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

EC REP

Emergo Europe Molenstraat 15 2513 BH, The Hague The Netherlands Phone: + 31 (0) 70 345 8570 Fax: + 31 (0) 70 346 7229

€ 0086

© Great Lakes NeuroTechnologies Inc. 2014

User's Guide REF No. G392-5001, Rev L DCO G285

Intended Use

Kinesia HomeView 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
- Do not use in conjunction with a defibrillator.
- Improper routing of cabling may result in a choking hazard.
- Do NOT expose the system to liquids. Liquid exposure may permanently damage the system.
- Do NOT turn the system on immediately if it has been stored in temperatures lower than 50°F or higher than 90°F. Wait at least two hours for the system to return to room temperature before it is turned on. Operate system with room humidity between 35% and 80%.
- Do NOT place the system next to a TV, air conditioning unit, or other household appliance that may cause interference and damage from magnetic fields.
- The Sensor may present a choking hazard. Keep away from children under 3 years of age.
- If the power supply or the cord is damaged, do not use the system.
- If you want to dispose of your device, please return it to Great Lakes NeuroTechnologies Inc.
- Keep the space around the Tablet PC free of debris to reduce the risk of overheating.
- DO NOT use an autoclave or other high temperature sterilization method on any Kinesia HomeView system component.
- If the power cord has a 3-pin plug, connect the power cord to a grounded (earthed) 3-pin outlet. Do not disable the power cord grounding pin by attaching a 2 pin adapter.

For more safety and regulatory information and for battery disposal information, refer to the Regulatory Safety and Environmental Notices provided with the Tablet PC'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:



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

Tablet PC; REF 502-0190	Tablet SN:
Sensor; REF 502-0202	Sensor SN:
Finger Sleeve (XS, black); REF 125-0006	
Finger Sleeve (S, brown); REF 125-0007	
Finger Sleeve (M, beige); REF 125-0008	
Finger Sleeve (L, white); REF 125-0009	
Finger Sleeve (XL, black); REF 125-0010	
USB Charging Pad; REF 059-0011	
USB flash drive; REF 501-0229	
Travel Case; REF 502-0191	
User's Guide (this document); REF G392-50	001

Date of Purchase: _____

Care and Use Instructions

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

It is not recommended to store Kinesia HomeView 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 Sensor, Tablet PC and USB Charging Pad is required after each patient use.

Use only the following products to safely clean and disinfect the Sensor, Tablet PC and USB Charging Pad:

- 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 Sensor, Tablet PC and USB Charging Pad.

TABLE OF CONTENTS

Intended Use	2	2
Warnings	2	2
Standards and Definitions:	3	3
Web Application System Recommendations	3	3
Package Contents and Warranty Information	3	3
Care and Use Instructions	2	1
Chapter 1: About Kinesia HomeView	6	3
Chapter 2: Patient Kit	7	7
Tablet PC	7	7
Sensor	8	3
USB Charging Pad	8	3
Chapter 3: Web Application	🤇)
Web Application Description	🤇)
Adding a New Patient	10)
Creating a New Study Definition	10)
Creating/Editing a Study Template	13	3
Chapter 4: Patient Application	15	5
Administrative Options	15	5
Update Patient Application Software	16	3
Patient Software Interface	16	3
Chapter 5: Executing a Patient Study	18	3
Preparing Patient Kit	18	3
Demo Mode	18	3
Patient Assembly At Home	18	3
Patient Use At Home	19)
Specific Motor Tasks	19)
Continuous Monitoring	20)
Sensor Status Indicator	21	I
Diary Entries	22	2
Chapter 6: Study Definition and Data Transfer	25	5
USB Drive Data Transfer	25	5
Mobile Broadband Data Transfer	26	3
Chapter 7: View Study Reports	27	7
Export Study Reports	27	7
Chapter 8: Conducting Video Calls	29)
Initiating a Video Call	29	9
Conducting a Video Call	30)
Chapter 9: Frequently Asked Questions (FAQs)	32	2

Chapter 1: About Kinesia HomeView

Kinesia HomeView™ is a medical system designed to capture and evaluate Parkinson's disease symptoms from patients' homes. A take home kit, programmed to a specific patient's symptoms and treatments, is sent home with the patient to complete a variety of motor tests throughout the day to assess tremor, upper and lower extremity bradykinesia, gait, and dyskinesia. The patient can also enter touch screen diary information about how they are feeling and when medications were taken. Physicians can view web-based reports including automated severity scoring and videos that show symptom changes during the day in response to treatment. Physicians can also conduct video calls with the patient.

Chapter 2: Patient Kit

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

- A. Tablet PC
- B. USB Charging Pad
- C. Sensor



Figure 1: Kinesia HomeView Hardware Components

Tablet PC

The touch screen Tablet PC is the central component of the Kinesia HomeView Patient Kit. A colorcoded system (Table 1) highlights where the AC power cable should be connected to the Tablet PC, as well as the location of the power button, camera, and a USB port for the charging pad. Patient data is stored on the Tablet PC while a study is in progress when mobile broadband is not available, or transferred to the Web Application in real time when mobile broadband is available.

Note: The system components must be connected to their corresponding color-coded markers and the power cord must remain connected to the Tablet PC at all times to ensure proper operation.

Component of HomeView System	Color Code		
Power button	Yellow		
AC power port	Green		
USB port for Charging Pad	Red		
Camera	White		

Table 1: Kinesia HomeView Color Code System

Sensor

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



Figure 2: Kinesia HomeView Sensor Positioning

USB Charging Pad

In order to be properly charged, the Sensor should be placed in the white rectangular target area (Figure 3) with the sensor label face down. The light indicator on the front of the Charge Pad will change from green to blue when the Sensor is correctly positioned. It is highly recommended that patients leave the sensor in this position between motor assessments.



Chapter 3: Web Application

Web Application Description

The Kinesia HomeView Web Application (Figure 4) is a HIPAA-compliant online interface that allows clinicians to create study definitions, upload study data, view study reports and conduct video calls with patients. The Web Application includes a patient database where you can easily add and update patient demographics and view studies. The status of a study is also displayed. Status indicators include: Setup Study, Pending Upload, New Report Ready and Archived Report. Web Application language can be toggled between English, Spanish, or German by selecting the appropriate flag next to "Language" in the bottom left corner of the Web Application.



Figure 4: Kinesia HomeView Web Application

Adding a New Patient

In order to add a new patient:

- 1. Log into the Web Application (<u>http://kinesia.GLNeuroTech.com</u>)
- 2. Select the 'Patients' tab on the top of the screen.
- 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.
- 4. Press 'Save' to add a new patient to the database, or 'Cancel' to return to the main screen.

Overview	Telemed	Patients	Studies
New Patient I	nformation		
Name:	Last	First	MI
Birthdate:			
Gender:	Select 💌		
Patient Id:			
Insurance Provider		_	
Address Line 1:			
Address Line 2:			
Phone:			
City:			
State:			
Zip:			
.eft Brain Target:	None 💌		
Right Brain Target	None 💌		

Figure 5: New Patient Data Entry Fields

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 e	xisting patient					
					Add New F	Patient
Patient ID	Last Name 🔺	First Name	DOB	Create Study	View Studies	
001	Doe	John	10/09/1972	+	Ê	

Figure 6: Create Study Definition

To configure the study definition:

- 1. Select Diary Mode
 - **Custom Diary** is a feature that allows you to enter symptoms and activities of daily living for the patient to rate throughout the day. The patient will be prompted to rate each entry on a 1 to 5 scale; 1 correlates to least severe and 5 to most.
 - **Dyskinesia Diary** mimics the standard paper diary sometimes used by patients. The patient will be required to select one of five diary options for each 30 minute period throughout the day. The diary options are as follows: Sleeping; OFF; ON without dyskinesia; ON with non-troublesome dyskinesia; ON with troublesome dyskinesia.

Note: A custom diary study does not require symptom and/or diary entries. Check the box on the top of the screen next to 'I do not want [specified feature]' (if applicable) to exclude a diary entry type.

Note: Custom diary symptom and activity ratings allow the patient to select from 1 to 5; however, these values are displayed on the Web Application as 0 to 4 severity/impairment ratings.

- 2. Select Motor Assessment Mode
 - **Specific Motor Tasks** objectively evaluate tremor, upper and lower bradykinesia, dyskinesia, and gait, at specific times during the day. Patients will be instructed to perform corresponding motor tasks (Table 2) while wearing the Sensor on the index finger or heel depending on the task. One must specify whether to assess the patient's left, right, or both sides.
 - **Continuous Monitoring** objectively evaluates tremor continuously throughout the day. Patients will be instructed to wear the Sensor on their index finger for a specified time period throughout the day before returning it to the Charging Pad. One must specify whether to assess the patient's left or right side, the start time, and duration.
 - **None** allows a study to be setup without Sensor-based assessments.

Note: Specific Motor Tasks and Continuous Monitoring cannot be done simultaneously.

	Web Application	Patient Application
	Rest Tremor	Arms Resting
	Postural Tremor	Arms Extended
ity	Kinetic Tremor	Touch Nose
mə.	Finger Taps	Finger Taps
TX C	Hand Movements	Hand Grasps
	Rapid Alternating Movements	Wrist Rotation
	Dyskinesia	Arms Resting & Arms Extended
,	Toe Taps	Toe Taps
'er mity	Leg Lifts	Leg Lifts
-ow ttrei	Gait	Gait
- <u>ů</u>	Freezing of Gait	Gait

Table 2: Specific Motor Tasks Labels

- 3. Set Dates and Times
 - For the Specific Motor Task study mode, select the dates and times when the Tablet PC will notify the patient to perform the video-guided upper and/or lower extremity motor tasks.
 - For the Continuous Monitoring study mode, select the dates when the Tablet PC will notify the patient to start wearing the Sensor throughout the day.

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

- 4. Set Motor Tasks (Only for the Specific Motor Task Mode)
 - Click and drag the upper and/or lower extremity motor tasks that the patient will perform over to the Selected Tasks box. The extremity side to be tested can be set to left, right, or both.
- 5. Set Med Diary
 - Select the medications that will appear on the Tablet PC when the patient records a dose taken. Custom medications can be entered by typing in the box and clicking 'Add'.
- 6. Set Symptom Diary and Set Activity Diary (Only for Custom Diary)
 - Select the symptoms and activities that the patient will rate on the Tablet PC at home. Custom additions can be made by typing in the box and clicking 'Add'.
- 7. Summary

- Review and verify study definition settings (Figure 7). Notes can be entered for the study which will also appear in the study report on the Web Application.
- 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 PC.

t Motor Assessment le	Tasks		Diary	
t Dates and Times	Motor Assessment Mode:	Specific Tasks	Diary Mode:	Dyskinesia Diary
t Motor Tasks	Dates:	7/6/2014		
t Med Diary	Motor Task Times:	6:00 PM	Med Diary:	Levodopa
t Symptom Diary	Upper Extremity Tasks:	1. Rest Tremor 2. Hand Movements		
t Activity Diary		3. Kinetic Tremor		
ummary	Lower Extremity Tasks:	1. Toe Taps		
	Notes:			
				+ Save
				_
				Finish 🛶

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 HomeView 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 template exists for an institution, all studies created by users will default to this template. However, one can specify study dates as well as update the remaining features (times, motor tasks, medications, symptoms, and activities on a per patient basis).

Chapter 4: Patient Application

Administrative Options

Administrative Options (Figure 8) allows the clinician to configure several Patient Application settings and can be accessed by first pressing the Administration Options button at the bottom right corner of the screen and entering the access key 'glnthv'.

	Administration Options	Close
Select Patient	Select a patient to setup study.	
SIM Config	Refresh List	
Network		
Devices		
Language		
Time & Date		
Remote Server Address	· · · · · · · · · · · · · · · · · · ·	Select
Display Options		Select

Figure 8: Administration Options

The following features are available in the Administrative Options screen:

- 1. **Select Patient**: Once a patient study is created on the Web Application, it is available to load on the Tablet PC. Press 'Select Patient', 'Refresh List', and enter the same username and password used to access the Kinesia Web Application. A list of available patient studies ready for download to the Tablet PC will be displayed. Highlight the patient who will be using the tablet and press 'Select'. You will be asked to confirm your selection and once you do, the tablet will be ready for use with that specific patient.
- 2. **Network***: The 3G network connection can be turned on or off.
- 3. **Devices***: The Kinesia HomeView Patient Kit (Figure 1) will include a Sensor that is specifically configured for your Tablet PC. If you receive a new sensor, it may be necessary to pair it with your Tablet PC using this feature.
- 4. Language: The Kinesia Patient Application language can be toggled between English, Spanish, German, French (France), French (Canada), Dutch and Korean.
- 5. **Remote Server Address***: This field specifies the Web Application address.

6. **Display Options**: Kinesia HomeView includes a symptom and medication diary and videoguided motor assessments. These features can be disabled on the home screen.

***Note**: It is recommended not to access this function unless instructed to do so by a Great Lakes NeuroTechnologies representative.

Note: Access to the Administration Options screen via the tool symbol is restricted to study administrators only. The login access key is not intended for patient use.

Update Patient Application Software

Great Lakes NeuroTechnologies will send an email notification when a new software update is available for download. Copy the file to the provided HomeView USB flash drive and plug the drive into the Tablet PC. When the 'Administration Options' menu appears, press 'Install Update'. Once the Patient Application has returned to the main screen, shut down the Tablet PC and turn it back on.

Note: Software updates should not be done when a study is still in progress on the Tablet PC.

Patient Software Interface

The Patient Application on the Tablet PC is the primary interface with which the patients interact (Figure 9). The home screen consists of several features specified by the clinician when creating the study definition on the Kinesia HomeView Web Application.

- 1. 'my Symptoms' includes several diary options
 - Rate Symptoms prompts the patient to subjectively rate symptoms and activities of daily living on a 1 to 5 scale, with one being least severe and 5 being the most.
 - Record a Video allows the patient to record a 30-second video (no audio).
 - If selected during setup through the website, the Dyskinesia Diary is used in place of the subjective symptom and activities of daily living diary.
- 2. 'my Meds' allows the patient to select a medication and time at which it was taken.
- 3. 'my Tests' allows the patient to manually initiate a Specific Motor Task assessment if configured in the study definition.

4. **'Current** date/time' and **'next test date/time**' notify the patient when they should return to the Tablet PC for additional instructions and testing.



Figure 9: Tablet PC Patient Application Home Screen

Chapter 5: Executing a Patient Study

Preparing Patient Kit

Before sending the Patient Kit home, several steps must be completed:

- 1. Check that components are in the carrying case.
- 2. Turn the Tablet PC on and from the Administration Options screen update the date and time.
- 3. Transfer the study definition from the Web Application to the Tablet PC by either using the mobile broadband connection or the HOMEVIEW USB flash drive (see Chapter 6).

Note: It is highly recommended that the Sensor is docked on the Charging Pad in the target area with the sensor label face down when a study definition is loaded onto the Tablet PC.

If a Continuous Monitoring study is in-progress, it must be completed before a Specific Motor Task study is loaded on the Tablet PC.

Demo Mode

Demo mode can be used to guide patients through their study in the clinic and practice the prescribed tests without saving or uploading any data to the Web Application. To use demo mode, the new study definition must first be transferred to the Tablet PC. This mode can be accessed by either:

- 1. Plugging the HOMEVIEW USB flash drive into the Tablet PC, and selecting 'Set Demo Mode'. Then remove the flash drive.
- 2. Selecting the Administration Options Button on the main screen and entering '*glnthv*'. Select the 'Display Options' tab and then select 'Set Demo Mode.' Select Close.
- 3. 'Demo Mode' will be displayed on the lower left corner of the Tablet PC software. Select 'my Tests' for the patient to practice the prescribed tests. To exit demo mode, turn off the Tablet PC. The newly created study definition that was uploaded to the Tablet PC will remain on the Tablet PC for home use after demo mode has been exited.

Patient Assembly At Home

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

- 1. Remove the Tablet PC and place it upright on an easily accessible table or desk.
- 2. Using the color-coded system from Table 1,

- Plug the AC power cable into the back of the stand by matching up the green markers and the other end into a nearby wall electrical outlet. The tablet must remain connected to AC power throughout the duration of the study.
- Remove the Charging Pad from the carrying case and place it next to the Tablet PC. Plug the connected cable into the back of the stand by matching up the red markers.
- 3. Place the Sensor in the center of the USB Charging Pad with the 'Kinesia' label face down.
- 4. Press the power button on the Tablet PC as indicated by a yellow marker.
- 5. The Tablet PC will be ready for use once the home screen appears.

To avoid tripping over the power cord, patients should place the Kinesia HomeView system somewhere that the electrical cord for the Tablet PC is out of the way of walking paths.

Patient Use At Home

The Tablet PC will notify the patient when to begin Sensor-based motor symptom testing when the 'Current Time' displayed on the screen reaches the 'Next Test Time'. Depending on the study definition loaded onto the tablet, the patient will follow one of two study modes:

Specific Motor Tasks

When the Tablet PC is setup with a 'Specific Motor Task' study and a new test session is scheduled to begin or 'my Tests' is manually selected, an alarm screen will alert the patient to begin the evaluation (Figure 10). The patient can then do the following:

- 'View How-To Video': Instructs the patient on proper positioning in front of Tablet PC, removing the Sensor from the USB Charging Pad, and placing it on the correct finger or foot.
- **'Snooze'**: Delays current test time 15 minutes.
- **'Cancel Test'**: Cancels the current test and returns you to the main screen. The Tablet PC will alarm at the next clinician-prescribed testing time.
- **'Start Test'**: Removing the Sensor from the USB Charging Pad enables the 'Start Test' button (turning it from gray to green). Pressing it initiates the specific motor tasks assessment.



Figure 10: Specific Motor Task Alarm Screen

When completing upper extremity motor tasks, the patient should slide the index finger through the Sensor sleeve. The Sensor label should be face up with the arrow pointing away from the patient. (Figure 2, left). In contrast, when completing lower extremity motor tasks, the patient should place the Sensor in the Foot Attachment without removing the finger sleeve and then attach it to their footwear (Figure 2, right). Only footwear that provides a secure attachment for the Foot Attachment should be used. Boots or shoes without a heel are not recommended.

Note: The Finger Sleeve should not be removed from the Sensor when using the Foot Attachment.

During the Specific Motor Task assessment, the patient will follow video-guided instructions on the Tablet PC and perform a series of short motor tasks to evaluate the clinician-specified motor symptoms. When the series of motor tasks is completed, the patient will be instructed to remove the Sensor from the Heel Attachment if need be, and return the Sensor to the USB Charging Pad on the target area with the sensor label faced down. Once successfully docked, a 'Dock succeeded!' message will appear on the screen. The Sensor should remain on the USB Charging Pad when not in use.

Note: The camera outlined by a white, circular target on the front of the Tablet PC will capture patients performing the instructed motor tests. If the patient is not properly positioned in front of the camera as outlined in the video instructions prior to each motor test, video review of study reports may be inconclusive.

Note: It is highly recommended that all patients are informed that the built-in camera will both record and display real-time video as they perform the motor testing with the Sensor.

Continuous Monitoring

When the Tablet PC is setup with a 'Continuous Monitoring' study and a new test session is scheduled to begin, the patient will be notified and instructed on the proper position of the Sensor and the time period over which the sensor should be worn throughout the day (Figure 11).

Page 20 of 32



Figure 11: Start Continuous Monitoring Alert

At the conclusion of a continuous monitoring test, the patient will be instructed to return the Sensor to the USB Charging Pad on the target area with the sensor label faced down. The Sensor should remain on the USB Charging Pad when not in use

Sensor Status Indicator

A green LED light on the side of the Sensor will indicate different sensor states depending on the Study Mode. (Table 3-4).

Sensor State	Light Pattern
Battery Charging	Alternate 2 sec ON, 2 sec OFF
Battery Fully Charged on Charge Pad	Always ON
Off Charging Pad: Sensor wireless radio connected	Alternate 3 msec ON, 2 sec OFF
Off Charging Pad: Sensor wireless radio NOT connected	Alternate 1 sec ON, 1 sec OFF
Sensor Turned Off ¹	OFF
Boot Mode ²	Alternate 100 msec ON, 100 msec OFF

Table 3: Sensor States (Specific Motor Task Study Mode)

¹In order to wake up the Sensor, it simply needs to be placed back on the Charging Pad. ²Boot mode should NEVER be seen in normal operation. If your Sensor is operating in boot mode, contact Great Lakes NeuroTechnologies customer support.

Sensor State	Light Pattern
Battery Charging (Between Motor Tasks)	Alternate 2 sec ON, 2 sec OFF
Battery Charging	Alternate 3x 200 msec ON 1 sec OFF
(During Motor Task)	
Battery Fully Charged on Charge Pad	Always ON
Off Charging Pad (Between Motor Tasks)	Alternate 3 msec ON, 2 sec OFF (wireless radio connected), or Alternate 1 sec ON, 1 sec OFF (wireless radio NOT connected)
Off Charging Pad (During Motor Tasks)	Alternate 100 msec ON, 12 sec OFF
Transferring Sensor Data to Tablet PC	Alternate 200 msec ON, 200 msec OFF
Sensor Turned Off/	OFF
Off Charging Pad Awaiting Task Start time	
Boot Mode ¹	Alternate 100 msec ON, 100 msec OFF

Table 4: Sensor States (Continuous Monitoring Study Mode)

¹Boot mode should NEVER be seen in normal operation. If your Sensor is operating in boot mode, contact Great Lakes NeuroTechnologies customer support.

Diary Entries

Either of two types of diary entries can be made: Custom and Dyskinesia. Both are initiated by pressing my Symptoms on the main screen.

Custom Diary

If a Custom diary has been defined in the study, pressing my Symptoms displays a screen that allows the patient to rate symptoms and activities of daily living (refer to Figure 12). Specify a rating by pressing the appropriate emoticon that becomes highlighted, then press Confirm Rating. After all requested activities are rated, the main menu is returned to the display.



Figure 12: Custom Diary - Symptom Rating

Dyskinesia Diary

If a Dyskinesia Diary has been defined for the study, pressing my Symptoms displays a screen that allows the patient to rate their dyskinesia symptoms at 30-minute intervals during the day. Refer to Figure 13.

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

The Finish 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.

Note: Interval rating is limited to the current 24-hour day. Once 12:00am on the next calendar day occurs, interval rating begins again at the12:00am – 12:30am interval for the current day. Ratings from previous days are retained and archived with the study.

leeping	
FF	
N without dyskinesia	
N with non-troublesome dys	kinesia
ON with troublesome dyskines	sia
Finish Later	Next

Figure 13: Dyskinesia Diary – Initial Interval Rating

Medication Diary

If a Medication diary has been defined for the system, pressing my Meds displays a screen with an adjustable clock setting, that allows the patient to enter the time of day specified medications were taken. Refer to Figure 14.



Figure 14: Medication Diary

Chapter 6: Study Definition and Data Transfer

USB Drive Data Transfer

When a mobile broadband connection is not available, the HOMEVIEW USB flash drive is required to load a new study definition and retrieve patient data from a completed study. This can be achieved by inserting the HOMEVIEW drive into the Tablet PC stand's USB port to access the Administration Options.

Transfer Study Definition to the Tablet PC

- 1. Log into the Web Application and navigate to the patient's study definition.
- 2. From the study setup summary screen, select 'Finish' when ready to finalize the study definition.
- 3. Select 'Download' to copy the study definition to the HOMEVIEW USB flash drive.
- 4. Ensure that the Tablet PC is turned on and the home screen appears.
- 5. Insert the HOMEVIEW USB flash drive in the Tablet PC stand.
- 6. Once the 'Administration Options' screen appears, select 'Setup New Study.'
- 7. Select 'Proceed' to transfer the study definition to the Tablet PC.
- 8. 'Transfer Successful' in red text will appear at the bottom of the screen.
 - If an error message appears. If this occurs, remove the HOMEVIEW USB flash drive, re-insert it, and attempt to transfer the study again. If the error continues, please contact customer support.
- 9. Remove the HOMEVIEW USB flash drive.
 - The time and date of the patient's first test will be shown in red on home screen.
- 10. Turn off the Tablet PC. The system is now ready to be sent home with the patient.

All patient data previous study will be deleted from the Tablet PC when a new study is loaded.

Transfer Patient Data to the Web Application

- 1. Ensure that the Tablet PC is turned on and the home screen appears.
- 2. Insert the HOMEVIEW USB flash drive in the Tablet PC stand.
- 3. Once the 'Administrative Options' screen appears, select 'Retrieve Study Data'.
- 4. Press 'Proceed' to remove the data from the tablet
 - If data transfer is successful, 'Study Transfer Successful' will appear in red.
 - If this message does not appear, remove the USB flash drive, re-insert it, and try again. If the transfer continues to fail, please contact customer support.
- 5. Remove and insert the HOMEVIEW USB flash drive into a computer connected to the internet and log in to the Kinesia HomeView Web Application.
- 6. Select the 'Upload' tab on the top of the screen
- 7. Press 'Select File' and navigate to the 'HOMEVIEW' USB flash drive on the computer.

- 8. Select the patient data file with the .khv file extension and click 'Open'. Once the file has been selected, it will appear in the text box next to the 'Select File' button. Select 'Upload' next to 'Select File' to initialize the file transfer.
- 9. 'Upload Complete' will appear when the transfer is done.

Note: After transferring patient data of a completed study from the Tablet PC to the HOMEVIEW USB flash drive, upload the data file to the Web Application before creating a new study definition or transferring patient data from another Kinesia HomeView system. This is the best way to avoid sending a unit home with the wrong study and/or loss of patient data.

Mobile Broadband Data Transfer

When a mobile broadband connection is available, one can transfer study definitions to the Tablet PC and patient data from a completed study to the Web Application without the HOMEVIEW USB flash drive.

Transfer Study Definition to the Tablet PC

- 1. Create a study definition on the Web Application and select 'Finish' from the study summary screen.
- 2. Ensure that the Tablet PC is turned on and the home screen appears.
- 3. Select the Administration Options Button in the lower right corner of the screen.
- 4. Enter the administrative login access key 'glnthv' and select 'Proceed'.
- 5. Press the 'Select Patient' tab followed by the 'Refresh List' button.
- 6. Enter your Web Application login credentials to view a list of patient studies.
- 7. Select the patient and press 'Select.
 - If study definition transfer is successful, 'Study Transfer Successful' will appear in red at the bottom of the screen.
 - If this message does not appear, repeat steps 5-7. If the transfer continues to fail, please contact Great Lakes NeuroTechnologies customer support.
- 8. Select 'Exit'. The time and date of the patient's first test will be shown in red.
- 9. Turn off the Tablet PC. The system is now ready to be sent home with the patient.

All patient data previous study will be deleted from the Tablet PC when a new study is loaded.

Transfer Patient Data to Web Application

When mobile broadband is enabled, patient data transfer to the Web Application is done automatically every ten minutes and/or when a new motor assessment or diary entry is completed. It is highly recommended that patients leave their Tablet PC turned on for at least fifteen minutes after completion of the last motor exam at the end of the day to ensure all data from that day's assessments have adequate time to upload to the Kinesia HomeView Web Application.

Chapter 7: View Study Reports

Once patient data has been uploaded to the Web Application, log in to the Web Application. Press the 'Studies' button on the top of the screen. Navigate to the report based on the patient name, ID, and study start date. Select 'Archived Report' or 'New Report Ready'. Each report will consist of three main features:

- 1. **Motor Trends** displays time stamped motor scores based on the patient data recorded by the Sensor in addition to medication and video diary entries. 'Specific Motor Tasks' will display 0 (green) to 4 (red) color-coded scores corresponding to no and high symptom severity, respectively (Figure 15).
- 2. Diary Trends displays patient-rated symptom and activity scores.
- 3. **Interpret** allows the clinician to enter his or her interpretation of the study results and the follow-up recommendation. Furthermore, any Notes saved on the Summary screen when creating a study will appear on this tab or can be entered at this time. Select 'Save' to add the entered text into the final report. Selecting 'Save' again will overwrite the interpretation and recommendation.

Export Study Reports

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

Note: All motor and diary data are automatically added to the exported study report. Time response plots are not included in the study report.

Note: The patient data displayed below the 'Interpret' text boxes will correspond to the selection(s) made in one of the Motor Trends, Diary Trends, or Time Response sections right before selecting Interpret. For example, if you select information in the Diary Trends section then select Interpret, only the selected Diary Trends data will appear.



Figure 15: Web Application Study Report

Chapter 8: Conducting Video Calls

The telemedicine feature allows the clinician to initiate and conduct a live video call with patients. Calls will be made between the Kinesia HomeView Web Application and the patient tablet.

Initiating a Video Call

Only the clinician may initiate a video call by the following actions:

- 1. Log in to the Web Application.
- 2. Select the 'Telemed' Tab on the top of the screen.

Overview	Telemed	Patients	Studies		Upload	Admin	
Patient ID	First Name	Last Name	Video Call		Device	Study Created	Device Contact
1234567	Jon	Doe	e	Report	2C138C76C2C	6/17/2014 2:01:50 PM	7/3/2014 9:08:52 AM

3. Select 'C' next to the patient's name under the 'Video Call' column (Figure 16). If a tablet is not available for a video call, the icon will be disabled.

Note: The clinician will be prompted to install a web browser plug-in the first time the video call feature is used on a computer.

Note: The web browser may need to be refreshed to update the Telemed display.

4. The clinician is presented with a Call Settings dialog box (Figure 17). This dialog allows the clinician to change between Camera, Speaker, and Microphone.

On the call settings dialogue box, select 'Call Patient.'

Integrated Webcam	•
Speaker	
Speakers (High Definition Audio Device)	•
Microphone	
Microphone (High Definition Audio Device)	•

Figure 17: Call Settings

Conducting a Video Call

Once the video call is initiated, actions are available to both the clinician and patient.

The clinician:

1) Upon initiating a call, a call progress bar is displayed, and then removed when the call is established. If a call to the tablet cannot be established, the clinician will be notified that the call failed.

Note: The call will fail if the patient is using the 'Rate Symptoms', 'Record a Video' or 'my Tests' features on the tablet at that time.

2) Once a call is established, the clinician is entered into a call room, awaiting the patient's incoming call response. The clinician will be notified by a dialogue box when the patient joins the call room. The patient's video feed (Figure 18) is displayed in a large window; the clinician's video feed is reduced in the lower right corner.

Note: The clinician will not be able to view the patient until the call is accepted.

3) To end the call, click the "X" under the video feed.

Note: The clinician will be notified if the patient ends the call.



Figure 18: Clinician Video Call Display on Web Application

The patient:

- 1) When the clinician initiates a call, the tablet display will prompt the patient to either accept or decline.
- 2) Upon accepting the video call, the patient and clinician will be displayed. (Figure 19). The Camera button toggles between the tablet front or rear camera. Selecting End Call ends the call and returns the previous screen on the tablet.



Figure 19: Patient Video Call Display on Tablet

Chapter 9: Frequently Asked Questions (FAQs)

- Q. I am unable to login and access the patient list on the patient unit using the Administration Options Button. I get a login failed error message.
- A. Ensure the mobile broadband is enabled using Toggle Remote Upload and verifying 3G does not have a red line through it on the upper right side of the Tablet PC. If 3G is enabled and you are still unable to login, contact a GLNT administrator at 1.855.GLNeuro (1.855.456.3876).
- Q. I set the study definition times but the system doesn't alarm at those times and says there are no more tests on for the patient to take.
- A. Ensure you selected dates for your study definition. If you did not specify dates and/or specified "n/a" for the duration, the study definition will not alarm at your specified times.
- Q. When I try to create a study for a patient the configuration options such as medications and times are pre-configured.
- A. There is likely a study template assigned to your institution. You can contact your institution administrator to change the template. Furthermore, you are able to adjust all of the template selections on a per patient basis as you create study definitions.
- Q. When I attempt to create a new study definition for a patient I am automatically redirected to an old study definition I had begun setting up but not yet finished.
- A. Only one study can be in the 'Setup Study' status for a patient at a time. You are redirected to an old study that had not been finished as a result of this functionality.
- Q. I cannot go back to edit the previous selections (dates, times, motor tasks, etc.) when I have progressed beyond them when setting up a study to make changes.
- A. Finish setting up the remaining options. When you arrive at the Summary screen you can go back and update the other tabs, but not until you have reached the Summary screen.
- Q. I do not know what my access key is to enter the Administration Options screen via the Administration Options Button.
- A. All users can access the Administration Options screen by entering the access key '*glnthv*'. Please do not share this access key with your patients.
- Q. My Tablet PC's 3G connection is active but it is not transferring patient data remotely.
- A. Verify that the tablet local time and date are set correctly from the Administration Options screen.
- Q: After establishing a video call, I am experiencing freezing of the video. How can this be addressed?
- A: Video quality is dependent on your mobile broadband connection. Attempts to reconnect or call at a time where connection factors are more optimal may improve video quality.
- Q: The patient is out of the camera view.
- A: Instruct the patient to adjust the tablet position to improve the viewing angle. Page **32** of **32**