

Tuning Maps for Deep Brain Stimulation Trials



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Product Development Manager
May 23rd, 2013

WILL BEGIN
AT 12:00 EST

Talking Points

1. Market Opportunities
2. DBS Tuning Maps
3. Kinesia ProView
4. Clinical Trial Data and Lessons
5. Kinesia Technology Value Added

Market Opportunities

Parkinson's Disease: Not So Simple!

SYMPTOMS

Tremor

Dyskinesias

Bradykinesia

Rigidity

Gait

Non-Motor et al.

TREATMENTS

Levodopa

Rasagiline

Duodopa

DBS

Exercise

Neuroprotection?

DEMOGRAPHICS

Over 60

Growing Incidence

Neurodegeneration

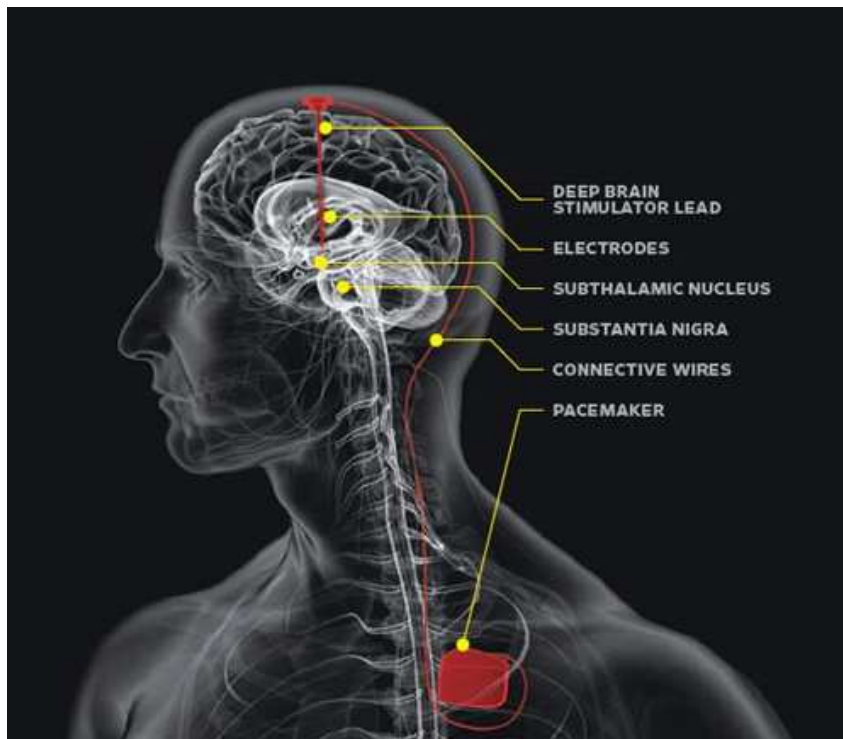
Medicare

VA

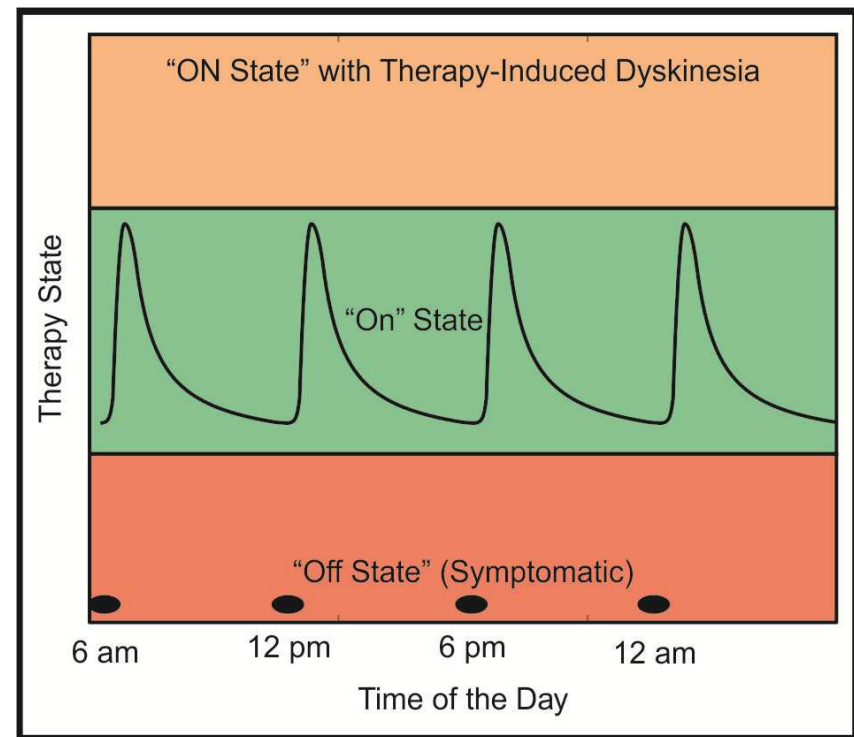
Access to Care

Deep Brain Stimulation

Targeted Electrical Stimulation of the Brain



Therapy State Management



Challenges with DBS Programming



Clinician Training



Paper Trails



Symptom Tracking



Sensitivity

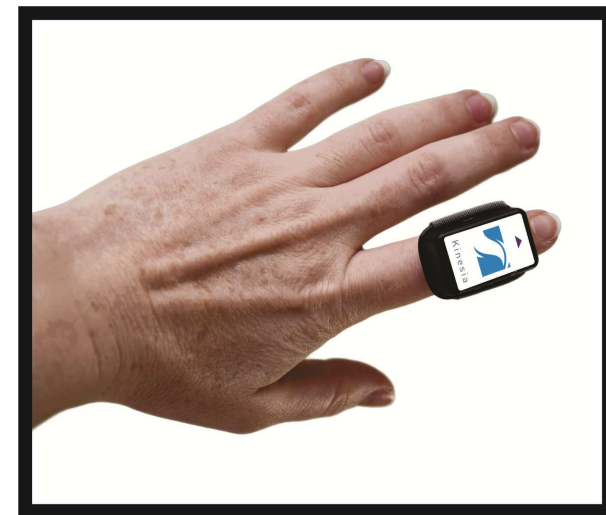
DBS Tuning Maps

Quantitative Motor Assessment

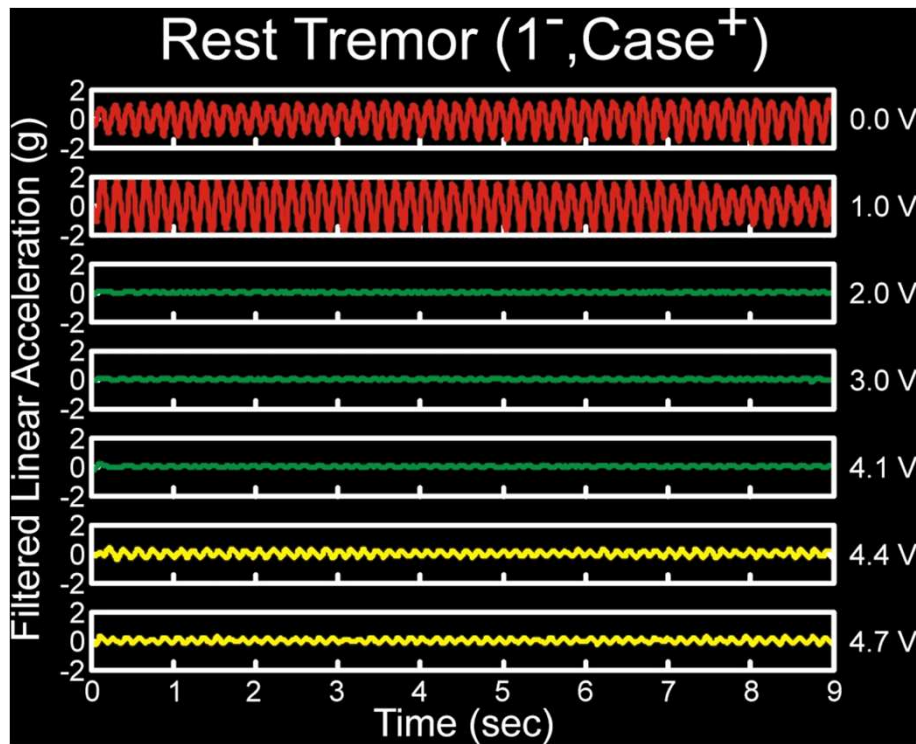
TRADITIONAL



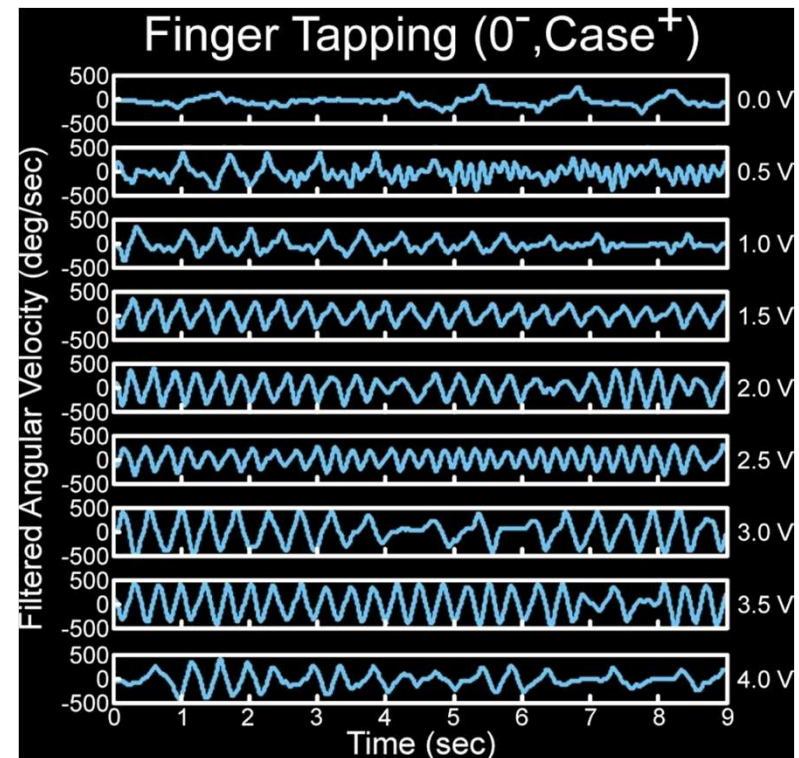
HIGH SENSITIVITY



Kinematic Response to DBS



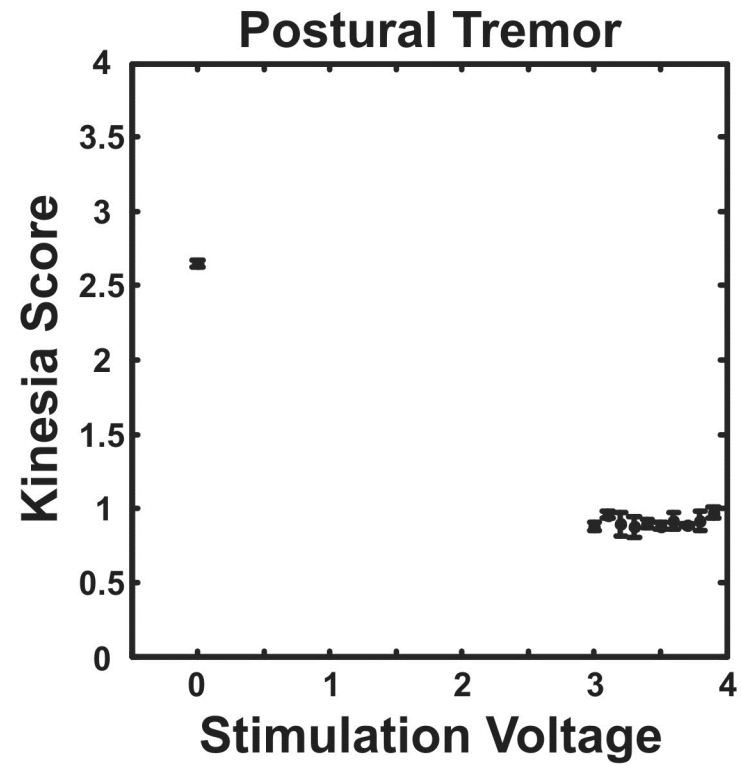
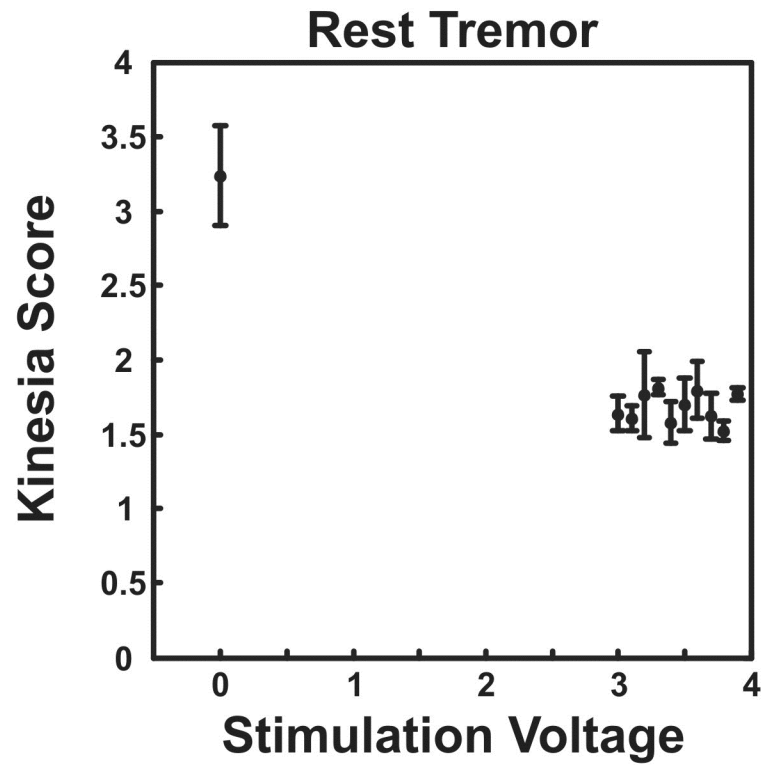
Tremor tuning produces sudden, dramatic effects



Bradykinesia tuning produces gradual, fine effects

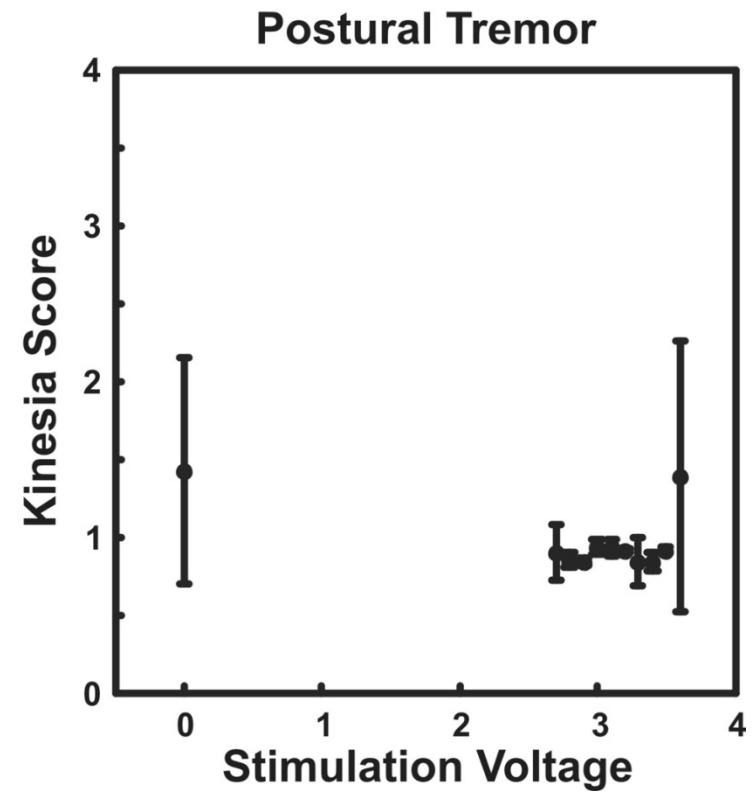
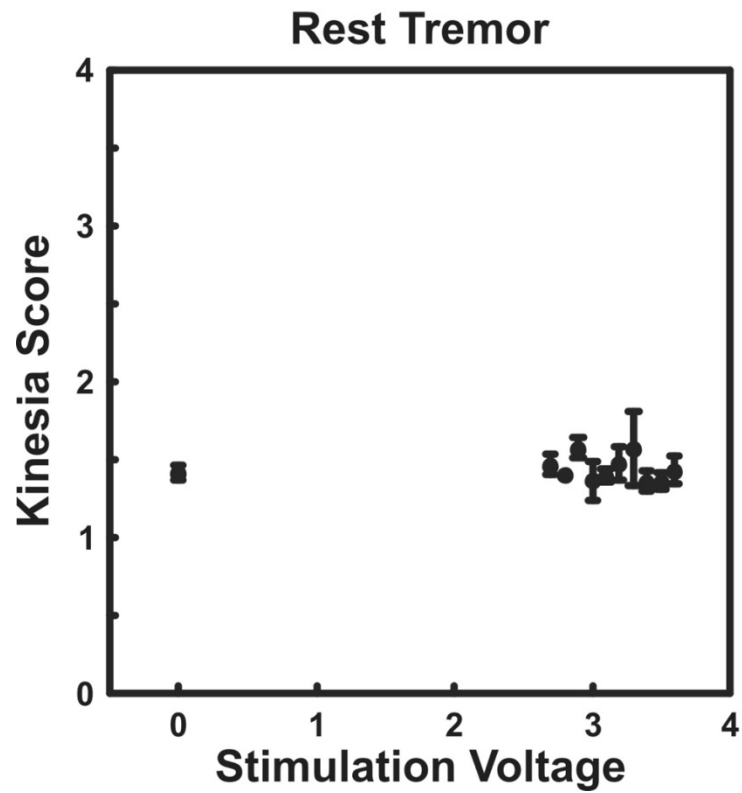
Monopolar Symptom Response

Patient 1



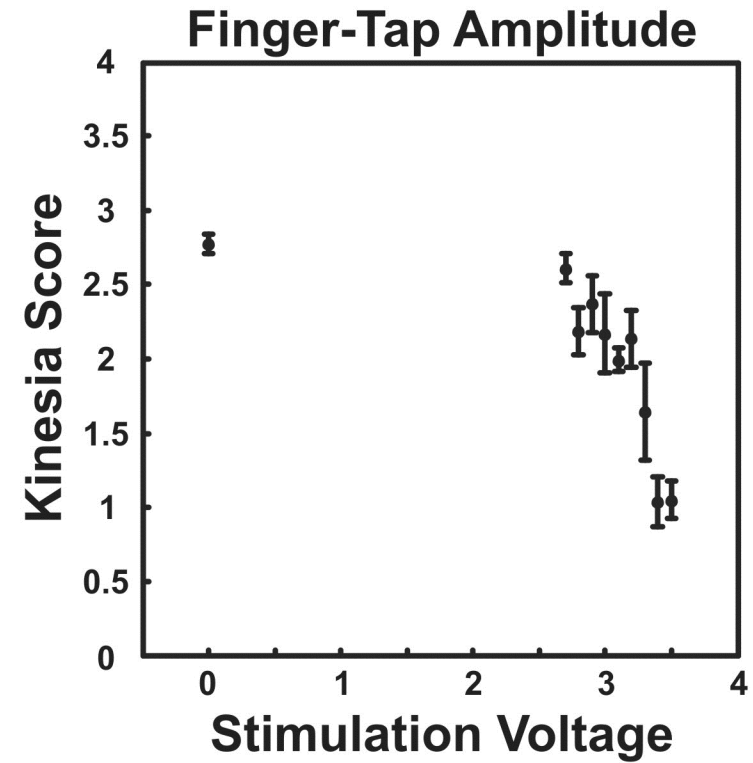
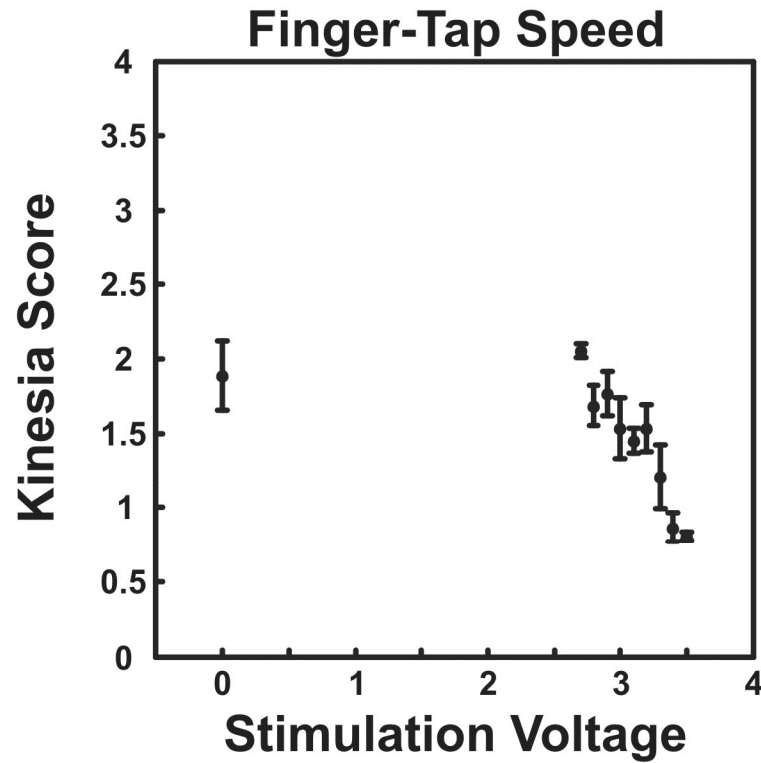
Monopolar Symptom Response

Patient 3



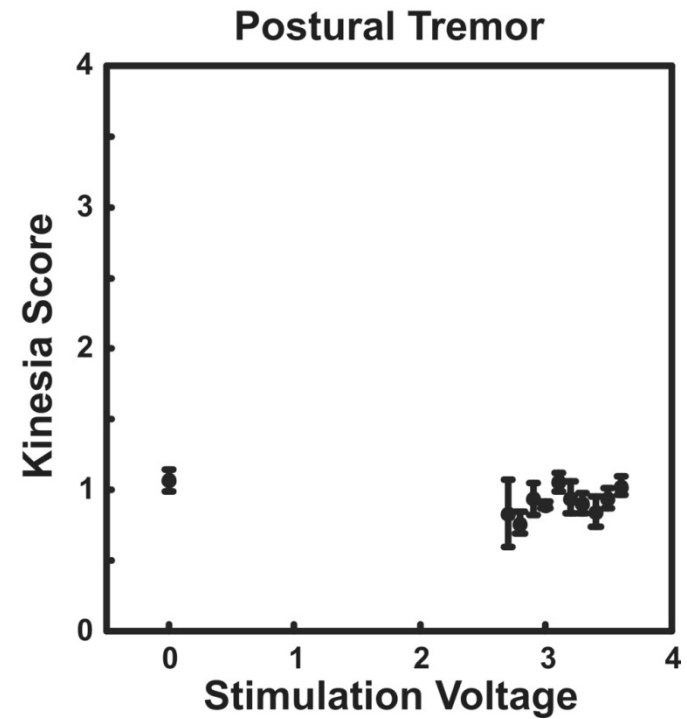
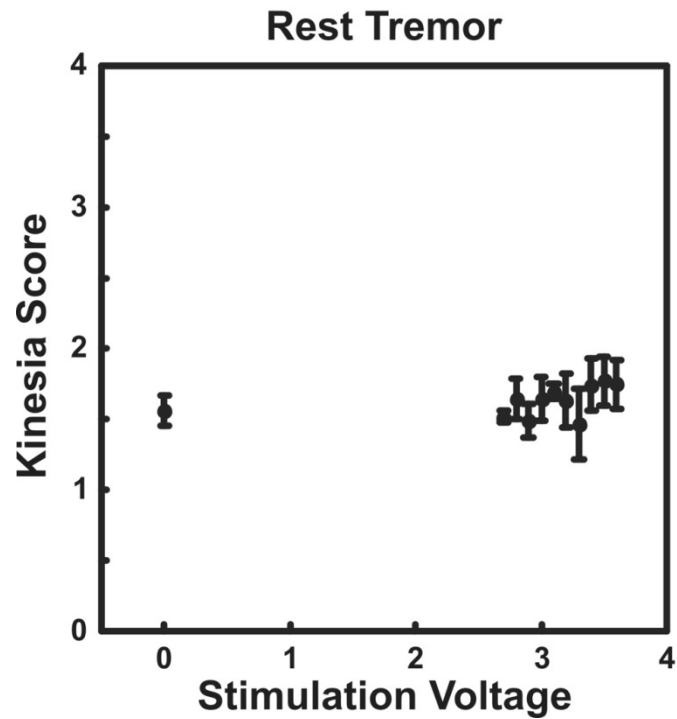
Monopolar Symptom Response

Patient 3



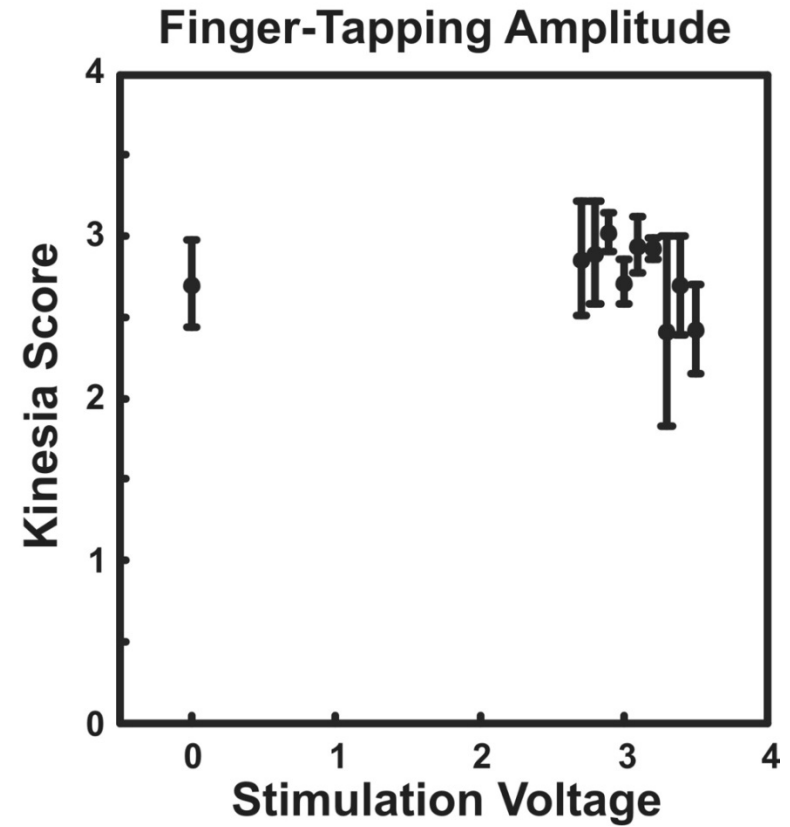
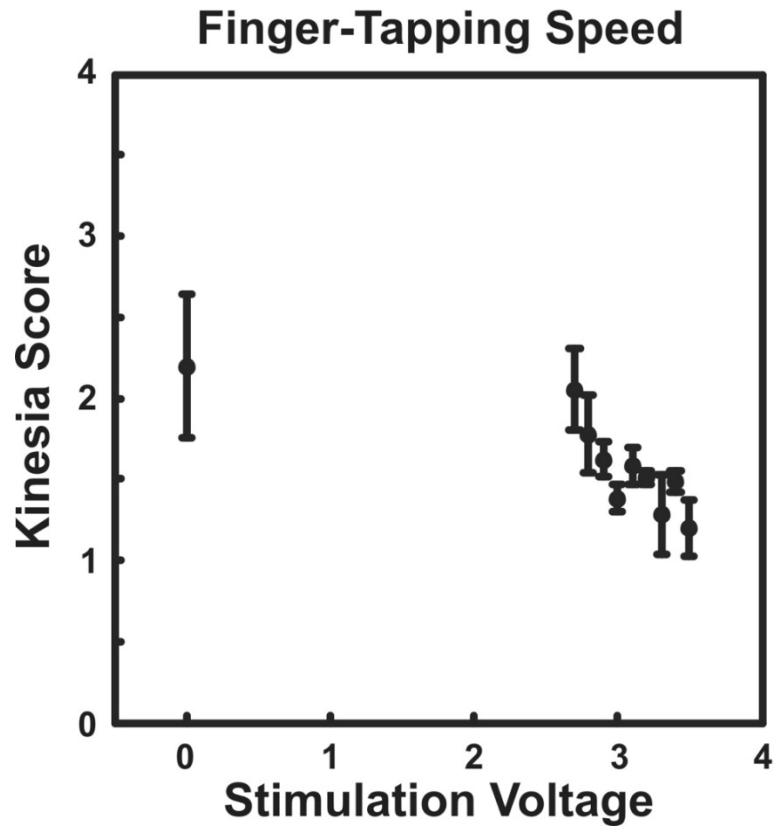
Monopolar Symptom Response

Patient 8

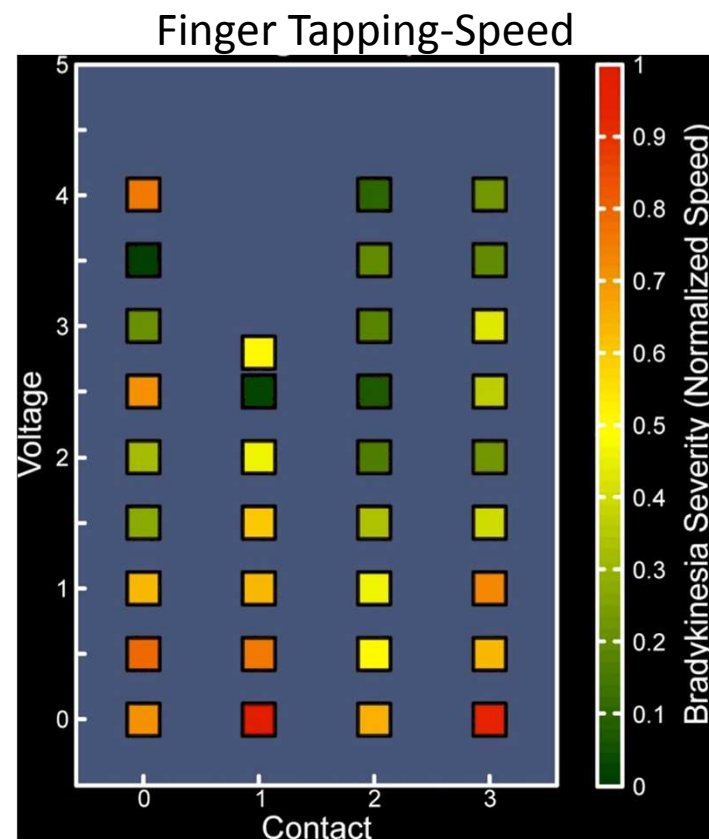
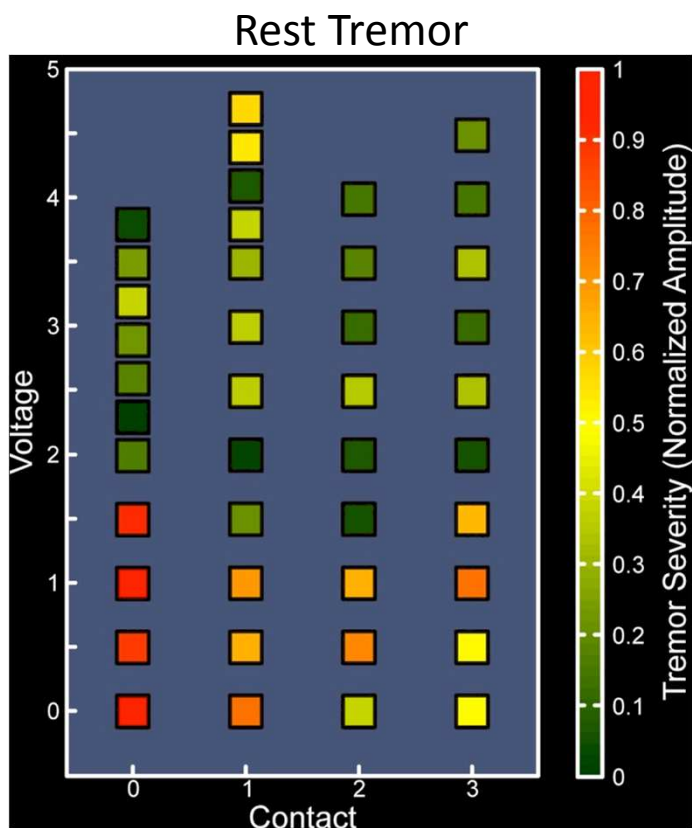


Monopolar Symptom Response

Patient 8



Tuning Maps: Visualizing the Programming Space



Peer-Review Publication



Kinematic optimization of deep brain stimulation across multiple motor symptoms in Parkinson's disease

Mera TO, Vitek JL, Alberts JL, Giuffrida JP

J. Neurosci. Methods, vol. 198, no. 2, pp. 280–286, 2011.

Kinesia ProView Product Demo



Commercialization

FDA Clearance to Market

- 510k Clearance to Market
 - Intended Use
 - Kinesia 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.

ISO, CE Mark, and TGA

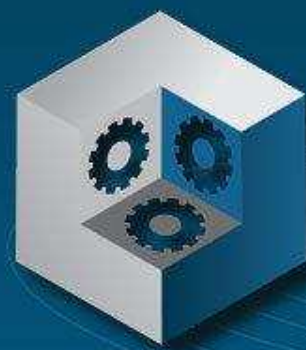
- ISO 13485:2003
- European Medical Device Directive 93/42/EEC
- Canadian Medical Device Conformity Assessment System
- EMERGO EUROPE: Authorized Agent



Standards and Testing

- Tested to IEC 60601 Standards
- Complies with FCC Part 15 Rules
- HIPAA Compliant

U.S. Patent Protection



Kinesia ProView



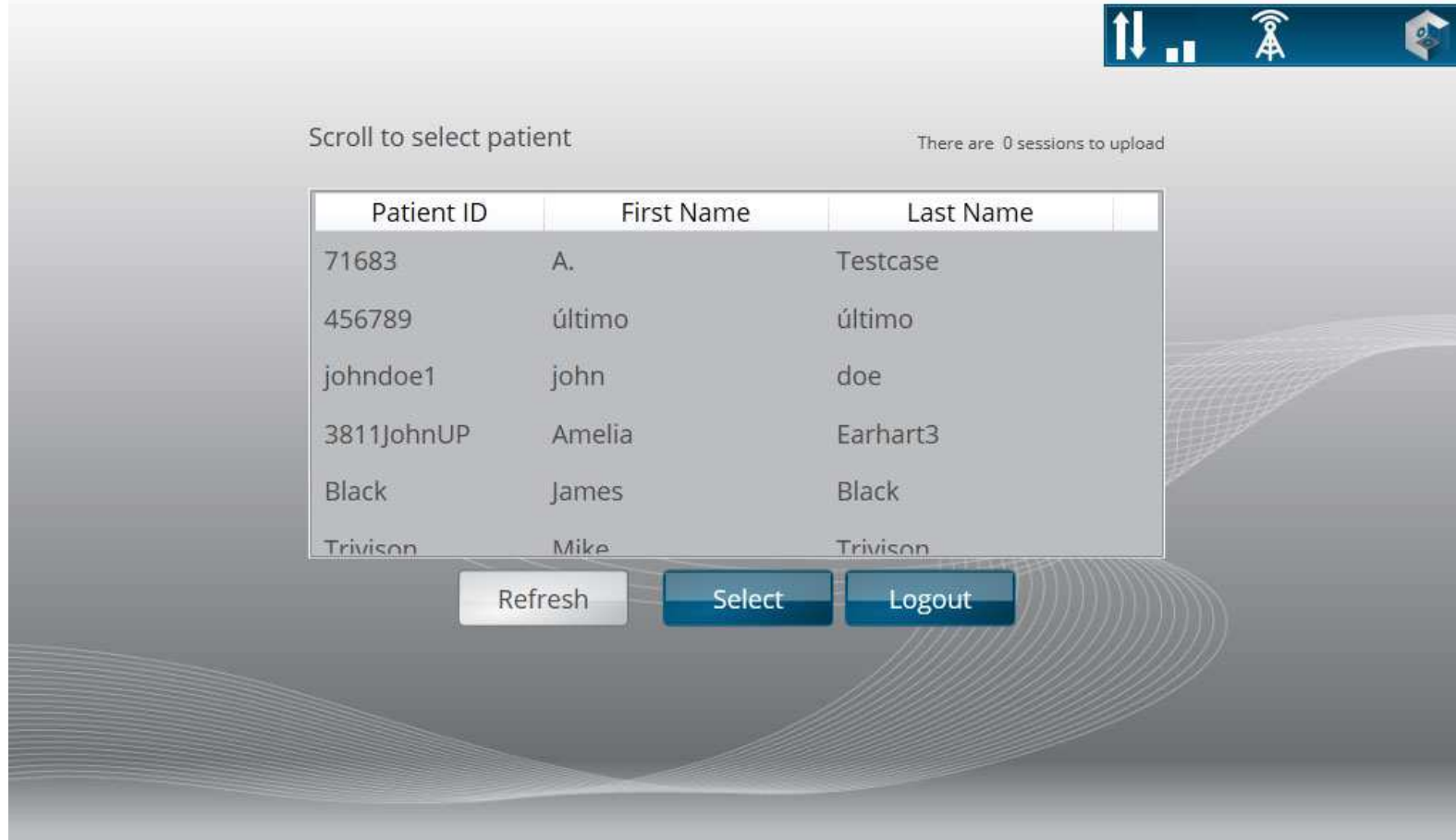
HIPAA-Compliant Log-In

User Name

Password

Admin Login

Institute-Specific Patient List



Scroll to select patient

There are 0 sessions to upload

Patient ID	First Name	Last Name
71683	A.	Testcase
456789	último	último
johndoe1	john	doe
3811JohnUP	Amelia	Earhart3
Black	James	Black
Trivison	Mike	Trivison

Refresh Select Logout

Programming Session Setup

Session Setup Amelia Earhart Patient ID: 3811

Brain Targets
Left Target: STN
Right Target: Gpi

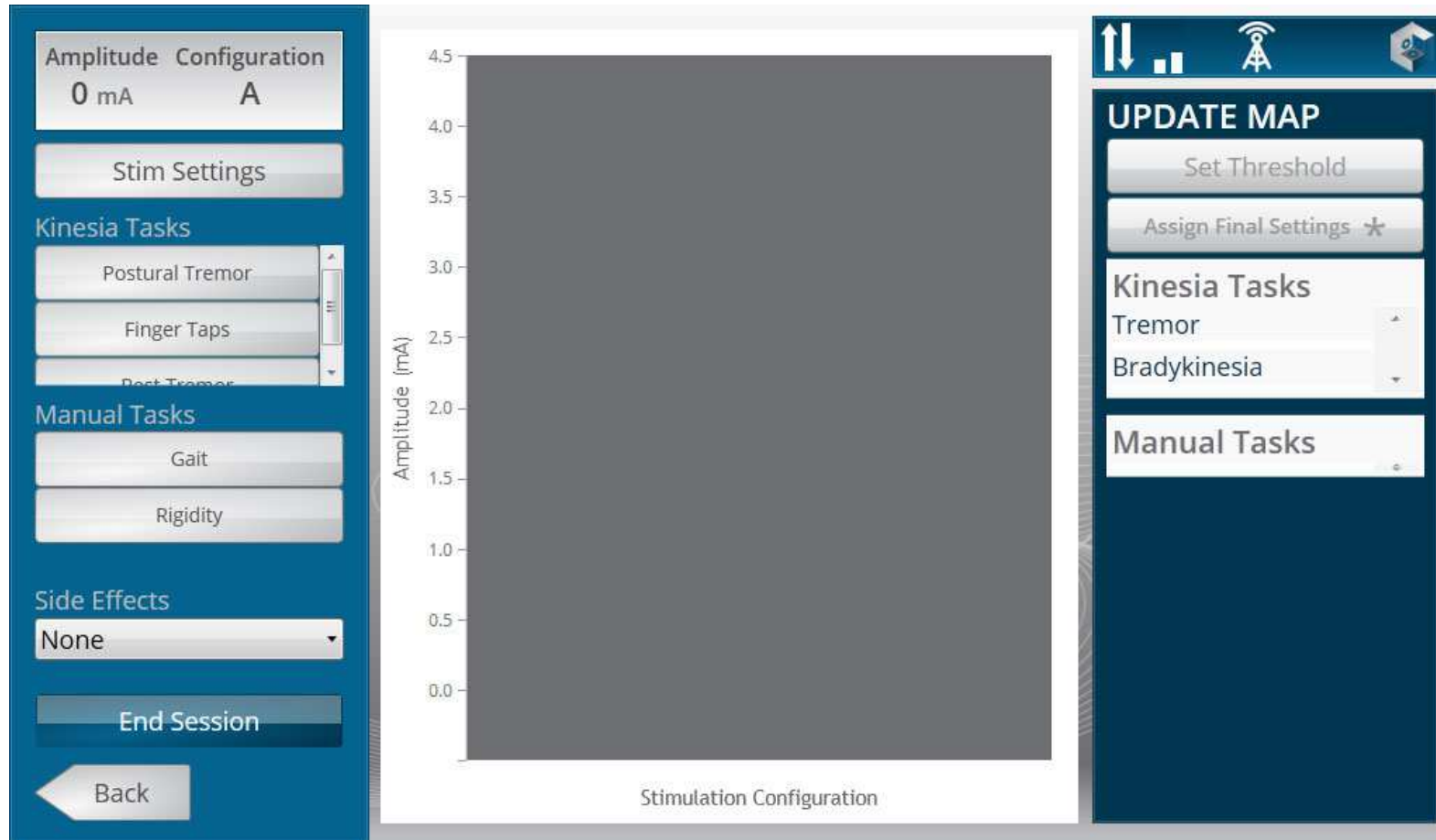
Programming Session Settings
Amplitude: Voltage, Current
Brain Hemisphere: Left, Right

Kinesia Tasks
Rest Tremor, Postural Tremor, Kinetic Tremor
Finger Taps, Hand Movements, R. A. M.

Manual Tasks
Gait, Rigidity

Back Task Videos Continue

Tuning Map Screen



Stimulation Setting Selection

The interface is divided into three main vertical sections:

- Left Panel (Blue):** Contains navigation and task selection options.
 - Amplitude Configuration: 0 mA, A
 - Stim Settings button
 - Kinesia Tasks: Postural Tremor (checked), Rest Tremor, Flexor Task
 - Manual Tasks: Gait, Rigidity
 - Side Effects: Muscle Twitch
 - End Session button
 - Back button
- Middle Panel (Dark Blue):** Stimulation Amplitude control.
 - 0 mA display
 - Vertical slider with '+' and '-' buttons
- Right Panel (Light Gray):** Stimulation Settings dialog box.
 - Accept button
 - Label: B1 (max: 2 characters)
 - Configuration A (left):
 - Polarity: 00 OFF, 01 OFF, 02 OFF, 03 OFF, 04 OFF, 05 OFF, 06 OFF, 07 OFF, 08 OFF
 - Frequency: 130 Hz
 - Pulse Width: 60 μ sec
 - Notes: Notes on this configuration would go here
 - Edit button
 - Select button (highlighted in yellow)
 - Configuration B1 (center):
 - Polarity: 00 +, 01 -, 02 -, 03 OFF, 04 OFF, 05 OFF, 06 -, 07 OFF, 08 OFF
 - Frequency: 130 Hz
 - Pulse Width: 60 μ sec
 - Notes: These are configuration notes.
 - Edit button
 - Save button
 - Configuration A (right):
 - Polarity: 00 OFF, 01 OFF, 02 OFF, 03 OFF, 04 OFF, 05 OFF, 06 OFF, 07 OFF, 08 OFF
 - Frequency: 130 Hz
 - Pulse Width: 60 μ sec
 - Notes: Notes on this configuration would go here
 - Edit button
 - Select button

Sensor-Based Assessment



Sensor-Based Assessment

The screenshot displays a software interface for a clinical assessment. On the left is a blue sidebar with the following sections:

- Amplitude Configuration:** 10.4 mA, A
- Stim Settings:** A button labeled "Stim Settings".
- Kinesia Tasks:** Buttons for "Rest Tremor" and "Finger Taps".
- Manual Tasks:** A list of tasks with values 3, 42, and 5.
- Side Effects:** A dropdown menu set to "None".
- End Session:** A button labeled "End Session".
- Back:** A button with a left-pointing arrow labeled "Back".

The main window features a top status bar with icons for volume, signal strength, Wi-Fi, and a cube icon. The central panel is titled "Task: Finger Taps" and "Sensor One" with a green dot indicator. It includes:

- A "Start Task" button.
- A waveform graph showing a signal.
- A large blue box with the number "11".
- "Accept" (blue) and "Cancel" (red) buttons.
- A video feed at the bottom showing a person's hand tapping a blue sensor on a black leather couch.

Manual Task Assessment

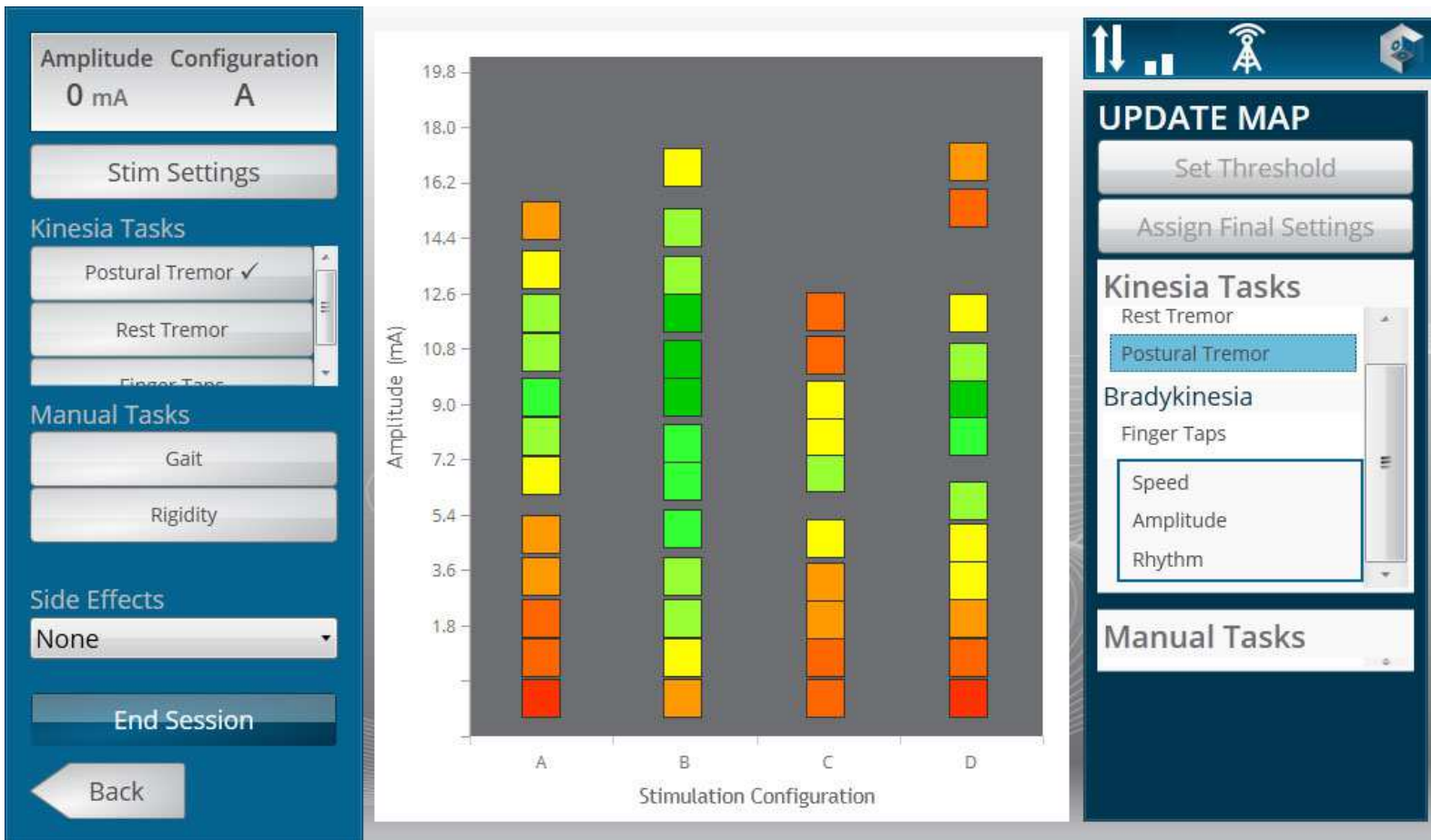
The screenshot displays a software interface for manual task assessment. On the left is a sidebar with the following sections:

- Amplitude Configuration:** Shows 0 mA and A.
- Stim Settings:** A button.
- Kinesia Tasks:** A list with 'Postural Tremor' checked, 'Rest Tremor', and 'Floor Tap'.
- Manual Tasks:** A list with 'Gait' and 'Rigidity'.
- Side Effects:** A dropdown menu currently showing 'Muscle Twitch'.
- End Session:** A button.
- Back:** A button with a left-pointing arrow.

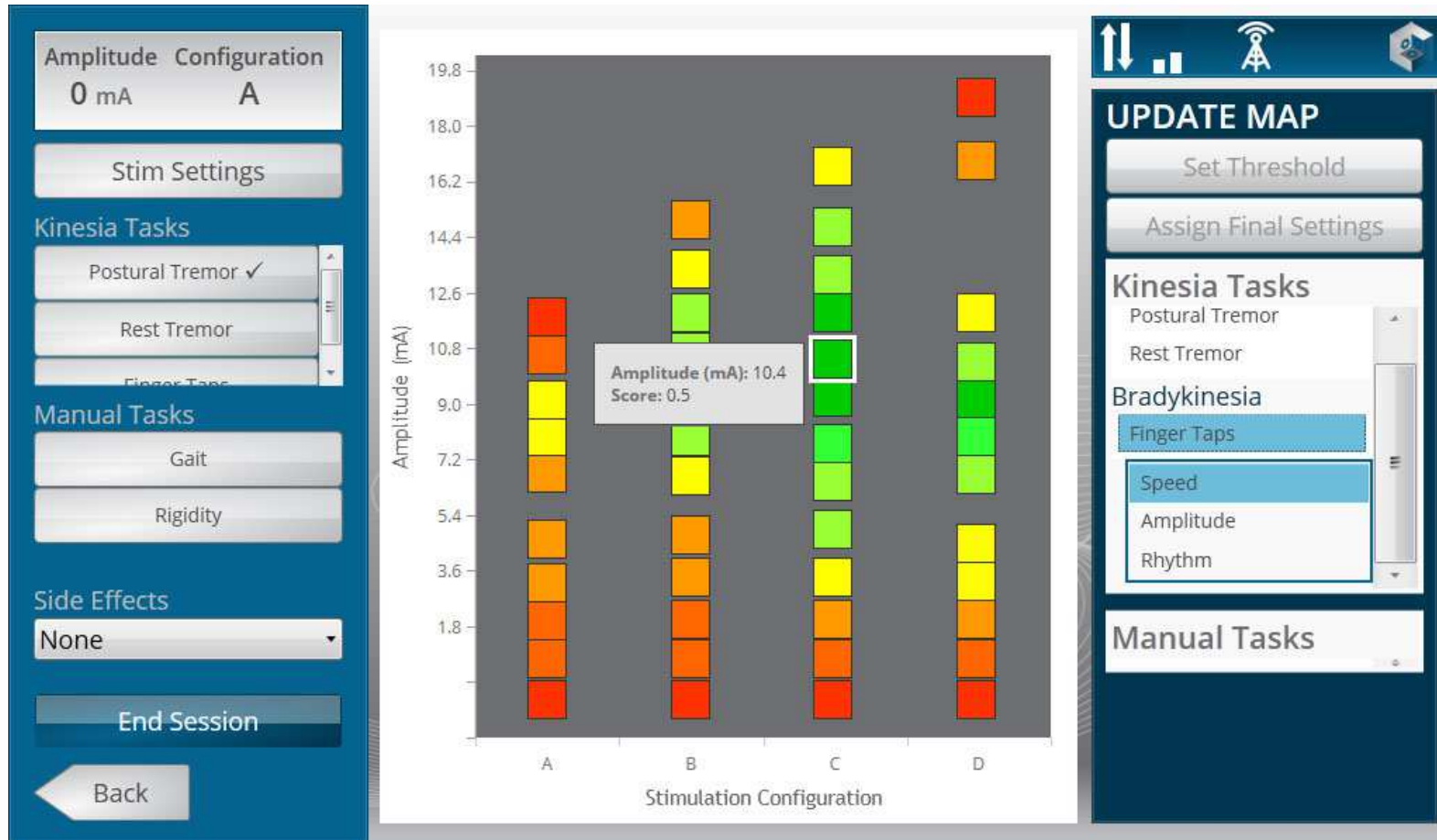
At the top right of the main area are icons for volume, signal strength, Wi-Fi, and a cube icon.

A 'Rigidity' dialog box is open in the center, featuring a scale from 0 to 4. The scale is represented by colored boxes: 0 (green), 1 (light green), 2 (yellow), 3 (orange), and 4 (red). The number '2' is highlighted with a white border. To the right of the scale are 'Save' and 'Cancel' buttons.

Populated Tuning Map



Context-Specific Information



Select Side Effect



Online Management

[Welcome admin](#) | [Log Out](#) | [Contact](#) | Institution:

[Overview](#) | [Patients](#) | [Studies](#) | [Upload](#) | [Admin](#)

Change the way you see PD

- 1 Create Study
- 2 Upload Study
- 3 Review Study

Setup Study
 Pending Upload
 Scoring In Progress
 New HomeView Report Ready
 Archived HomeView Report
 New ProView Report Ready
 Archived ProView Report
 Results per page: 10

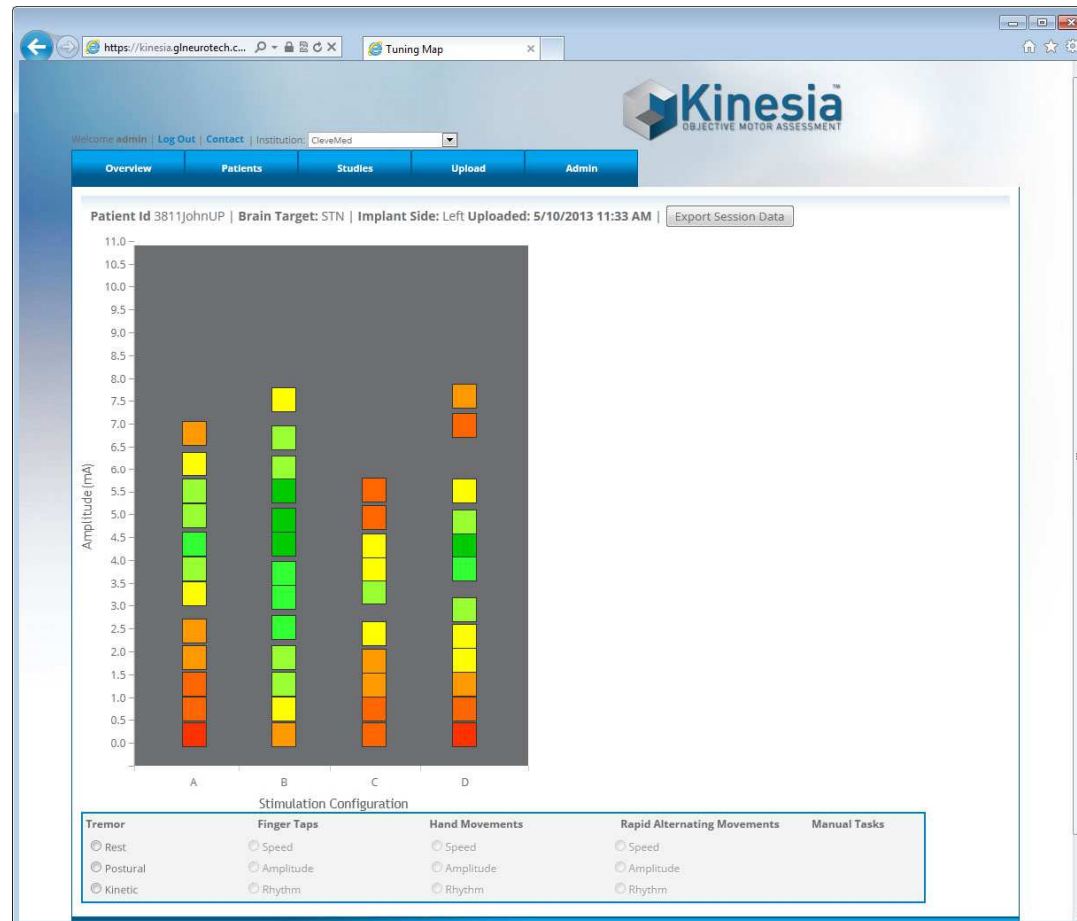
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New ProView Report Ready	Earhart3	Amelia	5/10/2013 11:33 AM		Review
New ProView Report Ready	Adhikari	Ashok	5/10/2013 11:22 AM		Review
Archived HomeView Report	Earhart	Amelia	5/10/2013 11:10 AM		Review
New ProView Report Ready	Adhikari	Ashok	5/9/2013 2:01 PM		Review
Setup Study	Trivison	Mike	5/9/2013 1:39 PM		
Archived ProView Report	Earhart3	Amelia	5/9/2013 1:38 PM		Review
Archived ProView Report	Earhart	Amelia	5/9/2013 1:34 PM		Review
New ProView Report Ready	Earhart	Amelia	5/9/2013 1:26 PM		Review
Archived ProView Report	Adhikari	Ashok	5/9/2013 1:19 PM		Review
Setup Study	Earhart3	Amelia	5/9/2013 1:13 PM		

1 2 3 4 5 6 7 8 9 10 ... >>

Language:

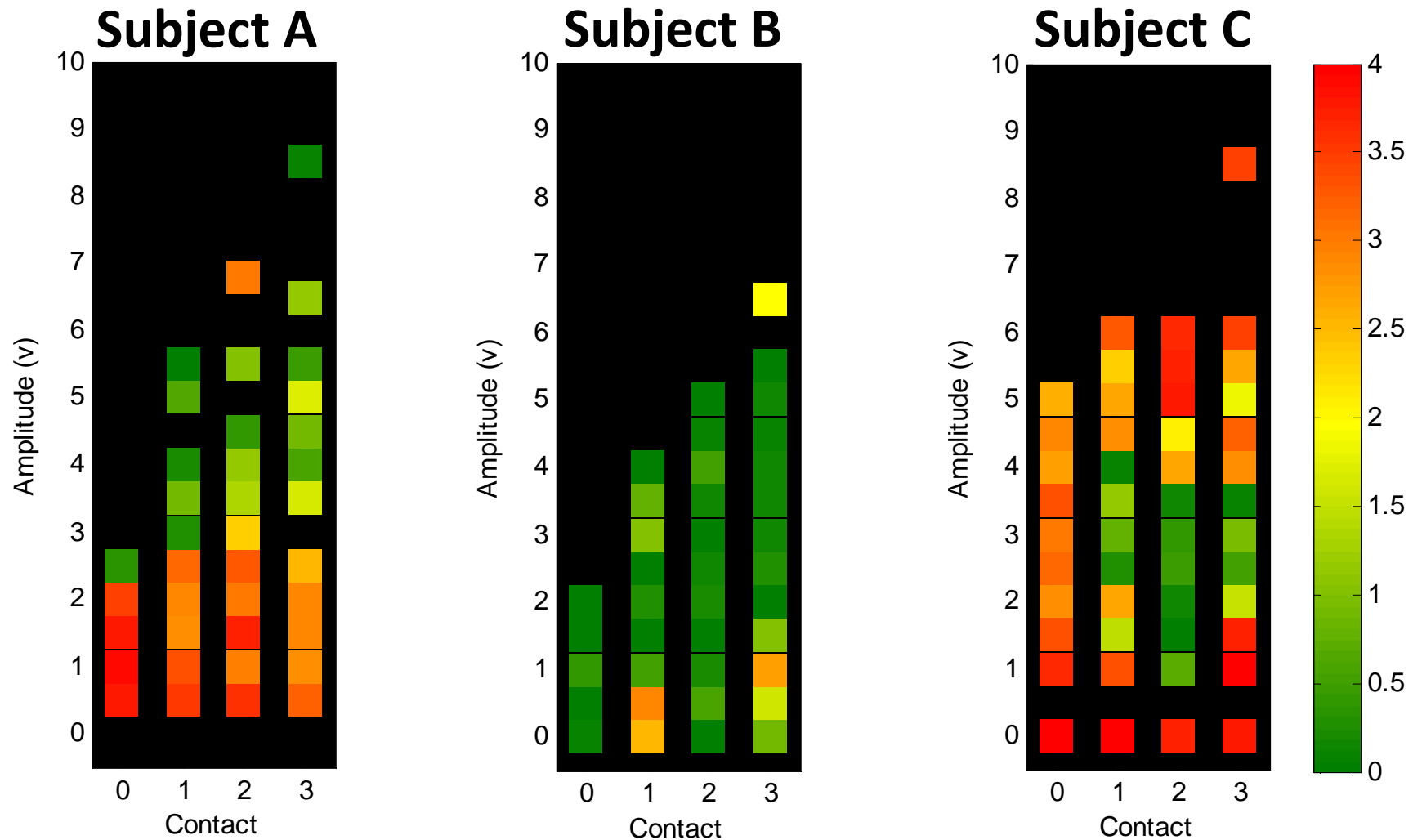
© 1998-2013 Great Lakes NeuroTechnologies | Version 4.5.326.17077

Online DBS Programming Reports



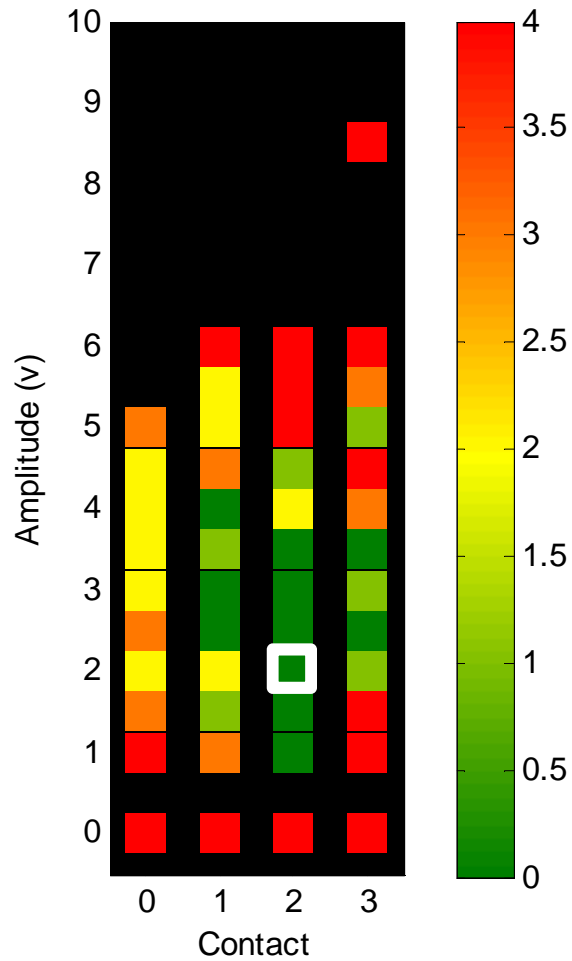
Clinical Trial Data and Lessons

Tuning Maps: Rest Tremor

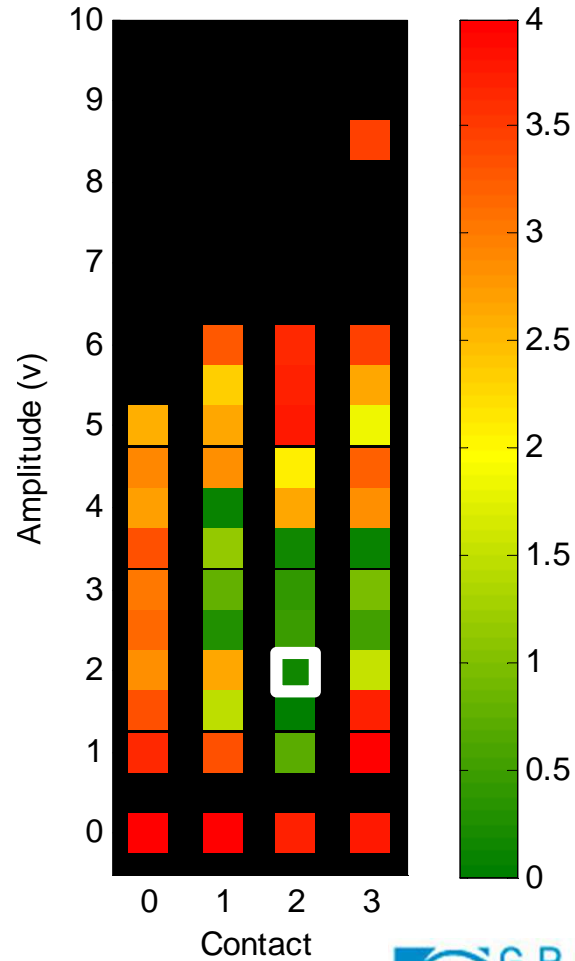


Subject 1: Rest Tremor

Clinician UPDRS



Kinesia ProView



Subject 1: Finger Tap

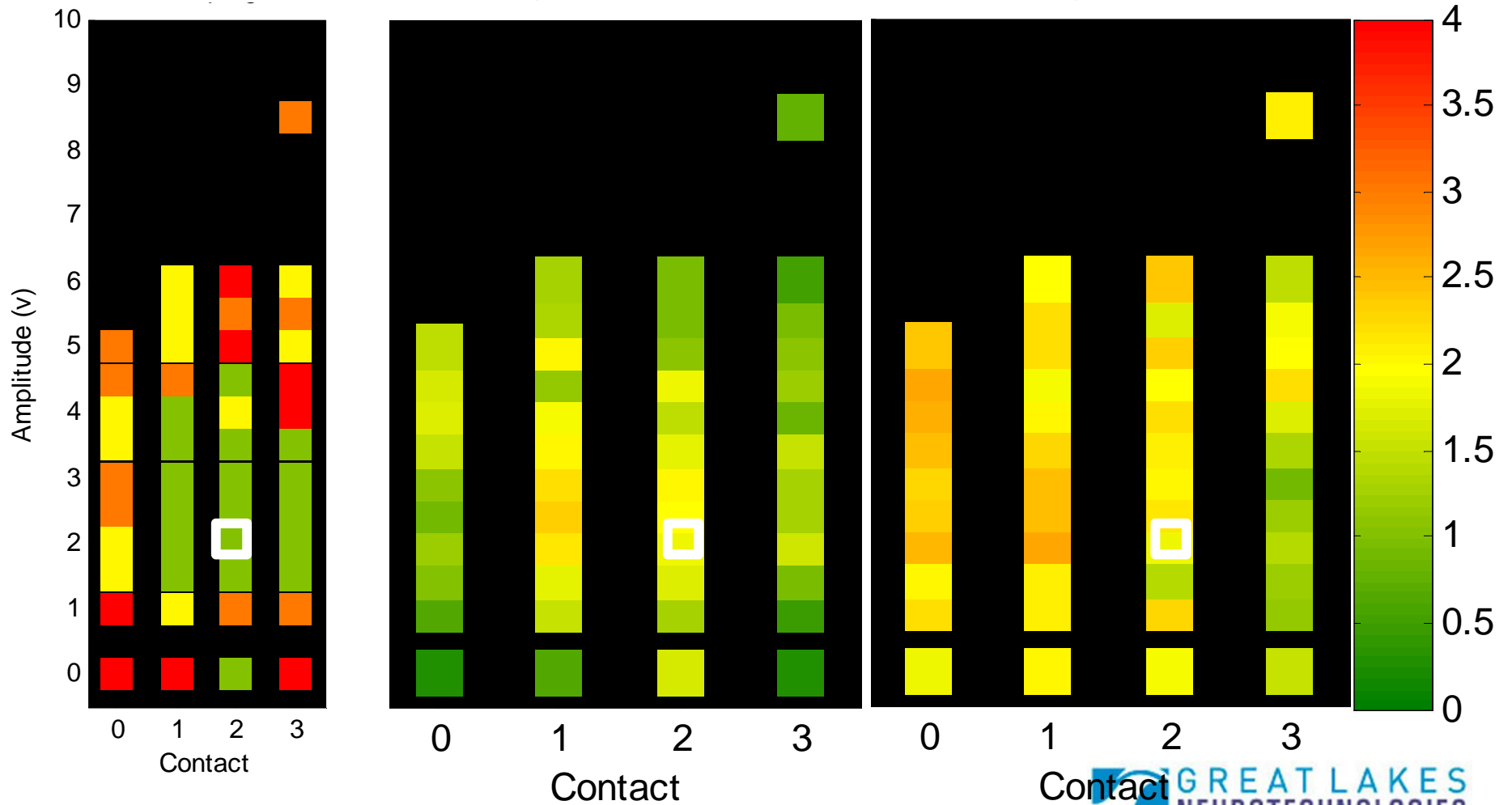
Clinician

ProView:

UPDRS

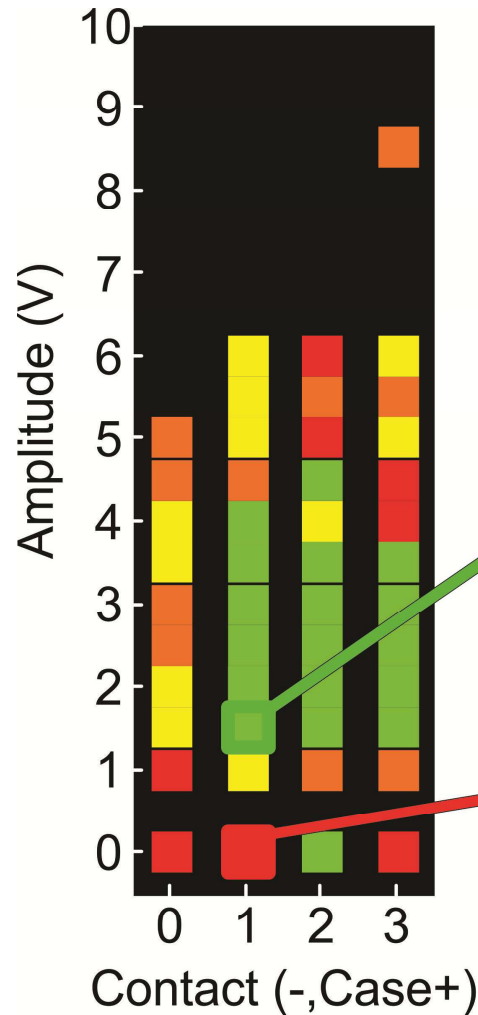
Speed

Amplitude

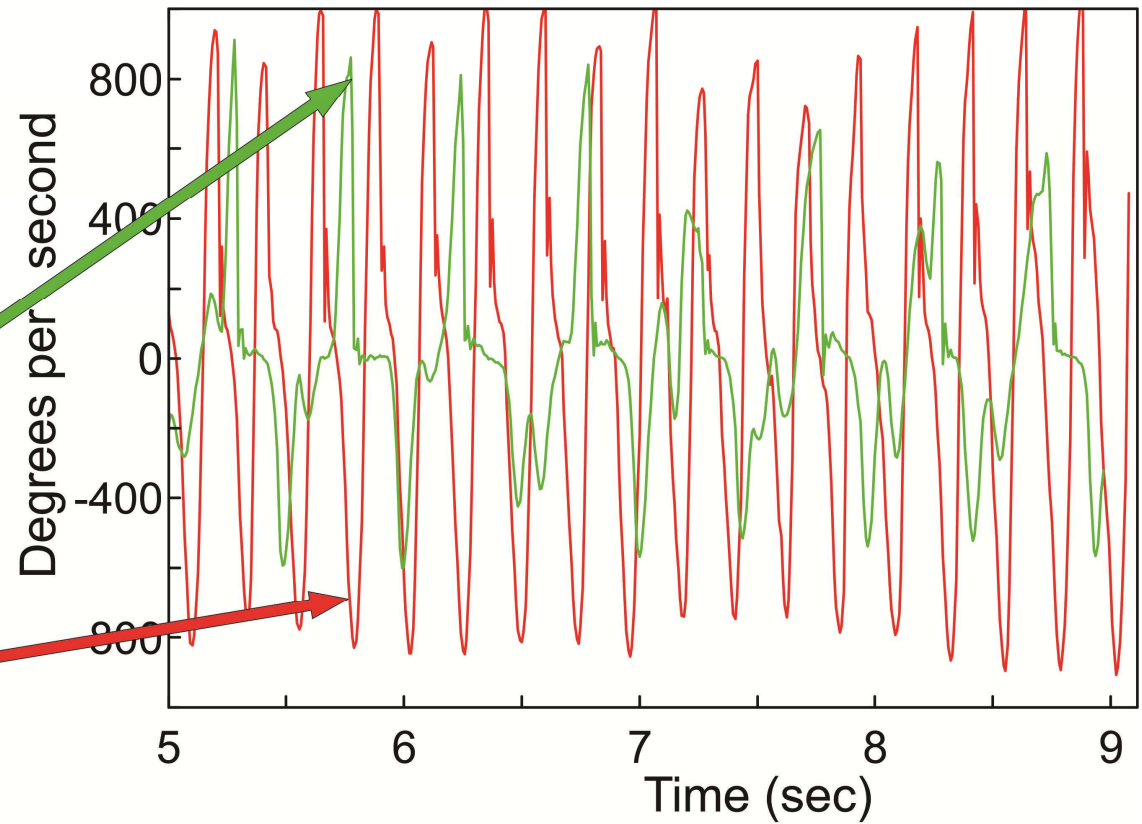


Subject 1: Finger Tap Detail

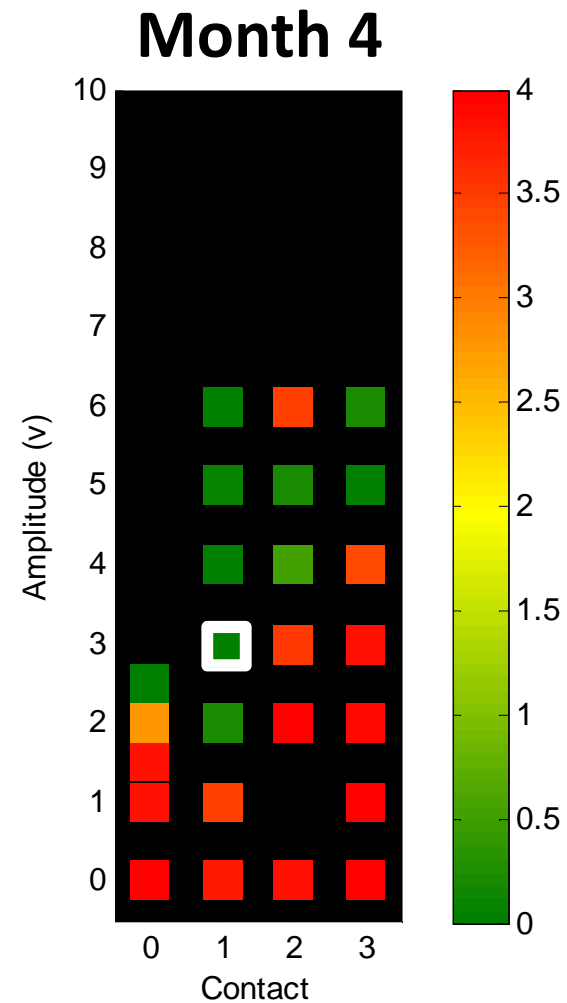
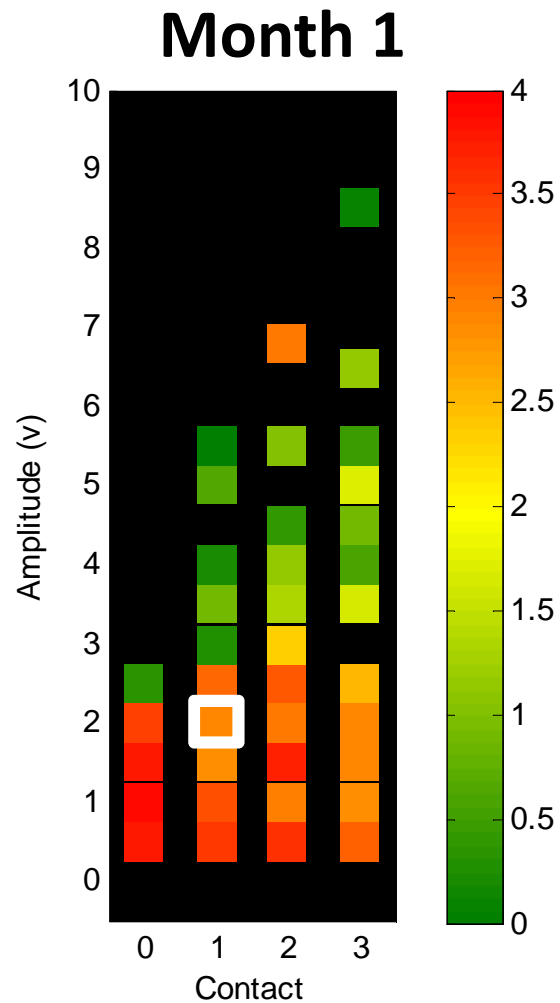
Clinician UPDRS



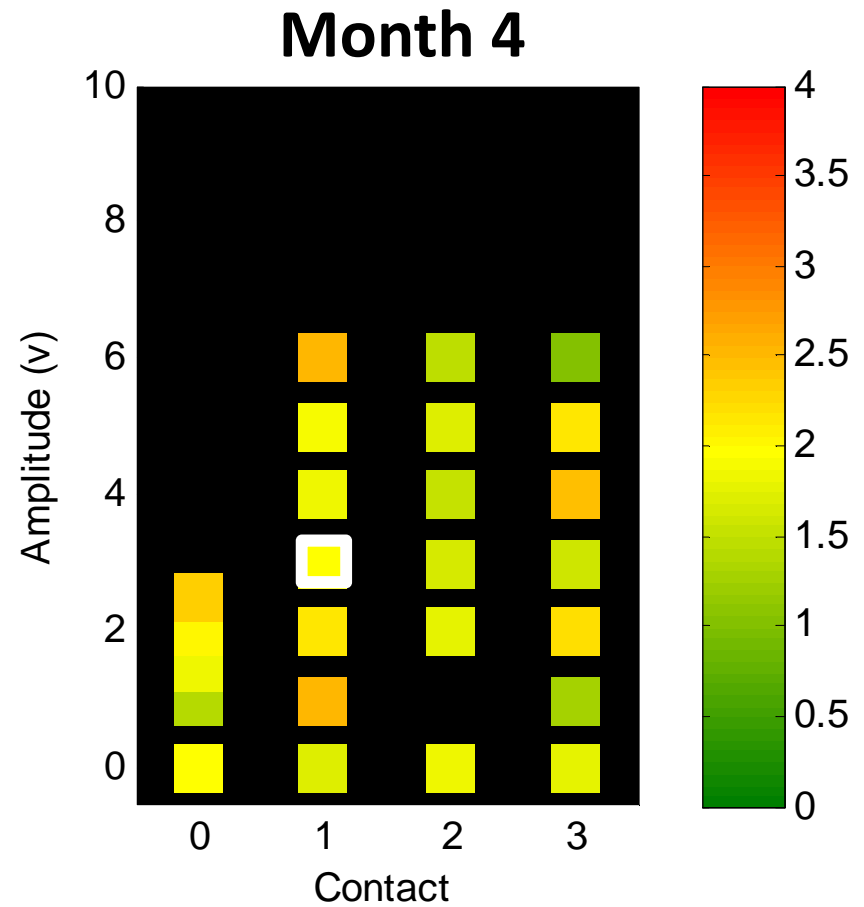
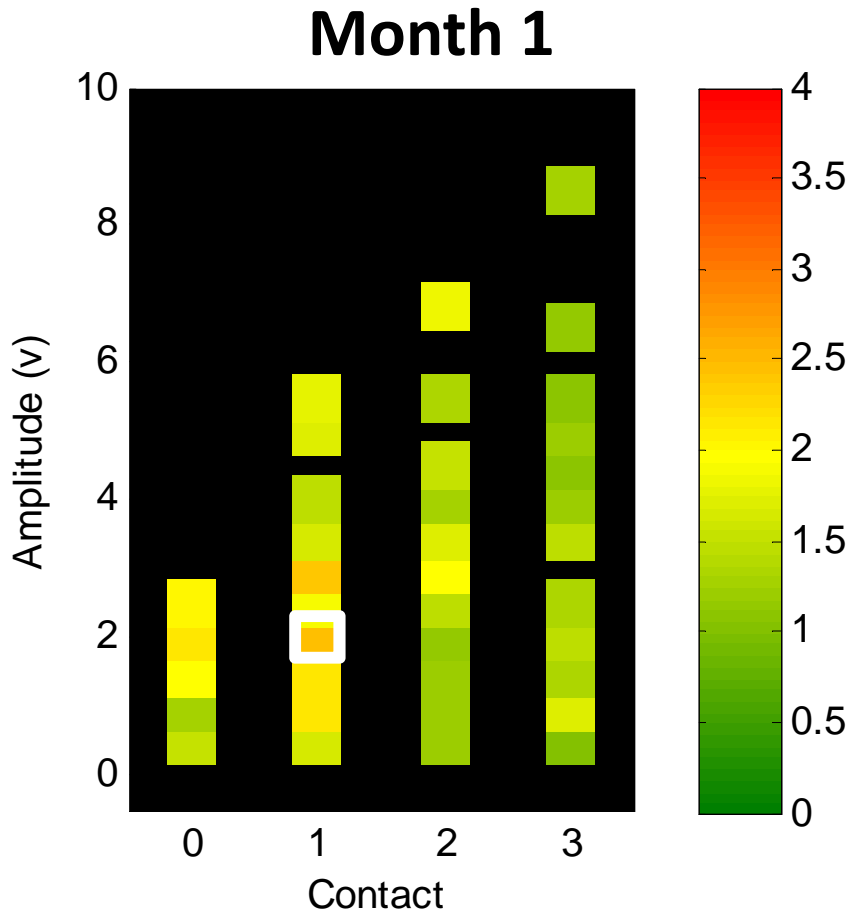
Motion Sensor Data



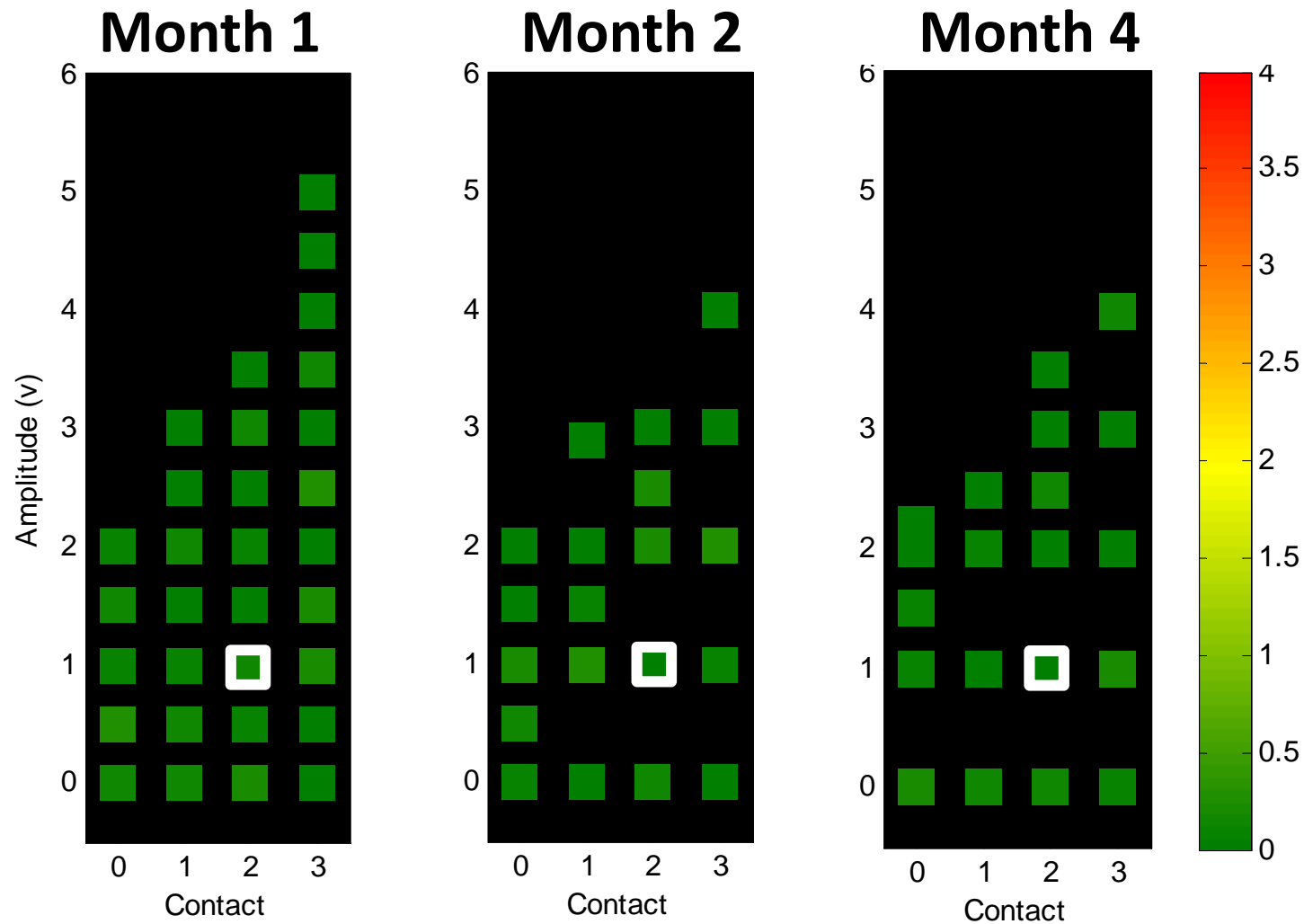
Subject 2: Rest Tremor



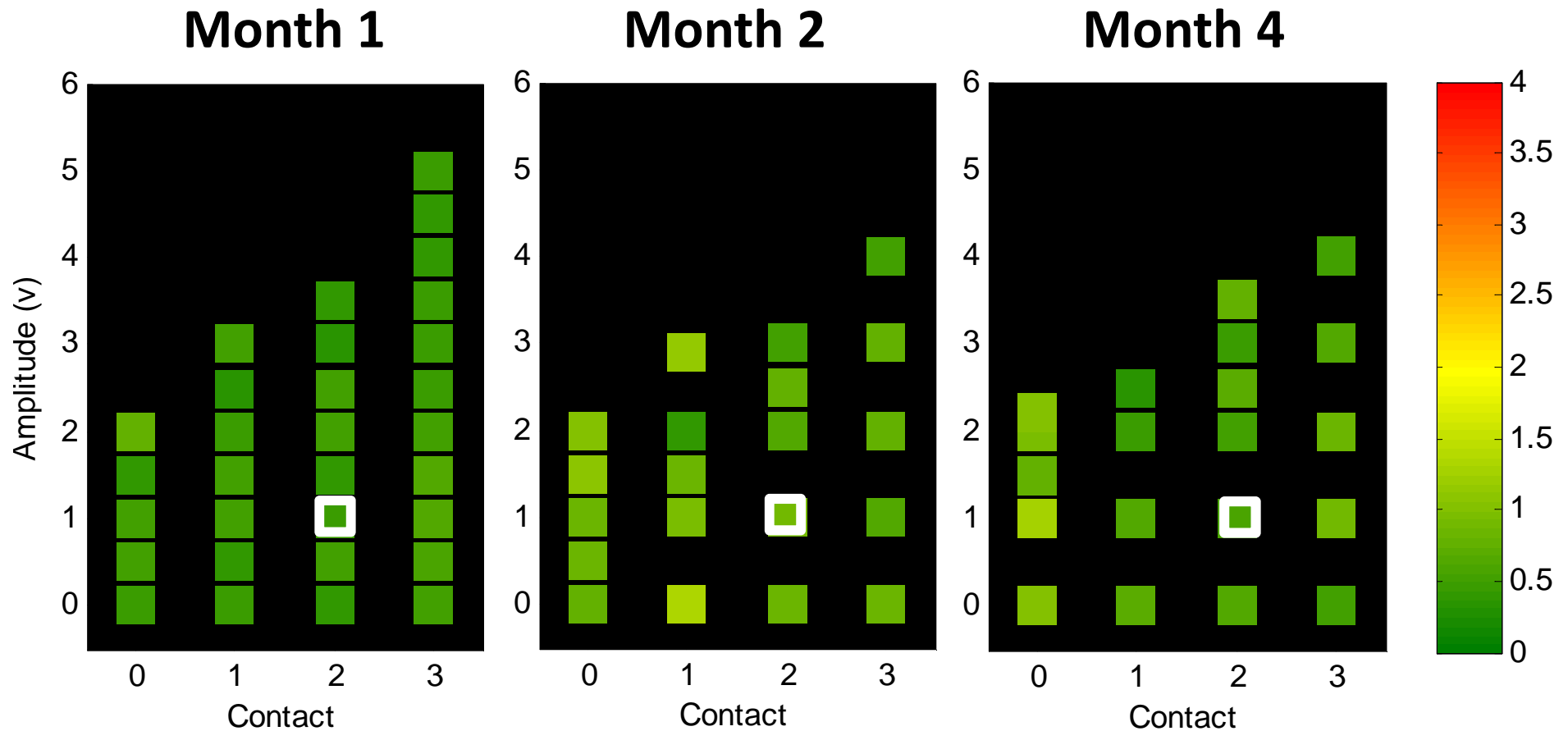
Subject 2: Finger Tap Bradykinesia



Subject 3: Rest Tremor



Subject 3: Finger Tap Bradykinesia



Kinesia Technology Value Added

ProView Value Added to DBS



Visual Assessment of Programming Space

- Minimize Symptoms, Maximize Battery Life

High Sensitivity Symptom Differentiation

- Detect Small Changes and Specific Symptom Response to Unique Stimulation Configurations

Cloud-Based Data Storage

- Track changes over time and minimize paper trails





Applications and Markets

- Patient Care
- Clinical Trials
- DBS Programming



Time	Rest Tremor	Postural Tremor	Finger Taps Speed	Finger Taps Amplitude	Finger Taps Rhythm	Dyskinesia
7:01 AM	4.0	3.5	2.5	2.4	2.2	0.0
7:02 AM	SINEMET (100mg)					
7:32 AM	3.4	3.3	1.7	1.4	1.0	0.0
8:01 AM	3.0	3.0	1.8	1.8	1.2	0.0
8:34 AM	2.9	2.8	1.3	1.2	1.0	0.0
9:00 AM	2.8	2.4	1.2	1.1	1.2	0.0
9:23 AM	2.8	2.6	1.0	1.0	1.0	0.0
10:00 AM	2.6	2.8	1.0	1.0	1.0	0.0
10:33 AM	3.2	3.3	1.5	1.9	1.5	0.0
11:01 AM	3.5	3.5	2.3	2.2	2.0	0.0
11:30 AM	3.7	3.8	2.0	2.0	1.8	0.0
12:00 PM	SINEMET (100mg)					
12:01 PM	3.3	3.8	2.6	2.7	2.0	0.0
12:32 PM	3.2	3.4	1.8	1.9	2.0	0.0
1:08 PM	2.6	3.1	2.0	1.4	1.8	0.0
1:28 PM	2.6	2.9	1.5	1.2	1.7	0.0
2:00 PM	2.7	2.7	1.3	1.0	1.5	0.0
2:32 PM	2.9	2.6	1.0	1.2	1.7	0.0
3:00 PM	3.0	2.9	1.1	1.5	1.3	0.0
3:29 PM	3.3	3.1	1.4	1.7	1.7	0.0
4:02 PM	3.8	3.6	1.6	1.8	1.8	0.0
4:30 PM	3.9	3.8	1.9	1.9	2.0	0.0
5:01 PM	3.9	3.9	2.5	2.4	2.0	0.0
5:15 PM	SINEMET (100mg)					
5:29 PM	3.5	3.6	2.1	2.2	2.0	0.0
6:02 PM	3.3	3.5	2.0	2.1	1.6	0.0
6:30 PM	3.0	2.9	1.9	2.0	1.5	0.0
7:00 PM	2.8	2.5	1.5	1.8	1.3	0.0
7:33 PM	2.6	2.6	1.2	1.5	1.1	0.0
8:04 PM	2.6	2.6	1.0	1.4	0.9	0.0
8:30 PM	2.9	2.8	1.2	1.5	1.1	0.0
9:02 PM	3.3	3.2	1.3	1.6	1.4	0.0
9:33 PM	3.5	3.6	1.6	1.8	1.8	0.0
10:00 PM	3.8	3.9	2.0	1.9	2.1	0.0
Mean	3.2	3.2	1.6	1.7	1.6	0.0
Fluctuation	0.4	0.5	0.5	0.4	0.4	0.0



Increase dose by 200mg, Dose interval unchanged

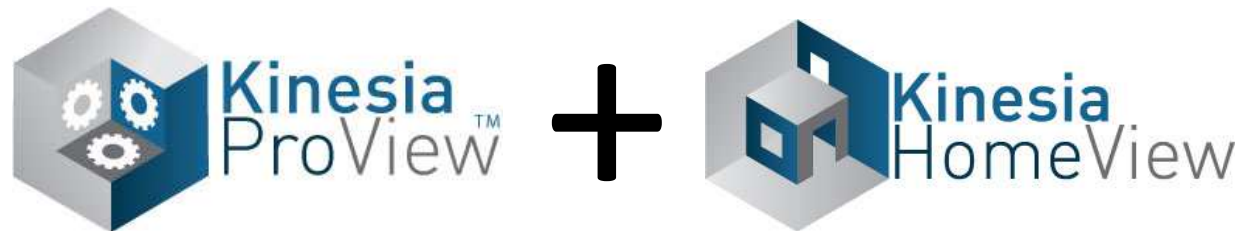
Time	Rest Tremor	Postural Tremor	Finger Taps Speed	Finger Taps Amplitude	Finger Taps Rhythm	Dyskinesia
6:55 AM	3.9	3.4	2.6	2.5	2.3	0.0
6:57 AM	SINEMET (300mg)					
7:28 AM	2.5	3.0	1.7	1.4	1.0	0.0
7:59 AM	0.5	1.9	1.8	1.5	1.2	1.3
8:30 AM	0.3	0.9	0.3	0.5	1.0	2.9
9:05 AM	0.1	0.5	0.2	0.2	1.2	3.5
9:33 AM	0.3	0.4	0.0	0.0	1.0	3.8
10:02 AM	0.5	0.1	0.5	0.3	1.0	3.7
10:31 AM	1.5	2.0	1.0	0.5	1.5	2.9
10:58 AM	3.0	3.1	2.3	2.2	2.0	0.0
11:35 AM	3.5	3.4	2.0	2.0	1.8	0.0
11:50 PM	SINEMET (300mg)					
11:56 PM	1.1	2.7	2.3	2.2	2.0	0.0
12:30 PM	0.2	2.0	1.8	1.9	2.0	3.0
1:04 PM	0.1	1.4	2.0	1.4	1.8	3.3
1:38 PM	0.0	1.1	0.8	0.9	1.7	3.5
2:02 PM	0.0	1.0	0.6	1.0	1.5	3.6
2:30 PM	0.2	1.0	1.0	1.2	1.7	2.4
3:07 PM	0.4	0.7	1.1	1.5	1.3	1.1
3:33 PM	0.5	1.3	1.4	1.7	1.7	0.0
4:03 PM	2.6	1.5	1.6	1.8	1.8	0.0
4:28 PM	3.5	2.0	1.9	1.9	2.0	0.0
5:00 PM	3.8	2.2	2.1	2.1	2.0	0.0
5:05 PM	SINEMET (300mg)					
5:39 PM	3.5	2.2	2.1	2.2	2.0	0.0
6:03 PM	2.3	2.0	2.0	2.1	1.6	0.0
6:29 PM	1.7	1.3	1.9	2.0	1.5	0.5
7:05 PM	0.8	1.1	1.5	1.8	1.3	1.0
7:36 PM	0.6	0.8	1.2	1.5	1.1	2.3
8:01 PM	0.3	0.6	1.0	1.4	0.9	3.8
8:28 PM	0.2	1.0	1.2	1.5	1.1	3.7
9:00 PM	0.3	1.1	1.3	1.6	1.4	1.3
9:34 PM	0.3	2.0	1.6	1.8	1.8	0.5
9:59 PM	2.8	2.3	2.0	1.9	2.1	0.0
Mean	1.3	1.6	1.4	1.5	1.6	1.6
Fluctuation	1.3	0.9	0.7	0.6	0.4	1.5



Decrease dose by 100mg, Decrease dose interval by 2 hours

Time	Rest Tremor	Postural Tremor	Finger Taps Speed	Finger Taps Amplitude	Finger Taps Rhythm	Dyskinesia
7:00 AM	3.5	3.2	2.7	2.5	2.4	0.0
7:01 AM	SINEMET (200mg)					
7:31 AM	2.0	2.1	1.9	2.1	2.2	0.0
8:00 AM	0.6	0.7	0.3	0.5	1.0	0.0
8:33 AM	0.3	0.5	0.2	0.2	1.2	0.0
8:59 AM	0.2	0.2	0.0	0.0	1.0	0.0
9:22 AM	0.2	0.0	0.5	0.3	1.0	0.0
9:59 AM	1.1	1.5	1.0	0.5	1.5	0.0
10:32 AM	SINEMET (200mg)					
11:00 AM	1.2	1.3	1.5	1.4	1.5	0.0
11:29 AM	0.3	0.3	0.5	0.6	2.1	0.0
11:59 PM	0.2	0.2	0.3	0.3	1.0	0.0
12:00 PM	0.1	0.0	0.4	0.1	2.3	0.0
12:31 PM	0.2	0.6	0.6	0.1	2.1	0.0
1:07 PM	1.2	1.6	1.7	1.6	1.7	0.0
1:27 PM	SINEMET (200mg)					
1:59 PM	1.0	0.8	1.0	0.9	1.0	0.0
2:31 PM	0.3	0.7	0.3	0.8	0.9	0.0
2:59 PM	0.2	0.5	0.2	0.5	0.9	0.0
3:28 PM	0.0	0.3	0.2	0.8	0.9	0.0
4:01 PM	0.5	0.8	0.9	1.6	1.7	0.0
4:29 PM	1.3	1.7	1.6	2.1	2.1	0.0
5:00 PM	SINEMET (200mg)					
5:14 PM	1.0	1.5	1.0	0.9	1.0	0.0
5:28 PM	0.3	0.6	0.3	0.8	2.4	0.0
6:01 PM	0.2	0.3	0.2	0.5	2.0	0.0
6:29 PM	0.0	0.0	0.2	0.8	1.7	0.0
6:59 PM	0.5	0.2	0.9	1.6	1.2	0.0
7:32 PM	1.3	0.9	1.6	2.1	1.0	0.0
8:03 PM	SINEMET (200mg)					
8:29 PM	0.8	0.6	0.5	0.7	0.5	0.0
9:01 PM	0.0	0.2	0.2	1.1	0.9	0.0
9:32 PM	0.0	0.1	0.9	1.6	1.3	0.0
9:55 PM	0.5	0.6	1.9	2.0	1.9	0.0
Mean	0.7	0.8	0.8	1.0	1.5	0.0
Fluctuation	0.7	0.7	0.7	0.7	0.5	0.0

ProView and HomeView Value Added to DBS



Patient Screening

- Ready for DBS? Matching patient characteristics to therapies

Post Programming Symptom Response

- Do symptoms remain stable at home?

Intelligent and Remote Programming

- Clinician controlled and algorithm-based programming via telemedicine and broadband communications



Questions?

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