

KinesiaU[™]
MOTOR ASSESSMENT SYSTEM

USER'S GUIDE

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Great Lakes NeuroTechnologies Inc.’s KinesiaU motor assessment system and its use is covered by one or more patents listed at: <https://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.

KinesiaU Apple/iPhone App REF: 700-0026 UDI: (01)00859584006102	KinesiaU Android App REF: 700-0025 UDI: (01)00859584006096
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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 levels over time.

Intended Use

Kinesia motor assessment systems are 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.

In Canada, Kinesia systems may only be used for therapeutic (not diagnostic) purposes of non-serious situations or conditions.

In the EU, KinesiaU™ motor assessment system may only be used to monitor physical motion and activity that are not physiological processes and may not be used for diagnostic or therapeutic purposes.

NOTE: Kinesia family of motor assessment systems are approved in many regions around the world, but due to individual country regulations, such as language translations, data restrictions, and other regulatory requirements, specific Kinesia products lines may not be approved or available and therefore should not be used in those locations.

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.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Per privacy regulations, avoid storing any personally identifiable information where possible.

Smartphone and Smartwatch Compatibility

The KinesiaU motor assessment system is designed for use with Android and iPhone smartphones and smartwatches but is NOT compatible with all models and is only validated for use with certain models.

For more information, please refer to:

<https://www.glneurotech.com/products/kinesiau/frequently-asked-questions/>

and for a list of validated models:

<https://www.glneurotech.com/products/validated-devices/>

Furthermore, 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.

All data in this manual was created for example purposes. No actual patient, provider, or institution is included. Images used in this manual and screens in the applications may vary slightly.

Chapter 2: Installing the App

Prerequisite

1. Make sure you have a compatible smartphone and smartwatch. A list of validated devices is available at <https://www.glneurotech.com/products/kinesiau/frequently-asked-questions/>
 - For Apple, make sure your Apple watch is paired with your iPhone.
 - For Android, make sure you have the appropriate wearable app installed for the Android watch. (Ex. “Watch” app for Google watches, “Galaxy Wearable” with Samsung) This watch needs to run Wear OS 3.0 or greater and the watch is paired with your phone.
2. Make sure you have the Apple App Store or Google Play Store set up properly.

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. Additionally, you may have your doctor contact Great Lakes NeuroTechnologies to enroll in KinesiaU.

Telephone: (216) 361-5410 or toll-free 1-855-GLNeuro (1-855-456-3876)

9:00 a.m. - 5:00 p.m. EST, Monday – Friday

Fax: (216) 361-5420

E-Mail:

- Customer Support: support@GLNeuroTech.com
- Sales: sales@GLNeuroTech.com

3. Make sure to provide your email address to your provider. This will be used to gain access to the KinesiaU app.
 - a. For iPhone users, this email should be the email address associated with the Apple Id used on the iPhone.
4. You will then receive a KinesiaU introductory email with instructions on how to download the app and sign into the app.

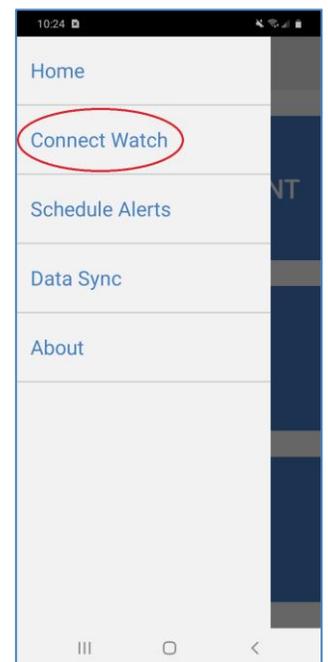
Installation

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 instructions 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 log in using your Google account. Be sure to enter the same email address provided in your prescription. If the account listed in the prescription is not listed, select the “Add another account” option. From there, you will need to sign in using the Google account associated with your prescription.
 - a. If the email address on your prescription is a Gmail address, then select that email address from the available list.
 - b. If the email address that was provided for your prescription is a non-Gmail address, then you need to register that non-Gmail address with google to verify you are the owner of that email address. The following steps will assist in that process (note: google may change their process at any time)
 - i. On your personal computer, open a new ‘Incognito’ or ‘InPrivate’ window (either from the Right-Click menu options or while in the browser Ctrl-Shift-N), then open <https://accounts.google.com>. It is important that you create a new Google account, not a new Gmail account. Creating a new Gmail account will not allow you to use your current email address.
 - ii. Click the Create Account link below the gray “sign in with your Google Account” box. If the “Choose your account” page appears, select the “Use another account option” then select “Create account” in the sign in box.
 - iii. Below the “Choose your username” field, click I prefer to use my current email address link.
 - iv. Enter your non-Gmail email address you would like to register with Google.
 - v. Finish filling out the new account form and accept Google’s Privacy Policy and Terms.
 - vi. Confirm your new account with the email address you provided.
 - vii. Once the account has been created, add this Google account to your Android device. This can be done through your device settings, under “Accounts and backup” > “Manage accounts”. Make sure you sign in as a Google Account.



Android App Configuration

1. To use the KinesiaU app, your smartwatch must be connected to your smartphone using the appropriate smartwatch app. Examples include Google’s “Watch” and “Galaxy Wearable”.
2. Click the menu button in the top left of the screen and select Connect Watch.
3. Follow the instructions to connect with the paired smartwatch.
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 opening the Apple Watch app. In this app, you can manage your watch's settings and manually install apps that are on your phone with accompanying watch apps. Look toward the bottom of your watch's settings in a section labelled "Available Apps" for the KinesiaU watch app.
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 have two options: an option to sign in or to use the demo. If you select the sign in option, skip to the next step. Once signed into the app, you will not see this option page again. The demo option opens a demonstration of how the app behaves once the user signs into the app. The demo behaves similarly to the actual app's features, but no data can be saved and all data displayed in the app has been artificially generated.
 - a. You can leave demo mode in the settings menu by selecting the option labelled "Exit Demo".
6. You will next be asked to sign into the app using your Apple ID account. Be sure to enter the same email address provided in your prescription. **If prompted, please 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, you will need to correct this issue before you will be able to sign into the app. 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.

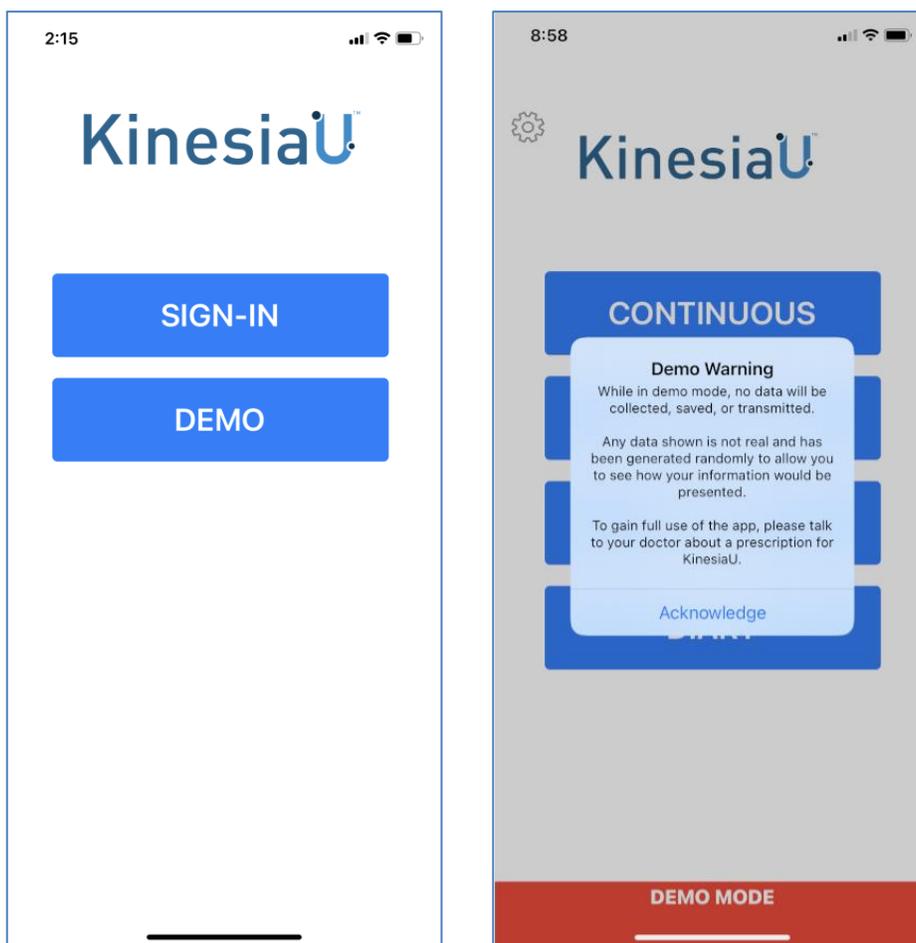
Research Mode and Clinical Studies

The KinesiaU iPhone app does offer a special mode to be used in clinical studies. For more information on this, please contact Great Lakes NeuroTechnologies.

Demo Mode (iPhone only)

When first opening the KinesiaU application, there are two options: Sign-In and Demo. To access your prescription account and move forward with regular application select “Sign-In” to continue with logging into your account. You will only see this screen upon opening the application the first time. After you have logged in for the first time, you will not see this screen again.

Demo Mode will allow you to perform various functions but will only show pre-set sample data. No data can be collected while in Demo Mode. All screens in Demo Mode are tagged at the bottom. An example page is included below.



Chapter 3: Navigating the App

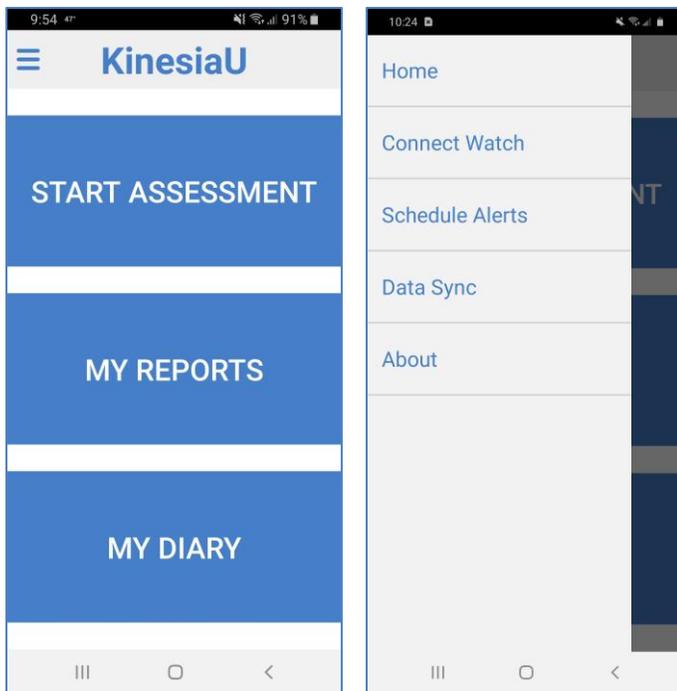
Home Screen

The Home Screen includes three (Android) or four (iPhone) 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 or Quick Tasks buttons are used to perform a motor assessment, the MY REPORTS or Reports buttons are used to view reports, and the MY DIARY or Diary buttons are used to enter diary events.

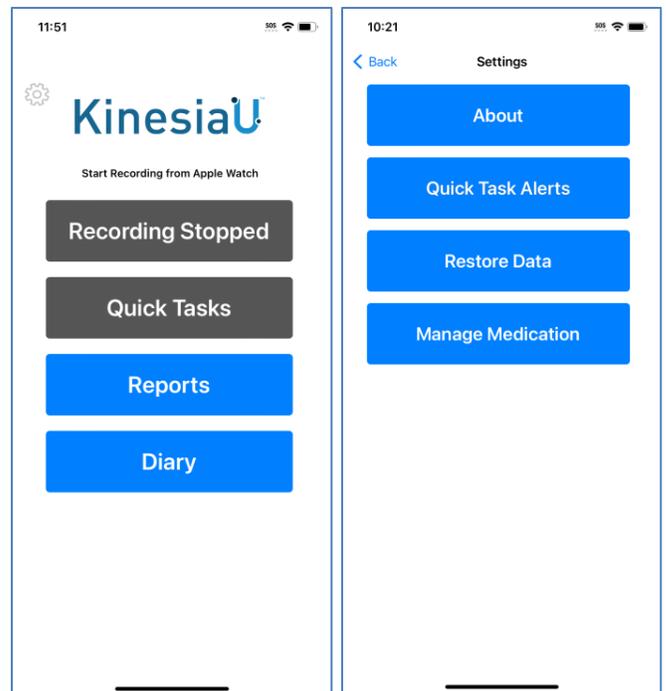
The iPhone app also contains separate options for performing the motor assessment and for continuous recording.

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, scheduling alerts, Data Sync, and viewing the About screen.



Android Home Screen and Settings



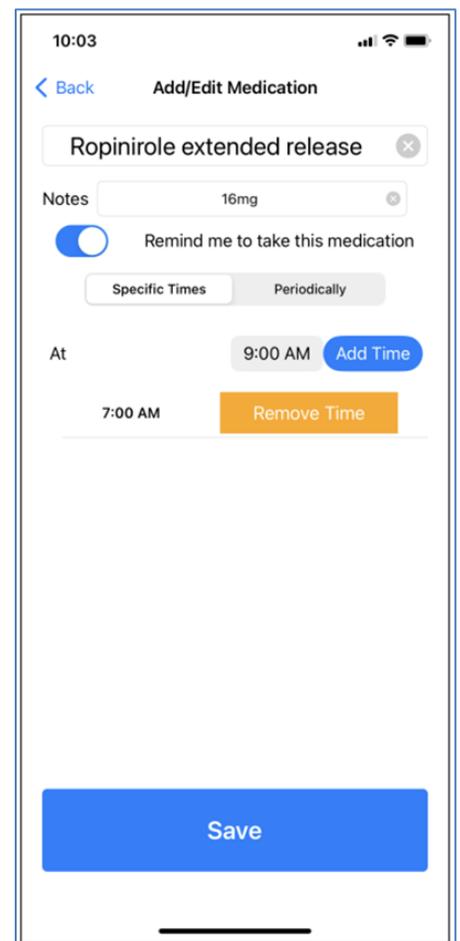
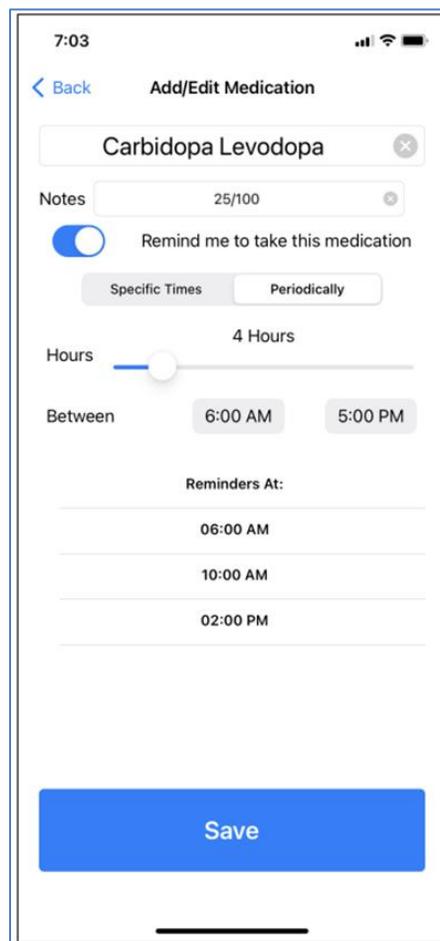
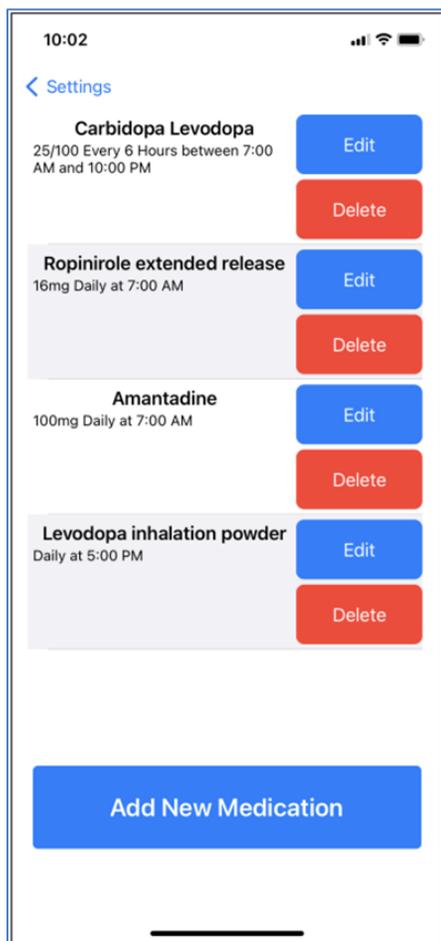
iPhone Home Screen and Settings

Chapter 4: Setting Medications and Reminders (iPhone Only)

In the KinesiaU iPhone app, you may enter in a list of your medications under **Settings (⚙️) > Manage Medication**. This will often include a medication name and dosage. When entering the medication name, options will autocomplete from a database based on what is typed in. Selecting from these options will complete the field. You may also type in text that is not in the database. The Notes field is optional and may be used to enter information such as dosage, number of pills, etc. You may also schedule reminders for when to take each medication. Options for reminders include Specific Times (where the reminders appear at specific times) and Periodically (where a start time, end time, and interval duration are entered). These reminders will occur daily and display a notification on your phone to take the medication.

The medications entered in this list will be used when creating medication events in the KinesiaU app. You can update information and reminders for existing medications. You can also delete medications from this list.

Medications and medication reminders can be transferred to a new phone using the Data Sync feature detailed in Chapter 10: Data Sync.



Chapter 5: Performing Motor Assessment (Quick) Tasks

Motor Assessment (Quick) Task

To perform a motor assessment (Quick task), tap the Start Assessment button (Android) or Quick Tasks button (iPhone) on the Home Screen. (Note: on the iPhone, quick tasks can only be completed during a continuous recording.) Make sure you are wearing the smartwatch snugly on the wrist corresponding to the side of the body to be assessed and the app on your smartwatch is active. The app on the smartphone will then guide you through two 7-second motor tasks: 1) Resting your arms and 2) Rotating your wrist. Depending on the watch model and setting, the watch may vibrate and/or beep to indicate the start and end of data collection during each of the two tasks. Instructions for performing the two tasks are as follows:

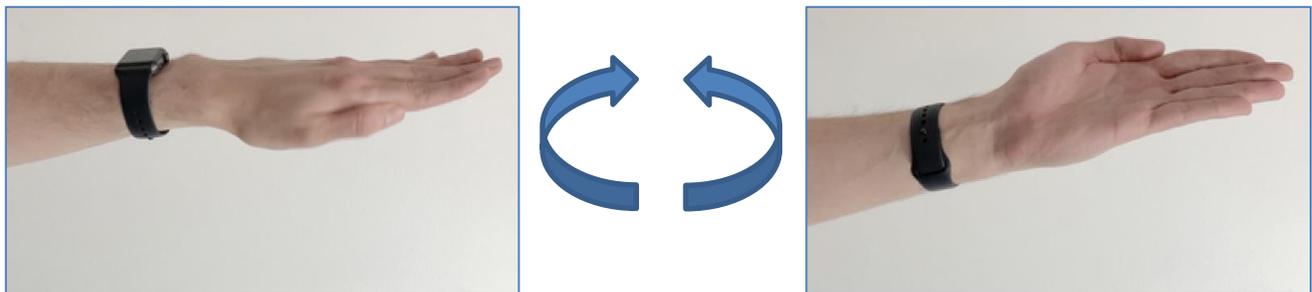
Resting your arms

For this task, remain seated with your feet flat on the floor and your forearms resting on your thighs. Keep your hands relaxed and allow them to hang between your legs. Your hands should not be touching each other and should not be touching your legs. Hold this position for the duration of the countdown showing on the phone screen.



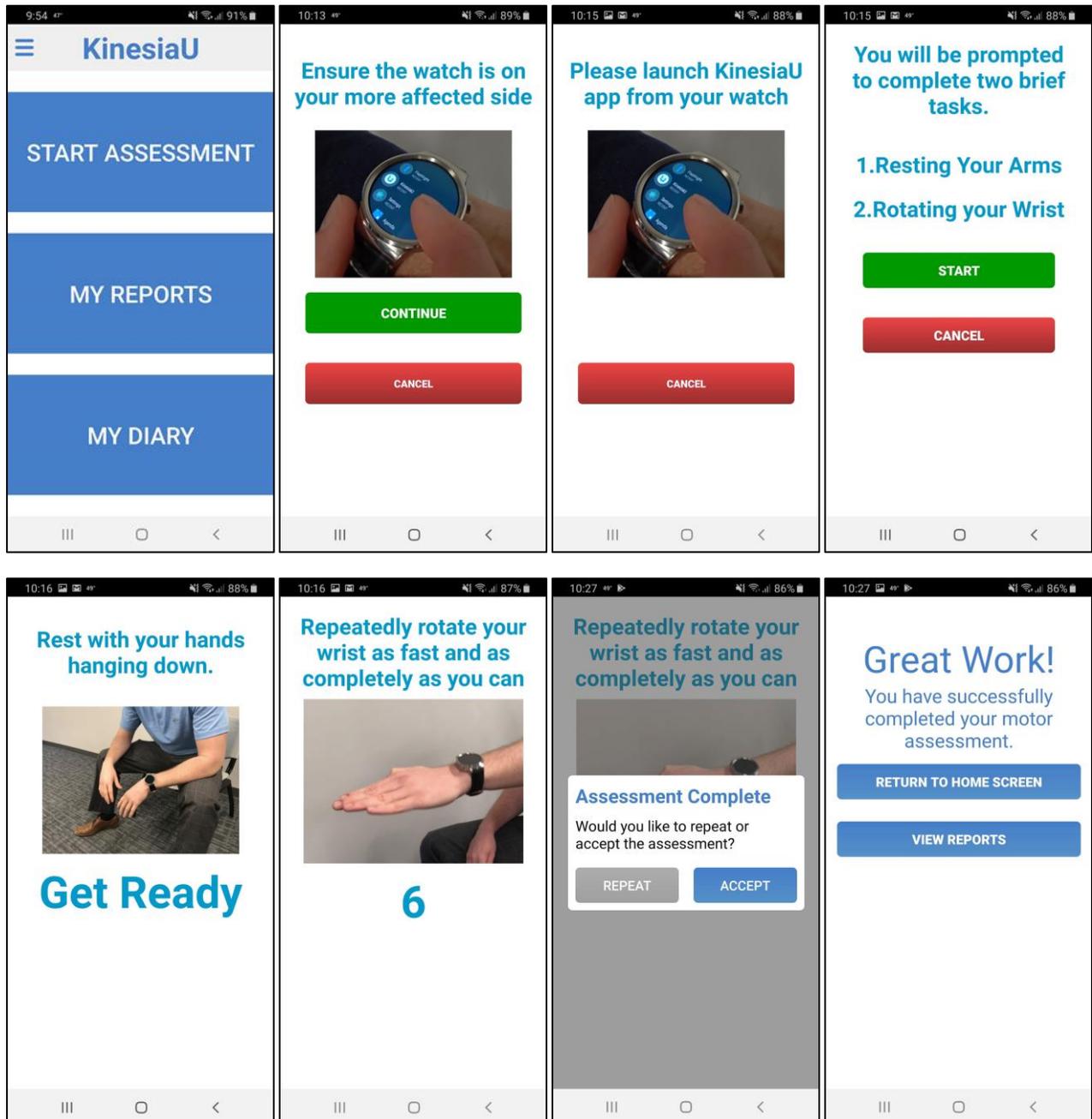
Rotating your wrist

While sitting with feet flat on the floor, hold your hand out in front of you with your arm fully extended and repeatedly rotate your wrist fully between palm-facing-up and palm-facing-down as fast as you can for the duration of the countdown showing on the phone screen.



During each motor task, the timer on the phone screen will count down from 7 seconds while you perform the specified task. After completion of the two tasks tap “Accept” if you successfully performed the tasks or “Repeat” if something prevented you from following the instructions (e.g., you were interrupted or distracted when performing the task). You may then choose to ‘Return To Home Screen’ or ‘View 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.)

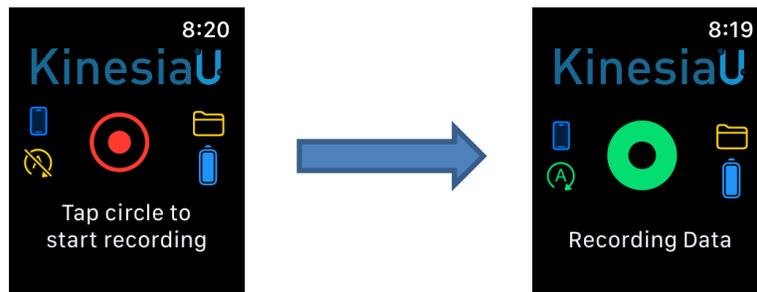


Chapter 6: Continuous (All Day) Recording (iPhone Only)

Continuous Recording

To start a continuous (all day) recording, tap the red dot on the KinesiaU watch app. A recording is in progress when the watch app shows a green dot, and the phone app will also indicate that the recording is in progress. Data will periodically transfer from the watch to the phone and be sent to Great Lakes NeuroTechnologies' cloud server for processing. Please regularly open both apps together while recording to allow these processes to happen.

Caution: Using other watch apps that capture motion data, like "Workout", will cause the KinesiaU Continuous recording to end. Any data up to that point will be saved, uploaded, and processed once the phone and watch apps are reopened.



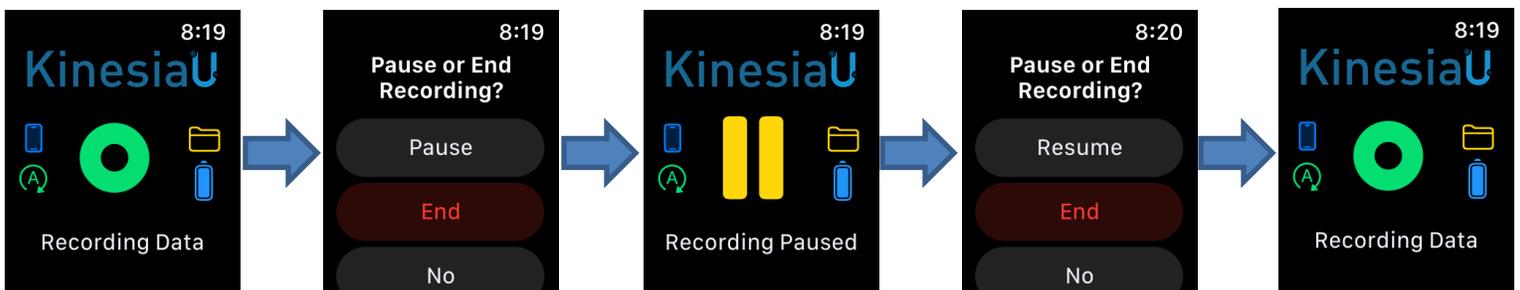
Pausing a Continuous Recording

If you need to remove your smartwatch during recording, tap the green dot on the KinesiaU watch app. Options will appear on the watch app to pause or end the recording. Select the pause option. Once selected, the phone and watch app will update and indicate that the recording has been paused.

To resume the recording, select the pause icon on the watch app. There is now an option to resume the recording listed where the pause option was. Selecting the resume option will resume the recording. Both apps will again indicate that the recording has resumed.

It is recommended to pause continuous recording during vigorous exercise as this can affect the results.

Note: Placing the watch on the charge pad will automatically pause any ongoing recording. Removing the watch from the charge pad will also automatically resume the recording.



Quick Tasks

There is an option to run the motor assessment tasks as described in Chapter 5: Performing Motor Assessment (Quick) Tasks. **To run this assessment on iPhone, a continuous recording must be ongoing.** The user is asked to run the two tasks. Each task can be started by the user and the user can stop running the tasks at any time. The order of tasks for this assessment is Arms Resting then Wrist Rotation.

For the app to display results, the user will need to complete both tasks.

Reports

It is possible to view reports for completed assessments while a continuous recording is being performed. The button on the home page will change colors, indicating that the data gathered during that recording is being processed. It will return to the default color once the results have been downloaded to the device. More details on this section can be found in Chapter 9: Viewing Reports.

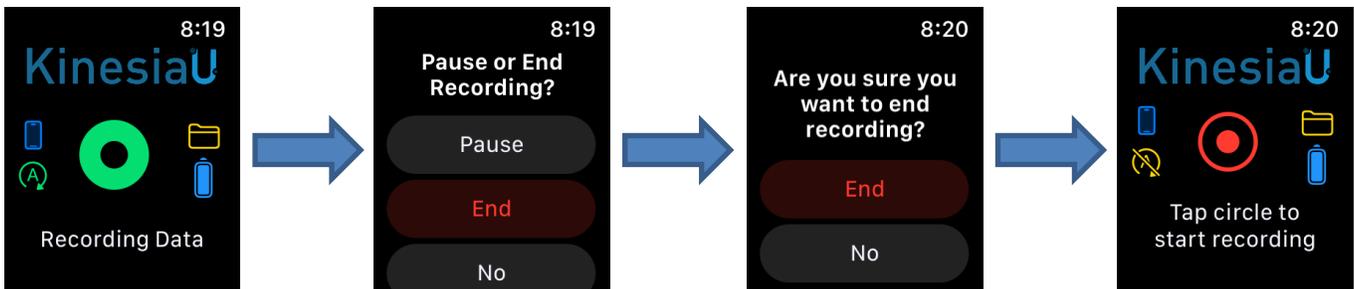
Diary

It is possible to create medication and exercise entries while a continuous recording is being performed. More details can be found in Chapter 8: Using the Diary.

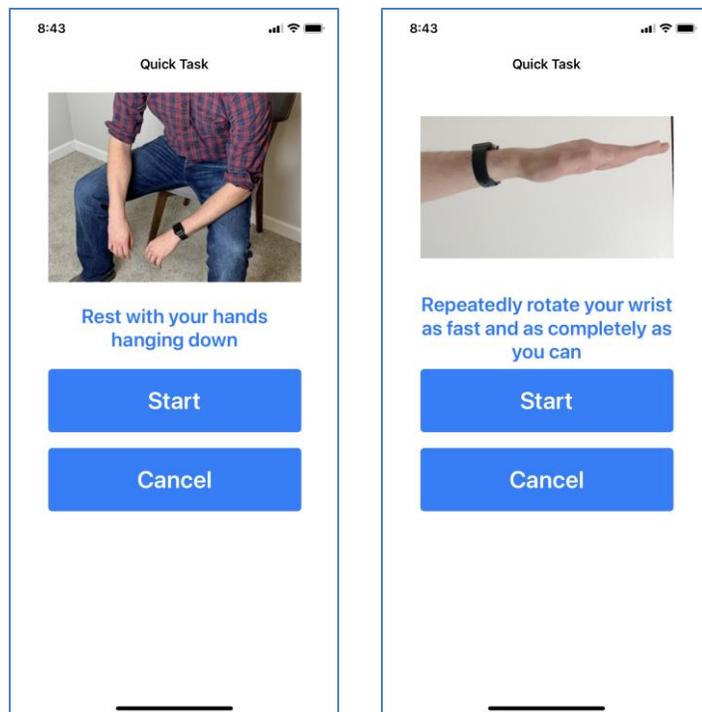
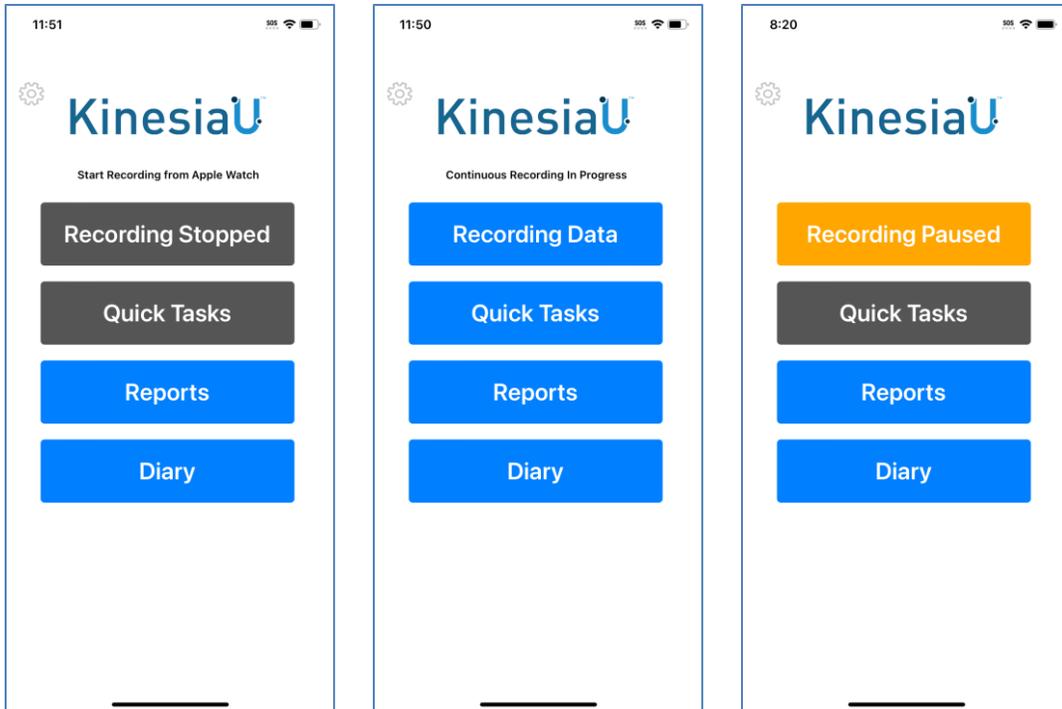
Stopping a Continuous Recording

Once started, it is not necessary to stop the recording for data to be processed. If the recording needs to be stopped for any reason, tap the green circle on the KinesiaU watch app. Options will appear, one of which is to end the recording. Tapping this option will cause a confirmation to appear. Confirming this will end the recording. The phone and watch apps will indicate that the recording is no longer running and the recording can be restarted from the watch.

Please keep the phone and watch apps open to allow files to transfer between devices then upload from the phone to Great Lakes NeuroTechnologies' cloud server.



Note: It is recommended that the recording is stopped before updating the KinesiaU app.



Understanding the Watch App Icons (iPhone only)

The KinesiaU iPhone watch uses various icons to detail the status of the watch. Below are examples of the various states of the icons and what they mean in these states.



Watch and phone are able to communicate

Watch and phone cannot communicate

Phone Connection Status

Assessment Recording Status



Assessment recording will always try to stay running

Recording will not automatically resume due to user interaction, such as pressing the stop button or a workout was initiated by another app

Recording will not automatically resume due to a system error, such as battery state, watch storage being full, or there's an app update pending




Watch has enough storage and all files are less than 7 days old

Watch free space is between 75% and 50%

Watch free space is between 50% and 25%

Watch free space is below 25% or has files older than 7 days

Watch Storage Space

Watch Battery Level



Watch battery is fully charged and still on the charger

Watch battery is fully charged

Progressive battery states



Assessment is running and recording data

Assessment has been paused either manually or due to the watch being on the charger

Assessment is not running

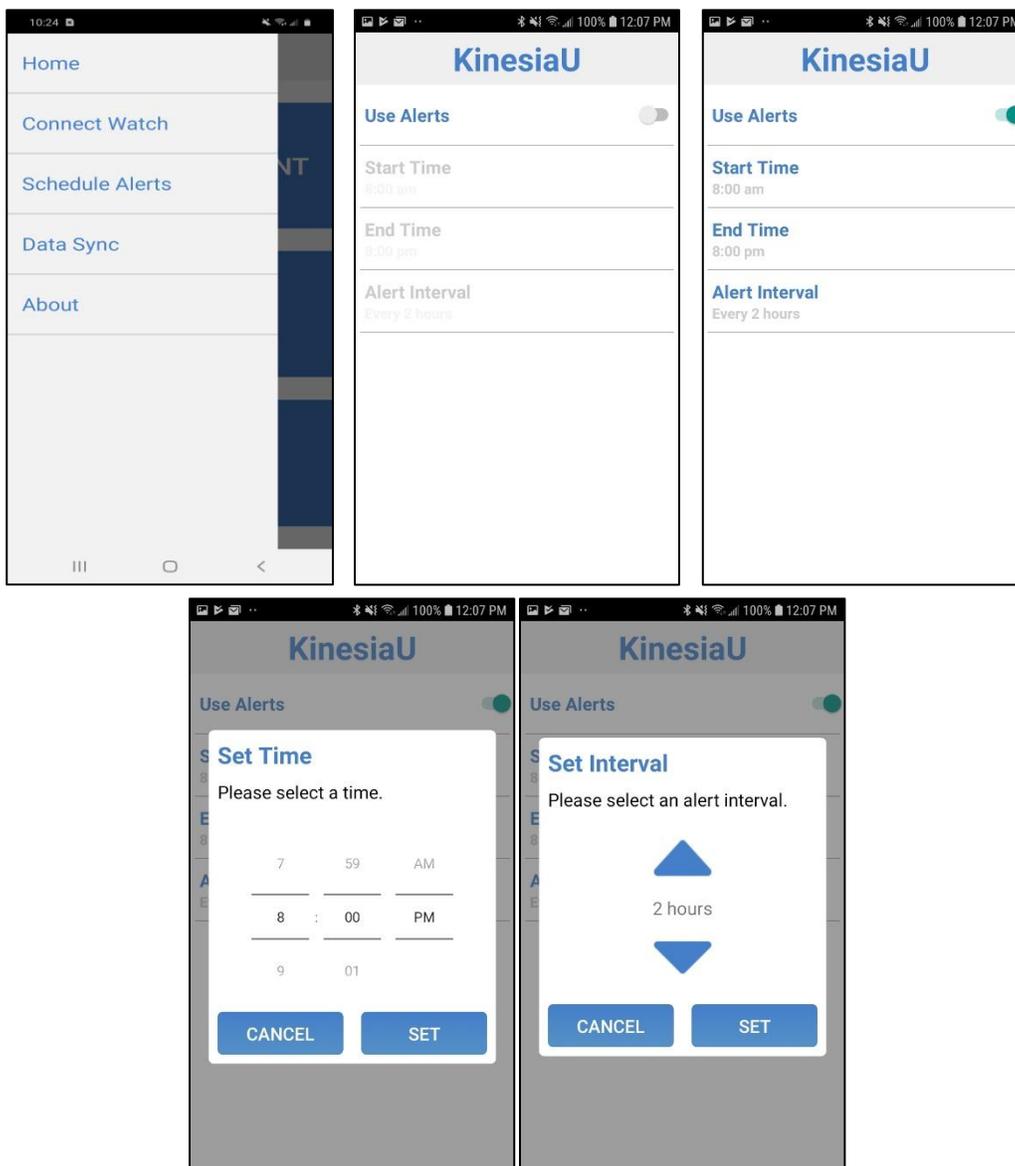
Watch is pending activation from the phone

Center Icon – Recording Status

Chapter 7: Quick Task Alerts

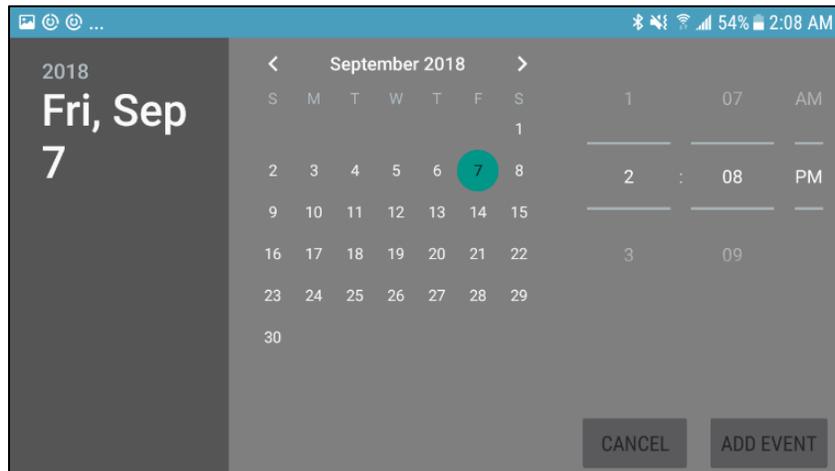
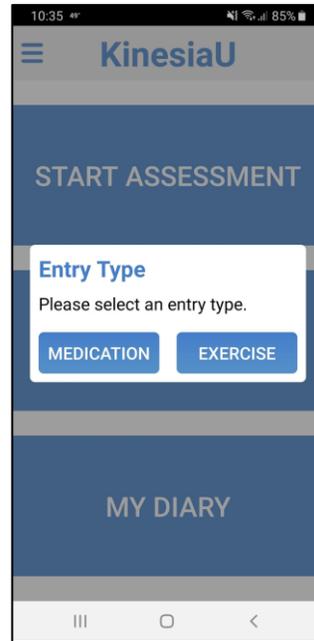
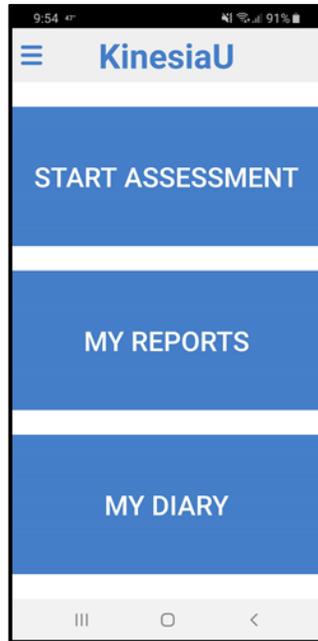
You may set alerts in the app to periodically remind you to perform motor assessments.

1. From the KinesiaU Application Main Screen, tap the Menu button and then select Schedule Alerts (Android) or Quick Task Alerts (iPhone).
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).

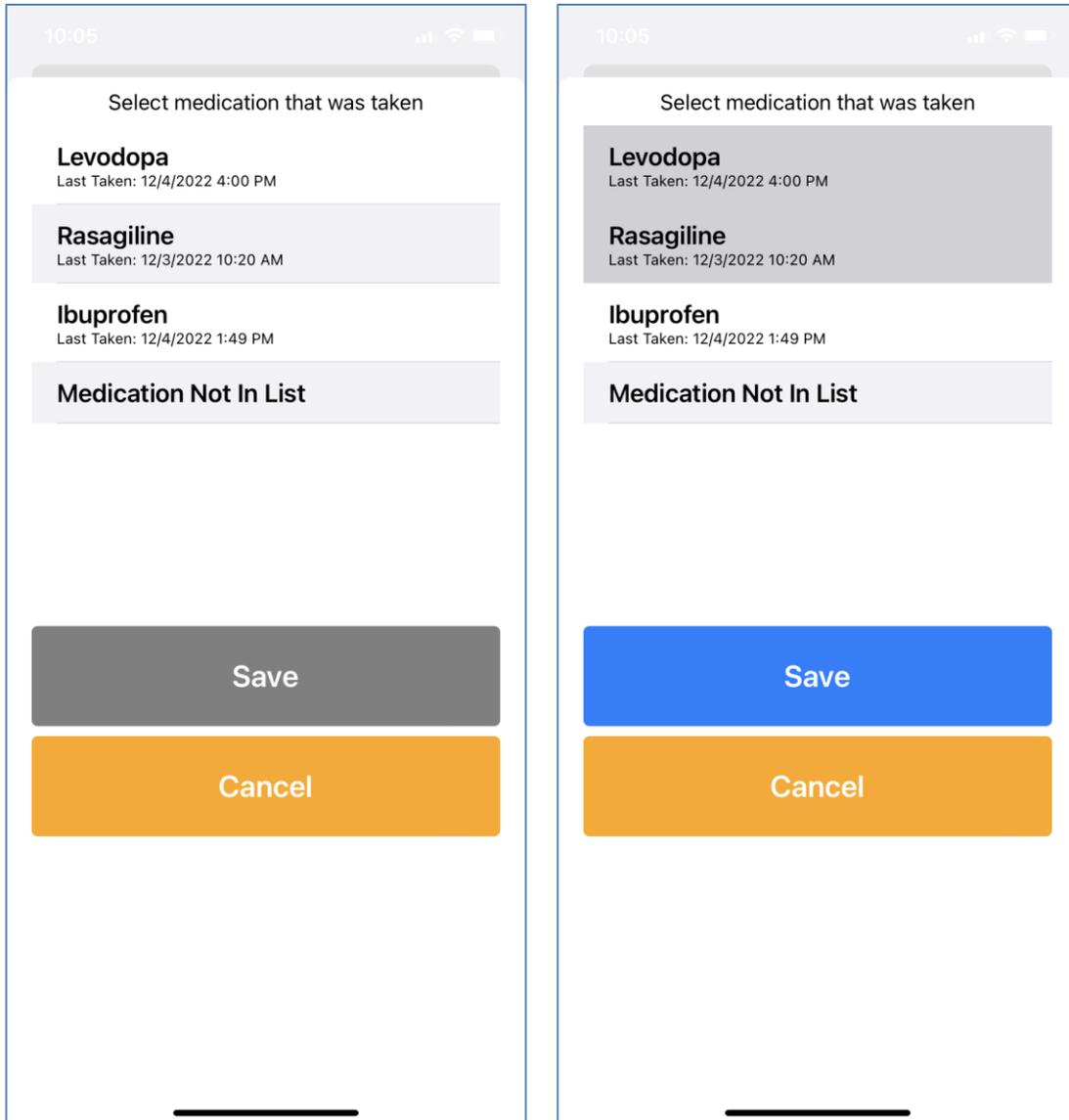


Chapter 8: Using the Diary

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.)



On iPhones, a list of entered medications will appear when entering a medication event. Select the medications that were taken at the time and select “Save”. Selecting the option “Medication Not In List” will mark a medication event without a specific medication associated with the event. Selecting “Cancel” will not create a medication event.



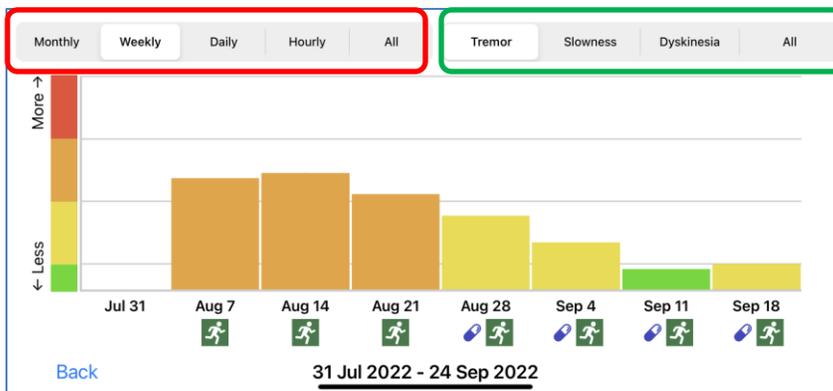
Chapter 9: Viewing Reports

Viewing the Reports

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

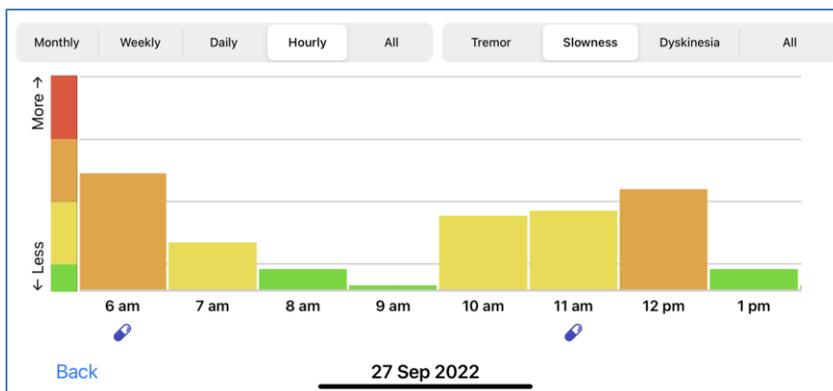
1. From the KinesiaU Application Main Screen, select My Reports.
2. The report page displays the level of the selected symptom averaged for the selected time range. The number below the symptom level bar (Android only) shows the number of assessments included in the average.
3. Swipe left or right to 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.)



In the iPhone app, the time selector is shown on the top left of the reports (outlined in red).

The symptom selector appears on the top right of the reports (outlined in green).



Understanding the Reports

The height of each bar indicates the symptom level with low bars indicating low levels and tall bars indicating high levels. The bars are also color-coded from green to yellow to orange to red indicating low to high levels. 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 consulting with 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.

Continuous Recording Report (iPhone Only)

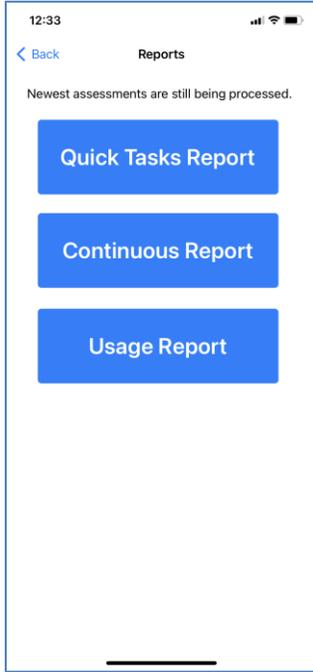
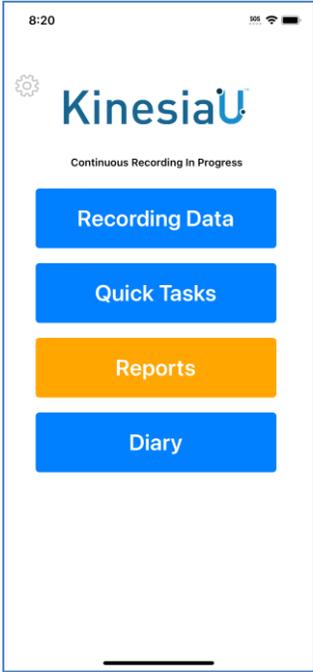
For the iPhone app, there are three types of reports: the one described above (referred to as “Quick Tasks Report”), the continuous recording report (referred to as “Continuous Report”), and the usage report. The continuous recording report is similar in format to the motor assessment report. Features of this report include:

1. Data is displayed in an hourly format (similar to the motor assessment report).
2. Swipe left or right to move forward and backward in time from the initial position. You may also use arrows towards the top of the screen to switch to the next or previous date. You may also select the data at the top of the report to select which day to view.
3. 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).
4. Medication and Exercise events will also appear under the hour the events occurred.
5. To return to the report selection screen, select the “Back” button in the lower left corner.
6. When assessment data is being processed, text will appear on the report selection page indicating this process is ongoing. The report button on the home page will also change colors during this process. Once results are downloaded, the button will return to its default color.

Understanding the Symptoms

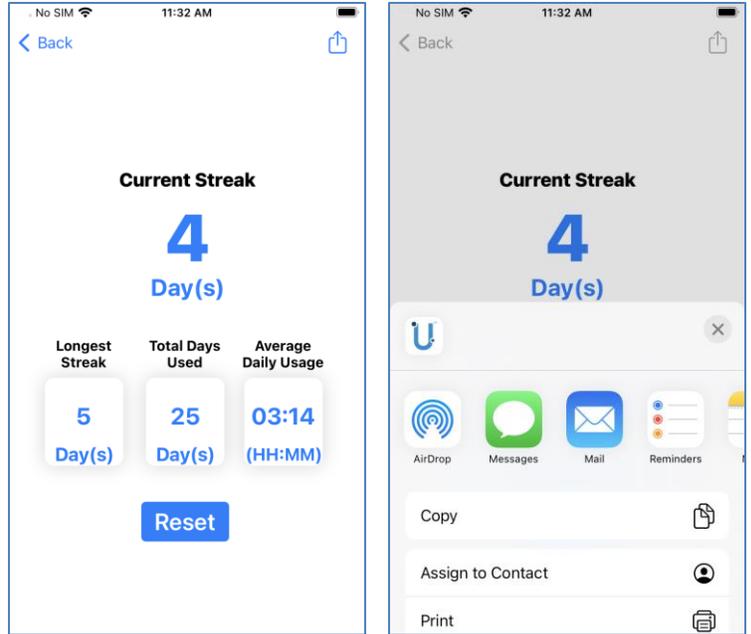
The system calculates the results for tremor, dyskinesia, and slowness. Hourly data is shown as an average of the results calculated every two minutes of recording. This hourly average is only calculated if there is over 30 minutes of recording within the hour and if the symptom was detected for at least six minutes within that hour. Dyskinesia results may not be calculated during long periods of walking. Slowness is calculated as a measure of how fast the patient is moving when movement is detected.

You can also hide or show walking percent for each hourly time interval. This shows what percentage of the hour walking was detected by the app (0%, bottom of chart, to 100%, top of chart).



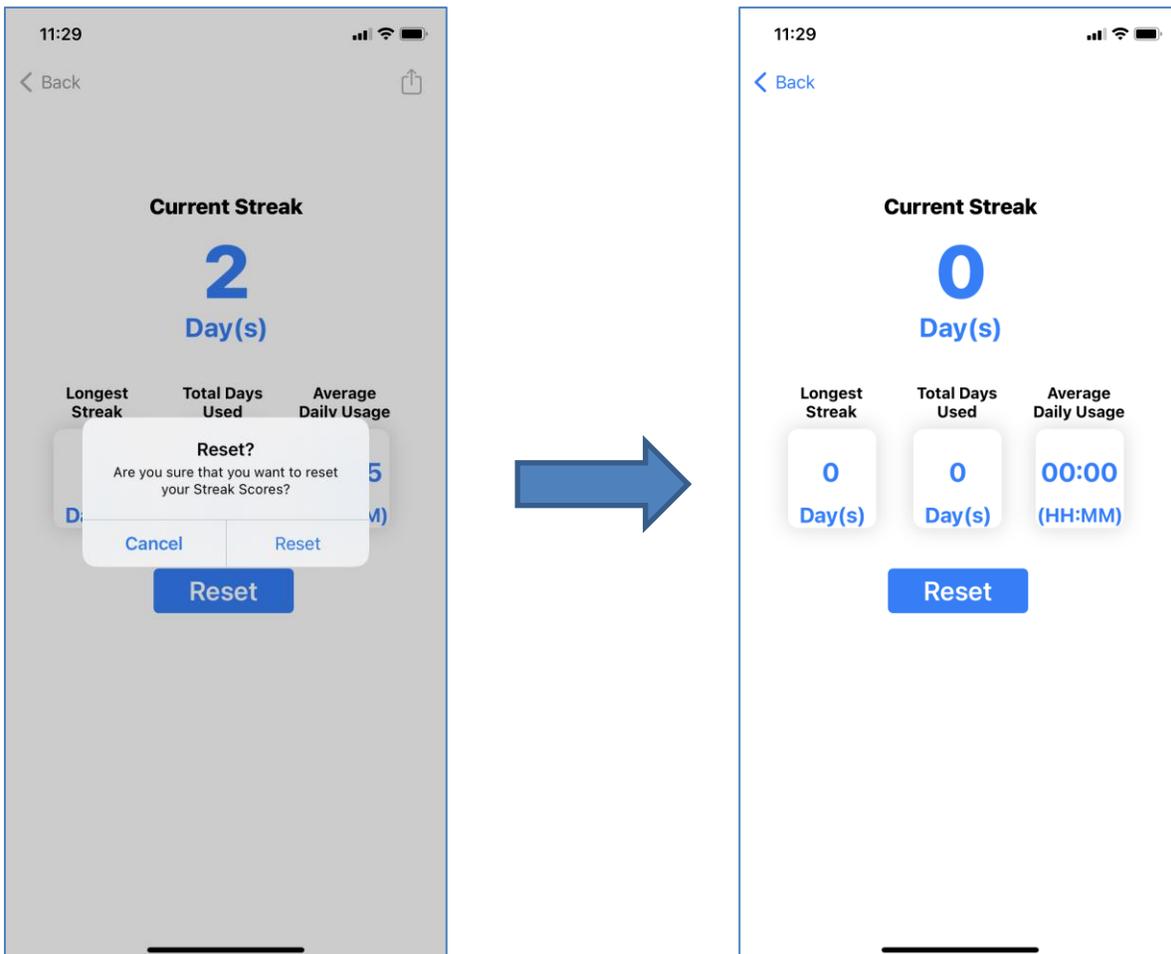
Usage Report (iPhone only)

The Usage Report is a feature in the iPhone app. This feature will display metrics depicting your usage of the KinesiaU app including longest sequential days of use, total number of days the app has been used for continuous recordings, and the average length of continuous recordings gathered. These metrics can be shared using the share icon  towards the top of the page. A prompt will be opened that allows you to share a screenshot of this page to available social media apps or to your device's files.



Resetting Metrics

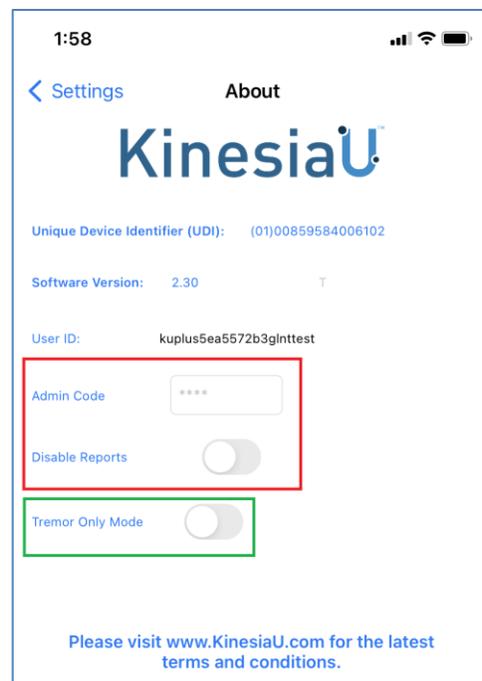
Users can reset these metrics using the button labelled 'Reset'. A confirmation message will appear before your metrics are reset.



Hiding the Patient Reports (iPhone only)

It is possible to disable the Reports button in the KinesiaU iPhone app. To do so, you will need to navigate to the Settings (⚙️) page and select the About option. On the resulting page, there is a toggle to 'Disable Reports' (Red). This toggle is disabled by default; therefore, the user can access the reports.

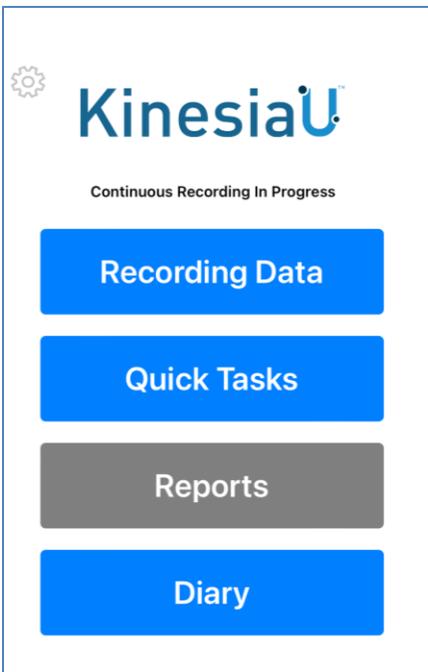
To enable this feature, you will need to contact GLNT to get an Admin Code. This code will need to be entered into the available text box. Once entered, the user can toggle this option. Without this code, the user is unable to change the toggle's status.



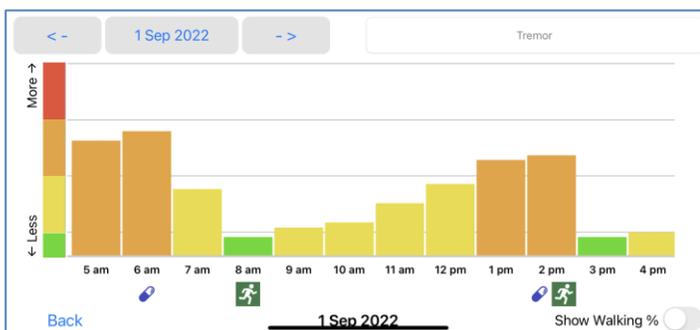
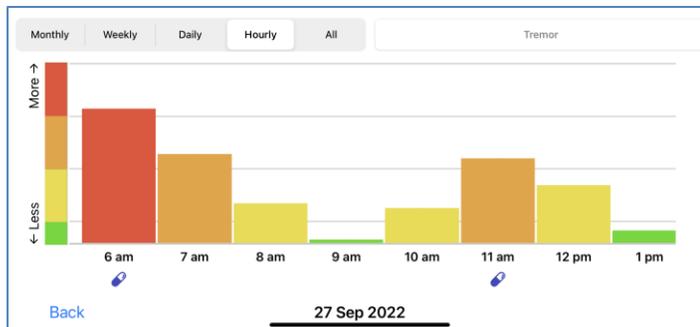
Tremor Only Reports (iPhone Only)

The KinesiaU iPhone app offers you an option to only display symptom results for Tremor. This option is located on the About page (under the app Settings ⚙️) and can be enabled/disabled without the Admin Code (Green). When enabled, only the tremor symptom will be selectable or shown in both the Quick Task and Continuous Reports.

This option is disabled by default and all symptoms will be shown in the reports.



Home Page with the Reports Disabled



Reports with Tremor Only Mode Enabled

Chapter 10: Data Sync

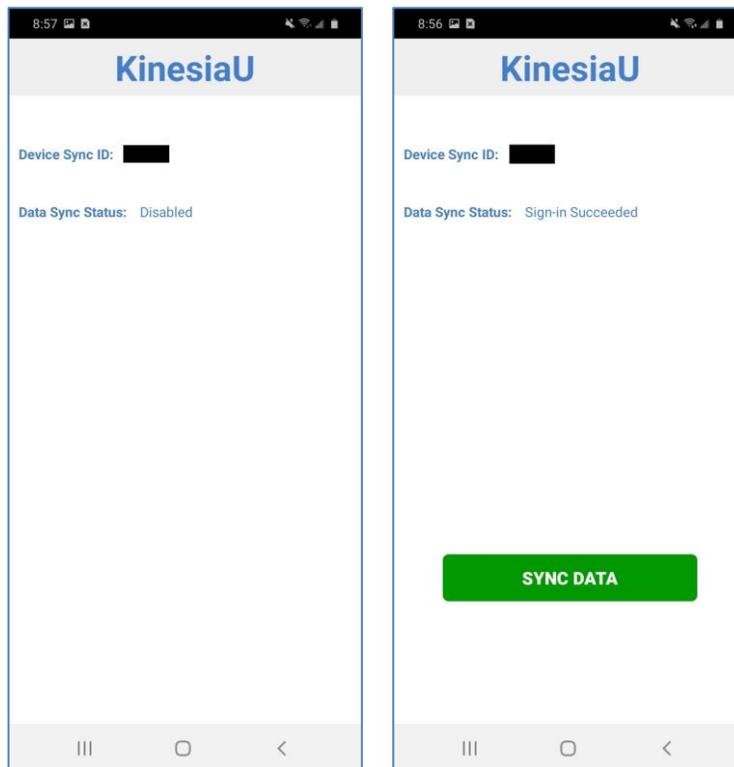
Connecting With Your Doctor

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 Great Lakes NeuroTechnologies 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 results and diary entries.

For iPhones, 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 Great Lakes NeuroTechnologies 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 11: Support

Additional information can be found at www.KinesiaU.com and a FAQ and Great Lakes NeuroTechnologies contact information can be found at www.glneurotech.com/products/kinesiau/frequently-asked-questions/ .

For information regarding KinesiaU Research Mode and clinical studies, please contact Great Lakes NeuroTechnologies.

Telephone: (216) 361-5410 or toll-free 1-855-GLNeuro (1-855-456-3876)

9:00 a.m. - 5:00 p.m. EST, Monday – Friday

Fax: (216) 361-5420

Customer Support: support@GLNeuroTech.com

Sales: sales@GLNeuroTech.com

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