeval on your phone's app store).

Backlight

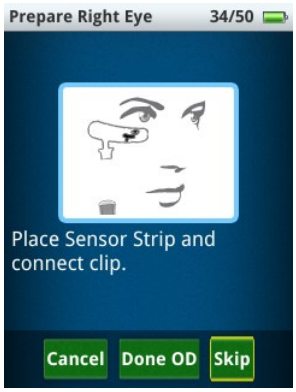
The LCD backlight for the operator's display can be adjusted separately for light-adapted and dark-adapted testing. The device will automatically switch between those two modes as appropriate during a test. Brighter settings may be more visible but will slightly reduce the number of patients you can test before needing to recharge in the docking station. For dark adapted testing, brighter settings reduce the time the operator needs to dark adapt to be able to see the screen clearly but may affect the patient's rod sensitivity. For light adapted testing, the operator's display can be set to high, medium, or low brightness. There is also a "red" option that makes the display only use red light. For dark adapted testing, there are

three levels of brightness that only use red light as well as dim full color. The default values are medium brightness for light adapted scenarios and dim red for dark adapted testing.

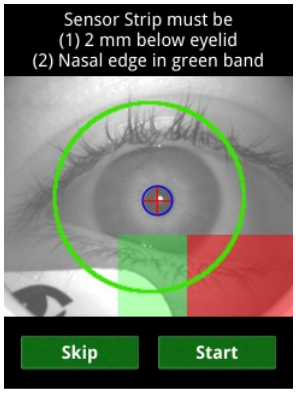


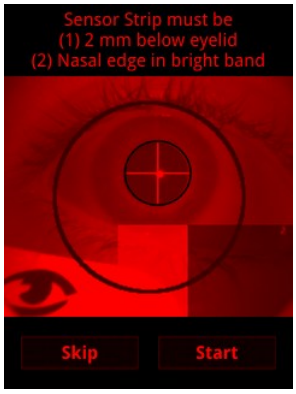
Testing

Select **Tested eye** to define which eyes you want to test. For example, you may be involved in a clinical trial where only the right eye is to be tested. By selecting **Right eye**, all protocols will only test the right eye. Choosing **Both eyes**, the default, tests both eyes. Selecting **Choose at test time** gives you the option to choose after pressing **New Test** to start running a test. Alternatively, the **Done (OD)** and **Done (OS)** buttons can be used on the connect electrode screen to skip all remaining tests for that eye.



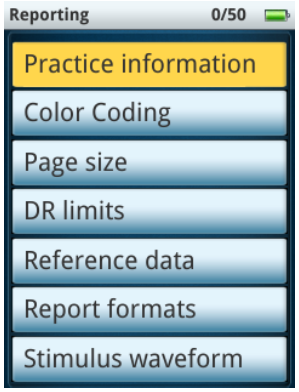
Immediately after sensing an electrode being connected, the device measures the electrical noise. If the noise is above a certain threshold, a warning message is displayed about excessive electrode noise (See the **Troubleshooting** section for details). If the noise is below that level, by default the measured value is not displayed. Under the **Display noise** option, you can choose to always have the electrode noise visible.





The **Alignment aid** option enables you to turn on/off real-time guidance for Sensor Strip placement. As described more fully on Page 13, the edge of the Sensor Strip should be placed directly under the pupil (when the subject is looking straight ahead) and 2 mm below the lower eyelid. This feature adds highlighted regions indicating the optimal nasal-lateral positioning of the Sensor Strip. For best results, ensure the edge of the Sensor Strip is inside the green band and not extending into the red band. When using red backlight option (e.g., dark adapted testing), the preferred sensor strip location is highlighted brighter and the region to avoid is darker.

Reporting



Under the reporting menu, there are many different options that affect the displaying of results both on the device and in the reports.

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 19. 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. The free data barcode application which runs on Windows (https://lkc.com/barcode) and smartphones (search for RETeval on your phone's app store). If the RETeval device has trouble scanning the barcode, ensure the eyecup is on or very close to the display and the display brightness is set to maximum.

Color coding

Color coding (green, yellow, red) of reference data is by default turned on for all protocols except PhNR. Through this menu, you can select to always show color coding, never show color coding, or use the default behavior described above. Turning off color coding may reduce confusion between reference limits and clinical decision limits, while having color coding on makes it easier to determine if results are consistent with someone having normal vision (See page 58).

Page size

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

DR limits

As described in DR Assessment section on Page 21, the limit criteria for the classification of normal for this test can be modified here.

Reference data

For many tests using Sensor Strip electrodes, reference distributions and reference intervals are built into the device. See Page 57. This section lets you turn the reference interval reporting off, which might be convenient, for example, if you know that the subjects you are testing are outside the reference population tested in the database.

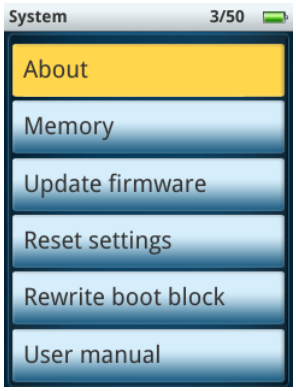
Report formats

With the **Report formats** menu, 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.

Stimulus waveforms

Luminance as a function of time can be plotted at the bottom of electrical response waveforms. By default, this is turned off for brief-flash stimuli, but is on for extended-duration stimuli such as long flash (on-off), sinusoidal and triangular waveforms. The advantage to showing the light waveform for the long flash stimulus would be to show, for example, when the off response is expected. Showing the stimulus waveform for a flicker test may be pedagogically useful as the stimulus isn't just near time = 0. Stimulus waveforms are shown both on the device and in the reports.

System



To view the device's serial number and what options are present, select **System** then **About** under **Settings**. The base RETeval device model indicates "RETeval -DR" in the screen header. The "Flicker ERG", "RETeval – S" and "RETeval Complete" options would be indicated as such. Also shown on this screen is the firmware version. The number of tests completed may also be reported here.

Selecting **Memory** allows you to view the number of tests stored in the device, out of the maximum allowed of 50. On this page, you have the option to **Erase all test results** or to **Erase everything**, which reformats the drive and then restores the factory default files onto the reformatted drive.

Update firmware is described on Page 26.

Reset settings enables you to restore all settings to the factory default condition, including the practice information.

The boot block is the first region of the device's storage that is read during boot. If sectors in the boot block become bad, the device may not turn on properly every time, for example, the power indicating LED may blink many times when the device is the docking station before staying steady green. **Rewrite boot block** might fix this issue; use this button only by the request of the LKC service department.

The user manual can be viewed on-screen by pressing **User manual**. The manual is also provided as a hardcopy, and the PDF is stored on the device.

Performing a Test

Step 1. Remove the RETeval device from the docking station.

Step 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 to change. See manual section **Choosing a protocol** on Page 21.

Step 3. Select **New Test** on the device.

Step 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. The free data barcode application which runs on Windows (https://lkc.com/barcode) and smartphones (search for RETeval on your phone's app store). The barcode application does not use the internet and does not store any patient information. If the RETeval device has trouble scanning the barcode, ensure the eyecup is on or very close to the display and the display brightness is set to maximum.

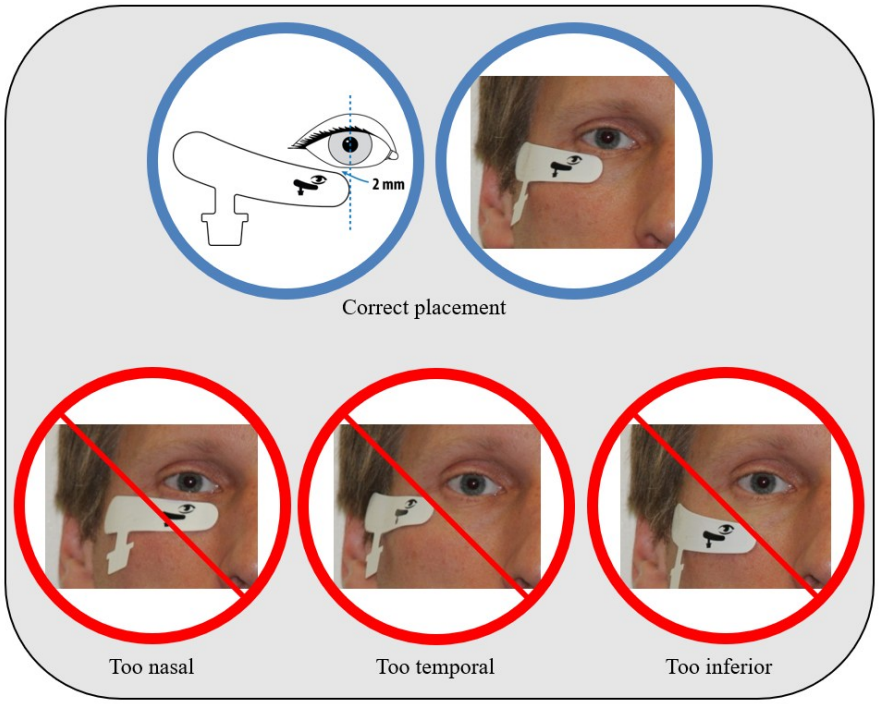
Step 5. Confirm that the protocol and patient information are correct.

Step 6. Select a Sensor Strip packet and scan the packet barcode by placing the eyecup of the device on or very near the barcode on the Sensor Strip packet. Scanning is automatic and does not require the joystick to be pressed. Use a new set of Sensor Strips for each test.

Step 7. Ask the patient to remove their eyeglasses. Contact lenses may be left in place.

Step 8. Place both the right and left Sensor Strips on the patient. Proper placement is shown below. Alternatively, you may find it easier to place just the right Sensor Strip, test that eye, then place the left Sensor Strip and test that eye. Handle the Sensor Strips by the connection tab as the hydrogel is very sticky.

If you are using Small Sensor Strips, both strips must be applied to read either eye.



The small side of the Sensor Strip should be placed on the lower eyelid, with the end of the Sensor Strip placed under the center of the eye. The side with the connection tab should be located near the temple.

Align the Sensor Strip such that there is no hair beneath it.

LKC Technologies recommends the use of NuPrep® (made by Weaver and company and sold on the LKC store, https://store.lkc.com), to prepare the patient's skin in the electrode contact area. Use of NuPrep will achieve electrical impedance levels comparable to corneal contact electrodes and improves adhesion on subjects with adhesion issues. Alternatively, soap and water, or an alcohol wipe may be used but will result in increased impedance. Use alcohol-based products with caution, as the alcohol fumes may cause irritation to the eye.

If adhesion is still a problem after using NuPrep a medical grade adhesive tape at the ends of the Sensor Strip can be used.

Step 9. Test the right eye.

Ask the patient to cover their left eye with the palm of their hand and also open their eyelids wider to make the pupil more visible. Small children may prefer to leave both eyes open and uncovered.

Connect the lead to the Sensor Strip below the patient's right eye with the blue lever away from the patient's skin.

Select **Next**. If the **Next** button is not present, the electrical connection to the patient is poor or the device is not connected properly to the Sensor Strip: See the **Troubleshooting** section of this manual.

Tell the patient to look at the red fixation light in the RETeval device and to open their eye as wide as possible. *Troland-based protocols require an unobstructed view of the patient's entire pupil.*

Press the device against the patient, positioning the device so that the patient's pupil is inside the large green circle. The RETeval device should be placed straight onto the subject, a small gap between the eye cup and the lateral portion of the face is fine, as long as the amount of ambient light reaching the eye through this gap isn't excessive.

Ask the patient to relax, and to try not to blink. The patient should not talk, smile, or grimace (doing so may lengthen the test time). For protocols that use multiple stimulus conditions, suggest to the patient that they blink when it's dark in order to reduce the amount of electrical artifacts that occur during the measurement phase of the test.

Select **Start Test** after the device has properly located the pupil. If the device erroneously indicates something else as the pupil, reposition the device and ensure the eyelids are sufficiently open until the pupil is properly identified. If **Start Test** is not highlighted, see the **Troubleshooting** section of this manual.

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

Wait while the device conducts the test. 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.

After the device has indicated that the testing is complete, disconnect the lead from Sensor Strip.

Step 10. Repeat Step 9 for the left eye.

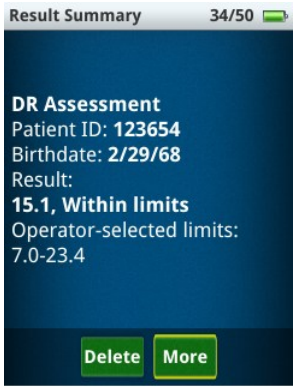
Step 11. The results summary appears as shown on Page 17. While the results are being shown, the device saves them. **Results** and **Main Menu** buttons appear along with a notification of successful storage upon completion of the save, which can take several seconds. By selecting **Results**, you can immediately view the patient's results and do additional testing without having to re-enter the patient or electrode information.

Step 12. Remove the Sensor Strips from the patient's face, starting with the end under the eye. Alternatively, ask the patient to remove the Sensor Strips. Dispose of the Sensor Strips in accordance with local guidelines.

Step 13. Clean the eyecup and other patient-contact parts of the device and Sensor Strip lead.

Viewing Results

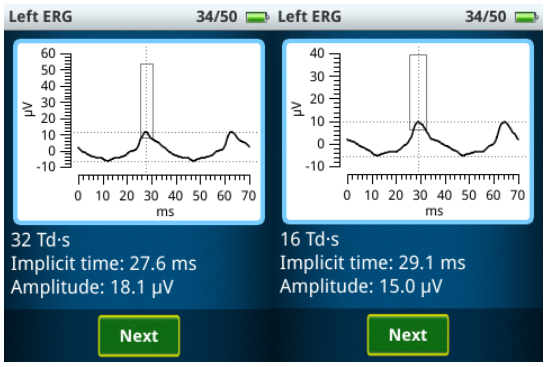
Results on the device



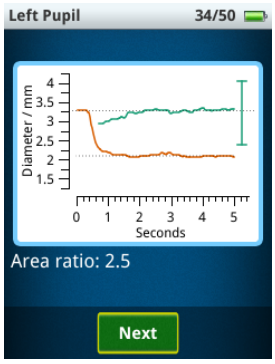
The DR Assessment protocol combines implicit time, amplitude, age, and pupil response to create a unified result, which is shown immediately after the test is complete.

Diabetics with vision-threatening diabetic retinopathy typically have a larger DR Score. For more information, refer to the DR Assessment protocol description on Page 21.

Details for the DR Assessment results can be seen by selecting **Results**. If selecting **Results** from the main menu, 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. After showing the same summary page, the electrical and pupil responses can be seen. The figures below show the results from the right eye; left eye results are similarly shown.



Two periods of the electrical response, as measured from the Sensor Strip to a 32 Td·s (left) and 16 Td·s (right) white flickering stimulus are shown. As shown on the bottom of the plot, the light flashes stimulating the retina occurred at time = 0 ms and near times = 35, 70 ms. The dotted lines indicate the measurement points for the peak-to-peak amplitude and implicit time (time-to-peak). The rectangle encloses the middle 95% of peaks in the reference data.



The pupil size as a function of time is shown for the 4 and 32 Td·s white flickering stimuli. The stimuli start at time = 0. The dotted lines show the extracted pupil diameters for the two stimuli. The ratio of pupil areas is shown below the plot, and it's 95% (two-tailed) reference interval is shown scaled for the dim stimulus near the right edge of the plot.

Results on a PC

Results can be transferred to the PC in PDF (and other) formats.

Step 1. Place the RETeval device into the docking station.

Step 2. Connect the USB cable to the docking station and to the PC.

Step 3. The device appears on the PC like an external drive.

You can now view results or copy them to the PC as you would files in any directory on the PC. If the RETeval device does not connect as a USB drive on your PC, see the **Troubleshooting** section below. Patient results are 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. Data can be exported from a collection of .rff files using the RFF Extractor program, sold on the LKC online store (https://store.lkc.com). Keeping the .rff data files is also recommended in case you require technical support from LKC.

The file naming convention for results is patientID_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 will be removed in the filename.

The PDF displays:

- Practice information, as specified in Settings (See Page 10 for changing practice information.)
- Patient information, as entered during the test
- Date and time of the test
- A description of the stimulus used. Brightness is reported in photopic units in either Trolands or candela/m^2, depending on the protocol. Color is reported in multiple ways. If the color is white (CIE 1931 chromaticity of 0.33,0.33), red, green, or blue those labels are used. Other colors are reported as chromaticity in the (x, y) color space from CIE 1931 or in terms of 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.

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

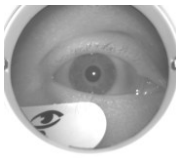
An example PDF report for the DR Assessment protocol is shown below.

Patient Information

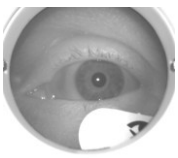
Patient ID: 123654
Birthdate: February 29, 1968
Test started: February 2, 2021, 2:22 PM
Report generated: February 2, 2021, 2:26 PM

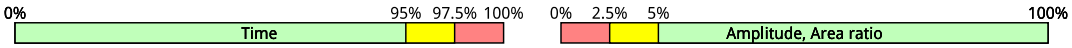
Device and Test Information

RETeval ™
Manufacturer: LKC Technologies, Inc.
Serial number: R000555
Firmware version: 2.11.0 Reference data: 2020.49 a794d4f
Test protocol: DR Assessment
Electrodes: Sensor Strips



DR Score	15.1
Operator-selected limits (7.0 ↔ 23.4)	Within limits
95% Reference interval (8.8 ↔ 21.6)	13%

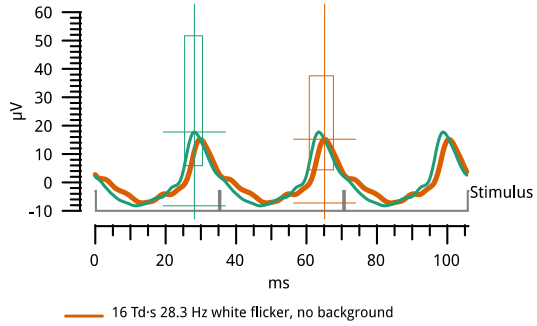




Right Eye

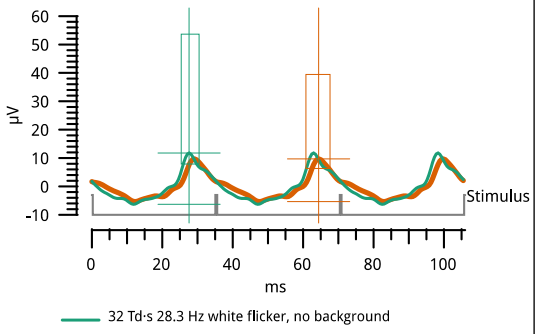
ERG

	ms		μV	
16 Td·s	29.8 (74%)	25.5 ↔ 32.3	22.5 (52%)	11.7 ↔ 44.8
32 Td·s	28.2 (68%)	25.4 ↔ 30.5	26.0 (50%)	14.2 ↔ 59.9



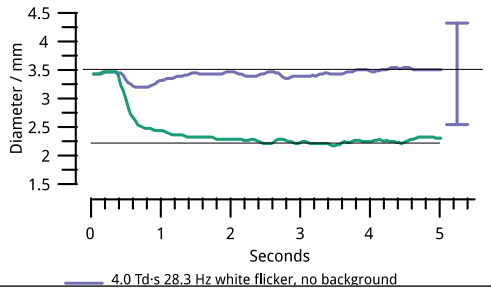
Left Eye

	ms		μV	
16 Td·s	29.1 (59%)	25.5 ↔ 32.3	15.0 (14%)	11.7 ↔ 44.8
32 Td·s	27.6 (53%)	25.4 ↔ 30.5	18.1 (12%)	14.2 ↔ 59.9

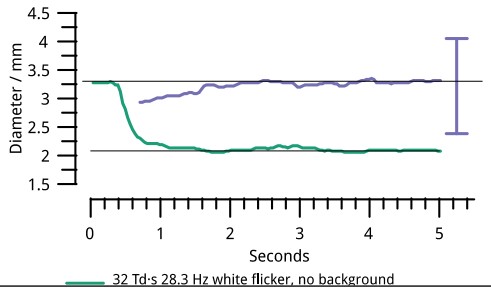


Pupil

Area ratio: 2.5 (91%) 1.3 ↔ 3.8

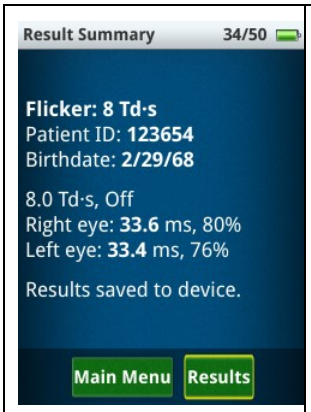
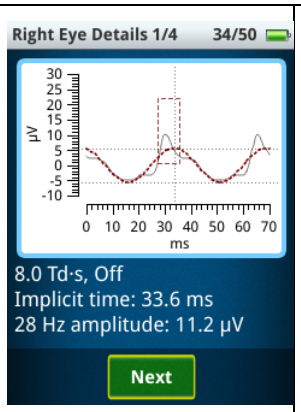
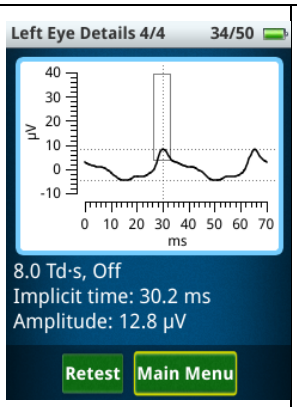
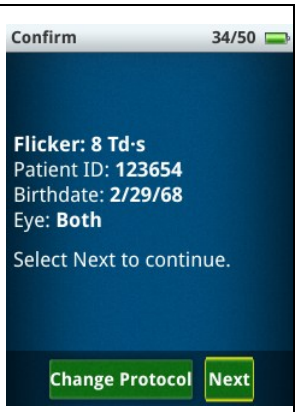


Area ratio: 2.5 (92%) 1.3 ↔ 3.8



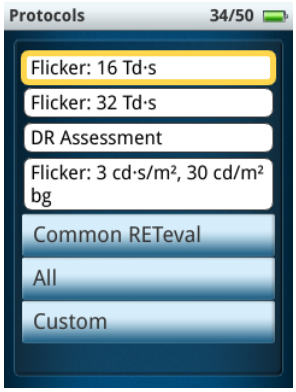
Reflex Testing

Additional testing can be performed on the same patient without having to reenter the patient and electrode information. To perform multiple tests on the same patient, do the following steps:

			
Step 1: At the end of the test, press “Results”.	Step 2: Review the results of the previous test.	Step 3: On the last page of results, choose “Retest”.	Step 4: Optionally choose “Change Protocol” before proceeding.

This reflex testing process can be repeated indefinitely. All PDF reports performed with reflex testing will be assembled into one multi-page report. The raw data (.rff) files are not combined.

Choosing a Protocol



The RETeval device enables you to change the stimulus conditions (called protocols) to best meet your needs via a protocol chooser. The flicker ERG option adds more than 10 protocols with varying flicker stimuli. The RETeval Complete option adds single flash stimuli protocols.

The protocol selection screen has the four most recently used protocols and folders for protocols commonly used with the device, ones recommended by ISCEV, custom protocols (if you have any), and all protocols.

DR Assessment

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

The DR Assessment protocol was developed using measurements of 467 people with diabetes aged 23 – 88 (Maa et al. 2016). The gold standard, 7-field, color, stereo, ETDRS-compliant fundus photography with non-physician expert grading (double-read with adjudication), classified each subject into a severity group (Table 1) based on the subject's worst eye. The study had a planned oversampling of low-prevalence retinopathy levels, and the subject population included 106 diabetics with VTDR in at least one eye. The average testing time for the RETeval device during the clinical trial was 2.3 minutes to test both eyes.

Table 1: Severity group definitions

International Clinical Classification (Wilkinson et al. 2003)	ETDRS Level	CSME
No NPDR	10 - 12	-
Mild NPDR	14 - 35	-
Moderate NPDR	43 - 47	-
CSME with No, Mild, or Moderate NPDR	10 - 47	+
Severe NPDR or Proliferative DR	53 - 85	+ / -
Ungradable ETDRS Level	?	+

The score produced by the DR Assessment protocol correlates with the presence and severity of diabetic retinopathy and clinically significant macular edema, as shown in Figure 1 (Maa et al. 2016).

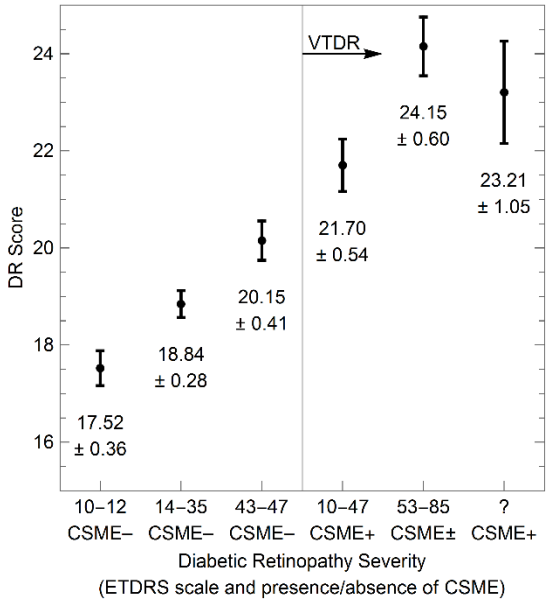


Figure 1. Dependence of RETeval measurements on diabetic retinopathy severity level. Plots show the mean and standard error of the mean for each severity group listed in Table 1.

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

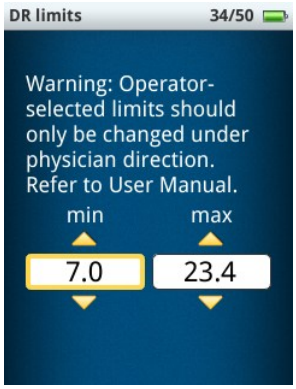
The patient's result is a combination of the following:

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

To help ensure accurate results, enter the correct birthdate.

Individuals with diabetes who have severe retinopathy typically have pupils that change size less than the pupils of healthy individuals. If the patient is on medications or has other conditions that impair the pupil response, extra care must be taken to properly interpret the RETeval device results, as these individuals are more likely to be erroneously classified as likely to have vision threatening DR. Further, ensure the contralateral eye is covered by the patient's hand, as shown on Page 14 to prevent uncontrolled light stimulation of the contralateral eye from affecting the pupil being measured. Do not use the DR Assessment protocol on patients whose eyes are pharmacologically dilated.

The report generated by the DR Assessment protocol includes reference intervals for each individual measurement and the DR Score, from our studies of normally sighted subjects. See the **Reference Intervals** section in the manual (starting on Page 57) for further details. These reference intervals enable you to compare the results to a cohort of subjects who do not have diabetes or diabetic retinopathy, and to also identify which aspects of a test are more concerning.



In addition to showing reference intervals, the DR Assessment protocol displays clinical decision limits, as specified by you. Unlike reference intervals, which include 95% of normally sighted subjects regardless of how that may classify someone with VTDR. Clinical decision limits consider diseased and normal subjects to optimize both test sensitivity as well as test specificity. Subjects within the clinical decision limits have low risk for disease while subjects outside clinical decision limits have higher risk for disease. When running the DR Assessment protocol for the first time, you will have the opportunity to set the decision limits which are labeled on the report as "operator-selected limits". This screen can be reached at any time by selecting **Settings**, then **Reporting**, then **DR Limits**.

As seen in Figure 1 above, increasing DR Scores are correlated with increasing disease severity. The lower clinical decision limit, therefore, is only useful to catch unexpectedly low results that likely indicate an issue with the test rather than an issue with the subject. A lower limit of 7 is smaller than the smallest measurement in the reference data and DR studies (score = 9.5, n = 595).

For the upper limit, several values have been proposed. Three cross sectional studies each proposed the point that maximized the sum of sensitivity and specificity (the upper left points on their ROC curves). In the longitudinal studies, the relative risk between a positive and negative result for a future ocular intervention was maximized.

Study	Gold standard	Upper clinical decision limit (largest value considered low risk)
Maa et al. (2016)	7-field stereo ETDRS photographs on dilated eyes, cross-sectional study	19.9
Degirmenci et al. (2018)	Slit lamp biomicroscopy and dilated fundus examination by indirect ophthalmoscopy, cross-sectional study	21.9
Zeng et al. (2019)	Slit-lamp biomicroscopy, 7-field stereo ETDRS photographs on dilated eyes, and OCT, cross-sectional study	23.0
Brigell et al. (2020)	Surgical interventions (laser, injections, or vitrectomy) over the subsequent 3 years, longitudinal study	23.4
Davis, Waheed, and Brigell (2025)	Treatable diabetic eye disease or treatment for diabetic eye disease over the subsequent 48 weeks, longitudinal study	26.8

The difference in proposed upper clinical decision limits may be because of differing gold standards. In this regard, longitudinal studies have the advantage because diagnoses generally get clearer with time. The shorter the time period, the larger the cutoff needs to be for being at high risk of needing treatment. In contrast to longitudinal studies, cross-sectional studies compare one method to a different method that predicts an outcome,

rather than having the outcome. For example, patients with high-risk PDR have only a 15.8% chance of having severe vision loss or vitrectomy with 5 years (Davis et al. 1998).

Other protocols

The RETeval device has two other protocols that are “flashlight” protocols where the device creates either 30 cd/m^2 or 300 cd/m^2 white light.

Additional Activities

Removing old results from the device

The RETeval device can store up to 50 test results. You must remove 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 RETeval device.

Removing selected results from the device

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

Step 1. Make sure that any results you want to keep have been copied to the PC.

Step 2. Turn on the RETeval device.

Step 3. Select **Results**.

Step 4. Select the desired result to be erased.

Step 5. Select **Delete**.

Step 6. Select **Yes**.

Removing all results from the device

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

Step 1. Make sure that any results you want to keep have been copied to the PC.

Step 2. Turn on the RETeval device.

Step 3. Select **Settings** then **Memory**.

Step 4. Select **Erase all test results**.

Step 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:

Step 1. Place the RETeval device into the docking station.

Step 2. Connect the USB cable.

Step 3. Wait for the device to appear as an external drive on the PC.

Step 4. Navigate to the Reports directory on the device.

Step 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 an 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.

Step 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. The raw data files (.rff) and XML files (.rffx) do not need to be deleted. The device will automatically remove those files as appropriate.

Updating firmware

Periodically LKC publishes an update to the device firmware. Follow these steps to update the device firmware:

Step 1. Download the firmware update file to the PC. (Follow instructions in the firmware update notice to find and download the update.)

Step 2. Connect the USB cable to the PC.

Step 3. Place the device into the docking station.

Step 4. Wait for the device to appear as an external drive on the PC.

Step 5. Copy the firmware update file from the directory on the PC to the firmware directory on the device.

Step 6. Eject the external drive that represents the device from the PC.

Step 7. Remove the device from the docking station.

Step 8. Select **Settings**, then **System**, then **Change Settings**, then **Update Firmware.**

Step 9. Select the firmware update you want.

Step 10. Select **Next**.

Step 11. Wait while the firmware is updated.

Step 12. After the firmware update completes the device will restart automatically.

If the RETeval 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.

Electronic medical record (EMR) support

The RETeval device supports EMR integration via passing files between a host PC and the EMR folder on the RETeval device. The patient ID and birthdate can be electronically transferred to the device, and only need to be confirmed on the device before starting a test. On completion of a test, docking the RETeval device back with the PC enables results to be electronically moved off the device and into the EMR. Contact LKC for more details about currently supported EMR systems and integration options with your EMR.

RETeval Flicker Option

The RETeval 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 skin below the eye. The device's patented technology enables measurements without dilating eye drops using real-time pupil size compensation and skin electrodes (Sensor Strips). The entire testing process for one patient should take less than 5 minutes.

Flicker implicit time has been correlated with a number of diseases of the retina, including retinitis pigmentosa (Berson 1993), enhanced S-cone syndrome (Audo et al. 2008), CRVO (Miyata et al. 2018), and diabetic retinopathy (Fukuo et al. 2016; Zeng et al. 2019). Flicker implicit time has also been used in testing preterm infants for retinopathy of prematurity (ROP) (Kennedy et al. 1997) and in identifying retinal toxicity from the anti-seizure drug vigabatrin (Miller et al. 1999; Johnson et al. 2000; FDA Advisory Committee 2009; Ji et al. 2019). Flicker tests have been successful in distinguishing pediatric patients with nystagmus between those with and without a primary retinal disorder (Grace et al. 2017).

Through a protocol chooser, the test protocol can be selected from more than 10 flicker options, including one specifically designed for vision-threatening diabetic retinopathy described on Page 21.

Flicker protocols

The RETeval device supports flicker ERG testing. Brief flashes of light are provided at the beginning of each stimulus period. For example, the built-in protocols use a stimulus frequency of about 28.3 Hz. Background illumination, where present, uses a PWM frequency near 1 kHz, which is well above the human critical fusion frequency and therefore is perceived as steady illumination.

Built-in 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.

Many of the protocols have constant retinal illuminance, which are described by the Troland unit (Td). These protocols are identified with "Td" in the user interface and PDF reports. In these protocols, the RETeval device measures the pupil size in real time and continuously adjusts the flash luminance to deliver the desired amount of light into the eye regardless of the size of the pupil according to the following formula: Troland = (pupil area in mm^2)(luminance in cd/m^2). Thus, pupils do not need to be dilated to achieve consistent results. Even when using mydriatics, people dilate to different diameters and results can be made more consistent by using the Troland-based stimuli. While Troland-based tests make results less dependent on pupil size, secondary factors such as the Stiles-Crawford effect and/or changes in the distribution of light on the retina prevent Troland-based tests from being completely independent of pupil size (Kato et al. 2015; Davis, Kraszewska, and Manning 2017; Sugawara et al. 2020).

Stimuli having flash retinal illuminance energies of 4, 8, 16, and 32 Td·s of white light (1931 CIE x, y of 0.33, 0.33) without background illumination are provided.

There are cases where the stimulus compensating for pupil size may be inconvenient. These protocols are identified with “cd” in the user interface and PDF reports. For example, the patient cannot keep their eyelids sufficiently open for the device to measure the pupil, there is a desire to stimulate the eye through a closed eyelid, or there is a desire to match the stimulus of a previous publication. When looking for the presence of any retinal function, a bright constant luminance stimulus may be sufficient. Stimuli that do not depend on the pupil size are described in terms of luminance (units of cd/m^2) or luminance flash energy (units of cd·s/m^2). Stimuli having flash luminance energies of 3 and 30 cd·s/m^2 of white light (1931 CIE x, y of 0.33, 0.33) without background illumination are provided. Additionally, a 3 cd·s/m^2 white flash with a 30 cd/m^2 white background and its Troland equivalent (85 Td·s with an 850 Td background) is provided to match the flicker stimulus described in the ISCEV ERG standard (Robson et al. 2022).

The signal processing for flicker tests uses a Fourier-based approach and is described in Davis, Kraszewska, and Manning (2017).

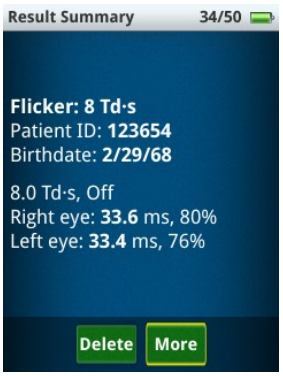
The ERG signal amplitude is lower with skin-contact electrodes such as Sensor Strips than with corneal-contact electrodes. For ERGs recorded with the active electrode on the skin, signal averaging is used. Skin electrodes may not be suitable to evaluate attenuated pathologic electroretinograms. It is recommended that users recording electroretinograms should master the technical requirements of their chosen electrode to obtain good contact, consistent electrode positioning and acceptable electrode impedance.

Custom protocols

If there is a protocol that you would like to run that is not built-in, the RETeval device has support for extending the number of options through custom protocols. Contact LKC (email: support@lkc.com) for more information on custom protocols. Exemplary custom protocols include replicate measurements, device-randomization of the presentation order of multiple stimuli, changes in flash intensity, frequency, color, and/or duration, and extended-duration stimuli such as on-off, ramp, and sinusoidal stimuli.

Custom protocols can be placed 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.

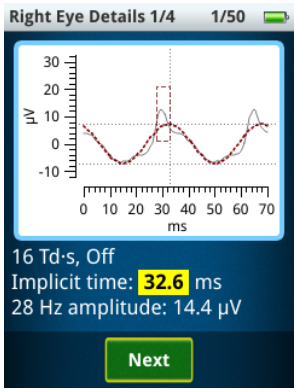
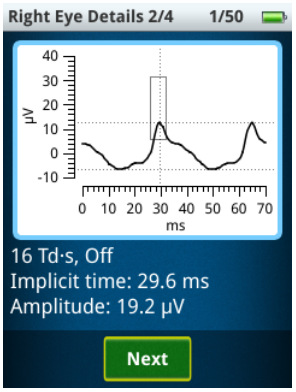
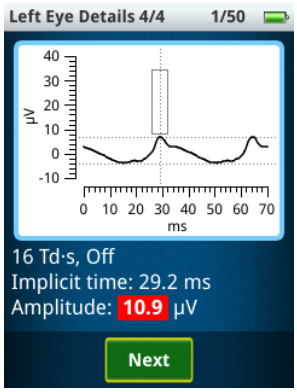
Flicker test results



Results are shown on the RETeval device when the test is completed successfully. Implicit times change substantially with flash intensity. When referring to the literature for clinical interpretation, it is important that your testing be done at the same flash intensity and background light level. The ISCEV standard states that each laboratory should establish or confirm typical reference values for its own equipment, recording protocols, and patient populations.

After the test, a result summary is presented, as pictured on the right.

Historical results can be seen 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. The summary shown above is displayed, as well as the stimulus, electrical amplitudes, and waveforms recorded by the Sensor Strips for each eye for each step. In the electrical waveform, two periods are shown. The light flashes stimulating the retina occurred at time = 0 ms and near time = 35 ms. Amplitudes and timing measurements are reported for both the fundamental of the response (i.e., the best-fitting sinusoid) and the whole waveform, because the scientific literature supports both methods. Using the fundamental 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), while using the whole waveform matches the ISCEV standard (Robson et al. 2022; McCulloch et al. 2015) and is diagnostically more useful in some cases (Maa et al. 2016). The black curve represents the electrical response of the eye to the flickering light. The red dashed curve (when present) represents the fundamental of the electrical response. Amplitude is reported as peak-to-peak. The dotted lines indicate the measurement values extracted from the waveforms. When reference intervals are available, a rectangular box is shown that encloses 95% of the data in the visually normal test population. Cursor measurements outside the rectangular box are therefore atypical. Atypical measurements associated with disease (long times or small amplitudes) are highlighted in red (i.e., < 2.5% for amplitudes or > 97.5% for times). Measurements close to the border of being highlighted red (the next 2.5%), are highlighted in yellow. See the **Reference Intervals** section in the manual (Page 57) for further details.

		
Fundamental response with timing highlighted yellow indicating a borderline measurement.	Waveform response with amplitude and time inside the reference interval	Waveform response with amplitude outside the reference interval

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

Just before “Start Test” is pressed in flicker tests, the RETeval device attempts to measure pupil size regardless of the stimulus type selected. If the pupil is successfully measured, its diameter will be shown in the PDF report at that test step. If the pupil size is not successfully measured before “Start Test”, which is possible for “cd” tests, the device will continue to try measuring the pupil size during the test and will instead report the average pupil diameter during the test.

Just after pressing “Start Test”, the RETeval device takes an infrared photograph of the eye, which is displayed on the PDF report. The photograph can be useful to estimate the subject’s dilation state, compliance, and electrode positioning.

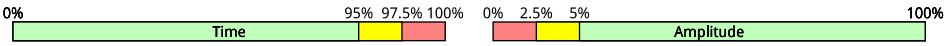
An example PDF report for the 8 Td·s protocol is shown below. Reports show reference data (See **Reference Intervals** section on Page 57).

Patient Information

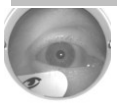
Patient ID: 123654
Birthdate: February 29, 1968
Test started: February 2, 2021, 2:28 PM
Report generated: February 8, 2021, 5:04 PM

Device and Test Information

RETeval ™
Manufacturer: LKC Technologies, Inc.
Serial number: R000555
Firmware version: 2.11.0 Reference data: 2020.49 a794d4f
Test protocol: Flicker: 8 Td·s
Electrodes: Sensor Strips

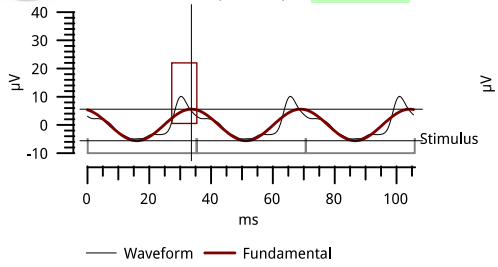


Test #1: Flash: 8.0 Td·s, Chromaticity (0.33, 0.33) at 28.3 Hz Background: 0.0 Td

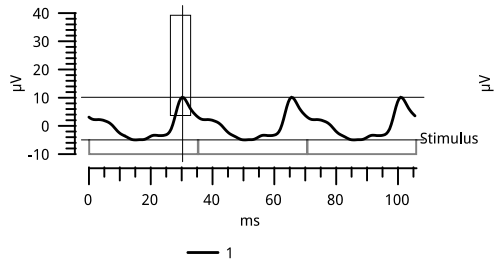


Right Eye (Pupil 3.4 mm)

28.3 Hz implicit time (ms) 33.6 (80%) 27.3 ↔ 35.4
28.3 Hz amplitude (μV) 11.2 (37%) 6.1 ↔ 27.6

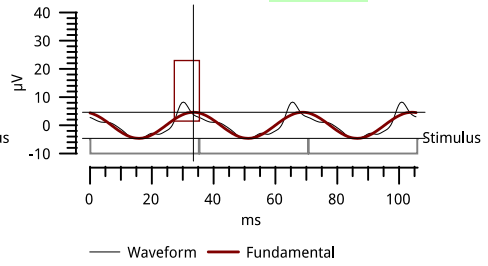


Waveform implicit time (ms) 30.3 (55%) 26.3 ↔ 32.9
Waveform amplitude (μV) 15.1 (33%) 8.6 ↔ 44.2

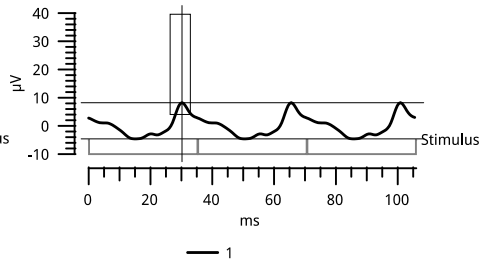


Left Eye (Pupil 2.9 mm)

28.3 Hz implicit time (ms) 33.4 (76%) 27.3 ↔ 35.4
28.3 Hz amplitude (μV) 9.2 (22%) 6.1 ↔ 27.6



Waveform implicit time (ms) 30.2 (51%) 26.3 ↔ 32.9
Waveform amplitude (μV) 12.8 (21%) 8.6 ↔ 44.2



[1]The literature supports two different methods to measure implicit times and amplitudes from flicker responses. The upper plots measure times and amplitudes from the best-fitting sine wave to the waveform at the stimulus frequency (the fundamental of the response), while the lower plots measure times and amplitudes directly from the waveform.

RETeval Complete Option

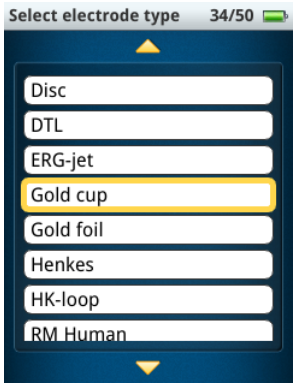
The RETeval Complete option makes the RETeval device a full-featured, ISCEV standard compliant (Robson et al. 2022; McCulloch et al. 2015) ERG device. The DR Assessment protocol and the protocols in the Flicker ERG option provide quick results for a number of diseases that can be assessed via cone responses. Nevertheless, there are many other diseases for which a rod assessment and single-flash assessments provide valuable insight into the state of the visual system. These protocols will take significantly longer to perform due to the dark adaption periods required to assess rod function.

Additionally, a protocol is provided for ISCEV-compliant flash VEP testing (Odom et al. 2016).

The ISCEV standard full-field ERG measurements have been useful for a number of diseases. Textbooks have been written (Heckenlively and Arden 2006; Fishman et al. 2001) as well as a journal (Documenta Ophthalmologica) dedicated to clinical electrophysiology of vision.

Through a protocol chooser, the test protocol can be selected from single-flash options in addition to flicker options and the protocol specifically designed for vision-threatening diabetic retinopathy.

An adapter cable for DIN electrodes is provided with the RETeval Complete option, you can use any 1.5 mm safety DIN electrode with the RETeval device. Chapter 17 in Heckenlively and Arden (2006) enumerates many electrodes that are acceptable for ERG recordings. Refer to the documentation provided by the electrode manufacturer and in the ISCEV standards for proper placement, skin preparation, cleaning, and disposal of these DIN electrodes. When performing a test, the RETeval device will prompt the operator to specify the electrode type. This information will be stored in the results and appropriate normative data (when available) will be displayed. The red lead is the positive connection, the black lead is the negative connection, and the green lead is the ground / right leg drive connection.



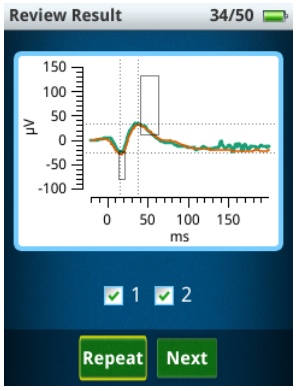
The ERG signal amplitude is lower with skin-contact electrodes such as Sensor Strips than with corneal-contact electrodes. For ERGs recorded with the active electrode on the skin, signal averaging is used. Skin electrodes may not be suitable to evaluate attenuated pathologic electroretinograms. It is recommended that users recording electroretinograms should master the technical requirements of their chosen electrode to obtain good contact, consistent electrode positioning and acceptable electrode impedance.

RETeval Complete protocols

The RETeval device supports single-flash and flicker ERG testing. Brief flashes of light are provided at the beginning of each stimulus period. A background light is also generated by providing brief flashes of light at about 1 kHz, which is well above the human critical fusion frequency and therefore is perceived as steady illumination. These protocols provide dark adaptation timers as well as an approximate ambient light level during the dark adaption. The ambient light level is approximated by taking the geometric mean of the light level measured inside the integrating sphere (ganzfeld) by a photodiode with an ambient light optical filter bonded onto it.

Many of the protocols have constant retinal illuminance, which are described by the Troland unit (Td). These protocols are identified with “Td” in the user interface and PDF reports. In these protocols, the RETeval device measures the pupil size in real time and continuously adjusts the flash luminance to deliver the desired amount of light into the eye regardless of the size of the pupil according to the following formula: Troland = (pupil area in mm^2) (luminance in cd/m^2). Thus, pupils do not need to be dilated to achieve consistent results. Even when using mydriatics, people dilate to different diameters and results can be made more consistent by using the Troland-based stimuli. While Troland-based tests make results less dependent on pupil size, secondary factors such as the Stiles-Crawford effect and/or changes in the distribution of light on the retina prevent Troland-based tests from being completely independent of pupil size (Kato et al. 2015; Davis, Kraszewska, and Manning 2017; Sugawara et al. 2020). The built-in ISCEV Troland protocols attempt to match the ISCEV candela protocols by assuming a 6 mm pupil diameter (28.3 mm^2 pupil area). For example, the Troland equivalent to the dark adapted 3.0 ERG, which has a flash luminance of 3 $cd{\cdot}s/m^2$, has a stimulus of (3 $cd{\cdot}s/m^2$)(28.3 mm^2) = 85 Td·s. If the pupil diameter is 6 mm, the 85 Td·s stimulus will be the same as a 3 $cd{\cdot}s/m^2$ stimulus and the resulting ERGs will therefore be the same.

There are cases where the stimulus compensating for pupil size may be inconvenient. These protocols are identified with “cd” in the user interface and PDF reports. For example, the patient cannot keep their eyelids sufficiently open for the device to measure the pupil, there is a desire to stimulate the eye through a closed eyelid, or there is a desire to match the stimulus of a previous publication. When looking for the presence of any retinal function, a bright constant luminance stimulus may be sufficient.



Subtests in 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 replicate. 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. When reference intervals are available, a rectangular box is shown that encloses 95% of the data in the visually normal test population. Cursor measurements outside the rectangular box are therefore atypical. Atypical measurements associated with disease (long times or small amplitudes) are highlighted in red (i.e., < 2.5% for amplitudes or > 97.5% for times). Measurements close to the border of being highlighted red (the next 2.5%), are highlighted in yellow. See the **Reference Intervals** section in the manual (Page 57) for further details.

For the dark adapted 0.1 Hz 85 Td·s and 3 $cd{\cdot}s/m^2$ tests, oscillatory potentials and cursors are reported. The oscillatory potential waveform is obtained by applying an 85 Hz - 190 Hz bandpass filter. 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.

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 RETeval 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. For the constant Troland tests, the flash duration may be longer than 5 ms for pupil sizes smaller than 1.9 mm. Modeling of the 3 stage activation phase of phototransduction, as described by (Cideciyan and Jacobson 1996) in equation A5, shows very small differences in rod or cone photocurrent between having an instantaneous flash and flash energies uniformly spread into flash durations as long as 10 ms as long as all measurements are considered relative to the center of the flash, as done by the RETeval device. If the pupil size is sufficiently small that the required flash energy for a Troland protocol is not obtainable, the RETeval device will produce its maximum flash energy.

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.

The number of flashes combined is specified in the tables below. If a different number of flashes is desired, a custom protocol can be created by modifying a protocol in the EMR/built-in-protocols folder and placing it in the Protocols/ folder on the device. Any text editor can be used to edit the protocol (e.g., Emacs or Notepad). Because of the relatively few flashes combined for the non-flicker tests, reducing the noise is more important in these tests; consequently, skin preparation is suggested for all patients to reduce the electrode contact impedance.

ISCEV ERG protocols

The following tables describe the ISCEV standard ERG protocols in detail.

This protocol **(ISCEV 6 step, light adapted first, cd)** performs the light adapted tests first, and assumes light adaptation occurs before the tests start. Some clinicians use room lights to do the light adaptation. ISCEV recommends 20 minutes of dark adaptation and 10 minutes of light adaptation.

ISCEV 6 step, light adapted first, cd				
Description	**Eye**	**Flash luminance energy (0.33, 0.33 white)**	**Background luminance (0.33, 0.33 white)**	**# flashes**
Light adapted 3.0 ERG	Right	3 cd·s/m² @ 2 Hz	30 cd/m²	30
Light adapted 3.0 flicker ERG	Right	3 cd·s/m² @ 28.3 Hz	30 cd/m²	141 – 424
Light adapted 3.0 ERG	Left	3 cd·s/m² @ 2 Hz	30 cd/m²	30
Light adapted 3.0 flicker ERG	Left	3 cd·s/m² @ 28.3 Hz	30 cd/m²	141 – 424
Dark adaptation timer	Both	Off	Off	
Dark adapted 0.01 ERG	Right	0.01 cd·s/m² @ 0.5 Hz	Off	9
Dark adapted 3.0 ERG	Right	3 cd·s/m² @ 0.1 Hz	Off	5
Dark adapted 10.0 ERG	Right	10 cd·s/m² @ 0.05 Hz	Off	5
Dark adapted 0.01 ERG	Left	0.01 cd·s/m² @ 0.5 Hz	Off	9
Dark adapted 3.0 ERG	Left	3 cd·s/m² @ 0.1 Hz	Off	5
Dark adapted 10.0 ERG	Left	10 cd·s/m² @ 0.05 Hz	Off	5

This protocol (ISCEV 6 step, dark adapted first, cd) switches the testing order to do the dark-adapted tests first. The RETeval device performs a calibration at the beginning of every protocol. So that the calibration light flashes do not affect the dark adaptation state of the subject, place the device on the patient's forehead when requested by the device. Skin color has a small, but measurable, effect on the light output (due to the skin's reflectance); thus, the test subject's forehead should be used. In this protocol, there is a light adaptation timer for each eye to be adapted to 30 cd/m^2. ISCEV recommends 20 minutes of dark adaptation and 10 minutes of light adaptation.

ISCEV 6 step, dark adapted first, cd				
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 ERG	Right	0.01 cd·s/m² @ 0.5 Hz	Off	9
Dark adapted 3.0 ERG	Right	3 cd·s/m² @ 0.1 Hz	Off	5
Dark adapted 10.0 ERG	Right	10 cd·s/m² @ 0.05 Hz	Off	5
Dark adapted 0.01 ERG	Left	0.01 cd·s/m² @ 0.5 Hz	Off	9
Dark adapted 3.0 ERG	Left	3 cd·s/m² @ 0.1 Hz	Off	5
Dark adapted 10.0 ERG	Left	10 cd·s/m² @ 0.05 Hz	Off	5
Light adaptation timer	Right	Off	30 cd/m²	
Light adapted 3.0 ERG	Right	3 cd·s/m² @ 2 Hz	30 cd/m²	30
Light adapted 3.0 flicker ERG	Right	3 cd·s/m² @ 28.3 Hz	30 cd/m²	141 – 424
Light adaptation timer	Left	Off	30 cd/m²	
Light adapted 3.0 ERG	Left	3 cd·s/m² @ 2 Hz	30 cd/m²	30
Light adapted 3.0 flicker ERG	Left	3 cd·s/m² @ 28.3 Hz	30 cd/m²	141 – 424

The next two protocols are the same as the previous two with the exception that the 10 cd·s/m^2 white flash is not performed.

ISCEV 5 step, light adapted first, cd				
Description	**Eye**	**Flash luminance energy (0.33, 0.33 white)**	**Background luminance (0.33, 0.33 white)**	**# flashes**
Light adapted 3.0 ERG	Right	3 cd·s/m² @ 2 Hz	30 cd/m²	30
Light adapted 3.0 flicker ERG	Right	3 cd·s/m² @ 28.3 Hz	30 cd/m²	141 – 424
Light adapted 3.0 ERG	Left	3 cd·s/m² @ 2 Hz	30 cd/m²	30
Light adapted 3.0 flicker ERG	Left	3 cd·s/m² @ 28.3 Hz	30 cd/m²	141 – 424
Dark adaptation timer	Both	Off	Off	
Dark adapted 0.01 ERG	Right	0.01 cd·s/m² @ 0.5 Hz	Off	9
Dark adapted 3.0 ERG	Right	3 cd·s/m² @ 0.1 Hz	Off	5
Dark adapted 0.01 ERG	Left	0.01 cd·s/m² @ 0.5 Hz	Off	9
Dark adapted 3.0 ERG	Left	3 cd·s/m² @ 0.1 Hz	Off	5

ISCEV 5 step, dark adapted first, cd				
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 ERG	Right	0.01 cd·s/m² @ 0.5 Hz	Off	9
Dark adapted 3.0 ERG	Right	3 cd·s/m² @ 0.1 Hz	Off	5
Dark adapted 0.01 ERG	Left	0.01 cd·s/m² @ 0.5 Hz	Off	9
Dark adapted 3.0 ERG	Left	3 cd·s/m² @ 0.1 Hz	Off	5
Light adaptation timer	Right	Off	30 cd/m²	
Light adapted 3.0 ERG	Right	3 cd·s/m² @ 2 Hz	30 cd/m²	30
Light adapted 3.0 flicker ERG	Right	3 cd·s/m² @ 28.3 Hz	30 cd/m²	141 – 424
Light adaptation timer	Left	Off	30 cd/m²	
Light adapted 3.0 ERG	Left	3 cd·s/m² @ 2 Hz	30 cd/m²	30
Light adapted 3.0 flicker ERG	Left	3 cd·s/m² @ 28.3 Hz	30 cd/m²	141 – 424

The next four protocols are similar to the ISCEV 5/6 step protocols above, except pupil-tracking is used to provide constant retinal illuminance, making pupil dilation optional. A 6 mm pupil was assumed to convert the ISCEV standard dilated luminance to Trolands.

ISCEV 6 step, light adapted first, Td				
Description	**Eye**	**Flash luminance energy (0.33, 0.33 white)**	**Background luminance (0.33, 0.33 white)**	**# flashes**
Light adapted 85 Td·s ERG	Right	85 Td·s @ 2 Hz	848 Td	30
Light adapted 85 Td·s flicker ERG	Right	85 Td·s @ 28.3 Hz	848 Td	141 – 424
Light adapted 85 Td·s ERG	Left	85 Td·s @ 2 Hz	848 Td	30
Light adapted 85 Td·s flicker ERG	Left	85 Td·s @ 28.3 Hz	848 Td	141 – 424
Dark adaptation timer	Both	Off	Off	
Dark adapted 0.28 Td·s ERG	Right	0.28 Td·s @ 0.5 Hz	Off	9
Dark adapted 85 Td·s ERG	Right	85 Td·s @ 0.1 Hz	Off	5
Dark adapted 280 Td·s ERG	Right	280 Td·s @ 0.05 Hz	Off	5
Dark adapted 0.28 Td·s ERG	Left	0.28 Td·s @ 0.5 Hz	Off	9
Dark adapted 85 Td·s ERG	Left	85 Td·s @ 0.1 Hz	Off	5
Dark adapted 280 Td·s ERG	Left	280 Td·s @ 0.05 Hz	Off	5

ISCEV 6 step, dark adapted first, Td				
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 0.28 Td·s ERG	Right	0.28 Td·s @ 0.5 Hz	Off	9
Dark adapted 85 Td·s ERG	Right	85 Td·s @ 0.1 Hz	Off	5
Dark adapted 280 Td·s ERG	Right	280 Td·s @ 0.05 Hz	Off	5
Dark adapted 0.28 Td·s ERG	Left	0.28 Td·s @ 0.5 Hz	Off	9
Dark adapted 85 Td·s ERG	Left	85 Td·s @ 0.1 Hz	Off	5
Dark adapted 280 Td·s ERG	Left	280 Td·s @ 0.05 Hz	Off	5
Light adaptation timer	Right	Off	848 Td	
Light adapted 85 Td·s ERG	Right	85 Td·s @ 2 Hz	848 Td	30
Light adapted 85 Td·s flicker ERG	Right	85 Td·s @ 28.3 Hz	848 Td	141 – 424
Light adaptation timer	Left	Off	848 Td	
Light adapted 85 Td·s ERG	Left	85 Td·s @ 2 Hz	848 Td	30
Light adapted 85 Td·s flicker ERG	Left	85 Td·s @ 28.3 Hz	848 Td	141 – 424

ISCEV 5 step, light adapted first, Td				
Description	**Eye**	**Flash luminance energy (0.33, 0.33 white)**	**Background luminance (0.33, 0.33 white)**	**# flashes**
Light adapted 85 Td·s ERG	Right	85 Td·s @ 2 Hz	848 Td	30
Light adapted 85 Td·s flicker ERG	Right	85 Td·s @ 28.3 Hz	848 Td	141 – 424
Light adapted 85 Td·s ERG	Left	85 Td·s @ 2 Hz	848 Td	30
Light adapted 85 Td·s flicker ERG	Left	85 Td·s @ 28.3 Hz	848 Td	141 – 424
Dark adaptation timer	Both	Off	Off	
Dark adapted 0.28 Td·s ERG	Right	0.28 Td·s @ 0.5 Hz	Off	9
Dark adapted 85 Td·s ERG	Right	85 Td·s @ 0.1 Hz	Off	5
Dark adapted 0.28 Td·s ERG	Left	0.28 Td·s @ 0.5 Hz	Off	9
Dark adapted 85 Td·s ERG	Left	85 Td·s @ 0.1 Hz	Off	5

ISCEV 5 step, dark adapted first, Td				
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 0.28 Td·s ERG	Right	0.28 Td·s @ 0.5 Hz	Off	9
Dark adapted 85 Td·s ERG	Right	85 Td·s @ 0.1 Hz	Off	5
Dark adapted 0.28 Td·s ERG	Left	0.28 Td·s @ 0.5 Hz	Off	9
Dark adapted 85 Td·s ERG	Left	85 Td·s @ 0.1 Hz	Off	5
Light adaptation timer	Right	Off	848 Td	
Light adapted 85 Td·s ERG	Right	85 Td·s @ 2 Hz	848 Td	30
Light adapted 85 Td·s flicker ERG	Right	85 Td·s @ 28.3 Hz	848 Td	141 – 424
Light adaptation timer	Left	Off	848 Td	
Light adapted 85 Td·s ERG	Left	85 Td·s @ 2 Hz	848 Td	30
Light adapted 85 Td·s flicker ERG	Left	85 Td·s @ 28.3 Hz	848 Td	141 – 424

The next three protocols are ISCEV photopic based protocols. These are protocols without the scotopic steps included. The protocols are the photopic single flash and flicker in standard dilated ISCEV candela luminance as well as in Trolands. There is also the Troland based ISCEV Flicker protocol.

ISCEV Photopic flash and flicker, cd				
Description	**Eye**	**Flash luminance energy (0.33, 0.33 white)**	**Background luminance (0.33, 0.33 white)**	**# flashes**
Light adapted 3.0 ERG	Right	3 cd·s/m² @ 2 Hz	30 cd/m²	30
Light adapted 3.0 flicker ERG	Right	3 cd·s/m² @ 28.3 Hz	30 cd/m²	141 – 424
Light adapted 3.0 ERG	Left	3 cd·s/m² @ 2 Hz	30 cd/m²	30
Light adapted 3.0 flicker ERG	Left	3 cd·s/m² @ 28.3 Hz	30 cd/m²	141 – 424

ISCEV Photopic flash and flicker, Td				
Description	**Eye**	**Flash luminance energy (0.33, 0.33 white)**	**Background luminance (0.33, 0.33 white)**	**# flashes**
Light adapted 85 Td·s ERG	Right	85 Td·s @ 2 Hz	848 Td	30
Light adapted 85 Td·s flicker ERG	Right	85 Td·s @ 28.3 Hz	848 Td	141 – 424
Light adapted 85 Td·s ERG	Left	85 Td·s @ 2 Hz	848 Td	30
Light adapted 85 Td·s flicker ERG	Left	85 Td·s @ 28.3 Hz	848 Td	141 – 424

ISCEV Photopic Flicker, Td				
Description	**Eye**	**Flash luminance energy (0.33, 0.33 white)**	**Background luminance (0.33, 0.33 white)**	**# flashes**
Light adapted 85 Td·s flicker ERG	Right	85 Td·s @ 28.3 Hz	848 Td	141 – 424
Light adapted 85 Td·s flicker ERG	Left	85 Td·s @ 28.3 Hz	848 Td	141 – 424

The following ISCEV protocols skip the DA3 test step and do not report OPs. When using a 10-minute dark adaption, these protocols match the “Non-standard abbreviated ERG protocol” specified in the 2022 update to the ISCEV standard (Robson et al. 2022). When using shortened dark adaption times, comparison of the rod responses to the reference data needs additional care, as the reference data was collected with 20 minutes of dark adaption.

ISCEV 4 step, light adapted first, cd				
Description	**Eye**	**Flash luminance energy (0.33, 0.33 white)**	**Background luminance (0.33, 0.33 white)**	**# flashes**
Light adapted 3.0 ERG	Right	3 cd·s/m² @ 2 Hz	30 cd/m²	30
Light adapted 3.0 flicker ERG	Right	3 cd·s/m² @ 28.3 Hz	30 cd/m²	141 – 424
Light adapted 3.0 ERG	Left	3 cd·s/m² @ 2 Hz	30 cd/m²	30
Light adapted 3.0 flicker ERG	Left	3 cd·s/m² @ 28.3 Hz	30 cd/m²	141 – 424
Dark adaptation timer	Both	Off	Off	
Dark adapted 0.01 ERG	Right	0.01 cd·s/m² @ 0.5 Hz	Off	9
Dark adapted 10.0 ERG	Right	10 cd·s/m² @ 0.05 Hz	Off	5
Dark adapted 0.01 ERG	Left	0.01 cd·s/m² @ 0.5 Hz	Off	9
Dark adapted 10.0 ERG	Left	10 cd·s/m² @ 0.05 Hz	Off	5

ISCEV 4 step, light adapted first, Td				
Description	**Eye**	**Flash luminance energy (0.33, 0.33 white)**	**Background luminance (0.33, 0.33 white)**	**# flashes**
Light adapted 85 Td·s ERG	Right	85 Td·s @ 2 Hz	848 Td	30
Light adapted 85 Td·s flicker ERG	Right	85 Td·s @ 28.3 Hz	848 Td	141 – 424
Light adapted 85 Td·s ERG	Left	85 Td·s @ 2 Hz	848 Td	30
Light adapted 85 Td·s flicker ERG	Left	85 Td·s @ 28.3 Hz	848 Td	141 – 424
Dark adaptation timer	Both	Off	Off	
Dark adapted 0.28 Td·s ERG	Right	0.28 Td·s @ 0.5 Hz	Off	9
Dark adapted 280 Td·s ERG	Right	280 Td·s @ 0.05 Hz	Off	5
Dark adapted 0.28 Td·s ERG	Left	0.28 Td·s @ 0.5 Hz	Off	9
Dark adapted 280 Td·s ERG	Left	280 Td·s @ 0.05 Hz	Off	5

Photopic negative response protocols

The photopic negative response is the slow negative response that follows the b-wave, and has been pharmacologically isolated to originate in the retinal ganglion cells (Viswanathan et al. 1999). Changes in the PhNR have been demonstrated, for example, in glaucoma (Viswanathan et al. 2001; Preiser et al. 2013).

Four photopic negative response protocols are provided. These protocols have a red flash (1.0 cd·s/m² or 38 Td·s) on a blue background (10 cd/m² or 380 Td) which emphasizes the cone system's response. The stimulus frequency is 3.4 Hz and uses either 200 (long protocol) or 100 (short protocol) flashes to reduce measurement noise. The long protocol records for about 60 seconds; the short protocol records for 30 seconds.

PhNR 3.4 Hz cd Long				
Description	**Eye**	**Flash luminance energy (red LED, 621 nm)**	**Background luminance (blue LED, 470 nm)**	**# flashes**
Red flash, blue background	Right	1.0 cd·s/m² @ 3.4 Hz	10 cd/m²	200
Red flash, blue background	Left	1.0 cd·s/m² @ 3.4 Hz	10 cd/m²	200

PhNR 3.4 Hz cd Short				
Description	**Eye**	**Flash luminance energy (red LED, 621 nm)**	**Background luminance (blue LED, 470 nm)**	**# flashes**
Red flash, blue background	Right	1.0 cd·s/m² @ 3.4 Hz	10 cd/m²	100
Red flash, blue background	Left	1.0 cd·s/m² @ 3.4 Hz	10 cd/m²	100

PhNR 3.4 Hz Td Long				
Description	**Eye**	**Flash luminance energy (red LED, 621 nm)**	**Background luminance (blue LED, 470 nm)**	**# flashes**
Red flash, blue background	Right	38 Td·s @ 3.4 Hz	380 Td	200
Red flash, blue background	Left	38 Td·s @ 3.4 Hz	380 Td	200

PhNR 3.4 Hz Td Short				
Description	**Eye**	**Flash luminance energy (red LED, 621 nm)**	**Background luminance (blue LED, 470 nm)**	**# flashes**
Red flash, blue background	Right	38 Td·s @ 3.4 Hz	380 Td	100
Red flash, blue background	Left	38 Td·s @ 3.4 Hz	380 Td	100

Reported results are from -20 ms to +200 ms, with the center of the flash at 0 ms. The extended post-stimulus display is used to better visualize the slow return to baseline.

Quantitative analysis is performed as follows. The a-wave and b-wave cursors are placed on the reported waveform at their respective peaks. The PhNR is the minimum point between 55 ms and 180 ms. The W-ratio is defined as follows:

W-ratio = (b – pmin) / (b – a)

where a, b and pmin are the voltages relative to baseline defined as a: a-wave peak, b: b-wave peak, pmin: minimum voltage between 55 ms and 180 ms. Note: the b-wave voltage typically reported (including in the RETeval device) is equal to (b-a). Based on the definition, the W-ratio is the ratio of the waveform height after to before the b-wave. If the PhNR amplitude is the same as the a-wave, the W-ratio is 1. The W-ratio is less than 1 if the depth of the PhNR is less than the depth of the a-wave. The W-ratio is the inverse of “PTR” as defined in Mortlock et al. (2010) and was found therein to have the lowest level of inter-individual, inter-session, and inter-ocular variability of the 5 ERG measurement techniques tested.

To generate the displayed waveform, novel and proprietary processing methods are used that are based on maximizing the difference between the PhNR between 144 subjects with glaucoma and/or optic neuropathy and 159 healthy subjects. The reference data uses the same processing method.

S-cone protocols

Two S-cone protocols are provided, which may be useful in the detection of enhanced s-cone syndrome (Yamamoto, Hayashi, and Takeuchi 1999). These protocols use a background of 560 cd/m² red light to attenuate the response from the L and M cones and a flash brightness of 1 cd·s/m² at 4.2 Hz. The resulting signal is very small, so a large amount of signal averaging is required. The long protocol uses 500 averages (120 seconds) matching Yamamoto, Hayashi, and Takeuchi (1999), while the short protocol uses 250 averages (60 seconds).

S-cone 4.2 Hz cd Long				
Description	**Eye**	**Flash luminance energy (blue LED, 470 nm)**	**Background luminance (red LED, 621 nm)**	**# flashes**
Bright blue flash, red background	Right	1 cd·s/m² @ 4.2 Hz	560 cd/m²	500
Bright blue flash, red background	Left	1 cd·s/m² @ 4.2 Hz	560 cd/m²	500

S-cone 4.2 Hz cd Short				
Description	**Eye**	**Flash luminance energy (blue LED, 470 nm)**	**Background luminance (red LED, 621 nm)**	**# flashes**
Bright blue flash, red background	Right	1 cd·s/m² @ 4.2 Hz	560 cd/m²	250
Bright blue flash, red background	Left	1 cd·s/m² @ 4.2 Hz	560 cd/m²	250

The S-cone processing is the same as the 2 Hz ISCEV flash response. The S-cone response occurs a little after 40 ms. The b-wave cursor will usually not select that peak, rather it will select the earlier LM-cone response.

DA red flash protocols

Two DA red flash protocols are provided, which may be useful in differentiating between the response from rods and dark-adapted cones (Thompson et al. 2018). These protocols use a red flash without a background. Due to differences in spectral sensitivity, cones are 31 times more sensitive than rods to the RETeval device's red light. The protocols use a photopic 0.3 cd·s/m^2 stimulus (or Troland equivalent). The rods therefore see only about a DA0.01 stimulus. Dark adapted cones generate a positive deflection in the ERG with a peak around 30-50 ms (termed the "x-wave"), while the rods generate a later peak around 100 ms. By choosing between a 5-minute and a 20-minute dark adaptation time, the relative amplitudes between the two responses can be modified, as the cones dark adapt at a faster rate than rods. Consult the ISCEV extended protocol for references describing the clinical

utility of this test. If you want to run this test in combination with another ISCEV protocol, run this test immediately prior to the DA0.01 test.

ISCEV DA Red Flash Td				
Description	**Eye**	**Flash luminance energy (red LED, 621 nm)**	**Background luminance**	**# flashes**
Dark adapted 0.3 red flash ERG	Right	0.3 cd·s/m² @ 0.5 Hz	Off	9
Dark adapted 0.3 red flash ERG	Left	0.3 cd·s/m² @ 0.5 Hz	Off	9

ISCEV DA Red Flash cd				
Description	**Eye**	**Flash luminance energy (red LED, 621 nm)**	**Background luminance**	**# flashes**
Dark adapted 0.3 red flash ERG	Right	8.4 Td·s @ 0.5 Hz	Off	9
Dark adapted 0.3 red flash ERG	Left	8.4 Td·s @ 0.5 Hz	Off	9

On-off (long flash) protocols

On-off protocols (also known as long flash protocols) have an extended-length stimulus to separate the on response from the off response in the ERG. Long flash protocols have been used for example in patients with retinitis pigmentosa (Cideciyan and Jacobson 1993), congenital stationary night blindness (Cideciyan and Jacobson 1993; Sustar et al. 2008), cone dystrophy (Sieving 1994), and enhanced s-cone syndrome (Audo et al. 2008). To better see when the off response should be, showing the stimulus as a function of time on the reports may be useful. See **Stimulus waveforms** on Page 11 for how to configure this option.

Two protocols (a short and long test duration) are provided that use a white light stimulus. The stimulus is a 250 cd/m^2 white light, which has been shown to have a near maximal d-wave (Kondo et al. 2000), with a 40 cd/m^2 white background to suppress the rod response. Thus, when the stimulus is on, the luminance is 290 cd/m^2; and when the stimulus is off, the luminance is 40 cd/m^2. The on and off times of the stimulus are both about 144.9 ms, which maximizes the amplitude of the d-wave (Sieving 1993; Sustar, Hawlina, and Brecelj 2006) while keeping the test duration as short as possible. The short protocol uses 100 averages (taking 30 seconds) and the long protocol uses 200 averages (taking 60 seconds).

On-off long: w/w 250/40 cd				
Description	**Eye**	**Stimulus luminance (0.33, 0.33 white)**	**Background luminance (0.33, 0.33 white)**	**# flashes**
White extended stimulus, white background	Right	250 cd/m², 144.9 ms on time @ 3.5 Hz	40 cd/m²	200
White extended stimulus, white background	Left	250 cd/m², 144.9 ms on time @ 3.5 Hz	40 cd/m²	200

On-off short: w/w 250/40 cd				
Description	**Eye**	**Stimulus luminance (0.33, 0.33 white)**	**Background luminance (0.33, 0.33 white)**	**# flashes**
White extended stimulus, white background	Right	250 cd/m², 144.9 ms on time @ 3.5 Hz	40 cd/m²	100
White extended stimulus, white background	Left	250 cd/m², 144.9 ms on time @ 3.5 Hz	40 cd/m²	100

Two additional protocols (a short and long test duration) are provided that use a colored stimulus. The stimulus is a 560 cd/m^2 red light with a 160 cd/m^2 green background. The on and off times are both about 209.4 ms. This protocol matches closely to Audo et al. (2008), with the green background suppressing the rod response. The short protocol uses 100 averages (taking 42 seconds) and the long protocol uses 200 averages (taking 84 seconds).

On-off long: r/g 560/160 cd				
Description	**Eye**	**Stimulus luminance (red LED, 621 nm)**	**Background luminance (green LED, 530 nm)**	**# flashes**
Red extended stimulus, green background	Right	560 cd/m², 209.4 ms on time @ 2.4 Hz	160 cd/m²	200
Red extended stimulus, green background	Left	560 cd/m², 209.4 ms on time @ 2.4 Hz	160 cd/m²	200

On-off short: r/g 560/160 cd				
Description	**Eye**	**Stimulus luminance (red LED, 621 nm)**	**Background luminance (green LED, 530 nm)**	**# flashes**
Red extended stimulus, green background	Right	560 cd/m², 209.4 ms on time @ 2.4 Hz	160 cd/m²	100
Red extended stimulus, green background	Left	560 cd/m², 209.4 ms on time @ 2.4 Hz	160 cd/m²	100

To generate the stimuli, the RETeval device uses a PWM stimulus near 1 kHz.

The analysis uses the same processing as the ISCEV protocols, with the following exceptions: The 0-phase high pass filter is set to 4 Hz to reduce electrode drift over the extended response duration. A 0–phase 300 Hz low pass filter is used instead of the wavelet denoising. The 0 time point in the response is when the stimulus is turned on.

VEP protocols

Flash VEP protocols flash light in the eye and measure the visual system's response on the back of the head. There are two flash VEP protocols: a 3 cd·s/m² @ 1 Hz protocol and a 24 Td·s @ 1 Hz. The two protocols are equivalent when the pupil diameter is 3.2 mm (8 mm^2 area). Both use 64 flashes to average the response.

The analysis uses the same processing as the ISCEV protocols, with the following exceptions: The passband of the 0-phase filter is 2 Hz to 31 Hz. Cursor placement is performed by assigning the peak closest in time to 120 ms to be P2, and the first trough past 25 ms to be N1. P1, N2, N3, and P3 are then added as appropriate. Because of heterogeneity in the flash VEP waveform, some of these 6 cursor measurement locations may not be found. The peak-to-peak amplitude of the VEP (Pmax – Nmin) is defined as the maximum amplitude of P1 and P2 minus the minimum amplitude of N1 and N2 because the dominant VEP peak is sometimes P2 and sometimes P1. Reference data is displayed for this peak-to-peak amplitude and the P2 time to simplify the report. The P2 time may not be flagged as atypical even for blind subjects, as random noise may also have a peak near 120 ms. Reference data for all cursor values are computed and stored in the raw data (rff) file.

Flash VEP measurements depend on the response from the retina being transmitted through the optic nerve to the occipital cortex and therefore can be used as an indicator of visual function. Flash VEP measurements are highly variable among individuals but are fairly repeatable for one individual. Running replicates, which is an option in these tests, can help distinguish the evoked response from other biological signals.

See **Performing a VEP test** on Page 47 for details on how to do a flash VEP.

Custom protocols

If there is a protocol that you would like to run that is not built-in, the RETeval device has support for extending the number of options through custom protocols. Custom protocols can be placed in the Protocols folder on the device and then can be selected through the User Interface in a manner like selecting a built-in protocol. 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. Contact LKC (email: support@lkc.com) if you would like assistance in making a custom protocol.

Examples of what can be done with custom protocols are described below.

Multiple test steps

Custom protocols can have multiple test steps. These test steps can have the same or different stimulation and analysis settings. They can be performed in a pre-specified or randomized order. Randomization may be useful to eliminate time being a confounding variable. The device can pause between test steps, enabling a review of the data and possible replication of the trial, or the device can proceed between steps as fast as possible (without operator review).

Stimulus

The stimulus can compensate for pupil size (Trolands) or not. When compensating for pupil size, one can also choose to compensate for the Stiles-Crawford effect. The stimulus color can be expressed in CIE 1931 (x,y) chromaticity or in brightness for each color LED separately (red, green, blue). Flash energy and background luminance can be specified. Alternatively, extended-duration stimuli, such as ramps (step on and step off), sinusoids, and square wave (on-off) stimuli can be specified. Using the on-off stimulus specification, one can, for example, experiment with variable-duration flashes. The RETeval sinusoidal stimulus has been carefully constructed to minimize the harmonic distortion (< 1% per harmonic), so that any harmonics in the response are attributable to nonlinearities in the visual system. The dominant wavelength and brightness range for each LED is shown in the specification table on Page 77. Luminance is specified in photopic units. The effective luminance for rods (scotopic units) is different as the spectral sensitivity between rods and cones differ. For the RETeval LEDs, the ratio of scotopic to photopic sensitivity is 0.032, 2.3, and 16 for red, green, and blue respectively. As an example, rods are 16 times more sensitive to blue light than cones. For white light (CIE 0.33, 0.33), rods are 3.0 times more sensitive than cones.

Analysis

The sampling rate can be selected to have a period of 2048 µs (~500 Hz), 1024 µs (~1 kHz), 512 µs (~2 kHz, default), or 256 µs (~4 kHz). Flicker tests can specify the number of harmonics to analyze, up to 32 harmonics. Flash tests can specify filtering used. The high-pass filter frequency cutoff (3 dB) point can be specified along with if the filter is causal or acausal. The low-pass filtering can be selected between wavelet denoising and a 0-phase filter. The low pass filter frequencies can be selected among 25, 50, 61, 75, 100, 125, 150 Hz for the ~500 Hz sampling rate; 50, 61, 75, 100, 122, 150, 200, 250, 300 Hz for the ~1 kHz sampling rate; 61, 100, 122, 150, 200, 244, 300, 400, 500, 600 Hz for the ~2 kHz sampling rate; and 61, 122, 200, 244, 300, 400, 488, 600, 800, 1000, 1200 Hz for the ~4 kHz sampling rate. The low-pass filter frequencies specify the edge of the pass band of the filter.

Pupil measurements can be collected regardless of the stimulus selected.

Any stimulus can be post-processed for oscillatory potential analysis.

Any stimulus can be post-processed for a- and b- wave cursors, and PhNR cursor analysis.

Reference data

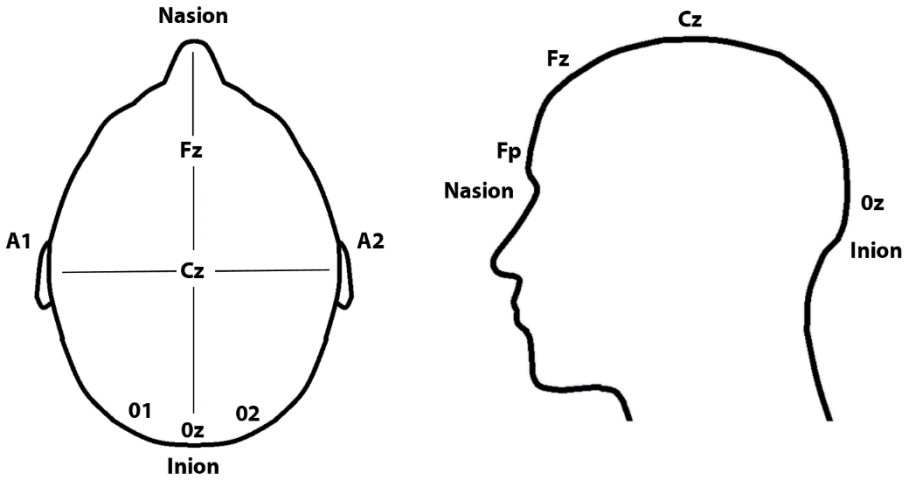
Reference data depends on the stimulus, electrode, and analysis used. If there is a match between a test step and the reference data on the device, the relevant reference data will be presented automatically. Reference data can also be explicitly disabled in a custom protocol.

Language translations

Custom protocols can be written in any language; however, they cannot be automatically translated into other languages.

Performing a VEP test

There is an ISCEV standard for performing flash VEPs (Odom et al. 2016; Odom et al. 2010). Place the electrodes as described below on the head and stimulate each eye in a similar manner to an ERG test. Perform replicates so that the aspects of the waveforms resulting from the light stimulation can be more easily identified.



Clean the electrode locations with NuPrep, an alcohol-based skin prep pad, or just an alcohol wipe.

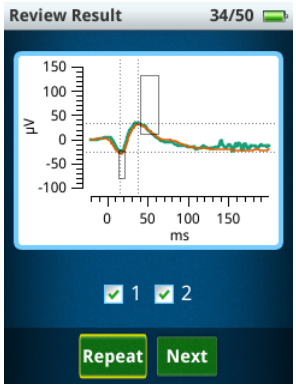
Connect the gold cup recording electrode (positive) to Oz. To locate Oz, identify the inion, the bony protrusion at the back of the skull. If the patient is an adult with a normal-sized head, the Oz is located about 2.5 cm (1 inch) above the inion on the midline. If the patient has an abnormal-sized head, is an infant, or if it is important that the electrodes are placed in the exact locations, making a few measurements will determine the locations for the recording sites. First, identify the nasion, the bony ridge along the brow line just above the nose on the front of the head. Measure the distance from the nasion, over the head, to the inion. Oz is located on the midline, 10% of the distance from the inion to the nasion above the inion. Part any hair to expose the skin at the recording site and vigorously clean the skin. If the patient's hair is long, bobby pins or other clips should be used to hold the hair out of the way during cleaning and electrode placement. Put a generous portion of electrode cream in the cup of the electrode and press the electrode firmly into place on the scalp. Cover the electrode with a 2 to 3 cm (1 to 1½ inch) square of tissue paper and press firmly again.

Place a Ag/AgCl ECG electrode as the reference electrode (negative) at hairline on the forehead. Fill the cups of the ear clip electrode with electrode gel (not cream) and clip it to the patient's ear lobe as the ground / right leg drive electrode.

On the device side, use the RETeval adapter cable for DIN electrodes in lieu of the Sensor Strip lead. Connect the gold cup recording electrode to the red lead of the adapting cable. Connect the Ag/AgCl reference electrode to the black lead of the adapting cable as the negative input (reference). Connect a gold cup ear clip electrode to the green lead of the adapting cable for the ground / right-leg drive connection.

Part numbers for these items can be found in **Purchasing supplies** and accessories on Page 94 or on the LKC store (https://store.lkc.com/RETeval-accessories).

RETeval Complete test results



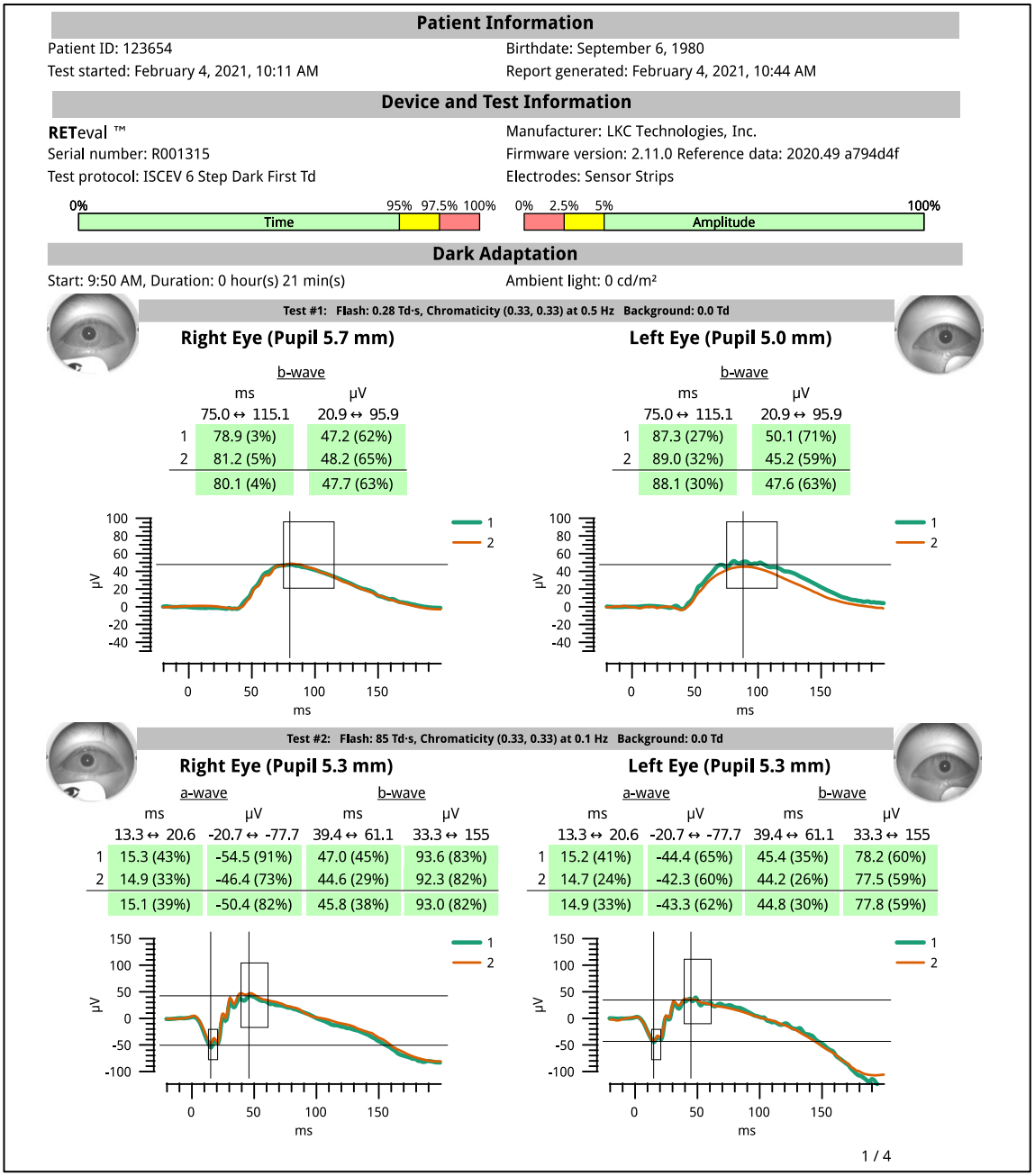
Incremental results are shown on the RETeval device after each test (except for flicker-only tests), with the option to repeat the test or continue to the next test. Successful cursor placement is indicated by dashed lines on the waveform indicating their location. If you do not see the successful cursor placement indication, repeat the measurement. When available, reference interval rectangles indicating the locations of the middle 95% of subjects with normal vision are shown.

Historical results can be seen 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. The results include the stimulus, electrical amplitudes, timings, and waveforms recorded by the electrodes for each eye for each step in the protocol. The graphs display the average cursor placements. A flash occurs at time = 0 for all tests. When reference intervals are available, a rectangular box is shown that encloses 95% of the data in the visually normal test population. Cursor measurements outside the rectangular box are therefore atypical. Atypical measurements associated with disease (long times or small amplitudes) are highlighted in red (i.e., < 2.5% for amplitudes or > 97.5% for times). Measurements close to the border of being highlighted red (the next 2.5%), are highlighted in yellow. See the **Reference Intervals** section in the manual (starting on Page 57) for further details.

Just before “Start Test” is pressed in flicker or flash tests, the RETeval device attempts to measure pupil size regardless of the stimulus type selected. If the pupil is successfully measured, its diameter will be shown in the PDF report at that test step. If the pupil size is not successfully measured before “Start Test”, which is possible for “cd” tests, the device will continue to try measuring the pupil size during the test and will instead report the average pupil diameter during the test.

Just after pressing “Start Test”, the RETeval device takes an infrared photograph of the eye, which is displayed on the PDF report. If replicates are taken, the photograph displayed is from the last replicate. The photograph can be useful to estimate the subject’s dilation state, compliance, and electrode positioning near the eye.

An example PDF report for the ISCEV 6 step, dark adapted first, Td protocol is shown below.



Patient Information

Patient ID: 123654
Birthdate: September 6, 1980
Test started: February 4, 2021, 10:11 AM
Report generated: February 4, 2021, 10:44 AM

Device and Test Information

RETeval ™
Manufacturer: LKC Technologies, Inc.
Serial number: R001315
Firmware version: 2.11.0 Reference data: 2020.49 a794d4f
Test protocol: ISCEV 6 Step Dark First Td
Electrodes: Sensor Strips

0% 95% 97.5% 100% Time
0% 2.5% 5% 100% Amplitude

Dark Adaptation

Start: 9:50 AM, Duration: 0 hour(s) 21 min(s)
Ambient light: 0 cd/m²

Test #1: Flash: 0.28 Td·s, Chromaticity (0.33, 0.33) at 0.5 Hz Background: 0.0 Td

Right Eye (Pupil 5.7 mm)

	b-wave ms	b-wave µV
	75.0 ↔ 115.1	20.9 ↔ 95.9
1	78.9 (3%)	47.2 (62%)
2	81.2 (5%)	48.2 (65%)
	80.1 (4%)	47.7 (63%)

Left Eye (Pupil 5.0 mm)

	b-wave ms	b-wave µV
	75.0 ↔ 115.1	20.9 ↔ 95.9
1	87.3 (27%)	50.1 (71%)
2	89.0 (32%)	45.2 (59%)
	88.1 (30%)	47.6 (63%)

Test #2: Flash: 85 Td·s, Chromaticity (0.33, 0.33) at 0.1 Hz Background: 0.0 Td

Right Eye (Pupil 5.3 mm)

	a-wave ms	a-wave µV	b-wave ms	b-wave µV
	13.3 ↔ 20.6	-20.7 ↔ -77.7	39.4 ↔ 61.1	33.3 ↔ 155
1	15.3 (43%)	-54.5 (91%)	47.0 (45%)	93.6 (83%)
2	14.9 (33%)	-46.4 (73%)	44.6 (29%)	92.3 (82%)
	15.1 (39%)	-50.4 (82%)	45.8 (38%)	93.0 (82%)

Left Eye (Pupil 5.3 mm)

	a-wave ms	a-wave µV	b-wave ms	b-wave µV
	13.3 ↔ 20.6	-20.7 ↔ -77.7	39.4 ↔ 61.1	33.3 ↔ 155
1	15.2 (41%)	-44.4 (65%)	45.4 (35%)	78.2 (60%)
2	14.7 (24%)	-42.3 (60%)	44.2 (26%)	77.5 (59%)
	14.9 (33%)	-43.3 (62%)	44.8 (30%)	77.8 (59%)

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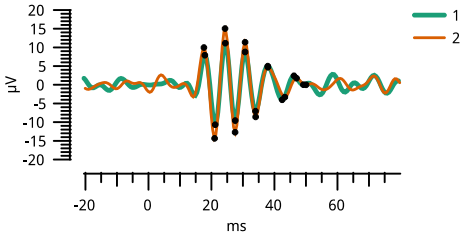
Patient ID: 123654
Birthdate: September 6, 1980
Test started: February 4, 2021, 10:11 AM
Report generated: February 4, 2021, 10:44 AM

Test #3: Flash: 85 Td·s, Chromaticity (0.33, 0.33) at 0.1 Hz Background: 0.0 Td

Right Eye (Pupil 5.3 mm)

OP Sum

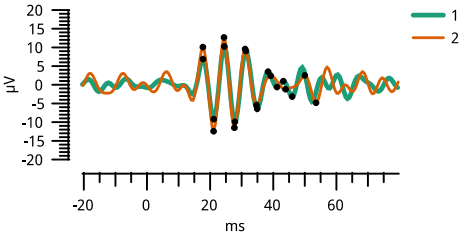
	ms 131.5 ↔ 171.5	µV 13.9 ↔ 86.2
1	157.0 (56%)	66.5 (82%)
2	157.5 (57%)	81.8 (95%)
	157.3 (56%)	74.1 (90%)



Left Eye (Pupil 5.3 mm)

OP Sum

	ms 131.5 ↔ 171.5	µV 13.9 ↔ 86.2
1	155.2 (49%)	59.9 (74%)
2	162.4 (85%)	72.6 (88%)
	158.8 (62%)	66.2 (81%)



Right Eye Oscillatory Potentials

	OP1		OP2		OP3		OP4		OP5	
	ms	µV	ms	µV	ms	µV	ms	µV	ms	µV
1	17.9	18.6	24.4	20.7	30.7	15.8	37.9	9.0	46.2	2.4
2	17.6	24.3	24.3	27.7	30.7	20.0	37.9	8.0	47.0	1.8

Left Eye Oscillatory Potentials

	OP1		OP2		OP3		OP4		OP5	
	ms	µV	ms	µV	ms	µV	ms	µV	ms	µV
1	17.8	16.1	24.5	20.2	31.3	15.4	38.4	4.1	43.2	4.1
2	17.7	22.5	24.4	24.2	31.1	15.0	39.2	3.6	50.0	7.3

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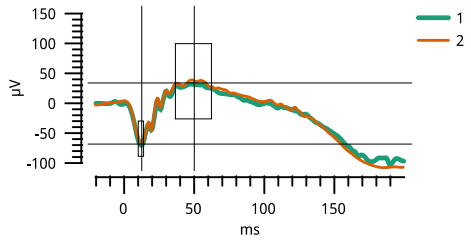
Patient ID: 123654
Test started: February 4, 2021, 10:11 AM

Birthdate: September 6, 1980
Report generated: February 4, 2021, 10:44 AM

Test #4: Flash: 280 Td·s, Chromaticity (0.33, 0.33) at 0.05 Hz Background: 0.0 Td

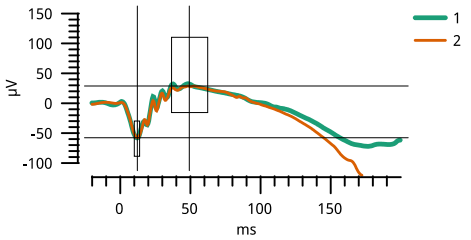
Right Eye (Pupil 5.9 mm)

	a-wave		b-wave	
	ms	µV	ms	µV
	10.1 ↔ 13.8	-29.6 ↔ -88.7	36.6 ↔ 62.3	42.2 ↔ 168
1	12.3 (46%)	-70.3 (87%)	49.5 (54%)	101 (88%)
2	12.8 (66%)	-66.2 (83%)	50.6 (67%)	103 (90%)
	12.5 (54%)	-68.3 (85%)	50.0 (59%)	102 (89%)



Left Eye (Pupil 4.4 mm)

	a-wave		b-wave	
	ms	µV	ms	µV
	10.1 ↔ 13.8	-29.6 ↔ -88.7	36.6 ↔ 62.3	42.2 ↔ 168
1	12.1 (39%)	-58.0 (70%)	48.3 (44%)	87.6 (69%)
2	12.2 (43%)	-57.5 (68%)	50.1 (60%)	85.4 (64%)
	12.2 (41%)	-57.8 (69%)	49.2 (51%)	86.5 (68%)



Light Adaptation

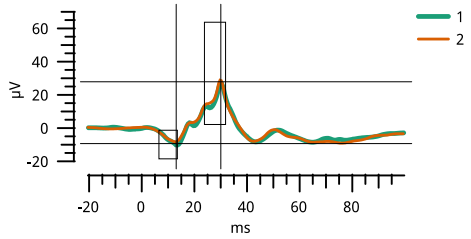
Right Eye

Start: 10:39 AM, Duration: 0 hour(s) 0 min(s)
Background: 0.0 cd/m²

Test #5: Flash: 85 Td·s, Chromaticity (0.33, 0.33) at 2 Hz Background: 850 Td, Chromaticity (0.33, 0.33)

Right Eye (Pupil 2.5 mm)

	a-wave		b-wave	
	ms	µV	ms	µV
	6.5 ↔ 13.5	-1.3 ↔ -18.5	23.8 ↔ 31.9	11.5 ↔ 73.0
1	13.4 (95%)	-10.3 (91%)	30.1 (80%)	37.0 (76%)
2	12.8 (81%)	-8.3 (72%)	29.9 (76%)	37.3 (76%)
	13.1 (87%)	-9.3 (84%)	30.0 (79%)	37.2 (76%)

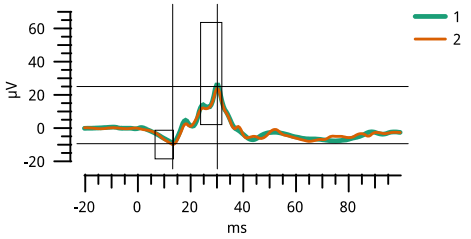


Left Eye

Start: 10:41 AM, Duration: 0 hour(s) 0 min(s)
Background: 0.0 cd/m²

Left Eye (Pupil 2.2 mm)

	a-wave		b-wave	
	ms	µV	ms	µV
	6.5 ↔ 13.5	-1.3 ↔ -18.5	23.8 ↔ 31.9	11.5 ↔ 73.0
1	13.2 (89%)	-8.9 (79%)	30.1 (80%)	35.1 (69%)
2	13.3 (92%)	-9.9 (88%)	30.1 (80%)	33.7 (66%)
	13.2 (91%)	-9.4 (85%)	30.1 (80%)	34.4 (68%)



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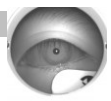
Patient ID: 123654
Test started: February 4, 2021, 10:11 AM

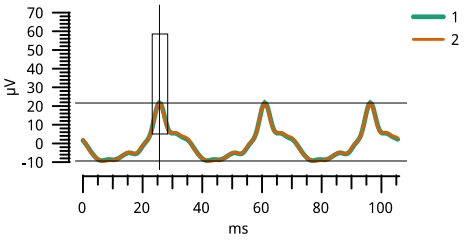
Birthdate: September 6, 1980
Report generated: February 4, 2021, 10:44 AM

Test #6: Flash: 85 Td·s, Chromaticity (0.33, 0.33) at 28.3 Hz Background: 850 Td, Chromaticity (0.33, 0.33)



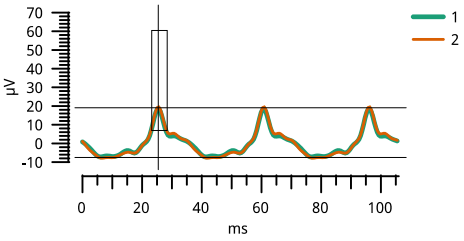
Right Eye (Pupil 2.6 mm)

	ms	µV
	23.2 ↔ 28.4	14.5 ↔ 68.0
1	25.7 (62%)	31.0 (61%)
2	25.6 (60%)	31.0 (62%)
	25.6 (61%)	31.0 (62%)



Left Eye (Pupil 2.2 mm)

	ms	µV
	23.2 ↔ 28.4	14.5 ↔ 68.0
1	25.4 (50%)	25.7 (39%)
2	25.4 (52%)	27.5 (46%)
	25.4 (51%)	26.6 (42%)



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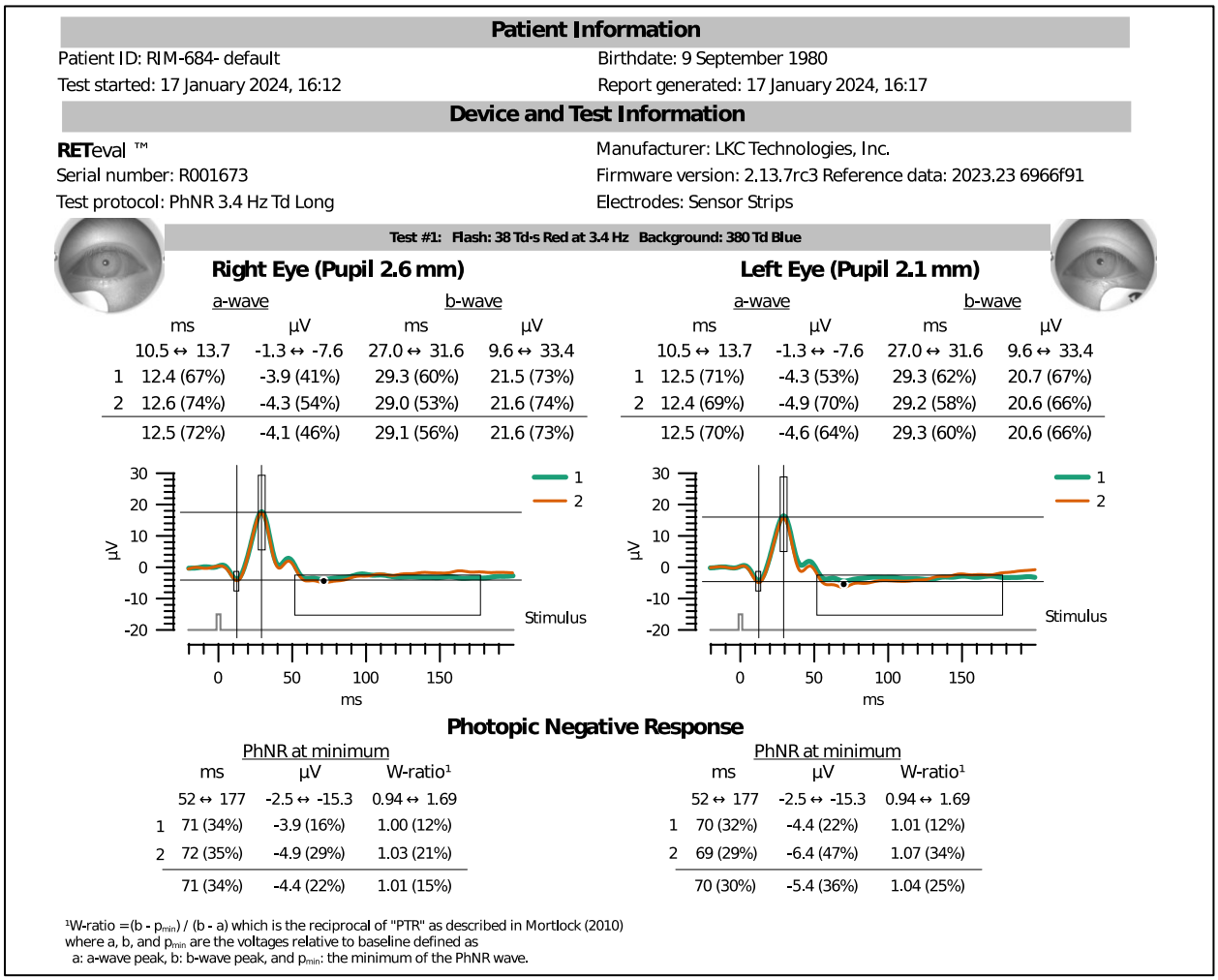
An example of a photopic negative response protocol with reference data is shown below. By default, the reference data coloring is not shown to reduce confusion between reference limits and clinical decision limits (See Page 58). To turn on/off coloring, see Color Coding on Page 11.



Patient Information

Patient ID: RIM-684- default
Birthdate: 9 September 1980
Test started: 17 January 2024, 16:12
Report generated: 17 January 2024, 16:17

Device and Test Information

RETeval ™
Manufacturer: LKC Technologies, Inc.
Serial number: R001673
Firmware version: 2.13.7rc3 Reference data: 2023.23 6966f91
Test protocol: PhNR 3.4 Hz Td Long
Electrodes: Sensor Strips

Test #1: Flash: 38 Td·s Red at 3.4 Hz Background: 380 Td Blue

Right Eye (Pupil 2.6 mm)

	a-wave ms	a-wave µV	b-wave ms	b-wave µV
	10.5 ↔ 13.7	-1.3 ↔ -7.6	27.0 ↔ 31.6	9.6 ↔ 33.4
1	12.4 (67%)	-3.9 (41%)	29.3 (60%)	21.5 (73%)
2	12.6 (74%)	-4.3 (54%)	29.0 (53%)	21.6 (74%)
	12.5 (72%)	-4.1 (46%)	29.1 (56%)	21.6 (73%)

Left Eye (Pupil 2.1 mm)

	a-wave ms	a-wave µV	b-wave ms	b-wave µV
	10.5 ↔ 13.7	-1.3 ↔ -7.6	27.0 ↔ 31.6	9.6 ↔ 33.4
1	12.5 (71%)	-4.3 (53%)	29.3 (62%)	20.7 (67%)
2	12.4 (69%)	-4.9 (70%)	29.2 (58%)	20.6 (66%)
	12.5 (70%)	-4.6 (64%)	29.3 (60%)	20.6 (66%)

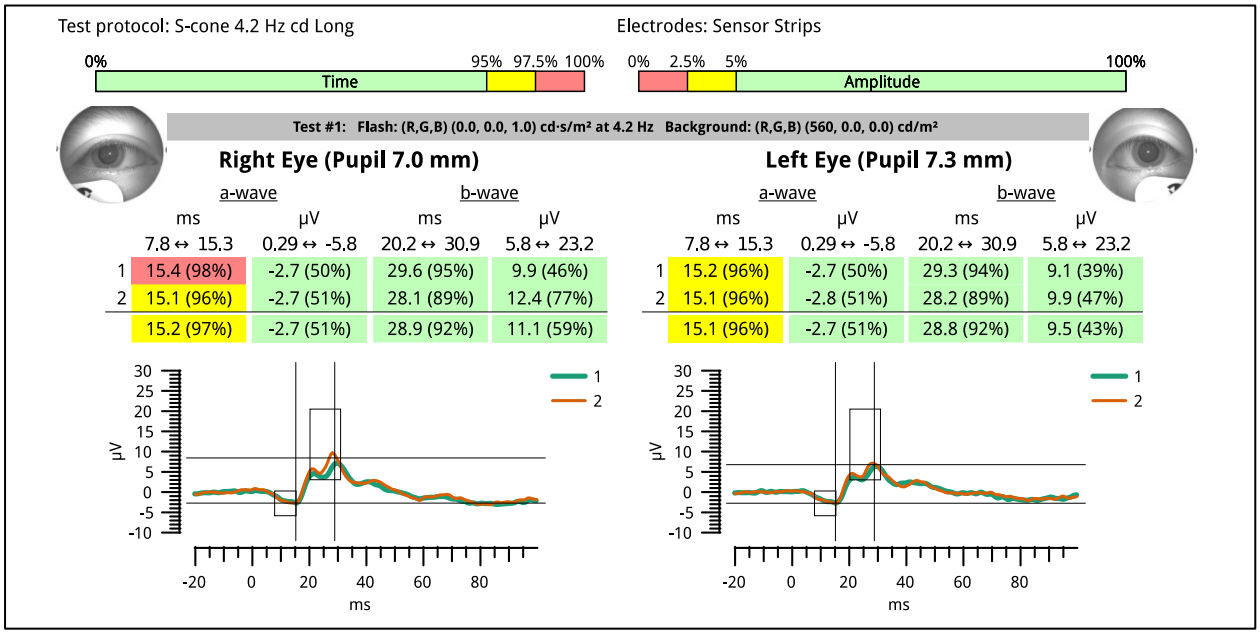
Photopic Negative Response

	PhNR at minimum ms	PhNR at minimum µV	PhNR at minimum W-ratio[1]
	52 ↔ 177	-2.5 ↔ -15.3	0.94 ↔ 1.69
1	71 (34%)	-3.9 (16%)	1.00 (12%)
2	72 (35%)	-4.9 (29%)	1.03 (21%)
	71 (34%)	-4.4 (22%)	1.01 (15%)

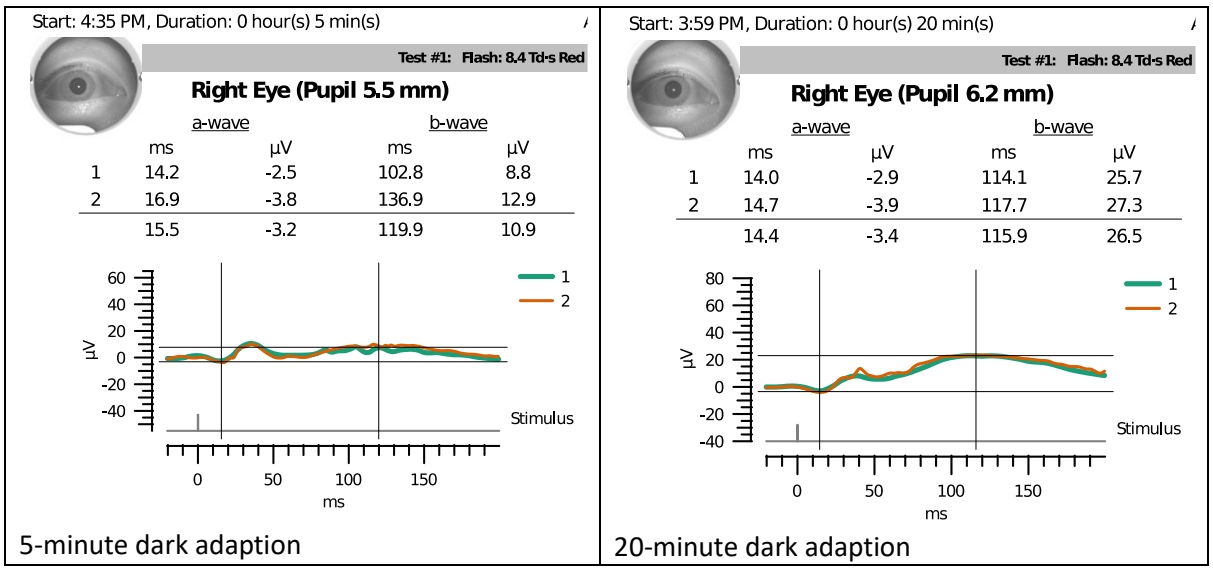
	PhNR at minimum ms	PhNR at minimum µV	PhNR at minimum W-ratio[1]
	52 ↔ 177	-2.5 ↔ -15.3	0.94 ↔ 1.69
1	70 (32%)	-4.4 (22%)	1.01 (12%)
2	69 (29%)	-6.4 (47%)	1.07 (34%)
	70 (30%)	-5.4 (36%)	1.04 (25%)

[1]W-ratio =(b - p_{min}) / (b - a) which is the reciprocal of "PTR" as described in Mortlock (2010)
where a, b, and p_{min} are the voltages relative to baseline defined as
a: a-wave peak, b: b-wave peak, and p_{min}: the minimum of the PhNR wave.

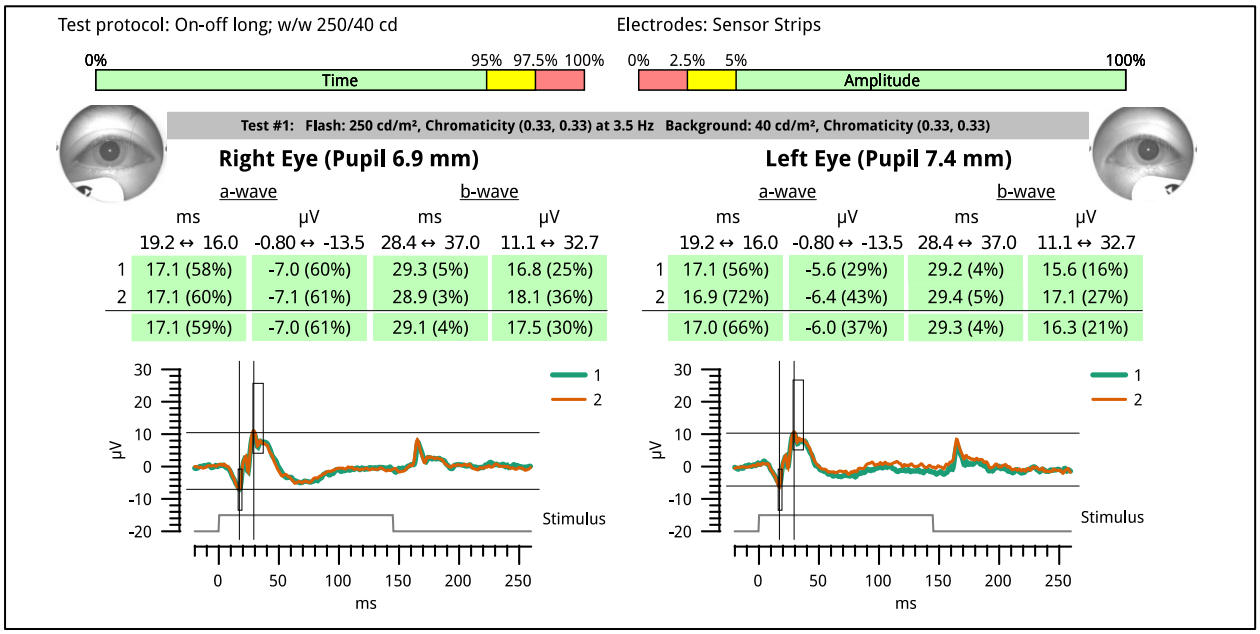
An example of an S-cone protocol is shown below. Note s-cone wave occurs just after 40 ms and is not the b-wave cursor, which is an LM-cone response (Gouras, MacKay, and Yamamoto 1993).



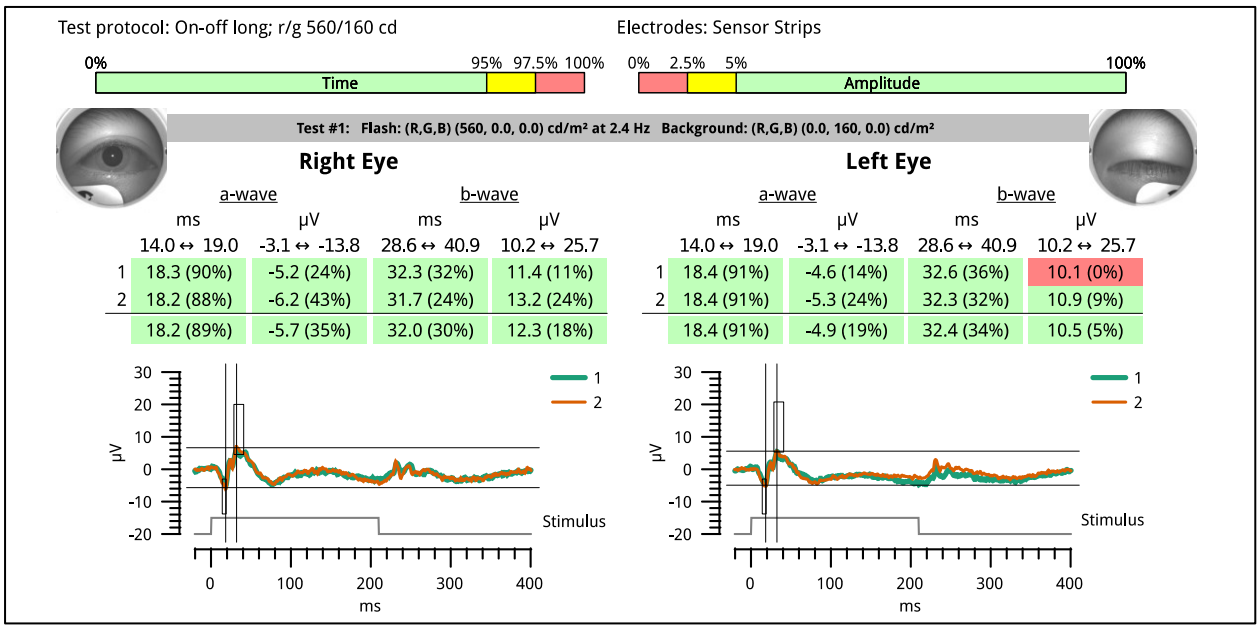
Examples of a DA red flash protocol are shown below. The left panel shows an eye with a 5-minute dark adaption time while the right panel shows the same eye after 20 minutes of dark adaption. The device does not have a separate x-wave cursor placement. There is no reference data for the DA red flash protocol. Nevertheless, the dark-adapted cone response at 30 - 40 ms is clearly separated from the dark-adapted rod response at 100 – 120 ms.



An example of the white/white on-off (long flash) protocol is shown below. The off response can be seen starting at about 163 ms, about 18 ms after the stimulus is turned off.



An example of the red/green on-off (long flash) protocol is shown below. The off response can be seen starting about 230 ms, about 21 ms after the stimulus is turned off, as indicated by the stimulus waveform.



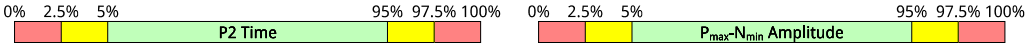
An example flash VEP report is shown below. In this report, the stimulation waveform is shown. See Page 11 for turning this feature on/off.

Patient Information

Patient ID: 456321
Birthdate: January 1, 1963
Test started: June 23, 2022, 2:49 PM
Report generated: June 24, 2022, 10:08 AM

Device and Test Information

RET*eval*™
Manufacturer: LKC Technologies, Inc.
Serial number: R13NE000117
Firmware version: 2.13.0 Reference data: 2022.13 991b51a
Test protocol: ISCEV Flash VEP: 24 Td·s
Electrodes: Gold cup



Reference data age range: 17-68

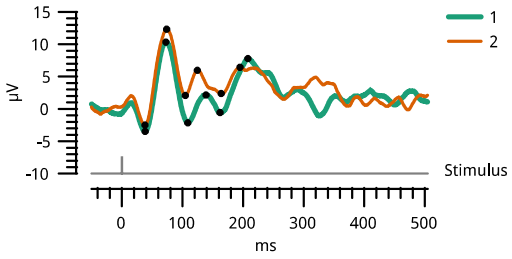
Flash: 24 Td·s White at 0.99 Hz Background: Off

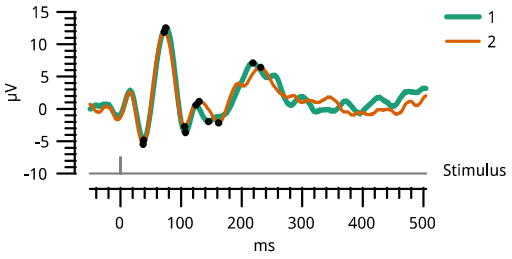
Right Eye (Pupil 3.0 mm)

	P2 ms	P_{max} - N_{min} µV
	85.5 ↔ 154.5	9.0 ↔ 27.2
1	138.7 (89%)	13.8 (29%)
2	124.5 (62%)	14.8 (38%)
	131.6	14.3

Left Eye (Pupil 2.8 mm)

	P2 ms	P_{max} - N_{min} µV
	85.5 ↔ 154.5	9.0 ↔ 27.2
1	124.6 (64%)	17.3 (56%)
2	129.9 (79%)	17.3 (56%)
	127.2	17.3





Right Eye

	N1		P1		N2		P2		N3		P3	
	ms	µV	ms	µV	ms	µV	ms	µV	ms	µV	ms	µV
1	38.2	-3.5	72.6	10.3	108.8	-2.2	138.7	2.1	161.9	-0.57	207.9	7.8
2	38.1	-2.5	73.8	12.3	104.7	2.1	124.5	6.0	163.8	2.4	194.9	6.4
	38.2	-3.0	73.2	11.3	106.7	-0.04	131.6	4.1	162.9	0.90	201.4	7.1

Left Eye

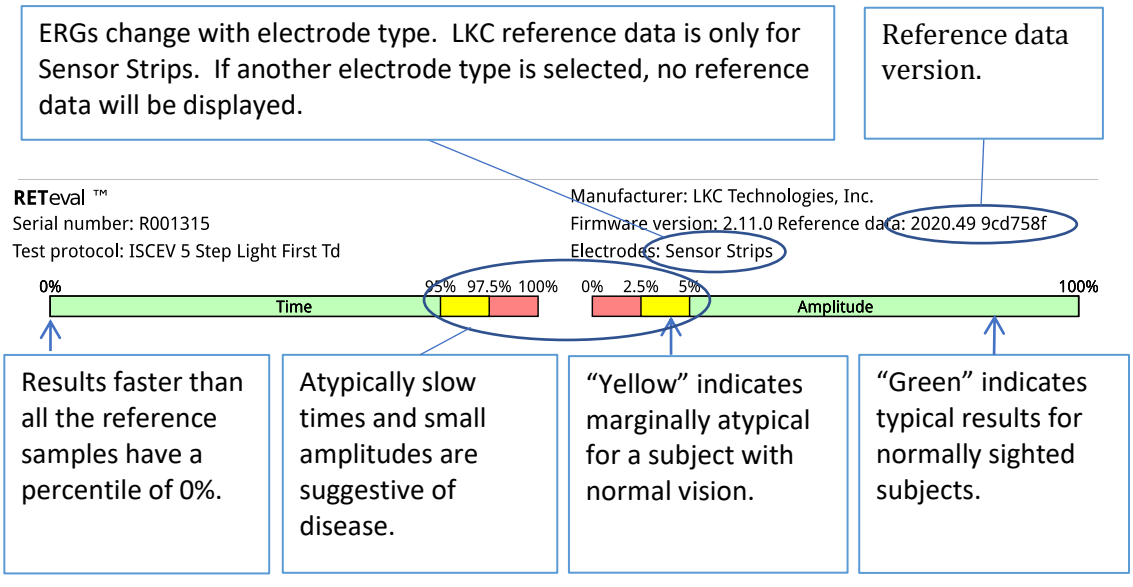
	N1		P1		N2		P2		N3		P3	
	ms	µV	ms	µV	ms	µV	ms	µV	ms	µV	ms	µV
1	38.1	-4.8	74.7	12.5	107.2	-3.6	124.6	0.61	145.4	-1.9	218.6	7.1
2	37.4	-5.5	72.3	11.9	105.8	-2.7	129.9	1.2	162.0	-2.1	231.5	6.4
	37.8	-5.1	73.5	12.2	106.5	-3.2	127.2	0.89	153.7	-2.0	225.1	6.8

Reference Intervals

LKC has gathered reference values (CLSI 2008; Davis and Hamilton 2021) to establish corresponding reference intervals. Reference intervals are sometimes referred to as "normal data" or "normative data".

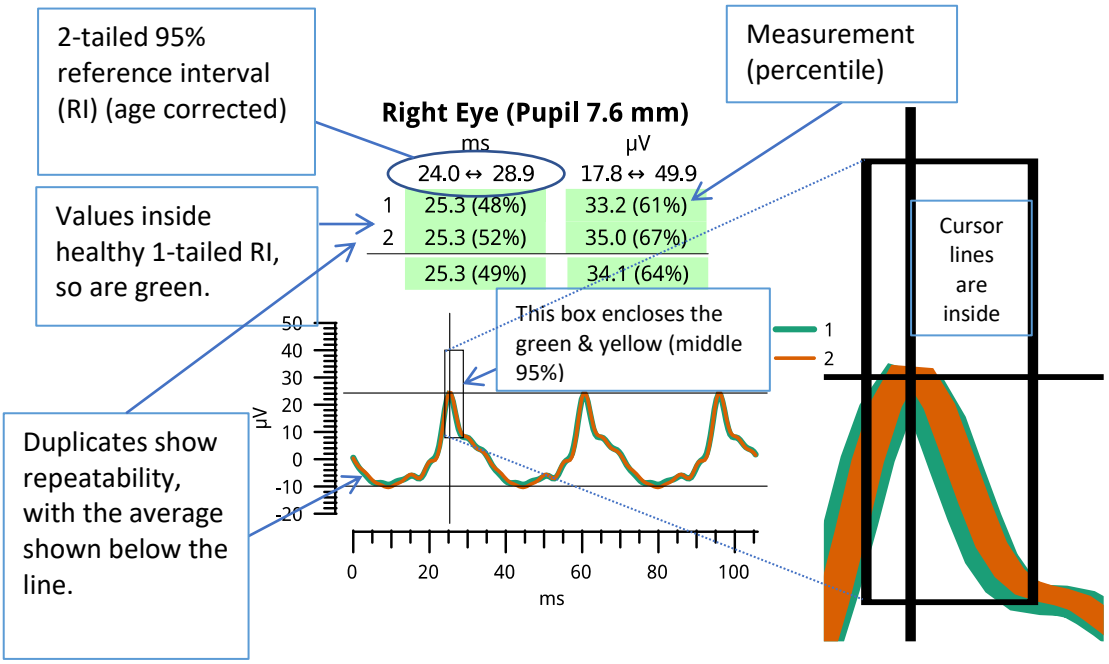
If reference data is available for a test and reference data reporting is on (see next section), age-matched reference data will automatically be displayed by the RETeval device. Please ensure both the birthdate and the system date on the RETeval device are correct for accurate age-matching of the reference interval information. ERG results also depend on the electrode type used. LKC's reference data was gathered using Sensor Strips and thus will only be shown if that electrode type is selected. Please ensure the correct electrode type is selected during the test.

Reference intervals can be used to compare an individual patient's measurements with those acquired in a normal population. All RETeval reference intervals (except OPs) are one-tailed, meaning that abnormally slow or small waveforms are colored yellow or red while fast or large waveforms, even if they are atypically fast or large, are colored green to better match what is known about how ERG waveforms are affected by disease. For timing, measurements from the 95th percentile to the 97.5th percentile are colored yellow and above the 97.5th are colored red. For amplitudes (and pupil area ratios), measurements from the 5th percentile to the 2.5th percentile are colored yellow and measurements smaller than the 2.5th percentile are colored red. Green (or the absence of color on the device UI) is used for the remaining 95% of the range. If a measurement is smaller than all the reference values, it has a percentile of 0%; if larger than all the reference values, 100%. The PDF report will also include the reference distribution percentile for each measurement.



In addition to the color coding and percentile reporting described above, the RETeval device also displays a rectangular box enclosing the middle 95% of values for most cursor measurements (2-tailed reference interval). Thus, it would be atypical for a patient with normal vision to have an ERG waveform peak outside this rectangular box. An atypical result

may still be colored green if it is not associated with disease (coloring follows the 1-tailed reference interval).



Using reference intervals as clinical decision limits

Clinicians must exercise judgement in the interpretation of a patient's result when compared to reference data. Never draw diagnostic conclusions from a single exam and heed the subject's medical history. It is the clinician's responsibility to make diagnostic interpretations of RETeval measurements.

Test specificity

Test specificity is the probability a test correctly identifies healthy subjects. About 1 in 40 visually normal subjects will be flagged as "red" and another 1 in 40 visually normal subjects will be flagged as "yellow". Thus, 1 in 20 visually normal subjects (5%) will not be marked as "green". Thus, if the reference interval is used as a clinical decision limit, the test specificity for "green" results is 95% and for "green or yellow" results is 97.5%.

Test sensitivity

Test sensitivity is the probability that a test will identify a diseased subject. Reference intervals are constructed only using healthy subjects. The effect that a particular disease has on any given test may be very large or may be nothing at all. By having 1-tailed reference intervals and only flagging atypical results in the direction associated with eye disease, test sensitivity is improved over 2-tailed reference intervals.

Turning reference data reporting on and off

Reference data reporting can be turned on and off through the user interface and through custom protocols. Turning off reference data can be useful, for example, if you know that the subjects you are testing are outside the reference population tested in the database

(e.g., testing subjects significantly outside the age range, testing natural-pupil subjects with constant luminance protocols, or testing non-human animals).

To see if reference data is currently enabled on the device, follow these steps:

Step 1. Turn on the RETeval device.

Step 2. Select **Settings** then **Reporting** then **Reference data**.

A protocol can set a flag to override this system default for displaying reference data. Please contact LKC support for assistance in creating a custom protocol that always shows (or always doesn't show) reference data.

Using your own reference data

The reference information database is located on the RETeval device in a folder called ReferenceData. The database is a text file that can be opened in any text editor (e.g., Notepad, vi, or Emacs). If you want to add your own reference data information, it can be added to this file and the RETeval device will automatically start using it. The reference data is version controlled by the year and week number as specified in the database file, along with the first 7 characters of a cryptographic hash (sha1) of the file. This information is displayed on the PDF report, so it is clear which reference data set is being used. During firmware updates, the current reference database will be saved as a backup in the same folder and replaced with a new reference database. Make backups of any changes you make to the reference database. Please contact LKC support for assistance in incorporating your own reference data.

The reference data released by LKC is version "2023.23 6966f91".

Reference data details

There are data from 562 reference individuals in the RETeval reference data, from 7 trial sites across the United States, Germany, China, and Canada. ERG reference data include 462 reference individuals while flash VEP include 100 reference individuals.

The reference individuals for ERG tests were 309 subjects aged 4 to 85 from 6 trial sites in the United States and Canada who were carefully examined to have normal vision. For the Troland-based ISCEV flicker test, data from an additional 153 children (aged 4 months to 18 years) are included (Zhang et al. 2021).

Dark adapted test results came from the Canadian site, which had 42 subjects aged 7 – 64 and used the protocol ISCEV 6 Step Dark First Td. This cohort has been published (Liu et al. 2018), although the analysis herein was done separately. These dark-adapted subjects all had the Troland version of the test, and these values are used in this reference data for both the Troland and candela version of the tests. All other tests used only the exact protocol in computing the reference data (i.e., the equivalence of the two stimulation methods was not used / assumed).

Eyes were classified as normal if the following criteria were met: BCVA of 20/25 (0.1 logMAR) or better, optic nerve cupping < 50%, no glaucoma or retinal diseases, no prior intraocular surgery (excepting non-complicated cataract or refractive surgery performed more than one year before), IOP ≤ 20 mmHg, no diabetes, and no diabetic retinopathy as determined by the ophthalmologist or optometrist. For children less than 3 years, there

was no BCVA requirement although they were required to have had term births (40 $\pm$ 2 weeks) and refractive errors between -3 D and +3 D (Zhang et al. 2021).

Some subjects (n=118) were tested after artificial dilation, while others were tested with natural pupils and constant Troland stimuli that compensate for pupil size (n=233+153 = 386). Dilated subjects who did not dilate to at least 6 mm were excluded from tests that did not compensate for pupil size.

The reference individuals for VEP tests came from a separate set of 100 subjects aged 17 to 68 from 1 trial site in Germany who were carefully examined to have normal vision. Subjects were classified as normal if they had a BCVA better than or equal to 20/25 (0.1 logMAR), and through an interview process determined to be free from having cardiovascular disease, diabetes, multiple sclerosis, epilepsy, migraine, Parkinson's, other neurologic diseases, glaucoma, macular degeneration, retinitis pigmentosa, optic neuritis, achromatopsia, cataract, and endocrine orbitopathy. The stimulus was 24 Td·s, and the resulting pupil diameter was 3.4 mm $\pm$ 0.95 mm (mean $\pm$ standard deviation). Because the pupil diameter was close to the 3.2 mm equivalent point for the constant luminance stimulus of 3 cd·s/m^2, these data are also used as reference data for the constant luminance stimulus test as well.

To calculate the reference intervals, far outliers (defined as 3 interquartile ranges away from the 25th and 75th percentiles) were removed after age correction. Replicates were averaged. Percentiles were computed from their rank (Schoonjans, De Bacquer, and Schmid 2011). No underlying distribution was assumed. A bootstrap method was used to compute the 90% confidence intervals of the 5% and 95% reference limits.

Age correction is generally done with a robust (bisquare) linear least squares fit. This method captures the age dependency smoothly, without (for example) jumps in the reference data every decade. For the ISCEV flicker waveform parameters, there is sufficient data for a more complex fit to better capture changes early in life. Here, a robust (bisquare) fit having an exponential term is added to the linear term to capture both maturation and slow decay (Zhang et al. 2021).

The tables below show the 5% and 95% reference limits, along with their 90% confidence intervals (CI). In addition, the median (50%) value in the reference data is shown. The data has been age adjusted to 0 years of age. The age coefficients (m, and when applicable a and τ) are also shown in the table. Use the following formulae to convert the reference limits in the table below to a particular age:

$$\text{ageCorrectedReference} = \text{referenceAtAge0} + \text{m} \times \text{age}$$

or

$$\text{ageCorrectedReference} = \text{referenceAtAge0} + \text{m} \times \text{age} + \text{a}(e^{-\text{age}/\tau} - 1)$$

where e is Euler's constant (2.71828….) and age is in years. For example, if m is negative (and a and τ aren't present), then the measurement is expected to decline with age, while if m is positive, the measurement is expected to increase with age.

Pupil area ratio. Flash: 32 Td·s : 4 Td·s white @ 28. Hz, Background: 0 Td white				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
Pupil area ratio	1.7 (1.6 – 1.7)	2.2 (2.1 – 2.2)	3.0 (2.8 – 3.3)	m = -0.00534

Pupil area ratio 4 to 16 Td-s. Flash: 16 Td·s : 4 Td·s white @ 28. Hz, Background: 0 Td white				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
Pupil area ratio 4 to 16	1.4 (1.4 – 1.5)	1.8 (1.8 – 1.9)	2.4 (2.3 – 2.5)	m = -0.00424
DR Score. Flash: 4, 16, and 32 Td·s white, Background: 0 Td white				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
DR Score	18.8 (18.1 – 19.6)	22.5 (21.9 – 23.0)	25.6 (25.1 – 26.2)	m = -0.0888
Light adapted 85 Td·s flicker ERG. Flash: 85 Td·s white @ 28. Hz, Background: 848 Td white				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
Fundamental implicit time / ms	23.1 (22.9 – 23.3)	24.7 (24.6 – 24.8)	26.8 (26.4 – 27.1)	m = 0.0388
Fundamental amplitude / µV	10.1 (9.7 – 10.7)	18.3 (17.9 – 18.8)	30.8 (29.4 – 32.9)	m = -0.0119
Waveform implicit time / ms	29.4 (29.3 – 29.5)	30.8 (30.8 – 30.9)	32.8 (32.5 – 33.1)	a = 6.72 τ= 2.53 m = 0.0311
Waveform amplitude / µV	2.4 (1.8 – 2.8)	14.3 (13.7 – 14.8)	31.9 (30.0 – 33.6)	a = -17.5 τ= 4.09 m = -0.0795
32 Td·s flicker ERG. Flash: 32 Td·s white @ 28. Hz, Background: 0 Td white				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
Fundamental implicit time / ms	24.2 (24.0 – 24.4)	25.7 (25.6 – 25.9)	27.8 (27.3 – 28.3)	m = 0.0556
Fundamental amplitude / µV	12.5 (11.2 – 13.4)	19.9 (19.0 – 20.7)	31.6 (29.9 – 33.0)	m = -0.0316
Waveform implicit time / ms	23.6 (23.4 – 24.0)	25.2 (25.1 – 25.3)	27.3 (27.0 – 27.7)	m = 0.0439
Waveform amplitude / µV	20.2 (19.5 – 21.4)	31.2 (30.0 – 32.1)	46.6 (44.6 – 47.8)	m = -0.0959
16 Td·s flicker ERG. Flash: 16 Td·s white @ 28. Hz, Background: 0 Td white				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
Fundamental implicit time / ms	25.4 (25.1 – 25.7)	27.1 (26.9 – 27.3)	29.7 (29.2 – 30.1)	m = 0.0601
Fundamental amplitude / µV	10.6 (9.9 – 11.3)	17.2 (16.7 – 17.9)	27.8 (26.2 – 29.1)	m = -0.0277
Waveform implicit time / ms	24.0 (23.8 – 24.2)	26.0 (25.8 – 26.2)	28.4 (28.0 – 29.0)	m = 0.0516
Waveform amplitude / µV	15.4 (14.7 – 16.3)	25.1 (24.2 – 25.8)	39.2 (37.6 – 40.8)	m = -0.0558
Pupil area ratio 4 to 16 Td·s	1.4 (1.4 – 1.5)	1.8 (1.8 – 1.9)	2.4 (2.3 – 2.5)	m = -0.00424
8 Td·s flicker ERG. Flash: 8 Td·s white @ 28. Hz, Background: 0 Td white				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
Fundamental implicit time / ms	27.3 (27.1 – 27.8)	29.6 (29.4 – 29.8)	32.1 (31.8 – 32.4)	m = 0.0526
Fundamental amplitude / µV	8.0 (7.3 – 8.5)	13.1 (12.6 – 13.7)	22.0 (20.8 – 23.2)	m = -0.0181
Waveform implicit time / ms	25.3 (25.0 – 25.5)	27.4 (27.2 – 27.6)	29.7 (29.5 – 30.0)	m = 0.0516
Waveform amplitude / µV	12.1 (11.3 – 12.8)	20.1 (19.5 – 20.6)	33.2 (31.7 – 34.5)	m = -0.0504
4 Td·s flicker ERG. Flash: 4 Td·s white @ 28. Hz, Background: 0 Td white				

Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
Fundamental implicit time / ms	30.8 (30.5 – 31.1)	33.0 (32.8 – 33.2)	35.0 (34.8 – 35.2)	m = 0.0447
Fundamental amplitude / µV	6.2 (5.9 – 6.4)	9.7 (9.1 – 10.0)	16.1 (15.3 – 16.7)	m = -0.0218
Waveform implicit time / ms	27.2 (27.0 – 27.5)	29.1 (28.9 – 29.2)	31.5 (31.0 – 31.8)	m = 0.0423
Waveform amplitude / µV	8.7 (8.4 – 9.3)	13.5 (13.0 – 14.1)	23.0 (22.1 – 23.9)	m = -0.0496
450 Td Sinusoidal flicker ERG. Flash: 450 Td peak white @ 28. Hz, Background: 0 cd/m²white				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
Fundamental implicit time / ms	27.6 (27.2 – 28.0)	29.9 (29.7 – 30.0)	32.1 (31.8 – 32.5)	m = 0.0379
Fundamental amplitude / µV	3.0 (2.7 – 3.3)	6.1 (5.8 – 6.4)	10.4 (9.7 – 11.2)	m = 0.000989
Waveform implicit time / ms	23.8 (23.5 – 24.2)	26.8 (26.4 – 27.1)	34.9 (34.4 – 35.6)	m = 0.033
Waveform amplitude / µV	3.7 (3.3 – 4.2)	7.1 (6.8 – 7.4)	12.2 (11.2 – 13.2)	m = 0.00653
900 Td Sinusoidal flicker ERG. Flash: 900 Td peak white @ 28. Hz, Background: 0 cd/m²white				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
Fundamental implicit time / ms	25.3 (25.0 – 25.7)	27.3 (27.1 – 27.5)	29.1 (28.9 – 29.4)	m = 0.036
Fundamental amplitude / µV	4.3 (4.0 – 4.6)	8.0 (7.7 – 8.4)	14.5 (13.1 – 15.8)	m = 0.000391
Waveform implicit time / ms	21.3 (21.2 – 21.6)	23.8 (23.6 – 24.0)	29.3 (28.6 – 30.0)	m = 0.0414
Waveform amplitude / µV	4.6 (4.4 – 4.9)	9.2 (8.8 – 9.6)	18.2 (16.0 – 19.9)	m = 0.0128
1800 Td Sinusoidal flicker ERG. Flash: 1800 Td peak white @ 28. Hz, Background: 0 cd/m²white				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
Fundamental implicit time / ms	23.5 (23.3 – 23.7)	25.3 (25.1 – 25.4)	27.0 (26.8 – 27.2)	m = 0.0385
Fundamental amplitude / µV	4.5 (4.1 – 5.1)	9.1 (8.8 – 9.4)	16.4 (14.8 – 18.3)	m = 0.00752
Waveform implicit time / ms	19.7 (19.5 – 19.9)	22.1 (21.9 – 22.3)	26.8 (25.7 – 28.2)	m = 0.0477
Waveform amplitude / µV	4.8 (4.5 – 5.3)	10.7 (10.2 – 11.1)	20.2 (17.7 – 22.5)	m = 0.0218
3600 Td Sinusoidal flicker ERG. Flash: 3600 Td peak white @ 28. Hz, Background: 0 cd/m²white				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
Fundamental implicit time / ms	22.6 (22.4 – 22.8)	24.3 (24.2 – 24.4)	26.0 (25.8 – 26.2)	m = 0.0369
Fundamental amplitude / µV	5.0 (4.6 – 5.4)	10.0 (9.6 – 10.4)	17.9 (15.9 – 19.6)	m = 0.0157
Waveform implicit time / ms	19.7 (19.6 – 20.0)	21.9 (21.7 – 22.2)	25.8 (25.2 – 26.3)	m = 0.0448
Waveform amplitude / µV	5.7 (5.3 – 6.1)	11.9 (11.3 – 12.3)	21.3 (19.2 – 23.1)	m = 0.0289
Light adapted 85 Td·s ERG. Flash: 85 Td·s white @ 2. Hz, Background: 848 Td white				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
a-wave / ms	9.4 (9.3 – 9.7)	11.1 (11.0 – 11.2)	12.8 (12.7 – 12.9)	m = 0.015
a-wave / µV	-2.4 (-2.9 – -1.9)	-7.0 (-7.2 – -6.8)	-11.6 (-12.2 – -11.1)	m = 0.0071
b-wave / ms	25.7 (25.5 – 25.9)	27.7 (27.6 – 27.7)	29.9 (29.8 – 30.1)	m = 0.0326
b-wave / µV	16.3 (15.0 – 17.8)	31.8 (30.7 – 32.8)	53.6 (50.8 – 56.0)	m = -0.0662

38 Td·s PhNR. Flash: 38 Td·s red @ 3.4 Hz, Background: 380 Td blue				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
a-wave / ms	10.0 (9.8 – 10.2)	11.3 (11.2 – 11.4)	12.6 (12.4 – 12.8)	m = 0.0177
a-wave / µV	-1.2 (-1.5 – -0.9)	-3.5 (-3.7 – -3.4)	-6.4 (-6.7 – -6.1)	m = -0.0156
b-wave / ms	24.8 (24.5 – 25.0)	26.5 (26.3 – 26.6)	28.8 (28.2 – 29.1)	m = 0.0577
b-wave / µV	8.1 (7.4 – 9.6)	16.1 (15.0 – 16.9)	27.2 (25.2 – 29.8)	m = 0.0513
PhNR min time / ms	63.9 (62.2 – 65.9)	87.6 (84.1 – 92.0)	181.0 (168.0 – 188.0)	m = -0.233
PhNR / µV	-4.6 (-4.8 – -4.4)	-8.4 (-8.7 – -8.0)	-15.5 (-16.6 – -14.4)	m = 0.0395
PhNR @ 72 ms / µV	-1.1 (-1.7 – -0.7)	-5.0 (-5.4 – -4.7)	-10.8 (-11.7 – -9.6)	m = 0.0136
PhNR P-ratio	0.1 (0.1 – 0.2)	0.4 (0.4 – 0.4)	0.8 (0.8 – 0.9)	m = -0.00202
PhNR W-ratio	1.1 (1.1 – 1.1)	1.2 (1.2 – 1.3)	1.7 (1.6 – 1.8)	m = -0.00285
Light adapted 3 cd·s/m² ERG. Flash: 3 cd·s/m² white @ 2. Hz, Background: 30 cd/m² white				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
a-wave / ms	10.3 (9.9 – 10.5)	11.6 (11.4 – 11.9)	13.4 (12.9 – 13.9)	m = 0.0134
a-wave / µV	-4.5 (-5.5 – -3.3)	-8.3 (-8.9 – -7.7)	-15.1 (-16.8 – -12.6)	m = 0.0164
b-wave / ms	25.2 (24.8 – 25.7)	27.3 (27.0 – 27.5)	29.4 (28.6 – 30.1)	m = 0.0404
b-wave / µV	22.5 (19.1 – 26.6)	39.5 (37.3 – 41.9)	60.6 (53.8 – 65.6)	m = -0.091
Light adapted 3 cd·s/m² flicker ERG. Flash: 3 cd·s/m² white @ 28. Hz, Background: 30 cd/m² white				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
Fundamental implicit time / ms	22.9 (22.6 – 23.4)	24.8 (24.3 – 25.2)	26.8 (25.7 – 28.2)	m = 0.0443
Fundamental amplitude / µV	13.1 (11.4 – 14.8)	20.9 (18.7 – 23.0)	31.4 (27.2 – 37.3)	m = -0.00629
Waveform implicit time / ms	23.0 (22.9 – 23.1)	24.2 (24.0 – 24.4)	26.1 (24.9 – 27.7)	m = 0.0276
Waveform amplitude / µV	22.5 (21.0 – 23.8)	35.0 (32.2 – 37.0)	51.7 (47.3 – 55.0)	m = -0.0816
3 cd·s/m² flicker ERG. Flash: 3 cd·s/m² white @ 28. Hz, Background: 0 cd/m² white				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
Fundamental implicit time / ms	23.2 (22.9 – 23.6)	25.2 (24.8 – 25.6)	27.5 (26.7 – 28.6)	m = 0.0546
Fundamental amplitude / µV	18.9 (16.6 – 21.7)	29.0 (27.1 – 30.5)	44.5 (38.2 – 51.2)	m = -0.0165
Waveform implicit time / ms	22.6 (22.1 – 23.0)	24.4 (23.9 – 24.9)	26.9 (25.7 – 28.6)	m = 0.0466
Waveform amplitude / µV	30.5 (29.3 – 31.7)	44.0 (41.4 – 47.0)	69.2 (62.3 – 73.6)	m = -0.126
1.0 cd·s/m² PhNR. Flash: 1 cd·s/m² red @ 3.4 Hz, Background: 10 cd/m² blue				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
a-wave / ms	11.1 (11.0 – 11.3)	12.1 (11.9 – 12.2)	13.3 (12.8 – 13.9)	m = 0.0145
a-wave / µV	-1.3 (-2.0 – -0.7)	-3.1 (-3.4 – -2.7)	-5.9 (-7.1 – -4.9)	m = -0.02
b-wave / ms	23.1 (22.6 – 23.6)	25.0 (24.7 – 25.3)	28.2 (27.6 – 28.8)	m = 0.0631
b-wave / µV	10.6 (9.6 – 12.2)	18.5 (15.7 – 21.1)	28.8 (27.1 – 30.7)	m = 0.0392
PhNR min time / ms	61.1 (58.5 – 65.0)	88.0 (81.1 – 97.7)	182.0 (173.0 – 189.0)	m = -0.218

PhNR / µV	-3.4 (-4.3 – -2.8)	-7.1 (-8.0 – -6.3)	-16.7 (-20.2 – -13.6)	m = 0.025
PhNR @ 72 ms / µV	1.3 (-0.1 – 2.8)	-2.6 (-3.2 – -2.0)	-10.0 (-11.6 – -7.5)	m = -0.019
PhNR P-ratio	-0.1 (-0.2 – -0.0)	0.1 (0.1 – 0.2)	0.5 (0.4 – 0.6)	m = 0.00186
PhNR W-ratio	1.0 (1.0 – 1.1)	1.2 (1.1 – 1.2)	1.6 (1.5 – 1.8)	m = -0.00171
1.0 cd·s/m² S-cone. Flash: 1 cd·s/m² blue @ 4.2 Hz, Background: 560 cd/m² red				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
a-wave / ms	8.1 (7.0 – 10.4)	12.3 (11.6 – 13.0)	14.8 (14.5 – 15.2)	m = 0.00343
a-wave / µV	-1.2 (-2.2 – -0.1)	-3.2 (-3.5 – -2.8)	-5.2 (-5.9 – -4.5)	m = 0.0122
b-wave / ms	18.7 (18.2 – 19.6)	24.6 (23.9 – 25.1)	28.0 (26.3 – 29.8)	m = 0.0385
b-wave / µV	6.4 (5.7 – 7.9)	10.4 (9.4 – 11.5)	16.9 (12.9 – 22.9)	m = -0.00637
560/160 cd/m² red/green on-off. Flash: 560 cd/m² on-off red @ 2.4 Hz, Background: 160 cd/m² green				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
a-wave / ms	14.5 (13.8 – 15.4)	16.8 (16.6 – 17.0)	18.0 (17.7 – 18.5)	m = 0.0119
a-wave / µV	-2.4 (-3.3 – -1.8)	-5.6 (-6.2 – -5.1)	-9.0 (-11.3 – -7.4)	m = -0.0219
b-wave / ms	25.6 (24.9 – 26.2)	29.3 (28.3 – 30.3)	35.0 (33.6 – 36.9)	m = 0.107
b-wave / µV	9.5 (9.0 – 10.2)	16.5 (14.8 – 17.7)	23.0 (20.8 – 24.7)	m = 0.0248
250/50 cd/m² white/white on-off. Flash: 250 cd/m² on-off white @ 3.5 Hz, Background: 40 cd/m² white				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
a-wave / ms	18.3 (17.8 – 18.8)	16.9 (16.8 – 17.0)	15.9 (15.6 – 16.2)	m = 0.00643
a-wave / µV	-2.7 (-4.1 – -0.4)	-6.3 (-6.8 – -6.0)	-11.1 (-13.0 – -9.0)	m = -0.0059
b-wave / ms	26.3 (25.3 – 27.1)	29.8 (29.5 – 30.2)	32.9 (32.2 – 33.8)	m = 0.0785
b-wave / µV	11.6 (10.2 – 13.4)	19.4 (18.0 – 21.6)	29.9 (26.8 – 32.1)	m = 0.0066
Dark adapted 0.28 Td·s ERG. Flash: 0.28 Td·s white @ 0.5 Hz, Background: 0 Td **Dark adapted 0.01 cd·s/m² ERG. Flash: 0.01 cd·s/m² white @ 0.5 Hz, Background: 0 cd/m²**				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
b-wave / ms	63.4 (60.6 – 65.8)	76.3 (74.2 – 77.9)	94.9 (91.1 – 98.4)	m = 0.453
b-wave / µV	16.4 (12.0 – 22.0)	36.0 (34.1 – 37.6)	61.8 (57.0 – 68.9)	m = 0.185
Dark adapted 85 Td·s ERG. Flash: 85 Td·s white @ 0.1 Hz, Background: 0 Td **Dark adapted 3 cd·s/m² ERG. Flash: 3 cd·s/m² white @ 0.1 Hz, Background: 0 cd/m²**				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
a-wave / ms	12.3 (12.0 – 13.1)	14.3 (14.0 – 14.7)	18.9 (16.8 – 20.0)	m = 0.0289
a-wave / µV	-19.9 (-23.0 – -17.4)	-36.8 (-38.8 – -34.8)	-55.7 (-62.7 – -49.5)	m = -0.072
b-wave / ms	39.0 (37.1 – 40.5)	45.0 (43.7 – 46.7)	56.0 (52.9 – 59.3)	m = 0.0682
b-wave / µV	37.6 (28.0 – 44.9)	63.6 (57.9 – 71.7)	107.0 (88.9 – 125.0)	m = 0.119
OP total time / ms	128.0 (123.0 – 134.0)	148.0 (146.0 – 150.0)	162.0 (156.0 – 166.0)	m = 0.187
OP total amplitude / µV	18.0 (12.3 – 30.7)	49.3 (45.7 – 52.7)	83.3 (75.1 – 91.8)	m = -0.0565
Dark adapted 283 Td·s ERG. Flash: 283 Td·s white @ 0.05 Hz, Background: 0 Td				

Dark adapted 10 cd·s/m² ERG. Flash: 10 cd·s/m² white @ 0.05 Hz, Background: 0 cd/m²				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age coefficients
a-wave / ms	9.8 (9.4 – 10.1)	11.4 (11.2 – 11.7)	12.7 (12.4 – 12.9)	m = 0.0233
a-wave / µV	-22.7 (-26.1 – -19.5)	-43.7 (-45.9 – -41.9)	-68.4 (-76.0 – -61.3)	m = -0.231
b-wave / ms	40.1 (38.6 – 41.4)	46.8 (45.6 – 47.8)	58.2 (53.1 – 61.2)	m = 0.0573
b-wave / µV	35.8 (30.8 – 45.2)	67.0 (60.8 – 73.5)	109.0 (95.1 – 122.0)	m = 0.21
24 Td·s Flash VEP. Flash: 24 Td·s white @ 0.99 Hz, Background: 0 Td **3 cd·s/m² Flash VEP. Flash: 3 cd·s/m² white @ 0.99 Hz, Background: 0 cd/m²**				
Cursor	5% limit (90% CI)	50% (90% CI)	95% limit (90% CI)	Age slope
n1 Amplitude / µV	-13.5 (-14.2 – -12.8)	-7.7 (-8.2 – -7.2)	-3.9 (-4.4 – -3.4)	-0.00197
n2 Amplitude / µV	-9.4 (-11.4 – -8.3)	-4.0 (-4.5 – -3.5)	2.0 (0.5 – 3.1)	0.0371
n3 Amplitude / µV	-14.4 (-15.6 – -12.9)	-6.1 (-6.7 – -5.5)	0.3 (-0.9 – 1.2)	0.103
p1 Amplitude / µV	-2.5 (-3.3 – -1.7)	3.0 (2.4 – 3.5)	10.4 (8.8 – 12.0)	0.0492
p2 Amplitude / µV	-1.0 (-2.3 – 0.1)	4.7 (4.1 – 5.2)	11.6 (10.7 – 12.6)	0.0436
p3 Amplitude / µV	0.2 (-0.6 – 1.0)	5.9 (5.3 – 6.4)	11.6 (10.7 – 12.2)	-0.0024
n1 Time / ms	35.1 (34.9 – 35.4)	39.5 (39.2 – 39.9)	50.9 (47.8 – 54.0)	-0.00433
n2 Time / ms	80.3 (78.3 – 82.3)	99.9 (98.1 – 102.0)	120.0 (114.0 – 127.0)	-0.0976
n3 Time / ms	118.0 (113.0 – 122.0)	139.0 (135.0 – 141.0)	178.0 (168.0 – 188.0)	0.233
p1 Time / ms	59.5 (57.9 – 60.8)	71.7 (70.0 – 73.2)	87.2 (83.1 – 91.8)	-0.0475
p2 Time / ms	75.6 (70.2 – 79.5)	104.0 (100.0 – 107.0)	134.0 (127.0 – 139.0)	0.271
p3 Time / ms	160.0 (156.0 – 168.0)	193.0 (190.0 – 195.0)	240.0 (229.0 – 248.0)	-0.131
P_{max} - N_{min} Amplitude / µV	8.1 (7.1 – 9.4)	14.3 (13.6 – 15.2)	22.8 (21.6 – 24.6)	0.0328

Troubleshooting Hints

The RETeval 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 Support at support@lkc.com. Note any error number shown in your email message.

Charge the battery when the charge is low

When the RETeval 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.

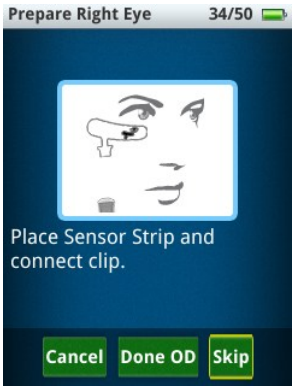
Measure the patient's right eye first

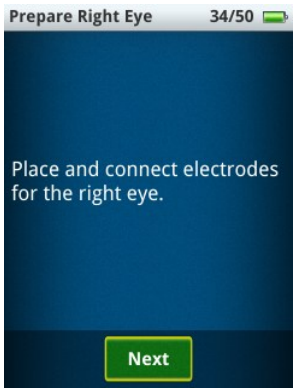
The RETeval device is designed to measure the patient's right eye first. If you only want to measure a patient's left eye, use the skip button to proceed past the right eye screen without testing the patient. The default is to test both eyes. Using the skip button, you can test only the right eye or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

Place the Sensor Strips under the correct eye

The RETeval Sensor Strips are specific for right and left eyes. Erroneous results will occur if the Sensor Strips are used with the wrong eye. Flicker timings will be wrong by about 18 ms. If you suspect the Sensor Strips were used with the wrong eye, repeat the test with a new pair of correctly applied Sensor Strips. The Sensor Strips have a pictograph to guide you in proper placement. See also Page 14 for photos of proper placement.

The device doesn't show the Next button after I connect to the Sensor Strip (or other electrode type) or after pressing the Start test button, I get an "The electrodes have been disconnected" error



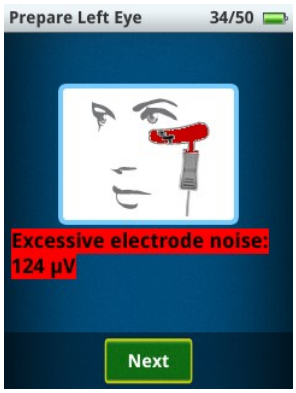


The RETeval device monitors the electrical impedance of the connection between pads on the Sensor Strip or other electrode types. If the impedance is too high, the Next button won't be displayed. During a test, if the electrical impedance gets too high or the inputs saturate the analog to digital converter, the "electrodes disconnected" message is

displayed. The impedance and/or electrode noise can be too high because of the following reasons:

1. The Sensor Strip lead is not correctly connected to the Sensor Strip. Try unclipping and reconnecting the lead. Ensure the blue lever on the lead is away from the patient's skin.
2. The Sensor Strip is poorly connected to the patient's skin. Ensure the Sensor Strip is not resting on the patient's sideburns or on heavy makeup. Press down lightly on the three electrode gel pads on each Sensor Strip to ensure the Sensor Strip is sticking well. Clean the skin with NuPrep® (made by Weaver and company and sold on the LKC store, https://store.lkc.com), soap and water or an alcohol wipe and reapply the Sensor Strip.
3. The Sensor Strip may be defective, try another Sensor Strip.

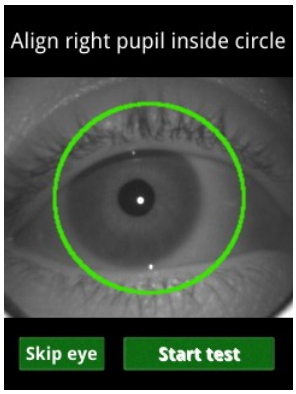
The device shows "Excessive electrode noise"



The RETeval device monitors the electrical noise of the connection between pads on the Sensor Strip or other electrode types. 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 Hz – 186 Hz to robustly estimate the peak-to-peak noise. If the electrode noise exceeds 55 µV for single-flash tests, 140 µV for VEP tests, or 5500 µV 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. You can toggle on and off displaying the noise when its level is acceptable by going to Settings then Testing then Display noise. The noise may be high for the following reasons:

1. The patient may be generating excessive electromyogram noise by grimacing or talking.
2. The impedance of the Sensor Strip or other electrode is too high. Ensure the Sensor Strip or other electrode type is not resting on the patient's sideburns or on heavy makeup. Press down lightly on the three electrode gel pads on each Sensor Strip to ensure the Sensor Strip is sticking well. Clean the skin with NuPrep® (made by Weaver and company and sold on the LKC store, https://store.lkc.com), soap and water or an alcohol wipe and reapply the Sensor Strip.
3. The Sensor Strip may be defective, try another Sensor Strip.

The device won't let me press the Start test button when I can see the eye



When using Troland-based protocols, the RETeval device measures the pupil size and adjusts the brightness of the flickering light for each flash based upon the pupil size. The Start test button is only enabled after the pupil is located. During a test, if the device cannot find the pupil for durations long compared to normal blink, the device generates the "pupil can no longer be found" error. The device may not be able to locate the pupil for the following reasons:

1. The eyelids are closed. Ask the patient to open their eyes.
2. An eyelid is obscuring all or part of the pupil. Ensure that the patient is covering their other eye with the palm of their hand. Ask the patient to open their eyes wider. Drooping eyelids that cover part of the pupil may require the operator to manually hold them open wider during the test. Use the eyecup to keep the eyelid open by using the thumb and forefinger to lift the patient's eyebrow upwards and simultaneously gently pull down on the skin below the eye while securing the eyecup in place.
3. The patient isn't looking at the red light. The bright glint dot in the figure in this section should be inside or near the pupil if the patient is looking at the red light. Ask the patient to look at the red light.
4. If the device cannot find the patient's pupil, testing cannot be performed with a Td protocol; run a cd protocol instead. If you believe that the device should have been able to find a pupil, switch to a cd protocol and send the resulting .rff file to LKC (support@lkc.com) for analysis. The .rff file is located in Data directory on the device.

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

The flicker implicit time changes with illumination levels. External light that reaches the eye under test can therefore affect results (making the timing faster). The eyecup is designed to block external light from reaching the eye. If the RETeval 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:

1. Rotate the RETeval device so the eyecup better contacts the skin around the eye.
2. Hold your hand near the patient's temple to block the light with your hand.
3. 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

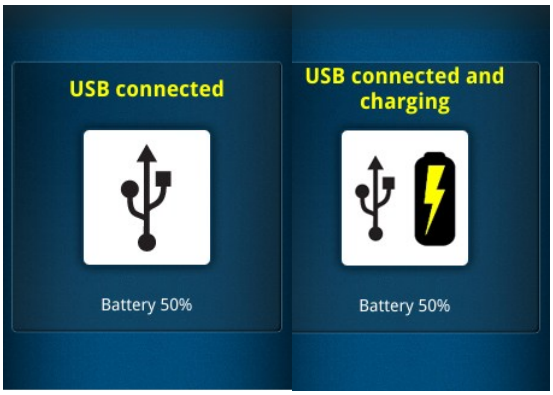
The RETeval device, after checking for ambient light, recalibrates the flash intensity and color to match the factory-calibrated settings. The white interior sphere that the patient looks into (the ganzfeld) redirects light from red, green, and blue LEDs to create a uniform, diffuse white light. A small change in the light reflectance of the ganzfeld will create a large change in the color or intensity of the light output, which is corrected by this recalibration. If the correction is too large, the RETeval 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 79) will improve the access to the ganzfeld for cleaning.

The screen is blank but the power light is on

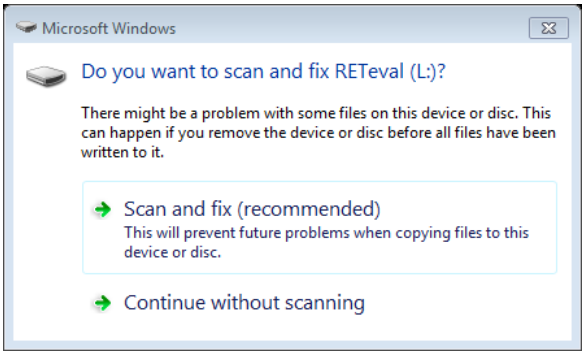
You can turn the device off at any time by pressing the power button and holding it down for at least 1 second. The screen goes blank immediately, but the device takes a few more seconds to turn off completely. If the power button is pressed just after the last blink, the display will fail to turn back 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, which is located in the handle of the device.

The RETeval device won't connect to my PC



The RETeval device acts like a USB drive, and therefore should connect to any modern PC that has a USB port, independent of the operating system. The RETeval device connects to your PC through the provided USB cable through the docking station and into the hand-held portion. USB power is indicated on the RETeval screen with one of the following two images. If one of these images isn'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 RETeval 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 LKC for service (+1 301 840 1992 or email support@lkc.com).

I get a "scan and fix" error from Windows® when placing the RETeval device in the docking station



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

Results are "not measurable"

The RETeval device attempts to quantify ERG results with automatically placed cursors. In some cases, with low signal-to-noise 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 (Grace et al. 2017). If testing non-human animals, the waveform timing may be sufficiently different than humans 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 RETeval device to the factory default settings. Follow these steps if there are problems with the device or if advised to do so by Support:

Step 1. Turn on the RETeval device.

Step 2. Select **Settings**, then **System**, then **Reset Settings**.

Step 3. 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
- Practice name
- Practice address
- Backlight
- Protocol

To put the RETeval 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.

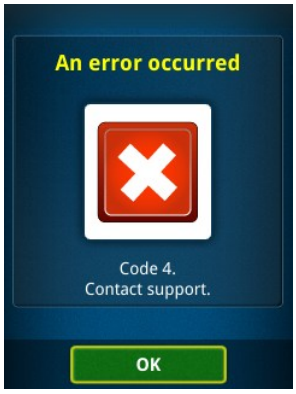
Step 1. Turn on the RETeval device. If the device is already on, turn it off, wait 5 seconds, then turn it back on.

Step 2. Select the second to the bottom of the 4 menu items (Settings) from the menu.

Step 3. Select the top menu item (Language).

Step 4. 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 call LKC for service (+1 301 840 1992 or email support@lkc.com). In addition, save and send to LKC any files found in the /Diagnostics folder on the device. Pressing OK will cause the RETeval device to reboot, which may correct the problem.

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Regulatory and Safety Information

RETeval is the product name, trade name, and reference name for this device.

Applicability

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

Intended use / Intended purpose

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

Intended users

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

Indications for use

RETeval is indicated for use in the measurement of visual electrophysiological potentials, including electroretinogram (ERG) and visual evoked potential (VEP). RETeval is also indicated for use in the measurement of pupil diameter.

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

Intended Target Groups

There are no specific intended target groups.

Clinical Benefit

Assist health care professionals with diagnosis and management of ophthalmic or visual pathway dysfunction/disease or to ensure drug safety.

Latex statement

The components of the RETeval 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.

Reporting of serious incidents

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Specifications

<table>
<tr><td>Light source</td><td>
<table>
<tr><th></th><th>Red LED (621 nm)</th><th>Green LED (530 nm)</th><th>Blue LED (470 nm)</th><th>White (RGB)</th></tr>
<tr><td>Flash luminance energies (cd·s/m^2)</td><td>0.0001 – 15</td><td>0.001 – 17</td><td>0.0001 – 5</td><td>0.002 – 30</td></tr>
<tr><td>Background luminance (cd/m^2)</td><td>0.03 – 3000</td><td>0.2 – 3500</td><td>0.03 – 1200</td><td>0.4 – 6000</td></tr>
</table>
To convert to Trolands, multiply luminance by the pupil area in mm^2.
</td></tr>
<tr><td>Input Type</td><td>Custom 3 pin connector with positive, negative, and right leg drive signals.</td></tr>
<tr><td>Noise</td><td>< 0.1 µVrms at the flicker frequency for flicker protocols</td></tr>
<tr><td>CMRR</td><td>> 100 dB at 50-60 Hz</td></tr>
<tr><td>Frequency Range</td><td>DC-coupled</td></tr>
<tr><td>Flicker Frequency</td><td>Approximately 28.3 Hz</td></tr>
<tr><td>Data Resolution</td><td>Approximately 71 nV / bit</td></tr>
<tr><td>Input Range</td><td>± 0.6 V</td></tr>
<tr><td>Sampling rate</td><td>Approximately 2 kHz</td></tr>
<tr><td>Timing accuracy [†] (electronic eye)</td><td>< ±0.1 ms</td></tr>
<tr><td>Timing precision [†] (human eye, 1σ)</td><td>Typically < ±1 ms</td></tr>
<tr><td>Pupil measurements</td><td>1.3 mm – 9.0 mm, < 0.1 mm resolution</td></tr>
<tr><td>Safety</td><td>Battery-powered. Complies with optical, electrical, and biocompatibility safety standards.</td></tr>
<tr><td>Power source</td><td>Li-Ion battery allows testing of approximately 70 patients before recharging, depending on the protocol used</td></tr>
<tr><td>Recharge time</td><td>4 hours – charger included</td></tr>
<tr><td>Size</td><td>2.8” W x 3.8” D x 8.4” H (7 cm x 10 cm x 21 cm)</td></tr>
<tr><td>Weight</td><td>8.5 oz. (240 g)</td></tr>
<tr><td>Docking station</td><td>Convenient storage location, charging stand, and USB connectivity to your computer and network</td></tr>
<tr><td>Protocols</td><td>Based on software options, choose from retinal illuminance (Td) and luminance (cd/m^2) versions of ISCEV standard protocols, flicker protocols, and a diabetic retinopathy assessment protocol.</td></tr>
</table>

[†]For Troland-based flicker protocols having a retinal illuminance energy ≥ 4 Td·s.

All specifications are subject to change.

Contraindications

Use of the RETeval device is contraindicated under these conditions:

- Do not use with patients diagnosed with photosensitive epilepsy.
- Avoid use when the orbit structure is damaged or surrounding soft tissue has an open lesion.

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.

CAUTION: 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 cloth moistened with water or isopropyl alcohol 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 RETeval 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.

Step 1. Remove all visible soil by wiping all exterior surfaces with a compatible wipe. Ensure that all visible contamination has been removed.

Step 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.

Step 3. Inspect for any visible damage prior to use. Discontinue use if any abnormalities are found.

Replacement eyecups and Sensor Strip leads are available. See Purchasing Supplies and Accessories on Page 94.

Sterilization

Neither the device nor the Sensor Strips require sterilization or are intended to be sterilized.

Biocompatibility

The patient-contact portion of the RETeval device and Sensor Strips comply with biocompatibility standard ISO 10993-1.

Calibration and Storage

Calibration:	The RETeval 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 (-4000 m to 13,000 m). Store Sensor Strips between temperatures noted on the Sensor Strip packaging. 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 (-4000 m to 13,000 m).

Service / Repairs

The RETeval device contains no user serviceable parts other than the eyecup, battery, and electrode leads, which can all be replaced without the need of tools. These parts are expected to last at least one year, and replacements can be ordered from your local LKC representative or from LKC directly.

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.

To replace the battery, slide the battery compartment door off. Gently pull near the connector to remove the battery. Install the new battery and slide the battery door back into place.

To replace an electrode lead, pull to remove from the device and push on the replacement, as shown in the **Getting Started** section above.

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.

Product performance

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

Contact your distributor or LKC if changes in performance are noted.

Essential performance

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

Operating environment

Temperature: 10 ^{o}C – 35 ^{o}C (50 ^{o}F – 95 ^{o}F)

Humidity: 10% – 90% non-condensing

Air pressure: 62 kPa – 106 kPa (-80 m / -260 feet – 4000 m / 13,000 feet)

Lifetime

The lifetime of the device is 5 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 / About screen beginning after the first 200 protocols have been performed.

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

Sensor Strips are single use only. Sensor Strips are not to be reused because (1) they may not stick well upon reuse, causing an excessively high electrode impedance and therefore noisy results, and (2) the biological risk associated with reuse across patients has not been analyzed.

Precautions

- All servicing of this equipment is to be performed by LKC Technologies, Inc. or by a center approved by LKC Technologies, Inc.
- 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 RETeval performance.
- Do not connect the patient to a high frequency (HF) surgical equipment simultaneously with the RETeval, as it may result in burns at the site of the electrodes and may damage the RETeval.
- Operation of the RETeval in close proximity to a shortwave or microwave therapy equipment may produce instability in the RETeval recordings.
- **WARNING:** To avoid the risk of electric shock, avoid accidental contact between an electrode connected to the RETeval and other conductive parts (e.g., metal) before applying the electrode to the patient. For example, connect electrodes to the patient before plugging them into the RETeval or use Sensor Strip electrodes.
- Input overload can occur in proximity to defibrillator or electrocautery devices.

- 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 RETeval 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 from 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 or GTM96060-0606, made by GlobTek Inc.
- To simultaneously disconnect all mains supply, remove the power brick from the mains outlet.
- Only connect the RETeval 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 RETeval 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 RETeval device is intended for use in the electromagnetic environment specified below. The customer or user of the RETeval device should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The RETeval 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	Class B	Class B

CISPR 11		
Harmonics IEC 61000-3-2	Class A	Class A
Flicker IEC 61000-3-3	Complies	Complies
		The RETeval 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 LKC which are specifically designed for use with the RETeval device.

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

	0 % UT; 250/300 cycle for 50 Hz and 60 Hz, respectively Single phase: at 0°	0 % UT; 250/300 cycle for 50 Hz and 60 Hz, respectively Single phase: at 0°	
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	30 A/m, 50 Hz or 60 Hz	30 A/m, 50 Hz or 60 Hz	Power frequency magnetic fields should be that of a typical commercial, hospital, or home environment.

Guidance and Manufacturer's Declaration – Immunity			
The RETeval device is intended for use in the electromagnetic environment specified below. The customer or user of the RETeval 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 MHz – 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)=3Vrms (E1)=3V/m	Portable and mobile communications equipment should be separated from the RETeval device by no less than the distances calculated/listed below: D= $\frac{3.5}{V1}\sqrt{P}$, 150kHz to 80MHz D= $\frac{3.5}{E1}\sqrt{P}$, 80 to 800 MHz D= $\frac{7}{E1}\sqrt{P}$, 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.
			To assure continued effectiveness, only use cables and accessories supplied by LKC

			which are specifically designed for use with the RETeval device.

Recommended Separations Distances for the RETeval device			
The RETeval device is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the RETeval device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the RETeval 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 RETeval product line is RoHS compliant in accordance with EU RoHS Directives 2002/95/EC, 2011/65/EU, 2015/863, 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). RETeval devices are also labeled with the CE mark indicating compliance with RoHS2.

The RoHS directives allow certain exemptions from its declared limits. The RETeval device 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 RETeval 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 RETeval 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 RETeval device has been categorized with an Environment Friendly Use Period (EFUP) of 25 years.

California Proposition 65

WARNING: This product can expose you to chemicals including lead, which are known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/

Substance Tables:

The table below lists substances which may be contained within this product. Substances listed as Type 1 are within permissible levels; substances listed as Type 2 are used in the production of some components used in this product and may be present at trace levels but are typically destroyed during processing.

Substance	CAS #	Type	Listed as causing:
Nickel	7440-02-0	1	Cancer
Acrylonitrile	107-13-1	2	
Ethylbenzene	100-41-4	2	
Crystalline Silica	14808-60-7	1	
Lead	7439-92-1	1	Cancer Developmental Toxicity Male Reproductive Toxicity Female Reproductive Toxicity
Methylene Chloride	75-09-2	2	Cancer
Bisphenol A	80-05-7	2	Female Reproductive Toxicity
N-Hexane	110-54-3	2	Male Reproductive Toxicity

The above warning is applicable to the RETeval device and its associated supplies and accessories (shown on Page 94).

Symbols

ISO 15223-1, Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.			
Symbol	**Reference**	**Title of Symbol**	**Description / Function**
	ISO 7000-0626	Keep away from rain	The transport package shall be kept away from rain and in dry conditions.
	ISO 7000-0632	Temperature limit	Indicates the maximum and minimum temperature limits at which the device shall be used or stored (on device), or transported (on shipping box).
	ISO 7000-1051	Do not re-use	This item is for single use only.
	ISO 7000-1135	General symbol for recovery/recyclable materials With added Li-Ion identifier text	indicates that the marked item is part of a recovery or recycling process. Contains “Lithium Ion”. This symbol indicates “General recovery / recyclable” and must not be disposed of as unsorted municipal waste and must be collected separately.
	ISO 7000-1641	Operator's manual; operating instructions	The operator should familiarize themself with the operating instructions before use of this device.
	ISO 7000-2492	Batch code	Identifies the manufacturer's lot number.
	ISO 7000-2493	Catalog number	Identifies the item’s catalogue number.
	ISO 7000-2497 IEC 60417-6049	Date of manufacture Country Code (CC)	Indicates the date on which the product was manufactured. US country code indicates the device was manufactured in the United States.
	ISO 7000-2498	Serial Number	Identifies the device’s serial number.
	ISO 7000-2607	Use-by date	Indicates that the item should not be used after the date accompanying the symbol.
	ISO 7000-3082	Manufacturer	Identifies LKC as the manufacturer of this device.

	ISO 7000-3650	Universal Serial Bus (USB), port/plug	indicate that the device is compatible with a USB port.
	ISO 7010-M002	Refer to instruction manual/booklet	Indicates that the Owner's Manual must be read before use.
	ISO 7010-W001	Caution	To indicate that caution is necessary when operating the device.
	ISO 15223-1, 5.1.2-23.2(d)	Authorized representative in the European Community / European Union	Identifies the authorized representative in the European Community / European Union.
	ISO 15223-1, 5.7.10-23.2(h)	Unique Device Identifier	Indicates a carrier that contains the Unique Device Identifier information.
	ISO 15223-1, 5.7.7-23.2(q)	Medical Device	Indicates a medical device.
	IEC 60417-5009	Stand-by	Identifies the control to shift to of low power consumption state. Sometimes called a "soft-power switch".
	IEC 60417-5031	Direct current	Indicates that the equipment is suitable for direct current only.
	IEC 60417-5333	Type BF applied part	Identifies a type BF applied part complying with IEC 60601-1.
	IEC 60417-5926	Polarity of DC power connector	Identifies the positive and negative connections on a piece of equipment to which a DC power supply may be connected.
	IEC 60417-6414	WEEE; waste electrical and electronic equipment	Indicates that separate collection for waste electric and electronic equipment (WEEE) is required.

Symbols to be used with medical device labels, labeling, and information to be supplied — as required by the indicated regulation or body.

Symbol	Reference	Title of Symbol	Description / Function
CE 2797	Regulation (EC) No 765/2008	CE marking for medical devices, including the notified body identifier	Indicates that the device is in conformity with European Community harmonization legislation; and identifies the Notified Body.

UK CA 0086	Regulation (GB) SI 2019/696	UKCA marking for medical devices, including the notified body identifier	Indicates that the device is in conformity with the relevant United Kingdom legislation; and identifies the Notified Body.
C ETL US LISTED Intertek 4007465	N/A	NRTL marking	Indicated 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 Certified To: CSA Std No. 60601-1
Rx ONLY	21 CFR 801.15	Prescription only	Indicates that the device is for use by prescription only. 21 CFR Part 801 Labeling, Section 801.15 Medical devices; prominence of required label statements; use of symbols in labeling FDMA 1997 SEC 126
CH REP	MU600_00_016 Version 5.0	Swiss Representative	Indicates the authorized representative in Switzerland.

Equipment identification

Each RETeval 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 takes 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

Intellectual Property

The RETeval device may be covered by one or more of the following US patents and their foreign counterparts: 7,540,613; 9,492,098; and 9,931,032.

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.

RETeval ™ and RETeval -DR™ are trademarks of LKC Technologies, Inc. RETeval is a registered trademark of LKC Technologies, Inc. in the following countries: Brazil, Canada, China, Japan, Mexico, Russian Federation, South Korea, and the United States of America.

Contact Information

Support

Contact support staff via email (support@lkc.com) or by phone at: +1 301 840 1992.

Warranty

LKC Technologies, Inc. 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 LKC Technologies, Inc. This Warranty is binding for one year from the 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 LKC Technologies, Inc.

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

DAMAGE UPON ARRIVAL. Each instrument leaves our factory, 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 LKC testing. The price of our instruments makes provision for such service, but it does not:

- Provide for transportation charges to our factory for service.
- Provide for services not performed or authorized by us,
- 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, or e-mail suspected defects or aspects of instrument operation that may be unclear. We advise you to inform us by phone, letter, or e-mail of the nature of the defect before returning an instrument for repair. An RMA authorization is necessary prior to returning a device to LKC 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 LKC 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, or e-mail any problem you may be experiencing.

Purchasing Supplies and Accessories

Users may purchase supplies and accessories by visiting the LKC store (https://store.lkc.com/) or by contacting your local distributor. Refer to this parts list:

Part Number	Item
26-066	RETeval Power Kit, includes Battery Charger and Blade Kit.
29-038	RETeval carrying case, which holds the device, docking station, AC adapter, cables, a 1 box of Sensor Strips in a hard-backed case with a handle.
81-262	Battery
81-266	Eyecup
81-269	Dust cover
81-298	RETeval mounting arm, which holds the device in an arm that mounts to a table.
91-193	Sensor Strip lead (i.e., the cable that connects the device to a Sensor Strip)
91-194	RETeval adapter cable for DIN electrodes
91-235	Small Sensor Strip lead (i.e., the cable that connects the device to a Small Sensor Strip)
91-240	Sensor Strip lead extension cable
95-068	Sensor Strip, quantity 50 pairs
95-076	RETeval VEP electrode kit
95-079	Pack of three, 4-oz. tubes of NuPrep
95-081	Sensor Strip, quantity 25 pairs
95-090	Small Sensor Strip, quantity 50 pairs

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Symbol

Swiss Representative

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LKC Technologies, Inc., established in 1987, is ISO 13485:2016 certified and holds MDSAP and FDA registrations and a CE certificate as a medical device manufacturer with quality products installed in over fifty countries.

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