

Reflex – Frequently Asked Questions

For education and training resources you can log into the Reflex Web Portal with your Reflex credentials: <u>web-portal reflexapp.io</u>. Here you'll be able to access multiple tutorial videos and Reflex specific content and publications.

Regulatory

Q: Is Reflex a medical device registered with the FDA?

A: Yes, Reflex is a Class I 510(k) Exempt medical device registered with the FDA under 21 CFR 886.1700.

Q: Can anyone use Reflex or just medical professionals?

A: Reflex can only be used by licensed medical professionals or for properly reviewed academic research. If you do not fit these criteria, then please ask you healthcare provider to have Reflex tests conducted.

Q: Is Reflex HIPAA complaint and certified?

A: Yes, Reflex is HIPAA compliant and certified through the Compliancy Group.

Q: Does Reflex collect patient health information (PHI) and/or personal identifiable information (PII)?

A: Yes, Reflex requires some PHI and PII to properly differentiate patients in the system and compare to age-controlled and sex-controlled norms. All data, including test videos which contain iridial maps, are encrypted and stored in compliance with HIPAA regulations.

Q: Does Reflex have BAAs signed with its vendors?

A: Yes, all vendors used by Reflex (e.g., AWS, MongoDB) have fully executed BAAs.

Reimbursement

Q: Is Reflex Reimbursable?

A: Yes, Reflex is reimbursable under the following CPT Codes:

CPT Codes	Description
95919	Quantitative pupillometry with physician or qualified health care professional interpretation and report, unilateral or bilateral has been added.
95921	Quantitative pupillometry for the rapid, noninvasive measurement of autonomic nervous system function. Quantitative pupillometry is the objective measurement of pupil size and reactivity through the use of an automatic, portable device that emits a standard light-emitting diode light source and records pupil reaction.

Q: What is the known average billable rate range?

A: Medical providers have had success in receiving payment for Reflex reibursement submissions using the 95919 and 95921 procedural codes.

Q: What ICD-10 codes can be used when billing Reflex with insurers?

A: Reflex is unable to provide specific guidance relating to the Internal Classification of Diseases coding system. There is no indication of use assigned for Reflex past its utility as a pupillometer under 21 CFR 886.1700 and is up to the provider to determine Reflex's appropriate ICD-10-CM utility. However, many free and paid resources exist, of which, you





may already have at your disposal to correctly identify an appropriate ICD-10-CM code. An example of a free resource is ICD10Data.com.

Q: How should I structure my submission for reimbursement with insurers?

A: To request reimbursement, you must submit a professional interpretation and report, along with the relevant ICD-10-CM diagnostic code. Reflex offers a streamlined solution for providers to include this interpretation and documentation directly in a comprehensive PDF report through the notes feature. All notes will be incorporated into the exported PDF results, which can be utilized for filing purposes. A screen capture of the notes section within Reflex for iOS is shown below.



Specifications

Q: Which Apple devices support Reflex?

A: iPhone models 8 and up can run Reflex provided they are on their latest iOS software versions. iPad Pros, excluding 1st generation (2015) models, and the latest generations of iPad Minis can run Reflex as well. When in doubt, simply check if there is a flash LED and camera on the back of the device. Some iPads do not have the flash LED (e.g., iPad Air) and cannot run Reflex.

Q: I don't have an iPad. Can I still use Reflex Pro?

A: Yes, some features for Reflex Pro are available on the iPhone version. However, we will provide you a new iPad as part of a 2-year service agreement with Reflex Pro if you desire to have on available at your clinic. This promotion is free of charge, and you get to keep the iPad at the end of the agreement period.

Q: Is Reflex available for Android?

A: No, Reflex is only available for iOS and iPadOS devices.

Q: Do you have an online web portal where I can see and interact with my collected data?

A: Yes, you can login with your reflex credentials here: web-portal.reflexapp.io- which will allow you to view your collected data, export tests to PDF and CSV files, conduct control charting, manage patients, and send out Reflex Telehealth requests.

Q: Is Reflex peer reviewed and its methods proven in research?

A: Yes, you can review a curated list of publications by logging into the <u>Reflex Web Portal</u> with your Reflex credentials and scrolling to the bottom of the homepage.

Q: Why does the Reflex screen look so small on my iPad?

A: This is because you downloaded the iPhone version of Reflex onto your iPad. Please download Reflex Pro by searching "Reflex Pro PLR Analyzer" in the App Store so you can start using a native version of Reflex built for the iPad.

Q: What is the difference between Reflex, Reflex Pro, and Reflex Telehealth?

A: Reflex is the iPhone version of the application, Reflex Pro is the iPad version of the application, and Reflex Telehealth is an iPhone version of the application specific to patients.





A standard Reflex subscription only includes the iPhone version. Subscribing to Reflex Progrants you access to both the iPad and iPhone applications. Only Reflex Pro + Reflex Telehealth subscribers can have their patients use Reflex Telehealth.

Q: What is Reflex Telehealth?

A: Reflex Telehealth is an add-on service to Reflex Pro which allows you to send tests to your patients at their home so they can take a remote Reflex test. They will not receive any data and you will be able to review data just like you would with Reflex Pro when it is available.

Q: Where is the data being stored?

A: Videos are stored in private and separate AWS S3 buckets. App data is stored on AWS instances with MongoDB being Reflex's databasing solution. All data is encrypted at rest.

Q: How is data communicated between Reflex and its servers?

A: Communications between Reflex and the database are encrypted and sent through SSL.

Q: What is Reflex's sampling rate?

A: Reflex samples at 30 Hz, a typical sampling rate for pupillometry.

Q: How fast is the "Flash" setting in Reflex?

A: The "Flash" setting has a 200 millisecond delay and lasts for a duration of approximately 300 milliseconds.

Q: How bright is the torch on Apple devices?

A: The torch brightness is 50 lumens when set to 100% and linearly decreases with your preferred setting.

Q: Does Reflex need to be calibrated?

A: No, Reflex auto-calibrates each time a test is conducted.

Testing

Q: How far away should I hold the phone from the patient's eye/face?

A: Reflex should be used about 7 inches away from the eye/face. The almond shaped cutout has been aligned for your device so if you align the corners of the eye with the corners of the cutout then you will be consistently about 7 inches away each time you test.

Q: How does blinking impact the test?

A: Blinking inherently shrouds the eye in brief darkness which will cause some minor dilation mid-test. It is up to your interpretation as to whether this data is still suitable (with one blink it most usually is depending on when it occurs in the test). However, too many blinks will result in an errored test, and you will be asked to retake the test.

Q: Can I test at an angle?

A: Yes, Reflex corrects for parallax and shortening by using automatic geometric corrections built into the app.

Q: Are baselines required?

A: No, baselines are not required with Reflex but can be helpful in data comparisons. We have included the ability to mark a test as a baseline prior to testing in Reflex and you can mark prior tests as baseline in the Reflex Web Portal.





Q: Can Reflex tests be taken in the dark?

A: Only if the test settings are set to have the light on for the duration of the test. Unlike infrared pupillometers, Reflex cannot be used in the dark without supplementary light. However, Reflex provides an "ambient adapt brightness level" that you can adjust to your liking that allows a small amount of light to be emitted when testing for dilation measures.

Q: What is the recommended room lighting when testing?

A: Standard ambient room lighting is fine to use Reflex in. It is recommended that you avoid large windows with lots of sunlight as this may create a glare and/or cause pupillary constriction which diminishes the pupillary response.

Q: What is the recommended adaptation period?

A: Pupils typically stabilize within 60 seconds but if many changes in lighting or multiple tests are occurring then you may need to wait as long as 180 seconds for consistency.

Q: What age ranges can be tested with Reflex?

A: All ages can be tested with Reflex. Ages tested by Reflex have included ages 2 through 102 but Reflex's normative data comparisons only support ages from about 7 to 78.

Q: Can Reflex be used in pediatrics?

A: Yes, any age range can be test with Reflex with the understanding that normative data might not be available for patients that fall below our bulk data repositories age range.

Troubleshooting

Q: Why does Reflex show a red banner that indicates I'm in a free trial or an inactive subscription when I have paid for my subscription?

A: This usually means you accidentally created a second account through Reflex. Sometimes, this can be technical issue that can be rectified in a few minutes. Please contact us so we can get you correctly set up with your active account (contact details at end of document).

Q: Why is the camera on the Reflex test screen not showing anything?

A: Permissions for Reflex to access your camera were likely turned off on accident through loading another application. Please navigate to Settings > Reflex and toggle the Camera item to "On" as indicated by the green coloration.

Subscription

Q: Will I be automatically billed after my 14-day free trial?

A: No, you will not be automatically billed but you may receive an invoice via the email you created your account with. This is an invoice, not a bill. If you choose not to continue service, then your account permissions will be automatically restricted.

Q: Should I subscribe through Apple or is there an alternative way to start my subscription?

A: If you subscribe through Apple then all subscription management is done through Apple with little flexibility. We can provide you secure Stripe invoice to pay so we can directly help you manage your subscription. Please contact us via chat, email, or phone to set this up (contact details at end of document).

Q: Is my subscription license for only one user and account?





A: Yes, your Reflex subscription license is for only one user and account.

Q: Do you have organization accounts where multiple authorized providers can see the and share the data?

A: Yes, we can help you service an entire organization unit through Reflex by allowing authorized data sharing and toggling between your tests and the organization's tests.

Q: I have multiple care givers at my operation that can use Reflex. Do you offer volume discounts on subscriptions?

A: Yes, we have tiered pricing on three or more accounts. We will adjust the volume pricing based on the quantity of needed accounts you share with us.

Account

Q: I have forgotten my password. How can I recover my account?

A: Please use the forgot password function in Reflex, Reflex Pro, or the Reflex Web Portal through Google Chrome. For security reasons, the Reflex team does not have access to user set passwords.

Q: What browsers are supported for my Web Portal account?

A: It is recommended that you use Google Chrome for accessing The Reflex Web Portal.

Q: How can I sign into my account?

A: Instead of using an email/password combination, you are able to quickly sign in via Apple, Google, and Facebook logins. Note: if you're using a Gmail account, and have already setup an email/password login, you can still login with the Google Login option.

Q: I use my Apple ID "Hide My Email" to log into Reflex. How do I sign into The Reflex Web Portal on a non-Apple device?

A: You will need the randomly generated "Hide My Email" private relay email (example: ak2bb4gae@privaterelay.appleid.com). You can find this by going to your Apple Device Settings, selecting your Apple ID name at the top, selecting "iCloud", then selecting "Hide My Email", and finding Reflex listed amongst the email generated.

Q: Can I sign into more than one device using my Reflex account?

A: Only a Reflex Pro subscription allows you to be signed into two devices (iPhone and and iPad) at the same time.





Questions?

Please contact our team if you have any questions regarding medical reimbursement with Reflex. You can reach us in the following ways:



www.reflexapp.io/contact



+1 (317) 681-3715



Chat with us directly in the Reflex App.

