Medtronic
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Percept™ PC Neurostimulator with BrainSense™ Technology

DBS Sensing White Paper

Percept™ PC Neurostimulator with BrainSense™ Technology

Supplemental Information for Sensing Only Configuration

Contents

Introduction

The Model B35200 Percept™ PC neurostimulator with BrainSense™ technology is Medtronic's next generation, primary cell, implantable device used to deliver deep brain stimulation (DBS). This device is compatible with Medtronic 1x4 lead Models 3387, 3389, extension Models 37085, 37086, SenSight™ directional (1-3-3-1*) lead Models B33005, B33015, SenSight™ extension Model B34000, programming/ telemetry devices. The Percept™ PC neurostimulator includes a feature capable of bioelectric data recording (passive brain sensing[1,2]) of local field potential (LFP) signals of interest (SOI) through one or two leads implanted in the brain.

1 Signal may not be present or measurable in all patients.

2 Clinical benefits of brain sensing have not been established.

Purpose

This document provides supplemental information about how the BrainSense™ features of the Percept™ PC neurostimulation system works and the data that is captured. The targeted audience includes clinicians and researchers interested in post-processing brain sensing data, from patients with any of the four treated indications**, outside of the clinical interaction with the patient. Refer to product labeling, including the A610 Clinician Programming Guide (M017563C), for specific information including indications, safety and warnings.

Screen shots included in the document are from the product demo software.

Sensing Feature Detailed Descriptions

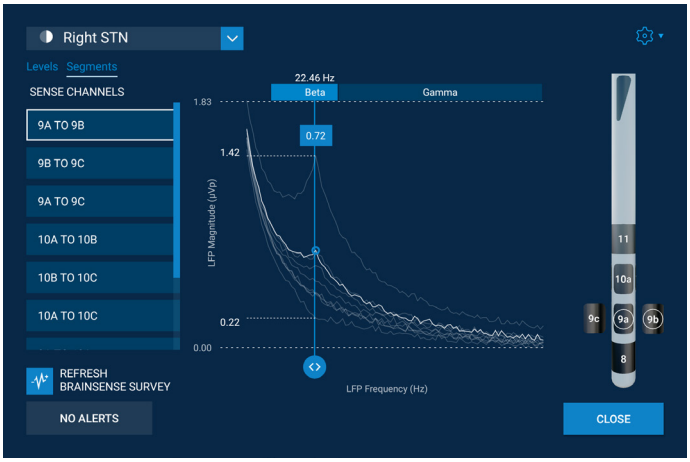
BrainSense™ Survey

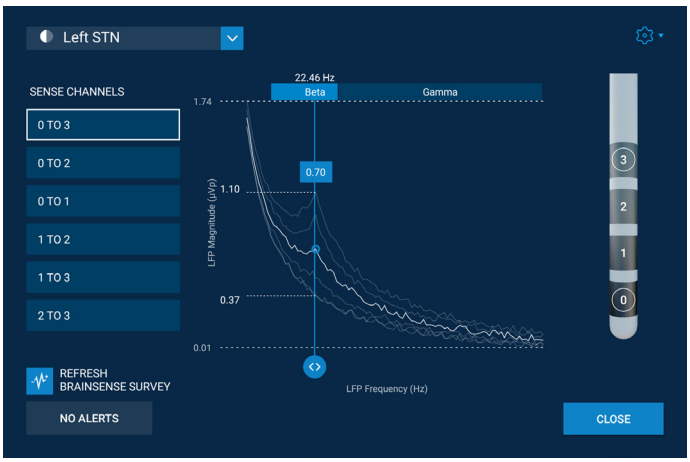
Purpose: Broad spatial overview of LFP signals measurable from both hemispheres of the patient with stimulation off.

Used: In-clinic, with approximately 40 second measurement duration for each grouping of electrode level pairs chosen to survey and approximately 70 second measurement duration for each grouping of segment electrode pairs chosen to survey.

Detailed Design:

- User Interface displays data in the Frequency Domain: LFP Magnitude (µVp) vs. Frequency (Hz)





* Electrode levels 0 and 3 are full rings, electrode levels 1 and 2 are split into 3 isolated electrodes to enable directional stimulation.

**Medtronic's DBS Therapy is approved for 4 indications: Parkinson's disease, essential tremor, dystonia and epilepsy. Device indications vary, refer to product labeling.

- Each LFP graph represents a **differential** signal between two contacts (up to 30 pairs total for SenSight™ leads - 6 electrode ring level pairs and 9 segment-to-segment pairs per lead, and up to 12 pairs total for 1x4 leads – 6 ring level pairs per lead). Therefore, the results are measures of how similar or different two areas of the brain are:
  - Large peak indicates electrode-pairs that are in electrically different regions of the brain
  - Small or absent peaks indicates electrodes that are in electrically similar regions of the brain
  - The largest peak indicates which contact pairs will provide the largest signal for sensing
- The Session Report also contains the BrainSense™ Survey Results in the Frequency Domain.
- Stimulation is off during the measurement.
- To maximize the chance of seeing LFP signals, consider factors that influence this such as medication state.
- An impedance test will be performed if not already done. Sense channels with potential shorts (<250 ohms) or opens (>10 Kohms) are excluded.
- Screening for artifacts (cardiac, motion) is performed. Sense channels with potential artifacts are excluded. The artifact screening can be turned off to view results – see Artifact Override.
- The survey is conducted per hemisphere for 1x4 leads. For SenSight leads, the survey is conducted per hemisphere and per segment pair groupings or electrode level pair groupings. The time domain data (i.e. LFP Magnitude (μVp) vs. time, sampled at 250Hz) for all channels is available in the JSON file only.
  - For 1x4 leads, when the survey is conducted for the first hemisphere, e.g. Left STN, all electrode pair combinations for that lead (0-1, 0-2, 0-3, 1-2, 1-3, 2-3) are recorded simultaneously. If a second lead is present, another survey must be performed for the second hemisphere, e.g. Right STN. This second survey will simultaneously record all electrode pair combinations for the second lead (8-9, 8-10, 8-11, 9-10, 9-11, 10-11).
  - For SenSight leads, after a hemisphere is chosen to survey, e.g. Left STN, a grouping of electrode pairs must also be chosen, consisting of either all electrode level pairs (0-1[a,b,c], 0-2[a,b,c], 0-3, 1[a,b,c]-2[a,b,c], 1[a,b,c]-3, 2[a,b,c]-3) or all segment-to-segment pairs. If electrode level pairs are chosen, all combinations are recorded simultaneously. If segment-to-segment pairs are chosen, the survey is conducted in two passes:

    Pass 1: 1a-1b, 1b-1c, 1a-1c, 2a-2b, 2b-2c, 2a-2c

    Pass 2: 1a-2a, 1b-2b, 1c-2c

    Two surveys, an electrode level survey and a segment-to-segment survey, must be performed to record all available electrode pair combinations for a SenSight lead in one hemisphere. If a second SenSight lead is present, e.g. Right STN, both an electrode level pairs survey and a segment-to-segment pairs survey must be performed to record all available electrode pair combinations for that hemisphere. The electrode level pairs survey will record all combinations simultaneously (8-9[a,b,c], 8-10[a,b,c], 8-11, 9[a,b,c]-10[a,b,c], 9[a,b,c]-11, 10[a,b,c]-11) and the segment-to-segment survey will be conducted in two passes, similarly as described above:

    Pass 1: 9a-9b, 9b-9c, 9a-9c, 10a-10b, 10b-10c, 10a-10c

    Pass 2: 9a-10a, 9b-10b, 9c-10c
- For each channel, the time domain data (about 20 seconds of data) is converted to the frequency domain using a Fast Fourier Transform (FFT). The frequency bins are 0.98 Hz wide with centers from 0-96.68 Hz. Both the time domain and frequency domain data are available in the JSON export.
- There is an advanced "Record Streaming" option on the same screen. This allows the user to stream as long as they desire, while recording LFP on stimulation-compatible electrode pairs (0-2, 0-3, 1-3, 8-10, 8-11, and 9-11 for 1x4 leads; 0-2[a,b,c], 0-3, 1[a,b,c]-3, 8-10[a,b,c], 8-11, and 9[a,b,c]-11 for SenSight leads). The time domain data (i.e. LFP Magnitude (μVp) vs. time, sampled at 250Hz) is available via JSON in an Indefinite Streaming structure. Data collected via the Record Streaming (Indefinite Streaming) is not displayed on the clinician tablet or included in the Session Report.

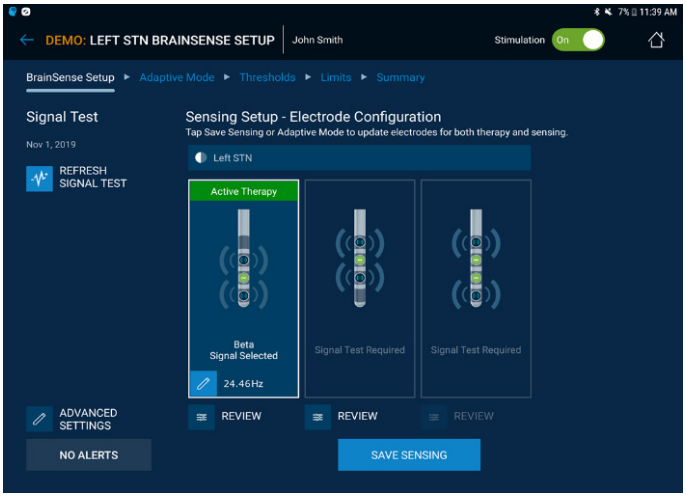
BrainSense™ Setup

Purpose: In order to use BrainSense™ technology in all manners besides BrainSense™ Survey, the user must first setup LFP sensing using BrainSense™ Setup and select a frequency band of interest (approximately 5Hz wide) to track chronically for this particular patient.

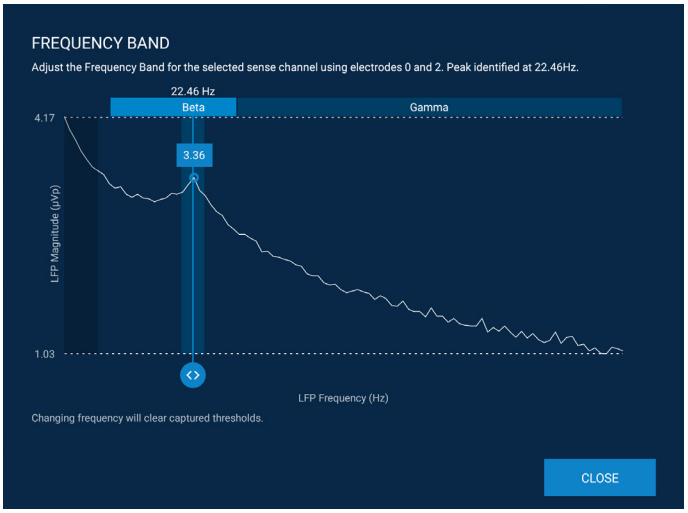
Used: In-clinic, with approximately 90 seconds measurement for setup.

Detailed Design:

- The user initiates a signal test which:
  - Performs an impedance test if not already done. Sense channels with potential shorts (<250 ohms) or opens (>10 Kohms) are excluded.
  - Detects artifacts, both with stimulation off and on.
  - Automatically selects the largest peak on a particular channel, if that peak is in the beta or gamma frequency range and exceeds a value of 1.1 µ Vp, as the frequency band.
- The user then defines which electrodes to use for sensing and which to use for stimulation (3 possibilities)



- The user then optionally defines/adjusts the desired frequency band to record.



- The user interface and Session Report only indicate if artifacts were detected, however the raw data used to determine if artifacts were detected is available in the JSON Export. See - Sensing Specific Data Structures.
- Optionally, the user can configure LFP Thresholds
  - Thresholds are used to categorize the LFP data relative to two clinician defined Thresholds. The LFP data can then later be viewed as above/below/between these thresholds.
  - Streaming and Timeline (see following sections) screens auto-scale their vertical axis to include threshold values, which may increase the utility of these screens.
  - To Setup Thresholds, stimulation is used as actuator to influence the LFP.
    1. Set the stimulation amplitude to elicit a larger LFP signal (e.g. low stimulation amplitude where efficacy is first observed, if the signal of interest is in the beta band of a PD patient), and then capture the Upper LFP Threshold.
    2. Set the stimulation amplitude to elicit a smaller LFP Signal (e.g. larger stimulation amplitude with efficacy but no side effect, if the signal of interest is in the beta band of a PD patient), and then capture the Lower LFP Threshold. Note: Consider factors that may influence the LFP signal when setting thresholds, such as medication.

BrainSense™ Timeline

Purpose: Once BrainSense™ Setup has been completed, the Timeline is 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).

Used: Outside-clinic, records LFP data chronically for follow-up data analysis in-clinic via the Timeline view.

Detailed Design:

- When the patient leaves the clinic, BrainSense™ LFP power domain data is continuously recorded when a BrainSense™ configured group is active. The neurostimulator measures raw time domain data sampled at 250Hz, converts this to the frequency domain, and then measures the power in the clinician specified band. The clinician specified band is approximately 5 Hz wide.
- If LFP thresholds were configured in this group, these also appear on the timeline view on the same plot as the recorded LFP data.
- The average stimulation amplitude, and patient limits (if configured) are also recorded and displayed to the user.
- The LFP power and the stimulation amplitudes are the average value measured over a 10 minute interval and these averages are recorded to the neurostimulator memory.

- Up to 60 days of LFP Data and Stimulation data can be stored on the device, after which the oldest day is overwritten unless BrainSense™ is turned off or the user changes to a group without BrainSense™ configured.
- Patient Marked Events, see BrainSense™ Events, also appear on the Timeline view in pink.
- Stimulation changes including Group Switch, Stim On/Off, CP Session, MRI Mode, and Impedance Test also appear on the Timeline view in green.

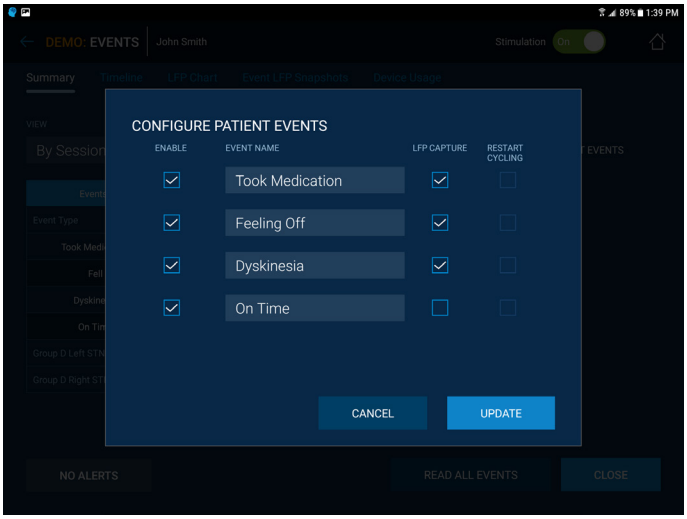
BrainSense™ Events

Purpose: 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 as configured by the clinician. Used to assess the occurrence of clinician-defined events, and associate LFP activity with those events.

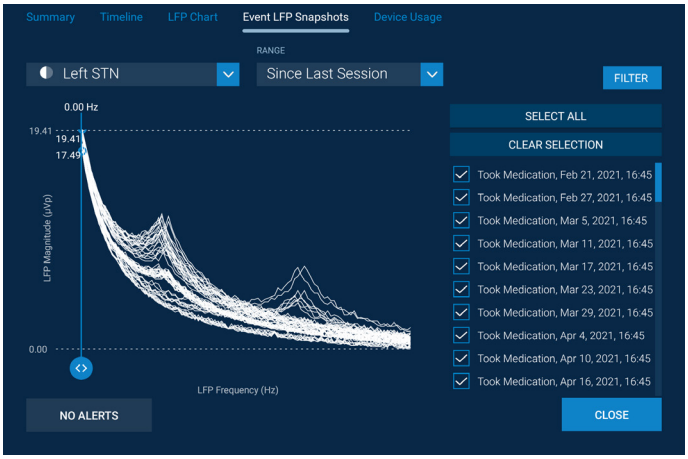
Used: Outside-clinic, with approximately 30 seconds of LFP measurement directly after patient marking an event.

Detailed Design:

- To capture LFP Snapshots when the patient records an event:
  - The active group must be one which has BrainSense™ configured.
  - The clinician must have configured Patient Events (up to 4), with "LFP Capture" selected as an option when the event is configured.



- When the LFP snapshot is captured, the neurostimulator measures approximately 30 seconds of LFP time domain data (250Hz sampling rate) and converts this to the frequency domain. Only the average frequency domain content is stored in the neurostimulator. Time domain data of the snapshot is **not** stored in the neurostimulator's memory. The 30 seconds of data is collected after the Patient Event is received by the neurostimulator.
- The frequency ranges from 0 to 96.68Hz. The upper frequency displayed on user interface may be limited, based on the stimulation frequency, to avoid displaying any potential stimulation artifacts from aliasing.

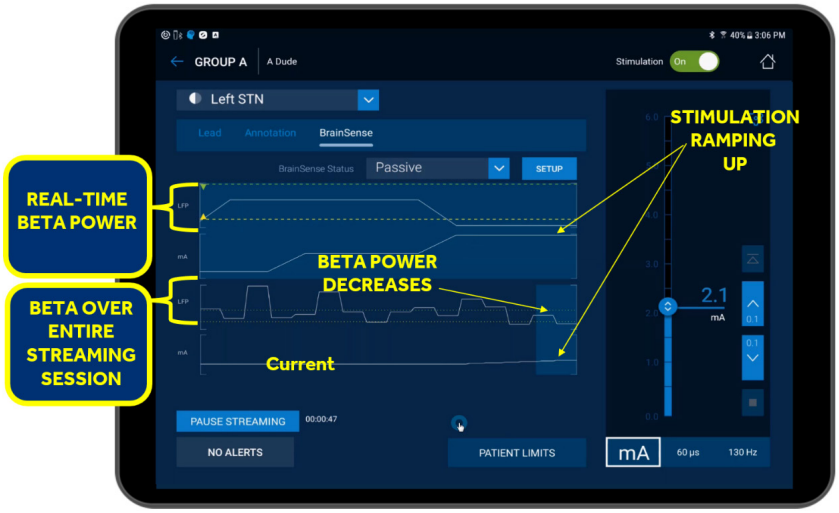


- The neurostimulator can record up to 400 LFP snapshots (e.g. 200 per hemisphere if bilateral). The most recent 400 LFP Snapshots are retained, older snapshots are overwritten.
- Events that do not record LFP can also be captured by the patient. Up to 900 Events can be stored, 400 of which can record LFP snapshots.

BrainSense™ Streaming

Purpose: 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.

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



Detailed Design:

- When start streaming is pressed, LFP data is streamed from both hemispheres, if both hemispheres have BrainSense™ Setup completed.
- Streaming data is viewed one lead at a time.
- The underlying sampling rate of the LFP power is 2Hz, but a unique solution is only calculated at the power averaging duration. Moreover, the power averaging duration is not a moving average it is a unique average, i.e. each average contains a unique set of data, not overlapping. This parameter is available in the Advanced Settings of the BrainSense™ Setup workflow. The underlying sampling of the time domain data is 250Hz.
- There is no maximum duration of streaming. However, consider that long streaming sessions:
- Will fill the tablet memory sooner
- Will take longer to generate the JSON Export
- Long telemetry sessions can impact battery longevity (see Longevity Considerations)
- To optimize streaming performance and minimize the chance of dropping streaming data:
  - See the A610 Clinician Manual for Percept™ PC M017563Cfor information about interference and how to best position the Communicator.
  - Use shorter distances between the INS and Communicator. If not in an intra-operative scenario where the sterile field must be preserved, consider fixating the Communicator to the patient.
  - Minimize any obstacles or people between any components.
  - When streaming data is dropping, the BrainSense™ Streaming screen will show a gap in data. The JSON file has mechanisms such as sequence numbers, time 'tick' counters, and packet size information in addition to time stamp information in order to understand if data was dropped.

Note: There is also a "Record Streaming" option available via the BrainSense™ Survey feature that allows 6 time domain streams to be recorded – See the BrainSense™ Survey section for additional details.

Summary of Sensing Data

The data collected while using the BrainSense™ feature set is available in locations specified in Table 1 BrainSense™ Data Locations.

Table 1: BrainSense™ Data Locations

Sensing Feature Data	Time Domain [LFP Magnitude (µVp) vs. Time]	Frequency Domain [Magnitude (µVp) vs. Hz]	Power Domain [LFP Power in Band vs. Time]	Channels per Hemisphere (1x4 lead)	Channels per Hemisphere (SenSight lead)	Stim: On or Off	Data Collection: In or Out of Clinic
BrainSense Survey							
On-screen	-	X	-	6	15	Off	In
Session Report	-	X	-				
BrainSense Data Viewer	-	X	-				
JSON Export	X	X	-				
BrainSense Survey Indefinite Streaming							
On-screen	-	-	-	3	3	Off	In
Session Report	-	-	-				
BrainSense Data Viewer	-	-	-				
JSON Export	X	-	-				
BrainSense Setup (Signal Check)							
On-Screen	-	X	-	3	3	Both	In
Session Report	-	-	-				
BrainSense Data Viewer	-	X	-				
JSON Export	X	X	-				
BrainSense Timeline Data							
On Screen (timeline)	-	-	X	1	1	Either	Out
Session Report	-	-	Summarized				
BrainSense Data Viewer	-	-	X				
JSON Export	-	-	X				
Events (LFP Snapshot)							
On Screen	-	X	-	1	1	Either	Out
Session Report	-	-	-				
BrainSense Data Viewer	-	X	-				
JSON Export	-	X	-				
BrainSense Streaming							
On-Screen	-	-	X	1	1	Either	In
Session Report	-	-	-				
BrainSense Data Viewer	-	-	X				
JSON Export	X	-	X				

Advanced Topics

Longevity Considerations

See the System Eligibility and Battery Longevity manual (M929534A122) for the impact to INS battery longevity due to chronically recording BrainSense™ signals (i.e. passive sensing).

Long clinician telemetry sessions with the Percept™ PC INS do have a small impact on the INS longevity. Using BrainSense™ streaming during these telemetry sessions does not add much additional energy usage since the primary energy use is the telemetry session itself. A rough order of magnitude estimate of the telemetry session impact for many patients is: a 1 hour telemetry session has approximately a 1 day impact to INS battery longevity.

Signal Processing Parameters

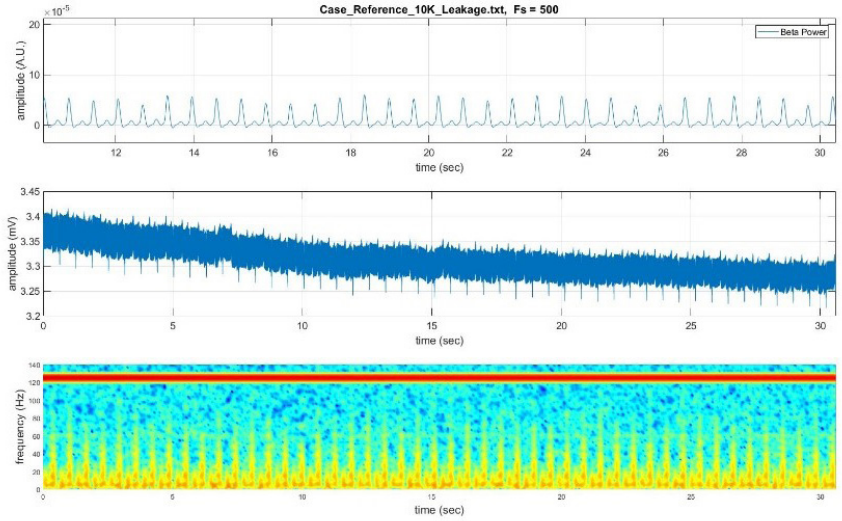
Some users may be interested in examining the raw measured LFP signal directly. For these users, it is important to understand how the raw data has been sampled and filtered. All recorded data is sampled at 250Hz. The data is passed through several filters. This includes 2 low pass filters at 100Hz, and two high pass filters. One high pass filter at 1Hz, and a second high pass filter at a user configurable 1Hz or 10Hz. The high pass filter setting is available in the Advanced Settings of the BrainSense™ Setup workflow.

Artifacts

An artifact is defined as a signal that is measured, which is not an LFP signal. The clinician application will display a message of artifact detected if it detects one of two possible artifact types; ECG and motion artifacts, discussed next. The system may also display artifact detected if the measured signal is significantly different than typical LFP signals. For example, a patient under anesthesia with only very large low frequency oscillations in LFP activity may be classified as artifact.

ECG Artifacts

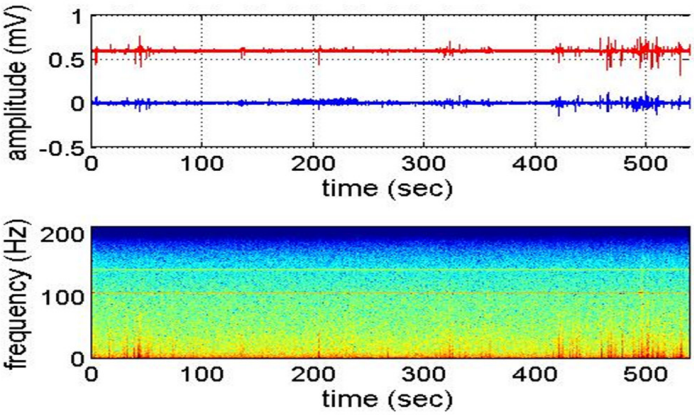
The first artifact the system detects is from the patient's heartbeat. It is possible that an ECG artifact conducts through the insulated pathway of the lead and extension. To investigate an ECG artifact, the time domain data in the .json file can be plotted (e.g. using Matlab). The example in Figure 1 is characteristic of an ECG artifact, where a large amplitude signal is observable at the heartrate of ~1-2Hz.



Medtronic Data on File: Figure 1: (Top) the power of the sensed signal in the selected band has an observable artifact at 1-2Hz. (Middle) the measured voltage of the raw data has a similar 1-2Hz artifact. (Bottom) the frequency spectrum has a broadband event at 1-2Hz.

Motion Artifacts

The second artifact the system detects is from the patient's movement. The artifactual signal in this scenario is not an LFP signal induced by motion, but instead a motion which causes the sensing apparatus (i.e. lead and/or extension) to move in a manner that produces an artifact. A motion artifact that is desired to be investigated is best observed when plotting the raw data in the .json file. The example in Figure 2 is characteristic of a motion artifact, where a very large amplitude signal is observable, that is not periodic, during times when the patient moves.



Medtronic Data on File: Figure 2: (Top) the measured voltage of the raw data has large amplitude spikes in it, that appear independent and not oscillatory. (Bottom) the frequency spectrum has broadband events during the spiking activity.

Artifact Override

The Artifact filter that prevents user selection of sensing channels that contain artifacts on BrainSense™ Setup and BrainSense™ Survey can be disabled in the Advanced Settings of the BrainSense™ Setup workflow.

Synchronization of data (external / internal)

Clinicians using external equipment such as accelerometers, video cameras, etc. may wish to synchronize these external devices with data from the Percept™ PC device.

Coarse-grained synchronization (e.g. seconds or minutes resolution) can be performed by synchronizing the Percept™ PC clock with the wall clock.

- Ensure that the tablet is on WIFI in order to sync the tablet clock with network time.
- Interrogate the implantable neurostimulator (INS).
- Navigate to the "About" screen using the Navigation menu in the upper right corner.
- Ensure the Time Source says "Tablet" and press the Update Device Time button.

All data saved in the reports, including BrainSense data, is stored using Coordinated Universal Time (UTC) (ISO-8601) timestamps.

For fine-grained synchronization (e.g. sub-second resolution), using timing relative to some clinical event could be used. One potential method is as follows:

- Place EEG electrodes over INS and burr hole.
- Deliver low frequency (e.g. 50Hz) and low amplitude stimulation with the Percept™ PC device, which may be imperceptible to subject.
- Start streaming with the Percept™ PC device and begin recording with external equipment.
- When complete with the activity, consider delivering a period of low frequency and/or low amplitude stimulation again with streaming on.
- Stimulation pulses can then be aligned between the raw LFP data (exportable via .json file) and external equipment using the low frequency/ amplitude markers at the start/end of the streaming session.
- For patients configured with stimulation cycling, the periodic on/off cycles in stimulation could be used for correlation when performing BrainSense™ Streaming.

JSON Export

The following high level data structures exist in the .json file that is exported when the user selects the "Export Json Session Data" option from the Reports functionality of the Clinician Programmer. Once generated the .json file is stored on the tablet in the /Reports folder, along with any generated session reports, MRI reports, etc.

Session Data and the JSON Export

The JSON export contains a summary of information in JSON format, rendered to be machine readable. The DBS Clinician app provides options to download a PDF of the Session report from each therapy session, or to export the same data in JSON format.

The Json Export Session Data report contains following information:

- Patient Information
- Device Information
- Battery Information
- Group Usage Percentage since last session in the form of combined groups array
- Lead Configuration
- Stimulation
- Groups
- Battery Check Reminder
- Battery Recharge (for applicable devices, currently Activa RC)
- Impedance
- Group History
- Annotations
- LFP Montage (Percept™ PC Only)
- Patient Events (Percept™ PC Only)
- Event Summary (Percept™ PC Only)
- Diagnostics Data

The JSON Export Session Data report is generated using the app's Patient Data Service.

JSON Structure Format

The information is fetched from various features in the app using respective mechanisms to retrieve the device state at the beginning/end of each therapy session. The information shown in the export varies, depending on whether all logs have been read from the device and stored or if activities like impedance measurements or streaming were conducted during the session. The JSON export file will indicate if the information in the export is incomplete, such as would be the case in events preventing a complete device reading of all logs. An example is a user canceling the background loading process.

Relevant information is grouped together as JSON Objects or Arrays in the output file.

Enumerated types are not translated as per JSON Normalization for Translation. Instead the enumeration is rendered as a _Def.name such that a consumer of the JSON can translate the enumeration to the proper locale using the JSON Enum Translation Files.

All the times mentioned in the export are UTC (ISO 8601) only. In addition, programmer locale and time zone values are included in the export.

All fields shown in the Session report need to be shown in the JSON export as well. In addition to field values, there are three types of raw data in the JSON export: Time Domain, Thresholds, and BrainSense LFP. Please see below for explanations of all JSON data structures and data sub-structures.

MATLAB Import

For Matlab import of .json files, see Matlab help documentation for command jsondecode. This command exists in Matlab version 2016b or later. The image below shows the Matlab workspace after importing a .json file using *jsondecode*. The data exists as a hierarchy of data structures.

Field	Value
AbnormalEnd	0
FullyReadForSession	1
FeatureInformationCode	'1X6'
SessionDate	'2019-10-04T20:08:29Z'
SessionEndDate	'2019-10-04T20:32:12Z'
ProgrammerTimezone	'Central Daylight Time'
ProgrammerUtcOffset	'-05:00'
ProgrammerLocale	'en_US'
ProgrammerVersion	'2.0.4580'
PatientInformation	*1x1 struct*
DeviceInformation	*1x1 struct*
BatteryInformation	*1x1 struct*
GroupUsagePercentage	*4x1 cell*
LeadConfiguration	*1x1 struct*
Stimulation	*1x1 struct*
Groups	*1x1 struct*
BatteryReminder	*1x1 struct*
MostRecentInSessionSignalCheck	*6x1 struct*
Impedance	*1x1 struct*
GroupHistory	*2x1 struct*
SenseChannelTests	*6x1 struct*
CalibrationTests	*4x1 struct*
Thresholds	*6x1 struct*
LfpMontageTimeDomain	*12x1 struct*
IndefiniteStreaming	*6x1 struct*
BrainSenseTimeDomain	*3x1 struct*
BrainSenseLfp	*2x1 struct*
LFPMontage	*12x1 struct*
PatientEvents	*1x1 struct*
EventSummary	*1x1 struct*
DiagnosticData	*1x1 struct*

One example of matlab code used for loading a .json file is:

```
[filename, pathname] = uigetfile('*.json');
json = fileread([pathname,'\',filename]);
datastruct = jsondecode(json);
```

Viewing .json files

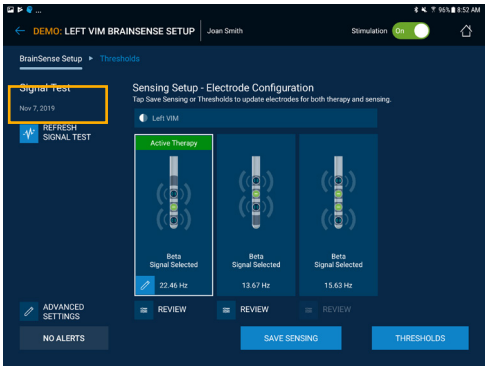
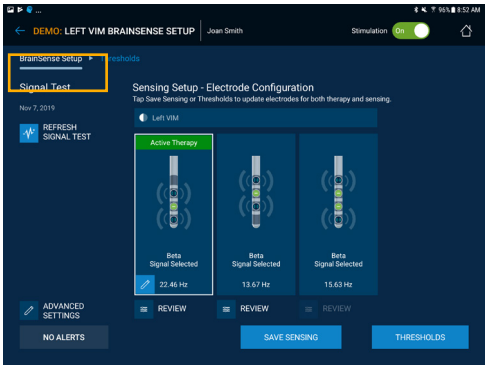
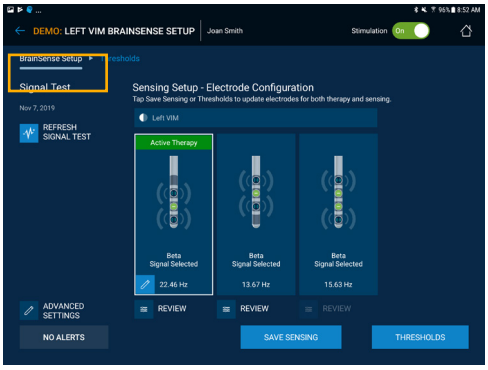
To view .json files, they can be opened in any text editor. For example, install Notepad++ and open the .json file. The image below is a Notepad++ view of an open .json file. Specific to Notepad++ the JSTool Plugin can be used to better navigate the .json file with a navigation pane. Several other open-source tools can be used to view .json files.

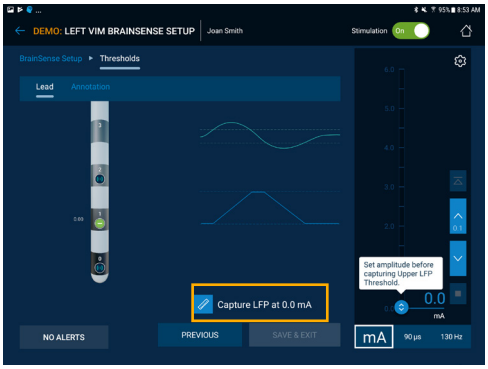
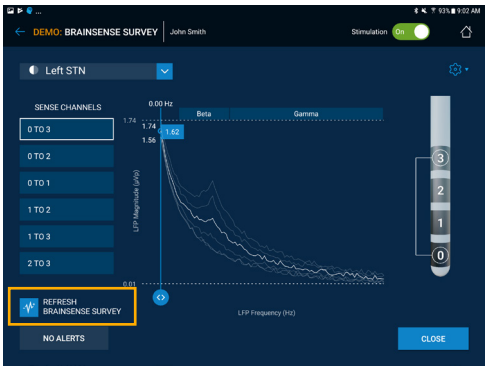
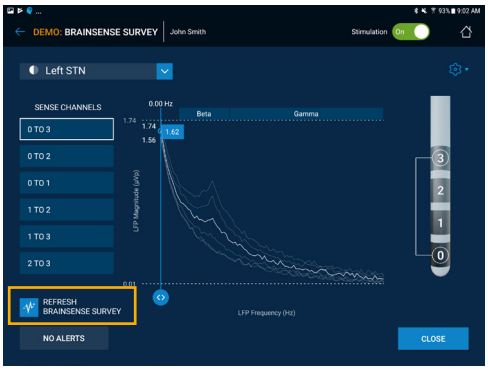
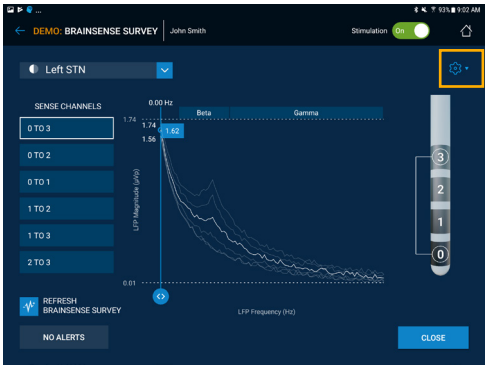
```
82    "LeadConfiguration": {
83        "Initial": [
84            {
85                "Hemisphere": "HemisphereLocationDef.Left",
86                "Model": "LeadModelDef.LEAD_3387",
87                "LeadLocation": "LeadLocationDef.Stn",
88                "ElectrodeNumber": "InsPort.ZERO_THREE",
89                "TipOffset": "TipOffsetDef.ZERO"
90            },
91            {
92                "Hemisphere": "HemisphereLocationDef.Right",
93                "Model": "LeadModelDef.LEAD_3387",
94                "LeadLocation": "LeadLocationDef.Stn",
95                "ElectrodeNumber": "InsPort.EIGHT_ELEVEN",
96                "TipOffset": "TipOffsetDef.EIGHT"
97            }
```

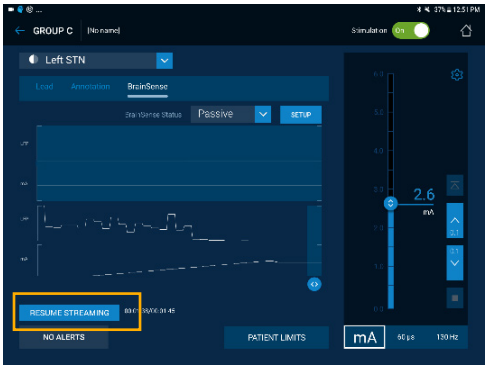
Note that some structures contain an 'initial' and 'final' state (where applicable) to highlight changes made during that session.

Sensing Specific Data Structures

Table 2: Sensing Specific Data Structures

Data Name	Description	Screen User uses to Collect Data	# of Records when used multiple times in a single CP session
MostRecentInSession SignalCheck	This section contains the last sense signal quality check results that session (6 channels amp/freq) – stimulation is OFF. Whenever the application streams time domain data for the quality check, the data is written to a file in the Patient Data Service (PDS) for later use. The clinician software performs a quality check for each set of LFP measurements. Then the clinician software uses the signal quality check algorithm to confirm there are no artifacts. The algorithm looks for: • Cardiac artifacts • Motion artifacts If artifacts are detected on a sense channel, the user is informed and allowed to retry the check.		1, the most recent only.
SenseChannelTests	This section contains the time domain data used to compute the sense signal quality result with stim OFF (6 channel). The application runs a signal check when all preconditions have been met. If the preconditions for sensing are not met, the button will be disabled and the user will not be allowed to run a signal check.		All times performed that session.
CalibrationTests	This section contains the time domain data used to compute the sense signal quality result with stim ON (4 channels).		All times performed that session.

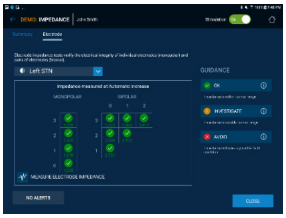
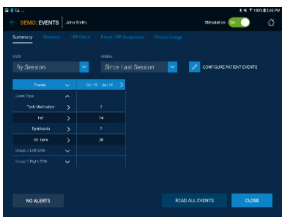
Thresholds	This section contains the power domain data used to compute any sensing thresholds set in this session.		All times performed that session.
LfpMontageTimeDomain	This section contains the time domain data used to compute the freq/amp plot in BrainsenseSurvey (12 channels for 1x4 leads, 30 channels for SenSight leads) – stimulation is OFF.		All times performed that session.
LFPMontage	This section contains the LFP amplitude and frequency data displayed to user from BrainsenseSurvey (12 channels for 1x4 leads, 30 channels for SenSight leads) – stimulation is OFF.		1, the most recent only.
IndefiniteStreaming	This section contains the time domain data recorded when using the "Record Streaming" option from BrainSenseSurvey Gear icon (6 channels) – stimulation is OFF.		All times performed that session.

BrainSenseTimeDomain	This section contains time domain data gathered when the user presses 'Start streaming" in Brainsense workflow – stimulation is in user defined state.		All times performed that session.
BrainSenseLfp	This section contains the raw data (Power data) gathered when the user presses 'Start streaming" in Brainsense workflow – stimulation is in user defined state.		All times performed that session.
DiagnosticData	This section contains the LFP Trend (60 days of LFP and Stim Amplitude; 10 min average data), the Device Event Logs (e.g. change group, stimulation on/off, clinician session start/end, impedance measurement) and the LFP Frequency Snapshot Events raw data (time of event, and raw LFP data (Freq/Amp)) for each event. All diagnostic data since the last session is saved on the tablet in the PDS session report, unless a request is made for a 'full' report, which would contain all diagnostic data on the INS. This data saved in PDS is available via a JSON export.	 & 	N/A, not a task that can be performed multiple times in a single CP session.

Other Data Structures

Table 3: Other Data Structures

Data Structure Name	Description/Contents	Screen User uses to Collect Data	# of Records when used multiple times in a single CP session
AbnormalEnd	This section is to indicate whether or not the clinician session for which the report is generated was ended abnormally. Possible causes for abnormal session end can be an application crash or an event where the application is killed from background, etc.	N/A: Data is read automatically at Device interrogation.	N/A, not a task that can be performed multiple times in a single CP session.
FullyReadyForSession	The application first establishes a connection and follows with initiation of the interrogation process. Interrogation performs data interrogation, data validation, and data correction based on the type of device in use. In addition, the device will have passed a firmware compatibility check, a device battery check, a CTM battery check, and a check for Power-On-Reset error conditions. An indication of the 'true' value indicates all these test conditions have been passed and the system is fully ready to initiate a new therapy session.	N/A: Data is read automatically at Device interrogation.	N/A, not a task that can be performed multiple times in a single CP session.
FeatureInformationCode	This code corresponds to the features the software permits to be enabled based on device type and/or the region in which the device is being utilized.	N/A: Data is read automatically at Device interrogation.	N/A, not a task that can be performed multiple times in a single CP session.
SessionDate	The system stamps each session with a time and date upon initiation. This includes the month, day, and year. The time is in 24-hour format and includes hours, minutes, and seconds. The format varies between locales.	N/A: Data is read automatically at Device interrogation.	N/A, not a task that can be performed multiple times in a single CP session.
SessionEndDate	The system stamps each session with an end date upon session end. It includes the same information as the session date. The end time is maintained exclusively for the JSON export data.	N/A: Data is read automatically at Device interrogation.	N/A, not a task that can be performed multiple times in a single CP session.
ProgrammerTimezone	The time zone in which the programmer is being used. Ex. Central Daylight Time.	N/A: Data is read automatically at Device interrogation.	N/A, not a task that can be performed multiple times in a single CP session.
ProgrammerUtcOffset	This is the value needed to adjust the UTC time value to match the selected time zone. If Central Daylight Time is selected, then the value is "-06:00".	N/A: Data is read automatically at Device interrogation.	N/A, not a task that can be performed multiple times in a single CP session.
ProgrammerLocale	This is the locale in which the user selects to operate the programmer. Aside from English, there are 26 language options.	N/A: Data is read automatically at Device interrogation.	N/A, not a task that can be performed multiple times in a single CP session.
ProgrammerVersion	The version of the programmer in use. In "0.0.0" format.	N/A: Data is read automatically at Device interrogation.	N/A, not a task that can be performed multiple times in a single CP session.

PatientInformation	This section contains name/gender/DOB/ ID/Notes/Diagnosis – can be de-identified when generated.	N/A: Data is entered by the user in Setup workflow and read automatically at Device interrogation.	Contains an initial (start of session) and final (end of session) record.
DeviceInformation	This section contains INS Model/ SN/Version/Implant Locations/ AccumulativeTherapyONTime.	N/A: Data is read automatically at Device interrogation.	Contains an initial (start of session) and final (end of session) record.
BatteryInformation	This section contains Percentage and estimated remaining battery life.	N/A: Data is read automatically at Device interrogation.	N/A, not a task that can be performed multiple times in a single CP session.
GroupUsageInformation	This section contains % of time in each group.	N/A: Data is read automatically at Device interrogation.	N/A, not a task that can be performed multiple times in a single CP session.
LeadConfiguration	This section contains lead models, implant locations, and the lead orientation value for SenSight leads.	N/A: Data is read automatically at Device interrogation.	Contains an initial (start of session) and final (end of session) record.
Stimulation	This section contains stim ON/OFF status at start and end of session.	N/A: Data is read automatically at Device interrogation.	Contains an initial (start of session) and final (end of session) record.
Groups	This section contains all programmable stimulation and sensing settings for every group configured.	N/A: Data is read automatically at Device interrogation.	Contains an initial (start of session) and final (end of session) record.
Impedance	This section contains electrode impedance results (in ohms for each electrode pair) run that session.		1, the most recent only.
GroupHistory	This section contains the session history stored on the device (up to last 5 Clinician Programmer sessions).	N/A: Data is read automatically at Device interrogation.	N/A, not a task that can be performed multiple times in a single CP session.
PatientEvents	This section contains the names of the Events for the patient, and their additional behavior (i.e. take LFP / restart cycling).	N/A: Data is read automatically at Device interrogation.	Contains an initial (start of session) and final (end of session) record.
EventSummary	This section contains the data used to populate the table on summary screen in CP app (above/below/between threshold percentage for each group – if sensing) and event counts used since last session.		N/A, not a task that can be performed multiple times in a single CP session.

Data Structure Details and Substructures

For each of the high level data structures in Table 2: Sensing Specific Data Structures and Table 3: Other Data Structures, Table 4: Data Structure Details and Substructures details the substructure (lower level) data within the high level structure.

Table 4: Data Structure Details and Substructures

Data Structure Name	SubStructures	Units and Sample Rate
MostRecentInSessionSignalCheck	6 Sensing Channels (3 electrode level pairs per lead)	N/A
	Each Channel Contains the following:	
	SignalFrequencies	Units of Hz. Post Spectral Analysis
	SignalPsdValues	Units of µVp. Post Spectral Analysis
SenseChannelTests	6 Sensing Channels (3 electrode level pairs per lead) Contains all Signal Quality Check data if run multiple times.	N/A
	Each Channel Contains the following:	
	SampleRateInHz	Units of Hz.
	TimeDomainData	Units of µV, with sample rate of SampleRateInHz
	Global Sequences	Lists packet identity sequentially. Used to identify missing packets, by missing sequence numbers. Rolls over at 255.
	GlobalPacketSizes	Lists number of samples per packet
	FirstPacketDatetime	Labels each Streaming Sample with initial DateTime value. 1 second resolution
CalibrationTests	4 Sensing Channels (2 electrode level pairs per lead)	N/A
	Contains all Calibration test data if run multiple times. Calibration Test is the 2nd step of signal quality checking, performed with stimulation on.	
	Each Channel Contains the following:	
	SampleRateInHz	Units of Hz.
	TimeDomainData	Units of µV, with sample rate of SampleRateInHz
	Global Sequences	Lists packet identity sequentially. Used to identify missing packets, by missing sequence numbers. Rolls over at 255.
	GlobalPacketSizes	Lists number of samples per packet
	FirstPacketDatetime	Labels each Streaming Sample with initial DateTime value. 1 second resolution
Thresholds	Each Threshold measurement Contains the hemisphere it was streamed from, and the following substructures:	N/A
	SampleRateInHz	Units of Hz
	LFPData: One data structure per hemisphere (left/right)	Unitless, with sample rate of SampleRateInHz. This is the representation of LFP Power in the sensing frequency band.

LfpMontageTimeDomain	12 Sensing Channels for 1x4 leads (6 electrode pairs per lead), up to 2 survey results depending on user requested measurements. First survey contains all electrode pair combinations for first hemisphere. Second survey contains all electrode pair combinations for second hemisphere. 30 Sensing Channels for SenSight leads (15 electrode pairs per lead), up to 4 survey results depending on user requested measurements. First survey contains all electrode level pair combinations for first hemisphere. Second survey contains all segment-to-segment pair combinations in two passes for first hemisphere. Third survey contains all electrode level pair combinations for second hemisphere. Fourth survey contains all segment-to-segment pair combinations in two passes for second hemisphere.	N/A
	Each Channel Contains the following:	
	SampleRateInHz	Units of Hz
	TimeDomainData	Units of µV, with sample rate of SampleRateInHz
	Global Sequences	Lists packet identity sequentially. Used to identify missing packets, by missing sequence numbers. Rolls over at 255.
	GlobalPacketSizes	Lists number of samples per packet
	FirstPacketDatetime	Labels each Streaming Sample with initial DateTime value. 1 second resolution
LFPMontage	12 Sensing Channels for 1x4 leads (6 electrode pairs per lead) 30 Sensing Channels for SenSight leads (15 electrode pairs per lead)	
	Each Channel Contains the following:	N/A
	ArtifactStatus	Flag for detecting artifact
	LFPFrequency	Units of Hz. Post Spectral Analysis
	LFPMagnitude	Units of µVp. Post Spectral Analysis

IndefiniteStreaming	6 Sensing Channels (3 electrode level pairs per lead). Contains non-adjacent electrode configurations.	
	SampleRateInHz	Units of Hz
	TimeDomainData	Units of µV, with sample rate of SampleRateInHz
	Global Sequences	Lists packet identity sequentially. Used to identify missing packets, by missing sequence numbers. Rolls over at 255.
	GlobalPacketSizes	Lists number of samples per packet
	TicksInMses	Lists the system time tick for each packet sent. 50 millisecond resolution
	FirstPacketDatetime	Labels each Streaming Sample with initial DateTime value. 1 second resolution
BrainSenseTimeDomain	Each Streaming Sample Contains the sensing channel the data is from, (the hemisphere and electrodes), and then has the following 2 substructures:	N/A
	SampleRateInHz	Units of Hz
	TimeDomainData	Units of µV, with sample rate of SampleRateInHz
	Global Sequences	Lists packet identity sequentially. Used to identify missing packets, by missing sequence numbers. Rolls over at 255. Packets are interleaved with BrainSenseLfp packets.
	GlobalPacketSizes	Lists number of samples per packet
	TicksInMses	Lists the system time tick for each packet sent. 50 millisecond resolution
	FirstPacketDatetime	Labels each Streaming Sample with initial DateTime value. 1 second resolution

BrainSenseLfp	Each Streaming Sample Contains the sensing channel the data is from, (the hemisphere and electrodes), and then has the following substructures:	N/A
	SampleRateInHz	Units in Hz.
	TherapySnapshot	Group/Program settings specific to streaming sample
	LfpData: One data structure per hemisphere (left/right)	LFP: Unitless, with sample rate of SampleRateInHz. This is the representation of LFP Power in the sensing frequency band. mA: Units of mA, with sample rate of SampleRateInHz. This is the Stimulation amplitude.
	FirstPacketDateTime	Labels each Streaming Sample with initial DateTime value. 1 second resolution
	Seq	Labels each LFPData sample with packet identity. Used to identify missing packets, by missing sequence numbers. Rolls over at 255. Packets are interleaved with BrainSenseTimeDomain GlobalSequences.
	TicksInMs	Labels each LfpData sample with the system time tick. 50 millisecond resolution.
DiagnosticData	Contains various Logs for tracking outside of clinician visit	N/A
	LfpTrendLogs: Contains up to 60 days of 10 minute averaged LFP and stim amplitude per hemisphere.	DateTime: Time of sample LFP: Unitless, this is the representation of LFP Power in the sensing frequency band. AmplitudeInMilliAmps: Units of mA. Stim amplitude Data may be censored to avoid artifacts, censored data is negative.
	EventLogs	Patient Interaction Log: (e.g. Switching groups, session start, stim on/off, Impedance Test)
	LfpFrequencySnapshotEvents: Contains up to 400 LFP Frequency snapshots, 200 if 2 hemispheres. Use "Read All Events" button in clinician application before exporting .json file to load all of these. 2 substructures, 1 per hemisphere.	Frequency: Units in Hz, Post Spectral Analysis FFTBinData: Units in µVp, Post Spectral Analysis Data may be censored to avoid artifacts, censored data is negative.
PatientInformation	Contains text for patient first and last name, gender, DOB, ID, ClincianNotes, and Diagnosis.	N/A

DeviceInformation	Contains INS Model, Serial Number, Firmware Versions, Implant Locations and AccumulativeTherapyONTimeSinceImplant/Followup	TherapyOnTime is in seconds
BatteryInformation	Contains Battery Percentage, Estimated Battery Life Remaining (in months), Battery Status	Percent is out of 100, and battery life is months.
GroupUsageInformation	4 substructures, one for each of Group A,B,C,D. Each contains usage percentage for that Group	Percent is out of 100
LeadConfiguration	2 substructures, one for each lead (one lead per hemisphere). Contains the lead model, the lead location, the INS bore/electrodes numbers, the tip electrode number for each lead, and the lead orientation value in degrees for SenSight leads.	N/A
Stimulation	Contains the Stimulation Status ON or OFF.	N/A
Groups	Initial and Final structures contain up to 4 substructures, one for each Group. Within each substructure is the Group Name, if it is the Active Group or not, the patient adjustable stimulation parameter for that group, and the following two substructures:	N/A
	Program Settings – contains program level stimulation and sensing parameters. Amplitude per electrode, Rate, Pulse Width, Electrodes, Thresholds, Sensing Frequency, Averaging Duration, Sense Channel Result for the Active channel.	Units are contained in variable name
	GroupSettings – contains group level stimulation and sensing parameters. SoftStart, Cycling, highpassfilter, sense blanking duration.	Units are contained in variable name
Impedance	Contains electrode impedance results for impedance test during that session. 2 substructures one for each hemisphere (lead). Within each substructure, 2 additional substructures:	N/A
	Monopolar: Contains the monopolar electrode pair impedance results	Ohms
	Bipolar: Contains the bipolar electrode pair impedance results	Ohms
GroupHistory	Contains up to 5 Group histories from 5 previous clinician programming sessions on different days. Within each of the 5 previous programming days, up to 4 substructures exist, one for each group. These substructures follow the same format as the Groups data structure above.	
PatientEvents	Contains the event name of up to four events, and if each event has additional behavior (LFP Snapshot or Restart Cycling).	N/A
EventSummary	Contains the data used to populate the table on summary screen in CP app (above/below/between threshold percentage for each group and average stimulation amplitude – if sensing) and event count used since last session.	Percent is out of 100. Average amplitude is in mA.

Time Domain Data Point Timestamps

BrainSenseTimeDomainData and IndefiniteStreaming have TimeDomainData structures with a clock value per telemetry message. Each message contains a variable number of data points. The following pseudocode is an example method to estimate the relative time each data point was sampled.

FOR each streaming sample:

1. Create time array [e.g. TDtime] for the TimeDomainData contained in the last (most recent) telemetry message.
2. Assign the last TimeDomainData data point to the last TicksInMses value.
3. Iterate backward in time over the size (GlobalPacketSizes) of the last message received, knowing that each data point in the message is spaced at 1/ SampleRateInHz.

   For example:
   TDtime = TicksInMses (end)- (GlobalPacketSizes (end)-1)/SampleRateInHz : 1/SampleRateInHz : TicksInMses (end)

FOR each prior message, starting from the last message above

IF Difference in TicksInMses > (1 + GlobalPacketSizes)/ SampleRateInHz

1. Assign the next most recent TimeDomainData data point to the next most recent TicksInMses value
2. Iterate backward in time over the size (GlobalPacketSizes) of the next most recent message received.
3. Assemble the data vector by appending the messages:

   [Next Most Recent, Most Recent]

   For example:
   Prev_packet = TicksInMses (i-1)- (GlobalPacketSizes (i-1)-1)/ SampleRateInHz :… 1/SampleRateInHz : TicksInMses (i-1TDtime = [Prev_packet,TDtime]

ELSE

1. Assign the next most recent TimeDomainData data point to 1/SampleRateInHz prior to the time value computed for the first data point in the prior message, i.e. assume the data is continuous.
2. Iterate backward in time over the size (GlobalPacketSizes) of the next most recent message received.
3. Assemble the data vector by appending the messages:

   [Next Most Recent, Most Recent]

   For example:
   Prev_packet = TDtime(1)- GlobalPacketSizes (i-1)/ SampleRateInHz: 1/SampleRateInHz : TDtime(1) – 1/SampleRateInHzTDtime = [Prev_packet,TDtime]

END

Optionally, use the first value in variable TicksInMses as a zero reference for plotting, by subtracting this value from the time vector.

Glossary

Abbreviation	Definition
DBS	Deep Brain Stimulation
CP App	Clinician Programmer Application
INS	Implantable Neurostimulator
LFP	Local Field Potential
PD	Parkinson's Disease
UTC	Coordinated Universal Time (ISO-8601)
µVp	Micro volts peak

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. 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.

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