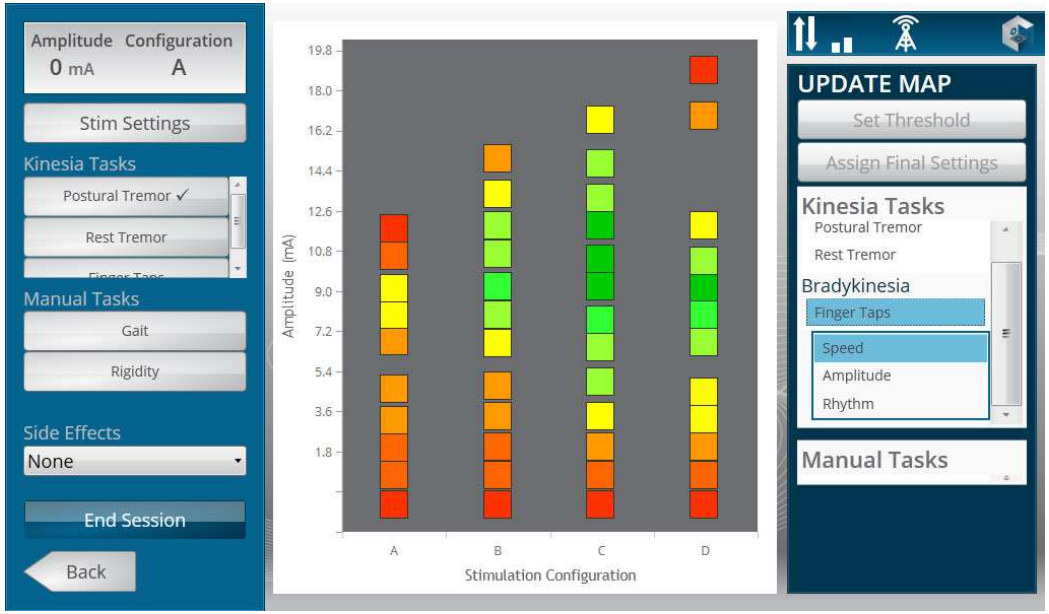
Tuning Maps for Deep Brain Stimulation Trials



Thomas Mera, MS
Product Development Manager
May 23rd, 2013

WILL BEGIN

AT 12:00 EST

GREAT LAKES NEUROTECHNOLOGIES

Talking Points

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

GREAT LAKES NEUROTECHNOLOGIES

Market Opportunities

GREAT LAKES NEUROTECHNOLOGIES

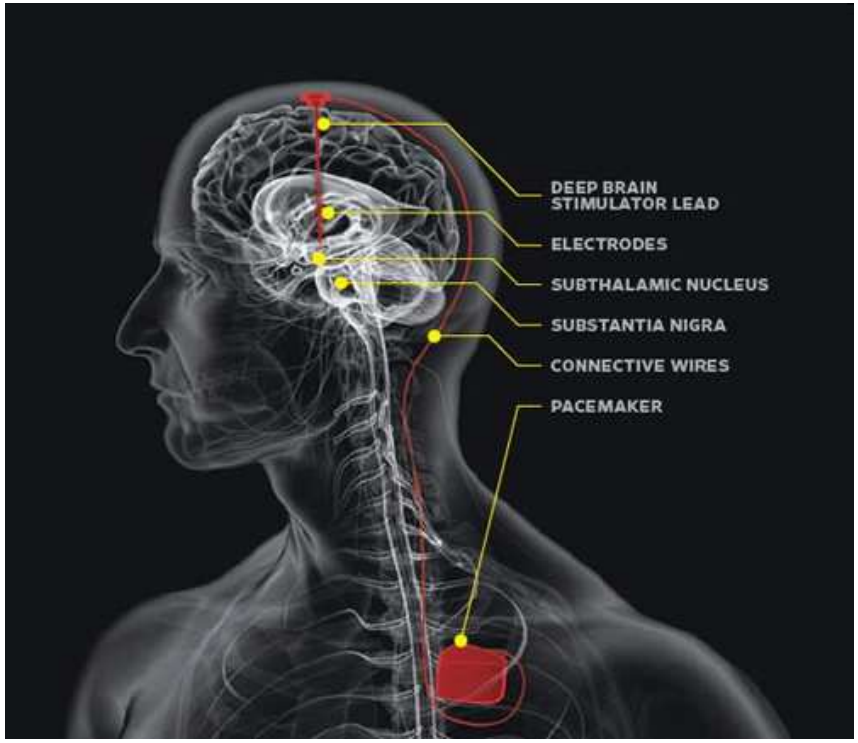
Parkinson's Disease: Not So Simple!

SYMPTOMS	TREATMENTS	DEMOGRAPHICS
Tremor	Levodopa	Over 60
Dyskinesias	Rasagiline	Growing Incidence
Bradykinesia	Duodopa	Neurodegeneration
Rigidity	DBS	Medicare
Gait	Exercise	VA
Non-Motor et al.	Neuroprotection?	Access to Care

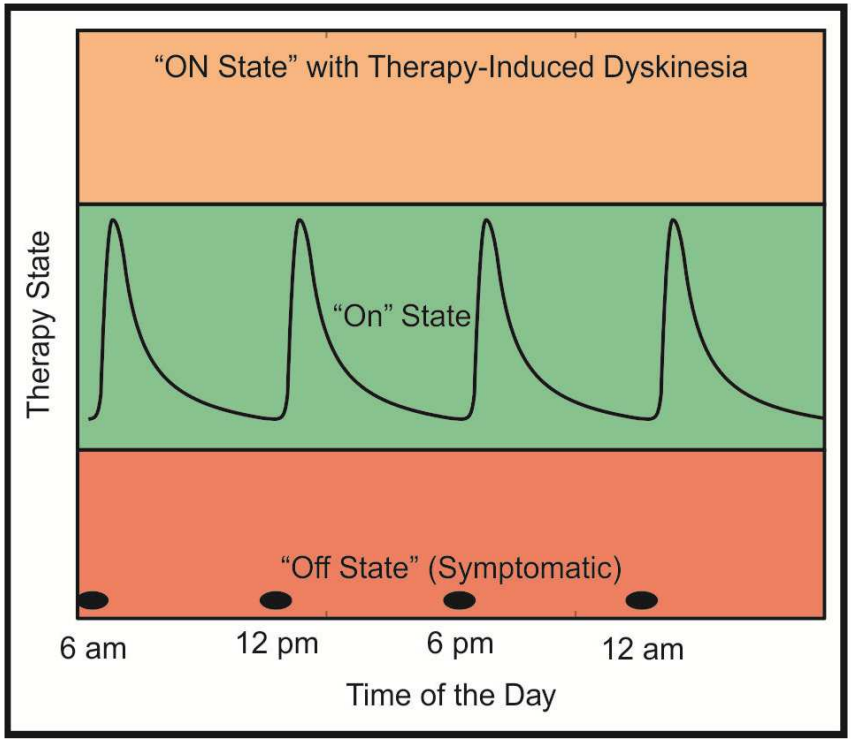
GREAT LAKES NEUROTECHNOLOGIES

Deep Brain Stimulation

Targeted Electrical Stimulation of the Brain



Therapy State Management



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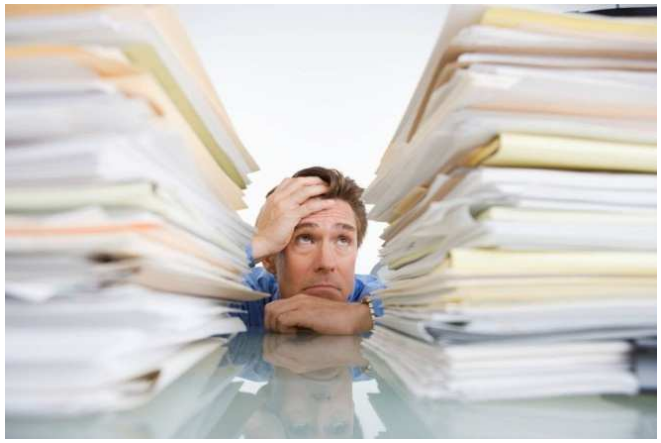
Challenges with DBS Programming

Clinician Training



Paper Trails

Symptom Tracking

Sensitivity

GREAT LAKES NEUROTECHNOLOGIES

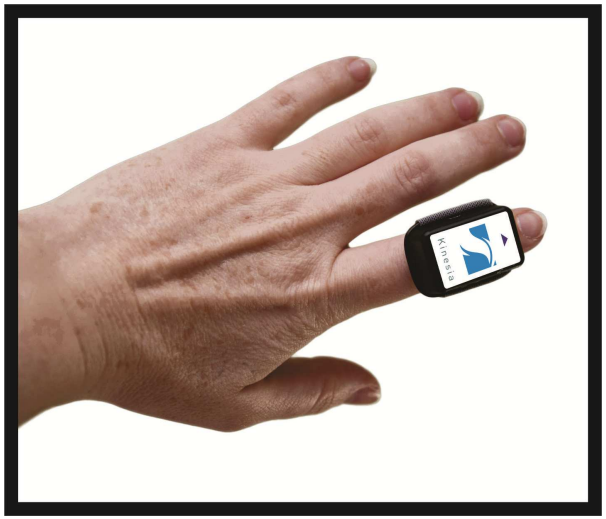
DBS Tuning Maps

GREAT LAKES NEUROTECHNOLOGIES

Quantitative Motor Assessment

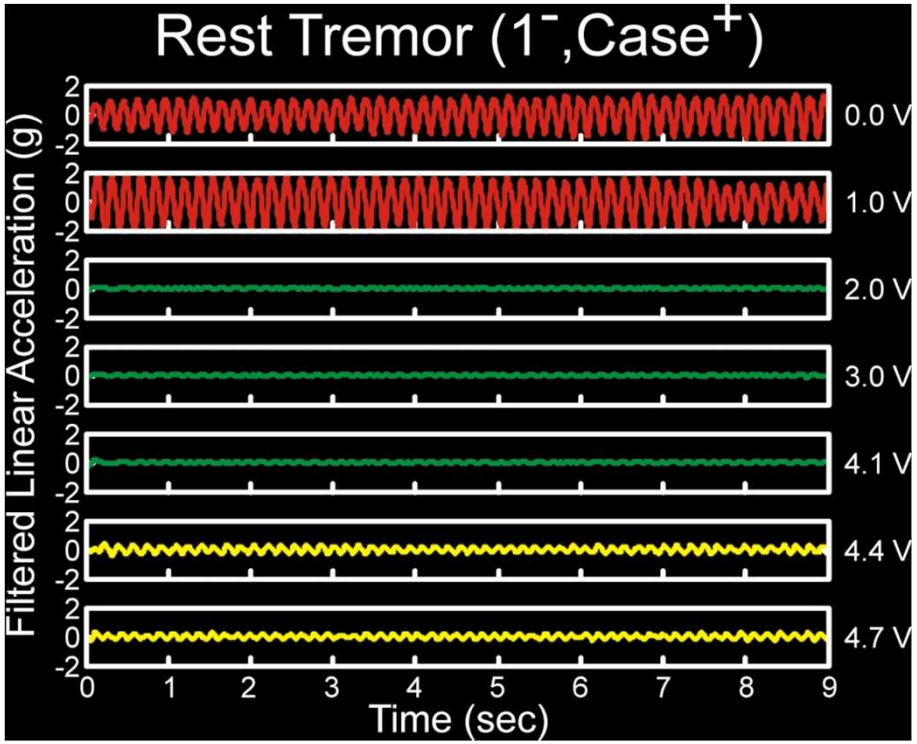
TRADITIONAL

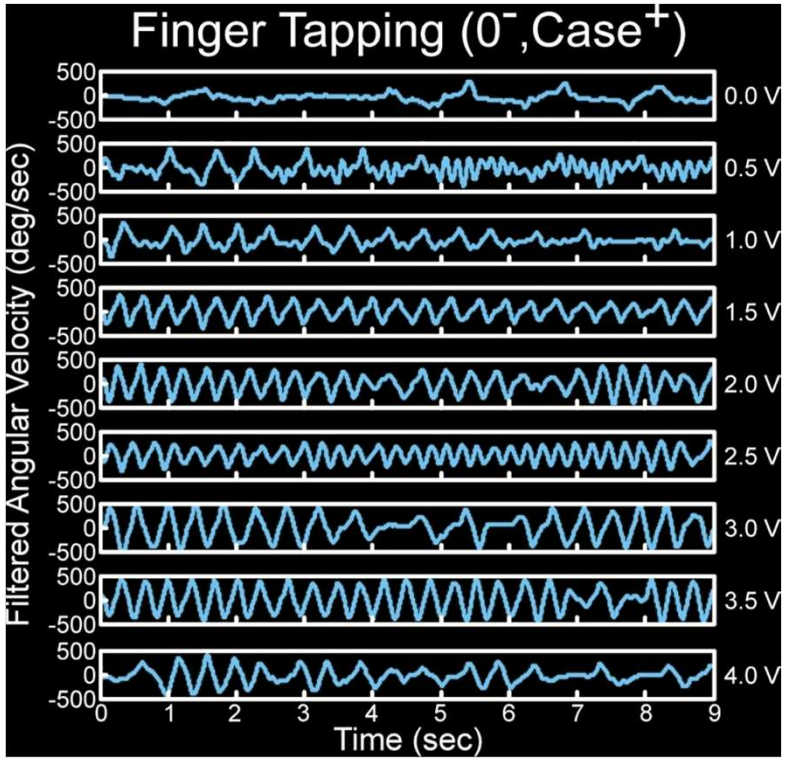
HIGH SENSITIVITY



GREAT LAKES NEUROTECHNOLOGIES

Kinematic Response to DBS





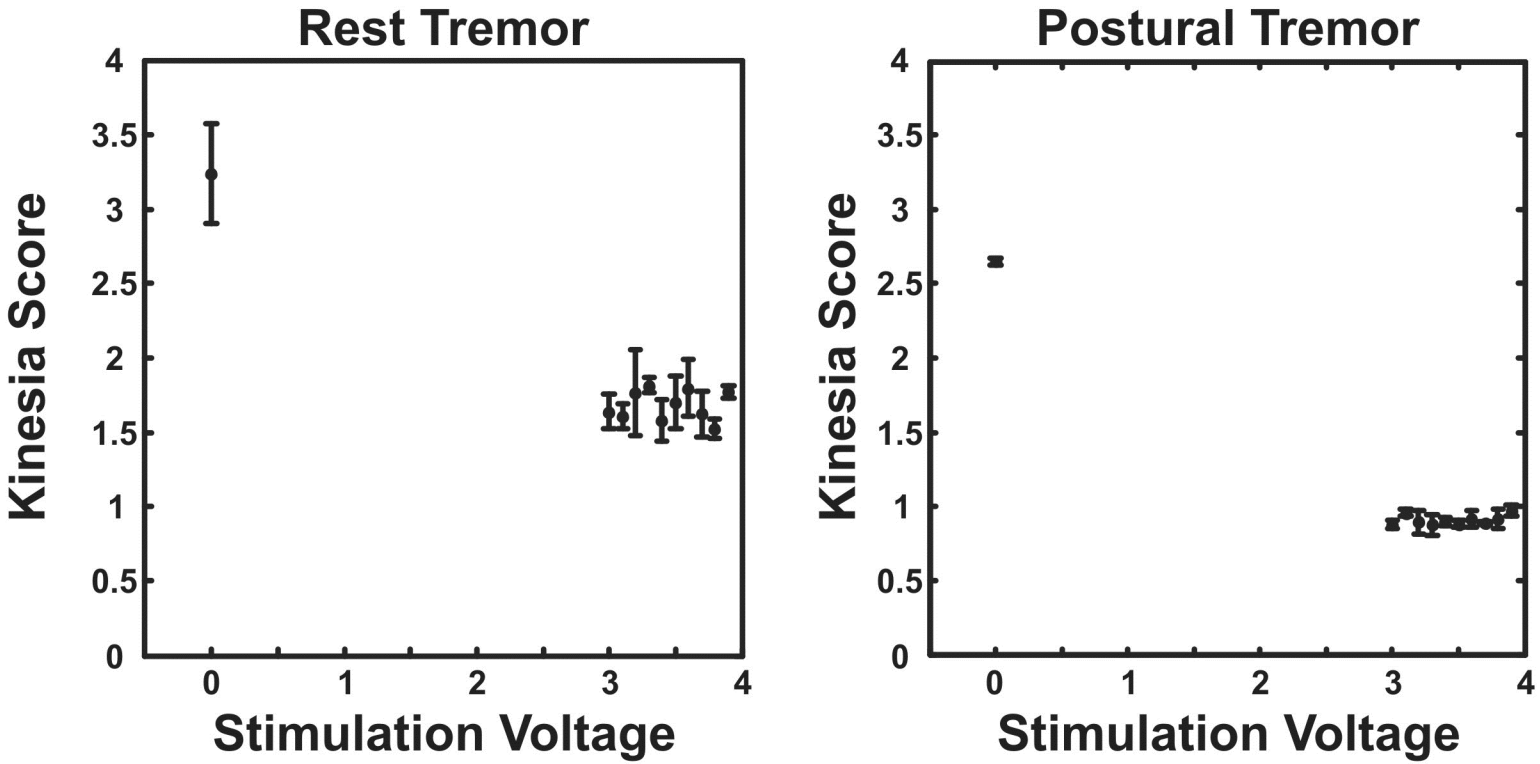
Tremor tuning produces sudden, dramatic effects

Bradykinesia tuning produces gradual, fine effects

GREAT LAKES NEUROTECHNOLOGIES

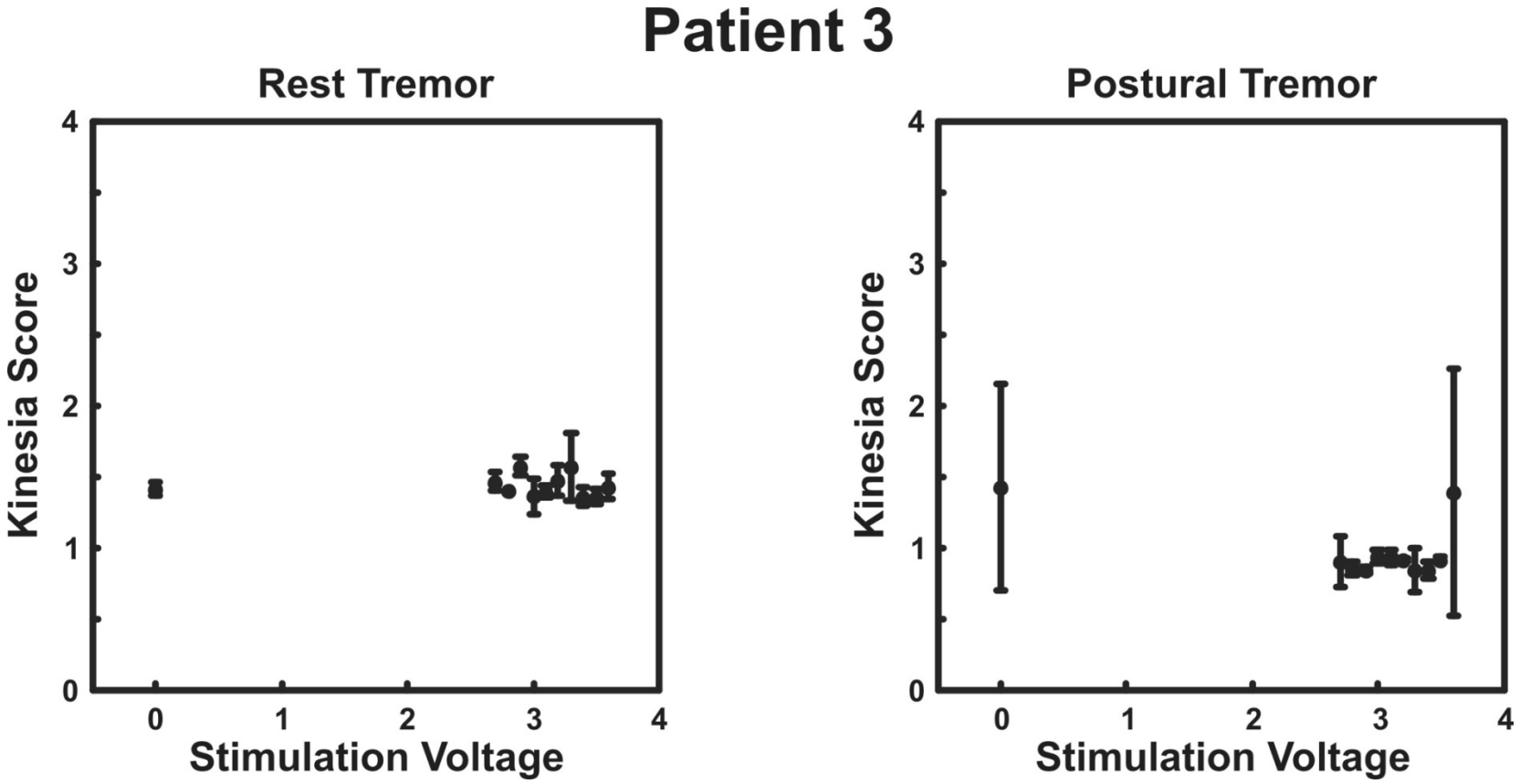
Monopolar Symptom Response

Patient 1



GREAT LAKES NEUROTECHNOLOGIES

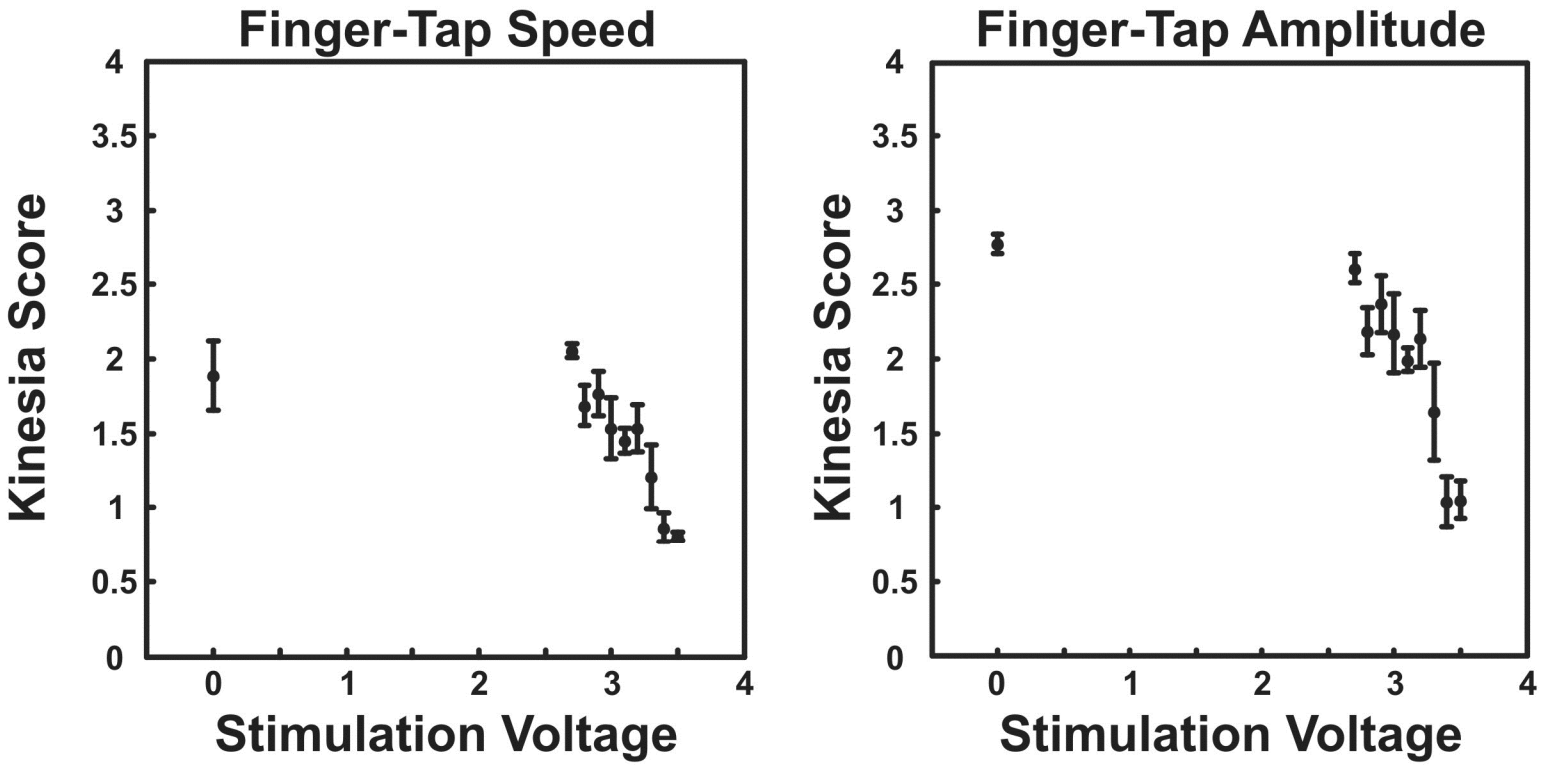
Monopolar Symptom Response



GREAT LAKES NEUROTECHNOLOGIES

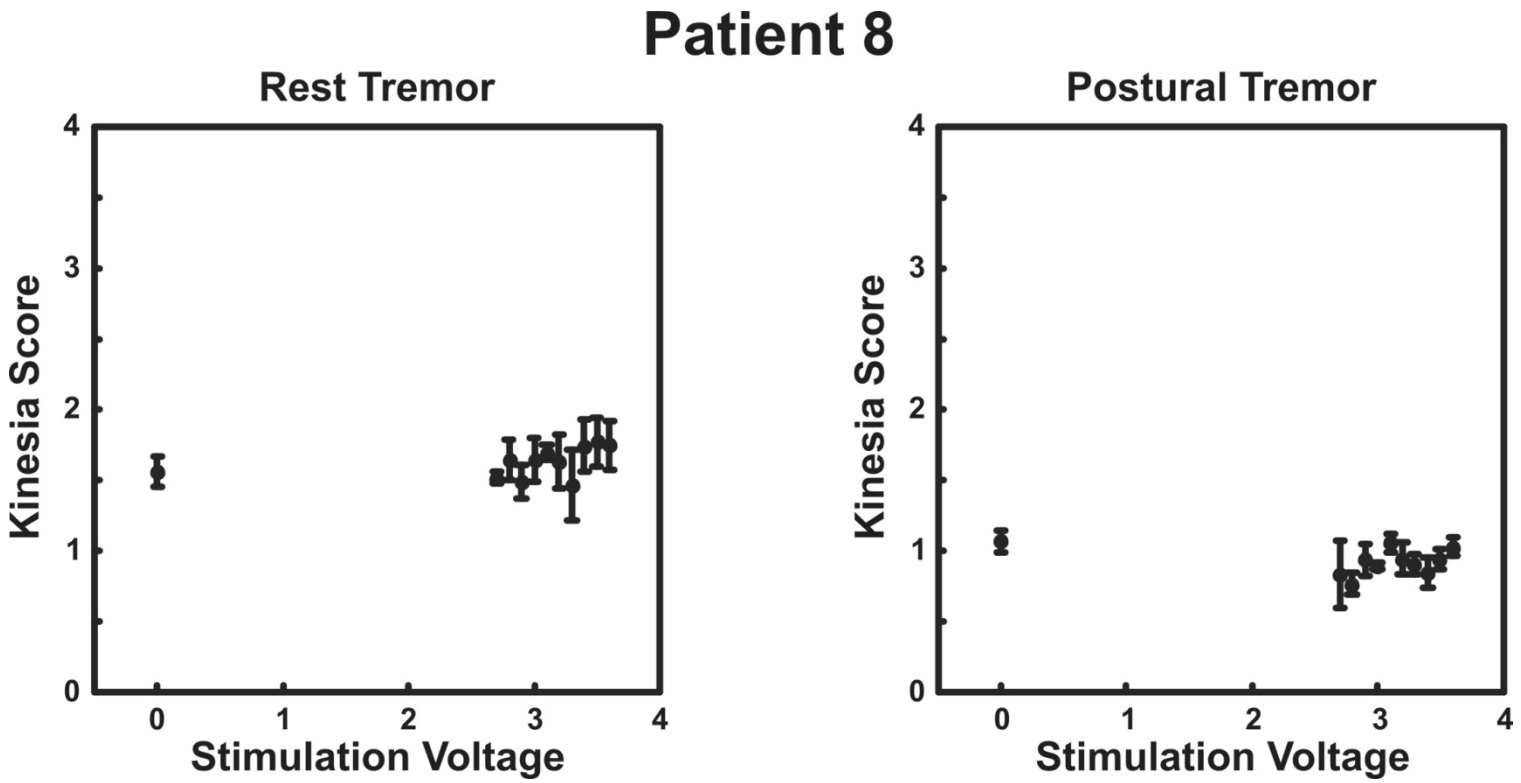
Monopolar Symptom Response

Patient 3



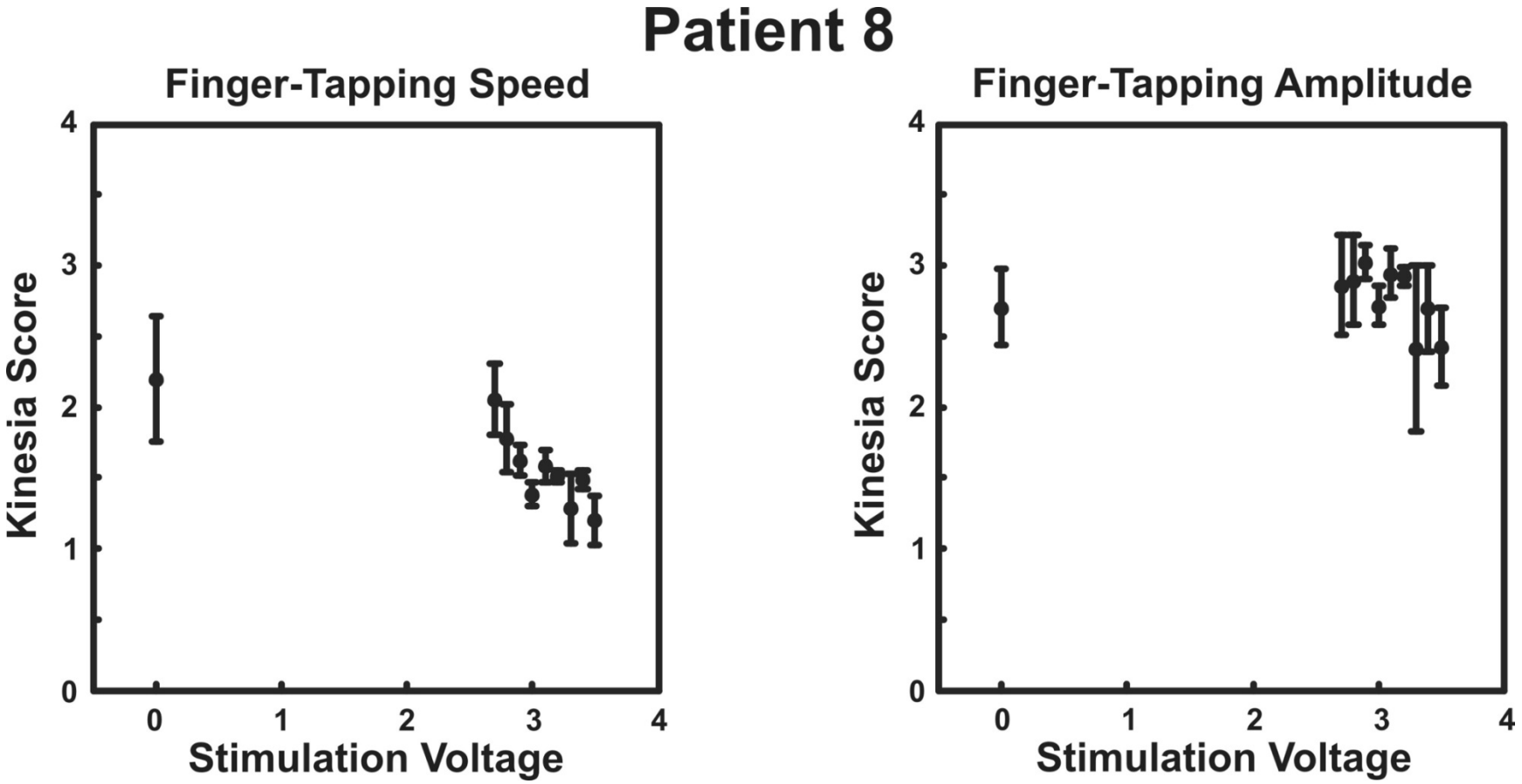
GREAT LAKES NEUROTECHNOLOGIES

Monopolar Symptom Response



GREAT LAKES NEUROTECHNOLOGIES

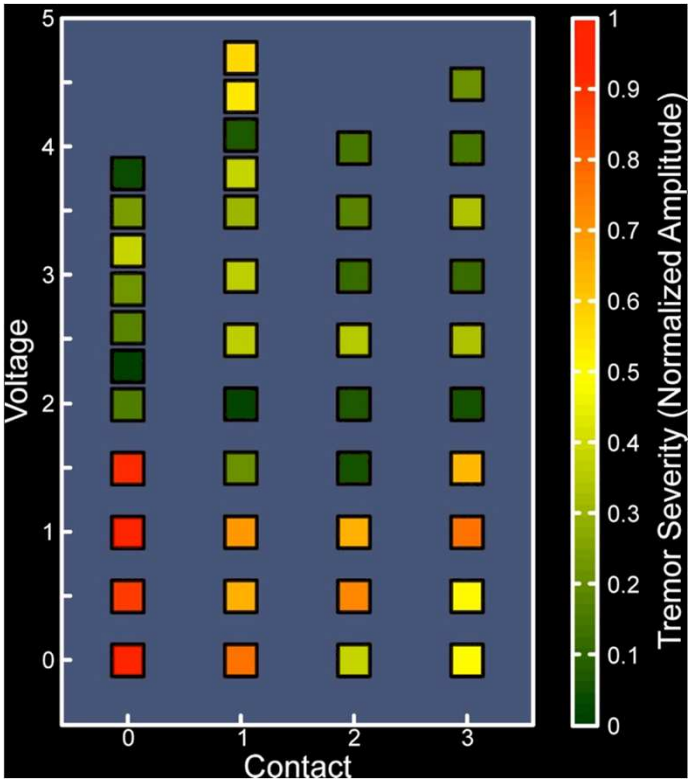
Monopolar Symptom Response



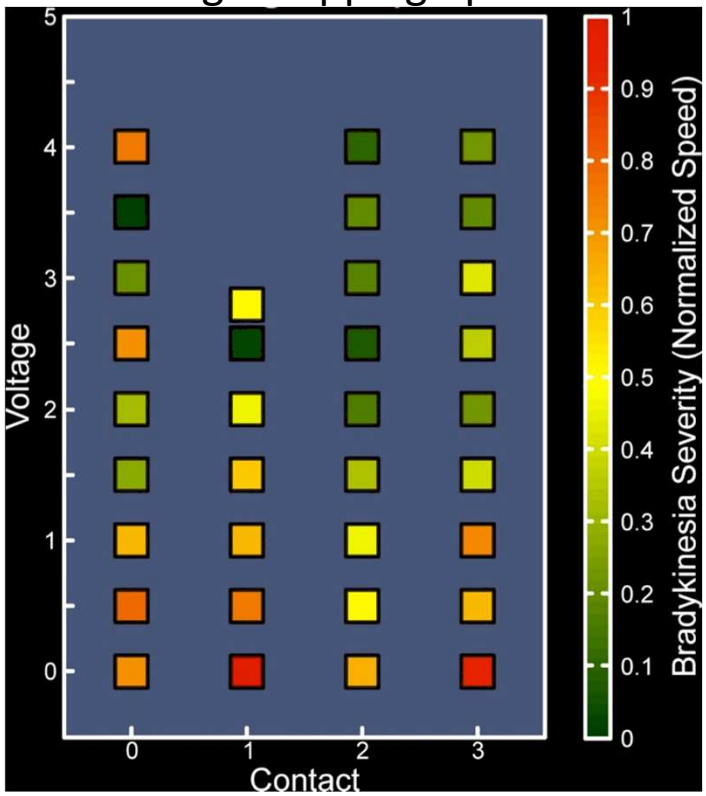
GREAT LAKES NEUROTECHNOLOGIES

Tuning Maps: Visualizing the Programming Space

Rest Tremor



Finger Tapping-Speed



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.

GREAT LAKES NEUROTECHNOLOGIES

Kinesia ProView Product Demo

GREAT LAKES NEUROTECHNOLOGIES

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

ISO 13485: 2003

CE 0086

Standards and Testing

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

U.S. Patent Protection

GREAT LAKES NEUROTECHNOLOGIES

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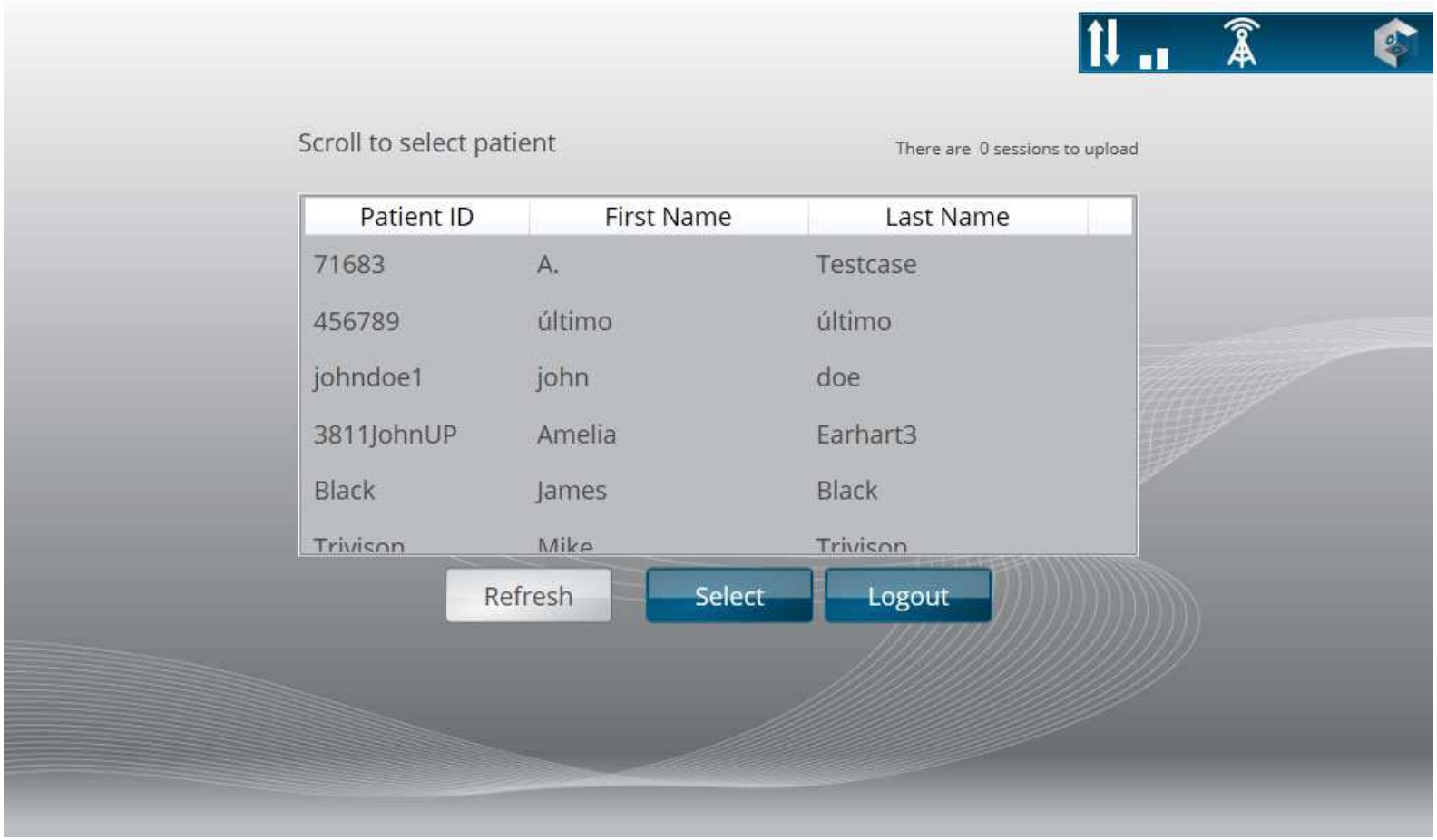
Kinesia ProView™

GREAT LAKES NEUROTECHNOLOGIES

HIPAA-Compliant Log-In

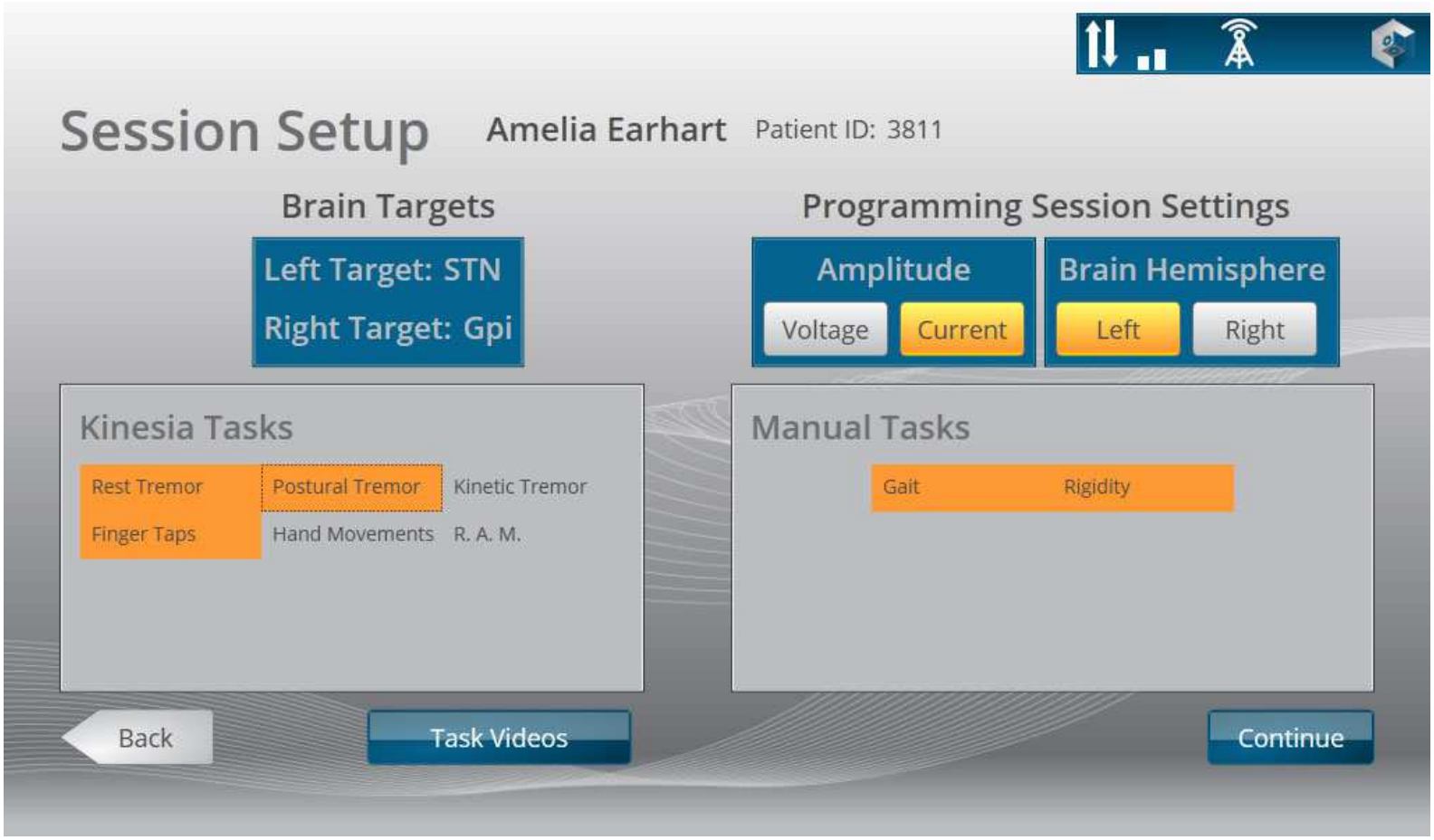
GREAT LAKES NEUROTECHNOLOGIES

Institute-Specific Patient List



GREAT LAKES NEUROTECHNOLOGIES

Programming Session Setup



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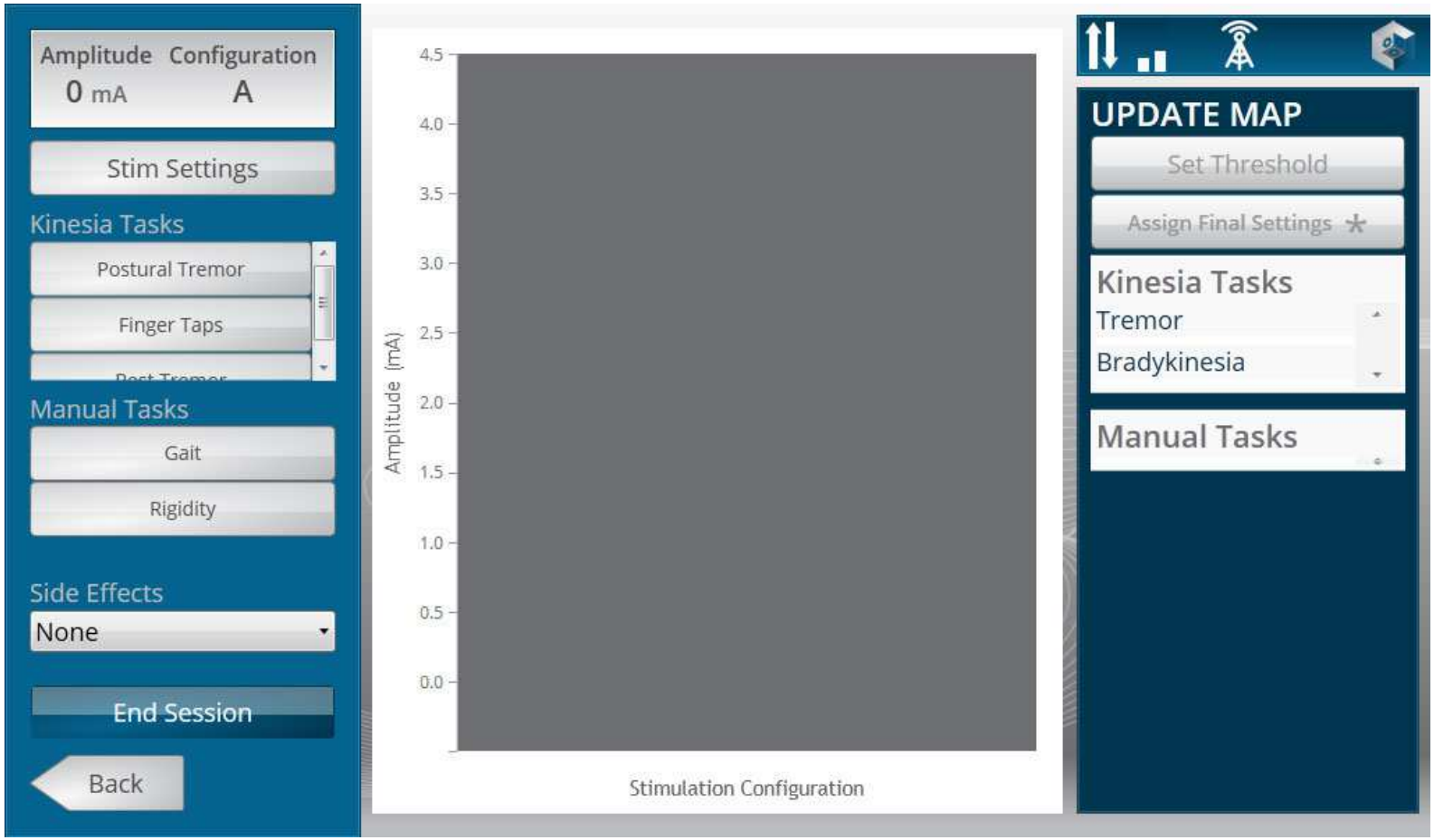
Tuning Map Screen



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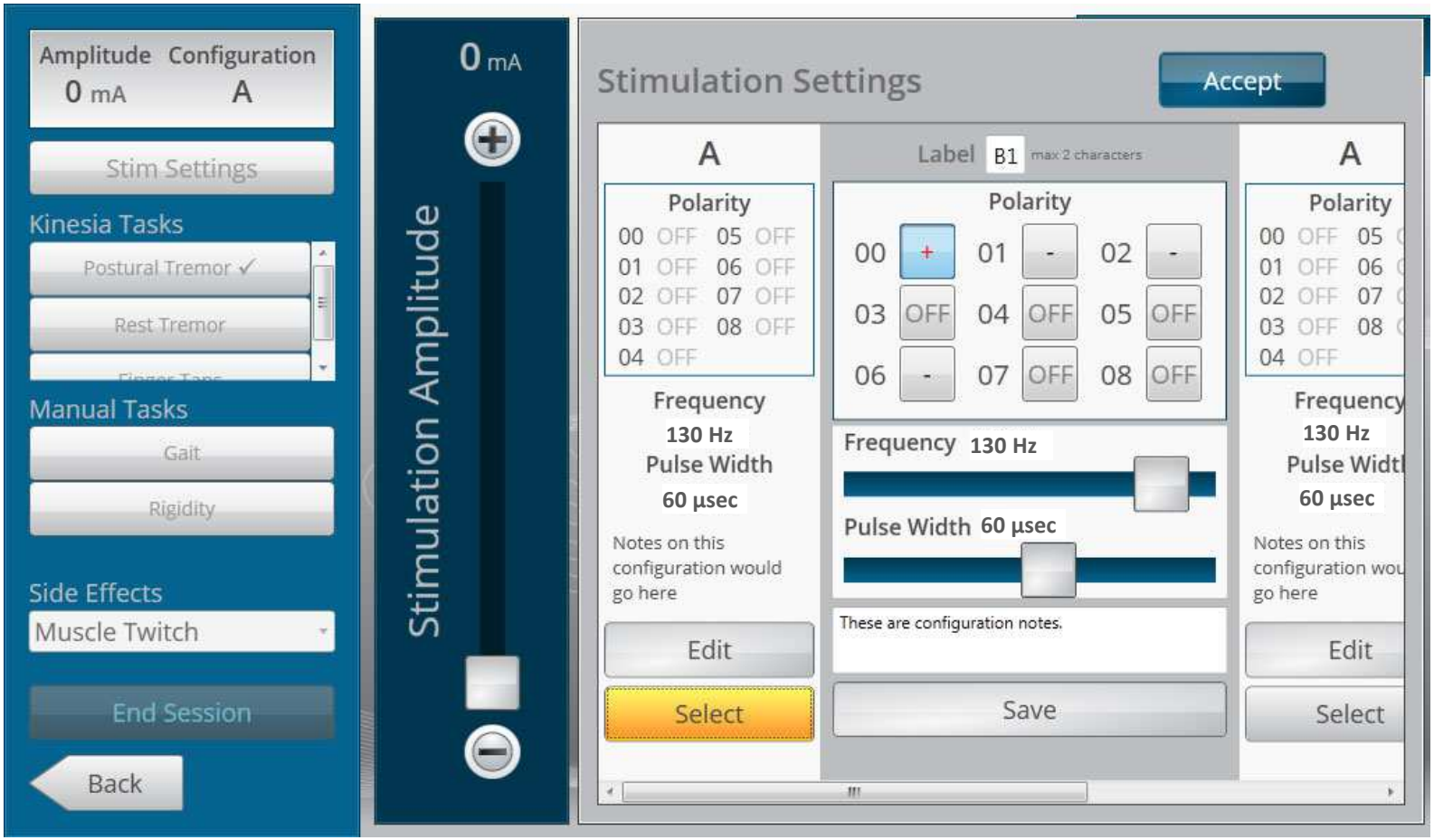
Stimulation Setting Selection



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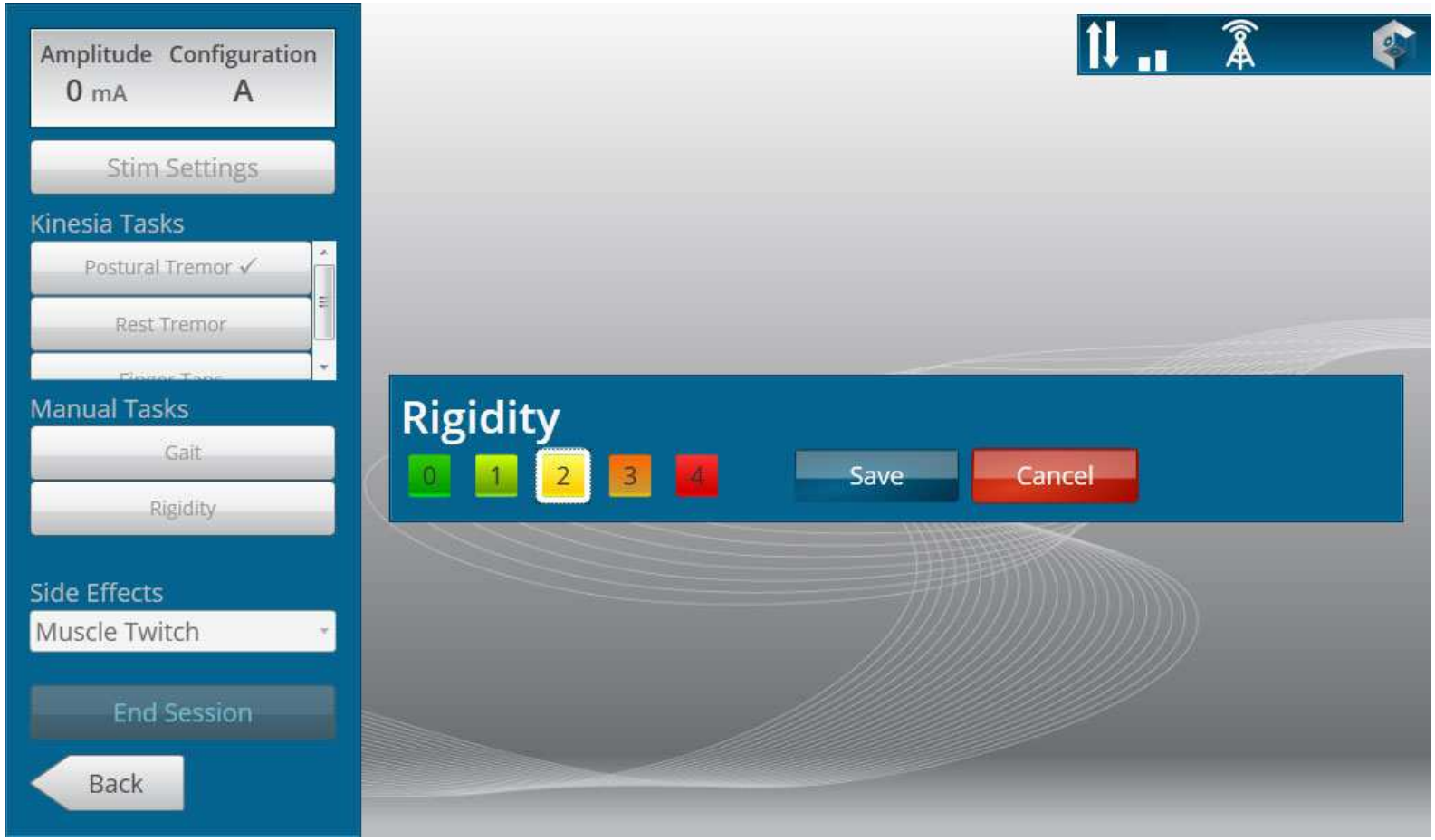
Sensor-Based Assessment

GREAT LAKES NEUROTECHNOLOGIES

Sensor-Based Assessment

GREAT LAKES NEUROTECHNOLOGIES

Manual Task Assessment



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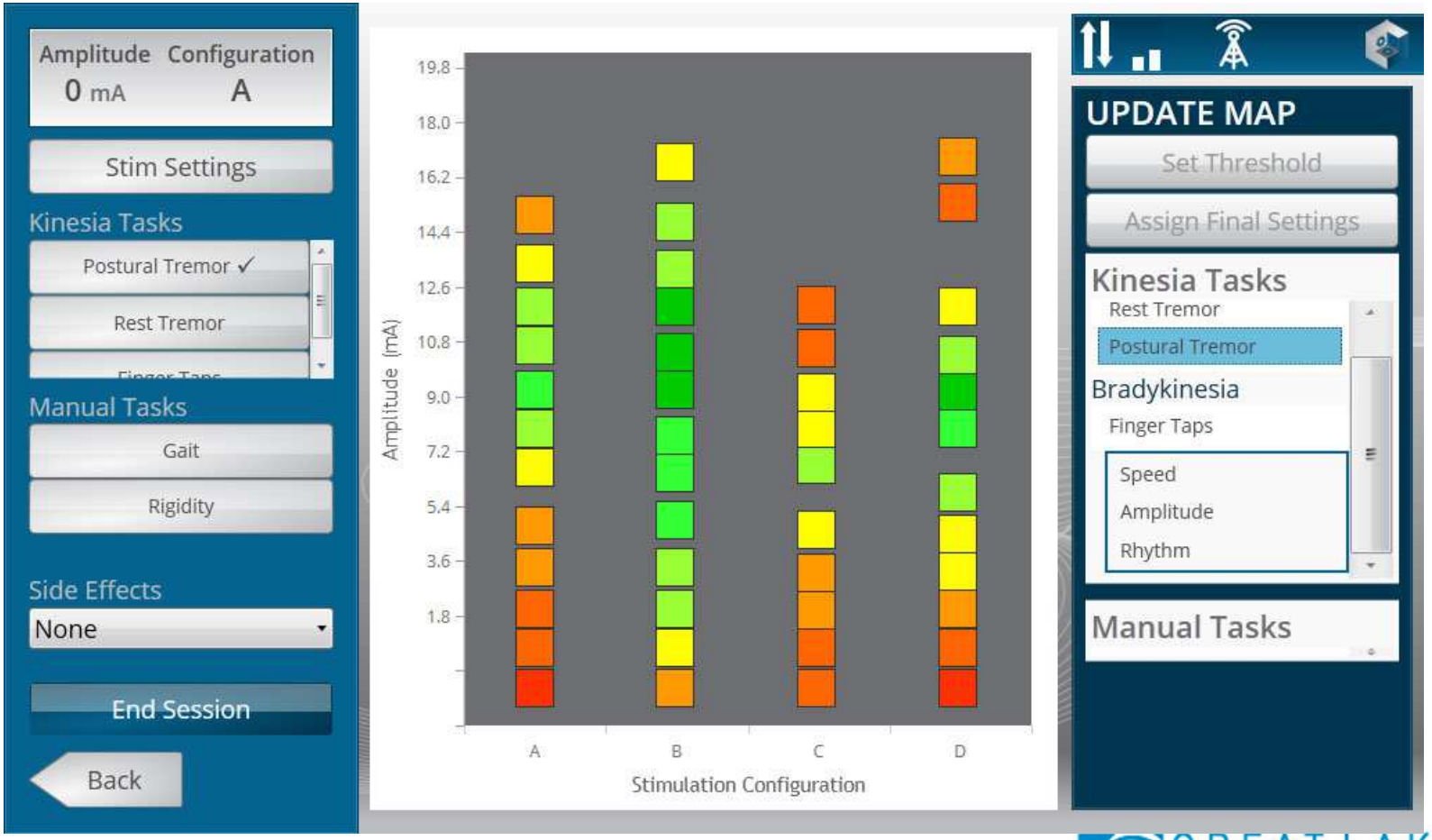
Populated Tuning Map



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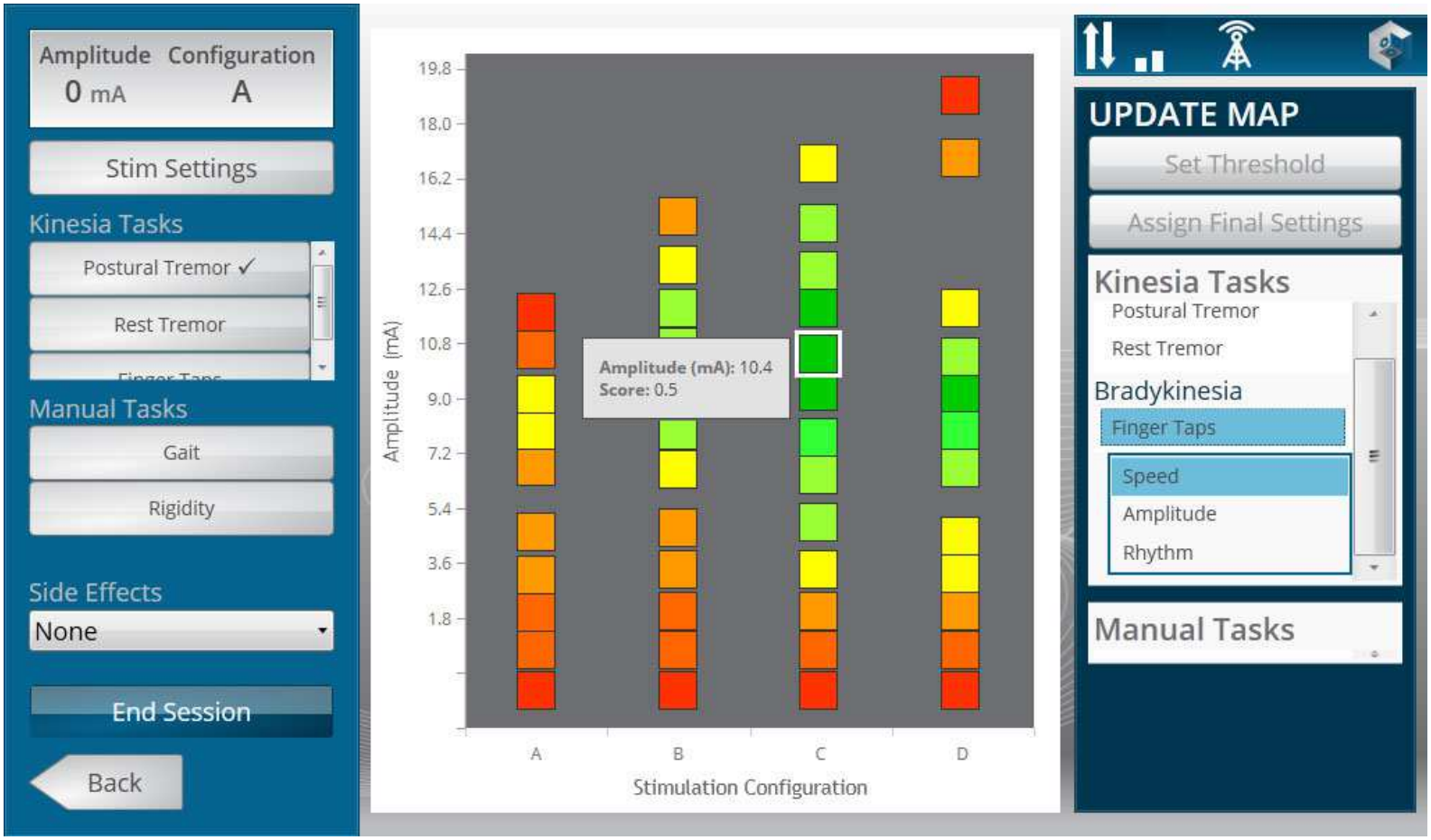
Context-Specific Information



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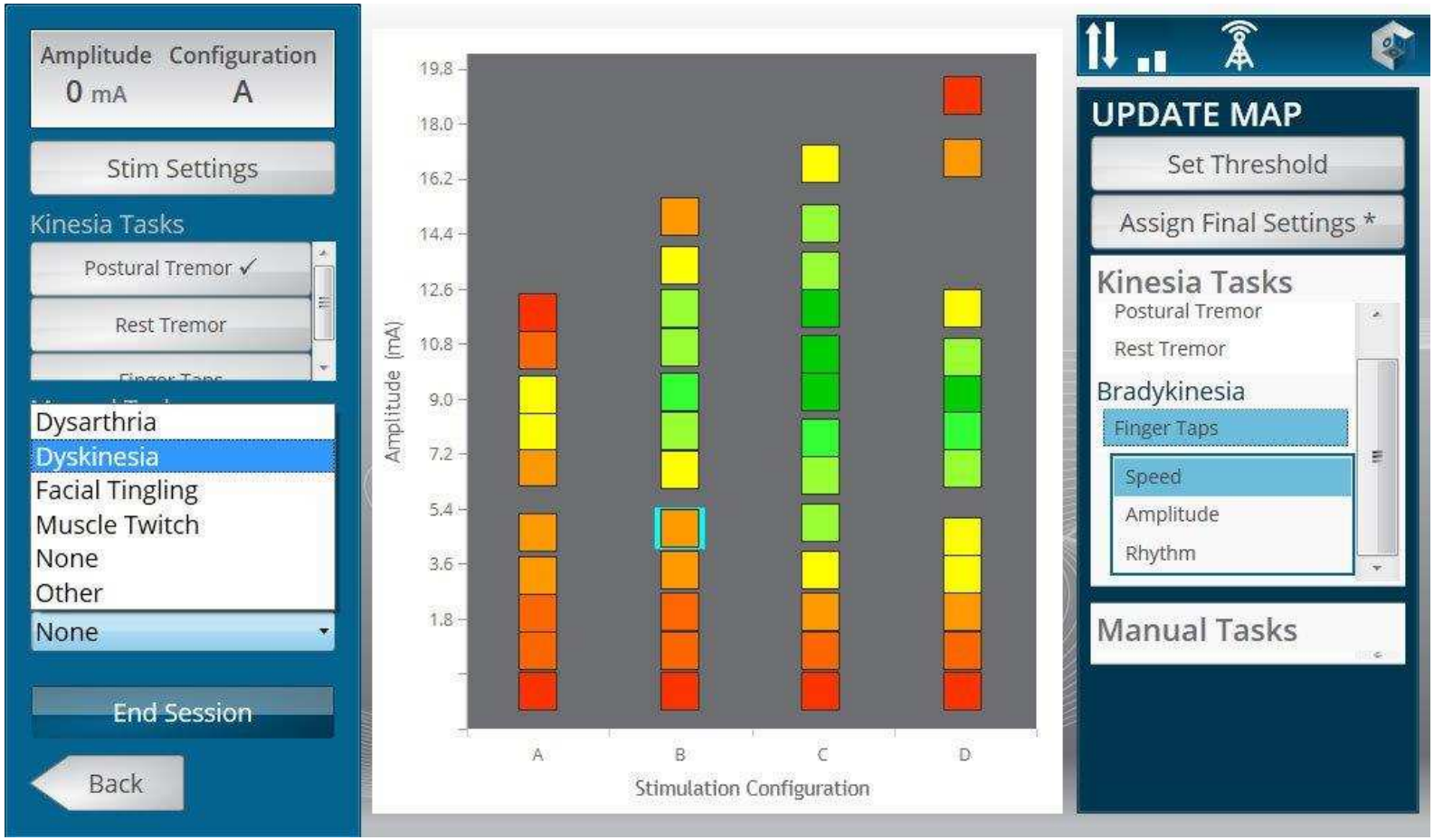
Select Side Effect



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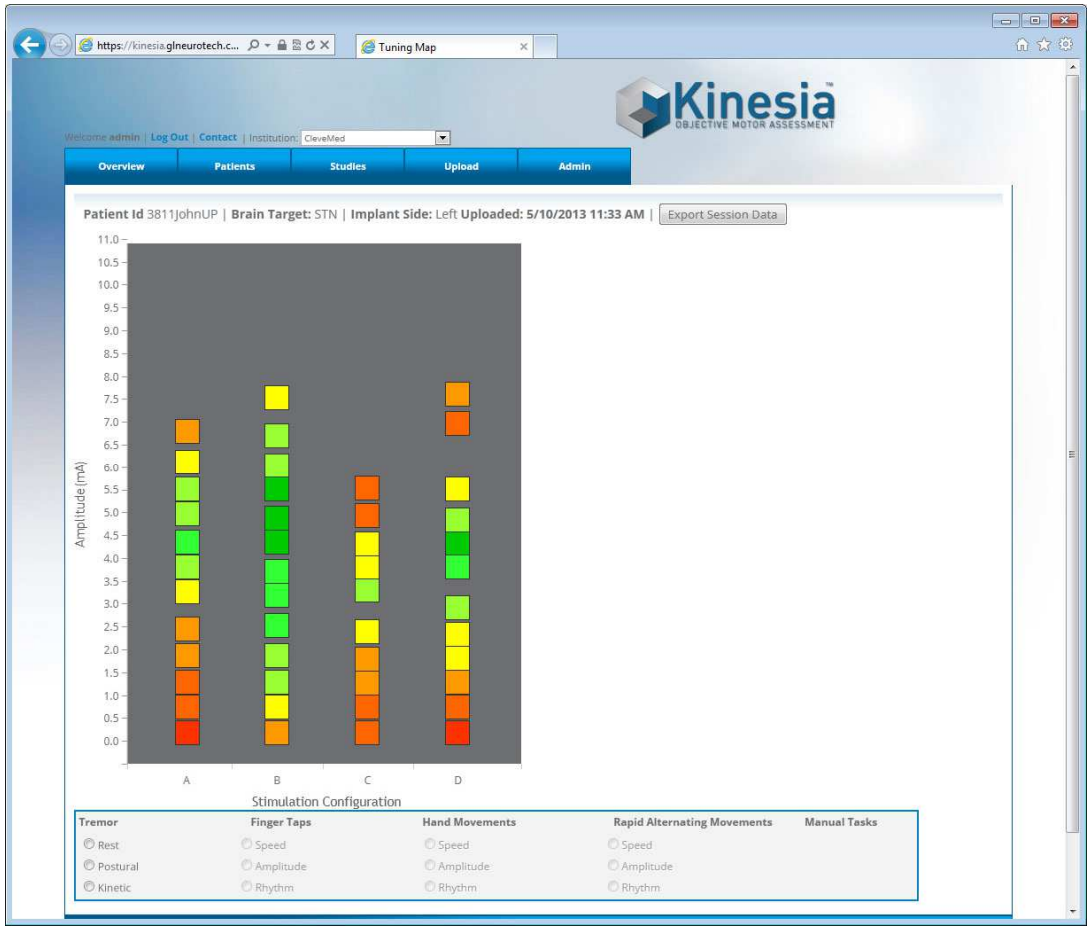
Online Management

GREAT LAKES NEUROTECHNOLOGIES

Online DBS Programming Reports

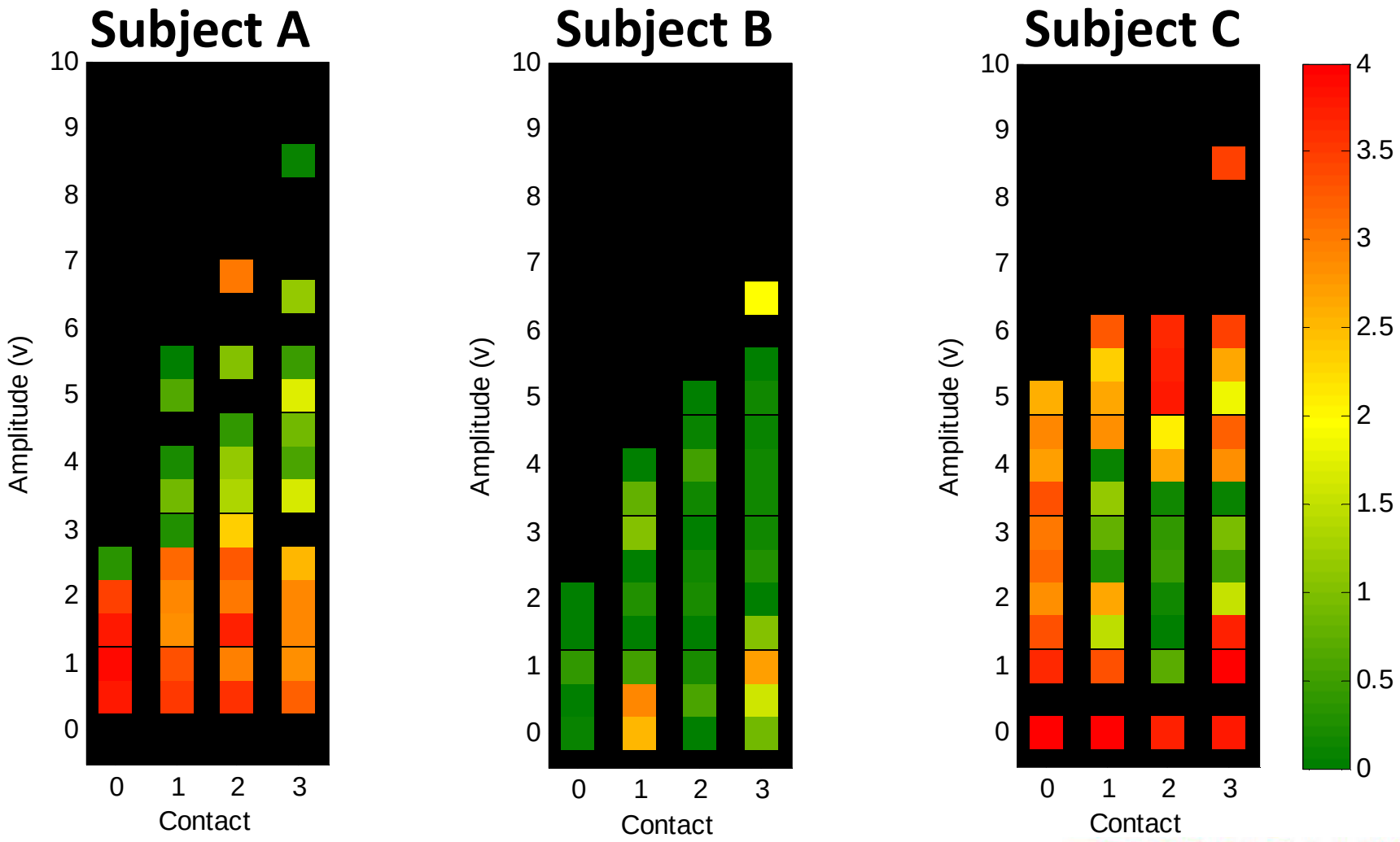


GREAT LAKES NEUROTECHNOLOGIES

Clinical Trial Data and Lessons

GREAT LAKES NEUROTECHNOLOGIES

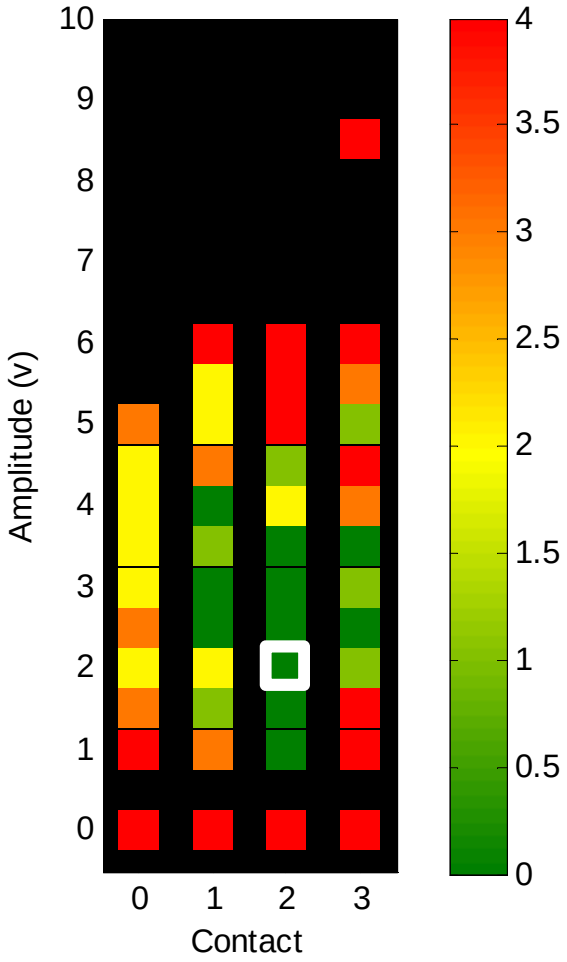
Tuning Maps: Rest Tremor



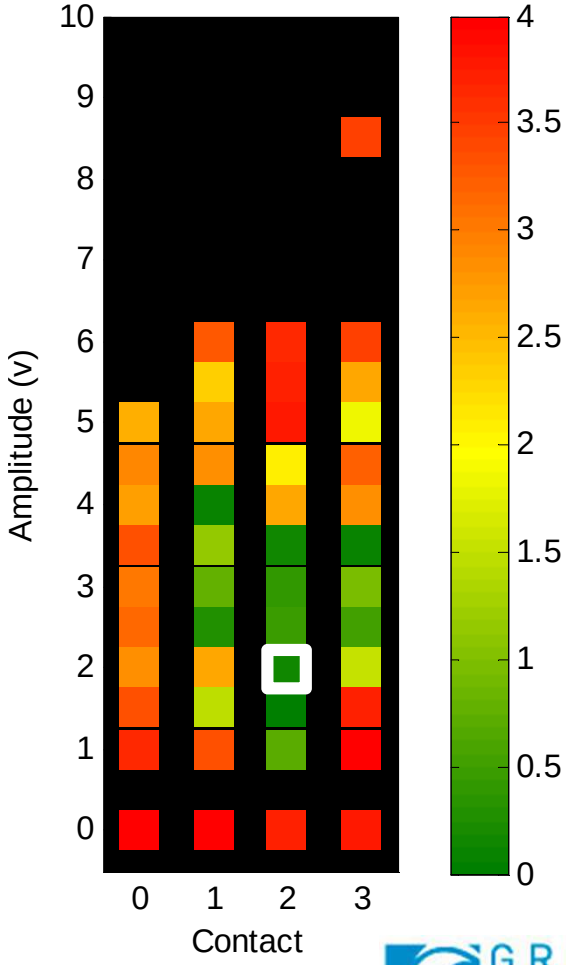
GREAT LAKES NEUROTECHNOLOGIES

Subject 1: Rest Tremor

Clinician UPDRS

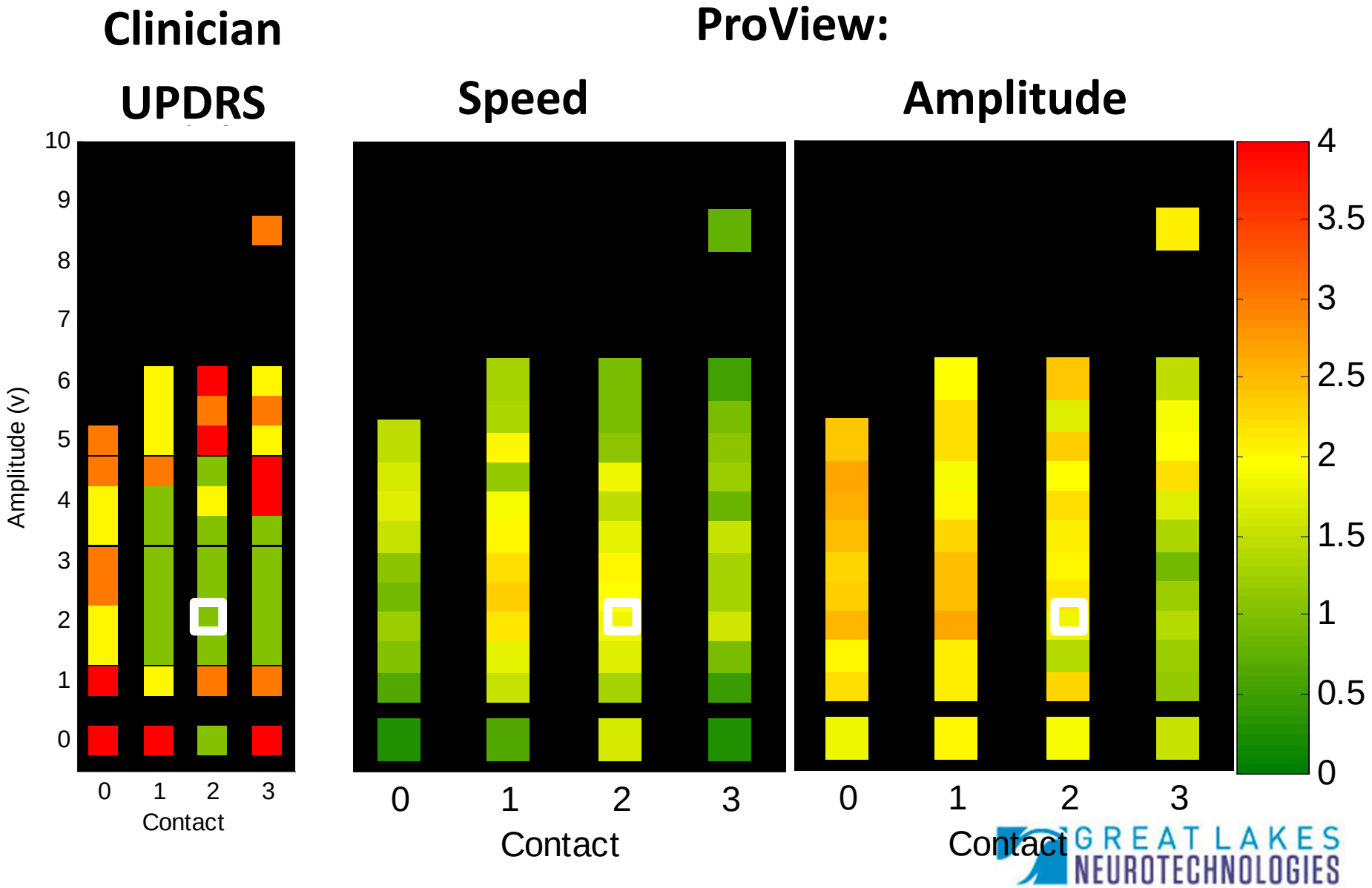


Kinesia ProView

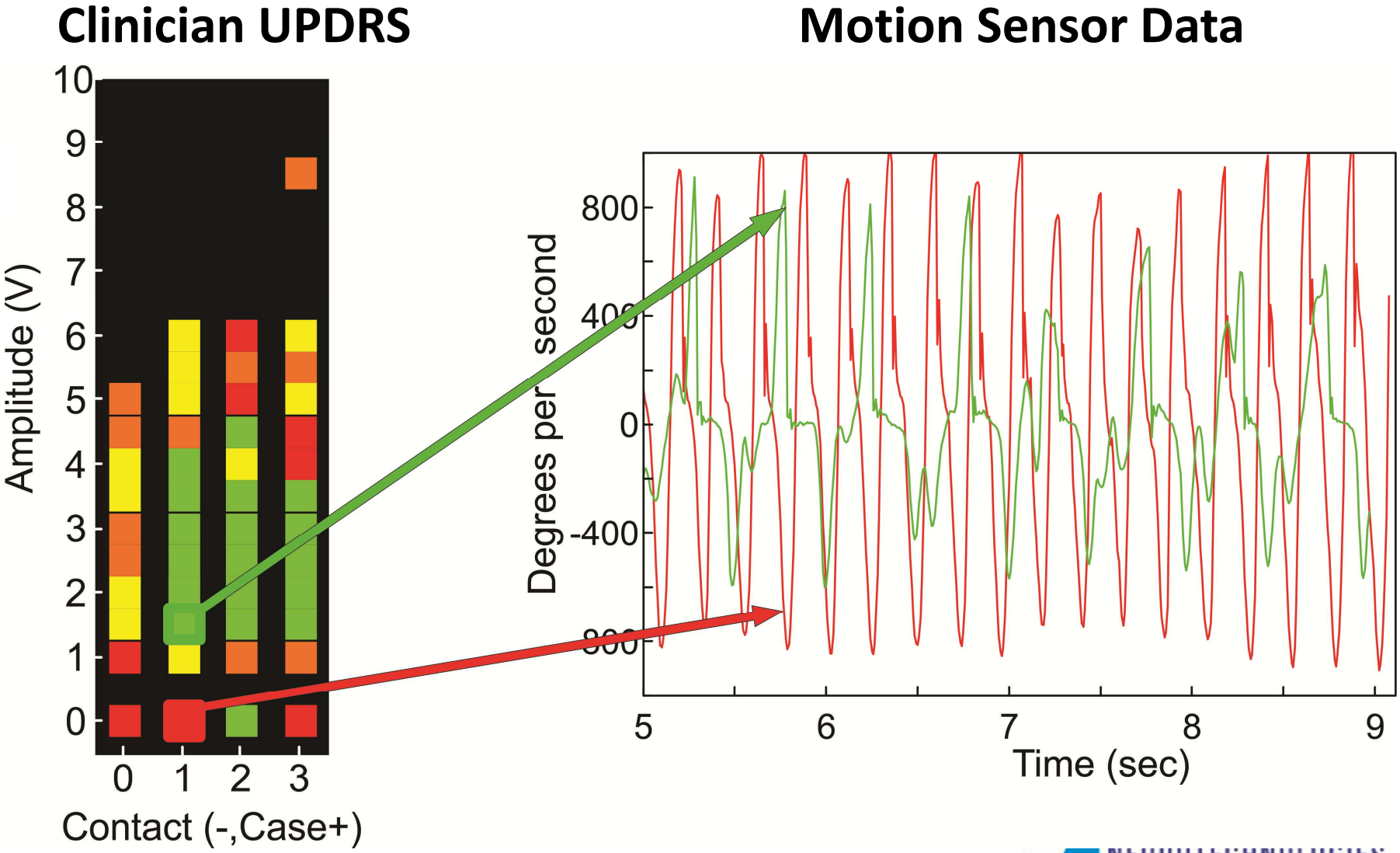


GREAT LAKES NEUROTECHNOLOGIES

Subject 1: Finger Tap

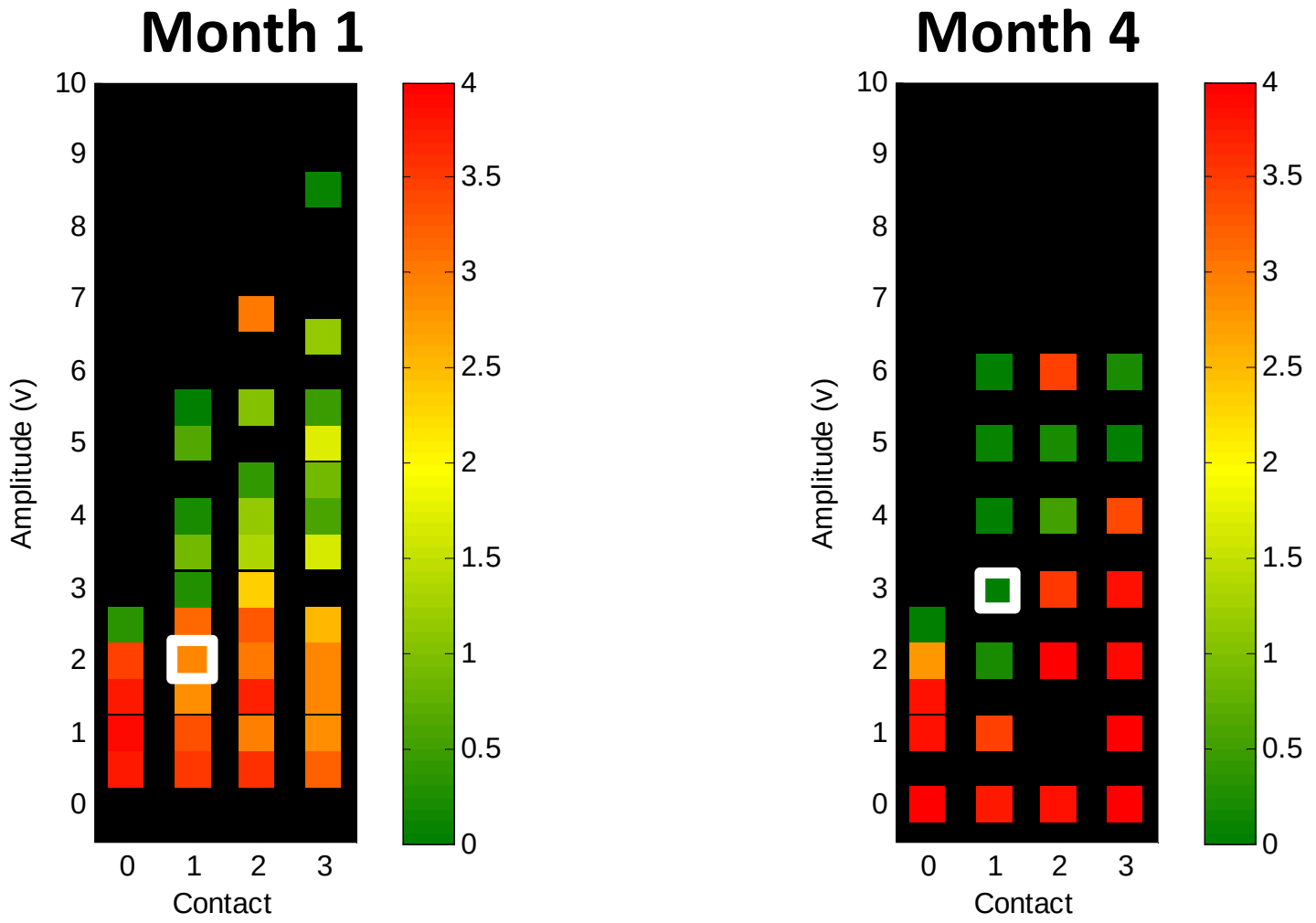


Subject 1: Finger Tap Detail



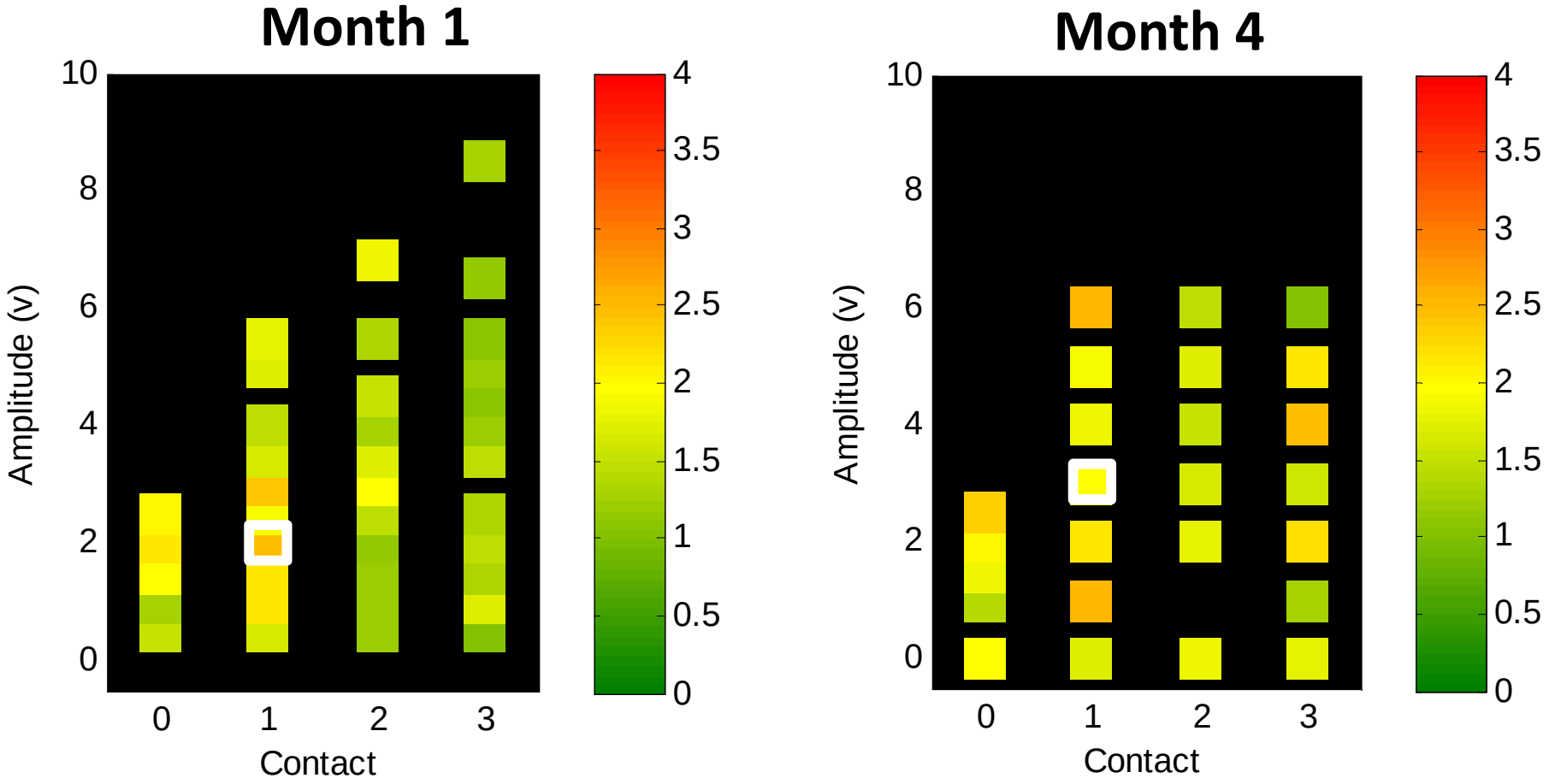
NEUROTECHNOLOGIES

Subject 2: Rest Tremor



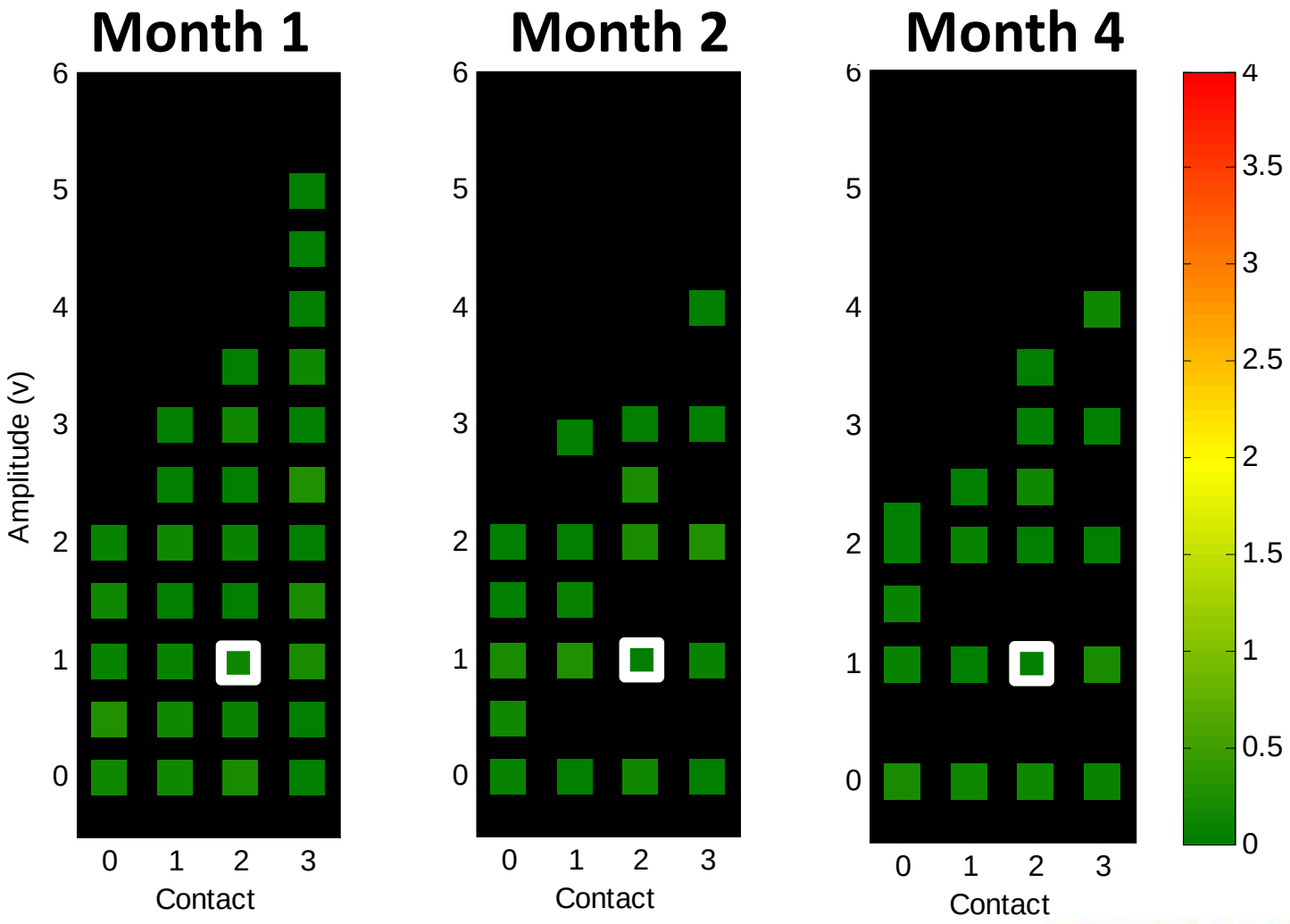
GREAT LAKES NEUROTECHNOLOGIES

Subject 2: Finger Tap Bradykinesia



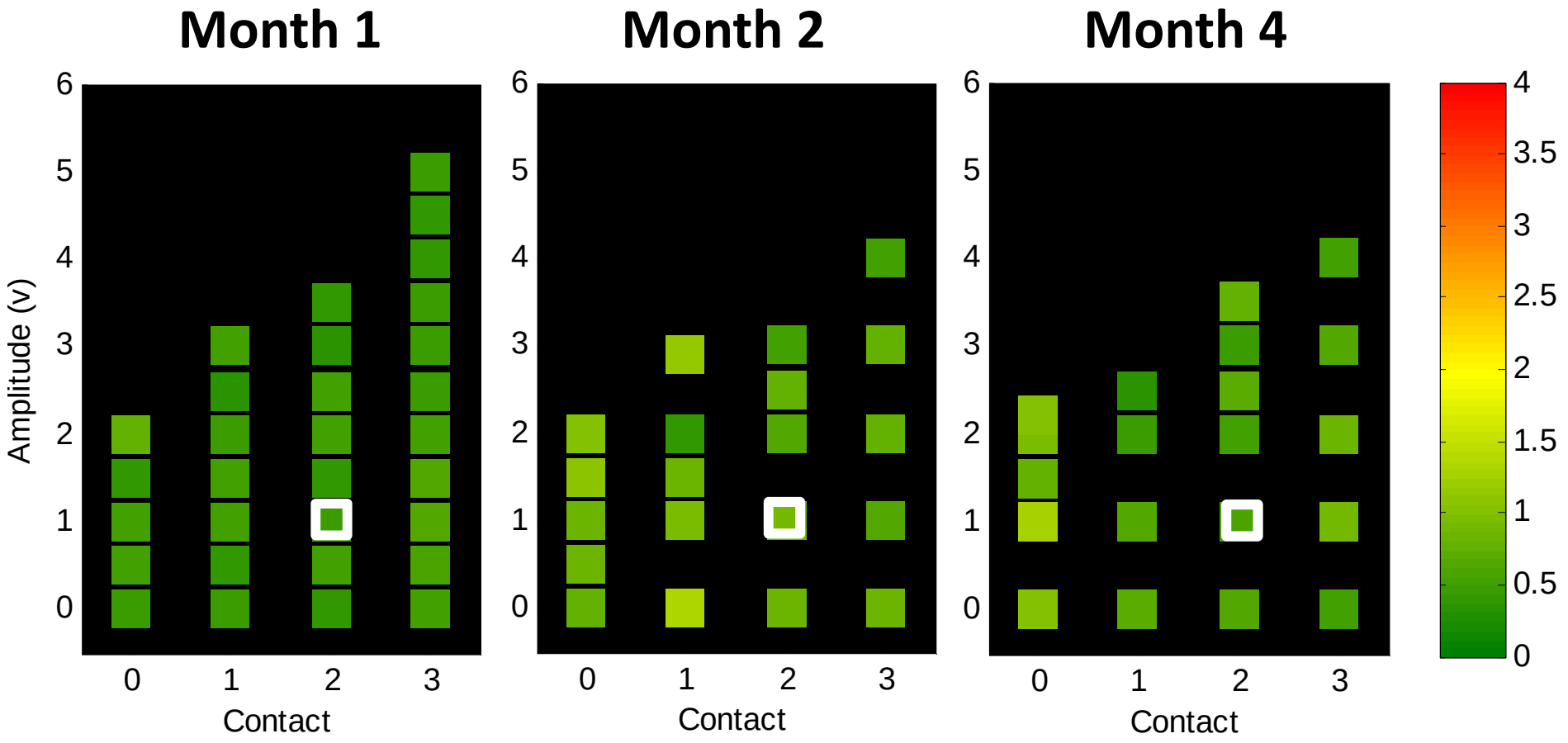
GREAT LAKES NEUROTECHNOLOGIES

Subject 3: Rest Tremor



GREAT LAKES NEUROTECHNOLOGIES

Subject 3: Finger Tap Bradykinesia



GREAT LAKES NEUROTECHNOLOGIES

Kinesia Technology Value Added

GREAT LAKES NEUROTECHNOLOGIES

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

GREAT LAKES NEUROTECHNOLOGIES

GREAT LAKES
NEUROTECHNOLOGIES

Kinesia HomeView

Applications and Markets

Patient Care

Clinical Trials

DBS Programming

GREAT LAKES NEUROTECHNOLOGIES

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

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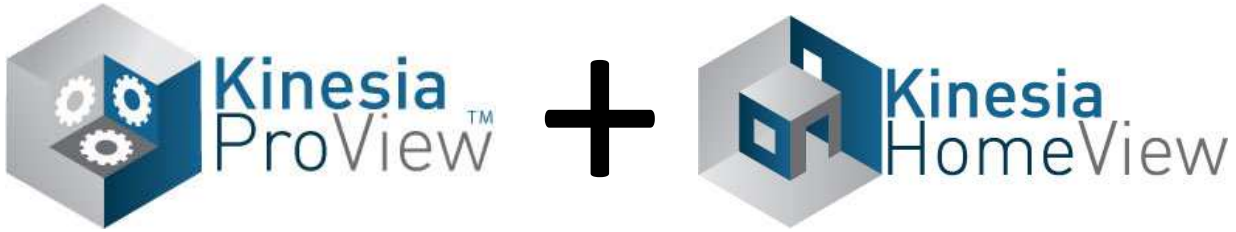
ProView and HomeView Value Added to DBS



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

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Questions?

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