

USER'S GUIDE



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Intended Use

Kinesia One 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

1

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.

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 UNDESIRED 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

Kinesia Web Application System Recommendations

Internet Explorer 8 and 9
1024 X 768 or greater display resolution
Adobe Reader
Microsoft® Silverlight
Broadband Internet access

Note: Macintosh® and Linux® operating systems are not supported. Certain features of the Web Application require Microsoft Silverlight

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

Travel Case; 501-0279

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

Date of Purchase: ______

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 Parkinson's disease 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 tests 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

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

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). Patient first and last name, birth date, and a unique patient ID are required.
 - 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.

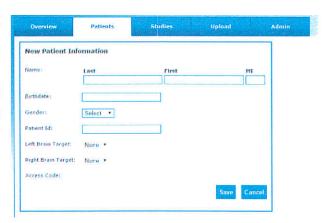


Figure 5: Add New Patient Data

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 '+' next to the patient's name under the 'Create Study' column to create a new study definition for a specific patient (Figure 6).



Figure 6: Create Study Definition

To configure the study definition:

1. Select Diary Mode

- Custom Diary is not supported with Kinesia One.
- Standard Dyskinesia Diary mimics a paper diary sometimes used by patients which
 logs 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 Sleeping;
 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 Sleeping, 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 setup without sensor-based assessments.

Patient Application Web Application Rest Tremor **Arms Resting** Postural Tremor Arms Extended Kinetic Tremor Touch Nose Extremity **Finger Taps Finger Taps** Hand Movements Hand Grasps Rapid Alternating Movements Wrist Rotation Dyskinesia Arms Resting & Arms Extended Toe Taps Toe Taps Extremity Lower Leg Lifts Leg Lifts Gait Gait Freezing of Gait Gait

Table 1: Specific Motor Tasks Labels

2. 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.

3. 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.

4. 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'.
- 5. Set Symptom Diary and Set Activity Diary are not supported with Kinesia One. If Custom Diary was selected as the Diary Mode (see Step 1), these options will be presented during the setup. Check "I do not want a symptom diary" at the top right of the screen then click 'Next'. Repeat this step with the Activity Diary.

6. 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.

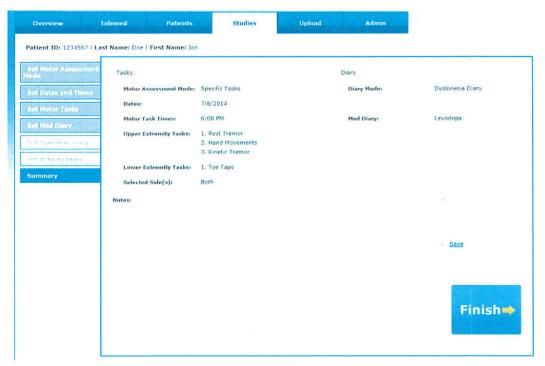


Figure 7: Patient Study Summary Screen

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

Settings

The following features are in the Settings screen (Figure 8) by selecting the == symbol in the top left

- 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 it is turned on and select the ID that matches the Kinesia Sensor from the Pair Sensor screen (Figure 9).
- 2. **Load Study Definition**: Once a patient study is created on the Kinesia Web Application, it is available to load on the Tablet. Enter the patient's five digit access code once a network connection is available (Figure 10). 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 WiFi connection or mobile broadband connection is available.

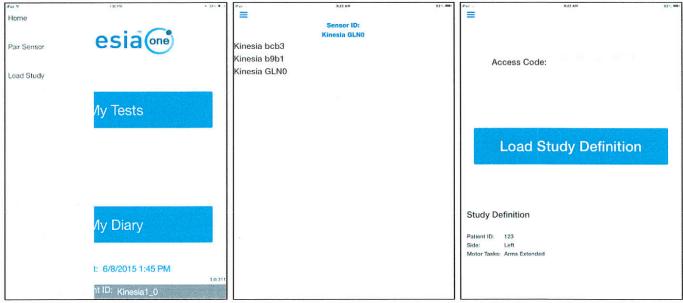


Figure 8: Settings

Figure 9: Pair Sensor

Figure 10: Load Study Definition

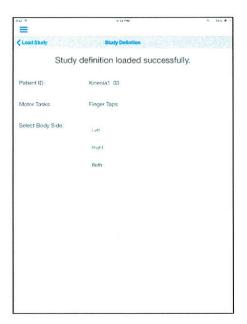


Figure 11. Select Which Side is Assessed

If needed, the side which is being assessed (right, left, or both) can be changed after downloading the study to the tablet (see Figure 11). The selection defaults to the option selected on the web app during creation of the patient study. Once the selection is final, tap "< Load Study" in the upper left hand corner to confirm.

Connecting to WiFi

If WiFi is being used for connectivity, follow these steps.

- 1. Click the Settings icon on the tablet and select WiFi.
- 2. Ensure that WiFi 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 WiFi a connectivity icon will display at the top left of the screen.

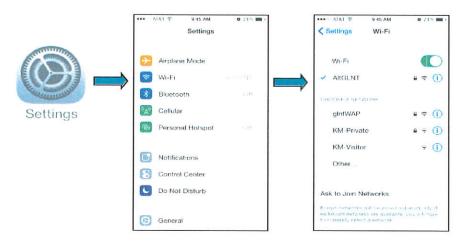


Figure 12: WiFi Settings

Setting the Language

The Kinesia One tablet application includes translation support for the following languages: English, German, French, 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

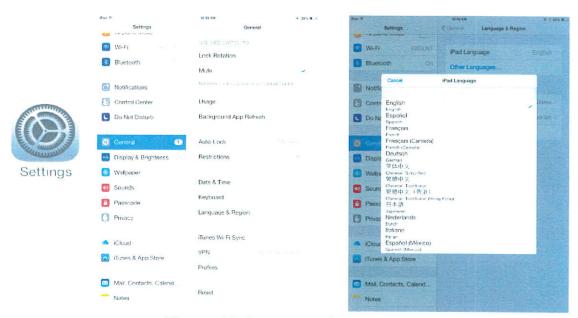


Figure 13: Language Settings

Motor Test

Based on the loaded study definition, patients can perform a Motor Test by selecting 'my Tests' from the application home screen. During the Motor Test, the patient will be guided through a short series of motor tasks while wearing the Kinesia Sensor. Each Motor Test will consist of a setup screen instructing the patient where to position the Kinesia Sensor and Motor Tasks (Figure 14).

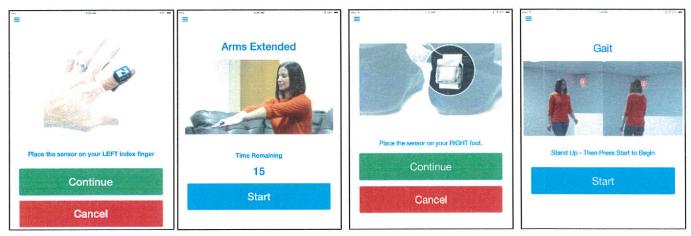


Figure 14: my Tests Setup and Task Performance

Alarms

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 test, the alarm will repeat every minute as a reminder.

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 top left and choose Pair Sensor (Figure 9). Ensure that your 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 ≡ symbol in the top left and choose Home 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.

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.

- 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. At the Kinesia Tablet, open the Kinesia One application, select the ≡ symbol in the top left and choose Load Study (Figure 8).
 - c. At 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 10).

- d. Select the ≡ symbol in the top left and choose Home to return to the display of the Home screen and prepare for patient use.
- e. To verify that the correct study has been loaded, confirm the Patient ID at the bottom center 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 cord for the Tablet is 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 test, 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 14).
- 2. The patient will perform the motor task specified on subsequent screens once the 'Start' button is pressed and the 15 second countdown timer begins (Figure 14).
- 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 15). Both are initiated by pressing My Diary on the main screen.

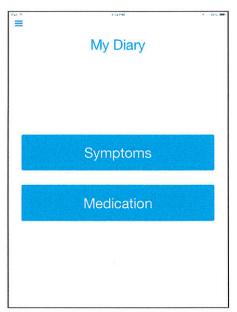


Figure 15. My Diary options

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 16.

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

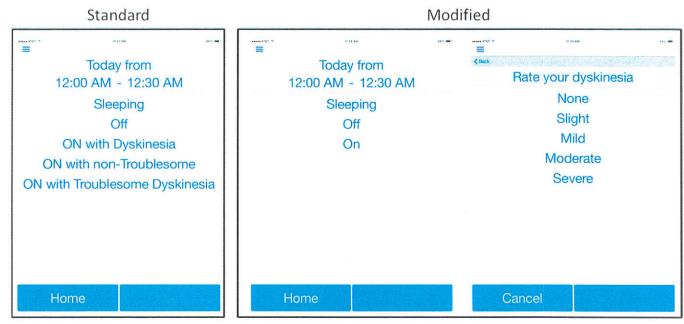


Figure 16. Dyskinesia Diary – Initial Interval Rating

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 the12:00am – 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 my Meds displays a screen a list of the defined medications. Selecting one of the medications displays a screen with an adjustable clock setting, that allows the patient to enter the time of day specified medications were taken. Refer to Figure 17.

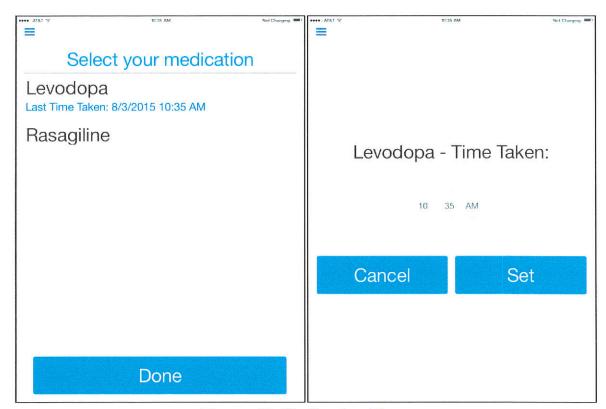


Figure 17. Medication Diary

Chapter 6: Study Definition and Data Transfer

Transfer Patient Data to Web Application

At the completion of each motor task, the application will attempt to upload the patient data to the Web Application. If network connection via WiFi or mobile broadband is not available, the application will continue to retry.

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.

Chapter 7: View Study Reports

Once patient data has been uploaded from the Tablet, log in to the Web Application. Press the 'Studies' button on the top of the screen. Navigate to the report based on the patient name, ID, and study start date. Select 'Archived Report' or 'New Report Ready'. 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 18).

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 18: Web Application Study Report

Chapter 8: Frequently Asked Questions (FAQs)

- Q. I continue to receive an error message when attempting to load a study definition.
- A. Ensure the wifi or mobile broadband is enabled. If both wireless connections are enabled and you are still unable to login, contact a GLNT administrator 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 had 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 test should be performed. If you are not on the Home Screen of the Patient Application, tap the symbol in the top left and choose Home. 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 in to 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 WiFi 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 WiFi 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 is necessary for internet connection. Please see the section in Chapter 5 on Patient Kit Preparation (page 18) for instructions to set the correct time zone.