



## USER'S GUIDE

**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](mailto:support@GLNeuroTech.com)

Sales: [sales@GLNeuroTech.com](mailto:sales@GLNeuroTech.com)

<http://www.GLNeuroTech.com>

R<sub>x</sub> MD

CE  
UK  
CA

**Mailing Address:**



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



AF Pharma Service Europe SL

Muntaner 281

08021, Barcelona

Espana

**Australia Sponsor**

Vicki Partridge Pty Ltd

46 The Peninsula, Paradise Point, QLD, 4216

Australia

Phone: +61755295508

**UK Responsible Person**

AF Pharma Service UK LTD – 2022040500254753

Suite 140 Temple Chambers, 3-7, Temple Avenue,

London, EC4Y 0DA, England, UK

Phone: +447862223321

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## ***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***

- Tripping Hazard – keep the electrical cord away from walking paths
- Do not use in conjunction with a defibrillator.
- Improper routing of cabling may result in a choking hazard.
- Do NOT expose the system to liquids. Liquid exposure may permanently damage the system.
- Do NOT turn the system on immediately if it has been stored in temperatures lower than 50°F or higher than 90°F. Wait at least two hours for the system to return to room temperature before it is turned on. Operate system with room humidity between 35% and 80%.
- Do NOT place the system next to a TV, air conditioning unit, or other household appliance that may cause interference and damage from magnetic fields.
- The Kinesia Sensor may present a choking hazard. Keep away from children under 3 years of age.
- If the power supply or the cord is damaged, do not use the system.
- If you want to dispose of your device, please return it to Great Lakes NeuroTechnologies Inc.
- Keep the space around the tablet free of debris to reduce the risk of overheating.
- DO NOT use an autoclave or other high temperature sterilization method on any Kinesia ONE system component.

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.

For more safety and regulatory information and for battery disposal information, refer to the Regulatory Safety and Environmental Notices provided with the Kinesia Tablet's documentation.

THIS DEVICE COMPLIES WITH PART 15 OF THE FCC RULES. OPERATION IS SUBJECT TO THE FOLLOWING TWO CONDITIONS: (1) THIS DEVICE MAY NOT CAUSE HARMFUL INTERFERENCE, AND (2) THIS DEVICE MUST ACCEPT ANY INTERFERENCE RECEIVED, INCLUDING INTERFERENCE THAT MAY CAUSE UNDESIRE OPERATION.

**Note:** The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate the equipment.

## ***Standards and Definitions:***

The following symbol on product labeling warns of potential choking hazards:



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



The following symbol on product labeling advises consultation of this document for the operating instructions needed for proper use:



The following symbol on product labeling warns against improper disposal:



The following symbol on product labeling indicates that the product is only available under the order of a physician.

## **Rx Only**

**Note:** Web Application performance may vary based on your system configuration.

## ***Package Contents and Warranty Information***

Great Lakes NeuroTechnologies Inc. thanks you for your recent product purchase. Great Lakes NeuroTechnologies offers phone technical support (9 AM-5 PM EST) and warrants Kinesia ONE (parts and labor) for 1 year from the date of purchase which covers material and workmanship under normal operating conditions and use. Technical support after the 1 year period will be charged hourly. Call Great Lakes NeuroTechnologies for hourly rates. For your benefit, we recommend that you record the pertinent details below. If necessary, this information will allow us to better serve your needs. We highly recommend that you staple a copy of the sales receipt to the blank pages in the back of this manual. Please check that your kit has the required components and record the requested data below:

Tablet Assembly (WIFI); 502-0269 or (WIFI+Cellular); 502-0270

Kinesia Sensor; 502-0263

Finger Sleeve (XS, black); 125-0006

Finger Sleeve (S, brown); 125-0007

Finger Sleeve (M, beige); 125-0008

Finger Sleeve (L, white); 125-0009

Finger Sleeve (XL, black); 125-0010

USB Charge Pad; 059-0013

User's Guide (this document); G392-0056

Date of Purchase: \_\_\_\_\_

Tablet SN: \_\_\_\_\_

Sensor SN: \_\_\_\_\_

## ***Care and Use Instructions***

When transporting Kinesia ONE, ensure all components are secured in the travel case to prevent damage.

It is not recommended to store Kinesia ONE in very hot or cold temperatures. If the system has been stored in an environment lower than 50°F or higher than 90°F, wait at least two hours for the system to return to room temperature before it is turned on.

Do not expose the system to liquid or excessive moisture to prevent mechanical or electrical damage.

**Note:** To prevent the possibility of cross contamination and to maintain hygienic safety, a thorough cleaning/disinfecting of the system components is required after each patient use.

Use only the following products to safely clean and disinfect the system components:

- Dimethyl benzyl ammonium chloride 0.3 % maximum concentration (i.e. germicidal disposable wipes)
- Alcohol-free glass cleaning fluids
- Water with mild (neutral pH) soap solutions (do not submerge any equipment, wipe down with damp cloth)
- Dry microfiber cleaning cloth or chamois cloth without oil
- Static-free cloth wipes

Avoid strong solvents such as alcohol wipes, acetone, ammonium chloride, methylene chloride and hydrocarbons which can permanently damage the surface of the system components.

## Chapter 1: About Kinesia ONE

**Kinesia ONE™** is a medical system designed to capture and evaluate motor symptoms from patients' homes. A take home kit, programmed to a specific patient's symptoms and treatments, is sent home with the patient to complete a variety of motor assessments throughout the day to assess tremor, upper extremity bradykinesia, and dyskinesia. Physicians can view web-based reports including automated severity scoring that show symptom changes during the day in response to treatment.

## Chapter 2: Patient Kit

The Kinesia ONE Patient Kit consists of three primary components (Figure 1):

- A. Tablet
- B. Kinesia Sensor
- C. Charge Pad



**Figure 1: Kinesia ONE Hardware Components (case and stand may vary)**

### ***Tablet***

The touch screen tablet is the central component of the Kinesia ONE Patient Kit. The preinstalled application provides guided instructions for patients to perform standardized motor tasks while wearing the Kinesia Sensor. Patient data is uploaded to the Kinesia Web Application to generate a study report for the clinician.



## ***Kinesia Sensor***

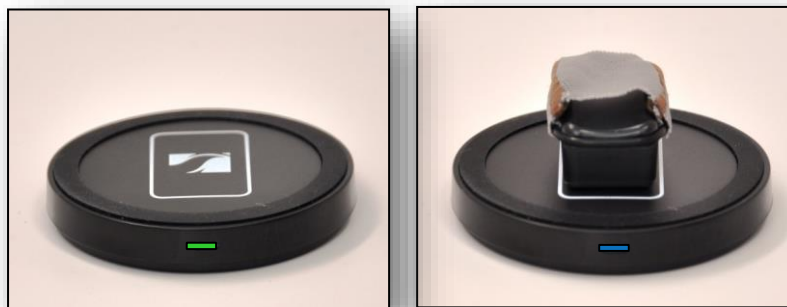
The Kinesia Sensor (Figure 2) is used to measure three-dimensional movement (acceleration and angular velocity) while a patient performs a motor symptom assessment. The Kinesia Sensor is designed to be worn on the index finger or shoe heel, depending on the symptom being assessed. Five different finger sleeves are provided: X-Small (black), Small (brown), Medium (beige), Large (white), and X-Large (black). A heel clip is provided for securing the sensor to the shoe.



**Figure 2: Kinesia Sensor Proper Positioning**

## ***Charge Pad***

In order to be properly charged, the Kinesia Sensor should be placed in the white rectangular target area (Figure 3) with the label face down. The Charge Pad can be connected to a USB port or wall outlet using the provided cables. The LED indicator on the front of the Charge Pad will change from green to blue when the Kinesia Sensor is correctly positioned and remain on when fully charged. It is highly recommended that patients leave the Kinesia Sensor in this position between motor assessments.



**Figure 3: Charge Pad**

## Chapter 3: Web Application

The Kinesia Web Application (Figure 4) is a HIPAA-compliant online interface that allows clinicians to create study definitions, upload study data, and view study reports. The Web Application includes a patient database where you can easily add and update patient demographics and view studies. The status of a study is also displayed. Status indicators include: Setup Study, Pending Upload, New Report Ready and Archived Report.



Figure 4: Kinesia Web Application (layout may vary based on user role/permissions)

### Logging in to the Kinesia Web Application

Upon purchase of Kinesia ONE you will be provided with a username and temporary password by your sales representative.

1. Log in to the Web Application (<https://kinesia.GLNeuroTech.com>) using your username and temporary password.
2. Click the Admin tab to change your password.

### Adding a New Patient

In order to add a new patient:

1. Log into the Web Application (<https://kinesia.GLNeuroTech.com>)
2. Select the 'Patients' tab on the top of the screen.
3. Select 'Add New Patient' and complete the patient information (Figure 5). A unique patient ID is required. The Secondary Identifiers (First Field/Second Field) are optional. **Per privacy**

**regulations, avoid using personally identifiable information in these fields.** This includes the patient's name, medical identifiers, and contact details.

- a. A five-digit alphanumeric Access Code is generated unique to each patient. This code will be used to load a patient's study onto a Tablet using the Kinesia ONE app.
4. Press 'Save' to add a new patient to the database, or 'Cancel' to return to the main screen.

The screenshot shows the 'Patients' tab selected in the top navigation bar. Below the navigation bar is a form titled 'New Patient Information'. The form contains the following fields: 'Patient Id:' with a single text input box; 'Secondary Identifier:' with two side-by-side text input boxes labeled 'First Field' and 'Second Field'; and 'Access Code:' with a single text input box. At the bottom right of the form are two buttons: 'Save' and 'Cancel'.

**Figure 5: Add New Patient Data**

## ***Creating a New Study Definition***

To create a new study definition:

1. Log in to the Web Application
2. Select the 'Patients' tab on the top of the screen
3. Select the '+' under the 'Create Study' column to create a new study definition for a specific patient (Figure 6).

The screenshot shows the 'Patients' tab selected in the top navigation bar. Below the navigation bar is a 'Patient Search' section with two text input boxes labeled 'First Field' and 'Second Field', and an 'ID' input box. Below these is a 'Find Existing Patient' button. Below the search section is a table. The table has a header row with columns: 'Patient ID', 'Access Code', 'First Field', 'Second Field', 'Create Study', and 'View Studies'. Below the header row is a data row. The 'Create Study' column in the data row contains a '+' sign, which is circled in red. To the right of the table is an 'Add New Patient' button.

**Figure 6: Create Study Definition**

To configure the study definition:

1. Select Diary Mode

- **Standard Dyskinesia Diary** mimics a paper diary sometimes used by patients to log the general medication state. The patient will be required to select one of five diary options for each 30-minute period throughout the day. The diary options are Asleep; OFF; ON without dyskinesia; ON with non-troublesome dyskinesia; ON with troublesome dyskinesia.
- **Modified Dyskinesia Diary** mimics a paper diary sometimes used by patients which logs dyskinesia severity in addition to the general medication state. The patient will be required to select one of three diary options for each 30-minute period throughout the day. The diary options are Asleep, OFF, and ON. If ON is selected, the patient is prompted to rate their dyskinesia by selecting one of five severity options. The dyskinesia severity options are None, Slight, Mild, Moderate, and Severe.

## 2. Select Motor Assessment Mode

- **Specific Motor Tasks** objectively evaluate tremor, bradykinesia, gait, and dyskinesia at specific times during the day. Patients will be instructed to perform corresponding motor tasks (Table 1) while wearing the Kinesia Sensor on the index finger for upper extremity tasks and on the heel for lower extremity tasks. One must specify whether to assess the patient's left, right, or both sides.
- **Continuous Monitoring** is not supported with Kinesia ONE.
- **None** allows a study to be set up without sensor-based assessments.

Table 1: Specific Motor Tasks Labels

	Web Application	Patient Application
Upper Extremity	Rest Tremor	Arms Resting
	Postural Tremor	Arms Extended
	Kinetic Tremor	Touch Nose
	Finger Taps	Finger Taps
	Hand Movements	Hand Grasps
	Rapid Alternating Movements	Wrist Rotation
	Dyskinesia	Arms Resting & Arms Extended
	Finger-Chin-Finger	Finger-Chin-Finger
	Arm Outstretched	Arm Outstretched
	Wing Beating	Wing Beating
Lower Extremity	Toe Taps	Toe Taps
	Leg Lifts	Leg Lifts
	Gait	Gait
	Freezing of Gait	Gait

### 3. Set Dates and Times

- For the Specific Motor Task study mode, select the date and time range and time interval when the Tablet will notify the patient to perform the sensor-based motor tasks.

**Note:** If 'I do not want to specify dates and times' is selected, that patient can manually start a Specific Motor Task assessment on the Tablet.

### 4. Set Motor Tasks

- Click and drag the motor tasks that the patient will perform over to the Selected Tasks box. The extremity side to be tested can be set to left, right, or both.

### 5. Set Med Diary.

- Select the medications that will appear on the Tablet when the patient records a dose taken. Custom medications can be entered by typing in the box and clicking 'Add'.

### 6. Set Event Labels.

- Event Labels can be specified for each time a motor assessment is performed. Custom events can be entered by typing in the box and clicking 'Add'. Checking the box for Other will allow the user to have the option to type in custom event labels on the Kinesia ONE tablet.
- If you do not wish to include event labels, check the box that reads, "I do not want event labels."

### 7. Set Activity Diary is not supported with Kinesia ONE.

### 8. Summary

- Review and verify study definition settings (Figure 7). Notes can be entered for the study which will also appear in the study report on the Web Application. If notes are entered, click 'Save' to the right of the text box before proceeding.
- Select 'Finish' to save the study definition. Once 'Finish' is selected, no changes can be made and the study is ready for transfer to the Tablet.

**Note:** If your institution has a Study Template associated with it, the study configuration will automatically start on the Summary page. To modify the study, use the menu on the left to navigate to the step you would like to change and proceed until you return to the Summary.

**Figure 7: Patient Study Summary Screen**

## ***Creating/Editing a Study Template***

Institution administrators can create, edit, or clear a study template. When a study template is created, all subsequent study definitions created by users affiliated with that institution will default to the template selections with the exception of the dates and times. However, each user can move through this template on a per patient basis to make any desired changes to the template.

To create a study template:

1. Login to the Kinesia Web Application.
2. Select the Studies tab.
3. Select the Create / Edit Study Template button.
4. Configure study template and select Finish.

**Note:** To clear a study template, the institution administrator must select the Studies tab and then Clear Study Template. A confirmation window will appear. Select OK to proceed with the deletion.

**Note:** Only institution administrators can create and edit templates and only one template per institution may exist at a time.

## Chapter 4: Patient Application

### Home Screen

The Home Screen of the Kinesia ONE includes options for starting the motor assessment (My Tests), entering symptom and medication entries (My Diary), and navigating to the app settings and the page to load studies (towards the bottom of the screen).

There are status indicators located towards the top of the home screen. These indicate the current status of data uploading and if the tablet's connection to the internet is slow or not available. Some examples of these statuses are shown below.

The Patient ID for the study currently loaded in the app is displayed towards the bottom of the screen. This section is blank when no study is loaded.

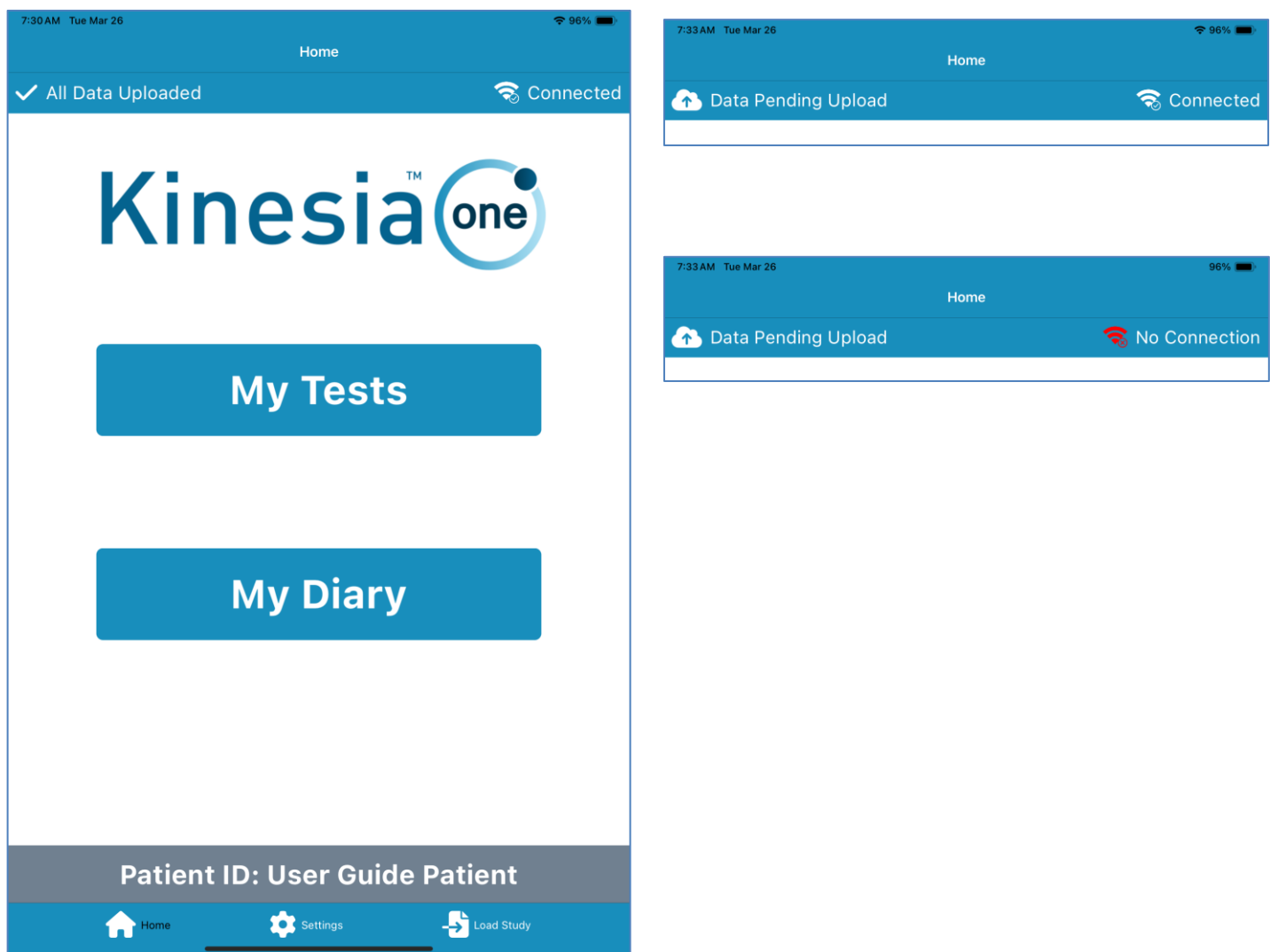



Figure 8: Home Screen and Statuses

## Settings and Loading a Study

The following features are located in the Settings screen (Figure 9) by selecting the  option in the bottom middle of the app:

1. **Pair Sensor:** The Patient Kit includes a Kinesia Sensor that is pre-configured for your tablet. If you receive a new sensor, it may be necessary to pair it with your tablet using this feature. In order to pair a sensor, ensure that the sensor is on the charge pad and select the ID that matches the Kinesia Sensor from the Pair Sensor screen (Figure 10).
2. **Sending Application Logs:** If you are experiencing issues with the Kinesia ONE app, Notify GLNT of what you are experiencing, and include the 6-character Service ID shown on the screen. Please enable this feature only after contacting a GLNT associate. Enabling this feature sends app logs to GLNT which will help to determine the issue being experienced.
  - a. **\*NOTE: No patient information is shared as part of the application logs**

**Load Study Definition:** Once a patient study is created on the Kinesia Web Application, it is available to load on the Tablet. The study can be loaded by opening the Load Study option in the bottom right of the app.

Enter the patient's five-digit access code once a network connection is available (Figure 11). A study summary (Patient ID, side, and motor tasks) will appear on the screen. The most recently created study will be downloaded to the tablet.

**Note:** An internet connection is required to load a Study Definition onto the tablet. Depending on the system version purchased, a Wi-Fi connection or mobile broadband connection is available.

**Note:** Functionality and screen layouts may vary based on the software version.

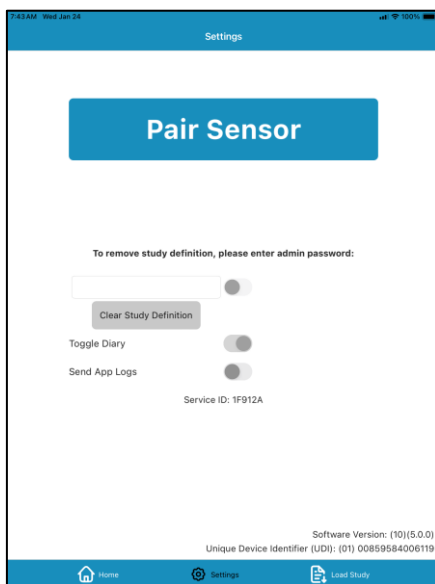


Figure 9: Settings



Figure 10: Pair Sensor

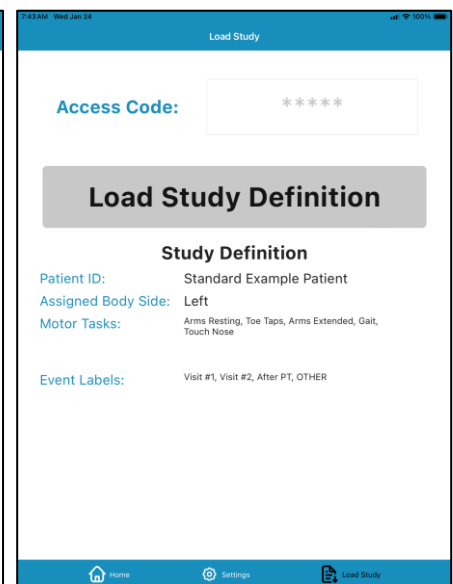
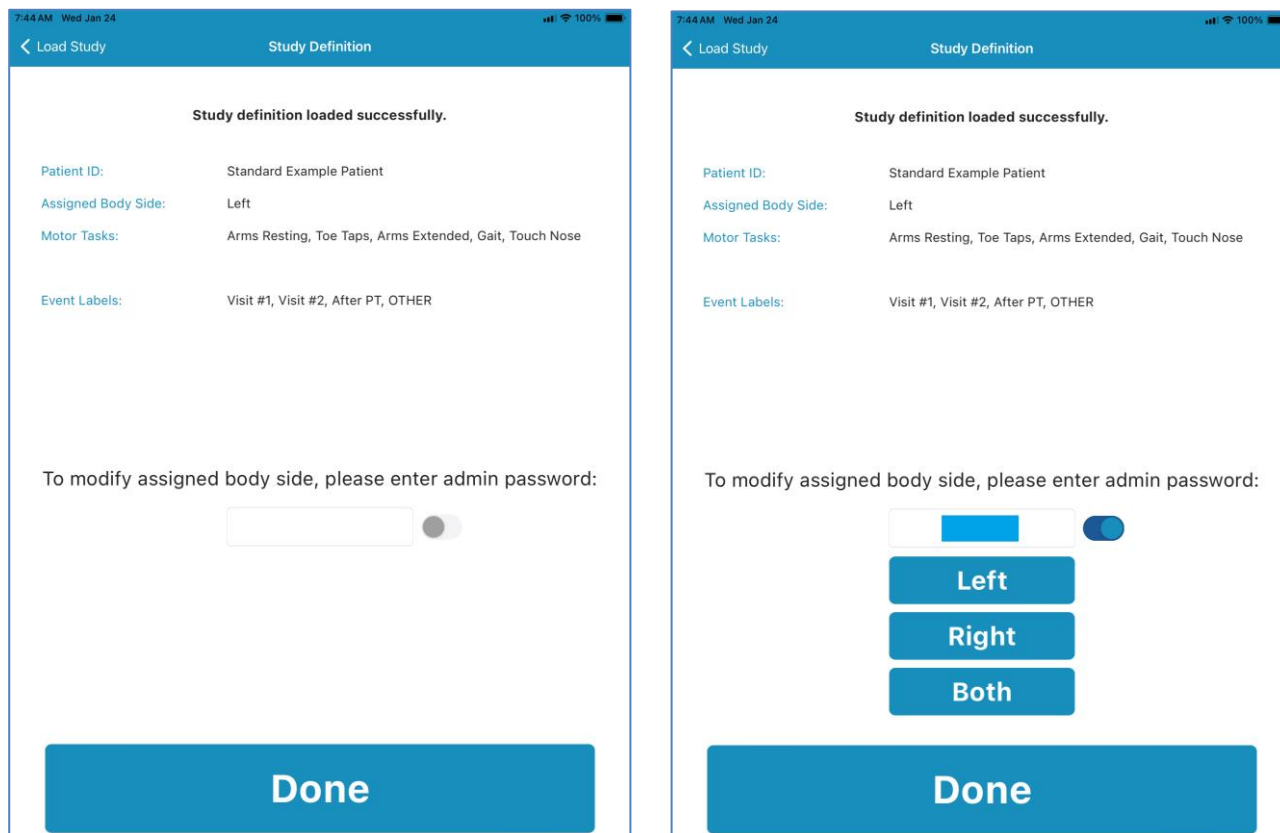


Figure 11: Load Study Definition





**Figure 12. Select Which Side is Assessed**

If needed, the side which is being assessed (right, left, or both) can be changed immediately after downloading the study to the tablet (see Figure 12). The selection defaults to the option selected on the web app during creation of the patient study. To change the selected body side, enter the admin password (Contact GLNT Support for admin code). Once the selection is final, tap “Load Study” in the upper left-hand corner or the button labeled “Done” to confirm.

## Connecting to Wi-Fi

If Wi-Fi is being used for connectivity, follow these steps.

1. Click the Settings icon on the tablet and select Wi-Fi.
2. Ensure that Wi-Fi is enabled using the slider next to Wi-Fi.
3. Select the appropriate network, enter the password, if prompted, and click Join.
4. If successfully connected to Wi-Fi a connectivity icon will display at the top left of the screen.

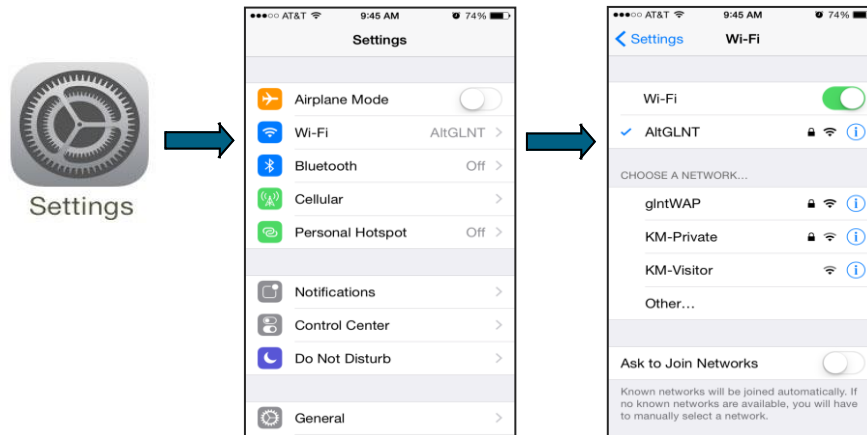


Figure 13: Wi-Fi Settings

## Setting the Language

The Kinesia ONE tablet application includes translation support for the following languages: English, German, French, Spanish, and Swedish. In order to change the language, follow these steps:

1. Click the Settings icon on the tablet and select General.
2. Select Language & Region from the menu on the right.
3. Tap iPad Language and select one of the supported languages from the list.

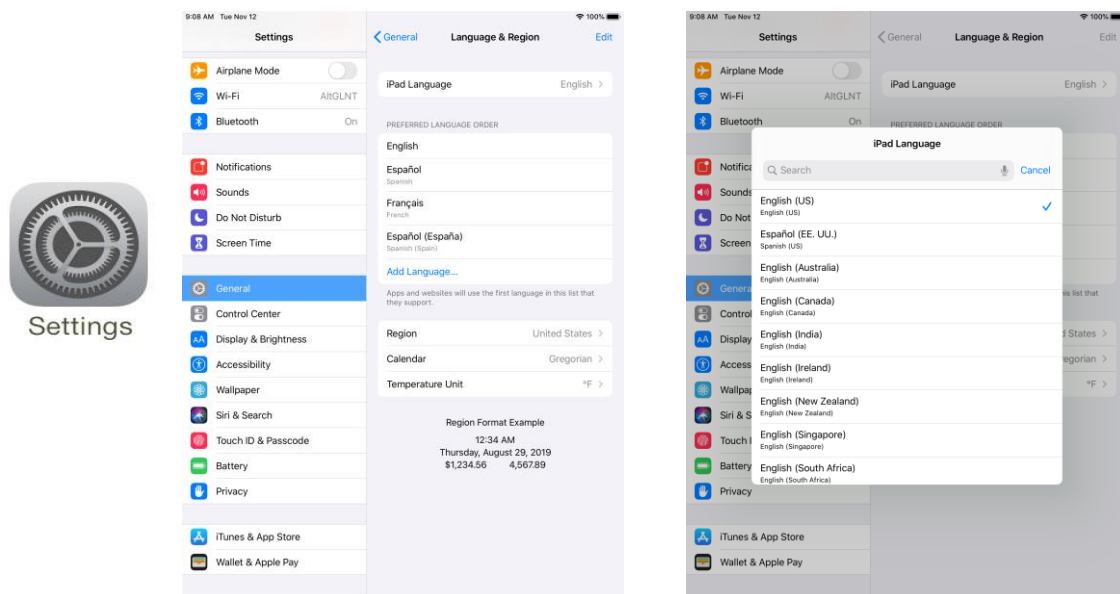


Figure 14: Language Settings

## Motor Assessment

Based on the loaded study definition, patients can perform a Motor Assessment by selecting 'My Tests' from the application home screen.

If event labels were set up during the study creation, the user will be asked to select from a set of defined event labels before performing each set of motor assessments. The selected event label will then appear at the bottom of the page, above the 'Back' and 'Next' buttons. The **Next** button is disabled until the user selects an option. If the OTHER option was included during the study setup, the user may select this option to open a text box. In this text box, the user can type out a custom label of their choice. Their custom choice will appear above the buttons once confirmed. If the user does not want to use any of the options, they may choose **NONE**. Once a selection is made, the 'Next' button will become available to continue with the assessment.

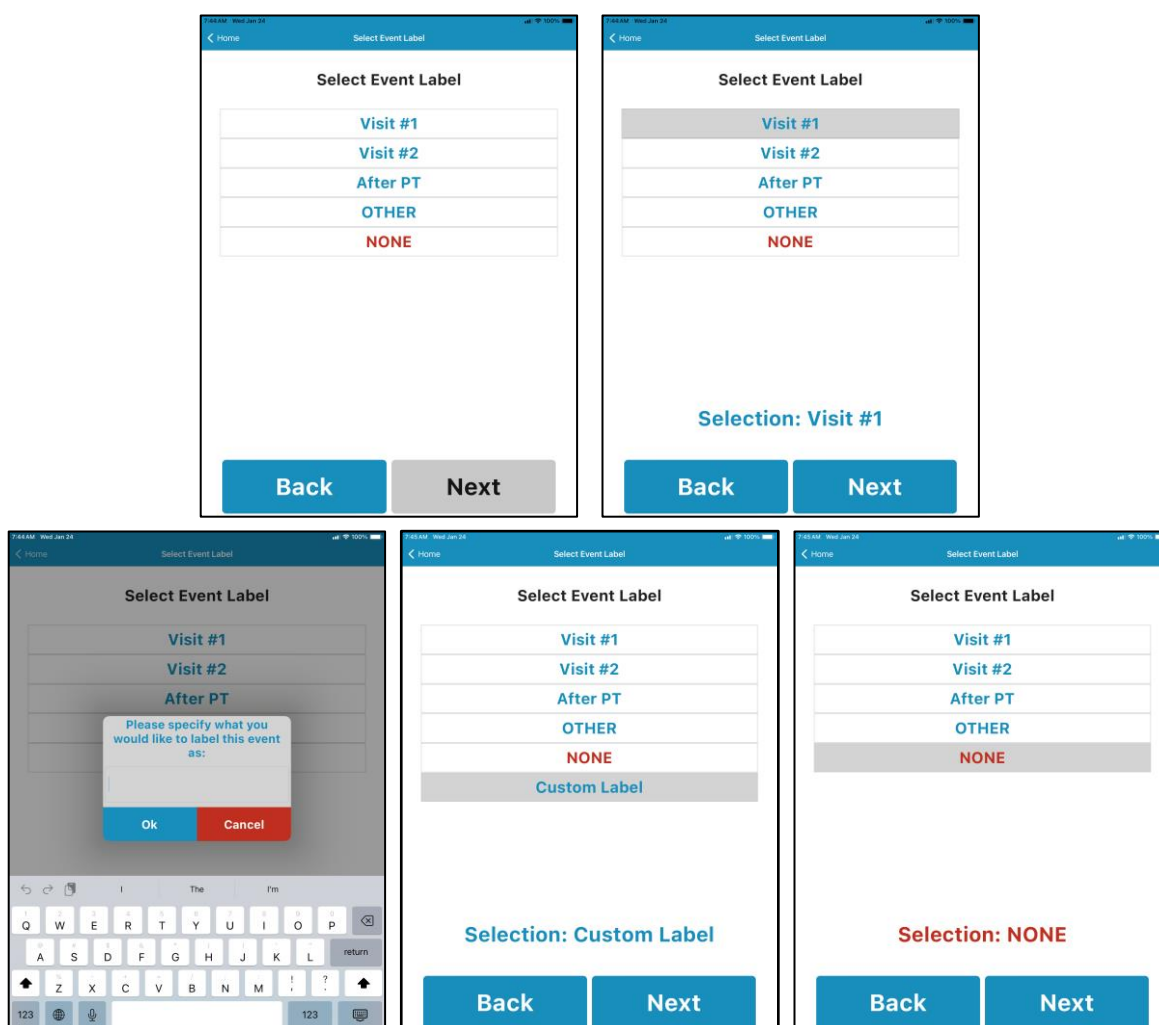


Figure 15: Event Labels

During the Motor Assessment, the patient will be guided through a short series of motor tasks while wearing the Kinesia Sensor. Each Motor Assessment will consist of a setup screen instructing the patient where to position the Kinesia Sensor and the motor tasks designated during study creation (Figure 16).

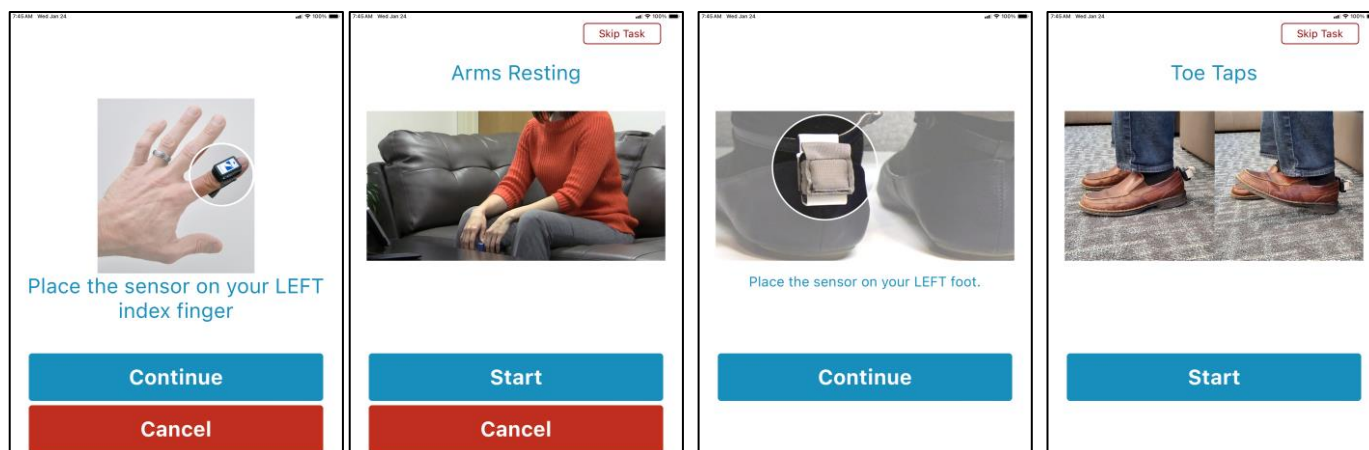


Figure 16: My Tests Setup and Task Performance

## Alarms

If selected during study creation in the web app; once an access code is entered, the tablet will alert the patient at specific times during the day to begin an evaluation based on the study definition. If the patient does not start a motor assessment, the alarm will repeat every minute as a reminder. The user is able to snooze the alarm for 10 minutes, after which the alarm will start to repeat unless snoozed again.

## Skipping Tasks

The user may skip a task by selecting the option at the top right corner of the task screen labeled “Skip Task.” This option is available for every task in the study definition. A message will appear asking to confirm the skip. (Figure 17). If skipped, no data will be recorded for this task and the Kinesia ONE app will move on to the next task.

**Note:** No score will be provided in the portal for skipped tasks.

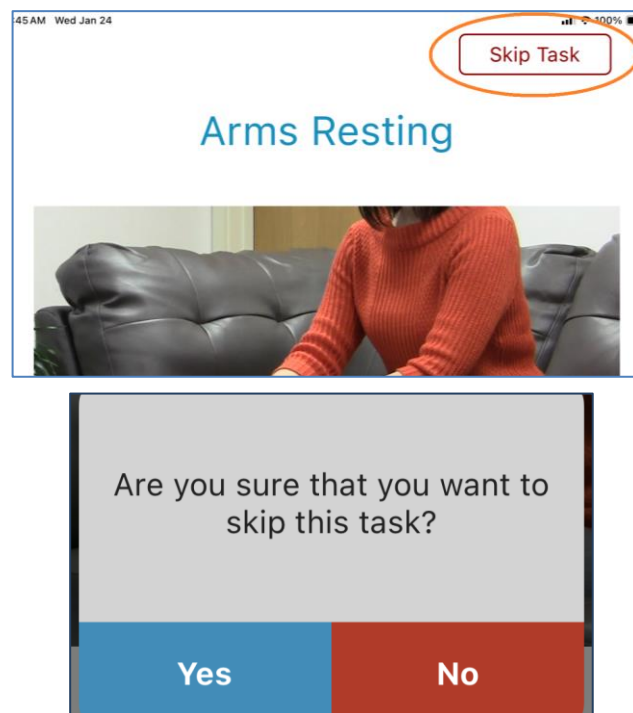



Figure 17. Skipping Motor Tasks

## Chapter 5: Executing a Patient Study

### ***Patient Kit Preparation***

Before sending the Patient Kit home, complete the following steps.

1. Check that all components are in the carrying case.
2. Turn on the tablet, select the  symbol in the bottom middle and choose Pair Sensor (Figure 10). Ensure that the sensor is properly paired with the tablet and appears in the Sensor ID field. If not, pair the sensor.
  - a. Identify the Sensor ID in the list of sensors. The sensor ID is the last 4 digits of the serial number, which is printed on the side of the sensor.
  - b. Tap the ID. The sensor becomes paired and appears in the Sensor ID field.
  - c. Select the Home option at the bottom left of the app to return to the Home screen.
3. If you do not have a cellular plan with your Kinesia ONE tablet, ensure that the correct time zone is set.
  - a. Tap the Settings icon on the tablet and tap General in the left column.
  - b. Tap Date & Time in the menu on the right.
  - c. Tap the slider to turn off Set Automatically
  - d. Tap Time Zone and enter the name of the nearest major city in the time zone that the patient will be using the device in.
  - e. Select a city and the Tablet will reset its time zone to match.
  - f. Power off by pressing and holding the power button until the “Slide to Power Off” bar appears, and then swipe the bar. The Tablet will power down.
  - g. Power on the Tablet by pressing the power button until the Apple logo appears, then let it go.
  - h. Once the internet connection has been established, return to Time & Date settings and turn on the option to Set Automatically.
4. Transfer the study definition from the Web Application to the Tablet.
  - a. Identify the Access Code associated with the patient. Refer to “Adding a New Patient”.
  - b. On the Kinesia Tablet, open the Kinesia ONE application, select the Load Study option in the bottom right of the app.
  - c. On the Load Study screen, enter the Access Code and tap ‘Load Study Definition’. Study Definition information is displayed at the bottom of the screen (Figure 11).
  - d. Select the Home option at the bottom left of the app to return to the display of the Home screen and prepare for patient use.

**Note:** Kinesia ONE Tablets with a cellular plan will automatically update the time. If the time zone does not match the local time when patients are using the system, data will still be successfully collected and uploaded. The time stamps displayed on the Web Application will reflect the local time set on the device.

- e. To verify that the correct study has been loaded, confirm the Patient ID at the bottom of the home screen.

### ***Patient Assembly At Home***

The Kinesia ONE system will be sent home with patients in an easily accessible carrying case. The patient should adhere to the following instructions for home assembly and use:

1. Remove the Tablet and case and position the tablet in a portrait position.
2. Power the Charge Pad using the provided black USB cable and AC power adapter.
3. Place the Kinesia Sensor in the center of the Charge Pad with the 'Kinesia' label face down.
4. Press and hold the Tablet power button down (top right) until the Tablet powers on.
5. Launch the Kinesia ONE app from the bottom of the Tablet home screen.

**Note:** The Tablet can be charged using the white USB cable and AC power adapter.

- *To avoid tripping over the power cord, patients should place the Kinesia ONE system somewhere that the electrical cords for the Tablet and charge pad are out of the way of walking paths.*

### ***Patient Use At Home***

Patients can perform an assessment by selecting 'My Tests' from the application home screen. During the motor assessment, the patient will be guided through the motor tasks while wearing the Kinesia Sensor.

1. After selecting 'My Tests' from the home screen, the patient will be instructed how and where to attach the Kinesia Sensor (Figure 16).
2. The patient will perform the motor task specified on subsequent screens once the 'Start' button is pressed and the 15 second or 12 second countdown timer begins, depending on the task. (Figure 16).

**Note:** All upper extremity tasks are set to 15 second countdowns. However, lower extremity tasks, like Toe Taps and Leg Lifts, are set to 12 second countdowns. The Gait task ends when the user taps a button but also automatically stops recording 2 minutes after starting the task.

3. Based on the study definition, alarms on the Tablet will instruct patients when to perform motor tasks. Alarms will continue until the patient selects 'My Tests' from the home screen.
4. If no alarms were programmed, patients can press 'My Tests' to manually initiate a motor assessment at any time.

## Diary Entries

Either of two types of diary entries can be made: Symptom and Medication (Figure 18). Both are initiated by pressing My Diary on the main screen.

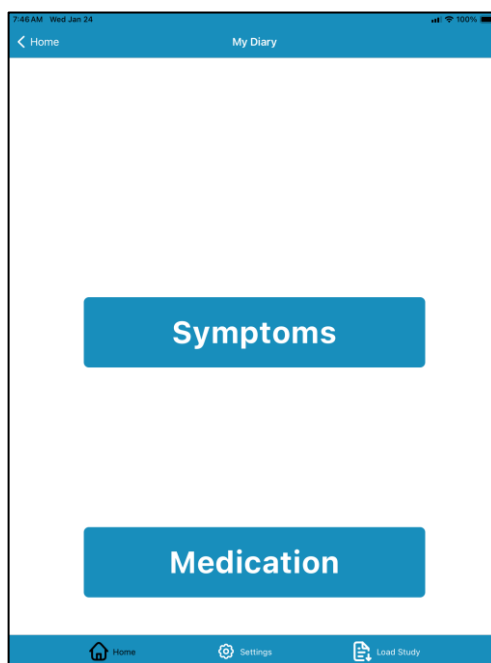


Figure 18. My Diary Options

### Symptom Diary

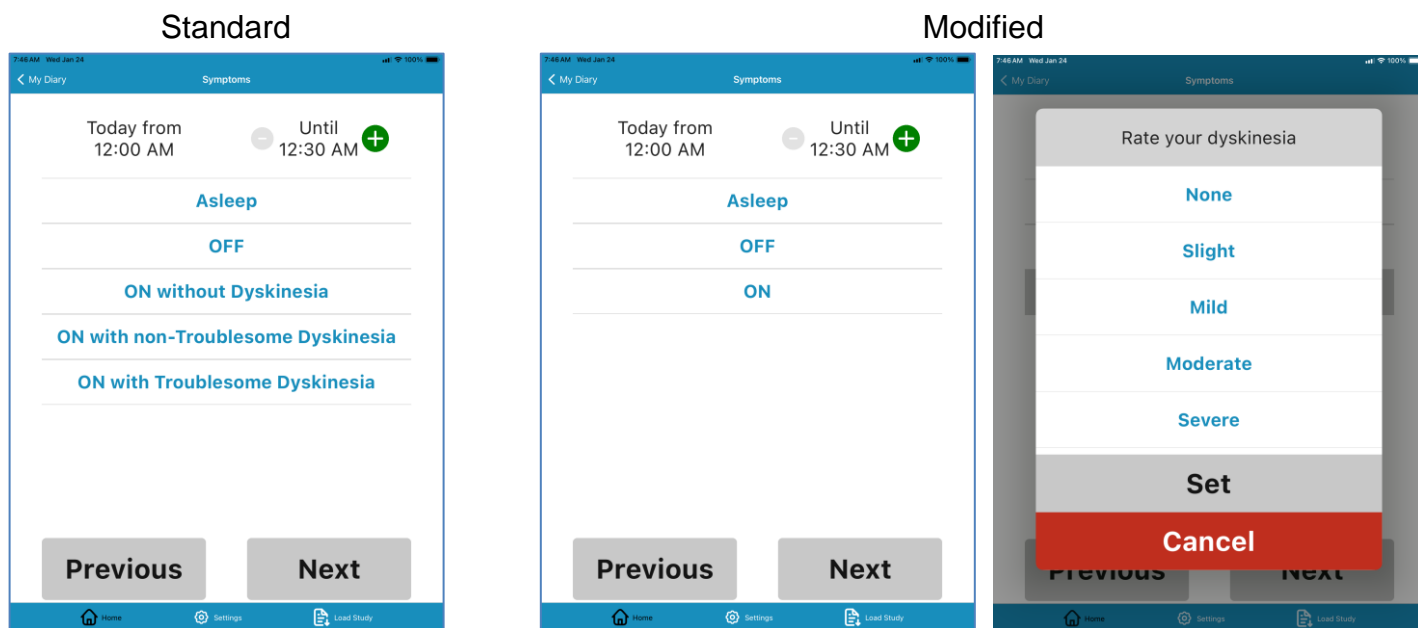
If a Dyskinesia Diary has been defined for the study, pressing Symptoms displays a screen that allows the patient to rate his/her dyskinesia at 30-minute intervals during the day. Refer to Figure 19.

**Note:** The specific diary options will be based upon which type of diary was selected in the study definition on the web app.

The first time the diary is accessed, the patient begins rating at the 12:00am-12:30am interval for the current day. Press the desired rating and then press Next. The next 30-minute interval rating is automatically requested, and rating continues until the current time is reached.

The user can set the end time to a later 30-minute interval by selecting the '+' plus sign in the symptom diary (see Figure 19). This allows the user to enter a symptom for multiple 30-minute intervals.

The Back button can be pressed to exit rating at any time. However, the rating automatically resumes upon subsequent diary access that day, beginning with rating after the last interval entered.



**Figure 19. Dyskinesia Diary – Initial Interval Rating**

**Note:** Interval rating is limited to the current 24-hour day. Once 12:00am on the next calendar day occurs, interval rating begins again at the 12:00am – 12:30am interval for the current day. Ratings from previous days are retained and archived with the study.



## Medication Diary

If a Medication diary has been defined for the system, pressing 'Medication' displays a list of the defined medications. Set the date and time taken by tapping the date and time in these fields. Tapping each of these fields respectively will open a date and time roller. Select the date or time that the medication was taken in the roller. Once these fields are entered accordingly, tap the medication that you wish to enter Refer to Figure 20.

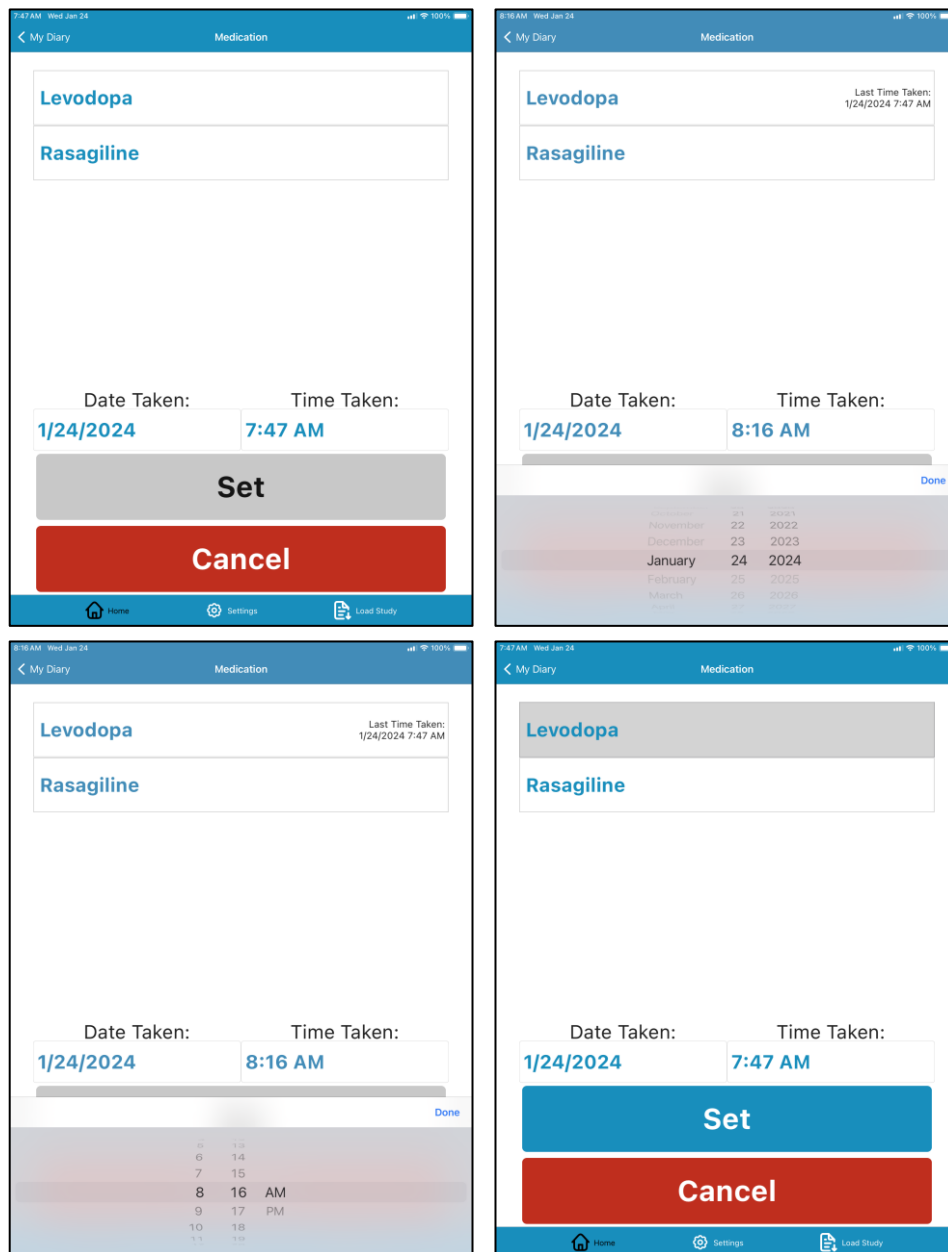


Figure 20. Medication Diary

## Chapter 6: Study Definition and Data Transfer

### Transfer Patient Data to Web Application

At the completion of each motor assessment, the tablet application will attempt to upload the patient data to the web application. If network connection via Wi-Fi or mobile broadband is not available, the application will continue to retry. **NOTE:** Data will NOT be lost if a connection is not available. Rather, data will be stored on the tablet until a network connection can be made.

**Note:** It is highly recommended that patients do NOT turn their tablet off after each use. This could delay the upload of data to the Kinesia Web Application.

### Clearing Patient Study Definition

To clear the loaded study definition, enter the admin code (contact GLNT support to obtain code) in the settings menu and toggle the switch. Then confirm that you wish to clear the study definition in the following pop-up. Completed assessment data that remains on the device will still be uploaded to the correct patient if the study definition is removed.

## Chapter 7: View Study Reports

Once patient data has been uploaded from the Tablet, log in to the Web Application. In the Overview tab, locate the patient ID. Select 'Archived Report' or 'New Report Ready' (the status for that patient ID). Each report will consist of three main features:

1. **Motor Trends** displays time stamped motor scores based on the patient data recorded by the Kinesia Sensor. Motor tasks will display 0 (green) to 4 (red) color-coded scores corresponding to no and high symptom severity, respectively (Figure 21).

**Note:** In addition to the speed, amplitude, and rhythm severity scores for the finger taps task, the number of taps is also calculated and displayed ("Finger Taps Count"). This column is not color coded.

2. **Diary Trends** displays the responses entered by the patient into the Dyskinesia diary.
3. **Interpret** allows the clinician to enter his or her interpretation of the study results and the follow-up recommendation. Furthermore, any Notes saved on the Summary screen when creating a study will appear on this tab or can be entered at this time. Select 'Save' to add the entered text into the final report. Selecting 'Save' again will overwrite the interpretation and recommendation.

### ***Export Study Reports***

To create a PDF or XLSX of a report, select either PDF or Excel on the 'Download Report' button on the left side of the motor report screen.

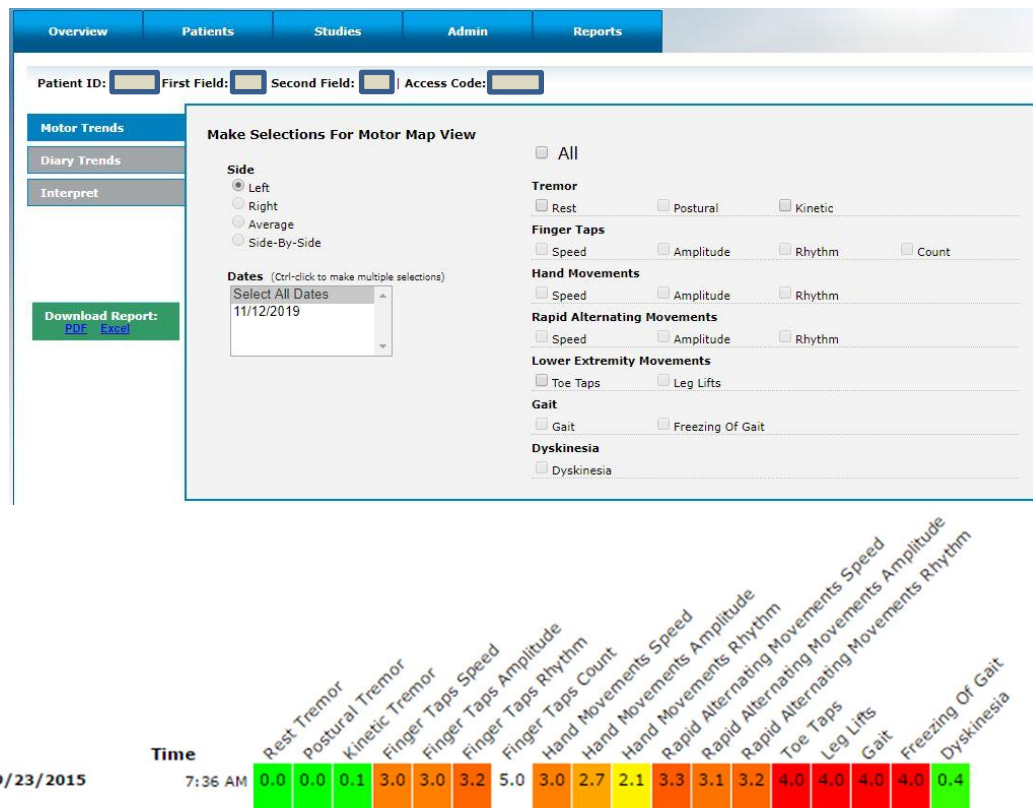


Figure 21: Web Application Study Report

## Chapter 8: Frequently Asked Questions (FAQs)

Q. My device has said that data is pending uploading for a while.

A. Try to navigate to the Kinesia ONE app settings then back to the home page to update this status message. You can also try to close and open the app to update this status.

Q. I continue to receive an error message when attempting to load a study definition.

A. Ensure the Wi-Fi or mobile broadband is enabled. If both wireless connections are enabled and you are still unable to log in, contact GLNT support at 1.855.GLNeuro (1.855.456.3876).

Q. When I attempt to create a new study definition for a patient, I am automatically redirected to an old study definition I had begun setting up but not yet finished.

A. Only one study can be in the 'Setup Study' status for a patient at a time. You are redirected to an old study that has not been finished as a result of this functionality.

Q. I hear an alarm, but I don't see the My Test button.

A. The audio alarm means that a motor assessment should be performed. If you are not on the Home Screen of the Patient Application, tap the Home option in the bottom left of the app. If the Patient Application was minimized, select the Kinesia ONE icon to reopen from the tablet home screen.

Q. During my test, the message "Connection Lost" appeared, and I could not finish my test.

A1. The sensor failed to collect data for your study. Return to the Home screen, tap My Tests, and begin the assessment again. If this issue occurs several times, please contact GLNT support.

A2. The sensor battery may have died which can be confirmed by viewing the LED on the sensor. If the LED is not blinking, place the sensor on the charge pad for at least 20 minutes before starting the next motor assessment.

Q. When I press 'My Tests' I am unable to initiate a motor assessment.

A1. Check that the sensor is on and charged. To do this, place the sensor on the charge pad with the white label facing down (Figure 3). Make sure you hear a 'beep', and then remove the sensor. When the sensor is off the charge pad, the LED on the sensor should be blinking.

A2. If the sensor LED is not blinking, it is likely that the battery has died. Place the sensor on the charge pad for at least 20 minutes to charge before starting a motor assessment. To mitigate this issue, it is recommended that the sensor be placed on the charge pad at all times when not in use.

Q. I have placed the motion sensor on the charge pad, but I do not hear a beep.

A1. Ensure that the sensor is being placed on the correct side of the charge pad. When the correct side of the charge pad is facing up, you will see a rectangle shape and logo similar to that on the Kinesia Sensor.

A2. Ensure that the sensor is placed on the charge pad with the white label facing down. The white label on the Kinesia Sensor should be in contact with the rectangular white label on the charge pad.

A3. Verify that the charge pad is receiving power. If it is, you will see a blue LED on the front. If you do not see this, check the connection of the cable on the charge pad and on the AC adapter that is plugged into an outlet. Make sure both ends are securely connected.

Q. I know the patient has completed motor assessments but there is no data on the Web Application.

A1. If the patient turns off the tablet after completing the motor assessments this may delay data upload to the clinician web application. Contact the patient to ensure the tablet is on.

A2. Ensure that Wi-Fi is connected or that there is a mobile broadband connection.

Q. I am unable to log in to the Web Application.

A1. If you have forgotten your username and/or password, please contact GLNT support.

A2. If multiple login attempts occur with an incorrect password, the system will automatically lock your account. Contact GLNT support to resolve.

Q. I'm trying to connect to Wi-Fi on the tablet but am receiving an error message.

A. If you do not have a cellular plan with your Kinesia ONE tablet the time will not automatically update, which may be necessary for an internet connection. Please see the section in Chapter 5 on Patient Kit Preparation for instructions to set the correct time zone.