

Medtronic BrainSense™ Technology: Report of User Experience

Medtronic data on file, BrainSense Survey, 2022

UK clinicians who were early adopters of Medtronic BrainSense Technology, were asked to complete a survey to record their experience and opinion of programming with this technology in clinic. This report presents the aggregated, anonymised results, in accordance with the legal requirements of GDPR, for clinicians interested in the early findings.

Background

The Percept™ PC neurostimulator with BrainSense technology captures brain signals (LFPs) using an implanted deep brain stimulation (DBS) lead(s). The brain signals can be recorded simultaneously while delivering therapeutic stimulation, during and outside the clinic. Clinicians can correlate the brain signals with stimulation and events; capturing medication, symptoms or side effects to deliver personalized, data driven treatment and adjust stimulation as patients' needs evolve. The survey results were based on use of the Medtronic Percept™ PC neurostimulator (Model B35200), with Medtronic SenSight™ directional (1-3-3-1) leads (Models B33005, B33015) and SenSight™ extensions (Model B34000).

Results

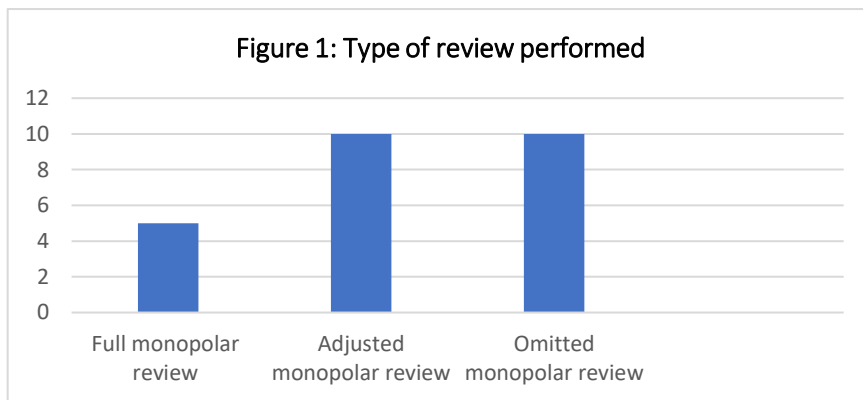
Data was collected from **25 programming sessions**, performed by **13 DBS Nurse Specialists** across **10 hospitals** in England and Ireland. The indications for DBS were Parkinson's (n=23), Tremor (n=1) and Dystonia (n=1).

A Local Field Potential (LFP) was seen with all 25 patients when the BrainSense Survey was performed.

80% (n=20) of clinicians recorded that they programmed based directly on the LFP result.

40% (n=10) omitted the monopolar review and 40% (n=10) performed an adjusted monopolar review (See figure 1).

95% reported that, when performed, the monopolar review correlated with the BrainSense survey results.



All BrainSense features have been used in clinic (See figure 2)

BrainSense Survey

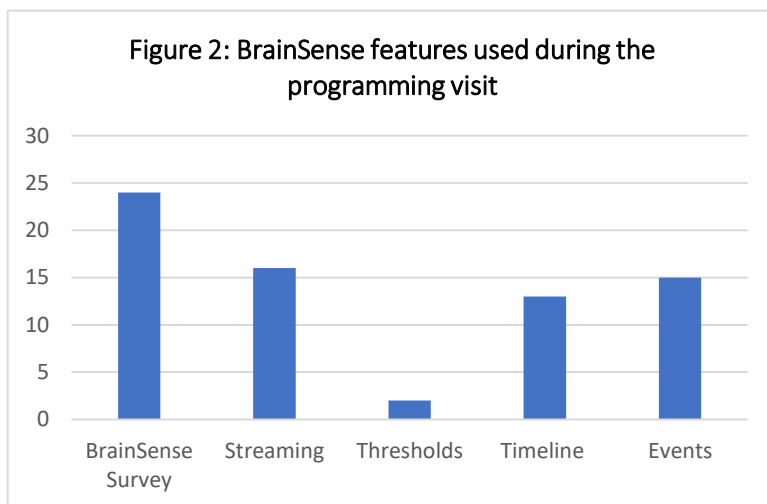
Identification of the LFPs measurable from both hemispheres and characterised into frequency bands.

Used during 96% (n= 24) of sessions

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 LFPs during active stimulation.

Used during 64% (n=16) of sessions



Features used outside of clinic: Recording LFP data chronically for follow-up

Brainsense Timeline

Once BrainSense Setup has been completed, the timeline is used to analyse the out-of-clinic 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).

Used during 52% (n=13) of sessions

Thresholds

This is the representation of LFP power in the sensing frequency band.

Used during 8% (n=2) of sessions

Events

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 as configured by the clinician, such as 'off' period, dyskinesia or medication.

Used during 60% (n=15) of sessions

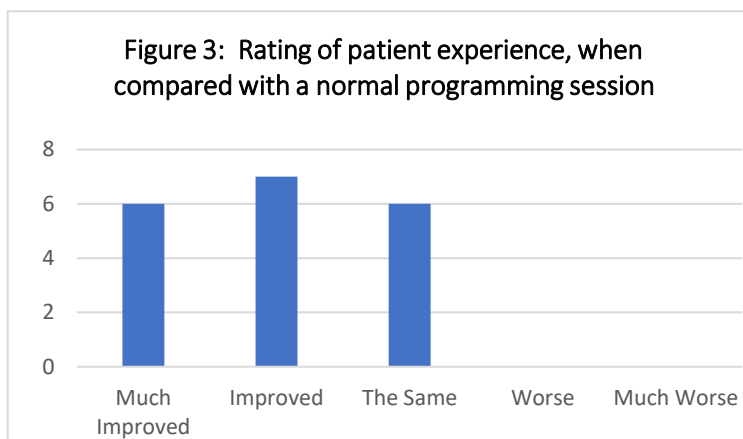
Benefits of BrainSense Features

Clinicians were asked to rate how 'useful' the BrainSense features will be to programming, using a scale of 0-5 stars. A **mean score of >4.0 for all features** illustrates the value attributed to these features both during and outside the clinic.

| | Mean Score | Minimum | Maximum |
|-------------------|------------|---------|---------|
| BrainSense Survey | 4.84 | ★★★★ | ★★★★★ |
| Streaming | 4.89 | ★★★★★ | ★★★★★ |
| Thresholds | 4.43 | ★★★ | ★★★★★ |
| Timeline | 4.65 | ★★★ | ★★★★★ |
| Events | 4.40 | ★★ | ★★★★★ |

Patient Experience

Anecdotal reports of improved patient experience when using BrainSense technology, led to the subsequent inclusion of this question in the survey. Hence, the incomplete data set. However, when asked to compare with previous, traditional programming sessions, it was reported that the **patient experience was 'much improved' in 31.5% (n=6) and 'improved' in 37% (n=7) of cases.** Though it was reported to be 'the same' in 31.5% (n=6) of cases, there were no reports of the experience being worse. (See figure 3.)



Conclusion

This report regarding the adoption of Medtronic BrainSense technology in the UK and Ireland illustrates its early adoption, and BrainSense features are being used appropriately and successfully during and outside of the clinic. Users reported excellent correlation between the BrainSense Survey results and the monopolar review, when performed. Clinicians recorded in additional feedback comments including '**patient experience much improved**', '**very satisfactory outcome**', '**excellent patient outcome**'. Furthermore, this technology can be used flexibly to integrate and align with the workflows of different teams and meet their specific requirements.

Future work will include an evaluation regarding potential time saving benefits in clinic with the use of sensing, given that 80% of users reported either omitting or performing a modified monopolar review during these sessions, when patients are without their Parkinson's medication. Ongoing support and guidance will be provided to clinicians as we continue this BrainSense journey together.

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. If using an MRI SureScan™ device, see the MRI SureScan™ technical manual before performing an MRI. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.eu. For applicable products, consult instructions for use on manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.