



myVisionTrack (mVT)

Patient Mobile App - Instructions for Use

myVisionTrack Rx only 

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General Information

Intended Use

mVT is intended for the detection and characterization of the central three degrees metamorphopsia (visual distortion) and as an aid in monitoring changes in metamorphopsia (e.g. due to disease deterioration or treatments) in patients with maculopathies.

mVT is intended to be used by patients with a capability to regularly perform a simple self-test at home and by their healthcare provider who have access to the test results.

mVT is not intended to diagnose. Diagnosis is the responsibility of the prescribing healthcare provider.

Limitations of Use

Data provided by mVT is not to be used as the basis to postpone or cancel regular appointments with your healthcare provider.

Product Description

myVisionTrack (mVT) is a secure cloud-based software consisting of a mobile application that runs on a smartphone or tablet (patient mobile app) and a web-portal (healthcare provider portal).

The mVT app allows patients to test their vision function at home, and a web-portal serves healthcare providers (HCP) and their staff to manage patients and view their test results.

The mVT app incorporates a shape discrimination hyperacuity (SDH/shape) activity which has been demonstrated to be accurate at detecting significant changes in vision function.

mVT app is easy to use by patients and allows for unsupervised and frequent self-testing for patients in routine clinical care. Patients can set reminders for regular self-testing and HCP and their staff can receive web-portal and email notifications associated with indications of significant changes in vision function.

The mVT app is prescribed by healthcare providers to be used by patients:

- Aged 18 years and above
- Able to proficiently use a smartphone

Warnings and Precautions

The health information provided through the mVT app is not a substitute for the advice of a qualified healthcare provider.

mVT does not provide interpretation of test results, give treatment recommendations, or provide diagnosis. Do not use this product as a tool for self-diagnosis.

Always present any questions you may have regarding your vision activity results, medical condition, or treatment directly to your healthcare provider.

If you notice a change in your vision, contact your healthcare provider.

The app is to be used only by the patient whom the application has been prescribed to ensure the reliability of the data provided to the healthcare provider.

Carefully follow the app's testing instructions to test the correct eye. Testing both eyes at the same time or testing the wrong eye leads to inaccurate results being sent to your healthcare provider.

Contraindications

None known

Environment for Use

The mVT app should be used in an environment with adequate lighting where you are able to position your smartphone or tablet in a stable position. See the "Before Starting the SDH Activity" section for more information about self-testing setup.

Compatibility and Security

mVT app is available for iOS and Android mobile smartphones or tablets, and available for download in the relevant app stores. Compatibility is listed in the app stores.

mVT is a prescribed application, and while it may be available for download by non-prescribed users, you will need a participating healthcare provider to invite you before using the app.

Only install and update this app from the official mVT app store listings, and ensure you have the latest version installed (or enable automatic app updates). This app is only to be used on phones or tablets running official mobile operating systems.

Your healthcare provider will invite you to use the app with your unique email address and a one-time verification code which will be sent to your mobile phone number.

Once you register, you will create a secure password that meets the password requirements of the application. Do not share your login information with others or use this app on unsecured networks.

Getting Started

Invitation and Installation

Your mVT invitation: Your HCP will create your invitation using your:

- Email address - this will be your login to the app
- Mobile phone number – an invitation text message will be sent to with a download link and verification code

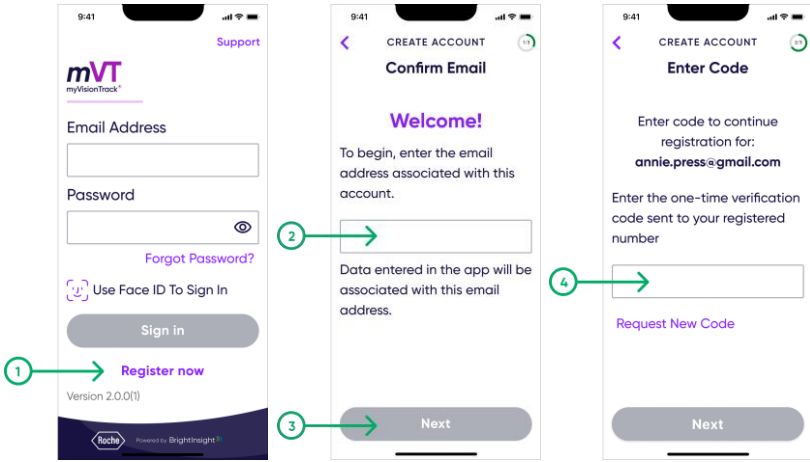
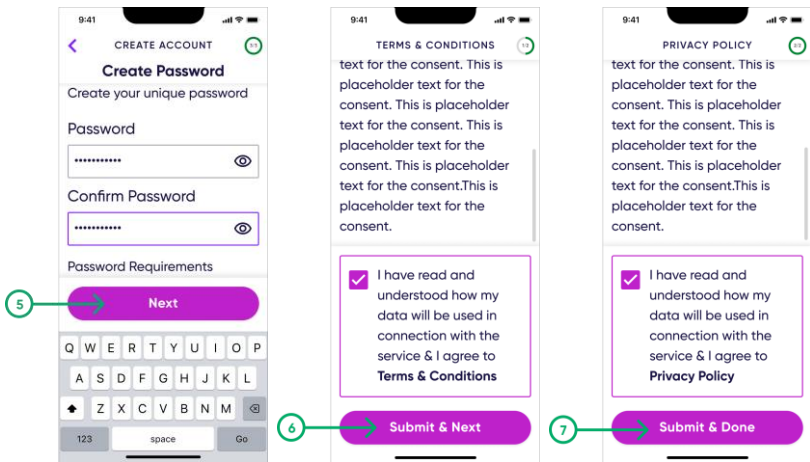
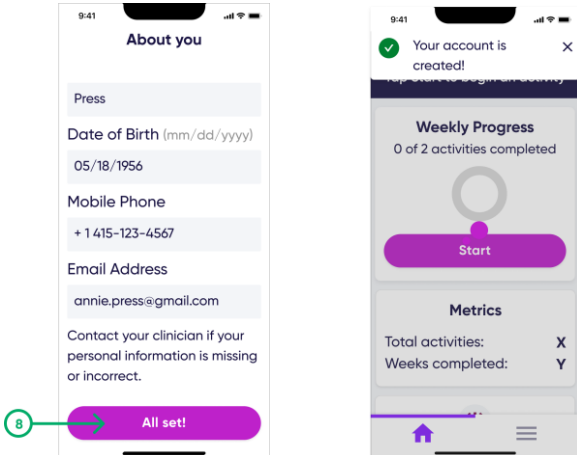
Downloading the mVT app: Search for “mVT” in the Apple App Store or Google Play Store and download the application to your smartphone or tablet – or use the download link included in your invitation text message.

Note about permissions: You may be prompted to enable optional permissions:

- Notifications: Set notification reminders to complete scheduled vision activities.
- Biometrics: Login to the app using biometrics if you’ve enabled them on your smartphone or tablet.
- Camera: Allows measurement of distance and ambient light while completing vision activities.

Registering Your Account

Open the app to register your account. Starting from the login screen:

<ol style="list-style-type: none">1.Touch “Register now”2.Enter the email address you provided to your HCP3.Touch “Next”4.Enter the code from your invitation text message and touch “Next”	
<ol style="list-style-type: none">5.Create your password and touch “Next”6.Review and accept Terms & Conditions, and touch “Submit and Continue”7.Review and accept Privacy Policy, and touch “Submit and Done”	
<ol style="list-style-type: none">8.Registration is now complete. View your “About You” account information. <p>Touch “All Set” and you’ll be taken to the home screen.</p>	

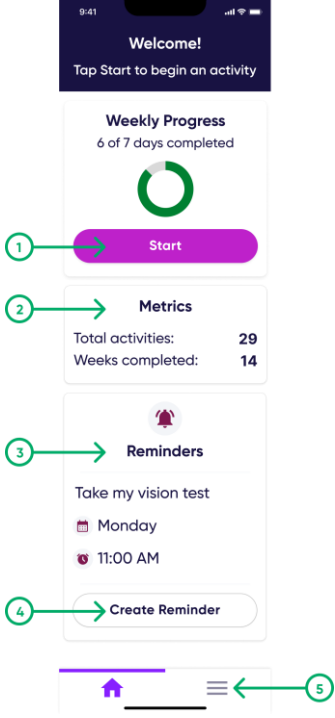
Using myVisionTrack

Logging In

After registration is complete, you'll use the email address associated with your account and your current password to login to the app.

Home Screen

From the Home Screen, you can start a vision activity, view metrics related to your completed vision activities, and view or setup reminders to take your vision activity.

1.Start an activity	
2.View activity metrics	
3.See next reminder	
4.Manage reminders	
5.Navigate to Menu Screen	

SDH Activity Overview

The Shape Discrimination Hyperacuity (SDH/Shape) Activity involves showing you multiple shapes on the screen, and you will touch the shape that looks different from the others.

Your HCP may prescribe you to test one or both eyes. One eye will be tested at a time, and you should cover the eye not being tested with the palm of your hand. The activity takes approximately 2-3 minutes per eye to complete.

For each eye tested, there will be multiple rounds of the activity, and each round it will become harder or easier to identify which shape looks different from the others.

You will always get to a point where it is difficult to identify which shape looks different from the others. When you get to this point it's okay to guess.

Before Starting the SDH Activity

Before starting the activity, disconnect power to your smartphone or tablet:

We recommend that you unplug the power cable from your smartphone or tablet before starting a session so that the cable does not interfere with your ability to complete the activity.

Internet and network connection:

We recommend that your smartphone or tablet is connected to the internet while performing activities. Check your smartphone or tablet to ensure there is a WiFi or mobile data connection before starting an activity.

Check your screen:

Check the screen for smudges and cracks. If smudges are present, wipe the screen with a soft cloth to remove before testing. The activity should not be completed on a smartphone or tablet with a cracked screen.

Positioning:

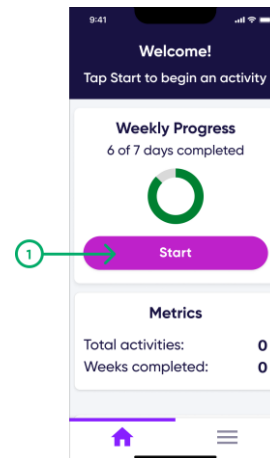
Place or hold your smartphone or tablet at the same distance you would use to hold a newspaper or book to read. If you have trouble holding it, please consider using a smartphone or tablet stand during the activity. Set up the stand on a table and place your smartphone or tablet in a vertical orientation so that the bottom of your phone or tablet is located at the bottom of the stand.

Lighting:

Choose a quiet location to perform the activity. Take a seat in a room with moderate lighting away from a windows or overhead lighting glare.

Completing SDH Activities

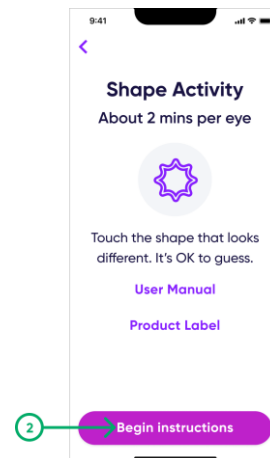
1. Touch “Start” from the Home Screen



2. The first time you start an Activity, you will be prompted to view the Pre-Activity test instructions. Touch “Begin Instructions” to continue

After your first Activity has been completed you will have the option to Skip Instructions

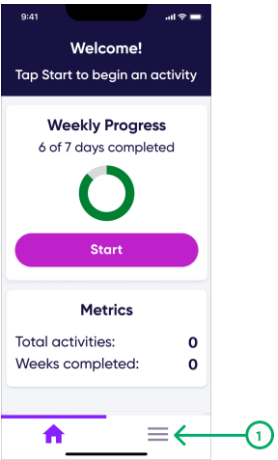
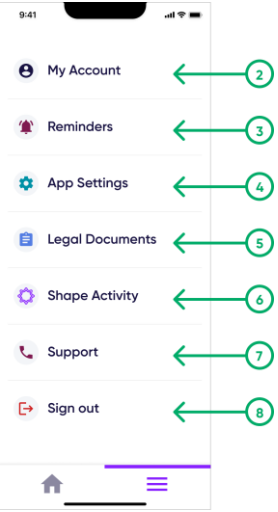
You will always be able to revisit Pre-Activity test instructions by navigating to the Menu Screen, touching “Shape Activity”, and then touching “Test Instructions”



Follow instructions as displayed in the App to complete your Activity.

Menu Screen Options

Access the Menu Screen to see additional features and access settings for the app.

<p>1.Touch the Menu button from the Home Screen</p>	
<p>2.My Account – View account info, update your password, or delete your account</p> <p>3.Reminders – Create, edit, or delete reminders</p> <p>4.App Settings – Manage notification and biometric permissions, language settings, text size settings</p> <p>5.Legal Documents – View Terms and Conditions, and Privacy Policy</p> <p>6.Shape Activity – View Pre-Activity test instructions, User Manual, and Product Label</p> <p>7.Support – View Support Contact Info</p> <p>8.Sign Out – Sign out of the app</p>	

Contact Us

You can contact support at the following email address or phone number:

For United States customers

mvt_support@gene.com

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