

# MEDTRONIC BRAINSENSE™ TECHNOLOGY: CLINICIAN CASE STUDY ON USE OF BRAINSENSE™ FEATURES

Data presented represents the experience, results, and recommendations of one clinician's use with the Percept™ PC device. Results in other case studies may vary.

In this case study, physician Dr. Sol De Jesus utilizes features of BrainSense™ Technology to assist with therapy programming. Percept™ PC with BrainSense™ technology\* was selected as the device of choice for a 69-year-old patient with Parkinson's disease to gain additional insights on patient's therapy inside and outside the office. Patient had a bilateral implant of STN.

## Patient Background Snapshot

- 69 year right handed woman with Parkinson's Disease. Symptom onset in 2010 with presenting symptom of left hand tremor.
- Exam showed: left predominant bradykinesia, rigidity, and rest tremor.
  - MDS-UPDRS OFF 65/132 ON 29/132
- Medication regimen:
  - Carbidopa-levodopa 1 tablet every 4 hours, 4 times a day.
  - Entacapone 200mg with each levodopa dose.
- Medication benefit: Variable "kicking in," 2-3.5hr ON time per dose (influenced by emotional state, level of activity, food, sleep). Mild dyskinesia.

## Patient and Clinician Goals

Goals for STN DBS therapy were to:

1. Reduce OFF time
2. Improve motor symptoms that were anxiety provoking
3. Reduce/eliminate tremor that impacted sleep

The BrainSense™ technology features were utilized to support the patient's therapy management and goal achievement.

Medtronic's Deep brain stimulation safely and effectively manages tremor, rigidity, and bradykinesia associated with Parkinson's disease. It may be a therapeutic option for patients with recent or longer-standing motor complications.

## Initial Programming Session

### 1. BrainSense™ Setup

A low-frequency peak (left STN: 4.88 Hz) and a small beta frequency peak (right STN: 19.53 Hz) at lower power (0.85  $\mu$ Vp) were identified (Figure 1) utilizing BrainSense™ Setup features.

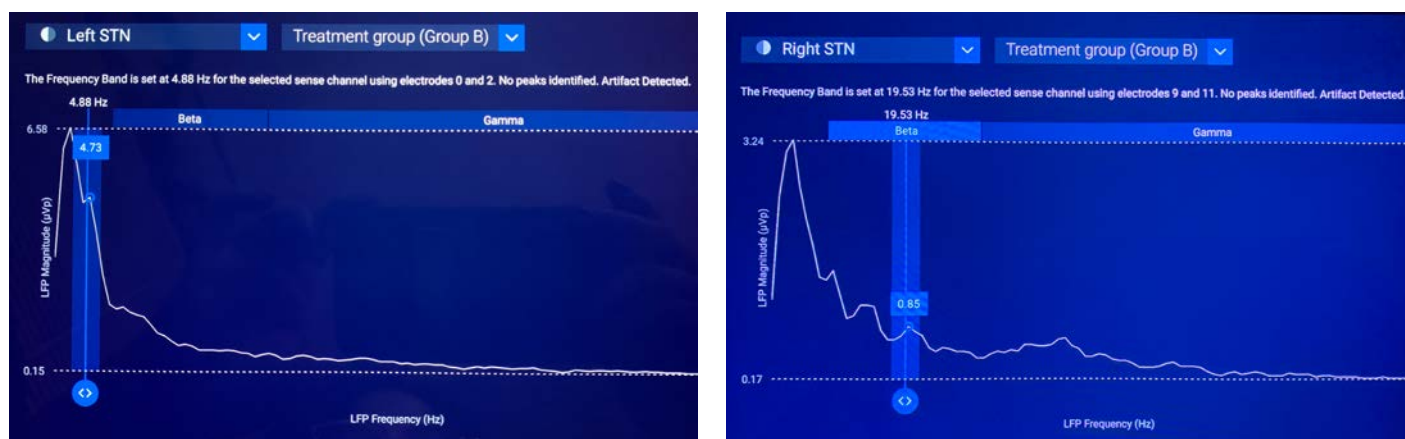


Figure 1: BrainSense™ Setup showing beta peaks in left and right STN

\* The sensing feature of the Percept™ PC system is intended for use in patients receiving DBS where chronically-recorded bioelectric data may provide useful, objective information regarding patient clinical status. Signal may not be present or measurable in all patients. Clinical benefits of brain sensing have not been established.

## 2. BrainSense™ Timeline

BrainSense™ Timeline was set up to track the frequency of interest (FOI) identified in the BrainSense™ Setup. Timeline allows the magnitude of the FOI to be followed while the patient is at home.

## 3. BrainSense™ Events

BrainSense™ Events were configured to include “Medication” as an event that could be tracked by the patient. The patient was instructed to log the event just prior to medication intake. This would create a time stamp and create a local field potential (LFP) snapshot at the time of the button press. This information may provide additional insights about the patient’s status prior to taking medication.

The patient was given a specific therapy group with sensing enabled. One week prior to the second programming visit, the patient was asked to switch to the sensing-enabled group.

## Second Programming Session – 1 month later

### 1. BrainSense™ Events

Events were reviewed to look at the frequency of interest related to the medication event (Figure 2). A total of 33 medication events were logged by the patient. The LFP profile showed a large peak in the left STN at the 7-8Hz correlating to patient’s tremor symptoms. The clinician examined the LFP profile immediately prior to taking the medication.

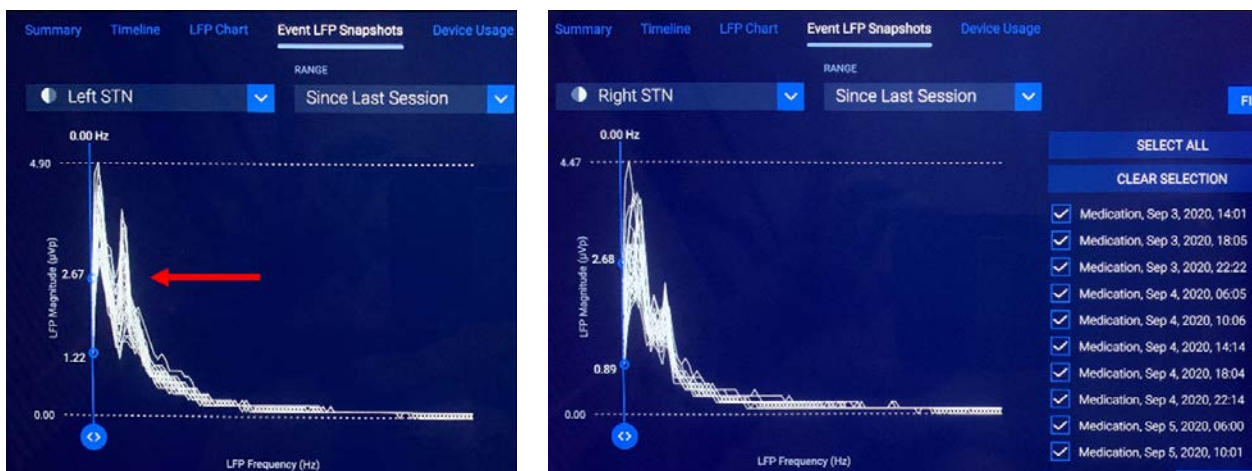


Figure 2: BrainSense™ Event with LFP snapshot

## 2. BrainSense™ Timeline

The timeline assessment (Figure 3) seemed to show some correlation between peak power with medication intake (ie, the signal amplitude reduced after medication), with potentially better control on the left versus the right STN.

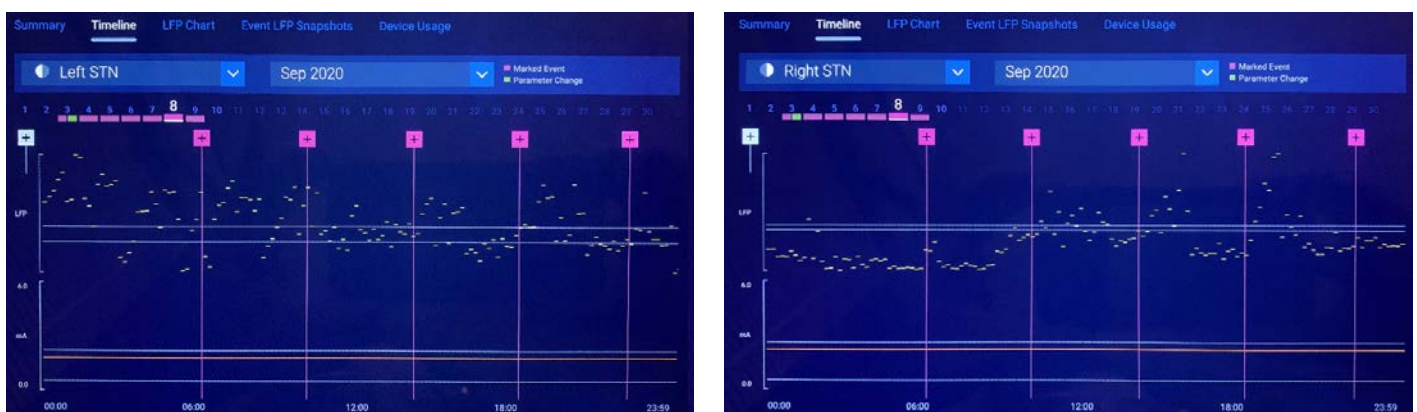


Figure 3: BrainSense™ Timeline with Events (purple)

## 3. Modifications

During the second programming session, the peaks that were being followed were adjusted to 7.81 Hz (left) and 10.74 (right).

A new event was provided for “OFF time” allowing the clinician more insight into the patient experience in relationship to the LFP status recorded outside of the clinic.

## Third Programming Session – 3 months later

The patient reported doing well but remained with nonspecific complaints of “feeling off” characterized as uneasiness/ internal shakiness.

### 1. BrainSense™ Events

Event snapshots continued to show a peak in the left STN during recordings of “OFF time” as there were symptoms of tremor, and no peaks on the right during “Medication.”

### 2. BrainSense™ Timeline

The BrainSense™ Timeline view showed lower peak power during sleep and higher power around the time of events.

### 3. BrainSense™ Streaming

In clinic, BrainSense™ Streaming was used to visualize the LFP relationship to DBS programming (Figure 4). LFP power was better suppressed when shifting from stimulation frequency of 135 Hz to 150 Hz.

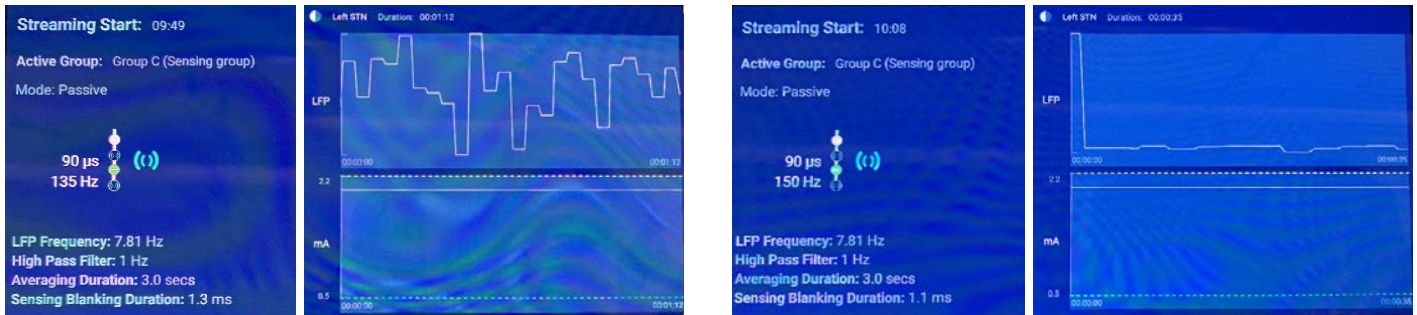


Figure 4: BrainSense™ Streaming

### 4. Modifications

Prior to the fourth programming session, an additional event was added titled “Feeling ON” so that “Feeling ON” comparisons could then be made between “OFF time” and “Feeling ON” markers.

## Key Take Aways from Case Study

- BrainSense survey should be performed in the OFF medication state for better signal capture.
- For initial programming visits, “medication” may be a simple first event to consider for tracking purposes.
- For subsequent visits, choose event types that correspond to patient symptoms that can be further optimized with DBS and medications (these may change from session to session).
- BrainSense™ Events can help confirm that the frequency chosen to track at initial programming is a relevant frequency to continue utilizing.
- BrainSense™ Events can be leveraged to show what is happening to LFP signals while at home and guide adjustments to FOI being tracked with timeline. This feature was utilized to gain additional insights between problem times and well controlled symptoms.

## Summary of purpose and use of each BrainSense™ feature

### BRAINSENSE™ SETUP

In order to use all features of BrainSense™ technology (with the exception of BrainSense™ Survey), the user must first setup LFP sensing using BrainSense™ Setup, and select a frequency band of interest (approximately 5Hz wide) to track while the patient is out of office.

Use: In-clinic, with approximately 90 seconds measurement for setup.

### BRAINSENSE™ SURVEY

Broad spatial overview of LFP signals measurable from both hemispheres of the patient with stimulation off.

Use: In-clinic, with approximately 90 second measurement duration.

### BRAINSENSE™ TIMELINE

Once BrainSense™ Setup has been completed, the Timeline can be used to analyze the out-of-office data when the patient returns to the clinic. This is used to assess the data for changes in LFP activity that may occur over the course of a day(s).

Use: Outside-clinic

### BRAINSENSE™ EVENTS

Once BrainSense™ Setup has been completed, BrainSense™ Events, a.k.a LFP Snapshots, can be recorded at a moment in time, showing the magnitude of the LFP signal over a range of frequencies. The LFP Snapshot is recorded when the patient records an event (eg, 'symptom' or 'medication intake') as configured by the clinician. This is used to assess the occurrence of clinician-defined events, and associated LFP activity with those events.

Use: Outside-clinic, the snapshot is representative of a period of approximately 30 sec after patient marking an event.

### BRAINSENSE™ STREAMING

Once BrainSense™ Setup has been completed, the user can view the LFP power in a selected frequency band in real-time, by streaming the data to the clinician tablet. This is used to observe changes in the LFP during active stimulation programming or while instructing and observing the patient performing activities. Moreover, Streaming can be used to collect time domain data from the selected channel(s) for offline analysis and signal processing.

Use: In-clinic, with no limit on streaming measurement duration, with or without stimulation.

### Brief Statement:

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

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De Jesus S. Neurology Workflow Considerations for Percept™ PC with BrainSense™ Technology. Neurology and Neurosurgery Workflow Considerations of Percept™ PC with BrainSense™ Technology; Jan 7, 2021. Virtual.

## Medtronic

### Europe

Medtronic International Trading Sàrl.  
Route du Molliau 31  
Case postale  
CH-1131 Tolochenaz  
www.medtronic.eu  
Tel: +41 (0)21 802 70 00  
Fax: +41 (0)21 802 79 00

### United Kingdom/Ireland

Medtronic Limited  
Building 9  
Croxley Park  
Hatters Lane  
Watford  
Herts WD18 8WW  
www.medtronic.co.uk  
Tel: +44 (0)1923 212213  
Fax: +44 (0)1923 241004

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