



User's Guide

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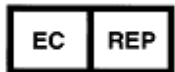
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Introduction

Intended Use

Kinesia ProView™ 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.
- ⚠ Do not place Charging Pad within nine inches of implanted pacemaker.
- ⚠ Improper routing of cabling may result in a choking hazard.
- ⚠ Do NOT expose the Tablet, Finger Sensor or Charging Pad to liquids. Liquid exposure may permanently damage these system components.
- ⚠ 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 TV's, air conditioning units or other appliances that may cause interference and damage from magnetic fields.
- ⚠ The Finger Sensor may present a choking hazard. Keep out of reach of 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.
- ⚠ To reduce the risk of overheating, make sure that the space around the Tablet and Charging Pad is open and free of debris.
- ⚠ DO NOT autoclave or use any other sterilization methods on any Kinesia ProView™ system components.
- ⚠ Plug the power cord into an easily accessible AC outlet at all times.
- ⚠ 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's documentation

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

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

Standards and Definitions:

The following symbol on product labeling warns of potential choking hazards:



Web Application System Recommendations

Internet Explorer 9
Windows XP Pro (32 bit), Windows Vista Business or Windows 7 Ultimate
Intel Core 2 Duo 6300 1.86GHz CPU (or equivalent)
1GB (2GB for 64-bit systems) RAM
1024 X 768 or greater display resolution
1GB or more available Hard Disk space
Microsoft compatible keyboard and mouse or other pointing device
Adobe Reader
Broadband Internet access

NOTE: *Macintosh and Linux operating systems are not supported.*

NOTE: *Windows XP Pro 64-bit not recommended.*

Functionality may vary based on system configuration.

*Product 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 warranties Kinesia ProView™ (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 to make sure your kit has the required components and record the requested data:

SN: _____

SN: _____

Date of Purchase: _____

🕒 Tablet with stylus; REF 502-0203

🕒 Charging Pad; REF 059-0011

🕒 Finger Sensor; REF 502-0202

🕒 Travel Case; REF 502-0191

🕒 User's Guide (this document); REF G392-5003

Care and Use Instructions

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

It is not recommended to store Kinesia ProView™ 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 Finger Sensor, Tablet and Charging Pad is required after each patient use.

Use only the following products to safely clean and disinfect the Finger Sensor, Tablet and 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 Finger Sensor, Tablet and Charging Pad.

Avoid fibrous material such as paper towels which can scratch the Tablet's touch-screen.

Note: to prevent the possibility of cross contamination and to maintain hygienic safety, the Finger Sensor Sleeves (P/N's 502-0251 through 502-0255) are intended for single patient use only.

Refer to the HP Tablet User's Guide, available at <http://bizsupport2.austin.hp.com/bc/docs/support/supportmanual/c03112061/c03112061.pdf>, for further cleaning and disinfecting instructions.

Chapter 1: About Kinesia ProView™

General Device Description

Kinesia ProView™ is a medical device capable of recording, analyzing, and displaying kinematic and user-entered data from movement disorder patients. Using data storage and miniaturization technologies, Kinesia ProView™ provides kinematic data acquisition that is untethered, thus allowing patients to move freely while performing instructed motor tasks. The purpose of this system is to provide users with a detailed report of how motor symptoms and side effects respond to deep brain stimulation (DBS) therapy as the stimulation settings are adjusted during a programming session.

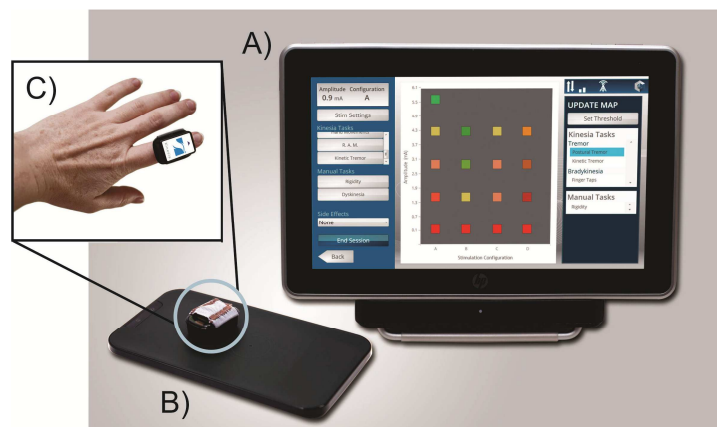


Figure 1. Kinesia ProView™ components. A) Tablet, B) Charging Pad, C) Finger Sensor. The clinician application is displayed on the Tablet. Web Application not shown.

Kinesia ProView™ consists of three hardware components: A) Tablet, B) Charging Pad, and C) Finger Sensor (Figure 1). The Tablet is used to record data during a programming session and display data (motor scores and side effects) at different combinations of DBS settings. The Charging Pad charges the Finger Sensor. The Finger Sensor collects and transmits kinematic motion data to the Tablet while the patient performs motor tasks.

The two software components are the Tablet software interface and Web Application. The pre-installed application software on the Tablet allows users to setup a programming session and then evaluate how Parkinson's disease (PD) symptoms respond to different combinations of DBS settings using Tuning Maps, which are color-coded graphs that display side effect indicators and 0.0 to 4.0 severity scores. The Web Application is used to manage patient profiles and programming session data as well as export reports.

Tablet and Stand

The touch-screen Tablet is designed for conducting and recording a DBS programming session. When resting on the provided stand, the AC power cable connector and power button are indicated using color-coded markers (Table 1). The power button should be slid down and released. The white light next to the slider will blink indicating that the Tablet is starting up. The same should be done to shut the Tablet down.

Table 1: Kinesia ProView™ Color Code System

Component of HomeView System	Color Code
Power button	Yellow
AC power port	Green
USB port	Red

Programming session data are stored on the Tablet while a session is in progress or when mobile broadband is not available, then transferred to the Web Application when mobile broadband is available.

NOTES: We highly recommend that the power cord remain connected to the Tablet stand at all times to ensure the system operates properly.

Charging Pad

The Charging Pad allows easy removal and return of the Finger Sensor following programming. It serves as the charging platform for the Finger Sensor when Kinesia ProView™ tasks are not being performed. Fully charging the Finger Sensor battery from empty will take approximately 3 hours. A flashing green light on the Finger Sensor will indicate that it is charging and remain ON once fully charged.

NOTES: We recommend removing the Finger Sensor from the Charging Pad once the green LED on the Finger Sensor stops blinking, indicating that a full charge has been reached.

NOTES: If plugged into the Tablet stand, the Charging Pad will only turn on when the Tablet is docked. Only one Finger Sensor can be charged at a time.

Finger Sensor

The Finger Sensor (Figure 2) is worn on the patient's index finger while performing Kinesia ProView™ motor tasks. During assessments, the patient should wear the Finger Sensor on the index finger with the Great Lakes NeuroTechnologies label facing up and the arrow pointed outward toward the tip of the finger. The sensor measures three-dimensional motion using accelerometers and gyroscopes. Accelerometers measure linear acceleration while gyroscopes measure angular velocity. Motion sensor data are sampled at 64 Hz. A fully charged Finger Sensor battery will last between 2-3 hours depending on use. Color-coded Finger Sensor sleeves come in five different sizes: XS (dark brown), S (black), M (white), L (light brown), and XL (black). Sleeves are intended for



Figure 2. Kinesia ProView™ Finger Sensor. The patient slides the tip of their index finger into the sleeve with the sensor box oriented up.

single patient use only.

Table 2: Charging Pad LED Operation

Operation	Light Indicator Response
Battery Charging	2 seconds on, 2 seconds off
Battery Fully Charged	always on
Downloading Data	10 ms on/10 ms off – Light indicator may appear is steadily ON, but at half intensity
Sensor Shutdown ¹	off
Boot Mode ²	100 ms on /100 ms off
Unit is Off the Charging Pad with Bluetooth Connected	3 milliseconds on, 2 seconds off
Unit is Off the Charging Pad Without Bluetooth Connected	150 milliseconds on, 500 milliseconds off

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

 To avoid tripping over the power cord, place the Kinesia ProView™ system so that the electrical cord for the Tablet is out of the way of walking paths.

Clinician Application (Tablet)

The clinician application on the Tablet is the primary interface that users interact with by using their finger or the provided stylus. This application has 4 main screens:

1. **Login Screen** allows the user to login to the Tablet using a unique username and password to ensure HIPAA-compliance and create a programming session that is associated with a patient profile on the Web Application. The user uses the same login information to access both the Web Application and Tablet. Once logged in, the user can select from a patient list.
2. **Administration Options** allows the user to customize advanced settings.
3. **Session Setup Screen** displays the patient ID, first and last name, and left and/or right brain target. The user can select the implant side to program, stimulation type (constant current or constant voltage), and motor tasks. Instructional videos for these motor tasks can be viewed with English, Spanish, or German audio.
4. **Programming Screen** allows users to select stimulation configuration label (A, B, C, D, E, F, G, H, I, or J which represent polarity, pulse width, and frequency) and amplitude and evaluate these settings while the patient performs the Kinesia ProView™ motor tasks using the Finger Sensor. Additionally, the user enters ratings for manual tasks and side effects on this screen. Separate Tuning Maps exist for each Kinesia and manual task.

Web Application (Online)

The Web Application is a HIPAA-compliant online interface that allows users to add patient profiles and view Tuning Maps and programming session information. The Web Application includes a patient database where users can easily add and update patient demographics and view studies. A “New ProView™ Report Ready” or “Archived ProView™ Report” status will indicate whether a programming session has already been viewed. The language on the Web Application can be changed from English to Spanish by selecting the appropriate flag next to “Language” in the bottom left corner of the Web Application.

NOTES: The Clinician Web Application is a central online interface for all Kinesia products including ProView™ and HomeView™.

Chapter 2: Administration Options

Administration Access

Users can access the Administration Options screen by entering the access key 'glntpv'.

Installing Updates

When a new software update is available, the 'Update' button will be enabled. Great Lakes NeuroTechnologies recommends you always install updates as they become available.

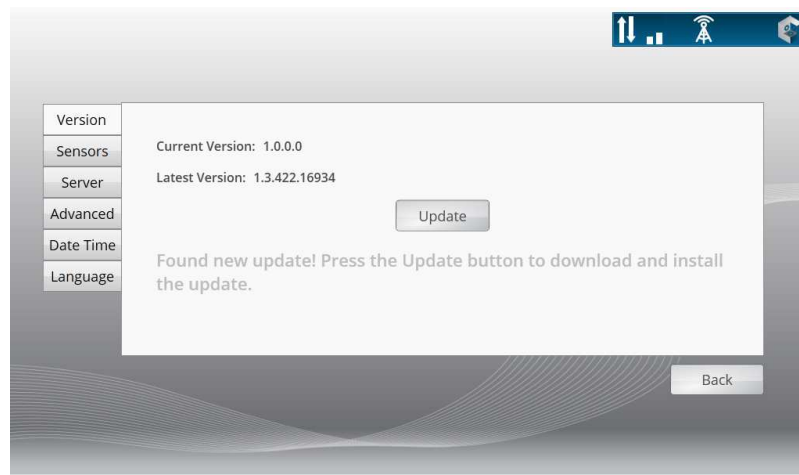
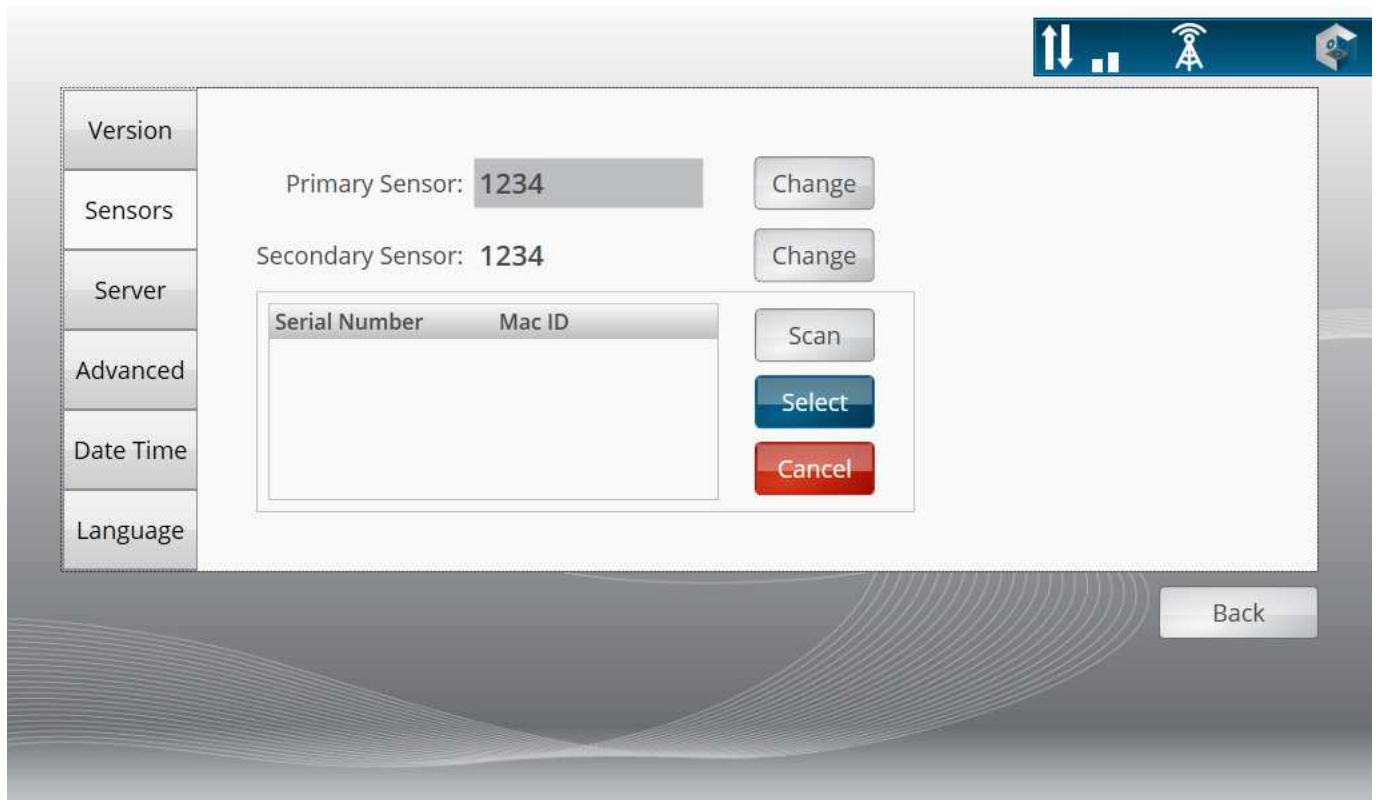


Figure 3. Administration Option Update Screen

NOTES: We recommend plugging the Tablet into a wall outlet during update download and install to ensure optimal system performance.

Finger Sensor ID Setup

The Kinesia ProView™ Tablet can be paired with up to two different Finger Sensors. The sensor will be preconfigured. To change the paired sensor, login to the Administration menu. Click the 'Sensors' tab. Click 'Change' next to the sensor (Primary or Secondary) that you want to be adjusted. Three options will appear: 'Scan,' 'Select,' and 'Cancel.' Ensure the sensor you would like to pair the tablet with is turned on (place on charging pad until green LED on sensor turns on) and click 'Scan.' The tablet will then list any sensors that are turned on in the vicinity. Find the serial number on the tablet that matches the desired sensor and select that sensor on the tablet and click 'Select.' That sensor is now paired with the tablet.



The screenshot shows a web application interface for sensor ID administration. On the left is a vertical sidebar with menu items: Version, Sensors, Server, Advanced, Date Time, and Language. The main content area is titled 'Administration Option Sensor ID Screen'. It features two input fields for sensor IDs, both currently set to '1234'. Each field has a 'Change' button to its right. Below these is a table with two columns: 'Serial Number' and 'Mac ID'. To the right of the table are three buttons: 'Scan' (light gray), 'Select' (blue), and 'Cancel' (red). A 'Back' button is located at the bottom right of the main content area. The top right of the interface includes a status bar with icons for signal strength, a Wi-Fi symbol, and a camera icon.

Serial Number	Mac ID

Figure 4. Administration Option Sensor ID Screen

Setting the Clinician Web Application Server

The server address should state “kinesia.glneurotech.com”.

Set Date and Time

The local date and time can be set to accurately time stamp all patient data collected by the ProView™ system during a programming session.

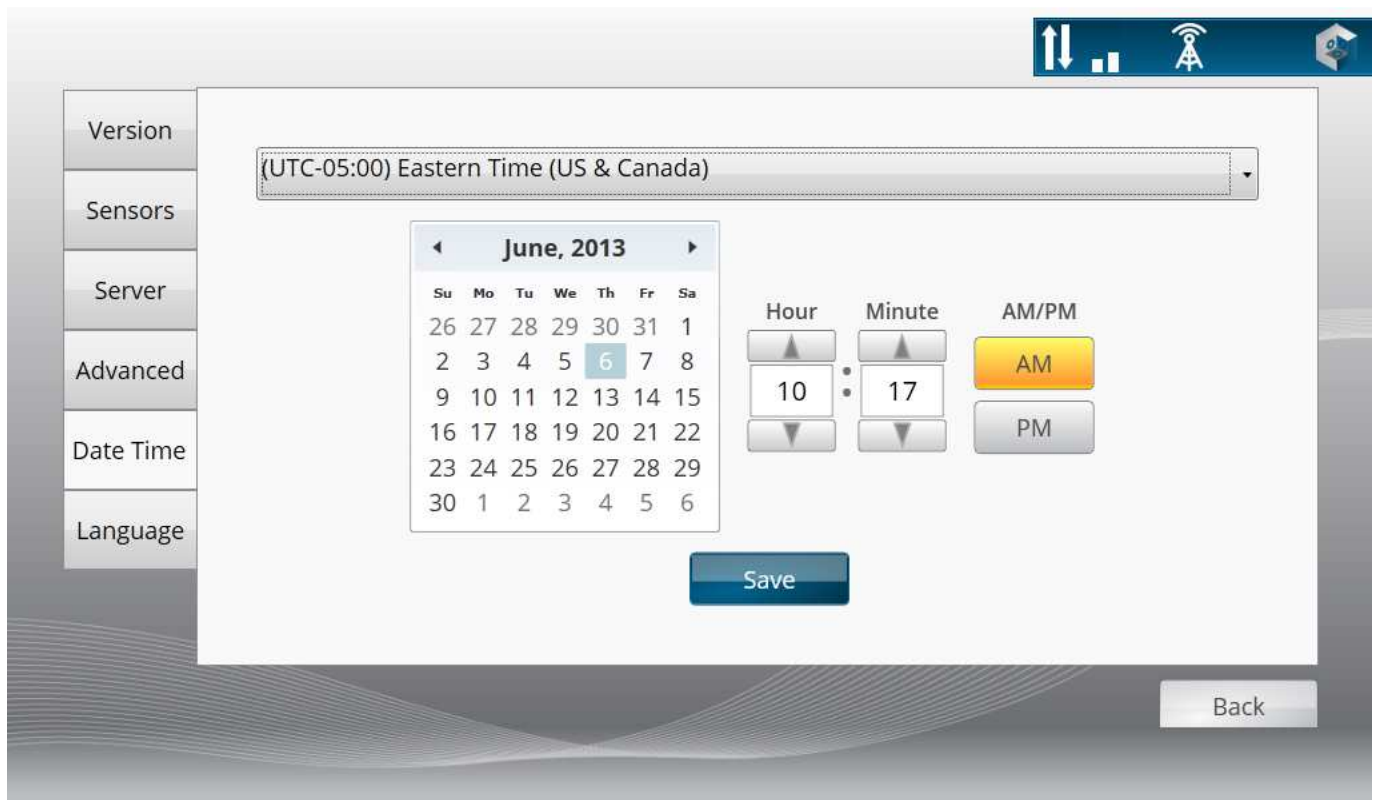


Figure 5. Administration Option Time/Date Screen

NOTES: *Ensure that the Tablet date and time are correctly set before starting a programming session using the ProView™ system.*

Set Language

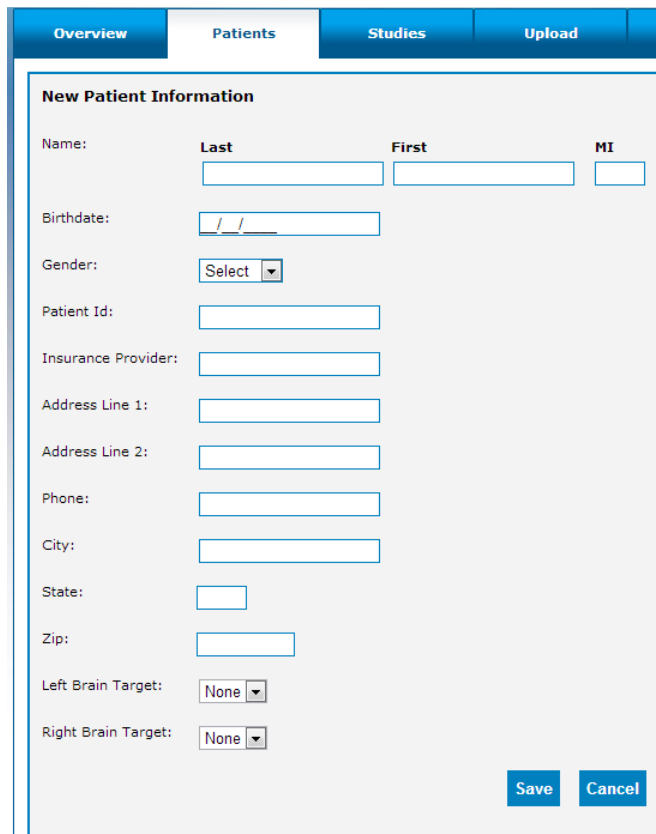
The instructional video and Stroop test language can be set to English, German, or Spanish. The software will restart if a language change is made.

Chapter 3: Programming Setup

Clinician Web Application

Add New Patient

1. Log into the Web Application (<https://Kinesia.GLNeuroTech.com>)
2. Click the 'Patients' tab on the top of the screen
3. Select 'Add New Patient' and complete the patient information (Figure 3)
 - Patient first and last name, birth date, and a unique patient ID are required.
 - Patient's left and/or right brain target.
4. Press 'Save' to add a new patient to the database, or 'Cancel' to return to the main screen.



New Patient Information

Name: Last First MI

Birthdate: / /

Gender: Select

Patient Id:

Insurance Provider:

Address Line 1:

Address Line 2:

Phone:

City:

State:

Zip:

Left Brain Target: None

Right Brain Target: None

Save Cancel

Figure 6. In order to add a new patient, complete the required fields and press 'Save.'

NOTE: The patient's left or right brain target must be changed from 'None' in order for the patient's ID to show up on the patient list on the Tablet.

Kinesia ProView™ Kit

Assembly

To setup the Kinesia ProView™ system:

1. Place the Tablet on the stand on an easily accessible table or desk.
2. Using the color-coded system from Table 1, plug the AC power cable into back middle of the Tablet stand by matching up the green markers.
 - Plug the other end of the AC power cable into a nearby wall electrical outlet.
3. Remove the Charging Pad from the carrying case and place it next to the Tablet. Plug the USB connector into the back middle of the Tablet stand by matching up the red markers.
4. Place the Finger Sensor on the Charging Pad such that the label is face down. The Finger Sensor will blink a green light when connected. Once fully charged on the Charging Pad, the Finger Sensor light will stop blinking and remain on.
5. Slide the power button down for one second on the right side of the Tablet indicated by a yellow marker.

NOTE: The Charging Pad must either be connected to the Tablet's USB port or the Tablet stand's USB port with the Tablet docked in order for the Finger Sensor to charge.

Chapter 4: Conducting a Programming Session

Creating Manual Task, Side Effect and Stimulation Configuration Templates

All institution users are able to add manual tasks, side effects and stimulation configurations on the Web Application for download to the Tablet for a programming session. Institution administrators are the only users who have privileges to delete items from the templates. All users will see the same template on the Tablet that exists on the Web Application. To add to the template on the web:

- Login to the Web Application and click the Admin tab
- Click the ProView Templates tab
- To add, enter the manual task or side effect or stimulation configuration in the appropriate text box, noting that the maximum number of characters per entry is 14 and click the 'Add' button. To add a stimulation configuration, click the 'Insert new configuration' button.
- Note the following limitations:
 - o No more than 50 manual tasks can exist on the template for an institution
 - o No more than 10 side effects can exist on the template for an institution
 - o No more than 10 stimulation configurations can exist for an institution
- To remove an item, click the trash icon next to the appropriate template item.
- When inserting a new stimulation configuration, the default values are 130Hz for the frequency, 60 μ S for the pulse width, - for contact 0, and all other contacts set to off. Frequency values can range from 2-255Hz (with increments of 1) and pulse width values can range from 10-450 μ S (with increments of 10). After changing desired values, click the "Insert" button to add it to the template, or "Cancel" to return to the template without updating it.

NOTE: If no side effects are added to the template on the website, a entry of "None" will appear on the tablet. A side effect entry of "None" will also be available for selection on the tablet once customized side effects have been added to the website template.

Online Connectivity

Patient data recorded by the ProView Tablet will be uploaded to the Web Application via a mobile broadband sim card inserted in the bottom left side of the Tablet.

Once a broadband connection has been established as indicated by  in the top right of the Tablet screen, signal strength bars and upload/download arrows will be displayed. The tower symbol will be crossed out  if the connection has been lost or the sim card is removed from the Tablet.

Login and Patient Selection

In order to populate the patient list to conduct a programming session, you must first enter on the Tablet the same credentials (username and password) as when logging into the Web Application. Administration Options can also be accessed from this screen.



Figure 7. Tablet Log In Screen

NOTE: You need to reboot the Kinesia ProView™ Tablet after inserting a SIM card for the mobile broadband to connect again.

NOTE: After 15 minutes of inactivity from any screen, you will automatically be returned to the log in screen. The previous programming session can be resumed by logging back in.

If a wireless broadband connection is available as shown by the signal strength indicator at the top right of the screen and the username and password are valid, the patient list will automatically be populated displaying the patient ID and last and first names.

- Select the name of the patient being programmed and then press “Select” to continue, or “Refresh” to download again the patient list from the Web Application.
- The number of sessions pending upload if network connectivity is not available will also be displayed on this screen

NOTE: You have five password attempts to log into the Tablet when a network connection is present. If you are unable to login on the Tablet, attempting to log into the Web Application will inform you whether your password must be reset.

If a wireless broadband connection is NOT available after attempting to log in, an “Offline” button will appear at the bottom of the log in screen.

- Press the “Offline” button and enter the access key, which will be separately provided to your institution administrator at the time of system purchase.
- The patient list (patient ID only) from the previous successful network log in on that Tablet will be viewable.

Session Setup

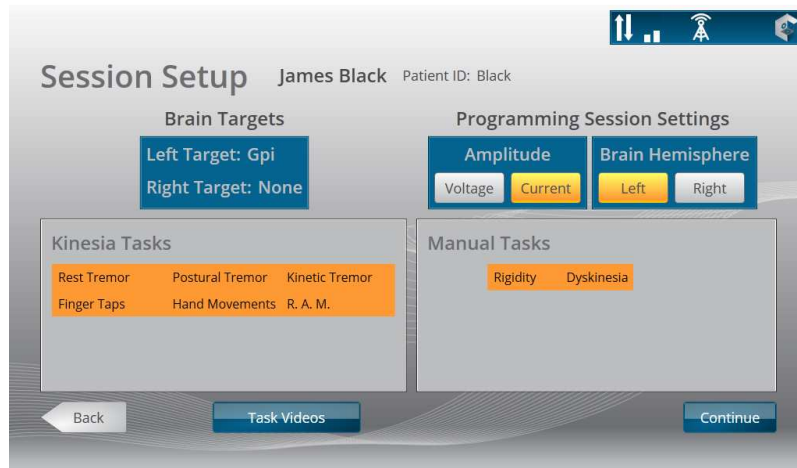


Figure 8. Tablet Programming Session Setup Screen

Once successfully logged in and having selected a patient, the following information will be displayed:

- First and Last Name
- Patient ID
- DBS Implants: Left Target and/or Right Target

Kinesia Tasks can be selected for evaluation during the DBS programming session:

- Rest Tremor
- Postural Tremor
- Kinesia Tremor
- Finger Taps
- Hand Movements
- Rapid Alternating Movements (R.A.M.)

Manual Tasks (which can be customized on the Web Application) are evaluated without the Finger Sensor by the user conducting the programming session.

Programming Session Settings must be customized for each individual programming session:

- Amplitude: constant voltage or constant current
- Brain Hemisphere: Left or Right

Instructional videos of the Kinesia Tasks can be viewed by pressing “Task Videos”. Audio can be played in English, German, or Spanish.

DBS Programming

The programming screen is broken up into three panels for: 1) Rating tasks and selecting stimulation settings (LEFT), 2) viewing Tuning Maps (CENTER), and 3) updating Tuning Maps (RIGHT).

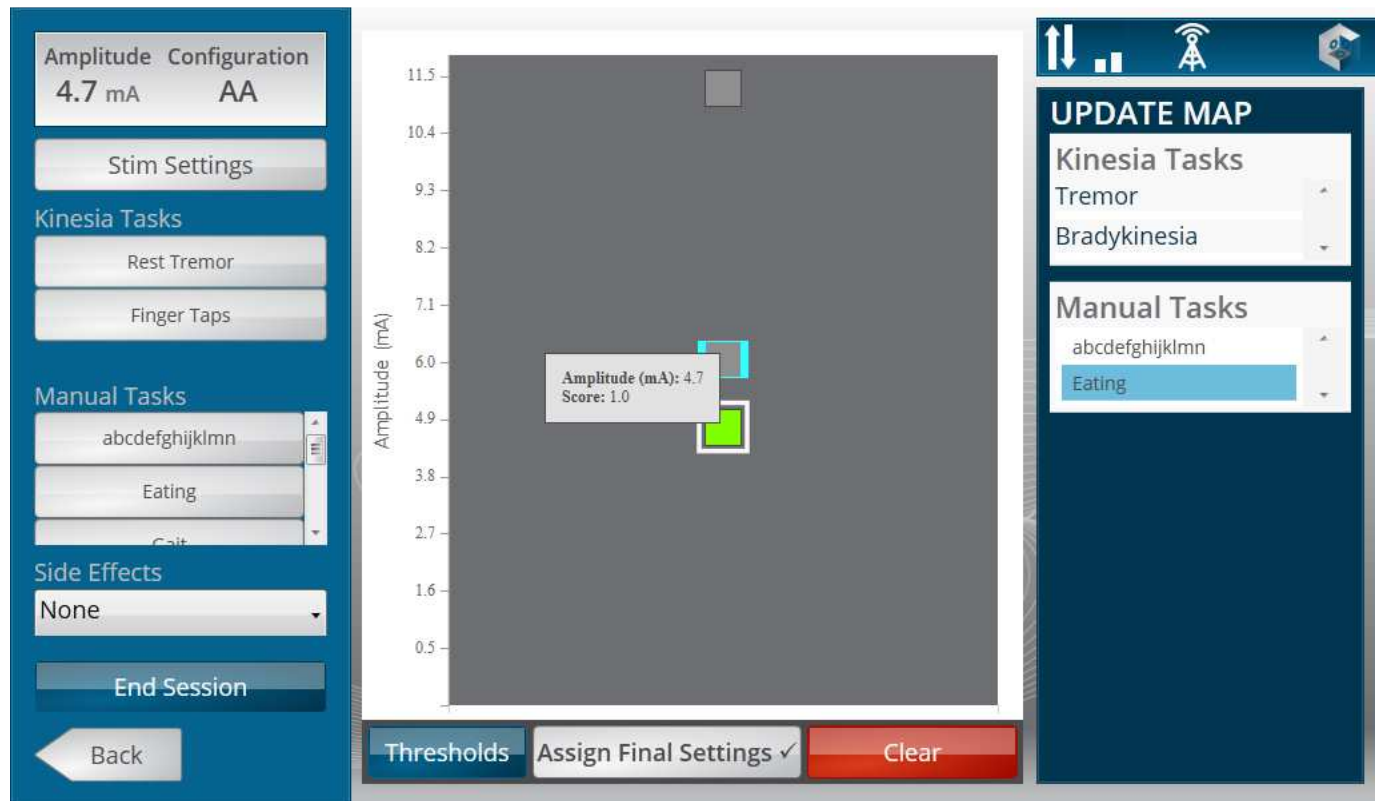


Figure 9. Tablet Programming Tuning Map Screen

1. Rating tasks and selecting stimulation settings (LEFT)

Stimulation Amplitude (V or mA) and Configuration are displayed at the top. Configuration is a text label specific to a stimulation polarity, pulse width, and frequency.

Set Stimulation Settings

Stimulation Amplitude and Configuration can be edited by pressing the 'Stim Settings' button. The Amplitude slider can be adjusted between 0-10.5V or 0-25.5mA, depending on the type of stimulation configured on the patient's implant. Pressing '+' and '-' will increase or decrease the amplitude by 0.1.

- The Stimulation Configuration can be switched between one of ten selections that can be customized on the Web Application or on the Tablet
- On the Tablet, the user can add new (+), edit existing (✎), and delete stimulation configurations (✖).

- When adding or editing a stimulation configuration, an ID (limited to 2 characters) is required. You can also add a description (limited to 120 characters) and enter off, + or – for contacts 0-8. Frequency (Hz) values can be increments of 1 from 2-255 and pulse width (µsec) values can be increments of 10 from 10-450.
- To test a selected stimulation configuration, click .

NOTE: If there are no settings defined in an institution's web-based template, one default setting will be added to the new tablet session with the default values of: Label "A", Contact 0 negative, all other contacts off, Frequency 130Hz, Pulse Width 60 microseconds.

NOTE: Stimulation configuration IDs must be unique, regardless of case (i.e. you cannot enter both A and a as IDs).

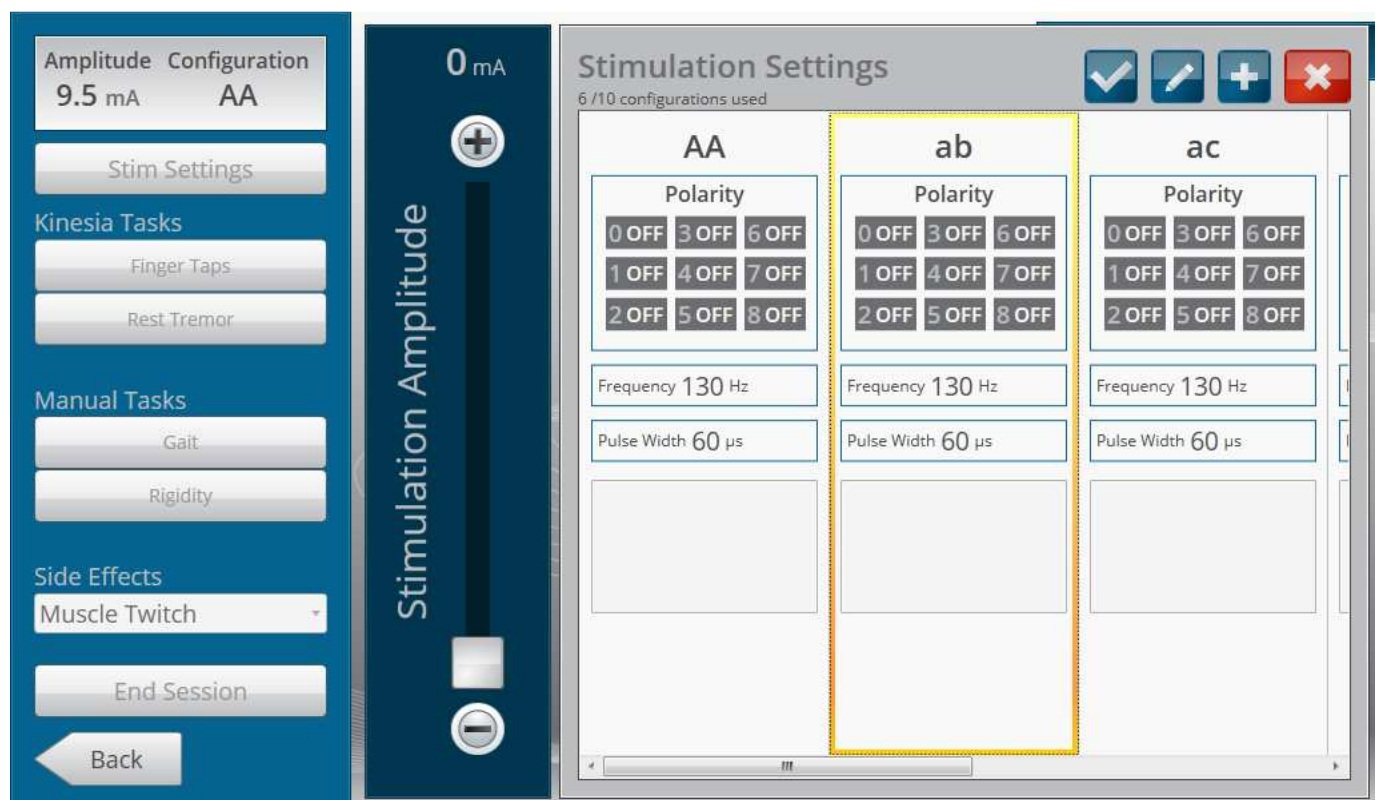


Figure 10. Tablet Assign Stimulation Settings Screen

Assess Kinesia Task

In order to evaluate a Kinesia Task, make sure that the patient is wearing the Finger Sensor on the side contralateral to the brain target being tested. Press the desired task button to begin the evaluation.

- Press 'Start Task' to begin the 15-second countdown. Motion data from the Finger Sensor will automatically stream to the Tablet as the patient is performing the task.
- Once the timer has reached 0 seconds,
 - A 0.0 (no severity) to 4.0 (high severity) score will automatically be calculated.

- Press 'Start Task' to repeat the task, 'Accept' to return to the main programming screen with the updated Tuning Map or 'Cancel' to return to the programming screen without updating the Tuning Map.



Figure 11. Tablet Perform Kinesia Task Screen

WARNING: Before evaluating a Kinesia Task, confirm that the Stimulation Amplitude and Configuration on the top left of the Tablet screen match the settings entered on the patient's stimulator.

NOTE: The Rest, Postural, and Kinetic Tremor Tasks will each generate a single tremor severity score while the Finger Taps, Hand Grasps, and Rapid Alternating Movements Tasks will each generate three scores: speed, amplitude, and rhythm deficits.

NOTE: The Rest Tremor Kinesia Task displays a Stroop Test instead of the timer countdown. Show the patient the screen during this evaluation with the instructions to speak the color the word is displayed in out loud, instead of the written word.

NOTE: If the Tablet is unable to connect to the Finger Sensor (e.g. sensor on Charging Pad, battery empty, communication issue), a message will appear on the screen to either 'Retry' the connection, 'Try Alternate Sensor,' or 'Cancel' to return to the main programming screen. The two Finger Sensors (current sensor and alternate) are paired with the specific Tablet in Administration Options from the Login Screen.

Rate Manual Task

In order to rate a Manual Task, press the desired task name and

- Select a 0 (no severity) to 4 (high severity) integer rating.
- Press 'Save' to return to the main programming screen with the updated Tuning Map.
- Press 'Cancel' to return to the main programming screen without updating the Tuning Map.



Figure 12. Tablet Rate Manual Task Screen

WARNING: *Before evaluating a Manual Task, confirm that the Stimulation Amplitude and Configuration on the top left of the Tablet screen match the settings entered on the patient's stimulator.*

Indicate Side Effect

In order to select a Side Effect, press the dropdown menu from the main programming screen and select the desired side effect.

- The Tuning Map will update with a bright blue border at the present stimulation amplitude and configuration.
- Deselect the Side Effect by selecting the marked box and choosing 'None.'

WARNING: *Before indicating a Side Effect, confirm that the Stimulation Amplitude and Configuration on the top left of the Tablet screen match the settings entered on the patient's stimulator.*

NOTE: *A side effect can be added to the Tuning Map without a Kinesia or Manual Task score.*

Clear Tuning Map Square

To remove a tuning map square if you performed an assessment at a different amplitude than the current settings, click on that square. Click on the red 'Clear' button. A confirmation will appear that allows you to either return without clearing ('Cancel') or clear the square ('OK'). Note that only scores can be cleared—side effects can only be cleared by selecting 'None' (or the blank option if there are custom side effects in the dropdown list).

Assign Final DBS Settings

To assign the selected DBS settings for the patient to a point on the tuning map, click a scored box at the appropriate stimulation configuration and amplitude. Then click the Assign Final Settings button. A checkmark will appear on that square. To remove the checkbox, click the square again and click the Assign Final Settings button again. An alternative would

be to select a different tuning map square (if that is the actual assigned setting) and click the Assign Final Settings button. This checkmark will also appear on the Web Application and the final settings will be indicated in an exported tuning map report.

End Session

Once the programming session is complete and no other stimulation settings will be evaluated, press 'End Session'. A message displaying "Are you sure? This message will be marked for upload and no further changes can be made" will appear.

Press the 'OK' button to continue to the log in screen, and all data recorded during the programming session will be uploaded to the Web Application if broadband connection is available. If not, data upload will commence once connectivity is re-established.

Press the 'Cancel' button to return to the programming screen.

2. Viewing Tuning Map (Center)

The Tuning Map is graphical representation of a patient's response to DBS across a range of stimulation amplitude (vertical axis) and configuration (horizontal axis) combinations. Kinesia Task scores will appear as color-coded squares according to 0 (green), 2 (yellow), and 4 (red) scores and interpolated in-between ratings while Manual Tasks will appear as either 0 (green), 1 (green-yellow), 2 (yellow), 3 (orange), or 4 (red).

- Press a desired square on the Tuning Map to complete the following:
 - o Display an information box of the stimulation amplitude and severity score. The Side Effect type will also be displayed if previously indicated.
 - o Assign therapeutic thresholds at the selected combination of stimulation amplitude and configuration. Press 'Assign' to bring up a new window.
 - Toggle the 'Efficacy' threshold (amplitude at which symptom severity improves to demonstrate therapeutic benefit).
 - Toggle the 'Side Effect' threshold (amplitude at which the stimulation-induced side effects manifest)
 - Press 'Accept' to return to the main programming screen with the Tuning Map updated.
 - Press 'Cancel' to return to the main programming screen without the Tuning Map updated.

NOTE: Each stimulation configuration should have at most one Efficacy and/or one Side Effect threshold assigned.

NOTE: Efficacy thresholds are only assigned to the stimulation amplitude and configuration for that specific Kinesia or Manual Task Tuning Maps while Side Effect thresholds are assigned across all Kinesia or Manual Tasks.

3. Updating Tuning Maps (RIGHT).

The Tuning Map will display scores for one Kinesia or Manual Task at a time. The Tuning Map can be updated by selecting the corresponding task.

Uploading Programming Session to Web Application

In order to view a study session on the Web Application, the patient data stored on the Tablet needs to be transferred to the Kinesia Web Application.

Automated Upload

When the user presses 'End Session' on the main programming screen and confirms that selection, all patient data from that programming session will automatically be uploaded in the background to the Web Application if network connectivity is available. Once the upload is complete, all patient data for that programming session will be erased from the Tablet.

If network connectivity is NOT available, the programming session will be stored on the Tablet until network connectivity is resumed.

Manual Upload

Patient data from programming sessions that are stored on the Tablet can be uploaded to the Web Application only if the user logs in when connected to the network, not using the 'offline' mode. Once the username and password have been confirmed with the Web Application and the patient list is population, the screen will display the number of pending programming sessions pending upload. Once uploaded, those programming sessions will be erased from the Tablet.

Reviewing a Programming Session on the Web Application

Once a study has been uploaded, log in to the Web Application using a supported web browser.

1. Press the 'Studies' button on the top of the screen.
2. Navigate to the report based on the patient name, ID, and session upload date and time.
3. Press on 'Archived ProView™ Report' or 'New ProView™ Report Ready' to view a customizable study summary.



Figure 13. Web Application Programming Session Report Screen

The Tuning Map can be customized by:

- Selecting one Kinesia Task or Manual Task Score Type to display on the Tuning Map.
- Select a Tuning Map Square to display the score, side effect type, and/or threshold type.
- Click and drag the mouse to zoom in. Double click to zoom out.

Downloading a ProView Report

To download an Excel/CSV file that contains information about the session, click to view a ProView report on the web application. Then click the 'Export Session Data' button. You are able to save or open the spreadsheet.

Chapter 5: Frequently Asked Questions (FAQs)

Question: I entered my username and password correctly on the log in screen; however, I continue to receive an error message. What do I do now?

Answer: First, confirm that the sim card is inserted into the Tablet and that the signal tower indicator on the top right of the Tablet screen is not crossed out. Second, confirm that you are still able to log into the Web Application using the same username and password. If prompted to reset your password, please complete that process before logging into the Tablet again.

Question: Why can't I connect to the Finger Sensor to conduct a Kinesia Task?

Answer: First, confirm that the green LED is blinking on the Finger Sensor. The wireless connection between the Tablet and Finger Sensor will shut off after 15 minutes of inactivity. If the LED is not blinking, return the Finger Sensor to the Charging Pad, wait several seconds before removing it. If the LED light does not begin blinking, the battery must be recharged. Second, confirm that the MacID in the Administration Options screen correctly matches the Finger Sensor you are trying to use.

Question: Why doesn't the completed programming session appear on the Web Application?

Answer: First, try refreshing the website page. If the ProView study still doesn't appear, confirm on the Tablet that there are no pending studies that have not been uploaded yet. This can be verified by entering your username and password on the log in screen and viewing the number of "sessions to upload" displayed above the patient list.