UTAS ECLIPSE™ Dark Adaptometry Software

User's Manual

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CE 2797

Rx only

Part No. 96-034-EN

EN - Printable instructions for use (IFU) in multiple languages are stored on the UTAS computer as PDF files in the IFU folder on the computer desktop screen, or go to www.lkc.com/IFUs

DE - Druckbare Nutzungsanweisungen (IFU) in mehreren Sprachen werden auf dem UTAS-Computer als PDF-Dateien im IFU Ordner auf Ihrem Desktop gespeichert. Alternativ können Sie www.lkc.com/IFUs besuchen.

ES - En el ordenador UTAS hay almacenadas como archivos PDF instrucciones imprimibles de uso en varios idiomas, en la carpeta IFU del escritorio del ordenador, o acceda a www.lkc.com/IFUs

FR - Des instructions d'utilisation à imprimer (IFU) dans plusieurs langues sont stockées sur l'ordinateur UTAS sous forme de fichiers PDF dans le dossier IFU présent sur le bureau. Vous pouvez également les obtenir sur www.lkc.com/IFUs

IT - Le istruzioni per l'uso stampabili (IFU) in più lingue sono archiviate sul computer UTAS come file PDF nella cartella IFU sul desktop. In alternativa, sono reperibili all'indirizzo www.lkc.com/IFUs

PL - Instrukcje obsługi (IFU) do druku w wielu językach przechowywane są na komputerze UTAS jako pliki PDF w folderze IFU na pulpicie komputera lub na stronie www.lkc.com/IFUs

European regulatory Data

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.

Reference 96-020 UTAS Hardware User Manual for complete regulatory information

European regulatory Data

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:

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1 Introduction

Intended Purpose/ and Intended Users

UTAS is an electrophysiology device used as a diagnostic and disease management aid in visual pathway dysfunctions or ophthalmic disorders.
UTAS performs electroretinogram (ERG), electro-oculogram (EOG), visual evoked potential (VEP), multi-focal ERG/VEP, and the measurement of psychophysical responses of the visual system, including dark adaptometry.

This equipment is offered for sale only to qualified Health Professionals.

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

Clinical Benefit

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

Intended Target Groups

There are no specific intended target groups.

Indications for use / Device Requirements

UTAS is indicated for use in the measurement of visual electrophysiological potentials, including electroretinogram (ERG) and visual evoked potential (VEP). UTAS is also indicated for use in the measurement of psychophysical responses of the visual system, including dark adaptometry. UTAS is intended as an aid in diagnosis and disease management in visual pathway dysfunctions or ophthalmic disorders (e.g., diabetic retinopathy, glaucoma).

Eclipse™ software specific tests

The LKC Technologies Eclipse™ Dark Adaptometry software is a software package that runs on LKC's UTAS equipped with a SunBurst™ or BigShot™ ganzfeld to perform the dark adaptometry test to aid in the diagnosis and disease management of the visual pathway dysfunctions or ophthalmic disorders.

Eclipse™ Dark Adaptometry software is only intended to use used with the UTAS device. The software will only run on computers using a Windows 10 or higher operating system and having very specific video control hardware. LKC only supports UTAS computers that have been supplied by LKC specifically for this software.

Reference 96-020 UTAS Hardware User Manual for details on UTAS hardware and regulatory information.

What is dark adaptometry?

Dark Adaptometry is the process of measuring the eye's sensitivity to light. The test presents a subject with dim flashes of light and adjusts the brightness of the flashes based on the subject's response until a threshold is determined.

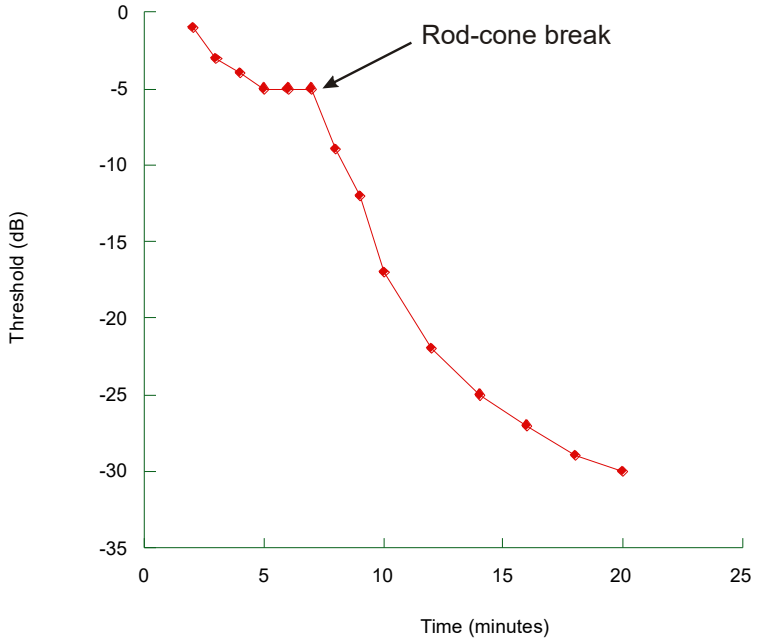
If an eye is exposed to the dark, its retinal sensitivity will change over a substantial period of time until full sensitivity is reached. The eye is sensitive to light over approximately an 11-log unit (100 000 000 000: 1) range and is capable of adjusting its sensitivity over about a 6-log unit (1 000 000: 1) range.

There are two common methods for performing Dark Adaptometry:

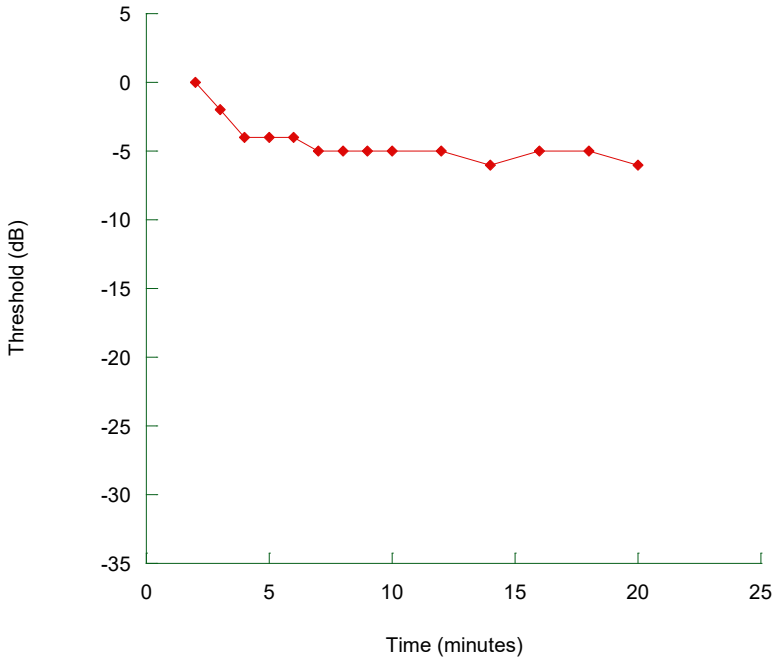
- To determine a subject's *final dark-adapted threshold*, the subject's eyes are adapted to the dark for a pre-determined time duration – typically 30 minutes. At the end of this period of dark adaptation, the patient's threshold is measured with the dark adaptometer.

- To determine a subject's *dark adaptation curve*, the subject is first exposed to a very bright light for several minutes. This bright light "bleaches" the photo pigment, suppressing rod and cone sensitivity. Then the light is turned out and the subject's threshold to light is measured at time intervals until the final threshold is reached.

Normal dark adaptation follows a characteristic two-branched course, with an inflection occurring at approximately 5-10 minutes. The early part of this curve corresponds to adaptation of the cone system, and the later part of the curve corresponds to adaptation of the rod system. The inflection point is called the rod-cone break. The typical course of dark adaptation over a 3-log unit range is shown in the figure below.



Several retinal diseases affect the ability of the eye to dark adapt. In many of these diseases, the time course of dark adaptation is relatively unchanged, but the final threshold that is reached is different. An example of a dark adaptation curve from a subject with congenital stationary night blindness (CSNB) is shown below.



What is a Ganzfeld dark adaptometer?

Early dark adaptometers, such as the Goldman-Weekers, measured dark adaptation using a 10° spot located to one side of the fovea. More modern dark adaptometers, such as LKC Technologies Eclipse™ Dark Adaptometry for UTAS measure dark

adaptation using a ganzfeld (full field) stimulus. For night blinding disorders, the older method and the newer method provide essentially the same information.[1]

When is dark adaptometry useful?

Dark adaptometry is useful in the diagnosis and management of night blinding conditions, including retinal degenerations, senile miosis, high myopia, vitamin-A deficiency, and others. For the majority of night blinding conditions, a measurement of the subject's final dark-adapted threshold is sufficient.

There are a few conditions, however, where the time course of dark adaptation is affected:

- In *Oguchi's disease*, the cone adaptation curve is nearly normal, but the rod-cone break may not occur for more than two hours.

- In *fundus albipunctatus*, both the rod and cone adaptation curves are delayed, and the rod-cone break may not occur for two hours or more.

There are also a few cone disorders, notably *progressive cone dysfunction* and *rod monochromacy*, where the time course of dark adaptation will be different from normal. However, in these disorders the electroretinogram will provide substantially more information.

The principal component of dark adaptation is governed by the rate of delivery of vitamin A–derived chromophore (retinol) from the retinal pigment epithelium cells to the rod and cone photoreceptors. In individuals with visual disease arising from defects in the retinoid visual cycle, measurements of the time course of dark adaptation delivery may be used to assess defects in retinoid synthesis and delivery quantitatively.

When is the dark adaptometry not useful?

Dark Adaptometry is a psychophysical test, requiring the patient to respond by pushing a button when they see a light. This test is not suitable for young children and older patients who may not be able to understand the test because of cognitive deficits.

Do I need to collect normal data?

We suggest that you collect data from several normal subjects before beginning to test patients. This will give you some experience performing the test and will provide some normal data for comparison.

How do I interpret the results?

Generally, there are 3 areas of the Dark Adaptometry curve that are of interest:

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[1] Peters AY, Locke KG, Birch DG. Comparison of the Goldmann-Weekers dark adaptometer and LKC Technologies Scotopic Sensitivity tester-1. *Documenta Ophthalmologica* 101(1):1-9, 2000.

1) **Rod-Cone Break**. The timing of the rod-cone break will be abnormal in several retinal diseases.

2) **Final Dark-Adapted Threshold**. This is usually the most important measurement in dark Adaptometry. It is the dimmest light that the subject is capable of seeing when fully adapted to the dark. The final dark-adapted threshold will change slightly with age, increasing approximately 1 dB for every 10 years of age. There are three primary reasons for shifts in dark adapted threshold.

    - Senile miosis, the inability of the pupil to fully dilate, will cause reductions in the ability of light to enter the eye.
    - Cataracts and yellowed lenses act as filters that absorb light entering the eye. The UTAS is relatively insensitive to these conditions since a long wavelength light is used in a full-field presentation.
    - Age-related changes in retinal and neural structures reduce the sensitivity to light. The primary age-related change appears to be in rhodopsin regeneration in the rods.

3) Initial slope of the curve after the rod-cone break. Immediately after the rod-cone break, the dark adaptation curve will normally plunge downward in what appears to be a linear manner. The slope of this line is dependent upon the transport of molecules necessary for the synthesis of rhodopsin across the retinal pigment epithelium.

2 UTAS Setup

NOTE: most of the screen shots shown in this manual are printed in black text on a white background which makes them easier to read when printed. In normal operation the monitor's background is set to black and the text to red so as not to interfere with the subject's dark adaption.

Arranging the hardware

In most cases, your hardware will be installed by LKC Technologies. In those cases where it is not, you will need to follow these guidelines.

Plug the push button into the back of the UTAS interface. There is only one location it will fit, which is labeled.

Room Preparation

This test must be performed in a totally darkened room. Even small amounts of light leaking in around the door or through the ceiling will cause shifts in the results obtained.

To determine if your room is sufficiently light tight, we suggest that you (or another normally-sighted person) sit in the darkened room for ½ hour. At the end of this time, you should be able to see any light leaks. We have found that the best way to fix light leaks though cracks or along a door is with commercially-available weather-stripping products. Foam tape and other products designed to keep air from leaking into a building also do a good job of sealing out light. Black vinyl electrical tape also does a good job of sealing light leaks through cracks.

Precautions for Software installation

WARNING: The installation of any software on the UTAS Windows based computer that is not provided directly by LKC can cause the device to stop functioning, crash unexpectedly, or disrupt the timing of the stimulus presentation and data collection.

The LKC UTAS device is a precision standalone medical device. The computer provided with the device has been manufactured and configured for this specific purpose. It is absolutely essential that the timing of the stimulus presentation and data collection not be impeded by any non-LKC provided software products.

The warranty on the UTAS does not cover problems caused by installation of non-approved software on the computer. The UTAS is a medical device that uses a Windows-based computer. Installation of additional software on the UTAS computer may result in improper operation of the UTAS. It is the customer's responsibility to ensure that any additional software installed on the UTAS computer does not affect the performance of their UTAS. LKC is not liable or responsible for improper operation of the UTAS caused by customer-installed software.

Therefore, LKC strongly recommends that UTAS be used as a standalone medical device. LKC also strongly recommends that:

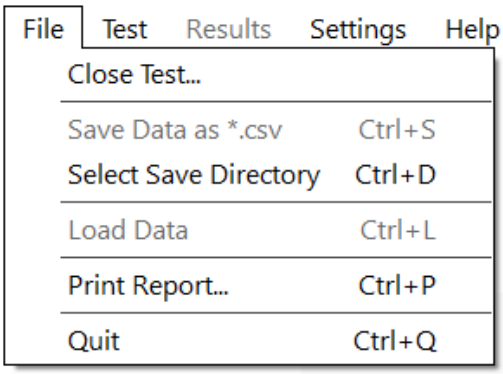
1. **The user does not change any user privileges or software settings.**
2. **No non-LKC approved software products be installed on the device**
3. **The supplied Eclipse™ software is not standalone and is only intended for use with the UTAS.**

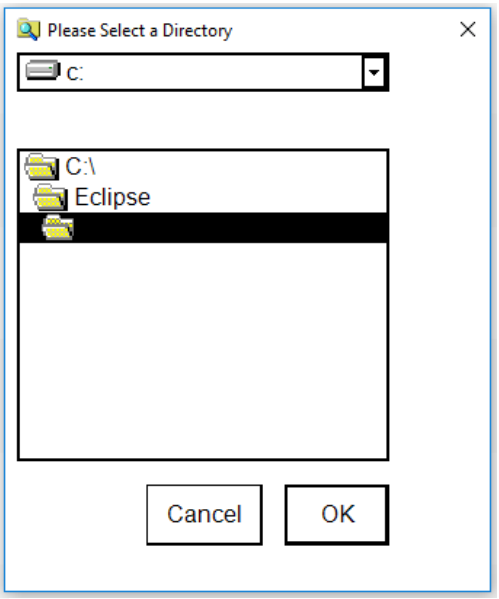
In most cases, your software will be installed by LKC Technologies. In those cases where it is not, follow the instructions provided.

Software Preferences

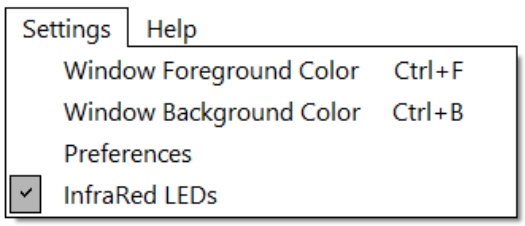
- Saving Directory

The default directory where all data will be saved *is C:\Program Files\Eclipse*. You may change the location of the Save Directory by going to *File -> Select Save Directory* and enter a new path in the window.





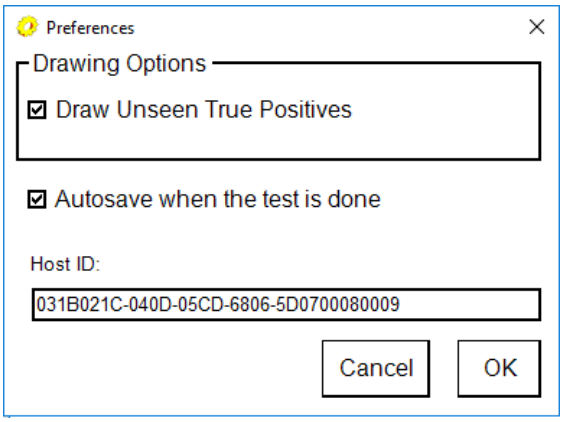
- Settings



Screen Color Scheme

Eclipse's software color scheme was setup to minimize the amount of blue light coming from the screen of the user monitor in order to reduce the effects on the patient's threshold. If you ever need to change the colors of the software you can do so by going to the settings menu and change the *Window Foreground Color* and/or the *Window Background Color.* A palette of colors will appear; select the color you desire.

Preferences
The software is setup to automatically save the test once the recording is stopped and to show unseen true positives (flash was presented but not seen by the patient).



Infrared LEDs
IR LEDS helps to see the eyes of the patient when in the dark. This option is only available on SunBurst and BigShot with built-in camera option. Because they produce a small amount of visible light, we recommend that you turn the IR LEDs off before recording any test.

3 Performing a Test

Selecting a test

The first step in performing a test is to decide whether you are performing a full Dark Adaptometry study or whether determination of a final dark-adapted threshold is sufficient. As noted in Section 1, a final dark-adapted threshold test takes much less time and, in many cases, will provide the needed clinical information.

Refraction

Because UTAS Eclipse uses a ganzfeld stimulus presentation, correct refraction of the patient is totally unnecessary!

During the Test

Use the camera to ensure that the patient is keeping their eyes open. Let the patient know that there will be a long series of flashes in the ganzfeld. Each flash will be announced by a beep at the beginning and one at the end of its duration. The patient can press the button at anytime during or after the flash presentation if the flash was seen.

Depending on how many catch trials you have selected in the test options at some time the ganzfeld will beep without flashing. You can review false positives and false negatives at the end of the test to determine if the patient really clicking when supposed to.

False positive: A trial where no stimulus is presented and the subject responds "Seen" (in other words, presses the button).

False negative: A trial at an intensity greater than where the user previously responded "Seen" but now says "Not Seen".

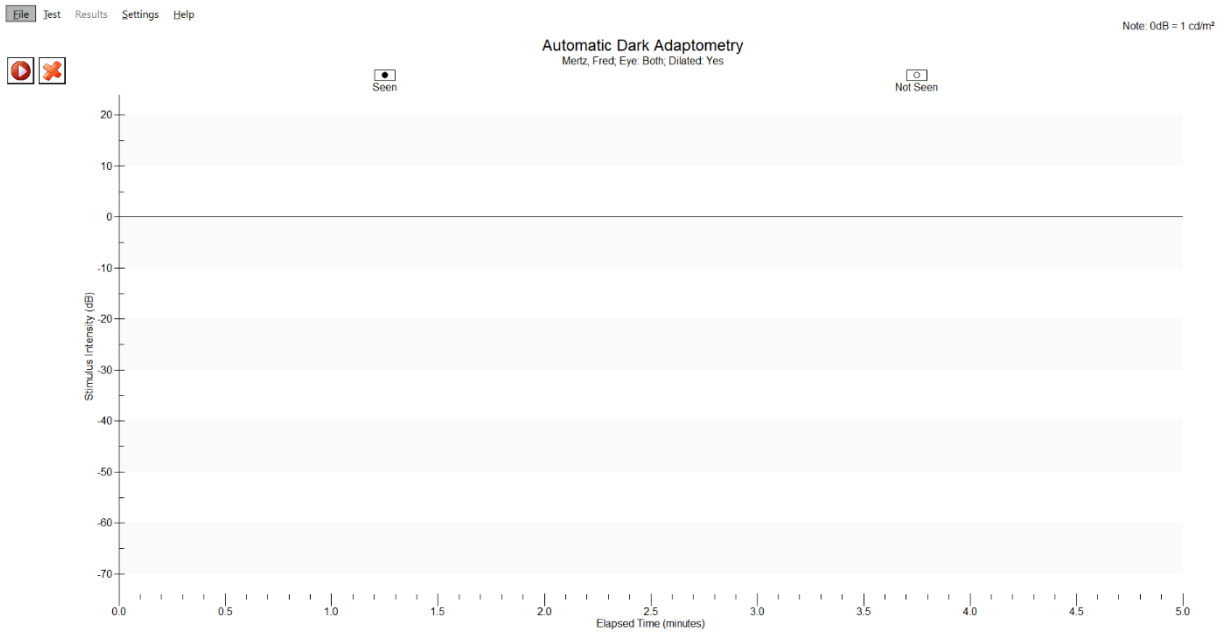
Ambient lighting

This test must be performed in a totally darkened room. Even small amounts of light leaking in around the door or through the ceiling can cause shifts in the results obtained.

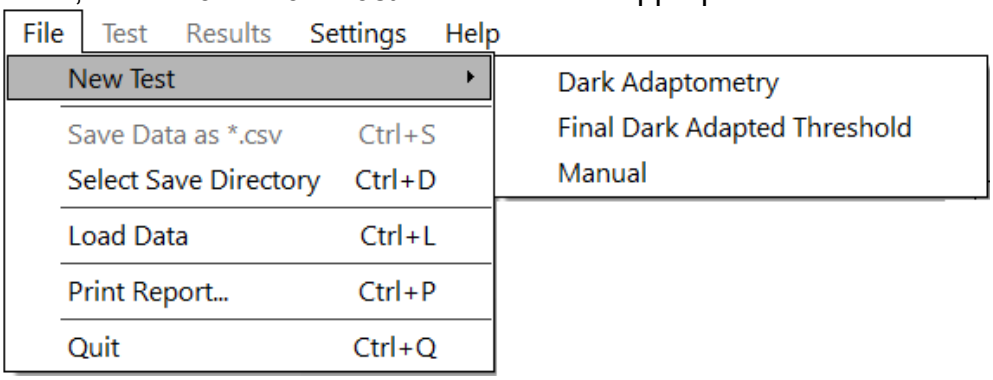
4 Using the Software

Running a test

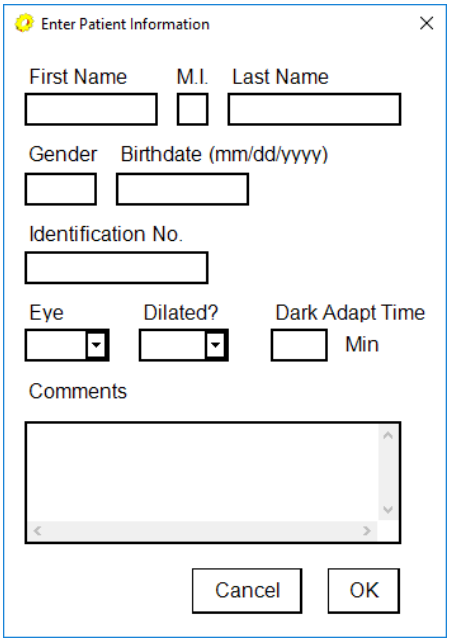
Open the software by double clicking on the Eclipse Icon on the desktop or click *Start -> Programs -> Eclipse.* The following window will appear



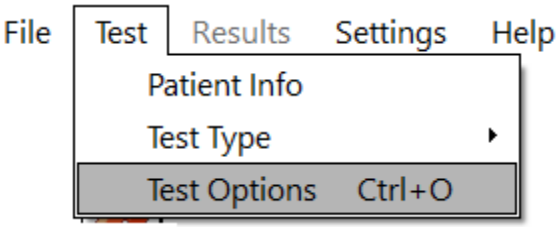
In order to run a test, click *File -> New Test* and Select the appropriate test.



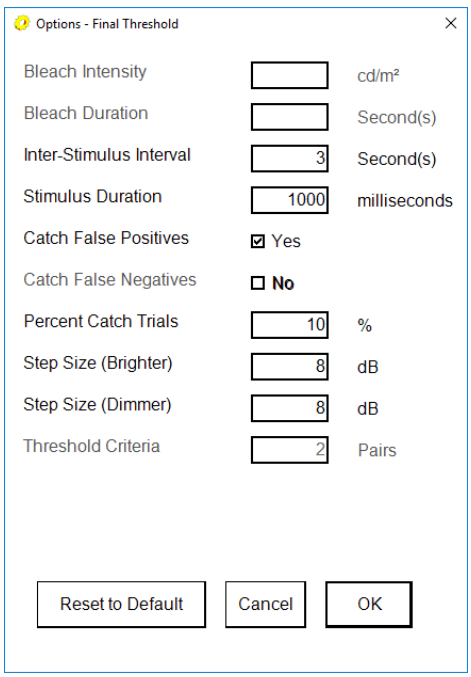
Once the test is selected, the Patient Information window will open – fill out as many fields as desired and click the **OK** button.

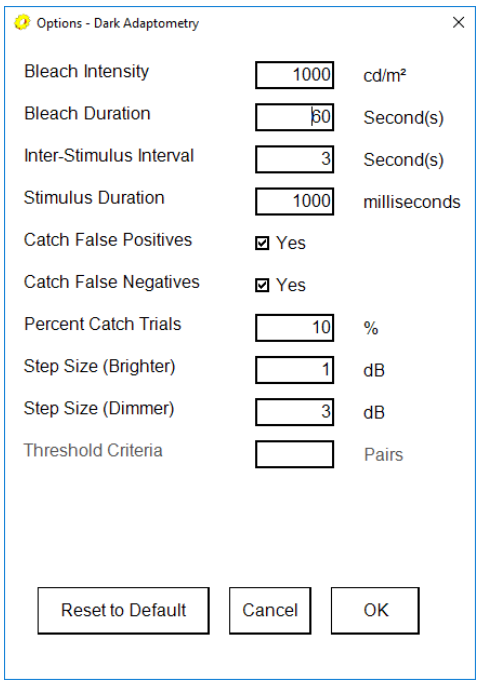


If at this point you realize that you selected the wrong test, you can switch the test type by clicking *Test -> Test Type* and selecting a new test type.



Once the correct test type is selected, click on *Test -> Test Options* to ensure that the test has the correct settings. Below are our recommended settings for Dark Adaptometry and Final Threshold.

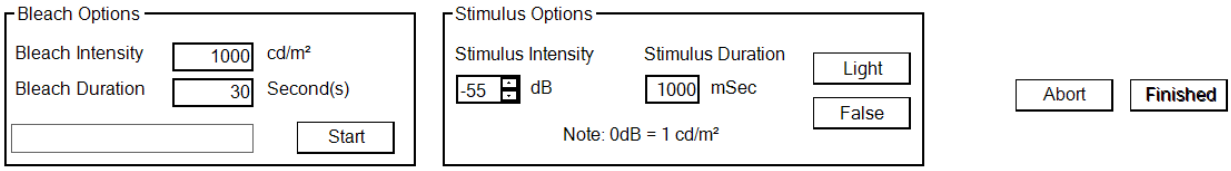




If you select Manual Test you will need to enter your settings on the lower part of the test page. You can select the bleach intensity and duration. A timer will count down

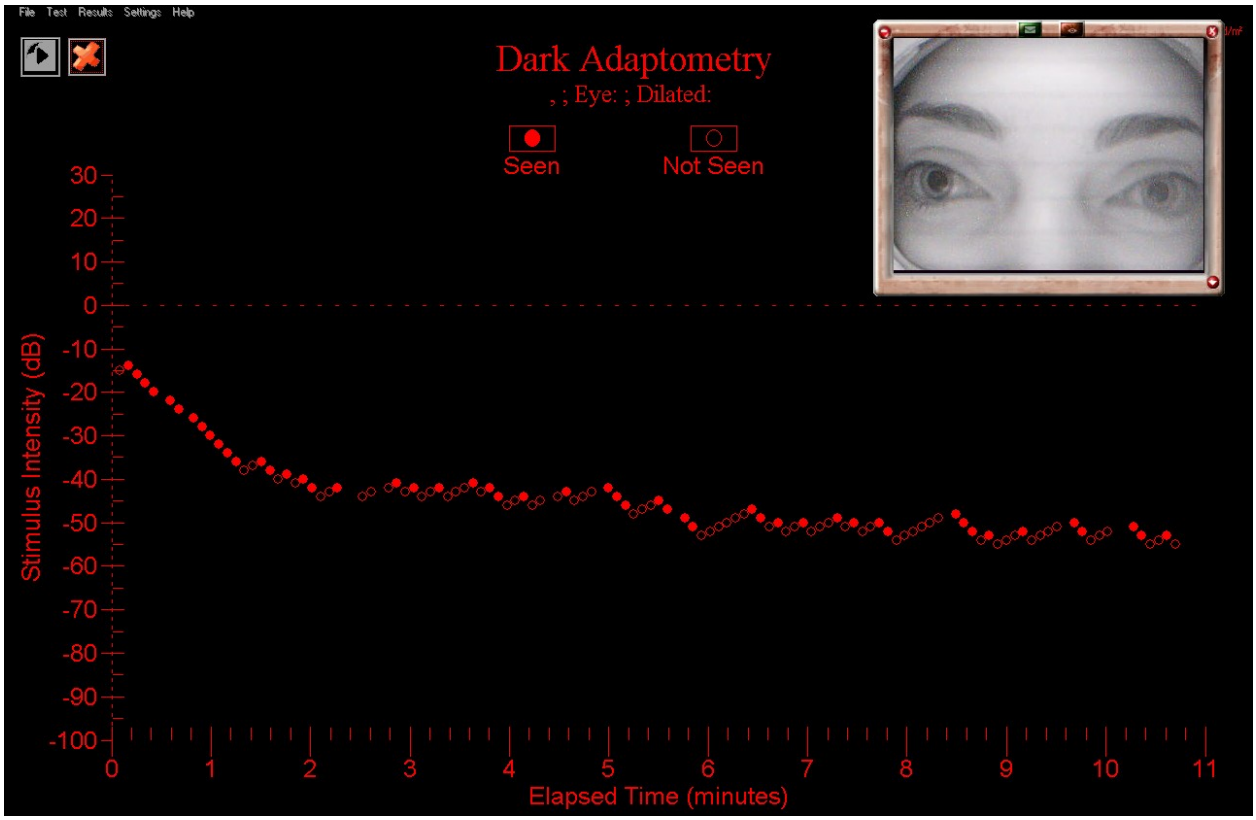
for the duration of the bleach. Then select the first intensity the patient will see after the bleach in the stimulus option. See below for standard options.

You will need to manually click on the **Light** button to present a flash (or click on the **False** button to create a False Negative) and increase or decrease the light intensity for the next flash.



To start and stop Dark Adaptometry and Final Threshold test click on the following icons:

See below for an example of a recording screen.



You should stop a dark adaptometry test when

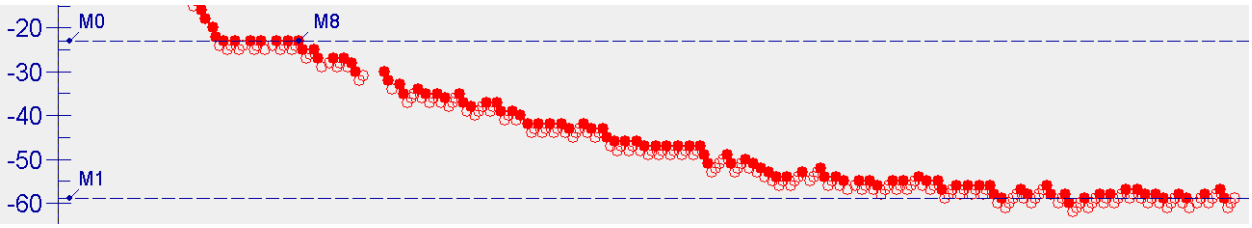
- it appears you have reached final dark-adapted threshold (typically 30 – 45 minutes)
- it is obvious that the DA curve is either normal or abnormal
- If there is some other reason you're measuring DA (like to get the slope just after the rod-cone break, or to define the time of the rod-cone break)

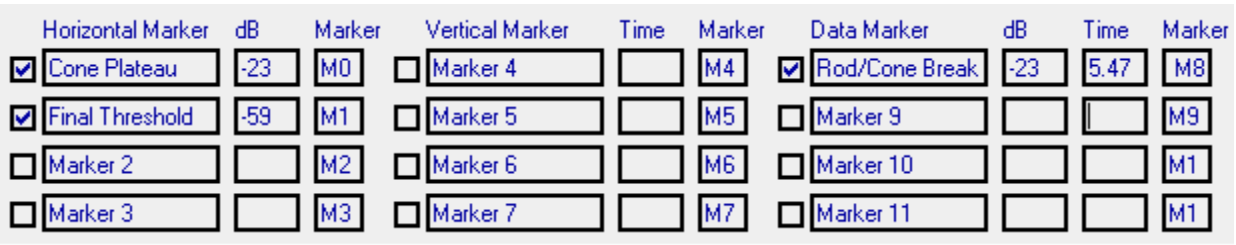
Analyzing Data

Once the test has stopped the marker window opens.

The *Horizontal Marker* will let you select a horizontal line on the report and give you the intensity in dB. This line can be placed anywhere on the graph.
The V*ertical Marker* will let you select a vertical line on the report and give you the time at of that line in minutes. This line can be placed anywhere on the graph.
The *Data Marker* will give you intensity in dB and time in minutes of a selected data point. Data Markers can only be placed on an existing data point.

Typical markers are the Cone Plateau, Rod/Cone break point and the Final Threshold. You can rename all the markers in the column named Marker (see example below).



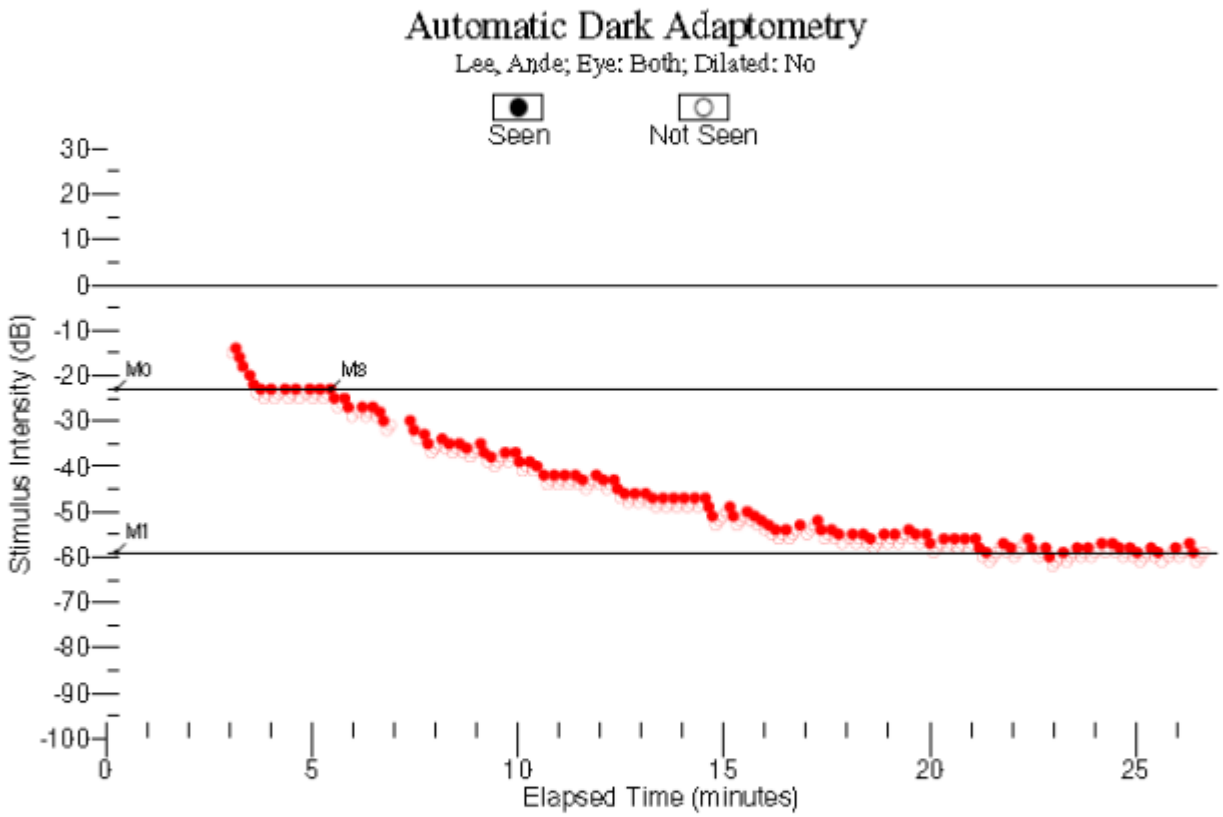


In order to print the report, go to *File -> Print*. See on the next page for an example of a report.

LKC Technologies Eclipse 1.0.0, Printed: Oct/22/2008 11:06:32
LeeAnde_DarkAdaptation_666_Both_10-22-2008_09-58-30

Patient Name:	Lee, Ande	**Test Type:**	DarkAdaptation
Identification:	666	**Test Date:**	10/22/2008
Birthdate:	02/01/1980	**Eye:**	Both
		Dilated:	False
		Darkadapt Time:	0 Minutes

Comments:



Note: 0dB = 1 cd/m²

Marker Name	dB	Label	Marker Name	t	Label	Marker Name	t	dB	Label
Marker 0	-23.00	M0							
Marker 1	-59.00	M1				Marker 8	5.47	-23.00	M8

Test CatchTrial Information

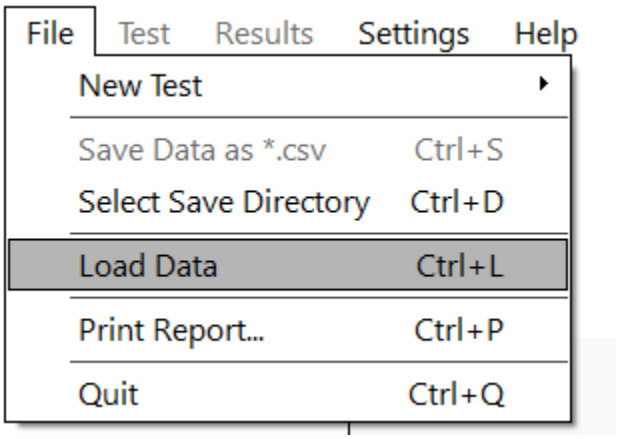
False Negatives:	2
Total Positive Catch Trials:	7
False Positives:	0
Total Negative Catch Trials:	4

Test Settings Information

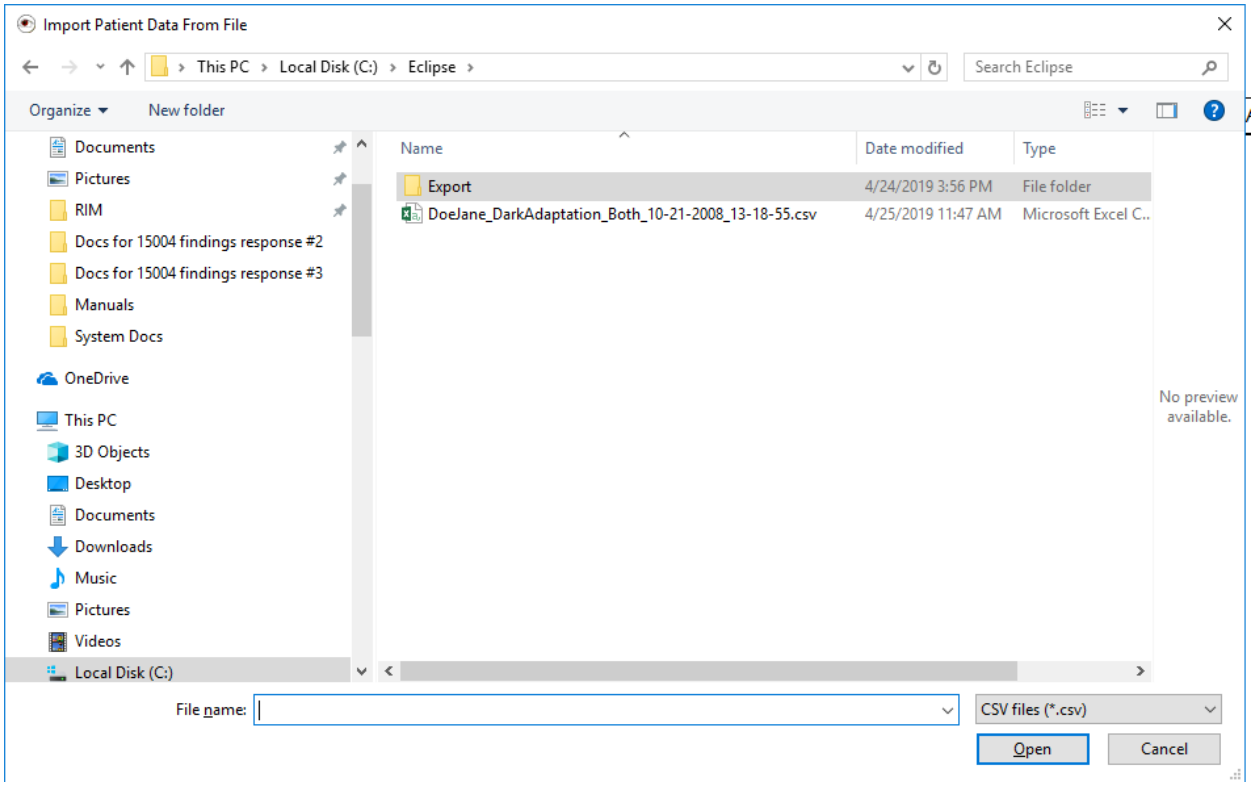
Bleach Intensity (cd/m^2):	1000
Bleach Duration (sec):	180
Stimulus Interval (sec):	5
Stimulus Duration (ms):	1000

Finding a patient's data

Go to *File -> Load Data* and select the data you want to load.

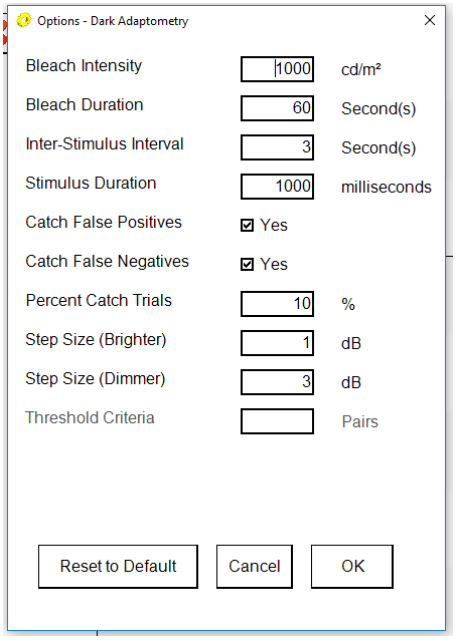


Data is saved in the following format:
(Last Name)(First Name)_(Test Type)_(Eyes)_(Date)_(Time).csv
Example:
DoeJane_DarkAdaptation_Both_10-21-2008_13-18-55.csv



Quick Guide for recording Dark Adaptometry

- Open *Video Monitor* camera by double clicking on the *Video Monitor* icon on the desktop
- Open *Eclipse* software by clicking on the *Eclipse* icon on the desktop
- Go to Settings and Turn the *IR LEDs* off
- Go to *File -> New Test -> Dark Adaptometry*
- Enter Patient Information
- Go to *Test -> Test Options* and make sure the following are selected then click OK



- Make sure all lights are off in the room; place the Red Screen protector on the monitor screen to minimize the light coming from it.
- Click on the start test icon.

- Once final dark-adapted threshold is reached stop the test using the stop icon

- Place markers were desired (cone plateau horizontal marker, rod-cone break data marker and final dark-adapted threshold horizontal marker)
- Store markers on the report by going to *File -> Save As*
- Print report by going to *File -> Print Report*
- To start another test, go to *File -> Close Test* and *File -> New Test*

Exporting to Other Software

All data is saved as a .CSV file and can be imported into any programs accepting that file type (Excel, Matlab…).

Patient information, test information and all data points will be included (see appendix 1 for an example). The default location of the .CSV file is C:\Program Files\Eclipse unless you change the *Save Directory* (see page 6)
Note that the time column is in milliseconds using the PC's timer you can convert those into minutes using the following formula:

Time[i] = (Value[i] - Value[0]) / 60,000

Backing Up Data

LKC recommends to back up saved data in order to ensure patient data is not lost unexpectedly. Therefore, it is good practice to frequently back up the data. How often depends on how much data is willing to be lost. To backup a results, go to the local C Drive. Under the local C drive, find the Eclipse folder. Locate the desired patient files to be saved. Copy the files and save it to an external drive or server for backup. It is recommended that tests be backed up to a different file system than the original database.

5 Troubleshooting Guide

Symptom	Suggested Actions
Ganzfeld not flashing	1. Make sure the UTAS interface is turned on 2. Make sure no other software is running
Pressing the button doesn't do anything	Make sure the button in plugged in the back of the UTAS interface

Appendix 1: .CSV File Example

Patient Information	
Patient Last Name	Lee
Patient First Name	Ande
Patient Middle Initial	
Gender	f
Birthdate	2/1/1980
Identification No.	666
Test Information	
Eye	Both
Pupils Dilated	False
Dark Adapt Time	0
Test Date and Time	10/22/2008 9:58:30 AM
Comments	
Test Catch Trial Information	
False Negatives	2
Total Positive Catch Trials	7
False Positives	0
Total Negative Catch Trials	4
Test Settings Information	
Test Type	Dark Adaptation
Bleach Intensity (cd/m^2)	1000
Bleach Duration (Seconds)	180
Stimulus Interval (Seconds)	5
Stimulus Duration (Milliseconds)	1000
Marker Data	
Marker Name	t dB Label
Test Data	

n	t	dB	Seen	Catch	Catch Expected
1	185031	-15	False	False	False
2	190141	-14	True	False	False
3	195250	-16	True	False	False
4	200360	-18	True	False	False
5	205469	-16	True	True	True
6	210578	-20	True	False	False
7	215688	-22	True	False	False
8	220797	-24	False	False	False
9	225906	-23	True	False	False

10	231016	-25	False	False	False
11	236125	-24	False	False	False
12	241235	-23	True	False	False
13	246344	-25	False	False	False
14	251453	-24	False	False	False
15	256563	-22	True	True	True
16	261672	-23	True	False	False
17	266781	-25	False	False	False
18	271891	-24	False	False	False
19	277000	-23	True	False	False
20	282110	-25	False	False	False
21	287219	-23	False	True	True
22	292328	-24	False	False	False
23	297438	-23	True	False	False
24	302547	-25	False	False	False
25	307656	-24	False	False	False
26	312766	-23	True	False	False
27	317875	-25	False	False	False
28	322985	-24	False	False	False
29	328094	-23	True	False	False
30	333203	-25	True	False	False
31	338313	-27	False	False	False
32	343422	-26	False	False	False
33	348531	-25	True	False	False
34	353641	-27	True	False	False