Kinesia™ 360

USER'S GUIDE

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NEUROTECHNOLOGIES

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User Guide, 392-0057 Rev H, DCO G415

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Intended Use

Kinesia 360 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

⚠ Tripping Hazard – keep the electrical cord away from walking paths

⚠ 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.

⚠ DO NOT use an autoclave or other high temperature sterilization method on any Kinesia 360 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 360 (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:

Android Tablet;	502-0271-1	Tablet SN: _____
Kinesia Sensor (Wrist);	502-0264	Sensor SN: _____
Wrist Attachment Strap;	502-0272	
Kinesia Sensor (Ankle);	502-0265	Sensor SN: _____
Ankle Attachment Strap;	502-0273	
Dual Charge Pad;	059-0015	
USB Cable;	116-0151	
User's Guide (this document);	392-0057	
Quick Start Guide;	392-0059-1	
Date of Purchase: _____		

Care and Use Instructions

When transporting Kinesia 360, ensure all components are secured in the case to prevent damage.

It is not recommended to store Kinesia 360 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 360

Kinesia 360™ is a medical system designed to capture and evaluate Parkinson's disease symptoms from patients' homes. A patient kit, programmed to a specific individual's symptoms and treatments, is sent home with the patient to use throughout the day to assess tremor and dyskinesia. The patient can also enter touch screen diary information about how they are feeling and when medications were taken. Clinicians can view web-based reports including automated severity scoring that show symptom changes during the day in response to treatment.

Chapter 2: Patient Kit

Components

The Kinesia 360 Patient Kit consists of the following primary components (Figure 1):

| Tablet | Sensors and Charge Pad | USB Cable | Charge Pad Power Cable |

Figure 1

A. Tablet

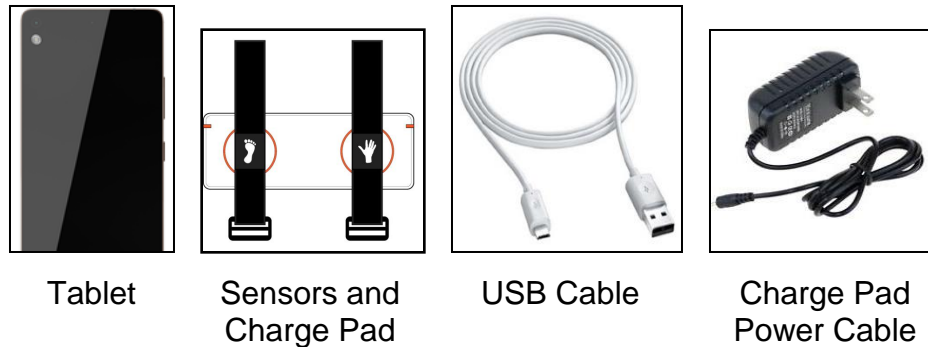The touch screen Tablet is the central component of the Kinesia 360 Patient Kit. The preinstalled application provides guided instructions for patients to collect their symptom data with the motion sensors and complete the medication and symptom diary logs. The tablet uploads all information to the Kinesia Web Application where summary reports are provided.

Power Button

Home Button
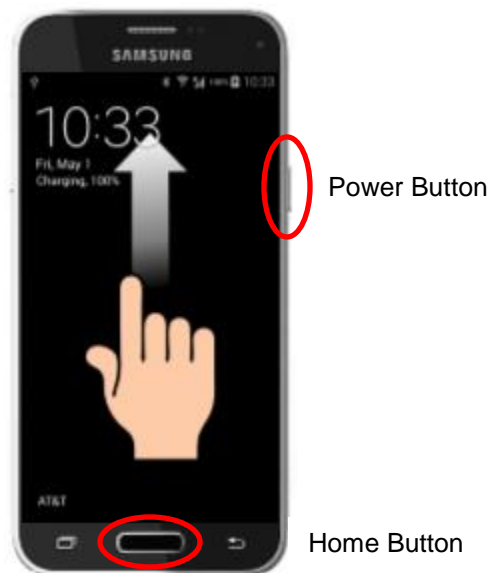
Figure 2

B. Kinesia Motion Sensors (with wearable Sensor Bands)

The Kinesia Motion Sensors are used to measure three dimensional movements (acceleration and angular velocity). Each sensor has a unique Sensor ID which is printed on the side of the sensor housing. The sensor bands are designed to allow patients to wear the motion sensors as they go about their normal routines. The straps are one-size-fits-all and are labeled on the underside to ensure that the sensors are placed in the proper location.

C. Charging Pad

The Charging Pad charges the Kinesia Motion Sensors and has a powered USB port for charging the Tablet.

Setup Instructions

The system should be set up the night before use so that all system components are fully charged.

1. Unpack the contents of the box. This should be done on a desk or table with a power outlet nearby. You will have the following items:
    -   Tablet
    -   Two Kinesia Motion Sensors Bands
    -   Charging Pad
    -   Tablet USB cable
    -   Charging Pad Power Cable

2. Place the Charging Pad on the table with the orange circles facing up. Plug the Charging Pad Power cable into the Charging Pad as shown below (Figure 3) and plug the other end into the power outlet.

Figure 3

3. Place the Kinesia Sensors Bands on the Charging Pad, centered on the orange circles as shown below (Figure 4). The sensors should remain in the straps while charging. The symbols embroidered on the underside of each strap (i.e., a hand or foot) should be facing upwards.
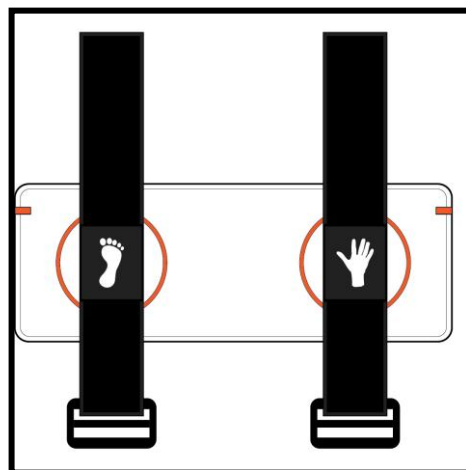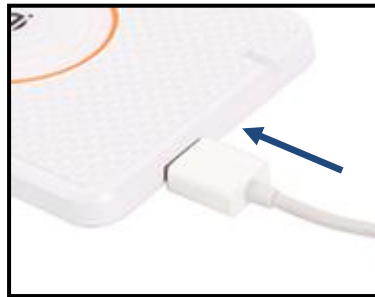

Figure 4. Sensors Correctly Placed on the Charge Pad

4. Plug the large end of the USB cable into the port on the side of the Charging Pad and plug the small end of the USB cable into the tablet as shown (Figure 5).

Figure 5

Charge Pad and Large
USB Connector

Tablet and Small
USB Connector

Chapter 3: Web Application

The Kinesia Web Application is a HIPAA-compliant web interface that allows clinicians to configure a Kinesia 360 Patient Kit and access the remotely collected data.

Accessing the Kinesia Web Application

Upon purchase of Kinesia 360 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.

Chapter 4: Creating a Patient Profile

Prior to using the Patient Kit, you must first create a profile in the Kinesia Web Application. The first step is to add a patient, including basic demographic information to the database. Once a patient is created, a study protocol (or study definition) must be defined.

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

Figure 6: Add New Patient Data

4. Press 'Save' to add a new patient to the database, or 'Cancel' to return to the main screen.
   a. A five digit alphanumeric Access Code is generated unique to each patient. This code will be used to load a patient's profile onto a Tablet using the Kinesia 360 app. It is displayed in the patient dashboard next to the Patient ID. (Figure 7)

   Note: Record this code so that it is easily retrievable when you are configuring the Tablet.

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 7).

Figure 7: Access Code Display and Creating Study Definition

To configure the study definition:

1. Select Diary Mode

- **Custom Diary** is not supported with Kinesia 360. Selecting this option will not impact the Kinesia 360 study.

- **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

- Select **Continuous** for the Motor Assessment Mode. The specifications for Side, Start Time, and Duration can be left as the default.

Figure 8. Select Motor Assessments

Note: If both Kinesia 360 and Kinesia One will be used, select **Specific Tasks** and configure the study according to the Kinesia One User's Guide.

3. Set Dates and Times

- Select the 'I do not want to specify dates and times' option in the upper right hand corner then click 'Next'.

Figure 9

4. Set Med Diary.

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

Figure 10

5. Summary

- 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.

Figure 11

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.

Note: Once a study template has been created, the study configuration will automatically proceed to the summary tab for new studies. To customize one or more elements (e.g., the dates and times of assessments), click the tab to move back to that section and make the desired changes. You must proceed to the summary and click finish for the changes to take effect.

Chapter 4: Preparing for Patient Use

Replace the Sensor Bands

The sensor bands are designed to be used multiple times, but should be replaced between patients. To place the motion sensor into a new strap, complete the following steps (Figure 12):

1. Remove the Kinesia Motion Sensors from the previous bands. We suggest discarding the old straps as the Velcro can wear over time.
2. Select one wrist band (labeled with a hand) and one ankle band (labeled with a foot). Lay each strap flat on the table with the buckle closest to you.
3. Take the Kinesia Motion Sensor for the upper extremity (identifiable by the 'U' character beneath the Sensor ID) and place it into the pocket on the wrist band. The Kinesia label should be facing down and the LED indicator should be towards you.
4. Repeat the process above, placing the Kinesia Motion Sensor for the lower extremity (identifiable by the 'L' character beneath the Sensor ID) into the ankle band.
5. Confirm that the Sensor ID of each sensor is visible.
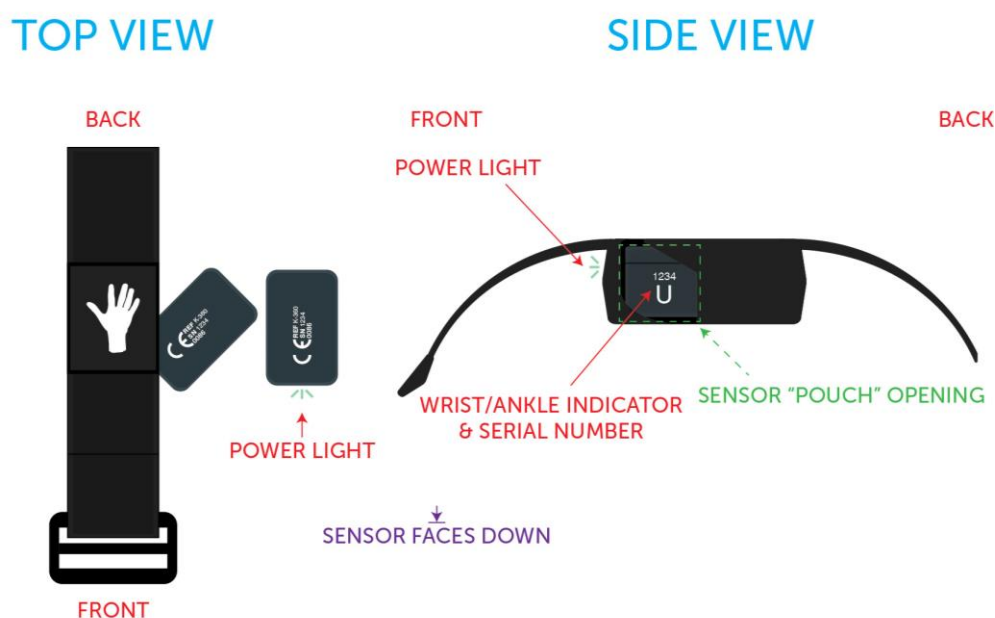

Figure 12

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. The sensor bands, however, are single patient use only and should be discarded.

Configure the Tablet Application

The following functions are accessible from the Kinesia 360 Application Settings menu (Figure 8) by pressing the ☰ symbol in the top left corner of the application window:

Load Access Code

Once a patient study is created on the Kinesia Web Application, it must be loaded on to the tablet prior to collecting any data. This is done by entering the patient-specific access code into the Tablet Application as follows:

1. Turn on the tablet and open the Kinesia 360 Application
2. Locate the Access Code for the patient (see Chapter 4. Creating a Patient Profile)
3. If you are not taken directly to the Load Access Code screen, select the ☰ symbol in the top left corner of the Kinesia 360 App and choose 'Load Access Code'
4. At the Load Access Code screen, enter the Access Code and tap 'Load Access Code'. Study information is displayed at the bottom of the screen (Figure 13).
5. To verify that the correct study has been loaded, confirm the Patient ID at the bottom center of the screen.
6. Select the symbol in the top left and choose Home to return to the display of the Home screen and prepare for patient use.
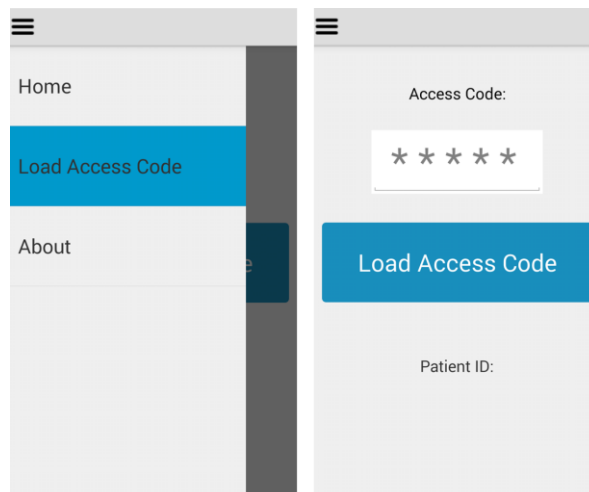

Figure 13

Note: An internet connection is required to load a Study Definition onto the tablet. The tablet supports both WiFi connections and/or mobile broadband connections. Once the study definition is downloaded, data can be collected using the 'Start Test' and 'My Diary' buttons on the Home Screen.

Admin

The Admin function allows you to turn certain features of the Kinesia 360 application off and on.

If you will not be using My Diary, which provides access to the Symptom and Medication diaries, toggle the switch into the Off position and the My Diary button will be removed from the application home screen. To enable My Diary, toggle the switch into the On position.

My Reports can also be turned off and on via the toggle switch. To remove the My Reports button from the application home screen, toggle the switch into the Off position. To enable My Reports, enter the passcode '5410' into the field and toggle the switch into the On position.

Pair Sensors

The Patient Kit includes Kinesia Sensors that are 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, complete the following steps:

1. Press the menu button ⠿ in the upper right of the screen and select 'Settings'
2. Select 'Bluetooth' from the menu
3. Place the Kinesia Sensors on the Charging Pad to turn them on
4. Pair each sensor by tapping it when it appears in the list and selecting 'Pair' when prompted. Note that a pairing code is not needed if the prompt will display one.
5. Press the Home button at the bottom of the tablet to return to the main screen.

If you are replacing a sensor, you will need to unpair the previous device, since only one can be paired. To unpair a sensor, navigate to the Bluetooth menu as described above, then click the gear symbol to the right of the sensor you would like to unpair and select 'Unpair' on the following screen.

Note: The Kinesia 360 Application requires that one upper extremity sensor and one lower extremity sensor is paired. You will not be able to start data collection without first having sensors paired.

Set Language

The Kinesia 360 Application includes translation support for the following languages: English, German, French, and Swedish. In order to change the language, follow these steps:

1. Navigate to the tablet home screen. If the Kinesia 360 Application is open, you can access the tablet home screen by pressing the house shaped icon on the front of the tablet.
2. Press the menu button ⠿ in the upper right of the screen and select Options
3. Select Settings and then select Language
4. Select one of the supported languages and press the home icon on the front of the tablet
5. After the language selection is made, restart the tablet using the power button for the regional date and time formatting to take effect
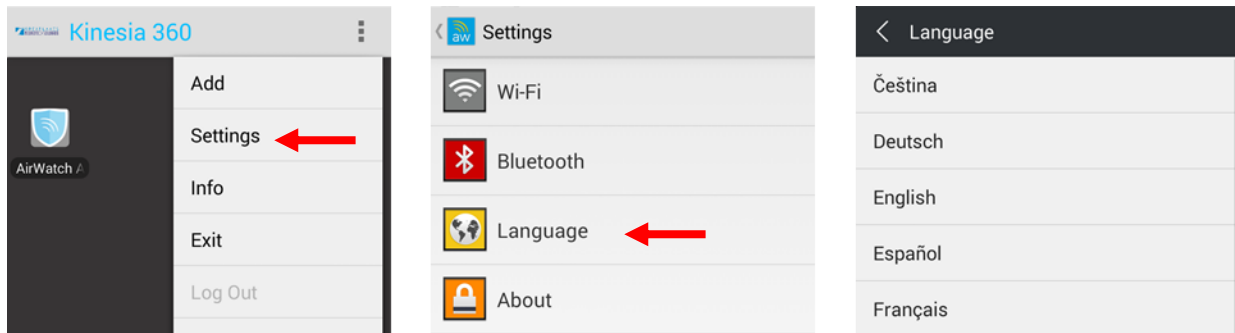
Figure 14

Note: The Kinesia 360 Application will default to English if a non-supported language is selected

Set up WiFi on the Tablet

If WiFi is being used for connectivity, follow these steps from the tablet home screen.

1. Navigate to the tablet home screen. If the Kinesia 360 Application is open, you can access the tablet home screen by pressing the home button on the front of the phone.
2. Press the menu button ⋮ in the upper right of the screen and select Options
3. Select Settings and then select Wifi
4. Ensure that the box in the upper right hand corner is checked to turn on Wifi
5. Press the Scan button
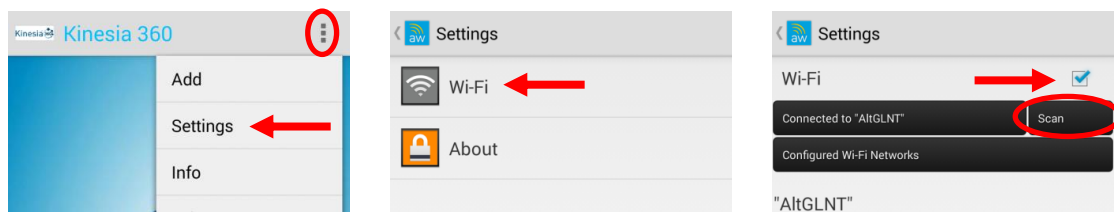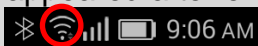6. Select the network from the list and enter the password

Figure 15

Note: Once successfully connected, a WiFi symbol should appear in the status bar at the top of the tablet. Check to ensure that this icon has appeared after entering the password for a WiFi network to confirm that you are properly connected.

Chapter 5: Patient Use

Overview

We recommend that patients set up the system the night before use so that all system components are fully charged. After waking up in the morning, patients should use the Kinesia 360 Application to start data collection and put the sensor bands on. Patients should keep the tablet with them throughout the day so that they can use diaries in the Kinesia 360 Application to rate their symptoms and log when they took their medication. The Kinesia 360 Application also includes a Pause/Resume feature in the event that the sensor bands need to be removed temporarily during the day (e.g., during exercise, bathing, etc.). At the end of the day, patients should use the Kinesia 360 Application to end data collection and return the sensor bands to the charging pad.

System Setup

The procedure for setting the system up is provided earlier in this document (see Chapter 2. Patient Kit – Setup Instructions).

Note: The Kinesia 360 system includes a Quick Start Guide that is packaged as a reference for patients to use at home. This guide contains illustrations for setting the system up, donning and doffing the sensors, and interacting with the tablet application.

⚠️ *To avoid tripping over the power cord, patients should place the Kinesia 360 system somewhere that the electrical cord for the charging pad is out of the way of walking paths.*

Collecting Symptom Data with the Motion Sensors

Starting Data Collection

When the patient is ready to begin a motor assessment, the following steps should be followed.

1. From the Kinesia 360 Application Main Screen, select 'Start Test'.
2. Ensure that the Kinesia Sensor Bands are on the Charging Pad in the proper orientation.
3. Press 'Next' once the confirmation dialogue appears.
4. Take each sensor off of the charging pad and place it on the correct body location. Adjust the tightness of the strap to ensure a secure and comfortable fit.
5. Once both sensors have been securely positioned, press the 'Start' button.

Note: There is a 10 second timeout period after the sensors are taken off of the charging pad. If the patient takes the sensors off of the charging pad but does not initiate data collection (by pressing the 'Start' button) within 10 seconds, he will need to return the sensors to the charging pad again to power them on before proceeding. We therefore advise that the patient leave the sensors on the charging pad until the Kinesia 360 Application prompts him to don the sensor bands.
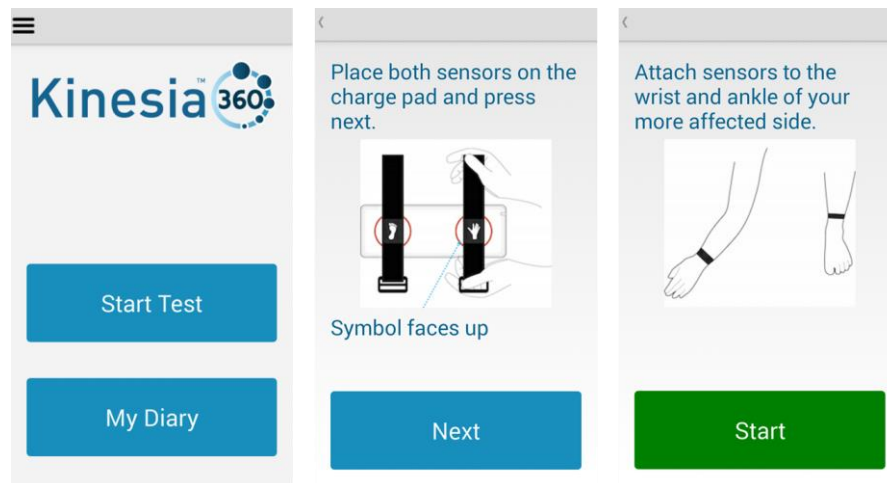
Figure 16

Pausing and Resuming Data Collection

If the patient needs to remove the sensors during the day (e.g., to bathe) but plans to continue wearing them, the pause/resume feature should be used as follows:

1. Prior to removing the Kinesia Motion Sensors, press the 'Pause' button on the Kinesia 360 Application Main Screen.
2. Remove the Kinesia Motion Sensors and place them in a secure location.
3. When ready, don the Kinesia Motion Sensors, paying careful attention to ensure that each sensor is placed on the correct limb. The sensor labeled with the hand symbol should be placed on the wrist and the sensor labeled with the foot symbol should be placed on the ankle.
4. Once the Kinesia Motion Sensors are on, press the 'Resume' button on the Kinesia 360 Application Main Screen.

Note: The times when the Pause/Resume is pressed are used to exclude certain periods of data from the analysis. If a patient puts the sensors back on but forgets to press the Resume button, this data will not be included in the report. It is, therefore, very important that patients are well instructed on the proper utilization of this feature.
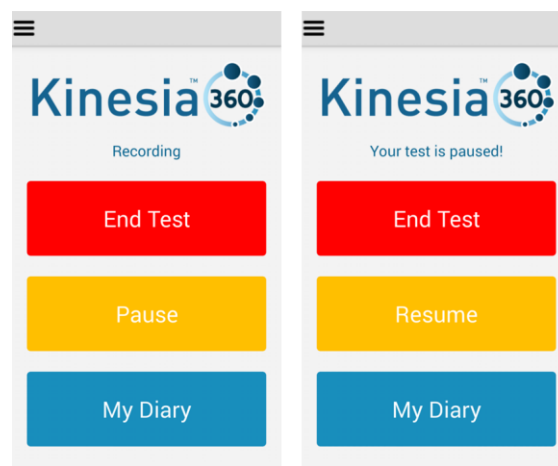

Figure 17

Ending Data Collection

Once the patient has completed the required assessment period, he or she can end data collection as follows:

1. From the Kinesia 360 Application Main Screen, select 'End Test.
2. Remove the Kinesia Sensor Bands and place them on the Charging Pad.
3. Press 'End'.

The tablet will then download the data and reset the sensor memory. Once these processes are complete, the 'Start Test' button is re-enabled for the next study.
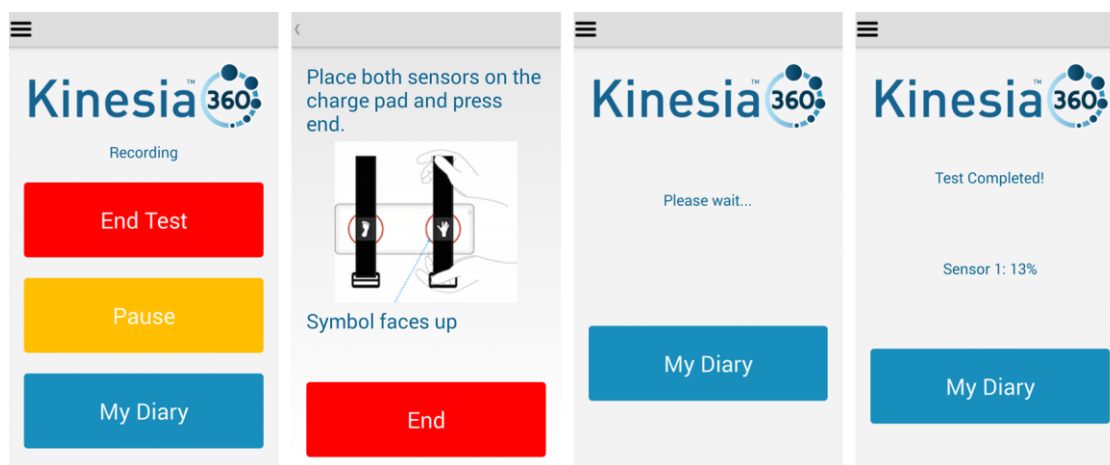

Figure 18

Note: To ensure prompt upload and processing of data, it is important that the tablet and motion sensors be left powered on and plugged in after ending data collection. We recommend that the system remain connected overnight.

Using the Dyskinesia Diary

If the Dyskinesia Diary is a part of the study protocol, the patient can complete these entries as follows:

1. From the Kinesia 360 Application Home Screen, select 'My Diary'.
2. Press the 'Symptoms' button to enter the Dyskinesia Diary
3. Select the option that describes the patient for the displayed time interval. For the Standard Dyskinesia Diary the options are Sleeping, OFF, ON without dyskinesia, ON with non-troublesome dyskinesia, and ON with troublesome dyskinesia. For the Modified Dyskinesia Diary, the options are Sleeping, OFF, and ON.
4. Press 'Next' to confirm selection.
    a. For the Modified Dyskinesia diary, if 'ON' is selected, the patient is prompted rate dyskinesia ('None', 'Slight', 'Mild', 'Moderate', 'Severe').
    b. Press 'Next' to confirm selection.
5. Continue entering diary information until it is up to date and press 'Home".

Note: The first time the diary is accessed, the patient begins rating from 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 19

Using the Medication Diary

If the Medication Diary has been enabled in the study protocol, the patient can note when medications were taken using the Medication Diary as follows:

1. From the Kinesia 360 Application Home Screen, select 'My Diary'.
2. Press the 'Medication' button to enter the Medication Log
3. Select which medication was taken from the list
4. Enter the time of the dose. This defaults to the current time but can be changed if the patient is retrospectively or prospectively entering information. Press 'Set' to confirm time.
5. Repeat as needed to record other doses.
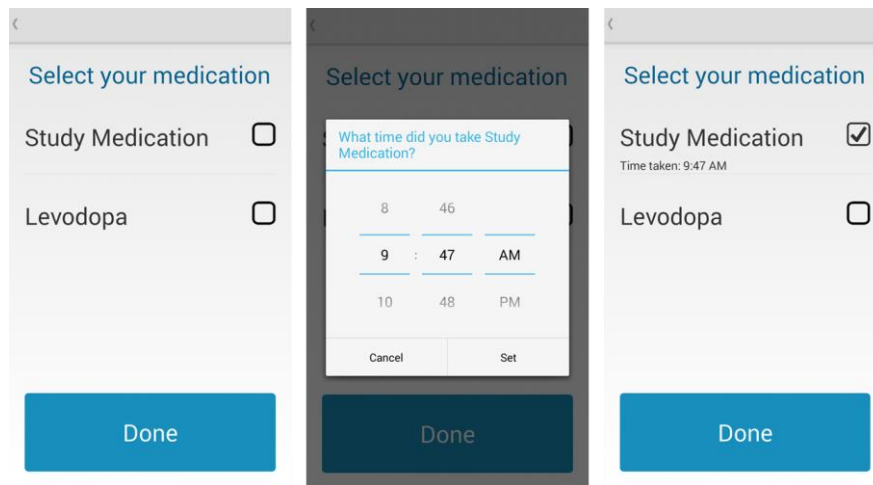6. Press 'Done' to finish.

Figure 20

Accessing My Reports

My Reports is an optional feature available in the Kinesia 360 application that allows the patient to view how their symptoms change in response to time or medication doses. To turn on the My Reports feature:

1. From the Kinesia 360 application home screen select the ☰ symbol at the top left of the screen and select 'Admin'.
2. A passcode is required to turn on the reports. Enter '5410' into the passcode field and tap the toggle bar to turn on the reports.
3. Press the ☰ symbol at the top left of the screen and select 'Home'.
4. The home screen will now display a button option labeled 'My Reports'.

Viewing My Reports

Two report options are available when accessing My Reports. The Symptom Report displays how a patient's symptoms change over time, by date. The Dose Report displays how a patient's symptoms change in response to different treatment dosages.

Symptom Report

The Symptom Report graphically displays the severity and occurrence of tremor, slowness, dyskinesia, and walking over time. The first date a patient uses the Kinesia 360 sensors will automatically display as the baseline measurement. If needed, the baseline date can be changed through the Kinesia Visualization Report Web Application.
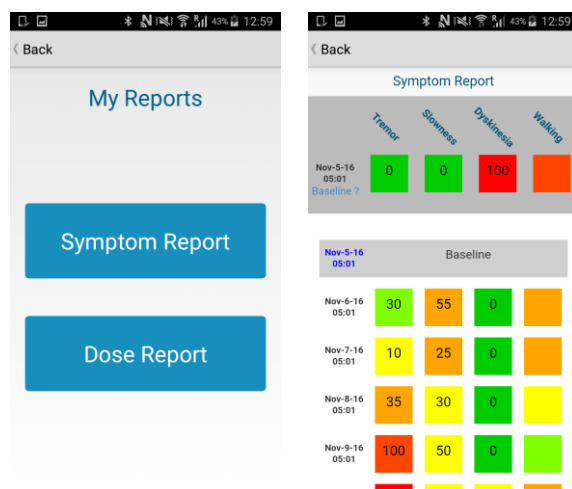

Figure 21

Each symptom and data collection date has a corresponding colored box which represents the occurrence and severity of that particular symptom. The color of the box indicates the symptom severity, with green being the least severe and red being the most severe. The number within the box represents the percent of the day that symptom was detected. Note that Walking does not include a number, as this is only an indication of a patient's mobility over the course of the day, with green being the most mobile and red being the least.

Dose Report

The Dose Report graphically displays a patient's response of tremor, slowness, dyskinesia, and walking to a particular medication dosage. If the Dose Report feature is enabled within your account, the patient will be prompted during the End Test process to select the appropriate medication dosage for that day. The text that displays on this screen and available dose options can be customized at your request.

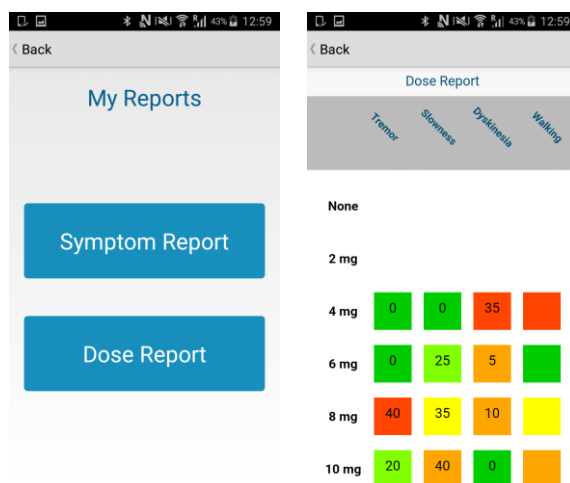Figure 22. Medication dose selection screen

Figure 23

Each symptom and dose has a corresponding colored box which represents the occurrence and severity of that particular symptom. The color of the box indicates the symptom severity, with green being the least severe and red being the most severe. The number within the box represents the percent of the day that symptom was detected. Note that Walking does not include a number, as this is only an indication of a patient's mobility over the course of the day, with green being the most mobile and red being the least.

Chapter 6: Data Upload from Tablet to Web Application

Once the patient returns the Kinesia Sensor Bands to the Charging Pad at the end of the day, the application will automatically download the data from the motion sensors and 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. Patient should not turn off tablet for at least 3 hours to allow for the upload to complete.

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

Chapter 7: View Study Reports in Web Application

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'. Select a date from the list and press 'Export' to download a XLSX spreadsheet containing the study data. This spreadsheet will contain four main sections (i.e., sheets):

Note: If you are using Kinesia One and Kinesia 360 simultaneously (i.e., the same access code is being used on both devices), the reporting page accessed by selecting 'Archived Report' or 'New Report Ready' will take you to the Kinesia One reporting page. From there, select the "Continuous Report" link on the left side of the page. This will take you to the Kinesia 360 reporting page, which will contain a table of links to download the individual XLSX spreadsheets.
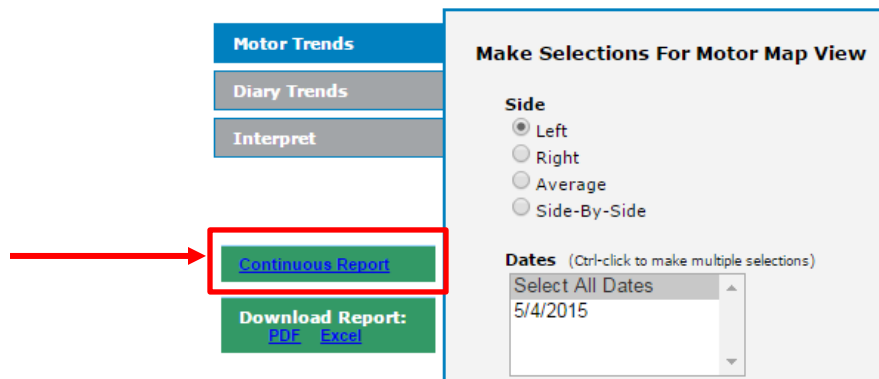

Figure 24

1. **Raw Data** contains the objective Kinesia 360 measurements on a 2-minute time resolution. It will contain 10 columns of information.

   The first column ('Subject ID') is populated by the Patient ID created in the Web Application. These values will be the same for a single spreadsheet but will facilitate import into various analytical packages. The second ('Date') and third ('Time') columns contain the date and time, respectively, for each symptom measurement.

   The fourth column ('Paused') contains a binary flag that is 1 when the subject paused data collection in the tablet application, and 0 when it was not paused.

   The fifth column ('Tremor Detect') contains a binary flag that is 0 when tremor was not detected and 1 when tremor was detected (i.e., Tremor Score > 0). The sixth column ('Tremor Score') contains the tremor severity score on a 0-4 scale.

   The seventh column ('Dyskinesia Detect') contains a binary flag that is 0 when dyskinesia was detected and 1 when dyskinesia was not detected. The eighth column ('Dyskinesia Prob') contains a likelihood index that is either 0 (no dyskinesia), 0.5 (possible dyskinesia), or 1 (likely dyskinesia). The ninth column ('Dyskinesia Score') contains the dyskinesia severity score on a 0-4 scale.

The tenth ('Medication Flag') and eleventh ('Medication Name') columns contain information logged by the user in the medication diary. Whenever a dose is entered, the flag is set to 1 and a comma-separated list of the name(s) of the medication(s) is displayed. Otherwise the flag is zero and the medication is shown as 'None'.

Note: Periods during which the Pause feature was enabled are excluded from the analysis. These rows of the Raw Data sheet are populated by null characters. If the Tablet Application was paused for any portion of a 2 minute interval, that entire interval is labeled as paused.

2. **Symptom Diary** contains the patient-reported symptom diary information on a 30-minute time resolution. It will contain five columns of information.

   The first column ('Subject ID') is populated by the Patient ID. The second ('Date') and third ('Time') columns contain the date and time, respectively, for each diary entry.

   The fourth column ('State') contains an integer on either a 0-4 scale for the Standard Dyskinesia Diary or a 0-6 scale for the Modified Dyskinesia Diary, where the numerical value indicates the diary state (Standard Diary: 0 – sleeping, 1 – OFF, 2 – ON without dyskinesia, 3 – ON with non-troublesome dyskinesia, 4 – ON with troublesome dyskinesia; Modified Diary: 0 – sleeping, 1 – OFF, 2 – ON None, 3 – ON Slight, 4 – ON Mild, 5 – ON Moderate, 6 – ON Severe). The fifth column contains the text label of the selected state.

3. **Med Diary** contains the user-reported medication diary information. It will contain four columns.

   The first column ('Subject ID') is populated by the Patient ID. The second ('Date') and third ('Time') columns contain the date and time, respectively, for each diary entry.

   The fourth column ('Med') contains the name of the medication that was logged.

4. **Summary Data** contains compiled information regarding tremor, dyskinesia, and mobility measured by Kinesia 360 and user reported diary information.

   For the Tremor Data Summary, the total time when tremor was or was not detected is calculated. The total times in the different categorical levels of tremor (0, 1, 2, 3, and 4) are calculated. These values are also calculated as a percentage of wear time in addition to being calculated in hours.

   For the Dyskinesia Data Summary, the total time when dyskinesia was or was not detected is calculated. The total times in the different categorical levels of dyskinesia (0, 0.5, and 1) are calculated. These values are also calculated as a percentage of wear time in addition to being calculated in hours.

   For the Mobility Data Summary, the total time at rest, total time active but not walking, and total time during gait are calculate. The total active time, or sum of the active (non-gait) and gait times is calculated. These values are also calculated as a percentage of wear time in addition to being calculated in hours. Additionally, the number of steps detected and the percentage of gait episodes during which arm swinging was detected are calculated.

For the Symptom Summary, the amount of time in the various categories (according to the patient-reported diary) is calculated. These values are also calculated as a percentage of a 24 hour period. Sleeping is excluded to calculate values as a percentage of the waking day.

Note: Periods during which the Pause feature was enabled are excluded from calculations of wear time, as well as tremor, dyskinesia, and mobility analyses.

Chapter 8: View Visualization Reports in the Web Application

If the feature has been enabled within your account, you will be able to view the same Symptom and Dose reports both on the Kinesia 360 application and on the Kinesia Visualization Report Web Application.

Accessing the Visualization Report Web Application

You will use the same username and password to access the Visualization Report Web Application.

1. Log in to the Visualization Report Web Application (https://kinesiav2.glneurotech.com) using your username and password.

Upon logging in, you will see a list of all available patients within your institution account.

Figure 25. Kinesia Visualization Report Web Application: Patient List

Locate the patient for whom you would like to view a report and click the symbol below Symptom Report or Dose Report.

Symptom Report

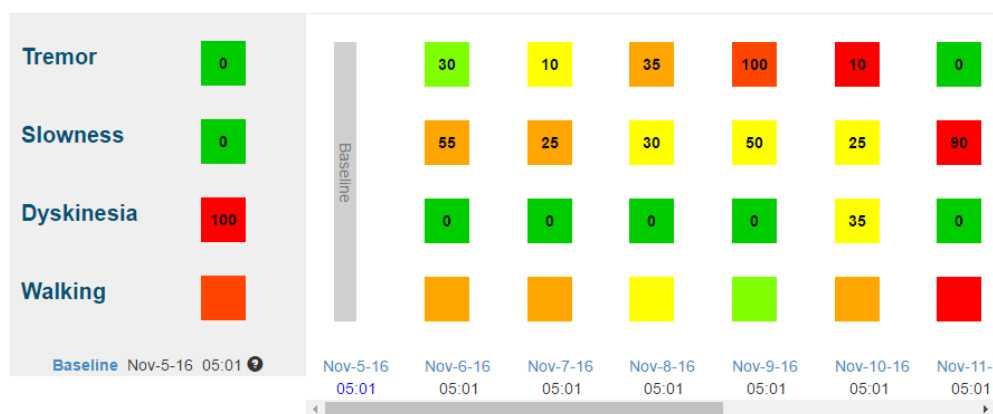The Symptom Report displays how tremor, slowness, dyskinesia, and walking change over time.

Figure 26. Kinesia Visualization Report Web Application: Symptom Report

The first date a patient wears the Kinesia 360 sensors will automatically default to the baseline measurement against which subsequent days of data can be compared. To change the baseline date, click 'Baseline' and enter the new baseline date.

Each colored box represents the occurrence and severity of that particular symptom. The color of the box indicates the symptom severity, with green being the least severe and red being the most severe. The number within the box represents the percent of the day that symptom was detected. Note that Walking does not include a number, as this is only an indication of a patient's mobility over the course of the day, with green being the most mobile and red being the least.

To view a more detailed report of a patient's symptoms for a particular day, click the date to download the Excel spreadsheet detailed in Chapter 7 of this guide.

Dose Report

The Dose Report displays how tremor, slowness, dyskinesia, and walking change as a function of different medication or therapy doses.

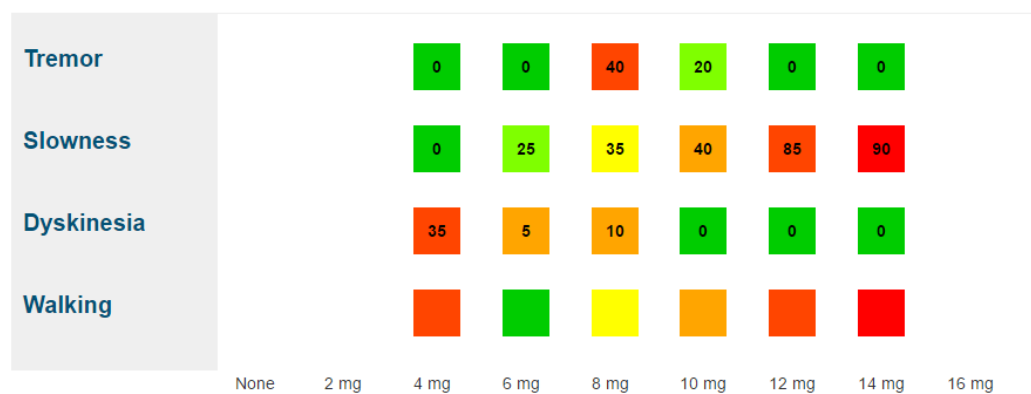Figure 27. Kinesia Visualization Report Web Application: Dose Report

The Dose Report displays data via colored boxes that represent the occurrence and severity of that particular symptom. The color of the box indicates the symptom severity, with green being the least severe and red being the most severe. The number within the box represents the percent of the day that symptom was detected. Note that Walking does not include a number, as this is only an indication of a patient's mobility over the course of the day, with green being the most mobile and red being the least.

Chapter 9: Frequently Asked Questions (FAQs)

Q. No buttons appear on the home screen of the app.

A. Enter a valid patient access code. Once an access code is entered, the Start Test and My Diary buttons will be enabled.
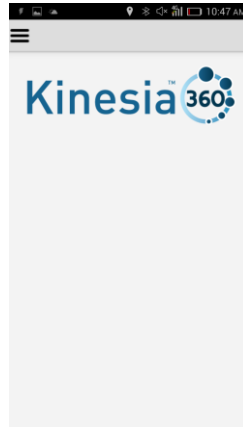

Figure 28. An access code has not been entered

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

A1. 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).

A2. Ensure that the patient access code is being properly entered.

A3. Ensure that you created a study for the patient on the web.

Q. The My Diary button is available on the home screen of the app, but the Start Test button is missing.

A. Follow the steps outlined in Chapter 4 for pairing the motion sensors. Once you have the upper and lower extremity sensors paired, the Start Test button will be enabled.
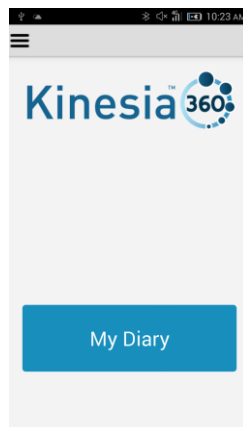

Figure 29. Motion sensors are not properly paired

Q. When I press 'Start Test' I am unable to initiate a motor assessment.

A1. Check that the motion sensors are on. To do this, place the sensor on the charge pad. Both the charging indicator on the charge pad and the LED on the sensor should be illuminated.

A2. If the sensor LED is not blinking, ensure that the sensor is placed into the wearable strap in the correct orientation. See Figure 12. With the sensor strap flat on the table (anatomical label facing downwards) and the buckle facing to the right, the motion sensor should be placed into the pocket with the white Kinesia label facing up and the LED facing to the right. The sensor ID on the side of the motion sensor should be visible after it is placed in the sensor strap. Once the sensor orientation is confirmed, ensure that the sensor strap is placed on the charging pad with the anatomical labels (hand or foot) facing up.

A3. Verify that the charge pad is receiving power. 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.

A4. If repeated attempts to start the test fail, take the sensors off of the charging pad and power the tablet off. Then power the tablet back on. Once the tablet returns to the lock screen, place the sensors back on the charging pad.

Note: The same steps should be followed to address issues with ending a motor assessment.
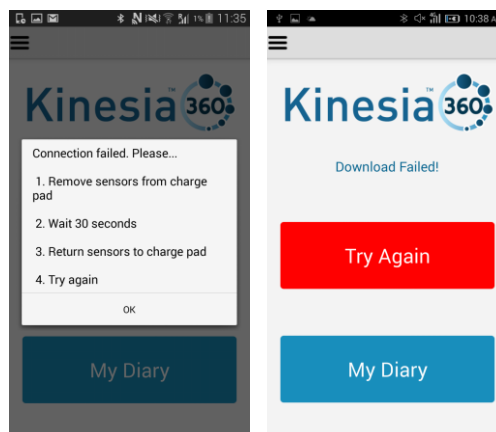

Figure 30. Connection failures when starting (left) and ending (right) a test.

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

A1. If the patient turns off the tablet after completing the motor assessment this may delay data upload to the 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.