

Distance Expert[®] – Neurophysiology Software Setup

Directions for Use

L011-76 (Rev B0, February 2015)



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Indications for use: The Distance Expert[®]–Neurophysiology Suite System is intended to assist in functional neurosurgical procedures in which recording from and stimulation of brain motor and sensory neurons will aid in the placement of depth electrodes.

Intended Use: The Distance Expert[®]–Neurophysiology Suite System is intended for use by neurosurgeons, neurologists and clinical neurophysiologists to accurately position depth electrodes during functional neurosurgical procedures.

WARNINGS AND CAUTIONS

 **WARNING:** For important safety precautions, warnings and instructions on proper use of the microTargeting[™] Guideline 4000 LP+[™], refer to its Directions for Use (L011-57: included with the Guideline 4000 LP+[™], and L011-57-02: included with the Breakout Box).

CAUTION: Incorrect setup may impair performance of the Distance Expert[®]–Neurophysiology Suite System.

 **WARNING:** A trained, FHC–authorized representative must set up the Distance Expert[®]–Neurophysiology Suite System. On completion of setup, an FHC-authorized remote Distance Expert[®] assumes control of the Distance Expert[®]–Neurophysiology Suite System.

CAUTION: Verify that backup modes of communication with the remote Distance Expert[®] (e.g., telephone, cell phone) are in place in the event of loss of Internet connection or other lapses.

ORDERING INFORMATION

65-GNC-DE-PHYS	Distance Expert [®] –Neurophysiology
66-GNC-DE-SW1.02	Distance Expert [®] –Neurophysiology Software and DAQ

This document contains directions for use of Distance Expert[®]–Neurophysiology Software.

PROCEDURAL INSTRUCTIONS

1. Set up the Distance Expert®–Neurophysiology Suite System

1.1. Refer to the Distance Expert®–Neurophysiology Suite System Setup Directions for Use (L011-75). Be sure to complete all steps well in advance of surgery.

2. Set up the Distance Expert®–Neurophysiology Software

2.1. Power up the Distance Expert®–Neurophysiology laptop PC and login to Windows using the password “distanceExpert” (case sensitive).

2.2. Launch the Distance Expert®–Neurophysiology Software.

2.3. Enter the desired “Application Options” from the first window using each of the four tabs (see Figures 1-4).

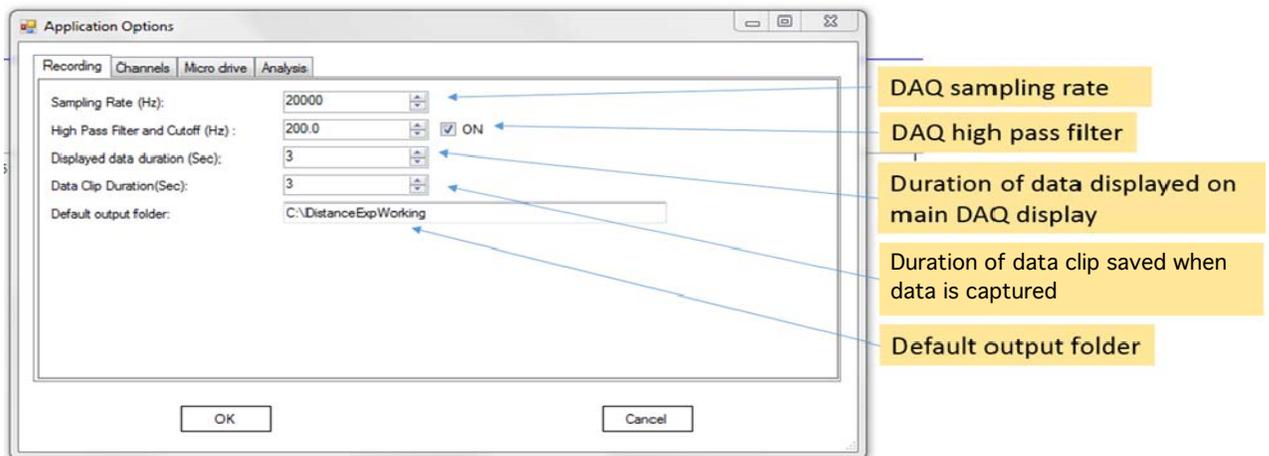


Figure 1. “Recording” tab

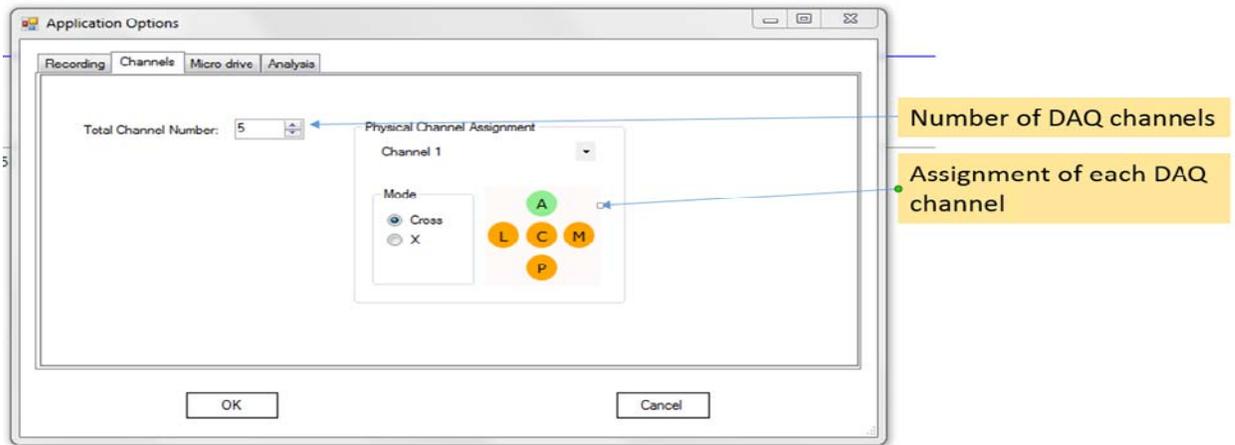


Figure 2. “Channels” tab

*Note: Assign each channel by clicking the “Channel” drop-down to select the channel and then its respective position in the matrix.

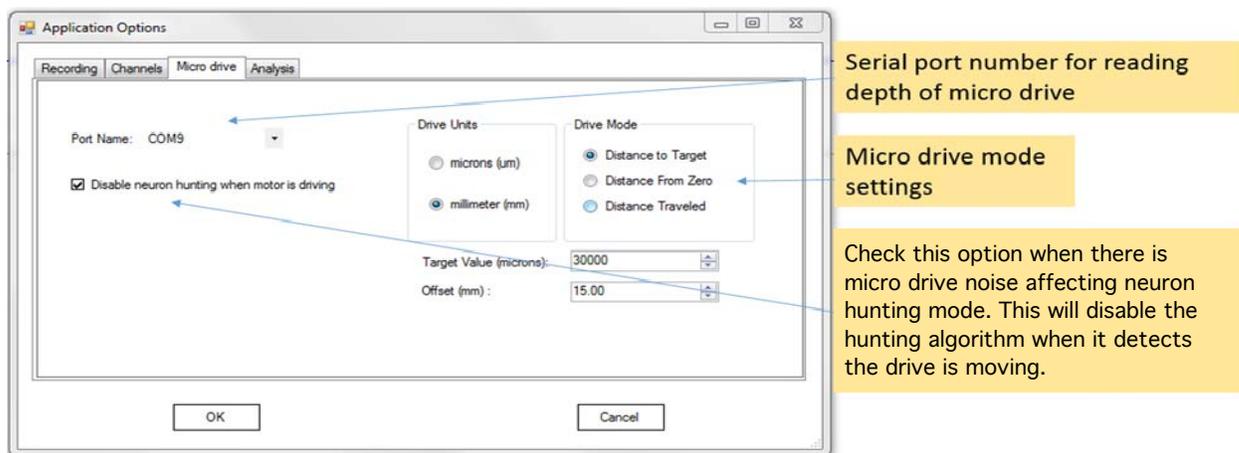


Figure 3. “Micro drive” tab

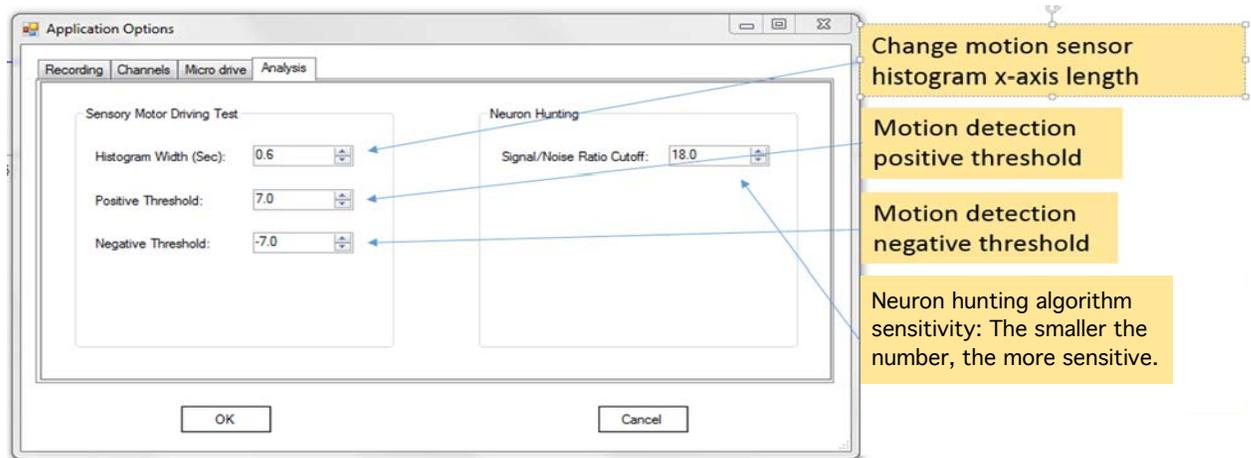


Figure 4. “Analysis” tab

*Note: It is recommended to leave these settings preset. If it is later determined that motion detection and sensitivity need to be adjusted, return to this tab.

2.4. Click “OK” to exit the window.

2.5. Enter the desired “Patient and Trajectory Information” from the second window using each of the two tabs (see Figures 5-6).

The screenshot shows a dialog box titled "Patient and Trajectory information" with two tabs: "Patient Information" (selected) and "Trajectory". The "Patient Information" tab contains the following fields:

First Name:	<input type="text"/>	Diagnosis:	Parkinson's disease
M.I.:	<input type="text"/>	Target:	STN
Last Name:	<input type="text"/>	DBS Side:	Left side
MRN:	<input type="text"/>	Surgery Date:	10/16/2014
Date of Birth:	10/16/2014	Note:	<input type="text"/>

At the bottom of the dialog box are "OK" and "Cancel" buttons.

Figure 5. “Patient Information” tab

*Note: “Diagnosis” and “Target” are the only required fields to create a data report.

The screenshot shows the same dialog box with the "Trajectory" tab selected. The "Trajectory" tab contains the following fields:

Traj. number:	1	DBS Lead?	<input type="checkbox"/>
Frame coordinates		AC PC	
AP (mm)	0	Medial/Lateral (X) (mm)	0
Lat (mm)	0	Anterior/Posterior (Y) (mm)	0
Vert (mm)	0	Depth (mm)	0
Ring (Degree)	0	Sagittal Angle (degree)	0
Arc (Degree)	0	Coronal Angle (degree)	0
Anterior (Click to change)	0 (mm)	Lateral (Click to change)	0 (mm)

A yellow callout box on the right side of the dialog box contains the text: "Trajectory number is an auto-increase number". A blue arrow points from this callout box to the "Traj. number" field. The number "2.5" is written below the callout box. At the bottom of the dialog box are "OK" and "Cancel" buttons.

Figure 6. “Trajectory” tab

*Note: These are all optional fields.

2.6. Click “OK” to exit the window.

3. Begin data recording

3.1. Click the green “Start/stop Data Recording” button in the upper left-hand corner to begin signal acquisition. The “Stream microelectrode data to hard drive” button will start flashing (see Figure 7).

*Note: To disable the data stream to the hard drive, click this button (it will stop flashing).

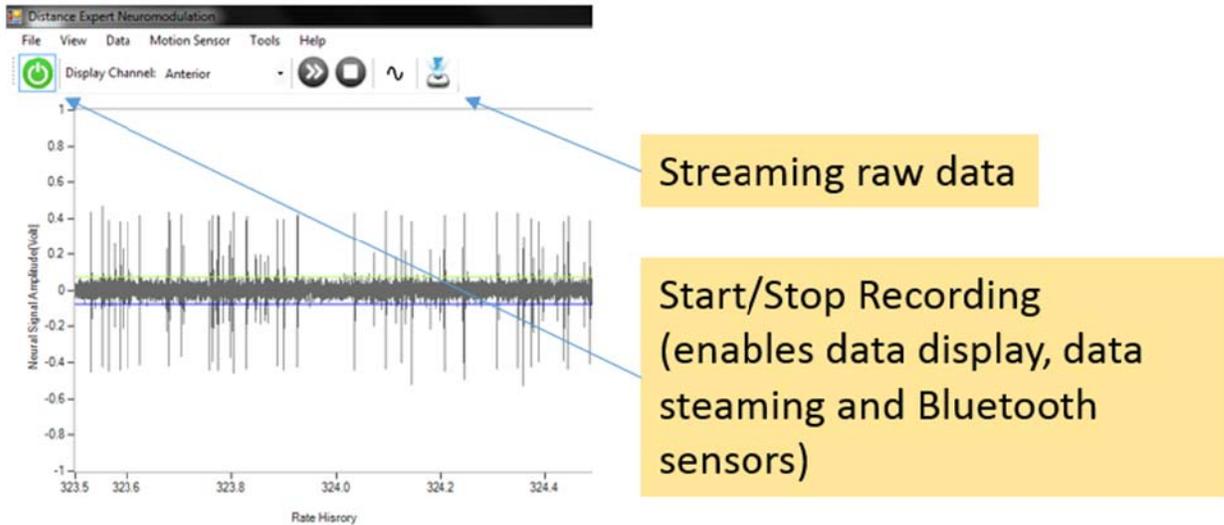


Figure 7. Data recording button locations

3.2. Verify both the “Sensory Motor Testing” and “Clear Sensory Motor testing” buttons on the upper right have become enabled.

3.3. Instruct the physician to advance the electrode past the protective and insertion tubes.

3.4. Data will populate each chart as information is detected (see Figure 8).

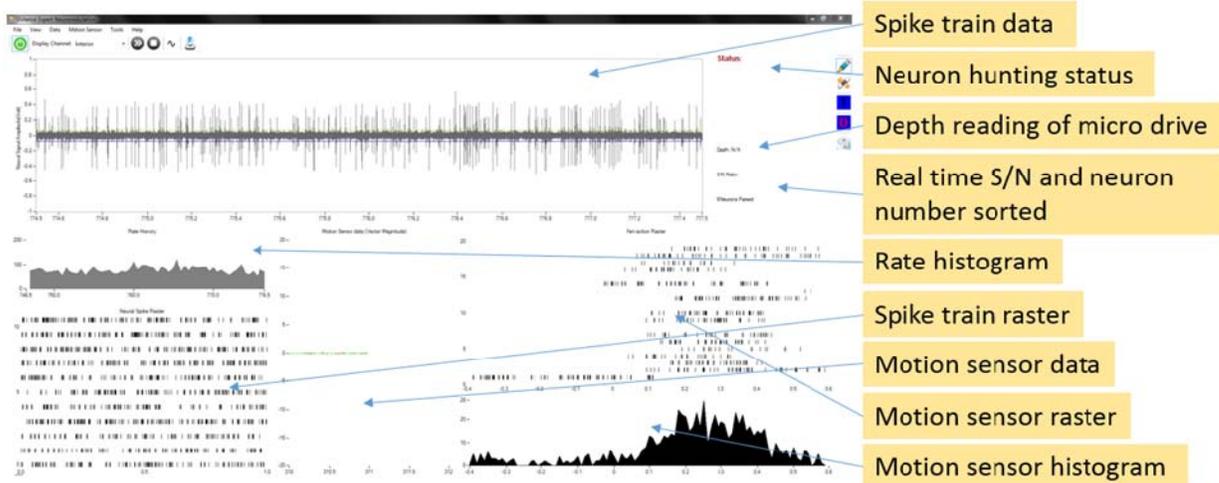


Figure 8. Data charts

3.5. Verify the “Depth” Status matches the reading on the microTargeting™ Controller.

3.6. Verify that the remote Distance Expert® is receiving real-time data through the remote workstation and audiovisual equipment.

4. Perform an impedance test.

4.1. Choose the desired channel by clicking the “Display Channel” drop-down and selecting the channel (or click Alt+channel number, e.g., “Alt+1” for channel 1).

4.2. Click the “Capture Data button” (or “Ctrl+D”). Record the desired values with which to populate the report (see Figure 9).

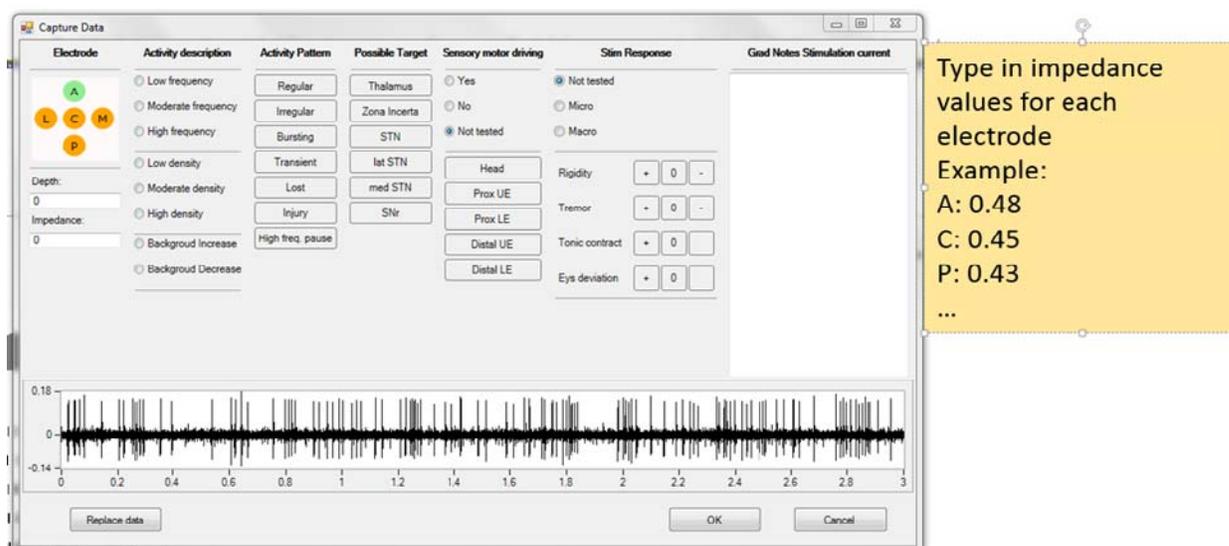


Figure 9. “Capture Data” window

4.3. Click “OK” to save inputs and close the window.

5. Begin neuron hunting

5.1. Click the “Start Neuron Hunting” button (or “Ctrl+H”) to begin searching all channels for a neuron (see Figure 10).

*Note: Switching the displayed channel and completing the neuron hunting mode automatically adjusts the threshold line for spike detection. To force the program to adjust the threshold, reselect the displayed channel by clicking the “Display Channel” drop-down and selecting the channel (or click Alt+channel number, e.g., “Alt+1” for channel 1).

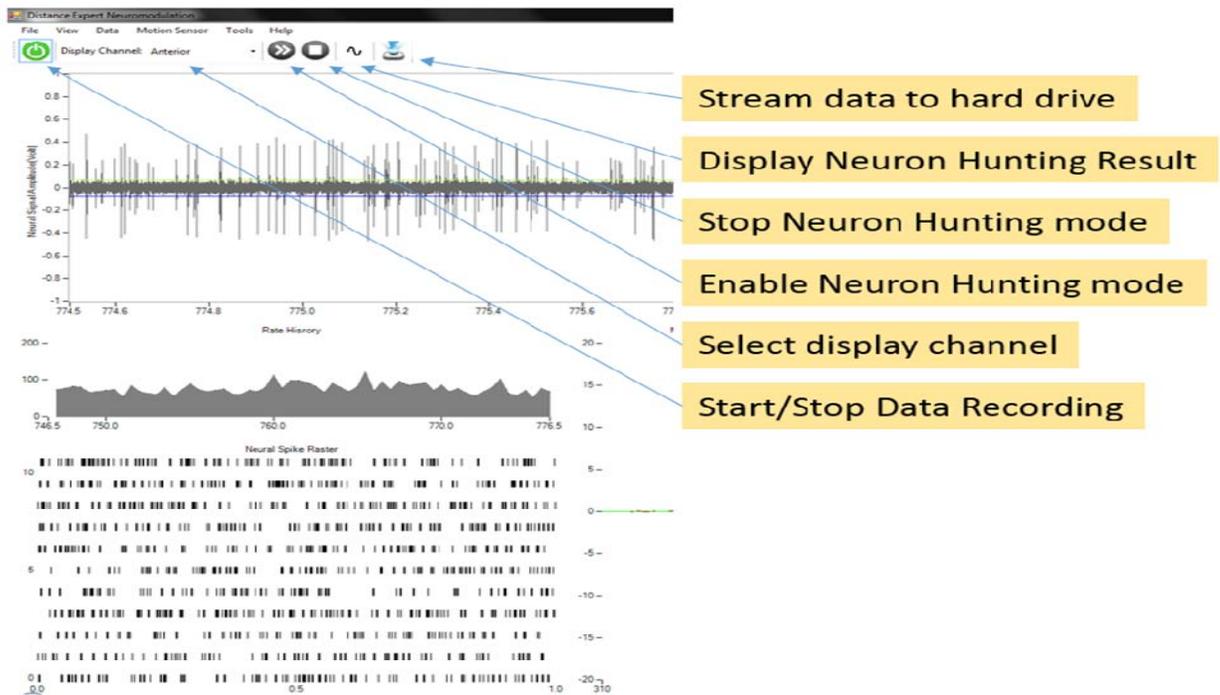


Figure 10. Neuron hunting button locations

5.2. As the physician advances the electrode, the “Neuron found” window will appear (see Figure 11).

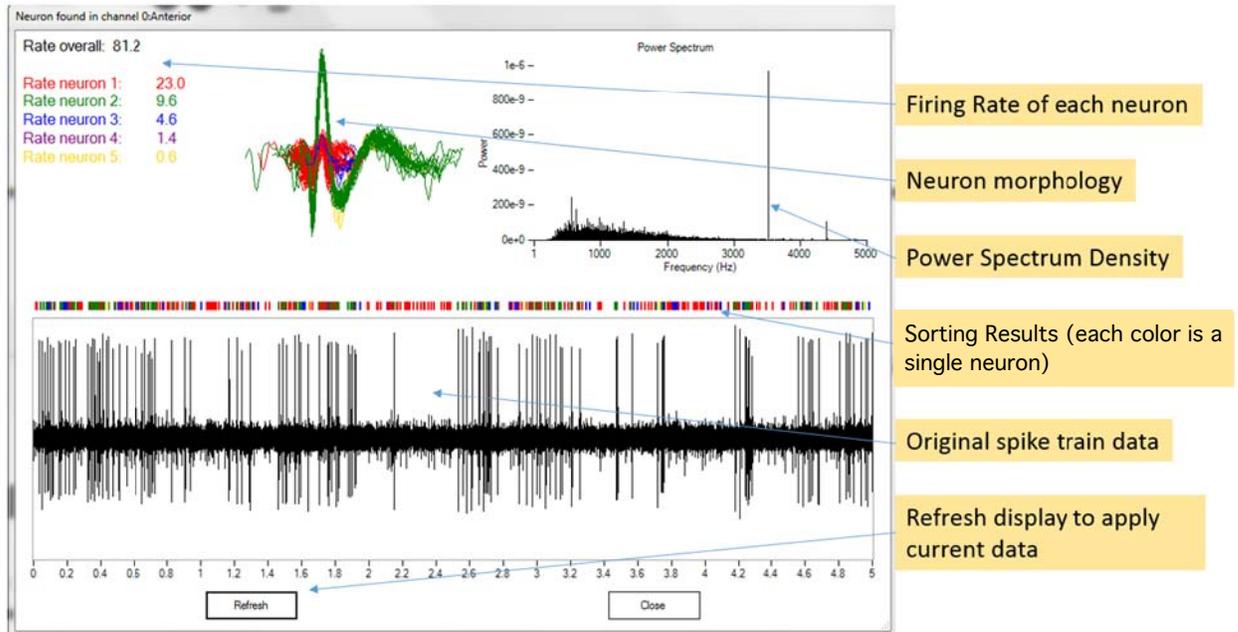


Figure 11. “Neuron found in channel 0:Anterior” window example

5.3. Click “Close” to close the window and continue.

5.4. Click the “Display neural sorting result” to review the spike train data sorting results.

5.4. Click the “Stop Neuron Hunting” button when finished.

6. Begin sensorimotor testing

6.1. Click the “Sensory Motor Testing” button. This will activate the Bluetooth transmission of motion sensor movement (see Figure 12).

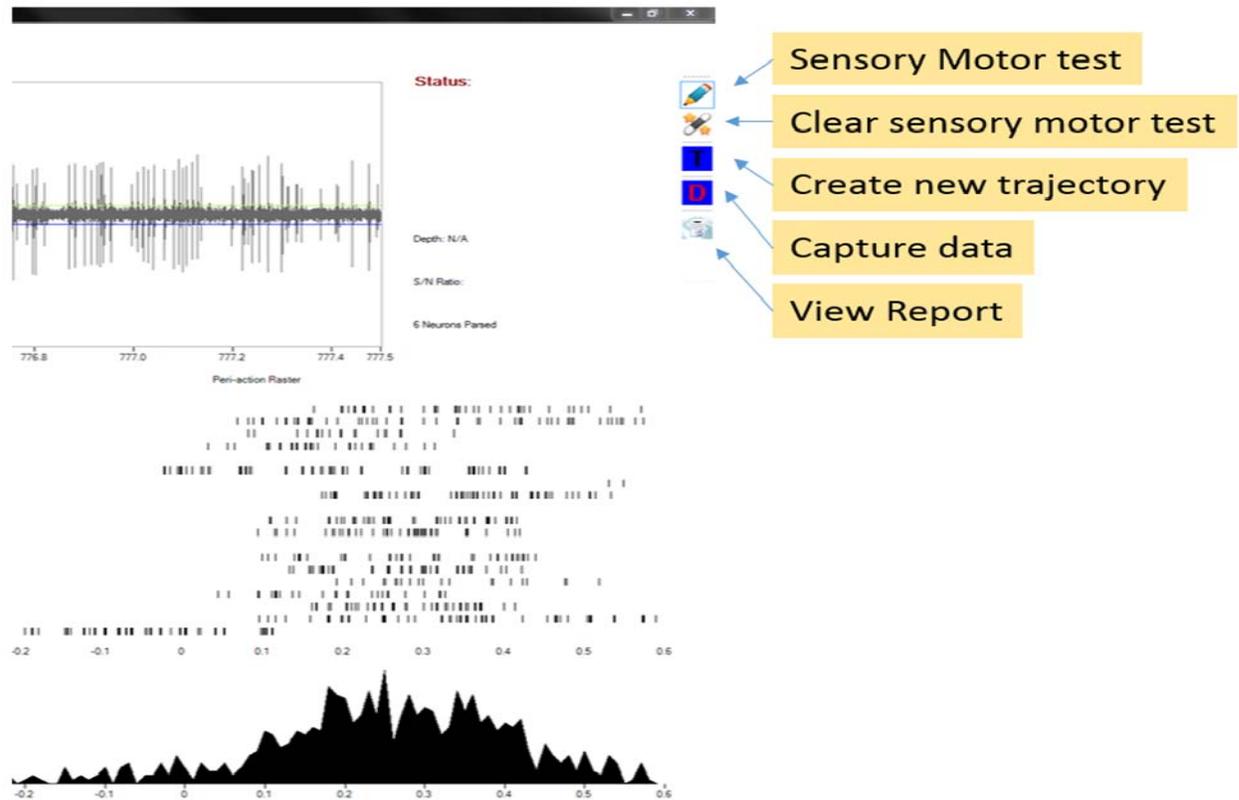


Figure 12. Sensorimotor testing button locations

6.2. Activate the motion sensor by wiggling it. Data will appear in the sensorimotor raster and histogram (see Figure 13).

*Note: If data does not populate the charts, switch motion sensors, then click the “Motion Sensor” drop-down, “Select Sensor” and choose the other sensor.

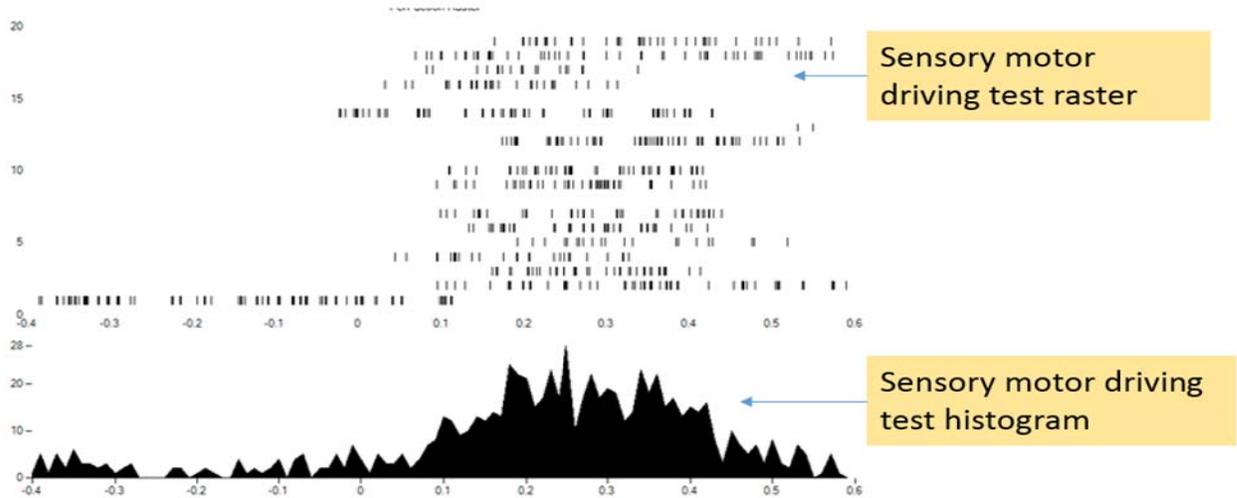


Figure 13. Sensorimotor data charts

6.3. Click the “Capture Data” button (or “Ctrl+D”) to save sensorimotor data to the report (see Figure 14).

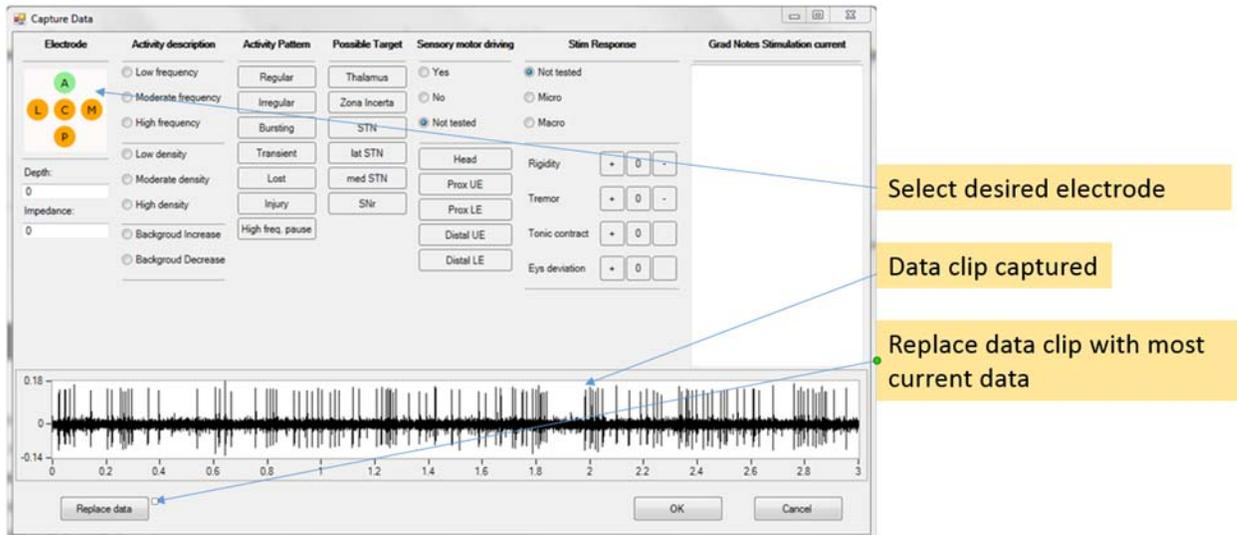


Figure 14. “Capture Data” window

6.4. Click “OK” to save inputs and close the window.

6.5. Click the “Clear Sensory Motor testing” button to clear the raster and histogram charts.

7. Review the report

7.1. Click the “View Micro recording reports” button to view the report window (see Figure 15).

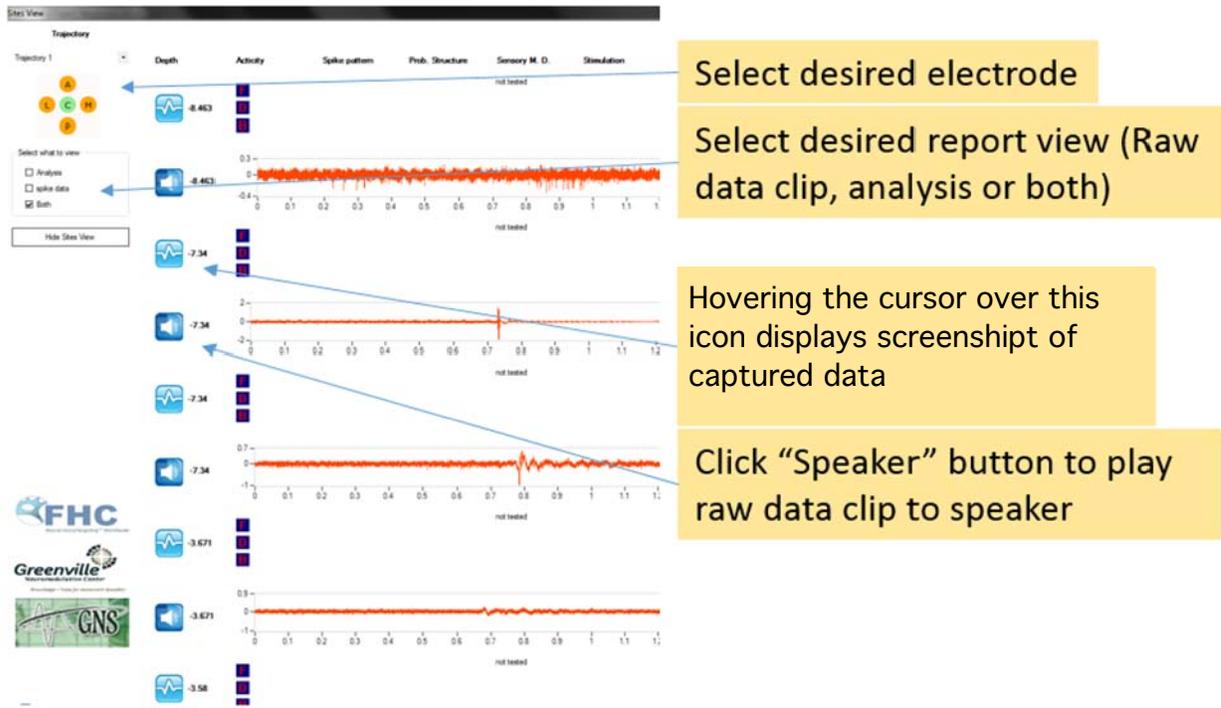


Figure 15. Recording reports window

7.2. Choose the desired electrode in the “Trajectory” drop-down.

7.3. Choose the desired report type in “Select what to view” by clicking the appropriate radio button.

8. Repeat neuron hunting, sensorimotor testing and data capture as needed

8.1. The remote Distance Expert[®] will guide the physician as to further data capturing and report population.

8.2. Go back to Steps 5 (Begin neuron hunting) and 6 (Begin sensorimotor testing) as many times as necessary to record and capture the desired data.

8.3. Data can be captured at any point by clicking the “Capture Data” button (or “Ctrl+D”) and selecting the desired fields (click “OK” to save inputs and close the window).

8.4. If it is determined that the identified target is suboptimal, return to the “Patient and Trajectory Information” window by clicking on the blue “T” button on the right hand side of the screen. Select the “Trajectory” tab and adjust the “Medial/Lateral (X) (mm)” and “Anterior/Posterior (Y) (mm)” settings. (See section 2.5 for reference.)

9. Finalize the procedure

- 9.1. Save the report by clicking the “File” drop-down and “Save Report.”
- 9.2. Once the optimal target has been identified, the physician may proceed with DBS surgery.

APPENDIX

A. Additional software operations

- A.1. Zooming in and out. To zoom in on any data plot graph, hold the “Ctrl” key and scroll forward on the mouse wheel. To zoom out, hold the “Ctrl” key and scroll backward.
- A.2. Panning across data graphs. To pan across any data plot graph in any direction, hold the “Ctrl” key, click and hold the left mouse button and move the mouse to the desired view.

B. Troubleshooting

- B.1. DAQ card overflow. DAQ card overflow occurs when data retrieval from the data acquisition hardware by the computer’s CPU for restoring system memory fails to occur in a timely manner. In such an event a “DAQ card overflow” error message appears. To ignore this message and continue streaming data, click the “Continue” button.