

KinesiaU[™]
MOTOR ASSESSMENT SYSTEM

USER'S GUIDE

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Great Lakes NeuroTechnologies Inc.'s KinesiaU motor assessment system and its use are covered by one or more patents listed at: www.glneurotech.com/patents/.

Use of the KinesiaU motor assessment system is governed by the terms and conditions and end user license agreement (EULA) at <http://www.glneurotech.com/eula> and privacy policy at <https://www.glneurotech.com/support/privacy-policy/>.

KinesiaU™ is a trademark of Great Lakes NeuroTechnologies Inc.

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Chapter 1. About KinesiaU Motor Assessment System

The KinesiaU motor assessment system is a medical system designed to capture and evaluate motor symptoms using a smartwatch and smartphone app. Patients can view reports that show symptom severities over time.

Intended Use

The KinesiaU™ motor assessment system is intended to monitor physical motion and muscle activity to quantify kinematics of movement disorder symptoms such as tremor and assess activity in any instance where quantifiable analysis of motion and muscle activity is desired.

Warnings

The product is to be used only under the direction of a qualified clinician and all changes to therapy regimens are to be based solely on the clinical judgment of the clinician.

Standards and Definitions:

The following symbol on product labeling advises consultation of this document for important safety related information:



Chapter 2: Installing the App

Prerequisite

1. Make sure you have a compatible Android phone & smartwatch. A list of approved devices is available at www.KinesiaU.com.
2. Make sure you have a Google Play Store set up properly, including a valid payment method.
3. Make sure you have Wear OS 2.0 installed and paired with your smartwatch.

Preparation

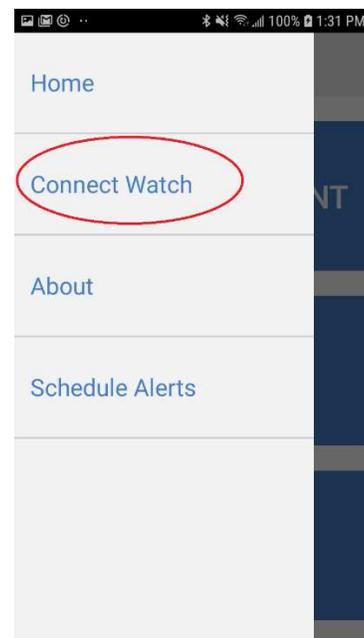
1. Have your doctor fax a prescription to Great Lakes NeuroTechnologies at (216) 361-5420 or mail it to:
KinesiaU c/o Great Lakes NeuroTechnologies
6100 Rockside Woods Blvd, N Suite 415
Independence, OH 44131
2. Make sure your email address is included in the prescription.
3. You will then receive a KinesiaU introductory email.
4. Once you have received the email, join the program by following the instructions in the email.

Installation

1. From your Android Phone, follow the link in the email to the Google Play Store and download and install the KinesiaU app.
2. After the KinesiaU app is installed on your phone, a notification may be displayed on your watch asking you to install the smartwatch companion app. Follow the instructions to download and install the KinesiaU smartwatch app. If you do not receive the notification to install the smartwatch companion app, you should install it manually by opening the Play Store on your smartwatch. In the Apps on your phone section, tap the download symbol next to KinesiaU icon and follow the instruction to download and install the app to your smartwatch.
3. Open the KinesiaU app on your smartphone.
4. After a fresh installation, the End User License Agreement (EULA) will pop up. You must agree to the EULA in order to proceed to the next step.
5. You will next be asked to enter your email address. Be sure to enter the same email address provided in your prescription.
6. Select a KinesiaU subscription option.
7. Follow the Google Play instructions to pay for your subscription.

App Configuration

1. Click the menu button in the top left of the screen and select Connect Watch.
2. Follow the instruction to connect with the watch paired through Wear OS.
3. The app is now ready for you to perform an assessment.



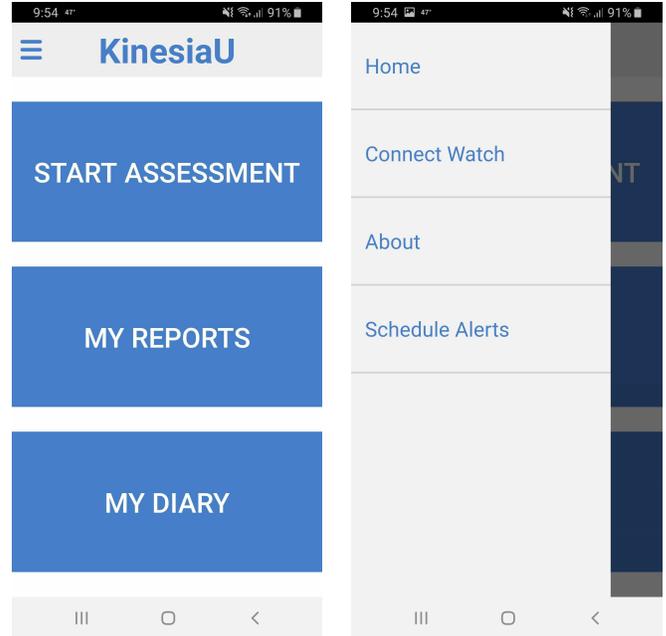
Chapter 3: Navigating the App

Home Screen

The Home Screen includes three large buttons and a menu button on the top left of the screen. The START ASSESSMENT button is used to perform a motor assessment (see Chapter 4: Performing Motor Assessment Tasks), the MY REPORTS button is used to view reports (see Chapter 7: Viewing Reports) and the MY DIARY button is used to enter diary events (see Chapter 6: Using the Diary)

Menu Button (≡)

The menu button is accessed by tapping on the three horizontal lines on the top left portion of the Home Screen. The menu includes options for returning to the Home Screen, connecting a smartwatch (see Chapter 2: Installing the App, App Configuration), viewing the About screen, and scheduling alerts (see Chapter 5: Setting Alerts)



Chapter 4: Performing Motor Assessment Tasks

Motor Assessment

To perform a motor assessment, tap the Start Assessment button on the Home Screen. Make sure you are wearing the smartwatch on the side to be assessed and tap Continue. You will then be instructed to launch the KinesiaU app on your smartwatch. The app on the smartphone will then guide you through two motor tasks: 1) Resting your arms and 2) Rotating your wrist. The watch will vibrate to indicate the starting and stopping of motion data collection during each of the two tasks. Instructions for performing the two tasks are as follows:

Resting your arms

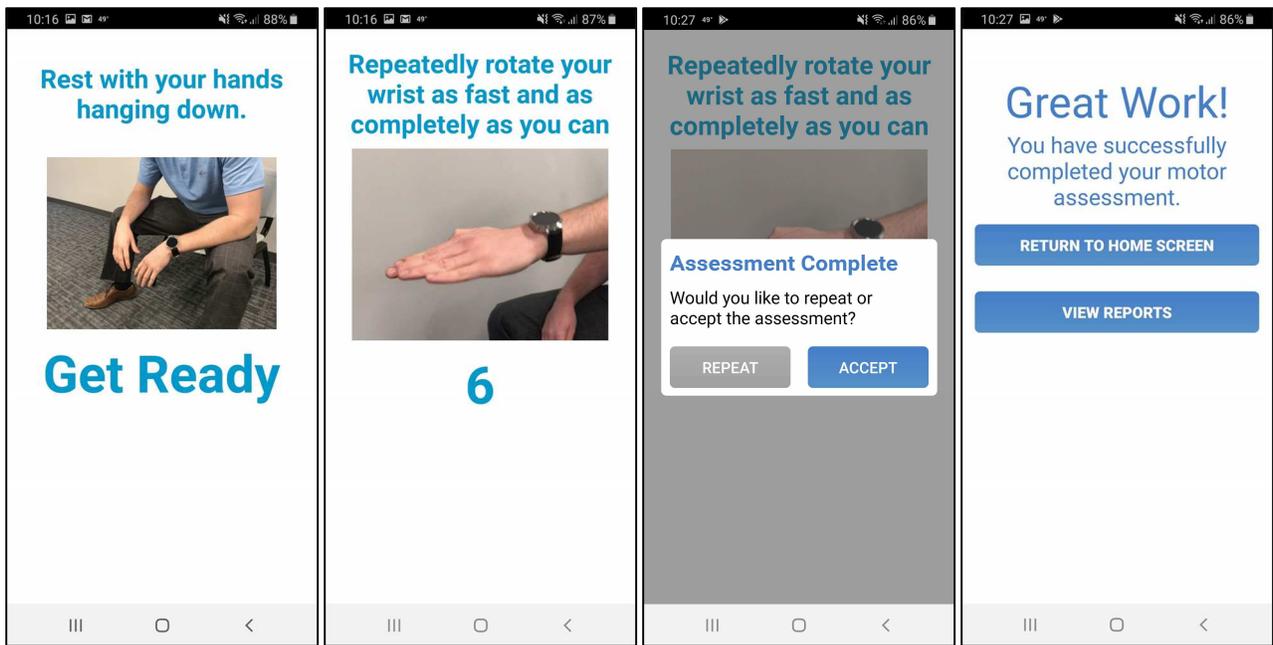
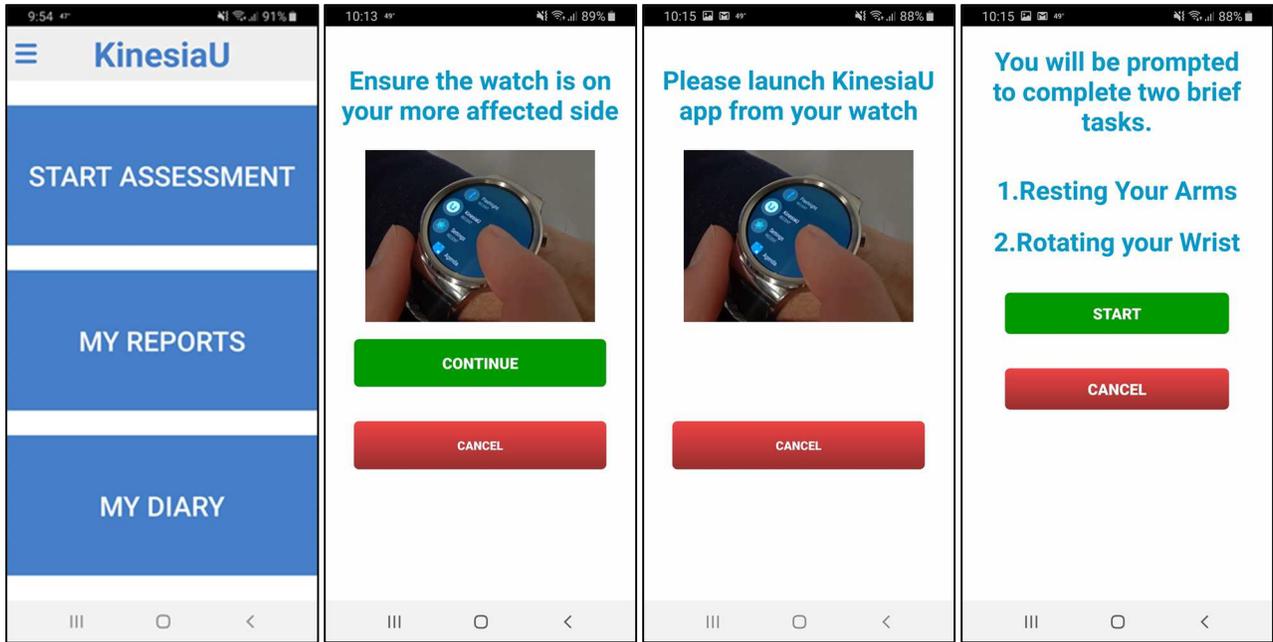
For this task, remain seated with both hands in your lap. Keep your hands relaxed and allow them to hang between your legs. Your hands should not be touching each other or your legs.

Rotating your wrist

Repeatedly rotate your wrist fully between palm-facing-up and palm-facing-down as fast as you can.

During each motor task, the timer will count down from 7 seconds, during which you should perform the specified task. After completion of the two tasks tap “Accept” if you properly performed the task or “Repeat” if something prevented you from following the instructions (e.g., you were interrupted or distracted when performing the task). You may then tap a button to return to the Home screen or view your reports.

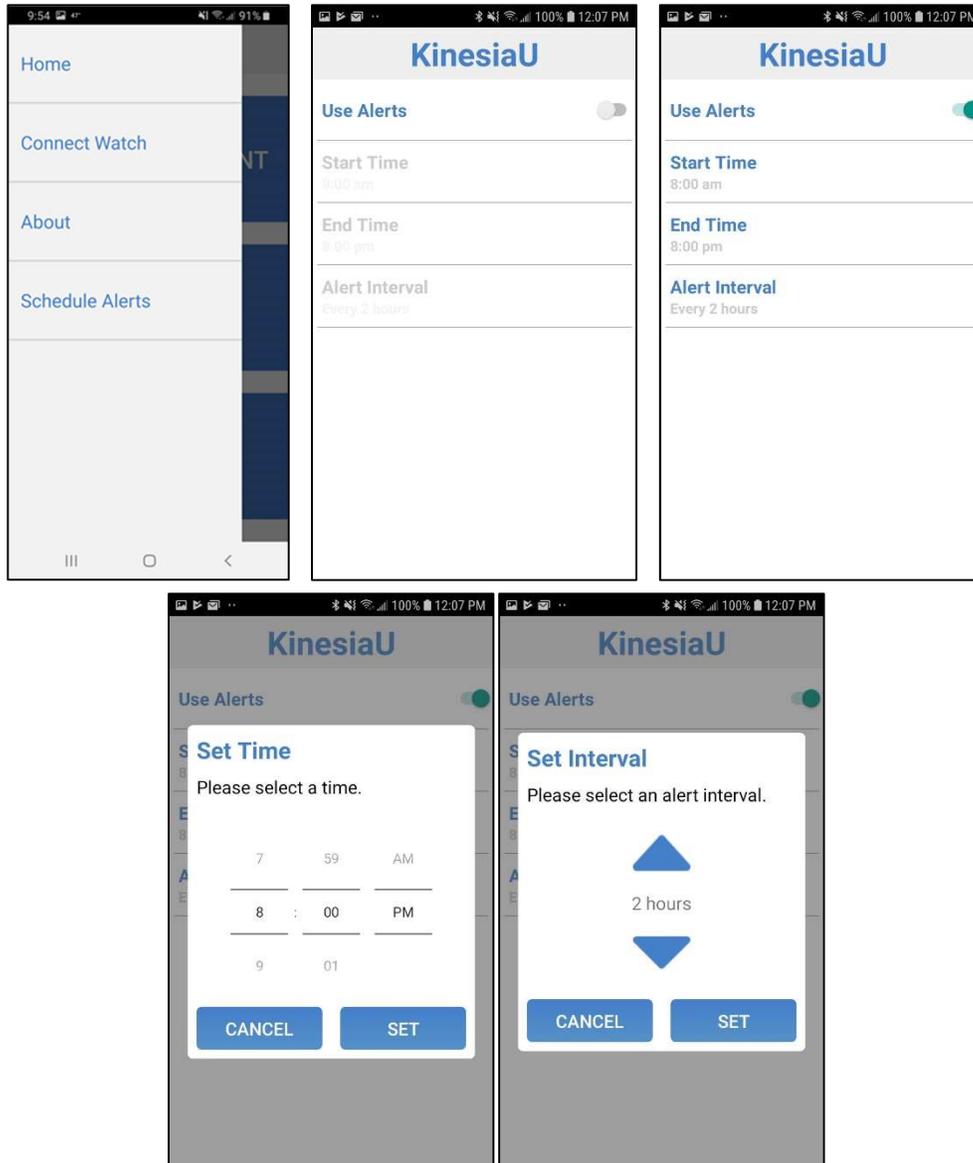
The images below show the screens you will see as you complete the motor assessment.



Chapter 5: Setting Alerts

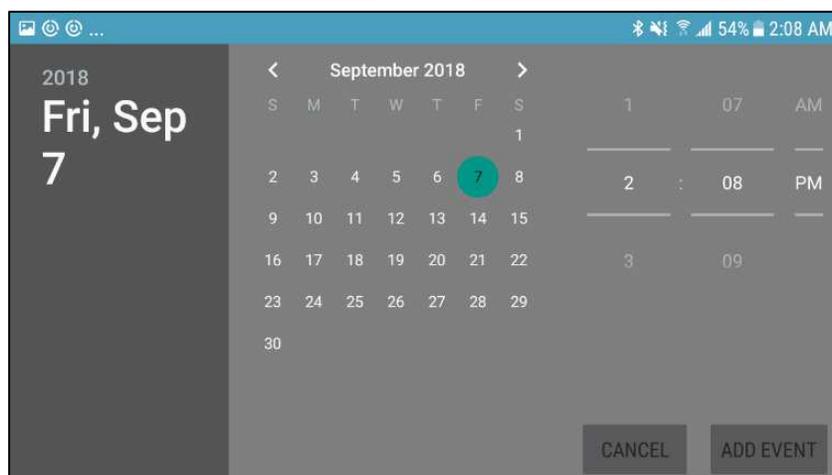
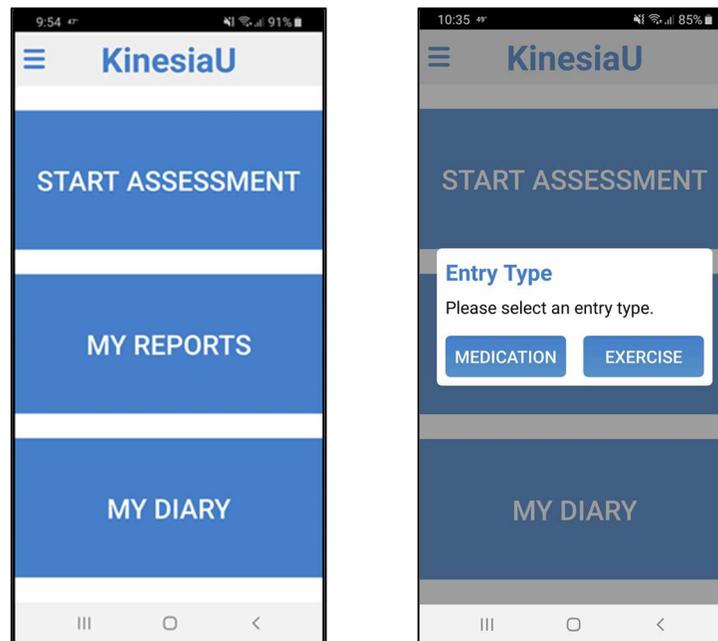
You may set alerts in the app to periodically remind you to perform motor assessments.

1. From the KinesiaU Application Main Screen, tap the Menu button and then select Schedule Alerts.
2. Swipe the switch next to “Use Alerts” to activate the Alert system.
3. Adjust the desired start and end times for your alerts.
4. Select the interval between alerts (minimum 30 minutes).



Chapter 6: Using the Diary

To add a Diary Event, tap the My Diary button on the Home screen. You can then select Medication or Exercise by tapping the corresponding button. Then select the date and time that the event took place. Note that Diary Events can also be added via the Actions menu when viewing a report.

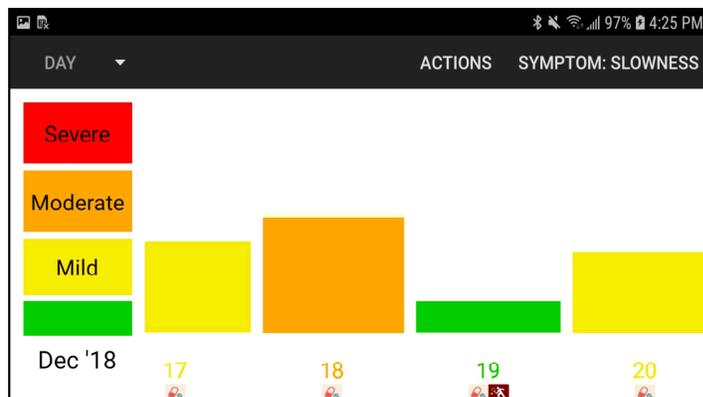


Chapter 7: Viewing Reports

Viewing the Reports

After recording motion assessments, you can view the results in the My Reports section:

1. From the KinesiaU Application Main Screen, select My Reports.
2. The report page displays the severity of the selected symptom averaged for the selected time range.
3. Swipe left or right to move forward and backward in time from the initial position.
4. In the upper left you can select to display results by different time periods. Alternatively, you can zoom in on a specific time interval by tapping on one of the bars.
5. In the upper right, the SYMPTOM selector lets you display results for each individual symptom (Tremor, Slowness, Dyskinesia,) or all three averaged together (All Symptoms).
6. To the left of the SYMPTOM selector, the ACTIONS button is used to add events (Medication or Exercise), toggle blank intervals on the report (Toggle Blanks) to appear (keep hour/day/week continuity) or disappear (only show the intervals when data was collected), generate PDF report files, and view saved PDF reports.
7. Press the arrow back button on the smartphone to return to the home screen.





Understanding the Reports

The height of each bar indicates the symptom severity with low bars indicate low severity and tall bars indicating high severity. The bars are also color-coded from green to yellow to orange to red indicating severity. The symbols  and  indicate medication and exercise events, respectively.



The KinesiaU app is designed to help you monitor your medical condition, but you, with the guidance of your Healthcare Provider(s), are responsible for your treatment and care. The content provided by the KinesiaU app should be treated similar to a patient diary as one of many factors in the discussion and modification of your therapeutic regimen and does not substitute for seeing your Healthcare Provider(s). Always consult with your doctor before starting, stopping or changing any course of treatment, therapy, diet, fitness, or other such course of action or program, or if you experience any pain or discomfort.

Saving a Report

You may save a PDF of your report to your smartphone by selecting Generate PDF on the ACTIONS menu. You can then select which symptoms to save, the report type, time interval and a filename for the PDF. A multi-page PDF will then be created with each page showing a corresponding screen from the My Reports section from this app for each time range and symptom selected. As such, the exact date range may not match the requested range.

11:30 49° 82%

HOUR ACTIONS SYMPTOM: TREMOR

Symptom(s): Tremor Slowness
 Dyskinesia All Symptom (Average)

Report Type: Daily

Interval: 3/1/2019 - 3/31/2019

Filename: _____

GENERATE REPORT

A list of previously saved PDF reports can be accessed by selecting Saved PDFs on the ACTIONS menu.

Chapter 8: Support

Additional information and FAQ can be found at www.KinesiaU.com.