



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

Sales: sales@GLNeuroTech.com

<http://www.GLNeuroTech.com>

Mailing Address: Great Lakes NeuroTechnologies Inc.

10055 Sweet Valley Drive

Cleveland, Ohio 44125



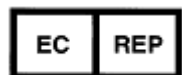
Great Lakes NeuroTechnologies Inc.

10055 Sweet Valley Drive

Cleveland, Ohio 44125

Phone: 216-361-5410

Fax: 216-361-5420



Emergo Europe

Molenstraat 15

2513 BH, The Hague

The Netherlands

Phone: + 31 (0) 70 345 8570

Fax: + 31 (0) 70 346 7229



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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 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:



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	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	
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):

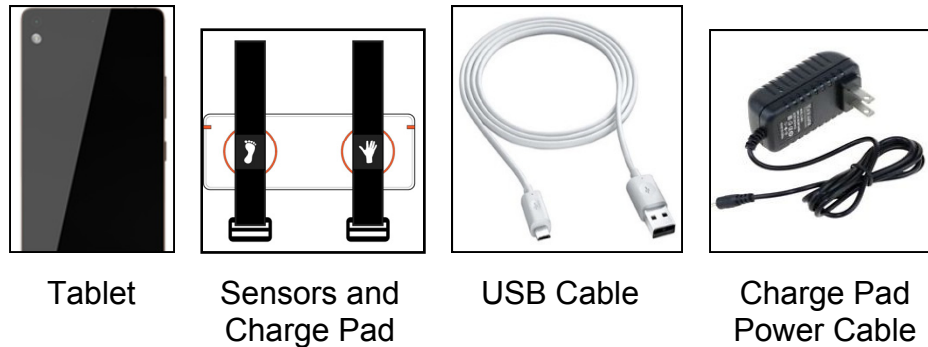


Figure 1

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.

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 2) and plug the other end into the power outlet.



Figure 2

3. Place the Kinesia Sensors Bands on the Charging Pad, centered on the orange circles as shown below (Figure 3). 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.

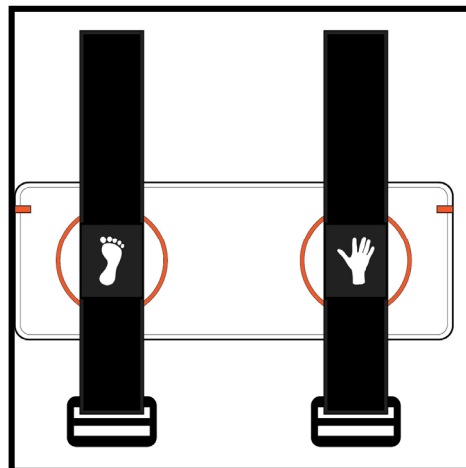
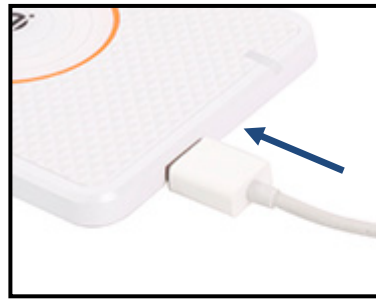


Figure 3. Sensors Correctly Placed on the Charge Pad

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 4).



Charge Pad and Large
USB Connector



Tablet and Small
USB Connector

Figure 4

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 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 profile onto a Tablet using the Kinesia 360 app.

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

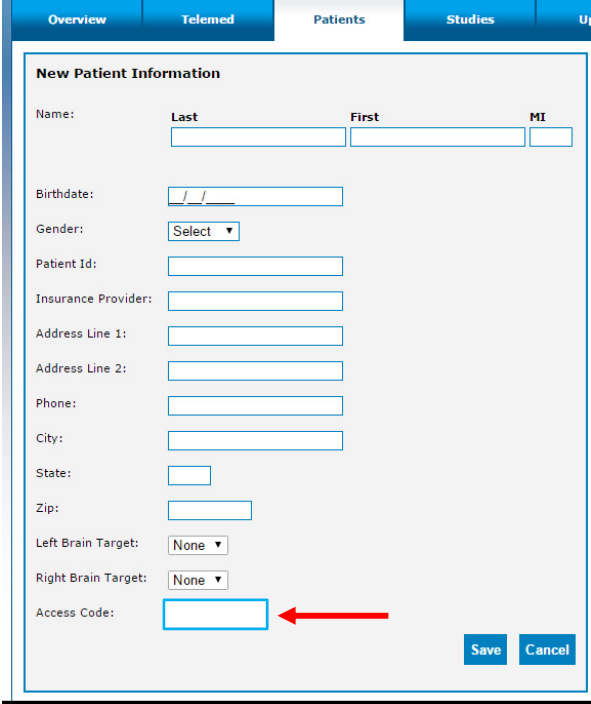
The image shows a screenshot of the 'New Patient Information' form in the Kinesia Web Application. The form is titled 'New Patient Information' and is located under the 'Patients' tab. It contains several input fields for patient data: Name (Last, First, MI), Birthdate, Gender (a dropdown menu), Patient Id, Insurance Provider, Address Line 1, Address Line 2, Phone, City, State, Zip, Left Brain Target (a dropdown menu), Right Brain Target (a dropdown menu), and Access Code. A red arrow points to the Access Code field, indicating its importance. At the bottom right of the form are 'Save' and 'Cancel' buttons.

Figure 5: Add New Patient Data

4. Press 'Save' to add a new patient to the database, or 'Cancel' to return to the main screen.

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).

Find existing patient

Add New Patient

Patient ID	Last Name ▲	First Name	DOB	Create Study	View Studies
001	Doe	John	10/09/1972	+ ←	📁

Figure 6: Create 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.
- **Dyskinesia Diary** mimics a paper diary sometimes used by patients. 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

- The option selected here does not impact the Kinesia 360 study. To simplify setup, you may select **Continuous**. The specifications for Side, Start Time, and Duration can be left as the default.

Set Motor Assessment Mode
Set Dates and Times
Set Motor Tasks
Set Med Diary
Set Symptom Diary
Set Activity Diary
Summary

Diary Mode

☐ Custom Diary
☒ Dyskinesia Diary

Motor Assessment Mode *

☐ Specific Tasks
☒ Continuous
☐ None

Side

☐ Left
☒ Right

Start Time

08 : 00 AM PM

Duration

5

* Continuous monitoring only supported for tablet software versions 4.0.227.17937 or newer.

NEXT →

Figure 7. 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 8

4. Set Med Diary.

- The customizable Medication Diary is not supported with Kinesia 360. The medications in the Kinesia 360 Tablet Application will automatically default to “Study Medication” and “Levodopa” without regard to what is configured here in the Web Application.

Figure 9

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.

Set Motor Assessment Mode

Set Dates and Times

Set Motor Tasks

Set Med Diary

Set Symptom Diary

Set Activity Diary

Summary

Tasks

Motor Assessment Mode: Continuous

Dates: N/A

Start Time: 8:00 AM

Duration: 5 hrs

Side: R

Diary

Diary Mode: Dyskinesia Diary

Med Diary: Levodopa
Rasagiline

Notes:

[Save](#)

Finish ➔

Figure 10

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: 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 11):

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.

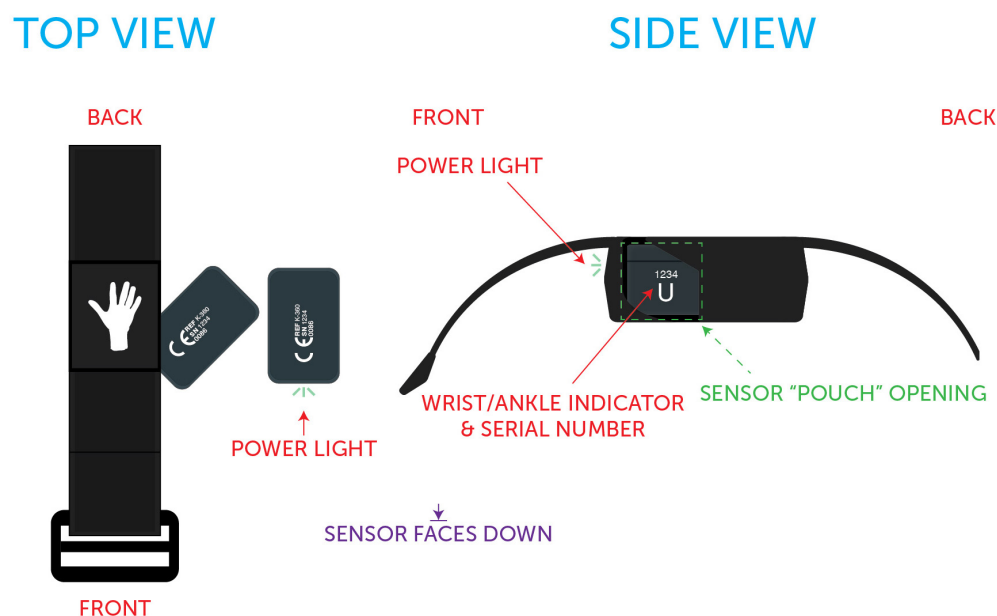



Figure 11

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:

Pair Sensor

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. Turn on the tablet by pressing the power button on the left side of the tablet.
2. Swipe up on the lock screen to unlock the tablet and press the Kinesia 360 icon to open the application
3. Place the motion sensors on the Charging Pad to turn them on. The LED on the sensors should be illuminated.
4. Select the ≡ symbol in the top left corner of the Kinesia 360 App and choose 'Pair Sensor'
5. Identify the Sensor IDs of the wrist and ankle sensors and tap your selection from the list. Once selected, the name of the sensor should be displayed in blue text as shown below.

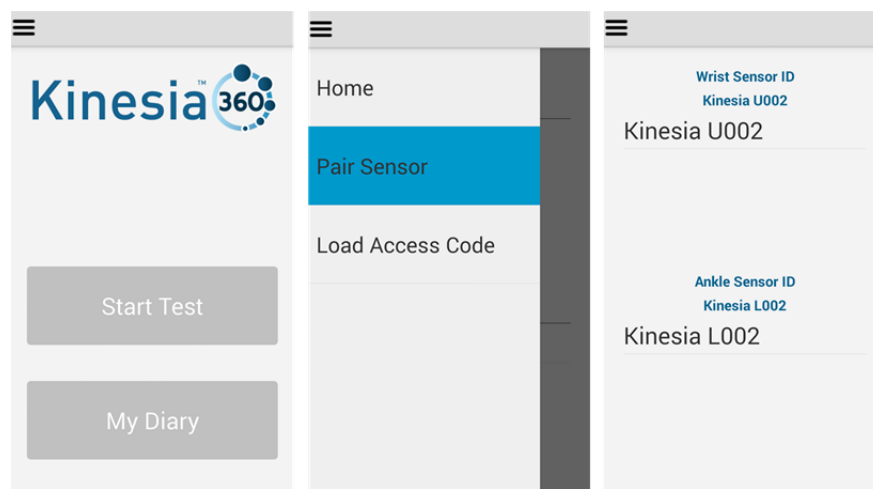


Figure 12

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. Select the ≡ symbol in the top left corner of the Kinesia 360 App and choose 'Load Study'
4. 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).
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.

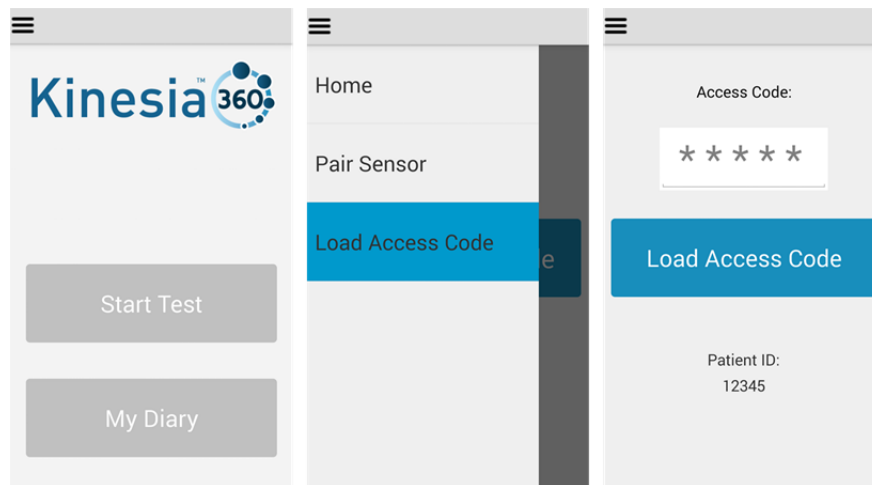



Figure 13

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.

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 house shaped icon 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

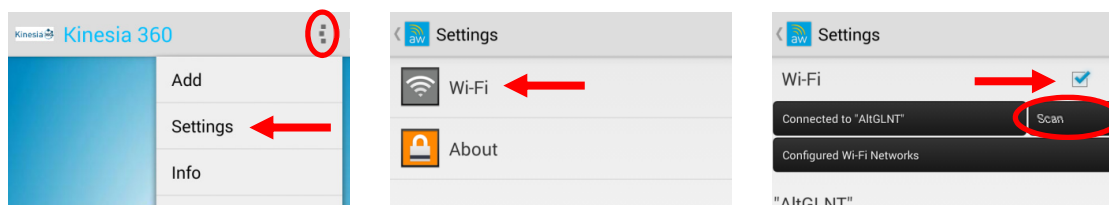



Figure 14

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.

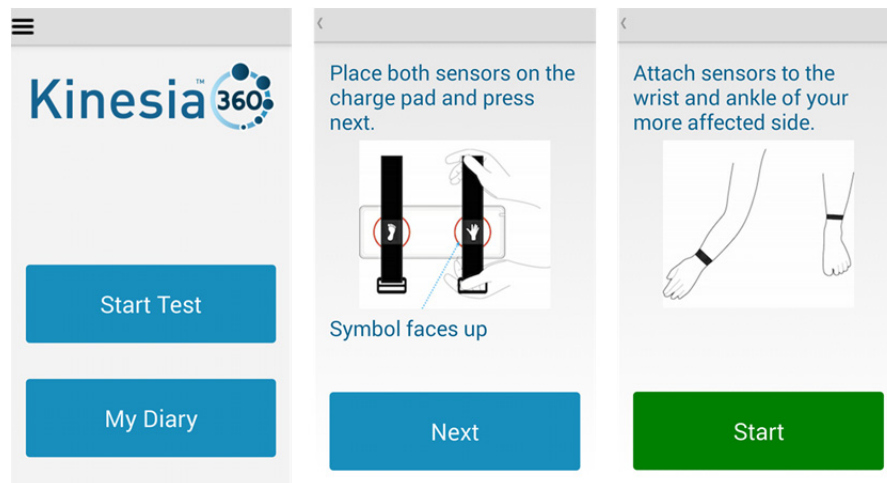


Figure 15

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.

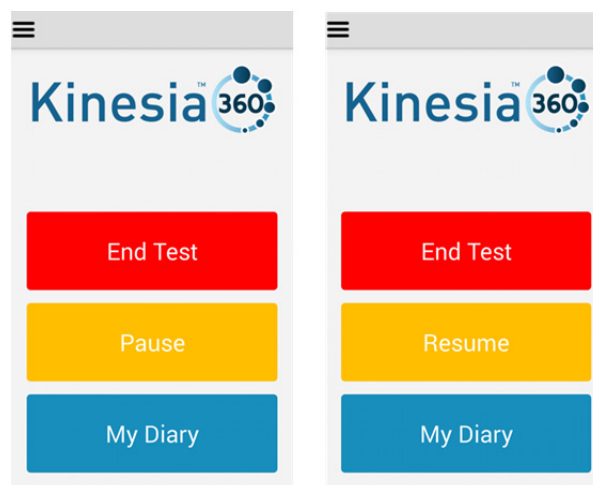


Figure 16

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.

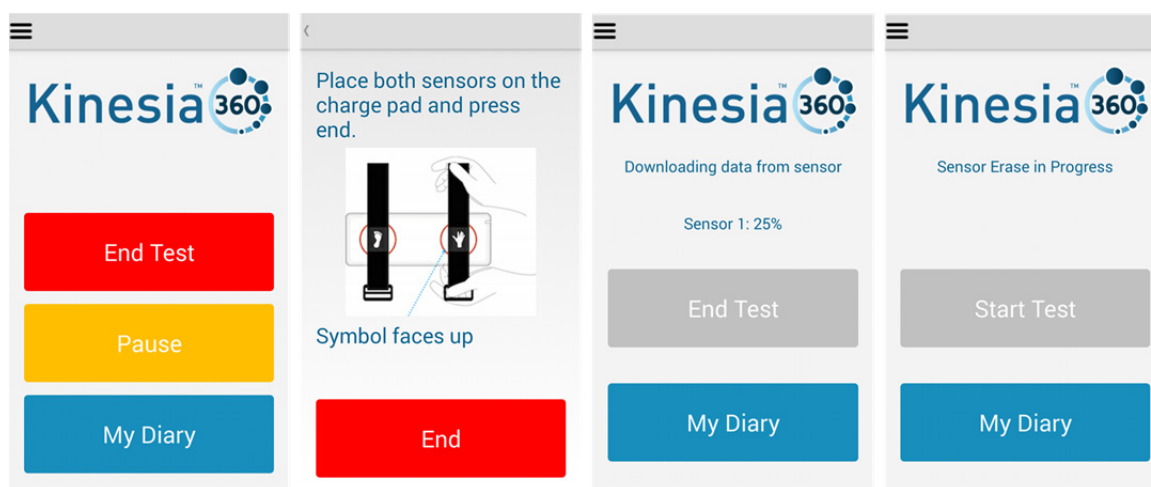


Figure 17

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 ('Sleeping', 'Off', or 'ON') that describes the patient for the displayed time interval.
4. Press 'Next' to confirm selection.
 - a. 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.

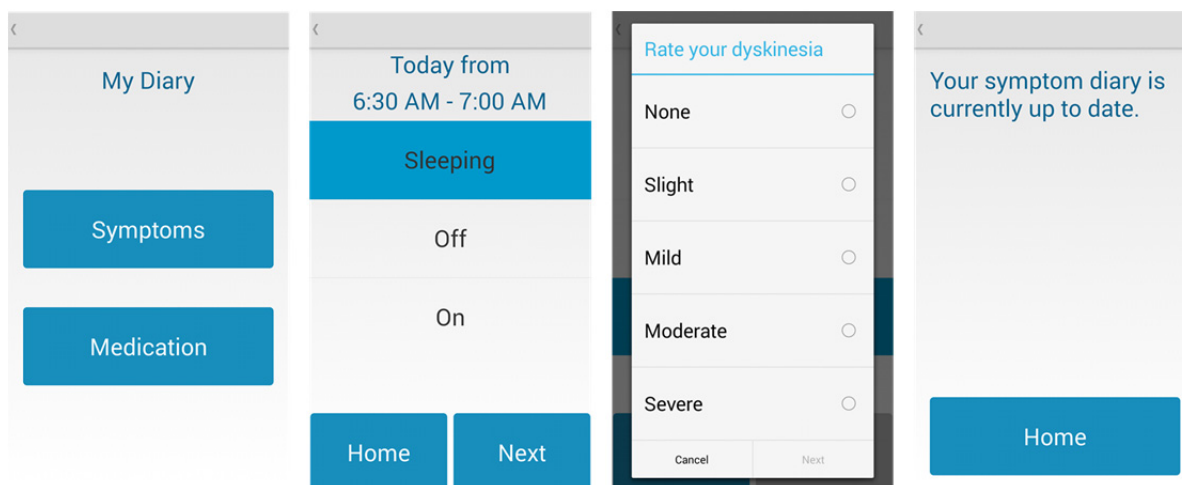


Figure 18

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.

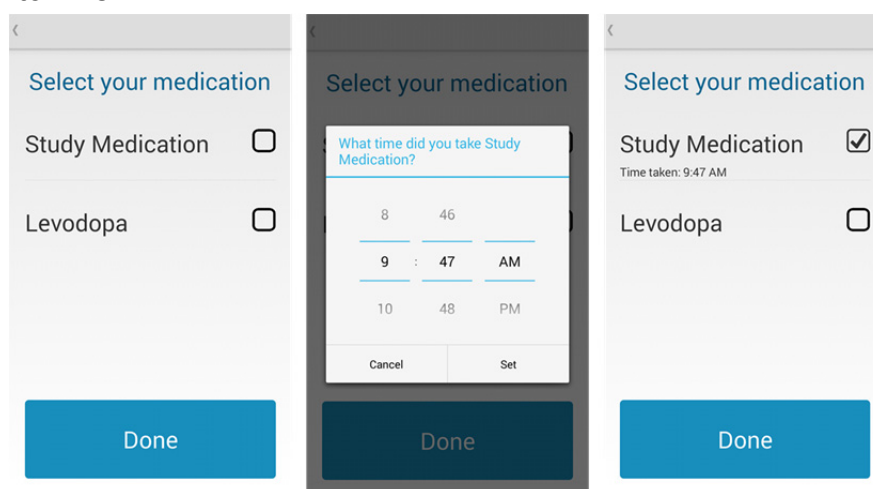


Figure 19

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 8: Frequently Asked Questions (FAQs)

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.

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 11. 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.

Q. The buttons on the tablet application home screen are inactive, how do I start data collection.

A. A study definition must be downloaded to the tablet before collecting data. Enter a patient access code through the load study menu before proceeding.

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.

Q1. 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.