

KinesiaU[™]
MOTOR ASSESSMENT SYSTEM

USER'S GUIDE

Mailing Address: Great Lakes NeuroTechnologies Inc.
6100 Rockside Woods Blvd. Suite 415
Cleveland, Ohio 44131
United States of America



Great Lakes NeuroTechnologies Inc.
6100 Rockside Woods Blvd. Suite 415
Cleveland, Ohio 44131
United States of America
Phone: 216-361-5410, Fax: 216-361-5420

© Great Lakes NeuroTechnologies Inc. 2021

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.

User Guide, 392-0069 Rev D, DCO G542

TABLE OF CONTENTS

Chapter 1. About KinesiaU Motor Assessment System	4
Intended Use	4
Warnings	4
Standards and Definitions:	4
Chapter 2: Installing the App.....	5
Prerequisite	5
Preparation.....	5
Installation	5
App Configuration	7
Chapter 3: Navigating the App.....	7
Home Screen	7
Menu Button (☰).....	7
Chapter 4: Performing Motor Assessment Tasks	8
Motor Assessment.....	8
Chapter 5: Setting Alerts.....	10
Chapter 6: Using the Diary.....	11
Chapter 7: Viewing Reports	12
Viewing the Reports	12
Understanding the Reports	13
Saving a Report	13
Chapter 8: Data Sync.....	14
Connecting with your doctor.....	14
Retrieving your data on a new phone.....	14
Chapter 9: Support	15

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:



Smartphone Compatibility

The KinesiaU motor assessment system includes software for Android and iPhone smartphones. Some features may only be available in one version or the other, and some screens will be displayed differently from the images shown in this guide depending on the platform, software version, and device settings.

Chapter 2: Installing the App

Prerequisite

1. Make sure you have a compatible smartphone and smartwatch. A list of approved devices is available at www.KinesiaU.com.
2. Make sure you have the Apple App Store or Google Play Store set up properly, including a valid payment method.
3. For Apple, make sure your Apple watch is paired with your iPhone. For Android, make sure you have Wear OS 2.0 installed and paired with your smartwatch.
4. For Android, if the email address that was provided for your prescription **is not** a Gmail address, the following steps must be completed to create a google account with your current email address.
 - a. Log out of any Gmail account(s) you're currently logged in to, then open <https://accounts.google.com>.
 - b. Click the Create Account link below the gray "sign in with your Google Account" box.
 - c. Below the "Choose your username" field, click I prefer to use my current email address link.
 - d. Enter your non-Gmail email address you would like to register with Google.
 - e. Finish filling out the new account form and accept Google's Privacy Policy and Terms.
 - f. Confirm your new account with the email address you provided.

Preparation

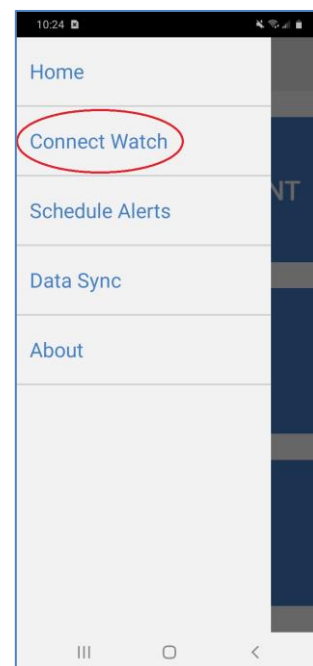
1. Have your doctor fax a prescription to Great Lakes NeuroTechnologies at (216) 361-5420 or mail it to:

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.

Installation

Android

1. From your Android phone, follow the link in the email to the Google Play Store and download and install the KinesiaU app. Alternatively, you may find the app in Google Play by searching for KinesiaU.
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 log in using your Google account. 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.

Android App Configuration

1. To use the KinesiaU app, your Wear OS smartwatch must be connected to your smartphone using Wear OS app. For detailed instructions, visit <https://support.google.com/wearos/answer/6056630>.
2. Click the menu button in the top left of the screen and select Connect Watch.
3. Follow the instruction to connect with the watch paired through Wear OS.
4. The app is now ready for you to perform an assessment.

iPhone

1. From your iPhone, follow the link in the email to the App Store and download and install the KinesiaU app. Alternatively, you may find the app in the App Store by searching for KinesiaU.
2. After the KinesiaU app is installed on your phone, the app should automatically start downloading to your watch. If the app does not download to your watch, you can manually download the app by looking at your watch's settings for any apps on your phone that could be downloaded to your watch.
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 log in using your Apple ID account. Be sure to enter the same email address provided in your prescription. If prompted, share your email with the KinesiaU app or you will be unable to sign in.
 - a. If you chose to hide your email from the app accidentally, you can disable this feature. Navigate to **Settings > [Your Apple Id] > Password & Security > Apps Using Apple ID > KinesiaU**. On this next page, choose the option to 'Stop Using Apple ID'. The next time you open KinesiaU, the app will prompt you to either share or hide your email address. Choose the option to share your email and continue signing into the app.
6. Select a KinesiaU subscription option.
7. Follow the instructions to pay for your subscription.

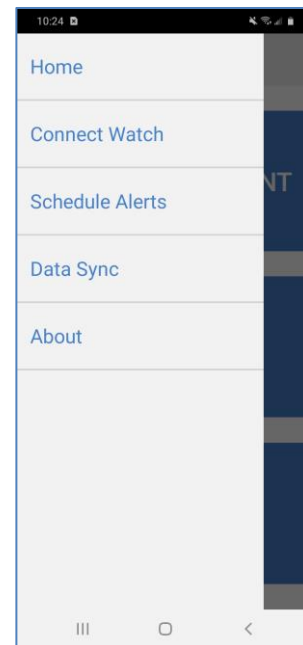
Chapter 3: Navigating the App

Home Screen

The Home Screen includes three large buttons and a menu button on the top left of the screen. The menu button appears as three lines for Android and a gear icon for the iPhone. 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 (≡ or ⚙)

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



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

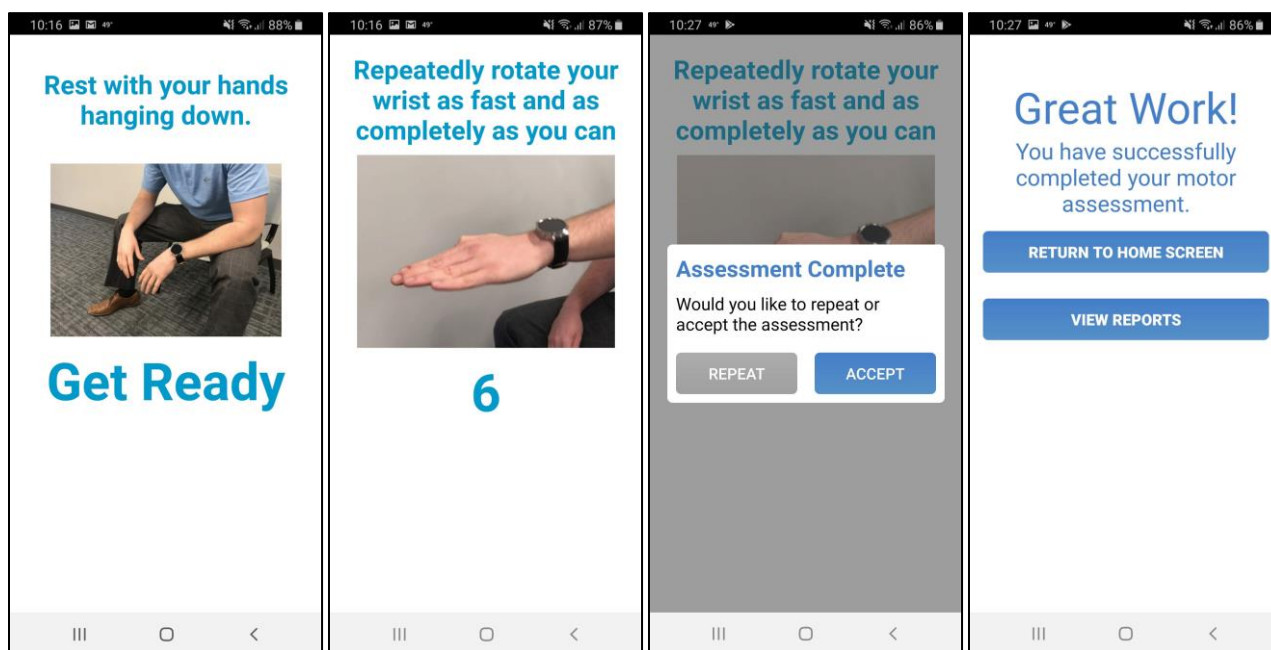
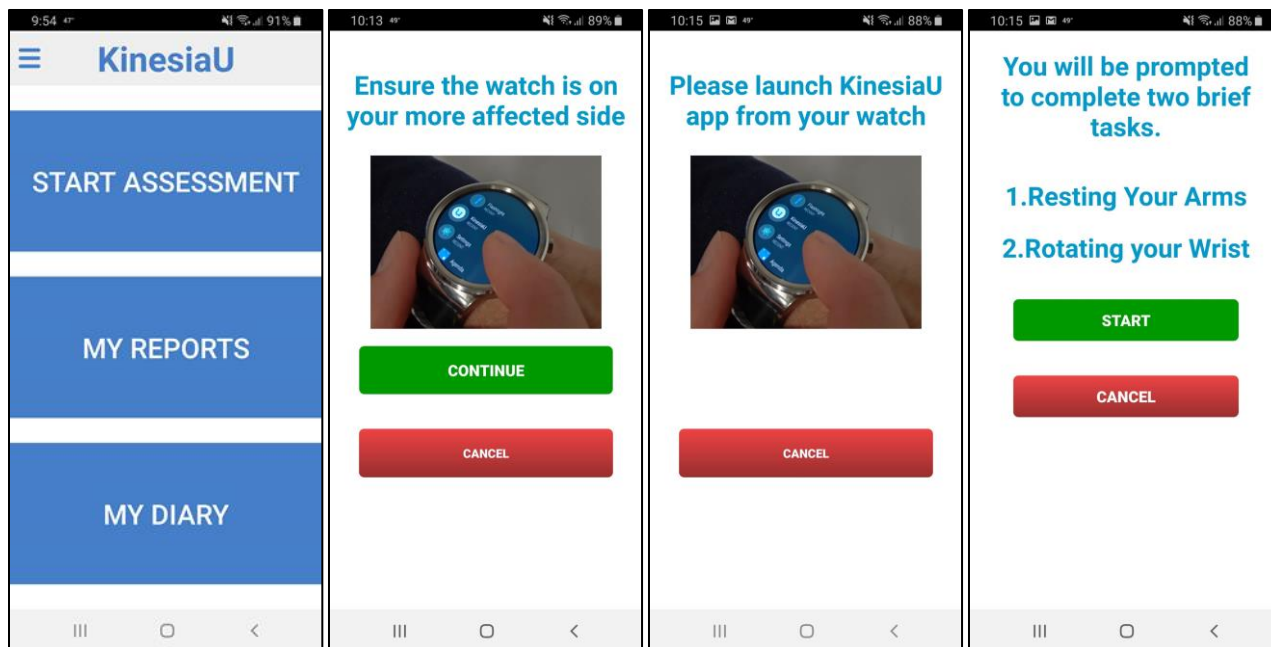
For this task, remain seated with both hands in your lap. Keep your hands relaxed and allow them to hang between your legs. Your hands should not be touching each other or your legs.

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.

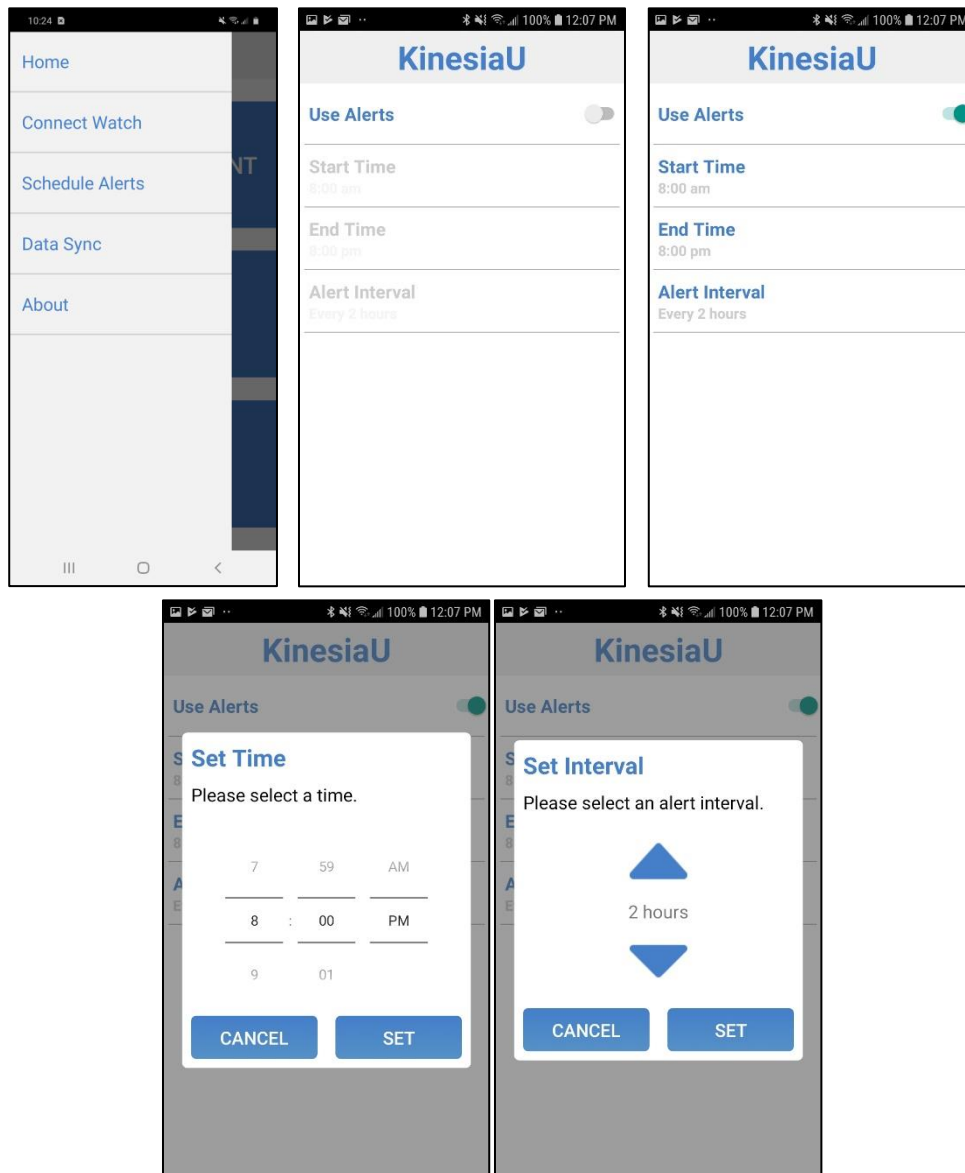
The images below show the screens you will see as you complete the motor assessment. (Screens may vary depending on your specific Android or iPhone version.)



Chapter 5: Setting Alerts

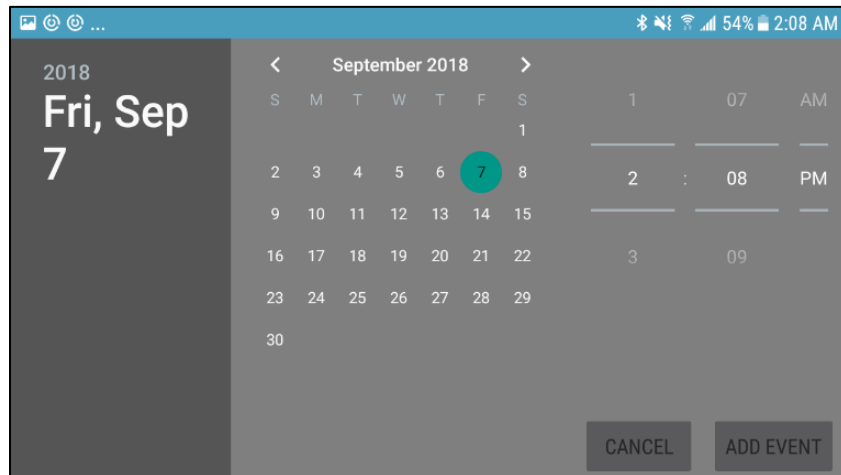
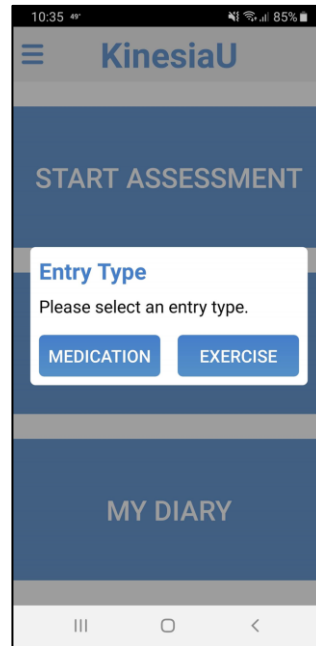
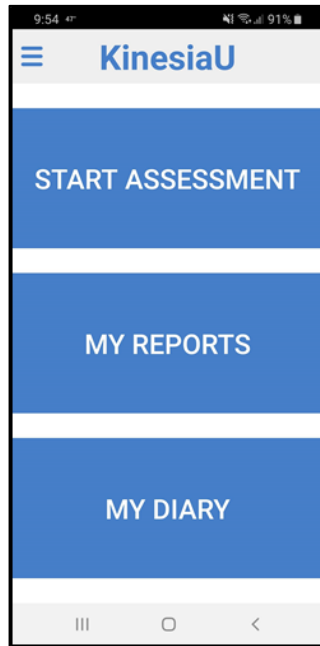
You may set alerts in the app to periodically remind you to perform motor assessments.

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. (Screens may vary depending on your specific Android or iPhone version.)



Chapter 7: Viewing Reports

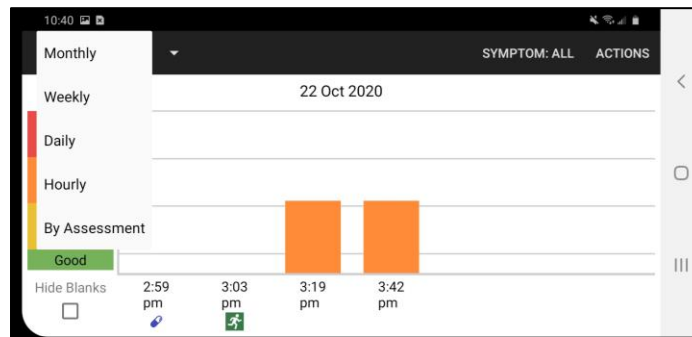
Viewing the Reports

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. The number below the symptom severity bar (Android only) shows the number of assessments included in the average.
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, you can select a symptom to display results for each individual symptom (Tremor, Slowness, Dyskinesia,) or all three averaged together (All Symptoms).
6. To the right of the SYMPTOM selector, the ACTIONS button is used to add events (Medication or Exercise) and generate PDF report files (Android only).
7. The Hide Blanks checkbox (Android only) on the report toggles if blank intervals are shown (keep hour/day/week continuity) or hidden (only show the intervals when data was collected).
8. To return to the home screen.
 - On an Android: click the phone's back button
 - On an iPhone click the word/link "Back" in the lower left corner

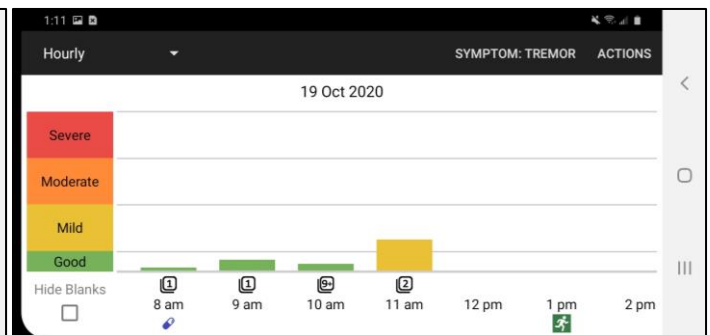
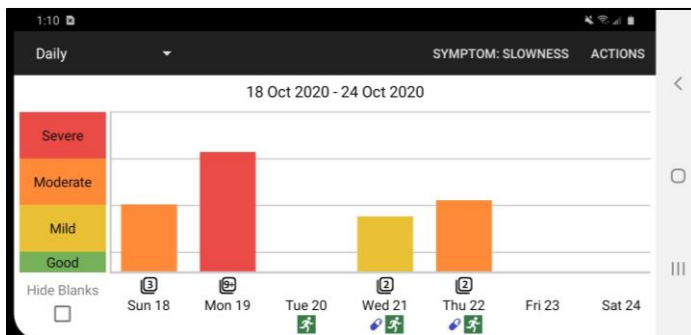
(Screens may vary depending on your specific Android or iPhone version.)

Options for Time Frame View Settings

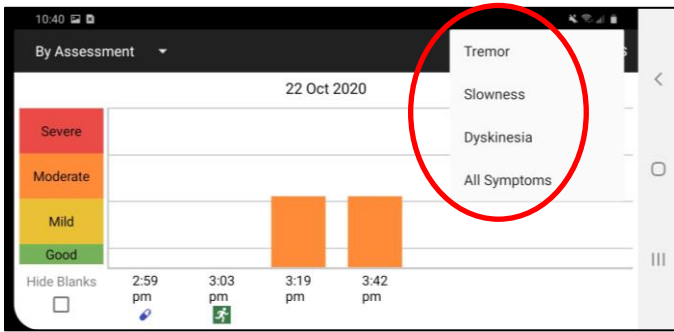


View set to Daily

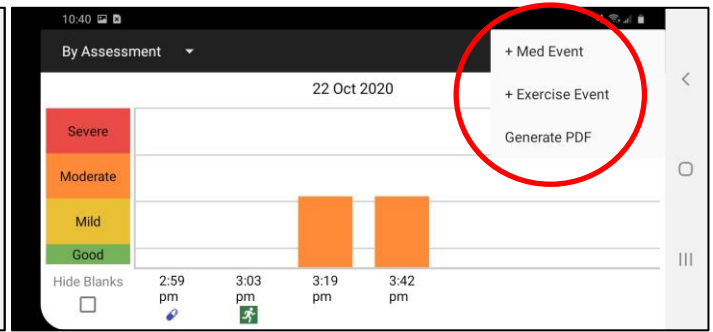
View set to Hourly





Options for Symptom Display



Options for Actions



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 (Android Only)

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.

Chapter 8: Data Sync

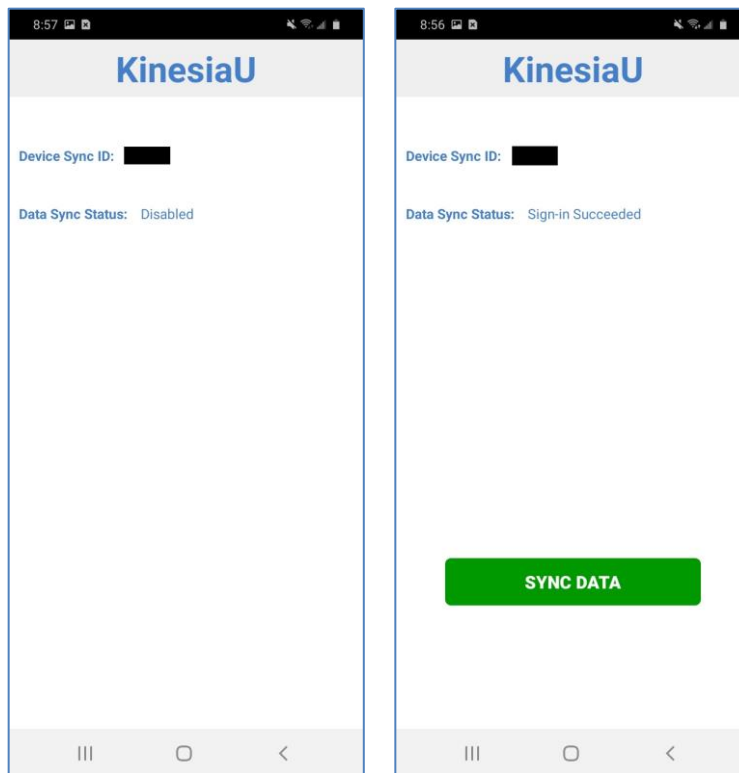
Connecting with your doctor

All of your assessment data and diary entries are uploaded to a secure server and viewable by your doctor in the KinesiaU Provider Portal. If you change doctors, please have your doctor contact Great Lakes NeuroTechnologies at KinesiaU@glneurotech.com.

Retrieving your data on a new phone

If you need to install the KinesiaU app on a new phone, you can retrieve data already uploaded by contacting Great Lakes NeuroTechnologies at KinesiaU@glneurotech.com to have Data Sync enabled. You will be instructed to go to the Data Sync page and provide the Device ID number shown. Once GLNT has enabled this new device to sync data, you will need to close the KinesiaU application on your phone. To do so, open the app menu on the phone (usually represented by three lines in the lower left of Android devices) and close the KinesiaU app. Open the app and a button will appear on the Data Sync page that will allow you to download any uploaded scores and diary entries.

For Apple devices, you will need to sign in with your Apple Id to see your device's status. Before use, data sync will still need to be enabled by GLNT by providing the Device ID number. You will need to close the Data Sync page, reopen the page, and sign in again. Data sync is enabled once the 'Restore Data' button is available.



Data Sync Disabled

Data Sync Enabled

Chapter 9: Support

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