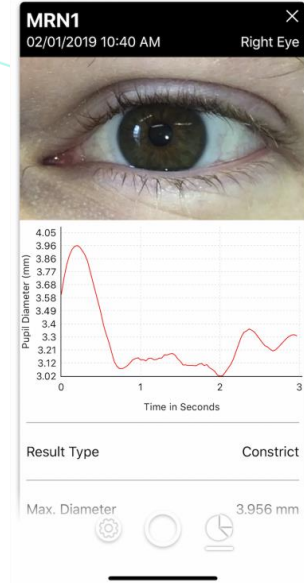




# Pupillometer User Guide

## Introduction

The Reflex pupillometer is a mobile based automated pupillometer that give medical professionals a quantitative way to monitor pupil size and reactivity. Reflex is designed to be implemented into healthcare and research facilities with iOS infrastructure and a clear mobile or wireless connection.



## Table of Contents

- CLASSIFICATION ..... 3**
- DEVICE WARNINGS AND CAUTIONS ..... 3**
  - WARNINGS ..... 3
  - CAUTIONS ..... 3
- PATENTS AND COPYRIGHT ..... 3**
  - PATENTS ..... 3
- GETTING STARTED ..... 4**
  - APPROVED IOS DEVICES ..... 4
  - DOWNLOADING ..... 4
- CREATING AN ACCOUNT ..... 4**
  - SINGLE USER ..... 4
  - ENTERPRISE ..... 5
  - LOGGING IN ..... 5
- CONFIGURING TEST CONDITIONS AND RESULTS ..... 5**
  - RECORDING SETTINGS ..... 5
  - RESULT FIELDS ..... 6
- ENTERING SUBJECT INFORMATION ..... 7**
  - SUBJECT ID OR MEDICAL RECORD NUMBER ..... 7
  - EYE SPECIFICATION ..... 7
  - DATE OF BIRTH ..... 7
  - SEX ..... 7
  - LAST TEST VALUES ..... 7
- MEASUREMENT ..... 8**
  - INITIATING THE TEST ..... 8
  - TIPS FOR BETTER TESTING ..... 8
  - TEST COMPLETION ..... 9
  - RESULTS CARD ..... 9

HISTORY .....	9
SEARCH .....	9
<b>CONSIDERATIONS .....</b>	<b>10</b>
EXCESSIVE MOTION .....	10
BLINKING .....	10
GAZE DIRECTION .....	10
<b>DATA EXPORTATION TRENDING .....</b>	<b>10</b>
EXPORTING DATA .....	10
TRENDING DATA .....	10
<b>FREQUENTLY ASKED QUESTIONS .....</b>	<b>10</b>
<b>UPDATES .....</b>	<b>12</b>
IOS APPLICATION UPDATES.....	12
<b>APPENDIX A – PARAMETERS.....</b>	<b>12</b>

## Classification

---

Reflex is Medical Equipment as listed under Class 1 21 CFR 886.1700.

**Manufacturer:**     **brightlamp, Inc.**  
200 S. Meridian St.  
STE 410  
Indianapolis, IN 46225  
[info@brightlamp.org](mailto:info@brightlamp.org)  
[www.brightlamp.org](http://www.brightlamp.org)

## Device Warnings and Cautions

---

### Warnings

Only devices with a completely functional camera and LED torch should run Reflex. Use with altered or damaged devices cannot be guaranteed for performance.

Mobile devices that are not regularly sanitized can contain harmful bacteria. It is recommended that Reflex is not used around critically ill patients susceptible to disease without proper sanitization.

### Cautions

Using high brightness settings can cause temporary vision occlusion. Please allow time for the oversaturated parts of the eye to equilibrate back to ambient conditions.

Mobile devices are susceptible to damage from strong electromagnetic fields. Please do not use Reflex near a Magnetic Resonance Imaging device or similar units to avoid damage.

## Patents and Copyright

---

Copyright © 2019 brightlamp, Inc., Indiana.

### Patents

Pat. No. 10,034,605 – Issued: July 2018 – Priority Date: March 2017

## Getting Started

### Approved iOS Devices

Reflex is approved for the following iOS devices:

- iPhone 7 & 7 Plus
- iPhone 8 & 8 Plus
- iPhone X
- iPhone XS & XS Max
- iPhone XR



Reflex iOS Application Icon

Performance of Reflex outside of the approved iOS device list is not guaranteed and brightlamp makes no performance claims of usage outside of the approved device list. While it is possible to use Reflex outside of this iOS device line up, brightlamp strongly recommends against it and to update your current iOS device model.

### Downloading

In order to get started with Reflex you can download the software for your iOS device by visiting [here](#) on your device. Alternatively, you can search for “Reflex – PLR Analyzer” on the iOS App Store and navigate to install the software.

Click on the Reflex icon to open the software.

### Creating an Account

Reflex has two convenient routes to creating an account. Single User accounts are the quickest way to get started and correspond with your Apple ID saved payment method. Enterprise accounts can consist of a single user but allow for an Administrator to setup a team’s accounts and provide independent payment methods.



#### Single User

In order to opt into a single user account, you must create a Reflex account using the following methods:

- Local Credential Creation
- Facebook Account Credentials
- Google Account Credentials

Your credentials are only used to access the device and are not stored or visible by brightlamp.

Sign Up
Login

Next

[Forgot password](#)

[By signing in you are agreeing that you have read and accept the Terms of Use.](#)

**Note:** If either your Google or Facebook account is compromised then please change your password on these accounts as soon as possible to protect your information.

## Enterprise

If you are a member of an enterprise account, please contact your account administrator to get your credentials set up.

## Logging In

Logging into your Reflex account is simple. Use the account link method that you created during account setup. If you forgot your password, then please follow the forgot password link to reset your credentials.

## Configuring Test Conditions and Results

### Recording Settings

Reflex gives maximum functionality to the user by allowing different recording settings and conditions. This increases the ability for users to record vast amounts of test cases to determine which set point is ideal for their test method. It is recommended that a user first starts at 50% **Torch Brightness Level** with 3 seconds of **Torch Duration** and 3 seconds of **Recording Duration**.

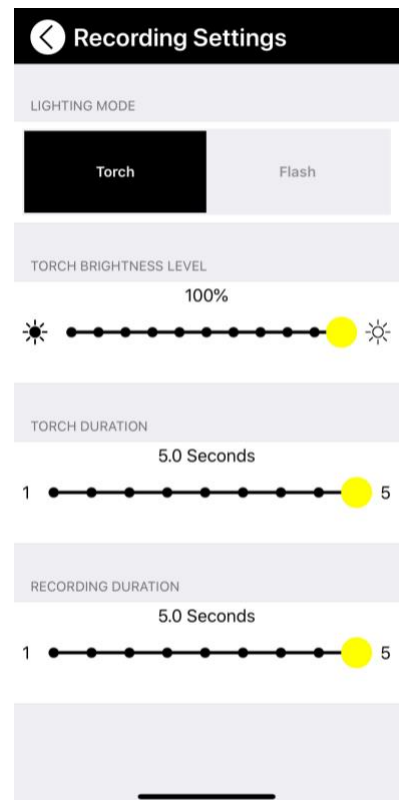
#### Torch vs. Flash

The **Torch** option is for variable control of brightness and test times. However, you can only control the torch being on down to 1 second. For a shorter light sequence please use the **Flash** option which is a burst of light that lasts milliseconds. You cannot adjust **Torch Brightness Level** or **Torch Duration** with the **Flash** option selected.

#### Torch Brightness Level

Brightness of the torch can be adjusted using the **Torch Brightness Level** slider from 0% to 100%.

**Tip:** 0% brightness is for users that wish to measure a response due to an external stimulus. For example, monitoring the brain's reaction to a sudden auditory response. Appropriate lighting conditions are required for a signal to be measured.



**Tip:** 100% brightness may be uncomfortable for test subjects, especially if they have suffered recent head trauma. It is recommended that a level below 100% brightness is selected and made consistent for subject testing.

**Note:** Pupillary response is influenced by external light. If the test location is too bright then the pupil may be at its minimum diameter and little to no response will be observed at any brightness level. We recommend using Reflex in typical room lighting conditions.

## Torch Duration

**Torch Duration** can be adjusted from 1 to 5 seconds when not using the **Flash** option. Duration adjustment can allow for shorter testing periods or for initiating a constriction response while monitoring pupillary dilation after.

**Tip:** A torch duration of too short may not cause the pupil to reach its true minimum diameter at that brightness level.

**Note:** Improper lighting conditions with a **Torch Duration** that is less than the recording duration can cause incorrect results. Please ensure proper lighting under these test conditions.

Constrict Fields	
Max Diameter	✓
Latency	✓
Maximum Constriction Velocity	✓
Average Constriction Velocity	✓
Minimum Diameter	✓
Constriction Time	✓
Average Diameter	✓

## Recording Duration

Adjustments can be made to the length of video recording taken through the **Recording Duration** slider from 1 to 5 seconds. This allows for flexibility in how long tests are conducted. In many cases, the full pupillary response is complete by second 3. A **Recording Duration** that is less than the **Torch Duration** will only record a video for the length of the **Recording Duration** and override torch duration.

## Result Fields

### Test Types

Reflex categorizes tests into three test types:

- No Light – **Torch Brightness Level** is set at 0%
- Constrict – **Torch Duration** is the same or greater than the **Recording Duration**
- Full Spectrum – **Torch Duration** is shorter than the **Recording Duration**

Reflex will attempt to calculate all events and metrics it sees but is defaulted to the presets indicated as follows. Default result calculations may be altered in ‘Settings’ under ‘CUSTOMIZE’.

## Entering Subject Information

### Subject ID or Medical Record Number

Reflex has two methods for entering subject identification numbers / medical record numbers. The most convenient way is to use the barcode scanner to the right of the entry field. If your subject database does not use a barcoding system, then identifying numbers will need to be entered in manually. You can do this by tapping on the “**Subject ID / Medical Record Number**” placeholder text and using the displayed keyboard to insert the information.

### Eye Specification

Eye specification is needed for determining which eye is being tested. It is recommended that the reference point is of the subject’s eye location. So, if the tester is testing the right eye from their reference then it would be the subjects **Left Eye**.

### Date of Birth

The **Birthday** entry field is another piece of data that can be used for identification of the subject. It is recommended that the correct Birthday of the subject is entered every time before testing to ensure proper identification in case of Subject ID mismatch.

### Sex

Indication of the test subject’s **Sex** is another piece of identifiable information. It is recommended that the test subject’s genetic **Sex** is used (Male/Female).

### Last Test Values

Reflex allows for rapid previous subject identification reentry by using the **Last Test Values** button on the top left corner of the information entry box.

**Tip:** You can use this feature to rapidly enter info to test the same subject’s opposite eye.

**Tip:** Retesting the same eye can be done using this feature if the previously recorded test failed. There is no time limit, but it will only populate the last data entry.

## Next

Once all necessary input fields are complete you may click **Next** to proceed with measurement.

## Measurement

### Initiating the Test

To begin the test, align the subject's eye within the *almond* shaped window so the eye fills the window cutout. Once you and the subject are ready you may tap the circular soft button in the bottom center of the screen that shows **0%** in the middle.

As the test is running **0%** will increase with the **Recording Duration** until it reaches **100%**. **100%** indicates that the test is complete.

### Tips for Better Testing

**Stability Tip:** Reflex performs stabilization operations of the test video but if too much motion occurs it can overwhelm the system. Recording with stability will help ensure consistent results. If your hand is shaky, we recommend propping them up onto a solid surface or using a phone-stand.

**Distance Tip:** Be sure to fill the eye inside the *almond* shaped window to ensure best results. Too far away and the system will not pick up a response. Too close, and the video will be too magnified to properly function.





**Gaze Tip:** It is important that the subject is looking directly at the camera. This helps with analysis and accurate conversion to special values (mm). Don't worry if the subject looks away momentarily and directs there gaze back to the camera. Typically, this does not impact output greatly.

### Test Completion

Once test acquisition is completed it will be processed by Reflex's back-end algorithm. You will see a notification badge pop up indicating the progress of the video being sent. Once sent, it takes about 5 to 8 seconds for results to display depending on the strength of your internet connection.

### Results Card

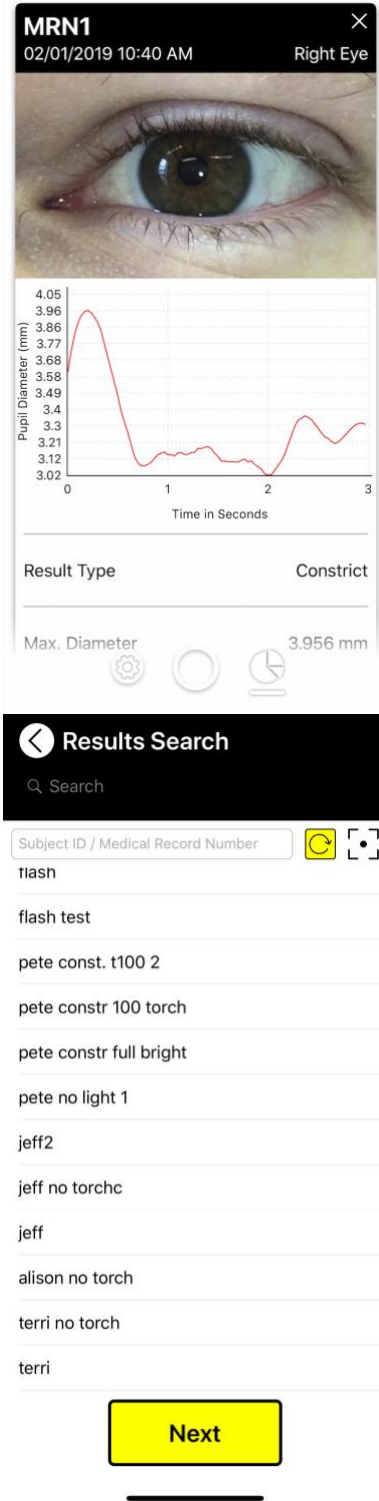
The results screen presents obtained data in a clean, concise format. Each test has a **Results Card** with the ID number, date & time taken, and eye location. Below the subject information is a cropped video around the eye location. The video will play once automatically and can be tapped to replay. A red line represents the raw PLR data values obtained as the pupil diameter in millimeters over time in seconds. Below this chart is the characterization type (**No light, Constriction, Full Spectrum**) and the default calculated parameters (or customized ones if altered) for that test type. Scrolling down will reveal the rest of the card.

### History

Historical tests can be pulled up for the current selected **Subject ID** of Medical Record Number by scrolling past the current test. If previous tests exist, they will load as you continue to scroll until there are no more tests to load.

### Search

Additionally, you may search for a specific **Subject ID** or Medical Record Number using the search feature on the results screen in the top right-hand corner. This will pull up a text entry field that finds most similar searches in the field below. Before text entry, all previous **Subject ID's** will be listed in order of when they were taken.



## Considerations

---

### Excessive Motion

Motion in the video outside of normal correction ranges can result in an inaccurate test or a failed test. Minimization of motion is ideal for consistent results.

### Blinking

While blinking is tolerated in Reflex it should be noted that too many blinks will result in an error due to Reflex's inability to reliably locate the iris. Additionally, blinks will cause momentary dilation of the pupil as it is covered from light. While Reflex measures this accurately, it may be an undesirable response and not representative of a standard PLR response.

### Gaze Direction

Ideally, the subject will look at the camera for the duration of the test. Off center gaze or directionally changing gaze can result in less accurate results. It is recommended that before testing the medical professional makes clear to the subject that they need to look directly into the camera for best results.

## Data Exportation Trending

---

### Exporting Data

The data exportation feature will send a secured data file via an encrypted zip folder to the supplied Reflex email. This will include all calculable parameters for a test and the time series data associated with it. You have the ability to send either the data for that specific test or data for the entire **Subject ID** history at the bottom of the results card.

Brightlamp's recommended unzipping tool is 7-Zip. If you are having trouble accessing your exported data, please contact us.

### Trending Data

Exported data can be used for trend analysis outside of Reflex. Time based trending can offer a lot of insight into temporal fluctuations of the pupillary light reflex. Baseline data is recommended for all subjects if possible. However, it is not necessary to have a baseline set for monitoring progression.

## Frequently Asked Questions

---

### Do I have to reenter the Subject ID or Medical Record Number every time?

Yes, but we have included a handy feature that will allow you to use the previous test's **Subject ID or Medical Record Number**. Use the button on the top-left hand side of the subject information card that says “**Last Test Values**” to import identification from the last test. This allows you to conveniently test both eyes or use multiple tests for the same person without having to reenter subject information.

### **Why do I have to subscribe for my free trial period?**

We do this to ensure uninterrupted service while transferring from the free trial period to the subscription. The free trial period gives you one month free and you can cancel anytime if you wish.

### **Is Reflex a medical device and approved by the FDA?**

Yes, Reflex is a Class I 510(k) Exempt medical device as laid out in 21 CFR 886.1700 by the FDA. This classification does not require formal approval by the FDA.

### **Is Reflex available on Android?**

Not yet! We are actively working on an Android version and will update our audience when it is ready to go.

### **Why doesn't Reflex work on my iPhone 6s or under?**

The computational sophistication of Reflex makes it to where we cannot guarantee that it will record tests correctly on the iPhone 6s or below. Because of this, we restrict the devices to iPhone 7 and up.

### **Why does the Pupillary Light Reflex chart look incorrect?**

There are many reasons that could result in a 'failed test'. As we improve our technology, we will be integrating new methods for failure mode catching and correction. The most common result is due to too much movement from the device. Try retesting with your arms anchored to a stable object. Additional problems include poor lighting conditions and the person looking away. If the problem persists then please contact us so we can help.

### **Why is Reflex giving me an error for the processed video?**

There are a few reasons that this could occur. 1) You are too far away from the individual for our system to reliably find the iris for processing or 2) The test conditions that are being run are causing Reflex to not process enough frames to make the data useful. We check every video for quality of measurement to ensure the best data is being delivered.

### **Why are there zero values in the data time series?**

If Reflex can process most of the video, without significant error, then it will deliver results back that include portions that were not able to be processed by Reflex. Sometimes this includes leading, trailing, or intermediary values. Typically, for intermediary values, Reflex can interpolate to determine a curve, so this does not occur frequently. Leading and trailing zeros indicate extrapolation is needed which Reflex will never do.

### **What happens if the test subject blinks?**

Typically, this does not present a large issue to the test. You will likely see a small rise in pupil diameter due to the quick blocking of incoming light to the pupil. The resulting curve should be okay depending on the duration the eye is closed. To be certain, you can retest the same eye without the subject blinking.

### **Can Reflex integrate with EMR?**

Not yet, but we are actively working with engineers for full EMR integration support.

### **Why is there a barcode scanner in Reflex?**

Many medical record systems use barcode technology to rapidly identify the individual it is corresponding to. We integrated this feature to make inputting the subjects medical record number (MRN) or identification number as easy as possible. If you are unsure that the barcode contains correct identifying information, then please use the manual identification number entry field.

### **Why can't I open the secure zip file that was sent to my email from Reflex?**

You may need to download a supplementary unzipping client to open the secure, encrypted, file. 7 Zip is a useful unzipping tool that will get your data ready to go.

## **Updates**

---

### **iOS Application Updates**

Updates for Reflex are issued periodically to increase functionality. It is recommended that **auto updates** for Reflex are turned **on**. This will allow for you to always stay current with the latest releases and patches.

Current version of Reflex as of this version of the User Guide: **Version 1.2.0**

## **Appendix A – Parameters**

---

Latency – Time taken for the pupil to respond to a light stimulus measured in seconds.

Maximum Diameter – The maximum diameter observed by Reflex measured in millimeters.

Maximum Constriction Velocity – The maximum velocity observed by Reflex over the constriction period measured in millimeters per second.

Average Constriction Velocity – The average velocity observed by Reflex over the total constriction period measured in millimeters per second.

Minimum Diameter – The minimum diameter observed by Reflex measured in millimeters.

Dilation Velocity – The average velocity observed by Reflex over the total dilation period measured in millimeters per second.

75% Recovery Time – The time take for the pupil to reach 75% of its initial diameter value measured in seconds.

Average Diameter – Average of all diameter measurements taken in a time series measured in millimeters.