



USER GUIDE

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Intended Use

Kinesia motor assessment systems are intended to monitor physical motion and muscle activity to quantify kinematics of movement disorder symptoms such as tremor and assess activity in any instance where quantifiable analysis of motion and muscle activity is desired.

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

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

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

Warnings

- Tripping Hazard – keep the electrical cord away from walking paths
- 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.

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

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

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

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

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

Note: Screenshots in this manual may vary based on phone model, Kinesia 360 app version, and desktop settings.

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 Portal System Recommendations

Microsoft Edge or Chrome browser

1024 X 768 or greater display resolution

Adobe Reader

Highspeed Internet access

Note: Macintosh® and Linux® operating systems are not supported.

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

Technical Specifications:

The Kinesia 360 sensors record 3 axes of acceleration and 3 axes of rotational velocity at 32 samples / second with a 50% duty cycle for up to 16 hours per charge. The reported data will be dependent on the data algorithms being applied for the given application. For further details for a given study, contact customer support.

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 attach a copy of the sales receipt to the back of this manual. Please check that your kit has the required components and record the requested data below:

Android Tablet or Smartphone; 502-0271

Tablet or Phone SN: _____

Kinesia Sensor (Wrist); 502-0264

Sensor SN: _____

Kinesia Sensor (Ankle); 502-0265

Sensor SN: _____

Dual Charge Pad; 059-0015

USB Cable; 116-0151

User Guide (this document); 392-0057

Quick Start and/or Site specific Guide(s);

Attachment Accessories

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:

- Germicidal disposable wipes (alcohol and bleach free)
- Alcohol-free glass cleaning fluids
- Water with mild (neutral pH) soap solutions (do not submerge any equipment, wipe 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.

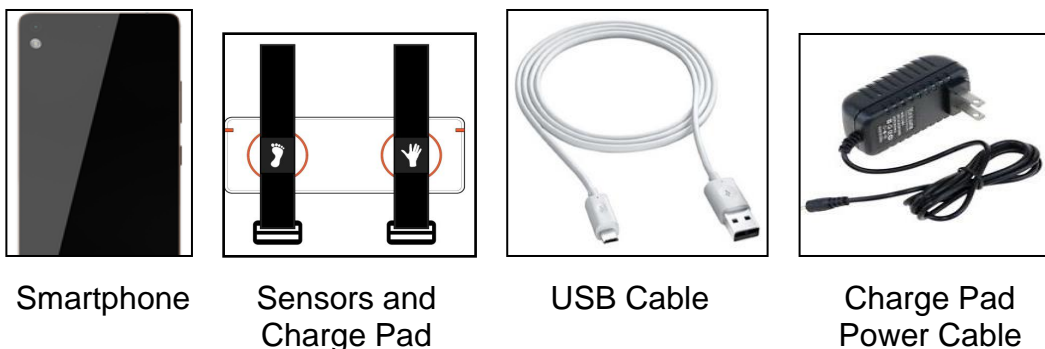
Chapter 1: About Kinesia 360

Kinesia 360™ is a medical system sent home with the patient to use throughout the day to capture and evaluate specific individual's symptoms and treatments. When enabled, the patient can also enter touch screen diary information about how they are feeling and when medications were taken. Web-based reports may be made available to clinicians, which include automated severity scoring that show symptom changes during the day in response to treatment.

Chapter 2: System Components

Components

The Kinesia 360 System consists of the following primary components:



A. Smartphone

The touch screen smartphone (Figure 1) is the central component of the Kinesia 360 System. The preinstalled application provides guided instructions for patients to collect their symptom data with the motion sensors and (if enabled) complete the medication and symptom diary logs. The smartphone uploads all information to the Kinesia Web Portal where summary reports may be accessed.

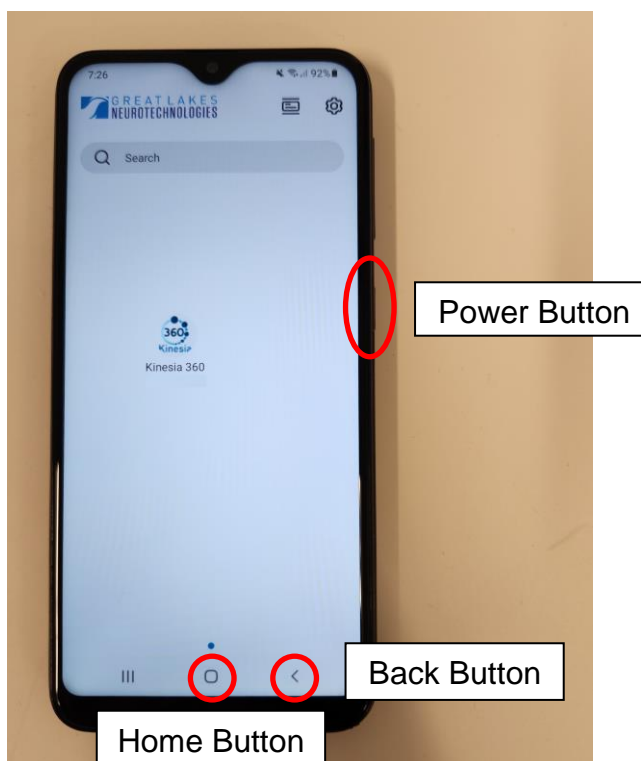


Figure 1

B. Kinesia Motion Sensors

The Kinesia Motion Sensors (Figure 2) 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 sensors are designed to be worn by the patients as they go about their normal routines. Various options including straps or clips are available depending on the specific application.



Figure 2

C. Charge pad

The Charge pad (Figure 3) charges the Kinesia Motion Sensors and has a powered USB port for charging the smartphone. The Charge pad has two LED lights to either side which indicate when the sensors are actively charging/are fully charged. These lights will help during set up and regular use to ensure the sensors have been placed in the correct location on the pad (within the orange circle.)



Figure 3

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:
 - Smartphone
 - Two Kinesia Motion Sensors

- Charge Pad
- Smartphone USB Charging cable
- Charge Pad Power Cable

2. Place the Charge pad on the table with the orange circles facing up. Plug the Charge pad Power cable into the Charge pad as shown below (Figure 4) and plug the other end into the power outlet.

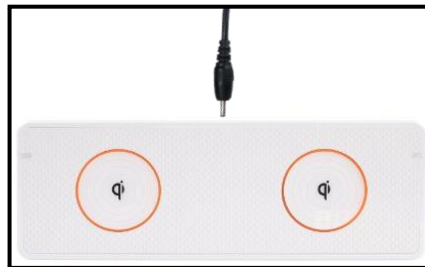


Figure 4

3. Place the Kinesia Sensors, centered on the orange circles (Figure 4). If the sensors were shipped inside of wrist/ankle straps (Figure 5), they 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 as shown below. If the sensors are not inside wrist/ankle straps, the sensors should be placed on the Charge pad with the Kinesia logo facing down to charge.

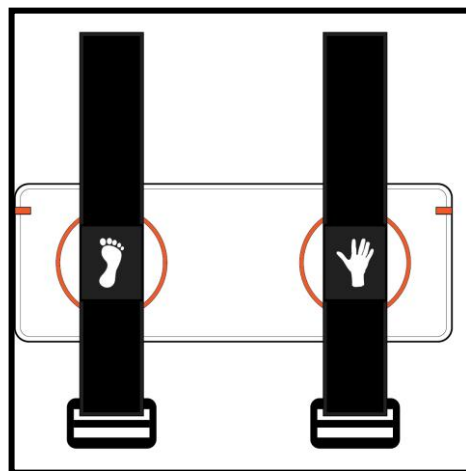


Figure 5. Sensors Correctly Placed on the Charge Pad

4. Plug the large end of the USB cable into the port on the side of the Charge Pad and plug the small end of the USB cable into the smartphone as shown (Figure 6).



Charge Pad and Large USB
Connector



Smartphone and
Small USB Connector

Figure 6

Chapter 3: Web Portal

The Kinesia Web Portal is a HIPAA-compliant web interface that allows clinicians to configure a Kinesia 360 System and access the remotely collected data. Specific access to and usability of this Web Portal is dependent on the study configuration.

Accessing the Kinesia Web Portal

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 Portal (<https://kinesia.glneurotech.com>) using your username and temporary password.
2. You will be automatically logged in on the Admin tab to change your password.

Note: Once your password has been changed, logging in will take you directly to the Overview tab.

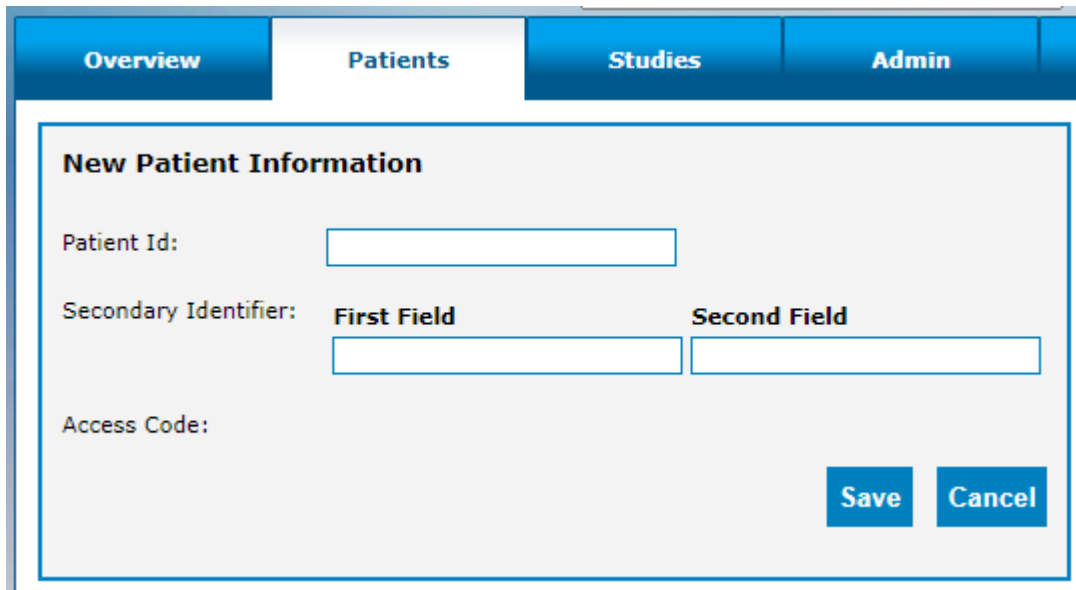
Chapter 4: Creating a Patient Profile

Prior to using the Kinesia 360 system, you must first create a profile in the Kinesia Web Portal. The first step is to add a patient 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 Portal (<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 7). A unique patient ID is required. Other information may also be entered as Secondary Identifiers.



The screenshot shows the 'New Patient Information' form in the Kinesia Web Portal. The form is titled 'New Patient Information' and is located under the 'Patients' tab. It contains three input fields: 'Patient Id:', 'Secondary Identifier: First Field', and 'Secondary Identifier: Second Field'. There is also an 'Access Code:' label. At the bottom right, there are 'Save' and 'Cancel' buttons.

Figure 7: Add New Patient Data

Note: Per HIPAA, GDPR, and other privacy regulations and guidelines, do not enter personally identifiable information in these fields.

4. Press 'Save' to add a new patient to the database, or 'Cancel' to return to the main screen.
 - a. A unique five-digit alphanumeric Access Code is generated for each patient ID. This code will be used to load a patient's profile onto a smartphone using the Kinesia 360 app. It is displayed in the patient dashboard next to the Patient ID. (Figure 8)

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

Creating a New Study Definition

To create a new study definition:

1. Log in to the Web Portal.
2. Select the 'Patients' tab on the top of the screen.
3. Select the '+' under the 'Create Study' column to create a new study definition for a specific patient (Figure 8).

The screenshot shows the 'Patients' tab in a web portal. At the top, there are tabs for Overview, Patients, Studies, Admin, Survey, Compliance, and Reports. Below the tabs is a 'Patient Search' section with input fields for 'First Field', 'Second Field', and 'ID', and a 'Find Existing Patient' button. Below this is a table of patients. A red arrow points to the '+' icon in the 'Create Study' column for the patient with ID 'GLNT01'.

Patient ID	Access Code	First Field ▲	Second Field	Create Study	View Studies	
GLNT01	HDKZN	GLNT01	Gait	+		Deactivate

Figure 8: Access Code Display and Creating Study Definition

To configure the study definition:

1. Select Diary Mode
 - **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 Asleep; OFF; ON without dyskinesia; ON with non-troublesome dyskinesia; ON with troublesome dyskinesia.
 - **Modified Dyskinesia Diary** mimics a paper diary sometimes used by patients which logs dyskinesia severity in addition to the general medication state. The patient will be required to select one of three diary options for each 30-minute period throughout the day. The diary options are Asleep, OFF, and ON. If ON is selected, the patient is prompted to rate their dyskinesia by selecting one of five severity options. The dyskinesia severity options are None, Slight, Mild, Moderate, and Severe.
2. Select Motor Assessment Mode
 - Select **Continuous** for the Motor Assessment Mode. The specifications for Side, Start Time, and Duration can be left as the default. (Figure 9)

Figure 9. 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 righthand corner then click 'Next'. (Figure 10)

Figure 10

4. Set Med Diary.

- Select the medications that will appear on the smartphone when the patient records a dose taken. Custom medications can be entered by typing in the box and clicking 'Add'.(Figure 11)

Figure 11

5. Set Event Labels

- Select the 'I do not want event labels' option in the upper righthand corner then click 'Next'. (Figure 12)

Note: Kinesia 360 does not support event labels as it is designed for continuous use by the patient, instead of task based, in office assessments.

Figure 12

6. 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 smartphone. (Figure 13)

The screenshot displays the 'Summary' screen of a study setup application. On the left is a vertical sidebar with the following menu items: 'Set Motor Assessment Mode', 'Set Dates and Times', 'Set Motor Tasks', 'Set Med Diary', 'Set Event Labels', 'Set Activity Diary', and 'Summary' (which is highlighted in blue). The main content area is divided into several sections:

- Tasks:** A box containing the following settings:
 - Motor Assessment Mode:** Continuous
 - Dates:** N/A
 - Start Time:** 8:00 AM
 - Duration:** 8 hrs
 - Side:** L
- Diary:** A box containing the following settings:
 - Diary Mode:** Dyskinesia Standard
 - Med Diary:** Levodopa, Rasagiline
 - Event Labels:** N/A
- Notes:** A large, empty text area for additional information.
- Save:** A small blue link labeled 'Save' located at the bottom right of the Notes section.
- Finish:** A large blue button with the text 'Finish' and a yellow arrow pointing to the right, located at the bottom right of the screen.

Figure 13

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 Portal.
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, 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 5: Preparing for Patient Use

Replace the Sensor Bands (if using)

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 14):

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.

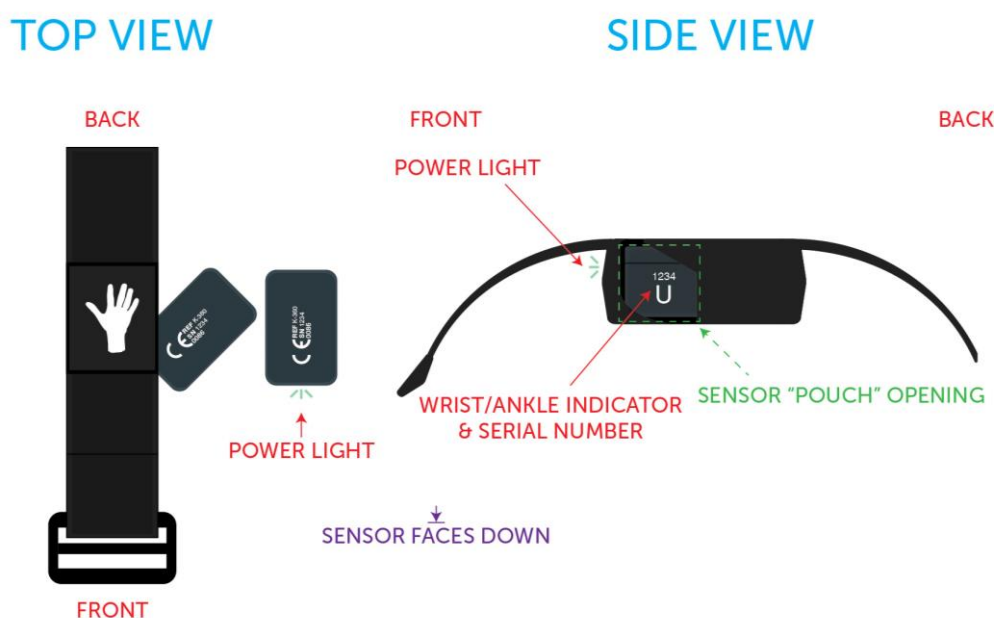


Figure 14

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 Smartphone Application

The following functions are accessible from the Kinesia 360 Application Settings menu (Figure 15) 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 Portal, it must be loaded on to the smartphone prior to collecting any data. This is done by entering the patient-specific access code into the Application as follows:

1. Turn on the smartphone and open the Kinesia 360 Application
2. Select the ☰ symbol in the top left corner of the Kinesia 360 App and choose 'Load Access Code'
3. 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 15).
4. To verify that the correct study has been loaded, confirm the Patient ID at the bottom center of the screen.
5. Select the symbol in the top left and choose Home to return to the display of the home screen and prepare for patient use.

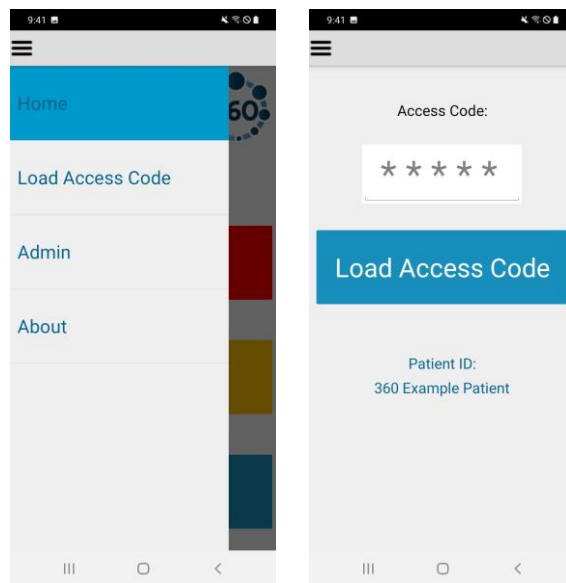


Figure 15

Note: An internet connection is required to load a Study Definition onto the smartphone. The smartphone supports both Wi-Fi connections and/or mobile broadband connections. Once the study definition is downloaded, data can be collected using the 'Start Recording' 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. This function needs a specific code to be entered into the provided field to enable the toggles for turning features on and off. For questions or assistance please contact customer support.

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 admin code (if needed, Contact GLNT to obtain Code) into the field and toggle the switch into the On position.

Pair Sensors

The System includes Kinesia Sensors that are pre-configured for your smartphone. If you receive a new sensor, it may be necessary to pair it with your smartphone using this feature (if not available you must contact customer support). In order to pair a sensor, complete the following steps:


1. Press the settings button  in the upper right of the phone's main screen
2. Select 'Bluetooth' from the menu
3. Place the Kinesia Sensors on the Charge Pad to turn them on
4. Pair each sensor by selecting its serial number 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 smartphone 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 sensor and one lower sensor is paired. You will not be able to start data collection without first having both sensors paired.

Set Language

The Kinesia 360 Application includes translation support for several languages. This may be locked on your device and you will need to contact customer support for assistance. If changing the language is not locked, follow these steps:


1. Navigate to the smartphone home screen. If the Kinesia 360 Application is open, you can access the home screen by pressing the home button at the bottom of the smartphone.
2. Select the settings button  in the upper right corner of the screen
3. Once in the settings menu, select 'Language' (if not available you must contact customer support)

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 smartphone using the power button for the regional date and time formatting to take effect.

Note: The Kinesia 360 Application will default to English if a non-supported language is selected. For a full list of supported languages, please contact GLNT support.

Set up Wi-Fi on the Smartphone

If Wi-Fi is being used for connectivity, follow these steps from the Smartphone home screen.

1. Navigate to the smartphone home screen. If the Kinesia 360 Application is open, you can access the home screen by pressing the home button on the front of the phone.
2. Select the settings button in the upper right corner of the screen 
3. In the Settings menu, select Wi-Fi (if not available you must contact customer support)
4. Ensure that the Wi-Fi is turned on based on the topmost option.
5. Select the network from the list and enter the password, if required.
6. When connected, the option selected will appear under your 'Current network' and show that it is connected.

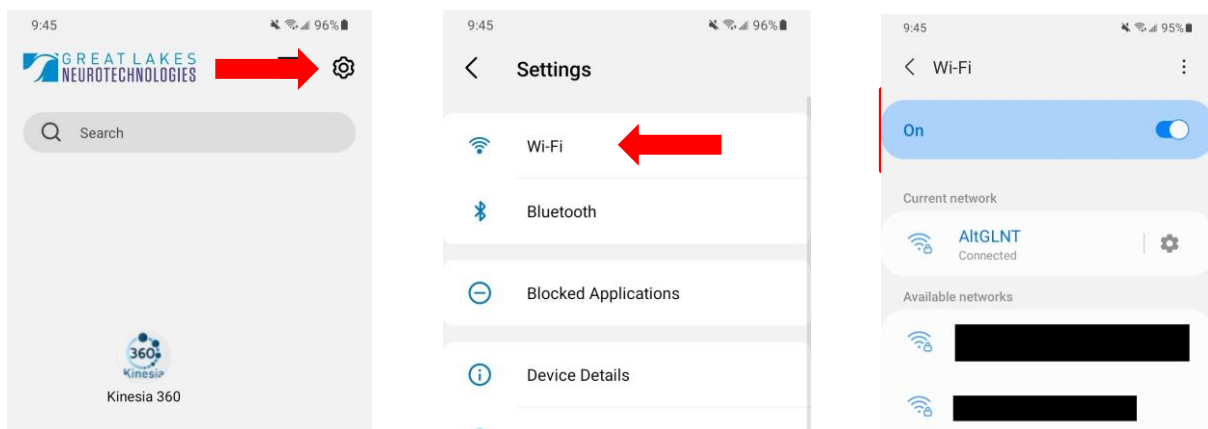



Figure 16

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

Chapter 6: 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 sensors on. Patients should keep the smartphone with them throughout the day so that they can use the Pause/Resume feature, which is used in case the sensors need to be removed temporarily during the day (e.g., during exercise, bathing, etc.). Patients should also keep the smartphone with them if they are using the diaries in the Kinesia 360 Application to rate their symptoms and/or log when they took their medication. At the end of the day, patients should use the Kinesia 360 Application to end data collection and return the sensors to the charge pad.

System Setup

The procedure for setting the system up is provided earlier in this document (see Chapter 2. System Components – 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.

Collecting 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 Recording'.
2. Ensure that the Kinesia sensors are on the Charge Pad in the proper orientation.
3. Press 'Next' once the confirmation dialogue appears.
4. Take each sensor off the charge pad and place it on the correct body location. Adjust as needed 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 charge pad. If the patient takes the sensors off of the charge pad but does not initiate data collection (by pressing the 'Start' button) within 10 seconds, he will need to return the sensors to the charge pad again to power them on before proceeding. We therefore advise that the patient leave the sensors on the charge pad until the Kinesia 360 Application prompts him to don the sensor bands.

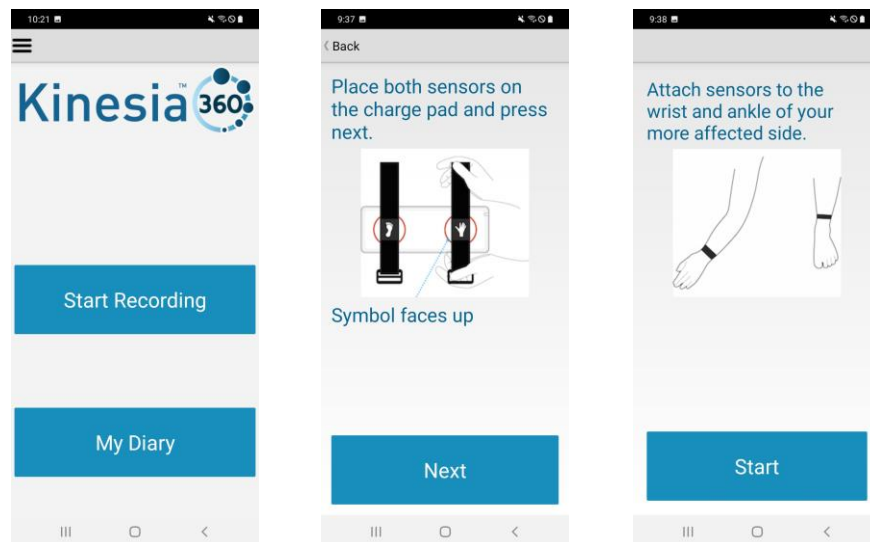


Figure 17

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 for the duration of activity.
3. When ready to resume, don the Kinesia Motion Sensors, paying careful attention to ensure that each sensor is placed in the correct position, using the icons on the sensors for reference.
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.

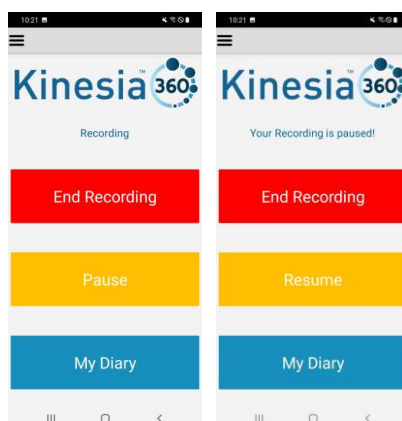


Figure 18

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 Recording'.
2. Follow prompts which instruct to remove the Kinesia Sensors and place them on the Charge Pad.
3. Press 'End'.

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

The Kinesia 360 app will display a message in the app when the maximum recording time has been reached (approximately 16 hours). Data will NOT be recorded after that point. The patient will need to end recording as described above to transfer the recorded data.

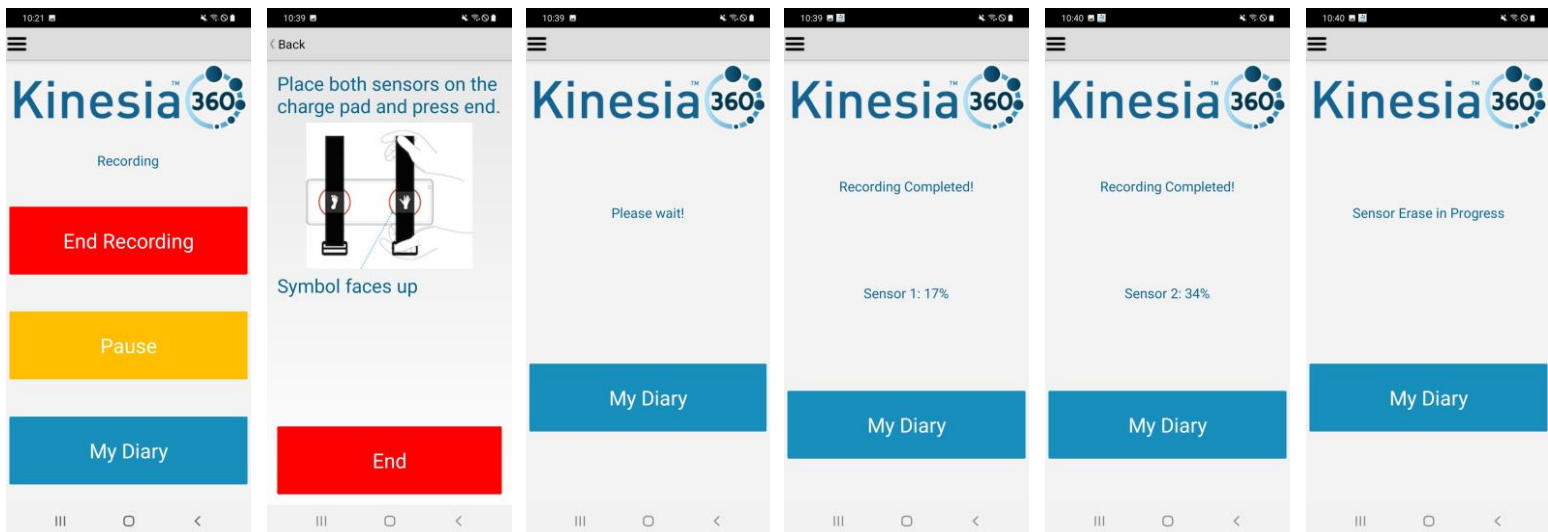




Figure 19

Note: To ensure prompt upload and processing of data, it is important that the smartphone be plugged in and the motion sensors be kept on the charge pad charging 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. Set the end time of the interval using the  and  icons to increase and decrease this time. The end time cannot exceed the current time, cannot be less than the start time, and will always be an increment of 30 minutes.
4. Select the option that describes the patient's sleep status or symptom experience for the displayed time interval. For the Standard Dyskinesia Diary, the options are Asleep, OFF, ON without dyskinesia, ON with non-troublesome dyskinesia, and ON with troublesome dyskinesia. For the Modified Dyskinesia Diary, the options are Asleep, OFF, and ON.
5. 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.
6. 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 back button (<) on the device can be pressed to exit rating at any time. However, the rating automatically resumes upon subsequent diary access that day, beginning with rating after the last interval entered.

Before the entries are saved, the patient can overwrite previous entries by pressing the button labelled "Previous". This will set the interval back 30 minutes for each individual press of the button. **Entries are not saved until the patient leaves the Symptoms page.**

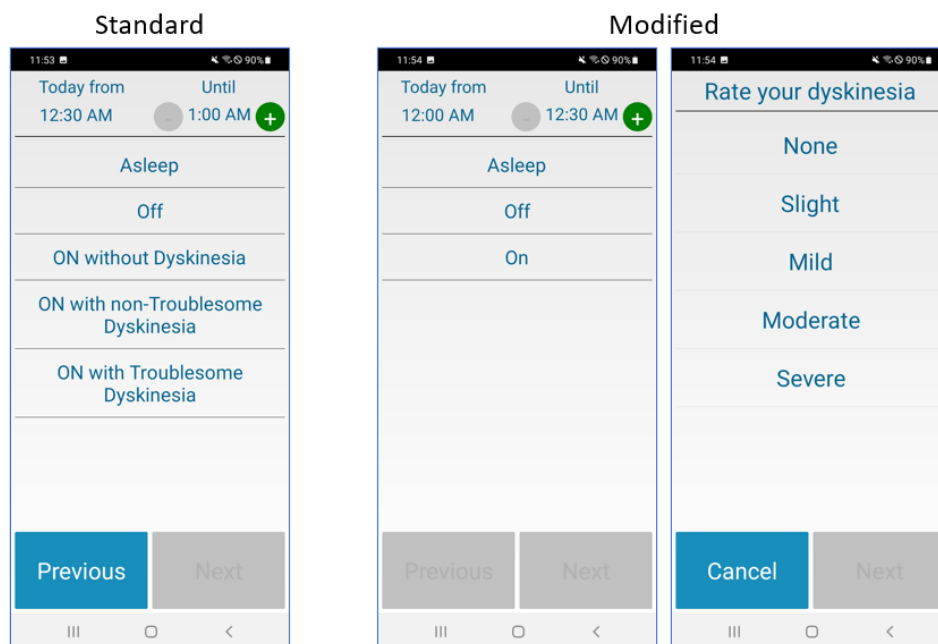


Figure 2

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.

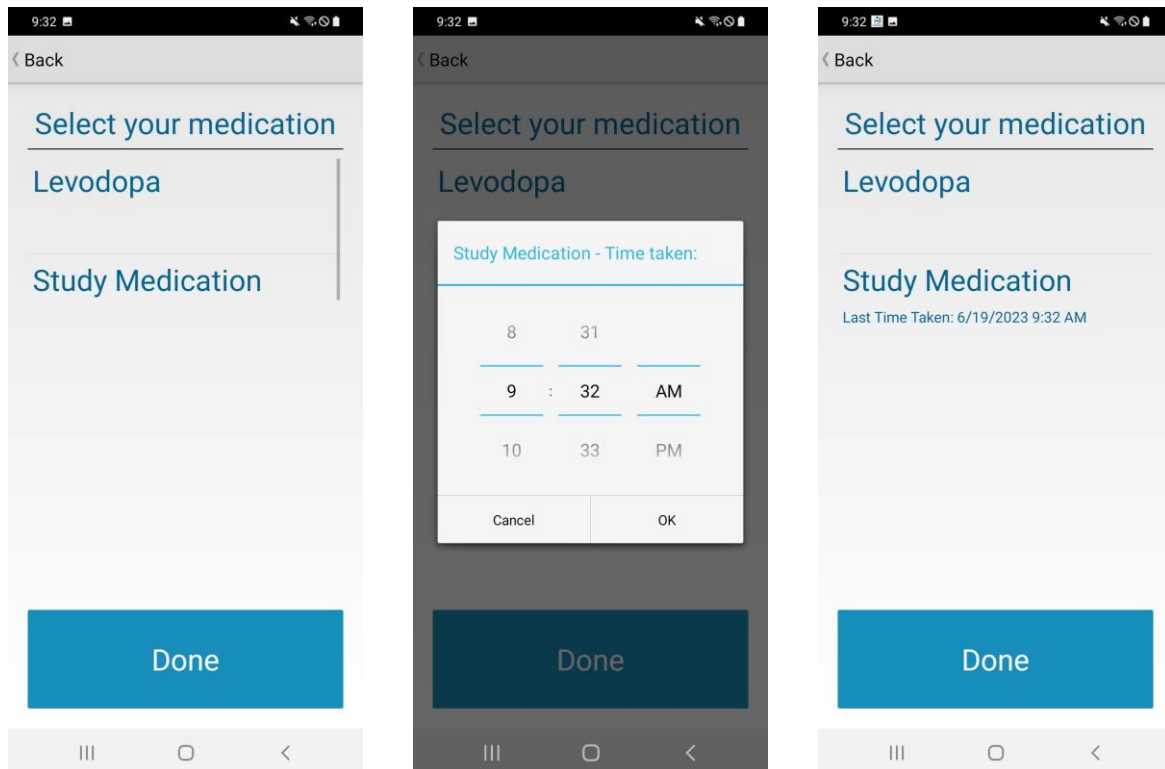


Figure 21

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 Admin code (If needed, please contact GLNT support) 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 in the Web Portal.

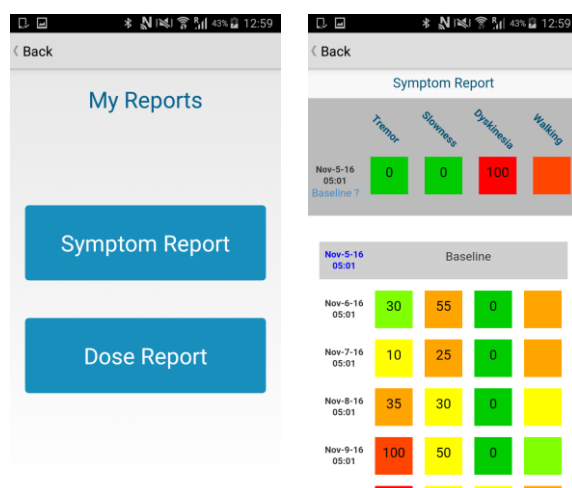


Figure 22

Each symptom and data collection date has a corresponding color-coded 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 Recording 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.



A mobile app screen titled "What medication dose did you use today?". It features a "Back" button at the top left. Below the title, there are nine blue buttons arranged in a grid: 1 mg, 2 mg, 3 mg, 4 mg, 5 mg, 6 mg, 7 mg, 8 mg, and 9 mg.

Figure 23. Medication dose selection screen

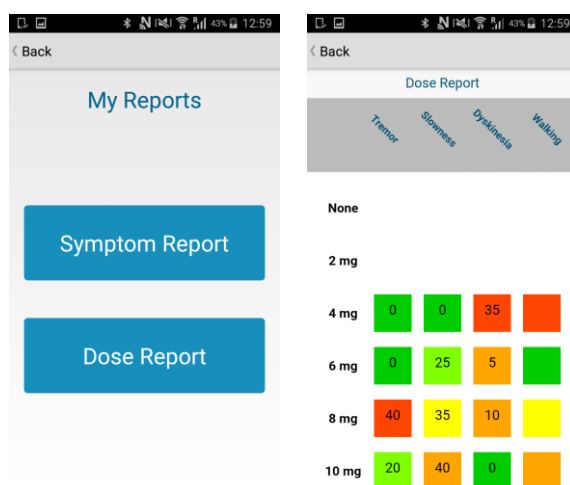


Figure 24

Each symptom and dose have a corresponding color-coded 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 7: Viewing the Compliance Dashboard

The compliance dashboard of the Web Portal can be used to confirm the patient uses the system and that symptom and medication diary entries are made. This feature is useful to confirm patients are using the system on specific days. To view the compliance dashboard:

1. Log into the Web Portal using your username and password.
2. Select the “Compliance” tab from the list of tabs towards the top of the screen (Figure 25)

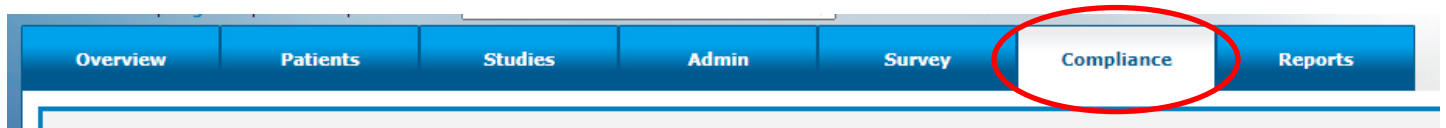


Figure 25

3. Verify your date range at the top of the tab – The selection defaults to the last 30 days, but can be changed from 1 week up to 1 year. If selecting “no Filter” it will show any recorded wearable use that has been tracked within the Web Portal for your institution.

Each patient ID will be listed to the left side of the screen, with a blue bar to the right which denotes the number of days worn. (Figure 26) To see more details for each patient ID’s wearable use, click on the blue bar next to the Patient ID you want to review. This will take you into a detail screen (Figure 27) showing the length of time worn for each day tracked, when diary entries were completed, any errors logged, and if a participant paused/resumed their test.



Figure 26

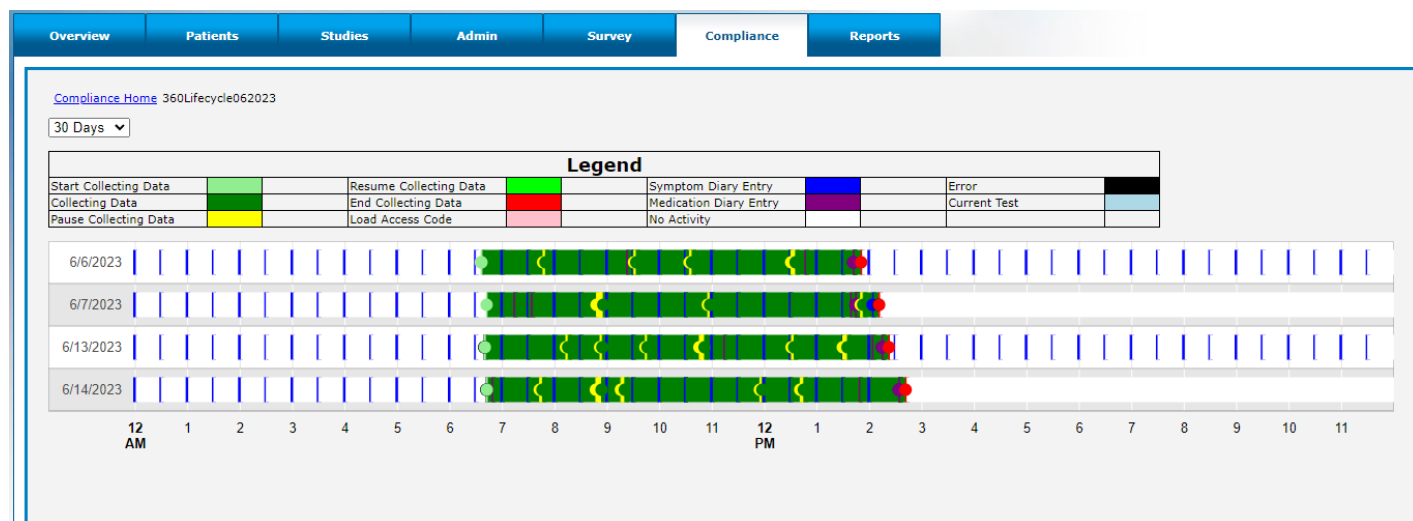


Figure 27

Chapter 8: Data Upload from Smartphone to Web Portal

Once the patient returns the Kinesia Sensors to the Charge Pad and ends the recording at the end of the day, the application will download the data from the motion sensors and will attempt to upload the patient data to the Web Portal. If network connection via Wi-Fi or mobile broadband is not available, the application will continue to retry. The patient should not turn off smartphone for at least 3 hours to allow for the upload to complete.

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

Chapter 9: View Study Reports in Web Portal

Once patient data has been uploaded from the Smartphone, a variety of reports can be accessed or requested in order to review the data collected. These include reports direct from the web portal as described below, reports developed by GLNT for specific studies with custom format, and a Report API for seamless integration of Kinesia 360 data into electronic data capture (EDC) platforms.

To retrieve a report directly from the web portal, first log in to the Web Portal. Press the 'Studies' button on the top of the screen. Navigate to the report based on the patient ID and study start date. Select 'Archived Report' or 'New Report Ready'. Click on a date from the list (Figure 29) to download a XLSX spreadsheet containing the study data or click Data Graph to view a plot of the Raw Data.

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.

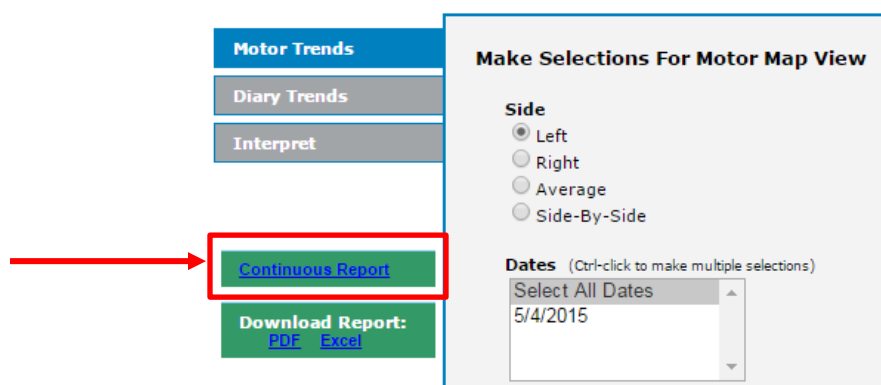


Figure 28 (Accessing the Continuous report from the Kinesia ONE report screen)

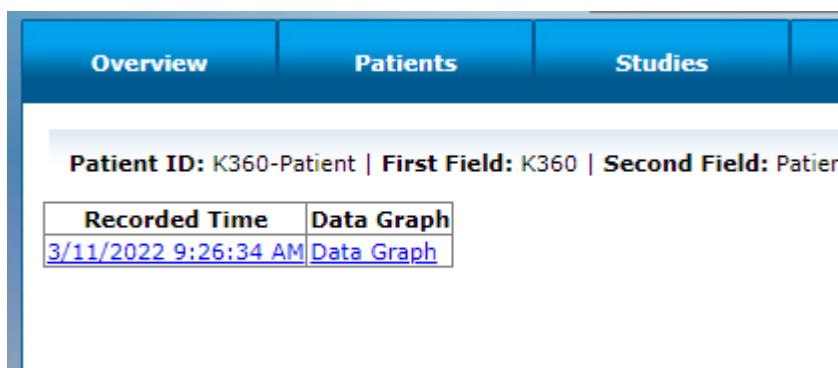


Figure 29

Spreadsheet Report

The spreadsheet will contain four main sections (i.e., sheets):

1. **Raw Data** contains the objective Kinesia 360 measurements captured in 2-minute increments. It will contain 14 columns of information.

The first column ('Subject ID') is populated by the Patient ID created in the Web Portal. 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. 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 not detected and 1 when dyskinesia was 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 column (Slowness Detect) contains a binary flag that is 0 when slowness was not detected and 1 when slowness was detected. The eleventh column (Slowness Score) contains the slowness score on a 0-4 scale. Slowness is a measure of how fast movements are when movement is detected by a sensor. When no movement is detected, no slowness score is given.

The twelfth column (Step) is the number of steps detected.

The thirteenth ('Medication Flag') and fourteenth ('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 Smartphone 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, slowness, 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, 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 Slowness Data Summary, the total time when slowness was or was not detected is calculated. The total times in the different categorical levels of slowness (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 Mobility Data Summary, the total time at rest, total time active but not walking, and total time during gait are calculated. 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, slowness, and mobility calculations.

Data Graph

The Data Graph is accessible from the same screen as the downloadable XLSX file. Selecting the “Data Graph” option will take you to a screen that reflects the raw data collected as a timeline-style graph (Figure 30).

For every two minutes of recorded data, the plot shows if tremor (red), slowness (orange), and dyskinesia (blue) is detected (top section) and the corresponding score (middle section). Symptoms can be shown or hidden using the three symptom checkboxes at the top. Periods in which walking was detected are marked in green at the bottom of the plot. Vertical blue lines show times when the patient marked in the medication diary that they took medication. The mouse cursor can be hovered over the top of the blue line to see the specific medication.

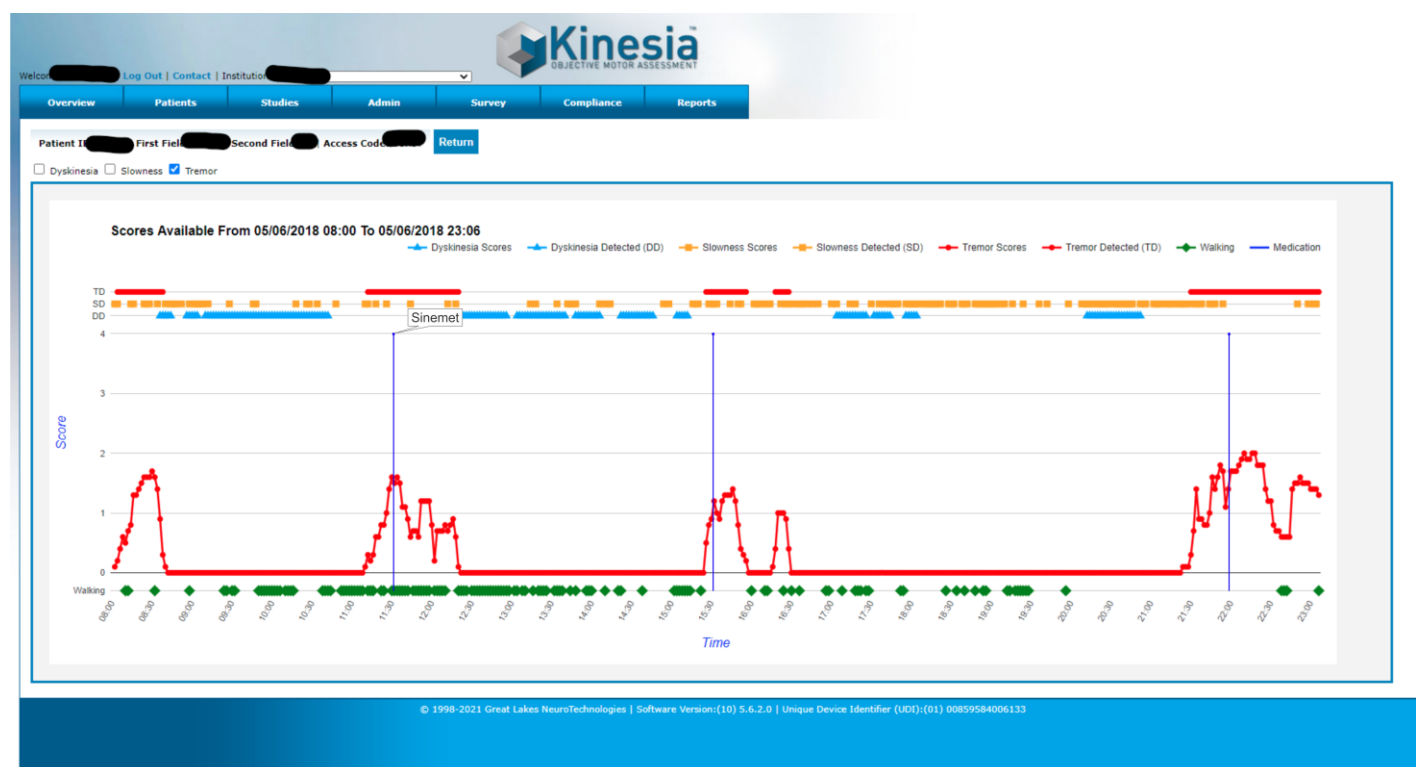


Figure 30. Sample Data Graph

Chapter 10: View Visualization Reports in the Web Portal

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 Portal.

Accessing the Visualization Report Web Portal

1. Log in to the Web Portal
2. Select the “Reports” tab from the tab selection at the top of the screen (Figure 31).

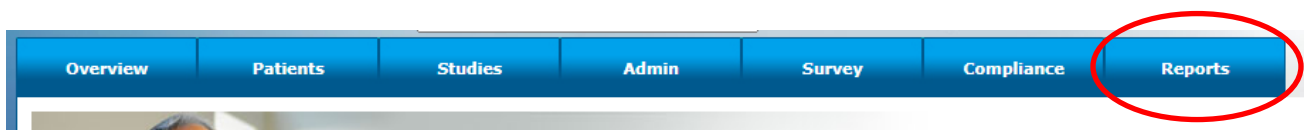


Figure 31

3. You will see a list of all available patients within your institution account. (Figure 32)

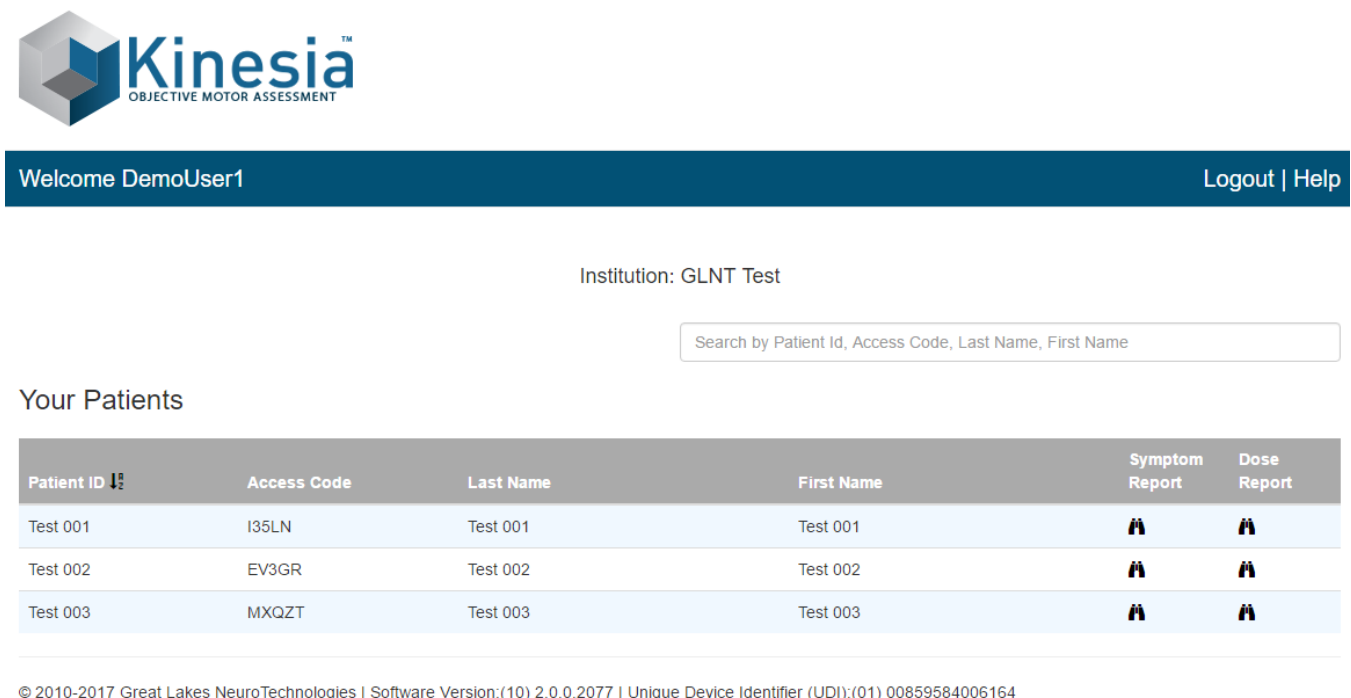
The screenshot shows the Kinesia logo at the top left. Below it is a dark blue header bar with 'Welcome DemoUser1' on the left and 'Logout | Help' on the right. The main content area has 'Institution: GLNT Test' centered. Below that is a search bar with the placeholder text 'Search by Patient Id, Access Code, Last Name, First Name'. The section is titled 'Your Patients' and contains a table with patient data. The table has columns for Patient ID, Access Code, Last Name, First Name, Symptom Report, and Dose Report. There are three rows of patient data, each with a person icon in the Symptom and Dose Report columns. At the bottom, there is a copyright notice: '© 2010-2017 Great Lakes NeuroTechnologies | Software Version:(10) 2.0.0.2077 | Unique Device Identifier (UDI):(01) 00859584006164'.

Figure 32. Kinesia Visualization Report Web Portal: Patient List

4. 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.



Welcome DemoUser1

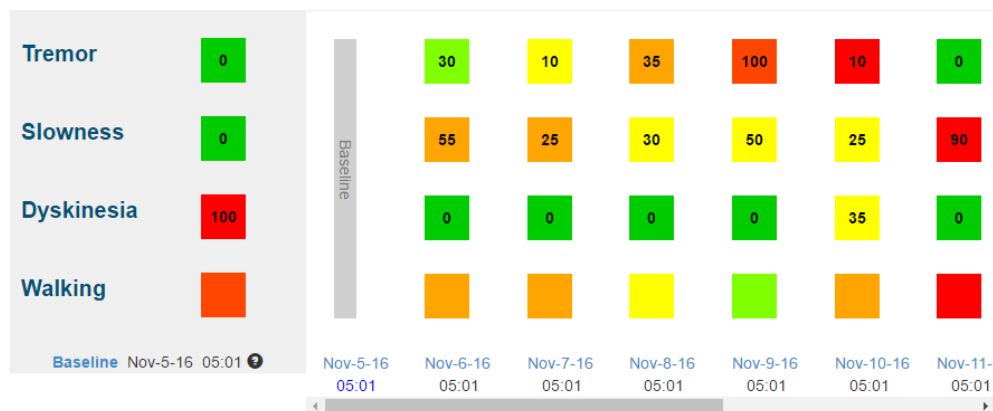
[Logout](#) | [Help](#)

[← Back to Patients](#)

Institution: GLNT Test

Patient ID: Test 001 Patient: Test 001, Test 001

Symptom Report



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Figure 33. Kinesia Visualization Report Web Portal: 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 color-coded 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 8 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.



Welcome DemoUser1

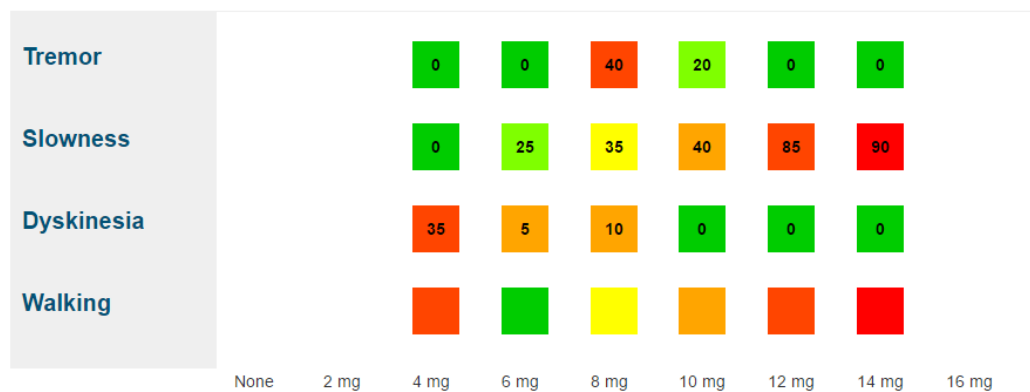
[Logout](#) | [Help](#)

[← Back to Patients](#)

Institution: GLNT Test

Patient ID: Test 001 Patient: Test 001, Test 001

Dose Report



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Figure 34. Kinesia Visualization Report Web Portal: Dose Report

The Dose Report displays data via color-coded 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 11: 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 Recording and My Diary buttons will be enabled.

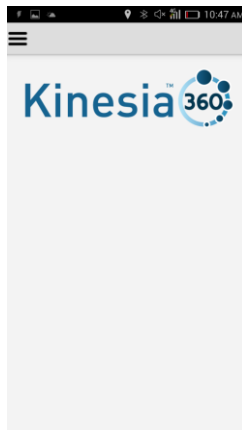


Figure 35. An access code has not been entered

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

A1. Ensure the Wi-Fi 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 Recording button is missing.

A. Follow the steps outlined in Chapter 5 for pairing the motion sensors. Once you have the upper and lower extremity sensors paired, the Start Recording button will be enabled.

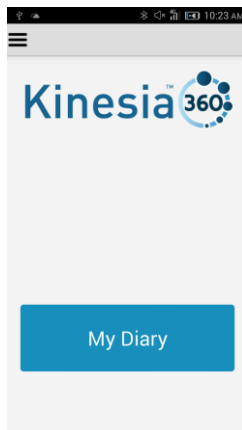


Figure 36. Motion sensors are not properly paired

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

- A1. Check that the motion sensors are on. To do this, place the sensors on the charge pad. Both the charging indicator on the charge pad and the LED on the sensor should be illuminated for both sensors.
- A2. 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.
- A3. If repeated attempts to start the test fail, take the sensors off of the charge pad and power the smartphone off. Then power the smartphone back on. Once the smartphone returns to the lock screen, place the sensors back on the charge pad.

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

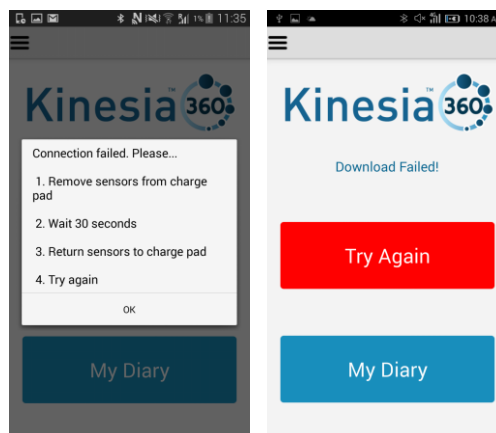


Figure 37. Connection failures when starting (left) and ending (right) a test.

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

- A1. If the patient turns off the smartphone after completing the motor assessment this may delay data upload to the Web Portal. Contact the patient to ensure the smartphone is on.
- A2. Ensure that Wi-Fi is connected or that there is a mobile broadband connection.

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

- 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.